Operator's Manual

HAMILTON-MR1

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Valid for devices with SN 2000 and higher

CE 0197

HAMILTON MEDICAL
Intelligent Ventilation since 1983

HAMILTON-MR1
Operator's Manual

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HAMILTON-MR1 software information

The software version for the HAMILTON-MR1 is visible in the **`System -> Info`** window. The software version should match the version on the title page of this manual. See Section 4.3.1 for details.

Definitions

WARNING

A warning alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION

A CAUTION alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTE:

A NOTE emphasizes information of particular importance.

NIV/ NIV-ST	Applies only when NIV/NIV-ST option is installed
DuoPAP/ APRV	Applies only when DuoPAP/APRV option is installed
	Applies only when Trend/Loops option is installed
	Applies only when the Neonatal option is installed.

Intended use

The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:

- In the MRI department
- In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room
- During transfer of ventilated patients within the hospital

The HAMILTON-MR1 ventilator is classified as MR Conditional with the use of 1.5 Tesla and 3.0 Tesla static magnetic field scanners.

The HAMILTON-MR1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

CAUTION

(USA only): Federal law restricts this device to sale by or on the order of a physician.

General operation notes

WARNING

- **Be sure to read the safety information in Section 3.2 for safety information related to working with the device in the MRI environment.**
- **Check the cables from the power transformer to the ventilator and to AC mains. Do not use the cables if there are any open contacts.**
- **Modifications to the device are not permitted.**

- The use of this equipment is restricted to one patient at a time.

- Additional information about installing the medical equipment, as well as additional technical information, is provided in the *Service Manual*.
- If there is visible damage to any part of the ventilator, do not use the device. Technical service is required.
- The intended patient population ranges from neonatal patients with 0.2 kg to 30 kg body weight to pediatric patients with 30 cm height (3 kg ideal body weight) up to adults up to 250 cm height (139 kg ideal body weight). The minimum tidal volume delivered shall be equal to or greater than 20 ml for adults/pediatrics, 2 ml for neonates.
- The displays shown in this manual may not exactly match what you see on your own ventilator.
- Familiarize yourself with this operator's manual before using the ventilator on a patient.
- Do not simultaneously touch conductive components (for example, the USB port) or conductive parts of the ventilator enclosure and the patient.
- Displayed information that is ghosted is not active and may not be selected.
- Dashes displayed in place of monitored data indicate that valid values are not yet available or do not apply.
- If a ventilator control does not respond when selected by touch or by the turn of a dial, the control is not active in this particular instance or the function is not implemented.

Monitoring and alarms

- Be sure to read the safety information in Section 3.2 for safety information related to working with the device in the MRI environment.
- The HAMILTON-MR1 is not intended to be a comprehensive vital sign monitor for patients on life-support equipment. Patients on life-support equipment should be appropriately monitored by qualified medical personnel and suitable monitoring devices. The use of an alarm monitoring system

does not give absolute assurance of warning for every type of issue that may arise with the ventilator. Alarm messages may not exactly pinpoint a problem; the exercise of clinical judgment is necessary.

- An alternative means of ventilation must be available whenever the ventilator is in use. If a fault is detected in the ventilator or its life-support functions are in doubt, disconnect the HAMILTON-MR1 from the patient and immediately start ventilation with such a device (for example, a resuscitation bag), using PEEP and/or increased oxygen concentration when appropriate. The ventilator must be removed from clinical use and serviced by a Hamilton Medical authorized service engineer.
- It is recommended that additional independent monitoring devices be used during mechanical ventilation. The operator of the ventilator must still maintain full responsibility for proper ventilation and patient safety in all situations.
- Do not silence the audible alarm when leaving the patient unattended.
- Do not use the exhaust port of the expiratory valve for spirometry. Due to the HAMILTON-MR1's base flow, the exhaust gas output is larger than the patient's actual exhaled volume.
- Do not put a vessel filled with a liquid on the ventilator. If a liquid enters the product, a fire and/or electric shock may occur.

Fire and other hazards

WARNING

Be sure to use an MR Safe or MR Conditional medical gas supply system.

- Be sure to read the safety information in Section 3.2 for safety information related to working with the device in the MRI environment.
- To reduce the risk of fire or explosion, do not place the ventilator in a combustible or explosive environment (for exam-

ple, around flammable anaesthetics or other ignition sources) or insufficiently ventilated areas. Do not use it with any equipment contaminated with oil or grease. Highly compressed oxygen together with flammable sources could lead to spontaneous explosions.

- To minimize the risk of fire, do not use high-pressure gas hoses that are worn or contaminated with combustible materials like grease or oil.
- The HAMILTON-MR1 can be used in an oxygen-enriched environment. To reduce the risk of fire, use only breathing circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.
- In case of fire, immediately secure the patient's ventilatory needs, switch off the ventilator, and disconnect it from its gas and electrical sources.
- Do not use if primary power source cables are damaged.
- To ensure that toxic constituents are not entrained into the breathing gas, ventilate the patient with 100% O2.

Service and testing

- To ensure proper servicing and to prevent possible physical injury, only Hamilton Medical authorized service personnel should attempt to service the ventilator.
- Do not attempt service procedures other than those specified in the service manual.
- Only use replacement parts supplied by Hamilton Medical.
- The preventive maintenance program requires a general service every 5000 hours or yearly, whichever comes first.
- To reduce the risk of electrical shock, disconnect electrical power from the ventilator before servicing. Be aware that battery power remains even after the mains is disconnected. Be aware that if the power switch is off, some parts still carry high voltage.
- To ensure the ventilator's safe operation, always run the preoperational check before using the ventilator on a patient. If the ventilator fails any tests, remove it from clini-

cal use immediately. Do not use the ventilator until necessary repairs are completed and all tests have passed.

- The manufacturer can only be responsible for the safety, reliability, and performance of the ventilator if all of the following requirements are met:
  - Appropriately trained personnel carry out assembly operations, extensions, readjustments, modifications, maintenance, or repairs.
  - The electrical installation of the relevant room complies with the appropriate requirements.
  - The ventilator system is used in accordance with the operator's manual.

Electromagnetic susceptibility

The HAMILTON-MR1 complies with the IEC 60601-1-2 EMC (Electromagnetic Compatibility) Collateral Standard. It is intended for use in the electromagnetic environment described in Tables A-16 through A-18.

General standards and approvals

NOTE:

Where standards are mentioned, the HAMILTON-MR1 complies with the versions listed in Table 1.

Table 1. Standards and approvals, valid versions

IEC 60601-1:2005/A1:2012
ANSI/AAMI ES60601-1:2005/(R)2012
CAN/CSA-C22.2 No. 60601-1:14
IEC 60601-1-2:2007
ISO 80601-2-12:2011 + Cor.:2011
ISO 80601-2-55:2011
CISPR 11:2009+A1:2010

Table 1. Standards and approvals, valid versions

IEC 61000-3-2:2005
IEC 61000-3-3:2008
IEC 61000-4-2:2008
IEC 61000-4-3:2006+A1:2007+A2:2010
IEC 61000-4-4:2004
IEC 61000-4-5:2005
IEC 61000-4-6:2003+A1:2004+A2:2006
IEC 61000-4-8:2009
IEC 61000-4-11:2004
EN ISO 5359:2008 + A1: 2011
EN ISO 13485:2012/AC:2012
IEC 60950-1:2005+A1:2009+A2:2013
ISO 15883-1:2006+A1:2014
ISO 15883-2:2006
ISO 15883-3: 2006
ISO 15883-4:2008
ISO 11607-1: 2006 + AMD1:2014
EN ISO 9001:2008
EN ISO 5356-1:2004
ISO 4135:2001
ASTM F2503-13 (2013)
MIL-STD-461F

For further Information see Section A.12.

Units of measure

NOTE:

In this manual pressure is indicated in cmH2O and length in cm. Magnetic field readings and thresholds are measured in milliTesla (mT).

On the HAMILTON-MR1, pressures are indicated in cmH2O, mbar or hPa. Hectopascals (hPa) are used by some institutions instead. Since 1 mbar equals 1 hPa, which equals 1.016 cmH2O, the units may be used interchangeably. Length is indicated in cm or inch.

Disposal

All parts removed from the device must be considered contaminated and pose infection risk. Dispose of all parts removed from the device according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it (for example, oxygen cell, batteries).

Year of manufacture

The year of manufacture is shown on the serial number label on the HAMILTON-MR1 ventilation unit.

Table of Contents

1 General information

1.1 Introduction

The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

Ventilation modes. This full-functioned intensive care ventilator offers a complete range of ventilation modes.

Table 1-1. Ventilation modes

Volume modes (adaptive pressure)	
Delivered by an adaptive volume controller, these modes combine the attributes of pressure-controlled with volume-targeted ventilation.	
(S)CMV+/APVcmv	Synchronized controlled mandatory ventilation
SIMV+/APVsimv	Synchronized intermittent mandatory ventilation
Pressure modes	
Conventional pressure-controlled ventilation.	
PCV+	Pressure-controlled ventilation
PSIMV+	Pressure-controlled synchronized intermittent ventilation
SPONT	Spontaneous pressure-supported ventilation
Related forms of pressure ventilation designed to support spontaneous breathing on two alternating levels of CPAP. Available as an option.	
DuoPAP	Dual positive airway pressure
APRV	Airway pressure release ventilation
Intelligent Ventilation	
Guarantees that the patient receives the selected minute ventilation with the optimal breath pattern (lowest pressure and volume, optimal rate to minimize work of breathing, and intrinsic PEEP).	
ASV®	Adaptive support ventilation *Not available for neonatal patients.*

Table 1-1. Ventilation modes *(continued)*

Noninvasive *Pressure support ventilation through a mask or other noninvasive interface. Available as options.*	
NIV	Noninvasive ventilation. Leak compensated with IntelliTrig in order to secure perfect patient–ventilator synchronization.
NIV-ST	Spontaneous/timed noninvasive ventilation. Leak compensated with IntelliTrig in order to secure perfect patient–ventilator synchronization.
nCPAP 	Nasal continuous positive airway pressure through a nasal interface (mask or prongs) for infants and neonates. This mode provides controlled airway pressure, without any breaths.
nCPAP-PC 	Nasal continuous positive airway pressure - pressure control through a nasal interface (mask or prongs) for infants and neonates. Provides pressure-controlled mandatory breaths, triggered by the ventilator.

Patient-triggered breaths are flow triggered.

Monitoring. The HAMILTON-MR1 offers a variety of monitoring capabilities. It displays monitored parameters as numbers. You can also see this data graphically, as a combination of real-time waveforms (curves), loops, trends, and special Intelligent Panels.

These Intelligent Panels include the Dynamic Lung, which shows the lung's activity, and the Vent Status, which indicates the patient's level of ventilator dependency.

The HAMILTON-MR1's monitored data is based on pressure and flow measurements collected by the Hamilton Medical proximal flow sensor[1], between the Y-piece and the patient, and on FiO2 measurements by the integrated oxygen monitor.

Alarms. The HAMILTON-MR1's operator-adjustable and non-adjustable alarms help ensure your patient's safety.

MRI environment. The HAMILTON-MR1 has been specially designed and shielded to ventilate your patient in the vicinity of an MRI device. It can accompany your patient from the ICU to the MRI for the duration of the test, and back to the ICU, increasing the safety of care. The onboard magnetic field navigator, TeslaSpy, continuously measures the background magnetic levels, and lets you know when levels exceed the ventilator's safety thresholds, using yellow and red indicator lights and audible alarms.

User interface. The ventilator's ergonomic design, including a 8.4-in. color touch screen, a press-and-turn dial, and keys, lets you easily access the ventilator settings and monitored parameters.

Customizability. You can customize the HAMILTON-MR1 so that it starts up with institution-defined settings.

Power. The HAMILTON-MR1 uses an external power supply connected to AC power as its primary source. If the primary power source fails, the ventilator automatically switches to backup batteries. The device has two internal batteries, which provide up to 9 hours of running time. The batteries cannot be removed.

Mounting variations for the HAMILTON-MR1 includes a modified standard trolley safe for use in the MRI environment with an auto-lock brake and safety tether, and includes a permanent mount for the external power supply and a mount for an MR Safe or MR Conditional medical gas supply system. The ventilator can also be mounted on a shelf.

1. In the neonatal nCPAP and nCPAP-PC modes, a pressure line is used instead of a flow sensor.

Nebulization function. The nebulization function lets your HAMILTON-MR1 power a pneumatic nebulizer connected to the nebulizer outlet. Pneumatic nebulization is disabled during neonatal ventilation.

Options[1]

The following options are available for the HAMILTON-MR1:

Table 1-2. Options

Option	Description
Some options require additional hardware. Options are enabled in Configuration mode.	
Adult/pediatric support	Ventilation of adult and pediatric patients.
Neonatal support	Ventilation of infants and neonates starting from a tidal volume of 2 ml.
nCPAP and nCPAP-PC ventilation modes	See Table 1-1.
DuoPAP and APRV ventilation modes	See Table 1-1.
NIV and NIV-ST ventilation modes	See Table 1-1.
Loops and trends	View 1-, 6-, 12-, 24-, or 72-h trends for monitored parameters.[1] Display a dynamic loop for a variety of parameter combinations, including pressure-volume, pressure-flow, and flow-volume.

1. 72-h trends not available in all markets.

1. Not all options are available in all markets

1.2 Functional description

The following paragraphs describe the operation of the HAMILTON-MR1 ventilator hardware.

1.2.1 System overview

The HAMILTON-MR1 is an electronically controlled pneumatic ventilation system with an integrated air compressing system. It uses an external power supply connected to AC mains with battery backup to protect against power failure or unstable power and to facilitate intra-hospital transport. The ventilator's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.

The user provides inputs to the microprocessor system through a touch screen, keys, and a press-and-turn (P&T) knob. These inputs become instructions for the pneumatics to deliver a precisely controlled gas mixture to the patient. The ventilator receives inputs from the proximal flow sensor and other sensors within the ventilator. Based on this monitored data, the ventilator adjusts gas delivery to the patient. Monitored data is also displayed by the graphic user interface.

The ventilator's microprocessor system controls gas delivery and monitors the patient. The gas delivery and monitoring functions are cross-checked by an alarm controller. This cross-checking helps prevent simultaneous failure of these two main functions and minimizes the possible hazards of software failure.

A comprehensive system of visual and audible alarms helps ensure the patient's safety.

- Clinical alarms can indicate an abnormal physiological condition.
- Technical alarms, triggered by the ventilator's self-tests including ongoing background checks, can indicate a hardware or software failure.

  In the case of some technical alarms, a special safety mode ensures basic minute ventilation while giving the user time for corrective actions.

When a condition is critical enough to possibly compromise safe ventilation, the ventilator is placed into the ambient state. The inspiratory channel and expiratory valves are opened, letting the patient inspire room air through the inspiratory channel and exhale through the expiratory valve.

The HAMILTON-MR1 has several means to ensure that safe patient or respiratory pressures are maintained. The maximum working pressure is ensured by the high pressure alarm limit. If the set high pressure limit is reached, the ventilator cycles into exhalation. The ventilator pressure cannot exceed 60 cmH2O.

The HAMILTON-MR1 uses an onboard sensor, TeslaSpy, to continuously monitor the surrounding magnetic field. The front of the device provides three indicator lights (green, yellow, and red) to indicate whether the levels are within acceptable limits for the device. Safe levels are indicated by a slowly blinking green indicator light. Elevated magnetic fields are indicated first by yellow, then by red flashing indicator lights, and by nonsilenceable alarms. For details, see Chapter 3, "Working in the MRI environment".

1.2.2 Gas supply and delivery

WARNING

Be sure to read the safety information in Section 3.2 before entering the MRI environment.

The HAMILTON-MR1 uses room air and high-pressure oxygen (Figure 1-1). The use of medical oxygen is mandatory. Air enters through a fresh gas intake port and is compressed together with the oxygen by the blower. Oxygen enters through a high-pressure[1] inlet.

1. High-pressure oxygen: Maximum permissible pressure 600 kPa

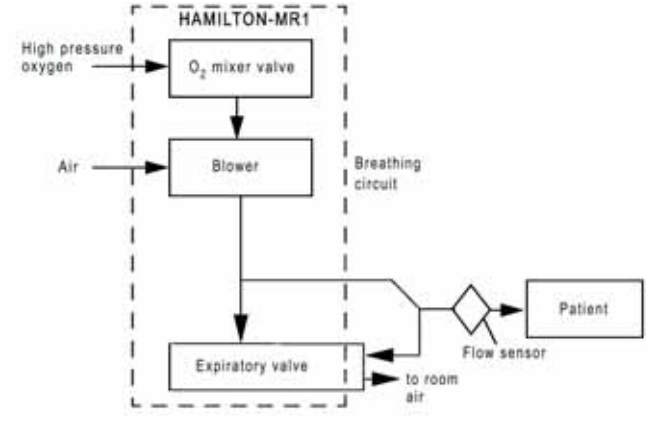


Figure 1-1. Gas delivery in the HAMILTON-MR1

Within the ventilator, the gas enters the ventilator's pneumatic system. A mixer valve provides for the operator-set concentration.

Gas is supplied to the patient via the blower. The microprocessor controls the size of the speed of the blower and the length of time it is running to meet the user settings.

The ventilator delivers gas to the patient through the inspiratory limb breathing circuit parts, which may include an inspiratory filter, flex tubes, the Y-piece, and the flow sensor. An internal pneumatic nebulizer supplies the nebulizer flow.

Gas exhaled by the patient passes through the expiratory limb breathing circuit parts, including flex tubes, the flow sensor, the Y-piece, and an expiratory valve cover and membrane. Gas is vented through the expiratory valve cover such that no exhaled gas comes into contact with any internal components of the ventilator. Measurements taken at the flow sensor are used in the pressure, flow, and volume measurements.

An oxygen cell (sensor) monitors the oxygen concentration of the gas to be delivered to the patient. This galvanic cell generates a voltage proportional to the partial pressure of oxygen in the delivered gas. This oxygen measurement is compensated for changes in pressure.

The operations of the blower and expiratory valve are coordinated to maintain system pressure levels.

1.2.3 Gas monitoring with the flow sensor

The HAMILTON-MR1 accurately measures flow, volume, and pressure in the patient's airway with the Hamilton Medical flow sensor. This proximal flow sensor lets the ventilator sense even weak patient breathing efforts. Between its highly sensitive flow trigger and fast response time, the ventilator helps minimize the patient's work of breathing.

The flow sensor contains a thin, diamond-shaped membrane within the outer housing and has a pressure port on either side. The membrane allows bidirectional flow through its variable orifice (Figure 1-2).

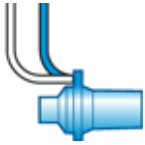


Figure 1-2. Flow sensor (adult/pediatric)

The area of the orifice changes depending on the flow rate. It opens progressively as the flow increases, creating a pressure drop across the orifice. The pressure difference is measured by a high-precision differential pressure sensor inside the ventilator. The pressure difference varies with flow (relationship determined during flow sensor calibration), so the patient's flow is determined from the pressure drop. The ventilator calculates volume from the flow measurements.

The flow sensor is highly accurate even in the presence of secretions, moisture, and nebulized medications. The ventilator flushes the sensing tubes with mixed gases (rinse flow) to prevent blockage.

1.3 Physical description

1.3.1 Breathing circuits and accessories

WARNING

- **Be sure to read the safety information in Section 3.2 before entering the MRI environment.**
- **To ensure proper ventilation operation, use only parts and accessories specified in Appendix F and in the product catalog, or that are specified as being compatible with this ventilator.**
- **Use only MR Safe or MR Conditional parts and accessories with the ventilator in an MRI environment.**

NOTE:

Pressure and volume measurement accuracy may be affected by using a breathing circuit with high resistance. Accuracy was tested with Hamilton Medical devices using the breathing circuits PN 281592 for neonates, and PN 260086 for adults and pediatrics.

Figure 1-3 shows the HAMILTON-MR1 with its breathing circuit and accessories. Contact your Hamilton Medical representative for details on breathing circuits and accessories supplied by Hamilton Medical.

See Appendix F of this manual and the product catalog for information on compatible breathing circuits and accessories.

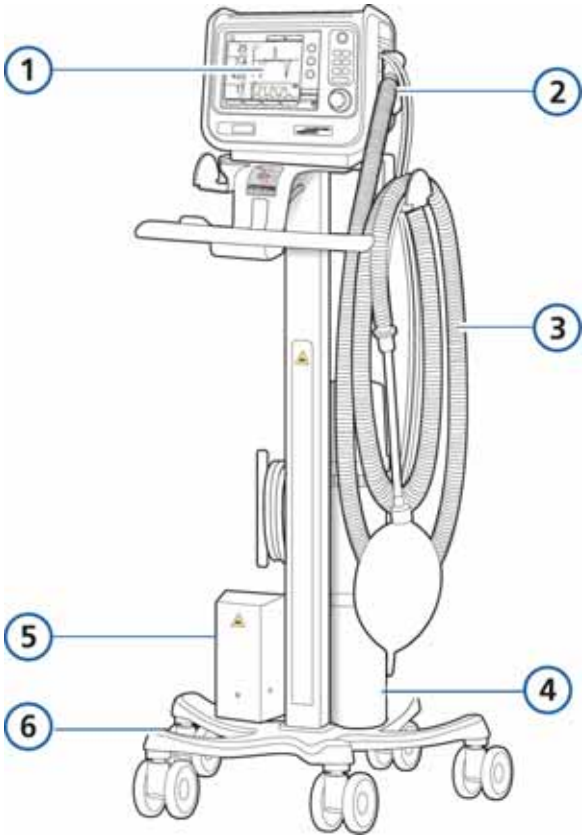


Figure 1-3. HAMILTON-MR1 with accessories

1	Display	**4**	O2 cylinder
2	Breathing circuit connections	**5**	Power supply
3	Breathing circuit	**6**	HAMILTON-MR1 trolley

1.3.2 Ventilator unit

Figures 1-4 through Figure 1-7 show the controls, indicators, and other important parts of the ventilator unit.

When a selected function is active, the indicator light next to the key is lit.

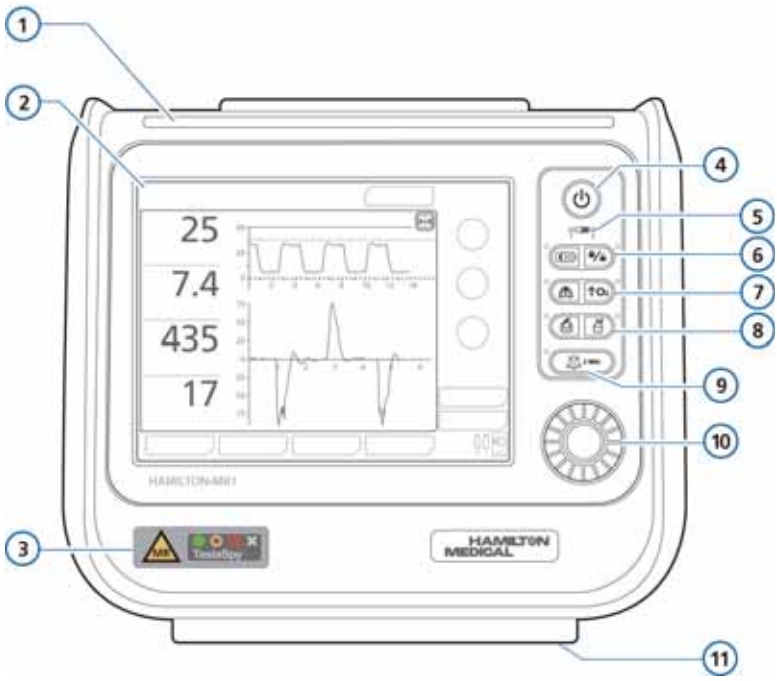
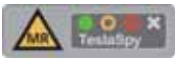


Figure 1-4. Front view

Item	Description
1	**Alarm lamp.** Entire lamp lights when an alarm is active (flashing red = high-priority alarm, flashing yellow = medium-priority alarm, solid yellow = low-priority alarm). In addition, a red light in the middle is continuously lit when alarm silence is active. This red light flashes when an alarm silence is inactive but an alarm is active.
2	**Display.** Touch screen that provides access to measurements and controls.

Item	Description
3 	**TeslaSpy status lights and alarms.** Shows the status of the background magnetic field. For details, see Chapter 3. GREEN light blinking. Surrounding magnetic field is within acceptable limits. YELLOW light blinking, accompanied by a nonsilenceable audible alarm. Surrounding magnetic field is above the acceptable limit. Immediately move the HAMILTON-MR1 further away from the scanning device to stop the alarm and to avoid damaging the device. Left RED light blinking, accompanied by a nonsilenceable audible alarm. Surrounding magnetic field is well above the acceptable limit, and may be damaging the device. Immediately move the HAMILTON-MR1 further away from the MRI scanner. Ventilate the patient using an alternative method, and disconnect the patient from the device. Do not use the device again until it has been serviced by Hamilton Medical authorized service personnel. Right RED X only illuminates in case of an internal error with the TeslaSpy navigator. Follow the same procedure as for the left red light.
4 	**Power/Standby key.** Turns the ventilator on and off and accesses standby. • To turn on the ventilator, press the key for ~ 3 s. • To put the ventilator into standby, press and quickly release the key, then touch **Activate Standby** on the display. For details, see Section 10.2. • To turn off ventilator power, press the key quickly to access standby window, then press the key again for > 3 s; or, if there is a technical fault, press and hold the key for > 10 s.
5 	**Battery charge indicator**. Each battery (1 and 2) has its own charge indicator. See Section 2.7. Lit to show the indicated battery is fully charged, even if the ventilator is turned off. Flashing to show the indicated battery is charging, even if the ventilator is turned off. Dark to show the indicated battery is not being charged (over temperature) or the ventilator is not plugged into a primary power source.

Item	Description
6 	**Day/Night key.** Switches between the Day and Night display brightness settings that are specified in the System window.
6 	**Screen lock/unlock key.** Prevents inadvertent change of settings. See Section 10.9. When screen lock is active, the green indicator is lit and the following items are inactive: touch screen, press-and-turn knob, and the Power/Standby, Day/Night, and Print screen keys The following keys are active: Alarm silence, Manual breath, O2 enrichment, Nebulizer
7 	**Manual breath/inspiratory hold key.** Triggers a mandatory breath when pressed and released during exhalation. Triggers an inspiratory hold when held down during any breath phase. See Section 10.6. When active, the green indicator is lit.
7 	**O2 enrichment key.** When active, the green indicator is lit. See Section 10.4. Adults/Pediatric: Delivers 100% oxygen for 2 min. The actually applied oxygen concentration is displayed on the oxygen control (green). Push the key a second time or manually change the oxygen concentration (FiO2) to end enrichment. Neonatal: Delivers 125% of the last oxygen setting for 2 min. The backlit color changes to green and the currently applied oxygen concentration is displayed on the oxygen control. Push the key a second time or manually change the oxygen concentration (FiO2) to end enrichment.
8 	**Print screen key.** Save a JPG file of the used current ventilator screen to a USB memory drive. The green indicator is lit while the device saves the image to the USB memory drive. See Section 10.8.
8 	**Nebulizer on/off key.** Activates pneumatic nebulizer, during the inspiration phase if high-pressure oxygen is connected. Nebulization stops automatically after 30 min. Turn it off earlier by pressing the key again. When active, the green indicator is lit. See Section 10.7.

Item	Description
9 	**Alarm silence key.** Silences the main ventilator audible alarm for 2 min. Press the key a second time to cancel the alarm silence. The red indicator next to the key flashes when an alarm is active but not muted. It is continuously lit while alarm silence is active. See Section 10.3.
10	**Press-and-turn (P&T) knob**. Used to select and adjust ventilator settings. A green ring around the knob is lit when the ventilator is turned on.
11	*Underside of ventilator:* **Expiratory valve bleed port, FireWire port for TeslaSpy** Do not obstruct the expiratory valve bleed port. The FireWire port is for internal use only.

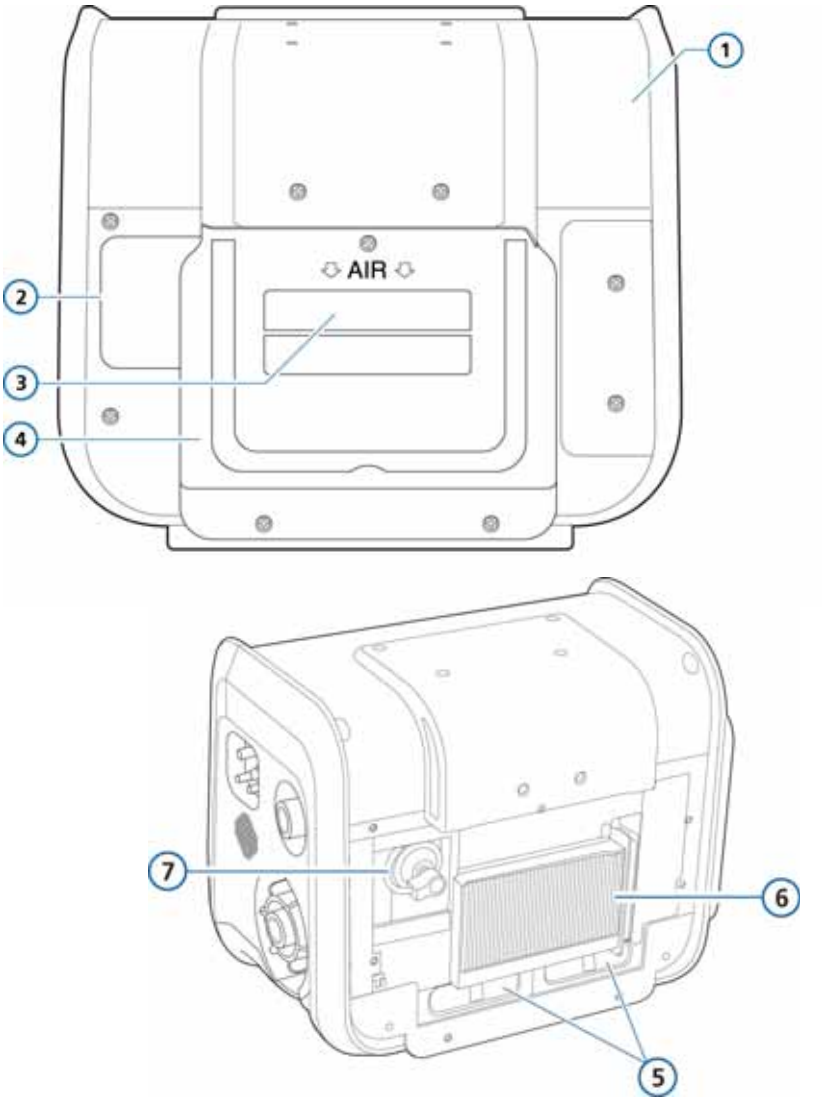


Figure 1-5. Rear view

Item	Description
1	**Label.** Provides device-specific information
2	**O2 cell** (under cover)
3	**Air intake and dust filter** Do not obstruct
4	**Rear compartment and cover** The cover has electromagnetic shielding behind the air intake/ dust filter; do not remove it.
5	**Batteries** Both batteries must always be installed when operating the device. See Section 2.7 and Chapter 11.
6	**HEPA filter** To exchange the HEPA filter, remove the rear cover. See Chapter 11. **NOTE:** The HEPA filter is required both to minimize the risk of bacterial or viral contamination of the breathing gas and physical damage to the inside of the device.
7	**Oxygen cell** To exchange the O2 cell, remove the rear cover. See Chapter 11.

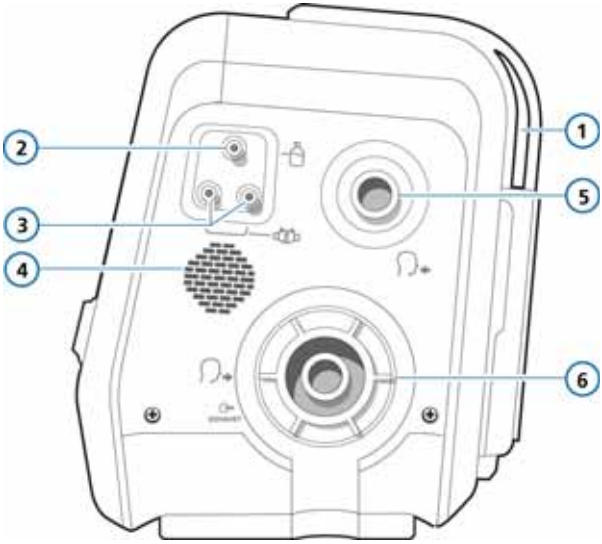


Figure 1-6. Side view, with breathing circuit connections

Item	Description
1	**Cooling air outlet** Do not obstruct
2	**Pneumatic nebulizer output connector** Port for pneumatic nebulizer. For details, see Section 10.7.
3	**Hamilton Medical flow sensor ports**
4	**Loudspeaker**
5	**To patient port** To connect the inspiratory filter and the inspiratory limb of the breathing circuit.
6	**From patient port with expiratory valve cover and membrane** To connect the expiratory limb of the patient breathing circuit. EXHAUST

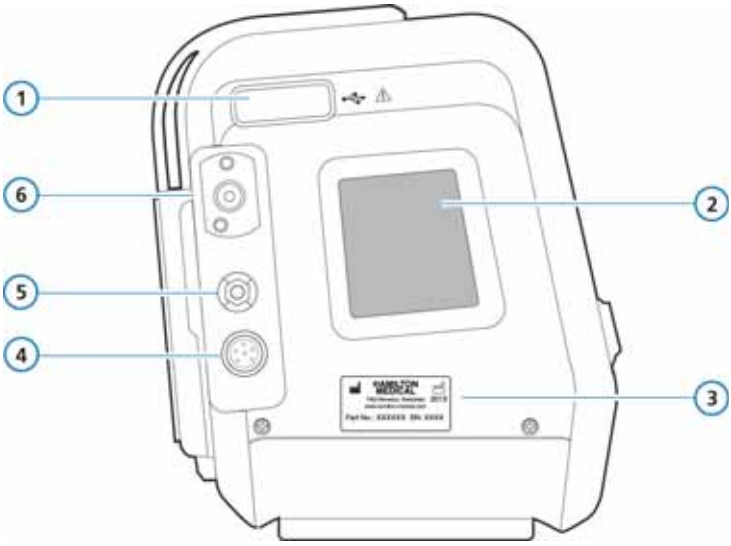


Figure 1-7. Side view, with gas connections

Item	Description
1	**USB connector**. Used by passive memory devices only, for software update, event log export, configuration setting export and import, and print screen. **WARNING** • **During transfer of a ventilated patient, to prevent water intake, the USB port must be covered with the silicon cover (included).** • **It is not allowed to use the USB port during transfer of a ventilated patient.** **NOTE:** Not for use as a wireless plug-in connection (that is, dongles). No wireless connections are to be made using the USB port.
2	**Cooling air intake and dust filter** Do not obstruct
3	**Serial number label**

Item	Description
4	**Power receptacle** Used to connect to the external power supply.
5 	**Equipotential grounding post** The potential equalization conductor can be used to connect the ventilator to a central point of grounding to equalize the ground level or reduce leakage current.
6	**Oxygen DISS or NIST inlet fitting**

1.3.3 Main display

Directly access all the windows for mode, controls, alarms, and monitoring from the main display during normal ventilation. Figure 1-8 shows the default display.

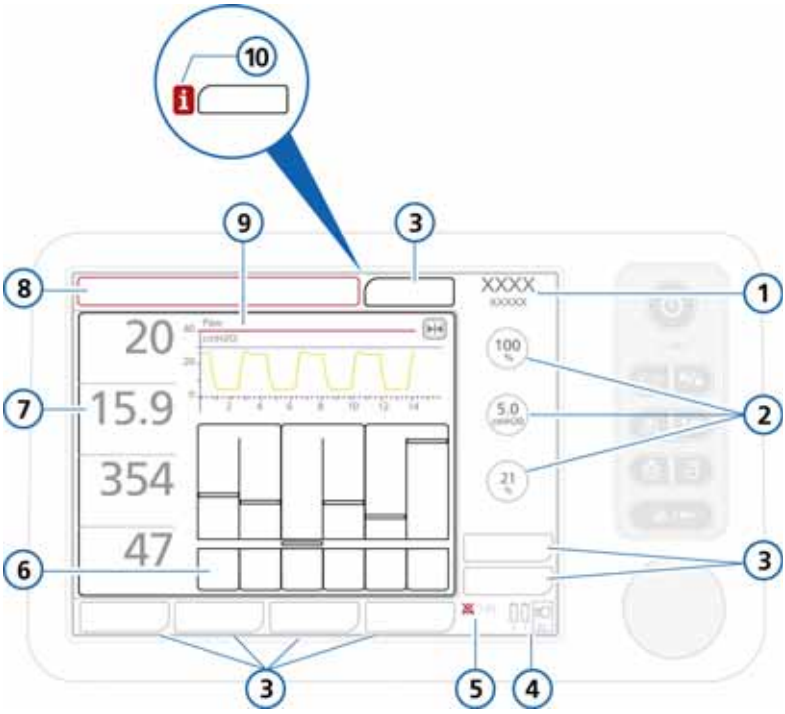


Figure 1-8. Default (basic) display

Item	Description
1	**Active mode and patient group**
2	**Main controls.** The most important controls. Touch the **Controls** button (**3**) to display all controls for the selected mode.
3	**Window buttons (tabs).** Open the associated windows.
4	**Input power.** Shows all available power sources. The framed symbol indicates the current source (AC = mains, 1 = battery 1, 2 = battery 2). The green part of the battery symbol shows the level of battery charge, while the red shows the level of discharge.

Item	Description
5	**Alarm silence indicator and countdown.** Shows whether alarm silence has been activated, and displays the remaining silence time. **NOTE:** The Alarm silence key does not apply to the TeslaSpy navigator magnetic field indication alarms; they cannot be silenced this way. See Chapter 3 for details on silencing the TeslaSpy alarms.
6	**Graphic display.** Shows user-selectable waveform or an Intelligent Panel graphic (Dynamic Lung, ASV graph, Vent Status).
7	**Main monitoring parameters (MMP).** Configurable list of monitored parameters. You can view *all* parameter values in the Monitoring window. MMPs change their colors when a corresponding alarm activates. The color reflects the priority of the alarm (red for high priority, yellow for medium or low priority).
8	**Message bar.** Displays color-coded alarm messages. If an alarm is active, touch the message bar to view the alarm buffer.
9	**Pressure/time waveform.** Always displayed. • The waveform shows the patient's breath cycles. • The (red) line across the top is the maximum pressure, corresponding to the Pmax alarm limit. • The (blue) line indicates the pressure limit value, set to the maximum pressure – 10 cmH20. • The pink triangles indicate the patient is triggering a breath. • The Freeze button freezes the graphic so you can scroll through the points and examine them in more detail.
10	**Alarm indicator (i-icon)**. Indicates that there is information about alarms in the alarm buffer. Touch the i-icon to view the alarm buffer.

1.4 Symbols used on device labels and packaging

Table 1-3. Symbols used on device labels and packaging

Symbol	Definition
	Power/standby key
	Manufacturer
	Date of manufacture
	Type B applied part (classification of medical electrical equipment, type B, as specified by IEC 60601-1)
	Consult operator's manual. Refer to the operator's manual for complete information. This label on the device points the user to the operator's manual for complete information. In the operator's manual, this symbol cross-references the label.
	Symbol for "Caution". Applied parts not protected against defibrillation.
CE 0197	CE Marking of Conformity, seal of approval guaranteeing that the device is in conformance with the Council Directive 93/42/EEC concerning medical devices
	The TÜV NRTL mark with the indicators "C" and "US" means that the product complies with Canadian requirements and the requirements of US authorities for safety
	Dispose according to Council Directive 2002/96/EC or WEEE (Waste Electrical and Electronic Equipment)
	Terminal for the connection of a potential equalization conductor
SN	Serial number
REF or PN	Part number
	Fuse
	MR Conditional. An item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
	This way up at transport and storage

Table 1-3. Symbols used on device labels and packaging *(continued)*

Symbol	Definition
	Fragile, handle with care at transport and storage
	Keep dry at transport and storage
	Temperature limitations at transport and storage
	Humidity limitations at transport and storage
	Atmospheric pressure limitations at transport and storage
	Stacking limitations at transport and storage
	Recyclable materials
	Mass
IP21	Protected against: • Insertion of fingers or similar objects • Dripping water (vertically falling drops) shall have no harmful effect

2 Preparing for ventilation

2.1 Introduction

WARNING

- **Be sure to read the safety information in Section 3.2 before entering the MRI environment.**
- **Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (for example, IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1, clause 16).**

  Anybody connecting additional equipment to medical electrical equipment configures a medical system and is, therefore, responsible that the system complies with the requirements for medical electrical systems. Note that local laws take priority over the above-specified requirements. If you have questions about how to proceed, consult your Hamilton Medical representative or technical service department.
- **In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death.**
- **The ventilator must not be used in a hyperbaric chamber.**
- **Before beginning ventilation, ensure the O2 cell is installed. See Section 11.3.3.**
- **Adding attachments or other components or subassemblies to the HAMILTON-MR1 can change the pressure gradient across the HAMILTON-MR1; these changes to the HAMILTON-MR1 can adversely affect the ventilator performance.**
- **To prevent back pressure and possible patient injury, do not attach any parts not expressly recommended by Hamilton Medical to the expiration port of the expiratory valve housing (for example, spirometers, tubes, or other devices).**

- **To prevent increased emissions, decreased immunity, or interrupted operation of the ventilator or any accessories, use only accessories or cables that are expressly stated in this manual.**
- **To prevent interrupted operation of the ventilator due to electromagnetic interference, avoid using it adjacent to or stacking other devices on it. If adjacent or stacked use is necessary, verify the ventilator's normal operation in the configuration in which it will be used.**
- **For important safety information about using the HAMILTON-MR1 trolley, see Section 2.9.**

CAUTION

- **Before using the ventilator for the first time, Hamilton Medical recommends that you clean its exterior and sterilize its components as described in Chapter 11.**
- **To electrically isolate the ventilator circuits from all poles of the primary power supply simultaneously, disconnect the power plug.**
- **To prevent possible patient injury, do not block the holes at the back and the side (cooling fan) of the ventilator. These holes are vents for the fresh air intake and the cooling fan.**

NOTE:

For details on setting up the ventilator for use in the MRI environment, including working with the trolley and positioning the ventilator, see Chapter 3.

2.2 Connecting the patient breathing circuit

WARNING

- **Be sure to read the safety information in Section 3.2 before entering the MRI environment.**
- **For each new patient, always use a new or properly decontaminated breathing circuit.**
- **To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.**
- **Make sure a HEPA filter is installed.**
- **To prevent patient or ventilator contamination, always use a bacteria filter or HMEF/HME between the patient and the inspiratory port.**
- **To reduce the risk of fire, use only breathing circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.**
- **Only use approved CE-labeled consumables as accessories.**

NOTE:

- Any bacteria filter, HMEF/HME, or additional accessories in the expiratory limb may substantially increase flow resistance and impair ventilation.
- To ensure that all breathing circuit connections are leak-tight, perform the tightness test every time you install a circuit or change a circuit part.
- For optimal ventilator operation, use Hamilton Medical breathing circuits or other circuits that meet the specifications given in Appendix A. When altering the Hamilton Medical breathing circuit configurations (for example, when adding components), make sure not to exceed these inspiratory and expiratory resistance values of the ventilator breathing system, as required by ISO 80601-2-12.

- Pressure and volume measurement accuracy may be affected by using a breathing circuit with high resistance. Accuracy was tested with Hamilton Medical devices using the breathing circuits PN 281592 for neonates, and PN 260086 for adults and pediatrics.

Connecting the adult/pediatric breathing circuit comprises the following steps. For neonatal ventilation, see Chapter 6.

		See
1.	Install the bacteria filter or HMEF/ HME	Section 2.2.1 on page 2-6
2.	Install the expiratory valve	Section 2.2.2 on page 2-7
3.	Select the appropriate breathing circuit and components	Section 2.2.3 on page 2-8
4.	Assemble the breathing circuit	Section 2.2.4 on page 2-9
5.	Adjust position of the breathing circuit	Section 2.2.5 on page 2-12
6.	Perform any required tests (tightness test and calibrations) and the preoperational check	Chapter 4

2.2.1 Connecting the bacteria filter or HMEF/HME

To prevent patient or ventilator contamination, be sure to install a bacteria (inspiratory) filter or HMEF/HME between the patient and the inspiratory port.

For neonatal patients, use an infant HMEF/HME.

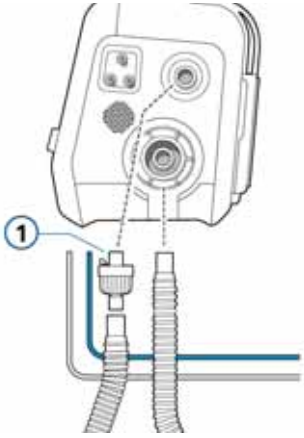


Figure 2-1. Installing a bacteria filter (1)

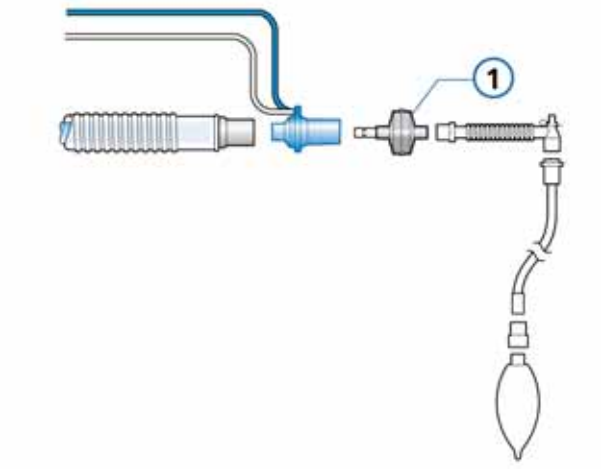


Figure 2-2. Installing an HMEF/HME (1)

2.2.2 Installing the expiratory valve

NOTE:

- Be sure to read the safety information in Section 3.2 before entering the MRI environment.
- Ensure you select the correct expiratory valve (adult/ pediatric or neonatal) for your patient. If the expiratory valve type does not match the selected patient group on the ventilator, the Wrong expiratory valve alarm is generated. See Table 9-2.

For neonatal ventilation, see Chapter 6.

1. Holding the expiratory valve housing (Figure 2-3), seat the silicone membrane onto the housing.

   The metal plate must face up and be visible.

2. Position the housing and twist clockwise until it locks into place.

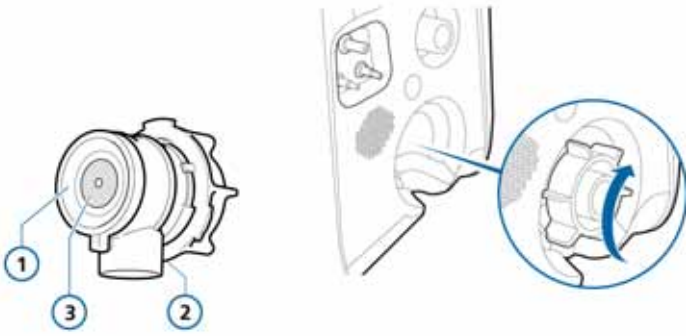


Figure 2-3. Installing the expiratory valve

1	Expiratory valve membrane	**3**	Metal plate facing the ventilator
2	Expiratory valve housing		

2.2.3 Selecting the breathing circuit

Select the correct breathing circuit parts for your patient from Table 2-1.

For neonatal ventilation, see Chapter 6.

Table 2-1. Adult/pediatric breathing circuit parts

Patient group	**Patient height** ***(cm)***	**IBW** ***(kg)***	**Tracheal tube ID** ***(mm)***	**Breathing circuit tube ID** ***(mm)***	**Flow sensor**
Pediatric	30 to 150 (11 to 59 in)	3 to 42	3 to 7	15	Adult/ pediat- ric
Adult	> 130 (51 in)	> 30	≥ 5	22	Adult/ pediat- ric

NOTE:
MR Safe breathing circuits apply to both adults and pediatrics. They are available in two lengths, 3.0 m and 4.8 m. See Chapter 3 and the ventilator product catalog.

2.2.4 Assembling the patient breathing circuit

Assembling the adult/pediatric breathing circuit comprises the following steps:

		See
1.	Connect the circuit	Figures 2-4 and 2-5 on page 2-10
2.	Install the flow sensor	Section 2.2.4.2 on page 2-12

2.2.4.1 Connecting the breathing circuit

Figures 2-4 through 2-5 show typical adult/pediatric breathing circuits. For neonatal ventilation, see Chapter 6.

For ordering information, contact your Hamilton Medical representative. Follow the specific guidelines for the different parts.

Connect the components as appropriate for your patient.

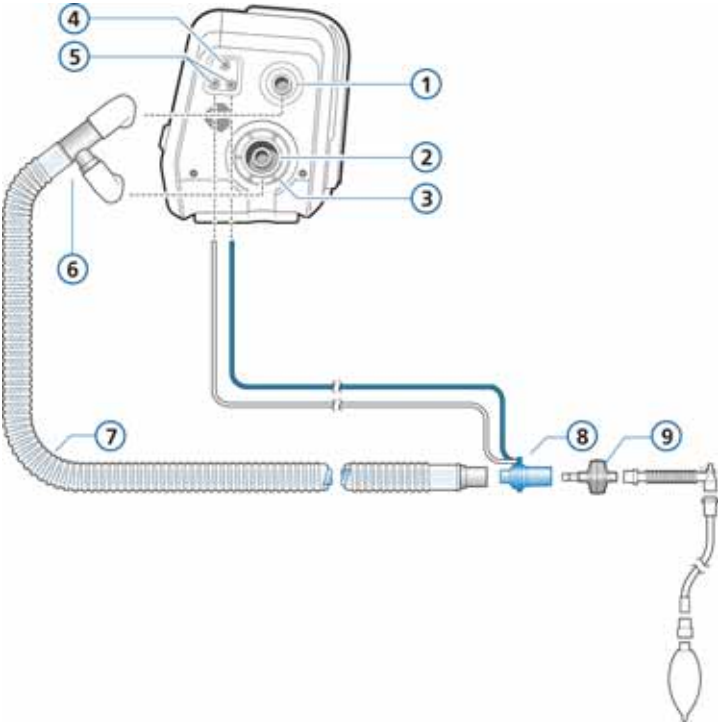


Figure 2-4. MR Safe coaxial breathing circuit with HMEF/HME for use in MRI environment (adult/pediatric)

1	To patient	**6**	Limb connector
2	From patient	**7**	Co-axial inspiratory/expiratory limb
3	Expiratory valve with membrane cover	**8**	Flow sensor
4	Nebulizer outlet	**9**	HMEF/HME
5	Flow sensor connectors		

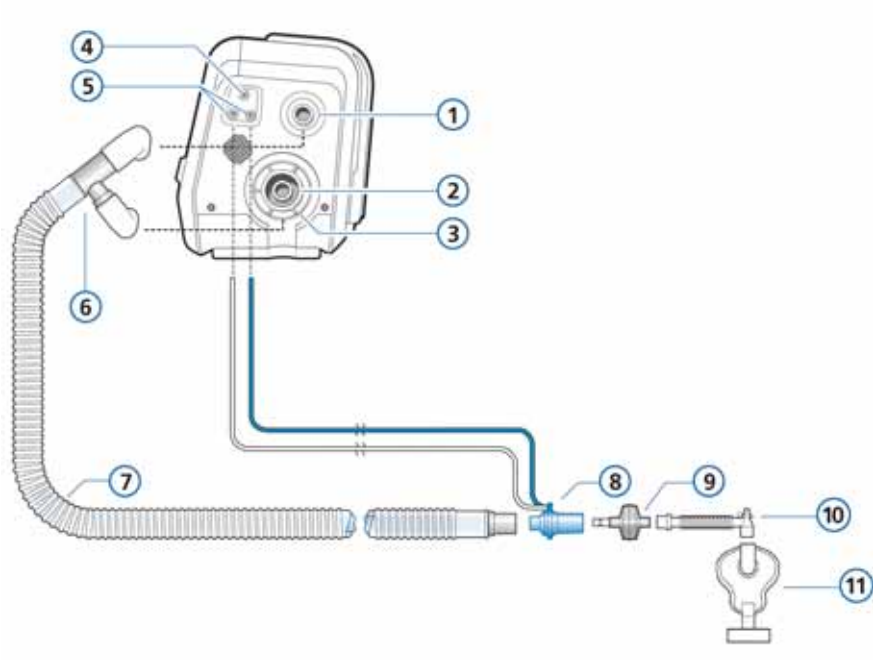


Figure 2-5. MR Safe coaxial breathing circuit for use with mask in MRI environment (adult/pediatric)

1	To patient	**7**	Co-axial inspiratory/expiratory limb
2	From patient		
3	Expiratory valve with membrane cover	**8**	Flow sensor
		9	HMEF/HME
4	Nebulizer outlet	**10**	Adapter
5	Flow sensor connectors	**11**	Mask (nonvented)
6	Limb connector		

2.2.4.2 Installing the flow sensor

NOTE:

To prevent inaccurate flow sensor readings, make sure the flow sensor is correctly installed:

- The flow sensor tubes must not be kinked.
- The flow sensor tubes must be secured with the included clamp (does not affect HAMILTON-MR1 breathing circuits).
- For neonatal ventilation, see Chapter 6.

1. Connect a flow sensor to the breathing circuit in front of the patient connection.

Figure 2-6. Flow sensor connected to coaxial breathing circuit

2. Connect the blue and clear tubes to the flow sensor connectors on the ventilator.

   The blue tube goes to the blue connector. The clear tube goes to the white connector.

2.2.5 Positioning the breathing circuit

After assembly, position the breathing circuit so that the hoses will not be pushed, pulled, or kinked as a result of patient movement, transport, or other activities, including scanner bed operation and nebulization.

The next step is to perform all required tests, calibrations, and the preoperational check. See Chapter 4.

2.3 Installing the pneumatic nebulizer

WARNING

- **Do not use an expiratory filter or HMEF in the patient's breathing circuit during nebulization. Nebulization can cause an expiratory side filter to clog, substantially increasing flow resistance and impairing ventilation.**
- **Connect the nebulizer in the inspiratory limb per your institution's policy and procedures. Connecting the nebulizer between the flow sensor and the endotracheal tube increases dead space and causes incorrect volume measurements.**
- **To prevent the expiratory valve from sticking due to nebulized medications, use only medications approved for nebulization and regularly check and clean or replace the expiratory valve membrane.**
- **Be aware that nebulization affects delivered oxygen concentration.**

NOTE:

Pneumatic nebulization is disabled during neonatal ventilation.

The nebulization feature provides a stable driving pressure to power a pneumatic nebulizer connected to the nebulizer outlet, optimally specified for a flow of approximately 8 l/min.

Connect the nebulizer and accessories as shown in Figure 2-7. See Appendix F for information about compatible nebulizers.

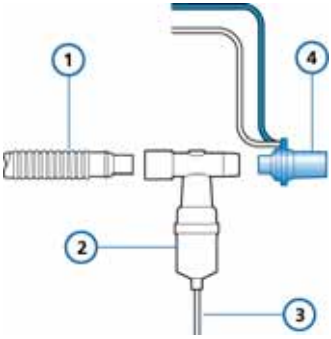


Figure 2-7. Installing a pneumatic nebulizer

1	Breathing circuit (coaxial shown)	**3**	Tube
2	Nebulizer	**4**	Flow sensor

2.4 Installing the Aeroneb Pro nebulizer

Be sure to read the safety information in Section 3.2 before entering the MRI environment.

NOTE:

Connect only approved piezo nebulizers to the HAMILTON-MR1 ventilator.

The Aerogen Aeroneb Pro nebulizer system is available as an option for the HAMILTON-MR1. Attach it to the mounting bracket. Consult the operating instructions supplied with the nebulizer for further installation and operating information.

2.5 Using an expiratory filter

CAUTION

- **The use of an expiratory filter can lead to a significant increase in expiratory circuit resistance. Excessive expiratory circuit resistance can compromise ventilation and increase patient work of breathing or AutoPEEP or both.**
- **Nebulization of drugs can cause an occlusion and increased resistance of the filter.**

NOTE:

Monitored parameters for increased expiratory resistance are not specific to the breathing circuit and may indicate increased patient airway resistance and/or increased resistance of the artificial airway (if used). Always check the patient and confirm adequate ventilation.

An expiratory filter is not required on the HAMILTON-MR1, but you may use one according to your institution's protocol. An expiratory filter is not required, because the expiratory valve design prevents internal ventilator components from contact with the patient's exhaled gas.

If you do use an expiratory filter, place it on the patient side of the expiratory valve cover. Remove any expiratory filter or HMEF/HME during nebulization. Monitor closely for increased expiratory circuit resistance. An **Exhalation obstructed** alarm may also indicate excessive expiratory circuit resistance. If the **Exhalation obstructed** alarm occurs repeatedly, remove the expiratory filter immediately. If you otherwise suspect increased expiratory circuit resistance, remove the expiratory filter or install a new filter to eliminate it as a potential cause.

2.6 Connecting to a primary power source

WARNING

- **Check the cables from the power transformer to the ventilator and to the AC power outlet. Do not use the cables if there are any open contacts.**
- **To avoid risk of electric shock, this equipment must only be connected to a power supply with protective earth.**

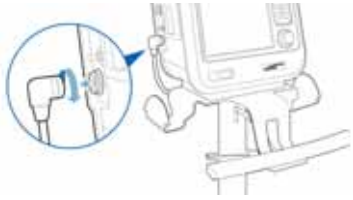
NOTE:

- Install the ventilator in a location where the primary power can be easily disconnected.
- Ensure the power connector is secured to the ventilator by turning the locking ring as described in step 3.
- The HAMILTON-MR1 requires protective earth grounding, because it is a class I device, as classified according to IEC 60601-1

The HAMILTON-MR1 uses an external power supply comprising a power transformer connected to AC power, and a cable from the power transformer that connects to the power socket on the ventilator.

To connect to primary power

1. Attach and secure the power transformer to the trolley or alternative mounting system.
2. Connect the power cable from the transformer to the ventilator.
3. Secure the connector to the ventilator by turning the locking ring clockwise until it is tight.



4. Connect the transformer to an outlet that supplies AC power between 100 and 240 V AC, 50/60 Hz. Always check the reliability of the AC outlet.

The AC power symbol in the bottom right-hand corner of the screen is displayed with a frame around it. See Figure 2-8.

2.7 About the batteries

WARNING

- **The batteries will not charge if the ambient temperature is above 43°C.**
- **Be aware that ventilation stops if the internal batteries are fully discharged and no external supply is available.**
- **Periodically check or replace the batteries.**

CAUTION

The use of both batteries is mandatory.

NOTE:

- HAMILTON MEDICAL recommends that the ventilator's batteries be fully charged before you ventilate a patient. If the batteries are not fully charged and AC power fails, always pay close attention to the level of battery charge.
- When operating the ventilator exclusively on battery power, monitor the remaining charge in the batteries. The bottom right corner of the ventilator display shows the power source symbols, which include indicators for the battery charge levels. See Figure 2-8.
- The device generates alarms to alert you to low battery capacity. For details, see the Battery low alarm description on page 9-13.
- The battery depletion rate may vary according to the age of the battery, ventilation mode, temperature, settings, etc.

The batteries protect the ventilator from low power or failure of the primary power source. When the primary power source fails, the ventilator automatically switches to operation on backup battery with no interruption in ventilation. An alarm sounds to signal the switchover.

Silence the alarm to confirm notification of the power system change; this resets the alarm.

The batteries power the ventilator until the primary power source is again adequate or until the batteries are depleted.

Hamilton Medical also provides high-capacity batteries[1] that have a longer operating time than the standard batteries. When installed, the text High-Cap appears next to the battery capacity information in the System -> Info window.

Fully charged high-capacity batteries typically power the ventilator for 8 h[2]. Two standard batteries typically power the ventilator for 5.5 h.

The ventilator also has a capacitor-driven backup buzzer that sounds continuously for at least 2 min when battery power is completely lost.

The ventilator charges the battery whenever the ventilator is connected to the primary power supply, with or without the ventilator being turned on. The battery charge indicator lights show the charging status as described in Table 2-2.

Table 2-2. Battery charging status

When the battery charge indicator is ...	The charging status is ...
Each battery (1 and 2) has its own charge indicator. See Figure 2-8.	
Lit	The indicated battery is fully charged, even if the ventilator is switched off.
Flashing	The indicated battery is charging, even if the ventilator is turned off.
Dark	The indicated battery is not being charged (over temperature) or the ventilator is not plugged into a primary power source.

1. Hamilton Medical Li-Ion batteries, revision 4 and later
2. If using previous revision batteries or a mix of revision 4 and older, operating time will be lower.

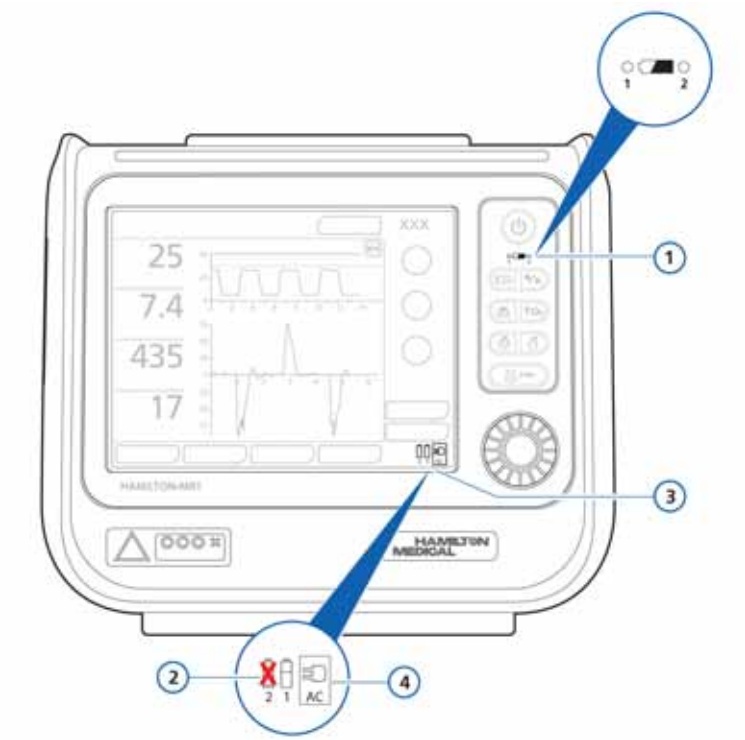


Figure 2-8. Power source symbols and battery charge indicator

1	Battery charge indicators (Table 2-2)	**3**	AC power symbol
2	Crossed-out battery means battery not available*	**4**	Frame indicates current power source

* ***This is an error condition.*** *You must immediately charge the device or replace the batteries as the HAMILTON-MR1 must only be operated with two functioning and charged batteries.*

The power source symbols in the bottom right-hand corner of the display show the available power sources. A frame around a symbol indicates the current ventilator power source. Green indicates the level of battery charge.

Each battery has its own icon, 1 and 2,

Check the battery charge level before connecting a patient to the ventilator and before unplugging the ventilator for transport or other purposes.

The battery symbols indicate the charge level as follows:

Table 2-3. Battery charge levels

When the battery symbol is ...	The battery is ...
Green	Fully charged
Orange and green	Partially charged
Crossed out (X)	Discharged or defective

If a battery is not fully charged, recharge it by connecting the ventilator to the primary power source for a minimum of 4 hours, until the battery charge level is 80% to 100%.

2.8 Connecting the oxygen supply

WARNING

- **Be sure to read the safety information in Section 3.2 before entering the MRI environment.**
- **It is *NOT* permitted to use the equipment with flammable gases or anaesthetic agents. Danger of fire!**
- **It is NOT permitted to use the ventilator with helium or mixtures of helium.**
- **An O2 cell must be installed.**

CAUTION

- **Always check the status of the oxygen cylinders or other supply before using the ventilator during transport.**
- **Make sure oxygen cylinders are equipped with pressure-reducing valves.**
- **To minimize the risk of fire, do not use high-pressure gas hoses that are worn or contaminated with combustible materials like grease or oil.**

NOTE:

- To prevent damage to the ventilator, connect only clean, dry medical-grade oxygen.
- For details on attaching medical gas to the ventilator in the MRI environment, see Chapter 3.

The HAMILTON-MR1 supports the use of oxygen from a high-pressure source.

High-pressure oxygen (2.8 – 6 bar / 280 to 600 kPa / 41 – 87 psi), provided by a central gas supply or a gas cylinder, is supplied through DISS or NIST male gas fittings (Figure 2-9). With the optional cylinder holder, you can mount oxygen cylinders to the trolley. If you use gases from cylinders, secure the cylinders to the trolley with the accompanying straps.

To connect the oxygen supply to the ventilator

Connect the oxygen hose to the HAMILTON-MR1's oxygen inlet fitting (**1**).

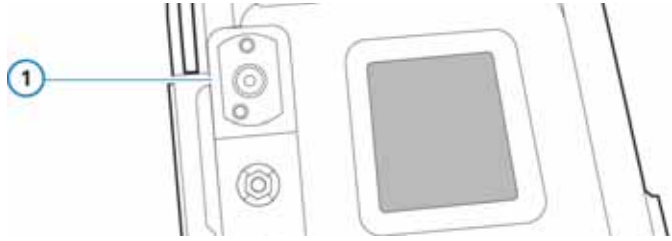


Figure 2-9. Oxygen inlet (1)

2.9 Working with the trolley

For details about working with the HAMILTON-MR1 trolley, see Chapter 3, "Working in the MRI environment".

2.10 Turning on the ventilator

CAUTION

To ensure the ventilator's safe operation, always run the preoperational check before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests have passed.

NOTE:

If the HAMILTON-MR1 is new, be sure it has been properly configured for default language, alarms, and other important settings (see Appendix G).

To turn on the ventilator

1. Press the ventilator Power/Standby key. The ventilator runs a self-test.

   After a short time, the patient setup window is displayed.

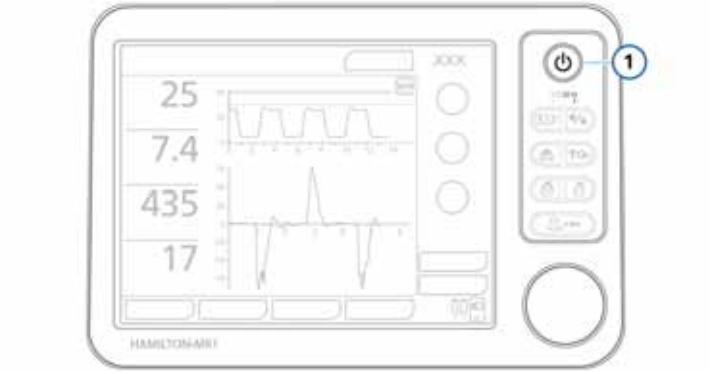


Figure 2-10. Power/Standby key (1)

2. Set up the ventilator as described in Chapter 5.
3. Run the preoperational check (Section 4.2).

2.11 Turning off the ventilator

NOTE:

- The TeslaSpy magnetic field sensor continuously samples the environment, measuring the background magnetic field, even when the ventilator is turned off.
- The ventilator remains connected to power when the power is turned off. This permits the battery to charge. To completely disconnect the ventilator from power, unplug it from the primary power outlet.

To turn off the HAMILTON-MR1

▶ Press and quickly release the Power/Standby key to access standby, then press the key again for > 3 seconds.

If there is a technical fault, press and hold the key for > 10 seconds.

2.12 Display navigation guidelines

Use the touch screen and the press-and-turn (P&T) knob to access the HAMILTON-MR1 ventilation parameters and monitored data. You typically use a *select–activate* or *select–activate–adjust–activate* procedure.

To open a window, touch the window tab to select and activate it, or turn the P&T knob to select the window tab (it is framed in yellow) and then press the knob to activate your selection.

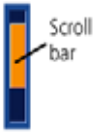
To close a window, touch the window tab or the X in the upper left-hand corner to select and activate it, or turn the P&T knob to select the X (it is framed in yellow) and then press the knob to activate your selection.

Selected

Activated

To adjust a control, touch the control to select and activate it; or turn the P&T knob to select the control (it is framed in yellow) and then press the knob to activate your selection. The activated control turns orange. Turn the knob to increase or decrease the value. Press the knob or touch the control to confirm the adjustment and deactivate.

To scroll through a list using the scroll bar or arrows, touch the scroll bar to select and activate it; or turn the P&T knob to select the scroll bar (it is framed in yellow) and then press it to activate your selection. Your selection turns orange when activated. Now turn the knob to scroll through the log. Touch the scroll bar or press the knob to deactivate.



3 Working in the MRI environment

3.1 Introduction

NOTE:

In an MRI environment, the HAMILTON-MR1 has been fully tested to ensure that it does not interfere with the MRI scanner in any manner when the ventilator is used as specified.

Be sure to review the safety information in Section 3.2 before using the device.

3.1.1 How the system works in the MRI environment

The HAMILTON-MR1 has been specially designed and shielded to ventilate your patient in the vicinity of an MRI scanner. It can accompany your patient from the ICU to the scanner for the duration of the test, and back to the ICU, increasing the safety of care.

The onboard magnetic field navigator, TeslaSpy, continuously measures the background magnetic levels. It lets you know when levels are safe and when they exceed the ventilator's safety threshold. The TeslaSpy navigator also performs continuous internal safety checks, verifying the integrity of the detection system itself.

The HAMILTON-MR1 ventilator is normally mounted on a trolley specifically designed for the MRI environment. However, it can also be mounted on a shelf.

Note that, while the device is specifically designed to allow use in an MRI environment, it is a fully functional ventilator that can be used in the ICU and during patient transport within the hospital.

3.1.2 How this chapter is organized

This chapter is designed for use together with the rest of this operator's manual.

It provides safety information for using the device in the MRI environment, and an overview of how to set up, position, and use the ventilator and trolley in the MRI environment, and also describes magnetic-field-related alarms, specifications, and compatible parts and accessories.

3.2 MRI safety information

The HAMILTON-MR1 is MR Conditional. The device may be safely used in an MR environment meeting the following conditions:

- 1.5T and 3T MRI systems only.
- External magnetic field of ≤ 50 mT.
- The TeslaSpy green indicator must be lit green and blink slowly.
- Use only MR Safe or MR Conditional parts and accessories.
- The trolley auto-lock brake must be engaged. See Section 3.4.1.
- The trolley must be attached to a wall anchor using the HAMILTON-MR1 tether. (USA only)
- The HAMILTON-MR1 ventilator must be secured to the selected mounting solution. See Section 3.5.
- Humidifiers are *NOT* MR compatible. *Do not* use humidifiers in the MR environment. You must use an HME/HMEF instead.

WARNING

- ***Do not* use the USB port on the ventilator during an MRI procedure.**
- **The device may become a projectile hazard if placed too close to the scanner!**
- **If the device is used for transporting the patient from the ICU or other location, it may be necessary to change the gas supply system and/or breathing circuit before entering the MRI environment.**
- **Position the ventilator slowly and with care, and closely monitor the TeslaSpy indicator lights as follows:**

1 **Green indicator.** Magnetic field is within acceptable limits
Device is in a safe position.

2 **Yellow indicator.** Magnetic field is too high
Move device away from scanner.

3 **Red indicator.** Magnetic field is unacceptably high
Device must be serviced.

4 **Red X indicator.** The TeslaSpy navigator has an internal error
Device must be serviced.

CAUTION

- **Due to the small amount of metal in the membrane, be sure to install the expiratory valve assembly outside of the MRI environment (if using the trolley), or as far away from the scanner as possible (if permanently installed in MRI room).**
- ***Do not* use the Aeroneb Pro nebulizer in the MRI environment.**

3.3 Setting up the ventilator for use in the MRI environment

Setting up the ventilator for use in the MRI environment comprises the following steps.

The order in which they are performed may depend on whether the device is used during patient transport from the ICU or whether it stays in the MRI environment.

For information on attaching the ventilator to the HAMILTON-MR1 trolley, see Section 3.4.

Table 3-1. Steps to set up ventilator for use in MRI environment

Step	See ...
☐ Mount the ventilator on an MR Safe or MR Conditional trolley, or other appropriate surface	Sections 3.4 and 3.4.2
☐ Connect the power supply to the trolley or shelf.	*HAMILTON-MR1 Trolley Setup and Instructions for Use*
☐ Connect a compatible medical gas supply. Be sure to only enter the MRI environment with an MR Safe or MR Conditional oxygen supply attached to the trolley.	Section 3.6
☐ Install the expiratory valve (outside of the MRI environment when using the trolley)	Section 2.2.2
☐ Ensure that the TeslaSpy is working and position the ventilator properly using the TeslaSpy navigator indicator lights.	Section 3.7
☐ Connect the breathing circuit and components. Be sure to only enter the MRI environment using an MR Safe or MR Conditional breathing circuit.	Section 3.7.1
☐ Perform the preoperational check, if not already done.	Section 3.7.2
☐ Review ventilator settings and adjust as needed.	Section 3.7.3

3.4 Working with the HAMILTON-MR1 trolley

WARNING

- **Be sure to read the safety information in Section 3.2 before entering the MRI environment.**
- **To prevent possible tipping of the trolley and equipment damage:**
  - **Lock the trolley's wheels when parking the ventilator.**
  - **Take care when crossing thresholds.**
  - **See also Table 3-2.**

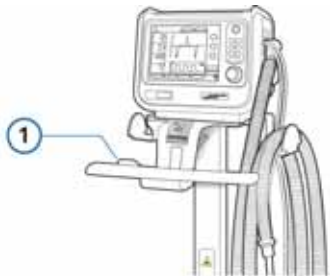
Table 3-2. HAMILTON-MR1 trolley warning labels

	**Make sure the wheel brakes are unlocked when moving the trolley.**
	**Do not lean on the trolley.**

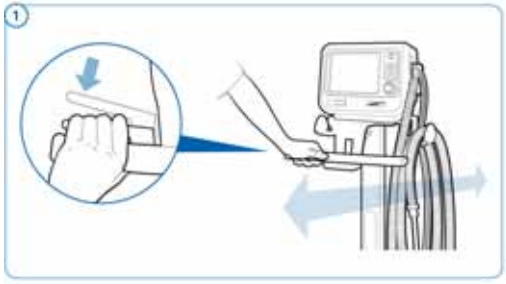
3.4.1 Moving and parking the trolley

To maximize patient and staff safety, the HAMILTON-MR1 ventilator trolley is equipped with an auto-lock brake **(1)**, with a brake release lever integrated into the handle for easy access.

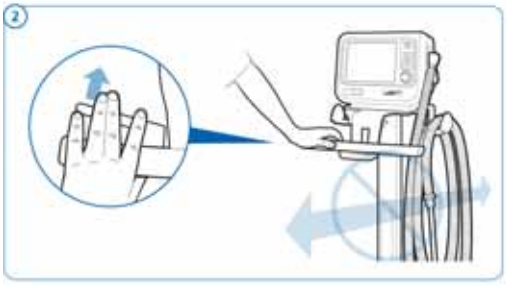
The brake automatically locks the trolley in position when you release the brake lever.



3.4.1.1 Moving the trolley a short distance



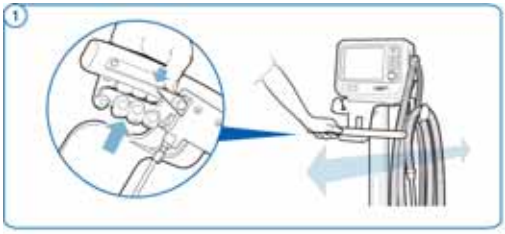
Squeeze the brake lever while moving the trolley.



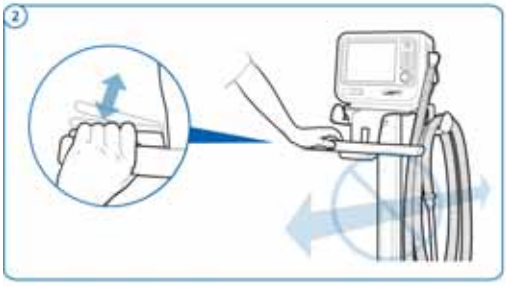
Release the lever to lock the brake and park the trolley.

3.4.1.2 Moving the trolley across longer distances

When you need to move the trolley a longer distance, for example, when transporting the patient between the ICU and other locations in the hospital, or storing the trolley, you can disengage the auto-lock brake for the trip.



Squeeze the brake handle to release the auto-lock brake, and press the locking lever forward with your thumb.



Before entering the MRI environment (or parking the trolley elsewhere), **re-engage the auto-lock brake** by squeezing and releasing the brake lever.

You can then reposition the trolley at the final destination by squeezing the brake lever, as described in Section 3.4.1.1.

3.4.2 Preparing the trolley for intrahospital transport

WARNING

- **Be sure to read the safety information in Section 3.2 before entering the MRI environment.**
- **Only the components listed in this section are approved for intrahospital transport.**
- **Ensure the ventilator is securely attached to the trolley before use. For details, see the *Setup and Use Instructions for HAMILTON-MR1 Trolley* (PN 161160).**

NOTE:

The following requirements apply only to intra-hospital transport using ventilators mounted on a HAMILTON-MR1 trolley. They do not apply to other mounting solutions.

If using a HAMILTON-MR1 trolley, the ventilator and its components, as well as the trolley, **must be** configured and positioned as follows during transport within the hospital:

- The ventilator must be securely mounted on the trolley
- The O2 cylinder must be securely attached to the trolley
- *Only* the following components are allowed to be connected during transport:
  - Breathing circuit
  - Flow sensor (or pressure line)
  - O2 cylinder

3.5 Securing the ventilator in the MRI environment

Once in the MRI environment, be sure the ventilator is safely secured and positioned.

Always position the ventilator using the TeslaSpy navigator magnetic field safety indicator lights and alarms to ensure that you are placing the device at a safe distance from the scanner. See Section 3.7.

Table 3-1. Securing the ventilator in the MRI environment

If using the HAMILTON-MR1 trolley	Ensure the ventilator, power supply, and gas cylinder are securely attached to the trolley. For details, see the *HAMILTON-MR1 Trolley Setup and Instructions for Use.*
	Auto-lock brake is engaged on the trolley.
	For added safety, securely attach the HAMILTON-MR1 trolley to a wall anchor using the HAMILTON-MR1 tether (PN 161690)[1]. For details, see the *HAMILTON-MR1 Tether User Guide*.
If securing the ventilator to a shelf or other surface	Ensure the ventilator and power supply are attached as described in Section 3.5.1, next.

1. Use of the HAMILTON-MR1 tether is required in the USA.

3.5.1 Attaching the ventilator and power supply to shelf mount or other surface

To ensure safe and secure attachment of the ventilator to the mounting surface, the following requirements must be met:

- Ensure the ventilator is securely attached as described here.
- Use only M6, INOX (minimum quality level A2) screws (for example, screws that comply with DIN 7991).
- Choose an appropriate screw length that ensures that between 6 to 10 mm of the screw are fastened inside the ventilator.

- Securely attach the power supply at least 1.5 m away from the center of the MR scanner opening, as far away as possible.

To attach the ventilator to a shelf or table

1. Drill the required screw holes (6.6 to 7.0 mm diameter required) into the surfaces as needed. Figure 3-1 provides positioning specifications.

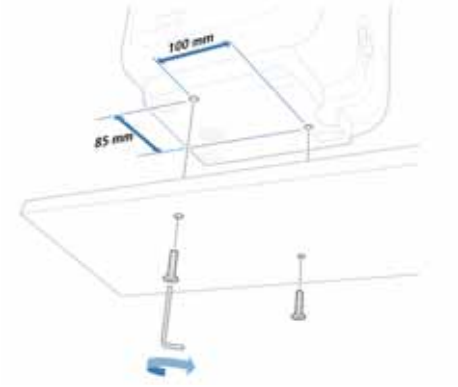


Figure 3-1. Positioning screw holes to attach ventilator

2. Insert and tighten the screws.

   Ensure that 6 to 10 mm of each screw extends into the ventilator.

3. Pull up gently on the ventilator to ensure it is securely attached.
4. Secure the power supply.

3.6 Connecting the gas supply for use in the MRI environment

CAUTION

- **Be sure to read the safety information in Section 3.2 before entering the MRI environment.**
- **Always check the status of the oxygen cylinders or other supply before using the ventilator during transport.**
- **Make sure oxygen cylinders are equipped with pressure-reducing valves.**

NOTE:

To prevent damage to the ventilator, connect only clean, dry medical-grade oxygen.

The HAMILTON-MR1 supports the use of oxygen from a high-pressure source.

With the optional cylinder holder, you can mount an oxygen cylinder to the trolley. If you use gases from cylinders, secure the cylinder to the trolley with the accompanying straps. Ensure the cylinder is MR Safe or MR Conditional.

For connection details, see:

- Section 2.8 for details on connecting the ventilator to the gas supply.
- *HAMILTON-MR1 Trolley Setup and Instructions for Use* to attach the cylinder to the trolley.

3.7 Positioning the ventilator using TeslaSpy

CAUTION

Be sure to read the safety information in Section 3.2 before entering the MRI environment.

When placing the ventilator in the room containing the MRI scanner, use the TeslaSpy navigator magnetic field safety indicator lights and alarms to ensure that you are placing the device at a safe distance from the scanner.

To safely position the HAMILTON-MR1 in the MRI environment

1. Upon entering the MRI environment, carefully monitor the TeslaSpy magnetic field safety indicator lights.
2. Position the ventilator so that the green TeslaSpy indicator light blinks slowly. See Figure 3-2.

   A blinking green indicator shows the magnetic field is within the acceptable range and the device is in a good position. The acceptable distance is typically no closer than 1 m from the front of the scanner.

Figure 3-2. TeslaSpy green indicator, safe distance

3. If you need to move the device closer to the scanner, move the device slowly closer, keeping it within range of the blinking green indicator.

   If the yellow indicator light starts blinking and an alarm sounds, the device is too close to the scanner and must be moved further away from the scanner. *Do not move the device any closer to the scanner.*

Figure 3-3. TeslaSpy yellow indicator, move device away from scanner

4. Once it is again at a safe distance, the green indicator light blinks (Figure 3-2), and the alarm is silenced.

For additional details about the TeslaSpy alarms, see Section 3.9.

3.7.1 Attaching the breathing circuit and components

NOTE:

- Be sure to read the safety information in Section 3.2 before entering the MRI environment.
- Any bacteria filter, HMEF, or additional accessories in the expiratory limb may substantially increase flow resistance and impair ventilation.
- To ensure that all breathing circuit connections are leak-tight, perform the tightness test every time you install a circuit or change a circuit part.

To connect the breathing circuit

1. Select the appropriate MR Safe breathing circuit parts for your patient.

   MR Safe breathing circuits apply to all patient groups, and are available in two lengths:

3.0 m	Adult/pediatric and neonatal patients
4.8 m	Adult/pediatric patients only

   Figures 3-4 through 3-5 show typical adult/pediatric breathing circuits.

   For neonatal ventilation, see Chapter 6.

2. Assemble the patient breathing circuit.
3. Properly position the breathing circuit after assembly. Make sure the hoses will not be pushed, pulled, or kinked during patient's movement, nebulization, or other procedures.

For details on the flow sensor, HME, and expiratory valve, see Section 2.2.

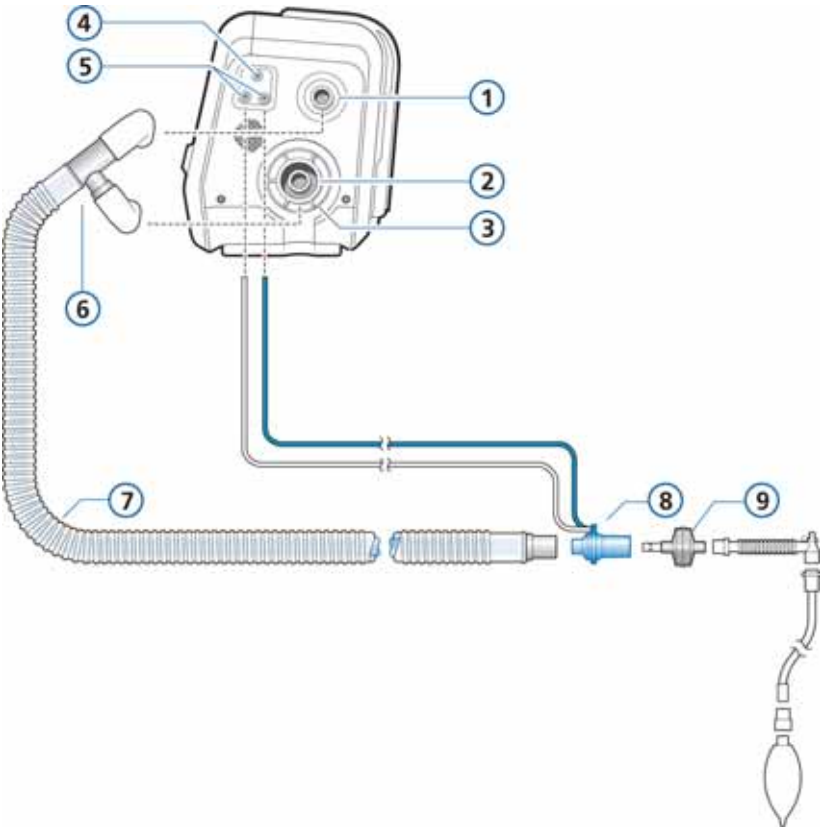


Figure 3-4. MR Safe coaxial breathing circuit with HMEF/HME for use in MRI environment (adult/pediatric)

1	To patient	**6**	Limb connector
2	From patient	**7**	Co-axial inspiratory/expiratory limb
3	Expiratory valve with membrane cover	**8**	Flow sensor
4	Nebulizer outlet	**9**	HMEF/HME
5	Flow sensor connectors		

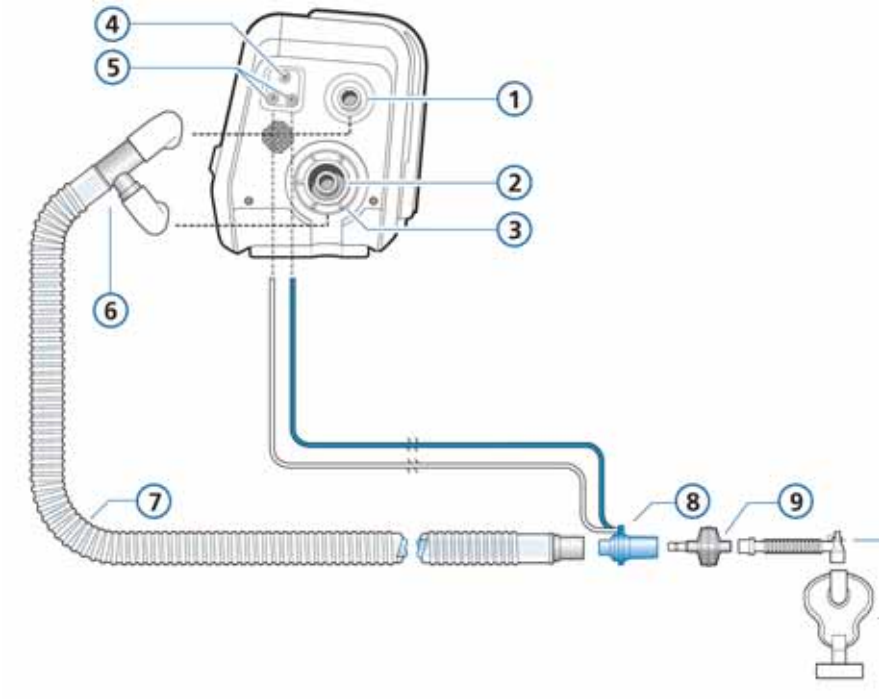


Figure 3-5. MR Safe coaxial breathing circuit for use with mask in MRI environment (adult/pediatric)

1	To patient	**7**	Co-axial inspiratory/expiratory limb
2	From patient		
3	Expiratory valve with membrane cover	**8**	Flow sensor
		9	HMEF/HME
4	Nebulizer outlet	**10**	Adapter
5	Flow sensor connectors	**11**	Mask (nonvented)
6	Limb connector		

3.7.2 Performing the preoperational check in the MRI environment

This step is only necessary if a preoperational check has not already been completed. Chapter 4 provides information on performing all tests and calibrations that comprise the preoperational check.

3.7.3 Verifying general ventilator settings

Review general ventilator settings, including patient group settings, alarm limits, mode and control settings, and the like. For details, refer to Chapters 4 through 9 in this Operator's Manual.

3.8 About magnetic field monitoring

The TeslaSpy magnetic field navigator is built into the ventilator and comprises two components:

- The TeslaSpy magnetic field sensor continuously samples the environment, measuring the background magnetic field, even when the ventilator is turned off.
- A built-in safety system continuously monitors the operation of the magnetic field sensor.

Four indicators on the front of the ventilator show the status of the surrounding magnetic field and of the TeslaSpy navigator itself (Figure 3-6). Table 3-6 shows the threshold values for the indicators.

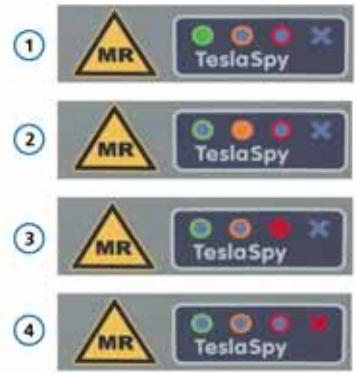


Figure 3-6. TeslaSpy magnetic field safety indicators

1	**Green indicator.** Magnetic field is within acceptable limits Device is in a safe position	**3**	**Red indicator.** Magnetic field is unacceptably high Device must be serviced
2	**Yellow indicator.** Magnetic field is too high Move device away from scanner	**4**	**Red X indicator.** The TeslaSpy navigator has an internal error Device must be serviced

3.8.1 About the magnetic field thresholds

The magnetic field thresholds for the different notification levels are expressed in milliTesla (mT) and are displayed using the TeslaSpy colored indicators, described in Section 3.10.2.

Because different MRI devices emit varying levels of static and pulsed magnetic fields, and the conditions in different MRI environments are also not necessarily the same, the acceptable distance between the MRI device and the HAMILTON-MR1 ventilator can change. The TeslaSpy navigator continuously monitors the background magnetic field to ensure the ventilator is kept in a safe operating environment.

3.9 Responding to alarms

NOTE:

- TeslaSpy magnetic field-related alarms are not logged in the ventilator Alarm buffer, and the HAMILTON-MR1 alarm lamp does not light. In addition, they are not listed in the Event log.
- Note that the Alarm silence key does not apply to TeslaSpy navigator magnetic field indication alarms; they cannot be silenced this way. You must physically move the device to a safe distance away from the MRI scanner, as indicated by the green TeslaSpy indicator light.

The HAMILTON-MR1 ventilator generates different classes of alarms:

- Magnetic-field-related TeslaSpy alarms. For details, see Table 3-3.
- General ventilation alarms. See Chapter 9.

Table 3-3. TeslaSpy alarms

Alarm	Definition	Action needed
Green indicator is lit and blinking	Magnetic field is within acceptable limits.	None Note that as the magnetic field increases, TeslaSpy samples the background more frequently, and the light blinks more rapidly.

Table 3-3. TeslaSpy alarms *(continued)*

Alarm	Definition	Action needed
Yellow indicator is lit Medium-priority alarm sounds	*Medium priority.* Magnetic field is high. The ventilator is too close to the MRI scanner. An audible alarm sounds.	Move the device away from the MRI scanner until the green indicator is again lit and blinking, and the alarm stops.
Any red indicator is lit High-priority alarm sounds	*High priority.* If the circular red indicator is lit, the ventilator has been too close to the MRI device. The magnetic field is unacceptably high and the ventilator may sustain or has sustained damage, depending on how long it has been in this high-magnetic-field environment. If the red X indicator is lit, the TeslaSpy navigator is not responding properly. Without proper monitoring, the ventilator may sustain damage.	Do the following, in order: 1. Immediately move the HAMILTON-MR1 further away from the MRI scanner. 2. Ventilate the patient using an alternative method, and disconnect the patient from the device. 3. Remove the ventilator from use. 4. Have the ventilator serviced by qualified Hamilton Medical technical personnel.

3.10 Specifications

This section provides specifications for MRI-related components, and is designed for use together with Appendix A.

The HAMILTON-MR1 has been fully tested to ensure that it does not interfere with the MRI scanner in any manner in the MRI environment.

3.10.1 MR Safe breathing circuit specifications

The following specifications apply to the MR Safe breathing circuits available for the HAMILTON-MR1 ventilator.

The breathing circuit includes the coaxial circuits (3.0 m or 4.8 m), limb connector, and integrated flow sensor.

Table 3-4. Ventilator MR Safe breathing circuit specifications

Parameter	Specification
Resistance	Coaxial circuit, 3.0 and 4.8 m: < 0.2 kPa at 30 l*min-1 (nominal flow rate)
Compliance	Coaxial circuit, 3.0 and 4.8 m: < 10 ml*kPa-1 per meter of tube length
Volume	Coaxial circuit, 3.0 m: Approximately 2.0 l Coaxial circuit, 4.8 m: Approximately 3.2 l Flow sensor: 9 ml (single-use) or 11 ml (reusable)
Bacteria filter	Particle size: Captures particles of 0.3 µm (micrometer) with > 99.99% efficiency Resistance: < 2 mbar at 60 l/min
Flow sensor dead space	< 9 ml (single use) and < 11 ml (reusable)
Pressure line and flow sensor	3.1 m

3.10.2 Magnetic field compatibility and accuracy

The HAMILTON-MR1 is rated for use in the following environments.

Table 3-5. External magnetic field specifications

Static magnetic field	≤ 50 mT Corresponds to approximately 1 m distance from the front of a 3.0 T MRI scanner.

In nonclinical testing, the device was found to be safe to operate at (or less than) a fringe magnetic of 50 mT.

The TeslaSpy navigator magnetic field readings are accurate within ±10%. The accuracy is maintained by performing self calibration.

Table 3-6. Magnetic field thresholds

Alarm/Action	**Magnetic field range (from center of device)[1,2]**	**Magnetic field range (external)[1,2]**	**Accuracy**
Green light, acceptable	< 30 mT	< 50 mT	±10%
Yellow light, too close, alarm sounds	≥ 30 mT and < 70 mT	≥ 50 mT and < 100 mT	
Red light, too close, alarm sounds	≥ 70 mT	≥ 100 mT	
Red X light, technical fault, alarm sounds	--	--	

1. These values are based on a comparison with a commercially available third-party gaussmeter. Since the integrated gaussmeter's magnetic sensors are located at the center of the HAMILTON-MR1's enclosure, it consequently measures the gauss levels at the center of the device. Furthermore, performance bench testing has shown that gauss levels of 30 mT in the center of the HAMILTON-MR1 correspond to < 50 mT on the outside of the HAMILTON-MR1's enclosure.

2. NOTE: The purpose of the three LED indicators on the integrated gaussmeter is to provide a visual representation of a range of gauss levels. For example, in the HAMILTON-MR1, when lit, the green LED shows that the integrated gaussmeter at the center of the ventilator is measuring gauss levels below 300 gauss (30 mT). This demonstrates that the HAMILTON-MR1 is considered to be located at an acceptably safe distance from the MRI scanner. The yellow LED represents a range of gauss levels from 300 gauss (30 mT) to 699 gauss (69.9 mT) at the center of the ventilator. At this range of gauss levels, the HAMILTON-MR1 will sound a warning alarm as a signal to the operator that the ventilator is too close to the MRI scanner and should be moved back until the green LED is lit. The red LED represents a gauss level of at least 700 gauss (70 mT) at the center of the ventilator. At that point, the red LED will continue flashing and the audible alarm will continue to be heard, even if the device were to be repositioned to a safer distance from the MRI scanner. The HAMILTON-MR1 would then need to be serviced by a Hamilton Medical trained specialist to make sure that no permanent damage to the HAMILTON-MR1 has occurred.

4 Tests, calibrations, and utilities

4.1 Introduction

NOTE:

The device provides automatic barometric pressure compensation.

The tests and calibrations described in this section help verify the safety and reliability of the HAMILTON-MR1. Perform the HAMILTON-MR1's tests and calibrations as described in Table 4-1.

If a test fails, troubleshoot the ventilator as indicated or have the ventilator serviced. Make sure the tests pass before you return the ventilator to clinical use.

Table 4-1. When to perform tests and calibrations

When to perform	Test or calibration
Before placing a new patient on the ventilator **CAUTION** **To ensure the ventilator's safe operation, always run the full preoperational check before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests have passed.**	Preoperational check
After installing a new or decontaminated breathing circuit or component (including a flow sensor or pressure line)	Tightness test, flow sensor calibration, and circuit calibration for nCPAP and nCPAP-PC
After installing a new oxygen cell or when a related alarm occurs	Oxygen cell calibration
As desired	Alarm tests

4.2 Running the preoperational check

CAUTION

- **To prevent possible patient injury, disconnect the patient from the ventilator before performing these tests. Make sure another source of ventilatory support is available.**
- **Be sure the green indicator on the TeslaSpy navigator is lit and blinks, and the red X light is not lit.**

When to perform: Before placing a new patient on the ventilator.

Required materials: See Table 4-2, next. To ensure that the ventilator also functions according to specifications on your patient, Hamilton Medical recommends that your test circuit be equivalent to the circuit used for ventilation.

For details on running the preoperational check for neonatal ventilation, see Chapter 6.

Table 4-2. Breathing circuit setup

Adult/pediatric patients	• Breathing circuit, 22 mm ID with 22F connectors • Flow sensor, pediatric/adult • Demonstration lung, 2 l, with adult ET tube between flow sensor and lung (PN 151815 or equivalent)

Procedure:

Do or observe…	Verify…	Notes
1. Connect ventilator to primary power and oxygen supply. Assemble the patient breathing circuit.	Breathing circuit is assembled correctly.	See Chapter 2. To prepare for the MRI environment, see Chapter 3.

Do or observe…	Verify…	Notes
2. Turn on power.	During the self test the red and yellow alarm lamp is flashed on in sequence and the buzzer sounds. After the self-test is passed the alarm lamp flashes red again.	The buzzer sounds only briefly.
3. Make sure the ventilator is in standby, and touch **Preop check** in the Patient setup window.		
4. Open the System -> Tests & calib window (Figure 4-2). Select and run the tightness test, then the flow sensor calibration. Follow all prompts.	These tests and calibrations pass.	For details on running these tests and calibrations, refer to Section 4.3.2.
5. If necessary, run the O2 cell calibration. Close window.	This calibration passes.	See Section 4.3.2.3.
6. Generate an alarm (for example, by disconnecting primary power).	Corresponding alarm message in message bar (for example, **`Loss of external power`**).	During standby, patient alarms are suppressed.
7. Resolve the alarm situation (for example, reconnect mains power).	Alarm is reset.	

Corrective action: If the ventilator does not pass the preoperational check, have it serviced.

4.3 System functions

You can run tests and calibrations, view device-specific information, and perform other ventilator system functions in the System window.

4.3.1 Info: Viewing device-specific information

Open the **`System -> Info`** window to view device-specific information including serial number, model, operating hours, hours since startup, time to service, battery capacity, software version, and installed options.

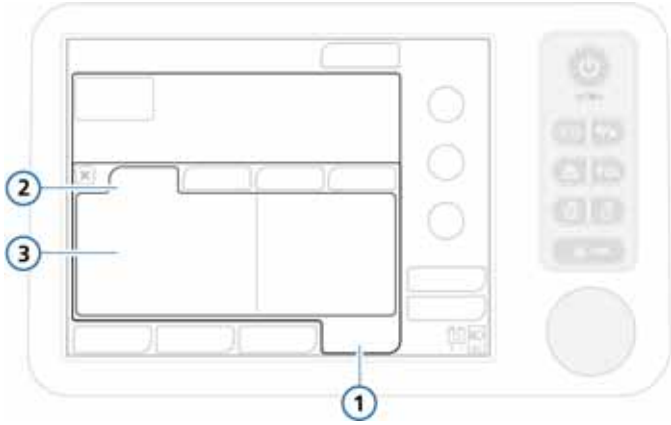


Figure 4-1. Info window

1	System	**3**	System details
2	Info		

4.3.2 Tests & calib: Running calibrations and the tightness test

NOTE:

- To enable or disable O2 monitoring, see Section 4.3.3.
- The audible alarm is silenced during the calibration functions and for 30 s thereafter.

The following tests and calibrations are provided, depending on your device and selected ventilation mode:

	See
Tightness test	page 4-7
Flow sensor calibration	page 4-8 and Chapter 6 (neonatal)
In the neonatal nCPAP and nCPAP-PC modes, flow sensor calibration is replaced by circuit calibration	Chapter 6
O2 cell calibration, if needed	page 4-10

Open the **`System -> Tests & calib`** window to access the tests and calibrations.

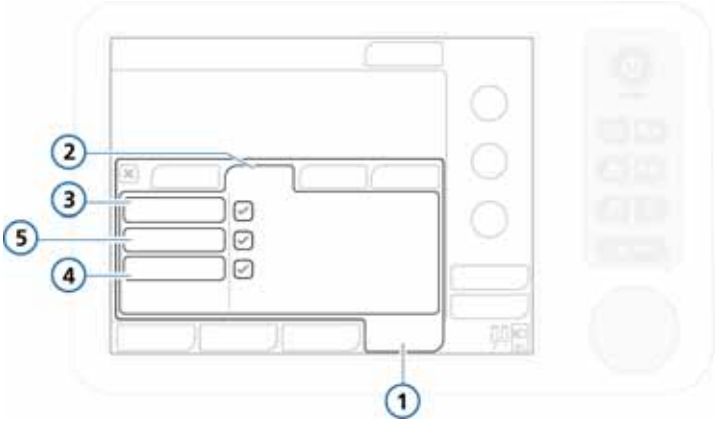


Figure 4-2. Tests & calib window

1	System	**5**	Depends on selected mode.
2	Tests & calib		*In the neonatal nCPAP-PC and nCPAP modes:* Circuit
3	Tightness		*In all other modes:* Flow sensor
4	O2 cell		

4.3.2.1 Tightness test

NOTE:

- Make sure another source of ventilatory support is available during this test. The patient must be disconnected from the ventilator during the test.
- To cancel the tightness test while it is in progress, select **`Tightness`** again.

Description: This test checks for leakage in the patient breathing circuit. The ventilator is pressurized to 45 cmH2O. The circuit is considered tight if this pressure can be maintained.

Procedure:

1. Set the ventilator up as for normal ventilation, complete with the breathing circuit.
2. Activate **`Tightness test`** from the **`Tests & calib`** window (Figure 4-2).

   The text **`Disconnect patient`** is now displayed.
3. Disconnect the breathing circuit at the patient side of the flow sensor. Do not block the open end of the flow sensor.

   The text **`Tighten patient system`** is now displayed.
4. Block the opening (wearing a sterilized glove is recommended).

   The text **`Connect patient`** is now displayed.
5. Connect the patient.
6. When the test is complete, verify that there is a green check mark in the **`Tightness`** checkbox.

In case of test failure

If the test fails, a red X is displayed in the Tightness checkbox.

Perform the following checks, repeating the tightness test after each one, until the test is successful:

- Check the breathing circuit for a disconnection between the ventilator and the flow sensor, or for other large leaks (for example, breathing circuit, humidifier).
- Check that the expiratory valve is correctly installed.
- Replace the breathing circuit, flow sensor, and expiratory valve.

If the problem still persists, have the ventilator serviced.

4.3.2.2 Flow sensor calibration

NOTE:

- Make sure another source of ventilatory support is available during this calibration. The patient must be disconnected from the ventilator during the test.
- To cancel the flow sensor calibration while it is in progress, select **`Flow Sensor`** again.
- Circuit resistance compensation is measured during calibration.
- If there is a mismatch between the active patient profile and the flow sensor type you are using, the calibration fails. Ensure you are using the correct flow sensor for the patient.

- Noninvasive neonatal ventilation in nCPAP and nCPAP-PC modes does not use a flow sensor. For details about neonatal ventilation, tests, and calibration, see Chapter 6.

Description: This calibration checks and resets the calibration points specific to the flow sensor in use.

Choose the appropriate process for the patient type:

- Adult/pediatric
- Neonate/infant. For details, see Chapter 6.

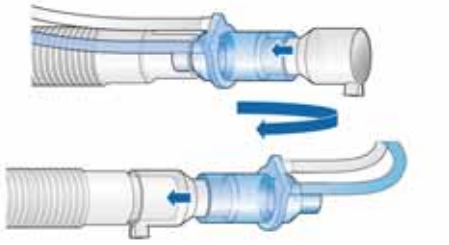
To calibrate an adult/pediatric flow sensor

1. Set the ventilator up as for normal ventilation, complete with breathing circuit and flow sensor.
2. Activate **`Flow Sensor`** from the **`Tests & calib`** window (Figure 4-2).

   If you have not already disconnected the patient, the message line displays **`Disconnect patient`**.
3. Disconnect the patient now.

4. Follow the instructions displayed in the message line, attaching the adapter when needed and turning the flow sensor around as indicated.

   If using the disposable flow sensor PN 281637, the additional adapter for calibration must be attached.



5. Follow the instructions displayed in the message line, turning the flow sensor back to its starting position when indicated.

6. When calibration is complete, remove the adapter and verify that there is a green check mark in the **Flow Sensor** checkbox.
7. When successful, touch the **Start ventilation** button in the Standby window, and connect the patient, as indicated.

In case of calibration failure

If the calibration fails, a red X is displayed in the **Flow Sensor** checkbox.

Perform the following checks, repeating the calibration after each one, until calibration is successful:

- Check the breathing circuit for a disconnection between the ventilator and the flow sensor, or for other large leaks (for example, breathing circuit, humidifier).
- Check that the correct flow sensor is connected, and that the flow sensor and expiratory valve/membrane are properly seated.
- If the calibration fails again, replace the flow sensor.
- If the calibration still fails, replace the expiratory valve/membrane.

If the problem persists, have the ventilator serviced.

4.3.2.3 Oxygen cell calibration

NOTE:

- The oxygen cell calibration requires that the ventilator's oxygen monitoring be enabled. To check for an oxygen cell, see Section 11.3.3. To determine whether oxygen monitoring is enabled, check the System -> Sensors on/off window and ensure the O2 cell checkbox is selected.
- The O2 cell requires approximately 30 minutes warm-up time to reach stable values. O2 monitoring during this time period may be more variable. Hamilton Medical recommends performing the calibration after the O2 cell is warmed up.

Description: During the 2-min calibration of the oxygen cell, the ventilator sets the oxygen concentration as shown in Table 4-3. The device tests the cell and resets the calibration points specific to the cell in use.

Table 4-3. Oxygen concentrations during O2 cell calibration

Standby or active ventilation	Connection status	Oxygen (FiO2) setting	Oxygen concentration used during calibration
Recommended settings for calibration at 100% oxygen			
Standby	Connected	> 21%	100%
Active ventilation	Connected	> 21%	100%
Settings for calibration at 21% oxygen			
Standby	Disconnected	any	21%
Standby	Connected	21%	21%
Active ventilation	Connected	21%	21%

Hamilton Medical recommends calibrating the O2 cell using 100% oxygen to improve the stability of measurements at higher oxygen concentrations during use. To this end, use the information in Table 4-3 to choose the associated settings and connections for calibration.

Procedure:

1. *Recommended.* To calibrate at 100% oxygen, adjust the settings on the ventilator as needed (Table 4-3).
2. In the **`Tests & calib`** window, select **`O2 cell`**.
3. When calibration is complete, verify that there is a green check mark in the O2 cell checkbox.

In case of calibration failure

If the calibration fails, a red X is displayed in the **O2 cell** checkbox.

Perform the following checks, repeating the calibration after each one, until calibration is successful:

- Ensure the O2 cell is connected and a Hamilton Medical O2 cell is used (PN 396200).
- If the second calibration attempt fails, replace the O2 cell.

If the problem persists, have the ventilator serviced.

4.3.3 Sensors on/off: Enabling/disabling O2 monitoring

CAUTION

The HAMILTON-MR1's oxygen monitoring function can be disabled. Ensure that an alternative means of oxygen monitoring is always available and enabled.

O2 cell monitoring is enabled by default.

To disable/enable O2 monitoring

1. Open the **System** -> **Sensors on/off** window.
2. Select the O2 checkbox to enable/disable monitoring. See Figure 4-3.

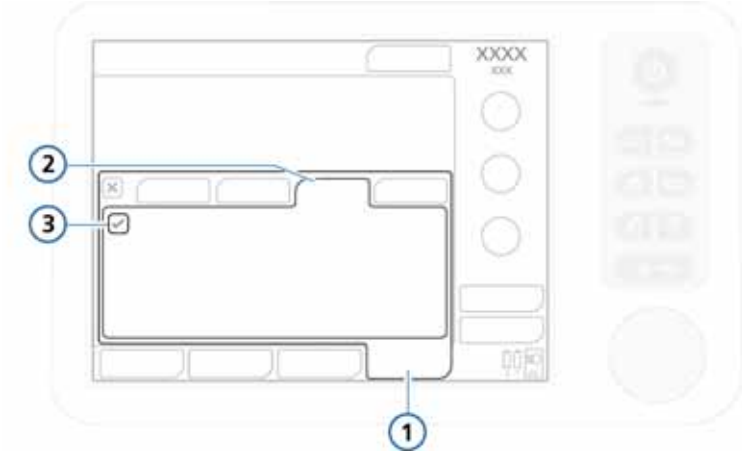


Figure 4-3. Sensor on/off window

1	System	**3**	O2 checkbox
2	Sensors on/off		

4.3.4 Setting day and night display brightness

NOTE:

- The day and night brightness controls are in the System -> Settings window.
- The **Day/Night** key lets you quickly switch between the default day and night settings. See Section 10.10.

Use these settings to set the brightness of the display for use during the day and night.

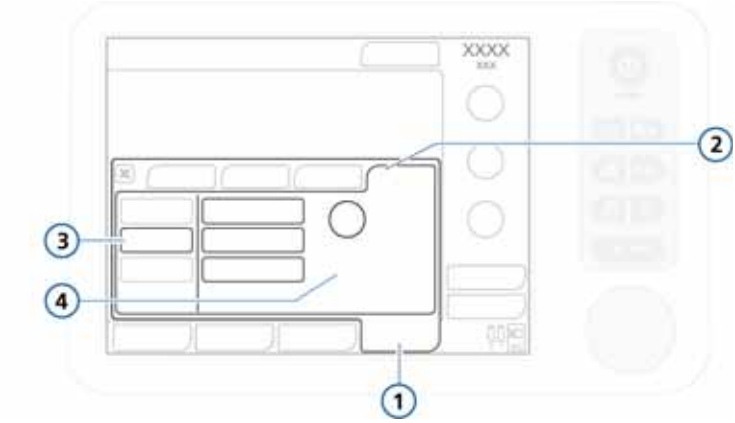


Figure 4-4. Day & Night window

1	System	**3**	Day & Night button
2	Settings	**4**	Day, Night, Brightness settings

To set the display brightness

1. Open the System -> Settings window.
2. To select Day mode with a bright display, touch the **Day** button.

   To select Night mode with a dimmer display, touch the **Night** button. When Night is selected, the green indicator next to the Day/Night key is lit, and the setting remains in effect when the device is restarted.
3. Adjust the brightness of the display in each mode using the **Brightness** control. The setting you choose becomes the new default for that mode.

Setting	Brightness range	Default
Day	10% to 100%	80%
Night	10% to 100%	40%

4. To have the device control the brightness based on ambient light, touch the **Automatic** button.

   The device senses the available light and dynamically adjusts the display brightness.

You can quickly switch the display brightness between the Day and Night settings by pressing the Day/Night key[1] on the ventilator. For details, see Section 10.10.

4.3.5 Setting date and time

NOTE:

- The date and time controls are in the System-> Settings window.
- Make sure the date and time are set correctly so that event log entries have accurate time and date stamps.

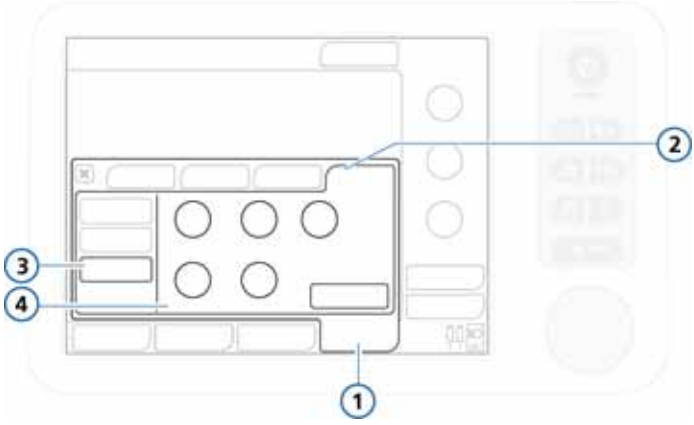


Figure 4-5. Date & Time settings

1	System	**3**	Date & Time
2	Settings	**4**	Date and time settings, Apply button

1. Not available in all markets.

To set the date and time

1. Open the System -> Settings window.
2. Touch **`Date & Time`** and adjust the day and time.
3. Touch the **`Apply`** button to save the changes.

4.4 Utilities

The Utilities window provides access to the following functions:

- Accessing the Configuration window. For details, see Appendix G.
- Transferring event log data to a USB drive.

4.4.1 Data transfer: Copying event log data to a USB memory drive

NOTE:

- Touch the HAMILTON-MR1 before using the USB port.
- The USB port is intended for passive memory devices only.
- If you remove the USB drive before the files are successfully transferred, you must reinitialize the USB port by turning the ventilator off and on again.
- The USB drive must be USB 1.1 compatible.
- A jpg file can be stored to the USB drive using the Print screen key.

You can save the event and service logs to a USB memory device. The device must have a FAT or FAT32 format and it must not have an operating system or a security system installed.

To save the logs

1. Place the ventilator into standby and insert a memory device into the USB connector.
2. Open the **`Utilities`** -> **`Data transfer`** window (Figure 4-6), and select **`Export logs`**.
3. Remove the memory device when **`File transfer successful`** is displayed.

   A folder named "MR1_sn<*Serial Number*>" is created on the USB stick containing all event log and service log files.

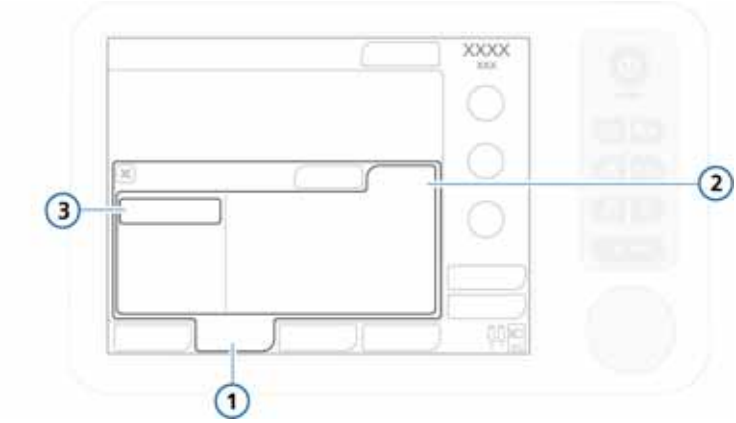


Figure 4-6. Data transfer window 1

1	Utilities	**3**	Export logs
2	Data transfer		

4.5 Alarm tests

The HAMILTON-MR1 performs a self-check during start-up and continuously during operation. This self-check verifies the alarm functionality. You may also want to run alarm tests, which demonstrate the alarms' operation.

Before performing the alarm tests, set the HAMILTON-MR1 up as for normal ventilation, complete with breathing circuit and 2 l demonstration lung assembly with ET tube.

4.5.1 High pressure

1. Make sure a 2 l demonstration lung assembly is connected to the ventilator.
2. Put the ventilator into the PCV+ mode.
3. Set the Pressure alarm limit to 15 cmH2O above the measured Ppeak.
4. Squeeze the demonstration lung hard during inspiration.
5. Verify that the High pressure alarm is activated, the ventilator cycles into exhalation, and pressure falls to the PEEP/CPAP level.

4.5.2 Low minute volume

1. Let the ventilator deliver 10 breaths with no alarms.
2. Adjust the minimum ExpMinVol alarm limit so it is higher than the measured value.
3. Verify that the Low minute volume alarm is activated.

4.5.3 Low oxygen alarm

1. Set the Oxygen control to 50%.
2. Wait for 2 min.
3. Disconnect the oxygen supply.

4. Verify the following:
   - The Oxygen concentration displayed in the monitoring window decreases.
   - The **Low oxygen** alarm activates.
5. Wait 30 s or until the oxygen concentration falls below 40%.
6. Reconnect the oxygen supply.
7. Verify that the Low oxygen alarm resets. The Low oxygen alarm should reset when the measured oxygen exceeds 45%.

4.5.4 Disconnection on patient side

1. Disconnect the demonstration lung.
2. Verify that the **Disconnection on patient side** alarm is activated.
3. Reconnect the demonstration lung.
4. Verify that the alarm resets and that the ventilator automatically resumes ventilation.

4.5.5 Loss of external power

1. With the ventilator connected to AC power, turn it on.
2. Disconnect the power cord.
3. Verify that the **Loss of external power** alarm is activated and that the ventilator is powered by its backup battery.
4. Reconnect the ventilator to AC power.
5. Verify that the alarm resets and that the ventilator is again powered by AC.

4.5.6 Exhalation obstructed

1. Block the expiratory valve exhaust port.
2. Observe the pressure rise.
3. Verify that the **Exhalation obstructed** alarm is activated.

4.5.7 Apnea

1. Put the ventilator into SPONT mode. Make sure apnea backup ventilation is disabled.
2. Wait for the set apnea time.
3. Verify that the **Apnea** alarm is activated.
4. Squeeze the demonstration lung.
5. Verify that the Apnea alarm resets.

5 Ventilator settings

5.1 Introduction

CAUTION

- **To prevent possible patient injury, make sure the ventilator is set up for the appropriate patient group with the appropriate breathing circuit parts as described in Chapter 2 and Chapter 6 (neonatal).**
- **To ensure the ventilator's safe operation, always run the preoperational check, as well as all required tests and calibrations before using the ventilator on a patient.**

  If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests have passed.
- **It is the clinician's responsibility to ensure that all ventilator settings are appropriate, even when "automatic" features such as ASV or standard settings are used.**

This section explains how to set up the HAMILTON-MR1 for ventilation on an individual patient. Prepare the ventilator as instructed in Chapter 2.

When ventilating neonatal patients, see also Chapter 6.

You must be familiar with using the touch screen and using the Press-and-turn knob to select, activate, and confirm parameters. For details, see Section 2.12.

5.2 Patient grouping

The HAMILTON-MR1 facilitates the ventilation of your patient by providing two patient groups, neonatal and adult/pediatric.

Table 5-1. Patient grouping

	Neonatal	**Adult/pediatric**
Patient group	**Weight:** 0.2 to 30 kg	**Gender:** M, F **Height:** 30 to 250 cm **IBW:** 3 to 139 kg
Specialities	nCPAP, nCPAP-PC	ASV, Dynamic Lung, Ventilation status

5.3 Quick setup settings

The HAMILTON-MR1 has three different Quick setup buttons per patient group.(Figure 5-1). Mode, mode controls settings, alarm settings, ventilation status settings and Vt/IBW or Vt/kg (neonatal) can be stored in each Quick setup.

To configure the Quick setup settings, see Section G.6.

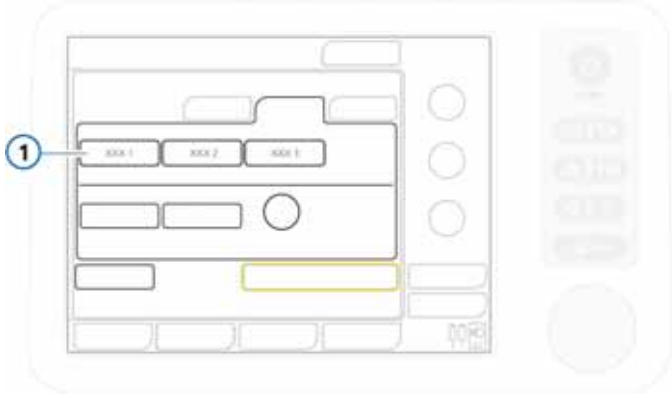


Figure 5-1. Quick setup buttons (1) in Standby window

5.4 Patient setup

WARNING

- **Ensure you choose the correct patient group: adult/ pediatric or neonatal, and choose the correct gender, if appropriate. Correct selections prevent possible hyper- or hypoventilation.**
- **For adult and pediatric patient groups, specifying a substantially incorrect height will generate incorrect IBW input, and will lead to a deviation of rate setting. Carefully check the value you specified in the Standby window.**

NOTE:

- When setting up for a new patient, the settings you see are the system default settings for mode, control, and the alarm settings.

  If you selected **`Last patient`**, the settings you see are the last active ventilator parameters in use.
- You can configure default settings for each patient group (mode and controls). See Appendix G.
- If an inadvertent setting is made but has not yet been confirmed, it will automatically be canceled after 30 seconds. Alternatively, the setting window closes after 3 min, again canceling your settings.

- If you select the Neonatal patient group, **`Neonatal`** appears on the screen.

After you initiate ventilation, the patient setup window is displayed (Figure 5-2), with default settings selected. Select, adjust, and activate the desired items.

Make sure the ventilator is configured with the appropriate breathing circuit parts, as described in Section 2.2. See also Chapter 6 for additional details about ventilating neonatal patients.

To start ventilation

1. If you have not already done so, select the **`Preop check`** button and perform the required tests.
2. Select the desired patient group:
   - **`Adult/Ped.`** For adult and pediatric patients (Figure 5-2). See Table 5-1 for age and weight ranges.
   - **`Neonatal.`** For neonatal patients (Figure 5-3). See Table 5-1 for age and weight ranges.
   - **`Last patient.`** Re-use the last active ventilator parameters in use.

   The selected patient group (**`Adult/Ped.`** or **`Neonatal`**) appears under the Mode name, in the top right corner of the display.

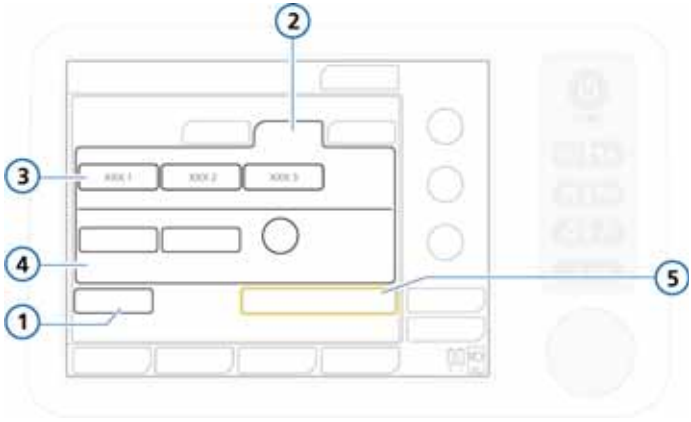


Figure 5-2. Patient setup/Standby window (adult/pediatric)

1	Preop check	**4**	Gender, Height, and IBW
2	Adult/Ped patient group	**5**	Start ventilation
3	Quick setup buttons		

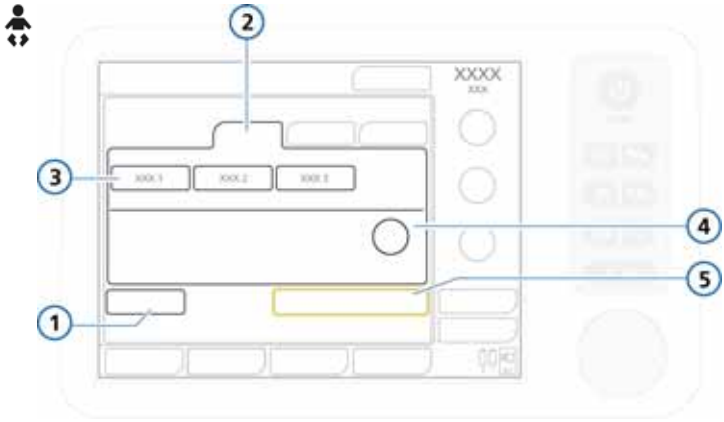


Figure 5-3. Patient setup/Standby window (neonatal)

1	Preop check	**4**	Weight
2	Neonatal patient group	**5**	Start ventilation
3	Quick setup buttons		

3. Adjust settings as follows:
   - For adult and pediatric patients, select the **Gender** and specify the patient height (**Pat. height**).

     The ideal body weight (**IBW**) is automatically calculated and displayed[1].
   - For neonatal patients, adjust the **Weight** setting.

     The system uses body weight; it does not calculate the IBW.
4. To start ventilating the patient, select **Start ventilation**.

1. The IBW, based on Pennsylvania Medical Center (adults) and Traub SL. Am J Hosp Pharm 1980 (pediatric patients), is calculated as follows:
   IBW: Ideal Body Weight [kg] BH: Body Height [cm]
   BH ≤ 70 cm IBW = 0.125 x BH – 0.75 70 < BH ≤ 128
   IBW = 0.0037 x BH – 0.4018 x BH + 18.62 BH ≥ 129
   Male IBW = 0.9079 x BH – 88.022, Female IBW = 0.9049 x BH – 92.006

5.5 Modes window: Setting the ventilation mode

NOTE:

- For details on modes, see:
  - Chapter 6 for the neonatal-only modes, nCPAP and nCPAP-PC
  - Appendix C (adaptive support ventilation, ASV)
  - Appendix D (noninvasive ventilation)
  - Appendix B (for all other modes)
- ASV mode is not supported for neonatal patients.

The active ventilation mode is displayed at the top right-hand corner of the display.

When first starting to ventilate a patient, a default mode is pre-selected. You can change it, if needed, as described next.

For details about modes and their controls, see Section 5.6 on page 5-8.

To change the mode

1. Open the **Modes** window. See Figure 5-4.
2. Select the mode to change to.
3. Touch **Confirm** to select the mode and display the control settings for the selected mode.

   The Controls window opens.
4. Review and, if needed, adjust the control settings (Section 5.6.2), and touch **Confirm** in the Controls window to enable the new mode.

   The newly selected mode is not active *until* you select **Confirm** in the Controls window. If you do not touch **Confirm**, the currently active mode remains in place.

   Note that the **Confirm** button is only displayed when changing modes.

   You can also touch **Cancel** to discard any changes and keep the currently active mode.

If the control settings are not confirmed, the window automatically closes after a period of time. The new mode selection will not be valid, and the previous settings remain in effect.

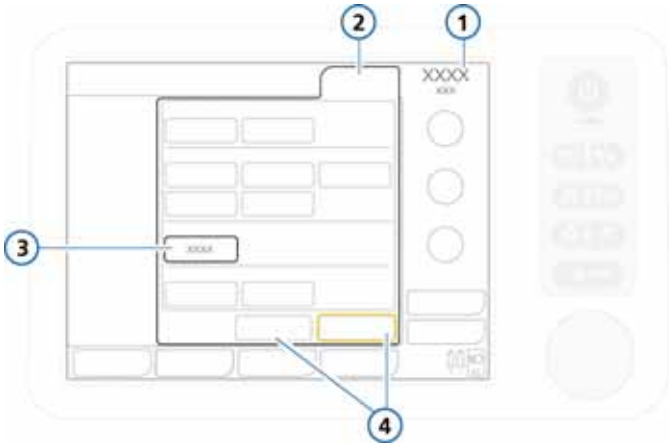


Figure 5-4. Changing the mode, Modes window

1	Active mode	**3**	New mode to apply
2	Modes	**4**	Confirm and Cancel buttons

5.6 Specifying mode settings

NOTE:

- In addition to control settings, the Basic window displays breath timing parameters determined from timing control settings; see Figure 5-5.
- For noninvasive ventilation modes (NIV, NIV-ST), see Appendix D.
- For neonatal modes (including nCPAP, nCPAP-PC), see Chapter 6.
- The alarm Flow sensor calibration needed may appear when changing to and from nCPAP modes.

You set controls on three Controls windows: Basic, More, Apnea.

You enable the Sigh function through the More window. You can set apnea backup through the Apnea window.

For additional information about control parameters, see:

- Table 5-2 defines the control parameter settings.
- Table A-6 describes control parameter ranges and default settings, including accuracy.
- Table A-7 lists control settings applicable to the different ventilation modes.

5.6.1 Changing parameter settings

NOTE:

You can adjust PEEP/CPAP, Oxygen, and an additional control setting (depending on active mode) from the main display without opening the Controls window.

The Controls window provides access to the parameter settings used by the active mode.

To change the parameter settings for the active mode

1. Open the **Controls** -> **Basic** window (Figure 5-5).
2. Select a parameter and adjust the value. The change takes effect immediately. Repeat for any other desired parameters.
3. Open the **Controls** -> **More** window (Figure 5-6), and select and adjust parameters as desired.
4. If applicable, open the **Controls** -> **Apnea** window (Figure 5-7). Select or deselect **Backup** as desired.

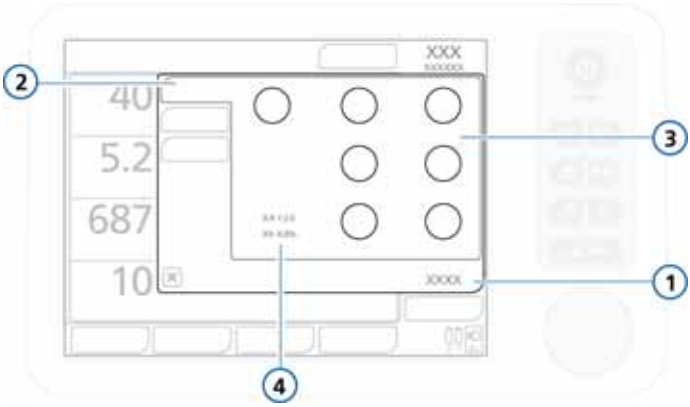


Figure 5-5. Basic settings, Controls window

1 Controls

2 Basic

3 Control settings corresponding to the mode

4 Timing parameters, determined from the timing settings (if control breaths are permitted in selected mode):

- I:E: Ratio of inspiratory time; applies mandatory breaths
- TE: Duration of expiratory phase, TI: Duration of inspiratory phase

When in the process of changing modes, Confirm and Cancel buttons are also displayed.

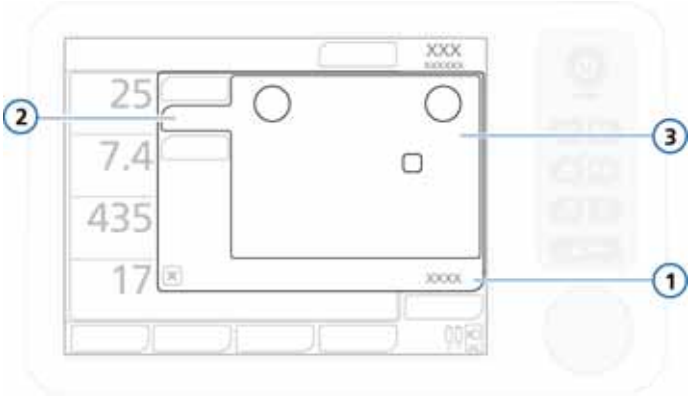


Figure 5-6. More settings, Controls window

1 Controls

2 More

3 Control settings corresponding to the mode

5.6.2 Changing parameter settings with mode change

After you select a different mode, the **Basic** window automatically opens (Figure 5-5), showing the new mode name and parameter settings. Review and confirm these proposed settings or the mode change will not be accepted.

To review and confirm the control settings

1. Select a parameter and adjust the value. The change takes effect as soon as you confirm the mode change. Repeat for any other desired parameters.
2. Open the **Controls** -> **More** window (Figure 5-6), and select and adjust parameters as desired.
3. If applicable, open the **Controls** -> **Apnea** window (Figure 5-7).

   Select or deselect **Backup** as desired. For details, see Section 5.6.3.

   Adjust parameters as desired. For details, see Section 5.6.4.

5.6.3 About apnea backup ventilation

CAUTION

Hamilton Medical recommends that apnea backup ventilation be enabled whenever a mode that allows spontaneous breathing is selected. For safety reasons, apnea backup is enabled by default.

The HAMILTON-MR1 provides apnea backup ventilation, a mechanism that minimizes possible patient injury due to apnea or cessation of respiration. Apnea can occur in all modes except (S)CMV+, PCV+, ASV, PSIMV+, NIV-ST, and nCPAP-PC.

When the ventilator is in such a mode and no inspiratory efforts are detected or control breaths are delivered during an operator-set interval, it assumes that apnea is present. If apnea backup ventilation is enabled, ventilation continues.

When apnea backup ventilation is enabled. Apnea backup provides ventilation after the apnea time passes with no breath attempts detected. (You set the **Apnea time** in the **Alarms** window.) When this occurs, the ventilator automatically and immediately switches into apnea backup ventilation. It annunciates a low-priority alarm, displays Apnea ventilation, and provides ventilation at the following settings:

If the original support mode is…	The ventilator enters this backup mode…
SIMV+/APVsimv	SIMV+/APVsimv
SPONT	SIMV+
DuoPAP/APRV	SIMV+
NIV	PCV+

The control setting for the apnea backup mode depends on the ideal body weight (or weight for neonates) of the patient. The default values can be overwritten by disabling the **Automatic** button.

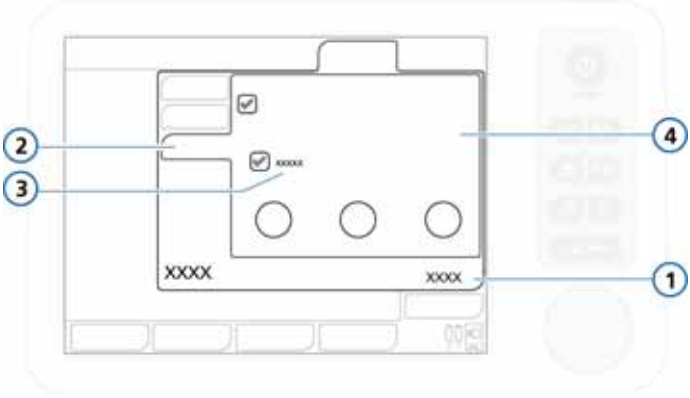


Figure 5-7. Apnea window, Automatic button

1	Controls	**3**	Automatic check box
2	Apnea	**4**	Control settings corresponding to the mode

If the patient triggers two consecutive breaths, the ventilator reverts to ventilation in the original support mode and at the original settings, and it displays Apnea ventilation ended.

Once apnea backup ventilation is enabled or disabled, it retains this status in all applicable modes. Apnea backup ventilation requires no clinician intervention, although you can freely change the mode during apnea backup ventilation, either switching to a new mode or accepting the backup mode as the new mode.

When apnea backup ventilation is disabled, the high-priority Apnea alarm is annunciated when apnea occurs.

5.6.4 Table of control parameter settings

The following table briefly describes each of the ventilator control parameters.

Table A-6 in Appendix A provides the control parameter ranges and default settings, including accuracy.

Table 5-2. Control parameters

Parameter	Definition
For additional details, including parameter ranges and accuracy, see Table A-6 on page A-7.	
Apnea backup	A function that provides ventilation after the adjustable apnea time passes without breath attempts. If "Automatic" is enabled, control parameters are calculated based on the patients IBW.
ETS	Expiratory trigger sensitivity. The percent of peak inspiratory flow at which the ventilator cycles from inspiration to exhalation. Increasing the ETS setting results in a shorter inspiratory time, which may be beneficial in patients with obstructive lung disease. The ETS setting lets you match the inspiratory time of pressure-supported breaths to the patient's neural timing. Applies to spontaneous breaths.

Table 5-2. Control parameters *(continued)*

Parameter	Definition
For additional details, including parameter ranges and accuracy, see Table A-6 on page A-7.	
Flow trigger	The patient's inspiratory flow that triggers the ventilator to deliver a breath. Changing the setting during the inspiratory phase affects the next breath. During the expiratory phase, affects the breath after the next breath. Applies to all breaths except nCPAP-PC. **CAUTION** **If auto-triggering occurs, first check the patient, breathing circuit, and other settings as possible causes before decreasing the trigger sensitivity.** **NOTE:** If the flow trigger is set higher than the patient is able to meet, a breath cannot be triggered. Reset the flow trigger to an achievable value, and deliver a manual breath to activate the new setting.
Gender	Sex of patient. Used to compute ideal body weight (IBW) for adults and pediatrics.
I:E	Ratio of inspiratory time to expiratory time. Applies to mandatory breaths.

Table 5-2. Control parameters *(continued)*

Parameter	Definition
For additional details, including parameter ranges and accuracy, see Table A-6 on page A-7.	
%MinVol	Percentage of minute volume to be delivered in ASV mode. The ventilator uses the %MinVol, Pat. height, and Gender settings to calculate the target minute ventilation. Typical %MinVol might be as follows: • Normal patient,100% (100 ml/min/kg body weight for adults and 300 ml/min/kg body weight for pediatric patients) • COPD patient, 90% • ARDS patient, 120% • Other patients, 110% • Add 20% per degree of body temperature > 38.5°C (101.3°F) Add 5% per 500 m (1640 ft) above sea level
Oxygen	Oxygen concentration to be delivered. Applies to all breaths. Not active when low-pressure oxygen is used.
Pasvlimit	The maximum pressure to apply in ASV mode. For the ASV controller to function correctly, Pasvlimit must be at least 15 cmH2O above PEEP/CPAP. Changing Pasvlimit or the Pressure alarm limit automatically changes the other: The Pressure alarm limit is always 10 cmH2O greater than Pasvlimit.
Pat. height	Patient height. It determines the ideal body weight (IBW), which is used in calculations for ASV and startup settings for adult and pediatric patients.
Pcontrol	The pressure (additional to PEEP/CPAP) to apply during the inspiratory phase in PCV+ and nCPAP-PC mode.
PEEP/CPAP	Positive end expiratory pressure and continuous positive airway pressure, baseline pressures applied during the expiratory phase. Applies to all breaths.
P high	The high pressure setting in APRV and DuoPAP modes. Absolute pressure, including PEEP.

Table 5-2. Control parameters *(continued)*

Parameter	Definition
For additional details, including parameter ranges and accuracy, see Table A-6 on page A-7.	
Pinsp	Pressure (additional to PEEP/CPAP) to apply during the inspiratory phase. Applies in PSIMV+ IntelliSync and NIV-ST.
P low	The low pressure setting in APRV.
P-ramp	Pressure ramp. Time required for inspiratory pressure to rise to the set (target) pressure. The P-ramp setting lets you fine-tune the initial flow output during a pressure-controlled or pressure-supported breath to match the ventilator flow to the patient's demand. Short P ramp settings (0 to 50 ms) provide higher initial flow rates and result in faster attainment of the target pressure. This may benefit patients with elevated respiratory drive. Lower P-ramp values have been correlated with reduced work of breathing in certain patients. Setting the P-ramp too low, especially in combination with a small ET tube (high resistance), may result in a noticeable pressure overshoot during the early stage of inspiration and a Pressure limitation alarm. Setting the P-ramp too high may prevent the ventilator from attaining the set inspiratory pressure. A square (rectangular) pressure profile is the goal. Applies to all breaths except nCPAP. **NOTE:** To prevent possible pressure overshoot in pediatric applications, it is recommended that P-ramp be set to at least 75 ms.
Psupport	Pressure support for spontaneous breaths in SPONT, NIV, and SIMV+ modes. It is the pressure (additional to PEEP/CPAP) to apply during the inspiratory phase. Pressure support helps the patient counteract the flow resistance of the breathing circuit and endotracheal tube. It compensates for the decreasing tidal volume and rising respiratory rate of a spontaneously breathing patient.

Table 5-2. Control parameters *(continued)*

Parameter	Definition
For additional details, including parameter ranges and accuracy, see Table A-6 on page A-7.	
Rate	Respiratory frequency or number of breaths per minute.
Sigh	Breaths delivered at a regular interval (every 50 breaths) at a pressure up to 10 cmH2O higher than non-sigh breaths, as allowed by the Pressure alarm limit. During sigh breaths, the Pressure and Vt alarm limits remain in effect to help protect the patient from excessive pressures and volumes. Not available for neonatal patients, or DuoPAP or APRV modes.
T high	Length of time at the higher pressure level, P high, in DuoPAP and APRV modes.
TI	Inspiratory time, the time to deliver the required gas (time to reach the operator-set Vt or Pcontrol value). Used with Rate to set the breath cycle time. In PCV+ and (S)CMV+ modes, TI can be controlled by rate and TI or by the I:E ratio; you set the desired method in Configuration. All other modes are controlled by rate and TI.
TI max	Maximum inspiratory time for flow-cycled breaths in NIV, NIV-ST, SPONT in neonatal modes.
T low	Length of time at the lower pressure level, P low, in APRV mode.
Vt	Tidal volume delivered during inspiration in (S)CMV+ and SIMV+ modes.
VT/kg	Tidal volume per weight.
Weight	Actual body weight. Used only with neonates.

5.7 Working with alarms

WARNING

Be sure to set the auditory alarm volume above the ambient sound level. Failure to do so can prevent you from hearing and recognizing alarm conditions.

NOTE:

These settings do not apply to TeslaSpy alarms. For details on magnetic field monitoring alarms with TeslaSpy, see Chapter 3.

Use the Alarms window to:

- Set alarm limits (Section 5.7.1)
- Adjust the alarm volume (Section 5.7.2)
- View active alarms (Section 5.7.3)

Details about device alarms are provided as follows:

- Table 5-3 describes each of the adjustable alarms
- Table 9-2 in Chapter 9 provides troubleshooting details
- Table A-10 in Appendix A provides ranges and accuracy information

5.7.1 Setting alarm limits

CAUTION

- **Although you can set all alarms quickly using the Auto alarm function, some settings are not appropriate under all clinical conditions. Hamilton Medical recommends that you set the alarms manually when possible. When circumstances require use of the Auto alarm function, verify the validity of the settings at the earliest opportunity.**
- **To prevent possible patient injury, make sure the alarm limits are appropriately set before you place the patient on the ventilator.**

NOTE:

- If the ventilator is in the (S)CMV+, or SIMV+ mode, be sure the Pressure alarm is appropriately set. This alarm provides a safety pressure limit for the device to appropriately adjust the inspiratory pressure necessary to achieve the target tidal volume.

  The maximum available inspiratory pressure is 10 cmH2O below the Pressure limit, indicated by a blue line on the pressure waveform display.

  Set Pressure to a safe value (e.g., 45 cmH2O, which limits the pressure target to a maximum of 35 cmH2O). If Pressure is set too low, there may not be enough margin for the device to adjust its inspiratory pressure in order to deliver the target tidal volume.
- Selecting **Auto** automatically sets all alarm limits around the current monitoring parameter values, except for the Vt and Apnea alarm limits. The Vt alarm limits remain unchanged, and must be set manually to the desired level.

- The **Auto** button is disabled during neonatal ventilation.

- After power has been interrupted for up to 120 seconds, the device stores the last settings, including any specified alarm limits. Upon reconnection with the power supply, the device resumes ventilation with these stored settings. Should the power failure exceed 120 seconds, the settings are still stored but the device starts in standby upon reconnection with the power supply.

You can access the Alarms window and change alarm settings at any time, without affecting ventilation.

The device offers two alarm-setting options:

- Manually set individual alarm limits.
- Use the **Auto** alarm function.

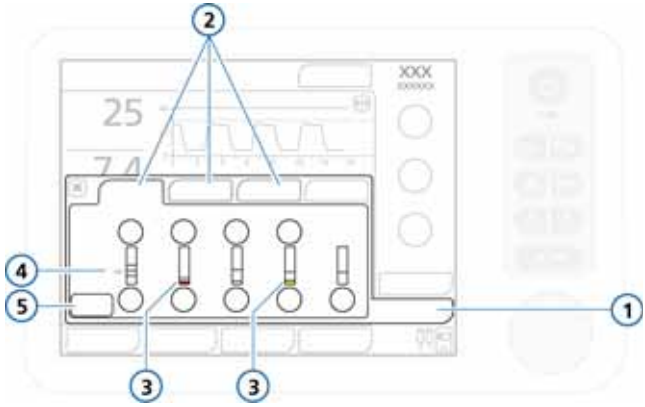


Figure 5-8. Limits window

1	Alarms	**4**	Current monitored value
2	Limits 1, 2, 3	**5**	Auto button
3	Red or yellow bar (depending on alarm priority: high, medium, or low) indicates the monitored value is out of range		

To review and adjust alarms

1. Touch the **Alarms** button.

   The Limits 1 window is displayed (Figure 5-8).

2. To set an alarm individually, select the alarm control and adjust the value. Repeat for any other alarm.

   Additional alarm settings are available in the Limits 2, and if used, Limits 3 windows.

3. To set alarm limits automatically, select the **Auto** button in the Limits 1 window.

   Selecting **Auto** automatically sets all alarm limits around the current monitoring parameter values, except for the Vt and apnea alarm limits. The Vt alarm limits remain unchanged, and must be set manually to the desired level.

4. Close the window.

5.7.2 Adjusting alarm volume (loudness)

WARNING

Be sure to set the auditory alarm volume above the ambient sound level. Failure to do so can prevent you from hearing and recognizing alarm conditions.

NOTE:

- The alarm volume cannot be set lower than the minimum specified for the device in Configuration (Section G.3.3).
- If the alarm volume was set to a value that is below the default setting (5 for adult/ped, 3 for neonates) before the ventilator was turned off, it will be reset to 5 (adult/ped) or 3 (neonates) when the ventilator is turned back on.

  However, if the minimum loudness setting is configured and is set to a value greater than 5, the higher value is retained.
- If you decrease the alarm volume during the night shift, do not forget to return it to its daytime setting.
- The alarm volume control is on the **Settings** tab.

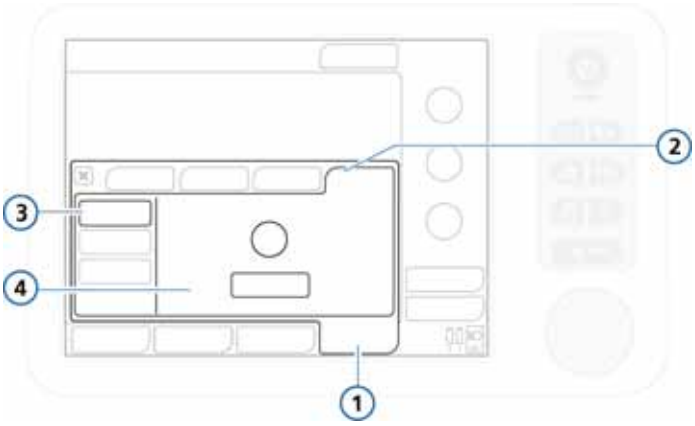


Figure 5-9. Alarm volume (loudness) control

1	System	**3**	Loudness button
2	Settings	**4**	Loudness dial and Test button

To adjust the alarm volume

1. Open the System -> Settings window.
2. Activate and adjust the **`Loudness`** dial, as needed.
3. Touch **`Test`** to check the volume.
   Ensure the volume level is above the ambient sound level.
4. Repeat the process as required, and close the window.

5.7.3 Buffer: Viewing alarm information

See Chapter 9 for a description of the alarm buffer.

5.7.4 Table of alarm limit settings

The following table briefly describes each of the adjustable ventilator alarms. Table A-10 in Appendix A provides the adjustable alarm ranges and default settings, including accuracy.

Table 5-3. Adjustable alarms

Alarm	Definition
For additional details, including alarm ranges and accuracy, see Table A-10 on page A-18.	
Apnea time	The maximum time allowed from the beginning of one inspiration to the beginning of the next inspiration. If the patient does not trigger a breath during this time, an alarm is annunciated. Apnea backup ventilation will begin, if enabled. Not applicable to nCPAP or nCPAP-PC.
ExpMinVol (low and high)	Low and high expiratory minute volume. If either limit is reached, a high-priority alarm is annunciated. Not applicable to nCPAP or nCPAP-PC.
Flow 	Only active in nCPAP and nCPAP-PC modes. The High Flow alarm sounds when the limit is reached.
fTotal (low and high)	Low and high monitored total breath rate (fTotal), including both spontaneous and mandatory breaths. If either limit is reached, a medium-priority alarm is annunciated. Not applicable to nCPAP or nCPAP-PC.

Table 5-3. Adjustable alarms *(continued)*

Alarm	Definition
For additional details, including alarm ranges and accuracy, see Table A-10 on page A-18.	
Pressure (low and high)	Low and high monitored pressure at the patient airway (Ppeak). If pressure (high) is reached or pressure (low) is not reached, a high-priority alarm sounds. In addition, when pressure (high) reaches Pressure minus 10 cmH2O, pressure is limited: no further pressure is applied. If pressure (high) is reached, the ventilator immediately stops gas flow to the patient and opens the expiratory valve to reduce pressure to the PEEP/CPAP level. The ventilator is designed to limit patient airway pressure to 60 cmH2O, but if pressure climbs to 75 cmH2O, the ambient valve opens, releasing pressure to the ambient level. An exception is sigh breaths, when the ventilator may apply inspiratory pressure 3 cmH2O below the Pressure alarm limit.
Vt (low and high)	Low and high expiratory tidal volume, for two consecutive breaths. If either limit is reached, a medium-priority alarm sounds. When the delivered Vt is > 1.5 times the set Vt high alarm, the Inspiratory volume limitation alarm is generated. In this case, the device aborts the breath and reduces the pressure to PEEP level. The APV controls reduce the pressure for the next breath by 3 cmH20. Not applicable to nCPAP or nCPAP-PC.

6 Neonatal ventilation

6.1 Introduction

WARNING

- **To prevent possible patient injury, make sure the ventilator is set up correctly for the neonatal patient. The ventilator must have the appropriate breathing circuit parts and neonatal flow sensor or neonatal pressure line (nCPAP/nCPAP-PC modes).**
- **Make sure you perform all tests and calibrations before using the ventilator.**

NOTE:

- When changing from an Adult/Pediatric to a Neonatal patient group or vice versa, you must calibrate the flow sensor or circuit (pressure line), and perform the tightness test.
- When changing from nCPAP/nCPAP-PC to another mode or vice versa, you must calibrate the flow sensor or circuit (pressure line).
- After connecting a new or decontaminated breathing circuit or component, perform a tightness test, and calibrate the flow sensor or circuit (pressure line, for nCPAP/nCPAP-PC modes).
- Pneumatic nebulization is disabled during neonatal ventilation.

While the process for ventilating neonates is very similar to that for other patients, neonatal ventilation presents some unique challenges and requirements. This chapter provides a comprehensive overview of these requirements and special conditions.

6.2 Setting up for neonatal ventilation

Setting up for neonatal ventilation comprises the following steps:

		See
1.	Install the neonatal expiratory valve.	Section 6.2.1 on page 6-3
2.	On the ventilator, select the patient group and specify weight.	Section 6.2.2 on page 6-6
3.	Select the ventilation mode.	Section 6.2.3 on page 6-7
4.	Set up the breathing circuit.	Section 6.2.4 on page 6-9
5.	Perform any required tests (tightness test and calibrations) and the preoperational check.	Section 6.2.5 on page 6-15

6.2.1 Installing the neonatal expiratory valve

CAUTION

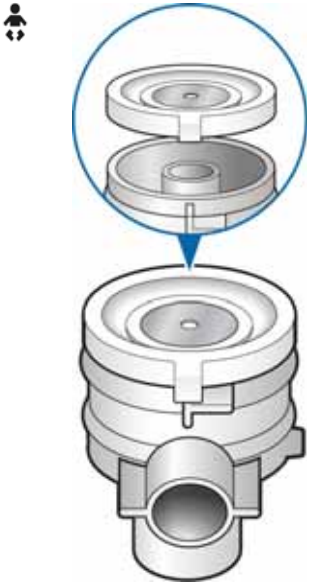
- **Be sure to read the safety information in Section 3.2 before entering the MRI environment.**
- **Make sure the correct type of expiratory valve for your patient is installed:**
  - **Ensure the Neonatal patient group is selected on the ventilator when using the neonatal expiratory valve. It cannot be used with the Adult/Ped patient group.**
  - **You must use a neonatal expiratory valve for neonates.**

NOTE:

Ensure you select the correct expiratory valve (adult/pediatric or neonatal) for your patient. If the expiratory valve type does not match the selected patient group on the ventilator, the Wrong expiratory valve alarm is generated. For details, see the Alarm troubleshooting table in Section 9.5.

Table 6-1 shows both neonatal and adult/pediatric expiratory valves, highlighting the differences.

Table 6-1. Neonatal and adult/pediatric expiratory valves

Neonatal expiratory valve	Adult/pediatric expiratory valve
	

To install the neonatal expiratory valve

1. Holding the expiratory valve housing (Figure 6-1), seat the silicone membrane onto the housing.

   The metal plate must face up and be visible.

2. Position the housing and twist clockwise until it locks into place.

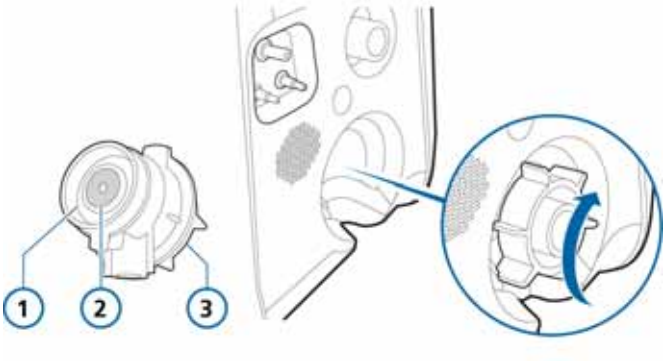


Figure 6-1. Installing the neonatal expiratory valve

1	Expiratory valve membrane	**3**	Expiratory valve housing
2	Metal plate toward ventilator		

6.2.2 Setting the patient group and weight

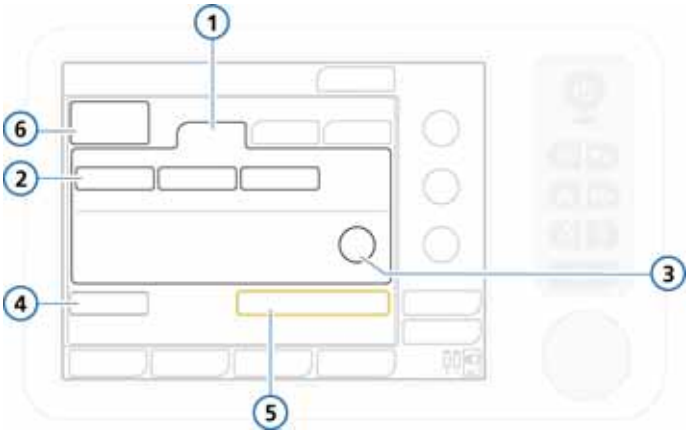


Figure 6-2. Neonatal patient group

1	Neonatal	**4**	Preop check
2	Quick setup buttons	**5**	Start Ventilation
3	Weight	**6**	Elapsed time in standby

To select the patient group

1. In the Standby window, touch the **Neonatal** tab. See Figure 6-2.
2. Touch the appropriate Quick setup button, if applicable.

   In Figure 6-2, they are labeled **Neonatal 1**, **Neonatal 2**, and **Neonatal 3**. (The button names can be changed during configuration.) These settings are defined in configuration (Section G.6). Quick setups allow you to specify default options, including the ventilation mode to use.
3. Touch the **Weight** control and set the patient's body weight.

   Setting the weight properly is critical for ensuring that the tidal volume and minute volume alarms are correctly set.

   By default, the weight is set to 2 kg.

You can now select the ventilation mode, if the desired mode is not already selected.

6.2.3 Selecting the ventilation mode

NOTE:

- You can only select nCPAP/ nCPAP-PC or change from nCPAP/ nCPAP-PC to another mode when in Standby.
- When changing from nCPAP/nCPAP-PC to another mode or vice versa, you must calibrate the circuit (for the pressure line) or flow sensor.

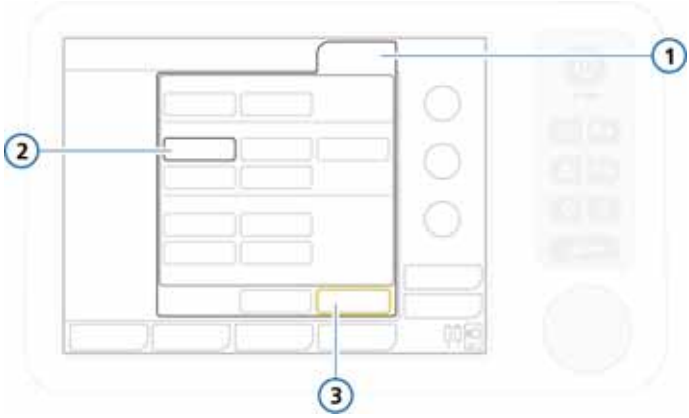


Figure 6-3. Neonatal modes

1	Modes	**3**	Confirm, Cancel
2	Selected mode		

To select the ventilation mode

1. Touch the **Modes** button at the top of the display.
   The Modes window appears (Figure 6-3).
2. Touch the desired mode.
   The Controls window for the selected mode appears.

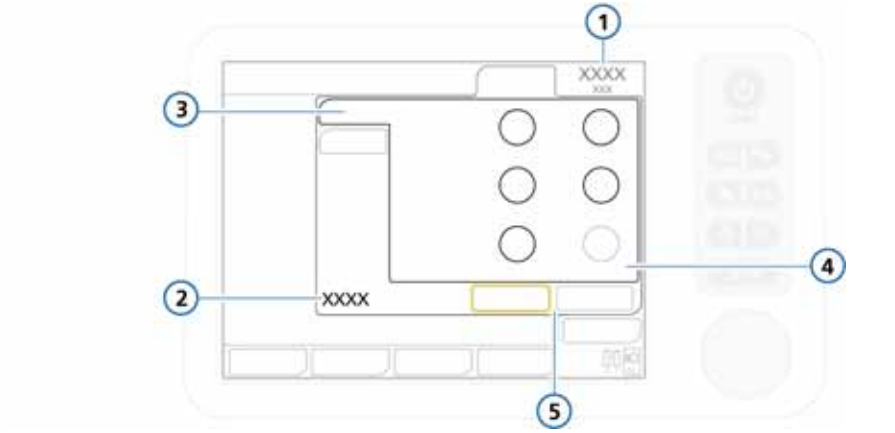


Figure 6-4. Controls window

1	Active mode	**4**	Mode controls
2	Newly selected mode	**5**	Confirm, Cancel
3	Basic		

3. Set the desired parameter values in the various tabs (Basic, More, Apnea) as appropriate and available, and touch **`Confirm`**.

   The next step depends on your mode selection.

   – If changing from nCPAP/nCPAP-PC to another mode or vice versa, the System -> Tests & calib window appears. Proceed to step 4.

   – If changing between any other modes, set the desired alarm limits. Proceed to step 5.

4. Perform the flow sensor or circuit (nCPAP, nCPAP-PC modes) calibration.

5. Touch the **`Alarms`** button and set the appropriate alarm limits in the Limits windows (Figure 5-8).

The device is ready for the appropriate preoperational checks and calibrations, if not already performed as described above.

6.2.4 Setting up the breathing circuit

Setting up a neonatal breathing circuit comprises the following steps:

		See
1.	Selecting the components	Section 6.2.4.1 on page 6-9
2.	Connecting the breathing circuit	Section 6.2.4.2 on page 6-10
3.	Installing the flow sensor	Section 6.2.4.3 on page 6-13
4.	Connecting the pressure line (nCPAP and nCPAP-PC modes)	Section 6.2.4.4 on page 6-14
5.	Positioning the circuit	Section 6.2.4.5 on page 6-15

6.2.4.1 Components for neonatal ventilation

CAUTION

To determine appropriate tidal and minute volumes for neonatal patients, you must consider (anatomic) dead space. Artificial airways (Y-piece, flow sensor, ET tube, and so on) may increase the dead space.

NOTE:

- An infant flow sensor is required with breathing circuits used for all ventilation modes except nCPAP and nCPAP-PC.
- When using the nCPAP or nCPAP-PC modes, remove the flow sensor and use the pressure line with the breathing circuit. See Section 6.2.4.4.

Select the correct breathing circuit parts for your patient from Table 6-1.

Table 6-1. Neonatal breathing circuit part specifications

Patient group	Weight (kg)	Tracheal tube ID (mm)	Breathing circuit tube ID (mm)	Flow sensor[1]
Neonatal	≤ 30	< 4	10	Infant

1. Not required for noninvasive nCPAP or nCPAP-PC neonatal modes; a pressure line is used instead.

6.2.4.2 Connecting the neonatal breathing circuit

Figure 6-5 shows a typical breathing circuit using an HME, applicable to most ventilation modes. Figure 6-6 shows a typical breathing circuit for use with the nCPAP or nCPAP-PC modes.

For ordering information, contact your Hamilton Medical representative. Follow the specific guidelines for the different parts.

Connect the components as appropriate for your patient.

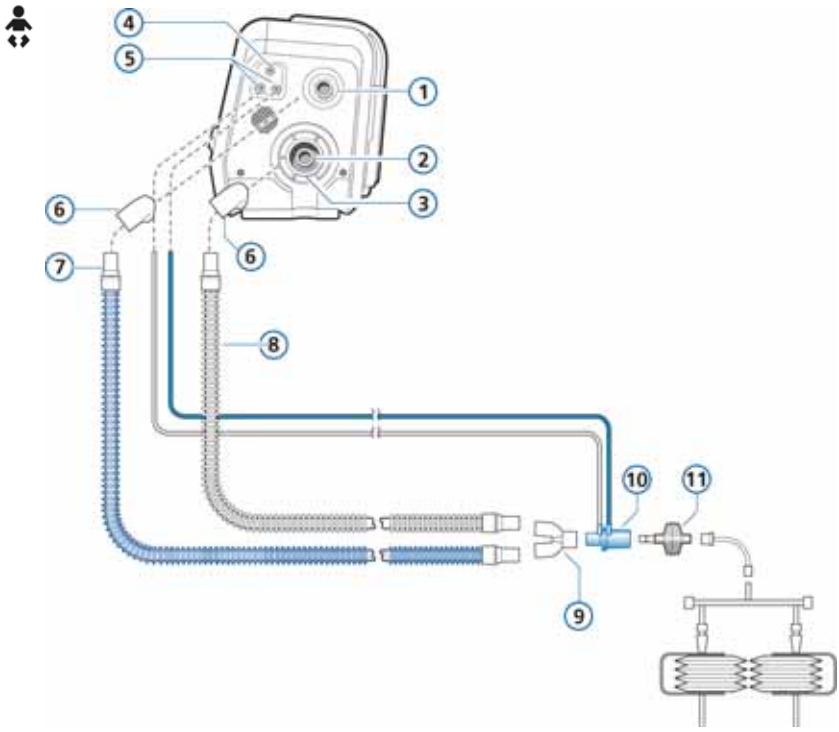


Figure 6-5. MR Safe dual-limb breathing circuit with HMEF/HME for use in MRI environment (neonatal)

1	To patient	**7**	Inspiratory limb
2	From patient	**8**	Expiratory limb
3	Expiratory valve with membrane cover	**9**	Y-piece
4	Nebulizer outlet	**10**	Flow sensor
5	Flow sensor connectors	**11**	HMEF/HME (infant)
6	Elbow adapters (optional)		

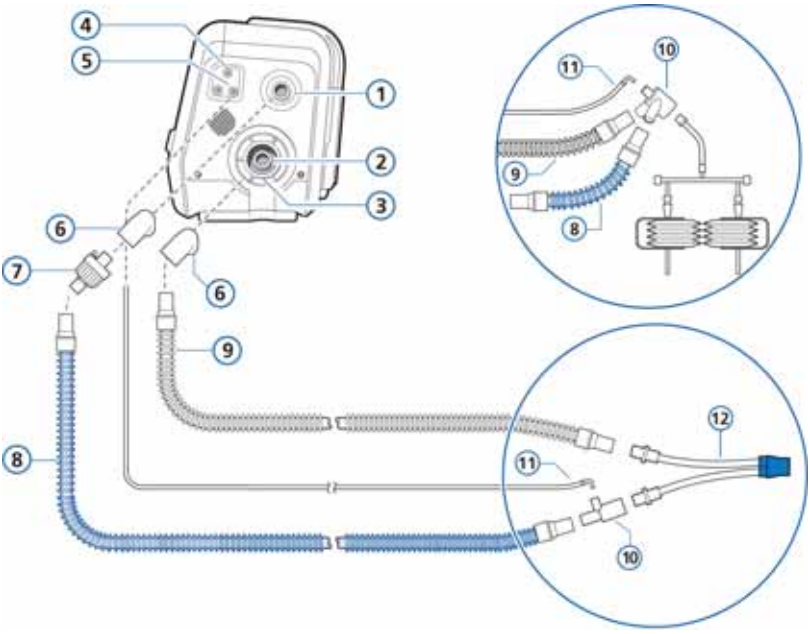


Figure 6-6. MR Safe dual limb breathing circuit with pressure line, for nCPAP and nCPAP-PC modes, with Y- or T-piece (neonatal)

1	To patient	**7**	Inspiratory filter
2	From patient	**8**	Inspiratory limb
3	Expiratory valve with membrane cover	**9**	Expiratory limb
4	Nebulizer outlet	**10**	T-piece with pressure line or Y-piece with pressure line
5	Pressure line connector (blue)	**11**	Pressure line
6	Elbow adapters (optional)	**12**	Patient interface (mask or nasal prongs)

Note that this circuit does not use a flow sensor. It uses a pressure line.

6.2.4.3 Installing the flow sensor

NOTE:

- To prevent inaccurate flow sensor readings, make sure the flow sensor is correctly installed:
  - The flow sensor tubes must not be kinked.
  - The flow sensor tubes must be secured with the included clamp.
- When using the nCPAP or nCPAP-PC modes, remove the flow sensor and use the pressure line with the breathing circuit. See Section 6.2.4.4.

Use a Hamilton Medical infant flow sensor to ventilate your neonatal patient. Do not use an adult flow sensor. The neonatal flow sensor has a dead space of < 1.3 ml.

To install the infant flow sensor

1. Insert a flow sensor between the Y-piece of the breathing circuit and the patient connection (Figure 6-7).

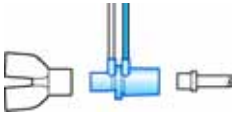


Figure 6-7. Installing the infant flow sensor

2. Connect the blue and clear tubes to the flow sensor connectors on the ventilator.

   The blue tube goes to the blue connector. The clear tube goes to the white connector.

3. Calibrate the flow sensor. See Section 6.2.5.2.

6.2.4.4 Connecting the pressure line (nCPAP modes)

Use the pressure line with the breathing circuit when using the nCPAP or nCPAP-PC modes. Do not use a flow sensor.

The pressure is measured by a built-in T-piece adapter in the inspiratory line, close to the patient, or (if available) over the optional pressure measuring connection at the Y-piece of the breathing circuit.

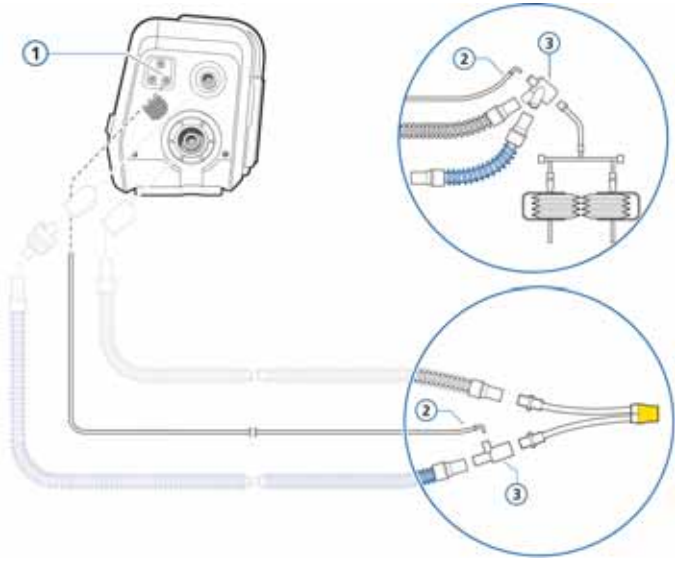


Figure 6-8. Connecting the pressure line

1	Pressure line connector (blue)	**3**	T-piece with pressure line or Y-piece with pressure line
2	Pressure line		

To connect the pressure line

1. Using an adapter, connect the pressure line to the small inlet at the top of the T- or Y-piece, whichever is used. See Figure 6-8.
2. Connect the pressure line to the blue flow sensor connector on the ventilator.
3. Calibrate the breathing circuit. See Section 6.2.5.3.

6.2.4.5 Positioning the breathing circuit

After assembly, position the breathing circuit so that the hoses will not be pushed, pulled, or kinked as a result of a patient's movement, nebulization, or other procedures.

6.2.5 Performing tests and calibrations

Be sure to perform a tightness test, and flow sensor or breathing circuit calibration, in addition to the preoperational checks. See Chapter 4 for details, as well as additional tests and procedures, for example, O2 cell calibration.

This section describes the following basic tests and calibrations required for neonatal ventilation:

		See
1.	Perform the tightness test	Section 6.2.5.1 on page 6-15
2.	Calibrate the infant flow sensor	Section 6.2.5.2 on page 6-18
	Calibrate the neonatal breathing circuit (nCPAP or nCPAP-PC modes only)	Section 6.2.5.3 on page 6-21
3.	Perform the preoperational check	Section 6.2.6 on page 6-23

6.2.5.1 Performing the tightness test

NOTE:

- Make sure another source of ventilatory support is available during this test. The patient must be disconnected from the ventilator for the duration of the test.
- To cancel the tightness test while it is in progress, select **`Tightness`** again.
- Perform this test after installing a new or decontaminated breathing circuit or component (including a flow sensor or pressure line).

Description: This test checks for leakage in the patient breathing circuit.

Procedure:

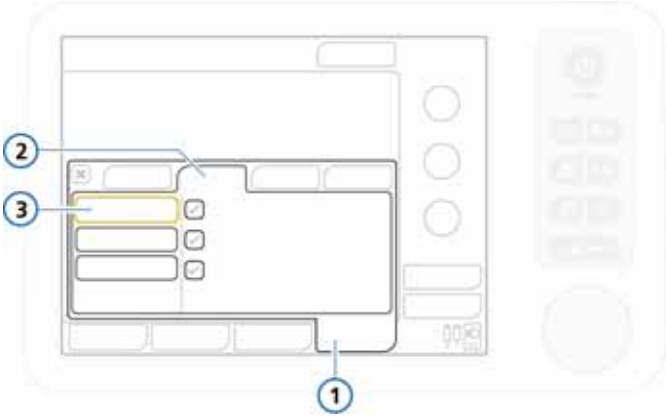


Figure 6-9. Tests & Calib window, Tightness test

1	System	**3**	Tightness
2	Tests & calib		

To perform the tightness test

1. Set the ventilator up as for normal ventilation, complete with the breathing circuit.
2. In the System -> Tests & calib window, select **`Tightness`**. See Figure 6-9.

   The text **`Disconnect patient`** is now displayed.
3. Disconnect the breathing circuit at the patient side of the flow sensor. Do not block the open end of the flow sensor.

   The text **`Tighten patient system`** is now displayed.
4. Block the opening (wearing a sterilized glove is recommended).

   The text **`Connect patient`** is now displayed.
5. Connect the patient.

6. When the test is complete, verify that there is a green check mark in the **Tightness** checkbox.

In case of test failure

If the test fails, a red X is displayed in the **Tightness** checkbox.

Perform the following checks, repeating the tightness test after each one, until the test is successful:

- Check the breathing circuit for a disconnection between the ventilator and the flow sensor or pressure line (nCPAP, nCPAP-PC modes), or for other large leaks (for example, breathing circuit).
- Check that the expiratory valve is correctly installed.
- Replace the breathing circuit, and flow sensor or pressure line (nCPAP, nCPAP-PC modes), and expiratory valve.

If the problem still persists, have the ventilator serviced.

6.2.5.2 Calibrating the infant flow sensor

NOTE:

- An infant flow sensor is required with breathing circuits used for all ventilation modes except nCPAP and nCPAP-PC.

  When using the nCPAP or nCPAP-PC modes, remove the flow sensor and use the pressure line with the breathing circuit. See Section 6.2.4.4.
- Make sure another source of ventilatory support is available during this calibration. The patient must be disconnected from the ventilator during the test.
- To cancel the flow sensor calibration while it is in progress, select **`Flow Sensor`** again.
- Circuit resistance compensation is measured during calibration.
- If there is a mismatch between the active patient profile and the flow sensor type you are using, the calibration fails. Ensure you are using the correct flow sensor for the patient.

Calibrate the flow sensor after connecting a new flow sensor or whenever the **`Flow sensor calibration needed`** alarm is generated.

During calibration, when the ventilator detects a mismatch between the set patient group and the flow sensor, the calibration fails.

Procedure:

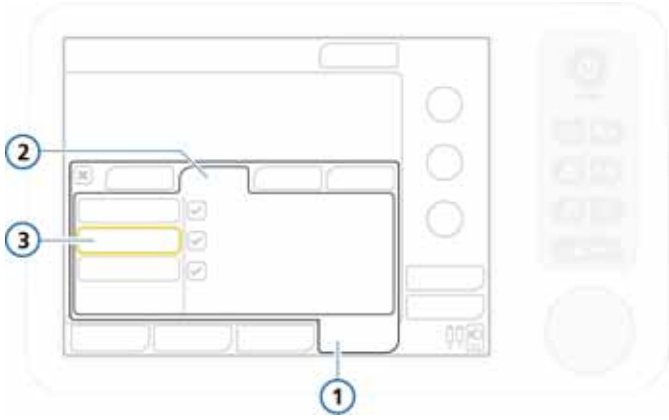


Figure 6-10. Tests & calib window, Flow sensor calibration

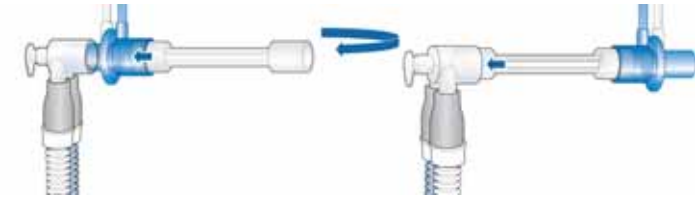
1	System	**3**	Flow Sensor
2	Tests & calib		

To calibrate the infant flow sensor

1. Set the ventilator up as for normal ventilation, complete with breathing circuit and expiratory membrane and cover.
2. Make sure that the Neonatal patient group is selected, an infant flow sensor and neonatal expiratory valve are installed, and the calibration adapter is available.
3. In the System -> Tests & calib window, select **`Flow Sensor`**.

   If you have not already disconnected the patient, the text **`Disconnect patient`** is displayed.
4. Disconnect the patient now.

5. Follow the instructions displayed in the message line, attaching the adapter and turning the flow sensor around as indicated.



6. When prompted to turn the flow sensor again, turn the flow sensor back to its starting position, and remove the calibration adapter.
7. When calibration is complete, verify that there is a green check mark in the **Flow Sensor** checkbox.
8. If the calibration is successful, connect the patient, and touch the **Start ventilation** button in the Standby window to start ventilation.

In case of calibration failure

If the calibration fails, a red X is displayed in the **Flow Sensor** checkbox.

Perform the following checks, repeating the calibration after each one, until calibration is successful:

- Check the breathing circuit for a disconnection between the ventilator and the flow sensor, or for other large leaks (for example, breathing circuit).
- Check that the correct flow sensor is connected, and that the flow sensor and expiratory valve/membrane are properly seated.
- If the calibration fails again, replace the flow sensor.
- If the calibration still fails, replace the expiratory valve/membrane.

If the problem persists, have the ventilator serviced.

6.2.5.3 Calibrating the neonatal breathing circuit (nCPAP and nCPAP-PC modes)

NOTE:

- We strongly recommend calibrating the breathing circuit before starting to ventilate the patient using either the nCPAP or nCPAP-PC mode.
- Make sure another source of ventilatory support is available when precalibration is not possible. The patient must be disconnected from the ventilator for the duration of the calibration.

The nCPAP and nCPAP-PC modes use a pressure line in the breathing circuit to measure the inspiratory pressure. Do not use a flow sensor.

This calibration ensures that the breathing circuit resistance compensation is accurate.

Procedure:

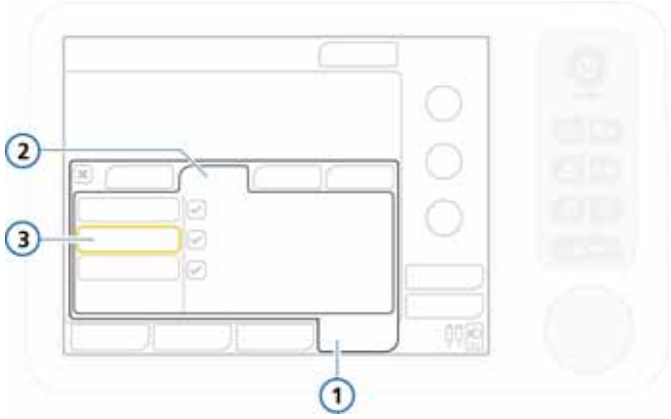


Figure 6-11. Tests & calib window, Circuit calibration

1	System	**3**	Circuit
2	Tests & calib		

To calibrate the circuit with the pressure line

1. In the System -> Tests & calib window, select **Circuit**.

   If you have not already disconnected the patient, the text **Disconnect patient** is displayed.

2. Disconnect patient as follows:
   - If using a Y-piece, disconnect the breathing circuit from the patient.
   - If using a T-piece, disconnect the interface from the patient.
3. Follow the instructions displayed in the message line.
4. When calibration is complete, verify that there is a green check mark in the **Circuit** checkbox.
5. When successful, touch the **Start ventilation** button in the Standby window, and connect the patient, as indicated.

In case of calibration failure

If the calibration fails, a red X is displayed in the **Circuit** checkbox.

Perform the following checks, repeating the calibration after each one, until calibration is successful:

- Check the breathing circuit for a disconnection between the ventilator and the pressure line, or for other large leaks (for example, breathing circuit).
- Check that the pressure line and expiratory valve/membrane are properly seated.
- If the calibration fails, replace the pressure line.
- If the calibration still fails, replace the breathing circuit and expiratory valve/membrane.

If the problem persists, have the ventilator serviced.

6.2.6 Performing the preoperational check

CAUTION

- **To ensure the ventilator's safe operation, always run the full preoperational check before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests have passed.**
- **To prevent possible patient injury, disconnect the patient from the ventilator before running this test. Make sure another source of ventilatory support is available.**

When to perform: Before placing a new patient on the ventilator.

Required materials: To ensure that the ventilator also functions according to specifications on your patient, Hamilton Medical recommends that your test circuit be equivalent to the circuit used for ventilation.

Breathing circuit	Neonatal, 10 mm ID with 10F connectors
Flow sensor	Infant, for all modes except nCPAP and nCPAP-PC
Pressure line	Neonatal, 1.6 or 3.1 m length Note that only the 3.1 m length is rated for the MRI environment. For nCPAP and nCPAP-PC modes (no flow sensor)
Test lung	Neonatal, with neonatal ET tube between flow sensor and lung model (an IngMar neonatal lung model is recommended)

Procedure:

Do or observe…	Verify…
1. Connect ventilator to AC power and oxygen supply. Assemble the patient breathing circuit.	Breathing circuit is assembled correctly. See Section 6.2.4 on page 6-9.
2. Turn on power.	When ventilator is turned on, buzzer sounds briefly and the red alarm lamp flashes. After the self-test is passed, the alarm lamp flashes red again.
3. Make sure the ventilator is in standby, and select **`Preop check`** in the Patient setup/Standby window.	
4. Open **`System`** -> **`Tests & calib`** window (Figure 4-2). Select and run the tightness test, then the flow sensor or circuit calibration. Follow all prompts.	These tests pass.
5. If necessary, run **`O2 cell`**. Close window.	These tests pass. For details, see Chapter 4.
6. Generate an alarm (for example, by disconnecting primary power).	Corresponding alarm message in message bar (for example, **`Loss of external power`**). Note that in standby, patient alarms are suppressed.
7. Resolve the alarm situation (for example, reconnect primary power).	Alarm is reset.

Corrective action: If the ventilator does not pass the preoperational check, have it serviced.

6.3 Ventilation modes for neonates

CAUTION

Auto triggering is harmful and can occur easily with sensitive trigger settings due to gas leaks around the ET tubes.

NOTE:

Because neonatal ET tubes normally do not have a cuff, leakage can be significant, that is, the inspiratory tidal volume (VTI) can be much greater than the measured expiratory tidal volume (VTE).

Check the VLeak parameter in the Monitoring window from time to time; the leak may not be predictable.

The neonatal modes available in the HAMILTON-MR1 are either pressure controlled or adaptive (pressure regulated and volume targeted) modes.

The following modes are supported for neonates (Figure 6-3):

PCV+	PSIMV+	(S)CMV+/ APVcmv	SIMV+/ APVsimv	SPONT
DuoPAP	APRV	NIV	NIV-ST	
nCPAP	nCPAP-PC			

For details about:

- Neonatal-only nCPAP modes, see Sections 6.3.1 and 6.3.2
- All other modes, see Appendix B

6.3.1 About the nCPAP mode

NOTE:

Apnea backup, trigger detection, disconnection detection, and volume measurements are not available in nCPAP mode.

The nCPAP (nasal Continuous Positive Airway Pressure) mode applies CPAP over a nasal interface (mask or prongs). Leaks are compensated due to the set High Flow limit.

The following parameters are used in the nCPAP mode:

- PEEP/CPAP
- Oxygen

The following monitoring parameters are used in the nCPAP mode:

- Insp Flow
- Flow

For details about these parameters, see Section 6.4.

When a manual breath is applied, the pressure changes to PEEP + 5 cmH2O for a period of 0.4 seconds, or so long as the button is pressed, to a maximum of 15 s. When the manual breath is completed, the pressure returns to the set CPAP level.

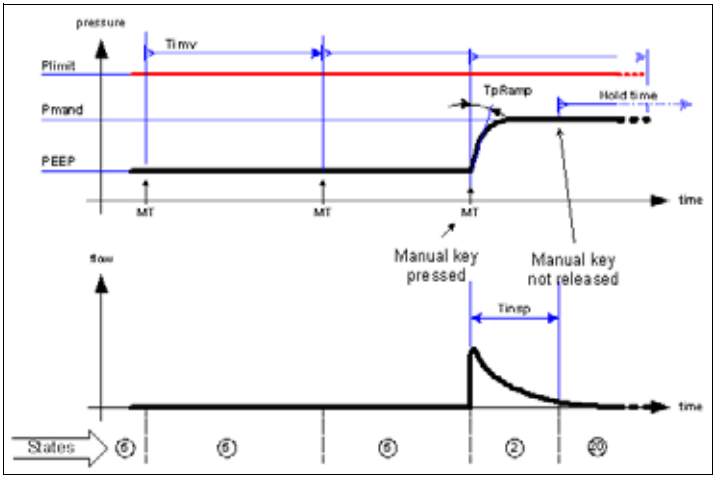


Figure 6-12. nCPAP breathing pattern

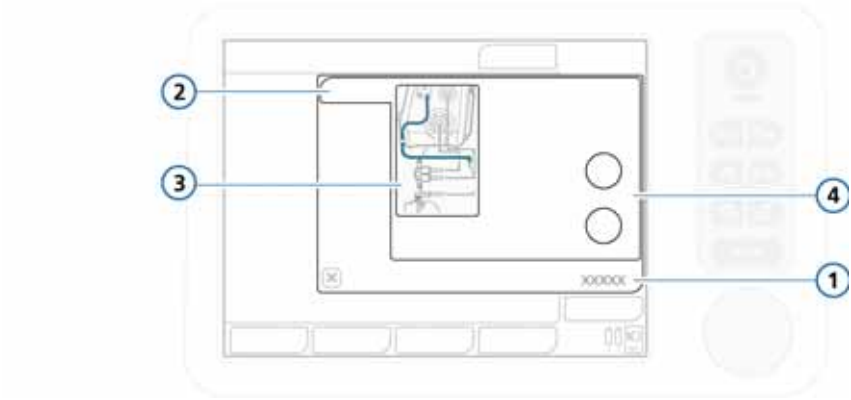


Figure 6-13. nCPAP mode Basic controls

1	Controls	**3**	nCPAP connection diagram
2	Basic	**4**	Mode controls: PEEP, Oxygen

For parameter details, see Table A-6 (Appendix A) for ranges, default settings, and accuracy of measurements applicable to neonatal patients.

6.3.2 About the nCPAP-PC mode

NOTE:

Apnea backup, trigger detection, disconnection detection, and volume measurements are not available in nCPAP-PC mode.

The nCPAP-PC (nasal Continuous Positive Airway Pressure - Pressure Control) mode delivers, in addition to the set CPAP, intermittent, time-cycled, and pressure-controlled breaths. This results in a biphasic breathing pattern.

The patient can also breathe freely at both pressure levels. The inspiratory flow follows the respiratory effort of the patient on both pressure levels. Leaks are compensated due to the set High Flow limit.

The following parameters are used in the nCPAP-PC mode:

- Rate
- Pcontrol
- TI
- P-ramp
- PEEP/CPAP
- Oxygen

The following monitoring parameters are used in the nCPAP mode:

- Insp Flow
- Flow

For details about these parameters, see Section 6.4.4.

When a manual breath is applied, the pressure changes to the Pcontrol setting for the length of time set by the TI (inspiratory time) or so long as the button is pressed, to a maximum of 15 s. When the manual breath is completed, the pressure returns to the set CPAP level.

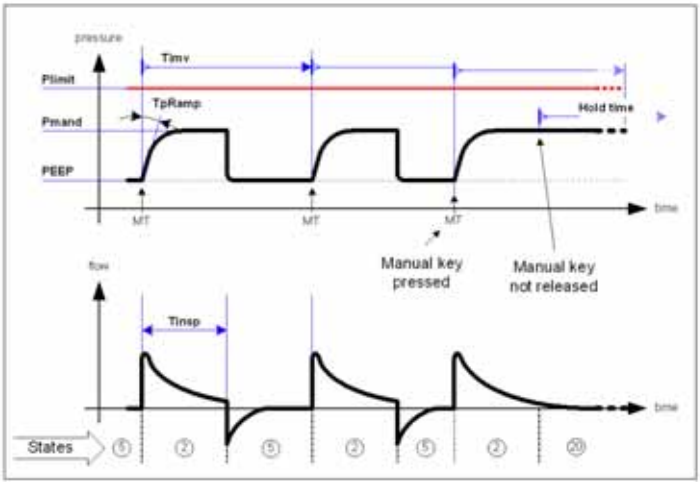


Figure 6-14. nCPAP-PC breathing pattern

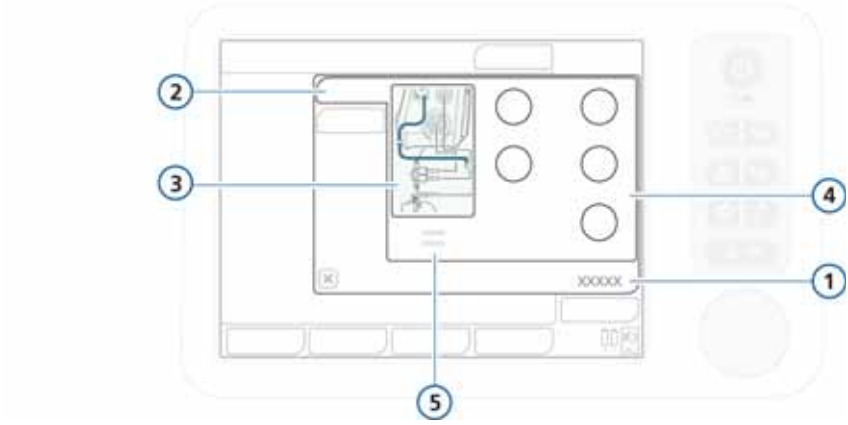


Figure 6-15. nCPAP-PC mode Basic controls

1	Controls	**4**	Mode controls: Rate, Pcontrol, TI, PEEP, Oxygen
2	Basic		
3	nCPAP connection diagram	**5**	I:E, TE

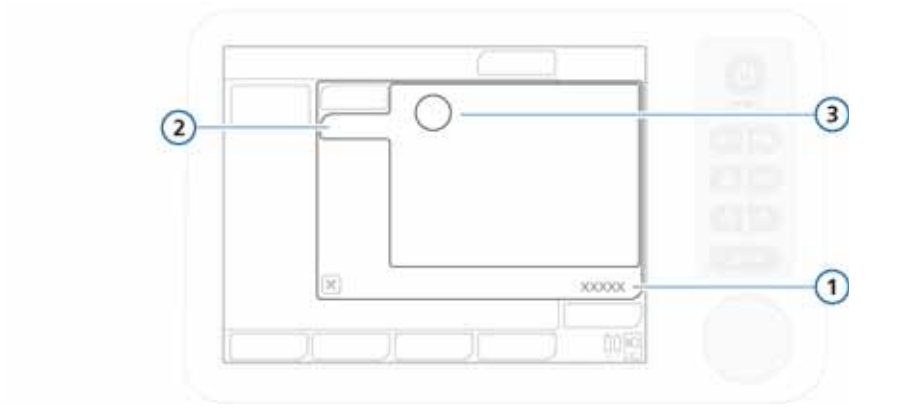


Figure 6-16. nCPAP-PC mode parameters More controls

1	Controls	**3**	Mode controls: P-ramp
2	More		

For parameter details, see Table A-6 (Appendix A) for ranges, default settings, and accuracy of measurements applicable to neonatal patients.

6.4 Parameters for neonatal ventilation

WARNING

- **Prolonged exposure to high oxygen concentrations may cause irreversible blindness and pulmonary fibrosis in preterm neonates.**
- **High rate settings, or very short TI or TE may cause incomplete inspiration or expiration.**

NOTE:

- Pneumatic nebulization is disabled in neonatal ventilation. If needed, use the Aerogen nebulizer in neonatal ventilation. Note that the use of the Aerogen nebulizer is not supported in the MRI environment.
- The ventilator generates a continuous and constant base flow from the inspiratory outlet to the expiratory outlet during the later part of exhalation. The base flow is set to a fixed 4 l/min for neonatal patients.

Some of the ventilation parameters require special consideration when setting up the ventilator for a neonatal patient.

This section briefly describes the following parameters:

- Weight
- ETS
- TI max
- P-ramp
- Flow (monitoring parameter)

For additional information on these and all other parameters, see:

- Table 5-2 (Chapter 5) for definitions of the ventilator control parameters
- Tables A-6 and A-8 for parameter ranges, default settings, and accuracy of measurements applicable to neonatal patients

6.4.1 Weight

For neonates, the ventilator uses actual body weight. Be sure to set the correct patient weight on the Patient setup screen before starting ventilation. See Section 6.2.1 on page 6-3.

Setting the Weight parameter correctly is very important in neonatal ventilation, as tidal volume and minute volume alarm limits are set based on patient weight.

By default, neonatal weight is set to 2 kg.

For parameter details, see Table A-6, Control settings, ranges and accuracy.

6.4.2 TI max

The TI max (maximum inspiratory time) parameter is set for spontaneous breaths in NIV and NIV-ST modes.

For all patient groups, the switchover from inspiration to exhalation in spontaneous breaths is normally controlled by the ETS (expiratory trigger sensitivity). If gas leakage is significant, however, the set ETS may never be reached. The TI max setting provides a backup so inspiration can be terminated. The ventilator switches over to exhalation when the set TI max is reached.

For parameter details, see Table A-6, Control settings, ranges and accuracy.

6.4.3 P-ramp

P-ramp is the pressure ramp, the time required for inspiratory pressure to rise to the set (target) pressure.

Note that P-ramp time cannot exceed one-third of the inspiratory time (TI). In the following modes, the maximum setting is 200 ms: SPONT, NIV, NIV-ST, nCPAP, nCPAP-PC.

By default, P-ramp is set to 50 ms for neonates.

If a neonatal patient has stiff lungs (for example, RDS), be careful when using a short P-ramp (pressure rise time). A very short P-ramp in this case may cause pressure overshoot.

For parameter details, see Table A-6, Control settings, ranges and accuracy.

6.4.4 Flow and Insp Flow

NOTE:

- Flow is only active in nCPAP and nCPAP-PC modes.
- A trend graph cannot be generated using the Flow parameter.

The Flow and Insp Flow parameters monitor average and peak flow, respectively, in nCPAP and nCPAP-PC modes, as described below.

Table 6-2. Flow parameters in nCPAP and nCPAP-PC

	nCPAP mode	**nCPAP-PC mode**
Flow (l/min)	Average flow, updated every second. Displayed in the Monitoring window.	Average flow during expiration, updated each breath. Displayed in the Monitoring window.
Insp Flow (l/min)	Peak flow during patient inspiration, measured every second. Insp flow is a main monitoring parameter (MMP) and is always displayed.	Peak flow during inspiration, measured every breath. Insp flow is a main monitoring parameter (MMP) and is always displayed.

Flow is affected by the setting of the Flow alarm (Section 6.5.1).

6.5 Alarms for neonatal ventilation

The following alarms require special consideration for a neonatal patient:

- Adjustable alarms:
  - Flow
  - Volume-related alarms, Vt and ExpMinVol
- Nonadjustable alarm (see Table 9-2):
  - Obstruction

For additional information about alarms and settings, see Tables 9-2 and A-10.

6.5.1 Flow alarm

CAUTION

Be sure to set the Flow alarm limit to an appropriate level above the current monitored peak flow to avoid potential gastric overinflation, and to be able to detect leaks and disconnection of the patient interface.

NOTE:

Only active in nCPAP and nCPAP-PC modes.

The primary purpose of the medium-priority Flow alarm is to help detect disconnection of the patient interface by monitoring the inspiratory flow (Insp Flow parameter).

When the flow exceeds the set limit, in addition to generating the High Flow alarm, the system reduces the delivered flow, and, as a result, the delivered pressure may be reduced.

To minimize the incidence of this alarm, observe the Insp Flow values, and then set the limit to a value above the average Insp Flow reading + known minimum leakage.

If the alarm sounds, check the patient interface and breathing circuit for disconnection or excessive leakage, and check the ventilator settings and alarm limits.

The alarm is adjustable from 8 to 30 l/min. By default, the flow limit is set to 15 l/min.

For additional details, see Table A-10.

6.5.2 Volume-related alarms, Vt and ExpMinVol

Note that the following adjustable alarms use patient weight to set the initial alarm limits:

- Tidal volume, high and low (VT)
- Minute volume, high and low (ExpMinVol)

Be sure to set the correct patient weight on the Patient setup screen in standby before starting ventilation. See Section 6.2.1.

6.6 O2 enrichment for neonates

WARNING

Prolonged exposure to high oxygen concentrations may cause irreversible blindness and pulmonary fibrosis in preterm neonates.

NOTE:

In nCPAP and nCPAP-PC modes, starting O2 enrichment or changing the Oxygen setting sets the flow to 10 l/min for 60 seconds. The flow then returns to its previous setting.

The applied oxygen concentration during the enrichment maneuver is increased by 25% of the last oxygen setting. For example, if the last oxygen setting = 40%, the resulting oxygen concentration during O2 enrichment maneuver will be 50%.

For additional details on performing O2 enrichment, see Section 10.4.

7 Monitoring ventilation

7.1 Introduction

CAUTION

- **To ensure that oxygen monitoring is always fully functional, replace an exhausted or missing oxygen cell as soon as possible or use an external O2 monitor that complies with ISO 80601-2-55.**
- **The HAMILTON-MR1's oxygen monitoring function can be disabled. Ensure that an alternative means of oxygen monitoring is always available and enabled.**
- **In case of a problem developing with the ventilator's built-in monitoring and in order to maintain an adequate level of patient monitoring at all times, it is recommended that additional independent monitoring devices be used. The operator of the ventilator must still maintain full responsibility for proper ventilation and patient safety in all situations.**

During ventilation, you can view patient data on the HAMILTON-MR1 screen (Figure 7-1). You can configure the screen layout with different waveforms, loops or trends, or with Intelligent Panel graphics to suit your institution's needs. Access the Monitoring window at any time without affecting breath delivery.

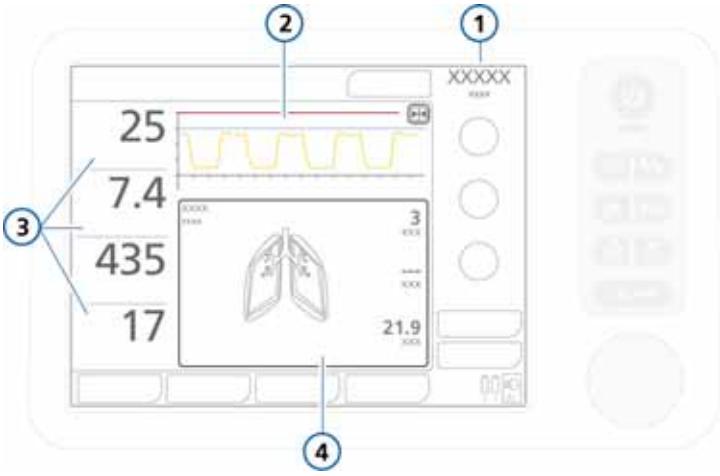


Figure 7-1. Main display

1	Current mode	**3**	Main monitoring parameters (MMP) (Section 7.2.1)
2	Pressure/time graph, non-configurable (Section 7.3)	**4**	Graphic display, configurable (Section 7.3.1)

7.2 Viewing numeric patient data

Numeric patient data is readily available in the following locations:

- The main display prominently shows the four main monitoring parameters (MMPs). See Section 7.2.1.
- The Monitoring window provides access to all of the parameter data. See Section 7.2.2.

7.2.1 About the main monitoring parameters (MMP)

The MMPs are the four numerical monitoring parameters shown on the left side of the display. Every displayed parameter has three critical elements: the current value, name, and unit of the monitoring parameter.

The factory default MMPs are peak pressure, expiratory minute volume, tidal volume, and total respiratory rate. The MMPs that are displayed, as well as their sequence on the display, can be changed in configuration (Section G.5). Any of the monitored parameters can be displayed as an MMP. As a result, since the display is configurable, MMPs may differ between individual ventilators.

MMPs are normally displayed in white. It may also be shown in yellow or red if it is directly related to an active alarm, such as Pressure high or Tidal volume low. The color of the MMP corresponds to the alarm priority (Chapter 9). After the alarm resets, the affected MMP returns to white.

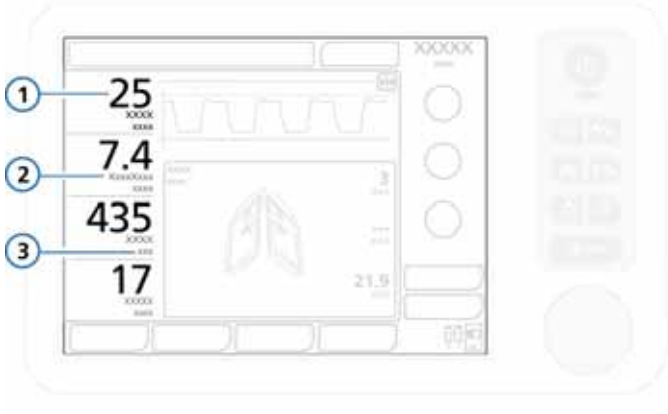


Figure 7-2. MMP components

1	MMP value	**3**	Unit of measure (for example, l/min)
2	Name of parameter (for example, ExpMinVol)		

7.2.2 Viewing patient data in the Monitoring window

The Monitoring window provides access to all of the parameter data.

Figure 7-3 shows the monitored parameters in window 1. Additional parameters are displayed in windows 2 and 3.

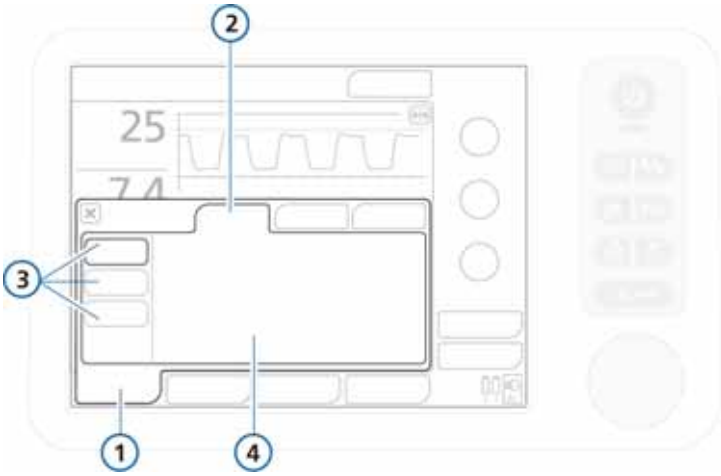


Figure 7-3. General monitoring window 1

1	Monitoring	**3**	1, 2, 3 buttons
2	General	**4**	Parameter values

1. Touch the **Monitoring** button.

   The contents of the General window are displayed.

2. In the General window, touch the **1**, **2**, or **3** button to view the parameter values in that window.

   Each window displays a different set of parameters.

7.3 Waveforms and graphs

The HAMILTON-MR1 offers two primary graphic areas on the display.

- The pressure/time waveform. This graph is always displayed and is not configurable. See item 4 in Figure 7-1.
- The following graphic views of the patient data: trends, loops, graphics (Intelligent panels), and waveforms. Table 7-1 shows the options for each graphic type.

Table 7-1. Graphics options

Graphic type	Options
Trends	1-, 6-, 12-, 24-, or 72-h[1] trend data for a selected parameter
Loops	• Pressure/volume • Flow/volume • Pressure/flow
Graphics	• Dynamic Lung • ASV Graph • Vent Status
Waveforms	• Flow • Off • Volume

1. 72-h trends not available in all markets.

Detailed information about the Intelligent Panels is provided in Chapter 8.

7.3.1 Selecting a graphical view of patient data

To select a graphic to display

1. Touch anywhere in the graphic area of the display to open the graphics window. See **(1)** in Figure 7-4.

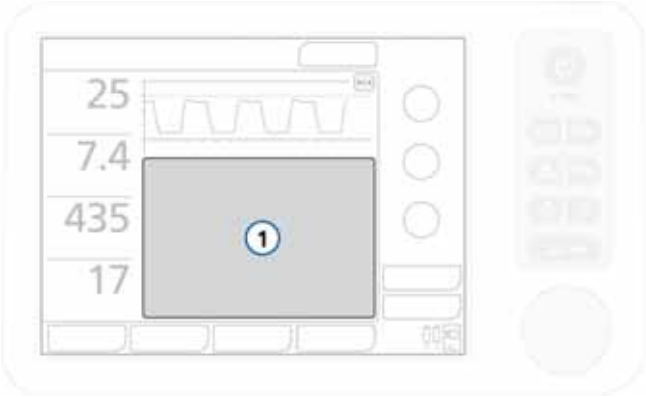


Figure 7-4. Display the graphics window (1)

2. The window displays four tabs, each of which offers different views of the data. By default, the Trends window is displayed.

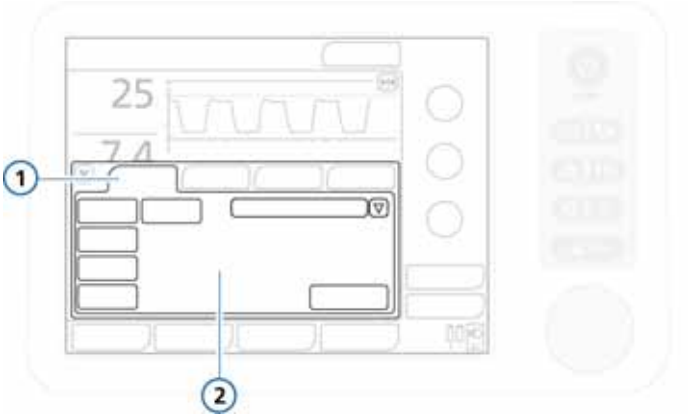


Figure 7-5. Graphics window

1	Trends, Loops, Graphics, Waveforms	**2**	Settings for each view

3. Touch the appropriate tab to access the desired options. See Table 7-1.

Details on these options are provided in this chapter, Chapter 8, and in Appendix C (ASV).

7.4 About graphic types

The following sections describe the different graphical display options available:

	See
Waveforms	Section 7.4.1
Trends	Section 7.5.1
Loops	Section 7.6.1
Intelligent panels (Dynamic Lung, Vent Status, ASV Graph)	Chapter 8

For details on accessing the graphics window, see Section 7.3.

7.4.1 Waveforms

NOTE:

The ventilator uses an autoscaling function, so the values displayed for individual waveforms may differ, based on the range of values to be displayed. For example, the flow scale may vary between one flow/time waveform to another.

The ventilator plots pressure, volume, and flow against time. A blue pressure limitation line shows the maximum "safe" pressure, which is 10 cmH2O below the set high Pressure alarm limit. The Pressure limit is shown as a red line.

The pressure/time graph is always present. You can choose to display a second waveform, as well. For details, see 7.4.1.1.

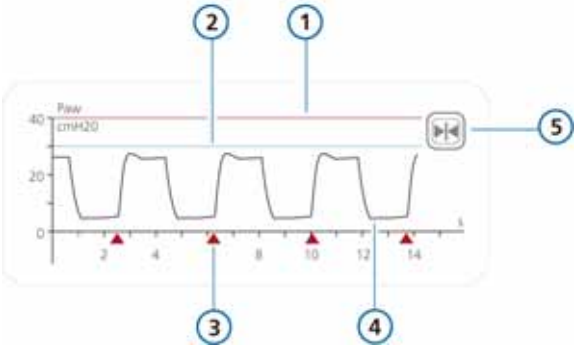


Figure 7-6. Pressure/time graph

1	Pressure high alarm limit	**4**	Airway pressure (Paw) waveform
2	Pressure limitation: *Pressure high alarm limit – 10 cmH2O*	**5**	Freeze button
3	Patient trigger indicator		

When the ventilator is in the (S)CMV+/APVcmv, or SIMV+/APVsimv mode, it uses the Pressure limit as a safety boundary for its inspiratory pressure adjustment. The ventilator does not apply inspiratory pressures higher than this pressure limitation value. An exception is sigh breaths, when the ventilator may apply inspiratory pressures 3 cmH2O below the Pressure alarm limit.

7.4.1.1 Displaying additional waveforms

To display an additional waveform

1. Touch the graphic area of the display to access the graphics window. See Section 7.3.1.
2. Touch the **Waveforms** tab.

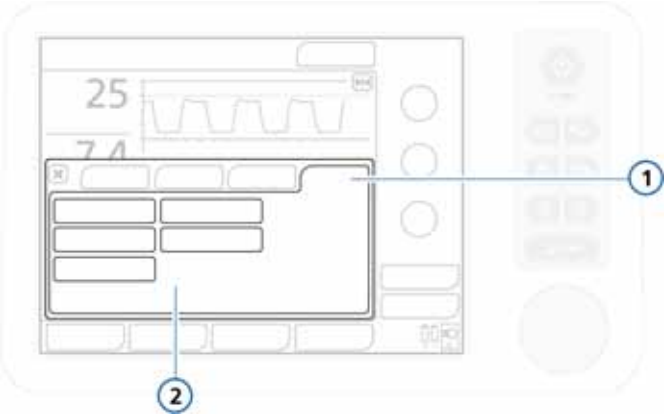


Figure 7-7. Waveforms tab, graphics window

1	Waveforms	**2**	Waveform options

3. Select the value to plot (pressure, volume, or flow) against time.
4. Touch the **X** to close the window.

The selected waveform is displayed.

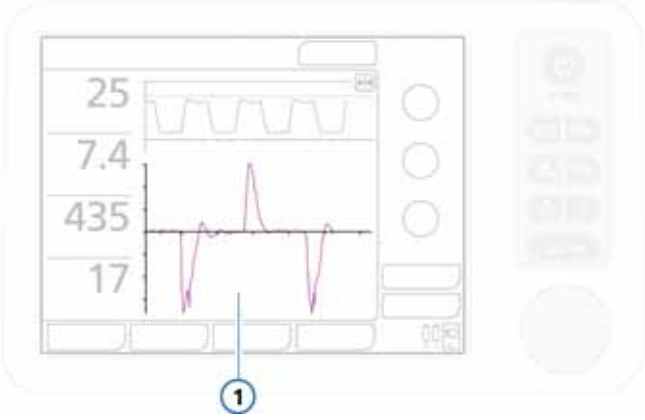


Figure 7-8. Waveform display (1)

7.4.2 Dynamic Lung

The Dynamic Lung panel visualizes tidal volume, lung compliance, patient triggering, and resistance in real-time.

For details about the panel and how to display it, see Chapter 8.

7.4.3 Vent Status

The Vent Status panel visualizes parameters related to oxygenation, CO2 elimination, and patient activity, and indicates the patient's level of ventilator dependence and when discontinuing ventilation should be considered.

For details about the panel and how to display it, see Chapter 8.

7.4.4 ASV Graph

Available in ASV mode, the ASV graph shows how the adaptive lung controller moves toward its targets. The graph shows both the target and real-time patient data for tidal volume, frequency, pressure, and minute ventilation.

For details about the panel and how to display it, see Chapter 8 and Appendix C.

7.5 Trends

NOTE:

- 72-h trends not available in all markets.
- The neonatal Flow parameter cannot be selected for a trend graph.

You can view monitored parameters as 1-, 6-, 12-, 24-, or 72-h trends. Trend data includes all data for the selected parameter since you turned on the ventilator for the past 1, 6, 12, 24, or 72 hours.

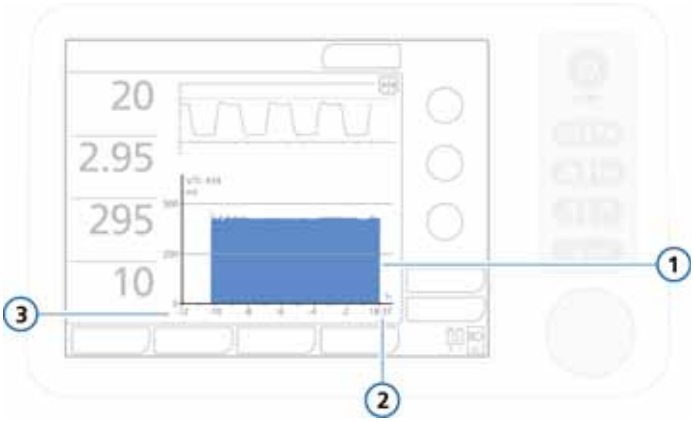


Figure 7-9. Trend display

1	Trend graph	**3**	Elapsed time relative to present
2	Current time		

From the time you turn on the HAMILTON-MR1, the ventilator continually stores the monitored parameters in its memory, so you have access to any of this data, even after standby. If the HAMILTON-MR1 is turned off, the data of the last patient is available in memory when ventilator is turned on again.

The freeze and cursor measurement function (Section 7.8) can also be used to examine points on trend waveforms. When trends are frozen, the time axis shows elapsed time relative to the present and the corresponding value of the monitored parameter.

All monitoring parameters can be trended. The following parameters are trended in combination:

- Ppeak/PEEP
- MVSPONT/ExpMinVol
- fTotal/fControl
- Vtalv/VTE

7.5.1 Displaying trends

To display trends

1. Touch the graphic area of the display to access the graphics window. See Section 7.3.1.
2. Touch the **Trends** tab.

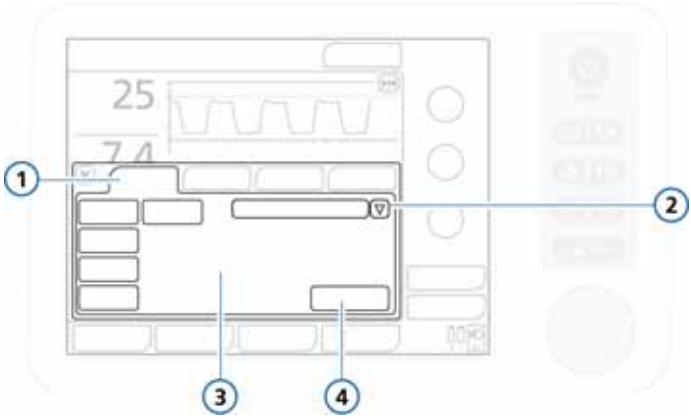


Figure 7-10. Trends tab

1	Trends	**3**	Trend time
2	Parameter list	**4**	Confirm button

3. Select the parameter to review:
   a. Touch the arrow next to the Parameter list, and turn the P&T knob to scroll through the list.
   b. Press the knob to select an entry.
4. Select the desired trend time button.
5. Touch the **Confirm** button.
6. Touch the **X** to close the window.

The selected trend information is displayed.

7.6 Loops

The HAMILTON-MR1 can display a dynamic loop based on the following parameter combinations, depending on the options installed.

- Pressure/volume
- Pressure/flow
- Flow/volume

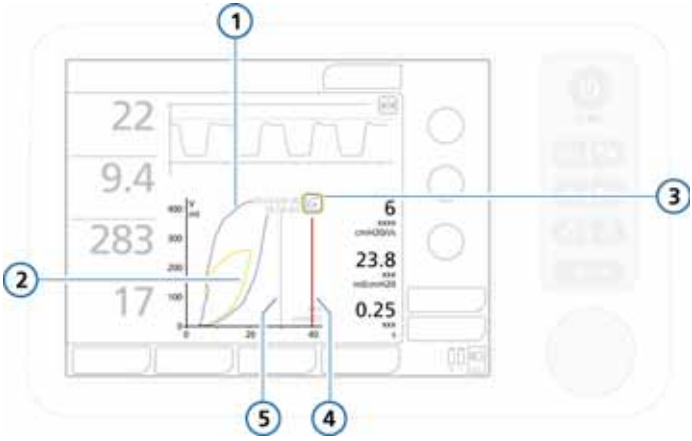


Figure 7-11. Loop display

1	Curve in the past (reference)	**4**	Pressure high alarm limit
2	Current curve	**5**	Pressure limitation: *Pressure high alarm limit –10 cmH2O*
3	Loop reference button		

7.6.1 Displaying loops

To display loops

1. Touch the graphic area of the display to access the graphics window. See Section 7.3.1.
2. Touch the **Loops** tab.

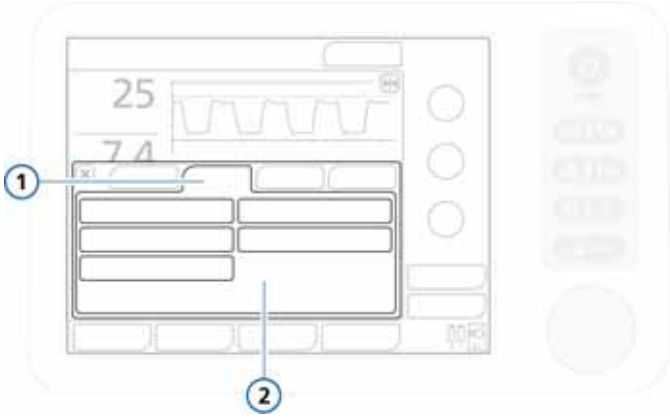


Figure 7-12. Loops tab

1	Loops	**2**	Parameter combination options

3. Touch the button for the parameter combination to display.
4. Touch the **X** to close the window.

The selected combination is displayed (Figure 7-11).

7.6.2 Storing loops

To store a new loop

In the Loop display (Figure 7-11), touch the **`Loop reference`** button (Figure 7-11) to store the loop curve with the current date and time. The past and current characteristics are shown.

If the parameter combination is changed and the **`Loop reference`** button is pressed again, the present curve is stored. The one before is lost.

7.7 Table of monitored parameters

NOTE:

The HAMILTON-MR1 automatically measures inspiratory resistance (Rinsp), compliance (Cstat), and AutoPEEP breath by breath, during mandatory and spontaneous breaths in all modes, without interruption in ventilation.

To obtain these measurements, the HAMILTON-MR1 uses a statistical technique called the Least Squares Fitting (LSF) method. This method is applied on a breath-by-breath basis, without the need for special inspiratory flow patterns and occlusion maneuvers, provided that the patient is relaxed or nearly relaxed.

Actively breathing patients can create artifacts or noise, which can affect the accuracy of these measurements, however. The more active the patient, the less accurate the measurements. To minimize patient participation during these measurements, you may want to increase Psupport by 10 cmH2O. After completion, return this control to its former setting.

Table 7-2 is an alphabetical list of the HAMILTON-MR1's monitored parameters. These parameters are displayed in the individual parameter windows 1, 2, and 3 (Figure 7-3). The display of monitored parameters is updated every breath.

Table A-8 in Appendix A provides the parameter ranges and accuracy.

Table 7-2. Monitored parameters

Parameter (unit)	Definition
For parameter ranges and accuracy, see Table A-8 on page A-13.	
AutoPEEP (cmH2O)	The difference between the set PEEP and the calculated total PEEP within the lungs. AutoPEEP is the abnormal pressure generated by air "trapped" in the alveoli due to inadequate lung emptying. Ideally, it should be zero. AutoPEEP is calculated using the LSF method applied to the entire breath. When AutoPEEP is present, volutrauma or barotrauma might develop. In active patients, AutoPEEP may present an extra workload to the patient. AutoPEEP or air trapping may result from an expiratory phase that is too short, which may be observed under these conditions: • Delivered tidal volume too large • Expiratory time too short or respiratory rate too high • Circuit impedance too high or expiratory airway obstruction • Peak expiratory flow too low
Cstat (ml/ cmH2O)	Static compliance of the respiratory system, including lung and chest wall compliances. It is calculated using the LSF method. Cstat can help diagnose changes in elastic characteristics of the patient's lungs. Also displayed in the Dynamic Lung panel. **NOTE:** Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase Psupport by 10 cmH2O. After completion, return this control to its former setting.
Exp Flow (l/min)	Peak expiratory flow.
ExpMinVol (l/min) MinVol NIV	Expiratory minute volume. The moving average of the monitored expiratory volume per minute over the last 8 breaths. ExpMinVol changes to MinVol NIV in noninvasive modes. MinVol NIV is an adjusted parameter taking into account the leakage.
fControl (b/min)	Mandatory breath frequency. The moving average of machine-delivered breaths per minute over the last 8 total breaths.

Table 7-2. Monitored parameters *(continued)*

Parameter (unit)	Definition
For parameter ranges and accuracy, see Table A-8 on page A-13.	
Flow (l/min)	Only active in the nCPAP and nCPAP-PC modes. Displays the current flow as follows: • In nCPAP mode, this value is the average flow, updated every second. • In nCPAP-PC mode, this value is the average flow during expiration, updated every breath. Flow can be configured as a main monitoring parameter (MMP). Flow is affected by the setting of the Flow alarm. See Chapter 6.
fSpont (b/min)	Spontaneous breath frequency. The moving average of spontaneous breaths per minute over the last 8 total breaths. An increased fSpont may indicate that the patient is compensating for a low compliance. This may indicate ventilatory fatigue due to imposed work of breathing.
fTotal (b/min)	Total breathing frequency. The moving average of the patient's total breathing frequency over the last 8 breaths, including both mandatory and spontaneous breaths. When the patient triggers or the user initiates a breath, fTotal may be higher than the Rate setting. **NOTE:** Respiratory rate monitoring on the HAMILTON-MR1 requires breath delivery followed by detection of expiratory flow at the proximal flow sensor.
I:E	Inspiratory:expiratory ratio. Ratio of the patient's inspiratory time to expiratory time for every breath cycle. This includes both mandatory and spontaneous breaths. I:E may differ from the set I:E ratio if the patient breathes spontaneously.
Insp Flow (l/min)	Peak inspiratory flow, spontaneous or mandatory, measured every breath.
MVSpont/ MVSpont NIV (l/min)	Spontaneous expiratory minute volume. The moving average of the monitored expiratory volume per minute for spontaneous breaths, over the last 8 mandatory and spontaneous breaths. In non invasive ventilation modes, MVSpont is replaced by MVSpont NIV. MV Spont NIV is an adjusted parameter taking into account the leakage.
Oxygen (%)	Oxygen concentration of the delivered gas. It is measured by the oxygen cell in the inspiratory pneumatics. This parameter is not displayed if the oxygen cell is not installed, is defective, or is not a genuine Hamilton Medical part; or if oxygen monitoring is disabled.

Table 7-2. Monitored parameters *(continued)*

Parameter (unit)	Definition
For parameter ranges and accuracy, see Table A-8 on page A-13.	
P0.1 (cmH2O)	**NOTE:** Due to changes in pneumatic impedance, P0.1 values may vary with different settings of the Trigger function. Airway occlusion pressure. The maximum slope of the airway pressure drop during the first 100 ms when the airway is occluded. P0.1 indicates the patient's respiratory drive and efforts. It applies to patient-triggered breaths only. A P0.1 value of -3 cmH2O indicates a strong inspiratory effort, and a value of -5 cmH2O, an excessive effort, possibly because the patient is "air hungry" (peak inspiratory flow or total ventilatory support is inadequate) or has an excessive drive. If P0.1 is below -3 cmH20: • Increase pressure or volume settings (depending on mode) • Increase %MinVol if in manual mode • Shorten P-ramp time
PEEP/CPAP (cmH2O)	Monitored PEEP (positive end expiratory pressure)/CPAP (continuous positive airway pressure). The airway pressure at the end of exhalation. Measured PEEP/CPAP may differ slightly from set PEEP/CPAP, especially in actively breathing patients.
Pinsp (cmH2O)	Inspiratory pressure, the automatically calculated target pressure (additional to PEEP/CPAP) applied during the inspiratory phase. Available in the Vent Status panel. Pinsp is: (S)CMV+, SIMV+: Automatically calculated target pressure (PCV+): Pcontrol setting PSIMV+, NIV-ST: Pinsp setting SPONT, NIV: Psupport setting APRV, DuoPAP: Phigh setting
Pmean (cmH2O)	Mean airway pressure. The absolute pressure, averaged over the breath cycle. Pmean is an important indicator of the possible impact of applied positive pressure on hemodynamics and surrounding organs.
Ppeak (cmH2O)	Peak airway pressure. The highest pressure during the previous breath cycle. It is influenced by airway resistance and compliance. It may differ noticeably from alveolar pressure if airway flow is high.

Table 7-2. Monitored parameters *(continued)*

Parameter (unit)	Definition
For parameter ranges and accuracy, see Table A-8 on page A-13.	
Pplateau *(cmH2O)*	Plateau or end-inspiratory pressure. The pressure measured at the end of inspiration when flow is or is close to zero. Pplateau is displayed for mandatory and time-cycled breaths. Pplateau is a rough representation of alveolar pressure.
PTP (cmH2O*s)	Inspiratory pressure time product. The measured pressure drop required to trigger the breath multiplied by the time interval until the PEEP/CPAP level is reached at the beginning of inspiration. The PTP indicates work by the patient to trigger the breath. The work depends on • The intensity of the patient's effort • The trigger sensitivity • The volume and resistance of the breathing circuit PTP is valid for patient-initiated breaths only. The PTP does not indicate total patient work. But it is a good indicators of how well the ventilator is adapted to the patient. If PTP values increase… • Check and remove water in tubes • Increase trigger sensitivity
RCexp (s)	Expiratory time constant. The rate at which the lungs empty, as follows: *Actual TE* *% emptying* 1 x RCexp 63% 2 x RCexp 86.5% 3 x RCexp 95% 4 x RCexp 98% RCexp is calculated as the ratio between VTE and flow at 75% of the VTE. In adults, an RCexp value above 1.2 s indicates airway obstruction, and a value below 0.5 s indicates a severe restrictive disease. Use RCexp to set optimal TE (Goal: TE ≥ 3 x RCexp): • In passive patients: Adjust rate and I:E. • In active patients: Increase Psupport and/or ETS to achieve a longer TE. These actions may reduce the incidence of AutoPEEP.

Table 7-2. Monitored parameters *(continued)*

Parameter (unit)	Definition
For parameter ranges and accuracy, see Table A-8 on page A-13.	
Rinsp (cmH2O/(l/s))	Resistance to inspiratory flow caused by the endotracheal tube and the patient's airways, during inspiration. It is calculated using the LSF method applied to the inspiratory phase. Also displayed in the Dynamic Lung panel. **NOTE:** Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase Psupport by 10 cmH2O. After completion, return this control to its former setting.
TE (s)	Expiratory time. In mandatory breaths, TE is measured from the start of exhalation until the set time has elapsed for the switchover to inspiration. In spontaneous breaths, TE is measured from the start of exhalation, as dictated by the ETS setting, until the patient triggers the next inspiration. TE may differ from the set expiratory time if the patient breathes spontaneously.
TI (s)	Inspiratory time. In mandatory breaths, TI is measured from the start of breath delivery until the set time has elapsed for the switchover to exhalation. In spontaneous breaths, TI is measured from the patient trigger until the flow falls to the ETS setting, for the switchover to exhalation. TI may differ from the set inspiratory time if the patient breathes spontaneously.
VLeak (%)/ MV Leak (l/min)	Due to the leakage at the patient interface, displayed exhaled volumes in the noninvasive modes can be substantially smaller than the delivered volumes. The flow sensor measures the delivered volume and the exhaled tidal volume; the ventilator displays the difference as VLeak in %, and as MVLeak in l/min, averaged over the past 8 breaths. VLeak/MVLeak can indicate leaks on the patient side of the flow sensor (endotracheal tube, chest tube, mask). They do not include leakage between the ventilator and flow sensor. Use VLeak and MVLeak to assess the fit of the mask or other noninvasive patient interface. Not applicable in nCPAP, nCPAP-PC modes.

Table 7-2. Monitored parameters *(continued)*

Parameter (unit)	Definition
For parameter ranges and accuracy, see Table A-8 on page A-13.	
VTE VTE NIV (ml)	Expiratory tidal volume. The volume exhaled by the patient. It is determined from the flow sensor measurement, so it does not show any volume added due to compression or lost due to leaks in the breathing circuit. If there is a gas leak at patient side, the displayed VTE may be less than the tidal volume the patient actually receives. In non invasive ventilation modes, VTE is replaced by VTE NIV. VTE NIV is an adjusted parameter taking into account the leakage
VTEspont (ml)	Spontaneous expiratory tidal volume. The volume exhaled by the patient. If there is a gas leak at patient side, the displayed VTEspont may be less than the tidal volume the patient actually receives. Only displayed for spontaneous breaths.
VTI (ml)	Inspiratory tidal volume. The volume delivered to the patient. It is determined from the Flow Sensor measurement. If there is a gas leak at the patient side, the displayed VTI may be larger than the displayed VTE.

7.8 Freeze and cursor measurement

This function lets you freeze the display of a graphic for up to 30 s.

The freeze function is particularly useful when you perform a breath hold maneuver. The screen automatically freezes following a successful inspiratory maneuver.

To freeze the graphic

1. In the pressure/time waveform, touch the **Freeze** button in the right upper corner (item 5 in Figure 7-6). The graphic is frozen for 30 s.
2. To analyze the curves, turn the Press-and-turn knob.
3. Unfreeze by pressing the **Freeze** button again or by pressing the Press-and-turn knob.

7.9 Monitoring the magnetic field levels

The onboard magnetic field navigator, TeslaSpy, continuously measures the background magnetic field levels. TeslaSpy indicates when levels are safe using a blinking green indicator light, and when they exceed the ventilator's safety thresholds using yellow and red indicator lights and audible alarms. For details, see Chapter 3, Working in the MRI environment.

8 Intelligent panels

You can lay out the ventilator screen to display any of the three types of Intelligent Panel, which are described in this chapter.

8.1 Dynamic Lung panel

NOTE:

The Dynamic Lung panel is not available for neonates.

The Dynamic Lung panel visualizes tidal volume, lung compliance, patient triggering, and resistance in real-time. The lungs expand and contract in synchrony with actual breaths. Numeric values for resistance (Rinsp) and compliance (Cstat) are displayed. In addition, the shape of the lungs and the bronchial tree are also related to the compliance and resistance values. If all values are in a normal range, the panel is framed in green.

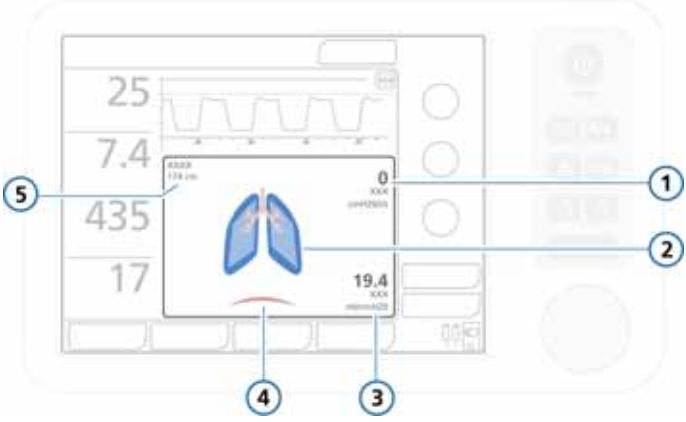


Figure 8-1. Dynamic Lung panel

1	Resistance of the lung (Rinsp)	**4**	Patient trigger (diaphragm)
2	"Normal" lungs (reference)	**5**	Gender and IBW
3	Compliance of the lung (Cstat)		

8.1.1 Displaying the Dynamic Lung

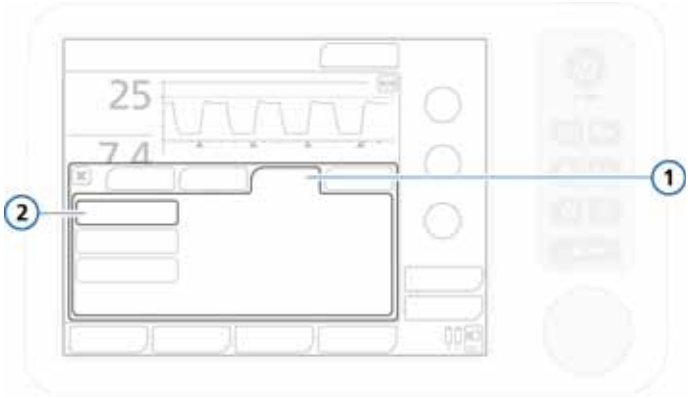


Figure 8-2. Graphics tab, Dynamic Lung

1	Graphics	**2**	Dynamic Lung

To display the Dynamic Lung

1. Touch the graphic area at the bottom half of the display to access the graphics-selection window. See Figure 7-4.
2. Touch the **`Graphics`** tab.
3. Touch the **`Dynamic Lung`** button.
4. Touch the **X** to close the window.

The Dynamic Lung is displayed. See Figure 8-1.

8.1.2 Tidal volume (Vt)

The Dynamic Lung expands and contracts to show tidal volume (Vt) in real-time. It moves in synchrony with actual breaths, based on the proximal flow sensor signal. The lung size shown is relative to "normal" size for the patient's height (IBW), based on a "normal" value of 10 ml/kg.

A disconnection alarm is visualized by a deflated lung. An Exhalation obstructed alarm is visualized by an inflated lung.

8.1.3 Compliance (Cstat)

The Dynamic Lung shows compliance (Cstat) breath by breath relative to "normal" values for the patient's height. As the figure shows, the shape of the lungs changes with compliance. The numeric value is also displayed. The lung in the middle shows "normal" compliance.

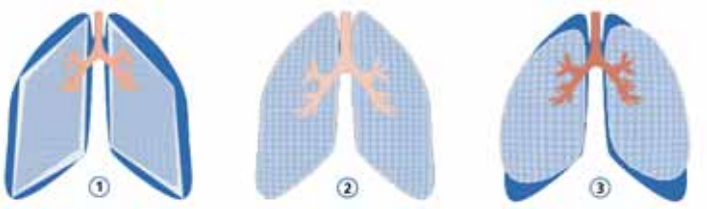


Figure 8-3. Compliance shown by the Dynamic Lung

1	Low compliance	**3**	High compliance
2	Normal compliance		

8.1.4 Patient triggering: Muscle

The muscle in the Dynamic Lung shows patient triggering.

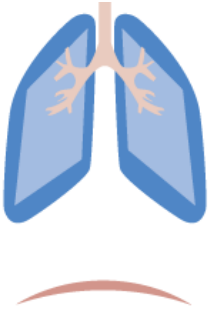


Figure 8-4. Patient triggering shown by the Dynamic Lung muscle

8.1.5 Resistance (Rinsp): Bronchial tree

The bronchial tree in the Dynamic Lung shows resistance (Rinsp) breath by breath relative to "normal" values for the patient's height. The numeric value is also displayed. The gray portion of the image shows the relative degree of resistance: the leftmost tree shows normal resistance.

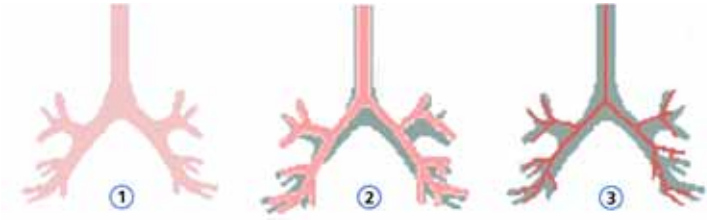


Figure 8-5. Rinsp shown by the bronchial tree of the Dynamic Lung

1 Normal resistance
2 Moderately high resistance
3 High resistance

Table 8-1. Dynamic Lung normal values

Parameter	Definition of normal value
Tidal volume (Vt)	10 ml/kg IBW (calculated from Pat. height)
Compliance (Cstat)	For Pat. height between 30 and 135 cm (11 and 53 in): 0.000395 * Pat. height $^{2.38}$ For Pat. height > 135 cm (53 in): -0.0028 * Pat. height^2 + 1.3493 * Pat. height - 84.268
Resistance (Rinsp)	For Pat. height ≤ 210 cm (83 in): (1.993 - 0.0092 * Pat. height) * 10.2 + 5 For Pat. height > 210 cm (83 in): 0.5 + 5

8.2 Vent Status panel

The Vent Status panel (Figure 8-6) displays six parameters related to the patient's ventilator dependence, including oxygenation, CO2 elimination, and patient activity.

A floating indicator (floater) moving up and down within the column shows the value for a given parameter. When the indicator is in the light blue (weaning) zone, a timer starts, showing how long that value has been in the weaning zone. When all values are in the weaning zone, the Vent Status panel is framed in green, indicating that weaning should be considered. The panel is updated breath by breath.

Table 8-2 describes the parameters shown in the Vent Status panel. You can configure the weaning zone ranges in configuration. To set these values, see Section G.6.2, step 9.

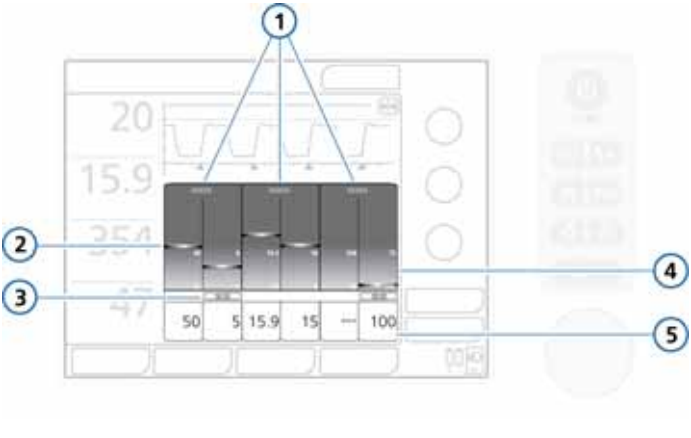


Figure 8-6. Vent Status panel

1	Group title	**4**	Light blue weaning zone with user-configurable limits
2	Monitored value, graphic (floater)	**5**	Monitored value, numeric
3	Elapsed time value has been in weaning zone		

The following table describes the Vent Status parameters. For parameter ranges and details, see the tables in Appendix A.

Table 8-2. Vent Status parameters

Parameter (unit)	Definition
For additional details, including ranges and accuracy, see Table A-6 on page A-7.	
Oxygen (%)	Oxygen setting.
PEEP (cmH2O)	PEEP/CPAP setting.
MinVol (l/min)	Normal minute ventilation (defined in Appendix C).
Pinsp (cmH2O)	Inspiratory pressure, the target pressure (additional to PEEP/CPAP) applied during the inspiratory phase.
RSB (1/(l*min))[1]	Rapid shallow breathing index. The total breathing frequency (fTotal) divided by the exhaled tidal volume (VTE). Because a patient with dyspnea typically takes faster, shallower breaths than a non-dyspnoeic patient, RSB is high in the dyspnoeic patient and low in the non-dyspnoeic patient. RSB is often used clinically as an indicator to judge whether a ventilated patient is ready for weaning. RSB has significance for spontaneously breathing patients only and is shown only if 80% of the last 25 breaths are spontaneous.
%fSpont (%)	Spontaneous breath percentage. The moving average of the percentage of spontaneous breaths over the last 8 total breaths.

1. Weaning zone defaults are based on a normal of <100/(l*min) for adult patients.

8.2.1 Displaying the Vent Status panel

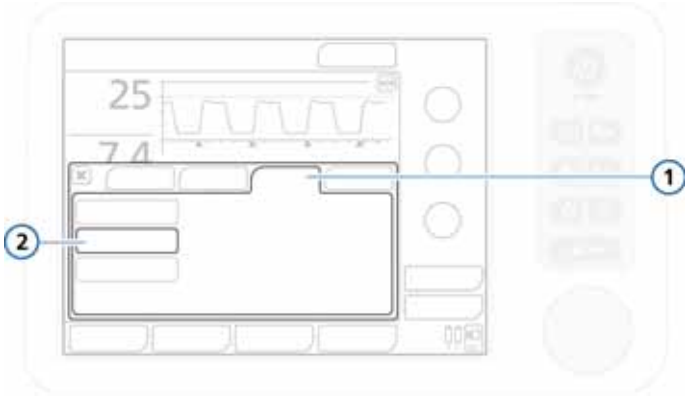


Figure 8-7. Graphics tab, Vent Status

1	Graphics	**2**	Vent Status

To display the Vent Status panel

1. Touch the graphic area of the display to access the graphics-selection window. See Figure 7-4.
2. Touch the **`Graphics`** tab.
3. Touch the **`Vent Status`** button.
4. Touch the **X** to close the window.

The Vent Status panel is displayed (Figure 8-6).

8.3 ASV Graph panel

Available in ASV mode, the ASV Graph shows how the adaptive lung controller moves toward its targets. The graph shows both the target and real-time patient data for tidal volume, frequency, pressure, and minute ventilation.

For details about the graph, see Figure C-5 in the ASV appendix.

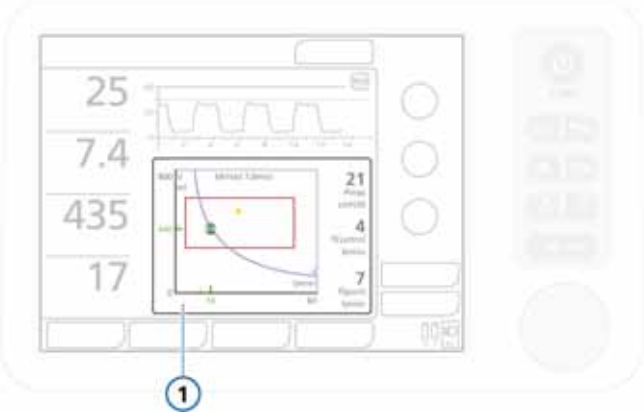


Figure 8-8. ASV target graphics window (1)

8.3.1 Displaying the ASV Graph

To display the ASV graph

1. Touch the graphic area of the display to access the graphics-selection window. See Figure 7-4.
2. Touch the **Graphics** tab. See Figure 8-9.

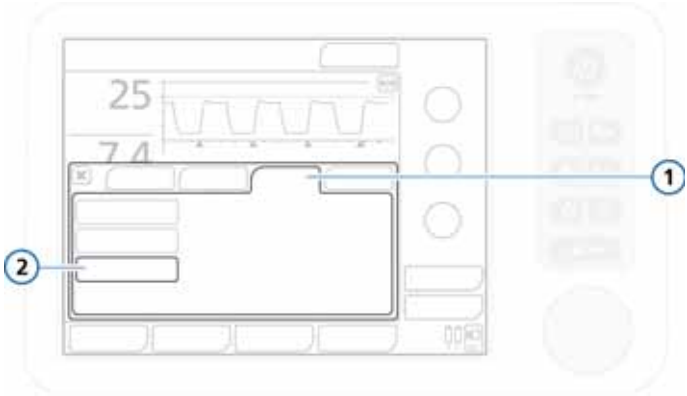


Figure 8-9. Graphics tab

1	Graphics	**2**	ASV Graph

3. Touch the **ASV Graph** button.
4. Touch the **X** to close the window.

The ASV target graphic is displayed (Figure 8-8).

9 Responding to alarms

9.1 Introduction

The HAMILTON-MR1 has two alarm systems:

- HAMILTON-MR1 alarms, which are related to ventilation and device issues
- TeslaSpy alarms, which are related to magnetic field levels at the current ventilator position. For details about TeslaSpy alarms, see Section 9.1.2 and Chapter 3, Working in the MRI environment.

  Note that TeslaSpy alarms are not logged in the ventilator Alarm buffer, and the HAMILTON-MR1 alarm lamp does not light.

9.1.1 About HAMILTON-MR1 alarms

The HAMILTON-MR1 alarms notify the operator of problems related to ventilation and the device.

These alarms can be categorized as:

- High priority
- Medium priority
- Low priority

Additionally there are other alarms conditions associated with technical fault alarms and operator messages.

The main monitoring parameters (MMP) change their colors when a corresponding alarm activates. The color reflects the priority of the alarm.

Table 9-1 shows the audio and visual characteristics of these types of alarm and tells you how to respond. Figure 9-1 shows the ventilator's visual alarm indications. You can review active alarms in the active alarm buffer (Figure 9-4). Information about the alarm is also stored in an event log (Section 9.4).

When an alarm condition is serious enough to possibly compromise safe ventilation, the device defaults to the ambient state (see Appendix B). The inspiratory valve closes, and the ambient and expiratory valves are opened, letting the patient breathe room air unassisted.

For details on setting alarm limits, see Section 5.7.1.

Table 9-1. Alarm indications on the HAMILTON-MR1

Alarm type	Message bar[1]	Alarm lamp	Audio	Action required
High-priority alarm	Red, with alarm message	Red, flashing	A sequence of 5 beeps, repeated until the alarm is reset. If the audible alarm is not silenced during the first minute, the continuous-tone buzzer also sounds.	The patient's safety is compromised. The problem needs immediate attention.
Medium-priority alarm	Yellow, with alarm message	Yellow, flashing	A sequence of 3 beeps, repeated periodically. If the audible alarm is not silenced during the first minute, the continuous-tone buzzer also sounds.	The patient needs prompt attention.
Low-priority alarm	Yellow, with alarm message	Yellow, solid	Two sequences of beeps. This is not repeated.	Operator awareness is required.
Technical fault	Red, with the text, **`Safetyventilation:xxxxxx`** or **`Technicalfault:xxxxxx`**	Red, flashing	Same as for high-priority alarm, if technically possible. At a minimum, a continuous buzzer tone. The buzzer cannot be silenced.	The ventilator enters the safety mode, or, if it cannot safely ventilate, the ambient state (see Appendix B). Provide alternative ventilation. Turn off the ventilator. Have the ventilator serviced.
Technical event	Depends on severity of the event. Can be low, medium, or high.	Same as the associated alarm level (as described above)	Same as the associated alarm level (as described above).	A technical alarm cannot typically be corrected by the operator. Ventilation continues. Have the ventilator serviced.
TeslaSpy alarms	Alarms indicator lights are on the front of the ventilator and operate independently of the ventilator alarms. For details, see Chapter 3.			

1. If more than one alarm is active, the associated alarm messages alternate in the message bar.

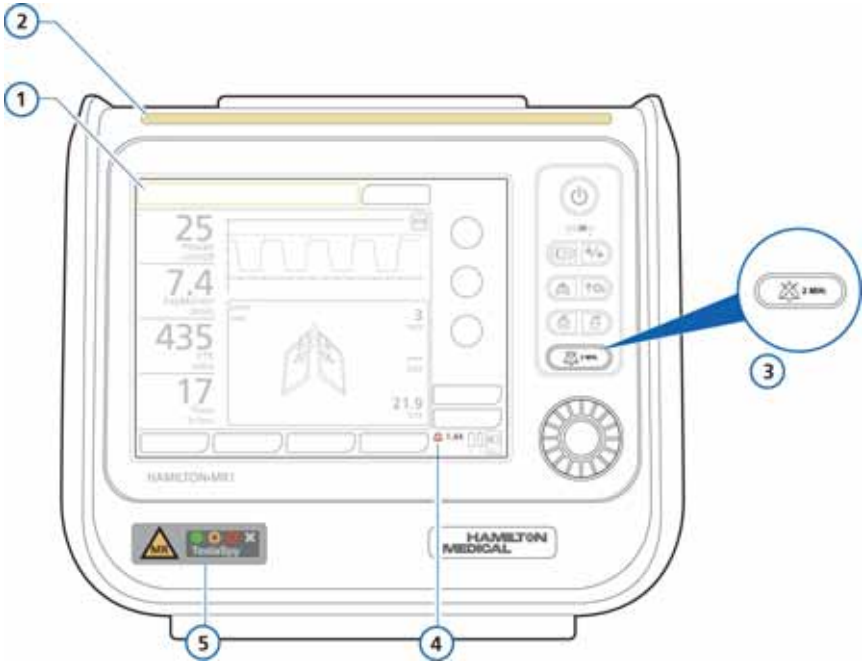


Figure 9-1. Visual alarm indications

1	Message bar	**4**	Alarm silence indicator and countdown
2	Alarm lamp	**5**	TeslaSpy navigator (see Chapter 3)
3	Alarm Silence key		

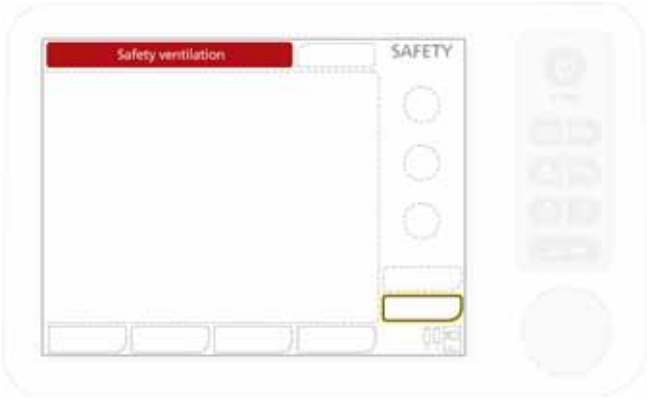


Figure 9-2. Safety ventilation

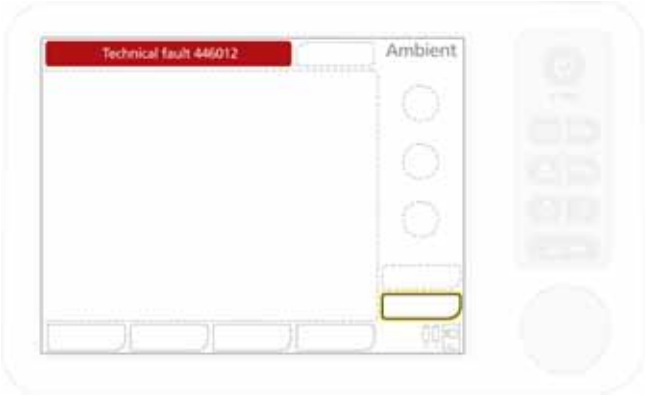


Figure 9-3. Ambient state

For details about the Safety mode and the Ambient state, see Appendix B.

9.1.2 About TeslaSpy magnetic field alarms

NOTE:

TeslaSpy magnetic field-related alarms are not logged in the ventilator Alarm buffer, and the HAMILTON-MR1 alarm lamp does not light. In addition, they are not listed in the Event log.

The TeslaSpy magnetic field navigator is built into the HAMILTON-MR1 and comprises two components:

- The TeslaSpy magnetic field sensor continuously samples the environment, measuring the background magnetic field, even when the ventilator is switched off.
- A built-in safety system continuously monitors the operation of the magnetic field sensor.

Four indicators on the front of the ventilator (Figure 9-1) show the status of the surrounding magnetic field and of the TeslaSpy navigator itself.

For all TeslaSpy details, including description of indicator lights, threshold values for each indicator, and how to respond to the alarms, see Chapter 3.

9.2 Responding to an alarm

WARNING

- **During an active alarm silence, newly triggered alarms (except for critical alarms) only appear on the display in the message bar and in the Alarm buffer. They do not trigger an audible alarm. The following alarms are considered critical and will trigger an audible alarm:**
  - **Apnea**
  - **External power loss**
  - **Oxygen supply failed**
  - **Technical event: 231003 (flow controller flow low)**
  - **Technical event: 243001 (alarm silence error)**
  - **Technical event: 243002 (alarm unknown)**

- **Technical event: 283007 (last settings error)**
- **Technical event: 284003 (service needed)**
- **Technical event: 285003 (backlight defect)**
- **All technical faults**

- **To prevent possible patient injury when alarms are active, check the patient for adequate ventilation. Identify and remove the cause of the alarms. Readjust the alarm limits only when they are inappropriately set for the current conditions.**
- **To prevent possible patient injury arising from any issues with the device, Hamilton Medical recommends that you immediately remove any ventilator with a technical fault from use, record the technical fault code, and have the ventilator serviced.**

CAUTION

Setting alarm limits to extreme values can render the alarm system useless.

NOTE:

- Be aware that an alarm may result from either a clinical condition or an equipment problem.
- Be aware that one alarm condition can induce multiple alarms. Normally only one or two indicate the root cause of the alarm; the rest are results. Your search for the causes of the alarm condition should be assisted by, but not limited to, the alarm messages displayed.
- For details about TeslaSpy alarms, see Chapter 3, Working in the MRI environment

To respond to an alarm

1. Approach the patient immediately. Secure sufficient and effective ventilation for the patient. You may silence the alarm if possible.
2. Correct the alarm condition from the alarm messages, referring to Table 9-2. For low-, medium-, and high-priority alarms, when the alarm triggering condition is corrected, the ventilator automatically resets the alarm. For a technical fault alarm, switch off ventilator power first; then correct the problem.

9.3 About the Alarm buffer

NOTE:

TeslaSpy magnetic field-related alarms are not logged in the ventilator Alarm buffer.

The alarm buffer shows up to six alarm messages:

- If there are currently active alarms, the alarm buffer shows the most recent active alarms (Figure 9-4). The associated alarm messages also alternate in the message bar. Active alarms are in boxes with rounded corners.
- If no alarms are active, the alarm buffer shows the most recent inactive alarms (Figure 9-5). Inactive alarms are in boxes with square corners.

To view alarms

Open the Alarms -> Buffer window by doing one of the following:

- Touch the message bar in the upper left-hand corner
- Touch the inactive alarm indicator (the i-icon) (Figure 9-5)

The most recent alarm is at the top of the list.

To clear the alarm messages for all inactive alarms, touch the **`Reset`** button (Figure 9-5). Closing the buffer does not erase its contents.

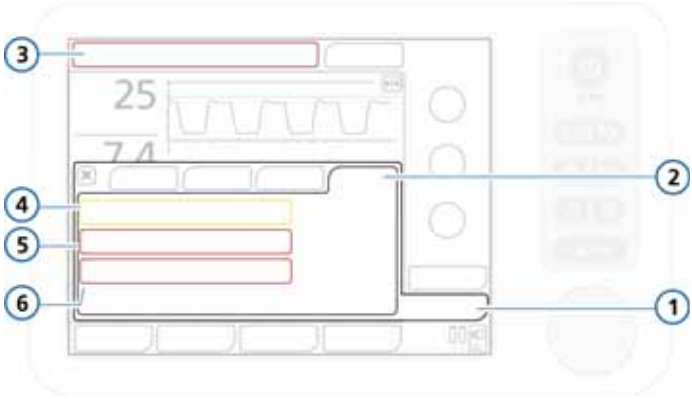


Figure 9-4. Alarm buffer with active alarms

1	Alarms	**4**	Low- or medium priority alarm (yellow)
2	Buffer	**5**	High priority alarm (red)
3	Currently active alarm	**6**	Round corners

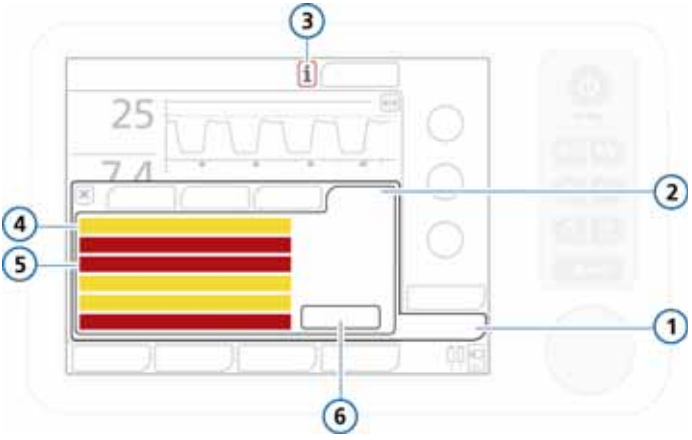


Figure 9-5. Alarm buffer with inactive alarms

1	Alarms	**4**	Inactive low- or medium-priority alarm (yellow square box)
2	Buffer	**5**	Inactive high-priority alarm (red square box)
3	i-icon: Inactive alarms	**6**	Reset button

9.4 About the event log

NOTE:

TeslaSpy magnetic field-related alarms are not logged in the Event log.

Once the ventilator is turned on, several event logs collect data about clinically relevant ventilator activities, including alarms, setting changes, calibrations, maneuvers, and special functions. The date, time, and a unique identification reference (ID) for event classification is included. Alarms are shown in color, depending on priority level (yellow for low or medium, red for high). Note that a more extensive log including technical and configuration information is available to service engineers.

When setting up a new patient:

- Data is appended to the existing event log when you select the Last patient tab.
- The event log is cleared and starts anew when you select a different patient group tab (Adult/Ped. or Neonatal).

Event log data persists after shutting off the ventilator or in the event of a power loss. A maximum of 1000 events is stored. When a log buffer is full, new events overwrite the oldest log entries.

View the event log in the Events window.

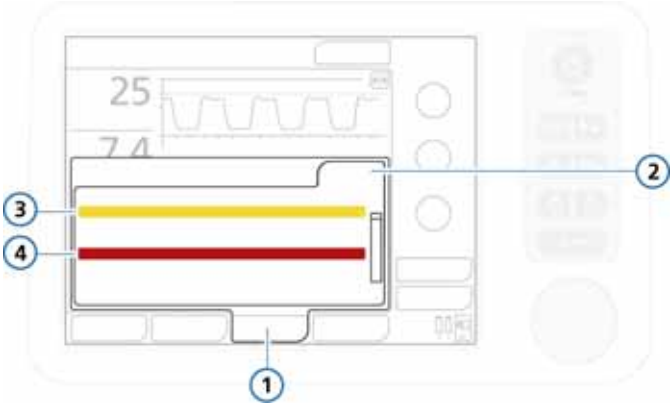


Figure 9-6. Events window

1	Events	**3**	Low- or medium-priority alarm (yellow)
2	All	**4**	High-priority alarm (red)

9.5 Alarm troubleshooting table

Table 9-2 is an alphabetical list of the alarm messages displayed by the HAMILTON-MR1, along with their definitions and suggested corrective actions. For ranges for adjustable alarms, see Table A-10 in Appendix A.

These corrective actions are sequenced to correct the most probable issue or to present the most efficient corrective action first. The proposed actions, however, may not always correct the particular problem.

If your issue is not resolved after performing the recommended tasks, contact your Hamilton Medical authorized service personnel.

For the list of TeslaSpy magnetic-field-related alarms, see Table 3-3 in Chapter 3.

Table 9-2. Alarms and other messages

Alarm	Definition	Action needed
Apnea	*High priority.* No patient trigger within the operator-set apnea time in SPONT, SIMV+, or NIV modes. Apnea backup is off.	Check the patient. Consider switching to a mandatory mode or increasing the mandatory rate.
Apnea ventilation	*Low priority.* Apnea backup ventilation has started. No breath delivered for the operator-set apnea time. Apnea backup is on.	The ventilator is in the corresponding backup mode. Check the control settings for the backup mode.
Apnea ventilation ended	*Low priority.* Backup mode was reset, and HAMILTON-MR1 is again ventilating in its original support (pre-apnea) mode.	No action required.
ASV: Cannot meet the target	*Low priority.* The operator-set %MinVol cannot be delivered, possibly because of setting conflicts.	Check the Pasv limit setting in the Controls window.
Battery 1, 2: calibration required	*Low priority.* One or both batteries require calibration. You may continue to use the ventilator.	Have the ventilator serviced to calibrate the battery.
Battery communication error	*High priority.* Battery data is not available. Ventilation continues.	There may be a problem with the battery connectors or installation. Have the ventilator serviced.
Battery 1,2: Defective	*High priority.* Battery defective.	Replace the batteries.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Battery low	The low battery alarm has different levels of priority, depending on how much charge is left, and which power supply is in use. Note that at 20% battery charge, the ventilator can generally continue operation for up to approx 10 min, depending on battery and operating conditions. *High priority.* The ventilator is running on battery power, and the total battery charge is below 20%. *Medium priority.* The ventilator is running on battery power, and the total battery charge is below 25%. *Low priority.* The ventilator is running on AC power, and the total battery charge is below 20%.	Connect the ventilator to its primary power source; this also charges the batteries. Replace the batteries.
Battery power loss	*High priority.* No battery is present.	Insert two batteries.
Battery 1, 2: replacement required	*Low priority.* Battery capacity is insufficient for reliable operation and must be replaced immediately.	Replace the batteries.
	NOTE: Battery life indications are approximate. The actual battery life depends on ventilator settings, battery age, and level of battery charge. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.	
Battery 1, 2: temperature high	*High priority.* The battery temperature is higher than expected.	Remove the ventilator from the sun or other heat source. Replace the batteries.
Battery 1, 2: Wrong battery	*Low priority.* The battery in use is not a HAMILTON-MR1 Li-Ion battery.	Replace the batteries.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Battery totally discharged	*High priority.* The battery charge level is below 5%. The ventilator switches to the ambient state.	Connect the device to the primary power supply and recharge or replace the batteries. Provide alternative ventilation. Have the ventilator serviced.
Blower fault	*High priority.* A blower malfunction was detected. A technical alarm cannot typically be corrected by the operator. The ventilator switches to the ambient state.	Provide alternative ventilation. Have the ventilator serviced.
Blower service required	*Low priority.* Blower has reached the end of its lifespan.	Have the ventilator serviced
Buzzer defective	*High priority.* A buzzer malfunction was detected. A technical alarm cannot typically be corrected by the operator. Ventilation continues.	Restart device. If the problem persists, have the ventilator serviced.
Check flow sensor	*High priority.* Flow sensor measurements are out of expected range. The ventilator switches over to PCV+ mode and displays ventilator pressure (Pvent) instead of Paw. The ventilator automatically returns to its previous mode when the measurements are within the expected range.	Check the flow sensor and the sensing tubes. Try to calibrate the flow sensor. Install a new flow sensor.
Check flow sensor tubing	*High priority.* The flow sensor sensing lines are disconnected or occluded. The ventilator switches over to PCV+ mode and displays ventilator pressure (Pvent) instead of Paw. The ventilator automatically returns to its previous mode when the measurements are within the expected range.	Check the flow sensor and the sensing lines. Try to calibrate the flow sensor. Install a new flow sensor.
Check settings	*Low priority.* A change to a control or alarm setting was not saved.	Check settings.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Circuit calibration needed	*Medium priority, Low after silence.* The ventilator does not have correct calibration data. Applies only in nCPAP and nCPAP-PC modes.	Calibrate the circuit (Section 6.2.5.3)
Device temperature high	*High priority.* The internal temperature of the ventilator is higher than expected.	Remove the ventilator from the sun or other heat source. Check the cooling fan filter and fan. Have the ventilator serviced.
Disconnection on patient side	*High priority.* VTE < 1/8 delivered VTI, and delivered VTI > 50 ml. Does not apply in nCPAP modes.	Check the patient. Check the breathing circuit for a disconnection between the patient and the flow sensor, or for other large leaks (for example, ET tube, bronchopleural fistula).
Disconnection on ventilator side	*High priority.* VTI measured at the airway < 1/2 delivered VTI, and delivered VTI > 50 ml. Does not apply in nCPAP modes.	Check the breathing circuit for a disconnection between the ventilator and the flow sensor or for other large leaks (for example, breathing circuit). Reconnect and calibrate the flow sensor.
Exhalation obstructed	*High priority.* End-expiratory pressure is too high End-expiratory flow is too low Note that you must use an inspiratory filter to prevent contamination. The ventilator may be contaminated if no inspiratory filter is used.	Check the patient. Check the expiratory limb for occlusion. Check the expiratory valve membrane and cover. Check the flow sensor tubes for occlusion. Adjust breath timing controls to increase the expiratory time. Have the ventilator serviced.
External flow sensor failed	*High priority.* The external flow sensor doesn't work properly.	Check flow sensor tubes. Change the flow sensor.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Fan failure	*Medium priority.* There is a problem with the cooling fan.	Disconnect the ventilator from the patient. Have the ventilator serviced.
	CAUTION **A fan failure could result in oxygen enrichment inside the ventilator and present a subsequent fire hazard.**	
Flow sensor calibration needed	*High priority.* The ventilator does not have correct calibration data or automatic recalibration of the flow sensor is impossible.	Calibrate the flow sensor.
Function key not operational	*Medium priority.* Function key defective.	Have the ventilator serviced.
High Flow	*Medium priority, Low after silence.* Flow has reached the set limit. Only active in nCPAP and nCPAP-PC modes.	Check the patient interface and breathing circuit for disconnection or excessive leakage. Check ventilator settings and alarm limits.
High frequency	*Medium priority.* The measured f*Total* > the set alarm limit.	Check the patient for adequate ventilation (VTE). Check the alarm limits. If the ventilator is in ASV mode, refer to Appendix C.
High minute volume	*High priority.* The measured ExpMinVol > the set alarm limit.	Check the patient. Check and adjust the ventilator settings, including alarms.
High oxygen	*High priority.* The measured oxygen is > 5% over the Oxygen control setting.	Calibrate the oxygen cell. Install a new oxygen cell.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
High PEEP	*Medium priority.* Monitored PEEP > (set PEEP + 5) for two consecutive breaths. *For DuoPAP and APRV only:* • Alarm applies to both Phigh and Plow settings. The alarm sounds when the monitored Phigh > (set Phigh + 5) or monitored Plow > (set Plow +5) for two consecutive breaths. • If Tlow is set to < 3 s, the High PEEP alarm is disabled for Plow settings. This reduces the incidence of false positive alarms.	Check the patient. Check and adjust the ventilator settings, including alarms.
High pressure	*High priority.* Measured inspiratory pressure > the set Pressure alarm limit (also referred to as Pmax). The ventilator immediately stops the blower to stop gas flow to the patient and opens the expiratory valve to reduce pressure to the PEEP/CPAP level. The ventilator attempts to limit patient airway pressure to 60 cmH2O, but if pressure climbs to 75 cmH2O, the ventilator enters the ambient state.	Check the patient. Adjust the Pressure alarm limit. Check the breathing circuit and flow sensor tubes for kinks and occlusions. Provide alternative ventilation once the ventilator enters the ambient state.
High pressure during sigh	*High priority.* A sigh cannot be fully delivered because excessive inspiratory pressure (Pressure - 3 cmH2O) would be required. The sigh is partially delivered.	Check the patient. Check the breathing circuit. Adjust the Pressure alarm limit. Consider disabling the sigh function.
Inspiratory volume limitation	*Medium priority.* The delivered Vt is > 1.5 times the set Vt high alarm limit. Pressure is reduced to PEEP level. The APV controls reduce the pressure for the next breath by 3 cmH20. Disabled in noninvasive modes.	Reduce the Psupport setting. Adjust the Vt high alarm limit.
IRV	*Low priority.* The set I:E ratio is above 1:1, leading to inverse ratio ventilation. Does not apply in APRV.	Check the timing control settings.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Loss of external power	*Low priority.* The HAMILTON-MR1 is running on battery power due to loss of its primary power source.	Silence the alarm. Check integrity of connection to primary power source. Check battery status. If you have spare batteries, prepare to swap if necessary. Prepare for possible power loss. Obtain alternative ventilation.
Loss of PEEP	*Medium priority.* Pressure during exhalation < (set PEEP/CPAP – 3 cmH2O) for more than 10 s.	Check the patient. Check the breathing circuit for leaks. Replace the breathing circuit, if necessary.
Loudspeaker defective	*High priority.* A loudspeaker malfunction was detected. A technical alarm cannot typically be corrected by the operator. Ventilation continues.	Have the ventilator serviced.
Low frequency	*Medium priority.* Measured fTotal < the set alarm limit.	Check the patient. Adjust the low fTotal alarm limit. If the ventilator is in ASV, check the %MinVol and Pat. height settings. Consider suctioning, check for a kinked ET tube, or consider the possibility of acute asthma.
Low minute volume	*High priority.* Measured ExpMinVol < the set alarm limit.	Check the patient. Check the breathing circuit. Check and adjust the ventilator settings, including alarms. If the ventilator is in ASV, check the %MinVol and Pat. height settings. Consider suctioning, check for a kinked ET tube, or consider the possibility of acute asthma.
Low oxygen	*High priority.* Measured oxygen is < the operator-set oxygen -5%.	Check the patient. Check the oxygen supply. Provide an alternative source of oxygen, if necessary. Calibrate the oxygen cell. Install a new oxygen cell.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Low pressure	*High priority.* Set pressure during inspiration not reached.	Check the patient. Check the breathing circuit for a disconnection between the patient and the flow sensor, or for other large leaks (for example, ET tube, bronchopleural fistula).
O2 cell calibration needed	*Low priority.* Oxygen cell calibration data is not within expected range, or cell is new and requires calibration.	Calibrate the oxygen cell.
O2 cell defective	*Low priority.* The oxygen cell is depleted.	Install a new oxygen cell.
	CAUTION **To ensure that oxygen monitoring is always fully functional, replace an exhausted or missing oxygen cell as soon as possible or use an external O2 monitor that complies with ISO 80601-2-55.**	
O2 cell missing	*Low priority.* There is no signal from the oxygen cell.	Install an oxygen cell or use an external O2 monitor, according to ISO 80601-2-55.
	CAUTION **To ensure that oxygen monitoring is always fully functional, replace an exhausted or missing oxygen cell as soon as possible or use an external O2 monitor that complies with ISO 80601-2-55.**	
	NOTE: To prevent leakage within the ventilator, make sure an oxygen cell is installed at all times, even if you use an external O2 monitor or disable oxygen monitoring.	
O2 cell not system-compatible	*Low priority.* The incorrect type of oxygen cell is installed.	Ensure O2 cell is connected and a Hamilton Medical O2 cell is used (PN 396200).

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Obstruction	*High priority.* End-expiratory pressure > (set PEEP/CPAP + 5) or Flow < 1 l/min Only active in nCPAP and nCPAP-PC modes.	Check the patient. Check the expiratory limb for occlusion. Check the expiratory valve membrane and cover. Check the pressure lines for occlusion. Adjust breath timing controls to increase the expiratory time. Have the ventilator serviced.
Options not found	*High priority.* Options were not found during startup.	Restart device. If the problem persists, have the ventilator serviced.
Oxygen supply failed	*High priority.* Oxygen source flow lower than expected.	Check the patient. Check the oxygen supply. Provide an alternative source of oxygen, if necessary.
Performance limited by high altitude	*Medium priority, Low after silence.* The airway pressure cannot be reached at the current altitude. As long as the device remains above the altitude limit, the pressure cannot be reached, and the alarm is active.	Check the patient. Provide alternative ventilation if needed.
Pressure limit has changed	*Low priority.* Applies in ASV. The Pasvlimit was changed. When this setting is changed, the device automatically adjusts the high Pressure alarm limit to 10 cmH20 above the specified Pasvlimit setting.	Make sure the pressure limit is high enough so that sufficient pressure can be applied for adequate breath delivery.
Pressure limitation	*Medium priority, Low after silence.* Inspiratory pressure, including PEEP/CPAP, is 10 cmH2O below Pressure. The ventilator limits applied pressure, so the target pressure or volume may not be achieved.	Check the patient for adequate ventilation. Check ventilator settings and alarm limits.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Pressure not released	*High priority.* Airway pressure has exceeded the Pressure limit, and the pressure was not released via the expiratory valve after 5 s. The ventilator enters the ambient state.	Provide alternative ventilation. Check expiratory valve and breathing circuit. Have the ventilator serviced.
Preventive maintenance required	*Low priority.* According to its operating hours, the ventilator requires preventive maintenance.	Have the ventilator serviced.
Real time clock failure	*Medium priority.* Date and time not set.	Set date and time.
Replace HEPA filter	*Low priority.* The air inlet HEPA filter shows increased resistance.	Replace the HEPA filter.
Replace O2 cell	*High priority.* Communication error, O2 cell defective	Replace O2 cell.
Safety ventilation: *xxxxxx*	*Technical fault.* A hardware or software issue was detected. The ventilator switches to the safety mode.	Provide alternative ventilation. Have the ventilator serviced.
	CAUTION **To prevent possible patient injury arising from issues with the device, Hamilton Medical recommends that you immediately remove any ventilator with a technical fault from use, record the code, and have the ventilator serviced.**	
Self test failed	*High priority.* The self test failed during startup. The **Start ventilation** button is ghosted. Note that if this error occurs when the device is restarting from a complete power loss, the device enters the ambient state.	Restart device. If the problem persists, have the ventilator serviced. If the device enters the ambient state, provide alternative ventilation and have the ventilator serviced.
Suctioning maneuver	*Low priority.* Ventilation suppression is active, and ventilator settings are being maintained, although the ventilator is not delivering breaths.	Resume ventilation when desired by first reconnecting the patient.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Technical error: *xxxxxx*	*Low, medium, or high priority.* A hardware or software issue was detected. A technical alarm cannot typically be corrected by the operator. Ventilation continues.	Have the ventilator serviced.
Technical event: *xxxxxx*	*Low, medium, or high priority.* A hardware or software issue was detected. A technical alarm cannot typically be corrected by the operator. Ventilation continues.	Have the ventilator serviced.
Technical fault: *xxxxxx*	*Technical fault.* A hardware or software issue was detected. The ventilator switches to the ambient state.	Provide alternative ventilation. Have the ventilator serviced.
	CAUTION **To prevent possible patient injury arising from issues with the device, Hamilton Medical recommends that you immediately remove any ventilator with a technical fault from use, record the code, and have the ventilator serviced.**	
Technical state failed	*High priority.* Technical state failed during startup.	Have the ventilator serviced.
Touch not functional	*Low priority.* Touch screen defective.	Have the ventilator serviced.
Turn Flow Sensor	*Medium priority.* The flow sensor connections are reversed. Ventilation continues, but the ventilator corrects for the reversed signal.	Reverse the ends of the flow sensor. The blue sensing line is close to the patient and must be attached to the blue connector. The clear sensing line is close to the ventilator and must be attached to the white connector.
Unknown part number	*High priority.* Part number of a part in the ventilator is unknown.	Have the ventilator serviced.
Ventilation canceled	*Technical fault.* A hardware or software issue was detected. The ventilator switches to the ambient state.	Provide alternative ventilation. Have the ventilator serviced.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Ventilator outlet temperature high	*High priority.* Measured inhalation temperature is too high.	Check whether the room temperature exceeds the ventilator's operating temperature limit. Have the ventilator serviced if temperature cannot be reduced.
Vt high	*Medium priority.* Measured VTE > the set limit for 2 consecutive breaths. If the delivered tidal volume is greater than 1.5 times the Vt high limit (Vt > 1.5 * Vt high limit), the Inspiratory volume limitation alarm is generated.	Reduce Psupport. Check and adjust the ventilator settings, including alarm limits.
Vt low	*Medium priority.* Measured VTE is below the set limit for 2 consecutive breaths.	Check the patient. Check and adjust the ventilator settings, including alarm limits. Check for leaks and disconnects. If the ventilator is in ASV, consider suctioning, check for a kinked ET tube, or consider the possibility of acute asthma.

Table 9-2. Alarms and other messages *(continued)*

Alarm	Definition	Action needed
Wrong expiratory valve	*Medium priority, Low after silence.* The type of expiratory valve installed does not match the selected patient group (Adult/Ped or Neonatal). In addition to the alarm message, after attempting to start ventilation, the device displays a dialog box describing the risks of proceeding with the wrong valve. Note that: • The use of an adult expiratory valve with a neonatal patient may affect ventilation performance and can cause pressure oscillation. • The use of a neonatal expiratory valve with an adult or pediatric patient may affect ventilation performance and can cause increased expiratory resistance and work of breathing. The alarm is recorded in the Events log and remains in the alarm buffer.	Install the appropriate expiratory valve. To start ventilating the patient, you must confirm that you are aware of the issue by selecting either Accept or Decline in the dialog box. • By selecting Accept, you accept the risks associated with using the wrong valve for the selected patient. Ventilation starts after touching Accept. This option is only to be used in emergency cases, where the appropriate expiratory valve for the patient group is not available and mechanical ventilation must be delivered. • By selecting Decline, the dialog box closes and you remain in standby. The selection you make (Accept or Decline) is recorded with the alarm in the Events log.
Wrong flow sensor	*High priority.* The type of flow sensor connected does not match the selected patient group (Adult/Ped or Neonatal).	Connect the appropriate flow sensor. Calibrate again.

10 Special functions

10.1 Introduction

Keys on the front of the ventilator provide access to important functions, including entering Standby mode and silencing an alarm.

When a selected function is active, the indicator light next to the key is lit.

This chapter describes all of the functions in detail.

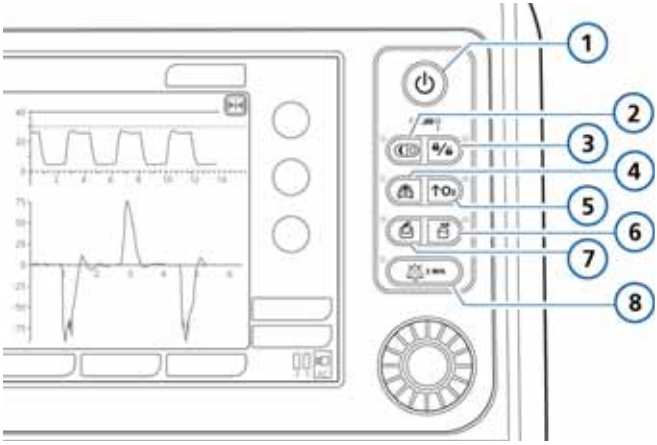


Figure 10-1. Special function keys

1	Power/Standby	**5**	O2 enrichment/suctioning
2	Day/Night	**6**	Nebulizer on/off
3	Screen lock/unlock	**7**	Print screen
4	Manual breathing/inspiratory hold	**8**	Alarm silence

10.2 Standby

WARNING

To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before entering the standby mode. You must confirm that no patient is attached before entering standby.

NOTE:

- To keep the battery fully charged, make sure the ventilator is connected to AC power while in Standby mode.
- When in standby, the ventilator does not automatically resume ventilation when the patient is reconnected. You must manually restart ventilation.
- Patient alarms are suppressed during standby.
- Acoustical patient alarms are suppressed for 1 minute after starting ventilation from standby.

Standby is a waiting mode that lets you maintain ventilator settings while the ventilator is not performing any ventilatory functions.

To put the ventilator into standby

1. Press and quickly release the Power/Standby key while the ventilator is powered on.

   The Activate standby window opens.

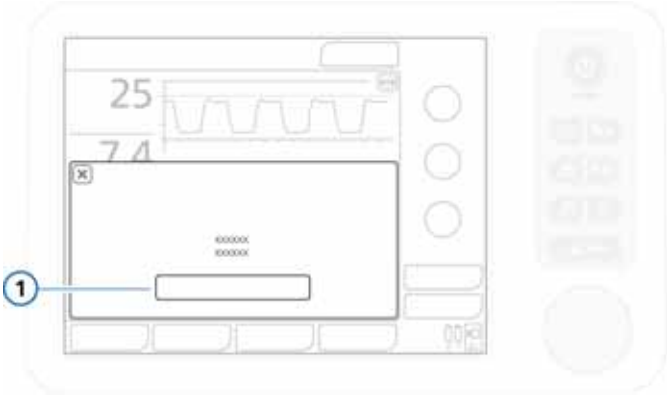


Figure 10-2. Activate Standby (1) window

2. Touch **`Activate standby`**.

   The Standby window opens. See Figure 10-3.

During standby, the window shows the elapsed time since standby was started.

To start ventilation (end standby)

Do either of the following:

- In the Standby window, touch the **`Start Ventilation`** button.
- Press and quickly release the Power/Standby key.

Ventilation resumes with the previous settings.

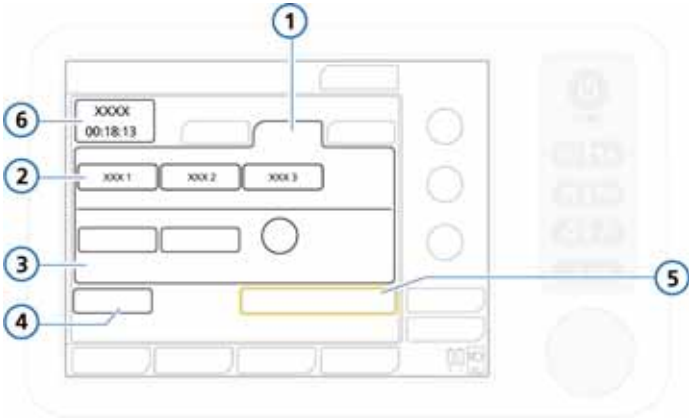


Figure 10-3. Standby window (adult/pediatric shown)

1	Adult/Ped patient group	**4**	Preop check
2	Quick setup buttons	**5**	Start Ventilation
3	Gender, Height, and IBW	**6**	Elapsed time in standby

For the Neonatal Standby window, see Figure 6-2 in Chapter 6.

10.3 Alarm silence

NOTE:

The High pressure alarm cannot be silenced.

For details on ventilator alarms, see Chapter 9.

To silence an alarm

▶ Press the Alarm silence key.

The audible ventilator alarm is muted for 2 min. Pressing the key a second time cancels the alarm silence.

The red indicator light next to the key flashes when an alarm is active but not muted. It is continuously lit while the alarm silence is active.

The display also indicates alarm silence is engaged (Figure 9-1):

- A countdown timer on the main display shows the remaining time for the silence.
- The red alarm silence icon is lit.

When the silence expires and the issue has not yet been resolved, the alarm sounds again.

10.4 O2 enrichment

NOTE:

Oxygen alarms are suppressed while the O2 enrichment function is active.

Oxygen enrichment is useful for pre- or post-oxygenation before/after tracheal suctioning or for other clinical applications. The O2 enrichment function lasts 2 minutes, unless interrupted.

O2 enrichment functions as follows, based on the selected patient group:

Adult/Ped	The O2 enrichment function delivers 100% oxygen for 2 minutes.
Neonatal	The applied oxygen concentration during the enrichment maneuver is increased by 25% of the last oxygen setting. For example, if the last oxygen setting = 40%, the resulting oxygen concentration during O2 enrichment maneuver will be 50%.

To start oxygen enrichment

▶ Press the O2 enrichment key.

After a short time, which is required for the oxygen concentration to rise, the HAMILTON-MR1 starts delivering 100% oxygen (adult and pediatric) or the current oxygen setting increased by 25% of the setting (infant/neonate).

The green indicator next to the key is lit and the Oxygen control turns green. A countdown timer is displayed, counting down from 2 min, showing the remaining time for the O2 flush.

When finished, the ventilator resets the concentration to the previous operator-set value.

To stop O2 enrichment manually

- ▶ Do either of the following:
  - – Press the O2 enrichment key again.

    Enrichment stops and ventilation resumes at the previously set value.
  - – Touch the Oxygen control and adjust it as needed; then confirm the change.

    Enrichment stops and ventilation resumes at the newly set value.

10.5 Suctioning tool

NOTE:

- The suctioning tool is inactive during NIV and NIV-ST modes.
- The suctioning tool is not supported in neonatal ventilation.
- The pre- and post oxygenation is displayed with green O2 control and timer (max. 120 seconds).
- Suctioning may affect measured values.

The suctioning maneuver is intended to withdraw an excess of tracheal and/or bronchial secretions in the patient's airways while protecting the user from possible contamination, as well as ensuring the patient's safety during the suctioning maneuver.

When active, the green indicator next to the key is lit.

To perform the suctioning maneuver

1. Press the O2 enrichment key for pre-oxygenation.
2. Disconnect the patient.

   Disconnecting the patient halts ventilation so that no gases are blown through the tubes. For 60 seconds all alarms are suppressed.

3. Use a suctioning tool (not included) to suction all secretions out of the patient's airways.
4. Reconnect the patient to the ventilator.

   Post-oxygenation starts and for another 60 seconds all acoustic alarms are suppressed. The alarm message and lamp are still active.

To prematurely terminate the pre- and/or post oxygenation maneuver, press the O2 enrichment key again.

10.6 Manual breath/inspiratory hold

This function lets you deliver a manually triggered breath or perform an inspiratory hold maneuver.

When active, the green indicator next to the key is lit.

To deliver a manual breath only

- Press and release the Manual breath key (Figure 10-1) during exhalation.

  In nCPAP mode, you can deliver a manual breath at any time.

  Do not press the key quickly and repeatedly. The manual breath uses the mandatory breath settings (standard or operator set).

  If you try to initiate a manual breath during the early stage of inspiration or the early stage of exhalation, the breath will not be delivered. This does not apply in nCPAP mode.

To perform an inspiratory hold

- Hold down the Manual breath key during any breath phase.

  If the ventilator is in exhalation, it delivers a mandatory breath, then performs a hold maneuver until the key is released, up to 15 seconds in addition to the set inspiratory time.

  If the ventilator is in inspiration, it performs a hold maneuver at the end of inspiration, lasting until the key is released, for up to 15 additional seconds.

10.7 Nebulizer

CAUTION

- **Do not use an expiratory filter or HMEF/HME in the patient's breathing circuit during nebulization. Nebulization can cause an expiratory side filter to clog, substantially increasing flow resistance and impairing ventilation.**
- **To prevent the expiratory valve from sticking due to nebulized medications, use only medications approved for nebulization and regularly check and clean the expiratory valve.**

NOTE:

- Delivered ventilation is compensated for the contribution of the internal nebulizer so that the expected volume and pressure are delivered.
- Pneumatic nebulization is disabled during neonatal ventilation.

The HAMILTON-MR1's pneumatic nebulization function powers a standard inline nebulizer for delivery of prescribed medications in the ventilator circuit. When nebulization is active, the nebulizer flow is synchronized with the inspiratory phase of each breath for 30 min. Nebulization can be activated in all modes of ventilation.

When active, the green indicator next to the key is lit.

To start nebulization

▶ Press the Nebulizer key.

To stop nebulization

▶ Press the Nebulizer key again.

For effective nebulization, use a pneumatic nebulizer jar (see Appendix F). Section 2.3 briefly describes how to install the nebulizer.

10.8 Print screen

NOTE:

Touch the HAMILTON-MR1 before using the USB port.

The print screen function saves a JPG file of the current ventilator screen to a USB memory drive.

To create a screen shot

1. Insert a USB memory drive into the USB port.
2. Press the Print screen key while the desired display is shown.

The device saves the image to the memory drive. The green indicator next to the key is lit while the device saves the image.

The filename takes this format:

screenshot_YYYYMMDD_hhmmss.jpg

where:

YYYY is the year

MM is the month

DD is the date

hh is the hour (in 24-hour format)

mm is the minute

ss is the second

10.9 Screen Lock/unlock

The Screen Lock/unlock function prevents inadvertent touch screen and device entries. When touching the locked screen, an acoustic BEEP sounds and a *Screen lock active* message is displayed.

When active, the green indicator next to the key is lit.

When screen lock is active, some device controls remain available, while others are disabled, as follows:

Active

- Alarm silence key
- Manual breath key
- O2 enrichment key
- Day/Night key
- Nebulizer key

Inactive

- Touch screen
- Power/Standby key
- Print screen key
- P&T knob

To lock or unlock the screen

▶ Press the Screen Lock/unlock key.

10.10 Day/Night

The Day/Night key[1] allows you to quickly switch between the display Day and Night settings. The device uses the brightness settings specified in the System window (Section 4.3.4).

When the Night setting is active, the green indicator next to the key is lit.

To change the display brightness to the pre-set Day or Night setting

- Press the Day/Night key.

The device changes the display brightness as follows.

Table 10-1. Day/Night key actions

The current brightness setting (in System window) is ...	When Day/Night key is pressed, the device switches to the default setting for ...
Day	Night When the Night setting is active, the green light next to the Day/Night key is lit.
Night	Day
Automatic	Night When the device is restarted, it resets the display brightness to the Day setting.

1. Not available in Japan.

11 Maintenance

11.1 Introduction

WARNING

No modification of this equipment is allowed. Servicing must be performed by Hamilton Medical-authorized personnel using the instructions provided in the Service Manual.

You must comply with these maintenance procedures to ensure the safety and reliability of the HAMILTON-MR1. All the procedures in this manual are to be performed by the operator. For additional maintenance requirements, contact your Hamilton Medical service representative.

11.2 Cleaning, disinfection, and sterilization

WARNING

- **Always disconnect the device from electrical power before cleaning and disinfection to reduce the risk of electric shock.**
- **DO NOT reuse single-use bacteria filters, flow sensors, and other accessories. They must be discarded after use. Follow your hospital procedures for disposal.**
- **Reusing, disassembling, cleaning, disinfecting, or sterilizing a single-use part may compromise its functionality and system performance, leading to a possible operator or patient hazard.**
- **Performance is not guaranteed if an item labeled as single-use is reused.**
- **Reuse of a single-use product voids the warranty.**
- **Always use caution when handling bacteria filters to minimize the risk of bacterial contamination or physical damage. Dispose of used filters immediately after use. Follow your hospital procedures for disposal.**

- **To prevent patient exposure to sterilizing agents and to prevent premature deterioration of parts, sterilize parts using the techniques recommended in this section only.**

CAUTION

- **DO NOT attempt to sterilize the interior components of the ventilator. DO NOT attempt to sterilize the entire device with ETO gas.**
- **Exposure to sterilizing agents may reduce the useful life of certain parts. Using more than one sterilization technique on a single part may damage a part.**
- **Intrusion of fluids, or immersing parts in fluids, will damage the device.**
- **Do not pour fluids onto the device surfaces.**
- **Do not use abrasives materials (for example, steel wool or silver polish) on surfaces.**
- **You can use bleaching agents according to the manufacturer's recommendations and the instructions provided in the *Compatibility of cleaning / disinfectant agents with HAMILTON MEDICAL ventilators* statement.**
- **Incorrect concentrations or residence times of sterilization agents may lead to bacterial resistance.**

NOTE:

- Because sanitation practices vary among institutions, Hamilton Medical cannot specify specific practices that will meet all needs or be responsible for the effectiveness of these practices.
- This manual only provides general guidelines for cleaning, disinfecting, and sterilizing. It is the operator's responsibility to ensure the validity and effectiveness of the actual methods used.
- For specific information on cleaning, disinfecting, and sterilizing autoclavable (reusable) accessories and components, refer to the appropriate *Reprocessing Guide* and *Instructions for Use* provided with each part.

The following sections provide general recommendations for cleaning, disinfecting, and sterilizing parts. Table 11-4 provides an overview of how to reprocess each part. For parts not supplied by Hamilton Medical, comply with the manufacturers' recommendations.

DO NOT attempt decontamination procedures unless specified by Hamilton Medical or the original manufacturer.

If you have any questions about the use of a particular cleaning or disinfection agent, contact the manufacturer of the agent.

If you are unsure how to clean and decontaminate a given part, contact your hospital hygiene administrator. This is especially important to avoid the spread of Hepatitis and HIV. Ensure you follow your hospital infection control procedures, as well as all local, state, and federal regulations.

After cleaning and decontaminating parts, perform any required tests and calibrations described in Chapter 4.

The following sections provide a general overview of how to clean and disinfect ventilator-related parts. Additional information for each part is included in Table 11-3.

11.2.1 General guidelines for cleaning

CAUTION

- **To prevent damage to the ventilator and components, DO NOT clean with hard brushes, pointed instruments, or rough materials.**
- **Cleaning and disinfection agent residues can cause blemishes or fine cracks, especially on parts exposed to elevated temperatures during sterilization.**
- **Incorrect concentrations or residence times of sterilization agents may lead to bacterial resistance.**
- **Use of a rinse agent reduces the lifespan of the product.**

Additional information for cleaning each part is included in Table 11-3.

To clean the device parts

1. Disassemble parts. Breathing circuits must be disassembled completely.
2. Wash parts in warm water and soap or an appropriate mild detergent solution.

   The following table shows supported cleaning agents. When available, refer to the documentation provided with the part for details about supported cleaning agents.

Table 11-1. Supported cleaning agents

Cleaning Agent	Description
Surfactant	Alconox®
Ammonia based	Solution of < 3% ammonia Glass cleaner
Alcohol based	Solution of 70% isopropanol Solution of 70% ethanol Glass cleaner

3. Rinse parts thoroughly with clean, warm water.
4. Air dry.
5. Inspect all parts, and replace if damaged.
6. If you will sterilize or disinfect the part, continue with the appropriate sterilization/disinfection procedure as described in the product documentation.

   If you will not sterilize or disinfect the part, reassemble and reinstall (if needed), and perform any required tests.

11.2.2 General guidelines for disinfection

CAUTION

Table 11-4 lists the materials used for HAMILTON-MR1 parts. To prevent premature deterioration of parts, make sure the disinfecting chemical is compatible with the part material. Check the manufacturer's recommendations.

Additional information for disinfecting each part is included in Table 11-3.

To disinfect the device parts

1. Clean, but DO NOT re-assemble.
2. Disinfect with an appropriate mild bactericidal chemical solution.

   Acceptable chemicals include:

   – Schülke & Mayr Lysetola AF and Gigasepta FF
   – Henkel-Ecolab Incidura
   – Sekusepta PLUS
   – CIDEX

   These agents have been tested according to the manufacturers' guidelines. Other brand names with similar active ingredients may also be suitable.

The following table, Table 11-2, shows appropriate alcohol and aldehyde concentrations, if preferred.

Table 11-2. Additional disinfection agents

Disinfection Agent	Description
Alcohol	Solution of ≤70% ethanol Solution of ≤70% 1- and 2-Propanol solution
Aldehyde	Solution of ≤3.6% glutaraldehyde

3. Reassemble and reinstall parts, and perform any required tests before reuse.

The following table summarizes the cleaning and disinfection guidelines for each major system component.

Table 11-3. Cleaning and disinfection methods parts

Part (material)	How to clean and disinfect	Remarks
Ventilator exterior, including housing, basket, tray, gas supply hoses, power cord, modules (Does not apply to touch screen.)	Wipe with an appropriate bactericidal agent after each patient use. Be particularly careful with infectious patients, and follow your hospital infection control procedures.	Use any of the following options. Dampen a lint-free cloth with any of the following. For examples and concentrations, see Tables 11-1 and 11-2. • Warm water (maximum 40°C (104°F)) and soap. • A dilute and nonacid agent • A surfactant • A cleaning agent in a base of ammonia or alcohol Do not use strong solvents, such as acetone or Trichlorethylene. DO NOT clean the ventilator interior. This can damage internal parts. Be sure to only clean around the connection ports, not inside them.

Table 11-3. Cleaning and disinfection methods parts *(continued)*

Part (material)	How to clean and disinfect	Remarks
Touch screen	Wipe the screen with a damp soft cloth, using either of the following: • An antibacterial cleaning agent • Cleaning agents recommended by your hospital	Lock the screen before cleaning. See Section 10.9. Handle the touch screen with care. DO NOT use any vinegar-based solutions. Avoid using gritty cloths. Do not pour fluids onto the screen during cleaning.
Aeroneb control module Control module cable Power adapter	Wipe clean with a damp cloth. Check for exposed wiring, damaged connectors, or other defects and replace if any are visible.	DO NOT autoclave.
Aeroneb mounting brackets	Wipe clean with a damp cloth and mild liquid detergent and antibacterial cleaning agent.	DO NOT use abrasive or sharp tools.

11.2.3 General guidelines for reprocessing

Reprocessing (decontamination) may include one or more of the following processes:

- Chemical disinfection
- ETO sterilization
- Steam autoclaving

Table 11-4 provides additional information for reprocessing individual parts.

For details about reprocessing the autoclavable expiratory valve, see Section 11.6.

To reprocess the device parts

1. Clean/disinfect.
2. Reassemble.

3. Inspect.
4. Autoclave.
5. Perform any required tests.

The following table provides additional information for reprocessing (decontaminating) individual parts.

Table 11-4. Reprocessing methods for parts

Part (material)	Reprocessing recommendations	Remarks
For specific information on cleaning, disinfecting, and sterilizing autoclavable (reusable) accessories and components, refer to the appropriate Reprocessing Guide and Instructions for Use provided with each part.		
Breathing tubes, reusable, autoclavable (silicone rubber)	Steam autoclave, chemically disinfect, or ETO sterilize	Roll tubes into large coils. DO NOT twist, kink, or cross tubes when sterilizing them. The tubing lumen must not have vapor or moisture before wrapping for autoclaving. Avoid exposing silicone rubber breathing tubes to grease, oil, silicone-based lubricants, organic solvents (benzene, ether, ketone, and chlorinated hydrocarbons), acids, concentrated alkaline cleaning products, and phenols and derivatives.
Mask, reusable, autoclavable (silicone rubber)	Steam autoclave, chemically disinfect, or ETO sterilize	Avoid exposing silicone rubber masks to grease, oil, silicone-based lubricants, organic solvents (benzene, ether, ketone, and chlorinated hydrocarbons), acids, concentrated alkaline cleaning products, and phenols and derivatives. Deflate air cushion before steam autoclaving to prevent possibility of explosion.

Table 11-4. Reprocessing methods for parts *(continued)*

Part (material)	Reprocessing recommendations	Remarks
For specific information on cleaning, disinfecting, and sterilizing autoclavable (reusable) accessories and components, refer to the appropriate Reprocessing Guide and Instructions for Use provided with each part.		
Flow sensor, reusable, autoclavable	Steam autoclave, chemically disinfect, or ETO sterilize	DO NOT use hard brushes, pointed instruments, or rough materials. These can damage the flow sensor's membrane.
Inspiratory filter, reusable autoclavable	Steam autoclave	After reprocessing, always inspect the filter media for cracks or foreign matter; replace if necessary.
Nebulizer jar, reusable (polysulfone)	Steam autoclave or chemically disinfect	
Expiratory valve cover (polysulfone) Expiratory valve membrane Y-piece Water traps Adapters Connectors (polysulfone) Temperature probe housing (polysulfone and silicone rubber)	Steam autoclave, chemically disinfect, or ETO sterilize For details about reprocessing the autoclavable expiratory valve, see Section 11.6.	DO NOT autoclave if medications containing chlorinated or aromatic hydrocarbons are used. Solutions such as Medizyme, Pyroneg, Control 3, Solution 2, and CIDEX® have been tested according to the manufacturers' guidelines. Other brand names with similar active ingredients may also be suitable.
Aeroneb adapter	Autoclave wrapped parts using steam sterilization pre-vacuum cycle, a minimum of 134°C (270°F – 275°F) for 20 minutes with drying cycle (sometimes referred to as a "Prion cycle").	DO NOT reassemble parts prior to autoclaving.

11.3 Preventive maintenance

NOTE:

- Dispose of all parts removed from the device according to your institution's protocols. Comply with all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it (for example, oxygen cell, batteries).
- Any attempt to modify the ventilator hardware or software without the express written approval of Hamilton Medical automatically voids all warranties and liabilities.
- Hamilton Medical recommends that you document all maintenance procedures.
- It is not allowed to perform service or maintenance on the device while a patient is connected.

Perform preventive maintenance on your HAMILTON-MR1 according to the schedule shown in Table 11-5. You can view the hours of ventilator operation in the System -> Info window. The following subsections provide details for some of these preventive maintenance procedures.

Table 11-5. Preventive maintenance schedule

Interval	Part/accessory	Procedure
Between patients and according to hospital policy	Breathing circuit (including mask, inspiratory filter, flow sensor, nebulizer jar, exhalation valve cover and membrane)	Replace with sterilized or new single-patient use parts. Run the tightness test and the appropriate calibration (Chapter 4).
	Entire ventilator	Run the preoperational checks (Section 4.2).
Every 2 days or according to hospital policy	Breathing circuit	Empty any water from breathing tubes or water traps. Inspect parts for damage. Replace as necessary.

Table 11-5. Preventive maintenance schedule *(continued)*

Interval	Part/accessory	Procedure
Every month (or more often, if required)	**WARNING** **To reduce the risk of patient cross-contamination through the fan filter, always perform maintenance at the prescribed interval.**	
	Fan filter (rear panel)	Check for dust and lint. If needed, clean or replace.
Every 6 months	Batteries	Recharge batteries by plugging the ventilator into a primary power source for at least 4 hours.
Yearly or every 5000 hours, whichever comes first, or as necessary	Oxygen cell	Replace if depleted.
	NOTE: Oxygen cell life specifications are approximate. The actual cell life depends on operating environment. Operation at higher temperatures or higher oxygen concentrations shortens cell life.	
	Air intake HEPA filter	Replace.
	Ventilator	Perform service-related preventive maintenance.[1]
Dynamic lifetime surveillance Typically 8 years	Blower	Replace if indicated[1]

1. Must be performed by Hamilton Medical authorized service personnel according to instructions in the *Service Manual*.

11.3.1 Servicing the air intake and fan filters

To service the air intake and fan filters

1. Remove the fan filter.

Figure 11-1. Removing the fan filter (1)

2. Remove the air intake dust filter.

Figure 11-2. Removing the air intake filter (1)

3. Remove the filter cover.

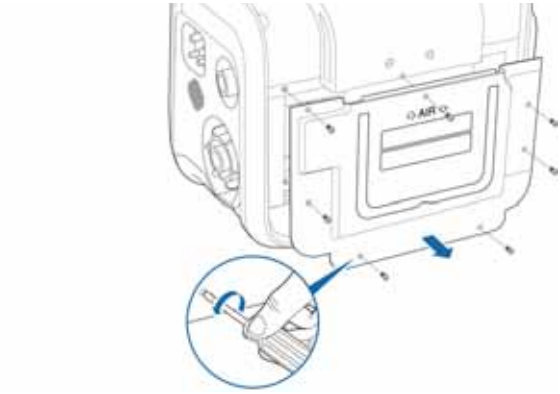


Figure 11-3. Removing the cover

4. Pull up the retaining clip and pull out the HEPA filter.

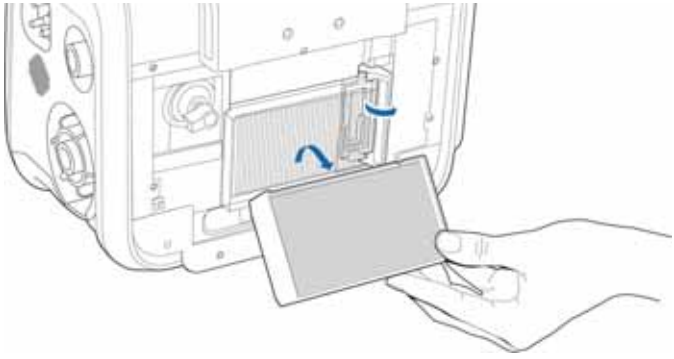


Figure 11-4. Removing the HEPA filter

5. Install a new HEPA filter as required.
6. Install a new fan filter (Figure 11-1) or wash the existing filter in a mild soap solution, rinse, dry and reinstall.
7. Install a new air intake dust filter (Figure 11-2) or wash the existing filter in a mild soap solution, rinse, dry, and reinstall.
8. Reattach the filter cover.

11.3.2 Working with the batteries

NOTE:

The batteries cannot be replaced during ventilation.

The HAMILTON-MR1 has two internal batteries, both of which are required for ventilator operation.

For specifications and details, see Sections 2.7 and A.4.

11.3.2.1 Charging and calibrating the battery

The batteries are charged with connected AC power. The batteries can also be charged with a Hamilton Medical supplied charger (PN 369104). Charge and calibrate the battery with the supplied charger following the instructions supplied with the charger/calibrator.

11.3.2.2 Removing and replacing the batteries

The rear panel on the ventilator provides access to the batteries.

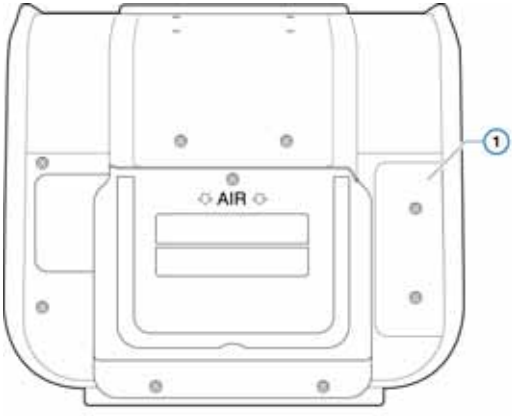


Figure 11-5. Rear panel (1)

To remove the batteries

1. Remove the seven (7) screws shown below on the rear panel of the device to remove it. See Figure 11-3.
2. Pull the white tab on the end of each battery to pull the battery out of the compartment.

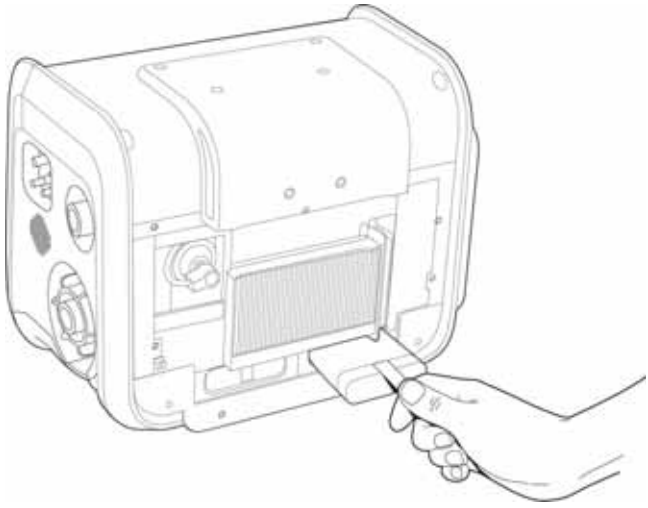


Figure 11-6. Remove batteries

To replace the batteries

1. With the rear cover off (see page 11-16), slide each battery into the empty compartment, with the Hamilton Medical logo facing up and the white tab in your hand. See below.
2. Reattach the cover, and insert and tighten the screws.

11.3.3 Replacing the oxygen cell

NOTE:

- Replace the oxygen cell with genuine Hamilton Medical parts only; otherwise, oxygen measurement will not function.
- To prevent leakage within the ventilator, make sure an oxygen cell is installed at all times, even if you use an external monitor or disable oxygen monitoring.
- To prevent a permanent alarm use special Hamilton Medical oxygen cells only.

To replace the oxygen cell, remove the cover, then disconnect and remove the cell (Figure 11-7). Install and reconnect the new cell; then replace the cover.

Run the oxygen cell calibration (see Chapter 4).

Figure 11-7. Replacing the oxygen cell

11.4 Storage

To maintain the battery charge and to prolong the life of the battery, keep the ventilator connected to its primary power source. Have the battery recharged every 6 months, depending on storage conditions (see specifications in Appendix A).

11.5 Repacking and shipping

CAUTION

Inform Hamilton Medical if you are shipping a contaminated (nonsterilized and nondisinfected) device for service.

If you must ship the ventilator, use the original packing materials. If these materials are not available, contact your Hamilton Medical representative for replacement materials.

11.6 Reprocessing the autoclavable expiratory valve

This recommendation is valid for the following products from the Hamilton Medical accessories and consumables program.

The autoclavable expiratory valve consists of the following materials.

Expiratory set, reusable, PN	**Pressure limitation**	**Materials**
161175 (adult / pediatric)	Body	Polycarbonate
161188 (neonatal)	Locking ring	Polyamide 12
	Membrane	Silicon rubber
	Cap on membrane	Stainless steel
Expiratory valve membrane and cover, reusable, PN	**Pressure limitation**	**Materials**
161390 (pack of 5)	Membrane	Silicon rubber
	Cap on membrane	Stainless steel

All materials used are heat resistant up to 140°C (284°F).

WARNING

- **Clean, disinfect, and sterilize the expiratory valve directly after use.**
- **Hamilton Medical cannot be held responsible for the correct functioning of expiratory valves that are not reprocessed and used according to these instructions.**
- **Ensure that only processes that have been specifically validated for the product or device are used, and that the validated parameters are used with every cycle.**
- **A used expiratory valve must be handled as a contaminated item. Follow all local, state, and federal regulations with respect to environmental protection when disposing of used expiratory valves.**

- **Follow hospital infection control procedures, as well as local laws and regulations. This applies in particular to the various regulations regarding an effective deactivation of prions.**

CAUTION

- **The autoclavable expiratory valve has a limited life span. The expiratory valve may be damaged due to the use of hard brushes, scouring agents, or by the exertion of too much force.**
- **The use of rinse aids will reduce the life span of the expiratory valve, as it can lead to early failure and cracks in the plastic expiratory valve body.**
- **The expiratory valve must not be autoclaved if medication containing aromatic or chlorinated hydrocarbons has been applied via a nebulizer. Discard the valve.**

Make sure that the reprocessing does not damage the steel ring and the membrane.

The steel ring is there to reinforce the membrane and to improve tightness. Make sure the ring does not get bent out of shape.

11.6.1 Expiratory valve reprocessing overview

The expiratory valve must be cleaned, disinfected, and sterilized before every use.

Reprocessing comprises the following steps:

1. Cleaning and disinfecting the valves.
2. Visually inspecting the valves after disinfection.
3. Packaging the valves.
4. Sterilizing the packaged valves.

These steps are described in this section, both for mechanical and manual reprocessing of the valves.

After each reprocessing cycle, the expiratory valve housing must be inspected for damage. If any changes are visible, the valve must be discarded. Perform a tightness test after each reprocessing cycle. If the test fails, it may be repeated once. The expiratory valve must be replaced if the tightness test fails the second time.

Rinse aids will cause premature damage and reduce product life span, and should not be used. Hamilton Medical does not guarantee the expiratory valve's life span if rinse aids are used.

11.6.2 Preparing and reprocessing the expiratory valve after use

The expiratory valve must be handled in accordance with all local, state, and federal regulations. Reprocess the expiratory valve immediately after use. The reprocessing cycle comprises cleaning, disinfection, and sterilization.

Remove macroscopic impurities of the expiratory valve by rinsing or wiping. You can add an aldehyde-free disinfection agent to the rinse water. You must not use any hard tools or hard brushes to remove resilient impurities.

Prior to sterilization, the expiratory valve must be cleaned and disinfected.

11.6.3 Cleaning and disinfecting the expiratory valve

The expiratory valve can be disinfected mechanically or manually.

NOTE:

Since mechanical disinfection is more effective and consistent, manual cleaning and disinfection is only permitted when no mechanical process is available.

Follow the chemical concentrations and soak times as stated in the corresponding manufacturer's instructions for use. Only use freshly made solutions. The disinfection solution must not foam.

Use only sterile water or water with a low microorganism count for all cleaning steps. Make sure that the particulate matter concentration in the water is low.

When selecting the cleaning and disinfection agent, consider whether the agents in question are suitable for the expiratory valve. Make sure the disinfection agents' effects are proven and the chemicals are compatible with the materials of the expiratory valve. In addition, instructions for cleaning with the selected agents must be available.

When in doubt contact the manufacturer of the disinfection or cleaning agent.

11.6.3.1 Mechanically cleaning and disinfecting the expiratory valve

The expiratory valves must be reprocessed in such a manner that hygienic and safe reuse can be assured. Cleaning / disinfection should only be carried out in a cleaning and disinfection device that complies with ISO 15883 and has been proven to be effective. Place the expiratory valve in such a manner that it is easy to clean and the effectiveness of cleaning and disinfection is not impaired.

To ensure safe cleaning, the expiratory valve must be connected to the corresponding receptors. The expiratory valve must not disconnect from the receptor during reprocessing.

Expiratory valves that disconnect during reprocessing must be processed again. After the cleaning process is complete, check that the expiratory valve is completely dry and undamaged. Damaged expiratory valves must be discarded.

The following program parameters must be met for successful mechanical cleaning:

Pre-rinse:	one cycle using cold water for 1 min
Cleaning:	one cycle at 55°C (131°F) for 5 min
Optional neutralization:	one cycle using cold water for 1 min
Rinsing:	one cycle using cold water for 1 min
Thermic disinfection:	one cycle at 83°C (181.4°F) for 10 min
Drying:	100°C (212°F) for 10 min and 95°C (203°F) for 30 min

11.6.3.2 Recommended equipment for mechanical reprocessing

CAUTION

Using a rinse aid will cause premature damage and reduce product life span.

Hamilton Medical recommends the DES-VAR-TD-Anaesthesia program, among others in the Miele PG8536 disinfector, together with the E436/3 injector tray.

Suitable cleaning agents:

Manufacturer	Product	Concentration
Dr. Weigert	Neodisher Mediclean forte®	1.00%

Suitable neutralizer:

Manufacturer	Product	Concentration
Dr. Weigert	Neodisher Z®	0.10%

11.6.3.3 Manually cleaning the expiratory valve

1. Disassemble the expiratory valve.
2. Submerge the expiratory valve in the cleaning solution (for example, Neodisher Mediclean forte®) and let it soak for the time defined by the manufacturer of the disinfection or cleaning agent. Make sure that all parts of the expiratory valve are fully submerged in the solution.
3. Rinse all parts at the beginning and the end of the soak time with the cleaning agent at least five times.
4. Remove matter and larger exterior impurities by carefully scrubbing the expiratory valve with a soft brush or soft towel.
5. Rinse the expiratory valve at least five times intensively, or according to the validated cleaning plan, in freshly distilled or deionized water.
6. Repeat the cleaning process if the last cleaning solution was not clear or there are still visible impurities on the expiratory valve.

11.6.3.4 Manually disinfecting the expiratory valve

1. Disassemble the expiratory valve and submerge it in the disinfection solution, and let it soak for the time defined by the manufacturer of the disinfection agent (for example, CIDEX® OPA). Make sure that all parts of the expiratory valve are fully submerged in the solution.
2. Rinse the expiratory valve at the beginning and at the end of the soak time with the disinfection solution at least five times, or in accordance with the validated disinfection plan.
3. Rinse the expiratory valve in freshly distilled or deionized water at least five times intensively, or according to the validated cleaning plan.
4. Repeat the cleaning process if the last cleaning solution was not clear or there are still visible impurities on the expiratory valve.

5. Dry the expiratory valve with filtered, oil-free compressed air.
6. Immediately package the expiratory valve using appropriate packaging.

11.6.4 Visual test

After each cleaning and disinfection cycle, the expiratory valve must be macroscopically clean, that is, free of visible residual matter and other impurities. If it is not, the entire cleaning and disinfection process must be repeated.

Visually check for external damage, such as cracks, broken or deformed parts, or discoloration.

11.6.5 Packaging

Make sure that the expiratory valves are not moist during packaging.

The packaging must conform to ISO 11607 and be suitable for vapor sterilization (heat resistance up to 141.0°C (285.8°F)) and be sufficiently permeable to vapor.

Only use packaging suitable for sterilization.

11.6.6 Sterilization

Sterilize the expiratory valve after cleaning and disinfection before use. Use one of the following methods:

- 134.0°C (273.2°F) with or without prevacuum, with an exposure time of a minimum of 3 min and a maximum of 18 min
- 121.0°C (249.8°F) with or without prevacuum, with an exposure time of a minimum of 30 min

Place the expiratory valve parts horizontally into the sterilizer; do not stack them. Note that Hamilton Medical is not responsible for the efficacy of any sterilization method, including but not limited to hot-air, ethylene oxide, formaldehyde, radiation, and low-temperature plasma sterilization.

11.6.7 Testing before use

WARNING

Defective expiratory valves or expiratory valves that fail the tightness test must not be used.

Carry out a visual check and a tightness test as described in the ventilator's operator's manual. Replace defective expiratory valves.

11.6.8 Expiratory valve life span

The expiratory valve can be cleaned, disinfected, and autoclaved at least 40 times. As long as the expiratory valve passes the tightness test during the preoperational check, the expiratory valve can be used. Tests and calibrations have to be carried out as specified in the ventilator's operator's manual. It is the user's responsibility to validate the processes used if the reprocessing procedures used differ from those in this guide.

11.6.9 Autoclaved and packaged expiratory valve: life span and storage conditions

The life span of an autoclaved and packaged expiratory valve depends on how long the packaging can keep the expiratory valve sterile. Follow the packaging manufacturer's specifications. At a minimum, the expiratory valve must be autoclaved every two years. Storage is subject to the same guidelines as the Hamilton Medical ventilator, as specified in the ventilator's operator's manual.

11.6.10 Disposal

A used expiratory valve must be handled as a contaminated item. Follow all local, state, and federal regulations with respect to environmental protection when disposing of used expiratory valves.

APPENDIX

A Specifications

A.1 Physical characteristics

Table A-1. Physical characteristics

Weight	6.8 kg (15 lb) 21 kg (46.2 lb) with trolley The trolley can accommodate a maximum safe working load of 44 kg (97 lb).[1]
Dimensions	See Figure A-1

1. The maximum safe working load applies to a stationary properly load-balanced trolley.

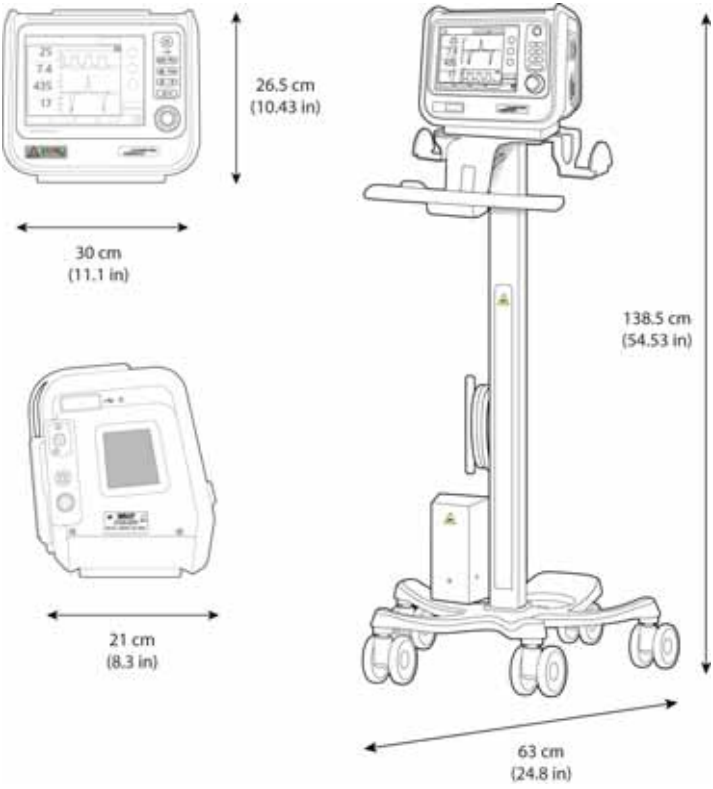


Figure A-1. HAMILTON-MR1 dimensions

A.2 Environmental requirements

CAUTION

Ambient temperature < 0°C: The oxygen concentration that is displayed may be inaccurate. Disable O2 monitoring. Ensure that an alternative means of oxygen monitoring is always available and enabled.

Table A-2. Environmental requirements

Temperature	Operating: 5°C to 40°C (41°F to 104°F) Storage: -20°C to 60°C (-4°F to 140°F), in original packaging -15°C to 60°C (5°F to 140°F) otherwise
Altitude	-650 to 3000 m (-2132 to 9.842 ft) above sea level
Atmospheric pressure	Operating pressure: 700 to 1100 hPa Storage pressure: 600 to 1100 hPa
Relative humidity	Operating/storage: 10% to 95%, relative humidity, noncondensing
Water protection	IP 21

A.3 Pneumatic specifications

Table A-3. Pneumatic specifications

High-pressure oxygen inlet	Pressure: 2.8 to 6 bar / 280 to 600 kPa / 41 to 87 psi Flow: Maximum of 200 l/min Connector: DISS (CGA 1240) or NIST
Air supply	Integrated blower
Gas mixing system	Delivered flow: • 260 l/min ±10% against ambient pressure (at sea level) • 120 l/min at 30 cmH20 • 0 to 200 l/min with 100% O2 • Flow limitation in neonatal modes: 40 l/min • Flow accuracy (for calibrated flow sensor) Adult/Ped: ±10% or ±300 ml/min (whichever is greater) Neonatal: ±2 ml/s or ±10% (whichever is greater) Delivered pressure: Adult: 0 to 60 cmH2O Neonatal: 0 to 45 cmH20
Inspiratory outlet (To patient port)	Connector: ISO 15 mm female/22 mm male conical
Expiratory outlet (From patient port)	Connector (on expiratory valve): ISO 15 mm female/22 mm male conical

A.4 Electrical specifications

Table A-4. Electrical specifications

Input power	100 to 240 VAC -15% / +10%, 50/60 Hz
Power consumption	50 W typical, 120 W maximum
Battery	**NOTE:** Battery life indications are approximate. The actual battery life depends on ventilator settings, battery age, and level of battery charge. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges. Hamilton Medical provides two high-capacity[1] batteries. Electrical specifications: 10.8 V DC, 6.7 Ah, 72 Wh, 50 W typical, 150 W maximum Type: Lithium-ion, supplied by Hamilton Medical only Operating time: Operating times are measured with two fully charged batteries, the blower in use, and with the following settings: Mode = PCV+, Rate = 10 b/min, Pcontrol = 10 cmH2O, I:E = 1:4, PEEP = 5 cmH2O, Flow trigger = 5 l/min, FiO2 = 40%. Approximate operating times under these conditions are as follows: • Display brightness = 80%: 8 h (default brightness setting) • Display brightness = 20%: 9.2 h This operating time applies to new, fully charged Li-ion batteries not exposed to extreme temperatures. The actual operating time depends on battery age and on how the battery is used and recharged. Recharge time: While the ventilator is connected to primary power, approximately 3.25 h to fully recharge one battery, approximately 6.25 h to fully recharge two batteries. Storage: • Recommended: -20°C to 40°C (-4°F to 104°F), ≤ 70% relative humidity • Long-term storage (> 3 months): -20°C to 20°C (-4°F to 68°F), ≤ 70% relative humidity • Minimum and maximum: -20°C to 60°C (-4°F to 140°F), ≤ 85% relative humidity • Note that extended exposure to temperatures above the recommended temperature range could degrade battery performance and life Storage place should be free from vibration, dust, direct sunlight, moisture, and corrosive gases.

1. PN 369108, revision 4 and later

A.5 Magnetic field specifications and accuracy

The HAMILTON-MR1 is rated for use in the following environments.

Table A-5. External magnetic field specifications

Static magnetic field	≤ 50 mT Corresponds to approximately 1 m distance from the front of a 3.0 T MRI scanner.

In nonclinical testing, the device was found to be safe to operate at (or less than) a fringe magnetic field of 50 mT.

The TeslaSpy navigator magnetic field readings are accurate within ±10%. The accuracy is maintained by the device performing self calibration.

For additional information, see Chapter 3.

A.6 Control settings

NOTE:

- Some modes are available as options, and may not be available in all countries or on all devices.
- Some default settings are configurable.
- The following parameters are based on ideal body weight (IBW): Vt, Rate, Thigh, Tlow, and TI
- The following parameters are set based on body weight (neonatal): Vt, Rate, Tlow, Thigh, TI, and TI max

Table A-6 provides the control parameter ranges, default settings, and accuracy of measurements. Definitions of the control settings are provided in Table 5-2.

Table A-6. Control settings, ranges and accuracy

Parameter or Setting (units)	Range		Default settings		Accuracy[1]
	Adult/Ped	Neonatal	Adult/Ped	Neonatal	
Apnea backup	On, Off	On, Off	On	On	
ETS[2] (%)	5 to 80	5 to 80	25 *In noninvasive modes:* 35	25 *In noninvasive modes:* 35	
Flow trigger[3] (l/min)	*(S)CMV+, PCV+:* 1 to 20, Off *Other modes:* 1 to 20	*(S)CMV+, PCV+:* 0.1 to 5.0, Off *Other modes:* 0.1 to 5.0	5	0.5	±10%
Height	*See Pat. height*				
I:E[11]	1:9 to 4:1	1:9 to 4:1	1:4	1:3	
IBW	*See Table A-8*				
%MinVol[4] (%)	25 to 350	--	100	--	
Mode	(S)CMV+, PCV+, SIMV+, PSIMV+, SPONT, ASV, NIV, NIV-ST, DuoPAP, APRV	(S)CMV+, PCV+, SIMV+, PSIMV+, SPONT, nCPAP-PC, nCPAP, NIV, NIV-ST, Duo-PAP, APRV	ASV	PSIMV+	
Oxygen (%)	21 to 100	21 to 100	50	40	± (volume fraction of 2.5% + 2.5% gas level)
Pasvlimit[4] (cmH2O)	5 to 60	--	30	--	

Table A-6. Control settings, ranges and accuracy *(continued)*

Parameter or Setting (units)	Range		Default settings		Accuracy[1]
	Adult/Ped	Neonatal	Adult/Ped	Neonatal	
Pat. height (cm) (in)	30 to 250 12 to 98	--	174 70	--	
Pcontrol[5] (cmH2O)	5 to 60	*nCPAP-PC:* 0 to 45 *Other modes:* 3 to 45	15	15	±5% or ±1 cmH2O, whichever is greater *Neo:* ±5% or ±0.5 cmH2O, whichever is greater
PEEP/CPAP (cmH2O)	0 to 35	3 to 25	5	5	±5% or ±1 cmH2O, whichever is greater *Neo:* ±5% or ±0.5 cmH2O, whichever is greater
Pinsp[6] (cmH2O)	3 to 60	3 to 45	15	15	±5% or ±1 cmH2O, whichever is greater *Neo:* ±5% or ±0.5 cmH2O, whichever is greater
P high (cmH2O) *in DuoPAP*	0 to 60 *absolute pressure*	3 to 45 *absolute pressure*	20	20	±5% or ±1 cmH2O, whichever is greater *Neo:* ±5% or ±0.5 cmH2O, whichever is greater

Table A-6. Control settings, ranges and accuracy *(continued)*

Parameter or Setting (units)	Range		Default settings		Accuracy[1]
	Adult/Ped	Neonatal	Adult/Ped	Neonatal	
P high (cmH2O) *in APRV*	0 to 60 *absolute pressure*	0 to 45 *absolute pressure*	20 *startup setting = PEEP+15*	20 *startup setting = PEEP+15*	±5% or ±1 cmH2O, whichever is greater *Neo:* ±5% or ±0.5 cmH2O, whichever is greater
P low (cmH2O) *in APRV*	0 to 35	0 to 25	5	5	±5% or ±1 cmH2O, whichever is greater *Neo:* ±5% or ±0.5 cmH2O, whichever is greater
P-ramp[7] (ms)	0 to 2000 *ASV, NIV, NIV-ST, SPONT:* max = 200	0 to 600 *NIV, NIV-ST, SPONT, nCPAP-PC:* max = 200	100	50	±10 ms
Psupport[8] (cmH2O)	0 to 60	0 to 45	15	15	±5% or ±1 cmH2O, whichever is greater *Neo:* ±5% or ±0.5 cmH2O, whichever is greater

Table A-6. Control settings, ranges and accuracy *(continued)*

Parameter or Setting (units)	Range		Default settings		Accuracy[1]
	Adult/Ped	Neonatal	Adult/Ped	Neonatal	
Rate[13] (b/min)	*(S)CMV+, PCV+:* 4 to 80 *PSIMV+, NIV-ST:* 5 to 80 *Other modes:* 1 to 80	*(S)CMV+, PCV+, PSIMV+, NIV-ST:* 15 to 80 *PSIMV (non-Intellisync):* 5 to 80 *nCPAP-PC:* 10 to 80 *Other modes:* 1 to 80	*3.0 to 5.8 IBW:* 38 *5.9 to 8.0 IBW:* 32 *8.1 to 20.0 IBW:* 25 *20.1 to 29.9 IBW:* 19 *30 to 39 IBW:* 17 *40 to 59 IBW:* 15 *60 to 200 IBW:* 12	*0.2 to 1.25 kg:* 60 *1.26 to 3.0 kg:* 45 *3.1 to 5.9 kg:* 35 *6.0 to 8.9 kg:* 30 *9.0 to 20.5 kg:* 25 *21 to 30 kg:* 20	±1 b/min
Sex	Male, Female	not shown	Male		
Sigh[9]	On, Off		Off		
T high[13] (s) *in DuoPAP*	0.1 to 40	0.1 to 40	*based on rate (IBW) and I:E = 1:4*	*based on rate (Weight) and I:E = 1:3*	±0.01
T high[13] (s) *in APRV*	0.1 to 40	0.1 to 40	5.4 *based on IBW*	1.4 *based on Weight*	±0.01
TI[10,11,13] (s)	0.1 to 12	0.1 to 12	*based on rate (IBW) and I:E = 1:4*	*based on rate (Weight) and I:E = 1:3*	±0.01
TI max[12] (s)	1 to 3	0.25 to 3.0	1.5	1.0 ≤ 10 kg 1.5 > 10 kg	± 0.1
T low (s) *in APRV*	0.2 to 40	0.2 to 40	0.6 *based on IBW*	0.2 *based on Weight*	± 0.01

Table A-6. Control settings, ranges and accuracy *(continued)*

Parameter or Setting (units)	Range		Default settings		Accuracy[1]
	Adult/Ped	Neonatal	Adult/Ped	Neonatal	
Vt[13] (ml)	20 to 2000	2 to 300	560	10 *based on 2 kg body weight*	Adult: ±10% or ±10 ml, whichever is greater *Neo:* ±10% or ±2 ml, whichever is greater
VT/kg[14] (ml/kg)	5 to 12	5 to 12	8	5	
Weight[15] (kg)	--	0.2 to 30.0	--	2.0	

1. The stated accuracy includes the tolerance interval for each measurement. See Section A.11.1 for details.
2. Expiratory trigger sensitivity, in % of inspiratory peak flow.
3. Flow trigger is leak compensated.
4. In ASV mode only.
5. Control pressure, added to PEEP/CPAP.
6. Inspiratory pressure, added to PEEP/CPAP.
7. P-ramp is limited by 1/3 of TI time. Adjustment of TI time can override P-ramp setting.
8. Pressure support, added to PEEP/CPAP.
9. Sigh is disabled in DuoPAP, APRV, and for neonates.
10. Inspiratory time; used with Rate to set the breath cycle time.
11. In PCV+ and (S)CMV+ modes, mandatory breath timing can be controlled by using a combination of inspiratory time (TI) and rate, or by the I:E ratio; set the method in Configuration. All other modes are controlled by using a combination of inspiratory time (TI) and rate.
12. Maximum inspiratory time for spontaneous breaths during noninvasive ventilation.
13. Startup setting derived from body weight setting (neonates), IBW (adults/pediatrics).
14. Set in configuration.
15. Actual body weight, used for neonates only. For adults and pediatrics, ideal body weight (IBW) is calculated instead.

Table A-7. Controls active in HAMILTON-MR1 ventilation modes

Mode type	Closed-loop	Mandatory		SIMV				DuoPAP/APRV		Pressure support		Neonatal	
Mode	**ASV**	**PCV+**	**(S)CMV+**	**PSIMV+ IntelliSync**	**PSIMV+**	**SIMV+**	**NIV-ST**	**DuoPAP**	**APRV**	**SPONT**	**NIV**	**nCPAP**	**nCPAP-PC**
Timing	--	Rate							Tlow	--			Rate
	--	I:E		TI				Thigh		--			TI
Mandatory breaths	--	Pcon-trol	Vt	Pinsp	Pcon-trol	Vt	Pinsp	Phigh		--			Pcontrol
Spontaneous breaths	--				Psupport			Psupport	--	Psupport			
	ETS	--		ETS					--	ETS			
	--						TImax	--		--	TImax		
Baseline pressure	PEEP/CPAP								Plow	PEEP/CPAP		PEEP/ CPAP	PEEP/ CPAP
General	Flowtrigger												
	P-ramp												
	Oxygen												
	Gender												
	Patient height												
ASV-specific	%MinVol	--											
	Pasvlimit	--											

A.7 Monitored parameters

Table A-8 provides the monitored parameter ranges, default settings, and accuracy of measurements. Definitions of the parameters are provided in Table 7-2.

Table A-9 lists the ranges of the real-time curves and loops. Pressure, flow, and volume measurements are based on readings from the flow sensor, and are expressed in BTPS (body temperature and pressure saturated).

You can show all monitored parameters as 1-, 6-, 12-, 24-, or 72-h trends[1].

Table A-8. Monitored parameters, ranges, and accuracy

Parameter (units)	Range		Accuracy[1]
	Adult/Ped	Neonatal	
Pressure			
PEEP/CPAP (cmH2O)	0 to 80	0 to 80	± (2% of full scale reading + 4% of actual reading)
Pinsp[2] (cmH2O)	0 to 80	--	± (2% of full scale reading + 4% of actual reading)
Pmean (cmH2O)	0 to 80	0 to 80	± (2% of full scale reading + 4% of actual reading)
Ppeak (cmH2O)	0 to 80	0 to 80	± (2% of full scale reading + 4% of actual reading)
Pplateau (cmH2O)[3]	0 to 80	0 to 80	± (2% of full scale reading + 4% of actual reading)
AutoPEEP[3] (cmH2O)	0 to 80	0 to 80	

1. 72-h trends not available in all markets.

Table A-8. Monitored parameters, ranges, and accuracy *(continued)*

Parameter (units)	Range		Accuracy[1]
	Adult/Ped	Neonatal	
Flow			
Insp flow, peak (l/min)	0 to 260	0 to 260	*Adult:* ±10% or 20 ml/s, whichever is greater *Neo:* ±10% or 2 ml/s, whichever is greater
Exp flow, peak (l/min)[3]	0 to 260	0 to 260	*Adult:* ±10% or 20 ml/s, whichever is greater *Neo:* ±10% or 2 ml/s, whichever is greater
Flow[4,5] (l/min)	--	0 to 30	±10% or 20 ml/s, whichever is greater
Volume			
ExpMinVol[3,6] or MinVol NIV[3,7] *(l/min)*	0 to 99.9	0 to 99.9	±10% or ±0.3 l/min, whichever is greater
MVSpont[3,6] or MVSpont NIV[3,7] *(l/min)*	0 to 99.9	0 to 99.9	±10% or ±0.3 l/min, whichever is greater
VTE[3,6] or VTE NIV[3,7] *(ml)*	0 to 9000	0 to 9000	*Adult:* ±10% or ±10 ml, whichever is greater *Neo:* ±10% or ±2 ml, whichever is greater
VTI[3] (ml)	0 to 9000	0 to 9000	*Adult:* ±10% or ±10 ml, whichever is greater *Neo:* ±10% or ±2 ml, whichever is greater

Table A-8. Monitored parameters, ranges, and accuracy *(continued)*

Parameter (units)	Range		Accuracy[1]
	Adult/Ped	Neonatal	
VLeak[3] (%)	0 to 100	0 to 100	±10% (for leak volumes between 100 and 2000 ml)
MVLeak[3] (l/min)	0 to 99.9	0 to 99.9	±10% or ±0.3 l/min, whichever is greater
Time			
I:E	9.9:1 to 1:99	9.9:1 to 1:99	--
fControl (b/min)	0 to 999	0 to 999	±1
fSpont[3] (b/min)	0 to 999	0 to 999	±1
fTotal (b/min)	0 to 999	0 to 999	±1
TI (s)	0 to 60	0 to 60	±100 ms
TE (s)	0 to 60	0 to 60	±100 ms
Other calculated and displayed parameters			
Cstat[3] (ml/cmH2O)	0 to 200	0 to 200	--
IBW[8] (kg)	3 to 139 *default:* 70	--	--
P0.1[3] (cmH2O)	-99 to 0	-99 to 0	--
PTP[3] (cmH2O * s)	0 to 100	0 to 100	--
RCexp[3] (s)	0.0 to 99.9	0.0 to 99.9	--
Rinsp[3] (cmH2O / l/s)	0 to 999	0 to 999	--
Trigger	No or Yes	No or Yes	
VTESpont[3] (ml)	0 to 9000	0 to 9000	±10% or ±10 ml, whichever is greater
Weight[8] (kg)	--	0.2 to 30 kg	

Table A-8. Monitored parameters, ranges, and accuracy *(continued)*

Parameter (units)	Range		Accuracy[1]
	Adult/Ped	Neonatal	
Oxygen			
Oxygen[9] (%)	3 to 105	3 to 105	± (volume fraction of 2.5% + 2.5% of actual reading)
O2 consumption[10] (l/min)	0 to 300	0 to 300	±10% or ±0.3 l/min, whichever is greater,

1. The stated accuracy includes the tolerance interval for each measurement. See Section A.11.1 for details.
2. Target inspiratory pressure in ASV mode.
3. *Not* applicable to nCPAP and nCPAP-PC modes.
4. *Only* applicable to nCPAP and nCPAP-PC modes.
5. A trend graph cannot be generated using the Flow parameter.
6. Used only with invasive modes.
7. The NIV parameter is used with noninvasive modes.
8. IBW is calculated using height and sex, and is used for adult and pediatric patients. Actual body weight is used for neonates.
9. A high setting of 105 is not available in all markets; in these cases, the high limit is 103.
10. Displayed after first 2.5 min of ventilation.

Table A-9. Real-time waveforms and loops

Parameter	Range		Scale
	Adult/Ped	Neonatal	
Real-time waveforms *All waveforms show Time on the x-axis. For adults/pediatrics, the time scale is 15 s; for neonates, 6 s.*			
Volume[1,2] (V) (ml) / time (s)	0 to 3200	0 to 300	0 to 5, 0 to 10, 0 to 25, 0 to 50 *(default Neo)*, 0 to 100, 0 to 200, 0 to 400, 0 to 800 *(default Adult)*, 0 to 1600, 0 to 3200
Flow[1,2] (l/min) / time (s)	-300 to 300	-30 to 30	±2.5, ±5, ±10 *(default Neo)*, ±15, ±25, ±45, ±75 *(default Adult)*, ±150, ±300
Airway pressure (Paw) (cmH2O) / time (s)	-10 to 80	-10 to 80	10/20, -10/40 *(default)*, -10/80

Table A-9. Real-time waveforms and loops *(continued)*

Parameter	Range		Scale
	Adult/Ped	**Neonatal**	
ASV graphs			
ASV target graphics: Tidal volume (Vt) (ml) / time (s)	0 to 3200	--	0 to 5, 0 to 10, 0 to 25, 0 to 50, 0 to 100, 0 to 200, 0 to 400, 0 to 800 *(default)*, 0 to 1600, 0 to 3200
ASV target graphics: Tidal volume (Vt) *(ml)* / / rate *(b/min)*	0 to 60	--	0 to 60
Loops[1]			
Pressure/Volume	x: 0 to 3200	x: 0 to 300	
x-axis: ml *y-axis: cmH20*	y: -10 to 80	y: -10 to 80	
Volume/Flow	x: 0 to 3200	x: 0 to 300	
x-axis: ml *y-axis: l/min*	y: -300 to 300	y: -30 to 30	
Pressure/Flow	x: -300 to 300	x: -30 to 30	
x-axis: l/min *y-axis: cmH20*	y: -10 to 80	y: -10 to 80	

1. Not applicable to nCPAP and nCPAP-PC modes.
2. Scaled automatically. Not leak compensated.

A.8 Alarms

Table A-10 provides details about the adjustable alarms, including priority, upper and lower limit range, default settings, and resolution. For alarm definitions and troubleshooting, see Table 9-2 in Chapter 9.

For additional details about alarms, see Chapter 5 and Chapter 9.

Table A-10. Adjustable alarm priority, range, defaults, and resolution

Alarm (units)	Priority	Range		Default setting		Resolution
		Adult/Ped	Neo	Adult/Ped	Neo	
Apnea time[9] (s)	*Adult:* High *Neonatal:* Medium	15 to 60	5 to 60	20[1]	15[1]	*Adult:* 5 s *Neonatal:* 1 < 15 s 5 ≥ 15
ExpMinVol, low [2,9] (l/min)	High	*in NIV, NIV-ST:* OFF/0.1 to 50/ OFF *other modes:* 0.1 to 50	OFF/0.01 to 10	4 *0.6 * Rate * Vt*	0.27 *0.6 * Rate * Vt*	*Adult:* 0.1 < 1 l/ min 0.5 ≥ 1 1 ≥ 10 *Neo:* 0.01 < 1 0.1 ≥ 1
ExpMinVol, high [2,9] (l/min)	High	*in NIV, NIV-ST:* 0.1 to 50/OFF *other modes:* 0.1 to 50	0.03 to 10/OFF	10 *1.5 * Rate * Vt*	0.67 *1.5 * Rate * Vt*	*Adult:* 0.1 < 1 l/ min 0.5 ≥ 1 1 ≥ 10 *Neo:* 0.01 < 1 0.1 ≥ 1
Flow (high)[3] (l/ min)	Medium; Low after silence	--	8 to 30	--	15	1
fTotal, low[9] (b/min)	Medium	0 to 99	0 to 200	0	0	1
fTotal, high[9] (b/min)	Medium	0 to 99	2 to 210	40	70	1

Table A-10. Adjustable alarm priority, range, defaults, and resolution *(continued)*

Alarm (units)	Priority	Range		Default setting		Resolution
		Adult/Ped	Neo	Adult/Ped	Neo	
Oxygen, low[4,5] (%)	High	18 to 97	18 to 97	45	45	1
Oxygen, high[4,5] (%)	High	18 to 105[6]	18 to 105[6]	55	55	1
Pressure, high (Pmax) (cmH2O)	High	15 to 70	*nCPAP, nCPAP-PC:* 10 to 55 *APRV:* 15 to 55 *other modes:* 18 to 55	40	40 *nCPAP:* 15 *nCPAP-PC:* Pcon-trol+PEEP +5	1
Pressure, low (cmH2O)	High	4 to 60	*nCPAP, nCPAP-PC:* 2 to 55 *other modes:* 4 to 55	PEEP	PEEP *nCPAP:* 3 *nCPAP-PC:* PEEP at startup	1
Pressure limita-tion (cmH2O)	Medium; Low after silence	5 to 60	*nCPAP, nCPAP-PC:* Pmax *APRV:* 5 to 45 *other modes:* 8 to 45	Pmax - 10	Pmax - 10	1

Table A-10. Adjustable alarm priority, range, defaults, and resolution *(continued)*

Alarm (units)	Priority	Range		Default setting		Resolution
		Adult/Ped	Neo	Adult/Ped	Neo	
Vt, low[7,9] (ml)	Medium	OFF[8]/10 to 3000	OFF[8,9]/ 0.1 to 300	280 *0.5 * Vt*	5 *0.5 * Vt*	*Adult:* OFF 5 < 100 ml 10 ≥ 100 and < 500 50 ≥ 500 *Neo:* OFF 0.1 < 10 1 ≥ 10 and < 100 5 ≥ 100
Vt, high[7,9] (ml)	Medium	10 to 3000/ OFF[9]	0.1 to 300/OFF[9]	850 *1.5 * Vt*	15 *1.5 * Vt*	*Adult:* OFF 5 < 100 ml 10 ≥ 100 and < 500 50 ≥ 500 *Neo:* OFF 0.1 < 10 1 ≥ 10 and < 100 5 ≥ 100

1. The default setting is configurable.
2. Startup setting derived from body weight setting (neonates), IBW (adults/pediatrics).
3. Only active in nCPAP and nCPAP-PC modes.
4. Active only when O2 monitoring (O2 sensor) is enabled.
5. The high and low oxygen alarm limits are automatically set in relation to the current oxygen setting as follows: O2 setting + 5 (Oxygen high limit) and O2 setting - 5 (Oxygen low limit). For example, if the Oxygen setting is 70%, the Oxygen high limit is set to 75 and the low limit is set to 65.
6. A high setting of 105 is not available in all markets; in these cases, the high limit is 103.
7. In ASV mode, this alarm only applies for spontaneous breaths.
8. OFF available in NIV, NIV-ST, and neonatal modes (other than nCPAP/nCPAP-PC).
9. Not applicable to nCPAP and nCPAP-PC modes.

A.9 Configuration specifications

The following table lists the parameters and settings that can be specified in the Configuration windows. For details, see Appendix G.

Table A-11. Configuration specifications

Parameter	Configuration range	Default setting
General		
Language	English, Chinese, Croatian, Czech, Danish, Dutch, Finnish, French, German, Greek, Hungarian, Indonesian, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Spanish, Swedish, Turkish	English
Units	Pressure: hPa, mbar, cmH2O Length: cm, inch	cmH20 cm
More	Minimum alarm loudness	1
Modes		
Philosophy	PCV+ / SIMV+: I:E, TI Mode label: (S)CMV+ / SIMV+, APVcmv / APVsimv	I:E (S)CMV+ / SIMV+
Graphics		
MMP[1]	MMP 1 to 4: Pmean, PEEP/CPAP, Ppeak, ExpMinVol, VTI, VTE, VLeak, fTotal, fSpont, Oxygen, Cstat, Rinsp, I:E, TI, TE, MVSpont, AutoP-EEP, P0.1, PTP, RCexp, Pplateau, VTES-pont	Ppeak[2], ExpMinVol, VTE, fTotal
Settings	For all mode, control, and alarm settings, see the appropriate tables in this appendix.	
Setups	The settings shown in this table apply to the default adult setups. You can also specify default neonatal settings.	
Mode Ctrls		
	Vt/IBW: 6 to 12 ml/kg	Adult: 8 ml/kg Neonatal: 5 ml/kg

Table A-11. Configuration specifications *(continued)*

Parameter	Configuration range	Default setting
Vent Status		
Oxygen[3] (%)	22 to 80	40
PEEP[4] (cmH2O)	1 to 20	8
Pinsp (cmH2O)	1 to 50	10
%MinVol high *(%)*	100 to 250	150
%MinVol low *(%)*	25 to 99	50
RSB *high* *(1/(l*min))*	50 to 150	100
RSB *low* *(1/(l*min))*	0 to 49	10
%fSpont[5] (%)	0 to 99	75

1. Additional parameters available when the Neonatal option is installed.
2. The default setting is configurable.
3. The low Oxygen setting is always 21%.
4. The low PEEP setting is always 0 cmH2O.
5. The high %fSpont setting is always 100%.

A.10 Ventilator breathing system specifications

The following table lists specifications for the HAMILTON-MR1 ventilator breathing system.

Table A-12. Breathing system specifications, Adult/Ped

Parameter	Specifications
Resistance	Coaxial circuit, 3.0 and 4.8 m: < 0.2 kPa at 30 l*min-1 (nominal flow rate)
Compliance	Coaxial circuit, 3.0 and 4.8 m: < 10 ml*kPa-1 per meter of tube length
Volume	Coaxial circuit, 3.0 m: Approximately 2.0 l Coaxial circuit, 4.8 m: Approximately 3.2 l Flow sensor: 9 ml (single-use) or 11 ml (reusable)
Bacteria filter	Particle size: Captures particles of 0.3 µm (micrometer) with > 99.99% efficiency Resistance: < 2 mbar at 60 l/min
Flow sensor dead space	< 9 ml (single use) and < 11 ml (reusable)

A.11 Technical performance data

Table A-13 lists technical performance data for the ventilator.

Table A-13. Technical performance data

Description	Specification
Patient ideal body weight (IBW, determined from Pat. height setting)	3 to 139 kg (6.6 to 306 lb)[1]
Weight (used for neonatal patients)	0.2 to 30 kg (0.44 to 66 lb)
Inspiratory pressure	0 to 60 cmH2O
Maximum limited pressure	60 cmH2O
Maximum working pressure	Adults/ped: 0 to 60 cmH2O (a combination of PEEP/CPAP and Pinsp). Ensured through pressure limiting. Neonatal: Limitation depending on frequency, to a maximum of 45 cmH20 at frequency of 80
Maximum inspiratory flow	260 l/min (120 l/min with 100% O2)

Table A-13. Technical performance data *(continued)*

Description	Specification
Tidal volume/target tidal volume	Adults/ped: 20 to 2000 ml Neonatal: 2 to 300 ml
Minute volume capability	Up to 60 l/min
Inspiratory time (spontaneous breaths)	0.2 to 3 s
Minimum expiratory time	20% of cycle time; 0.2 to 0.8 s
Automatic expiratory base flow	Adults/ped: fixed at 3 l/min Neonatal: fixed at 4 l/min
Means of inspiratory triggering	Flow (flow trigger control setting)
Oxygen mixer accuracy	± (volume fraction of 2.5% + 2.5% of actual reading)
Measuring devices	Continuous oxygen measurement Measurement: Delivered oxygen concentration, range: 18% to 105% Response time: < 45 s to reach 90% of final oxygen concentration Initialization time (time from turning device on until operating performance): < 40 s Drift: ≤ 2.5% at 60% Oxygen over 6 h
Tests and special functions	Tightness test, flow sensor/circuit/O2 cell/CO2 sensor calibration, O2 enrichment, manual breath, inspiratory hold maneuver, nebulization (30 min, 8 l/min), leak compensation, communication interface, compensation of breathing circuit resistance and compliance
Display device	Display of settings, alarms, and monitored data: Type: TFT color Size: 640 x 480 pixels, 8.4 in (134 mm) diagonal
Brightness setting for display	The range is 10% to 100% brightness. By default, Day is set to 80%; Night is set to 40%.
Alarm volume (Loudness[2])	The range is 1 to 10. The default for adults is 5, for neonates, 3.
Sound power level[3]	50 dB(A) ±3 dB(A)
Sound pressure level[3]	42 dB(A) ±3 dB(A)

1. Actual patient weight can be much greater (e.g., 300 kg or 661 lb)
2. Volume at 1 m distance from ventilator. A setting of 1 = 60 dB(A), 5 = 70 dB(A), and 10 = 83dB(A), with accuracy of ±3 dB(A).
3. Per ISO 80601-2-12

A.11.1 Accuracy testing

The ventilator's parameter and measurement accuracy is tested using an IMT FlowAnalyser™. The tolerance intervals for the data generated by the FlowAnalyser are as specified below, and are included in the accuracy information provided in this manual.

Table A-14. Tolerance intervals for accuracy testing

Parameter type	Tolerance interval of measurement
Volume	≤ 50 ml: ±1% > 50 ml: ±1.75%
Pressure	±0.75% or ±0.1 cmH20, whichever is greater
Flow	±1.75% or ±0.5 l/min, whichever is greater
O2	±1%

Test equipment intended to test a pulse oximeter probe's or a pulse oximeter monitor's function cannot be used to assess their accuracy.

A.11.2 Essential performance

Table A-15. Essential performance

Component	Requirement
Gas supply failure	Gas supply failure must be detected and the operator informed.
Oxygen level alarm condition	If O2 is higher or lower than the set alarm limits, this must be detected and the operator informed through an alarm.
Pressure	The airway pressure must be monitored. If it is higher or lower than the set alarm limits, this must be detected and the operator informed through an alarm.
Volume	The applied and expired volumes must be monitored. If they are higher or lower than the set alarm limits, this must be detected and the operator informed through an alarm.
Electrical supply failure	An electrical supply failure must be detected and the operator informed.

Table A-15. Essential performance

Component	Requirement
Internal electrical power source nears depletion	The remaining battery capacity must be monitored and qualitatively indicated. At last 5 min prior to depletion, an alarm must be issued.
MR conditional	No effect on the ventilator's functionality or other above-mentioned essential performance from a 1.5T and 3T MRI scanner, when the ventilator is placed at a magnetic field gradient line of less than 50 mT.

A.12 Standards and approvals

NOTE:

Where standards are mentioned, the HAMILTON-MR1 complies with the versions listed in Table 1 on page ix.

The HAMILTON-MR1 was developed in accordance with pertinent international standards.

The ventilator is manufactured within an EN ISO 13485 and EN ISO 9001, Council Directive 93/42/EEC, Annex II, Article 3 certified quality management system.

The ventilator meets the Essential Requirements of Council Directive 93/42/EEC, Annex I.

The ventilator meets relevant parts of the following standards, among others:

- **IEC 60601-1:** Medical electrical equipment, Part 1: General requirements for basic safety and essential performance. The device classification is: Class I, Type B applied part (ventilator breathing system, VBS), continuous operation
- **IEC 60601-1-2:** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- **ISO 80601-2-12:** Medical electrical equipment - Part 2-12: Particular requirements for the basic safety and essential performance of critical care ventilators
- **CAN/CSA-C22.2 No. 60601-1:** Lung ventilators - Part 1: Particular requirements for critical care ventilators
- **ANSI/AAMI ES60601-1:** Medical electrical equipment: General requirements for safety
- **ASTM F2503-8:** Standard practice for marking medical devices for safety in the magnetic resonance environment.
- **EN ISO 5356-1:** Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
- **MIL-STD-461F:** Control of electromagnetic interference
- **ISO 80601-2-55:** Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

- **EN ISO 5359:** Low-pressure hose assemblies for use with medical gases

A.13 EMC declarations (IEC 60601-1-2)

The HAMILTON-MR1 ventilator is intended for use in the electromagnetic environment specified in Tables A-16 and A-17. The customer or the user of the HAMILTON-MR1 ventilator should ensure that it is used in such an environment.

The HAMILTON-MR1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HAMILTON-MR1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HAMILTON-MR1 as recommended in Table A-16, according to the maximum output power of the communications equipment.

The HAMILTON-MR1 has been fully tested to ensure that is does not interfere with the MR scanner in any manner in the MRI environment when the ventilator is used as specified.

NOTE:

- U_T is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table A-16. Guidance and manufacturer's declaration – electromagnetic emissions (IEC 60601-1-2)

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The HAMILTON-MR1 ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11, conducted	Class B	The HAMILTON-MR1 ventilator is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **The HAMILTON-MR1 is not intended for home use.**
RF emissions CISPR 11, radiated	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table A-17. Guidance and manufacturer's declaration – electromagnetic immunity (IEC 60601-1-2)

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV (line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Table A-17. Guidance and manufacturer's declaration – electromagnetic immunity (IEC 60601-1-2) *(continued)*

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HAMILTON-MR1 ventilator requires continued operation during power mains interruptions, it is recommended that the HAMILTON-MR1 ventilator be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1] 10 Vrms 150 kHz to 80 MHz in ISM bands[1]	10 V 10 V	Portable and mobile RF communications equipment should be used no closer to any part of the HAMILTON-MR1 ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 0.35\sqrt{P}$ $d = 1.2\sqrt{P}$

Table A-17. Guidance and manufacturer's declaration – electromagnetic immunity (IEC 60601-1-2) *(continued)*

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).[2] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[3], should be less than the compliance level in each frequency range[4]. Interference may occur in the vicinity of equipment marked with the symbol 

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulas used in calculating the recommended separation distance for transmitters in these frequency ranges.
3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HAMILTON-MR1 ventilator is used exceeds the applicable RF compliance level above, the HAMILTON-MR1 ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HAMILTON-MR1 ventilator.
4. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table A-18. Recommended separation distances between portable and mobile RF communications equipment and the HAMILTON-MR1 ventilator

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	Conducted RF		Radiated RF	
	150 kHz to 80 MHz outside ISM bands $d = 0.35\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23

NOTES:

- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- An additional factor of 10/3 has been incorporated into the formulas used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

A.14 Warranty

LIMITED WARRANTY

THE WARRANTY DESCRIBED IN THIS AGREEMENT IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. HOWEVER, IMPLIED WARRANTIES ARE NOT DISCLAIMED DURING THE PERIOD OF THIS LIMITED WARRANTY.

Hamilton Medical guarantees its products to be shipped free from defects in material and workmanship. The warranty does not include disposable items. Disposable items and consumable products are considered to be of single use or of limited use only and must be replaced regularly as required for proper operation of the product following the operator's manual.

Hamilton Medical and the manufacturer shall have no obligations nor liabilities in connection with the product other than what is specified herein, including without limitation, obligations and/ or liabilities for alleged negligence, or for strict liability. In no event shall the company be liable for incidental or consequential damages, either direct or contingent.

This Limited Warranty shall be void and not apply:

1. If the product has not been installed and connected by an authorized local representative of Hamilton Medical in accordance with the instructions furnished by Hamilton Medical and by a Hamilton Medical representative.
2. If replacements and/or repairs have not been performed by authorized or properly trained personnel.
3. If no evidence is present that the occurrence of damage/ repair happened within the certified warranty period.
4. If the serial number has been altered, effaced or removed and there is no bill of sale or evidence to verify the product's purchase date.
5. If the defects arise from misuse, negligence, or accidents or from repair, adjustment, modification or replacement made outside Hamilton Medical's factories or other than an authorized service center or authorized service representative.
6. If the product has been modified, or in any nature altered without prior written authorization from Hamilton Medical.
7. If yearly maintenance is not performed.

8. If the product is or has been used in any way that is not specified under “Intended Use” (see “General cautions and notes”).
9. If the product has been used by anyone, but properly trained personnel under the supervision of a physician.

Replacements and/or repairs furnished under this Limited Warranty do not carry a new warranty, but carry only the unexpired portion of the original Limited Warranty. The warranty of repaired and/or replaced components does not exceed the Limited Warranty of the device.

To obtain service under this Limited Warranty, claimant must promptly notify the country’s sales partner of Hamilton Medical regarding the nature of the problem, serial number and the date of purchase of the Product.

Except as stated above, Hamilton Medical shall not be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages. Nor will Hamilton Medical be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages resulting from misuse of the device or failure to comply with any of the provisions made in this manual.

A.15 Miscellaneous

The general terms and conditions of Hamilton Medical shall be applicable. This agreement shall be governed by and construed in accordance with the laws of Switzerland and may be enforced by either party under the jurisdiction of the court of Chur, Switzerland.

APPENDIX

B Modes of ventilation

B.1 Introduction

NOTE:

- For details about the neonatal-only nCPAP and nCPAP-PC modes, see Chapter 6.
- Some modes use different parameters for the Neonatal patient group. When present, these differences are shown.
- The Sigh setting is only for adult/pediatric patients. It does not apply to neonatal patients.

This section discusses the principles of operation for the HAMILTON-MR1 ventilation modes. It lays the groundwork by describing the biphasic concept, which is at the heart of the device's pneumatic design and which is vital to understanding how the HAMILTON-MR1 ventilates in all modes.

The HAMILTON-MR1 has a full range of ventilation modes that provide full and partial ventilatory support. Table B-1 classifies these modes according to a scheme developed by Branson et al[1]. The table classifies modes based on primary breath type and characteristics of mandatory breaths in that mode. Table A-7 lists the controls active in all modes.

Volume modes in the HAMILTON-MR1 are delivered by an adaptive volume controller. Combining the advantages of pressure-controlled ventilation with volume-targeted ventilation, the adaptive volume controller ensures that the target tidal volume is delivered but without undue application of pressure, even when lung characteristics change. The operation of the adaptive volume controller is described as part of the (S)CMV+ mode description, Section B.3.1.

1. Branson RD, Hess DR, Chatburn RL. Respiratory Care Equipment. Philadelphia: Lippincott Williams & Wilkins Publishers, 1999;359-93.

The HAMILTON-MR1 modes have these general characteristics:

- **Mandatory breaths.** See Table B-1 for information on mandatory breaths as they apply to the various modes. Not listed in the table are operator-initiated mandatory (manual) breaths, which are pressure controlled and time cycled. Mandatory breaths have a decelerating flow waveform.
- **Spontaneous breaths.** Spontaneous breathing is allowed in all modes at any time. Additionally, in PSIMV+, SPONT, SIMV+, NIV, NIV-ST, and DuoPAP, spontaneous breaths are pressure supported and time cycled if the users set flow trigger threshold is passed. In the modes (S)CMV+ and PCV+, a spontaneous effort of the patient activating the flow trigger, results in a pressure controlled and time cycled breath.
- **Triggering.** Breaths can be patient (flow) triggered in all modes except nCPAP and nCPAP-PC, based on an operator-set flow sensitivity. All modes permit operator-initiated manual breaths.
- **Pressure.** A positive baseline pressure (PEEP/CPAP) may be set for all breaths in all modes.
- **Pressure rise time.** An operator-set pressure ramp (P-ramp) defines the time required for inspiratory pressure to rise to the set (target) pressure.
- **FiO2**. FiO2 can be set in all modes except when oxygen is provided by a low-pressure supply.

Table B-1. Classification of HAMILTON-MR1 ventilation modes

Mode name	Breathing pattern[1]	Mandatory breaths			
		Control type[2]	Trigger[3]	Limit[4]	Cycle[5]
PCV+	PC-CMV	Setpoint	F, T	P	T
	Operational logic: Every breath is pressure controlled and mandatory.				
PSIMV+	PC-IMV	Setpoint	F, T	P	T, F
	Operational logic: Mandatory breaths are pressure controlled.				

Table B-1. Classification of HAMILTON-MR1 ventilation modes *(continued)*

Mode name	Breathing pattern[1]	Mandatory breaths			
		Control type[2]	Trigger[3]	Limit[4]	Cycle[5]
SPONT	PC-CSV	Setpoint	F	P	F
	Operational logic: Every breath is spontaneous.				
(S)CMV+ (APVcmv)	PC-CMV	Adaptive	F, T	V, P	T
	Operational logic: Every breath is volume targeted and mandatory.				
SIMV+ (APVsimv)	PC-IMV	Adaptive	F, T	V, P	T
	Operational logic: Mandatory breaths are volume targeted.				
NIV	PC-CSV	Setpoint	F	P	F
	Operational logic: Every breath is spontaneous. Leakage is compensated for.				
NIV-ST	PC-IMV	Setpoint	F, T	P	T, F
	Operational logic: Mandatory breaths are pressure controlled. Leakage is compensated for.				
DuoPAP	PC-IMV	Setpoint	F, T	P	F, T
	Operational logic: Mandatory breaths are pressure controlled. Leakage is compensated for.				
APRV	PC-APRV	Setpoint	T	P	T
	Operational logic: Mandatory breaths are pressure controlled. Leakage is compensated for.				
nCPAP	PC-IMV	---	---	Pressure	Time
nCPAP-PC	PC-IMV	Set-point or adaptive	Time	Pressure	Time

1. A designator that combines the primary control variable (PC = pressure control) for the mandatory breaths (or in CSV, for the spontaneous breaths) with the breath sequence (CMV = continuous mandatory ventilation – all breaths are mandatory, IMV = intermittent mandatory ventilation – spontaneous breaths between mandatory breaths, CSV = continuous spontaneous ventilation –all breaths are spontaneous). The control variable is the independent variable that the ventilator manipulates to cause inspiration.
2. The way pressure and volume are controlled within or between breaths. Setpoint means the ventilator output automatically matches a constant, unvarying, operator preset input value (like the production of a constant inspiratory pressure or tidal volume from breath to breath). Optimum is a control scheme that uses automatic adjustment of setpoints to optimize other variables as respiratory mechanics change. Adaptive control means one setpoint (e.g., the pressure limit) of the ventilator is automatically adjusted over several breaths to maintain another setpoint (e.g., the target tidal volume) as the mechanics of the respiratory system change.
3. A trigger variable starts inspiration.
4. A limit variable can reach and maintain a preset level before inspiration ends but it does not end inspiration.
5. A cycle variable is a measured parameter used to end inspiration.

B.2 The biphasic concept

It is widely accepted that early spontaneous breathing is beneficial for many ventilated patients, provided the device lets the patient inspire and exhale whenever the respiratory muscles contract and relax. In other words, the ventilator needs to be in synchrony with the patient's muscle contractions, regardless of how the ventilator's controls are set.

Accordingly, the HAMILTON-MR1's pneumatics were designed to permit the patient's free spontaneous breathing. The ventilator never forces the patient into a preset breathing pattern but always yields to spontaneous breathing. This is achieved through a special valve control system independent of any trigger mechanism. This concept is called "biphasic," because gas can flow into and out of the patient at any time. The biphasic concept applies in all HAMILTON-MR1 ventilation modes.

Implementation of the biphasic concept improves patient breathing comfort[1], as spontaneous breathing is encouraged[2], less sedation is required even with prolonged inspiratory phases[3], and there is a free delivery of flow to the patient at any time. The decelerating inspiratory waveform improves gas distribution, oxygenation, and lowers peak pressures [2,3,4,5,6].

Figures B-1 through B-3 illustrate this concept. Figure B-1 shows a passive patient ventilated by pressure-controlled ventilation. Gas flows into the patient when pressure rises and gas flows out of the patient when inspiratory pressure falls.

1. 1996 Mar;153(3):1025-33
2. Kuhlen R, Putensen C, Editorial: Maintaining spontaneous breathing efforts during mechanical ventilatory support, Int Care Med 1999;25:1203-5
3. Sydow M, Burchardi H, Ephraim E, Zielmann S, Crozier TA, Long-term effects of two different ventilatory modes on oxygenation in acute lung injury. Comparison of airway pressure release ventilation and volume-controlled inverse ratio ventilation. Am J Respir Crit Care Med 1994 Jun;149(6):1550-6
4. Al-Saady N, Bennett ED, Decelerating inspiratory flow waveform improves lung mechanics and gas exchange in patients on intermittent positive pressure ventilation. Int Care Med 1985;11(2):68-75
5. Tharatt R St, Allen RP, Albertson TE, Pressure controlled inverse ratio ventilation in severe adult respiratory failure, Chest 1988 Oct;94(4):755-62
6. Davis K Jr, Branson RD, Campbell RS, Porembka DT, Comparison of volume and pressure control ventilation: is flow waveform the difference? J Trauma 1996 Nov;41(5):808-14

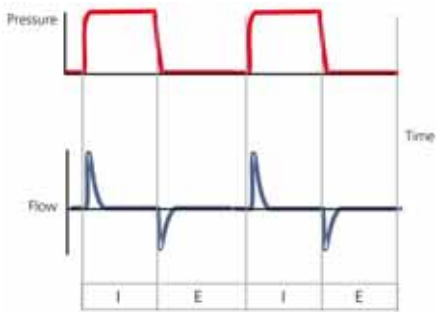


Figure B-1. Conventional pressure-controlled ventilation in a passive patient. Flow to patient during inspiration (I); flow from patient during exhalation (E) only.

Figure B-2 shows a partially active patient during conventional pressure-controlled ventilation when the trigger is disabled. If respiratory activity is present during the machine-determined inspiratory phase, gas flows only into the patient. Gas flow out of the patient is impossible due to the closed expiratory valve (see Flow curve).

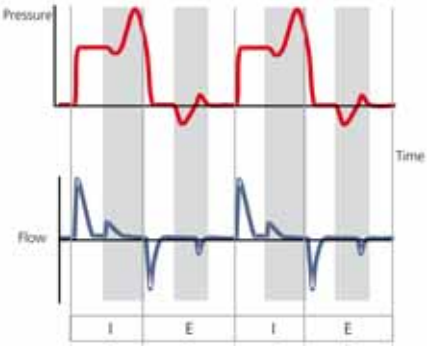


Figure B-2. Conventional pressure-controlled ventilation in an active patient when the trigger is off. Pressure increases when the patient tries to exhale (E) and pressure decreases when the patient tries to inspire (I), as valves are closed.

During the machine-determined expiratory phase, gas flows only out of the patient. Gas flow to the patient is impossible due to the closed check valve (see Flow curve).

Figure B-3 shows a partially active patient in the HAMILTON-MR1's biphasic PCV+ mode. Note that inspiration and exhalation are possible at any time, thereby offering the best synchronization possible between patient and machine. PCV+ acts like an artificial atmosphere to the patient: the machine varies the airway pressure to guarantee a minimal ventilation and the patient contributes whatever they can.

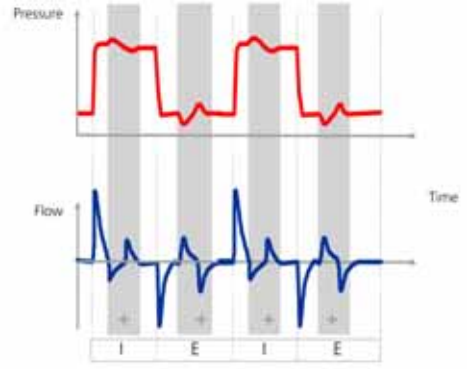


Figure B-3. Biphasic PCV+ in an active patient when trigger is off. The patient can freely inspire and exhale during any phase of ventilation (+).

B.3 Mandatory modes

The mandatory ventilation modes, (S)CMV+ (or APVcmv) and PCV+, deliver time-cycled mandatory breaths.

B.3.1 (S)CMV+ mode (APVcmv)

The (S)CMV+ (synchronized controlled mandatory ventilation) mode provides volume-targeted mandatory breaths using an adaptive volume controller. The adaptive volume controller delivers the set target volume (Vt) at the lowest possible pressure, depending on lung conditions.

The control settings active in the (S)CMV+ mode are shown in Figures B-4 and B-5.

- The tidal volume (Vt) setting defines the delivered volume.
- The Rate and I:E control settings determine the breath timing.

Breaths can be triggered by the ventilator, the patient, or by the ventilator operator.

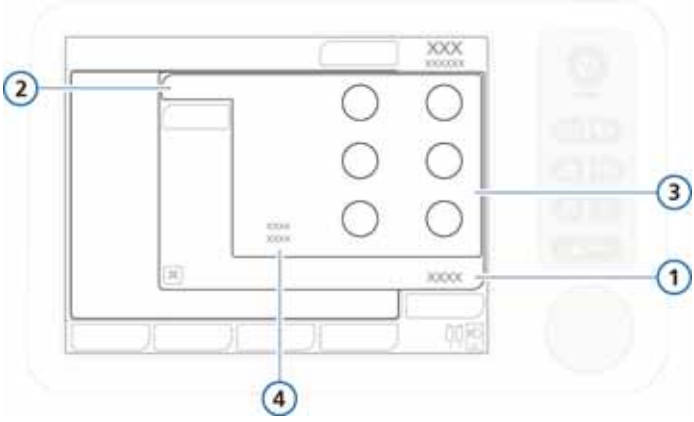


Figure B-4. (S)CMV+ Basic controls

1	Controls	**3**	Mode controls: Rate, Vt, I:E, PEEP, Flow trigger, Oxygen
2	Basic	**4**	TI, TE

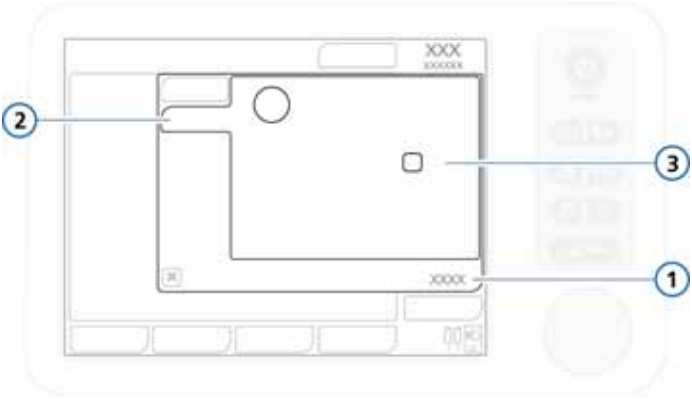


Figure B-5. (S)CMV+ More controls

1	Controls	**3**	Mode controls: P-ramp, Sigh*
2	More		*The Sigh setting is *only* for adult/ pediatric patients, not neonates.

The adaptive volume controller works by comparing the user-set tidal volume with the average of delivered and exhaled tidal volumes. The controller in turn adjusts the inspiratory pressure that will be applied during the next breath in order to obtain the target volume. The inspiratory pressure is adjusted in steps, to a maximum of 2 cmH2O per breath. The controller adjusts the total inspiratory pressure applied (including PEEP) so it is between (PEEP + 3 cmH2O) and (Pressure - 10 cmH2O), to a maximum of 60 cmH2O (Figure B-6).

The ventilator recalculates the minimal inspiratory pressure needed to achieve the target volume as lung characteristics change. This continuous reassessment of the patient's dynamic lung status helps guarantee the required ventilation while preventing hypoventilation or barotrauma.

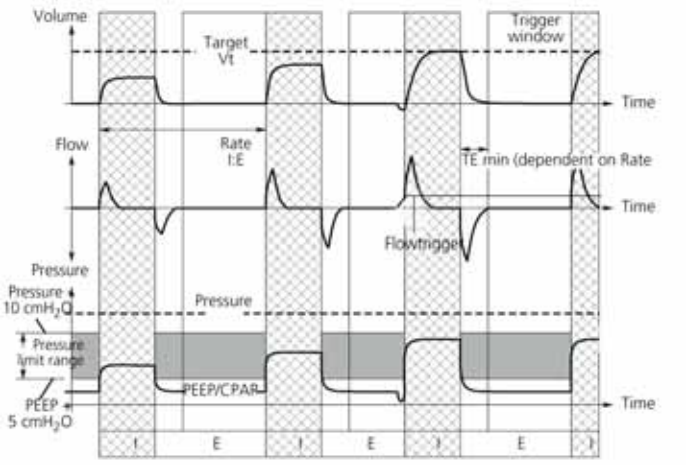


Figure B-6. Breath delivery by the adaptive volume controller

B.3.2 PCV+ mode

The PCV+ (pressure-controlled ventilation) mode provides pressure-controlled mandatory breaths. The mode's biphasic nature allows free breathing at both the PEEP and the Pcontrol pressure levels.

The control settings active in the PCV+ mode are shown in Figures B-7 and B-8.

- The pressure control (Pcontrol) setting defines the applied pressure.
- The Rate and I:E control settings determine the breath timing.

Breaths can be triggered by the ventilator, the patient, or by the ventilator operator.

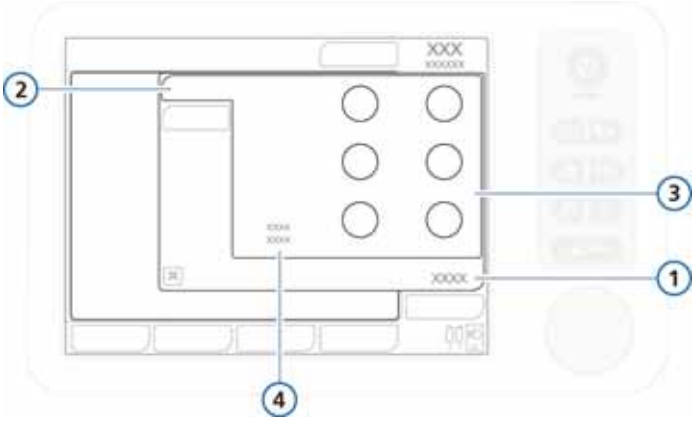


Figure B-7. PCV+ Basic controls

1	Controls	**3**	Mode controls: Rate, Pcontrol, I:E ratio, PEEP, Flow trigger, Oxygen
2	Basic	**4**	TI, TE

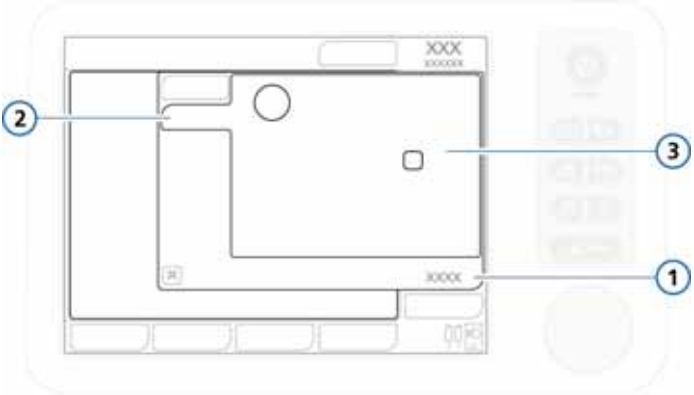


Figure B-8. PCV+ More controls

1	Controls	**3**	Mode controls: P-ramp, Sigh*
2	More		*The Sigh setting is *only* for adult/ pediatric patients, not neonates.

B.4 Spontaneous modes (SPONT and NIV)

The spontaneous or pressure support modes, SPONT and NIV (noninvasive ventilation), deliver spontaneous breaths and user-initiated manual (mandatory) breaths. SPONT is designed for an intubated patient, while NIV is designed for use with a mask or other noninvasive patient interface. See Appendix D for clinical application information on the noninvasive modes. In SPONT and NIV, the ventilator functions as a demand flow system. The patient's spontaneous breathing efforts can also be supported with the set pressure support. When pressure support is set to zero, the ventilator functions like a conventional CPAP system.

The control settings active in the SPONT mode are shown in Figures B-9 through B-12. The control settings active in the NIV mode are shown in Figures B-13 through B-15.

- The pressure support (Psupport) setting defines the applied pressure.
- The patient determines the breath timing.

Breaths can be triggered by the patient or by the ventilator operator.

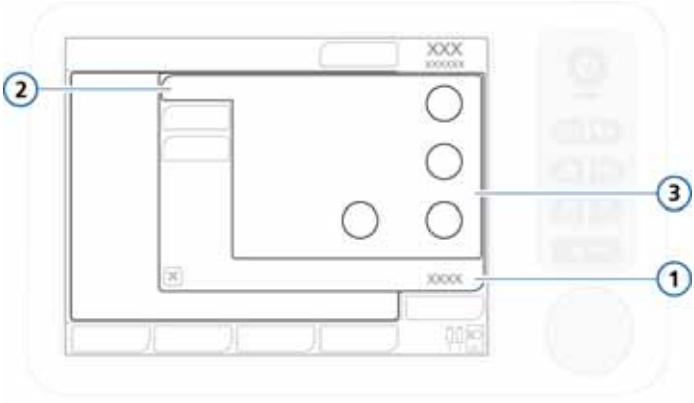


Figure B-9. SPONT Basic controls

1	Controls	**3**	Mode controls: Psupport, PEEP, Flow trigger, Oxygen
2	Basic		

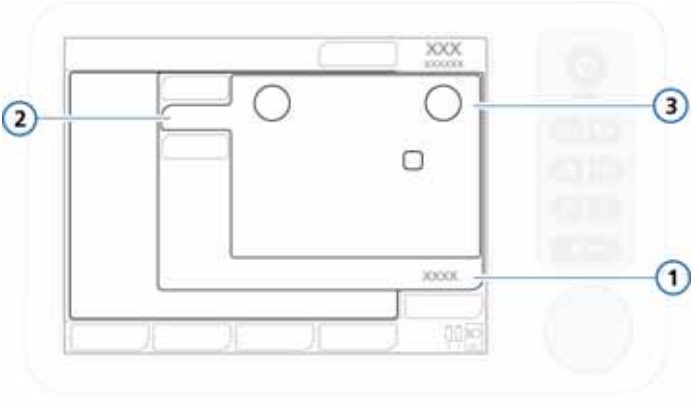


Figure B-10. SPONT More controls (adult/pediatric)

1	Controls	**3**	Mode controls: P-ramp, ETS, Sigh
2	More		

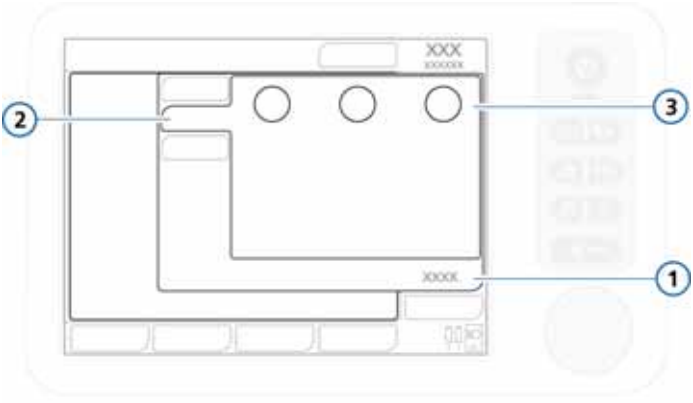


Figure B-11. SPONT More controls (neonatal)

1	Controls	**3**	Mode controls: P-ramp, TI max, ETS
2	More		

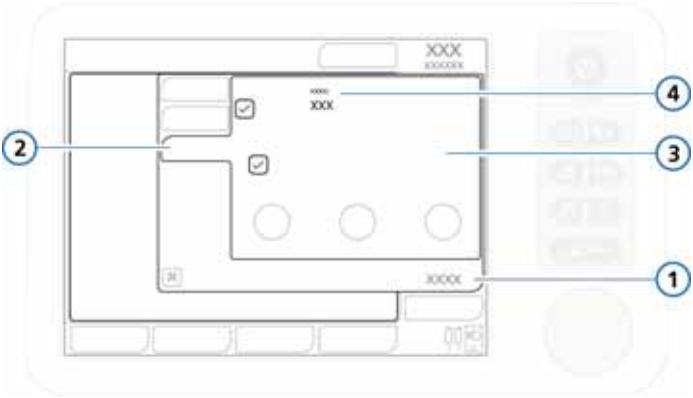


Figure B-12. SPONT Apnea controls

1	Controls	**3**	Mode controls: Backup, Automatic
2	Apnea	**4**	Backup mode

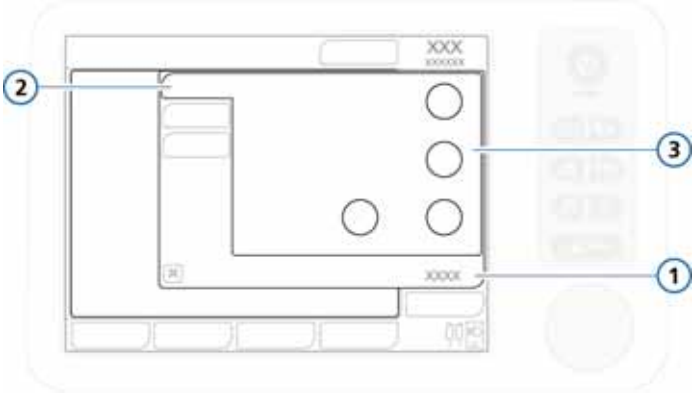


Figure B-13. NIV Basic controls

1	Controls	**3**	Mode controls: Psupport, PEEP, Flow trigger, Oxygen
2	Basic		

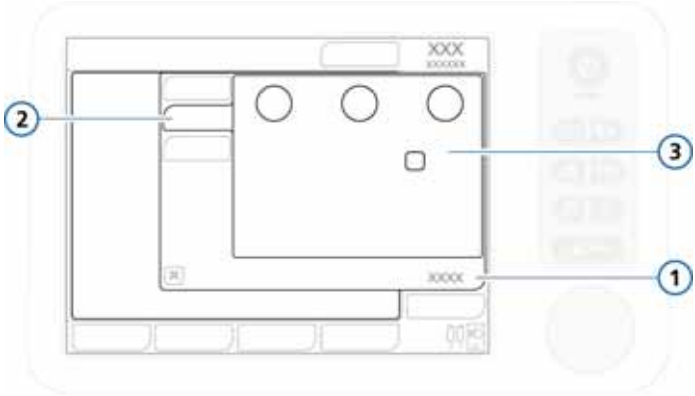


Figure B-14. NIV More controls

1	Controls	**3**	Mode controls: P-ramp, TI max, ETS, Sigh*
2	More		*The Sigh setting is *only* for adult/ pediatric patients, not neonates.

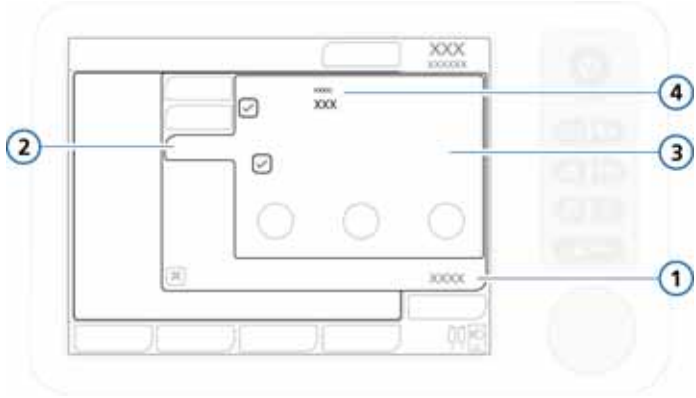


Figure B-15. NIV Apnea controls

1	Controls	**3**	Mode controls: Backup, Automatic
2	Apnea	**4**	Backup mode

B.5 SIMV modes

The SIMV (synchronized intermittent mandatory ventilation) modes, SIMV+ (APVsimv), PSIMV+, and NIV-ST, guarantee breath delivery at the operator-set rate. Both mandatory and spontaneous breaths may be delivered in the SIMV modes. Because the SIMV modes are mixed modes with attributes of both a mandatory and a spontaneous pressure support mode, you set the parameters specific to the applicable mandatory mode and to the spontaneous mode.

Each SIMV breath interval includes mandatory time (Tmand) and spontaneous time (Tspont) portions (Figure B-16). During Tmand, the ventilator waits for the patient to trigger a breath. When the patient triggers a breath, the ventilator immediately delivers a mandatory breath. If the patient does not trigger a breath, the ventilator automatically delivers a mandatory breath at the end of Tmand. After the mandatory breath is delivered, the patient is free to take any number of spontaneous breaths for the remainder of the SIMV breath interval.

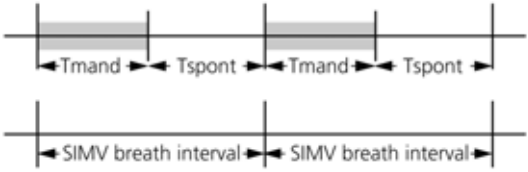


Figure B-16. Breath delivery in SIMV modes

B.5.1 SIMV+ mode (APVsimv)

The SIMV+ mode combines attributes of the (S)CMV+ and SPONT modes, delivering volume-targeted, time-cycled mandatory breaths and pressure-supported, flow-cycled spontaneous breaths. As with the (S)CMV+ mode, the SIMV+ mode ensures that the set target volume is delivered during the mandatory breaths.

Each SIMV+ breath interval, timv has a trigger window, ttrigger, during which the ventilator waits for a patient trigger (Figure B-17). If the patient triggers a breath during this time, the ventilator immediately delivers a mandatory breath with the target volume. If the patient does not trigger a breath, then the ventilator automatically delivers a mandatory breath at the end of ttrigger. After the mandatory breath is delivered, the patient can take any number of spontaneous breaths for the remainder of timv.

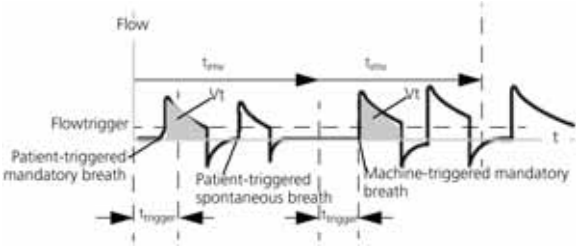


Figure B-17. Breath timing in SIMV+

The control settings active in the SIMV+ mode are shown in Figures B-18 through B-20. The SIMV+ mode requires that you set the parameters needed for both mandatory and spontaneous breath types.

- As for (S)CMV+ breaths, the tidal volume (Vt) setting defines the delivered volume of mandatory breaths.
- The Rate and TI control settings define the breath timing.
- For spontaneous breaths, the expiratory trigger sensitivity (ETS) setting defines the percentage of peak flow that cycles the ventilator into exhalation.

Breaths can be triggered by the ventilator, the patient, or by the ventilator operator.

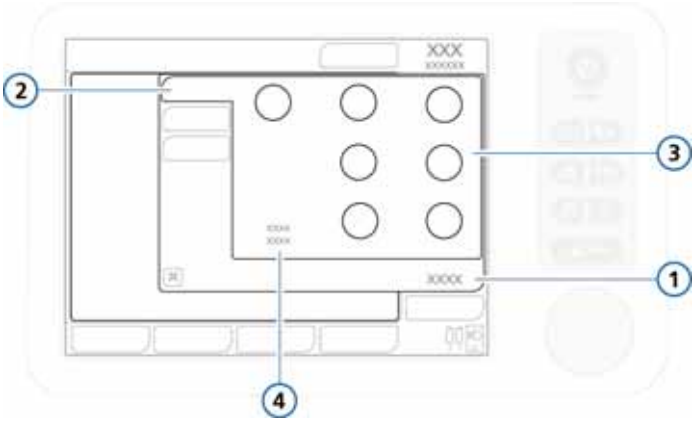


Figure B-18. SIMV+/APVsimv Basic controls

1	Controls	**3**	Mode controls: Psupport, Rate, Vt, TI, PEEP, Flow trigger, Oxygen
2	Basic	**4**	I:E, TE

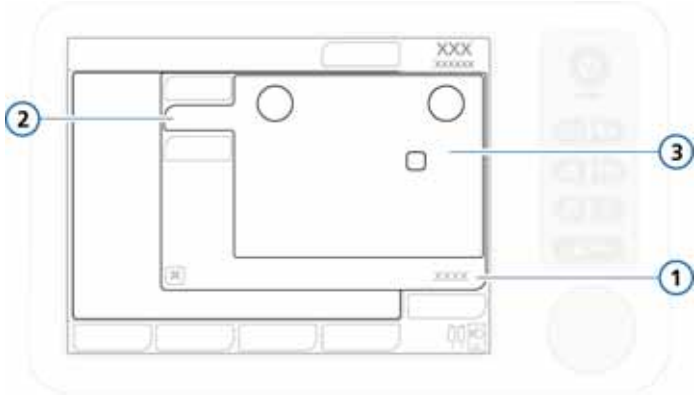


Figure B-19. SIMV+/APVsimv More controls

1	Controls	**3**	Mode controls: P-ramp, ETS, Sigh*
2	More		*The Sigh setting is *only* for adult/pediatric patients, not neonates.

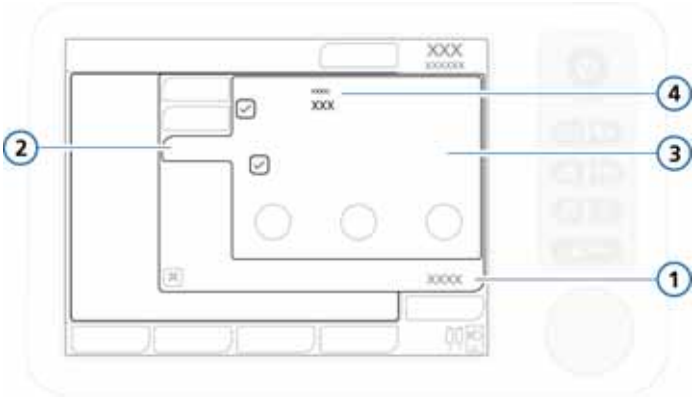


Figure B-20. SIMV+ Apnea controls

1	Controls	**3**	Mode controls: Backup, Automatic
2	Apnea	**4**	Backup mode

B.5.2 PSIMV+ mode

Two PSIMV+ modes are available: PSIMV+ and PSIMV+ with IntelliSync. See Sections B.5.2.1 and B.5.2.2, respectively.

IntelliSync is an additional setting to apply the same pressures for spontaneous and controlled breaths. It allows patients to breath spontaneously when they are able to maintain the operator-set guaranteed rate.

B.5.2.1 PSIMV+ mode

In the PSIMV+ mode, the mandatory breaths are PCV+ breaths (Section B.3.2). These can be alternated with SPONT breaths.

The PSIMV+ mode does not guarantee the delivery of an adequate tidal volume at all times. When using this mode, carefully monitor changes in the patient's status.

Each PSIMV+ breath interval, timv, has a trigger window, ttrigger, during which the ventilator waits for the patient to trigger a breath (Figure B-21). If the patient triggers a breath during this time, the ventilator immediately delivers a mandatory breath with the target volume. If the patient does not trigger a breath, the ventilator automatically delivers a mandatory breath at the end of ttrigger. After the mandatory breath is delivered, the patient can take any number of spontaneous breaths for the remainder of timv.

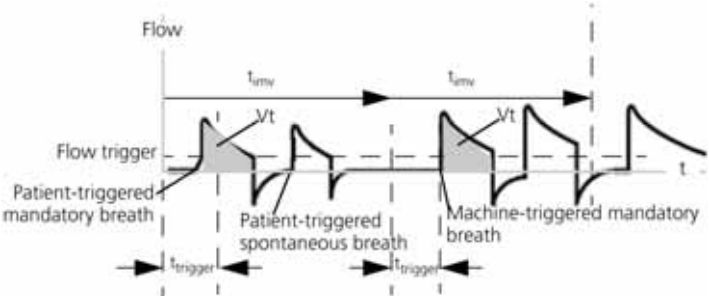


Figure B-21. Breath timing in PSIMV+

The control settings active in the PSIMV+ mode are shown in Figures B-22 and B-23. The SIMV+ mode requires that you set the parameters needed for both mandatory and spontaneous breath types.

- Similar to (S)CMV+ breaths, the tidal volume (Vt) setting defines the delivered volume of mandatory breaths.
- The Rate and TI control settings define the breath timing.
- For spontaneous breaths, the expiratory trigger sensitivity (ETS) setting defines the percentage of peak flow that cycles the ventilator into exhalation.

Breaths can either be triggered by the ventilator, the patient, or by the ventilator operator.

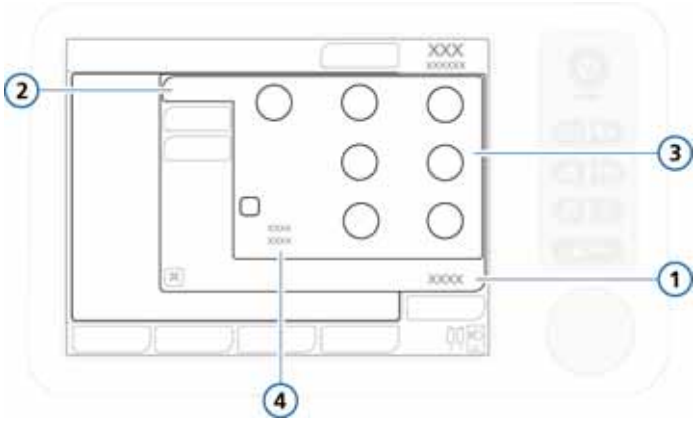


Figure B-22. PSIMV+ Basic controls

1	Controls	**3**	Mode controls: Rate, Pinsp, TI, PEEP, Flow trigger, Oxygen
2	Basic	**4**	I:E, TE, IntelliSync

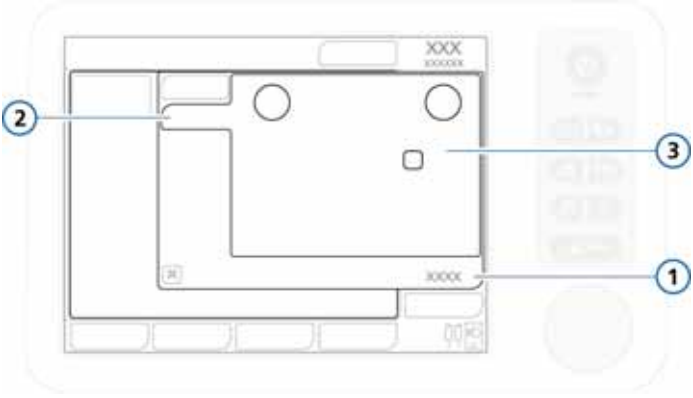


Figure B-23. PSIMV+ More controls

1	Controls	**3**	Mode controls: P-ramp, ETS, Sigh*
2	More		*The Sigh setting is *only* for adult/ pediatric patients, not neonates.

B.5.2.2 PSIMV+ Intellisync

The PSIMV+ IntelliSync (pressure-controlled SIMV) delivers pressure-controlled, time-cycled mandatory breaths and pressure-supported, flow-cycled spontaneous breaths. PSIMV+ combines attributes of the PCV+ and SPONT modes and like SPONT, it is designed for an intubated patient.

As with the PCV+ mode, PSIMV+ IntelliSync delivers a preset pressure, but does not guarantee a fixed tidal volume, especially during changes in respiratory system compliance, airway resistance, AutoPEEP, or the patient's respiratory activity.

If the patient triggers a breath during the breath interval timv, the ventilator immediately delivers a spontaneous breath (Figure B-24). If the patient does not trigger an inspiration during this time, the ventilator initiates a mandatory breath at the end of timv.

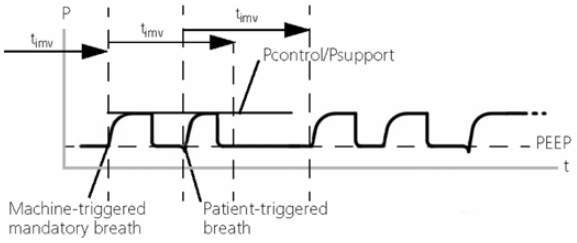


Figure B-24. Breath timing in PSIMV+ IntelliSync

The control settings active in the PSIMV+ IntelliSync mode are shown in Figures B-25 and B-23 (the controls in the More window are the same as for PSIMV+ without IntelliSync). This mode requires that you set the parameters needed for both mandatory and spontaneous breath types.

- The inspiratory pressure (Pinsp) setting defines the applied pressure for both mandatory and spontaneous breaths.
- The Rate and TI (inspiratory time) control settings define the breath timing.
- For spontaneous breaths, the expiratory trigger sensitivity (ETS) setting defines the percentage of peak flow that cycles the ventilator into exhalation.

Breaths can either be triggered by the ventilator, the patient, or by the ventilator operator.

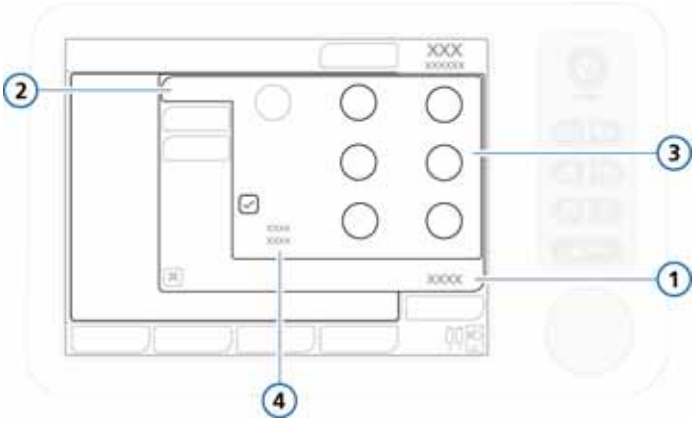


Figure B-25. PSIMV+ IntelliSync basic controls

1	Controls	**3**	Mode controls: Rate, Pinsp, TI, PEEP, Flow trigger, Oxygen
2	Basic	**4**	I:E, TE, IntelliSync

See Figure B-23 for the P-ramp, ETS, and Sigh controls in the Controls > More window.

B.5.3 NIV-ST mode

NIV-ST (spontaneous/timed noninvasive ventilation) mode delivers pressure-controlled, time-cycled mandatory breaths and pressure-supported, flow-cycled spontaneous breaths. It combines attributes of the PCV+ and NIV modes. NIV-ST, like NIV, is designed for use with a mask or other noninvasive patient interface. See Appendix D for clinical application information on the noninvasive modes.

As with the PCV+ mode, NIV-ST both delivers a preset pressure, but does not guarantee a fixed tidal volume, especially during changes in respiratory system compliance, airway resistance, AutoPEEP, or the patient's respiratory activity.

If the patient triggers a breath during the breath interval timv, the ventilator immediately delivers a spontaneous breath (Figure B-26). If the patient does not trigger an inspiration during this time, the ventilator initiates a mandatory breath at the end of timv.

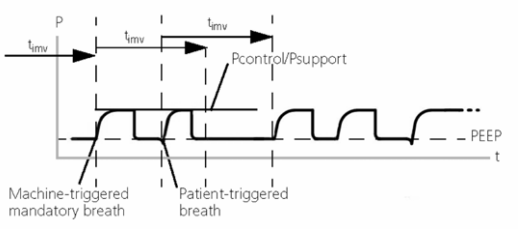


Figure B-26. Breath timing in NIV-ST

The control settings active in the NIV-ST mode are shown in Figures B-27 and B-28. You must set the parameters needed for both mandatory and spontaneous breath types.

- The inspiratory pressure (Pinsp) setting defines the applied pressure for both mandatory and spontaneous breaths.
- The Rate and TI (inspiratory time) control settings define the breath timing.
- For spontaneous breaths, the expiratory trigger sensitivity (ETS) setting defines the percentage of peak flow that cycles the HAMILTON-MR1 into exhalation.

Breaths can be triggered by the ventilator, the patient, or by the ventilator operator.

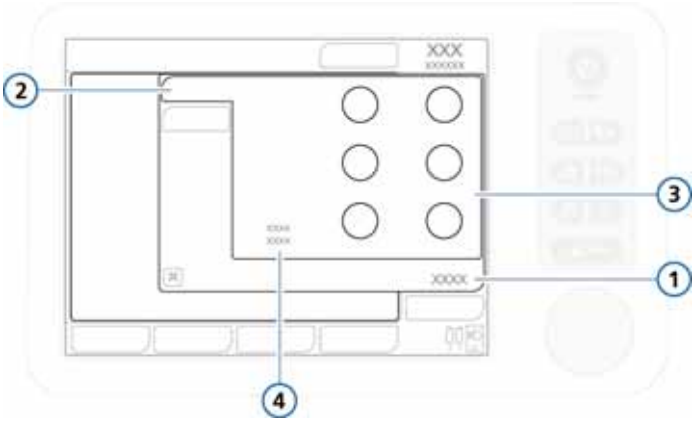


Figure B-27. NIV-ST Basic controls

1	Controls	**3**	Mode controls: Rate, Pinsp, TI, PEEP, Flow trigger, Oxygen
2	Basic	**4**	I:E, TE

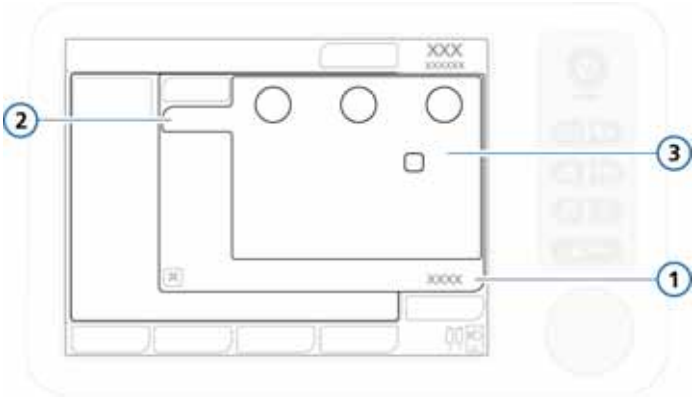


Figure B-28. NIV-ST More controls

1	Controls	**3**	Mode controls: P-ramp, TI max, ETS, Sigh*
2	More		*The Sigh setting is *only* for adult/ pediatric patients, not neonates.

B.6 DuoPAP (Duo positive airway pressure) mode

DuoPAP is a related form of pressure ventilation designed to support spontaneous breathing on two alternating levels of CPAP. In these mode, the ventilator switches automatically and regularly between two operator-selected levels of positive airway pressure or CPAP. The patient may breathe freely at either level. In DuoPAP pressure support can be added to these spontaneous breaths. Cycling between the levels is triggered by DuoPAP timing settings or by patient effort. Pressure/time curve for this mode is shown in Figure B-29.

The control settings active in the DuoPAP mode are shown in Figures B-31 through B-33.

In DuoPAP (Figure B-29), the switchover between the two levels is defined by pressure settings Phigh and PEEP/CPAP and time settings Thigh and Rate. Like PEEP/CPAP, Phigh is relative to atmospheric pressure.

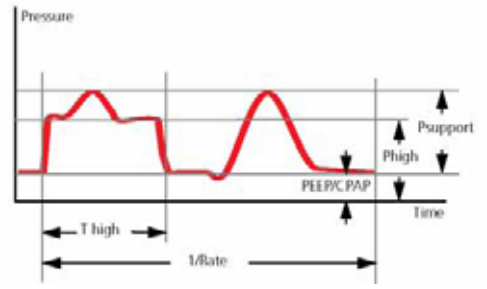


Figure B-29. DuoPAP pressure curve

B.6.1 The many faces of DuoPAP

With different patients and with different combinations of control settings, DuoPAP can be made to resemble a variety of conventional ventilation modes.

At conventional settings and in the absence of spontaneous breathing, DuoPAP resembles PCV+. As you decrease the rate, keeping Thigh short relative to the time at the lower pressure level, the modes look more like PSIMV+, with spontaneous breaths following mandatory breaths. If Thigh almost set to breath cycle time with just enough time at the low level to allow full or near-full exhalation, these mode looks like APRV. By setting PEEP/CPAP and Phigh equal to one another and adjusting other parameters, the mode can be made to resemble SPONT.

B.6.2 Pressure support in DuoPAP breaths

Pressure support can be set to assist spontaneous breaths in DuoPAP, whether they occur at the PEEP/CPAP or Phigh level. Psupport is set relative to PEEP/CPAP the target pressure becomes PEEP/CPAP. That means that spontaneous breaths at the Phigh level are supported only when this target pressure is greater than Phigh. Figure B-30 (a) shows the situation where breaths at both the PEEP and Phigh level are pressure-supported. Figure B-30 (b) shows the situation where only breaths at the PEEP/CPAP level are pressure-supported.

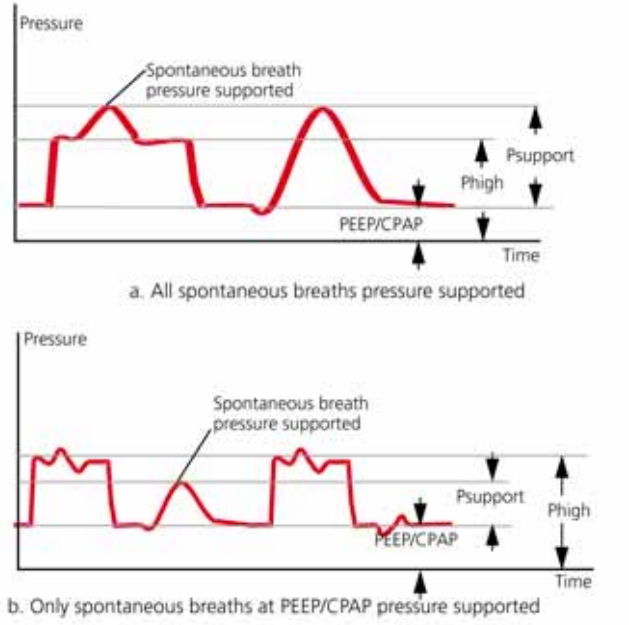


Figure B-30. Pressure support in DuoPAP

B.6.3 Synchronization

To adapt easily to the patient's spontaneous breathing pattern, the change-over from low to high pressure level and vice versa are synchronized with the patient's spontaneous breathing.

The frequency of the change-over is kept constant, even with patient synchronization, by defining a trigger time window with a fixed time constant.

B.6.4 DuoPAP controls

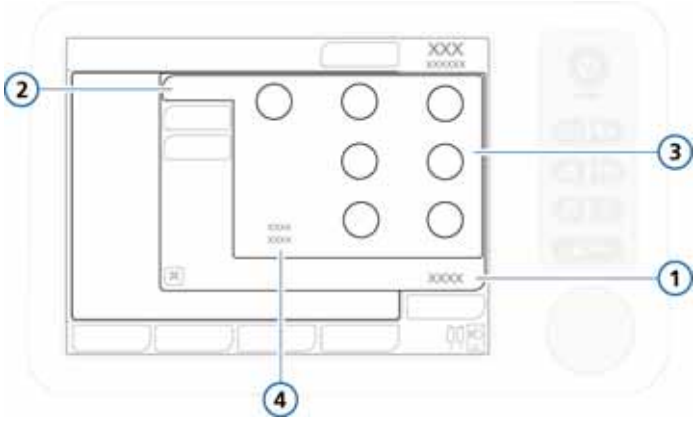


Figure B-31. DuoPAP Basic controls

1	Controls	**3**	Mode controls: Psupport, Rate, P high, T high, PEEP, Flow trigger, Oxygen
2	Basic	**4**	I:E, T low

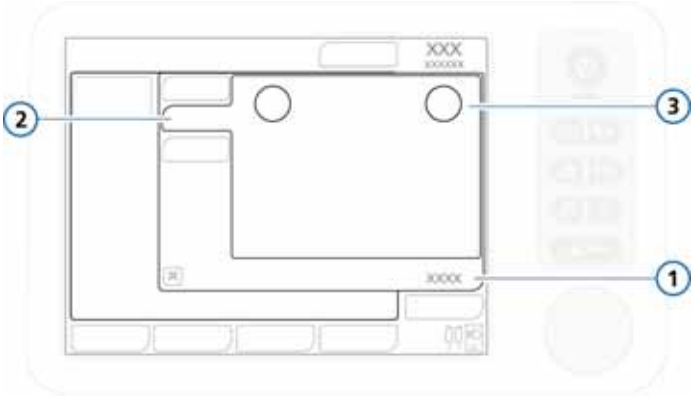


Figure B-32. DuoPAP More controls

1	Controls	**3**	Mode controls: P-ramp, ETS
2	More		

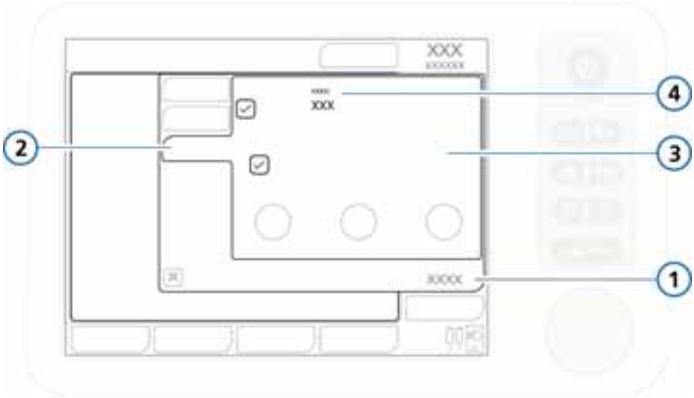


Figure B-33. DuoPAP Apnea controls

1	Controls	**3**	Mode controls: Backup, Automatic
2	Apnea	**4**	Backup mode

B.7 APRV (airway pressure release ventilation) mode

APRV produces alveolar ventilation as an adjunct to CPAP. Set airway pressure Phigh is transiently released to a lower level Plow, after which it is quickly restored to reinflate the lungs. For a patient who has no spontaneous breathing efforts, APRV is similar to pressure-controlled inverse ratio ventilation.

APRV allows spontaneous breathing at any time during the respiratory cycle.

Tidal volume (Vt) for APRV breath depends on lung compliance, respiratory resistance, the magnitude and duration of the pressure release and the magnitude of the patient's spontaneous breathing efforts.

Figure B-34 shows the breath timing and pressure settings in APRV.

Figure B-34. APRV breath timing

B.7.1 Initialization of APRV

NOTE:

When applying long Thigh phases without patient activity, you may adjust the apnea time alarm setting to avoid switching to apnea backup ventilation.

When switching to APRV the first time, timing and pressure settings proposed are based on Table B-2. Settings for Phigh, Thigh, and Tlow will be stored when switching back to another mode, but recalled when returning to APRV again.

The initialization occurs as shown or last set value in APRV.

Table B-2. Control parameters for initialization of APRV[1]

IBW (kg)	Phigh / Plow (cmH20)	Thigh (s)	Tlow (s)
0.2 to 3	20 / 5	1.4	0.
3 to 5	20 / 5	1.7	0.3
6 to 8	20 / 5	2.1	0.3
9 to 20	20 / 5	2.6	0.4
21 to 39	20 / 5	3.5	0.5
40 to 59	20 / 5	4.4	0.6
60 to 89	20 / 5	5.4	0.6
90 to 99	23 / 5	5.4	0.6
≥ 100	25 / 5	5.4	0.6

1. When switching to APRV a second time (repeatedly) the former settings are kept.

B.7.2 Sustained high-pressure recruitment maneuvers

One approach to lung recruitment has been that of sustained high-pressure recruitment maneuvers. APRV can be set to apply elevated pressures for up to 40 seconds.

B.7.3 APRV controls

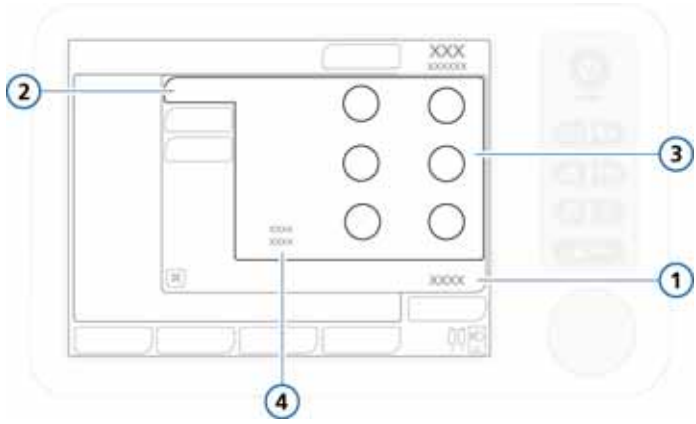


Figure B-35. APRV Basic controls

1	Controls	**3**	Mode controls: T high, P high, T low, P low, Flow trigger, Oxygen
2	Basic	**4**	I:E, Rate

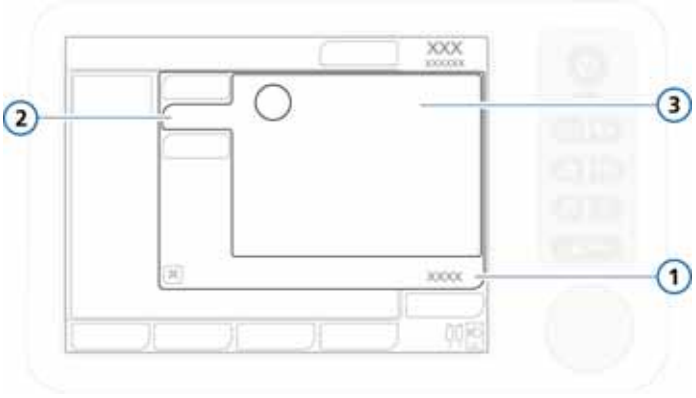


Figure B-36. APRV More controls

1	Controls	**3**	Mode controls: P-ramp
2	More		

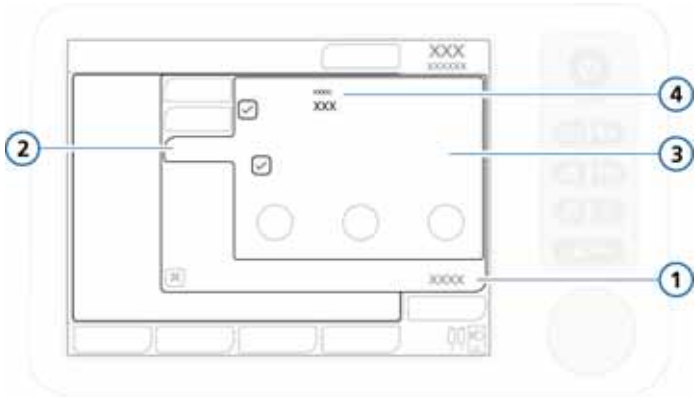


Figure B-37. APRV Apnea controls

1	Controls	**3**	Mode controls: Backup, Automatic
2	Apnea	**4**	Backup mode

B.8 Safety mode and ambient state

In the event of certain technical failures, the ventilator switches to SAFETY mode. This gives you time to arrange for corrective actions, including organizing a replacement ventilator.

The blower runs constantly to create inspiratory pressure (Pinsp) (Table B-3). The expiratory valve switches system pressure levels between PEEP and inspiratory pressure. Patient sensing is nonfunctional during safety ventilation. You must switch off ventilator power to exit safety ventilation.

If the technical fault alarm is serious enough to possibly compromise safe ventilation, the ventilator enters the ambient state. The inspiratory channel and expiratory valves are opened, letting the patient breathe room air unassisted. You must switch off ventilator power to exit the ambient state.

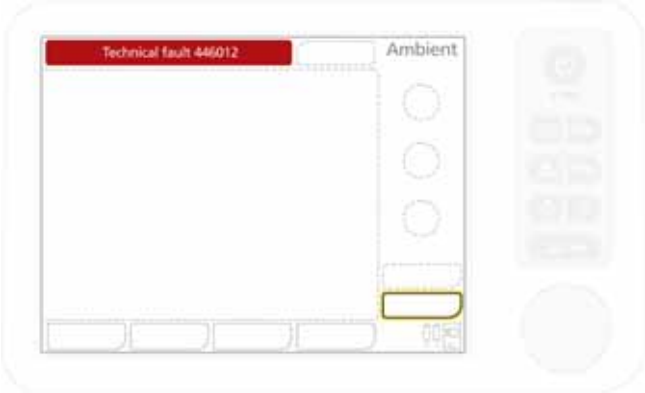


Figure B-38. Ambient state

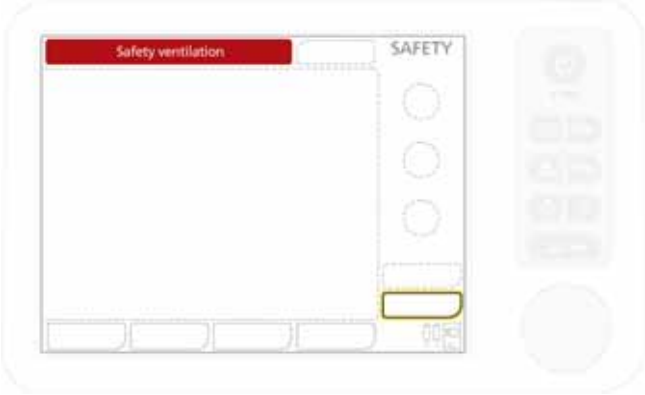


Figure B-39. Safety mode

Table B-3. Safety mode settings

IBW (kg)	Pinsp (cmH2O)	Rate (b/min)	I:E	PEEP[1]	O2
< 3	15	< 35	1:3		> 21%
3 to 5	15	30	1:4		> 21%
6 to 8	15	25	1:4		> 21%
9 to 20	15	20	1:4		> 21%
21 to 29	15	15	1:4		> 21%
30 to 39	15	14	1:4		> 21%
40 to 59	15	12	1:4		> 21%
60 to 89	15	10	1:4		> 21%
90 to 99	18	10	1:4		> 21%
≥ 100	20	10	1:4		> 21%

1. Set PEEP plus circuit resistance (+ 5 cmH2O).

APPENDIX

C ASV, adaptive support ventilation

C.1 Introduction

WARNING

This appendix describes ASV as it is implemented in the HAMILTON-MR1. It does not replace the clinical judgment of a physician and is not to be used for clinical decision making.

NOTE:

ASV is not supported in neonatal ventilation.

In 1977, Hewlett et al. introduced mandatory minute volume (MMV). "The basic concept is that the system is supplied with a metered, preselected minute volume of fresh gas, from which the patient breathes as much as he is able, the remainder being delivered to him via a ventilator. Thus the patient is obliged to breathe, one way or the other, a Mandatory Minute Volume MMV" (Hewlett 1977).

Since then, many ventilators have included versions of MMV under different names. However, all commercially available MMV algorithms have clear limitations, which lead to certain risks for the patient (Quan 1990). These include rapid shallow breathing, inadvertent PEEP creation, excessive dead space ventilation, and inadvertent wrong operator settings due to very complicated use.

Adaptive Support Ventilation (ASV) was designed to minimize those risks and limitations. ASV maintains an operator-preset, minimum minute ventilation independent of the patient's activity. The target breathing pattern (tidal volume and rate) is calculated using Otis' equation, based on the assumption that if the optimal breath pattern results in the least work of breathing, it also results in the least amount of ventilator-applied inspiratory pressure when the patient is passive. Inspiratory pressure and machine rate are then adjusted to meet the targets. A lung protection strategy ensures ASV's safety.

In contrast to MMV, ASV attempts to guide the patient using a favorable breathing pattern and avoids potentially detrimental patterns like rapid shallow breathing, excessive dead space ventilation, breath stacking (inadvertent PEEP), and excessively large breaths.

Contrary to some opinions, ASV does not eliminate the need for a physician or clinician. However, ASV alleviates the need for tedious tasks and laborious readjustments of the ventilator; thus, it is a modern tool for the clinician. As such, ASV does not make clinical decisions. ASV executes a general command from the clinician and the clinician can modify it. This command can be summarized, where the modifiable parts are in bold:

Maintain a **present minimum minute ventilation**,

- take spontaneous breathing into account,
- prevent tachypnea,
- prevent AutoPEEP,
- prevent excessive dead space ventilation,
- fully ventilate in apnea or low respiratory drive,
- give control to the patient if breathing activity is okay, and
- all this without exceeding a plateau pressure of 10 cmH_2O below the **upper pressure limit**.

This appendix explains in practical terms how to use ASV at the patient's bedside and provides a detailed functional description. Since Otis' equation (Otis 1950) is the cornerstone of the optimal-breath pattern calculation, this equation is included and described. A table of detailed technical specifications and pertinent references is also given.

C.2 ASV use in clinical practice

ASV does not require a special sequence of actions. It is used in much the same way as are conventional modes of ventilation. Figure C-1 summarizes how to use ASV, while the subsequent sections explain it in detail. Figures C-2 and C-3 show the control settings active in the ASV mode.

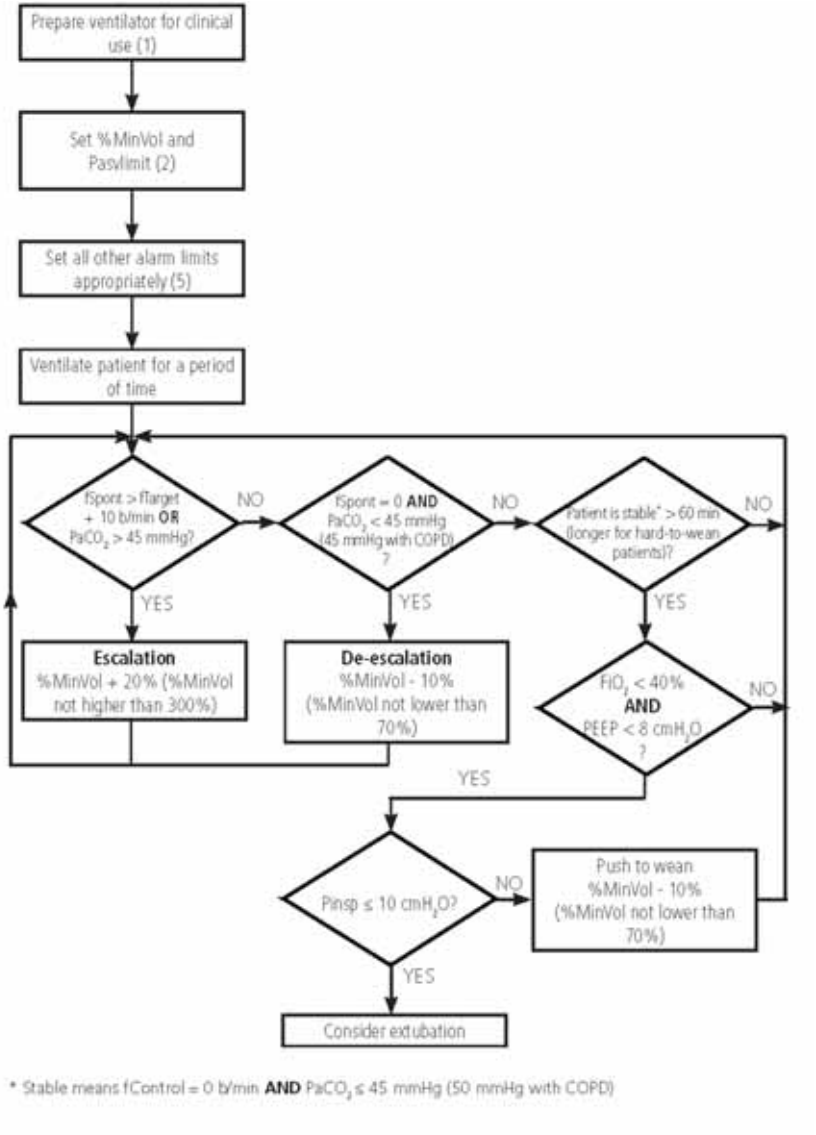


Figure C-1. Clinical use of ASV

The numbers in parentheses are step numbers, which are explained in the next sections.

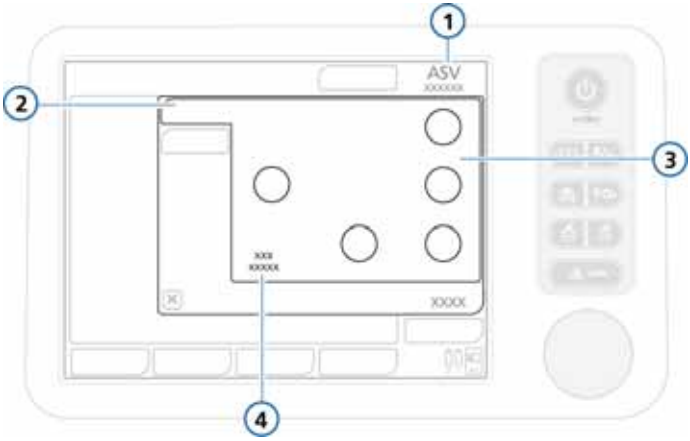


Figure C-2. ASV Basic controls

1	ASV mode	**3**	Mode controls: Pat. height, %MinVol, Pasvlimit, PEEP, Flow trigger, Oxygen
2	Basic	**4**	IBW, target %MinVol

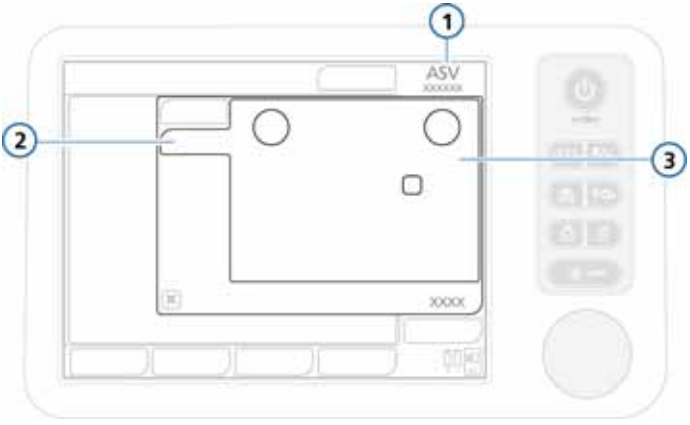


Figure C-3. ASV More controls

1	ASV mode	**3**	Mode controls: P-ramp, ETS, Sigh
2	More		

Step 1: Before connecting the patient to the HAMILTON-MR1

It is important to prepare the HAMILTON-MR1 for clinical use according to Chapter 2. This includes, but is not limited to, performing the preoperational procedures and testing indicated.

Step 2: Preparing the HAMILTON-MR1 for ASV before ventilation

NOTE:

The high limit must be at least 25 cmH2O above PEEP/CPAP.

ASV requires that you set the following basic parameters:

Pressure	High Pressure alarm limit, in cmH20
Patient height	Patient height, in cm or inches
Gender	Sex of patient
%MinVol	Desired minute ventilation, in % of normal values

It is suggested you do the following before connecting the patient to the ventilator:

1. Remove the demonstration lung, when a demonstration lung is used, and silence the alarm.
2. Set the high Pressure alarm limit to an appropriate value (e.g., 45 cmH20 or 50 cmH20 for COPD patients).

   The maximum inspiratory pressure delivered in ASV (Pasv) will be **10 cmH2O below the preset high pressure limit**, indicated by a blue band on the pressure curve display.

   The maximum inspiratory pressure for ASV can be also set using the Pasv control in the Controls window. Changing the Pasv value will also change high Pressure limit.
3. Activate ASV in the Modes window and then **Confirm** the mode change. The Controls window automatically opens.

4. Specify the following control settings:
   - **Patient height**
   - **Gender**
   - **%MinVol.** A logical starting point is a %MinVol that will result in the same minute volume as a previous mode, if applicable. The %MinVol for a normal patient might be 100%; for a COPD patient, 90%; for an ARDS patient, 120%; and for other patients, 110%. Add 20% if body temperature > 38.5°C (101.3°F) and 5% per 500 m (1640 ft) above sea level.
   - **Trigger.** Suggested settings are a Flowtrigger of 2 l/min; or you can leave the previous patient trigger method and sensitivity, if applicable.
   - **ETS.** A suggested setting is 25% (40% for a COPD patient); or you can you can leave this unchanged, if applicable.
   - **Other settings.** Set PEEP/CPAP and Oxygen values according to clinical requirements. You can leave the P-ramp setting at its standard value unless clinical judgment calls for adjustment. To set it, see Chapter 5.
5. **Confirm** the settings.
6. Connect the patient to the ventilator if applicable. This will initiate three test breaths.

Step 3: Compensation for changes in apparatus dead space

NOTE:

Changes in alveolar dead space due to ventilation/perfusion mismatch must be compensated via the %MinVol control.

The HAMILTON-MR1 calculates the (anatomical or "series") dead space based on the IBW calculated from the patient height input. Dead space is calculated as 2.2 ml per kg (1 ml per lb). This dead space is a nominal value that is valid, on average, for intubated patients whose endotracheal tube is connected to the Y-piece of the ventilator by a standard catheter mount. If this dead space is altered by an artificial airway configuration such as a the use of a heat and moisture exchanging filter (HMEF) or nonstandard tubing, modify the Patient height setting accordingly to take into account the added or removed dead space.

Consider the following when compensating dead space:

- A shorter-than-standard endotracheal or tracheostomy tube probably does not require compensation.
- Different sizes of endotracheal tube probably do not require compensation.
- A much longer-than-normal catheter mount may require compensation.
- A bacterial filter or an HMEF may require compensation. The volume of these devices, for an adult, is on average 50 to 60 ml, but may be as high as 95 ml (Mallinckrodt Hygroster). For an HMEF, a simple rule of thumb is to add 10% to the IBW (by adjusting the Patient height control).

Step 4: Adjusting ventilation: Maintaining adequate ventilation

WARNING

It is inappropriate to adjust the IBW (through the Patient height control) to change minute volume. Always use the %MinVol control to adjust minute volume.

Once ASV is started, the HAMILTON-MR1 calculates an optimal breath pattern and associated target values for tidal volume and rate according to the rules in ASV, then adjusts the inspiratory pressure (Pinsp) and machine rate (fControl) to achieve the targets.

Once the calculated targets are reached, the result of the ventilation needs to be assessed. All HAMILTON-MR1 monitored parameters can be used for this purpose. However, to assess respiratory acid-base status, it is recommended that arterial blood gases be measured and minute ventilation be adjusted accordingly. Table C-1 provides examples of how to adjust the %MinVol setting.

Table C-1. Blood gas and patient conditions and possible adjustments for ASV

Condition	%MinVol change	Remarks
Normal arterial blood gases	None	--
High PaCO2	Increase %MinVol	Pay attention to inspiratory pressures
Low PaCO2	Decrease %MinVol	Pay attention to mean pressures and oxygenation status
High respiratory drive	Consider increase in %MinVol	Consider sedation, analgesia, or other treatments
Low O2 saturation	None	Consider increase in PEEP/CPAP and/or Oxygen

Step 5: Alarm settings review and special ASV alarms

To monitor the breathing pattern, you must review the alarm settings periodically and set them according to clinically acceptable values. As described below, ASV changes the breathing pattern according to the respiratory system mechanics and within the boundaries resulting from the operator's settings for ASV. However, you can closely monitor ASV's actions through the alarm system, since the alarm settings work totally independently of ASV.

It is possible to select a %MinVol that is incompatible with the lung-protective rules that govern ASV (for a detailed description, see section C.3.3). For example, you might want a high ventilation for a COPD patient in spite of severe pulmonary obstruction. In such a case, ASV tries to achieve the maximum possible ventilation and alarms that ASV: Cannot meet target. Such a case is shown in Figure C-4, where a high ventilation (300% at 70 kg) was set by the operator for a patient with severely obstructed lungs (Raw = 40 cmH2O/(l/s).

The high ventilation moves the minimum minute volume curve to the right while the obstructive disease causes the safety limit of rate to shift to the left. These two effects cause the minute volume curve to lie outside the safety limits as determined by the lung-protective rules strategy (see functional description below). ASV thus chooses the safest point closest to the user-set minute volume.

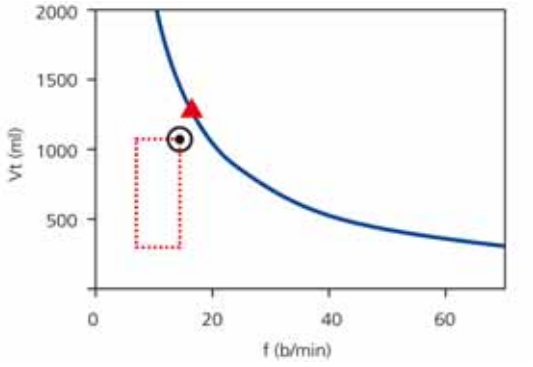


Figure C-4. Hypothetical example of high %MinVol setting incompatible with the lung-protective rules strategy

The open circle denotes the actual target, the closed triangle (never shown on the ventilator) denotes the (energetically) optimal target according to Otis' equation. The HAMILTON-MR1 will alarm and inform the user that the ASV target cannot be achieved.

Step 6: Monitoring ASV

ASV interacts with the patient continuously. Whenever the patient's respiratory mechanics change, ASV adapts to this change. Whenever the patient's breathing activity changes, ASV adapts. To let you view the current status, the HAMILTON-MR1 provides the ASV target graphics (ASV Graph) window (Figure C-5).

To monitor progress over time, it is recommended that you plot trends for Pinsp, fTotal, and fSpont. Interpret these trends, together with the %MinVol setting. Tables C-2 through C-4 provide interpretation of typical ventilatory patterns.

For details on displaying the ASV Graph, see Section 8.3.

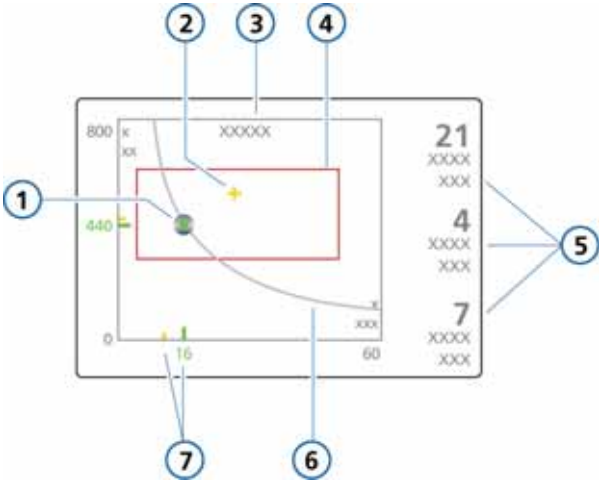


Figure C-5. ASV target graphics window

1 Current measured point, formed by intersection of measured tidal volume (Vt, on the y-axis) and rate (f, on the x-axis)

2 Target point, formed by intersection of target tidal volume and target rate

3 Numerical value of target minute volume

4 Safety frame in which target point may move.

5 fSpont = spontaneous breath rate, fControl = machine rate, Pinsp =inspiratory pressure set by ventilator

6 Minute volume curve

7 Numerical value of the current measured point (in green) and relative position of the target value (in yellow)

Table C-2. Interpretation of breathing pattern at 100 % MinVol setting

Pinsp	fControl	fSpont	Interpretation
> 10	> 10	0	Fully controlled, mechanical ventilation. To start weaning, consider reducing %MinVol.
> 10	0	Acceptable	Supported spontaneous breathing. Consider reducing %MinVol.
< 8	0	Acceptable	**Unsupported breathing**. Consider extubation.
> 10	0	High	Dyspnea. Consider increasing %MinVol and other clinical treatments. Check for autotriggering.

Table C-3. Interpretation of breathing pattern at much higher than 100% MinVol setting

Pinsp	fControl	fSpont	Interpretation
> 10	> 10	0	Fully controlled mechanical ventilation. Check arterial blood gases. To start weaning, consider reducing %MinVol.
> 10	0	Acceptable	Supported spontaneous breathing. Check reason for increased ventilation requirement. Consider reducing %MinVol.
< 8	0	Acceptable	**Unsupported breathing.** Check reason for increased ventilation requirement. Consider reducing %MinVol and extubation.
> 10	0	High	Dyspnea. Check reason for increased ventilation requirement. Consider other mode of ventilation and clinical treatment. Check for autotriggering.

Table C-4. Interpretation of breathing pattern at much lower than 100% MinVol setting

Pinsp	fControl	fSpont	Interpretation
>10	> 10	0	Danger of hypoventilation. Check arterial blood gases and consider increasing %MinVol.
>10	0	Accept-able	Enforced weaning pattern. Monitor arterial blood gases and patient respiratory effort. Consider decreasing or increasing %MinVol accordingly.
<8	0	Accept-able	**Unsupported breathing**. Consider extubation.
>10	0	High	Dyspnea. Consider increasing %MinVol and other clinical treatments. Check for autotriggering.

Step 7: Weaning

Weaning patients from the ventilator is a clinical task that requires tremendous experience and involves more than just ventilation issues. This appendix does not intend to provide clinical information other than that needed to operate the ventilator with ASV.

ASV always allows patients to take spontaneous breaths. Episodes of spontaneous breathing can occur and are supported by ASV even within a period of fully controlled ventilation. In other words, weaning can start with ASV so early that it may go unrecognized clinically. It is therefore important to monitor the spontaneous efforts of the patient over time.

The weaning progress can be monitored in the trends display when inspiratory pressure (Pinsp), total rate (fTotal), and spontaneous rate (fSpont) are plotted. If the patient tolerates minimum respiratory support after a period of time with

Pinsp < 8 cmH2O fControl = 0

weaning can be considered achieved, if at a minimum, fSpont is acceptable, ExpMinVol is acceptable.

What is “acceptable” must be defined by the clinician.

It may be necessary to reduce the %MinVol setting to 70% or even lower to "motivate" the patient to resume spontaneous breathing. If a patient can sustain minutes or even hours with a low %MinVol setting, it does not mean that weaning is complete. In fact, the %MinVol setting must always be interpreted in conjunction with the level of Pinsp needed to achieve the set minute ventilation. Only if Pinsp and fControl are at their minimal values can weaning be assumed to be complete.

C.3 Detailed functional description of ASV

C.3.1 Normal minute ventilation

ASV defines normal minute ventilation according to the graph in Figure C-6.

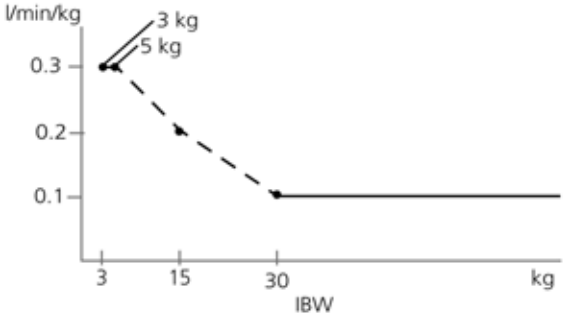


Figure C-6. Normal minute ventilation as a function of ideal body weight (IBW)

For adult patients, minute ventilation is calculated as 0.1 l/kg * IBW (solid line). For pediatric patients, the value indicated by the dotted line is used. Minute ventilation for a 15 kg patient thus is calculated as

0.2 l/kg * 15 kg = 3 l/min

For example, for an IBW of 70 kg, normal minute ventilation corresponds to 7 l/min.

C.3.2 Targeted minute ventilation

When you chose ASV, you must select an appropriate minute ventilation for the patient. Minute ventilation is set with the %MinVol control, which, together with the Patient height control, determines the total minute ventilation in liters per minute.

A %MinVol setting of 100% corresponds to a normal minute ventilation, as discussed above. A setting less than 100% or higher than 100% corresponds to a minute ventilation lower or higher than normal.

From the %MinVol, the target minute ventilation (in l/min) is calculated as:

Bodyweight (in kg) x NormMinVent (in l/kg/min) x (%MinVol/100)

where NormMinVent is the normal minute ventilation from Figure C-6.

For example, with a %MinVol = 100 and an IBW = 70 kg, a target MinVol of 7 l/min is calculated. This target can be achieved with a number of combinations of tidal volume (Vt) and respiratory rate (f). This is shown in Figure C-7, where all possible combinations of Vt and f lie on the bold line, the target minute volume curve.

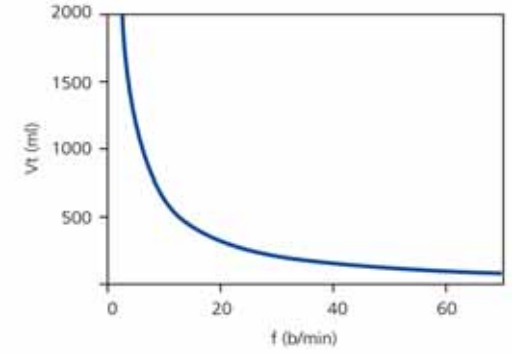


Figure C-7. MinVol = 7 l/min

All possible combinations of Vt and f that result in a minute ventilation of 7 l/min lie on the bold line.

C.3.3 Lung-protective rules strategy

Not all combinations of Vt and f shown in Figure C-7 are safe for the patient. The high tidal volumes will over distend the lungs and the small tidal volumes cannot produce alveolar ventilation at all. Another risk lies in inadequate respiratory rates. High rates can lead to dynamic hyperinflation or breath stacking, and thus inadvertent PEEP. Low rates can lead to hypoventilation and apnea.Therefore, it necessary to limit the number of possible combinations of Vt and f. When limits are imposed on the possible combinations of Vt and f, then ASV uses a double strategy:

- The operator input for ASV determines the absolute boundaries.
- Internal calculations based on patient measurements further narrow the limits to counteract possible operator errors and to follow changes of respiratory system mechanics.

The effect of the strategy is shown in Figure C-8 and explained in the subsequent sections.

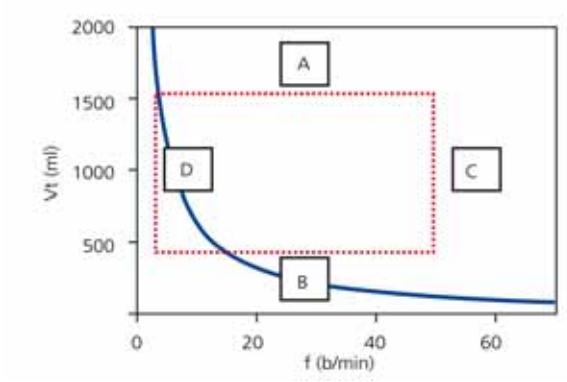


Figure C-8. Lung-protective rules strategy to avoid high tidal volumes and pressures (A), low alveolar ventilation (B), dynamic hyperinflation or breath stacking (C), and apnea (D)

A: High tidal volume limit

WARNING

Check Vt high setting to make sure the target minute ventilation can be reached in passive patients.

The tidal volume applied by ASV is limited (see A in Figure C-8) by three operator settings: high Pressure alarm limit, Vt high alarm limit, and Patient height.

The operator must set the high Pressure limit before connecting a patient to the ventilator. It was recommended by a group of physicians (Slutsky 1994) that the plateau pressure not exceed 35 cmH2O. To achieve this with ASV, the high Pressure limit must be set to 45 cmH2O. The maximum pressure to be applied in the ASV mode is 10 cmH2O below the high Pressure limit.

For example, a normal 70 kg normal (post-operative) patient would have a compliance of about 50 ml/cmH2O. A high Pressure limit of 45 cmH2O will result in a maximum applied pressure of 35 cmH2O. With a PEEP level of 5 cmH2O, the effective pressure swing will be 30 cmH2O. This in turn leads to an effective Vt of equal to, or less than 1500 ml. If the patient's lungs stiffen, to a compliance of 30 ml/cmH2O, the maximum tidal volume becomes 900 ml.

If the operator sets the Pressure limit to a very high pressure, say 60 cmH2O, the target volume is limited by the second criterion: 22 x IBW. For the 70 kg sample patient, a maximum target volume of 1540 ml results.

Additionally the target volume is limited to 1.5 * VT high limit, and pressure support actually is limited in a way that the inspired volume does not exceed Vt high limit in mechanical breaths for more than a few breaths.

B: Low tidal volume limit

To determine the minimum target Vt in ASV (see B in Figure C-8) use the IBW calculated from the Patient height, which corresponds to 4.4 ml/kg. In this example for a 70 kg patient, the minimum target Vt is 308 ml.

The operator must use caution with low tidal volumes to avoid insufficient alveolar ventilation. The determining parameter for alveolar ventilation is dead space (VDaw). Tidal volume value must always be greater than the VDaw value. It is widely accepted that a first approximation of dead space can be obtained by the following simple equation (Radford 1954):

The lower limit for tidal volume is based on this equation and calculated to be at least twice the dead space. Or, the minimum Vt is 4.4 x IBW.

$$VDaw = 2.2 * IBW \quad (1)$$

C: High rate limit

You derive the maximum rate (see C in Figure C-8) from the operator-set %MinVol and the calculated IBW, which is calculated from the operator-set Patient height. The equation used to calculate the maximum rate is:

$$fmax = \text{target MinVol} / \text{minimum Vt} \quad (2)$$

For example, the 70 kg patient described above will have a maximum rate of 22 b/min, when %MinVol is set to 100%.

However, as an example, if you choose an excessively high %MinVol of 350%, the maximum rate becomes 77 b/min. To protect the patient against such high rates, ASV employs a further safety mechanism, which takes into account the patient's ability to exhale.

A measure of the ability to exhale is the expiratory time constant (RCexp) (Marini 1989, Brunner 1995). To achieve a nearly complete exhalation to the equilibrium point of the respiratory system (90% of the maximum potential volume change), an expiratory time of at least 2 x RCexp is theoretically required.

For this reason, ASV calculates the maximum rate based on the principle of giving a minimum inspiratory time equal to 1 x RCexp and a minimum expiratory time equal to 2 x RCexp, which results in these equations:

$$fmax = 60 / (3 \times RCexp) = 20 / RCexp$$
$$fmax \leq 60 \text{ b/min} \quad (\mathbf{3})$$

For example, the 70 kg patient with a respiratory system compliance of 50 ml/cmH2O (equal to 0.05 l/cmH2O), an airway resistance including endotracheal tube of 5 cmH2O/l/s, and a resistance of the expiratory hose and valve of another 5 $cmH_2O/l/s$, would have an RCexp of

$$0.05 \text{ l/cmH2O} \times (5+5) \text{ } cmH_2O/l/s = 0.5 \text{ s}$$

and thus a maximum rate of 40 b/min. Since this value is higher than the one calculated above, the lower of the two values is in effect, that is, 22 b/min.

This limit applies to the respiratory rate of the ventilator only, *not* to the respiratory rate of the patient.

D. Low rate limit

The lowest target rate (see D in Figure C-8) is fixed at 5 b/min. This low rate in turn limits the maximum tidal volume to 1400 ml in the example of the 70 kg patient above, when %MinVol is set to 100%.

C.3.4 Optimal breath pattern

Although the lung-protective rules strategy limits possible combinations of Vt and f, ASV prescribes an explicit target combination. Using the example in Figure C-8, this shows considerable room for selection within the dotted rectangle. The selection process is an exclusive feature of ASV. The device works on the assumption the optimal breath pattern is identical to the one a totally unsupported patient will choose naturally (assuming the patient is capable of maintaining the pattern).

It is common knowledge that the choice of breathing pattern is governed by either work of breathing, or the force needed to maintain a pattern. ASV uses the original equation by Otis (Otis 1950) and calculates the optimal rate based on operator entries of %MinVol and the IBW (based on the Patient height setting) as well as on the measurement of RCexp (see Section C.4).

For example, with the 70 kg patient, a setting of 100 %MinVol, and a measured RCexp of 0.5 s, the optimal rate is 15 b/min according to Otis' equation.

Once the optimal rate is determined, the target Vt is calculated as:

$$Vt = \text{target MinVol} / \text{optimal rate} \quad (4)$$

In the example of the 70 kg patient, the target Vt becomes 467 ml (see Section C.4 for details).

Figure C-9 shows the position of the target breathing pattern as well as the safety limits imposed by the lung-protective rules strategy.

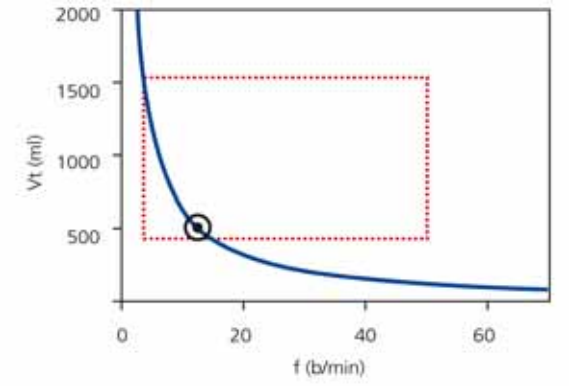


Figure C-9. Anatomy of the ASV target graphics window

The rectangle shows the safety limits; the circle shows the target breath pattern.

C.3.4.1 Initial breaths: How ASV starts

How does the operator make this determination: how to achieve the target values in a given patient if it is not known whether or not the patient can breathe spontaneously? For this purpose, ASV uses a synchronized intermittent mandatory pressure ventilation mode.

Each breath triggered by the patient is pressure-supported and flow-cycled, or, the transition to exhalation is made based on flow. In contrast, if the patient does not trigger the breath, the delivery of the breath is pressure-preset and time-cycled.

The operator-set controls (manual):

- PEEP/CPAP
- Oxygen
- P-ramp
- ETS
- Trigger type and sensitivity

This list of controls is adjusted automatically by ASV, and cannot be adjusted by the operator:

- SIMV rate: to change total respiratory rate
- Inspiratory pressure level: to change inspiratory volume
- Inspiratory time: to allow gas flow into the lungs
- Startup breath pattern

To safely start ASV, the operator inputs the Patient height setting, which is used to calculate the IBW.

Three initial test breaths are delivered. The resulting rate and tidal volume are measured and compared with the target values. ASV then responds to the differences between the actual and target Vt as well as the actual and target rates.

C.3.4.2 Approaching the target

Figure C-10 shows a possible scenario after the three initial test breaths. The actual breath pattern, which is plotted as the patient symbol, shows clear deviation from the target. The task of ASV is now to move the patient symbol as close to the circle as possible.

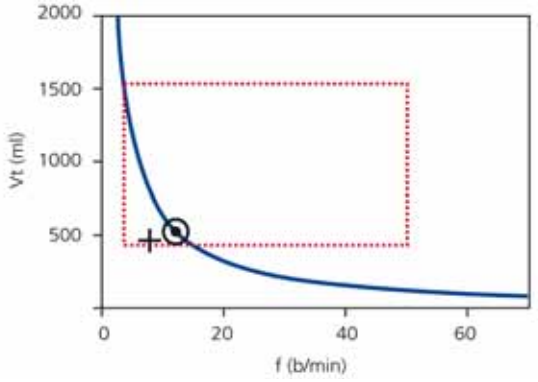


Figure C-10. Example of a situation after the three initial breaths

The patient symbol marks the actual measured values for Vt and rate.

To achieve the target, use this strategy:

- If actual Vt < target Vt, the inspiratory pressure is increased.
- If actual Vt > target Vt, the inspiratory pressure is decreased.
- If actual Vt = target Vt, the inspiratory pressure is left unchanged.
- If actual rate < target rate, the SIMV rate is increased.
- If actual rate > target rate, the SIMV rate is decreased.
- If actual rate = target rate, the SIMV rate is left unchanged.

As a result, the patient symbol in Figure C-10 moves toward the circle. The actual Vt is calculated as the average of inspiratory and expiratory volumes of the last 5 breaths. This definition compensates in parts for leaks in the breathing circuit, including the endotracheal tube.

C.3.5 Dynamic adjustment of lung protection

The operator preset values are not changed by ASV, and the corresponding safety limits remain as defined above. However, if the respiratory system mechanics change, the safety limits change accordingly and as defined in Section C.3.3 The safety limits are updated on a breath-by-breath basis.

For example, if the lungs stiffen, the high Vt limit is lowered proportionally, and the high Rate limit is increased according to Equation 5.

This dynamic adjustment ensures that ASV applies a safe breathing pattern at all times. In graphical terms, the dotted rectangle changes as shown in Figure C-11.

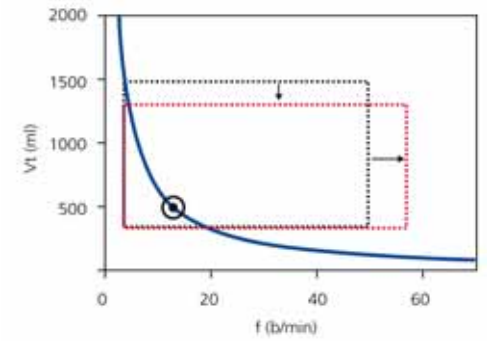


Figure C-11. Lung-protective limits are changed dynamically and according to the respiratory system mechanics. However, the limits derived from the operator input are never violated.

C.3.6 Dynamic adjustment of optimal breath pattern

After calculated, the optimal breath pattern is revised with each breath according to the measurements of RCexp. Apply Otis' equation and a new target breathing pattern is calculated. The targets do not change under steady-state conditions. However, if the patient's respiratory system mechanics change, the target values also change.

In this example: the bronchi of our normal 70 kg sample patient (being ventilated at 15 b/min and with a Vt of 467 ml) constrict due to asthma, and the expiratory resistance increases to values higher than 5 cmH2O/l/s. For this reason, more time is needed during exhalation for the lungs to reach the end-expiratory equilibrium position. In technical terms, the RCexp has increased and this increase requires a longer expiratory time.

For a given minute ventilation, this calls for an increase in Vt and a decrease in rate (longer expiratory time). Otis' equation yields new targets:

f = 11 b/min and Vt = 636 ml

Figure C-12 shows the change. Notice also that the increase in resistance results in a decrease in the volume/pressure ratio (V/P). The changes in RCexp and dynamic compliance affect the safety limits accordingly and with each breath (see Section C.3.5).

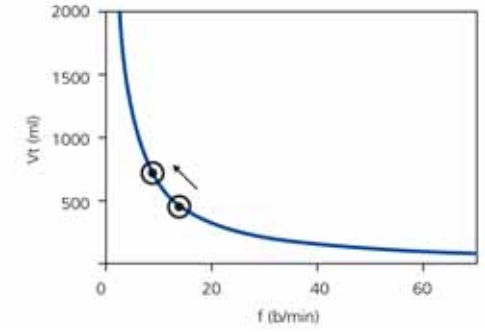


Figure C-12. Changes of target values in broncho-constriction

For clarity, the safety limits are omitted. For clinical examples, see Belliato 2000.

C.4 Minimum work of breathing (Otis' equation)

Otis' basic question was: how do mammals choose their breathing pattern and on what parameters does it depend (Otis 1950)? The same question was investigated years before by Rohrer and a very similar result was obtained (Rohrer 1925). The hypothesis was that the breath pattern with the least work of breathing (WOB) is chosen by mammals. Figure C-13 shows the relationship between rate and WOB graphically, for resistive load, elastic load, and total load to breathing.

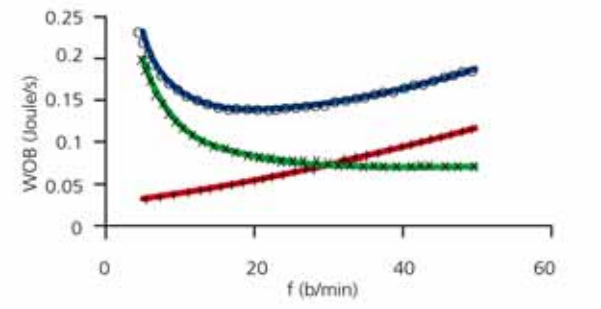


Figure C-13. Three different relationships between rate and WOB are plotted for a hypothetical lung: (+) purely resistive load causes WOB to rise with rate, (x) purely elastic load creates highest load at low rates, (o) the total lung shows a clear minimum which can be calculated according to the equation below.

The following equation was found to represent the rate where WOB is minimum:

$$f = (1 + 2a*RCe*(MinVol-f*Vd)/(Vd))^{-0.5} -1/a*RCe$$

where *a* is a factor that depends on the flow waveform. For sinusoidal flows, *a* is $2\pi^2/60$.

The corresponding tidal volume is calculated as:

$$Vt = MinVol/f$$

Example: A 70 kg male patient with normal lungs (Rtotal = 5 cmH2O/l/s, expiratory resistance hose and valve = 5 cmH2O/l/s, Crs = 50 ml/cmH2O) may have a measured RCexp of 0.5 s, an estimated VDaw of 154 ml, and an operator-set %MinVol of 100%. With these values, the target MinVol becomes

MinVol = 100% x 70 kg x 0.1 l/min/kg = 7 l/min

Next, Otis' equation is applied with the following parameters:

MinVol = 7 l/min

VDaw = 154 ml

RCexp = 0.5s

$a = 2\pi^2/60$

f = 10 b/min (this is always used as a starting value)

The result is a new rate f(1)

f(1) = 15 b/min

This rate is again inserted into Otis' equation, the calculation is performed again, and the next estimate for rate f(2) is obtained. This procedure is repeated until the difference between subsequent results for rate (f) becomes lower than 0.5 b/min. In the present example, one iteration step is sufficient, i.e.,

ftarget = 15 b/min

Finally, the target tidal volume is obtained by dividing MinVol by f:

Vtarget = 7000 ml/min / 15 b/min = 467 ml

C.5 ASV technical data

Table C-5 lists technical data related to ASV.

Table C-5. ASV technical data

ASV-related operator settings	
%MinVol	25% to 350%
Patient height	Adults: 130 to 250 cm / 50 to 100 in Pediatric: 30 to 150 cm / 12 to 60 in
Internal calculations	
IBW	In kg, calculated based on Patient height and Gender (see Section 5.2)
MinVol (target)	In l/min, target minute volume is calculated as: IBW (in kg) x NormMinVent (in l/kg/min) x %MinVol/100 where NormMinVent is the normal minute ventilation from Figure C-6.
fTotal	In b/min, calculated on the basis of Otis' equation
VDaw	2.2 ml/kg IBW
Vt (target)	MinVol/ f(target)
ASV monitor	
Target values (numerical)	MinVol, Vt, fTotal
Current achieved values (numerical)	MinVol, Vt, fTotal, Vt = (VTI+VTE)/2
Status of patient (numerical)	fSpont, fControl, Pinsp
Graphics display (curve)	f versus Vt, target value, actual value, safety boundaries
Alarms	
All alarms are functional except apnea alarms	See Chapter 9
Special	ASV: Check high press limit, ASV: Cannot meet target

Table C-5. ASV technical data *(continued)*

Performance specifications	
Response time (90% of steady state)	< 1 min (typical)
Overshoot/undershoot	< 20%
Maximum pressure change per breath	2 cmH2O
Lung-protective rules	
Maximum Vt	Limited to 1.5 x Vthigh. Depends on high Pressure alarm limit and volume/pressure ratio (V/P) always < 22 x IBW
Minimum Vt	4.4 x IBW
Maximum machine rate	Depends on RCexp, but always < 60 b/min
Minimum target rate	5 to 15 b/min
Maximum Pinsp	High *Pressure* alarm limit - 10 cmH2O - PEEP
Minimum Pinsp	5 cmH2O above PEEP/CPAP
Minimum inspiratory time (TI)	0.5 s or RCexp, whichever is longer
Maximum inspiratory time (TI)	2 s
Minimum expiratory time (Te)	2 x RCexp
Maximum expiratory time (Te)	12 s
I:E range	1:4 to 1:1

C.6 ASV startup

When ASV is started, the device delivers 3 (three) test breaths in the synchronized intermittent mandatory pressure ventilation mode. The device automatically selects the values for SIMV rate, inspiratory time (TI), and inspiratory pressure (Pinsp) based on the calculated IBW, which is determined from the operator-set Patient height and Gender settings, and according to information described in Tables C-6 and C-7.

Table C-6. Initial breath pattern for Adult settings

IBW (kg)	P insp (cmH2O)	TI (s)	SIMV rate (b/min)	Minimum target rate (b/min)
30 to 39	15	1	14	7
40 to 59	15	1	12	6
60 to 89	15	1	10	5
90 to 99	18	1.5	10	5
> 100	20	1.5	10	5

Table C-7. Initial breath pattern for Pediatric settings

IBW (kg)	P insp (cmH2O)	TI (s)	SIMV rate (b/min)	Minimum target rate (b/min)
3 to 5	15	0.4	30	15
6 to 8	15	0.6	25	12
9 to 11	15	0.6	20	10
12 to 14	15	0.7	20	10
15 to 20	15	0.8	20	10
21 to 23	15	0.9	15	7
24 to 29	15	1	15	7

C.7 References

- **Hewlett AM, Platt AS, Terry VG.** Mandatory minute volume. A new concept in weaning from mechanical ventilation. Anaesthesia 1977, 32:163-9.
- **Radford EP Jr.** Ventilation standards for use in artificial respiration. N Engl J Med 1954, 251:877-83.
- **Otis AB, Fenn AWO, Rahn H.** Mechanics of breathing in man. J Appl Physiol 1950, 2:592-607.
- **Marini JJ, Crooke PS, Truwit JD.** Determinants and limits of pressure-preset ventilation: a mathematical model of pressure control. J Appl Physiol 1989, 67:1081-92.
- **Slutsky AS.** Consensus conference on mechanical ventilation- January 28-30, 1993 at Northbrook, Illinois, USA. Int Care Med 1994, 20:64-79.
- **Lourens MS, Van den Berg BV, Aerts JGJ, Verbraak AFM, Hoogsteden HC, Bogtaard JM.** Expiratory time constants in mechanically ventilated patients with and without COPD. Int Care Med 2000, 26:1612-18.
- **Quan SF, Parides GC, Knoper ST.** Mandatory Minute Volume (MMV) Ventilation: An Overview. Resp Care 1990, 35:898-905.
- **Belliato M, Maggio M, Neri S, Via G, Fusilli N, Olivei M, Lotti G, Braschi A.** Evaluation of the adaptive support ventilation (ASV) mode in paralyzed patients. Intensive Care Med 2000, 26, Suppl. 3:S327.
- **...more** and updated references on www.hamilton-medical.com

APPENDIX

D NIV, noninvasive ventilation

D.1 Introduction

CAUTION

When using a mask for noninvasive ventilation, pay special attention to how the mask is attached to prevent patient skin irritation.

NOTE:

- Noninvasive ventilation in critically ill patients should only be used by properly trained and experienced personnel.
- As a precaution, you must be prepared to intubate the patient and start invasive ventilation at any time while noninvasive ventilation is in use.
- The use of a mask can increase dead space. Always comply with the mask manufacturer's instructions when using noninvasive ventilation.
- If you are using the neonatal noninvasive modes, nCPAP and nCPAP-PC, see Chapter 6.

The noninvasive ventilation mode (NIV) and the spontaneous/timed noninvasive ventilation mode (NIV-ST) are implementations of noninvasive positive pressure ventilation (NPPV). NPPV can use as its patient interface a mask, mouthpiece, or helmet-type interface, rather than an invasive conduit such as an endotracheal tube.

Used for years in home care and subacute care settings, NPPV can also benefit intensive care ventilation patients by decreasing the need for intubation and promoting early extubation. Benefits such as reduced mortality (COPD patients), reduced ventilation time (COPD and ARF patients), and reduced complication rates (of ventilator-associated pneumonias) have been clearly demonstrated[1,2].

1. Mehta S et al. Noninvasive ventilation. Am J Respir Crit Care Med 2001 Feb;163(2):540-77.
2. Hess DR. The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: a systematic review of the literature. Respiratory Care 2004 Jul;49(7):810-25.

Intended for actively breathing patients, noninvasive ventilation is provided through a nonvented or nonported mask interface. Because this open breathing circuit permits air to leak around the mask or through the mouth, the ventilator achieves and maintains the prescribed pressure by adjusting the inspiratory flow. If the leak is large, the ventilator's inspiratory flow can be large—up to 260 l/min—thus compensating at least in part for most leaks. The NIV modes were also designed to minimize nuisance leak-related alarms.

NIV is an adaptation of the SPONT mode, while NIV-ST is an adaptation of the PSIMV+ mode. The primary difference between SPONT and NIV or PSIMV+ and NIV-ST is that SPONT and PSIMV+ are designed for an intubated patient, while the NIV modes are designed for use with a mask or other noninvasive patient interface. See Appendix A for technical details about the ventilator's noninvasive modes.

D.2 Benefits of noninvasive ventilation

Noninvasive ventilation offers these short-term benefits[1,2]:

- Relieves respiratory symptoms
- Optimizes patient comfort
- Reduces work of breathing
- Improves or stabilizes gas exchange
- Improves patient-ventilator synchrony
- Minimizes risks associated with aspiration, intubation, injury to the mucus membranes and teeth, and circulatory reactions

Noninvasive ventilation offers these long-term benefits:

- Improves sleep duration and quality
- Maximizes quality of life
- Enhances functional status
- Prolongs survival

1. Mehta S et al. Noninvasive ventilation. Am J Respir Crit Care Med 2001 Feb;163(2):540-77.
2. Hess DR. The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: a systematic review of the literature. Respiratory Care 2004 Jul;49(7):810-25.

D.3 Required conditions for use

CAUTION

- **To prevent possible patient injury, DO NOT use noninvasive ventilation on patients with no or irregular spontaneous breaths. Noninvasive ventilation was intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.**
- **To prevent possible patient injury, DO NOT attempt to use noninvasive ventilation on intubated patients.**

Ensure these requirements are met to use noninvasive ventilation:

- The clinician's instructions must be strictly followed.
- The patient must not be intubated.
- The patient must be able to trigger the ventilator and must have regular spontaneous breaths.
- The patient must be conscious.
- The patient must be able to maintain an adequate airway.
- The patient must be monitored by external monitors.
- Intubation must be possible at any time.
- The mask should fit face structures well.

D.4 Contraindications

- Intolerance of interface
- Inability to trigger breath
- Facial or brain injury
- Recent upper airway or esophageal surgery
- Hemodynamic instability
- Gastric distension
- Inability to protect airway

D.5 Potential adverse reactions

- Skin breakdown from interface (pressures sores)
- Aspiration
- Conjunctivitis
- Gastric insufflation
- Claustrophobic reaction
- Potential hemodynamic instability

D.6 Selecting a patient interface

CAUTION

Make sure to follow the instructions for use of the manufacturer when using any noninvasive patient interface. Incorrectly used masks can cause skin irritations.

The quality and performance of the patient interface largely determine the effectiveness of noninvasive ventilation.

The following types of interfaces are supported:

- Face (oronasal) mask that covers the mouth and nose
- Nasal mask that covers the nose only
- Mouthpiece
- Helmet

In general, an interface used with the noninvasive modes must meet these requirements:

- It must be of the nonvented/nonported design
- Gas leakage should be controllable at low mask application pressures
- The material in contact with the face should be soft, biocompatible, and nonallergenic
- It should be easy to install and remove
- It should remain properly positioned when the patient moves their head

If you try using a nasal mask, but there is significant gas leakage through the open mouth, switch to a face mask.

D.7 Control settings

WARNING

The exhaled volume from the patient can differ from the measured exhaled volume due to leaks around the mask.

CAUTION

- **When ventilating with a mask, avoid high airway pressures. High pressures may cause gastric distension.**
- **Peak pressures exceeding 33 cmH2O may increase the risk of aspiration due to gastric insufflation[1]. When ventilating with such pressures, consider using an invasive mode.**

When a significant leak occurs, the inspiratory flow can never fall below ETS, thus not allowing the ventilator to cycle into exhalation and resulting in endless inspiration. For this reason, the TI max setting was added, providing an alternative way to cycle into exhalation. When inspiration lasts longer than TI max, the ventilator cycles into exhalation.

When the ventilator cycles are based on ETS setting rather than TI max, it is the most comfortable for the patient. Ensure the TI max setting is sufficiently long to give ETS the chance to cycle the ventilator. Adjusting the TI max setting increases or decreases the allowable inspiratory time. Increasing ETS above the default 25% allows the ventilator to cycle to terminate inspiration at a higher flow, to accommodate larger leaks.

1. Bach JR, Alba AS, Saporito LR. Intermittent positive pressure ventilation via the mouth as an alternative to tracheostomy for 257 ventilator users. Chest 1993;103:174-182.

Other controls require special attention. Carefully observe the patient/ventilator interaction. The leakage in this mode reduces the actual applied PEEP/CPAP and give rise to autotriggering. Adjust Psupport or Pinsp to obtain appropriate tidal volumes. Adjust PEEP/CPAP further, considering oxygenation and AutoPEEP.

D.8 Alarms

NOTE:

The Inspiratory volume limitation alarm is inactive in noninvasive modes.

Due to the changing and unpredictable amount of leakage, volume alarms are less meaningful in noninvasive than in other modes. Alarms are based on the returned expiratory gas volume measured at the flow sensor; this value can be significantly lower than the delivered tidal volume, because the delivered tidal volume is the sum of the displayed VTE and the leakage volume. To avoid nuisance volume alarms, set the low Vt and ExpMinVol alarms to a low level.

Because the noninvasive modes are pressure modes, however, do pay attention to the pressure-related alarms. If the defined PEEP and inspiratory pressure can be maintained, the ventilator is compensating the gas leak sufficiently.

D.9 Monitored parameters

NOTE:

Due to the changing and unpredictable amount of leakage, these numeric monitoring parameters cannot be used for reliable analysis of patient conditions: ExpMinVol, RCexp, Rinsp, Insp Flow, AutoPEEP, and Cstat. Continuous monitoring of the clinical parameters and patient comfort is of critical importance.

Due to the leakage at the patient interface, displayed exhaled volumes in the noninvasive modes can be substantially smaller than the delivered volumes. The flow sensor measures the delivered volume and the exhaled tidal volume; the ventilator displays the difference as VLeak in %, and as MVLeak in l/min. Use VLeak and MVLeak to assess the fit of the mask or other noninvasive patient interface.

While a leak at the patient interface influences the tidal volume measurement, leaks in the breathing circuit itself do not influence the tidal volume measurement.

Besides all the other clinical parameters, TI, Ppeak, PEEP/CPAP, I:E, fTotal, Pmean, and fSpont can be used to assess the patient's ventilatory status.

D.10 Additional notes about using noninvasive ventilation

NOTE:

If the mask fit cannot be improved, select an alternative treatment method.

Due to some unique characteristics of noninvasive ventilation, consider the following points when using it. Consistent with best practices, monitor the patient closely to evaluate the adequacy of the prescribed therapy.

IntelliTrig (intelligent trigger) function. With its IntelliTrig function, the ventilator can automatically adapt to changing breath patterns and system leaks to achieve optimum synchronization between patient and device.

To synchronize, IntelliTrig compensates any leaks and resistances between the ventilator and the patient, and with each breath it measures the leakage at the patient interface (mask). With this information IntelliTrig adapts the trigger mechanism so leakage and the changing breath pattern do not influence the operator-set trigger sensitivity (flow trigger).

Maintaining PEEP and preventing autotriggering. Significant leakage can be present in noninvasive ventilation, which can serve to reduce the actual applied PEEP/CPAP and give rise to autotriggering. If you cannot reach the set PEEP/CPAP, check the mask fit.

The ventilator maintains PEEP with the expiratory valve in combination with a compensating base flow delivered by the check valve through the breathing circuit.

The **Loss of PEEP** alarm alerts you to uncompensated leaks (that is, when the measured PEEP/CPAP is 3 cmH2O lower than the set PEEP/CPAP).

Inspect mask fit and position. For noninvasive ventilation to function as intended, the mask must fit well and remain in place. It is desirable to maintain a good seal and minimize leakage.

Inspect the mask position regularly and adjust as necessary. If the mask slides away from the mouth and nose (patient disconnection), reinstall and secure it. React promptly and appropriately to any alarms.

The ventilator's Leak parameter provides one indicator of mask fit. To check the proper fit of the mask verify that the patient can trigger and flow-cycle inspiration and by verify that:

Ppeak = (PEEP/CPAP + Psupport/Pinsp) ±3 cmH2O

CO2 rebreathing in noninvasive ventilation. CO2 rebreathing per breath can increase in noninvasive ventilation. Typically this is not critical, because there is also generally significant leakage in noninvasive ventilation. CO2 rebreathing can occur because there is not the usual dead space reduction from an endotracheal tube or tracheostomy. And because the mask or other noninvasive interface creates additional dead space. Consider this additional dead space when prescribing a specific type of noninvasive patient interface. Despite the use of a noninvasive interface, the dead space ventilation per minute can decrease when the therapy results in an increase in tidal volume and decrease in respiratory rate.

D.11 References

- **Hess DR.** The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: a systematic review of the literature. Respir Care 2004 Jul;49(7):810-25.
- **Mehta S et al.** Noninvasive ventilation. Am J Respir Crit Care Med 2001 Feb;163(2):540-77.
- **Arroliga AC.** Noninvasive positive pressure ventilation in acute respiratory failure: does it improve outcome? Cleveland Clin J Med. 2001 Aug;68(8):677-80.
- **Hill NS.** Noninvasive ventilation in chronic obstructive pulmonary disease. Clin Chest Med. 2000 Dec;21(4):783-97.
- **AARC.** Consensus statement: Noninvasive positive pressure ventilation. Respir Care 1997;42(4):365-9.
- **Evans TW et al.** Noninvasive positive pressure ventilation in acute respiratory failure: Report of an international consensus conference in intensive care medicine, Paris, France, 13 - 14 April 2000. Reanimation 2001;10:112-25.

APPENDIX

E Pneumatic diagram

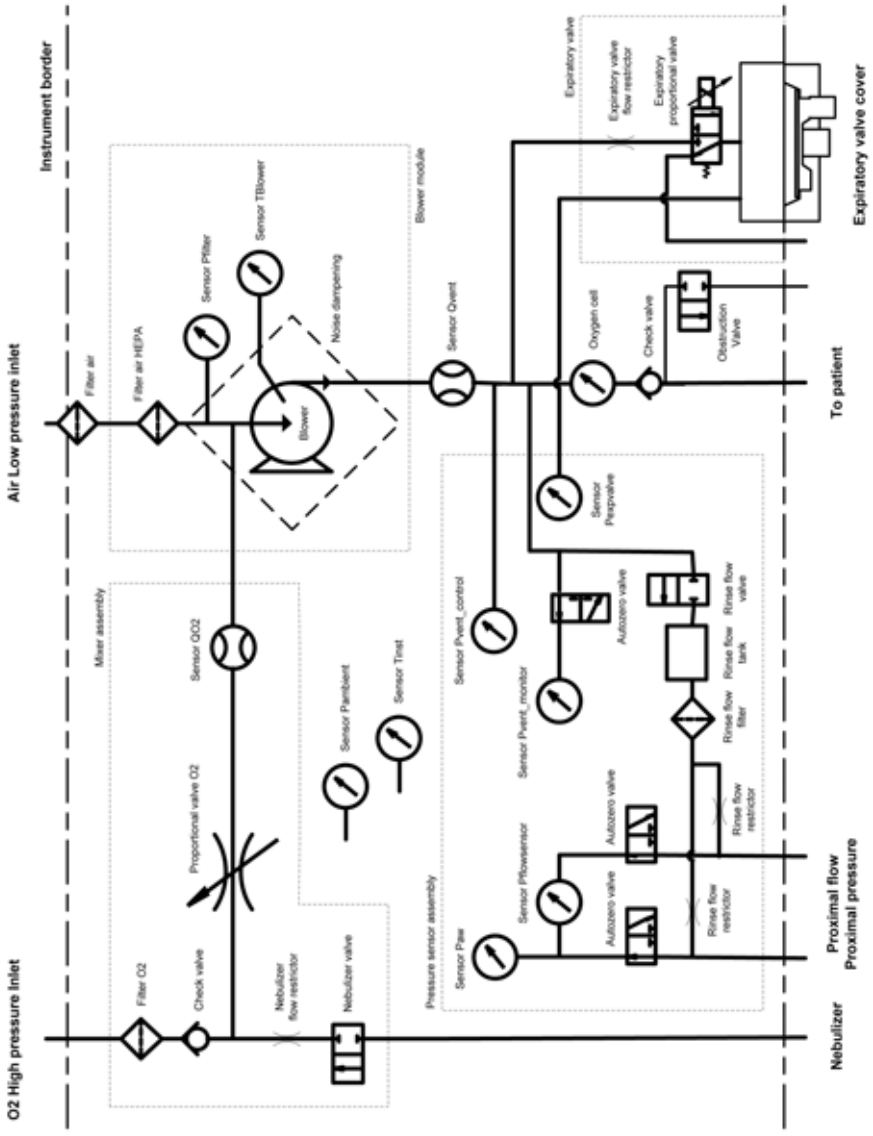


Figure E-1. Pneumatic diagram

APPENDIX

F Parts and accessories

This appendix lists the parts available for the HAMILTON-MR1 ventilator.

WARNING

To ensure proper ventilation operation, use only parts and accessories specified in this appendix and in the product catalog, or that are specified as being compatible with this ventilator.

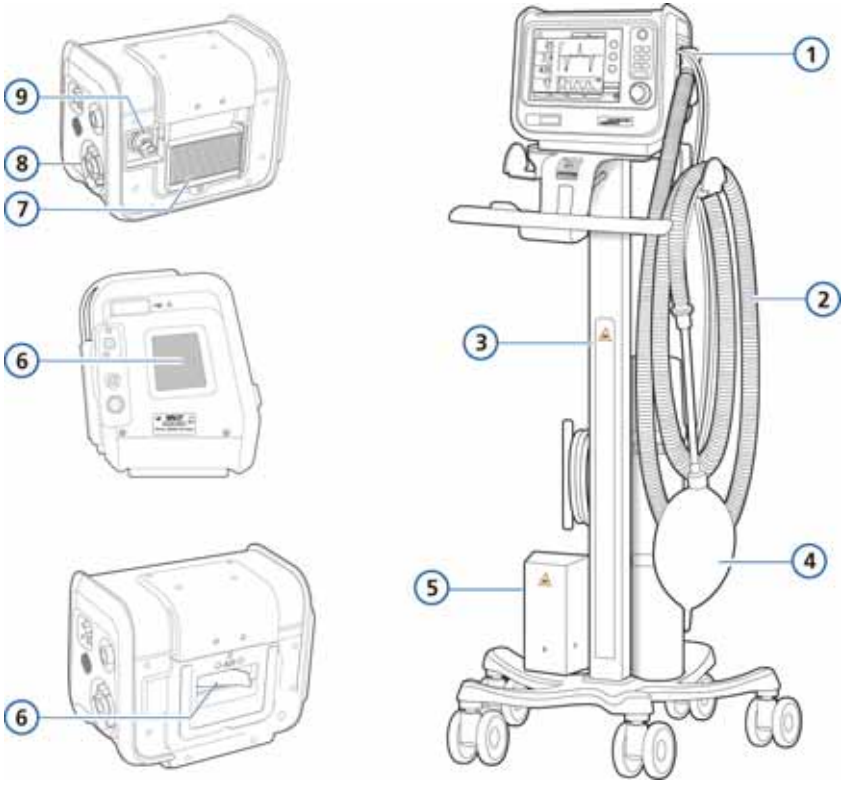


Figure F-1. Ventilator parts and accessories

NOTE:

- Not all parts are available in all markets.
- For additional parts and accessories, see the product catalog or contact your Hamilton Medical representative.
- The MR rating column in Table F-1 indicates whether a component is certified as safe for use in the MRI environment. These components are marked as follows:

MR Safe

MR Conditional

Not for use in MRI environment

Table F-1. Ventilator parts and accessories

Item no. (Fig. F-1)	Description	PN	MR rating
1	**Ventilator unit** Includes: • Ventilator • Expiratory valve • Flow sensor • Dust and HEPA filters • Demonstration lung • Coaxial breathing circuit, adult, 3 m • Oxygen cell • 2 internal Li-Ion batteries • Power supply	161010	

Table F-1. Ventilator parts and accessories *(continued)*

Item no. (Fig. F-1)	Description	PN	MR rating
2	**Breathing set, pediatric/adult, single use**		
	Breathing set, coaxial, incl. flow sensor and elbow adapters, length 1.8 m, box of 20[1]	260087	
	Breathing set, coaxial, incl. flow sensor and elbow adapters, length 2.4 m, box of 20[1]	260094	
	Breathing set, coaxial, incl. flow sensor and elbow adapters, length 3.0 m, box of 10	260145	
	Breathing set, coaxial, incl. flow sensor and elbow adapters, length 4.8 m, box of 8	260144	
	Breathing set, pediatric/adult, single use, with expiratory valve set		
	Breathing set, coaxial, incl. flow sensor, elbow adapters, and expiratory valve, length 1.8 m, box of 20[2]	260128	
	Breathing set, coaxial, incl. flow sensor, elbow adapters, and expiratory valve, length 2.4 m, box of 20[2]	260127	
	Breathing set, coaxial, incl. flow sensor, elbow adapters, and expiratory valve, length 3.0 m, box of 10	260167	
	Breathing set, coaxial, incl. flow sensor, elbow adapters, and expiratory valve, length 4.8 m, box of 8	260168	
	Breathing set, neonatal, single-use		
	Breathing set, dual limb, incl. flow sensor, pressure line, Y-piece, and elbow adapters, length 1.5 m, box of 20[1]	260180	
	Breathing set, dual limb, incl. flow sensor, pressure line, Y-piece, and elbow adapters, length 3.0 m, box of 10	260182	

Table F-1. Ventilator parts and accessories *(continued)*

Item no. (Fig. F-1)	Description	PN	MR rating
2	**Flow sensors**		
	Flow sensor, pediatric/adult, single patient use, 1.88 m, box of 10[1]	281637	
	Flow sensor, pediatric/adult, reusable, 1.88 m, box of 10[1]	155362	
	Flow sensor, pediatric/adult, autoclavable, 1.88 m, box of 1[1]	950185	
	Flow sensor, infant/neonatal, single patient use, 1.6 m, box of 10[1]	260177	
	Flow sensor, infant/neonatal, single patient use, 1.88 m, box of 10[1]	155500	
	Flow sensor, infant/neonatal, single patient use, 3.1 m, box of 10	260179	
not shown	Flow sensor calibration adapter, pediatric/adult, single patient use, box of 10	279937	
	Flow sensor calibration adapter, infant/neonatal, single patient use, box of 10	279964	
not shown	**Pressure line (for nCPAP, nCPAP-PC modes)**		
	Pressure line for nCPAP and nCPAP-PC, infant/neonatal, single patient use, 1.6 m, box of 10[1]	260174	
	Pressure line for nCPAP and nCPAP-PC, infant/neonatal, single patient use, 3.1 m, box of 10	260176	
	Luerlock Adapter Kit for nCPAP/nCPAP-PC with breathing set RT225 and similar, single patient use, box of 50	282438	
3	**Trolley**		
	Trolley, equipped with: • Auto-lock brake • Storage position for breathing circuit • Storage for power supply and cable • Storage position for oxygen cylinder	161160	

Table F-1. Ventilator parts and accessories *(continued)*

Item no. (Fig. F-1)	Description	PN	MR rating
4	**Demonstration lung**		
	IntelliLung, maximum 1 liter	281869	
	Demonstration lung assembly with endotracheal tube, adult, 2 liter, with 15 mm male x 22 mm male connector	151815	
	Demonstration lung, neonatal, 15 mm A passive lung simulator with two independent compartments for simulating infant and neonatal patients.	R53353	
	Filter		
6	Filter set Includes 5 sets. Each set includes 2 air intake dust filters and 1 fan filter.	161825	
7	Filter, air intake (HEPA)	161236	
not shown	**Patient filter**		
	HME/HMEF, adult	279963	
	Inspiratory bacteria filter	279204	
5	**Power cord and power supply**		
	Power cord with US plug, 3 pin	355271	
	Power cord with British angled-plug, 3 pin	355272	
	Power cord with continental European plug, 3 pin	355270	
	Power cord with Swiss plug, 3 pin	355269	
	Power supply	161840	
not shown	**Batteries**		
	2 internal Li-Ion batteries	369106	

Table F-1. Ventilator parts and accessories *(continued)*

Item no. (Fig. F-1)	Description	PN	MR rating
8	**Expiratory valve**		
	Expiratory valve set, pediatric/adult, autoclavable, incl. cover and membrane, box of 1	161175	
	Expiratory valve set, neonatal, autoclavable, incl. cover and membrane, box of 1	161188	
	Expiratory valve membrane, autoclavable, box of 5	161390	
	Expiratory valve set, adult/pediatric, single patient use, box of 10	161186	
9	**Oxygen cell**	396200	
not shown	**High-pressure oxygen connector**		
	DISS – diameter index safety standard	160470	
	NIST – no interchangeable screw thread	160471	
not shown	**Gas source switch**		
	O2 switch mounting set for HAMILTON-MR1 trolley	161655	
	Gas source switch	279947	
	O2 hose switch, NIST	279952	
	O2 hose switch, DIN, 0.5 m	279953	
not shown	**HAMILTON-MR1 safety tether (for trolley)[3]**	161690	

Table F-1. Ventilator parts and accessories *(continued)*

Item no. (Fig. F-1)	Description	PN	MR rating
not shown	**Masks and accessories** *See the Hamilton Medical Accessories catalog*	689304	--
	nCPAP starter kit, small	282330	
	nCPAP starter kit, large	281975	
	NIV mask starter kit	282013	
	Nebulizer and accessories *See the Hamilton Medical Accessories catalog*	689304	--
	Adapters *See the Hamilton Medical Accessories catalog*	689304	--
	Tools and test equipment *See the Hamilton Medical Accessories catalog*	689304	--
	Language kit		
	English	161040	--
	German	161041	--
	Spanish	161042	--
	French	161043	--
	Italian	161048	--
	Russian	161044	--
	Chinese	161045	--
	Portuguese	161046	--
	USA only	161047	--
	Extended warranty *The standard warranty period is two years*		
	Extended warranty of 1 year	700803	
	Extended warranty of 2 years	700804	
	Extended warranty of 3 years	700805	

1. This part is rated MR Safe but we do not recommend its use in the MRI environment due to its length.
2. This part is rated MR Conditional but we do not recommend its use in the MRI environment due to its length.
3. Use of the tether is required in the USA.

APPENDIX

G Configuration

G.1 Introduction

During configuration, you set up the ventilator with a default language, main monitoring parameter display, startup settings for a new patient, and unit of measure for pressure, among other settings.

G.2 Entering Configuration mode

You can access configuration mode when the ventilator is in Standby. Access requires a configuration code; contact your administrator.

To access configuration mode

1. Touch the **Utilities** button at the bottom of the screen, and then touch the **Configuration** tab.

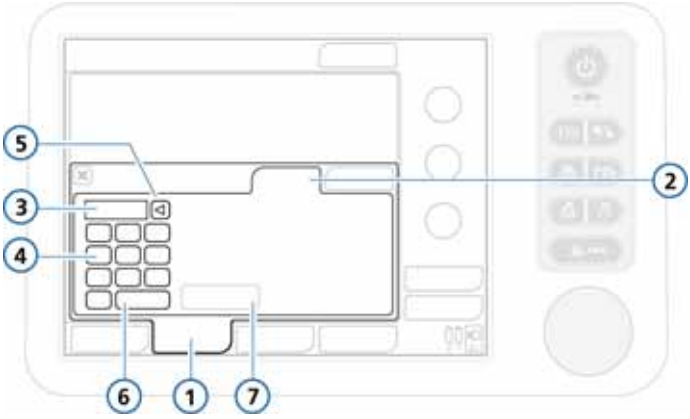


Figure G-1. Accessing configuration

1	Utilities	**5**	Delete
2	Configuration	**6**	Enter
3	Text field to type code	**7**	Configuration button
4	Keypad		

2. Touch the text field and, using the keys on the onscreen keypad, type the configuration code; then touch **Enter**.

   The **Configuration** button is enabled.

3. Touch the **Configuration** button.

   The Configuration window appears, displaying the Language tab.

You can now define settings and add options.

G.3 Configuring general settings

You can configure some general default settings for the ventilator, including language, units of measure, and minimum alarm loudness.

G.3.1 Language: Selecting the default language

Open the General -> Language window and select the desired language for screen display.

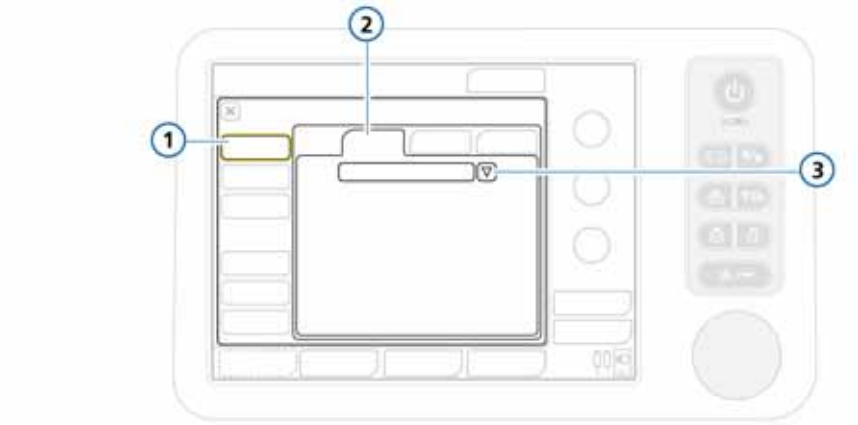


Figure G-2. Language configuration window

1	General	**3**	Language list
2	Languages		

G.3.2 Selecting the default units of measure

Open the General -> Units window and select the unit of measure for pressure and length.

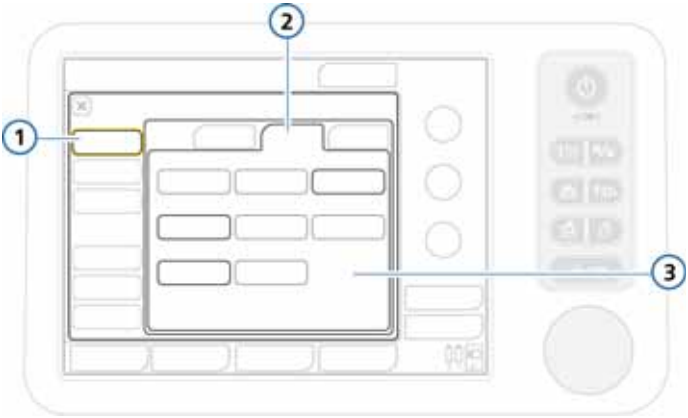


Figure G-3. Units configuration

1	General	**3**	Pressure and length units
2	Units		

G.3.3 Setting the minimum alarm loudness (volume)

You can set a minimum alarm loudness (also referred to as *alarm volume*) setting for the device. Once set, the device operator cannot set the alarm volume below the value set here in Configuration.

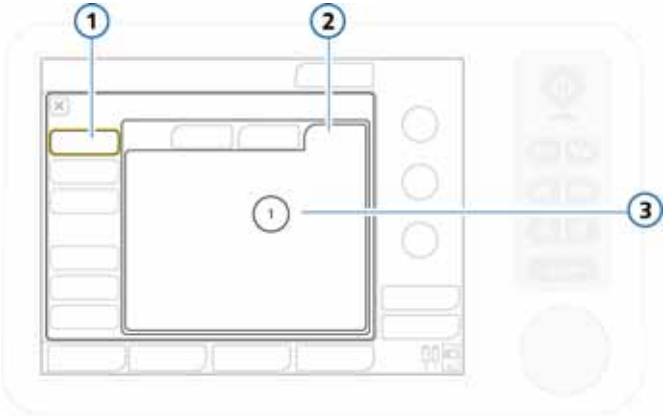


Figure G-4. Minimum alarm loudness configuration

1	General	**3**	Min. loudness
2	More		

To set the minimum alarm loudness

1. Open the General -> More window (Figure G-4).
2. Touch the **Min. Loudness** button and choose the minimum alarm volume to allow on the device. By default, set to 1.
3. Continue setting configuration options or exit Configuration mode.

The setting is applied to the device. Note that if the new minimum is greater than the currently set alarm loudness, the alarm loudness is reset to the new minimum level.

To verify the setting, check the **Loudness** value in the System -> Settings window.

G.4 Setting breath timing and mode naming options

You can choose which mandatory breath timing philosophy to use for PCV+ and SCMV+ modes (I:E or TI), and the naming convention to use for volume controlled pressure adaptive modes.

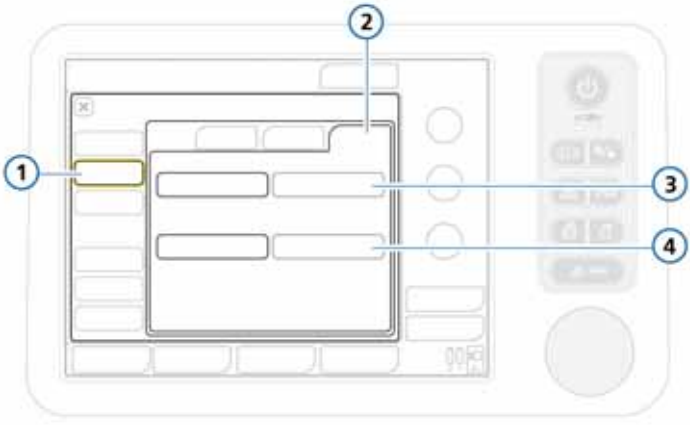


Figure G-5. Setting breath timing and labeling options

1	Modes	**3**	Breath timing options
2	Philosophy	**4**	Mode naming options

G.4.1 Setting breath timing options for PCV+ and (S)CMV+ modes

The ventilator controls mandatory breath timing using a combination of inspiratory time (TI) and rate. For two modes, PCV+ and (S)CMV+, you can set the ventilator to use the inspiratory:expiratory (I:E) ratio to control breath timing instead.

To change breath timing for PCV+/(S)CMV+ modes

- In the Modes window, select either **I:E** (the default) or **TI** for the desired timing option. See Figure G-5.

G.4.2 Choosing the mode naming convention

You can select the naming convention used for adaptive (pressure regulated and volume targeted) modes.

To select the mode naming convention

Select either **(S)CMV+/SIMV+** (the default) or **APVcmv/ APVsimv**.

G.5 Configuring default MMP display

You can define a default set of main monitoring parameters (MMPs) to display on the ventilator.

Open the **Graphics -> MMP** window (Figure G-6). Select the desired parameter to be displayed in that position on the screen. Repeat for the remaining parameters.

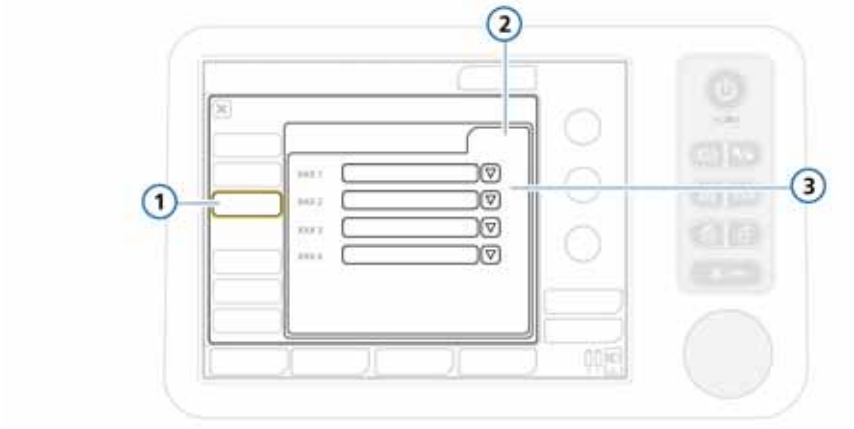


Figure G-6. MMP configuration

1	Graphics	**3**	Parameter list for MMP 1 through MMP 4
2	MMP		

G.6 Setup window (quick setup configuration)

A *Quick setup* refers to a group of settings you define, including patient characteristics (group and weight), mode selection and control settings, alarm limit settings, and weaning zone limits, that is automatically applied when the setup is selected in the Standby window.

You can configure up to three Quick setups, and can specify a setup to be selected by default when the ventilator is turned on (Section G.6.2).

G.6.1 Configuring individual setup settings

To configure a Quick setup

1. In Standby mode, configure the ventilator with the parameters you will save as a Quick setup. Select:
   - Patient group and gender/height (adult/pediatric) or weight (neonatal)
   - Ventilation mode
   - Mode control settings
   - Alarm limits
2. Enter Configuration mode (Section G.2).
3. In the Configuration window, touch **Setups**, and then touch the button (1, 2, or 3, or your custom-defined labels) for the setup to configure.

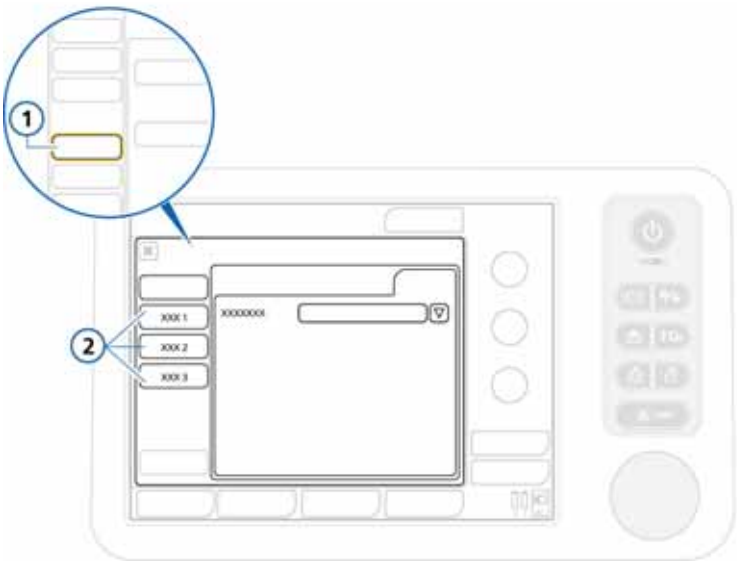


Figure G-7. Accessing setup configuration

1	Setups button in main Configuration window	**2**	Quick setup buttons

The General setup configuration window is displayed (Figure G-8). Note that the buttons in the left panel now change to provide access to the setup options.

4. Touch **Rename setup** to give the setup a meaningful name.

   You must define a name, as it is used as the Quick setup button label in Standby, as well as in this configuration window.

5. Select the configuration settings to apply to this setup by touching the appropriate button (Figure G-8):
   - To apply the ventilator settings you selected in step 1, touch **Use current settings**.
   - To apply factory settings, touch **Use factory settings**.

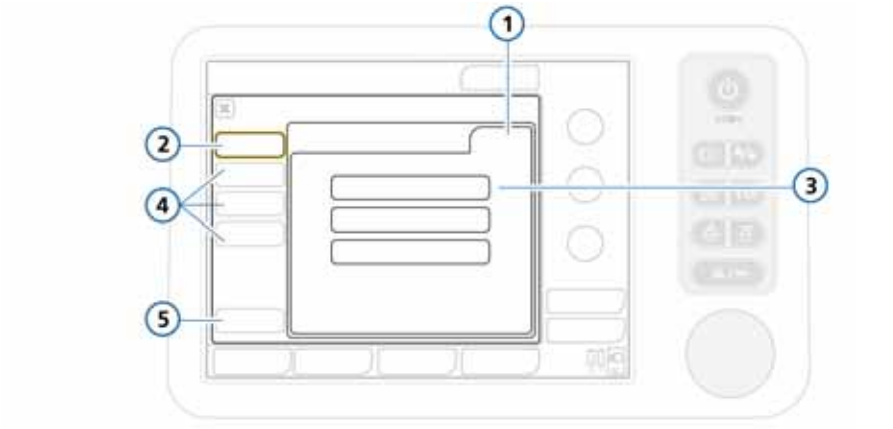


Figure G-8. Setup configuration window

1, 2	General	**4**	Mode Ctrls, Alarms, Vent Status buttons
3	Rename setup, Use current settings, Use factory settings buttons	**5**	Back (return to main Configuration window)

6. Touch **Mode Ctrls -> Controls** to review patient parameter settings. Note that the following parameters are not displayed, as they are based on weight:
   - The following parameters are set based on ideal body weight (IBW): Vt, Rate, Thigh, Tlow, and TI.
   - The following parameters are set based on body weight (neonatal): Vt, Rate, Tlow, Thigh, TI, and TI max.
7. Touch **Vt/IBW** (or **Vt/Weight** for neonatal) to set the tidal volume per IBW or weight (neonatal). See Figures G-9 and G-10.

   The ventilator uses the Vt/IBW or Vt/Weight (neonatal) setting in calculations for the following:
   - To set the initial delivered Vt in volume-controlled modes
   - To set the initial high and low alarm limits for Vt and ExpMinVol

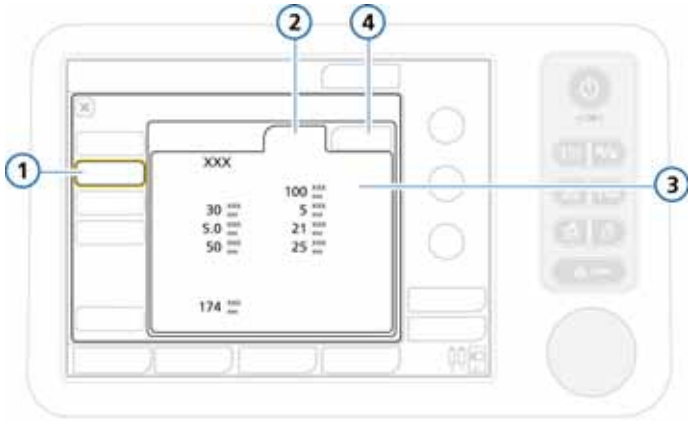


Figure G-9. Mode controls configuration

1	Mode Ctrls	**3**	Mode and patient parameter settings
2	Controls	**4**	Vt/IBW or Vt/Weight (neonatal)

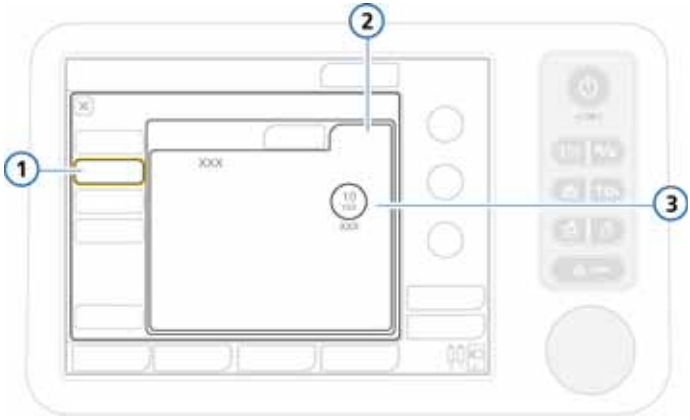


Figure G-10. Mode controls configuration, Vt/IBW

1	Mode Ctrls	**3**	Mode and Vt/IBW or Vt/Weight (neonatal)
2	Vt/IBW or Vt/Weight (neonatal)		

8. Review the alarm settings in the **Alarms** window.

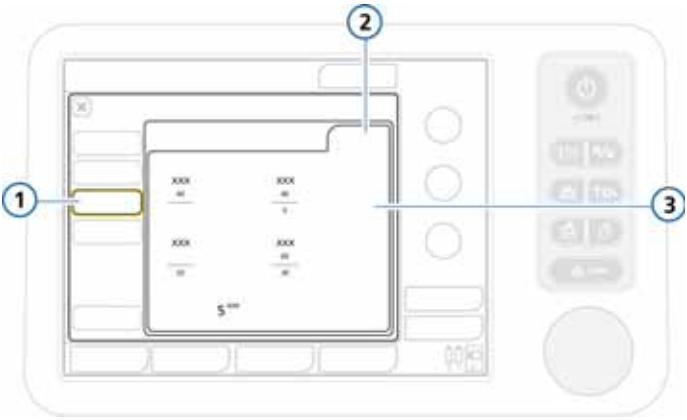


Figure G-11. Reviewing alarm settings

1, 2	Alarms	**3**	Alarm settings

9. In Vent status, set patient parameters manually.

   The Vent Status window (Figure G-12) configures the weaning zone ranges of the Vent Status intelligent panel (Figure G-13) according to your institution's protocol.

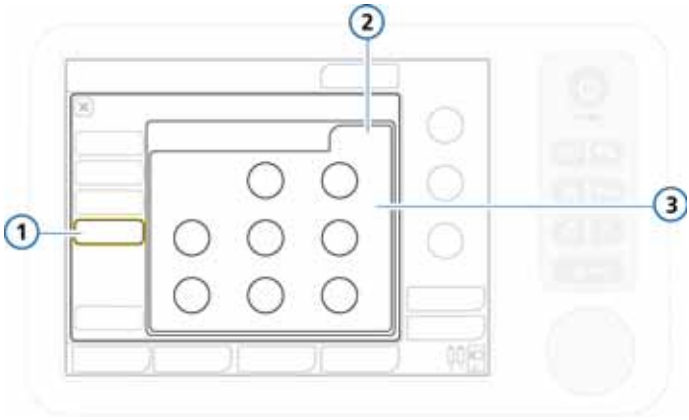


Figure G-12. Vent Status configuration

1, 2	Vent Status	**3**	Parameter weaning-zone settings: Oxygen, PEEP, %MinVol, Pinsp, RSB, %fspont

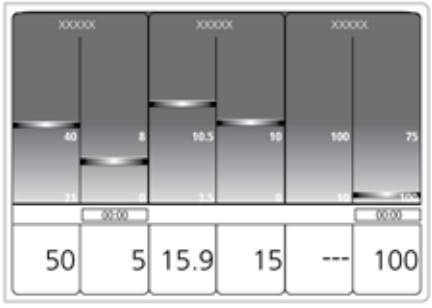


Figure G-13. Vent Status intelligent panel

10. Touch the **Back** button to return to the Default setup window.

The next time you turn on the ventilator, the configured settings will be used by default.

G.6.2 Selecting a default quick setup

A default setup comprises a group of settings that are automatically loaded when turning on the ventilator.

After you have configured one or more quick setups, select the default to use.

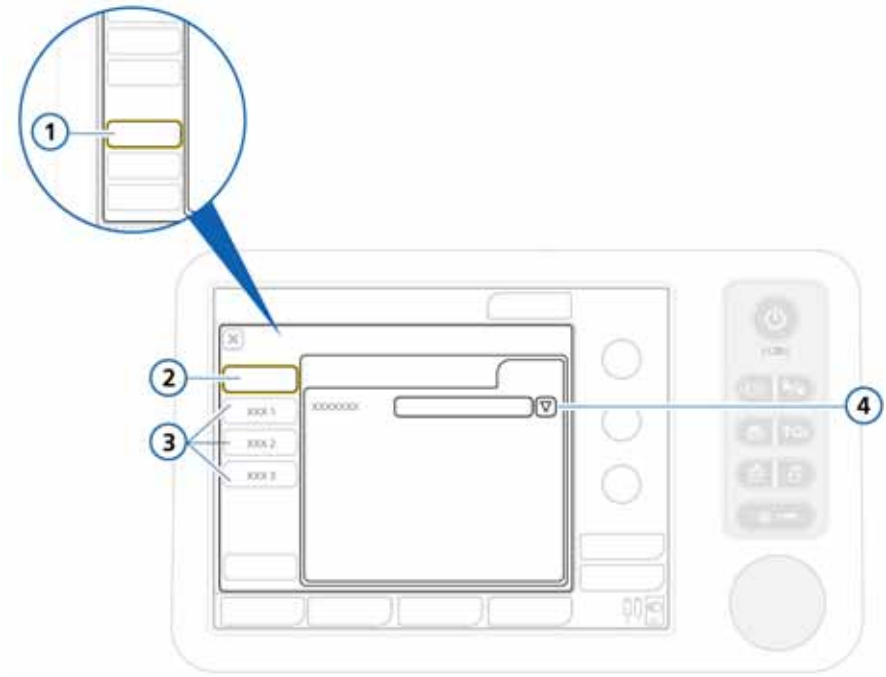


Figure G-14. Default setups configuration

1	Setups button in main Configuration window	**3**	Quick setup 1 through 3
2	Default setups	**4**	Default setup selection list

To select a default quick setup

1. In the Setups window (Figure G.6.1), open the **Default setup** window.
2. Select the setup to use from the list.

G.7 Copying configuration settings to other devices

You can copy the configuration settings to a USB drive and quickly transfer the settings to other HAMILTON-MR1 devices.

NOTE:

- Touch the HAMILTON-MR1 before using the USB port.
- If you remove the USB drive before the files are successfully transferred, you must reinitialize the USB port by turning the ventilator off and on again.
- The USB drive must be USB 1.1 compatible.

1. Insert a USB drive into the USB port on the side of the ventilator. See Figure 1-7.
2. In the Configuration window, touch the **Transfer** button.
3. In the Transfer window, touch **Import** or **Export** to transfer configuration data with a USB drive.

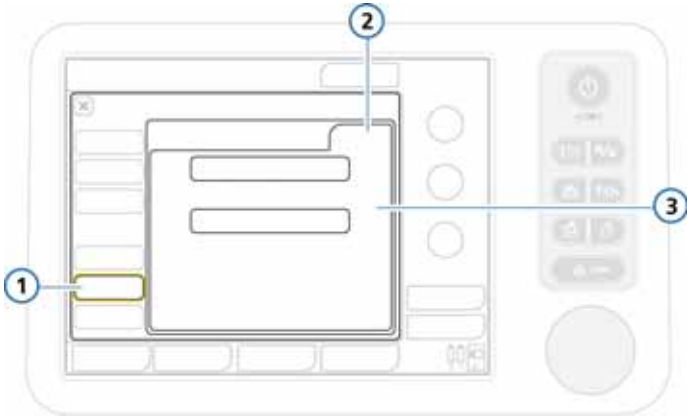


Figure G-15. Transfer window

1,2	Transfer	**3**	Import, Export

G.8 Configuring software options

Before use, you must add and enable software options.

G.8.1 Reviewing installed options

To view installed options

▶ In the Configuration window, touch the **Options** button. The **SW options** window is displayed. See Figure G-16.

G.8.2 Adding software options

The following software options are added using license keys[1]:

- Neonatal
- NeoNIV (nCPAP)
- NIV/NIV-ST
- DuoPAP/APRV
- Trends/Loops

Trial versions of software options may be available. Trial options expire and are automatically deactivated after 30 days.

Have available all required keys before proceeding.

To add a software option

1. In the Configuration window, touch the **Options** button. The **SW options** window is displayed. See Figure G-16.

1. This list might not be comprehensive. Refer to your order and product catalog for details.

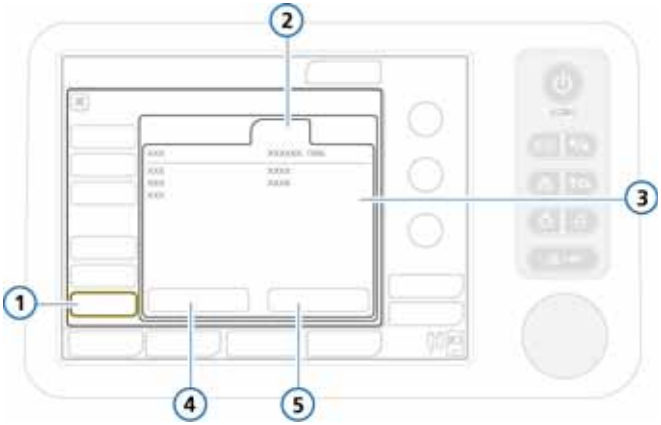


Figure G-16. SW options tab

1	Options	**4**	Add options
2	SW options	**5**	Clear options
3	Installed options		

2. Touch the **Add options** button.

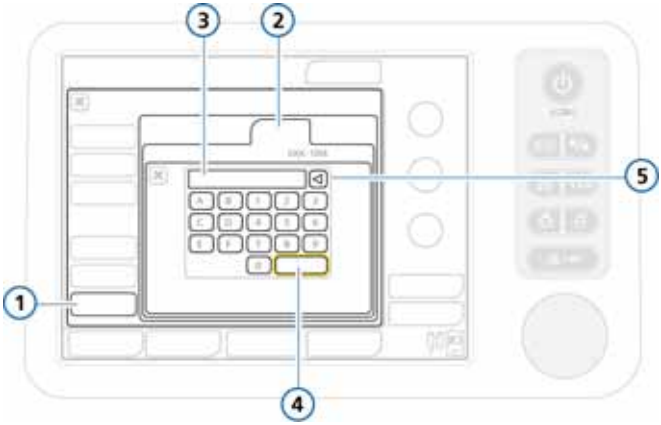


Figure G-17. Add options window

1	Options	**4**	Enter
2	SW options	**5**	Delete
3	Text field to type license key		

3. Type the activation code exactly as provided into the field and touch **Enter**.

   If the message *Option code invalid* appears, re-enter the code. The message *Option valid* indicates the code is correct and the option has been added.

4. Repeat until all desired software options are added.
5. Touch the **X** to close the window.
6. Restart the ventilator to enable the options.

Upon turning on the ventilator, the added options are available for use.

G.8.3 Removing software options

NOTE:

- The **Clear options** function removes *all* non-trial options. You cannot remove just one or a few. If that is your goal, clear the options and re-add those that are needed.
- The patient groups on the ventilator, Adult/Ped and Neonatal, are both treated as options. Clearing options also removes these patient groups and the associated ventilation modes.

  Before the ventilator can be used on a patient, the required patient groups (and associated modes) must be re-added. Follow the steps to add options (Section G.8.2) and add the necessary patient groups. The associated ventilation modes are also added.
- Options are removed after restarting the ventilator.

To remove software options

You can remove all non-trial software options from the ventilator.

1. In the SW options window, touch **Clear options**.

   You are prompted to confirm deletion of all non-trial options, including the Adult/Ped and/or Neonatal patient groups. See Note above.

2. Touch **Clear options** to remove the options.

   Touch **Cancel** to leave the options installed.

3. Restart the ventilator.

   Once you restart the ventilator, all options (including patient groups) listed in the window are cleared.

4. To re-add the patient groups and any other desired options, re-enter Configuration mode.

5. Add the required patient groups and any desired options, as appropriate. See Section G.8.2.

Glossary

A	Ampere, a unit of current.
AC	Alternating current.
alarm buffer	Contains information on the four most recent alarm occurrences.
alarm lamp	Lamp atop the ventilator that lights in a color corresponding to the active alarm.
Alarm Silence key	Silences alarm sound for 2 min.
Ambient state	An emergency state in which the ventilator opens the inspiratory channel and expiratory valve. This lets the patient breathe room air unassisted by the ventilator.
apnea	Cessation of breathing.
Apnea time	The maximum time allowed without a breath trigger, an alarm setting.
APRV	Airway Pressure Release Ventilation.
ASV target graphics panel	ASV graphical data representation, an Intelligent Panel.
ASV monitored data window	ASV numeric patient data, an Intelligent Panel.
ATP	Ambient temperature and pressure.
ATPD	Ambient temperature and pressure, dry.
auto-lock brake	A brake that disengages and allows movement when pressure is applied, for example, when holding down a lever. The brake engages when all pressure is released, for example, the lever is released. Also called a deadman's brake. On the MR1 trolley, you must hold in the brake lever to move the trolley; when the brake lever is released, the trolley automatically locks in place. You can disable the auto-lock brake during patient transport.

AutoPEEP	Unintended positive end-expiratory pressure, a monitored parameter.
Backup	Apnea backup ventilation.
backup buzzer	The buzzer designed to sound for at least 2 min as a backup to the alarm speaker.
base flow	A continuous and constant gas flow from the inspiratory outlet to the expiratory outlet.
b/min	Breaths per minute.
breathing circuit	Includes one or more of the inspiratory-expiratory tubing, humidifier, and filters.
bronchial tree	A part of the Dynamic Lung that shows resistance.
BTPS	Body temperature, barometric pressure at sea level, saturated with water vapor.
C	Compliance.
CE	A certification mark that indicates compliance with the Medical Device Directive, 93/42/EEC.
cm	Centimeter, a unit of length.
cmH2O	Centimeters of water, a unit of pressure. 1 cmH2O is approximately equal to 1 mbar, which equals 1 hPa.
CMV	Controlled mandatory ventilation.
COPD	Chronic obstructive pulmonary disease.
CPAP	Continuous positive airway pressure.
CSA	Canadian Standards Association.
Cstat	Static compliance, a monitored parameter.
DC	Direct current
dB(A)	Decibel, a unit of acoustic power.
DISS	Diameter index safety standard, a standard for high-pressure gas inlet fittings.
DuoPAP	Duo Positive Airway Pressure.

Dynamic Lung	An Intelligent Panel that graphically represents tidal volume, lung compliance, patient triggering, and resistance in real time.
E	Exhalation.
EMC	Electromagnetic compatibility.
EMI	Electromagnetic interference.
EN	European Norm, a European standard.
ET	Endotracheal.
ETO	Ethylene oxide.
ETS	Expiratory trigger sensitivity, a control setting.
event log	A record of clinically relevant ventilator occurrences, including alarms, setting changes, calibrations, maneuvers, and special functions since the ventilator was powered on.
Exp Flow	Peak expiratory flow, a monitored parameter.
ExpMinVol	Expiratory minute volume, a monitored parameter and alarm setting. In the Vent Status panel, ExpMinVol is the percentage of normal minute ventilation, based on IBW.
f	Respiratory rate.
fControl	Mandatory breath frequency, a monitored parameter. It is displayed in monitored data window.
FiO2	Fraction of inspired oxygen.
Flow (parameter)	In the neonatal nCPAP and nCPAP-PC modes, monitored parameter that measures and displays the current flow. The upper limit is controlled by the Flow alarm.
Flow trigger	The patient's inspiratory effort that causes the ventilator to deliver a breath, a control setting.
fSpont	Spontaneous breathing frequency, a monitored parameter.
fTotal	Total breathing frequency, a monitored parameter and alarm setting.

ft	Foot, a unit of length.
gauss (G)	Unit of measure related to magnetic field strength.
gaussmeter	A device that measures magnetic field strength, in gauss.
gender	Sex of patient, a control setting.
HEPA	High efficiency particle air filter.
HME, HMEF	Heat and moisture exchanger (artificial nose), heat and moisture exchanging filter
hPa	Hectopascal, a unit of pressure. 1 hPa is equal to 1 mbar, which is approximately equal to 1 cmH2O.
HPO	High-pressure oxygen.
Hz	Hertz, or cycles per second, a unit of frequency.
I	Inspiration.
IBW	Ideal body weight.
ICU	Intensive care unit.
ID	Inner diameter.
IEC	International Electrotechnical Commission.
I:E	Inspiratory:expiratory ratio, a setting, timing parameter, and monitored parameter. Ratio of inspiratory time to expiratory time.
in	Inch, a unit of length.
Insp Flow	Peak inspiratory flow, a monitored parameter.
inspiratory hold	A respiratory maneuver in which gas is retained in the patient's airways, often for X-raying purposes.
Intelligent Panel	A type of graphic display on the ventilator. The Intelligent Panels include the Dynamic Lung, Vent Status, ASV target graphics panel, and ASV monitored data window panels.
IntelliSync	Applies same pressures for spontaneous and controlled breaths. Allows the patient to breath spontaneous if he is able to keep the user set guaranteed rate.

IntelliTrig	Intelligent trigger, a feature that ensures that the set trigger sensitivity can trigger a breath independent from leakage and breath pattern.
IRV	Inverse ratio ventilation
ISO	International Organization for Standardization, a world-wide federation of national standards bodies.
kg	Kilogram, a unit of mass.
kPa	Kilopascal, a unit of pressure.
l	Liter, a unit of volume.
l/min	Liters per minute, a unit of flow.
lb	Pound, a unit of weight.
loops	Special graphic type.
loudness	The loudness (volume) setting for the audible ventilator alarms.
LSF	Least squares fitting, a mathematical procedure for finding the best fitting curve to a given set of points by minimizing the sum of the squares of the offsets of the points from the curve.
m	Meter, a unit of length.
mandatory breath	A breath for which either the timing or size is controlled by the ventilator. That is, the machine triggers and/or cycles the breath.
manual breath	A user-triggered mandatory breath started by pressing the manual breath key.
%MinVol	Percentage of minute ventilation, a control setting in ASV mode.
MinVol	Minute volume, a calculated and monitored parameter used in ASV mode. Based on the operator-set %MinVol, the ventilator calculates the target MinVol in l/min, then measures and displays it in the ASV target graphics panel.
ml	Milliliter, a unit of volume.

MRI	Magnetic resonance imaging, a diagnostic medical imaging technique.
MRI compatible	Classification of an item that can be safely used in the vicinity of MRI devices. Includes components that are rated MR Safe and MR Conditional.
MRI environment	A room or set of rooms where an MRI scanner is located, and thus have specific requirements for equipment that will or might interact with the magnetic field generated by the scanner.
MR Conditional	Classification of an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
MR Safe	Classification of an item that poses no known hazards in all MRI environments.
ms	Millisecond, a unit of time.
mT	Millitesla, a unit of measure of magnetic flux density, which measures the magnitude of a magnetic field. 1 mT = 0.001 T (Tesla)
MVLeak	Total minute volume leakage. MVLeak shows VLeak * frequency (breath rate).
MVSpont	Spontaneous expiratory minute volume, a monitored parameter.
nCPAP	Neonatal-only ventilation mode that applies CPAP over a nasal interface (mask or prongs).
nCPAP-PC	Neonatal-only ventilation mode that delivers, in addition to the set CPAP, intermittent, time-cycled, and pressure-controlled breaths.
NIST	Noninterchangeable screw thread, a standard for high-pressure gas inlet fittings.
NIV	Noninvasive ventilation, a ventilation mode.
NIV-ST	Spontaneous/timed noninvasive ventilation, a ventilation mode.
NPPV	Noninvasive positive pressure ventilation.

O2	Oxygen.
Oxygen	Oxygen concentration of the delivered gas, a control setting, monitored parameter, and, in LPO mode, an alarm setting.
P&T knob	Press-and-turn knob. Used to navigate the display, select list items, activate controls and set values.
Pasvlimit	Maximum pressure to be applied in ASV, a control setting.
Pat. height	A control setting. It is used to compute the patient's ideal body weight (IBW) in calculations for ASV and start-up settings.
Paw	Airway pressure.
Pcontrol	Pressure control, a control setting in PCV+ mode. Pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase.
PCV+	Pressure controlled ventilation
PEEP/CPAP	PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure), a control setting and monitored parameter. PEEP and CPAP are constant pressures applied during both the inspiratory and expiratory phases.
Phigh	High pressure in APRV and DuoPAP mode
Pinsp	Inspiratory pressure, the target pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase. It is operator-set in the PSIMV+ and NIV-ST and a displayed parameter in the Vent Status panel and the ASV target graphics panel.
Plow	Low pressure in APRV mode
Pmax	High pressure alarm limit
press-and-turn knob	Also called *P&T knob*. Used to navigate the display, select list items, activate controls and set values.
Pressure	Maximum pressure allowed in the patient breathing circuit, an alarm setting.
Pmean	Mean airway pressure, a monitored parameter.

PN	Part number.
Ppeak	Peak airway pressure, a monitored parameter.
Pplateau	Plateau or end-inspiratory pressure. The pressure measured at the end of inspiration when flow is or is close to zero.
P-ramp	Pressure ramp, a control setting. The time required for the inspiratory pressure to rise to the set (target) pressure.
pressure control	Maintenance of a consistent transrespiratory pressure waveform despite changing respiratory system mechanics.
psi	Pounds per square inch, a unit of pressure.
PSIMV+	Pressure-controlled synchronized intermittent mandatory ventilation mode.
Psupport	Pressure support, a control setting valid during spontaneous breaths in SPONT, SIMV+, and NIV modes. Psupport is pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase.
Rate	Breath frequency or number of breaths per minute, a control setting.
RCexp	Expiratory time constant, a monitored parameter.
Rinsp	Inspiratory flow resistance, a monitored parameter.
s	Second, a unit of time.
Safety mode	An emergency state that ensures a basic minute ventilation while giving the user time for corrective actions in case of some technical fault alarms. The default inspiratory pressure is maintained, the expiratory valve opens as needed to switch system pressure levels between PEEP and inspiratory pressure, and patient sensing is nonfunctional.
(S)CMV+	Synchronized controlled mandatory ventilation mode.
sigh	Breaths delivered to deliberately increase tidal volume at a regular interval. If enabled, a sigh breath is delivered every 50 breaths with an additional 10 cmH2O.

SIMV+	Synchronized intermittent mandatory ventilation mode.
SPONT	Spontaneous (pressure support) mode of ventilation.
spontaneous breath	A breath for which both the timing and size are controlled by the patient. That is, the patient both triggers and cycles the breath.
standby	The ventilator is in a waiting state, during which time there is no breath delivery.
STPD	Standard temperature and pressure, dry. Defined as dry gas at 0°C (32°F) at 758 mmHg (101 kPa) pressure at sea level.
T (Tesla)	See *Tesla*.
TE	Expiratory time, a monitored parameter.
technical fault	A type of alarm, resulting because HAMILTON-MR1's ability to ventilate safely is questionable.
TF	Technical fault.
Tesla (T), milliTesla (mT)	Units of measure for magnetic field strength.
TeslaSpy magnetic field navigator	Magnetic field monitor built into the HAMILTON-MR1.
Thigh	Maximum time in APRV and DuoPAP mode.
TI	Inspiratory time, a control setting and monitored parameter.
TI max	Maximum inspiratory time, a control setting in NIV and NIV-ST modes.
timv	SIMV breath interval.
trigger	Trigger window in SIMV modes.
Tlow	Minimum time in APRV mode
Trends	Special graphic type.
V	Volt, a unit of electric potential or volume.
VA	Volt-ampere, a unit of electric power.

VDaw	Airway dead space.
ventilator breathing system (VBS)	A breathing system bounded by the low-pressure gas input port(s), the gas intake port(s), and the patient connection port, together with the fresh-gas inlet and exhaust port(s), if fresh-gas inlet or exhaust ports are provided, as described in ISO 4135:2001.
Vent Status panel	An Intelligent Panel that visualizes six parameters related to the patient's ventilator dependency, including oxygenation and patient activity.
VLBW	Very Low Birth Weight
VLeak	Leakage percent, a monitored parameter.
Vt	Tidal volume, a control setting, an alarm setting and a monitored parameter in the Vent Status panel.
VTE	Expiratory tidal volume, a monitored parameter. It is the integral of all negative flow measurements during exhalation.
VTI	Inpiratory tidal volume, a monitored parameter.

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HAMILTON MEDICAL
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