Respimatic 100

Emergency Respiration Assist Device

Operating Manual

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Contains system specifications including BVM (AMBU) bag specifications, Power Supply specifications etc.

Introduction

Adult patients can get non-invasive respiratory support using Respimatic-100. The target market is remote areas with minimum infrastructure such as compressed gas and oxygen pipeline.

For patients who don't need intubation or the more complicated breathing settings of an ICU ventilator, Respimatic-100 offers a cost-effective, dependable, and durable equipment. The technology offers a straightforward and uncomplicated Human-Machine Interface to reduce the learning curve for the medical professional.

The Respimatic-100 offers four regularly used ventilation modes: CMV, ACV, SIMV, and PSV. From initial admission until ultimate weaning, all patient circumstances are covered by these four modes. Furthermore, Respimatic-100 provides a complete spectrum of breath parameters in all possible combinations for all ventilation modes. Additionally, it offers complete assistance for patient-initiated (spontaneous) breathing with full breath synchronisation, volume control, and pressure support.

The Respimatic-100 also includes a full variety of safety features. Every conceivable error scenario has a fallback mechanism so that breathing never pauses.

System Elements

Figure 1: Core System Elements

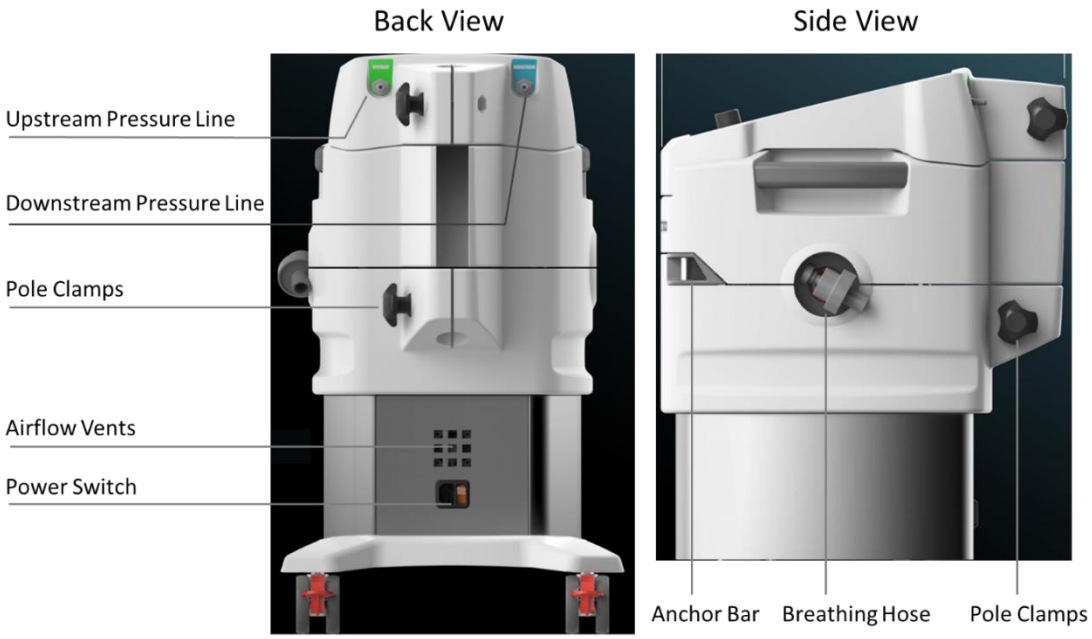


Figure 2: Different views of Core System

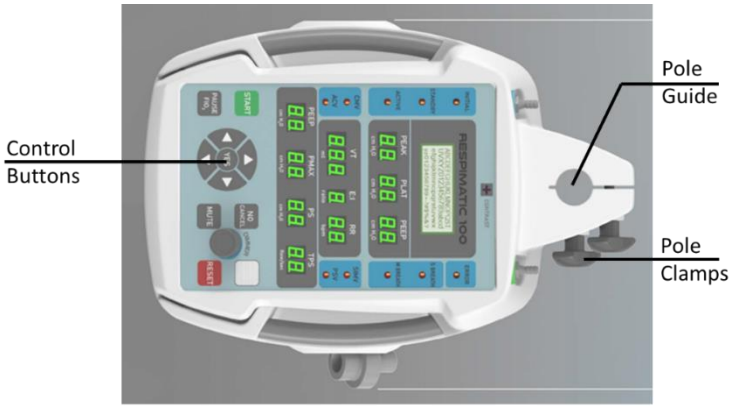


Figure 4: Human Machine Interface Panel

Figure 3: Control Panel Bottom View

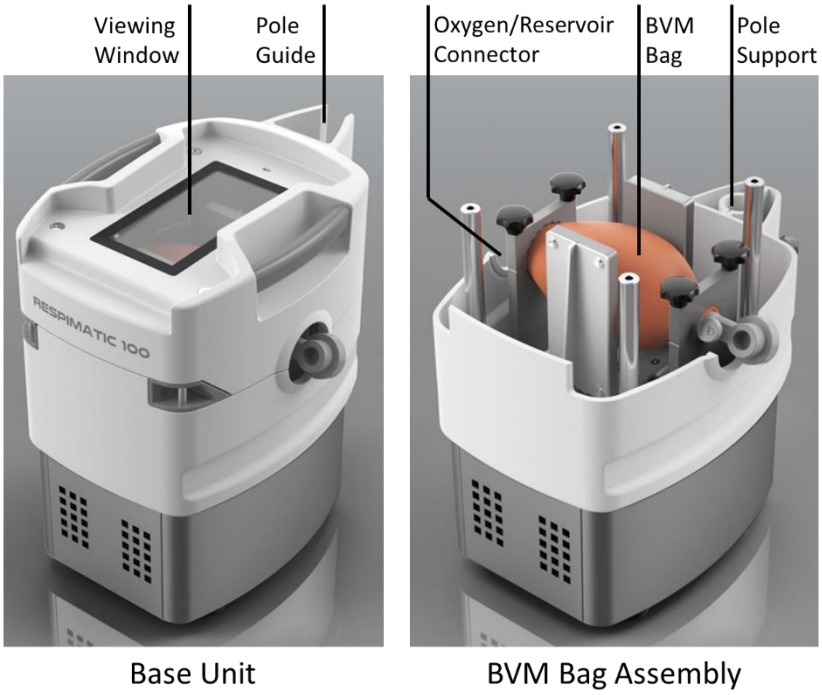


Figure 5: BVM Bag Receptacle

Figure 6: Possible System Configurations

Important Safety Instructions

⚠ Review the Operating Manual completely before use. Improper usage may result in patient injury.

⚠ The system must be operated by a qualified person conversant with breathing physiology and with a knowledge of ventilator systems. The system is not intended for home use.

⚠ A UPS (uninterruptable Power Supply) must be connected to the power supply input of the system to ensure continued operation in the event of a power failure. The UPS used must be equipped with an alarm to alert the operator when power is switched to battery power.

⚠ Clinical monitoring (e.g., SpO2 with finger pulse oximetry and arterial blood gases) must be conducted to make sure the patient is achieving adequate oxygenation.

⚠ The system is targeted for adult patients and is not suitable for children or infants.

⚠ The breathing mask must fit snugly on the patient's mouth and nose.

⚠ Adequate clearance between the system and other items must be provided to ensure adequate airflow around the system.

⚠ All breathing system connectors must fit snugly on the receptors to eliminate leakage.

⚠ A HME filter must be installed before the PEEP valve as shown in the Breathing circuit diagram.

⚠ The oxygen cylinder level (if used) must be checked to ensure adequate quantity of oxygen remaining.

⚠ The system must not be used with inlet gases other than medical air or oxygen.

⚠ The clinician must ensure that the oxygen source is appropriately selected with respect to the range of pressure, flow rate and oxygen concentration.

⚠ The BVM bag must be replaced after appropriate number of compressions as specified in the BVM specifications. Pre-use checks can be used to find the number of compressions the BVM bag has undergone since installation.

⚠ In case of a reusable breathing system, it must be autoclaved before reuse.

⚠ On power-up, all the Pre-use checks must be performed as detailed in the section on Pre-use checks.

⚠ The maximum inspiration pressure (PMAX) must be appropriately set depending upon the patient's weight, size, and physiology.

Remote Monitoring via a WEB Dashboard

If there is an available Wi-Fi network, the system can be configured for remote monitoring. In addition, a remote Recorder and Analyzer is also provided.

(See the document on Respimatic WebApps for further details.)

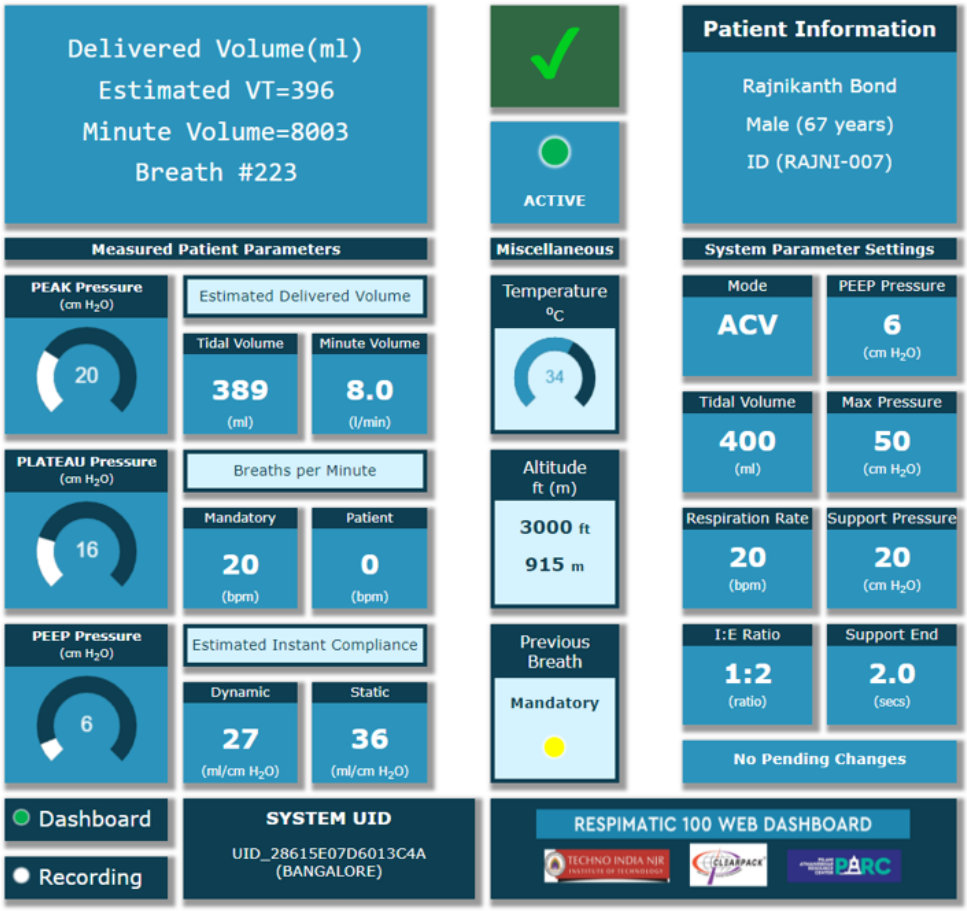


Figure 7: Online WEB Dashboard

Update System Firmware to a new release

If there is an available Wi-Fi network, the system can be configured for remote monitoring. In addition, a remote Recorder and Analyzer is also provided.

(See the document on Respimatic WebApps for further details or open URL below.)

https://www.respimatic.com/firmware/Firmware-Update-Steps.html

Figure 8: Firmware Update Session

System Overview

The system is in one of the six states depicted in the following figure at any given time. Different types of operation are made possible by the various states. All changes between states are clearly stated and readily apparent.

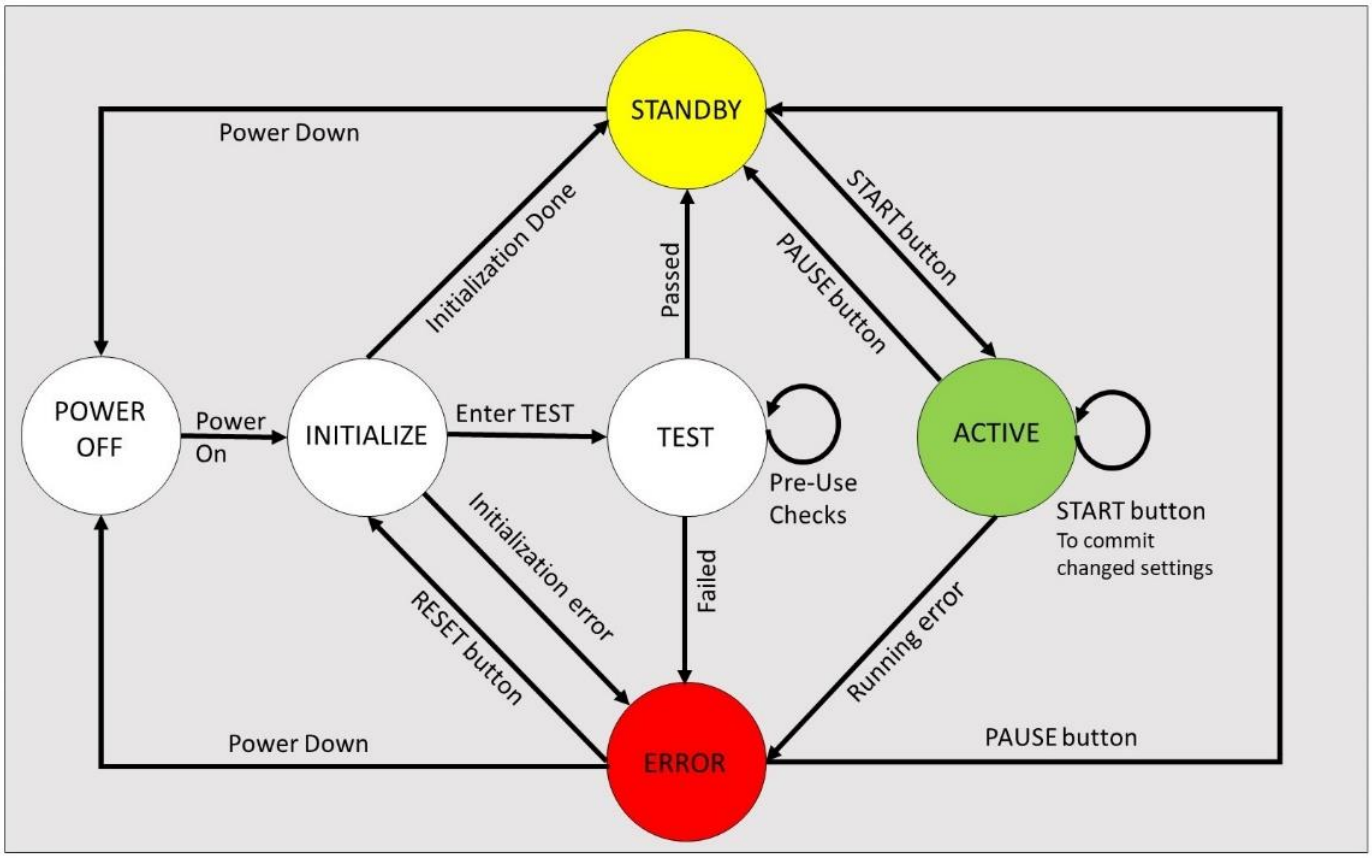


Figure 9: State Transitions

Front Control Panel

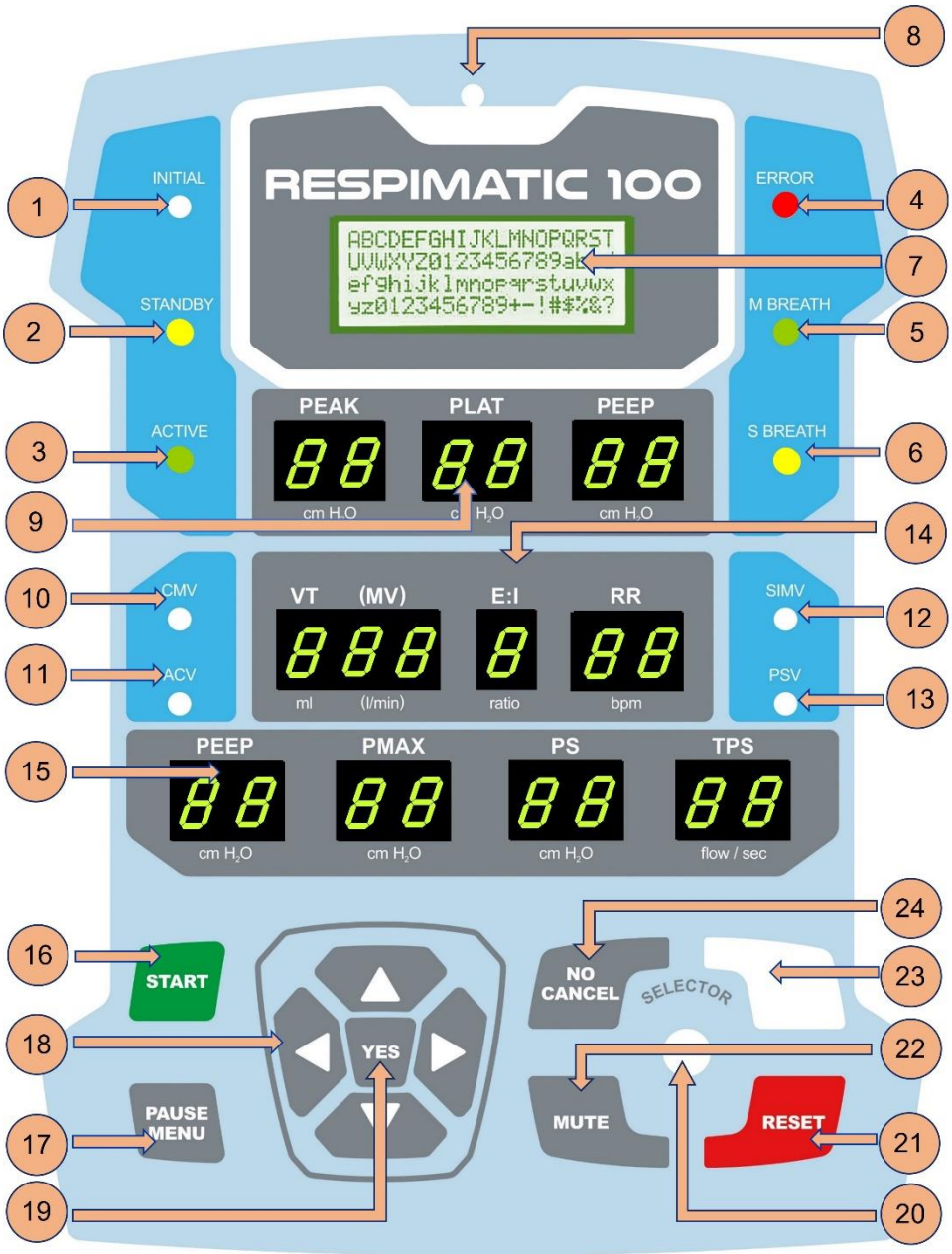


Figure 10: Front Control Panel

1. System in INITIALIZE state.
2. System in STANDBY state.
3. System in ACTIVE state.
4. System in ERROR state.
5. Current Breath is MANDATORY.

6. Current Breath is patient-initiated (SPONTANEOUS).

7. LCD 20x4 Screen. It displays notifications, prompts, and error messages.

8. Contrast adjustment for the LCD display.

9. Measured values for various parameters during the ACTIVE state.
    - PEAK – Peak Inspiration Pressure in cm H_2O.
    - PLAT – For Volume-controlled breaths, the Plateau Pressure in cm H_2O. For Pressure-supported breath, the mean pressure in cm H_2O.
    - PEEP – Peak End Expiration Pressure in cm H2O.

10. Selected Ventilation mode is CMV.

11. Selected Ventilation mode is ACV.

12. Selected Ventilation mode is SIMV.

13. Selected Ventilation mode is PSV.

14. Currently selected input settings. If not blinking, these display the current settings in use. If blinking, they display new settings that have yet to be committed.
    - VT (MV) – Tidal Volume in ml when in CMV, ACV or SIMV Ventilation mode. Minute Volume in litres/min when in PSV Ventilation mode.
    - E/I – Expiration time to Inspiration time ratio.
    - RR – Respiration rate in breaths per minute.

15. Currently selected input settings. If not blinking, these display the current settings in use. If blinking, they display new settings that have yet to be committed.
    - PEEP – Required Peak End Expiration Pressure in cm H_2O.
    - PMAX – Max Inspiration Pressure allowed in cm H_2O.
    - PS – Support Pressure for Pressure Supported breaths in cm H_2O.
    - TPS – Auto Flow-dependant mode or duration of Inspiration phase for a Pressure supported breath in seconds.

16. START Button – Press while in STANDBY state to start breath delivery using the currently displayed settings. If settings are changed while in ACTIVE state, this button also serves as a COMMIT button for the new settings.

17. PAUSE/MENU Button – Long Press (more than 1 sec) while in ACTIVE state to cause entry into STANDBY state. A short press (less than 1 sec) while in ACTIVE state will cause an inspiration pause in the next volume-controlled breath that is sometimes useful for measuring plateau pressure. When in STANDBY state, any press on this button this button causes entry into the STANDBY menu where settings such as FiO2 etc. can be changed.

18. UP, DOWN, LEFT, RIGHT buttons. These buttons are used to navigate menus and change input settings or to manually move the pressing plates forwards or backwards in TEST mode.

19. YES/ACCEPT button to answer prompts and questions posed on the LCD panel.

20. DIMMER – This is a rotary knob used to adjust the brightness level of the display at any time.

21. RESET Button – Press any time to reset the system and cause it to enter INITIALIZE state.

22. MUTE button is used to mute the alarm buzzer. It unmutes after 2min.

23. BUZZER – Audible alerts for errors, warnings, and notifications.

24. NO/CANCEL button to answer prompts and questions posed on the LCD panel.

Installing or Replacing the BVM (AMBU) Bag

The system is designed for easy installation and replacement of the BVM bag. The steps are as below.

1. Loosen the Control Panel clamp on the pole.
2. Slide the control Panel upwards.
3. Unscrew the BVM cover. There is no need for a screwdriver or any other tool for this. The screws can be turned by hand.
4. Install the BVM bag between the mounts.
5. Screw the BVM cover back on.
6. Slide the Control Panel down and clamp it back on the pole.

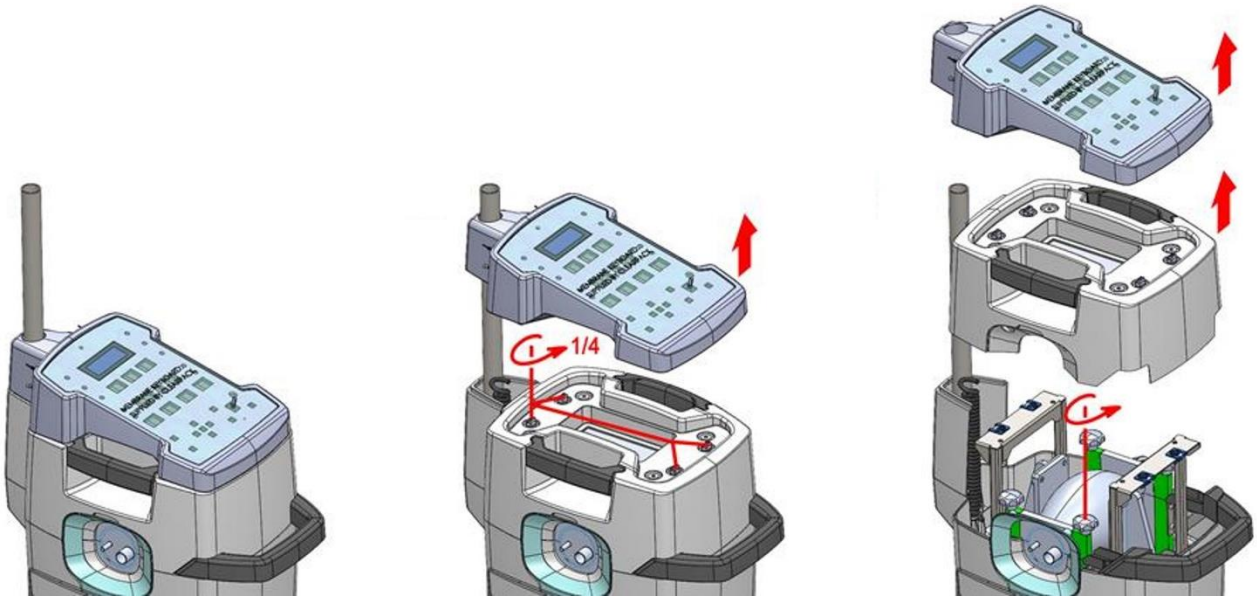


Figure 11: Installing BVM Bag

Complete System Schematic

The complete system with the respirator and the breathing circuit is as shown in Figure below. The recommended breathing system is Oxylog-1000 or equivalent.

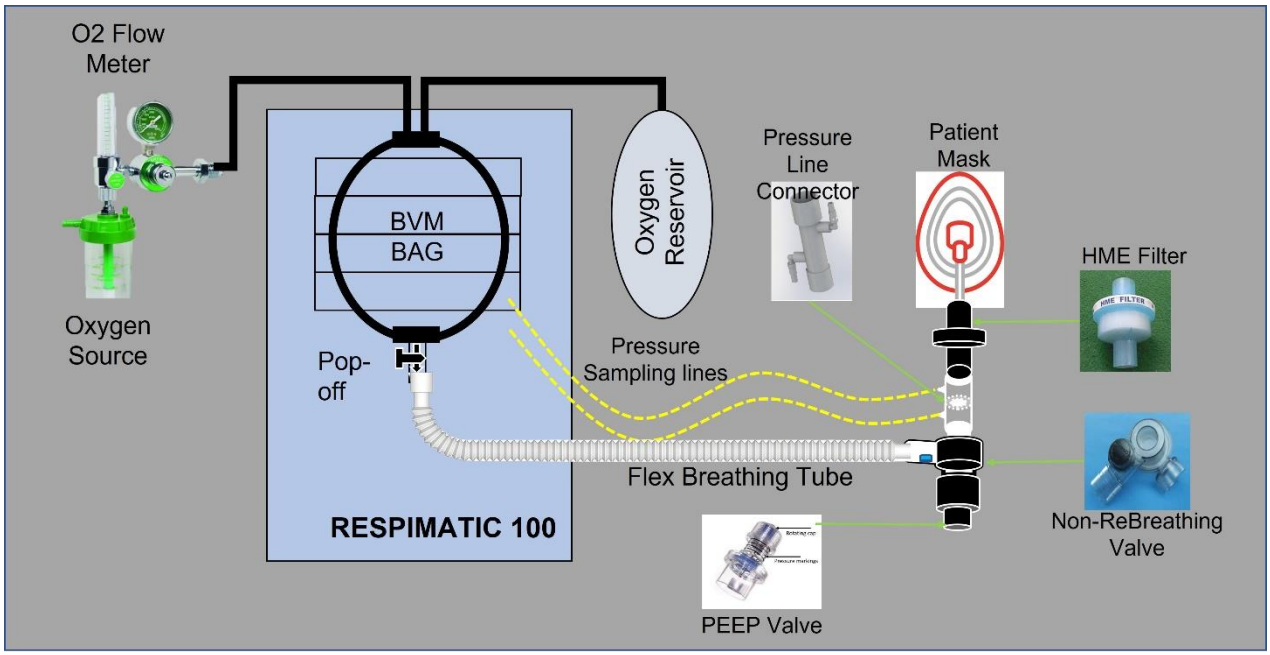


Figure 12: Complete Respirator System

There is one proprietary, patent-pending connector that is a part of the breathing system that is used to connect two pressure lines to Respimatic. The two pressure lines are color-coded and must be connected to the appropriate ports of the system.

Figure 14: Off-the-shelf Breathing Circuit

Figure 13: Proprietary patent-pending Dual Pressure-line Connector

Operation Overview

Glossary of Acronyms

The table below summarizes all the abbreviations used in this document.

Symbol	Variable	Description
VT	Tidal Volume	Volume of air delivered each inspiration phase (ml)
RR	Respiratory Rate	Breaths per minute
E/I	Expiration/Inspiration ratio	Ratio of expiration vs inspiration time in a breath cycle
PMAX	Max Inspiration Pressure	MAX inspiration pressure never to be exceeded (cm H_2O)
PEAK	Peak Inspiration Pressure	Max pressure during Inspiration phase of breath delivery (cm H_2O)
PLAT	Plateau Pressure	Plateau pressure during breath delivery (cm H_2O)
PEEP	Peak End Expiration Pressure	Pressure in the lungs that exists at the end of expiration (cm H_2O)
PS	Pressure Support	Level of support pressure to assist patient-initiated (spontaneous) breaths (cm H_2O)
TPS	PS Inspiration duration	Termination of the inspiration phase for which the pressure support is to be delivered. It can be Flow controlled (%age of Peak Flow) or Time controlled (secs).
FiO_2	Fraction of Inspired Oxygen	Concentration of oxygen in the inspired air. This is guided by the system but controlled outside the system in the Oxygen source. (%age)

Table 1: Glossary of Acronyms

System Initialization upon Installation

To ensure sustained operation during a potential power outage, Respimatic-100 needs to be powered by a UPS system.

Respimatic-100 walks the user through a series of tests step-by-step the first time it is powered up. The following requires explanation, even though all the checks are self-explanatory.

- Current Altitude or Elevation – For correct operation, Respimatic-100 requires to know the altitude at the deployment site. The altitude at the deployment site can be easily queried through Google or any other search engine. The user is guided step-by-step through this process. For subsequent power-ups, this information need not be re-entered if the deployment site remains the same. It can be changed at any power-up through a menu entry in Pre-Use Checks. *(See section on Pre-Use Checks)*. Use ARROW buttons or the SELECTOR knob to change the values and press YES when done.

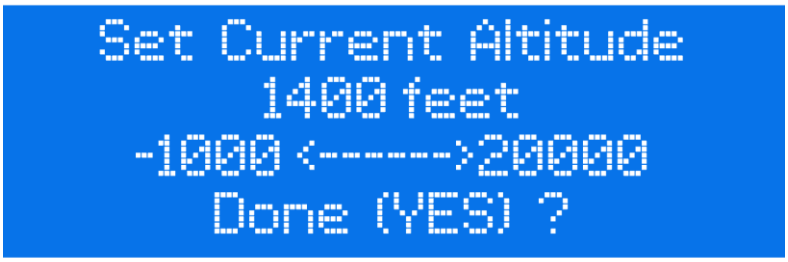


Figure 15: Display for Altitude setting

System RESET

1. Normal Reset – This is accomplished by simply pressing the RESET button at any time. It preserves all the current system settings.

2. Factory Reset – This is accomplished by pressing the RESET button while keeping the SELECTOR knob button pressed down. Keep SELECTOR knob pressed down till the LCD displays the Factory Reset prompt. All previously set parameters are erased and the system is restored to Factory settings forcing a re-initialization.

Routine Operation of the System

The overall operation of the system is summarized below.

- Make sure that a power backup (UPS) is connected to the system.
- Connect the Breathing Circuit to the Respirator as shown in Figure XXX.
- Turn ON the system. It will display the version number on the LCD screen following which it will go through a series of self-tests.
- Execute all the Pre-use checks BEFORE connecting the system to the patient. Though it is recommended to go through all the checks, the system will ensure that the mandatory checks are performed. *(See section on Pre-Use Checks)*
- After Pre-use checks, the system will enter STANDBY mode and the following message will be displayed.

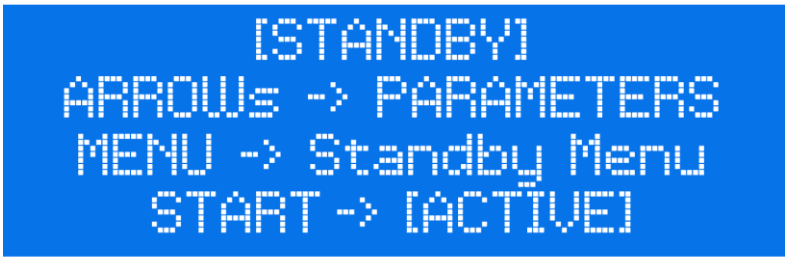


Figure 16: Standby State message

- While in STANDBY state, the MENU button will bring up a menu of possible actions as shown in Figure below. This may be needed if the user missed the earlier prompts, or some settings need to be changed mid-session.

- Select the Respiration Mode via the Front Panel. *(See section on Setting Operating Parameters)*
- Set the Respirator operating parameters via the Front Panel. *(See section on Setting Operating Parameters)*
- Connect the system to the patient.
- Press START button to start breath delivery.
- As breaths are delivered, monitor PEAK, PLAT and PEEP and the patient physically.
- Adjust the PEEP valve till the measured PEEP matches the desired PEEP. *(See section on PEEP adjustment)*.
- During breath delivery, the system will cycle through displaying various informational messages on the LCD screen.
- Adjust Respirator operating parameters if required.

- Long Press PAUSE at any time to go into STANDBY mode.
- While breath delivery is in progress, a short press (less than 1 sec) on the PAUSE button will cause the next volume-controlled breath to introduce an inspiration pause which is sometimes useful to determine plateau pressure. The duration of the inspiration pause can be set during Pre-Use checks and defaults to 1.5 secs.
- After each change of operating parameters, press START to commit the new parameters.
- Press the NO/CANCEL push button to back out mid-way through changing operating parameters. The system will cancel the parameter changes in progress and revert to the previous set of operating parameters.
- In ERROR state, the ERROR LED starts blinking, and the BUZZER starts beeping. To silence the BUZZER, press on the MUTE push button switch. The ERROR LED will continue blinking.
- If the buzzer is in MUTE state for 2 minutes and the error has not been attended to, the system will start beeping again.

Error Handling

In case of errors encountered during breath delivery, the following sequence is followed.

1. Alarm is sounded and the alarm message displayed on the LCD screen.
2. If possible, the system enters a breath maintenance mode. A set of safe breath parameters are used to continue delivering volume-controlled breaths till the error condition is attended to and rectified by the attendant. The following sample messages will be displayed alternately.

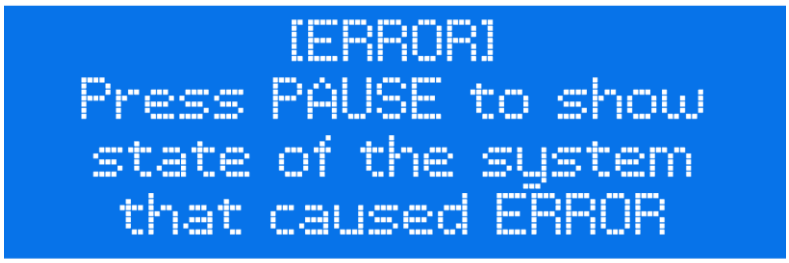


Figure 17: Error State message

3. The maintenance breath parameters can be set during pre-use checks using the appropriate menu item. Else it uses the system default.
4. It is recommended that the attendant long press the PAUSE button (more than 1sec) when ready to attend to the error condition. Pressing the PAUSE button will cause the system to enter STANDBY state.
5. After entry into PAUSE from ERROR state, the display will show the exact input parameters and the measured parameters at the time of error.

6. Now the attendant can either change input parameters and restart by pressing START or, if she believes that the error was a glitch, she can keep the same settings and restart by press START.
7. System attempts to recover from transient errors automatically.

Power ON Sequence

⚠ It is extremely important to disconnect the breathing system from the patient before system power-ON. Connect the breathing system to the patient only when instructed to do so by the system.

1. Make sure that a BVM Bag is installed properly in the base unit of the system.
2. The BVM bag should be the correct size and be clamped down properly *(See Section on BVM installation).*
3. Turn ON power to the system. If necessary, press the RESET button.
4. After a battery of self-tests, the system adjusts the BVM pressing plates till they just touch the BVM bag. This is an automatic operation.
5. It is recommended to visually inspect the BVM bag (through the viewing window) to ensure that the pressing plates have homed in properly. If needed, minor adjustments can be made using the ARROW buttons or the SELECTOR knob, but it is not necessary.
6. Next, the user is prompted to optionally enter Patient information and/or connect to the Internet via W-Fi. Neither of these are necessary for proper operation of the system but it is recommended to do so. *(See Web Apps document for further details.)*
7. The system is now ready for Pre-Use checks. (See Section on Pre-Use checks).
8. After successful completion of Pre-Use checks the system enters the

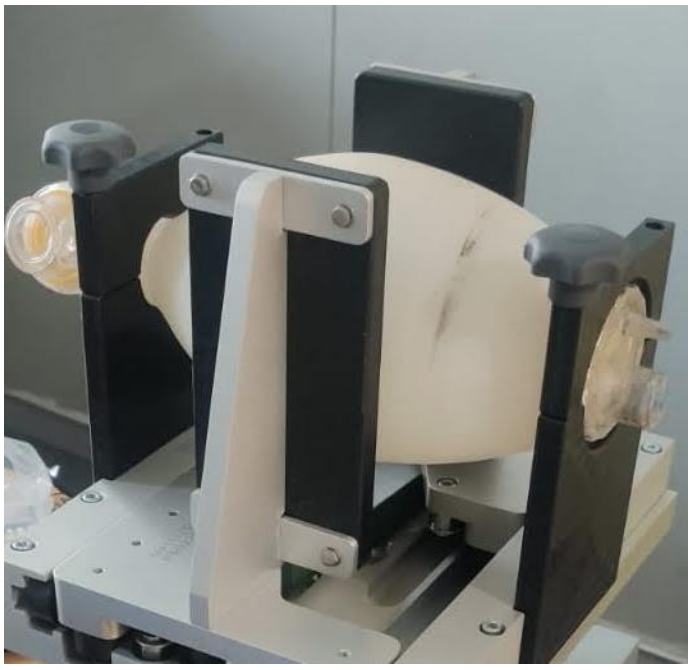


Figure 18: BVM Bag Pressing Plates

STANDBY state and it is now safe to connect the breathing system to the patient.

9. Now the respiration parameters can be changed, and breath delivery started.

Recommended Power OFF Sequence

To power off the Respirator, follow the steps below.

1. Make sure the system is in STANDBY or INITIALIZE state before powering off.
2. If the system is in ACTIVE or ERROR state, long press PAUSE to transition it into STANDBY state.
3. Once in STANDBY state, it is safe to power off the entire system.

Setting Operating Parameters

The respirator's operating parameters can be changed at any time while the system is in STANDBY or ACTIVE state. The operating parameters of the system are as described in the table below.

Symbol	Variable	Description
MODE	Respiration mode	ACV, CMV, SIMV or PSV
VT	Tidal Volume	Desired Volume (ml) of air to be delivered each inspiration phase
RR	Respiratory Rate	Desired Breaths per minute
E/I	Expiration/Inspiration ratio	Desired Ratio of expiration vs inspiration time in a breath cycle
PMAX	Max Inspiration Pressure	MAX inspiration pressure (cm H_2O) never to be exceeded
PEEP	Peak End Expiration Pressure	Desired Pressure (cm H_2O) in the lungs at the end of expiration
PS	Pressure Support	Desired Level of support pressure (cm H_2O) to assist every patient-initiated (spontaneous)breath
TPS	PS Inspiration duration	Auto Flow-controlled mode (10, 20, 30, 40, 50 or 60% of peak flow) or time duration for which the pressure support is to be delivered
FiO_2	Fraction of Inspired Oxygen	Concentration (%age) of oxygen in the inspired air. This must be controlled outside the system in the breathing circuit following recommended values by the system.

Table 2: Glossary of Respirator Operating Parameters

To change any of the operating parameters except FiO_2, follow the steps below.

1. Respirator must be in CHANGE mode which is indicated by one or more of the LEDs corresponding to the parameters in Table XXX blinking rapidly.
2. If not already in CHANGE mode, simply press one of the UP, DOWN, LEFT or RIGHT buttons. A MODE LED will start blinking rapidly indicating that the MODE field is the currently selected field for any changes.
3. The rapidly blinking parameter is the selected parameter to which changes will be applied.

4. To change the setting of the rapidly blinking parameter, use the UP / DOWN buttons or use the SELECTOR knob. It will cycle through all the settings available for that parameter.
5. After changing the setting on one parameter, use the LEFT / RIGHT buttons to navigate to a different parameter. A different parameter will start blinking rapidly indicating that it is now the current selection for changes. The previously changed parameters will continue blinking but at a slow rate. Unchanged parameters' LEDs will stay steady and not blink.
6. Continue in the above fashion till the entire desired set of parameters have been set according to requirements.
7. At any time, the display will show the current changed set of parameters. The parameters that have not been changed will not be blinking. The parameters that have changed will be blinking slowly. The parameter which is the current selection will be blinking rapidly.
8. None of these changed parameters will take effect till the YES button is pressed. Press YES once the entire parameter set is what is desired. If parameters are changed while in ACTIVE mode, the following message will be displayed.

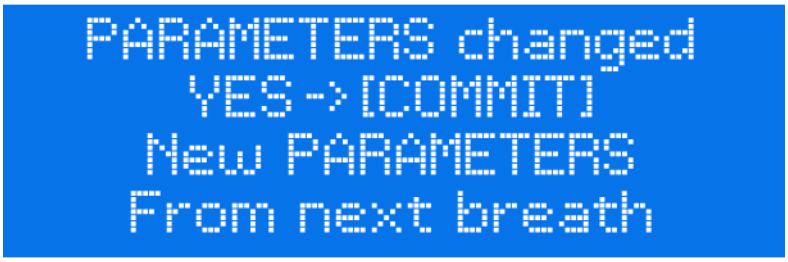


Figure 19: Parameter Change Message

9. The new set of parameters will take effect from the next breath delivery onwards after pressing START.
10. If the entered parameters are inconsistent, the following error message will be displayed showing the exact cause of conflict and the new set of parameters will not be committed till the conflict is resolved by the user.

Figure 20: Parameter Conflict Message

(See section on FiO_2 Settings for changing FiO_2)

Setting PEEP values

The recommended process for setting the PEEP valve to match the PEEP settings is as below.

On power-up, during Pre-use Checks, the user is prompted to set the PEEP valve dial to the desired setting. At this stage, the user relies only on the markings on the PEEP cylinder, turning the rotatable cap to match the pressure markings on the PEEP valve as shown in the Figure XXX below.

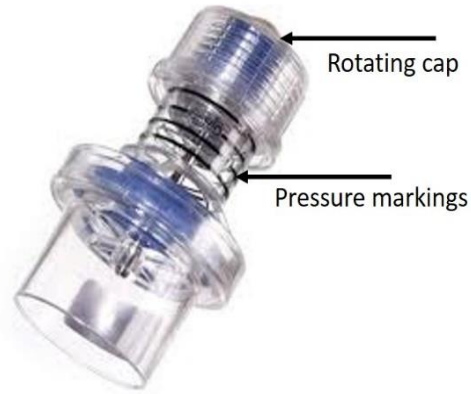


Figure 21: PEEP Valve

Once breath delivery starts, PEEP is monitored by the system and if it is measured to be different from the desired setting, an alarm is issued, and the user is prompted to change either the physical PEEP cap position or the desired setting.

Breath delivery is not interrupted, and the user can observe the changing PEEP from breath to breath as the dial is adjusted. When the dial reaches the correct position and the measured PEEP value matches the PEEP setting, the alarm turns off.

If desired, the user can change the PEEP setting instead of adjusting the physical PEEP valve setting. In that case, the user must commit the new input parameter setting by pressing the START button as usual.

This monitoring and reporting process continues all through breath delivery. The mismatch, if any, is displayed as below. It shows the difference between desired PEEP and measured PEEP.

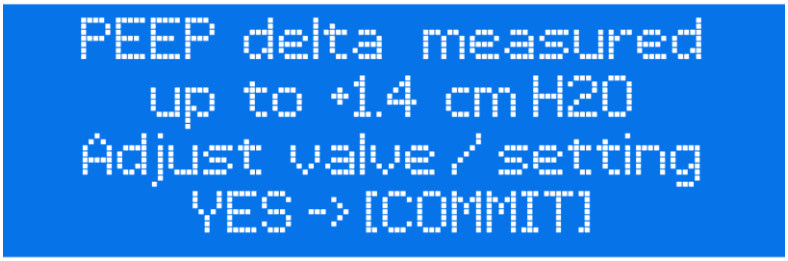


Figure 22: PEEP Mismatch message

STANDBY Menu

To change other parameters, use the STANDBY menu. STANDBY menu is accessed while in STANDBY state by pressing the MENU button. This menu allows setting/resetting values of various parameters that are not directly visible on the Front Panel.

The actions available through the STANDBY menu is shown in the Figure below.

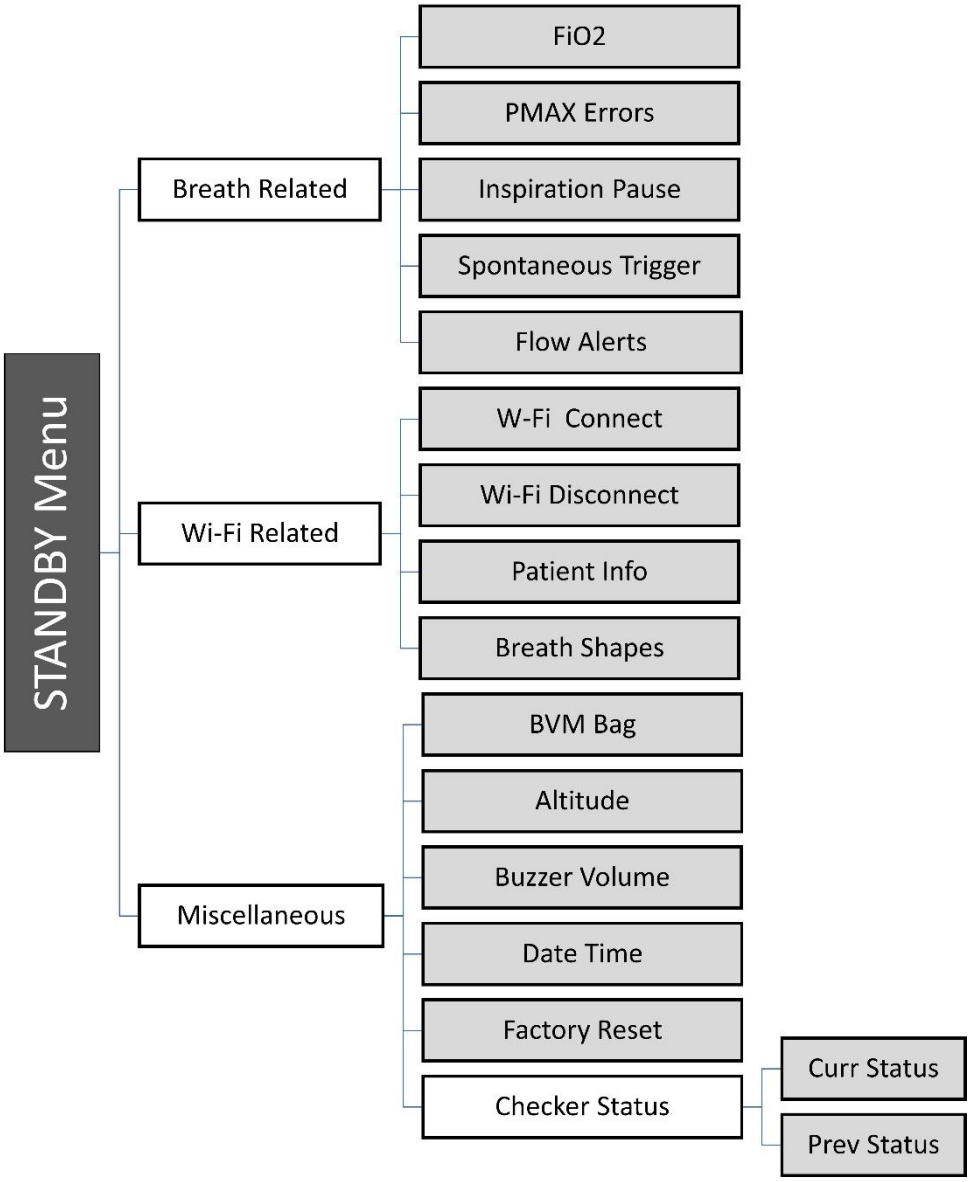


Figure 23: STANDBY Menu Hierarchy

FiO_2 Settings

⚠ Respimatic does not directly measure FiO_2. Techniques such SpO_2 with finger pulse oximetry or equivalent must be used to ensure that the patient is achieving adequate oxygenation.

The oxygen concentration delivered to the patient (FiO_2) is determined by the oxygen content of the source, flow rate of the oxygen source, and the patient minute ventilation. The patient minute ventilation, in its turn, is the product of the respiratory rate (RR) in breaths per minute (bpm) and tidal volume (VT).

To deliver a FiO_2 which matches the source oxygen concentration, the source flow rate must be greater than the patient's minute ventilation. Otherwise, atmospheric air will be pulled into the system and reduce FiO_2. The Oxygen source could be an Oxygen cylinder, a concentrator or piped Oxygen.

FiO_2 control is accomplished by connecting the oxygen source (cylinder or wall outlet) to the oxygen inlet of the BVM and adjusting the flow rate on the oxygen flow meter which is an integral part of whichever oxygen source is utilized.
With no oxygen source connected, the system delivers 21% FiO_2 which is the normal oxygen content of the atmosphere. In this case there is no need for the optional oxygen reservoir bag to be connected to the BVM.

To achieve FiO_2 other than 21% (or whatever the ambient atmosphere Oxygen percentage is at the deployment altitude), the optional oxygen reservoir must be connected to the BVM as shown in the figure below.

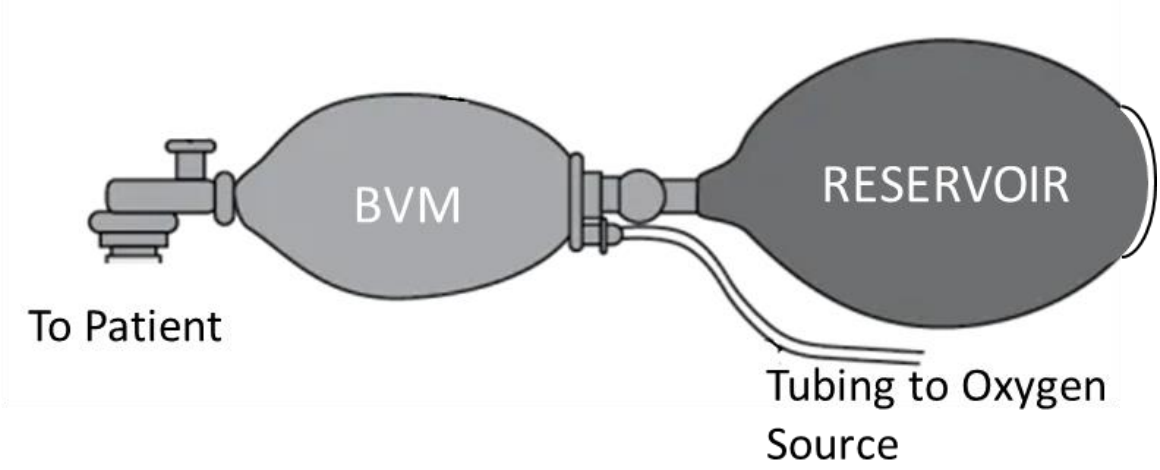


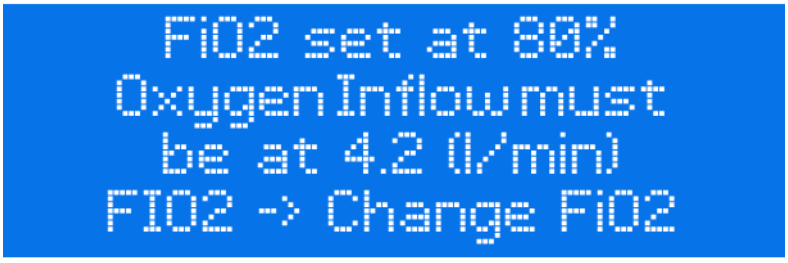
Figure 24: Oxygen Reservoir Connection

Some important points about the reservoir system are listed below.

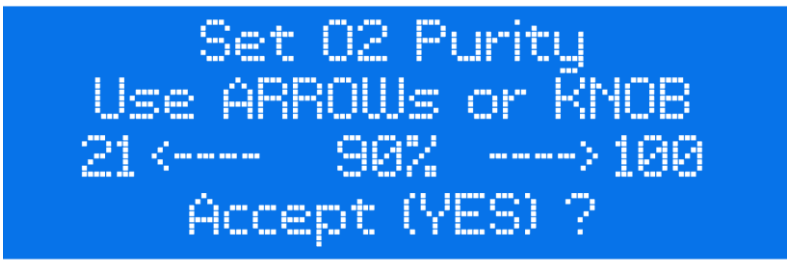
- Reservoir must be at least the volume of the BVM bag.
- The oxygen flow rate must be set as determined by the FiO_2 calculator. The required flow rate is displayed by the system automatically.
- The air inlet valve allows room air to enter if oxygen flow is inadequate.
- The outlet valve allows oxygen to escape if pressure is excessive.
- The flow rate of the oxygen source must be set depending upon the Tidal volume and Respiration rate settings of the system.

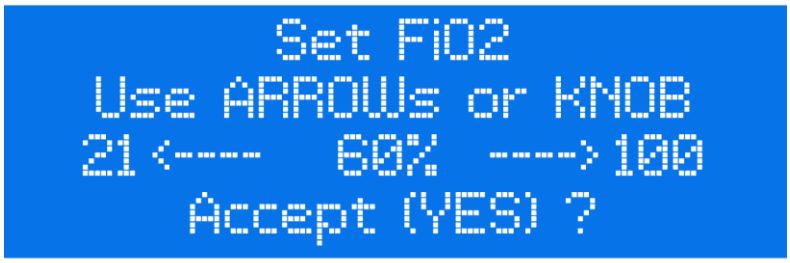
The Respimatic 100 guides the user through calculating the appropriate Oxygen input flow rate required for a desired FiO2. The process is as below.

1. System must be in STANDBY state to change FiO_2. If in ACTIVE state, long press PAUSE to enter STANDBY state.
2. Pressing the MENU button while in STANDBY state brings up the following menu. Select "Breath Related->FiO2" to change FiO2 settings at any time.

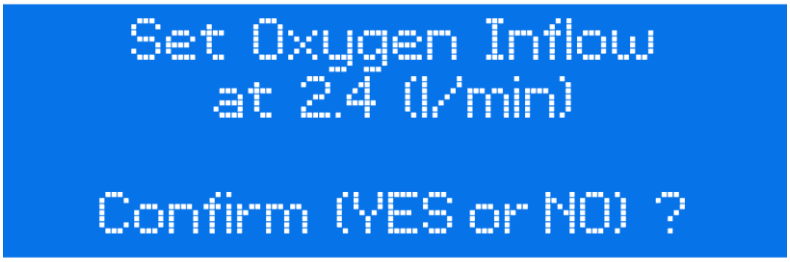


3. The system guides the user step-by-step through entering new parameters. Use the ARROW buttons or the SELECTOR knob to change the displayed values. Press YES when done entering a new value.





4. The system then calculates the required inflow and asks for confirmation that it has been set.



5. Finally, if at any time, other parameters are changed that affect the required Oxygen infow rate to maintain the set FiO2, the system alerts the user.

In addition, there also a stand-alone FiO2 calculator provided at the following URL. https://www.respimatic.com

(See the Respimatic WebApps document for further details.)

Ventilation Modes

Continuous Mandatory Ventilation (CMV)

In CMV mode, a set volume of air is delivered to the patient's lungs at periodic intervals subject to the following settings.

1. Tidal Volume (VT)
2. Respiration rate (RR)
3. Expiration/Inspiration ratio (E/I)
4. Peak End Expiration pressure (PEEP)
5. MAX Inspiration pressure (PMAX)
6. Oxygen Percentage (FiO_2)

This mode is characterized by the following.

1. Deliver a mandatory (set) number of breaths with a set volume (VT)
2. RR and E/I must be set.
3. Once a breath is triggered, a consistent tidal volume VT is delivered.
4. Patient-initiated (spontaneous) breaths are ignored but kept track of. The number of such breaths is periodically displayed on the LCD screen.

Synchronized Assist Control Ventilation (ACV)

In ACV mode, a set volume of air is delivered to the patient's lungs at periodic intervals subject to the following settings.

1. Tidal Volume (VT)
2. Respiration rate (RR)
3. Expiration/Inspiration ratio (E/I)
4. Peak End Expiration pressure (PEEP)
5. MAX Inspiration pressure (PMAX)
6. Oxygen Percentage (FiO_2)

This mode is characterized by the following.

1. Deliver a mandatory (set) number of breaths with a set volume (VT) while supporting spontaneous breath efforts by the patient.
2. RR and E/I must be set.
3. Once a breath is triggered, a consistent tidal volume VT is delivered.
4. Patient-initiated (spontaneous) breaths are delivered when the airway pressure drops below the end-expiratory pressure (PEEP).
5. If no spontaneous breath trigger (from the patient) received within the time set by RR, machine triggers a cycle.
6. The system synchronizes mandatory breaths as shown in Fig. 7 below.
7. Tidal volume is delivered at regular intervals T_i. If spontaneous breath occurs during this interval at time T_s, the set tidal volume is delivered in response, and the next mandatory breath is set for (T_s+ T_i). Again, if another spontaneous breath is detected before T_s + T_i, a mandatory breath scheduled T_i time in future.

8. Monitor Peak Pressure –alarm is sounded if a preset limit (PMAX) is breached.
    - Peak pressure is measured while air flow is ongoing. At this time, the pressure is largely determined by the resistance of the patient airways or dynamic lung compliance.
9. Monitor Plateau and PEEP pressure
    - Plateau pressure is measured after air flow stops. At this time, the pressure is determined by static lung compliance.
    - PEEP pressure is measured at the end of the expiration phase.

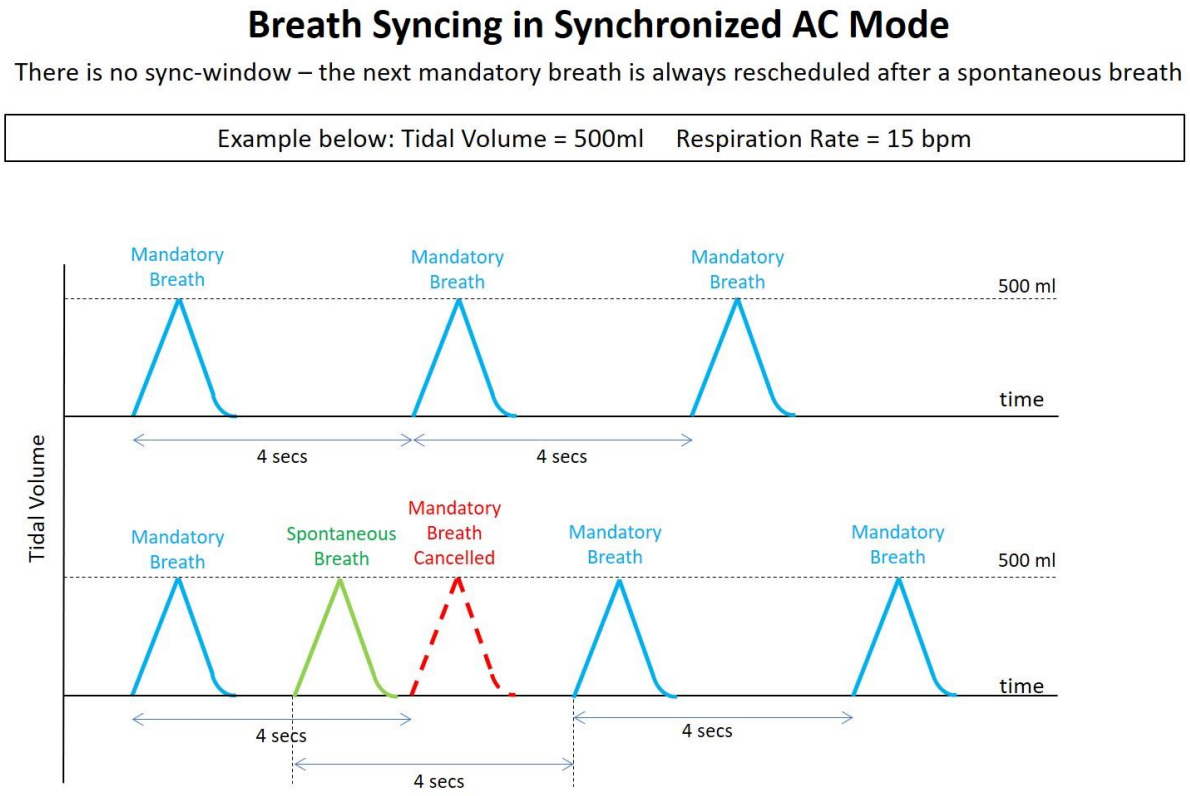


Figure 25: ACV Breath Synchronization

Synchronized Intermittent Mandatory Ventilation (SIMV)

In SIMV mode, a volume of air is delivered to the patient's lungs at periodic intervals subject to the following settings.

1. Tidal Volume (VT)
2. Respiration rate (RR)
3. Expiration/Inspiration ratio (E/I)
4. Peak End Expiration pressure (PEEP)
5. MAX Inspiration pressure (PMAX)
6. Support Pressure (PS)
7. PS Inspiration duration (TPS)
8. Oxygen Percentage (FiO_2)

This mode is characterized by the following.

1. Deliver a mandatory (set) number of breaths with a set volume while at the same time allowing spontaneous breaths triggered by the patient.
2. RR and E/I must be set.
3. Patient-initiated (spontaneous) breaths are delivered when the airway pressure drops below the end-expiratory pressure (PEEP).
4. In contrast to ACV, SIMV will deliver a level of support pressure (PS) to assist every spontaneous effort.
5. Pressure support (PS) is added to enhance the volume of spontaneous breaths.
6. TPS controls the time for which Pressure support is provided. If TPS is set to Auto Flow-dependant mode (10, 20, 30, 40, 50, 60), the pressure support will stop once the flow falls the set percentage below the peak flow.
    - 10 – Terminate pressure support when flow reaches 10% of peak
    - 20 – Terminate pressure support when flow reaches 20% of peak
    - 30 – Terminate pressure support when flow reaches 30% of peak
    - 40 – Terminate pressure support when flow reaches 40% of peak
    - 50 – Terminate pressure support when flow reaches 50% of peak
    - 60 – Terminate pressure support when flow reaches 60% of peak
    - 1.0 – Terminate pressure support after 1.0 secs
    - 1.5 – Terminate pressure support after 1.5 secs
    - 2.0 – Terminate pressure support after 2.0 secs
    - 2.5 – Terminate pressure support after 2.5 secs
7. The ventilator synchronizes the delivery of mandatory breaths with the spontaneous efforts of the patient.
8. Monitor Peak Pressure –alarm will sound if a preset limit (PMAX) is breached.
    - Peak pressure is measured while air flow is ongoing. At this time, the pressure is largely determined by the resistance of the patient airways and dynamic lung compliance.
9. Monitor Plateau and PEEP pressure
    - Plateau pressure is measured after air flow stops. At this time, the pressure is determined by static lung compliance.
    - PEEP pressure is measured at the end of the expiration phase.

Pressure supported breaths in SIMV mode.

All through the inspiration phase of a pressure supported breath, the pressure is monitored and maintained at the target level (PS).

The inspiration time for a Pressure Supported breath is determined by the set TPS setting. If set to Auto Flow-dependant mode (F1 through F6), the pressure support is terminated when the inspiration flow falls below a pre-set level.

SIMV Breath Synchronization

- In SIMV mode, again tidal volume is delivered at regular intervals T_i .
- If a patient-initiated (spontaneous) breath occurs during this interval at time T_s, a pressure supported breath is delivered in response.
- If the next mandatory breath was scheduled within a sync window, it is rescheduled for T_i later. Else it remains scheduled as it was. This prevents breath stacking issues.

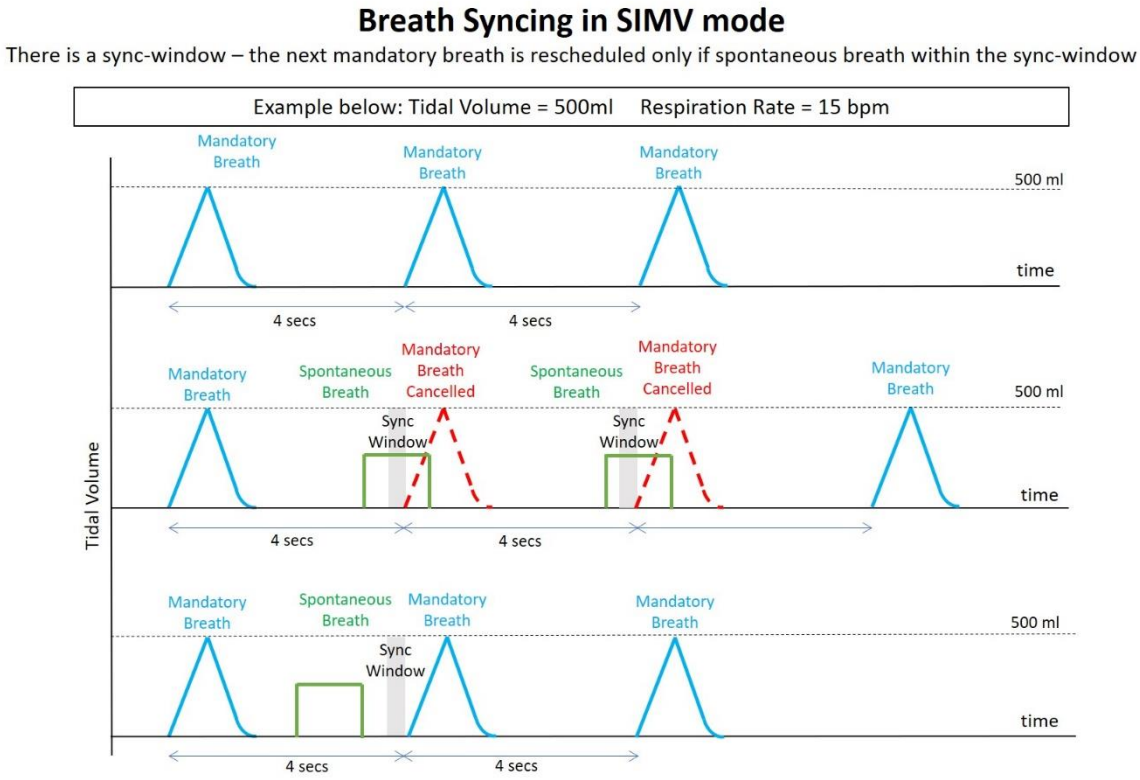


Figure 26: SIMV Breath Synchronization

Pressure Support Ventilation (PSV)

In PSV mode, only patient-initiated (spontaneous) breaths are honored, and pressure supported. There are no mandatory breaths delivered except in an exceptional situation. Again, TPS settings are used to control when to terminate the pressure support for a spontaneous breath.

Assume that a minimum Minute-Volume of 9.5 litres/min is expected while a particular patient is on PSV. Violating the Minute-Volume will result in an ERROR.

The input settings to set on Respimatic should be as follows.

Mode=PSV (In PSV mode, the display changes to allow MV entry)
MV= 9.5 (litres/min)
PS = Desired Support Pressure
TPS = Termination setting for Pressure Supported breaths

The response of Respimatic will be as follows.

- Wait for Spontaneous breath triggers from the patient.
- Apply PS support pressure for the duration of spontaneous breaths.
- If, at any time, Minute-Volume falls below 90% of expected (8.55 litres/min for our test case), issue an ERROR alarm and go into ERROR mode.
- While in ERROR mode, the system transitions into SIMV mode and delivers maintenance breaths till the ERROR is attended to.
- The fallback SIMV parameters are calculated heuristically. In this case VT=450, RR=21, EI=2
- If time between any two consecutive spontaneous breath triggers exceeds 200% of expected (expected time is determined from the calculated RR above), deliver a mandatory breath and issue a WARNING, not an ERROR.
- Monitor Peak Pressure as usual – an alarm will sound if a preset limit (PMAX) is breached. Also, monitor Plateau and PEEP pressure as usual.

PSV	SIMV Backup		
MV (l/min)	VT (ml)	RR (bpm)	E:I
2.0	200	10	2
4.0	300	13	2
6.0	300	20	2
8.0	400	20	2
10.0	500	20	2
12.0	500	24	2
14.0	600	23	2
16.0	600	26	2
18.0	600	30	2

Table 3: Sample SIMV Backup for PSV

Pressure supported breaths in PSV mode.

All through the inspiration phase of a pressure supported breath, the pressure is monitored and maintained at the target level (PS).

The inspiration time for a Pressure Supported breath is determined by the set TPS setting.

Exceptional Mandatory Breath during PSV

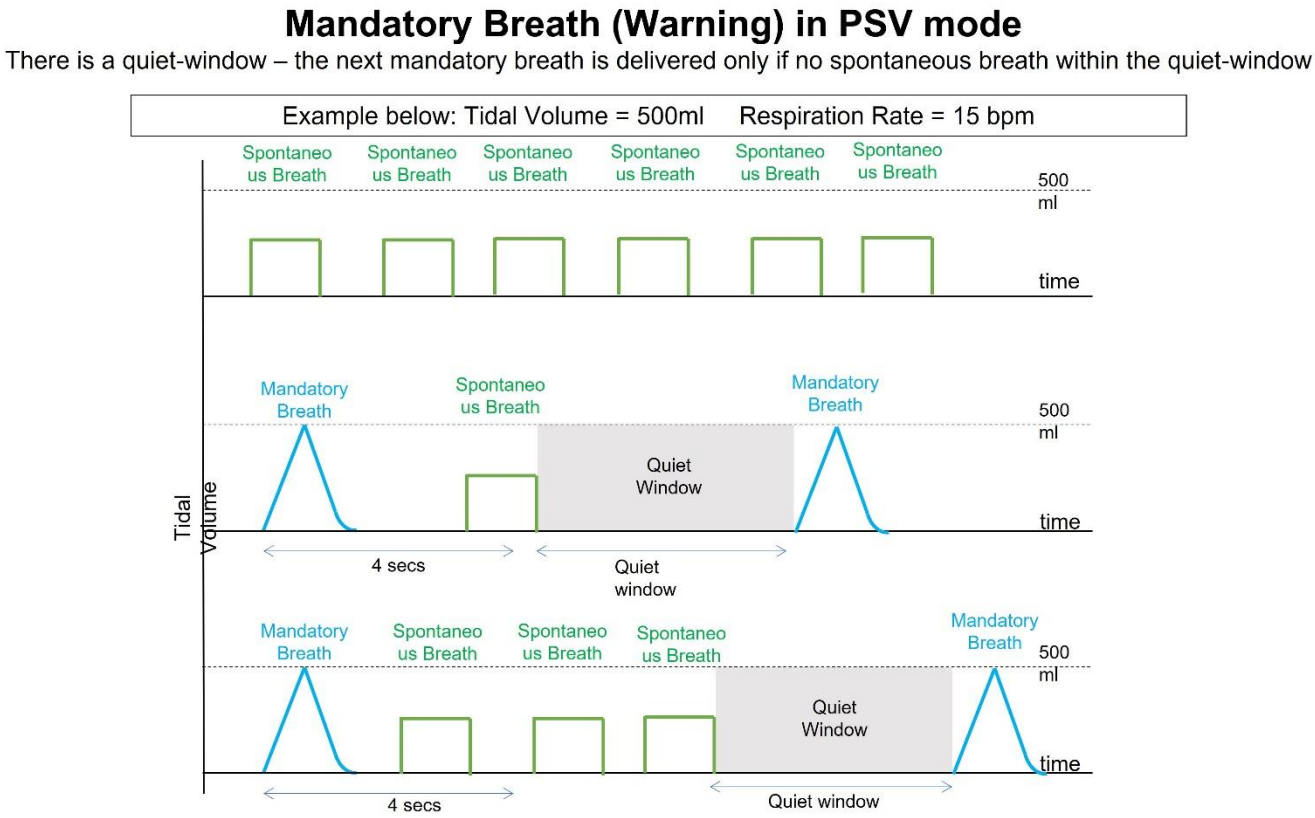


Figure 27: PSV Mandatory Breath

Human Machine Interface

Control Mechanisms

Control	Feedback	Mechanism	Comments
RESET	State LEDs	Push Button	Resets the entire system. Same as Power-on.
RESET+ KNOB Switch	State LEDs	Push Buttons	Pressing RESET while START is pressed reverts the system to Factory settings.
MUTE	Buzzer	Push Button	Mutes the BUZZER for 2 minutes.
START	State LEDs	Push Button	Starts breath delivery according to the displayed parameters
PAUSE	State LEDs	Push Button	Pauses the breath delivery at any time. Transitions into STANDBY state if pressed for more than 1sec. A short press on this button introduces an inspiratory pause in the next volume-controlled breath.
ROTARY KNOB	Various	Rotary Encoder	Adjust LED display brightness at any time. Also used to navigate menus and change parameter values.
CONTRAST	LCD Contrast	Screw	Adjust LCD contrast levels at any time.
YES/ACCEPT	LCD Display	Push Button	Used to answer questions posed by Pre-Use checks
NO/CANCEL	LCD Display	Push Button	Used to answer questions posed by Pre-Use checks
UP, DOWN LEFT, RIGHT ROTARY KNOB	LEDs and LCD	Push Buttons Rotary KNOB	Used for navigating to the parameter to change. While in TEST mode, these buttons (or SELECTOR knob) are also used to navigate the menu presented on the LCD screen or to manually move plates.

Table 4: Control Mechanisms

Options for Respirator Operating Parameters

Parameter	Options	Feedback	Control
Respiration Mode	CMV	CMV LED	UP / DOWN LEFT / RIGHT SELECTOR
	ACV	ACV LED	
	SIMV	SIMV LED	
	PSV	PSV LED	
Tidal Volume VT (ml)	200 through 600 in increments of 50	Selection displayed on a 3-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Minute Volume MV (litres/min)	2.0 through 18.0 in increments of 0.5	Selection displayed on a 3-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Respiration Rate RR (bpm)	10 through 30 in increments of 1	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR
E:I Ratio	1	Selection displayed on a 1-digit display	UP / DOWN LEFT / RIGHT SELECTOR
	2		
	3		
PEEP Pressure PEEP (cm H_2O)	4 through 15 in increments of 1	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Max Inspiratory Pressure PMAX (cm H_2O)	20 through 50 in increments of 5	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Support Pressure PS (cm H_2O)	5 through 35 in increments of 1	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Termination of Support Pressure TPS (secs/% Peak Flow)	Flow-control (10%to 60%) or time-control (1.0 - 2.5 secs)	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR

Table 5: Respirator Operating Parameter Options

Monitored Parameters

Measured Parameter	Options	Feedback	Comments
Peak Inspiration Pressure PEAK (cm H_2O)		Measured Number displayed on a 2-digit display	Updated after each breath
Plateau Pressure PLAT (cm H_2O)	Mean Pressure for PS Breaths	Measured Number displayed on a 2-digit display	Updated after each breath
PEEP Pressure PEEP (cm H_2O)		Measured Number displayed on a 2-digit display	Updated after each breath
Minute Volume (litres/min)		Estimated numbers displayed on the LCD screen.	Updated after each breath. Displays info for the previous minute.
Breaths per minute Mandatory/Spontaneous (bpm)		Measured numbers displayed on the LCD screen.	Updated after each breath. Displays info for the past minute.
Instantaneous Static and Dynamic Lung Compliance (ml/cm H_2O)		Estimated numbers displayed on the LCD screen.	Updated after each VC breath. Displays info for the previous breath.
Messages	Errors	Displayed on a 20x4 LCD Character display	Each message is 4 lines of 20 characters each.
	Alarms		
	Prompts		
	Info		
Current Breath Type	Mandatory	Green LED	Displayed for each breath delivered
	Spontaneous	Yellow LED	
Respirator State	INITIALIZE	White LED	Displays the current state of the system.
	STANDBY	Yellow LED	
	ACTIVE	Green LED	
	ERROR	Red LED	

Table 6: Monitored Parameters

Alarms

There are 3 types of alarm messages, some of them accompanied by a buzzer beep. While the buzzer is beeping it can be muted by pressing the MUTE button. If the alarm persists beyond the next 2 minutes after muting, the buzzer will sound again.

1. ERROR
    - ERROR LED flashes rapidly and the buzzer sounds long beeps.
2. WARNING
    - ERROR LED flashes slowly and the buzzer sounds medium beeps.
3. NOTIFICATION
    - Buzzer sounds short beeps. ERROR LED does not flash.

The ERROR messages during Pre-Use checks require immediate remedying and can be recovered from only through a system RESET.

The ERROR and WARNING messages during STANDBY typically require a change in parameter settings.

The ERROR and WARNING messages during breath delivery (ACTIVE state) are explained below in detail. The system automatically switches to a safe fallback operation upon encountering these errors till an operator intervenes and remedies the problem.

PMAX Exceeded Alarm

The maximum inspiration peak pressure is set by the PMAX parameter value.

If the peak pressure exceeds the PMAX value, the system limits the Tidal Volume so as not to exceed the maximum pressure limit. The user is alerted with a rapidly blinking alarm LED and long buzzer beeps.

The breath delivery continues with these fallback set of parameters till the user pauses the system using the PAUSE button. Upon entering the STANDBY state, the system displays the state of the system including all the measured parameters as they were at the time of the error.

The user must determine the future course of action which typically requires a change of respiration parameters and restarting the breath delivery.

PSV Minute Volume Alarm

The desired minute volume is calculated as (VT x RR) ml/min.

In PSV ventilation mode, if the minute-volume falls below the above calculated volume an ERROR message is issued, and the system goes into ERROR mode and starts delivering maintenance breaths in SIMV mode. PSV mode is exited and SIMV mode with the same set of parameters is deployed instead. The user is alerted with a rapidly blinking alarm LED and long buzzer beeps.

The breath delivery continues with these fallback set of parameters till the user pauses the system using the PAUSE button. Upon entering the STANDBY state, the system displays the state of the system including all the measured parameters as they were at the time of the error.

The user must determine the future course of action which typically requires a change of respiration parameters and restarting the breath delivery.

Pressure Loss Alarm

This alarm is typically caused by a loose connection between the connectors in the breathing system or by the patient mask getting loose.

The user is alerted with a rapidly blinking alarm LED and long buzzer beeps. Breath delivery continues with the same set of parameters.

The system automatically recovers after the loose connection is rectified. Alternatively, the PAUSE button can be used to put the system into STANDBY state till the problem is resolved.

Temperature Alarm

This alarm is triggered if the system gets too hot or too cold. The user is alerted with a rapidly blinking alarm LED and long buzzer beeps.

The fan and the filters must be examined to check if they are in proper working condition. The system automatically recovers once the system temperature falls back into the normal operating range.

Motor Fault Alarm

This alarm should never happen. If it does, the system automatically recovers and continues with the breath delivery. During recovery time (typically 5 secs) the user is alerted with a rapidly blinking alarm LED and long buzzer beeps.

Description of various Alarms

ERROR	CAUSE	ALARM	COMMENTS
Exceeded Maximum Inspiration Pressure	Peak Inspiration pressure exceeded the set PMAX limit	YES	May have to reduce the Tidal volume, BPM, EI ratio or increase PMAX
Pressure Loss	Disconnected Breathing Circuit or non-working Pressure Sensor	YES	Check breathing circuit for disconnections. Also check Patient mask.
Measured PEEP does not match set value	Measured PEEP value differs from the set PEEP value for consecutive breaths	NO	Check PEEP valve or the Pressure Sensor. Adjust PEEP valve
Abnormal Pressure Signal	Too many pressure peaks and troughs observed for 3 consecutive breaths	NO	Patient may be coughing or hiccupping
PARAMETER Conflict PS less than PEEP	Attempt to set PS (Support Pressure) less than PEEP	NO	Change setting and retry
PARAMETER Conflict PMAX less than PEEP	Attempt to set PMAX (Max Inspiration Pressure) less than PEEP	NO	Change setting and retry
PARAMETER Conflict PMAX less than PS	Attempt to set PMAX (Max Inspiration Pressure) less than PS (Support Pressure)	NO	Change setting and retry
Combination of settings invalid	Internal System Error	YES	Call Support - System issue
Unable to achieve set PS	Cannot achieve the required support pressure in TPS period	YES	May have to reduce PS or increase TPS
Unable to Deliver set Tidal Volume	Requirement exceeds system capability	NO	Change Tidal Volume setting
Unable to Deliver set Minute Volume	Requirement exceeds system capability	YES	Change Minute Volume setting
Failed to home Pressing Plates	System unable to initialize the position of pressing plates	YES	Call Support - System issue

Table 7: System Alarms & Messages

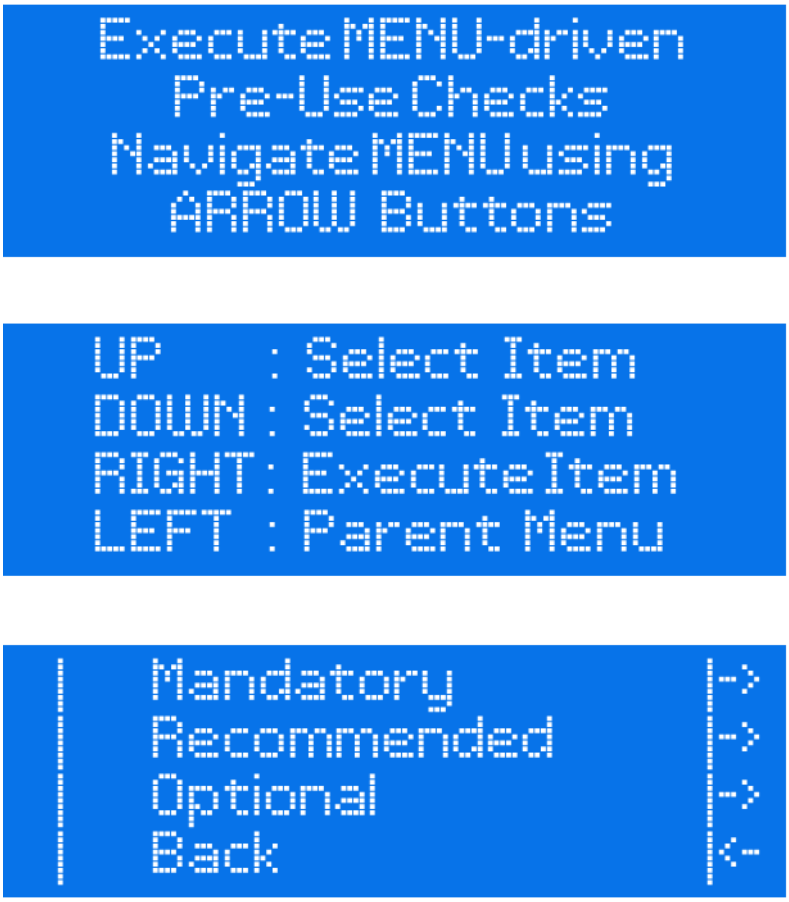
ERROR	CAUSE	ALARM	COMMENTS
Pressure sensor calibration error	Pressure Sensor Offset measured is beyond the allowable limit	YES	Call Support - System issue
Self-Test Failed	Power-on self-test failure	YES	Call Support - System issue
Pre-Use Checks Failed	Faulty components	YES	Call Support - System issue
Temperature Sensor CRC Error	Temperature sensor failure	YES	Call Support - System issue
System is overheating	System Temperature measured below -10 deg C	YES	Call Support - System issue
System is too cold	System Temperature measured above 55 deg C	YES	Call Support - System issue
Portal Timeout	Data Entry for Patient or Wi-Fi portal took more than 2min	NO	Try again
Settings are beyond system capabilities	The required combination of VT, RR and EI is not supported by the system	YES	Call Support - System issue
Undiagnosed Fault	Low pressures. Problem with the motor, pressing plates, pressure sensors or breathing system leakage.	YES	Call Support - System issue

Table 8: System Alarms & Messages (contd..)

Executing Pre-Use Checks

It is a MUST to execute a set of pre-use checks before connecting the respirator to a patient. These checks ensure the health and proper working of the system. The checks are menu driven and the user is guided through messages and prompts on the LCD screen.

On entering the Pre-use Checks, the following three screens are presented in succession.



The Pre-Use checks are divided into three categories as below.

Figure 28: Pre-Use Checks LCD Messages

Mandatory Checks

These checks must be executed before the system allows a transition to any other state. These checks are critical. The system disallows exit from Pre-use checks till these checks are executed successfully.

Recommended Checks

These checks are also recommended but the user can choose to skip them if necessary.

Optional Checks

These are additional optional checks.

The procedure for running the Pre-Use checks is as below.

1. Power-on the system.
2. The INITIALIZE state LED turns on and the system goes through a self-testing exercise.
3. The system then enters a TEST mode where a menu of Pre-use checks is presented on the LCD screen. The following three LCD screens are presented sequentially.
4. The menu displayed on the LCD screen is a hierarchical menu which can be navigated using the UP, DOWN, LEFT and RIGHT buttons. Figure below shows a sample menu display.

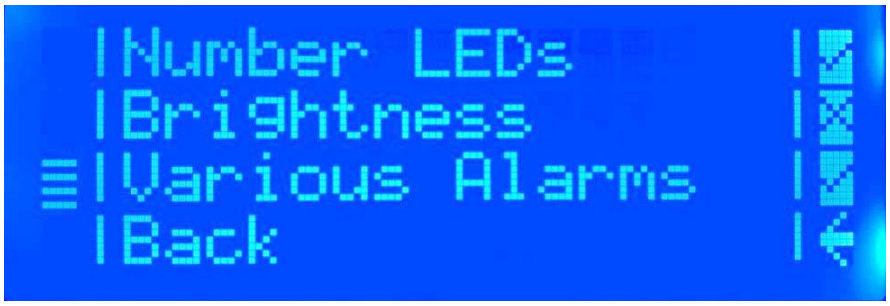


Figure 29 : Sample Pre-Use Menu display

5. The leftmost column indicates the currently selected menu item – use UP or DOWN arrows to navigate to any other menu item on the current menu.
6. If the leftmost column shows horizontal bars, it indicates that the menu item has a child menu, else it indicates that it is an executable check by displaying a STAR glyph in the leftmost column.
7. The rightmost column indicates the status of each executable check executed during the current session for an item which is not a parent-menu itself. A blank indicates that the check has not been done, a check mark indicates that the check was done, and it was successful while a cross mark indicates that the check was done but it failed.
8. The back arrow in the rightmost column indicates that this menu has a parent menu which can be navigated to using the LEFT button.
9. A right arrow in the rightmost column indicates that the menu item has a child menu which can be navigated to using the RIGHT button.

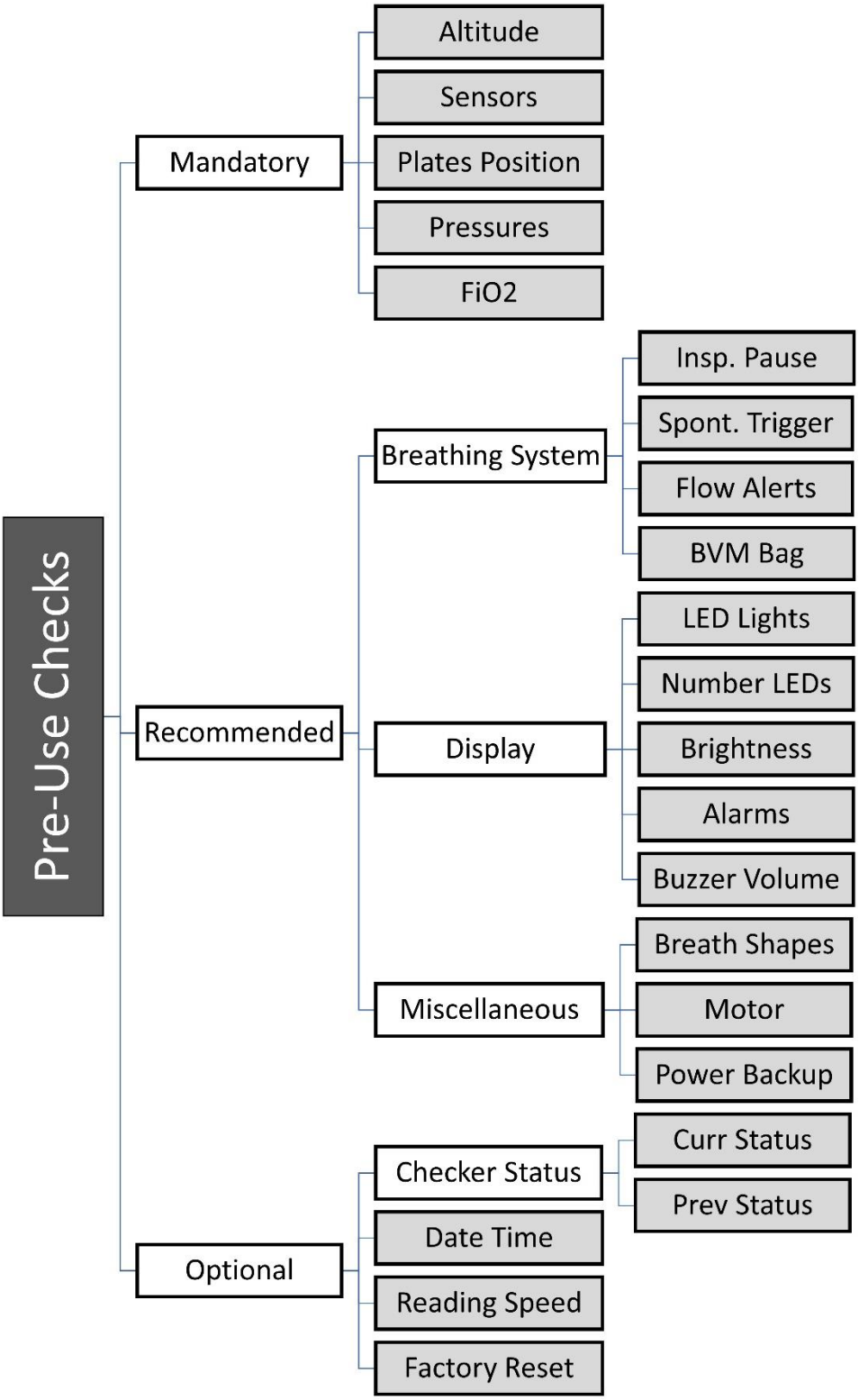


Figure 30: Menu Hierarchy of Pre-Use Checks

Mandatory Checks

Though it is highly recommended that all the Pre-use checks be carried out on system startup before hooking up the patient to the breathing system, the following checks are enforced by the system. The system will guide the user through all these checks.

Sensor Checks

On every power-up of the system, the pressure sensors must be calibrated and checked for proper operation. The messages on the LCD screen will guide the user step-by-step through this check.

1. Disconnect the breathing system from the patient.
2. Leave the mask opening open to the atmosphere. This will be used to calibrate the pressure sensor.

In addition, checks must be performed to ensure that the pressure lines are connected properly and there is no breakage. The messages on the LCD screen will guide the user step-by-step through this check.

1. Disconnect the breathing system from the patient.
2. Block the mask opening open with the fingers of your hand. This will be used to check that the pressure lines are connected to the appropriate port.

Plates Position

On every power-up of the system, the BVM bag pressing plates must be brought to a home position where they are just touching the bag. The messages on the LCD screen will guide the user step-by-step through this procedure.

1. Disconnect the breathing system from the patient.
2. Wait for motor to reset.
3. When prompted, block the mask opening with your fingers. The plates will be automatically moved to the home position.
4. Next, when prompted, keep the mask opening open to atmosphere. This will be used to determine the size of the BVM bag.

Pressure Checks

On every power-up of the system, and subsequently on every change in PEEP settings, the PEEP valve must be checked for proper operation. The messages on the LCD screen will guide the user step-by-step through this check.

1. Confirm the PEEP setting as on the display.
2. Adjust the PEEP valve dial to match the display setting.
3. The PEEP valve dial is not fully accurate, but the system will monitor the PEEP pressure during the first few breaths (and throughout breath delivery) and present an accurately measured PEEP value.
4. If the difference between the measured PEEP and the PEEP setting is beyond a threshold, a notification will be issued so that the user can adjust the PEEP valve dial. Breath delivery will continue regardless.

In addition, it is extremely important to set the maximum pressure setting (PMAX) for the intended patient. The messages on the LCD screen will guide the user step-by-step through this check.

1. Adjust the PMAX setting on the display using arrow buttons.
2. Confirm the PMAX setting as on the display.

FiO_2 Checks

1. Set the required FiO_2 level and the incoming Oxygen purity level.
2. The system will calculate the incoming Oxygen flow rate required to achieve the required FiO_2.
3. Note that the incoming Oxygen flow rate must be controlled external to the system.

(See Section on FiO2 Settings)

Recommended Checks

Though it is highly recommended that all the Pre-use checks be carried out on system startup before hooking up the patient to the breathing system, the following checks are not enforced by the system. It is still recommended that the user executes these checks before hooking a patient to the Respirator. The system will guide the user through all these checks.

Breathing System Checks

Set Inspiration Pause

The system executes an inspiration pause maneuver on a short press of PAUSE button during breath delivery. The pause duration can be set using this menu item.

Set Spontaneous Breath Trigger

By default, a fall in pressure of 2 cm below PEEP is recognized as an attempt by the patient to take a spontaneous breath. The trigger value can be changed using this menu item.

Set Flow Alert Thresholds

To guide the external Oxygen flow rate settings, the system guides the user on what to set the Oxygen inflow rate at. This depends upon the minute volume being delivered. If the minute volume changes during a session (due to patient-initiated (spontaneous) breaths), the user is alerted to change the Oxygen inflow rate. This menu item sets the threshold of change percentage before alerting the user.

BVM Bag

The BVM bag has a limited lifetime. Using this Pre-use check, the user can determine the number of compressions the bag has undergone since replacement and thus decide whether it is time to replace the bag.

Display System Checks

LED Checks

Check that the LED lights are functioning as expected.

Number LED Checks

Check that the 7-segment LEDs are functioning as expected.

Display Brightness Checks

Check that the display brightness can be adjusted.

Alarms Check

Check that the alarm light and buzzer are functioning as expected.

Buzzer Sound Check

Check and set buzzer volume.

Miscellaneous Checks

Altitude Check

Set and confirm the altitude (elevation) at the place of deployment.

Breath Shapes

Set the frequency at which detailed pressure data will be sent to remote dashboard for individual breaths.

Motor Check

Quick check that the motor can run at different rpms.

Power Backup Check

Check that the system will continue functioning if there is a power outage.

Optional Checks

Checker Status

The status of various checks can be viewed for the current and previous sessions.

Date and Time

Confirm and set current date and time.

Reading Speed Check

Test and set appropriate message persistence time for the user's reading speed.

Factory Reset

Restore the system to factory settings. It requires a RESET immediately afterwards.

Errors during Pre-Use Checks

The following table lists the possible errors that could be flagged during Pre-Use checks.

Errors: Pre-Use Checks	ERROR	CAUSE	ALARM	COMMENTS
	LCD not responding	Hardware/Software	YES	System Error. Call Technician
	Light LED Failure	Hardware/Software	YES	System Error. Call Technician
	Number LED Failure	Hardware/Software	YES	System Error. Call Technician
	Display Brightness Failure	Hardware/Software	YES	System Error. Call Technician
	Alarms Failure	Hardware/Software	YES	System Error. Call Technician
	Motor Failure	Hardware/Software	YES	System Error. Call Technician
	Plates movement Failure	Hardware/Software	YES	System Error. Call Technician
	Power Backup Failure	Hardware/Software	YES	System Error. Call Technician
	Pressure Sensor Failure	Hardware/Software	YES	System Error. Call Technician
	PEEP Valve Failure	Hardware/Software	YES	System Error. Call Technician
	Up/Down Pressure lines swapped	Setup Error	YES	Switch the two pressure line connections
	Upstream Pressure line Disconnected	Setup Error	YES	Check the pressure line
	Downstream Pressure line Disconnected	Setup Error	YES	Check the pressure line

Table 9: Pre-Use Check Errors

Safety Features

The system incorporates a host of mechanisms to ensure the safety of patients. The important ones are listed below.

- Self-test on power-up
- Ability to set maximum inspiration pressure.
- Ability to detect a loss of pressure during breath delivery.
- Ability to detect the patient coughing or hiccupping.
- Pop-off valves at a critical junctions.
- Pressure calibration enforced at power-up.
- PEEP valve checked for proper functioning at power-up.
- A battery of menu-driven pre-use checks which the user must perform before connecting the breathing system to the patient.
- Checking of inconsistent input parameter setting.
- Constant checking of Motor malfunction conditions.
- System Temperature monitoring and alarms.
- Keeping track of the number of compressions the BVM has undergone.
- Storing of the results of checks in non-volatile memory for later retrieval.

BVM (AMBU) Bag Specifications

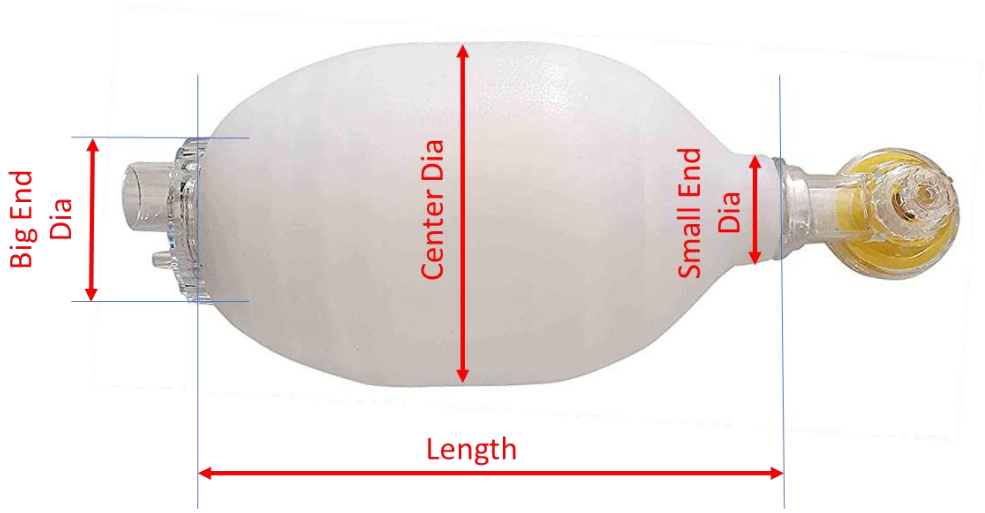


Figure 31: BVM Bag

	Units	Min	Max
Length	mm	210	215
Center Diameter	mm	120	125
Big End Diameter	mm	60	65
Small End Diameter	mm	25	30
Connector Diameter	mm	22	22
Volume	ml	1600	1800

Table 10: BVM Bag Specifications

Power Supply

Input Voltage	200V – 250V
Power Consumption	100 Watts
Recommended UPS wattage	300 VA
50AH UPS Battery	5 Hours Backup operation
100AH UPS Battery	10 Hours Backup operations

Table 11: Respirator Power Supply

System Specifications

CATEGORY	SPECIFICATION
General Standards Compatibility	
EMC Compatibility	
Patient Range (Kg)	
Operating Temperature Range	
Input Power Supply Range	200V – 250V
Power Consumption	100 Watts
Dimensions	
Weight	
Breathing System Connectors	

Table 12: Respirator Specifications

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