

Respimatic 100

Emergency Respiration Assist Device



Operating Manual

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Manual Organization

Introduction

Explains the intended use scenarios for the system.

System Elements

Explains the various elements and possible configurations of the system.

Important Safety Instructions

Checklist of the system do's and don'ts to ensure proper working of the system.

System Overview

Block diagrams for the entire system. Basic User interface navigation.

Operation Overview

Provides brief procedures for the complete use of the ventilator including the performing the Pre-use Check and entering respiration settings.

Ventilation Modes

Lists all available ventilation modes Lists settings required for each mode and defines the breathing parameters.

Monitored Parameters

Lists all monitors displaying the patient breathing data as it is collected by the ventilator.

Alarms

Contains tables listing all alarms, Pre-use Check messages, error messages, and technical error messages. Describes possible causes and remedies for error messages.

Specifications

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

Introduction

Respimatic-100 provides non-invasive respiration support for adult patients. The target market is remote areas with minimum infrastructure such as compressed gas and oxygen pipeline.

Respimatic-100 provides a budget-friendly, reliable, and robust device for use by patients who do not require intubation and the more complex ventilation modes of an ICU ventilator. The system provides a simple and intuitive Human-Machine Interface so that the learning curve for the medical practitioner is minimized.

Respimatic-100 supports four commonly used ventilation modes – CMV, ACV, SIMV and PSV. These four modes cover all the phases of patient conditions, from first admission to final weaning. In addition, Respimatic-100 supports a full range of breath parameters across all combinations for all ventilation modes. It also provides complete support for spontaneous breaths, both volume controlled, and pressure supported, with full breath synchronization.

Finally, Respimatic-100 incorporates a full range of safety. A fallback mode is provided for every possible error condition so that the breath delivery never stops.

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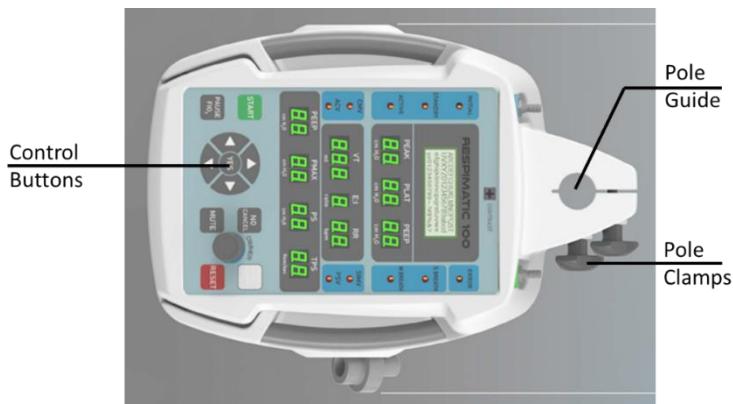
System Elements



Figure 1: Core System Elements



Figure 2: Different views of Core System



HMI Control Panel



Figure 3: Control Panel Bottom View

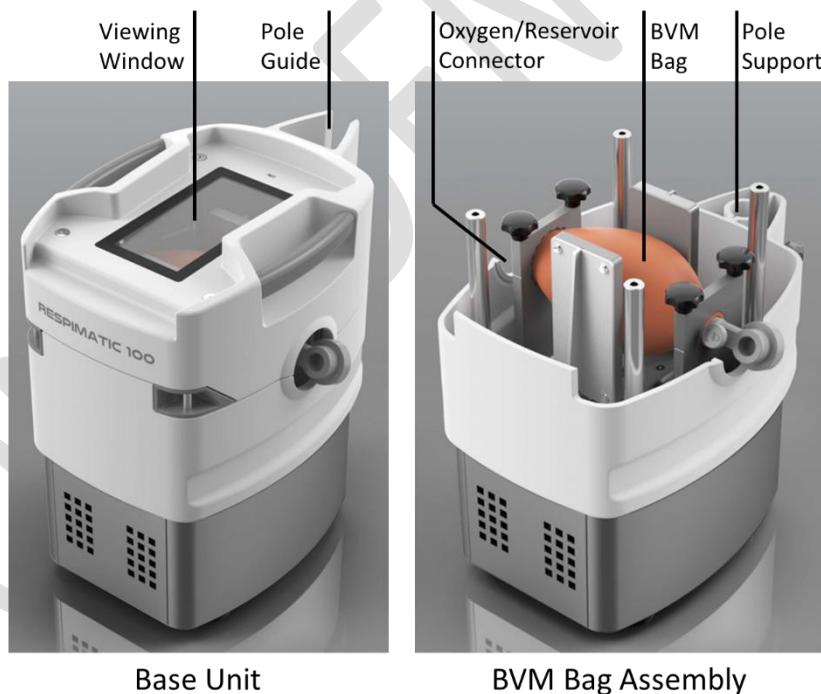


Figure 5: BVM Bag Receptacle



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.)

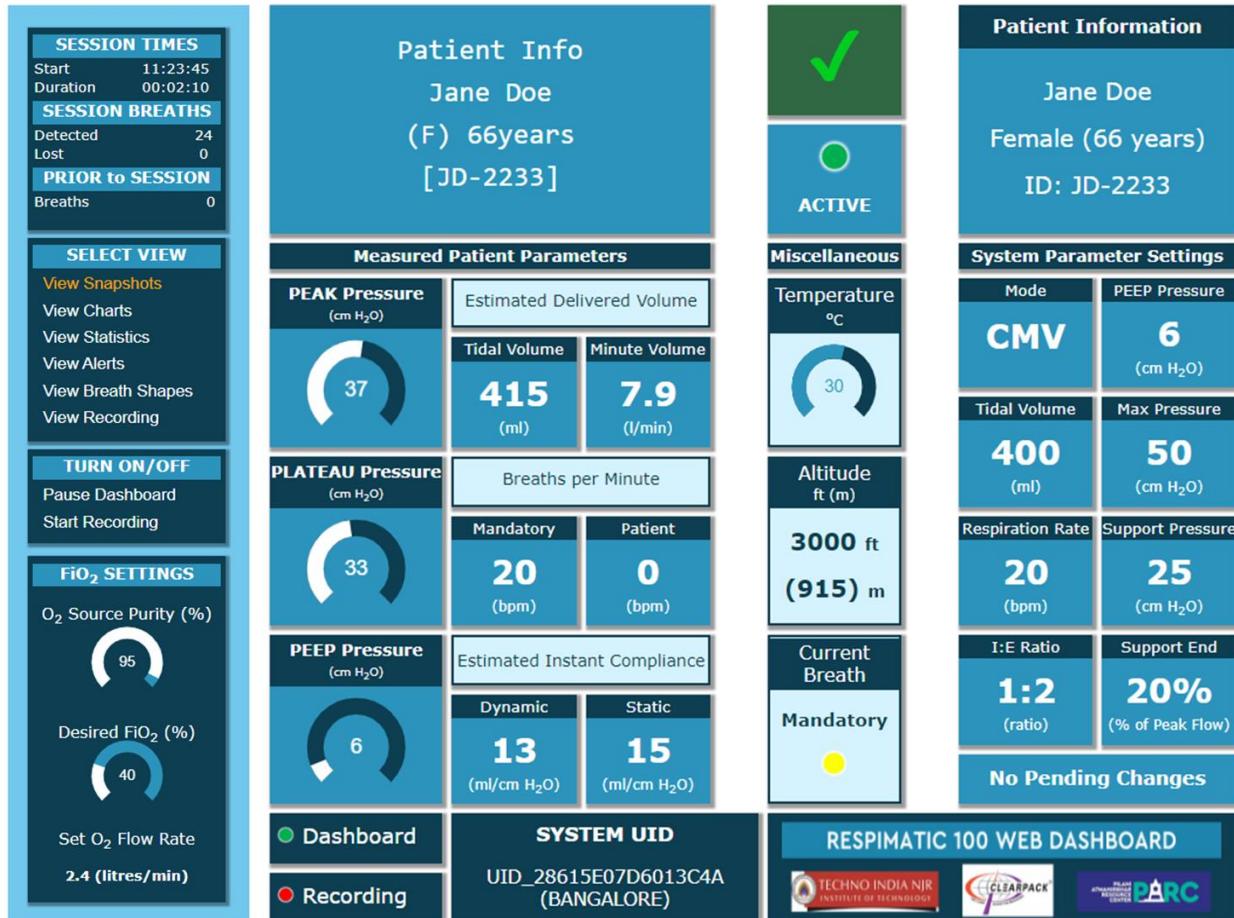


Figure 7: Online WEB Dashboard

System Overview

At any point in time, the system is in one of 6 states as shown in Figure and Table below. The different states enable different modes of operations. All transitions between states are well defined and intuitive.

| State | Entry into State | | Exit from State | | Description |
|------------|-------------------|---|-----------------|----------------|--|
| | From State | Causing Event | Causing Event | To State | |
| INITIALIZE | ANY | Power-ON RESET | After Self-Test | TEST | INITIAL state is the first state entered upon a Power-on RESET. This state initializes the system and performs self-tests. |
| TEST | INITIALIZE | After Self-Test | Tests PASSED | STANDBY | TEST state enables the execution of Pre-use checks which must be performed before connecting the system to a patient. The system guides step-by-step through all the relevant tests that need to be performed. |
| | | | Tests FAILED | ERROR | |
| STANDBY | TEST ACTIVE ERROR | After Pre-Use Checks Done or PAUSE button | START Button | ACTIVE | No breaths are delivered while in STANDBY state. All parameter settings can be changed while in this state. The new settings take effect from the next breath delivery onwards. |
| ACTIVE | STANDBY | START Button | PAUSE Button | STANDBY | Breath delivery happens while in ACTIVE state. Also, all settings can be changed while breath delivery is ongoing. The new settings take effect from the next breath after committing (pressing START). |
| ERROR | ANY | Any Error | RESET | INITIALIZE | Any error encountered while operating in any state leads to an ERROR state. An appropriate error message is displayed, the ERROR LED blinks and the buzzer sounds. The system switches to providing pre-defined maintenance breaths if possible. |
| | | | PAUSE Button | STANDBY | |
| Power-OFF | STANDBY | ON/OFF Button | INITIALIZE | Power-on RESET | It is recommended that power be switched OFF only when in STANDBY or ERROR state to ensure an orderly shutdown. |
| | ERROR | | | | |

Table 1: State Transition Table

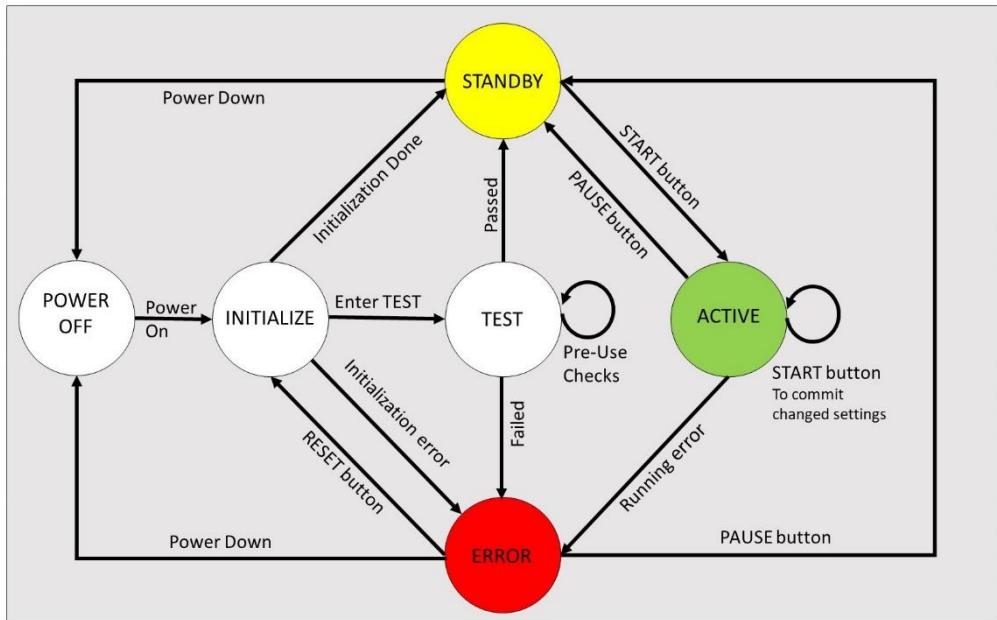


Figure 8: State Transitions

The above state transitions and all input, control and monitoring functions are supported by the Front Control Panel shown in Figure Below.

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Front Control Panel

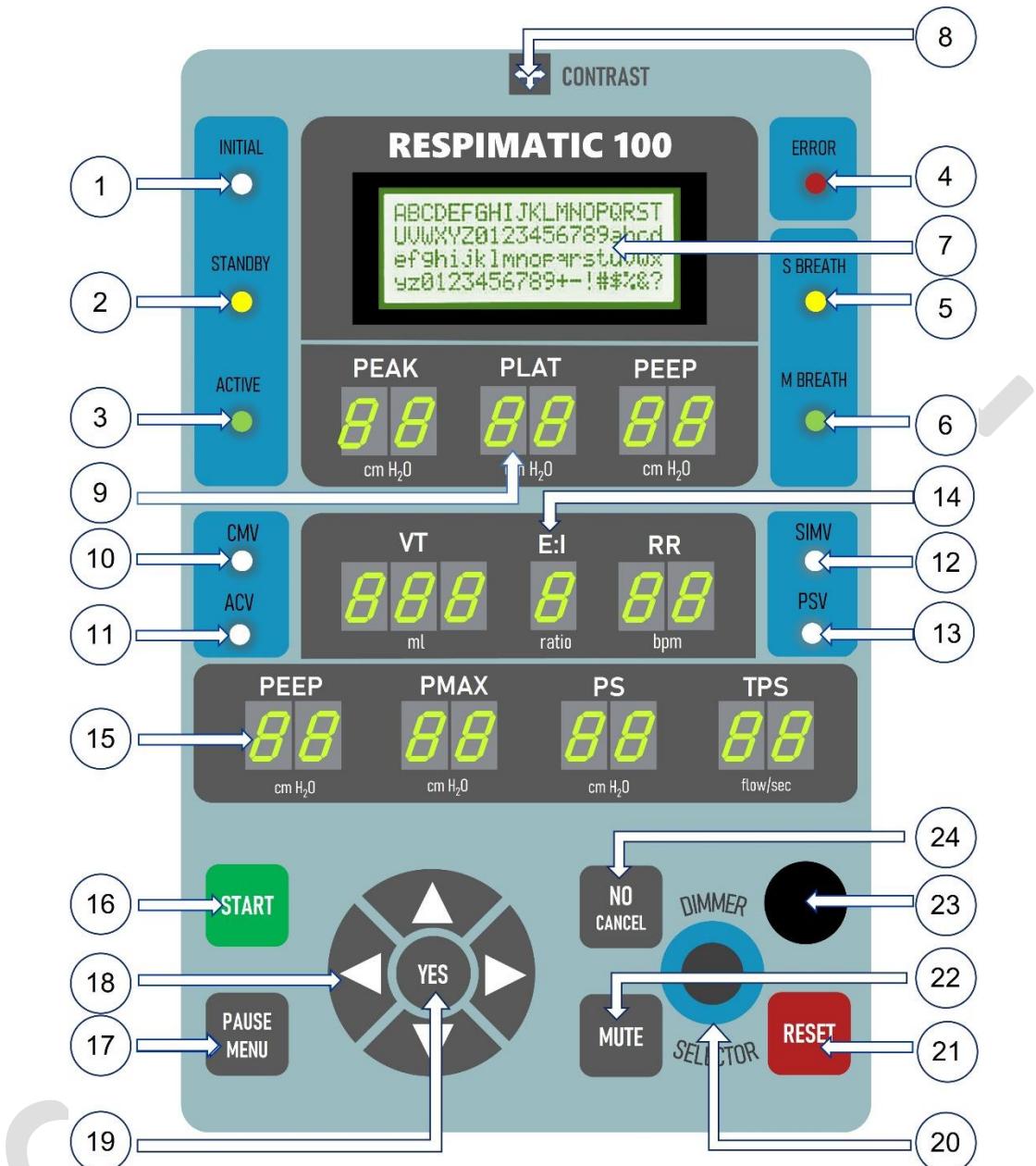


Figure 9: Front Control Panel

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

6. Current Breath is MANDATORY.
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 H₂O.
 - PLAT – For Volume-controlled breaths, the Plateau Pressure in cm H₂O. For Pressure-supported breath, the mean pressure in cm H₂O.
 - 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 – Tidal Volume in ml.
 - 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 H₂O.
 - PMAX – Max Inspiration Pressure allowed in cm H₂O.
 - PS – Support Pressure for Pressure Supported breaths in cm H₂O.
 - 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 – Press while in ACTIVE state to cause entry into STANDBY state. A long press (more 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, this button causes entry into the STANDBY menu where settings such as FiO₂ 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.

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Installing the BVM (AMBU) Bag

This section needs to be filled in after getting details from AMV Design.

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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.

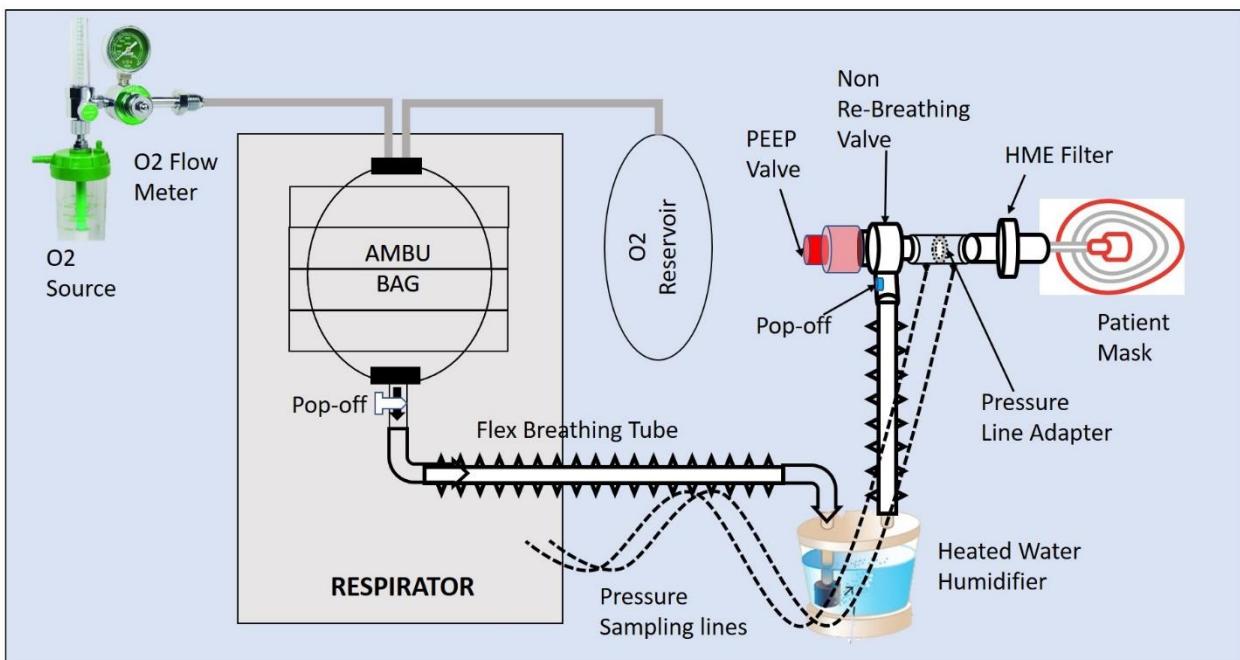


Figure 10: Complete Respirator System

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 12: Off-the-shelf Breathing Circuit



Figure 11: 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 ₂ O) |
| PEAK | Peak Inspiration Pressure | Max pressure during Inspiration phase of breath delivery (cm H ₂ O) |
| PLAT | Plateau Pressure | Plateau pressure during breath delivery (cm H ₂ O) |
| PEEP | Peak End Expiration Pressure | Pressure in the lungs that exists at the end of expiration (cm H ₂ O) |
| PS | Pressure Support | Level of support pressure to assist spontaneous breaths (cm H ₂ O) |
| 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 2: Glossary of Acronyms

System Initialization upon Installation

Respimatic-100 must be powered through a UPS system to ensure continued operation through a possible power-outage.

The very first time Respimatic-100 is powered up, it guides the user step-by-step through a battery of checks. All the checks are self-explanatory but the following merits an explanation.

- 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 13: 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.

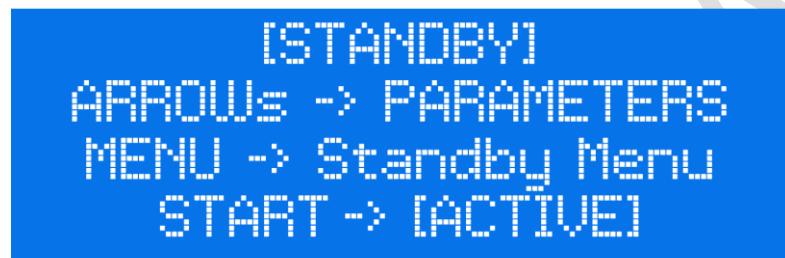


Figure 14: Standby State message

- 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.

- Single Press PAUSE at any time to go into STANDBY mode.
- While breath delivery is in progress, a long press (more 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.

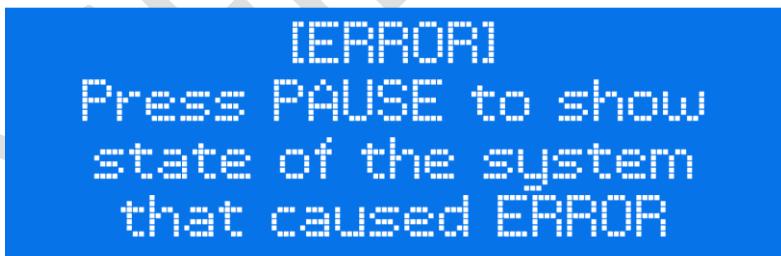


Figure 15: Error State message

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 press the PAUSE button 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.

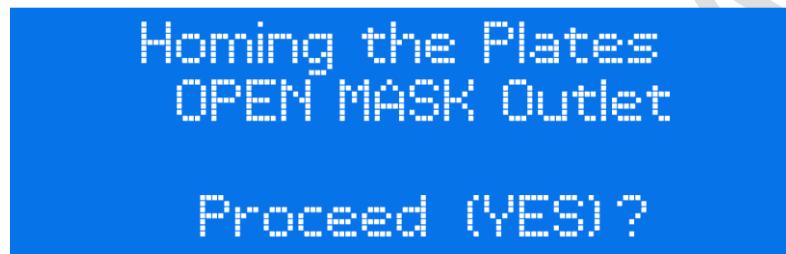
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Power ON Sequence



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.

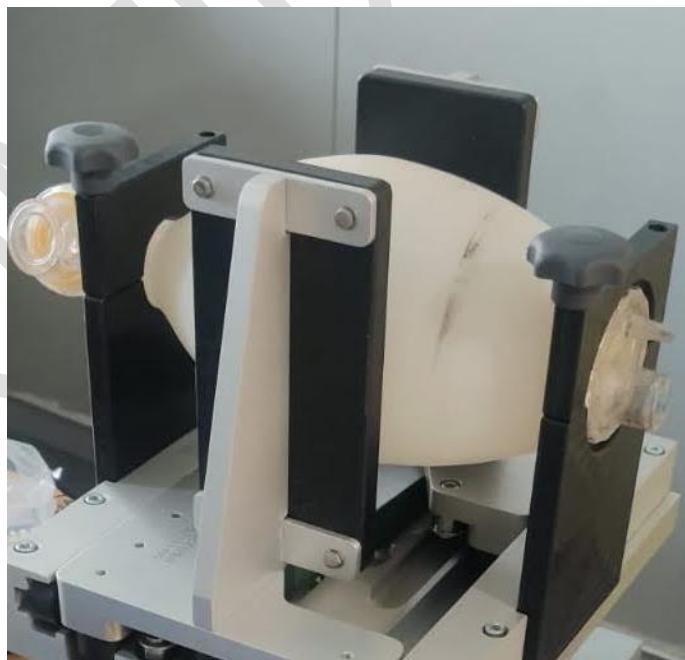


Figure 16: BVM Bag Pressing Plates

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 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, 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 ₂ O) never to be exceeded |
| PEEP | Peak End Expiration Pressure | Desired Pressure (cm H ₂ O) in the lungs at the end of expiration |
| PS | Pressure Support | Desired Level of support pressure (cm H ₂ O) to assist every spontaneous breath |
| TPS | PS Inspiration duration | Auto Flow-controlled mode (10, 20 or 30% of peak flow) or time duration for which the pressure support is to be delivered |
| FiO ₂ | Fraction of Inspired Oxygen | Concentration (%) of oxygen in the inspired air. This must be controlled outside the system in the breathing circuit following recommended values by the system. |

Table 3: Glossary of Respirator Operating Parameters

To change any of the operating parameters except FiO₂, 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.

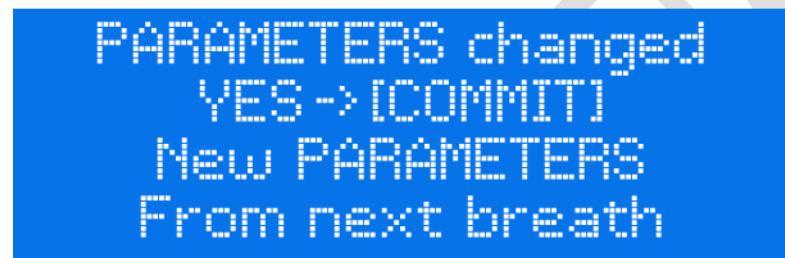


Figure 17: Parameter Change Message

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.

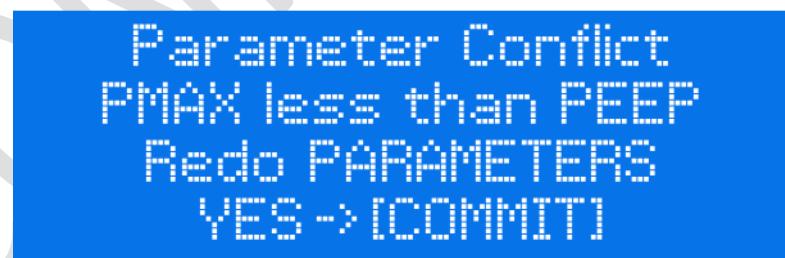


Figure 18: Parameter Conflict Message

(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.

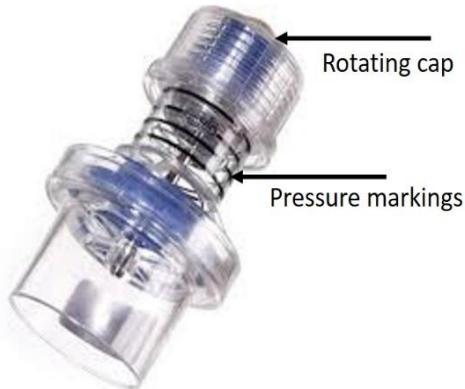


Figure 19: PEEP Valve

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.

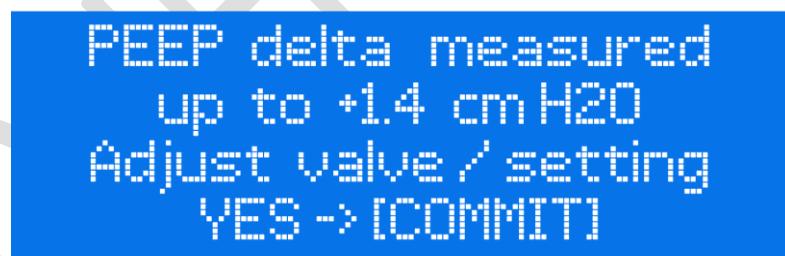


Figure 20: PEEP Mismatch message

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/restting values of various parameters that are not directly visible on the Front Panel.

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

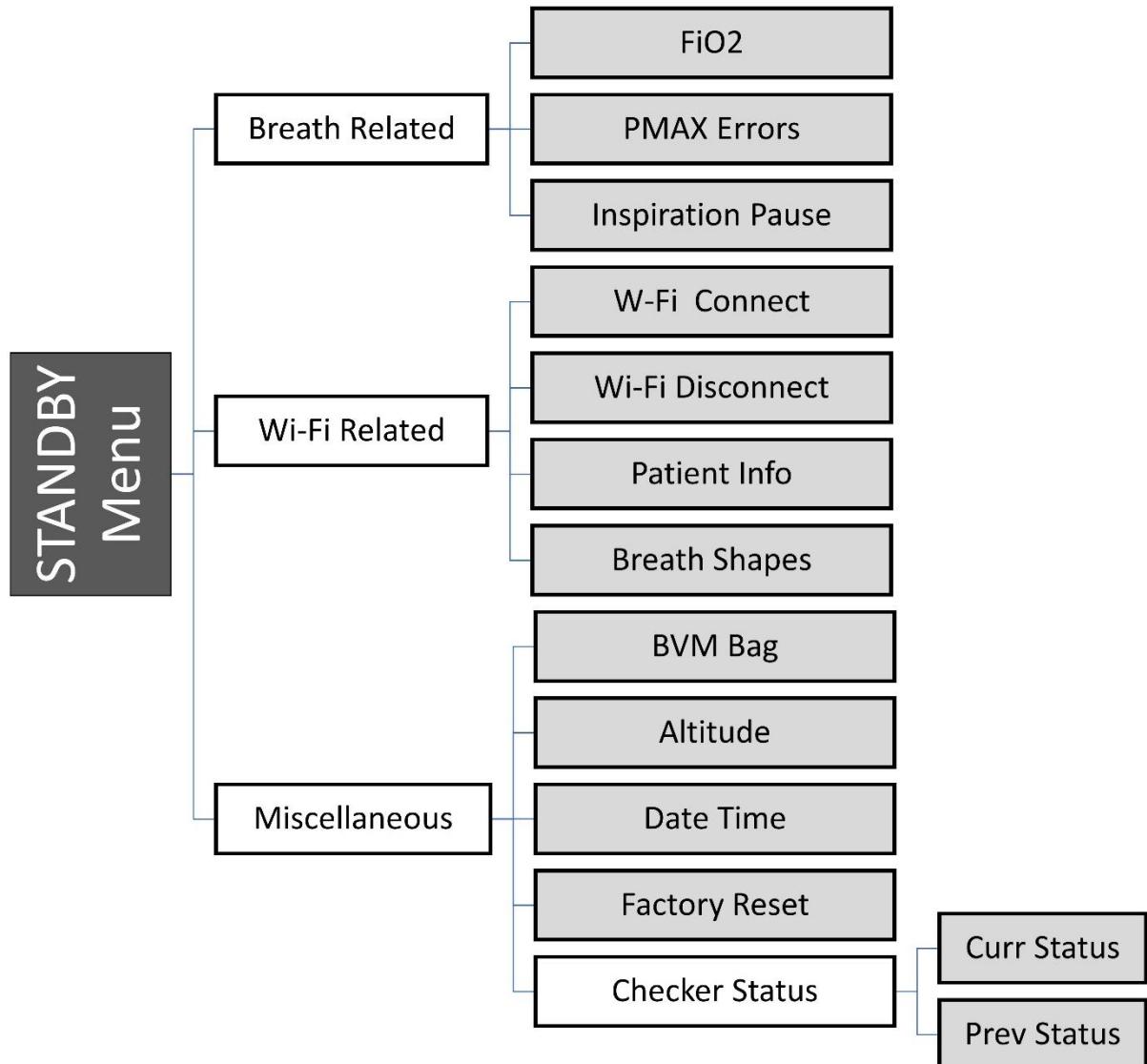


Figure 21: STANDBY Menu Hierarchy

FiO_2 Settings



Respimatic does not directly measure FiO_2 . Techniques such as 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.

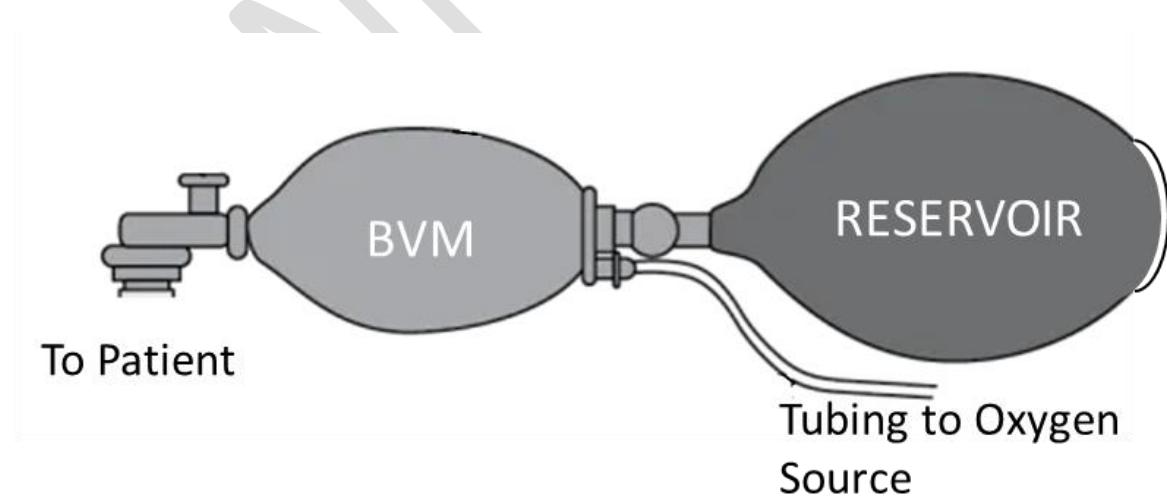


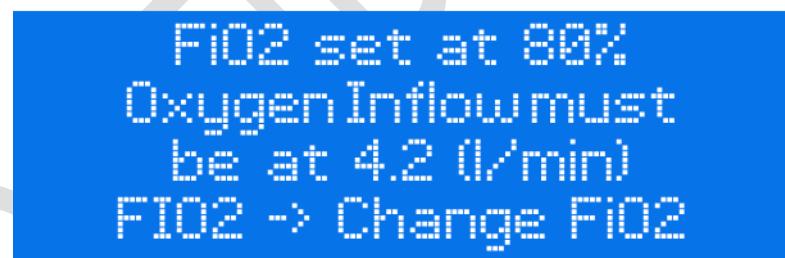
Figure 22: Oxygen Reservoir Connection

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 FiO₂ 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 FiO₂. If in ACTIVE state, 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.

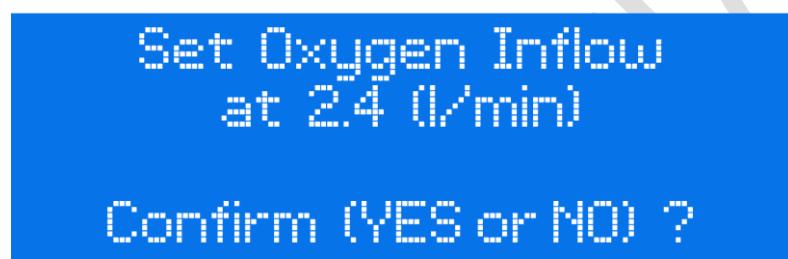


3. The system guides the user step-by-step through entering new parameters. Use the ARROW buttons or the SELECTOR knob to change the displayed values. Press YES when done entering a new value.





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 inflow 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. Spontaneous breaths are ignored.

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. 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.

Breath Syncing in Synchronized AC Mode

There is no sync-window – the next mandatory breath is always rescheduled after a spontaneous breath

Example below: Tidal Volume = 500ml Respiration Rate = 15 bpm

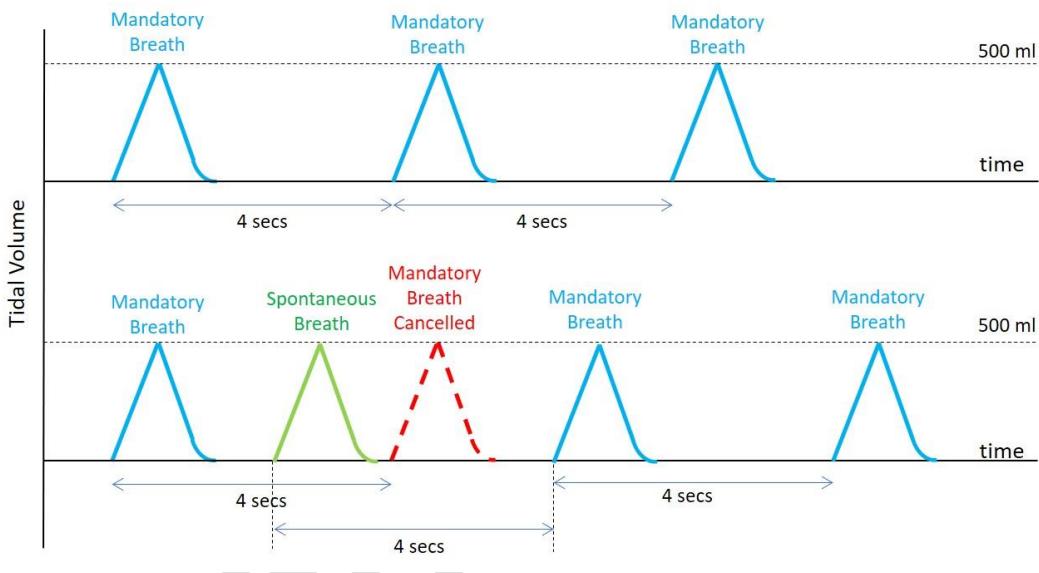


Figure 23: ACV Breath Synchronization

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 (P_{MAX})
6. Support Pressure (PS)
7. PS Inspiration duration (TPS)
8. Oxygen Percentage (FiO₂)

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. 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), 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
 - 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 (P_{MAX}) 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 F3), 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 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.

Breath Syncing in SIMV mode

There is a sync-window – the next mandatory breath is rescheduled only if spontaneous breath within the sync-window

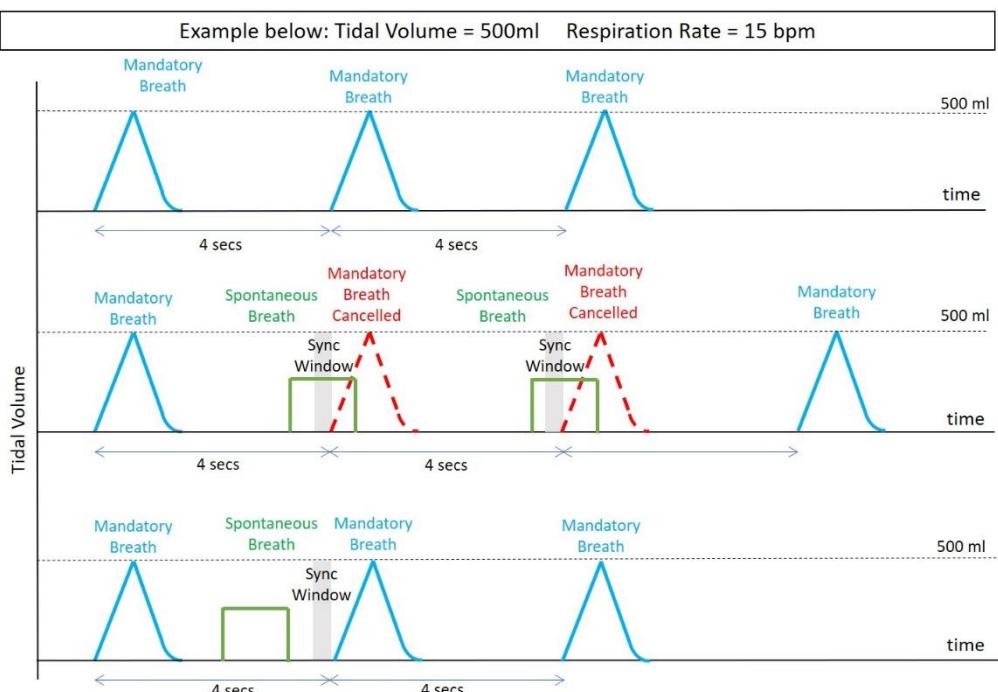


Figure 24: SIMV Breath Synchronization

Pressure Support Ventilation (PSV)

In PSV mode, only 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.

This mode is best described through an example.

Assume a spontaneous BPM of 15 and minimum Minute-Volume of 6 litres/min is expected while a particular patient is on PSV. Violating the expected BPM will result in a WARNING while violating the Minute-Volume will result in an ERROR.

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

Mode=PSV

PS = Desired Support Pressure

TPS = Termination setting for Pressure Supported breaths

RR = 15 (spontaneous BPM expected for our test case)

VT= 400 (Minute Volume/RR)

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 time between any two consecutive spontaneous breath triggers exceeds 150% of expected (i.e. more than 6 sec for our example case), deliver a mandatory breath (using VT, RR and E/I) and issue a WARNING. Do not go into ERROR mode.
- If, at any time, Minute-Volume falls below 90% of expected (5.4 litres/min for our test case), issue an ERROR alarm and go into ERROR mode.
- While in ERROR mode, deliver maintenance breaths as set during Pre-use checks till the ERROR is attended to.
- Note that VT, RR and E/I must be set appropriately to allow the system to issue warnings and alarms at the right time.
- Monitor Peak Pressure –alarm will sound if a preset limit (PMAX) is breached.
- Monitor Plateau and PEEP pressure

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

Mandatory Breath (Warning) in PSV mode

There is a quiet-window – the next mandatory breath is delivered only if no spontaneous breath within the quiet-window

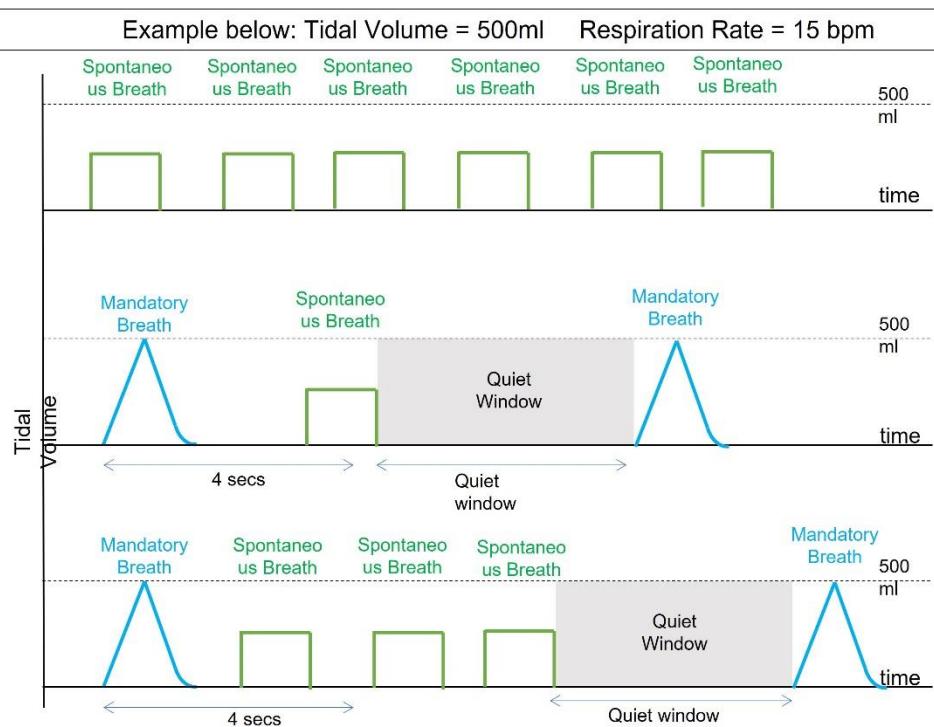


Figure 25: PSV Mandatory Breath

Human Machine Interface

Control Mechanisms

| RESPIRATOR CONTROLS | Control | Feedback | Mechanism | Comments |
|---------------------|-------------------------------------|--------------------|----------------|---|
| | RESET | State LEDs | Push Button | Resets the entire system. Same as Power-on. |
| | RESET+START | 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. Transition into STANDBY state. A long press on this button introduces an inspiratory pause of 1.5 sec in the next volume-controlled breath. |
| | FIO2 | LCD Display | Push Button | Causes the system to enter FiO ₂ setting procedure |
| | ROTARY KNOB | Display Brightness | 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 KNOB | LEDs and LCD | Push Buttons | 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

| INPUT PARAMETERS | Parameter | Options | Feedback | Control |
|---|---|--|---------------------------------------|---------|
| Respiration Mode | CMV | Designated LED | UP / DOWN LEFT / RIGHT SELECTOR | |
| | ACV | Designated LED | | |
| | SIMV | Designated LED | | |
| | PSV | Designated LED | | |
| Tidal Volume VT (ml) | 200 through 600 in increments of 50 | 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 | | |
| E:I Ratio | 1 | Selection displayed on a 1-digit display | UP / DOWN LEFT / RIGHT SELECTOR | |
| | 2 | | | |
| | 3 | | | |
| PEEP (cm H ₂ O) | 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 ₂ O) | 20 through 50 in increments of 5 | Selection displayed on a 2-digit display | | |
| Support Pressure PS (cm H ₂ O) | 5 through 30 in increments of 1 | Selection displayed on a 2-digit display | UP / DOWN LEFT / RIGHT SELECTOR | |
| PS Breath Inspiration Termination TPS | Flow-control (10%, 20%, 30%) or time-control (1.0 - 2.5 secs) in 0.5 increments | Selection displayed on a 2-digit display | | |

Table 5: Respirator Operating Parameter Options

Monitored Parameters

| Measured Parameter | Options | Feedback | Comments |
|--|--|--|--|
| Peak Inspiration Pressure PEAK (cm H ₂ O) | | Measured Number displayed on a 2-digit 7-seg display | Updated after each breath |
| Plateau Pressure for VC Breaths PLAT (cm H ₂ O) | Mean Pressure for PS Breaths (cm H ₂ O) | Measured Number displayed on a 2-digit 7-seg display | Updated after each breath |
| PEEP Pressure (cm H ₂ O) | | Measured Number displayed on a 2-digit 7-seg display | Updated after each breath |
| Minute Volume (ml) | | Estimated numbers displayed on the LCD screen. | Updated after each breath. Displays info for the previous minute. |
| Spontaneous v/s Mandatory Breaths (bpm) | | Measured numbers displayed on the LCD screen. | Updated after each breath. Displays info for the previous minute. |
| Instantaneous Static and Dynamic Lung Compliance | | 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 immediately switches to a CMV fallback set of parameters. These parameters can be set during Pre-Use checks. 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 $(VT \times RR)$ 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 Alarms

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 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 | YES | 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 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 |
| Failed to home Pressing Plates | System unable to initialize the position of pressing plates | YES | Call Support - System issue |
| Motor Malfunction | Motor encountered an unexpected error | YES | The system automatically recovers. Call Support - System issue |
| Settings are beyond system capabilities | The required combination of VT, RR and EI is not supported by the motor | 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 |
| System Internal Consistency Error | Unexpected system state | YES | Call Support - System issue |
| Undiagnosed Q Fault | Low pressures. Problem with the motor, pressing plates, pressure sensors or breathing system leakage. | YES | Call Support - System issue |

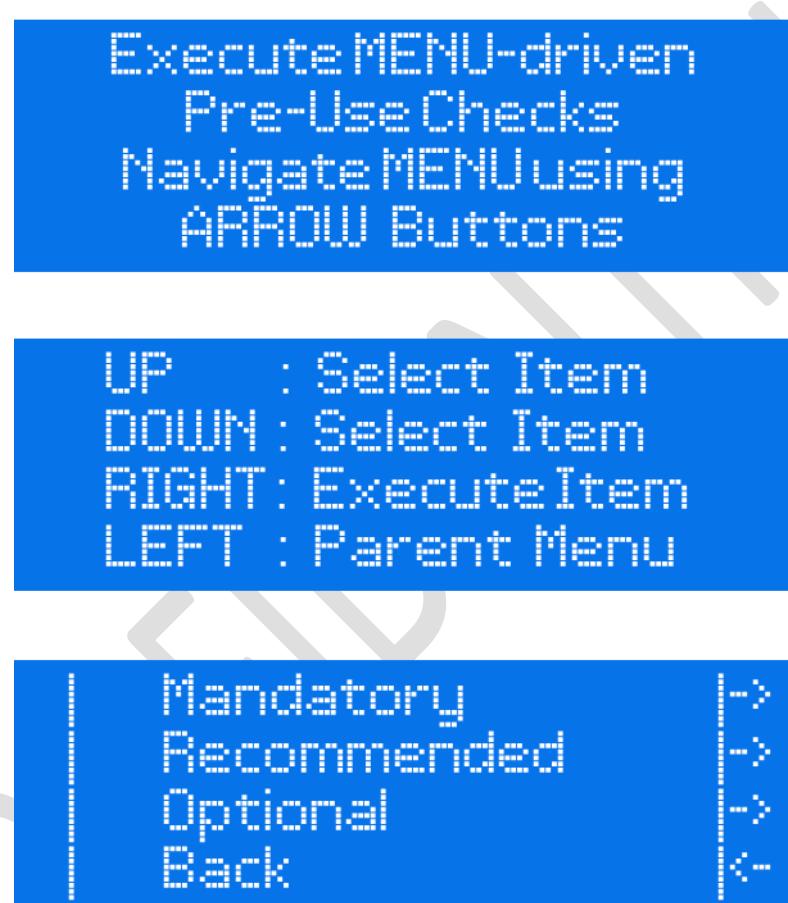
Table 8: System Alarms & Messages (contd..)

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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 26: 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 27: 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.

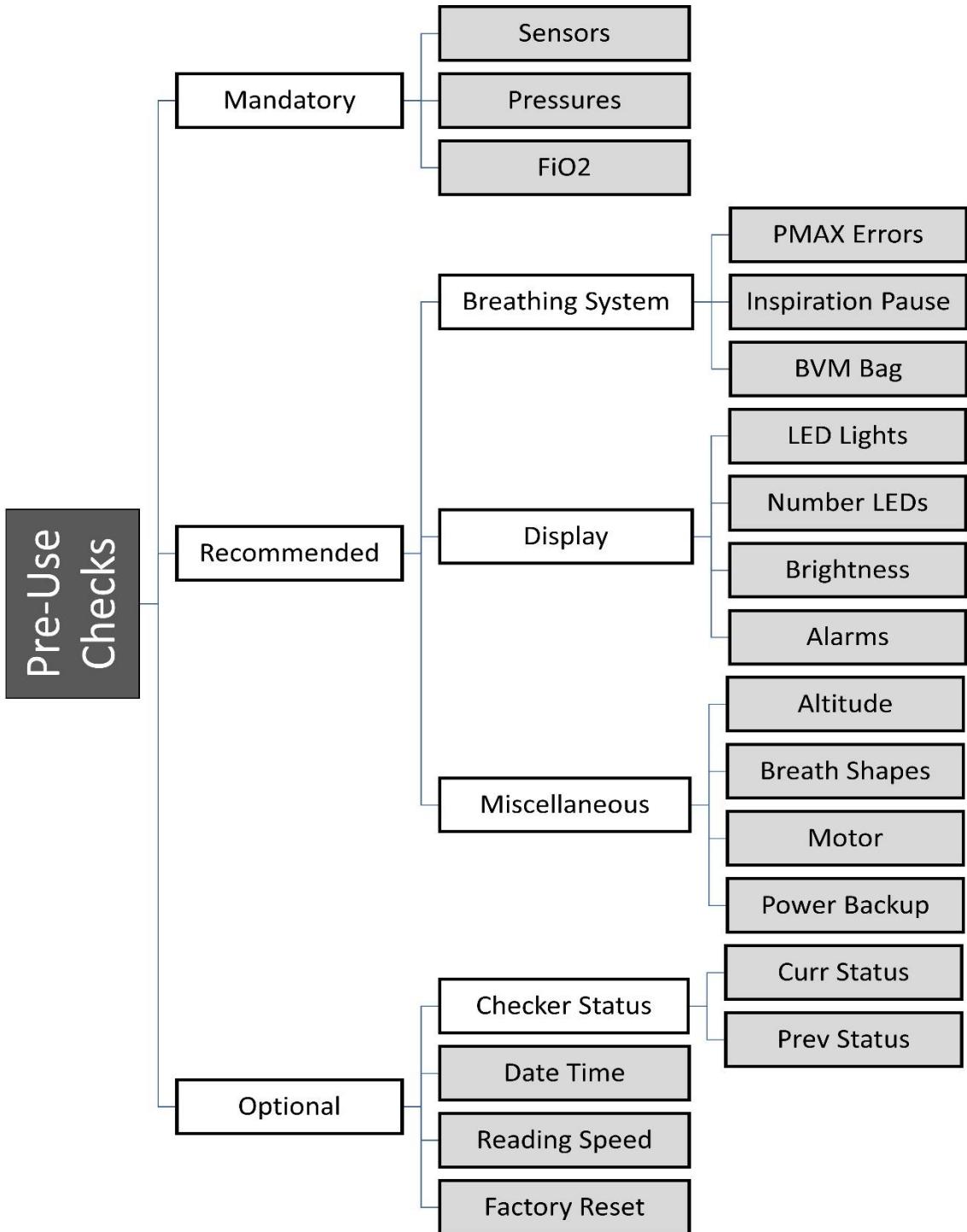


Figure 28: Menu Hierarchy of Pre-Use Checks

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 palm of your hand. This will be used to check that the pressure lines are connected to the appropriate port.

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.

FiO₂ Checks

1. Set the required FiO₂ 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*)

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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 execute these checks before hooking a patient to the Respirator. The system will guide the user through all these checks.

Breathing System Checks

Set PMAX Error Breaths

If the inspiration pressure ever exceeds the PMAX limit, the system transitions into a maintenance breath mode where it switches to delivering breaths according to a preset set of parameters.

By default, the preset maintenance breaths are delivered with Mode=CMV, VT=200, RR=15, EI=2. During pre-use checks these preset parameters can be changed via this menu item.

Set Inspiration Pause

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

BVM Bag

The BVM bag has a limited lifetime. Using this Pre-use check, 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.

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.

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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.

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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 couple of 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

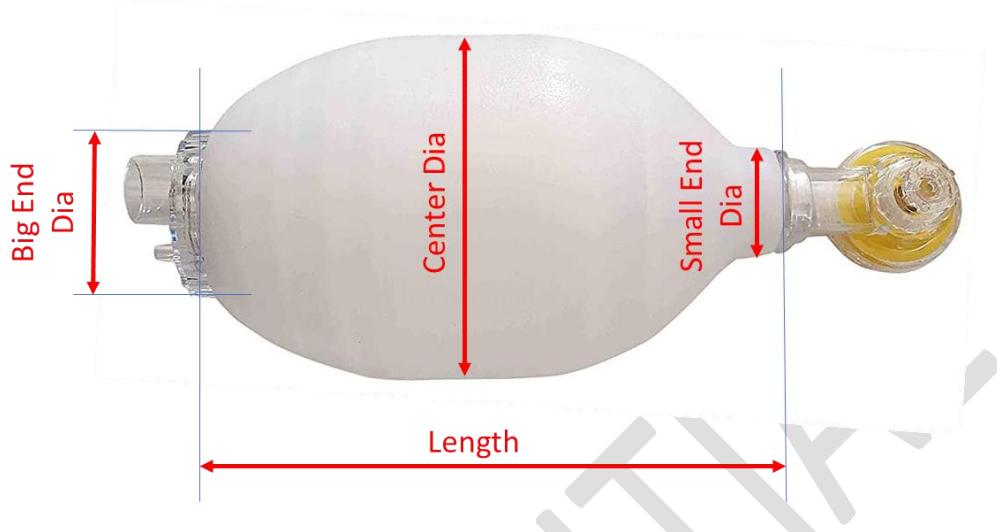


Figure 29: BVM Bag

| | 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 |

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

CONFIDENTIAL

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