

INSPIRE - 100

An Emergency Ventilator 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 all 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

Provides 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. Size and Weight etc.

Introduction

INSPIRE-100 is designed to provide respiratory support for adult patients. It is ideal for remote areas that lack infrastructure such as compressed gas and oxygen pipelines.

INSPIRE-100 offers a cost-effective, dependable, and durable solution for patients that require mainstream respiration modes and parameters. The technology offers a straightforward and uncomplicated Human-Machine Interface to reduce the learning curve for the medical professional.

The INSPIRE-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, INSPIRE-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 INSPIRE-100 also includes a full variety of safety features. Every conceivable error scenario has a fallback mechanism so that the breathing never stops.

System Elements



Figure 1: Core System Elements

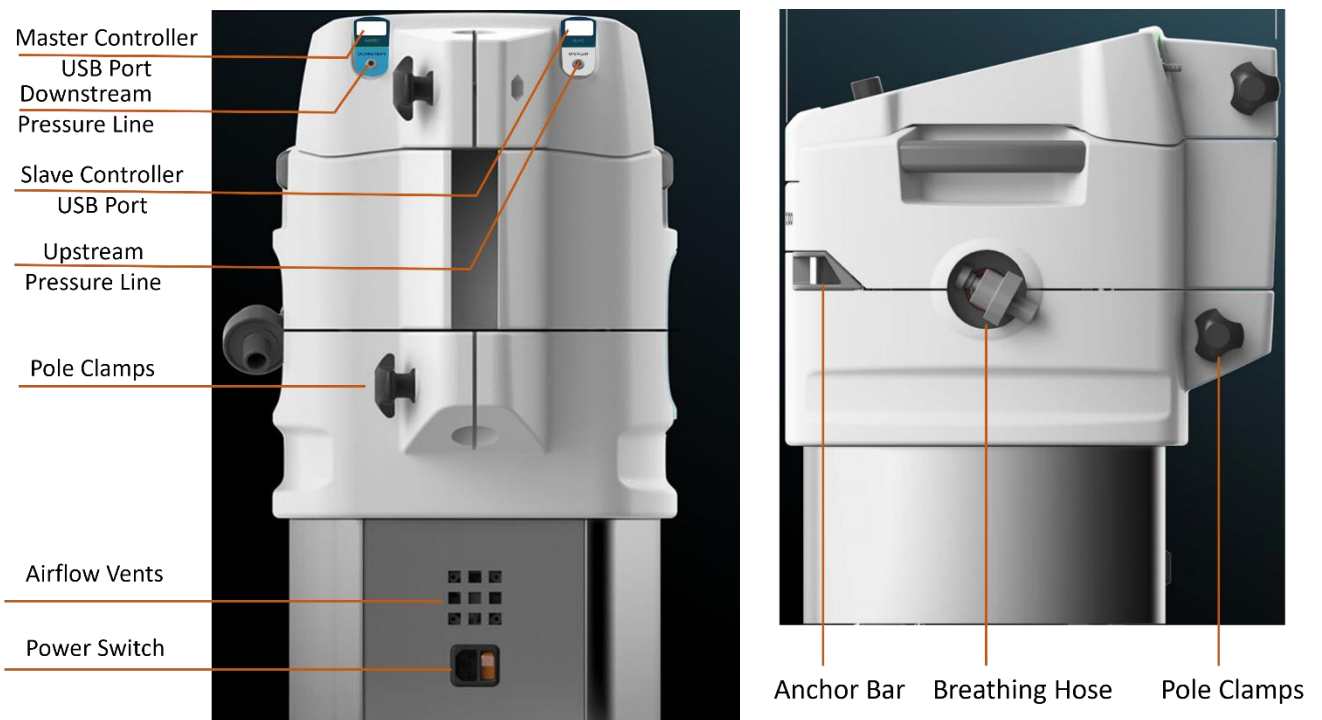


Figure 2: Different views of Core System

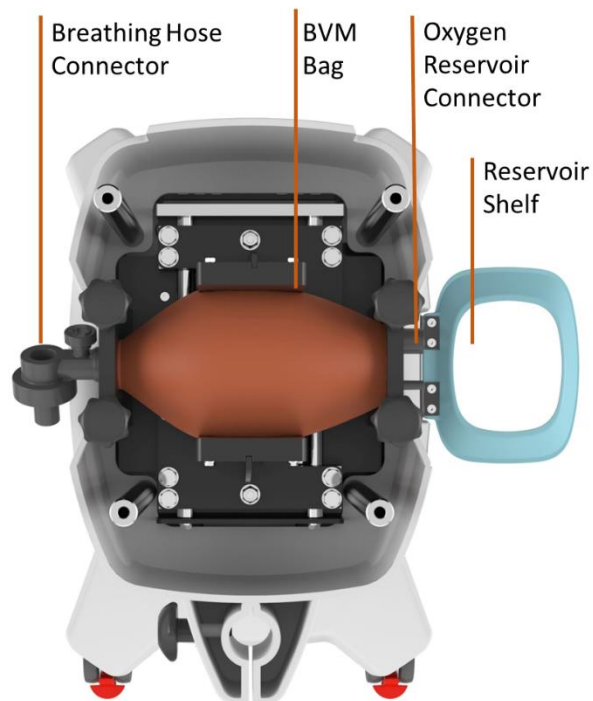
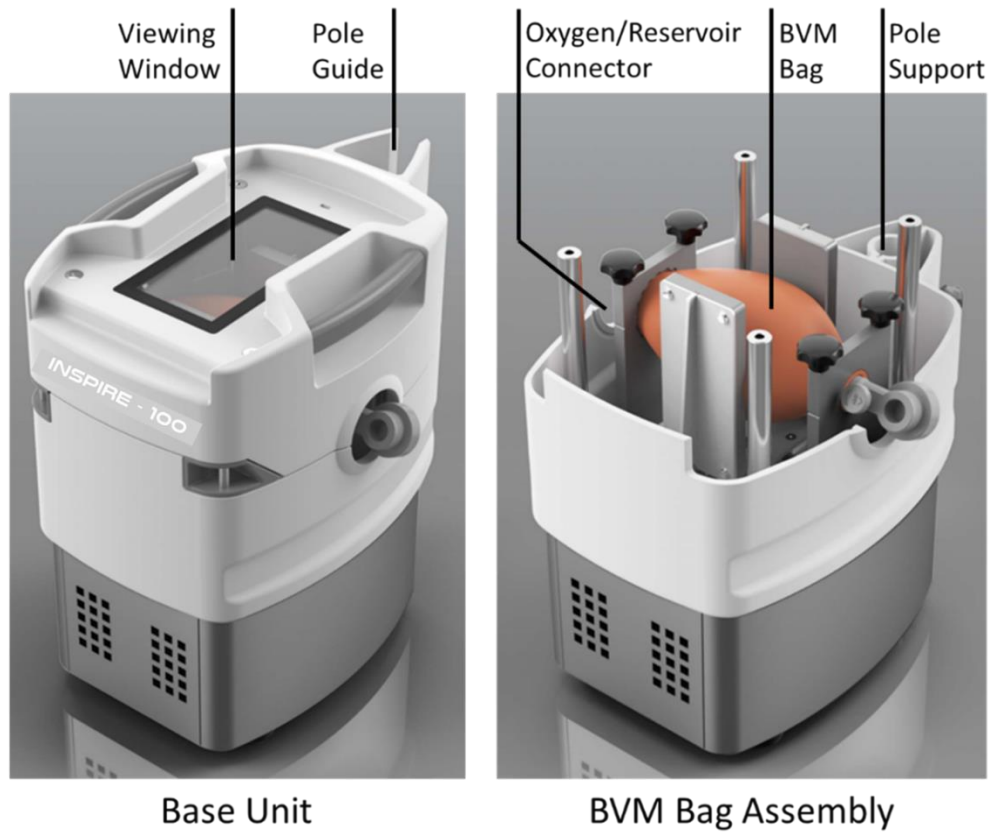
















Figure 3: BVM Bag Receptacle

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.
-  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, if used, 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 HEPA filter must be installed for safety as shown in the Breathing circuit diagram.
-  The oxygen cylinder level (if used) must be checked to ensure an adequate quantity of oxygen remains.
-  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 the 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 (P_{MAX}) 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 INSPIRE-100 Web Applications Manual for further details.)

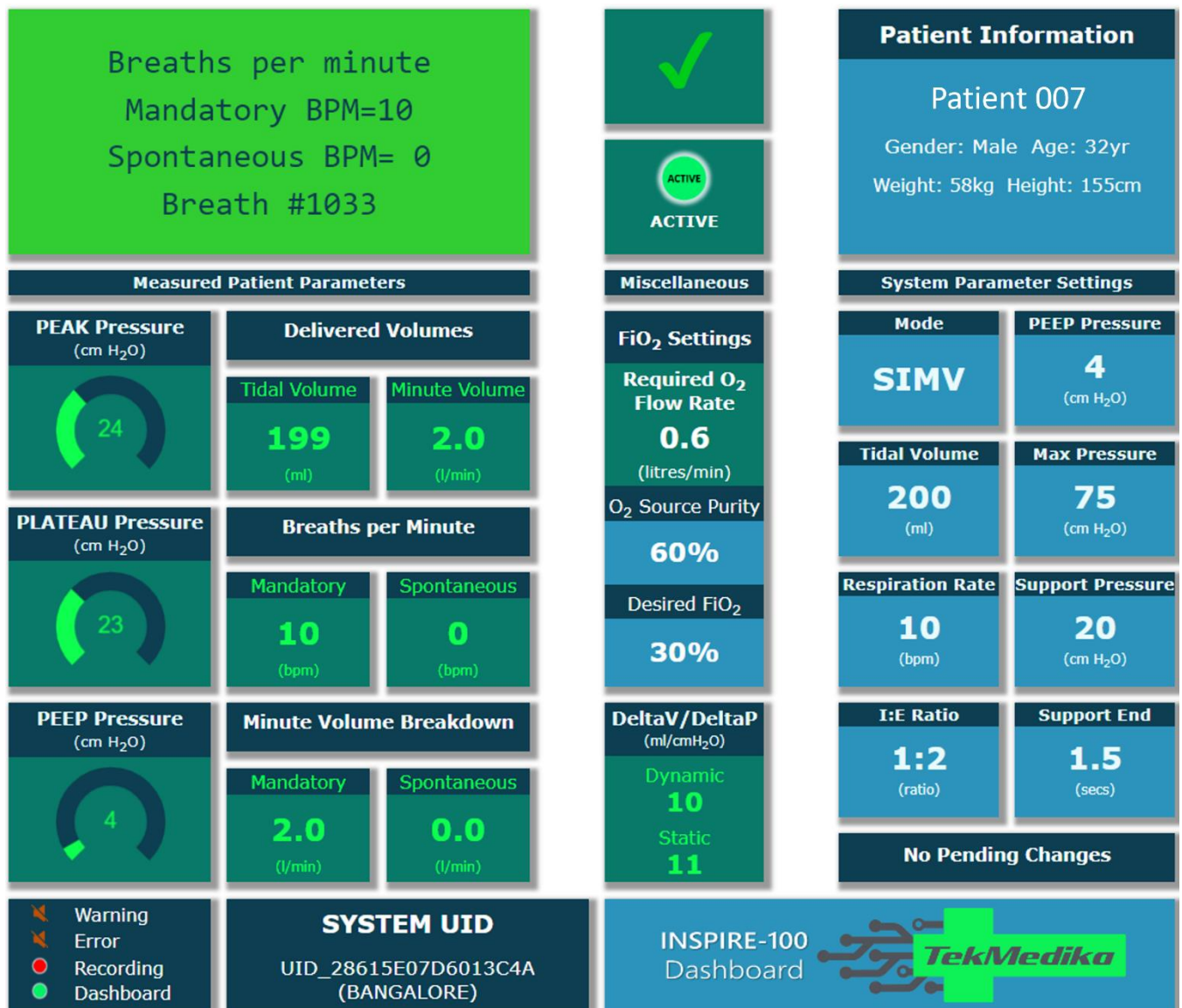


Figure 4: Online WEB Dashboard

Updating System Firmware

Over time, as the firmware evolves with new features and bug-fixes, there is a need to upgrade the firmware for systems already deployed in the field. INSPIRE-100 provides an App (WINDOWS and MACOS) to update the system firmware using a laptop and an internet connection. The firmware upgrade process entails two steps.

1. Preparation
Download and install the Firmware Upgrade App. This is one-time activity. Once installed, the App can be used at any time to upgrade the system firmware.
2. Firmware Installation
Launch the Firmware Upgrade App and follow step-by-step instruction to upgrade the system firmware to the latest available version.

(See the document on INSPIRE-100 Firmware Upgrade Manual for further details.)

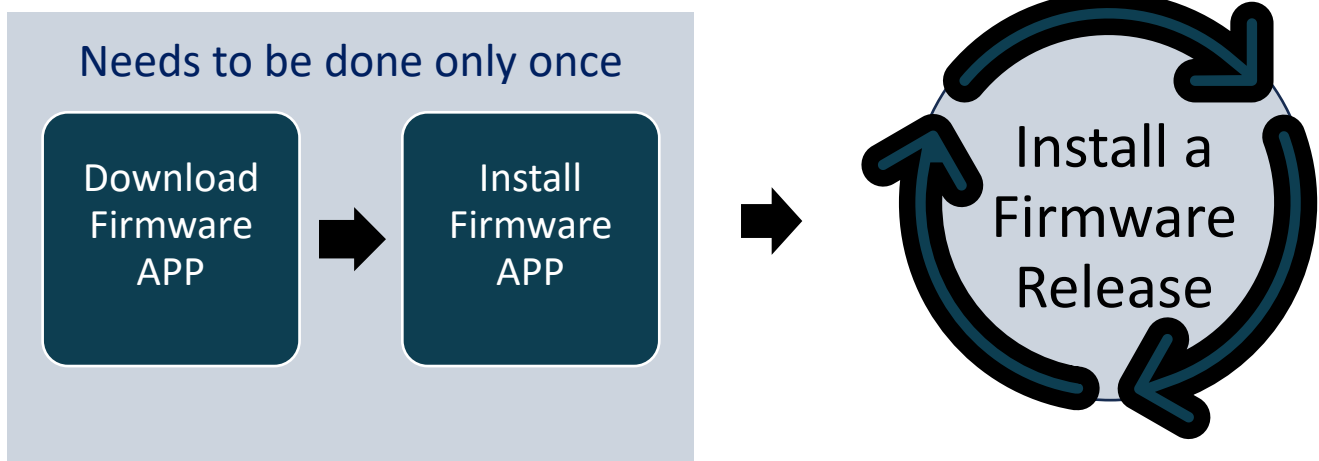


Figure 5: Firmware Update Process

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.

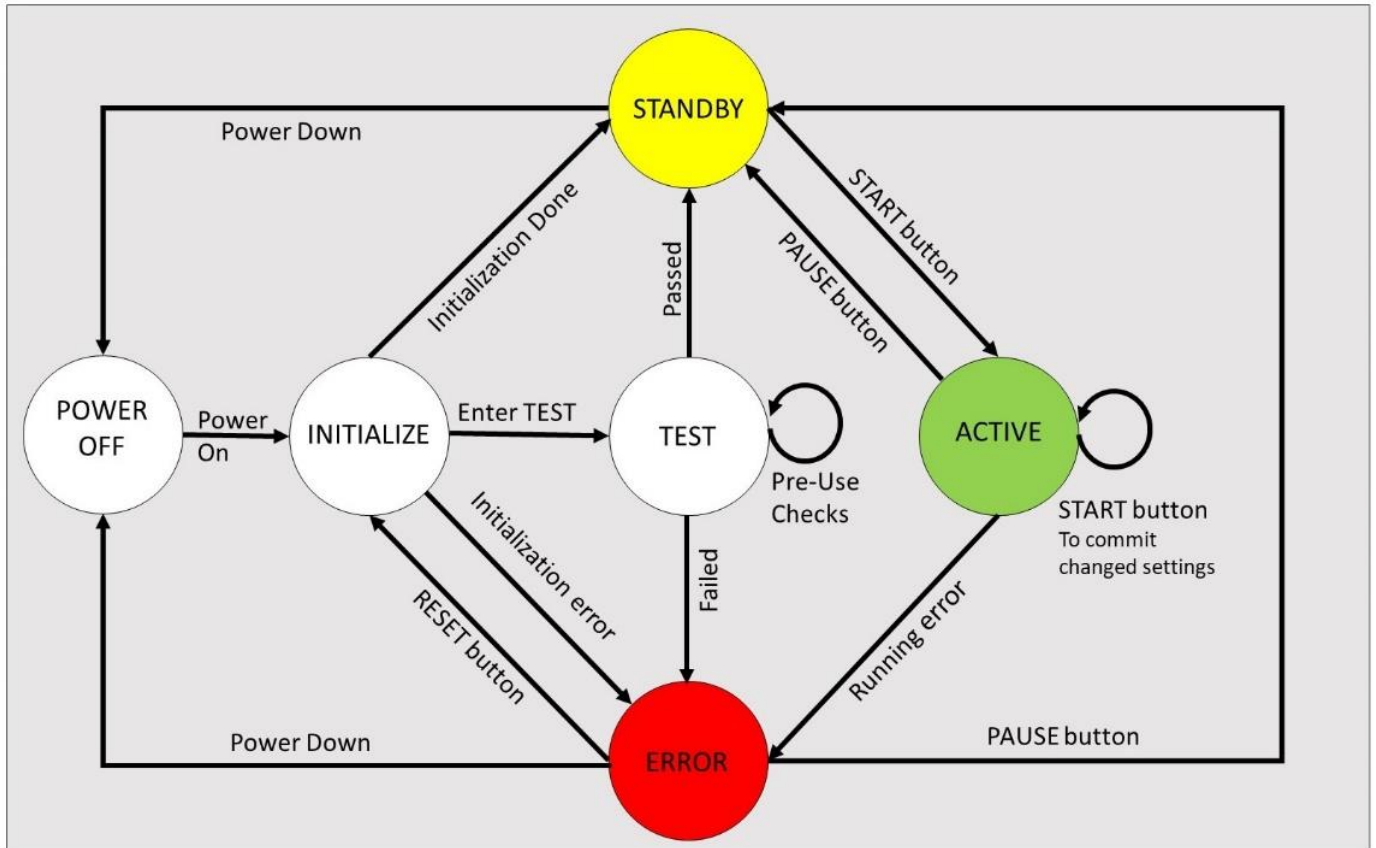


Figure 6: State Transitions

Front Control Panel Description

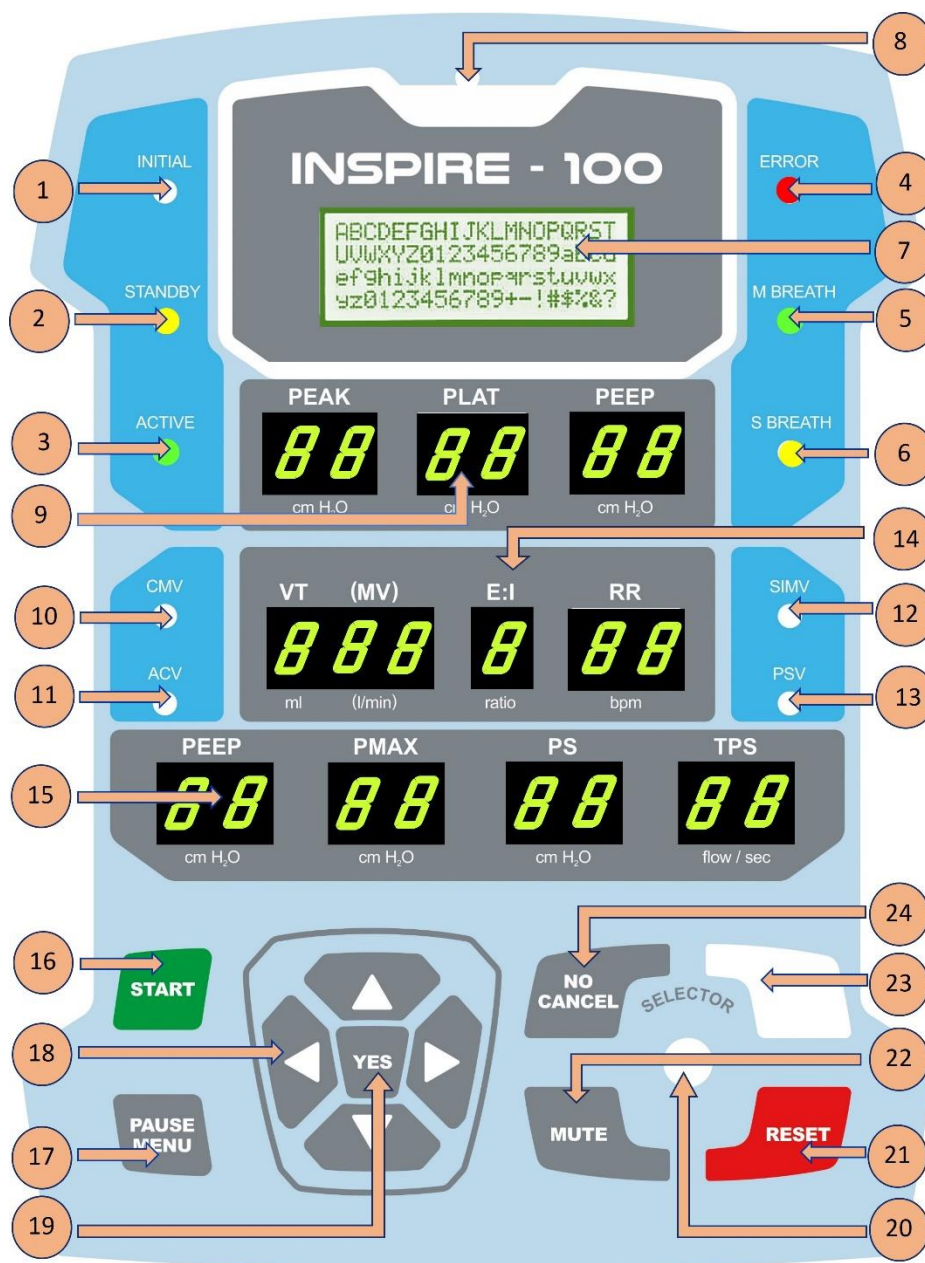


Figure 7: Front Control Panel

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 SPONTANEOUS (patient-initiated).
7. LCD 20x4 Screen. It displays menus, 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 (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 H₂O.
 - PMAX – Max Inspiration Pressure allowed in cm H₂O.
 - PS – Support Pressure for Pressure Supported breaths in cm H₂O.
 - TPS – Flow-triggered or Time-triggered termination for a Pressure supported breath.
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 3 sec) while in ACTIVE state to cause entry into STANDBY state. Keep the PAUSE button pressed till the system enters 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 various settings 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 button to answer prompts and questions posed on the LCD panel.
20. SELECTOR – This is a rotary knob used to adjust the brightness level of the display at any time. It is also used for menu navigation.
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 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.

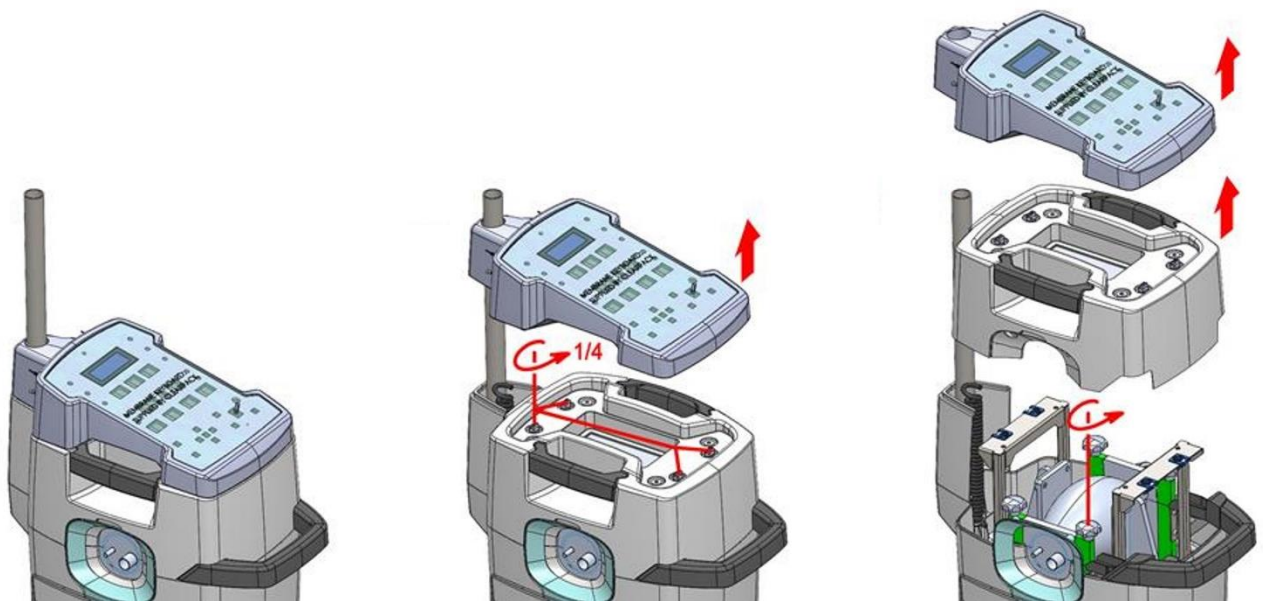


Figure 8: Installing BVM Bag

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.

There is one proprietary connector that is a part of the breathing system that is used to connect two pressure lines to INSPIRE-100. The two pressure lines are color-coded and must be connected to the appropriate ports of the system.

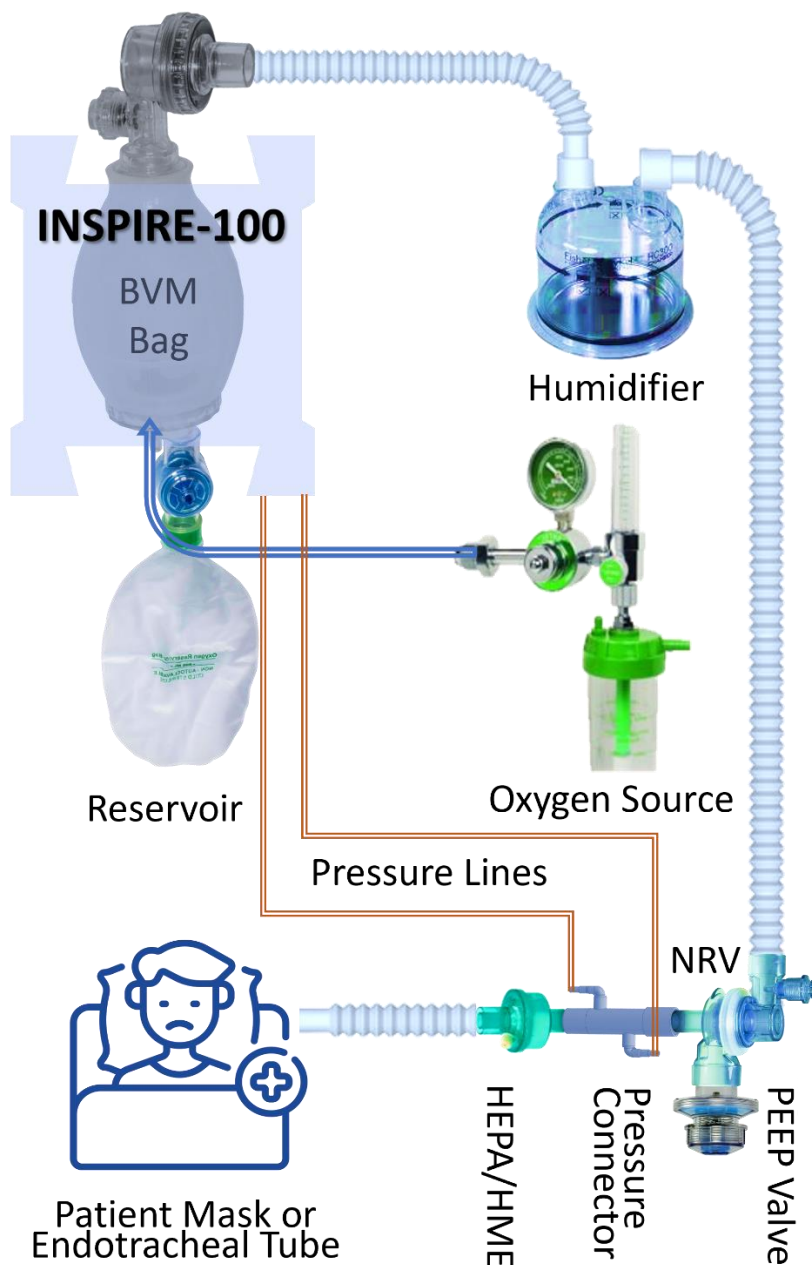


Figure 9: Complete Respirator System



Figure 10: Proprietary patent-pending Dual Pressure-line Connector



Figure 11: Off-the-shelf Breathing Circuit

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 breath (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 patient-initiated (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 triggered (%age of Peak Flow) or Time triggered (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 at the Oxygen source. (%age) |

Table 1: Glossary of Acronyms

System Initialization upon Installation

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

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

- Current Location – For correct operation, INSPIRE-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. For subsequent power-ups, this information need not be re-entered if the deployment site remains the same.

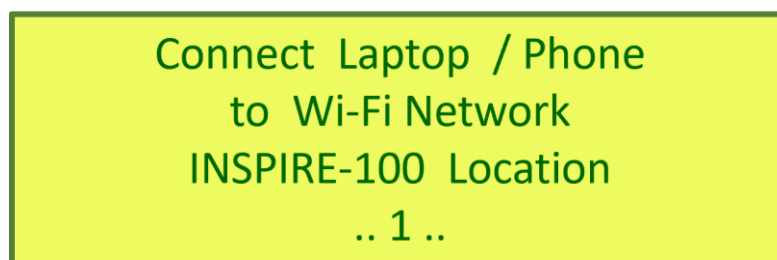


Figure 12: Display for Altitude setting

A dark blue vertical form titled "INSPIRE-100 Location Info" in white text on a blue header. Below the title, there is a "Location Name" label followed by a white text input field. Then, a "Location Altitude" label is followed by a white text input field and a unit selector dropdown menu showing "ft" with a downward arrow. At the bottom, there is a green "SUBMIT" button.

The steps for entering the location information are as below.

- a. The INSPIRE-100 System sets up a WiFi network called “INSPIRE-100 Location”
- b. Log in to this network and a portal is automatically presented on the device that you logged on with.
- c. Enter the information and press “SUBMIT”. A confirmation page is presented which, when confirmed, completes the process.

Entering Patient Information

Next, the user is presented an opportunity to enter patient information for record-keeping. This information is later prominently displayed on the WEB Dashboard and periodically displayed on the LCD screen.

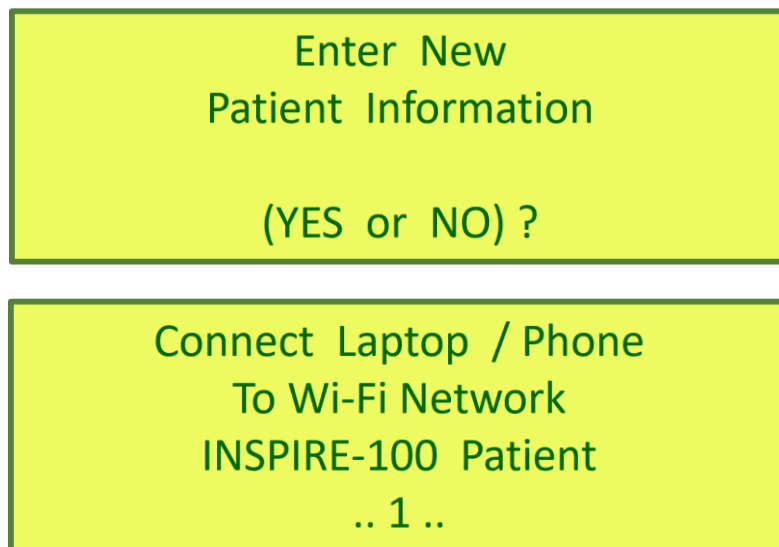


Figure 13: Connect to INSPIRE-100 Patient network

To enter new patient information, the user must use a laptop or a smart phone to connect to a Wi-Fi network named “INSPIRE-100 Patient”. Upon login to this network a patient information form is automatically presented.

In case the portal does not automatically open, open a browser and navigate to 192.168.1.4 (URL) after connecting to the “INSPIRE-100 Patient” network.

After form submission, the next browser screen presents an opportunity to confirm or edit again before the system saves the entered information as patient details. This patient information is available and used till the next time a new patient’s details are entered.

INSPIRE-100

Enter Patient Details

Patient Name

| | |
|-------------|------------------------------------------------------------|
| Gender | <input type="radio"/> Male <input type="radio"/> Female |
| Age (yr) | |
| Weight (kg) | |
| Height (cm) | |

SUBMIT

Figure 14: Patient Information Portal

System RESET Handling

In addition to the normal Power-on reset, the system provides three other RESET mechanisms. Upon every type of RESET, the system runs a battery of self-tests before control is passed to the user.

1. Manual RESET Button
 - a. This causes the system to shut down and restart in an orderly fashion while it is in normal operating mode. All relevant data gets saved before system shutdown.
 - b. After a manual RESET, the system is in the same state as after a Power-on RESET.
2. Watchdog RESET
 - a. This is a system self-generated panic RESET which is activated if the system encounters any unanticipated failure. This is not a replacement for normal ALARM conditions which are handled routinely by the system. The user has no control over the watchdog RESET.
 - b. After a watchdog RESET, appropriate alarms are displayed, and the system automatically restarts to a Power-on state. It can be restarted from there in the usual manner.
3. Factory RESET
 - a. This RESET can be performed using either the Pre-use Checks menu or the Standby Menu.
 - b. It can also be accomplished by powering up the system while keeping the START button pressed down. Keep the START button pressed down till the LCD displays the Factory Reset prompt.
 - c. All previously set parameters are erased and the system is restored to Factory settings forcing a re-initialization.

Manual RESET Button Use Model

The use model for the manual RESET button is as below.

1. RESET must be pressed continuously for 4 secs. Any shorter RESET button press is ignored.
2. If recognized, a screen is displayed prompting for RESET confirmation.
3. The user now has a timeout period (6 secs) within which to confirm the RESET.
4. The RESET confirmation can be actively denied by pressing any button except YES or it can be passively denied by letting the timeout period run out.
5. Upon confirmation within the timeout period, the system is shut down in an orderly fashion.
6. If the RESET confirmation is declined, the system behaves as if nothing happened and carries on with no change in behavior despite this disruption. It behaves as if the RESET button was never pressed in the first place.

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 9.
- 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 at least 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.
- 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 Ventilation Mode via the Front Panel. *(See section on Setting Operating Parameters)*
- Set the Ventilator 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 (more than 3 sec) at any time to go into STANDBY mode. Keep it pressed till STANDBY state is entered.
- 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 automatically unmute the buzzer.

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.

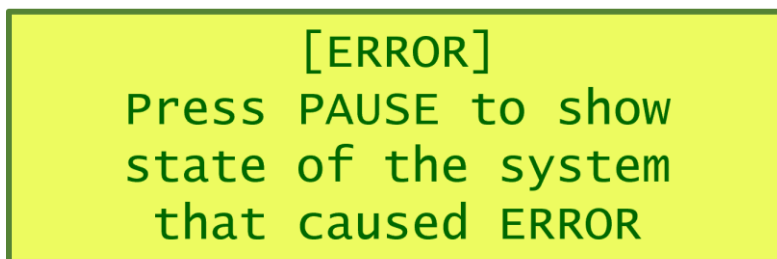


Figure 15: Error State message

3. It is recommended that the attendant long press the PAUSE button (more than 3 sec) when ready to attend to the error condition. Pressing the PAUSE button will cause the system to enter STANDBY state.
4. After entry into PAUSE from ERROR state, the display will show the exact input parameters and the measured parameters at the time of error.
5. 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.
6. System attempts to recover from transient errors automatically.

Power ON Sequence



It is extremely important to disconnect the breathing system from the patient before the system is powered-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. 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.*)
6. The system is now ready for Pre-Use checks. (See Section on Pre-Use checks).
7. 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.
8. 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 (more than 3 sec) to transition it into STANDBY state. Keep PAUSE button pressed till entry into STANDBY state is displayed.
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.

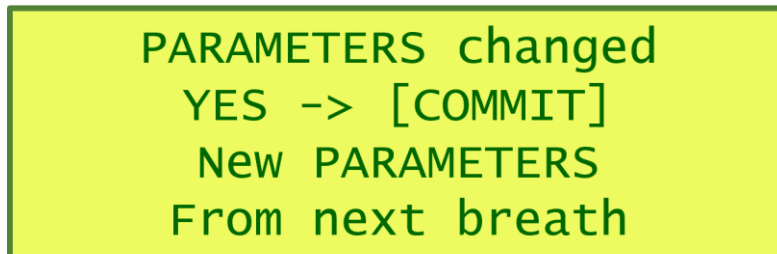
| Symbol | Variable | Description |
|------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MODE | Respiration mode | ACV, CMV, SIMV or PSV |
| VT | Tidal Volume | Desired Volume (ml) of air to be delivered each breath |
| 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 patient-initiated (spontaneous) breath |
| TPS | PS Inspiration Termination | Flow-triggered mode (10, 20, 30, 40, 50 or 60% of peak flow) or time-triggered i.e. 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 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 2 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.

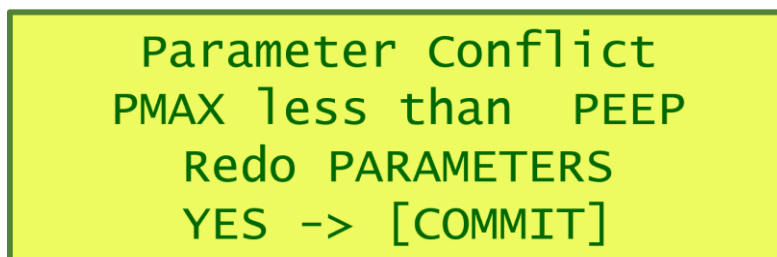
7. At any time, the display will show the current changed set of parameters. The parameters that have not been changed will not be blinking. The parameters that have changed will be blinking slowly. The parameter which is the current selection will be blinking rapidly.
8. None of these changed parameters 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.



PARAMETERS changed
YES -> [COMMIT]
New PARAMETERS
From next breath

Figure 16: 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.



Parameter Conflict
P_{MAX} less than PEEP
Redo PARAMETERS
YES -> [COMMIT]

Figure 17: Parameter Conflict Message

(See section on FiO₂ Settings for changing FiO₂)

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 19 below.

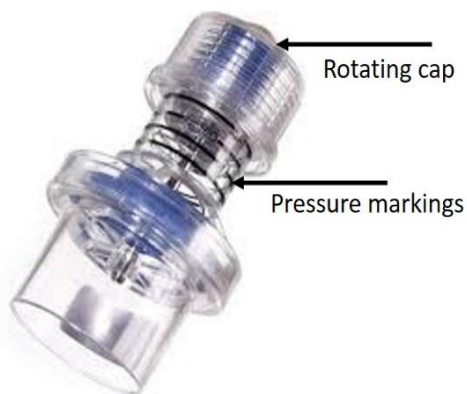


Figure 18: PEEP Valve

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 PEEP 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.

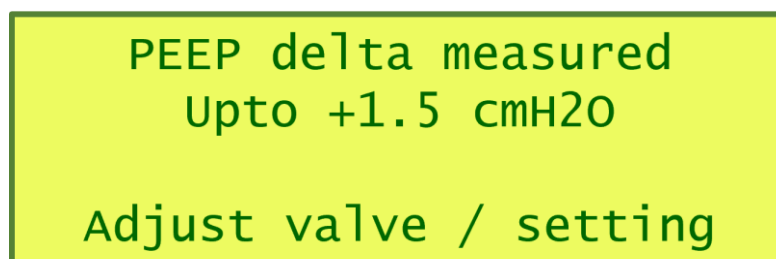


Figure 19: PEEP Mismatch message

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.

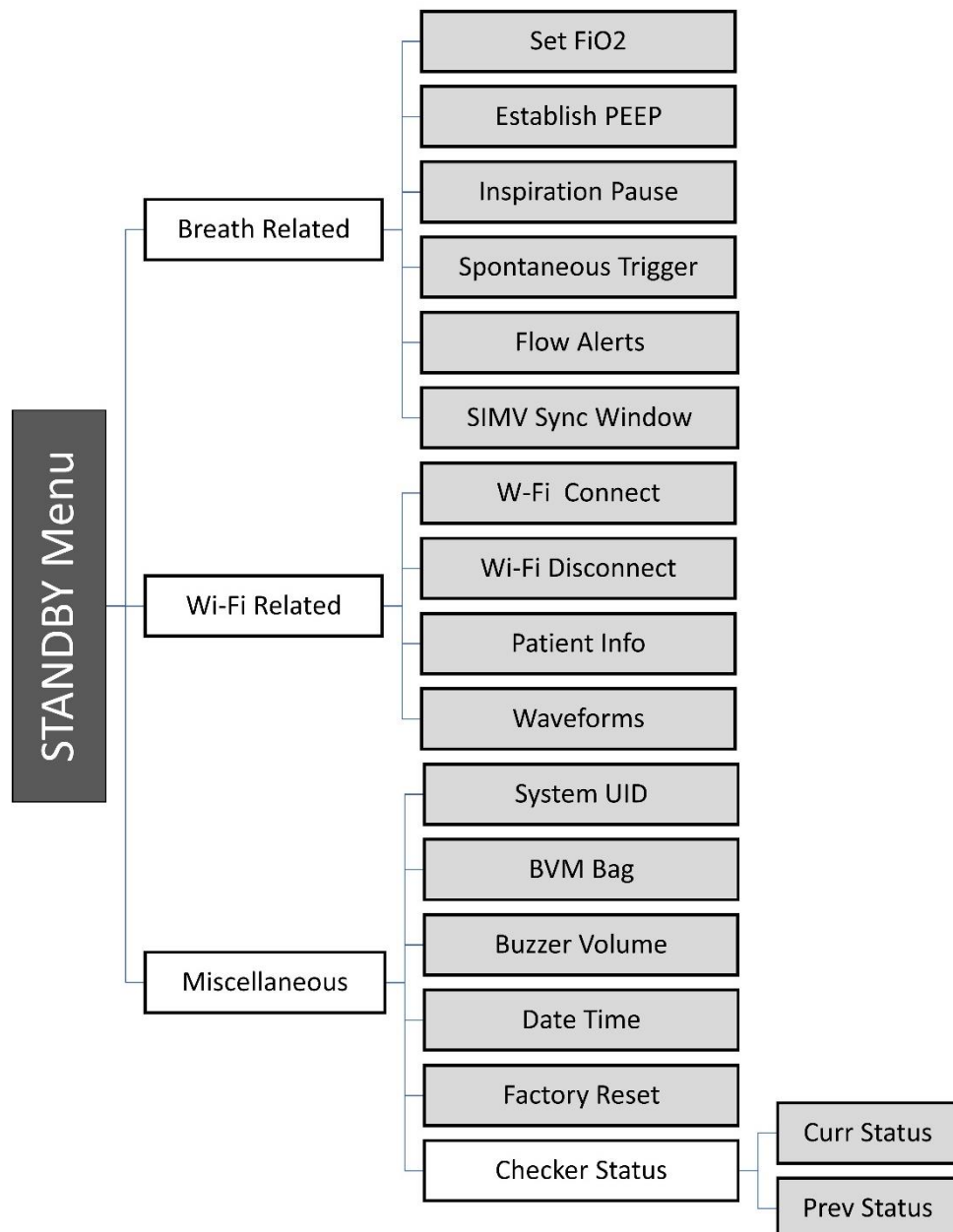


Figure 20: STANDBY Menu Hierarchy

FiO₂ Settings



INSPIRE-100 does not directly measure FiO₂. Techniques such as SpO₂ 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 (FiO₂) 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 FiO₂ 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 FiO₂. The Oxygen source could be an Oxygen cylinder, a concentrator or piped Oxygen.

FiO₂ 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% FiO₂ 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 FiO₂ 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.

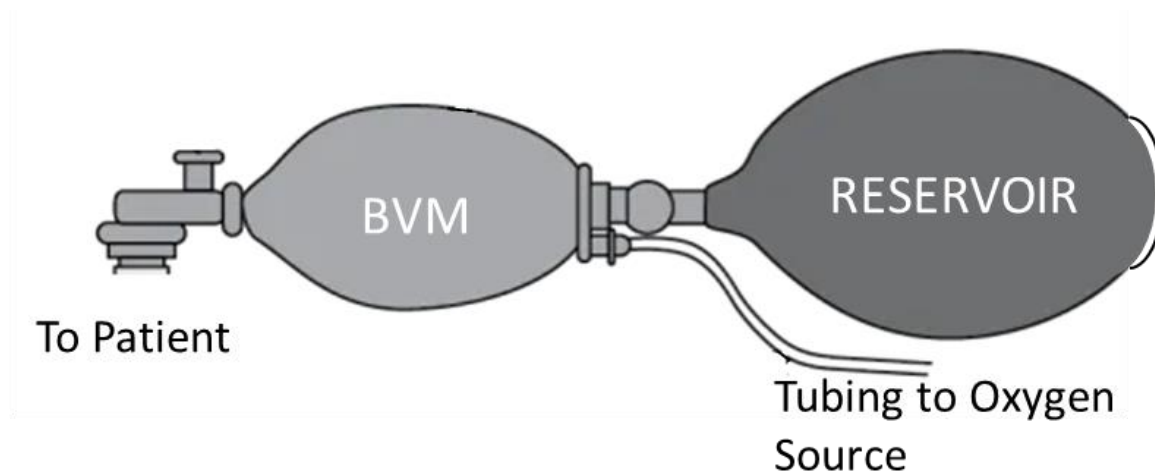


Figure 21: Oxygen Reservoir Connection

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 INSPIRE-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, long press PAUSE (more than 3 sec) 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.

| | | |
|--|----------------|----|
| | Breath Related | -> |
| | Wi-Fi Related | -> |
| | Miscellaneous | -> |
| | Exit | <- |

| |
|-----------------------------|
| FiO ₂ set at 80% |
| Oxygen Inflow must |
| be at 4.2 (l/min) |
| Confirm (YES) ? |

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.

| |
|---------------------------|
| Set O ₂ Purity |
| Use ARROWS or KNOB |
| 21 <-- 90% --> 100 |
| Accept (YES) ? |

Set FiO2
Use ARROWS or KNOB
21 <-- 60% --> 100
Accept (YES) ?

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

Set Oxygen Inflow
at 2.4 (l/min)
Confirm (YES) ?

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.tekmedika.com/INSPIRE-100.com> (See the *INSPIRE-100 Web Applications Manual* 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 (P_{MAX})
6. Oxygen Percentage (FiO₂)

This mode is characterized by the following.

1. Deliver a mandatory (set) number of breaths per minute 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 (P_{MAX})
6. Oxygen Percentage (FiO₂)

This mode is characterized by the following.

1. Deliver a mandatory (set) number of breaths per minute 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). These breaths are volume-controlled to set VT.
5. If no spontaneous breath trigger (from the patient) received within the time set by RR, machine triggers a mandatory breath cycle.
6. The system synchronizes mandatory breaths as shown in the section 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 (P_{MAX}) is breached.

- Peak pressure is measured while air flow is ongoing. During 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. During 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

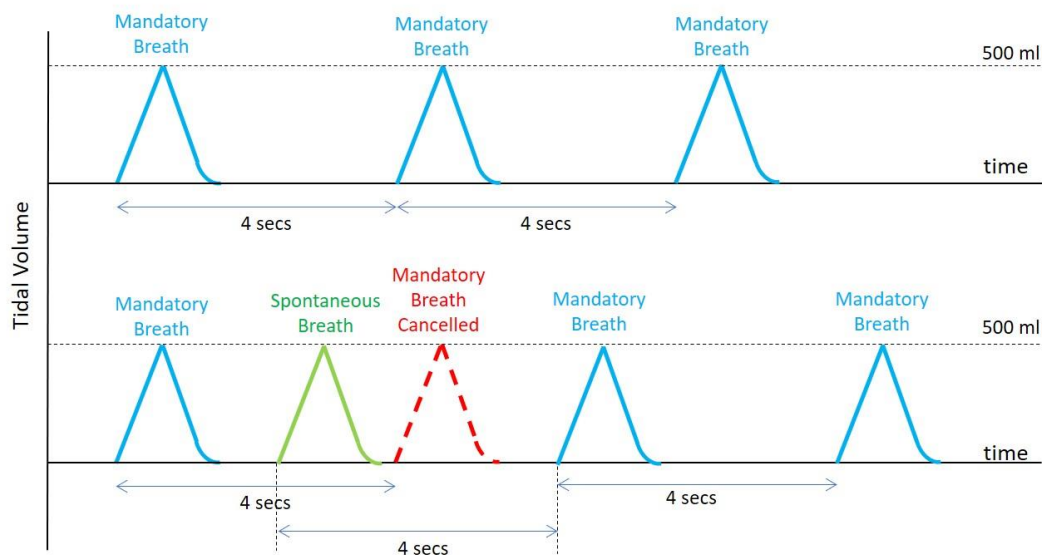


Figure 22: ACV Breath Synchronization

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 per minute 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. So, the patient-triggered breaths will be pressure-supported.
5. TPS controls the time for which Pressure support is provided. If TPS is set to Flow-triggered mode (10, 20, 30, 40, 50, 60), the pressure support will stop once the flow falls the set percentage below the peak flow. If TPS is set to time-triggered mode, the pressure support will be terminated after the set time.
 - 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
6. The ventilator synchronizes the delivery of mandatory breaths with the spontaneous efforts of the patient as described in the section below.
7. Monitor Peak Pressure –alarm will sound if a preset limit (P_{MAX}) is breached.
 - Peak pressure is measured while air flow is ongoing. During this time, the pressure is largely determined by the resistance of the patient airways and dynamic lung compliance.
8. Monitor Plateau and PEEP pressure
 - Plateau pressure is measured after air flow stops. During 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 as described above.

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.
- Sync window can be changed via the Standby Menu. The default is 33%.

Breath Syncing in SIMV mode

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

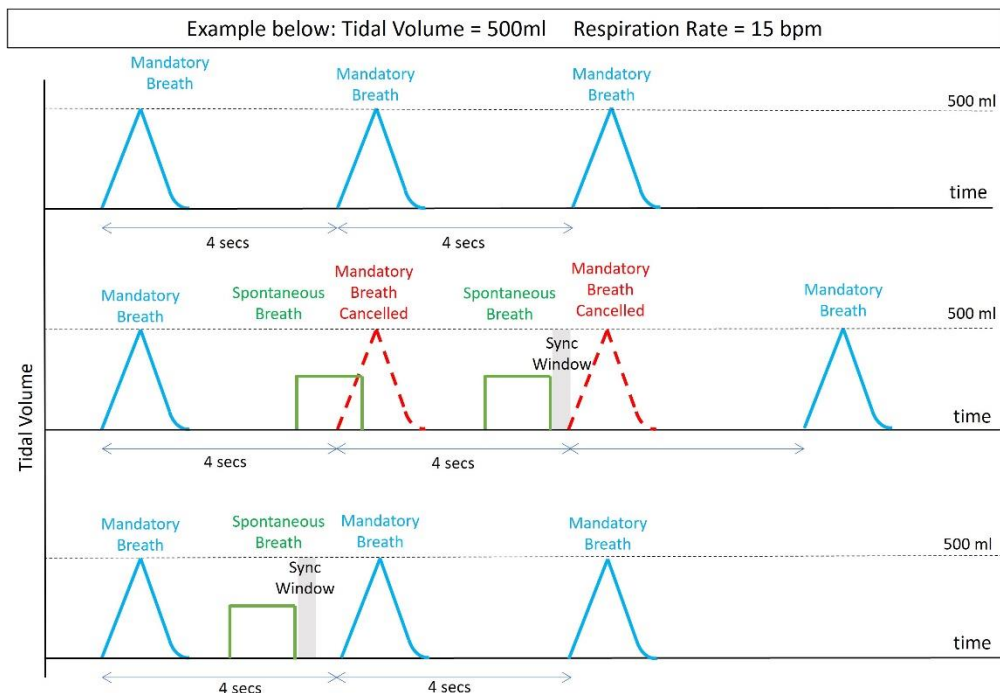


Figure 23: SIMV Breath Synchronization

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 INSPIRE-100 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 INSPIRE-100 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. This check is not done if the Minute-Volume (MV) is set to “---”.
- 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 heuristically 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 (P_{MAX}) 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 Heuristic 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

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

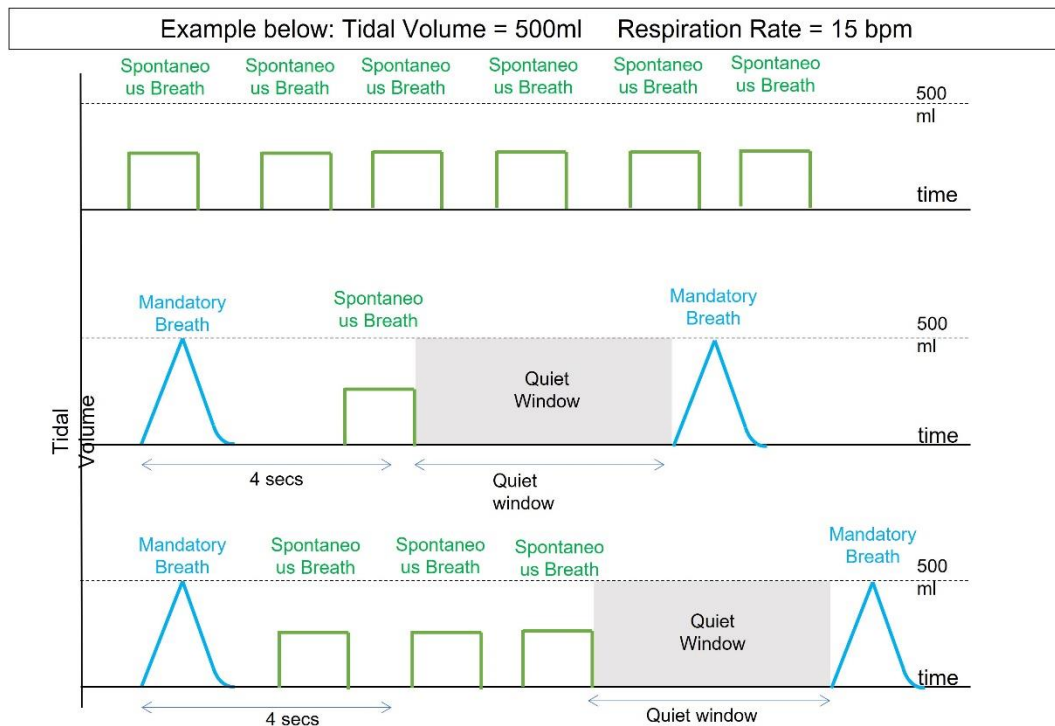


Figure 24: PSV Mandatory Breath

Human Machine Interface

Control Mechanisms

| Control | Feedback | Mechanism | Comments |
|-------------------------------------------------|--------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RESET | State LEDs | Push Button | Resets the entire system. Same as Power-on. |
| RESET + START | State LEDs | Push Buttons | Pressing START while powering ON the system 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 3sec. 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 | 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 H₂O) | 4 through 15 in increments of 1 | Selection displayed on a 2-digit display | UP / DOWN LEFT / RIGHT SELECTOR |
| Max Inspiratory Pressure P_{MAX} (cm H₂O) | 20 through 50 in increments of 5 | Selection displayed on a 2-digit display | UP / DOWN LEFT / RIGHT SELECTOR |
| Support Pressure PS (cm H₂O) | 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-triggered (10%to 60%) or time-triggered (1.0 – 3.0 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 H₂O) | | Measured Number displayed on a 2-digit display | Updated after each breath |
| Plateau Pressure PLAT (cm H₂O) | Mean Pressure for PS Breaths | Measured Number displayed on a 2-digit display | Updated after each breath |
| PEEP Pressure PEEP (cm H₂O) | | 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 H₂O) | | 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.
 - The volume of the ERROR alarm is preset and cannot be changed.
2. WARNING
 - ERROR LED flashes slowly and the buzzer sounds medium beeps.
 - The volume of the WARNING alarm can be set via the initial pre-use checks or during STANDBY state using the STANDBY menu.
3. NOTIFICATION
 - Buzzer sounds short beeps. ERROR LED does not flash.
 - The volume of the NOTIFICATION alarm can be set via the initial checks or during STANDBY state using the STANDBY menu.

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.

This alarm may be caused by a blockage in the breathing circuit, or it may be that the patient's airway is blocked due to aspiration etc. The user must determine the future course of action which may require aspirating the patient or a change of respiration parameters.

PSV Minute Volume Alarm

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.

Breathing System Blockage Alarm

This alarm is caused either by some blockage in the breathing circuit or if the patient's airway itself are blocked.

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 blockage is rectified. Alternatively, the PAUSE button can be used to put the system into STANDBY state till the problem is resolved.

Pressure Loss Alarm

This alarm is typically caused by the connectors in the breathing system or by the patient mask getting disconnected.

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 disconnection is rectified. Alternatively, the PAUSE button can be used to put the system into STANDBY state till the problem is resolved.

Pressure Leak 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 |
|----------------------------------------------------------|--------------------------------------------------------------------------------------------|-------|------------------------------------------------------------------------------------------------------------------------|
| Airway Blockage | Blockage in breathing tube or the patient's airways | YES | Check Breathing circuit. Check if patient needs aspiration. |
| Exceeded Maximum Inspiration Pressure | Peak Inspiration pressure exceeded the set P _{MAX} limit | YES | Breathing Systems may have blockage or may have to reduce the Tidal volume, BPM, EI ratio or increase P _{MAX} |
| 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 P_{MAX} less than PEEP | Attempt to set P _{MAX} (Max Inspiration Pressure) less than PEEP | NO | Change setting and retry |
| PARAMETER Conflict P_{MAX} less than PS | Attempt to set P _{MAX} (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.

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.



| | |
|-------------|----|
| Mandatory | -> |
| Recommended | -> |
| Optional | -> |
| Back | <- |

Figure 25: Pre-Use Checks LCD Messages

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.
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.

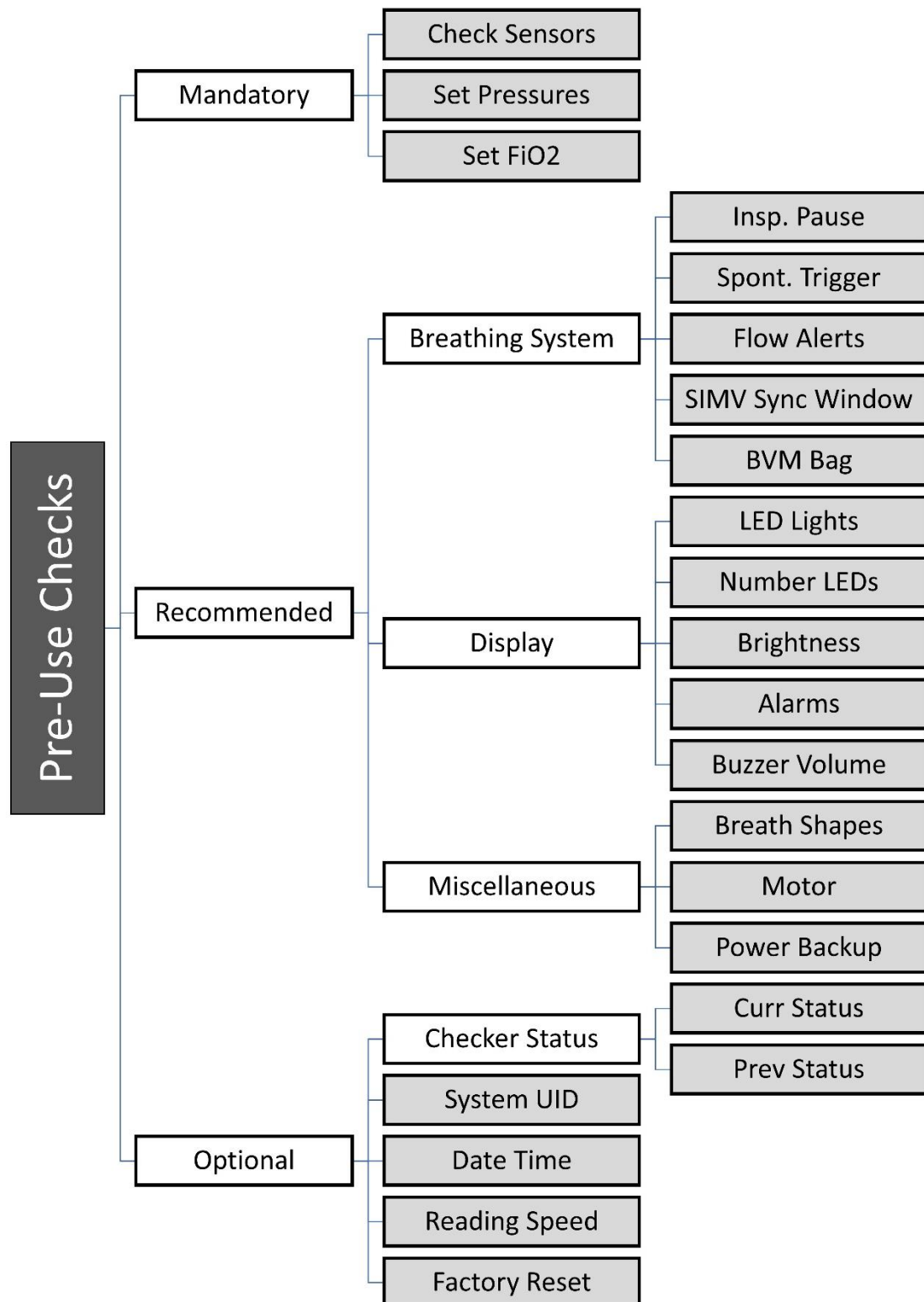


Figure 26: Menu Hierarchy of Pre-Use Checks

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.

Check Sensors

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 correct pressure lines are connected to the appropriate port.

During this check, the BVM bag pressing plates are also brought to a home position where they are just touching the bag. This is done automatically by the system.

Set Pressures

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.

Set FiO₂

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 FiO₂.
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 inspiration 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 set 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. It also sets the minimum time interval between alerts. The Oxygen flow rate requirement is monitored every breath, and a required change is immediately displayed on the LCD screen but the warning alarms will be sounded taking into account the minimum alert interval set using this menu item.

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 Waveforms

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 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 and/or extreme 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

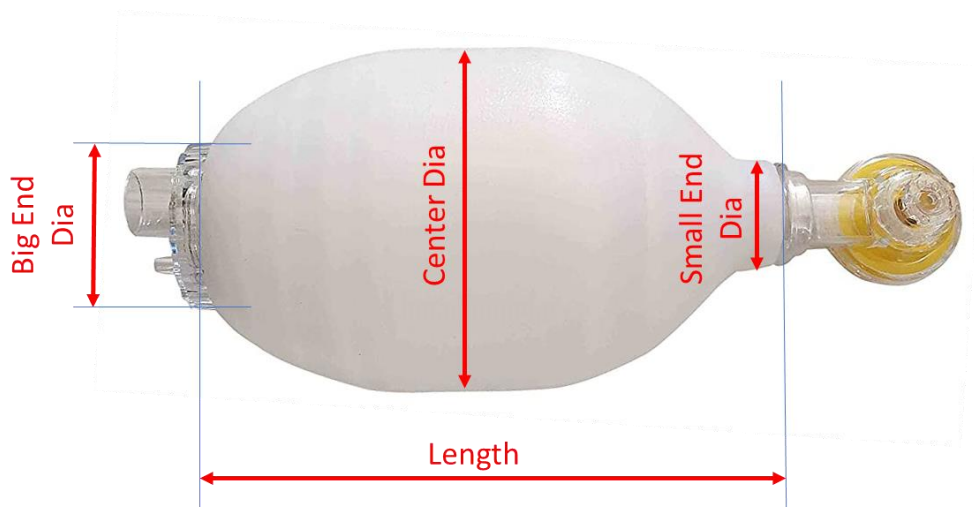


Figure 27: BVM Bag

| | 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 | <120 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) | 30 Kg to 100 Kg |
| Operating Temperature Range | -30 to +55 degC |
| Input Power Supply Range | 200V – 250V |
| Power Consumption | <120 Watts |
| Dimensions | 34 x 46 x 60 cm |
| Weight | 25 Kg |
| Breathing System Connectors | Industry Standard |

Table 12: Respirator Specifications

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