INSPIRE - 100

An Emergency Ventilator Device

Operating Manual

TekMedika

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Introduction

INSPIRE-100 is a patent-pending ventilator design tailored for adult patients, providing comprehensive ventilatory support from initiation to weaning.

It features a user-friendly Human-Machine Interface with a clear front panel and advanced remote monitoring capabilities accessible via laptops, desktops, tablets, or mobile devices. This device is particularly suited for facilities without access to compressed gas or oxygen pipelines and is built to withstand challenging environmental conditions.

INSPIRE-100 supports four commonly used ventilation modes: CMV, ACV, SIMV, and PSV. It offers a full range of breath parameters across all modes, ensuring complete assistance for patient-initiated breathing with features such as breath synchronization, volume control, and pressure support.

Additionally, the INSPIRE-100 is equipped with a comprehensive set of safety features, including fallback mechanisms for all error scenarios until they are resolved.

System Elements

Figure 1: Core System Elements

Control Faceplate

Detachable Control Panel

Breathing Hose Connector

Oxygen Reservoir Connector

Airflow Vents

Trolley

Lockable Wheels

Master Controller USB Port

Downstream Pressure Line

Slave Controller USB Port

Upstream Pressure Line

Pole Clamps

Airflow Vents

Power Switch

Anchor Bar   Breathing Hose   Pole Clamps
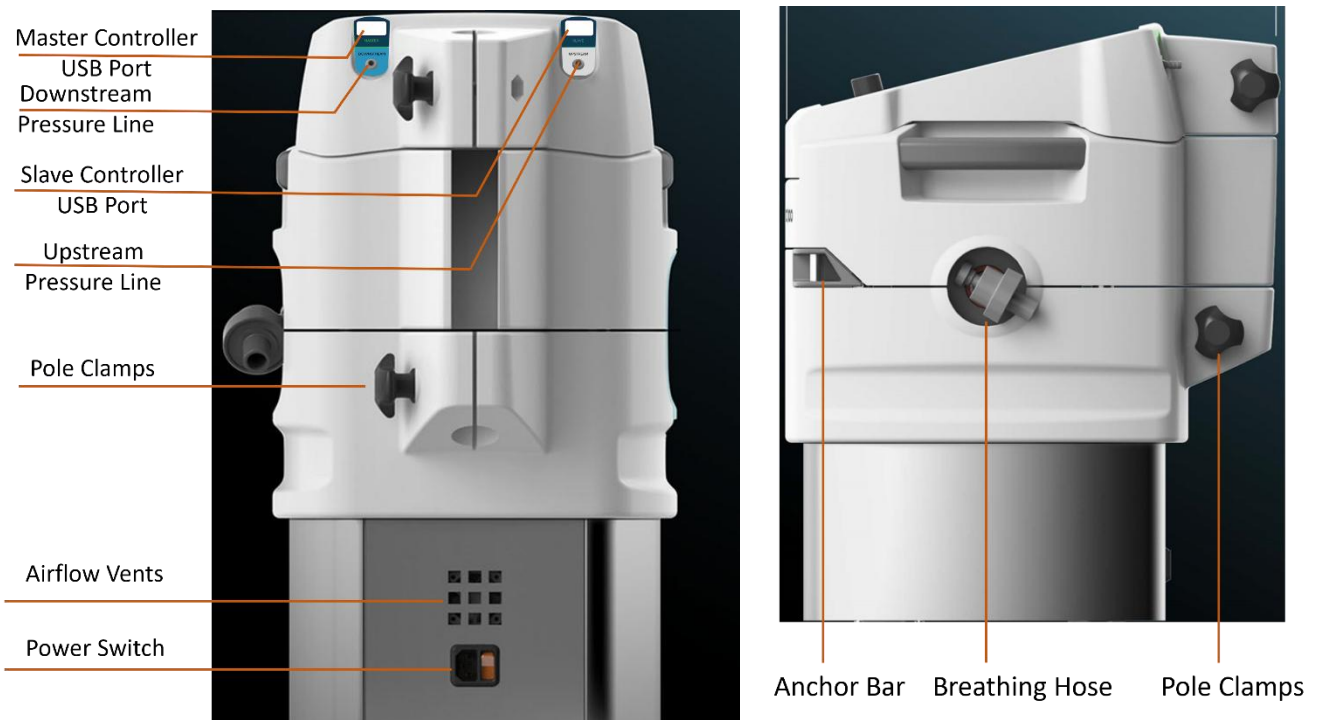
Figure 2: Different views of Core System

Base Unit

BVM Bag Assembly
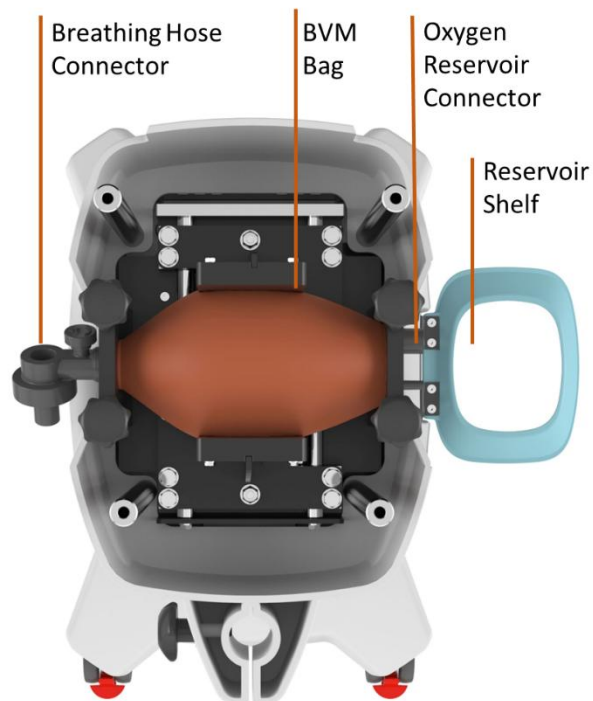
Figure 3: BVM Bag Receptacle

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 (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. Remote Recorder and Playback applications are also provided.

(*See the document on INSPIRE-100 Web Applications Manual for further details.*)
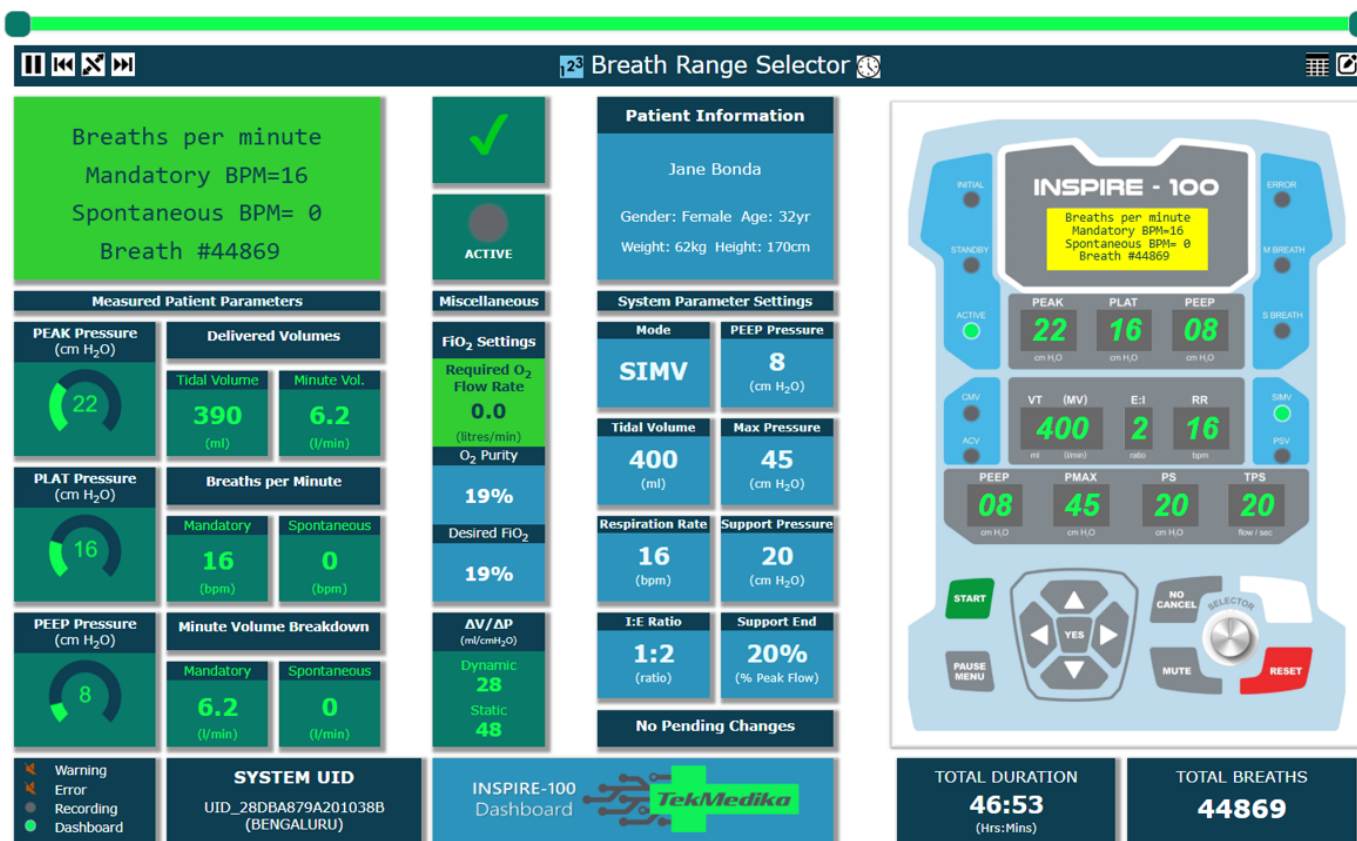
Figure 4: Online WEB Dashboard

Updating System Firmware

Over time, as the firmware evolves with new feature, 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.*)
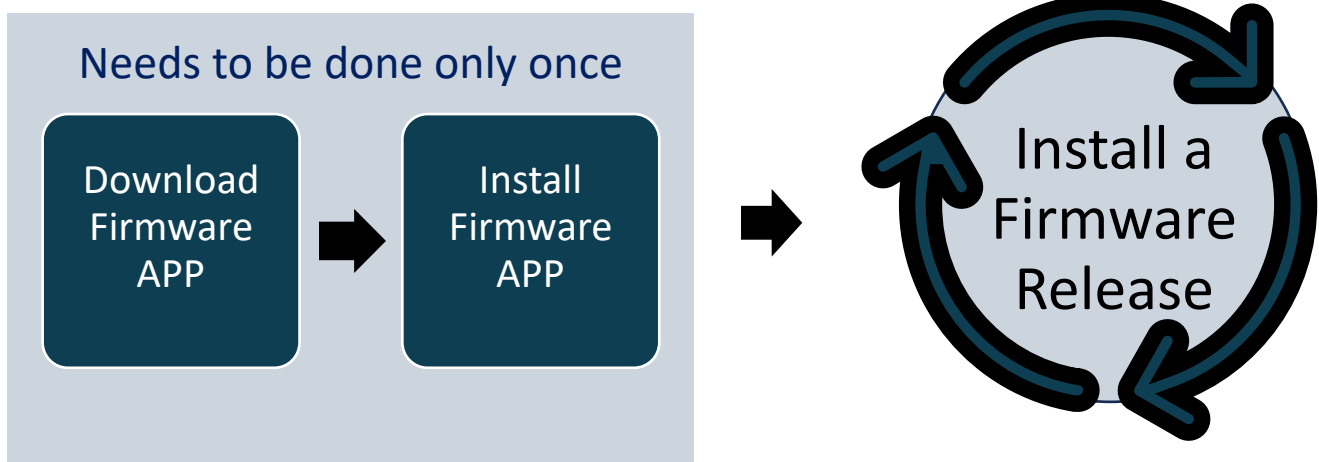
Figure 5: Firmware Update Process

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.
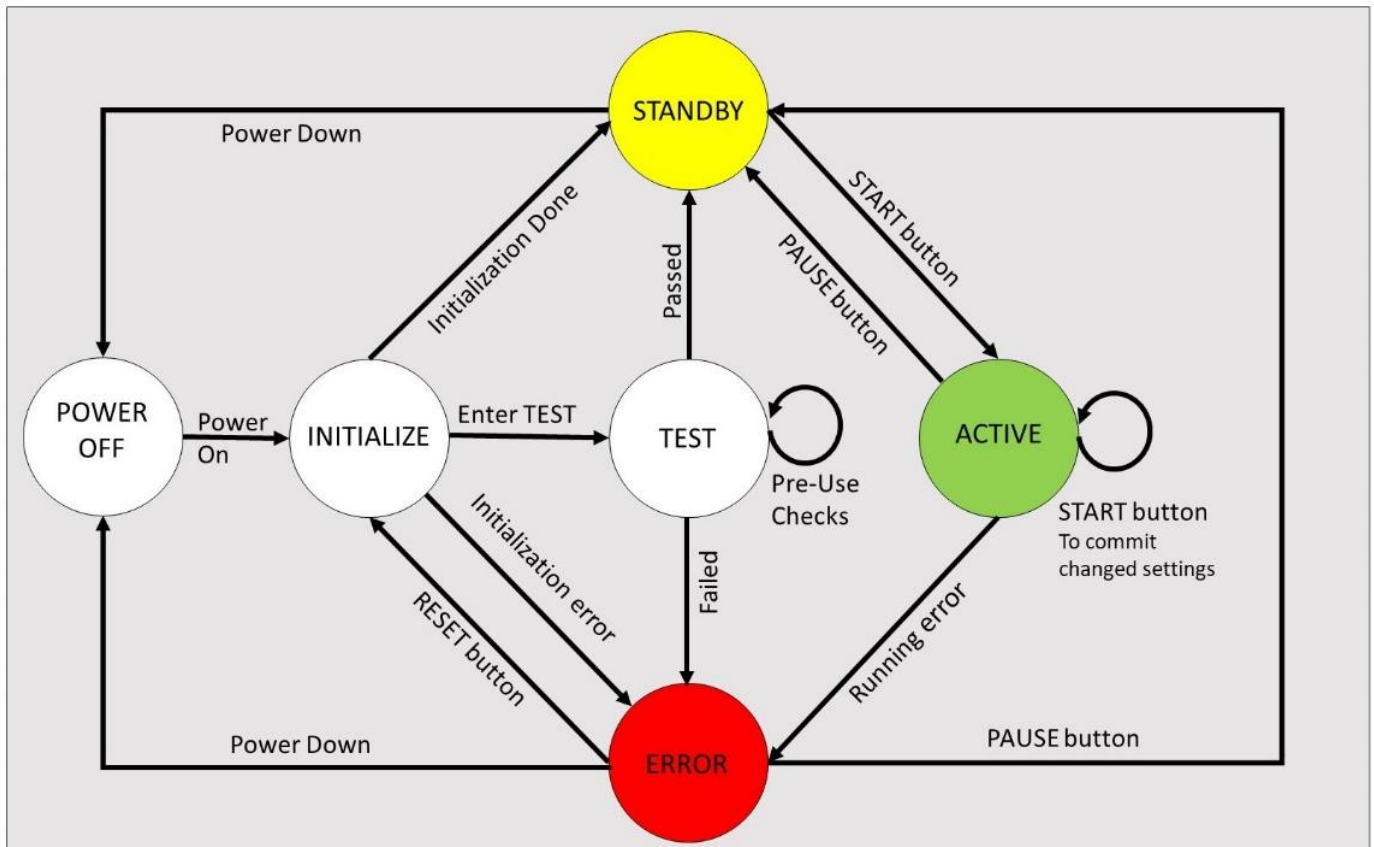
Figure 6: State Transitions

Front Control Panel Layout
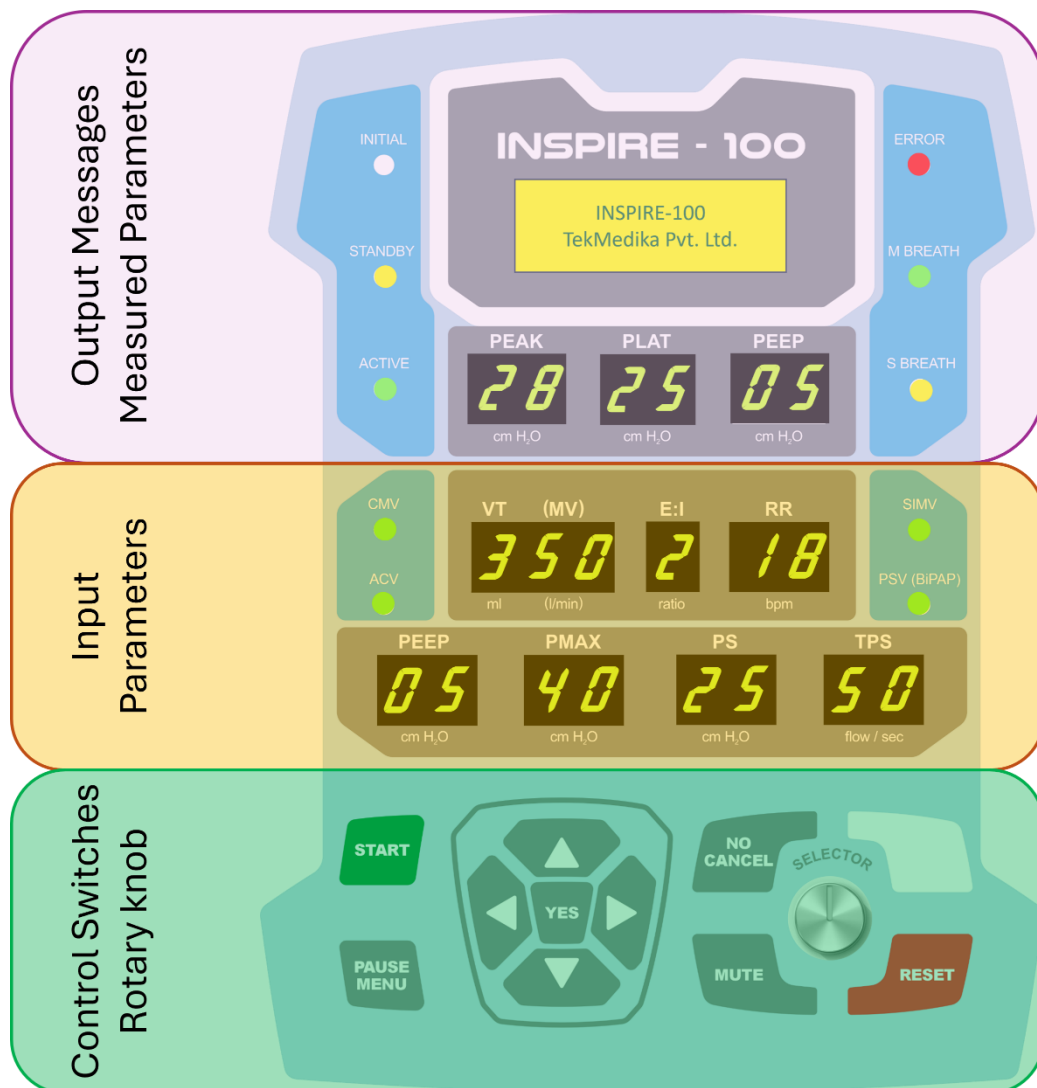
Figure 7: Front Panel Layout

The front panel is divided into three sections as shown in the Figure above.

1. All system messages and measured parameters are in the first section. It also includes various LEDs to indicate the state of the system

2. The second section displays all the input settings

3. The last section holds all the buttons and a rotary knob to control the system

Front Control Panel Description
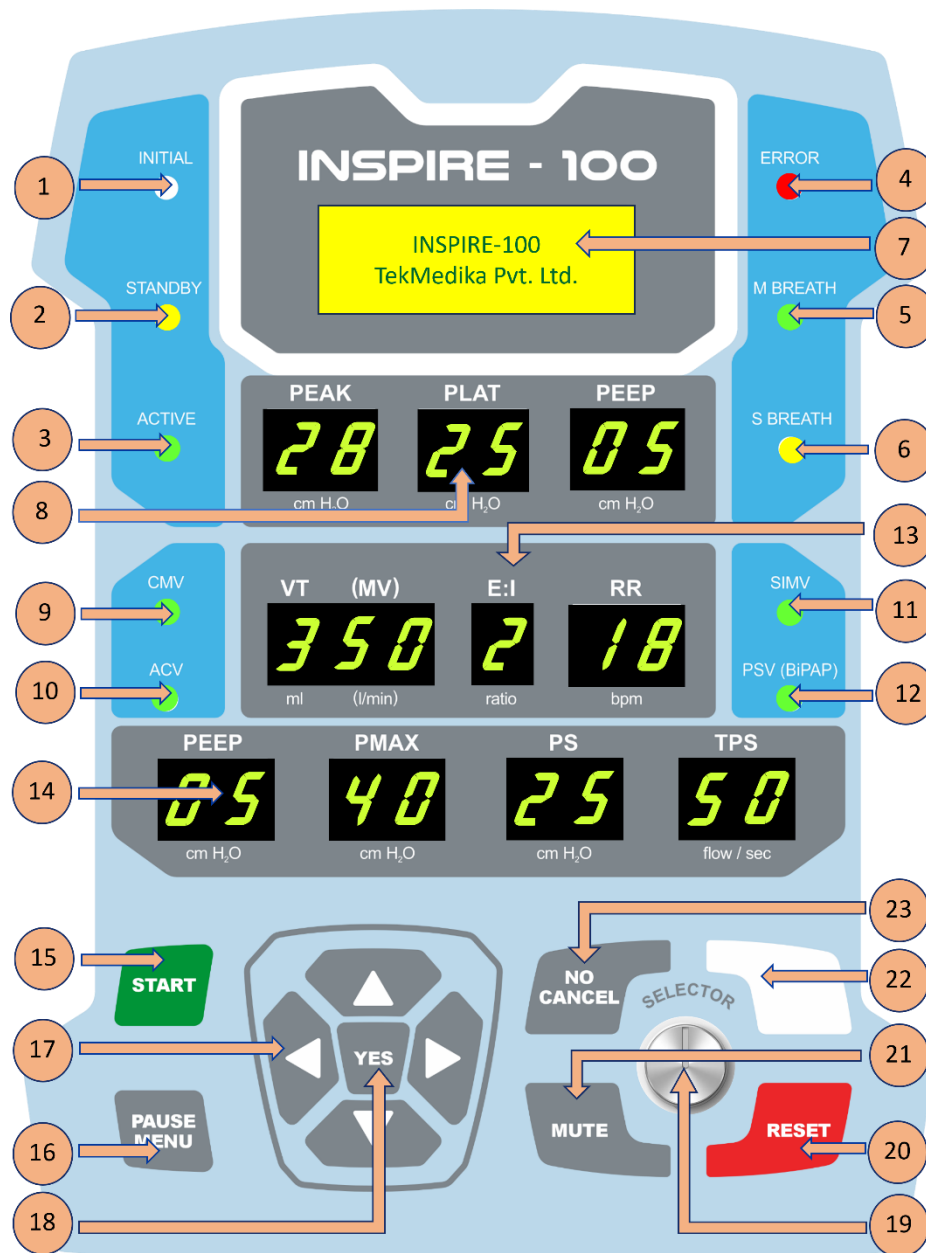
Figure 8: Front Control Panel Elements

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

9. Selected Ventilation mode is CMV.

10. Selected Ventilation mode is ACV.

11. Selected Ventilation mode is SIMV.

12. Selected Ventilation mode is PSV (BiPAP).

13. 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 (BiPAP) Ventilation mode.
    - E/I – Expiration time to Inspiration time ratio.
    - RR – Respiration rate in breaths per minute.

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.
    - PEEP – Required Peak End Expiration Pressure in cm H_2O.
    - PMAX – Max Inspiration Pressure allowed in cm H_2O.
    - PS – Support Pressure (relative to PEEP) for breaths in cm H_2O.
    - TPS – Flow-triggered termination for a Pressure supported breath.

15. 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.

16. PAUSE/MENU Button – Long Press (more than 2 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, a long press on this button this button causes entry into the STANDBY menu where various settings can be changed.

17. UP, DOWN, LEFT, RIGHT buttons. These buttons are used to navigate menus and change input settings. These buttons are inactive while the ventilator is delivering breaths.

18. YES button to answer prompts and questions posed on the LCD panel.

19. 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. Pressing down on the SELECTOR knob acts as a button to initiate a factory reset.

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

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

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

23. 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 9: Installing BVM Bag

Complete System Schematic

The complete system with the ventilator 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 10: Proprietary patent-pending Dual Pressure-line Connector

Figure 11: Off-the-shelf Breathing Circuit

Figure 12: Complete Ventilator System

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_2O)
PEAK	Peak Inspiration Pressure	Max pressure during Inspiration phase of breath delivery (cm H_2O)
PLAT	Plateau Pressure	Plateau pressure during breath delivery. (cm H_2O)
PEEP	Peak End Expiration Pressure	Pressure in the lungs that exists at the end of expiration (cm H_2O)
PS	Pressure Support	Level of support pressure to assist patient-initiated (spontaneous) breaths (cm H_2O). The value is relative to PEEP.
TPS	Pressure Support duration	Termination of the inspiration phase for which the pressure support is to be delivered. It is Flow triggered (percentage of Peak Flow).
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. (percentage)

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. For subsequent power-ups, this information need not be re-entered if the deployment site remains the same.

- The entry portal for INSPIRE-100 can be used for determining the deployment location's elevation. The URL for the INSPIRE-100 portal is https://tekmedika.com/inspire-100. A screenshot is shown below. Use the link shown in the screenshot. Or else, the location altitude can easily be googled.
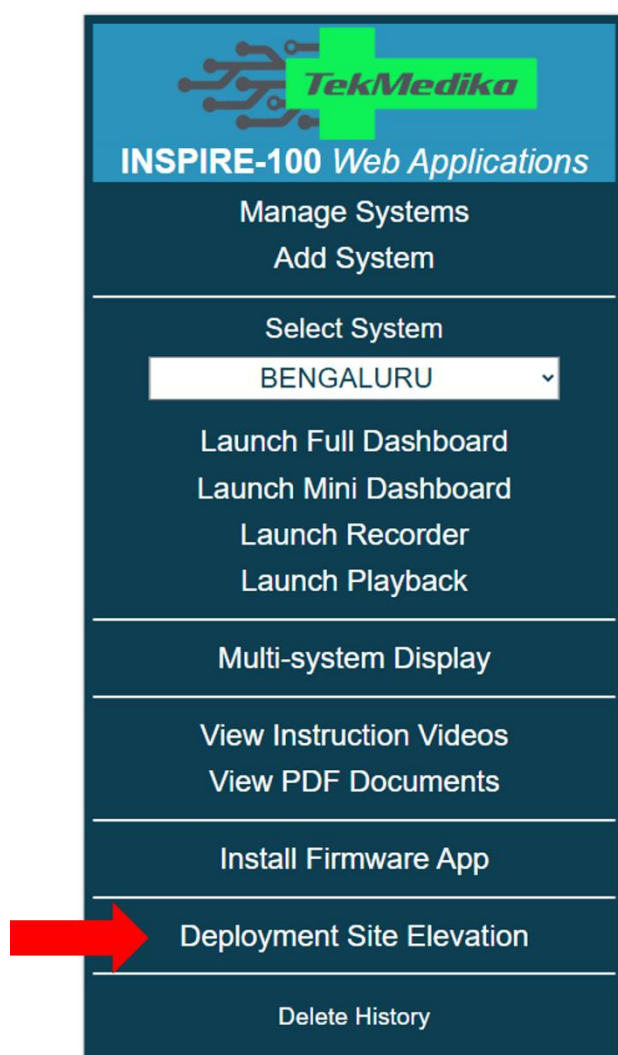
The steps for entering the location information are as below.

a. The INSPIRE-100 System sets up a WiFi network called "INSPIRE-100 Location"


```
Connect Laptop / Phone
    To Wi-Fi network
 INSPIRE-100 Location
       .. 1 ..
```
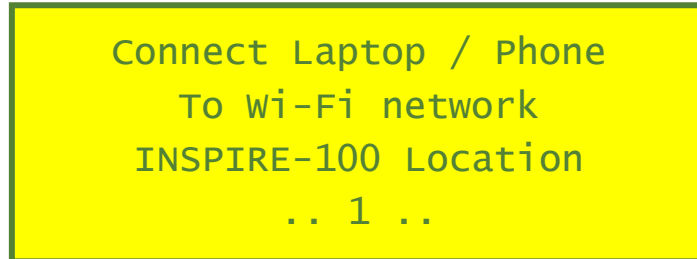
b. Log in to this network and a portal is automatically presented on the device that you logged on with.

Figure 13: Location Information Entry Form

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.

```
        Enter New
    Patient Information


       (YES or NO) ?
```

```
    Connect Laptop / Phone
       To Wi-Fi network
      INSPIRE-100 Patient
            .. 1 ..
```
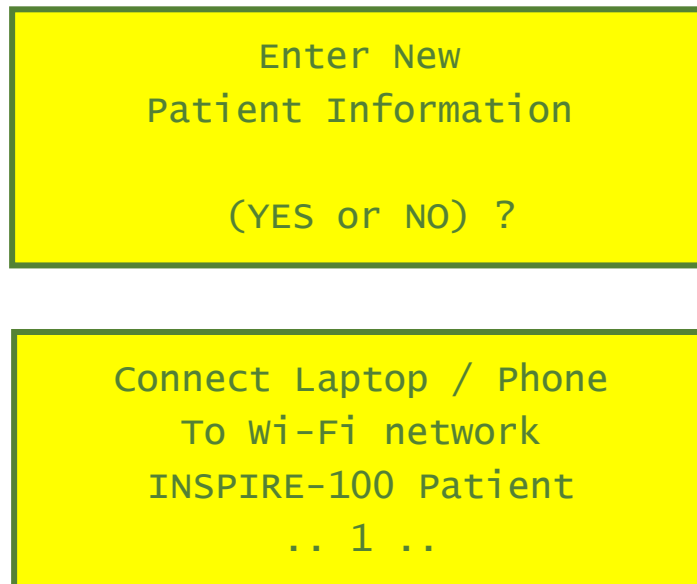
Figure 14: Connect to INSPIRE-100 Patient network

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.

Figure 15: Patient Information Portal

System RESET Handling

In addition to the standard Power-on reset, the system features three additional RESET mechanisms. Each type of RESET initiates a series of self-tests before user control is restored.

1. Manual RESET Button
   a. Pressing this button causes the system to shut down and restart in an orderly manner while in normal operation. All relevant data is saved prior to shutdown.
   b. After a manual RESET, the system returns to the same state as it would after a Power-on RESET.

2. Watchdog RESET
   a. This is an automatic panic RESET triggered by the system in response to unexpected failures. It does not replace normal ALARM conditions, which the system manages routinely. The user cannot control this RESET.
   b. Following a watchdog RESET, the system displays appropriate alarms and automatically restarts to a Power-on state, from which it can be restarted normally.

3. Factory RESET
   a. This RESET can be executed by pressing on the SELECTOR knob until the LCD shows the Factory Reset prompt.
   b. Alternatively, it can be executed through the Pre-use Checks menu or the Standby Menu.
   c. This action erases all previously set parameters and restores the system to its Factory settings, requiring re-initialization.

Manual RESET Button Use Model

The procedure for using the manual RESET button or the FACTORY RESET button is as follows:

1. The RESET (or FACTORY RESET) button must be held down for 4 seconds; shorter presses will be ignored.
2. If recognized, a screen will prompt for RESET (or FACTORY RESET) confirmation.
3. The user has a timeout period of 6 seconds to confirm the RESET (or FACTORY RESET).
4. Confirmation can be denied by pressing any button except YES or by allowing the timeout to expire.
5. If confirmed within the timeout period, the system will perform RESET (or FACTORY RESET) in an orderly manner.
6. If confirmation is declined, the system continues functioning as if the RESET (or FACTORY RESET) button was never pressed.

Routine Operation of the System

The operation of the system is summarized below:

- Ensure a power backup (UPS) is connected.
- Connect the Breathing Circuit to the Ventilator as illustrated in Figure 9.
- Turn ON the system, which will display the version number on the LCD and undergo a series of self-tests.
- Perform all Pre-use checks before connecting the system to the patient. While it is advisable to complete all checks, the system will ensure that at least mandatory checks are conducted *(refer to the Pre-Use Checks section)*.
- After the checks, the system enters STANDBY mode, displaying a relevant message.
- While in STANDBY, pressing the MENU button will display possible actions (as shown in the accompanying figure), useful if any earlier prompts were missed or if settings need adjustment mid-session.
- Select the Ventilation Mode via the Front Panel *(see the section on Setting Operating Parameters)*.
- Set the Ventilator operating parameters via the Front Panel *(see the section on Setting Operating Parameters)*.
- Connect the system to the patient.
- Press the START button to initiate breath delivery.
- Monitor PEAK, PLAT, and PEEP, as well as the patient's physical condition.
- Adjust the PEEP valve until the measured PEEP aligns with the desired PEEP *(see the section on PEEP adjustment)*.
- During breath delivery, the system will cycle through various informational messages on the LCD.
- Adjust Ventilator operating parameters as necessary.
- Long press PAUSE (more than 2 seconds) at any time to enter STANDBY mode; keep it pressed until the STANDBY state is achieved.
- A short press (less than 1 second) on the PAUSE button during breath delivery will introduce an inspiration pause for the next volume-controlled breath, useful for determining plateau pressure. The duration of this pause can be set during Pre-Use checks and defaults to 1.5 seconds.
- After any change in operating parameters, press START to apply the new settings.
- Press the NO/CANCEL button to cancel changes mid-way, reverting to the previous parameters.
- In an ERROR state, the ERROR LED blinks, and the BUZZER sounds. Pressing the MUTE button silences the BUZZER, though the ERROR LED continues to blink.
- If the BUZZER remains muted for 2 minutes without addressing the error, 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.

```
      [ERROR]
   Press PAUSE to show
   State of the system
    That caused ERROR
```
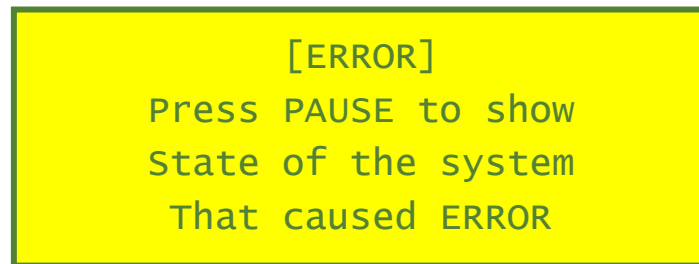
Figure 16: Error State message

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 crucial to disconnect the breathing system from the patient prior to powering on the device. The breathing system should only be connected to the patient when specifically instructed by the system.

1. Ensure that a BVM bag is correctly installed in the base unit of the system.
2. The BVM bag must be the appropriate size and securely clamped *(refer to the BVM installation section)*.
3. Power on the system. If needed, press the RESET button.
4. The system will conduct a series of self-tests and automatically adjust the BVM pressing plates until they lightly touch the BVM bag.
5. The user will then have the option to enter patient information and/or connect to the Internet via Wi-Fi. While these steps are not essential for the system's operation, they are recommended *(see the Web Apps document for more details)*.
6. The system is now prepared for Pre-Use checks *(refer to the Pre-Use checks section)*.
7. After successfully completing the Pre-Use checks, the system will enter the STANDBY state, at which point it is safe to connect the breathing system to the patient.
8. At this stage, respiration parameters can be adjusted, and breath delivery can commence.

Recommended Power OFF Sequence

To power off the Ventilator, follow the steps below.

1. Confirm that the system is in the STANDBY or INITIALIZE state before shutting it down.
2. If the system is in the ACTIVE or ERROR state, press and hold the PAUSE button (for more than 3 seconds) to transition it to the STANDBY state. Continue holding the PAUSE button until the STANDBY state is displayed.
3. Once in the STANDBY state, it is safe to power off the entire system.

Setting Operating Parameters

The ventilator'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.
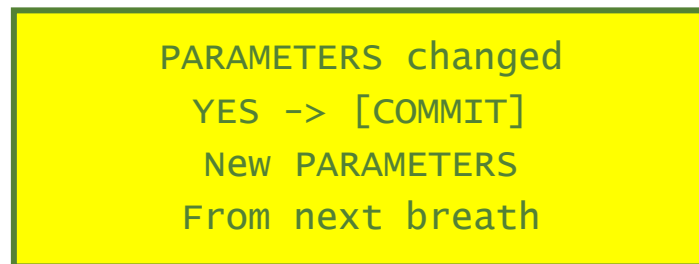
Symbol	Variable	Description
MODE	Respiration mode	ACV, CMV, SIMV or PSV (BiPAP)
VT	Tidal Volume	Desired Volume (ml) of air to be delivered each breath
RR	Respiratory Rate	Desired Breaths per minute
E/I	Expiration/Inspiration ratio	Desired Ratio of expiration vs inspiration time in a breath cycle
PMAX	Max Inspiration Pressure	MAX inspiration pressure (cm H_2O) never to be exceeded
PEEP	Peak End Expiration Pressure	Desired Pressure (cm H_2O) in the lungs at the end of expiration
PS	Pressure Support	Desired Level of support pressure (cm H_2O) to assist every patient-initiated (spontaneous)breath. The value is relative to PEEP.
TPS	PS Inspiration Termination	Flow-triggered (20, 30, 40, 50 percent of peak flow)
FiO$_2$	Fraction of Inspired Oxygen	Concentration (percentage) 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 Ventilator Operating Parameters

To change any of the operating parameters except FiO$_2$, follow the steps below.
1. The Ventilator must be in STANDBY mode before any parameters can be changed. Further, the Ventilator 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.
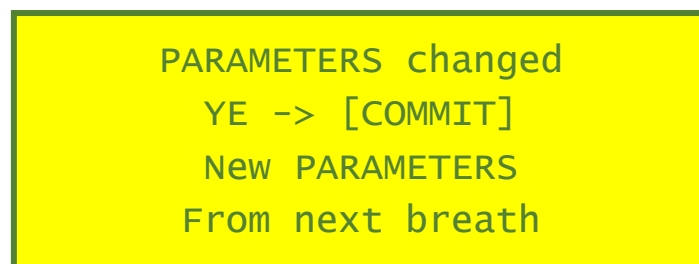
6. Continue in the above fashion till the entire desired set of parameters have been set according to requirements.

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.

9. The new set of parameters will take effect from the next breath delivery onwards after pressing START.

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

Figure 17: Parameter Change Message

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.

```
PARAMETERS changed
 YE -> [COMMIT]
 New PARAMETERS
From next breath
```

Figure 18: Parameter Conflict Message

(See section on FiO$_2$ Settings for changing FiO$_2$)

Setting Tidal Volume Ramp-up time

Every time the operating parameters are changed, the system prompts to set the period of time over which the tidal volume should be ramped up to the desired value. The following display on the LCD screen prompts for this setting. The arrow buttons or the rotary dial can be used to set the desired value.

```
     Set Tidal Volume
    Ramp-up approx time
  0<-    0 min(s)    ->15
        DONE (YES) ?
```
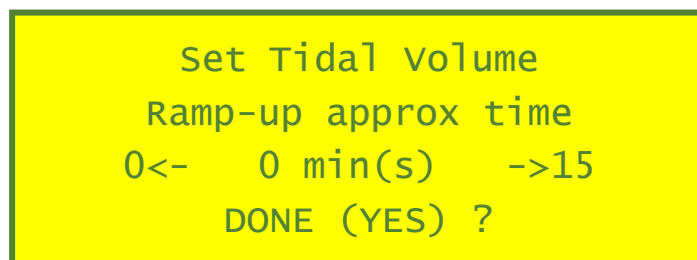
Figure 19: Tidal Volume Ramp-up time

The delivered tidal volume starts at a low volume and then gradually increases till it reaches the desired tidal volume setting. The ramp-up time is specified in minutes and ranges from 1 to 15 minutes. A value of 0 indicates that the ramp-up should be accomplished as quickly as possible.

If the system is made to enter STANDBY mode during the ramp-up period, the ramp-up will resume from where it left off upon restarting breath delivery. While in STANDBY mode, the ramp-up time can be changed using the STANDBY menu. In case of a change to the ramp-up time while in STANDBY mode, the system will start the ramp-up afresh.

(See section on STANDBY menu)

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.
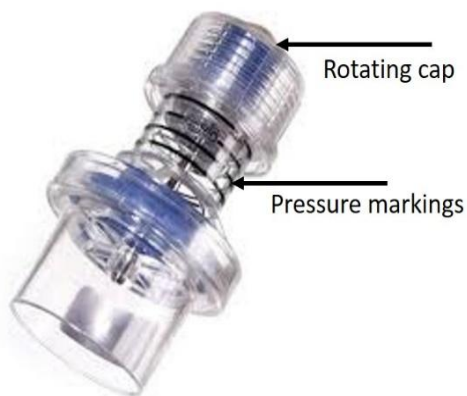
Figure 20: PEEP Valve

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.


```
PEEP delta measured
   Upto +1.5 cmH2O


Adjust valve / setting
```
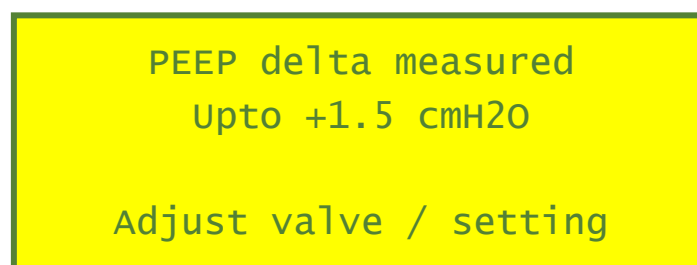
Figure 21: PEEP Mismatch message

STANDBY Menu

To change other parameters, use the STANDBY menu. STANDBY menu is accessed while in STANDBY state by a long-press of 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.
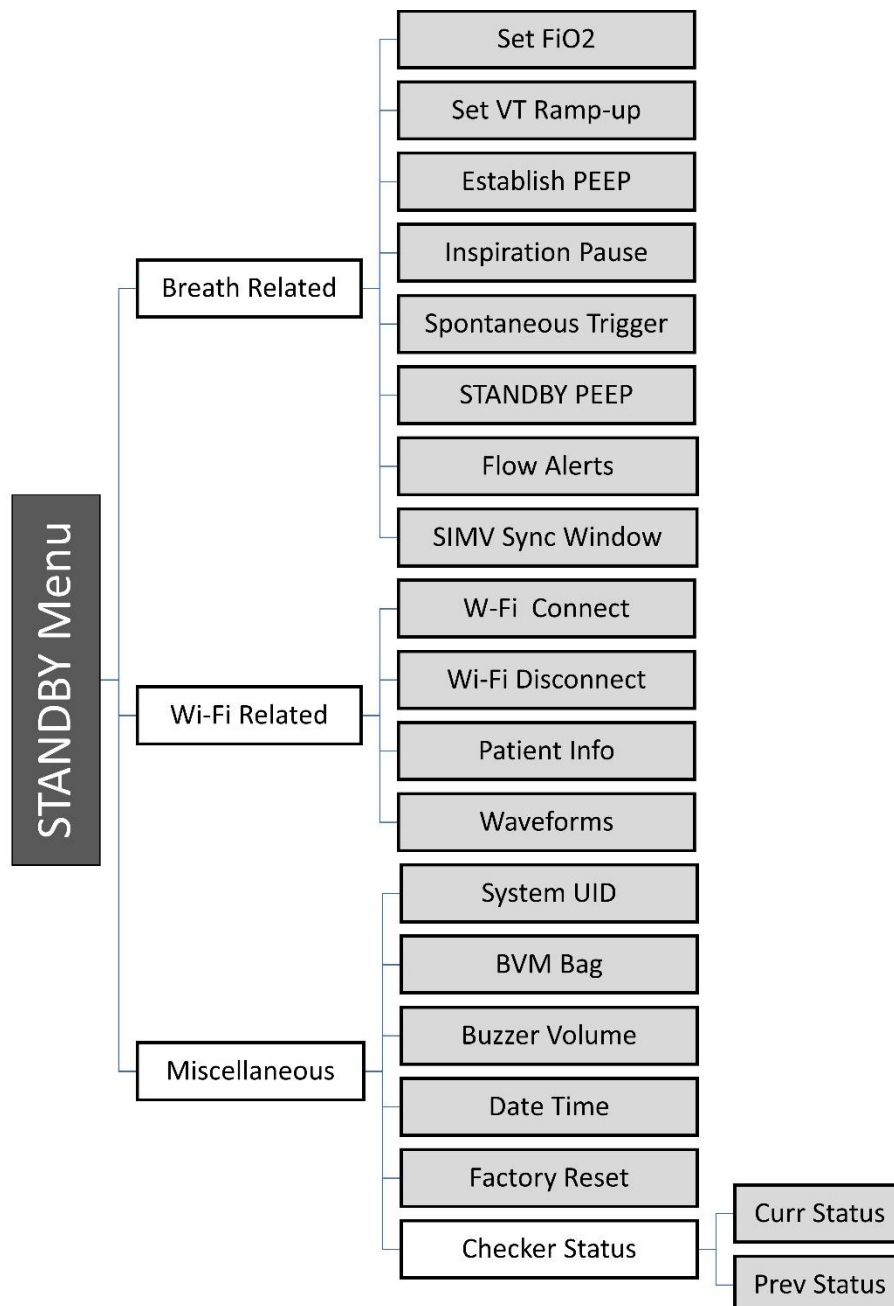
Figure 22: STANDBY Menu Hierarchy

FiO₂ Settings

⚠️ **INSPIRE-100 does not directly measure FiO₂. Techniques such 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.
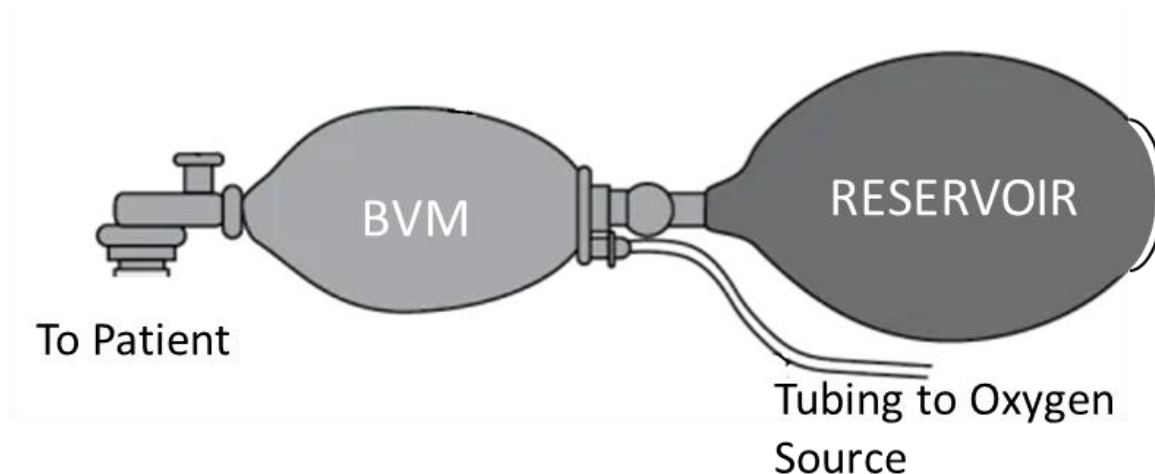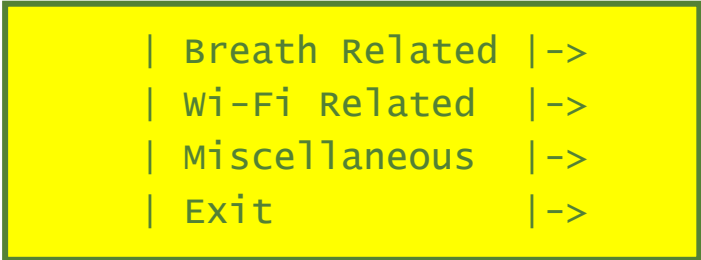
Figure 23: Oxygen Reservoir Connection

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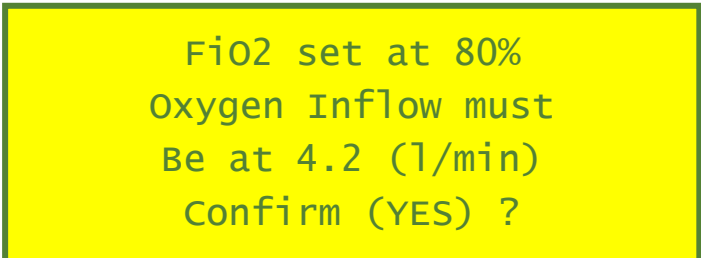
- Reservoir must be at least the volume of the BVM bag.
- The oxygen flow rate must be set as determined by the FiO_2 calculator. The required flow rate is displayed by the system automatically.
- The air inlet valve allows room air to enter if oxygen flow is inadequate.
- The outlet valve allows oxygen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

The 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 FiO_2. 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.
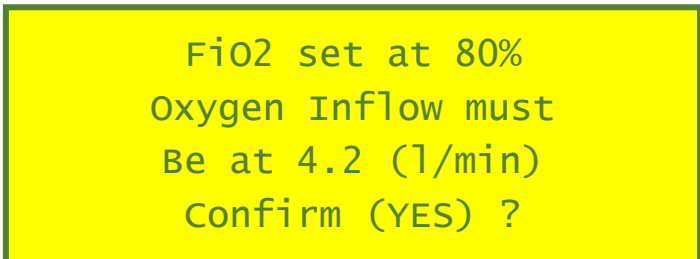
```
| Breath Related |->
| Wi-Fi Related  |->
| Miscellaneous  |->
| Exit           |->
```

```
   FiO2 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.

```
   FiO2 set at 80%
 Oxygen Inflow must
  Be at 4.2 (l/min)
   Confirm (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 (PMAX)
6. Oxygen Percentage (FiO$_2$)

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 (PMAX)
6. Oxygen Percentage (FiO$_2$)

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 (PMAX) 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 Synchronization in ACV Mode
e.g. RR=15 bpm (4 secs per breath)
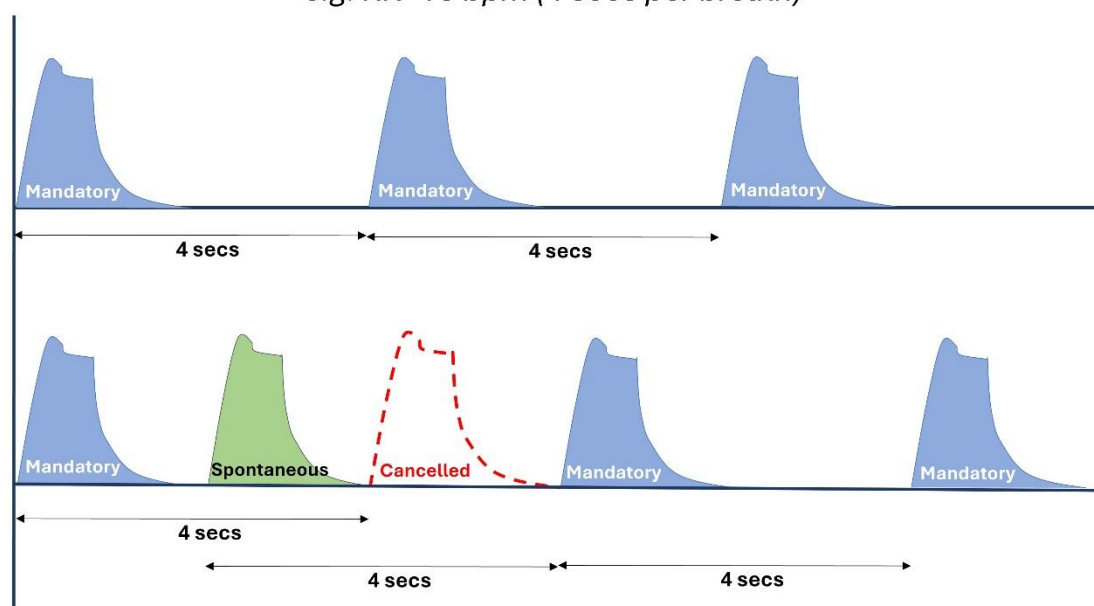
Figure 24: ACV Breath Synchronization

Synchronized Intermittent Mandatory Ventilation (SIMV)

In SIMV mode, a volume of air is delivered to the patient's lungs at periodic intervals subject to the following settings.
1. Tidal Volume (VT)
2. Respiration rate (RR)
3. Expiration/Inspiration ratio (E/I)
4. Peak End Expiration pressure (PEEP)
5. MAX Inspiration pressure (PMAX)
6. Support Pressure (PS)
7. PS Inspiration Termination (TPS)
8. Oxygen Percentage (FiO$_2$)

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. The pressure support will stop once the flow falls below a set percentage of the peak flow.
    - 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
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 (PMAX) 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). Note that the PS value is relative to PEEP.

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 Synchronization in SIMV Mode
e.g. RR=15 bpm (4 secs per breath)
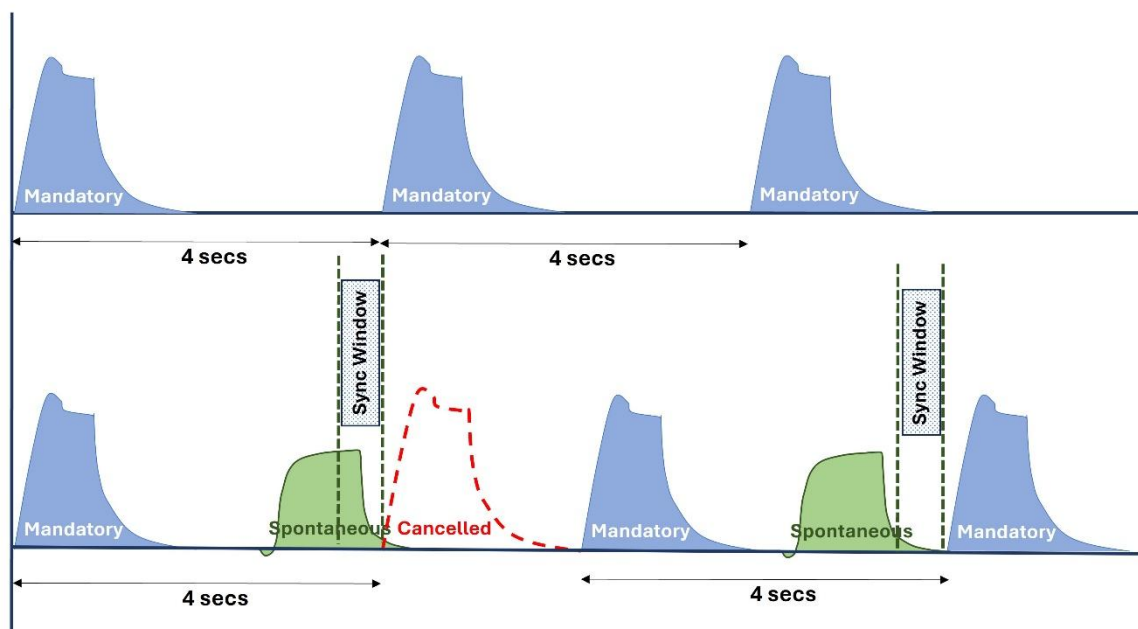
Figure 25: SIMV Breath Synchronization

Pressure Support Ventilation (PSV (BiPAP))

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 (BiPAP) . Violating the Minute-Volume will result in an ERROR.

The input settings to set on INSPIRE-100 should be as follows.

Mode=PSV (BiPAP) (The display changes to allow MV entry)
MV= 9.5 (litres/min)
PS = Desired Support Pressure. Note that the PS value is relative to PEEP.
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.
- 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 (PMAX) is breached. Also, monitor Plateau and PEEP pressure as usual.

Pressure supported breaths in PSV (BiPAP) 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.

Mandatory Breath in PSV Mode (Warning)
e.g. RR=15 bpm (4 secs per breath)
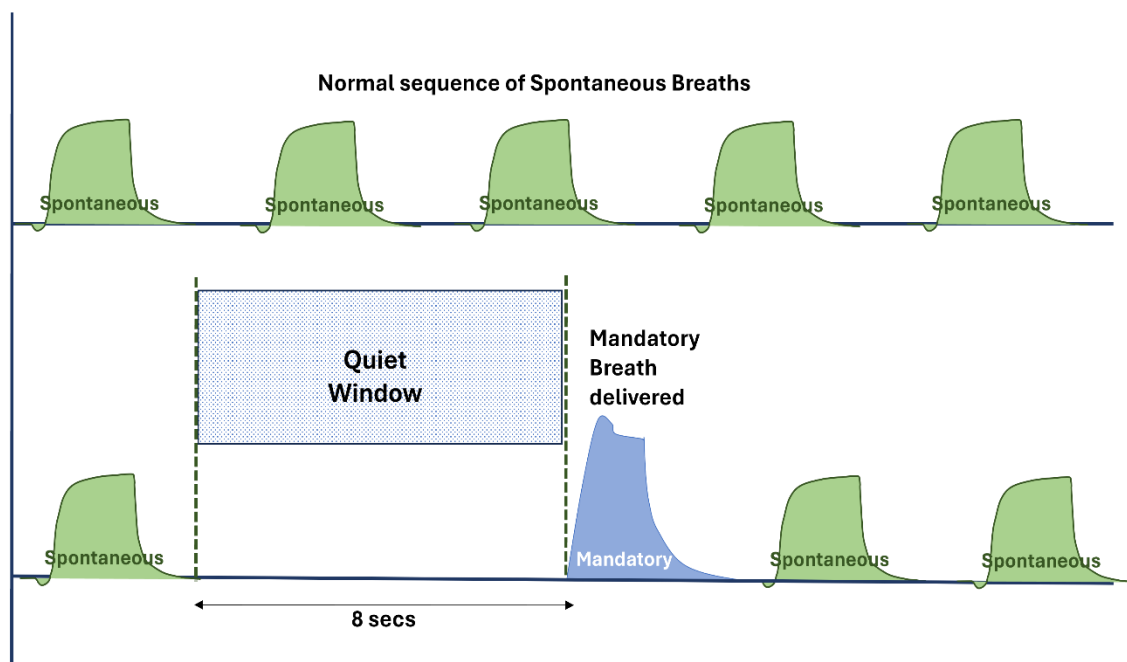
Figure 26: PSV Mandatory Breath

Bilevel Positive Airway Pressure (BiPAP)

The non-invasive BiPAP mode of ventilation is the same as the PSV mode with a patient mask. The table below is a quick comparison.

Comparison	PSV	BiPAP
Invasive/Non-invasive	Invasive	NIV
Needs an intact patient's drive to breathe	Yes	Yes
Patient triggered breaths are pressure supported	Yes	Yes
Constant pressure at the end of the breath	PEEP	EPAP
Pressure delivered when breath initiated	PS	IPAP
Patient controls inspiration duration and breath cycling	Yes	Yes

To emulate BiPAP using BiPAP terminology, set INSPIRE-100 ventilation mode to PSV, set PEEP to desired EPAP value, and set PS to desired IPAP value.

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 3: Control Mechanisms

Options for Ventilator Operating Parameters

Parameter	Options	Feedback	Control
Respiration Mode	CMV	CMV LED	UP / DOWN LEFT / RIGHT SELECTOR
	ACV	ACV LED	
	SIMV	SIMV LED	
	PSV (BiPAP)	PSV (BiPAP) 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)	3.0 through 18.0 in increments of 0.5	Selection displayed on a 3-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Respiration Rate RR (bpm)	10 through 30 in increments of 1	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR
E:I Ratio	1	Selection displayed on a 1-digit display	UP / DOWN LEFT / RIGHT SELECTOR
	2		
	3		
PEEP Pressure PEEP (cm H_2O)	4 through 15 in increments of 1	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Max Inspiratory Pressure PMAX (cm H_2O)	20 through 50 in increments of 5	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Support Pressure PS (cm H_2O)	5 through 30 in increments of 1	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR
Termination of Support Pressure TPS (% Peak Flow)	Flow-triggered (20%to 50%)	Selection displayed on a 2-digit display	UP / DOWN LEFT / RIGHT SELECTOR

Table 4: Ventilator 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 display	Updated after each breath
Plateau Pressure PLAT (cm H$_2$O)	Mean Pressure for PS Breaths	Measured Number displayed on a 2-digit display	Updated after each breath
PEEP Pressure PEEP (cm H$_2$O)		Measured Number displayed on a 2-digit display	Updated after each breath
Minute Volume (litres/min)		Estimated numbers displayed on the LCD screen.	Updated after each breath. Displays info for the previous minute.
Breaths per minute Mandatory/Spontaneous (bpm)		Measured numbers displayed on the LCD screen.	Updated after each breath. Displays info for the past minute.
Instantaneous Static and Dynamic Lung Compliance (ml/cm H$_2$O)		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	
Ventilator State	INITIALIZE	White LED	Displays the current state of the system.
	STANDBY	Yellow LED	
	ACTIVE	Green LED	
	ERROR	Red LED	

Table 5: 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 (BiPAP) Minute Volume Alarm

In PSV (BiPAP) 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 (BiPAP) 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 is 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

In the unlikely case of a motor fault, 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.

Executing Pre-Use Checks

It is a MUST to execute a set of pre-use checks before connecting a patient to the ventilator. 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        |->
| Exit            |->
```

Figure 27: 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.
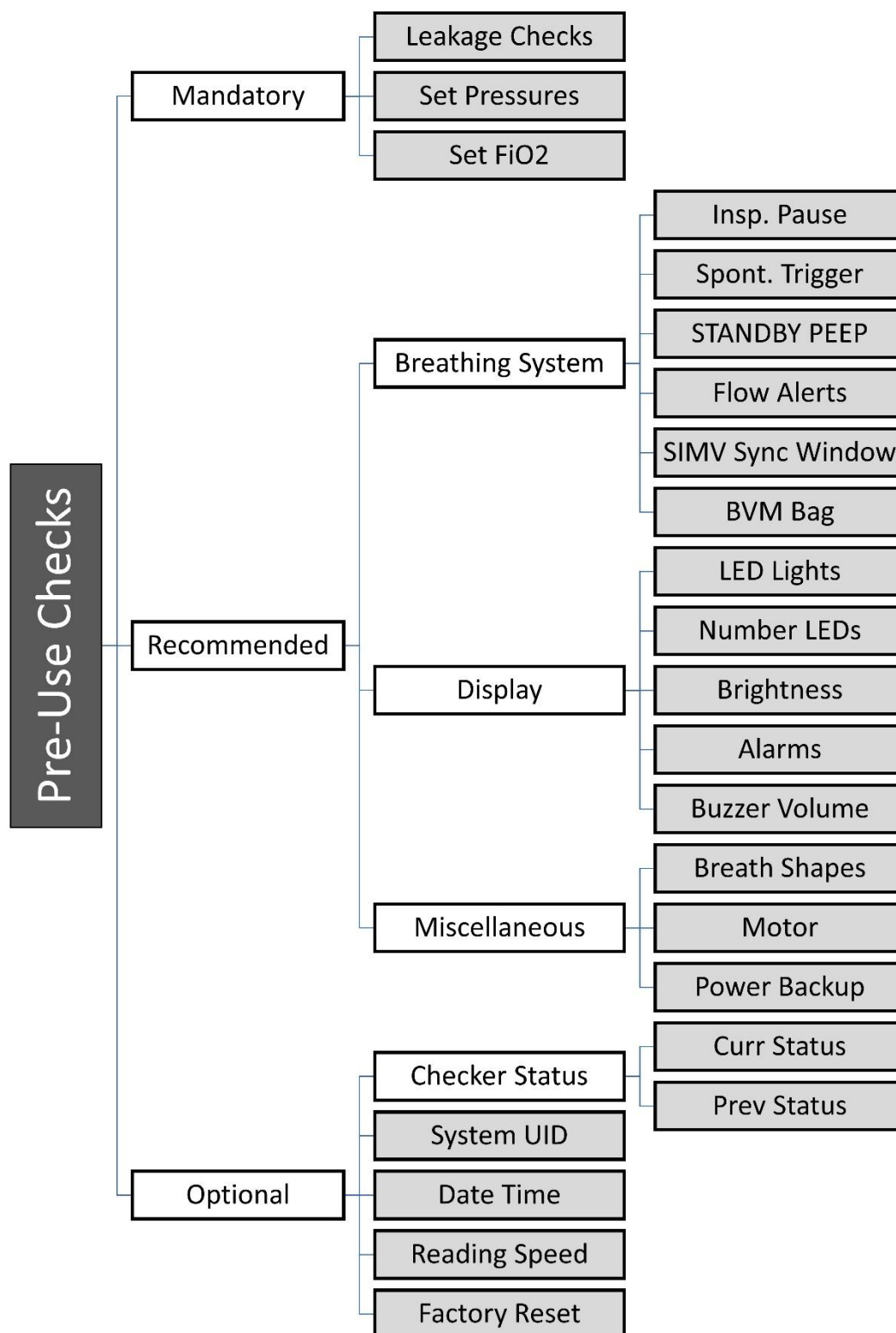

Figure 28: Menu Hierarchy of Pre-Use Checks

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.

Leakage Checks

On every power-up of the system, checks must be performed to ensure that the pressure lines are connected properly and there is no leakage. 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 when prompted with the palm of your hand.

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 FiO$_2$

1. Set the required FiO$_2$ level and the incoming Oxygen purity level.
2. The system will calculate the incoming Oxygen flow rate required to achieve the required FiO$_2$.
3. Note that the incoming Oxygen flow rate must be controlled externally 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 Ventilator. 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.

Standby PEEP
By default, the system tries to maintain PEEP at the set value while it is in STANDBY state. This menu item can be used to enable/disable this action.

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.

	ERROR	CAUSE	ALARM	COMMENTS
Errors: Pre-Use Checks	**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 6: 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 check for pressure leaks or airway blockage.

- 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 settings.

- Constant checking of Motor malfunction conditions.

- System Temperature monitoring and alarms.

- BVM end-of-life monitoring and alarms.

- Alerts for when it is time for system servicing.

- Storing of the results of checks in non-volatile memory for later retrieval.
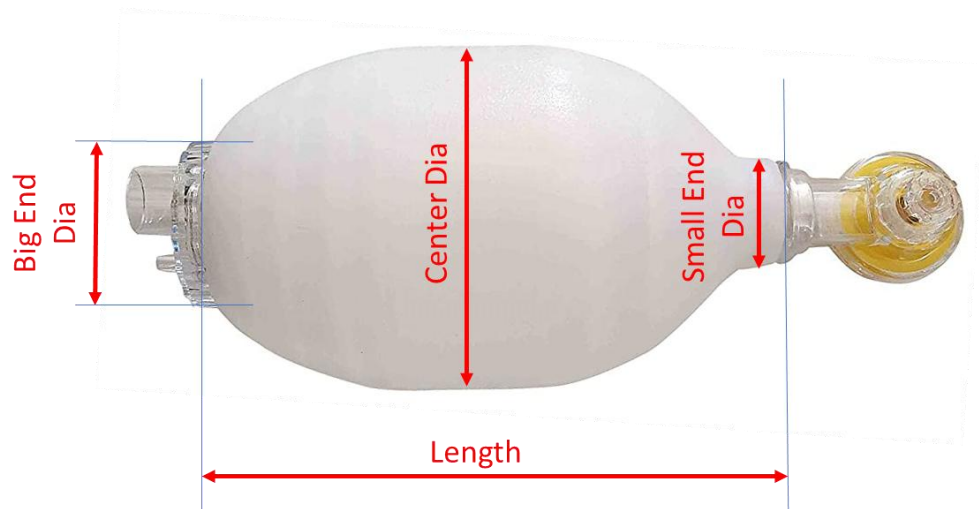
BVM (AMBU) Bag Specifications

Figure 29: BVM Bag

	Units	Min	Max
Length	mm	210	215
Center Diameter	mm	115	125
Big End Diameter	mm	60	65
Small End Diameter	mm	25	30
Connector Diameter	mm	22	22
Volume	ml	1600	1800

Table 7: 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 8: INSPIRE-100 Power Supply

System Specifications

CATEGORY	SPECIFICATION
General Standards Compatibility	ISO 13485:2016 ISO 9001:2015
EMC Compatibility	IEC 60601-2
Patient Range (Kg)	30 Kg to 100 Kg
Operating Temperature Range	-30 to +55 degC
Input Power Supply Range	200V – 250V
Power Consumption	<100 Watts
Dimensions	34 x 46 x 60 cm
Weight	30 Kg
Breathing System Connectors	Industry Standard

Table 9: Ventilator Specifications

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