

INSPIRE - 100

An Emergency Ventilator Device



***Frequently Asked
Questions***



Table of Contents

Glossary of Acronyms	3
Why is INSPIRE-100 less expensive than the competing products?	4
Why is INSPIRE-100 suitable only for adult patients?.....	4
What is Non-invasive ventilation?	5
What is Invasive ventilation?	5
How do you decide between Invasive and Non-Invasive ventilation?	5
What is “weaning”?	5
What is a BVM bag?	6
When should the BVM bag be replaced?	6
What is an oxygen reservoir?	6
What is a PEEP valve?	7
What is a HEPA/HME filter?	7
What is a Non-Rebreathing valve?	8
What is respiratory dead space?.....	8
Does INSPIRE-100 support BiPAP ventilation mode?.....	9
Why block the breathing outlet during pre-use checks?.....	10
Does INSPIRE-100 monitor FiO2?	10
Why is the target pressure or volume not achievable sometimes?.....	10
Which parts should be replaced or cleaned between patients?	10
What patient monitoring is recommended with INSPIRE-100?	11
Why does INSPIRE-100 ask for deployment altitude?	11
Where is the WEB dashboard recording saved?	11
Why does the Dashboard occasionally report Packet loss?	11

Glossary of Acronyms

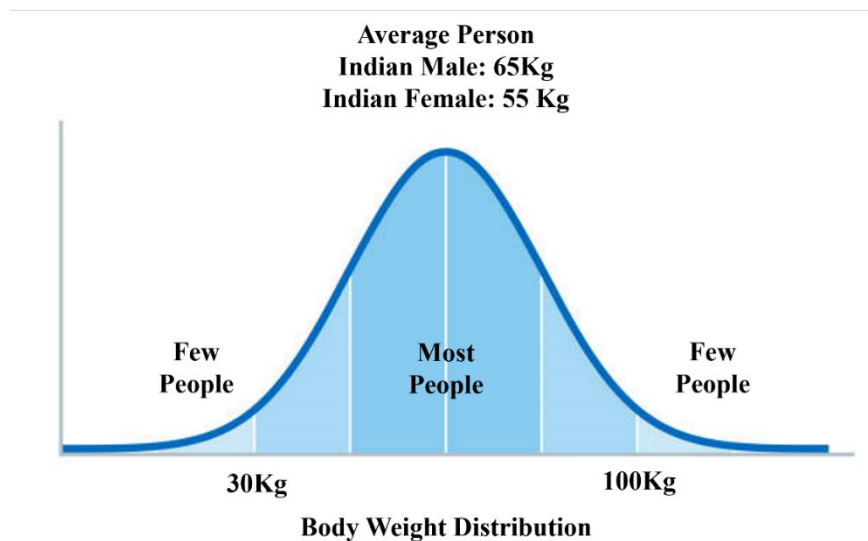
The table below summarizes all the abbreviations used in this document.

Symbol	Variable	Description
VT	Tidal Volume	Volume of air delivered each inspiration phase (ml)
RR	Respiratory Rate	Breaths per minute
E/I	Expiration/Inspiration ratio	Ratio of expiration vs inspiration time in a breath cycle
PMAX	Max Inspiration Pressure	MAX inspiration pressure never to be exceeded (cm H ₂ O)
PEAK	Peak Inspiration Pressure	Max pressure during Inspiration phase of breath delivery (cm H ₂ O)
PLAT	Plateau Pressure	Plateau pressure during breath delivery (cm H ₂ O)
PEEP	Peak End Expiration Pressure	Pressure in the lungs that exists at the end of expiration (cm H ₂ O)
PS	Pressure Support	Level of support pressure to assist 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 controlled (%age of Peak Flow) or Time controlled (secs).
FiO ₂	Fraction of Inspired Oxygen	Concentration of oxygen in the inspired air. This is guided by the system but controlled outside the system in the Oxygen source. (%age)

Why is INSPIRE-100 less expensive than the competing products?

The INSPIRE-100 focuses on essential features for 95%+ of patients, using proprietary algorithms instead of expensive sensors to reduce costs. Rarely used features for outliers are excluded to keep the price down.

- Design for the Bell curve to cover 95%+ of patients.
- Proprietary Algorithms in lieu of some expensive sensors.
- Essential Features must be included regardless of cost.
- Conversely, Costly Features should be included only if essential.



For instance, the figure above shows the weight distribution of adults in India as just one example of designing for the bell-curve. There will be a miniscule percentage of patients who are above 100Kg or below 30Kg in weight and may require the rarely used features of a more expensive ventilator, but the assertion is that the bulk of patients should not be burdened by the cost of providing for the outliers.

Why is INSPIRE-100 suitable only for adult patients?

The main difference between adult and paediatric ventilators is the range of flows and volumes they can deliver. The ranges that INSPIRE-100 can deliver are suitable only for adult patients.

Neonatal and Paediatric ventilators deliver lower flows and volumes at faster rates and deliver breaths with a shorter response time to patient-triggered effort compared to adult ventilators.

What is Non-invasive ventilation?

Using a face mask to get air from the ventilator into your lungs is called non-invasive ventilation. The face mask fits tightly over the patient's nose and mouth to help the patient breathe. This method is recommended if the patient's breathing problems are not severe enough to require a breathing tube. This method is also used to help the patient get used to breathing on his own after the breathing tube is removed.

The benefits of this type of ventilation are as below.

- It can be more comfortable than a breathing endotracheal tube.
- It allows the patient to cough.
- The patient may be able to talk and swallow.
- The patient may need less sedatives and pain medicines.
- It lowers some risks, such as pneumonia, that are associated with an endotracheal tube.

What is Invasive ventilation?

In more serious cases, a breathing tube is placed into the patient's windpipe, and the breathing tube (also called an endotracheal tube) is connected to a ventilator that blows air directly into the patient's airways. The process of inserting the tube into the patient's windpipe is called intubation.

Usually, the breathing tube is inserted into the patient's nose or mouth. The tube is then moved down into the throat and windpipe. The endotracheal tube is held in place by tape or a strap that fits around the patient's head.

How do you decide between Invasive and Non-Invasive ventilation?

This decision is the responsibility of the attending Intensivist / Pulmonologist. It is pertinent to point out that there are many recent studies that point to the efficacy and lack of complications from a Non-Invasive ventilation strategy. There are instances where Invasive Ventilation is the only option.

What is “weaning”?

"Weaning" is the process of gradually reducing ventilator support to the point when the patient can start breathing on his own. Once the patient shows that he can successfully breathe on his own, he is disconnected from the ventilator.

What is a BVM bag?

A bag valve mask (BVM), sometimes referred to as an Ambu bag or a Manual Resuscitator Bag, is a self-inflating bag used to provide ventilation to the person not breathing normally. It consists of a self-inflating bag, one-way valve, mask, and an oxygen reservoir.



When should the BVM bag be replaced?

BVM bags have a limited lifetime, and should be replaced if they fail to deliver desired pressures/volumes, show signs of fatigue, or between patients. The system issues a warning when it is time to replace the one in use. In addition, the BVM bag should be monitored for signs of fatigue every 4 hours of use. Inspire-100 has been tested with the Surginatal Disposable Resuscitator.

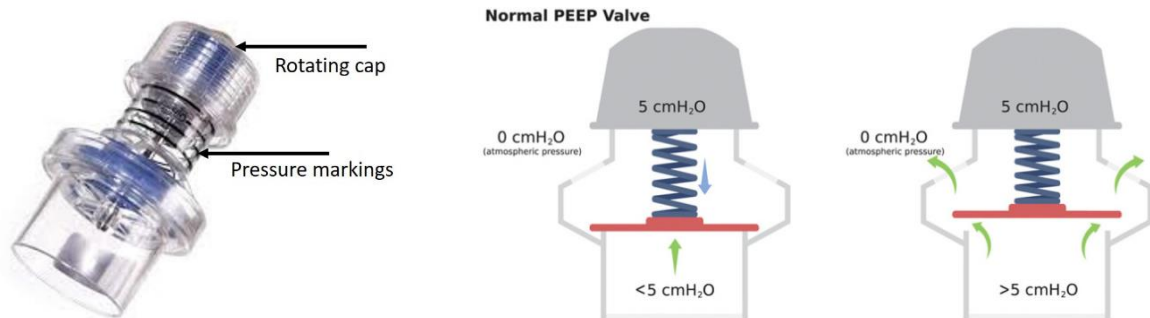
What is an oxygen reservoir?

A bag valve mask can be used without being attached to an oxygen tank to provide "room air" (21% oxygen) to the patient. However, BVM devices also can be connected to a separate bag reservoir, which can be filled with pure oxygen from a compressed oxygen source, thus increasing the amount of oxygen delivered to the patient.

An oxygen reservoir has two one-way valves. The properties of the reservoir are as below.

- Reservoir must be at least the volume of the bag.
- Oxygen flow rate equal to, or higher than, the minute volume of the patient allows 100% oxygen to be delivered.
- Inlet valve allows room air to enter if fresh gas flow is inadequate and an outlet valve allow oxygen to flow out if pressure is excessive.

What is a PEEP valve?



PEEP valves are adjustable pressure release valves. They are commonly used in conjunction with bag valve masks (BVMs) and vent exhaled gases to the atmosphere. When the pre-valve pressure exceeds the valve setpoint, a diaphragm opens and allows flow. When pre-valve pressure drops below the valve setpoint, the diaphragm closes and flow across the valve stops.

What is a HEPA/HME filter?



Heat and Moisture Exchanger Filter (HMEF) is usually incorporated with a microbiological filter that provides passive humidification.

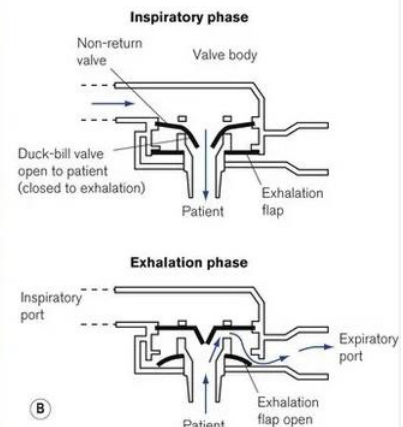
A pleated high-performance HEPA filter is integrated with Heat and Moisture Exchanger (HME) to support infection control in ventilation treatment.

These filters typically include a gas sampling port with tethered strap and cap.

Hydrophobic media supports bacterial/viral efficiency of 99.99%.

What is a Non-Rebreathing valve?

Non-rebreathing valves prevent rebreathing of the gases by ensuring unidirectional flow of gases. The inhaled and exhaled gases follow different paths, and the exhaled gas never finds its way into the inhalation tube.

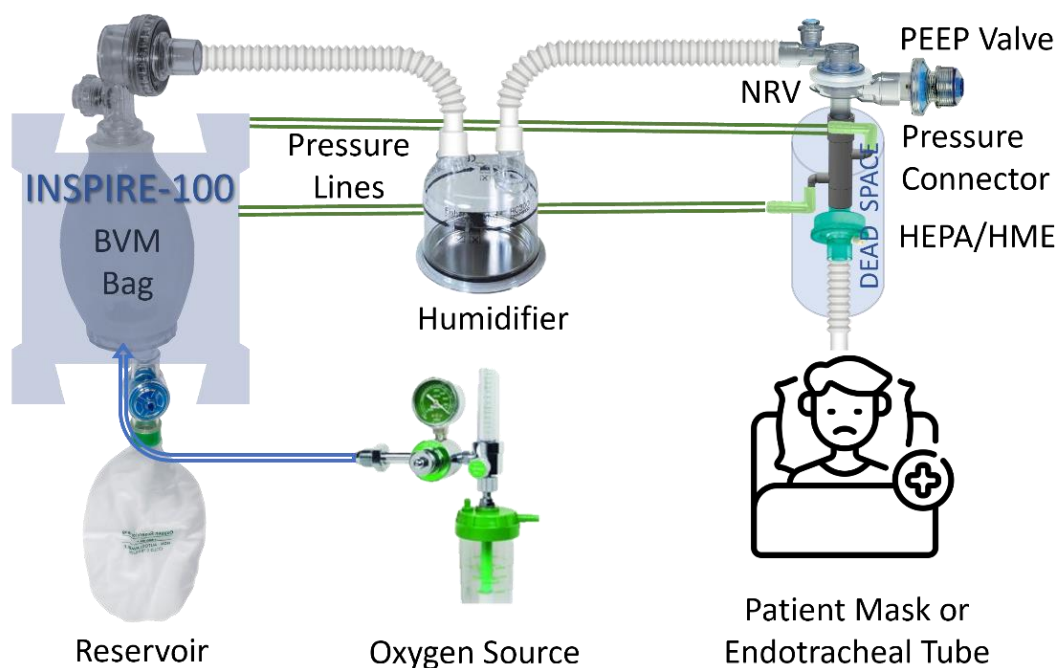


What is respiratory dead space?

Dead space simply means volume in the respiratory circuit that does not participate in gas exchange in the lungs. Gas exchange occurs at the alveoli in our lungs so every anatomical structure above it is dead space. This includes the nasal/oral passages, pharynx, larynx, trachea, and the bronchi.

In a patient who is not on a ventilator, the source of gas is the ambient air, and the anatomical dead space starts at the mouth opening. In a ventilator patient, the source of gas is the ventilator and its tubing.

The breathing circuit for Inspire-100 is as in Figure below. The blue-cylindrical area is the ventilator dead space. The key point is that the inspiratory limb is constantly filled with fresh gas and can be thought of as an extension of the ventilator itself. So, for all practical purposes, the source of gas in a ventilated patient is the Non-Rebreathing-Valve component of the ventilator circuit.



Any equipment that is between the patient and the Non-Rebreathing-Valve constitutes dead space (in addition to the anatomical dead space itself). At minimum, this includes the endotracheal tube in an intubated patient. Other potential sources include heat and moisture exchanger (HME) etc. It is important that the Non-Rebreathing-Valve be placed as close to the patient as possible to reduce dead space to a minimal.

Does INSPIRE-100 support BiPAP ventilation mode?

A non-invasive BiPAP mode of ventilations is similar to PSV mode with a patient mask. 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.

There is an additional feature provided by INSPIRE-100 via the Minute Volume parameter. If the Minute Volume parameter is set to anything other than “---” (don’t-care), the minute volume is monitored during PSV mode and alarms are issued if the measured value falls short of the desired set value. If this condition persists, the PSV mode is replaced by SIMV mode automatically.

Why block the breathing outlet during pre-use checks?

INSPIRE-100 has two pressure tubes connecting to the system from the breathing circuit. These are the upstream and downstream pressure tubes respectively. The system checks for proper connection of the upstream and downstream pressure tubes by detecting the blocked outlet.

Since it is not advisable to have the patient connected during Pre-use checks, a simpler process is to simply block the breathing tube outlet with the fleshy portion of your palm to enable the system to perform this check.

Does INSPIRE-100 monitor FiO2?

INSPIRE-100 doesn’t have an internal oxygen sensor. You can use an accessory FiO2 monitor, and SpO2 pulse oximetry to monitor patient oxygenation. See the Inspire-100 Operating Manual for more information on FiO2 flow and minute ventilation.

Why is the target pressure or volume not achievable sometimes?

It depends upon the size of the BVM bag and whether it is fatigued. Adjust the respiratory rate (RR) or inspiratory to expiratory time ratio (I:E ratio). Check the breathing system for obstructions or kinks. Replace the BVM bag.

Which parts should be replaced or cleaned between patients?

Replace all parts outside of the INSPIRE-100 chassis between patients. These include the external ventilator tubing, filters, HME, patient valve assembly, and pressure sensing tubing. The BVM bag, inside the chassis, should also be replaced between patients.

What patient monitoring is recommended with INSPIRE-100?

It is recommended to monitor patient arterial blood gases and SpO₂, at a minimum. If you use Assist Control, it is also recommended that you conduct CO₂ monitoring as well.

Why does INSPIRE-100 ask for deployment altitude?

The system uses the altitude to determine ambient pressure and oxygen content for its algorithms. This information only needs to be entered once during installation or relocation. Once entered, the system stores and uses this information for all subsequent runs.

Where is the WEB dashboard recording saved?

INSPIRE-100 dashboard saves the recording database in the browser on the disk of the computer being used. Thus, the recording saved on one browser is not directly available on another browser even though it may be on the same computer. Use the import/export feature to transfer the recording database between browsers or between computers.

Once created, the recording is accessible forever unless explicitly deleted by the user. Both the Recorder and Playback Apps allow deletion of selected recordings.

Why does the Dashboard occasionally report Packet loss?

The INSPIRE-100 system communicated with the remote Dashboard via the local Wi-Fi followed by the Internet in the cloud. Occasional packet loss can occur due to internet congestion when communicating with the remote dashboard.

The Dashboard indicates the missing interval but does not stop monitoring and the rest of the intervals are correctly captured and displayed.