AVI Healthcare Pvt Ltd

Manufacturing Medical Equipment "Glocally"

ICU Ventilators

VIHA dv10

This Instructions for Use (IFU) is intended for trained healthcare professionals and authorized personnel.

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User Operation and Maintenance Manual

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Responsibility of the User

- This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided.
- This Product must be checked for any damages due to transportation before using it for the first time. A damaged product should not be used; AVI Healthcare Private Limited must be notified via telephone or email.
- This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. For any kind of repair or replacement, AVI Healthcare Private Limited must be notified via telephone or email.
- This Product or any of its parts should not be repaired other than in accordance with written instructions provided by AVI Healthcare Private Limited and by AVI Healthcare Private Limited's trained personnel.
- The Product must not be altered without the prior written approval of AVI Healthcare Private Limited.
- The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than AVI Healthcare Private Limited.
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- AVI Healthcare is by no means responsible for any malfunction arising from a user ignoring the instructions for operation and maintenance described in this Manual as well as for any accident attributable to repair by someone other than technical personnel belonging to AVI Healthcare

Responsibility of Manufacturer

AVI Healthcare Private Limited only considers itself responsible for any effects on safety, reliability and performance of the Equipment if:

- The electrical installation of the relevant room or vehicle complies with the IEC or national requirement.
- The instrument is used according to the instructions for use presented in this manual.

Quality

AVI Healthcare Private Limited is a certified EN ISO 13485:2016 company and confirms to the standards set by the ISO as well as Indian Medical Device Rules, 2017.

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About this Manual

Scope

This manual provides a comprehensive description of the components of ICU Ventilators and its operation, installation and maintenance details. Detailed technical information has been enumerated for the benefit of the user to facilitate correct and effective application of the device. AVI Healthcare is by no means responsible for any malfunction arising from a user ignoring the instructions for installation, operation and maintenance described in this Manual as well as for any accident attributable to repair by someone other than technical personnel belonging to AVI Healthcare.

Indications for Use

To provide temporary support to patients with respiratory trouble

Intended Patient Population

1. Adult: 50 – 200 kg
2. Pediatric: 5 – 50 kg (VT <= 350mL)
3. Neonates: 0.4 – 5 kg

Intended Users

This device should only be operated by healthcare providers under the direct supervision of a licensed healthcare practitioner who are trained in its operation and familiar with the risks of this type of device. It must be operated according to the Instruction for use (User / Operating manual) provided.

Intended Purpose/use

ICU Ventilators – VIHA dv10 is developed to supply invasive and non-invasive ventilatory support to patients with impairment of respiratory functions in intensive or semi-intensive care, post- operative care, post-anaesthetic recovery (PAR) or intra- hospital transport. It is to be used under the direct supervision of a licensed healthcare practitioner.

List of Abbreviation/Definition

Abbreviation	Description
Apnea Time	Detect lack of breathing by measuring time since last expiration
$C_{Dynamic}$	Dynamic lung compliance
C_{static}	Static lung compliance
EtCO2	End-tidal carbon dioxide
Exp Breath Window	Expiratory spontaneous breathing window
FiO_2	Fraction of inspired oxygen
$FLOW_{Peak\_exp}$	Peak expiratory flow (Minimum negative patient flow during expiration)
$FLOW_{Peak\_insp}$	Peak inspiratory flow (Minimum negative patient flow during inspiration)
Flow cycle trigger	Used for triggering pressure support expirations in modes where PS is allowed, set as a percentage of maximum flow in PS inspiration
Flow trigger	Triggering synchronised breaths using flow
I: E	Inspiratory time to Expiratory time ratio
I: E Ratio, I Set	I factor of I: E Ratio if I set > 1.0 it becomes Inverse I: E ratio Ventilation
I: E Ratio, E Set	E factor of I: E Ratio
Insp Breath Window	Inspiratory spontaneous breathing window
Insp Flow	Inspiratory flow
Leakage Comp.%	Leakage Compensation volume % setting of the set Tidal Volume VT ml
LPO	Low Pressure Oxygen mode

HPO	High Pressure Oxygen mode
HFNO	High Flow Nasal Oxygen
Max PRVC	Maximum pressure in PRVC mode
Min PRVC	Minimum pressure in PRVC mode
MV_e	Expiratory Minute Volume
$MV_{e\ Mand}$	Mandatory expiratory minute volume
$MV_{e\ Spon}$	Spontaneous expiratory minute volume
MV_i	Inspiratory Minute Volume
$MV_{i\ Mand}$	Mandatory inspiratory minute volume
$MV_{i\ Spon}$	Spontaneous inspiratory minute volume
IV	Invasive Ventilation
NIV	Non-invasive Ventilation
No.	Number
O/P Flow	Output Flow
P0.1	Pressure built up by the patient in 100ms during inspiration against closed valve
PaCO2	Partial Pressure of Carbon Dioxide in arterial blood
P_{aw}	Airway Pressure (measured at the patient)
PRVC	Pressure Regulated Volume Controlled in modes, which adapt the inspiratory pressure set point to realize an operator set target volume
PEEP	Positive End-Expiratory Pressure
P_{high}	High level pressure set in APRV mode
PBW	Predicted Body Weight for Pediatric & Adult patient type
P-id	Patient ID
P_{insp}	Inspiratory pressure set in pressure controlled modes
PIP	Peak Inspiratory Pressure (highest pressure reached during the inspiration)
P_{max}	Maximum pressure (safety systems make sure this pressure can't be exceeded)
P_{mean}	Mean pressure
$P_{plateau}$	Plateau pressure (pressure at the end of inspiration)
Pressure Trigger	Triggering synchronised breaths using pressure
PS	Pressure Support
PS above PEEP	Pressure Support above PEEP
PS above P_{high}	Pressure support above P_{high}
PS above PIP	Pressure Support above PIP
Rise time	time to reach the selected airway pressure
RC_{exp}	Expiratory RC time
RC_{insp}	Inspiratory RC time
RL_{ung}	Lung Resistance
RR bpm	Respiratory rate, amount of breaths per minute [bpm] or [1/min]
RR_{Mand}	Mandatory respiratory rate, amount of spontaneous breaths per minute [bpm] or [1/min]
RR_{Spon}	Spontaneous respiratory rate, amount of spontaneous breaths per minute [bpm] or [1/min]
RSBI	Rapid shallow breathing index [1/(L*min)], measure for successful spontaneous activity

T_{exp}	Expiration Time set
T_{high}	Time set for which High level pressure (P_{high}) will be delivered in APRV mode
T_{insp}	Inspiration time set
T_{peep}	Time set for which Low level pressure (PEEP) will be delivered in APRV mode
Rise Time	Time required to achieve Pinsp pressure from PEEP level
Trigger sensitivity	Spontaneous detection sensitivity
V_{leak}	Total Leak Volume
VT	Set Tidal Volume
VT_e	Expiratory tidal volume per stroke
$VT_{e\ Mand}$	Expiratory tidal volume per stroke of the mandatory strokes
$VT_{e\ Spon}$	Expiratory tidal volume per stroke of spontaneous strokes
VT_i	Inspiratory tidal volume per stroke
$VT_{i\ Mand}$	Inspiratory tidal volume per stroke of the mandatory strokes
$VT_{i\ Spon}$	Inspiratory tidal volume per stroke of spontaneous strokes

List of Units

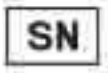
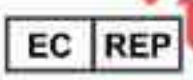
Abbreviation	Description
bpm	Breath Per Minute
cmH2O	Centimetre of water
dB	Decibel
Hz	Hertz
L/min (LPM)	Litre per Minute
Kg	Kilogram
kPa	Kilopascal
mAh	Milli Ampere hour
mbar	Millibar
ml	Milli litre
mm	Millimetre
mmHg	Millimetre(s) of mercury
ms	Millisecond
psi	Pounds per square inch
sec	Seconds
VAC	Volts Alternating Current
VDC	Volts Direct Current
°C	Degree Celsius
%	Percentage

List of Symbols

Symbol	Meaning
	General Warning
	Caution
	Do not re-use

	Protective Earth
	Person, general; patient, normal
	Baby
	Respiratory Mask

Symbols used on Equipment label

Symbol	Meaning
	Alternating Current
	Temperature Limitation
	Humidity Limitation
	Type B Applied Part
	Serial Number
	Model number
	Name and Address of Manufacturer
	Country of manufacture / Date of manufacture
	Name and address of EU representative
	Refer to Instruction manual/booklet
	Medical Device
	Unique Device Identifier
	CE mark symbol
	WEEE symbol

Symbols used on Packaging

	This way up
	Fragile, Handle with Care

	Keep dry
	Keep away from sunlight

MANUFACTURER'S DECLARATION – ELECTROMAGNETIC COMPATIBILITY

The equipment has been tested according to standard IEC 60601-1-2. AVI Healthcare Private Limited declares the compliance of the device with the EMC requirements based on the test reports.

EMC GUIDANCE

Changes or modifications to this system not expressly approved by AVI Healthcare Private Limited could cause EMC failures with this or other equipment. This system is designed and tested to comply with applicable regulation regarding EMC and needs to be installed and put into service according to the EMC information stated as follows:

NOTE:

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

⚠ **WARNING:**

- Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ICU Ventilators including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. If adjacent or stacked use is necessary, the ICU Ventilators should be observed to verify normal operation in the configuration in which it will be used.
- If the ICU Ventilators momentarily switches off due to electrostatic discharge, then the operator should restart the unit after five minutes.
- MR UNSAFE. Keep away from magnetic resonance imaging (MRI) equipment. The device poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

Manufacturer's guidance and declaration regarding electronic emissions

The ICU Ventilators are intended for use in the electronic environment specified below. The user of the ICU Ventilators should ensure that it is used in such an environment.

EMC Sheet		
Particulars	Conforms to IEC 60601-1-2 as per the following tests conducted.	
Test Type	**Test Parameters Complied to**	**Electromagnetic environment guidance**
Radiated Emission	CISPR 11: Group 1- Class A	The ICU Ventilators use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The ICU Ventilators are suitable for hospital and clinic use only, other than domestic and
Mains terminal disturbance voltage (Conducted Emissions)	CISPR 11: Group 1- Class A	

Harmonic current Emissions	IEC 61000-3-2	those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage changes, voltage fluctuation and flicker EMISSIONS	IEC 61000-3-3	
Electrostatic Discharge Immunity IEC 61000-4-2	± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%
Electrostatic Discharge Immunity IEC 61000-4-2	± 8 kV Contact Discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/ burst Immunity IEC 61000-4-4	±2kV for power supply lines	Mains power quality should be that of a typical hospital environment.
Surge Immunity IEC 61000-4-5	Differential Mode: ± 0,5 kV, ± 1 kV Common Mode: ± 0,5 kV, ± 1 kV, ± 2 kV	Mains power quality should be that of a typical hospital environment.
Power frequency magnetic field Immunity IEC 61000-4-8	30 A/m @ 50 Hz	Power frequency magnetic fields should be at levels of a typical hospital environment.
Voltage dips, short interruptions and voltage variations Immunity IEC 61000-4-11	Voltage dips 0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle 70 % U_T; 25 cycles Single phase: at 0° Short interruptions 0 % U_T; 250/300 cycle U_T is the A.C mains voltage prior to application of test level.	Mains power quality should be that of a typical hospital environment. If the user of the ICU Ventilators requires continued operation during power mains interruptions, it is recommended that the ICU Ventilators be powered from an uninterruptible power supply or a battery.

Table of Contents

1.Safety Instructions

The following safety precautions must be observed during all phases of operation, service, and repair of this equipment. Failure to comply with these precautions, or with specific warnings elsewhere in this manual, violates safety standards of design, manufacture, and intended use of the equipment. The warnings, cautions and instructions in this section relate to the equipment in general and apply to all aspects of the equipment. Be sure to read the entire manual before use, because there are additional warnings and cautions that relate to specific features of the equipment. Follow the instructions given as per the manual.

This product is intended to be used by authorised and qualified medical personnel who are aware of currently known hazards and benefits of ICU Ventilators. This equipment must only be used for the specified purpose in the Intended use together with the appropriate monitoring.

1.1 General Instructions

- **The use of this equipment is restricted to one patient at a time.** It may pose severe risk to the patients if used for multiple patients at a time.
- The device is for hospital use only. It is not to be used at home. The equipment must be operated by qualified professionals, who must maintain vigilance during use. Do not leave the patient unattended while using the device.
- Do not use the device without a thorough understanding and knowledge of its operation, as it may risk patients as well as the user's life. Familiarize yourself with this operator's manual before using the ICU Ventilators on a patient.
- Before the first use or after each patient's use, clean and disinfect the equipment.
- After usage, the accessories MUST be disinfected and sterilized as per your hospital's guideline before its next use, whenever the same are reusable.
- All of the equipment's parts that came into contact with fluids from the patients must undergo a high-level disinfection process or sterilization when discarded or be discarded as potentially infected medical waste. Device disposition should be as per local/national guidelines.
- **To ensure the ICU Ventilators safe operation, it is recommended to always run the pre operational check i.e. check that the Displays are working properly and responding to touch, also System Check/ Calibration is done before using the ICU Ventilators on a patient.** If the ICU Ventilators fails any tests, remove it from clinical use immediately. Do not use the ICU Ventilators until necessary repairs are completed and all tests
- have been passed.
- It is the clinician's responsibility to ensure that all ICU Ventilators settings are appropriate, even when the standard settings are used.
- If there is visible damage to any part of the ICU Ventilators, do not use the device. Technical service is required. Do not use the equipment if the problem cannot be solved
- An alternative means of ventilation must be available whenever the ICU Ventilators is in use. If a fault is detected in the ICU Ventilators or its life-support functions are in doubt, disconnect the device from the patient and immediately start ventilation with such a device (for example, a resuscitation bag), using PEEP and/or increased oxygen concentration when appropriate. The ICU Ventilators must be removed from clinical use and serviced by AVI Healthcare authorized service engineers.
- Switch off the device and the mains power before replacing the fuse. Do not use the wrong fuse rating and type.
- Keep the equipment away from any kind of spillage of water or any other liquid.
- Please follow all the guidelines for safety of the patient as well as the use

1.2 General Operation And Important Check Points

A. Regular Monitoring:

- After the ventilation starts, verify if the ICU Ventilators parameters indicated by the monitor display are appropriate.
- Ensure that the clinical condition of the patient is regularly reviewed.

B. Standalone device:

- The device is not intended to be used in combination with other devices or any equipment for its intended purpose. The device is a standalone device maintaining the ventilation of the patient and does not require any other device or equipment to achieve the same.
- Any additional equipment used with the device must comply with respective IEC or ISO Standards; furthermore; all configurations shall comply with the requirements for medical electrical systems IEC 60601-1 general safety standard

C. Monitoring and Alarms

- The Alarms and Warnings must be promptly attended to in order to maintain the equipment's operation and the patient's security.
- The device is not intended to be a comprehensive vital sign monitor for patients on life-support equipment. Patients on life-support equipment should be appropriately monitored by qualified medical personnel and suitable monitoring devices. The use of an alarm monitoring system does not give absolute assurance of warning for every type of issue that may arise with the ICU Ventilators. Alarm messages may not exactly pinpoint a problem; the exercise of clinical judgment is necessary.

D. Power Supply

- The equipment has an independent power supply and its own battery backup system. The device is not intended to receive its power from other equipment.
- Connect an AC power cord to a three-pin socket. Do not use any multiple socket outlet or extension cords to connect the device to the power supply.
- Ensure that the power cord is connected properly before switching on the device.
- In the event of loss of main power, the unit will operate on battery.
- Proper earthing of the unit must be ensured to prevent Electrocution of the user.
- Ensure the power supply is continuous, earthed, approved for hospital use and complies with the voltage specified on the unit.

E. Battery

- Maintain the equipment connected to a power source even when it is turned ON and not in use, in order to maintain the internal batteries permanently charged
- Completely recharge the batteries after use or after a long stocking period, as the insufficient battery status can stop the operation, on any power outage.

F. Fire Safety:

- In case of fire, immediately secure the patient's needs, switch off the ICU Ventilators, and disconnect it from its gas and electrical sources.
- To reduce the risk of fire or explosion, do not place the ICU Ventilators in a combustible or explosive environment (for example, around flammable anaesthetics or other ignition sources) or insufficiently ventilated areas. Do not use it with any equipment contaminated with oil or grease. Highly compressed oxygen together with flammable sources could lead to spontaneous explosions. Do not keep flammable agents like ether or alcohol, may pose hazardous explosion.

G. Accessories:

- **For each new patient, always use a new or properly decontaminated breathing circuit.**
- To prevent patient or ICU Ventilators contamination, always use a HEPA/HME between the patient and the inspiratory port.
- For the neonatal patient, make sure to use the appropriate breathing circuit & Artificial airways (Y-piece, patient flow sensor, ET tube, CO2 airway adapter, etc.), which are meant for neonatal patient that minimises dead space.
- Check that the accessories are securely mounted.
- Do not fiddle with the breathing circuit while the device is in use as it may loosen the connection.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not lean on the device or any of its accessories; it may lead to imbalance of the device and can pose a risk to the patient.
- To ensure that all breathing circuit connections are leak-tight, perform the **Hose Compliance & Hose Resistance** every time you install a circuit or change a circuit part.
- Ensure that antistatic or electrically conductive hoses or tubing are not to be used in the ventilator breathing system.

Handling Instructions while using ICU Ventilators with Trolley:

- Always lock the castor wheels of the stand when the device is stand still and ensure that the wheels are unlocked while moving the device.
- Do not keep any object on the ICU Ventilators.

⚠ 1.3 Warning

- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- Do not cover the ventilator or place in a position that affects proper operation.
- Do not block the gas intake port or emergency intake port, thereby interfering with patient ventilation
- Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or serious deterioration of health
- Do not add any attachments or accessories to the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health
- The ICU Ventilators must not be used in a hyperbaric chamber. Such use might cause the device to not function correctly, causing patient death or serious deterioration of health
- The ventilator shall not be used with nitric oxide. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health
- The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health
- The accuracy of the ventilator may be affected by gases added to the ventilator breathing system via the use of pneumatic nebulizers. The device has inbuilt control to be compatible with the ultrasonic nebulizer, and users should follow the recommended guidelines for nebulizer use to ensure ventilator performance is not compromised.
- It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health
- When using nebulization or humidification, breathing system filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.

1.4 Basic Servicing Instructions

a. Switch off the unit, unplug the power cord of the ICU Ventilators before cleaning/maintenance/repair the unit.
b. Ensure all the ICU Ventilators parts and accessories are in place before returning the device to service.
c. Do not try to service/maintain/clean/disinfect the device while the device is in use.
d. Be aware that battery power remains even after the mains is disconnected.
e. To ensure proper servicing and to prevent possible physical injury, only AVI Healthcare authorized service personnel should attempt to service the ICU Ventilators.
f. Use replacement parts supplied by AVI Healthcare only. Any attempt to modify the ICU Ventilators hardware or software without the express written approval of AVI Healthcare automatically voids all warranties and liabilities.

⚠ 1.5 Possible Long Term Effects

a. Developing Pneumonia
b. Pneumothorax
c. Pulmonary Oedema
d. Lung Damage
e. Vocal cord damage
f. Weak diaphragm and other breathing muscle

1.6 Site Conditions – User Responsibility

The hospital/user is responsible for ensuring proper site readiness before installation and during use. Minimum requirements include:

- Stable electrical power supply within the specified voltage range
- Proper earthing/grounding as per standards
- Servo stabilizer/UPS where power fluctuations are common
- Clean, dust-free, well-ventilated, free from water-leakage or electromagnetic interference environment

NOTE:

- The device is for hospital use only and under the supervision of knowledgeable medical practitioner. It is not to be used at home.
- Please follow all the guidelines for safety of the patient as well as the user.
- The manufacturer will not be responsible for device malfunction, damage, or performance issues arising due to improper site conditions

2. General Information

2.1 Background

Mechanical ventilation helps patients breathe by assisting the inhalation of oxygen into the lungs and the exhalation of carbon dioxide. Depending on the patient's condition, mechanical ventilation can help support or completely control breathing by using them in prescribed modes.

AVI Healthcare's ICU Ventilators is specifically designed to provide ventilation and respiratory assistance, monitoring and treatment to neonate, paediatric and adult intensive care patients who cannot breathe on their own or who require assistance to maintain adequate ventilation in acute and sub-acute care surroundings. It provides invasive mandatory and supports non-invasive modes as well.

2.2 Clinical Advantages of using a ICU Ventilators

A ventilator is a device that supports or takes over the breathing process, pumping air into the lungs. People require ventilation if they are experiencing respiratory failure. When this occurs, a person cannot get enough oxygen and may not be able to expel carbon dioxide very well either. It can be a life-threatening condition. A ventilator pumps air usually with extra oxygen into patients' airways when they are unable to breathe adequately on their own. If lung function has been severely impaired due to injury or an illness, patients may need a ventilator. It is also used to support breathing during surgery. Ventilators, also known as life-support machines, won't cure an illness, but they can keep patients alive while they fight an infection, or their body heals from an injury. Without ventilation, such a patient would likely die, or his/her health would deteriorate. The benefits are thus the remaining lifetime of the patient as he/she survives with as little deterioration of his/her health due to the absence of ventilation or ventilator support as possible.

2.3 Introduction

The VIHA dv10 ICU Ventilators are intended to provide positive pressure ventilation support to adults and paediatrics, and infants/neonates.

Ventilation modes - This full-functioned intensive care ICU Ventilators offers a complete range of invasive and non-invasive ventilation modes in all patient types including high flow oxygen therapy & Bubble CPAP for neonates.

Monitoring - It offers a variety of monitoring capabilities. It displays monitored parameters as numbers. You can also see this data graphically, as a combination of real-time waveforms (curves), loops, trends, and special Intelligent Panels.

Alarms – It's operator- adjustable and non-adjustable alarms help ensure your patient's safety.

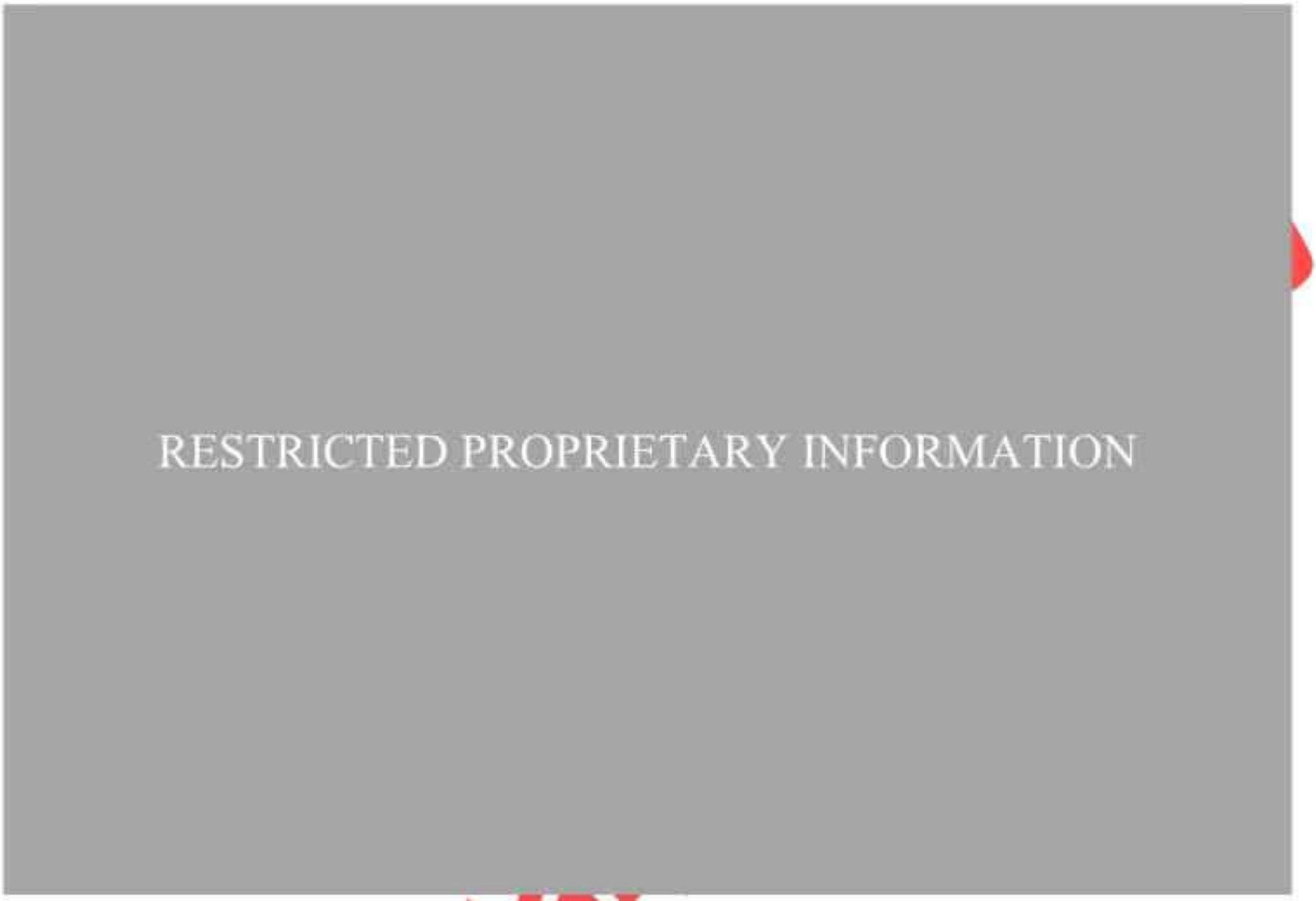
User Interface – The ICU Ventilators ergonomic design including colour touch screen lets you access the ICU Ventilators readings and monitored parameters.

Power – It uses AC Power as primary source. If the primary source fails, the ICU Ventilators automatically switch to backup batteries.

Trolley – It includes a standard trolley with bracket for humidifier, and ICU Ventilators arm.

2.4 System Overview

2.5 Block Diagram



List of Detachable Items

Fuse close type

List of Critical Components

2.6.1 List of Accessories

Sr. No	Accessories List / Detachable Part	Quantity
1	Breathing Circuit	1
2	Test lung	1
3	Flow Sensor	1
4	Pressure Regulator with filter	1
5	Oxygen Hose Pipe	1
6	HME Filter	3
7	NebHME Filter(Adult/Paediatric)	1

2.6.2 Recommended Flow Sensor (Disposable)

Flow Sensor type	Manufacturer	Specifications	Picture
Adult	RESTRICTED PROPRIETARY INFORMATION		
Paediatric			
Neonate			

2.6.3 Recommended Oxygen Sensor

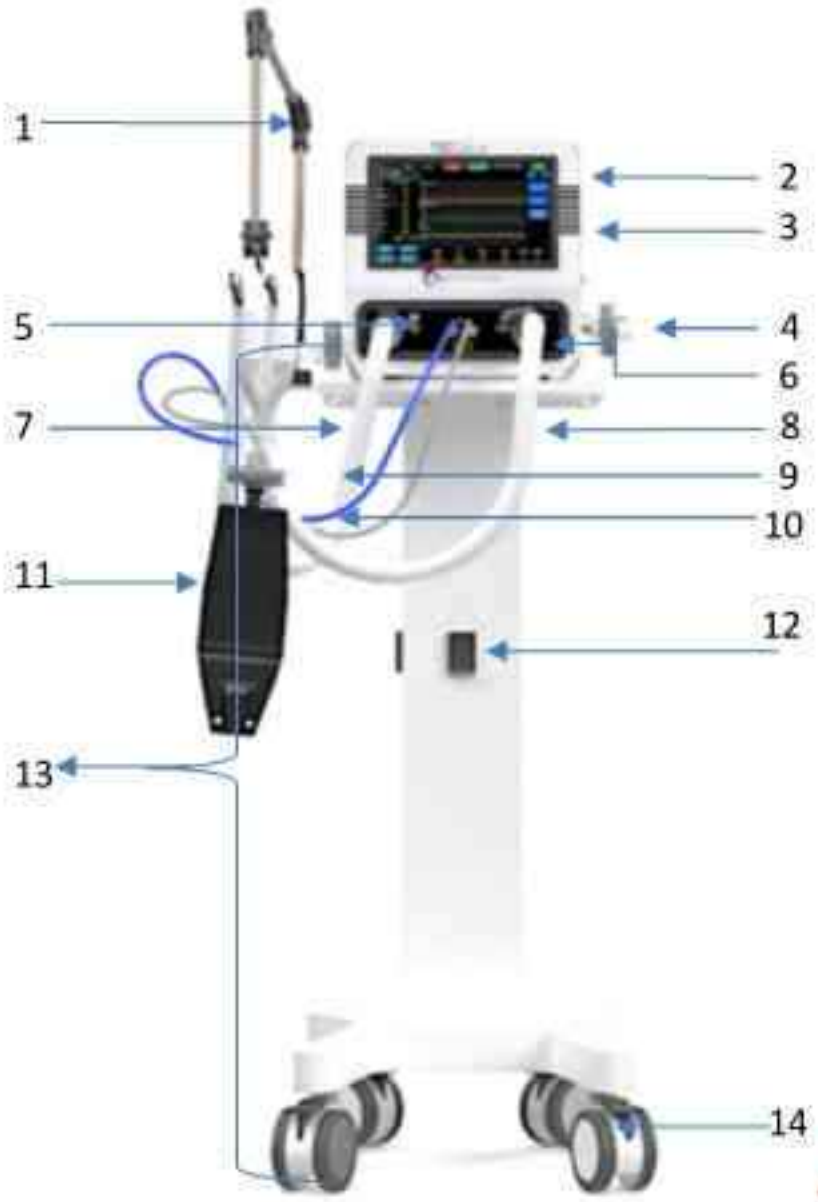
Oxygen Sensor type	Manufacturer	Specifications	Picture
Analog	RESTRICTED PROPRIETARY INFORMATION		

2.6.4 Recommended Breathing Circuit Specification (Disposable)

Patient Type	Inner Diameter	Maximum Resistance
Adult / Paediatric	15-22 mm	≤ 0.06 cmH2O/(L/min)
Neonatal	10-15 mm	≤ 0.15 cmH2O /(L/min)

3. Device Description

3.1 Front View



1	ICU Ventilators Arm
2	ICU Ventilator
3	Holding Bracket (on each side)
4	HME Filter
5	Nebulizer Port
6	Expiratory valve connection
7	To Patient End
8	From Patient End
9	Breathing Circuit
10	Flow sensor connection
11	Test lung
12	Humidifier bracket provision
13	ICU Ventilators Trolley
14	Castor wheels with brake

3.2 Back View

1	Air Vent
2	Slider Switch
3	Oxygen inlet port
4	Exhaust Fan
5	Power cable connection
6	On/Off Switch

3.3 Side view

1	Holding Bracket (on each side)
2	Pressure Regulator with filter
3	Oxygen Sensor
4	HME/HEPA Filter
5	EtCO2 socket

4. Preparing the Ventilator for Use

4.1 Preparation Before Use

Read the entire user manual and all its accompanying documents thoroughly before switching on the unit.

1. ICU Ventilators should be properly mounted on the trolley with a ICU Ventilators arm.
2. **Oxygen Line Connection**
   a. Ensure that pressure regulator with filter is connected to the backside of the ICU Ventilators at the oxygen inlet port.
   b. Connect the oxygen hose to pressure regulator inlet.
   c. Connect the other end of the oxygen hose to a high pressure oxygen wall mount via a suitable nozzle.
   d. Ensure that the pressure on the pressure valve in the dial gauge is between 3 to 6 bar. To adjust the pressure, pull the knob and rotate clockwise to decrease pressure and anticlockwise to increase the pressure. Push the knob back once the pressure is adjusted.

NOTE:

- Remove Pressure regulator while using LPO.
- Oxygen gas nozzle of LPO has to be directly attached to the ICU Ventilators unit and should not have flow more than 8 LPM.
- Select Oxygen Delivery Pressure as LPO at SERVICE MENU>>SYSTEM CONFIG.>>LPO
- To prevent damage to the ventilator, connect only clean, dry medical grade oxygen.
- Always use officially approved oxygen cylinders and pressure regulator that attend to local legal government requirements.
- It is recommended that Pressure in Pressure Regulator should be Set by Qualified person.

3. **Power source**
   a. Plug the power cord into the mains port at the backside of the ICU Ventilators.
   b. Connect the 3-pin plug of the power cord into the wall socket.
   c. Turn on the power switch to power up the ICU Ventilators.

4. **Expiratory valve**
   a. Connect the Expiratory valve to the from Patient port with outward direction of flow.
   b. Connect the silicone tube to the nozzle near the from patient port. Other end of the tube should be inserted in the Expiratory valve port.

NOTE:

- Expiratory end of the breathing circuit should be connected to the Expiratory valve.

5. **HME Filter**
   a. Connect HME Filter at Air intake, Exhaust ports and at the patient end.

NOTE:

- It is mandatory to connect HME Filter at the patient end in Adult and Paediatric Patient Type i.e. between patient mouth-piece and flow sensor for appropriate readings.
- Do not reuse the single use accessories, like breathing circuit, patient flow sensor, airway adapter, HME filter, as it may cause cross contamination to the patient.
- During ventilation, regularly check the breathing circuit, HME filter for increased resistance and blockage.

6. **Breathing circuit**
   a. Firmly connect the inspiratory limb to the TO patient port.
   b. Expiratory circuit limb must be firmly connected to the Expiratory valve.

Neonatal Breathing circuit connection if used with a Servo Humidifier (Optional)

a. Attach the short (single tube), inspiratory limb to one of the humidifier chamber port and other end to the ICU Ventilators Inspiratory Port.
b. Connect the angle elbow of the inspiratory limb to the outer port of the humidifier chamber.
c. Connect its other end to the Expiratory valve with the water trap levels below the inspiratory & expiratory limbs so as to accumulate the water condensed.
d. If required, use a high efficiency filter between the inspiratory limb and ICU Ventilators Port.
e. The central temperature probe (with Dual tip sensors) is for chamber outlet temperature should be positioned into the sensor ports in the angle elbow of the inspiratory limb with locking notch.
f. The other probe (with Single tip) at the end of the sensor should be inserted into the sensor ports at the patient airway of the inspiratory limb.
g. Check that the probes are firmly seated to avoid leaks and ensure the tip is correctly position at the centre of the limb.
h. Connect the heater wire on the elbow of the inspiratory limb.

NOTE:

- When using active humidification, Ensure that the flow sensor is positioned in such a way that it will prevent water accumulation in the flow sensor and water will go into the water trap of the breathing circuit. Excess water can affect the flow sensor measurements and lead to inaccurate volume delivery.
- **We recommend that the humidifier used shall comply with the requirements of relevant IEC/ISO Standards.**

7. **Flow sensor**

Use appropriate flow sensor as mentioned in **2.6.2**, depending on patient type.

8. **EtCO2 Connection (Optional)**

EtCO2 adapter should be connected in between the flow sensor and the breathing circuit (Patient End) as shown in figure.

9. **Nebulizer Connection (Optional)**

Connection for Adult/Paediatric Patient type

Nebulizer should be connected in between the flow sensor and NebHME Filter in Adult/Paediatric Patient type as shown in figure.

Note:

Do not connect HME Filter while the Breathing Circuit connected to Nebulizer in Adult/Paediatric Patient type except NebHME Filter.

Connection for Neonatal Patient type

Nebulizer should be connected in between the flow sensor and patient End In Neonatal Patient type as shown in figure.

4.2 Verification Before Use

1. Verify if the equipment is turned off.
2. Perform a visual inspection concerning the equipment and its components, looking to identify their intactness.
3. Verify if all of the equipment's components are correctly connected and inserted.
4. Verify a firm connection to the Expiratory valve. It is important to verify the diaphragm's presence.
5. Verify a firm connection of the external flow sensor.
6. Check if the breathing circuit is securely connected and is appropriate to the patient.
7. Check for secure connection of oxygen gas hoses.
8. Check if gas inlet pressure is according to specification.

> ⚠ **CAUTION**
> Pressures above upper limit specification can damage the equipment.

9. Verify a firm connection of the electric cord, when applicable. The ICU Ventilators can be used in battery operation for up to 360 minutes continuously under normal ventilation of the patient.

> ⚠ **WARNING**
> - If the ICU Ventilators usage is extended on battery, **BATTERY CRITICALLY LOW** alarm may occur, provide an IMMEDIATE connection of the power supply to the network power supply. If it was not possible, arrange for appropriate means of ventilation support, and DISCONNECT the patient from the equipment as soon as possible.

10. If all items are check marked as OK, the equipment is ready for use.

4.3 Installation Instruction

1. Assemble the ICU Ventilators trolley and stand on the wheel base & lock the caster wheels.
2. The ICU Ventilators is positioned on its stand next to the patient bedside. The Unit is attached to the stand using four bolts.
3. Ensure that the pressure regulator is connected to the backside of the ICU Ventilators at the oxygen inlet port.
4. Connect the oxygen hose to pressure regulator inlet.
5. Install the ICU Ventilators arm for patient tubing support on the fittings given on the stand.
6. Plug the power cord into the mains port at the backside of the ICU Ventilators.
7. Connect the 3-pin plug of the power cord into the wall socket.
8. Turn on the wall power socket, followed by the mains switch at the backside of the ICU Ventilators.
9. Also check that slider switch should be on the **LEFT** position.

SLIDER SWITCH:

Note:

- When the Battery is completely discharged and ICU Ventilators is not getting started, even after connecting AC supply, slide FAST CHARGING switch on the back side of the machine, in the ON position shown (Right position) and connect the AC supply.
- keep the switch in this position for 15-30 minutes, after which you can slide switch back to Normal position (Left position) to start the machine.
- During FAST CHARGING mode ON, the machine cannot be used for the Treatment.

NOTE:

- The ICU Ventilators employs a battery backup system if AC power becomes unavailable, a fully charged battery provides up to 6 hours of power to the ICU Ventilators.
- To move the ICU Ventilators around, use the handle provided on the stand.
- This installation should be performed by a trained / qualified person only. For Installation Video please contact us.
- Make sure its exhaust fan on back, Air Intake Port & Exhaust Port are not blocked.

4.4 ICU Ventilators shutdown procedure

1. Press the STOP button on the screen to stop ventilation.
2. Switch off the switch on the back panel to turn off the ICU Ventilators.
3. Remove all the accessories and follow cleaning and maintenance instructions.
4. Dispose all the single use accessories.

5. Ventilator Overview

5.1 User Interface

5.1.1 Initializing Screen

- Turn on the equipment using the ON/OFF button on the rear side of the equipment.
- After turning on the equipment the initial screen will be presented which will show the message "**Self Test Initializing... Please keep the Patient end open**". This Self-test will check blower operation and calibrate internal sensors and external O2 sensor.

5.1.2 Welcome Screen

- If the self-test is passed, a welcome screen will be displayed which includes the patient and services available options, according to the ICU Ventilators model.
- If the self-test is failed, Pop up message with available options for emergency use will be shown.
- On the welcome screen, select the option from patient type by touching on the correspondent icon for New Patient or Press Last Patient button to continue with the same patient.

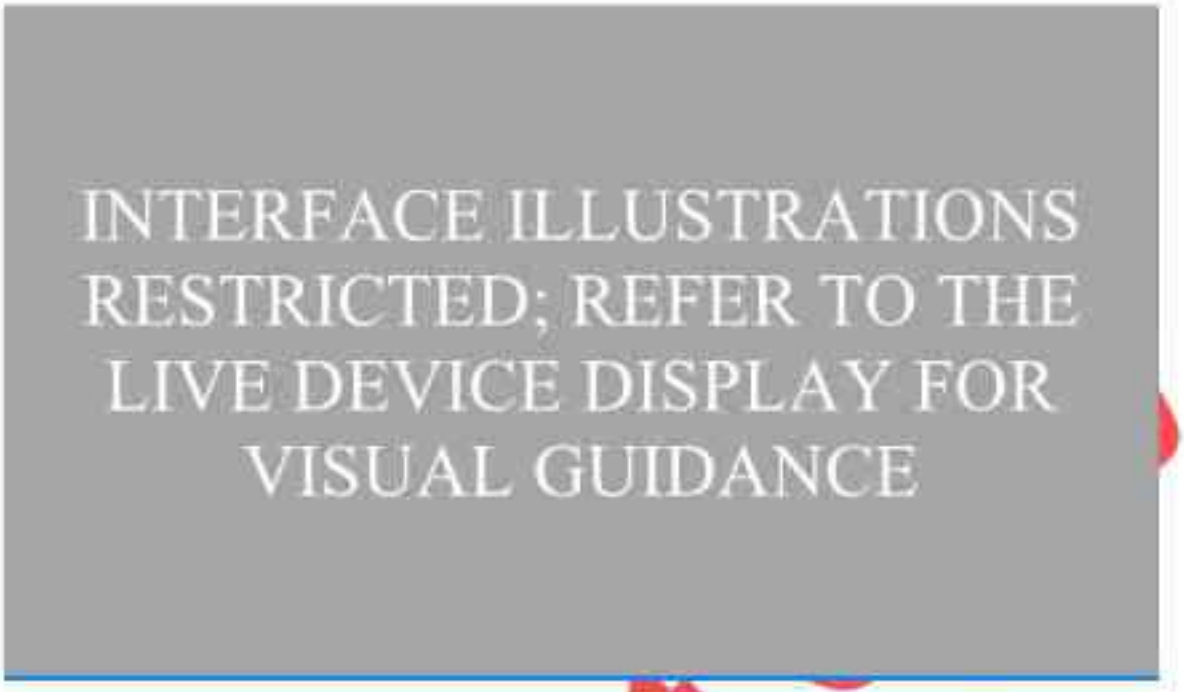
5.1.3 Menu Screen with pop up message

- After the patient type selection, this Menu screen pops up with the message shown as "**Please Do Calibration For New Patient Sensor & Breathing Circuit.**"

> ⚠ **Caution**
> Please note the pressure, flow & volume will be delivered with the specified accuracy, only if the flow sensor & breathing circuit hose is calibrated every time before starting ventilation and AVI Health care will not responsible if any kind of malfunction happens during operation.

5.2 Calibration

- Calibration of Oxygen sensor, Flow sensor, Hose Resistance and Hose Compliance can be performed here, individually with respect to the Patient type. e.g. If the flow sensor is changed, only the flow sensor can be calibrated from here.



Note: The patient must be disconnected from the ICU Ventilators during the System Check and calibration procedures.

- **Patient flow calibration** includes a test of patient flow sensor in forward & reverse direction.

Note:

- If there is a mismatch between the selected patient group and the type of flow sensor connected, the calibration fails. Ensure you are using the correct flow sensor and Breathing Circuit for the patient.
- When changing from an Adult/Paediatric to a Neonatal patient group or vice-versa, you must calibrate the flow sensor or perform system check.
- To prevent inaccurate flow sensor readings, make sure the flow sensor is correctly installed. The flow sensor tubes must not be kinked.

- **Hose resistance calibration** checks the breathing circuit type as per set patient type & calibrates its resistance. It is performed in order to guarantee optimal ventilation performance.

- **Hose compliance calibration** includes a functional test of the safety valve and a leakage indication of the hose system.

⚠ **CAUTION**

- Ensure that the patient end of the breathing circuit is blocked/closed during Hose Compliance.

Oxygen Sensor:

There are two ways to calibrate **Oxygen Sensor by Air** and **Oxygen** Source.

For Air Source, disconnected Oxygen inlet port if attached as shown in below figure.

For Oxygen Source, Oxygen input pressure should be in between **3 to 6 Bars.**

INTERFACE ILLUSTRATIONS RESTRICTED; REFER TO THE LIVE DEVICE DISPLAY FOR VISUAL GUIDANCE

Note

- Oxygen calibration can be done with O2 or Air options; we recommend to use O2 option i.e. with Oxygen supply connected while calibrating the Oxygen sensor for better performance.

5.3 System Check

System check can be used for maintenance of the system or for conformity of the operation of the system, sensors, breathing circuit hose connections before admission of new patient. It includes five different tests.

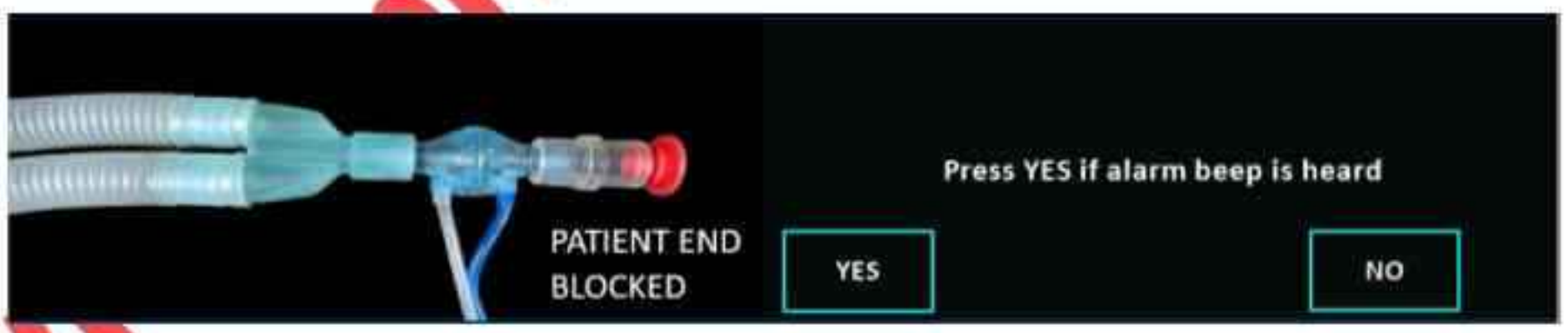
- **Self-Test** checks blower operation and calibrate internal sensors and external O2 sensor.

CAUTION

- Flow is generated during the self-test thus no patient should be connected. The Patient end must not be blocked.

INTERFACE ILLUSTRATIONS RESTRICTED; REFER TO THE LIVE DEVICE DISPLAY FOR VISUAL GUIDANCE

- **Buzzer Test** will generate the audio buzzer pattern to confirm the working of the buzzer for generating audio alarms, select Yes if the buzzer pattern is audible.



WARNING

- We strongly advise to not skip the system check before starting the ventilation. However, User can skip this self-test in case of an emergency and directly jump on the ventilation screen, only if the previous test is passed and it is the responsibility of the User to make sure that the correct patient type with appropriate flow sensor is selected along with leak-proof breathing circuit with their connection in use.

5.4 Menu Screen

INTERFACE ILLUSTRATIONS RESTRICTED; REFER TO THE LIVE DEVICE DISPLAY FOR VISUAL GUIDANCE

5.4.1 VENTILATION MENU

a. ADMIT PATIENT: Patient details such as name, height, weight, sex can be entered here. Users can also get a pre-calculated range of default set values by entering weight, and also get this range for patient whose weight is not calculated by PBW (Predicted Body Weight). Device will automatically calculate predicted body weight for adult and paediatric patient type by measured height. Patient type can also be changed from here.

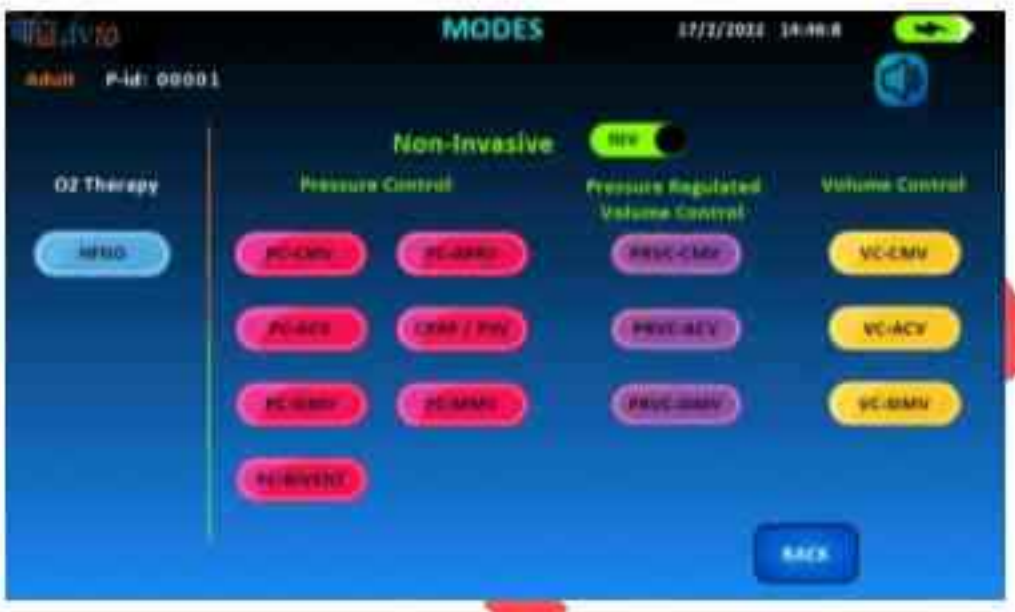
NOTE:

- PBW is not available in Neonatal Patient Type, manually add up the weight for suggested ventilation.

b. VENTILATION SCREEN – This is a ventilation main screen with waveforms and set values.

c. MODES – Required mode can be selected here. ***Refer 6.1 Ventilation Modes*** for details.

Adult/Paediatric:



Neonatal:

d. PATIENT LOG – Detailed patient logs of last 72 hours of set values, achieved values are displayed here. Data of up to 100 patients can be accessed from here.

PATIENT DETAILS:

Note:

- Make sure the date and time are set correctly so that event log entries have accurate time and date.

SET PARAMETER LOG:

e. HELP – Scan this QR Code to view a list of demonstration videos.

5.4.2 SERVICE MENU

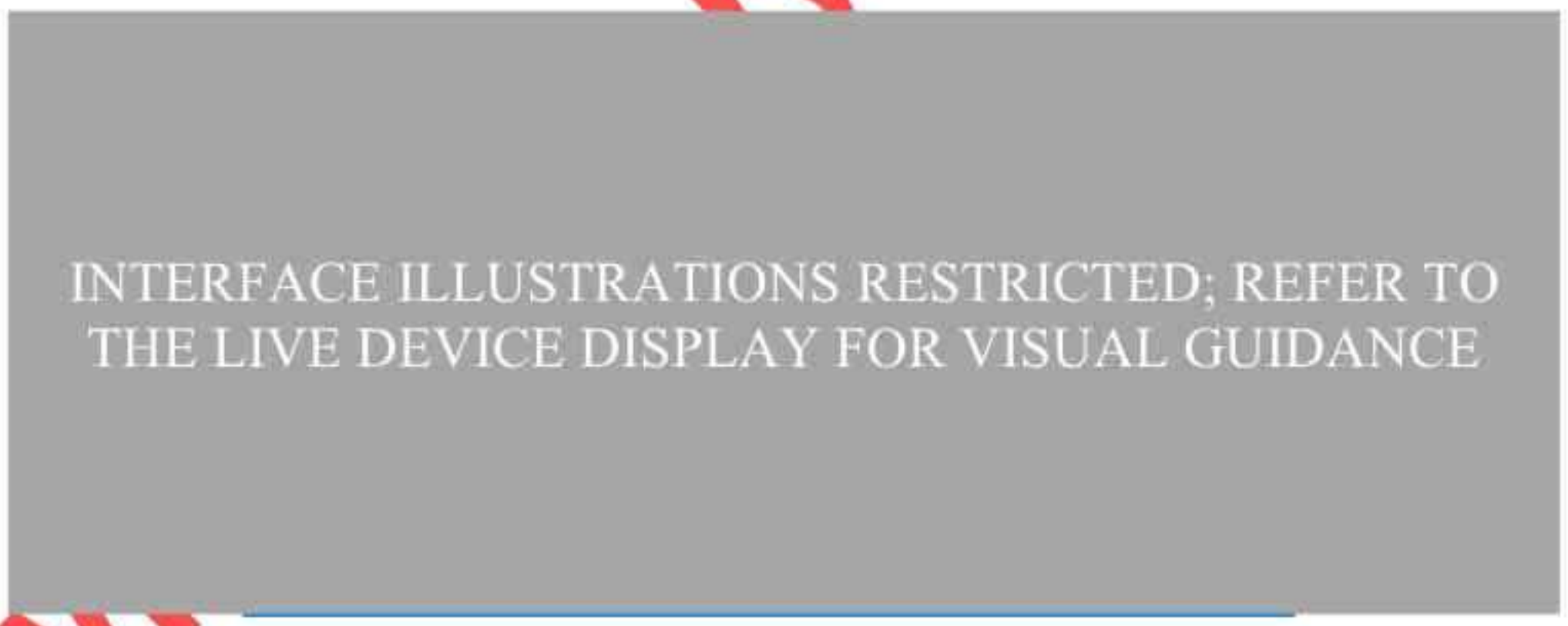
SERVICE – This is service screen for advanced diagnostics and troubleshooting to be accessed only by Authorised Service engineer of AVI Healthcare.

SYSTEM CONFIGURATION -

Configuration of time, date, respiratory time setting, oxygen delivery pressure setting and brightness and alarm volume control is possible on this screen.

To set the date and time:

1. Open the Service Menu▼ System Configuration.
2. Touch the day, month, year, hours & minutes blocks one by one & set the values using numeric keyboard.
3. Touch the SET button to set the changes made for date and time.



NOTE:

- Respiratory Time Setting option is only applicable for adult and paediatric patient types. Using this either I: E ratio or Inspiratory Time (Tinsp) along with Respiratory rate can be used to set respiration timings.
- For Neonatal Patient type, Inspiratory Time (Tinsp) setting is mandatory.
- Be aware that, higher Respiratory rate settings, or very short Tinsp or Texp may cause incomplete inspiration or expiration.

Sensor Output –

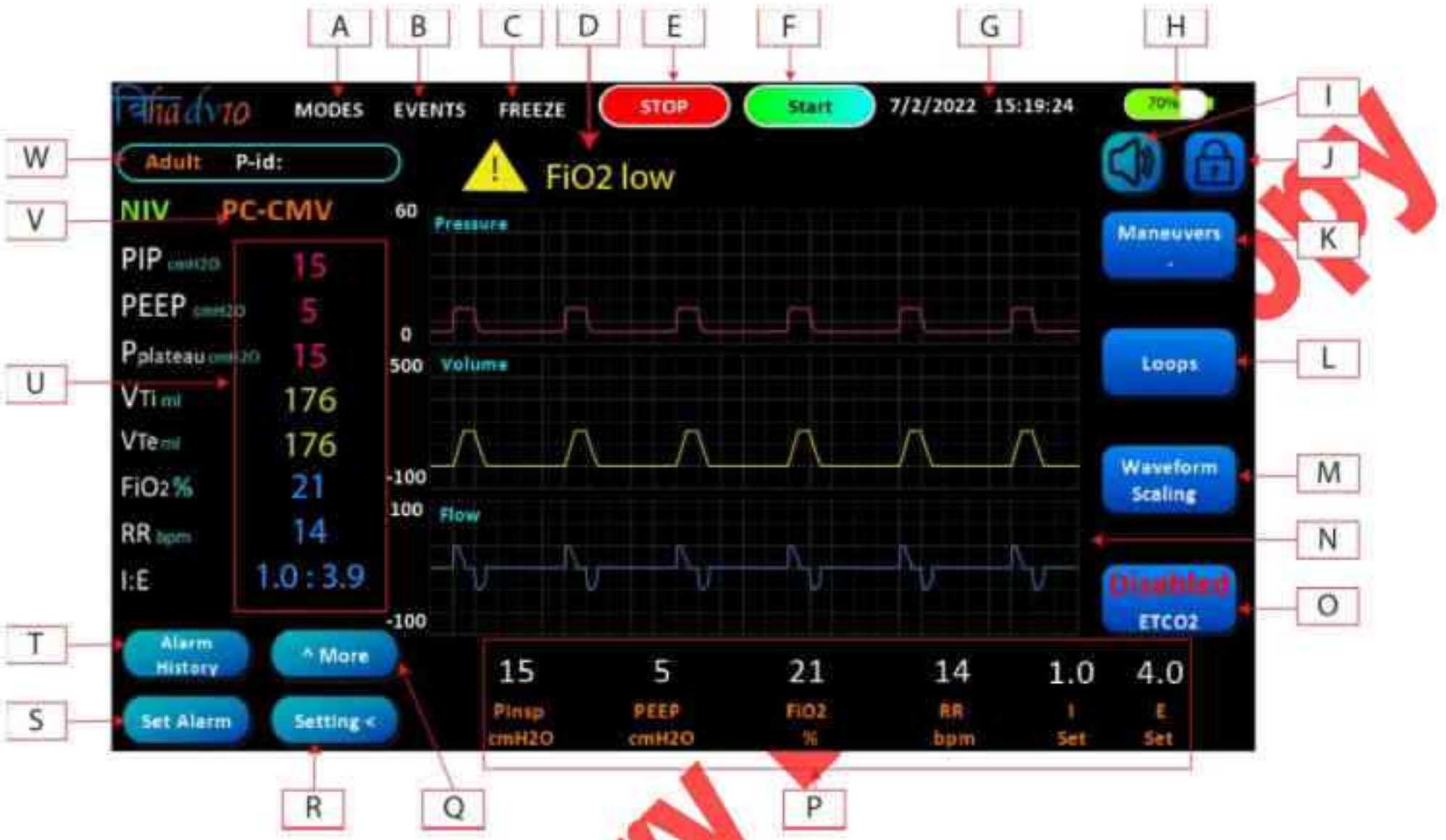
Real time output of all the sensors inside the ICU Ventilators is seen here. This helps the service engineer to diagnose any issue inside the ICU Ventilators and troubleshoot the same.

INTERFACE ILLUSTRATIONS RESTRICTED; REFER TO THE LIVE DEVICE DISPLAY FOR VISUAL GUIDANCE

Alarm History –

This screen logs all the alarms in the past 72 hours.

6. Ventilation Menu Details



Indication	Description
A	**Mode's selection Screen** User can select or change the mode by touching here.
B	**Events & Alarms Screen** User can see all Real-time alarms generated and events occurred.

INTERFACE ILLUSTRATIONS RESTRICTED; REFER TO THE LIVE DEVICE DISPLAY FOR VISUAL GUIDANCE

	INTERFACE ILLUSTRATIONS RESTRICTED; REFER TO THE LIVE DEVICE DISPLAY FOR VISUAL GUIDANCE
C	**FREEZE** Click this button to Freeze and unfreeze the waveforms for clinical analysis.
D	**ALARMS** Real time alarms get displayed here which are colour coded as per the criticality.
E	**STOP** User can stop the ventilation by touching this button.
F	**START / STANDBY** User can start or pause the ventilation by touching this button.
G	**REAL TIME** date and time can be seen here.
H	**BATTERY STATUS**  Battery charged with equipment connected to electric network  Battery charging with equipment connected to electric network  Battery partially charged and equipment disconnected from electric network  Battery at 40% charge with battery low alarm activated and equipment in operation  Battery at 25% charge with critically low battery alarm activated and equipment in standby mode
I	**MUTE** - Alarms can be muted for 120 seconds.
J	**LOCK/UNLOCK** - Protection system against accidental change. Lock or unlock the touch screen.
K	**MANEUVERS** – **a) O2 Flush** Keeping the oxygen concentration at 100% for 30 seconds after pressing. This feature can be used for procedures of pre- and post- aspiration of secretions in the airways. **b) Inspiratory hold** Allows maneuvers of suspension of inspiratory time, widely used. By pressing this button, the inspiration will be extended for a maximum period of 10 sec. At any point by re-pressing this button it will immediately suspend the inspiration. **c) Expiratory hold**

Allows extension expiration time maneuvers (prolonged expiration time). By pressing this button, the expiration will be extended for a maximum period of 10 sec. At any point by re-pressing this button it will immediately suspend the expiration.

d) P0.1

P0.1 is often used as references for weaning the patient. After pressing P0.1, at the start of the next patient triggered (synchronized) inspiration, No flow is delivered for 0.1 seconds and the negative pressure generated by the patient is measured and displayed on the same button as P0.1 pressure.

e) Recruitment

The Recruitment maneuver interrupts the regular breathing pattern to insert a specified number of high-pressure strokes and then returns to 'normal' ventilation again. This maneuver is used to open the lungs by applying a fixed number of strokes with a high inspiratory pressure and a high PEEP and adapted duration time.

The strokes are pressure controlled. The pressures, time, rise time and number of breaths can be set. The default values are Number of breaths = 1, Pinsp = 30, PEEP = 10, Pressure Rise time = 1000 ms, Tinsp = 1.0sec and Texp = 0.5sec.

The breathing cycles are counted and after the required number has been applied normal ventilation continues.

f) Nebulizer

The Nebulizer flow is synchronized with the inspiration (inspiratory flow). The nebulization time can be set from 0 to 30 mins to provide the required amount of medication for decreasing secretions and improve ventilation. The nebulization time remaining is displayed on the button.

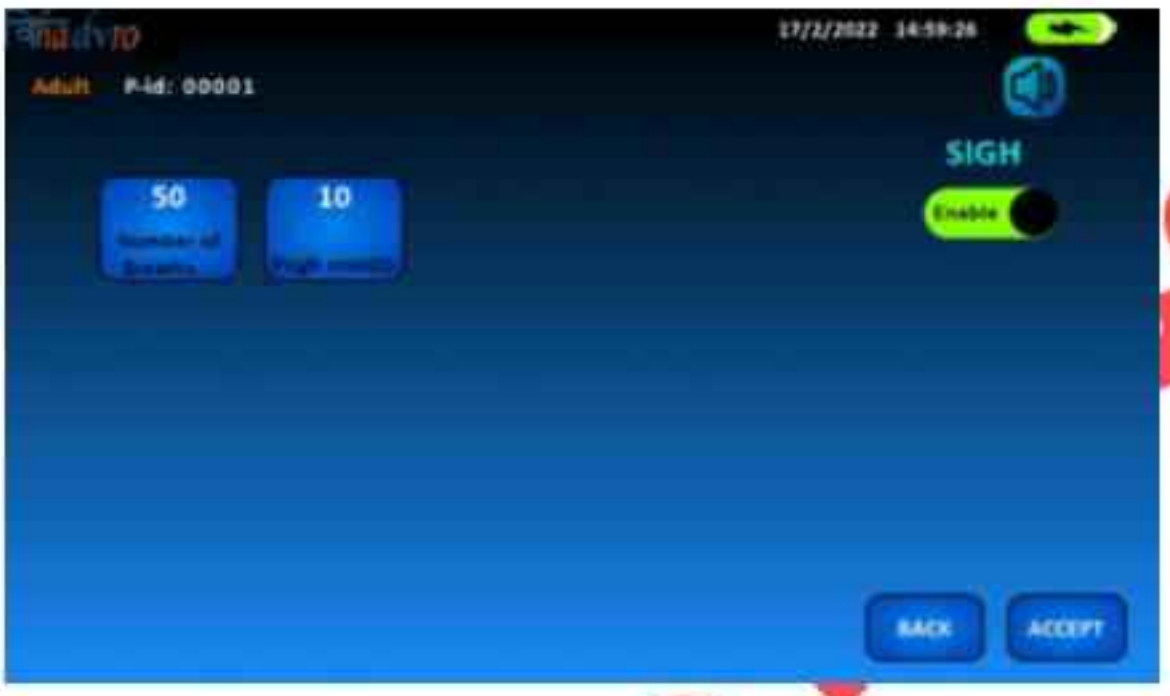
g) PEEPi

Intrinsic PEEP is also known as auto PEEP and gas tapping which is accumulation of air in alveoli, increases alveolar pressure at the end of expiration. It is used to prevent the lung and chest wall from reaching an elastic equilibrium point.

During the intrinsic PEEP maneuver the flow delivery is stopped for a short period of time, such that the patient airway pressure becomes equal to the actual PEEP pressure in the lungs or the alveolar pressure which is measured & displayed on the same button as Intrinsic PEEP value. A new Intrinsic PEEP Maneuver cannot be activated, when the previous inspiration was an intrinsic PEEP. The Intrinsic PEEP maneuver is only valid when there is no leakage and no spontaneous patient activity is present.

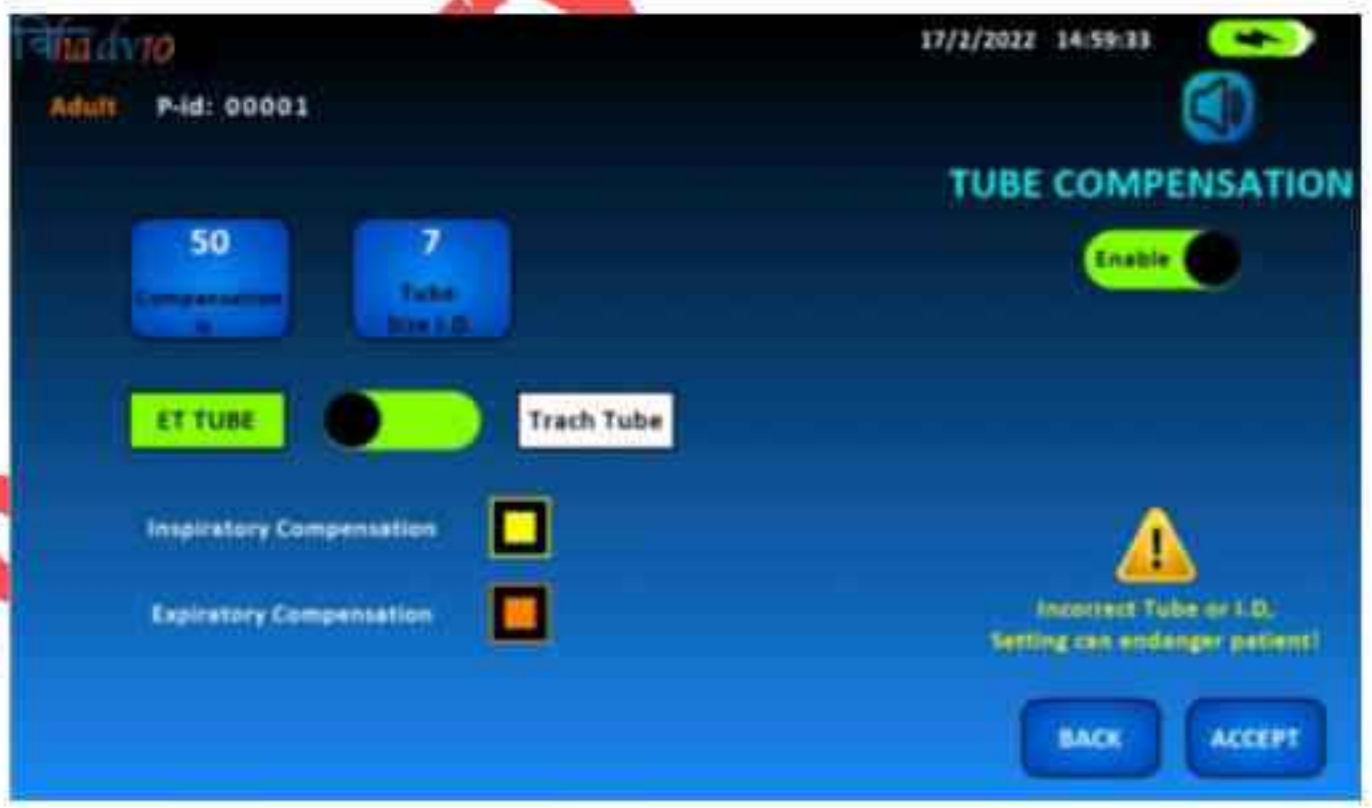
h) SIGH

SIGH is a deep breath i.e. when this is selected, the ICU Ventilators periodically delivers one larger breath (deep) than normal mechanical breath pressure or volume controlled throughout the entire course of mechanical ventilation. Sigh breath is continuously provided to patient unless ventilation is turned off or SIGH is manually disabled. For PC & PRVC modes Psigh above Pinsp & for VC modes Vsigh above Vti is set by the user which will occur after the set No. of Normal breaths.



i) Tube Compensation

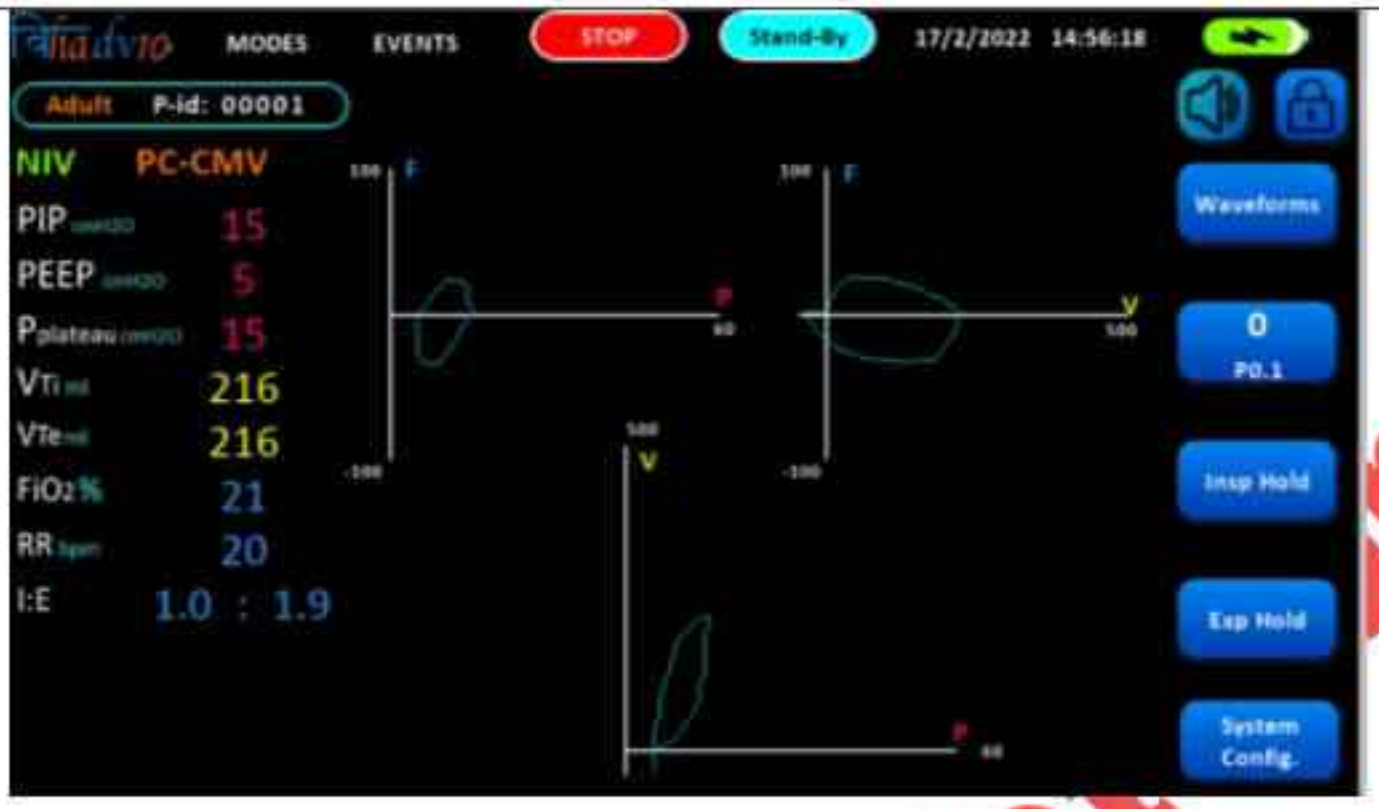
During mechanical ventilation, the resistance imposed by the artificial airway makes spontaneous breathing more difficult. Tube Compensation adds support to eliminate the effects of the airway resistance and continuously adapts this level of support throughout the respiratory cycle even if mode is changed. It is enabled and disabled manually.



j) Suction Control

When performing a suction control maneuver, ventilation continues and the current settings do not need to be adjusted and all Alarms will be mute for 30 seconds.

L	**LOOPS** Following loops can be observed in real time. Pressure x Volume Loop, Volume x Flow loop, Pressure x Flow loop. There is access to P0.1, Inspiratory Hold & Expiratory hold maneuvers. There is also provision for System Config. for changing to LPO/HPO during ventilation



M **WAVEFORM SCALING**

Pressure, Volume and Flow graphs can be scaled with respect to Amplitude scale and Time Scale i.e., Small, Medium or Large.

N	**GRAPHS:** Pressure, Flow and Volume graphs can be observed here
O	**EtCO2 (End Tidal carbon dioxide)** $EtCO_2$ is a non-invasive technique which represents the partial pressure or maximal concentration of CO_2 at the end of exhalation. Normal value range is 35-45 mmHg. When CO_2 diffuses out of the lungs into the exhaled air, a device called Capnometer which is attached near to patient mouth end, measures CO_2 whose value is indicated on the button and by pressing the button the waveforms of CO_2 scale can be viewed. 
P	**SET PARAMETERS** Main Set Parameters for any mode can be set here by clicking on the particular parameter and changing the parameter to required value.
Q	**MORE - ADDITIONAL MONITORED PARAMETERS** Additional monitored parameters which are not displayed on the ventilation screen can be seen here.

INTERFACE ILLUSTRATIONS RESTRICTED; REFER TO THE LIVE DEVICE DISPLAY FOR VISUAL GUIDANCE

NOTE:
% - Indicates percentage of spontaneous activity of patient.

R **SETTINGS - ADDITIONAL SET PARAMETERS**

Additional Set parameters which are not displayed on the ventilation screen can be set here.

S **ALARM SETTINGS**

High and Low Alarm settings can be set over here. Auto-set will set the limits to default values.

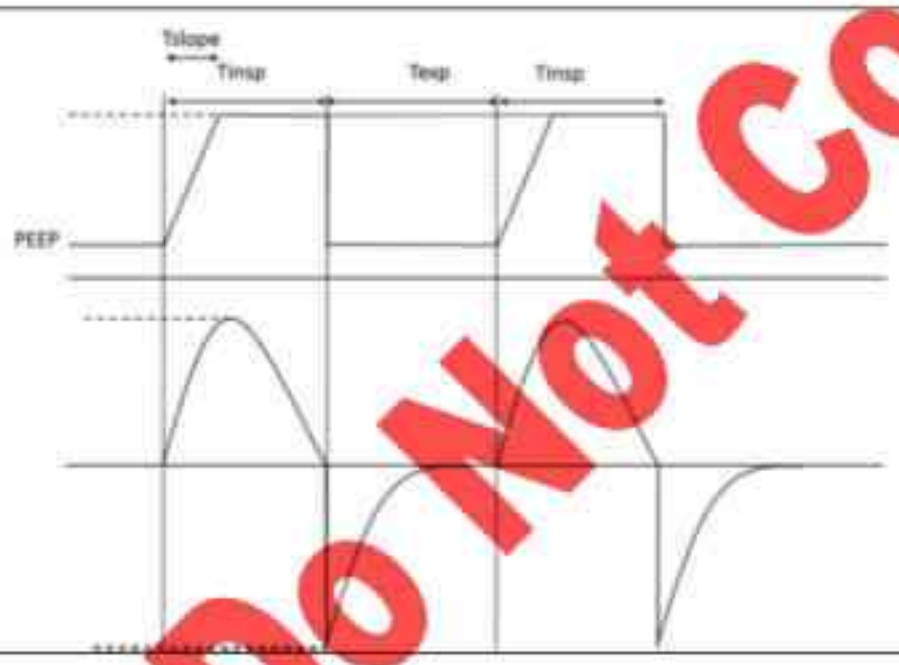
T	**ALARM HISTORY** Past 72 hours of alarm history can be viewed here. 
U	**MONITORED PARAMETERS** Following parameters are monitored continuously and displayed every breath cycle – a) **PIP** in cmH2O – Peak inspiratory pressure b) **PEEP** in cmH2O – Peak end Expiratory pressure c) **Pplateau** in cmH2O – Plateau pressure d) **VTi** in ml – Inspiratory tidal volume e) **VTe** in ml – Expiratory tidal volume f) **FiO2** in % - Fraction of Oxygen delivered to patient g) **RR** in bpm – Respiratory rate h) **I: E** Ratio – Inspiratory time: Expiratory time ratio
V	**CURRENT MODE** gets displayed here
W	**PATIENT DETAILS:** Patient type i.e. Adult, Paediatric and Neonatal gets displayed here along with Patient id. By clicking here, patient details log gets displayed 

6.1 Ventilation Modes

> ⚠ **CAUTION**
>
> - The user is responsible for selecting reasonable ventilation settings for the selected ventilation mode such that, during normal situations, the patient can complete its exhalation and the airway pressure can settle sufficiently towards PEEP level during mandatory expirations.
>   - An exception is made for the ventilation mode PC-APRV.

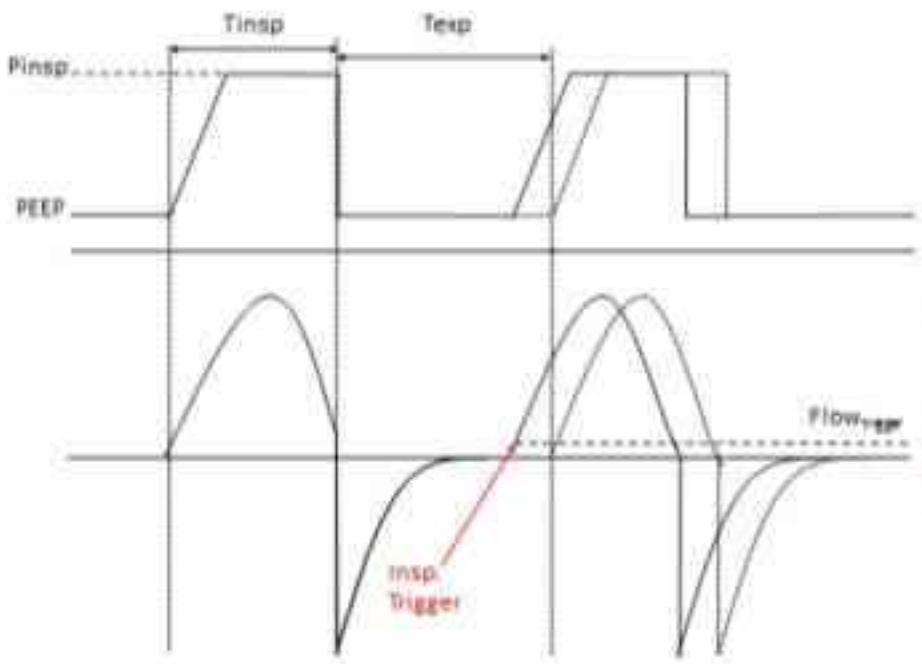
6.1.1 PC-CMV

PC-CMV (Pressure Controlled – Controlled Mandatory Ventilation) is a ventilation mode in which the ICU Ventilators fully controls the ventilation. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio. They are not triggered by the patient. The patient can breathe spontaneously, but this does not influence the cycling of the breathing phases.



6.1.2 PC-ACV

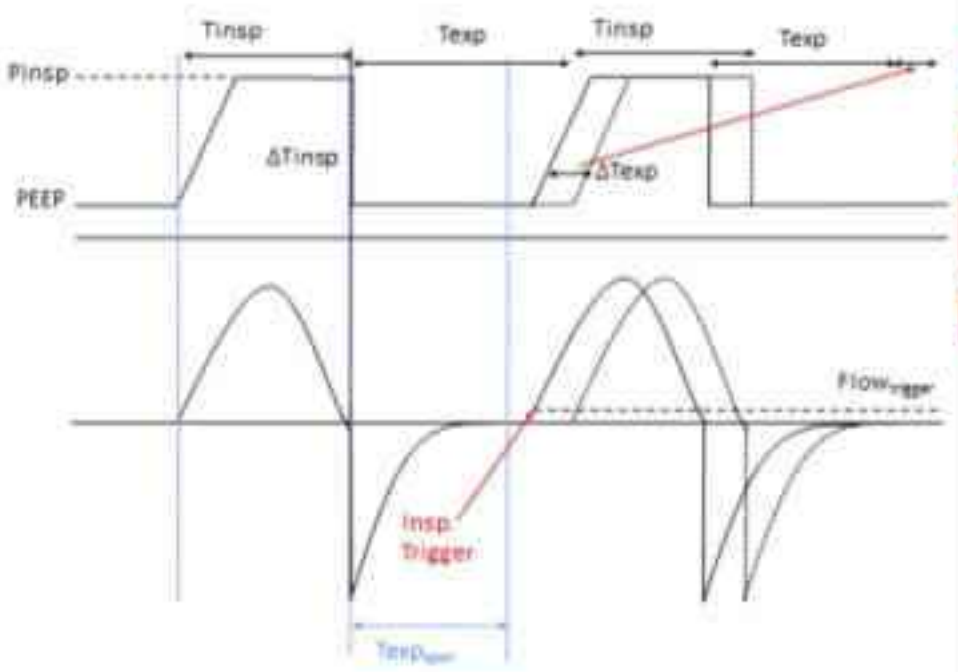
PC-ACV (Pressure Controlled – Assist Control Ventilation) is a ventilation mode in which the ICU Ventilators controls the ventilation, but it can be influenced by the patient. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient. This can lead to an increase of the Respiratory Rate.



6.1.3 PC-SIMV

PC-SIMV (Pressure Controlled – Synchronized Intermittent Mandatory Ventilation) is a ventilation mode in which the ICU Ventilators controls the ventilation, but it can be influenced by the patient. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio, when the patient does not breathe spontaneously. However, during expiration, an inspiration can be triggered by the patient, within a settable trigger window. This window starts after the time Texpspon (an adjustable percentage of Texp) has elapsed.

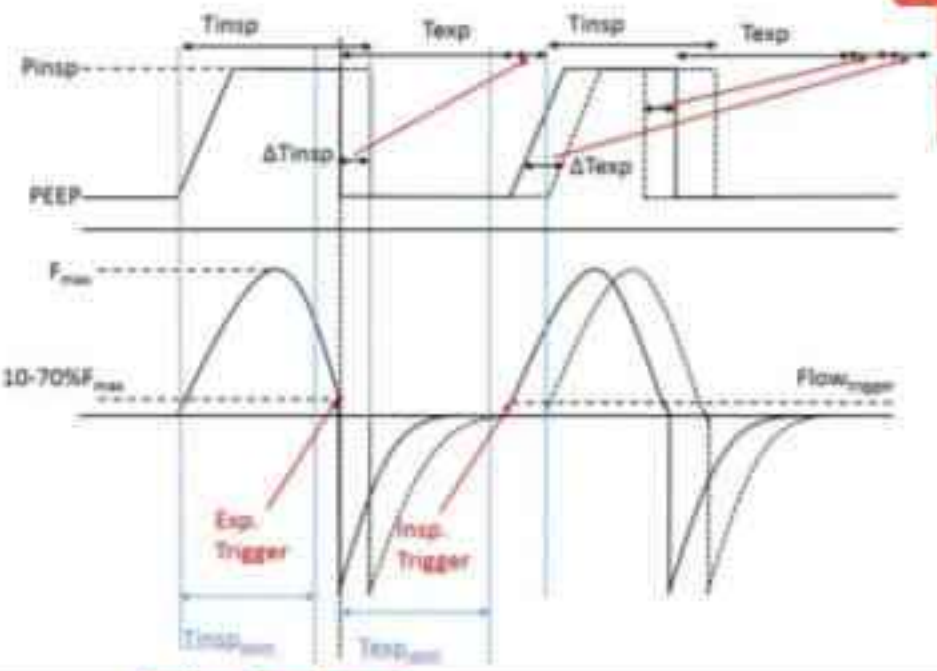
RR compensation is active: The period the inspiration is started earlier (ΔTexp) is compensated in the next expiration. This prevents an increase of the average respiratory rate (RR). The expiration time can differ due to previous triggering; the maximum extension of an expiration is 5 times the original expiration time.



6.1.4 PC-BIVENT

PC-BIVENT (Pressure Controlled – BILEVEL VENTILATION) is a ventilation mode in which the ICU Ventilators controls the ventilation, but it can be influenced by the patient. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, during a trigger window. This window starts after the time $Texp_{spon}$ (an adjustable percentage of Texp) has elapsed. The period the inspiration is started earlier is compensated in the next expiration. During inspiration, an expiration can be triggered by the patient, during a trigger window. This window starts after the time $Tinsp_{spon}$ (an adjustable percentage of Tinsp) has elapsed.

RR compensation is active: The period the expiration is started earlier (ΔTinsp), as well as the period the inspiration is started earlier (ΔTexp) is/are compensated in the next expiration. This prevents an increase of the average respiratory rate (RR). The expiration time can differ due to previous triggering , the maximum extension of an expiration is 5 times the original expiration time.



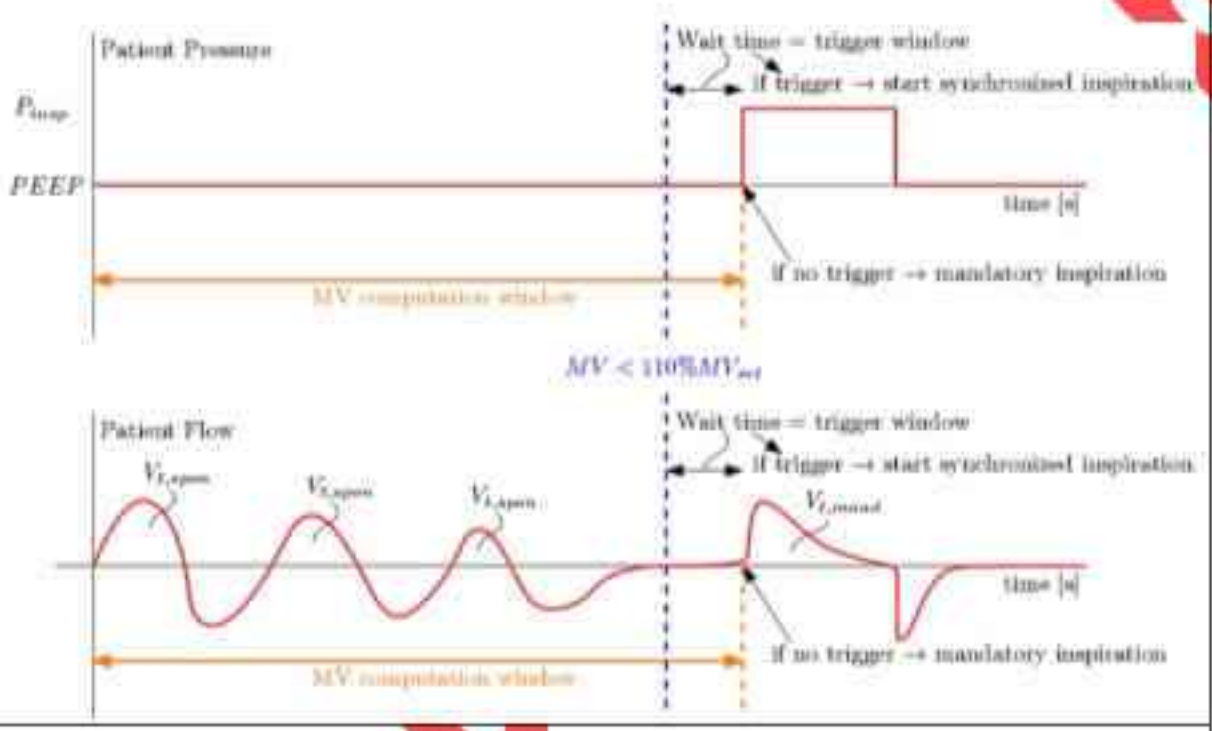
6.1.5 PC-MMV

PC-MMV (Pressure Controlled – Mandatory Minute Volume) is a ventilation mode in which the patient breathes spontaneously. If the patient does not breath sufficiently in order to receive a large enough minute volume, this ventilation mode guarantees that the patient always gets at least the set minute volume (MVset), by applying a machine controlled stroke with a set $Pinsp$ and $Tinsp$, see Figure below.

The inspiratory minute volume is computed with a computational window of 20 seconds for adults and paediatric patients, and 10 seconds for neonates, and is updated every second. When the Inspiratory Minute Volume (MVi) will drop below 110% of the set minute volume, the PC-MMV mode will react as follows:

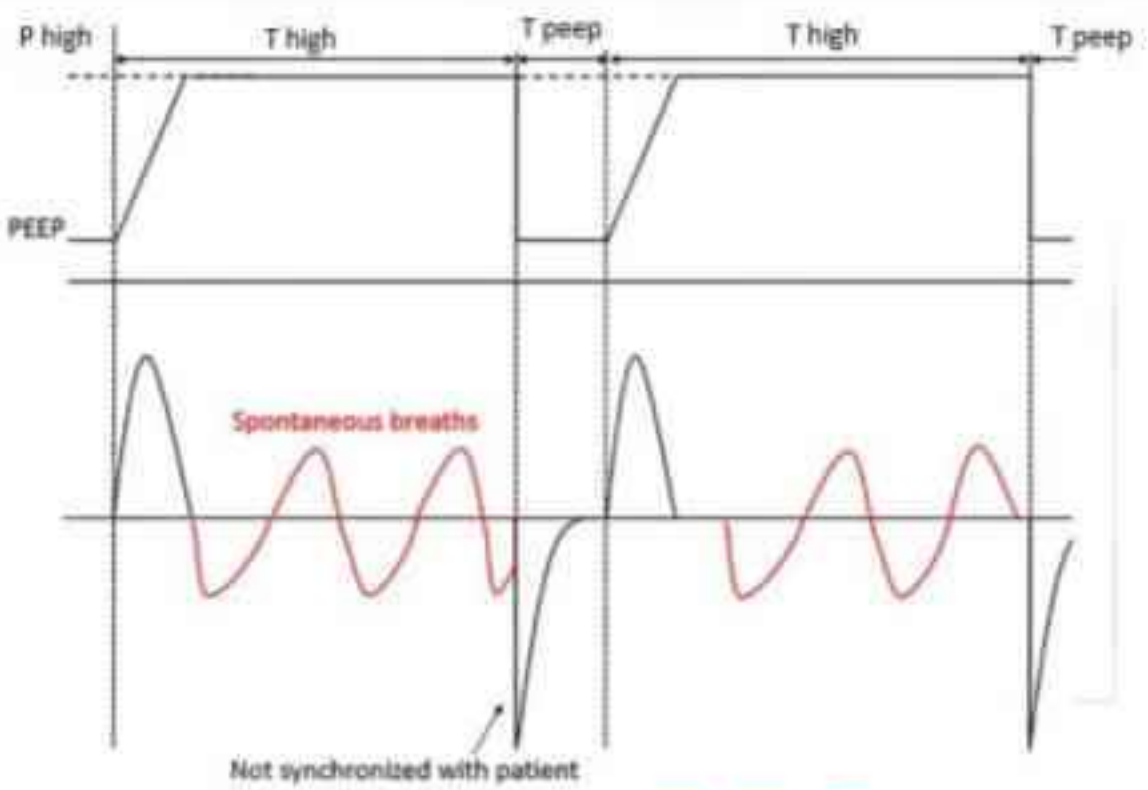
- During wait time (2 sec for adult/paediatric and 1 sec for neonates), the ICU Ventilators will respond to a patient's breathing attempt with a triggered stroke.

- When a triggered stroke is not initiated during this Wait time, the inspiratory tidal volume will have dropped further and a mandatory stroke is initiated to guarantee the set minute volume.



6.1.6 PC-APRV

PC-APRV (Pressure Controlled – Airway Pressure Release Ventilation) is a ventilation mode in which the patient breathes spontaneously on high level (P high), with mandatory short expirations induced by the ICU Ventilators in order to support CO_2 elimination. The alternation between the two pressure levels is machine-triggered and time cycled. The high level (P high) duration is set by T high (inspiration time). The inspiration time is much longer than the expiration time (T peep), in general the expiration time is too short to breathe spontaneously.



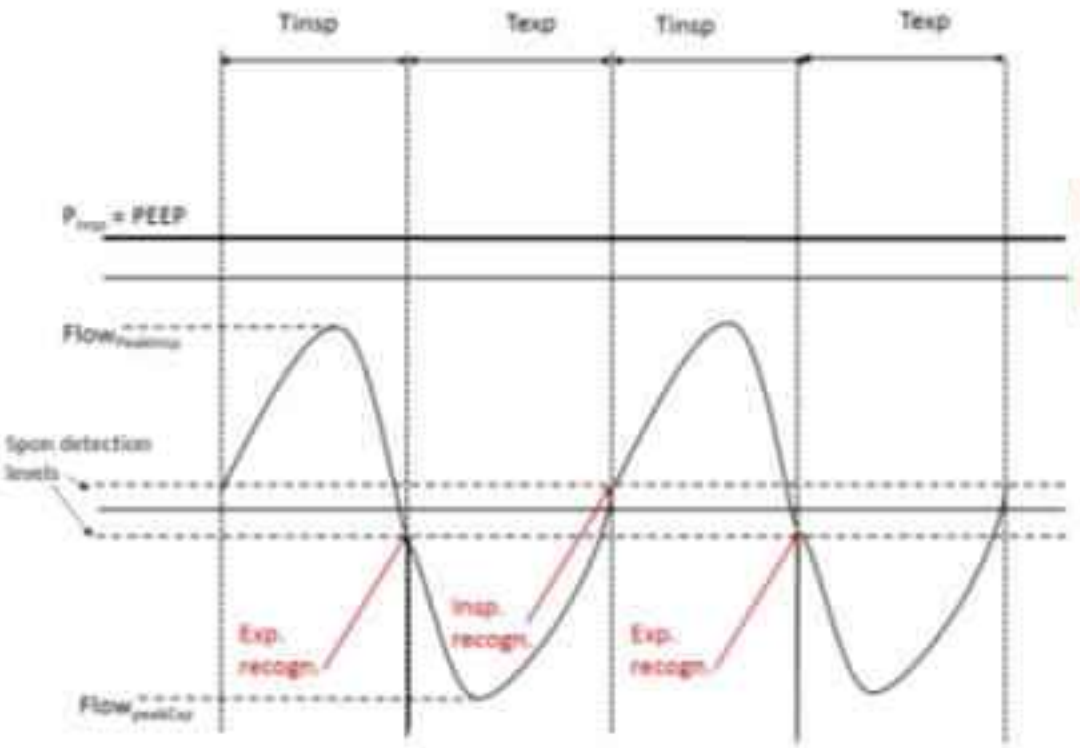
6.1.7 CPAP/PSV

CPAP (Continuous Positive Airway Pressure) is a ventilation mode in which the patient breathes spontaneously. In CPAP, with no options activated, the ICU Ventilators does not deliver any mandatory or triggered breaths.

In CPAP mode if you set up Pressure support pressure with activation of flow / pressure triggering, it works as Pressure Support Ventilation (PSV).

The spontaneous breathing phases (inspiration and expiration) are detected using inspiratory and expiratory phase recognition, using a flow level detector.

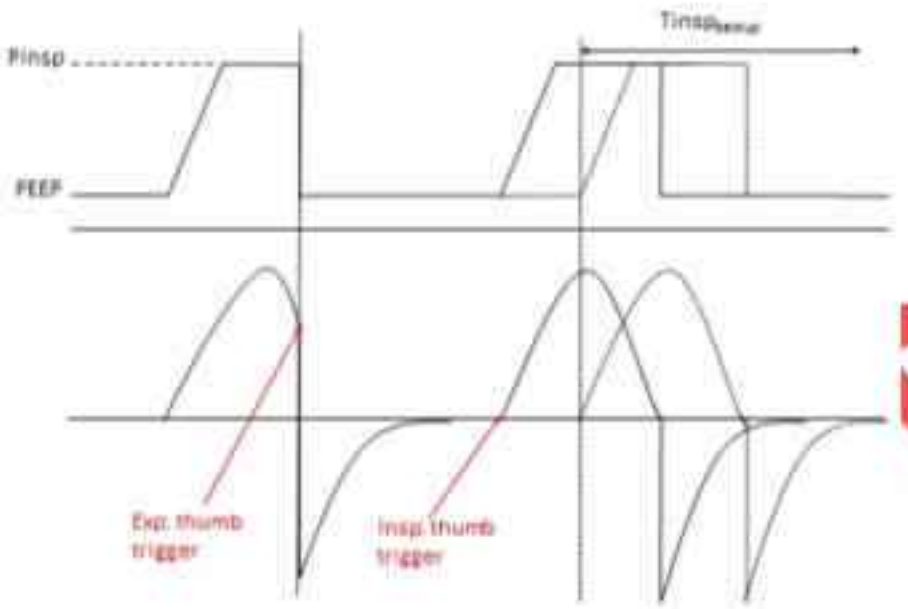
In this mode, Apnea Time is set up along with alarm setting, if No breaths detected for apnea duration, Apnea alarm is indicated with Backup Ventilation mode PC-SIMV active, to provide the controlled ventilation strokes set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio.



If during Back up ventilation, 2 consecutive spontaneous breaths are detected, CPAP/PSV is activated again along with the Apnea detection algorithm and the cycle continues.

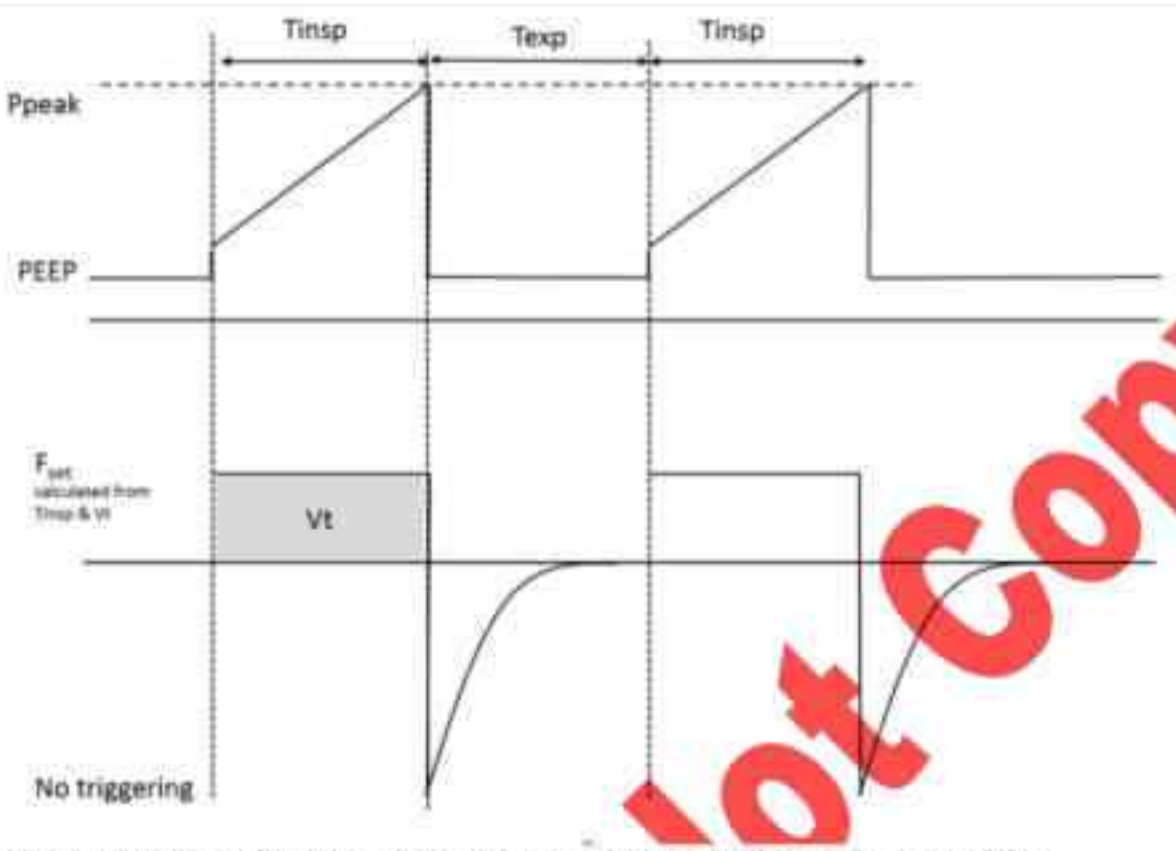
6.1.8 PC-AMV

PC-AMV (Pressure Controlled – Assisted Manual Ventilation) is a **neonatal ventilation mode** in which the user controls the ventilation. The strokes are cycled by the T-piece trigger. This trigger is initiated by closing and opening the T-piece of the patient hose. Closed is inspiration (Insp. Thumb trigger), open is expiration (Exp. Thumb trigger). After a maximum inspiration time of 15 seconds the expiration is started. This is necessary to prevent a too long inspiration during which spontaneous breathing is more difficult than during expiration because of the higher pressure. The minimum inspiration and minimum expiration times of 150 ms are maintained.



6.1.9 VC-CMV

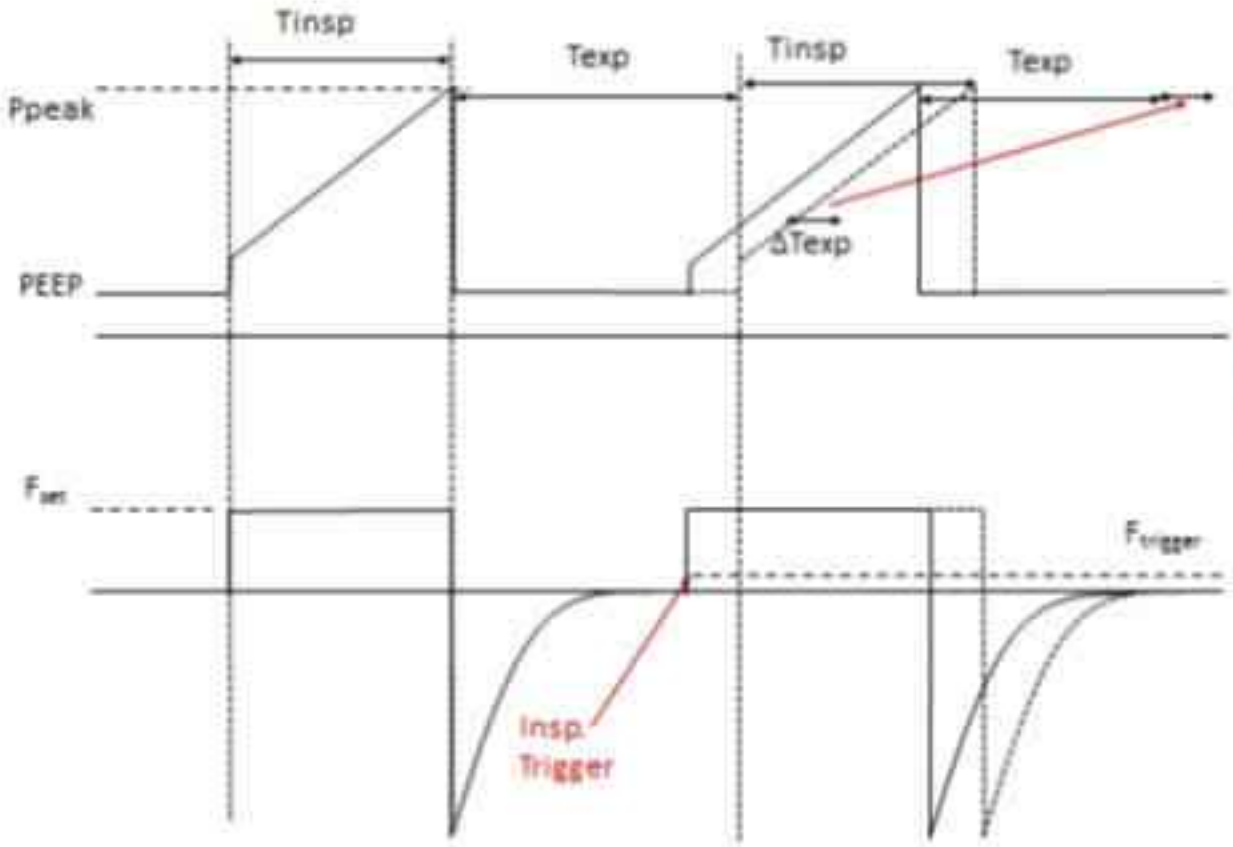
VC-CMV (Volume Controlled – Controlled Mandatory Ventilation) is a ventilation mode in which the ICU Ventilators fully controls the ventilation. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio. They are not triggered by the patient. The inspiration is flow controlled until the inspiratory volume is delivered, after this the plateau phase (maintains inspiratory pressure) and the expiration phase is pressure controlled (maintains PEEP level).



Setting up different inspiratory flow patterns such as Square, Ascending and Descending are possible.

6.1.10 VC-ACV

VC-ACV (Volume Controlled – Assist Control Ventilation) is a ventilation mode in which the ICU Ventilators controls the ventilation, but it can be influenced by the patient. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient. This can lead to an increase of the breathing frequency or respiratory rate (RR).

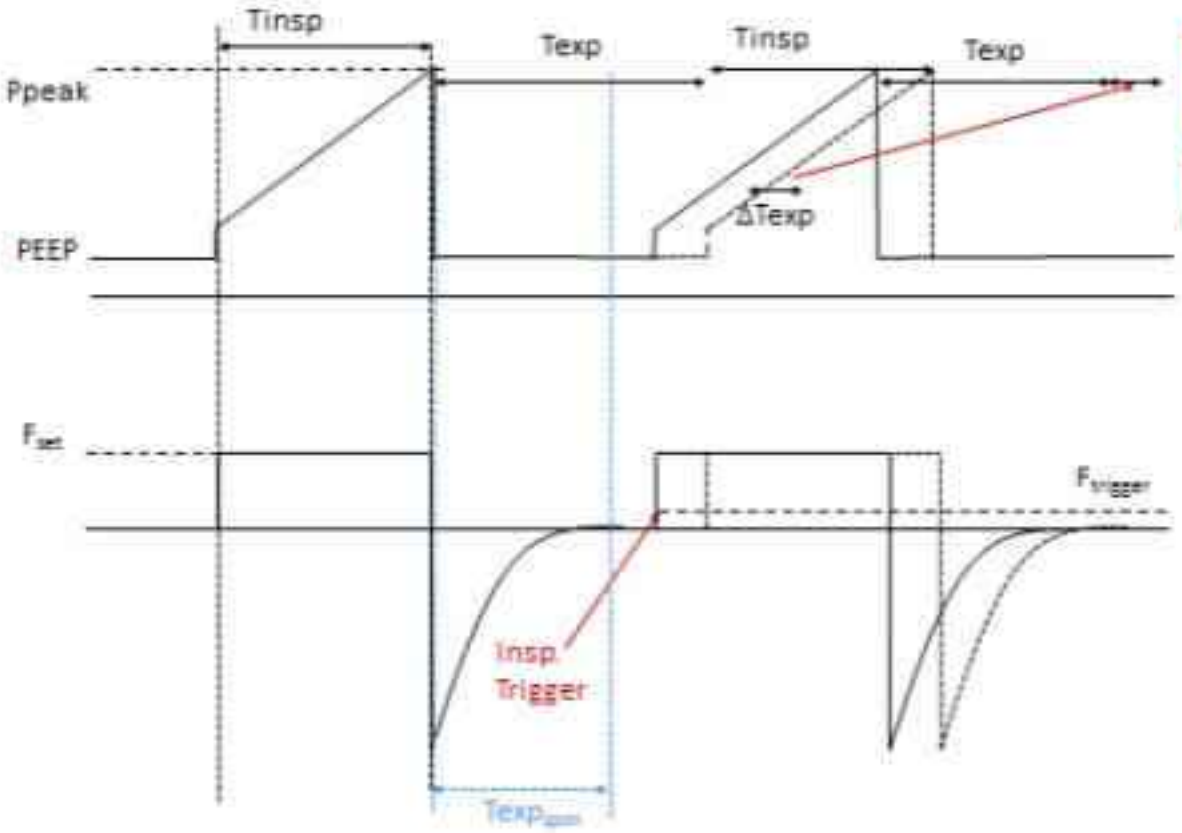


Ventilation with plateau phase and different inspiratory flow patterns are also possible, similar as in VC-CMV.

6.1.11 VC-SIMV

VC-SIMV (Volume Controlled – Synchronized Intermittent Mandatory Ventilation) is a ventilation mode in which the ICU Ventilators controls the ventilation, but it can be influenced by the patient. The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, within a trigger window. This window starts after the time Texpspon (an adjustable percentage of Texp) has elapsed.

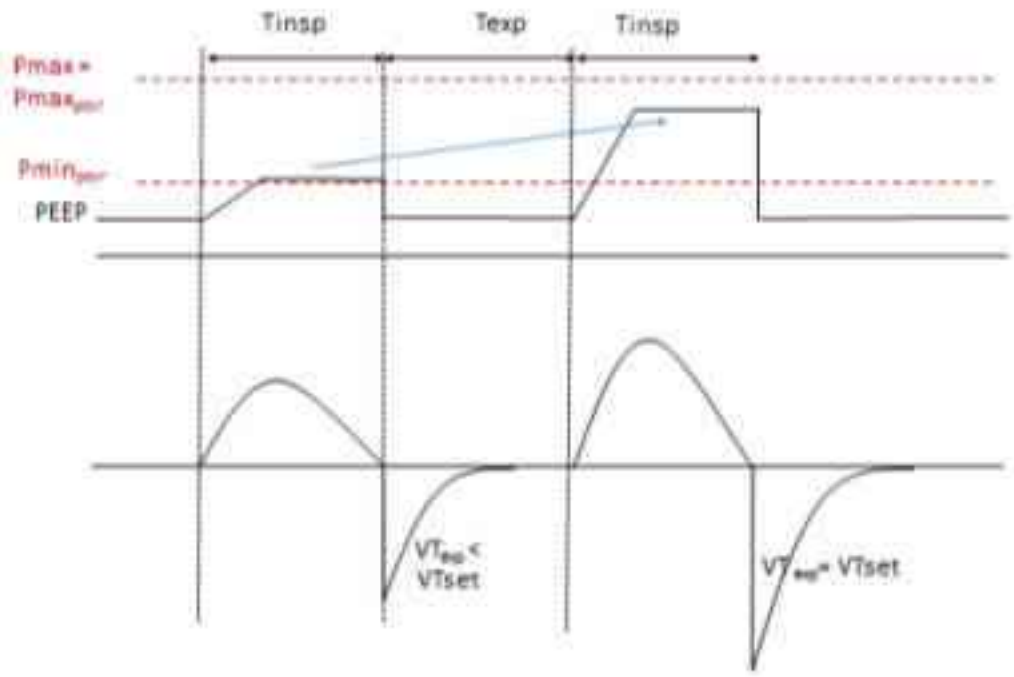
RR compensation is active: The period the inspiration is started earlier (ΔTexp) is compensated in the next expiration. This prevents an increase of the average respiratory rate (RR). The expiration time can differ due to previous triggering, the maximum extension of an expiration is 5 times the original expiration time.
Ventilation with plateau phase & different inspiratory flow patterns are also possible similar as in VC-CMV.



6.1.12 PRVC-CMV

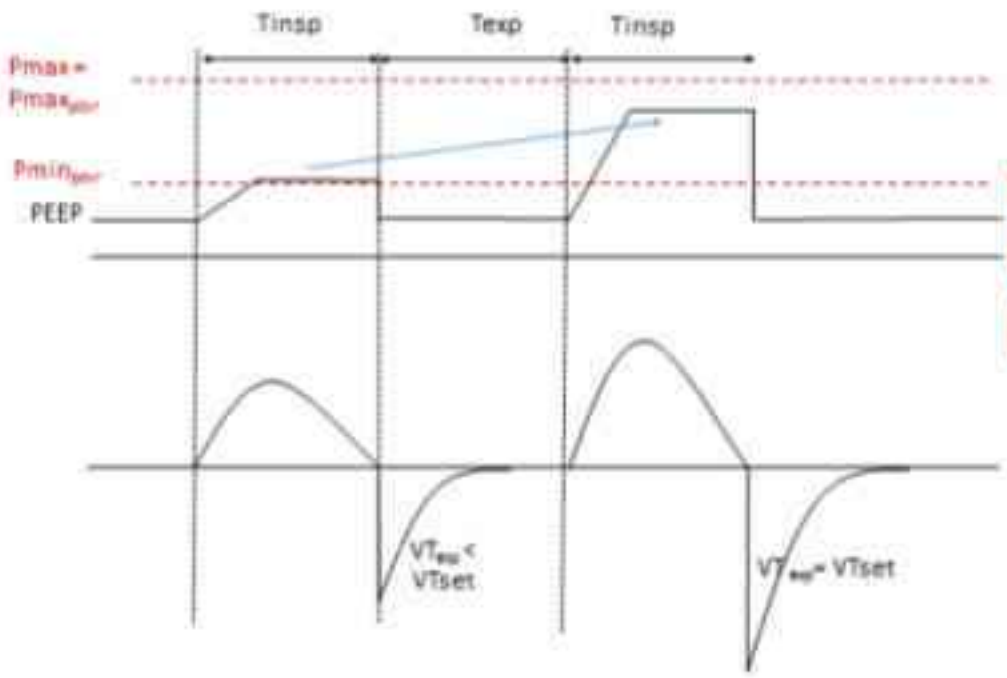
PRVC-CMV (Pressure Regulation Volume Control – Controlled Mandatory Ventilation) is a ventilation mode that assures a set tidal volume (VT) by adjusting the inspiratory pressure level Pinsp of the ventilation. When the measured expiratory tidal volume is too low the inspiratory pressure setting of the next inspiration is increased a little bit until the target volume is reached. Likewise, when the volume is too high the pressure is decreased.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio. They are not triggered by the patient. The patient can breathe spontaneously, but this does not influence the cycling of the breathing phases.



6.1.13 PRVC-ACV

PRVC-ACV (Pressure Regulation Volume Control – Assist Control Ventilation) is a ventilation mode assures a set tidal volume (VT) by adjusting the inspiratory pressure level Pinsp of the ventilation. When the measured expiratory tidal volume is too low the inspiratory pressure setting of the next inspiration is increased a little bit until the target volume is reached. Likewise, when the volume is too high the pressure is decreased.

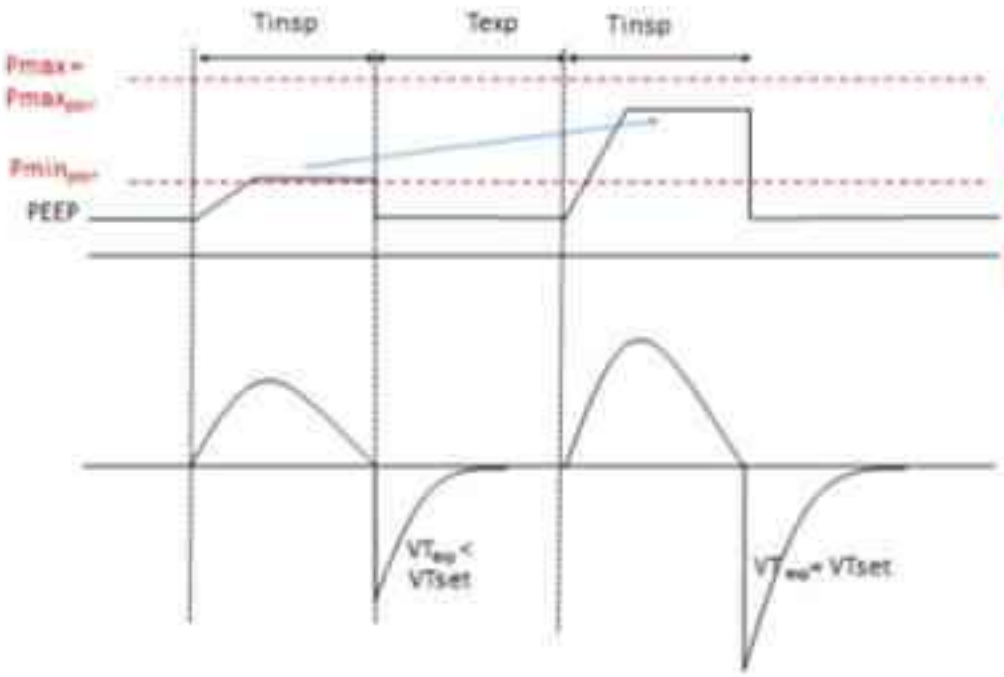


The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient. This can lead to an increase of the breathing frequency or respiratory rate (RR).

6.1.14 PRVC-SIMV

PRVC-SIMV (Pressure Regulation Volume Control – Synchronized Intermittent Mandatory Ventilation) is a ventilation mode assures a set tidal volume (VT) by adjusting the inspiratory pressure level Pinsp of the ventilation. When the measured expiratory tidal volume is too low the inspiratory pressure setting of the next inspiration is increased a little bit until the target volume is reached. Likewise, when the volume is too high the pressure is decreased.

The strokes are time cycled with a fixed inspiratory time and a fixed expiratory time, set by the Respiratory Rate (RR) and Inspiratory time (Tinsp)/ I: E Ratio, when the patient does not breathe spontaneously. However, during expiration an inspiration can be triggered by the patient, within a settable trigger window. This window starts after the time $Texp_{span}$ (an adjustable percentage of Texp) has elapsed.



6.1.15 HFNO

HFNO – High Flow Nasal Oxygen Mode

In this mode a constant flow can be delivered to the patient which is used for O2 therapy. This mode is used with patients with a nasal cannula or a mask.

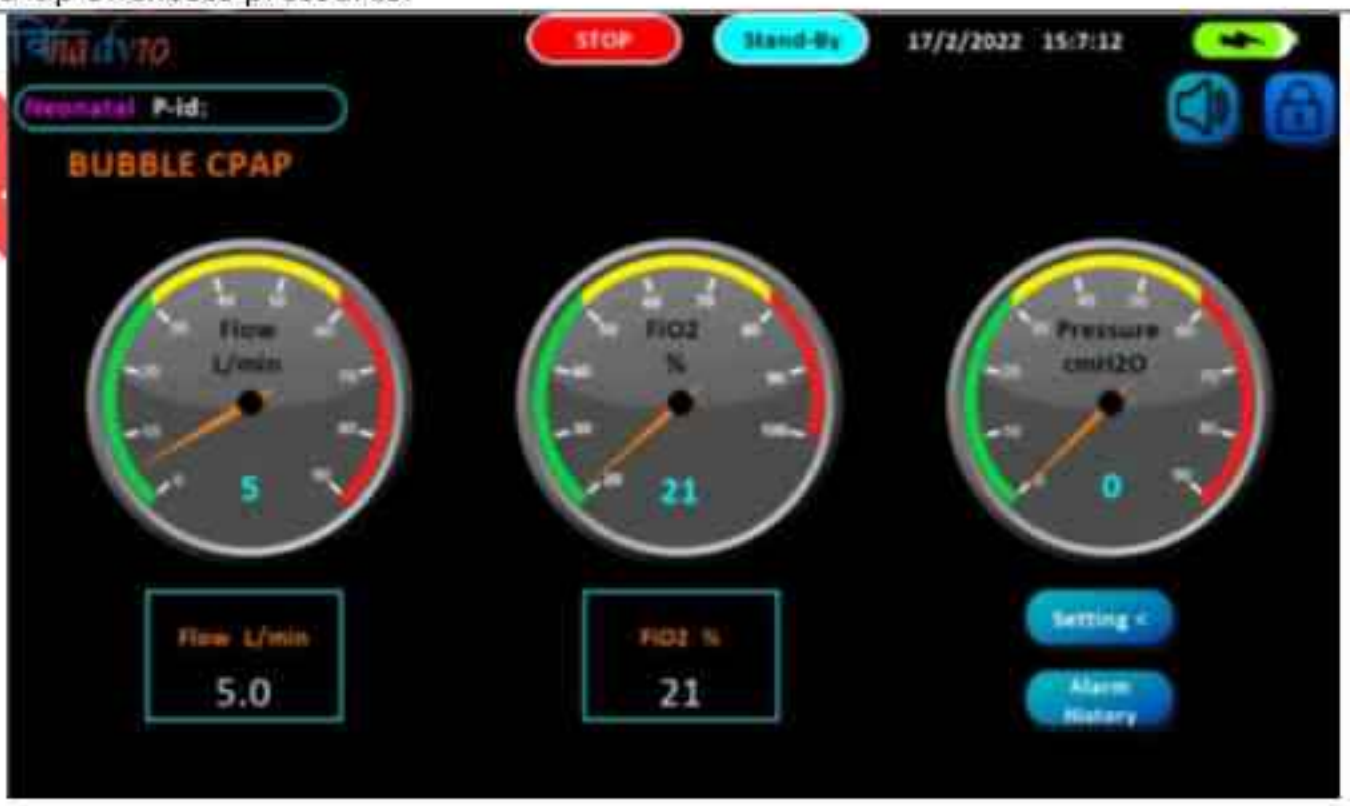
If the pressure (measured on the output pressure sensor) gets higher than the set Pmax, the pressure is clipped to Pmax. As soon as the flow gets higher than the set flow, the pressure is not limited anymore.

NOTE:

HFNO mode is always used without a patient sensor.

6.1.16 Bubble CPAP

It is a **Neonatal O2 Therapy mode,** in which Continuous Positive Airway Pressure (CPAP) is delivered to a spontaneously breathing new-born to maintain lung volumes during expiration. Bubble CPAP mode is used to supply non-invasive support to patient. With this method, blended and humidified oxygen is delivered via short nasal prongs or a nasal mask and pressure in the circuit is maintained by immersing the distal end of the expiratory tubing in water. The depth to which the tubing is immersed underwater determines the pressure generated in the airways of the infant. As the gas flows through the system, it "Bubbles" out and prevents build-up of excess pressures.



6.2 Non-Invasive Ventilation

NOTE:
- Non-Invasive ventilation in critically ill patients should only be used by properly trained and experienced personnel.
- As a precaution, you must be prepared to intubate the patient and start invasive ventilation at any time while non-invasive ventilation is in use.

NIV is delivered using positive-pressure ventilation through an accessory such as a nasal mask or mouthpiece. These accessories are often attached to the patient's head to increase the quality of the airway seal to minimize airway leaks. It is intended for actively breathing patients; non-invasive ventilation is provided through a non-vented or non-ported mask interface. Because this open breathing circuit permits air to leak around the mask or through the mouth, the ICU Ventilators achieve and maintain the prescribed pressure by adjusting the inspiratory flow. NIV is available for all ventilation modes and is accessible through the window ventilation options. Enable the button on the modes screen to use NIV.

NIV performs a leakage compensation of the measured patient flow signal. Triggering may be limited; the user may need to increase the trigger levels to prevent false triggering. During large leakages in all volume-controlled ventilation modes Leakage Compensation (LC) can be applied by setting **Leakage Comp%.** The measured 'Leakage Volume' can help the user to determine the desired percentage of the set Tidal Volume. When Leakage compensation is activated, NIV must also be activated.

⚠ **WARNING:** The exhaled volume of the patient can differ from the measured exhaled volume due to leaks around the mask.

Benefits of Non-Invasive ventilation:

i. Relieves respiratory symptoms
ii. Optimizes patient comfort
iii. Reduces work of breathing
iv. Improves or stabilizes gas exchange
v. Improves patient-ICU Ventilators synchrony
vi. Minimizes risks associated with aspiration, intubation, injury to the mucus membranes and teeth, and circulatory reactions

Requirements for Use

Ensure these requirements are met to use non-invasive ventilation:
- The clinician's instructions must be strictly followed.
- The patient must not be intubated.
- The patient must be able to trigger the ICU Ventilators and must have regular spontaneous breaths.
- The patient must be conscious.
- The patient must be able to maintain an adequate airway.
- It is recommended to monitor the patient by external monitors.
- Intubation must be possible at any time.
- The mask should fit face structures well

NOTE:
- The material in contact with the face should be soft, biocompatible, and non-allergenic.
- It should be easy to install and remove.
- It should remain properly positioned when the patient moves their head.

⚠ **CAUTION**
- To prevent possible patient injury, DO NOT use non-invasive ventilation on patients with no or irregular spontaneous breaths. Non-invasive ventilation was intended to provide supplemental Ventilatory support to patients with regular spontaneous breaths.
- To prevent possible patient injury, DO NOT attempt to use non-invasive ventilation on intubated patients.

7. Safety Alarms

It has audio-visual alarms to notify the operator of occurrence of any problems. It is necessary to attend the patient immediately. These alarms can be classified as High and Medium priority alarms. Alarm History has the log of alarms triggered in the last 72 hours and this can be checked by pressing the Alarm history button on the active mode screen, *refer* ***6 Ventilation Menu Details point number T***.

Alarm limits can also be set for respective modes, *refer* ***6 Ventilation Menu Details point number S***.

⚠ **CAUTION**

- To prevent possible patient injury when alarms are active, check the patient for adequate ventilation. Identify and remove the cause of the alarms. Readjust the alarm limits only when they are inappropriately set for the current conditions.
- Setting alarm limits to extreme values can render the alarm system useless.

NOTE:

- Be aware that an alarm may result from either a clinical condition or an equipment problem.
- Be aware that one alarm condition can induce multiple alarms. Normally only one or two indicate the root cause of the alarm; the rest are results. Your search for the causes of the alarm condition should be assisted by, but not limited to, the alarm messages displayed.
- To mute the audible alarm, press the quick access button. The audible alarms are disabled for the 120 seconds.
- Following are two lists of alarms, condition/cause & suggested action for the user, which only provides general guidelines for the cause & the corrective action, it does not replace hospitals clinical protocol. It is the operator's responsibility to ensure the validity and effectiveness of the actual methods used.

7.1 High Priority Alarms

High priority alarms are flashed continuously in RED colour and need to be attended immediately. It is an audio-visual alarm which can be muted for 120 sec. All high priority alarms get muted if any One alarm is muted for 120 sec. Following is the list of High priority alarms:

Alarm Name on the Display	Alarm condition / cause	Action
ADC Conversion Malfunction	ADC reference voltage outside conversion range, sensor output accuracy is affected.	● Internal sensors calibration & maintenance is required, Contact company's authorized representative for assistance.
Air Flow Sensor Failed	Air Flow sensor output is out of range; thus ICU Ventilators Estimate Flow Air will be Total Flow Output – Flow Oxygen.	● Internal sensors calibration & maintenance is required, Contact company's authorized representative for assistance.
Air Input Flow Low	Measured air flow is low which is an indication for a clogged input filter or air intake obstruction.	● Check the HME filter on the air intake port, for any clogging, & replace the filter accordingly. ● Check whether any obstruction is present on the air intake port and remove it.
Apnea Detected	No valid breaths were detected for the set Apnea Time in CPAP/PSV mode.	● Check the status of the patient. ● Check for leaks in the patient circuit or airway. ● Review the Apnea Time setting in Alarm Setup.
Battery Critically Low	Complete Failure on the system's internal battery, caused by using a ICU	● Connect the ICU Ventilators to a primary power source.

	Ventilators on battery even after Battery Low alarm. ICU Ventilators will go in Standby Mode!	● In the absence of the power source, immediately provide alternative ventilation. ● Switch off the ICU Ventilators before the battery is completely discharged.
Blower Fail	Blower is unable to generate the required air flow, may be due to clogged input filter or air intake obstruction.	● Check the HME filter on the air intake port, for any clogging, & replace the filter accordingly. ● Check whether any obstruction is present on the air intake port and remove it.
	Blower may have failed.	● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Emergency Pressure Release	Patient airway pressure (Paw) > (Pmax + 15 with max. of 102) for 20 ms OR output pressure Pout > 110 mbar for 100 ms For above conditions, Pressure is released through Safety valve for 10 sec & Ventilation is temporarily OFF.	● Check patient condition. ● Check whether any blockages in the breathing circuit causing High pressures, & remove blockages accordingly. ● Check for clogging on the HME filters and replace the filters accordingly.
ETCO2 Sensor Disconnect	Communication between EtCO2 module and main controller is failed	● Check if Mainstream EtCO2 airway adapter- Compatible to Respironics is used & connected on the EtCO2 port on the ICU Ventilators. ● Check whether Airway adapter is intact & mainstream EtCO2 module is properly seated on the airway adaptor. ● Check whether Airway adapter is installed on the proximal end of the circuit between HME filter & ICU Ventilators Y-piece. ● If the problem still persists, then contact company's authorized representative for assistance.
FiO2 High	The measured oxygen exceeds the set high Oxygen alarm limit.	● Check FiO2 high alarm limits with respect to FiO2 settings, suitable for patient condition. ● Check if O2 flush maneuver is active, if yes you can ignore this alarm or Reset alarm limits. ● Check other alarms like Air input flow low & do corrective action accordingly. ● Calibrate the oxygen sensor. ● If the problem still persists, then contact company's authorized representative for assistance.
FiO2 Low	The measured oxygen is below the set alarm limit (low pressure oxygen).	● Check FiO2 low alarm limits with respect to FiO2 settings, suitable for patient condition. ● Check patient condition. ● Check the oxygen supply. Provide an alternative source of oxygen, if necessary. ● Calibrate the oxygen sensor. ● Provide alternative ventilation, if needed.

		● If the problem still persists, then contact company's authorized representative for assistance.
Input Gas Temperature Sensor Fail	Sensor measures open/short circuit.	● Ensure input oxygen gas is supplied at the correct temperatures as per standards, till the alarm condition is corrected. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Internal Flow Measurement Fail	The three internal flow sensors do not match each other (roughly FlowAir + FlowO2 = FlowTotal).	● Avoid using VC-modes and use PC-modes till the alarm condition is corrected. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Invalid Patient Flow Measurement	Patient flow calibration is out of range.	● Recalibrate Patient flow sensor following the procedure properly. ● If the calibration fails again, try using a new Patient flow sensor. ● Check if patient flow sensor of the correct patient type is used as suggested. ● If the problem still persists, then contact company's authorized representative for assistance.
LPO Error	When LPO is active & Oxygen supply pressure > 800 mbar OR oxygen flow > 8 LPM.	● Make sure Oxygen supply pressure is less than 500 mbar(0.5kg/cm^2) & flow set up to 8 LPM for LPO mode. ● If the problem still persists, then contact company's authorized representative for assistance.
Max Pressure Reached	Patient airway pressure Paw > (Pmax -1) for 20 ms.	● Check patient condition. ● Check whether any blockages in the breathing circuit causing High pressures, & remove blockages accordingly. ● Check for clogging on the HME filters and replace the filters accordingly.
Motor Temperature High	The Motor temperature is more than 70°C & less than 100°C Ventilation is ON with warning	● Check if the ICU Ventilators is kept in the proper medical ambient environment. ● Check for clogging on the HME filters, at the air intake port & change filter accordingly. ● Try providing additional cooling source, near the ICU Ventilators. ● Take Action to reduce Tramp and/ or Pmean . ● In the absence of other corrective actions, be prepared to provide alternative ventilation. ● If the problem still persists, then contact company's authorized representative for assistance.
Motor Temperature Out of Range	If Motor temperature is more than or equals to 100°C Ventilation is OFF with warning	● Immediately provide alternative ventilation.

		● Contact company's authorized representative and have the ICU Ventilators serviced.
Motor Temperature Sensor Fail	Motor Temperature Sensor shows open/ short circuit. Ventilation is ON with warning	● Risk of undetected blower overheat and module damage when extreme settings are used. ● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
MVe Expiration High	Alteration of Patient's Respiratory Mechanics.	● Check patient condition
	The measured expiratory minute volume (sum of mandatory & spontaneous) exceeds the set alarm limit.	● Establish suitable parameters for the Ventilatory support. ● Check and confirm settings, including alarms.
	Patient flow sensor disconnected or white tube is loose.	● Check patient flow sensor tube connections and its direction.
MVe Expiration Low	Alteration of Patient's Respiratory Mechanics.	● Check patient condition. ● Check for leaks in patient circuit or airway.
	The measured expiratory minute volume is below the set alarm limit while the patient is connected.	● Establish suitable parameters for the Ventilatory support. ● Check and confirm settings, including alarms. ● Check patient flow sensor tube connections and its direction.
No Pressure Sensor Available	Valid Patient airway pressure sensor is not available or the sensor has a malfunction.	● Try recalibrating the patient flow sensor. ● If problem persists, change patient flow sensor & recalibrate & use. ● If the problem still persists, then contact company's authorized representative for assistance.
Obstruction Detected	Obstruction in expiratory limb or Exhaust Port detected ICU Ventilators will open safety valve for 10 secs.	● Check for any blockage in the expiratory limb, Expiratory valve, exhaust output, clogging in the HME filters and remove the blockage accordingly.
	Expiratory Time set by I:E ratio & Respiratory rate is too small for the selected patient type.	● Correct the ventilation parameter setting for I, E & RR
Output Flow Sensor Fail	Output flow sensor out of range. Oxygen delivery will be stopped, see alarm Backup Gas Source Active. ICU Ventilators will estimate Flow Output with Flow Air.	● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Output Gas Temperature Sensor Fail	Sensor measures open/short circuit. Ventilation is ON with warning.	● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Output Pressure Sensor Fail	The ICU Ventilators is not able to measure Output pressure given to the patient.	● Perform System Check to assure accuracy of the Patient airway pressure sensor (flow sensor).

	Output pressure is based on the Patient airway pressure sensor.	● Contact company's authorised service provider for assistance.
Oxygen Flow Sensor Failed	Oxygen Flow sensor out of range. Oxygen delivery will be stopped, see alarm Backup Gas Source Active. Estimate Flow Output with Flow Air	● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Oxygen Sensor Fail	Oxygen sensor out of range. Oxygen delivery will be continued with warning and FiO2 set may not be accurate.	● If ICU Ventilators is in use, shift patient to alternative ventilation & then try following measures: ● Check connection of the oxygen sensor. ● Calibrate the oxygen sensor & check ● If problem persists, Replace the oxygen sensor & calibrate & then use. ● If the problem still persists, then contact company's authorized representative for assistance.
Oxygen Supply Pressure Sensor Fail	Oxygen supply Pressure sensor out of range. Oxygen delivery will be stopped, see alarm Backup Gas Source Active. ICU Ventilators will estimate Flow Output with Flow Air.	● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Oxygen Supply Pressure Too Low	Oxygen supply may be disconnected or connection loosed up or supply pressure may be low.	● Check for any leakage in the oxygen input connection & correct it.
	Oxygen cylinder may be empty.	● Check the pressure on the Oxygen inlet manometer, if less than 3 bar use alternative source of oxygen.
	Measured oxygen supply pressure < 2.5 bar (OR kg/cm^2) (when using in HPO and FiO2 setting Percentage > 21%) Oxygen delivery will be continued till pressure greater than or equals 1.1 bar, thereafter Backup Gas Source will be active.	● Be ready with an alternative oxygen source/oxygen cylinder. ● Replace the oxygen source/oxygen cylinder if Back up gas source active alarm appears OR FiO2 set is not achieved.
Oxygen Valve Fail	Oxygen delivery valve is failed. Oxygen delivery will be stopped, see alarm Backup Gas Source Active. ICU Ventilators will estimate Flow Output with Flow Air.	● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Patient Airway Pressure High	Patient Airway pressure (at patient end) is greater than the Paw high alarm limit.	● Check and confirm settings, including alarms. ● Check patient's condition. ● Check whether any blockage in the breathing circuit causing increasing pressure and remove the blockage accordingly or reposition the respiratory valve diaphragm. ● If the problem still persists, then contact company's authorized representative for assistance.
	Expiratory valve may be Reversed.	● Correct the Expiratory valve direction coming out from the machine.

	Alteration of Patient's Respiratory Mechanics.	● Establish suitable parameters for the Ventilatory support.
	Obstruction of Breathing circuit's expiratory Limb or its Expiratory valve.	● Check whether any blockage in the breathing circuit causing increasing pressure and remove the blockage accordingly or reposition the respiratory valve diaphragm. ● If the problem still persists, then contact company's authorized representative for assistance.
	Obstruction of the patient's airways.	● Remove obstructions or aspirate the patient's airways
	Inspiratory pressure monitored is greater than expected.	● Check the setting of inspiratory pressure (absolute), whose value is the sum of the controlled pressure (relative) with PEEP.
	PIP is much higher than Pplateau	● Increase the set Rise Time.
Patient Airway Pressure Low	Patient Airway pressure (at patient end) is lesser than the Paw low alarm limit.	● Check and confirm settings, including alarms ● Check patient's condition ● Check whether any leakage in the breathing circuit is causing decrease in pressure, & remove blockages accordingly. ● If the problem still persists, then contact company's authorized representative for assistance.
	Alteration of Patient's Respiratory Mechanics.	● Establish new parameters for Ventilatory support.
	Excessive leakage on Breathing circuit.	● Locate leakage and correct it.
	Expiratory valve tube may not be connected.	● Connect the Expiratory valve tube & tighten the expiratory valve.
Patient Airway Pressure Sensor Fail	Patient flow sensor disconnected or blue tube connection has become loose.	● Ensure Patient flow sensor connection is tightened & is in the right direction. ● Calibrate the flow sensor. ● Replace the flow sensor & recalibrate & use. ● If the problem still persists, then contact company's authorized representative for assistance.
Patient Disconnect	The breathing circuit is disconnected	● Locate the disconnection and connect firmly.
	Lack of Inspiratory Flow.	● Verify the existence of an inspiratory flow and increase it, if necessary.
	Alteration of Patient's respiratory Mechanics.	● Establish new parameters for Ventilatory support.
	Expiratory valve diaphragm mounted incorrectly or damaged.	● Place the diaphragm in the right position or substitute the diaphragm.
	Failure on pressure control electronic system.	● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Patient Flow Sensor Fail	Non compatible circuits or Flow Sensor as per selected patient type.	● Use specified Flow sensor & ICU Ventilators Circuit type as per the selected patient type

		● Ensure Patient flow sensor connection is tightened & is in the right direction. ● Calibrate the flow sensor. ● Replace the flow sensor & recalibrate & use. ● If the problem still persists, then contact company's authorized representative for assistance.
PEEP High	PEEP high can be caused by obstruction in the expiratory circuit path, expiratory valve, exhaust port OR HME filter.	● Check patient condition. ● Check and confirm settings, including alarms. ● Check the expiratory valve cover and membrane for possible obstructions. ● Check for obstructions in the ● expiratory limb and remove it accordingly.
PEEP Low	PEEP low can be caused by leakage in the expiratory limb.	● Check patient condition. ● Check and confirm settings, including alarms. ● Check the expiratory valve cover and membrane for possible leakages. ● Check for any leakages in the ● expiratory limb and correct it accordingly.
Pilot Valve Fail	Comparison of the actual and set pilot valve voltage, only during self-test. (Expiratory valve control tube).	● Follow the procedure of Self-test ● Try replacing expiratory valve/tube & recheck. ● If the problem still persists, then contact company's authorized representative for assistance.
Relief To Ambient Pressure	Patient airway pressure, Paw > (Pmax + 2) for 300 ms Causes Stop Ventilation for 3 secs	● Check patient condition. ● Check the expiratory valve cover and membrane for possible obstructions. ● Check for obstructions in the expiratory limb and remove it accordingly.
Relief To Peep	Patient airway pressure, Paw > (Pmax + 2) for 170 ms Causes Forced Expiration.	● Check patient condition. ● Check the expiratory valve cover and membrane for possible obstructions. ● Check for obstructions in the expiratory limb and remove it accordingly.
RR High	Measured respiratory rate is greater than the RR high alarm limit.	● Check patient condition. ● Check for leaks in patient circuit or airway. ● Check and confirm settings, including alarms. ● Check & update flow/ pressure trigger settings suitable for the patient. ● If the problem still persists, then contact company's authorized representative for assistance.
RR Low	Measured respiratory rate from the ICU Ventilators is less than the RR low alarm limit.	● Check patient condition. ● Check for leaks in patient circuit or airway. ● Check the airway module. ● gas sampling line connection. ● Check for an occlusion in. ● the airway module gas sampling line

		● Check and confirm settings, including alarms and trigger. ● If the problem still persists, then contact company's authorized representative for assistance.
Safety Valve Fail	Safety valve does not open during Hose Compliance Calibration, or current to valve is incorrect. Pressure relief during an obstruction event or emergency pressure relief event is not possible.	● Repeat System check & Hose compliance test. ● Check No leakage is present at the breathing circuit, during Hose Compliance test. ● If the problem still persists, then contact company's authorized representative for assistance and do not use the machine.
Supply Voltage Critically Low	Supply to the Respiratory module very low, causing it to stop the ventilation Caused by, Complete Failure on the system's power supply, i.e. SMPS or internal battery.	● Connect the ICU Ventilators to a primary power source. ● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
System Communication Fail	Communication between main & secondary processor is failed.	● Immediately provide alternative ventilation. ● Switch off & try Restarting ICU Ventilators & recheck. ● Contact company's authorized representative and have the ICU Ventilators serviced.
User Setting Error	Not possible setting of ventilation parameters by the user e.g. PEEP setting is higher than Pinsp setting.	● Correct the ventilation parameter setting.
VT Insp High	Inspiratory Tidal volume (mandatory) measured exceeds, the VT insp high alarm limits.	● Check patient condition. ● Check the pressure and volume ● settings for potential leaks and/or disconnections. ● Check and confirm settings, including alarms. ● Check for trigger settings in Pressure support modes.
VT Insp Low	Inspiratory Tidal volume (mandatory) measured is lower than the VT insp low alarm limits.	● Check patient condition. ● Check and confirm settings, including alarms. ● Check the breathing circuit and artificial airway of the patient for leaks and/or disconnection.

7.2 Medium Priority Alarms

Medium priority alarms are flashed continuously in YELLOW colour and need to be attended immediately. It is an audio-visual alarm which can be muted for 120 sec. When such an active alarm is muted, newly medium priority triggered alarms will only be displayed on the screen and will not trigger an audible alarm, whereas high priority alarms will trigger both audible & visual alarm.

Alarm Name on the Display	Alarm condition / cause	Action
AC Power Connected	AC power cable plug in event	● No action required.

AC Power Fail, Battery Connected	AC power is failed, & ICU Ventilators runs on battery	● Check whether the power cord is connected properly. ● Note the battery status & if battery is low i.e. <40%, prepare for AC power restoration, or alternative ventilation for the patient.
Ambient Pressure Measurement Error	Measurement from the ambient sensors is erroneous Ventilation will be ON with warning	● If ventilator is in use, temporarily ignore this alarm, after the patient is disconnected, restart the ICU Ventilators & Check. ● If alarm persists, contact company's authorized representative for assistance.
Ambient Pressure Sensor 1	Ambient Sensor 1 measurement outside range, Measurement based on Ambient sensor 2 Ventilation will be ON with warning	● If ventilator is in use, temporarily ignore this alarm, after the patient is disconnected, restart the ICU Ventilators & Check. ● If alarm persists, contact company's authorized representative for assistance.
Ambient Pressure Sensor 2	Ambient Sensor 2 measurement outside range, Measurement based on Ambient sensor 1 Ventilation will be ON with warning	● If ventilator is in use, temporarily ignore this alarm, after the patient is disconnected, restart the ICU Ventilators & Check. ● If alarm persists, contact company's authorized representative for assistance.
Back Up Ventilation Active	Apnea has been detected. Back up PC-SIMV mode with the user setting is activated	● Check the status of the patient. ● Review the ICU Ventilators settings. ● Confirm the current mode in Mode Settings to continue using backup ventilation settings. ● Confirm a different mode in Mode Settings to end backup ventilation.
Backup Gas Source Active	Hardware malfunctions detected that makes oxygen delivery impossible or possibly dangerous Estimate Flow Output with Flow Air	● Check for oxygen source for leakage or lack of oxygen pressure & correct it. ● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Battery Low	Low voltage is detected on the internal battery, after usage without power source. ICU Ventilators is still in operation.	● Connect the ICU Ventilators to a primary power source. ● In the absence of primary power, be prepared to provide alternative ventilation.
CPAP/PSV Active	CPAP/PSV mode is activated as per the user setting after detection of two consecutive spontaneous breaths from the patient, back up ventilation PC-SIMV mode is stopped till the next Apnea detection	● Check patient condition. ● If the patient is not breathing and if it was a false breath detection, change the trigger setting/ mode setting. ● Check if there is need of changing the set Apnea time.
Display Communication Fail	No Input/ Output from Display & Touch screen	● If ventilator is in use, provide an alternative ventilation. ● Switch off & restart the ICU Ventilators & Check. ● If alarm persists, contact company's authorized representative for assistance.
ETCO2 High	Measured ETCO2 is greater than the ETCO2 High alarm limit.	● Check patient condition. ● Check and confirm settings, including alarms.

		● Check for the requirement of changing the Respiratory Rate or I: E ratio setting. ● If alarm persists, contact company's authorized representative for assistance.
ETCO2 Low	Measured ETCO2 is less than the ETCO2 Low alarm limit.	● Check patient condition. ● Check and confirm settings, including alarms. ● Check for the requirement of changing the Respiratory Rate or I: E ratio setting. ● If alarm persists, contact company's authorized representative for assistance.
Expiratory Hold Active	Expiratory Hold maneuver is Enabled by the User	● Check the status of the patient. ● Review the ICU Ventilators settings for Expiratory Hold of the patient.
Flow Rate High	Output flow rate exceeds Flow Rate High limit in HFNO mode	● Check patient condition. ● Check and confirm settings, including alarms. ● Check for obstructions in the Breathing circuit and remove it
Flow Rate Low	Output flow rate is less than Flow Rate Low limit in HFNO mode	● Check patient condition. ● Check and confirm settings, including alarms. ● Check for leakages in the Breathing circuit and correct it accordingly.
INCO2 High	Measured INCO2 is greater than the INCO2 High alarm limit.	● Check patient condition. ● Check and confirm settings, including alarms. ● Check for the requirement of changing the Respiratory Rate or I: E ratio setting. ● If alarm persists, contact company's authorized representative for assistance.
Input Gas Temperature High	Temperature of the input gas is > 40°C Ventilation is ON with the warning	● Ensure input oxygen gas is supplied at the correct temperatures per standards, till the alarm condition is corrected. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Inspiratory Hold Active	Inspiratory Hold maneuver is Enabled by the User	● Check the status of the patient. ● Review the ICU Ventilators settings for Inspiratory Hold of the patient.
Nebulizer Active	Nebulizer is Enabled by the User	● Check the status of the patient. ● Confirm the ICU Ventilators settings for Nebulizer of the patient. ● Confirm Nebulized medication are delivered to patient, synchronised with Mandatory Inspiration. ● Disable the nebulizer when not required.
O2 Flush Active	O2 Flush maneuver is Enabled by the User (for 30 sec)	● Check the status of the patient. ● Review the ICU Ventilators settings for O2 Flush and check if FiO2 has become 100%. ● Disable the O2 flush maneuver when not required.
Output Gas Temp High	Temperature of the output gas is > 68 °C	● Ensure input oxygen gas is supplied at the correct temperatures per standards.

	Ventilation is ON with the warning	● Check if the ICU Ventilators is kept in the proper medical ambient environment. ● Check for clogging on the HME filters, at the air intake port & change filter accordingly. ● Try providing additional cooling source, near the ICU Ventilators ● In the absence of other corrective actions, be prepared to provide alternative ventilation. ● If the problem still persists, then contact company's authorized representative for assistance.
P0.1 Maneuver Active	P0.1 maneuver is Enabled by the User	● Check the status of the patient. ● Review P0.1 pressure, reading on the Event button.
Patient Sensor Readout Error	Patient sensor measurement out of range	● Check the direction of the patient flow sensor. ● Check the type of the patient flow sensor is correct as per patient type selected. ● Recalibrate the patient flow sensor. ● Replace the flow sensor & recalibrate & use. ● If the problem still persists, then contact company's authorized representative for assistance.
PEEPi Active	Intrinsic PEEP maneuver is Enabled by the User	● Check the status of the patient. ● Review Intrinsic PEEP pressure, reading on the Event button.
PRVC Max Reached	In PRVC modes, Maximum Inspiratory pressure limit to reach Set Tidal Volume is reached	● Check the status of the patient. ● Review PRVC Max pressure settings, to achieve Set Tidal Volume. ● Decrease the Set Tidal Volume to achieve that in the set PRVC limit.
PRVC Min Reached	In PRVC modes, Minimum Inspiratory pressure limit to reach Set Tidal Volume is reached	● Check the status of the patient. ● Review PRVC Min pressure settings, to achieve Set Tidal Volume. ● Increase the Set Tidal Volume to achieve that in the set PRVC limit.
Recruitment Maneuver Active	Recruitment maneuver is Enabled by the User	● Check the status of the patient. ● Review Recruitment No. of breaths (High PIP & PEEP), are delivered to the patient with set values .
Screen Locked	Screen Lock button is pressed Touch screen input is disabled by the user	● To unlock, press the unlock button
Screen Unlocked	Screen Unlock button is pressed Touch screen input is enabled by the user	● To lock, press the lock button
Sigh Active	Sigh maneuver is Enabled by the User	● Check the status of the patient. ● Review the ICU Ventilators settings for Sigh breath of the patient, after No. of non-sigh breaths, Psigh/Vsigh setting as per the selected mode.
Stand-By Mode	Standby Mode is turned ON	● Ventilation is paused & standby mode is active

		● Press the Start/Stand-By button again to re-start the ventilation.
Supply Voltage Low	Supply to Respiratory module drops to 20V	● Connect the ICU Ventilators to a primary power source. ● Be prepared to provide alternative ventilation. ● If the problem still persists, contact the company's authorized representative for assistance.

7.3 Adjustable Alarms

Alarm	Set Parameter Range			Limit	Default Parameters			Units
	Adult	Paediatric	Neonatal		Adult	Paediatric	Neonatal	
Patient Airway Pressure (Paw)	0-100	0-80	0-60	**Lower**	10	0	0	**cmH2O**
				Upper	80	60	40	
PEEP	0-40	0-30	0-25	**Lower**	0	0	0	**cmH2O**
				Upper	20	20	20	
Tidal Volume insp	0-5000	0-1000	0-200	**Lower**	0	0	0	**ml**
				Upper	1000	250	50	
MVe Expiration	0-50.0	0-15.0	0-5.0	**Lower**	0.0	0.0	0.0	**LPM**
				Upper	20.0	10.0	2.0	
Respiration Rate	0-100	0-100	0-250	**Lower**	0	0	0	**bpm**
				Upper	40	80	120	
FiO2	18-100	18-100	18-100	**Lower**	18	18	18	**%**
				Upper	100	100	100	
Apnea Time	5-60	5-60	5-60	**NA**	10	10	10	**sec**
ETCO2	0-150	0-150	0-150	**Lower**	20	20	20	**mmHg**
				Upper	100	100	100	
INCO2	0-20	0-20	0-20	**Upper**	7	7	7	**mmHg**

NOTE:

- Whenever the equipment is turned on or there is an exchange of patient type or end the power of the battery without the ICU Ventilators is connected to the power grid, the alarms will assume default values.
- Applies only to the basic alarms ventilation (maximum pressure, PEEP, volume, minute volume, rate, FiO2, ETCO2 and INCO2).

8. Cleaning and Maintenance

It is important to establish a routine for cleaning, disinfection or sterilization of equipment and its components. The device must be cleaned at least once a week or after each patient and especially the single use accessories must be discarded after the treatment of each patient. The following describes the main forms of cleaning, disinfection or sterilization according to the characteristics of each component and equipment.

NOTE:
This manual only provides general guidelines for cleaning, disinfecting, and sterilizing. It is the operator's responsibility to ensure the validity and effectiveness of the actual methods used. It does not replace hospitals infection control policies.

IMPORTANT CHECK POINTS

- Always disconnect the device from electrical power before cleaning and disinfection to reduce the risk of electric shock.
- Ensure all oxygen and air supplies are turned off & disconnected before performing cleaning procedures. Explosion or Fire hazards may occur when cleaning in an oxygen-enriched environment.
- DO NOT reuse single-use bacteria filters, flow sensors, breathing circuits and other accessories. They must be discarded after use. Follow your hospital procedures for disposal.
- Performance is not guaranteed if an item labelled as single-use is reused.
- Reuse of a single-use product voids the warranty.
- Always use caution when handling bacteria filters to minimize the risk of bacterial contamination or physical damage. Dispose of used filters immediately after use. Follow your hospital procedures for disposal.
- Do not allow liquids to seep into electrical housings or any inlets nor let it get collected.
- To prevent damage to the device and components, do not clean with hard brushes, pointed instruments, or rough materials.
- Exposure to cleaning and disinfection agents may reduce the useful life of certain parts.
- Use the cleaning solution sparingly on a cloth when cleaning the device. Do not saturate the unit – excessive solution causes damage to internal components.
- Do not use solvents or abrasive cleaning solutions for cleaning surfaces of the device.

8.1 Cleaning Procedure

1. Always follow hospital and local guidelines for cleaning frequencies.
2. Before cleaning, remove and discard all used disposable products using the recommended method of disposal.
3. Dust all plastic surfaces with a clean damp soft cloth.
4. Dust all accessible metal surfaces with a clean soft cloth or paper towel.
5. Ensure no part of the device or its accessories are immersed in a cleaning agent.
6. Apply the cleaning solution with a clean cloth or sponge.
7. Clean all parts of the device and its accessories at ambient conditions.
8. Dry all surfaces after cleaning with a clean soft cloth or paper towel.
9. Wipe the screen with a damp, soft cloth using isopropyl alcohol or a nonabrasive glass cleaned

NOTE

- Do not clean or disinfect the control and display unit during ventilation. Switch off the device and disconnect the mains plug prior to cleaning or disinfection.
- Handle the touch screen with care.
- Do not use any vinegar-based solutions and avoid using gritty cloths.

8.2 Disinfection Procedure

Always follow standard hospital guidelines.

8.3 Device Disposal

The disposal of this device and its components must comply with local, state, and federal environmental regulations. Any parts that have been in direct contact with the patient (e.g., breathing circuits, flow sensors, filters) must be considered contaminated and should be disposed of per your institution's infection control protocols. Electronic components, such as the oxygen sensor and battery, must be disposed of in accordance with applicable e-waste and battery disposal regulations in your region. Do not incinerate or discard batteries or sensors in general waste. Non-contaminated mechanical or electronic parts should be handled according to applicable environmental protection laws.

8.4 Preventive Maintenance

The following subsections provide details for some of the preventive maintenance procedures and schedules.

NOTE

- These are general guidelines and do not replace the maintenance schedule of the hospital in anyway.
- Any attempt to modify the ICU Ventilators hardware or software without the express written approval of AVI Healthcare automatically voids all warranties and liabilities.
- AVI Healthcare recommends that you document all maintenance procedures.
- It is not allowed to perform service or maintenance on the device while a patient is connected.
- The unit should be serviced and maintained by qualified service personnel. Follow hospital and local regulations for scheduled maintenance frequency.

Interval	Part/Accessory	Procedure
Between patients and according to hospital policy	Breathing circuit (including mask, inspiratory filter, flow sensor, nebulizer jar, Expiratory valve, Humidifier Chamber)	Replace with sterilized or new single patient use parts, whichever applicable. Perform the system check/calibration before use as per section 5 Ventilator Overview i.e. 5.2 calibration & 5.3 System Check
	Entire ICU Ventilators	Perform system check as per section 5.3 System Check
Every 2 days or according to hospital policy	Breathing circuit	Empty any water from breathing tubes or water traps. Inspect parts for damage. Replace as necessary.
	HME Filter	Check for dust or any visible soiling particles and change the filter
Every week	Batteries	Recharge batteries by plugging the ICU Ventilators into a primary power source.
Every month (or more often, if required)	⚠ **Caution:** To reduce the risk of patient cross-contamination, always perform maintenance at the prescribed interval.	
	Air vents on back side	Clean the dust with cloth
Yearly	Oxygen Sensor	Replace if depleted
	CO2 sensor	If the CO2 option is installed, have a CO2 accuracy check performed.
	ICU Ventilators	Call and schedule service-related preventive maintenance with the manufacturer.

9. Technical Specifications

9.1 Physical and Environmental Specifications

Parameter	Specification	Unit
DIMENSIONS AND WEIGHT (BASIC UNIT)		
Length	300	mm
Depth	330	mm
Height	330	mm
Weight	12	kg
DIMENSIONS AND WEIGHT (WITH STAND)		
Length	420	mm
Depth	550	mm
Height	1300	mm
Weight	27	kg
OPERATION		
Temperature	10 to 30	°C
Barometric Pressure	50 to 106	kPa
Relative Air Humidity (non-condensing)	15 to 95	%
STORAGE and TRANSPORT		
Temperature	-20 to 60	°C
Barometric Pressure	50 to 106	kPa
Relative Air Humidity (non-condensing)	15 to 95	%

9.2 Electrical Specifications

Parameter	Specification	Unit
EXTERNAL POWER SUPPLY AC		
Voltage	190 to 240	VAC
Frequency	50/60	Hz
Power Consumption	155	Watts
Fuse	3A, 250VAC	-
INTERNAL BATTERY		
Voltage	Restricted Proprietary Information	VDC
Capacity		mAh
Autonomy of internal batteries with full load and normal use	Up to 360	minutes
Average time to recharge to full load	5	hours
OTHER		
Noise (at one-meter distance)	< 45	dB

NOTE:
Battery life indications are approximate. The actual battery life depends on ICU Ventilators settings, battery age, and level of battery charge. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.

9.3 Pneumatic specification

High Pressure Oxygen inlet (HPO)	
Pressure	3 to 6 bar / 300 to 600 kPa / 43.5 to 87 psi (Medical grade)
Flow	≤ 200 L/min
Low Pressure Oxygen inlet (LPO)	
Peak Pressure	< 500 mbar / 50 kPa / 7.2 psi (Medical grade)
Flow	≤ 8 L/min
Inbuilt Air Source	

Air Source	Integrated blower
Control Parameters	
Inspiratory pressure (Pinsp)	5 - 60 cmH2O
Pressure Support (PS)	0 - 60 cmH2O
Maximum error of the airway pressure (Paw) at the end of the inspiratory phase in relation to the set value	± (5% or 1 cmH2O), whichever is higher
PEEP	0 - 40 cmH2O
Maximum error of the PEEP in relation to the set value	± (5% or 1 cmH2O), whichever is higher
Maximum limited pressure settable	30-100 cmH2O for Adult Patients 30-70 cmH2O for Paediatric Patients 30-60 cmH2O for Neonatal Patients
Tidal Volume (VT)	2 - 2000 ml
Maximum error of the inspiratory volume in relation to the set tidal volume for volume control modes in normal condition	± (10% or 10 ml), whichever is higher for Adult/Paediatric Patients, ± (10% or 1 ml), whichever is higher for Neonatal Patients in PRVC
O2 concentration (FiO2)	21 - 100%
Maximum error of the inspiratory oxygen concentration (FiO_2) at the patient connection port in relation to the set value	± (2.5% + 2.5%vol)
Response time for the FiO2 in the delivered volume to change from a volume fraction of 21% to 90 % of the maximum settable FiO2	<40 seconds
Pressure Trigger	-10 to 0 cmH2O
Flow Trigger	0.0 to 20.0 LPM
Expiratory Flow Cycle Trigger	0-75% of maximum flow in PS inspiration
O2 Therapy Flow Setting	0.0 to 65.0 LPM for Adult Patients 0.0 to 50.0 LPM for Paediatric Patients 0.0 to 20.0 LPM for Neonatal Patients
Respiratory Rate (RR)	4 - 200 bpm
I:E Ratio	1:9.9 to 9.9:1
Inspiratory Time (Tinsp)	0.2 to 9.9 seconds
Maneuvers	O2 Flush, Sigh, P0.1, Lung Recruitment, Inspiration Hold, Expiration Hold, Nebulizer, Tube Compensation, Intrinsic PEEP
Nebulizer	Ultrasonic Nebulizer - Compatible with Aerogen Solo, Time - 0 to 30 mins, Inspiration Synchronized

9.4 Monitored Parameters

Monitored Parameters	
Tidal Volume	0-2000 ml
Accuracy of the inspiratory volume monitoring equipment, VTi>50ml	± (10% or 10 ml), whichever is higher
Accuracy of the inspiratory volume monitoring equipment, Vti<50ml	± (10% or 1 ml), whichever is higher
Accuracy of expired volume monitoring equipment, VTe >50 ml	± (10% or 10 ml), whichever is higher
Accuracy of expired volume monitoring equipment, VTe ≤50 ml	± (10% or 1 ml), whichever is higher
Pressure	0-100 cmH2O
Accuracy of Pressure measurements (PIP, PEEP, Pplat, P mean)	± (5% or 1 cmH2O), whichever is higher
Flow	0-200 L/min

9.5 Classification

Parameter	Specification
Operation	Continuous
Device type	Class I Medical Electrical Equipment
Breathing Circuit	Type B Applied part
Use case	Not Suitable for use in the presence of flammable anaesthetics
IP Classification	IP31 The Ingress Protection classification of IP31 is for solid particle protection greater than 2.5 mm in diameter, and liquid ingress protection against vertically dripping water
Regulation Compliance Device Classification	European Union: EU MDR 745/2017 Class IIb; Indian MDR 2017 Class C device
Standards and Approvals	The device complies with the latest recognised standards of EN/IEC 60601-1, EN/IEC 60601-1-2, EN/IEC 60601-1-6, EN/IEC 60601-1-8, ISO 80601-2-12
Expected lifetime / Service life	Approximately 10 years[1*]

NOTE

- [1*] The ventilator lasts a minimum of 10 years in normal operation when operated, maintained, and serviced as described in the instructions supplied in the User Manual. With correct maintenance and repairs, the service life can be extended as long as service parts are available.

10. Troubleshooting

Indication	Possible Cause	Corrective Action
AC Power Fail, Battery Connected	AC power is failed, & ICU Ventilators runs on battery.	● Check whether the power cord is connected properly. ● Note the battery status & if battery is low i.e. <40%, prepare for AC power restoration, or alternative ventilation for the patient.
Air Input Flow Low	Measured air flow is low which is an indication for a clogged input filter or air intake obstruction.	● Check the HME filter on the air intake port, for any clogging, & replace the filter accordingly. ● Check whether any obstruction is present on the air intake port and remove it.
Audible alarm inoperative	Mute alarm is active	● Turn off the mute alarm.
	Electronic failure	● Contact company's authorized representative for assistance.
Back Up Ventilation Active	Apnea has been detected. Back up PC-SIMV mode with the user setting is activated	● Check the status of the patient. ● Review the ICU Ventilators settings. ● Confirm the current mode in Mode Settings to continue using backup ventilation settings. ● Confirm a different mode in Mode Settings to end backup ventilation.
Backup Gas Source Active	Hardware malfunctions detected that makes oxygen delivery impossible or possibly dangerous Estimate Flow Output with Flow Air	● Check for oxygen source for leakage or lack of oxygen pressure & correct it. ● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Battery Critically Low Alarm	Complete Failure on the system's internal battery, caused by using a ICU Ventilators on battery even after Battery Low alarm. ICU Ventilators will go in Standby Mode!	● Connect the ICU Ventilators to a primary power source. ● In the absence of the power source, immediately provide alternative ventilation. ● Switch off the ICU Ventilators before the battery is completely discharged.
Internal Battery is not Charging	Absence of Primary Power Source	● Connect the ICU Ventilators to a primary power source. ● Check if Battery indication with Charging is there on the Ventilator screen.
	Fuse may be blown	● Check 3A Fuse Continuity by switching off the Device. ● If there is no continuity, Replace the Fuse and Switch ON the device and Check if Battery indication is Charging on the Ventilator screen. ● If the problem still persists, then contact company's authorized representative for assistance.
Battery Low Alarm	Low voltage is detected on the internal battery, after usage without power source. ICU Ventilators is still in operation.	● Connect the ICU Ventilators to a primary power source. ● If necessary, be prepared to provide alternative ventilation.
Blower Fail	Blower is unable to generate the required air flow, may be due to clogged input filter or air intake obstruction.	● Check the HME filter on the air intake port, for any clogging, & replace the filter accordingly. ● Check whether any obstruction is present on the air intake port and remove it.
	Blower may have failed	● Immediately provide alternative ventilation.

		● Contact company's authorized representative and have the ICU Ventilators serviced.
Device does not start ventilation	Device may be in Stand-By mode	● Press the Start/Stand-By button again to re-start the ventilation.
	Any other reason	● Switch off the device and try to restart it again by following all the steps as per user manual. ● If the ventilation still does not start, immediately contact company's authorized representative for assistance.
Device does not switch ON	Slider Switch may be on Right position	● If Yes, Slide the Fast Charging Switch from Right to Left position. Connect the ICU Ventilators to AC supply. ● Switch ON the Power supply switch from the Back side of Device and Check if Device is ON.
	Battery may be completely drained	● If necessary, be prepared to provide alternative ventilation. ● Fast Charging Slider Switch on the back side of the device, slide from Left to Right position and Connect the ICU Ventilators to AC supply. ● keep the switch in this position for 15-30 minutes, after which you can slide switch back to Normal position (Left position) and Check if Device is ON.
		● If the problem still persists, then contact company's authorized representative for assistance.
Display Communication Fail	No Input/ Output from Display & Touch screen	● Switch off & restart the ICU Ventilators & Check. ● If alarm persists, contact company's authorized representative for assistance.
MVe Expiration High	Alteration of Patient's Respiratory Mechanics	● Check patient condition.
	The measured expiratory minute volume (sum of mandatory & spontaneous) exceeds the set alarm limit.	● Establish suitable parameters for the Ventilatory support. ● Check and confirm settings, including alarms.
	Patient flow sensor disconnected or white tube is loose	● Check patient flow sensor tube connections and its direction.
MVe Expiration Low	Alteration of Patient's Respiratory Mechanics	● Check patient condition. ● Check for leaks in patient circuit or airway.
	The measured expiratory minute volume is below the set alarm limit while the patient is connected	● Establish suitable parameters for the Ventilatory support. ● Check and confirm settings, including alarms. ● Check patient flow sensor tube connections and its direction.
MVe Expiration Low with flow Trend Reversed/ VTi- VTe is Zero	Patient flow sensor connected in Reverse direction	● Ensure Patient flow sensor connection is in the right direction i.e. Blue pipe on sensor near Patient side & on machine side is connected on blue marked nozzle-left. ● If the problem still persists, contact the company's authorized representative for assistance.
Obstruction Detected	Obstruction in expiratory limb or Exhaust Port detected	● Check for any blockage in the expiratory limb, Expiratory valve, exhaust output, clogging in

	ICU Ventilators will open safety valve for 10 sec	the HME filters and remove the blockage accordingly.
	Expiratory Time set by I:E ratio & Respiratory rate is too small for the selected patient type	● Correct the ventilation parameter setting for I, E & RR.
Oxygen Supply Pressure Too Low	Oxygen supply may be disconnected or connection loosed up or supply pressure may be low	● Check for any leakage in the oxygen input connection & correct it.
	Oxygen cylinder may be empty.	● Check the pressure on the Oxygen inlet manometer, if less than 3 bar use alternative source of oxygen.
	Measured oxygen supply pressure < 2.5 bar (OR kg/cm^2) (when using in HPO and FiO2 setting Percentage > 21%) Oxygen delivery will be continued till pressure greater than or equals 1.1 bar, thereafter Backup Gas Source will be active	● Be ready with an alternative oxygen source/oxygen cylinder. ● Replace the oxygen source/oxygen cylinder if Back up gas source active alarm appears OR FiO2 set is not achieved.
Parameter setting returns to the previous value.	The setting was not confirmed	● Confirm the setting by pressing the APPLY button.
Patient Airway Pressure High Alarm	Patient Auxiliary pressure is greater than the Paw high alarm limit.	● Check and confirm settings, including alarms. ● Check patient's condition. ● Check whether any blockage in the breathing circuit causing increasing pressure and remove the blockage accordingly or reposition the respiratory valve diaphragm. ● If the problem still persists, then contact company's authorized representative for assistance.
	Expiratory valve may be Reversed.	● Correct the Expiratory valve direction (→ coming out from the machine).
	Alteration of Patient's Respiratory Mechanics.	● Establish suitable parameters for the Ventilatory support.
	Obstruction of breathing circuit's expiratory Limb or its Expiratory valve.	● Check whether any blockage in the breathing circuit causing increasing pressure and remove the blockage accordingly or reposition the respiratory valve diaphragm. ● If the problem still persists, then contact company's authorized representative for assistance.
	Obstruction of the patient's airways.	● Remove obstructions or aspirate the patient's airways.
	Inspiratory pressure monitored is greater than expected.	● Check the setting of inspiratory pressure (absolute), whose value is the sum of the controlled pressure (relative) with PEEP.
	PIP is much higher than Pplateau	● Increase the set Rise Time.
	Patient Auxiliary pressure is lesser than the Paw low alarm limit.	● Check and confirm settings, including alarms. ● Check patient's condition.

Patient Airway Pressure Low Alarm		● Check whether any leakage in the breathing circuit is causing decrease in pressure, & remove blockages accordingly. ● If the problem still persists, then contact company's authorized representative for assistance.
	Alteration of Patient's Respiratory Mechanics.	● Establish new parameters for Ventilatory support.
	Excessive leakage on breathing circuit.	● Locate leakage and correct it.
	Expiratory valve tube may not be connected	● Connect the Expiratory valve tube & tighten the expiratory valve.
Patient Airway Pressure Sensor Fail	Patient flow sensor disconnected or blue tube connection has become loose	● Ensure Patient flow sensor connection is tightened & is in the right direction. ● Calibrate the flow sensor. ● Replace the flow sensor & recalibrate & use. ● If the problem still persists, then contact company's authorized representative for assistance.
Patient Disconnect Alarm	The breathing circuit is disconnected	● Locate the disconnection and connect firmly.
	Lack of Inspiratory Flow	● Verify the existence of an inspiratory flow and increase it, if necessary.
	Alteration of Patient's respiratory Mechanics.	● Establish new parameters for Ventilatory support.
	Expiratory valve diaphragm mounted incorrectly or damaged.	● Place the diaphragm in the right position or substitute the diaphragm.
	Failure on pressure control electronic system.	● Immediately provide alternative ventilation. ● Contact company's authorized representative and have the ICU Ventilators serviced.
PIP pressure higher than Pinsp set, causing spike	Rise Time set is lesser than required to achieve PIP	● Increase the Rise Time to reduce the PIP spikes
System Communication Fail	Communication between main & secondary processor is failed	● Immediately provide alternative ventilation. ● Switch off & try Restarting ICU Ventilators & recheck. ● Contact company's authorized representative and have the ICU Ventilators serviced.
Touch on Display not working	Screen may be locked	● To unlock, press the unlock button.
	Any other reason	● Contact company's authorized representative for assistance.
User Setting Error	Not possible setting of ventilation parameters by the user e.g. PEEP setting is higher than Pinsp setting	● Correct the ventilation parameter setting.
Waveform does not move	Device may be in freeze mode	● Check the freeze button and press the freeze button again to unfreeze the waveforms.
	Any other reason	● If the ventilator is in use, provide alternative ventilation. ● Switch off the device and try to restart it again by following all the steps as per user manual. ● If the ventilation still does not start, immediately contact company's authorized representative for assistance.
System Check Fail		

Hose Compliance Fail	Wrong configuration of Breathing circuit	● Use specified configuration of the breathing circuit.
	Patient End maybe open or there is leakage in the breathing circuit or thorough Expiratory valve	● Patient End should be closed tightly and there should be No leakage in the breathing circuit or through Expiratory valve. ● Try replacing Expiratory valve. ● Make sure the flow sensor is connected properly to the breathing circuit.
Hose Resistance Fail	Wrong configuration of Breathing circuit	● Use specified configuration of the breathing circuit.
	Any blockage on patient end	● Check for any blockage in the patient circuit or air inlet port and remove it accordingly.
Patient Flow Sensor Fail/ Invalid Patient flow measurement	Non-compatible circuits or Flow Sensor as per selected patient type.	● Use specified Flow sensor & ICU Ventilators Circuit type as per the selected patient type. ● Ensure Patient flow sensor connection is tightened & is in the right direction. ● Remove HME/ HEPA filter from exhaust and air inlet port. ● Calibrate the flow sensor. ● Replace the flow sensor if found damaged or clogged. ● Recalibrate the new sensor and use only the successfully calibrated flow sensor to the patient.
Self-Test Fail	Wrong configuration of Breathing circuit	● Use specified configuration of the breathing circuit.
	Any blockage on patient end or air intake port	● Check for any blockage on the patient/ air intake port and remove it accordingly.
	Oxygen Sensor Fail	● Replace the Oxygen sensor.

For more Information/ support please contact: M/s AVI Healthcare Private Limited.
Number: +91-8591516113 (Service Support) / +91-8591530230 (Sales Support)

11. Warranty

Separate Warranty card is provided with each unit. It is to be read in association with the user manual.

12. Guide to Raise a Service Request/Book Warranty

1. Locate the QR code on your device label.
2. Scan it using Google Lens or any QR code scanner and click on the link that appears.
3. Select "Book Warranty" or "Raise New Service Request."
4. Follow the on-screen prompts, fill in the required details, and submit.
5. For further assistance, contact our Service Support team.