AgVa Healthcare

Software Version 1.3

SERVICE MANUAL
AGVA PRO

Pro Ventilator for Pro Users

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WARNING

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property

NOTE

A NOTE provides additional information intended to avoid inconvenience during operation.

User Group Requirements

The phrase "**user group**" pertains to the individuals who have been designated by the operating entity to carry out a specific task on a product.

Responsibilities of the operational entity

The operational entity is responsible for ensuring the following:

1. Each user group possesses the necessary qualifications (e.g., through specialized training or experience) for their assigned tasks.
2. Adequate training has been provided to each user group for their designated tasks.
3. Each user group has reviewed and comprehended the relevant sections within this document.

User groups

Clinical users

This specific user category operates the product as per its intended use.

Users within this group possess specialized medical knowledge in the field of ventilation and are well-versed in device monitoring and ventilation care.

1. **Personnel responsible for reprocessing**

   This particular user group performs the essential procedures to reprocess the product.

   Personnel within this category possess specialized expertise in the reprocessing of medical devices.

Service personnel

This group of users is responsible for both installing the product and conducting service-related tasks.

Service personnel possess expert-level understanding in electrical and mechanical engineering, coupled with hands-on experience in servicing medical equipment.

In cases where product-specific expertise or tools are necessary, the service tasks should be handled by dedicated service personnel. These specialized service individuals have undergone training provided by **'AgVa Healthcare'** specifically for performing service activities on this product.

Intended Purpose

In the intensive care unit, in the recovery room or intra hospital transfer provided compressed oxygen is supplied in case supplemental oxygen is required. The AgVa PRO Ventilator is intended for use by qualified, trained personnel under the direction of a licensed physician and within the limits of its stated technical specifications.

Intended Medical Indication

- Airway protection in a patient who is obtunded or has a dynamic airway
- Hypercapnic respiratory failure due to a decrease in minute ventilation
- Hypoxemic respiratory failure due to a failure of oxygenation
- Cardiovascular distress whereby mechanical ventilation can offload the energy requirements of breathing
- Expectant course, e.g., anticipated patient decline or impending transfer
- Acute Respiratory insufficiency or inadequate respiratory effort
- Improve oxygenation
- And other clinical scenarios where respiratory support is required.

Patient selection criteria

- Subject undergoing invasive, non-invasive, continuous or intermittent ventilation by using AgVa Pro Ventilator manufactured by AgVa Healthcare as per the instructions provided in the IFU.
- Subject undergoing the treatment for the intended medical indications in the intended use environment by a qualified, trained personnel under the direction of a physician.
- Subject willing and able to complete required study visits or assessments.

Used for

- Invasive.
- Non-invasive.
- HFNC/O2 Therapy.

Use Environment

- Hospital
- Intensive care unit
- Intra-hospital transfer
- Recovery Room
- Emergency Room

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Ventilation Period

Ventilator is a Continuous Operating Device and can be used for more than 30 Days or Continuously.

Usage Frequency

Multiple Use

General Safety Information

The upcoming WARNING and CAUTION declarations apply to the general operations of the medical device.

WARNING and CAUTIONS that are specific to certain subsystems or particular features of the medical device appear in all the respective sections of the instructions for use for this medical device.

WARNING

POSSIBILITY OF IMPROPER FUNCTIONING AND MISUSE

The proper usage of the medical apparatus necessitates a comprehensive comprehension and meticulous adherence to all portions of these usage guidelines. The medical apparatus should solely be employed for the objective explicitly outlined under the "Intended Purpose" section.

Thoroughly adhere to all WARNING and CAUTION declarations present in these usage instructions, as well as all statements found on the labels of the medical device. Neglecting to follow these safety information statements signifies utilizing the medical device in a manner that deviates from its intended purpose.

WARNING - SERVICE

Potential for danger if regular servicing is neglected

Neglecting routine servicing could lead to potential malfunctions, posing risks of personal harm and property damage. Conduct the servicing as outlined in the "Service" section.

WARNING - ACCESSORIES

Risk due to incompatible accessories The use of incompatible accessories may adversely affect the functional integrity of the product. Personal injury and property damage may occur as a consequence. Use only compatible accessories. The accessories that are compatible with this product are listed in the list of accessories supplied with the product.

WARNING - NOT FOR USE IN EXPLOSION PRONE AREAS

Risk due to incompatible accessories the use of incompatible accessories may adversely affect the functional integrity of the product. Personal injury and property damage may occur as a consequence. Use only compatible accessories. The accessories that are compatible with this product are listed in the list of accessories supplied with the product.

WARNING - CONNECTED DEVICES

Risk of electrical shock and equipment malfunction

Establishing electrical connections with equipment not specified in these usage instructions or assembly guidelines is permissible only upon individual manufacturer approval.

Prior to operating the medical device, rigorously adhere to the usage instructions provided for all interconnected devices or combinations of devices.

Patient Safety

The structure of the medical apparatus, along with its accompanying documentation and the labels affixed to it, are constructed under the assumption that acquisition and utilization of the device are confined to individuals well-versed in its key inherent attributes.

Consequently, the instructions as well as the WARNING and CAUTION declarations are primarily focused on the distinct aspects of the AGVA medical device.

The usage instructions intentionally omit information on the subsequent aspects:

1. Evident hazards discernible to users
2. Ramifications of unmistakably inappropriate utilization of the medical device
3. Possible adverse consequences for patients with varying underlying ailments

Making alterations to the medical device or employing it incorrectly can pose significant risks.

WARNING **POTENTIAL FOR PATIENT HARM**

Refrain from formulating therapeutic judgments exclusively on the basis of individual measured values and monitoring parameters.

Patient Monitoring

The responsibility falls upon the medical device user to select an appropriate patient monitoring system that offers relevant insights into both the performance of the medical device and the patient's status.

Ensuring patient safety can encompass diverse strategies, ranging from electronically monitoring medical device functionality and patient well-being to directly observing clinical indicators.

The sole authority for determining the most suitable degree of patient monitoring rests with the user of the medical device.

Electromagnetic Compatibility (EMC)

Special precautionary measures pertain to the electromagnetic compatibility of medical electrical equipment. These measures should be observed during installation and prior to the device's initial operation.

WARNING

Risk of patient harm due to electrostatic discharge:

The potential for patient-endangering malfunctions increases if protective precautions against electrostatic discharge are not taken in the subsequent scenarios:

1. When handling connectors' pins labeled with the ESD warning symbol.
2. When creating connections with these aforementioned connectors.

To avert malfunctions, adhere to the ensuing steps and instruct pertinent staff:

Implement preventive measures against electrostatic discharge. These measures could encompass wearing anti-static attire and footwear, ensuring contact with a potential equalization pin before and during the connection process, or employing electrically insulating and anti-static gloves.

Adhere to the stipulations concerning the electromagnetic environment.

CAUTION - STORING INSTRUCTIONS FOR USE

Risk of incorrect use

Instructions for use must be kept accessible to the user.

WARNING - DISPOSABLE PRODUCTS

Potential for patient harm due to accessory malfunction

Single-use items are designed, tested, and produced exclusively for one-time usage. Attempting to reuse, reprocess, or sterilize them may result in accessory failures that could harm the patient.

Avoid reusing, reprocessing, or sterilizing disposable products.

CAUTION - STERILE PACKAGED ACCESSORIES

Potential for medical device malfunction and patient harm

Avoid utilizing accessories packaged in a sterile manner if the packaging has been unsealed, is compromised, or displays indications of lacking sterility.

WARNING POTENTIAL FOR EQUIPMENT MALFUCTION

Attach accessories to the core device as per the basic device's usage instructions. Ensure a secure and reliable connection to the core device.

Product-specific safety information

WARNING

RISK OF IMPROPER USAGE

This medical device is exclusively designed for utilization by the user group defined as "users."

RISK OF MISSING ALARM NOTIFICATIONS

Insufficient alarm volume could lead to the failure of audible alarm notifications.

1. Adjust the alarm volume to an audible level within the device's surroundings.
2. The user must remain in proximity to hear alarm signals.

RISK ARISING FROM ALTERATIONS

Tinkering with the product may trigger malfunctions and unforeseen hazards, potentially causing harm to the patient, user, or property.

Avoid making any modifications to this product.

RISK OF ELECTRICAL SHOCK

Simultaneous contact with interface connectors and the patient may result in electric shock.

Refrain from concurrently touching both interface connectors and the patient.

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WARNING

RISK OF IGNITION

The utilization of unapproved O2 pressure reducers could result in excessive pressure leading to fire.

When providing the ventilator with oxygen from a compressed gas cylinder, solely employ pressure reducers conforming to ISO 10524 standards.

Open pressure reducers manually and gently, refraining from using tools.

POTENTIAL FOR FIRE

Avoid deploying the medical device alongside flammable gases or solutions capable of mingling with air, oxygen, nitrous oxide, or any other ignition sources, as the device might ignite.

Prevent any contact between the medical device and potential sources of ignition.

RISK OF PATIENT HARM

The correct operation of the medical device might be compromised during Magnetic Resonance Imaging (MRI, NMR, NMI).

Refrain from employing the medical device while undergoing magnetic resonance imaging.

RISK OF PATIENT HARM

The proper functioning of the medical device could be impeded within hyperbaric chambers.

Do not operate the medical device within hyperbaric chambers.

Risk of electric shock. Live components are situated beneath the housing cover.

Avoid removing the cover.

CAUTION

POTENTIAL FOR UNNOTICED ALTERATION IN INSPIRATORY O2 CONCENTRATION

Introducing supplementary flows (e.g., NO, nitrous oxide) from external sources could lead to disparities between displayed O2 concentration values and actual values.

If necessary, consider employing additional monitoring techniques, such as external SpO2 monitoring.

Risk of medical device overheating

Heat sources like direct sunlight, radiators, or spotlights might induce overheating in the medical device.

Ensure that sources of heat are kept at a distance from the medical device. Employ the medical device solely within adequately ventilated spaces.

CAUTION

RISK OF OPERATIONAL ISSUES

The touch screen is equipped with a delicate surface. Harm to this surface can lead to malfunctions in the touch-sensitive controls. Avoid using sharp objects to interact with the screen. Take care not to damage the screen's surface while cleaning or during transportation.

RISK OF ELECTRICAL SHOCK

If an improperly functioning device lacking safety extra-low voltage (SELV) is linked to the medical device, there's a potential for electric shock upon touching the housing. Ensure that only devices adhering to safety extra-low voltage (SELV) standards are connected to the serial port and nurse call interfaces.

Monitoring Ventilation

Various parameters are monitored by the ventilator based on the mode that has been sleected. The modes and accompanying monitored parameters have been listed further.

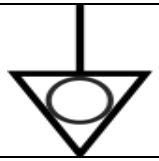
MODE	TAB	PARAMETERS
PC- AC	**1. Basic**	FiO_2, Ti, RR, Trigger, PEEP, Δ Pinsp
	2. Advanced	INVERSE I:E, P limit, Slope
	3. Smart SpO_2	Smart FiO_2, Tg.SpO_2, PR Limit, Δ FiO_2
	4. V-TAS	V-TAS, Target VT, P limit
PC- CMV	**1.Basic**	FiO_2, Ti, RR, Trigger, PEEP, Δ Pinsp
	2.Advanced	INVERSE I:E, P limit, Slope
	3.SpO_2	Smart FiO_2, Tg, SpO_2, PR Limit, ΔFiO_2
	4.V-TAS	V-TAS, Target VT, P limit
PC-SIMV	**1.Basic**	FiO_2, Ti, RR, Trigger, PEEP, Δ Pinsp, Δ Psupp
	2.Advanced	INVERSE I:E, Plimit, Slope Insp Term
	3.Smart SpO_2	Smart FiO_2, Tg.SpO_2 , PR Limit, ΔFiO_2
	V-TAS	V-TAS, Target VT, P limit
	Backup	Backup, RR apnea, T apnea, VT apnea
PC-BPAP	**1. Basic**	FiO_2, Ti, RR, Trigger, PEEP, Δ Pinsp, Δ Psupp
	2. Advanced	INVERSE I:E, P limit, Slope Insp Term
	3. Backup	Backup, RR apnea, T apnea, VT apnea
	4. Smart O_2	Smart FiO_2, Tg. SpO_2,PR Limit, Δ FiO_2
VC-AC	**1. Basic**	FiO_2, Ti, VT, RR, Trigger, PEEP, Δ Pinsp
	2. Advanced	INVERSE I:E, P limit, In Pause
	3. SpO_2	Smart FiO_2, Tg. SpO_2, PR limit, Δ FiO_2
VC-CMV	**1. Basic**	FiO_2, Ti, VT, RR, Trigger, PEEP
	2. Advanced	INVERSE I:E, P limit, In Pause
	3. Smart O_2	Smart FiO_2, Tg. SpO_2, PR limit, Δ FiO_2
VC-SIMV	**1. Basic**	FiO_2, Ti, RR, Trigger, PEEP, Δ Pinsp, Δ Psupp
	2. Advanced	INVERSE I:E, P limit, In Pause
	3. Smart O_2	Backup, RR apnea, T apnea, VT apnea

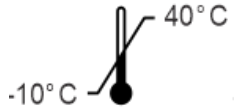
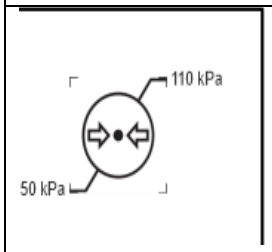
	4. Backup	Smart FiO_2, Tg. SpO_2, PR limit, Δ FiO_2
CPAP/PS	**1. Basic**	FiO_2, Ti, RR, Trigger, PEEP, Δ Pinsp, Δ Psupp
	2. Advanced	INVERSE I:E, Plimit, Slope Insp Term
	3. Backup	Backup, RR apnea, T apnea, VT apnea
	4. Smart O_2	Smart FiO_2, Tg. SpO_2, PR limit, Δ FiO_2
NIV		
AI-VENT		
HFNC	**1. Basic**	FiO_2, Flow

Equipment Symbols

The following symbols may be referenced on the ventilator or in accompanying documentation.

Symbol	Source/Compliance	Meaning
	ISO 15223_2021	Signifies that the instruction manual/booklet must be read
	ISO 15223_2021	This switch is for emergency stopping of the system.
IP21	ISO 15223_2021	Protected from touch by fingers and objects greater than 12mm. Protected from water spray less than 15 degrees from vertical.
	IEC 60601-1	Identifies a type BF.
	ISO 15223_2021	The device is not suitable for use in MRI environment
	ISO 15223_2021	This symbol indicates that the equipment contains material(s) that are harmful to the environment if disposed of incorrectly.
	ISO 15223_2021	Indicates a medical device that needs to be protected from moisture

	ISO 15223_2021	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223_2021	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	ISO 15223_2021	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 15223_2021	Identifies the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential
	ISO 15223_2021	Indicates the need for the user to consult the instructions for use.
	ISO 15223_2021	Battery can be recycled by specialized battery recyclers

	ISO 15223_2021	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223_2021	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223_2021	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

Theory of Operations

General Description

Mechanical ventilation is a complex process that involves the application of positive pressure breath, relying heavily on the compliance and resistance characteristics of the airway system. These factors determine the amount of pressure required from the ventilator to deliver a specified tidal volume (TV), which refers to the volume of air entering the lungs during inhalation. It's important to note that compliance and resistance are dynamic, meaning they can be influenced by the underlying disease state(s) that necessitated intubation in the first place.

Breaking down the process further, mechanical ventilation comprises four distinct stages, each playing a crucial role in maintaining respiratory support. The initial stage is the trigger phase, which marks the commencement of inhalation. This phase can be initiated either by the patient's own respiratory effort or by predefined parameters set on the mechanical ventilator. Following this, the inspiratory phase ensues, encompassing the actual intake of air into the patient's lungs.

Moving along, the cycling phase represents a brief interval where inhalation subsides, but exhalation has not yet commenced. Finally, the expiratory phase comes into play, involving the passive release of air from the patient's lungs. These stages collectively form the intricate process of mechanical ventilation, ensuring adequate respiratory support for individuals in need.

Rationale for the qualification of the product as a medical device

As per Medical device regulation (EU) 2017/745, Article 2 (1):

‘Medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological,

immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

devices for the control or support of conception;

products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Hence, as per definition of medical device, AgVa Pro Ventilator is a device intended by the manufacturer to be used in combination with the accessories, for providing invasive, non-invasive, continuous or intermittent respiratory support to neonate, pediatric and adult patient population.

Classification & Justification

Class IIb as per **Rule 9** of ANNEX VIII of REGULATION (EU) 2017/745

Rule 9 –

All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

AgVa Pro Ventilator is an active therapeutic device intended to administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy. Hence, this rule is applicable.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

AgVa Pro Ventilator is an active device but is not intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance. Hence, this rule is not applicable.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

AgVa Pro Ventilator is an active device but is not intended for controlling, monitoring, or directly influencing the performance of active implantable devices. Hence, this rule is not applicable.

Conclusion:

*Hence as per **Rule 9** of ANNEX VIII of Regulation (EU) 2017/745, **AgVa Pro Ventilator** is classified as **Class IIb** as it is an active therapeutic device intended to administer and exchange energy with the human body in a potentially hazardous way*

*Hence as per **Rule 9** of ANNEX VIII of Regulation (EU) 2017/745, **AgVa Pro Ventilator** is classified as **Class IIb** as it is an active therapeutic device intended to administer and exchange energy with the human body in a potentially hazardous way.*

General Information about Physical and Functional Attributes

ATTRIBUTES	MODEL AgVa Pro and AgVa Pro+
Physical Attributes	
Dimensions (LBH)	152 X 46 X 42
Weight	50 Kg
Display	24 inch
Resolution	1920 x 1080
I/P	100-230 VAC 50/60 Hz, 230 VA
Fuses	10 A
Battery backup time	Fully charged battery should give backup for 3 hours min in working condition
Oxygen- High Pressure	2.8 – 6 Bar normal operating range
Oxygen -Low Flow	0 -80 LPM, 0.5 psig(Max)/0.035 Bar
Leakage (ml/min)	Adult Test < 300, Pediatric<200, Neonatal<100 = pass
Peak Flow	Up to 150 LPM regulated
IP	21
Life time	10 years of commercial life time
Functional Features	▪ Digital Proximal Sensor for Neonate ▪ Volume, Pressure & Flow Target Modes ▪ Exceptional Flow and Volume Accuracy ▪ V-TAS (Volume Targeted Augmentation System) ▪ Smart FiO2 ▪ Large Alarm LED ▪ IOT based Servicing ▪ Self-Cleaning Expiratory Flow Sensor ▪ Side Stream Cooling for Blower ▪ Lifetime O2 Sensor ▪ Reusable Digital Neonate Sensor ▪ Rugged Expiratory valve and Flow Sensor ▪ Inbuilt Nebulizer ▪ Inbuilt SpO2 Monitoring

ATTRIBUTES	MODEL AgVa Pro and AgVa Pro+
Performance attributes	▪ Next Gen high Performance Turbine with exceptional lifetime and super silent operation. ▪ Built in Turbine 150 LPM Regulated ▪ Adult to Neonate Universal Ventilator
Storage Conditions	▪ AgVa Pro Ventilator shall be stored in a cool, dry place away from direct sunlight and the following conditions shall be maintained: ▪ Temperature: -10 to 50 ℃ ▪ Humidity: 10 to 95 %RH, non- condensing ▪ Atmospheric pressure: 50 kPa to 110kPa **Caution:** The device shall be stored away from any sources of radiation.
Operating Conditions	▪ **Temperature**: -10 to 40 ℃ ▪ **Humidity:** 10 to 95 %RH, non- condensing ▪ **Atmospheric pressure:** 50 kPa to 110kPa **Caution:** The device shall be operated away from any sources of radiation.

General description of the key functional elements

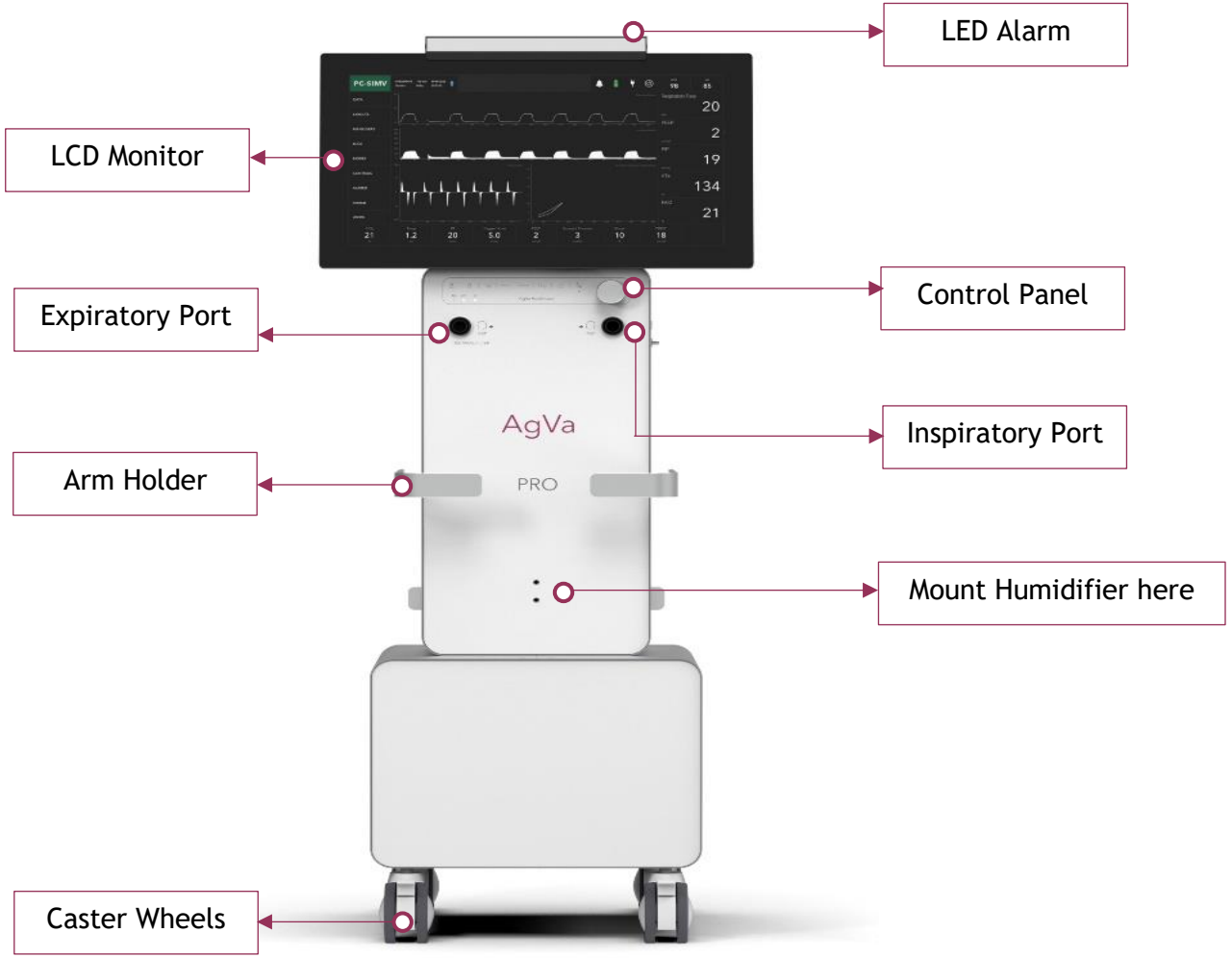
S.No.	Part Name	Item Description	Functionality
1.	EC-0109	Turbine	Turbine is a high speed centrifugal air pressure and flow generator. Which creates the necessary working flow and pressure for the device.
2.	ECA-0266	PCB Main Board	PCB main board is the central computing and transducing unit for the ventilator. It controls essential functions of the ventilator. Further it has various transducers, safety interlocks and power handling units installed over it.
3.	ECA-0259	PCB LED bar	This consists up of multiple light emitting diodes that are capable of emitting light at multiple wavelengths. This is used to inform the healthcare practitioner of any alarms or warnings.
4.	EC-0456	DISPLAY 23.8”	It is 23.8” captive touch-based GUI
5.	ECA-0260	Motor Driver PCB	This driver is responsible to provide accurate pluses of current to drive the Turbine
6.	EC-0166	SMPS	SMPS of switch mode power supply is used to reduce the AC voltage to the required DC voltage required by the ventilator system.
7.	EC-0162	BATTERY	Li-ion Battery pack that provides power backup in case of power failure by mains supply.
8.	EC-0092	DC FAN COOLING-12VDC	This unit blows the hot air from inside the ventilator to the external environment.
9.	MH-0321	Pressure Control Regulator	This a mechanical pressure regulator that regulates the line pressure to a set pressure.
10.	ECA-0029	Spo2 module	This module converts the analog pulse-oximetry data to machine readable digital data.
11.	MH-0301	2/2 Proportional Valve	This valve is a variable flow 2/2 solenoid valve that regulates the flow rate based on electrical inputs
12.	ECA-0246	Flow meter PCB	This is a module that computes the data sent by neonate flow sensor to the ventilator.

S.No.	Part Name	Item Description	Functionality
13.	MH-0367	Inlet HEPA Filter	Filtration of particles Matter and Bacteria
14.	EC-0058	Flow Sensor - Inspiratory	Used to measure the flow rate of the inspired gasses.
15.	EC-0331	Neonatal Flow Sensor	Flow sensor for measuring the flow rate at proximal end for neonate
16.	EC-0129	Flow Sensor - Expiratory	Used to measure the flow rate of the expired gasses.
17.	SW.Version 1.3	Graphical User Interface	AgVa Pro Ventilator Graphical User Interface allows users to Add, Adjust or Cancel Setting Parameters. AgVa Pro Ventilator Graphical User Interface is also used for the Monitoring of Parameters in Digital Format as well as in Graphical formats like Waveforms and /Or Loops. The AgVa Pro Ventilator Graphical User Interface is used as the Input/output Device to Communicate with the internal Algorithm Provided by the Blower Module Communication protocol.

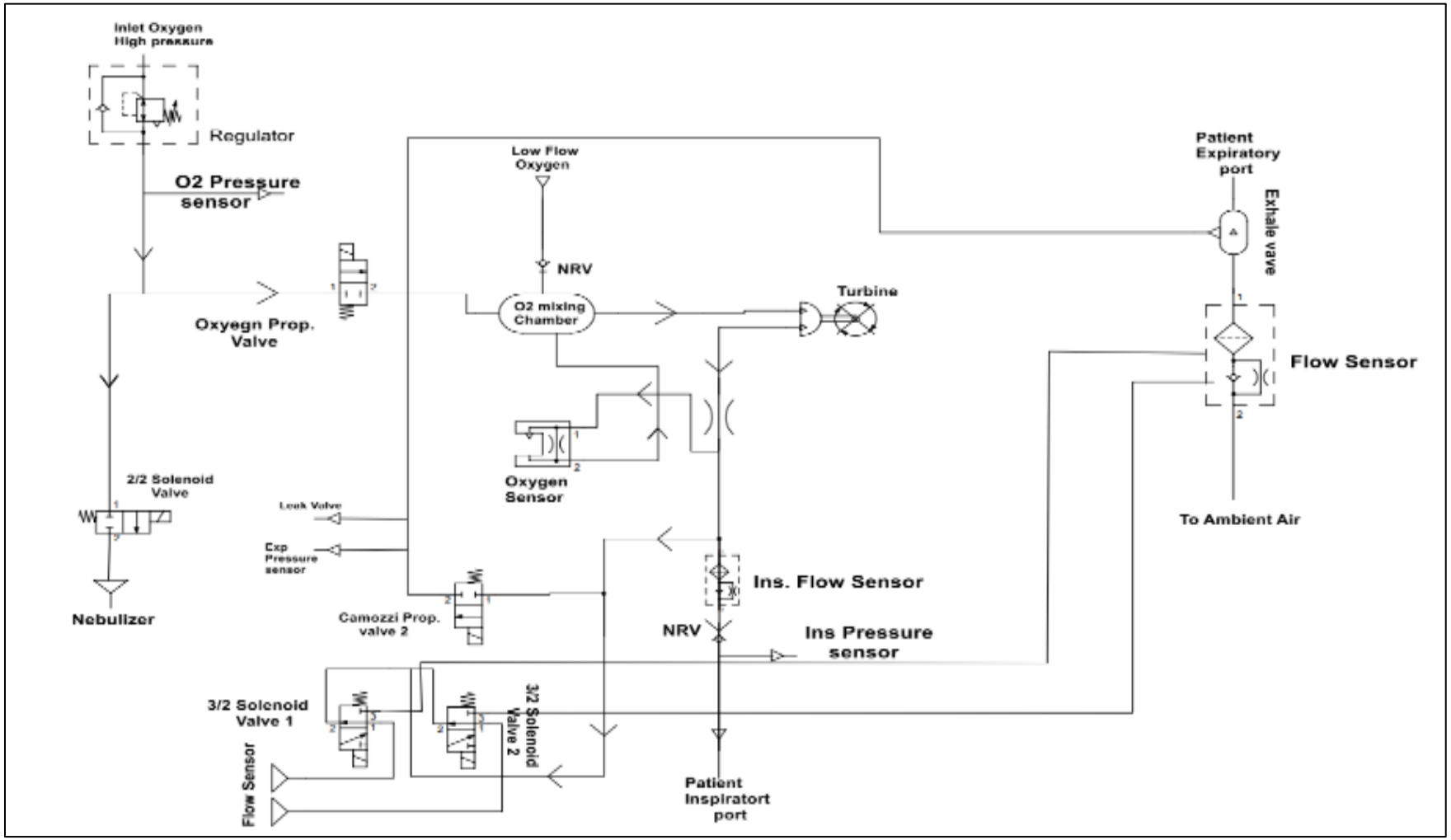
Brief description of the accessories and their use

S.No.	Name	Material Description
1.	Breathing Circuit	This is a patient tubing used to provide passage of inspiratory and expiratory gasses to and from the patient.
2.	High pressure Oxygen Pipe	It is used to connect the high-pressure oxygen source to the ventilator.
3.	AC Power Cord	AC power cord is a detachable way of providing an alternating current of electric energy from a mains power supply to Ventilator 3 pin Top Molded & 3 Meter length Material: Copper
4.	Calibration Tube	It is used to connect the inspiratory port to expiratory port during the Calibration
5.	SPO2 Probe	SpO2 Sensor is used to measure the oxygen saturation in blood.
6.	Neonate Sensor with Cable	It is a proximal sensor to measure inspiraotry flow in neonate patients.
7.	Breathing Bag	This is used to replicate a lung during testing conditions of the ventilator.

Modular Diagram of the Ventilator



Pneumatics Module



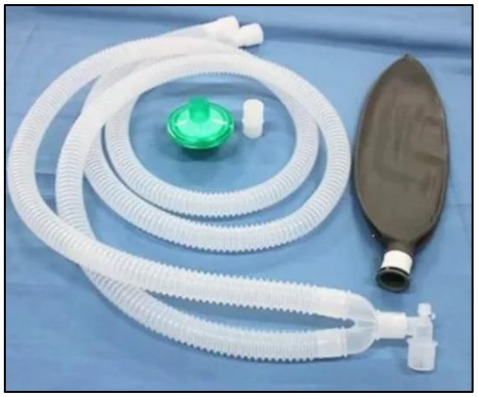
Pneumatics of the Ventilator

Parts and Accessories

WARNING:

1. The use of AGVA PRO ventilator-specific cables, accessories, or transducers with other ventilators or equipment is not recommended, as it may result in increased emissions or decreased device immunity.
2. Improper component installation can lead to barotrauma, hypoventilation, hyper-ventilation, inappropriate FiO2 levels, contaminated breathing gases, and fire hazards. When servicing the ventilator, please refer to the Technical Reference Manual for instructions.
3. Only connect devices to the ventilator that have been designated as part of the ventilator system or deemed compatible with the ventilator system. Using incompatible parts may harm the ventilator's performance.
4. Instructions for replacing interchangeable or detachable parts can be found in the Technical Reference Manual.
5. All components of the ventilator are safe for use in a patient's environment.

1. Breathing Circuit and Test lung



Breathing Circuit and Test Lung`

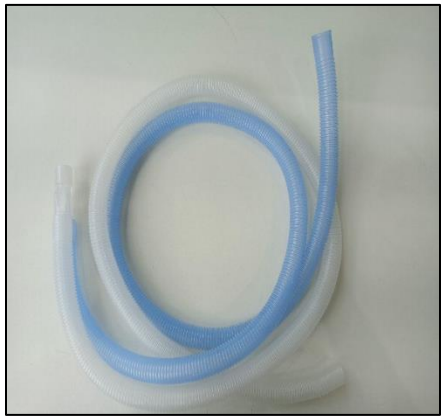
The breathing system or breathing circuit is a medical device utilized to administer oxygen, eliminate carbon dioxide, and deliver inhalational anesthetic agents to a patient.

2.High Pressure Oxygen Pipe

High Pressure Oxygen Pipe

This is employed to link the oxygen cylinder to the ventilator.

3. Tubing Circuit



Tubing Circuit

The tubing circuit is a medical device designed to facilitate the delivery of oxygen, removal of carbon dioxide, and administration of inhalational anesthetic agents to a patient.

4.AC Power Cord

AC Power Cord

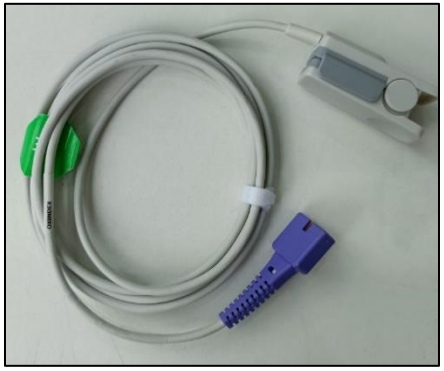
The AC power cord is a removable means of supplying alternating current electric energy from a mains power supply to the ventilator.

5.Calibration Tube

Calibration Tube

During calibration, this is used to connect the inspiratory port to the expiratory port

6.SpO_2 Probe



SpO_2 Probe

The SpO2 sensor is employed to measure the oxygen saturation in red blood cells. Typically, these small clip-like devices can be attached to the fingers, toes, earlobes, and other areas.

7. Neonate Sensor with Cable

Neonate Sensor with Cable

The Neonate Sensor is utilized for high-precision monitoring of low flow and is connected to the Controller via a cable. High flow is not permitted when using the Neonate Sensor.

Installation Instructions

This chapter provides instructions for installing and initializing the AGVA PRO ventilator.

Basic contents of the carton

S.No.	Delivered Contents	Quantity
1	AgVa Pro ICU Universal Ventilator (Adult-Pediatric Neonate)	01
2	High Pressure Oxygen pipe	01
3	Tubing Circuit (Adult)	01
4	AC Power Cord	01
5	Calibration Tube (22mm)	01
6	SpO_2 Probe	01
7	Neonate Sensor with Cable	01
8	Breathing Bag	01

Preparing the ventilator

WARNING:

Potential for Personal Harm

Failure to properly reprocess medical devices may elevate the chances of infection for both hospital personnel and patients. Therefore, it is essential to follow the provided instructions for use and reprocess the device and all associated accessories before every use.

1. Connecting the Power Cable

1. Take the power cable and insert it at the spot given behind the ventilator as shown.

2. Plug in the power cord.

3. Secure the power cord by pulling down the clip on it like this

WARNING:

Hazard from Inaccurate Main Voltage or Absent Protective Ground

When the device is plugged into an electrical outlet with an incorrect main voltage or into an outlet lacking a protective ground, there is a potential risk of electric shock. Ensure that the device is exclusively connected to power outlets with the correct main voltage and a protective ground.

NOTE

During operation, it is essential that the power socket used remains easily accessible.

1.Connecting mains power supply

Prerequisites:

- Mains voltage: 100 to 260 VAC, 50 to 60 Hz.
- Insert the mains power cable in the ventilator as explained on Page-30.
- Insert the power plug into the power socket.
- White LED below the  symbol will light up indicating AC power supply is plugged in.

Battery Supply

WARNING

Explosion Hazard

Electrolytic gas may develop during battery charging, and when present in sufficient concentration, it can lead to an explosion. Always ensure that the device is positioned in a well-ventilated area when connected to the mains power source.

Battery Characteristics	Specification
Detachable Battery	
Battery Type	Li-Ion
Nominal Voltage	14.8 VDC
Nominal Pack Capacity	5.2 AH
Charging Time	3 Hours Maximum

Duration of Operation of battery

The highest achievable duration of operation is attained when the battery is brand new and at full charge. The duration of operation is influenced by several factors, including:

- Battery charge level
- Battery age
- Number of charging cycles
- Turbine speed (increased loads, such as higher ventilation pressure or flow acceleration, can result in a reduced operating time).

WARNING:

Explosion Hazard

Pressurized oxygen, when in contact with oil or grease, may ignite spontaneously. Avoid any contact between oxygen supply components and oil or grease.

WARNING:

Potential Patient Harm

The use of compressed gases not designated for medical purposes may compromise the device's proper operation.

Ensure that only compressed gases approved for medical applications are utilized. The compressed gases must be free of dust and oil particles and dry.

2.Connecting the High-Pressure Oxygen Pipe

1 This is where you need to plug in the high-pressure oxygen pipe with a 12 mm DISS connector.

3. After connecting the DISS connector, screw it tight to secure it.

Ventilation in the AGVA PRO utilizes ambient air, which is drawn in by an internal turbine. Oxygen (O2) is sourced from one of the following options:

- High Pressure Oxygen supply
- Low Pressure Oxygen supply

3.Connecting Low-Pressure Oxygen Pipe

1. This is where the low-pressure oxygen pipe should be plugged.

2. After plugging the low-pressure oxygen pipe in, make sure it is perfectly secured and inserted.

4.Breathing Circuit Installation

1.Attach the inspiratory breathing tube in the inspiratory port.

2.Attach the viral/bacterial filter to the expiratory port.

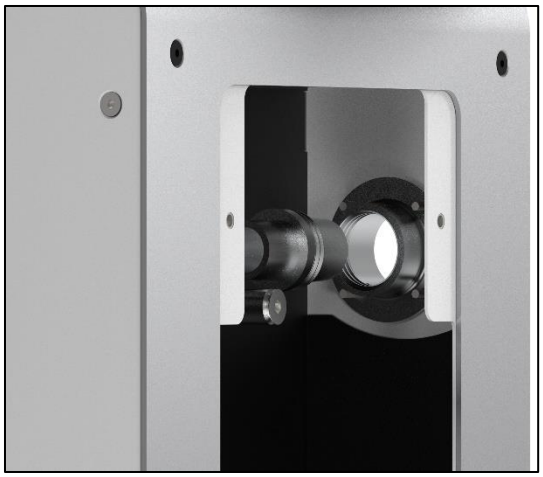
3.Attach the expiratory tube to the expiratory port through the viral/bacterial filter.

4.The breathing circuit is now installed.

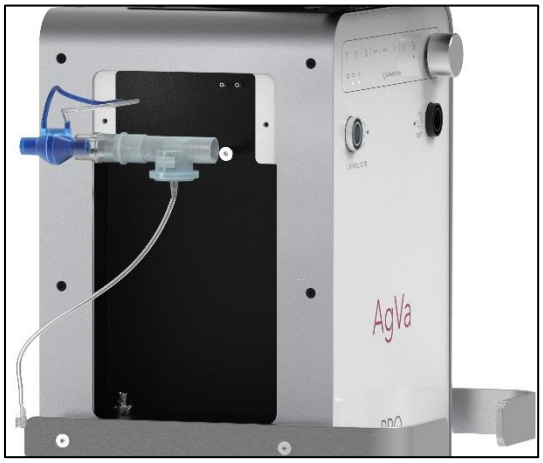
4.Exhale Valve with Flow Sensor Installation

1.This is where the exhale valve needs to be attached.

2.First, insert the 22 mm connector into the slot.



3.Attaching the connector.

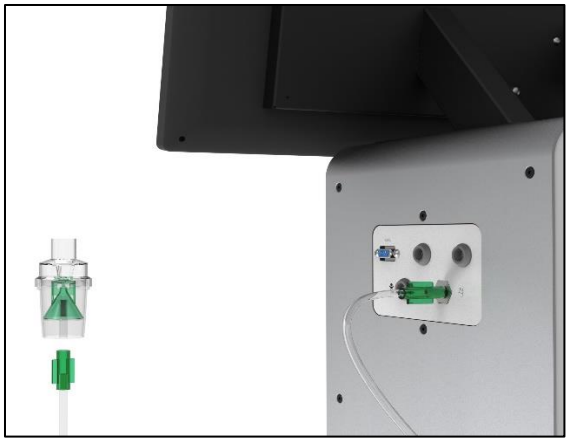


4.Now, insert the exhale valve fitted with the flow sensor into the connector attached earlier.

5.Attach the connecting wire of the exhale valve to the

5.Nebulizer Installation

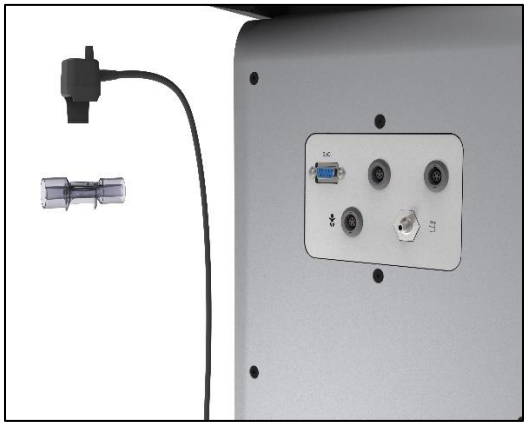
1.Insert the nebulizer cable into the nebulizer port



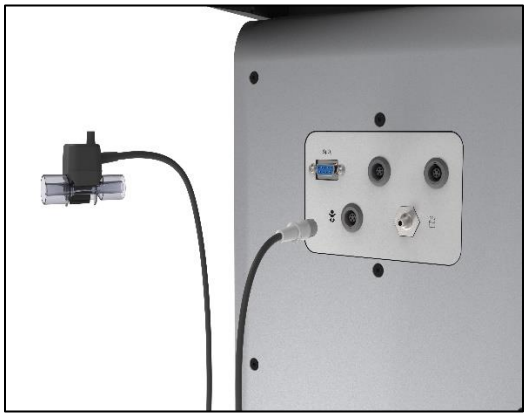
2. Insert the other end of the nebulizer cable into jet nebulizer

3.The nebulizer circuit is now complete.

6.NEO Breathing ciruit for neonates Installation



1. Connect the NEO cable to the NEO sensor.



2. After connecting the NEO cable to the NEO sensor, insert the connector part of the NEO cabe into the NEO port marked with an icon of a baby on the side.

3.Connect the NEO breathing circuit tube to the NEO sensor.

4.Now, Install the viral/bacterial filter on the expiratory port and attach the expiratory tube of the NEO breathing circuit to the expiratory port through the viral/bacterial filter.

5.Now, insert the inspiratory tube into the inspiratory port.

Information on breathing circuits and additional components

Additional components in the breathing circuit can increase the inspiratory and expiratory resistance values and exceed standard requirements.

Examples of additional components:

1. Bacterial filters, inspiratory and expiratory.
2. HME.
3. CO_2 cuvette
4. Humidifier
5. Coaxial hoses.

Caution

Altered Compliance and Resistance Due to Augmentation

The incorporation of supplementary elements, such as bacterial filters, HMEs, or CO2 cuvettes, within the breathing circuit can augment dead space, compliance, and resistance in the circuit. Depending on the ventilation mode, either the flow or pressure may experience elevation. When employing additional components, it is imperative to exercise meticulous care and maintain vigilant monitoring.

Elevated Resistance

The act of nebulizing medication and employing active humidification can lead to an increase in the resistance of bacterial filters. It is advisable to periodically inspect these filters for any signs of heightened resistance."

Consequences of high resistance

Elevated Resistance Levels Result in Greater Breathing Effort and Trigger Assistance in Ventilation

When resistance values are high, it increases the effort required for breathing, particularly in assisted ventilation scenarios. Under adverse conditions, this may result in an unwanted intrinsic Positive End Expiratory Pressure (PEEP), which can be identified when expiratory airflow fails to return to its baseline at the end of expiration. If the PEEP reaches an unacceptable level, an alarm will indicate this situation. The measured PEEP will then be approximately 8 millibars (8 cmH2O) above the set PEEP.

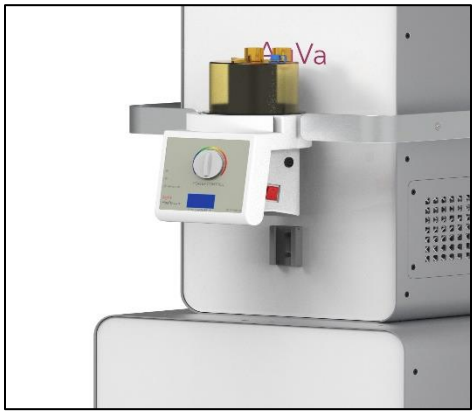
Caution

Infection Risk

Without the use of an inspiratory/expiratory bacterial filter, there is a potential for the patient to become infected by inhaling ambient air. It is advisable to employ an inspiratory/expiratory bacterial filter for protection.

Fitting the Humidifier to the universal humidifier holder

1. A notch or a holder for any humidifier has been provided on the front side of the AGVA PRO ventilator.



2. Place the humidifier on the notch or holder provided

3. Connect the breathing circuit to the humidifier to put it to use.

Safety Information

WARNING

Risk of patient injury

Ventilation does not take place in standby mode. Patients connected to the device are endangered.

Only set the device to standby mode when no patient is connected to the device.

CAUTION

Malfunctions through condensation

When the device is moved from a cold storage location to a warm environment, condensation can form.

Only switch on the device when the condensation has dried.

Switching on the Ventilator

NOTE

When the device is switched on and no breathing circuit or test lung is connected, AGVA PRO will not be able to perform automatic calibration of the flow sensor.

Prerequisites:

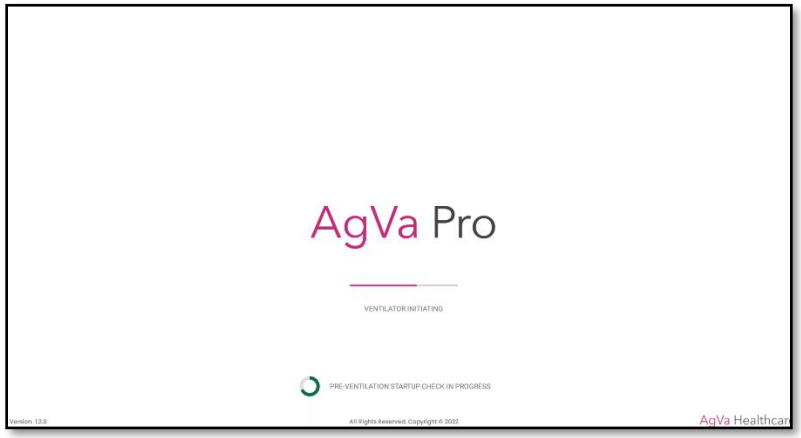
1. AGVA PRO and its accessories are ready.
2. Mains power supply or power supply with internal battery is established.
3. O_2 supply is ensured.

1. **Turn on the ventilator**

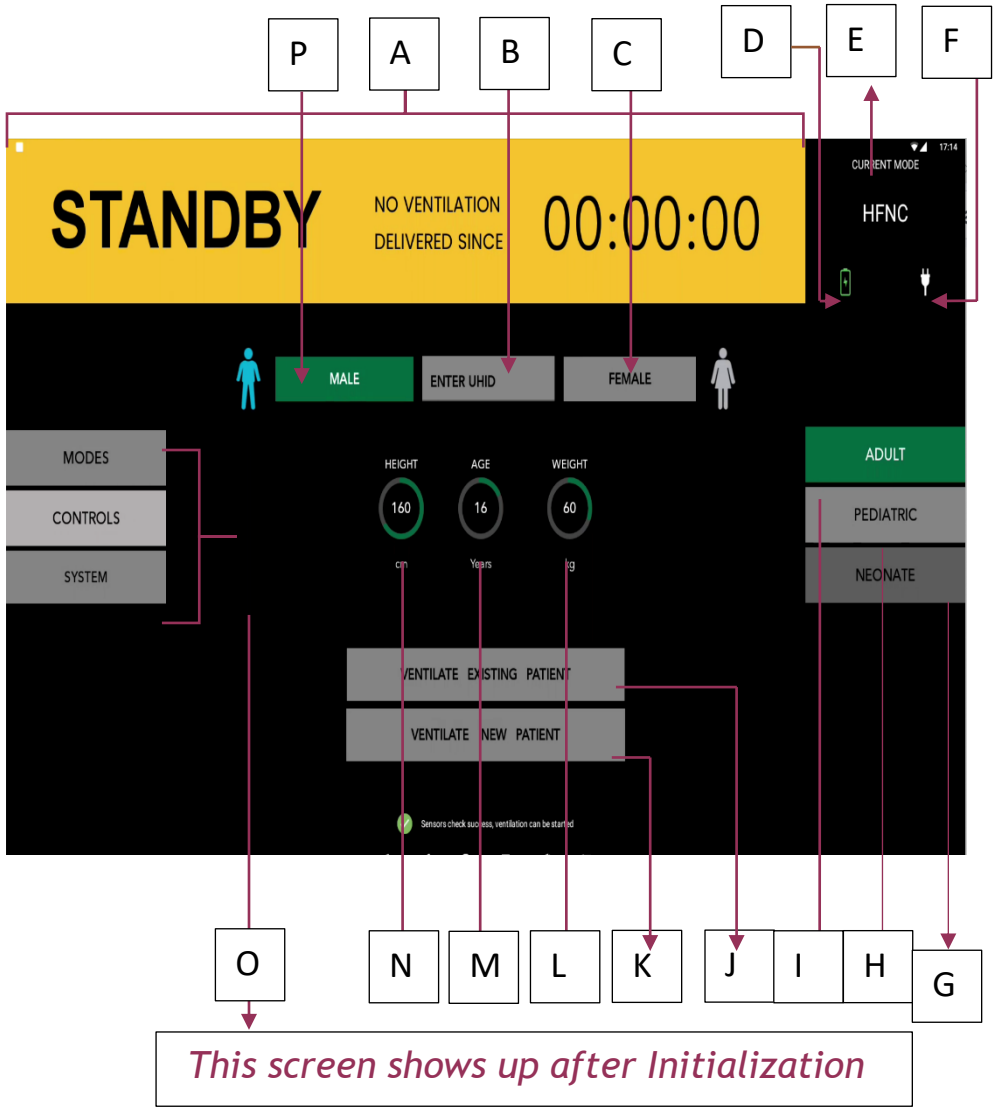
   Turn on the mains power supply (not needed when on battery) then, switch on the ventilator by turning the red switch on from behind the ventilator. Make sure the power cord attached to the ventilator is secured by pulling the clip down.

Starting Up

The system start is performed. The progress bar shows the progression of the system start.



AGVA PRO is in standby mode when turned on. This is the screen that shows up once the initializing is complete.



A. **Standby since:** Displays the amount of time it has been since the ventilator has been on standby and the amount of time it has been since last ventilation
B. **Enter UHID**
C. **Female:** Tap on this tab to set the sec of the patient to female. After selection of this option the accompanying icon will turn pink.
D. **Battery:** Indicates whether the battery is charging or displays the battery level.
E. **Current Mode:** Displays the current selected mode of ventilation.
F. **On direct power/Off direct Power:** Indicates whether the ventilator is power through the AC cable or not.
G. **Neonate**: Tap on this tab to ventilate a neonate patient in the age range of: 0 to 2.
H. **Pediatric:** Tap on this tab to ventilate a pediatric patient in the age range: 2 to 18.
I. **Adult:** Tap on this tab to ventilate an adult patient in the age range: 18 to 100.
J. **Ventilate Existing Patient:** Tap on this tab to ventilate a patient who has been ventilated on this ventilator before to maintain seamless continuity of care.
K. **Ventilate New Patient:** Tap on this tab to ventilate a new patient who has not yet been ventilated on this ventilator.
L. **Weight:** Tap on this circular dial to enter the weight of the patient. Once selected, the inner area of the dial will turn yellow.
M. **Age:** Tap on this circular dial to enter the age of the patient. Once selected, the inner area of the dial will turn yellow.
N. **Height:** Tap on this circular dial to enter the height of the patient. Once selected, the inner area of the dial will turn yellow.
O. **Modes:** Tap on this button to access several modes of ventilation available on AGVA PRO
Controls: Tap on this button to manipulate and understand different parameters of the current engaged mode.
System: Tap on this tab to pass the ventilator and it's components through different calibrations tests.
P. **Male:** Tap on this tab to set the sex of the patient to male. After selection the accompanying icon will turn blue.

Before using the device on the patient

1. Select the patient type i.e. Adult, Pediatric or Neonate.
2. Select the height, weight and age of the patient.
3. Select mode and check out control and system tab too.
4. Choose whether to ventilate existing patient or new patient.
5. Perform all the tests and calibrations.

Setup for starting ventilation

Patient Setup for a New Patient

Upon completion of the loading progress bar, the patient's screen will be displayed, presenting the following options:

1.Sex selection: Click on either the MALE or FEMALE button. The color blue is associated with the male option, while pink represents the female option.

2.Patient type selection: Choose between Adult, Pediatric, or Neonatal by selecting the appropriate option. Neonatal refers to newborns, Pediatric includes patients aged 1 to 18 years, and Adult encompasses individuals aged 18 years or older.

3.Height and weight adjustment: Set the desired values for height and weight by clicking on the provided option. To increase the value, turn the knob towards the right, and to decrease it, turn the knob towards the left. Once the desired values are selected, confirm the settings by pushing the knob once.

4.After confirming the height and weight, proceed by clicking on the **'start new ventilation'** button to initiate the ventilation process.

Patient setup for an Existing or Old Patient

"When the ventilator is first activated, the 'Ventilate Existing Patient' button appears, enabling doctors to access previous patient settings, alarm limits, trends, and historical data. This feature ensures smooth care continuity in cases where a patient is re-intubated after extubating setbacks. To activate the previous patient feature, simply click on the “Ventilate Existing Patient" option.

After confirming the patient's height and weight, click on the **"System"** button. This window will display four buttons:

a. Info (Hold on it to expand)

b. Startup

c. Calibration

d. Setting

e. Tube

A. Info Tab

1.Model: This section displays the name of the ventilator model.

2.Software Version: It indicates the version of the ventilator's software.

3.Hardware Version: It shows the version of the ventilator's hardware.

4.Log Device ID: This displays the unique device identification.

5.Battery Level: It provides the current battery level of the ventilator (% Battery).

6.Battery Health: This section indicates the battery health of the ventilator.

7.Battery Remaining Time: It shows the estimated remaining battery time.

8.Operating Hours: This indicates the total number of hours the ventilator has been in operation.

9.Hours Since Last Service: It displays the number of hours elapsed since the last service of the ventilator.

10.Connection Status: This section shows the connection status of the ventilator.

B. Startup

Already discussed in “Starting Up” section.

C. Calibration

After accessing the Info tab, the subsequent tab is dedicated to test and calibration. In this tab, various calibration options are available. The screen will display the following information:

Checkboxes: These checkboxes indicate the selection status of respective functions

1. Calibrate Exp Flow
2. Calibrate Oxygen
3. Calibrate Exhale Valve

D. Setting

Following the Calibration tab, the subsequent tab is the Settings tab. Within this tab, you will encounter the "Loudness" option and Change option, (Loudness option is pre-selected.). On the screen, a test box will be available to assess the loudness level. Here's how to adjust it:

- Click on the "Loudness" option and utilize the knob to increase or decrease the value within the range of 0 to 10.
- Tap on the “Test” button to test the loudness of the alarm.

Tap on “Change” option to toggle Knob dialogue on or off.

E. Tube

The final tab following the Settings tab is the Tube tab.

Within the Tube tab, you will find two options:

1.Tube Compliance Calibration

2.Tube Resistance Calibration.

By selecting either Tube Compliance Calibration or Tube Resistance Calibration, you can complete the calibration process for both options one after the other

Caution:

Failure to complete a System Check may result in unreliable delivery and monitoring, potentially jeopardizing the safety of the patient.

Calibration and Tests

Verification of AGVA PRO's Operational Readiness involves conducting both the device check and the breathing circuit check. Furthermore, it is essential to validate the functionality of switching to battery operation."

WARNING

Potential Patient Safety Concern

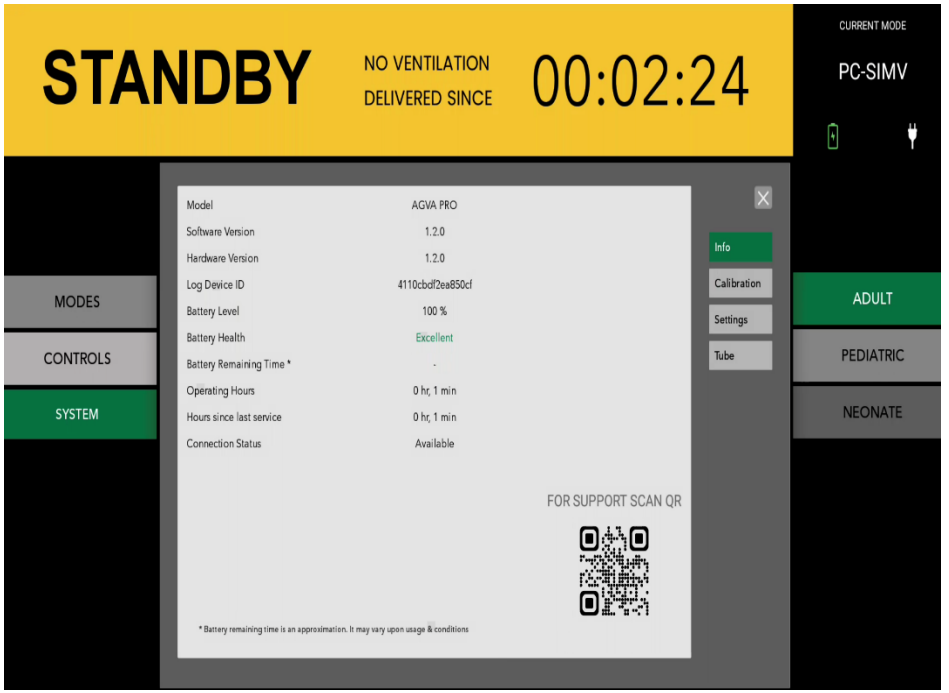
Prior to utilizing the device on a patient, it is imperative to conduct a comprehensive device check. In the event that any malfunctions are identified during the critical safety assessment steps, there exists a risk of harm to the patient.

Ventilation should only commence after the successful completion of the device check.

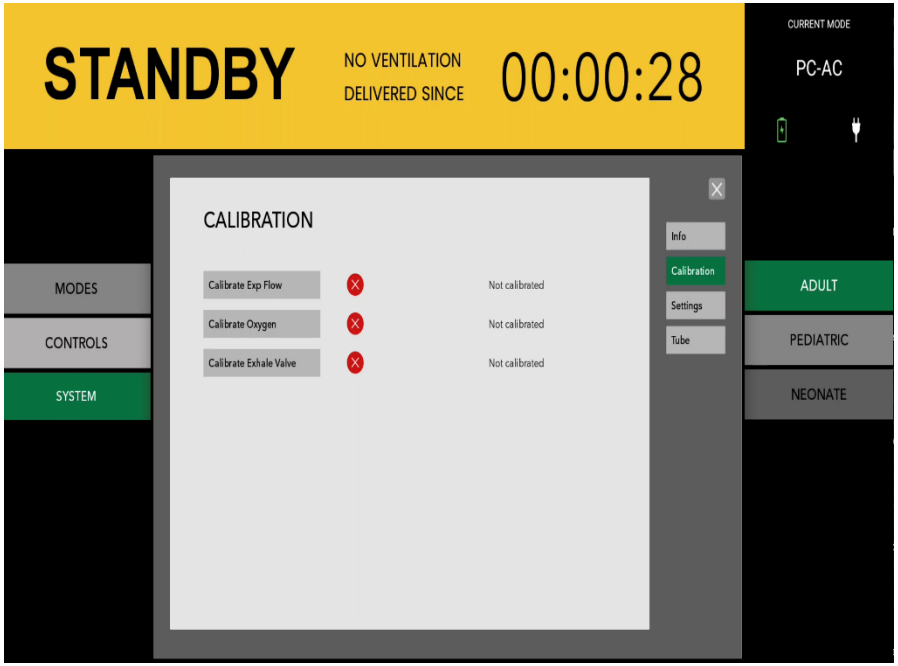
Prerequisite: AGVA PRO Ventilator is prepared and in standby mode.

- Touch the ***"System"*** tab.
- Information tab will get opened with 3 more options:
    1. Calibration
    2. Settings
    3. Tube

1.Info



1.Calibration

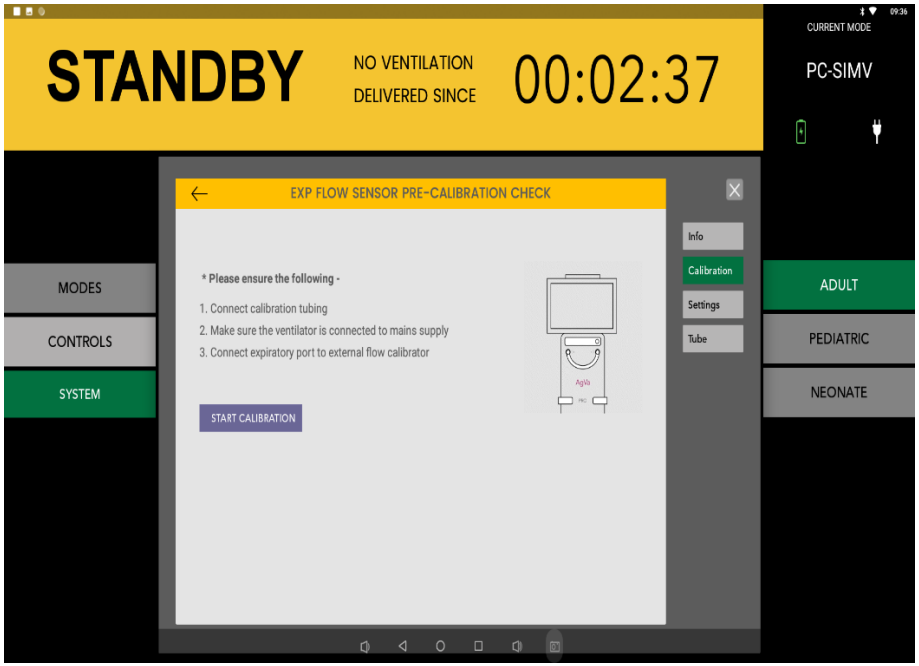


The options under **"Calibration"** tab are:

a. Calibration Exp. Flow
b. Calibrate Oxygen
c. Calibrate Exhale Valve

Tap on any on these tabs to run a calibration test.

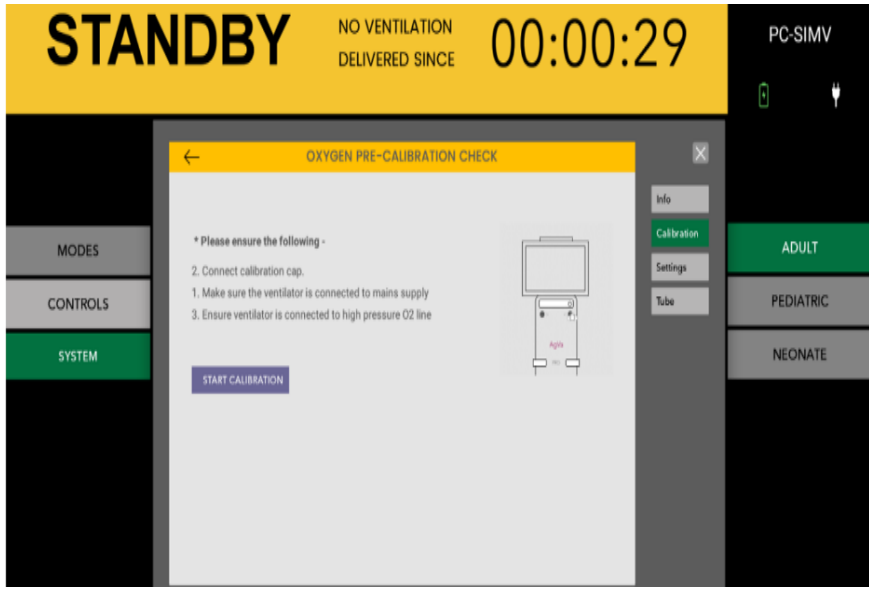
a. Calibrate Exp Flow



Tap on the **"Calibrate Exp Flow"** tab to enter the **"Exp Flow Sensor Pre-Calibration Check"** window.

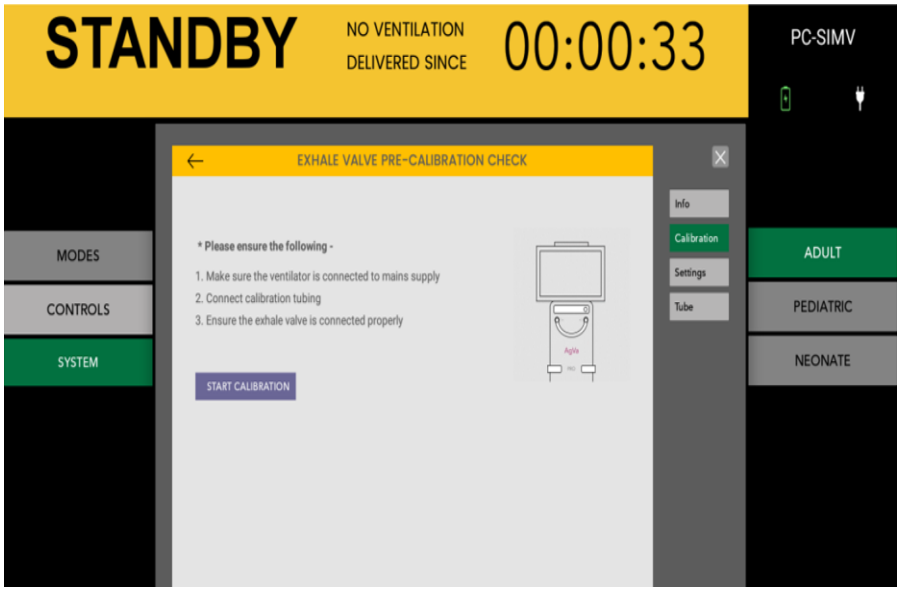
Make sure to follow the steps mentioned on the screen and tap on **"Start Calibration"** button to start the calibration process.

b. Calibrate Oxygen



Tap on "***Calibrate Oxygen***" Tab and you'll be redirected to the screen as shown above. Ensure everything is ready for the calibration and then press on the ***"START CALIBRATION"*** button.

c. Calibrate Exhale Valve



Tap on "***Calibrate Exhale Valve***" Tab and you'll be redirected to the screen as shown ahead. Ensure everything is ready for the calibration and then press on the ***"START CALIBRATION"*** button.

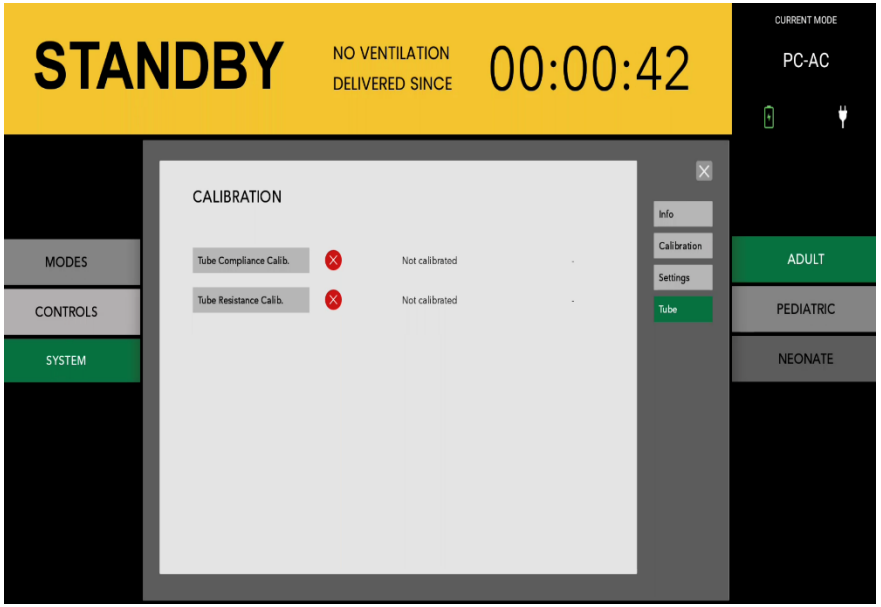
2.Tube

Starting the breathing circuit check:

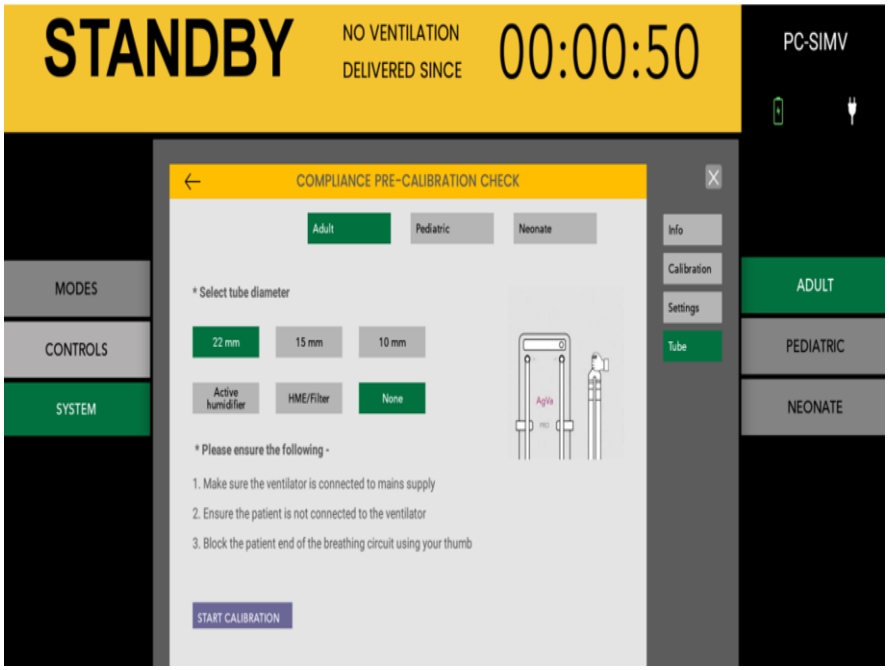
1. Tap on ***"Tube"*** tab to check tube calibration and tube resistance calibration.
2. Tap on any of the two, a new window will appear where you'll have to select few specifications like diameter of tube, patient type etc.
3. Tap on Start Calibration button to start the test.
4. An Error window will pop up if the calibration fails.
5. Recalibrate the breathing circuit, but if the error is recurring, change the breathing circuit with a new one.

Under the "Tube" tab you'd be displayed two options:

a. Tube Compliance Calib
b. Tube Resistance Calib



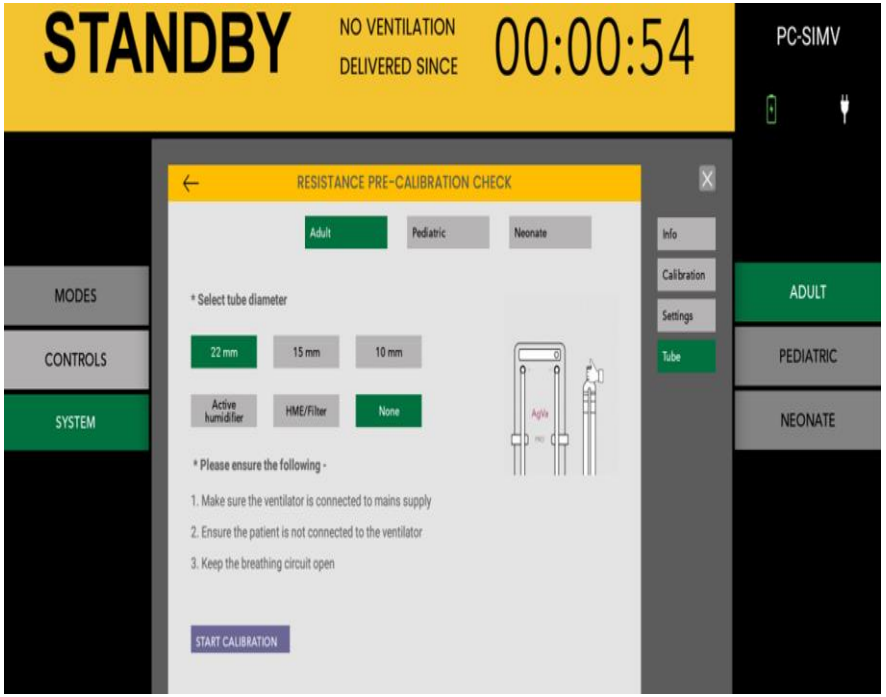
a. Tube Compliance Calibration



To verify the tube compliance:

1. Firstly, select the approp+riate Patient Group, as Adult and Pediatric share the same breathing circuit (22 mm), while Neonatal requires a different breathing circuit (10 mm).
2. Ensure the ventilator is connected to the mains supply.
3. Make sure the patient is not connected to the ventilator.
4. Block the patient end of the breathing circuit using your thumb.
5. Click on "Start calibration." If there is a leak in the breathing tube, calibration will fail; replace the breathing tube and repeat the process with a new breathing tube.

b. Tube Resistance Calibration



To perform the Tube Resistance Check:

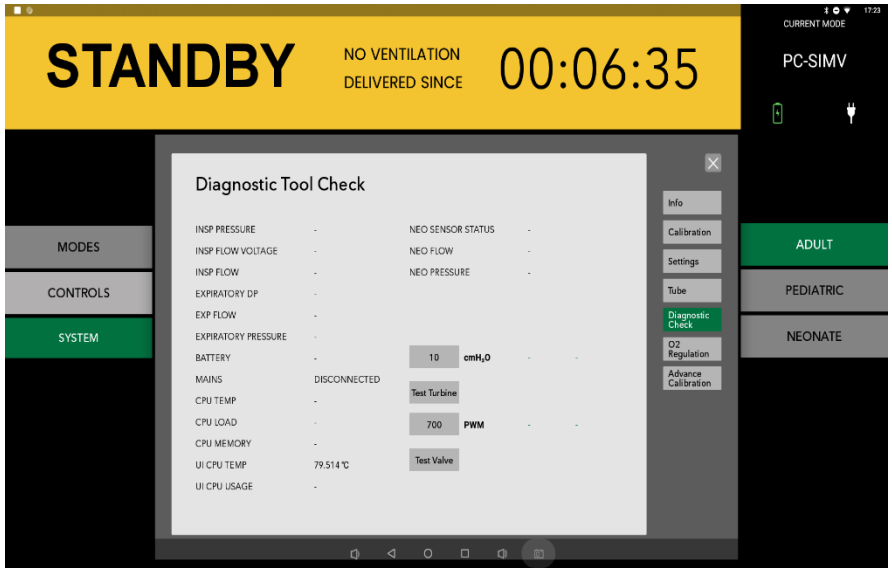
1. Firstly, select the appropriate Patient Group; for Adult and Pediatric patients, use the same breathing circuit (22 mm), while Neonatal patients require a different breathing circuit (10 mm).
2. Ensure the ventilator is connected to the mains supply.
3. Make sure the patient is not connected to the ventilator.
4. Keep the patient end of the breathing circuit open.
5. Click on "Start calibration." Calibration will only succeed if there is no resistance in the breathing tube. If there is resistance, replace the breathing tube and repeat the process with a new one.

Hidden Options for service engineers

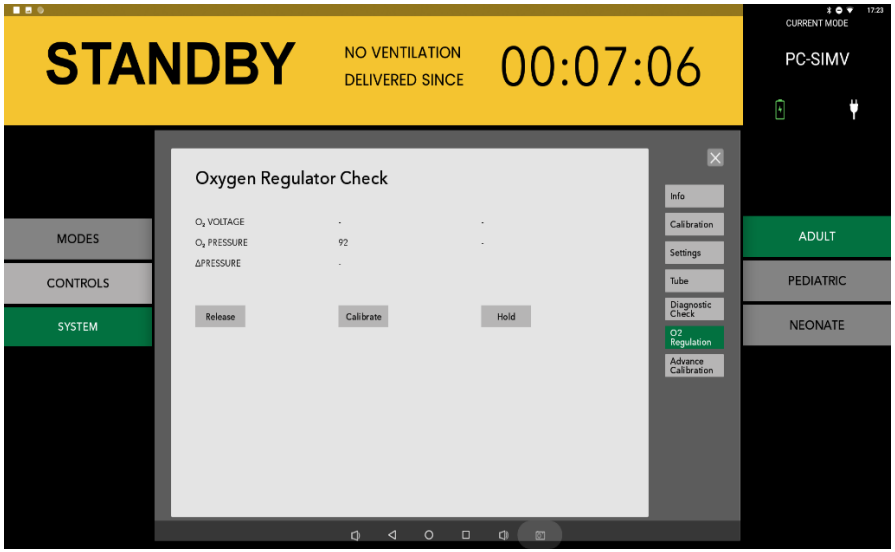
Hold onto the info tab for longer to unveil more options, namely:

1. Diagnostic Check
2. O2 Regulation
3. Advanced Calibration

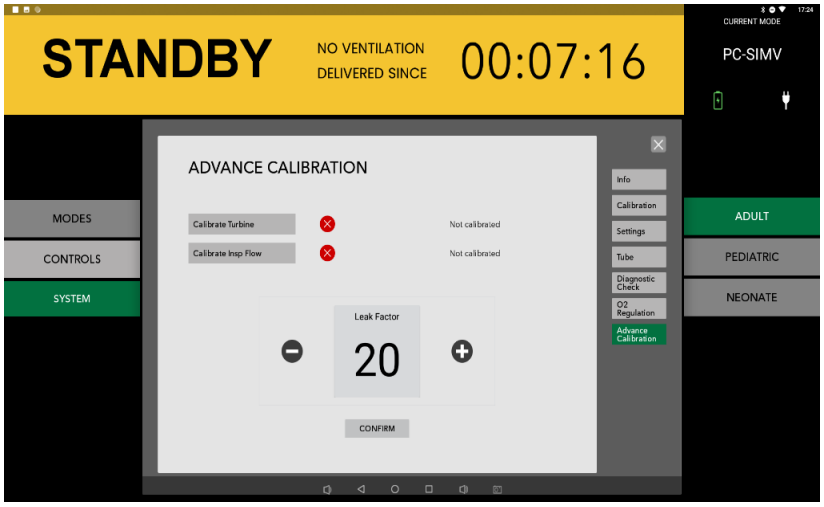
1.Diagnostic Tool Check



2.O_2 Regulation



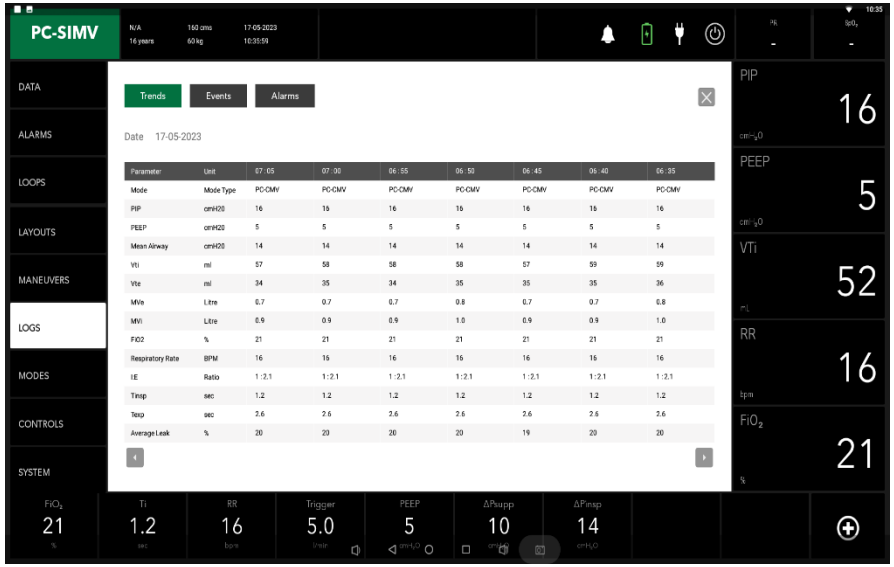
3. Advanced Calibration



Displaying Waveforms

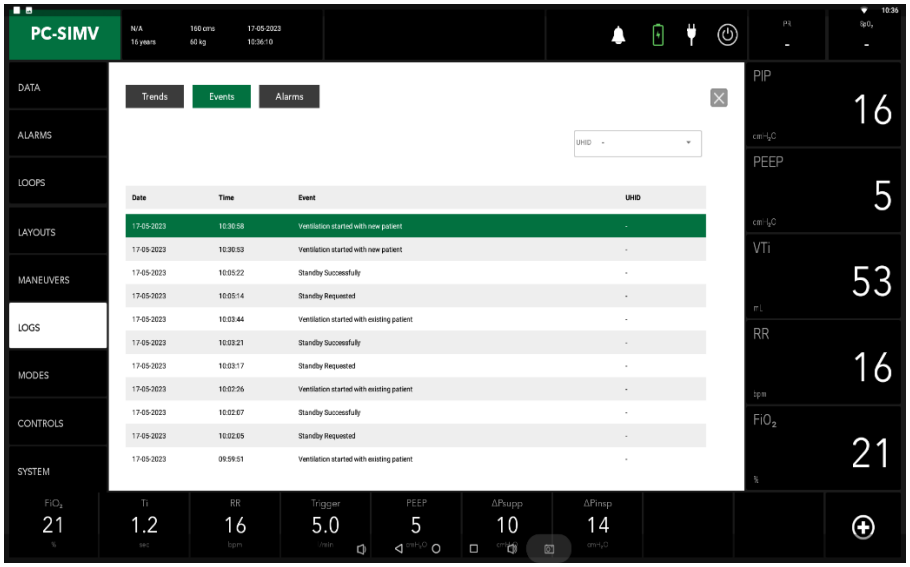
Once the ventilation is initiated, the user will be introduced to this screen where you can monitor the parameters displayed with their respective waveform projections.

Trends Display



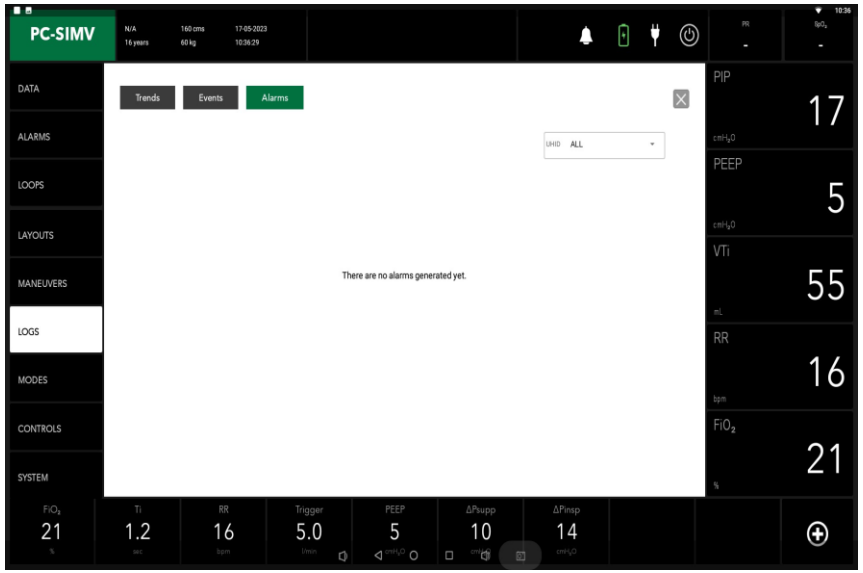
Under the Logs tab, tap on the “Trends” button. Under the Trends tab the user will be able to monitor different parameters on one single screen. You can monitor parameters like PIP, PEEP, Mean Airway, Vti, Vte, MVe etc.

Displaying Event Logs



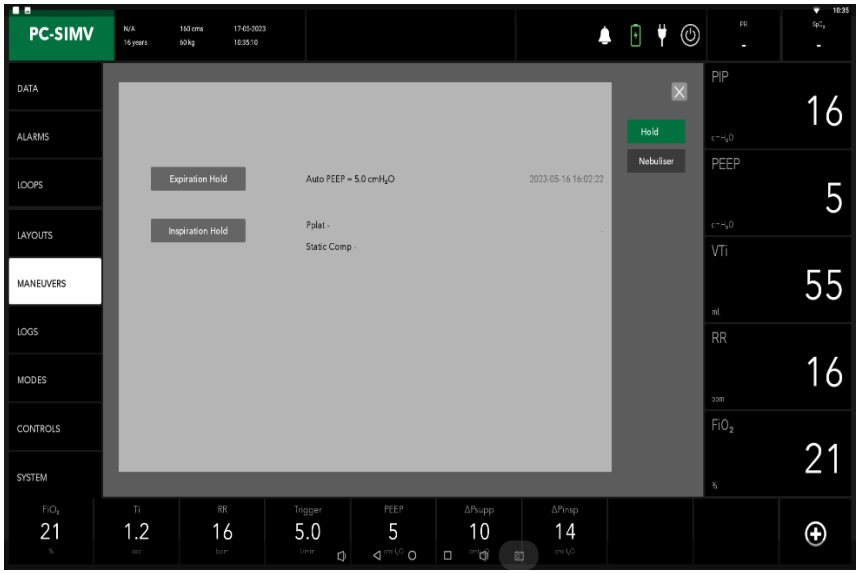
Under the Logs tab, tap on the “Events” button. Under the Events you will be able to all the events that have occurred during ventilation like, alarms, standby requests etc.

Displaying Alarms



Under the Logs tab, tap on the “Alarms” tab. Under this tab, the user will be able to monitor the alarms that have been triggered since the initialization of ventilation.

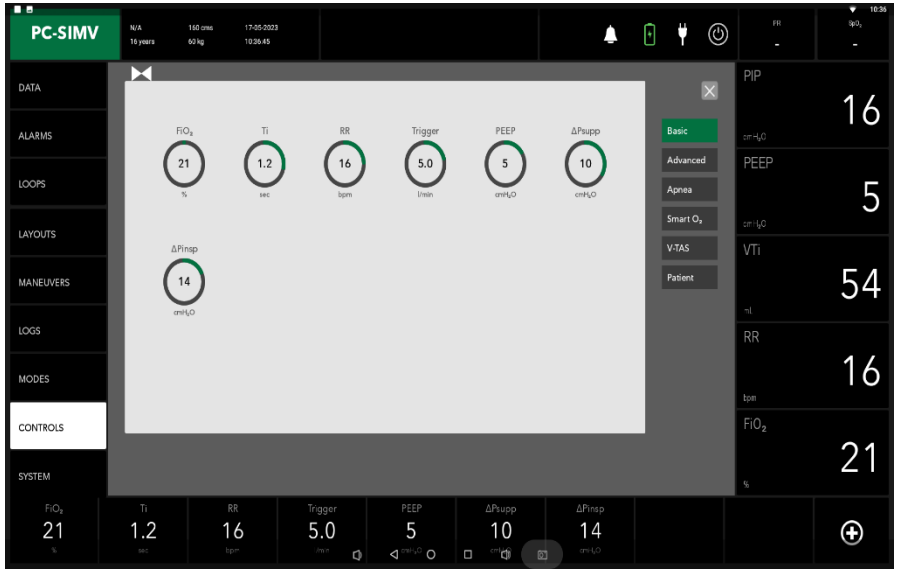
Displaying Maneuvers



Under the “Maneuvers” tab, the user will introduced to few tabs:

1. **Under Hold tab, in Maneuvers Section**
    - Expiration Hold
    - Inspiration Hold
2. **Tap on the Nebulizer tab, in Maneuvers Section to start nebulization process.**

Displaying Controls

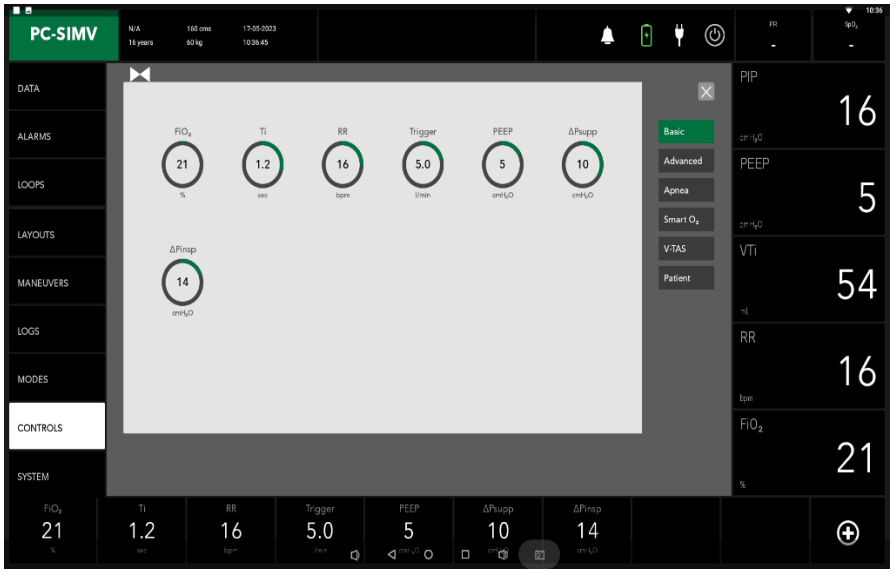


Under the “Controls” tab, the user will be able to select and monitor different parameters:

1. Basic
2. Advanced
3. Apnea
4. Smart O_2
5. V-TAS
6. Patient

Under each of the mentioned tabs you will be able to monitor the parameters of the currently engaged mode.

Displaying System



Under the “System” tab, the user will be able to carry out the calibration and tests and also monitor information of the device. Hidden options can be unraveled by the service engineer by taping and holding onto the “Info” tab. Information about this section have been discussed in earlier sections on this manual.

Modes

Setting Ventilation Modes

Upon confirming the patient's height and weight, navigate to the System tab. Within this window, you will find the following available modes:

A. Volume Controlled

1.VC - CMV: Volume Controlled – Continuous Mandatory Ventilation

2.VC-SIMV: Volume Controlled – Synchronized Intermittent Mandatory Ventilation

3.VC-AC: Volume Controlled- Assist Control

B. Pressure Controlled

1.PC-CMV: Pressure Controlled – Continuous Mandatory Ventilation

2.PC-SIMV: Pressure Controlled – Synchronized Intermittent Mandatory Ventilation

3.PC-AC: Pressure Controlled – Assist Control

4.PC-PSV: Pressure Controlled – Pressure Support Ventilation

C. Intelligent Ventilation

AI-Vent

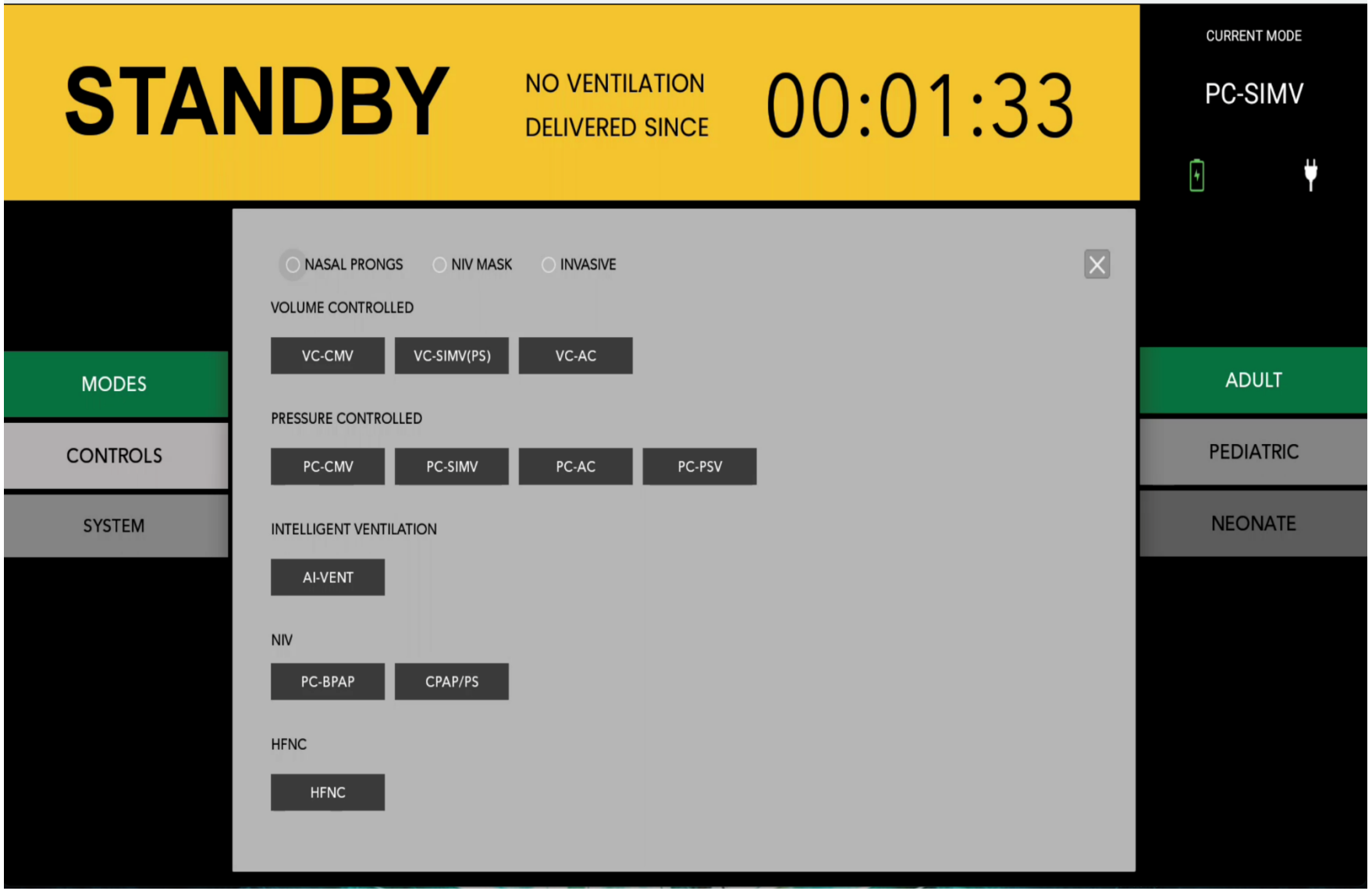
D. Flow Cycle

1. PC-BPAP: Pressure Controlled – Biphasic Positive Airway Pressure

2. CPAP/PS: Continuous Positive Airway Pressure/ Pressure Support

E. HFNC

Mode Selection Screen



Modes Description

Ventilation Modes:

Ventilator operation offers various patient ventilation techniques, categorized as mandatory and spontaneous breathing methods. Under mandatory methods, the equipment regulates breathing, while spontaneous methods allow independent patient breathing at PEEP level or with equipment support. AGVA PRO equipment's ventilation modes fall into three groups: volume-controlled, pressure-controlled, and spontaneous/assisted modes.

Before choosing any mode, select whether you want invasive or non-invasive ventilation. After choosing any of the modes out of the 11 options that are listed in this section, you'd be introduced to a new window where all the measurements will be listed out under following different tabs that you can tap on to access:

1. Basic
2. Advance
3. Smart O2
4. Backup (only available in VC-SIMV(PS), PC-SIMV, PC-PSV, PC-BPAP, CPAP/PS,)
5. V-TAS (only available in PC-CMV, PC-SIMV, PC-PSV)

Pressure Controlled Mandatory Ventilation Mode

Pressure-control Mandatory ventilation (PCMV) is a pressure-targeted, time-cycled ventilation technology. Two pressure levels are maintained during pressure-controlled ventilation: the lower pressure level PEEP and the upper-pressure level Pinsp. Volume and decelerating flow, which may change depending on lung mechanics, are the result determinants. The Pinsp pressures are the values that the device regulates and maintains at a baseline. The pressures of PEEP, Pinsp, and necessary breaths per minute (RR) may all be changed.

The minute volume (MV) is a variable that can alter over time. The pressure rise may be set to the upper; k-pressure level using the slope control, based on the patient. The flow adjustment is widely used to assess this pressure rise during infant respiration. Both alterations determine the duration of the pressure increase from the lower to the higher-pressure level. Because the pressure is maintained, the patient is never exposed to dangerously high pressures. This method of respiration protects against barotraumas.

Pressure Controlled-Assist Control Ventilation Mode

Under Pressure Controlled – Assist Control (PC-AC) mode, every observed breath at PEEP level elicits a mandatory breath, leaving the patient in control of the count of supplementary obligatory breaths. To allow ample exhalation time, an immediate additional mandatory breath post a completed one isn't feasible.

Should no mandatory breath be triggered upon expiration completion, an automatic mandatory breath is administered (backup frequency). Hence, the Respiratory Rate (RR) adjuster sets the baseline ventilation frequency.

The tidal volume (VT) arises from the pressure differential between PEEP and Pinsp, lung mechanics, and the patient's exerted breathing effort. If lung Resistance (R) or Compliance (C) changes during ventilation, the administered tidal volume (VT) fluctuates accordingly.

Given that the quantity of mandatory breaths hinges on both the patient and the designated frequency (RR), the minute volume (MV) also possesses the potential to vary.

Pressure Control-Continuous Mandatory Ventilation

The Pressure Control – Continuous Mandatory Ventilation (PC-CMV) tidal volume supplied to the patient depends on the pressure difference between PEEP and Pinsp, the lung mechanics and the breathing effort of the patient. The number of mandatory breaths is defined by the breathing frequency (RR). The mandatory breaths are machine-triggered and not triggered by the patient.

Pressure Controlled - Pressure Support Ventilation

In Pressure Controlled – Pressure Support Ventilation (PC-PSV), the patient can breathe spontaneously at PEEP level. Every detected inspiration effort can be pressure-supported. The absolute level of pressure support is defined by Pinsp. The duration of inspiration is flow-cycled and thus depends on the lung mechanics of the patient.

The patient determines the number, point of time and duration of the pressure-supported mandatory breaths. If the breathing frequency of the patient is lower than the set backup frequency (RR) or there is no spontaneous breathing, machine-triggered flow-cycled mandatory breaths with the set pressure Pinsp are applied. The tidal volume (VT) results from the pressure difference between PEEP and Pinsp, the lung mechanics and the breathing effort of the patient. If the Resistance (R) or Compliance (C) of the lung changes during the ventilation treatment, the supplied tidal volume (VT) and thus the minute volume (MV) also vary.

Pressure Controlled-Synchronized Intermittent Mandatory Ventilation Mode

In Pressure Controlled – Synchronized Intermittent Mandatory Ventilation (PC-SIMV) the patient can breathe spontaneously at any time, but the number of mandatory breaths is specified.

The mandatory breaths are synchronized with the patient's own breathing attempts. A patient-triggered mandatory breath can only be triggered within a trigger window. If the expiration phase and with it the spontaneous breathing time is shortened on account of synchronization, the next expiration phase will be extended. This adaptation prevents a change in the number of mandatory breaths (RR).

If no independent breathing attempt is detected during the trigger window, the machine-triggered mandatory breath are applied. The mandatory tidal volume (VT) results from the pressure difference between PEEP and Pinsp, the lung mechanics and the breathing effort of the patient. If the Resistance (R) or Compliance (C) of the lung changes during the ventilation treatment, the supplied tidal volume (VT) and thus the minute volume (MV) also vary.In this ventilation mode, the patient can breathe spontaneously during the complete breathing cycle. During spontaneous breathing at PEEP level, the patient can be supported using PS.

Volume Controlled – Continuous Mandatory Ventilation

Within the Volume Controlled – Continuous Mandatory Ventilation (VC-CMV) mode, the patient is administered the designated tidal volume (VT) during each obligatory breath, irrespective of fluctuations in lung mechanics. The quantity of mandatory breaths is determined by the frequency (RR), thus ensuring a consistent minute volume (MV) throughout.

Volume Control – Assist Control

In the ventilation mode Volume Control – Assist Control (VC-AC), the patient always receives at least the set tidal volume (VT). In VC-AC, every detected inspiration effort of the patient at PEEP level triggers an additional mandatory breath. The patient thus determines the number of additional mandatory breaths. To give the patient sufficient time for expiration, it is not possible to trigger another mandatory breath immediately after a completed breath.

If after the completion of the expiratory time no mandatory breath has been triggered, a mandatory breath is automatically applied (backup frequency). The control knob for respiratory rate (RR) therefore defines the minimum ventilation frequency.

Because the number of mandatory breaths depends both on the patient and the set frequency (RR), the minute volume (MV) can vary

Volume Controlled-Synchronized Intermittent Mandatory Ventilation

In Volume Control-Synchronized Intermittent Mandatory Ventilation (VC-SIMV), the patient is supplied with the set tidal volume VT during the mandatory breaths.

The mandatory breaths are synchronized with the patient‘s own breathing attempts. To prevent a mandatory breath from being applied during spontaneous expiration, a patient-triggered mandatory breath can only be triggered within a trigger window. If the expiration phase and with it the spontaneous breathing time is shortened on account of synchronization, the next expiration phase will be extended. This adaptation prevents a change in the number of mandatory breaths.

If no independent breathing attempt is detected during the trigger window, the machine-triggered mandatory breaths are applied. Thus, the minute volume MV remains constant over time. If the breathing attempts of the patient are insufficient to trigger the mandatory breath, the machine-triggered mandatory breaths are applied. The patient can breathe spontaneously at PEEP level during the expiration phase. During spontaneous breathing at PEEP level, the patient can be pressure-supported using PS

Artificial Intelligence Ventilation:

Artificial Intelligence Ventilation, also known as AI-Vent, is a mode implemented in the AGVA PRO Ventilator that harnesses the power of artificial intelligence. This innovative feature proves particularly valuable in scenarios where the doctor or ventilator operator is unavailable. The AI-Vent Mode allows anyone to operate the ventilator by simply entering the basic patient details such as age, gender, height, and weight. This user-friendly approach ensures accessibility and convenience in providing ventilation support.

Non-Invasive Ventilation

Non-invasive ventilation (NIV) utilizes face masks, nasal masks, or helmets to deliver respiratory assistance. Positive pressure is applied, often combined with supplemental oxygen, through the mask. The pressure levels are adjusted based on the inhalation and exhalation phases. This approach is referred to as "non-invasive" because it does not involve tracheal intubation, as it relies on a well-fitted mask over the face or head rather than a tube inserted through the mouth into the windpipe.

Pressure Control – Biphasic Positive Airway Pressure

In Pressure Control-Biphasic Positive Airway Pressure (PC-BPAP) mode, the patient can breathe spontaneously, yet the count of obligatory breaths is defined. These breaths synchronize with the patient's own efforts for both inhalation and exhalation. Shortening a mandatory breath due to synchronization with expiration leads to extending the subsequent one; similarly, synchronization with inspiration shortens the expiration phase. This adaptation prevents increasing the set mandatory breathing frequency (RR). In the absence of a spontaneous inhalation within the inspiratory trigger window, machine-triggered obligatory breaths come into play.

The mandatory tidal volume (VT) stems from the pressure contrast between PEEP and Pinsp, lung mechanics, and the patient's breathing endeavor. Lung Resistance (R) or Compliance (C) alterations during ventilation provoke variations in supplied tidal volume (VT) and, consequently, minute volume (MV).

Within this mode, the patient enjoys complete breathing cycle spontaneity. While breathing spontaneously at PEEP level, support through PS is feasible.

Continuous Positive Airway Pressure/Pressure Support

In Continuous Positive Airway Pressure/Pressure Support (CPAP/PS), the patient breathes at the PEEP level. Compared to the atmospheric pressure, the airway pressure is increased during the complete breathing cycle, i.e. during inspiration and expiration. If the patient is too weak to manage the complete breathing effort independently, there is the option of pressure support (PS). Every detected inspiration attempt at PEEP level triggers a patient-triggered, flow-cycled, pressure-supported mandatory breath. The point of time, the number and the duration of the pressure-supported breaths are determined by the patient. If the lung mechanics of the patient change, the applied volume varies with fixed (PS).

HFNC

High-Flow Nasal Cannula (HFNC) therapy is a specialized oxygen delivery system that provides highly humidified and heated oxygen at flow rates of up to 60 liters per minute, with the ability to deliver up to 100% oxygen concentration.

Alarms

Introduction

Alarms come after events in the logs.

1. Click on alarms button.
2. You'll get a list of all the alarms that have been generated, as well as their start and stop times.

Optical alarm signals

AGVA PRO Ventilator displays the following optical alarm signals:

The system displays the relevant alarm message in the alarm message field of the header bar.

1.For alarms with critical priority, the red LED Flashes

2.For alarms with medium priority, the amber LED blinks.

3.For alarms with lower priority, the amber LED stays on continuously without blinking.

Other displays

Clicking on the Alarm menu, it will show the three option i.e, Basic, Advance and Active Alarms.

The optical alarm signals are designed as follows:

1.The device that has generated an alarm can be identified at a distance of 4 m (157 in).

2.The alarm message can be clearly read at a distance of 1 m (39 in).

The optical alarm signals are designed as follows:

1. The device that has generated an alarm can be identified at a distance of 4 m (157 in).
2. The alarm message can be clearly read at a distance of 1 m (39 in).

Perceptibility of alarm signals

S.No.	Alarm Color	Alert Level
1.		Critical
2.	This light blinks in Medium alert level	Medium
3.	This light glows without blinking in Low alert level	Low

Acoustic alarm signals

1. The alarm with the critical priority or alarm with high priority are signaled acoustically. The alarm signal continues to sound until either the cause for the alarm has been resolved or the alarm signal is suppressed.
2. The alarm with medium priority or alarm with low priority are signaled acoustically. The alarm signal continues to sound until either the cause

for the alarm has been resolved or the alarm signal is suppressed.

Alarm priorities

If the loudspeaker for the alarm signal (main alarm) fails due to a defect, an alarms message will be displayed on the monitors of ventilator.

The background color of the alarm message field indicates the priority of the active alarm. If several alarms occur simultaneously, the alarm with the critical/highest priority is displayed first. Critical/High-priority alarm messages that are no longer active are displayed in the background color of the alarm message field. The parameter box of the parameter triggering the alarm flashes in the color of the corresponding alarm priority.

Alarm silence

- The acoustic alarm signal can be suppressed for a maximum of 2 minutes.
- If an alarm with a Critical priority occurs during this time, the alarm signal will display on the monitors.
- If the fault triggering the alarm is not eliminated after 2 minutes, the alarm signal sounds again.
- •During the device check when testing the alarm signals/calibrations then no alarm signal comes but the alarm signal will display on the monitors.

The alarm signal cannot be suppressed in the following situation:

- During the alarm Standby mode activated

Suppressing the alarm signal

Press the Audio paused 2 min. key.

AGVA PRO ventilator displays the symbol and the remaining time for the suppressed alarm signal in the header bar.

Press the Audio paused 2 min. key.

Dismissing alarm messages and alarm signal

After the fault has been eliminated, the alarm signal stops and also alarm messages dismisses.

Setting of Alarm Limits

Opening the Alarms dialog window

Touch the “Alarms” button, then, 3 options will be displayed like Basic, Advance and Active Alarm.

Click on the Basic, Advance and touch the parameters then set the alarm limit by rotating the knob.

Alarm limits and setting ranges

In the following table, the alarm limits are listed with setting ranges

Alarm	Setting range
PIP	0-60 cm H2O
VTe	0-2000 ml
PEEP	0-50 cm H2O
RR	2-200 bpm
MVi	0-100 liter
FiO2	21-100 %
SpO2	90-100 %

.;

Tabs on Ventilation Screen

This chapter encompasses comprehensive information about the ventilator's settings. Proper operation of the ventilator is limited to authorized medical personnel who have undergone extensive training in its usage. It is essential to adhere strictly to the instructions outlined in the user's reference manual, and specific tasks should be performed using the tools and equipment specified within this document.

Data Button

Upon loading the ventilation mode screen feat, the home screen will be displayed, presenting a menu list. To proceed, select the "Data" button, which comprises two options: "General" and "SpO2." Next, choose the "General" or “SpO_2” option by tapping on it.

Alarm Button

Moving along the ventilation screen menu list, the next item is the Alarms option. Upon selecting Alarms, three choices will appear on the screen:

1. Basic
2. Advanced
3. Active Alarms

Basic:

Upon selecting Basic, various parameters will be displayed on the screen:

1. PIP-: 0-60 cmH2O
2. VTe-: 0-2000 ml
3. PEEP-: 0-50 cmH2O
4. RR-: 2-200 bpm
5. MVi-: 0-100 liters

By clicking on the parameters, you can adjust the values using the rotating knob.

Advance-

When you click on Advance, 2 parameters will appear on the screen:

1. FiO2-: 21-100%
2. SpO2-: 90-100%

By clicking on the parameters, you can adjust the values using the rotating knob.

Active Alarm

After selecting the Active Alarm, current occurring alarms will be displayed on the screen.

Loops Button:

To access the loop options, navigate to the menu and choose "Loops."

This action will bring up a new screen displaying three loops and one graph:

1. FP Loop
2. FV Loop

3. PV Loop
4. Flow Graph

To select a specific loop or graph, click on the desired one.

Layout Button

Upon selecting the layout option, five different layout options with default buttons choices will be displayed.

Default: It consists of 3 horizontal graphs

1. The first graph will show pressure in cmH2O.
2. The second graph will show volume in ml.
3. The third graph will show flow in l/min.

Layout 1:

Layout 1 consists of three waveforms and a loop.

1. The first graph will show pressure in cmH2O.
2. The second graph will show volume in ml.
3. The third graph will show flow in l/min
4. The fourth graph will show FV loop.

Layout 2:

Layout 2 consists of two waveforms graphs

1. The first graph will show pressure in cmH2O.
2. The second graph will show flow in l/ml.

Layout 4:

Layout 4 consists of one waveform graph and two loops.

1. The first graph will show pressure in cmH2O.
2. The second graph will show FP loop.
3. The Third graphs will show PV loop

Loops: layout 4 consists of three loops and one waveform:

1. The first loops will show FP loop
2. The seconds loops will show FV loop
3. The third graph will show flow in l/min.
4. The Fourth loop will show PV loop.

Maneuvers Button

The next menu option after the layout window is Maneuvers, which contains two options:

1. Hold
2. Nebulizer

There are two options in the hold window; Expiration hold and Inspiration hold.

When you click on Expiration hold:

A new window will pop up after clicking on Expiration hold, with a duration timer in the middle of the screen. You can set the duration timer (1-2.5) for the desired respiratory hold.

Click on the start button to start the process.

When you click on the Inspiration hold:

When you select Inspiration hold, a window will display with a duration timer (1-2.5) in the middle of the screen to set respiration hold, similar to Expiration hold.

Click on the start button to start the process.

After tapping on the nebulizer option, a new window will open with a time dial in the middle, manipulate it with the help of the knob, press to confirm and click on start nebulization button.

LOGS

After Maneuvers, the next menu option is Logs, which has three options.

Trends, Events, Alarm.

TRENDS

Click the trends button to select the trend option.

It shows a table which consist of values at different time intervals for different modes and the mode type

EVENTS

After trends the next option is events.

1. Click on events button.
2. A table will display in the Events window, giving the date and time for the events like standby, Battery Critically etc as well as the values specified by the operators and their range.

ALARMS

Alarms come after events in the logs.

1. Click on alarms button.
2. You'll get a list of all the alarms that have been generated, as well as their start and stop times.

MODES

1. To select the Mode.
2. Click on Modes.
3. A popup window with various modes will appear.
4. Choose the desired mode.
5. A notification will appear; press the knob to confirm the mode you have chosen.

CONTROL

The next option is control and it offers you list of 6 options to choose from:

1. Basic.
2. Advanced.
3. Apnea.
4. Smart O2.
5. V-TAS.
6. Patients.

SYSTEM

Basic: 5 parameters will appear under this tab:

1. FiO2-:21-100 %
2. Ti-:1.2-1.9 sec

3. RR-:16-25 bpm
4. PEEP:5-26 cm H2O
5. Pinsp-:6-35 cm H2O

Advanced: a new set of options will be presented under this tab:

1. INVERSE I:E-: Active/Inactive
2. Slope
3. Plimit-:40-60 cm H2O
4. Smart O_2-: Following are the parameters under this tab:

Smart FiO2-: Inactive/Active

1. Tg.SpO_2-:95-100 %
2. PR Limit-:90-120 bpm
3. FiO2-10-25 %

V-TAS-: Click on the V-TAS that show the different parameter

1. V-TAS-: Inactive /Active
2. Target VT-: 500 -2000 ml
3. P Limit-: 40-60 cmH2O

Patient-: You will be introduced to two categories under this tab:

1. Male
2. Female.
3. Also, you will see three parameters namely. Height, Age and Weight as per patient type.
4. Ventilation time can be set using the Reset button.

The next menu choice after the modes is system, which offers 3 options:

1. Info
2. Calibration
3. Settings
4. Tube

Info-: On clicking Info option it shows the following parameters:

1. Model, Software version.
2. Hardware version.
3. Log Device ID.
4. Battery level.
5. Battery Health.
6. Battery remaining Time*.
7. Operating Hours.
8. Hours since last service.
9. Connection Status.

Tap and hold for few seconds on the “Info” option to enable service option after the tube option.

Calibration-: upon tapping on settings option, you will be introduced to following parameters:

1. Calibrate exp Flow
2. Calibrate Oxygen,
3. Calibrate Exhale Valve

Settings- On clicking settings option it shows the following parameter:

Loudness-:10

Tube-: On clicking Tube option it shows the calibration status of the following:

1. Tube Compliance Calibration
2. Tube Resistance Calibration

Service-: On clicking service option it shows the previous services done and also to add a new service. It will also display the Date and Time of the Service Done.

Troubleshooting

S.NO.	Alarm	Cause	Remedy
1.	Patient Disconnection	Average leakage is more than 90%	1. Check the breathing circuit 2. Check whether the patient is connected or not
2.	Air Supply Low	1. HEPA filter is blocked 2. Connection of the turbine fails	1. Check the condition of the HEPA filter and replace it with a fresh one if it needs to be changed. 2. Check the connections of the Turbine.
3.	Battery activated	Internal supply of the battery is activated because the mains supply is missing.	**NOTE**: The maximum time the ventilator can operate on battery is 4 hours. Re-establish main power supply or charge the ventilator from and external battery within 4 hours.
4.	Calibration of expiratory flow sensor failed	Test of expiratory flow sensor failed.	1. Check whether the sensor is connected correctly. 2. Repeat device check. 3. Replace flow sensor.
5.	Calibration of gas delivery system required (Low Pressure).	O_2 delivery is not properly	Check regulator connection. Check line pressure.
6.	Continuous nebulization activated	Nebulization is ON and has not terminated since long.	1. Wait until nebulization is completed. **or** 2. Terminate nebulization prematurely.
8.	Expiratory Hold Interrupted	Expiratory Hold button must have been pressed for too long.	Release the Expiratory Hold button.
9.	Turbine communication failure.	Internal turbine internal failure.	Check turbine
10.	Inspiratory hold interrupted	The key is stuck, faulty, or it was pressed for a longer period of time.	1. Ventilation functions are not affected. 2. Release the key. 3. If the error persists, contact specialized service personnel.

S.No.	Alarm	Cause	Remedy
11.	Inspiratory hold interrupted	The key is stuck, faulty, or it was pressed for a longer period of time.	1. Check for leakages in breathing circuit. 2. Make sure that the tube is connect correctly. 3. Make sure that the tube is connected correctly.
12.	Neonatal flow sensor disconnected	Tube is disconnected	Check the tube
13.	Pressure Limited – VT not reached	Required volume is delivered and pressure remains limited.	Change the pressure limit.
14.	Service date reached	The threshold of operating hours of the turbine has been reached.	Call upon the service engineer to update the data or turbine.
15.	Service date approaching	The threshold of operating hours of turbine is near.	Service Required
16.	Setting not confirmed	Failure of the system to communicate with the hardware.	Resend the setting.
17.	Ventilation mode not confirmed	Failure of the system to communicate with the hardware.	Resend the setting.
18.	VT not reached	The volume (VT) set has not been completely or properly delivered.	1. Check the Plimit. 2. Check the leakage in the expiratory circuit.
19.	VT not reached leakage?	1. The leakage is more than 60% 2. The set volume has not been reached.	1. Check whether there is any obstruction in circuit. 2. Check whether there is any leakage from the expiratory circuit.
20.	VT has not reached Pmax active yet.	1. The volume has not been delivered after pressure is maximum. 2. The settings were changed but were not confirmed, due to which VT does not reach Pmax value.	

S.No	Alarm	Cause	Remedy
21.	Apnea Ventilation	Ventilator detected the apnea and automatically switched to "Apnea Ventilation".	1. Check ventilation settings and patient condition. 2. To return to original ventilation mode, press the "Alarm reset" key. 3. After 4 continuous breaths, apnea ventilation is normalized.
22.	Audio paused due to key over use	The key is either faulty or has been over used by pressed way to frequently.	1. Acknowledge message by pressing "Alarm reset" key. 2. The alarm function may not be available as long as the fault exists. 3. If the alarm button isn't working anymore, contact a specialized service personnel.
23.	Battery Failure	1. Battery is faulty. 2. Main power supply has failed and there is no internal battery available.	1. Restore main power supply. 2. Make power supply available through external battery and continue ventilation.
24.	Battery Low (Medium Priority)	1. Operating time threshold for the battery may soon elapse. 2. The external battery doesn't have sufficient charge.	1. In case internal battery is being used, switch to main power supply or use and external battery. 2. In case external battery is being used, arrange for a new one or make sure the external battery regains its charge.
25.	Device check failed	1. If the device failed during the pre-ventilator use check, following checks must have been failed: a) Test of acoustic alarm. b) Auxiliary acoustic alarm. c) Expiratory valve d) Safety Valve. 2. Test of breathing circuit failed. 3. Test of humidifier failed. 4. Test of expiratory flow sensor failed.	1. Perform device check under "Failed test steps and remedy" 2. If test of breathing circuit has failed, then connect the breathing circuit and repeat the device check. 3. If the test of humidifier has failed then, connect humidifier and repeat device check. 4. If the test of expiratory flow sensor failed, check whether the device is connected correctly and repeat the device check or just replace the flow sensor.
26.	Expiratory flow measurement failed.	Expiratory valve is faulty.	Replace expiratory valve.
27.	Expiratory flow sensor is faulty.	Test of expiratory flow sensor failed.	Check whether the flow sensor is connected correctly and repeat the device check.

S.No.	Alarm	Cause	Remedy
28.	Expiratory valve is incompatible (High Pressure)	1. Expiratory valve incorrectly connected to the port. 2. Flow sensor is faulty.	1. Insert expiratory valve correctly. 2. Replace the flow sensor.
29.	Flow sensor ventilation impaired (High Pressure)	Flow sensor seated incorrectly in flow sensor sleeve of expiratory valve.	Insert flow sensor correctly

Preventive Maintenance

WARNING:

- AGVA PRO ventilators should only undergo maintenance and repair work by authorized, trained professionals. Ensure appropriate measuring and testing equipment is available for calibration.
- Before maintenance, switch off and disconnect the mains, and clean and disinfect the ventilator. If any error message occurs during the self-test or ventilator quick check, refrain from using AGVA PRO on a patient.
- Immediately take it out of service if performance concerns arise.
- Maintenance and repair must be conducted by trained professionals to avoid hazards to users, patients, or the ventilator.
- Never use a defective AGVA PRO, as malfunctions may directly or indirectly risk the patient's health.
- Regular maintenance includes expiratory circuit calibration, inspiratory circuit calibration, turbine calibration, exhale valve calibration, O_2 calibration, air filter changes every six months or whenever the filter turns black.

WARNING:

Only clean and disinfected AGVA PRO should be returned.

CAUTION:

Do Not Immerse Agva Pro In Water Or Sterilize It In An Autoclave.

Manual Disinfection:

Option 1: Use wipes for disinfecting surfaces.

Step 1: After cleaning, unfold a Wipe and thoroughly wipe the entire surface of the AGVA PRO enclosure.

Ensure that the treated surface remains visibly moist for three minutes.\

If needed, use additional wipes to keep the surface moist for the required three minutes.

Step 2: Wipe the enclosure using a clean lint-free cloth dampened with purified water for one minute.

Step 3: Allow the AGVA PRO enclosure to air-dry

Option 2: 10% bleach (Clorox EPA REG. NO.: 5813-1)

Step 1: Prepare a 10% bleach solution using purified water.

Use a clean lint-free cloth dampened with the bleach solution to wipe the entire AGVA PRO enclosure.

If there is heavy soiling, use additional dampened cloths to remove it.

Ensure that the treated surface remains visibly moist for five minutes.

If necessary, use more dampened cloths to maintain the surface moist for five minutes.

Step 2: Wipe the AGVA PRO enclosure with a clean lint-free cloth dampened with purified water for one minute.

Step 3: Allow the enclosure to air-dry.

Option 3: 5% H2O2, Hydrogen Peroxide (EPA REG. NO.: 335-1)

Step 1: Prepare a 5% H2O2 solution using purified water.

Use a clean lint-free cloth dampened with the H2O2 solution to wipe the entire AGVA PRO enclosure.

If there is heavy soiling, use additional dampened cloths to remove it.

Cleaning AGVA PRO accessories

Ensure that the treated surface remains visibly moist for five minutes.

If needed, use more dampened cloths to maintain the surface moist for five minutes.

Step 2: Wipe the AGVA PRO enclosure with a clean lint-free cloth dampened with purified water for one minute.

Step 3: Allow the enclosure to air-dry.

Following these steps will help ensure the proper cleaning and disinfection of your AGVA PRO equipment. Always refer to the specific guidelines and safety instructions provided by the manufacturer for optimal usage.

Caution:

When using the ventilator, ensure to always use a clean, disinfected patient circuit. The purpose of cleaning the circuits is to eliminate pathogens from the surfaces.

To disassemble the patient circuit, follow these steps:

1. Remove the entire circuit from the ventilator.
2. Take out the exhalation valve and flow sensing kit.
3. Disassemble the circuit to expose all surfaces for cleaning.

Cleaning the Breathing Circuit

Reusable (Single Patients) Circuit

The patient circuit, including 22mm ID breathing tube, exhalation valve, and flow sensing kit (quick connector), should be cleaned and disinfected once weekly during use. When reassembling the patient circuit for patient use, always use a clean, disinfected exhalation valve. Regularly inspect the patient circuit for excessive wear or damage and replace if needed. To maintain the quality of the reusable (single patient) components, do not exceed 20 cleaning cycles or half a year of usage (whichever occurs first).

Disinfecting the Breathing Circuit Components

1. Use a gentle flow of running water or air to clear tubing and passages from organic matter.
2. Immerse in mild detergent or liquid cleanser for at least 10 minutes during bathing.
3. Employ a soft brush to wash all components of the patient circuit.
4. Thoroughly rinse with sterile, distilled water, ensuring all traces of the cleanser are removed.
5. Shake off excess water and place all parts on a clean towel to air dry (avoid using heat or blow dryers).

Soak plastic and metal parts in any of the following solutions:

- One part 5% Acetic Acid (white vinegar) and two parts sterile, distilled water for two hours (for home use only).
- Glutaraldehyde solution (Cidex [2%]) for two hours.

Rinse with sterile, distilled water, removing all traces of the cleanser.

8. Air dry

CAUTION:

The patient circuit from AgVa Healthcare is made of a Polyester Elastomer, a high-temperature material, and includes a silicone rubber cuff. To prevent any damage to the circuit, handle it only by the silicone cuffs when attaching or detaching. Avoid pulling or twisting the circuit. If you are using the AgVa healthcare patient circuit, follow the provided cleaning and disinfecting instructions below. However, if you are using a patient circuit from another manufacturer approved by AgVa Healthcare, refer to the specific manufacturer's cleaning instructions.

Reusable and autoclavable breathing circuit and flow sensor kits

1. Rinse the circuit components with water and air to clear flow sensor tubing and passages of any soil residues.
2. Soak the circuit components in mild detergent for at least 10 minutes.
3. Thoroughly wipe all external surfaces of the test article with a soft cloth moistened with detergent solution to remove any visible soil residues.
4. Rinse the circuit components thoroughly under distilled water for at least 30 seconds to remove all traces of the detergent.
5. Shake off excess water and place all parts on a clean towel to air dry.
6. Sterilize using a validated autoclave procedure at 134°C (273°F).
7. Dry the circuit components by shaking off excess water, and place all parts on a clean towel to air dry.

Cleaning Reusable Dual Limb Exhalation Valve and Diaphragm.

Perform cleaning and disinfection of the Exhalation Valve twice a week during use.

To disassemble the exhalation valve, follow these steps:

1. Remove the exhalation valve from the patient circuit.
2. Rotate the top cap of the exhalation valve counterclockwise and lift it off.
3. Lift out the valve drive line fitting and separate it from the diaphragm.

To disinfect the exhalation valve, follow these steps:

Soak the plastic and metal parts in any of the following solutions:

- **Glutaraldehyde solution (Cidex [2%])** for two hours; Then, rinse with sterile, distilled water.
- Boil distilled water for 15 minutes, ensuring the valve is fully covered. Allow the water to cool and then drain (for home use only).

2. Allow the components to air dry.

Once the exhalation valve is dry, reassemble it following the provided procedure to ensure proper ventilator operation.

To disassemble the exhalation valve, follow these steps:

1. Disconnect the patient circuit.
2. Press the pin and rotate the exhalation valve cover 1/4 turn counterclockwise.

3. Carefully remove the diaphragm by pulling the diaphragm tip.

To clean the dual limb exhalation valve and diaphragm, use the following steps:

1. Wash the dual limb valve and diaphragm with a soft brush using mild detergent (such as liquid soap).
2. Rinse the exhalation valve and diaphragm thoroughly with sterile, distilled water.
3. Shake off excess water, and place them on a clean towel to air dry (do not heat or blow dry).

CAUTION:

Patient circuit and flow sensor kits are supplied non-sterile.

Avoid any contact between patient circuit components and the following solutions, as they may lead to tubing disintegration: Hypochlorite, Phenol (>5%), Inorganic Acids, Formaldehyde, Ketone, Chlorinated Hydrocarbons, and Aromatic Hydrocarbons.

After disinfection, inspect the patient circuits for signs of deterioration. If the circuit is damaged or shows excessive wear, replace it with a new one.

Replacing Air Inlet Particle Filter in AGVA PRO ventilator

To disinfect the dual limb exhalation valve and diaphragm, follow these procedures:

Wipe with an appropriate bacterial agent after each patient use or soak the valve and diaphragm in any of the following solutions:

Boil distilled water for 15 minutes, ensuring the valve is fully covered. Allow the water to cool and then drain (for home use only).

The air inlet particle filter, situated on the right side of the ventilator behind the Filter Cover, acts to prevent dirt and particles from entering the ventilator's piston system. When the filter gets dirty, it may impede the airflow into the ventilator.

Inspect the inlet filter on a weekly basis. Replace it with a new filter once the majority of the filter surface area has transitioned from clean white to dirty brown color.

NOTE

Please note that inlet filters are not designed for reuse

WARNING:

•Always ensure the AGVA PRO Ventilator is equipped with a clean inlet particle filter before operating.

•Never attempt to reverse the inlet particle filter when it becomes dirty.

Maintenance

Component	Interval
O_2	If FiO_2 measurements failed alarm message is displayed or if calibration is no longer possible
HEPA Filter	Every 12 months
Dust Filter Set	Every 4 weeks or every 12 months
Diaphragm of the reusable expiratory valve	Every 12 months
Internal battery	Every 12 months or Every 2 years
Real-time clock	Every 6 years
Turbine	Every 4.5 years

Preventive Maintenance:

To maintain the AGVA PRO Ventilator's optimal performance, follow these steps:

Weekly, inspect the Air Inlet Filter located behind the filter cover. Replace it when the majority of the filter surface area changes from pristine white to a dirty brown tint.

Please note that reusable Air Inlet Filters are not available.

Regularly check the AGVA PRO Ventilator power cord for any signs of damage, such as breakage or fraying.

Ensure there are no cracks or damages on the exhalation valve and flow orifice.

Periodically wipe off the ventilator housing's surface to remove accumulated dust.

If you need assistance, please contact your service provider.

The internal O2 sensor should be replaced annually as recommended. For detailed instructions, consult the Service Manual. If the monitored FiO2 value differs from the set FiO2 by 8 [FiO2%], O2 sensor calibration is necessary and should be conducted by a certified Flight 60 technician.

WARNING:

Under no circumstances should you attempt to reuse the dirty inlet particle filter by reversing it.

NOTE

25,0000 Hour Maintenance

A comprehensive maintenance should be performed after 25,000 hours or 5 years of operation, whichever comes first. The 40,000-hour maintenance includes replacement of the turbine.

Contact your provider or Agva Healthcare for detailed information on the 25,000-hour maintenance.

CAUTION:

Do not try to open or perform any service procedures on the AGVA PRO Ventilator. Only AgVa Healthcare skilled personnel are authorized to service the ventilator. For assistance, please contact AgVa Healthcare or your Home-care Dealer.

WARNING:

1. Preventive maintenance, repairs, or servicing must only be performed by AgVa Healthcare qualified or factory-approved personnel.
2. When handling equipment contaminated with bodily fluids, always adhere to standard hospital practices or physician guidelines.
3. After each patient, carefully clean and disinfect the ventilator and its accessories. Follow approved hospital practices, physician prescriptions, or instructions from the home care dealer to clean and disinfect all external parts and accessories.
4. Be cautious while cleaning and disinfecting the exhalation valve and front panel of the ventilator, as they are made of materials sensitive to certain organic solvents (e.g., phenols, halogen-releasing compounds, and strong organic acids). Exposure to these substances may cause damage that may not be immediately apparent.
5. During operation, regularly disinfect the reusable (single patient) patient circuit, including the exhalation valve, flow sensor kit, and other parts that directly contact the patient.

Disposal

Once the user has determined the medical device is no longer serviceable and desires to dispose of the device, the user shall dispose of the device in such a way that it can no longer be used for its intended purpose according to Directive 2002/96/EC, “on waste electrical and electronic equipment (WEEE)” or as per the local legal regulations. Before disposing of the device, all personal health information / Patient data and other data must be removed or deleted from the device to avoid unauthorized access. In case of any queries contact the manufacturer.

Disposing of the Packaging Material:

Please dispose of the packaging material of the device and the accessories listed in the list of accessories in compliance with the relevant laws and regulations.

Disposal Guidelines

Disposing of the Batteries:

The medical device contains batteries with toxic substances. According to the law on the return and disposal of used batteries, users are required to return batteries containing toxic substances either to the manufacturer/sales outlet or to a collection center operated by public waste disposal corporations. Before disposal of the device, the battery installed in the device must be removed by service personnel. Please adhere to the applicable laws and regulations for battery disposal.

Disposing of the O2 Sensors:

O2 sensors can be returned to AgVa Healthcare.

Disposing of the Device:

The disposal of electrical and electronic devices is subject to special guidelines. Ensure to dispose of this device following the national regulations in place.

WARNING:

1. To ensure device is not unsafely operated after disposal, it should be made inoperable before disposal.
2. The cables that power the device and other electrical connections should be disconnected and removed.
3. Do not dispose of the device (or any parts of it) with industrial or domestic waste.
4. This device contains hazardous materials which require special disposal. Incorrect disposal of any of these materials or parts may lead to serious environmental pollution.
5. Incorrect disposal of data stored on the device may have serious privacy implications.

Specifications

Physical Specifications

The AGVA PRO with cart currently holds the following physical parameters.

Description	Specifications
Ventilator Weight	50 kg
Ventilator Dimensions	153x42x45.4cm
Reusable Single Patient Circuit	Reusable (single patient) 22 mm OD 180 cm. length adult/pediatric circuit with 2.75 mm ID proximal pressure sensing line, 2.75 mm ID exhalation valve control drive line, 2.75 mm I.D. flow sensing line, exhalation valve, flow sensing orifice and quick connector
Single Use Patient Circuit	Single use 22 mm OD 180 cm. length adult/pediatric circuit with 2.75 mm ID proximal pressure sensing line, 2.75 mm ID exhalation valve control drive line, 2.75 mm I.D. flow sensing line, exhalation valve, flow sensing orifice and quick connector.
Connectors	Gas Outlet: ISO 22 mm OD conical. Oxygen Inlet: ISO 30 mm female fitting and DISS connector
Display	24-inch multitouch Screen

NOTE

Please note that all physical specifications of the ventilator are approximate and subject to change without prior notice.

WARNING:

Refrain from using the AGVA PRO Ventilator if it does not pass this procedure.

Electrical Specifications

Voltage	Frequency	Current Consumption
100-240 VAC	50-60 Hz	1.6 Amp MAX
12-15 VDC	NA	8.0 Amp Max

Internal battery specifications

Battery Characteristics	Specification
Detachable Battery	
Battery Type	Li-Ion
Nominal Voltage	14.8 VDC
Nominal Pack Capacity	5.2 AH
Charging Time	3 Hours Maximum

Safety and Particular Standards Specifications

Standard	Standard
IEC 60601-1	Medical electrical equipment general requirements for basic safety and essential performance
IEC 60601-1-2	General requirements for basic safety and essential performance; Collateral standard: electromagnetic compatibility.
IEC 60601-1-8	Parts 1-8: general requirements for safety; Collateral standard: general requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.
ISO 80601-2-12	Particular requirements for the safety of lung ventilators – Critical care ventilators.

Environmental specifications

Condition	Range
Operating Temperature	-10 ºC to 40 ºC
Storage Temperature	-10 ºC to 50 ºC
Operating Pressure	50 KpA to 110 KpA,
Humidity	10% to 95% RH

Low Flow Port Oxygen specifications

Items	Specifications
Connector type	Press Fit
Oxygen Flow	0-80 L/M
Oxygen Pressure	0.5 PSI Max (0.035 Bar)

High Flow Port Oxygen Specifications

Items	Specifications
Connector type	DISS
Oxygen Flow	0-80 L/M
Oxygen Pressure	40-58 PSI Max (2.8 - 4 Bar)

Icons and Insignia

S.No.	Icons or Insignia	Description
1		This button is used to mute/ unmute the alarm. When Alarm is on mute, the alarm icon background will turn yellow and 180-seconds countdown timer will be started.
2		This symbol stands for nebulizer, pushing this button will start nebulization.
3		Pushing this button will provide 100% Oxygen to the patient for a period of 2 minutes only.
4		This b utton provides a hold on inhaling according to the time set by the operator.
5		Pushing this button will assist the patient in manual breathing.
6		Pushing this button will assist the patient in manual breathing
7		Use of the home button will close all the pop-ups and the home screen will reappear.
8		The White power light indicates that the ventilator’s AC power is in.
9		The White LED below the symbol will glow indicating that the battery mode is engaged or indicates the battery is getting charged.
10		This symbol indicates whether the ventilator is switched on or off. The LED below the symbol will glow with white light whilst it is switched on.
11		The knob helps in increasing and decreasing the indicated value. Turning the Knob to the clockwise increases the value while turning the knob to anti clock wise decrease it.