AgVa Healthcare

AGVA PRO

User Manual

Warning:

To properly use this medical device, read an d comply with these instructions for use

Ventilator Software

Version 1.2

Table of Contents

1. Introduction

Greetings and welcome to **AgVa**, a trusted provider of innovative medical solutions. Within the pages of this comprehensive user manual, we are excited to guide you through the seamless process of effectively initiating and navigating the functionalities of your remarkable **AGVA PRO ventilator.** Designed with utmost precision and advanced technology, the AGVA PRO ventilator stands as a beacon of excellence in the realm of medical devices. Our primary goal is to ensure that you, as a valuable user, are equipped with the knowledge and expertise to harness the full spectrum of capabilities this ventilator offers.

At its core, the AGVA PRO ventilator has been meticulously engineered to deliver positive pressure ventilatory support. This support extends not only to adult and pediatric patients, but also offers the remarkable option of catering to the needs of infant and neonatal patients, making it a versatile tool in the hands of skilled medical practitioners. We emphasize that the operation of the AGVA PRO ventilator should be undertaken exclusively by qualified and trained medical personnel. Furthermore, all usage must occur under the vigilant direction of a licensed physician. This dual-layered approach to usage safety underscores our commitment to ensuring the well-being of patients and the facilitators of their care.

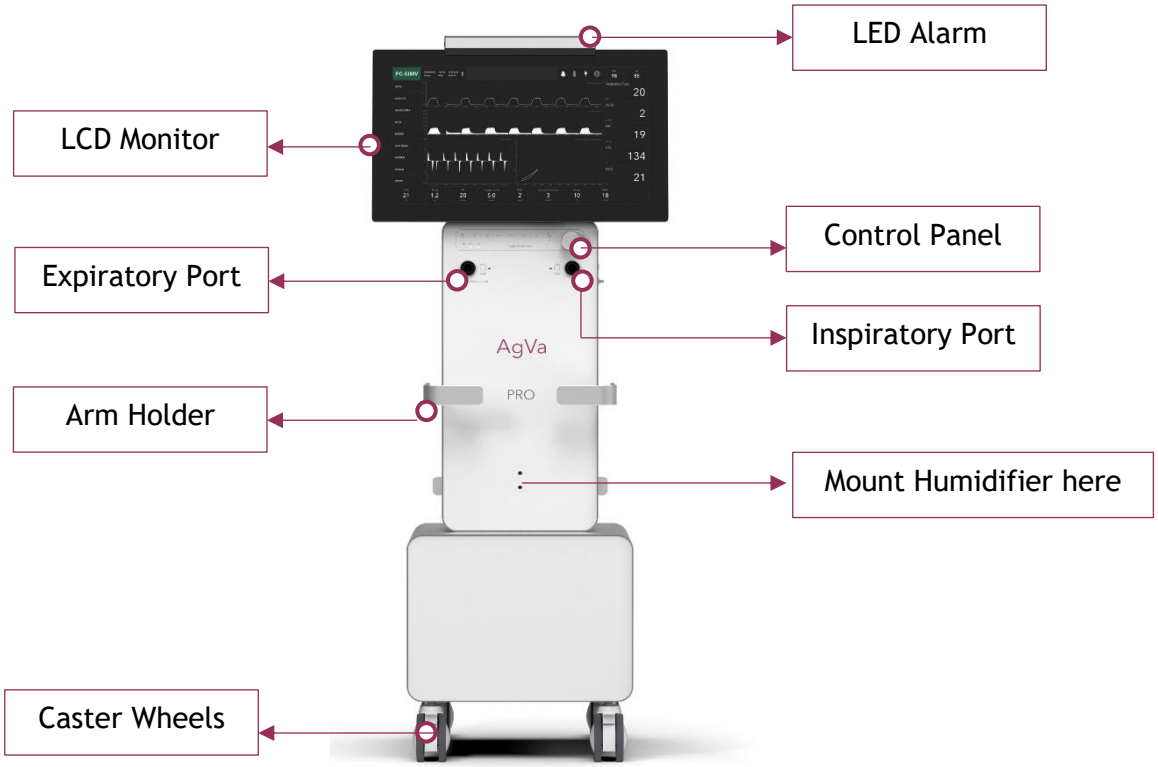
As you journey through this manual, be prepared to embark on a comprehensive exploration of each facet of the AGVA PRO ventilator's operation. From its initial setup to the nuanced adjustments that tailor its performance to individual patient requirements, this manual leaves no stone unturned. Vivid illustrations and step-by-step instructions will serve as your compass, guaranteeing a successful and informed experience.

Once again, we extend our warmest welcome to you, and we trust that your engagement with the AGVA PRO ventilator will be marked by efficacy, comfort, and the highest standards of medical care. Your commitment to enhancing patient outcomes is commendable, and we stand by your side every step of the way as you navigate the realm of advanced ventilatory support.

Warning: Prior to usage, it is important to thoroughly review the instructions for proper use. AgVa should only be utilized by individuals who have received appropriate training.

These instructions for use are specifically intended for the designated ventilator type and software version.

1.1 Device Illustration



1.2 Supported ventilation modes

Environment of use: hospitals, sub-acute care facilities and intra-hospital transfer

When used on neonatal patients: The environment of use is the Neonatal Intensive Care Unit (NICU)

1. **PCV** - Pressure Controlled Ventilation
2. **PC-AC** - Pressure Controlled / Assist Ventilation
3. **PC-CMV** - Pressure Controlled Continuous Mandatory Ventilation
4. **PC-PSV** - Pressure Controlled-Pressure Support Ventilation
5. **PC-SIMV** - Pressure Controlled Synchronized Intermittent Mandatory Ventilation
6. **VC-CMV** - Volume Controlled Continuous Mandatory Ventilation
7. **VC-AC** - Volume Controlled / Assist Ventilation
8. **AI Vent** - Artificial Intelligence Ventilation
9. **NIV**- Non-Invasive Ventilation Mode
10. **BPAP** - Bi-Level Positive Airway Pressure
11. **CPAP** - Continuous Positive Airway Pressure
12. **HFNC** - High Flow Nasal Cannula

1.3 Validity of this user manual

This user manual is applicable to:

1. AGVA PRO
2. AGVA PRO +

1.4 Technical Support

If you encounter any unexpected problem with AGVA PRO, kindly notify your sales representative or contact AgVa Healthcare directly

Contact number: +91-73 30 40 50 60
E-Mail: support@agvahealthcare.com

1.5 Safety Information

Warning
Indicates a potential hazard to life or limb.

Caution
Indicates that a hazard can lead to damaging of AGVA PRO

1.6 Liability

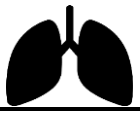
The manufacturer cannot be held responsible for any damages resulting from failure to comply with the instructions in this User Manual. The warranty and liability terms stated in the manufacturer's sales and delivery terms and conditions remain unchanged by the following provisions.
If the device is used in a manner other than its intended purpose, the responsibility for its performance lies with the owner or operator.
Modifications to the device are strictly prohibited.

1.7 General Instructions

This comprehensive manual succinctly outlines the diverse array of functions and safety features meticulously integrated into the AGVA PRO Ventilator System. While it offers valuable insights, it is important to acknowledge that its coverage is not exhaustive, and it **must not be misconstrued as a replacement for proper training.**

1. Prior to initiating any procedures, it is imperative to consistently undertake a meticulous *Pre-check*, an indispensable step that precedes the connection of the ventilator to a patient.
2. In the event that any of the subsequent circumstances materialize, it is imperative to promptly discontinue the usage of the ventilator and promptly seek the assistance of a certified service technician.
3. Unexpected appearance of unfamiliar pop-up windows on the display screen.
4. Persistent and unresolved alarms that resist resolution.
5. Emission of unfamiliar auditory signals or sounds
6. Occurrence of any unprecedented or unexplained events that defy immediate comprehension
7. Maintaining the ventilator in an upright orientation during its operation is of paramount importance to ensure its optimal functionality.
8. Once the ventilator establishes a connection with a patient, it is incumbent upon the user to exercise constant vigilance and refrain from leaving the patient unattended.
9. The presence of a fully equipped resuscitator in close proximity is an essential requisite while the ventilator is linked to a patient, ensuring a swift and effective response to any exigencies.
10. A continuous monitoring of the settings and measurements displayed on the screen is a responsibility that underscores the commitment to the patient's well-being and the ventilator's performance.

1.8 Symbols and Conventions

Symbol/Insignia Illustration	Symbol/Insignia Description
	Nebulizer
	Power Cord Attached
	On Battery
	Charging
	Full Battery
	Neonate
	Patient Trigger
	Standby Button
	Close
	Control setting increment
	Control setting decrement

1.9 Alarm Priorities

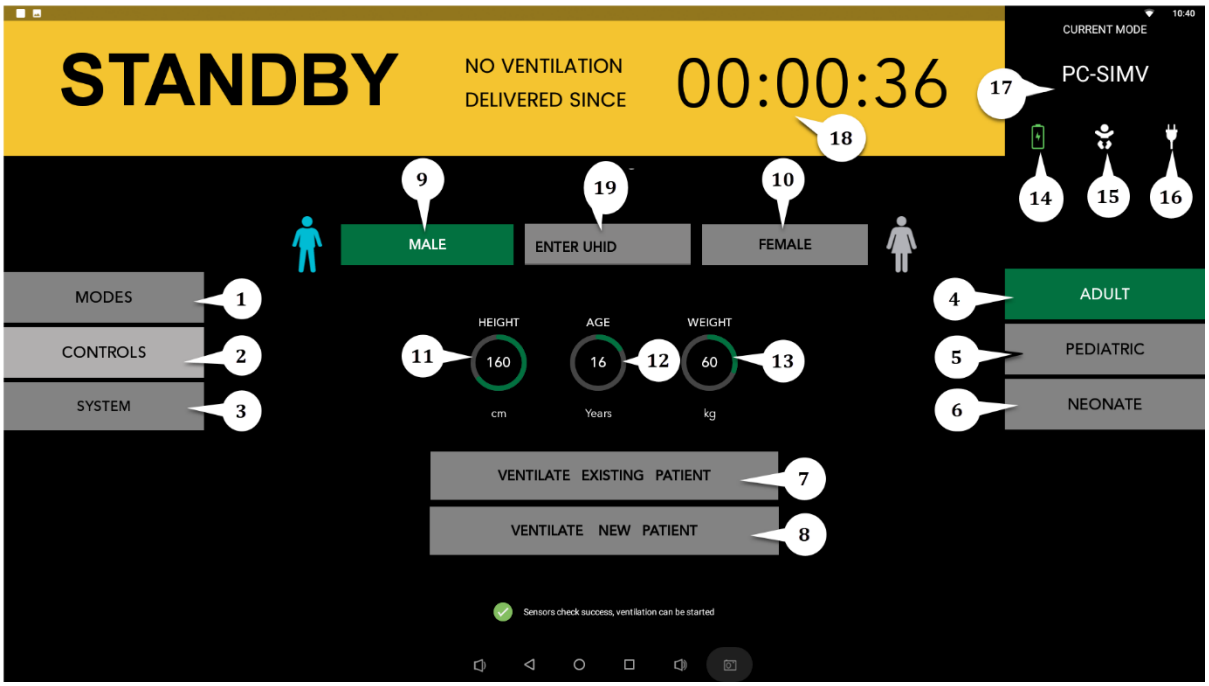
Depending on the urgency of the alarm notifications, AGVA PRO distinguish three priorities.

Symbol	Description
	**High priority:** Urgent response necessary to prevent a situation that could potentially endanger a person's life. The alarm will beep continuously and red alarm lights will flash readily.
	**Moderate priority:** Swift action needed to prevent a potentially life-threatening situation in a timely manner. The alarm will sound intermittently and an amber alarm light will blink and flash continuously.
	**Low priority:** Swift action and attention needed to handle or tackle the situation in a timely manner. The alarm will sound intermittently and an amber alarm light will stay on continuously without blinking

2. System Overview

2.1 User Interface Constituents of the Main Screen

The subsequent sections outline general methods for interacting with the user interface. More comprehensive instructions for particular tasks can be located in subsequent chapters.

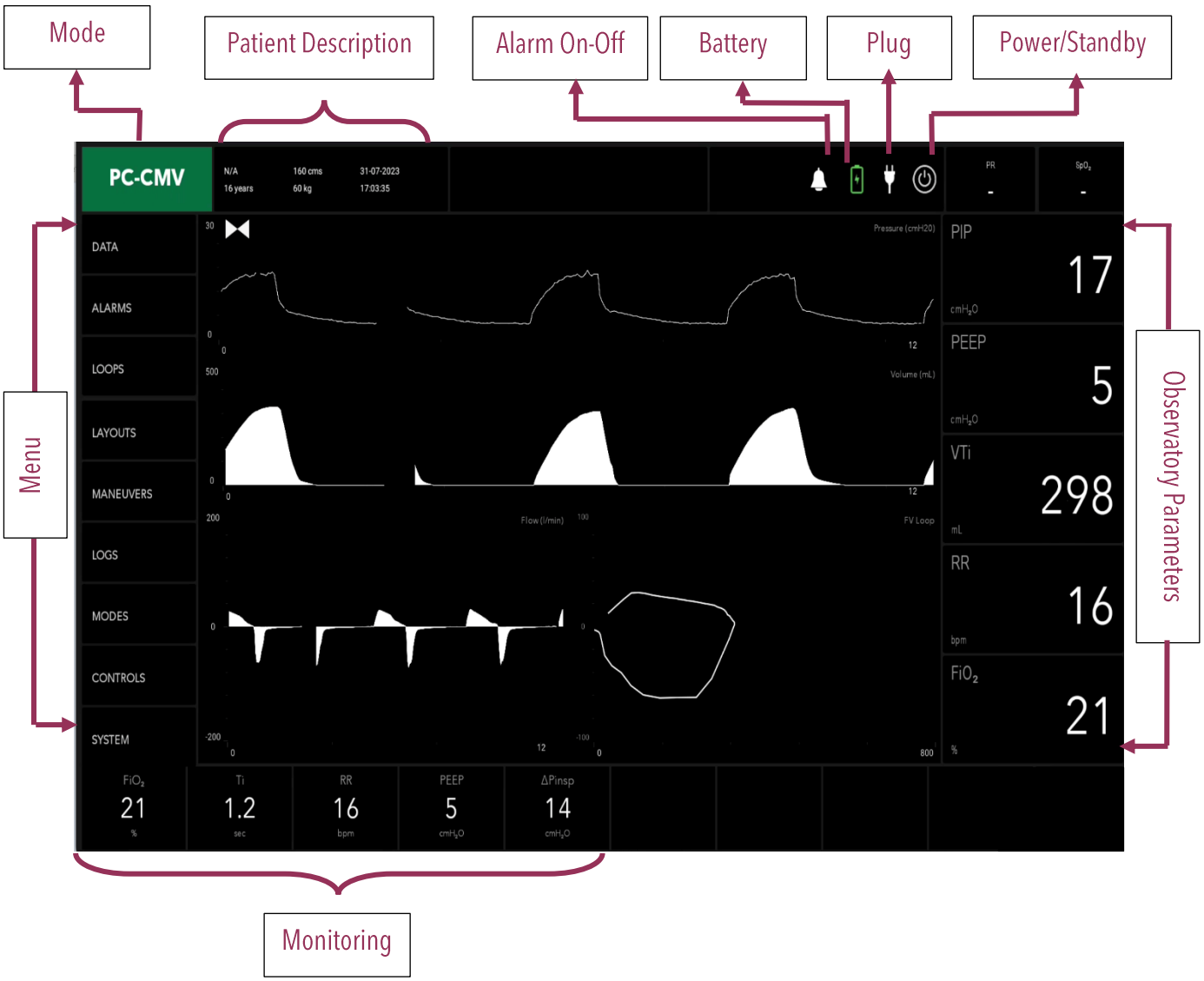


1. **Modes:** Tap on this button to access several modes of ventilation available on AGVA PRO
2. **Controls:** Tap on this button to manipulate and understand different parameters of the current engaged mode.
3. **System:** Tap on this tab to pass the ventilator and it's components through different calibrations tests.
4. **Adult:** Tap on this tab to ventilate an adult patient in the age range: 18 to 100
5. **Pediatric:** Tap on this tab to ventilate a pediatric patient in the age range: 2 to 18
6. **Neonate:** Tap on this tab to ventilate a neonate patient in the age range of: 0 to 2
7. **Ventilate New Patient:** Tap on this tab to ventilate a new patient who has not yet been ventilated on this ventilator.
8. **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.
9. **Male:** Tap on this tab to set the sex of the patient to male. After selection the accompanying icon will turn blue.
10. **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.
11. **Height:** Tap on this circular dial to enter the height of the patient. Once selected, the inner area of the dial will turn yellow.
12. **Age:** Tap on this circular dial to enter the age of the patient. Once selected, the inner area of the dial will turn yellow.
13. **Weight:** Tap on this circular dial to enter the weight of the patient. Once selected, the inner area of the dial will turn yellow.

14. **Neonate:** Indicates whether the neonate mode is engaged or not.
15. **Battery:** Indicates whether the battery is charging or displays the battery level.
16. **On direct power/Off direct Power:** Indicates whether the ventilator is power through the AC cable or not.
17. **Current Mode:** Displays the current selected mode of ventilation.
18. **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
19. **Enter UHID**

2.2 Mode Display User Interface Constituents

Once you start ventilating the patient after dialing in their information



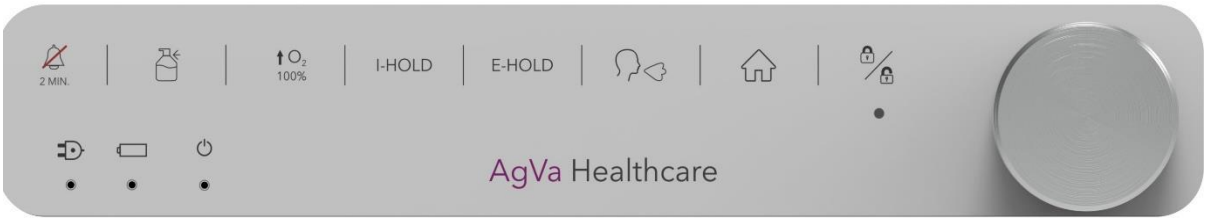
The various options and parameters available on the screen displayed here have been explained in detail in further sections. Here's a brief introduction to them:

1. **Data:** This tab shows the data regarding the various active parameters in the mode selected; eg: percentage leakage, RSBI

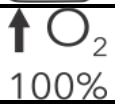
2. **Alarms**: In this tab, three options are available namely; **Basic**, **Advanced** and **Active Alarms**.
3. **Loops:** In this tab**, FP, FV, PV** and **Flow(l/min)** loops will be represented
4. **Layouts:** In this tab, 5 layout styles will be listed to be chosen from.
5. **Maneuvers:** In this tab, two options are presented to you namely, **Hold** and **Nebulizer**.
6. **Logs:** This tab will display **Trends, Events** and **Alarms** of active ventilation mode.

7. **Modes:** This tab displays all the available mode options depending on whether you have selected **Invasive** or **Non-Invasive** ventilation mode.
8. **Controls:** In this tab, various other options are available to yout to choose from. The options and the parameters displayed in each tab shows the parameters of the selected mode.
9. **System:** In this tab, various calibration and tests are provided to be performed before initiating ventilation

3. Control Panel



Illustrated above, is the control panel and below is the description of all the functionalities available on the panel.

S.No.	Button/Label	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 button provides a hold on inhaling according to the time set by the operator.
5.		This button provides a hold on exhaling according to the time set by the operator.
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.

4 Warnings

The subsequent warnings signify a potential danger to one's life and physical well-being.

Warning:

4.1 Introduction

• Carefully read the user manual before using AGVA PRO. Failure to do so may result in product misuse, which may cause equipment damage or patient mistreatment.

• Use AGVA PRO only if you are a trained professional. Untrained users may set up the ventilator inadequately, which can result in patient injury or death.

• Make sure you have the user manual that matches with the ventilator and with the software version to avoid a potential hazard for user, patient, or ventilator.

4.2 Known side effects and risk factors

Consider the risks and contraindications of positive pressure ventilation with AGVA PRO. Failure to do so may result in serious injury or death of the patient.

• Complications of airway intubation

• Complications of positive pressure ventilation

• Baro- or volutrauma

• Cardiovascular complications

• Patient-ventilator asynchrony

• Adverse effects of sedation and paralysis

• Oxygen toxicity influencing processes of peripheral and cerebral control of breathing and can cause respiratory pauses and have toxic effects on lung tissue and retinopathy, retinal detachment for neonates.

• Other complications specific to diseases.

Warning:

4.3 Installation and environmental conditions

• Avoid obstructing or covering the air intakes of the ventilator. This could result in inadequate patient ventilation and overheating of the device.

• Take precautions to prevent liquids from entering the AGVA PRO housing. Do not place liquid-filled containers or other objects on top of the ventilator.

• Ensure that the power cord is kept away from the patient to prevent any risk of strangulation.

• When using oxygen, ensure that the room is well-ventilated and avoid using AGVA PRO in environments with high oxygen levels. Elevated ambient oxygen concentrations can pose a fire hazard or lead to insufficient oxygen supply for the patient.

• Do not operate AGVA PRO near flammable substances or open flames, as oxygen can increase their flammability.

• Avoid using AGVA PRO in the following environments, as it may result in serious malfunctions:

- Temperature, pressure, and humidity conditions outside the specified ambient range ("Ambient Conditions").
- Proximity to known sources of electromagnetic interference (EMI) with medical devices, such as magnetic resonance imaging (MRI) systems, diathermy, electrocautery, radio frequency identification (RFID), and electromagnetic security systems like metal detectors. Note that the presence of RFID devices may not be readily apparent.
- Close proximity to equipment emitting diagnostic or therapeutic acoustic pressure.
- Close proximity to equipment emitting therapeutic radiation.
- Hyperbaric chambers.

Warning:

4.4 Gas supply

- Use medical oxygen only
- Exclusively utilize medical oxygen with AGVA PRO. Avoid using other gases such as air, anesthetic gases, nitrogen oxide, helium, or Heliox, as AGVA PRO is not designed for their usage. The use of these gases may pose significant risks to the patient or user.
- Utilize the oxygen monitoring and alarm features of AGVA PRO to ensure a sufficient oxygen supply for the patient and prevent any shortages.
- In the event of an oxygen leak, promptly shut off the oxygen source to eliminate the risk of fire hazards or inadequate oxygen supply to the patient.

4.5 Infection control, cleaning, and sterilization

- In order to mitigate the risk of cross-contamination, adhere to the manufacturer's guidelines and use a new breathing circuit and expiration valve before each new patient when using AGVA PRO.
- To minimize the risk of infection, utilize a new bacterial filter on the inspiratory patient connector in accordance with the manufacturer's recommendations before each new patient.
- Properly dispose of used breathing circuits, bacterial filters, and expiration valves in accordance with the regulations set by the local hospital.
- Following each use, AGVA PRO must be thoroughly cleaned and disinfected.
- Please be aware that the exhaled air from the patient may be contaminated. If necessary, utilize an expiratory filter.

Warning:

4.6 Accessories, combination with other devices

- Use AGVA PRO solely with accessories, replacement parts, and breathing circuits that are either approved by the manufacturer or meet the specifications for compatible accessories (refer to "Accessories").
- The use of unapproved or non-compliant parts may compromise the proper functioning of AGVA PRO, diminish ventilation performance, and pose risks to the safety of the patient and/or user.
- To prevent electric shocks to the patient and/or user, avoid using anti-static or electrically conductive breathing circuits or lines.
- Follow the instructions provided by the accessories manufacturer (e.g., humidifier) to ensure patient safety and prevent any potential damage to AGVA PRO.
- Position the humidifier at a lower level than AGVA PRO and the patient to prevent water aspiration or flooding of the device.

4.7 Maintenance and repair

- Prior to any repair
- Shut down and unplug AGVA PRO
- Clean and disinfect AGVA PRO
- Cease the use of AGVA PRO immediately if there are concerns about its performance or behavior or if an error message is displayed during self-test or the ventilator check.
- Maintenance and repair should only be carried out by trained professionals to prevent potential risks to users, patients, or the ventilator.
- Do not use a defective AGVA PRO as malfunctions can directly or indirectly endanger the patient's health. Arrange for prompt repair of any defects.

4.8 Regular maintenance tasks:

- Calibrate the FiO2 sensor as required. An uncalibrated O2 sensor can result in measurement errors and inadequate alarms.
- Replace the intake air filter every month. A dirty, incorrect, or missing air intake filter can lead to insufficient ventilation of the patient, overheating of the ventilator, or contamination.
- Perform a comprehensive annual maintenance every 12 months.

4.8 MRI Safety Information

The ventilation system is not safe for use in the MRI environment. Please ensure it remains outside the MRI scan room as it poses a risk of becoming a projectile

5. Cautions

Caution: Indicates hazards that can lead to damage of AGVA PRO

Caution:

5.1 Touch-screen operation

• Only use the tip of your finger to operate the touch screen, as sharp objects can cause damage.

5.2 Indication of potential errors

• Please report any observations of potential errors or ambiguities in AGVA PRO or its accompanying documentation to AgVa.

• The treating physician bears full responsibility for patient safety, and their judgment supersedes the instructions provided in this user manual.

5.3 Start-up

• Use a power cord that is no longer than 3 m (9 ft).

• Avoid using a defective power cord.

• Ensure the power cord is grounded and in good condition; otherwise, operate AGVA PRO in battery mode.

• Do not utilize extension cords or double plugs/adapters.

5.4 Installation and environmental conditions

• Operate AGVA PRO in an upright position and secure it to prevent damage.

• Note that AGVA PRO is not designed for use as an ambulance transport device; handle it with care when moving.

• Avoid blocking or covering the ventilator's air intakes to ensure proper patient ventilation and prevent overheating.

• Keep liquids away from the AGVA PRO housing and avoid placing liquid-filled containers or objects on top of it.

• Ensure the power cord is kept away from the patient to prevent strangulation hazards.

Caution:

Avoid using AGVA PRO in the following environments, as it may lead to serious malfunctions:

- Outside the specified ambient conditions of temperature, pressure, and humidity.
- In the presence of known sources of electromagnetic interference (EMI) with medical devices, such as magnetic resonance imaging (MRI) systems, diathermy, electrocautery, Radio Frequency Identification (RFID), and electromagnetic security systems like metal detectors. Note that the presence of RFID devices may not be obvious. Refer to the "Appendix/Manufacturer's EMC declaration" for detailed information on electromagnetic compliance (EMC).
- In close proximity to equipment emitting diagnostic or therapeutic acoustic pressure.
- In the vicinity of equipment emitting therapeutic radiation.

5.5 Attaching oxygen

- • Ensure you use clean and undamaged oxygen tubing. Connect the oxygen cylinder first and then slowly open the valve of the oxygen cylinder.

5.6 Battery operation

- • Regularly monitor the remaining battery life, especially after making changes to the settings. If AGVA PRO has been stored for at least 6 months, connect it to mains power for 4 hours to recharge the battery before using it.

5.7 Transportation

- • AGVA PRO is a medical device and should be handled with care during transportation. Keep the original packaging in a dry location.

6. Important safety Instructions

6.1 Liability

The operator refers to the facility that assumes responsibility for operating the AGVA PRO medical device after its purchase.

The manufacturer cannot be held liable for any damages resulting from non-compliance with this User Manual. The warranty and liability terms specified in the manufacturer's sales and delivery conditions remain unaffected by the following provisions.

6.2 Introduction

If the device is used contrary to its intended purpose, the owner or operator assumes full liability for AGVA PRO's performance.

Modifications to the device are strictly prohibited.

Please carefully read through the User Manual before operating AGVA PRO. This User Manual is applicable only to specific device types and software versions stated on the initial pages.

Always keep this User Manual easily accessible near AGVA PRO..

6.3 Training Documentation

This User Manual serves as introductory documentation for teaching the primary user control functions and cannot be used as replacement for training.

Notes and measures with which operation of AGVA PRO can be made easier and more efficient.

6.4 Staff Qualification

AGVA PRO is intended to be operated by qualified medical and technical personnel. After suitable training, individuals without medical qualifications, such as patients and nursing staff, may operate the patient cockpit.

If AGVA PRO is improperly serviced or repaired by unauthorized individuals, the owner or operator assumes liability for its performance as per the manufacturer's instructions.

6.5 How to operate AGVA PRO safely

AGVA PRO is intended to be operated by qualified medical and technical personnel. After suitable training, individuals without medical qualifications, such as patients and nursing staff, may operate the patient cockpit.

If AGVA PRO is improperly serviced or repaired by unauthorized individuals, the owner or operator assumes liability for its performance as per the manufacturer's instructions.

6.6 Correct User Manual

To prevent any risks to the user, patient, or device, ensure that you have the appropriate User Manual corresponding to the specific device and software.

6.7 Use of a functional AGVA PRO

The use of a defective AGVA PRO may directly or indirectly jeopardize the patient's health. Therefore, always verify the proper functioning of AGVA PRO before putting it into operation. If any defects are found, promptly arrange for repairs.

For external power connection, ensure that only hospital-grade receptacles are used to maintain proper grounding. Prior to servicing, ensure the external power supply is switched off. When used in the presence of flammable anesthetics, there is a risk of explosion.

1. Adjust all breathing mode settings and modifications in accordance with a physician's approved therapy.
2. Avoid using patient circuits that conduct electricity.
3. Always use a sterilized and clean patient circuit.
4. Install an outlet filter or similar device at the Airway Pressure Connector to protect the internal transducers from moisture and impurities.
5. When utilizing the AGVA PRO Ventilator on a patient, employ suitable monitoring methods to ensure sufficient oxygenation and ventilation, such as a pulse oximeter and/or capnograph.
6. Failure to identify and rectify alarm violations could result in harm to the patient.
7. If a fault in the ventilator is discovered and doubts arise regarding its life support functions, discontinue use immediately and switch to an alternative ventilation method until the issue is resolved. Additionally, contact your provider or AgVa Healthcare promptly.
8. The AGVA PRO Ventilator is ready for use only when it is fully assembled. The Quick Check Procedure, including the calibration of the exhalation valve, must be performed successfully. Qualified medical professionals should be present at all times during ventilation using the AGVA PRO Ventilator.
9. The capacity of Li-Ion batteries to hold a charge diminishes over time with repeated charging and discharging, potentially reducing the ventilator's battery runtime.

6.8 Prior to using the ventilator make sure of the following

1. Replace the batteries when they no longer meet the user's requirements, which can be determined based on various factors including settings and usage patterns.
2 Prior to using the AGVA PRO Ventilator for transportation purposes, ensure that the internal batteries are fully charged.
3 Charge the batteries for a minimum of three hours before using them to power the ventilator to ensure a full charge.
4 Charge the batteries for at least three hours every 30 days during storage to maintain their full charge.
5 To optimize battery performance, always connect the AGVA PRO Ventilator to an AC power supply when not in use.
6 The HEPA filter located on the left side of the ventilator may experience increased flow resistance with repeated use. Ensure regular replacement of the filter.
7 The AGVA PRO Ventilator is only compatible with breathing circuits approved by AgVa Healthcare.
8 When using a breathing circuit for neonatal ventilation, ensure that it is specifically designed for neonates.; consider using a neonatal Flow Sensor with neonatal patient circuit to minimize dead-space.
9 The AGVA PRO Ventilator should only be used with an authorized exhalation valve from AgVa Healthcare.

11. Perform exhalation valve calibration when fitting a circuit/exhalation valve.
12. Dispose off the disposable breathing circuit and exhalation valve (single-use) responsibly to avoid the risk of cross-contamination. Do not clean, disinfect, or sterilize the circuit or exhalation valve for reuse.

6.9 Incompatibilities

1. Complications with airway intubation
2. Complications from positive pressure ventilation
3. Baro- or Volutrauma
4. Oxygen toxicity
5. Cardiovascular complications
6. Breathing effort and patient-respirator asynchrony
7. Adverse effects of sedation and paralysis.
8. Effectively monitor the patient.
9. Other disease-related complications

6.10 Note about Potential Errors

If you have any doubts or reservations regarding the functioning or behavior of AGVA PRO, it is crucial to promptly remove it from service. Please report any observations you have concerning potential errors or ambiguities in AGVAPRO or its accompanying documentation. The attending physician or nursing staff hold the responsibility for the safety of the ventilated patient, and their judgment supersedes the information provided in this User Manual. Always ensure that suitable measures are in place to.

6.11 Startup

To minimize the risk of electrical hazards, it is essential to use cables with proper grounding.

Please avoid:

- Power cord sets exceeding 3m in length.
- Faulty power cord sets.
- Power cord sets lacking grounding.
- Extension cables.
- Double plugs or adapters.

Ensure the power cord set is positioned away from the patient to prevent any possibility of strangulation. Additionally, maintain convenient access to the power supply for quick disconnection from the mains if required.

In the event of ventilator malfunction, the absence of an alternative ventilation method, such as a self-priming, user-operated resuscitator equipped with a breathing mask (ventilation bag as specified in ISO 10651-4), can lead to fatal consequences for the patient.

If there are any concerns about the condition or configuration of the grounded cable, it is advisable to operate AGVA PRO solely in battery mode.

To ensure reliable grounding, connect the device to a socket specifically designated for medical equipment use.

Prevent the obstruction of the expiratory valve.

Using a bacterial filter that is either omitted or incorrect can lead to pathogen transmission to the patient and contamination of AGVA PRO.

Follow the manufacturer's instructions to change the bacterial filter before each new patient. Dispose of used filters as medical waste.

To avoid electric shocks to the patient and/or user, do not use antistatic or electrically conductive tubes or lines.

The inclusion of additional accessories in the breathing circuit can significantly increase flow resistance or dead space volume, negatively affecting ventilation performance

6.11.1 Installation and ambient conditions

Adhere to the humidifier manufacturer's instructions to prevent hazards to the patient and damage to AGVA PRO. Position the humidifier at a lower level than AGVA PRO and the patient to prevent water aspiration and flooding of AGVA PRO. During non-invasive ventilation, significant variations in volume and capnography values during expiration can occur due to leakage.

The power installations for AGVA PRO must be properly grounded and adhere to the relevant standards.

Use oxygen exclusively in well-ventilated rooms, avoiding any hazardous areas or proximity to combustible materials or gases. AGVA PRO batteries and accessories should not be operated in explosive environments or near combustible materials or gases.

AGVA PRO must not be utilized for combustible mixtures of anesthetic gases or anesthetic agents with air, oxygen, and/or nitrous oxide.

Avoid operating AGVA PRO in areas prone to splashing, such as near bathtubs or showers, or in the vicinity of an open flame, such as a candle.

Ensure that AGVA PRO is not covered and that the openings for suctioning patient air or the device fan are not blocked, as this may lead to overheating and inadequate air supply to the patient.

Do not place liquid-filled containers or other objects on top of AGVA PRO.

To prevent the accidental excessive supply of oxygen to the patient, avoid using AGVA PRO near free-flowing oxygen sources.

Position AGVA PRO in an upright position to prevent tipping.

AGVA PRO has undergone testing for electromagnetic interference according to the EN 60601-1-2 standard. Operation of AGVA PRO may be affected by electromagnetic interference; therefore, it should not be operated near magnetic resonance imaging scanners, mobile phones, or any other potentially disruptive devices or systems.

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Connecting AC Power Cable

First step to get AGVA PRO up and running

1

This is where you need to plug in the AC power cable.

2

Now, the AC power cable is plugged in.

Notice the metal clip above the able?

3

Pull the clip down to secure the power cable so that the cable doesn't get plugged out due to accident.

Connecting High Pressure Oxygen Pipe

Make sure that the connector used with the pipe is DISS connector of 12 mm diameter

1

This is where you need to plug in the high pressure oxygen pipe having 12 mm DISS connector.

Note that the pressure allowed for use is 40 to 58 PSI maximum (2.8 to 4 bar)

2

Now, the high pressure oxygen pipe is connected. Make sure to secure it by tightening the connector.

Connecting Low Pressure Oxygen Pipe

The connector and the port is of male-female fit configuration in this case

1

This is where you need to plug in the low pressure oxygen pipe.

Note that the pressure allowed for use is 0.5 PSI maximum (0.035 bar) with a capacity of oxygen flow range from 0 to 80 LPM.

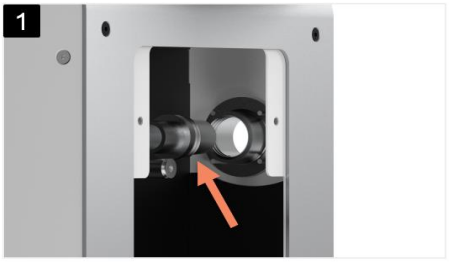
2

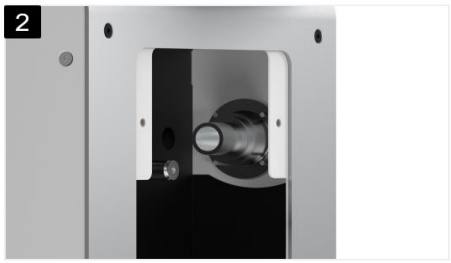
Now, the low pressure oxygen pipe is connected.

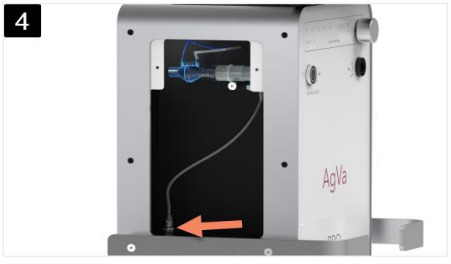
Breathing Circuit Installation

1. Attach the inspiratory breathing tube in the inspiratory port
2. This round object is Viral/bacterial filter. Attach it to the expiratory port.
3. The Viral/bacterial filter is now attached and attached and will help filtering out the contaminants
4. Attach the expiratory tube to the expiratory port throught the viral?bacterial filter.
5. The breathing circuit is now installed

Exhale Valve with Flow Sensor Installation





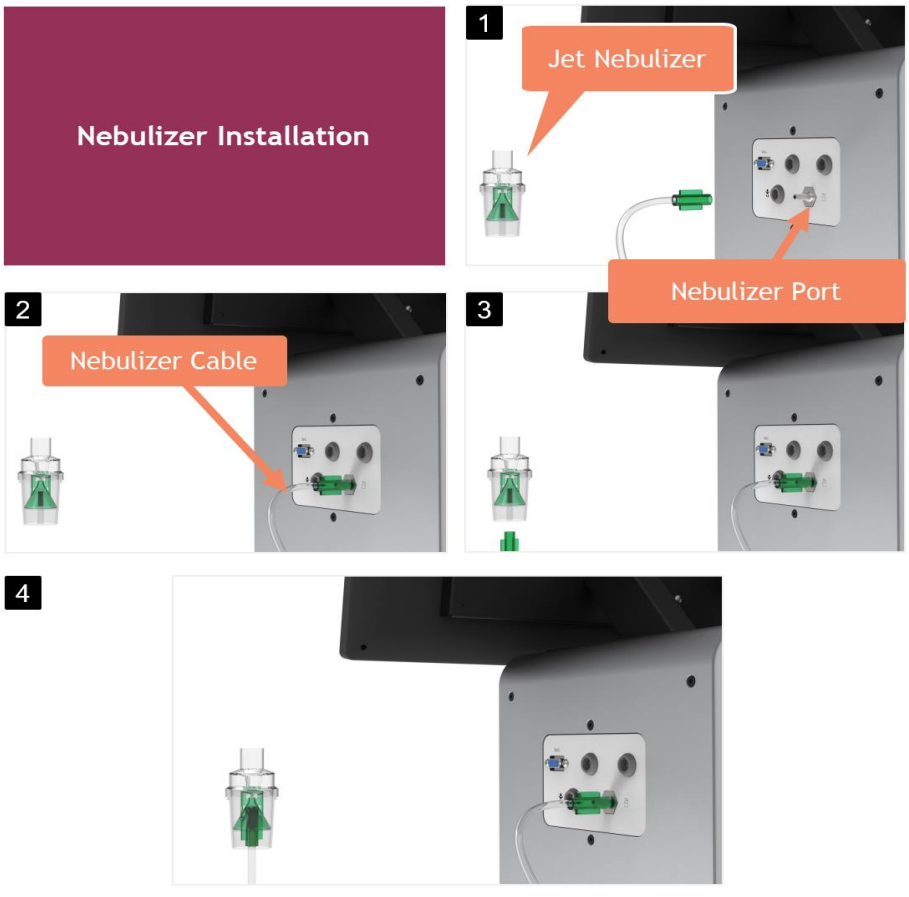


1. The object is a 22 mm connector for the exhale valve
2. Fix the connector at the slot.
3. The is the exhale valve and the blue part is the attached flow sensor
4. Now, fix the flow sensor attached with the exhale valve to the connector slot
5. Attach the connecting wire of the exhale valve here.

Humidifier Installation

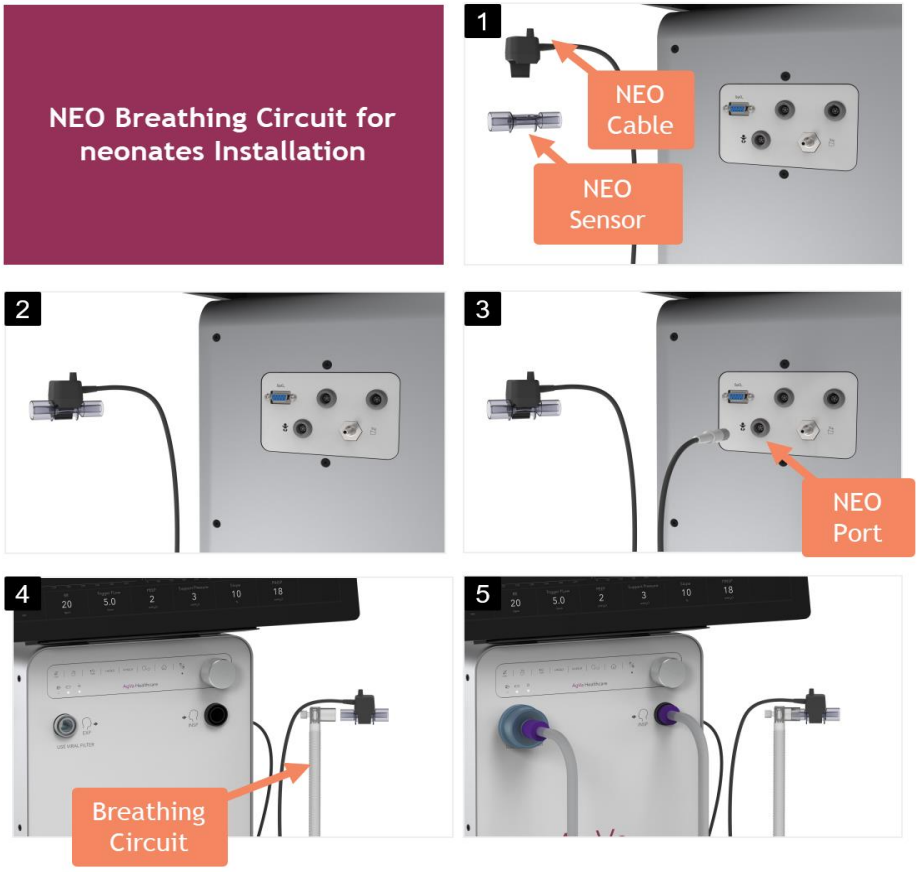
1. The marked area is the notch where the humidifier will be mounted
2. This object is the humidifier, take it and mount it over the notch.
3. Once over the notch, slide it down to fit it on the ventilator
4. The humidifier is now fit on the ventilator
5. Connect the humidifier with the breathing circuit of the ventilator using the Y piece and then route it to the patient through the output.

Nebulizer Installation



1. Connect the Nebulizer cable to the nebulizer port
2. The nebulizer cable is now attached to the nebuliser port
3. Insert the free end of the nebulizer cable into jet nebulizer.
4. Now, the nebuliser circuit is complete

NEO Breathing Circuit for neonates Installation



1. The NEO cable needs to be connected with the NEO sensor
2. NEO Cable and NEO sensor are now connected.
3. Now attach the other end of the NEO cable to the NEO port
4. Now, attach the NEO breathing circuit tube to the NEO sensor.
5. Now attach the expiratory tube and inspiratory tube to thier respective ports. Now the NEO breathing circuit for neonate patients is complete.

Caution

It is the operator's responsibility to ensure that AGVA PRO is solely operated with approved accessories. The use of non-approved accessories or cables can have several detrimental effects, including compromising the safety of the patient and/or user, hindering the proper functioning of AGVA PRO, diminishing performance, undermining EMC protection, and resulting in non-compliance with legal regulations.

Refrain from reusing single-use accessories, as doing so can have adverse effects on sterility, functionality, and overall performance. Additionally, avoid using antistatic breathing circuits.

Ensure the use of clean and intact oxygen tubing. Open the flow valve of the oxygen cylinder gradually and only after connecting it to AGVA PRO. Any oxygen leakage in the O2 supply or within AGVA PRO can pose a fire hazard or result in inadequate oxygen supply to the patient.

Regularly inspect the system for any leaks. If a leak is detected, immediately turn off the oxygen source. Oxygen should only be used in well-ventilated rooms to ensure proper air circulation.

Warning

Use only medical oxygen. Do not connect nitrogen oxide, helium, heliox, or any other gases. To ensure appropriate oxygen supply and avoid insufficient or excessive oxygen levels, utilize the AGVA PRO oxygen monitoring system and alarm options. It is crucial to be aware that the use of oxygen can result in severe complications, including disruptions to peripheral and cerebral respiratory control, leading to respiratory pauses.

Ensure the use of clean and intact oxygen tubing. Open the flow valve of the oxygen cylinder gradually and only after connecting it to AGVA PRO. Any oxygen leakage in the O2 supply or within AGVA PRO can pose a fire hazard or result in inadequate oxygen supply to the patient.

Regularly inspect the system for any leaks. If a leak is detected, immediately turn off the oxygen source. Oxygen should only be used in well-ventilated rooms to ensure proper air circulation.

6.11.2 Nebulization

Avoid using a nebulizer simultaneously with the capnography sensor to prevent inaccurate measurements. During nebulization, refrain from using expiratory or HME filters.

If a nebulizer is installed between the Y-piece (or expiratory valve) and the patient, it increases dead space ventilation. Only utilize nebulization with medicinal products approved specifically for nebulization.

Regularly check, clean, or replace the expiratory valve, as nebulization can affect its performance. Additionally, note that nebulization impacts the administered oxygen concentration.

6.11.3 External sensors (SpO2 and CO2)

Only use the sensor in combination with other methods when monitoring a patient's vital functions. Utilize the sensor on a patient only if you possess the necessary expertise. Always consider the dead space volume of the capnography airway adapter.

6.11.4 Communication interface

The data provided through a network or data sharing system is intended for reference purposes only. Clinical decisions regarding patient treatment should be based on direct patient observation and made by the clinician.

Ensure that only recommended connecting cables are used. The devices being connected must be approved medical devices that comply with EN 60601-1 standards.

Connecting AGVA PRO to a network or data sharing system that includes other devices can introduce unforeseen risks to the patient, user, or third parties.

Certain changes made to the network or data sharing system can result in risks and necessitate additional analysis. Such changes may include:

- Modifications to the configuration
- Addition of supplementary elements
- AGVA PRO should be equipped with a monitoring device for measuring expiratory carbon dioxide concentration, as per ISO 80601-2-55, before startup. This monitoring device can be placed in the expiratory section of the breathing circuit or at the patient port. In accordance with EN/ISO 80601-2-12, AGVA

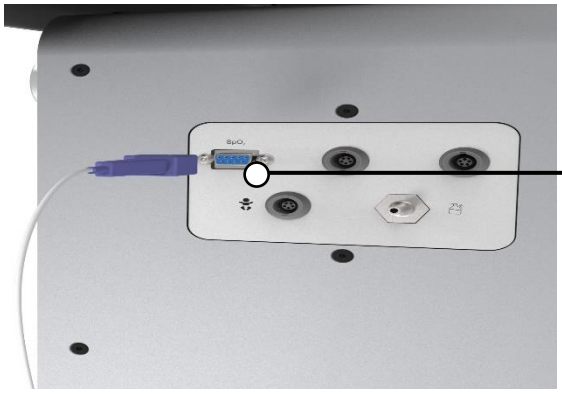
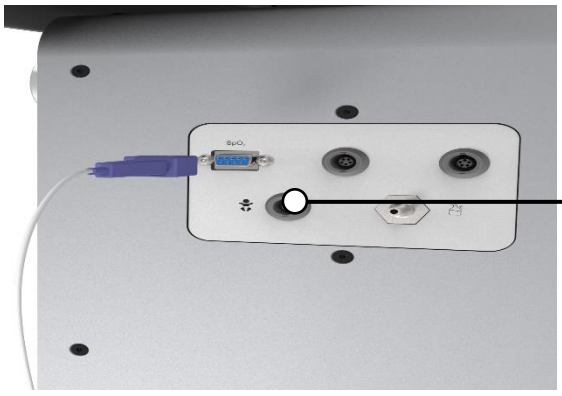
7. Description of Components

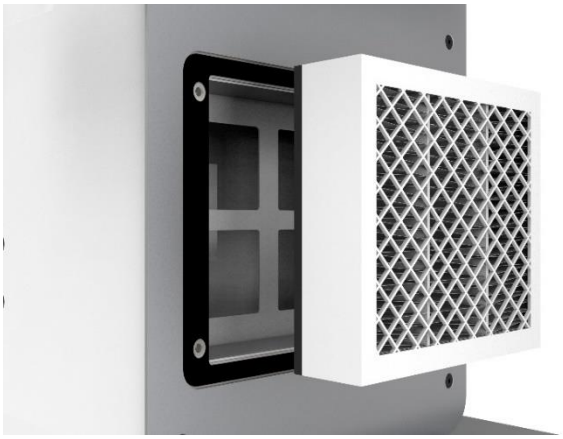
Before proceeding with the installation of AGVA PRO ventilator, carefully review the instructions provided in this section. It is vital to adhere to all specified instructions to ensure safe operation. Combine the information in this section with relevant hospital protocols and instructions from your home-care distributor.

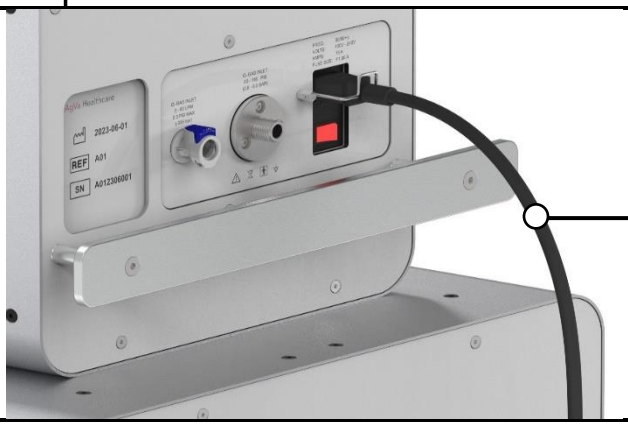
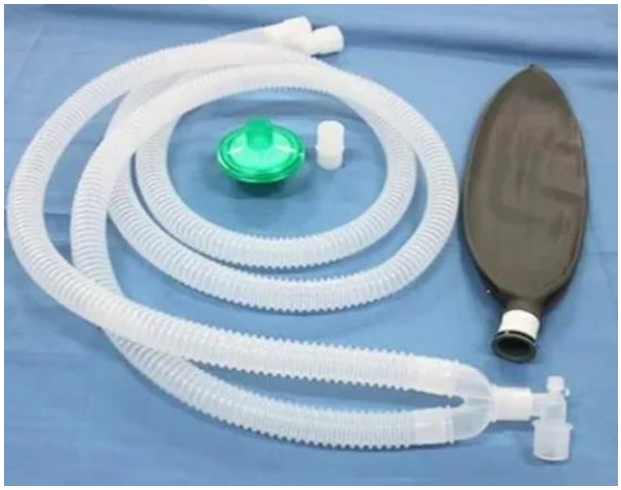
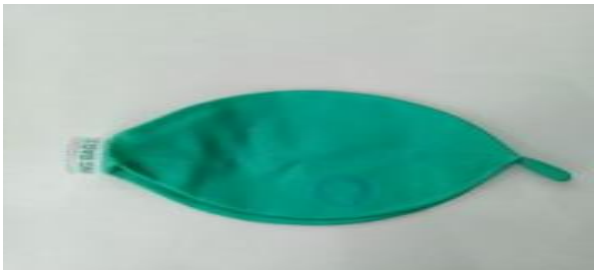
7.1 Removing the ventilator parts from the box:

Familiarize yourself with the different components before installing the ventilator. Unpack all items from the delivery box and carefully inspect each part and component for completeness and any shipping damage .

S.No.	Component Illustration	Component Description
1.		AGVA PRO Ventilator
2.		24 Inch Display
3.		Arm Holder

S.No.	Component Illustration	Component Description
4.		SpO_2 Port
5.		High pressure oxygen pipe DISS connector (12 mm)
6.		Neonate Sensor Port

S.No.	Component Illustration	Component Description
7.		Expiratory Port
8.		Respiratory Humidifier
9.		HEPA filter

S.No.	Component Illustration	Component Description
10.		Power Cable
11.		Breathing Circuit
12.		Calibration Tube
13.		Breathing Bag

S.No.	Component Illustration	Component Description
14.		AC Power Cord
15.		High Pressure Oxygen pipe with DISS connector(22mm)

8. Installation and Initial Tests

Important Information:

- The ventilator installation should be performed by properly trained personnel.
- Do not pen the box without an AgVa Healthcare representative present
- Filling up the Dispatch Check sheet is mandatory.

8.1 Mounting the ventilator:

Follow the instructions provided in the User Manual to mount all accessories on the AGVA PRO Ventilator.

The service engineer from AgVa Healthcare will complete the General Checklist of AgVa inspection report.

The service engineer will test the machine and fill out the "User evaluation of ventilator Checklist," including the following tests:

1. Pressure check and calibration
2. Starting the ventilator
3. Screen size and display
4. Graphics and numerical display
5. Breathing circuit assembly
6. Mode selection
7. Ventilator setup
8. Initiating ventilation
9. Standby mode
10. Major and minor alarms
11. NIV mode
12. Weaning mode
13. Set vs Measured parameter
14. FIO2 control
15. Battery backup
16. Range of use

After completing all the tests, the service engineer will fill and verify the "Installation Verification Report."

8. 2 Plugging in the power cord (for AC):

1. Connect the AGVA PRO ventilator's power socket to an AC power cord supplying power between 100 and 240 V AC, 50/60 Hz.
2. Always ensure the reliability of the AC outlet. When connected to AC power, the AC symbol in the bottom right-hand corner of the screen will have a frame around it.
3. The ventilator will charge the battery whenever it is connected to the power supply.
4. The battery charge indicator lights will show that the battery is being charged. The power source symbols in the bottom right-hand corner of the screen will indicate the available power sources.
5. A frame around a symbol indicates the current power source for the ventilator.
6. The color green indicates the level of battery charge.

8.3 Attaching the breathing circuit:

The following steps explain how to connect a patient circuit to the ventilator:

1. Connect the breathing hoses to the inspiratory port and the expiratory port.
2. Connect the inspiratory port to the respiratory humidifier using the breathing hoses.
3. Connect the respiratory humidifier to the water trap through breathing hoses.
4. Connect the water trap to the test lung through breathing hoses.
5. Connect the expiratory port to the water trap through breathing hoses.
6. Connect the water trap to the test lung through breathing hoses.

8.4 Breathing Circuit Test:

The breathing circuit check should be performed after the following actions:

1. Replacement of the breathing circuit
2. Replacement of the breathing gas humidifier

The following test steps are performed:

1. Leakage of the breathing circuit
2. Compliance of the breathing circuit
3. Tube resistance

8.5 Preparing the breathing circuit check:

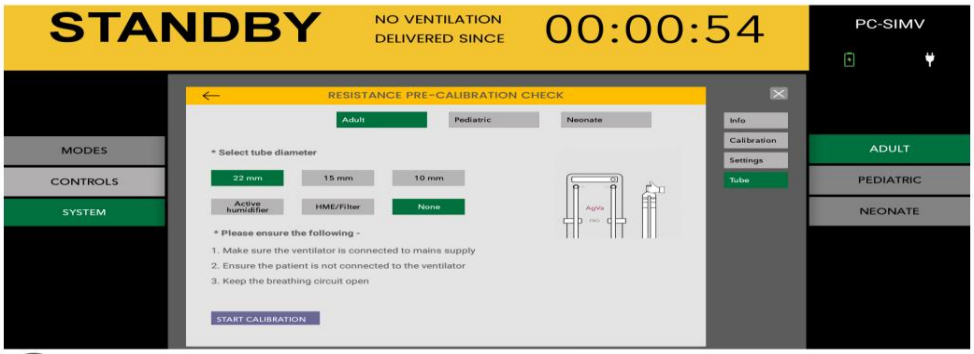
Prerequisite: AGVA PRO Ventilator is prepared and in standby mode.

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

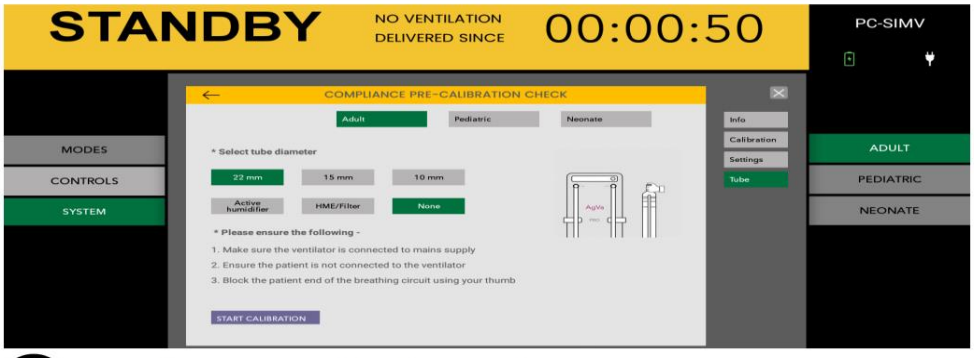
8.6 Starting the breathing circuit check:

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.

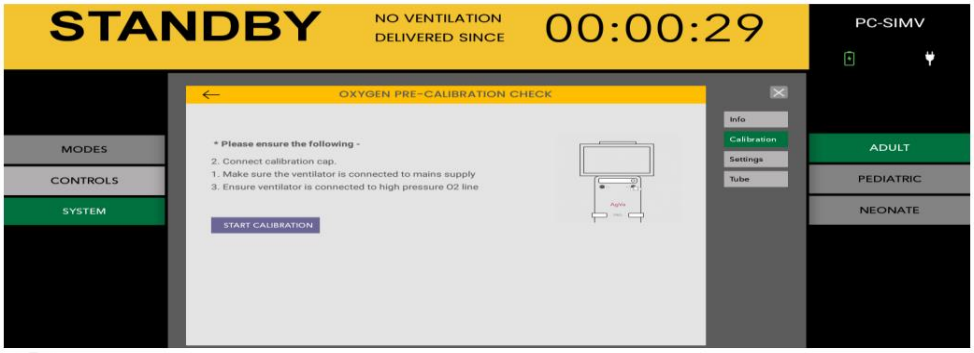
Calibration Checks as explained before



1 Resistance Pre-Calibration Check



2 Compliance Pre-Calibration Check



3 Oxygen Pre-Calibratiom Check

4 Exhale Valve Pre-Calibration Check

8.7 Connecting the oxygen supply:

Oxygen enrichment can be obtained from a high or low-pressure source, depending on the options:

1. High pressure Oxygen Supply System.
2. Low pressure Oxygen Supply.

8.8 High pressure Oxygen Supply System

Connect the ventilator to a high- pressure source or central gas supply system or from compressed gas cylinder using the high- pressure hose. Plug the hose to the high-pressure O2 on the ventilator's back panel.

Feature	Specification
Connector Type	DISS
Input pressure - Oxygen	40-85 psig/2.8-6Bar
FiO_2	21% to 100%
Accuracy	±5%
21% to 90% FiO_2 response -time	Up to 20 seconds

8.9 Low Pressure Oxygen Supply System

Connect the ventilator to a low- pressure source or O2 Concentration using the low-pressure hose. Plug the hose to the O2 Concentration on the ventilator's back panel.

Feature	Specification
Connector type	Press Fit
Input pressure – Oxygen	0.5 psig (Max)/0.035Bar
FiO_2	21% to 100%
Accuracy	±5%
Flow	0-80 LPM

Caution:

The oxygen pressure must be less than 85 psi.

Warning:

The actual delivered oxygen concentration will fluctuate when oxygen is administered with a low flow source. Significant leaks may reduce the amount of oxygen that is inhaled. concentration. FiO2 should be measured and recorded. It's important to utilize the right alarm settings

Warning:

Check to make sure that oxygen source is not empty before and during oxygen enrichment.

9.Basic Operations

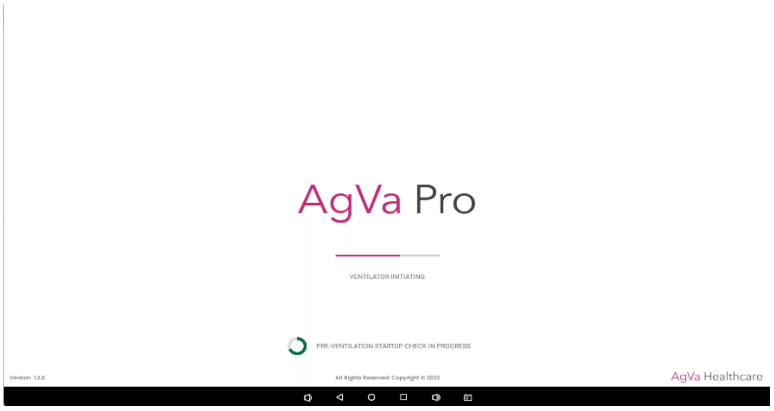
To ensure the safe and effective ventilation of patients, it is crucial to acquaint yourself thoroughly with the instructions when utilizing the AGVA PRO Ventilator. By familiarizing yourself with these instructions, you will be equipped to operate the ventilator in a manner that prioritizes the well-being and safety of the patients. It is imperative to adhere to all the instructions provided for the proper functioning of the ventilator and to minimize any potential risks or complications that may arise. By diligently following the prescribed guidelines, you will not only ensure the optimal performance of the AGVA PRO Ventilator but also contribute to the overall success of the patient's ventilation process.

Warning: The ventilator should only be operated by someone who has been adequately trained with applicable rules and regulations.

Caution: Check that the internal batteries are fully charged before using the ventilator, whether with an AC or DC power source.

9.1 Turning on the ventilator

Once the power cord is inserted, the indicator on the device will emit a bright white glow, serving as a visual confirmation that the main power has been successfully activated.



Upon starting, the AGVA PRO logo and a labelled progress bar will appear. Once loading is finished, the message “sensors check success, ventilation can be started” will appear.

9.2 Turning off the ventilator

Here are the steps to follow:

1. Firstly, disconnect the patient's breathing equipment from the circuit.
2. Next, select the Standby button. A pop up will appear asking you to confirm the action, select the button for confirmation.
3. Finally, power off the ventilator by pressing the power switch located at the back.

The progress bar can take a maximum 30 sec to load.

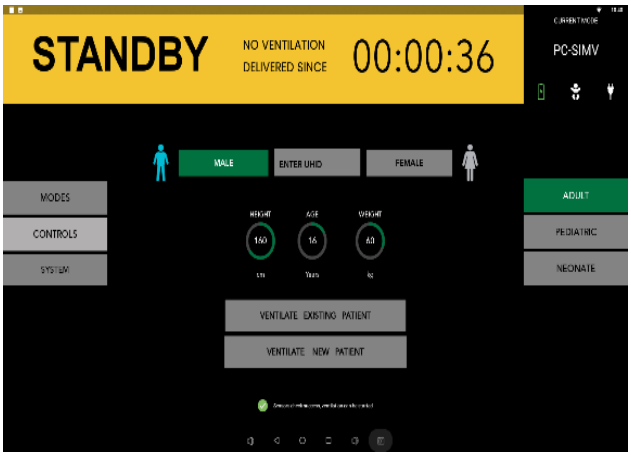
Caution:

Do check that no patient is connected to the ventilator before turning it off.

9.3 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 a new patient: Select sex, patient type, their height and weight here.

Warning:

The screen will feature a timer in the top-right corner, indicating the duration since ventilation has not been initiated.

A new popup window will then appear, presenting a range of modes to choose from.
Select the desired mode from the available options.
Following your selection, a window will appear prompting you to choose from three options provided on the right side:

a. Basic
b. Advanced
c. Smart O_2.

Finally, tap on the start ventilation button.

9.4 Patient setup for an **Existing or Old Patient**

Upon initial activation of the ventilator, the **"Ventilate Existing Patient"** button becomes visible. This feature allows doctors to access the settings and alarm limits from the previous patient, as well as review trends and historical data, similar to the previous case. In situations where a patient has been extubated but experiences a setback and necessitates re-intubation, the healthcare practitioner may utilize the settings from the previous patient for seamless continuity of care.

To activate the previous patient feature, simply click on the "Ventilate Existing Patient" option.

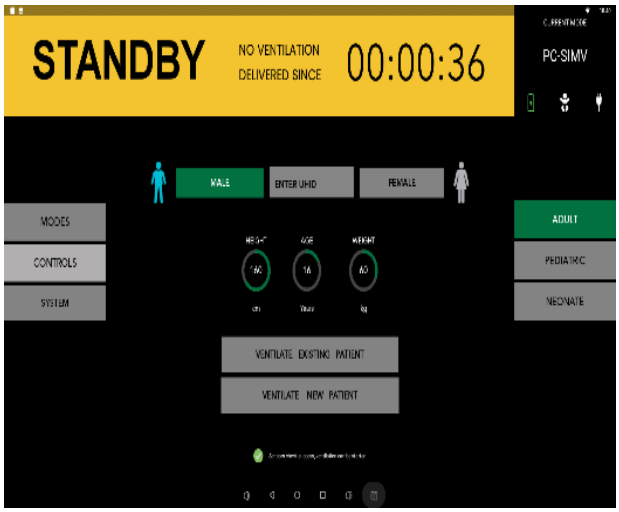
After confirming the patient's height and weight, click on the **"System"** button. This window will display four buttons:

a. Info

b. Calibration

c. Setting

d. Tube



Patient setup for an Existing patient: Select sex, patient type, their height and weight here.

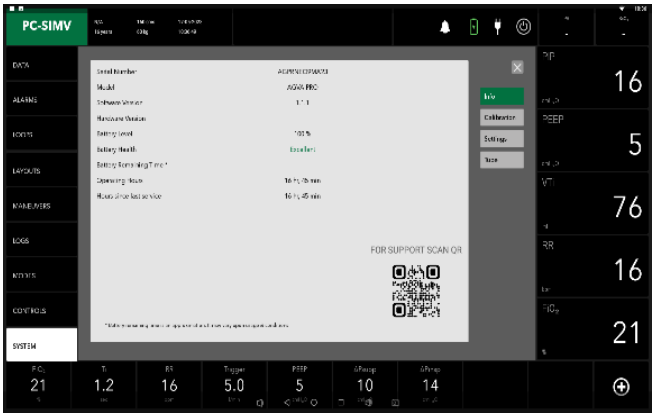
Caution:

A normal shutdown sequence is only played when the previous patient data is saved.

Warning: Upon successfully completing a standard shutdown procedure, the previous patient data is specifically stored. However, it's important to note that if a sudden or unexpected power loss occurs, the storage of this data cannot be guaranteed.

9.5 Information Screen

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.



Information Screen

9.6 Test & Calibration Screen:

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:

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

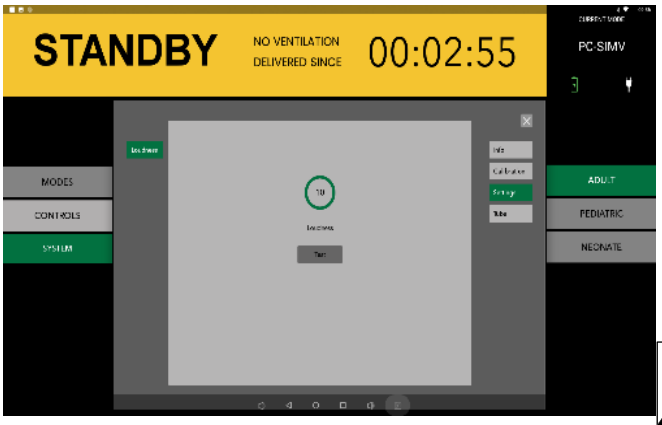
Checkboxes: These checkboxes indicate the selection status of respective functions

Test and Calibration

9.7 Settings:

Following the Test and Calibration tab, the subsequent tab is the Settings tab. Within this tab, you will encounter the "Loudness" option, which 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.



Settings

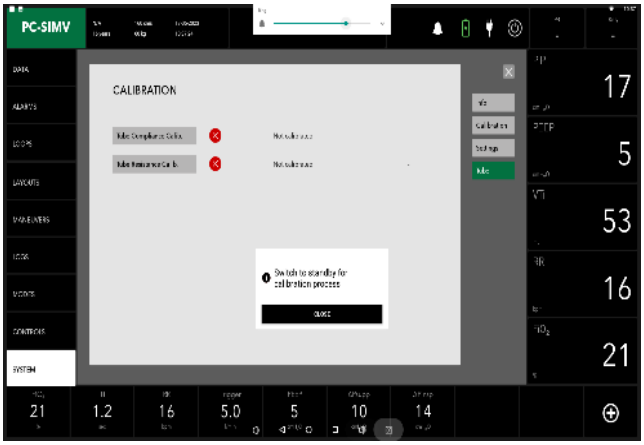
9.8 Tube tab

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



Tube

9.9 System Check Overview

Prior to conducting the system check, ensure that the ventilator is thoroughly cleaned and prepared for patient use. It is strongly advised to perform all the necessary system checks between patients to help guarantee the optimal functioning of the system.

Caution:

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

Warning:

1. During the System Check, it is imperative that the patient remains disconnected from the ventilator.
2. Verify the proper functioning of the breathing circuit and relevant accessories intended for use during ventilation.
3. Failure to perform a System Check for the current patient means that all internal adjustments rely on the compliance and resistance data obtained from the most recent completed System Check for the same patient type. Differences in ventilation characteristics may occur if there are notable disparities between the current and previous breathing circuits, impacting the compensation process.

9.10 Modes Check:

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

Modes

10. Modes

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:

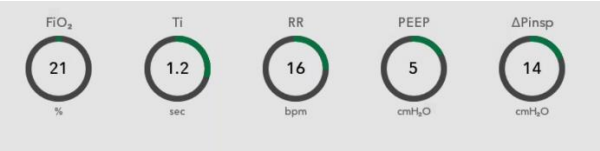
1. **Basic**
2. **Advance**
3. **Smart O_2**
4. **Backup** (only available in VC-SIMV(PS), PC-SIMV, PC-PSV, PC-BPAP, CPAP/PS,)
5. **V-TAS** (only available in PC-CMV, PC-SIMV, PC-PSV)

Caution:

Comprehensive information regarding the settings and features offered by each mode can be discovered within the descriptions of the respective ventilation modes.

10.1. 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.

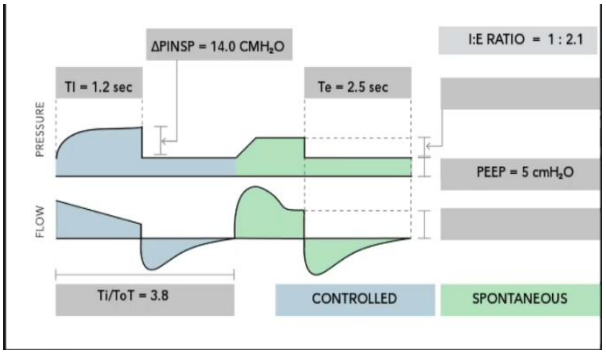


PC-CMV Basic

PC-CMV Advanced

PC-CMV Smart SpO_2

PC-CMV V-TAS



PC-CMV Waveform

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.

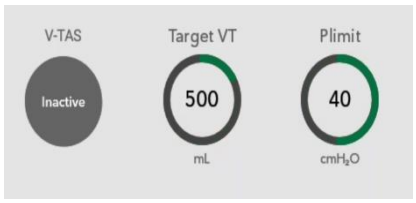
10.2. Pressure Controlled-Assist Control Ventilation Mode

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.

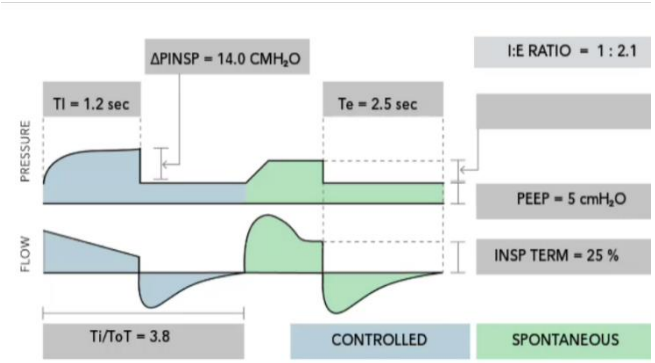
PC-AC Basic

PC-AC Advanced

PC-AC Smart O_2



PC-AC V-TAS



PC-AC Waveform

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.

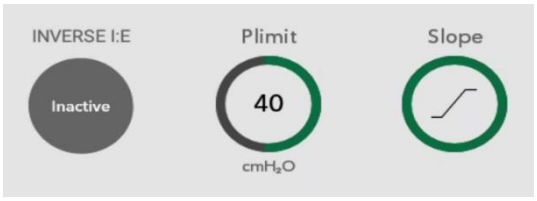
The tidal volume (VT) arises from the pressure differential between PEEP and Pinsp, lung mechanics, and the patient's exerted breathing effort. If lung Resistance (R) or Compliance (C) changes during ventilation, the administered tidal volume (VT) fluctuates accordingly.

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.

10.3. Pressure Control-Continuous Mandatory Ventilation

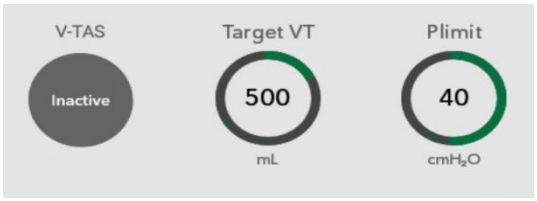
The **Pressure Control - Continuous Mandatory Ventilation (PC-CMV)** tidal volume supplied to the patient depends on the pressure difference between PEEP and Pinsp, the lung mechanics and the breathing effort of the patient. The number of mandatory breaths is defined by the breathing frequency (RR).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

PC-CMV Basic

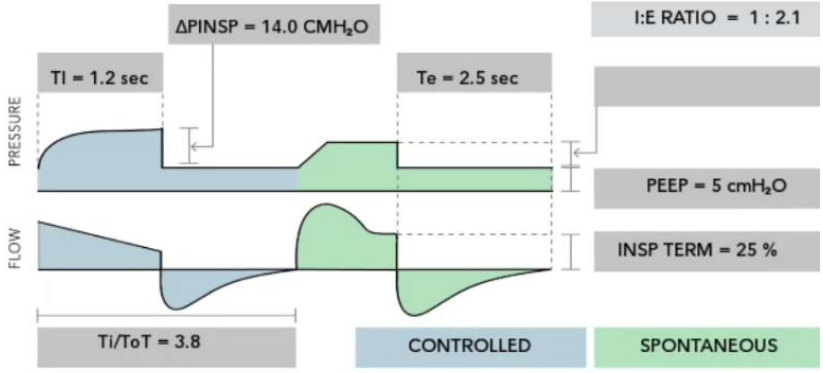


PC-CMV Advanced

PC-CMV SpO_2



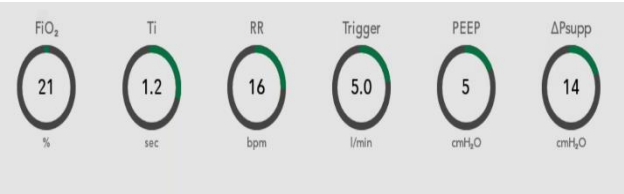
PC-CMV V-TAS



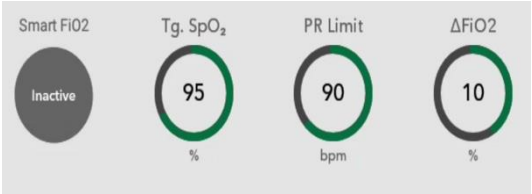
PC-CMV Waveform

10.4 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.



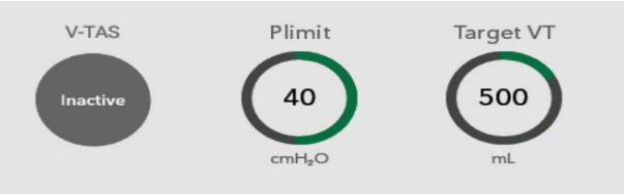
PC-PSV Basic



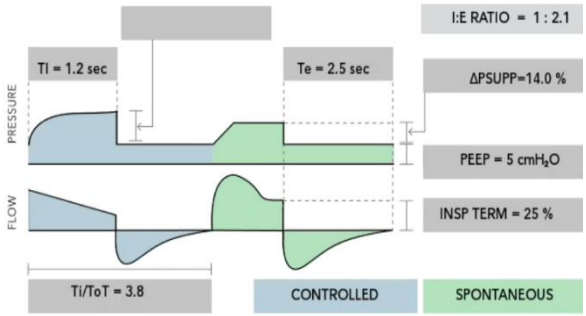
PC-PSV Smart O_2

PC-PSV Advanced

PC-PSV Backup



PC-PSV V-TAS



PC-PSV Waveform

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.

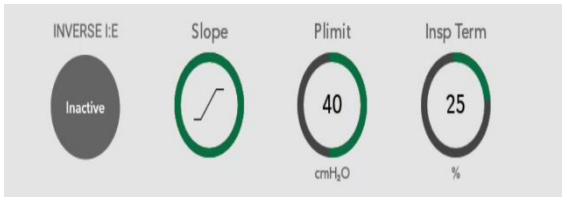
10.5. Pressure Controlled-Synchronized Intermittent Mandatory Ventilation Mode

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.

PC-SIMV Basic

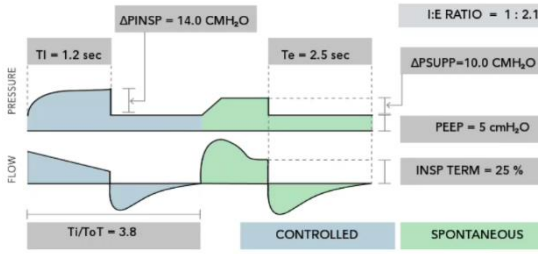


PC-SIMV Advanced

PC-SIMV Smart O_2

PC-SIMV V-TAS

PC-SIMV Backup

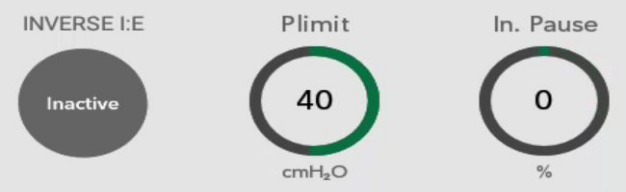


PC-SIMV Waveform

10.6. 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.

VC-CMV Basic



VC-CMV Advanced

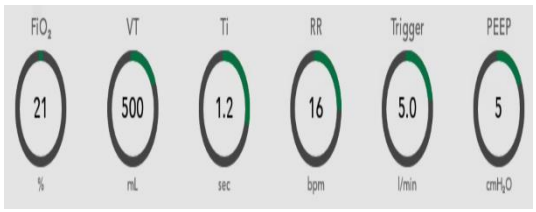
VC-CMV Smart O_2

10.7. Volume Control – Assist Control

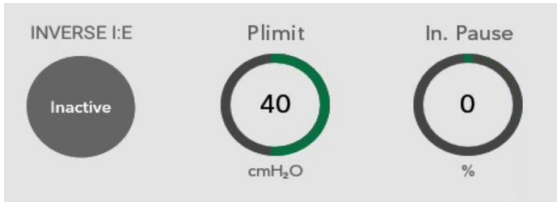
In the ventilation mode **Volume Control - Assist Control (VC-AC),** the patient always receives at least the set tidal volume (VT). In VC-AC, every detected inspiration effort of the patient at PEEP level triggers an additional mandatory breath. The patient thus determines the number of additional mandatory 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



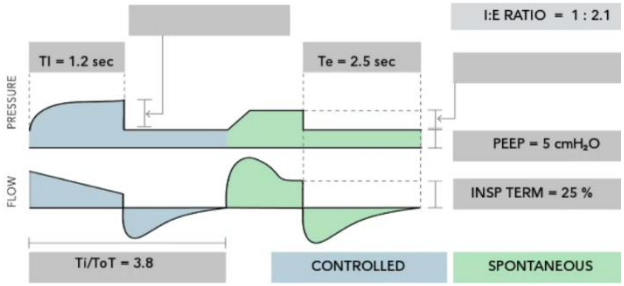
VC-AC Basic



VC-AC Advanced

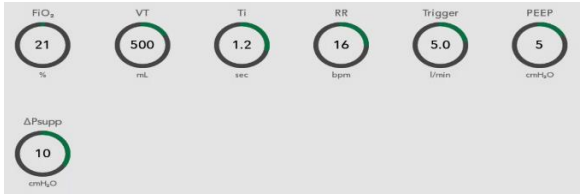
VC-AC SpO_2

VC-AC Waveform

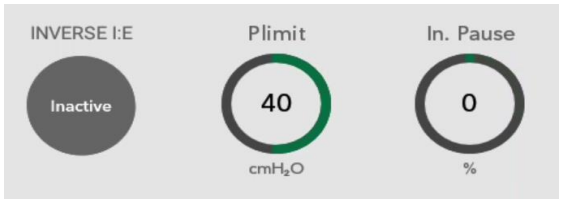


10.8. Volume Controlled-Synchronized Intermittent Mandatory Ventilation

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



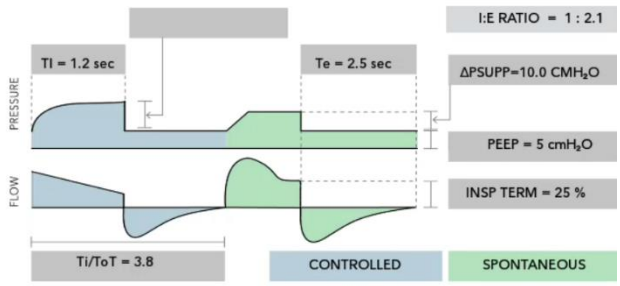
VC-SIMV Basic



VC-SIMV Advanced

VC-SIMV Backup

VC-SIMV Smart O_2



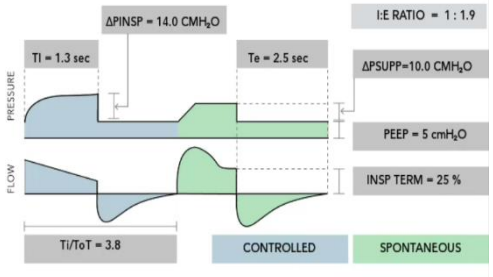
VC-SIMV Waveform

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

10.9. 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.



AI-VENT Waveform

Warning: Non-Invasive Ventilation Requirements:

1. Patient's ability to activate the ventilator and breathe spontaneously.
2. Patient's wakefulness and awareness.
3. Patient's ability to maintain an open airway.
4. Suitability for incubation.
5. Comfortable mask or interface.

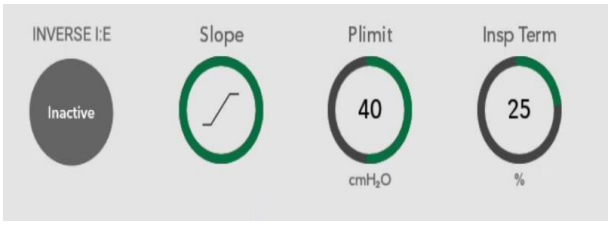
10.10. Non-Invasive Ventilation

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.

10.11. 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.

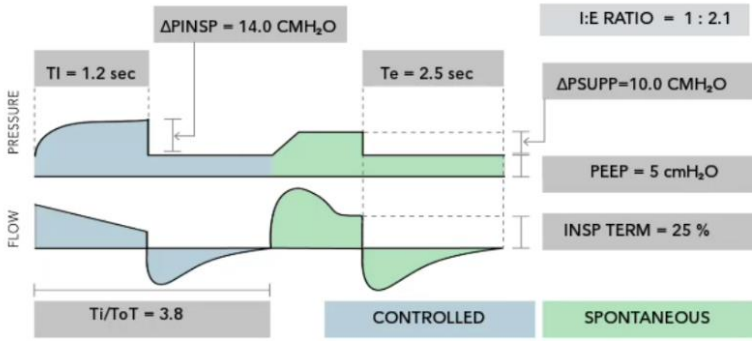
PC-BPAP Basic



PC-BPAP Advanced

PC-BPAP Backup

PC-BPAP Smart O_2



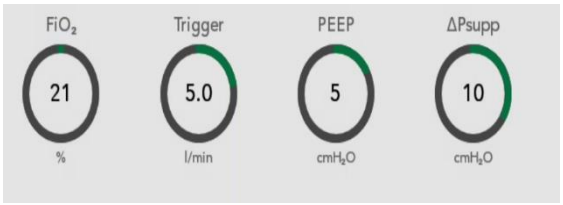
PC-BPAP Waveform

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.

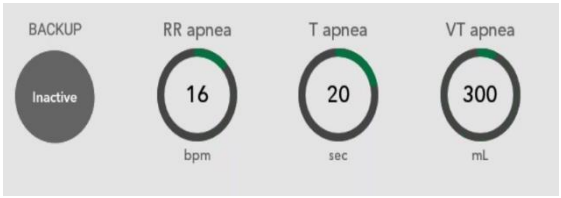
10.12 Continuous Positive Airway Pressure/Pressure Support

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).



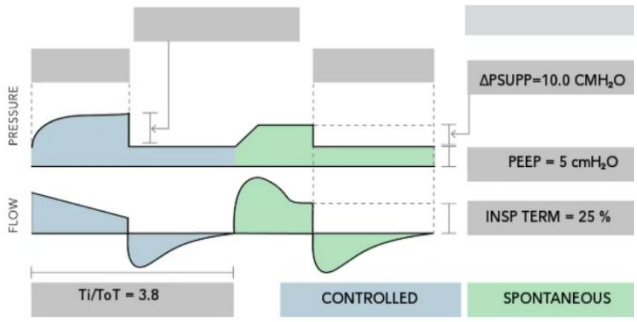
CPAP/PS Basic

CPAP/PS Advanced



CPAP/PS Backup

CPAP/PS Smart O_2

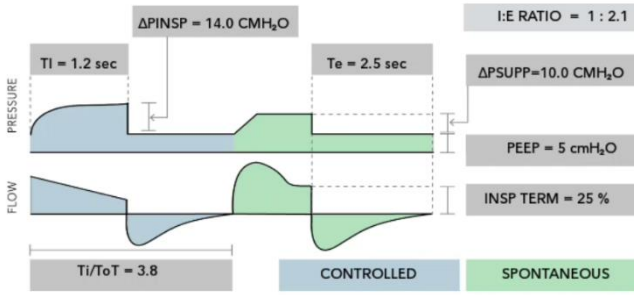


CPAP/PS Waveform

10.13. 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.

HFNC Basic



HFNC Waveform

Warning:

Continuous Positive Airway Pressure (CPAP) cannot be used in the following scenarios or conditions:

1. Inability of the person to breathe spontaneously.
2. Aggressive or agitated behavior in the person.
3. Unprotected airway due to altered consciousness (e.g., extreme illness, intoxication, coma, etc.).
4. Unstable condition due to respiratory arrest.
5. Facial trauma or burns in the person.

Additionally, individuals who have undergone previous facial, esophageal, or stomach surgery may find this treatment option challenging or unsuitable.

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11. Settings

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.

Warning:

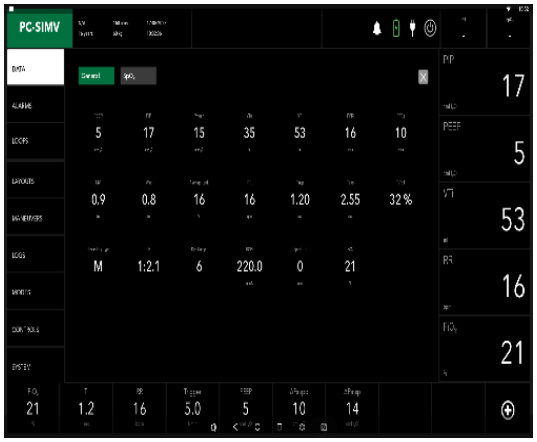
ease ventilator usage and promptly contact a service hnician if any of the subsequent events transpire:

1. Unusual pop-up windows displayed on the screen
2. Alarms persistently unresolved
3. Unfamiliar sounds detected
4. Any unexpected or inexplicable incidents observed

Caution: Before using the ventilator read all the general warnings and cautions

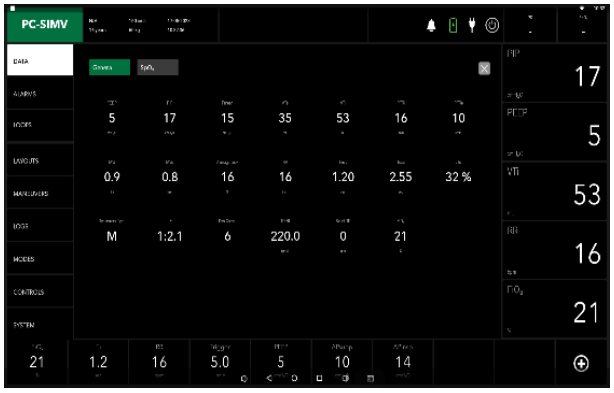
11.1 Data Button

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" option by clicking on it.



Data Button

Warning: The selected button will be indicated by a green background, while the non-selectedbutton will be indicated by a grey background.



Parameters displayed after selecting the general option

On the left, you will find an image displaying the detailed parameters after selecting the General option.

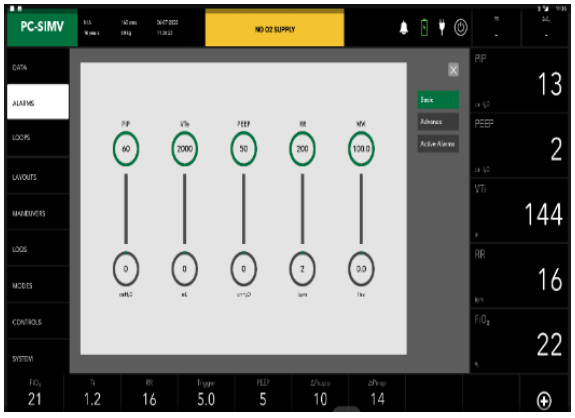
Parameters displayed after selecting the SpO_2 option.

On the left you will find an image displaying the parameters that appear on screen if you choose the SpO_2 option.

11.2. 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 Alarm

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. FiO_2-: 21-100%
2. SpO_2-: 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.

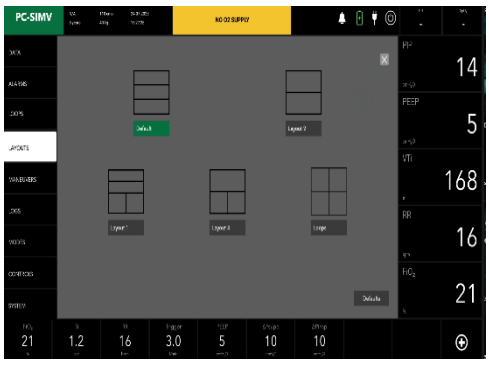
11.3. Loops Button:

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

11.4. 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 cmH_2O.
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 waveforms:

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

11.5. Maneuvers Button

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

1.Hold
2.Nebuliser

- To open the Maneuvers window, first click on Maneuvers.
- Select the hold button.

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.

11.6. LOGS

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

Trends, Events, Alarm.

11.7. 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

11.8. 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.

11.9. 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.

11.10. MODES

To select the Mode.

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

11.11. 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.

11.12. 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

Smart O_2-: Following are the parameters under this tab:

1. Smart FiO2-: Inactive/Active
2. Tg.SpO_2-:95-100 %
3. PR Limit-:90-120 bpm
4. 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.

12 Ventilator Alarms

Alarms are signaled optically and acoustically according to their alarm priority

12.1. Display of alarms

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).

12.2. 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

12.3. 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

12.4. 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.

12.5. 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:

1. During the alarm Standby mode activated

12.6. 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.

12.7 Dismissing alarm messages and alarm signal

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

12.8 Setting of Alarm Limits

Opening the Alarms dialog window

1. Touch the **"Alarms"** button, then, 3 options will be displayed like Basic, Advance and Active Alarm.
2. Click on the Basic, Advance and touch the parameters then set the alarm limit by rotating the knob.

12.9 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 %

13. Troubleshooting

In life-support conditions, the AGVA PRO ventilator is used. As a result, all users of the AGVA PRO Ventilator, including physicians and support workers, must have a complete understanding of how it works. This should include an understanding of the pneumatic and electronic systems of the ventilator.

The practical troubleshooting part below is intended to serve as a training resource for anyone learning how to use the AGVA PRO ventilator, as well as a reference tool for those who are already familiar with it. It's important to remember that this outline isn't exhaustive and is only meant to serve as a guide.

Caution: -

If you have any questions or concerns about the AGVA PRO ventilator's functioning, contact your Home-care Dealer, physician, or AGVA Healthcare.

The ventilator should only be operated by fully qualified individuals. The AGVA PRO ventilator is a restricted, medical device intended for use by Respiratory Therapists or other appropriately trained and qualified individuals under the supervision of a physician and in line with applicable state rules and regulations.

Upcoming pages will guide you through the troubleshooting.

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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.
11.			1. Check for leakages in breathing circuit. 2. Make sure that the tube is connect correctly. 3. Make sure that the tube is connected c

S.No.	Alarm	Cause	Remedy
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.	
35.	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.
36.	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.

S.No	Alarm	Cause	Remedy
37.	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.
38.	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.
44.	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.
45.	Expiratory flow measurement failed.	Expiratory valve is faulty.	Replace expiratory valve.
46.	Expiratory flow sensor is faulty.	Test of expiratory flow sensor failed.	Check whether the flow sensor is connected correctly and repeat the device check.
47.	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.
48.	Flow sensor ventilation impaired (High Pressure)	Flow sensor seated incorrectly in flow sensor sleeve of expiratory valve.	Insert flow sensor correctly.

S.No	Alarms	Cause	Remedy
49.	Turbine internal failure (High Pressure)	When turbine stops working	Call service engineer.
50.	Minute Volume High	The minute volume exceeds the upper alarm limit.	1. Check patient condition. 2. Check ventilation settings. 3. Adjust alarm limit if necessary.
51.	Minute Volume Low	1. There's water in the flow sensor. 2. The minute volume has fallen below lower alarm limit 3. Obstruction 4. Leakage or disconnection. 5. Device failure	1. In case there is water in the flow sensor, drain the water out of the breathing circuit and leave it to dry. 2. In case, the minute volume is low: a) Check the patient condition b) Check ventilation settings. c) If necessary adjust alarm limits. 3. In case of obstruction: a) Check patient condition. b) Check breathing circuit. c) Check tube or mask. 4. In case there is some leakage or disconnection: a) Check breathing circuit for tight connections. b) Make sure that the expiratory valve is properly engaged. c) Make sure that the tube or mask is connected correctly. 5.In case of a device failure: a) Disconnect the patient from ventilator and without delay use another independent ventilator. b) Contact specialized service personnel.
52.	Neonatal sensor cable is disconnected (High Priority)	Neonatal cable is disconnected.	Reconnect the wire properly.
53.	Neonatal flow sensor disconnected (High Priority)	When flow sensor placed at the end of the neonatal cable is disconnected.	Reconnect the sensor properly.
54.	No O_2 supply (High Priority)	When you set the FiO_2 more than 21% and there is no oxygen supply connected.	Connect the oxygen supply.

S. No.	Alarm	Causes	Remedy
55.	Faulty O_2 sensor	1. O_2 measurement is providing invalid values. 2. The O_2 sensor is faulty or has not been installed yet.	1. Calibrate O_2 sensor 2. Install and calibrate a new O_2 sensor.
56.	VT High	When volume is delivered more than the set VT.	Check for any leakage in the breathing circuit and check the correct calibration of the exhale valve.
57.	VT Low	When volume is delivered less than 90% of set VT.	Check for any blockage in the breathing circuit and check the correct calibration of the exhale valve.
58.	Respiratory rate low	The patient's respiratory rate is low.	1. Attend the patient's condition. 2. Check ventilation settings or spontaneous respiratory rate. 3. Adjust alarm limit if necessary.
59.	SpO_2 high - acknowledgement	When the current SpO_2 is set above the alarm limit.	1. Check patient condition. 2. Adjust the alarm limit if necessary.
60.	SpO_2 Low - acknowledgement	When current SpO_2 is set below the alarm limit.	1. Check patient condition. 2. Adjust the alarm limit if necessary.
61.	Patient disconnected - acknowledgement.	Leakage in the breathing circuit.	Check the tube or check whether there's any leakage in breathing circuit.
62.	Exhale Valve Error acknowledgement	When exhale valve is not connected properly.	Connect the exhale valve properly.
63.	PEEP High	Delivered PEEP is higher than the set value of PEEP.	Check the exhale valve. Recalibrate the exhale valve.
64.	PEEP Low	Delivered PEEP is lower than the set value of PEEP.	1. Check the exhale value. 2. Calibrate the exhale valve. 3. Check the leakage in breathing circuit.
	Leakage	1. Leakage in breathing circuit. The calculated leakage minute volume is larger than the measured expiratory minute volume.	

14. Cleaning and Maintenance

A. Cleaning

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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.

AGVA PRO must be shipped with its original accessories and packaging.

Warning: Only clean and disinfected AGVA PRO should be returned.

Caution: Do not immerse AGVA PRO in water or sterilize it in an autoclave.

14.1 Battery

Battery can be replaced if damaged, but the battery itself doesn’t carry any warranty.

14.2 Wiring

Can be replaced if faulty.

14.3 PCB servicing

Can be replaced if faulty

14.4 Disposal

Can be replaced if faulty or damaged

The AGVA PRO ventilator should not be thrown away with household waste; instead, it must be handed in for disposal as electrical and electronic equipment. Dispose of accessories and consumables following the relevant instructions for use. For disposal information, reach out to your local environmental or regulatory agency, or an appropriate waste disposal company.

14.5 Cleaning

AgVa Healthcare acknowledges the varying cleaning and disinfection procedures in different healthcare facilities. It cannot provide specific practices that meet all demands or take responsibility for the cleanliness of the patient care area. The guidebook offers general cleaning and disinfecting instructions, and it is the user's responsibility to ensure the validity and effectiveness of the methods employed.

The AGVA PRO ventilator and patient circuits are delivered in a clean but non- sterile state. Patient circuits that are reusable (single patient) should be disinfected before being reapplied to the patient. In addition to hospital policy, physician prescriptions, and Home-care Dealer guidelines, use the information in this area.

14.6 Cleaning AGVA PRO Ventilator

Step-by-Step Cleaning and Disinfection Procedure for AGVA PRO

Before beginning the cleaning process, switch off the AGVA PRO and unplug it from the mains to avoid any damage caused by liquid penetration.

1. Cleaning:

- Use an appropriate cleaning agent based on the chosen option to remove any visible soiling from the AGVA PRO enclosure.

14.7 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.

14.8 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.

14.9 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).

14.10 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).

6. 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

7. 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.

14.11 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.

14.12 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:

1. 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.

14.13 Replacing Air Inlet Particle Filter in AGVA PRO ventilator

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

1. Wipe with an appropriate bacterial agent after each patient use or soak the valve and diaphragm in any of the following solutions:
2. 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.

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.

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

.B Maintenance

Preventive Maintenance:

1. To maintain the AGVA PRO Ventilator's optimal performance, follow these steps:
2. 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.
3. Regularly check the AGVA PRO Ventilator power cord for any signs of damage, such as breakage or fraying.
4. Ensure there are no cracks or damages on the exhalation valve and flow orifice.
5. Periodically wipe off the ventilator housing's surface to remove accumulated dust.
6. 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.

It is advisable to replace the batteries if they no longer meet the user's time requirements. To extend the internal batteries' lifespan; whenever possible, connect the AGVA PRO Ventilator to an external power source for charging.

When traveling by automobile, utilize the Auto Lighter Cable accessory to power the AGVA PRO Ventilator.

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.

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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.

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.

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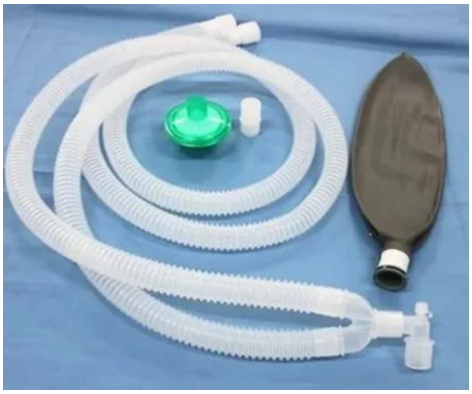
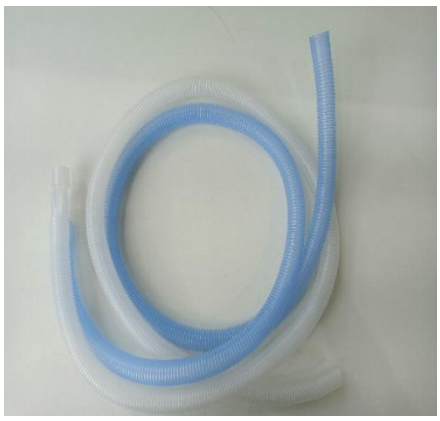
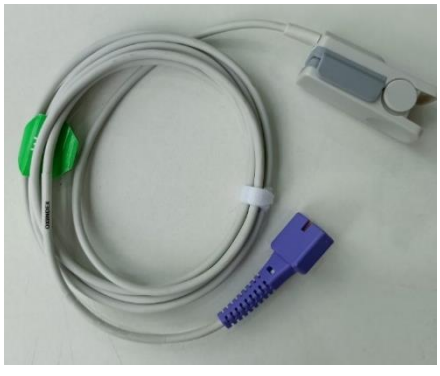
15 Parts and Accessories

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.

S.No.	Illustration of Accessories	Description of Accessories
1.		**Breathing Circuit** 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** This is employed to link the oxygen cylinder to the ventilator.

S.No.	Illustration of Accessories	Description of Accessories
2.		**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.
3.		**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.
4.		**Calibration Tube:** During calibration, this is used to connect the inspiratory port to the expiratory port.
5.		**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.

S.No.	Illustration of Accessories	Description of Accessories
6.		**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.
7.		**Breathing Bag:** The breathing bag is a device employed to provide temporary assistance to a patient's breathing. When a patient requires respiratory support, a respiratory therapist, doctor, or nurse places the breathing bag's face mask over the patient's mouth and nose.

16 Disposal

16.1 Safety Information

Caution:

There is a risk associated with inappropriately reprocessed products as they may become contaminated with infectious agents. Before disposal, make sure to reprocess the product following the guidelines outlined in the "reprocessing" chapter.

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.

16.2 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.

17. Procedure to check the device

During the initial setup of the ventilator, ensure proper ventilator operation by conducting the Device Check Procedure. This procedure aims to help qualified operators establish a routine program for verifying the FLIGHT 60 Ventilator's correct functioning. Perform this procedure each time the ventilator is prepared for clinical use.

Repeat the Device Check Procedure whenever the ventilator is used on a new patient or when the patient circuit/exhalation valve is changed. Before initiating the test, conduct a pretest inspection and configure the ventilator accordingly.

The Device Check Procedure involves the following tests:

1. Checking the power management.
2. Verifying the alarms.
3. Assessing the monitored parameters.

17.1 Checking the Power Management:

To verify the power management:

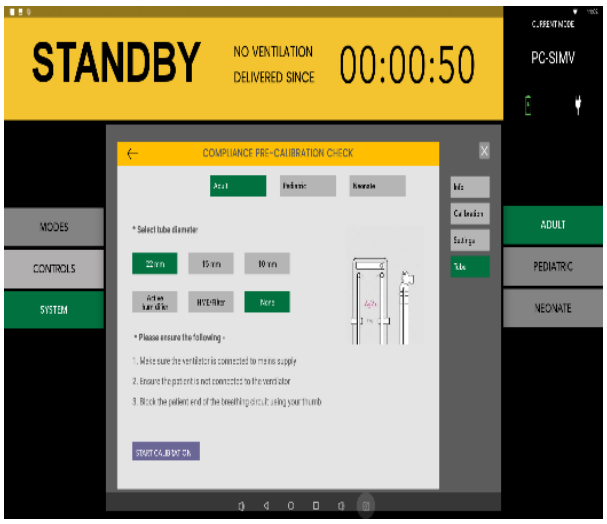
1. Disconnect the AC power cord. Check for a Power Switch over caution message and intermittent audible caution.
2. Ensure that the arrows on the battery's icons are facing down to indicate depleted batteries.
3. Disconnect the detachable battery. Confirm the presence of a Low Battery caution message and intermittent audible caution.
4. Reconnect the detachable battery and the AC power.
5. Verify that the arrows on the battery's icons are facing up to indicate charged batteries.

17.2 Checking Tube compliance

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

To verify the tube compliance

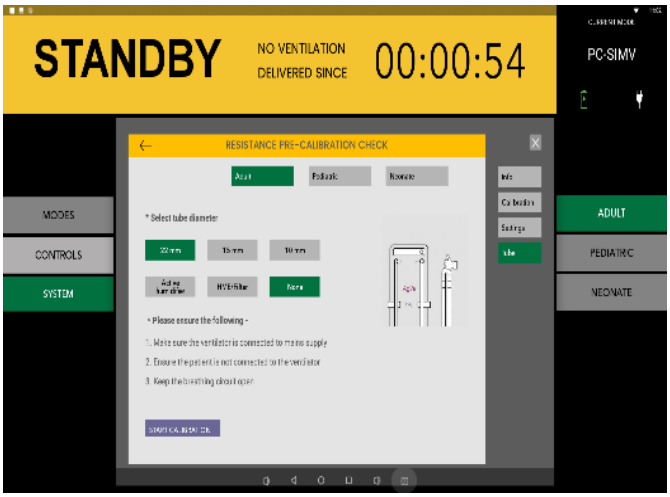
1. Firstly, select the appropriate Patient Group, as Adult and Pediatric share the same breathing circuit (22 mm), while Neonatal requires a different breathing circuit (10 mm).
2. Ensure the ventilator is connected to the mains supply.
3. Make sure the patient is not connected to the ventilator.
4. 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.



17.3 Tube Resistance Check:

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.



18. Specifications

18.1Physical Specifications

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

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

18.2 Electrical Specifications

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

18.3 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

18.4 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.

18 .5 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

18.6 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)

18.7 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)