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Automatic Breathing Unit (ABU) – ABU v01

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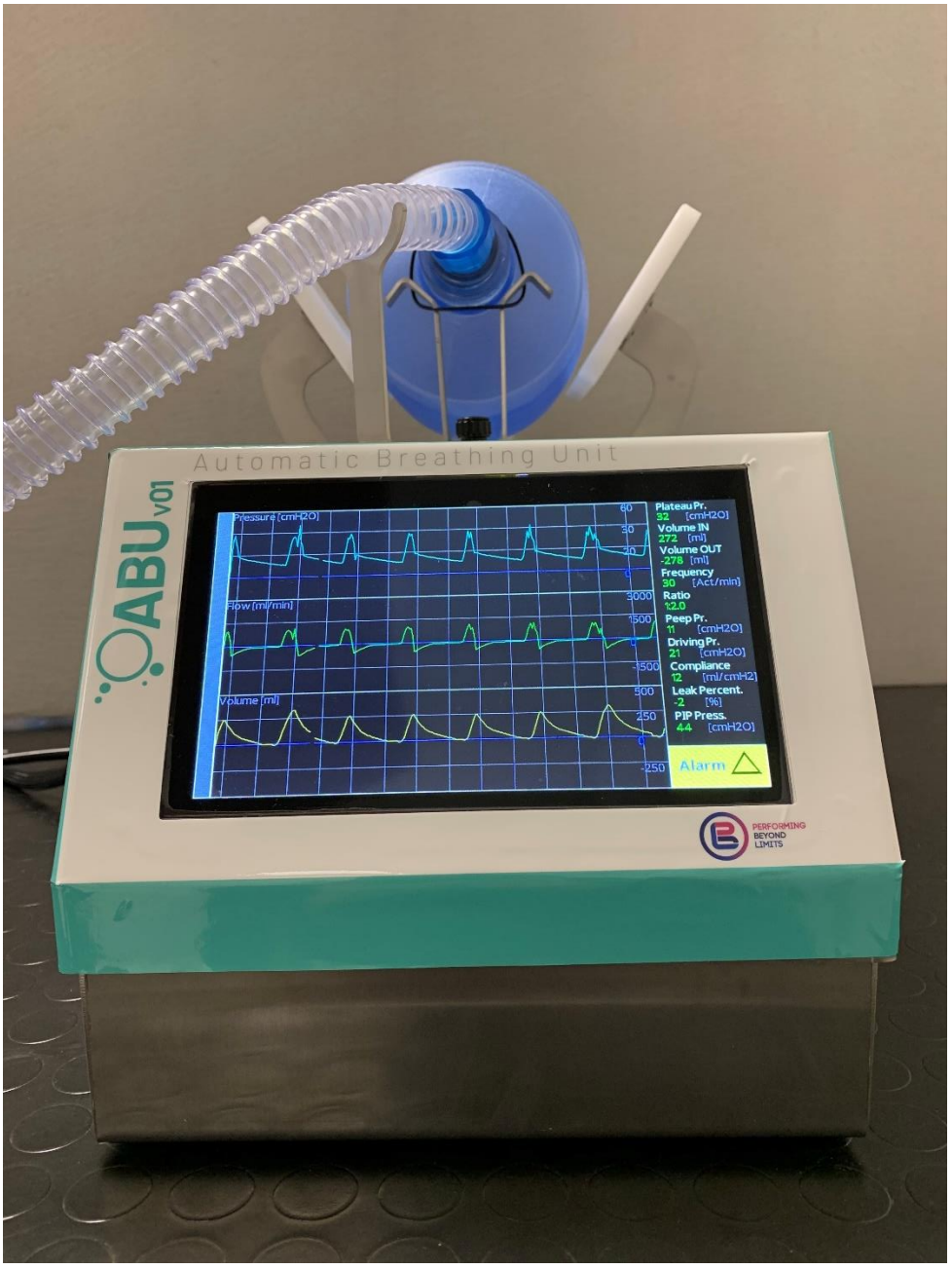
PERFORMING BEYOND LIMITS

Instruction For Use

Automatic Breathing Unit – ABU v01



WARNING:
To properly use this medical device, read and comply with these instructions for use.

Typographical conventions

Safety information definitions

These Instruction For Use (IFU) use three indicators to highlight critical information: Warning, Caution and Note. These are defined as follows:

	WARNING A WARNING statement provides important information about a potential hazardous situation which, if left unattended, could result in death or serious injury.
	CAUTION A CAUTION statement provides important information about a potentially hazardous situation which, if left unattended, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property
	NOTE A NOTE provides additional information intended to improve the user experience and avoid complication.

Definitions

For this medical device users, service personnel and technical experts are defined as target groups.

Target groups have been instructed in the use of the medical device herein presented and have the required knowledge to operate, install and maintain the medical device.

P.B.L. emphasizes that the medical device must be operated, installed and maintained by defined target groups.

P.B.L. uses the term "Accessory" not only for accessories in the sense of IEC 60601-1, but also for consumable parts/elements, third-party accessories/parts. The difference between consumable parts/elements and third-party accessories will be specified herein when required by the context.

Users
They are represented by healthcare personnel trained in the use of ABU ventilator and authorized by national laws to operate Intensive Care Unit (ICU) ventilators according to their intended use.

Service personnel
They are persons responsible for the maintenance of the medical device

Technical experts
They are persons authorized by P.B.L. SRL to carry out repair and complex maintenance operations on the medical device.

These instructions For Use (IFU) presents

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1 – General Safety Information

1.1 Overview of Warnings

1.1.1 Warnings regarding Use of Equipment

WARNING:
The ventilator shall be used only under the responsibility and on the prescription of a doctor or an authorized healthcare professional.

WARNING:
The ventilator shall be used according to its intended use. Refer to section 2.1, "Intended Use"

WARNING;
The ventilator shall be used according to its essential performance. Refer to section A.3.1, "Essential performance".

WARNING:
Never connect the ventilator to the patient or ventilate the patient without having previously read these instructions for use.

WARNING:
While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem, especially for ventilator-dependent patients.

WARNING:
To ensure that ventilation continues uninterrupted ensure alternative power sources are available (AC power source, extra batteries). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use—particularly for ventilator-dependent patients.

WARNING:
Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

WARNING:
The ventilator shall not be used with flammable anaesthetic substances.

WARNING:
Ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the unit. Also ensure

that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.

WARNING:
Ventilator-dependent patient should always be monitored by trained and competent medical personnel. Ensure that the patient's caregiver is able and prepared to take suitable action in the event the ventilator identifies an alarmed condition or experiences a problem.

WARNING:
Do not use a patient circuit with a leak accessory for ventilator-dependent patients.

WARNING:
Do not perform ventilator alarm tests while the patient is connected to the ventilator. Provide the patient with an alternate means of ventilation before conducting these tests.

WARNING:
Verify the functionality of the alarm conditions before connecting the patient to the ventilator.

WARNING:
If the ventilator fails any alarm test or if you cannot complete tests, see the Troubleshooting section (Chapter 9, section 9.6 "Troubleshooting") of this manual or call your equipment supplier

WARNING:
When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator

WARNING:
A medium priority alarm condition will be activated if the ventilator main power supply switch is turned off while ventilation is in progress. When the power switch is tuned back on again, ventilation will resume without having to press the ON/OFF button.

WARNING:
To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

WARNING:
A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet port is recommended.

WARNING:
Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.

WARNING:
Any violation of the product could render it unusable or defective, exposing to high risks patient's life.

WARNING:
When the ventilator is switched back on after it was switched off while ventilation was in progress, it will immediately begin ventilating-without the user first having to press the 'Start' button.

WARNING:
This manual tells you how to respond to ventilator alarms, but it does NOT tell you how to respond to the patient.

WARNING:
If the ambient temperature where the device is operated is greater than 35 °C (95 °F), the flow supplied at the device outlet may exceed 41 °C (106 °F). This may lead to undesirable side effects for the patient. To avoid injury to the patient, move the patient and the ventilator to a cooler location. For more information, contact P.B.L. or local supplier.

WARNING:
To reduce the risk of fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.

WARNING:
Do not start ventilation until you ensure that the device is suitably assembled, that the air filters are properly installed and are not obstructed, and that there is proper clearance all around the unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including hoses, is not damaged or obstructed.

1.1.2 Warnings Regarding Installation and Environment of Use

WARNING:
The ventilator should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately.

WARNING:
Always position the ventilator in the orientation show in Figures 3.1, 3.2, 3.3, 3.4, meaning with the mechanical clamps facing upwards and the only completely flat surface touching the floor or the support plane.

WARNING:
Always make sure that the support plane can sustain more than 20 Kg for a long period of time that exceeds the duration of 4 or 5 weeks.

WARNING:
To avoid damage to the ventilator, in particular the batteries or electrical components, fluids must not be allowed to enter the device, particularly through the apertures of the arms of the mechanical pincher located in the rear panel of the ventilator.

WARNING:
To ensure correct and lasting operation of the device, ensure that the ventilator is installed and operated in the environmental conditions recommended in Chapter 4, "Installation and Assembly" and Appendix A, "Specifications".

WARNING:
Do not leave power cables lying on the ground where they may pose a hazard.

WARNING:
Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.

WARNING:
Avoid using the ventilator, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake and other filters.

WARNING:
Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.

WARNING:
Place the ventilator in a safe place when ventilating and according to the recommendations in this manual.

WARNING:
Do not place the ventilator in a position where a child can reach it or in any position that might cause it to fall on the patient or someone else.

WARNING:
To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (main inlet or cooling) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.

WARNING:
If the ventilator has been transported or stored at a temperature that differs more than ±20 °C (± 36 °F) from the temperature in which it will be operating, the ventilator should be allowed to stabilize in its operating environment for at least one (1) hour prior to use.

WARNING:
If the ventilator has been transported or stored at humidity out of the range reported in Table A.9, the ventilator should be allowed to stabilize in its operating environment for at least one (1) hour prior to use.

WARNING:
The ventilator is not equipped with an altitude compensating technology; for this reason, if the ventilator is used at an altitude higher than 550 m (1804 ft) above sea level, users shall monitor constantly patient's vital parameters and adjust ventilation parameters accordingly or consider the use of a different, suitable ventilator, equipped with altitude compensating technology.

WARNING:
Regularly check the cleanliness of the air inlet filter located upstream with respect to the patient-ventilator interface system, on the ventilator side. If necessary, replace the filter before (see section 8.1, "Replacing the antibacterial and antiviral filter"). This is particularly important when the ventilator is installed in emergency scenarios, because environmental conditions may cause the filter to become dirty more rapidly.

WARNING:
Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.

WARNING:
Portable and mobile RF communications equipment can affect the performance of the ABU ventilator. Install and use this device according to the information contained in this manual.

WARNING:
The ventilator should not be used adjacent to or stacked with other equipment, except as specified in this manual. If adjacent or stacked use is necessary, the ventilator should be observed to verify normal operation in the configuration in which it will be used.

WARNING:
The ventilator shall be placed in a position where its moving parts cannot hit accidentally the patient, the user or other persons.

WARNING:
Do not attempt to insert fingers or any part of the body inside the gaps of the ventilator.

1.1.3 Warnings regarding Electrical Power Supplies

WARNING:
Never connect your ventilator to an electrical outlet controlled by a wall switch because the power may be inadvertently turned off.

WARNING:
The user should connect the ventilator to an AC power source whenever available, for safer operation.

WARNINNG:
The user should connect the ventilator to an AC power source socket equipped with a good earth connection.

WARNING:
The maximum recommended shelf life of the internal battery is two (2) years. Do not use a battery that has been stored for two years prior to its first use.

WARNING:
The maximum recommended lifetime, under normal operating conditions, of the ABU v01 is ten (10) years. Do not use the ventilator if it has been used for more than ten (10) years without consulting the manufacturer, even if it has always been used under normal operating conditions.

WARNING:
Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for periods longer than seven (7) days, without recharging, as this may reduce the maximum life and the amount of stored energy available in case of immediate and unexpected use.

WARNING:
The power supply to which the ventilator is connected (AC) must comply with all applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the side of the ventilator to ensure correct operation. Refer also to the electrical specifications found in Appendix A, section A.2, "Electrical".

WARNING:
Ensure that the ventilator's internal battery is fully charged before connecting the ventilator to a patient. Connecting the ventilator to the AC ("mains") power supply without turning the ventilator on, does not enable its internal battery to recharge.

WARNING:
Due to its limited internal battery's reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.

WARNING:
Even if the "INTERNAL BATTERY" charging indicator is off, charging of the battery may sometimes be incomplete if the ambient temperature is above 40 °C (104 °F) because of the battery's physical limitations.

WARNING:
When the "5 Mins. Battery remaining" alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery.

WARNING:
Batteries should be disposed of according to environmental legislation in your country and locality.

WARNING:
Never expose any batteries to direct flame.

WARNING:
Ensure that the AC power cable is in perfect condition and not compressed. The device should not be turned on if the AC power cable is damaged.

WARNING:
Fuses shall be replaced by Technical experts designated by P.B.L.. Changing the fuses of the ventilator my put your life in danger in any circumstance, do not attempt to that by yourself!

1.1.4 Warnings regarding Hoses and Accessories

WARNING:
The ventilator must not use, nor be connected to, any anti-static or electrically conductive hoses, tubing, or conduits.

WARNING:
Leak Percentage alarm parameters must be properly set to warn in the event of patient disconnection.

WARNING:
Before opening the packaging for the Breathing Circuit, ensure that no damage is evident to the packaging or its contents. Do not use if evidence of damage exists.

WARNING:
Do not use components of the Breathing Circuit that are supposed to be sterile if their packaging is damaged or broken.

WARNING:
The patient circuit should not be changed during ventilation.

WARNING:
On a DAILY basis, inspect the patient circuit to ensure that it shows no signs of damage, is properly connected, and is operating correctly without leakage.

WARNING:
Single Use accessories shall not be reused.

WARNING:
During invasive ventilation (when an artificial airway bypasses the patient's upper respiratory system), the patient's upper respiratory system cannot humidify the incoming gas. For this reason, the use of a humidifier, to minimize drying of the patient's airway and subsequent irritation and discomfort, must be used.

WARNING:
Before cleaning the ventilator, first disconnect the ventilator and the patient circuit.

WARNING:
The patient circuit should always be positioned to avoid hindering the patient's movements, to prevent accidental disconnection or leakage, and to minimize the risk of patient strangulation.

WARNING:
The breathing circuit of the ventilator shall always be used with recommended components, listed in Table A.2, in order to ensure proper ventilation settings. Such components shall be replaced as reported in Table A.2 and as recommended by the manufacturer.

WARNING:
Adding attachments to the ventilator breathing system can cause the pressure at the patient connection port to increase.

WARNING:
Users shall always possess an additional breathing circuit while using the ABU v01 ventilator.

WARNING:
If a humidification device is used, always ensure it is positioned lower than both the ventilator and the patient. Use water traps, if necessary, to limit water in the patient circuit and periodically empty these water traps.

WARNING:
If a heated humidifier is used, you should always monitor the temperature of the gas delivered to the patient. Gas delivered from the ventilator that becomes too hot may burn the patient's airway.

WARNING:
Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

WARNING:
Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may affect the accuracy of the parameters measured by the ventilator.

WARNING:
When using non-invasive ventilation (NIV) without an exhalation valve, use a vented nose or face mask or a non-vented combined with a leak accessory. When using non-invasive ventilation (NIV) with an exhalation valve, use a non-vented mask.

WARNING:
Handle the ventilator with care after use, particularly when ambient temperatures are high. Some ventilator surfaces may be very hot, even if safety specifications are not exceeded.

WARNING:
After each use and after each cleaning procedure check the status of the ABU sensor pack simply by connecting it to the ventilator, turning it on and checking if any alarm related to sensor pack or sensors in general is shown. See section C.1, "ABU sensor pack test".

WARNING:
If ABU ventilator displays any alarm regarding ABU sensor pack or sensors in general, or if the user detects any malfunctioning or unusual behavior in the parameters displayed by the ventilator, replace the ventilator with another and contact the manufacturer or its legal representative.

1.1.5 Warnings regarding Settings

WARNING:
Before starting ventilation, always verify that all settings are properly set in accordance with the required prescription.

WARNING:
Before starting ventilation, ensure that the device is properly assembled and that the air inlet, and alarm sound diffusion holes are not obstructed. Ensure also that the patient circuit is of the proper configuration (with or without continuous fresh airflow), properly connected to the ventilator, and that the circuit hoses are neither damaged nor compressed and contain no obstructions or foreign bodies.

WARNING:
The CPAP mode does not provide a set respiratory rate. Do not use this mode for ventilator-dependent patients.

WARNING:
Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient.

WARNING:
Monitor the patient's state of health in order to ensure that the ventilator's settings are always suited to the patient's current physiological requirements.

WARNING:
In adult use, ensure that the set tidal volume is compatible with the needs of the patient.

WARNING:
Do not conduct any ventilator alarm test while the patient is connected to the ventilator. Switch the patient to an alternate means of ventilation before testing.

WARNING:
The backup ventilation trigger time should be set to a shorter time for ventilator dependent patients in order for the Apnea Alarm to activate.

WARNING:
Setting Alarm limits to extreme values can cause the ventilator alarms to malfunction.

WARNING:
Ensure the Breathing Frequency and I:E ratio settings are compatible with the physiological requirements of the patient.

WARNING:
Adjustable alarms should not be systematically acknowledged (i.e., ACK Alarms); instead, they should be adjusted according to the needs and condition of the patient.

WARNING:
A medium priority alarm condition will be activated if the ventilator main power supply switch is turned off while ventilation is in progress. When the power switch is turned back on again, ventilation will resume without having to press the ventilation 'Start' button.

WARNING:
The inspiration trigger thresholds should be carefully modified in order to avoid the risk of false triggering or "auto triggering" of the ventilator.

1.1.6 Warnings regarding Maintenance

WARNING:
Never use a ventilator or any components or accessories that appear to be damaged.

WARNING:
To ensure proper servicing and avoid the possibility of physical injury to personnel or damage to the ventilator, only personnel authorized and qualified by P.B.L. should attempt to service or make authorized modifications to the ABU v01 ventilator.

WARNING:
If you cannot determine the cause of a problem with your ventilator, contact your equipment supplier. Do not use the ventilator until the problem has been corrected.

WARNING:
On a DAILY basis, ensure the proper connection and operation of the patient circuit.

WARNING:
If a problem with the ventilator is suspected, FIRST CHECK THAT THE PATIENT IS NOT IN DANGER. If necessary, remove the patient from the ventilator and provide an alternative means of ventilation.

WARNING:
After assembling, cleaning, or reassembling the patient circuit, and on a DAILY basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.

WARNING:
Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your ventilator. Use only those solutions listed in Chapter 7, "Cleaning".

WARNING:
Never use a liquid cleaner inside the patient circuit, or on any component of a gas pathway. Clean the patient circuit only as specified by the manufacturer's instructions.

WARNING:
Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorized and qualified by P.B.L. should repair, open or service the ventilator.

WARNING:
If the ventilator is damaged or its external housing is not correctly closed or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odor, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.

WARNING:
The patient circuit is intended for single use by a single patient and should be changed according to the manufacturer's recommendations and according to the patient circuit lifetime. Refer to the instructions for use supplied by the manufacturer of the patient circuit (included with the ventilator) and Chapter 4, "Installation and Assembly."

WARNING:
A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet port is recommended.

WARNING:
Regularly check the cleanliness of the air inlet filter located upstream with respect to the patient-ventilator interface system, on the ventilator side. If necessary, replace the filter before (see section 8.1, "Replacing the antibacterial and antiviral filter"). This is particularly important when environmental conditions may cause the filter to become dirty more rapidly.

WARNING:
For environmental protection, the ventilator and its components, whatever their respective conditions of operation, cannot be disposed of with household waste and must be submitted for suitable selective collection and possible recycling. Observe all applicable regulations when disposing of the ventilator and any of its components.

WARNING:
Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds. Back up ventilators or those in storage should be connected to an AC power source to protect the integrity of the battery. Please, be advised that to recharge the internal batteries of ABU v01, it is necessary to have it connected to the AC main supply and have it turned on with the main power supply switch on I position.

WARNING:
The maximum recommended shelf life of the internal battery is two (2) years. Do not use a battery that has been stored for two years prior to its first use.

WARNING:
The maximum recommended lifetime, under normal operating conditions, of the ABU v01 is ten (10) years. Do not use the ventilator if it has been used for more than ten (10) years without consulting the manufacturer, even if it has always been used under normal operating conditions.

WARNING:
Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for periods longer than seven (7) days, without recharging, as this may

reduce the maximum life and the amount of stored energy available in case of immediate and unexpected use.

WARNING:
To connect the ventilator to an external power source, first ensure the ventilator's I/O switch is off (O). Then, connect the desired power cable to the ventilator. Finally, connect the power cable to the external power source.

WARNING:
To disconnect the ventilator from an external power source, first power-down the ventilator and make sure that the ventilator's I/O switch if off (O). Then, the power cable from the external power source and, finally, the ventilator.

WARNING:
Connect the external electrical power source by first connecting the power cable to the ventilator and then to the external power source. Follow the reverse procedure to disconnect the device from electrical power sources.

1.1.7 Warnings Regarding Oxygen

WARNING:
The fractionation of oxygen inside the ABU balloon is subject to the connection of the ABU device to an external O2 reserve. The reference values are those given in section 4.6, "Connection to Oxygen supply or Oxygen blender", if an oxygen blender is not installed and the ABU is connected directly to an external O2 tank.

WARNING:
The ventilator must not be used with flammable anesthetic substances.

WARNING:
The ventilator must not be used in Oxygen rich environment.

WARNING:
Please, be aware that ABU v01 is not equipped with any sort of Oxygen Monitoring or Controlling Equipment. If such an external device is used, it shall conform with the following subclasses of ISO 80601-2-55:2018:

- **201.7.4.3;**
- **201.7.9.2.9.101;**
- **201.12.1.101;**
- **201.12.1.102;**
- **201.12.1.103;**
- **208.6.2**

WARNING:
Please, be aware that ABU v01 is not equipped with any sort of Oxygen Monitoring or Controlling Equipment. The ventilator, by exploiting the oxygen port present in the

majority (but not the entirety) of the bag-valve masks, can provide an Oxygen concentration of either 21% or almost 100%.

WARNING:
Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, be aware that inappropriate oxygen use may potentially lead to serious complications, including, but not limited to, patient injury.

WARNING:
Strictly follow the instructions provided in section 4.6, "Connection to Oxygen Supply or Oxygen blender," which include the use of a flow regulator and special oxygen connector.

WARNING:
In the event of an oxygen leak, shut down the supply of oxygen at its source. In addition, remove and/or keep any incandescent source away from the device, which may be enriched with oxygen. Circulate fresh air into the room to bring the oxygen level down to normal.

WARNING:
The hose connecting the ventilator to the oxygen source shall be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.

WARNING:
Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen or air.

WARNING:
The oxygen supply must be shut off when ventilation is interrupted. Before disconnecting the oxygen hose, allow the ventilator to continue for a few cycles without oxygen to flush the patient circuit of excess oxygen.

1.1.8 Warnings regarding Electromagnetic Interference

WARNINGS:
Even though the ABU v01 ventilator meets current safety standards according to IEC 60601-1-1 and ISO 80601-2-12, ABU v01 requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, "Specifications." In particular, the use of nearby mobile and portable communications equipment using radio frequencies (RF), such as mobile telephones or other systems exceeding the levels set in the IEC 60601-1-2 standard, may affect its operation. Refer to section A.8, "Manufacturer's Declaration." Ensure that other medical electrical devices are used no closer than 30 cm (12 inches) to any part of the ABU v01 ventilator, including cables specified by the manufacturer.

WARNING:
The use of any accessory other than those specified, with the exception of the power supplies or cables sold by P.B.L., may lead to an increase in electromagnetic emissions or a decrease

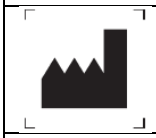
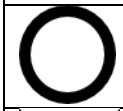
in the equipment protection against electromagnetic emissions. If the ventilator is used adjacent to such accessories or stacked with such devices, the ventilator's performance should be monitored to verify normal operation.

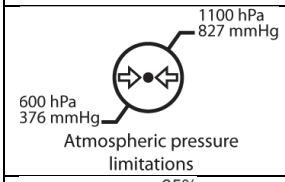
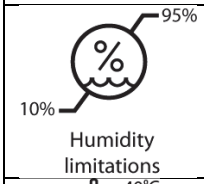
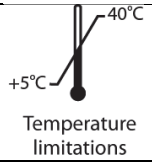
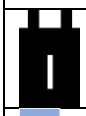
WARNING:
Always use compatible power supply cable compliant with IEC 60320 C14 and with what declared in section A.9, "Standards Compliance and IEC Classification".

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

1.2 Symbols and Markings

Table 1.1. List of symbols

Symbol	Explanation
	Caution: Consult Instructions For Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the ventilator itself. This symbol appears on the ventilator's left side.
	Application part type B A regulatory standard for protection against electrical shock for the part of the device that contacts the patient. This symbol appears on the ventilator's left side.
	Warning: Strictly follow Instructions For Use. This symbol appears on the ventilator's left side.
	Manufacturer This symbol appears on the ventilator's left side.
	Date of manufacture This symbol appears on the ventilator's left side.
	Catalogue number This symbol appears on the ventilator's left side.
	Serial Number This symbol appears on the ventilator's left side.
	Labelling in accordance with Directive 93/42/EEC concerning medical products This symbol appears on the ventilator's left side.
IP21	Index of protection rating for the ventilator's enclosure, defined in IEC 60529. The first digit, 2, indicates protection against intrusion of fingers (> 12.5 mm) into the ventilator. The second digit, 1, indicates protection against water dripping or falling vertically, as well as an environment featuring water vapor condensation and/or light rain. This symbol appears on the ventilator's right side.
	Switch in "On" position (IEC 60417-5007). This symbol appears on the I/O (power on/off) switch on the left side of the ventilator to indicate the switch's "On" position.
	Switch in "Off" position (IEC 60417-5007). This symbol appears on the I/O (power on/off) switch on the left side of the ventilator to indicate the switch's "Off" position.
	WEEE (Waste Electrical and Electronic Equipment). This symbol means that this product must not be disposed of with household waste. Observe local ordinances for proper disposal. This symbol appears on the ventilator's left side.

	USB port. This symbol indicates a communications port for interfacing with a USB connector. This symbol appears on the ventilator's right side.
	Sensor Cable port. This symbol indicates a communications port for the connection with the Sensor Package This symbol appears on the ventilator's right side.
	Atmospheric pressure limitation This symbol appears on the ventilator's left side.
	Humidity limitations This symbol appears on the ventilator's left side.
	Temperature limitation This symbol appears on the ventilator's left side.
2x 250V F6.3AL 	Fuse specifications This symbol appears on the ventilator's left side.
	Distributed Alarm System Connection Port. This symbol appears on the ventilator's left side
	Reset touchscreen Button This symbol appears on the ventilator's left side
	Battery Start Button. This symbol appears on the ventilator's left side
	Battery Charge Qualitative Status. This graphic shows the current qualitative status of the battery charge, and appears only when the ventilator is operating on battery instead of the AC main supply. This symbol appears on the ventilator's screen when the device is operating in battery mode.
	High-priority Alarm Symbol. This graphic appears on the ventilator's screen when a high-priority alarm is active.
	Medium-priority Alarm Symbol. This graphic appears on the ventilator's screen when a medium-priority alarm is active.
	Alarms ACK Button. This graphic appears on the ventilator's alarm page at the bottom.
	Silence Alarms Button. This graphic appears on the ventilator's alarm page at the bottom.

1.3 Labels

Various labels are affixed to the ventilator that describes precautions to be taken for correct use of the ventilator and traceability of the product and help to locate the positions of buttons and communication ports present on the ventilator. See figures and tables on the following pages for illustrations of these labels and markings and their locations on the ventilator.

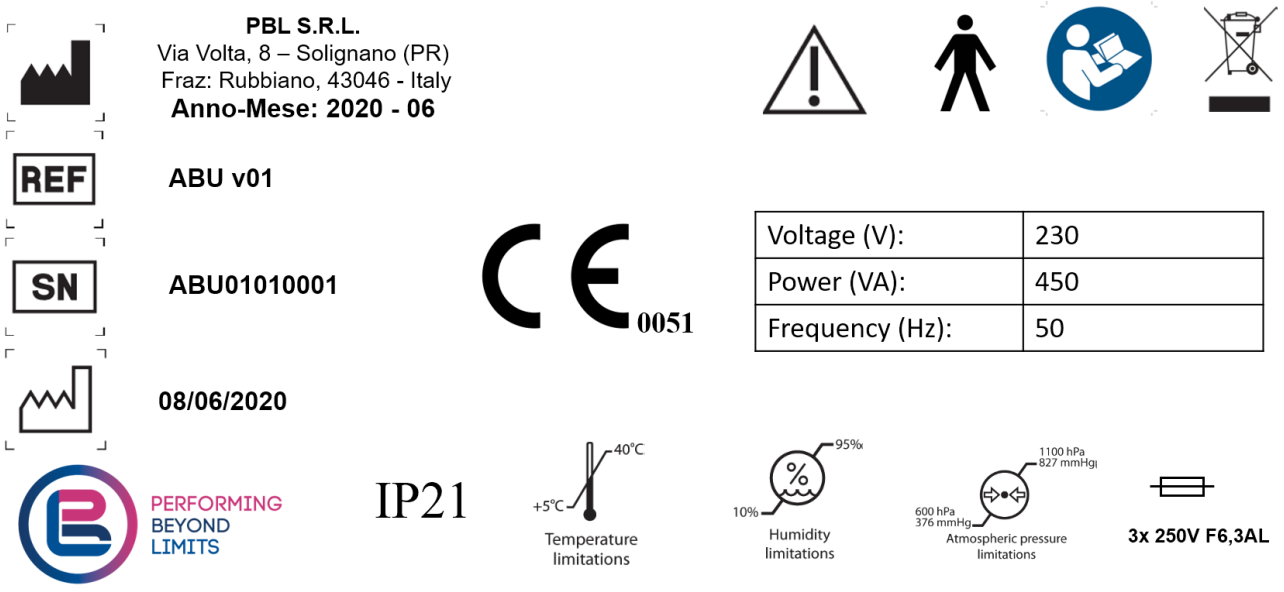


Figure 1.1. Main label of the ventilator that reports traceability information and precautions to be taken for the correct use of the device.

Table 1.2. Other Ventilator labels

Distributed Alarm System Connection Port (Figure 1.2)	Reset Touchscreen Button (Figure 1.3)	Battery Start Button (Figure 1.4)	USB port (Figure 1.5)	Sensor Cable port (Figure 1.6)

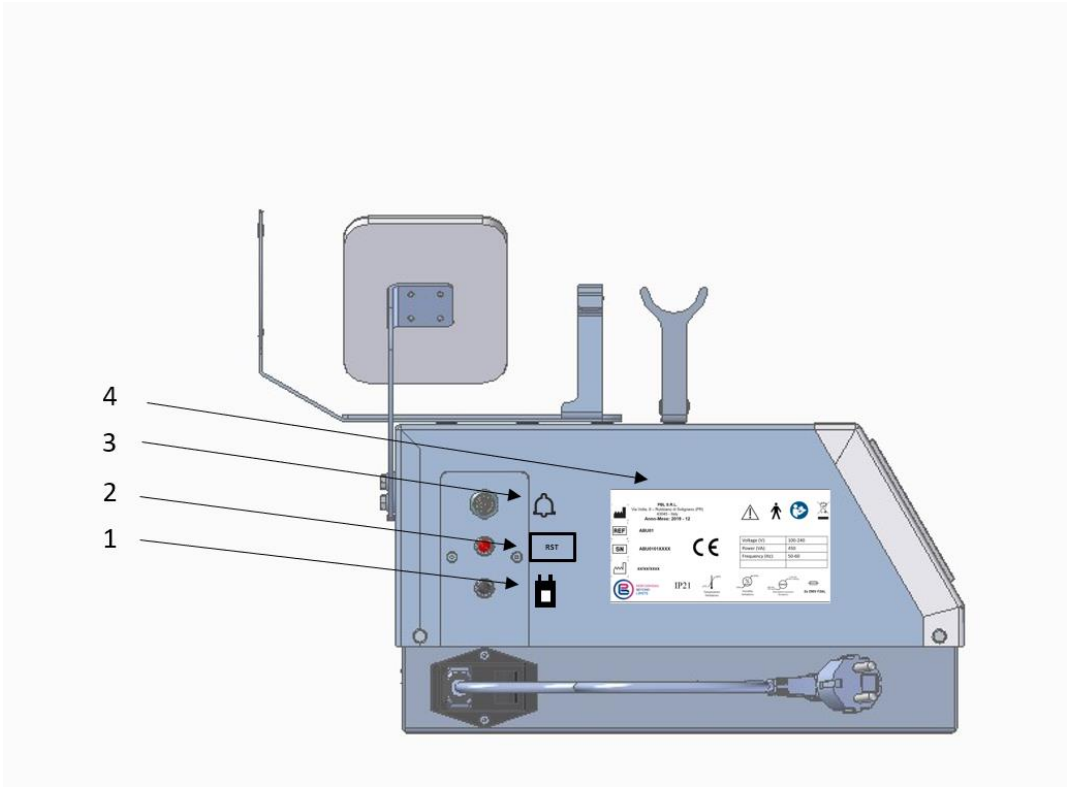


Figure 1.7. Locations of labels on the left side of the ventilator.

1. Battery Start Button	2. Reset Touchscreen Button
3. Distribute Alarm System Connection Port	4. Main Label

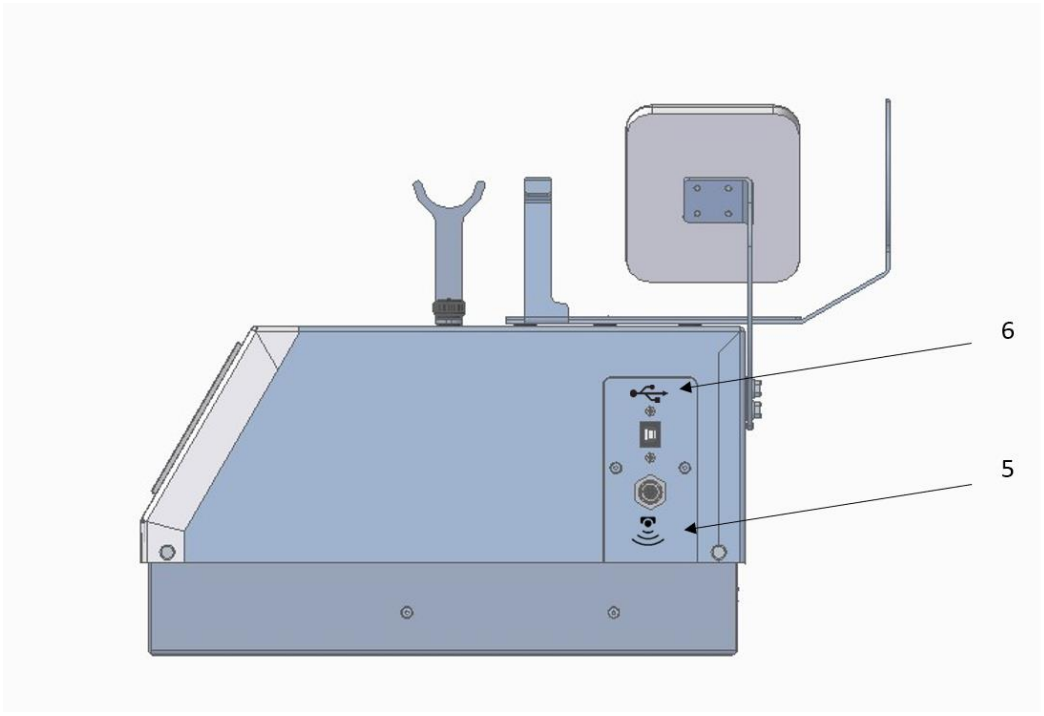


Figure 1.8. Label positions on the right side of the ventilator.

5. Sensor Cable Port	6. USB Port

2- Indications for Use

2.1 Intended Use

The ABU v01 is a medical device for the mechanical ventilation of adult patients. It is designed for invasive and non-invasive ventilation (NIV). ABU v01 provides both mandatory and assisted ventilation modes. ABU v01 shall not be used with paediatric patients.

2.2 Indications for use and contraindications

Indications
ABU v01 is intended for treating patients who require temporary or longer-term respiratory support for different medical reasons.

Contraindications
There are no additional contraindications a part from the contraindications contained in chapter 1, “General Safety Information”.

It is the responsibility of the user to select the appropriate respiratory mode and setting the proper ventilation parameters and alarm conditions for the underlying disease of the patient. For all possible combinations of ventilatory settings, the user needs to take into account the respiratory status and the general state of health of the patient in order to adapt the settings to the patient’s conditions. Any changes to the patient’s condition need to be monitored continuously.

2.3 Users

The ventilator may be operated by the following type of users:

- Doctors
- Authorized nurses
- Authorized healthcare professionals

2.4 Environment of use

ABU v01 is intended for stationary use in Intensive Care Units.
Do not use the device in the following environments:

- Hyperbaric chambers
- Magnetic Resonance imaging facilities (MRI, NMR, NMI)
- In conjunction with flammable gases or flammable solutions that can mix with air, oxygen or nitrous oxide
- Oxygen rich environment
- In areas of explosion hazard
- In areas with combustible or explosive substances
- In rooms without sufficient ventilation

The device shall be operated only with room air or medical grade Oxygen.
Do not operate the device with helium or helium mixtures.

WARNING:
The ventilator shall be used only under the responsibility and on the prescription of a doctor or an authorized healthcare professional.

WARNING:
While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem., especially for ventilator-dependent patients.

WARNING:
To ensure that ventilation continues uninterrupted ensure alternative power sources are available (AC power source, extra batteries). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use—particularly for ventilator-dependent patients.

WARNING:
Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

WARNING:
The ventilator shall not be used with flammable anaesthetic substances.

WARNING:
Users shall always possess an additional breathing circuit while using the ABU v01 ventilator.

WARNING:
Even though the ABU v01 ventilator meets current safety standards according to IEC 60601-1-1 and ISO 80601-2-12, ABU v01 requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, "Specifications." In particular, the use of nearby mobile and portable communications equipment using radio frequencies (RF), such as mobile telephones or other systems exceeding the levels set in the IEC 60601-1-2 standard, may affect its operation. Refer to section A.8, "Manufacturer's Declaration." Ensure that other medical electrical devices are used no closer than 30 cm (12 inches) to any part of the ABU v01 ventilator, including cables specified by the manufacturer.

WARNING:
The use of any accessory other than those specified, with the exception of the power supplies or cables sold by P.B.L., may lead to an increase in electromagnetic emissions or a decrease in the equipment protection against electromagnetic emissions. If the ventilator is used adjacent to such accessories or stacked with such devices, the ventilator's performance should be monitored to verify normal operation.

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

3 – ABU v01 Overview

~~Developed by P.B.L. at the beginning of the pandemic due to the spread of the coronavirus called Covid-19 in Italy, ABU v01 is a cheap and simple ICU ventilator. Since then, ABU has been the object of great interest and appreciation by a large number of doctors and hospital managers globally.~~

~~Given the simple, but effective, functionality of the device, low cost and ease of large-scale production, P.B.L. SRL has been working since March 2020 with representatives of the Italian government and local realities to start, through the procedure called 'compassionate use', the trial of the device on patients affected by Covid-19 who need mechanical ventilation. This has allowed the device to be used, exceptionally, both on patients affected by Covid-19 and on healthy subjects, demonstrating the ability of ABU to make up for the lack of standard mechanical ventilators with excellent results.~~

ABU v01 ventilator is the result of the combination of an electromechanical mechanism and a manual ventilation system with certified expandable balloon (i.e., Bag-mask valve) and equipped with appropriate safety mechanisms such as overpressure valves and dedicated sensors.

ABU v01 ventilator shall only be used by qualified medical personnel and emergency personnel with knowledge of pulmonary ventilation and advanced cardiac resuscitation techniques. Only personnel trained in the use of ABU may use this device.
Under no circumstances shall ABU ventilator be disassembled, tampered with or otherwise modified except by technical specified also previously.

WARNING:
Any unauthorized violation of the product could render it unusable or defective, exposing to high risks patient's life.

WARNING:
Never use a ventilator or any components or accessories that appear to be damaged.

WARNING:
To ensure proper servicing and avoid the possibility of physical injury to personnel or damage to the ventilator, only personnel authorized and qualified by P.B.L. should attempt to service or make authorized modifications to the ABU v01 ventilator.

WARNING:
If you cannot determine the cause of a problem with your ventilator, contact your equipment supplier. Do not use the ventilator until the problem has been corrected.

3.1 ABU v01 device description

ABU is a medical device, able to transform a traditional AMBU (Artificial Manual Breathing Unit) or, more in general, a bag-valve mask (BVM) system, into a mechanical ventilator through the use of both air flow and differential pressure sensors and a high precision electronic feedback system.

The device is able to automate the processes of **mandatory and assisted ventilation**, operating, through a mechanical mechanism, the expandable balloon that makes up the BVM system without the help of the health care worker.

The ABU allows you to **electronically monitor** the following clinical parameters.

1. Peak Inspiratory Pressure (PIP), which, according to EN 80601-2-12 clause 201.7.9.2.9.101 – a, is referred to P_{WMAX}
2. Plateau Pressure, which, according to EN 80601-2-12 clause 201.7.9.2.9.101 – a, is referred to P_{LIM}
3. Air flow
4. Respiratory frequency
5. Inspiratory Tidal Volume (Volume IN)
6. Expiratory Tidal Volume (Volume OUT)
7. Ratio between inhalation and exhalation time (I:E Ratio)
8. Positive End Expiratory Pressure (PEEP)
9. Pulmonary Compliance
10. Driving Pressure
11. Leak Percentage

High pressure risk is also minimized by the use of BVM based on certified expandable balloons equipped with a safety overpressure valve.

3.2 Device Classification

The ventilator's IEC/EN 60601-1 classification is as follows:

- Protection/Insulation class (electric shock): Class II
- Protection index of enclosure: IP21
- Medical Device Directive (i.e., Directive 93/42/EEC and amendment 2007/47/EC)): II B
- Degree of protection against risk of electric shock: B
- Power: External (AC-mains) or Internal (DC-battery)
- Operation mode: Continuous

For additional information, see Appendix A, "Specifications".

3.3 ABU v01 - Front Panel

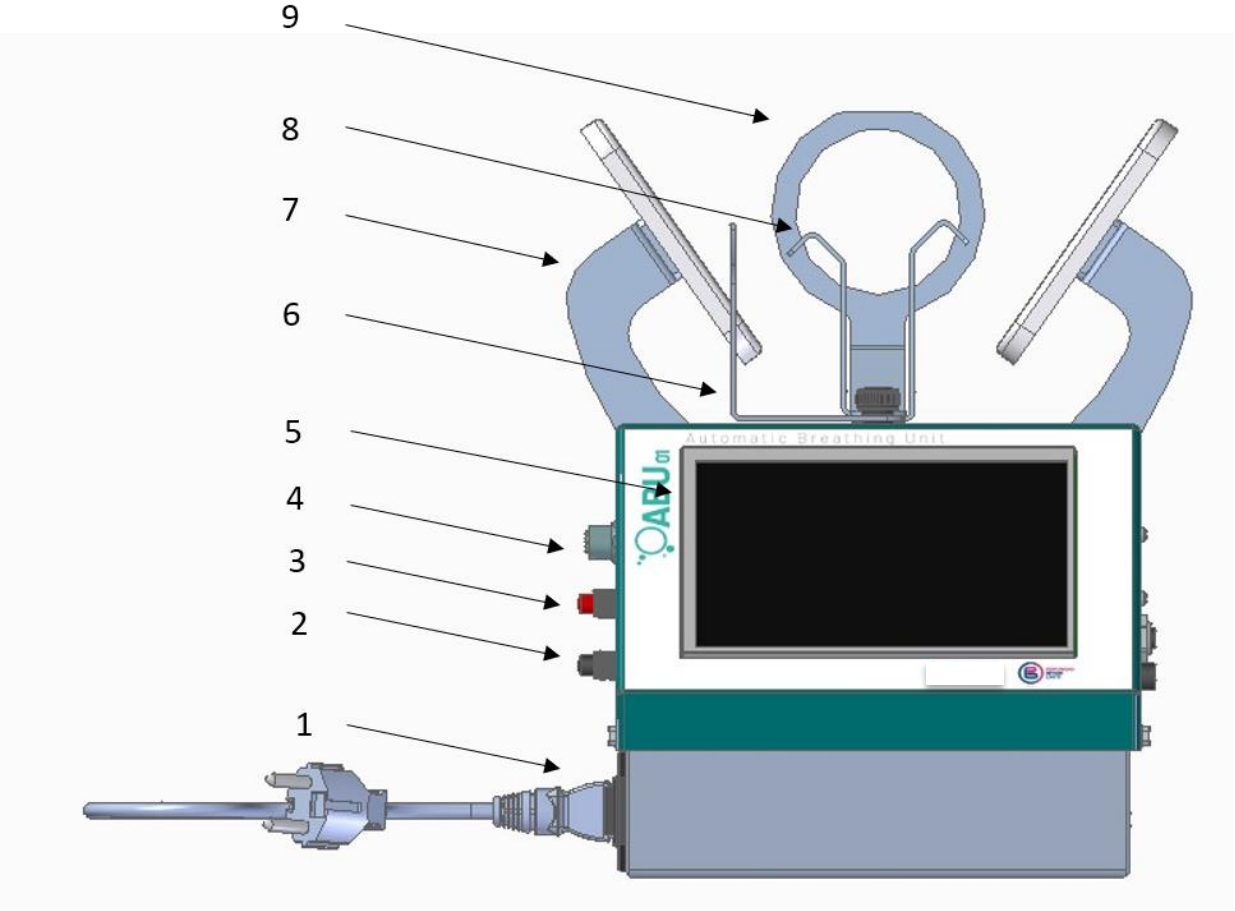


Figure 3.1. Ventilator Front-side view.

1. On/Off (I/O) switch. Device powered on in position I; while on position 0, the main power supply is excluded and the ventilator is either switched off or working on battery mode.	2. Battery Start Button. ABU will be switched on in battery mode by pressing and holding this button for more than 2 seconds.
3. Reset touchscreen button. By pressing this button, the touchscreen can be reset without stopping the ventilation, in case of jamming of the touchscreen.	4. Distributed Alarm System Connection Port. Through this connector it is possible to attach the ventilator to a distributed alarm system. To do so, an M12 4 poles male connector is required.
5. Touchscreen. It displays information about the ventilator including software version, manufacturer, ventilation modes and settings, monitored ventilation parameters and waveforms, and alarms.	6. Hose holder. Hose exiting the BVM balloon can be laid down on it.
7. Mechanical arm of the gripper. This pair of components are actuated by a stepper motor in order to compress and release the BVM balloon during ventilation.	8. BVM balloon front holder. This component allows to place and secure the BMV balloon on its patient's side (side where airflow generated by the compression of the balloon exits)
9. BVM balloon back holder. This component hosts the opposite side of the BVM balloon with respect to the side secured by component 8.	

3.4 ABU v01 - Back Panel

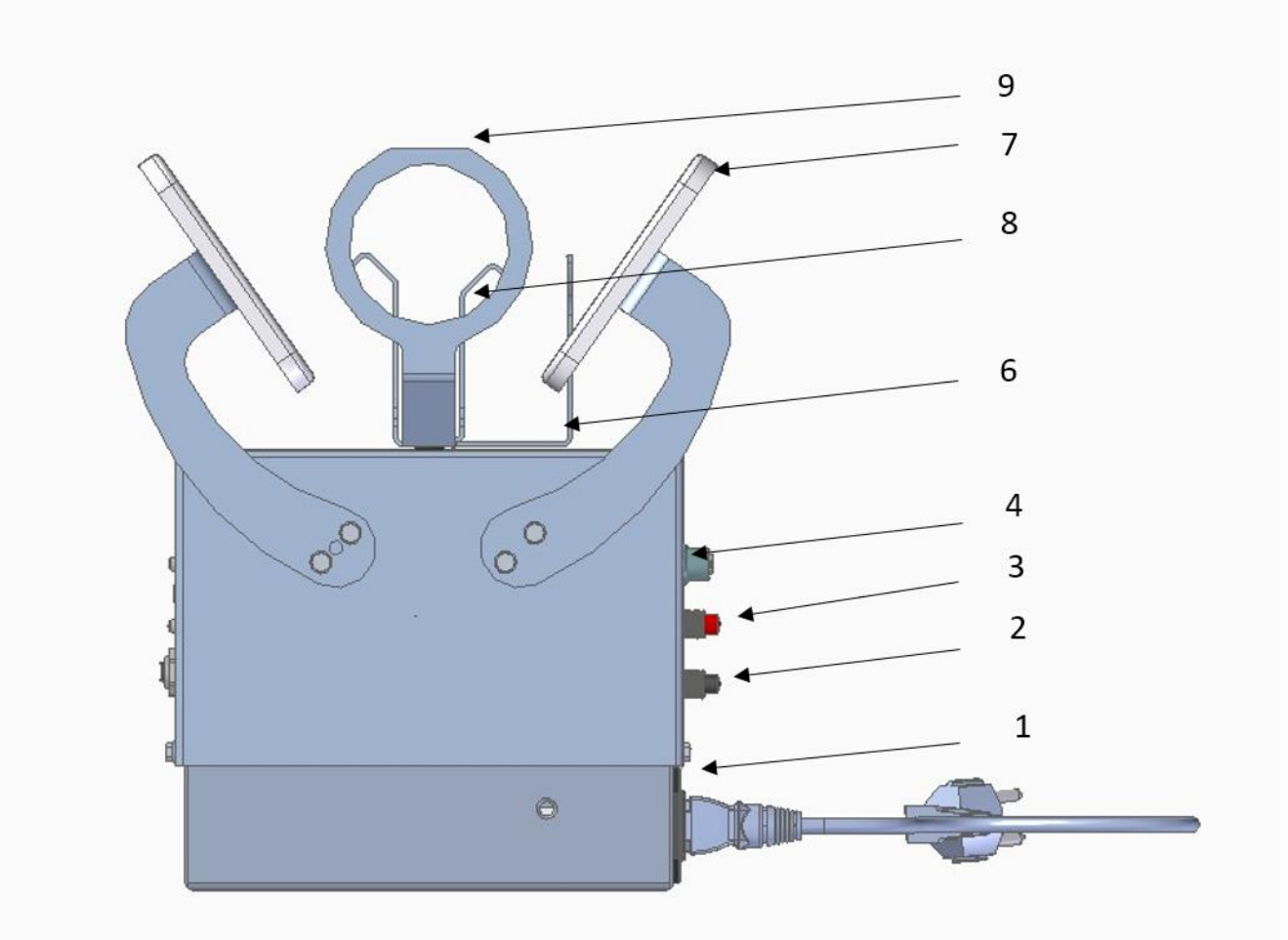


Figure 3.2. Ventilator Back side.

3.5 ABU v01 - Right-side Panel

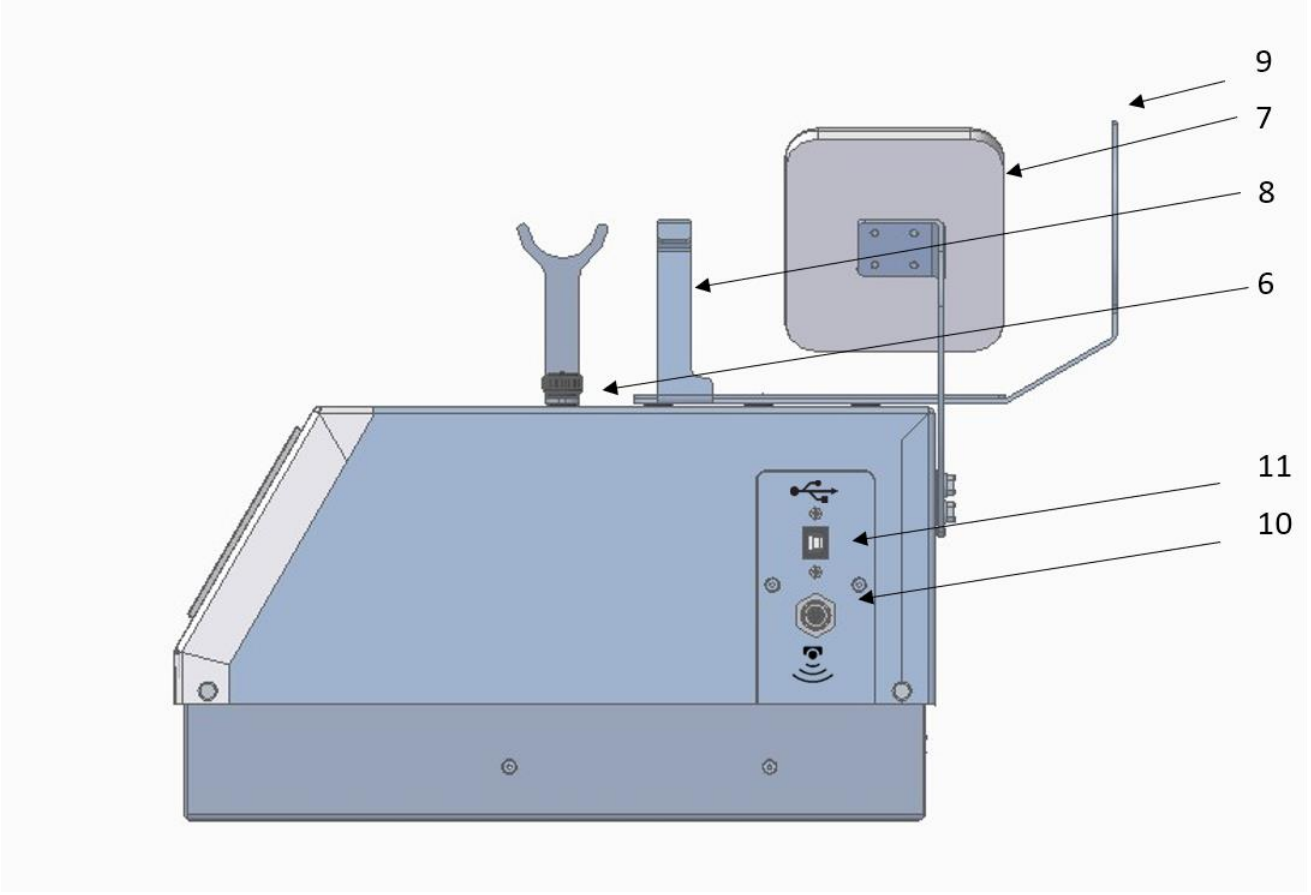


Figure 3.3. Ventilator right side.

10. Sensor Pack Cable Port. This port connects the ventilator to the sensor pack (Figure 3.5). It is a M12 8 poles female connector type, while the sensor pack cable is built with s a M12 8 poles male connector type.	11. ABU USB port. This is a USB type B port that allows for the connection of the ventilator with a computer in order for the user to download ventilation parameters, alarms and events logs.

3.6 ABU v01 - Left-side Panel

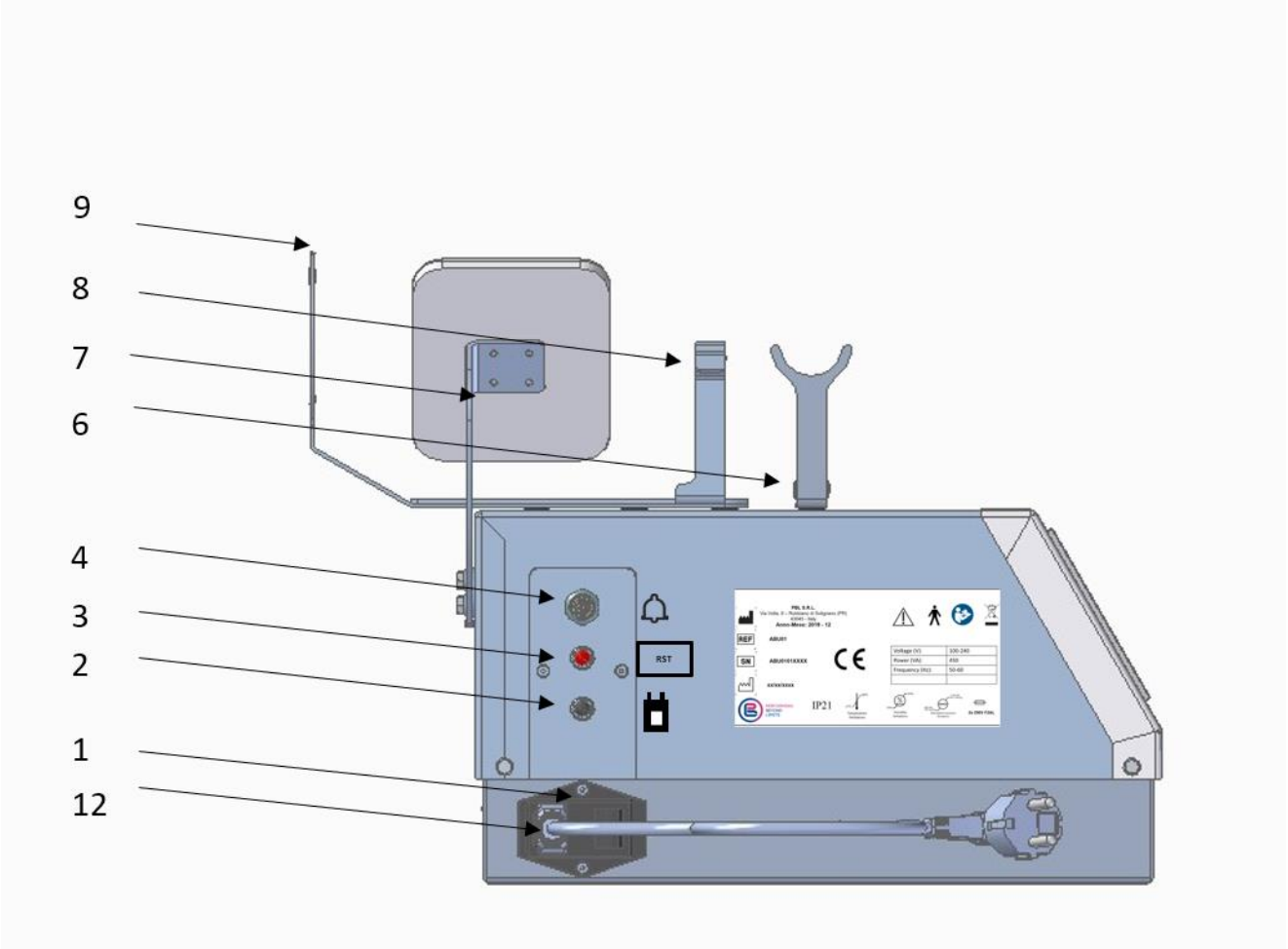


Figure 3.4. Ventilator left side.

12. AC power cable connector, to connect the device to an external power source.

3.7 ABU v01 – Breathing Circuit

The breathing circuit of ABU v01 consists of a standard BMV (from now on named ABU balloon) circuit for manual ventilation plus the ABU v01 sensor pack that allows to measure, and thus control, airways pressure and flows. Below, the details of the components.

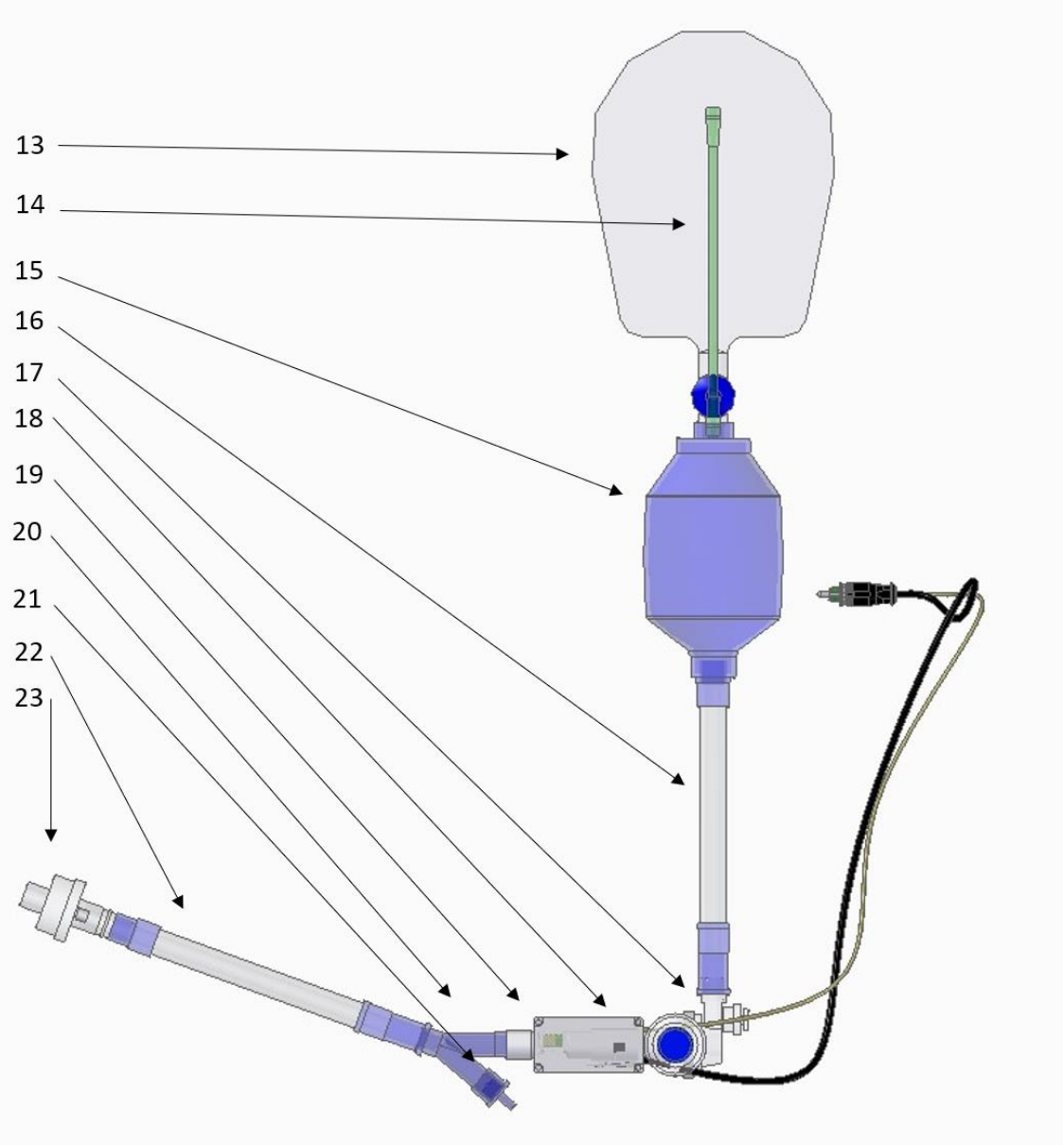


Figure 3.5. ABU Breathing circuit view from above.

13. ABU Reservoir sack. It allows oxygen enrichment. It is commonly used in BVM system	14. Oxygen pipe. This is a standard, usually green, pipe that allows to connect BVM or ABU v01 to an oxygen supply or an oxygen blender.
15. ABU balloon. This is a BVM balloon for manual ventilation that, in this context, it is compressed and released by the mechanical grippers of ABU v01 ventilator.	16. Standard, disposable breathing hose commonly used in combination with mechanical ventilators. It allows to connect ABU balloon to the check valve (17).
17. ABU check valve. This is a 3-way valve that is normally used in MVB ventilation system.	18. ABU sensor pack. It contains the bidirectional flow sensor, the differential pressure sensor

<table>
<tr><td>It is defined as a 3-way valve since it allows airflow coming from ABU balloon to pass through it and it deviates the airflow coming from the patient towards the ABU PEEP valve (22). It is also equipped with safe overpressure valve that opens up and releases air into the atmosphere when airways pressure reaches a value higher than 60 cmH_2O in order to avoid patient's airways damages.</td><td>and their relative control electronics. It is equipped with a cable that has to be inserted into the sensor cable port (10). It is equipped with cables that have to be connected to the ventilator through dedicated ports.</td></tr>
<tr><td>19. ABU sensor Y-connector fitting. This plastic component allows to connect the ABU sensor pack to the ABU Y-connector (20).</td><td>20. ABU Y-connector. This Y-shaped plastic connector allows to insert fresh air in case air leakages during non-invasive ventilation are too high. It presents 3 openings: the one on the left (considering its orientation in Figure 3.5) has to be connected to a patient-ventilator interface system or a filter or another hose, while the port on the upper right (considering the orientation of the component in figure 3.5) must be connected to the ABU sensor pack (18) and, the other openings that contains a one-way valve (21) that allows air to enter the breathing circuit but not to leave it, can be connected to a medical grade oxygen supply or oxygen blender. If no additional airflow is required, ABU Y-connector can be ignored and not installed.</td></tr>
<tr><td>21. ABU Y-connector one-way valve. This one-way valve is inserted in the free openings of the ABU Y-connector (20) in such an orientation that would allow air to enter the breathing circuit (if required) but not to leave it.</td><td>22. Standard, disposable breathing hose commonly used in combination with mechanical ventilators. It allows to connect ABU Y-connector or ABU sensor pack, if the ANU Y-connector is not used, to a filter, a patient-ventilator interface or any kind of additional component that can be connected to it.</td></tr>
<tr><td colspan="2">23. Disposable antiviral/antibacterial filter. This is a common filter used with mechanical ventilators in order to filter and block pathogens contained in the airflow sent to the patient.</td></tr>
</table>

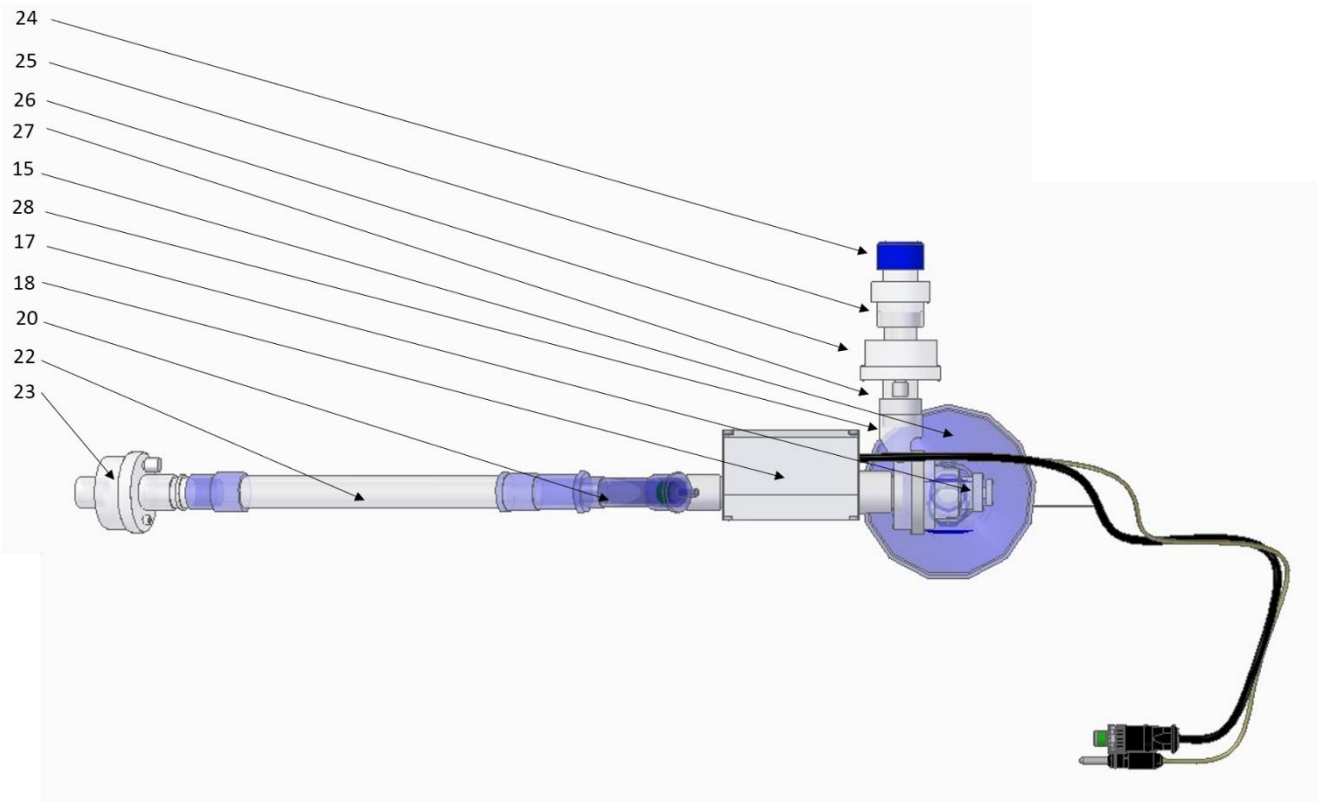


Figure 3.6. ABU Breathing circuit side view.

24. ABU PEEP valve. This is a mechanical valve that if turned clockwise it allows to increase PEEP value and, if turned anti-clockwise, it allows to decrease PEEP value.	25. ABU PEEP-filter fitting. This plastic component allows to connect ABU PEEP valve (24) with a disposable antiviral/antibacterial filter (25)
26. Disposable antiviral/antibacterial filter. This is a common filter used with mechanical ventilator in order to filter as much as possible airflow exhaled from the patient and sent to the atmosphere.	27. ABU filter-PEEP adapter. This plastic component allows to connect to ABU PEEP adapter (28) a disposable antiviral/antibacterial filter (26)
28. ABU PEEP adapter. This plastic component allows to connect the ABU check valve (17) to ABU PEEP valve or ABU PEEP-filter fitting. It is equipped with a rubber gasket that avoid any air leakage at the its junction with ABU check valve.	

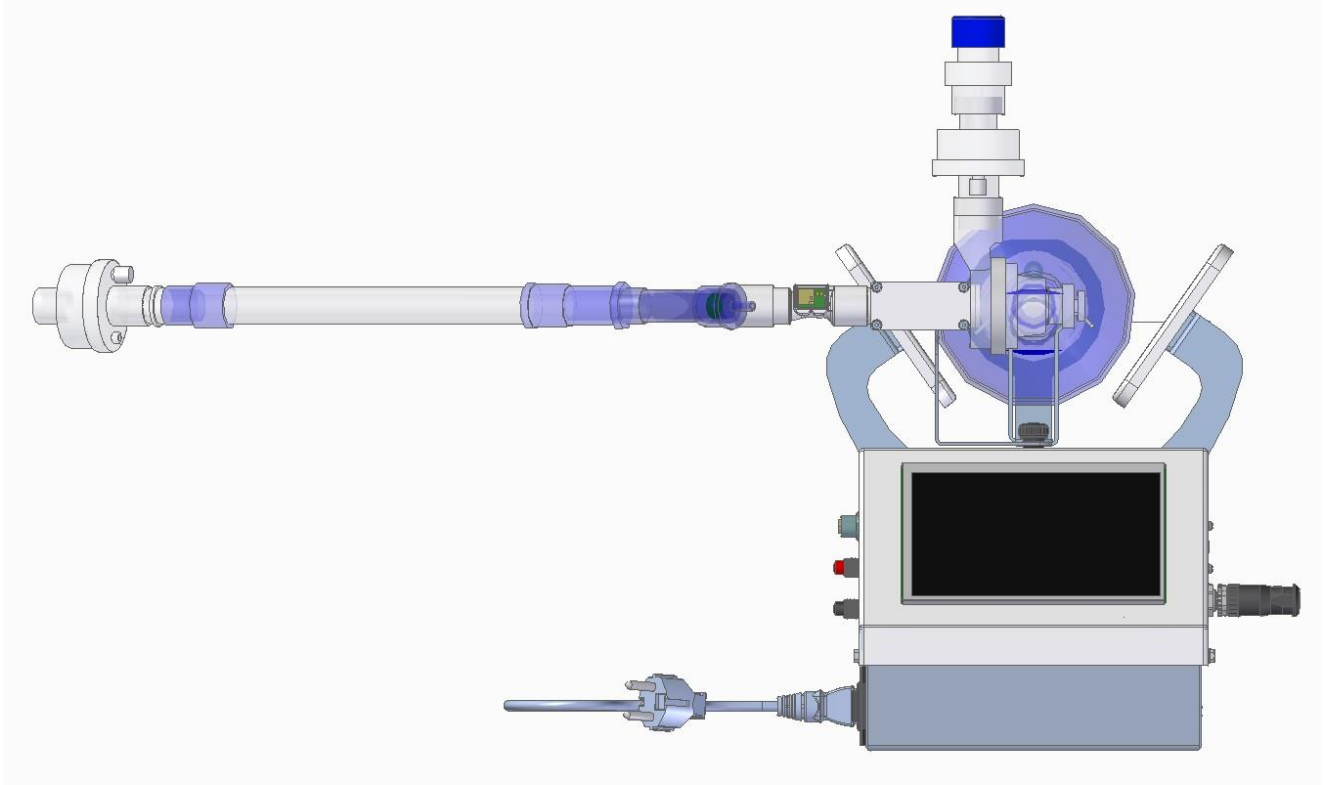


Figure 3.7. ABU v01 ensemble.

AS explained in section 4.3, “Mounting the device”, ABU breathing circuit must be placed with ABU balloon between the mechanical grippers of ABU ventilator with the sensor cable connect in order for the ventilator to operate.

4 – Installation and Assembly

WARNING:
Before operating the ventilator, read, understand, and strictly follow the information contained in chapter 1, "General Safety Information".

WARNING:
A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet port is recommended.

To install your ABU v01 ventilator:

1. Choose an area where air can circulate freely. Avoid proximity to loose fabrics, such as curtains, and direct exposure to sunlight.
2. Set the ventilator on a flat and stable surface so that its basement is all in contact with the surface. Make sure that air inlets are not obstructed and the device cannot fall and possibly cause damage and/or personal injury.

WARNING:
The user should connect the ventilator to an AC power source whenever available, for safer operation.

WARNING:
To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (main inlet or cooling) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.

WARNING:
Do not place the ventilator in a position where a child can reach it or in any position that might cause it to fall on the patient or someone else.

WARNING:
Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.

WARNING:
Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.

WARNING:
If the ambient temperature where the device is operated is greater than 35 °C (95 °F), the flow supplied at the device outlet may exceed 41 °C (106 °F). This may lead to undesirable side effects for the patient. To avoid injury to the patient, move the patient and the ventilator to a cooler location. For more information, contact P.B.L. or local supplier.

WARNING:
To reduce the risk of fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.

WARNING:
Never connect your ventilator to an electrical outlet controlled by a wall switch because the power may be inadvertently turned off.

WARNING:
Even if the "Battery Charge Qualitative Status" indicator is off, charging of the battery may sometimes be incomplete if the ambient temperature is above 40 °C (104 °F) because of the battery's physical limitations.

WARNING:
The use of any accessory other than those specified, with the exception of the power supplies or cables sold by P.B.L., may lead to an increase in electromagnetic emissions or a decrease in the equipment protection against electromagnetic emissions. If the ventilator is used adjacent to such accessories or stacked with such devices, the ventilator's performance should be monitored to verify normal operation.

WARNINGS:
Even though the ABU v01 ventilator meets current safety standards according to IEC 60601-1-1 and ISO 80601-2-12, ABU v01 requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, "Specifications." In particular, the use of nearby mobile and portable communications equipment using radio frequencies (RF), such as mobile telephones or other systems exceeding the levels set in the IEC 60601-1-2 standard, may affect its operation. Refer to section A.8, "Manufacturer's Declaration." Ensure that other medical electrical devices are used no closer than 30 cm (12 inches) to any part of the ABU v01 ventilator, including cables specified by the manufacturer.

WARNING:
The ventilator must not use, nor be connected to, any anti-static or electrically conductive hoses, tubing, or conduits.

4.1 Connection to External AC Power

WARNING:
Never connect the ventilator to the patient or ventilate the patient without having previously read these instructions for use.

WARNINNG:
The user should connect the ventilator to an AC power source socket equipped with a good earth connection.

WARNING:
The power supply to which the ventilator is connected (AC) must comply with all applicable standards and provide electrical power corresponding to the voltage characteristics inscribed on the side of the ventilator to ensure correct operation. Refer also to the electrical specifications found in Appendix A, section A.2, "Electrical".

WARNING:
Ensure that the AC power cable is in perfect condition and not compressed. The device should not be turned on if the AC power cable is damaged.

WARNING:
Connect the external electrical power source by first connecting the power cable to the ventilator and then to the external power source. Follow the reverse procedure to disconnect the device from electrical power sources.

WARNING:
Do not leave power cables lying on the ground where they may pose a hazard.

AC Power source must respect the requirements reported on the main label of the ventilator (Figure 1.1) or in section A.2, "Electrical".

To connect the AC power cable:

1- Connect the female end of the ventilator's AC power cable to the AC connector on the left side of the ventilator (Figure 4.1).

Figure 4.1. Connecting the AC power cable to the ventilator.

2- Connect the male end of the AC power cable to the AC power outlet.

If the AC power cable becomes disconnected or AC power source fails, a “Main Power Supply” alarm starts the internal battery operation mode of the device.

To disconnect the AC power cable:

1- Disconnect the AC power cable from the AC power outlet.
2- Disconnect the AC power cable from the ventilator’s AC connector on the left side of the device.

Note:
When the ventilator is working with its internal battery, it will automatically send a medium priority “Main Supply” alarm. On the Main page of its touchscreen the symbol of battery status will appear and it will disappear when AC power supply comes back.

4.2 Internal Battery

WARNINGS:
Even though the ABU v01 ventilator meets current safety standards according to IEC 60601-1-1 and ISO 80601-2-12, ABU v01 requires special precautions for electromagnetic compatibility and should be installed and started according to the recommendations found in Appendix A, “Specifications.” In particular, the use of nearby mobile and portable communications equipment using radio frequencies (RF), such as mobile telephones or other systems exceeding the levels set in the IEC 60601-1-2 standard, may affect its operation. Refer to section A.8, “Manufacturer’s Declaration.” Ensure that other medical electrical devices are used no closer than 30 cm (12 inches) to any part of the ABU v01 ventilator, including cables specified by the manufacturer.

WARNING:
The maximum recommended shelf life of the internal battery is two (2) years. Do not use a battery that has been stored for two years prior to its first use.

WARNING:
Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for periods longer than seven (7) days, without recharging, as this may reduce the maximum life and the amount of stored energy available in case of immediate and unexpected use.

WARNING:
Ensure that the ventilator’s internal battery is fully charged before connecting the ventilator to a patient. Connecting the ventilator to the AC (“mains”) power supply without turning the ventilator on, does not enable its internal battery to recharge.

WARNING:
Due to its limited internal battery's reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.

WARNING:
Even if the "Battery Charge Qualitative Status" indicator is off, charging of the battery may sometimes be incomplete if the ambient temperature is above 40 °C (104 °F) because of the battery's physical limitations.

WARNING:
When the "5 Mins. Battery remaining" alarm is triggered, immediately connect the ventilator to an AC power supply to maintain ventilation and recharge the internal battery

WARNING:
Before using the ventilator's internal battery, ensure that the battery is fully charged and that the charge holds. Back up ventilators or those in storage should be connected to an AC power source to protect the integrity of the battery. Please, be advised that to recharge the internal batteries of ABU v01, it is necessary to have it connected to the AC main supply and have it turned on with the main power supply switch on I position.

Note:
The ventilator is programmed to shut down when battery voltage reaches a value below 22 V.

Note:
Before battery voltage reaches its minimum allowed level, the ventilator will send to the operator two high priority alarms: the first when 10 minutes of internal energy are left, the second when 5 minutes of battery energy are left

Note:
The ventilator, when connected to an AC power supply, will recharge its internal battery if the battery voltage is below 26,5 Volts and will stop the recharge when it reaches 27 Volts.

Note:
When the ventilator is completely stopped and turned off, but still connected to the AC power supply, the internal battery will not be charging. In order to charge internal battery, the ventilator must be connected to the AC power supply and turned on with the I/O switch set to I position.

4.2.1 Battery Capacity and Charging

The reserve capacity offered by the internal battery depends on the level of the ventilator parameters, the environmental conditions (primarily in terms of temperature) and the physiological characteristics of the patient.

With a fully charged battery at a normal room temperature of 25 °C (± 5 °C), the ventilator can be expected to operate on internal battery power for the average durations shown in Table 4.1.
Checking the battery charge level does not require that the ventilator be running on battery power at the time of the battery check. To check the battery charge level, simply read the voltage battery value on the bottom-right corner of the Setup page and check if the SH6 relay status is on 'ON' status (i.e., battery charging in progress, if AC power supply is available) or 'OFF' status (i.e., battery charge completed). See Figure 4.2 below.

Figure 4.2. Battery relay. The red square highlights the area where information regarding the battery status, while the green square shows if AC main supply is available and connected. The number contained in the red square on the left of 'SH6' shows the real-time value of the battery voltage, if SH6 is followed by the word 'ON', that means that battery is charging, but only if AC power supply is available and connected to the ventilator, while, when SH6 is followed by the word 'OFF', that means the battery is charged. The number contained in the green square instead, preceded by the writing "A0 IN Supply [V]:" expresses the DC voltage present on the internal motor: if this value is higher than 46 Volts, that means that AC power supply is connected and available to the ventilator.

1- When the ventilator is working with its internal battery, the display will be showing the 'Battery Charge Qualitative Status' bar on the left side of home page:

2- The ventilator can be turned on while it is connected to the AC power supply, simply by placing the on/off switch on I position.

Battery consumption conditions	Average operating time on internal battery Power[1]
Lowest energy consumption condition: Breathing frequency = 5 acts per minute I:E ratio = 1:1	1,5 hours
Highest energy consumption condition: Breathing frequency = 35 acts per minute I:E ratio = 1:4	40 minutes

Table 4.1. Average durations shown are with fully charged battery having less than 50 charge/recharge cycles.

Note:
At this point, if the ventilator is disconnected from the AC power supply or if this last fails, the internal battery will provide energy to the system preventing it from stopping. In addition, the ventilator can work on its internal battery if the on/off switch is placed on O position while ventilator is turned on and running.

3- The ventilator can also be turned on without AC power supply simply by pressing the black button identified by the following label for more than 2 seconds:

Figure 4.3. Press the Battery Start Button and hold it for more than 2 seconds to turn on the ventilator using its internal battery

4- To charge the device simply connect the AC power supply to the ventilator and to the AC power supply and place the on/off switch on position I.

Figure 4.4. Set the I/O switch to I position in order to turn on the ventilator using the external AC power supply

5- When the device is charging the SH6 relay indicator will be showing the 'ON' status and the "A0 IN Supply [V]:" (i.e., the voltage of the motor when AC power supply is present) is above 46 Volts.

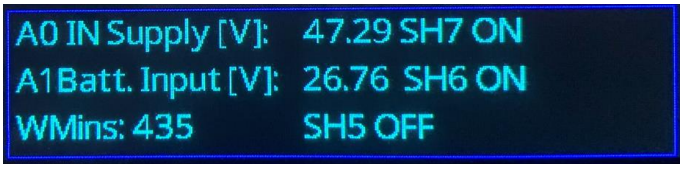


Figure 4.5 Information display by the ventilator when its internal battery is charging.

6- When the charging of the battery is over, the same SH6 relay indicator will be showing the 'OFF' status.

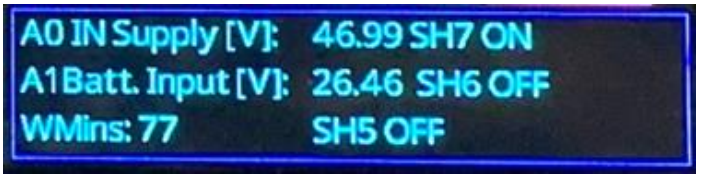


Figure 4.6 Information display by the ventilator when its internal battery is sufficiently charged.

CAUTION:
Notice that when SH6 shows the 'ON' status, but the "A0 IN Supply [V]:" shows a value below 46 Volts, it means that the ventilator is not charging because it is not connected to an AC power supply.

Note:
The ventilator works with 24 Volts internal battery; battery voltage can be monitored on the bottom-right side of the setup page, looking at the value displayed after the wording "A1 Batt. Input[V]:".

Note:
When the device is in storage it should be recharged monthly to maximize battery life.

Note:
If the battery is stored for more than one month at a temperature greater than 21 °C (70 °F), or for more than one or two weeks at a temperature greater than 45 °C (113 °F), the reserve capacity of the battery may be affected. It will then be necessary to recharge the battery before using it again.

Note:
If the ventilator has been in storage for longer than 30 days connect it to an AC power source, turn on the unit by the I/O switch at the rear of the ventilator, and let it charge for 15 minutes prior to starting ventilation.

Note:
Fully charge the internal battery prior to disconnecting from AC Power source (“mains”).

Note:
The battery should not be stored for more than two years, whatever the conditions.

4.2.2 Testing the Internal Battery

On a monthly basis you should disconnect the ventilator from the external AC power supply to check the integrity of the connections linking the internal battery to other ventilator components.

4.3 Mounting the device

WARNING:
Always position the ventilator in the orientation show in Figures 3.1, 3.2, 3.3, 3.4, meaning with the mechanical clamps facing upwards and the only completely flat surface touching the floor or the support plane.

WARNING:
Always make sure that the support plane can sustain more than 20 Kg for a long period of time that exceeds the duration of 4 or 5 weeks.

WARNING:
Never connect the ventilator to the patient or ventilate the patient without having previously read these instructions for use.

WARNING:
The ventilator shall be used only under the responsibility and on the prescription of a doctor or an authorized healthcare professional.

WARNING:
The ventilator shall be used according to its intended use. Refer to section 2.1, “Intended Use”

WARNING:
While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem, especially for ventilator-dependent patients.

WARNING:
Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

WARNING:
Ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.

WARNING:
Ventilator-dependent patient should always be monitored by trained and competent medical personnel. Ensure that the patient's caregiver is able and prepared to take suitable action in the event the ventilator identifies an alarmed condition or experiences a problem.

WARNING:
Do not use a patient circuit with a leak accessory for ventilator-dependent patients.

WARNING:
Do not perform ventilator alarm tests while the patient is connected to the ventilator. Provide the patient with an alternate means of ventilation before conducting these tests.

WARNING:
Verify the functionality of the alarm conditions before connecting the patient to the ventilator.

WARNING:
To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

WARNING:
A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet port is recommended.

WARNING:
Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.

WARNING:
Any violation of the product could render it unusable or defective, exposing to high risks patient's life.

WARNING:
If the ambient temperature where the device is operated is greater than 35 °C (95 °F), the flow supplied at the device outlet may exceed 41 °C (106 °F). This may lead to undesirable side effects for the patient. To avoid injury to the patient, move the patient and the ventilator to a cooler location. For more information, contact P.B.L. or local supplier.

WARNING:
Do not leave power cables lying on the ground where they may pose a hazard.

WARNING:
Do not operate the ventilator in direct sunlight, near heat sources, outdoors, or near installations where liquid may pose a risk without first providing adequate protection for the device.

WARNING:
Avoid using the ventilator, if possible, in dusty environments. Dusty environments may require more vigilant monitoring, cleaning, and/or replacement of air intake and other filters.

WARNING:
Ensure that the ventilator's immediate surroundings allow for the proper operational connection of the device without folding, pinching, or damaging any of the required cables or tubes, and that the connection of the patient circuit to the patient provides for a secure, comfortable fit.

WARNING:
Place the ventilator in a safe place when ventilating and according to the recommendations in this manual.

WARNING:
Do not place the ventilator in a position where a child can reach it or in any position that might cause it to fall on the patient or someone else.

WARNING:
To ensure correct and lasting operation of the ventilator, ensure that its air circulation holes (main inlet or cooling) are never obstructed. Place the device in an area where air can freely circulate around the ventilator and avoid installing it near floating fabrics, such as curtains.

WARNING:
If the ventilator has been transported or stored at a temperature that differs more than ±20 °C (± 36 °F) from the temperature in which it will be operating, the ventilator should be allowed to stabilize in its operating environment for at least one (1) hour prior to use.

WARNING:
If the ventilator has been transported or stored at humidity out of the range reported in Table A.9, the ventilator should be allowed to stabilize in its operating environment for at least one (1) hour prior to use.

WARNING:
Handle the ventilator with care during and after use, particularly when ambient temperatures are high. Some ventilator surfaces may become hot, even if safety specifications are not exceeded.

WARNING:
The ventilator should not be used adjacent to or stacked with other equipment, except as specified in this manual. If adjacent or stacked use is necessary, the ventilator should be observed to verify normal operation in the configuration in which it will be used.

WARNING:
The ventilator shall be placed in a position where its moving parts cannot hit accidentally the patient, the user or other persons.

WARNING:
Do not attempt to insert fingers or any part of the body inside the gaps of the ventilator.

WARNING:
Always use compatible power supply cable compliant with IEC 60320 C14 and with what decalred in section A.9, “Standards Compliance and IEC Classification”.

Below, detailed installation instructions for the ABU v01 ventilator are reported.

CAUTION:
It is important that the operator read this instruction manual and become familiar with the assembly of the essential components of the ABU v01 device in order to avoid situations in which doubts and uncertainties may result in a loss of time that could put the patient's safety at risk!

CAUTION:
Be aware that the combination of ABU v01 device with other medical devices is subject to the user's choice. This latter may only be represented by qualified medical personnel and emergency personnel with knowledge of pulmonary ventilation and advanced cardiac resuscitation techniques. Only personnel trained in the use of ABU v01 shall use this device.

Note:
ABU v01 ventilator can be assembled into 2 (two) different configurations:

- **Configuration with No Continuous Fresh air Flow (NCFF)**
- **Configuration with Continuous Fresh air Flow (CFF)**

Both configurations share common assembly steps and they differ only in the presence of the ABU Y-connector that allows to insert a continuous flow of fresh air that counteract excessive air losses especially when non-invasive ventilation modes are used such as BIPAP and CPAP.

In the following, a detailed description of the two possible mounting configurations is presented along with the ventilation modes allowed. For both mounting configurations refer to Figure 4.7 and the following table for a description of the components.

Figure 4.7: Description of the components.

ID	Number of components	Component
1	1	ABU v01 ventilator
2	1	IEC 60320 C14 – AC power cable
3	1	ABU balloon
4	1	Standard, disposable breathing hose
5	1	Fixing elastic
6	1	ABU Check-valve
7	1	ABU PEEP adapter
8	1	ABU filter-PEEP adapter
9	1	Disposable antiviral/antibacterial filter
10	1	ABU PEEP-filter adapter
11	1	ABU PEEP valve
12	1	ABU sensor pack
13	1	ABU sensor Y-connector fitting
14	1	ABU Y-connector
15	1	ABU Y-connector one-way valve
16	1	ABU Y-connector oxygen port
17	1	Standard, disposable breathing hose
18	1	Standard disposable breathing hose connector
19	1	ABU Reservoir sack
20	1	Oxygen pipe
21	1	ABU USB cable

4.4 - ABU v01: Configuration with No Continuous Fresh air Flow (NCFF)

CAUTION:

The configuration described below is suitable for the ventilation of patients with a small patient-ventilator interface type such as an endotracheal tube. In this configuration the Maximum inspiratory tidal volume that the ventilator can supply is 1.500 ml. This may not enough if the patient-ventilator interface shows higher volume leakages. For CPAP, BIPAP and similar types of ventilation that may involve more severe air leakages, the user is suggested to adopt the 'Configuration with Continuous Fresh-air Flow (CFF)" (see section 4.5, "ABU v01: Configuration with Continuous Fresh air Flow")

1- Connect the power cable to the AC port placed on the left side of the ventilator, as shown in Figure 4.8.

Figure 4.8. AC power cable connection to the AC power cable connector.

2- Place the ABU balloon (3) as shown in Figure 4.9.

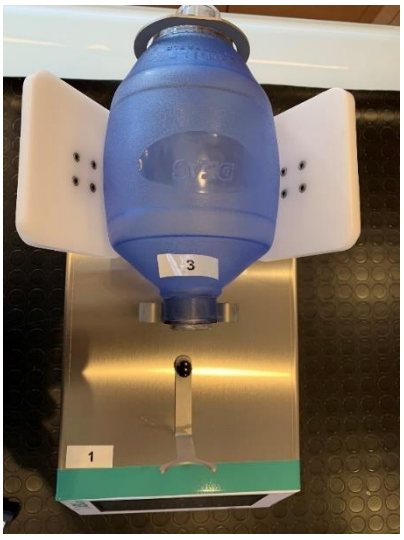


Figure 4.9: Positioning the ABU balloon.

3- Place the breathing hose (4) inside the ABU balloon (5) exit port as shown in Figure 4.10.

Figure 4.10: Breathing hose connection.

4- Attach the ABU balloon (3) to the ABU ventilator (1) using the fixing elastic (5) as shown in Figure 4.11.

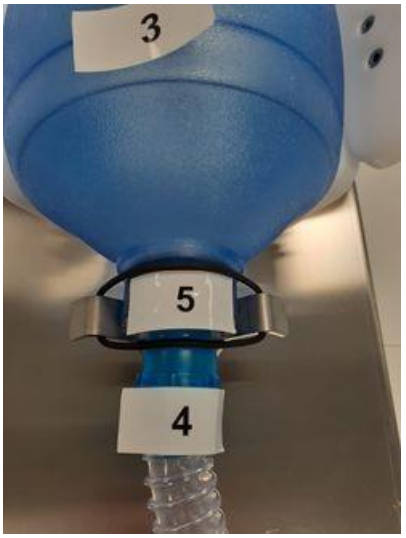


Figure 4.11: Attaching the AMBU balloon to the ABU ventilator.

5- Connect the first part of the ABU Check-valve (6) with the free end of the breathing hose (4) as shown in Figure 4.12.

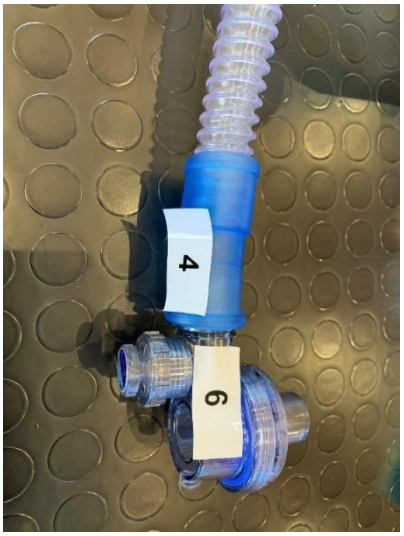


Figure 4.12: Connection of the ABU Check-valve to the breathing hose.

6- Add ABU Check-valve (6) with ABU PEEP adapter (7) (Figure 4.13). Make sure that the rubber part completely seals the joint.

Figure 4.13: Connection of the ABU Check-valve to PEEP adapter.

7- Connect the ABU filter-PEEP adapter (8) to the ABU PEEP adapter (7) as shown in Figure 4.14.

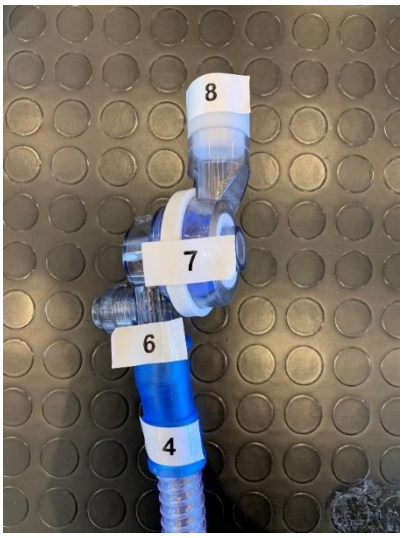


Figure 4.14: ABU PEEP valve group assembling part 1

8- Connect the disposable antiviral/antibacterial filter (9) to the ABU filter-PEEP adapter (8) as shown in Figure 4.15.

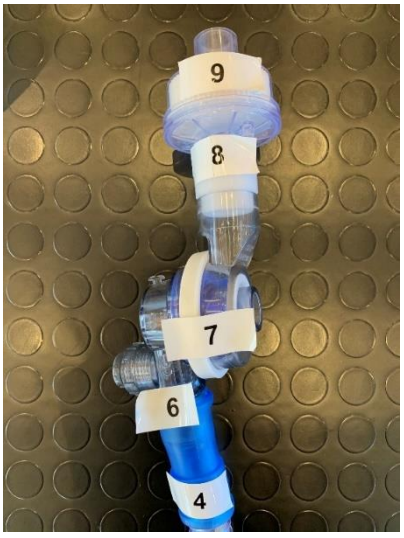


Figure 4.15: ABU PEEP valve group assembling part 2

9- Connect ABU PEEP-filter adapter (10) to the disposable antiviral/antibacterial filter (9) as shown in Figure 4.16.

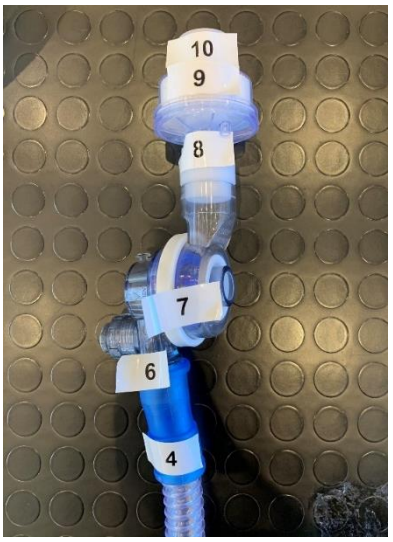


Figure 4.16: ABU PEEP valve group assembling part 3

10- Connect ABU PEEP-filter adapter (10) to the ABU PEEP valve (11) as shown in Figure 4.17.

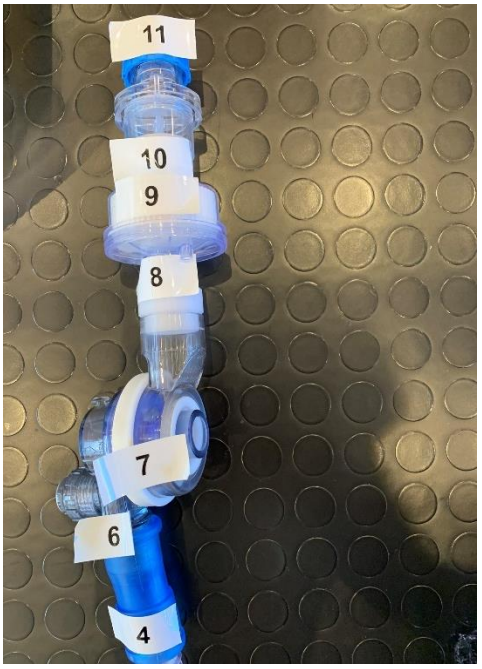


Figure 4.17: ABU PEEP valve group assembling part 4

11- Connect the ABU sensor pack (12) to the ABU check-valve (7) as shown in Figure (Figure 4.18). Be aware that the cable coming out of the ABU sensor pack must face the ABU check-valve as shown in Figure 4.18.

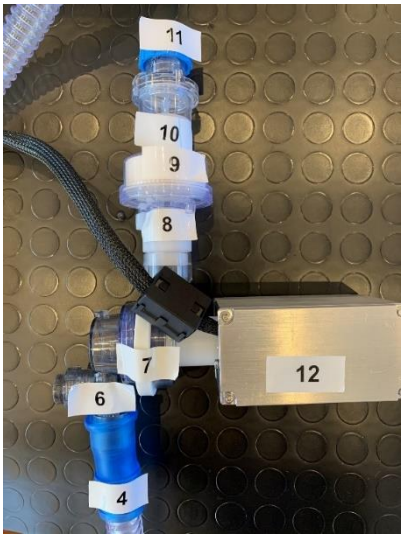


Figure 4.18: Connecting ABU sensor pack.

12- Connect the ABU sensor pack (12) cable to the sensor cable port as shown in Figure 4.19. To properly fix the connector to the ventilator, turn the ring placed on the sensor cable clockwise as far as it will go.

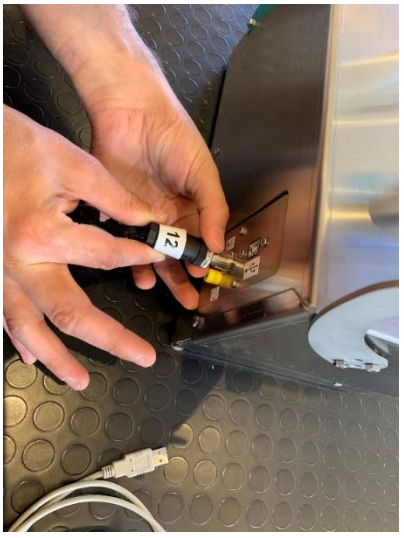


Figure 4.19: Connecting the ABU sensor pack cable to the ABU sensor pack cable port.

13- Connect the earth wire coming out of the ABU sensor (12)pack cable as shown in Figure 4.20.

Figure 4.20. Connection of the earth wire of the ABU sensor pack cable to the ABU ventilator.

14- To conclude, connect a second standard, disposable breathing hose (17) to the free end of the ABU sensor pack (12).

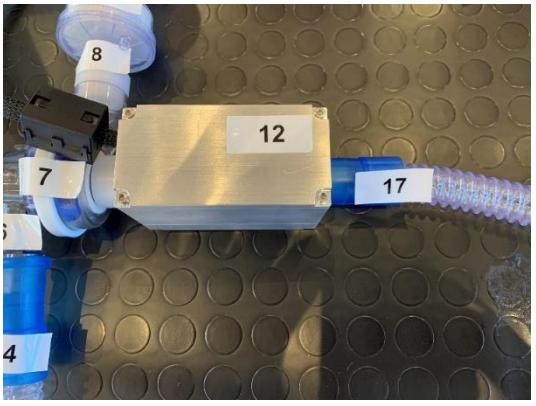


Figure 4.21. Connecting the ABU sensor pack to a standard disposable breathing hose.

Caution:
The user should consider to use a standard, disposable breathing hose (17) as short as possible, the air passing through it, will be the air exhaled by the patient that has not escaped the circuit through the PEEP valve during the previous breathing act. This causes a rebreathing of the air already breathed by the patient previously. The shortest the hose, the lowest the rebreathing effect.

15- If necessary, connect the free end of the standard, disposable breathing hose (17) to the standard disposable breathing hose connector (18), otherwise skip to next step (Figure 4.22).

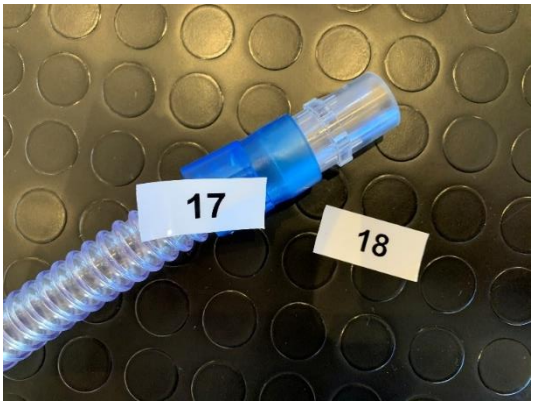


Figure 4.22. Connecting the standard disposable breathing hose connector to a standard disposable breathing hose.

Caution:
Always use a disposable antiviral/antibacterial filter placed between the disposable breathing hose and the patient-ventilator interface to avoid contamination with dirt and pathogens of the air breath by the patient.

16- If necessary, connect a patient-ventilator interface, provided it is certified as a medical device and compliant with ISO 5356-1:2004, to the standard disposable breathing hose connector mounted in the previous step (Figure 4.23).

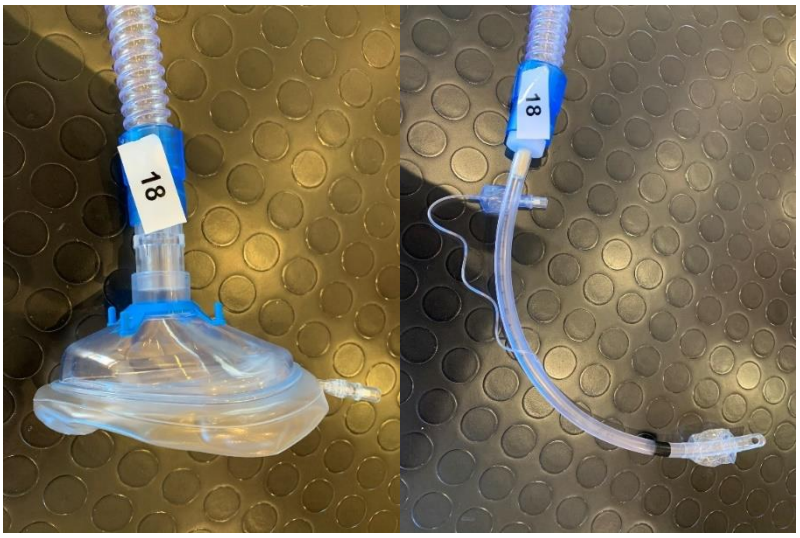


Figure 4.23 Connection of the standard disposable breathing hose of the ventilator to a patient-ventilator interface such as a mask (left) or endotracheal tube (right).

CAUTION:
The choice of the patient-ventilator interface depends on the authorized user's opinion and the patient's clinical needs.

4.5 - ABU v01: Configuration with Continuous Fresh-air Flow (CFF)

To install the ABU v01 ventilator in the CFF configuration, follow instructions 1 to 13 reported above in section 4.4. Once these steps (1 to 13) have been performed, please continue with the following steps.

17- Connect the ABU sensor Y-connector fitting (13) to the ABU sensor pack (12) as shown in Figure 4.24. Be aware that the ABU sensor Y-connector fitting (13) can only be inserted on the free end of the ABU sensor pack (Figure 4.14).

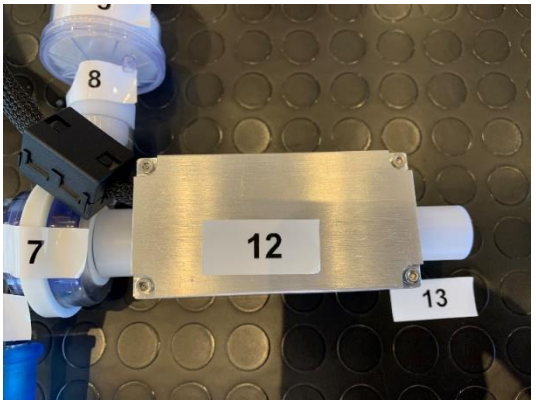


Figure 4.24: Connection of ABU sensor Y-connector fitting to the ABU Sensor Pack.

18- Take the ABU Y-connector (14), the ABU Y-connector one-way valve (15) and the ABU Y-connector oxygen port (16) (Figure 4.15).

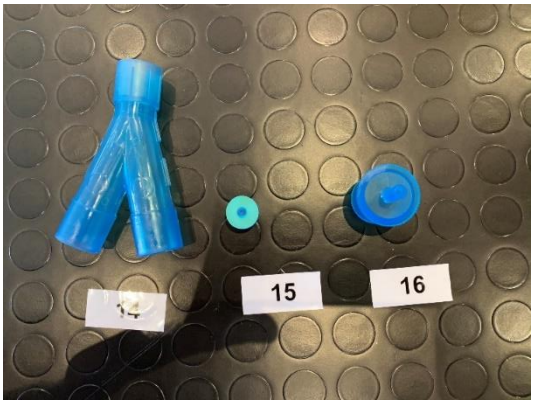


Figure 4.25: Assembling the ABU Y-connector part 1

19- Insert, in the right direction shown in Figure 4.25, the ABU Y-connector one-way valve (15) into one of the free openings of the ABU Y-connector (14) as shown in Figure 4.26.

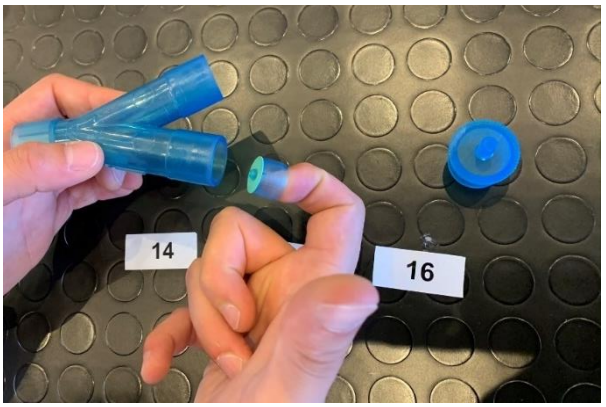


Figure 4.26: Assembling the ABU Y-connector part 2

20- Push the ABU Y-connector one-way valve (15) as far as possible inside the ABU Y-connector (14). See Figure 4.27.

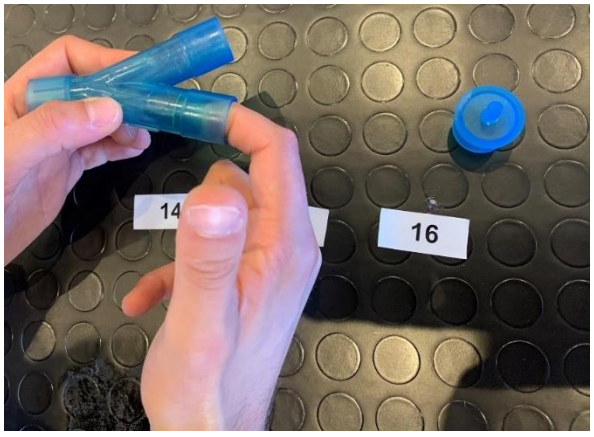


Figure 4.27: Assembling the ABU Y-connector part 3

21- Insert the ABU Y-connector oxygen port (16) on the openings of the ABU Y-connector (14), containing the one-way valve (15) (Figure 4.28).

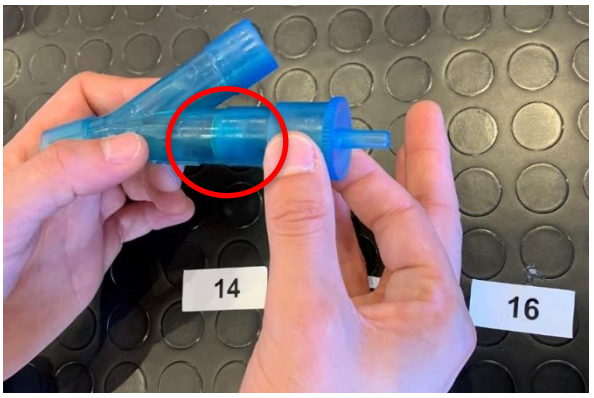


Figure 4.28. Assembling the ABU Y-connector part 4. See the position of the ABU Y-connector one-way valve (15) with respect to the ABU Y-connector oxygen port (16) (Red circle).

22- Connect the ABU Y-connector ensemble (14-15-16) to the ABU sensor Y-connector fitting (13), as shown in Figure 4.29.

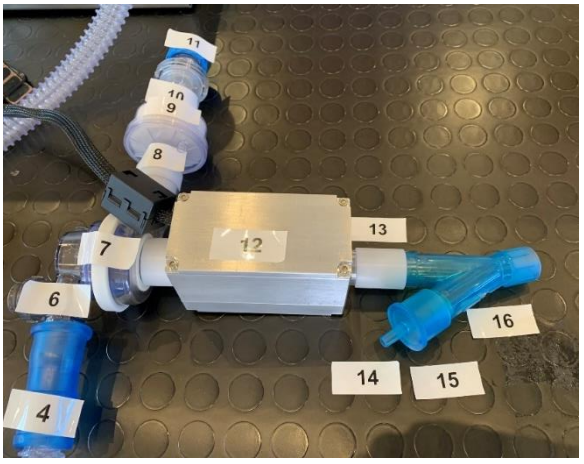


Figure 4.29: Connecting the ABU Y-connector ensemble (14-15-16) to the ABU sensor Y-connector fitting (13).

23- Connect a second standard, disposable breathing hose (17) to the ABU Y-connector ensemble (14-15-16) as shown in Figure 4.30.

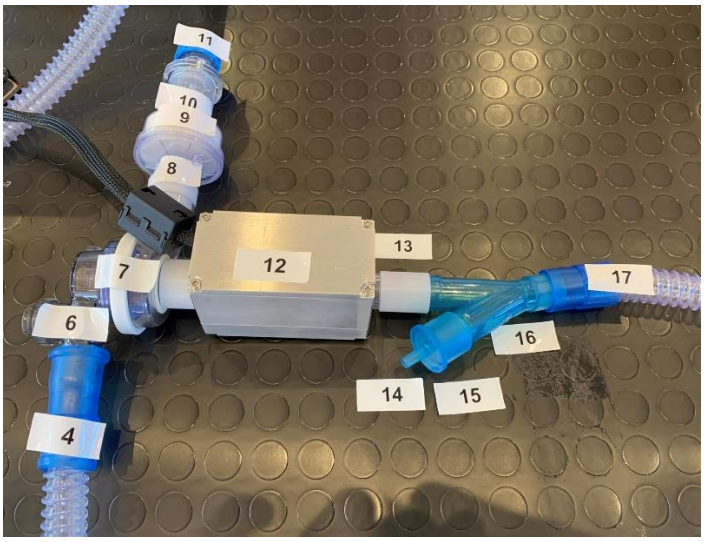


Figure 4.30. Connecting a standard disposable breathing hose (17) to the ABU Y-connector ensemble (14-15-16).

24- To connect the patient to the ventilator follows instructions 15 and 16 reported in section 4.4 “ABU v01: Configuration with No Continuous Fresh air Flow (NCFF)”.

4.6 – ABU v01: connection to Oxygen supply or Oxygen blender

WARNING:
The fractionation of oxygen inside the ABU balloon is subject to the connection of the ABU device to an external O2 reserve. The reference values are those given in the table below if an oxygen blender is not installed and the ABU is connected directly to an external O2 tank.

WARNING:
The ventilator must not be used with flammable anesthetic substances.

WARNING:
The ventilator must not be used in Oxygen rich environment.

WARNING:
Please, be aware that ABU v01 is not equipped with any sort of Oxygen Monitoring or Controlling Equipment. If such an external device is used, it shall conform with the following subclasses of ISO 80601-2-55:2018:

- **201.7.4.3;**
- **201.7.9.2.9.101;**
- **201.12.1.101;**
- **201.12.1.102;**
- **201.12.1.103;**
- **208.6.2**

WARNING:
Please, be aware that ABU v01 is not equipped with any sort of Oxygen Monitoring or Controlling Equipment. The ventilator, by exploiting the oxygen port present in the majority (but not the entirety) of the bag-valve masks, can provide an Oxygen concentration of either 21% or almost 100%.

WARNING:
Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, be aware that inappropriate oxygen use may potentially lead to serious complications, including, but not limited to, patient injury.

WARNING:
In the event of an oxygen leak, shut down the supply of oxygen at its source. In addition, remove and/or keep any incandescent source away from the device, which may be enriched with oxygen. Circulate fresh air into the room to bring the oxygen level down to normal.

WARNING:
The hose connecting the ventilator to the oxygen source shall be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.

WARNING:
Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.

WARNING:
The oxygen supply must be shut off when ventilation is interrupted. Before disconnecting the oxygen hose, allow the ventilator to continue for a few cycles without oxygen to flush the patient circuit of excess oxygen.

The ABU v01 ventilator can also be connected with medical gas oxygen supply systems. The choice to decide whether or not to connect the ventilator to an oxygen source is dependent on the patient's clinical status and user's opinion.

ABU v01 can be connected to a pure medical-grade oxygen tank or to an oxygen blender.

25- After having completed either step 15 in section 4.4 “ABU v01: Configuration with No Continuous Fresh air Flow (NCFF)” or step 23 in section 4.5 “Configuration with Continuous Fresh air Flow (CFF), connect the ABU Reservoir Sack (19) to the back of the ABU balloon (3) as shown in Figure 4.31.

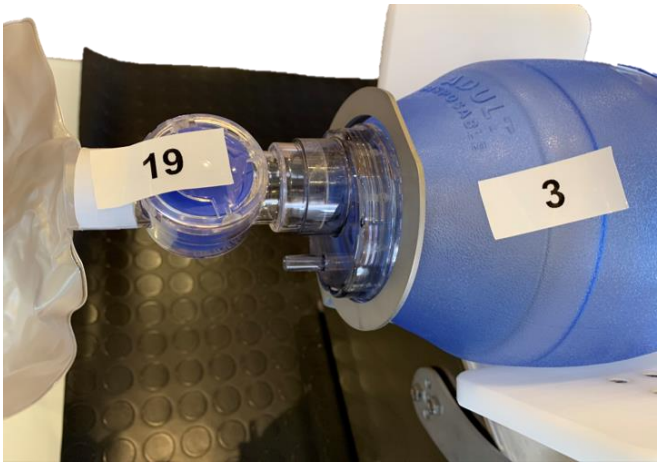


Figure 4.31. Connecting ABU balloon to ABU Reservoir sack.

26- Connect the oxygen pipe (20) to the oxygen port placed at the back of the ABU balloon (3) as shown in Figure 4.32.

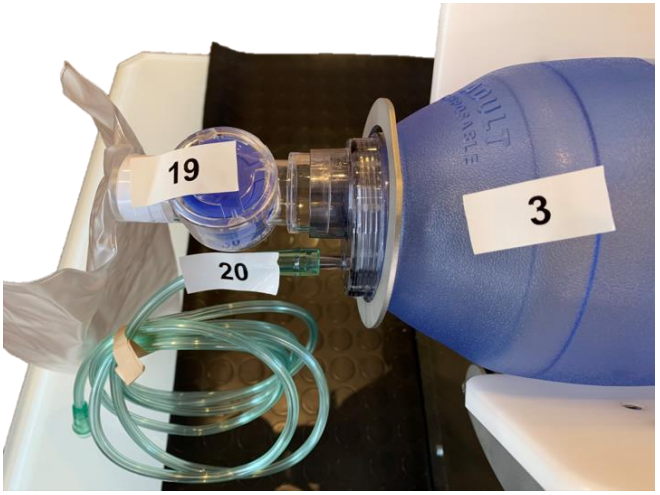


Figure 4.32. Connecting oxygen pipe to the AMBU balloon back port.

25. If a Continuous Flow of Fresh Air is required to compensate for air leakages and remove rebreathing effect, connect a second oxygen pipe (20) to the ABU Y-connector oxygen port (14) as shown in Figure 4.33.

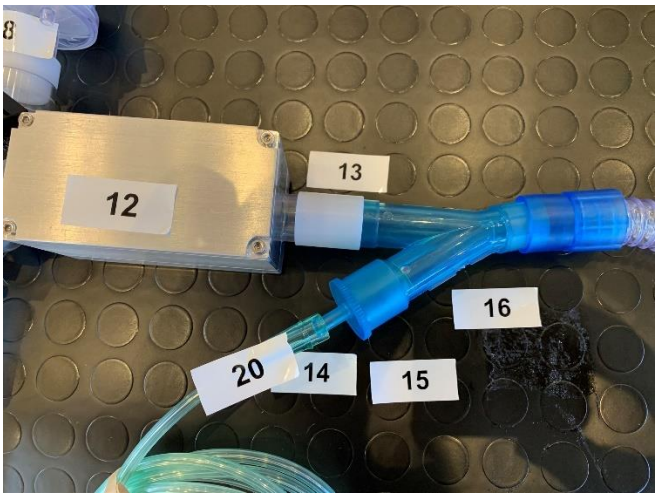


Figure 4.33. Connecting a second oxygen pipe to ABU ventilator to remove rebreathing and compensate for air leakages.

27- Connect the free ends of the oxygen pipes previously connected to the ABU ventilator to a medical-grade oxygen tank or oxygen blender, using any sort of Oxygen Monitoring or Controlling Equipment.
If such an external device is used, it shall conform with the following subclasses of ISO 80601-2-55:2018:

- 201.7.4.3;
- 201.7.9.2.9.101;
- 201.12.1.101;
- 201.12.1.102;
- 201.12.1.103;
- 208.6.2

4.7 ABU v01 assembled

Once assembled as described above, ABU v01 it will appear as shown in Figure 4.34.

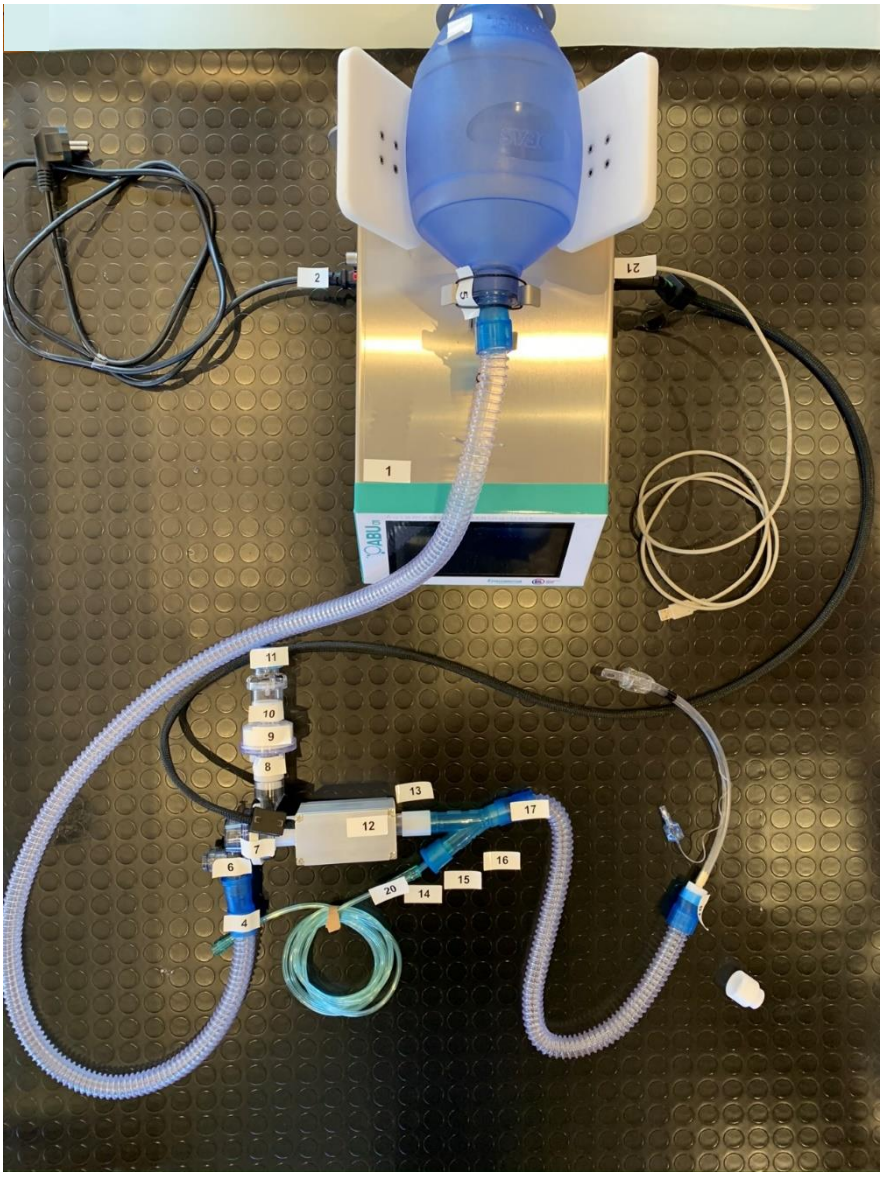


Figure 4.34. Example of ABU v01 ventilator assembled with Y-connector ensemble (14-15-16).

CAUTION:
Notice that, as specified above, ABU v01 can be assembled either in the Continuous Fresh air Flow (CFF) configuration, that includes ABU Y-connector, to minimize rebreathing and compensate for possible air leakages, especially when used with Non-invasive NIV patient-ventilator interface, or in the Non-Continuous Fresh air Flow (NCFF), that does not include the ABU Y-connector and is primarily meant for Invasive ventilation modes.

5 – Functional Description

WARNING:
The breathing circuit of the ventilator shall always be used with recommended components, listed in Table A.2, in order to ensure proper ventilation settings. Such components shall be replaced as reported in Table A.2 and as recommended by the manufacturer.

The following description shows the functional cycle of the ABU device associated with the use of a manual ventilation system based on a certified bag-valve mask system and equipped with appropriate safety and operating mechanisms such as PEEP valves, control valves, overpressure safety valves, unidirectional filters. It should also be noted that the ABU v01 already includes, the BVM kit as illustrated in section 3.7, "ABU v01 – Breathing Circuit".

5.1 Forced ventilation modes

Figure 5.1 shows the functional block diagram of ABU v01 ventilator in forced ventilation mode.

CAUTION:
Be aware that the combination of ABU v01 device with other medical devices is subject to the user's choice. This latter may only be represented by qualified medical personnel and emergency personnel with knowledge of pulmonary ventilation and advanced cardiac resuscitation techniques. Only personnel trained in the use of ABU v01 shall use this device.

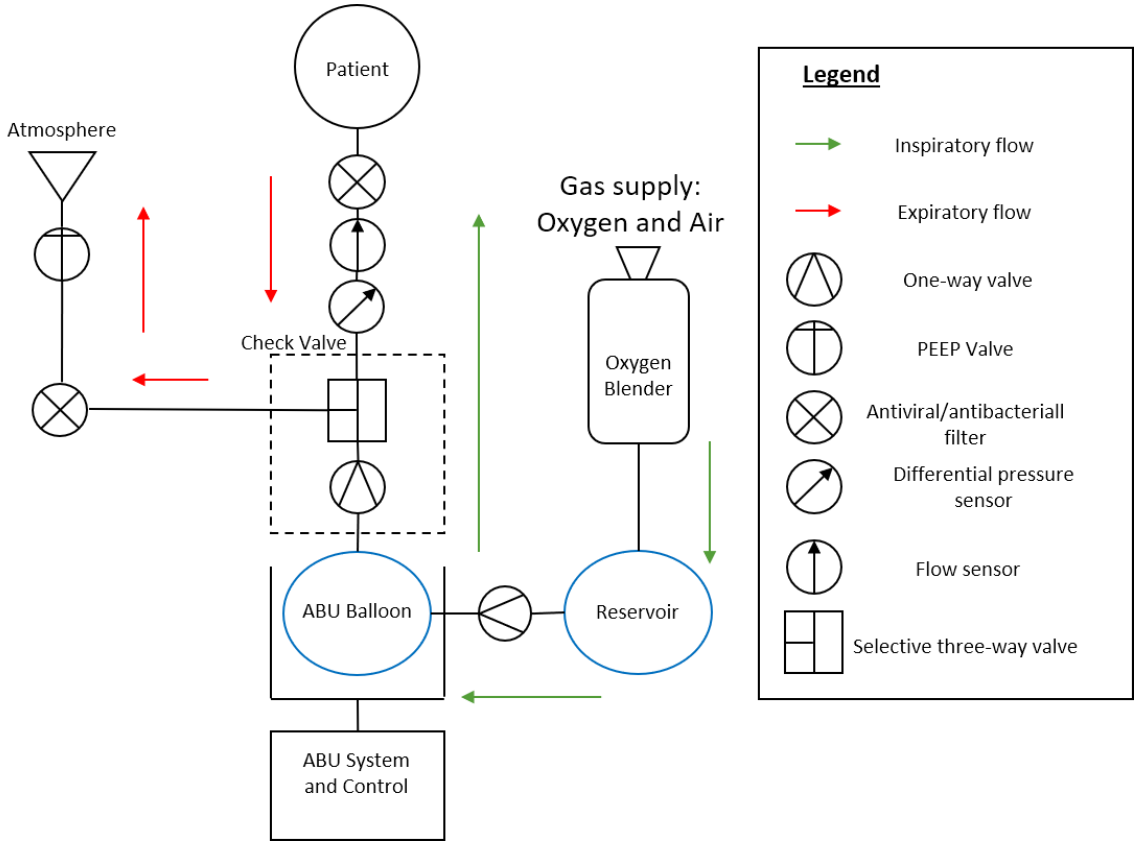


Figure 5.1: Functional block diagram of the ABU v01 ventilator in forced ventilation mode.

Parameters setting

- Once the ABU ventilator is connected to the patient, the ABU balloon is inserted between the clamps of the ABU device, as described in sections 4.3, 4.4, 4.5, 4.6 and 4.7.
- The user sets through the ABU control and ABU PEEP valve the following operating values:
    - Breathing frequency
    - Inspiration/Expiration ratio
    - Inspiratory Tidal Volume (Volume IN)
    - Plateau Pressure
    - PEEP value
    - PIP range (with respect to Plateau Pressure)
    - Leak Percentage

Inspiratory phase

- Once the parameters have been set, the ABU grippers will compress the ABU balloon according to the operator's settings.
- The inspiratory air will pass through the ABU Check valve which, thanks to its valve configuration, will divert the airflow completely to the patient eliminating any dispersion to the environment.
- The One-way valve contained inside the ABU balloon, between the ABU Reservoir sack and the ABU balloon exit towards the patient, prevents dispersion towards the ABU Reservoir sack.
- The flow sensor will measure the volume of air to the patient
- The ABU control system will calculate the Inspiratory Tidal Volume to the patient, integrating the measured flow with the elapsed time, and stop the gripper movement once the Inspiratory Tidal Volume set for each breathing cycle is reached.
- The differential pressure sensor will control the compression speed of the gripper on the ABU balloon in order to keep the airways pressure below the Plateau Pressure value set by the operator.
- If the Inspiratory Tidal Volume delivered to the patient does not reach the value set by the user, due to a pressure value required higher than the set values, the ABU control system will end the compression of the balloon to allow an opposite air flow from the patient and therefore the expiratory phase. In this case, ABU control system will activate a medium-priority alarm to signal the user that the target value has not been reached.

Expiratory phase

- The ABU gripper will release the ABU balloon, which will be filled with a new volume of air coming from the ABU Reservoir sack and/or the air contained in the external environment.
- The air exhaled by the patient is diverted towards the PEEP valve and thus sent to the external environment by the ABU Check-valve
- The differential pressure sensor reads the pressure difference between the external environment and the lung pressure.
- The same differential pressure sensor is used to measure the PEEP value present at the start of any new inspiratory cycle.
- The air is filtered through a possible anti-viral and anti-bacterial filter before being released outside into the external environment.
- The differential pressure sensor at the beginning of a new inspiratory cycle will be use for measuring the patient's airways pressure in order to find the Driving Pressure (dP) value, calculated as: $dP = (P_{Plateau} - PEEP)$ where $P_{plateau}$ is the average pressure value calculated during the inspiratory cycle minus the value of the Peak Inspiratory Pressure (Maximum pressure reached by the system during the inspiratory cycle).

- From the dP value, the system will calculate and display the patient's Pulmonary Compliance (C) value, calculated as: $C = V_i/(P_{Plateau} - PEEP)$

In forced ventilation mode the ABU device implements a PRVC (Pressure Regulated Volume Control) type ventilation.
This implies that instead of delivering an exact inspiratory tidal volume to each respiratory act, the ABU ventilator will vary the inspiratory flow at each act to reach the target volume keeping the maximum pressure value below the Peak Inspiratory Pressure (PIP) set by the operator. Inspiratory time (Ti), the value of which is imposed by the breathing frequency and the I:E ratio, limits the duration of the inspiratory cycle. Regulated pressure mode such as PRVC can be imagined as switching from a volume-controlled mode to a pressure-controlled mode with the advantage of maintaining more control over the current volume than a purely pressure mode.
Based on the above observations, the operator should set appropriate parameters to reach the target volume; in fact, it is likely, especially with patients suffering from pneumonia caused by Covid-19, that ventilation will require higher than standard airways pressures to reach the desired Inspiratory Tidal Volume.

5.2 Assisted ventilation modes

It is important to remind for Assisted ventilation mode, user can opt for the configuration with Continuous Fresh-air Flow (CFF) or with the configuration without Continuous Fresh-air Flow (NCFF). For further details, see sections 4.4 and 4.5.

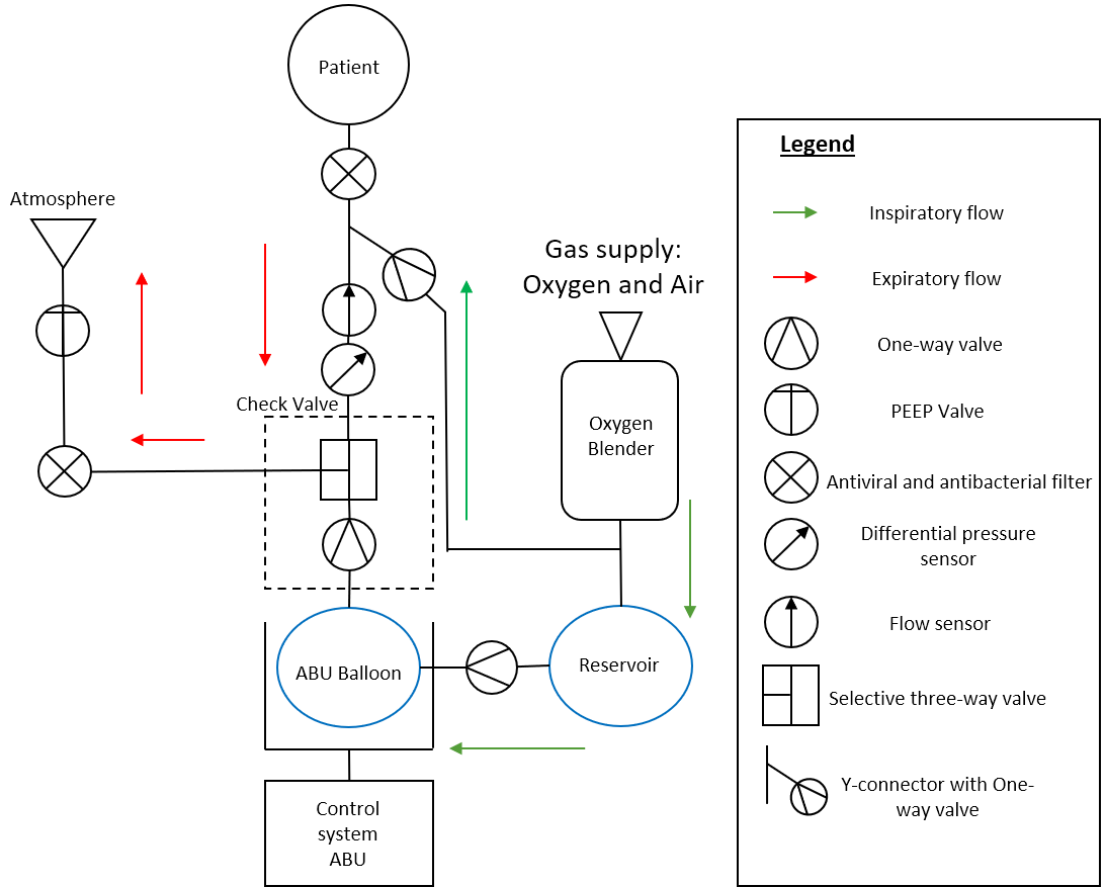


Figure 5.2: Functional block diagram of the ABU ventilator in assisted ventilation mode with CFF.

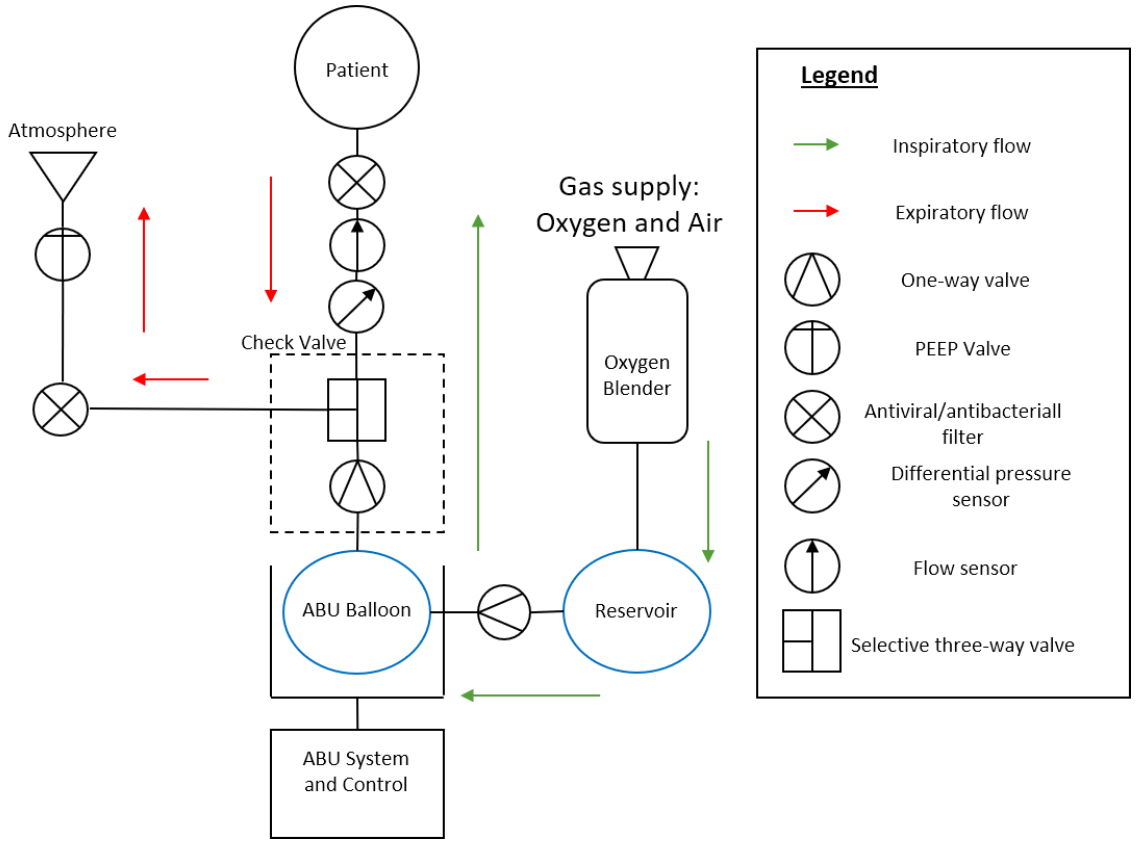


Figure 5.3: Functional block diagram of the ABU ventilator in assisted ventilation mode without CFF.

Parameters setting

- After connecting the ABU v01 ventilator to the patient, the ABU balloon is inserted between the clamps of the ABU device.
- The operator sets through the ABU control and the ABU PEEP valve the following operating values:
  - Pressure acceleration
  - Support pressure
  - Start Pressure Trigger
  - Start Flow Trigger
  - Stop Support Trigger
  - Target PEEP valve
  - Backup Time or maximum waiting time for spontaneous breath detection before forced baseline ventilation activates (in case of apnea)

Inspiratory phase

- Once the parameters have been set, the ABU ventilator contninuously reads the differential pressure sensor and the flowmeter to detect the moment when the patient tries to perform a spontaneous breathing act.
- If a spontaneous breath is detected, ABU grippers will then compress the ABU balloon according to the operator's setting.
- The inspiratory air will pass through the ABU Check valve which, thanks to its valve configuration, will divert the airflow completely to the patient eliminating any dispersion to the environment.
- The One-way valve contained inside the ABU balloon, between the ABU Reservoir sack and the ABU balloon exit towards the patient, prevents dispersion towards the ABU Reservoir sack.

- The flow sensor will measure the volume of air to the patient
- The ABU control system will stop the movement of the clamps once the flow value is reached, on the decreasing front, corresponding to the percentage of flow required by the operator compared to the maximum flow value measured in the same respiratory act. For more details, see step 7 of section 6.2.5, "Setting Assisted ventilation parameters".
- The differential pressure sensor will control the compression speed of the clamps on the flask in order to maintain the support pressure at the value set by the operator.
- If the ABU control system does not detect a spontaneous breathing act during the Backup Time set by the user, ABU ventilator will perform a forced breathing act according to the parameters set by the user for the assisted ventilation mode.

Expiratory phase

- The ABU grippers will release the ABU balloon, which will be filled with a new volume of air from the reserve and/or the air contained in the external environment.
- The air exhaled by the patient is diverted towards the ABU PEEP valve and thus sent to the external environment by the ABU Check-valve
- The differential pressure meter reads the pressure difference between the external environment and the airways pressure.
- The same differential pressure sensor is used to measure the PEEP value present at the beginning of any new inhalation cycle.
- The air is filtered through a possible anti-viral and anti-bacterial filter before being released outside into the external environment.
- By using ABU Y-connector, equipped with ABU Y-connector one-way valve (as in Figure 5.3) connected to an air source or oxygen mixture (e.g., an oxygen blender) it is possible to equip the ABU ventilator with CFF at positive pressure of the set PEEP value, able to eliminate excess CO_2 residues from the circuit and compensate the losses of the circuit itself.

5.2.1 Weaning and SIMV

The ventilation mode described in this section can be used to implement an assisted ventilation for previously treated and forced-ventilated intubated patients requiring weaning therapy (WEANING). In this case, the ABU Y-connector, included within the ventilator equipment, may be removed, or not used, because CFF configuration is not required for this mode.

To set such an assisted ventilation mode, simply set the parameters for assisted mode and the ventilator will work by implementing assisted ventilation of type SIMV (i.e., Synchronized Intermittent Mandatory Ventilation). SIMV is in fact the ventilation mode used during weaning from the ventilator. The breathing acts provided by the ventilator are synchronized with the patient's inhalation. If the patient does not initiate a spontaneous respiratory act within the time range set by the user (i.e., Backup Time), the ventilator intervenes by delivering a forced respiratory act, using the parameters set by the user for the assisted mode. The current volume varies according to the patient's efforts, but the ventilator ensures that the patient performs a predetermined minimum number of breathing acts per minute.

5.2.2 NIV ventilation

1- The same assisted ventilation mode can be used for non-invasive assisted ventilation otherwise known as NIV.
For example, by connecting, through the ABU Y-connector equipped with ABU Y-connector one-way valve, a CFF of regulated air to a suitable source of FiO2, leaving the ABU control system in standby, but manually setting only the PEEP value, it is possible to implement a positive pressure mechanical ventilation, commonly called C-PAP.

2- Using the same configuration described above for C-PAP (1) and starting the assisted ventilation mode on the ABU device it is instead possible to implement a Biphasic Continuous Positive Pressure ventilation, commonly called B-PAP.

Finally, using the assisted mode and the addition of a continuous positive pressure airflow (or CFF), all non-invasive ventilation (NIV) modes can be implemented using all patient-ventilator interfaces, whether these are CPAP masks, helmets or other systems as long as they are certified and therefore meet ISO 5356-1:2004 standards for standard connection to ventilation circuits.

Note:
Finally, using ABU ventilator in assisted mode and the addition of a positive pressure CFF, all non-invasive ventilation (NIV) modes can be implemented using all patient-ventilator interfaces, whether these are CPAP masks, helmets or other systems as long as they are certified and therefore meet ISO 5356-1:2004 standards for standard connection to ventilation circuits.

6-Operating procedures

Below operating procedures of the ABU v01 ventilator are reported.

CAUTION:
the combination of the ABU ventilator with other medical devices is subject to the user's choice. This operator may only be represented by qualified medical personnel and emergency personnel with knowledge of pulmonary ventilation and advanced cardiac resuscitation techniques. Only personnel trained in the use of ABU may use this device.

6.1 Turning on the Ventilator

WARNING:
Before operating the ventilator, read, understand, and strictly follow the information contained in chapter 1, "General Safety Information".

WARNING:
If the ventilator has been transported or stored at a temperature that differs more than ±20 °C (± 36 °F) from the temperature in which it will be operating, the ventilator should be allowed to stabilize in its operating environment for at least one (1) hour prior to use.

WARNING:
To reduce the risk of fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (such as flammable anesthetics and/or heaters) away from the ventilator and oxygen hoses.

WARNING:
While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem, especially for ventilator-dependent patients.

WARNING:
To ensure that ventilation continues uninterrupted ensure alternative power sources are available (AC power source, extra batteries). Be prepared for the possibility of power failure by having an alternative means of ventilation ready for use—particularly for ventilator-dependent patients.

WARNING:
Do not start ventilation until you ensure that the device is suitably assembled, that the air filters are properly installed and are not obstructed, and that there is proper clearance all around the unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including hoses, is not damaged or obstructed.

WARNING:
Users shall always possess an additional breathing circuit while using the ABU v01 ventilator.

WARNING:
Verify the functionality of the alarm conditions before connecting the patient to the ventilator.

WARNING:
Before starting ventilation, always verify that all settings are properly set in accordance with the required prescription.

WARNING:
If the ventilator fails any alarm test or if you cannot complete tests, see the Troubleshooting section (Chapter 9, section 9.6 "Troubleshooting") of this manual or call your equipment supplier

WARNING:
Due to its limited internal battery's reserve capacity, the ventilator should only be operated on the internal battery when no other power source is available. Ensure that the internal battery never becomes fully discharged.

To turn the ventilator on user can use two (2) different modes:

- Turning ventilator on using AC (main) power supply
- Turning ventilator on using internal battery

6.1.1 Turning ventilator on using AC (main) power supply

Set the I/O switch (a covered, rocker-type switch located on the left side of the ventilator) to the I position, as shown in Figure 6.1.

Figure 6.1. Turning ABU ventilator on using AC external (main) power supply.

6.1.2 Turning ventilator on using internal battery

Press and keep pressed for more than 2 seconds the black button identified by the following label for more than 2 seconds as shown in Figure 6.2:

Figure 6.2. Turning on ABU ventilator using the internal battery

6.1.3 Ventilator turned on

Once one of the operations described in sections 6.1.1, “Turning ventilator on using AC (main) power supply” or 6.1.2, “Turning ventilator on using internal battery”, are performed, the following events occur:

- The ventilator is powered on
- The ‘Welcome Menu’ shown in Figure 6.3 below appears:

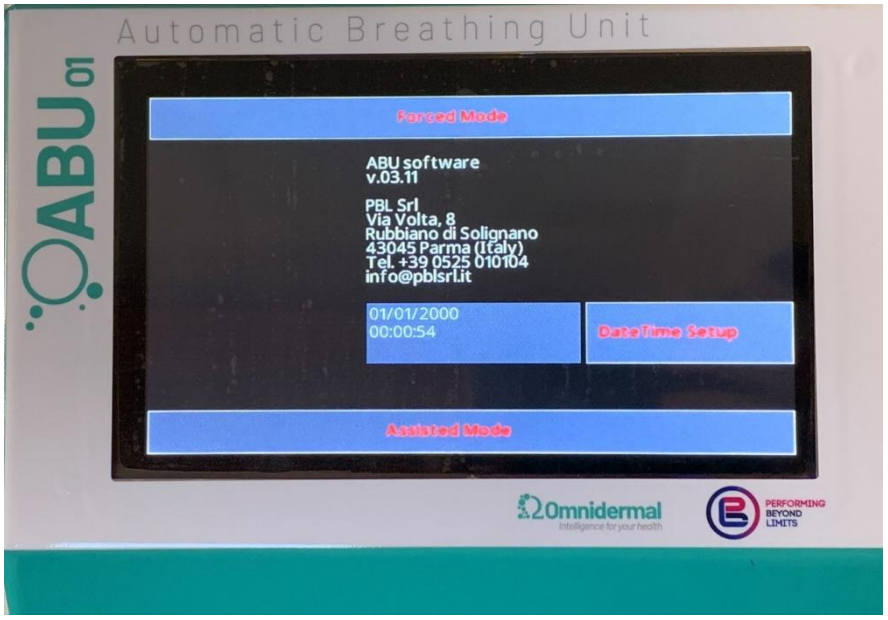


Figure 6.3. ‘Welcome Menu’

Note:
If the ventilator had been previously powered off, for any reason, while the ventilation was in progress, the ventilator starts directly in ventilation mode, when it is powered on again, using the all settings present before being powered off.

Note:
The Alarms and Events logs are stored in non-volatile memory on the Main CPU PCB, ensuring that the information is retained when the ventilator is powered off and during power loss conditions.

6.1.4 Settings date and time

To set Date and Time press the 'Date Time Setup' button on the Welcome Menu as shown in Figure 6.3 above. The system will show the 'Date Time Setup' page as shown in Figure 6.4.

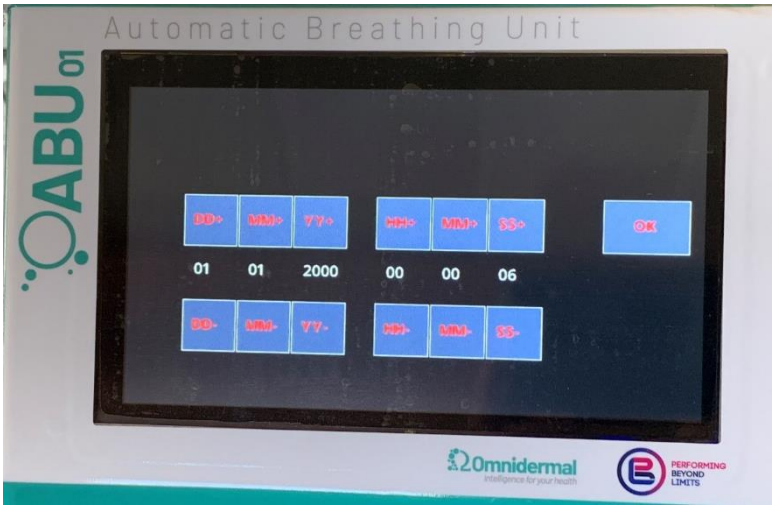


Figure 6.4. 'Date Time Setup' page.

To set the Date:

- Press the 'DD+' button or the 'DD-' button in order to increase or decrease respectively the number of the corresponding day
- Press the 'MM+' button or the 'MM-' button in order to increase or decrease respectively the number of the corresponding month
- Press the 'YY+' button or the 'YY-' button in order to increase or decrease respectively the number of the corresponding year

To set the Time:

- Press the 'HH+' button or the 'HH-' button in order to increase or decrease respectively the number of the corresponding hour
- Press the 'MM+' button or the 'MM-' button in order to increase or decrease respectively the number of the corresponding minute
- Press the 'SS+' button or the 'SS-' button in order to increase or decrease respectively the number of the corresponding second

Once the Date and Time are set, press the 'Ok' button.

6.2 Setting Up ventilation parameters

6.2.1 ABU PEEP valve setting

Adjusting ABU PEEP valve according to the desired value:

- ABU PEEP valve is adjusted manually by screwing or unscrewing the cap (Figure 6.5).

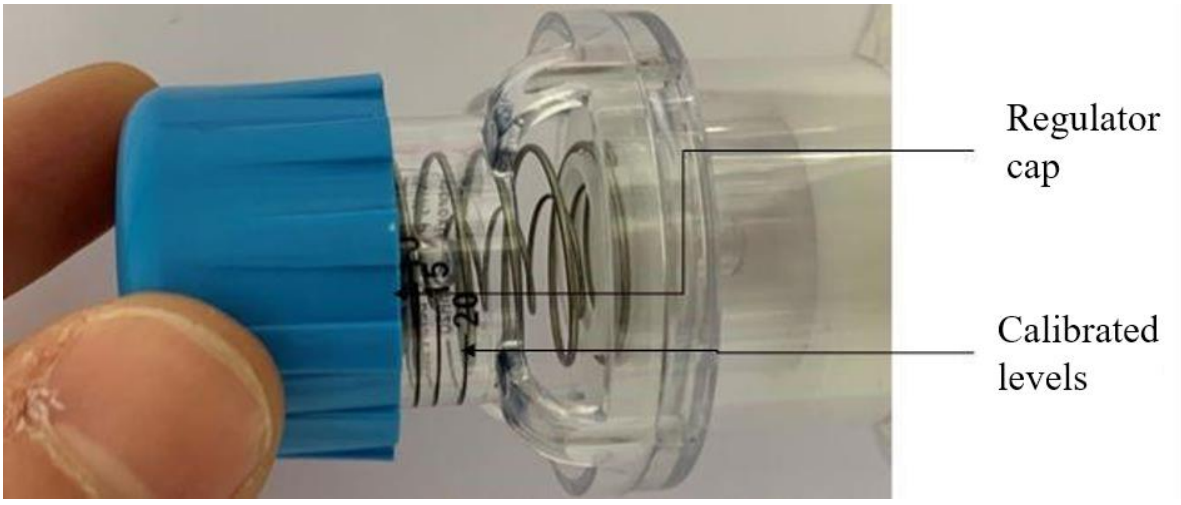


Figure 6.5: Adjustment of the PEEP valve.

CAUTION:
It is important to highlight that the valve calibration represented by the black lines printed on the valve below the cap may not represent the real value of PEEP set. For this reason, ABU ventilator is equipped with a PEEP monitoring system by which the user inserts the target PEEP value and if, during the ventilation, the target PEEP value is not reached, an alarm will activate. See section 9.5, "Overview of Alarms".

6.2.2 FiO2 setting

WARNING:
The ventilator must not be used with flammable anesthetic substances.

WARNING:
Please, be aware that ABU v01 is not equipped with any sort of Oxygen Monitoring or Controlling Equipment. If such an external device is used, it shall conform with the following subclasses of ISO 80601-2-55:2018:

- **201.7.4.3;**
- **201.7.9.2.9.101;**
- **201.12.1.101;**

- **201.12.1.102;**
- **201.12.1.103;**
- **208.6.2**

WARNING:

Please, be aware that ABU v01 is not equipped with any sort of Oxygen Monitoring or Controlling Equipment. The ventilator, by exploiting the oxygen port present in the majority (but not the entirety) of the bag-valve masks, can provide an Oxygen concentration of either 21% or almost 100%.

WARNING:

Oxygen therapy for patients with respiratory failure is a common and effective medical prescription. However, be aware that inappropriate oxygen use may potentially lead to serious complications, including, but not limited to, patient injury.

WARNING:

Strictly follow the instructions provided in section 4.6, "ABU v01: Connection to Oxygen Supply or Oxygen blender", which include the use of a flow regulator and special oxygen connector.

WARNING:

In the event of an oxygen leak, shut down the supply of oxygen at its source. In addition, remove and/or keep any incandescent source away from the device, which may be enriched with oxygen. Circulate fresh air into the room to bring the oxygen level down to normal.

WARNING:

The hose connecting the ventilator to the oxygen source shall be designed exclusively for use with medical-grade oxygen. Under no circumstances should the oxygen hose be modified by the user. In addition, the hose must be installed without the use of lubricants.

WARNING:

Ensure that the only gas supplied to the ventilator through the dedicated oxygen supply connector is medical-grade oxygen.

WARNING:

The oxygen supply must be shut off when ventilation is interrupted. Before disconnecting the oxygen hose, allow the ventilator to continue for a few cycles without oxygen to flush the patient circuit of excess oxygen.

WARNING:

The fractionation of oxygen inside the ABU balloon is subject to the connection of the ABU device to an external O2 reserve. The reference values are those given in the Table 6.1 below if an oxygen blender is not installed and the ABU is connected directly to an external O2 tank.

ABU ventilator can offer only 2 FiO_2 levels: 21 % (without Reservoir and without source of oxygen connected) and 99% (with Reservoir and with pure oxygen source of medical grade connected to ABU ballon).

These values are obtained either by leaving the ventilator detached by any oxygen source (i.e., 21% of FiO_2) or connecting one end of the oxygen pipes to the back port of ABU balloon and the free end of the ABU Y-connector,

and the other end to a pure Oxygen tank as explained in section 4.6, "ABU v01: Connection to Oxygen supply or Oxygen blender".

Alternatively, in order to obtain variable FiO_2 values contained within the 21% and 100% range, an oxygen blender device may be connected to the oxygen pipes, described above, instead of a pure oxygen tank.

The fractionation of oxygen inside the ABU balloon is subject to the connection of the ABU device to an external O_2 reserve. The reference values are those given in the Table 6.1 below if an oxygen blender is not installed and the ABU is connected directly to an external O_2 tank.

Ventilator's configuration	**FiO_2**
No Oxygen source attached	21 %
Pure oxygen source connected to the back of the ABU ballon to which the Reservoir sack is attached	Higher than 98% (according to DEAS srl specifications for model CPR1700, reference deas data sheet of model CPR1700, file name: ST CPR1700-3, Rev.:0 3)
Pure oxygen source connected to the back of the ABU ballon to which the Reservoir sack is NOT attached	45% (according to DEAS srl specifications for model CPR1700, reference deas data sheet of model CPR1700, file name: ST CPR1700-3, Rev.:0 3)
Oxygen Blender attached	In the range between: 21% and 100% (Depending on the medical device used)

Table 6.1. FiO_2 range

6.2.3 Selecting ventilation mode

WARNING:
Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

WARNING:
Ensure that the device is suitably assembled, that the air inlet filter is properly installed and is not obstructed, and that there is proper clearance all around the unit. Also ensure that the patient circuit is suitably connected to both the ventilator and the patient and that the patient circuit, including all hoses, is not damaged or obstructed.

WARNING:
Ventilator-dependent patient should always be monitored by trained and competent medical personnel. Ensure that the patient's caregiver is able and prepared to take suitable action in the event the ventilator identifies an alarmed condition or experiences a problem.

WARNING:
This manual tells you how to respond to ventilator alarms, but it does NOT tell you how to respond to the patient.

As explained in chapter 5, "Functional Description", ABU ventilator offers only 2 ventilation modes:

1- forced ventilation

2- assisted ventilation

To select either the forced mode or the assisted mode, the relative button in the ‘Welcome Menu’ page must be pushed as shown in Figure 6.6 below.

Note:
The Welcome Menu page can be accessed only when the ventilator is turned on once it had been previously switched off when previous ventilation was stopped. See section 6.1.

6.2.4 Setting Forced ventilation parameters

1- On the ‘Welcome Menu’ page select “Force Mode”

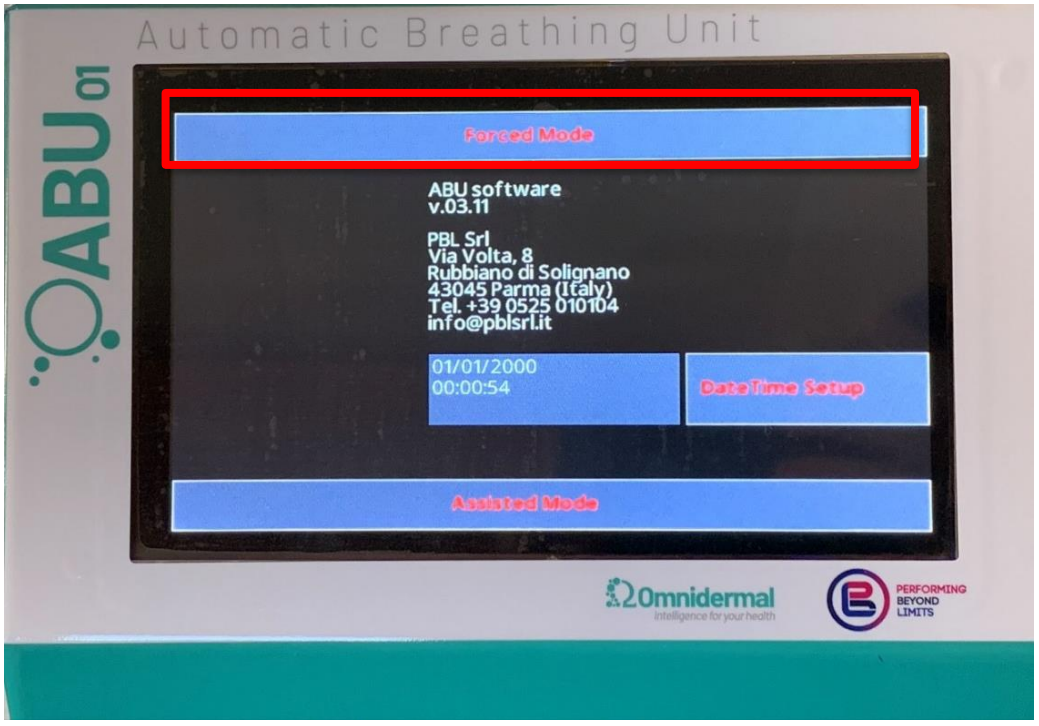


Figure 6.6. ‘Welcome Menu’ of ABU v01 ventilator. Touch the “Forced Mode” button to access forced ventilation mode.

2- The display shows the ‘Home’ page for the forced mode.

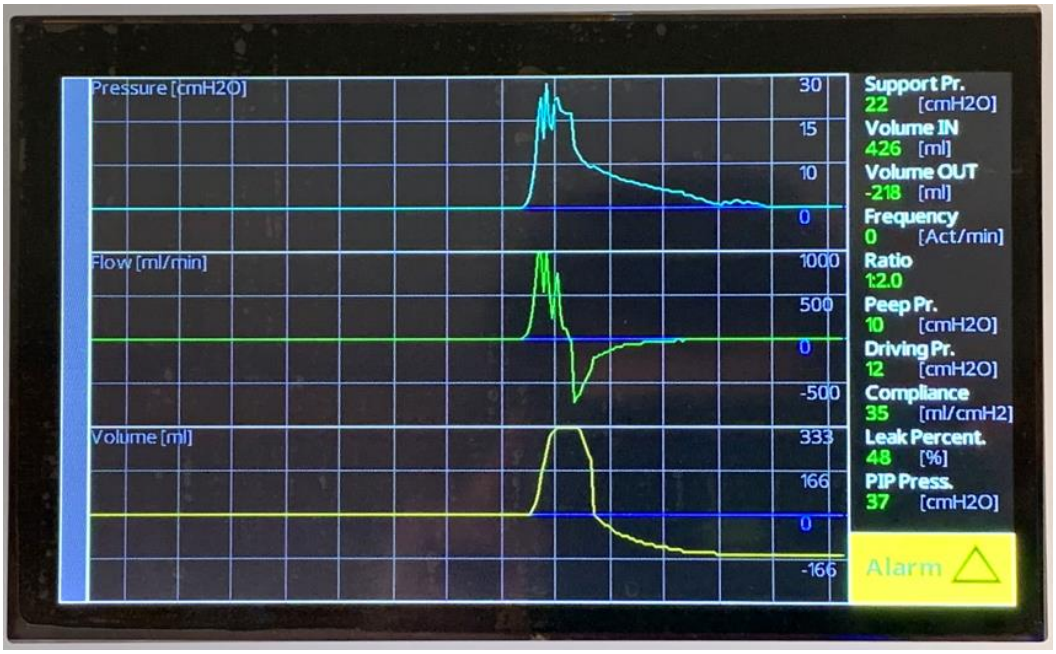


Figure 6.7. ‘Home page’ of ABU v01. The light blue line shows the real-time value of the airway pressure measured by the ABU sensor pack. The green line, in the middle, shows the actual value of the flow measured by the ABU sensor pack. The bottom line displays the volume of air calculated by the ventilator integrating the value of the flow over time

The ‘Home’ page shows at the center the real-time values and graphs of airways pressure (upper graph), air Flow (middle graph) and Tidal Volume (lower graph). On the far-right column, the ‘Home’ page shows, updated at the end of each breathing act, the following measured parameters:

- Plateau Pressure
- Volume IN (i.e., Inspiratory Tidal Volume)
- Volume OUT (i.e., Expiratory Tidal Volume)
- Frequency (i.e., Breathing frequency)
- Ratio (i.e., I:E Ratio)
- Peep Pr. (i.e., PEEP value)
- Driving Pr. (i.e., Driving pressure)
- Compliance (i.e., Pulmonary compliance)
- Leak Percent. (i.e., Leak percentage)
- PIP Press. (i.e., PIP pressure)

3- Touch anywhere on the touchscreen except for the “Alarms” button as shown in Figure 6.8.

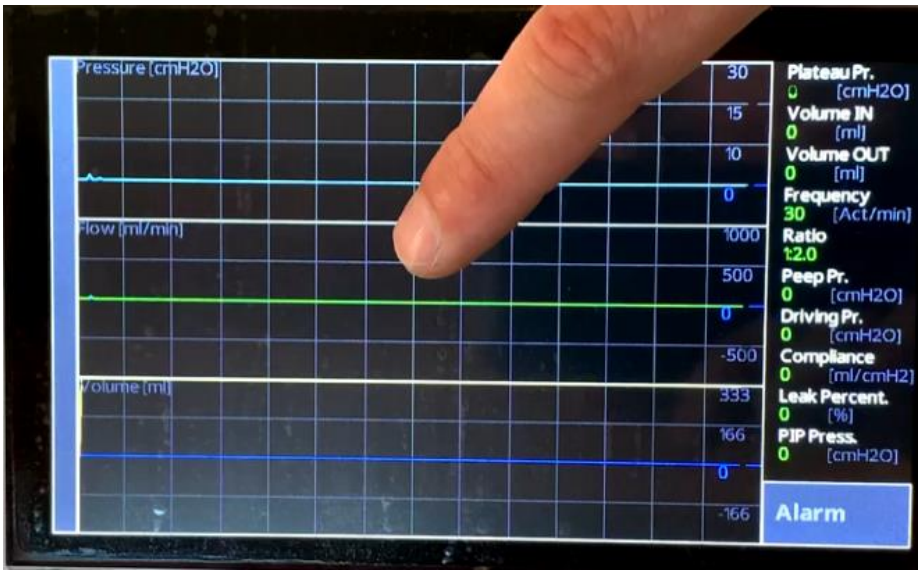


Figure 6.8. Accessing the ‘Setup’ page. Simply touch anywhere on the screen apart from the ‘Alarm’ button found on the bottom-right corner.

4- The screen will show the ‘Setup’ page (Figure 6.9).

Figure 6.9. ‘Setup’ page for forced mode.

5- To set ventilation parameters, focus on the left-bottom part of the screen as shown below, in Figure 6.10.

Figure 6.10. 'Setup' page panel to control ventilation parameters.

To change the values of one parameter, follow instructions below:

- By pressing the '+' button it is possible to increase of one (1) unit the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the '-' button it is possible to decrease of one (1) unit the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the '+10' button it is possible to increase of ten (10) units the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the '-10' button it is possible to decrease of ten (10) units the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the '+100' button it is possible to increase of one hundred (100) units the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the '-100' button it is possible to decrease of one hundred (100) units the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the 'Next' button, it is possible to select the following parameter contained in the software list
- By pressing the 'Prev.' button, it is possible to select the previous parameter contained in the software list

6- The first parameter that can be set is the Breathing Frequency expressed in breathing acts per minutes (Figure 6.11):

Figure 6.11. Setting Breathing Frequency

Set the desired value as explained at point 5

7- The second parameter that can be set is the Target Volume to be delivered to the patient (i.e., Inspiratory Tidal Volume), expressed in ml (Figure 6.12):

Figure 6.12. Setting Target Inspiratory Tidal Volume.

Set the desired value as explained at point 5

8- The third parameter that can be set is the Plateau Pressure that, for ABU ventilator, represents the Maximum average airways pressure that can be reached during a forced ventilation act. It is expressed in cmH_2O (Figure 6.13):

Figure 6.13. Setting Plateau Pressure

Set the desired value as explained at point 5

9- The fourth parameter that can be set is the Inspiratory versus Expiratory time ratio (i.e., 'I:E ratio) (Figure 6.14):

Figure 6.14. Setting I:E Ratio.

Set the desired value as explained at point 5

10- The fifth parameter that can be set is the Leak Percentage Alarm threshold. It represents the maximum percentage of air leakage allowed before the relative alarm is activated. It is calculated as:

$$\frac{V_i - V_e}{V_1} * 100$$

Where V_i is the real Inspiratory Tidal Volume delivered to the patient during the inspiratory phase of a forced breathing act and, V_e the real Expiratory Tidal Volume exhaled by the patient during the expiratory phase of a forced breathing act. Leak percentage, as the name suggests, is expressed in % (Figure 6.15). If, at the end of a forced breathing act, the measured Leak percentage is higher than the Leak percentage set by the user, ABU will activate a specific alarm.

Figure 6.15. Setting Leak Percentage Alarm threshold

Set the desired value as explained at point 5

11- The sixth parameter that can be set is the target PEEP value. During ventilation, ABU control system checks the PEEP value and if it does not match the target PEEP value set at this point or if it exceeds the following ranges: Real PEEP < PEEP (set) -1 or Real PEEP > PEEP (set)+1, an alarm will activate. PEEP is expressed in cmH_2O (Figure 6.16):

Set the desired value as explained at point 5

Figure 6.16. Setting PEEP.

12- The tenth and final parameter that can be set is the 'PIP range'. Expressed in cmH_2O (Figure 6.17), this parameter allows the user to set the alarm for the maximum Peak Inspiratory Pressure allowed before the system activates an alarm. The alarm will be activated if the following condition is met:

$$Measured\ PIP > \ set\ Plateau\ Pressure + set\ PIP\ Range$$

Let' suppose for example that the user sets a Plateau Pressure of 10 cmH_2O and a PIP Range of 5 cmH_2O. If, during the inspiratory phase of a forced breathing act, the measured PIP is higher than 10 cmH_2O + 5 cmH_2O (i.e., Set Plateau Pressure + set PIP Range), ABU will activate an alarm.

Set the desired value as explained at point 5

Figure 6.17. Setting PIP alarm threshold.

6.2.5 Setting Assisted ventilation parameters

1- On the ‘Welcome Menu’ page select “Assisted Mode” (Figure 6.18):

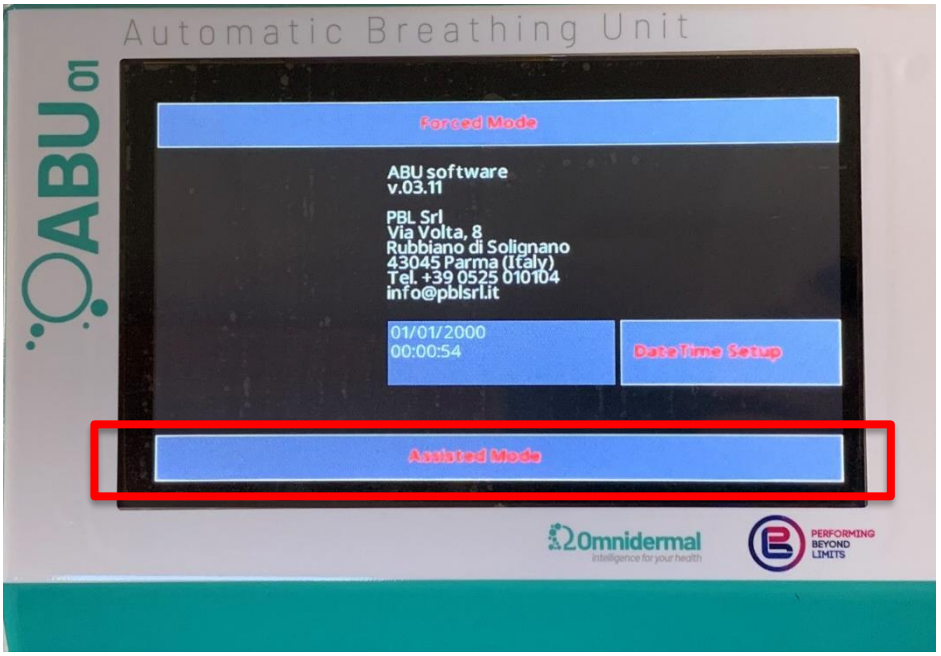


Figure 6.18. ‘Welcome Menu’ of ABU v01 ventilator. Touch the “Assisted Mode” button to access assisted ventilation mode.

2- The screen will show the ‘Home’ page for the assisted mode (Figure 6.19)

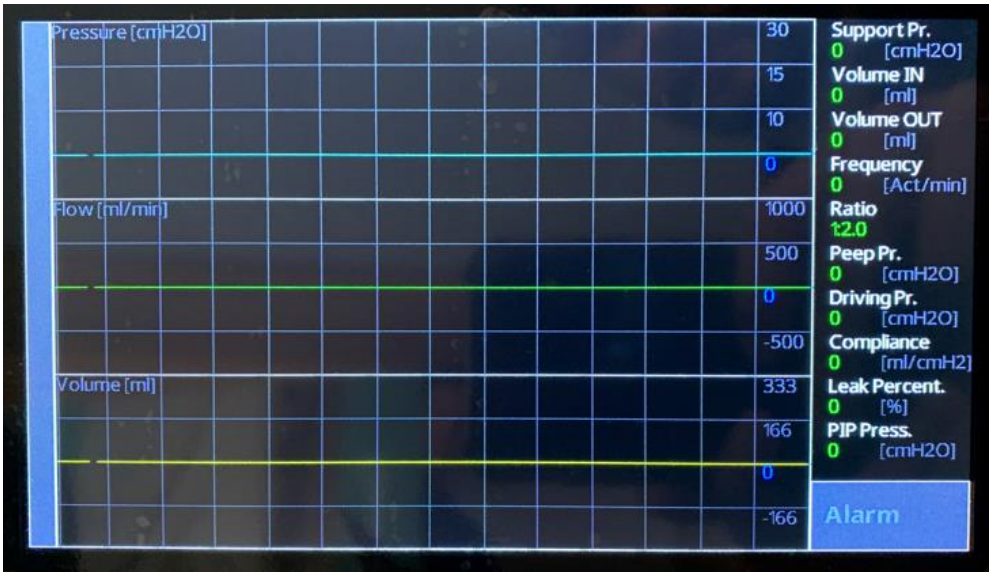


Figure 6.19. Home page for assisted mode.

The ‘Home’ page shows at the center the real-time values and graphs of airways pressure (upper graph), air Flow (middle graph) and Tidal Volume (lower graph). On the far-right column, the ‘Home’ page shows, after the end of each breathing cycled, the following measured parameters:

- Support Pressure
- Start Pressure Trigger
- Start Flow Trigger
- Stop Support Trigger
- Backup Time
- Pressure Acceleration

3- Select anywhere on the screen except for the ‘Alarms’ button, as shown below (Figure 6.20):

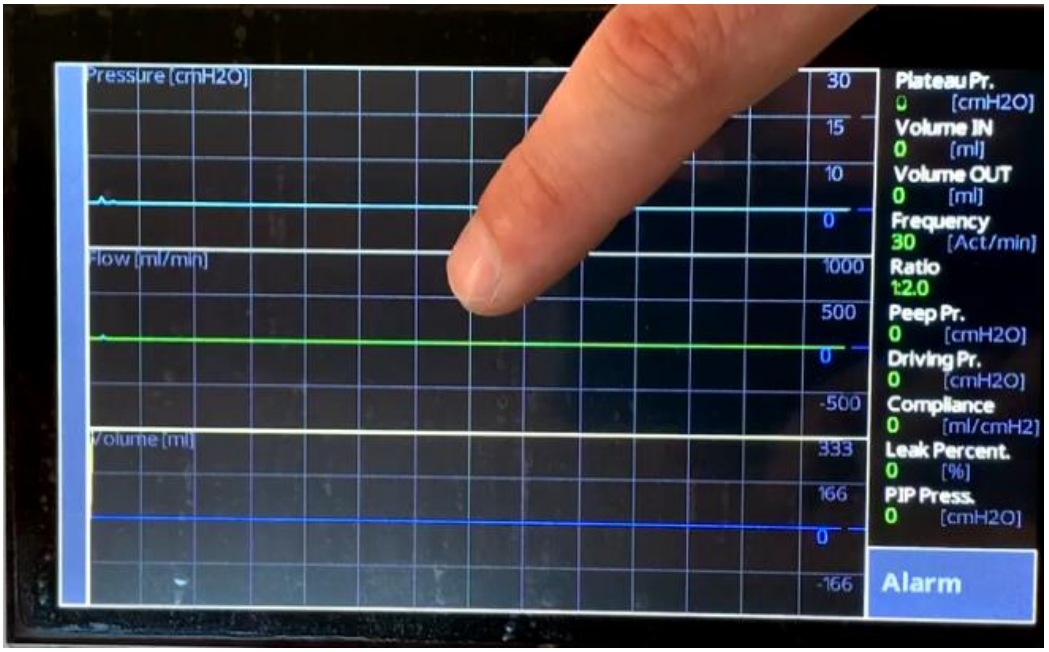


Figure 6.20. Accessing the ‘Setup’ page. Simply touch anywhere on the screen apart from the “Alarm” button found on the bottom-right corner.

4- The screen will show the Setup page for assisted mode (Figure 6.21):
5- To set ventilation parameters, focus on the left-bottom part of the screen as shown:

- By pressing the ‘+’ button it is possible to increase of one (1) unit the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the ‘-’ button it is possible to decrease of one (1) unit the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the ‘+10’ button it is possible to increase of ten (10) units the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the ‘-10’ button it is possible to decrease of ten (10) units the value of the parameter selected until the maximum or minimum allowed value is reached

- By pressing the '+100' button it is possible to increase of one hundred (100) units the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the '-100' button it is possible to decrease of one hundred (100) units the value of the parameter selected until the maximum or minimum allowed value is reached
- By pressing the 'Next' button, it is possible to select the following parameter contained in the software list
- By pressing the 'Prev.' button, it is possible to select the previous parameter contained in the software list

Figure 6.21. 'Setup' page for assisted mode.

6- The first parameter that can be set is the Support Pressure expressed in cmH_2O (Figure 6.22). It represents the target airways pressure that ABU ventilator will try to reach during a breathing act.

Set the desired value as explained at point 5

Figure 6.22. Setting Support Pressure

7- The second parameter that can be set is the 'Start Pressure Trigger'. It is expressed in cmH_2O (Figure 6.23) and represents the airways pressure threshold that ABU ventilator will set as the target value that once reached will signal to ABU control unit that a spontaneous breathing act has been detected and it is the right time to trigger an assisted breathing act. It can span the range between 0 to -10 cmH_2O.

Set the desired value as explained at point 5

Figure 6.23. Setting the Start Pressure Trigger.

8- The third parameter that can be set is the 'Start Flow Trigger'. It is expressed in ml/min (Figure 6.24) and represents the threshold of the inspiratory flow that ABU ventilator sets as the target value that once reached will signal to the ABU control unit that a spontaneous breathing act has been detected and it is the right time to trigger an assisted breathing act. It can span the range between 0 to 100 ml/min.

Set the desired value as explained at point 5

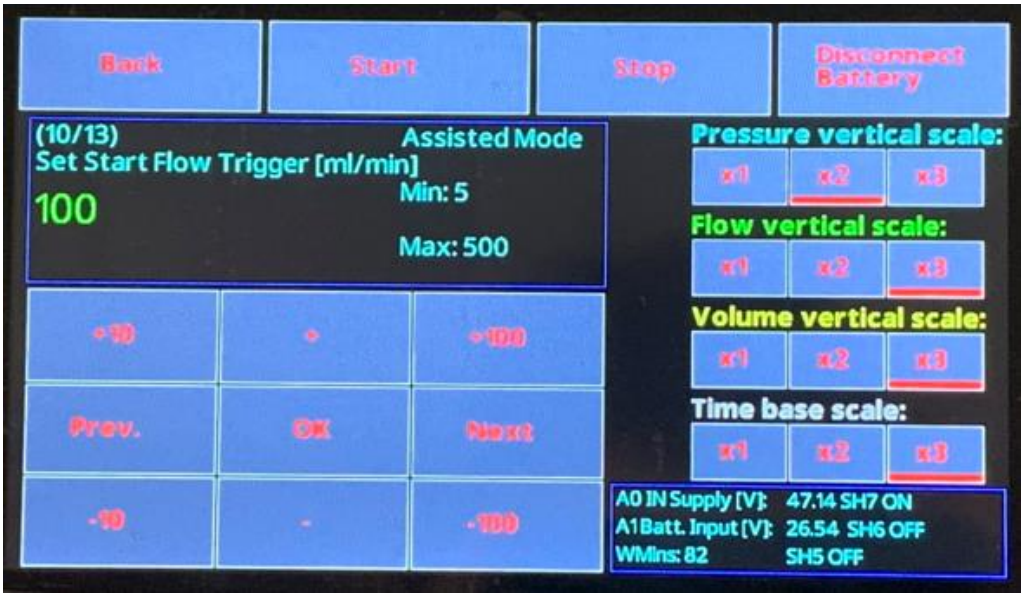


Figure 6.24. Setting the Start Flow Trigger

Note:

Abu ventilator possesses two types of triggers for assisted ventilation:

- **A pressure trigger (see point 7 above)**
- **A volume trigger (see point 8 above)**

This double system has a safety purpose, so that in case one trigger fails, there is another that can activate the assisted breathing act.

9- The fourth parameter that can be set is the ‘Stop Support Trigger’; expressed in percentage (%), it defines the moment when the support of the ventilator will have to cease in order to let the patient to exhale (Figure 6.25).

Set the desired value as explained at point 5

Figure 6.25. Setting the Stop Support Trigger.

It is expressed as a percentage and represents the percentage of flow that is missing to reach the zero value with respect to the maximum value that the flow reached during the inspiratory phase of the assisted breathing act. As shown in the Figure 6.26 below, once the assisted breathing act starts, during its inspiratory phase, the flow rapidly reaches a maximum value, due to the fact that patient’s lungs are empty, and then starts to decrease. The ‘Stop Flow trigger’ represents the percentage with respect to the maximum value reached by the flow, during that particular breathing act, that is missing to reach a flow value equal to zero.

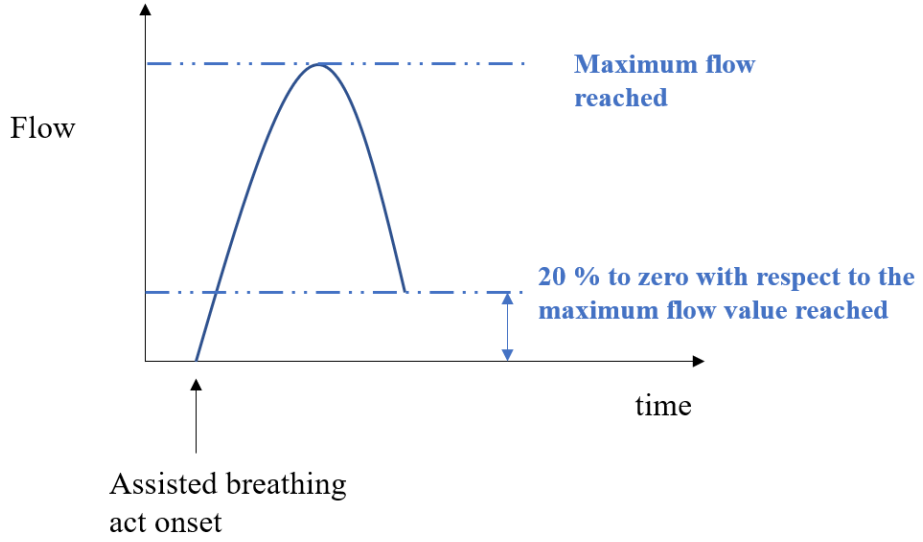


Figure 6.26. Graph representing the qualitative behaviour of the flow during the inspiratory phase of an assisted breathing act.

10- The fifth parameter that can be set is the ‘Backup Time’. It is expressed in seconds (Figure 6.27) and represents the maximum time that can elapse between two spontaneous breathing acts. This means that, if ABU ventilator does not detect a spontaneous breathing act, within the Backup Time range, it will start a forced breathing act using the parameters set for the assisted mode. It is sometimes defined as backup ventilation time.

Set the desired value as explained at point 5

Figure 6.27. Setting the Backup Time.

Note:

It is important to highlight that ABU ventilator will activate an high-priority alarm if it does not detect any spontaneous breathing act during five consecutive ‘Backup Time’ time ranges.

11- The sixth and last parameter that can be set is the ‘Pressure Acceleration’. It is expressed as an integer number that can span the range between 1 to 15 (Figure 6.28). The higher its value, the faster ABU ventilator will attempt to reach the Support Pressure.

Set the desired value as explained at point 5

Figure 6.28. Setting Pressure Acceleration

6.3 Starting ventilation

WARNING:
Verify the functionality of the alarm conditions before connecting the patient to the ventilator.

WARNING:
Before starting ventilation, ensure that the device is properly assembled and that the air inlet, and alarm sound diffusion holes are not obstructed. Ensure also that the patient circuit is of the proper configuration (with or without continuous fresh airflow), properly connected to the ventilator, and that the circuit hoses are neither damaged nor compressed and contain no obstructions or foreign bodies.

To start ventilation independently on the ventilation mode press the “Start” button (Figure 6.29).

Figure 6.29. Starting the ventilation

The values of the ventilation parameters are displayed on the screen as described in section 6.2.4, “Setting Forced ventilation parameters” or 6.2.5, “Setting Assisted ventilation parameters” (depending if the ventilation mode selected is the forced or assisted ones respectively).

6.4 Stopping ventilation

WARNING:

Do not allow a patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primarily carbon dioxide, may be inhaled by the patient. In some circumstances, inhaling carbon dioxide may lead to under-ventilation, suffocation, and serious injury or death.

1- To stop ventilation press and hold for more than 2 seconds the “Stop” button as show in Figure 6.30 below.

Figure 6.30. Stopping the ventilation.

2- Hold pressure on the “Stop” button for more than 2 seconds until the active bar display inside the button does not cover its entirety (Figure 6.31).

Figure 6.31. Stopping the ventilation. To stop the ventilation push and hold the ‘Stop’ button until the red bar completely covers the button as shown.

Note:
ABU ventilator in order to stop ventilation requires the user to press and hold the “Stop” button for more than 2 seconds; this is a safety function that prevents accidental stopping of the ventilation.

6.5 Turning Off the Ventilator

WARNING:
When the ventilator is switched back on after it was switched off while ventilation was in progress, it will immediately begin ventilating-without the user first having to press the ‘Start’ button.

WARNING:
Handle the ventilator with care after use, particularly when ambient temperatures are high. Some ventilator surfaces may be very hot, even if safety specifications are not exceeded.

To turn off the ventilator:

1- Set the I/O switch to the O position; this operation will activate internal battery energy supply (Figure 6.32)

Figure 6.32. To turn off the ventilator, first set the I/O switch to the O position

2- Press and hold for more than 2 seconds “Disconnect Battery” button, until the active bar display inside the button does not cover its entirety (Figure 6.33)

Figure 6.33. To turn off the ventilation push and hold the ‘Disconnect Battery’ button until the blue bar completely covers the button as shown.

Note:

ABU ventilator in order to be turned off requires to set the I/O switch to O position and to press and hold the ‘Disconnect battery’ button for more than 2 seconds; this is a safety function that prevents accidental turning off of the device.

Note:
When the ventilator is completely stopped and turned off, but still connected to the AC power supply, the internal battery will not be charging. In order to charge internal battery, the ventilator must be connected to the AC power supply and tuned on (meaning the I/O switch set to I position).

6.6 PC connection

ABU v01 can be connected to a PC to allow the download of Alarms and Events Logs and real-time ventilation parameters.

Note:
ABU v01 ventilator distinguishes between Alarms and Event:

- **Alarms can be defined as acoustic and visive signal for potentially hazardous situations that threaten patient's life.**
- **Events are represented by all those operations of modification of the ventilation parameters that the user brings during ventilation**

Note:
ABU v01 allows to save up to 1000 Alarms and 1000 Events in its internal memory, in addition, it allows to save real-time ventilation parameters by connecting the ventilator to a PC through a dedicated software.

Note:
For PC requirements see Appendix A.6, "PC connection"

To connect the ventilator to a PC and download Data follows the instructions below.

6.6.1 Downloading and saving of Alarm and Events log.

- Connect the ABU USB cable (21) to the ABU USB port as shown in Figure 6.34.

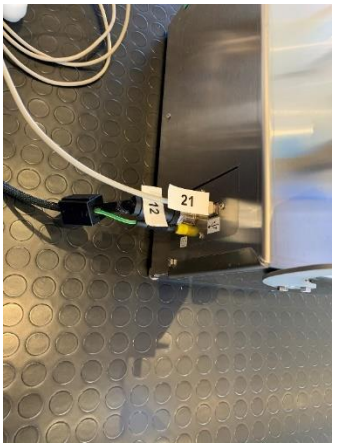


Figure 6.34. Connecting the ABU USB cable to the ABU USB port.

- Connect the other end of the ABU USB cable (21) to a USB port of a PC equipped with Windows operative system (compatible versions: 7, 8 and 10).

- On the PC open the ‘SerialArduino.exe’ file provided by your local representative

  SerialArduino.exe

- The screen shown in Figure 6.35 will appear:

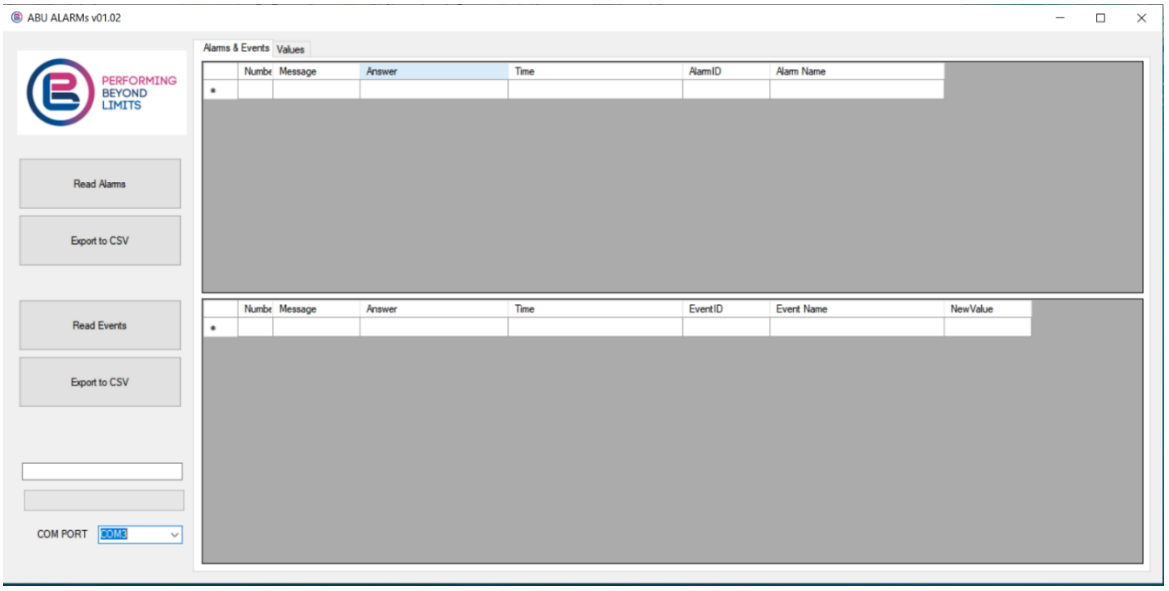


Figure 6.35. Main page of “SerialArduino.exe” software

- Open the Device Manager of Windows (Figure 6.36) and check the number of the USB port assigned to ‘Arduino Zero’ under ‘Ports (COM & LPT)’, in the example in Figure 6.36, the assigned number is 3 (i.e., COM3).

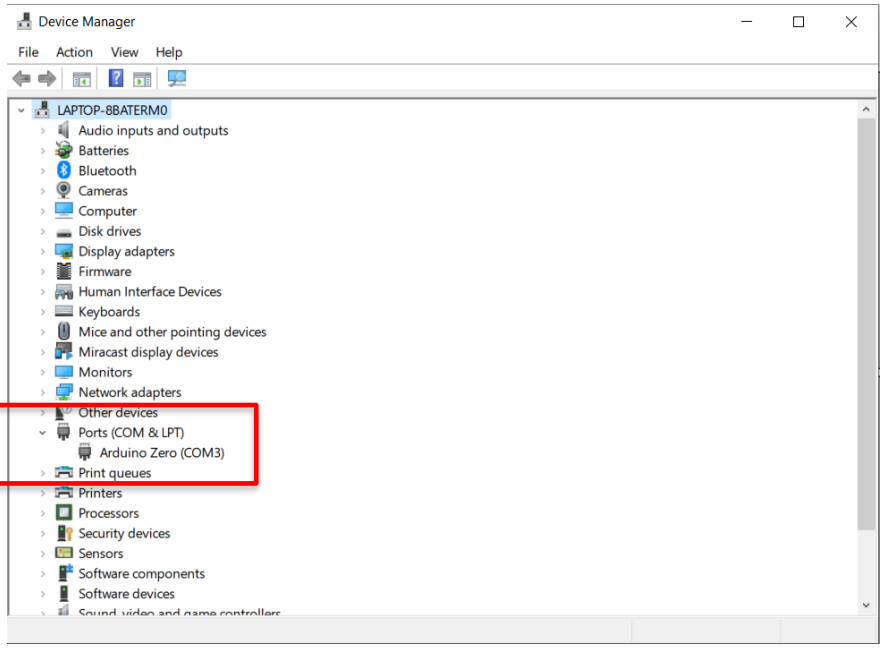


Figure 6.36. Assignment of USB port for ABU v01.

- Select the USB port on the ‘Serial Arduino’ page as shown in Figure 6.37, under ‘COM PORT’

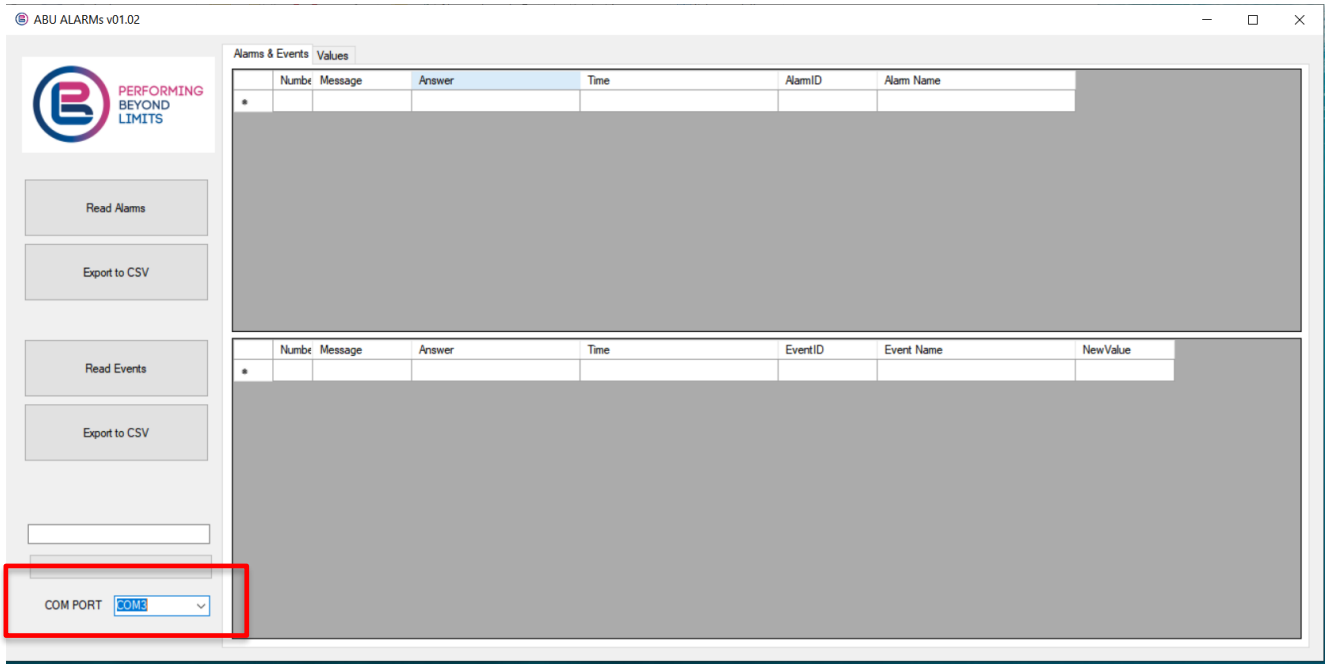


Figure 6.37. COM PORT selection.

- Press ‘Read Alarms’ button to download the Alarms saved within ABU v01 Alarm Log (Figure 6.38):

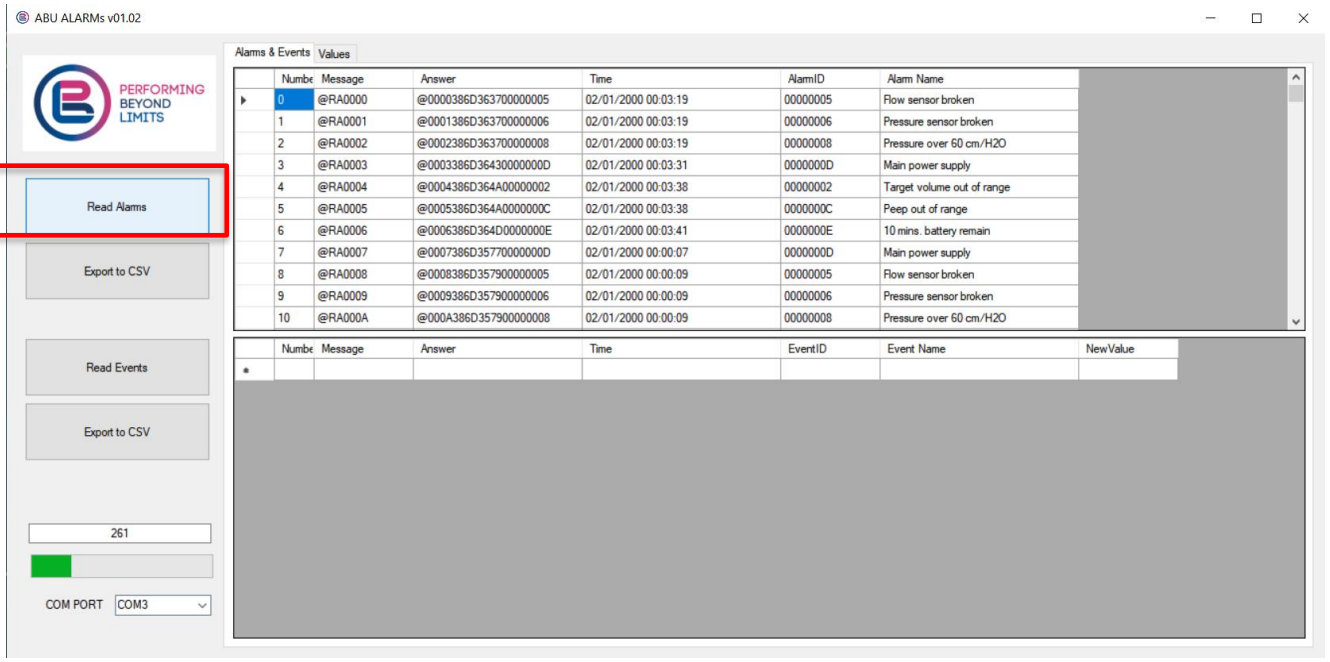


Figure 6.38. Download ABU v01 Alarm Log on the PC. The advancing green bar, on the bottom-left of the window, gives a quantitative measure of the percentage of data missing to complete the download.

- If you want to save the Alarm Log, press “Export to CSV” under “Read Alarms” button, and select the position and the file name for the .CVS file, containing the Alarm Log, that “Serial Arduino.exe” will create on the PC (Figure 6.39).

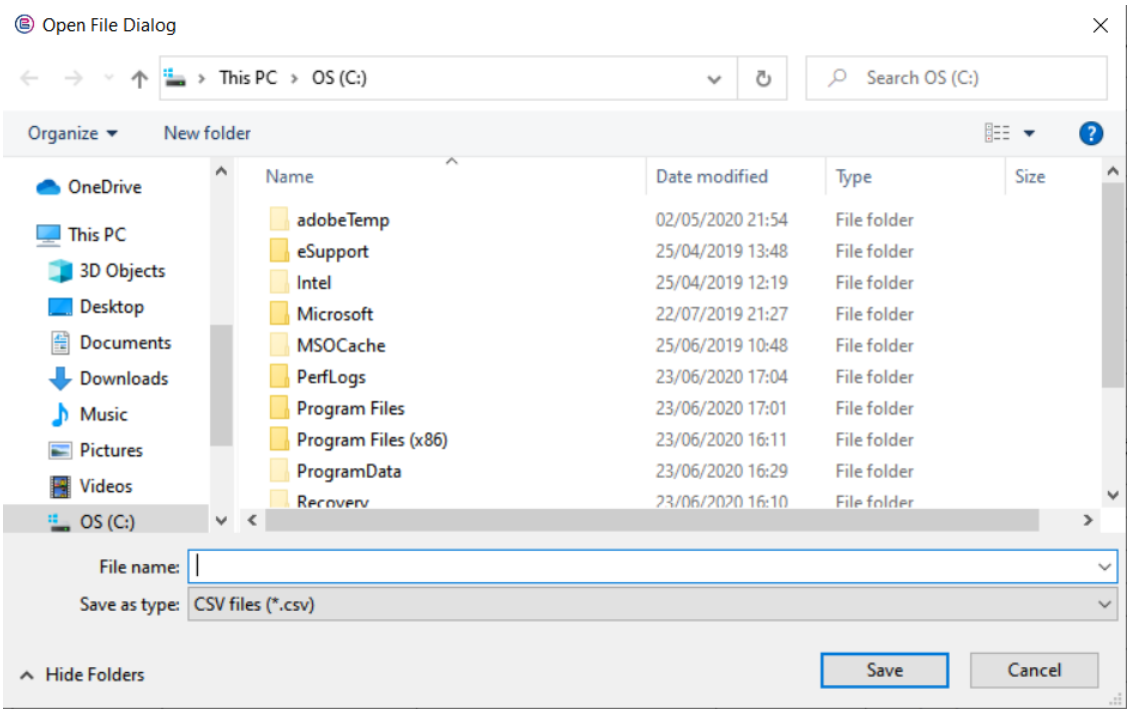


Figure 6.39. Saving window for CVS file created.

- Press ‘Read Events’ button to download the Events saved within ABU v01 Alarm Log (Figure 6.40):

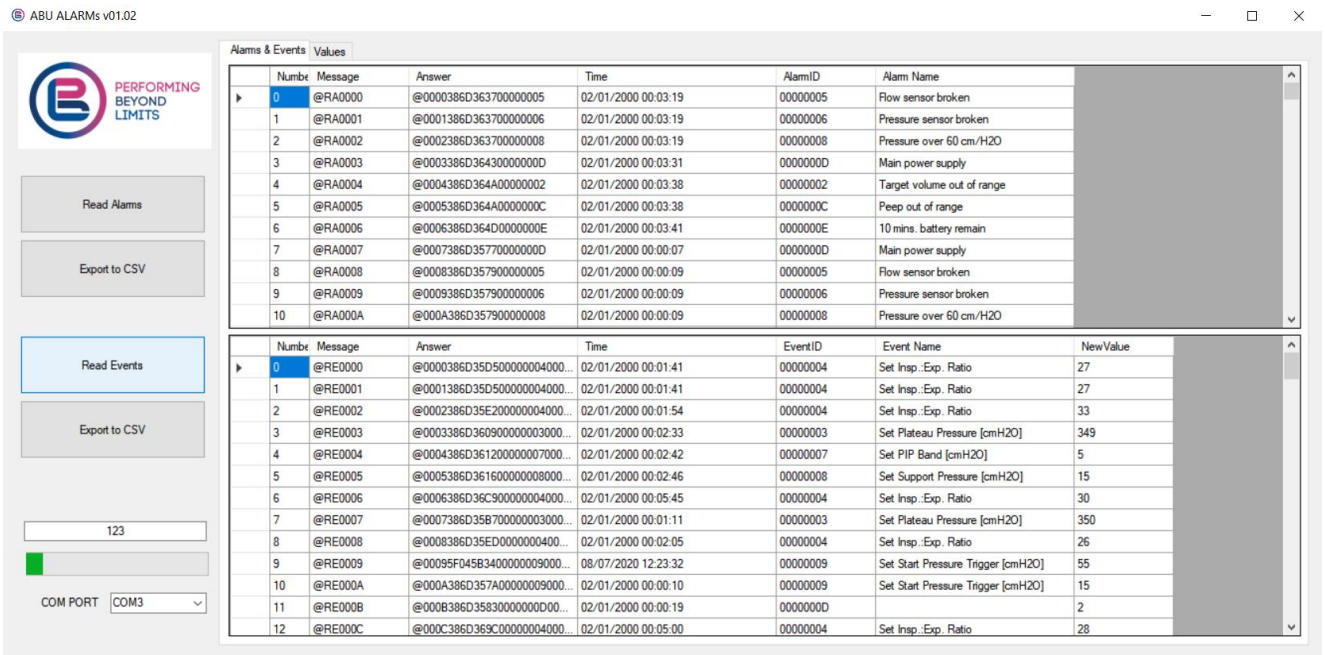


Figure 6.40. Download ABU v01 Events Log on the PC. The advancing green bar, on the bottom-left of the window, gives a quantitative measure of the percentage of data missing to complete the download.

- If you want to save the Events Log, press ‘Export to CSV’ under ‘Read Events’ button, and select the position and the file name for the .CVS file, containing the Events Log, that ‘Serial Arduino.exe’ will create on the PC as shown for Alarms Log in Figure 6.39.

6.6.2 Downloading and savings of real-time ventilation parameters

- On the main window of the software ‘SerialArduino.exe’, press the ‘Value’ tab as shown in Figure 6.41.

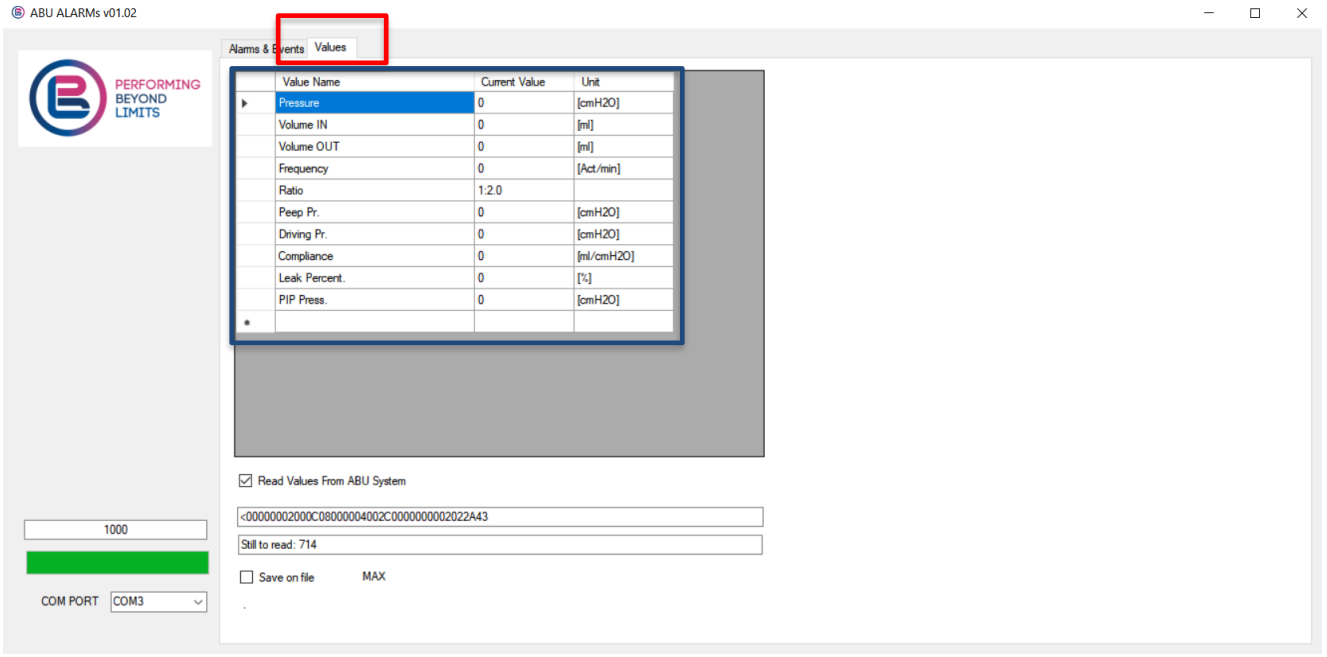


Figure 6.41. Tab for real-time values reading.

- In this tab, by checking the ‘Read values From ABU System’ option, the window will start showing the real time values of the ventilation parameters in the blue square of Figure 6.41. The real-time parameters shown are:

  - Pressure (i.e., airways pressure)
  - Volume IN (i.e., Inspiratory Tidal Volume)
  - Volume OUT (i.e., Expiratory Tidal Volume)
  - Frequency (i.e., breathing Frequency)
  - Ratio (i.e., I:E ratio)
  - Peep Pr. (i.e., PEEP)
  - Driving Pr. (i.e,, Driving Pressure)
  - Compliance (i.e., Pulmonary Compliance)
  - Leak Percent. (i.e., Leak Percentage)
  - PIP Press. (i.e., PIP pressure)

- By checking the ‘Save on file’ option, it is possible to start registering the real-time values that the ventilator is measuring from the time when the option has been checked. Before beginning the registration, the program requires to insert the location and the file name for the .CVS file, containing the ventilation values registered (Figure 6.42). The registration will stop if the ‘Save on file’ option is unchecked or if the number of saved values reaches 5000. In any case, at the end of the registration, the program will save the .CVS file as requested by the user.

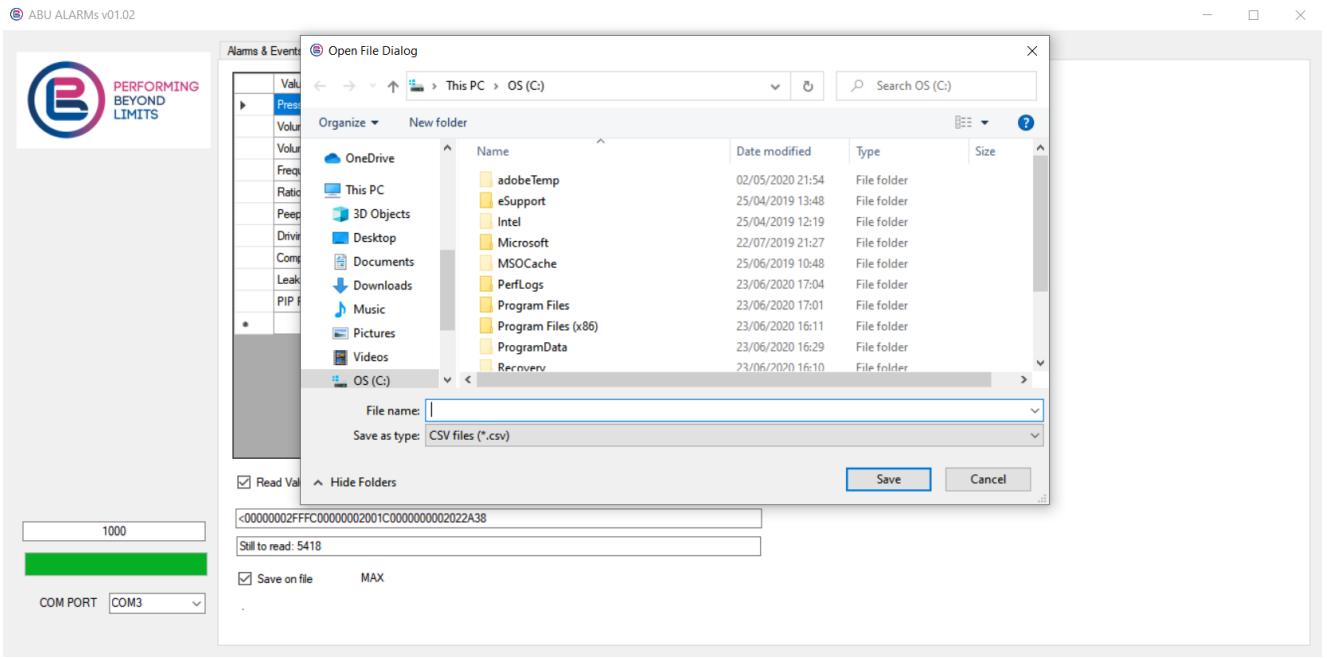


Figure 42. Ventilation parameters saving on PC.

Note:

ABU v01 allows to save up to 5000 samples of all the ventilation parameters listed in section 6.6.2 'Downloading and savings of real-time ventilation parameters'

7-Cleaning

WARNING:
A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection. The use of a bacterial filter at the ventilator's outlet port is recommended.

WARNING: To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

7.1 Cleaning the ventilator

Clean all external panels and surfaces before and after each patient use and as often as necessary to keep the ventilator clean. You should clean the ventilator periodically, whenever it is soiled or dirty, before any maintenance operation, and before storing the ventilator.

WARNING:
WARNING: Use all cleaning solutions and products with caution. Read and follow the instructions associated with the cleaning solutions you use to clean your ventilator. Use only those solutions listed in Table 7.1.

WARNING:
The ventilator should never be immersed in any liquid, and any liquid on the surface of the device should be wiped away immediately.

WARNING:
To avoid damage to the ventilator, in particular the batteries or electrical components, fluids must not be allowed to enter the device, particularly through the apertures of the arms of the mechanical pincher located in the rear panel of the ventilator.

To clean the surface of the ventilator:

1. Dip a clean, soft cloth into a mixture of mild soap and water, or other approved cleaning solution. See Table 7.1 below, for a list of approved cleaning solutions.

Description
Mild dishwashing detergent
70% isopropyl alcohol (rubbing alcohol)
Hospital disinfectant cleaners
Hydrogen peroxide
15% ammonia (85% tap water)
Ammonia based household cleaners

Household cleaners

Table 7.1 – Approved cleaning solutions for exterior ventilator surfaces

2. Squeeze the cloth thoroughly to remove excess liquid

3. Lightly wipe the external casing of the ventilator, taking care not to allow excess moisture to enter any of the openings on the ventilator's surface. See the warning, above.

4. Dry the ventilator surface with a clean, soft, lint-free cloth.

7.2 Cleaning the accessories

Follow the accessory manufacturer's instructions for cleaning the ventilator's accessories and components, including the breathing circuit a part from ABU sensor back; for this last, see section below.

WARNING:
After assembling, cleaning, or reassembling the patient circuit, and on a DAILY basis, inspect the hoses and other components to ensure that there are no cracks or leaks and that all connections are secure.

WARNING:
Never use a liquid cleaner inside the patient circuit, or on any component of a gas pathway. Clean the patient circuit only as specified by the manufacturer's instructions.

7.3 Cleaning ABU sensor pack

WARNING:
After each use and after each cleaning procedure check the status of the ABU sensor pack simply by connecting it to the ventilator, turning it on and checking if any alarm related to sensor pack or sensors in general is shown. See section C.1, "ABU sensor pack test".

WARNING:
If ABU ventilator displays any alarm regarding ABU sensor pack or sensors in general, or if the user detects any malfunctioning or unusual behavior in the parameters displayed by the ventilator, replace the ventilator with another and contact the manufacturer or its legal representative.

WARNING:
ABU sensor pack should never be immersed in any liquid and it should never be cleaned by spraying directly on it any detergent.

To clean ABU sensor pack:

1- Dip a clean, soft cloth into a mixture of mild soap and water, or other approved cleaning solution. See Table 7.1, for a list of approved cleaning solutions.

2- Lightly wipe the internal surface of the pipe contained inside the ABU sensor pack, taking care not to allow excess moisture to enter the pipe. See the warning, above.

3- Lightly wipe the internal surface of the pipe contained inside the ABU sensor pack with a damp cloth of water only in order to rinse the detergent use in the previous passage.

4- Dry the internal surface of the pipe contained inside ABU sensor pack with a soft, lint-free cloth.

8- Maintenance

WARNING:
On a DAILY basis, inspect the patient circuit to ensure that it shows no signs of damage, is properly connected, and is operating correctly without leakage.

WARNING:
Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorized and qualified by P.B.L. should repair, open or service the ventilator.

WARNING:
Regularly check the cleanliness of the air inlet filter located upstream with respect to the patient-ventilator interface system, on the ventilator side. If necessary, replace the filter before (see section 8.1, "Replacing the antibacterial and antiviral filters"). This is particularly important when the ventilator is installed in emergency scenarios, because environmental conditions may cause the filter to become dirty more rapidly.

WARNING:
The maximum recommended lifetime, under normal operating conditions, of the ABU v01 is ten (10) years. Do not use the ventilator if it has been used for more than ten (10) years without consulting the manufacturer, even if it has always been used under normal operating conditions.

8.1 Replacing the antibacterial and antiviral filters

To replace the antiviral/antibacterial filters mounted within the breathing circuit upstream with respect to the patient-ventilator interface and just upstream of the ABU PEEP valve see instructions below:

1- Use only sterile filters compliant with ISO 5356-1, listed in Table A.2, to ensure fittings with other breathing circuit components.

2- Mount the new filters as described in section 4.3, "Mounting the device".

8.2 Recommended schedule of maintenance

When used under normal circumstances, meaning a relatively dust-free environment, and without damage to the device and its accessories, the intervals for replacing the ventilator's consumable elements are report in Table A.2 in section A.1.1

For recommended third-party accessories/parts, listed in section A.1.2 "Recommended third-party accessories" herein, follows the indications for their maintenance reported in their relative instructions for use.

WARNING:
Failure to observe these recommendations may result in a loss of performance, excessive overheating, a loss of certain function and, in the long term, compromise the longevity of the ventilator.

8.2.1 Maintenance of internal battery

The internal battery does not need to be removed to verify its correct operation.

ABU ventilator continuously and automatically measures the voltage of the internal battery, as an efficient indicator of its charge status, even when the internal battery is not used as the main power source.
However, the battery charge status should be checked everytime before using the ventilator, especially if the ventilator has not been used for days.

WARNING:
The maximum recommended shelf life of the internal battery is two (2) years. Do not use a battery that has been stored for two years prior to its first use.

WARNING:
Periodic recharging is important to help maximize useful life of the battery. Do not store the internal battery for periods longer than seven (7) days, without recharging, as this may reduce the maximum life and the amount of stored energy available in case of immediate and unexpected use.

8.2.2 Replacement of the internal battery

The internal battery should be replaced when the battery capacity drops below 2000 mAh. Keep in mind that, for environmental protection, the ventilator and its components – including its internal battery – cannot be disposed of with household waste. You must submit the ventilator and its components for suitable collection and possible recycling and observe all applicable national regulations.

8.2.3 Replacement of fuses

WARNING:
Fuses shall be replaced by Technical experts designated by P.B.L.. Changing the fuses of the ventilator may put your life in danger in any circumstance, do not attempt to that by yourself!

Fuses shall be replaced only by authorized service personnel, previously instructed by technical experts designated by P.B.L..

8.3 Service Assistance

WARNING:
If a problem with the ventilator is suspected, FIRST CHECK THAT THE PATIENT IS NOT IN DANGER. If necessary, remove the patient from the ventilator and provide an alternative means of ventilation.

WARNING:
Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorized and qualified by P.B.L. should repair, open or service the ventilator.

In the event of a problem with the ventilator, see chapter 9, “Alarms and Troubleshooting”. If you cannot determine the cause of the problem, contact your equipment supplier of ventilator’s manufacturer.

9 – Alarms and Troubleshooting

WARNING:
Setting Alarm limits to extreme values can cause the ventilator alarms to malfunction.

WARNING:
When an alarm condition is triggered, or there is evidence of a patient-ventilator fault or problem, examine the patient first before examining the ventilator.

CAUTION:
Setting any alarm limits to extreme high or low values can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the caregiver to situations that may require intervention.

Note:
All alarm conditions and settings are recorded in the ventilator's non-volatile memory, and are retained when powering down or in the event of a total loss of power.

9.1 Alarm Level Priority

The alarm hierarchy for signaling the level of alarm criticality is listed below.

- **High priority (HP): Critical situation in the short term; ventilation may be potentially compromised:**
  For situations that require immediate intervention of the user.
  High speed intermittent sound signaling/Red Alarm icon illumination displayed/With Message

- **Medium Priority (MP): Critical situation in the long term; ventilation is not affected in the short term:**
  For situations that require not immediate intervention of the user; situations where ventilation may not be that efficient but do not threaten patient's life in the short term.
  Medium speed intermittent sound signaling/ Yellow Alarm icon displayed/With Message.

Note:
Currently, there are no Low Priority (LP) alarms

9.2 Alarm Display

During operation, when an alarm is activated:

- One of the red or yellow alarm icons flashes to the bottom-right corner of the ‘Home’ page (see Figure 9.1 and Figure 9.2, below)

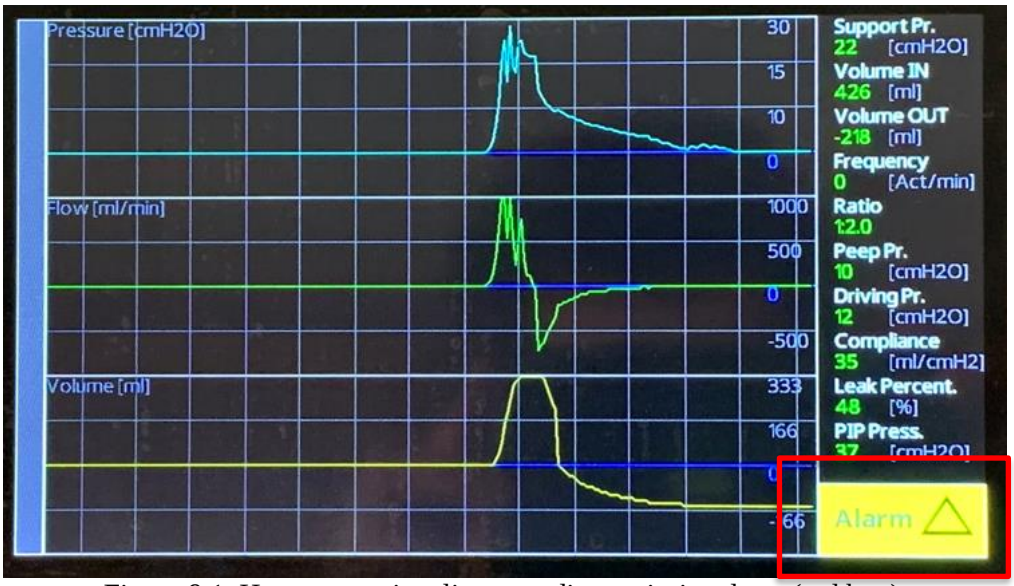


Figure 9.1. Home page signaling a medium-priority alarm (red box).

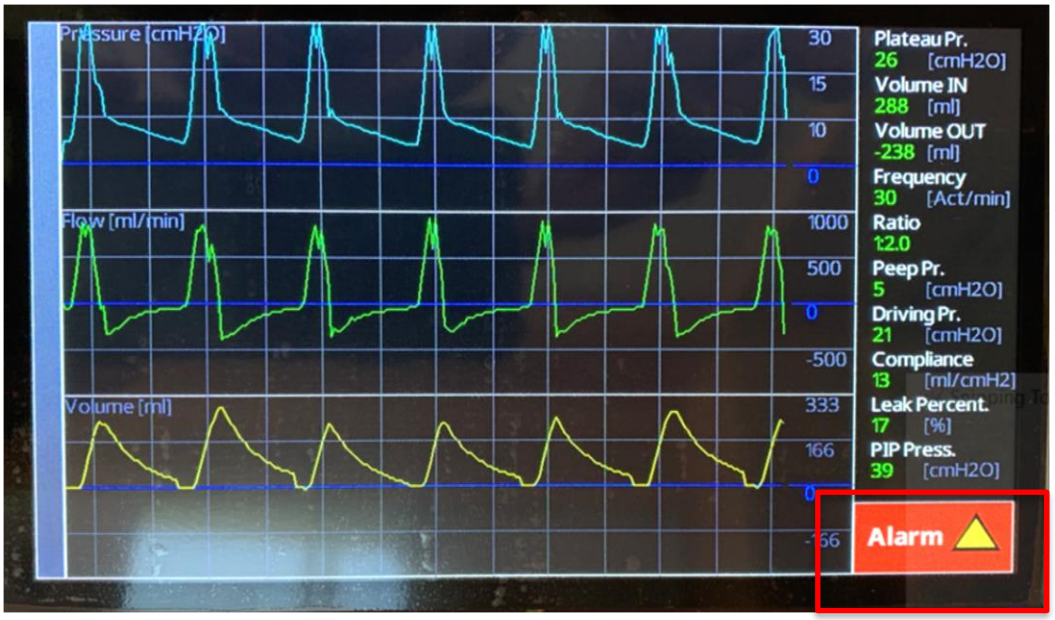


Figure 9.2. Home page signaling a high-priority alarm (red box).

- An alarm tone sounds.

- A message is displayed in the ‘Alarm’ page that can be accessed by pressing the “Alarm” button in the bottom-right corner of the ‘Home’ page (see Figure 9.3, below).

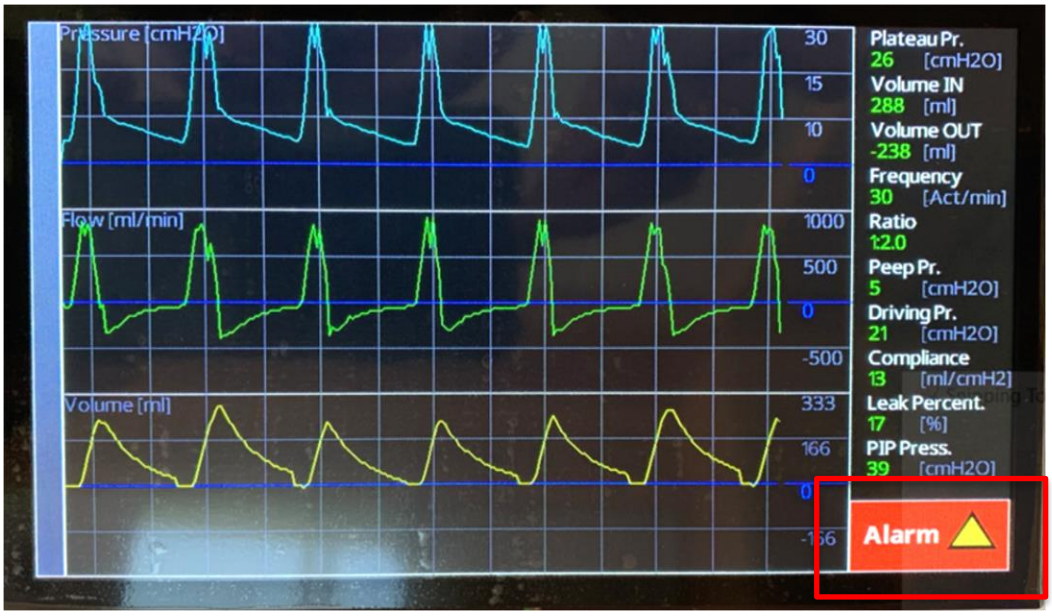


Figure 9.3. By pressing the “Alarm” button you will access the “Alarm” as shown in Figure 9.4 (below)

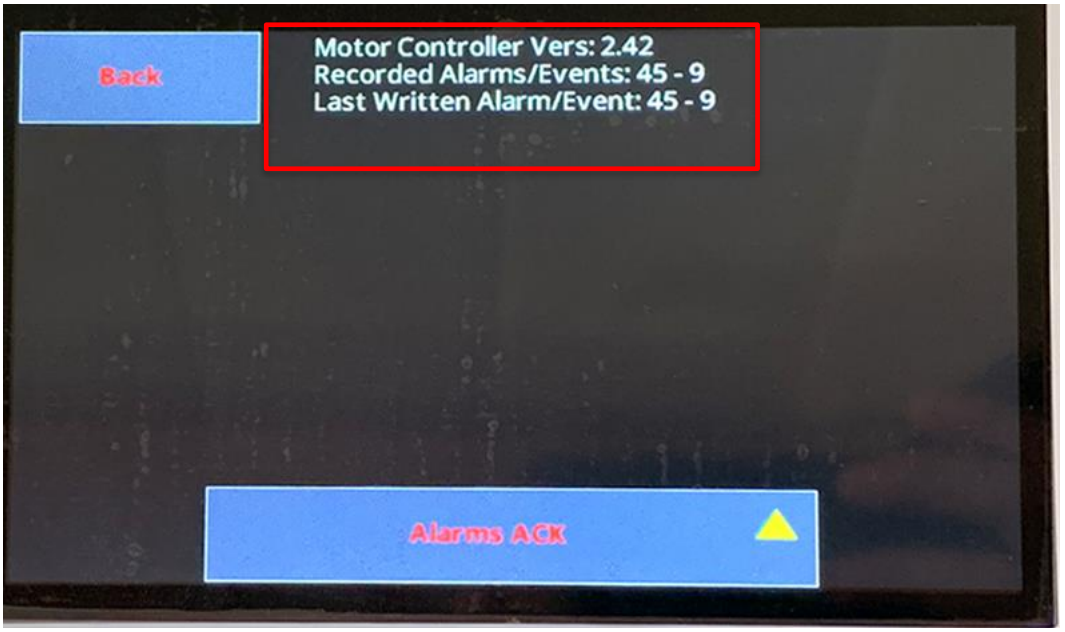


Figure 9.4. ‘Alarm’ page where alarm messages are reported. Red box displays information regarding Motor controller software version (top line), Number of recorded Alarms and Events: the first number refers to alarms the second number refers to events (middle line); number of last written alarm and event (first and second number respectively, bottom line).

Note:

In the event that several alarms are activated at the same time, the highest priority audible and visual alarm is highlighted; however, all active messages are displayed in the ‘Alarm’ page.

Note:
All alarms must be reset even if the alarm condition has ceased to exist before silencing/resetting the relative alarm.

9.3 Alarm Logs Menu

All alarms are recorded in the ventilator's non-volatile internal memory at the time of activation and are retained when powering down or in the event of a total loss of power. The Alarms Log is used to display the last 1000 (one thousand) alarms activated, along with their date and time of activation.

To access the Alarm Log, you need a PC connected with the provided USB cable to the ventilator as explained in section 6.6, "PC connection".

9.4 Resetting or Silencing Alarms

You may reset an alarm condition by pressing 'Alarm ACK' Button, placed at the bottom of the 'Alarm' page, see Figure 9.5 below.

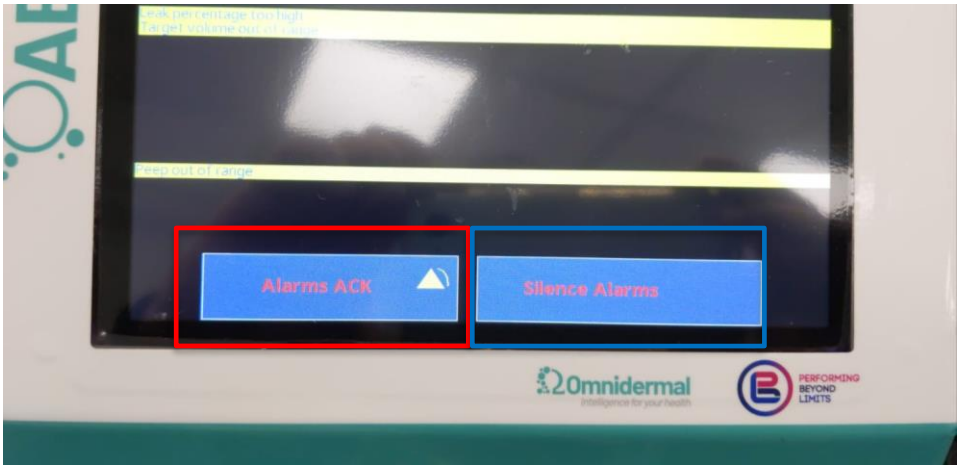


Figure 9.5. Resetting or Silencing alarms by pressing either the "Alarms ACK" button, shown in the red square, or the "Silence Alarms" button, shown in the blue square.

When "Alarms ACK" button is pressed:

- All alarms conditions are reset

Note:
If multiple alarms are activated, It is not possible to reset only one condition, as the 'Alarms ACK' button reset all active alarms.

Note:
If the 'ACK Alarms' button is pressed and one or more alarm conditions are still present, the ventilator will activate the relative alarms immediately after.

When "Silence Alarms" button is pressed:

- All alarms are silenced, but:
  - HP alarms are silenced for 60 seconds;
  - MP alarms are silenced for 2 minutes.

Note:
All alarm sounds are reactivated automatically after a certain amount of time that depends of the priority of the alarm, as explained above.

Note:
If multiple alarms are activated, It is not possible to silence only one condition, as the 'Silence Alarms' button silences all active alarms.

9.5 Overview of Alarms

Alarm Message	Cause/Ventilation Response	Priority	Alarm reset Avail.	Ventilation mode
Main Power Supply	Cut-off of the AC (mains) power supply. Alarms activation occurs immediately after the cut-off of the AC supply occurs. Consequence: ABU ventilator switches to internal battery.	MP	YES	ALL
10 Mins. Battery remaining	Less than 10 minutes of battery charge available Alarms activation occurs when internal battery voltage reaches 23 Volts.	HP	YES	ALL
5 Mins. Battery remaining	Less than 5 minutes of battery charge available Alarms activation occurs when internal battery voltage reaches 22.5 Volts. Consequence: if the ventilator is not connected to an AC power supply, the	HP	YES	ALL

	ventilator will switch off after less than 5 minutes when the internal battery voltage reaches 22 Volts.			
General System Error	ABU ventilator, every machine cycle, checks its internal status, if an error condition or malfunctioning is detected an alarm will be activated.	HP	YES	ALL
Target Volume out of range	If the Target Inspiratory Tidal Volume set by the user is not reached during a breathing act, an alarm will be activated at the end of that breathing act.	MP	YES	FORCED
Peep out of range	If the PEEP value is not in the range: Set PEEP – 1 cmH_2O < Measured PEEP < set PEEP +1 cmH_2O, An alarm will be activated at the end of a breathing act.	MP	YES	ALL
PIP too high	If the PIP reaches or exceeds the limit represented by: Set Plateau Pressure + set PIP range, an alarm will be activated at the end of the relative breathing act.	HP	YES	FORCED
Pressure over 60 cmH_2O	If the airways pressure exceeds, for any reason, the value of 60 cmH_2O, an alarm is activated immediately.	HP	YES	ALL
Support pressure not reached	If, during the inspiratory phase of an assisted breathing act, the support pressure set by the operator is not reached, the ventilator will activate an alarm.	MP	YES	ASSISTED
Too many breath timeouts	If, during the assisted ventilation, the ventilator does not detect a spontaneous breathing act within the set 'Backup Time' range, for 5 consecutive times, an alarm will be activated.	HP	YES	ASSISTED
Leak Percentage too high	If, at the end of a forced breathing act, the leak percentage calculated as detailed in section 6.2.4, "Setting Forced ventilation parameters" or 6.2.5, "Setting assisted ventilation parameters", reaches or exceeds the set leak percentage limit, an alarm will be activated.	MP	YES	ALL
Flow sensor broken	If the ABU v01 control unit loses communication with ABU sensor pack or the communication with the flow sensor, contained inside the ABU sensor pack, is malfunctioning or the readings coming from the flow sensor have no physical meaning, an alarm will be activated.	HP	YES	ALL

	If this happens ABU v01 ventilator will work with the ventilation settings of the previous free-of-malfunctioning breathing act. Even if the ventilator, in this case, has lost the readings coming from the pressure sensor, its control unit will use the same motor motion of the previous free-of-malfunctioning breathing act.			
Pressure sensor broken	If the ABU v01 control unit loses communication with ABU sensor pack or the communication with the pressure sensor, contained inside the ABU. sensor pack, is malfunctioning or the readings coming from the pressure sensor have no physical meaning, an alarm will be activated. If this happens ABU v01 ventilator will work with the ventilation settings of the previously free-of-malfunctioning breathing act. Even if the ventilator, in this case, has lost the readings coming from the pressure sensor, its control unit will use the same motor motion of the previous free-of-malfunctioning breathing act.	HP	YES	ALL

Table 9.1. Overview of Alarms

9.6 Troubleshooting

WARNING:
This manual tells you how to respond to ventilator alarms, but it does NOT tell you how to respond to the patient.

WARNING:
To ensure proper servicing and avoid the possibility of physical injury to personnel or damage to the ventilator, only personnel authorized and qualified by P.B.L. should attempt to service or make authorized modifications to the ABU v01 ventilator.

WARNING:
Do not attempt to open, repair or otherwise service the ventilator yourself. Doing so might endanger the patient, damage the ventilator, and/or void your warranty. Only personnel authorized and qualified by P.B.L. should repair, open or service the ventilator.

Table 9.2, offers a guide to the most likely ventilator alarms, possible reasons for the alarms, and corrective actions.

Alarm Message	Possible Reason(s) for the Alarm Event	Corrective Action
Main Power Supply	AC ("mains") power supply cut off.	Reset the alarm and check the supply cable and/or the effective availability of a voltage on the AC power supply
	I/O switch set in O position	Reset the alarm and place the I/O switch on the I position
	Current limiting fuse of the device blown.	Replace the ventilator and call for the maintenance technician.
	AC Power cable disconnected	Reset the alarm and check the supply cable and/or the effective availability of a voltage on the AC power supply
10 Mins. Battery remaining	Internal battery voltage reached 23 Volts due to extensive operation using the ABU internal battery	Reset the alarm and connect the ventilator to an external AC power supply and place the I/O switch in the I position.
5 Mins. Battery remaining	Internal battery voltage reached 22.5 Volts due to extensive operation using the ABU internal battery; the ventilator is going to turn off in less than 5 minutes	Reset the alarm and immediately connect the ventilator to an external AC power supply and place the I/O switch in the I position. Alternatively, if no AC power supply is available, be ready to practice manual ventilation by squeezing and releasing ABU balloon, as it happens with bag-valve mask systems.
General System Error	Probably some electrical connections, some electronic components or some mechanical parts (such as the ventilator clamps) are malfunctioning	Immediately replace the ventilator and call for the maintenance technician
Target Volume out of range	The set Inspiratory Tidal Volume has not reached its target value	Reset the alarm and try to adjust ventilation parameters and the position of the ABU PEEP valve in order to obtained the desired ventilation. Only for authorized users and healthcare personnel expert in artificial ventilation and sufficiently trained in the use of ABU ventilator.
Peep out of range	The measured PEEP does not fall in the range: Set PEEP – 1 cmH_2O < Measured PEEP < set PEEP +1 cmH_2O	Reset the alarm and try to adjust ventilation parameters and the position of the ABU PEEP valve in order to obtained the desired ventilation. Only for authorized users and healthcare personnel expert in artificial ventilations and sufficiently trained in the use of ABU ventilator.
PIP too high	The measure PIP reached or exceeded the threshold calculated as: Set Plateau Pressure + set PIP range	Reset the alarm, check if there are no obstructions within the breathing circuit and, if this is not the case, try to adjust ventilation parameters and the position of the ABU PEEP valve in order to obtained the desired ventilation. Lowering the Plateau pressure is suggested. Only for authorized users and healthcare personnel expert in artificial

		ventilations and sufficiently trained in the use of ABU ventilator.
Pressure over 60 cmH_2O	The airways pressure reached or exceeded 60 cmH_2O. It is a dangerous situation	Reset the alarm, check if there are no obstructions within the breathing circuit. Remove eventual obstruction and if this is not the case, lower Plateau pressure and try to adjust ventilation parameters and the position of the ABU PEEP valve in order to obtained the desired ventilation. Only for authorized users and healthcare personnel expert in artificial ventilations and sufficiently trained in the use of ABU ventilator.
Support pressure not reached	The support pressure was not reached during the last inspiratory phase of an assisted breathing act.	Reset the alarm, check breathing circuit connections and look for possible air leakages. If this is not the case, it may probably mean that the patient does not need such a high support pressure.
Too many breath timeouts	ABU ventilator may not be able to detect spontaneous breathing acts	Reset alarm, check breathing circuit connections and look for possible air leakage. If this is not the case, try to lower trigger thresholds. If even this operation does not work, think of changing ventilators or pass to forced ventilation mode.
Leak Percentage too high	The leak percentage reached or exceeded the set threshold during the last breathing act.	Reset alarm, check breathing circuit connections and look for possible air leakages. If this is not the case, look for obstructions within the breathing circuit and remove them. If this is not even the case, but patient's parameters are acceptable, think of increasing the alarm threshold. If none of the above solutions work, replace the ventilator and call for maintenance technician.
Flow sensor broken	ABU v01 control unit, contained inside the ventilator, always checks the ABU sensor pack connection; if the connection is lost or the information received from the flow sensor is incomplete or physically inconsistent, an alarm will be activated. This event may happen if the ABU sensor pack cable is disconnected from the ventilator or if the sensor is broken.	Reset alarm, check breathing circuit connections and look for possible air leakages, check that the ABU sensor pack cable is properly connected to the ventilator through the ABU sensor pack cable port. If none of the above solutions work, replace the ventilator and call for maintenance technician.
Pressure sensor broken	ABU v01 control unit, contained inside the ventilator, always checks the ABU sensor pack connection; if the connection is lost or the information received from the pressure sensor is incomplete or	Reset alarm, check breathing circuit connections and look for possible air leakages, check that the ABU sensor pack cable is properly connected to the ventilator through the ABU sensor pack cable port.

	physically inconsistent, an alarm will be activated. This event may happen if the ABU sensor pack cable is disconnected from the ventilator or if the sensor is broken.	If none of the above solutions work, replace the ventilator and call for maintenance technician.

Table 9.2. Alarms and corrective actions.

WARNING:
If the device is damaged, its external housing is not correctly closed, or it behaves in a way that is not described in this manual (excessive noise, heat emission, unusual odor, alarms not triggered during the start-up procedure), the oxygen and power supplies should be disconnected and use of the device stopped immediately.

WARNING:
If you cannot determine the cause of a problem with your ventilator, contact your equipment supplier. Do not use the ventilator until the problem has been corrected.

A - Specifications

A.1 Physical

Ventilator Weight	10 Kg (22 lb)
Ventilator Dimensions	242 mm wide x 435 mm deep x 325 mm high (9.5 in wide x 17.1 in deep x 12.8 in high)
Connectors	Breathing circuit connector: (on ABU balloon) ISO 22 mm (OD) Oxygen Inlet: (on ABU balloon back side) male connector
Device Maximum airway volume without Continuous Fresh Flow (i.e., NCFF)	1500 ml
Air filters	Dimensions: compliant with ISO 5356-1:2004 fitting standard. Efficiency: 99.999982% at 30 lpm (filtering microbes 3.3 μm). For more details refer to Table A.2 below.
Inspirator antiviral/antibacterial filter requirement	Maximum allowable flow resistance: 4 mbar at 60 lpm
ABU sensor pack cable length	1500 mm

Table A.1. Physical Description (excluding accessories)

A.1.1 Recommended components of the breathing circuit

WARNING:
Before opening the packaging for the Breathing Circuit, ensure that no damage is evident to the packaging or its contents. Do not use if evidence of damage exists.

WARNING:
Do not use components of the Breathing Circuit that are supposed to be sterile if their packaging is damaged or broken.

WARNING:
The breathing circuit of the ventilator shall always be used with recommended components, listed in Table A.2, in order to ensure proper ventilation settings. Such components shall be replaced as reported in Table A.2 and as recommended by the manufacturer.

CAUTION:
To ensure proper ventilation settings, components of the breathing circuit listed in Table A.2 should be use. Alternatively, components showing the same physical properties of the pieces listed in Table A.2 should be considered.

The table below reports the recommended components to be used in order to assembly the ABU breathing Circuit together with their replacement moment:

Component Name for ABU	**Manufacturer's reference code**	**Manufacturer**	**Replacement**
ABU PEEP valve	03986	DEAS S.r.l.	After 24 hours of continuous use (according to the results of internal tests conducted on artificial lungs)
Standard disposable breathing hose	04221	DEAS S.r.l.	After 24 hours of continuous use and for each new patient ventilated to minimize the risk of pathogen contamination
ABU balloon, ABU check valve and ABU Reservoir sack	CPR1700	DEAS S.r.l.	After 24 hours of continuous use (according to the results of internal tests conducted on artificial lungs)
Antibacterial and Antiviral filter	07750	DEAS S.r.l.	After 24 hours of continuous use and for each new patient ventilated to minimize the risk of pathogen contamination

Table A.2 Recommended components for ABU Breathing circuit.

A.1.2 Recommended third-party accessories

WARNING:
Please, be aware that ABU v01 is not equipped with any sort of Oxygen Monitoring or Controlling Equipment. If such an external device is used, it shall conform with the following subclasses of ISO 80601-2-55:2018:

- **201.7.4.3;**
- **201.7.9.2.9.101;**
- **201.12.1.101;**
- **201.12.1.102;**
- **201.12.1.103;**
- **208.6.2**

WARNING:
Please, be aware that ABU v01 is not equipped with any sort of Oxygen Monitoring or Controlling Equipment. The ventilator, by exploiting the oxygen port present in the majority (but not the entirety) of the bag-valve masks, can provide an Oxygen concentration of either 21% or almost 100%.

WARNING:
If a heated humidifier is used, you should always monitor the temperature of the gas delivered to the patient. Gas delivered from the ventilator that becomes too hot may burn the patient's airway.

WARNING:
Adding accessories to the ventilator breathing circuit, such as a humidifier and water trap(s), may result in a decrease in tidal volume delivered to the patient due to the added

compressible volume of the accessory. Always assure that the patient is receiving the appropriate inspired volume when altering the breathing circuit configuration.

Third-party accessories/parts that can be added to ABU v01 ventilator are listed below. Always make sure that the third-party accessories used are compliant and accordingly-certified to the standards reported below.

CAUTION:
Always follow Instructions For Use of the recommended third-party accessories/parts used with ABU v01 ventilator.

- Oxygen Monitoring or Controlling equipment. If any Oxygen Monitoring or Controlling Equipment is to be used, it shall conform with the following subclasses of ISO 80601-2-55:2018:
    - 201.7.4.3;
    - 201.7.9.2.9.101;
    - 201.12.1.101;
    - 201.12.1.102;
    - 201.12.1.103;
    - 208.6.2;

- Heated Humidifier. If an heated humidifier is to be used, use the recommended third-party accessory listed below:

    - Fisher and Paykel Healthcare MR850

A.2 Electrical

Note:
ABU v01 ventilator only allows the use of IEC 60320 C14 power cable.

Voltage	**Frequency**	**Consumption**
100 VAC to 240 VAC	50 Hz / 60 Hz	450 VA max

Table A.3. Electrical Supply

Voltage	24 VDC
Full-load capacity	4.6 Ah
Charging current	300mA /hr (duration (< 10 hr.)

Average operating time at 25 °C (± 5°C) with a fully charged battery (having less than 50 charge/discharge cycles) at the following displayed operating conditions:	
<u>Lowest energy consumption condition:</u> Breathing frequency = 5 acts per minute, I:E ratio = 1:1	1.5 hr (-10 %)
<u>Highest energy consumption condition:</u> Breathing frequency = 35 acts per minute, I:E ratio = 1:4	40 minutes (-10 %)

Table A.4. Internal lead acid batteries

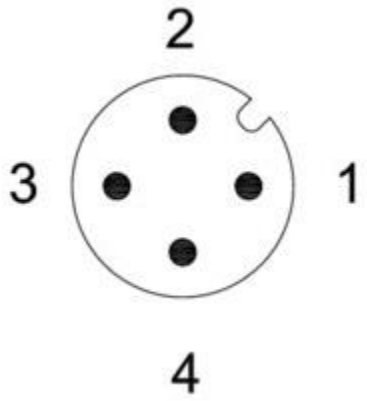
Distribute Alarm System Connection Port (DASCP): it provides for remote alerts of ventilator alarm conditions. An example of a setting that requires such a feature is when the ventilator is used in an isolation room. ABU ventilator signals an alarm using a normally open (NO) signal. A remote alarm is activated when an alarm condition occurs, unless alarms are reset using 'Alarms ACK' button as explained in chapter 9. The alarm delay, once generated from the ventilator, to the DASCP cable is less than 100 ms. The remote alarm port is a 4-pin female connector. Allowable current is 100 mA at 24 VDC (maximum).	 Distribute Alarm System Connection Port (DASCP), view from the left-side panel of ABU ventilator.

Table A.5. Remote Alarm.

Pin	Signal	Remote Alarm Wire Color
1	Normally Open (NO)	Brown
2	Not used	White
3	No used	Blue
4	Relay Common	Black

Table A.6. Distributed Alarm System Connection Port – Pin connection.

A.3 Performance

A.3.1 Essential performance

The essential performance consists in a controlled and monitored patient ventilation with user-defined settings for the monitoring functions:

- tidal volume,
- maximum airway pressure,
- Positive End-Expiratory Pressure (i.e., Peep)
- Spontaneous breathing act detection

or, if a set limit is exceeded, an appropriate alarm.

Additionally, the integrated monitoring alarms in the following situations:

- Battery discharge or loss of AC (main) power supply
- Sensor malfunctioning

A.3.2 Essential Specifications

Parameter name	Type (numeric, alphanumeric, character)	Range	Unit of measurement	Tolerances
Breathing Frequency (mod.: forced)	*Numerical*	*5-35*	*Breathing acts/minute*	*± 1 act/min*
Target Inspiratory Tidal Volume	*Numerical*	*50-1500*	*ml*	*±15% (compared to the set value)*
Plateau Pressure (mod.: forced)	*Numerical*	*1-50*	*cmH2O*	*±1 cmH2O (compared to the set one)*
Inspiratory: Expiratory time ratio (mod.: forced)	*Numerical*	*1:1, 1:1.5, 1:2, 1:2.5, 1:3, 1:3.5, 1:4*	*Adimensional (being a relationship)*	*±5% (compared to the set value)*
Leak Percentage	*Numerical*	*5-90*	*%*	*±1% (compared to the set value)*
PEEP	*Numerical*	*0-25*	*cmH2O*	*± 1 cmH2O (compared to the set one)*
Support pressure (mod.: assisted)	*Numerical*	*0-30*	*cmH2O*	*± 1 cmH2O (compared to the set one)*
(Support) Pressure Acceleration (mod.: assisted)	*Numerical*	*1-15*	*Dimensional*	*Irrelevant*
Start Pressure Trigger (mod.: assisted)	*Numerical*	*-1 a -15*	*cmH2O*	*± 0.5 cmH2O (compared to the set one)*
Start Flow Trigger (mod.: assisted)	*Numerical*	*5 a 500*	*ml/min*	*±15% (compared to the set value)*
Stop Flow Trigger (mod.: assisted)	*Numerical*	*0 a 99*	*%*	*±5% (compared to the set value)*
Backup Time (mod.: assisted)	*Numerical*	*2 a 20*	*s [sec]*	*± 5% (compared to the set value)*

Table A.7. Performance parameter specifications and tolerances.

A.3.3 Monitored Parameters

Parameter name	Type (numeric, alphanumeric, character)	Range	Resolution	Unit of measurement	Tolerances (compared to expected value)	Direct/Calculated Measurement
Flow	*Numerical*	*-100, +250*	*1*	*slm[1]*	*7 % m.v.[2] asl (on full range)*	*Measured*

Differential pressure	*Numerical*	*-50, +50*	*1*	*mbar*	*± 1 % (on full scale)[3]*	*Measured*
Plateau Pressure (mod.: forced)	*Numerical*	*0 a 50*	*1*	*cmH2O*	*± 1 cmH2O*	*Direct*
PIP Pressure	*Numerical*	*0 a 50*	*1*	*cmH2O*	*± 1 cmH2O*	*Direct*
Inspiratory Tidal Volume	*Numerical*	*ND[5]*	*1*	*ml*	*± 15%*	*Calculated[6]*
Expiratory Tidal Volume	*Numerical*	*ND*	*1*	*ml*	*± 15%*	*Calculated[6]*
Breathing Frequency	*Numerical*	*ND*	*1*	*Breathing acts/minute*	*± 1 act/min*	*Calculated[7]*
PEEP Pressure	*Numerical*	*0 a 50*	*1*	*cmH2O*	*± 1 cmH2O*	*Direct*
Driving Pressure (mod.: forced)	*Numerical*	*ND*	*1*	*cmH2O*	*± 1 cmH2O*	*Calculated[8]*
Compliance (mod.: forced)	*Numerical*	*ND*	*1*	*ml/cmH2O*	*± 5%*	*Calculated[9]*
Leak Percentage (or percentage of loss)	*Numerical*	*ND*	*1*	*%*	*± 1%*	*Calculated[4]*
Support Pressure (mod.: assisted)	*Numerical*	*0 a 35*	*1*	*cmH2O*	*± 1 cmH2O*	*Direct*

Table A.8. Monitored parameters.

[1]slm: mass flow measured in liters per minute at standard conditions (T = 20 °C, p = 1013.25 mbar)

[2] % m.v. = % measured value = % of reading

[3] Total accuracy is the combined error from offset and span calibration, linearity, pressure hysteresis, and temperature effects. Linearity is the measured deviation based on a straight line. Hysteresis is the maximum output difference at any point within the operating pressure range for increasing and decreasing pressure. Calibration errors include the deviation of offset and full scale from nominal values.

[4]DN means that the parameter is a dependent variable so its range depends on the values of the indirect parameters related to it.

[5]Volume calculated as integral flow over time: $V = \int_{-\frac{T}{2_0}}^{+\frac{T}{2_0}} F\ dt$*, where T corresponds to the period of a respiratory act.*

[6]Breathing frequency calculated as: 1/T.

[7]Driving Pressure (dP) calculated as: dP = Plateau Pressure – PEEP

[8]Compliance is calculated as: C = Inspiratory Tidal Volume/ dP

[9]Leak percentage calculated as: (Inspiratory Tidal Volume – Expiratory Tidal Volume)/ Inspiratory Tidal Volume 100*

A.4 Environmental

WARNING:
If the ventilator has been transported or stored at a temperature that differs more than ±20 °C (± 36 °F) from the temperature in which it will be operating, the ventilator should be allowed to stabilize in its operating environment for at least one (1) hour prior to use.

WARNING:
If the ventilator has been transported or stored at humidity out of the range reported in Table A.9, the ventilator should be allowed to stabilize in its operating environment for at least one (1) hour prior to use.

Temperature	Humidity	Atmospheric pressure	Altitude
-40 °C to + 70 °C (-40 °F to +158 °F)	10% to 95% RH	500 hPA 1060 hPa (7 psi to 15.4 psi)	-150 m to 3964 m (500 ft to 13,000 ft)

Table A.9. Environmental conditions for Storage or Transport

Temperature	Humidity	Atmospheric pressure	Altitude
+5 °C to 40 °C (+41 °F to 104 °F)	10% to 95% RH	600 hPa to 1100 hPa (8.7 psi to 16.0 psi)	-152 m to 3964m (-500 ft to 13,000 ft)

Table A.10. Environmental conditions for Operation.

Under extreme conditions of use, within the limits of a supply voltage of –20% and temperatures ranging from normal to 45 °C (113 °F) with ≤ 75% RH, the ventilator should not malfunction nor endanger the user. However, operating the device for prolonged periods or repeatedly under such extreme conditions could result in premature aging of components and more frequent maintenance.

A.5 PC connection

ABU ventilator allows user to connect a PC to download Alarms and Events Logs and real-time ventilation parameters.

By connecting a PC using the USB cable (USB-B to USB-A) provided with ABU ventilator, user can download all information regarding the ventilator and its history. For more details see section 6.6, “PC connection”.

Requirements:

- PC or laptop with Windows 7 or 10
- “SerialArduino.exe” file provided with ABU ventilator
- A USB-A-USB-B ended cable, provided with the ventilator

A.6 ABU ventilator memory capability

ABU ventilator is equipped with an internal static memory that can store:

- up to 1000 Alarms occurrences

-up to 1000 Events (i.e., operations performed on the ventilator).

A.7 Pneumatic

For airways Resistances of the breathing circuit, the user is redirected to the breathing circuit manufacturer's recommendation (Table A.2), keeping in mind that the influences of ABU sensor pack connected to that is on average as follows:

0.2 mbar at 30 lpm ±0.1 mbar
1.1 mbar at 300 lpm ± 0.1 mbar

Table A.11. ABU sensor pack airway resistance.

Working pressure	Maximum pressure limit	Inspiratory triggering response time
1 mbar- 55 mbar	60 mbar	100 ms

Table A.12. Performance specifications.

A.8 Manufacturer's declaration

The following tables, Table A.12 through Table A.18 contain the manufacturer's declarations for the ventilator's electromagnetic emissions, electromagnetic immunity, and recommended separation distances between the ventilator and portable and mobile RF communications equipment, as well as a list of compliant cables.

WARNING:
Portable and mobile RF communications equipment can affect the performance of the ABU ventilator. Install and use this device according to the information contained in this manual.

WARNING:
The ventilator should not be used adjacent to or stacked with other equipment, except as specified in this manual. If adjacent or stacked use Is necessary, the ventilator should be observed to verify normal operation in the configuration in which it will be used.

The ABU Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.		
RF emissions CISPR 11 / EN 55011	Group 1	The ventilator uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11 / EN 55011	Class A	The ventilator is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC / EN 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC / EN 61000-3-3	Not Applicable	

Table A.13 – Electromagnetic Emissions

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should ensure that it is used in such an environment.			
Immunity Test	**IEC / EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment–Guidance**
Electrostatic discharge (ESD) IEC / EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC / EN 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	AC power (“mains”) quality should be that of a typical commercial or hospital environment.

Table A.14. Electromagnetic Immunity

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should ensure that it is used in such an environment.

Immunity Test	IEC / EN 60601 Test Level	Compliance Level	Electromagnetic Environment–Guidance
Surge IEC / EN 61000-4-5	± 1 kV lines/lines ± 2 kV lines/earth	± 1 kV lines/lines ± 2 kV lines/earth	AC power (“mains”) power quality should be that of a typical professional environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC / EN 61000-4-11	< 0% UT for 0.5 <0% UT for 1 cycle (> 95% dip in UT for 0.5 cycle) 70% UT (30% dip in UT for 25 cycles) < 0% UT (> 95% dip in UT for 5 s)	< 0% UT <0% UT for 1 cycle (> 95% dip in UT for 0.5 cycle) 70% UT (30% dip in UT for 25 cycles) < 0% UT (> 95% dip in UT for 5 s)	AC power (“mains”) power quality should be that of a typical professional environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC/ EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional environment.

Note:
UT is the AC mains voltage prior to application of the test level.

The ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.

Immunity Test	**IEC / EN60601 -1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1] 10 Vrms inside ISM bands[1]	3 Vrms 150 kHz to 80 MHz outside ISM bands 10 Vrms inside ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0.35\sqrt{P}$ $d = 1.2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[2]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[3], should be less than the compliance level in each frequency range.[4]Interference may occur in the vicinity of equipment marked with the following symbol: 

Note:
At 80 MHz and 800 MHz, the higher frequency range applies

Note:
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table A.15. Electromagnetic Immunity – Conducted and Radiated RF

1. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz'; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ventilator is used exceeds the applicable RF compliance level above, the ABU v01 Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ABU v01 Ventilator.
4. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

The ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter**			
	150 kHz to 80 MHz (outside ISM bands) $d = 0.35\sqrt{P}$	**150 kHz to 80 MHz (in ISM bands)** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.035 m	0.12 m	0.12 m	0.23 m
0.1	0.11 m	0.38 m	0.38 m	0.73 m
1	.35 m	1.2 m	1.2 m	2.3 m
10	1.1 m	3.8 m	3.8 m	7.3 m
100	3.5 m	12 m	12 m	23 m

Table A.16. Recommended Separation Distances

The ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter			
	150 kHz to 80 MHz (outside ISM bands) $d = 0.35\sqrt{P}$	150 kHz to 80 MHz (in ISM bands) $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note:
The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

Note:
An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note:
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table A.17. Recommended Separation Distances (Continued)

WARNING:
Always use compatible power supply cable compliant with IEC 60320 C14 and with what declared in section A.9, "Standards Compliance and IEC Classification".

Cable or Accessory	Maximum length
UK AC power cable assembly	1.8 m (5.9 ft)
USA AC power cable assembly	1.8 m (5.9 ft)
Europe AC power cable assembly	1.8 m (5.9 ft)
Canada AC power cable assembly	1.8 m (5.9 ft)

Nurse call cable	< 1 m (3.2 ft)
Oxygen inlet connector	-

Table A.18. Compliant AC Cables

A.9 Standards Compliance and IEC Classification

General Standards

- Medical Electrical Equipment: General Requirements for Safety IEC 60601-1:2005 + Amd1:2012 (ed.3.1).
- The ventilator will be constructed to comply with the following product Classifications as detailed in Clause 5 of 60601-1:
  - Class II Equipment
  - Internally Powered Equipment
  - Type B Applied Parts
  - IP21 with respect to access to hazardous parts and ingress of moisture
  - Not suitable for use in the presence of flammable anesthetic mixtures
  - Not suitable for sterilization
  - Suitable for continuous operation
  - Detachable power supply cable
- Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment - Part 1: General Requirements for Safety.
- UL 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety: 2003.

Collateral Standards

- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests IEC 60601-1-2:2014 (ed. 4).
- Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance -Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2006 and +Amd1:2012 (ed. 2.1).
- Medical device software - Software life cycle processes. IEC 62304:2006+AMD1:2015 CSV.
- Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-12:2020 (ed. 2).

B – Operational Verification Checklist

The operational verification and safety checks listed in Table B.1 below should be performed to ensure the ventilator is operating properly in the following circumstances:

- Prior to using the ventilator with a patient
- Monthly while the ventilator is in use
- Following maintenance or changes in ventilator settings

WARNING:
If the ventilator fails any alarm test or if you cannot complete tests, see the Troubleshooting section (Chapter 9, section 9.6, "Troubleshooting") of this manual or call your equipment supplier

WARNING:
Do not perform ventilator alarm tests while the patient is connected to the ventilator. Provide the patient with an alternate means of ventilation before conducting these tests.

WARNING:
To reduce the risk of infection, wash your hands thoroughly before and after handling the ventilator or its accessories.

1	Verify the proper appearance and cleanliness of the ventilator	☐ Pass
2	Verify all the labels and markings on the ventilator are clear and visible	☐ Pass
3	Confirm the antibacterial/antiviral filters are clean and correctly installed	☐ Pass
4	Ensure the AC cable does not exhibit any signs of damage, such as kinks, breaks, or damaged insultation	☐ Pass
5	Connect the AC power cable.	☐ Pass
6	Push the power switch I/O to the position I to activate the ventilator using external AC power supply.	☐ Pass
7	Perform the Functioning Alarms Test. See Appendix C, "Alarms Tests"	☐ Pass
8	Verify that the preventive maintenance schedule for the ventilator s followed. See chapter 8, "Maintenance"	☐ Pass
9	Ensure that the patient breathing circuit is correctly attached to the ventilator, with all the necessary components, and is free from any signs of damage and leaks.	☐ Pass

Table B.1. Operational Verification Checklist.

C – Alarms Tests

Before connecting the ventilator to the patient, perform the following tests to ensure the ventilator's alarms are working properly.

WARNING:
Do not perform ventilator alarm tests while the patient is connected to the ventilator. Provide the patient with an alternate means of ventilation before conducting these tests.

WARNING:
If the ventilator fails any alarm test or if you cannot complete tests, see the Troubleshooting section (Chapter 9, section 9.6 "Troubleshooting") of this manual or call your equipment supplier

Note:
Most of these tests require that an approved patient circuit be connected to the ventilator. Ensure that your patient circuit is properly connected prior to performing these tests.

C.1 ABU sensor pack test

1- Before proceeding, set the ventilation and alarm parameters specified by the patient's clinician as explained in section 6.2, "Setting Up ventilation parameters".

2- Press "Start" button to start ventilation as explained in section 6.3, "Starting ventilation"..

3- Detach ABU sensor pack cable from the ventilator as shown in Figure C.1 below.

Figure C.1. ABU sensor pack test. At the beginning of the test the ABU sensor pack cable is connected to the ventilator (left); to perform the test the same cable must be disconnected as shown above (right).

4- The following HP alarms will be activated:

- “Flow sensor broken”
- “Pressure sensor broken”

5- If the above reported alarms are activated, reconnect the ABU sensor pack cable and reset the alarm by pressing the “Alarms ACK” button as explained in section 9.4, “Resetting Alarms”.

CAUTION:
If the above reported alarms are not activated, do not use the ventilator and substitute it with another one before using it on a patient

C.2 Ventilator test

Perform a ventilator test whenever replacing or altering a patient breathing circuit. Ensure the patient is fully disconnected from the ventilator.

Part 1

1- Once the breathing circuit is connected to the ventilator, but not to the patient as described until step 13 reported in section 4.4, “ABU v01: Configuration with No Continuous Fresh air Flow (NCFF)” in order to have the same configuration reported in Figure C.2, start the ventilation in forced mode as described in chapter 6, “Operating procedures”, without setting any particular parameter value.

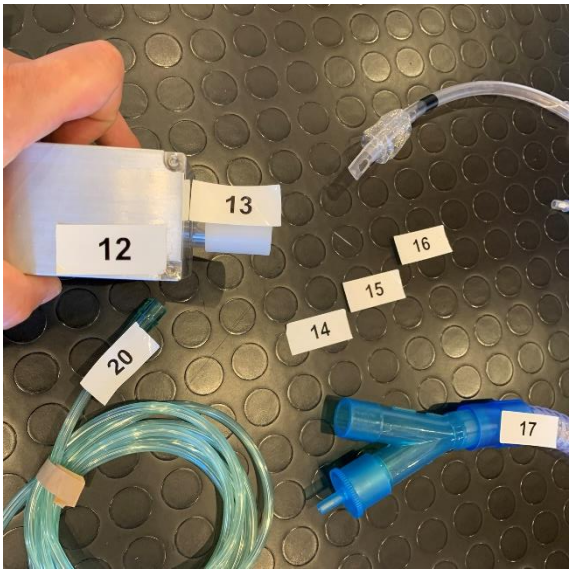


Figure C.2. Part 1 of ventilator test. Assembly the ventilator as described in section 4.4 until you reach step number 13. You should find yourself in a situation as the one shown here: with the exit port of the ABU sensor pack left free.

2- Once the ventilation starts, the ventilator should activate the following alarms:

- Leak percentage too high
- Target volume out of range
- Peep out of range

3- If the above reported alarms are activated, reset the alarms, be pressing the “Alarms ACK” button as explained in section 9.4, “Resetting Alarms”, and skip to part 2 of this section.

CAUTION:
If the above reported alarms are not activated, do not use the ventilator and substitute it with another one before using it on a patient

Part 2

4- Set the Plateau pressure to 48 cmH_2O and the PIP range to 5 cmH_2O, and start the ventilation

5- Once the mechanical pinchers are in the closing phase (i.e., they are squeezing the ABU balloon), plug abruptly the free exit of ABU sensor pack as shown in Figure C.3, in order to increase suddenly the resistance of the breathing circuit.

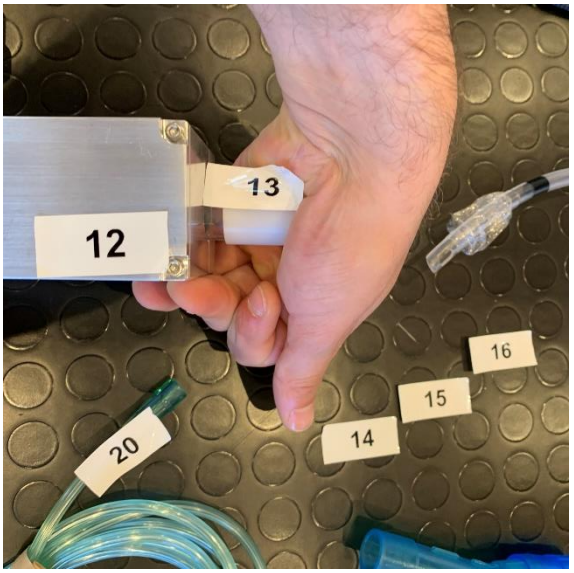


Figure C.3. Part 2 of ventilator test. Abruptly plug the free exit of the ABU sensor pack in order to suddenly increase the resistance of the breathing circuit.

6- One or all of the following alarms should be activated:

- PIP too high

- Pressure over 608 cmH_2O

7- If one or all of the above reported alarms are activated, reset the alarms, by pressing the 'Alarms ACK' button as explained in section 9.4, "Resetting Alarms", and consider passed the ventilator test.

CAUTION:
If none of the above reported alarms are not activated, do not use the ventilator and substitute it with another one before using it on a patient

C.3 Power failure test

Note:
If the ventilator is operating on either the external power supply or the internal battery, you must plug it in to an AC power source before beginning this test.

1- Disconnect the ventilator from its AC power supply. Ensure that the following events occur:

- The Medium-priority alarm "Main power supply" is activated

- The Battery Charge Qualitative Status (Figure X below) appears on the left side of the 'Home' page.

Figure C.4. Icon appearing on the left of the 'Home' page when the ventilator is functioning with its internal battery.

2- Reconnect the ventilator to its AC power supply

3- If all the events above occur, reset the alarm by pressing the 'Alarms ACK' button as explained in section 9.4, "Resetting Alarms", and consider passed the ventilator test.

CAUTION:
If all the events reported above do not occur, do not use the ventilator and substitute it with another one before using it on a patient.

D – Glossary

AC Power
Alternating current.

Alarm Reset or Alarms ACK
This functions resets the visual and audible alarm message

Apnea
The absence of breathing or a breathing pattern capable of supporting an individual's respiratory needs.

Assisted mode
In Assisted mode, the ventilator delivers an assisted breath set support pressure when the patient's breathing effort creates a flow or pressure drop that is greater than the trigger setting. In absence of patient breathing effort, the ventilator will deliver a forced breath of the set support pressure.

Assisted breath
A volume or pressure breath triggered, controlled and terminated by the ventilator.

Battery Level
Display of the remaining battery capacity; located on the left of the Home page.

bpm
An abbreviation for “breaths per minute,” which is the unit of measure for breath rate (see below).

Breath Rate
The total number of breaths, both machine and spontaneous, delivered by a ventilator in one minute.

Caregiver
An individual who assists a patient with the tasks of daily living. This may be a family member, a live-in assistant, or the nursing staff of a health care facility.

cmH2O
An abbreviation for “centimeters of water,” which is a unit of measure for pressure.

CPAP (Continuous Positive Airway Pressure)
Continuous airway pressure maintained throughout a spontaneous breath cycle.

DC Power
Direct current.

Expiratory/Exhalation Phase
Phase of the breath cycle during which the patient exhales.

Expiratory/Exhaled Tidal Volume (VTE)
Exhaled volume measured for all breath types through the exhalation phase.

Fraction of Inspired Oxygen (FiO2)
Concentration of oxygen of the air delivered to the patient.
FiO2 Sensor
The sensor which measures the concentration of oxygen of the air delivered to the patient.

Flow
Volume of gas delivered by the ventilator compared to time, expressed in liters per minute (lpm).

hPa
An abbreviation for “hectopascal” which is a unit of measure for atmospheric pressure.

I:E ratio
Inspiratory time versus exhalation/expiratory time ratio.

Inspiratory Phase
Phase of the breath cycle during which the patient inspires.

Inspiratory Pressure (Pi)
The operator-set inspiratory pressure during a pressure control (PC) mandatory breath.

Inspiratory Tidal Volume (VTI)
Volume delivered to the patient at each inspiratory phase.

I Time (Inspiratory Time)
Inspiratory time measure.

L
liters (a unit of volume).

Leak
it is the average unexpected leak during each cycle.

Leak percentage
Calculated as (VTI-VTE)/VTI*100

lpm
Liters per minute (a unit of volume flow rate).

Machine Hours
Counter for the total ventilation time since manufacture or the last CPU board change.

Mains
AC power supply.

mbar
An abbreviation for “millibar,“ which is a unit of measure for atmospheric pressure.

Mean Airway Pressure
Average patient pressure during each breath.

Patient Breath
Breathing cycle initiated by the patient.

Patient circuit
Tubing between the ventilator and the patient.

Peak Inspiratory Pressure (PIP)
The highest pressure measured in the patient circuit during the inspiration phase.

Plateau pressure
It is the average airway pressure calculated during the lapse of time of the inspiratory phase of a forced breathing act excluding the first maximum.

Positive End Expiratory Pressure (PEEP)
Pressure in the patient circuit at the end of expiration.

Pressure Control Volume Target (PCVT)
It is the ventilation mode by which the ventilator tries to deliver a certain VTI while controlling the airways pressure in order not to exceed a preset pressure value.

PSI
Pounds Per Square Inch.
PSV (Pressure Support Ventilation)
Pressure support ventilation.

Ramp
A-dimensional Parameter set by the user that controls the velocity of increase of the support pressure during the inspiratory phase of an assisted breathing act.

Rebreathing
The patient breathes his/her exhaled gas.

Respiratory rate
The number of breath cycles (inspiration + expiration) completed within one minute. Normal resting adult respiratory rates are from 12 – 20 breaths per minute (bpm).

SIMV (Synchronized Intermittent Mandatory Ventilation)
A ventilator mode which provides a mechanism for synchronizing the ventilator-delivered breaths with a patient's inspiration, as detected by the ventilator.

Spontaneous Breath
A volume or pressure breath triggered by the patient but then controlled and terminated by the ventilator.

Standby
The operational mode of the ventilator where it is powered (power supply I/O button set to the I position), but is not ventilating the patient.

Support pressure
Inspiratory airway pressure that the ventilator tries to reach during the inspiratory phase of an assisted breathing act.

Tidal volume (Vt)
Volume of gas delivered to the patient in a breath.