Instruction Manual

Automatic Breathing Unit (ABU)

Version	Date	Author
1a-EN	25/03/2020	Omnidermal Biomedics
2a-EN	08/04/2020	Omnidermal Biomedics
3a-EN	11/04/2020	Omnidermal Biomedics

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1 - Certifications, warnings, precautions and notes

The ABU device is a medical device designed to assist emergency pulmonary ventilation on patients requiring both assisted and forced ventilation. Developed at the beginning of the pandemic due to the spread of the coronavirus called Covid-19, ABU is in the process of CE certification according to Directive 42/93/EEC and subsequent amendments. The device was developed by Omnidermal Biomedics Srl together with Italian anaesthetists and resuscitators

who are at the forefront of the treatment of infected patients. ABU has been the object of great interest and appreciation by a large number of doctors and hospital managers. Annex I consists of letters of support for the use of the technology issued by anaesthetist doctors throughout Italy.

Given the simple, but effective, functionality of the device, low cost and ease of large-scale production, Omnidermal Biomedics 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 use 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.

With a view to rapid CE certification, on 4 April 2020, the Italian Technical Scientific Committee (CTS), with its operational headquarters at the well-known Gemelli Hospital in Rome, carried out functional testing according to CEI 62-142 of 11/2006 and CEI 62-141 of 11/2006. The ABU device was found to comply with all the requirements listed above, as demonstrated by the document in Annex II. The above mentioned testing tests represent in fact the normal tests that are carried out by clinical engineers to validate the operation of certified mechanical fans on the market. Therefore, it can be stated that the ABU device works exactly like a standard mechanical fan.

The ABU device also complies with guidelines issued by MHRA and FDA for the production of emergency ventilators required for mechanical ventilation of Covid-19 patients. For these reasons, the U.S. federal agencies FDA (Food and Drug Administration) and HHS (Health Human Services) have considered the use of ABU to compensate for the lack of ventilators during the health emergency caused by Covid-19.

Since the first week of April 2020, Omnidermal Biomedics Srl has started the necessary procedures for a rapid CE certification according to Directive 42/93/EEC. This certification is expected to be obtained at the end of April 2020.

Therefore, in light of the above observations and until the approval by the government agencies responsible for the authorization of the marketing, Omnidermal Biomedics srl declines any responsibility for damages inflicted to persons or property through the use of the ABU device. The use of the ABU device for the mechanical ventilation of human patients is therefore under the full responsibility of the medical personnel or health care facility or the competent authority that authorizes its use.

IMPORTANT: It is strictly necessary that health care personnel responsible for the use of the ABU device for the mechanical ventilation of human patients read this instruction manual appropriately in order to avoid situations that could endanger the safety of the patient. Omnidermal Biomedics srl therefore declines any responsibility for damages inflicted to persons or things deriving from an unconscious use of the device in question.

Correct use of the device does not involve direct contact with the patient.

The ABU device is the result of the combination of an electromechanical mechanism and a manual ventilation system with certified expandable balloon and equipped with appropriate safety mechanisms such as overpressure valves. The safety of this mechanical ventilation system therefore does not depend on the ABU device or on Omnidermal Biomedics itself.

The ABU device may 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. The user is advised that, although the correct ventilation operation has been tested and approved by the Italian CTS following the regulatory references CEI-62-142 of 11/2006 and CEI 62-14 of 11/2006 on 08/04/2020 (Annex I), the parameters calculated and measured by the ABU device are still in the process of certification. In fact, ABU is a device designed for forced and assisted ventilation of patients affected by Covid-19.

Under no circumstances shall the ABU be disassembled, tampered with or otherwise modified except by personnel authorised by the manufacturer. Any violation of the product could render it unusable or defective.

If the device has any faults in any of its components, this may affect its operation. In this case, contact the supplier for a replacement part.

It is recommended that you read carefully both this user manual and the manual enclosed in the package.

Keep the device away from heat or magnetic sources; do not immerse in water or other liquids; do not approach open flames; avoid shocks.

2 - ABU device description

ABU is a medical device, able to transform a traditional AMBU (Artificial Manual Breathing Unit) or, more n general, a manual ventilation system based on expandable balloon, into a possible "Volume-targeted" (or Volumetric) artificial ventilator through the use of both flow and pressure sensors and a high precision electronic feedback system.

The device is able to automate the processes of **forced and assisted ventilation**, operating the expandable balloon device without the help of the health care worker, through a mechanical mechanism.

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

1. **PEEP pressure** (i.e. minimum pressure at the end of exhalation)
2. **Maximum peak pressure**

3. **Plateau Pressure**
4. **Air flow**
5. **Respiratory frequency**
6. **Tidal volume**
7. **Ratio between inhalation and exhalation time (I:E ratio)**
8. **Oxygen mixture percentage adjustment**
9. **Pulmonary Compliance and Driving Pressure Measurement**
10. **Audible alarm system**

Ventilation safety is also guaranteed by the use of manual ventilation systems based on certified expandable balloons equipped with appropriate safety mechanisms such as overpressure valves.

2.1 - Package contents

The ABU package contains the following components:

1. No. 1 ABU device,
2. No. 1 IEC 60320 C14 power cable,
3. No. 1 Breathing circuits,
4. N.1 Check Valve,
5. N.1 PEEP valve,
6. N.1 Flowmeter with connection cable,
7. N.1 Differential pressure gauge with connection cable,
8. N.1 Kit 3 fittings,
9. N.2 Anti-viral/antibacterial filters,
10. N.1 1 AMBU 1.6 L. ball,
11. N.1 Collection Reserve/Reservoir,
12. N.2 Connection pipe to oxygen source, if any,
13. N.1 Y-connector with connectors and one-way valve ,
14. N.1 User Manual

2.2 - ABU device components

The main components of the ABU are described and shown in Figure 1 and the table below.

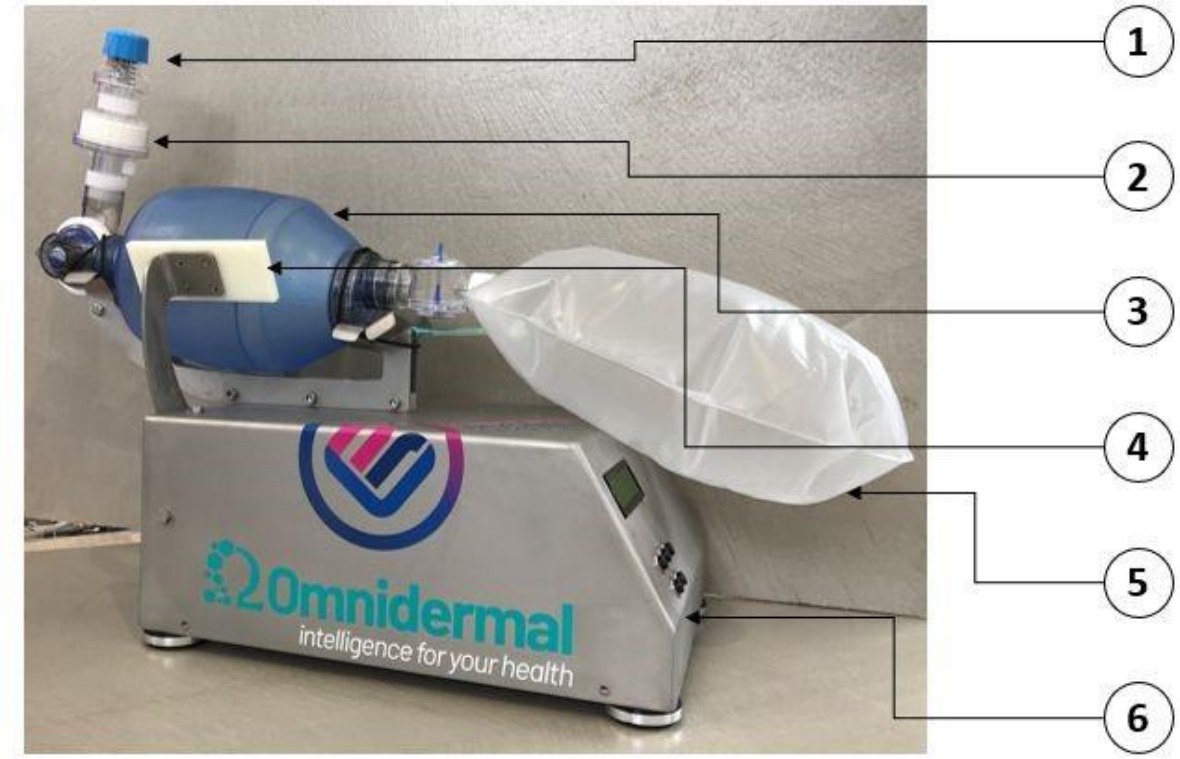

Figure 1: Overall picture of the main components of the ABU system.

ID	Component
1	PEEP Valve
2	Antiviral and antibacterial filter
3	AMBU 1.6 L balloon
4	ABU Device Pliers
5	Collection Reserve/Reservoir
6	ABU Device Control Unit

2.3 General technical information

The table below shows the general technical data for the correct installation and use of the ABU device.

Feature	**Specify**	**Notes**
Supply voltage	48V (motor), 5V (control board)	Powered by mains (220V) with IEC type power socket 60320 C14
Electrical power consumption	15 W	Maximum absorption value
DM Class	Class IIb	CEI EN 93/42
Electric class	Type BF	According to CEI EN 60601-1
Net weight	10 kg	Not connected to external cylinder
Overall dimensions	220 mm x 435 mm x 225 mm	
Noisy emissions	None	
IVD device	No	
Active implantable device	No	
Need for ventilation or air conditioning	No	
Stock temperature conditions	-25 - +55 [°C]	

Operating temperature conditions	+5 - +40 [°C]	
Vibration generation	No	
Explosive atmospheres	Interacts externally with explosive atmospheres	Insulated from instantaneous heat sources by
Emission or treatment of chemicals	No	

3 - Functional description

The following description shows the functional cycle of the ABU device associated with the use of a manual ventilation system based on a certified expandable flask 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 system already includes, included in the package, the manual ventilation kit as illustrated in section 2.1. Therefore Omnidermal Biomedics Srl declines any further responsibility deriving from the use of a different manual ventilation system or from a different manufacturer than the one supplied inside the package.

3.1 Forced ventilation modes

Figure 2 shows an example of forced mechanical ventilation by ABU device. Please note that the combination of the ABU device with other medical devices is subject to operator 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.

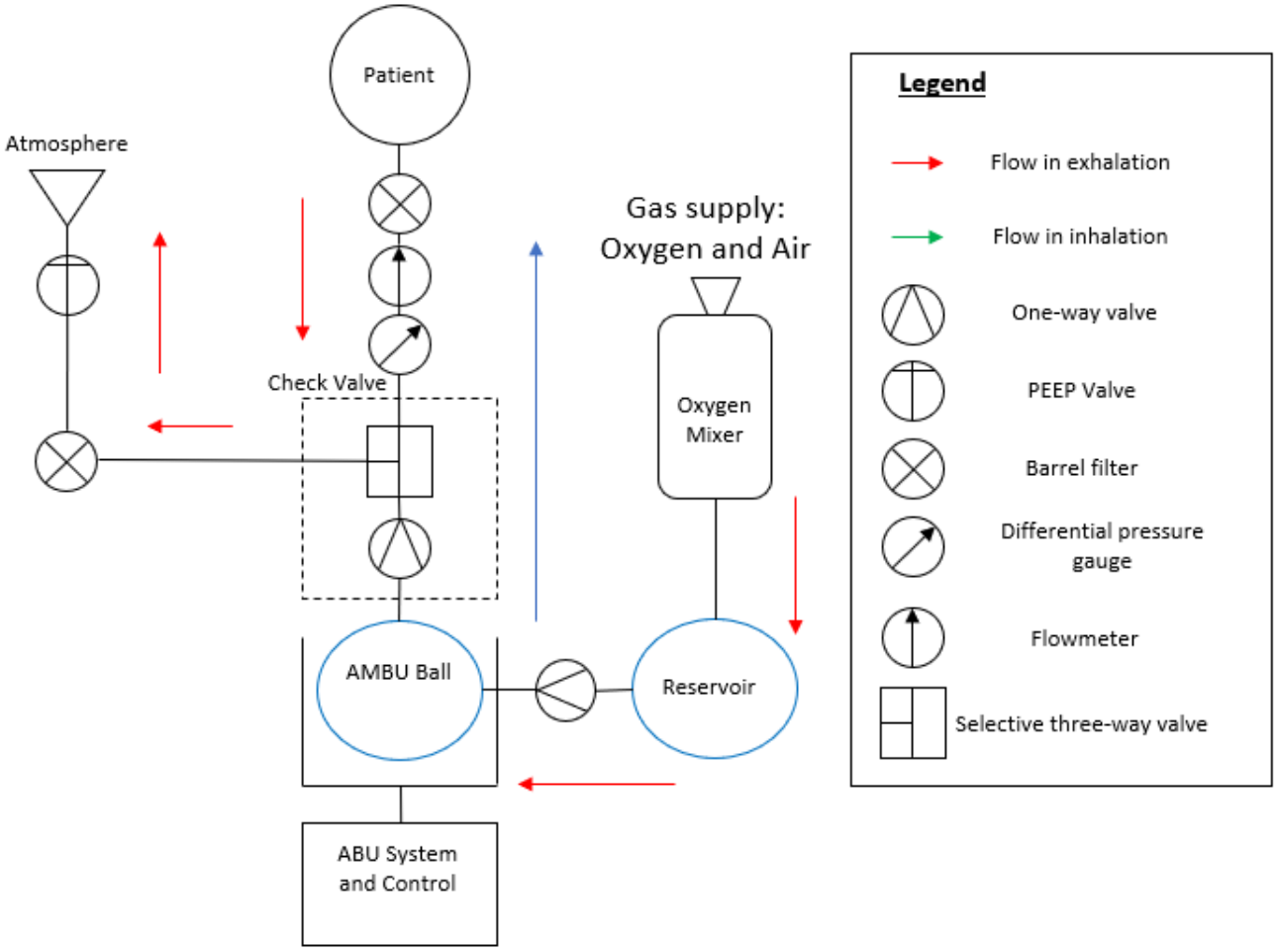

Figure 2: Function block diagram of the ABU system in forced ventilation mode.

Parameter setting.

- Once the AMBU system is connected to the patient, the AMBU balloon is inserted between the clamps of the ABU device.
- The operator sets through the ABU control and manually on the PEEP valve the following operating values
  Pumping frequency
- Exhalation/inspiration time ratio
- Air volume pumped in inhalation
- Maximum permissible pressure
- Control pressure on PEEP valve

Cycle of possible inhalation

- Once the parameters have been set, the ABU clamps will compress the AMBU balloon according to the operator's settings.
- The inhaled air will pass through the Check Valve which, through the One-way valve and the Selective Three-way Valve, will divert the airflow completely to the patient eliminating any dispersion to the environment.

- The One-way valve placed between the collection reserve and the AMBU balloon prevents dispersion towards the reserve.
- The flowmeter will measure the volume of air to the patient
- The ABU control system will calculate the air volume to the patient, integrating the measured flow into the elapsed time, and stop the clamp movement once the volume set for each cycle is reached.
- The differential pressure gauge will control the compression speed of the clamps on the flask in order to keep the pressure below the threshold set by the operator.
- If the air volume to the patient does not reach the value set by the operator, due to too high a required pressure, the ABU control system will end the compression of the expandable flask to allow the air flow from the patient and therefore the expiratory phase.

Possible exhalation cycle

- The ABU device clamps will release the AMBU 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 to the environment through the Check Valve's Selective Three-way Valve to the PEEP Valve
- The differential pressure meter 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 inhalation cycle.
- The air is filtered through a possible anti-viral and anti-bacterial filter before being released outside.
- The differential pressure meter will control the start of a new inhalation cycle by measuring the patient's chest pressure in order to calculate a possible Driving Pressure (dP) value, calculated as: $dP = (P_{Plateau} - PEEP)$where $P_{plateau}$ is the average pressure value calculated in the inhalation phase minus the value of the Peak Pressure (Maximum pressure reached by the system in the inhalation phase).

- 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, otherwise known as Pressure Controlled at Volume Target.
This implies that instead of delivering an exact current volume to each respiratory act, the ABU device will vary the inspiratory flow at each act to reach the target volume keeping a maximum pressure value below the maximum set by the operator. Inspiratory time (Ti) limits the duration of the inspiratory cycle and therefore the ratio of inspiratory time to expiratory time (I/E ratio). 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 pressures to reach the desired tidal volume.

3.2 Assisted ventilation modes

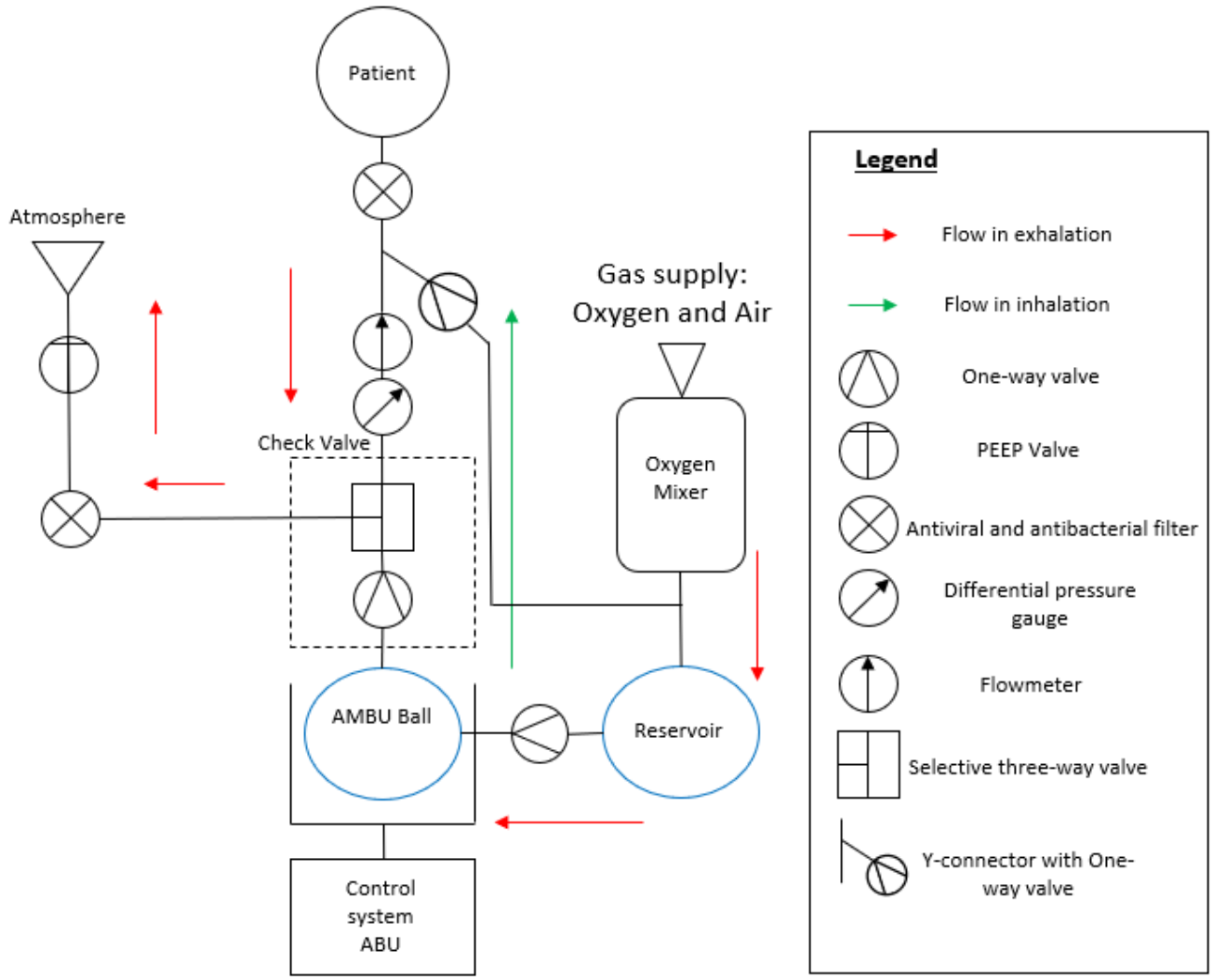

Figure 3: Function block diagram of the ABU system in assisted ventilation mode with or without constant flow at positive pressure.

Parameter setting.

- After connecting the AMBU system to the patient, the AMBU balloon is inserted between the clamps of the ABU device.
- The operator sets through the ABU control and manually on the PEEP valve the following operating values
- Ramp speed of increase in support pressure
- Support pressure
- Pressure tripters
- Flow Trigger

- Exhalation trigger
- Control pressure on PEEP valve
- Release time of forced baseline ventilation (in case of apnea)

Cycle of possible inhalation

- Once the parameters have been set, the ABU control system periodically reads the differential pressure sensor and the flowmeter to detect the moment when the patient tries to perform a spontaneous breathing act.
- The ABU clamps will then compress the AMBU balloon according to the operator's setting.
- The inhaled air will pass through the Check Valve which, through the One-way valve and the Selective Three-way Valve, will divert the airflow completely to the patient eliminating any dispersion to the environment.
- The One-way valve placed between the collection reserve and the AMBU balloon prevents dispersion towards the reserve.
- The flowmeter will control the flow trend instant by instant by memorizing the maximum value
- 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.
- The differential pressure gauge 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 in the baseline time set by the operator, the clamps will be forced to perform a forced breathing act according to the parameters set by the operator for the assisted ventilation mode,

Possible exhalation cycle

- The ABU device clamps will release the AMBU 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 to the environment through the Check Valve's Selective Three-way Valve to the PEEP Valve
- The differential pressure meter 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 inhalation cycle.
- The air is filtered through a possible anti-viral and anti-bacterial filter before being released outside.
- By using the Y connection equipped with a One-way valve (as in figure 3) connected to an air source or oxygen mixture (e.g., an Oxygen Blender) it is possible to equip the ABU device with a continuous flow at positive pressure of the set PEEP value, able to eliminate excess $_{CO2}$ residues from the circuit and compensate the losses of the circuit itself.

3.2.1 Weaning and SIMV

The mode described in this section can be used to implement an assisted ventilation system for previously treated and forced-ventilated intubated patients requiring weaning therapy (WEANING). In this case, the Y-piece included in Figure 3 may be removed, or not used, because positive pressure continuous flow is not required for this mode.

For this mode, simply set the parameters of the ABU device's assisted mode and it will work by implementing assisted ventilation of type: SIMV (i.e., Synchronized Intemittent Madatory Ventilation) or better known as Synchronized Intermittent Mandatory Ventilation. SIMV is in fact the ventilation mode used during weaning from the ventilator. The acts provided by the ventilator are synchronized with the patient's inhalation. If the patient does not initiate a spontaneous respiratory act, the ventilator intervenes by delivering a respiratory act. The current volume varies according to the patient's efforts, but the ventilator ensures that the patient performs a predetermined minimum number of acts per minute.

3.2.2 NIV ventilation

The same mode can be used for non-invasive assisted ventilation otherwise known as NIV. For example, by connecting, through the Y-connector equipped with One-way valve, a continuous flow of regulated air to a suitable source of FiO_2, 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.

Using the same configuration described above for C-PAP and starting the assisted ventilation mode on the ABU device it is instead possible to implement biphasic continuous positive pressure ventilation, commonly called B-PAP.

Finally, with the ABU device assisted mode and the addition of a continuous positive pressure airflow, all non-invasive ventilation (NIV) modes can be implemented using all patient connection devices, 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.

4 - Mounting the device

Below are detailed installation instructions for the ABU device . Please note that the combination of the ABU device with other medical devices is subject to the operator'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. In addition, please note that the ABU device is in the CE certification phase and therefore, in light of the above comments and until the approval by the government agencies responsible for the authorization of the marketing, Omnidermal Biomedics srl declines any responsibility for damage to persons or property caused by the use of the ABU device. The use of the ABU

device for the mechanical ventilation of human patients is therefore under the full responsibility of the medical staff or health care facility or the competent authority that authorizes its use.

The following is a description of the two possible mounting configurations depending on whether the device is used for forced ventilation or assisted ventilation. For both mounting configurations refer to Figure 4 and the following table for a description of the components.

IMPORTANT:
It is important that the operator read this instruction manual and become familiar with the assembly of the essential components of the ABU 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! Omnidermal Biomedics Srl therefore disclaims any liability for damage to persons or property due to unconscious and incorrect use of the ABU device.

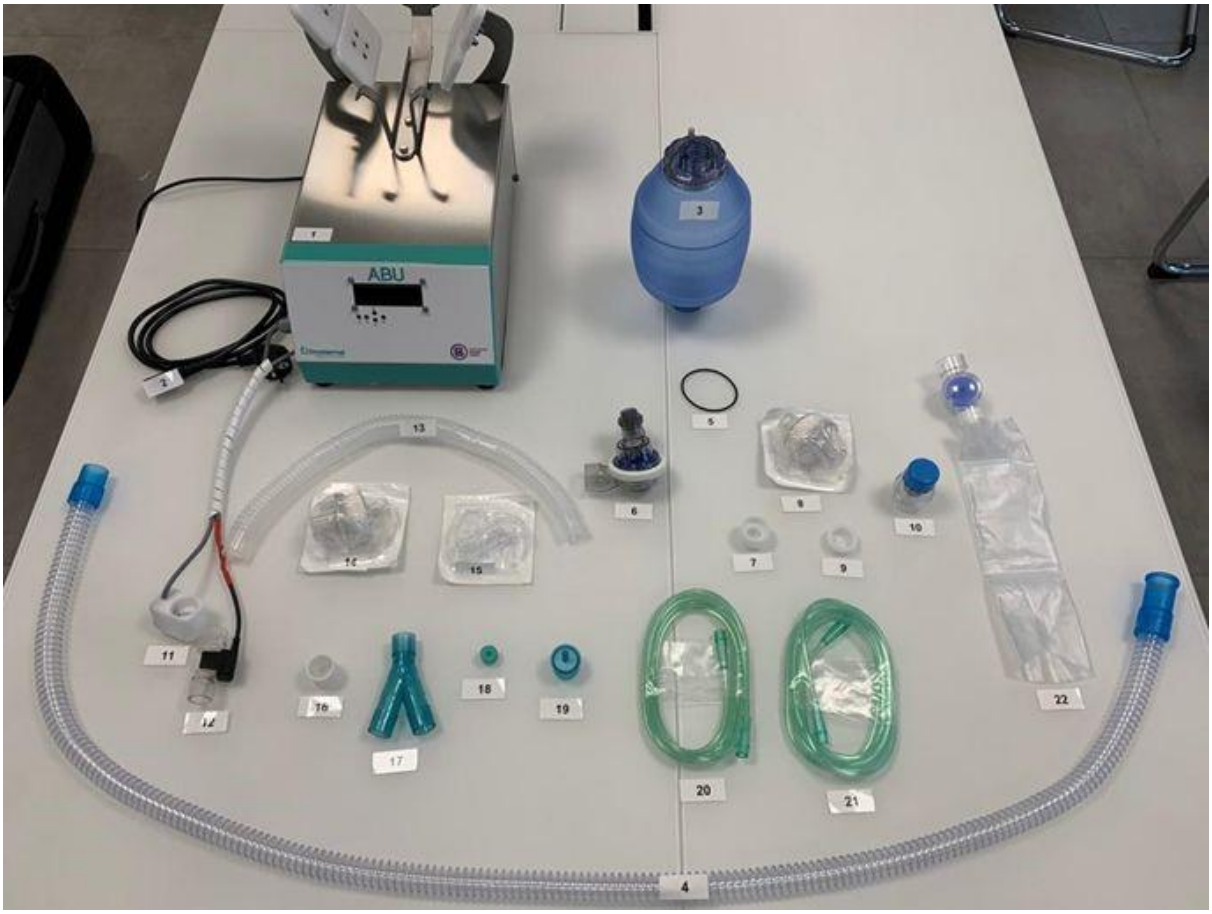

Figure 4: Description of the component.

ID	Component
1	ABU Device
2	EIC cable for power supply
3	AMBU Ball
4	Air hose
5	Fixing elastic
6	Check valve
7	PEEP connector 1
8	Antiviral and antibacterial filter 1
9	PEEP 2 connector
10	PEEP Valve
11	Pressure sensor
12	Flowmeter
13	Variable length air hose
14	Antiviral and antibacterial filter 2
15	Filter connector
16	Valve connector
17	Y-connector
18	Unilateral valve for the Y-connector
19	Oxygen tube adapter for Y-connector
20	Oxygen tube 1
21	Oxygen tube 2
22	Collection Reserve or Reservoir

4.1 - ABU mounting for forced ventilation mode configuration

1. Place the AMBU balloon (3) as shown in Figure 5.

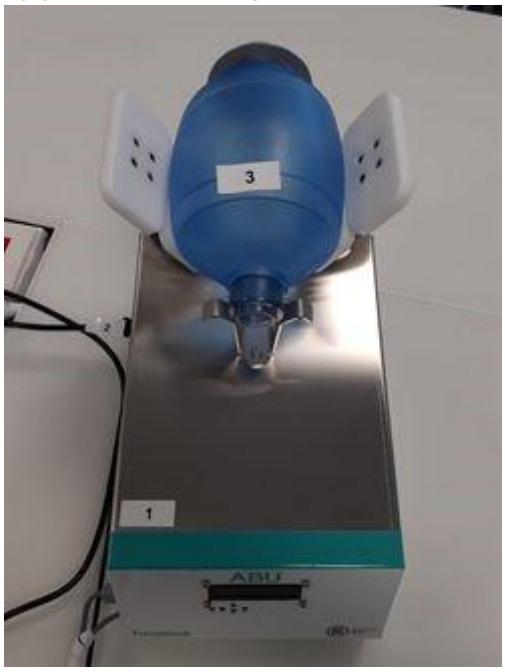

Figure 5: Positioning the Ambu balloon.

2. Place the standard ventilation tube (4) or the adjustable length ventilation tube (13) inside the AMBU balloon exit port as shown in Figure 6.

Figure 6: Air hose connection.

3. Attach the AMBU balloon (3) to the ABU system (1) using the silicone gasket (5) as shown in Figure 7.

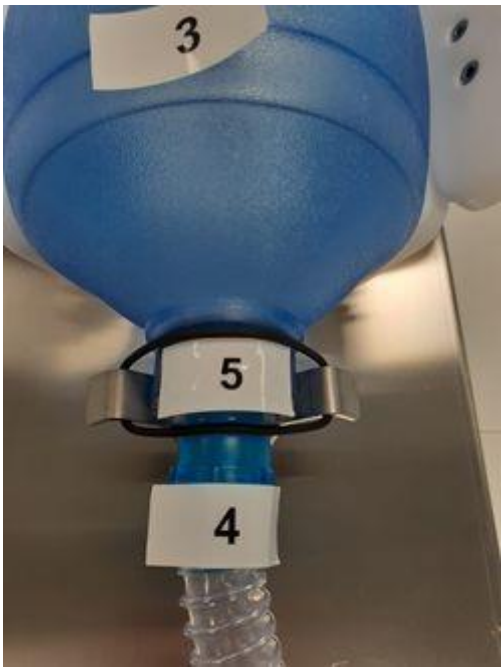

Figure 7: Attaching the AMBU balloon to the ABU device.

4. Connect the first part of the valve (6) with the ventilation pipe (4) (Figure 8).

Fig. 8: Connection of the non-return valve to the air hose.

5. Add check valve (6A) with PEEP connector (6B) (Figure 9).

Fig. 9: Connection of the non-return valve to PEEP.

6. Connect the antiviral/antibacterial filter (8) to the PEEP valve (10) and the first part of the valve (6) using the adapters (7 and 9) as shown in Figure 10.

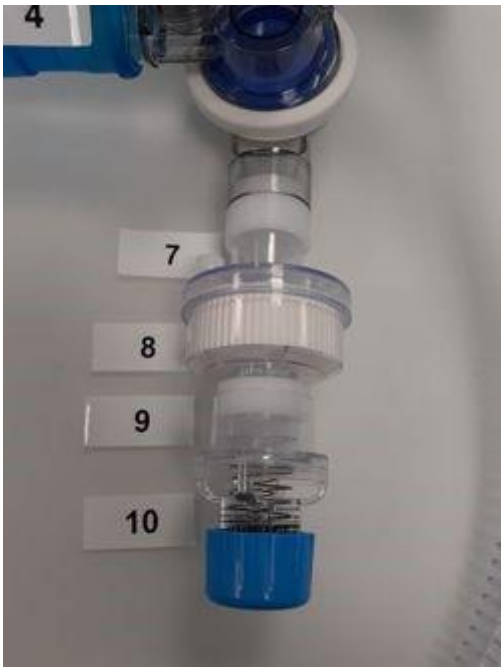

Figure 10: PEEP valve group.

7. Connect the pressure sensor (11) and flow sensor (12) to the first part of the valve (6) as shown in Figure 11.

Figure 11: Connection of flow and pressure sensors.

8. Connect or adjust the length of the ventilation tube (13) to the flow sensor (12) as shown in Figure 12.

Figure 12: Connection of the sensors with the air hose.

9. Connect the antibacterial/antiviral filter (15) to the ventilation pipe (4) or the adjustable length ventilation pipe (13) via the connector (14) (Figure 13).

Figure 13: Connection of the filter to the adjustable air hose.

10. Connect the antibacterial/antiviral filter (15) to the patient's endotracheal tube (Figure 14).

Figure 14: Connection of the system to the endotracheal tube.

11. Connect one end of the oxygen tube (21) to the back door of the AMBU balloon and the other end to a 100% oxygen supply or oxygen blender (Figure 15).

Figure 15: Connection of the oxygen tube to the AMBU balloon.

12. Connect the reservoir bag (22) to the rear door of the AMBU balloon (Figure 16).

Figure 16: Connection of the tank to the AMBU balloon.

4.2 - ABU mounting for assisted ventilation mode configuration

To install the ABU in this configuration, follow instructions 1 to 7 above for installation in forced ventilation mode. Once these steps have been performed, please continue with the following steps.

1. Take the Y connector (17), the one-way valve (16) and the oxygen adapter (19) and mount them as shown in Figure 17.

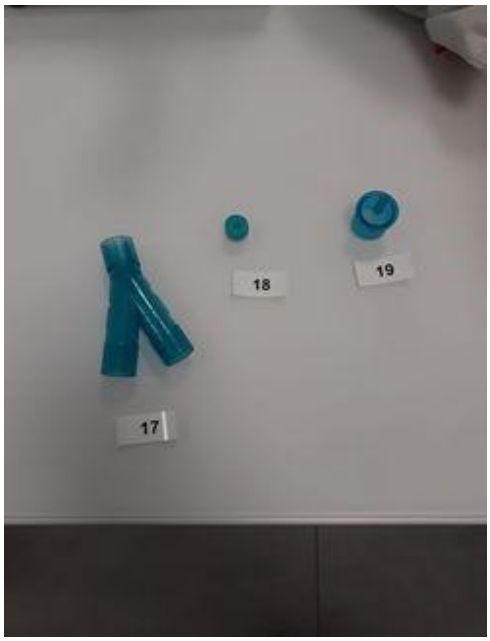

Figure 17: Y-connector and its parts.

2. Insert the one-way valve (18), in the right direction, into one of the branches of the Y-connector (17) as shown in Figure 18.

Figure 18: Unilateral valve insertion.

3. Push the one-way valve (18) as far as possible (Figure 19).

Figure 19: Method for inserting the one-sided valve.

4. Insert the oxygen adapter (19) on the branch containing the one-way valve (18) (Figure 20).

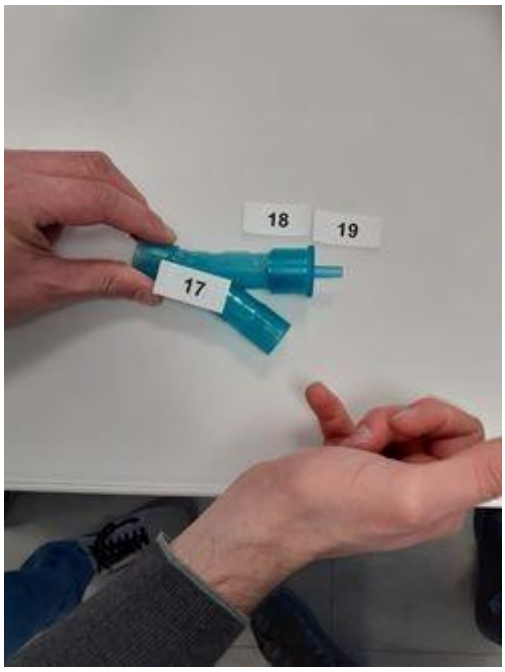

Figure 20: Inserting the oxygen connector.

5. Connect the assembled Y-tube (17) to the adapter (16) as shown below (Figure 21).

Figure 21: Connection of the Y-connector to the sensors.

6. Connect one end of the green oxygen tube (20) to the assembled Y-connector (17) as shown in the figure (Figure 22). Connect the other end to an oxygen supply or oxygen blender.

Figure 22: Oxygen tube connection.

7. Connect the ventilation pipe (4) or the adjustable length ventilation pipe (13) to the Y-assembled connector (17) as shown in Figure 23.

Figure 23: Connection of the adjustable air hose to the Y-connector.

8. Connect the antibacterial/antiviral filter (15) to the ventilation pipe (4) or the adjustable length ventilation pipe (13) via the connector (14) (Figure 24).

Figure 24: Connection of the filter to the adjustable air hose.

Connect the free end of the anti-viral and anti-bacterial filter (15) to any patient-ventilator interface system, be it a C-PAP mask, helmet, endotracheal tube or other, provided it is certified and complies with ISO 5356-1:2004.

5 - Commissioning the ABU device

Below is the commissioning of the ABU device. Please note that the combination of the ABU device with other medical devices is subject to the operator'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. In addition, please note that the ABU device is in the CE certification phase and therefore, in light of the above comments and until the approval by the government agencies responsible for the authorization of the marketing, Omnidermal Biomedics srl declines any responsibility for damage to persons or property caused by the use of the ABU device. The use of the ABU device for the mechanical ventilation of human patients is therefore under the full responsibility of the medical staff or health care facility or the competent authority that authorizes its use.

5.1 - PEEP valve setting and O2 fractionation adjustment

The PEEP valve is adjusted manually by screwing or unscrewing the cap. The set value of the valve will coincide with the calibration mark at the bottom of the cap itself (Figure 25).

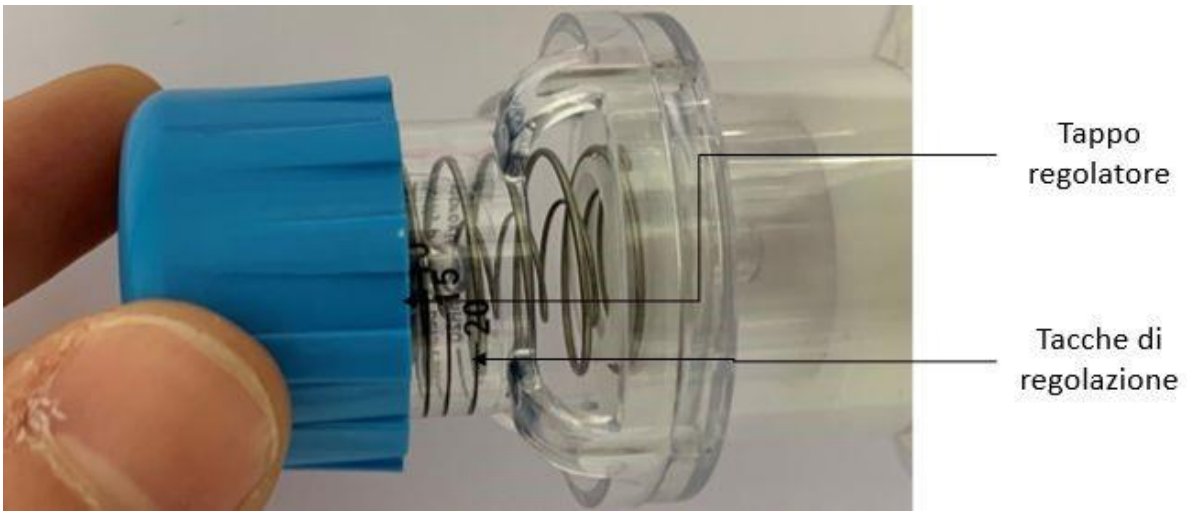

Fig. 25: Adjustment of the PEEP valve.

The fractionation of oxygen inside the AMBU 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.

Ball Volume	**Volume Dispatchable**	**% O2 without reservation**	**% O2 with reservation**
1,6 L	700 mL	45 %	99%

5.2 - Starting the device and selecting the ventilation mode

For the following portion of the description and for paragraphs 5.3 and 5.4 of the ABU device commissioning, please refer to Figure 26 concerning the ABU device control keyboard. Users are advised that the values that can be set on the device are within the ranges shown in the table below.

VALUE	MINIMUM	MAXIMUM
FREQUENCY RESPIRATORY	8 acts resp./ min	30 acts resp./ min
TIDAL VOLUME	200 ml	1.000 ml
REPORT TIME EXPIRATION / INSPIRATION	1 : 1	1 : 2,5
PRESSURE MAX CONTROLLABLE	0 cm H_2O	60 cm H_2O
PEEP PRESSURE	0 cm H_2O	20 cm H_2O

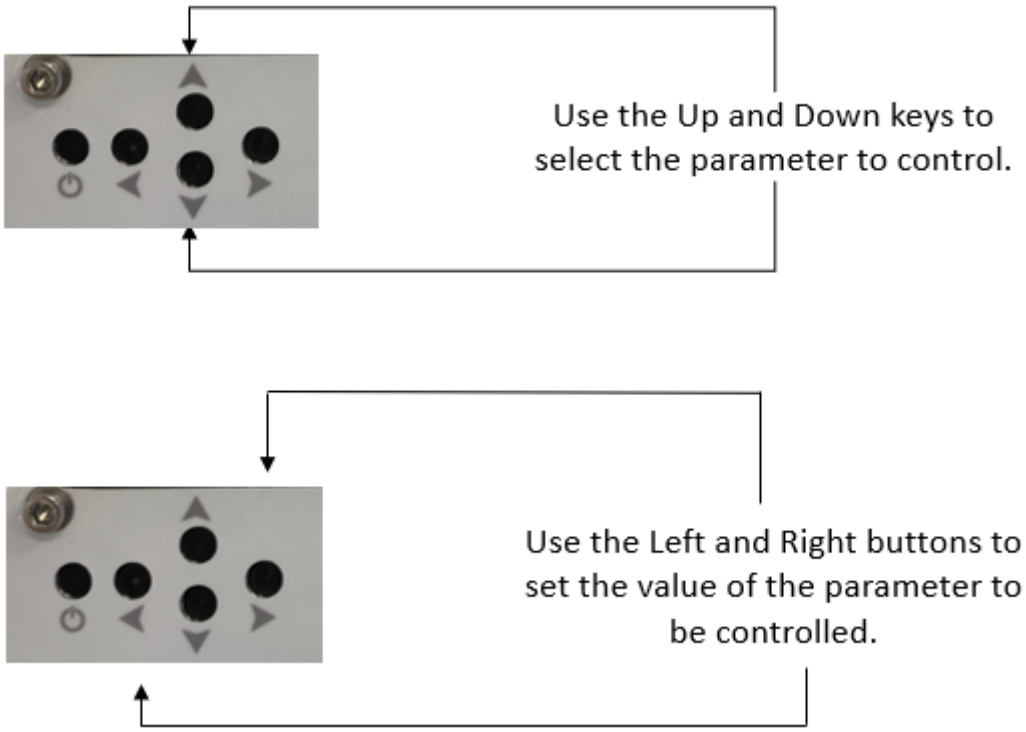

Figure 26: Description of the ABU device control keyboard.

The user is asked to follow the instructions below for switching on and setting the operating parameters.

1. Press the power button (Figure 27).

Figure 27: Device power button.

2. The following screens will appear a few moments apart (Figures 28 and 29).

Figure 28: First boot screen.

Figure 29: Second boot screen.

3. Use the Left and Right buttons to select the desired ventilation mode: Assisted or Forced (Mandatory or Asssited). Once the mode has been selected, the screen in Figure 30 (Assisted for example) will appear for confirmation.

Figure 30: Confirmation of selected mode.

5.3 - Forced ventilation modes

1. Once the forced ventilation mode is selected, you must set the ventilation rate in respiratory acts per minute as shown in Figure 31.

Figure 31: Respiratory rate setting screen.

2. Set the volume in ml of inhalation for each respiratory act (Figure 32).

Figure 32: Screen for setting the inhalation volume per respiratory act in ml.

3. Set the value of the maximum allowed pressure cm of H_2O (Figure 33).

Figure 31: Screen for setting the maximum permissible pressure in cm of H_2O.

4. Set the ratio between inspiration time and exhalation time (Figure 34).

Figure 34: Screen for setting the ratio of inhalation and exhalation time.

5. Set the tolerable loss percentage between inhaled and exhaled volume, above which the audible alarm sounds (Figure 35).

Figure 35: Alarm volume percentage setting screen.

6. Press the Start button to start ventilation (as shown in Figure 36).
7. With the same button you can stop the ventilation and put the system in standby. By pressing the same button again, you can resume ventilation with the same settings as before standby.

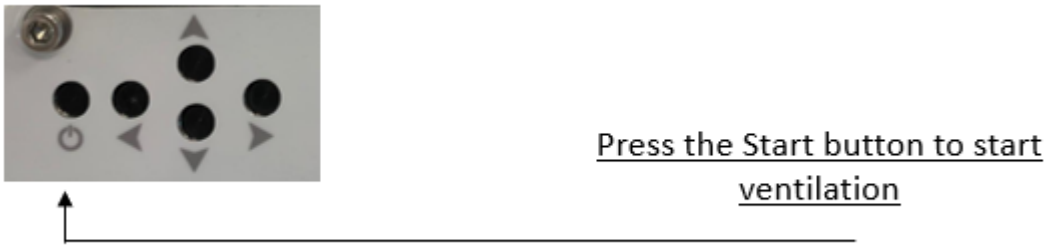

Figure 36: Ventilation start command. The same button can be used to stop and then put ventilation on standby.

8. If the process was performed correctly, the operating screens showing the parameters measured during the last respiratory act will be displayed by the user as shown in Figures 37 and 38. To navigate from one screen to another, simply press the Right and Left buttons (Figure 39). .

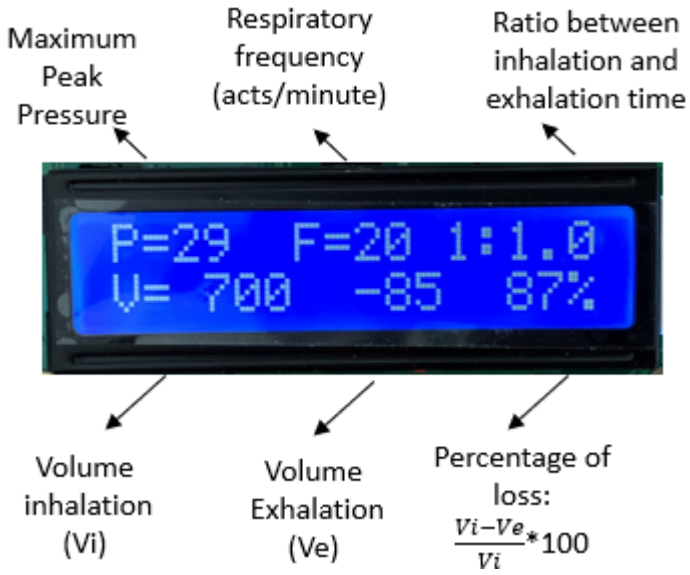

Figure 37: Screenshot 1 of ABU operation with user-set values and description.

Figure 38: Screenshot 2 of ABU operation with user-set values and description.

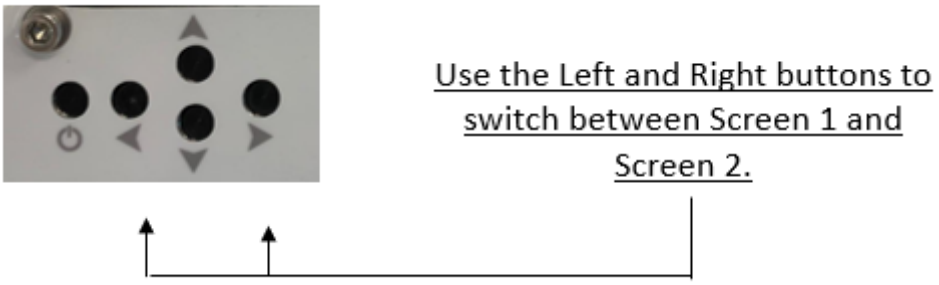

Figure 39: Commands for user navigation between screens 1 and 2 shown in Figures 37 and 38.

5.4 - Assisted ventilation

1. Select the assisted ventilation mode as described in section 5.2.
2. Select the Ramp, i.e. the support pressure increase rate (from 1 to 15), as in Figure 40.

Figure 40: Ramp parameter selection screen.

3. Set the duration of the Timeout, i.e., the time to wait before performing a forced breathing act (otherwise known as baseline) as described in Figure 41.

Figure 41: Timeout time setting screen.

4. Set the minimum flow level, expressed as a percentage from a flow value of 0 to the maximum reached by the flow during the same respiratory act, to end the single respiratory act on the decreasing front of the flow graph during an inspiratory act as shown in Figure 42.

Figure 42: Setting the minimum volume level to end the breathing act.

5. Set the minimum flow value (i.e., flow trigger) that allows the ABU device to activate the single act of breathing as shown in Figure 43.

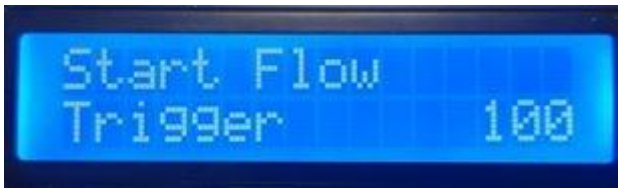

Figure 43: Minimum flow volume setting screen to activate the individual respiratory act.

6. Set the minimum pressure required in cmH2O (i.e., pressure trigger) to activate the individual respiratory act in cmH2 O as shown in Figure 44.

Figure 44: Screen for setting the minimum pressure level to activate the individual breathing act.

Once all the listed parameters have been set, assisted ventilation can be initiated by following the instructions in steps 6 and 7 of section 5.3 Forced Ventilation Modes . **Note**: If the ABU control system is forced to activate forced ventilation 5 consecutive times, an alarm will sound to warn that the patient is unable to ventilate independently or the set trigger values are too high. The respiratory act will be activated at the first reading between the volume and pressure triggers.

5.5 - Alarms and security systems

The system has internal diagnostics to detect malfunctions and clinical complications. For each of the listed alarms the ABU device will emit a sound signal.

General malfunction alarm: is shown if the device is not operating according to the parameters set by the user or if one of its components has been damaged. The user is required to pay maximum attention to the components regardless of the alarm being triggered as it should not be considered exhaustive in identifying a technical problem. If this alarm is triggered, the user will see the screen shown in Figure 45. In this case proceed with a new setting of the machine by turning it off and on again and checking the ventilation system connections, taking care of the patient's clinical condition. Should the alarm be reactivated, disconnect the device from the patient and contact the manufacturer's service department.

Figure 45: General malfunction alarm screen.

Percentage loss alarm for discrepancy between inhaled and exhaled volume. It is activated when the ratio between the inhaled and exhaled volume is greater than the one set by the operator (point 5 of section 5.3 of this manual). In this case proceed to check the ventilation system and the connections to detect and correct any leaks. If the problem persists, change the AMBU system on the ABU. If the problem still persists, contact the manufacturer's service department. It may also be that, despite the presence of considerable leakage, the ventilation and clinical performance of the patient are optimal, in which case the operator may simply

raise the threshold for the percentage of leakage that triggers the alarm to silence the alarm. If the alarm is triggered, the user will see the screen shown in Figure 46.

Figure 46: Loss percentage alarm screen.

Pressure alarm too high: If the system pressure exceeds 60 cmH2O for even a moment, an alarm will be triggered. In this case, the user must check the status of the safety valve and replace it if it is damaged. Should the alarm be reactivated, the operator is advised to lower the value of the maximum allowable pressure of the system, check the connections of the ventilation system, the status of the sensors. If the problem persists, the operator is advised to replace the ventilator with a working ventilator to avoid patient damage and contact the manufacturer for technical assistance. If the alarm sounds, the user will see the screen shown in Figure 47.

Figure 47: High pressure alarm screen, over 60 cmH2O.

Malfunctioning Flow Sensor Alarm: The ABU system will send a visual and audible alarm when communication with the flow sensor is lost and the control system is no longer able to read Flow values. This alarm also appears when the values read by the sensors do not meet reasonable physical significance.

If this alarm occurs, the ABU control system will continue to ventilate according to the settings used during the previous respiratory act. In the event of an alarm linked to one of the sensors, the user is encouraged to replace the ventilator with a working ventilator to secure the patient and, once disconnected from the patient, the user is encouraged to turn the ABU device off and on again. If the problem persists, the user is encouraged to contact the manufacturer for technical assistance. If the alarm sounds, the user will see the screen shown in Figure 48.

Figure 48: Malfunctioning flow sensor alarm screen.

Malfunctioning pressure sensor alarm: The ABU system will send a visual and audible alarm when communication with the differential pressure sensor is lost and the control system is no longer able to read Flow values. This alarm also appears when the values read by the sensors do not meet reasonable physical significance.

If this alarm occurs, the ABU control system will continue to ventilate according to the settings used during the previous respiratory act. In the event of an alarm linked to one of the sensors, the user is encouraged to replace the ventilator with a working ventilator to secure the patient and, once disconnected from the patient, the user is encouraged to turn the ABU device off and on again. If the problem persists, the user is encouraged to contact the manufacturer for technical assistance. If the alarm sounds, the user will see the screen shown in Figure 49.

Figure 49: Faulty differential pressure sensor alarm screen

IMPORTANT:

Electromechanical safety system: In the event that the ABU motor control system should detect sudden changes in the required copy on the motor shaft, which generally corresponds to strong pressure changes within the ventilation system, the system itself will remove power from the electronic motor drive so that the clamps can be opened instantly, thus avoiding the possibility of inflicting barotrauma on the ventilated patient.

At the next respiratory act, the system will return to ventilation according to the settings entered by the operator. If this behaviour occurs more than twice in a row, the operator is required to modify the ventilation parameters as they are not suitable for the physical characteristics of the ventilated patient. This safety behaviour is often accompanied by the message 'Pressure alarm too high' (Figure 47). If only the mechanical behaviour occurs, without the activation of the above mentioned alarm (a possible event, since the two safety systems are intentionally independent), the operator is in any case obliged to modify the ventilation settings.

6 - Maintenance

1. It is suggested to keep the device always dry and away from staining substances, especially near the electronic sensors as it could compromise its operation.
2. Avoid keeping the device near heat sources.
3. In case of malfunction, contact the manufacturer and report the problem. Refrain from attempted repair or modification without prior indication by the technical personnel appointed by the manufacturer. Any attempt to tamper with the device may result in its malfunction.
4. You can clean and disinfect the appliance with a cotton cloth moistened with ethanol or a disinfectant solution. Pay attention when performing this operation in the vicinity of the electronic sensors.

7 - Certifications

The Manufacturer **OMNIDERMAL BIOMEDICS S.R.L.** declares under its own responsibility that the device shown below and the relative software necessary for its operation has been tested by the Italian Technical Scientific Committee based at the Gemelli Hospital in Rome on April 4, 2020 and that the CE certification process is in progress in accordance with Directive 42/93/EEC and subsequent amendments.

Model or nr. Article	**Name**	**Classification**
ABU01	ABU	Class IIb

8 - Producer body and contacts

The ABU device and software have been developed and distributed by:

Omnidermal Biomedics, S.R.L.

Via Alessandro Volta 8 - 43040 Rubbiano – Parma - ITALIA P.I.: 02895260343

Su distribucion fuera de Italia es exclusivamente autorizada a:

Switrace SA

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