



The manufacturer of the pulmonary ventilator ABU (Automated Breath Unit), PBL srl, declares that the previous version of the ABU named ABU01 has been replaced by the new version of the same device named ABU v01.

- According to the Directive 93/42/EEC, ABU01 was classified as class I medical device.
- According to the Directive 93/42/EEC, ABU v01 is now classified as class IIB medical device, CE certification is attached to this document.

Omnidermal Biomedics srl is the official distributor of the ABU v01
Below are listed the major functionalities of the ABU v01

ABU v01 **Class IIB medical device for pulmonary ventilation**

Volume Mode

- **Assisted Ventilation (AC):** the ventilator provides a respiratory act every time the patient begins to breathe. In fact, the ventilator perceives a negative pressure given by the inspiratory effort and delivers a respiratory act according to the set tidal volume;
- **Synchronized Intermittent Mandatory Ventilation (SIMV):** is the ventilation mode used during the weaning phase. The acts delivered by the respirator synchronize with the patient's inspiration. If the patient does not start a spontaneous respiratory act, the ventilator intervenes by delivering a respiratory act. The tidal volume varies according to the patient's efforts, but the ventilator ensures that the patient performs a pre-established minimum number of acts per minute.
- **Non-Invasive Mechanical Ventilation (NIMV), otherwise indicated as NIV (Non-Invasive Ventilation) or NPPV (Non-Invasive Positive Pressure Ventilation)** guarantees positive pressure mechanical ventilation support that uses different ventilation strategies.

Pressure Mode

- **Continuous Positive Airway Pressure (CPAP):** the ventilator provides to the patient a continuous high pressure that overlaps the patient's spontaneous ventilation, improving oxygenation and reducing ventilation and cardiac work.

Variable Flow Mode

- **Pressure Regulated Volume Control (PRVC)** This implies that instead of delivering an exact tidal volume to each respiratory act, a target volume is set and the ventilator will vary the inspiratory flow at each act to reach the target volume at the lowest possible peak pressure. The inspiratory time (Ti) limits the duration of the inspiratory cycle and therefore the value of the ratio between inspiratory time and expiratory time (I / E ratio). Pressure-regulated mode such as PRVC or Auto-flow (Draeger) can be imagined as the transition from a volume-controlled mode to a pressure-controlled one with the advantage of maintaining greater control over the tidal volume compared to a purely mode pressure.

Additional features

- **Alarm system** the ventilator includes all the alerts required by the Directive and the alert system can be connected to the alert management of the hospital through a dedicated cable
- **Battery** the ventilator includes a battery that ensures 50 minutes of operation in the event of a power failure
- **Data export** the ventilator allows to export all the data with JSON format
- **Removable AMBU bag** the ventilator includes an AMBU bag that can be replaced or removed from the ventilator

TABLE

Volumetric Mode	Assisted Control (AC)	Synchronized Intermittent Mandatory Ventilation (SIMV)	NIV (Non-Invasive Ventilation) or NPPV (Non-Invasive Positive Pressure Ventilation)
Pressure Mode	Continuous Positive Airway Pressure (CPAP)		
Variable Flow Mode	Pressure Regulated Volume Control (PRVC)		

Sincerelly,
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