BREEZE MECHANICAL VENTILATOR

USER MANUAL
2020

I. Medical Note

The ventilator does not include the necessary equipment to measure the patient's oxygen saturation level (saturometer). Monitoring these saturation levels to ensure adequate oxygenation is highly recommended. Use of this ventilator is recommended with a heat and moisture exchanger at the interface between the endotracheal tube and the ventilator tubing.

A closed-system suctioning system proximal to a heat and moisture exchanger (HME) filter will enable clearing of secretions and reduce exposure risk. If resources preclude this, catheter mounts can be used instead.

***DISCLAIMER: BREEZE IS NOT RESPONSIBLE FOR ANY DAMAGES, INJURIES, COMPLICATIONS OR ANY ADVERSE EVENTS THAT OCCUR WITH THE USE OF THE DESIGN/VENTILATOR. IT IS OBLIGATORY THAT A TRAINED MEDICAL PROFESSIONAL OPERATE THE DEVICE. BREEZE AND ITS FOUNDERS ARE FREE FROM ANY AND ALL LIABILITY. It is recommended that individuals follow current Public Health Guidelines and instructions from their respective medical institutions for cleaning their ventilator. The below are suggestions from health care professionals but should not be treated as medical advice. While alarms aim to ensure the patient's safety and well-being, they cannot be used for absolute safety. Patient safety and mechanical ventilation protocols should be followed.

II. Hardware Operation

a. Providing Power to the Ventilator Unit

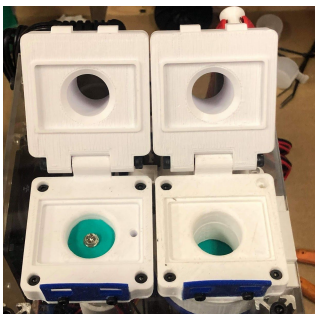
Table 1. Powering the Unit

i. Mains Supply	Allows the operator to simultaneously (1) power the ventilator unit and (2) charge both the internal and external battery (if connected). No further action is required on the part of the user to initiate battery charging.
ii. External 12V Battery	Allows the operator to power the ventilator using a commercially available 12V battery. To connect the external battery, the operator can use the provided alligator clips which connect directly to the poles of the battery (+Pole/RED Jumper, - Pole/BLACK Jumper). The external battery automatically charges when the ventilator is connected to the mains supply. The charging status and battery life are displayed on the user interface.
Iii. Internal 12V Battery	A 12V rechargeable battery which is sufficient to operate the system independently for a short duration (ex. switching operations, power outages). It should not be used for long-term operation as the 1-3 hour window depends on operational demands. The internal battery is housed within the ventilator, can be accessed via partial disassembly of the unit, and charges automatically when the system is connected to a mains source. Both charging status and battery life are displayed on the user-interface.

b. Turning on the Device

In order to power on the ventilator unit, first (1) activate the alarm switch which should make an audible alarm followed by the (2) main power switch which will turn off the alarm. If you do not hear the alarm do not use the device. Both switches are located on the front-panel of the ventilator and identified with labels. The ventilator display is automatically activated when connected to one of the three power sources described in section I.a.

c. Changing the Device's Filters

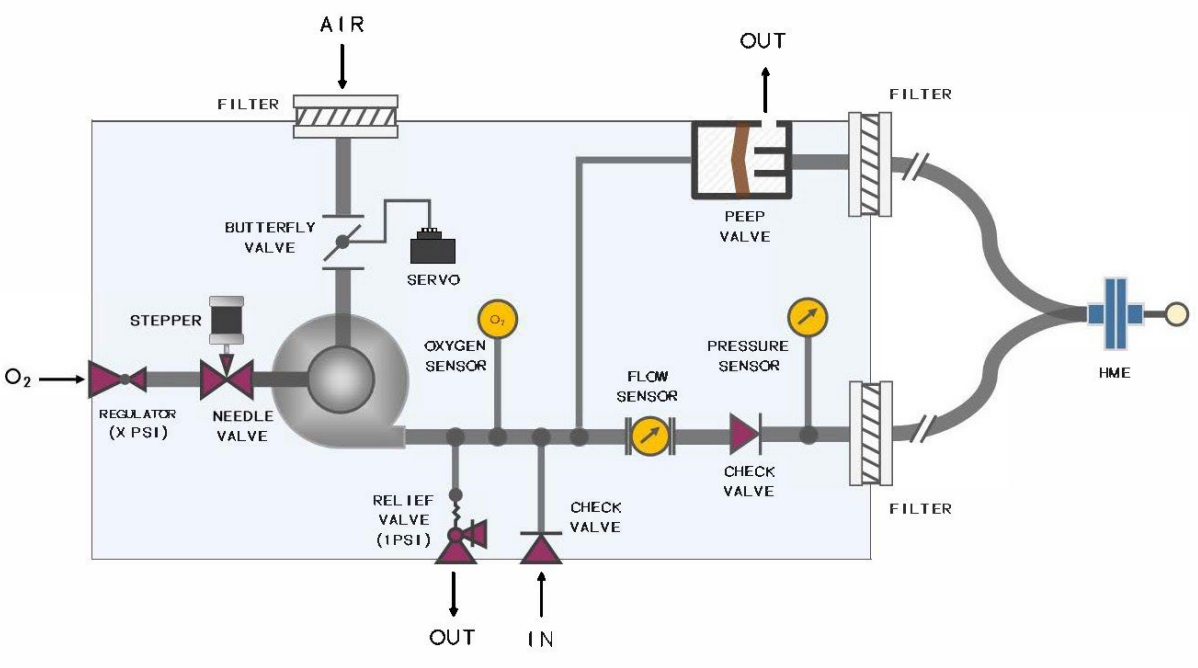


The filter housings are located on the top panel of the ventilator unit. To change the existing filters, the operator can lift the blue latches on the filter housing assembly, remove the soiled ones and replace with HEPA filters. An additional air intake filter is mounted to the side panel. The air intake filter can be pressed into the body of the unit.

d. Connecting Patient Tubes

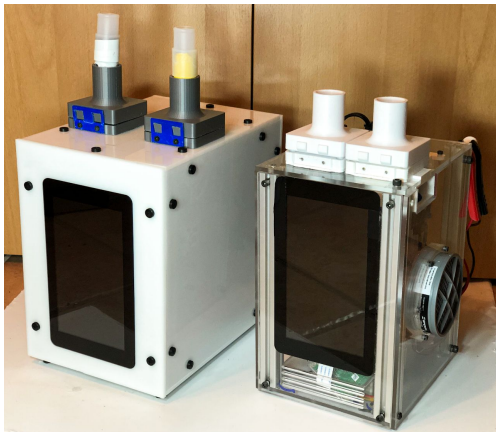
The patient y-tube consisting of standard medical corrugated tubing fitted with 22 mm universal adapters easily slots into the filter housings.

e. Supplying Oxygen to the Device



The ventilator unit contains an adapter enabling the attachment of a pressurized oxygen line. The oxygen source can be a pressurized tank or any other source of pressurized medical oxygen. The maximum oxygen line pressure that can safely be delivered to this ventilator is 200 psi. For the ambient air supply, no additional action is required.

f. Cleaning your Device



All exposed surfaces can be disinfected. The ventilator surface can withstand all standard medical-grade hospital ventilator disinfectants.

- The external and internal surfaces include the tablet, 3D printed parts, acrylic casing and all wires.
- The filter housings can be detached from the body of the ventilator and either disinfected or printed again.
- The air intake filter can be replaced between patients.
- The tubing circuit should be handled as usual.
- For added risk mitigation, the PEEP valve may be disinfected with any standard medical disinfectants.

g. Powering off your Device

To power off the device, first disable the main power, then the alarm switch. It is not necessary to unplug the device from the mains source or to disconnect the internal/external batteries.

III. Software Operation

After the ventilator has booted up, a helpful setup screen appears, with an option to run automated validation tests.

Setup Screens

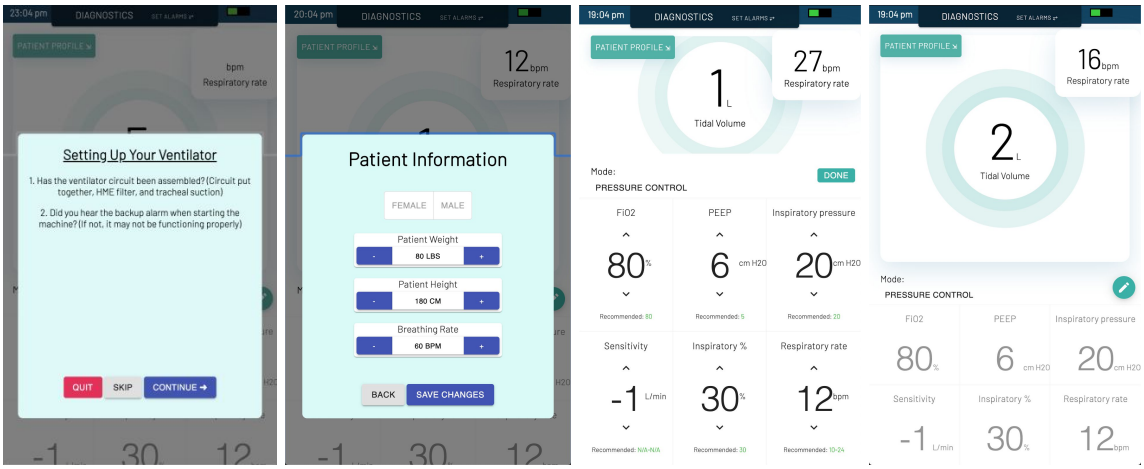


Table 2. The Interface

i. Parameters Screen	Recommendations for how to set each parameter are integrated in the software. *(See section below for details on setting up the screen)*
ii. Alarms Screen	Alarm thresholds must be set. A history of the alarms that have sounded in the last 24 hours are available on the display.
iii. Observation Screen	Two values are displayed at all times to facilitate monitoring the patient's condition: tidal volume and pressure. A standby mode ceases flow in the ventilator system to minimize exposure to viral particles when changing filters.

IV. Setting the Parameters

Prior to the ventilatory settings, you will be asked to enter the patient's measurements.

Table 3. Breath Parameters

i. Pressure Control and Pressure Support	At the top of the parameters setting screen, two initial settings allow you to **choose between Pressure Control and Pressure Support**. The chosen mode depends on the patients' respiratory rate and spontaneous breaths as Pressure Control breaths have a fixed time cycle and Pressure Support breaths are flow-cycled.
ii. Respiratory Rate	The respiratory rate (for Pressure Control mode only) reflects the number of breaths a patient will receive in a minute.
iii. Fi02	Fi02 represents the fraction of inspired oxygen, i.e. the proportion of the inspired gas delivered to the patient that is composed of oxygen.
iv. PEEP	The PEEP is the positive end-expiratory pressure, the amount of pressure left in the ventilated lungs at the end of expiration.
v. Sensitivity	This sensitivity represents the inspiratory flow which signals to the ventilator that the patient is initiating a breath. This ventilator's detection threshold value is set to 1L/min and does not require operator setting.
vi. Inspiratory Pressure	This pressure will support the patient's work of breathing.
vii. Inspiratory time or Inspiratory:Expiratory (I:E) Ratio	This value is only pertinent in pressure control mode. It represents the time spent inspiring relative to the total time of the breath (inspiration+expiration together).

Table 4. Alarms

i. High minute ventilation	The high minute ventilation alarm sounds when the volume of air entering and exiting the patient's lung is above a threshold value. This alarm often indicates a high respiratory rate or an increase in patient demand for air caused by pain or anxiety.
ii. Low minute ventilation	The low minute ventilation alarm sounds when the volume of air entering and exiting the patient's lungs are below a threshold value.
iii. High Pressure	This alarm detects high pressure in the circuit and can be triggered by secretions, coughing, bronchospasm, or obstructed tubin.
iv. Low Expiratory Pressure	Low pressure alarms reflect a sudden drop in ventilator circuit pressure and are usually associated with leaks or disconnections.