Fi@UCSD

Ventilator User Guide & Validation Tests

Summary

The Fi@UCSD Ventilator is a portable device capable of providing mechanical ventilation as a cost-effective, easy to build, functional solution. The device is made up of a control module, a bellow-piston air pump, and a typical patient airway circuit with a single-use ventilator mask; in addition, the mask can be detached to connect to any standard hospital ventilator mask.

This guide serves as an aid to familiarize the user with the machine and its operating modes for proper usage. This equipment should only be operated by medical personnel with knowledge of the input and functions of traditional ventilators. This guide contains general information regarding the control module inputs, components, operation, and technical information.

General Information:

Intended Use

This device applies mechanical ventilation for a patient by relying on forced air; thus, this device is especially beneficial for patients that have compromised breathing rates or lack of air to the lungs, as well as a way to slowly wean lung function back to safe breathing conditions.

General Description

The ventilator consists of a control module, a patient airway circuit, a bellow-piston configuration, and a standard ventilator mask; in addition, oxygen saturation can be implemented through a separate oxygen tank.

The system is battery-powered and driven by an Arduino codebase. The pressure-driven system creates a compressional movement in the piston-bellow system using a motor and rack-and-pinion configuration, triggering the opening of a valve to allow airflow towards the patient; the use of pressure controls the valve to shut once the input inspiratory pressure is reached in the lungs. During the expiration period, the bellow refills by a solenoid valve opening the concentrated oxygen tank and a one-way valve with upstream as the atmospheric air.

Operation of the device:

The ventilator is a pressure controlled device that provides mechanical ventilation for patients that have minimal to no control over lung movement by applying positive pressure, driving airflow into their lungs. To operate the system, the control module must first be powered on; since the system is battery-powered, no outlet connection is necessary. Once the system is fully assembled, the ventilator must be operated with the desired control conditions. The 4 dials on the control module control 4 essential aspects of the ventilator, shown in Table x.

Table 1: System Knob Parameters and Ranges

Knob	1	2	3	4
Parameter	P_{insp}	FiO_2	Breathing Rate	IE Ratio
Range (units)	0 to 40 (cmH_2O)	21 to 100 (%)	6 to 40 (Breaths/Minute)	1 to 6 (N/A)

As this is a pressure controlled system, the expiratory pressure must also be set; this is done by manually adjusting the valve on the expiration circuit. When starting the ventilator, the system should be run for 1-2 cycles before allowing a patient to use it; this allows the residual air currently inside the piston-bellow system to exit, which allows for the FiO_2, or fractional oxygen intake, to be accurate according to the dial. Once this is done, the operator can place the ventilator mask over the patient's mouth to commence the mechanical ventilation process. The breathing rate in conjunction with the IE ratio can determine the inspiratory and expiratory time to match with the patient's breathing capabilities, while the FiO_2 dial can increase oxygen concentration. The control module contains an LCD screen that displays Tidal Volume in milliliters; depending on the patient, the dials can be adjusted to change this value.

Validation Tests:

Validation tests can be run to determine how functional the ventilator is after a certain time. To perform a functional test, follow the steps below:

1. Turn off the device by pressing the power switch at the back of the device.
2. Check the condition of the device and accessories. Inspect the device and all accessories. Damaged components should not be used.
3. Check the patient circuit setup. Check the integrity of the patient circuit (device and provided accessories) and that all connections are secure.
4. Turn on the device and test alarms with input; alarms in consideration correspond to incorrect inspiration/expiration pressures and disconnections in circuit.

The frequency of tests for the ventilator is shown in Table 2 below:

Table 2: Service Preventive Maintenance Frequency

Frequency	***Part***	***Maintenance***
Every 6 months	Entire ventilator	Run extended self-test (EST). Test alarm system.
Every 6 months	Battery	Perform battery test (as part of EST)
Every year	Entire ventilator	Perform electrical safety test and inspect ventilator for mechanical damage and for label illegibility.
Every 3 years OR when the battery test fails.	Battery	Replace battery. Actual battery life depends on the history of use and ambient conditions.

Below are some concerns for when operating the ventilator:

1. Make sure the area around the device is dry, clean and clear of bedding or clothes or other objects that could block the air inlet. Blocking the cooling vents could lead to overheating of the device. Blocking the air inlet could lead to patient injury.
2. To prevent possible damage to the ventilator, always secure it to its stand or place it on a flat, stable surface. For mobile situations, ensure the device is contained within its mobility bag. Ensure the device is protected against water if used outdoors.