

fitbit®



Fitbit Flow User Manual Version A

129-0575-01
May 2020

WARNING



The Fitbit Flow has not been FDA cleared or approved;

The Fitbit Flow has been authorized by FDA under an EUA;

The Fitbit Flow is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of ventilators under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown and may pose a risk to the patient.

Table of Contents

Glossary	6
Purpose of this manual	9
Safety Information	9
Definitions	9
General Warning Statements	9
Symbols and Markings	12
Fitbit Flow Overview	14
Indications for Use	14
Target Patients	14
Target Environment	14
Operational Use	14
Breathing Circuit	16
Respiratory Parameter Controls	17
Safety Features	17
Compatible Manual Ventilator	18
Tubing, Sensors, and Valves (outside enclosure)	18
Tubing, Sensors, and Valves (inside enclosure)	18
Risks and Benefits	19
Device Description	20
User Interface	20
Controls, Indicators, and Displays	20
Front Panel	22
Back Panel	23
Left Panel	24
Right Panel	25

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Size and Weight	26
Environmental Conditions	26
Alarms and Troubleshooting	27
Alarm Level of Priority	27
Alarm Display	28
Silence Alarms	28
Alarm List	29
Additional Troubleshooting	30
Installation and Setup	31
Assemble the Stand	31
Components	31
Assembly Instructions	33
Assemble the Fitbit Flow Air Pathway System	36
Components	36
Assemble the Patient Circuit	39
Assemble the BVM Inside the Fitbit Flow	41
Power the Fitbit Flow	42
Operating Procedures	43
Turn On the Fitbit Flow	43
Start Ventilation	43
Ventilation Modes	43
Volume Control Mode	43
Pressure Control Mode	45
Stop Ventilation	47
Turn off the Fitbit Flow	47
Adjust Settings and Alarm Parameters	47
Cleaning and Maintenance	49

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Cleaning the Fitbit Flow	49
Cleaning the Manual Resuscitator Bag	49
Replace Accessories	50
Specifications	50
Physical	50
Accuracy	51
Labeling Parameters	51
Electrical	52
Alarm Conditions	53
Standards Compliance	54
General Standard	54
Particular Standards	54
User Assistance Information	55
Technical Support	55
Trademark Information	55

Glossary

A

Acute respiratory distress syndrome (ARDS)

A life-threatening lung condition in which fluid enters the lungs, causing low blood oxygen

Assist control (AC)

An optional setting which provides support for patient-triggered breaths when enabled

B

Bag valve mask (BVM)

See *Manual resuscitator*.

D

Dual limb breathing circuit

Patient circuit with two tubes: one tube between the gas outlet and the patient for inspiratory gas, and one tube between the patient and the exhalation block for exhalation gas

E

Endotracheal tube

A plastic tube that is placed through the patient's mouth into the trachea

Expiratory tidal volume (VTe)

The volume of air moved out of the lungs in a breath

I

I:E ratio

The ratio of the inspiratory time as compared to the expiratory time

Inspiration time (IT)

The amount of time it takes to deliver air to the patient's lungs

Inspiratory pressure (Pins)

The level of pressure applied to the lungs during the inspiration phase

Inspiratory tidal volume (VTi)

The volume of air moved into the lungs in a breath

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M

Manual resuscitator

A bag used to provide positive pressure ventilation to patients who are not breathing. Also known as a bag valve mask (BVM).

P

Patient-triggered breath

A breath initiated by the patient

Peak inspiratory pressure (PIP)

The highest pressure measured during the inspiration phase

Plateau Pressure (Pplt)

The pressure within the breathing circuit following an end-inspiratory pause

Positive end-expiratory pressure (PEEP)

Pressure that is applied by the ventilator at the end of the patient's breath

Pressure (P)

The force of air applied per unit area

Pressure control mode (PCV)

A mode of ventilation in which a fixed pressure is applied during the inspiratory phase

R

Respiratory rate (RR)

The number of breaths per minute (bpm) a patient takes

T

Tidal volume (Vt)

The volume of gas delivered to the patient in one breath

U

Uninterruptible power supply (UPS)

A backup device that supplies electricity when the regular power source fails

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V

Volume control mode (VCV)

A mode of ventilation in which a fixed volume is applied during the inspiratory phase

Purpose of this manual

This user manual contains information on the safe and effective use, setup, and maintenance of your Fitbit Flow. Before operating the Fitbit Flow, be sure to read and understand all the instructions in this manual. The Fitbit Flow is intended for use by qualified, trained personnel under the direction of a physician only when an FDA-cleared clinical ventilator is not available.

Safety Information

Definitions

This manual uses the following type of indicator to highlight critical information:

WARNING



WARNING indicators describe potentially hazardous conditions that could result in death or serious injury.



General Warning Statements

- **Use only as directed. Review the User Manual completely before use. Improper usage or unauthorized modification of this product may result in user or patient injury.**
- **The use of a UPS (Uninterruptible Power Supply) designed for a clinical setting is mandatory as loss of power may result in patient injury or death.**
- **The UPS connected to the Fitbit Flow should be equipped with an alarm to alert the operator when power is switched to battery power. The UPS should also indicate how much battery power and/or time remains.**
- **The system does not have the capability to sound an alarm due to a power outage to the system. If the power source is interrupted, the system will revert to the default settings when power is restored. The operator will need to change any desired settings and restart ventilation.**
- **Clinical monitoring (e.g. SpO₂ with finger pulse oximetry and arterial blood gases) should be conducted to make sure the patient is achieving adequate oxygenation. The Fitbit Flow does not directly measure the %FiO₂ delivered to the patient, and one should not assume that the delivered %FiO₂ is equal to the %O₂ of the source.**
- **The Fitbit Flow has not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.**

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- The Fitbit Flow has not been tested for MRI scanner compatibility and should not be used in the vicinity of an MRI scanner.
- Do not pull on the oxygen tube. Doing so could dislodge or otherwise move the manual resuscitator within the enclosure.
- The Fitbit Flow has been tested for 24 hours of continuous use. If using longer than 24 hours, check for signs of wear and tear, particularly on the manual resuscitator.
- The Fitbit Flow has not been characterized under leakage test conditions. If there is significant patient circuit leakage, the device may under-deliver tidal volume to the patient.
- Provide sufficient space around the Fitbit Flow for adequate air flow. Do not position next to objects that may block the flow of air. Failure to do so may cause the equipment to overheat, thereby interfering with patient ventilation.
- Do not block the gas intake port or emergency intake port. This may interfere with patient ventilation.
- Do not add any attachments or accessories to the Fitbit Flow that contravene the instructions for use of the Fitbit Flow, as the Fitbit Flow might not function correctly, leading to the risk of patient death or serious deterioration of health.
- The Fitbit Flow shall not be used in a hyperbaric chamber. Such use might cause the Fitbit Flow to not function correctly, causing patient death or serious deterioration of health.
- The Fitbit Flow does not support the delivery of gas anesthesia agents, and is not intended for use with such medications. Such use might cause the Fitbit Flow to not function correctly, causing patient death or serious deterioration of health.
- The Fitbit Flow shall not be used with inlet gases other than medical air or oxygen, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the Fitbit Flow to not function correctly, causing patient death or serious deterioration of health.
- It is the responsibility of the clinician to ensure that the oxygen source is appropriately selected with respect to the range of pressure, flow rate and oxygen concentration.
- Breathing system filters and heat and moisture exchangers may require more frequent replacement to prevent increased resistance and blockage.
- When moving the Fitbit Flow, disconnect it from the patient and turn off the device.
- Lock the stand's caster wheels whenever the Fitbit Flow is in use.
- Do not attempt to move the Fitbit Flow when it is connected to a patient.
- Do not cover or obstruct the alarm button. The operator must be able to see the alarm button when the device is connected to the patient, particularly in noisy environments where the operator may not hear the alarm.
- Frequent alarms are possible. When an alarm is triggered, always check the cause and respond accordingly. Failure to respond to alarms can result in serious harm or death.
- Failure to follow the cleaning and maintenance instructions could result in equipment damage and potentially harm the patient.
- Do not attempt to clean or re-use single use accessories.
- Do not reuse single-use components. Doing so increases the risk of cross-contaminations between patients.

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- When operating in PCV (Pressure Control Mode) the Fitbit Flow may not achieve a constant pressure throughout the entire inspiratory period, which may reduce the delivered tidal volume.
- When Assist Control is enabled, it is important to monitor for breath stacking (also called breath dyssynchrony stacking), which can result in unintended high tidal volumes as a consequence of incomplete exhalation between consecutive cycles. Continuous CO₂ monitoring (also called capnography) and arterial blood gas sampling should be conducted to detect high CO₂ levels which may be a consequence of hypoventilation.
- In some patients, especially those with abnormal lung compliance, an inspiratory hold of one second may not be long enough for the pressure to equilibrate in the lungs. In such cases, the reported plateau pressure will not be accurate.

Federal law restricts this device to sale by or on the order of a Physician.

Symbols and Markings

Symbol	Meaning
	<p>This symbol appears in the user manual.</p> <p>It is essential to read, understand, and follow these instructions or warnings before using the Fitbit Flow.</p>
	<p>This symbol appears in the Fitbit Flow box.</p> <p>Pinch point. Keep hands and fingers clear during operation.</p>
	<p>This symbol appears on the Fitbit Flow's back panel.</p> <p>It signifies where the AC connector cable is located.</p>
	<p>This symbol appears on the Fitbit Flow's back panel in two locations: the holes where the external display attachment should be screwed in, and above the HDMI and USB connections.</p> <p>It signifies where to connect the optional external display.</p>
	<p>This symbol appears on the Fitbit Flow's back panel above a USB connection.</p> <p>It signifies where to connect to the Fitbit Flow in order to service it.</p>
	<p>This symbol appears on the control panel's alarm button.</p> <p>It is used to display alarm details and silence an active alarm.</p>
	<p>This symbol appears on the control panel's up button.</p> <p>It is used to scroll up through menu items or increase a parameter value.</p>
	<p>This symbol appears on the control panel's down button.</p> <p>It is used to scroll down through menu items or decrease a parameter value.</p>
	<p>This symbol appears on the control panel's back button.</p> <p>It is used to return to the previous menu.</p>
	<p>This symbol appears on the control panel's confirm button.</p> <p>It is used to accept a new setting.</p>



This symbol appears on the control panel's start/stop button.
It is used to start or stop ventilation.

Fitbit Flow Overview

Indications for Use

The Fitbit Flow is indicated for the continuous mechanical ventilatory support of adult patients. The Fitbit Flow is an accessory to a manual resuscitator and consists of a reusable mechanical actuator and the single-use, disposable tubing assembly. The Fitbit Flow supports conventional Volume Control and Pressure Control modes of ventilation, as well as an “Assist Control” feature to support breaths triggered by the patient. The Fitbit Flow is intended for use by qualified, trained personnel under the direction of a physician only when an FDA-cleared clinical ventilator is not available during the COVID-19 pandemic.

Target Patients

The Fitbit Flow is intended for adult patients who require the following types of invasive or non-invasive ventilatory support, as prescribed by an attending physician:

- Positive Pressure ventilation
- Breath types including Volume Control and Pressure Control
- Assist/Control

The Fitbit Flow is applicable to patients with severe respiratory symptoms, including those with Acute Respiratory Distress Syndrome (ARDS), who require respiratory support.

Target Environment

The Fitbit Flow is intended for use in hospitals and hospital-type facilities (including field hospitals), that provide care for patients requiring respiratory support.

The Fitbit Flow is not intended for home use. The Fitbit Flow must be operated by respiratory therapists, doctors, or nurses. The Fitbit Flow should only be used on adult patients when an FDA-cleared clinical ventilator is not available.

Operational Use

The Fitbit Flow is designed to provide continuous ventilation through automated activation of an FDA-cleared manual resuscitator (also called bag valve mask (BVM)). The system consists of the box and a dual-limb breathing circuit attached to the patient, shown in Figure 1.

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FlowJoe Air Pathway revX14.1

Final | May 14, 2020

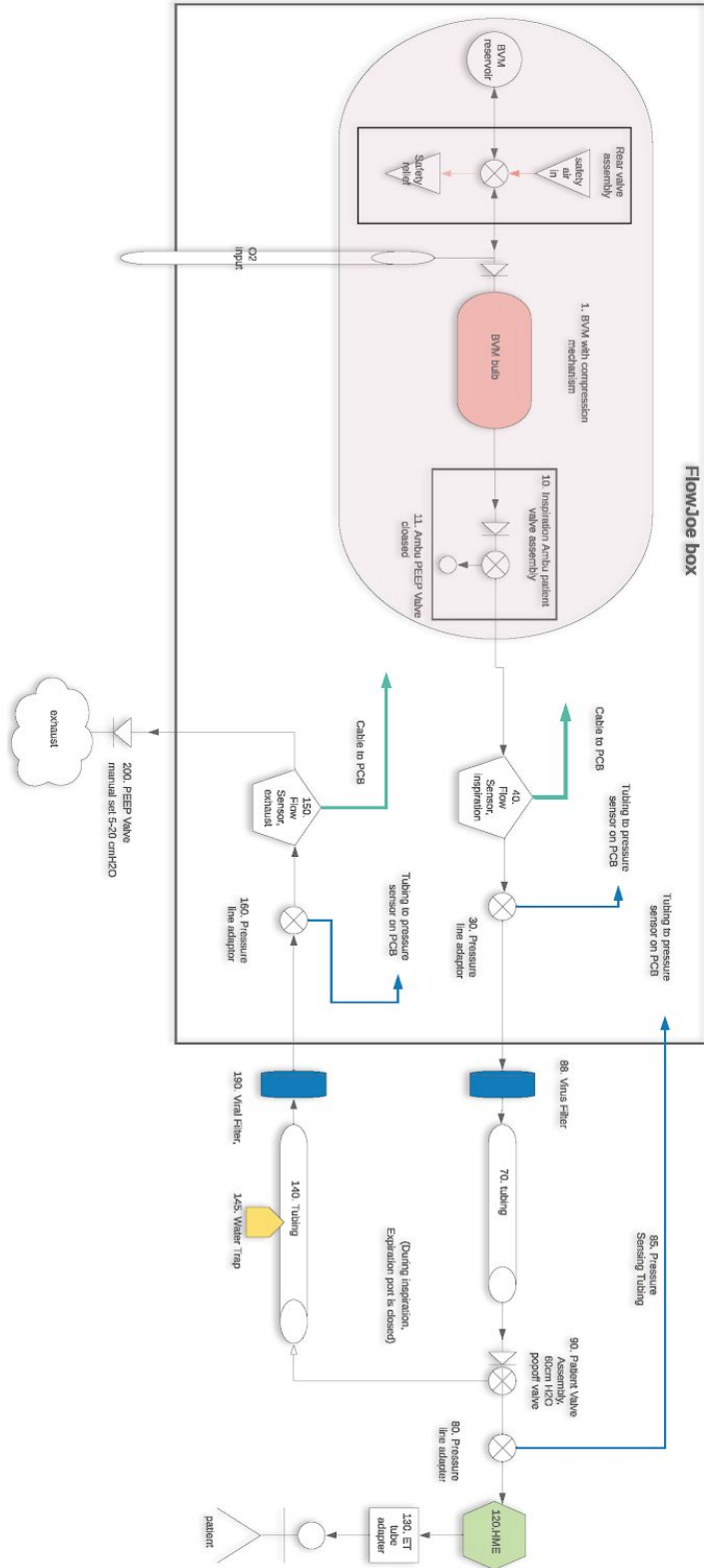


Figure 1: System Diagram

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The Fitbit Flow should only be used on adult patients and when an FDA-cleared clinical ventilator is not available. The Fitbit Flow is designed to provide continuous mechanical ventilation to the patient.

Ventilation modes include a volume control mode (VCV) and a pressure control mode (PCV). An optional Assist Control setting provides support for patient-triggered breaths when enabled. Enabling Assist Control allows the software to automatically detect when the patient is attempting to trigger spontaneous breaths in between ventilator cycles, by sensing the pressure below the positive end-expiratory pressure (PEEP) on the inspiration limb. When a patient-triggered breath is sensed, the Fitbit Flow will provide support for that breath to achieve the target volume or pressure. When Assist Control is disabled, the respiratory rate is entirely determined by the ventilator rate setting.

Breathing Circuit

The medical gas source is connected to the box and the gas flows through the resuscitator bag within the box (see Figure 2) into the standard breathing circuit tubing outside of the box and into the patient’s airway through a standard endotracheal tube.

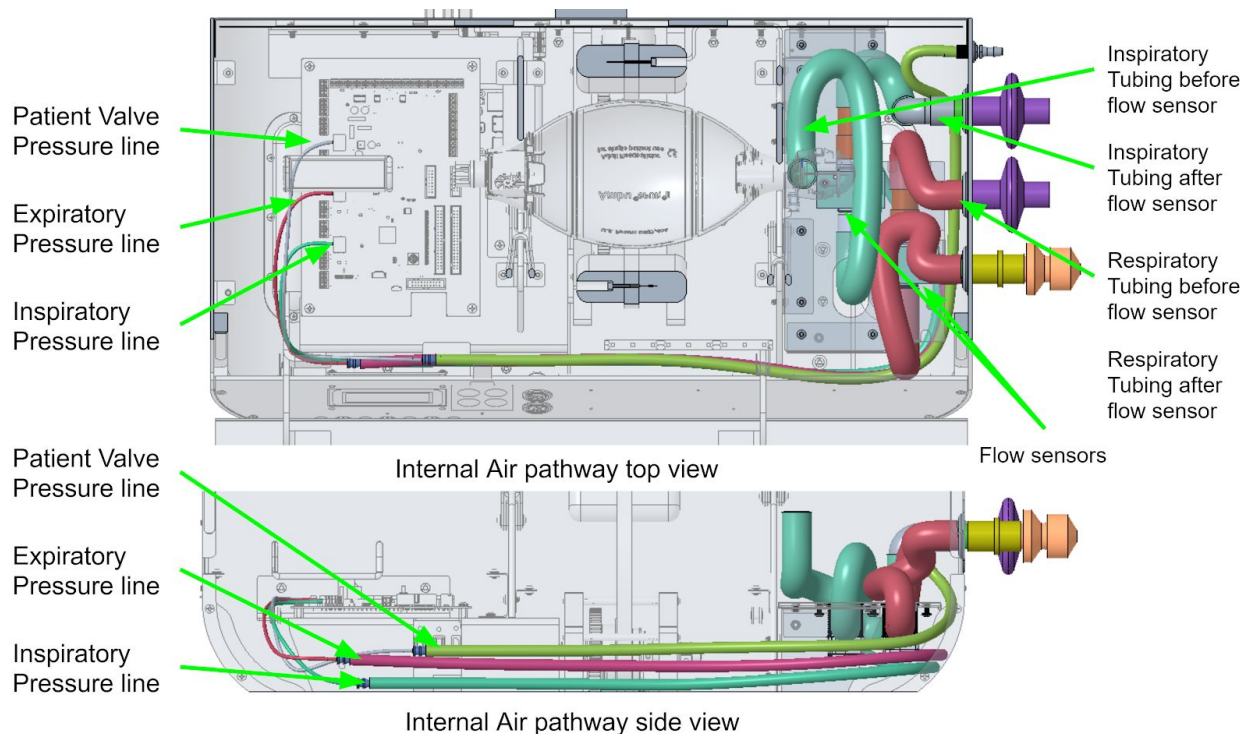


Figure 2: Internal Air Pathway

The Fitbit Flow connects to a medical gas source through the manual resuscitator bag or the reservoir bag, as per the indications of use of the manual resuscitator. The Fitbit Flow accessory uses motorized arms to automatically compress a resuscitator bag (see Figure 3).

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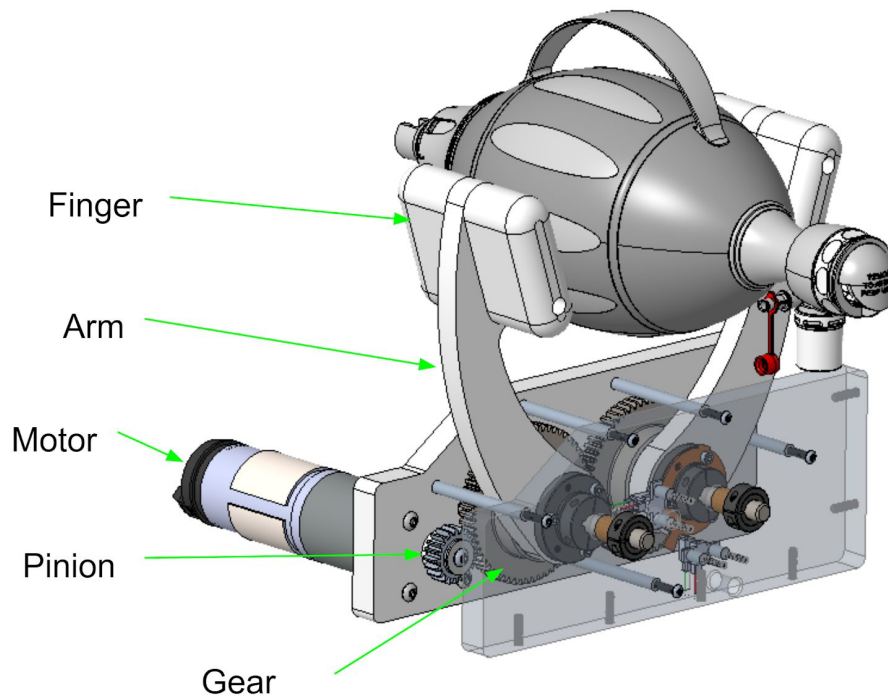


Figure 3: Compression Mechanism

Respiratory Parameter Controls

Controls are provided for setting respiratory parameters:

- Respiratory Rate (RR)
- Inspiratory:Expiratory ratio (I:E)
- Tidal Volume (Vt)
- Inspiratory Pressure (P)

PEEP is set by a compatible manual valve made by the resuscitator or ventilatory accessory manufacturer.

Safety Features

The Fitbit Flow accessory has a pressure sensor at the patient connection and flow sensors on the inspiratory path and expiratory path for monitoring and feedback control. These pressure and flow sensors connect to standard ventilator tubing connectors, as listed below. There are hardware pressure valves which limit the pressure in either limb to 1 PSI (70 cmH₂O). There is also a pressure-limiting valve, which is an optional part available for the resuscitator bag, that limits the pressure to 40 cmH₂O (typical). In addition, you can set software limits that trigger audible alarms for pressure and flow values. For more information on alarms, see [Alarms and Troubleshooting](#).

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Compatible Manual Ventilator

Part	Supplier	Part
Ambu SPUR II Adult Resuscitator	Ambu	Ambu Spur II

Tubing, Sensors, and Valves (outside enclosure)

Part	Supplier	Part	Quantity
Heat Moisture Exchange (HME) plus virus filter, 22 mm connector	Hsiner	70531	1
Virus filter, 22OD/22ID connector	Hsiner	70530	2
PEEP Valve, 30 mm ID, manual adjustable 5-20cm H2O	Hsiner	60019	1
Non Rebreathing Valve (NRV or patient valve) with 60cm H2O pop off valve and expiratory diverter for PEEP connection, 30 mm OD	Hsiner	60031	1+2 extra
Tubing Adapter 22 mm ID x 30 mm OD	Hsiner	70080	1
Adapter 30mm ID x 22 mm OD	Hsiner	70065	1+2 extra
Corrugated Tubing 22 mm ID - cut to 60 inch segment	Hsiner	70204	1
Corrugated Tubing 22 mm ID - cut to 30 inch segment	Hsiner	70202	2
Pressure line adapter, 22mm OD x 22mm ID, for 4-6 mm ID pressure tubing	Hsiner	70084	1
Flexible tubing for air, fits pressure sensor adapter, 3/16" ID, 60 inch long	Saint Gobain	ADF00012	1
Water Trap, 22M, Adult, disposable	Hsiner	70520	1
Catheter mount adapter, 22Fx22M15F, disposable	Hsiner	70130 or 70131	1

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Tubing, Sensors, and Valves (inside enclosure)

Part	Supplier	Part	Quantity
Digital Flow sensor	Sensirion	SFM3019	2
Digital flow sensor cable (to MB)	Sensirion IAC	6017A0254301	2
Pressure line adapter, 22mm OD x 22mm ID, for 5-7 mm ID pressure tubing	Teleflex	1642	2
Tubing Adapter 22 mm OD x 22 mm OD	Hsiner	70019	3
Elbow adapter 22mm ID - 22mm OD	Teleflex	1641	1
Corrugated Tubing 22 mm ID - cut to 18 inch segment	Hsiner	70226	1
Corrugated Tubing 22 mm ID - cut to 6 inch segment	Hsiner	70201	1
Corrugated Tubing 22 mm ID - cut to 12 inch segment	Hsiner	70231	1
Corrugated Tubing 22 mm ID - cut to 6 inch segment	Hsiner	70201	1
Flexible tubing for air, fits pressure sensor adapter, 3/16"ID, 30 inch long	Saint Gobain	ADF00012	3
Flexible tubing for air, fits pressure sensor port (1.9 mm OD), 1/16" ID, 12 inch long	Saint Gobain	ADF00002	3
Eldon James 1/4-18 NPSM to 3/16" x 3/16" Barbed Bulkhead Adapter	Eldon James	BH4S-3-3-200 NK	1
Tight-Seal Moisture-Resistant Barbed Tube Fitting			
Plastic, for Air and Water, Reducer, 3/16" x 1/16" Tube ID	Eldon James	C3-1-200NK-Q C	3

Risks and Benefits

The benefits for the use of the Fitbit Flow have been reviewed against the risks of use and have found to outweigh the risks of use during the COVID-19 health emergency.

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Device Description

User Interface

The user interface consists of an LCD panel and control buttons and knobs on the front of the box. The LCD screen displays values from the system sensors, as well as mode and alarm settings. Settings may be selected and adjusted with the buttons and knobs as described below (Figure 4).

Controls, Indicators, and Displays

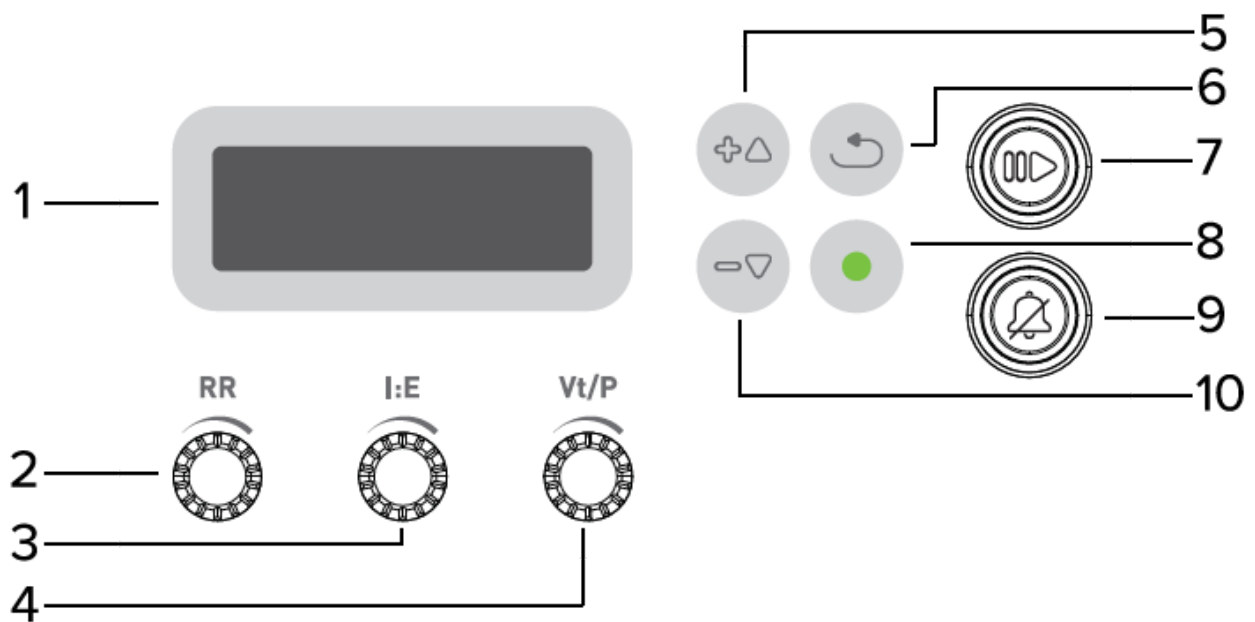


Figure 4: User Interface

Reference and Name		Description
1	LCD Screen	Displays ventilator parameters, sensor values, and alarm information
2	Respiratory Rate	Change the respiration rate (RR). Turn the knob clockwise to increase the value; counter-clockwise to decrease the value. The value is displayed on the LCD screen.
3	Inspiration:Expiration Ratio	Change the inspiration to expiration time ratio (I:E). Turn the knob clockwise to increase the value; counter-clockwise to decrease the value. The value is displayed on the LCD screen.
4	Tidal Volume / Inspiratory Pressure	Change the tidal volume (Vt) in volume control mode or inspiratory pressure (P) in pressure control mode. Turn the knob clockwise to increase the value; counter-clockwise to decrease the value. The value is displayed on the LCD screen.
5	Up	Scroll up through menu items or increase a parameter value
6	Back	Return to the previous menu
7	Start/Stop	Start or stop the Fitbit Flow
8	Confirm	Accept the new setting
9	Alarm	Press to see information on an active alarm. Press and hold to silence an active alarm.
10	Down	Scroll down through menu items or decrease a parameter value

Front Panel

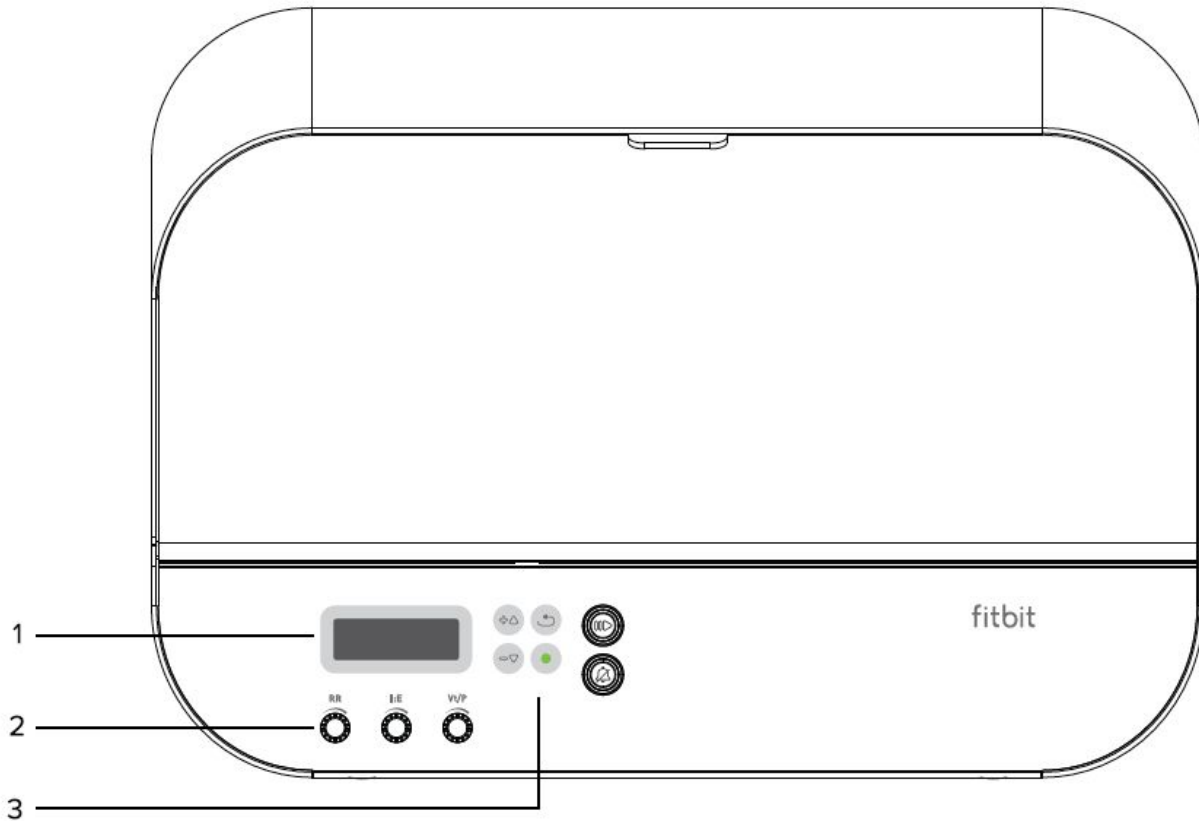


Figure 5: Front Panel

Reference and Name		Description
1	LCD Screen	Displays ventilator parameters, sensor values, and alarm information
2	Knob Controls	Used to adjust respiration rate, inspiration time, tidal volume, and inspiratory pressure
3	Button Controls	Used to navigate the UI, see alarm details, and start/stop ventilation

Back Panel

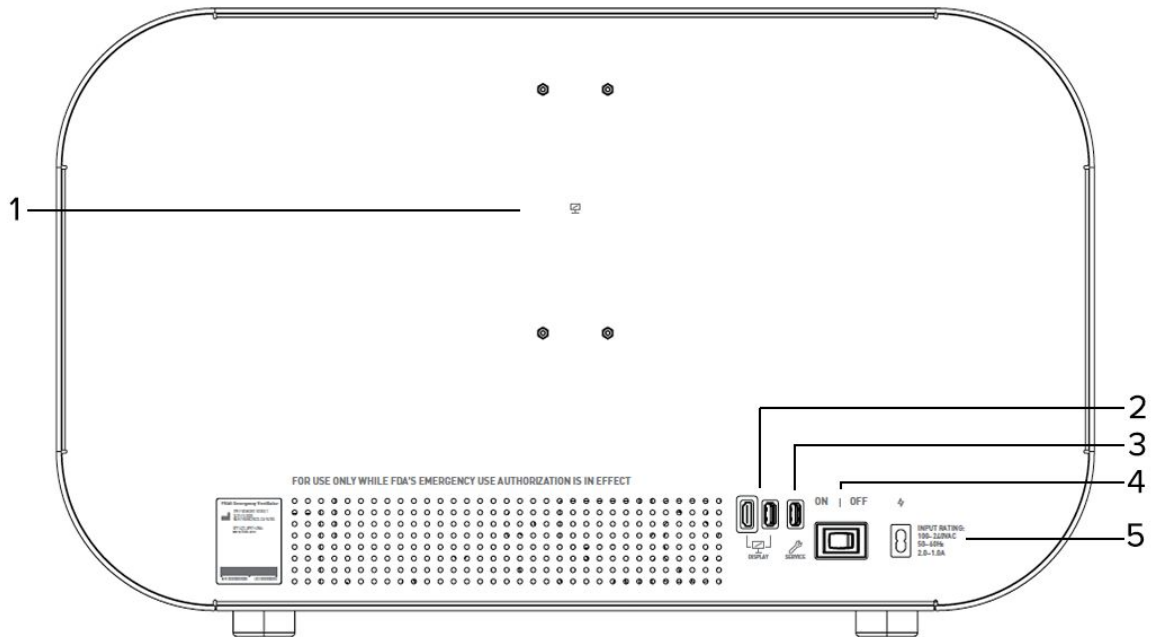


Figure 6: Back Panel

Reference and Name		Description
1	Display attachment	Holes to attach an optional external display
2	Display connector	HDMI and USB connections for an optional external display
3	Service connector	USB connection for when the Fitbit Flow needs to be serviced
4	On Off Switch	Switch to turn the Fitbit Flow on and off
5	AC Power Cable Connector	AC power cable connector

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Left Panel

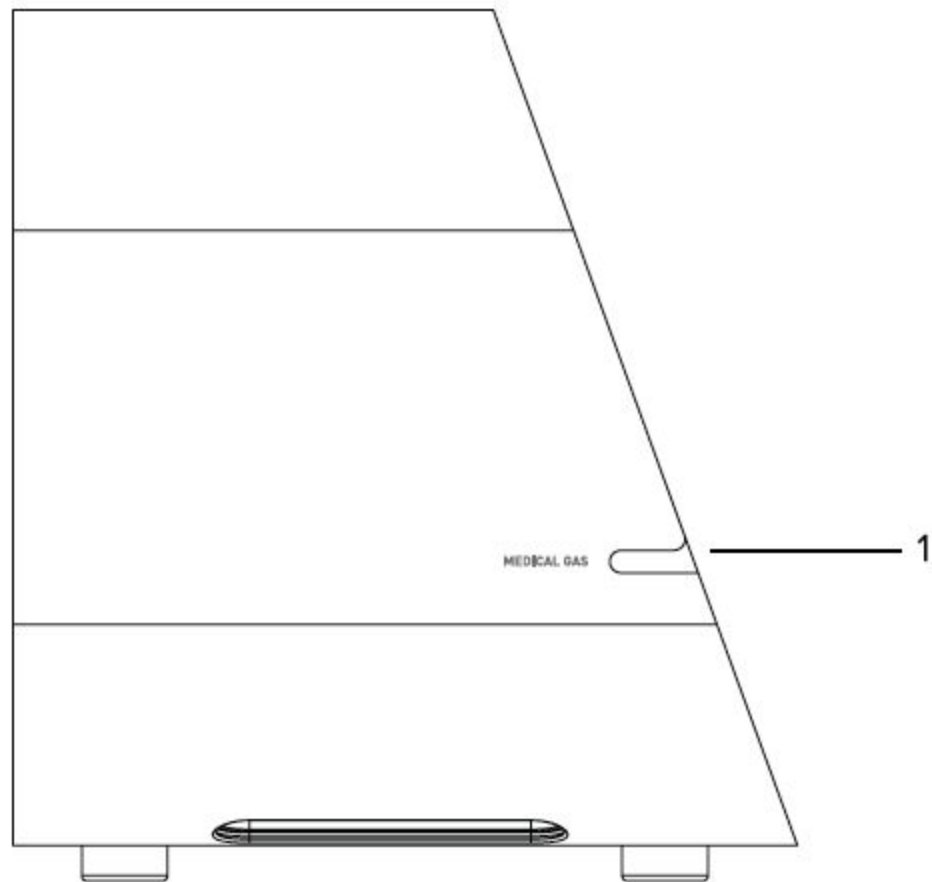


Figure 7: Side Panel (Left)

Reference and Name		Description
1	Medical gas inlet	Connects the Fitbit Flow to a medical gas source

Right Panel

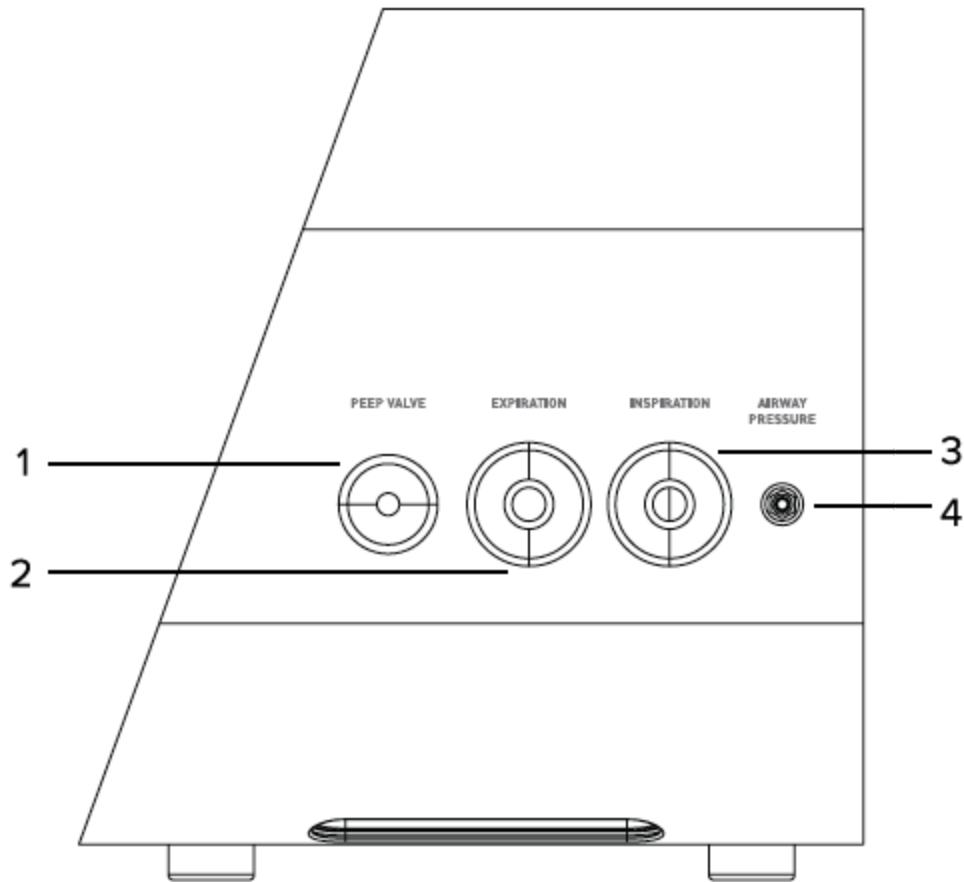


Figure 8: Side Panel (Right)

Reference and Name		Description
1	PEEP Valve	Connector for PEEP valve to maintain positive end-expiratory pressure.
2	Expiration	Inlet for expiratory air coming from the patient via the patient circuit.
3	Inspiration	Outlet for inspiratory air to be delivered to the patient via the patient circuit.
4	Airway Pressure	Connects to the pressure line to monitor the patient airway pressure.

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Size and Weight

Item	Height	Width	Depth	Weight
Fitbit Flow	25.2 inches 641.0 centimeters	13.7 inches 348.3 centimeters	15.2 inches 386.9 centimeters	40.3 lb 18.2 kg
Stand	37.5 inches 95.2 centimeters	28.4 inches 72.2 centimeters	22.2 inches 56.4 centimeters	28.0 lb 12.7 kg

Environmental Conditions

Operating Temperature	0°C to 50°C
Relative Humidity	Up to 95% RH
Storage and Transportation	-20°C to 70°C Recommended <30°C and up to 85% RH
Environmental Pressure Range	70kPa to 130kPa

Alarms and Troubleshooting

WARNING



Do not cover or obstruct the alarm button. The operator must be able to see the alarm button when the device is connected to the patient, particularly in noisy environments where the operator may not hear the alarm.

Frequent alarms are possible. When an alarm is triggered, always check the cause and respond accordingly. Failure to respond to alarms can result in serious harm or death.

Alarm Level of Priority


To identify the level of alarm criticality, use the information below:

Alarm Priority	Alarm Indicators
Very High Priority —Immediate critical situation; ventilation is impossible	<ul style="list-style-type: none">• Audible: Continuous sound• Visual: Solid red illumination• Identified by the letter V in the Alarm details on the LCD screen
High Priority —Critical situation in the short term; ventilation is potentially compromised	<ul style="list-style-type: none">• Audible: High-speed intermittent sound• Visual: Rapidly blinking red illumination• Identified by the letter H in the Alarm details on the LCD screen
Medium Priority —Critical situation in the long term; ventilation is not affected in the short term	<ul style="list-style-type: none">• Audible: Medium-speed intermittent sound• Visual: Intermittently blinking red illumination• Identified by the letter M in the Alarm details on the LCD screen

Alarm Display



```
+-----+
| Alarms |
| 1 H Fan fault |
| 2 H Temp motor |
| 3 H Vti low |
+-----+
```

When an alarm is triggered:

- The alarm button illuminates: 
- An audible alarm sounds




Press the alarm button to show the alarm details on the LCD screen.

Figure 9: Example of Alarms Screen

If there are multiple alarms, use the up  and down  buttons to scroll through them. Each alarm is numbered. The letter (V/H/M) indicates the priority level:

- **V**: Very high priority
- **H**: High priority
- **M**: Medium priority

A brief description of the alarm is shown to the right. For more details, including the time the

alarm was triggered and any applicable measurement values, use the up  and down  buttons to select an alarm, and then press the confirm button . For more information on each type of alarm, see [Alarm List](#).

Silence Alarms


Press and hold the alarm button for 3 seconds to silence the audible alarm for 60 seconds.

Press and hold the alarm button for 6 seconds to silence the audible alarm and the visual indicator for 60 seconds.

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Alarm List



To identify why an alarm activated, press the alarm button  to show the alarm details on the LCD screen. The table below lists the different possible alarms, as well as what corrective action to take.

Alarm name and Description	Possible cause	Corrective action
VTi hi Inspiratory tidal volume is over programmed limit	In PCV mode, inspiratory pressure target is set too high	Reduce P in PCV mode.
VTi low Inspiratory tidal volume is below programmed limit	The Fitbit Flow cannot achieve set Vt due to physiology, high PEEP, or occlusion in inspiratory pathway	Check for kink or occlusion in the inspiratory path. Reduce PEEP. Adjust P in PCV mode.
VTe low Expiratory tidal volume does not match inspiratory volume within some tolerance.	Leak in patient valve or expiratory pathway. Occlusion or restriction in the expiratory pathway.	Check the patient valve and expiratory pathway for leaks or occlusions.
Pmax Peak airway inspiratory pressure is above programmed limit	In VCV mode, set Vt causes limit to be reached due to lung physiology. Restriction or occlusion in the patient airway.	Reduce Vt and/or RR. Check the patient airway tube for restriction.
Pins hi Inspiratory pressure above programmed limit set above target pressure.	In PCV mode, ventilation parameters set too high for lung physiology. Restriction or occlusion in the patient airway.	Reduce RR and/or P (PCV). Check the patient airway for restrictions or occlusions.
Pins low Inspiratory pressure below the programmed limit set below target pressure.	Leak in patient valve or inspiratory pathway.	Check the breathing circuit for leaks.
PEEP low PEEP falls below	Manual valve set too low to achieve desired PEEP.	Increase setting on manual PEEP valve.

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programmed limit.	Leak in breathing circuit (including patient valve)	Check the breathing circuit for leaks.
Spontaneous Breath Spontaneous breath detected (drop in inspiratory pressure 2 cmH ₂ O below PEEP) when AC mode is not on.	(1) Patient sedation wearing off. (2) Patient increased work of breathing.	Assess patient and adjust care as necessary.
SYSTEM ALARMS		
Sys temp	Motor temperature out of tolerance range	Contact Technical Support . Place patient on another resuscitator/ventilator.
Motor fault	Motor not functioning as expected	Contact Technical Support . Place patient on another resuscitator/ventilator.
Fan fault	Fan not functioning as expected	Contact Technical Support . Place patient on another resuscitator/ventilator.
Sensor fault	Flow and pressure sensors not functioning as expected	Contact Technical Support . Place patient on another resuscitator/ventilator.
FW fault	Firmware watchdog triggered	Contact Technical Support . Place patient on another resuscitator/ventilator.
Lid open	The Fitbit Flow box lid is open while it is running	Close the lid of the Fitbit Flow. For user safety, the Fitbit Flow does not operate when the lid is open.

Additional Troubleshooting

See the table below for additional troubleshooting steps.

Condition	Possible cause	Corrective action
Motorized arms stop compressing the bag	Power loss	Manually operate by squeezing the resuscitator bag with two hands to

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		provide ventilation.
The Fitbit Flow screen doesn't turn on, the alarm sounds, and both buttons illuminate.	System failure	Contact Technical Support .
Multiple unsustained alarms	Conditions that reach a high pressure, such as the patient coughing	No corrective action needed.

Installation and Setup

Set up the Fitbit Flow in an area where air can circulate freely. Avoid direct exposure to sunlight, and set the Fitbit Flow on a flat, stable surface where air inlets and outlets are not obstructed.

Assemble the Stand

WARNING

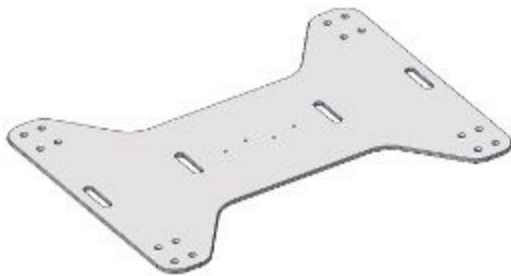


Lock the stand's caster wheels whenever the Fitbit Flow is in use.

Do not attempt to move the Fitbit Flow when it is connected to a patient.

Components

- 1x Floor plate (**Part A**)

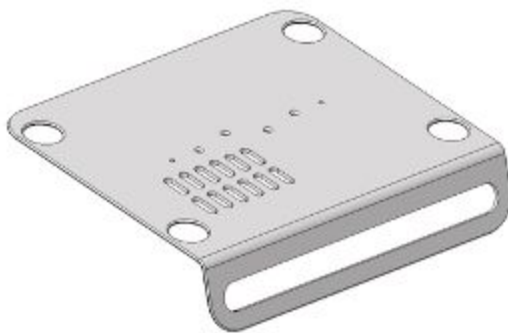


- 1x Vertical support (**Part B**)

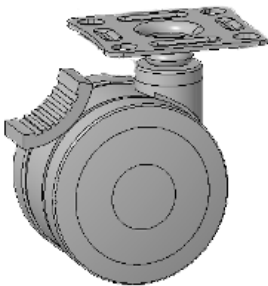
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- 1x Device plate (**Part C**)



- 4x Casters (**Part D**)



- 16x Caster screws (M6x16, Hex Flathead) (**Part E**)
- 16x Caster nuts (M6) (**Part F**)
- 4x Floor plate: vertical support screws (M5x25, Hex, Button Head) (**Part G**)
- 4x Floor plate: vertical support washers (M5 Flat Washer) (**Part H**)
- 2x O2 retainer (**Part J**)

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- 2x O2 retainer knob (**Part K**)



- 4x Device plate: vertical support screws (M5x16, Hex, Flat Head) (**Part L**)
- 2x Device plate: device screws (M4x22 mm, Hex, Button Head) (**Part M**)
- 2x Device plate: device washers (M4 Flat Washer) (**Part N**)

Assembly Instructions

1. Attach casters (**Part D**) to floor plate (**Part A**) with 4 screws (**Part E**) and nuts (**Part F**). Repeat for each caster. Lock each caster with its foot pedal for the remainder of the assembly steps.

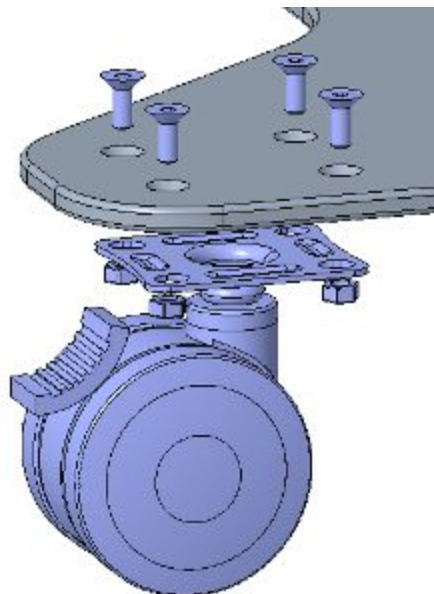


Figure 10: Attaching Casters to Floor Plate

2. Add 1 M5 washer (**Part H**) to each screw (**Part G**). Use the screws to attach the vertical support (**Part B**) to the floor plate (**Part A**). The M5 screws are secured using a 3mm hex wrench.

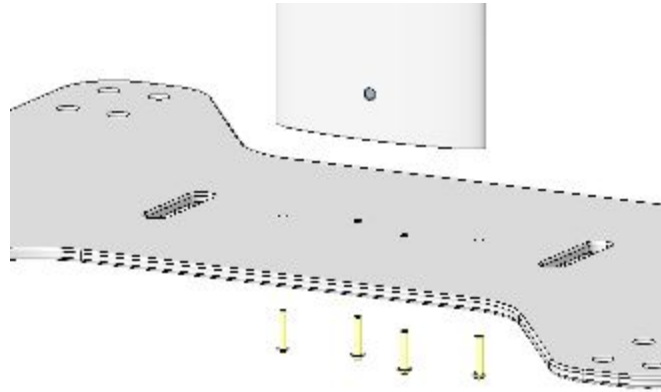


Figure 11: Attaching Vertical Support to Floor Plate

3. Slide the 2 O2 retainers (**Part J**) onto the vertical support. Insert 1 knob (**Part K**) through each retainer to lock it in place.

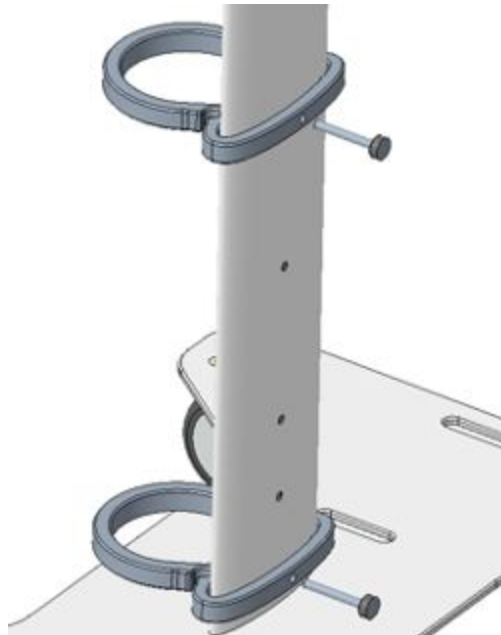


Figure 12: Attaching O2 Retainers to Vertical Support

4. Attach the device plate (**Part C**) to the vertical support with 4 screws (**Part L**).

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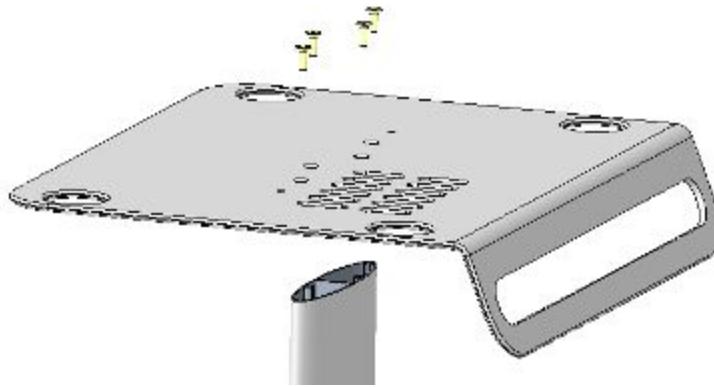


Figure 13: Attaching Device Plate to Vertical Support

5. Place the Fitbit Flow on the stand, inserting the Fitbit Flow's feet in the holes

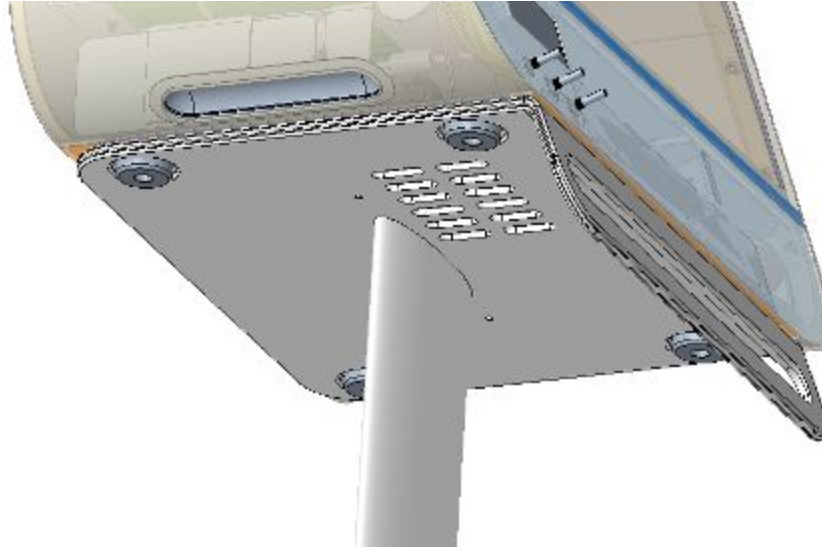


Figure 14: Positioning the Fitbit Flow on Device Plate

6. Add 1 washer (**Part N**) to each screw (**Part M**). Secure the Fitbit Flow with 2 screws from the underside of the device. The M4 screws are secured using a 2.5mm hex wrench.

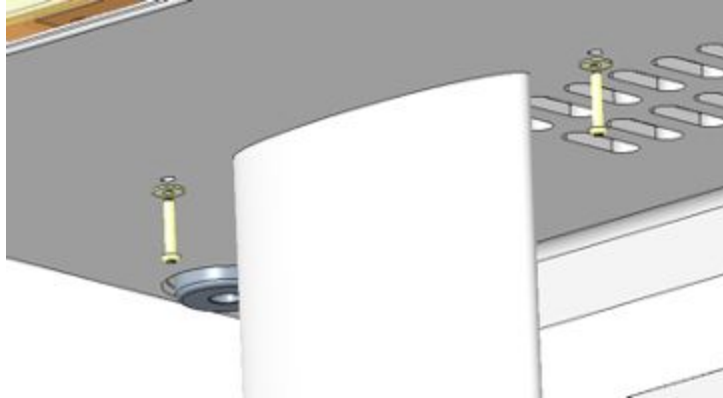


Figure 15: Attaching Fitbit Flow to Device Plate

Assemble the Fitbit Flow Air Pathway System

Components

- 1x Bag valve mask (BVM) with reservoir bag and oxygen input tubing, no safety valve, no PEEP valve, no mask (**Part A**)



- 1x Heat moisture exchange (HME) plus virus filter, 22 mm connector (**Part B**)



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- 2x virus filter, 22OD/22ID connector (**Part C**)



- 1x Patient Valve (or Non Rebreathing Valve (NRV))- with 60cm H₂O pop off valve and expiratory diverter for PEEP connection, 30 mm OD (**Part D**)



- 1x Tubing adapter for PEEP valve, 22mm ID x 30 mm OD (**Part E**)



- 1x Tubing adapter for patient valve, 30mm ID x 22 mm OD (**Part F**)



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- 1x Corrugated tubing, 60 inches (**Part G1**)
- 2x Corrugated tubing, 30 inches (**Part G2**)



- 1x pressure line adapter, 22mm OD x 22mm ID, fits 3/16" ID pressure sensing tubing (**Part H**)



- Flexible tubing for air way inspiratory pressure sensing, 3/16-inch ID, 60 inch long (**Part I**)



- 1x Water trap, 22M, adult, disposable (**Part J**)



- 1x Catheter mount adapter, 22Fx22M15F, disposable (**Part K**)



- 1x PEEP valve, 30 mm ID, manual adjustable 5-20cm H₂O (**Part L**)



Assemble the Patient Circuit

1. Connect the virus filters (**Part C**) to both the inspiratory and expiratory ports on the right-hand side of the Fitbit Flow housing.
2. Connect the 60-inch long corrugated tubing (**Part G1**) to the end of the virus filter on the inspiratory limb to the inspiratory port of the NRV patient valve (**Part D**).
3. Connect the 30-inch long corrugated tubing (**Part G2**) to the viral filter on the expiratory limb.
4. Connect the expiratory limb to the water trap (**Part J**).

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5. Connect a second 30-inch piece of corrugated tubing (**Part G2**) to the other port of the water trap (**Part J**).
6. Use the tubing adapter (**Part F**) to connect the corrugated tubing **G2** to the expiratory diverter port on the NRV patient valve (**Part D**).
7. Connect the patient port of the NRV patient valve (**Part D**) to the pressure line adapter (**Part H**).
8. Connect the ¼-inch tubing (**Part I**) to the pressure line adapter (**Part H**).
9. Connect the other end of the ¼-inch tubing (**Part I**) to the inspiratory pressure port on the Fitbit Flow.
10. Connect the pressure line adapter (**Part H**) to the HME (**Part B**).
11. Use a catheter mount adapter (**Part K**) to connect the HME to the patient intubation tube (not provided). This completes the patient airway circuit.
12. Use the tubing adapter (**Part E**) to connect the adjustable PEEP valve (**Part L**) to the PEEP valve port on the Fitbit Flow.

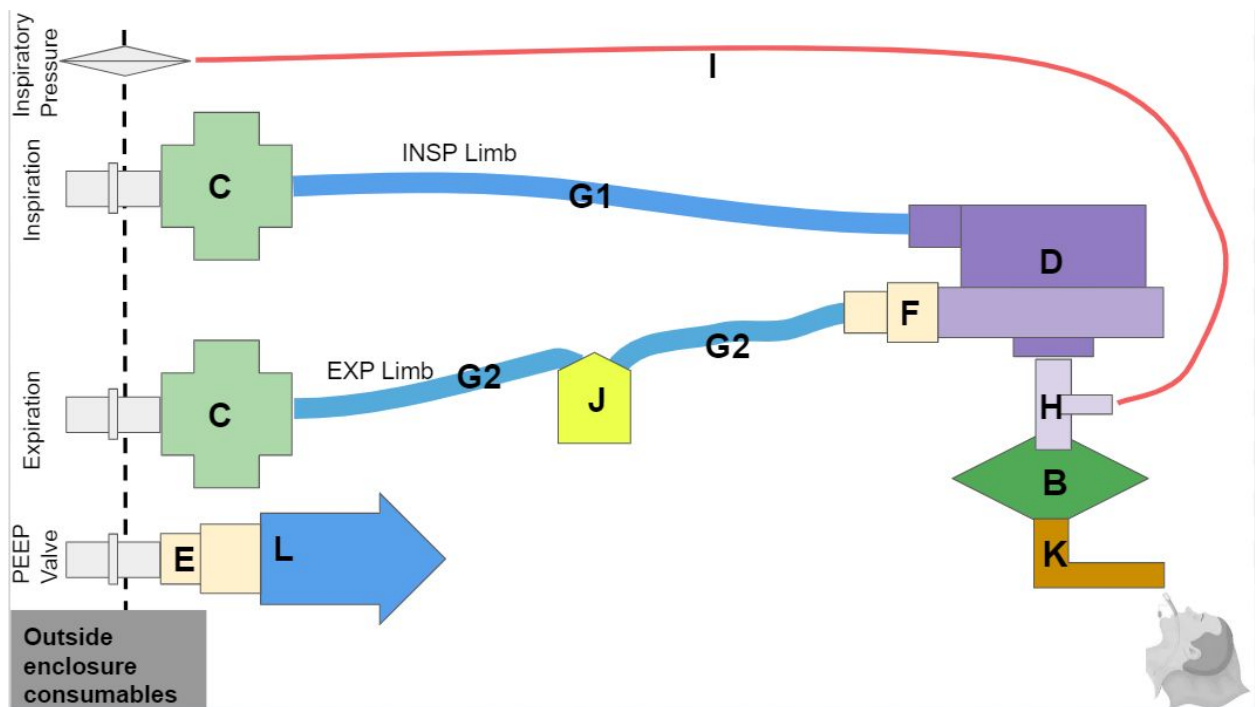


Figure 16: Patient Circuit Assembly

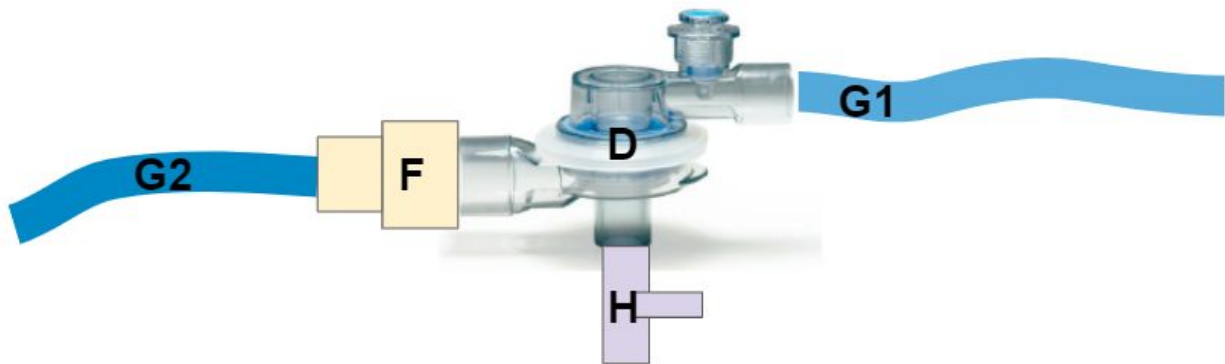


Figure 17: Patient Valve Assembly

Assemble the BVM Inside the Fitbit Flow

1. Open the Fitbit Flow lid.
2. Place the BVM (**Part A**) onto the “wave” support so that the integrated handle faces up, the ends fit snugly in the holders, and the reservoir bag and oxygen tubing sit freely inside the box.
3. Secure the BVM with the attached stretch straps. Test the BVM to ensure it is immobilized against the support plates.
4. Connect the inspiratory port of the BVM to the corrugated tubing on the right-hand side of the Fitbit Flow.
5. Place the oxygen tubing on the BVM through the slot on the left-hand side of the Fitbit Flow.
6. Close the Fitbit Flow lid.
7. The Fitbit Flow air pathway system should be checked routinely for leaks.

WARNING



The Fitbit Flow has not been characterized under leakage test conditions. If there is significant patient circuit leakage, the device may under-deliver tidal volume to the patient.

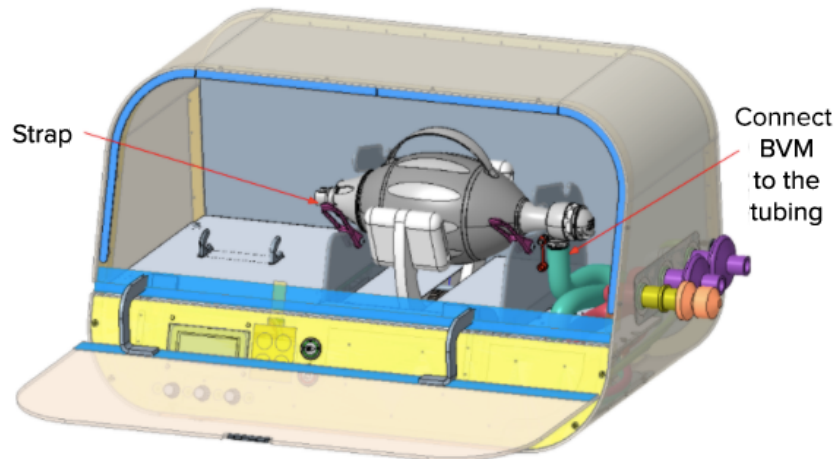


Figure 18: BVM Installation

Power the Fitbit Flow

WARNING



The Fitbit Flow does not have an internal backup battery and does not have the capability to sound an alarm when power is interrupted. Connect the Fitbit Flow to a UPS to provide backup power.

The Fitbit Flow is powered with an AC connection.

1. Connect the female end of the Fitbit Flow's AC power cable to the AC connector on the back of the Fitbit Flow.



Figure 19: AC Power Cable Connector

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

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Operating Procedures

WARNING



When moving the Fitbit Flow, disconnect it from the patient and turn off the device. Failure to do so could result in the Fitbit Flow unintentionally being turned off if it is unplugged during transport.

Turn On the Fitbit Flow

To turn on the Fitbit Flow, turn the ON | OFF switch to the **ON** position, as shown below.

ON | OFF

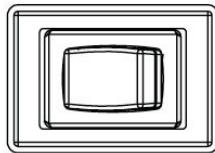



Figure 20: ON | OFF Switch (“ON” Position)

The LCD screen will display a welcome message and the current firmware version for 5 seconds when the Fitbit Flow turns on. To skip the welcome message, press any button.

Start Ventilation

To start ventilation, press and release the start/stop button . The button illuminates green on each inspiration, indicating the breathing rate.

Ventilation Modes

Ventilation modes are:



- Volume control mode (PCV)
- Pressure control mode (VCV)

Both modes have an optional Assist Control setting which provides support for patient-triggered breaths when enabled.

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Volume Control Mode

From the main menu on the LCD screen:


1. Press the up button  (if needed) to move the selector to **VCV**.
2. Press the confirm button  to choose the ventilation mode.

If the VCV mode is already active, you'll see the following critical settings and measurements:


- **VCV**: Indicates VCV mode is selected
- **AC**: Indicates that Assist Control is enabled. If it's not enabled, you'll only see the name of the mode in the top line
- **AC***: The asterisk indicates that Assist Control is enabled and was triggered on the previous breath
- **RR**: Displays the current respiratory rate
- **I:E**: Displays the current inspiratory:expiratory time ratio
- **VTi**: Displays the measured tidal volume of the previous breath
- **PIP**: Displays the measured peak inspiratory pressure of the previous breath
- **Pins**: Displays the measured mean airway pressure during the inspiratory cycle of the previous breath
- **PEEP**: Displays the measured end-expiratory pressure of the previous breath

```
+-----+
|VCV AC*      |
|RR      20   PIP  19 |
|I:E 1:2.5   Pins 14 |
|VTi   407   PEEP  9 |
+-----+
```



Figure 21: Example of VCV Active Screen

To change the parameters, press the confirm button .

If the mode is not yet active, or you pressed the confirm button from the active screen, you'll see the following adjustable parameters:

- **VCV Set**: Indicates which mode you selected
- **RR**: Displays the respiratory rate parameter. Use the RR knob  to adjust the RR from 8-30 in steps of 2.

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- **I:E**: Displays the inspiratory:expiratory ratio parameter. Use the I:E knob  to adjust the I:E from 1:1 to 1:4 in steps of 0.5.
- **VT**: Displays the tidal volume parameter. Use the Vt/P knob  to adjust the Vt target from 200mL to 700mL in steps of 50mL.



```

+-----+
| VCV Set      |
| RR      20  AC ON |
| I:E 1:2.5  More |
| VT      400 >Accept |
+-----+


```


Figure 22: Example of VCV Set Screen

To turn on Assist Control on or off:

1. Press the up button  to move the selector to **AC ON** or **AC OFF**.
2. Press the confirm button  to turn Assist Control on or off.

To accept and apply any new settings, use the up and down buttons (if needed) to

navigate to **Accept** and press the confirm button . If ventilation is not in progress, the Fitbit Flow will use the selected parameters when ventilation is turned on. If ventilation is already in progress, the selected parameters are applied on the next breath.

To return to the previous screen without applying any changed settings, press the back button .

Pressure Control Mode



WARNING



When operating in PCV (Pressure Control Mode) the Fitbit Flow may not achieve a constant pressure throughout the entire inspiratory period, which may reduce the delivered tidal volume.

From the main menu on the LCD screen:

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3. Press the down button  to move the selector next to **PCV**.
4. Press the Confirm button  to choose the ventilation mode.

If the mode is already active, you'll see the following critical settings and measurements:


- **PCV**: Indicates which mode you selected
- **AC**: Indicates that Assist Control is enabled. If it's not enabled, you'll only see the name of the mode in the top line
- **AC***: The asterisk indicates that Assist Control is enabled and was triggered on the previous breath
- **RR**: Displays the current respiratory rate
- **I:E**: Displays the current inspiratory:expiratory ratio
- **Vt**: Displays the measured tidal volume of the previous breath
- **PIP**: Displays the measured peak inspiratory pressure of the previous breath
- **Pplt**: Displays the measured plateau pressure of the previous breath
- **PEEP**: Displays the measured positive end-expiratory pressure of the previous breath

```




+-----+
| PCV AC*          |
| RR      20    PIP 19 |
| I:E 1:2.5    Pplt 14 |
| Vt     400    PEEP 9.2 |
+-----+

```

Figure 23: Example of PCV Mode Active Screen

To change the parameters, press the confirm button .

If PCV mode is not yet active, or you pressed the confirm button from the active screen, you'll see the following adjustable parameters:

- **PCV Set**: Indicates you selected PCV mode
- **RR**: Displays the respiratory rate parameter. Use the RR knob  to adjust the RR from 8-30 in steps of 2.
- **I:E**: Displays the inspiratory:expiratory ratio parameter. Use the I:E knob  to adjust the I:E from 1:1 to 1:4 in steps of 0.5.
- **PIP**: Displays the peak airway pressure during the inspiratory cycle of the previous breath. Use the Vt/P knob  to adjust the PIP target from 4 to 40 in steps of 2.



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You should always monitor the delivered tidal volume when operating in PCV mode.


```
+-----+
| PCV Set      |
| RR      20  AC ON |
| I:E 1:2.5  More |
| Pins    25 >Accept |
+-----+
```

Figure 24: Example of PCV Mode Set Screen

To turn on Assist Control on or off:

3. Press the up button  to move the selector to **AC ON** or **AC OFF**.
4. Press the confirm button  to turn Assist Control on or off.

To accept and apply any new settings, use the up and down buttons (if needed) to

navigate to **Accept** and press the confirm button . If ventilation is not in progress, the Fitbit Flow will use the selected parameters when ventilation is turned on. If ventilation is already in progress, the selected parameters are applied on the next breath.

To return to the previous screen without applying any changed settings, press the back

button .

Assist Control

WARNING



When Assist Control is enabled, it is important to monitor for breath stacking (also called breath dyssynchrony stacking), which can result in unintended high tidal volumes as a consequence of incomplete exhalation between consecutive cycles. Continuous CO₂ monitoring (also called capnography) and arterial blood gas sampling should be conducted to detect high CO₂ levels which may be a consequence of hypoventilation.

The Assist Control feature may be enabled in either Volume Control or Pressure Control mode. When Assist Control is enabled, a patient's spontaneous breath can trigger the delivery of a

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mechanical ventilator breath, outside of the cycle time determined by the respiratory rate. A spontaneous breath is detected when the airway pressure drops 2 cmH₂O below PEEP.

When Assist Control is enabled, the software performs additional safety checks to avoid the unintended delivery of high tidal volumes. These include:


1. Up to two consecutive assist breaths will be delivered. The third consecutive spontaneous breath will not result in an assist breath. After a normal, unassisted ventilator breath, assist breaths will resume.
2. Upper limits are set on volume and pressure, based on the set targets and alarm limits. If during an assist breath these limits are reached, the assist breath will be stopped, and the system will switch to expiration phase.

When Assist Control is enabled, if an assist breath is not delivered because of the above conditions, then an alarm will be activated.

When Assist Control is disabled, an alarm will trigger if spontaneous breaths are detected.

Inspiratory Hold

The inspiratory hold function pauses the Fitbit Flow at end-inspiration for one second. This maneuver can be used to measure the patient's plateau pressure (also called alveolar pressure). To perform an inspiratory hold:

1. Press and release the start/stop button . **HOLDING THE START/STOP BUTTON DOWN FOR 5 SECONDS WILL TURN OFF THE FITBIT FLOW.**
2. **IH** will appear at the top of the LCD screen, indicating an inspiratory hold is pending.
3. The inspiratory hold will occur on the subsequent breath cycle.
4. On the LCD screen, the **Pins** label will temporarily change to **Pplt** to indicate the inspiratory hold completed.


IMPORTANT: The inspiratory hold will be postponed if a spontaneous breath is detected or the volume or pressure limit alarms are triggered. The inspiratory hold will be attempted during the next mechanical breath.

WARNING



In some patients, especially those with abnormal lung compliance, an inspiratory hold of one second may not be long enough for the pressure to equilibrate in the lungs. In such cases, the reported plateau pressure will not be accurate.

Stop Ventilation

To stop ventilation, press and hold the start/stop button  for 5 seconds.

Turn off the Fitbit Flow

To turn off the Fitbit Flow, turn the ON | OFF switch to the **OFF** position, as shown below.

ON | OFF

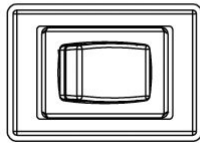










Figure 25: ON | OFF Switch (“OFF” Position)

The LCD screen turns off.

Adjust Settings and Alarm Parameters

To adjust the ventilator parameters, including PEEP and alarm limits:

1. Choose a ventilation mode (**PCV** or **VCV**).
2. If the ventilation mode is already active, press the confirm button  to show the Set screen.
3. Press the up button  to move the selector to **More**.
4. Press the confirm button . You'll see the PCV/VCV Set 2 screen.
5. Use the up button  and down button  to move the selector to the parameter you want to change.
6. Press the confirm button . You can now use the up button  and down button  to adjust the parameter.

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7. When the parameter is set to the number you want, press the confirm button .

8. Press the back button  to return to the previous screen.

Adjustable parameters include:

- **Pmax:** This parameter sets the maximum allowed airway pressure. If it's exceeded, the Pmax alarm is triggered and the inspiration cycle in progress is immediately terminated.
- **Pins:** This parameter sets the thresholds for the allowed inspiratory pressure (below Pmax). If it's exceeded in either direction, the Pins hi or Pins low alarm is triggered.
- **VTi:** This parameter sets the thresholds for the allowed inspiratory tidal volume. If it's exceeded in either direction, the VTi hi or VTi low alarm is triggered.
- **PEEP:** Set this parameter to match the setting of the unit's physical PEEP valve. If the measured PEEP falls too far below this threshold, the PEEP low alarm is triggered.

For more information on the default settings and thresholds, see [Alarm Conditions](#).

Cleaning and Maintenance

WARNING



Failure to follow the cleaning and maintenance instructions could result in equipment damage and potentially harm the patient.

Do not attempt to clean or re-use single use accessories.

The Fitbit Flow has been tested for 24 hours of continuous use. If using longer than 24 hours, check for signs of wear and tear, particularly on the manual resuscitator bag.

The Fitbit Flow has not been characterized under leakage test conditions. If there is significant patient circuit leakage, the device may under-deliver tidal volume to the patient.

Clinicians and care providers should inspect the manual resuscitator bag for signs of heavy wear every four hours, or approximately 2800 compressions. In the event of alarms, attending medical care providers should immediately inspect the integrity of the bag and breathing circuit to ensure no leaks or disconnections occurred. Please note that signs of wear on the resuscitator bag are expected due to the automatic compression. Signs of wear include markings or abrasions on the bag surface. Signs such as tearing of the bag or the bag not expanding to its full capacity indicate that the mechanical integrity of the bag may be degraded. If such wear is noticed on the bag it needs to be replaced immediately.

Cleaning the Fitbit Flow

Clean all external surfaces before and after each patient use, and as needed to keep the Fitbit Flow clean. To clean the surfaces:

1. Dampen a soft, clean cloth with a mild soap solution. Remove any excess liquid.
2. Wipe the external case of the Fitbit Flow with the damp cloth. Do not immerse the Fitbit Flow in liquid.
3. Dry the surface with a soft, clean cloth, removing all liquid.
4. Wipe the surface with a disinfectant solution per manufacturer instructions of disinfectant.

Cleaning the Manual Resuscitator Bag

Follow the accessory manufacturer's instructions for cleaning the manual resuscitator bag. The bag should not be reused between patients.

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Replace Accessories

The resuscitator bag and breathing circuit is designed to be used for a single patient and should be discarded and replaced after each use. If the breathing circuit is damaged, replace it. If necessary, the exterior surface of the tubes can be cleaned with a damp cloth, then dried with a soft, clean cloth.

WARNING



Do not reuse single-use components. Doing so increases the risk of cross-contaminations between patients.

Specifications

The Fitbit Flow provides continuous mechanical ventilation by automatically compressing a resuscitator bag. The Fitbit Flow can operate in Volume Control mode, Pressure Control mode, with or without the Assist Control setting. The ventilatory parameters are listed below.

Physical

Parameter	Value
Ventilation modes	Volume Controlled, Pressure Controlled
Patient connection	Connects to standard ventilator tubing
Pins	15-40 cmH ₂ O
PEEP	5 - 20 cmH ₂ O, set by a manual valve
RR	8 - 30 breaths per minute
VT	200 - 700 mL
I:E	1:1 - 1:4
PIP	15 - 60 cmH ₂ O
Assist Control pressure trigger (below PEEP)	-2 cmH ₂ O

Accuracy

Parameter	Max Error
Control	
V _{ti} Control	±(-1.20 + (4.60% of set Vt)) mL
P _{aw} control	±(0.66 + (1.58% of set pressure)) cmH ₂ O
Measurement	
PEEP	±(0.42 + (0.20% of meas. PEEP)) cmH ₂ O
PIP	±(0.73 + (1.69% of meas. PIP)) cmH ₂ O
V _{ti}	±(-2.98 + 4.82% of meas. Vti)) mL
V _{te}	±(3.74 + (1.51% of meas. Vte)) mL

Labeling Parameters

Parameter	ARDSnet Conformance	Comment
PC/VC	PC / VC	PC / VC with Assist Control
4-6 cc/kg TV	Weight <115 kg	*Calculated for 6cc/kg limit
FiO ₂ (.21-1.0)	No	*FiO ₂ is not measured by system. A table (see Appendix Table A.1) is provided as guidance for matching the source gas flow to minute ventilation, to maintain desired FiO ₂ . SpO ₂ monitoring is recommended.
I:E ratio (1:1-1:3)	Yes*	*Can do 1:4
RR (up to 35)	No*	RR max 30
PEEP (up to 24 cm H ₂ O)	No*	PEEP max 20 H ₂ O, set by manual PEEP valve
P _{plateau}	Yes	ARDSnet goal P _{plateau} ≤ 30 cmH ₂ O. An inspiratory hold of 1 seconds can be done to measure plateau pressure.
Validation and Performance Conformance		
Validated reservoir bags	AMBU Bag SPUR II Adult*	Met ISO 10651-4
Accuracy of Monitored parameters (as applicable)	Volumes ± 10%	V _{ti} : ±(-2.98 + 4.82% of meas. V _{ti}) mL V _{te} : ±(3.74 + (1.51% of meas. Vte)) mL
	Pressures (2 + 4 % of the actual reading) hPa (cmH ₂ O)	±(0.73 + (1.69% of meas. PIP)) cmH ₂ O
Accuracy Delivered (as applicable)	Volumes ± 20%	±(-1.20 + (4.60% of set Vt)) mL
	Pressures ± 10%	±(0.66 + (1.58% of set pressure)) cmH ₂ O

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Spontaneous Breathing detection	Yes	Device can detect spontaneous breathing (Assist Control) and has mechanisms to prevent breath stacking
Internal power source ventilation duration capacity	30 minutes	Back-up Battery checked at maximal device performance for 30 minutes. Battery is accessory with stand.
Contamination risk to environment	No*	*Need bacterial/viral filter (filtration efficiency 99.99%) at exhaust.
Durability	Yes	Tested for 24 hours with single AMBU bag , and performance was maintained throughout test, that the user-powered resuscitator was not damaged, that the breathing system remained connected and that the user-powered resuscitator remained in place.
Alarms		
Power-off Alarm	No	There is not a power-off alarm.
Disconnect Alarm (Low PIP alarm)	Yes (within two breaths)*	LED and audible alarm *within two breaths
External power supply failure Alarm	Yes*	External power supply will have its own set of alarms.
Back-up Battery	Yes*	External backup-battery (UPS) part of accessory with stand.
Low FiO ₂ alarm	No	No FiO ₂ alarm. Requires vigilance to ensure adequate oxygen flow rates to specify needed FiO ₂ . Standard patient monitoring (e.g. pulse oximetry) should be also used.
Maximum PIP alarm	Yes at 40cm H ₂ O	LED and audible alarm @40cm H ₂ O. Software configurable.
Occlusion alarm/Continuing Pressure	Yes	LED and audible alarm
TV not met/exceeded alarm	Yes	Flow sensors on inspiratory and expiratory paths used to compare inspiratory and expiratory volumes.
Implications for <i>additional</i> clinical monitoring	Standard ARDS clinical monitoring + continuous SpO ₂ *	*continuous SpO ₂ monitoring recommended as FiO ₂ is not monitored by the system.
Training		
Training required	Read the instructions for use before operating the Fitbit Flow.	

Acronyms: PC – Pressure Control, VC – Volume Control, FiO₂ – Fraction of Inspired Oxygen, I:E ratio – inspiration – expiration ratio, RR – respiratory rate, PEEP – positive end-expiratory pressure, P_{plateau} – Plateau Pressure, PIP – peak inspiratory pressure, T_v -tidal volume

Electrical

The Fitbit Flow uses a 138W medical-grade Class II power supply, which supports 100-240 VAC, 47-63 Hz. The power supply accepts a 2 prong, detachable power cord and is compliant

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with IEC 60601-1 with support for U.S. and international voltages. There is no internal battery. The Fitbit Flow must be used in conjunction with an external UPS to provide backup power.

In case of an emergency or power failure, the resuscitator bag may be manually operated by squeezing with two hands to provide ventilation, as per the intended use of the manual resuscitator.

Alarm Conditions

The Fitbit Flow has a set of visual and audible alarms to alert the operator when ventilator conditions exceed set limits. Default values are listed, but values should be changed based on recommendations from professionals caring for COVID-19 patients.

Condition	Default Settings	Limits
Ventilation Alarms		
High VTi	700mL	700mL
Low VTi	200mL	200mL
VTi , VTe difference	±20% of VTi	Fixed
High Pins	40 cmH ₂ O	60 cmH ₂ O
Low Pins	5 cmH ₂ O	0 cmH ₂ O
High PEEP	20 cmH ₂ O	30 cmH ₂ O
Low PEEP	5 cmH ₂ O	0 cmH ₂ O
Spontaneous breath when AC is disabled	Detection of spontaneous breath when AC is disabled, as detected in drop of airway pressure 2 cmH ₂ O below PEEP.	N/A
Assist breath alarm when AC is enabled	In AC mode, an Assist Breath alarm will be triggered if: <ol style="list-style-type: none"> 1. The two previous breaths were assist breaths. 2. The pressure has reached an alarm limit. 	N/A

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	3. The volume has reached an alarm limit.	
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Appendix

A.1 FiO₂ Flow and Minute Ventilation

The percentage of oxygen in the air delivered to the patient (FiO₂) is determined by the source oxygen content and flow rate, and the patient minute ventilation. The minute ventilation is the product of the respiratory rate (RR) in breaths per minute (bpm) and tidal volume (V_T) in milliliters (mL). In order to deliver a %FiO₂ which matches the source %O₂, the source gas flow rate should be greater than the patient's minute ventilation. Otherwise, room air will be pulled into the system and reduce FiO₂. Table A.1 shows the minute ventilation for different combinations of RR and V_T as guidance. For example,

- 1) If the source gas is 100% O₂, and the desired FiO₂ is also 100%, then for an RR of 12 bpm and a V_T of 500 mL, the flow rate should be greater than 6.0 liters per minute (lpm).
- 2) If the source gas is 60% O₂, and the desired FiO₂ is also 60%, then for an RR of 16 bpm and a V_T of 600 mL, the flow rate should be greater than 9.6 liters per minute (lpm).

WARNING



Clinical monitoring (e.g. SpO₂ with finger pulse oximetry and arterial blood gases) should be conducted to make sure the patient is achieving adequate oxygenation. The Fitbit Flow does not directly measure the %FiO₂ delivered to the patient, and one should not assume that the delivered %FiO₂ is equal to the %O₂ of the source.

Table A.1: Minute ventilation in liters per minute (lpm) based on respiration rate (RR) and tidal volume (V_T).

RR (bpm)	V _T (mL)					
	200	300	400	500	600	700
8	1.6	2.4	3.2	4.0	4.8	5.6
10	2.0	3.0	4.0	5.0	6.0	7.0
12	2.4	3.6	4.8	6.0	7.2	8.4
14	2.8	4.2	5.6	7.0	8.4	9.8
16	3.2	4.8	6.4	8.0	9.6	11.2
18	3.6	5.4	7.2	9.0	10.8	12.6
20	4.0	6.0	8.0	10.0	12.0	14.0

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Standards Compliance

The Fitbit Flow was designed and constructed to be in compliance of the following standards. However, external review of compliance with these standards has not been performed.

General Standard

- IEC 60601-1: 2012: *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-8:2006: *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*
- ISO 80601-2-12 Second Edition 2020-02: *Medical Electrical Equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*
- ISO 80601-2-80 First Edition 2018-07: *Medical Electrical Equipment - Part 2-80: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency*

Particular Standards

The manual resuscitator bag that has been tested with the Fitbit Flow is the Ambu Spur II. This is an FDA cleared device. The Ambu Spur II claims conformance to the following standards:


- ISO 10651-4: *Lung ventilators – Part 4: Particular requirements for operator powered resuscitators*
- ISO 5356-1: *Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets*

User Assistance Information

This manual is for SKU: FB605WTWT.

Technical Support

For assistance or support, email support_flow@fitbit.com or call 1-800-676-1401 (Mon-Fri: 5am-5pm PT, Sat-Sun: 8am-5pm PT) .

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