CHANGE SUMMARY

Rev #	Date	Description	CO#
00	21-Apr-2020	EUA requirements	CO-2020-348
01	28-Apr-2020	Liberate Medical Electrodes	CO-2020-382

Liberate MEDICAL

VentFree™

Respiratory Muscle Stimulator

User Manual

VentFree has not been FDA cleared or approved.

VentFree has been authorized by FDA under an Emergency Use Authorization (EUA).

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

DOCUMENT: MAN-006-01
Effective: 28-Apr-2020
CONTROL NUMBER: CO-2020-382

1 Product Description

Figure 1: VentFree

VentFree is an electrotherapy device that monitors the patient's breathing activity using an airflow sensor, and during the expiratory phase of breathing, applies transcutaneous neuromuscular electrical stimulation (NMES) to the abdominal wall muscles over two stimulation channels.

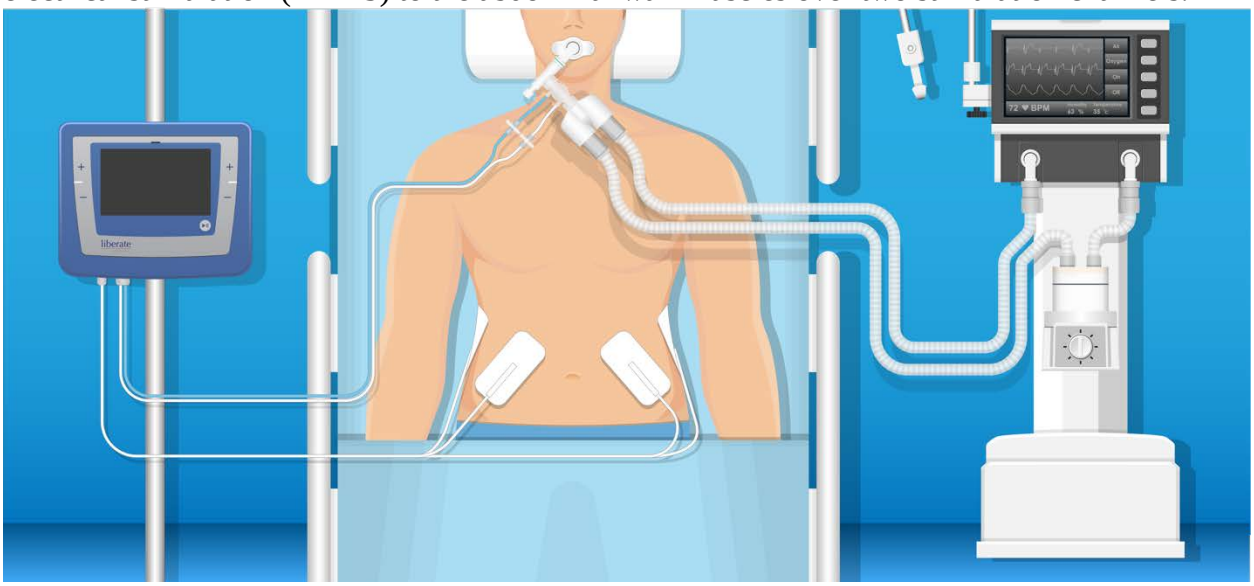

Figure 2 Illustration of the VentFree muscle stimulator setup

1.1 Principles of Operation

NMES elicits muscle contractions through the delivery of small electrical pulses to the motor nerve endings that supply a muscle. When NMES is applied to the abdominal wall muscles in synchrony

with exhalation, the effect on ventilation is similar to a physiological contraction of the abdominal wall muscles. An important advantage of using NMES in critically ill respiratory patients is that it can be used to recruit the abdominal wall muscles in the absence of patients' voluntary or automatic recruitment of those muscles.

1.2 VentFree Features

- Does not depend on patient participation.
- Non-invasive NMES.
- Stimulator protected against defibrillation potentials.
- Audible and visual notifications when the electrodes are not connected or if the flow sensor is not functional.
- Simple user interface for navigating menus and manipulating settings.
- Real time graphical display of patient's respiration.
- Two independent digital intensity controls.
- Timed therapy sessions with customizable length.
- Manual control of stimulation.
- Touch Screen operation of non-critical functions.
- Illuminated backlight display.
- Easy to clean surface.
- End of treatment review that displays the session length, starting intensity, average intensity, and disposables information.
- Displayed battery charge level.
- Powered from rechargeable smart battery source that indicates if the remaining charge will suffice for at least one treatment.
- Consumables tagged to ensure they are not used for more than the prescribed number of times or used past their expiration date.
- High Impedance monitor
- Charged balance stimulation
- Current Control stimulation
- Maximum Conformance voltage monitoring
- Battery status indicator
- Battery health monitoring
- Easy to Pause Treatment button

1.3 VentFree Indications for Use

The VentFree muscle stimulator applies transcutaneous neuromuscular electrical stimulation to the abdominal wall muscles during the expiratory phase of breathing in conjunction with a mechanical ventilator.

The VentFree muscle stimulator is for treatment of patients on mechanical ventilation adults who require mechanical ventilation, including patients with COVID-19, over the duration of the emergency use authorization. The VentFree muscle stimulator may prevent or retard disuse atrophy of the abdominal wall muscles and reduce the number of days of ventilator support in adults who require mechanical ventilation.

The VentFree muscle stimulator is intended to be used by healthcare professions in a healthcare facility. It is recommended to be used for two 30 minute sessions per day (one in the morning and one in the afternoon / evening), five days per week, for six weeks or until successful weaning, whichever occurs sooner.

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

1.4 ⚠ VentFree Contraindications

VentFree should NOT be used for the following situations or patients with:

- Do not use with demand type implanted pacemaker or defibrillator.
- Do not use electrical stimulation over pregnant uterus.
- Do not use on a patient with recent abdominal surgery with open abdominal wounds.
- Do not use on open or damaged skin.
- Do not use on patients under 18 years of age.

1.5 ⚠ VentFree Warnings

Regional Use – ALWAYS use the AC/DC converter with the corresponding regional AC Inlet plug **.**
Use Setting- This device should only be used in a hospital ICU setting.
Cleaning - Clean device with disinfectant wipe between uses (after use-before storage and before use). Only use approved chemicals for cleaning/disinfection (refer to Section 6).
Patient Supervision - Clinicians should regularly monitor patient for adequate stimulation level throughout the treatment.
Multiple Patient Use - If the device is used on more than one patient, the operator should follow facility infection control procedures.
Prescription and Use – This device should only be prescribed and operated by a clinician that is familiar with the precautionary measures and operational functions associated with the unit.
Electrode Placement- Electrodes should only be placed on the abdomen in compliance with the directions for use (refer to Section 2)
Cutting Electrodes - Electrodes should not be cut other than as indicated by the dotted lines in the back of the electrodes.
Reposition of Electrodes- Electrodes should not be repositioned during treatment sessions.
Throat Stimulation – Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are placed across the throat or mouth. This may be strong enough to close off the airway or cause breathing difficulty.
Transthoracic Stimulation – Do not apply electrical stimulation transthoracically (through the chest area) in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
Other Electrode Placement - Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck(especially the carotid sinus), or placed on the chest, upper back or crossing over the heart.
Electrical Shock – To prevent electrical shock, disconnect the unit from the power source and remove the battery before attempting any maintenance procedures.
Accessories – Use only accessories that are specifically designed for this device. Do not use this device with accessories manufactured by companies other than Liberate Medical. Liberate Medical, LLC is not responsible for any consequence resulting from using products manufactured by other companies. The use of accessories, transducers, or cables other than those specified by the manufacturer, may result in increased emissions or decreased immunity of the VentFree muscle stimulator.

Defibrillation Signals – In certain circumstances, there can be risk of burns under the electrode sites during the defibrillation.
Safety – The safety and efficacy of the VentFree system depends on the proper use and handling of the device and accessories. If used improperly, VentFree has a potentially hazardous electrical output. It must be used only as prescribed.
Electrode Safety- Electrode burns may result from misuse. Electrodes should be securely adhered to the patient to prevent disconnection. Check accessories regularly as they may show signs of wear over time and replace if needed.
Electrode Uses- Electrodes should not be shared between patients but may be reused on the same patient.
Flow Sensor – The Flow Sensor should not be shared between patients but may be reused on the same patient.
Mechanical Ventilation- VentFree should not be used as a replacement for a mechanical ventilator.
Intended Use – VentFree should not be used as a replacement of any medical treatment not specified in VentFree's Intended Use.
Mechanical Damage (Casing/LCD) – Do not disconnect VentFree from power if casing or LCD display becomes compromised.
Mechanical Damage (Electrode leads) – Do not touch device electronics or electrode leads if casing or insulation becomes compromised.
Mechanical Damage (AC/DC converter) – Do not use VentFree if external AC/DC converter enclosure is damaged.
Battery Safety – Care should be taken if signs of hazardous gaseous or liquid chemicals are leaking from the battery.
Environment – Do not use device outside of specified environmental conditions.
Repair – Only authorized personnel can open / repair the device.
Modifications – Modifications to the VentFree device or its AC/DC converter are prohibited.
Skin Infection – Care should be taken when using electrodes on patients with skin infections and the clinician should determine when to change the electrodes.
Network / Data Couplings – USB / DATA Ports in the connector panel of VentFree are for Factory Use ONLY or as authorized by Liberate Medical, LLC. Any other use is strictly prohibited.
Proximity to other Equipment – Use of this equipment adjacent to or stacked with other equipment such as RFID equipment , Diathermy, Electrocautery and Electrosurgical Equipment or others should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Surgery – Discontinue the use of VentFree if high-frequency surgical equipment are to be used during a stimulation session.
Diathermy treatment - Discontinue the use of VentFree if Diathermy treatment is to be conducted during a stimulation session.
Electrocautery treatment - Discontinue the use of VentFree if Electrocautery treatment is to be conducted during a stimulation session.

Neurally Adjusted Ventilatory Assist (NAVA) Ventilation - Do not use device if in conjunction with NAVA ventilation mode

1.6 VentFree Dangers

Dangerous voltage – Stimulus delivered by VentFree, in certain configurations, may deliver a voltage of up to 100 Volts per pulse.

Biohazardous materials – Handle, clean and dispose of components and accessories that have encountered bodily fluids according to National, Local and Facility rules, regulations and procedures.

Stimulus delivered by the VentFree waveforms of this device, in certain configurations, will deliver a charge of 25 micro coulombs (µC) or greater per pulse and may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.

Handle, clean and dispose of components and accessories that have come in contact with bodily fluids according to National, Local and Facility rules, regulations and procedures.

1.7 Cautions

Uncomfortable Stimulation – If the stimulation levels are uncomfortable for the patient, reduce the intensity level. Contact the prescribing physician if the problem persists.
Gastric Residual – Closely monitor any patient with suspected gastric residual.
Skin Reactions – On rare occasions, therapy can result in transient skin reactions such as rash, inflammation, irritation, or burns. These skin reactions may be the result of individual sensitivity to the condition of the skin at the onset of treatment, reaction to the materials in the electrodes, or a poor connection between the electrodes and the patient's skin. If a visible skin reaction does occur, discontinue the treatment and consult the prescribing physician.
Skin & Vascular Problems – Do not use this device over swollen, inflamed or infected areas, or skin eruptions.

MRI Scans – Do not allow patient to wear electrodes during Magnetic Resonance Imaging (MRI) scans as this may result in the metal overheating causing skin burns around the patch.
Feeding Tube – Do not use device if patient is being fed through a feeding tube.
Tripping – Care should be used to avoid tripping on lead wires.
High Frequency Surgical Devices – Simultaneous connection of a patient to a high frequency surgical device may result in burns at the site of the electrodes and possible damage to the device.

Damage from Liquids – Do not immerse the device in water or other liquids. Water or liquids could cause malfunction of internal components of the system, causing a risk of injury to the patient.
Proper Electrode Size – Output current density is related to electrode size. Improper application may result in patient injury. If any question arises as to the proper electrode size, consult a licensed practitioner prior to therapy session.
Sedated Patients – Clinician's discretion should be used when setting stimulation levels on sedated patients or on skin areas with reduced sensation.
Colostomy – Patients with a colostomy should be closely monitored while using VentFree.
Heart Problems – Use caution for patients with suspected or diagnosed heart problems.
Epilepsy – Use caution for patients with suspected or diagnosed epilepsy when using this device.
Hemorrhages – Use caution when there is a tendency to hemorrhage such as following acute trauma or fracture.
Post-Surgical Use – Use caution following recent abdominal surgical procedures when muscle contraction may disrupt the healing process.
Sensory Loss – Use caution where sensory nerve damage is present, causing a loss of normal skin sensation.
Unequal Electrode Size – Use caution and follow clinician instructions when using different size electrodes together. Improper use can cause skin irritation or increased stimulation intensity under the smaller electrode.
Keep Out of Reach of Children – Keep this device out of the reach of children.
Leads and Electrodes – Use the device with only the leads and electrodes provided for use by the manufacturer. The safety of other products has not been established and their use could result in injury to the patient. Use only the electrode placements and stimulation settings prescribed by your practitioner.
Monitoring Equipment – Electronic monitoring equipment (such as ECG and ECG alarms) may not operate properly when electrical stimulation is in use.
Flammable – Do not use the device in an environment where flammable or explosive fumes may exist.
External Use – This device is for external use only.
Sharp Objects – Do not use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel or the touch screen.
Cables and Connectors – Inspect cables and connectors before each use.
Drugs – Treatment outcome may be influenced by the patient's use of certain drugs.
Negative Reaction to Stimulation – Patients who react negatively to the stimulation sensation after an adequate trial period or who find stimulation intolerable should not undergo further treatment.
Operation Conditions – This unit should be operated in temperatures between 41 °F and 95 °F (5 °C and 35 °C), atmospheric pressure between 70 kPa to 106 kPa (10.2 psia to 15.4 psia) and relative humidity between 10% and 95%.
Transportation & Storage Conditions – This unit should be transported and stored in temperatures between 41 °F and 95 °F (5°C and 35°C) and relative humidity between 10% and 95%.

Heat and Cold Products – The use of heat or cold producing devices such as electric heating blankets, heating pads or ice packs may impair performance of the electrode or alter the patient's circulation/sensitivity and increase the risk of injury to the patient.
Body Mass Index (BMI)- VentFree may not be effective on patients with a BMI over 35.
External AC/DC Converter – Use only the VentFree external AC/DC converter approved by Liberate Medical, LLC.
Gastric and Bladder Pacemaker- Use precaution when using VentFree on patients with a gastric or bladder pacemaker.
PPE – Operators should follow facility's IC procedures on PPE when handling patients.
EKG - Precaution shall be used when using VentFree on patients with an EKG machine.
Shaving – Medical staff should use care when shaving patients.
Device Transport – The VentFree device is installed with a lithium ion battery. Lithium Ion batteries cannot be shipped by Air.
EMC Information - Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

1.8 Electrode Cautions

- DO NOT place electrodes on broken skin. If skin irritation develops, discontinue use and consult prescribing physician
- Replace electrodes when they do not adhere or become uncomfortable.
- For single patient use only. However, the electrodes may be repositioned several times on the same patient.
- Stimulation should not be applied transcerebrally or over the anterior neck region.
- Electrodes should ONLY be placed as described in the directions for use.
- Keep electrodes separated during treatment.
- DO NOT remove electrode by pulling on the lead wire.
- DO NOT modify electrodes other than as indicated in the instructions for use.. Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns.
- DO NOT remove more than one electrode at a time.
- There should be no stimulation present during disconnection.
- DO NOT touch adhesive when handling electrodes.
- Electrode leads should be disinfected in between uses and prior to storage.
- Replace electrode leads if they are not fully intact.
- Replace electrodes if the gel appears dry.

1.9 Flow Sensor Cautions

- Each Flow Sensor is for single patient use only.
- Flow Sensors should be high-level disinfected prior to each use.

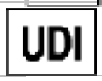
- If the Flow Sensor becomes dirty, it can be washed with soap and water and then properly disinfected unless the facility's IC procedures indicate that the disposable be discarded.
- Do not alter the Flow Sensor tubing.
- Follow Instructions for use provided with the Flow Sensor.

1.10 ⚠ Stimulator Adverse Effects

- Skin irritation, muscle soreness and increase work of breathing, electric shock, and burns beneath the electrodes are potential adverse reactions.

1.11 Glossary of Symbols

Symbol	Description
CE 0459	Indicates European Community technical conformity and the Notified Body number
EC REP	Indicates the medical device Authorized Representative in the European Community.
	Refer to Instructions or User's Manual to signify that instructions for use must be read.
	**Dangerous voltage –** Stimulus delivered by VentFree, in certain configurations, may deliver a voltage of up to 100 Volts per pulse.
	Indicates the need for the user to consult the User's Manual for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on VentFree itself.
	**Biohazardous materials –** Handle, clean and dispose of components and accessories that have encountered bodily fluids according to National, Local and Facility rules, regulations and procedures.
	Recycle: Electronic Equipment. Do not throw in trash.
	Keep Dry. Indicates that VentFree needs to be protected from moisture.
	Indicates the range of humidity that VentFree can be safely exposed to.
	Indicates the range of temperature that VentFree can be safely exposed to.
	Indicates the range of atmospheric pressure that VentFree can be safely exposed to.
	Fragile, handle with care. Indicates that VentFree can be broken or damaged if not handled carefully.
	This side up. Indicates the side of the packaging that shall be face upward to prevent damage to the equipment.
	Indicates that VentFree or its accessories should not be used if the package is damaged.
Rx Only	VentFree requires a prescription to be used.

	Indicates VentFree Manufacturer.
	Indicates manufacturing date.
	Indicates UDI (Unique Device Identifier).
	Indicates manufacturing serial number.
	Indicates the catalog number for VentFree and its accessories.
	Indicates the identification number of manufacturing batch or lot.
	Indicates the expiration or use by date of the accessories.
	Indicates that VentFree or its accessories have not been subject to a sterilization process.
IP22	Indicates the degree of protection provided by the enclosure. VentFree is protected against solid foreign objects of 12.5mm or greater (similar to fingers) and against the effects of vertically dripping water when the enclosure is tilted at an angle of 15° from its normal position. A total of four positions are tested within two axes.
	Indicates that the electrodes and leads are Defibrillation Proof type BF applied parts.
	Keep away from magnetic resonance imaging (MRI) equipment.

2 VentFree Directions for Use

2.1 Getting Started

Figure 3 shows:

- VentFree device
- External AC/DC converter
- Stimulation electrodes
- Flow Sensor

Figure 3: VentFree Components

2.2 External Power

VentFree can be battery operated or connected to an external source of power (as shown in Figure 3). When connected to the external AC/DC converter, the battery will also be charged.

Do not use VentFree if external AC/DC converter enclosure is damaged.

ONLY use an AC/DC converter with VentFree that is approved by Liberate Medical, LLC.

Ensure that the location of VentFree when connected to the AC/DC converter prevents tripping with the AC/DC converter cable and accidental disconnections of the AC/DC converter from the Mains or from VentFree.

Ensure that the location of the Mains outlet where the AC/DC converter will be connected to allow the converter to be readily available at all times while connected to VentFree.

ALWAYS use the AC/DC converter with the corresponding regional AC Inlet plug.

2.3 Electrode Setup

1. The unit must be turned off and electrodes disconnected from VentFree before and after each treatment or as directed by prescribing physician.

2. Clean electrode application area with soap and water or as directed by prescribing physician. Rinse and dry. Electrodes should only be applied to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas). It is recommended that patients with excessive body hair be shaved prior to applying electrodes.
3. Remove electrode from liner by grasping the edge of the electrode and peeling it off the liner. Retain liner for storage.
4. The stimulation electrodes should be positioned over the posterolateral side of the abdominal wall, so that the transverse abdominal, internal oblique, and external oblique muscles will be stimulated. The placement of the stimulation electrodes is illustrated in Figure 4. This configuration has been demonstrated to be the most effective method of generating abdominal muscle contraction compared with alternative configurations.

   There are two channels of stimulation with each channel comprising of two electrodes. The blue electrodes should be placed on the proper right side of the abdomen and the gray electrodes should be placed on the proper left side of the abdomen. Each channel of stimulation includes an anterior (“2” and “3” in Figure 4) and a lateral electrode (“1” and “4” in Figure 4). The anterior electrodes should be on the anterior superior iliac spine and angled obliquely along the costal margin and toward the xiphoid process. The lateral electrodes should be placed on the intersection between the posterior midaxillary line and the iliac crest and angled toward the midaxillary line. The electrodes should bilaterally symmetrical. Small adaptations of the electrode configuration can be made based on individual anatomical differences.

⚠ CAUTION: Electrodes are single patient use ONLY

⚠ CAUTION: Electrodes MUST NOT be placed over broken skin

5. Attach lead wire to unit and begin treatment.
6. Following treatment, turn the unit off.
7. Remove electrode from skin by peeling electrode edge.
8. Return electrode to liner.
9. Disinfect the top of the electrode pads with disinfectant wipe.
10. Place the liner with electrode in the storage bag.

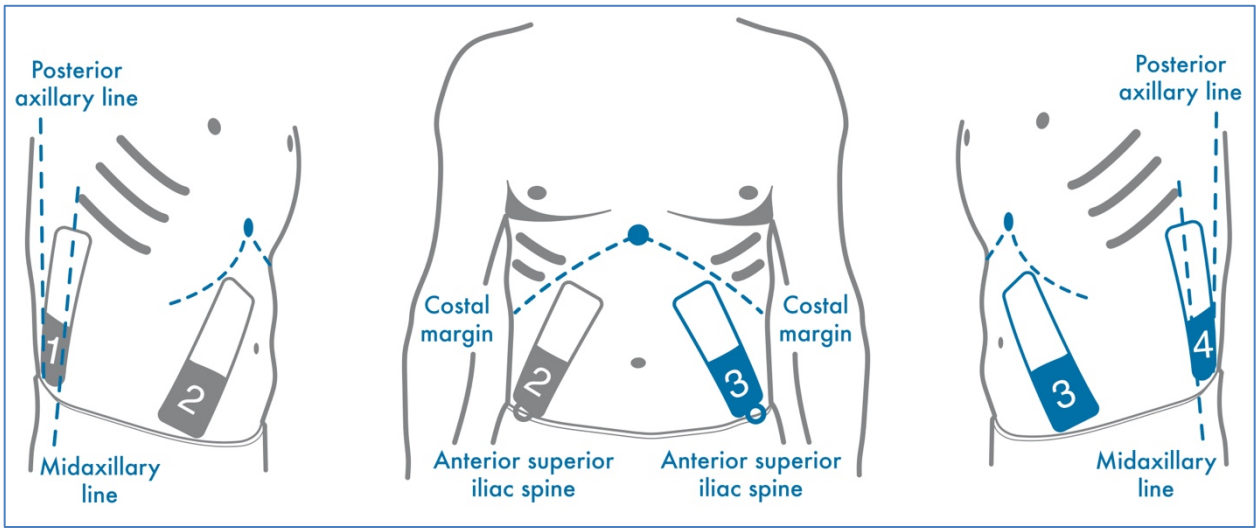


Figure 4. Optimal Electrode Placement

2.4 Electrode Cautions

DO NOT place electrodes on broken skin. If skin irritation develops, discontinue use. Consult prescribing physician. Replace electrodes when they do not adhere or treatment becomes uncomfortable.

For single patient use only. However, the electrodes may be repositioned several times on the same patient.

Keep electrodes separated during treatment.

DO NOT remove electrode by pulling on the lead wire.

Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns.

DO NOT cut electrodes other than as indicated by the dotted lines in the back of the electrodes.

2.5 Electrode Warnings

Stimulation should not be applied transcerebrally or over the anterior neck region.

Severe spasm of the laryngeal and pharyngeal muscles may occur when the electrodes are placed across the throat or mouth. This may be strong enough to close off the airway or cause breathing difficulty.

Do not apply electrical stimulation transthoracically (through the chest area) as the introduction of electrical current into the heart may cause cardiac arrhythmias.

Other Electrode Placement - Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or placed on the chest and the upper back or crossing over the heart.

2.6 Re-Application and Storage of Electrodes

- If the electrode gel appears dry, replace it with a non-expired set.
- If electrode accumulates dirt/dust in the adhesive, the impedance increases, usually leading to increased dissipation at the electrode which can lead to skin burns. Inspect the electrode for dust and dirt accumulation before reuse. Feel the electrode to ensure that it is still tacky. If the electrode accumulates too much dirt/dust, it will no longer adhere. Replace electrode when it does not adhere.
- Between uses, return electrode to liner and store in resealable bag in a cool place out of direct sunlight.

Note: The life of the electrode varies depending on skin conditions, skin preparation, type of stimulation, storage, and climate.

ELECTRODES MUST NOT BE USED IN MULTIPLE PATIENTS. ELECTRODES ARE DESIGNED TO BE MULTI-USE, SINGLE PATIENT ONLY.

2.7 User Interface

The user interface of VentFree utilizes a 6-button interface on the device. The available functions include a "PLAY/PAUSE" button with "+" (increment Parameter) and "-" (decrement Parameter) buttons on either side of the LCD screen as well as a MAIN MENU button. In addition to the six user buttons there is a Stimulation LED Indicator light at the top of the screen.

2.8 Connections

The bottom side of VentFree contains several connection ports along with the power switch as shown in Figure 4. The Flow Sensor Port has a custom connection to the Flow Sensor tubing. The electrode port connects to the lead cable from the electrodes.

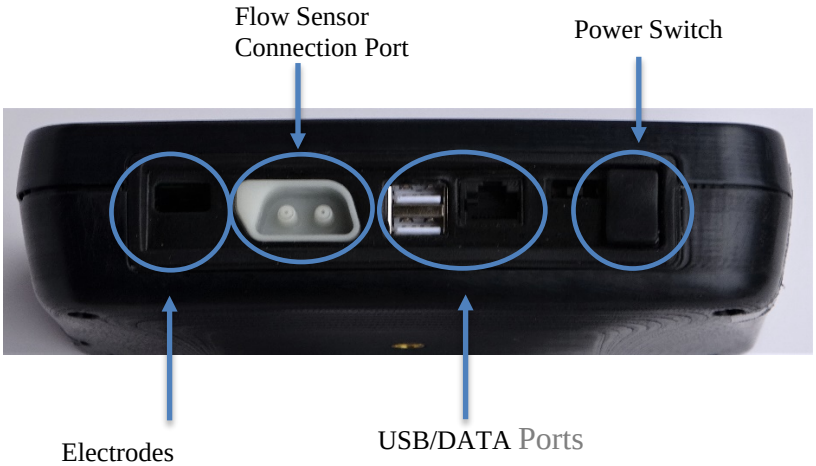


Figure 5: VentFree connection ports

⚠ USB/DATA PORTS are for Factory ONLY or as authorized by Liberate Medical, LLC. Any other use is strictly prohibited.

2.9 Connecting the System

1. The device should be disinfected before use.
   Before setting up VentFree, verify that the power switch is in the “off” position (refer to Figure 5).

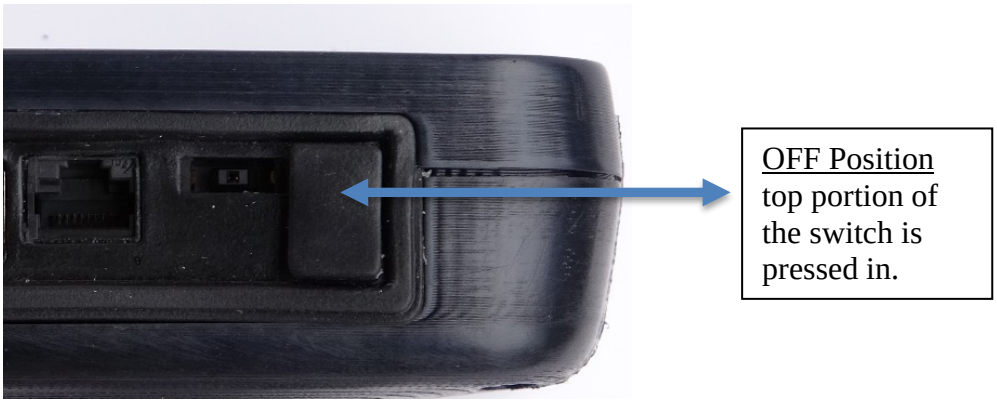


Figure 6: Power Switch OFF Position

2. Connect the Flow Sensor to VentFree to measure airflow direction (Figure 6).

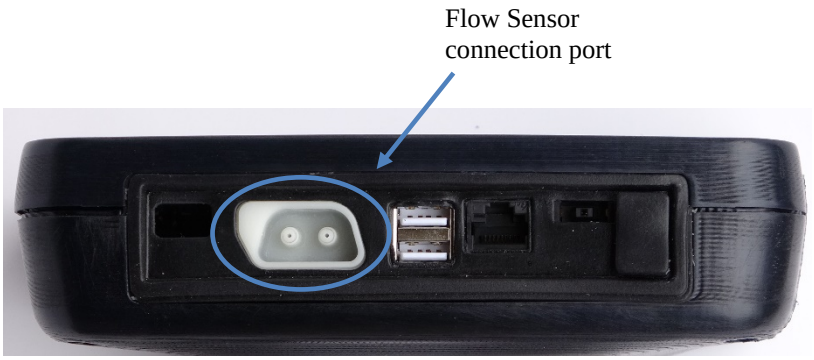


Figure 7: Flow Sensor Port

3. Insert the Flow Sensor between the patient's endotracheal tube and Wye joint, making sure that the blue tube on the flow sensor is proximal to the patient. The patient setup is shown below in Figure 7. If the sensor was installed from a prior treatment, remove and discard the caps. Reconnect the Flow Sensor assembly tubing to the Flow Sensor closer to the patient.

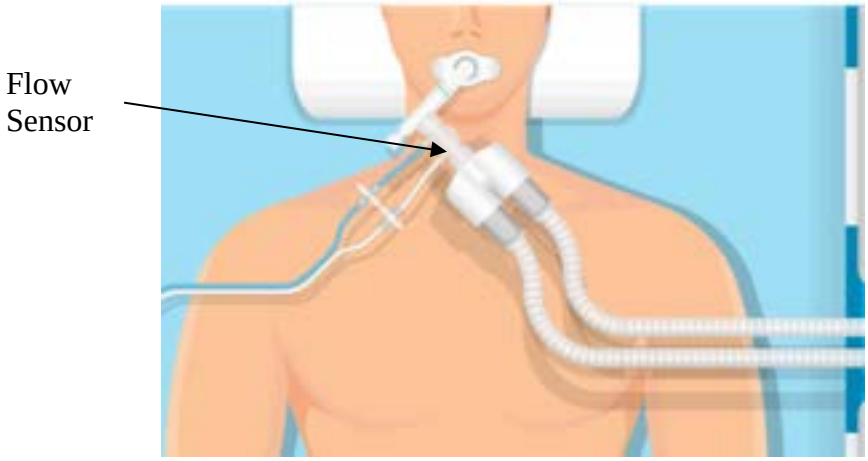


Figure 8: Flow Sensor Setup

4. The stimulation electrodes should be positioned over the posterolateral side of the abdominal wall, so that the transverse abdominal, internal oblique, and external oblique muscles will be stimulated. The placement of the stimulation electrodes is illustrated in Figure 8. This configuration has been demonstrated to be the most effective method of generating abdominal muscle contraction compared with alternative configurations.

   There are two channels of stimulation with each channel comprising of two electrodes. The blue electrodes should be placed on the proper right side of the abdomen and the gray electrodes should be placed on the proper left side of the abdomen. Each channel of stimulation includes an anterior (“2” and “3” in Figure 9) and a lateral electrode (“1” and “4” in Figure 9). The anterior electrodes should be on the anterior superior iliac spine and angled obliquely along the costal margin and toward the xiphoid process. The lateral electrodes should be placed on the intersection between the posterior midaxillary line and the iliac crest and angled toward the midaxillary line. The electrodes should bilaterally symmetrical. Small adaptations of the electrode configuration can be made based on individual anatomical differences.

   Refer to Section 2.3 for additional details on electrode setup.

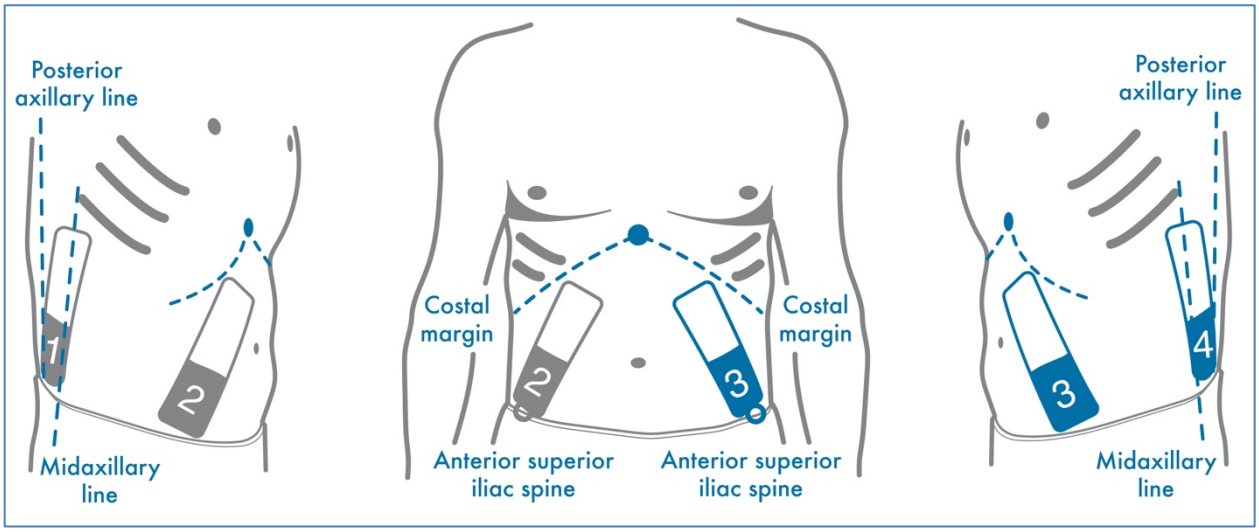


Figure 9: Electrode Placement

⚠ CAUTION: Electrodes are single patient use ONLY

⚠ CAUTION: Electrodes MUST NOT be placed over broken skin

5. Plug the electrode cable header into VentFree as shown in Figure 9.

Figure 10: Electrodes Connection Port

NOTE: The Flow Sensor is equipped with a radio-frequency identification (RFID) tag that logs expiration dates and number of uses.

NOTE: The electrodes are equipped with electrically erasable programmable read-only memory (EEPROM) to track expiration dates, number of uses (max of 5 treatment days), the part name, type identifier, lot identifier of the electrodes and Liberate Medical, LLC contact information.

3 Setting up the System

1. If not done before, using the mounting fixture on the back panel, mount VentFree on a dedicated pole as shown in Figure 10. Consult with Liberate Medical, LLC regarding alternative mounting options.

Figure 11: VentFree Mounting

WARNING: to prevent the accidental ingress of fluids, ALWAYS use VentFree in a vertical position as shown above.

2. Following device mounting and accessory connections, power up VentFree by pressing the bottom portion of the power switch (Figure 11).

Figure 12 Power Switch ON Position

3. Following power up, the device will display a screen for the User to verify he/she has read the warnings, cautions and contraindications of VentFree before use. Upon completion, press CONTINUE.

Figure 13 User Verification of reading warnings, cautions and contraindications

4. The Liberate Medical, LLC company logo screen will then appear as shown in Figure 13.

<u>ON Position</u> bottom portion of the switch is pressed in.

Figure 14 : Logo screen

Figure 15: Connections screen

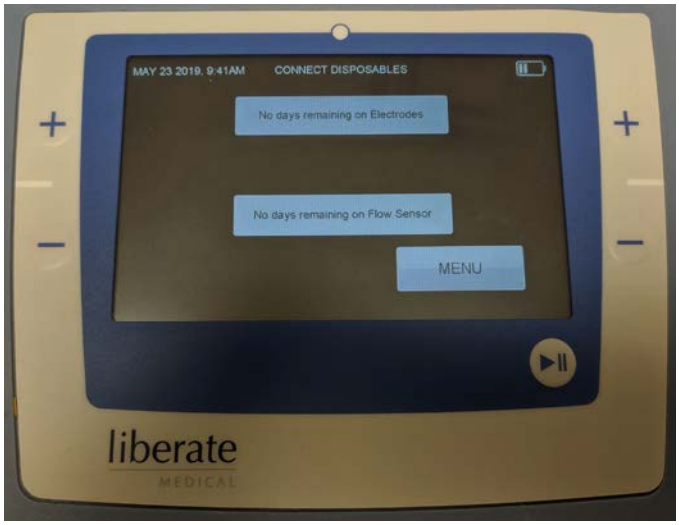


Figure 16: Connections Screen (Expired Disposables)

5. After the LOGO screen is pressed, the CONNECTIONS screen will appear (Figure 13). The CONNECTIONS screen will verify that the Flow Sensor and electrodes are properly connected and not expired (refer to Figure 15 for screen with expired disposables). The CONNECTIONS screen will also inform the user if the battery has enough charge to complete a treatment session.

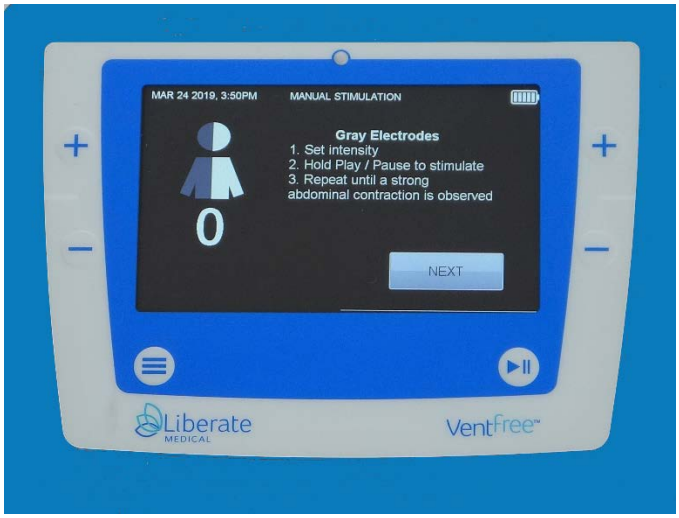


Figure 17: Manual stimulation screen 1

Figure 18: Manual stimulation screen 2

Figure 19: Manual stimulation screen 3

6. After the setup is confirmed with the CONNECTIONS screen, the MANUAL STIMULATION screen (Figure 16, Figure 17, Figure 18) will display. The setup is intended to adjust stimulation levels to the point where visible and comfortable muscle contractions are observed. Follow the directions on the screen to set up the patient.

7. Stimulation levels can be adjusted on each channel by pressing the corresponding +/- buttons on either side of the screen. VentFree will output stimulation anytime the "PLAY/PAUSE" button is pressed. Stimulation will cease when the button is released. Refer to the Stimulation Levels section for further details on adjusting levels.
8. The "MENU" button can be selected to adjust BRIGHTNESS, KEY VOLUME, SESSION LENGTH, TIME & DATE, STIM SETTINGS (refer to the MAIN MENU section for additional details).
9. To begin therapy, press BEGIN TREATMENT.

3.1 Stimulation Levels

It is recommended that stimulation be applied at 30 Hz with a pulse width of 350 µs as these settings were used for clinical testing of VentFree. These are the device default settings; however, they can be adjusted based on physician judgement using in the device menu. The stimulation amplitude (level) should be titrated for each patient and each stimulation session. The stimulation level should be set at the maximum level which does not result in patient discomfort (based on clinical judgement or a Richmond Agitation – Sedation Score ≥ 2). Stimulation should result in a strong visible or palpable contraction of the muscle. Ultrasound can be used to verify whether stimulation results in visible contraction of the lateral abdominal muscles (internal oblique, external oblique and transverse abdominis).

⚠ WARNING: If there is no contraction at the maximum stimulation level which does not result in patient discomfort, then the patient is not suitable for therapy with the VentFree device.

⚠ WARNING: If there is patient discomfort prior to achieving a strong visible or palpable contraction, then the patient is not suitable for therapy with the VentFree device.

Each channel of stimulation may require a different stimulation intensity. The VentFree device user interface will first allow stimulation level titration for only the gray electrodes (Figure 16) then only the blue electrodes (Figure 17). It is recommended to start the stimulation level at 10 and proceed in steps of 5 – 10. If patient discomfort is observed, then the stimulation level should be reduced in steps of 5 until no patient discomfort is observed during stimulation.

After the stimulation level is set for each channel individually, the stimulation level should be checked for both the stimulation channels applied in synchrony (see Figure 18).

⚠ WARNING: If patient discomfort is observed when stimulation is applied synchronously to both channels, then the stimulation level should be reduced in steps of 5 until no patient discomfort is observed.

Note: The stimulation level should be checked at the start of each session, however, it is common that no or only small changes in stimulation level will be required between treatment sessions for an individual patient.

3.2 Begin treatment

1. To begin a treatment session, select “BEGIN TREATMENT” on the MANUAL STIMULATION screen.
2. VentFree is now set up in automated mode to apply stimulation in synchrony with exhalation. Figure 19 shows the information displayed while in automated mode. Stimulation levels will be those set during the manual mode. At any given point, by using the +/- button on each side of the screen, individual channel stimulation levels can be adjusted to maximize muscle contraction at a comfortable level. Refer to the Stimulation Settings section for further details.

⚠ WARNING: If there is patient discomfort is observed during stimulation session then the stimulation level should be reduced in steps of 5 until no patient discomfort is observed.

3. Treatment will continue in automated mode until the session time has expired. Treatment is paused by pressing the PLAY/PAUSE button or an error is displayed.

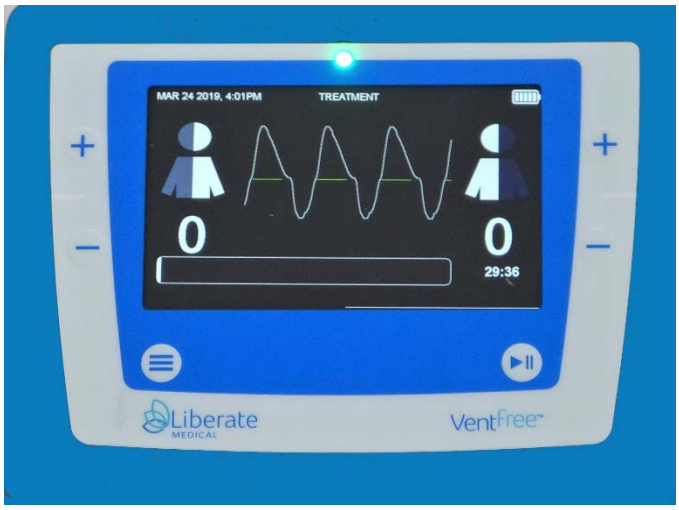


Figure 20: Treatment display

3.3 Treatment Pause

1. To pause the treatment session, press the PLAY/PAUSE button. The screen will display the information shown in Figure 20.

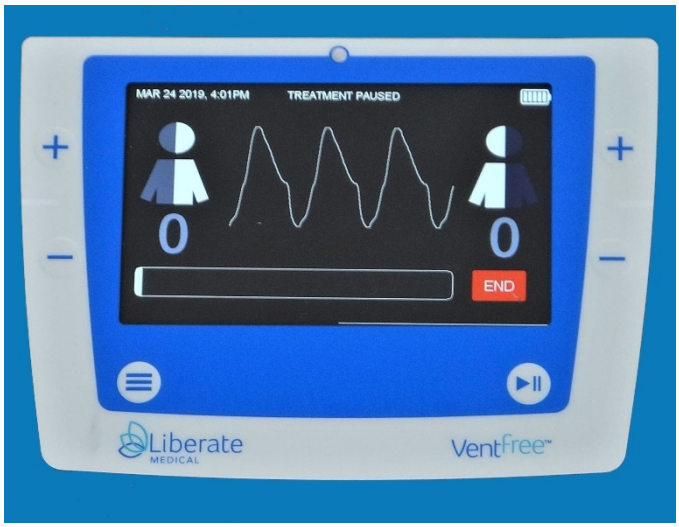


Figure 21:Paused Treatment

2. To restart the treatment, press the PLAY/PAUSE button.
3. If treatment is to be stopped or discontinued, press the END button.

3.4 Treatment Discontinuation

1. Once the stimulation session has been completed or stopped, the END OF TREATMENT screen will appear. The screen will display the starting intensity, minimum intensity, maximum intensity, average intensity, remaining Flow Sensor uses, and remaining electrode uses as shown in Figure 21.

NOTE: The Flow Sensor is equipped with a radio-frequency identification (RFID) tag that logs expiration dates and number of uses.

NOTE: The electrodes are equipped with electrically erasable programmable read-only memory (EEPROM) to track expiration dates, number of uses (max of 5 treatment days), the part name, type identifier, lot identifier of the electrodes and contact information of Liberate Medical, LLC.

Figure 22: End of treatment summary

The device can now be safely powered down and the patient disconnected by following the power removal and device disconnection instructions below (Section 3.5).

3.5 Power Removal and Device Disconnection

1. Press FINISH on the END OF TREATMENT screen.
2. Power down VentFree by pressing the top portion of the Power Switch.
3. Disconnect the electrodes and Flow Sensor from VentFree.
4. Carefully remove the electrodes from the patient.
5. If the END OF TREATMENT screen shows 0 days remaining for the disposables, dispose the electrodes and Flow Sensor according to local guidelines.
6. If the END OF TREATMENT screen shows more than 0 days remaining for the disposables:
    a. Return electrodes to the backing sheet and place back into respective storage bag.
    b. Disconnect the Flow Sensor from the patient by unplugging the tubing from the Luer Lock connections near the Flow Sensor.
    c. Using NEW Luer Lock caps, cap the open ends of the tubing close to the Flow Sensor.
    d. Clean and disinfect the remaining assembly following the instructions in the Disinfection and Cleaning section (refer to Section 6). Then, return items to corresponding packaging.

⚠ CAUTION:

- DO NOT LEAVE THE PATIENT'S END OF THE FLOW SENSOR UNCAPPED
- IF FLOW SENSOR IS REMOVED FROM THE PATIENT'S BREATHING CIRCUIT, DISCARD THE FLOW SENSOR ASSEMBLY AND REPLACE WITH A NEW ONE PRIOR TO THE NEXT USE

- ALWAYS USE NEW CAPS TO CAP THE FLOW SENSOR TUBING

7. The device and all accessories should be cleaned after use by wiping surfaces down with disinfectant. Refer to the Disinfection and Cleaning Section 6 for further instructions.

3.6 MAIN MENU

Figure 23 MAIN MENU

3.6.1 Brightness

The Screen Contrast is adjustable and can be accessed through the BRIGHTNESS menu option from the MAIN MENU. Once on the screen, the "+/-" buttons, on either side of the screen can be pressed to adjust the screen contrast.

Figure 24: Screen Contrast

3.6.2 Key Volume

The KEY VOLUME is adjustable and can be accessed through the MAIN MENU. Once on the screen, the "+/-" buttons, on either side of the screen can be pressed to adjust the volume.

Figure 25:Key Volume

3.6.3 Session Length

The SESSION LENGTH is adjustable on VentFree. Once on the screen, the "+/-" buttons, on either side of the screen, can be pressed to adjust the session length between 5 and 60 minutes.

Figure 26:Session Length

3.6.4 Date/time menu

The DATE/TIME menu available on VentFree is used to adjust the current date and time on the device.

Figure 27 Date/time menu

3.6.5 Stim Settings

Reserved for Factory Settings.

3.6.6 About

Information about VentFree can be found on the ABOUT screen which can be accessed through the MAIN MENU. The last calibration date, software version, and hardware version can be found here. The information of the electrically erasable programmable read-only memory (EEPROM) in the electrodes used to track expiration dates, number of uses (max of 5 treatment days), the part name, type identifier, lot identifier of the electrodes and contact information of Liberate Medical, LLC will be displayed on this screen as well.

Figure 28: About screen

4 Error Messages and Troubleshooting

REASON	MESSAGE
Low battery	CAUTION: Battery will run out before session end!
No battery	CAUTION: No battery detected!
Reversed Flow Sensor	CAUTION: Reversed Flow Sensor detected Reverse Flow Sensor connection.
Low flow	CAUTION: Low flow detected! Check Flow Sensor and connection to patient.
No Flow	CAUTION: No flow detected! Check Flow Sensor and connection to patient.
High breath rate	CAUTION: High breathing rate detected! Check Flow Sensor and connection to patient.
Low breath rate	CAUTION: Low breathing rate detected! Check Flow Sensor and connection to patient.
High flow	CAUTION: High flow detected! Check Flow Sensor and connection to patient.
High Impedance Blue Electrodes	CAUTION: High impedance on Blue Electrodes! Check Blue Electrodes and replace if necessary.
Open electrode Blue Electrodes	CAUTION: Open circuit detected Blue Electrodes! Check Blue Electrodes and replace if necessary.
High Impedance Grey Electrodes	CAUTION: High impedance on Grey Electrodes! Check Grey Electrodes and replace if necessary.
Open electrode Grey Electrodes	CAUTION: Open circuit detected Grey Electrodes! Check Grey Electrodes and replace if necessary.
Electrodes unplugged after connections screen	CAUTION: Electrodes are not detected. Connect Electrodes.
Flow Sensor unplugged after connection screen	CAUTION: Flow Sensor Not Detected. Connect Flow Sensor to the device.
Last day of use for accessories	CAUTION: This is the last day of use for connected disposables. Replace disposables for use after today.
Battery malfunction	WARNING: Battery charging voltage has exceeded maximum.

5 Technical Data

5.1 Power Source

5.1.1 Battery

- Nominal Voltage: 7.5 V
- Max Voltage: 8.7 V
- Capacity: 6.4 Ah (48 Wh)
- Approvals: CE, FCC, UR

The Battery is part of VentFree.

ONLY Batteries supplied by Liberate Medical, LLC shall be used.

5.1.2 AC/DC Converter (Power Supply)

- Input: 100 ~ 240 VAC, 50 ~ 60 Hz
- Output Voltage: 9 VDC
- Output Current: 5.5 A
- Approvals: CB, FCC, UR
- Isolation Level: Primary – Secondary: 2 x MOPP

The AC/DC converter is part of VentFree.

ONLY AC/DC Converters supplied by Liberate Medical, LLC shall be used.

5.2 Standard Measurement Conditions

- Temperature: 25° C +/- 5° C
- Load: 1000 ohm
- AC/DC converter 9V DC +/- 10%

5.3 Outputs

The VentFree muscle stimulator provides current controlled biphasic symmetrical rectangular pulses. An example waveform in shown in Figure 29. The device has the following stimulation output ranges:

- Stimulation frequency: 30 Hz – 50 Hz
- Stimulation pulse width: 100 µs – 400 µs
- Stimulation amplitude: 0 mA, 2 mA – 100 mA

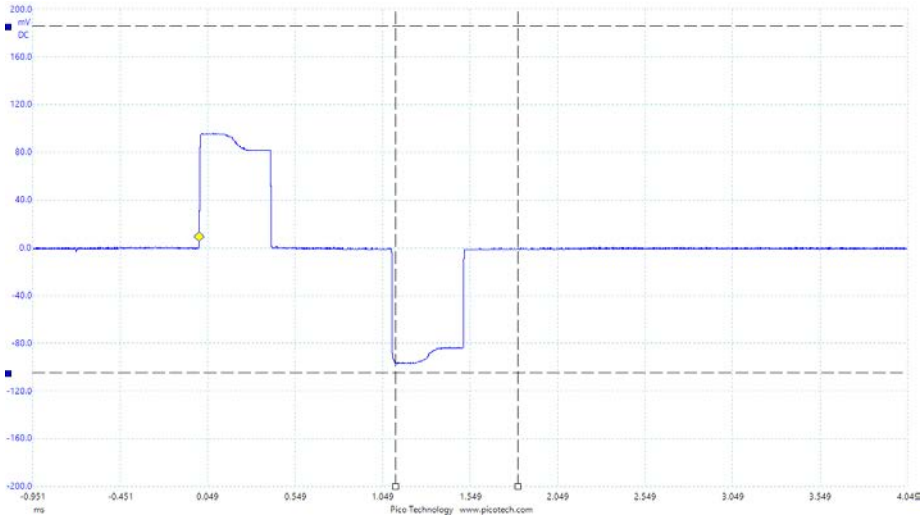


Figure 29 Stimulation output 100 mA 700 us interphase, 400 us Pulse Width, 50Hz Frequency

5.4 Typical Waveforms

The following are typical waveforms as measured through a 100 ohm current sense resistor while providing maximum stimulation to purely resistive loads of 1000 ohm and 500 ohm.

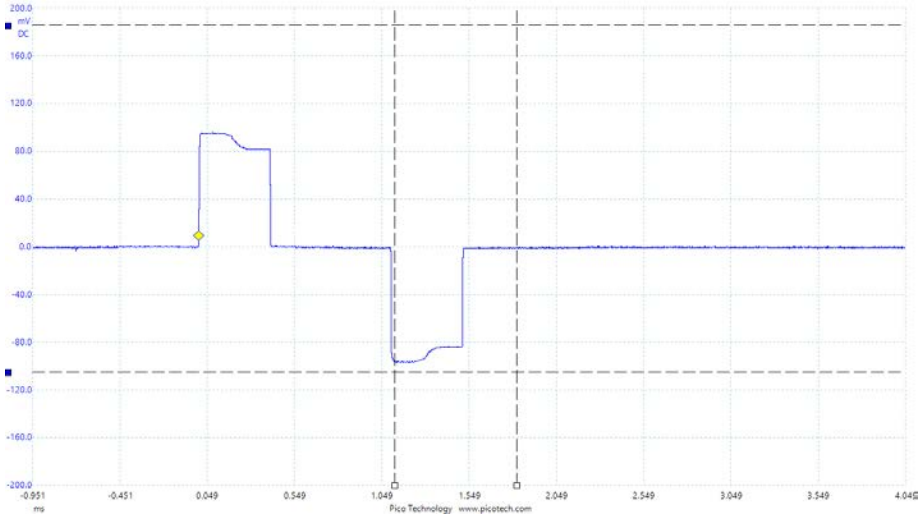


Figure 30: Stimulation output 100 mA 700 us interphase, 400 us Pulse Width, 50Hz Frequency

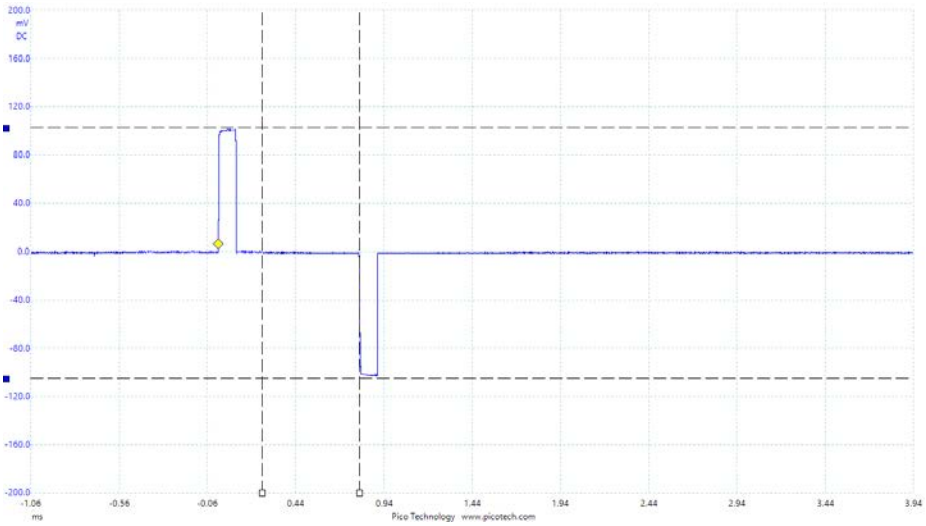


Figure 31: Stimulation output 100 mA 700 us interphase, 100 us Pulse Width, 50Hz Frequency

5.5 Treatment Duration

The treatment timer is adjustable from 5 – 60 minutes with 30 minutes used as the default session length.

5.6 Output Signal Indication

Active stimulation output from the device is indicated by a yellow LED above the touchscreen and by a green line under the flow signal depiction on VentFree's screen.
Stimulation Level of each channel is indicated with numerical characters showing the circulating current intensity with 20% Accuracy and Precision levels.

5.7 Physical Characteristics

- Size: 6" x 7.5" x 1.75"
- Weight: ~1 lb. 13 ounces

5.8 Accessories

WARNING: ONLY accessories supplied by Liberate Medical, LLC shall be used

WARNING: DO NOT modify Flow Sensor

WARNING: ONLY modify electrodes following instructions provided by Liberate Medical, LLC

5.8.1 Electrodes

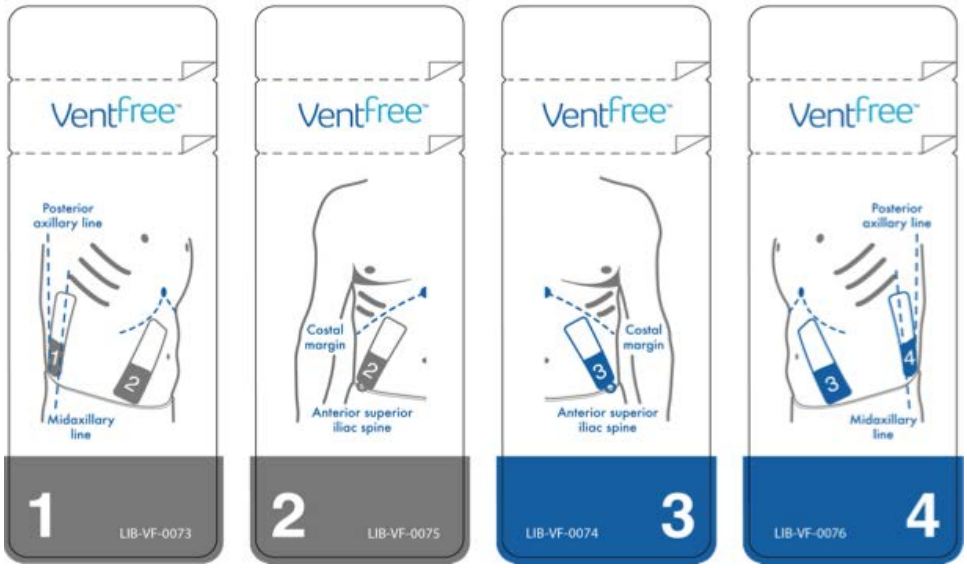


Figure 32. VentFree Electrodes

- There are 3 size options for the VentFree electrodes.
- To decrease electrodes size, tear the electrodes at the desired dashed line shown in the top of Figure 33.
- Part Number: Electrodes patches are part of the VentFree Accessory Kit Assembly,

PN: LIB-VF-0070 and are not sold individually by Liberate Medical, LLC

5.8.2 Flow Sensor

Figure 33: VentFree Flow Sensor

Part Number: The flow sensor is part of the VentFree Accessory Kit Assembly, PN: LIB-VF-0070 and are not sold individually by Liberate Medical, LLC

5.8.3External AC/DC Converter

Figure 34. External AC/DC Converter

Reorder Number: LIB-VF-307 / Part Number: MEANWELL 60109-LI

5.9 Environmental Conditions

- Operational Temperature: 41 °F and 95 °F (5 °C and 35 °C)
- Humidity (Maximum): 10% to 95% RH
- Atmospheric Pressure: 70 kPa to 106 kPa (10.2 psia to 15.4 psia)
- Transport & Storage: Store in Dry, Cool Place 41 °F and 95 °F (5° C to 35° C)

5.10 EN 60601-1 Classification

Defibrillation Proof Type BF Applied Part (Electrode Pads and Electrode Leads)

- Internally and externally powered
- Ordinary protection ingress of liquids
- Continuous operation

5.11 Electromagnetic Compatibility (EMC) Tables

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

VentFree muscle stimulator is intended for use in the electromagnetic environment specified in the table below. The user of the VentFree device should assure that it is used in such an environment.

VentFree is not intended to be used in proximity or in conjunction with HF surgical equipment. Discontinue the use of VentFree as indicated in Treatment Discontinuation Section 3.4 prior to the use of any HF surgical equipment.

Guidance and Manufacturer's declaration – electromagnetic emissions
NOTE: The EMISSIONS characteristics of VentFree make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and Manufacturer's Declaration – Immunity
The EUT is intended for use in the electromagnetic environment specified below. The customer or user of the EUT should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±8kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±8kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV Line-to-line	±0.5 kV, ±1 kV Line-to-line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EUT requires continued operation during power mains interruptions, it is recommended that the EUT be powered by an uninterruptible power supply or battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30A/M 50/60 Hz	30A/M 50/60 Hz	

Guidance and Manufacturer's Declaration – Immunity			
The EUT is intended for use in the electromagnetic environment specified below. The customer or user of the EUT should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 6Vrms (In ISM Bands) 150 kHz to 80 MHz	3Vrms 6Vrms (In ISM Bands) 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the EUT including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ $d = 2,3\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[b].  Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	80MHz to 2.7GHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and VentFree

The VentFree device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VentFree device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VentFree device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter [W]	Separation Distance According to Frequency of Transmitter [m]		
		80 MHz to 800 MHz	800 MHz to 2.5GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagations is affected by absorption and reflection from structures, objects, and people.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VentFree, including cables specified by Liberate Medical, LLC. Otherwise, degradation of the performance of this equipment could result.

6 Disinfection and Cleaning

6.1 Agents

Refer to the specific disinfecting agent label for specific instructions for use.

VentFree enclosure has to be disinfected in between treatments following the specific disinfecting agent label for instruction for use.
The enclosure and Flow Sensor (Exterior only) are compatible with Quaternary Ammonium Chloride (5000ppm) /Alcohol (55%), 1:50 – 1:100 Bleach, and Hydrogen Peroxide (1.4%) based Wipes.
Electrodes are compatible with Quaternary Ammonium Chloride (5000ppm) /Alcohol (55%)
Consult Liberate Medical, LLC about the use of other surface disinfectant products.

6.2 VentFree and AC/DC Converter Cleaning and Disinfection Methods

After and before each use, the electrodes shall be cleaned and disinfected following the instructions below:

1. Turn VentFree off.
2. Remove all connections from VentFree.
3. Keep VentFree always in the vertical upright position.
4. Using any of the wipes listed above, wipe every surface of VentFree and the External AC/DC Converter to remove any visible signs of soil or body fluids.
5. Care must be taken to prevent any excess of liquid from reaching the connectors in the connector panel.
6. If heavy visible contamination is observed, repeat steps 4 and 5 using a new wipe
7. Follow the specific disinfecting agent label to assure that the minimum recommended contact time of the cleaning / disinfecting agent is achieved.
8. Dispose the wipes following the manufacturer's recommendations after this procedure.

⚠ ONLY USE approved cleaning agents

⚠ ALWAYS follow the institution Infection Control procedures regarding the use of Personal Protective Equipment when handling cleaning and disinfection agents

⚠ ALWAYS follow the institution Infection Control procedures regarding any logging of equipment disinfection.

6.3 Electrodes Cleaning and Disinfection Methods

Before and After each use, VentFree shall be cleaned and disinfected. Following are instructions for cleaning electrodes After treatment:

1. Turn VentFree off.
2. Disconnect the Electrodes from the patient and VentFree, if not done before.
3. Return the electrodes to storing liner.
4. Using any of the wipes listed above, wipe the back of the electrodes where the instructions for use are displayed, the leads and external surface of the electrode connector to remove any visible signs of soil or body fluids.
5. Care must be taken to prevent the contact of the wipes with the hydrogel of the electrodes.
6. If heavy visible contamination is observed, repeat steps 4 and 5 using a new wipe.
7. Follow the specific disinfecting agent label to assure that the minimum recommended contact time of the cleaning / disinfecting agent is achieved.
8. Dispose the wipes following the manufacturer's recommendations after this procedure.

ONLY USE approved cleaning agents

ALWAYS follow the institution Infection Control procedures regarding the use of Personal Protective Equipment when handling cleaning and disinfection agents

ALWAYS follow the institution Infection Control procedures regarding any logging of equipment disinfection.

Electrodes are SINGLE PATIENT USE ONLY

6.4 Cleaning and Disinfection of the Flow Sensor

Before and After each use, the Flow Sensor Assembly shall be cleaned and disinfected. Following the instructions for After a treament:

1. Disconnect the Flow Sensor tubing by unplugging the Luer Lock connections close to the Flow Sensor.
2. Using NEW Luer Lock caps, cap the open ends of the tubing close to the Flow Sensor.

CAUTION:

- DO NOT LEAVE THE PATIENT END OF THE FLOW SENSOR UNCAPPED
- IF FLOW SENSOR IS REMOVED FROM THE PATIENT'S BREATHING CIRCUIT, DISCARD THE FLOW SENSOR ASSEMBLY AND REPLACE WITH A NEW ONE PRIOR TO THE NEXT USE
- ALWAYS USE NEW CAPS TO CAP THE FLOW SENSOR TUBING

3. Turn VentFree off.
4. Using any of the wipes listed above, wipe the **external** surface of the Flow Sensor, its tubing and connector to remove any visible signs of soil or body fluids.

CAUTION: DO NOT ALLOW CONTACT OF THE WIPES WITH INTERNAL PARTS OF THE FLOW SENSOR ASSEMBLY

5. If heavy visible contamination is observed, repeat step 4 using a new wipe.
6. Follow the specific disinfecting agent label to assure that the minimum recommended contact time of the cleaning / disinfecting agent is achieved.
7. Dispose the wipes following the manufacturer's recommendations after this procedure.

 ONLY USE approved cleaning agents

 ALWAYS follow the institution Infection Control procedures regarding the use of Personal Protective Equipment when handling cleaning and disinfection agents

 ALWAYS follow the institution Infection Control procedures regarding any logging of equipment disinfection.

 The Flow Sensor assembly SINGLE PATIENT USE ONLY

 If visible signs of body fluids are observed inside the Flow Sensor, rinse with sterile water and air dry

7 Battery Replacement

The battery supply of VentFree powers the device for a duration of approximately 7 hours of stimulation. This represents 14 sessions of 30 minutes each. When VentFree determines that the battery does not have enough charge to complete a treatment session, it will display a "Low Battery" warning and will not proceed to the stimulation activity. The battery can be recharged using the VentFree charging cable. Stimulation can be provided while the device is connected to the power main.

If the battery in VentFree is no longer holding a charge long enough for a stimulation session or is not charging, the battery needs to be replaced. Only batteries supplied by Liberate Medical, LLC should be used in VentFree.

To replace the battery in VentFree:

CAUTION – Only Authorized and Trained personnel should replace the battery.

WARNING – DO NOT REPLACE battery while a patient is being treated

WARNING – Lithium Ion batteries cannot be shipped by Air.

1. Discontinue a treatment.

Figure 35: Power Switch

2. Turn off the device by pressing the top portion of the power switch (Figure 36).

Press to turn the device OFF.

3. Disconnect VentFree from the external AC/DC converter.
4. Disconnect the Electrodes Leads and Flow Sensor.

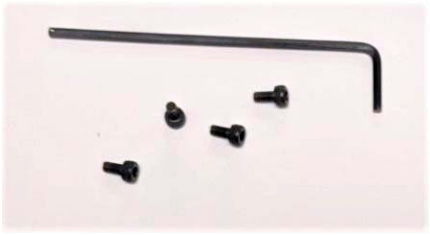


Figure 36: VentFree with screws removed

5. Place VentFree facing down and unscrew each corner screw of the device (Figure 37).

Figure 37: VentFree with back panel removed

6. Remove the back panel (Figure 38).

Figure 38: VentFree battery with pull tab

7. Remove the current battery by gently lifting it vertically from the device using the battery's pull tab (Figure 39).

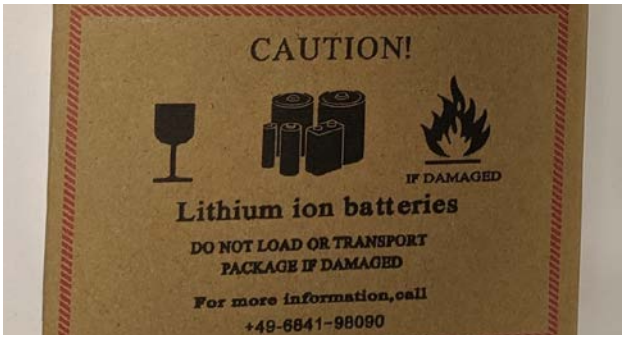


Figure 39 : VentFree battery packaging

8. Remove the new battery from its packaging (Figure 40).

Figure 40: VentFree battery replaced

Figure 41: VentFree battery seated

9. Place the new battery in VentFree. The battery should slide vertically over the connector (Figure 41). Make sure the battery is seated into the battery compartment (Figure 42).

Figure 42: VentFree back panel and screws replaced

10. Replace the back panel of VentFree and replace the screws (Figure 43).

7.1 Battery Disposal

Do not dispose of batteries in regular trash or recycling bins.

Refer to local guidelines on how to dispose Lithium Ion Batteries.

8 Calibration and Maintenance

Liberate Medical has determined that no maintenance or routine calibration procedures, other than those related to battery replacement, are required throughout the lifetime of VentFree. Such period of time has been determined to be 5 years from the manufacturing date.

8.1 Repairable Parts

VentFree does not have repairable parts. In the event of any malfunction other than those requiring a change of battery or accessories, contact Liberate Medical, LLC.

8.2 Equipment Disposal

Do not dispose of VentFree or any of its accessories in regular trash or recycling bins.

Refer to local guidelines on how to dispose Medical Electrical Equipment and related Accessories.

9 Manufacturer Information

VentFree Electrical Stimulator is Manufactured for:

Liberate Medical, LLC

6400 Westwind Way, Suite A
Crestwood, KY 40014

1-800-683-5526