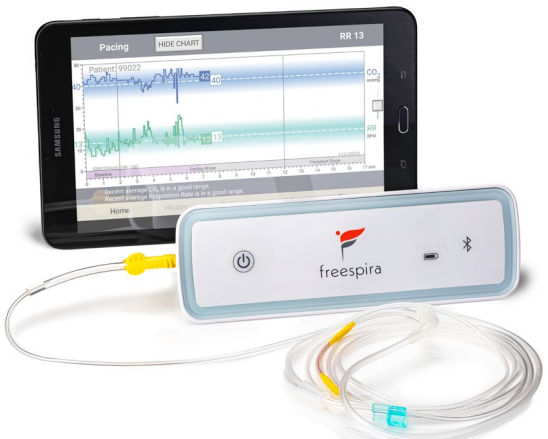


# User Manual

freespira

# Contact Information

Our Customer Service team is available to assist you with any questions or issues.

**CALL** 800.735.8995

**EMAIL** cs@freespira.com

**WEB** www.freespira.com

**MAIL** **Freespira, Inc.**
12020 113th Ave. NE, Suite 215
Kirkland, WA 98034

# Contents

## INDICATIONS FOR USE

Freespira is indicated as an adjunctive treatment of symptoms associated with Panic Disorder (PD) and/or Post-Traumatic Stress Disorder (PTSD), to be used under the direction of a licensed healthcare professional, together with other pharmacological and/or non-pharmacological interventions.

## CONTRAINDICATIONS

Pregnant women should not use Freespira.

Patients diagnosed with Obesity Hypoventilation Syndrome (OHS) should not use Freespira.

## CLINICAL RESULTS

Freespira has been clinically evaluated and FDA-cleared in patients over 18 years of age with a current diagnosis of:

1) Panic Disorder (PD) or symptoms of PD (including panic attacks), with or without Agoraphobia.

2) Post-Traumatic Stress Disorder (PTSD)

Freespira has also been clinically evaluated in patients 13-17 years old with at least moderate anxiety illness and panic attack symptoms (PDSSA >=10) or PTSD symptoms (PCL>=33) and is being made available as permitted by FDA's COVID-19 Enforcement Discretion Guidance.

Freespira has not been studied for, and therefore should not be used to treat, individuals with any of the following:

- a history of Bipolar Disorder, psychosis or delusional disorders,
- substance abuse or dependence,
- suicidal tendencies,
- presence of an organic mental disorder,
- Severe Persistent Mental Illness (SPMI), or seizures,
- chronic respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) or Emphysema.

Freespira should be used only by the individual for whom it is authorized and only in the manner for which it is intended.

## PRECAUTIONS

- Do not use Freespira while driving.
- Do not use Freespira while focused on other activities, or while operating heavy machinery.
- Stay awake and alert while using Freespira.
- Use Freespira only while sitting, with system located within arm's reach on a stable, horizontal surface.
- The system should be operated in strict accordance with precautions regarding Electromagnetic Compatability (EMC).

***See the section "Electromagnetic Compatability" for more information.***

- Portable and mobile communications devices can affect proper operation of the system. See the section “Electromagnetic Compatibility” for more information.
- If Electromagnetic Interference (EMI) appears to be a problem, it may become necessary to reorient and/or relocate the system components to avoid interfering equipment. See the section “Electromagnetic Compatibility” for more information.

## WARNINGS

To avoid the risk of electrical shock, burns, or damage to the device, the Freespira sensor should be charged and operated only with the white charger (AC adapter) supplied with the system.

The cannula tubing may present a potential strangulation or choking hazard. Arrange the cannula tubing appropriately while in use and take care to keep the cannula out of reach of children and pets.

To avoid the risk of infection, do not share the cannula.

To avoid the risk of electrical shock, burns or damage to the device:

- Do not open or modify the Freespira sensor or tablet. The system does not contain any user maintainable parts. In particular, the battery is not user replaceable.
- Use only components and accessories provided by Freespira.
- Keep Freespira out of reach of children and pets at all times.
- Do not use the sensor if there is visible damage, loose parts, or if it emits unusual noises.
- Do not immerse the Freespira sensor in water or expose to moisture of any kind.

The use of components or accessories other than those provided or suggested for use with Freespira may cause electromagnetic interference to, or interference from, other electronic devices. See the section on “Electromagnetic Compatibility” for additional information.

Avoid placing the sensor in bright sunlight or near heat sources, which can raise the temperature of the sensor and cause malfunction.

To ensure proper performance, avoid sudden movements of the sensor while in use.

Some feelings of dizziness or lightheadedness may be experienced when using Freespira, particularly during the first few sessions. If these or any other symptoms are concerning, stop the breathing exercises and contact your healthcare provider.

Continue to take currently prescribed medications while using Freespira, unless directed otherwise by your prescribing physician.

Freespira is designed to be used indoors in a cool, clean, dry environment. To ensure proper operation, avoid exposing the unit to excessive lint, dust, or extreme temperatures.

Use of unauthorized parts and accessories with the system will void the warranty.

To ensure proper performance, do not use the cannula if it appears to be damaged or broken.

The cannula is disposable and is not designed to be cleaned. If the cannula becomes damaged or soiled, discard it and use a new one.

## OVERVIEW OF FREESPIRA

Freespira is authorized by a licensed healthcare provider. It is used in 17-minute sessions twice daily for 4 consecutive weeks.

The system consists of a hand-held electronic tablet and carbon dioxide ($CO_2$) sensor, fitted with a disposable nasal cannula. The cannula delivers exhaled breath to the sensor for analysis, determining End Tidal Carbon Dioxide ($ETCO_2$) and Respiration Rate (RR). These measurements transmit wirelessly via Bluetooth to the tablet, upon which the Freespira app displays the data. By providing real-time audio-visual feedback, the app guides the patient's breathing pattern re-training process.


FIGURE 1

## THE FOLLOWING ITEMS ARE INCLUDED FOR MODEL #FS-4275

- Freespira sensor (1) SM-4050
- Calibration cartridges with return pouch (5) CC-4045
- Measurement unit (1) (installed in sensor) MU-4040
- White AC adapter/charging cable for charging the sensor 03267/03268/03316
- Two (2) Freespira $CO_2$ cannulas (including instructions) CN-4273
- Tablet (with cover), with the Freespira app installed AC-4035
- Black/gray AC adapter/charging cable for charging the tablet 03016/03017
- Documentation: Freespira Start Here, Information & Resources and Week 2 guides, return mailing label 05180/05181/05179


**CONTACT CUSTOMER SERVICE FOR ADDITIONAL CANNULAS, CARTRIDGES OR ANY OTHER REPLACEMENT ACCESSORIES.**

FIGURE 2

## GETTING STARTED

To set up Freespira, please refer to the included Start Here and/or Information & Resources guides for instructions.

## THE FREESPIRA SENSOR

Measures respiration rate (RR) and $CO_2$ in sampled, exhaled air. While the Freespira app is running on the tablet, and the sensor is on, the two components will automatically connect via Bluetooth.

The Freespira sensor battery is rechargeable using the supplied white AC adapter and charging cable.

No other chargers should be used with the sensor.

The Freespira sensor can be used while the white AC adapter and charging cable are connected.

## FEATURES OF THE SENSOR

**Power Button:** Press and release the power button to turn the sensor on or off.

**Status Indicator:** Changes color to indicate sensor status. Green: sensor is ready for use; Red: the sensor needs attention (such as calibration) before you can continue; Blue: calibration in progress; White: breathing session has begun.

**Battery Status Indicator:** When the charger is connected to the sensor and plugged into a power outlet, the battery indicators cycle until the sensor is fully charged. Once the sensor is fully charged, all 5 indicator lights remain on. If the sensor is not connected to its charger, the battery indicator lights will show how full the battery is.

**Bluetooth Light:** The Bluetooth light will flash blue while it attempts, for 5 minutes, to connect with the tablet. If it is successful, the light will stay a steady blue. If it is unsuccessful, the Bluetooth light will continue to flash.

**Cannula Connection Port:** On the left-facing end of the sensor, adjacent to the power button, there is a cylindrical port that seats the tabbed yellow end of the cannula tubing.

**Charging Port:** To charge the sensor, plug the sensor AC adaptor into an AC power source and connect the charging cable into the charging port.

**Sensor Reset:** Sensor reset is used when the sensor does not turn on or operate even after it's been charged. Insert a toothpick or a bent paperclip into the sensor reset slot and push gently for one second. The sensor should power on. If it doesn't, please contact Customer Service at 800.735.8995.

**Ring Light:** During sensor preparation, the white ring light will progressively illuminate, fully encircling the sensor front panel when complete.

## FREESPIRA SENSOR

FRONT PANEL VIEW

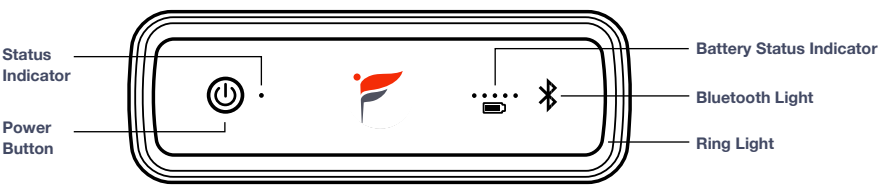


FIGURE 3

SIDE VIEW

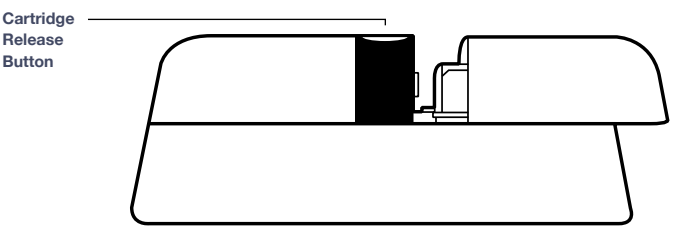


FIGURE 4

END VIEW

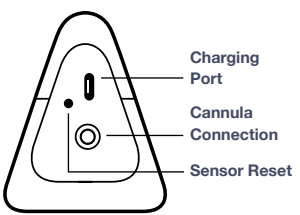


FIGURE 5

## TABLET

The Freespira tablet battery is rechargeable using the supplied black/gray AC adapter and charging cable.

No other chargers should be used with the tablet.

The tablet can be used while the black/gray AC adapter and charging cable are connected.

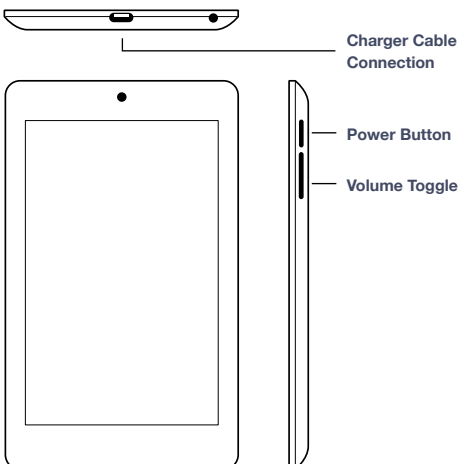


FIGURE 6

## FEATURES OF THE TABLET

- **Power Button:** Press and release the power button to turn the tablet on or off. If your tablet goes into sleep mode, press the power button once quickly to wake the screen.
- **Volume Toggle:** Press the top of the toggle to increase the volume and the bottom of the toggle to decrease it.
- **Charger Cable Connection:** To charge the tablet, plug the black/gray tablet AC adaptor cable into the charger cable connection.

## SYMPTOM ASSESSMENT

A prompt to take the symptom assessment survey will appear before the second session and then weekly (PD) or at the end of treatment (PTSD). The type of survey seen will vary according to treatment for PD or PTSD (see figures 7 and 8). The results help track patient progress for supportive and reporting purposes. To exit the survey without responding, press the Exit Survey button. The assessment prompt will continue to appear at every session until answers are submitted. For those in treatment for PD, the survey will appear once weekly thereafter. For PTSD, the survey will appear only once more, at the conclusion of treatment.

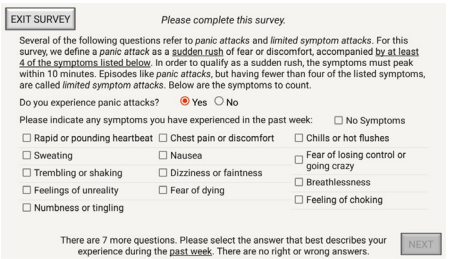


FIGURE 7

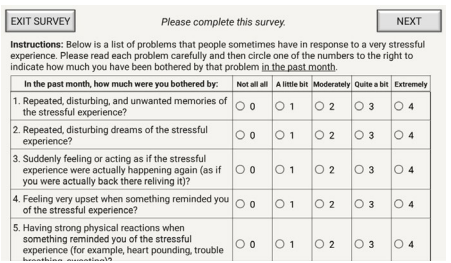


FIGURE 8

## BASELINE · PACING · TRANSITION

During the 2-minute Baseline Stage, the app records $CO_2$ levels and respiration rate (RR) without displaying the values, providing “Baseline” measurements of a patient’s natural breathing pattern.

**During Baseline:**

- Listen to the instructions and then sit quietly with eyes closed.
- Breathe normally through your nose.

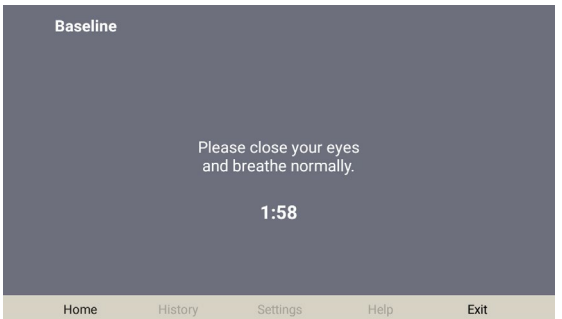


FIGURE 9

BASELINE · **PACING** · TRANSITION

During the 10-minute Pacing Stage, a series of repeating tones plays. Audio and written instructions help guide the patient to adjust breathing in order to reach target $CO_2$ and RR levels. The tones are paced at 13 breaths per minute (BPM) for week one, 11 BPM for week two, 9 BPM for week three, and 6 BPM for week four.

## CONTROLS ON THE PACING SCREEN

- **Current $CO_2$ Level:** The number in the blue box shows the $CO_2$ from the last breath. The blue line leading up to the blue box shows $CO_2$ values across the session.
- **Target $CO_2$ Level:** The dotted line in the blue shaded area represents the target $CO_2$ of 40mmHg (millimeters mercury), which is also noted in the white box next to the current $CO_2$ level on the graph.
- **Current Respiration Rate:** The number in the green box shows the current respiration rate (RR). The green line leading up to the green box shows RR across the session.
- **Target Respiration Rate:** The dotted line in the green shaded area shows the target RR, which is also noted in the white box next to the current RR level on the graph.


FIGURE 10

BASELINE · **PACING** · TRANSITION

The goal is to breathe at the target respiration rate while maintaining the $CO_2$ value within the target range of 36–44mmHg.

Some patients may find it easy to reach the target RR level. However, many users find it challenging to make even small increases to their $CO_2$. It is important to remember that the key to increasing $CO_2$ is to take in less air while continuing to breathe with the tones.

**During the Pacing Stage**:

- Inhale as the pacing tone rises
- Exhale as the pacing tone descends

There are two pauses in the tones, one at the end of the inhale and one at the end of the exhale. Patients should pause their breathing during these intervals.

### Controls on the Pacing Screen

- **Volume Control:** This square slider will adjust the volume. Touch and move upward to increase the volume. Touch and move downward to decrease the volume.
- **View Option (Graph/Chart):** Touch the Hide Chart button in the top left of the screen to toggle the view between Table and Chart. Hide Chart will show only a table (Figure 12) of Current $CO_2$ and RR vs. Target. This will also display written messages while audio feedback continues uninterrupted. Session time elapsed appears beneath the table.
- **Skip:** To skip the verbal instructions at the beginning of each of the 3 phases (Baseline, Pacing, Transition), press the Skip button which is visible only at the beginning of each session stage.

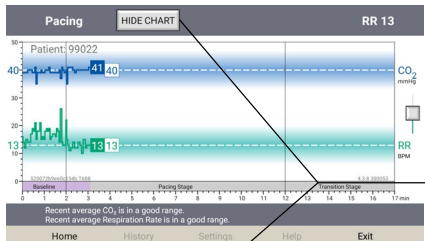


FIGURE 11

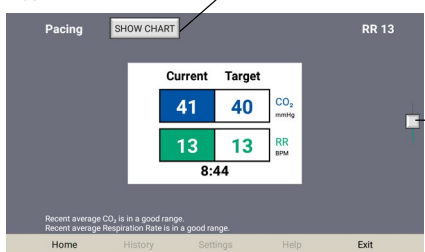


FIGURE 12

## BASELINE · PACING · **TRANSITION**

During the 5-minute Transition Stage, patients are asked to continue meeting the targeted $CO_2$ and RR without the aid of the audio tones.

- Patients attempt to maintain the same target BPM and $CO_2$ as in pacing.
- The goal is to decrease reliance on the displayed values for feedback by gradually increasing the time between checks to 30-seconds or more.

When the session is complete, an option appears to review the session or exit the app. All completed session data, including graphs, are stored under the History tab. Please see the section “History Tab” for more information.

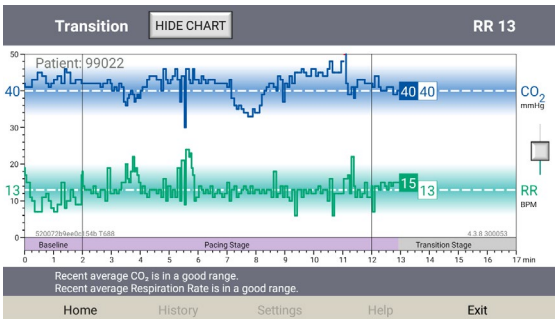


FIGURE 13

***Once the session is complete, remove the cannula and exit the app. The sensor will turn off automatically.***

***As a reminder, the sensor will require preparation/calibration weekly. When the prompt appears on the app, remove the used cartridge and install an unused one. Place all used cartridges in the provided pouch for return upon completion of treatment.***

## HOME, HISTORY, SETTINGS, HELP AND EXIT TABS IN THE FREESPIRA APP

### HOME TAB

Displays sensor preparation progress and session readiness messages (Figure 14).

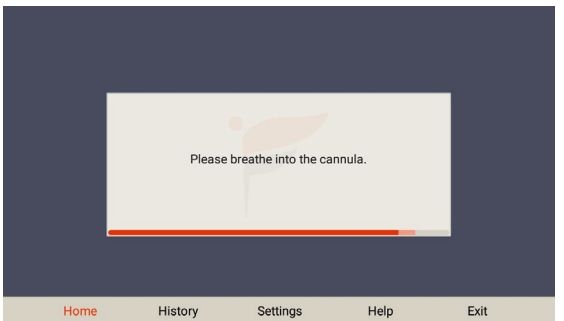


FIGURE 14

## HISTORY TAB

Displays a list of sessions completed (Figure 15).

**View:** To view a graph of the session data:

- Touch the row associated with the desired session for review and then touch the View button, or
- Touch and hold the row of the session.

Choosing a session from the Session History screen (Figure 15) will display the graph of the selected session (Figure 16).

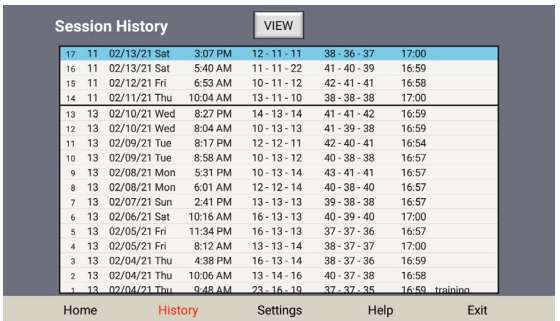


FIGURE 15

## HISTORY TAB (CONTINUED)

### Controls on the Session Review Page

- **Previous:** Touch this button to view the data for the session before the one currently on display.
- **Next:** Touch this button to view the data for the session after the one currently on display.
- **Averages:** The solid blue and green horizontal bars across the bottom of the graph indicate average $CO_2$ and RR respectively, for each of the 3 session stages.

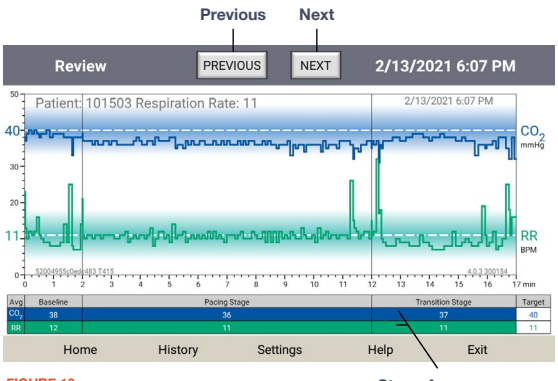


FIGURE 16

## SETTINGS TAB

### Controls on the Settings Screen

- **Manual Update:** Press to send data from any sessions not already uploaded to the Freespira Server for your provider to review. The tablet must be connected to the Internet via 3G/LTE or WiFi for the update to occur.
- **Respiration Rate:** The target RR will progress automatically each week. To set the RR manually, unclick “Automatic” and choose the desired BPM.
- **More:** See the following page for details about settings that can be adjusted using the More button.

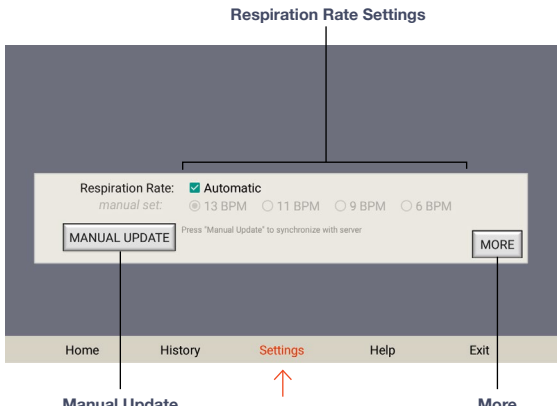


FIGURE 17

## SETTINGS TAB (CONTINUED)

**These options are available after pressing the More button on the Settings Tab (Figure 17):**

- **Training:** Touch the Training button on the Settings screen to enter training mode. The training mode allows you to pause and “Fast Forward” (skip ahead) through the parts of a session to practice the different stages without spending the entire 17 minutes to complete it.
- **Select Sensor:** If the tablet has been connected with one Freespira sensor and needs to be connected to another, use the Select sensor button. For more information about this option, see the “Troubleshooting” section.
- **Admin:** The Admin button (password protected) may be used by your therapist or coach to access other features.

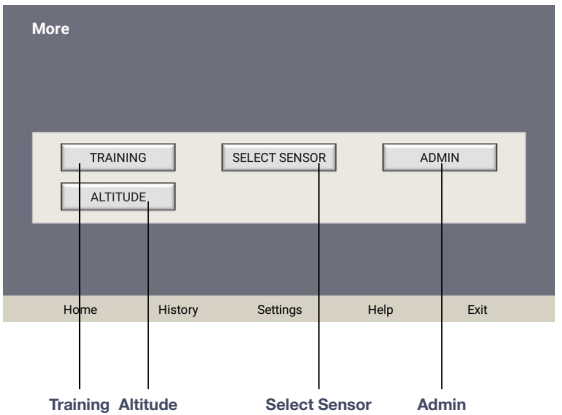


FIGURE 18

## HELP AND EXIT TABS

Touch the Help button (Figure 19) to access links to Frequently Asked Questions, Terms and Conditions, and the Freespira Privacy Notice.

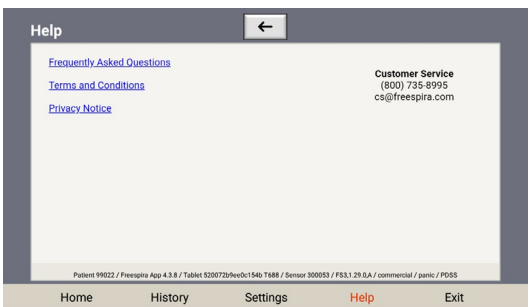


FIGURE 19

Touching the Exit button (Figure 20) will close the app and bring the user back to the Freespira home screen. This is the recommended action after each session.

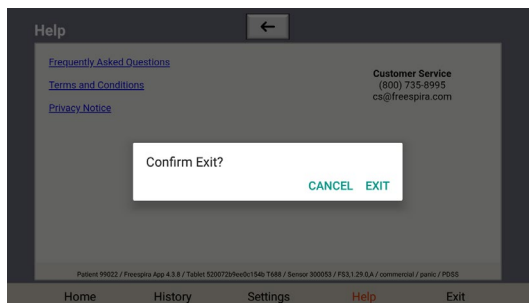


FIGURE 20

This table describes problems the user may encounter and the most likely solution in each case. If the problem is not listed, please contact Freespira, Inc. Patient Care at 800.735.8995 or email cs@freespira.com.

## COMMON PROBLEMS

| Problem | Possible Solutions |
|---|---|
| Sensor will not turn on | • Assure the sensor is charged or plugged into an electrical outlet using the white AC adapter and charging cable.<br>• Assure that the AC outlet the adapter is plugged into is energized (plug in a lamp or other device to the same outlet and check its function).<br>• Press and release the power button on the sensor.<br>• Reset the sensor by inserting a toothpick or bent paperclip into the sensor reset slot and push gently for one second. The sensor should then power on. |
| Red status indicator light | • Check the message on the tablet for instructions.<br>• Call Customer Service for further assistance 800.735.8995. |
| $CO_2$ readings are low or fluctuating | • Check the entire length of the cannula tubing and ensure there are no kinks or cuts/breaks.<br>• Check that the cannula prongs are seated snuggly in the nostrils and confirm that the patient is breathing exclusively through the nose.<br>• Replace the cannula. |

## SENSOR MESSAGES – DURING START UP

| Tablet Message | Action by User |
|---|---|
| Oops, the sensor preparation did not work. Please insert an unused cartridge and press Retry. | Press Retry. |
| Unfortunately, something isn't working. Please call Customer Service for additional assistance 800.735.8995. | Call Customer Service for additional assistance. |
| Looks like the cannula is blocked or pinched. Please check the line. | Check cannula. |
| Unfortunately, something went wrong with the cannula. Please replace your cannula and then press Retry. | Replace cannula. |
| Temperature of the sensor is too hot. Sensor needs to cool down before use. | Move the sensor to cooler location. |
| Temperature of the sensor is too cold. Sensor needs to warm up before use. | Move the sensor to warmer location. |
| Your measurement unit has expired. Please call Customer Service at 800.735.8995 to obtain a replacement. | Call Customer Service. |
| Sensor battery is low XX%. Please start charging before beginning session. | Plug sensor into charger. |
| Tablet battery is low XX%. Please start charging before beginning session. | Plug tablet into charger. |

| Tablet Message | Action by User |
|---|---|
| Oops, something is wrong with the sensor. Please turn sensor off/on to retry connection. | Turn the sensor off and on. |
| Oops, something is wrong with the sensor. Please exit app, wait 10 seconds, then restart app. | Exit out of app, wait 10 seconds and restart app. |

## SENSOR MESSAGES – DURING A SESSION

| Tablet Message | Action by User |
|---|---|
| Temperature of the sensor is too hot. Sensor needs to cool down before use. | Move the sensor to cooler location. |
| Temperature of the sensor is too cold. Sensor needs to warm up before use. | Move the sensor to warmer location. |
| Oops, something is wrong with the sensor. Please turn sensor off/on to retry connection. | Turn the sensor off and on. |
| Session paused. Please insert cartridge. | Insert calibration cartridge. |
| Session paused. Please insert measurement unit. | Insert measurement unit. |
| Looks like the cannula is blocked or pinched. Please check the line. | Check the cannula. |

| | |
|---|---|
| Unfortunately, something went wrong with the cannula. Please replace your cannula and press Resume. | Replace cannula. |

## SENSOR ERROR CODES

| Error Code | Meaning | Fix |
|---|---|---|
| 1000–1001 | Bluetooth connection problem | Turn everything (sensor and tablet) off and then back on |
| 2000 | Measurement unit fail | Call Customer Service for replacement |
| 2001 | Measurement unit has expired | Replace measurement unit or sensor |
| 2002 | Water damage detected | Replace measurement unit or sensor |
| 2003 | Measurement unit is most likely damaged | Replace measurement unit or sensor |
| 2004 | Room air validation failed | Re-calibrate sensor. If same error happens again on same unit, replace sensor |
| 2005 | Film is damaged or sensor is giving bad readings | Re-calibrate sensor. If same error happens again on same unit, replace sensor |

| | | |
|---|---|---|
| 2006 | Sensor is reporting really high $CO_2$ numbers | Re-calibrate sensor. If same error happens again on same unit, replace sensor |
| 3001–3007 | Preparation failure | Replace cartridge with new one |

| Error Code | Meaning | Fix |
|---|---|---|
| 7003 | Measurement unit was removed from sensor | Insert measurement unit into sensor |
| 7004 | Cartridge was removed from sensor | Insert cartridge into sensor |
| 9999 | Unexpected error | Call Customer Service |

## THE SENSOR AND APP ARE NOT COMMUNICATING

If the Freespira sensor and app are not connecting automatically (Bluetooth not connecting), take the following steps:

1. Power on your sensor. If the sensor does not power on, make sure that it is charged, or the AC adapter/charger is connected to the sensor using the charger cable and is plugged into a working AC outlet. If the sensor is not charged, connect the AC adapter/charger cable to it, plug it in to an AC outlet and wait two hours before starting a session on battery power or 30 minutes if using power from the charger/outlet.

2. Locate the serial number on the bottom of the sensor (Figure 21).

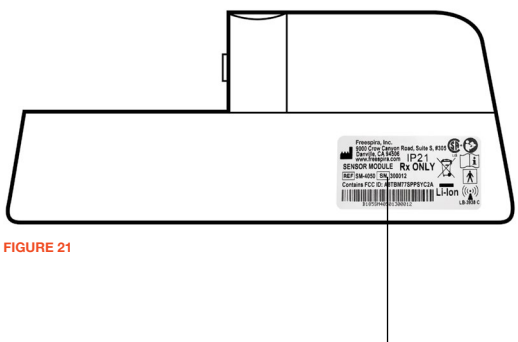


FIGURE 21

3. Go to the Settings tab (Figure 22).

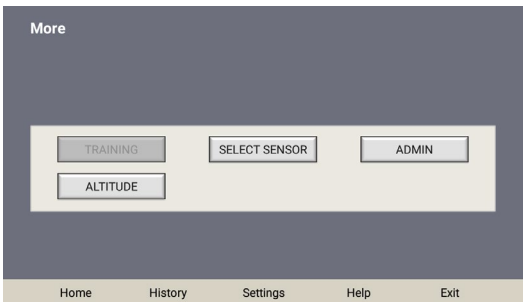


FIGURE 22

4. Touch the Select Sensor button (Figure 23).

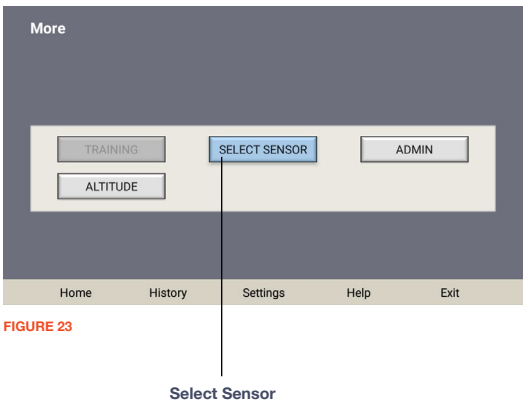


FIGURE 23

5. Sensors available for connection will appear in a pop-up list (Figure 24).
   - Note the serial number following “Freespira-300053” in the example.
   - If the serial number shown on the popup is not the same as on the sensor label, press the “SCAN FOR OTHER SENSORS” bar at the bottom of the screen.
   - The tablet will scan for other Freespira sensors and will identify available sensors.
6. Touch the serial number of the Freespira sensor desired for connection.
7. The sensor will now be connected to the tablet.

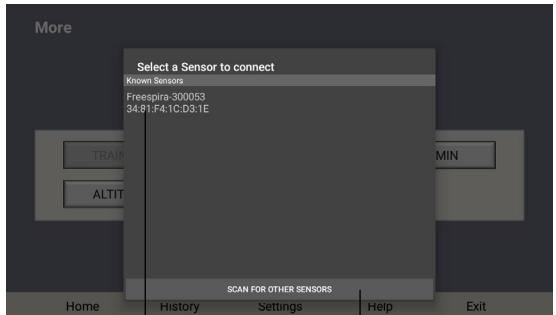


FIGURE 24

## STORAGE INSTRUCTIONS

Turn sensor off when not in use.

Store the sensor and charger in a cool, clean, dry place to prolong the life of the internal rechargeable battery.

Allow the sensor and charger to recover to room conditions for up to 2 hours after being transported or stored at extremes of environmental conditions beyond the specified operating conditions. See Technical Information.

## CLEANING AND MAINTENANCE

The Freespira sensor and accessories are provided clean but not sterile.

To clean the sensor, wipe the exterior using a cloth or paper towel slightly dampened with water. Then wipe with a dry cloth to remove any residual moisture.

## SYSTEM RETURN

When the 4-week Freespira treatment is complete, the system (including all used and unused calibration cartridges) must be returned to Freespira using the original shipping container and enclosed return label. Please dispose of any used nasal cannulas and do not include with return shipment.

## SPECIFICATIONS – SENSOR

| | |
|---|---|
| Model name | Freespira sensor |
| Model # | FS-4275 |
| Power source | Internal, rechargeable battery, 3.7V Li-Ion battery contained in the sensor |
| AC adapter/charger rating | 6 watts (maximum); 105V-240V @ 0.2 amps (50/60Hz) |
| Battery minimum operating time (as supplied) | Calibration and four (4) 17-minute sessions |
| Battery minimum life | 8 rental cycles |
| Battery recharge time | Fully charged in 6 hours |
| Expected service life | 3 years or 24 rental cycles whichever comes first; performance shall be maintained through calibration, replacement measurement units, and factory repair as necessary |
| Shelf life | Shelf life of parts and accessories are less than the expected service life of the sensor |
| Stabilization time | 2 hours from minimum or maximum storage temperatures |

| | |
|---|---|
| Weight | 0.9 Pounds |
| Outer product dimensions | 7 1/4” wide x 2 3/8” deep x 3.0” high |
| $CO_2$ measurement range | 20 to 50 mmHg (2.6% to 6.6%) |
| $CO_2$ accuracy ranges | 20 to 40mmHg ±2mmHg; 41 to 50mmHg ±5% of reading; <20mmHg and >50mmHg - unspecified |
| Respiration rate range | 4 to 35 breaths per minute (BPM) |
| Respiration rate accuracy | ± 1 breath (4 to 20 BPM) |

**Operating Conditions**

| | |
|---|---|
| Temperature | 15°C to 30°C (59°F to 86°F) |
| Humidity | 15% to 85% (non-condensing) |
| Pressure | 106kPA to 70kPA (-1,253 to 9,878 feet altitude) |

**Storage/Transportation**

| | |
|---|---|
| Temperature | -5°C to 35°C (23°F to 95°F) |
| Humidity | 15% to 85% (non-condensing) |
| Pressure | 106kPA to 70kPA (-1253 to 9,878 feet altitude) |

| Wireless Technology | |
|---|---|
| Communication | Wireless communication between the sensor and the tablet operates over the 2400-2485MHz ISM band, per the Bluetooth 3.0 Core Specification. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:<br>• Reorient or relocate the receiving antenna.<br>• Increase the separation between the equipment and receiver.<br>• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.<br>• Consult the dealer or an experienced radio/TV technician for help.<br>***Contains Transmitter Module FCC ID: A8TBM77SPPSYC2A*** |

## BLUETOOTH SECURITY

Bluetooth data packets transmitted between the Freespira sensor and the tablet are not encrypted.

The information contained in these data packets does not contain any information that could identify the user of the device. However, it is important for the user to know that this data could be monitored by other Bluetooth devices.

Data packets contain information on $CO_2$ level, respiration rate (RR), status and error messages sent between the sensor and the system application running on the tablet.

## WIFI SECURITY

The Freespira app is downloaded and installed onto the tablet at the factory; thus WiFi is not required when using Freespira for its intended use.

## QUALITY OF WIRELESS SERVICE

If problems are experienced with the connection between the Freespira sensor and the tablet, try to minimize the amount of radio frequency (RF) emitting equipment in the local vicinity including cell phones, laptops, wireless home network devices, Bluetooth enabled computer accessories, Walkie-Talkies, and Electronic Article Surveillance Systems.

## DECLARATION OF CONFORMANCE

The Freespira system has been designed, tested, and is compliant with, the following electromedical safety, transportation, and labeling standards and regulations:

| Source SDO / Number | Title / Description |
|---|---|
| United States Government Title 49 (US DOT) CFR 173.185 | Pipeline and Hazardous Materials Safety Admin., DOT, Lithium cells and batteries and UN Dangerous Goods Regulation UN 3481 PI 967 Section II Li Ion Batteries contained in or Packaged with Equipment. Includes part testing according to UN Test Manual Lithium Battery Requirements section 38.3 |
| United States Government Title 49 (US DOT) CFR 172 and 173.101 | Pipeline and Hazardous Materials Safety Admin., DOT, Purpose and Use of Hazardous Materials Table – $C0_2$, Nitrogen and Helium compressed gas form, UN1013 designation |
| ISO 7010: 2011-06-01, Ed 2 | Graphical symbols - Safety colors and safety signs - Registered safety signs [Including Amendment 1 (2012) through Amendment 7] |
| IEC 60417:2002 | Graphical symbols for use on equipment |
| IEC 7000, DB: 2008 | Graphical symbols for use on equipment – Registered symbols |

| Source SDO / Number | Title / Description |
|---|---|
| AAMI / ANSI / ISO 15223-1:2016 | Medical Devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements. |
| ISO 780:2015 | Packaging - Distribution packaging - Graphical symbols for handling and storage of packages |
| BS/EN-50419:2006 | Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE) |
| IEC 60601-1:2015, Ed. 3.1 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-11:2015 | Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment |
| IEC 60601-1-2:2014 | Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests |
| United States Government Title 47 (FCC) CFR Part 15 | Federal Communications Commission (FCC), Telecommunications, RF Devices |

**List of Standards Development Organizations (SDO) or Regulatory Authorities:**

- American National Standards Institute (ANSI)
- Association for the Advancement of Medical Instrumentation (AAMI)
- European Norm (EN) European standards for products and services by European Committee for Standardization
- Federal Communications Commission (FCC)
- International Electrotechnical Commission (IEC)
- International Organization for Standardization (ISO)
- Department of Transportation (DOT) United Nations (UN) number
- Food and Drug Administration (FDA)
- Code of Federal Regulations (CFR)

## MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

Freespira is intended for use in the electromagnetic environment specified below. The customer or the user of Freespira should assure that it is used in such an environment.

| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
|---|---|---|
| RF emissions BS/EN 55011:2016 CISPR 11: 2015 | Group 2 | Freespira must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| RF emissions BS/EN 55011:2016 CISPR 11: 2015 | Class B 30 MHz to 1 GHz | Freespira is suitable for use in all establishments, including domestic establishments and those directly connect to the public low-voltage (110V) power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC/EN61000-3-2 | Class B | |
| Voltage fluctuations/flicker emissions IEC/EN61000-3-3 | Complies | |

## MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Freespira is intended for use in the electromagnetic environment specified below. The customer or the user of Freespira should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| Electrostatic Discharge (ESD) IEC/EN61000-4-2 | ± 2, 4, 8kV contact discharge | 8 kV | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| | ± 2, 4, 8, 15kV air discharge | 15 kV | |
| Electrical fast transients/bursts IEC/EN 61000-4-4 | ± 2 kV for power supply lines | ± 2 kV | Mains power quality should be that of a typical commercial or hospital environment. |
| | ± 1 kV for input/output lines | ± 1 kV | |
| Surge IEC/EN 61000-4-5 | ± 1 kV line(s) to line(s) | ± 1 kV | Mains power quality should be that of a typical commercial or hospital environment. |
| | ± 2 kV line(s) to earth | ± 2 kV | |

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11 | <5 % $U_T$ (>95 % dip in $U_T$) for 0.5 cycle | <5% | Mains power quality should be that of a typical commercial or hospital environment. If the user of Freespira requires continued operation during power mains interruptions, it is recommended that Freespira be powered from an uninterruptible power supply or a battery. |
| | 40 % $U_T$ (60 % dip in $U_T$) for 5 cycles | 40% | |
| | 70 % $U_T$ (30 % dip in $U_T$) for 25 cycles | 70% | |
| | <5 % $U_T$ (>95 % dip in $U_T$) for 5 s | <5% | |
| Power frequency (50/60Hz) magnetic field IEC/EN61000-4-8 | 30A/m | 30A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

Note: $U_T$ is the a.c. mains voltage prior to application of the test level.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| Conducted RF IEC/ EN61000-4-6 | 3 Vrms 80% at 2 Hz 150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the Freespira system, including cables, than the recommended separation distance calculated from the equation applicable to the Frequency of the transmitter. Recommended separation distance:<br>d =(1.2)√P 80MHz to 800MHz  d =(2.3)√P 800MHz to 2.7GHz<br>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).<br>Conducted Immunity: d=(1.2)√P 150 kHz to 80 MHz<br>Field strength from fixed RF transmitters, as determined by an electro-magnetic site survey[a], 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 Immunity IEC/EN61000-4-3 | 10 V/m 80% at 2 Hz 80MHz to 2.7 GHz | 10 V/m | |

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Freespira system is used exceeds the applicable RF compliance level above, the Freespira system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Freespira system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the system:**

Freespira is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system 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) | | |
|---|---|---|---|
| | 150kHz to 80MHz ($d=1.2\sqrt{P}$) | 80MHz to 800MHz ($d=1.2\sqrt{P}$) | 800MHz to 2.5GHz ($d=2.3\sqrt{P}$) |
| 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 |

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

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

| Symbol / Icon | Symbol Designation | Name or Title | Meaning and Function |
|---|---|---|---|
| freespira | N/A | Freespira Logo | Freespira product logo |
|   | EN 50419 Figure 1 (Modified) | The word Li-Ion under the WEEE symbol | The symbol indicating separate collection for EEE. According to the Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU. Contains a Lithium Ion battery, dispose of it properly. Check with your local authority for recycling advice. |
|  | ISO 7000-2607 ANSI/ AAMI/ISO 15223-1 5.1.4 | Use-by date | To indicate the date after which the medical device is not to be used. This symbol shall be accompanied by a date in the format YYYY-MM. |
|  | IEC 60417-5140 | Non-ionizing electromagnetic radiation | To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems, e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment. |
|   | ISO 7000-2493 ANSI/ AAMI/ISO 15223-1 5.1.6 | Catalog number | To Indicate the manufacturer's catalog number, reference number, or reorder number so that the medical device can be identified. The catalog number shall be adjacent to the symbol. |

| | | | |
|---|---|---|---|
|  | IEC 60417-5333 | Type BF applied part | To identify a Body Floating type applied part complying with IEC 60601-1. |
|  | SO 7010-M002 | Refer to instruction manual/booklet | Safety sign for mandatory action. To signify that the instruction manual/booklet must be read. |
|  | ISO 7000-2498 ANSI/ AAMI/ISO 15223-1 5.1.7 | Serial number | To indicate the manufacturer's serial number so that a specific medical device can be identified. The serial number shall be adjacent to the symbol. |
|  | ISO 7000-2492 ANSI/ AAMI/ISO 15223-1 5.1.5 | Batch code | To indicate the manufacturer's batch code, lot number, or batch number so that the batch or lot can be identified. The batch code shall be adjacent to the symbol. |
|  | ISO 7000-3082 ANSI/ AAMI/ISO 15223-1 5.1.1 | Manufacturer | To indicate the medical device manufacturer. This symbol shall be accompanied by the name and address of the manufacturer adjacent to the symbol. The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. |

| | | | |
|---|---|---|---|
|   | IEC 60529 | Ingress Protection Rating | Ingress protection rating for enclosure of equipment. First digit represents solids, second digit represents water. Solid 2 – Protected against a solid object greater than 12.5 mm such as a finger. Water 1 – Protected against vertically falling drops of water |
|  | ISO 7000-1641 ANSI/ AAMI/ISO 15223-1 5.4.3 | Consult instructions for use | To indicate the need for the user to consult the instructions for use, operator's manual, operating instructions, user's guide, or user's manual. |
|  | ISO 7000-0434A ANSI/AAMI/ISO 15223-1 5.4.4 | Caution, consult accompanying documents | To indicate the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself. |
|  | ISO 7000-0632 ANSI/ AAMI/ISO 15223-1 5.3.7 | Temperature Limit | To indicate the maximum and minimum temperature limits at which the item shall be stored, transported, or used. The symbol should be accompanied by the applicable temperature limits. |
|  | ISO 7000-2620 ANSI/ AAMI/ISO 15223-1 5.3.8 | Humidity Limitation | To indicate the acceptable upper and lower limits of relative humidity at which the item shall be stored, transported, or used. The symbol should be accompanied by the applicable relative humidity limits. |

| | | | |
|---|---|---|---|
|  | ISO 7000-2621 ANSI/ AAMI/ISO 15223-1 5.3.9 | Atmospheric Pressure Limitation | To indicate the acceptable upper and lower limits of atmospheric pressure at which the item shall be stored, transported, or used. The symbol should be accompanied by the applicable atmospheric pressure limits. |
|  | ISO 700-0626 ANSI/ AAMI/ISO 15223-1 5.3.4 | Keep away from rain; Keep dry | To indicate that the device and/or transport package needs to be protected from moisture or rain and in dry conditions |
|  | IEC 60417- 5001B | Battery status | To identify the battery condition indicator. In combination with an indicator such as an LED, this symbol may be used to indicate the battery is being charged |
|  | IEC 60417-5172 | Class II equipment | To identify equipment meeting the safety requirements specified for Class II or double insulated equipment according to IEC 61140. Class II equipment does not require a safety connection to electrical earth (ground). |

| | | | |
|---|---|---|---|
|  | IEC 60417-5009 | Stand-by | To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption. |
|  | ISO 7000-2609 ANSI/ AAMI/ISO 15223-1 5.2.7 | Non-sterile | To indicate that the device that is normally provided sterile in the same or similar packaging has not been sterilized. This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions. |
|  | N/A | Single Patient Use | Indicates that the item is intended for use on a single patient. |
|  | EN 15986 | Contains or Presence of Phthalates, DEHP | Indicates that the material used for the manufacture of this specific medical device contains Bis(2-ethylhexyl)phthalate (DEHP). |

| | | | |
|---|---|---|---|
|   | N/A | Does not contain natural rubber latex | Indicates that the product does not contain natural rubber latex or is not made with natural rubber latex. |
|  | N/A | Bluetooth Symbol / Logo | To indicate that the device is a Bluetooth wireless technology enabled product. |
|   | N/A | Canadian Standards Association certification | Indicates that the product was tested and has met the certification requirements for electrical, plumbing and/or mechanical products. The “US” signifies that the product has been evaluated to the applicable ANSI/UL Standards, for use in the U.S. |
|   | N/A | Rx ONLY | To indicate that the device is a prescription device. “Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed healthcare provider.” References: Section 126 of the FDA Modernization Act. Guidance for Industry and FDA on Alternative to Certain Prescription Device Labeling Requirements, document number 1150. |

| | | | |
|---|---|---|---|
|  | USB Specification Rev 2.0 Figure 6.5 | USB 2.0 | To indicate a Universal Serial Bus (USB) Connection. |
|  | N/A | Do not use tools. | To indicate that the device should not be modified or opened with tools. |
|  | IEC 60417-6042 | Caution, risk of electric shock | To identify equipment, for example, the welding power source, that has risk of electric shock. |
|  | N/A | Strangulation warning | To indicate that the cords or tubing on the product present a potential strangulation hazard. |




℞