User Manual

freespira

Contact Information

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

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INDICATIONS FOR USE

Freespira is indicated as an adjunctive treatment of symptoms associated with Panic Disorder (PD) or Post-Traumatic Stress Disorder (PTSD), to be used under the direction of a 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 Compatibility" 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 and then used twice a day at home for 4 consecutive weeks. It provides biofeedback to help patients retrain their breathing.

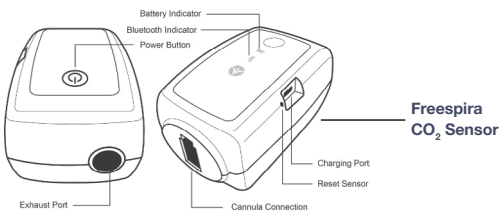
The system consists of a CO_2 sensor fitted with a disposable nasal cannula. The sensor samples and analyzes exhaled breath to determine End Tidal Carbon Dioxide ($ETCO_2$) and Respiration Rate (RR) and transmits this data via Bluetooth® wireless technology to the display device (tablet) for display using the Freespira software application (App).

The App displays the breathing pattern including treatment session progress, respiratory rate, and $ETCO_2$ levels.

By providing visual and audio feedback, the App guides the patient through a series of breathing exercises while coaching them on how to adjust their breathing.

THE FOLLOWING ITEMS ARE INCLUDED FOR MODEL

- Freespira CO_2 sensor
- White AC adapter/charging cable for charging the sensor
- Two (2) Freespira CO_2 cannulas
- Tablet (with cover), with the Freespira app installed
- Black AC adapter/charging cable for charging the tablet
- Documentation: Freespira Start Here, Information & Resources and return mailing label



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

GETTING STARTED

Refer to the Freespira Start Here Guide that comes with the system for information on how to set up Freespira.

THE FREESPIRA SENSOR

The Freespira sensor contains sophisticated technology that measures respiration rate (RR) and the amount of carbon dioxide (CO_2) in sampled exhaled air. The sensor communicates using Bluetooth with the tablet running the Freespira App and will connect automatically when the sensor is turned on and the App is started on the tablet.

The Freespira sensor is equipped with a rechargeable battery and is charged using the white colored AC adapter/charger and cable.

The white AC adapter/charger and cable provided with the sensor are the only ones that should be used to charge the sensor. It is a good practice to charge the Sensor overnight every day after you finish the day's second session.

Please charge the sensor before you first use it. When the battery in the sensor is fully charged you will be able to use the sensor for at least four 17-minute sessions. To use the sensor under battery operation for a single 17-minute session be sure you have charged it for at least 2 hours.

The Freespira sensor can be used while the AC adapter/charger is connected.

FEATURES OF THE SENSOR

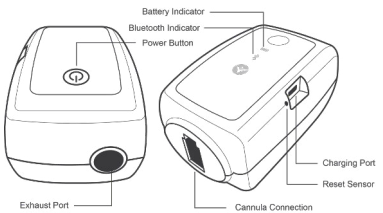


FIGURE 1

Sensor Power Button: Press and release the power button to turn the sensor on or off. The light on the power button will turn green if the sensor turns on successfully. If the light on the power button flashes orange, it means that there is not enough charge remaining for one 17-minute session and you must charge the sensor before use.

Battery Indicator: When the charger is connected to the sensor and plugged into an AC power outlet, the battery indicator light will blink green until the battery is fully charged. When it is fully charged the battery indicator light will stay a steady green.

Bluetooth Indicator: The Bluetooth indicator 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 light will continue to flash.

Cannula Connection Port: This is where you plug the Freespira cannula to the sensor.

Reset Sensor: 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.

Charger Connection: To charge the sensor, plug the Sensor AC Adaptor cable into the charger connection.

Exhaust Port (not shown): The sensor will analyze your breath and the gases will exit through this port.

TABLET

The tablet is equipped with a rechargeable battery and comes with its own specific (black) AC adapter / charger and cable. The AC adapter / charger and cable that are provided with the tablet are the only ones that should be used with the tablet.

FEATURES OF THE TABLET

- **Tablet Power Button:** Press and release the power button to turn the sensor on or off. If your tablet goes into sleep mode, press the power button once quickly to wake the screen.
- **Volume Button:** Press the volume button up to increase the volume and down to decrease it.
- **Charger Cable Connection:** To charge the tablet, plug the sensor AC adaptor cable into the charger cable connection.

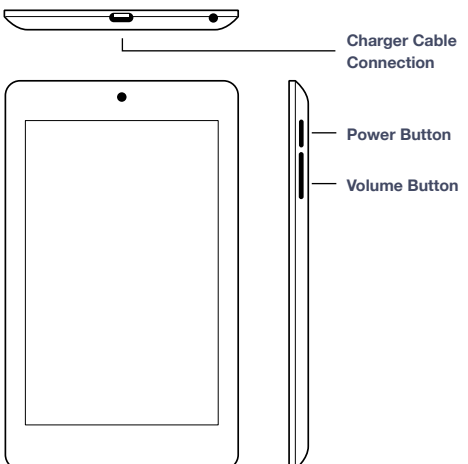


FIGURE 2

PANIC DISORDER SEVERITY SCALE (PDSS)

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 3 and 4). 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.

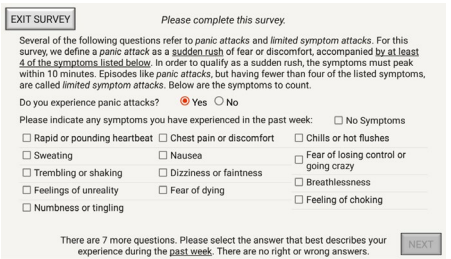


FIGURE 3

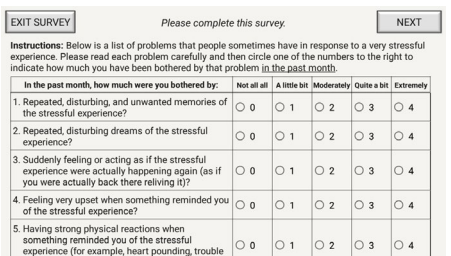


FIGURE 4

For assistance in setting up and using the Freespira system, watch the Freespira Video which is available on the tablet home screen.

A session is 17 minutes long and consists of three stages:

BASELINE · PACING · TRANSITION

During the 2-minute Baseline stage, the App records your End Tidal Carbon Dioxide ($ETCO_2$) and Respiration Rate (RR) without showing you the values. The Baseline Stage information can be reviewed by you and your provider/trainer later.

During Baseline:

- Sit quietly with your eyes closed and listen to the instructions.
- Breathe normally through your nose.

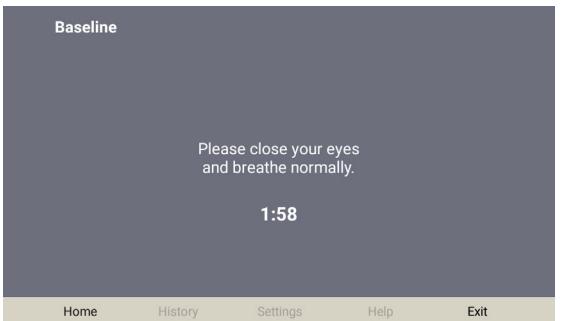


FIGURE 5

BASELINE · **PACING** · TRANSITION

The Pacing stage is 10 minutes long. During this time, you breathe with the tones and adjust your $ETCO_2$ by varying the amount of air inhaled with each breath. The tones are set for 13, 11, 9 or 6 breaths per minute and are changed each week of the program. Figure 6 is the screen displayed during Pacing. Messages are shown in the area below the graph to provide feedback and guidance.

CONTROLS ON THE PACING SCREEN

- **Current $ETCO_2$ Level:** The number in the blue box shows the $ETCO_2$ from your last breath. The blue line leading up to the blue box shows a record of your CO_2 level during the current breathing session.
- **Target $ETCO_2$ Level:** The white box next to the current CO_2 level shows the Target CO_2 level, which is 40 mmHg ("millimeters of Mercury").
- **Current Respiration Rate:** The number in the green box shows your current respiration rate (RR). The green line leading up to the green box shows a record of your RR during the current breathing session.
- **Target Respiration Rate:** The white box next to the current respiration (RR) rate shows the Target RR.

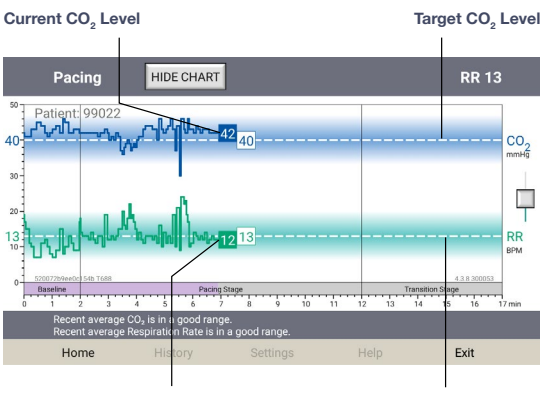


FIGURE 6

Your goal is to breathe at both the target RR while maintaining your CO_2 value within the target range.

You 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 or to prevent CO_2 from decreasing when they slow down their breathing. 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. Do your best to meet the CO_2 goal, even if you are only making small increases in your CO_2 level.

During the Pacing Stage, you will be directed to:

- "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 tone and one at the end of the exhale tone. You should pause your breathing during these pauses.

Remember your goal during the Pacing stage is to increase your CO_2 levels to the 37-42 mmHg Range.

Make sure you can hear the tones and instructions, if you cannot hear the tones, increase the volume of the App. See Figure 7 for the volume control and the Icons on the Pacing stage screen.

Icons on the Pacing Screen

- **Pause/Play:** Touch this icon to pause the session. When the session is paused this icon turns into a **Play** Button which you can touch to resume the session. After 6 minutes of pausing, it will stop the session, save it in the History and return to the Home Screen.
- **Volume Control:** You can move this icon up to increase the volume or move it down to decrease the volume.
- **View Option (Graph/Chart):** Touch the icon in the top left of the screen to toggle the view between Table and Chart using the **SHOW CHART** and **HIDE CHART** icons. The Table view (Figure 8) shows just the CO_2 and respiration rate values plus messages but not the chart.

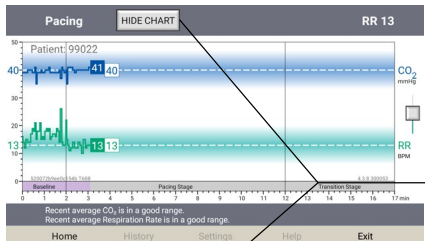


FIGURE 7

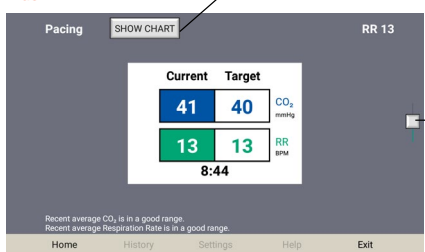


FIGURE 8

BASELINE · PACING · **TRANSITION**

After the 10-minute Pacing stage you will hear audio instructions as the session moves automatically into the Transition stage.

The goal of this 5-minute Transition stage is to continue meeting the targeted CO_2 and respiration rate (RR) without the aid of the pacing tones.

- Try to maintain the same breaths per minute and $ETCO_2$ levels as during Pacing.
- Try to only look at the screen occasionally, working your way to only checking about every 30 seconds.

When the session is completed, take off the cannula and you can review the session or exit the App.

The sensor will turn off automatically.

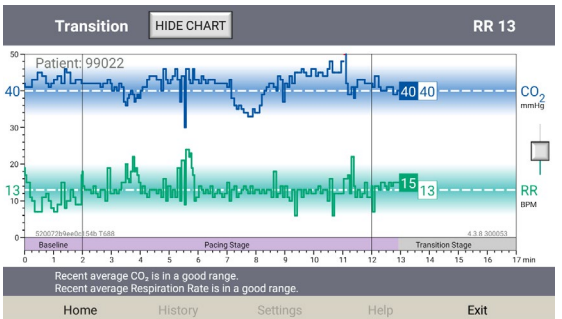


FIGURE 9

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

The previous section talked about breathing session screens. In this section are descriptions of the other screens in the Freespira App.

HOME TAB

This screen shows sensor preparation messages and will display “Please breathe into the Cannula” when it is ready to begin a session (Figure 10).

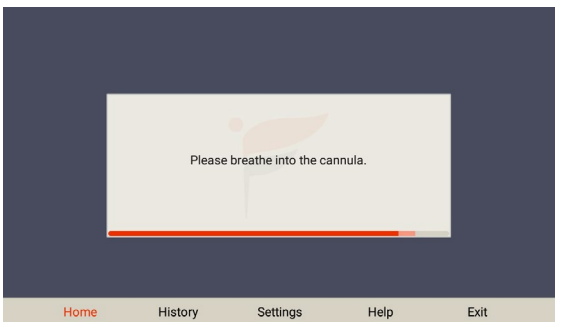


FIGURE 10

HISTORY TAB

Touch the History button to display a list of the sessions that you have completed to date (Figure 11).

View: To view a graph of the session data:

- Touch the row associated with the session you want to review and then touch the **View** button, or
- Touch and hold the row of the session you want to review.

When you choose a session from the History screen (Figure 11), you will see the chart from the selected session (Figure 12).

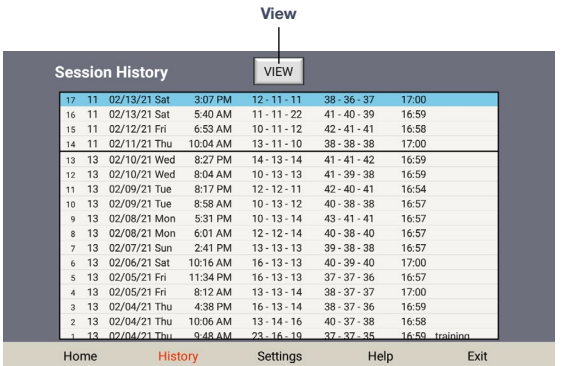


FIGURE 11

HISTORY TAB (CONTINUED)

Controls on the Session Review Page

- **Previous:** Touch this button to view the data for the session in the session history list that was most recently recorded before this session.
- **Next:** Touch this button to view the data for the session in the session history list that was recorded after this session.
- **Averages:** At the bottom of the screen is a table which shows your average $ETCO_2$ and RR during each stage of the session.

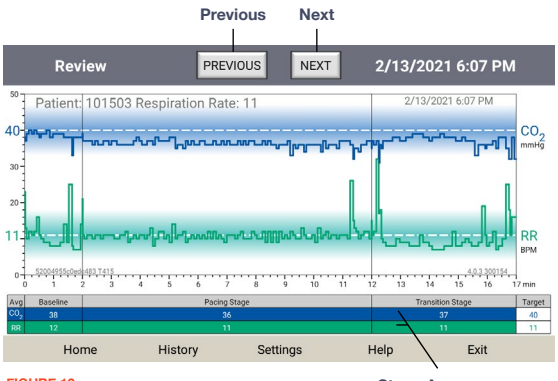


FIGURE 12

SETTINGS TAB

Controls on the Settings Screen

- **Manual Update:** This button is used 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:** This button is for setting the target respiration rate for your weekly sessions.
- **More:** See the following page for details about settings that can be adjusted using the More button.

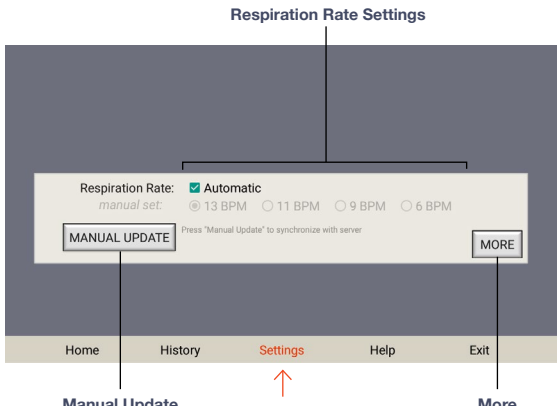


FIGURE 13

SETTINGS TAB (CONTINUED)

These options are available after pressing the More button on the Settings Tab (Figure 14)

- **Training:** Touch the Training button on the Settings screen to enter training mode. The training mode allows you to “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 section “Troubleshooting Information”.
- **Admin:** The Admin button (password protected) may be used by your therapist or trainer (only) to access other features.

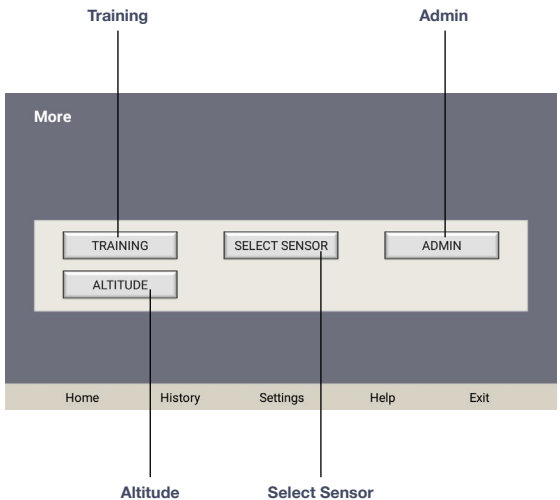


FIGURE 14

HELP TAB

Touching the **Help** icon on the tablet will open the Help screen (Figure 15). The Help screen has links with instructions as well as links to the Freespira Privacy Notice and Terms and Conditions.

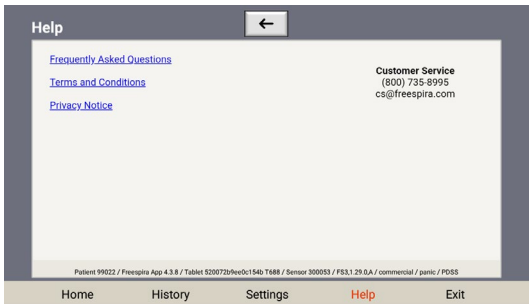


FIGURE 15

The table below describes problems that you 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 the AC Adapter. • 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 it functions). • Press and hold the **ON** button on the Sensor. The **ON** button will turn green indicating that the power is on. • Reset the Sensor by inserting a toothpick or a bent paperclip into the Reset Sensor slot and push gently for one second. The Sensor should then power on. • After the power is on, the Sensor needs to warm up for approximately 4 minutes before it is ready to start as a breathing session. Do not turn the Sensor off during this time or the startup process will need to be repeated.
"Session Aborted" Message appears	• Press **START** to begin a new session.

App gives “Sensor Not Connected” Error message and/or Bluetooth Indicator is Orange	• Check the message on the tablet for instructions. • Call Customer Service for further assistance 800.735.8995.
$ETCO_2$ Readings are low or fluctuating	• Check the entire length of the Cannula tube and assure there are no kinks or cuts/breaks in it. • Replace Cannula

SENSOR MESSAGES – DURING START UP

Tablet Message	Action by User
Sensor Preparing...Please wait to put on cannula.	Nothing.
Connecting to the sensor.	Nothing.
The Sensor is in Sleep Mode, Attempting to wake Sensor.	Press **START** or power cycle the Sensor.
Check the Cannula is not occluded or kinked and the Sensor exhaust port is clear.	Check the 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.

Tablet Message	Action by User
Sensor battery is low (=< 15%). Please start charging before beginning session.	Plug sensor into charger.
Tablet battery is low (=< 15%). Please start charging before beginning session.	Plug tablet into charger.
Check the Cannula connection. Failed to Calibrate – Please disconnect and reinsert the cannula and power cycle the sensor.	Make sure cannula isn't on during warm up. Power cycle the sensor.
Oops, something is wrong with the sensor. Please turn sensor off/on to retry connection.	Turn the sensor off and on.

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.	Power cycle the sensor.
Sensor Error. Check the Cannula is not occluded or kinked, and the Sensor exhaust port is clear.	Check the cannula.

SENSOR ERROR CODES

Error Code	Meaning	Fix
1000–1001	Bluetooth connection problem	Turn everything (sensor and tablet) off and then back on.
2004	Room air validation failed	Re-prepare sensor. If same error happens again on same unit, replace sensor.
2006	Sensor is reporting really high $ETCO_2$ numbers	Re-prepare sensor, If same error happens again on same unit, replace 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.
3. Go to the **Settings** Tab.
4. Touch the **MORE** button.

5. Touch the **Select Sensor** button (Figure 16).

- You will see a pop up that lists the sensor available to connect (Figure 17).
- You can see the Serial Number following “Freespira-” (Freespira-300053 in the example to the right) (Figure 17).
- If the serial number shown on the popup does not match the one on the bottom of the Freespira sensor you want to connect, press the Scan for unpaired CO_2 sensor devices bar at the bottom of the popup (Figure 17).
- The tablet will scan for other Freespira sensors and will show you if it finds another one.

6. Touch the serial number of the Freespira sensor you want to connect to (Figure 17).
7. You are now ready to start a Freespira session with the newly connected sensor.

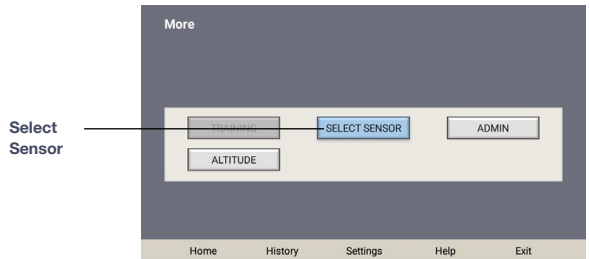


FIGURE 16

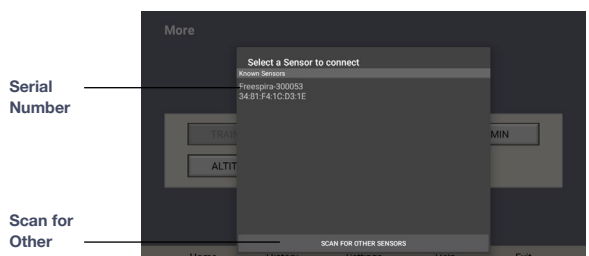


FIGURE 17

STORAGE INSTRUCTIONS

Be sure your Freespira sensor is turned off when you are not using it.

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 Specifications.

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.

DISPOSAL

When you have finished your Freespira treatment, the system must be returned to Freespira using the original shipping containers.

Refer to the Start Here Guide for how to return Freespira.

FREESPIRA CO_2 SENSOR

Model name	Freespira CO_2 Sensor
Model #	AS-3140
Power source	Internal, rechargeable Battery
AC adapter/charger rating	6 Watts (Maximum), 105V-240V @ 0.2 Amps (50/60Hz)
Battery life	Four (4) 17 Minute Sessions per fully-charged Battery
Battery recharge time	Fully charged in 6 hours
Expected service life	90 Days; Single User, Multi-use
Shelf life	1 year
Warm Up Time	Up to 2 minutes

End Tidal CO_2 Range	20 to 50 mmHg
Weight	0.5 pounds
Outer Product Dimensions	2 3/8” Wide x 3 5/8” Deep x 2.0” High

Operating Conditions

Temperature	5°C to 40°C (41°F to 104°F)
Humidity	15% to 85% (Non-condensing)
Pressure	1060hPA to 700hPA (-1000 Feet to 10,000 Feet Altitude)

Storage/Transportation

Temperature	-5°C to 35°C (23°F to 95°F)
Humidity	15% to 85% (non-condensing)
Pressure	1060hPA to 700hPA (-1000 Feet to 10,000 Feet Altitude)

Wireless Technology

Communication	Wireless Communication between the Sensor and the Tablet operates over the 2400-2480MHz ISM Band, per the Bluetooth 3.0 Core Specification. The Sensor incorporates a Bluetooth Class 2 Radio Module from ST Microelectronics, P/N SPT2632C2A.AT2. The specified distance range is 10 Meters. The maximum RF Output Power is -1.36dBM ***Contains Transmitter Module FCC ID: X3ZBTMOD5 IC: 8828A-MOD4***

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, and 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, Wi-Fi 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 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
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
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 Annex IX of Directive 2012/19/EU (WEEE)

Source SDO / Number	Title / Description
IEC 60601-1:1998 +A1:1991+A2:1995, ED. 2.0	Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-1-11:2010	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 60601-1-2:2007	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
AAMI/ANSI/ISO 10993-1:2009/(R)2013	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within A Risk Management Process
United States Government Title 47 (FCC) CFR Part 15	Federal Communications Commission (FCC), Telecommunications, Radio Frequency 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)
- 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 EN 55011:2009+A1:2010, CISPR 11: 2009+A1:2010	Group 2	Freespira must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions EN 55011:2009+A1:2010, CISPR 11: 2009+A1:2010	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	± 6 kV contact	2,4,6	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	± 8 kV air	2,4,8	
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 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: d =(1.2)√P 80MHz to 800MHz, d =(2.3)√P 800MHz to 2.5GHz 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). Conducted Immunity: d=(1.2)√P 150 kHz to 80 MHz Field strength from fixed RF transmitters, as determined by an electromagnetic 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	3 V/m 80MHz – 2.5GHz	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√P)	80MHz to 800MHz (d=1.2√P)	800MHz to 2.5GHz (d=2.3√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 application 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	Name or Title
freespira	Freespira Product Logo
	Caution: Consult Accompanying Documents
	Battery Check
	Bluetooth Connection
REF	Catalog Number
	Consult Instructions for Use

	Do Not Use if Package is Damaged
	Output; Exit
	Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed healthcare provider
	Humidity Limitation
	Input Connection

	Keep Dry
	Manufacturer
	Non-Sterile
	Presence of DEHP
	Stand By

	Reset
	Serial Number
	Temperature Limitation
	USB Connection
	Separate Collection: Please contact your Distributor or the Manufacturer for recycling of this Device
	Type BF Applied Part

	Class 2 Device: The CO_2 Sensor relies on supplemental insulation to protect user from electrical power
	To indicate that the cords or tubing on the product present a potential strangulation hazard.
	Safety sign for mandatory action. To signify that the instruction manual/booklet must be read.
	Indicates that that the item is intended for use on a single patient.
	To indicate that the device should not be modified or opened with tools.

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