

FreeStyle® Comfort®

Portable Oxygen Concentrator with autoSAT®, UltraSense® and autoDOSE®



User Manual (us)









































RX ONLY

U.S. Federal Regulation restricts this device to sale by order of physician.

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Glossary of Symbols

	Manufacturer ISO 15223-1 #5.1.1 (7000:2019 #3082)		Caution ISO 15223-1 #5.1.4
	Date of Manufacture ISO 15223-1 #5.1.3		Serial Number ISO 15223-1 #5.1.7 (7000:2019 #2498)
	Catalogue Number ISO 15223-1 #5.1.6 (7000:2019 #2493)		Temperature Limit ISO 15223-1 #5.3.7 (7000:2019 #0632)
	Keep Dry ISO 15223-1 #5.3.4 (7000:2019 #0626)		Medical Device ISO 15223-1 #5.7.7
	Consult Instructions for Use ISO 15223-1 #5.4.3 (7000:2019 #1641)		This way up ISO 7000:2019 #0623
	Fragile, handle with care ISO 7000:2019 #0621		Stacking limit by number ISO 7000:2019 #2403
	Recycle ISO 7000:2019 #1135		Atmospheric pressure limitation ISO 7000:2019 #2621
	Storage Humidity Range ISO 7000:2019 #2620		ETL: Certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards.
	Contains hazardous substances ISO 7000:2019 #3723		Country of Manufacture ISO 7000:2019 #6049
	Power Switch ISO 7000:2019 #5009		No Smoking ISO 7010:2019 #P002
	Refer to instruction manual/booklet ISO 7010:2019 #M002		“Warning” symbol ISO 7010:2019 #W001
	No open flame ISO 7010:2019 #P003		Alternating Current IEC 60417 #5032
	Direct current IEC 60417 #5031		Non-ionizing Electromagnetic Radiation IEC 60417 #5140
	Class II Equipment, Double Insulated IEC 60417 #5172		Indicates the device would be unsafe in any MR environment. ASTM F2503-05
	Type BF Applied Part IEC 60417 #5333	IP22	Ingress protection against the insertion of fingers and protection against vertically or nearly vertically dripping water. IEC 60601-1 / EN 60529
	Low priority technical alarm 60601-1-8		RTCA/DO-160 Section 21 Category M Compliant The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria and use on board aircraft.
RX ONLY	Prescription Use Only: Federal law restricts this device to sale by or on the order of a physician.		Do not disassemble
	Use no oil or grease		Decrease flow
	Increase flow		O2 Outlet
	Menu button		Authorized Representative in the European Community EC REP: ISO 15223-1 #5.1.2 EU REP: ISO 15223-1:2021/Amd 1:2025
	Unique Device Identifier ISO 15223-1 #5.7.10		
	Waste Electrical and Electronic Equipment. Do not dispose of in unsorted municipal waste.		

FreeStyle Comfort

Introduction

Notice: Refer to this manual for operating instructions, troubleshooting, warnings, cautions, and specifications for the FreeStyle Comfort.

This manual may refer to FreeStyle Comfort as the device, (oxygen) concentrator, or unit interchangeably. Patient and user may be used interchangeably.

Introduction: The FreeStyle Comfort combines advanced oxygen concentrator and oxygen conserving technologies to create a portable device that allows for maximum portability and ambulation. The advanced pulse flow delivery quickly senses when the user breathes in and delivers a pulse of oxygen at the beginning of each inhalation. Pulse flow delivery is ideal for activities and time away from home. It conserves oxygen and extends battery life as opposed to continuous flow. The FreeStyle Comfort is lightweight enough to be carried via shoulder strap. It can be operated on AC (wall), DC (vehicle) or battery power.

Intended Use

The FreeStyle Comfort Oxygen Concentrator can deliver concentrated supplemental oxygen with either a fixed-minute pulse delivery or can be set to operate using autoSAT pulse delivery. The device is not intended for life support, nor does it provide any patient monitoring capabilities.

The FreeStyle Comfort is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation. The device is designed for use in the home, in a vehicle, and for use during air travel.

Indications for Use and Clinical Benefit

The FreeStyle Comfort Oxygen Concentrator can deliver concentrated oxygen with either a fixed-minute pulse delivery or can be set to operate using autoSAT pulse delivery. The FreeStyle Comfort is used on a prescriptive basis by patients requiring supplemental oxygen to increase blood oxygen saturation. FreeStyle Comfort may be used in the home, institution, and transport modes.

Contraindications

- This device is not intended to be used for life support. Additional monitoring may be required for any user who is unable to communicate discomfort.

- This device is not intended for use with a tracheotomized patient.
- This device is not intended for use in or near magnetic resonance environments, such as MRI machines.
- DO NOT use this oxygen concentrator until you first seek medical advice. This device should not be used without first being prescribed by a physician. In certain circumstances, the use of non-prescribed oxygen can be hazardous.
- DO NOT change the flow selection unless you have been directed to do so by a licensed clinician. It is very important to select only the prescribed level of oxygen. The Equipment Provider who supplies your oxygen equipment will demonstrate how to set the prescribed flow rate. Pulse dose mode settings must be determined for each user individually for their needs at rest, during exercise, and when traveling.
- DO NOT use in the presence of flammable anesthetics.
- Some respiratory efforts of the patient might not trigger the conserving function.

Patient Population

Oxygen Concentrators are intended to supply supplemental oxygen to users suffering from ailments which affect the efficiency of one's lungs to transfer oxygen in the air to their bloodstream. Oxygen concentrator use requires a physician's prescription.

This device is not intended for and has not been tested or approved for use with newborn, infant, or pediatric patient populations.

Users typically have good cognitive abilities and must be able to communicate discomfort. If the user is unable to communicate discomfort, or unable to read and understand the concentrator labeling and instructions for use, then use is recommended only under the supervision of one who can.

If any discomfort is felt while using the concentrator, users are advised to contact their healthcare provider. Users are also advised to have back-up oxygen available (i.e. cylinder oxygen) in the event of a power outage or concentrator failure. There are no other unique skills or user abilities required for concentrator use.

Service Life

The expected service life is five years.

Unpacking Your FreeStyle Comfort

Verify that all of the components listed are included in the package. If any items are missing, contact your oxygen provider immediately.

Standard Accessories

- Portable Oxygen Concentrator
- Carrying Bag
- Shoulder Strap
- 8-Cell Battery Pack
- AC Power Supply
- AC Power Cord
- DC Power Cable
- User Manual

Optional Accessories

- Additional 8-Cell Battery Pack
- 16-Cell Battery Pack
- Desktop Charger
- Accessory Bag

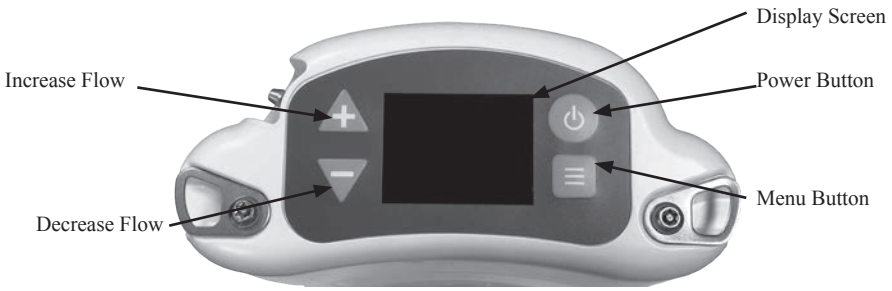
Getting to Know Your FreeStyle Comfort

Become familiar with the key features of the FreeStyle Comfort and its user interface.

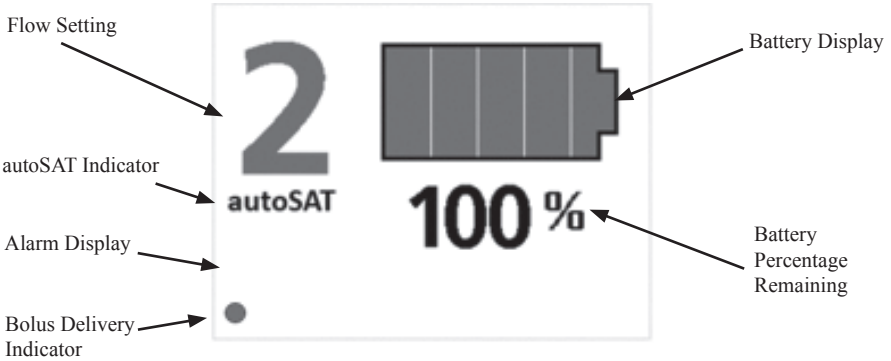
Front View



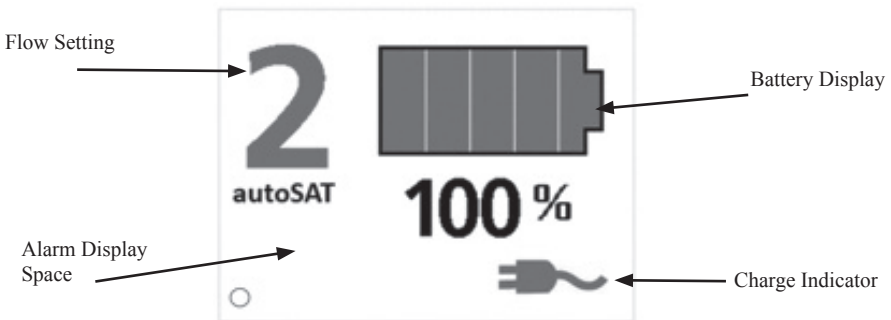
Top View



Display Screen On Battery



Display Screen On AC/DC Power



Safety Instructions

Important: Safety instructions are defined as follows:

- **WARNING:** Important safety information for hazards that might cause serious injury.
- **CAUTION:** Important information for preventing damage to the FreeStyle Comfort.
- **Note:** Information needing special attention.



WARNING:

- Federal (USA) law restricts this device to sale or rental by order of a physician or other licensed health care provider.
- Do not operate this equipment without first reading and understanding this manual. If you are unable to understand the warnings and instructions, contact your equipment provider before attempting to use this equipment; otherwise, injury or damage may result.
- If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.
- In the event there is a serious incident occurring with this device, the user should immediately report the incident to the provider and/or the manufacturer. A serious incident is defined as an injury, death, or potential to cause injury/death should there be a reoccurrence of the incident. The user can also report the incident to the competent authority in the country where the incident occurred.
- This product can expose you to chemicals including nickel, which is known to the state of California to cause cancer. For more information, go to www.p65warnings.ca.gov.
- The US Department of Transportation (DOT) and United Nations (UN) regulations require the removal of the battery from the device for all international airline travel when the oxygen concentrator is checked as luggage. When shipping the oxygen concentrator, the battery must also be removed from the device and packaged properly.
- Properly secure, belt or otherwise restrain the oxygen concentrator when in a vehicle during transport to prevent damage or injury.
- This device supplies high-concentration oxygen that promotes rapid burning. Do not allow smoking or open flames within the same room of (1) this device, or (2) any oxygen-carrying accessory. Failure to observe this warning can result in severe fire, property damage, and/or cause physical injury or death.
- “No Smoking – Oxygen in Use” signs must be prominently displayed in the home, or where oxygen is in use. Users and their caregivers must be informed about the dangers of smoking in the presence of, or while using, medical oxygen.
- Smoking while using oxygen is the number one cause of fire injuries and related deaths. You must follow these safety warnings:
 - Smoking while wearing an oxygen cannula may cause facial burns and possibly death.
 - Removing the cannula and putting it on clothing, bedding, sofas, or other cushion material will cause a flash fire when exposed to a cigarette, heat source, or flame.
- Do not leave a nasal cannula on or under clothing, bed coverings or chair cushions. If the unit is turned on but not in use, the oxygen will make the material flammable. Ensure the power is off when the oxygen concentrator is not in use.
- If you smoke, these 3 steps may save your life: turn off the oxygen concentrator, take off the cannula, and leave the room where this device is located.
- Do not use your oxygen concentrator in the presence of flammable gases. This can result in rapid burning causing property damage, bodily injuries or death.
- Approved oxygen delivery accessories are designed to reduce the propagation of fire for the safety of the patient. Use of unapproved accessories may increase the risk of injury or damage related to fires.

Operation

- Use no oil, grease, or petroleum-based or other flammable products with the oxygen-carrying accessories or the oxygen concentrator. Only water based, oxygen compatible lotions or salves should be used. Oxygen accelerates the combustion of flammable substances.
- The concentrator should be located as to avoid smoke, pollutants or fumes.

Smoking, Fire

- Do not allow smoking, candles, or open flames in the same room with the device or the oxygen-carrying accessories.

FreeStyle Comfort

- Do not operate the unit in a restricted or confined space (i.e., a small case or handbag) where ventilation can be limited. This can cause the oxygen concentrator to overheat and impair performance. The device should only be used with recommended bags and accessories.
- Do not allow either the air intake or the air outlet vents to become blocked. Do not drop or insert any objects into any openings on the device. This can cause the oxygen concentrator to overheat and impair performance.
- Operating the oxygen concentrator outside of the operational temperature specifications can limit the concentrator's ability to meet oxygen concentration specifications. Refer to the specification section of this manual for temperature limits.
- Wind or strong drafts can adversely affect accurate delivery of oxygen therapy.
- If the oxygen concentrator has been dropped, damaged beyond typical wear and tear or exposed to water, please contact your equipment provider for inspection or possible repair of the device.
- Only use accessories recommended by the manufacturer. Use of any other may be hazardous, cause serious damage to your oxygen concentrator and will void the warranty.
- The use of some oxygen administering accessories not specified for this oxygen concentrator may impair its performance. Recommended accessories are referenced within this manual.
- Do not attempt any maintenance other than the possible solutions listed within this manual.
- Small parts may present a potential choking hazard.
- Avoid contact with exhaust air vent for longer than 10 seconds as it may be warm.

Power

- As with any electrically powered device, the user may experience periods of non-operation as a result of electrical power interruption, or the need to have the oxygen concentrator serviced by a qualified technician. The oxygen concentrator is not appropriate for any user who would experience adverse health consequences as the result of such temporary interruption.
- Inspect the power cord and plug for signs of

damage. Do not use the oxygen concentrator if it has a damaged power cord or plug.

- Do not use extension cords with this unit or connect too many plugs into the same electrical outlet. The use of extension cords could adversely affect the performance of the device. Too many plugs into one outlet can result in an overload to the electrical panel causing the breaker/fuse to activate or fire if the breaker or fuse fails to operate.
- While using the portable oxygen concentrator outdoors with the ac power supply, connect the power supply into a ground fault interrupted (GFI) outlet only.
- The oxygen concentrator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is unavoidable, the device should be observed to verify normal operation.
- Use of cables and adapters other than those specified, with the exception of cables and adapters sold by the manufacturer of the medical electrical equipment as replacement parts for internal components, may result in increased emissions of decreased immunity of the oxygen concentrator.
- Use only electrical voltage specified on the specification label affixed to the device.
- This device is not approved for use in all environments. Exposure to certain electromagnetic sources may result in interference or unintended device performance. In the event of interference, the device should be shut down immediately.

Battery

- The oxygen concentrator must be off and disconnected from external power before removing the battery pack.
- The oxygen concentrator should not be operated or plugged in to external (AC/DC) power without a battery installed. Do not attempt to power on the unit or connect it to external power when the battery pack is removed.
- Only remove the battery pack when the unit is powered off and unplugged from the power supply. Do not attempt to remove the battery pack while the unit is still on or plugged into the power supply.

- The incorrect use of the battery can cause the battery to get hot, ignite, and may cause serious injury. Be sure not to pierce, strike, step on, drop the battery, or otherwise subject the battery to strong impacts or shocks. The use of a damaged battery may cause personal injury.
- Do not short-circuit the battery's metal contacts with metallic objects, such as keys or coins. This may cause sparks or excessive heat to be generated.

**CAUTION:**

- To prevent a void warranty, follow all manufacturers' instructions.
- No modification of this equipment is permitted.
- Only use the Manufacturer's provided batteries. For proper battery disposal, contact your Equipment Provider or your local government agency for disposal requirements.
- For oxygen concentrators equipped with batteries: Store in a cool and dry location to help ensure the longevity of your battery. Storing your oxygen concentrator for extended periods of time at high temperatures or with a fully charged or completely discharged battery can degrade its overall battery life. Do not attempt to open the battery; there are no serviceable parts inside the battery. Keep batteries away from children.
- In the event of an alarm or you observe the oxygen concentrator is not working properly; consult the Troubleshooting section in this manual. If you cannot resolve the problem, consult your Equipment Provider.
- Always disconnect AC power supply from the wall before disconnecting the AC power supply from the oxygen concentrator.
- Do not position the oxygen concentrator so that it is difficult to access the power cord.
- Always place oxygen supply tubing and power cords in a manner that prevents trip hazard or possible accidental strangulation.
- When using the oxygen concentrator in an automobile, boat, or on other DC sources with the DC power supply, make sure that the vehicle is started and running before connecting the oxygen concentrator. Failure to follow these instructions can result in the power supply not supplying power to the oxygen concentrator.
- DO NOT leave the oxygen concentrator or the power supply plugged into the vehicle if the ignition is in the OFF position. Doing so may drain the vehicle's battery.
- When the automobile in which you are using the oxygen concentrator unit is turned off, disconnect and remove the device from the automobile.
- Do not store the oxygen concentrator in a very hot or cold automobile or in other similar, high- or low-temperature environments.
- Operating or storing the oxygen concentrator outside of its normal operating temperature range and ambient pressure range (altitude) can affect performance and decrease battery run time and/ or increase battery charge time. Refer to the Specifications section in this manual for storage and operating temperature limits.

NOTE:

- There is never a danger of depleting the oxygen in a room when you use your oxygen concentrator unit.
- The manufacturer does not recommend the sterilization of this equipment.
- Do not operate the oxygen concentrator without the air intake filter in place. If a second filter is provided, insert the replacement filter before you clean the dirty filter. Clean the dirty filter in a warm soap and water solution, then dry thoroughly prior to use.
- Ensure the cannula is fully inserted and secure. This ensures that the oxygen concentrator can properly detect inspiration for oxygen delivery. During inhalation, you should hear or feel oxygen flow to the prongs of the nasal cannula.
- To mitigate harm caused by concentrator failure or power failure, equipment provider should assess the need for back-up oxygen during installation and periodically when these attributes change:
 - The condition of the patient
 - The environment in which the patient lives
 - The ability to resupply the patient with back-up supplies of supplementary oxygen.
- Lithium batteries may permanently lose capacity when exposed to extremely hot temperatures with the batteries fully charged or completely depleted. For extended storage, it is recommended that batteries be charged 25 to 50% and remain within a temperature range of -4°F – 68°F (-20°C – 20°C).

FreeStyle Comfort

- If the oxygen concentrator has been stored for an extended period of time outside of its normal environmental operating conditions shown in the specifications table, it should be allowed to return to normal operating temperature before being powered on.
- Portable and mobile RF communications equipment can affect medical electrical equipment.

Special Features

autoSAT

Traditional pulse dosing (fixed minute pulse) supplies the same amount of oxygen delivered to the patient per minute. If the patient inhales more often, such as during physical activity like walking, the amount of oxygen delivered decreases per breath to maintain the same amount per minute.

The autoSAT (automatic titration to patient's respiratory rate) function delivers a consistent pulse dose (bolus) volume of oxygen (up to 40 breaths per minute). As breath rate increases, such as during increased physical activity, the amount of oxygen delivered will stay the same per breath, which increases the amount of oxygen delivered per minute.

The autoSAT function is a default setting in the FreeStyle Comfort. The user can change the setting to traditional dosing by using the membrane keypad to switch off the autoSAT function. During normal operation, if after more than 15 seconds the device does not detect breath inhalation, the device will automatically begin dosing @ 20 breaths per minute until breath inhalation is detected. Upon detection, the device will resume normal operation in autoSAT mode.

UltraSense

This sensitive pulse dose trigger detects the pressure change during your breath and releases the pulse of oxygen when you inhale.

autoDOSE

Should a “no breath alarm” occur, this feature will pulse oxygen at 20 breaths per minute at the unit's current flow setting until the alarm state is resolved.

Inhalation Sensitivity

The FreeStyle® Comfort® offers an inhalation sensitivity mode. The user can adjust the sensitivity settings values from 1-5, where 1 is the least

sensitive, 5 is the most sensitive. The sensitivity function has a default setting of >-0.1 cm H₂O and a maximum adjustable range of -0.3 to -0.40 cm H₂O, negative pressure (inhalation) to trigger the flow (bolus) of O₂ to the user. In cases where shallow breathing cannot be detected at the device (default) sensitivity setting, the user can adjust the setting with the membrane keypad to increase inhalation sensitivity to trigger oxygen delivery at the desired flow setting.

myCAIRE

The FreeStyle Comfort Oxygen Concentrator utilizes wireless connectivity technology that pairs the oxygen concentrator to a mobile device or tablet using the myCAIRE app.

The myCAIRE™ app connects patients with home care providers (DME), allowing DMEs to view usage hours and flow settings of a connected CAIRE oxygen concentrator. The system uses wireless technology (BLE) to transmit information from the concentrator to a smart device, which then sends it to the provider. Home care providers can assist patients by addressing device notifications and supplying recommendations for troubleshooting remotely.



myCAIRE shares data from CAIRE oxygen concentrators without altering settings, performance, or therapy. It is not intended for monitoring, diagnosis, or treatment. The connection only sends data to the app in raw format, decodable solely by CAIRE, with no Protected Health Information or Personally Identifiable Information transmitted.

Data is linked to the patient account, encrypted, and stored securely in the Cloud. Both the app and DME web portal are password protected, ensuring only authorized access. A patient cannot sign up to the system by themselves. The DME must connect the patient to the concentrator provided to them. This adds an additional layer of security against potential misuse.

The system prevents unauthorized viewing of patient information across different DMEs. Patients can access the user manual, and request service from their home care provider.

Accessories

For proper performance and safety, use only these listed accessories supplied by CAIRE through your oxygen provider. Use of accessories not listed below could adversely affect the performance and/or safety of the concentrator.

FreeStyle Comfort Standard Accessories

Carrying Bag	MI396-1
Backpack	MI459-1
Shoulder Strap	MI397-1
AC Power Supply (All Cords Included)	PW036-1S
DC Power Cord	CD041-1
External Gross Particle Filter (Right)	FI226-1
External Gross Particle Filter (Left)	FI227-1

Optional Accessories Available

Additional 8-Cell Battery Pack	BT034-2S
16-Cell Battery Pack	BT035-1S
Desktop Battery Pack Charger	BT036-1
Carry-all Accessory Bag	MI320-2

Note: Additional options may be available for country-specific power cords where noted above. Contact CAIRE or your oxygen provider if alternate options are needed for order.

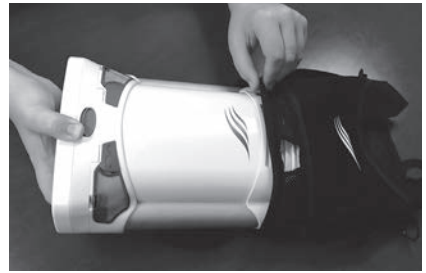
Carrying Bag Instructions

To insert and secure your FreeStyle Comfort in the carrying bag, utilize the following instructions.



INSERTING UNIT INTO CARRYING BAG

1. Insert unit into bottom of bag, properly aligning filters and battery openings.



2. Secure zipper around bottom of pouch.



SHOULDER STRAP INSTALLATION

1. Shoulder strap can be attached to either the unit directly or the carrying bag.
2. Clip strap onto the ring on the unit or bag.



FreeStyle Comfort

Operating Instructions

1. Locate and position the FreeStyle Comfort in a proper location for use.

- a. The concentrator should be well-ventilated so that the air intake filters and air outlet are not obstructed.
- b. The concentrator should be positioned so that all audible and visual indicators and alarms can be easily seen and heard.
- c. Be sure the air intake filters are in place before operating the unit. If the unit is missing a filter, contact your equipment provider.

2. Install a Battery Pack in the concentrator.

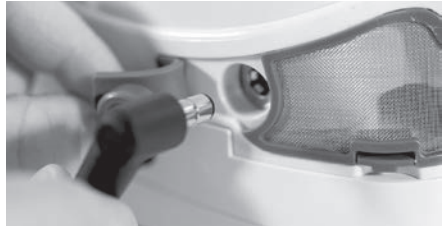
- a. Align the battery with the bottom housing from the center of the FreeStyle Comfort.



- b. Slide the battery inward until you hear a click to confirm that it has locked in place.

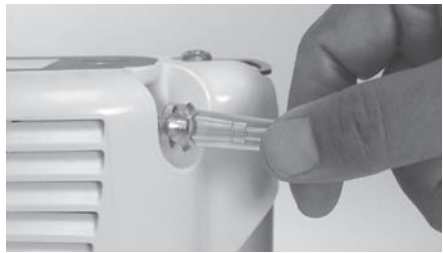


3. Insert the AC or DC power supply into the power port receptacle on the front, bottom right side of the unit.



4. Connect a nasal cannula to the oxygen outlet barb. Ensure the connection is secure before operation.

Note: Any cannula(s) used other than the recommended may affect performance.



Note: To Equipment Provider: The following oxygen administration accessories are recommended for use with the FreeStyle Comfort:

- Nasal Cannula with 7 feet (2.1 m) of tubing (Maximum LPM: 6 LPM): CAIRE Part Number 5408-SEQ
- Additional recommended accessories information is available online at www.caireinc.com.

5. Turn on the FreeStyle Comfort by pressing the power button and select your prescribed flow setting utilizing the increase (+) or decrease (-) flow buttons.



A brief audible alarm will sound to indicate the device has powered on.

Note: When the FreeStyle Comfort is initially turned on the default flow setting is 2. If the setting is changed, the unit will power on to the previous flow setting.

6. Position the nasal cannula on your face per the manufacturer's instructions provided with the cannula and breathe normally. You should feel a puff of oxygen delivered through the nasal cannula each time you inhale.

7. To change the flow setting, press the increase (+) or decrease (-) flow buttons to the desired flow rate. It is normal to hear a difference in sound as you change the flow settings.



autoSAT Pulse Volume (mL)*Setting					
Breath Rate	1	2	3	4	5
15	10.5	21.0	31.5	42.0	52.5
20	10.5	21.0	31.5	42.0	52.5
25	10.5	21.0	31.5	42.0	42.0
30	10.5	21.0	31.5	35.0	35.0
35	10.5	21.0	30.0	30.0	30.0
40	10.5	21.0	26.3	26.3	26.3

*Tolerance is +/- 15%

NON-autoSAT Pulse Volume (mL)* Setting					
Breath Rate	1	2	3	4	5
15	14.0	28.0	42.0	56.0	70.0
20	10.5	21.0	31.5	42.0	52.5
25	8.4	16.8	25.2	33.6	42.0
30	7.0	14.0	21.0	28.0	35.0
35	6.0	12.0	18.0	24.0	30.0
40	5.3	10.5	15.8	21.0	26.3

8. Turn the FreeStyle Comfort off by pressing the power button.

Note: The display screen will enter standby mode and dim after 20 seconds. Press any button to wake the screen out of standby mode.

9. For Advanced Features see Menu Navigation Instructions

FreeStyle Comfort

Power Supplies

The FreeStyle Comfort can be powered in three ways:

- Rechargeable Battery Pack
- AC Power
- DC Power

Information on the operation of each of these components is in the following sections.



WARNING: Use only the power supplies outlined in this user's manual. Use of non-CAIRE power supplies and battery packs can cause damage to the unit and improper operation.

BATTERY PACK

The FreeStyle Comfort can be operated by the rechargeable battery pack which is supplied with the device. There are no operational limitations of the concentrator when running from the battery pack. All flow rates are available on battery power.



INSTALLING THE BATTERY

Align the battery with the bottom housing from the center of the FreeStyle Comfort. Push the battery inward until you hear a click to confirm that it has locked in place.



REMOVING THE BATTERY

Push the battery release button downward away from the FreeStyle Comfort. While HOLDING this button, slide the battery out by pulling it away from the concentrator.



WARNING: The oxygen concentrator must be OFF and disconnected from external power before removing the battery pack.



CHECKING BATTERY PACK CHARGE

To check the battery charge when it is installed in the FreeStyle Comfort, reference the battery icon and the estimated time remaining on the display.

	80–100%
	60–80%
	40–60%
	20–40%
	20%

Note: If the power supply is attached, a plug indicator will show instead of the charge percentage remaining.

To check the battery charge when it is not installed in the FreeStyle Comfort, lay it flat and press the TEST button. The battery gauge indicator lights (25-100%) will illuminate to the right of the TEST button to indicate the level of the battery pack charge.



INITIAL CHARGING

The new battery supplied with your FreeStyle Comfort is only partially charged when it is shipped from the factory. Before using for the first time, you should fully charge the battery pack using either AC or DC power.

GENERAL CHARGING INFORMATION

The FreeStyle Comfort will recharge the battery pack anytime it is installed in the concentrator and the concentrator is connected to an external AC or DC power source (except on an airplane).

Battery is fully charged when it displays 100%.

Alternately, the battery pack may be charged using the optional desktop charger.

BATTERY OPERATING DURATION

When external AC or DC power is disconnected, the concentrator will automatically switch over to using battery power if a charged battery is installed. The table below shows the typical durations for a new battery pack. Battery pack durations will remain constant regardless of your breath rate.

Pulse Setting	Single (8-cell) Battery Duration	Double (16-cell) Battery Duration
1	up to 6 hours	up to 11 hours
2	up to 4 hours	up to 8 hours
3	up to 3 hours	up to 6 hours
4	up to 2.25 hours	up to 4.5 hours
5	up to 2 hours	up to 4 hours

TYPICAL BATTERY RECHARGE TIME

The typical time to fully recharge your battery pack from a fully discharged battery is 3.5 hours for a single battery, and 6.0 hours for a double battery.

Note: The battery may not initially start charging if the battery pack has been fully depleted.

BATTERY SERVICE LIFE

The FreeStyle Comfort batteries are designed to last 300 charge/discharge cycles.

FreeStyle Comfort

AC & DC Power Supply

The FreeStyle Comfort comes standard with AC and DC power supplies.

The AC power supply includes the following:

- AC Power brick that operates between 100-240 volts, 50-60Hz.
- AC Power cord to connect to the power brick and corresponding AC outlet.



The DC power supply consists of a cord that plugs directly into the unit and the DC outlet.



AC POWER

AC power is for use at home or wherever standard AC outlet power is available. The FreeStyle Comfort is fully functional on AC power. The FreeStyle Comfort will also recharge the battery pack any time AC power is available (except on an airplane). The battery pack will recharge whether the FreeStyle Comfort is powered on or off.



WARNING: Do not connect external power without a battery pack installed in the oxygen concentrator.

To connect the FreeStyle Comfort to AC Power:

1. Connect the AC power brick to the power connector inlet on the front, right bottom of the FreeStyle Comfort. Be sure to push inward so that the connection is secure.



2. Connect the AC power cord to the AC power brick.



3. Connect the opposite end of the AC power cord to the wall or other appropriate electrical outlet.



- Turn on the FreeStyle Comfort by pressing the power button and select your prescribed flow setting utilizing the increase (+) or decrease (-) flow buttons.



Note: If the battery pack needs to be recharged, the battery icon on the display will have a single orange bar.

DC POWER

DC power is for use in the accessory outlets of automobiles, boat, or other motor vehicles. The FreeStyle Comfort is fully functional for use on DC power. The FreeStyle Comfort will also recharge the battery pack if needed any time DC power is available. The battery pack will recharge both if the unit is off, or on and in use.



WARNING: DO NOT connect external power without a battery pack installed in the oxygen concentrator.

- Turn on your motor vehicle.
- Connect the DC power supply to the power port receptacle front, bottom right side of the FreeStyle Comfort. Be sure to push inward so that the connection is secure.



- Connect the opposite end of the DC power cord to the automobile or other DC accessory outlet.



- Turn on the FreeStyle Comfort by pressing the power button and select your prescribed flow setting utilizing the increase (+) or decrease (-) flow buttons.



CAUTION: To prevent possible fire or overheating, ensure the 12V DC power outlet is free of debris and the adapter plug of the DC Power Supply fits properly and remains securely in place.

CAUTION: DC power supply metal surfaces can become VERY HOT when in use due to high current. Allow sufficient time for surfaces to cool before touching.

CAUTION: Do not use the DC power supply with any extensions, splitters, or adapters. Use of unapproved accessories may result in them overheating or being damaged.

CAUTION: Attaching the device to a 12V DC power outlet can deplete the vehicles battery if the engine is not running, even if the device is turned off.

CAUTION: Do not jump-start a vehicle while the DC power supply is connected.

FreeStyle Comfort

Cleaning, Care & Routine Maintenance

ROUTINE MAINTENANCE

Preventative Maintenance

The device is maintenance free. Filters inside the device are intended to last the lifetime of the device. If the device is not working properly, the unit should be returned to provider for repair. Servicing of internal components inside of the cabinet of the FreeStyle Comfort must be performed by the oxygen provider.

The operator of the unit is responsible for the following maintenance procedure.

- Weekly – Clean the Air Intake Filters



WARNING: DO NOT attempt to open or remove the plastic covers of the oxygen concentrator. The unit should only be opened by a qualified service technician.

AIR INTAKE FILTERS

Air enters the FreeStyle Comfort through air intake filters located on the front, bottom of the oxygen concentrator. These filters prevent dust and other large particles in the air from entering the unit. At least once per week, the air intake filters should be cleaned. Your oxygen provider may advise you to clean them more frequently, depending upon the operating conditions. Follow these steps to properly clean the air intake filters.

1. Remove the two filters from the front of the FreeStyle Comfort by pushing up on the corresponding tab and pulling outward.



2. Wash both filters in a warm solution of soap and water.
3. Rinse the filters thoroughly and remove excess water with a soft, lint-free cloth. Ensure the filters are completely dry before replacing it.
4. Re-install the clean, dry filters.



WARNING: DO NOT operate the oxygen concentrator without the air intake filter in place.

BATTERY PACK CARE

Do not allow the battery pack to be exposed to liquids.

Do not attempt to disassemble or open the battery pack.

Do not expose the battery to open flames.

Do not drop the battery pack.

Keep the battery pack away from children.

If your battery pack appears damaged, contact your oxygen provide before use.

Do not place the battery in or near a microwave or other cooking appliances.

BATTERY PACK STORAGE

The oxygen concentrator battery does not need to be fully discharged before recharging. It is recommended to charge the oxygen concentrator battery after each use.

Do not leave the battery in a location exposed to excessive heat, such as in direct sunlight or in a car. Doing so could cause the battery's performance and life to deteriorate. It may also cause the battery to generate heat, smoke, catch fire, or explode. The battery pack should be stored in a stable environment characterized by low-humidity (less than 70% RH) and free of corrosive gases. To prevent rust, avoid conditions that can create condensation such as rapid fluctuations in the ambient temperature.

For storage of a month or more, a discharged or partial charged state of charge between 50% and 75% (two to three LEDs) is recommended. Once charged, remove the battery from the oxygen concentrator.

CLEANING

Turn OFF the unit and disconnect from AC or DC power before any cleaning. DO NOT spray the outer case directly. Use a damp (not wet) cloth or sponge. Spray the cloth or sponge with a mild household cleaner solution to clean the cabinet and power supplies. Proceed as directed by the cleaner manufacturer.



WARNING: Turn off the unit and disconnect the power cord from the electrical outlet before you clean the unit to prevent accidental electrical shock and burn hazard. Only your equipment provider or a qualified service technician should remove the covers or service the unit.

WARNING: Care should be taken to prevent the oxygen concentrator and the battery pack from getting wet or allowing fluids to enter the unit. This can cause a malfunction or shut down, and cause an increased risk for electrical shock or burns.

WARNING: DO NOT use liquid directly on the unit. A list of undesirable chemical agents includes but is not limited to the following: alcohol and alcohol-based products, concentrated chlorine-based products (ethylene chloride), and oil-based products. These are not to be used to clean the plastic housing on the concentrator, as they can damage the unit.

WARNING: Clean the cabinet, control panel, and power cord only with a mild household cleaner applied with a damp (not wet) cloth or sponge, and then wipe all surfaces dry. Do not allow any liquid to get inside the concentrator. Pay special attention to the oxygen outlet for the cannula connection to make sure it remains free of dust, water, and particles.

WARNING: Use a damp (not wet) cloth or sponge to clean the battery pack. First spray the cloth or sponge with a mild household cleaner and clean the battery pack housing.

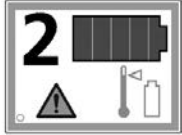
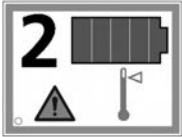



WARNING: DO NOT clean with automated washing system.


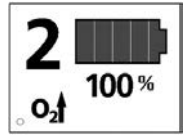
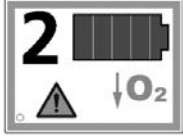

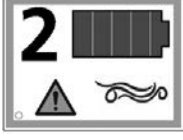



CANNULA REPLACEMENT

Always follow the cannula manufacturer's instructions for proper use. Replace the nasal cannula or oxygen tubing every 3 to 6 months (if daily use, 3 months) as per manufacturer's recommendation as recommended by the cannula manufacturer or your oxygen provider. Your physician or oxygen provider will provide you with cleaning and replacement instructions.


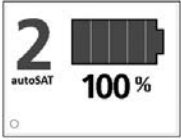
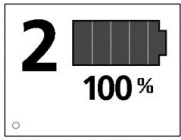
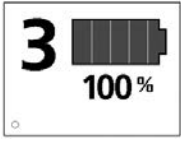

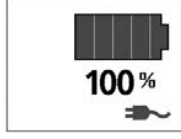
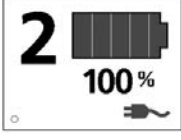

Additional supplies for replacement are available through your oxygen provider.

Alarm Conditions

Priority #	Alarm Description	Display	Audible Signal	More Details / Suggested Action
1	System Malfunction Battery High Temperature		1 beep every 20 sec	Unit will alarm when battery temperature is approaching safety shutdown threshold. If shutdown threshold is reached, unit will shut down. If external power is connected, alarm screen will display and audible alarm will continue for 2 min. Test with battery at room temperature. If problem persists, contact provider.
2	System Malfunction High Temperature		1 beep every 20 sec	Unit will alarm when internal temperature is approaching shutdown threshold. If shutdown threshold is reached, unit will shut down and alarm screen will display and audible alarm will continue for 2 min. Ensure there are no blockages on any vents of the unit. If problem persists, contact provider.
3	System Malfunction High Pressure (High System Pressure or Compressor Fault)		1 beep every 20 sec	If shutdown threshold is reached, unit will shut down and alarm screen will display and audible alarm will continue for 2 min. If problem persists, contact provider.
4	System Malfunction Flow Rate (OCD Valve Failure, Obstruction of Gas Pathway)		1 beep every 30 sec	If problem persists, contact provider.
5	Low Battery Shut Down		1 beep every 30 sec	Alarms until battery runs out of power and unit shuts down. Charge battery.

Priority #	Alarm Description	Display	Audible Signal	More Details / Suggested Action
6	No Breath Detected		1 beep every 10 min	No breath detected for 15 seconds. Activated after first breath or warm up screen is off, whichever comes sooner. Check cannula for kinks or leaks. Increase the sensitivity setting. If problem persists, contact provider.
7	Warm Up		none	Unit will start by auto-dosing until a breath is detected or Warm up ends, whichever is sooner.
8	Low Concentration		1 beep every 10 min, for up to 30 min	If problem persists, contact provider.
9	Low Battery Warning		1 beep, no repeat	Charge battery.
10	Breathing Rate Exceeded		1 beep, no repeat	Breathing Rate exceeds 40 bpm. If dose is being falsely triggered, decrease the sensitivity setting. If problem persists, contact provider.
11	System Malfunction Fan Failure		none	If problem persists, contact provider.
12	System Malfunction Low Pressure		none	If problem persists, contact provider.
13	System Malfunction Low Temp		none	Allow unit to warm up to room temperature. If problem persists, contact provider.

FreeStyle Comfort

Priority #	Alarm Description	Display	Audible Signal	More Details / Suggested Action
Info	Start up		1 info beep	Screen displays at power-on and you should hear one beep to confirm buzzer is functioning Start up screen display current firmware revision in bottom right corner.
Info	Normal Run Screen in autoSAT Mode (no DC Power connected)		none	
Info	Normal Run Screen with autoSAT disabled (No DC Power connected)		None	
Info	Setting Changed		1 info beep	
Info	Plug in external Power in the off condition	 	none	Display CAIRE screen for 2 seconds, followed by Battery & Plug status for 5 sec before screen turns off
Info	Plug in external power in the run condition		none	
Info	Unplug external power in the off Condition		1 info beep	Display CAIRE screen for 2 seconds and then turn display off.

Priority #	Alarm Description	Display	Audible Signal	More Details / Suggested Action
Info	Unplug external power in the run Condition (with battery present)	A battery icon with a '2' to its left and '100%' below it. A small circle is at the bottom left.	1 info beep	
Info	In Standby Mode - when up or down button is pressed display shows battery and charging state	 Two battery icons. The top one shows '100%'. The bottom one shows '100%' with a charging symbol (a plug) below it.	none	Screen will display for 5 sec then turn off
Info	Airplane Mode on battery power	A battery icon with a '2' to its left, an airplane icon below the '2', and '100%' below the battery. A small circle is at the bottom left.	1 long beep	
Info	Airplane Mode while plugged in	A battery icon with a '2' to its left, an airplane icon below the '2', '100%' below the battery, and a charging symbol (a plug) below the battery. A small circle is at the bottom left.	1 long beep	

Menu Navigation Instructions

You can enter the Menu in Standby or Run mode. In Run Mode, if an alarm condition occurs the menu will automatically be exited. If no buttons are pressed for 20 seconds, the Menu will automatically be exited. In Standby, you may need to press the Menu button twice to wake unit, then enter the Menu.


There are four Menu screens:


1. Status screen: Displays Firmware rev number, run time, battery discharge cycles
2. Airplane mode (ON/OFF)
3. Sensitivity: adjustable (1-5)
4. autoSAT (ON/OFF)

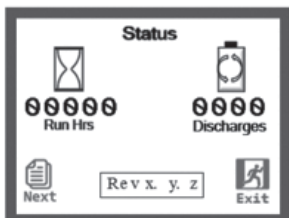


Example Status Screen

SETTINGS MENU OPERATION

Settings menu is entered by pressing Menu/Select button  in Run or Standby modes.

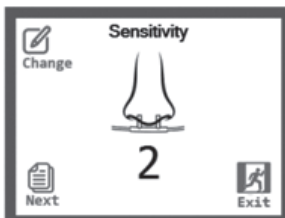
To scroll through the menus, push the .



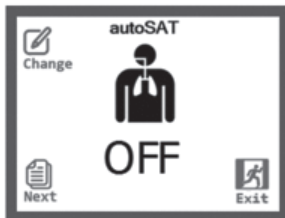
Status Page



Airplane Mode



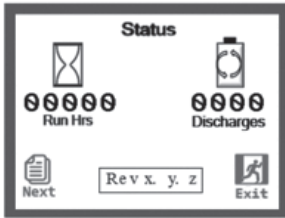
Sensitivity



autoSAT

STATUS PAGE

The Status Page of the Freestyle Comfort shows Firmware Revision, Run Hours, and number of battery cycles on the attached battery.



Status Page


Run hours are shown in whole hours. Battery Discharges is the number of cycles the attached battery has been drained and recharged.

AIRPLANE MODE

The FreeStyle Comfort ships with Airplane Mode turned off.





Airplane Mode Main Screen

To turn the mode on, press  while the CHANGE icon is visible. The value will toggle to the blue word "ON".



Airplane Mode On Selected


To confirm Airplane Mode on, press  while the SAVE icon is visible. The value will toggle to the black word "ON".

To cancel Airplane Mode on, press  while the CANCEL icon is visible.



Airplane Mode On Confirmed

To turn Airplane Mode off, repeat above while toggling to OFF.

Pressing  when the screen show the "Next" symbol will move the menu page to the next screen option.

Airplane Mode is intended for use in Run Mode. Airplane Mode will be automatically disabled if the unit is left in Standby on battery power.

Note: See section Activate Airplane Mode for more information about Airplane Mode.


SENSITIVITY MODE

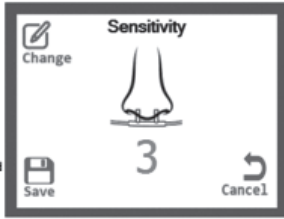
The FreeStyle Comfort ships with a default Sensitivity Mode setting of 2 from the factory and should not require adjustment under normal conditions. Sensitivity Setting can be adjusted between values 1-5, where 1 is the least sensitive, 5 is the most sensitive.




Sensitivity Mode Screen at Setting 2


FreeStyle Comfort

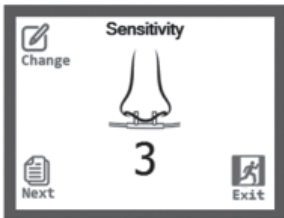
To adjust the Sensitivity Mode, press  while the CHANGE icon is visible. The value will toggle to the next blue number.



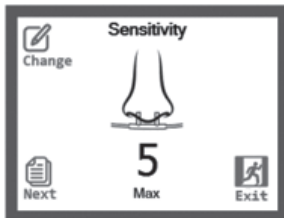
Sensitivity Mode Setting 3 Selected

To confirm Setting 3 in Sensitivity Mode, press  while the SAVE icon is visible. The value will toggle to the black "3".


To cancel the Sensitivity Mode change, press  while the CANCEL icon is visible.



Sensitivity Mode Setting 3 Confirmed



Sensitivity Mode Setting 5 (Max) Confirmed


Pressing  when the screen show the "Next" symbol will move the menu page to the next screen option.

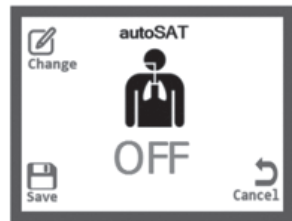
AUTOSAT MODE

The FreeStyle Comfort ships with autoSAT Mode turned on.





autoSAT Mode Main Screen

To turn the mode off, press  while the CHANGE icon is visible. The value will toggle to the blue word "OFF".



autoSAT Mode Off Selected


To confirm autoSAT Mode off, press  while the SAVE icon is visible. The value will toggle to the black word "OFF".

To cancel autoSAT Mode on, press  while the CANCEL icon is visible.



autoSAT Mode Off Confirmed

To turn autoSAT Mode on, repeat above while toggling to ON.

Pressing  when the screen show the "Next" symbol will move the menu page to the next screen option.

Troubleshooting

Problem	Probable Cause	Solution
FreeStyle Comfort displays alarm and produces intermittent beep.	Refer to Alarm Conditions table.	Refer to Alarm Conditions table.
Oxygen concentrator does not turn on.	Battery is discharged. Not connected to external power. General malfunction.	Power the unit through the AC or DC outlet. Ensure that external connects are secure. Perform a Full Power Cycle by removing the battery and disconnecting any AC or DC external power source. Then reinstall battery, and the power cycle is complete. Reconnect external power source if desired. Contact your Equipment Provider, and change to another source of oxygen as necessary.
All other problems.		Perform a Full Power Cycle by removing the battery and disconnecting any AC or DC external power source. Then reinstall battery, and the power cycle is complete. Reconnect external power source if desired. Change to another source of oxygen as available, and contact your Equipment Provider.

Note: Some alarms will cause the unit to shut down.

Note: During a total power loss, the alarm system resets (clears any previous alarms) and will only display an alarm if the condition still exists once power is restored.

FreeStyle Comfort

Travel Information

The FreeStyle Comfort meets FAA guidelines for use on-board commercial aircraft. Prior to any travel (airline, train, cruise, etc.) you should:

- Ensure the concentrator is in good operation condition.
- Contact your carrier at least 48 hours prior to departure to inform them you will be traveling with a FreeStyle Comfort.

It is suggested to always carry extra batteries with you on trips. For airline travel, please allow enough battery life to account for ground time (preflight check in, security, etc.) and layovers. Most airlines require that you have an adequate number of fully charged battery packs to power the device for at least 150% of the expected maximum trip duration (flight times, ground time before and after the flight, connections, and unexpected delays).

Note: If flying, it is recommended that extra batteries are carried on in a secure carrying bag.

FAA REGULATION

Spare batteries must be individually protected to prevent short circuits by placement in the original retail packaging or by otherwise insulating the terminals, e.g. by taping over exposed terminals or placing each battery in a separate plastic bag or protective pouch, and carried in carry-on baggage only.

ACTIVATE AIRPLANE MODE

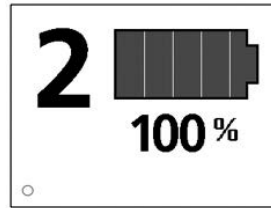
Battery Power

POC can be used on an aircraft per normal operating procedures using Battery Power ONLY, when no external power source is connected

External Power

On an airplane, if an electrical outlet is available, operable, and its location is appropriate for use as a POC power source, it may serve as a back up to POC batteries. In this case, the following recommended procedure regarding the transition from battery to aircraft electrical power must be followed:

1. Turn POC On using Battery Power ONLY, when no external power source is connected.

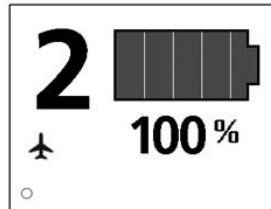


2. Enable Airplane Mode using one of the following methods:

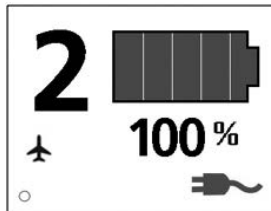
- a. Follow directions to enable Airplane Mode in Menu Navigation Instructions section.



- b. Press and hold both Up and Down buttons for 5 seconds until you hear a long beep and see the Airplane symbol appear.



3. When the airplane symbol is displayed, plug in the POC.



Note: Due to aircraft limitations, the batteries do not charge in Airplane Mode.

Disposal and Reuse

Always return FreeStyle Comfort, including all components, to your equipment provider for proper disposal. You can also contact your local city or town offices for instructions on proper disposal of the battery. The unit can be reused between people but must be returned to equipment provider for reprocessing.

WEEE



This symbol is to remind the equipment owners to return it to a recycling facility at the end of its life, per Waste Electrical and Electronic Equipment (WEEE) Requirements.



CAUTION: For proper disposal, contact your equipment provider or local government agency for disposal instructions

CAUTION: Always dispose of molecular sieve in accordance with all federal, state, and local environmental control regulations.

Materials in Direct Contact with the Operator

- Concentrator Casing: PC/ABS
- Concentrator Control Panel: Polyester EBG7 or equivalent
- Oxygen Outlet, Nozzle: Aluminum
- Unit Label: Lexan
- Cord Connectors: Polycarbonate/Vinyl chloride
- Power Cord: PVC, Metal
- Power Supply: Lexan 940(Polycarbonate)
- Battery Pack: PC/ABS
- Battery Pack, Power Supply Labels: Polyester film
- Concentrator Carrying Case: Cordura, Neoprene, Nylon Lining
- Strap: Polypropylene, Acetyl, Vinyl, Cordura, Neoprene

FreeStyle Comfort

Specifications

	FreeStyle Comfort
Dimensions (with Single Battery)	10.0 x 7.3 x 3.1 in (25.4 x 18.5 x 7.9 cm)
Dimensions (with Double Battery)	11.0 x 7.3 x 3.1 in (27.9 x 18.5 x 7.9 cm)
Weight (with Single Battery Pack)	5 lbs (2.3 kg)
Weight (with Double Battery Pack)	6 lbs (2.7 kg)
Operating Nominal Sound Level***	Max 43.0 dBA @ 2 Maximum sound power of 51 dBA Maximum system sound pressure of 51 dBA Typical alarm sound pressure of 56.49 dBA (sound pressure level measured at 1 meter per ISO 3744)
Flow Settings	Pulse Setting 1, 2, 3, 4, 5
O2 Output Setting ([@20bpm STPD] All Volumes +/- 15%)	Setting 1 - 210 mL/min Setting 2 - 420 mL/min Setting 3 - 630 mL/min Setting 4 - 840 mL/min Setting 5 - 1050 mL/min
Oxygen Concentration*	90% (+5.5% / -3%)
Oxygen Monitor	Yes
Maximum Outlet Pressure	<30 PSI
Dosing Sensitivity	> -0.1 cm H ₂ O (adjustable)
AC Power	100–240 VAC, 50-60Hz, 120W Max
DC Power	11–18 VDC (10 max amp)
Battery Type	Lithium Ion
Battery Capacity	Single cell: 6700 mAh; Double cell: 13400 mAh
Battery Re-Charge Time	Single Battery: 3.5 hours Double Battery: 6.0 hours
Battery Pack Durations	Single Battery Duration: Setting 2 - up to 4 hours Double Battery Duration: Setting 2 - up to 8 hours
Operating Temperature**	41°F to 104°F (5°C to 40°C)
Transportation and Storage Temp. (Unit)	-13°F to +158°F (-25°C to +70°C) up to 10000 ft (3048 m)
Transportation and Storage Temp. (Battery)	-13°F to +158°F (-25°C to +70°C) up to 10000 ft (3048 m)
Operating Altitude**	-1250 to 10,000 ft (-381 to 3048 m) (tested to 700 – 1060 hPa)
Operating Humidity	15 - 95% relative humidity (non-condensing)
Storage Humidity	0 - 90% Non-Condensing
Wireless Technology	Connection types SSP, iAP2, GATT Frequency 2402 to 2480 MHz Max RF power output +4 dBm Operating range 10m (Class 2) It is recommended that the machine is at a minimum distance of 0.43" (1.1 cm) from the body during operation. Not applicable to masks, air tubing, or accessories.

<p>FCC Notice</p> <p>Contains FCC ID: WAP2001</p>	<p>This device may contain CYBLE-022001-00, including the antenna 2450AT18B100 from Johnson Technology, complies with par 15 of the FCC rules. The device meets the requirements for modular transmitter approved as detailed in FCC public notice DA00-1407. Transmitter operation is subject to the following two conditions (1) The device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation. The product may be covered by one or more patents, US and international. Please visit our website below for the listing of applicable patents. Pat: www.caireinc.com/corporate/patents</p>
<p>Limited Warranty</p>	<p>See Warranty Statement</p>

* Based on an atmospheric pressure of 14.7 psi (101 kPa) at 70°F (21°C)

** The unit will function in all environments as long as the environment is with the specified temperature and humidity ranges. Operating outside of these operational specifications can limit the concentrator's ability to meet Oxygen Concentration specification at higher liter flow rates. Warm up screen may continue to display until the concentrator has reached target concentration or up to 15 minutes. Continue to use unit during this time.

***Sound level measured per test method Nr. 14-1 10/2018 MDS-Hi.

The expected service life is a minimum of five years.

EMC Testing


Guidance and Manufacturer's Declaration—Electromagnetic Emissions		
<p>The FreeStyle Comfort is intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle Comfort should assure that it is used in such an environment.</p>		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
<p>RF emissions CISPR 11</p>	<p>Group 1</p>	<p>The FreeStyle Comfort uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</p>
<p>RF emissions CISPR 11</p>	<p>Class B</p>	<p>The FreeStyle Comfort is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</p>
<p>Harmonic emissions IEC 61000-3-2</p>	<p>Class A</p>	
<p>Voltage fluctuations/ flicker emissions IEC 61000-3-3</p>	<p>Complies</p>	

FreeStyle Comfort

Guidance and Manufacturer's Declaration—Electromagnetic Immunity			
The FreeStyle Comfort is intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle Comfort should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electromagnetic environment – guidance IEC 61000-4-2	±8 kV contact ±15 kV air discharge	±8 kV contact ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines N/A	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2kV common mode on AC lines ±1kV differential on AC lines ±2kV common mode on outdoor I/O lines	±1 kV line(s) to line(s)	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0% U_T for 1 cycle (0°) 70% U_T (30% dip in U_T) for 25/30 cycles (0°) 0% U_T for 250/300 cycles (0°)	0% U_T for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0% U_T for 1 cycle (0°) 70% U_T (30% dip in U_T) for 25/30 cycles (0°) 0% U_T for 250/300 cycles (0°)	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments. If the user of the FreeStyle Comfort requires continued operation during power mains interruptions, it is recommended that the FreeStyle Comfort is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	3 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a professional healthcare facility and home healthcare environments.
NOTE U_T is the A.C. mains voltage prior to application of the test level.			
NOTE In some cases, the Freestyle Comfort may reset after a significant Electrostatic Discharge, and may require a Full Power Cycle to resume normal operation. See Troubleshooting section for more details.			

Guidance and Manufacturer's Declaration–Electromagnetic Immunity

The FreeStyle Comfort is intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle Comfort should assure 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	10 Vrms 150 kHz to 80 MHz	10 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the FreeStyle Comfort, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} = 80 \text{ MHz to } 800 \text{ MHz}$ $d = 1.2\sqrt{P} = 800 \text{ MHz to } 2700 \text{ MHz}$ 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 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 IEC 61000-4-3	10 V/m 80 MHz to 2700 MHz	10 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

^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 FreeStyle Comfort is used exceeds the applicable RF compliance level above, the FreeStyle Comfort should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FreeStyle Comfort.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

FreeStyle Comfort

Recommended separation distances between portable and mobile RF communications equipment and the FreeStyle Comfort

The FreeStyle Comfort is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FreeStyle Comfort can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FreeStyle Comfort 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		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 1.2\sqrt{P}$
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
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 propagation is affected by absorption and reflection from structures, objects and people.

Classification

Type of protection against electric shock:

Class II Protection from electric shock is achieved by double insulation.

Degree of protection against electric shock:

Type BF Equipment providing a particular degree of protection against electric shock regarding

- 1) allowable leakage current;
- 2) reliability of protective earth connection (if present).

Not intended for direct cardiac application.

Independent testing for Medical Electrical Equipment Standard:

Tested to be in compliance with

- IEC 60601-1 edition 3.1: Medical Electrical equipment - Part 1 General Requirements for safety.
- CAN/CSA C22.2 No. 60601-1-8 edition 2.1, Medical Electrical Equipment – Part 1: General Requirements for Safety

Protection against potential electromagnetic or other interference between the equipment and other devices.

- Tested to be in compliance with EN 60601-1-2 /IEC 60601-1-2: 4th Edition.
- Tested to be in compliance with RTCA/DO160 Section 21 Category M.
- CISPR 11 / EN 55011 Class B Group 1, “Industrial, Scientific, and Medical (ISM) Equipment”
- FCC Part 15, Subpart B – Class B Unintentional Radiators

IP22 - Protection against ingress of fingers or similar objects greater than 12.5 mm diameter. Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle of 15° from its normal position.

Method of cleaning and infection control allowed:

Please refer to “Cleaning, Care, and Proper Maintenance” section of this FreeStyle User Manual.

Degree of safety of application in the presence of flammable anesthetic gases:

Equipment not suited for such application.

Mode of operation: Continuous duty.

Warranty

Limited Warranty Statement and Liability Disclaimer for CAIRE FreeStyle Comfort™ (“Equipment”)

CAIRE Inc. (“CAIRE”) provides limited warranty coverage for its equipment. The specific terms, conditions, and duration of any applicable warranty are documented separately and may vary by product, region, or purchase agreement (the “Warranty Statement”). A copy of the Warranty Statement is provided with the user manual. For additional copies or questions, please contact CAIRE Customer Service by e-mail at customerservice.usa@caireinc.com.

Except as expressly stated in the applicable Warranty Statement, CAIRE makes no other warranties, express or implied, including any implied warranties of merchantability or fitness for a particular purpose.

TO THE FULLEST EXTENT PERMITTED BY LAW, CAIRE SHALL NOT BE LIABLE FOR, AND PURCHASER SHALL INDEMNIFY, DEFEND AND HOLD CAIRE HARMLESS FROM ANY CLAIMS ARISING OUT OF THE USE, SALE, OR LEASE OF THE EQUIPMENT, CAIRE’S COMPLIANCE WITH PURCHASER’S DESIGNS, SPECIFICATIONS OR INSTRUCTIONS, OR MODIFICATION OF ANY EQUIPMENT BY PARTIES OTHER THAN CAIRE, PURCHASER’S FAILURE TO COMPLY WITH THE APPLICABLE WARRANTY STATEMENT, OR USE OF THE EQUIPMENT IN COMBINATION WITH OTHER EQUIPMENT. PURCHASER’S RECOVERY FROM CAIRE FOR ANY CLAIM SHALL NOT EXCEED PURCHASER’S PURCHASE PRICE FOR THE EQUIPMENT GIVING RISE TO SUCH CLAIM, AND PURCHASER SHALL NOT IN ANY EVENT BE ENTITLED TO, AND PURCHASER SHALL INDEMNIFY, DEFEND AND HOLD CAIRE HARMLESS FROM, ANY CLAIMS FOR, INDIRECT, SPECIAL, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY NATURE. **THE FOREGOING SHALL APPLY IRRESPECTIVE OF THE NATURE OF THE CLAIM, WHETHER BASED ON CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE. THE REMEDIES AND WARRANTIES STATED IN THE WARRANTY STATEMENT ARE EXCLUSIVE AND IN LIEU OF ALL OTHER REMEDIES AND WARRANTIES GRANTED UNDER APPLICABLE LAW, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF QUALITY, PERFORMANCE AND DESIGNS, AND ALL OTHER WARRANTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR ARISING FROM COURSE OF DEALING OR USAGE OF TRADE, ALL OF WHICH ARE HEREBY EXPRESSLY DISCLAIMED BY CAIRE.**

Contact Information

Questions about FreeStyle Comfort?	Please contact CAIRE at: customerservice@caireinc.com 800-482-2473 2200 Airport Industrial Drive, Suite 500 Ball Ground, GA 30107
Questions about your condition or prescription?	Please contact your prescribing physician or healthcare provider.
Healthcare Professionals and Consumers:	To report an adverse event experienced while using your FreeStyle Comfort, please contact CAIRE customer service at customerservice@caireinc.com Or report directly to: • US: United States Food and Drug Administration (FDA) at MedWatch: www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program or 1-800-FDA-1088. • Canada: Visit Health Canada at www.canada.ca/en/health-canada to Report a medical device problem. • International: Please contact your healthcare provider. • In an emergency, please dial 911.



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