CAIRE®

FreeStyle® Comfort®

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

User Manual (English)

User Controls & System Status Indicators

ISO 7000; Graphical symbols for use on equipment—Index and synopsis	
	Read user's manual before operation. Reg. # 1641
	Operating temperature limitation of these units is 41°F to 104°F (5°C to 40°C). Storage temperature limitation range is -13°F to +158°F (-25°C to +70°C). Reg. # 0632
	Humidity range is 10 to 95%. Reg. # 2620
	Atmospheric pressure limitation. Reg. # 2621
	Name and address of manufacturer. Reg. # 3082
	Date of manufacturer. Reg. # 2497
	Catalog Number. Reg. # 2493
	Serial Number. Reg. # 2498
	This way up. Reg. # 0623
	Fragile, handle with care. Reg. # 0621
	Keep away from rain, keep dry. Reg. # 0626
	Stacking limit by number. Reg. # 2403
ISO 7010: Graphical symbols—Safety colors and safety signs—Registered safety signs	
	The instruction manual must be read. Reg. # M002
	Keep away from open flame, fire, sparks. Open ignition source and smoking prohibited. Reg. # P003
	Do not smoke near unit or while operating unit. Reg. # P002
	Type BF applied part (degree of protection against electric shock). Reg. # 5333
	Warning. Reg. # W001

Council Directive 93/42/EEC; concerning medical devices	
	Authorized representative in the European Community
	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. It bears the CE marking as shown. CE#### indicates notified body number.
IEC 60417	
	Class II Equipment, Double Insulated Reg. # 5172
	Power switch. Reg. # 5009
ETL Certification	
	Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment
Internal Symbols	
	Keep away from flammable materials, oil and grease.
	Do not disassemble.
	Increase flow.
	Decrease flow.
	Menu button.
RTCA/DO-160 Section 21 Category M Compliant	RTCA DO160 Section 21 Category M Compliant. FAA SFAR 106 requirement
	Class II Equipment, Double Insulated
	FAA Approved – POC
21 CFR 801.15: Code of Federal Regulations Title 21	
RX ONLY	Federal law restricts this device to sale by or on the order of a physician.

Council Directive 2012/19/EU: waste electrical and electronic equipment (WEEE)	
	WEEE

IEC 60601-1: Medical electrical equipment Part 1 General requirements for basic safety and essential performance	
IP22	Drip Proof

This product may be covered by one or more patents, US and international. Please visit our website below for the listing of applicable patents. Pat.: patents.cairemedical.com.

What is the Oxygen Concentrator

The air we breathe contains approximately 21% oxygen, 78% nitrogen, and 1% other gasses. In the FreeStyle® Comfort®, room air is drawn into the machine through the air intakes. It then passes through an adsorbent material called molecular sieve. This material separates the oxygen from the nitrogen and allows only the oxygen to pass through. The result is a flow of high-concentration oxygen delivered to the user.

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.

Why Your Physician Prescribed Oxygen

Many people suffer from a variety of heart, lung, and other respiratory diseases. A significant number of these people can benefit from supplemental oxygen therapy at home, when traveling, or while participating in daily activities away from home.

Oxygen is a gas that makes up 21% of the ambient air we breathe, and our bodies depend on a steady supply to function properly. Your physician prescribed a flow or setting to address your particular respiratory condition.

Although oxygen is a non-addictive drug, unauthorized oxygen therapy can be dangerous. You must seek medical advice before you use this oxygen concentrator. The Equipment Provider who supplies your oxygen equipment will demonstrate how to set the prescribed flow rate.

Operator Profile

Concentrators are intended to supply supplemental oxygen to users suffering from discomfort due to ailments which effect the efficiency of one's lungs to transfer oxygen in the air to their bloodstream. Portable oxygen concentrators (POCs) do not store or contain oxygen. They do not need to be refilled, and can recharge anywhere AC or DC power is available (except on an airplane). This makes the user relatively self-sufficient in terms of in-home use, ambulation (both within and outside of the home), mobility, and overall lifestyle. Oxygen concentrator use requires a physician's prescription and is not intended for life support use.

Although oxygen therapy can be prescribed for users of all ages, the typical oxygen therapy user is older than 65 years of age and suffers from a variety of respiratory diseases, including Chronic Obstructive Pulmonary Disease (COPD). 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.

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 Supply
- User Manual

Optional Accessories
- Additional 8-Cell Battery Pack
- 16-Cell Battery Pack
- Desktop Charger
- Carry-all Accessory Bag

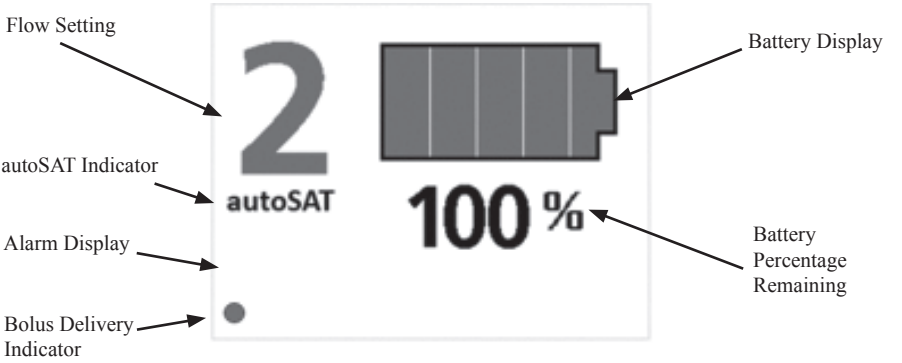
Getting to Know Your FreeStyle Comfort

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

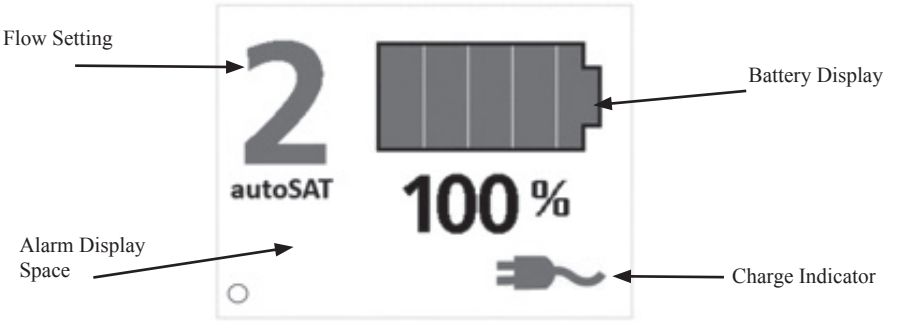
Front View

Top View

Display Screen On Battery



Display Screen On AC/DC Power



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.

Indications for Use

WARNING: IT IS VERY IMPORTANT TO SELECT ONLY THE PRESCRIBED LEVEL OF OXYGEN. DO NOT CHANGE THE FLOW SELECTION UNLESS YOU HAVE BEEN DIRECTED TO DO SO BY A LICENSED CLINICIAN.

WARNING: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE OR RENTAL BY ORDER OF A PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER.

WARNING: THIS UNIT IS NOT TO BE USED FOR LIFE SUPPORT. GERIATRIC, PEDIATRIC, OR ANY OTHER USER UNABLE TO COMMUNICATE DISCOMFORT WHILE USING THIS DEVICE MAY REQUIRE ADDITIONAL MONITORING. USERS WITH HEARING AND/OR SIGHT IMPAIRMENT(S) MAY NEED ASSISTANCE WITH MONITORING ALARMS.

WARNING: PULSE DOSE MODE SETTINGS MUST BE DETERMINED FOR EACH USER INDIVIDUALLY FOR THEIR NEEDS AT REST, DURING EXERCISE, AND WHEN TRAVELING.

WARNING: SOME RESPIRATORY EFFORTS OF THE PATIENT MIGHT NOT TRIGGER THE CONSERVING FUNCTION.

WARNING: THE FREESTYLE COMFORT IS NOT INTENDED FOR USE WITH A TRACHEOTOMISED PATIENT.

WARNING: PREGNANT OR NURSING WOMEN SHOULD NOT USE ACCESSORIES RECOMMENDED IN THIS MANUAL, THEY MAY CONTAIN PHTHALATES.

Contraindications for Use

WARNING: IN CERTAIN CIRCUMSTANCES, THE USE OF NON-PRESCRIBED OXYGEN CAN BE HAZARDOUS. THIS DEVICE SHOULD ONLY BE USED WHEN PRESCRIBED BY A PHYSICIAN.

WARNING: NOT FOR USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

WARNING: 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.

Safety Guidelines

WARNING: NO MODIFICATION OF THIS EQUIPMENT IS PERMITTED

WARNING: 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.

WARNING: DO NOT OPERATE 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.

WARNING: THE CONCENTRATOR SHOULD BE LOCATED AS TO AVOID SMOKE, POLLUTANTS OR FUMES.

WARNING: THE USE OF SOME OXYGEN ADMINISTRATING ACCESSORIES NOT SPECIFIED FOR THIS OXYGEN CONCENTRATOR MAY IMPAIR ITS PERFORMANCE. RECOMMENDED ACCESSORIES ARE REFERENCED WITHIN THIS MANUAL.

WARNING: IF THE OXYGEN CONCENTRATOR HAS BEEN DROPPED, DAMAGED OR EXPOSED TO WATER, PLEASE CONTACT YOUR HOME CARE PROVIDER FOR INSPECTION OR POSSIBLE REPAIR OF THE DEVICE. DO NOT USE THE OXYGEN CONCENTRATOR IF IT HAS A DAMAGED POWER CORD OR PLUG.

WARNING: PROPERLY SECURE, BELT OR OTHERWISE RESTRAIN THE OXYGEN CONCENTRATOR WHEN IN A VEHICLE DURING TRANSPORT TO PREVENT DAMAGE OR INJURY.

WARNING: 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.

WARNING: 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.

WARNING: IF YOU FEEL DISCOMFORT OR ARE EXPERIENCING A MEDICAL EMERGENCY, SEEK MEDICAL ASSISTANCE IMMEDIATELY.

WARNING: OPERATING THE OXYGEN CONCENTRATOR OUTSIDE OF THE OPERATIONAL TEMPERATURE SPECIFICATIONS CAN LIMIT THE CONCENTRATOR'S ABILITY TO MEET OXYGEN CONCENTRATION SPECIFICATION. REFER TO THE SPECIFICATION SECTION OF THIS MANUAL FOR TEMPERATURE LIMITS.

WARNING: 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.

WARNING: DO NOT ALLOW EITHER THE AIR INTAKE OR THE AIR OUTLET EXHAUST 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.

WARNING: 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.

WARNING: 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.

WARNING: WHILE USING THE PORTABLE OXYGEN CONCENTRATOR OUTDOORS WITH THE AC POWER SUPPLY, CONNECT THE POWER SUPPLY INTO A GROUND FAULT INTERRUPTED (GFI) OUTLET ONLY.

WARNING: 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.

WARNING: 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.

WARNING: USE ONLY ELECTRICAL VOLTAGE SPECIFIED ON THE SPECIFICATION LABEL AFFIXED TO THE DEVICE.

WARNING: 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.

CAUTION: 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.

CAUTION: To prevent a void warranty, follow all manufacturers' instructions.

WARNING: DO NOT ATTEMPT ANY MAINTENANCE OTHER THAN THE POSSIBLE SOLUTIONS LISTED WITHIN THIS MANUAL. DO NOT REMOVE COVERS, ONLY YOUR EQUIPMENT PROVIDER OR A QUALIFIED SERVICE TECHNICIAN SHOULD REMOVE THE COVERS OR SERVICE THIS DEVICE.

WARNING: ONLY ACCESSORIES RECOMMENDED BY THE MANUFACTURER. USE OF ANY OTHER MAY BE HAZARDOUS, CAUSE SERIOUS DAMAGE TO YOUR OXYGEN CONCENTRATOR AND WILL VOID THE WARRANTY .

WARNING: THE MANUFACTURER RECOMMENDS AN ALTERNATE SOURCE OF SUPPLEMENTAL OXYGEN IN THE EVENT OF A POWER OUTAGE, ALARM CONDITION, OR MECHANICAL FAILURE. CONSULT YOUR PHYSICIAN OR EQUIPMENT PROVIDER FOR THE TYPE OF RESERVE SYSTEM REQUIRED.

WARNING: 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.

WARNING: SMOKING WHILE USING OXYGEN IS THE NUMBER ONE CAUSE OF FIRE INJURIES AND RELATED DEATHS. YOU MUST FOLLOW THESE SAFETY WARNINGS:

WARNING: DO NOT ALLOW SMOKING, CANDLES, OR OPEN FLAMES IN THE SAME ROOM WITH THE DEVICE OR THE OXYGEN-CARRYING ACCESSORIES.

WARNING: SMOKING WHILE WEARING AN OXYGEN CANNULA MAY CAUSE FACIAL BURNS AND POSSIBLY DEATH.

WARNING: 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.

WARNING: "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.

WARNING: 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.

WARNING: 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.

WARNING: 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.

WARNING: THE OXYGEN CONCENTRATOR MUST BE OFF AND DISCONNECTED FROM EXTERNAL POWER BEFORE REMOVING THE BATTERY PACK.

WARNING: SMALL PARTS MAY PRESENT A POTENTIAL CHOKING HAZARD.

WARNING: AVOID CONTACT WITH EXHAUST AIR VENT FOR LONGER THAN 10 SECONDS AS IT MAY BE WARM.

WARNING: WIND OR STRONG DRAUGHTS CAN ADVERSELY AFFECT ACCURATE DELIVERY OF OXYGEN THERAPY.

WARNING: 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.

CAUTION: Always disconnect AC power supply from the wall before disconnecting the AC power supply from the Oxygen Concentrator.

CAUTION: Do not position the Oxygen Concentrator so that it is difficult to access the power cord.

CAUTION: Always place oxygen supply tubing and power cords in a manner that prevents trip hazard or possible accidental strangulation.

CAUTION: 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.

CAUTION: 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.

Note: Portable and mobile RF communications equipment can effect medical electrical equipment.

CAUTION: 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.

CAUTION: 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.

CAUTION: 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.

CAUTION: ONLY USE the Manufacturer's provided batteries. For proper battery disposal, contact your Equipment Provider or your local government agency for disposal requirements.

Note: 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.

Note: 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).

Note: The use of some oxygen administration accessories not specified for use with this oxygen concentrator may impair its performance. Recommended accessories are referenced within this manual.

Note: 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.

Note: The Manufacturer does not recommend the sterilization of this equipment.

Note: There is never a danger of depleting the oxygen in a room when you use your oxygen concentrator unit.

WARNING: 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.

Note: If the oxygen concentrator has been stored for an extended period of time outside of its normal environmental operating conditions shown in the table above, it should be allowed to return to normal operating temperature before being powered on.

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)
Nominal Sound Level	43 dbA @ 2
Flow Settings	Pulse Setting 1, 2, 3, 4, 5
O2 Output Setting (@ 20bpm)	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
Default Dosing Sensitivity	> -0.1 cm H_2O (adjustable)
AC Power	100–240 VAC, 50-60Hz
DC Power	11–18 VDC (10 max amp)
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)
Limited Warranty	3 years unit 1 year battery & power supplies

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

**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.

The expected service life is a minimum of five years. The expected shelf life of the sieve beds is approximately one year if concentrator is unused during the entire period.

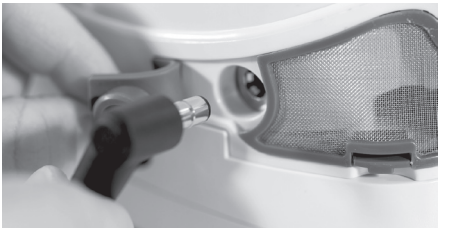
Operating Instructions

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.

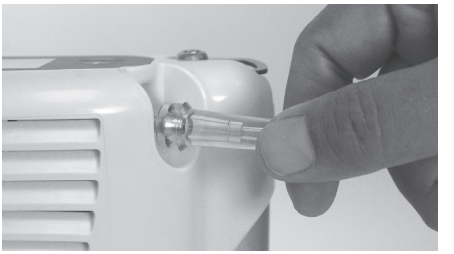
   b. Slide the battery inward until you hear a click to confirm that it has locked in place.

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 Oxygen Concentrator:

- Nasal Cannula with 7 feet (2.1 m) of tubing (1 to 6 LPM): PN 5408-SEQ
- For any additional recommended accessories, please see the Accessories Catalog (PN ML-LOX0010) available on www.CAIREmedical.com.

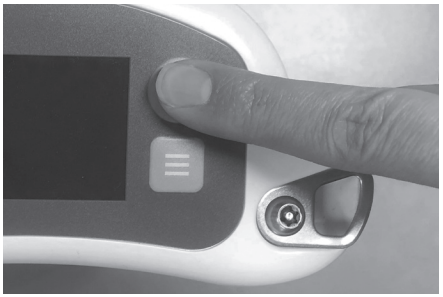
A firebreak is required for use with any cannula.

- CAIRE offers the OxySafe™. This is intended to be used in conjunction with the oxygen concentrator. The OxySafe™ is a thermal fuse to stop the flow of gas in the event that the downstream cannula or oxygen tubing is ignited and burns to the OxySafe. It is placed in-line with the nasal cannula or oxygen tubing between the patient and the oxygen outlet of the FreeStyle Comfort.

For proper use of the OxySafe, always refer to the manufacturer's instructions (included with each OxySafe kit).

CAIRE offers an OxySafe™ kit that includes a cannula headpiece, OxySafe™, and 7' tubing: PN 20629671.

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

SPECIAL PRODUCT FEATURES

autoSAT®
This feature adjusts oxygen concentrator performance to guarantee the prescribed amount of oxygen is delivered with each breath.

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.

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 battery is in the process of charging, 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 8 hours	up to 16 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.

AC & DC Power Supply

The FreeStyle Comfort comes standard with AC and DC power supplies.
The AC power supply includes the following:

a. AC Power brick that operates between 100-240 volts, 50-60Hz.

b. 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.

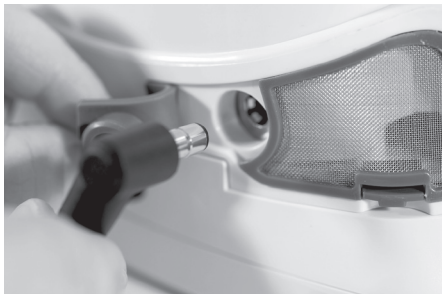
AC POWER

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.

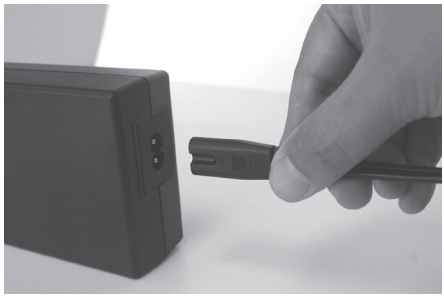
WARNING: DO NOT CONNECT EXTERNAL POWER WITHOUT A BATTERY PACK INSTALLED IN THE OXYGEN CONCENTRATOR.

To connect the FreeStyle Comfort to AC Power:

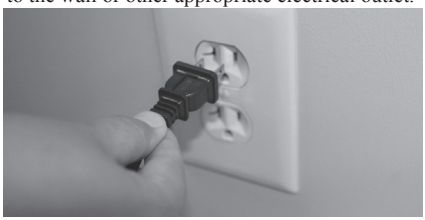
1. Connect the AC power brick to the power connector inlet on the front, right bottom of the FreeStyle Comfort. Be sure to push inward so that the connection is secure.



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.



4. 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.

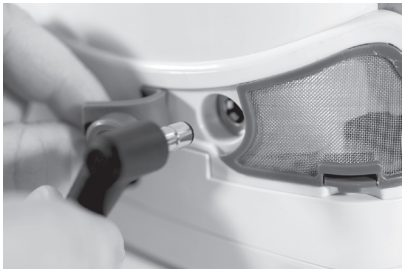
DC POWER

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.

WARNING: DO NOT OPERATE THE DEVICE ON 12 VDC CAR OUTLETS WHILE THE VEHICLE IS TURNED OFF.

1. Turn on your motor vehicle.
2. 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.



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

4. 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.

Cleaning, Care & Routine Maintenance

ROUTINE MAINTENANCE

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 procedures.

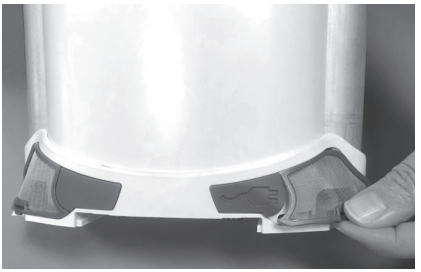
• Weekly – Clean the Air Intake Filters

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 gasses. 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 or disinfection. DO NOT spray the outer case directly. Use a damp (not wet) cloth or sponge. Spray the cloth or sponge with a mild disinfectant 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.

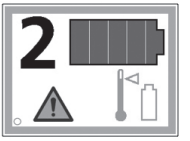
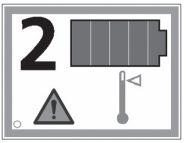
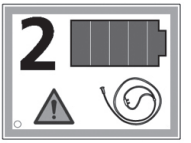
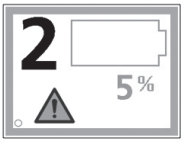
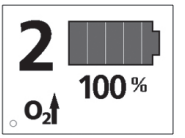
WARNING: DO NOT DISINFECT/CLEAN WITH AUTOMATED WASHING SYSTEM.

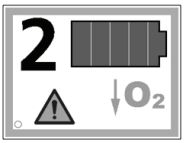
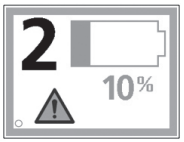
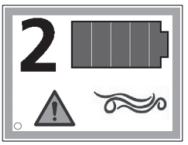
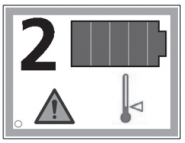
CANNULA REPLACEMENT

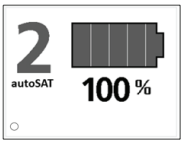
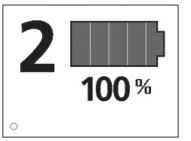
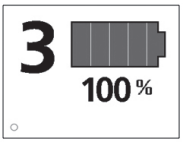
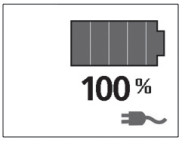
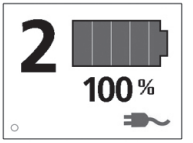
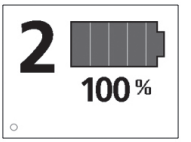
Always follow the cannula manufacturer's instructions for proper use. Replace the nasal cannula or oxygen tubing every 3 to 6 months (if daily use, 3 months) as per manufacturer's recommendation as recommended by the cannula manufacturer or your oxygen provider. Your physician or oxygen provider will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

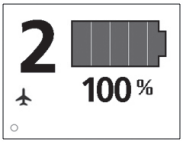
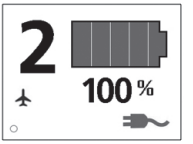
Additional supplies for replacement are available through your oxygen provider.

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		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	No Breath Detected		1 beep every 30 sec	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.
5	Low Battery Shut Down		1 beep every 30 sec	Alarms until battery runs out of power and unit shuts down. Charge battery.
6	Warm Up		none	Unit will start by auto-dosing until a breath is detected or Warm up ends, whichever is sooner.

Priority #	Alarm Description	Display	Audible Signal	More Details
7	Low Concentration		1 beep every 30 sec, for up to 5 min	If problem persists, contact provider.
8	System Malfunction Flow Rate (OCD Valve Failure, Obstruction of Gas Pathway)		1 beep every 30 sec	If problem persists, contact provider.
9	Low Battery Warning		1 beep, no repeat	Charge battery.
10	Breathing Rate Exceeded		1 beep every 60 sec	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.
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.

Priority #	Alarm Description	Display	Audible Signal	More Details
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.
Info	Unplug external power in the run Condition (with battery present)		1 info beep	

Priority #	Alarm Description	Display	Audible Signal	More Details
Info	In Standby Mode - when up or down button is pressed display shows battery and charging state		none	Screen will display for 5 sec then turn off
Info	Airplane Mode on battery power		1 long beep	
Info	Airplane Mode while plugged in		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:

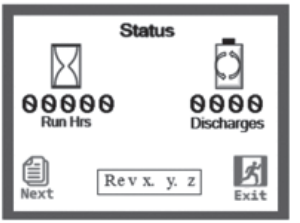
1. Status screen – Displays Firmware rev number, run time, battery discharge cycles
2. Airplane mode(ON/OFF)
3. Sensitivity : adjustable (1-5)
4. autoSAT (ON/OFF)

Example Status Screen

SETTINGS MENU OPERATION

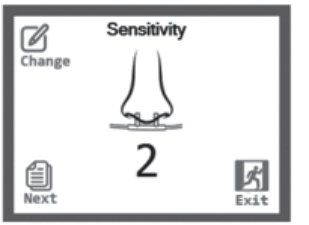
Settings menu is entered by pressing Menu/Select button in Run or Standby modes.

To scroll through the menus, push the .

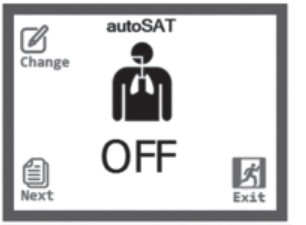


Status

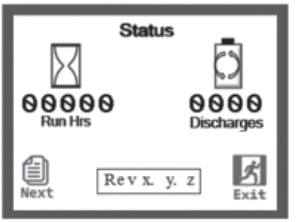
Airplane Mode



Sensitivty



autoSAT



Status Page

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.

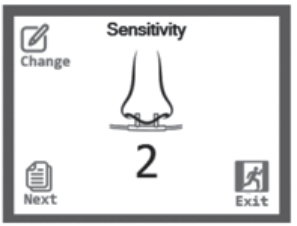
Pressing ▼ when the screen show the “Next” symbol will move the menu page to the next screen option.

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.

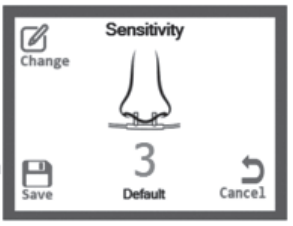
SENSITIVITY MODE

The FreeStyle Comfort ships with a default Sensitivity Mode setting of 3 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

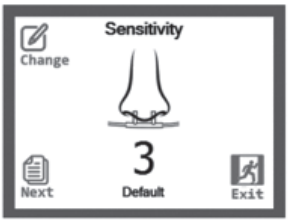
To adjust the Sensitivity Mode, press ▲ while the CHANGE icon is visible. The value will toggle to the next blue number.



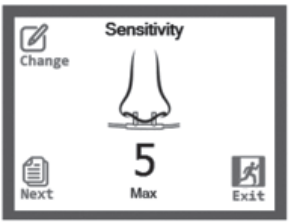
Sensitivity Mode Setting 3 Selected

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

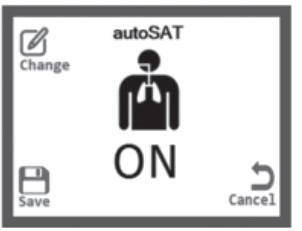


Sensitivity Mode Setting 5 (Max) Confirmed

Pressing ▼ when the screen show the “Next” symbol will move the menu page to the next screen option.

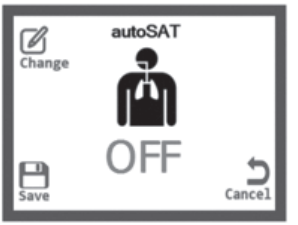
AUTOSAT MODE

The FreeStyle Comfort ships with autoSAT Mode turned on.



autoSAT Mode Main Screen

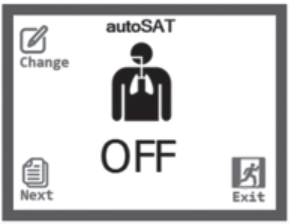
To turn the mode off, press ▲ while the CHANGE icon is visible. The value will toggle to the blue word “OFF”.



autoSAT Mode On 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.

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

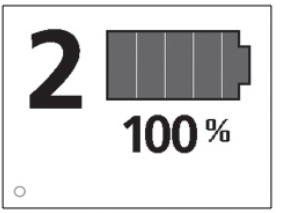
Battery Power

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:

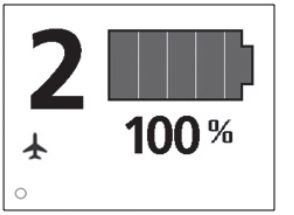
1. Turn POC On using Battery Power ONLY, when no external power source is connected.



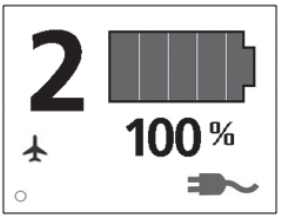
2. Enable Airplane Mode using one of the following methods:

   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.

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	BT034-1S
16-Cell Battery Pack	BT035-1S
Desktop Battery Pack Charger	BT036-1
Carry-all Accessory Bag	MI372-2

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.

Disposal

Always return FreeStyle Comfort, including all components, to your homecare provider for proper disposal. You can also contact your local city or town offices for instructions on proper disposal of the battery.

WEEE and RoHS

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) Directive.

Our products will comply with the restriction of Hazardous Substances (RoHS) directive. They will not contain more than trace amounts of lead or other hazardous material content.

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

Materials in Direct Contact with the Operator

Concentrator Casing	PC/ABS
Concentrator Control Panel	Polyester EBG7 or equivalent
Concentrator Handle	Polycarbonate
Oxygen Outlet, Nozzle	Polycarbonate
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

EMC Testing

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

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.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class B	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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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 (0^0) 70% U_T (30% dip in U_T) for 25/30 cycles (0^0) 0% U_T for 250/300 cycles (0^0)	0% U_T for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0% U_T for 1 cycle (0^0) 70% U_T (30% dip in U_T) for 25/30 cycles (0^0) 0% U_T for 250/300 cycles (0^0)	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 MHz to 800 MHz $d = 1.2\sqrt{P}$ = 800 MHz to 2700 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 metres (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.

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 metres (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.

Notes

Notes

Notes

CAIRE®

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