

User Manual



FreeStyle™

FreeStyle™ & FreeStyle™ 5

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User Controls & System Status Indicators

Symbol	Definition
	Consult instructions for use
	No Smoking Icon: Do not smoke near unit.
	This side up
RTCA/DO-160 Section 21 Category M Compliant	RTCA DO160 Section 21 Category M Compliant. FAA SFAR 106 requirement
	Fragile – handle with care
	Type BF Equipment
	Name and address of manufacturer
	Authorized representative in the European Community
	Catalog number
	Do not get wet.
	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. It therefore bears the CE marking as shown.
	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.

Symbol	Definition
	Do not disassemble
	Use no oil or grease.
	No open or naked flames.
	Safety agency for CAN/CSA C22.2 No. 60601-1-08 M90 for medical electrical equipment
	Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment
	FAA Approved – POC
	Serial Number
	Date of Manufacture
	Class II Equipment, Double Insulated
	Prescription only
	Indicates the temperature limits to which the medical device can be safely exposed.

What is the Oxygen Concentrator

The air we breathe contains approximately 21% oxygen, 78% nitrogen, and 1% other gasses. In the FreeStyle and FreeStyle 5, room air is drawn into the machine through the air intake. 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.

FreeStyle and FreeStyle 5 combine advanced oxygen concentrator and oxygen conserving technologies to create a portable device that allows for maximum portability and ambulation. Their

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 and FreeStyle 5 are both lightweight enough to be carried via handle, shoulder strap, or backpack. They can be operated on AC, 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 room air we breathe. 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 ones 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. 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 Disorder (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 or FreeStyle 5

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

FreeStyle:

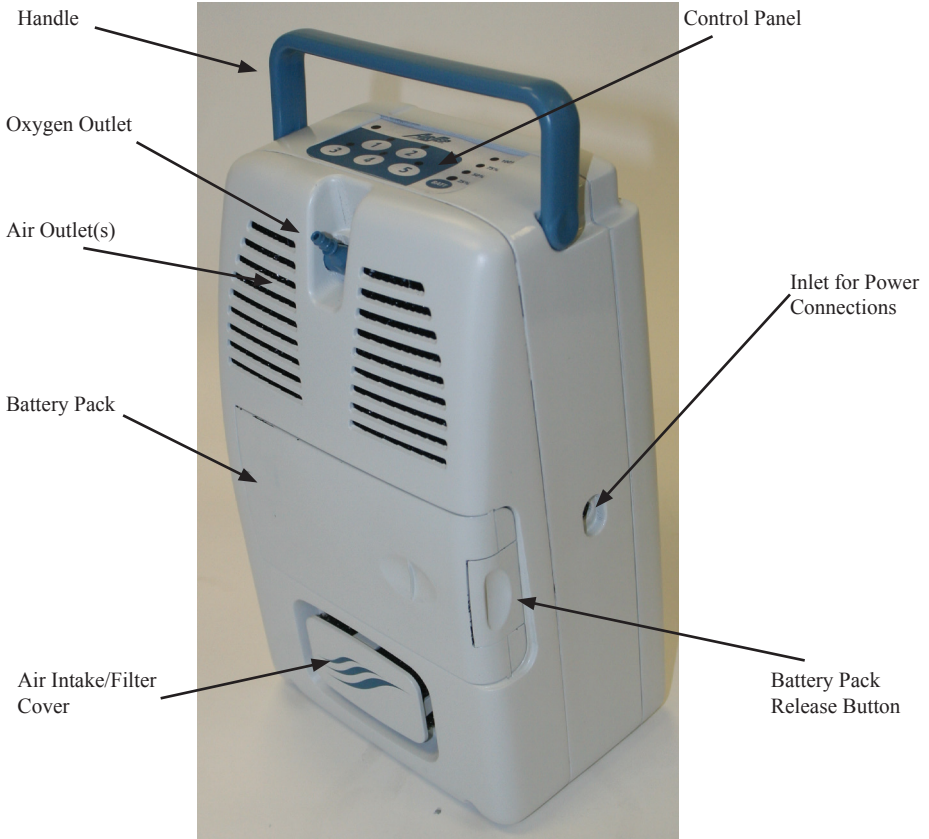
- Portable Oxygen Concentrator
- Carrying Bag
- Shoulder Strap
- Carry-All Accessory Bag
- Battery Pack
- AC/DC Universal Power Supply
- AC Power Cord
- DC Power Cable
- User's Manual

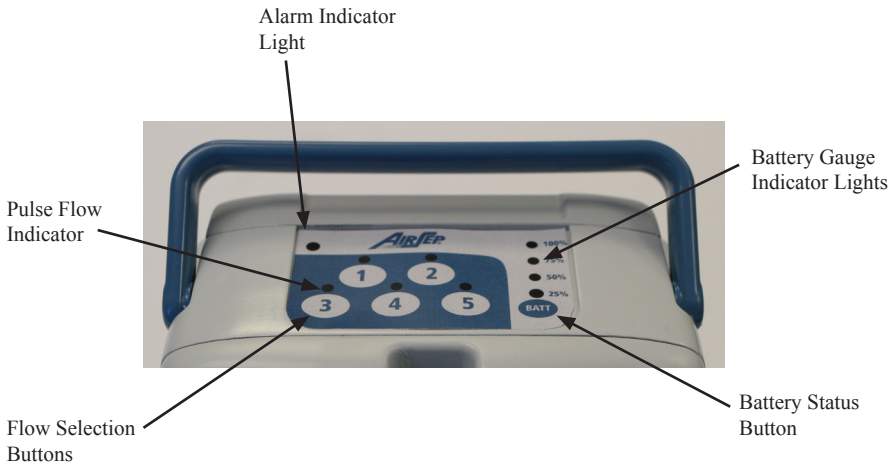
FreeStyle 5:

- Portable Oxygen Concentrator
- Carrying Bag
- Shoulder Strap
- Carry-All Accessory Bag
- Battery Pack
- AC Power Supply
- DC Power Supply
- User's Manual

Getting to Know Your FreeStyle or FreeStyle 5

Become familiar with the key features of the FreeStyle and FreeStyle 5 and their control panels





Flow Selection Buttons:

To power the device ON or OFF, press the numeric button of your prescribed pulse flow setting. The Pulse flow indicator light will illuminate green above the selected flow setting when the unit is ON. You can also change flow settings by pressing the numeric button of the desired setting.

Pulse Flow Indicator Lights:

Will illuminate green to indicate the selected flow setting. The light above the flow selection button indicates it is running at that flow setting. The pulse flow indicator light will blink with each inhalation to indicate oxygen has been delivered.

Alarm Indicator Light:

Indicates an alarm condition on the concentrator. A prompt response is necessary. Refer to the troubleshooting table in this manual, and contact your homecare provider if necessary for assistance.

Battery Status Button:

Press once to display the battery gauge indicator to determine how much time is remaining on the charge of the installed battery pack.

Battery Gauge Indicator Lights:

Each light represents approximately 25% of the total battery pack charge. Battery charge will display when the battery status button is pressed. When the battery is charging, the indicator lights will blink until the % capacity level is reached. Once the capacity level is reached they will turn solid.

Important!

Safety Instructions are defined as follows:



WARNING: IMPORTANT SAFETY INFORMATION FOR HAZARDS THAT MAY CAUSE SERIOUS INJURY.



CAUTION: Important information for preventing damage to the FreeStyle or FreeStyle 5.

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. THE PORTABLE OXYGEN CONCENTRATOR MAY BE USED DURING SLEEP UNDER THE RECOMMENDATION OF A QUALIFIED 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.

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: 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: 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 YOU SMOKE, YOU MUST ALWAYS FOLLOW THESE 3 IMPORTANT STEPS FIRST: TURN OFF THE OXYGEN CONCENTRATOR, TAKE OFF THE CANNULA, AND LEAVE THE ROOM WHERE THIS DEVICE IS LOCATED.



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 FREESTYLE OR FREESTYLE 5 MUST BE OFF AND DISCONNECTED FROM EXTERNAL POWER BEFORE REMOVING THE BATTERY PACK.



CAUTION: Always disconnect AC power supply from the wall before disconnection the AC power supply from the oxygen concentrator.

CAUTION: Do not position the 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. If the DC power supply does not illuminate and requires resetting, disconnect the DC power supply from the DC outlet, restart your vehicle, and then reconnect your DC power supply into the DC outlet. 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 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 73°F ± 35°F (23°C ± 2°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 FREESTYLE OR FREESTYLE 5 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	FreeStyle 5
Dimensions	8.6 in x 6.1 in x 3.6 in (21.8 cm x 15.5 cm x 9.1 cm)	10.7 in x 6.6 in x 4.4 in (27.2 cm x 16.8 cm x 11.2 cm)
Weight (w/ Battery Pack)	4.9 lbs (2.2 kg)	6.7 lbs (3.0 kg)
Nominal Sound Level	41 dB(A) at setting 2 44 dB(A) at setting 3	48 dB(A) at setting 3 51 dB(A) at setting 5
Flow Settings	Pulse Settings 1, 2, 3	Pulse Setting 1, 2, 3, 4, 5
Oxygen Concentration	90% oxygen +5.5/-3%	90% oxygen +5.5/-3%
AC Power	100-240 VAC, 50-60 Hz (1.75 amps max)	100-240 VAC, 50/60 Hz (2 amps max)
DC Power	11-16 VDC (8.0 amps max)	12-24 VDC (15 amps max)
Battery Pack	Rechargeable, lithium battery	Rechargeable, lithium battery
Battery Pack Durations	Setting 1 – 6.5 hours Setting 2 – 3.5 hours Setting 3 – 3 hours	Setting 1 – 4.25 hours Setting 2 – 2.5 hours Setting 3 – 1.75 hours Setting 4 – 1.5 hours Setting 5 – 1.25 hrs
Warm Up Time	2 minutes	2 minutes
Operating Temperature	41°F to 104°F (5°C to 40°C)	41°F to 104°F (5°C to 40°C)
Storage Temp. (Unit)	-4°F to 140°F (-20°C to 60°C)	-4°F to 140°F (-20°C to 60°C)
Storage Temp. (Battery)	1 month -4°F to +122°F (-20 to +60 C) 3 months -4°F to +104°F (-20 to +45C) 1 year -4°F to +68°F (-20 to 20C)	1 month -4°F to +122°F (-20 to +60 C) 3 months -4°F to +104°F (-20 to +45C) 1 year -4°F to +68°F (-20 to 20C)
Operating Altitude	Up to 12,000 ft (3,657.6 m)	Up to 12,000 ft (3,657.6 m)
Operating Humidity	<95%, non-condensing	<95%, non-condensing

* 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

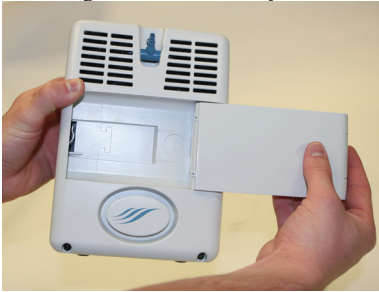
Operating Instructions

1 Locate and position the FreeStyle or FreeStyle 5 in a proper location for use.

- a The concentrator should be well-ventilated so that their air intake and air outlets are not be 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 filter and filter cover are in place before operating the unit. If the unit is missing the filter or filter cover, contact your equipment provider.

2 Install a Battery Pack in the concentrator

- a Align the battery with the front housing from the right side of the FreeStyle or FreeStyle 5.



- 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 receptacle on the right side of the unit if recharging the battery pack and/or running from the external power source.



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

NOTE: The maximum length of tubing that can be used is 25 ft (7.62 m).



5 Turn on the FreeStyle or FreeStyle 5 by pressing the numeric flow selection button of the pulse flow setting prescribed by your physician to turn on the device.



A brief audible alarm will sound to indicate the device has powered on and the green light above the flow selection button you pressed should remain illuminated.

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. The green light above the selected flow rate button will blink with each dose of oxygen delivered.

7 To change the flow setting, press the numeric button of the new desired flow rate. It is normal to hear a difference in sound as you change the flow settings.

8 Turn the FreeStyle or FreeStyle 5 off by pressing the button corresponding to the pulse flow indicator light that is illuminated.



Power Supplies

The FreeStyle and FreeStyle 5 can be powered in 3 ways:

- Re-chargeable 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 or FreeStyle 5 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 front housing from the right side of the FreeStyle or FreeStyle 5 so that it will slide into the empty compartment. Push the battery inward until you hear a click to confirm that it has locked in place.



REMOVING THE BATTERY:

Pull the battery release button outward away from the FreeStyle or FreeStyle 5. While HOLDING this button, slide the battery out by pulling it away from the concentrator. Use the depressed finger slot to grip the battery when pulling outward.



WARNING: THE FREESTYLE OR FREESTYLE 5 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 or FreeStyle 5, press the "BATT" battery status button on the control panel of the concentrator. The battery gauge indicator lights (25-100%) will illuminate above the BATT button to indicate the level of the battery pack charge.

Note: If the battery is in the process of charging, the gauge indicator lights will show the status without pressing the BATT button.



To check the battery charge when it is not installed in the FreeStyle or FreeStyle 5, turn the battery on its back 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 or FreeStyle 5 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 and FreeStyle 5 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.

While charging a fully discharge battery, the 25% battery gauge indicator light on top of the FreeStyle or FreeStyle 5 will begin by blinking rapidly for a few minutes, and then start to blink at a slower rate (every ½ second). The LED will continue to blink until 25% battery capacity is reached. The LED will then turn solid. Each of the 4 battery gauge indicator lights (25-100%) will blink as stated above during charging, then turn solid when they reach capacity.

When all 4 of the battery gauge indicator lights are solid, the battery is fully charged. The lights will remain on for a short period of time to indicate a full charge, and will then turn off.

Alternately, the battery pack may be charged using the optional desktop charger. Reference the manual for the desktop charger (MN221) for instructions on its operation.

BATTERY OPERATING DURATION:

When external AC or DC power is disconnected, the concentrator will automatically switch over to using battery power if the battery pack is installed and has a charge. 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	FreeStyle	FreeStyle 5
1	6.5 hours (6 hrs, 30 minutes)	4.25 hrs (4 hrs, 15 minutes)
2	3.5 hours (3 hrs, 30 minutes)	2.5 hrs (2 hrs, 30 minutes)
3	3.0 hours (3 hrs)	1.75 hrs (1 hr, 45 minutes)
4	-	1.5 hrs (1 hr, 30 minutes)
5	-	1.25 hrs (1 hr, 15 minutes)

TYPICAL BATTERY RECHARGE TIME:

The typical time to recharge your battery pack inside of the FreeStyle or FreeStyle 5 to achieve full capacity from a fully discharged battery is between 4-5 hours.

If using the optional desktop charger, the battery pack will fully charge in 4-5 hours.

FreeStyle AC & DC Power Supply

The FreeStyle is equipped with a universal AC/DC power supply to keep your concentrator powered wherever you go. It replaces separate AC and DC power supplies so you only have a carry and keep up with one power supply.

The universal power supply includes the following:

1. Universal power supply (brick) which operates on:
 - a. AC Power between 100-240 volts, 50-60Hz.
 - b. DC Power sources including 12V automobile accessory outlets
2. Removable AC power cord
 - a. Plug style varies by country or location of purchase
3. Removable DC Power Cord



AC POWER

AC power is for use at home or wherever standard AC outlet power is available. The FreeStyle is fully functional on AC power. The FreeStyle will also recharge the battery pack if needed any time AC power is available. The battery pack will recharge whether the FreeStyle is powered on or off.



WARNING: DO NOT CONNECT EXTERNAL POWER WITHOUT A BATTERY PACK INSTALLED IN THE FREESTYLE OR FREESTYLE 5.

To connect the FreeStyle to AC Power:

1. Connect the universal power supply to the power connector inlet on the side of the FreeStyle. Be sure to push inward so that the connection is secure.



2. Connect the AC power cord to the unmarked AC inlet on the power supply



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



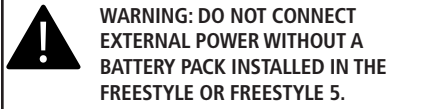
4. Ensure the green light on top of the Universal power supply is illuminated. This indicates that the power supply is receiving power from the outlet. If the green light is not illuminated, check for secure connections and refer to the troubleshooting section of this manual.



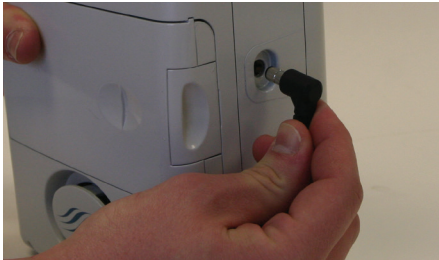
5. If the battery pack is in need of re-charge, the battery status indicator lights should blink accordingly to show charging.
6. Turn on the FreeStyle by pressing the numeric flow selection button of the pulse flow setting prescribed by your physician to turn on the device.

DC POWER

DC power is for use in the accessory outlets of automobiles, boat, or other motor vehicles. The FreeStyle is fully functional on DC power for use. The FreeStyle 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.



1. Connect the universal power supply to the power connector inlet on the side of the FreeStyle. Be sure to push inward so that the connection is secure.



2. Connect the DC power cord to the inlet marked "ACCESSORY DC IN" on the universal power supply



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



4. Turn on your motor vehicle.

5. Ensure the green light on top of the Universal power supply is illuminated. This indicates that the power supply is receiving power from the outlet. If the green light is not illuminated, disconnect the power supply from the DC outlet, restart the motor vehicle, and then reconnect the power supply to the DC outlet.



6. If the battery pack is in need of re-charge, the battery status indicator lights should blink accordingly to show charging.
7. Turn on the FreeStyle by pressing the numeric flow selection button of the pulse flow setting prescribed by your physician to turn on the device.

FreeStyle 5 AC & DC Power Supply

The FreeStyle 5 is equipped with separate power supplies for AC and DC operation.

The FreeStyle 5 includes the following:

1. AC power supply which operates on AC Power between 100-240 volts, 50-60Hz.
2. Removable AC power cord
3. DC Power Supply which operates on DC Power sources including 12V automobile accessory outlets



AC POWER

AC power is for use at home or wherever standard AC outlet power is available. The FreeStyle 5 is fully functional on AC power for use. The FreeStyle 5 will also recharge the battery pack if needed any time AC 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 FREESTYLE OR FREESTYLE 5.

To connect the FreeStyle 5 to AC Power:

1. Connect the AC power supply to the power connector inlet on the side of the FreeStyle 5. Be sure to push inward so that the connection is secure.



2. Connect the AC power cord to the inlet on the power supply.



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



4. Ensure the green light on top of the AC power supply is illuminated. This indicates that the power supply is receiving power from the outlet. If the green light is not illuminated, check for secure connections and refer to the troubleshooting section of this manual.



5. If the battery pack is in need of re-charge, the battery status indicator lights should blink accordingly to show charging (See Battery Pack section).

6. Turn on the FreeStyle 5 by press the numeric flow selection button of the pulse flow setting prescribed by your physician to turn on the device.

DC POWER

DC power is for use in the accessory outlets of automobiles, boat, or other motor vehicles. The FreeStyle is fully functional on DC power for use. The FreeStyle 5 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 FREESTYLE OR FREESTYLE 5.

1. Connect the DC Power Supply to the power connector inlet on the side of the FreeStyle. Be sure to push inward so that the connection is secure.



2. Connect the DC power cord to automobile or other DC accessory outlet.



3. Turn on your motor vehicle.

4. Ensure the green light on top of the DC supply is illuminated. This indicates that the power supply is receiving power from the outlet. If the green light is not illuminated, disconnect the power supply from the DC outlet, restart the motor vehicle, and then reconnect the power supply to the DC outlet.



5. If the battery pack is in need of re-charge, the battery status indicator lights should blink accordingly to show charging (See Battery Pack section) .
6. Turn on the FreeStyle 5 by pressing the numeric flow selection button of the pulse flow setting prescribed by your physician to turn on the device.

Cleaning, Care & Routine Maintenance

ROUTINE MAINTENANCE

Servicing of internal components inside of the cabinet of the FreeStyle or FreeStyle 5 must be performed by the oxygen provider.

The operator is responsible for the following maintenance procedures.

- Weekly – Clean the Air Intake Filter



WARNING: DO NOT ATTEMPT TO OPEN OR REMOVE THE PLASTIC COVERS OF THE FREESTYLE OR FREESTYLE 5. THE UNIT SHOULD ONLY BE OPENED BY A QUALIFIED SERVICE TECHNICIAN.

AIR INTAKE FILTER

Air enters the FreeStyle and FreeStyle 5 through an air intake filter located under the cover on the lower front of the oxygen concentrator. This filter prevents dust and other large particles in the air from entering the unit.

At least once per week, the Air Intake Filter should be cleaned. Your oxygen provider may advise you to clean it more frequently, depending on the operating conditions. Follow these steps to properly clean the Air Intake Filter

1. Remove the filter cover from the front of the FreeStyle or FreeStyle 5 by pulling it outward.



2. Remove the filter from the cover.



3. Wash the filter in a warm solution of soap and water
4. Rinse the filter thoroughly and remove excess water with a soft, absorbent towel. Ensure the filter is completely dry before replacing it.
5. Replace the clean and dry filter in the filter cover and re-install the filter cover in the FreeStyle or FreeStyle 5.



WARNING: DO NOT OPERATE THE FREESTYLE OR FREESTYLE 5 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 visually, contact your oxygen provide before use

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 place the battery in or near a microwave or other cooking appliances. 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. For 1 year of storage, it is recommended the battery remains within a temperature range of -4°F to +68°F (-20°C to +20°C). Every 6 months charge the battery between 50% and 75% (two to three LEDs) and remove it from the Oxygen Concentrator. For 3 months of storage, it is recommended that the battery remains within a temperature range of -4°F to +104°F (-20°C to +40°C). For 1 month of storage, it is recommended that the battery remains within a temperature range of -4°F to +122°F (-20°C to +50°C).

BATTERY DISPOSAL

Your battery is rechargeable and can be recycled. Always return 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.



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

CLEANING

Turn OFF the unit and disconnect from AC or DC power before any cleaning or disinfection activity. DO NOT spray the outer case directly. Use a damp (not wet) cloth or sponge. Spray the cloth or sponge with a mild detergent 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, CONCENTRATOR CHLORINE-BASED PRODUCTS (ETHYLENE CHLORIDE), AND OIL-BASED PRODUCTS (PINE-SOL, LESTOIL). 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.

CANNULA REPLACEMENT

Always follow the cannula manufacturer's instructions for proper use. Replace the nasal cannula or oxygen tubing 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

START-UP ALARM

A brief alarm sounds when the FreeStyle or FreeStyle 5 is first powered on. This is normal. The concentrator begins to operate once the brief alarm stops.

LOW BATTERY ALARM

As the battery pack power approaches a low level, a brief alarm sounds intermittently and the yellow 25% battery gauge indicator light will illuminate intermittently. When this occurs, connect the FreeStyle or FreeStyle 5 to an AC or DC power outlet, or change to an alternate oxygen source. When connected to AC or DC power, the concentrator will operate while recharging the battery pack.

CANNULA DISCONNECT

When FreeStyle or FreeStyle 5 is operating but does not sense breathing, a constant alarm sounds, and the alarm light illuminates after 15 minutes. If this occurs, check the connection from the cannula to the FreeStyle or FreeStyle 5 unit, make sure that the nasal cannula is positioned properly on your

face, and ensure that you are breathing through your nose. If the alarm continues to sound, change to another source of oxygen as available, and contact your Equipment Provider.

BREATH RATE EXCEEDED

If your breathing rate causes the capacity of FreeStyle or FreeStyle 5 to be exceeded, a rapid alarm sounds every ½ second, and the alarm light illuminates red intermittently. When this occurs, the concentration of oxygen that the FreeStyle or FreeStyle 5 is supplying is outside of the unit specifications. You should reduce any physical activity, reset alarm by turning unit off and back on, and then if necessary change to another source of oxygen as available, and contact your Equipment Provider.

GENERAL MALFUNCTION

If FreeStyle or FreeStyle 5 has a general malfunction, a rapid alarm sounds every ½ second, and the alarm light illuminates red continuously. When this occurs, the concentration of oxygen that FreeStyle is supplying is below unit specifications. You should change to another source of oxygen as available, and contact your Equipment Provider.

Status	Audible Alarm	Light	Indicates	Action
Start-Up	Brief, continuous at start-up	(Green) pulse; continuous light	FreeStyle or FreeStyle 5 has been turned on	You may begin to operate your FreeStyle unit.
Normal Operation	No	(Green) pulse; intermittent light	FreeStyle or FreeStyle 5 is delivering oxygen as a pulse flow.	Continue using FreeStyle normally.
Alarm	Continuous: Beep	(Red) alarm; continuous light	No breath detected by the unit for a predetermined time period.	Check the cannula connection. Ensure that you are breathing through your nose. If the alarm persists, contact your Equipment provider.
Alarm	Intermittent: Beep, beep, beep.	25% (Yellow) BATT; battery indicator.	Battery voltage is too low to operate FreeStyle.	Connect the FreeStyle or FreeStyle 5 unit into a DC outlet or an AC outlet immediately.
Alarm	Rapid intermittent: Beep, beep, beep.	(Red) alarm; intermittent light	Breathing rate is exceeding the capacity of the FreeStyle or FreeStyle 5 unit.	Reduce activity, then if necessary use another source of oxygen as available. Contact your Equipment Provider.
Alarm	Rapid intermittent: Beep, beep, beep.	(Red) alarm; continuous light	General malfunction of the FreeStyle or FreeStyle 5 unit has occurred.	Turn off the unit. Change to another source of oxygen, and contact your provider.

Troubleshooting

Problem	Probable Cause	Solution
FreeStyle does not operate when a pulse flow selection button is pressed.	Battery is discharged. Malfunction.	Power the unit through the DC outlet, or an AC outlet. Contact your Equipment Provider, and change to another source of oxygen as necessary.
A continuous alarm sounds and the (yellow) alarm light illuminates continuously.	FreeStyle has not detected a breath for 15 minutes.	Check the cannula connection. Ensure that cannula tubing is not kinked. Make sure that the cannula is positioned properly and that you are breathing through your nose. For mouth-breathing your clinician may recommend a chin strap.
Intermittent alarm condition, and the (yellow) BATT light illuminates intermittently.	Battery requires charging.	Connect to a DC or an AC outlet within 2 minutes, or exchange battery packs for a fully charged pack.
Rapid alarm condition, and the (yellow) BATT light illuminates intermittently and FreeStyle shuts down.	Battery pack charge is too low to operate the FreeStyle unit.	Connect to DC or an AC outlet immediately.
Intermittent alarm condition, and the (red) alarm light illuminates intermittently.	Breathing rate has exceeded the capacity of the FreeStyle unit	Reduce activity, and then turn unit off and back on again to reset unit. If necessary, change to another source of oxygen as available and contact your Equipment Provider.
Intermittent alarm condition, and the (red) alarm light illuminates continuously.	A general malfunction has occurred.	Change to another source of oxygen as available, and contact your Equipment Provider.
Unit does not start on battery pack power.	Unit may be hot or cold if left outdoors such as in an automobile.	Allow the unit to reach normal operating temperature, which may take several minutes if exposed to temperature extremes.
Delay in recharging internal battery.	Internal battery exceeds charging temperature.	Unit may be operated; however, charging may not resume until battery temperature is reduced.
Unit alarms while in automobile and connected to the DC outlet.	No power to the unit if battery depleted and DC outlet not charging.	Disconnect the power supply from the automobile outlet, restart the automobile, and then reconnect the power supply into the automobile DC outlet to reset the breaker within DC power supply.
All other problems.		Change to another source of oxygen as available, and contact your Equipment Provider.

Travel Information

The FreeStyle and FreeStyle 5 are both FAA approved 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 travelling with a FreeStyle or FreeStyle 5.

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 or the carry-all accessory bag provided.

FAA REGULATION

Spare batteries must be individually protected to prevent short circuits by placement in the original retail packaging or by otherwise insulation 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.

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 Standard Accessories (Included With Package):	
Carry-all Accessory Bag	MI320-1
Carrying Case	MI419-1
Shoulder Strap	MI426-1
Universal AC Power Supply (All Cords And Components Included)	PW032-1 (US Cord) PW032-2 (EU Cord) PW032-3 (UK Cord)
Battery Pack	BT033-1
Air Intake Filter	FI144-1

FreeStyle 5 Standard Accessories (Included With Package):	
Carry-all Accessory Bag	MI372-1
Carrying Case	MI420-1
Shoulder Strap	MI426-1
AC Power Supply (Cord Included)	PW035-1 (US Cord) PW035-2 (EU Cord) PW035-4 (UK Cord)
DC Power Supply	PW034-1
Battery Pack	BT033-1
Air Intake Filter	FI194-1
Optional Accessories Available	
Desktop Battery Pack Charger	BT032-1 (US Cord) BT032-2 (EU Cord) BT032-4 (UK Cord)

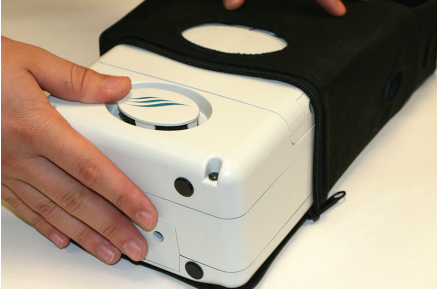
Note: Additional options may be available for country-specific power cords where noted above. Contact CAIRE or your oxygen provider if alternate options are needed for order.

Carrying Bag Instructions

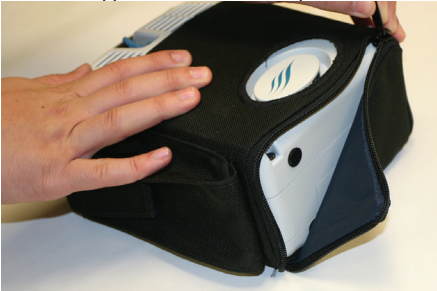
To insert and secure your FreeStyle or FreeStyle 5 unit in the carrying bag, utilize the following instructions.

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. Unclip the carry handle.



2. Insert long section into same clip.



3. Attach remaining end to other side of carry handle.



Materials in Direct Contact with the Operator

- Concentrator Casing.....PC/ABS.
- Concentrator Control Panel.....Polyester EBG7 or equivalent
- Concentrator HandlePolycarbonate
- Oxygen Outlet, Nozzle.....Polycarbonate
- Unit LabelLexan
- Cord ConnectorsPolycarbonate/Vinyl chloride
- Power CordPVC, Metal
- Power SupplyLexan 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 and FreeStyle 5 are intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle and FreeStyle should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The FreeStyle and FreeStyle 5 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 and FreeStyle 5 are 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 and FreeStyle 5 are intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle and FreeStyle 5 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	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 commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FreeStyle and FreeStyle 5 require continued operation during power mains interruptions, it is recommended that the FreeStyle and FreeStyle are 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 typical commercial or hospital environment.

NOTE U_T is the A.C. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The FreeStyle and FreeStyle 5 are intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle and FreeStyle 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the FreeStyle and FreeStyle 5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} = 80 \text{ MHz to } 800 \text{ MHz}$ $d = 1.2\sqrt{P} = 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 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 and FreeStyle 5 are used exceeds the applicable RF compliance level above, the FreeStyle and FreeStyle 5 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 and FreeStyle 5.

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

Recommended separation distances between portable and mobile RF communications equipment and the FreeStyle or FreeStyle 5

The FreeStyle and FreeStyle 5 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FreeStyle and FreeStyle 5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FreeStyle and FreeStyle 5 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 General Requirements for safety.
 - CAN/CSA C22.2 No. 60601-1-08 M90 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 EN60601-1-2 (EMC).

- 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

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.



CAIRE Inc.

2200 Airport Industrial Dr., Ste 500
Ball Ground, GA 30107
www.CAIREmedical.com

EC REP

Medical Product Services GmbH
Borngasse 20
35619 Braunfels, Germany
Tel: +49 (0) 6442-962073
E-mail: info@mps-gmbh.eu
Worldwide: www.CAIREmedical.com

CE
0459


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