

FreeStyle™

Patient Manual

FreeStyle™ Portable
Oxygen Concentrator

AIRSEP®



English: A multilingual version of the manual is available through your equipment provider.
Español: Una versión multilingüe del manual está disponible a través de su proveedor de equipo.
Français: Une version multilingue du manuel est disponible par l'intermédiaire de votre fournisseur de matériel.
Deutsche: Eine mehrsprachige Version des Handbuchs ist in Ihrer Geräte-Anbieter.

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AirSep’s FreeStyle™ Portable Oxygen Concentrator

This Patient Manual will acquaint you with AirSep’s FreeStyle™ Portable Oxygen Concentrator (POC). Make sure you read and understand all the information contained in this manual before you operate your FreeStyle unit. Should you have any questions, your Equipment Provider will be happy to answer them for you.

Symbols

Symbols are frequently used on equipment and/or the manual in preference to words with the intention of decreasing the possibility of misunderstanding caused by language differences. Symbols can also permit easier comprehension of a concept within a restricted space.

The following table is a list of symbols and definitions used with the FreeStyle Portable Oxygen Concentrator.

Symbol	Description	Symbol	Description
	Warning – Describes a hazard or unsafe practice that can result in severe bodily injury or death		Class II
	Caution – Describes a hazard or unsafe practice that can result in minor bodily injury or property damage		CE Mark
	Note – Provides information important enough to emphasize or repeat		Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment
	Refer to Patient Manual Instructions		Keep unit and accessories dry
	No oil or grease		Proper disposal of waste of electrical and electronic equipment required
	No Smoking		Do not disassemble

	Type BF Equipment		Consult instructions for use
<small>RTCA/DO-160D Section 21 Category M Compliant FAA Approved</small>	RTCA/DO-160D Section 21 Category M Compliant FAA SFAR 106 requirement		

 **WARNING** In the event of an alarm, you observe the FreeStyle is not working properly, or if you feel discomfort, consult your Equipment Provider and/or your physician immediately.

 **WARNING** This unit is not to be used for life support. Geriatric, pediatric, or any other patients unable to communicate discomfort while using this machine may require additional monitoring. Patients with hearing and/or sight impairment(s) may need assistance with monitoring alarms.

 **WARNING** This device supplies high-concentration oxygen that promotes rapid burning. Do not allow smoking or open flames within five feet (1.5 m) of (1) this device, or (2) any oxygen-carrying accessory.

 **WARNING** Use no oil, grease, or petroleum-based products on or near FreeStyle.

 **WARNING** Disconnect the power cord from the electrical outlet before you clean or service the unit.

 **WARNING** While using the FreeStyle outdoors with the AC power supply, connect the power supply into a Ground Fault Interrupted (GFI) outlet only.

 **WARNING** Care should be taken to prevent the unit from getting wet or allowing water to enter the unit.

Why Your Physician Prescribed Oxygen

Many people suffer from a variety of heart, lung, and other respiratory diseases. A significant number of these patients 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.



It is very important to select the prescribed level of oxygen flow. Do not increase or decrease the flow until you first consult your physician.



The FreeStyle Portable Oxygen Concentrator may be used during sleep under the recommendation of a qualified clinician.

What is the FreeStyle Portable Oxygen Concentrator?

Oxygen concentrators were introduced in the mid-1970's and have become the most convenient, reliable source of supplemental oxygen available today. Oxygen concentrators are the most cost-effective, efficient, and safest alternative to using high-pressure oxygen cylinders or liquid oxygen. An oxygen concentrator provides all the oxygen you need with no cylinder or bottle deliveries required.

The air we breathe contains approximately 21% oxygen, 78% nitrogen, and 1% other gases. In the FreeStyle unit, room air passes through a regenerative, adsorbent material called "molecular sieve." This material separates the oxygen from the nitrogen. The result is a flow of high-concentration oxygen delivered to the patient.

FreeStyle combines advanced oxygen concentrator technology along with oxygen conserving technology for the world's smallest and lightest portable oxygen concentrator at just 4.4 lb (2 kg). The FreeStyle efficiently produces its own oxygen, and quickly delivers it as a pulse of oxygen when you breathe at the very beginning of your inhalation. This eliminates the waste associated with a continuous flow oxygen device that flows oxygen while you are exhaling. This pulsing of the oxygen is equivalent to continuous flow. FreeStyle produces the equivalent of up to 3 LPM (liters per minute) in a lightweight package that can be easily carried and used away from the home.

FreeStyle operates from four different power sources. (Refer to the Power Supplies section of this manual.)

FreeStyle for Airline Travel – FAA-Approved

FreeStyle has received the US Federal Aviation Administration's (FAA) acceptance for onboard in-flight use by oxygen passengers on commercial airlines via a 2006 amendment to SFAR 106.

In addition, as of May 13, 2009, a new Department of Transportation (DOT)/FAA ruling has determined that US-based carriers, as well as international flights with origination or destination in the US, must allow passengers with FAA-approved portable oxygen concentrators to use them on board, and in flight, as medically necessary. Check directly with the individual airlines with which you would like to travel for up-to-date information on their specific POC policies.

Important Safety Rules

Carefully review and familiarize yourself with the following important safety information about the portable FreeStyle Oxygen Concentrator.



In the event of an alarm, you observe the FreeStyle is not working properly, or if you feel discomfort, consult your Equipment Provider and/or your physician immediately.



This unit is not to be used for life support. Geriatric, pediatric, or any other patients unable to communicate discomfort while using this machine may require additional monitoring. Patients with hearing and/or sight impairment(s) may need assistance with monitoring alarms.



Never use FreeStyle with the device itself located in the trunk of an automobile.



Do not allow either the air intake or the air outlets to become blocked. This may affect the performance of the FreeStyle during use, such as under an automobile or airline seat, or in a carrying bag or case that is not supplied through AirSep.



When the automobile in which you are using the FreeStyle unit is turned off, disconnect and remove the unit from the automobile with you. Never allow FreeStyle to be stored in a very hot automobile or in other similar, high-or low-temperature environments. (Refer to the Specifications section in this manual.)



If the unit has been stored for an extended period of time in a cold environment (outside its normal operating range), the unit should be allowed to warm up to ambient temperature before being turned on.



Federal (USA) law restricts this device to sale by order of a physician.



When using FreeStyle in an automobile, boat, or other vehicle with the DC power supply, make sure that the vehicle is started and running before connecting the FreeStyle unit. 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.



Although FreeStyle is a low-voltage device, do not remove its housing. Only your Equipment Provider should remove the unit covers.



While using FreeStyle outside of its normal operating temperature range, there may be a decrease in battery performance or an increase in charge time.

Getting Started with Your FreeStyle Portable Oxygen Concentrator

The FreeStyle packaging contains the following items, as shown in Figures 1-3. If any are missing, contact your Equipment Provider.

- FreeStyle Portable Oxygen Concentrator with carrying case.
- Patient manual (not shown)
- AC power supply (100-240 volts, 50/60 Hz) with power cord.
- Automobile DC power supply



Figure 1: FreeStyle Unit



Figure 2: FreeStyle AC Power Supply/Power Cord



Figure 3: FreeStyle DC Power Supply

Optionally, you may also have an AirBelt for extended battery duration. That packaging contains the following, as shown in Figure 4:

- AirBelt battery belt
- AC power supply (100-240 Volt, 50/60 Hz) with power cord

 **WARNING** The incorrect use of the FreeStyle AirBelt can cause the battery to get hot, ignite, and may cause serious injury. Be sure not to pierce, strike, step on, or drop the battery, or otherwise subject the battery to strong impacts or shocks.

 **WARNING** Never allow FreeStyle or its AirBelt to be stored in a very hot automobile or in other similar, high-or low-temperature environments. (Refer to the Specifications section in this manual.)

Other optional accessories include a harness to easily convert the FreeStyle carrying bag to a backpack (part number MI284-1), as shown in Figure 5. The FreeStyle can also be worn on the waist if desired by feeding the AirBelt or other belt you are wearing through the loops on the FreeStyle carrying case. (See Figure 6.) The optional accessories bag (part number MI286-1) enables even more convenient travel when transporting all power accessories and optional AirBelts and/or the harness for use at your intended destination.



Figure 4: AirBelt and AC Power Supply/Power Cord



Figure 5: FreeStyle unit worn backpack style

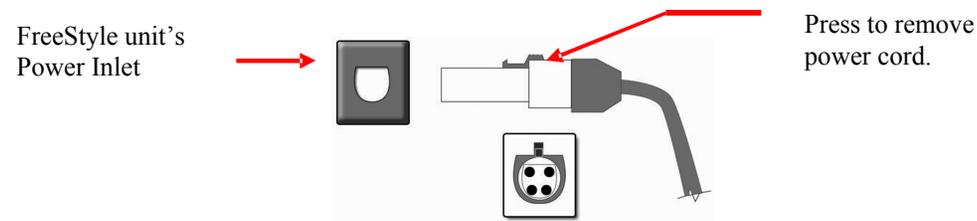


Figure 6: FreeStyle unit worn on the waist

Before operating FreeStyle for the first time, familiarize yourself with the major components. These are illustrated in the figures on the following pages and discussed later in the manual.

Battery Charging

Check to make sure your unit's battery is fully charged before venturing out with FreeStyle for the first time or upon subsequent use. To check the level of charge of the internal battery, press the BATT button on FreeStyle's keypad. The battery gauge/indicator(s) LEDs above the BATT button illuminate to indicate the level of internal battery charge (25-100%). Note: The internal battery is charging whenever the unit is operating on AC or DC power. To charge FreeStyle's internal battery, simply connect its AC power supply or DC power supply into the unit's power connection inlet (as shown in Figure 7). Be certain to first properly align the power cord to this inlet. To do this, take note of the "D"-shaped plug of both the power cord connector and the FreeStyle's inlet connection. These must be properly aligned and when removing the power cord, the release button must be pressed to remove it from the FreeStyle unit. This ensures that neither the unit nor the power accessories are damaged.



Optional AirBelt

The optional AirBelt, which can increase FreeStyle's total battery duration up to 10 hours, requires approximately 3 hours to completely charge when the external battery is fully depleted. To recharge AirBelt, connect its own AC power supply to the end of AirBelt's power cord (as shown in Figure 8), and the other end of the power supply into a proper AC power outlet. A separate battery gauge/indicator for checking the level of charge on the AirBelt's battery is located on this accessory's cord and functions exactly like the internal battery's indicator on the keypad.



Figure 7: Internal Battery Charging



Figure 8: AirBelt Battery Charging

- The FreeStyle's internal battery will completely recharge from its fully depleted state in approximately 3 ½ hours, whether or not the unit is in use on AC or DC power.
- While charging a fully discharged battery, initially the 25% LED will start blinking rapidly for a few minutes, then start to blink at a slower rate every (1/2 second).
- The LED will continue to blink until 25% capacity is reached. The LED will then turn solid.
- Each of the four LEDs, 25% -100% , will blink as stated above, then turn solid when they reach their capacity.
- When all LEDs illuminate solid, the battery is fully charged and the LEDs will remain solid for a period of time, then all four LEDs will turn off.



NOTE

Charging may take several minutes after connecting the power to initiate, depending on the battery's internal operating temperature. This is a normal condition and is intended for safe battery charging. This circumstance is more likely when the battery has been fully discharged.



NOTE

The rechargeable battery that is used in the FreeStyle unit does not need to be fully depleted before recharging. It is recommended to charge the battery after each use.



NOTE

When connected to AC or DC power, the unit's battery charges until it reaches full capacity, either while the unit is operating or turned off.



NOTE

If the power supply remains connected when the internal battery is fully charged, the four LEDs will turn off after approximately one hour.



NOTE

If the internal battery fully depletes and the FreeStyle unit shuts down, the unit cannot be restarted with the AirBelt. Should this occur, connect your FreeStyle to its AC or DC power supply for a short period of time in order to provide sufficient internal battery power to start the unit. AirBelt can then be connected to provide additional run time.



NOTE

Storing your AirBelt for extended periods of time at high temperatures or with a fully charged/completely discharged battery can degrade its overall battery life.

Nasal Cannula

A nasal cannula and tubing are used to deliver oxygen from the FreeStyle unit to the user. The tubing is connected to the unit's oxygen outlet (See Figure 9).



Figure 9: Connecting Cannula to FreeStyle's Oxygen Outlet

AirSep recommends a nasal cannula with 7 ft (2.1 m) of tubing, AirSep Part No. CU002-1. Other lengths of tubing up to 25 ft (7.6 m) maximum, including nasal cannula, may be used.

FreeStyle Unit Components



Figure 10: FreeStyle Exterior View - Front

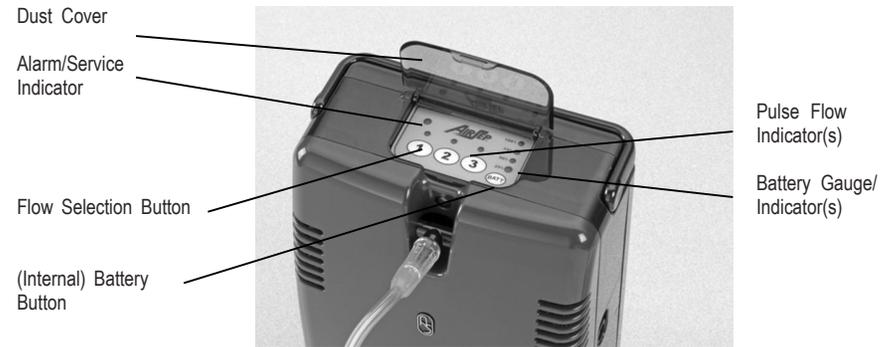
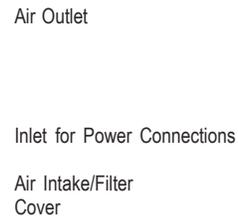


Figure 11: Close-Up of Keypad/Alarm Display



RTCA DO160D indicates that FreeStyle unit has been tested and approved to comply with FAA standards.



Figure 12: FreeStyle Exterior View - Back

Now that you are familiar with FreeStyle’s components, review the instructions on the following pages to operate the FreeStyle unit.

Operating Instructions

1. Locate and position the FreeStyle so that the air inlets and air outlets are not obstructed.
2. Power the unit from (a) the internal battery; (b) AirBelt; (c) DC outlet (i.e. automobile or motor boat); or (d) an AC outlet (i.e. normal household electric). (Refer to the Power Supplies section of this Patient Manual.)



It may be necessary to initially connect the AC or DC FreeStyle power supply to the FreeStyle unit before the unit will operate for the first time on battery power. Your Equipment Provider may have already performed this step for you.



Each time the FreeStyle unit is turned on, it cycles through an automatic start-up period for approximately seven minutes. During this time, it maintains a constant speed regardless of setting. After this period, it is normal to hear a change in speed at the 1 and 2 settings. This variation in sound represents the differences in oxygen production the unit makes at each setting.

1. Connect your cannula to the oxygen outlet.
2. Lift the dust cover on the unit.
3. Turn the FreeStyle unit on by pressing 1, 2, or 3 button on the unit's keypad for the liter flow prescribed by your physician. The green LED above the button selected illuminates. Each time you turn on the FreeStyle unit, a brief alarm sounds. This indicates that FreeStyle is powered for use.
4. To change the pulse flow setting, press the appropriate button. After the automatic start-up mode, it is normal to hear a difference in sound as you change the settings.
5. To turn FreeStyle off, press the button corresponding to the pulse flow setting light that is illuminated.

When FreeStyle senses inhalation, oxygen is supplied to you through your cannula.

The time required to reach maximum oxygen concentration after turning on the FreeStyle unit is approximately two minutes.

Power Supplies

FreeStyle can be powered in four different ways – the internal battery, an AC power supply, DC power supply, and an optional AirBelt battery belt in combination with the unit's internal battery.

1. **Internal Battery:** A rechargeable internal battery is located within each FreeStyle unit. When it is fully charged, it supplies power to the FreeStyle unit for up to 3 ½ hours. An audible alarm sounds when the battery power is getting low. The alarm is discussed in the Alarm/Light Indicators section of this manual.
Battery Charging: To charge the internal battery, connect FreeStyle to either the AC power supply and a 100-240 volt, 50/60 Hz AC power outlet, or connect it to a DC power outlet in an automobile (boat, motor home, etc.). A discharged battery requires approximately 3 ½ hours to fully charge. It is recommended to recharge the battery, even if only partially depleted, as often as possible.
2. **AC Power Supply:** An AC power supply allows FreeStyle to be connected to a 100-240 volt, 50/60 Hz outlet. The power supply converts 100-240 volt AC to a DC voltage for the FreeStyle unit. When FreeStyle is operated with the AC power supply, power from the AC outlet powers the unit and recharges FreeStyle's battery simultaneously.
3. **DC Power Supply:** A DC power supply can be connected from the FreeStyle unit to an automobile's (boat, motor home, etc.) 12 volt DC outlet. When FreeStyle is connected to the automobile's DC outlet, power from the automobile battery powers the FreeStyle unit and recharges the FreeStyle battery simultaneously.
4. **Optional AirBelt (External Battery Belt):** FreeStyle can also be powered by an external battery belt. This belt can be worn around the waist, and when used in combination with a fully charged internal battery, supplies power to FreeStyle for up to 10 hours. The belt pack connects to the FreeStyle unit's power inlet, and it can be recharged by connecting it to the battery belt's own AC power supply.

When using the AirBelt with a fully charged internal battery, the FreeStyle's internal battery will deplete before the AirBelt. The AirBelt must be connected to the FreeStyle unit before the FreeStyle's internal battery is depleted. Observe and connect the AirBelt to the FreeStyle unit before its internal battery discharges to 25% or less.



If the internal battery fully depletes and the FreeStyle unit shuts down, the unit cannot be restarted with the AirBelt. Should this occur, connect your FreeStyle to its AC or DC power supply for a short period of time in order to provide sufficient internal battery power to start the unit. AirBelt can then be connected to provide additional run time.

Filters

Air enters FreeStyle through an air intake filter located under the cover on the lower front of the oxygen concentrator. (See Figures 13 and 14.) This filter prevents dust and other large particles in the air from entering the unit. Before you operate FreeStyle, make sure this filter is clean and positioned correctly.



Figure 13: Removal of Air Intake Filter Cover



Figure 14: Removal of Filter from Filter Cover



Use only AirSep Part No. FI144-1 as the air intake filter for this unit.

Setting of the Flow Selector

The FreeStyle unit has three pulse flow settings: 1, 2, and 3, providing flows equivalent to 1-3 LPM oxygen. Lift the dust cover on the unit's keypad, and press the 1, 2, or 3 button, which corresponds to the oxygen pulse flow that your physician has prescribed. (See Figures 15 and 16.)



Figure 15: Lifting Dust Cover on Keypad Display



Figure 16: Pressing Flow Selection Button



It is very important to select only the prescribed level of oxygen. Change the pulse flow selection only under the guidance of your physician.

Alarm/Light Indicators

When the FreeStyle unit senses inhalation, a pulse of oxygen is sent through the nasal cannula. The green light above the selected pulse flow setting displays intermittently each time a breath is detected.

Additionally, when the unit is operating on and simultaneously being charged through the AC or DC power supply, the FreeStyle unit's battery gauge/indicator(s) display the charge level of the battery and remain on for approximately one hour after reaching a full charge.

An audible alarm sounds if FreeStyle has a low battery, if the cannula is disconnected, or if performance of the unit is outside specifications. The light and audible alarm conditions are explained in detail below and summarized on the chart later in this section of the manual.

- **Start-Up**

A brief alarm sounds at start-up. FreeStyle begins to operate when the alarm stops.

- **Low Battery**

As the battery power approaches a low level, a brief alarm sounds intermittently, and the yellow 25% Battery gauge / indicator (Figure 11) light also illuminates intermittently. When this occurs, connect FreeStyle to a DC power outlet or to an AC power outlet, or change to another source of oxygen within two minutes. When FreeStyle is connected to DC power outlet or AC power outlet, the unit operates while recharging FreeStyle's battery simultaneously. The level of battery charge is indicated by the battery gauge/indicator(s).

- **Cannula disconnected**

When FreeStyle 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 unit, make sure that the nasal cannula is positioned properly on your face, and ensure that you are breathing through your nose. (Your physician may recommend the use of a chin strap if needed.) If the alarm continues to sound, change to another source of oxygen as available, and contact your Equipment Provider.

- **FreeStyle's capacity is exceeded**

If your breathing rate causes the capacity of FreeStyle 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 FreeStyle 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 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.

How to Respond to FreeStyle's Alarm/Light Indicators

Status	Audible Alarm	Light	Indicates	Action
Indicator	Brief, continuous at start-up	(Green) pulse; continuous light	FreeStyle has been turned on	You may begin to operate your FreeStyle unit.
Indicator	No	(Green) pulse; intermittent light	FreeStyle is delivering oxygen as a pulse flow.	Continue using FreeStyle normally.
Indicator	No	Level indicator	Battery charge level.	Charge as indicated.
Indicator	No	(Yellow) continuous light	Service required.	Return unit to Equipment Provider for inspection/service.

Status	Audible Alarm	Light	Indicates	Action
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 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 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 unit has occurred.	Turn off the unit. Change to another source of oxygen, and contact your Equipment Provider.

Cleaning, Care, and Proper Maintenance

Cabinet



Turn off the FreeStyle unit, and disconnect the power cord from FreeStyle before you clean the cabinet.



Do not use liquid directly on the FreeStyle unit to clean it. A list of **undesirable** chemical agents includes but is not limited to, the following, according to the plastics manufacturer: alcohol and alcohol-based products, concentrated chlorine-based products (ethylene chloride), and oil-based products (Pine-Sol, Lestoil). These are NOT to be used to clean the plastic housing on FreeStyle, they can damage the unit's plastic.



Replace the disposable cannula periodically following normal usage. Additional supplies are available from your Equipment Provider.



Keep the FreeStyle unit clean and free from moisture and dust. Clean the plastic housing periodically by wiping with a lint-free cloth or with a mild household cleaner applied with a damp cloth or sponge. Pay special attention to the oxygen outlet for the cannula connection to make sure it remains free of dust, water, and particles.



To prevent a voided AirSep warranty, follow all manufacturer's instructions.

Filter

Air Intake Filter

At least one time each week, remove the cover on the lower front of the unit, and wash the air intake filter, which is positioned on the inside of the cover. Your Equipment Provider may advise you to clean it more often, depending upon your operating conditions. Follow these steps to properly clean the air intake filter:

1. Remove the filter from the air intake filter cover, and wash it in a warm solution of soap and water.
2. Rinse the filter thoroughly, and remove excess water with a soft, adsorbent towel. Ensure that the filter is dry before replacing it.
3. Replace the dry filter.



Do not operate FreeStyle without the air intake filter in place. If a second filter is provided, insert the “replacement” filter before you clean the dirty filter.



AirSep does not recommend the sterilization of this equipment.

Carrying Bag

To clean the carrying bag and strap, brush only with warm soapy water (do not saturate the bag), then allow to air dry. Do not machine wash or dry the bag.

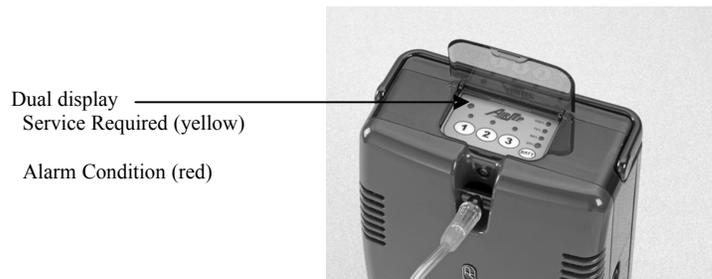


Figure 16: Indicator of Required Inspection/Service

Alarm/Service Indicator

When the alarm service/indicator illuminates (yellow), it is time for your FreeStyle unit to be inspected/serviced by your Equipment Provider. After any necessary service and the performance is verified by the Equipment Provider, the alarm service/indicator light will be reset.

FreeStyle Accessories

In addition to the nasal cannula, AirSep recommends that you do not use accessories with FreeStyle other than those listed below as supplied by AirSep through your Equipment Provider. Use of accessories not listed below could adversely affect the performance and/or safety of the FreeStyle Portable Oxygen Concentrator.

Description/Part Number

AC Power Supply with appropriate power cord (PW013-1)

DC Power Supply (PW012-1)

Air Intake Filter (FI144-1)

Carrying Bag (MI283-1)

Shoulder Harness option enables converting the supplied FreeStyle carrying bag to a backpack (MI284-1)

AirBelt and AirBelt Power Supply with appropriate power cord (BT017-1)

AirBelt Extender (MI240-2)

FreeStyle Airline Adapter (CD031-1)

Carry-All Accessory Bag (MI286-1)

Reserve Oxygen Supply

Your Equipment Provider may recommend another source of supplemental oxygen therapy in case there is a mechanical failure or a power outage.

Troubleshooting

The FreeStyle product is designed for years of trouble-free use.

If your FreeStyle Portable Oxygen Concentrator fails to operate properly, refer to the chart on the following pages for possible causes and solutions and, if needed, consult your Equipment Provider.



Do not attempt any maintenance other than the possible solutions listed below.

NOTE

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 (red) 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 connect to the optional AirBelt.

Problem	Probable Cause	Solution
Rapid alarm condition, and the (yellow) BATT light illuminates intermittently and FreeStyle shuts down.	Battery voltage 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 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. Temporarily connect your AC or DC power supply to the unit's power inlet and power source, as needed, to reset the unit's internal battery.
Delay in recharging internal battery.	Internal battery exceeds charging temperature.	Unit may be operated; however, charging may not resume until battery temperature is reduced. (See page 9 notes.)
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 DC power supply from the automobile outlet, restart the automobile, and then reconnect the DC 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.

FreeStyle Specifications

Oxygen Concentration:*	1-3 pulse settings; equivalent to a continuous flow of 90% oxygen \pm 3%
Dimensions:	8.6 in. high x 6.1 in. wide x 3.6 in. deep (21.8 cm high x 15.5 cm wide x 9.1 cm deep)
Weight:	4.4 lb (2.0 kg); 1.8 lb (.8 kg) optional AirBelt
Power:	AC Power Supply: 100 – 240 VAC (1.0 amp at 120 VAC) DC Power Supply: 11-16 VDC (6.0 amps at 12 VDC)
Battery duration (Rechargeable lithium Battery)	3 LPM – 2 hours; 2 LPM – 2.5 hours; 1 LPM – 3.5 hours Optional AirBelt when combined with the internal battery: 3 LPM – 5 hours; 2 LPM – 6 hours; 1 LPM – 10 hours
Battery recharge time:	3.5 hours; optional AirBelt: 3 hours
Warm-up time:	2 minutes
Battery cycle life:	Approximately 300 cycles, then 80% capacity or below.
Audible alarms and pulse visual indicators:	Start-up – audible and visual (GREEN indicator light); Pulse flow – visual (GREEN light); Battery condition – battery level (GREEN indicator lights); cannula disconnect- audible and visual (RED alarm light); System overdraw – audible and visual (RED warning and alarm lights); High and low pressure – audible and visual (RED alarm light); Service required: visual (YELLOW alarm light)
Sound:	38 dBA at 1 setting: 41 dBA at 2 setting: 44 dBA at 3 setting
Temperature range:	Operational temperature: 41°F to 104°F (5°C to 40°C) Storage temperature: -2°F to 140°F (-20°C to 60°C)
Max Operational Altitude:	up to 12,000 ft (3,657.6 m) Higher altitudes may affect performance

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

* Operating unit outside of operational temperature range can affect performance.

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 by Intertek Testing Services NA Inc. to be in compliance with IEC 60601-1:1988 + A1:1991, A2:1995
General Requirements for safety.

Tested by Intertek to be in compliance with applicable requirements of the Standards, CAN/CSA C22.2 No.
601.1 M90 for Medical Electrical Equipment.

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

Tested by Ultratech Group of Labs to be in compliance with EN60601-1-2: 2001 Edition (EMC).

Tested by Ultratech Group of Labs to be in compliance with RTCA/DO160D Section 21 Category M.

Method of cleaning and infection control allowed:

Please refer to "Cleaning, Care, and Proper Maintenance" section of this FreeStyle Patient Manual.

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

Equipment not suited for such application.

Mode of operation:

Continuous duty.

Limited Warranty

AirSep Corporation warrants the FreeStyle Oxygen Concentrator to be free from defect in parts for three years (as specified on the original invoice provided) from the date of delivery to the original purchaser, under normal use and operation. The battery is warranted for one year. AirSep Corporation's obligations under this warranty are limited to the repair or replacement of any such item of equipment (or part thereof) shown to be defective or, at AirSep Corporation's option, to refund the purchase price of any such defective item of equipment.

Each item of equipment for which a warranty claim is asserted shall, at the request of AirSep Corporation, be returned on a prepaid basis with proof of purchase date to the AirSep factory at the expense of the purchaser. The purchaser will be responsible for return freight charges. Replacement parts shall be warranted as stated above for the unexpired portion of the original three-year parts warranty (as specified on the original invoice provided). This warranty does not extend to any item or part subjected to misuse, accident, improper maintenance, or application, or which has been repaired or altered outside of the AirSep Corporation factory without the express prior written authorization of AirSep Corporation.

THE FOREGOING WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IN FACT OR IN LAW, INCLUDING WITHOUT LIMITATION THE WARRANTY OF MERCHANTABILITY OR THE WARRANTY OF FITNESS FOR PARTICULAR PURPOSE. IT IS EXPRESSLY UNDERSTOOD THAT PURCHASER'S SOLE AND EXCLUSIVE REMEDY FOR DEFECT IN PARTS IS LIMITED TO ENFORCEMENT OF AIRSEP CORPORATION'S OBLIGATION AS SET FORTH ABOVE, AND AIRSEP CORPORATION SHALL NOT BE LIABLE TO PURCHASER OR OTHERS FOR LOSS OF USE OF THE EQUIPMENT OR FOR OTHER SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES.

For European representative:

Gavin Ayling
9 Bungham Lane
Penkridge Stafford
Staffordshire ST19 5NH England

E-mail: euorepcontact@airsep.com

For service on your FreeStyle Portable Oxygen Concentrator, please contact your local Equipment Provider at:



**Manufactured by:
AirSep Corporation
Buffalo, NY 14228-2085 USA**



MN123-1 Rev B