FreeStyle™

Patient Manual

FreeStyle™ Portable Oxygen Concentrator

AIRSEP®

260 Creekside Drive
Buffalo, NY 14228-2085 USA

CE 0459

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 COULD OCCUR.

WARNING

Smoking while using oxygen is the number one cause of fire injuries and related deaths. You must follow these safety warnings:

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

Smoking while wearing an oxygen cannula can cause facial burns and possibly result in death.

Removing the cannula and placing it clothing, bedding, sofas, or other cushion material will cause a flash fire when exposed to a cigarette, heat source, spark or open flame.

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.

"No Smoking – Oxygen in Use" signs must be prominently displayed in the home, or where oxygen is in use. Patients and their caregivers must be informed about the dangers of smoking in the presence of, or while using, medical oxygen.

Federal (USA) law restricts this device to sale or rental by order of a physician or other licensed health care provider.

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 if not avoided can result in severe bodily injury, death or property damage		Class II Equipment, double insulated
	Caution – Describes a hazard or unsafe practice that can result in minor bodily injury or property damage		Complies with the 93/42/EEC directive drawn up by the approved organization No. 0459
	Note – Provides information important enough to emphasize or repeat		See Instructions
	Consult the accompanying documents		Keep unit and accessories dry
	Use no oil or grease		Proper disposal of waste of electrical and electronic equipment required

Symbol	Description	Symbol	Description
	No Smoking		Do not disassemble
	Type BF Equipment		Consult instructions for use
RTCA/DO-160 Section 21 Category M Compliant	RTCA DO160 Section 21 Category M Compliant. FAA SFAR 106 requirement		Safety agency for CAN/CSA C22.2 No. 60601-1-08 M90 for medical electrical equipment
	This side up		Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment
	Fragile – handle with care		FAA Approved – POC
	Manufacturer		Do not expose to open flames
EC REP	Authorized Representative in the European Community	SN	Serial Number
REF	Catalog number		Date of Manufacture

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.

What is the FreeStyle Portable Oxygen Concentrator?

Oxygen concentrators were introduced in the mid-1970's and has 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.)

Operator Profile:

AirSep's Concentrators are intended to supply supplemental Oxygen to users suffering from discomfort due to ailments which effect the efficiency of ones lungs to transfer the oxygen in air to their bloodstream. POC's provide the convenience of using a non-delivery POC system rather than delivery system (O2 tank) which 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 <u>not</u> intended for life support use.

Although Oxygen therapy can be prescribed for patients of all ages the typical oxygen therapy patient is older than 65 years of age and suffers from Chronic Obstructive Pulmonary Disorder (COPD). Patients 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, patients are advised to contact their healthcare provider. Patients 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.

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 Transporation (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.

"No Smoking – Oxygen in Use" signs must be prominently displayed in the home, or where oxygen is in use. Patients and their caregivers must be informed about the dangers of smoking in the presence of, or while using, medical oxygen.

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.

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.

Do not leave a nasal cannula on clothing, bed coverings or chair cushions. If the unit is turned on but not in use, the oxygen will make the material flammable. Set the I/0 power switch to the 0 (Off) position when the Oxygen Concentrator is not in use.

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.

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

Pulse Dose Node settings must be determined for each patient individually for their needs at rest, during exercise, and when traveling.

If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.

Electrical shock hazard. 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.**

Care should be taken to prevent the Oxygen Concentrator and the battery 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

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

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 device.** Pay special attention to the oxygen outlet for the cannula connection to make sure it remains free of dust, water, and particles.

While using the portable Oxygen Concentrator outdoors with the AC power supply, connect the power supply into a Ground Fault Interrupted (GFI) outlet only.

Always disconnect AC Power Supply from the wall before disconnecting the AC Power Supply from the oxygen concentrator.

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.

No modification of this equipment is permitted.

Use of cables and adapters other than those specified, with the exception of cables and adapters sold by the manufacturer of the medical electrical equipment as replacement parts for internal components, may result in increased emissions of decreased immunity of the Oxygen Concentrator.

Use only electrical voltage specified on the specification label affixed to the device.

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.

Operating outside of the operational specifications can limit the concentrator's ability to meet Oxygen Concentration specification. Refer to the specifications section of this manual for storage and operating temperature limits.

The incorrect use of the battery can cause the battery to get hot, ignite, and may cause serious injury. Be sure not to pierce, strike, step on, drop the battery, or otherwise subject the battery to strong impacts or shocks. The use of a damaged battery may cause personal injury. DO NOT expose the battery to fire or dispose of in a fire. This may cause the battery to explode and cause potential injury.

DO NOT short-circuit the battery's metal contacts with metallic objects, such as keys or coins. This may cause sparks or excessive heat to be generated.

Contraindications for Use: In certain circumstances, the use of non-prescribed oxygen can be hazardous. This device should only be used when prescribed by a physician.

NOT FOR USE IN THE PRESENCE OF FLAMMABLE ANETHETICS.

As with any electrically powered device, the user may experience periods of non-operation as a results 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 patient who would experience adverse health consequences as the result of such temporary interruption.

Properly secure, belt or otherwise restrain the oxygen concentrator when in a vehicle during transport to prevent damage or injury.

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.

Cet appareil produit de l'oxygène à concentration élevée, favorisant une combustion rapide. Ne pas permettre de fumer ou des flammes nues dans la même chambre: (1) cet appareil ou (2) tout accessoire contenant de l'oxygène. Ne pas utiliser de produits à base d'huile, de graisse ou de pétrole sur ou à proximité de l'unité. Déconnecter le cordon d'alimentation de la prise électrique avant de nettoyer ou de faire l'entretien de l'unité.

Risque de choc électrique. Ne pas enlever les couvercles lorsque l'unité est branchée. Seuls votre fournisseur d'équipement ou un technicien de service qualifié devrait enlever les couvercles ou faire l'entretien de l'unité.

Federal (USA) law restricts this device to sale or rental by order of a physician or other licensed health care provider.

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

The concentrator should be located as to avoid smoke, pollutants or fumes.

Always place oxygen supply tubing and power cords in a manner that prevents a trip hazard.

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.

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.

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.

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.

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.

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.

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.

If the Oxygen Concentrator has been stored for an extended period of time outside its normal operating temperature range, the unit should be allowed to return to normal operating temperature before being turned on. (Refer to the Specifications section in this manual.)

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.

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.

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

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.

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.

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.

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.

Always follow the cannula manufacturer's instructions for proper use. Replace the disposable cannula as recommended by the cannula manufacturer or your Equipment Provider. Additional supplies are available from your Equipment Provider.

NOTE

Charging of the battery 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.

If the device power supply remains connected when the battery is fully charged, the four LEDs will turn off within approximately 1 hour.

***For oxygen concentrators equipped with batteries*:**

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.

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

To Equipment Provider: The following oxygen administration accessories are recommended for use with the Oxygen Concentrator:

- Nasal Cannula with 7 feet (2.1 m) of tubing: Part No. CU002-1
- Use only the manufacturer's replacement air intake filter: Part No. FI144-1
- OxySafe Kit Part No. 20629671

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.

The Manufacturer does not recommend the sterilization of this equipment.

NOTE

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

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

There is never a danger of depleting the oxygen in a room when you use your Oxygen Concentrator unit.

NOTE

AirSep offers the OxySafe as an optional accessory. This is intended to be used in conjunction with the FreeStyle concentrator. For customers in regions requiring compliance to EN ISO 8359:1996-Ammendment1:2012, this accessory will meet this need.

The OxySafe is a thermal fuse to stop the flow of gas in the event that the downstream cannula or oxygen tubing is ignited and burns to the OxySafe. It is placed in-line with the nasal cannula or oxygen tubing between the patient and the oxygen outlet of the Visionaire.

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

AirSep offers an OxySafe kit that includes OxySafe with 2" of tubing to connect to the oxygen outlet; PN 20629671

Important Safety Rules for Optional AirBelt

WARNING

For oxygen concentrators equipped with the optional Airbelt :

1. The incorrect use of AirBelt can cause the battery to get hot, ignite, and can 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.
2. Replace safety cap on AirBelt cord when not in use.

NOTE

For oxygen concentrators equipped with batteries:

1. 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.
2. If the internal battery fully depletes and the Oxygen Concentrator shuts down, the unit cannot be restarted with the optional AirBelt. Should this occur, connect your Oxygen Concentrator 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

For oxygen concentrators equipped with the optional Airbelt:

1. The AirBelt does not need to be fully discharged before recharging. It is recommended to charge it after each use.
2. Depending upon the temperature of the AirBelt, it can take several minutes for the charging cycle to start after connecting to power. This is a normal condition and is intended for safe charging.

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)
- Universal AC/DC power supply (100-240 volts, 50/60 Hz) with power cord.
- DC Power Cable

Figure 1: FreeStyle Unit

Figure 2: FreeStyle Universal AC/DC Power Supply/Power Cord

Figure 3: FreeStyle DC Power

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

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

WARNING

The incorrect use of AirBelt can cause the battery to get hot, ignite, and can 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.

All AirBelt Warnings, Cautions and Notes should be read first before proceeding with your equipment.
See pg 10, "Important Safety Rules for Optional AirBelt".

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 MI320-1) 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 Universal AC/DC Power Supply/Power Cord

Figure 5: FreeStyle unit worn backpack style

Figure 6: FreeStyle unit worn on the waist

WARNING

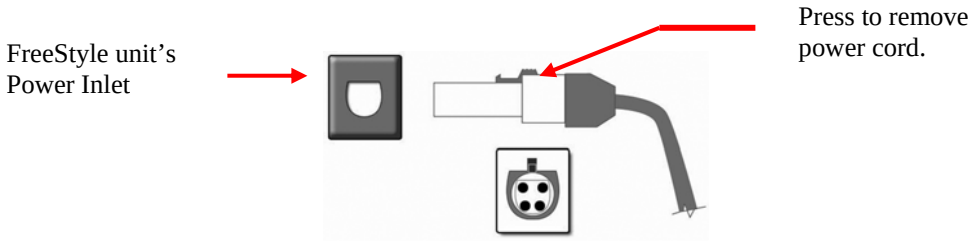
Replace safety cap on AirBelt cord when not in use

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.

[Read the Important Safety Rules section before operating this equipment.]

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 Universal AC/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.

NOTE

For oxygen concentrators equipped with the optional Airbelt:

3. The AirBelt does not need to be fully discharged before recharging. It is recommended to charge it after each use.
4. Depending upon the temperature of the AirBelt, it can take several minutes for the charging cycle to start after connecting to power. This is a normal condition and is intended for safe charging.

[Read the Important Safety Rules section before operating this equipment.]

NOTE

Charging of the battery 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.

If the device power supply remains connected when the battery is fully charged, the four LEDs will turn off within approximately 1 hour.

***For oxygen concentrators equipped with batteries*:**

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.

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).

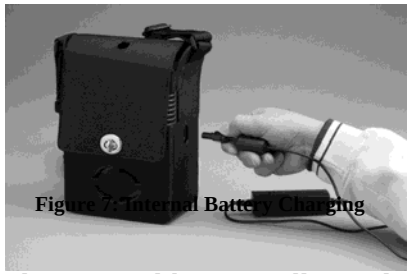


Figure 7: Internal Battery Charging

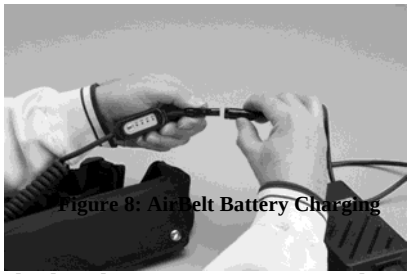


Figure 8: Airbelt Battery Charging

- 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 Universal AC/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.

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).

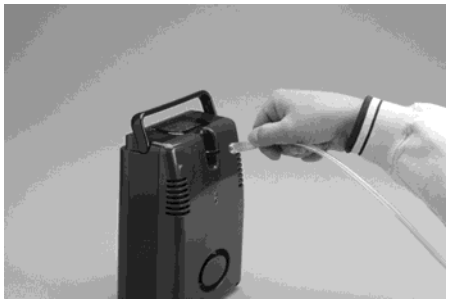


Figure 9: Connecting Cannula to FreeStyle's Oxygen Outlet

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.

NOTE

Cannula tubing must be non-kinking, which can be used for a total length of up to 25 ft (7.6 m) maximum.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.

Always follow the cannula manufacturer's instructions for proper use. Replace the disposable cannula as recommended by the cannula manufacturer or your Equipment Provider. Additional supplies are available from your Equipment Provider.

FreeStyle Unit Components

Figure 10: FreeStyle Exterior View - Front

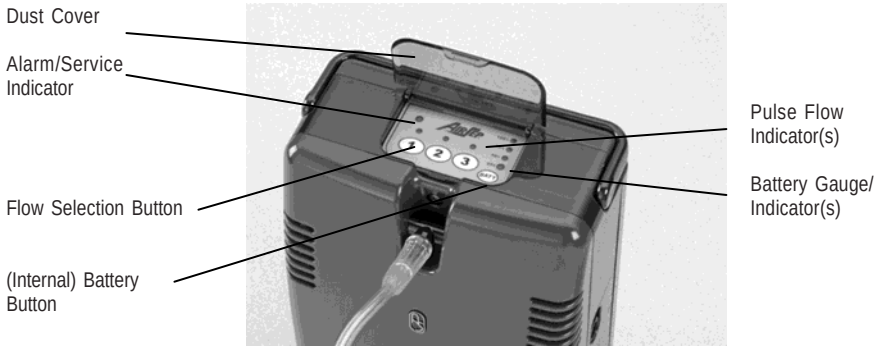


Figure 11: Close-Up of Keypad/Alarm Display

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.)
3. Connect your cannula to the oxygen outlet.
4. Lift the dust cover on the unit.
5. 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.
6. 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.
7. To turn FreeStyle off, press the button corresponding to the pulse flow setting light that is illuminated.
8. When FreeStyle senses inhalation, oxygen is supplied to you through your cannula.
9. The time required to reach maximum oxygen concentration after turning on the FreeStyle unit is approximately two minutes.

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.

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.

Do not leave a nasal cannula on clothing, bed coverings or chair cushions. If the unit is turned on but not in use, the oxygen will make the material flammable. Set the I/0 power switch to the 0 (Off) position when the Oxygen Concentrator is not in use.

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. ***(See additional warnings on page 18 of this manual)***

WARNING

Operating outside of the operational specifications can limit the concentrator's ability to meet Oxygen Concentration specification. Refer to the specifications section of this manual for storage and operating temperature limits.

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.

No modification of this equipment is permitted.

Use of cables and adapters other than those specified, with the exception of cables and adapters sold by the manufacturer of the medical electrical equipment as replacement parts for internal components, may result in increased emissions of decreased immunity of the Oxygen Concentrator.

Use only electrical voltage specified on the specification label affixed to the device.

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.

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

Pulse Dose Node settings must be determined for each patient individually for their needs at rest, during exercise, and when traveling.

If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.

NOTE

It may be necessary to initially connect the Universal AC/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.

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.

Always follow the cannula manufacturer's instructions for proper use. Replace the disposable cannula as recommended by the cannula manufacturer or your Equipment Provider. Additional supplies are available from your Equipment Provider.

Power Supplies

FreeStyle can be powered in four different ways – the internal battery, a Universal AC/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 Universal AC/DC 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. **Universal AC/DC Power Supply**: A Universal AC/DC 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 Universal AC/DC power supply, power from the AC outlet powers the unit and recharges FreeStyle's battery simultaneously.
3. **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.

For oxygen concentrators equipped with batteries:

1. 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.
2. If the internal battery fully depletes and the Oxygen Concentrator shuts down, the unit cannot be restarted with the optional AirBelt. Should this occur, connect your Oxygen Concentrator 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.

FreeStyle™ Universal AC/DC Power Supply (Instructions for use)

Connections for removable AC or DC power cord

Connects to FreeStyle unit

Figure 13

AirSep's new universal power supply for the FreeStyle Portable Oxygen Concentrator (POC) is an all-in-one way to keep you fully powered, yet traveling even lighter – wherever you go. The universal power supply (Part Number PW022), described in this insert, enables you to operate your unit while charging its internal battery – all from one component – whether you are driving to the grocery market, taking a vacation flight, or simply relaxing at a friend's home. This universal power supply replaces the two separate AC and DC power supplies that were previously packaged with the FreeStyle unit and covered in your patient manual.

Your power supply kit is packed complete with three essential accessories, as follows:

- universal power supply (PW017-1), which operates on AC power from 120-240 volts and with multiple DC power sources, including automobile and airplane power
- removable AC power cord
  - -CD023-2 US-style
  - -CD017-2 Euro-style, depending on usage location
  - -CD025-1 Australian-style, or
  - -CD017-4 UK-style
- removable DC power cord, which incorporates both the connector for automobile-type outlets and the D-shaped, 4-pin connector for EmPower®-type outlets commonly used on airlines (CD034-1).

Note: FreeStyle's internal battery will completely recharge from its fully depleted state in approximately 3½ hours, whether the unit is in use on AC or DC power.

Start with the Universal AC/DC Power Supply and FreeStyle Connection

For all procedures below, it is recommended that you first connect the universal power supply to the FreeStyle POC inlet, as shown in Figure 14. Be sure to properly connect to the unit by ensuring that the carrying case alignment with the FreeStyle unit inlet allows you to obtain a secure connection so that the cord "locks" in place.

When disconnecting the power supply from the FreeStyle POC, make sure you press down on the tab near the end of the cord to properly disengage the connection to the unit and release the cord.

Figure 14

Use with AC Electric

1. Make sure your power supply is securely connected to the FreeStyle inlet, as shown in Figure 14.
2. Connect the proper end of the AC electrical cord to the unmarked AC inlet on the power supply, as shown in Figure 15.
3. Connect the opposite end of the AC electrical cord to the wall or other appropriate electric outlet, as shown in Figure 16.
4. To operate the POC, press the FreeStyle [1], [2], or [3] setting on the unit's top panel, as determined by your prescription. To turn the unit off, press the setting associated with the LED illuminated above it.

Figure 15

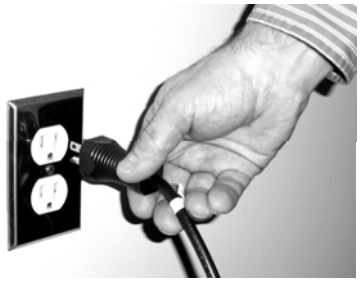


Figure 16

Use with DC Power (Automobile, Motorboat etc..)

Caution: When using FreeStyle with the universal power supply in an automobile, boat, or other motor vehicle, make sure that the vehicle is started and running before turning on and operating the FreeStyle unit. If the power supply indicator light does not illuminate and requires resetting, disconnect the power supply from the motor vehicle's DC outlet, restart your vehicle, and then reconnect your power supply into the DC outlet.

1. Make sure your power supply is securely connected to the FreeStyle inlet, as shown in Figure 14.
2. Connect the proper DC power cord end to the inlet marked ACCESSORY DC IN on the power supply, as shown in Figure 17.
3. Turn on your motor vehicle.
4. Connect the DC power cord to the motor vehicle's DC outlet, as shown in Figure 18.
5. To operate the POC, press the FreeStyle [1], [2], or [3] setting on the unit's top panel, as determined by your prescription. To turn the unit off, press the setting associated with the LED illuminated above it.

Figure 17

Figure 18

Use with AirLine Power at Passenger seat (with 4 pin connection configuration

AirSep's FAA-approved FreeStyle enables you to use this POC in-flight on most commercial airlines around the world. Each airline establishes its own policy for FAA-approved POC use, as well as the requirements for, and the availability of, optionally allowing you to power your unit onboard the aircraft. Aircraft-equipped passenger power may include one or more of the following sources: an AC power outlet, a DC power outlet similar to that typically found in an automobile, or a DC power outlet with a 4-pin configuration.

If the specific airline on which you are traveling allows you to connect your POC unit at a seat equipped with a 4-pin DC power configuration, take the following steps:

1. Make sure your power supply is securely connected to the FreeStyle inlet, as shown in Figure 14.
2. Connect the proper DC power cord end to the ACCESSORY DC IN inlet on the power supply, as shown in Figure 19.
3. Remove the tip of the DC connector by pressing on the tab to expose the 4-pin connector, as shown in Figure 20.
4. Insert the 4-pin connection to the airline passenger DC outlet optionally available at your seat.
5. To operate the POC, press the FreeStyle [1], [2], or [3] setting on the unit's top panel, as determined by your prescription. To turn the unit off, press the setting associated with the LED illuminated above it.

Figure 19

Figure 20

For more information on the universal power supply for FreeStyle or any AirSep product accessories, please contact your local equipment provider.

Filters

Air enters FreeStyle through an air intake filter located under the cover on the lower front of the oxygen concentrator. (See Figures 21 and 22.) 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 21: Removal of Air Intake Filter Cover

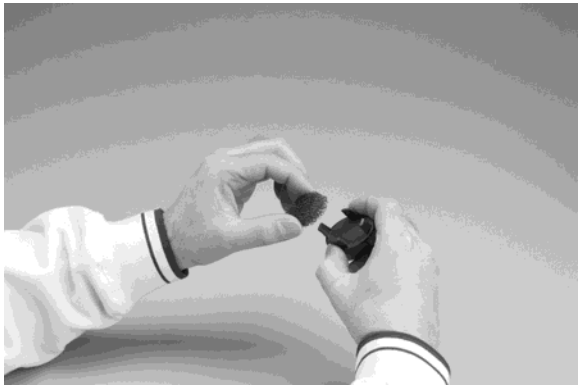


Figure 22: Removal of Filter from Filter Cover

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.

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

The Manufacturer does not recommend the sterilization of this equipment

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 23 and 24.)

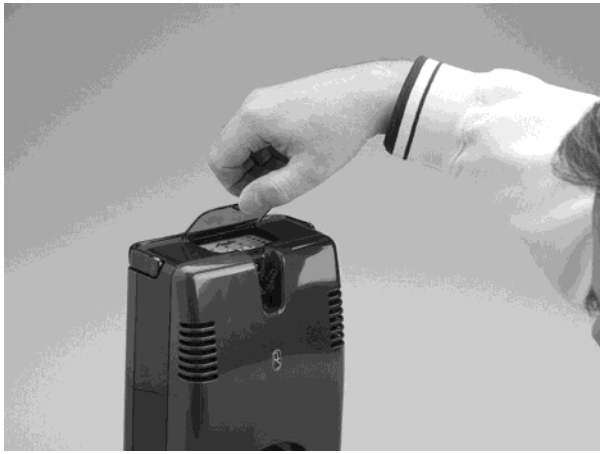


Figure 23: Lifting Dust Cover on Keypad Display

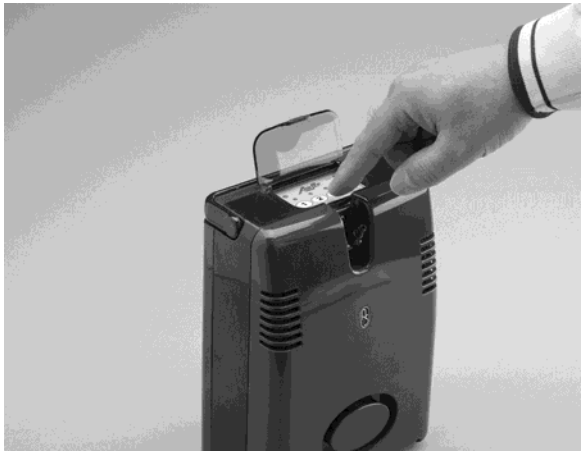


Figure 24: Pressing Flow Selection Button

CAUTION

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.

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.

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 Universal AC/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.

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

Pulse Dose Node settings must be determined for each patient individually for their needs at rest, during exercise, and when traveling.

If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.

In the event of an alarm or you observe FreeStyle is not working properly; consult the Troubleshooting section in this manual. If you cannot resolve the problem, consult your Equipment Provider.

- **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.

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

Pulse Dose Node settings must be determined for each patient individually for their needs at rest, during exercise, and when traveling.

If you feel discomfort or are experiencing a medical emergency, seek medical assistance immediately.

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.
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

Cleaning, Care, and Proper Maintenance

Cabinet

Electrical shock hazard. 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.**

Care should be taken to prevent the Oxygen Concentrator and the battery 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

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

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 device.** Pay special attention to the oxygen outlet for the cannula connection to make sure it remains free of dust, water, and particles.

While using the portable Oxygen Concentrator outdoors with the AC power supply, connect the power supply into a Ground Fault Interrupted (GFI) outlet only.

Always disconnect AC Power Supply from the wall before disconnecting the AC Power Supply from the oxygen concentrator.

Always follow the cannula manufacturer's instructions for proper use. Replace the disposable cannula as recommended by the cannula manufacturer or your Equipment Provider. 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 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.

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

The Manufacturer 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.

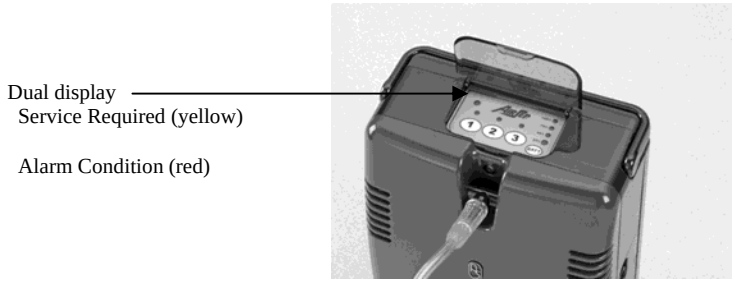


Figure 25: Indicator of Required Inspection/Service

*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.

**This feature is not available in all models.*

FreeStyle Accessories

For proper performance and safety, use only these listed accessories 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

		Freestyles Bag Set includes the following:
includes:	MI320-1	Carry – All Accessory Bag
	MI283-1	Carrying Bag, FreeStyle
	MI304-1	Shoulder Strap, FreeStyle (This is part of the MI283-1)
CD034-1		DC power cord (33in / 860mm)
PW022-1,2,3 or 4		*Universal AC/DC Power Supply with battery charger including the following power cords as applicable:*
	PW022-1	Universal AC/DC Power Supply (4ft / 1.2m) w/ CD023-2 Power Cord 120V (8ft / 2.4m) and CD034-1DC power cord (33in / 860mm)
	PW022-2	Universal AC/DC Power Supply (4ft / 1.2m) w/ CD017-2 Euro Power Cord (8 ft-2 in / 2.5m) and CD034-1DC power cord (33in / 860mm)
	PW022-3	Universal AC/DC Power Supply (4ft / 1.2m) w/ CD025-1 Australian Power Cord 250 VAC (6 ft-6 in / 2.6m) and CD034-1 DC power cord (33in / 860mm)
	PW022-4	Universal AC/DC Power Supply (4ft / 1.2m) w/CD017-4 UK Power Cord (8 ft-2 in / 2.5m) and CD034-1 DC power cord (33in / 860mm)
		Optional AirBelt includes the following:
BT017-1,2,3 or 4		*AirBelt with Power Supply including the following power cords as applicable*:
	BT017-1	AirBelt with Power Supply PW008-1 (BT017 extended cord length 4 ft / 1.2m) w/ CD023-2 Power Cord 120VAC (8 ft / 2.4m)
	BT017-2	AirBelt with Power Supply PW008-2 (BT017 extended cord length 4 ft / 1.2m) w/ CD017-2 Euro Power Cord (8 ft-2 in / 2.5m)
	BT017-3	AirBelt with Power Supply PW008-3 (BT017 extended cord length 4 ft / 1.2m) w/ CD025-1 Australian Power Cord 250 VAC (6 ft-6 in / 2.6m)
	BT017-4	AirBelt with Power Supply PW008-4 (BT017 extended cord length 4 ft / 1.2m) w/ CD017-4 UK Power Cord (8 ft-2 in / 2.5m)
		Additional or Other Options:
MI240-2		AirBelt Extender
MI078-1		AirBelt Extender New Velcro Version
MI284-1		Shoulder Harness option enables converting the supplied FreeStyle carrying bag to a backpack
FI144-1		Air Intake Filter

No modification of this equipment is permitted.

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.

Materials in direct or indirect contact with the patient

- Concentrator casing ……..….Valtra/ABS/Polystyrene
- Concentrator Control Panel……..…..Polyester EBG7 or equivalent
- Control Panel Door …….Polycarbonate
- Concentrator Handle ……..Polycarbonate
- Gas Outlet, Nozzle ……..……Polycarbonate
- Unit Label ……..…….Lexan
- Coil Cords……..…..Polyurethane
- Cord connectors ……..…....Polycarbonate/Vinyl chloride
- Power Cord……..….PVC, Metal
- Power Supply……..….Lexan 940(Polycarbonate)
- Battery Pack……..……...Lexan 945
- Battery Pack, Power Supply Labels…….Polyester film
- Concentrator carrying case…….....100% Polyester microfiber w/ PCV backing
- Battery carrying case, Belt and Strap……..100% Polyester microfiber w/ PVC backing

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.

NOTE

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

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 Universal AC/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 Universal AC/DC 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.

FreeStyle Specifications

Oxygen Concentration:*	1-3 pulse settings; equivalent to a continuous flow of 90% oxygen +5.5/-3% Flow Rate Settings: 1 ,2 & 3 LPM (equivalent to continuous flow) Settings 1 through 3 ±10%
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:	Universal AC/DC Power Supply (100-240VAC 1.75A Max 50/60Hz) (11-16VDC 8.0A Max)
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) (Up to 95% RH (non-condensing) Storage temperature: -4°F to 140°F (-20°C to 60°C)
**Max Operational Altitude:	up to 12,000 ft (3,657.6 m) (483mmHg) Higher altitudes may affect performance

* 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.

Medical equipment needs special precautions regarding EMC and need to be installed and put into service according to the EMC information provided in this section.

Guidance and manufacturer’s declaration ± electromagnetic immunity			
The FreeStyle is intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment ± guidance**
Electrostatic discharge (ESD) IEC 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 Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power. 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 5s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FreeStyle requires continued operation during power mains interruptions, it is recommended that the FreeStyle be powered from an uninterruptible power supply (UPS) or a battery.
Power frequency 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 is intended for use in the electromagnetic environment specified below. The customer or the user of the FreeStyle should assure that it is used in such an electromagnetic 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	Portable and mobile RF communications equipment should be used no closer to any part of the FreeStyle including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	D= 1.2 x √P D= 1.2 x √P from 80MHz to 800MHz D= 2.3 x √P from 800MHz to 2.5GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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 is used exceeds the applicable RF compliance level above, the FreeStyle 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 .

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

The FreeStyle is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FreeStyle can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FreeStyle 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)		
	from 150kHz to 80MHz **$d = 1.2 \times \sqrt{P}$**	**from 80MHz to 800MHz** **$d = 1.2 \times \sqrt{P}$**	**from 800MHz to 2.5GHz** **$d = 2.3 \times \sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

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

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

Guidance and manufacturer's declaration - electromagnetic emissions

The FreeStyle is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 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 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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 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.

For European representative:

EC REP

Medical Product Services GmbH (MPS)
Borngasse 20
35619 Braunfels, Germany
Tel: +49 (0) 6442-962073

E-mail: info@mps-gmbh.eu

CE 0459

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

Manufactured by
AirSep Corporation

MN123-1 Rev F