

Focus™

Patient Manual

Focus™ Portable Oxygen Concentrator



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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.



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 on clothing, bedding, sofas, or other cushion material will cause a flash fire when exposed to a cigarette, heat source, spark or flame. 4

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 the 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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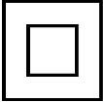








AirSep's Focus™ Portable Oxygen Concentrator















This Patient Manual will acquaint you with AirSep's Focus™ Portable Oxygen Concentrator (POC). Make sure you read and understand all the information contained in this manual before you operate your Focus 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 Focus Portable Oxygen Concentrator.

Symbol	Description	Symbol	Description
	ON (power switch on)		OFF (power switch off)
	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 if not avoided 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		Safety agency for CAN/CSA C22.2 No. 60601-1-08 M90 for medical electrical equipment
	Consult the accompanying documents		See Instructions
	Catalog Number		Date of Manufacture

	Fragile – handle with care		Keep unit and accessories dry
	Use 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
	FAA Approved - POC		Do not expose to open flames
RTCA/DO-160 Section 21 Category M Compliant	RTCA DO160 Section 21 Category M Compliant. FAA SFAR 106 requirement		This side up
	Manufacturer		Authorized Representative in the European Community
	Serial Number		

Method of disposing of waste: All waste from AirSep's Focus Oxygen Concentrator must be disposed of using the appropriate methods specified by local authorities.

Method for disposing of the device: In order to preserve the environment, the concentrator must be disposed of using the appropriate methods specified by local authorities.

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 operate the Focus Portable Oxygen Concentrator.

What is the Focus Portable Oxygen Concentrator?

Oxygen concentrators were introduced in the mid-1970s 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 Focus 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.

Focus combines advanced oxygen concentrator technology with oxygen conserving technology for the world's smallest and lightest portable oxygen concentrator at just 1.75 lb (0.8 kg). The unit efficiently produces its own oxygen, and quickly delivers it as a pulse of oxygen at the very beginning of your inhalation. This eliminates the waste associated with a continuous flow oxygen device that delivers oxygen even while you are exhaling. Focus produces the equivalent of 2 LPM (liters per minute) continuous flow oxygen in a lightweight package that patients can wear easily away from the home.

Focus 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 affect the efficiency of one's 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 not 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 disease (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.

Focus for Airline Travel – FAA-Approved

Focus has received the US Federal Aviation Administration's (FAA) acceptance for onboard in-flight use by oxygen passengers on commercial airlines via a 2012 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.

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

Important Safety Rules

Carefully review and familiarize yourself with the following important safety information about the portable Focus 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.



WARNING

This device supplies high-concentration oxygen that promotes rapid burning. **Do not allow smoking or open flames within the same room of (1) this device, or (2) any oxygen-carrying accessory.** Failure to observe this warning can result in severe fire, property damage, and/or cause physical injury or death.

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/O 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.



WARNING

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 Mode 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.



WARNING

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 ANESTHETICS.

As with any electrically powered device, the user may experience periods of non-operation as a result of electrical power interruption, or the need to have the oxygen concentrator serviced by a qualified technician. The oxygen concentrator is not appropriate for any 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.



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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.

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



AirSep offers the OxySafe as an optional accessory. This is intended to be used in conjunction with the Focus 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



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.



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.



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.

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

Getting Started with Your Focus Portable Oxygen Concentrator

The Focus packaging contains the following items, as shown below. If any items are missing, contact your Equipment Provider.

- 1) Focus unit with carrying bag.
- 2) Coil Cord w/Switch, connects battery to Focus
- 3) Battery Pack, Lithium Ion/Rechargeable (2 supplied)
- 4) Battery case
- 5) Universal Power Supply (AC/DC)
- 6) AC Power Cord
- 7) DC Power Cord
- 8) Coil Cord without switch, connects battery to power supply charger to battery
- 9) Focus shoulder strap
- 10) Bag W/Battery Pockets
- 11) Patient Manual (not shown)



Figure 1: Focus with battery

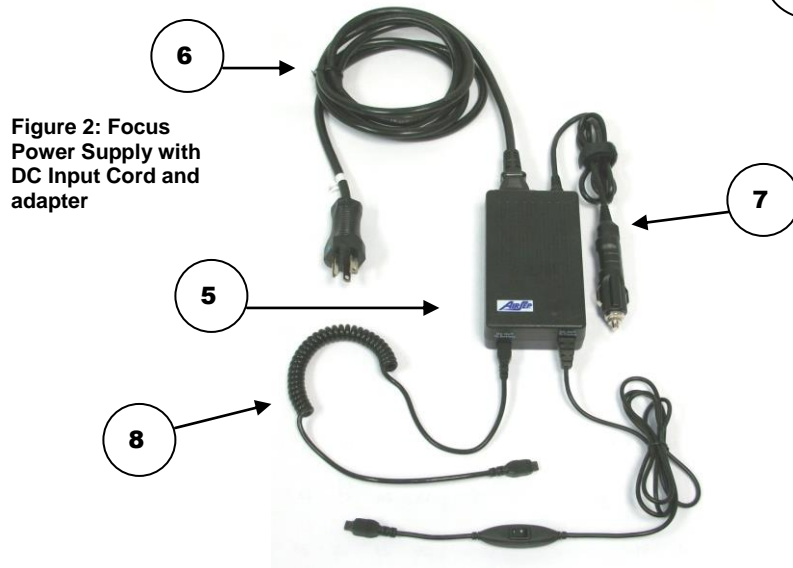


Figure 2: Focus Power Supply with DC Input Cord and adapter



Figure 4: Bag W/Battery Pockets



Figure 3: Focus shoulder strap

Before operating Focus 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.

Connecting to the Focus Power Inlet:

Locate the arrow marking at the top of the connector. Insert connector (Figure 5) into the Focus power inlet (Figure 6) with the arrow on the side of the connector facing outward. Do not force the connector into the power inlet, as it can be inserted only one way. This ensures that neither the unit nor the power accessories are damaged.



Focus operates from four different power sources.

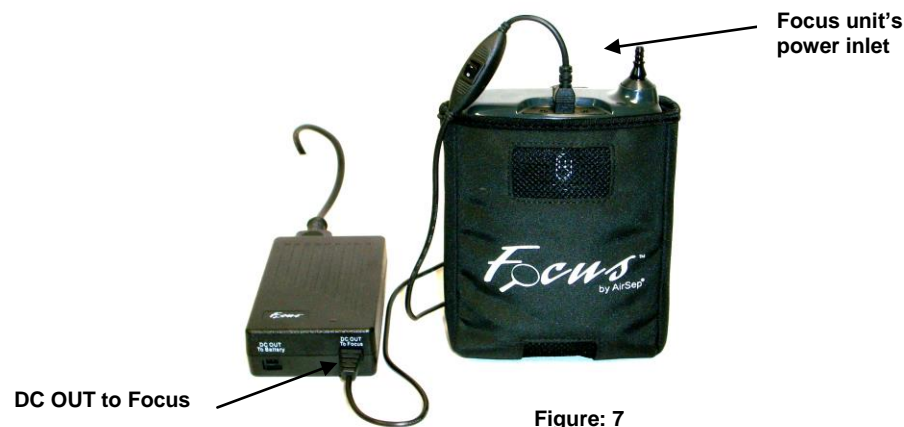
NOTE: Always connect to the Focus power inlet first before connecting to a power supply.

1) Connecting Focus to AC electrical power:

When you are near an AC outlet, you may choose to operate Focus with the universal AC/DC power supply rather than the battery.

Connect the cord on the power supply labeled as DC OUT To Focus into the Focus unit's power inlet, as shown in Figure 7. Do not force the plug, as it should be inserted only one way.

From the other end of the power supply, connect the 3-prong AC cord from the power supply into any standard outlet.



2) Connecting Focus to a DC power source:

The universal power supply can also be used to operate the Focus unit from any 12-Volt DC power source.

For example: to an automobile, (boat, motor home, etc.) with a 12-Volt DC outlet.

Connect the power supply cord labeled DC OUT To Focus into the Focus unit's power inlet, as shown in Figure 8.

Place the DC accessory adapter on the end of the DC power cord.

Connect the other end into the power supply input connection labeled Accessory DC IN.

You can then connect the DC power cord (with adapter attached) into the 12-Volt DC power source.

Do not force the cords, as they can be inserted only one way.



Figure: 8

3) Connecting Focus with the Battery, as shown:

Before using the battery, check that it has a sufficient charge.

The battery is equipped with a gauge (Figure 9) to indicate the level of battery charge (25-100%). To check the level of charge of the battery, press the button on the battery's keypad. The battery gauge/indicator(s) LEDs to the left of the button illuminate to indicate the level of battery charge (25-100%).

Connect the switch end of the battery cord into the Focus unit's power inlet only, as shown in Figures 5 and 6.

Connect the other end into the battery. Do not force the cords, as they can be properly inserted only one way.

Refer to the instructions on charging the battery in the Battery Charging section.



Belt / Shoulder
Strap clip

Figure: 9

Bag with Battery Pockets: The Focus with carrying bag (Item 1) can be placed in the bag with battery pockets (Item 10). This will allow you the ability to carry additional battery power in one bag while still operating the Focus.

The Focus shoulder strap (Item 9) can be used with either the Focus in the carrying bag (Item 1) or with the Focus with carrying bag (Item 1) placed in the Focus bag with battery pockets (Item 10).

Focus is very light weight and easy to wear using the AirSep-supplied shoulder strap (Figure 3), or you may clip the battery on either your shoulder strap or belt.

Focus can be worn on the waist by the Focus bags S-Clip to your own waist belt or the optional AirBelt, (Figure 11). Focus can also be worn over the shoulder with the use of the AirSep-supplied shoulder strap as shown (Figure 12).



Figure 10: Focus unit worn on the waist



Figure 11: Focus unit worn with AirBelt



Figure 12: Focus unit worn with the shoulder strap

Battery Charging

Check to make sure your unit's battery is fully charged before venturing out with Focus for the first time or upon subsequent use. To check the level of charge of the battery, press the button on the battery's keypad. The battery gauge/indicator(s) illuminate to indicate the level of battery charge (25-100%).

To charge the Focus battery while using Focus:

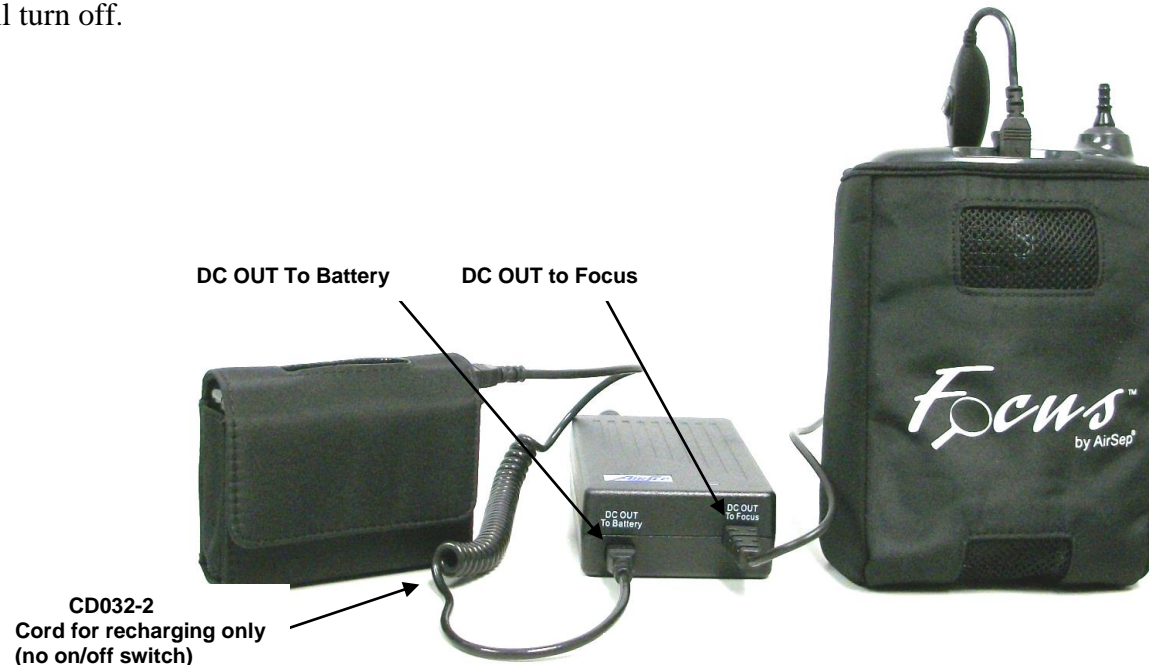
1a) Using AC Power: Follow the instructions in the Connecting Focus to AC electrical power section.

1b) Using DC Power: Follow the instructions in the Connecting Focus with the Battery section.

2) Connect the coiled battery cord (no on/off switch) into the Universal AC/DC power supply outlet labeled DC OUT To Battery. Connect the other end to the battery.

Note: The battery is charging whenever the unit operates on AC or DC power.

- The Focus battery will completely recharge from its fully depleted state in approximately 4 hours, whether the unit is in use on AC or on DC power.
- While charging a fully discharged battery, 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 the battery reaches it's 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.



Optional AirBelt

Optionally, you may also have an AirBelt for extended use of Focus.

The optional AirBelt (Figure 14), can power the Focus unit for up to 4 hours.

Before using AirBelt, check that it is sufficiently charged. It requires approximately 3 hours to completely charge.

AirBelt is equipped with a battery gauge/indicator to indicate the level of battery charge (25-100%). To check the level of charge, press the button on the AirBelt keypad. The battery gauge/indicator(s) illuminate to indicate the level of battery charge (25-100%). Connect the interface cable (Figure 15) into the AirBelt, then plug the other end of the interface cable into the Focus, as shown in Figure 16. For proper orientation of the connector, see Connecting to the Focus Power Inlet section.

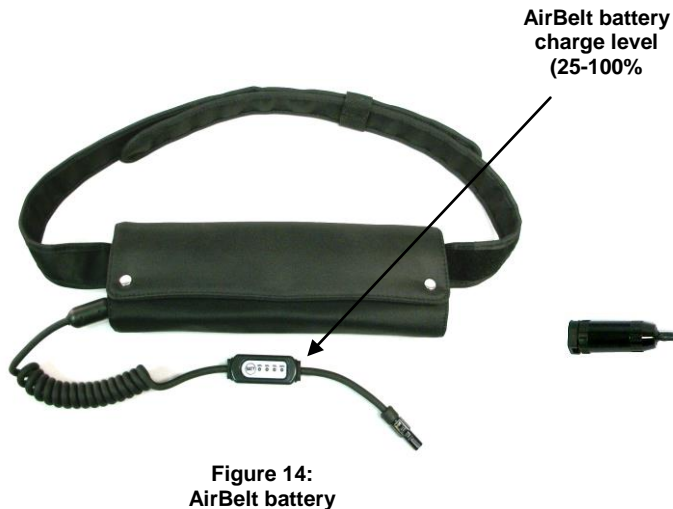
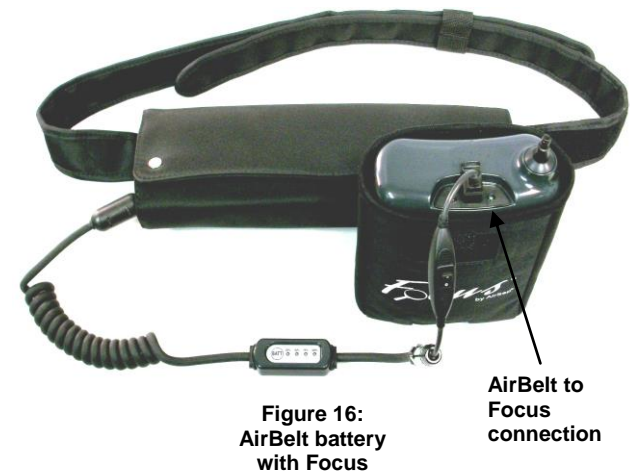


Figure 15:
AirBelt to Focus cord



Charging the Optional AirBelt

To charge the AirBelt battery for extended use:

- 1) Release safety cap from end of the AirBelt cord.
- 2) Connect the Universal AC/DC power supply (included with AirBelt Accessory kit) to the end of AirBelt's power cord, as shown in Figure 17.
- 3) Connect the AirBelt power supply to an AC electrical outlet to recharge.

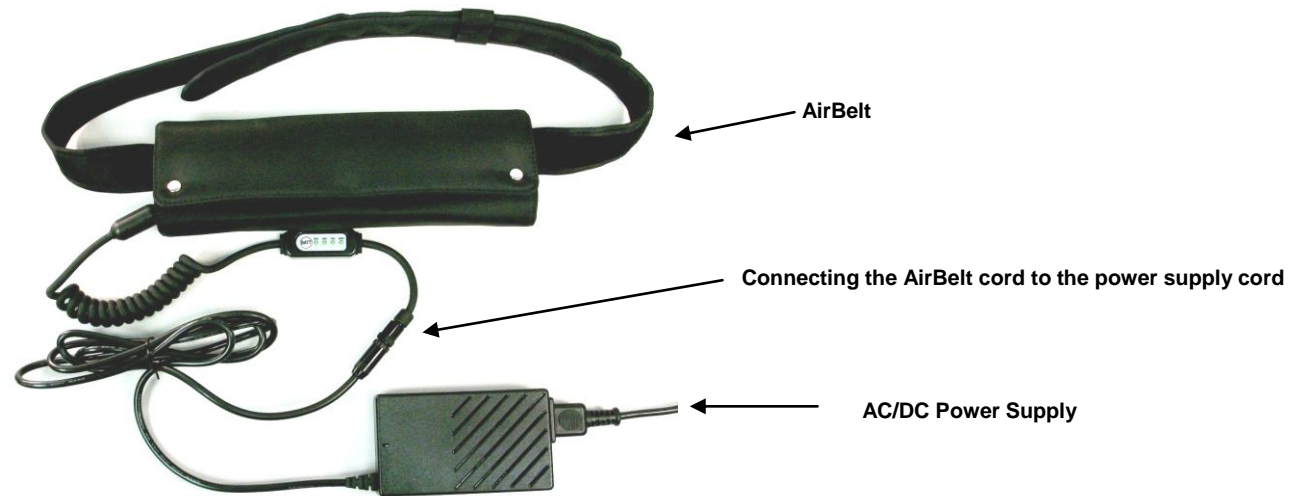


Figure 17: AirBelt Battery Charging set-up



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.



Do not attempt to charge the optional AirBelt with the Focus power supply or the AirBelt can be damaged. Use only the AirBelt power supply provided to charge AirBelt.

- The optional AirBelt will completely recharge from its fully depleted state in approximately 3 hours.
- While charging a fully discharged battery, 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 the battery reaches it's 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.



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.



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.



For oxygen concentrators equipped with the optional Airbelt:

1. If the AirBelt power supply remains connected when AirBelt is fully charged, the four LEDs will turn off within 15 minutes.
2. 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).

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

Nasal Cannula

A nasal cannula with tubing are used to deliver oxygen from the Focus unit to the user. The tubing is connected to the unit's oxygen outlet (See Figure 18).

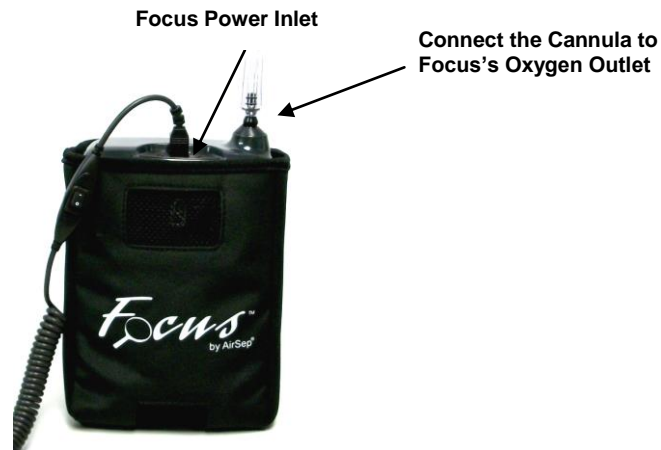


Figure: 18

AirSep recommends a nasal cannula with 7 ft (2.1 m) of tubing, AirSep Part No. CU002-1, or other suitable cannula. Other lengths of non-kinking/star channel cannula can be used for a total length of up to 25 ft (7.6 m) maximum.

When Focus is operating but does not sense breathing for 15 minutes, a constant alarm sounds, and the amber alarm light illuminates simultaneously. If this occurs, check the connection from the cannula to the Focus 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 condition continues, change to another source of oxygen as available, and contact your Equipment Provider.



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.

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

Focus Unit Components



Figure 20: Focus Exterior View - Front

Focus Control Panel (Top view): Alarm Display and Power Inlet

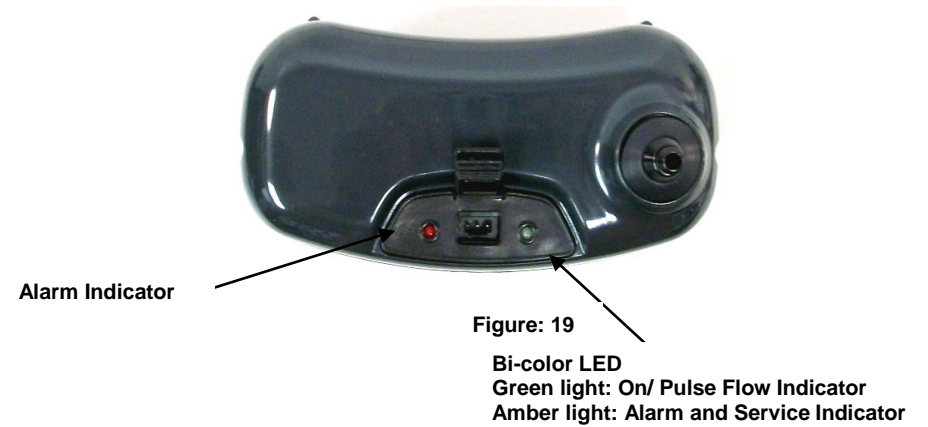


Figure 21: Focus Exterior View - Back

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

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

Operating Instructions

1. Locate and position Focus so that the air inlet and outlet are not obstructed.
2. Power the unit from (a) the battery; (b) DC outlet (i.e. automobile or motor boat); or (c) an AC outlet (i.e. normal household electric). (Refer to the Power Supplies section of this Patient Manual.
(Refer to Connecting to Focus's Power Inlet section for specific instructions on the connection of power sources.)
3. Securely connect your cannula to the oxygen outlet, as shown in Figure 18.



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.

4. Lift the control panel tab on the unit's power inlet and connect the selected power source. (i.e., battery, AC or DC power supply, or optional AirBelt)
5. Turn the Focus unit on by pressing the power switch to the on position (I). The LEDs on the control panel will illuminate, alternating between green and red, momentarily. Also, each time you turn on Focus, a brief alarm sounds. This indicates that Focus is powered for use.

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

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

6. To turn Focus off, press the power switch to the off position (O).

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

Power Supplies (Overview)

Focus can be powered in four different ways – the battery, AC power, DC power, or an optional AirBelt. The Focus power supply functions both as an AC power supply and a DC power supply.

(Refer to Connecting to Focus's Power Inlet section for specific instructions regarding the connection of optional power sources.)

- **Battery:** Two rechargeable batteries are supplied with Focus. Each battery, when fully charged, supplies power to the Focus unit for up to 1 ½ hours. An audible alarm sounds when the battery power is getting low. The alarm is discussed in the Audible Alarm and Indicator Lights section of this manual. The 25% capacity LED will blink every ½ second to indicate a low state of charge when the button is pressed.



NOTE

During this condition, change to another battery or alternate power source.

- Battery Charging (Battery Charging section): To charge the battery, connect the battery to either the power supply and a 100-240 volt, 50/60 Hz AC power outlet, or connect the power supply to a DC power outlet in an automobile (boat, motor home, etc.). A discharged battery requires approximately four hours to fully charge. It is recommended to recharge the battery, even if only partially depleted, as often as possible.
- **Universal Power Supply**
 - The AC power supply side of the universal power supply, allows the Focus unit to connect to a 100-240 volt, 50/60 Hz outlet. The power supply converts 100-240 volt AC to a DC voltage for the Focus unit to operate while recharging the Focus battery simultaneously.
 - The DC power inlet on the universal power supply, allows the Focus unit to connect to a motor vehicle's 12-Volt DC outlet for the Focus unit to operate while recharging Focus's battery simultaneously.
- **Optional AirBelt:** Focus can also be powered with AirBelt. AirBelt can be worn around the waist. When fully charged, the battery supplies power to Focus for up to 4 hours. AirBelt connects to the Focus unit's power inlet. It can be recharged by connecting it only to the AirBelt AC power supply.

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

Audible Alarm and Indicator Lights

When the Focus unit senses inhalation, a pulse of oxygen is delivered through the nasal cannula. The green light on the unit's control panel blinks each time a breath is detected.

Additionally, when the unit is operating and the battery is simultaneously being charged through the Universal AC / DC power supply, the battery for the Focus unit will display the charge level of the battery (25% to 100% state of charge) on the battery gauge/indicator(s) and when at 100%, LEDs (lights) remain on for approximately 15 minutes after reaching a full charge.

An audible alarm sounds if Focus has a low battery, if the cannula is disconnected, or if performance of the unit is outside of 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 and the green and red LEDs (lights) will alternate at start-up. Focus begins to operate when the alternating LEDs (light) stop and green LED (lights) remains on.

- **Low Battery**

- **Focus unit indicators:** As the battery power approaches a low level, the amber light on the Focus unit will flash on for ½ second with a 5-second pause and simultaneously, a ½ second alarm sounds with a 5-second pause. Following the battery warning indicators, if action is not taken, the unit will shut down. This will be indicated when the amber light flashes 2 times with a 5-second pause and simultaneously, a ½ second alarm sounds 2 times with a 5 second pause.
- **Battery indicator:** The green light indicator on the battery gauge (Figure 9) light illuminates intermittently.

When either of these conditions occurs, connect Focus to a DC power outlet or to an AC power outlet, or change to another source of oxygen within two minutes. The level of battery charge is indicated by the battery gauge/indicator(s). You can also check the state of charge at any time by pressing the button.

As noted above, when the unit is connected to AC or DC power outlet, you may simultaneously charge the Focus battery supplied with the unit while using the unit.



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

- **Cannula disconnected**

When Focus is operating but does not sense breathing for 15 minutes, a constant alarm sounds, and the amber alarm light illuminates simultaneously. If this occurs, check the connection from the cannula to the Focus 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 condition continues, change to another source of oxygen, as available, and contact your Equipment Provider.

- **Focus's capacity is exceeded**

If your breathing rate causes the capacity of Focus to be exceeded, an alarm sounds 3 times every ½ second with a 5 second pause, and the amber alarm light illuminates simultaneously. 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**

A general malfunction may be one of the following:

- 1) An audible alarm sounds (beep,beep) and the red alarm light illuminates.

If this alarm condition occurs, change to another source of oxygen as available, and contact your Equipment Provider.

- 2) An audible alarm sounds (beep,beep,beep) and the red alarm light illuminates.

If this alarm occurs, check air inlet and exhaust vents for obstruction. Clear obstruction at air inlet and exhaust.

- **Service light**

If the Focus unit's normally green light changes to solid amber with no audible alarm, contact your Equipment Provider. When the service indicator illuminates solid amber, it is time for your Focus unit to be inspected and/or serviced by your Equipment Provider. After any necessary service and the performance is verified by the Equipment Provider, the service indicator light will be reset.

Figure 22: Indicator of Required Inspection/Service



Dual display
Service Required (amber)

How to Respond to Focus's Audible Alarm and Indicator Lights

Status	Audible Alarm	Light	Indicates	Action
Indicator	Brief, continuous at start-up	(Green) and (Red) alternate; then (Green) continuous light	Focus has been turned on.	You may begin to operate your Focus unit.
Indicator	No	(Green) flashes; on each breath	Focus is delivering oxygen as a pulse flow.	Continue using Focus normally.
Indicator	No	(Amber) continuous light	Inspection and/or Service required.	Return unit to Equipment Provider for inspection and/or service.
Battery Indicator	No	25% (Green) light; flashes	Battery charge is low.	Connect the Focus unit into a DC outlet or an AC outlet immediately. Charge battery.
Alarm	Intermittent: Beep	(Amber) alarm; intermittent light	Warning: Battery voltage approaching too low a level to continue operating Focus.	Connect the Focus unit into a DC outlet or an AC outlet immediately. Charge battery.
Alarm	Intermittent: Beep, beep	(Amber) alarm; intermittent light	Battery shutdown: Battery voltage is too low to operate Focus.	Connect the Focus unit into a DC outlet or an AC outlet immediately. Charge battery.
Alarm	Continuous: Beep	(Amber) 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	(Amber) alarm; intermittent light	Breathing rate is exceeding the capacity of the Focus unit.	Reduce activity, and then if necessary use another source of oxygen, as available. Contact your Equipment Provider.
Alarm	Audible alarm sounds (beep,beep) Audible alarm sounds (beep,beep,beep)	(Red) light	General malfunction of the Focus unit has occurred.	Turn off the unit. Change to another source of oxygen, and contact your Equipment Provider. Check air inlet and exhaust vents for obstruction. Clear obstruction at air inlet and exhaust.

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.

The Manufacturer does not recommend the sterilization of this equipment.

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

Carrying Bag, Battery Case, Belt and Strap

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

Focus 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 Focus Portable Oxygen Concentrator.

MI332-1	Focus Bag Set includes the following:	
includes:	MI333-1	Battery Case, Focus
	MI379-1	Bag W/Battery Pockets
	MI380-1	Shoulder Strap, Focus
	MI345-1	Carrying Bag, Focus
BT023-1		Lithium Ion battery pack, (2 supplied)
CD034-1		DC power cord (33in / 860mm)
CD032-1		Battery-to-Focus cord with On/Off Switch (18in / 456mm)
CD032-2		Battery-to-Power Supply cord (only) for charging battery (18in / 456mm)
PW023-1,2,3 or 4		<i>Universal AC/DC Power Supply with battery charger including the following power cords as applicable:</i>
	PW023-1	Universal AC/DC Power Supply (4ft / 1.2m) w/ CD023-2 Power Cord 120V (8ft / 2.4m) and CD034-1DC power cord (33in / 860mm)
	PW023-2	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)
	PW023-3	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)
	PW023-4	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		<i>AirBelt with Power Supply including the following power cords as applicable:</i>
	BT017-1	AirBelt with Power Supply (BT017 extended cord length 4 ft. / 1.2m) w/ CD023-2 Power Cord 120VAC (8 ft. / 2.4m)
	BT017-2	AirBelt with Power Supply (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 (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 (BT017 extended cord length 4 ft. / 1.2m) w/ CD017-4 UK Power Cord (8 ft-2 in / 2.5m)
	Cord for connecting AirBelt to Focus	
CD035-1		AirBelt-to-Focus cord with On/Off switch (8in / 203.2mm)

Materials in direct or indirect contact with the patient

- Concentrator casingValtra/ABS/Polystyrene
- Concentrator Control Panel.....Nitrile Rubber
- Gas OutletDelrin
- ON/OFF Power Switch.....Thermoplastic
- Unit LabelLexan
- Coil cordsPolyurethane
- Cord connectorsPolycarbonate/Vinyl chloride
- Cord switch.....Nylon
- 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
- Power Supply, 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.



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

Troubleshooting

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

If your Focus 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.

Problem	Probable Cause	Solution
Alarm condition, Intermittent: Beep, beep (Amber) light illuminates simultaneously and Focus shuts down.	Battery voltage is too low to operate the Focus unit.	Connect to DC or an AC outlet immediately.
Alarm condition, Intermittent: Beep, beep, beep and the (Amber) alarm light illuminates simultaneously.	Breathing rate has exceeded the capacity of the Focus 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.
Unit does not start on battery power, although the battery indicates a charge.	Battery may be hot too or cold if left outdoors such as in an automobile.	Allow the battery 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.
Delay in recharging battery.	Battery exceeds charging temperature.	Unit may be operated; however, charging may not resume until battery temperature is reduced.
Unit alarms, does not start in automobile while connected to a properly functioning DC outlet.	Focus power supply needs resetting.	Turn off unit. 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 DC power supply.
Alarm condition, Audible alarm sounds (beep, beep) and (Red) alarm light illuminates (OR) Alarm condition, Audible alarm sounds: (beep, beep, beep) and (Red) alarm light illuminates	A general malfunction has occurred.	Turn off unit. Change to another source of oxygen as available, and contact your Equipment Provider. Check air inlet and exhaust vents for obstruction. Clear obstruction at air inlet and exhaust.
All other problems.		Turn off unit. Change to another source of oxygen as available, and contact your Equipment Provider.

Focus Specifications

Oxygen Concentration:*	Pulse setting equivalent to a continuous flow of 90% oxygen - 3% / +5.5%	
Pulse Dose:	17.25ml ± 10%	
Dimensions:	6.4 in. high x 4.8 in. wide x 2.5 in. deep (16.4 cm high x 12.2 cm wide x 6.1 deep)	
Weight:	Concentrator 1.75 lb (0.8 kg) Battery 0.53 lb (0.2 kg) Optional AirBelt Battery 1.8 lb (0.8 kg)	
Power:	Universal Power Supply: AC Power Supply: Input # 1_100 – 240 VAC (1.5 Amps max at 120 VAC 50/60 Hz) DC Power Supply: Input # 2_11-16 VDC 5.0 Amps max	
Battery duration (Rechargeable lithium Battery)	Battery: 1 ½ hours (per battery) Optional AirBelt Battery: 4 hours	
Battery recharge time:	4 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 Pulse flow – visual Cannula disconnect – audible and visual Breath rate alarm – audible and visual General malfunction – audible and visual Service required – visual Low battery – audible and visual Battery condition – battery level indicator on battery	
**Temperature range:	Normal operating 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)	
**Operational Altitude:	Operational Altitude: up to 10,000 ft. (3,048m) (523 mmHg) 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..

“Specifications continued”

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 Focus is intended for use in the electromagnetic environment specified below. The customer or the user of the Focus 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 Focus requires continued operation during power mains interruptions, it is recommended that the Focus 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 Focus is intended for use in the electromagnetic environment specified below. The customer or the user of the Focus 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Focus including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p>$D = 1.2 \times \sqrt{P}$</p> <p>$D = 1.2 \times \sqrt{P}$ from 80MHz to 800MHz $D = 2.3 \times \sqrt{P}$ from 800MHz to 2.5GHz</p> <p>where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency range. ^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div></div>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>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 Focus is used exceeds the applicable RF compliance level above, the Focus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Focus.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the Focus			
The Focus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Focus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Focus 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
<p>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.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Guidance and manufacturer's declaration - electromagnetic emissions		
The Focus is intended for use in the electromagnetic environment specified below. The customer or the user of the Focus should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment guidance
RF emissions CISPR 11	Group 1	The Focus 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. The Focus 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.
RF emissions CISPR 11	Class B	
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 by QPS Testing Services NA Inc. to be in compliance with,
IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety

Tested by QPS to be in compliance with applicable requirements of the Standard,
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 by Ultratech Group of Labs to be in compliance with:
EN 60601-1-2 Medical Electrical Equipment, Part 1: General Requirements for Safety-Collateral Standard:
Electrical Compatibility - Requirements and Tests
RTCA-DO160 Airborne Equipment, Sec. 21, Emission of Radio Frequency Energy
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 Focus 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:



Medical Product Services GmbH (MPS)

Borngasse 20

35619 Braunfels, Germany

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