

Patient Manual

Focus[™] Portable Oxygen Concentrator







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 CAN RESULT.



NO SMOKING signs should be prominently displayed in the home or wherever Focus is in use. Proper information about the dangers of smoking in the presence of medical oxygen should be relayed.

English: A multilingual version of the manual (MN172-1) is available through your Equipment Provider.

Español: Una versión multilingüe del manual (MN172-1) está disponible a través de su proveedor de equipo.

Français: Une version multilingue du manuel (MN172-1) est disponible par l'intermédiaire de votre fournisseur de matériel.

Deutsche: Eine mehrsprachige Version des Handbuchs (MN172-1) ist in Ihrer Geräte-Anbieter.

TABLE OF CONTENTS

AirSep[®] Focus[™] Portable Oxygen Concentrator

| AirSep's Focus™ Portable Oxygen Concentrator | 1 |
|--|-------|
| Symbols | 1-2 |
| Why Your Physician Prescribed Oxygen | 2 |
| What is the Focus Portable Oxygen Concentrator? | 3 |
| Important Safety Rules | 4-7 |
| Getting Started with Your Focus Portable Oxygen Concentrator | 8-11 |
| Battery Charging | 12 |
| Optional AirBelt / Charging the Optional AirBelt | 13-15 |
| Nasal Cannula | 16-17 |
| Focus Unit Components | 17 |
| Operating Instructions | 18 |
| Power Supplies | 19 |

TABLE OF CONTENTS

AirSep[®] Focus[™] Portable Oxygen Concentrator

| Audible Alarm and Indicator Lights | 20-21 | |
|--|-------|--|
| How to Respond to Focus's Audible Alarm and Indicator Lights | 22 | |
| Cleaning, Care, and Proper Maintenance | 23 | |
| Cabinet | 23 | |
| Carrying Bag | 23 | |
| Focus Accessories | 24 | |
| Reserve Oxygen Supply | 24 | |
| Troubleshooting | 25-26 | |
| Focus Specifications | 27 | |
| Classification | 28 | |
| Limited Warranty | 29 | |

AirSep's Focus[™] Portable Oxygen Concentrator

This Patient Manual will acquaint you with Air Sep's FocusTM Portable Oxygen Concentrator (POC). Make sure you r ead and understand all the inform ation 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 m anual in preference to words with the intention of decreasing the possibility of misunderstanding caused by la nguage differences. Symbols can also perm it 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) | 0 | OFF (power switch off) |
| WARNING | 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 | Caution — Describes a hazard or unsafe practice that if not avoided can result in minor bodily injury or property damage | C € 0459 | Complies with the 93/42/EEC directive drawn up by the approved organization No. 0459 |
| NOTE | Note – Provides information important enough to emphasize or repeat | Certified Electrical Safety CERTIFIED TO CSA STD C222 No. 601.1 | Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment |
| | Consult the accompanying documents | 学 | Keep unit and accessories dry |
| | Use no oil or grease | X | Proper disposal of waste of electrical and electronic equipment required |

| (3) | No smoking | ® | Do not disassemble |
|---|--|----------|------------------------------|
| * | Type BF equipment | i | Consult instructions for use |
| ♠ ()₂ (⊙ | Oxygen outlet connection to the cannula | ® | Do not expose to open flames |
| $\mathbf{R}_{\scriptscriptstyle{ONLY}}$ | Caution: Federal law (USA) restricts this for sale or rental by or on the order of a physician or licensed health care provider. | | Do not block fan |

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 respirat ory diseases. A significant nu mber 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 m akes up 21% of the room air we breath e. 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-additive drug, unauthorized oxygen therapy can be dangerous. You must seek medical advice before you use this oxygen concentrator. The Equipm ent Provider who supplies your oxygen equipm ent 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 safe stalternative 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 m inute) 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.)

---- [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.



This device supplies high-concentration oxygen that promotes rapid burning. Do not allow smoking or open flames within five feet (1.5 m) of this device, or any oxygen-carrying accessory. Failure to observe this warning can result in severe fire, property damage, and/or cause physical injury or death.



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



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



Use no oil, grease, or petroleum-based or other flammable products on the oxygen carrying accessories or the Focus unit. Oxygen accelerates the combustion of flammable substances.



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



While using the Focus unit outdoors with the AC power supply, connect the power supply into a Ground Fault Interrupted (GFI) outlet only to prevent accidental electrical shock hazard.



Electrical shock hazard. Disconnect the power cord from the electrical outlet before you clean the unit to prevent accidental electrical shock hazard. Only your Equipment Provider or a qualified service technician should remove the covers or service the unit.



Care should be taken to prevent Focus from getting wet or allowing water to enter the unit. This can cause the unit to malfunction or shut down.



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



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



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



Operating the Focus unit 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.)



Do not allow either the air intake or the air outlet vents to become blocked. This can cause the Focus unit to overheat and affect performance.



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 Focus unit to overheat and affect performance.



Storing the Focus unit outside of its temperature specifications may affect performance. (Refer to the Specifications section of this manual)



When using Focus 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 Focus unit. If the DC power supply does not illuminate and requires resetting, disconnect the DC power supply from the DC outlet, restart your vehicle, and then reconnect your DC power supply into the DC outlet. Failure to follow these instructions can result in the power supply not supplying power to Focus.



When the automobile in which you are using the Focus unit is turned off, disconnect and remove the unit from the automobile with you. Do not store Focus in a very hot automobile or in other similar, high-or low-temperature environments. Operating or storing the unit outside the normal temperature range can affect the performance of the Focus. (Refer to the Specifications section in this manual.)



If the Focus 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.)



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



Depending upon the temperature of the Focus battery, 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.



The Focus battery does not need to be fully discharged before recharging. It is recommended to charge the Focus battery after each use.



If the Focus power supply remains connected when the battery is fully charged, the four LEDs will turn off within $\frac{1}{2}$ hour.



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



NO SMOKING signs should be prominently displayed in the home or wherever Focus is in use. Proper information about the dangers of smoking in the presence of medical oxygen should be relayed.

Important Safety Rules for Optional AirBelt



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.



Replace safety cap on AirBelt cord when not in use.



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



Do not allow Focus or AirBelt to be stored in a very hot automobile or in other similar, high- or low-temperature environments. Operating AirBelt outside the normal temperature range can affect the performance. (Refer to the Specifications section in this manual.)



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



Depending upon the temperature of the Focus battery, 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,



AirBelt does not need to be fully discharged before recharging. It is recommended to charge AirBelt after each use.



If the AirBelt power supply remains connected when AirBelt is fully charged, the four LEDs will turn off within ½ hour.

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/Rechargable (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 only
- 9) Focus Belt
- 10) Focus shoulder strap
- 11) Patient Manual (not shown)

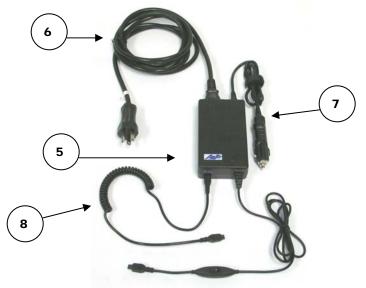


Figure 2: Focus Power Supply with DC Input Cord and adapter

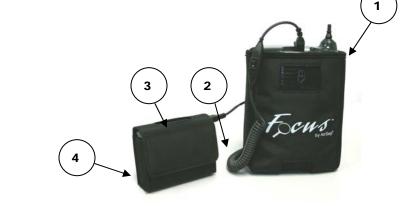


Figure 1: Focus with Battery



Figure 3: Focus belt



Figure 4: Focus shoulder

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.

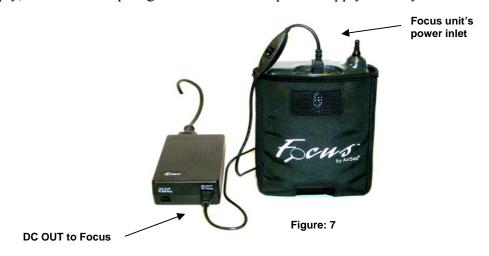


Focus operates from four different power sources.

NOTE: <u>Always</u> 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 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.

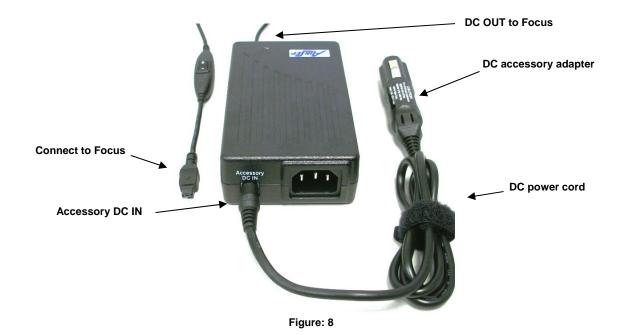
Connect the power supply cord labeled DC OUT To Focus into the Focus unit's power inlet, as shown in Figure 8.

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.

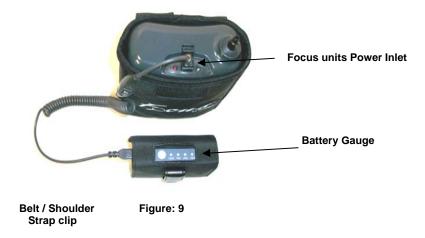


3) Connecting Focus with the Battery, as shown:

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.



Focus is very light weight and easy to wear using the AirSep-supplied shoulder strap (Figure 4), or belt (Figure 3). You may clip the battery on to either the strap or belt.

Focus can be worn on the waist by feeding the AirSep-supplied waist belt (Figure 10) or the optional AirBelt, (Figure 11) through the loops on the back of the Focus unit's carrying bag. 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 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.

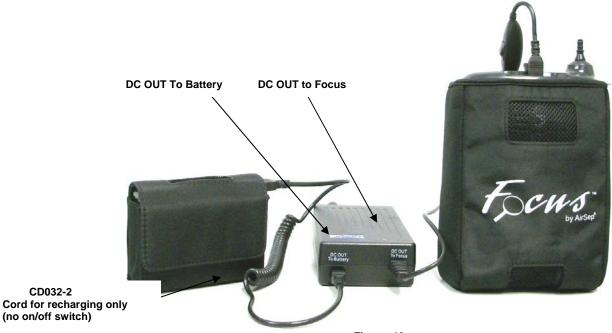


Figure: 13

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 ½ 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.



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 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.

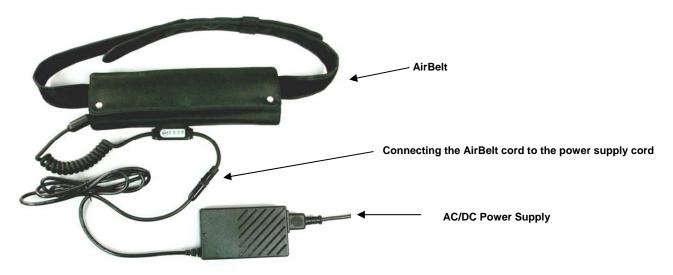


Figure 17: AirBelt Battery Charging set-up



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 Focus AirBelt will completely recharge from its fully depleted state in approximately 3 ½ 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.



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



Do not store Focus or AirBelt in a very hot automobile or in other similar, high- or low-temperature environments. Operating or storing the AirBelt outside the normal temperature range can affect its performance. (Refer to the Specifications section in this manual.)



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



Depending upon the temperature of the Focus battery, 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.



AirBelt does not need to be fully discharged before recharging. It is recommended to charge it after each use.



If the AirBelt power supply remains connected when it is fully charged, the four LEDs will turn off within ½ hour.

Nasal Cannula

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

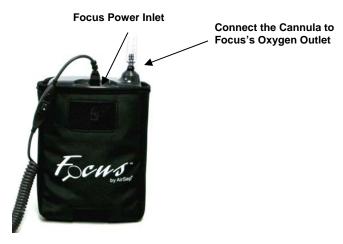


Figure: 18

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.



Always follow the cannula manufacturer's instructions for proper use. Consult your licensed health care provider to determine how often the cannula should be replaced.



Ensure the cannula is fully inserted and secure. This ensures that the Focus unit can properly detect inspiration for oxygen delivery.



Focus Unit Components



Figure 20: Focus Exterior View - Front



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 f rom (a) the battery; (b) DC outlet (i. e. automobile or motor boat); or (c) an AC outlet (i.e. norm al 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 on the oxygen carrying accessories or the Focus unit. 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)

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 (**0**).

Power Supplies (Overview)

Focus can be powered in four different ways – the battery, AC power, DC power, or an optional AirBe lt. 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 L ights 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.



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 autom obile (boat, motor home, etc.). A discharged battery requires approxim ately four hours to fully charge. It is recomm ended 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, all lows 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 pow er supply, allows the Focus unit to conne ct 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 3 ½ hours. AirB elt connects to the Focus unit's power inlet. It can be recharged by connecting it only to the AirBelt AC power supply.

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 ope rating and the battery is simultaneously being charged through the AC or DC power s upply, the battery for the Focus unit will displae y the charge level of the battery (25% to 100% state of charge) on the battery gauge/indicator(s) and remain on for approximately one hour after reaching a full charge.

An audible alarm sounds if Focus has a low battery, if the cannul a is disconnected, or if perfor mance of the unit is outside of specifications. The light and audi ble alarm conditions are explained in detail below and summ arized 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 pa use 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.



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 u nit, 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 capac ity of Focus to be ex ceeded, 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 co ntact your Equipment Provider.

General malfunction

If Focus has a general malfunction, an a udible alarm sounds and the red alarm light illuminates. If this alarm condition occurs, change to another source of oxygen as available, and contact your Equipment Provider.

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.





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

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 | (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. |

Cleaning, Care, and Proper Maintenance

Cabinet



Disconnect the power cord from the electrical outlet before you clean or service the unit to prevent accidental electrical shock hazard.



Do not use liquid directly on the Focus unit to clean it. 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 Focus, as they can damage the unit's plastic.



Replace the disposable cannula periodically following normal usage according to your Equipment Provider's recommendations.



Keep the Focus 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.



AirSep does not recommend the sterilization of this equipment.

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 AirS ep through your Equipment Provider. Use of accessories not listed below could adversely affect the performance and/or safety of the Focus Portable Oxygen Concentrator.

Part Number / Description

| Tart Hamber / Description | | |
|---------------------------|---------|--|
| MI332-1 | | Focus Bag Set includes the following: |
| includes: | MI333-1 | Battery Case, Focus |
| | MI334-1 | Shoulder Strap, Focus |
| | MI335-1 | Belt, Focus |
| | MI345-1 | Carrying Bag, Focus |
| BT023-1 | | Lithium Ion battery pack, (2 supplied) |
| CD034-1 | | DC power cord |
| CD032-1 | | Battery-to-Focus cord with On/Off Switch |
| CD032-2 | | Battery-to-Power Supply cord (only) for charging battery |
| PW019-1 | | Power Supply with battery charger for AC/DC connections, including |
| | | appropriate AC power cord |
| | | Optional AirBelt includes the following: |
| BT017-1 | | AirBelt battery |
| PW009-2 | | Power Supply for AirBelt, including appropriate AC power cord |
| | | Cord for connecting AirBelt to Focus |
| CD035-1 | | AirBelt-to-Focus cord with On/Off switch |

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.



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 C oncentrator 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. |
| | | |

| Problem | Probable Cause | Solution |
|--|---|---|
| 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 and the (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. |
| Solid (Amber) light without audible alarm. | Focus need inspection and / or service. | Contact your Equipment Provider. 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 alarm service/indicator light will be reset. |
| 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% |
|---|--|
| 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 ½ 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) Storage temperature: -2°F to 140°F (-20°C to 60°C) |

^{*} Based on an atmospheric pressure of 14.7 psi (101 kPa) at 70°F (21°C) * Operating unit outside of normal operational temperature range can affect performance.

Classification

Type of protection against electric shock:

Class II Protection from electric shock is achieved by double insulation.

Degree of protection against electric shock:

Type BF Equipment providing a particular degree of protection against electric shock regarding

- 1) allowable leakage current;
- 2) reliability of protective earth connection (if present).

Not intended for direct cardiac application.

Independent testing for Medical Electrical Equipment Standard:

Tested by QPS Testing Services NA Inc. to be in compliance with, IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety

2nd edition 1988, A1 1991, A2 1995.

Tested by QPS to be in compliance with applicable requirements of the Standard, CAN/CSA C22.2 No. 601.1-M90 Medical Electrical Equipment – Part 1: General Requirements for Safety, General instruction No. 1; Supplement No. 1; 1994 Amendment 2 – 1998 and General instruction No. 2 November 2003

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 60601-1-2:2007 (EMC) (2nd Edition), Medical Electrical Equipment, Part 1: General Requirements for Safety-

Collateral Standard: Electrical Compatibility - Requirements and Tests

RTCA-DO160F Airborne Equipment, Sec. 21, Emission of Radio Frequency Energy

CISPR 11:2004 / EN 55011:1998 +A1:1998 & A2:2002, 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.

Limited Warranty

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

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

THE FOREGOING WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IN FACT OR IN LAW, INCLUDING WITHOUT LIMITATION THE WARRANTY OF M ERCHANTABILITY OR THE WARRANTY OF FITNESS FOR PARTICUL AR PURPOSE. IT IS EXPRESSLY UNDERSTOOD THAT PURCHASER'S SOLE AND EXCLUSIVE REMEDY FOR DEFECT IN PARTS IS LIMITED TO ENFORCEMENT OF AIRSEP CORPORATION'S OBLIGATION AS SET FORTH ABOVE, AND AIRSEP CORP ORATION SHALL NOT BE LIABLE TO PURCHASER OR OTHERS FOR LOSS OF US E OF THE E QUIPMENT OR FOR OTHER SPECIAL, INDIRECT, I NCIDENTAL, OR CONSEQUENTIAL DAMAGES.

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

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

