



FreeStyle™ and FreeStyle 5™

Portable Oxygen Concentrators with UltraSense™
And Patient-Removable Battery

Provider Technical Service Manual

FreeStyle™



TABLE OF CONTENTS

General Information	4
Introduction to the FreeStyle	5
Introduction to the FreeStyle 5	7
Operating Specifications	9
Alarm Types	10
Classifications	11
Provider Support Policy	12
Definition of Symbols	13
How the FreeStyle and FreeStyle 5 Work	14
Flow Rates	15
Indications for Use	16
Contraindications	17
Introduction	18
Pre-Delivery Checklist	18
Operation Check	19
Alarm System	19
Oxygen Concentration Test	21
Safety, Warnings, and Cautions	22
Training the Patient	23
Removable Battery Pack	23
Connecting to External Power	27

Control Panel Indicators and Alarms	39
Selecting the Proper Flow Setting	39
Active Lifestyle Training	39
Routine Maintenance by the Patient	42
Patient Training Checklist	45
Equipment Provider Maintenance	47
Service	52
Housing Removal	53
PSA Removal	55
Compressor Replacement	61
Product Manifold Replacement	63
Solenoid Valve Replacement	65
Sieve Bed Replacement	66
Feed/Waste Manifold Replacement	69
Measuring the System Pressure	71
FreeStyle Hour Meter	73
Motor Controller Board Replacement	75
Circuit Board Replacement	77
Key Pad Replacement	81
Fan Replacement	84
Troubleshooting	86
Accessories	90
CAIRE Inc. Contact Information	91

GENERAL INFORMATION




This technical manual will familiarize you with provider-specific information regarding the FreeStyle and FreeStyle 5 portable oxygen concentrators.

Instructions in this manual are intended to help ensure that:

- Providers are familiar with the FreeStyle and FreeStyle 5 system components and system principles of operation
- Providers are given proper guidance in the use of the FreeStyle and FreeStyle 5 and their accessories that can be conveyed to patients
- Providers are made aware of the care, diagnostics, maintenance, and repair of the FreeStyle and FreeStyle 5 units

Warning and Caution Statements

Safety instructions are defined as follows:

	Warning – Important safety information for hazards that might cause serious injury.
	Caution – Important information for preventing damage to the FreeStyle and FreeStyle 5.
	Note – Places emphasis on an operating characteristic or important consideration.

INTRODUCTION TO THE FREESTYLE



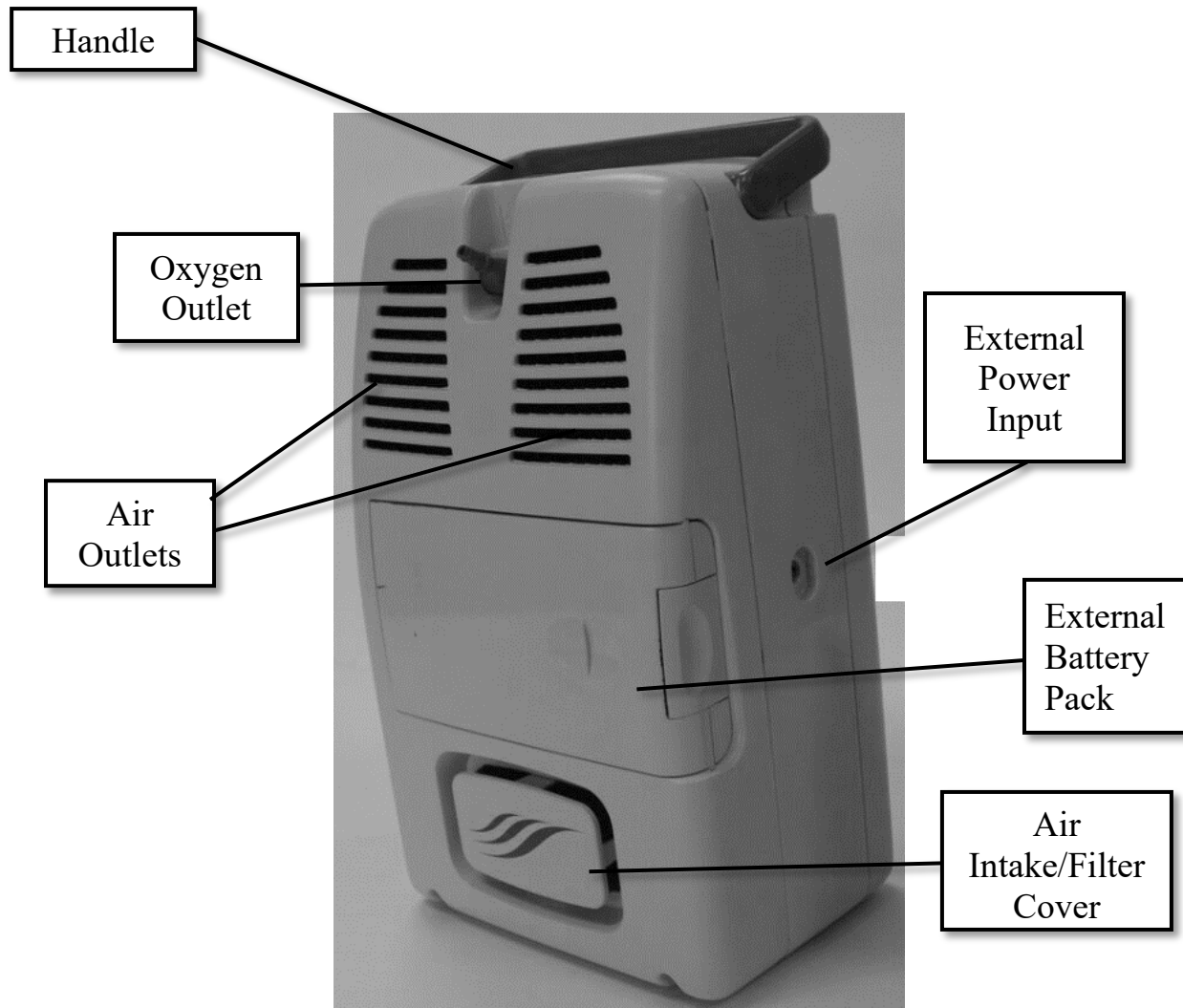


Figure 1.1: External Components

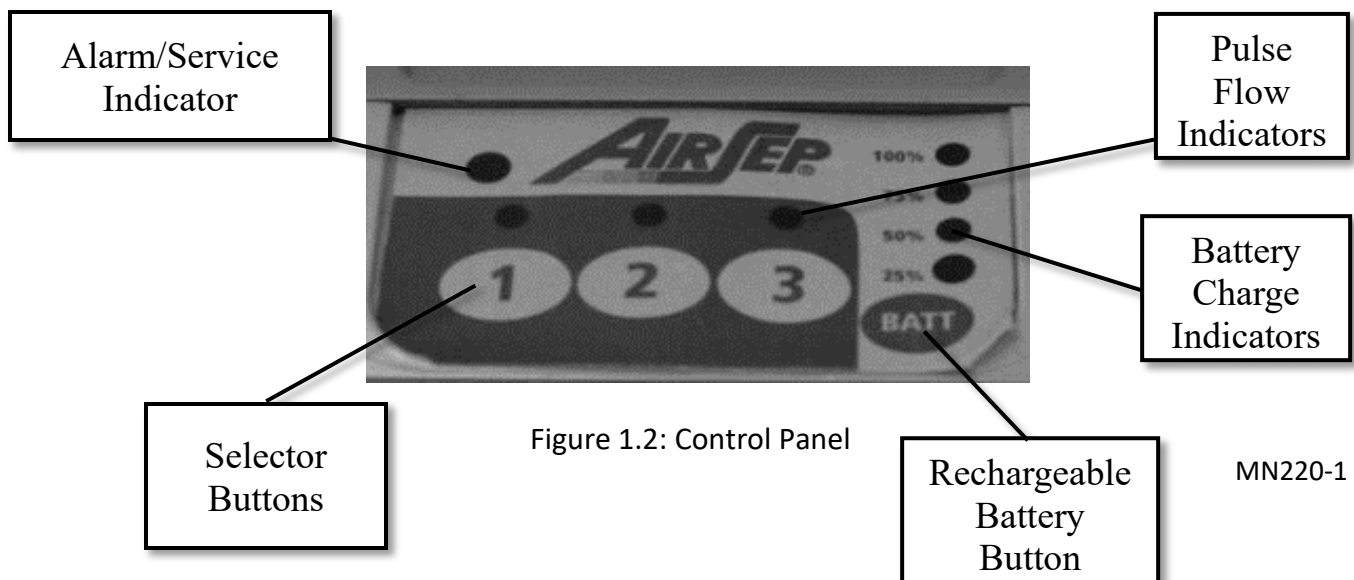


Figure 1.2: Control Panel

INTRODUCTION TO THE FREESTYLE 5



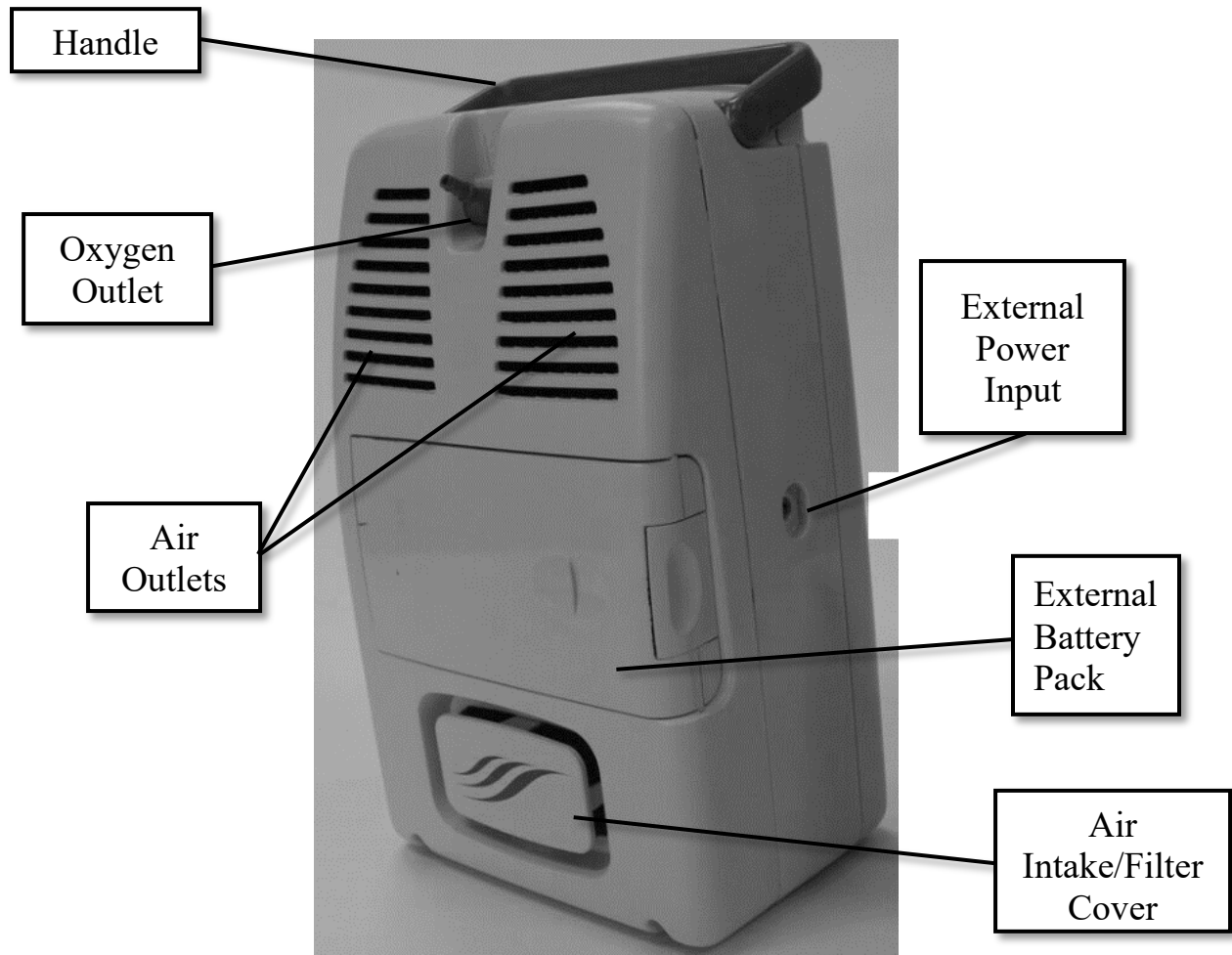


Figure 2.1: External Components

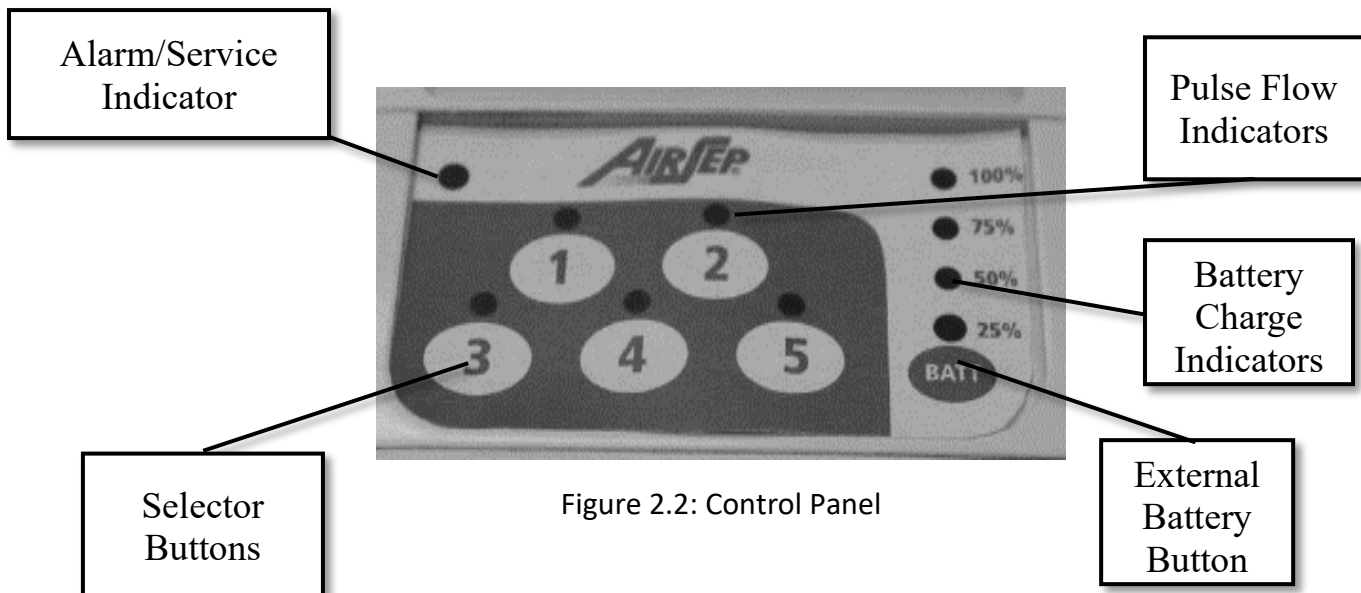


Figure 2.2: Control Panel

FREESTYLE AND FREESTYLE 5 SPECIFICATIONS

	FreeStyle	FreeStyle 5
Dimensions	8.6 in x 6.1 in x 3.6 in (21.8 cm x 15.5 cm x 9.1 cm)	10.7 in x 6.6 in x 4.4 in (27.2 cm x 16.8 cm x 11.2 cm)
Weight (w/ Battery Pack)	4.9 lbs (2.2 kg)	6.7 lbs (3.0 kg)
Sound Level	41 dB(A) at 2 setting 44 dB(A) at setting 3	43 dB(A) at setting 2 51 dB(A) at setting 5
Flow Settings	Pulse Settings 1, 2, 3	Pulse Setting 1, 2, 3, 4, 5
Oxygen Concentration*	90% oxygen +5.5/-3%	90% oxygen +5.5/-3%
AC Power	100-240 VAC, 50-60 Hz (1.75 amps max)	100-240 VAC, 50/60 Hz (2 amps max)
DC Power	11-16 VDC (8.0 amps max)	12-24 VDC (15 amps max)
Battery Pack	Rechargeable, lithium battery	Rechargeable, lithium battery
Battery Pack Durations	Setting 1 – 6.5 hours Setting 2 – 3.5 hours Setting 3 – 3 hours	Setting 1 – 4.25 hours Setting 2 – 2.5 hours Setting 3 – 1.75 hours Setting 4 – 1.5 hours Setting 5 – 1.25 hrs
Warm Up Time	2 minutes	2 minutes
Operating Temperature	41°F to 104°F (5°C to 40°C)	41°F to 104°F (5°C to 40°C)
Storage Temp. (Unit)	-4°F to 140°F (-20°C to 60°C)	-4°F to 140°F (-20°C to 60°C)
Storage Temp. (Battery)	1 month -4°F to +122°F (-20 to +50 C) 3 months -4°F to +104°F (-20 to +40C) 1 year -4°F to +68°F (-20 to +20C)	1 month -4°F to +122°F (-20 to +50 C) 3 months -4°F to +104°F (-20 to +40C) 1 year -4°F to +68°F (-20 to +20C)
Operating Altitude	Up to 12,000 ft (3,657.6 m)	Up to 12,000 ft (3,657.6 m)
Operating Humidity	<95%, non-condensing	<95%, non-condensing

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

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



The battery durations listed above are for new, fully charged batteries. Battery durations will degrade over time due to environmental operating conditions, usage, and operational condition of the concentrator.

FREESTYLE AND FREESTYLE 5 ALARMS

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

FREESTYLE AND FREESTYLE 5 CLASSIFICATIONS

Classification

Type of protection against electric shock:

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

Degree of protection against electric shock:

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

- 1) Allowable leakage current
- 2) Reliability of protective earth connection (if present).

Not intended for direct cardiac application.

Independent testing for Medical Electrical Equipment Standard.

Tested to be in compliance with:

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety

Tested 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

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

Device with accessories tested 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 allowed:

Please refer to the “Cleaning, Care, and Proper Maintenance” section of this Technical Manual.

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

Equipment not suitable for such application.

Mode of operation:

Continuous duty.

PROVIDER SUPPORT POLICY

Objective: As a manufacturer our organizational goal is to provide customer support and assistance to the highest level of excellence.

Customers are Providers (which include Dealers, Distributors and Agents).

Support includes, but is not limited to, troubleshooting and Return Material Authorizations (RMA).

Business Hours: Monday – Friday, 8:30am – 5:00pm EST.

CAIRE can only support customers who are recognized as Providers, Dealers, Distributors and/or Agents. These partnerships are qualified as having an existing account or are in the process of credit application completion. All patient or end-user inquiries including but not limited to RMA, warranty or serial number questions must be handled by their Provider.
























Provider Support Policy: CAIRE is unable to provide direct assistance, clinical advice, or recommendations to a patient or end-user. Providers have sole responsibility in assisting their patients.

DEFINITION OF SYMBOLS

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

The following table is a list of symbols and definitions used with the FreeStyle and FreeStyle 5:

Symbol	Definition	Symbol	Definition
	Consult instructions for use		Do not disassemble
	No Smoking Icon: Do not smoke near unit.		Use no oil or grease.
	This side up		No open or naked flames.
RTCA/DO-160 Section 21 Category M Compliant	RTCA DO160 Section 21 Category M Compliant. FAA SFAR 106 requirement		Safety agency for CAN/CSA C22.2 No. 60601-1-08 M90 for medical electrical equipment
	Fragile – handle with care		Safety agency for CAN/CSA C22.2 No. 601.1 M90 for medical electrical equipment
	Type BF Equipment		FAA Approved – POC
	Name and address of manufacturer		Serial Number
	Authorized representative in the European Community		Date of Manufacture
	Catalog number		Class II Equipment
	Do not get wet.		Prescription only
	If the product unique device identifier (UDI) label has the CE#### symbol on it, the device complies with the requirements of Directive 93/42/EEC concerning medical devices. The CE#### symbol indicates notified body number.		
	This symbol is to remind the equipment owners to return it to a recycling facility at the end of its life, per Waste Electrical and Electronic Equipment (WEEE) Directive.		

HOW THE FREESTYLE AND FREESTYLE 5 WORK

The FreeStyle and FreeStyle 5 are portable oxygen concentrators (POC) used to extract oxygen from the atmosphere, concentrate it to 87–95.5%, and present the oxygen to the patient in the form of a bolus (pulse dose). These devices operate from either external power or from a rechargeable battery pack.

Description of Operation

Air enters the POC through an external air intake / gross particle filter. This filtered air enters the compressor via a suction intake muffler that quiets the compressor's suction sound. Pressurized air then exits the compressor and passes through a heat exchanger to reduce the temperature.

Next, a solenoid feed valve directs the air into one of two sieve beds that contain molecular sieve. The unique property of molecular sieve enables it to physically attract (adsorb) nitrogen when air passes through this material, thereby separating the nitrogen from the oxygen in ambient air.

There are two sieve beds: While one produces high-concentration oxygen, the other purges the nitrogen it adsorbed via the solenoid waste valve and exhaust. Oxygen exits the product tank after first passing through the integrated product filter.

In addition to the molecular sieve and product tank, the FreeStyle and FreeStyle 5 contain an Oxygen Conserving Device (OCD) valve that controls delivery of high-concentration oxygen to the patient when the pressure sensor senses the patient's inspiration.

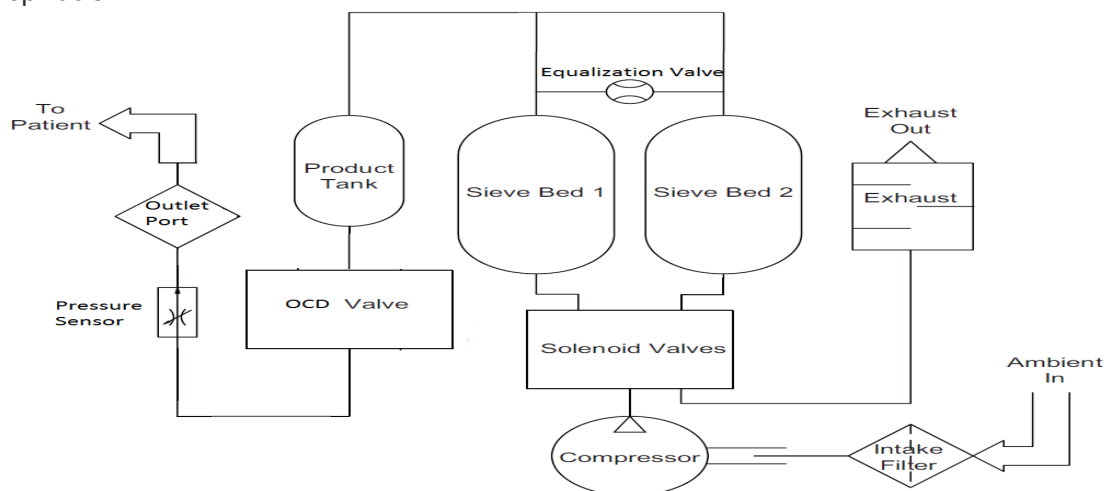


Figure 3: Flow Schematic Diagram

FREESTYLE AND FREESTYLE 5 FLOW RATES

The pulse delivery will adjust the volume delivered each breath to maintain a constant volume per minute:

Flow Setting	FreeStyle Volume(mL/min)	FreeStyle 5 Volume (mL/min)
Setting 1	227.5 mL/min	227.5 mL/min
Setting 2	420 mL/min	420 mL/min
Setting 3	500 mL/min	630 mL/min
Setting 4	N/A	840 mL/min
Setting 5	N/A	1000 mL/min

Figure 4: Pulse Profiles

Example Calculation: Setting 2 at 20 Breaths Per Minute (BPM)

$$\frac{\text{Minute Volume (mL/min)}}{\text{Breath Rate (bpm)}} = \text{Bolus Volume} \left(\frac{\text{mL}}{\text{breath}} \right)$$






$$\frac{420 \text{ mL/min}}{20 \text{ BPM}} = 21 \text{ mL/breath}$$

INDICATIONS FOR USE





The FreeStyle and FreeStyle 5 POC's are indicated for the administration of supplemental oxygen. These devices are not intended for life support nor do they provide any patient monitoring capabilities.

A physician must prescribe a specific oxygen pulse dose setting to meet patients' individual needs.

Recommended oxygen flow rates should be adjusted only under the advice of a physician.

 WARNING	Federal (USA) law restricts this device to sell or rental by order of a physician or other licensed health care provider.
 WARNING	It is very important to select only the prescribed level of oxygen. Do not change the flow selection unless you have been directed to do so by a licensed clinician.
 WARNING	This unit is not to be used for life support. Geriatric, pediatric, or any other user unable to communicate discomfort while using this device may require additional monitoring. Users with hearing and/or sight impairment(s) may need assistance with monitoring alarms.
 WARNING	Pulse dose settings must be determined for each user individually for their needs at rest, during exercise, and when traveling.
 CAUTION	The portable oxygen concentrator may be used during sleep under the recommendation of a qualified clinician.

CONTRAINDICATIONS

	The FreeStyle and FreeStyle 5 POC's are not intended for life supporting or life sustaining applications, nor do they provide any patient monitoring capabilities.
	In certain circumstances, the use of non-prescribed oxygen can be hazardous. These devices should only be used when prescribed by a physician.
	Not for use in the presence of flammable anesthetics.
	<p>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 POC unit serviced by a qualified technician.</p> <p>The FreeStyle and FreeStyle 5 units are not appropriate for any user who would experience adverse health consequences as a result of such temporary interruption.</p>

INTRODUCTION

Welcome to the CAIRE FreeStyle and FreeStyle 5 portable oxygen concentrators. Setting up and training your patient to use the FreeStyle or FreeStyle 5 has never been easier! You can expect your patients and care providers to easily learn how to use the device by following the directions in this section. While setting up and training a patient, be sure to point out the advantages of the FreeStyle and FreeStyle 5. For example:

- Easy-to-use controls
- FreeStyle battery pack
- Quiet operation
- Alarm system

After completing each training procedure, ask your patient if he or she has any questions. Proper training of your patients will result in fewer service calls, improved compliance, and increased patient satisfaction.

PRE-DELIVERY CHECKLIST

Verify that the FreeStyle or FreeStyle 5 is provided to the patient with the following items:

FreeStyle:

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

FreeStyle 5:

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



The FreeStyle comes with a universal (AC and DC) power supply. The FreeStyle 5 comes with an AC power supply and a separate DC power supply.

FREESTYLE AND FREESTYLE 5 OPERATION CHECK

CAIRE tests every FreeStyle and FreeStyle 5 POC thoroughly after manufacture. The provider must perform the following checks and tests to ensure that no damage occurred in shipping or handling:



Do not connect external power without a battery pack installed in the FreeStyle or FreeStyle 5



The FreeStyle or FreeStyle 5 must be off and disconnected from external power before removing the battery pack.

1. Install the battery pack.
2. Connect the AC Power Supply to the POC, and connect the AC power cord from the Power Supply to a 100-240 volt, 50/60 Hz electrical outlet.
3. Turn the unit on by pressing flow setting 2. Check to see that the following sequence occurs:
 - a. A brief, continuous alarm sounds to indicate that the POC has been turned on.
 - b. The compressor starts.
 - c. Exhaust air flows from the unit.
4. Perform an oxygen concentration test, as described in the OXYGEN CONCENTRATION TEST section of this manual.

FREESTYLE AND FREESTYLE 5 ALARM SYSTEM

START-UP ALARM

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

LOW BATTERY ALARM

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

When connected to AC or DC power, the concentrator will operate while recharging the battery pack.

CANNULA DISCONNECT

When a FreeStyle or FreeStyle 5 is operating but does not sense breathing, a constant alarm sounds, and the alarm light illuminates after 15 minutes. If this occurs, check the connection from the cannula to the unit, make sure that the nasal cannula is positioned properly on your face, and ensure that you are breathing through your nose. If the alarm continues to sound, change to another source of oxygen as available, and contact your Equipment Provider.

BREATH RATE EXCEEDED




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

GENERAL MALFUNCTION

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

OXYGEN CONCENTRATION TEST AND SPECIFICATION


To ensure that FreeStyle or FreeStyle 5 oxygen output is within specification, the provider must perform an oxygen concentration test. Test the unit upon delivery to a patient and at periodic intervals.

 WARNING	Do not connect external power without a battery pack installed in the FreeStyle or FreeStyle 5
 WARNING	The FreeStyle or FreeStyle 5 must be off and disconnected from external power before removing the battery pack.
 NOTE	Equipment Providers, based upon their own expertise and documentation, may establish and implement their own protocol to check oxygen concentration.




1. Connect the POC using the supplied AC power supply to a 100-240 volt, 50/60 Hz electrical outlet.
2. Turn unit on by pressing setting 2 on keypad.
3. Simultaneously press and hold settings [1] and [3] for ten seconds if using a FreeStyle. Simultaneously press and hold settings [1] and [5] for ten seconds if using a FreeStyle 5. After approximately ten seconds, the alarm will sound and the LEDs above each flow setting will illuminate verifying auto pulse mode (Test Mode).
4. Allow the unit to warm-up for 5 minutes before recording oxygen concentration.
5. Connect a calibrated oxygen analyzer to the oxygen outlet and record the unit's concentration, a 12" tube is recommended. The specification in test mode is 87% or higher.

SAFETY GUIDELINES AND OPERATIONAL SAFETY, WARNINGS, AND CAUTIONS

Provider should review all safety guidelines and operational safety Warnings/Cautions with each patient. In addition, provider should carry out a risk assessment prior to installation of the FreeStyle or FreeStyle 5 to assure proper connection and compatibility with other equipment the patient may be using.

	<p><u>No Smoking or Open Flames.</u> For safety concerns, all possible sources of ignition must be kept away from the oxygen system and preferably out of the room in which it is being used. Smoking in the proximity of an operation oxygen concentrator is extremely dangerous and can permanently damage the device and void the warranty. Keep the POC at least five (5 ft) feet (1.5 m) from heat sources, sparking objects, or open flames.</p>
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Ask your patient where they would like to set up the device. While unpacking and setting up the device, tell your patient about these important cautions and warnings:

	<p>Locate the unit in a well-ventilated space that provides adequate air flow. Ensure that furniture, draperies, or clothing will not impede air circulation. Avoid placing the unit over a floor heat register or against a baseboard heating system.</p> <p>Do not use in the presence of flammable anesthetics, solvents, aerosols, or flammable cleaning agents.</p> <p>Avoid high pollutant environments.</p>
	<p>Some patients are highly mobile and may use the device under varying circumstances. Make sure your patient or patient caregiver completely understands the basic precautions to safely locate the device.</p>
	<p>After completing this training procedure, ask your patient if they have any questions.</p>

TRAINING THE PATIENT

It is important that patients thoroughly understand how to operate the FreeStyle or Freestyle 5 unit. This enables proper treatment as prescribed by a qualified, licensed physician. You must explain that the purpose of this therapy is to alleviate symptoms. If patients experience any discomfort or if the unit alarms, they must notify their Equipment Provider and/or physician immediately.

Give the patient a copy of the Users Manual and advise them to read prior to operating the unit. Open the manual and briefly review the Table of Contents, including subheadings. Show your patient the icons and symbols and explain what each one means. Explain each step in the operation of the unit to the patient with reference to the patients User Manual.



Advise your patient to thoroughly read the User Manual and keep the manual in a safe place for future reference.

Power Supplies

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

Battery Pack

AC Power

DC Power



Do not connect external power without a battery pack installed in the FreeStyle or FreeStyle 5

Information on the operation of each of these components is in the following sections:

BATTERY PACK

The FreeStyle or FreeStyle 5 can be operated by the rechargeable battery pack which is supplied with the device. There are no operational limitations of the concentrator when running from power supplied from the battery pack. All flow rates are available on battery power.

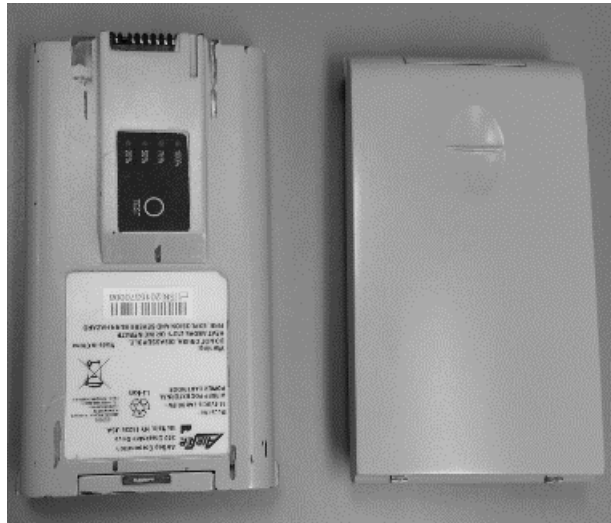


Figure 5.1: Removable Battery Pack

INSTALLING THE BATTERY:

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



Figure 5.2: Battery Pack Installation

REMOVING THE BATTERY:



The FreeStyle or FreeStyle 5 must be off and disconnected from external power before removing the battery pack.

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

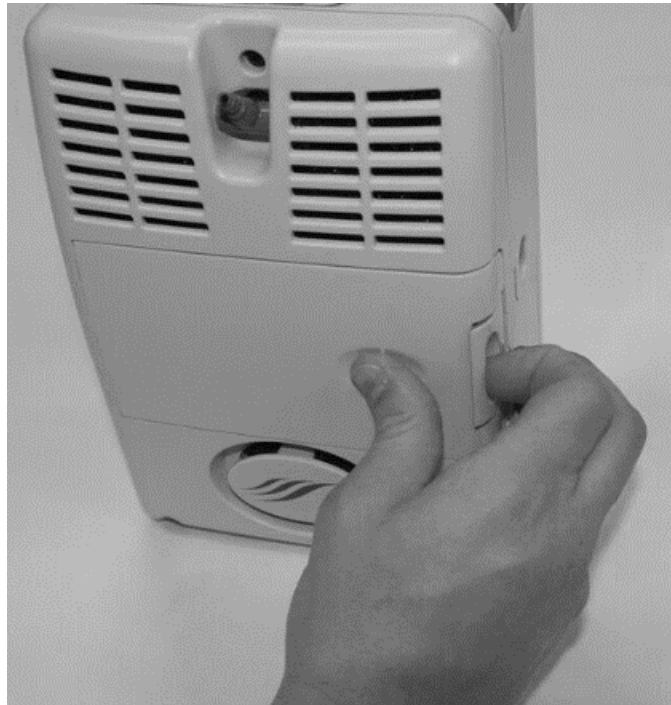


Figure 5.3: Battery Pack Removal

CHECKING BATTERY PACK CHARGE:

To check the battery charge when it is installed in the FreeStyle or FreeStyle 5, press the “BATT” battery status button on the control panel of the concentrator. The battery gauge indicator lights (25-100%) will illuminate above the BATT button to indicate the level of the battery pack charge.



Figure 5.4: Keypad Battery Status Indicator

To check the battery charge when it is not installed in the FreeStyle or FreeStyle 5, turn the battery on its back and press the TEST button. The battery gauge indicator lights (25-100%) will illuminate, to the left of the TEST button, to indicate the level of the battery pack charge.



Figure 5.5: Battery Pack TEST Button

CONNECTING TO EXTERNAL POWER

INITIAL CHARGING:

The new battery supplied with your FreeStyle or FreeStyle 5 is partially charged when it is shipped from the factory. Before using for the first time, you should fully charge the battery pack using either AC or DC power.



Do not connect external power without a battery pack installed in the FreeStyle or FreeStyle 5

GENERAL CHARGING INFORMATION:

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

When all 4 of the battery gauge indicator lights are solid, the battery is fully charged. The lights will remain on for a short period of time to indicate a full charge, and will then turn off. Alternately, the battery pack may be charged using the optional desktop charger. Reference the manual for the desktop charger (MN211) for instructions on its operation.

BATTERY OPERATING DURATION:

When external AC or DC power is disconnected, the concentrator will automatically switch over to using battery power if the battery pack is installed and has a charge. The table below shows the typical durations for a new battery pack.

Battery pack durations will remain constant regardless of your breath rate.

FreeStyle	FreeStyle 5
Setting 1 - 6.5 hours (6 hrs, 30 minutes)	Setting 1 - 4.25 hours (4 hrs, 15 minutes)
Setting 2 - 3.5 hours (3 hrs, 30 minutes)	Setting 2 – 2.5 hours (2 hrs, 30 minutes)
Setting 3 - 3.0 hours (3 hrs)	Setting 3 - 1.75 hours (1 hr, 45 minutes)

	FreeStyle 5
-	Setting 4 - 1.5 hours (1 hr, 30 minutes)
-	Setting 5 -1.25 hours (1 hr, 15 minutes)



The battery pack durations listed above are for new, fully charged batteries. Battery pack durations will degrade over time due to environmental operating conditions, usage, and operational condition of the concentrator.

TYPICAL BATTERY RECHARGE TIME:

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

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

FREESTYLE AC & DC POWER SUPPLY

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

The universal power supplied with the Freestyle includes the following:

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



Figure 6: FreeStyle Universal Power Supply

AC POWER

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

To connect the FreeStyle to AC Power:

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



Figure 6.1: Connecting Power Supply to FreeStyle

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



Figure 6.2: Connecting AC Cable to Power Supply

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



Figure 6.3: Connecting Power Supply to AC Outlet

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

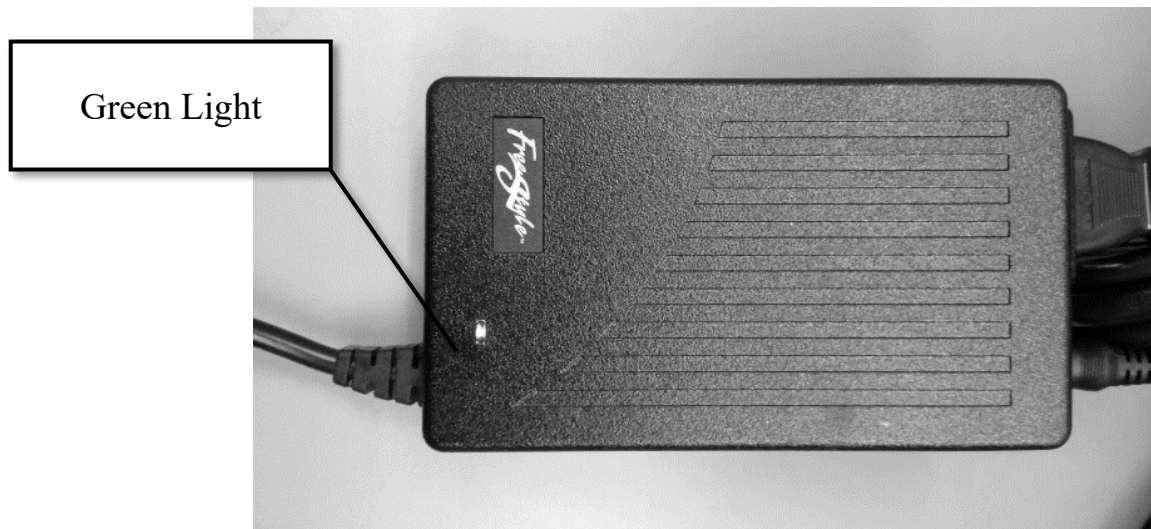


Figure 6.4: Green Light on Universal Power Supply

If the battery pack is in need of re-charge, the battery status indicator lights should blink accordingly to show charging (reference page xx for charging information).

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

DC POWER

DC power is for use in the accessory outlets of automobiles, boat, or other motor vehicles. The FreeStyle is fully functional on DC power for use. The FreeStyle will also recharge the battery pack if needed any time DC power is available. The battery pack will recharge both if the unit is off or on and in use.

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



Figure 6.5: Connecting Power Supply to FreeStyle

Connect the DC power cord to the inlet marked “ACCESSORY DC IN” on the universal power supply



Figure 6.6: Connecting DC Cable to Universal Power Supply

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

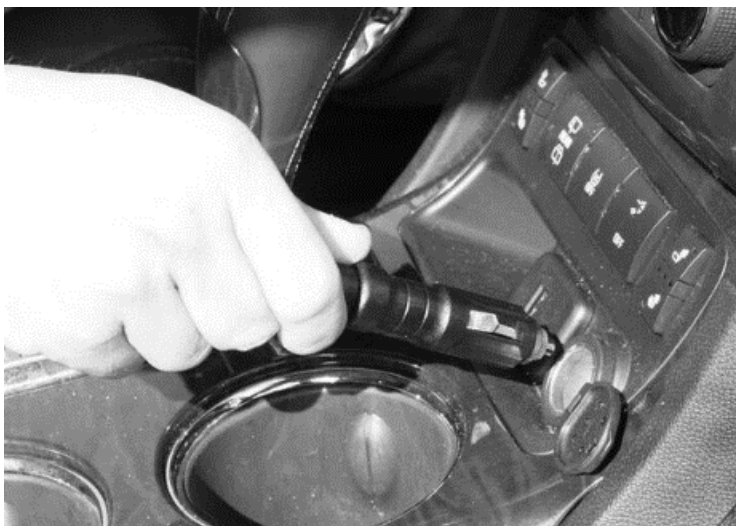


Figure 6.7: Insert DC Adapter to DC Outlet

Turn on your motor vehicle.

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

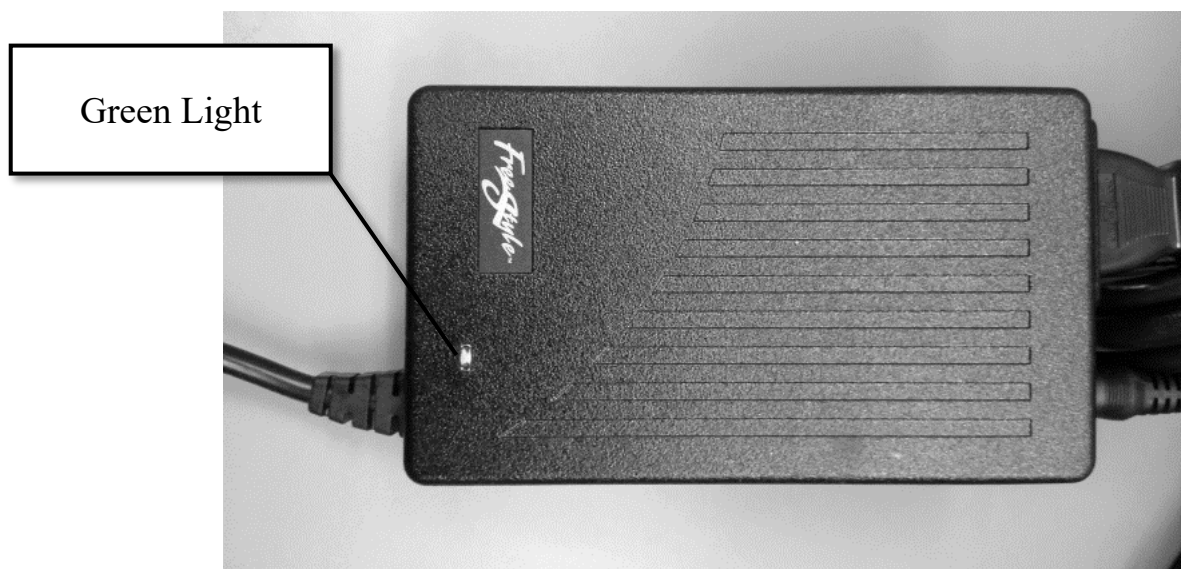


Figure 6.8: Green Light on Universal Power Supply

If the battery pack is in need of re-charge, the battery status indicator lights should blink accordingly to show charging.

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

FREESTYLE 5 AC & DC POWER SUPPLY

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

The FreeStyle 5 includes the following:

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



Figure 7: FreeStyle 5 DC and AC Power Supplies

AC POWER

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

needed any time AC power is available. The battery pack will recharge both if the unit is off or on and in use.

To connect the FreeStyle 5 to AC Power:

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



Figure 7.1: Connecting Power Supply to FreeStyle 5

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



Figure 7.2: Connecting AC Cable to Power Supply

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



Figure 7.3: Connecting Power Supply to AC Outlet

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



Green Light

Figure 7.4: Green Light on AC Power Supply

If the battery pack is in need of re-charge, the battery status indicator lights should blink accordingly to show charging (reference page xx for charging information).

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

DC POWER

DC power is for use in the accessory outlets of automobiles, boat, or other motor vehicles. The FreeStyle 5 is fully functional on DC power for use. The FreeStyle 5 will also recharge the battery pack if needed any time DC power is available. The battery pack will recharge both if the unit is off or on and in use.

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



Figure 7.5: Connecting Power Supply to FreeStyle 5

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



Figure 7.6: Insert DC Adapter to DC Outlet

Turn on your motor vehicle.

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

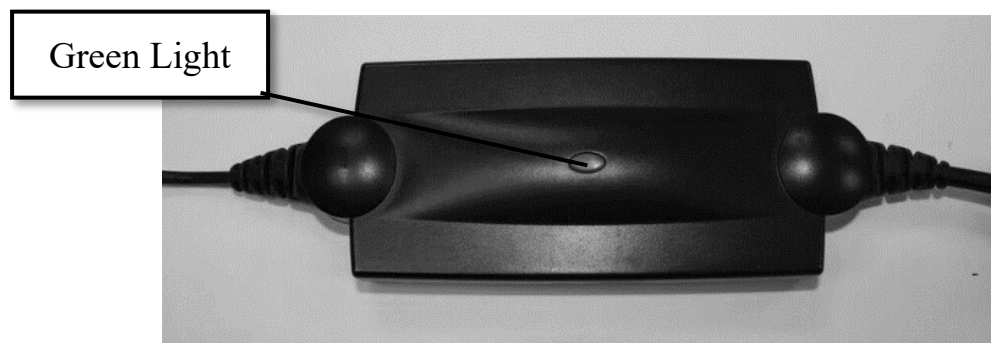


Figure 7.7: Green Light on AC Power Supply

If the battery pack is in need of re-charge, the battery status indicator lights should blink accordingly to show charging (reference page xx for charging information).

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

SHOWING PANEL BUTTONS, INDICATORS, AND ALARMS

Show your patient where each button is located on the POC Control Panel and how each button and indicator operates. Go over the alerts and alarms and how to handle alert and alarm conditions.

SELECTING THE PROPER FLOW SETTING

The recommendations of the qualified clinician responsible for the patient's care should always be followed when instructing patients on the use of Pulse Dose Mode.



Do not attempt to prescribe oxygen level settings. Warn your patient that only a qualified clinician or physician is to perform the necessary tests to prescribe treatment.

ACTIVE LIFESTYLE TRAINING




Small, lightweight, and easily moved about, the FreeStyle and FreeStyle 5 units are ideally suited to an active lifestyle. The AC and DC power supplies enable recharge of the battery during longer excursions. CAIRE recommends a nasal cannula with 7 ft (2.1 m) of tubing, CAIRE Part Number CU002-1, or 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.



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.






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

 NOTE	<p>Ensure the cannula is fully inserted and secure. This ensures that the unit can properly detect inspiration for oxygen delivery.</p>
 WARNING	<p><u>No Smoking or Open Flames.</u> For safety concerns, all possible sources of ignition must be kept away from the oxygen system and preferably out of the room in which it is being used. Smoking in the proximity of an operation oxygen concentrator is extremely dangerous and can permanently damage the device and void the warranty. Keep the POC at least five (5 ft) feet (1.5 m) from heat sources, sparking objects, or open flames.</p>
 CAUTION	<p>Always place oxygen supply tubing and power cords in a manner that prevents trip hazards or possible accidental strangulation.</p>

To train your patient on mobility and ambulation, follow the procedures below:

TRAVELING BY VEHICLE

Ask your patient whether he or she will be using the device to travel by vehicle. If so, show your patient how to safely use the POC while driving. Refer to the CONNECTING TO EXTERNAL POWER section of this manual for proper setup of the unit in a vehicle.

 NOTE	<p>Whenever possible, go to your patient's vehicle to demonstrate how to connect the unit to DC power.</p>
 CAUTION	<p>Be sure to accurately determine the amount of current the vehicle accessory outlet is rated to supply.</p>
 WARNING	<ul style="list-style-type: none"> • Avoid placing the FreeStyle or FreeStyle 5 in direct sunlight. • Do not store the unit in a vehicle where the device may be subject to extreme temperatures. Extreme heat or cold may impair operation and damage the device and degrade the battery. • When using the FreeStyle or FreeStyle 5 in a vehicle, check the cannula to make sure it is not pinched or occluded.

TRAVELING BY AIR

A new US Department of Transportation regulation regarding portable oxygen concentrators took effect on May 13, 2009. Under this regulation, every FAA approved portable concentrator is now authorized for use during any commercial flight that departs or arrives in the USA, regardless of whether the airline itself has approved the device or not.

If the airline allows use of the FreeStyle or FreeStyle 5, DO NOT use DC or AC Power Adapters on the aircraft. The patient must ensure that they have an adequate number of spare batteries to last for the duration of their trip.

During taxi, take-off and landing the unit must be turned off and stowed under the seat or in another approved stowage location as to not block the aisle way or the entry way into the row if the unit will not be used.

During taxi, take-off and landing the user must be in a seat location that does not restrict any other passenger's access to, or use of any required emergency or regular exit, or the aisle(s) in the passenger compartment of the aircraft if the unit is used.

Users are not permitted to be seated in an exit row if using the FreeStyle or FreeStyle 5.

If the FreeStyle or FreeStyle 5 is used when decompression of the cabin occurs, and the cabin oxygen system deploys, then the user is to discontinue use of the POC and use the aircraft supplemental oxygen. The FreeStyle or FreeStyle 5 unit is to be turned off after securing the aircraft supplemental oxygen.

Prior to travel, the user needs to inspect the unit to ensure that it is in good operational condition.

Visit our website, www.cairemedical.com, and look for the Travel Approved document on our *Respiratory Knowledge Center* for helpful travel tips.



Each airline has their own requirements and CAIRE recommends checking those requirements prior to making a trip.

TRAVELING BY CRUISE SHIP

When traveling by watercraft, instruct your patient to inform the cruise line that the FreeStyle or FreeStyle 5 will be used onboard. Each cruise line has a Special Needs coordinator that can answer any questions regarding travel and the cruise line's individual requirements. Have your patient contact the cruise ship Special Needs Coordinator directly.

TRAVELING BY TRAIN

When traveling by train, instruct your patient to inform the rail line in advance that the FreeStyle or FreeStyle 5 will be used onboard. Operate the unit only from the battery pack. The patient must ensure that they have an adequate number of spare batteries to last for the duration of their trip.

USAGE DURING SLEEP





CAIRE recommends that the FreeStyle or FreeStyle 5 be used while sleeping with the guidance of the prescribing clinician. In addition, some patients who mouth-breathe while asleep may benefit from the use of a chin strap.

ROUTINE MAINTENANCE BY THE PATIENT

To ensure accurate output and efficient operation of the unit, the patient must perform simple routine maintenance tasks:

- Clean the air intake / gross particle filter, cabinet, and power supplies weekly.

CLEANING THE AIR INTAKE / GROSS PARTICLE FILTER

 WARNING	Turn OFF the unit and disconnect the power cord from the electrical outlet before you clean the unit to prevent accidental electrical shock and burn hazard.
 WARNING	Remove the battery from the unit before performing any maintenance to prevent accidental electrical shock and burn hazard.
 WARNING	The FreeStyle or FreeStyle 5 must be off and disconnected from external power before removing the battery pack.
 NOTE	The patient must clean this filter weekly, as described below. The filter may require daily cleaning if the unit operates in a harsh environment, for example, a house heated by wood, kerosene, or oil, or one with excessive cigarette smoke.

1. The air intake / gross particle filter can be found on the lower front of the unit, as seen in the figure below.

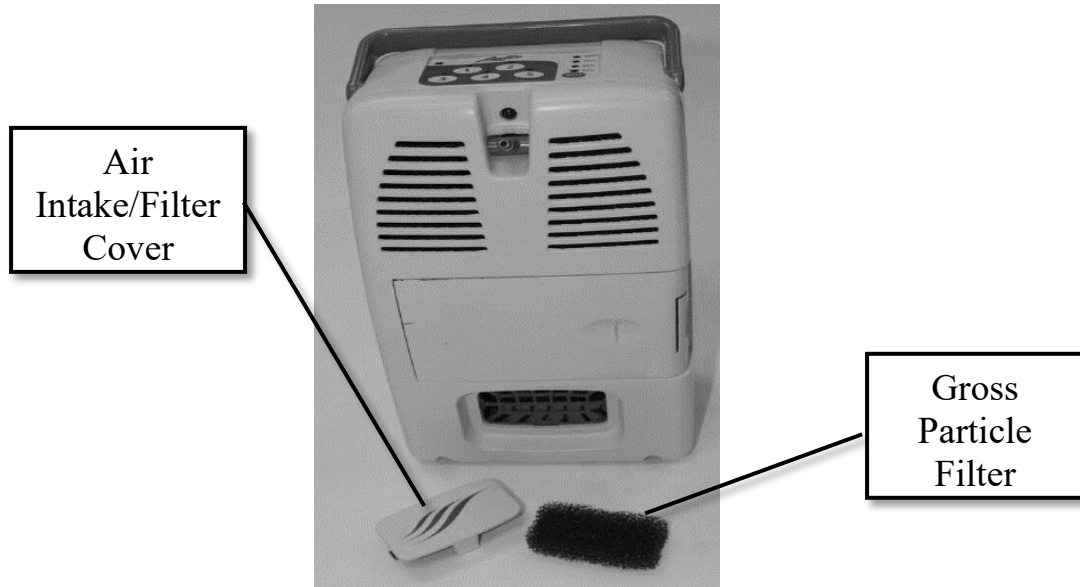




Figure 8: Air Intake and Gross Particle Filter

2. Power down the unit
3. Pull the filter cover off the front of the unit and remove the filter. Wash filter in a warm water and soap solution
4. Rinse the filter thoroughly, and remove excess water with a soft, absorbent towel. Ensure that the filter is dry before replacing it.
5. Replace the dry filter into the filter cover.
6. Place the filter cover back into the housing and gently push into place.

CLEANING THE CABINET AND POWER SUPPLIES

 WARNING	<p>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.</p>
 WARNING	<p>Remove the battery from the unit before performing any maintenance to prevent accidental electrical shock and burn hazard.</p>



The FreeStyle or FreeStyle 5 must be off and disconnected from external power before removing the battery pack.

1. Turn OFF the unit and disconnect it from AC or DC power before any cleaning or disinfection activity.
2. Remove the battery from the unit.
3. Use mild detergent and water solution.
4. Use a damp (not soaking wet) cloth or sponge.
5. Spray or wet the cloth or sponge with the mild detergent solution. DO NOT spray the cabinet, control panel, or power supplies.
6. Wipe down the cabinet, control panel, and power supplies.

CANNULA REPLACEMENT

Always follow the cannula manufacturer's instructions for proper use. Replace the nasal cannula or oxygen tubing as recommended by the cannula manufacturer or your oxygen provider. Your physician or oxygen provider will provide you with cleaning and replacement instructions.

Additional supplies for replacement are available through your oxygen provider.

PATIENT TRAINING CHECKLIST

Patient Name:		
Unit Serial #	AC/DC Power Supply Serial #	
Training Topic		Initials
Pre-Delivery Check List		
Indications for Use		
Contraindications		
Basic Concept Training		
Advise to read the User's Manual		
Go over all Accessories included with the Unit		
Safety Guidelines and Operational Safety Warnings/Cautions		
Locating the Unit		
Panel Buttons and Indicators		
Alerts and Alarms		
Selecting Flow Setting		
Connecting the AC Power Supply		
Connecting the DC Power Supply		
Active Lifestyle Training		
Operating the unit Battery power		

Use Around the House	
Traveling by Vehicle	
Traveling by Air	
Traveling by Boat	
Traveling by Train	
FreeStyle Maintenance	
Weekly: Clean the Air Inlet Gross Particle Filter	
Weekly: Clean the Cabinet, Control Panel, and Power Supplies	
Trained By:	





EQUIPMENT PROVIDER MAINTENANCE

NO SCHEDULED MAINTENANCE

FreeStyle and FreeStyle 5 units are maintenance-free due to their technologically advanced design. CAIRE does not require preventative maintenance or service on these concentrators as long as the concentrator remains within specifications. To ensure that the unit's output of oxygen is within specification, you must establish and implement a protocol to check oxygen concentration upon delivery to a patient and at periodic intervals (Reference OXYGEN CONCENTRATION TEST section of this manual).

AIR INTAKE / GROSS PARTICLE FILTER

The external air intake gross particle filter is located in the air intake/filter cover. You can easily remove it by hand. Instruct the patient to clean this filter weekly. (Reference CLEANING THE AIR INTAKE / GROSS PARTICLE FILTER section of this manual).

 NOTE	The filter may require more frequent cleaning if the unit operates in a harsh environment – a house heated by wood, kerosene, or oil, or one with excessive cooking or cigarette smoke.
 WARNING	Turn OFF the unit and disconnect the power cord from the electrical outlet before you clean the unit to prevent accidental electrical shock and burn hazard.
 WARNING	Remove the battery from the unit before performing any maintenance to prevent accidental electrical shock and burn hazard.
 WARNING	The FreeStyle or FreeStyle 5 must be off and disconnected from external power before removing the battery pack.

PRODUCT FILTER REPLACEMENT

The product filter is designed to last the life of the unit. If it is determined that the product filter needs to be replaced, follow the instructions below:

1. Turn unit off and disconnect the power cord.
2. Remove the back housing, and locate the product filter/volume tank. See figure below.
3. Disconnect tubing from the inlet of the product filter/volume tank.
4. Unscrew the product filter/volume tank from the product manifold
5. Place the o-ring into the o-ring groove located on top of the volume tank.
6. Fasten the new product filter/volume tank to the product manifold.
7. Connect the tubing and secure with a tie-wrap.

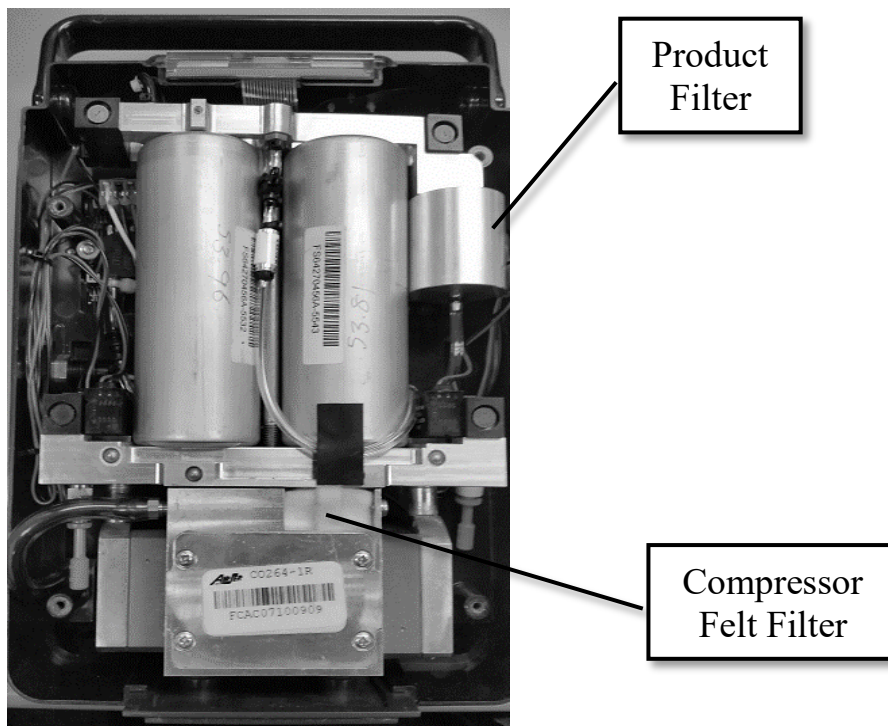


Figure 9: Product Filter






NOTE


If the compressor inlet felt filter (shown above) is contaminated, a replacement felt filter can be ordered by contacting CAIRE and referencing Part Number FI143-2

CLEANING AND PREPARING FOR NEW PATIENT USE

When you remove the FreeStyle or FreeStyle 5 from a patient's home, always detach and dispose of the used nasal cannula. Clean the exterior of the unit 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. Be careful not to get any liquid into the interior of the unit.



Next, clean the exterior with a common chemical disinfectant before any other patient uses the unit. Do not use liquid directly on the unit to clean it.

	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.
	Remove the battery from the unit before performing any maintenance to prevent accidental electrical shock and burn hazard.
	The FreeStyle or FreeStyle 5 must be off and disconnected from external power before removing the battery pack.

	Do not use liquid directly on the FreeStyle or FreeStyle 5 unit to clean it. A list of undesirable chemical agents includes but is not limited to the following, according to the plastics manufacturer: alcohol and alcohol-based products, concentrated chlorine-based products (ethylene chloride), and oil-based products (Pine-Sol, Lestoil). These are NOT to be used to clean the plastic housing on the FreeStyle or FreeStyle 5, they can damage the units' plastic.
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Clean or replace the air intake / gross particle filter with warm soapy water between each patients use. The patients should be instructed to clean this filter at least once per week, depending on the environment, during normal operation.

Allow the unit to air dry. Then re-test oxygen concentration, test the duration of the battery pack, and ensure the AC and DC power supplies are in good working condition before you return the unit to your inventory.

 NOTE	Make the bleach solution a 1:100 dilution of 5.25% sodium hypochlorite. Mix one part household bleach (e.g., Clorox with 99 parts cold tap water). To measure the solution easily, take 1/4 cup of household bleach, and mix it with a gallon of cold tap water. Allow the mixture to sit on potentially contaminated surfaces for ten minutes.
 NOTE	CAIRE does not recommend the sterilization of this equipment.

RECORDING MAINTENANCE

Whenever maintenance or service is performed on a unit, an entry should be made in the service log for that concentrator or recorded in accordance with your company's standard procedure.

[illegible]

SERVICE

TOOLS FOR FREESTYLE AND FREESTYLE 5 SERVICE AND MAINTENANCE

In addition to a pressure test gauge, the following tools are generally readily available for purchase in your local area, and can assist you in servicing and maintaining the FreeStyle or FreeStyle 5 unit.

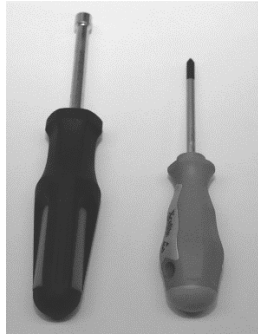


Figure 11.1:
.25in hexnut screwdriver and
Phillips-head screwdriver



Figure 11.2:
5/32-in allen-based driver

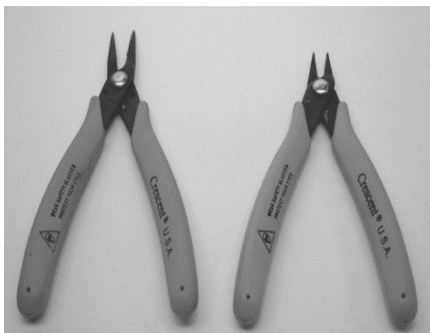


Figure 11.3:
Needle-nose pliers and side cutters



Figure 11.4:
Tie-wrap gun

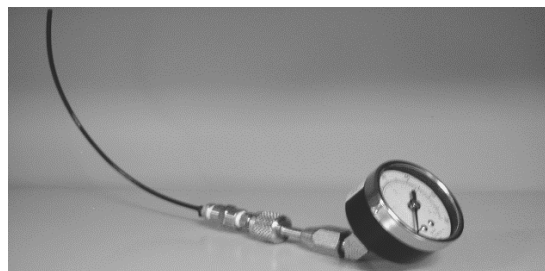







Figure 11.5: Pressure Test Gauge

COMPONENTS

The design of CAIRE's FreeStyle and FreeStyle 5 Portable Oxygen Concentrators allows for easy access and removal of most components. This allows you to perform scheduled maintenance and to repair and replace parts with minimal time and effort.

 CAUTION	<p>For your safety, be sure to disconnect the unit from the AC/DC power outlet before you service the concentrator.</p>
 WARNING	<p>Remove the battery from the unit before performing any maintenance to prevent accidental electrical shock and burn hazard.</p>
 WARNING	<p>The FreeStyle or FreeStyle 5 must be off and disconnected from external power before removing the battery pack.</p>
 NOTE	<p>Note all scheduled maintenance. See EQUIPMENT PROVIDER MAINTENANCE section.</p>

HOUSING REMOVAL

 WARNING	<p>Turn OFF the unit, remove the battery, and disconnect the power cord from the electrical outlet before servicing to prevent accidental electrical shock and burn hazard.</p>
---	---

Removing Front Cover:

1. Place the unit on its back and position the outlet nozzle upwards facing forward.
2. Locate the three screws securing the front cover (top center, lower left, and lower right).
3. Using a Philips-head screwdriver, loosen and remove the screws.
4. Lift off the front cover.



Figure 12.1: Removing Front Cover

Removing Back Cover:

1. Place the unit on its front.
2. Locate the four screws securing the back cover.
3. Using a Philips-head screwdriver, loosen and remove the screws.
4. Lift off the back cover.



Figure 12.2: Removing Back Cover

PSA REMOVAL



Turn OFF the unit, remove the battery, and disconnect the power cord from the electrical outlet before servicing to prevent accidental electrical shock and burn hazard.

1. Disconnect the unit from the AC or DC outlet.
2. Remove the battery.
3. Remove the front housing.
4. Disconnect the 8-pin connector (J5 for FreeStyle or J17 for FreeStyle 5) with multi-colored wires from the circuit board. Care must be taken not to pull on the wires.

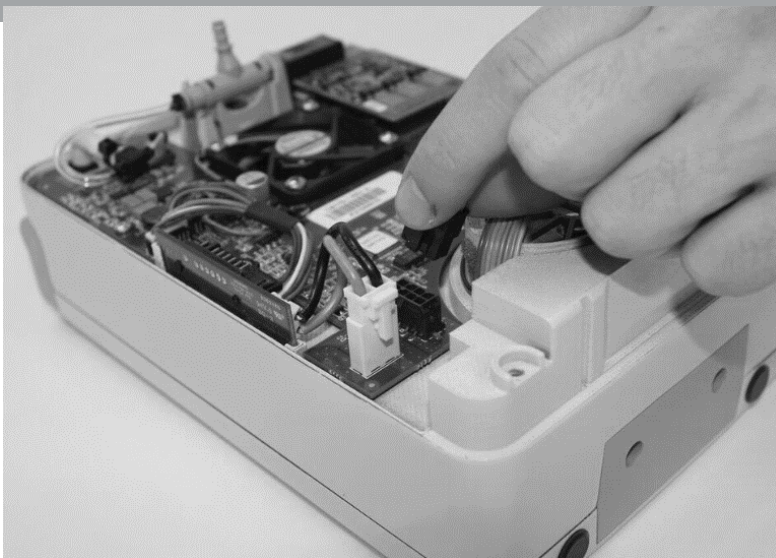


Figure 13.1: J5 8-Pin Connector

5. Remove and discard foam from the top of the oval opening. (See Figure 13.2)

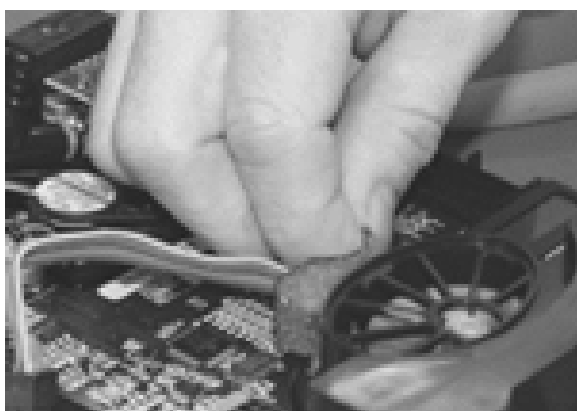


Figure 13.2: Foam Removal



Steps 6 and 7 require extreme caution to ensure the black pressure sensor (U3 for FreeStyle or U9 for FreeStyle 5) is not damaged.

6. Remove the adjustable nozzle by gently pulling it upward until it comes out of the left side retaining clips. When the left side is out, pull the nozzle to the left to completely remove it from its cradle.

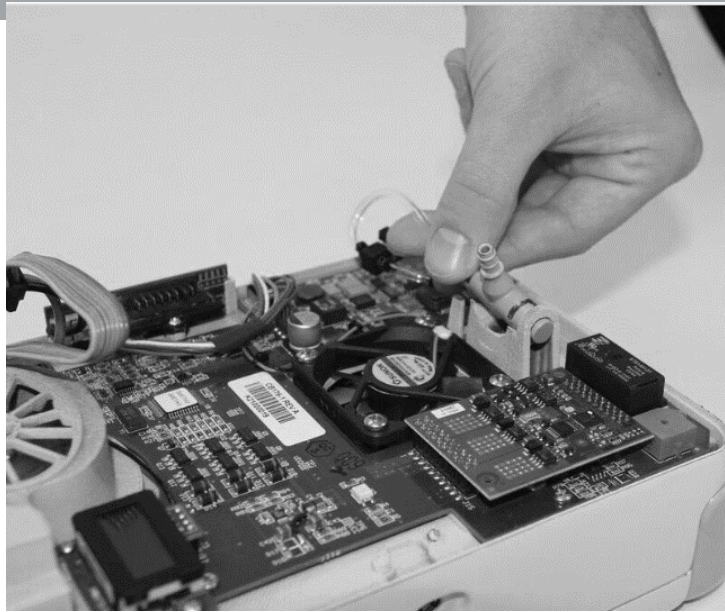


Figure 13.3: Nozzle Removal

7. Carefully disconnect the 1/8" OD tubing coming from the back of the unit to the limiting orifice.

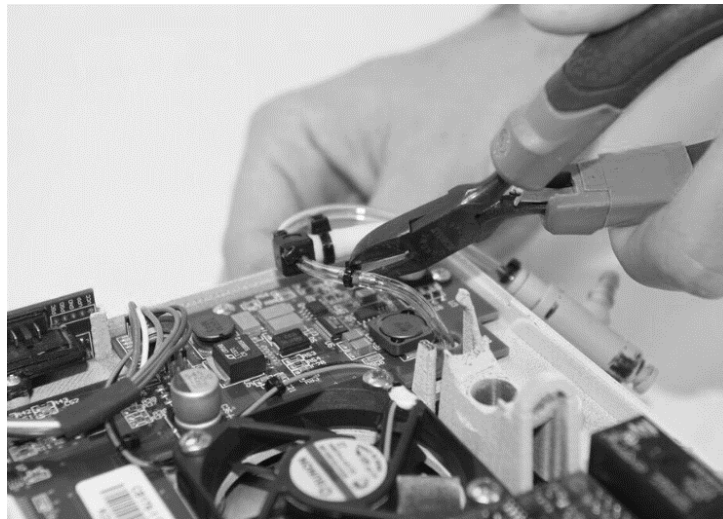


Figure 13.4: Disconnecting Black Tubing

8. Remove the 8-32 x 1/4" Philips screws located in the center of the outlet nozzle cradle.

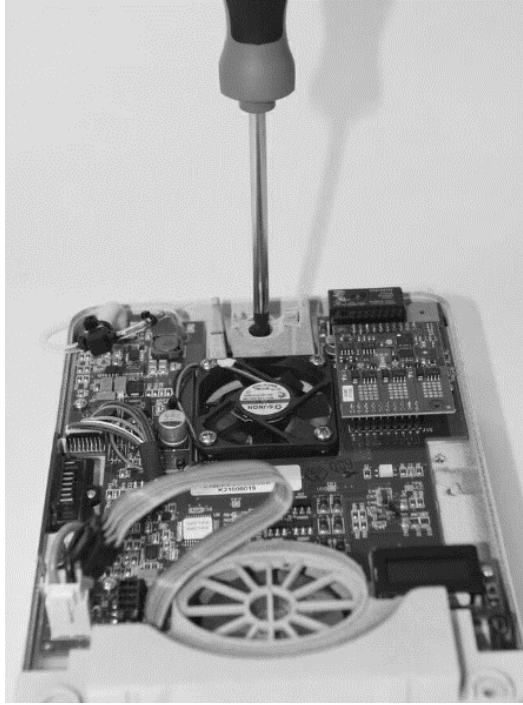


Figure 13.5: Outlet Nozzle Cradle Screw Removal

9. Turn the unit over and remove the back housing.
10. Disconnect the ground wire (connected to the compressor on its upper right side near the air inlet filter) using a Philips screwdriver.

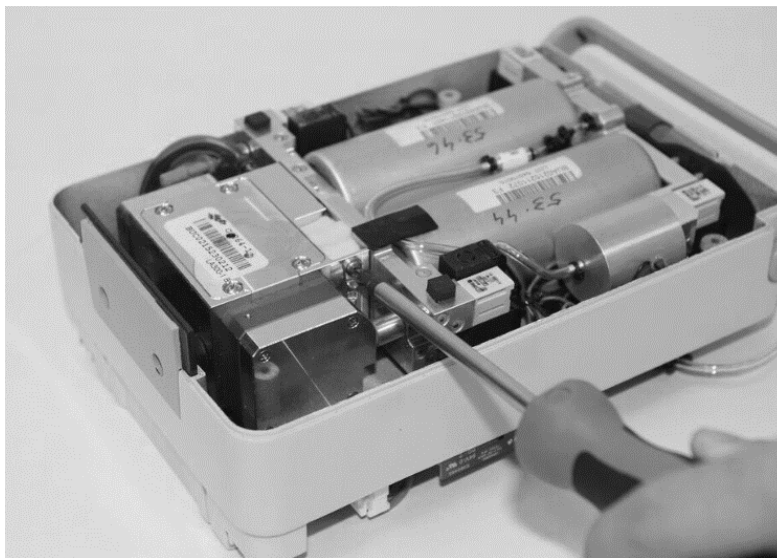


Figure 13.6: Disconnecting Ground Wire

11. Disconnect the 1/8" OD tube from the Y-Connector, or T-Connector, that connects to the pressure transducer on the left side (located at the back of the PSA System).
12. For the FreeStyle, remove each tie-wrap around the upper top screw bosses.

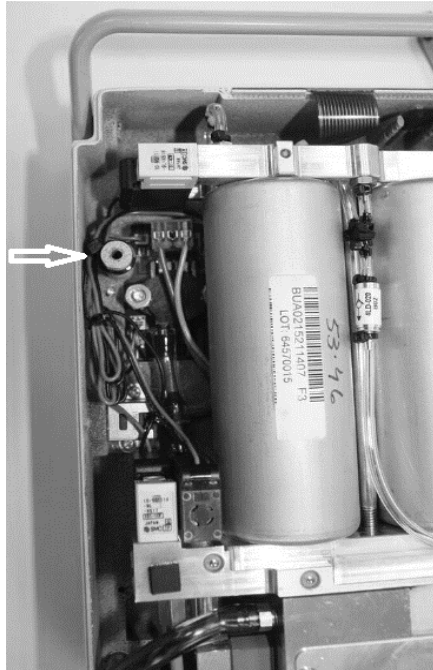


Figure 13.7: Tie-wrap Removal

13. Using needle-nose pliers, disconnect all of the valves from the circuit board, carefully noting where each valve is connected. Do not disconnect by pulling on the wires.

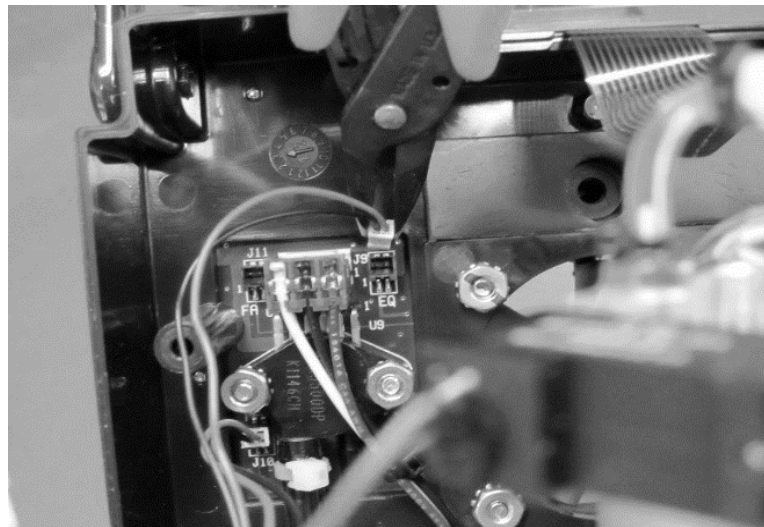


Figure 13.8: Disconnecting the Equalization Valve

14. Carefully remove the complete PSA assembly from the center housing by pulling it upwards and slipping the compressor Molex connector through the center section.

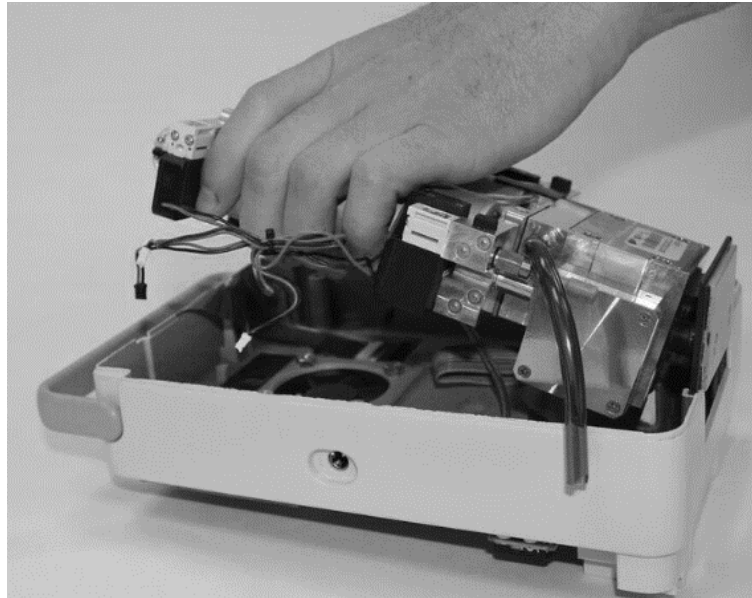


Figure 13.9: Removing the PSA Assembly

15. Remove the compressor plate by removing the two screws.

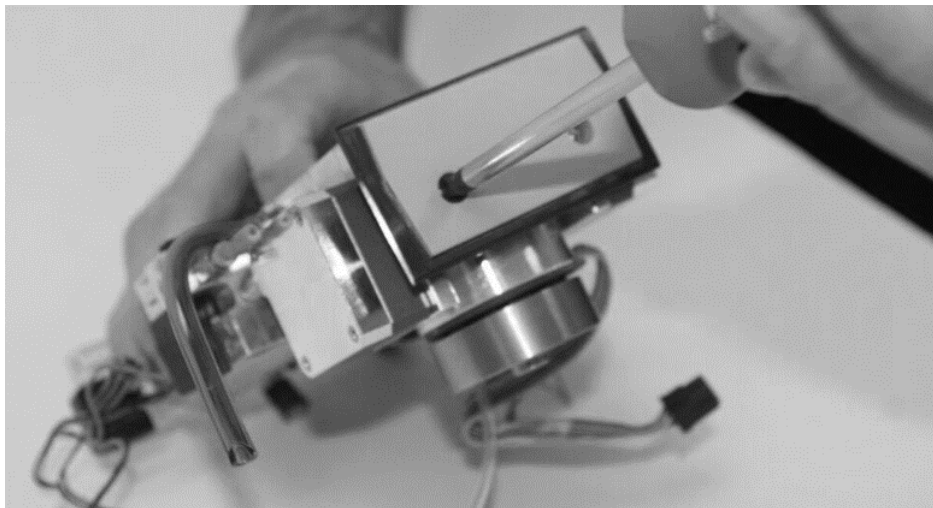


Figure 13.10: Compressor Plate

16. Remove the two mounts from the compressor.

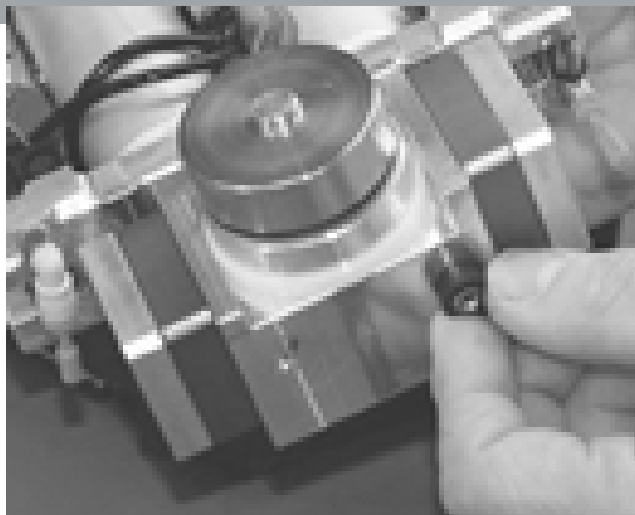


Figure 13.11: Compressor Mounts

COMPRESSOR REPLACEMENT

The compressor is the “pump” within the oxygen concentrator that pushes room air into the bottom of the sieve beds. Over time, the cup seals may wear and the compressor will not operate properly. To replace the compressor, follow the steps below:

1. Remove the PSA assembly per the PSA REMOVAL section in this manual.
2. Stand the PSA assembly upright and loosen the center bolt using a 5/32” Allen wrench.

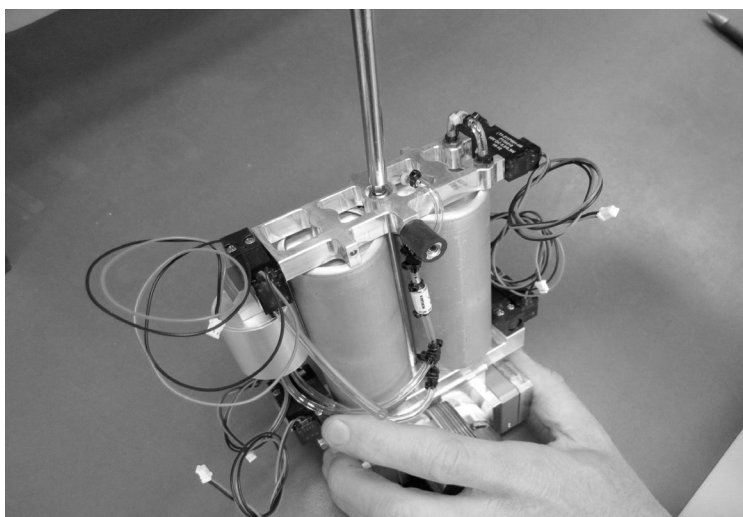


Figure 14.1: Center Bolt of PSA Assembly

3. Remove the compressor by pulling the compressor away from the PSA assembly. Care should be taken not to separate the manifold from the beds.

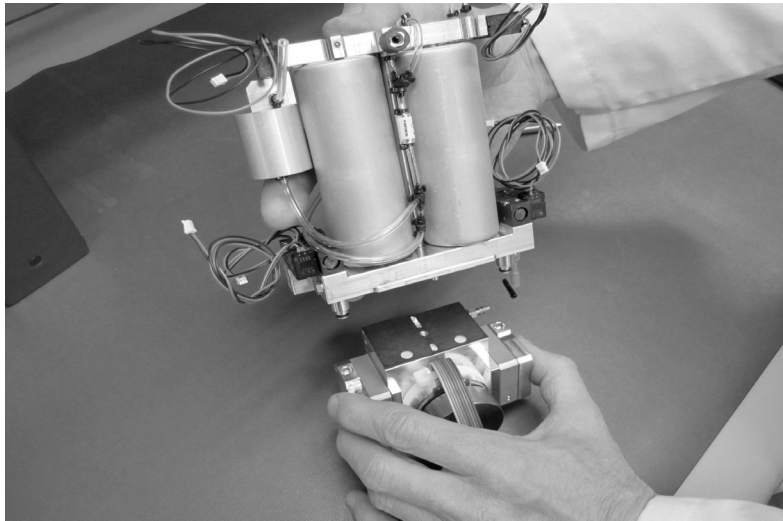


Figure 14.2: Removing the Compressor

4. If either of the two fittings connecting the compressor to the manifold is connected to the compressor, remove it and insert it back into the manifold.

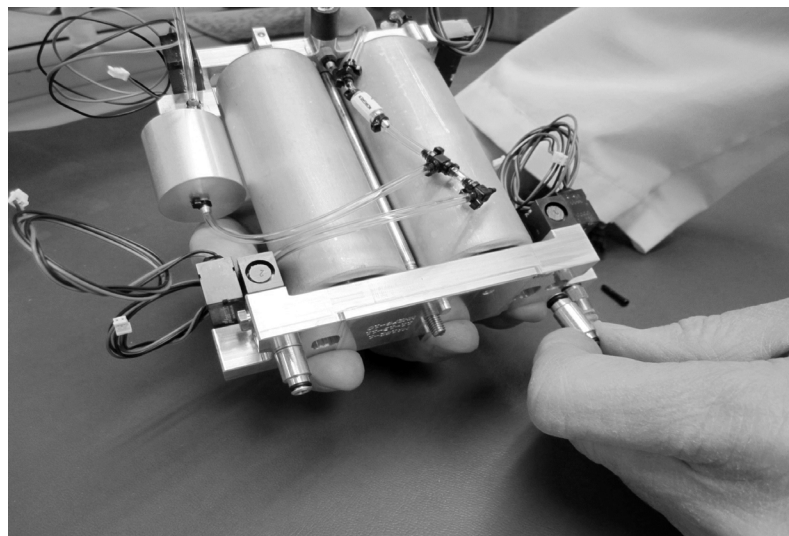


Figure 14.3: Compressor to Manifold Fittings

5. Connect the new compressor to the PSA assembly, and tighten the bolt to a torque of 15 in-lbs.

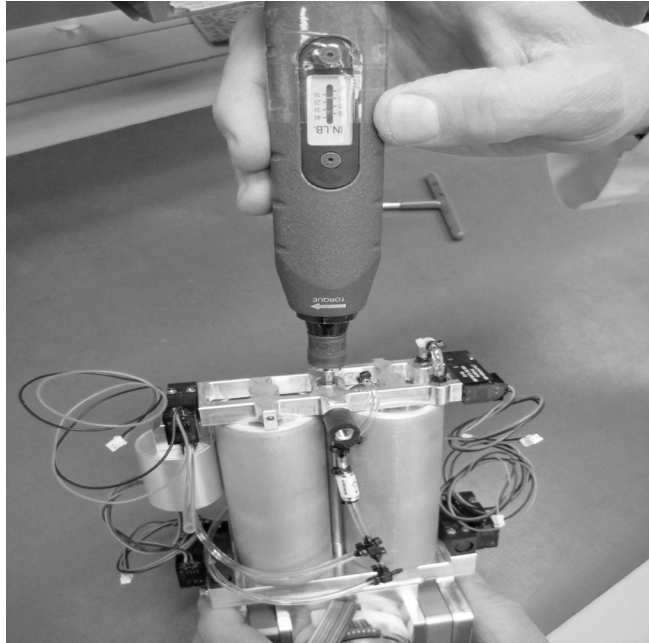


Figure 14.4: Tightening Center Bolt

COMPRESSOR ASSEMBLY INSTALLATION

To install the new compressor assembly, perform the compressor removal procedure in reverse order.



After replacing the unit's compressor, you must reset the hour meter. For a FreeStyle, please reference the HOUR METER FUNCTIONALITY section of this manual. If replacing the compressor on a FreeStyle 5, you must refer to the instructions for reading and recording hours in the Hour Meter Kit - Part Number KI406-1.

PRODUCT MANIFOLD REPLACEMENT

1. Remove the PSA system per the PSA REMOVAL section in this manual.
2. Disconnect the tubing assembly from the barb(s) on the product manifold, mixing tank, and one end of the purge tube.

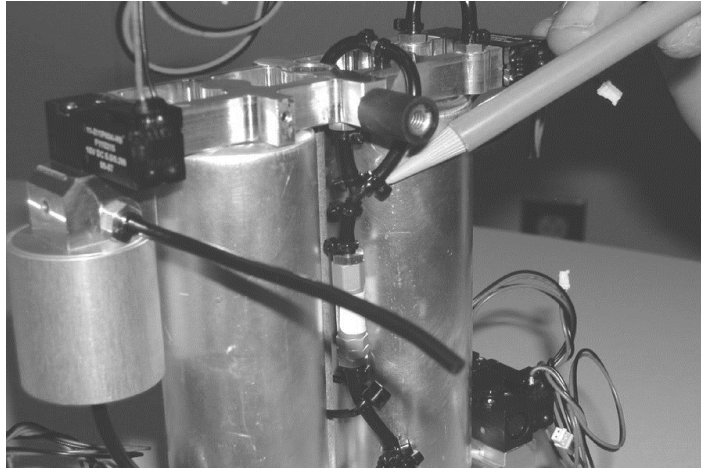


Figure 15.1: Manifold Tubing



Figure 15.2: Mixing Tank Tubing



Figure 15.3: Purge Tubing

3. Remove the tie wraps that bundle the solenoid valve wires together.
4. Loosen and remove the center bolt from the PSA assembly using a 5/32" Allen wrench.

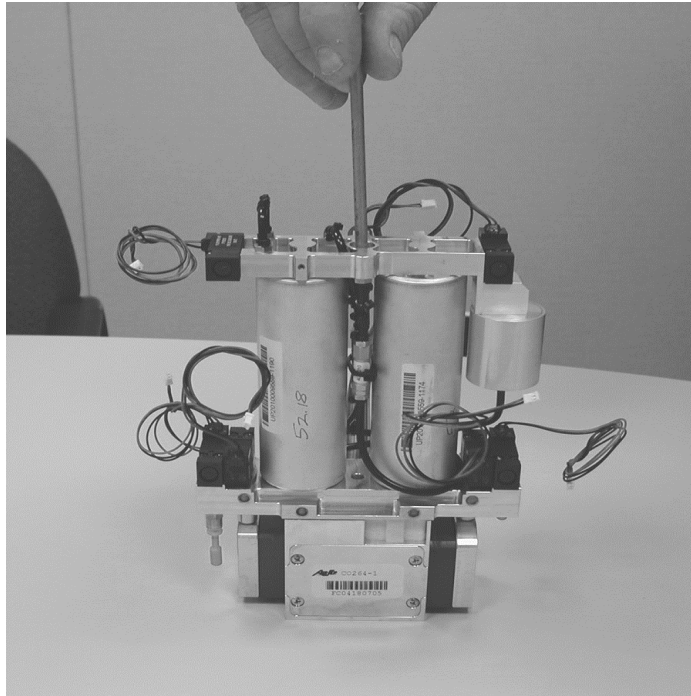


Figure 15.4: Center Bolt Removal

5. Holding the sieve beds in place, gently pull upward on the product manifold to remove. Keep tubing assembly in place.
6. Align the new product manifold with the outlet of the sieve beds, and gently push the manifold down into place.
7. Reconnect the tubing assembly to the new product manifold.
8. Place center bolt through the product manifold and tighten to 15 in-lbs.

SOLENOID VALVE REPLACEMENT



Turn OFF the unit, remove the battery, and disconnect the power cord from the electrical outlet before servicing to prevent accidental electrical shock and burn hazard.



It may not be necessary to completely remove the PSA system assembly to replace the solenoid valve(s). The Feed B/Waste B and OCD valve will require the PSA system to be partially removed.

1. Remove the back cover panel.
2. Determine which valve needs to be replaced. (Reference the PRESSURE PROFILE and TROUBLESHOOTING sections of this manual for more information)
3. Remove the tie wraps that bundle the valve wires.
4. Carefully disconnect the Molex connector from the circuit board by pulling on the Molex connector, not the valve wires.
5. Using a small Philips screwdriver, remove the two screws fastening the valve.
6. Remove the valve.
7. Fasten the new valve using the two screws provided.
8. Re-bundle wires and tie-wrap.
9. Start the unit and leak test around the area where the gasket is located on the valve.

SIEVE BED REPLACEMENT

1. Remove the PSA system assembly per the PSA REMOVAL section in this manual.
2. Loosen and remove the center bolt from the PSA assembly using a 5/32" Allen wrench.
3. While holding the adsorbent beds, gently pull up on the product manifold to remove it.

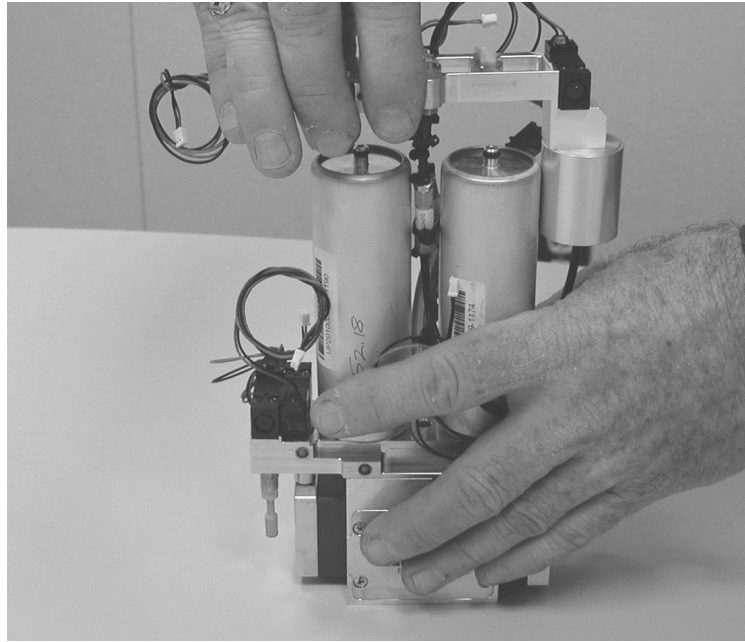


Figure 16.1: Product Manifold Removal

4. Pull upward on the adsorbent beds to remove them from the feed/waste manifold.

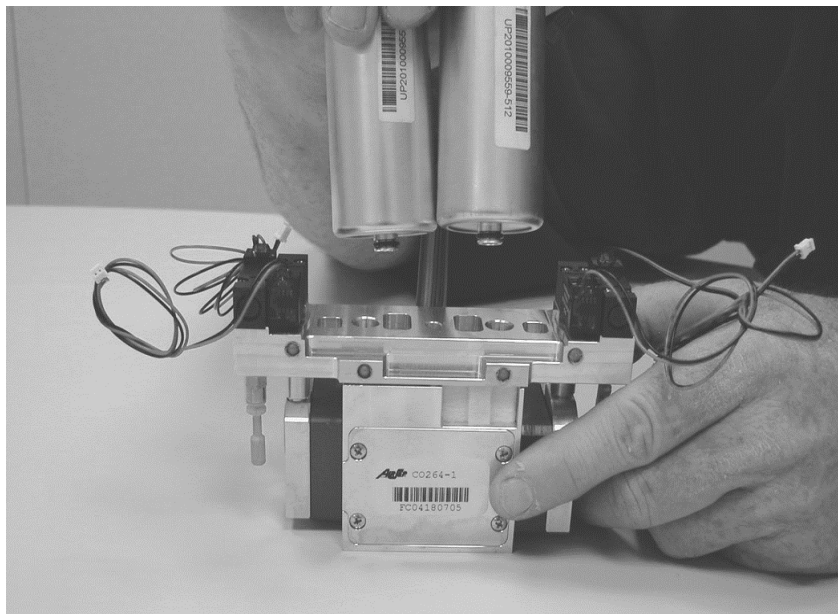


Figure 16.2: Sieve Bed Removal

5. Remove the plugs from the top and bottom of the new adsorbent beds.
6. Place a 1.5mm CS X 6mm ID o-ring on the bottom cap of the adsorbent bed cap.

7. Place a 1.5mm CS X 3.5mm ID o-ring on the top cap of the adsorbent beds.
8. Align the product manifold with the outlet on the new adsorbent beds and gently push down until the o-rings are completely seated.

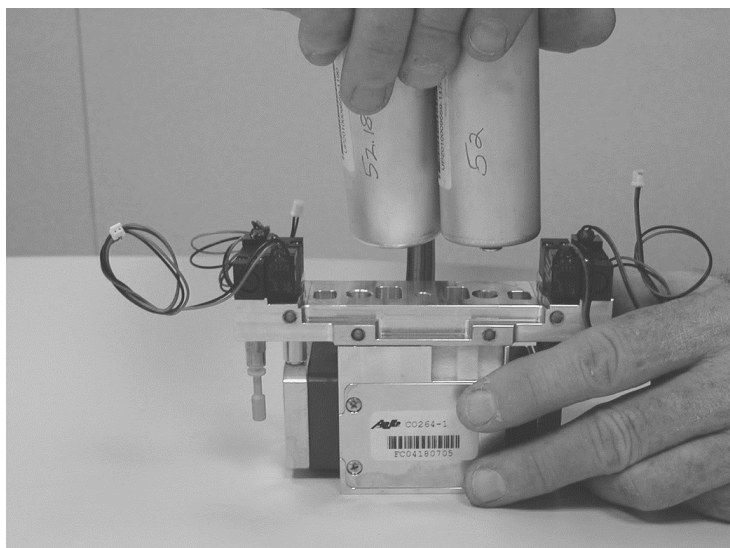


Figure 16.3: Attaching New Sieve Beds

9. Connect the product manifold to the sieve beds and place the center bolt through the product manifold then tighten to 15 in-lbs.

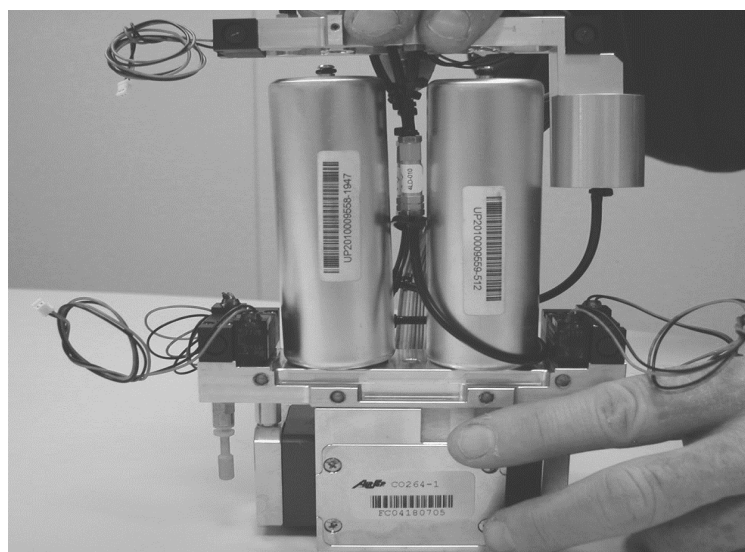


Figure 16.4: Attaching Product Manifold

10. Reassemble the unit and leak test at the sieve bed connections.

FEED/WASTE MANIFOLD REPLACEMENT

1. Remove the PSA system assembly per the PSA REMOVAL section in this manual.
2. Carefully remove the tie wraps that bundle the solenoid valve wires together.
3. Loosen and remove the center bolt from the PSA assembly using a 5/32" Allen wrench.
4. Holding both sieve beds, gently pull upwards, removing the product manifold and sieve beds. Set the product manifold and sieve bed assembly aside, keeping the top of the sieve beds connected to the product manifold.

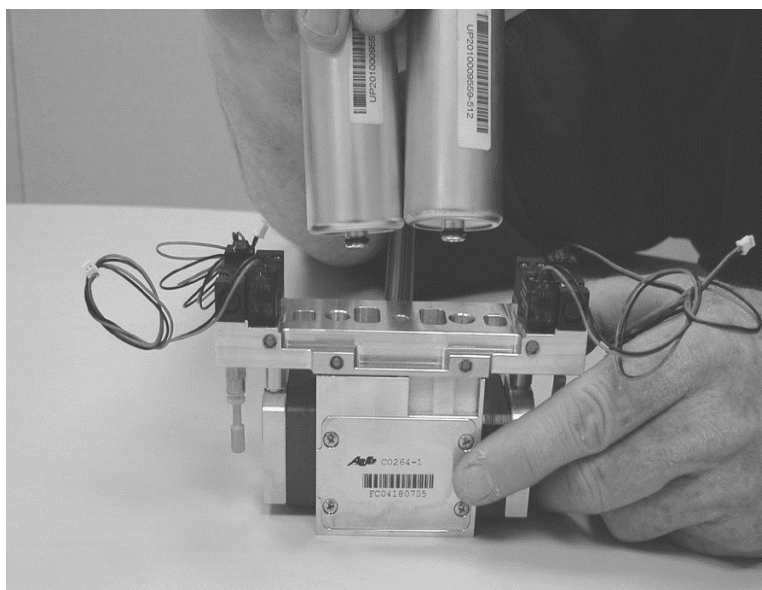


Figure 17.1: Removing the Feed/Waste Manifold

5. Remove the feed/waste manifold by pulling upward on the manifold. Both fittings from the manifold to the compressor should still be connected to the manifold. If not, remove the fitting(s) from the compressor.

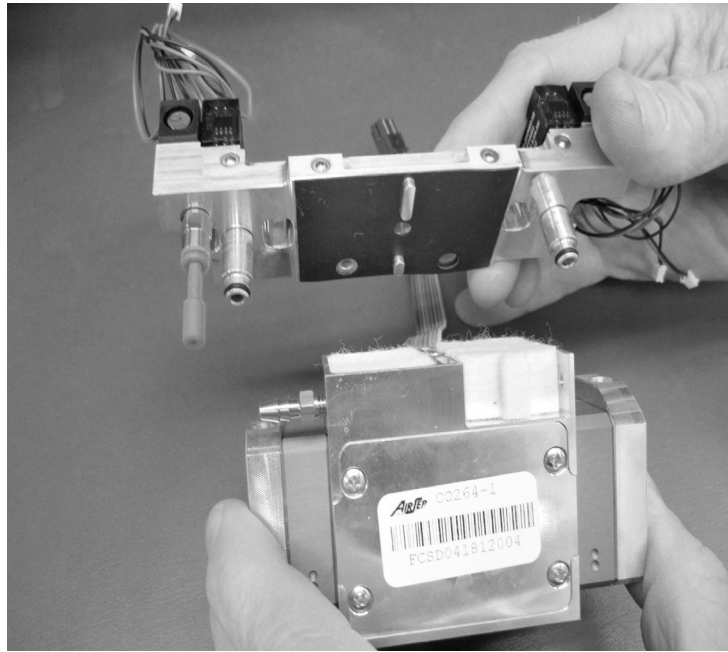


Figure 17.2: Feed/Waste Manifold with Fittings

6. Place the new feed/waste manifold onto the compressor. Gently push the manifold down until the compressor fittings are seated into the compressor head.

MEASURING THE SYSTEM PRESSURE

1. Remove the back cover.
2. Locate the brass fitting with the orange plug on the left side of the feed/waste manifold.
3. Remove the plug.

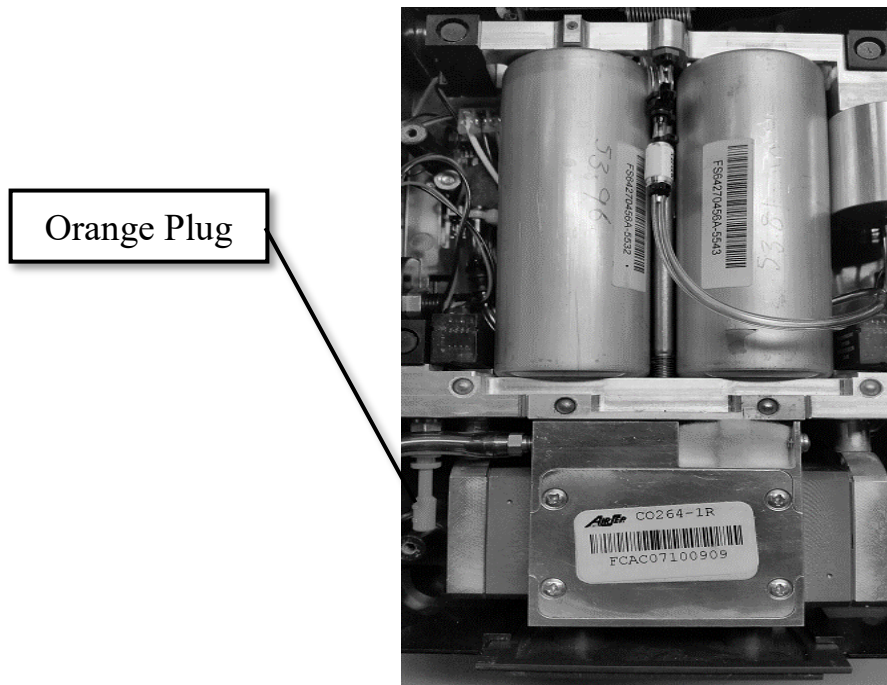


Figure 18: Pressure Test Port

4. Using the pressure gauge with 1/8" OD tubing, push tube into the fitting.
5. Turn the unit on by pressing the [2] setting.
6. Make sure that the connections from the pressure gauge to the manifold are leak free.
 - i. Part No. KI036-1 Pressure Test Kit (gauge and connector) and KI340-1 Adaptor
7. Put the unit into test mode (Press the [1] and [3] settings simultaneously for ten seconds if the unit is a FreeStyle. Press the [1] and [5] settings simultaneously for ten seconds if the unit is a FreeStyle 5). Once the alarm sounds, the LED's above each flow setting will illuminate. The unit will then start to automatically pulse. Reference the PRESSURE PROFILES section of this manual for the pressure swing process.

PRESSURE PROFILES

The following pressure profiles illustrate the range of normal operating pressures at sea level. These are approximate pressures. A unit may be out of the range shown below and still be within specification, for example, in higher altitude environments.

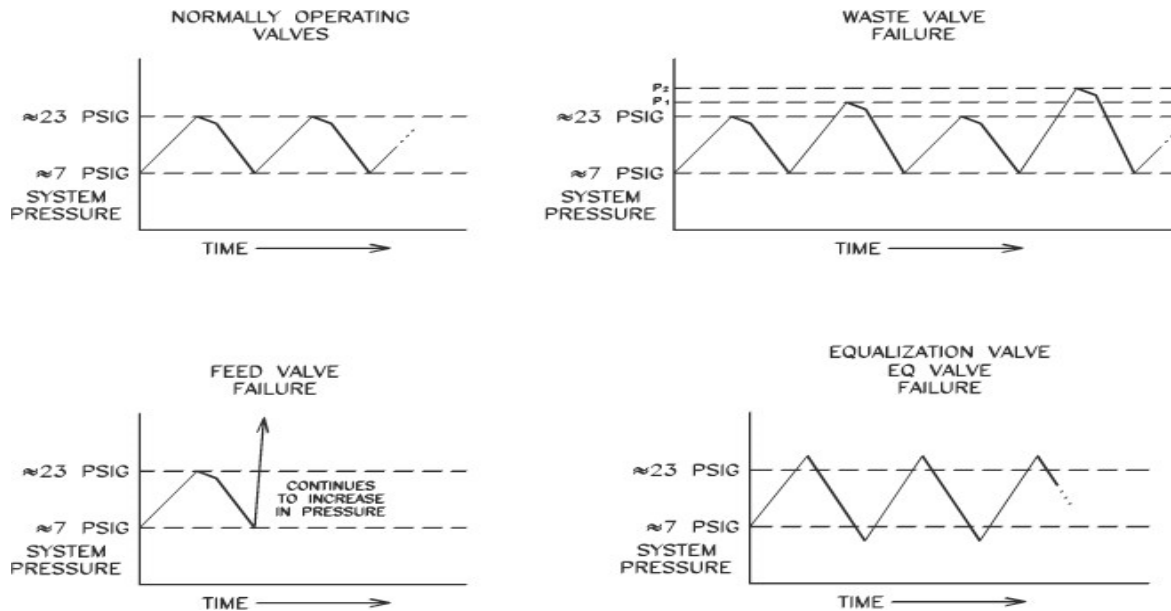


Figure 19.1: Pressure Profile Quadrant for FreeStyle

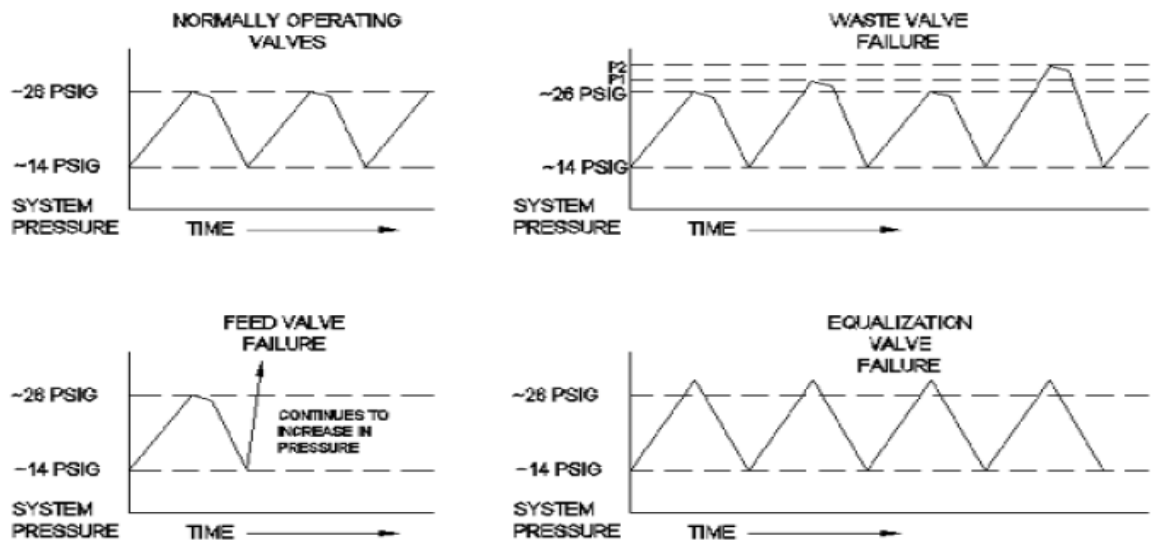


Figure 19.2: Pressure Profile Quadrant for FreeStyle 5

FREESTYLE HOUR METER

General Information

The FreeStyle's hour meter includes two monitoring channels: a historical channel that cannot be reset, and a maintenance channel. An onboard, momentary-action pushbutton can be used to toggle the display between the two channels. The historical channel is generally used to monitor total operating hours over the life of the FreeStyle unit, while maintenance channel provides the hours logged between service intervals. While displaying the maintenance channel, the switch can be used to reset the accumulated maintenance hours to zero.

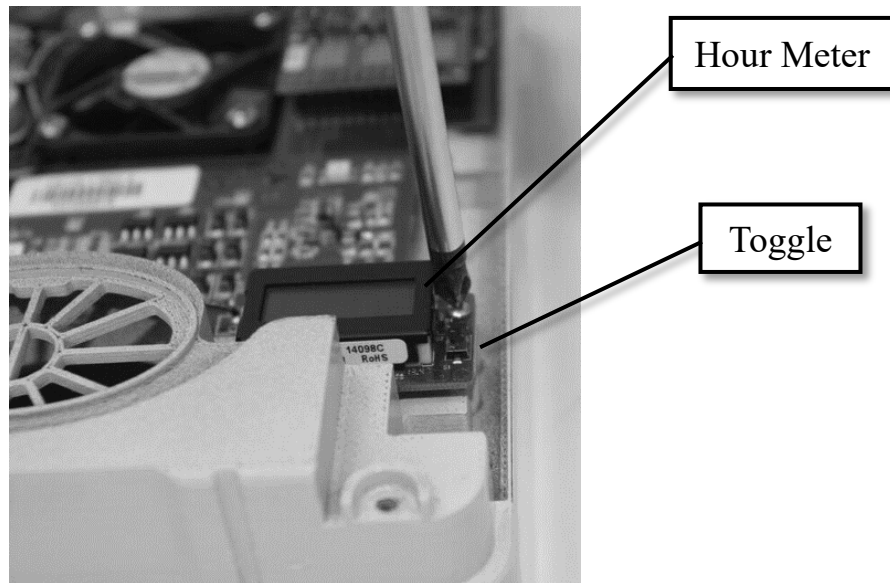


Figure 20: Hour Meter



NOTE

The FreeStyle 5 does not have an hour meter on the circuit board. Please reference the FREESTYLE 5 HOUR METER FUNCTIONALITY section for more information.

Hour Meter Icons

Two LCD icons are used to indicate each mode. In historical mode, an “hour-glass” is displayed to indicate hours. While enabled, the hour-glass will illuminate intermittently. In maintenance mode, both a “TMR1” symbol and an hour-glass are displayed.

Power

When the FreeStyle is connected to AC or DC power, the historical hour meter reading is displayed along with the hour-glass icon.

When the FreeStyle is connected to AC or DC power supply, the hour count is displayed, but the time does not accumulate. When the FreeStyle compressor is started when the unit is turned on,


the historical hour meter will function. The hour-glass icon will flash to indicate that time is being accumulated.

Toggle/Reset Switch

This switch (showing in Figure 20) toggles the display or resets the maintenance channel depending on the activation time and the current display mode.

Upon power-up, the display defaults to the historical display mode. The display will remain in historical mode until the pushbutton is used to toggle the display into maintenance mode. The hour meter will remain in this mode until toggled or until power is removed. The hour-glass icon will remain on and the “TMR1” icon will be displayed below the hour-glass icon. As with the historical display mode, the hour-glass icon will flash to indicate that time is being accumulated and the TMR1 icon will remain on solid. The historical channel cannot be reset. To reset the maintenance channel, begin with the module in maintenance mode, and then press the toggle/reset switch for five seconds. A reset is indicated by a “0” display.

HOURLY METER REPLACEMENT FOR FREESTYLE ONLY

	<p>When removing the front cover to replace the hour meter on a FreeStyle, always use an ESD safe-work area. Also, use an ESD wrist strap to protect electronic circuitry.</p>
--	--

1. Remove the front cover housing per the HOUSING REMOVAL section of this manual.
2. Ensure that all power sources are disconnected.
3. Locate the hour meter (shown in Figure 20).
4. Using a small Philips head screw driver, remove the 2 screws.
5. Gently pull upward to remove the hour meter from the 8-pin connector (J3). When removing, take care not to bend or break any pins on the J3 connection header.
6. Replace hour meter.

FREESTYLE 5 HOUR METER FUNCTIONALITY

The Freestyle 5 logs the hours of use on the internal circuit board. An interface kit can be purchased that allows you to retrieve this hour reading. The Hour Meter Kit can be ordered through CAIRE Customer Service (1-800-482-2473) by using PN KI406-1.

The Hour Meter Kit software allows you to read the total number of hours for the unit as well as the ability to access a resettable hour counter for service purposes. This can be used to keep records as to when a component, such as the compressor, was last replaced. The software also allows you to easily reset the second hour meter by selecting the "Clear" button.

The FreeStyle 5 does not have an "hour meter" like the FreeStyle, but the unit itself will display the number of hours that it has been in operation on the flow display LEDs. The procedure to enter "Time Reading Mode" is listed below:

1. Turn the FreeStyle 5 on and wait until the startup tone is complete.
2. Press and hold the 1 and 3 buttons for three seconds to enter the Time Reading Mode. Once in this mode, all 5 LEDs will light up and the unit will beep.
3. After the unit has entered this mode, the hours will be displayed in the following manner:
 1. Flow Setting LED 1 will display the digit in the ones place.
 2. Flow Setting LED 2 will display the digit in the tens place.
 3. Flow Setting LED 3 will display the digit in the hundreds place.
 4. Flow Setting LED 4 will display the digit in the thousands place.

MOTOR CONTROLLER BOARD REPLACEMENT



When replacing the motor controller circuit board, always use an ESD safe-work area. Also, use an ESD wrist strap to protect electronic circuitry.

1. Remove the front cover housing per the HOUSING REMOVAL section of this manual.
2. Ensure that all power sources are disconnected.
3. Lift the motor controller board from the circuit board, being careful not to break the connector pins while gently rocking it back and forth to loosen and disconnect.

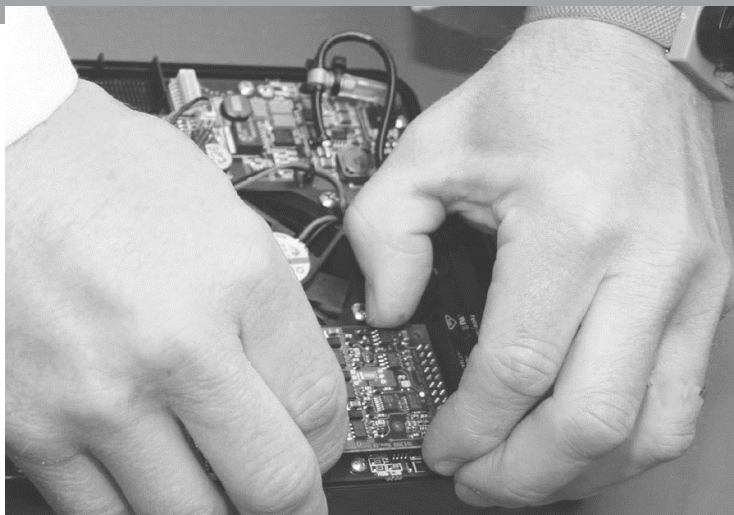


Figure 21.1: Removing Motor Controller Board

4. Before replacing the board, ensure that the main circuit board and all pins are straight and unbroken (intact).
5. Locate the composite side marked “top”, or the side with the single row connector, and properly align the connections.

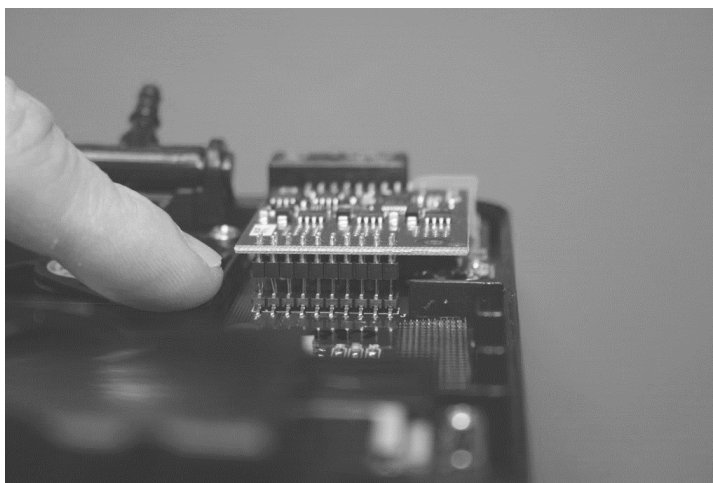




Figure 21.2: Aligning Pins to the Connection

6. View the replacement board from the side and at an angle to make certain that the pins are aligned properly before seating the connector.
7. When the replacement board is properly aligned, gently press the board into place until properly seated.

CIRCUIT BOARD REPLACEMENT

 WARNING	Turn OFF the unit, remove the battery, and disconnect the power cord from the electrical outlet before servicing to prevent accidental electrical shock and burn hazard.
 CAUTION	When replacing the circuit board, always use an ESD safe-work area. Also, use an ESD wrist strap to protect electronic circuitry.

1. Remove the front and back covers per the HOUSING REMOVAL section of this manual.
2. Remove the inlet screen.
3. Remove the PSA system per the PSA REMOVAL section of this manual.
4. Remove the DC power input connector from the J11 (for FreeStyle) or J13 (for FreeStyle 5) location on the circuit board.

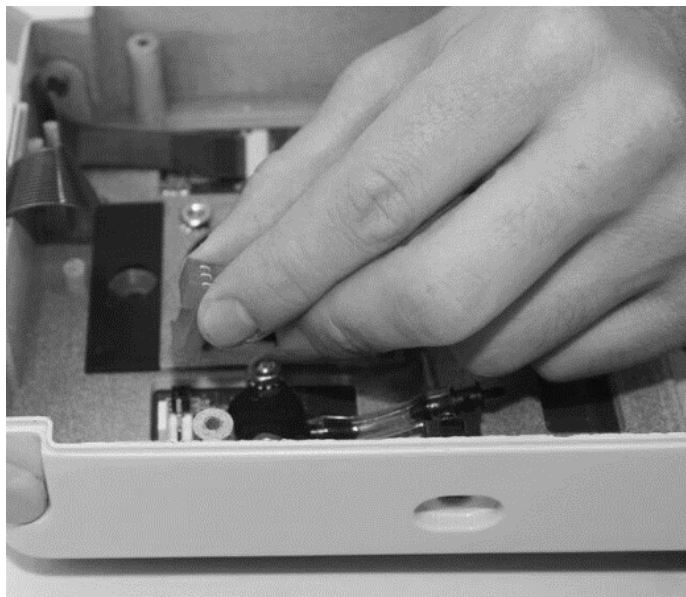


Figure 22.1: J11 Connection

5. Disconnect the control panel/keypad flex circuit from the Ziff (zero insertion force) connector by carefully lifting upward on the locking tab. This connection is J8 for the FreeStyle and J9/J10 for the FreeStyle 5.

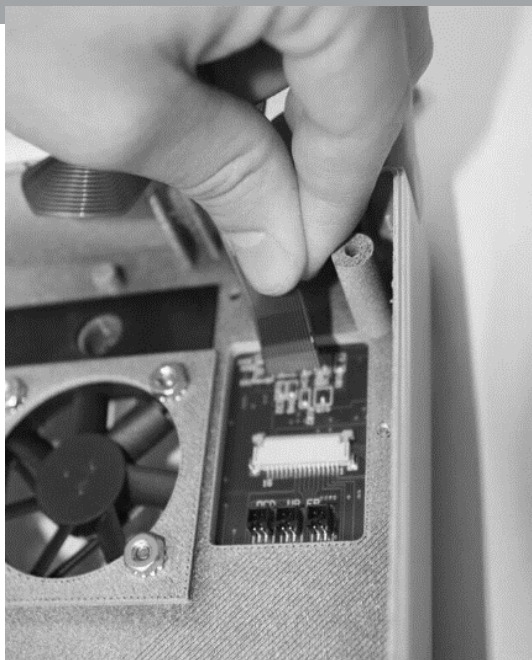


Figure 22.2: Disconnecting Flex Circuit

6. Turn the unit over so that the main circuit board is facing upwards.
7. Remove the motor controller board per the MOTOR CONTROLLER BOARD REPLACEMENT section of this manual.
8. If replacing the circuit board on a FreeStyle, remove the hour meter per the HOUR METER REPLACEMENT section of this manual.
9. Remove the cannula nozzle tuning by cutting the tie wrap (use small-size cutter). Carefully pull the tubing from the nozzle barb.

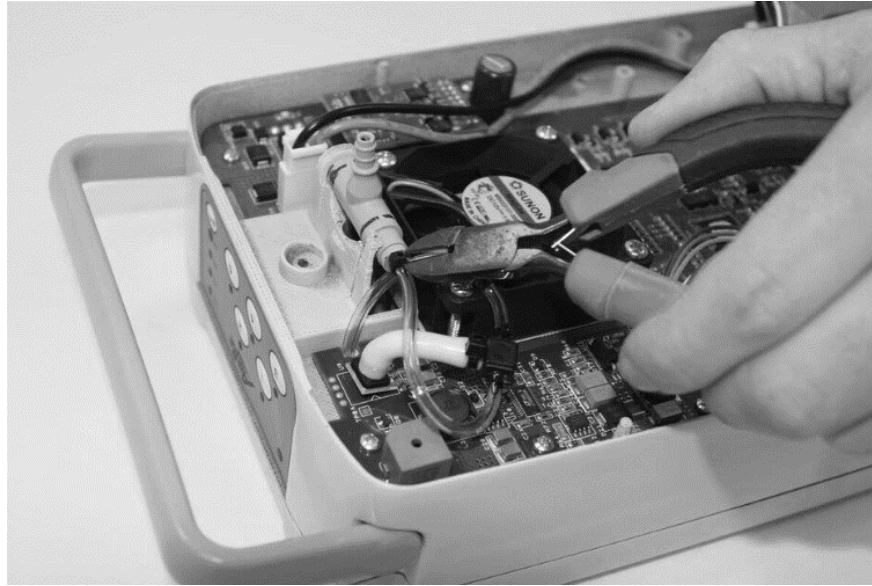


Figure 22.3: Cannula Nozzle Tubing

10. Disconnect the fan wire from the main circuit board by using needle-nose pliers and carefully pulling upwards on the connector housing on the main circuit board. Connection J6 for the FreeStyle or connection J15 for the FreeStyle 5.
11. Remove the 4-20 self-tapping screws from the main circuit board. There are 6 screws on the FreeStyle and 8 screws on the FreeStyle 5.

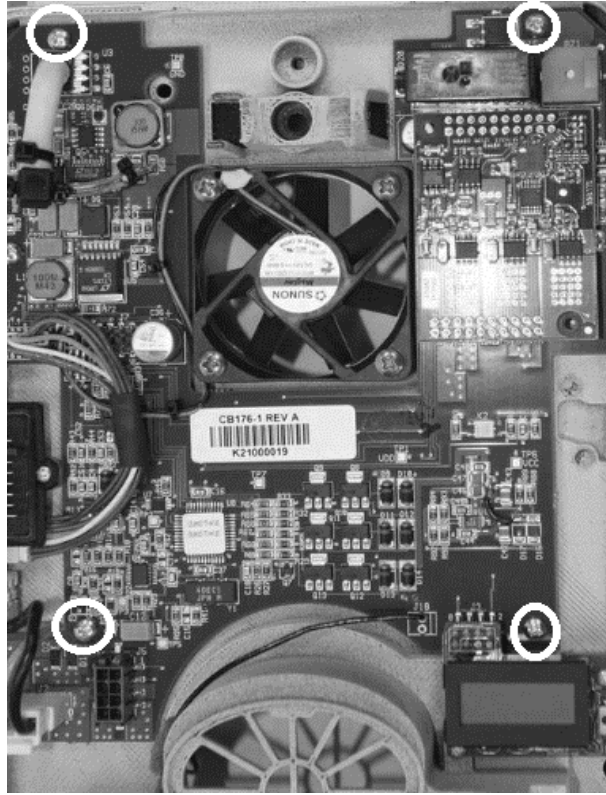


Figure 22.4: Self-Tapping Screws

12. Remove the main circuit board from the center section assembly.

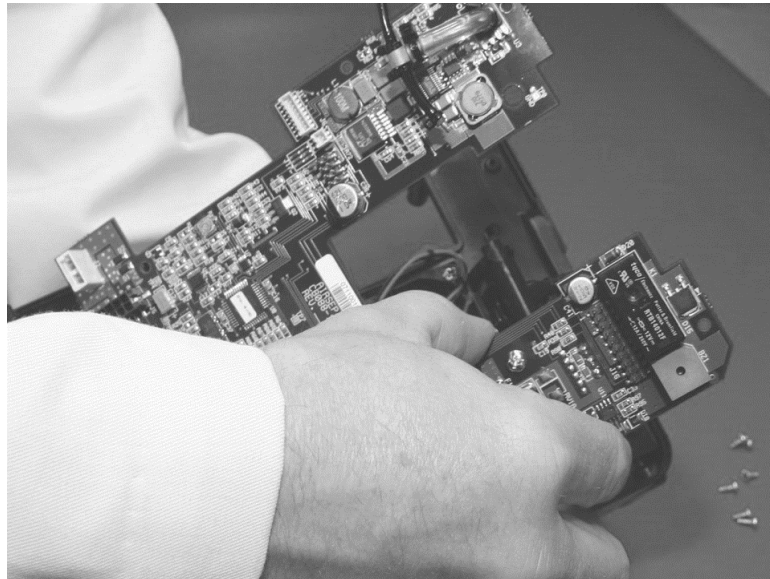


Figure 22.5: Main Circuit Board Removal

13. Replace the main circuit board; reverse order of steps 1-13 of this section.

CONTROL PANEL / KEY PAD REPLACEMENT

When replacing the control panel/key pad, always use an ESD safe-work area. Also, use an ESD wrist strap to protect electronic circuitry.

1. Remove the front and rear cover per the HOUSING REMOVAL section of this manual.
2. Remove the PSA system per the PSA REMOVAL section of this manual.
3. Remove the control panel/keypad flex circuit from the Ziff (zero insertion force) connector by carefully lifting upward on the locking tabs. This is connection J8 for the FreeStyle and connection J9/J10 for the FreeStyle 5.
4. Remove the flex tab circuit from the rib guides, and peel off the control panel/keypad from the center enclosure.
5. Replace control panel/keypad with the new control panel / keypad.
6. Check recessed area of enclosure center section to ensure that the plastic is clean.
7. Remove the adhesive backing and seal backing from the new control panel/key pad.

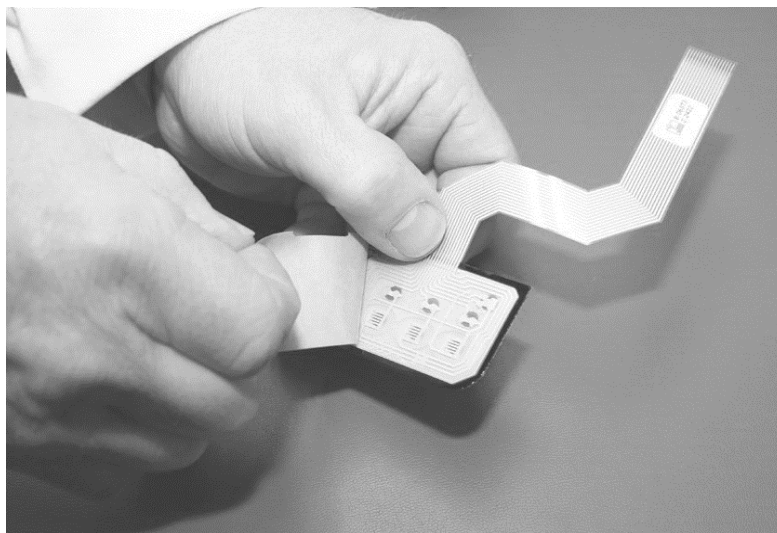


Figure 23.1: New Control Panel

8. Carefully align the new control panel/keypad with the recessed control panel area, and press the control panel/keypad evenly to ensure that all adhesive is in contact with the plastic surface.



Figure 23.2: Adhering New Control Panel

9. Route the flex circuit through the control panel/keypad slot.

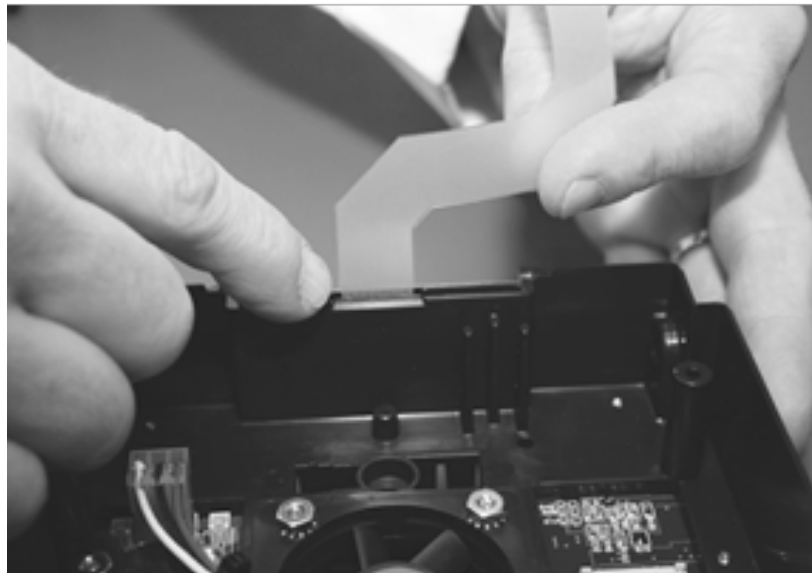


Figure 23.3: Control Panel Flex Circuit Slot

10. Bend the flex circuit 180 degrees, being careful not to crease or fold the flex circuit.



If creased or folded, the flex circuit will be damaged.

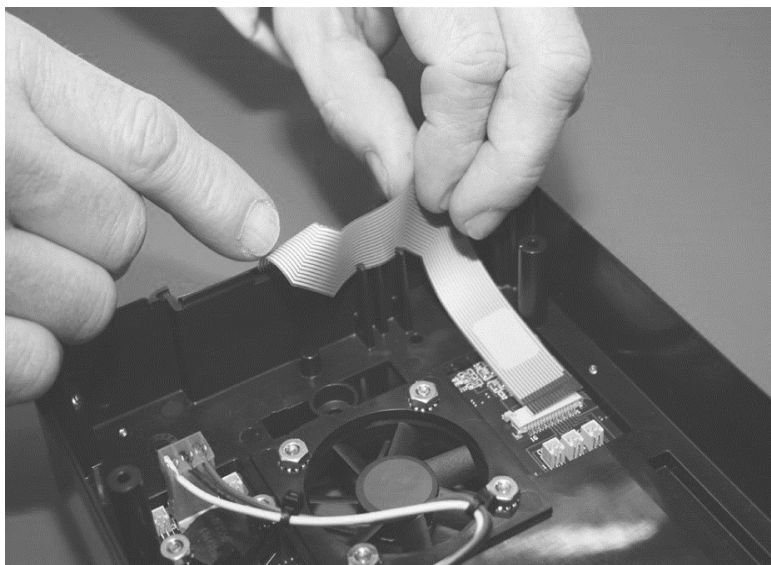


Figure 23.4: Bending the Flex Circuit

11. Insert the flex circuit into the rib section and connect the flex circuit with carbon contacts facing toward you.
12. Insert into Ziff (zero force insertion) connector(s), making sure that the flex circuit seats into the connector. Carefully press the Ziff connector locking tab in a downward direction. Ensure that the latch is seated properly.

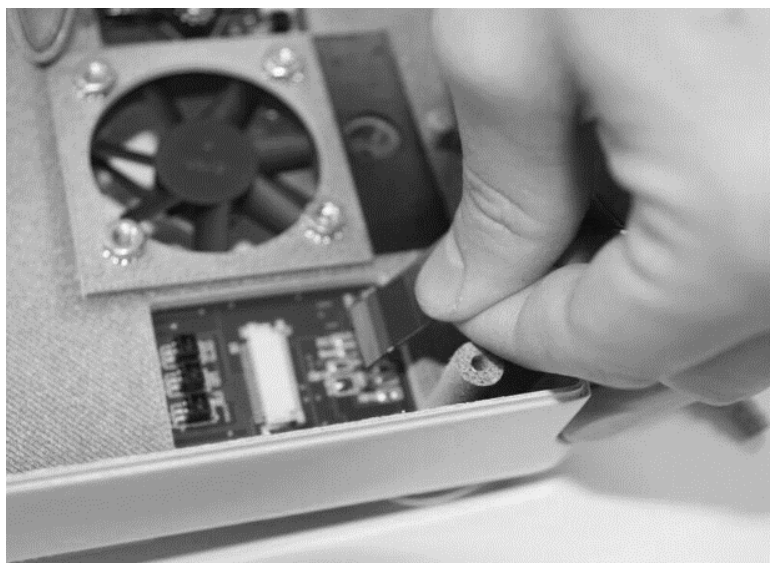


Figure 23.5: Connecting the Flex Circuit

13. Re-install the PSA system and housing, and ensure that the control panel functions properly.

FAN REPLACEMENT



When replacing the fan, always use an ESD safe-work area. Also, use an ESD wrist strap to protect electronic circuitry.

1. Remove the PSA system per the PSA REMOVAL section of this manual.
2. Disconnect the Molex connector from the circuit board to the fan.

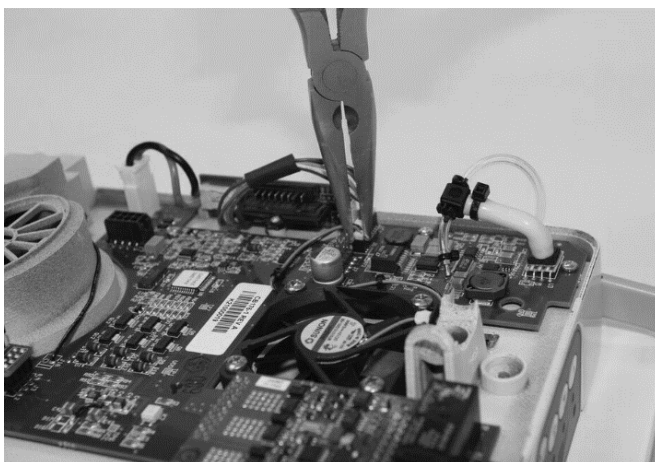


Figure 24.1: Fan Molex Connection

3. Remove the four Philips head screws that secure the fan to the center section.

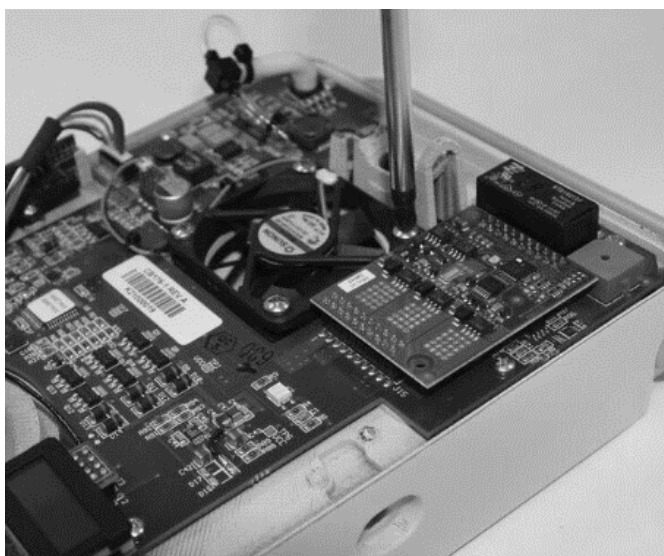


Figure 24.2: Fan Screw Removal

4. When installing a new fan, be sure the arrow on the side of the fan is pointing outwards toward the front cover. This arrow indicates the direction of the airflow of the fan. For the FreeStyle, ensure the two wires coming from the fan are located on the upper left side. For the FreeStyle 5, ensure the two wires coming from the fan are located on the upper right side.

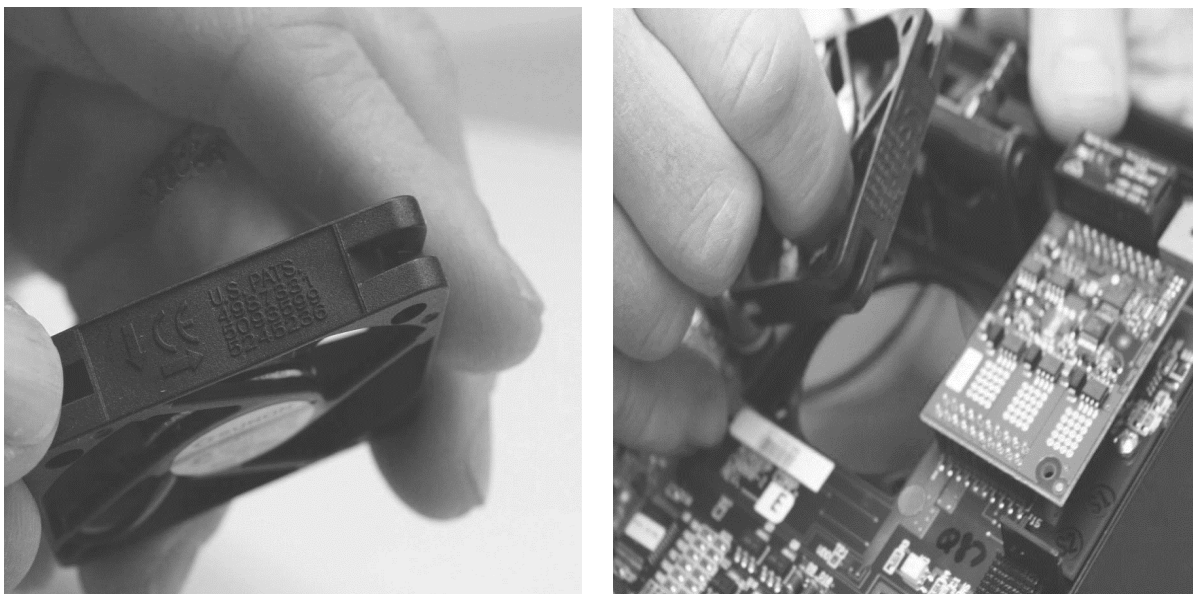


Figure 24.3: Replacing the Fan

5. Insert the four screws through each of the four corners of the fan. Secure with nut. **DO NOT OVER TIGHTEN.**
6. Connect the Molex connector from the fan to the circuit board.

TROUBLESHOOTING

GENERAL TROUBLESHOOTING

Before reviewing the Troubleshooting Chart, the following steps may be useful to isolate any malfunctions:

1. Make sure all filters are clean.
2. Turn the unit on by pressing flow setting [2] if a FreeStyle, or flow setting [3] if a FreeStyle 5. A brief, continuous alarm sounds to indicate that the unit has been turned on. Allow the compressor to start-up and run for approximately ten seconds.
3. If a FreeStyle, activate the test mode by pressing flow settings [1] and [3] simultaneously for ten seconds. If a FreeStyle 5, activate the test mode by pressing flow settings [1] and [5] simultaneously for ten seconds.
4. Make sure that the unit is leak-free by testing all tubing connections and fittings with leak-testing solution. Protect the circuit board from the solution, and start the leak test at the compressor, following the air flow of the unit to the oxygen outlet. Repair all leaks by tightening connections and fittings.
5. After five minutes, measure the oxygen concentration.

Review the Troubleshooting Chart that follows to isolate and repair a malfunction:

Problem	Probable Cause	Solution
FreeStyle does not operate when a pulse flow selection button is pressed.	<p>Battery is discharged.</p> <p>Malfunction.</p>	<p>Power the unit through the DC outlet, or an AC outlet.</p> <p>Contact your Equipment Provider, and change to another source of oxygen as necessary.</p>
A continuous alarm sounds and the (red) alarm light illuminates continuously.	FreeStyle has not detected a breath for 15 minutes.	<p>Check the cannula connection.</p> <p>Ensure that cannula tubing is not kinked.</p> <p>Make sure that the cannula is positioned properly and that you are breathing through your nose. For mouth-breathing your clinician may recommend a chin strap.</p>
Intermittent alarm condition, and the (yellow) BATT light illuminates intermittently.	Battery requires charging.	Connect to a DC or an AC outlet within 2 minutes, or exchange battery packs for a fully charged pack.

Rapid alarm condition, and the (yellow) BATT light illuminates intermittently and FreeStyle shuts down.	Battery pack charge is too low to operate the FreeStyle unit.	Connect to DC or an AC outlet immediately.
Intermittent alarm condition, and the (red) alarm light illuminates intermittently.	Breathing rate has exceeded the capacity of the FreeStyle unit.	Reduce activity, and then turn unit off and back on again to reset unit. If necessary, change to another source of oxygen as available and contact your Equipment Provider.
Intermittent alarm condition, and the (red) alarm light illuminates continuously.	A general malfunction has occurred.	Change to another source of oxygen as available, and contact your Equipment Provider.
Unit does not start on battery pack power.	Unit may be hot or cold if left outdoors such as in an automobile.	Allow the unit to reach normal operating temperature, which may take several minutes if exposed to temperature extremes. Remove the battery pack and re-install it to reset the battery pack.
Delay in recharging battery.	Battery exceeds charging temperature.	Unit may be operated; however, charging may not resume until battery temperature is reduced.
Unit alarms while in automobile and connected to the DC outlet.	No power to the unit if battery depleted and DC outlet not charging.	Disconnect the power supply from the automobile outlet, restart the automobile, and then reconnect the power supply into the automobile

		DC outlet to reset the breaker within DC power supply.
For FreeStyle Only: No hour meter display.	Defective hour meter.	Replace hour meter.
All other problems.		Change to another source of oxygen as available, and contact your Equipment Provider.

ACCESSORIES

For proper performance and safety, use only these listed accessories supplied by CAIRE. Use of accessories not listed below could adversely affect the performance and/or safety of the concentrator.

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

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

CAIRE INC. CUSTOMER SERVICE CONTACT INFORMATION

If you need any additional assistance, contact CAIRE Inc.:

By mail:

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Ball Ground, GA 30107 USA

By telephone: 800.482.2473



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