

SeQual[®] Technologies Inc.

Eclipse[®] 2 Oxygen System
Model 1000A

eclipse[®]2
with autoSAT[™]



Provider Technical Manual

Table of Contents

General Information.....	6
WARNING AND CAUTION STATEMENTS.....	6
INTRODUCTION TO THE ECLIPSE 2 OXYGEN SYSTEM	7
Eclipse Oxygen System Specifications	8
OXYGEN CONCENTRATOR.....	8
PULSE MODE SPECIFICATIONS.....	9
POWER ACCESSORY SPECIFICATIONS	9
AC Power Supply	9
DC Power Supply	10
Power Cartridge (Battery).....	10
INDEPENDENT SAFETY TESTING	10
How The Eclipse 2 Works	13
INTRODUCTION	14
ATF® CONCENTRATOR MODULE	14
COMPRESSOR AND COMPRESSOR ENCLOSURE	15
POWER DISTRIBUTION	15
CONTROL MODULE.....	15
CONTROL PANEL.....	16
CONTINUOUS FLOW MODE.....	18
PULSE FLOW MODE.....	18
PROVIDER MODE FUNCTIONS.....	19
Alarm Code.....	19
Display Total Hours of Operation	19
Display Software Version	19
Pulse Mode Sensitivity Adjustment	19
LCD Contrast.....	19
SERVICE MODE FUNCTIONS	20
Data Logging	20
Event History	20
Usage Meters	20
POWER SUPPLIES.....	21
AC Power Supply	21
DC Power Supply	22
POWER CARTRIDGE.....	23
Typical New Power Cartridge Operation Time	24
Training A New Patient.....	27
INTRODUCTION	28
Pre-Delivery Check List.....	28
CONTRAINDICATIONS	29
BASIC CONCEPT TRAINING.....	30
Safety Guidelines and Operational Safety Warnings/Cautions.....	30
Locating the Eclipse	30
The Users Manual	31
Showing Panel Buttons, Indicators, Alerts and Alarms	31
Showing Power Cartridge Power Level.....	31
Selecting the Proper Flow Mode and Setting	31
Selecting Continuous Flow Mode.....	32
Selecting Pulse Flow Mode	32
Adjusting the Pulse Mode Sensitivity Setting	33
Connecting the AC Power Supply	33
Connecting the DC Power Supply.....	34

ACTIVE LIFESTYLE TRAINING	36
Attach the Cart.....	36
Using Around the House	36
Traveling by Vehicle	36
Traveling by Air.....	38
Traveling by Boat.....	39
Traveling by Train.....	39
HOW TO MAINTAIN THE ECLIPSE.....	40
Clean the Air Inlet Filter	40
Clean and Care for the Tubing and Cannula.....	40
Clean the Cabinet and Control Panel and Power Supplies.....	40
Care for the Power Cartridge	41
PATIENT TRAINING CHECKLIST	42
Provider Maintenance.....	43
INTRODUCTION	44
Periodic Maintenance List	44
Checking and Replacing the Power Cartridge	44
Proper Care for the Power Cartridge.....	44
MAINTENANCE PROCEDURES.....	45
Remove and Replace the Unit Cover.....	45
Remove and Replace 9 Volt Battery	49
Remove and Replace HEPA Filter	51
Remove and Replace the Compressor Intake Filter	54
TEST PROCEDURES	56
Eclipse Purity and Flow Rate Test Procedure - Preferred Method	56
Purity and Flow Rate Test Procedure-Alternate Method.....	56
Assembly and Alarm Verification Tests.....	57
Electrical Safety Test.....	59
Cleaning the Eclipse.....	59
SERVICE AND MAINTENANCE RECORD.....	60
Shipping and Transporting the Eclipse.....	61
Storing the Eclipse.....	61
Discarding.....	61
System Troubleshooting and Alarms	62
TROUBLESHOOTING	62
ALARM CONDITIONS AND ALARM CODES.....	63
Service and Repair Procedures	65
SYSTEM SCHEMATICS AND DIAGRAMS	66
Simplified Block diagram	66
OXYGEN CIRCUIT	68
Remove and Replace the ATF Module	68
Remove and Replace the Product Tank Assembly.....	72
Routing Diagram for Pneumatic Tubing	74
ELECTRONICS	75
Remove and Replace the Control Module Assembly.....	75
Remove and Replace the Buzzer Wire Harness.....	77
Control Module Connector Diagram.....	78
Remove and Replace the Power Manager Printed Circuit Board	79
Power Manager PC Board Connector Diagram	82
COMPRESSOR	83
Remove and Replace the Compressor Box	83
PREVENTATIVE MAINTENANCE PARTS	87
REPLACEMENT PARTS LIST	87
SeQual Customer Service Contact Information	88

Table of Tables

TABLE 1: PULSE PROFILES.....	18
TABLE 2: FLOW MODES FOR DC POWER SUPPLY OPERATION.	38
TABLE 3: ECLIPSE STARTUP SEQUENCE INDICATIONS.....	57
TABLE 4: SAMPLE ECLIPSE MAINTENANCE RECORD	60

Table of Illustrations

FIGURE 1: ECLIPSE SYSTEM BLOCK DIAGRAM.....	12
FIGURE 2: FLOW SENSOR BOARD DIAGRAM.....	15
FIGURE 3: CONTROL PANEL BUTTONS AND INDICATORS	14
FIGURE 4: ECLIPSE SERVICE PORT	20
FIGURE 5: AC POWER SUPPLY	21
FIGURE 6: DC POWER SUPPLY	22
FIGURE 7: ECLIPSE POWER CARTRIDGE	23
FIGURE 8: POWER CARTRIDGE STATUS GAUGE.....	25
FIGURE 9: DC POWER SUPPLY INPUT POWER SWITCH	37
FIGURE 10: CLEANING THE AIR INLET FILTER.....	40
FIGURE 11: MAINTENANCE TOOLS.....	45
FIGURE 12: REMOVING SCREWS TO OPEN THE FRONT COVER.....	46
FIGURE 13: OPENING THE FRONT COVER.	46
FIGURE 14: REMOVING THE CONTROL PANEL RIBBON CABLE.....	47
FIGURE 15: DISCONNECTING THE OXYGEN OUTLET TUBE.	48
FIGURE 16: FRONT COVER REMOVAL.	48
FIGURE 17: CONTROL PANEL RIBBON CABLE INSTALLATION.....	49
FIGURE 18: REMOVING THE 9-VOLT BATTERY	50
FIGURE 19: DISCONNECTING THE 9-VOLT BATTERY.....	50
FIGURE 20: REMOVING THE HEPA FILTER.....	51
FIGURE 21: DISCONNECTING THE HEPA FILTER.....	52
FIGURE 22: INSTALLING THE HEPA FILTER.....	52
FIGURE 23: REMOVING THE COMPRESSOR INTAKE FILTER.....	54
FIGURE 24: INSTALLING THE COMPRESSOR INTAKE FILTER.....	55
FIGURE 25: SEQUAL RECOMMENDED TEST SETUP TO VERIFY PERFORMANCE OF OXYGEN CONCENTRATOR.....	56
FIGURE 26: DATA OUTPUT FORM	58
FIGURE 27: ECLIPSE OXYGEN SYSTEM SIMPLIFIED BLOCK DIAGRAM.	66
FIGURE 28: TOP CASE COMPONENTS.....	66
FIGURE 29: BOTTOM CASE COMPONENTS.....	67
FIGURE 30: REMOVAL OF ATF MODULE PRODUCT HOSE	68
FIGURE 31: REMOVAL OF ATF MODULE PRESSURE AND VACUUM TUBES.....	68
FIGURE 32: REMOVE ATF MODULE FROM ECLIPSE CASE.....	69
FIGURE 33: ATF MODULE GROMMET INSTALLATION	69
FIGURE 34: TUBE ROUTING UNDER ATF MODULE.....	70
FIGURE 35: PRODUCT TANK INLET AND OUTLET CONNECTIONS.....	72
FIGURE 36: PRODUCT TANK REMOVAL.....	73
FIGURE 37: OXYGEN TUBING ROUTING	74
FIGURE 38: CONTROL MODULE REMOVAL (ATF MODULE NOT SHOWN FOR CLARITY).....	75
FIGURE 39: CONTROL MODULE INSTALLATION.....	76
FIGURE 40: BONDING THE BUZZER TO THE CASE.....	77
FIGURE 41: BUZZER INSTALLATION.....	77
FIGURE 42: CONTROL MODULE CONNECTOR DIAGRAM.....	78

FIGURE 43: BATTERY BRIDGE BOARD REMOVAL.....	79
FIGURE 44: POWER MANAGER PC BOARD REMOVAL.....	80
FIGURE 45: EXHAUST TUBE REMOVAL.....	80
FIGURE 46: ATF MOTOR, 9-VOLT BATTERY, AND CONTROL PC BOARD COMMUNICATIONS WIRE HARNESS REMOVAL.....	81
FIGURE 47: POWER MANAGER PC BOARD CONNECTOR DIAGRAM.	82
FIGURE 48: CASE BOTTOM COVER REMOVAL.	83
FIGURE 49: COMPRESSOR BOX ELECTRICAL CONNECTIONS.	84
FIGURE 50: EXHAUST TUBE REMOVAL.....	84
FIGURE 51: REMOVAL OF COMPRESSOR PRESSURE AND VACUUM HOSES FROM ATF MODULE. .	85
FIGURE 52: REMOVE COMPRESSOR BOX SCREWS.....	86

General Information

This technical manual will familiarize you with Provider-specific information regarding the Eclipse 2 Oxygen System. Instructions in this manual are intended to help ensure that:

- Providers are familiar with Eclipse system components and system principles of operation
- Patients are given proper guidance in the use of the Eclipse and its accessories
- Providers are guided in the care, maintenance, and repair of the Eclipse Oxygen System

Warning and Caution Statements

Definitions of Warnings and Cautions as used on Eclipse

WARNING:	Important safety information for hazards that might cause serious injury.
	
CAUTION:	Important information for preventing damage to the Eclipse Oxygen System.
	
NOTE:	Places emphasis on an operating characteristic or important consideration.

Introduction to the Eclipse 2 Oxygen System



Eclipse Oxygen System Specifications

Oxygen Concentrator

Dimensions (H x W X D)	19.3 x 12.3 x 7.1 inches (49.0cm x 31.2cm x 18.0cm)
Weight With Power Cartridge Without Power Cartridge	17.9 pounds (8.1 kg) 14.5 pounds (6.6 kg)
Flow Settings Continuous Flow Pulse Flow	0.5 to 3.0 LPM, 0.5 LPM increments Settings of 1.0 to 6.0, in 0.5 increments
Continuous Flow Accuracy	+/- 10% or 200ml/min, whichever is greater
Oxygen concentration	90% +/- 3% for all flow settings
Maximum System Pressure	15 psig (103.5 kPa)
Oxygen Output Pressure	5.0 psig (34.5 kPa) nominal
Oxygen Concentration Indicator	Green Light = Normal Operation Yellow Light = Warning or Caution, less than 85% $\pm$ 3% Red Light Flashing = Abnormal Operation, less than 70% $\pm$ 5%
Nominal Sound Level 3 LPM Continuous Flow 0.5LPM Continuous Flow	48 dB(A) 40 dB(A)
Operating Environment Temperature Humidity	50° F to 104° F (+10° to 40°C) 10% to 95%, Non-condensing, 82.4°F (28°C) Maximum Dew point
Storage Environment Temperature Humidity	-4° F to 140° F (-20° to 60°C) Up to 95% Non-condensing
Nominal Power 0.5 LPM Continuous flow 3 LPM Continuous Flow 1.0 Pulse Flow Setting 6.0 Pulse Flow Setting	48 Watts 145 Watts 45 Watts 95 Watts
Nominal Power Cartridge operating time Continuous Flow 1.0 LPM 3.0 LPM Pulse Flow 1.0 6.0	4.4 hours 1.3 hours 4.4 hours 2.1 hours Note: Times will decrease with higher bolus size, breath rate, ambient temperature, power cartridge age and use over time.
Continuous Flow Indication	Expressed in liters per minute (LPM)

Audible Alarm Indicators	Loss of Power/Hot Power Cartridge Low Power Cartridge/Warm Power Cartridge Low Oxygen Output O ₂ Flow Outside Normal Limits Unit Malfunction
Back-Up Alarm Power	9V Internal Battery
Filters	Air Inlet, HEPA, Compressor Intake
Device Classification	IEC Class I, Type B Applied Part, IPX0

Pulse Mode Specifications

Pulse Settings	1.0 to 6.0, in increments of 0.5
Trigger Sensitivity	Adjustable between settings of 1 (most sensitive) to 6 (least sensitive)
Trigger Criteria	• Cannula pressure has dropped below the trigger point (typically between 0.15 – 0.45 Cm of H₂O of negative pressure) • At least 1¼ seconds has passed since the last pulse began
Minimum time between breaths	1.25 seconds (max. 3 consecutive breaths)
Response to Missing Breaths	• Yellow LED is activated if no inspiration has been detected after 45 seconds. • Switch to Continuous Mode if no inspiration has been detected for 60 seconds with an audible alarm.

Bolus Volume and Breath Rates

Pulse Flow Setting	Bolus Size (± 15%)	Min Breath Rate	AC Power Supply and Power Cartridge	10 Amp Switch Setting DC Power Supply	15 Amp Switch Setting DC Power Supply
			Max Breath Rate	Max Breath Rate	Max Breath Rate
1.0	16	6	40	40	40
2.0	32	6	40	40	40
3.0	48	6	40	40	40
4.0	64	6	39	31	39
5.0	80	6	31	25	31
6.0	96	6	26	20	26

Power Accessory Specifications

AC Power Supply

Input Voltage	100-240VAC, 50-60 Hz
Input Power	245-260 VA
Output Voltage	28 VDC
Output Power	200W

DC Power Supply

Input Voltage	11.5-18VDC
Output Voltage	26 VDC
Output Power	150W Max

Power Cartridge (Battery)

Output voltage	14.8 VDC
Capacity	Quantity (2) 97.5 W-hrs batteries (Each containing 7.92 grams equivalent Lithium content)
Nominal Power Cartridge Life	80% Capacity after 500 Charge/Discharge cycles
Power Cartridge Recharge Time	1.4 to 5.0 hours, dependent on flow setting, to achieve 80% capacity from a fully discharged Power Cartridge

Independent Safety Testing

Eclipse System and Eclipse Concentrator, Model 1000A	
Safety	IEC 60601-1 :1988 + A1 :1991 + A2 :1995 + Corrigendum (6/95) EN 60601-1(1990) + A1(1993) + A2(1995) + A12(1993) + A13(1996) + Corrigenda (7/94)
Electromagnetic Compatibility	FCC 15B (Sec. 107 & 109), EN55011, EN60601-1-2 :2001, EN6100-3-2, EN61000-3-3, IEC61000-4-2, IEC61000-4-3, IEC61000-4-4, IEC61000-4-5, IEC61000-4-6, IEC61000-4-8, IEC61000-4-11, IEC 60601-1-2 :2001, RTCA DO 160 Rev E
AC Power Supply, Model 4123	
Safety	IEC 60601-1:1988 + A1:1991 + A2:1995
Electromagnetic Compatibility	FCC 15B (Sec. 107 & 109), EN55011, EN60601-1-2 :2001, EN6100-3-2, EN61000-3-3, IEC61000-4-2, IEC61000-4-3, IEC61000-4-4, IEC61000-4-5, IEC61000-4-6, IEC61000-4-8, IEC61000-4-11, EN55014-1
DC Power Supply, Model 4124	
Safety	Portions of IEC 60601-1:1988 + A1:1991 + A2:1995
Electromagnetic Compatibility	FCC 15B (Sec. 109), EN55011, EN60601-1-2 :2001, IEC61000-4-2, IEC61000-4-3, IEC61000-4-4, IEC61000-4-6, IEC 60601-1-2 :2001
Power Cartridge 2400, PN 1056	
Safety	UL2054, UL60950-1, First Edition (UL File MH29443), IEC 60601-1:1988 + A1:1991 + A2:1995, UN Transportation Tests T1-T8
Electromagnetic Compatibility	EN 61000-6-3 :2001 (EN55022 :1998+A1 :2001+A2 :2003), EN61000-6-1 :2001, EN61000-4- 2 :1995+A1 :1998, EN61000-4-3 :2002
<i>Any CSA-CUS mark for the Eclipse system does not encompass operation with the DC Power Supply Model 4124.</i>	

ELECTROMAGNETIC COMPATIBILITY

This equipment has been tested and found to comply with the limits for medical devices to the IEC60601-1-2 Electromagnetic Compatibility standard. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed according with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation distance between the equipment.
- Connect the equipment into an outlet on a circuit different from that which the other device(s) are connected.
- Consult with SeQual Technical Support for help.

Guidance and Manufacturer's declaration - electromagnetic emissions		
The SeQual Technologies Eclipse Oxygen System is intended for use in the electromagnetic environment specified below. The customer or the user of the SeQual Technologies Eclipse Oxygen System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions EN 55011	Group 1	The SeQual Technologies Eclipse Oxygen System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN 55011	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	The SeQual Technologies Eclipse Oxygen System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low - voltage power supply network that supplies buildings used for domestic purposes.

-PAGE INTENTIONALLY BLANK-

How The Eclipse 2 Works

Introduction

The Eclipse 2, Personal Ambulatory Oxygen System with AutoSat Technology is a portable medical device used to extract oxygen from the atmosphere, concentrate it to greater than 90% and present it to the patient. The device will operate in continuous flow or Pulse Flow Modes. In Continuous Flow Mode the oxygen is provided at a constant flow rate between 0.5 and 3.0 LPM. In Pulse Flow Mode, oxygen is supplied in a bolus at the beginning of each inspiration, providing a selectable range setting of flow between 1.0 and 6.0. A setting of 1 in Pulse Flow Mode delivers the equivalent amount of oxygen (FIO₂) as a Continuous Flow Mode setting of 3 LPM.

The Eclipse operates from either external power or from an internal rechargeable Power Cartridge. The system includes a “Smart Battery” charger that recharges the internal Power Cartridge whenever the Eclipse is connected to external power. The system monitors and controls both the power source and the Power Cartridge charger.

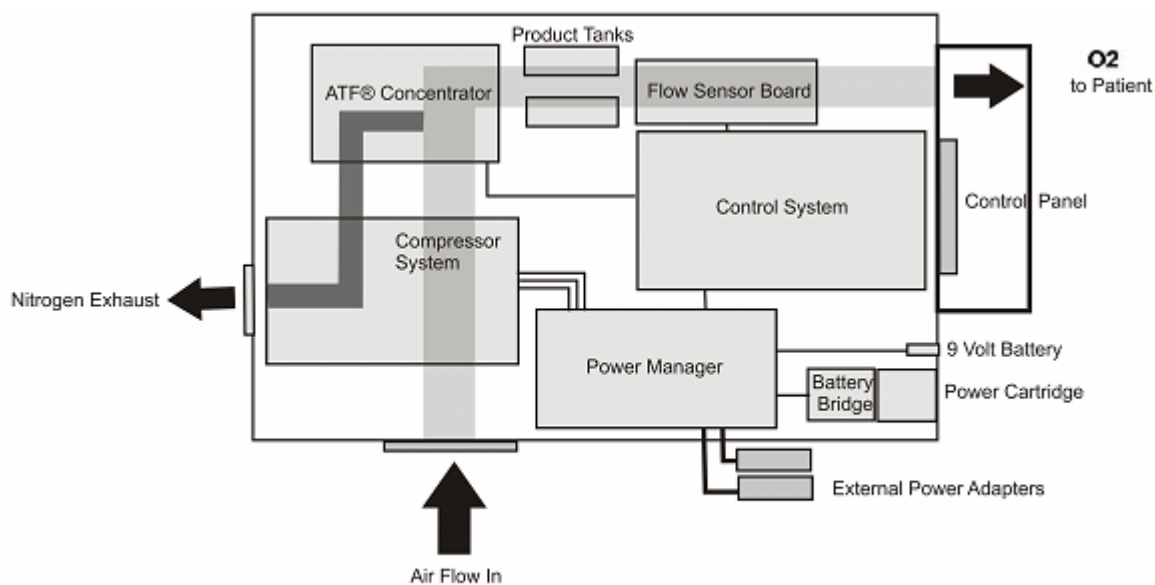


Figure 1: ECLIPSE System Block Diagram

ATF® Concentrator Module

The Eclipse uses a passive system to separate oxygen from air. Air flows into the Eclipse where it is filtered and then enters the compressor. Pressurized air flows from the compressor into the ATF® Concentrator Module where it is separated into oxygen and nitrogen components. The air separation process uses a rotary valve system to force air through a series of pressurized sieve beds. Through a process known as “pressure swing adsorption,” nitrogen molecules are collected on an adsorbent material allowing the concentrated oxygen to be forced through a sieve bed into the product tank. The nitrogen molecules are then purged from the adsorbent material using a vacuum pressure cycle.

Oxygen flows from the product tank through a HEPA filter and past a sensor that measures flow and concentration. A flow control valve regulates the flow of concentrated oxygen presented to the patient. The process is continuously repeated during operation.

Compressor and Compressor Enclosure

The Eclipse compressor is a two-cylinder, variable speed wobble piston compressor, driven by a highly efficient Brushless DC (BLDC) motor. When air flows into the compressor enclosure, it passes through an air intake filter/muffler that muffles sound and filters out impurities. Using one cylinder, the compressor takes in filtered air and delivers it to the ATF Module under pressure. The second cylinder draws a vacuum on the ATF module and exhausts nitrogen rich gas to the exhaust vent.

Using a multifaceted approach, sound, heat, and vibration generated by the compressor are mitigated by the compressor enclosure. Vibration and structure-borne noise are addressed by the dual axis gimbal that supports the compressor and the tubing that connects the compressor to the ATF module. The rigid walls of the compressor enclosure and the sound adsorbing foam that lines it diminish the radiated noise. The centrifugal blower mounted within the compressor enclosure serves to efficiently draw cooling air in over the compressor cylinders while simultaneously pushing exhaust gas out of the concentrator.

Power Distribution

The Power Manager takes external power that comes into the Eclipse from the power supplies or Power Cartridge and monitors and controls power distribution to the rest of the Eclipse system. The Power Manager drives the compressor, ATF module motor, blower, and provides power to the control module. In addition, when the unit is connected to an external power source, the power manager monitors and controls the recharging of the Power Cartridge.

Control Module

The control module is at the center of nearly all Eclipse functions. The module constantly monitors dynamics such as temperatures, pressures, product flow and concentration, and user input. It determines proper compressor and ATF motor speeds needed in order to provide optimum system performance. In addition, this system supports the operation of the Control Panel and its indicators.

The Control Module utilizes a proprietary ultrasonic flow and concentration sensor and a flow control valve to accurately control the flow of oxygen in Continuous and Pulse Flow Modes.

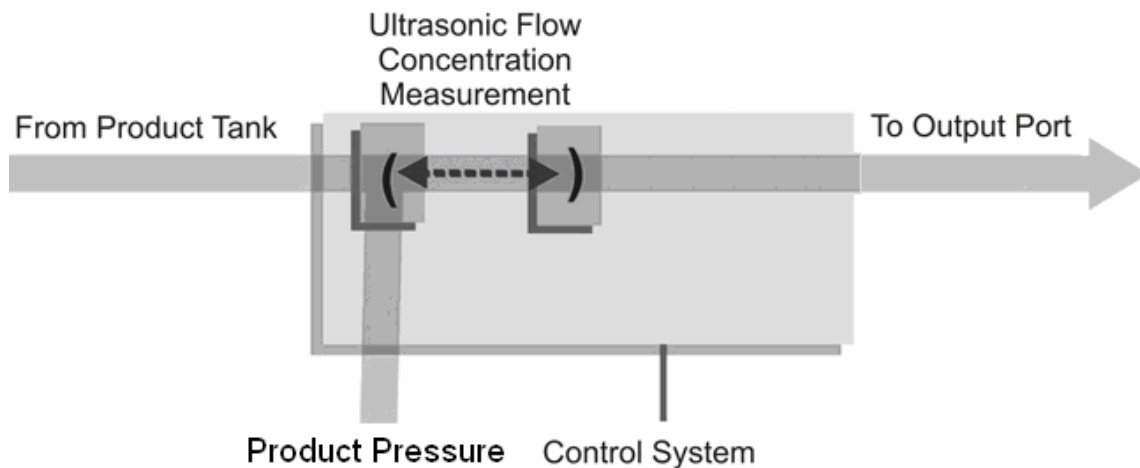


Figure 2: Flow Sensor Diagram

Control Panel

The control panel provides a user interface consisting of a membrane panel keyboard, Liquid Crystal Display (LCD), external power present indicator, Power Cartridge capacity indicator, alarm status indicators, and an audio transducer. The user interface informs the user of the system status and allows the user to set the desired flow rate and flow mode.



USER CONTROLS AND SYSTEM STATUS INDICATORS

Figure 3



ON/OFF Button (Green) Indicator: This button powers the device ON or powers it OFF. The Green Indicator is illuminated when the device is powered ON.



Increase or Decrease Flow Setting Button: Use these buttons to set the flow to your prescribed level.



Flow Mode Button and Indicator: The Eclipse contains a button to toggle between Continuous Flow and Pulse Flow mode. The Pulse Flow mode allows a significant increase in the duration-of-use time the device can operate from the Power Cartridge. When the Pulse Flow Mode is activated, the green Flow Mode Indicator illuminates and a pulse of oxygen is delivered with each inspiratory effort. When the pulse of oxygen is delivered, the flow mode indicator turns off momentarily. Changes in flow mode should only be made on the recommendation of your physician.



ALERT (Yellow) Indicator - Low and Medium Priority Alerts:

When illuminated, this indicates a low priority awareness condition or Caution. Continue to use your system and refer to the Alerts, Alarms, and Troubleshooting Table for the proper response. A flashing yellow indicates a medium priority alert. A prompt response is necessary.



ALARM (Red) Indicator – High Priority Alarms: Indicates a high priority alarm condition. An immediate response is necessary. Refer to the Alerts, Alarms, and Troubleshooting Table and contact your home care provider.

Buzzer: An audible alarm (or buzzer) is used to alert you to the operating condition of the device, either a warning or failure, and to confirm a valid key press by the user.



Flow Setting Indicator: This is the main focus on your control panel. Your home care provider will correctly set your prescribed flow for either the Continuous Flow Mode (LPM) and/or your Pulse Flow Mode settings. **DO NOT** change these settings unless it is with the recommendation and under the order of your physician. Each time you power the device ON, the previous flow mode and flow setting has been saved and will be used at start-up.



Power Cartridge Status Gauge: This indicator displays the charge remaining in the Power Cartridge. When the Power Cartridge is fully charged all 4 gray bars are illuminated. Each gray bar represents approximately 25% of the total Power Cartridge charge. When the Power Cartridge is being charged, the charge indicator bars will blink in a waterfall-type fashion.

If the Power Cartridge is not installed, or if it is improperly installed, the Power Cartridge Status Gauge will not be illuminated.



External Power is Present Indicator: When the Eclipse is properly plugged in and is using the AC or DC Power Supply, this indicator will appear on the User Control Panel.

Continuous Flow Mode

The user may set the Eclipse oxygen flow rate and mode. Continuous Flow Mode delivers a constant flow of oxygen to a patient by means of tubing and a nasal cannula at rates between 0.5 LPM and 3.0 LPM. Within the Eclipse, concentrated oxygen is stored in a 500ml product tank at pressures in the range of 5 to 9 psi. This pressure gives Continuous Flow Mode the capability to deliver the indicated flow rate to the patient even if extension tubing is used, up to 50 feet long. In addition, the Eclipse Continuous Flow Mode is fully compatible with humidifier use.

Pulse Flow Mode

The Eclipse Pulse Flow Mode delivers a high flow of oxygen at the very beginning of each inspiration. The approach is based on the manner in which gas is absorbed into a patient's airway. Eclipse users may select pulse volume delivery rates at settings between 1 and 6. Regardless of setting, the pulse profile is a simple square-wave pulse based on a 16-ml/liter volume. (Refer to "Pulse Profiles" table below). Pulse durations are no less than 100 milli-seconds. Pulse durations do not exceed 450 milli-seconds due to dead space considerations.

Flow Setting	Pulse Peak Flow, LPM (volumetric)	Pulse Duration (milli-second)	Bolus Volume (ml)
1	8	120	16
2	9	213	32
3	10	288	48
4	11	349	64
5	12	400	80
6	13	443	96

Table 1: Pulse Profiles

The fundamental approach to triggering and controlling the oxygen bolus in Pulse Flow mode is as follows:

The user may select a pulse trigger sensitivity in settings ranging from 1 to 6. The pulse will be triggered when the system meets all of the following criteria:

- The cannula pressure has dropped below the trigger point (typically between 0.15 and 0.45 cmH2O)
- At least 1¼ seconds has passed since the last pulse began

Provider Mode Functions

Providers can access provider mode software functions using the control panel. All provider mode information is displayed on the LCD. The software shall advance the following ***display mode*** when the “No Smoking” icon is pressed:

1. Alarm Code (AC)
2. Hours of Operation (H)
3. 9-volt Battery Status (9V)
4. Software Version (SW)
5. Pulse Sensitivity (PS)
6. LCD Contrast (CT)

Alarm Code

While in Continuous Flow Mode, pressing the “No Smoking” icon displays the current Eclipse alarm code on the LCD. This code may be used to help diagnose conditions indicated by the alert and alarm indicators. The LCD will show “AC=”. Refer to the “Provider Maintenance” section for further information.

Hours of Operation

The Eclipse hour meter provides valuable information on hours of operation. Providers may display the total number of hours of operation using the control panel. The display counts up to “99,999.9” hours, then rolls over to “00000.” The LCD will show “H=”. Refer to the “Provider Maintenance” section for further information.

9-Volt Battery Status

The status of the 9-Volt Battery is provided. This is the actual voltage of the 9-Volt battery. The LCD will show “9V=”.

Software Version

Providers may occasionally need to obtain the software version on the Eclipse to perform maintenance. The provider may display software version numbers for both the Control System and the Power Manager software using the control panel. Refer to the “Provider Maintenance” section for further information.

Pulse Mode Sensitivity Adjustment

During patient setup, a qualified clinician may adjust the Pulse Mode sensitivity to best suit patient inspiratory effort. The LCD will show “PS=”.

LCD Contrast

Providers may need to adjust the LCD contrast. The contrast may be set from 0 to 10, with 10 being the highest contrast. The LCD will show “CT=”.

Service Mode Functions

Factory maintenance or service updates may sometimes be required on the Eclipse. Factory and qualified factory-trained technicians can access service mode software functions by using the Service Port located on the back of the unit. The Service Port is not for patient use.

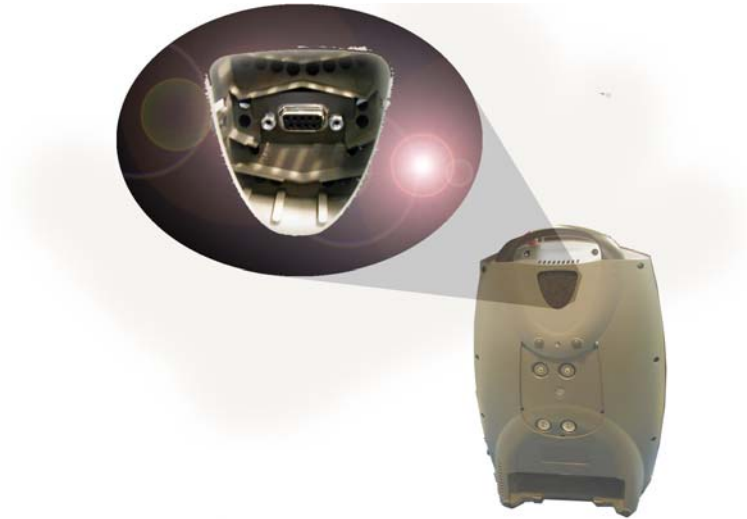


Figure 4: Eclipse Service Port

Data Logging

The Eclipse provides various operational data on demand. Data that may be reported includes:

- System Status
- Compressor Speed
- Component Temperature
- Power Cartridge Data
- Oxygen flow rate and purity
- Process pressure and temperature
- Breath detection (Pulse Mode Only)
- Bolus Delivery (Pulse Mode Only)
- External Power

Event History

The Eclipse detects and records events such as changes in status, alarm states, and changes in user settings.

Usage Meters

The Eclipse usage meter provides the following information:

- Total hours of operation.
- Total hours of operation at High and Low compressor temperatures
- Total hours of operation at Low, Medium, and High compressor speeds

Power Supplies

The Eclipse may operate from either the AC or DC Power Supply or Power Cartridge. When power is available from an external supply, the Eclipse, in the majority of cases, will always draw from the external source rather than depleting the Power Cartridge. Connection to external power is indicated when the External Power Present Indicator located on the Control Panel is illuminated.

AC Power Supply

The AC Power Supply is a universal input type, capable of accepting 100-240VAC, 50/60 Hz. It is capable of delivering up to 200W of 28VDC output. The input cord requires a grounded receptacle. Country specific cords may be used with the AC Power Supply, as the supply is equipped with a universal input receptacle. When used in a medical care facility, international safety standards require the use of hospital grade AC power cord with the Eclipse.



Figure 5: AC Power Supply

During periods of high load, an internal fan comes on to cool the AC Power Supply. Like the Eclipse, the AC Power Supply should be located in a well-ventilated area.

Located near the output cord, there is a Green LED that is illuminated when the AC Power Supply is supplying 28VDC power. When output voltage falls outside of this range, the LED will turn red. If the LED is not illuminated, there is no input power available. In addition, the Power Supply contains protection circuits for output over-current, input over-voltage, and internal over-temperature conditions. If any of these conditions exist, output power will be interrupted and the red LED will illuminate. However, these three conditions are self-resetting, such that output power will resume when protection circuits fall back into acceptable operating ranges.

DC Power Supply

The DC Power Supply is intended for use with DC accessory outlets, such as those found in motor vehicles. Input voltage to the DC Power Supply is 11.5-18 VDC. Sized to be compatible with most passenger vehicle electrical systems, it is capable of delivering up to 150W of 26VDC output to the Eclipse.



Figure 6: DC Power Supply

Located near the output cord, there is a Green LED that is illuminated when the DC Power Supply is supplying 26VDC power. When output voltage falls outside of this range, the LED will turn red. If the LED is not illuminated, there is no input power available. The Power Supply contains protection circuits for output over-current, input over-voltage, and internal over-temperature conditions. If any of these conditions exist, output power will be interrupted and the red LED will illuminate. However, these three conditions are self-resetting, such that output power will resume when protection circuits fall back into acceptable operating ranges.

Located near the input cord, there is a two-position switch to determine how much power is available from the DC accessory outlet for the Eclipse. In the 10A position, the Eclipse will draw up to 100W from the DC Power Supply. In the 15A position, up to 150W will be drawn. This switch must be set according to the power availability at the accessory outlet. Refer to the vehicle's operating manual if necessary.

In addition to these indicators and safety circuits, the DC Power Supply includes an audible alarm that sounds if the input voltage to the DC supply falls below 11.5VDC. Patients should not continue to use the DC supply to power their Eclipse after they have turned off their vehicle engine. The DC Power Supply alarm is intended to remind the patient that their vehicle battery is being depleted and further depletion may cause the vehicle not to start.

Power Cartridge

The Power Cartridge allows operating the Eclipse away from AC or DC power. The Power Cartridge used with the Eclipse contains Lithium ion battery cells, similar to those used in laptop computers and cell phones. The Eclipse Power Cartridge contains a quantity of two 97.5 Watt hour battery packs. Each battery pack contains 7.92 grams of equivalent lithium content.



Figure 7: Eclipse Power Cartridge

Connect the Eclipse to the AC Power Supply, DC Power Supply or optional Desk Top Charger accessory to recharge the Power Cartridge.

The fastest way to recharge the Power Cartridge is from the AC Power Supply. The Eclipse unit may not charge the Power Cartridge when operated from the DC Power Supply under some conditions.

Operating and caring for the Power Cartridge will ensure longer life and higher performance. It is important to follow the tips and recommendations when storing and operating the Eclipse on the Power Cartridge.

The Eclipse Power Cartridge operation time may be affected by several factors such as bolus size, breathing rates, ambient temperature, age of power cartridge and use over time. The table below describes the typical operating time for a new Power Cartridge.

If the Eclipse is used in Pulse Flow mode then there will be longer operating time. Consult your physician for a prescription for pulse flow mode.

Typical New Power Cartridge Operation Time

	Power Cartridge ()	
FLOW RATE SETTING	Continuous Flow Mode (LPM)	Pulse Flow Mode (Setting)
0.5	4.4 hours	-
1.0	3.7 hours	4.4 hours
2.0	2.4 hours	3.6 hours
3.0	1.3 hours	3.0 hours
4.0	-	2.6 hours
5.0	-	2.3 hours
6.0	-	2.1 hours

Note: Times will decrease with higher bolus size, breath rate, ambient temperature, age and use over time.

The Power Cartridge packaged with the Eclipse is not fully charged. Before using the Eclipse Oxygen System for the first time, the Power Cartridge must be fully charged.

Store the power cartridge in a cool, dry location.

When checking the Eclipse as baggage on a commercial airline flight for international travel, remove the Power Cartridge and properly package.

If the Power Cartridge gets too warm, charging will not begin until the Power Cartridge sufficiently cools. There will be an audible alarm. Consider removing the Power Cartridge to allow faster cooling.

Do not leave the Eclipse or Power Cartridge in a vehicle or in the truck during a hot day.

The Power Cartridge operating time is longer if the Eclipse is operated in Pulse Flow Mode.

When shipping the Eclipse for any reason, remove the Power Cartridge from the Eclipse.

The typical time to recharge the Power Cartridge to achieve 80% capacity from a fully discharged Power Cartridge is 1.4 hours to 5.0 hours, dependent upon the flow setting.

The Power Cartridge may not recharge, or the charge time may increase significantly, when operating from the DC Power Supply.

WARNING



DO NOT tamper with, disassemble, crush or heat the Power Cartridge above 140° F (60° C). The Power Cartridge may present a risk of fire or explosion and will void the warranty.

CAUTION

Store the Power Cartridge in a cool, dry place when not in use.

CAUTION

DO NOT leave the Eclipse or the Power Cartridge in a vehicle or in the trunk during a hot day.

CAUTION

The Eclipse system can only work with a SeQual Power Cartridge. Use of another Power Cartridge or Battery may damage the unit, present a risk of fire or explosion and will void the warranty.

The capacity of the Eclipse Power Cartridge is determined by electronics and the Eclipse software.



Figure 8: Power Cartridge Status Gauge

While the Eclipse Power Cartridge allows the concentrator to operate at its full range of capabilities, the primary purpose of the Power Cartridge is to allow a patient to ambulate while they are moving between stationary power sources. The Eclipse's Power Cartridge, like all lithium ion batteries, is susceptible to permanent damage from excessive heat. Exposure to excessive heat may shorten the Power Cartridge's service life significantly.

Each Power Cartridge contains multiple temperature sensors to monitor battery cell temperature. The amount of heat the Power Cartridge can safely endure varies depending on how the Power Cartridge is being used. During discharge, the Eclipse software will alarm when internal battery cell temperature exceeds 60°C, and will shut the system down if internal battery cell temperature exceeds 70°C. While the Power Cartridge is charging, software will interrupt charger operation when the internal battery temperature exceeds 45°C or temperature is less than 0°C. In both of these cases, when internal battery cell temperature falls below these limits, the Eclipse will resume normal operation. Operation near these temperature limits will not damage the Power Cartridge, but are in place to ensure that the service life of the Power Cartridge is preserved.

Heat in the Power Cartridge is generated during discharge, and can also be the result of operating the Eclipse in high ambient temperatures. The amount of internally generated heat varies with the flow setting – higher flows induce greater Power Cartridge heating. While high ambient temperatures are typically the result of operation on a hot day, running the Eclipse with inadequate ventilation can also induce them. Always ensure that the Eclipse is operated in a well-ventilated space, the air intake filter is clean, and intake and exhaust vents are unobstructed.

Charging Algorithm

The charging algorithm is performed by the Power Manager software and must make three basic decisions:

1. When to start charging
2. How fast to charge
3. When to stop charging

Charging begins when Power Cartridge voltage falls below 16.0 volts.

The charging current is limited by the charger capability and the rated capacity of the Power Cartridge. Under certain conditions, the Eclipse may not have enough external power available to charge the batteries at the full rate. In this case, the charging rate will be limited to the available power.

As the Power Cartridge accumulates charge, the charging current required will eventually fall. When the charging current for each Power Cartridge has fallen below 5% of the rated capacity, charging is complete and the Power Cartridge charger is shut off.

The software will only charge when the Power Cartridge temperature is at or below 45°C. The software will always run the cooling fan whenever the charger is enabled. The Power Cartridge charger is disabled and the cooling fan is set to maximum whenever the Power Cartridge temperature exceeds 45°C. The Power Cartridge charger is disabled when temperature is less than 0°C.

All lithium ion batteries self-discharge at very low rates when not in use. Eclipse Power Cartridges are shipped from SeQual in a partially charged state (nominally 40%). When stored in a cool, dry location, the Power Cartridge can sit unused for up to 12 months without appreciable self-discharge occurring. Nevertheless, SeQual recommends a first in, first out rotation of Power Cartridge inventory for maximum Power Cartridge service life.

Training A New Patient

Introduction

Welcome to the Eclipse 2, Personal Ambulatory Oxygen System with AutoSat Technology. Setting up and training your patient to use the Eclipse 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 Eclipse. For example:

- ❖ Slim and sleek appearance
- ❖ Easy-to-use controls
- ❖ Quiet operation
- ❖ Lower electric bills
- ❖ Self-monitoring alarm system
- ❖ More consistent FIO₂ at higher breath rates

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

Pre-Delivery Check List

Before delivering the device, check and log the status of the following:

- Parts Inventory – Verify that each Eclipse is provided to the patient with the following items:
 - Users Manual
 - Go Smart Travel Tips
 - Limited Warranty Card
 - Product Registration Card
 - Eclipse Smart Tip Pamphlet
 - DC Power Supply Smart Tip Card
 - Cart
 - AC Power Cord
 - AC Power Supply
 - DC Power Supply
 - Power Cartridge (Battery)
 - Air Inlet Filter and Spare
 - Cannula
- Power Sources – Insert and check the following for proper operation:
 - AC Power Supply
 - DC Power Supply
 - Power Cartridge
- Electrical System – Use the control panel to check and/or adjust the following:
 - Pulse Setting
 - Flow Setting
 - Hour meter
 - Pulse Flow Sensitivity
 - Power Cartridge Status Gauge
 - 9V Battery Status
 - Software Revision
 - Display Contrast

The Eclipse is shipped from SeQual at default flow settings of 2 LPM Continuous Flow, 2.0 Pulse Flow, and 3 for Pulse Mode Inspiration Sensitivity. You may adjust these settings to your patient's requirements when you deliver and set up the device.

Indications for Use

The Eclipse Oxygen System is indicated for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

Your physician has prescribed a specific oxygen flow rate setting to meet your individual needs.

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

WARNING:	FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
	

Contraindications

WARNING:	THE ECLIPSE IS NOT INTENDED FOR LIFE SUPPORTING OR LIFE SUSTAINING APPLICATIONS, NOR DOES IT PROVIDE ANY PATIENT MONITORING CAPABILITIES.
	

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

WARNING:	Not for use in the presence of flammable anesthetics.
	

WARNING:	Use of an oxygen mask other than the Southmedic OxyMask, at low flows (0.5 – 3.0 LPM) is contraindicated due to the possibility of re-breathing of exhaled carbon dioxide.
	

Basic Concept Training

The following section is intended to assist the provider train the patient or caregiver to use the Eclipse. Topics in this section should be discussed with each patient prior to release for use of the Eclipse.

Safety Guidelines and Operational Safety Warnings/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 Eclipse to assure proper connection and compatibility with other equipment the patient may be using.

WARNING:	
	No Smoking or Open Flames. 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 operating oxygen concentrator is dangerous, and can permanently damage the device and void the warranty.

Locating the Eclipse

Ask your patient where they would like to set up the device. Whenever possible, the Eclipse should be in the same room as the patient for convenience and to ensure that the patient can adequately hear and respond to Eclipse alerts and alarms. While unpacking and setting up the device, tell your patient about these important cautions and warnings:

WARNING:	
	▪ Locate the Eclipse in a well-ventilated space that provides adequate airflow. ▪ 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. ▪ Do not use in the presence of flammable anesthetics, solvents, aerosols or flammable cleaning agents. ▪ Avoid dusty environments.

CAUTION:	
	Some patients are highly mobile and may use the device under many circumstances. Make sure your patient or patient caregiver completely understands the basic precautions to safely locate the device.

NOTE:	
	After completing this training procedure, ask your patient if s/he has any questions.

The Users Manual

Give your patient a copy of the Eclipse Users Manual. Open the manual and briefly review the Table of Contents, including subheadings. Show your patient the icons and symbols and explain what each means.

CAUTION:	Advise your patient to thoroughly read the Eclipse Users Manual and keep the manual in a safe place for future reference.
	

Showing Panel Buttons, Indicators, Alerts and Alarms

Open the Users Manual to the section on “Control Panel Features” and show your patient where each button is located on the Eclipse control panel and how each button and indicator operates. Go over the alerts and alarms and how to handle alert and alarm conditions. Detailed instructions for each button and indicator can be found in the Eclipse Users Manual. Detailed instructions for alerts and alarms can be found in the Eclipse Users Manual.

Showing Power Cartridge Power Level

The waterfall display on the control panel shows the amount of Power Cartridge capacity available. Point out the table showing typical new Power Cartridge duration-of-use time in the Users Manual.

WARNING:	The display gives an <i>approximate</i> level of remaining battery power. If the patient is dependent on oxygen therapy, the users should always have a backup oxygen supply or access to a DC or AC Power Supply in the event of loss of battery power.
	

Selecting the Proper Flow Mode and Setting

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

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

Selecting Continuous Flow Mode

When delivered from SeQual, the Eclipse is set to Continuous Flow Mode. Refer your patient to the Users Manual for instructions on how to select Continuous Flow Mode. Demonstrate the procedure on the device. Set the prescribed flow using the increase or decrease flow rate buttons.

CAUTION:	- Continuous Flow Mode is required in order to use a humidifier bottle. - Continuous Flow Mode is required in order use 50 foot tubing.
	

Selecting Pulse Flow Mode

Pulse Flow Mode, delivers a high flow oxygen pulse at the beginning of each inspiration. Refer to the Users Manual for instructions on how to select Pulse Mode. Demonstrate the procedure for your patient. Set the prescribed flow using the increase or decrease flow rate buttons. Verify that the patient is able to adequately trigger the oxygen delivery while speaking, sitting quietly, and walking. If the patient is not able to satisfactorily trigger oxygen delivery, the Pulse Mode sensitivity may need to be adjusted.

NOTE:	The Eclipse defaults to Continuous Flow Mode if a breath is not detected within 60 seconds.
--------------	---

CAUTION:	- Do not use a humidifier when in Pulse Mode. - Use only a 7-foot cannula when in Pulse Mode. Do not use a tubing extension.
	

Review with the patient the breath rate capabilities of pulse mode for their prescription.

Bolus Volume and Breath Rates

Pulse Flow Setting	Bolus Size (± 15%)	Min Breath Rate	AC Power Supply and Power Cartridge	DC Power Supply 10 Amp Switch Setting	DC Power Supply 15 Amp Switch Setting
			Max Breath Rate	Max Breath Rate	Max Breath Rate
1.0	16	6	40	40	40
2.0	32	6	40	40	40
3.0	48	6	40	40	40
4.0	64	6	39	31	39
5.0	80	6	31	25	31
6.0	96	6	26	20	26

Adjusting the Pulse Mode Sensitivity Setting

The oxygen delivery trigger sensitivity may be adjusted to satisfy patient requirements. The default setting for units coming from SeQual is “3”. To adjust the trigger sensitivity, perform the following steps:

1. Have the patient sit quietly, with the nasal cannula properly fitted.
2. Put the Eclipse into Pulse Mode at the patients prescribed flow setting.
3. Press the “No Smoking” icon until the “PS=” value is displayed.
4. Press the “+” button to raise the sensitivity. **Raising the sensitivity will require additional inspiratory effort to trigger the oxygen pulse.**
5. Press the “-” button to lower the sensitivity. **Lowering the sensitivity will require less inspiratory effort to trigger the oxygen pulse.** Too low of a setting may result in false triggering.
6. Verify that the patient is able to adequately trigger the oxygen delivery while speaking, sitting quietly, and walking. Steps 1-6 may be repeated until the patient is able to adequately trigger oxygen delivery.

WARNING:	As with all conserving devices, the Eclipse may not be able to detect some respiratory efforts.
	

NOTE:	The Eclipse algorithms require a minimum of one minute to stabilize after a change. After a setting change, always wait at least one minute before determining if another adjustment is necessary.
--------------	--

Connecting the AC Power Supply

The Eclipse operates from external power when connected to a power outlet.

To connect the Eclipse to the AC Power Supply, follow these steps:

1. Insert the AC supply plug tip into the Eclipse.
2. Insert the power cord into the AC Power Supply.
3. Plug the power cord into a grounded outlet.
4. The LED displays green to indicate that the AC Power Supply is drawing power. The External Power Present Indicator on the control panel illuminates. The fan inside the supply will run periodically.

NOTE:	If the Power Supply Status LED displays red after inserting the plug into a grounded outlet, check to make sure the Power Supply and power cords are securely plugged into the Eclipse.
--------------	---

WARNING:	• Ensure adequate clearance around AC Power Supply. • The AC Power Supply is universal input, but the AC power cord is appropriate to specific country's electrical service. Ensure that power cord is appropriate to country's electrical service.
	

CAUTION:	• DO NOT connect the Eclipse to an extension cord or electrical outlet controlled by a switch.
	

NOTE:	When removing the AC Power Supply from the Eclipse, remove the plug from the AC outlet before removing the AC Power Supply plug from the Eclipse..
--------------	--

International safety standards require the use of hospital grade AC power cords when using the Eclipse in a medical care facility. Contact SeQual to obtain a hospital grade AC power cord for the Eclipse if necessary.

Connecting the DC Power Supply

The Eclipse DC Power Supply provides easy travel for your patient. There are two settings on the DC Power Supply. Ensure the DC Power Supply is set-up properly to the vehicle being used. In order to ensure correct operation and safety, you must help your patient install the DC Power Supply in their vehicle by following the instructions in the Users Manual.

To install the DC Power Supply, follow these steps:

1. Consult your patient's vehicle owner's manual for DC Accessory outlet requirements.

CAUTION:	The DC Power Supply is designed for 12VDC vehicle electrical systems. Do not attempt to operate with 6V, 24V, or other vehicle electrical system.
	

2. Set switch on DC Power Supply to "10A" for a 15A or less outlet. Set the switch to "15A" for a 20A or greater outlet.
3. Always secure the Eclipse and DC Power Supply in the vehicle.
4. Attach the Power Supply plug to the Eclipse.
5. Start the vehicle's engine before inserting the DC power supply plug into the DC Accessory outlet.
6. Insert supply plug into DC Accessory outlet.
7. Use the Eclipse in Pulse Flow mode if prescribed by your clinician

When Eclipse is running from external (AC or DC) Power Supply, the External Power Present Indicator will illuminate. Eclipse will always operate from external power when external power is available.

WARNING:	• Ensure adequate clearance around the DC Power Supply and the Eclipse. • Ensure the DC Power Supply and Eclipse are secured in the vehicle so that it does not become a projectile in the event of a sudden stop. • DO NOT operate Eclipse while vehicle engine is not running. The Eclipse could quickly drain the vehicle battery in some vehicles in such a scenario.
	

CAUTION:	When operating the DC Power Supply at a 10A setting at flows above 2 LPM, the Eclipse will automatically drop back to 2 LPM continuous flow and will emit a beep and will display a flow setting of 2.0.
	

NOTES:	• The green LED on Power Supply indicates that the Power Supply is properly functioning; the red LED indicates a Power Supply fault. • An audible alarm on DC Power Supply will sound when vehicle voltage drops below 11.5VDC. If this occurs, unplug the DC Power Supply from vehicle and operate the Eclipse using the Power Cartridge.
---------------	---

Active Lifestyle Training

Small, lightweight, and easily moved about, the Eclipse is ideally suited to an active lifestyle. The AC and DC power supplies enable recharge of the Power Cartridge during longer excursions and even extended overnight travel. To train your patient, follow the procedures below.

CAUTION:	Always check to see that the Air Inlet and the exhaust vent are not blocked and the air inlet filter is clean before using your system.
	

NOTE:	• Do not drop or bang the Eclipse or Eclipse power supplies. If dropped or damaged, the patient should call the provider to verify unit performance. • The Eclipse will not detect a cannula that has come disconnected from the Oxygen Outlet Port.
--------------	--

Attach the Cart

Your patient will enjoy the mobility offered by the Eclipse telescoping handle cart in and outside the home. Show your patient how to perform the following important activities:

- Mounting the Eclipse to the Cart
- Extending and collapsing the telescoping handle

CAUTION:	• The Eclipse cart may be difficult to maneuver on rough or uneven terrain. • Do not lift the Eclipse by the cart handle.
	

Using Around the House

Your patient may use a 50' tubing when operating the Eclipse in the house. In order to use extended tubing, the device must be in Continuous Flow Mode.

Traveling by Vehicle

Ask your patient whether he will be using the device to travel by vehicle. If so, show your patient how to safely use the Eclipse while driving.

NOTE:	Whenever possible, go to your patient's vehicle to demonstrate this procedure.
--------------	--

To instruct your patient, follow these steps:

1. Place the Eclipse and secure in the vehicle. Explain that securing the device will prevent damage to the unit during sudden stops. Ensure that the alerts and alarms are conspicuous.
2. Refer to the vehicle's operation manual to determine the current rating on the vehicle's DC accessory outlet. This information may be found in the vehicle Users Manual, marked near the outlet, or printed in the vehicle fuse box.
3. If the current rating is equal to or greater than 20 amps, move the red switch on the Power Supply to the "15A" setting. If the current rating is equal to or less than 15 amps, move the red switch on the Power Supply to the "10A" setting.

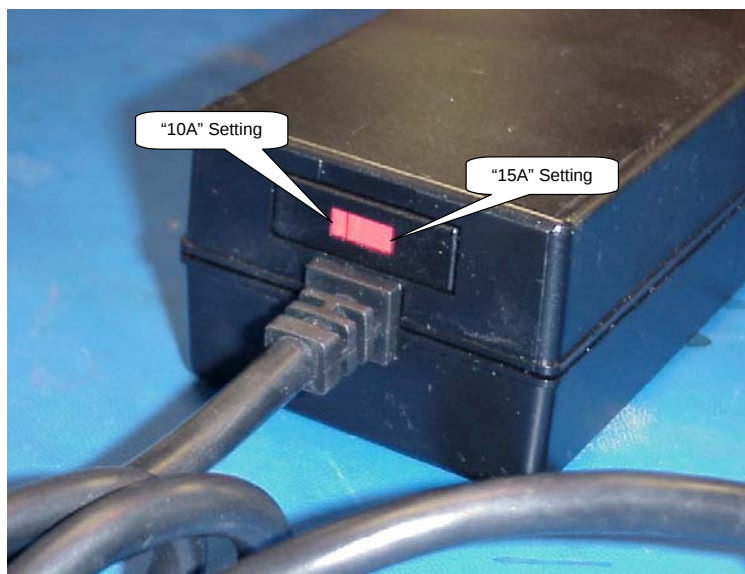


Figure 9: DC Power Supply Input Power Switch

CAUTION:	Be sure to accurately determine the amount of current the vehicle accessory outlet is rated to supply. Setting the Power Supply to draw 15 amps of current from a 10 amp power socket may damage your patient's vehicle electrical system.

4. Insert the DC Power Supply plug into the Eclipse.
5. Start the vehicle's engine.
6. Insert the plug into the vehicle's accessory outlet.

WARNING:	When using the Eclipse in a vehicle, always check the cannula to make sure it is not pinched or occluded.
	

WARNING:	• Avoid placing the device in direct sunlight. • Do not store the Eclipse 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 Power Cartridge.
	

Use the following table to determine whether your patient's vehicle DC power is sufficient to supply the necessary current to sustain your patient's desired flow rate.

It is recommended to use Pulse Flow if it is prescribed by the clinician.

The DC-DC Power Supply compatibility is as follows:

Flow Mode	Flow Setting	DC Power Supply Operation	
		15 Amp Mode	10 Amp Mode
Continuous	0.5 LPM	Yes	Yes
Continuous	1.0 LPM	Yes	Yes
Continuous	1.5 LPM	Yes	Yes
Continuous	2.0 LPM	Yes	Yes
Continuous	2.5 LPM	Yes	No
Continuous	3.0 LPM	Yes	No
Pulse	1	Yes	Yes
Pulse	2	Yes	Yes
Pulse	3	Yes	Yes
Pulse	4	Yes	Yes
Pulse	5	Yes	Yes
Pulse	6	Yes	Yes

Table 2: Flow Modes for DC Power Supply Operation.

Traveling by Air

When traveling by air, instruct your patient to remove the Power Cartridge from the Eclipse before checking the unit as checked baggage or cargo. Transport of the Eclipse as cargo or checked baggage with the Power Cartridge installed is prohibited by international air cargo regulations.

Air regulations allow individual airlines to restrict devices from being used on board aircraft. This includes the Eclipse Oxygen System. Instruct your patient to check with the airline company to determine if they permit the Eclipse Oxygen System to be used on board.

A list of airlines that allow the Eclipse to be used onboard the aircraft can be found at www.sequal.com. Each airline have their own requirements and it is recommended to check prior to making your trip.

If the airline allows use of the Eclipse Oxygen System, only operate the Eclipse from the Power Cartridge. The patient must ensure that they have an adequate number of spare Power Cartridges to last for the duration of their trip.

Traveling by Cruise Ship

When traveling by boat, instruct your patient to inform the cruise line that the Eclipse will be used on board. Each cruise line has a Special Needs coordinator that can answer any questions regarding travel and the cruise line 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 Eclipse will be used on board. Operate the Eclipse only from the Power Cartridge. The patient must ensure that they have an adequate number of spare Power Cartridges to last for the duration of their trip.

How to Maintain the Eclipse

Training your patient to maintain the Eclipse properly will lead to longer service intervals and lower maintenance costs. Train your patient to perform the following procedures:

Clean the Air Inlet Filter

The air inlet filter, located at the rear of the unit, must be cleaned at least once a week. To clean the filter:

1. Remove the filter from the back of the cabinet.
2. Wash the filter in warm water using a mild detergent solution.
3. Rinse the filter thoroughly and squeeze out the excess water.
4. Allow the filter to air dry thoroughly.
5. Re-insert the filter in the cabinet.



Figure 10: Cleaning the Air Inlet Filter

CAUTION:	• The filter should be completely dry before using it again. Excess moisture may impair proper operation or damage the unit. • Replace the Air Inlet Filter as needed. If the Eclipse is operated in a dusty environment, the filter may need to be cleaned or replaced more often. Do not operate the Eclipse for more than 30 minutes without a filter installed.

Clean and Care for the Tubing and Cannula

Provide your patient instructions on cleaning, disinfection and/or replacement information for the tubing and cannula.

Clean the Cabinet and Control Panel and Power Supplies

To clean the cabinet, control panel or power supply do the following:

1. Turn OFF the Eclipse and disconnect from AC or DC power before any cleaning or disinfection activity.
2. Use mild detergent and water solution.

3. Use a damp (not soaking wet) cloth or sponge.
4. Spray or wet the cloth or sponge with the mild detergent solution. **DO NOT** spray the cabinet, control panel or power supplies.
5. Wipe down the cabinet, control panel or power supplies.
6. To disinfect the Eclipse, use Lysol® Brand II disinfectant. Spray or wet a cloth or sponge with the disinfectant. **DO NOT** spray the cabinet, control panel or power supplies. Proceed as directed by the manufacturer.

Care for the Power Cartridge

The Power Cartridge (battery) in the Eclipse requires special care to assure a longer life and the highest level of performance. The SeQual Power Cartridge is the only approved Power Cartridge recommended for use with the Eclipse. The following are generic guidelines for the Power Cartridge:

- Avoid high temperatures
- Avoid cold temperatures
- Do not drop Power Cartridge
- No not poke objects into contacts

Power Cartridge Cleaning: Use a damp (not soaking wet) cloth or sponge. First spray the cloth or sponge with a mild detergent and then clean the Power Cartridge case and the latch.

WARNING:	Exposing the Power Cartridge to water or other liquids may cause personal injury or harm.
	

WARNING:	<u>DO NOT</u> tamper with or try to repair the Power Cartridge. There are no serviceable parts inside.
	

Power Cartridge Disposal: The Power Cartridge can be recycled. Contact the local city or town offices for instructions on proper disposal of the Power Cartridge. Alternately, SeQual may be contacted for the Power Cartridge disposal.

Power Cartridge Storage: The Power Cartridge should be stored in a cool and dry location.

Patient Training Checklist

Use the following checklist as a guide to assist in training a patient on the use of the Eclipse and its accessories.

Patient Name:	
Eclipse Serial #	DC Power Supply Lot #
AC Power Supply Lot #	Power Cartridge Lot #
Training Topic	Initials
Basic Concept Training	
Safety Guidelines and Operational Safety Warnings/Cautions	
Locating the Eclipse	
Panel Buttons and Indicators	
Alerts and Alarms	
Power Cartridge Power Level	
Selecting Flow Mode and Setting	
Connecting the AC Power Supply	
Connecting the DC Power Supply	
Active Lifestyle Training	
Attach the Cart	
Use Around the House	
Traveling by Vehicle	
Traveling by Air	
Traveling by Boat	
Traveling by Train	
How to Maintain the Eclipse	
Clean the Air Inlet Filter	
Clean and Care for the Cannula	
Clean the Cabinet and Control Panel	
Care for the Power Cartridge	
Trained By:	Date:

Provider Maintenance

Introduction

Maintaining the Eclipse will ensure longer life and higher performance. Periodic maintenance is recommended.

Periodic Maintenance List

Perform the following maintenance procedures, as needed. The frequency of the periodic maintenance should be based on the environment in which the Eclipse is used within.

- Check and clean air inlet filter. Replace as needed
- Check Power Cartridge
- Inspect AC and DC Power Supply plugs and cords for damage. Replace as needed
- Verify that the AC and DC Power Supplies operate with the Eclipse
- Readjust the Pulse Flow Sensitivity Adjustment, in between patients as needed
- Check 9V battery. Replace if needed
- Check cart for functioning wheels and telescoping handle. Replace as needed
- Read and record hour meter
- Check flow rate, purity, Pulse Mode and alarm functions
- Check compressor intake filter, replace as needed.
- Perform electrical safety test (Required only for PN 5701, Hospital Grade Power Cord)
- Replace HEPA filter

Checking and Replacing the Power Cartridge

Typically, the Power Cartridge will require no routine maintenance beyond cleaning by the patient.

SeQual recommends that the Power Cartridge be replaced if there is physical damage to the cartridge enclosure or connector, or if the excursion time is significantly less than published values at a given flow rate.

Proper Care for the Power Cartridge

- Avoid high temperatures
- Avoid cold temperatures
- Do not drop Power Cartridge
- No not poke objects into contacts

NOTE:	Dispose the Power Cartridge in accordance with local disposal regulations or return to SeQual.
--------------	--

Maintenance Procedures

The following section lists procedures that are necessary to maintain the Eclipse. Service should only be performed by a qualified technician. To perform periodic maintenance, the only tools that should be necessary are:

- #1 Phillips Screwdriver
- Wire-cutting pliers
- Small cable ties

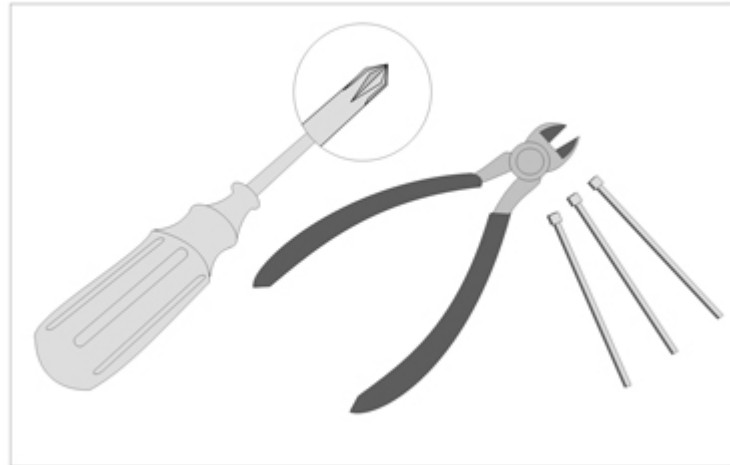


Figure 11: Maintenance Tools.

Remove and Replace the Unit Cover

1. Disconnect power supplies and remove Power Cartridge before removing the unit cover.
2. Place the unit horizontally on the front cover.
3. Using a Phillips #1 screwdriver, remove a total of 10 screws (M3x12 Pan Head SEM Screw, P/N 6974-312) from the back of the unit.

WARNING:	
	• Keep hands out of moving parts • Disconnect power supplies and remove Power Cartridge before removing the unit cover.

CAUTION:	The Eclipse contains electrostatic sensitive components. Do not open or handle except at a static free workstation.
	



Figure 12: Removing screws to open the Front Cover

4. Place the unit horizontally on the back cover.
5. Remove the front cover -- pop the bottom end off first and rotate it towards the handle. Be careful not to tear the control panel ribbon cable that is attached to the front cover.



Figure 131: Opening the Front Cover.

6. Disconnect the cable from the control panel as follows:
- Grasp the circuit board firmly between your fore fingers and thumb.
 - Grasp the head of the Membrane Panel Overlay cable in your other hand.
 - Gently pull the cable away from the board. It may be necessary to rock the connector slightly to dislodge the pins of the header.

CAUTION:	
	Do not disconnect the Membrane Panel Overlay cable by pulling on the ribbon cable.

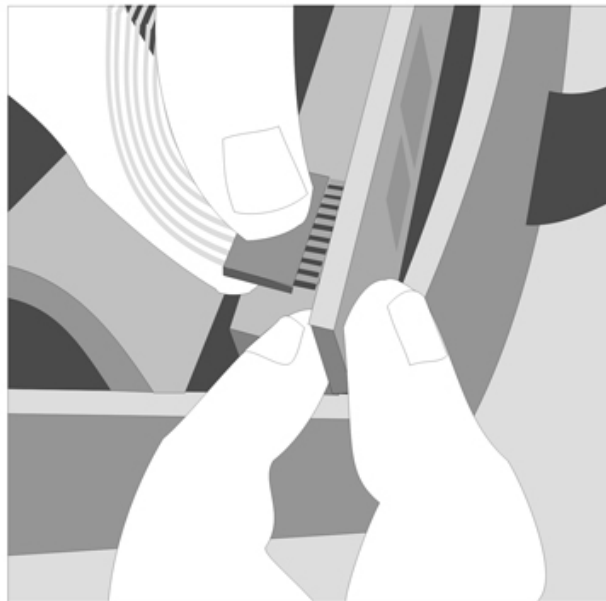


Figure 14: Removing the Membrane Panel Overlay Ribbon Cable.

7. Disconnect the silicone tube from the oxygen outlet tube at the top of the cover. First cut the cable tie, then pull the silicone tube off of the tube.

NOTE:	Always cut head of cable ties to avoid damaging the tubing.
--------------	---

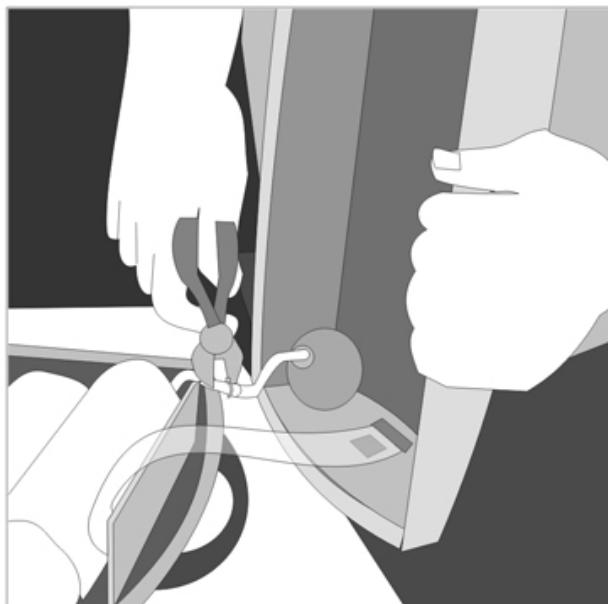


Figure 15: Disconnecting the Oxygen Outlet Tube.

8. Lay the front panel away from Eclipse. Perform necessary maintenance.

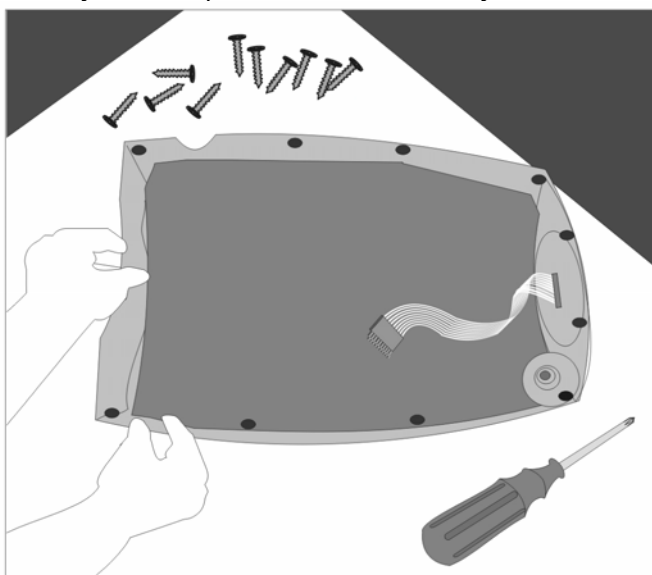


Figure 16: Front Cover Removal.

To re-install the cover, follow the steps using the reverse order. Ensure that the Membrane Panel Overlay cable plug is correctly lined up with circuit board connection and that there are no twists in the ribbon cable.



Figure 17: Membrane Panel Ribbon Cable Installation.

Align control panel over control module and then gently position cover. Verify that the black rubber gasket is aligned and fits properly. Do not over tighten cover screws.

NOTE:	After the cover has been reinstalled, but before installing screws on the cover, re-connect power and start unit. If alarm sounds, troubleshoot unit and repeat process.
--------------	--

NOTE:	Whenever the cover of the Eclipse is removed, proper functionality should be checked by following the Test Procedure described in this manual.
--------------	--

Remove and Replace 9 Volt Battery

Replace the 9-volt battery when the unit beeps three times at the end of power-on self-test or when voltage is less than 7.0 Volts. To replace the 9-volt battery, follow these steps:

WARNING:	Disconnect power supplies and remove Power Cartridge before removing the unit cover. Do not touch exposed circuits during maintenance.
	

1. Lift the battery out of the compartment located at the bottom right corner of the unit.

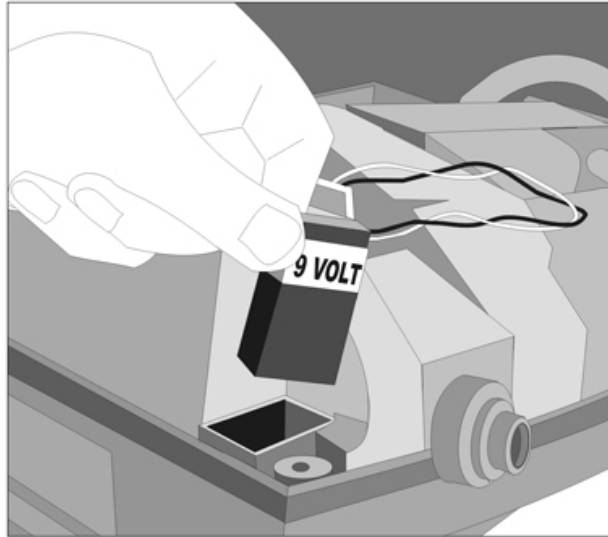


Figure 18: Removing the 9-volt Battery

2. Disconnect the 9-volt battery strap.
3. Remove and replace the 9-volt battery.

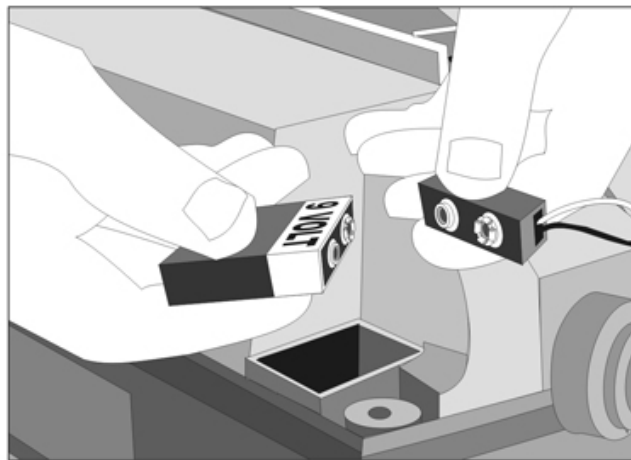


Figure 19: Disconnecting the 9-volt Battery.

4. Reconnect the battery strap. Ensure that the terminals are aligned correctly.
5. Place the battery back into the compartment.

Remove and Replace HEPA Filter

Replace the HEPA filter as needed. To replace the HEPA filter, follow these steps.

WARNING:	<u>DO NOT</u> use any petroleum based or other lubricants. A spontaneous and violent ignition may occur if oil, grease or other petroleum substances come into contact with oxygen under pressure. Keep these substances away from the oxygen system, tubing and connections and any other oxygen source.
	

NOTE:	Always cut head of cable ties to avoid damaging the tubing.
--------------	---

1. Cut the three cable ties on the silicone tubes attached to the HEPA filter.

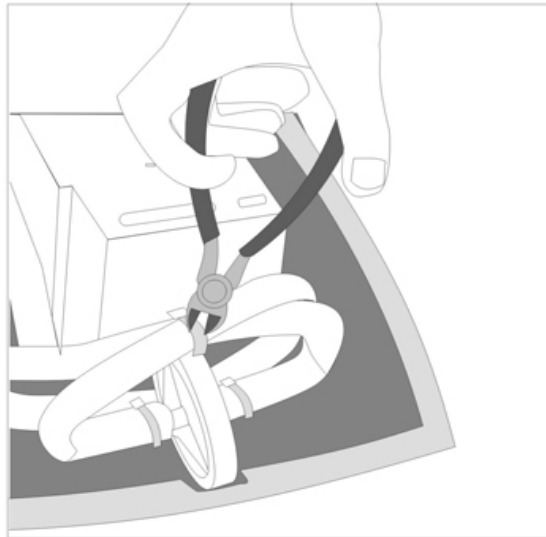


Figure 20: Removing the HEPA Filter.

2. Disconnect both tubes from the filter nipples.

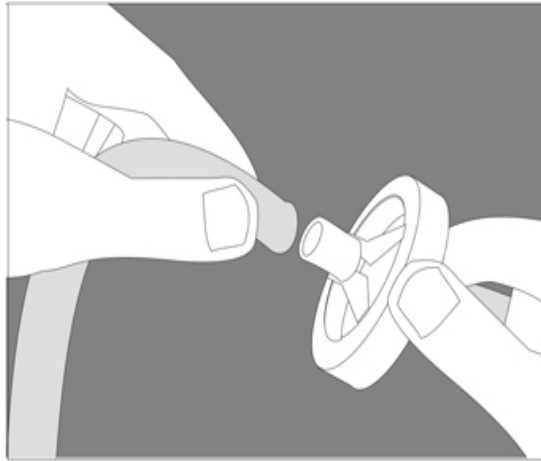


Figure 21: Disconnecting the HEPA Filter.

3. Remove and replace the filter.
4. Reconnect silicone tubes to the filter. Ensure that the feed tubes are not blocked, crimped or kinked upon completion of the installation or the unit will alarm for no/low oxygen flow after the warm-up cycle is complete. Route tubing as shown in Figure 22 below. Place HEPA filter into slot in case.

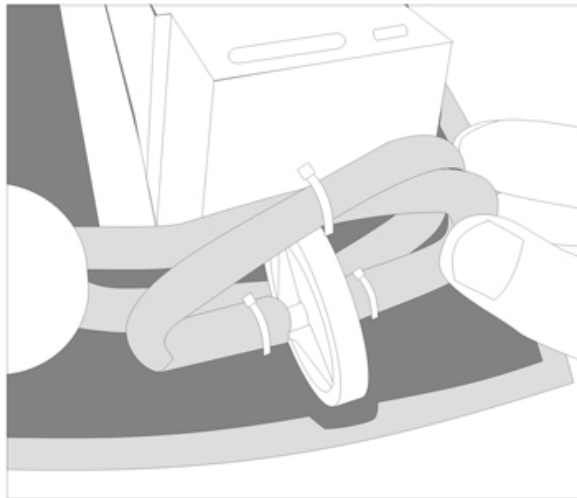


Figure 22: Installing the HEPA Filter.

NOTE:	Route tubing as shown in Figure 22. Install cable ties loosely as shown.
--------------	--

3. Re-install cable ties on silicone tubes.

CAUTION:	Once the silicone tubes are disconnected from the HEPA filter the oxygen circuit is exposed to the atmosphere. Replace and reconnect the filter <u>immediately</u> in order to minimize exposure to debris and humidity which may result in ATF Module damage.
	

Remove and Replace the Compressor Intake Filter

Replace the compressor intake filter as needed. The compressor intake filter may become clogged depending upon the amount of contaminants in the air (smoke, dust, dirt, pollen, etc.) and may need to be changed more frequently. The most common cause of low concentration and eventual system failure is a dirty or clogged compressor inlet filter. Environmental conditions usually determine the effective life of a filter.

CAUTION:	
	Operating the Eclipse with a clogged compressor intake filter may reduce performance and lead to system damage or premature failure.

NOTE:	Always cut head of cable ties to avoid nicking tubing.
--------------	--

To replace the compressor intake filter, follow these steps:

1. Cut the cable tie on the silicone tubes attached to the compressor intake filter.



Figure 23: Removing the Compressor Intake Filter.

2. Remove the silicone tubes attached to each end of the filter body.
3. Install a new filter by pushing each tube completely over the barb on the filter body.

4. Reconnect silicone tubes to the filter. Ensure that the feed tubes are not blocked, crimped or kinked upon completion of the installation or the unit will alarm for low oxygen purity after the warm-up cycle is complete.



Figure 24: Installing the Compressor Intake Filter.

5. Re-install two cable ties on silicone tubes.

After replacing the Compressor Intake Filter, check the following:

- Verify proper seating of the filter in the Eclipse. The arrow on the filter body should point toward the 9-volt battery.
- Ensure that the inlet tube is inserted securely into its hole in the compressor box and is not pinched.

After filter is replaced and unit cover reinstalled, proper functionality should be checked by following the Test Procedures described in this manual.

Test Procedures

Eclipse Purity and Flow Rate Test Procedure - Preferred Method

It is recommended that the Eclipse be tested for oxygen concentration and flow performance. SeQual recommended test setup is shown on the following diagram. Oxygen monitors may or may not have an internal pump to draw samples of oxygen to be measured. Placement of the oxygen monitor in the test setup depends whether they have an internal pump. Only one oxygen monitor is needed though. An oxygen monitor such as Salter Labs' PRO₂ Check Elite™ or equivalent may be used.

- Connect the circuit per the diagram shown below.
- Turn the concentrator on and set the target flow on the Eclipse to 3 LPM continuous flow.
- Allow the Eclipse to stabilize (can take up to 10 minutes).
- Verify the O₂ concentration and O₂ flow rate are within specification.

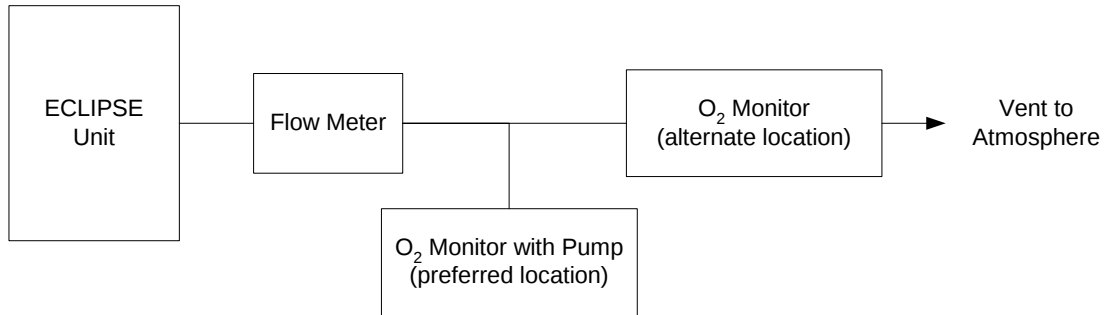


Figure 25: SeQual Recommended Test Setup to verify performance of Oxygen Concentrator

NOTE:	The Eclipse oxygen concentration and flow sensor cannot be calibrated in the field. If you suspect that the Eclipse flow and oxygen purity measurement is out of calibration, please return it to SeQual for service.
--------------	---

Purity and Flow Rate Test Procedure-Alternate Method

Attach a calibrated oxygen monitor to the oxygen outlet port in accordance with oxygen monitor manufacturer's recommendations.

NOTE:	Some sensing equipment may restrict the actual flow rate below what the Eclipse can provide and provide inaccurate concentration readings. If testing is performed with the oxygen monitor in the alternate location pictured above, ensure that the oxygen monitor does not significantly restrict oxygen flow.
--------------	--

Assembly and Alarm Verification Tests

To ensure proper assembly and functionality of the Eclipse after it has been reassembled, the following steps should be followed.

1. Install the Power Cartridge into the Power Cartridge compartment of the Eclipse. Plug the AC Power Supply into the wall outlet and connect it to the External Power Connector of the Eclipse.
2. Press the ON button and set the Eclipse to 2 LPM. At initial start-up Eclipse units light the Green, Yellow and Red LED's accompanied by a beep. As concentration increases to ~70%, the Red LED turns off and the Yellow and Green remain on. When the concentration reaches normal operating range (above 85%), the Yellow LED will turn off. The Green LED will stay lit indicating normal operation. Table 3 shows the normal start-up operating conditions for Eclipse Oxygen Systems. If LED is not green within 7 minutes there may be a problem with the Eclipse.

Green Indicator	Yellow Indicator	Red Indicator	Audible Alarm	Alarm code	Operating Condition
Off	Of	Blinking	Beeps	04	Purity < 70%
Off	Blinking	Off	Off	08	Purity between 70% and 85%
On	Off	Off	Off	00	Normal Operating Condition

Table 3: Eclipse Startup Sequence Indications

3. Verify that the Power Cartridge is charging as indicated by the Power Cartridge Status Gauge is moving from low to high. If the Power Cartridge Status Gauge is not moving, verify that the Power Cartridge is properly engaged.
4. Check the Control Panel by pressing each of the Increase/Decrease, Pulse Mode and No Smoking button and observe that the Eclipse buttons function normally.
6. Turn ON the Eclipse. Press the Pulse Mode button and set the Eclipse to the patient's normal Pulse Mode setting. Confirm that without breathing from the unit, the Pulse Flow Mode Indicator is illuminated and the Eclipse beeps, changes automatically to 2 LPM Continuous Mode within approximately 60 seconds and the Pulse Flow Mode Indicator turns off.
7. Block the Cannula Fitting Outlet with your finger for 2 minutes and confirm that the visual and audible alarm occurs. Unblock the Cannula Outlet Port and let it stabilize until the alarm stops.
8. Disconnect the AC Power Supply and allow the Eclipse to run for about one minute. Set the Eclipse to the patient's normal Continuous Mode setting. Confirm that the Power Cartridge Status Gauge is illuminated and External Power Present Indicator is off.
9. Remove the Power Cartridge and verify that the Eclipse alarms and red Alarm Indicator is flashing and the alarm sounds. After about 5 seconds, re-install the Power Cartridge and connect the AC Adapter and observe that the Eclipse automatically restarts. Confirm that the External Power Present Indicator is illuminated.
10. Turn off Eclipse and unplug the AC Power Supply.
11. Record results, initial and date the Service and Maintenance Record.

Record Hours of Operation and Software Version

To help maintain the Eclipse, you may obtain the Total Hours of Operation and software version numbers for the Control System and the Power Manager Systems.

To obtain system information, follow these steps:

Enable Provider Mode Functions:

- If connected to the AC or DC Power Supplies, press the “No Smoking” icon on the control panel and advance to the following display mode for each time the icon is depressed:
 - Alarm Code (AC)
 - Hours of Operation (H)
 - 9-volt Battery Status (9V)
 - Software Version (SW)
(Control Board and Power Manager Board)
 - Pulse Sensitivity (PS)
 - LCD Contrast (CT)
- If external power is not available and the power cartridge is installed, start by pressing the ON/OFF key for 1 second.
- If no key press is sensed within 5 seconds, the Eclipse will drop out of Provider Mode.

Figure 26: Data Output Form

Alarm Code		
Hours of Operation		
9-Volt Battery Status		Volts
Control Board Software Version		
Power Manager Board Software Version		
Pulse Sensitivity		
Contrast		

Log the Results

Notes:

- 1) The SW is displayed as two sets of numbers.

SW 21 20

- The left number set (21) is the Control Board Software Version
- The right number set (20) is the Power Manager Board Software Version

- 2) The display accrues to “99,999.9” hours, then rolls over to “00,000”.

Electrical Safety Test

To test the basic electrical safety of the Eclipse AC Power Supply, SeQual recommends using an LKG-601 Electrical Safety Analyzer (Netech Corporation, Hicksville, NY) or equivalent to verify that the current leakage to ground is within appropriate limits. **This is required only for the Eclipse Oxygen System, PN 5701 that utilizes the Hospital Grade Power Cord.**

1. Plug the AC Power Supply into the electrical safety analyzer. Disconnect the AC Power Supply from the Eclipse unit.
2. Plug the electrical safety analyzer into a wall outlet.
3. Follow the analyzer manufacturer's instructions for measuring both the forward and reverse earth leakage current only. Verify that forward and reverse-current leakage to ground is $\leq 250 \mu\text{A}$ (100/115VAC applications) and $\leq 500 \mu\text{A}$ (220/240VAC applications).
4. Disconnect the AC Power Supply from the electrical safety analyzer.
5. If the AC Power Supply measures leakage current greater than the criteria in step 3, please return it to SeQual for service.

Cleaning the Eclipse

Clean inside the unit, as needed, using a small vacuum cleaner or brush to remove any accumulation of dust or debris prior to attaching the covers. After reinstalling the cover, verify that the rubber gasket is installed correctly.

Use mild detergent solution to clean the cabinet, control panel and power supplies. Turn OFF the Eclipse and disconnect from AC or DC power before any cleaning or disinfection activity. **DO NOT** spray the cabinet control panel or power supplies. Use a damp (not soaking wet) cloth or sponge. Spray the cloth or sponge with a mild detergent solution to clean the cabinet and power supplies. To disinfect the Eclipse, use Lysol® Brand II disinfectant. Proceed as directed by the manufacturer.

WARNING:	
	Unplug Power Cords, AC or DC Power Supplies before cleaning the exterior cabinet. DO NOT use denatured alcohol or apply liquid spray or aerosol cleaners.

Service and Maintenance Record

Whenever maintenance or service is performed on an Eclipse unit, an entry should be made in the service log for that concentrator or recorded in accordance with your company's standard procedure. Whenever the case of the Eclipse is opened, the flow rate, purity, and alarm status should be verified per the Test Procedures in this manual

[illegible]

Table 4: Sample Eclipse maintenance record

Shipping and Transporting the Eclipse

When shipping the Eclipse use original packaging, if possible. Always remove the Power Cartridge and cart from the Eclipse prior to shipping.

If original packaging material is available repack the Eclipse, Power Cartridge, cart and power supplies in the designated packaging areas.

If original packaging material is not available, then place the Eclipse in a plastic bag and surround the concentrator with a minimum of two inches of soft foam packing material or bubble wrap. Wrap each accessory in a similar manner. Place the Eclipse and accessories in an appropriate cardboard box for shipping.

WARNING:	<u>DO NOT</u> exposes the Eclipse to water. The Eclipse enclosure does not provide protection against the harmful effects of liquid ingress. Electrical shock or damage to the unit may result.
	

When the Eclipse must be transported in a delivery vehicle, simply secure the Eclipse and its accessories to prevent damage. Do not expose the device to extreme heat, cold, or humidity.

Storing the Eclipse

Heat and humidity may degrade performance or severely damage the Eclipse. Store the device in a cool, dry, protected area away from high temperatures, moisture and humidity. Remove the Power Cartridge when storing the device.

Discarding

Power Cartridge Disposal: The Power Cartridge can be recycled. Contact the local city or town offices for instructions on proper disposal of the Power Cartridge. Alternately, SeQual may be contacted for the Power Cartridge disposal.

Eclipse Oxygen System Disposal: Local environmental laws may prohibit disposal of electrical and/ or electronic equipment such as the Eclipse, AC Power Supply or the DC Power Supply. Contact the local city or town offices for instructions on proper disposal of electrical or electronic equipment. Alternately, SeQual may be contacted for disposal information.

System Troubleshooting and Alarms

Troubleshooting

SYMPTOM	PROBABLE CAUSE	REMEDY
Eclipse does not power on when On/OFF button is pressed	No Power Cartridge installed	Install charged Power Cartridge or plug into external power
	Power Cartridge is discharged	Plug into external power
	Malfunction	Contact SeQual
No Oxygen	Blocked or kinked tubing	Check tubing or replace
	Filter Blocked	Clean Air Inlet Filter
	Humidifier	Check humidifier attachment and tubing
	Inlet or Exhaust Vent obstructed	Ensure proper ventilation
	Eclipse not ON	Turn Eclipse ON
	Tubing or cannula is not properly connected or kinked	Check tubing, cannula and connections
	Power Cartridge is discharged or no external power is present	Install charged Power Cartridge or attach external power
	Malfunction	Contact SeQual
Low Oxygen Concentration	Restriction in tubing or humidifier	Repair or replace tubing or humidifier
	Filter restricted	Clean or replace air inlet filter
	Malfunction	Contact SeQual
Low Oxygen Flow	Restriction in humidifier or tubing	Repair or replace humidifier or tubing
	Filter Blocked	Clean or replace air inlet filter
	Malfunction	Contact SeQual
No Oxygen delivered in Pulse Mode	Tubing/cannula longer than 7 feet (2.1m)	Attach 7 foot (2.1m) tubing/cannula
	Humidifier attached	Remove humidifier
	No inspiration detected	Increase Pulse Flow Sensitivity by changing sensitivity value to a lower number
	No inspiration detected	Contact SeQual
Auto-triggers in Pulse Mode (random pulsing)	Pulses without patient inhalations	Decrease Pulse Flow Sensitivity by changing sensitivity value to a higher number
Power Cartridge Status Gauge never indicates fully charged	Power Cartridge needs replaced	Replace with new Power Cartridge

Alarm Conditions and Alarm Codes

Use the table below to decode Eclipse alarm conditions. If other alarm codes are displayed by the Eclipse, contact SeQual for assistance.

Note: The following table is intended as a guide for the provider, not the user.

	Condition	Green Indicator	Yellow Indicator	Red Indicator	Audible Alarm	Alarm Code	What to do
TYPICAL CONDITIONS	"Warming Up. Please Wait."	On	On	On	Off	04	Wait. The system typically takes 3 - 5 minutes to reach specified performance.
	"3.0" (or flow setting)	On	Off	Off	None	00	Nothing. The system is operating properly at the specified flow rate.
UNIT NEEDS ATTENTION	"Low Power Cartridge"	On	Blinking	Off	Beeps	10	Plug into external power or replace with a charged Power Cartridge.
	"Warm Power Cartridge"	On	Blinking	Off	Beeps	02	Plug into external power or replace with a charged Power Cartridge.
	"9-Volt Battery"	Off	Off	Off	3 Beeps		The internal 9-Volt battery needs replaced.
	"O ₂ Concentration < 85%"	Off	Blinking	Off	Off	08	Continue Use. Check or clean air intake filter. If condition persists, service is required.
	"O ₂ Concentration < 70%"	Off	Off	Blinking	Beeps	04	Continue Use. Check or clean air intake filter. If condition persists, service is required.
	"Flow Rate Error/Blocked Flow"	Off	Blinking	Off	Beeps	20	Check tubing and/or humidifier for obstruction. Check/clean air intake filter. If condition persists past 10 minutes. If condition persists, service is required.
	"Cannot Charge Power Cartridge"	Off	On	Off	Off	01	Instruct patient to seek an external power source. Remove Power Cartridge and allow to cool to room temperature. If Power Cartridge malfunction persists, service is required.
	"No Inspiration Detected" (in Pulse Flow Mode only)	On	On	Off	Off	20	Make sure tubing does not exceed 7 ft (2.1m) when using Pulse Flow Mode. An alert (yellow LED) will begin after 45 seconds if no inspiration is detected. If no inspiration is detected 15 seconds after that, the Eclipse will activate a single beep and will automatically switch to Continuous Flow Mode operation.

	Condition	Green Indicator	Yellow Indicator	Red Indicator	Audible Alarm	Alarm Code	What to do
SHUTDOWN CONDITIONS	"Power Cartridge Shutdown or hot Power Cartridge " (with no external power present)	Off	Off	Blinking	On		Instruct patient to seek an external power source. Remove Power Cartridge and allow to cool to room temperature. If Power Cartridge malfunction persists, service is required.
	"Loss of External Power" (without charged Power Cartridge installed) *Note: Stars will be flashing in the LCD *****"	Off	Off	Blinking	On	40	Instruct patient seek an alternative oxygen supply until external power is restored or install a charged Power Cartridge.
	"System Fault"	Off	Off	On	On		Instruct patient to use back up oxygen supply. Service is required.

Service and Repair Procedures

System Schematics and Diagrams

Simplified Block diagram

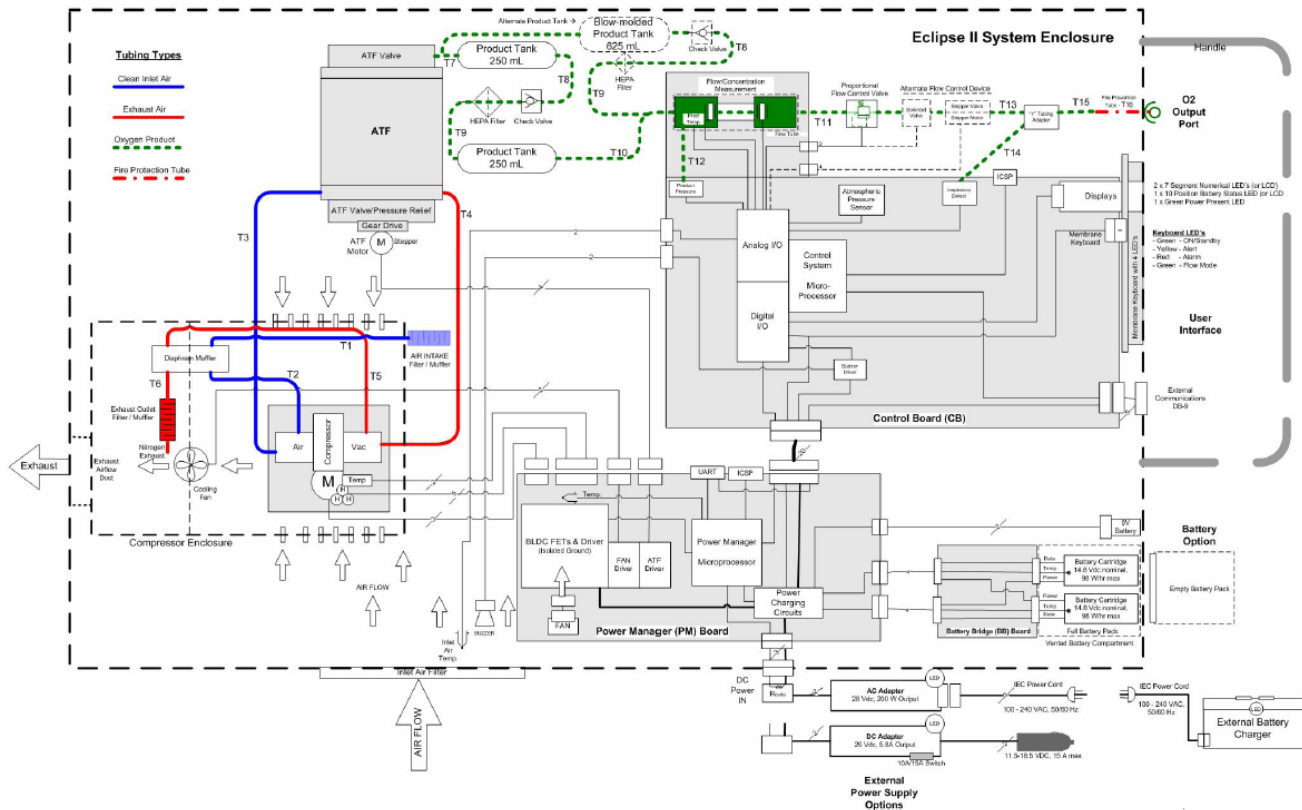


Figure 27: Eclipse 2 Oxygen System Simplified Block Diagram.

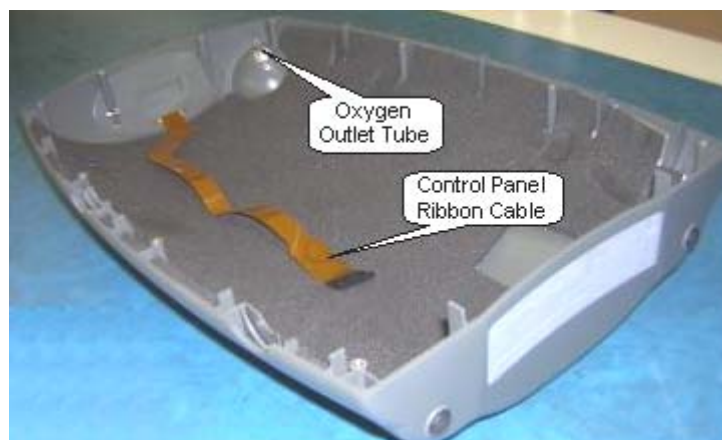


Figure 28: Top Case Components.

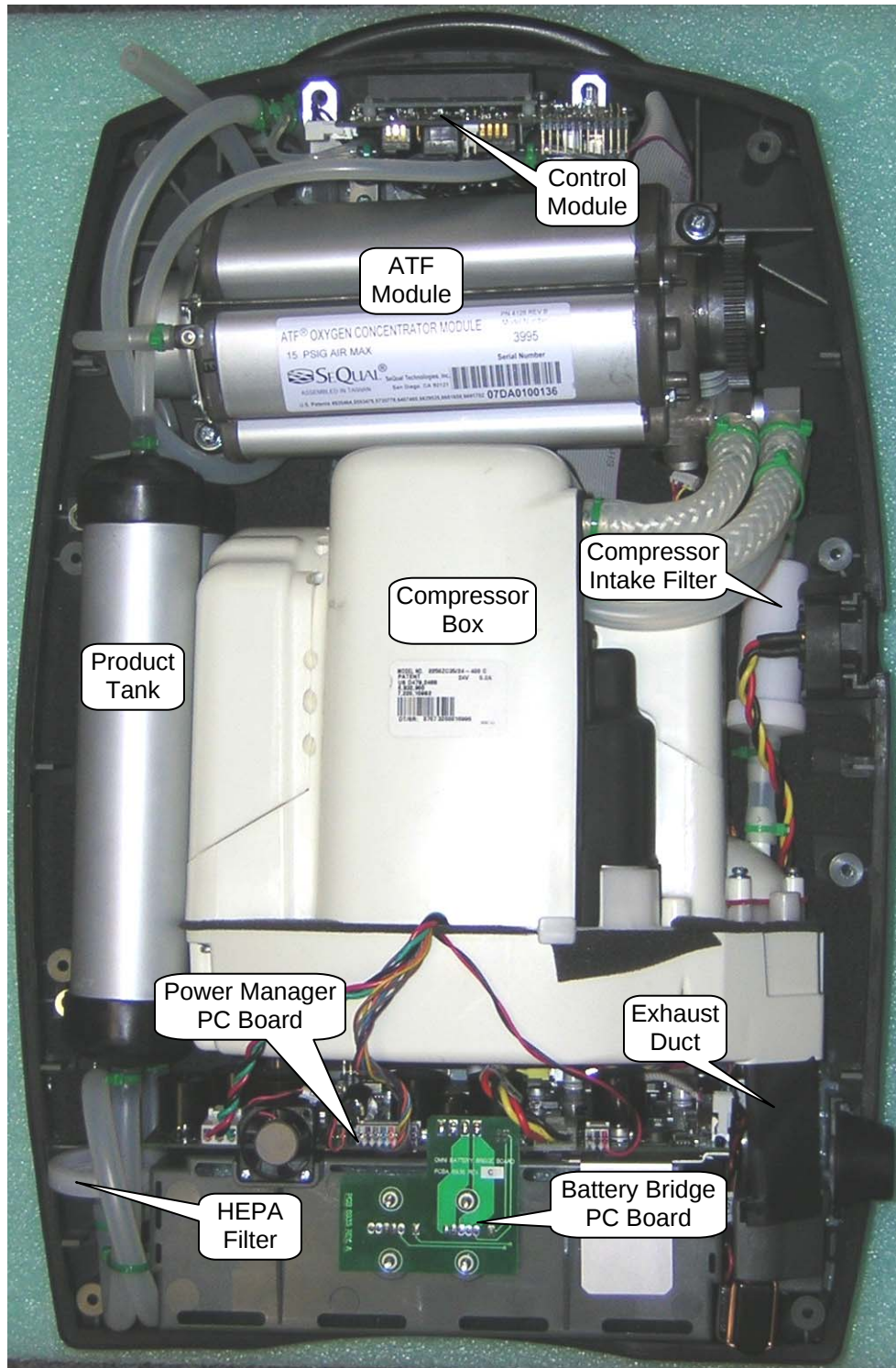


Figure 29: Bottom Case Components.

Oxygen Circuit

Remove and Replace the ATF Module

NOTE:	There are no serviceable parts inside the ATF Module. Do not attempt to disassemble or modify the ATF Module.
--------------	---

7. Remove the Unit Cover as described in the section Remove and Replace the Unit Cover.
8. Cut the green tie as shown below, and disconnect the silicone tube that goes into the product port of the ATF; this tube comes from the Product Tank.

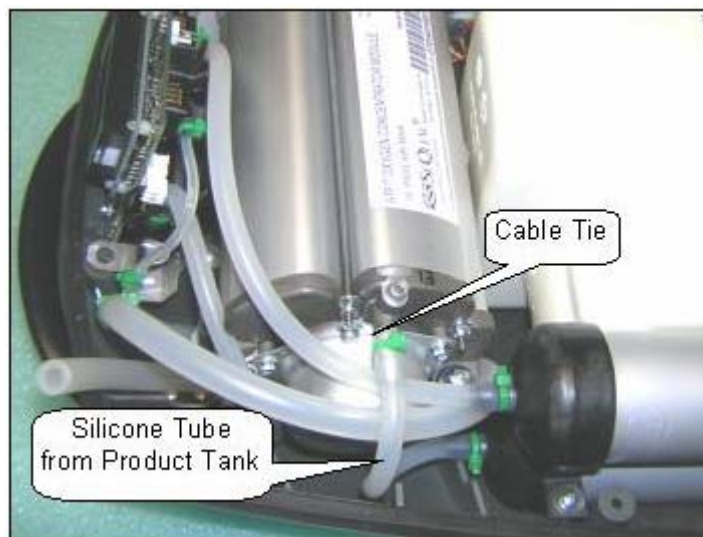


Figure 30: Removal of ATF Module Product Hose.

9. Cut the green cable tie that secures the silicone tube to the braid tube at shown in below Figure.

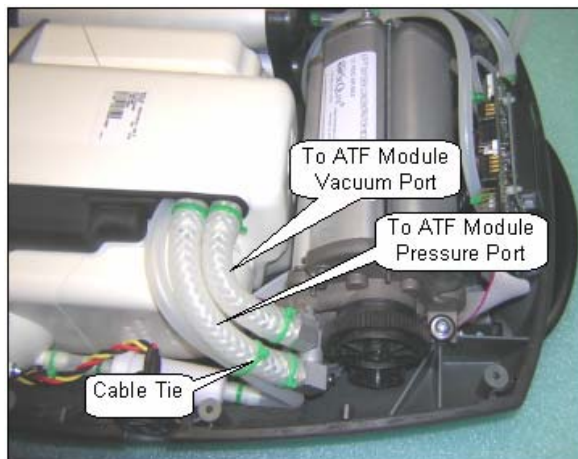


Figure 31: Removal of ATF Module Pressure and Vacuum Tubes.

10. Cut the green cable ties to the braided tubes that connect into the ATF pressure and vacuum ports as shown in below Figure. Disconnect the braided tubes.
11. Unscrew the 3 screws (M4x16 Pan Head Machine Screw, P/N 6961-416) and remove the screws and washers (M4 Flat washer, P/N 6985-04) as shown below.

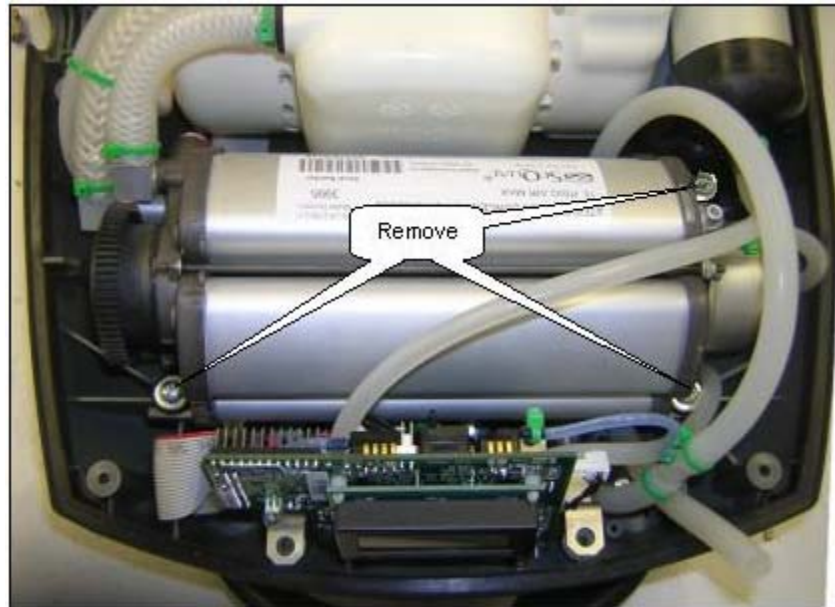


Figure 32: Remove ATF Module from Eclipse Case.

12. Lift the ATF. Take off the 3 grommets. Disconnect the wire harness from the gearbox of the ATF.
13. Remove the ATF and cap the product, pressure and vacuum ports.
14. Install 3 Grommets into the mounting slots on the ATF as shown below. Position the ATF into the bottom cover but DO NOT install the mounting screws yet. Route the 16" Silicone Tube under the ATF as shown on Figure 34 below.



Figure 33: ATF Module Grommet Installation.

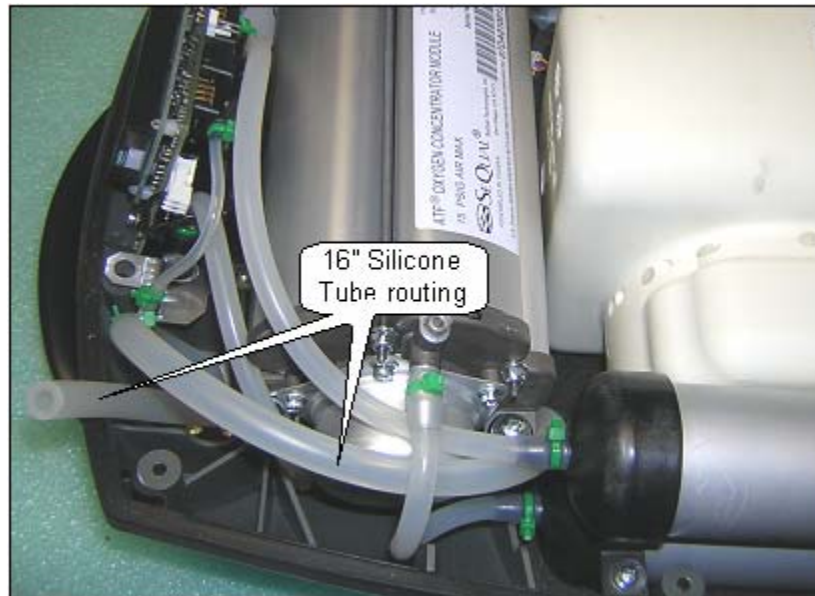


Figure 34: Tube Routing under ATF Module.

15. Place the ATF in the Unit Case and remove the caps from the ATF Ports. Install the Braided Tubes into the ATF pressure and vacuum ports as shown on Figure 31. Do not use oil or grease if the tubing is difficult to install. Secure joints with Cable ties.

WARNING:	DO NOT use any petroleum based or other lubricants. A spontaneous and violent ignition may occur if oil, grease or other petroleum substances come into contact with oxygen under pressure. Keep these substances away from the oxygen system, tubing and connections and any other oxygen source.
	

NOTE:	Inspect all tubing before securing with a cable tie.
--------------	--

16. Mount the ATF with 3 M4x16 screws and 3 washers as shown on Figure 32 above. Apply Loctite® 425 Thread Locker on the threaded tips of the screws before installing. Tighten screws but **DO NOT** squash the grommets.

CAUTION:	Remove caps on ATF ports ONLY before connecting the tubes. DO NOT leave the ports open unless ready to install the tubes. Also place the removed caps from the new ATF and place on the ports of the replaced ATF.
	

17. Remove caps from ATF Module.
18. Connect the silicone tube from the Product Tank into the product port of the ATF and secure joints with cable ties as shown on Figure 30 above.
19. Use cable tie to secure the silicone tube to the braid tube to ensure that there is NO kinking on the bend as shown on Figure 31 above. Hand-tighten the cable tie. Inspect the tubing to ensure the tubing is not kinked.
20. Installation of the Unit Cover on the unit is described in the Remove and Replace of the Unit Cover.

Remove and Replace the Product Tank Assembly

1. Remove the Unit Cover as described in the section Remove and Replace the Unit Cover.
2. Cut the 2 green cable ties that secure the silicone tubes to the top of the Product Tank as shown in Figure 35 below. Disconnect these two silicone tubes. Pinch the silicone tube coming from the ATF product port and secure with a cable tie as shown on Figure 36 below.

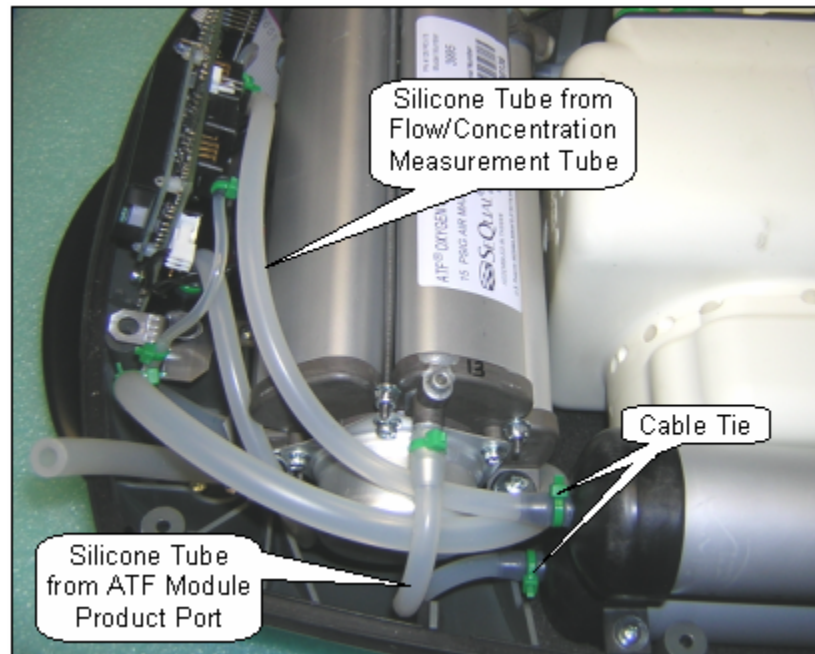


Figure 35: Product Tank inlet and Outlet Connections.

3. Unscrew the 2 screws (M3x10 Plastite Screw, P/N 6950-310) and remove the screws and washers (M3 Flat Washer, P/N 6950-03) as shown in Figure 36 shown below.

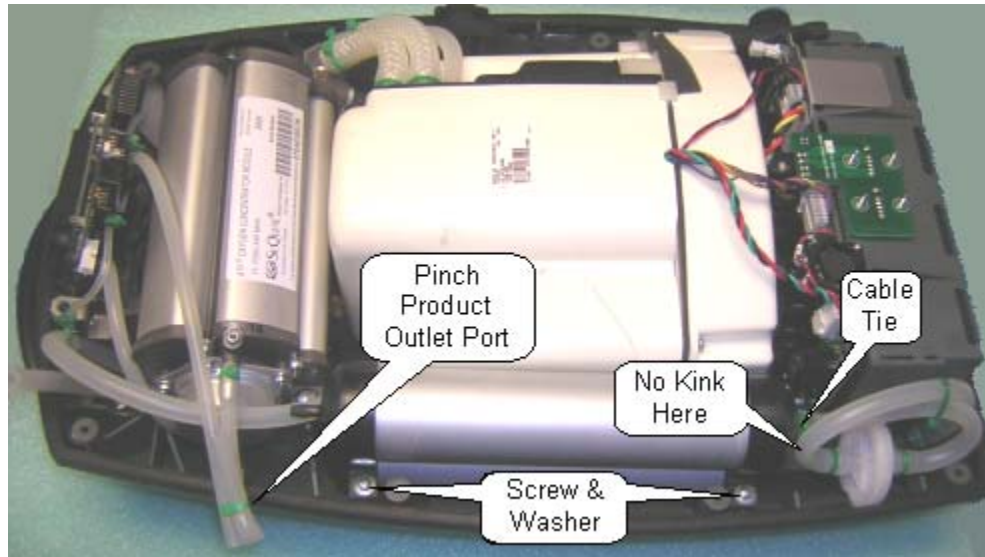


Figure 36: Product Tank Removal.

4. Remove the Product Tank.
5. Cut the 2 green cable ties that secure the silicone tubes to the bottom of the Product Tank as shown in Figure 35 above. Disconnect these two silicone tubes.
6. To reinstall, secure the 2 silicone tubes coming from the HEPA filter to the bottom ports of the Product Tank. Orient the HEPA filter so the loop is above the filter as shown in Figure 36 above. Secure joints with cable ties. Inspect the tubing to ensure the tubing is not kinked.
7. Install the silicone tube that comes from the ATF product port to the bottom Product Tank as shown in Figure 35 above. Secure with a cable tie. Inspect the tubing to ensure the tubing is not kinked.
8. Install the silicone tube that comes from the flow tube of the control module to the top product tank as shown in Figure 35 above. Secure with a cable tie. Inspect the tubing to ensure the tubing is not kinked.
9. Install Product Tank with 2 screws and 2 flat washers into the Unit Case as shown in Figure 36 above.
10. Installation of the Unit Cover on the unit is described in the Remove and Replace of the Unit Cover.

Routing Diagram for Pneumatic Tubing

Use the picture below as an aid to ensure proper routing of oxygen tubing in the Eclipse.

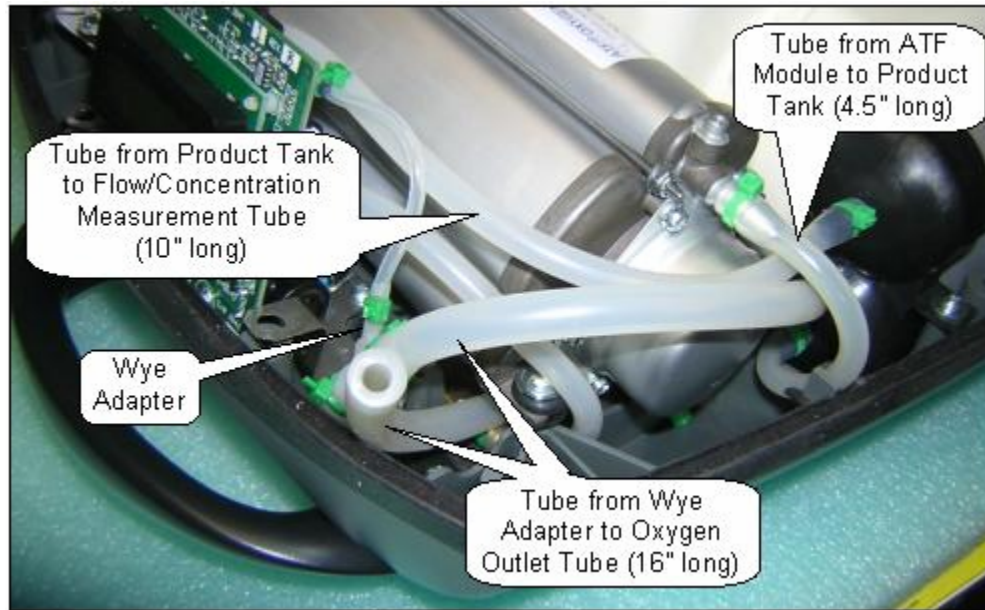


Figure 37: Oxygen Tubing Routing

Electronics

Remove and Replace the Control Module Assembly

CAUTION:		The Eclipse contains electrostatic sensitive components. Do not open or handle except at a static free workstation.

NOTE:	The Control Module Assembly is factory calibrated as a single unit. Do not disassemble the Control Module Assembly.
--------------	---

1. Remove the Unit Cover as described in the section Remove and Replace the Unit Cover.

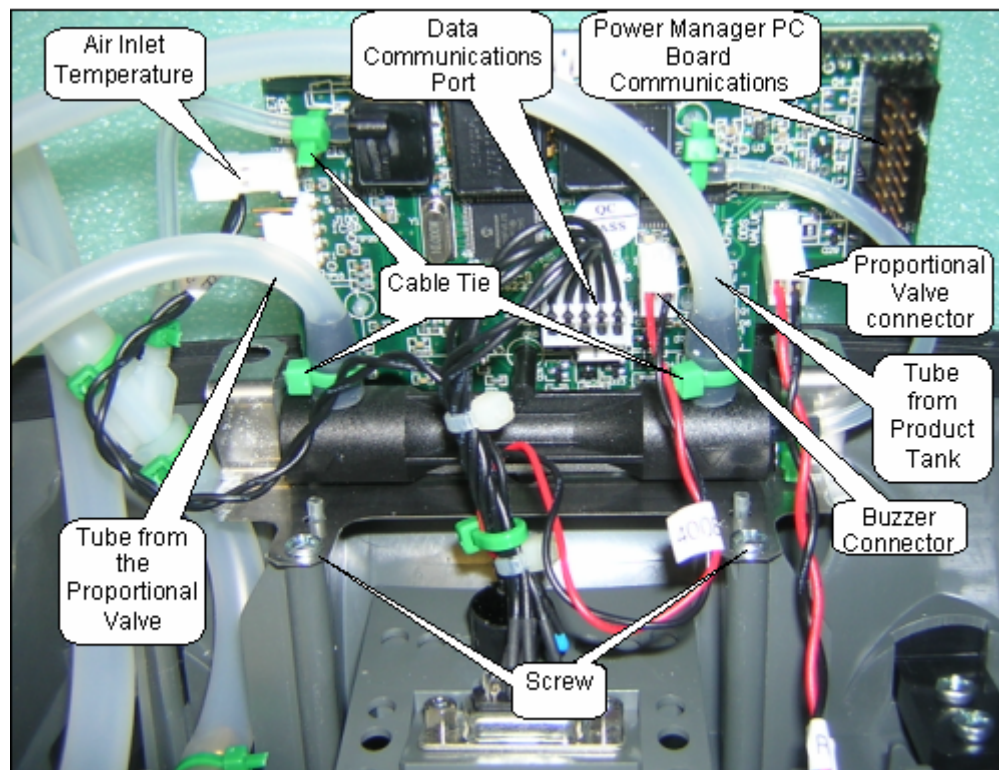


Figure 38: Control Module Removal (ATF Module not shown for clarity).

2. Remove the 2 screws (M3x10 Plastite Screw, P/N 6950-310) holding the Control Module Assembly to the Unit Case as shown in Figure 38.

NOTE:	Use a magnetized Phillips #1 screwdriver to remove the screws. This greatly reduces the chances of dropping a screw in the Unit Case.
--------------	---

3. Lift the Control Module Assembly and disconnect the Inlet Air Temperature, Data Communications Port, Power Manager PC Board Communications, Proportional Valve wire harness, and Buzzer wire harnesses as shown in Figure 38.
4. Lift the control module out of the Unit. Cut the green cable tie to the silicone tube that is connected to the sensor as shown in Figure 39. Disconnect the silicone tube that is attached to the sensor. Cut the green cable ties to the silicone tubes that are connected to the flow tube as shown in Figure 39. Disconnect the silicone tubes that are attached to the flow tube.
5. Pinch the silicone tube coming from the ATF product port and secure with a cable tie.
6. Remove the Control Module Assembly.
7. To install a new Control Module Assembly, cut the cable tie used to pinch the silicone tube coming from the product tank. Attach this tube and the tubes from the Proportional Valve and from the Product Tank to the flow tube as shown in Figure 38. Secure with a cable tie. Connect the silicone tube to the sensor as shown in Figure 38. Secure with a cable tie. Place the 2 screws in the sheet metal bracket as shown in Figure 39. Inspect the tubing to ensure the tubing is not kinked.
8. Lower the Control Module Assembly into the Unit Case only to where the aligning pins go through the sheet metal bracket; make sure the sheet metal bracket is 1/8" above the supporting ribs – this will ensure the 2 screws stay in the bracket and do not fall in the unit case as shown in Figure 39. Start the 2 screws by turning them 2 times into the unit case. After starting **both** screws, lower the Control Module Assembly onto the supporting ribs; tighten the 2 screws to the unit case.

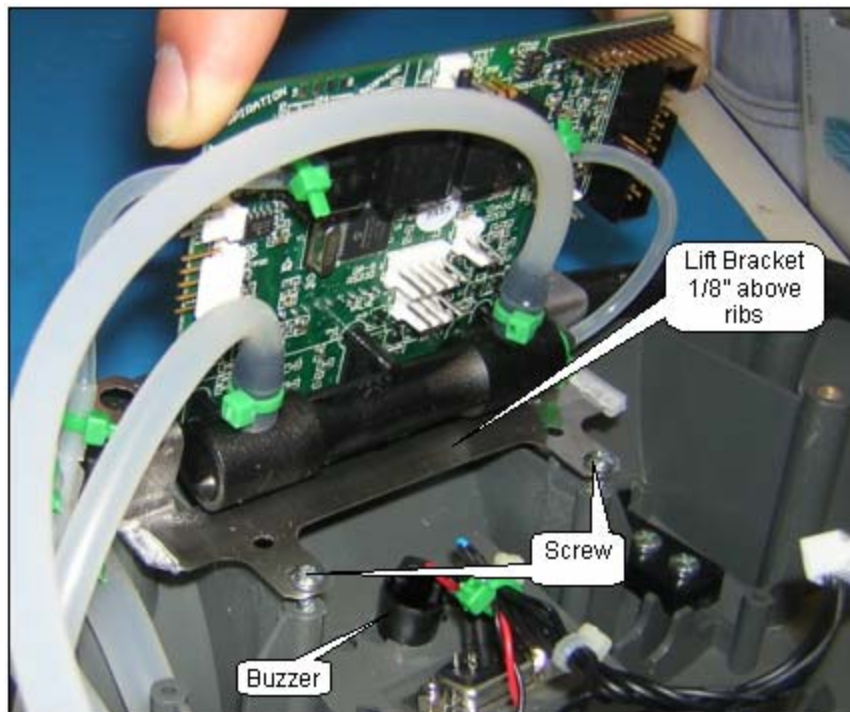


Figure 39: Control Module Installation.

9. Connect the Inlet Air Temperature, Data Communications Port, Power Manager PC Board Communications, Proportional Valve wire harness and Buzzer wire harnesses as shown on Figure 38.
10. Installation of the unit cover on the unit is described in the Remove and Replace of the Unit Cover.

Remove and Replace the Buzzer Wire Harness

1. Unplug the buzzer from the Control Module PC Board.
2. Remove the Control Module.
3. To remove the buzzer from the case, cut the cable tie, grasp the buzzer body with a pair of pliers and rotate the buzzer to break the adhesive joint.
4. To install a new buzzer, apply a ring of cyanoacrylate adhesive (Super Glue) around the inlet hole as shown in Figure 40.

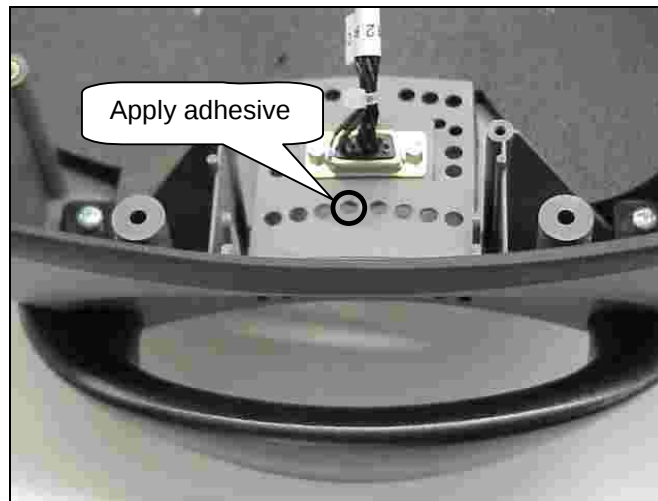


Figure 40: Bonding the Buzzer to the case.

5. Place buzzer as shown in figure 41. Ensure that the buzzer opening is centered over the grill hole. Hold in place until adhesive cures.

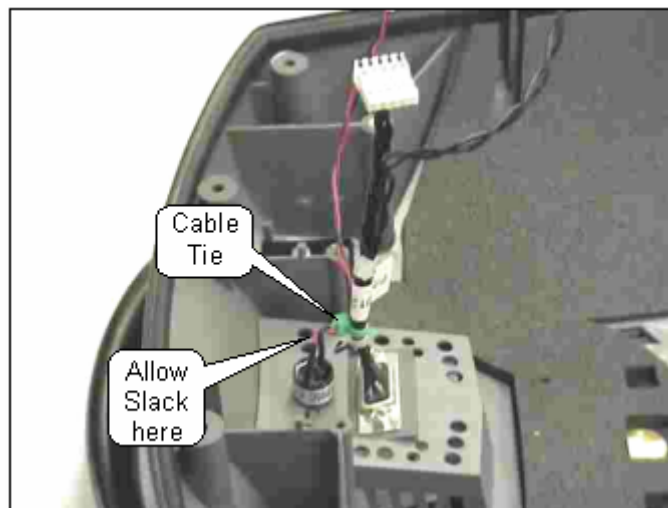


Figure 41: Buzzer Installation.

6. Install the Control Module Assembly. Secure the wire harness with Cable as shown on Figure 41. Insure that there is a slack on the wire harness before tightening the Cable Tie. Plug in the buzzer.

Control Module Connector Diagram

Use the figure below as an aid to ensure proper connection of wire harnesses to the Power Manager printed circuit board.

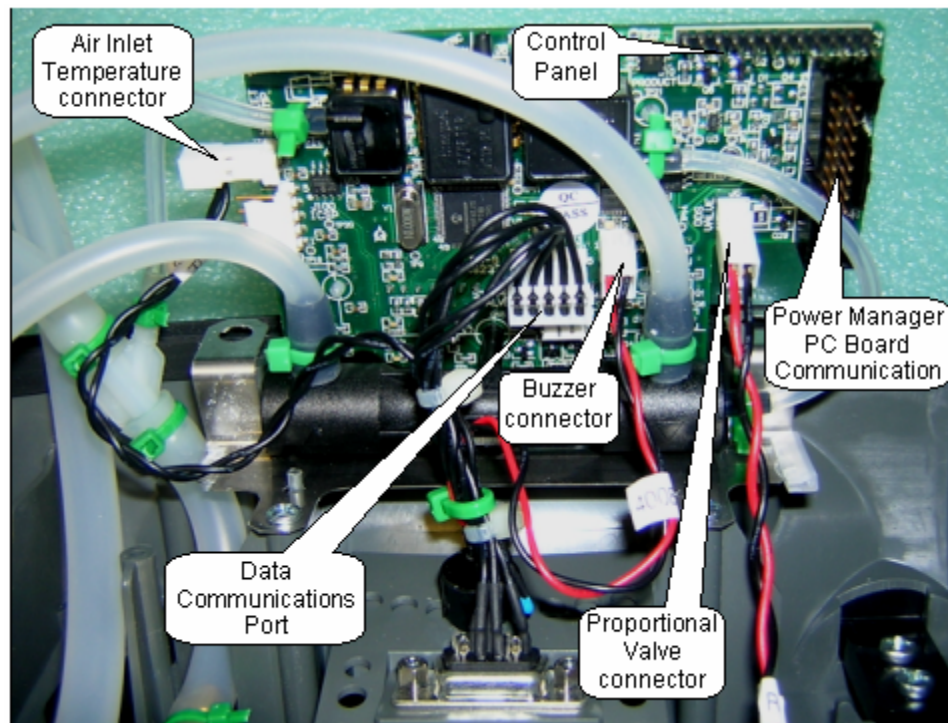


Figure 42: Control Module Connector Diagram.

Remove and Replace the Power Manager Printed Circuit Board

CAUTION:	The Eclipse contains electrostatic sensitive components. Do not open or handle except at a static free workstation.
	

1. Remove the Power Cartridge and unscrew the 4 screws (M3x12 Pan Head SEM Screw, P/N 6974-312) shown in Figure 43.

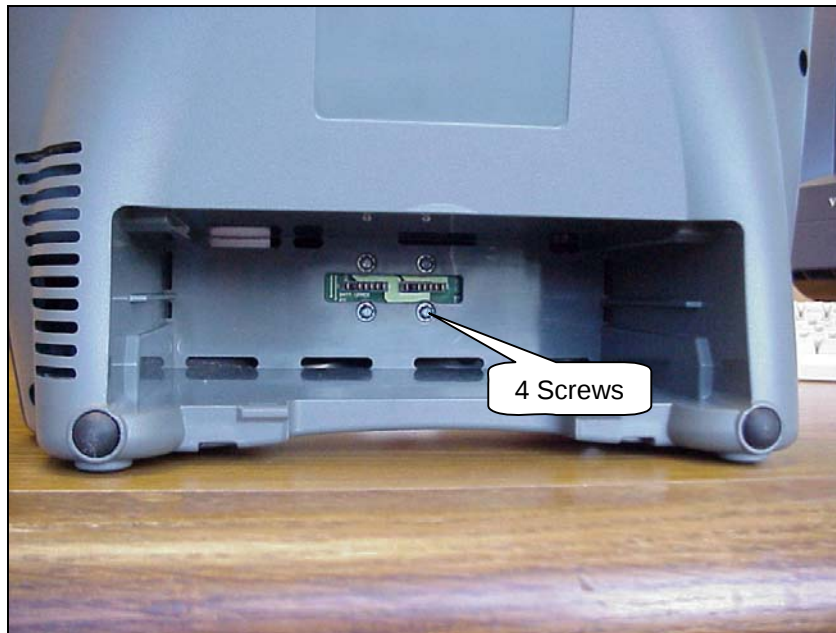


Figure 43: Battery Bridge Board Removal.

2. Remove the Unit Cover as described in the section Remove and Replace the Unit Cover.
3. Disconnect the 5 wire harnesses as shown in Figure 44. Remove the Battery Bridge PCB as shown in Figure 44

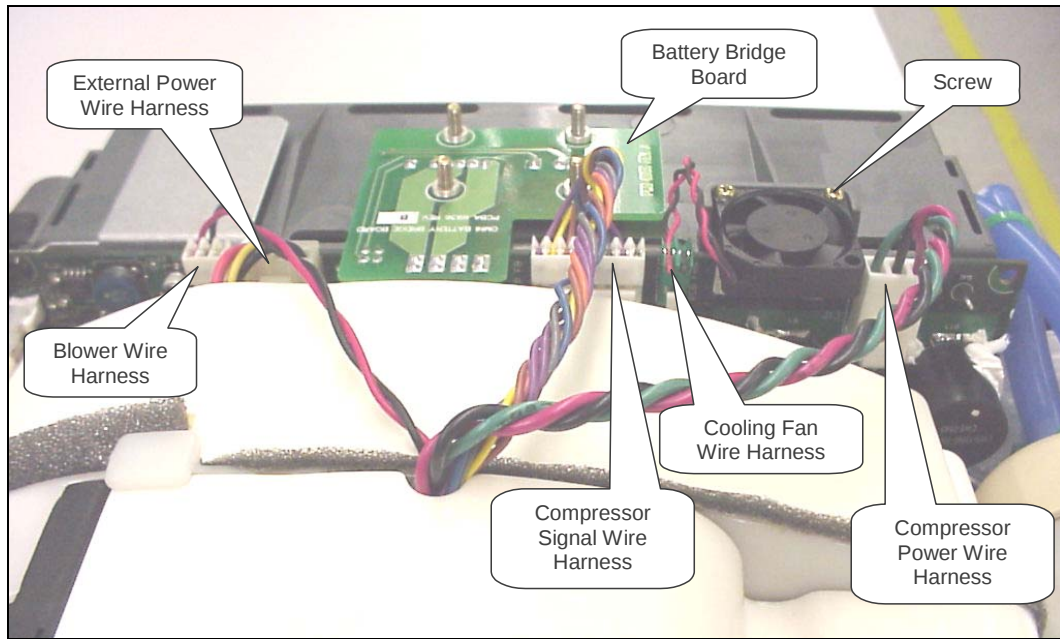


Figure 44: Power Manager PC Board Removal.

4. Unscrew the 2 screws (M2x10 Pan Head Machine Screw, P/N 6961-210) holding the fan shown in Figure 44. Remove fan.
5. Remove the Exhaust Tube shown in Figure 45

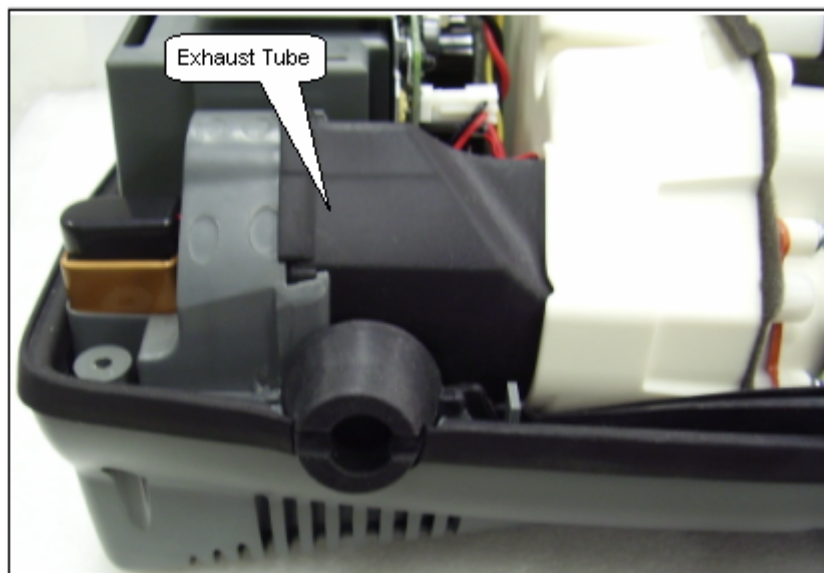


Figure 45: Exhaust Tube Removal.

6. Pull the Power Manager PCB 1" out of the unit case. Gently push the Compressor Box away from the Power Manager PCB by 1/8". Disconnect the 2 wire harnesses and the ribbon cable shown in Figure 46. Remove the Power Manager PC Board.

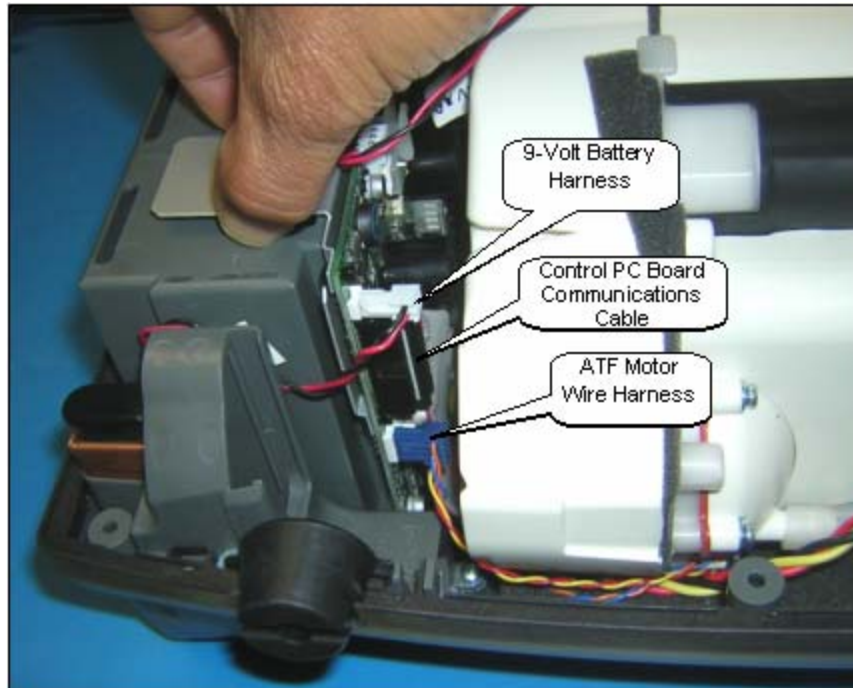


Figure 46: ATF Motor, 9-Volt Battery, and Control PC Board Communications Wire Harness Removal.

7. Position the new Power Manager PCB 1" out of the unit case as shown in Figure 47. Gently push the Compressor Box away from the Power Manager PCB by 1/8". Connect the 2 wire harnesses and the ribbon cable. Position the Power Manager PCB into the slots on the Unit Case.
8. Install the fan with the 2 screws and lightly tighten as shown in Figure 44. Apply Loctite 425 Thread Locker on the tips of the screws before installing. Ensure that it is blowing down as indicated by the arrow on the side of the Fan.
9. Install the Battery Bridge PCB and 4 wire harnesses shown in Figure 44.
10. Screw in the 4 screws shown in Figure 43.
11. Hold onto the Compressor Box and lift the Bottom Case in standing position. Insert the Exhaust Tube into the slot of the Exhaust Duct as shown on Figure 45 above. Ensure that it is secure without any gaps.
12. Install the Unit Cover as described in the section Remove and Replace the Unit Cover.

Power Manager PC Board Connector Diagram

Use the picture below as an aid to ensure proper connection of wire harnesses to the Power Manager printed circuit board.

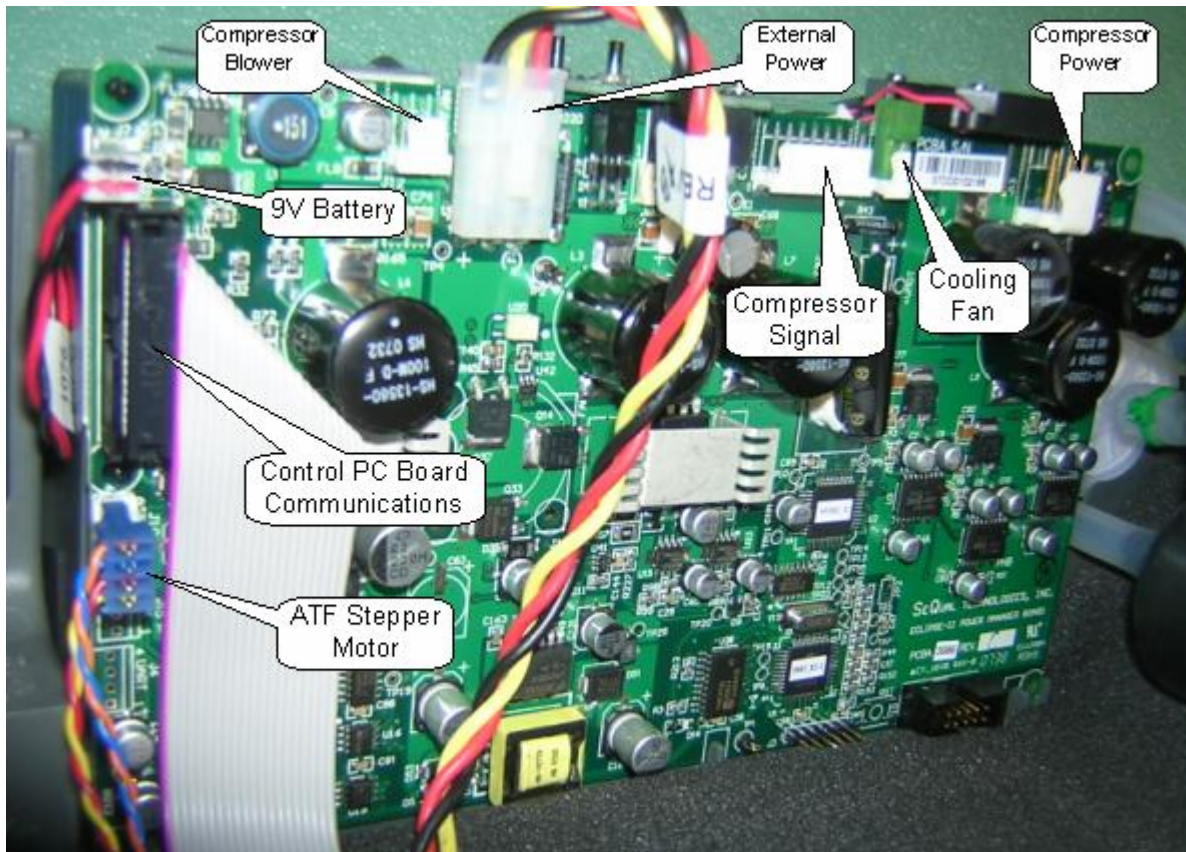


Figure 47: Power Manager PC Board Connector Diagram.

Compressor

Remove and Replace the Compressor Box

NOTE:	There are no field serviceable parts inside the Compressor Box. Do not attempt to disassemble or modify the Compressor Box in the field.
--------------	--

1. Remove the Unit Cover as described in the section Remove and Replace the Unit Cover.

CAUTION:	The Eclipse contains electrostatic sensitive components. Do not open or handle except at a static free workstation.
	

2. Flip unit over onto a padded ESD safe surface. Using a small flat tip screwdriver to pry open the cover at each pry point, remove the Case Bottom Cover as shown in Figure 48.

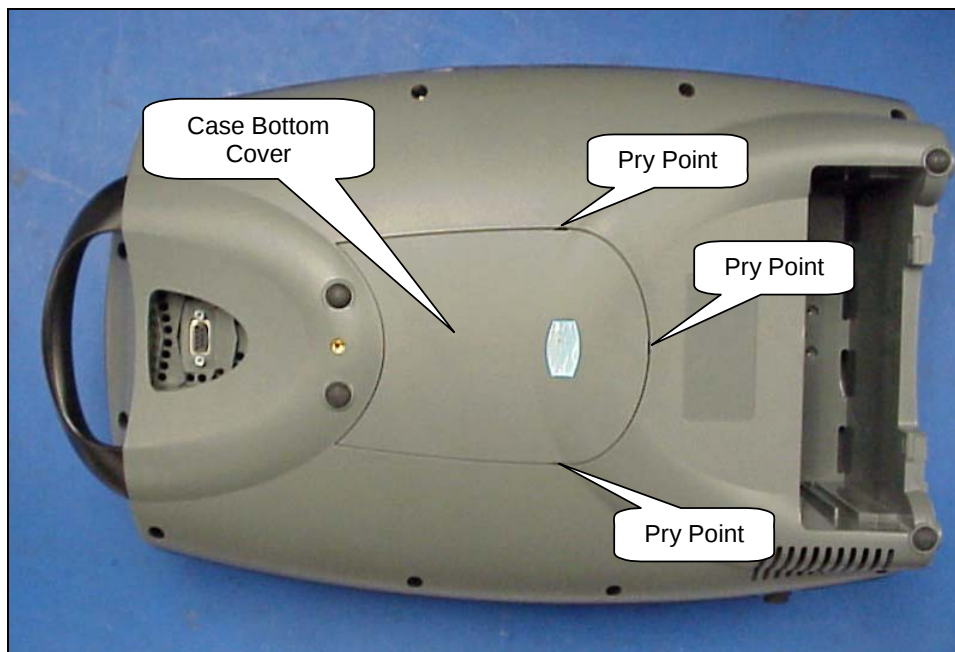


Figure 48: Case Bottom Cover Removal.

3. Disconnect the 3 wire harnesses shown in Figure 49.

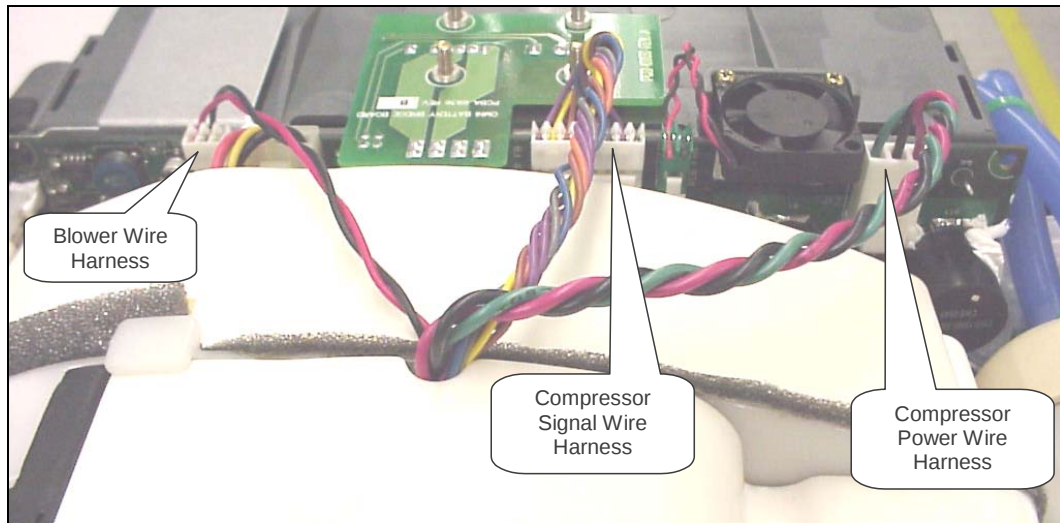


Figure 49: Compressor Box electrical connections.

4. Remove the Exhaust Tube as shown in Figure 50.

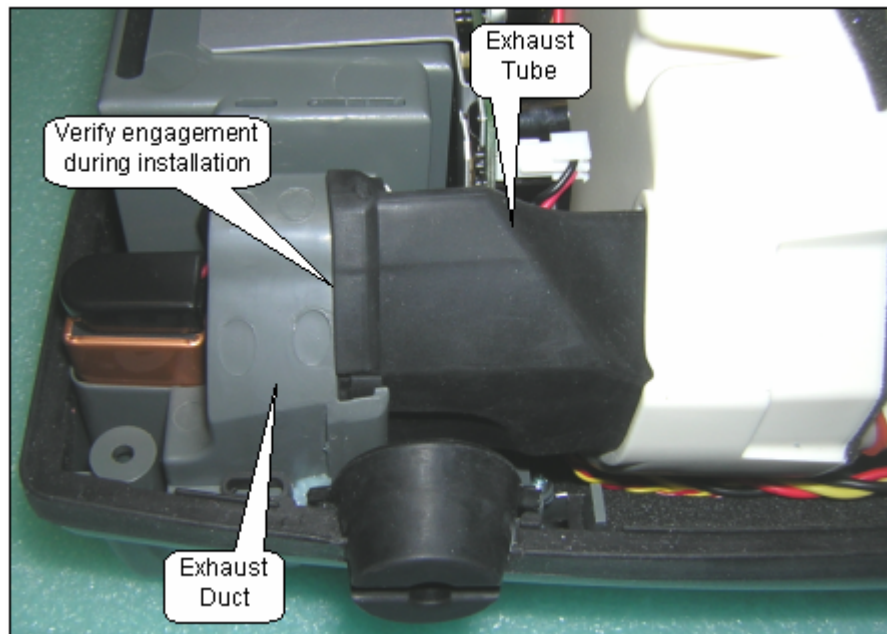


Figure 50: Exhaust Tube Removal.

5. Cut the three green cable ties shown in Figure 51. Disconnect the two braided hoses from the pressure and vacuum ports of the ATF. Cap the three ATF module ports using tight fitting vinyl caps or vinyl electrical tape.

CAUTION:	Once the braided hoses are disconnected from the ATF Module the ATF Module is exposed to the atmosphere. Cap the ATF Module ports <u>immediately</u> in order to minimize exposure to debris and humidity which may result in ATF Module damage.
	

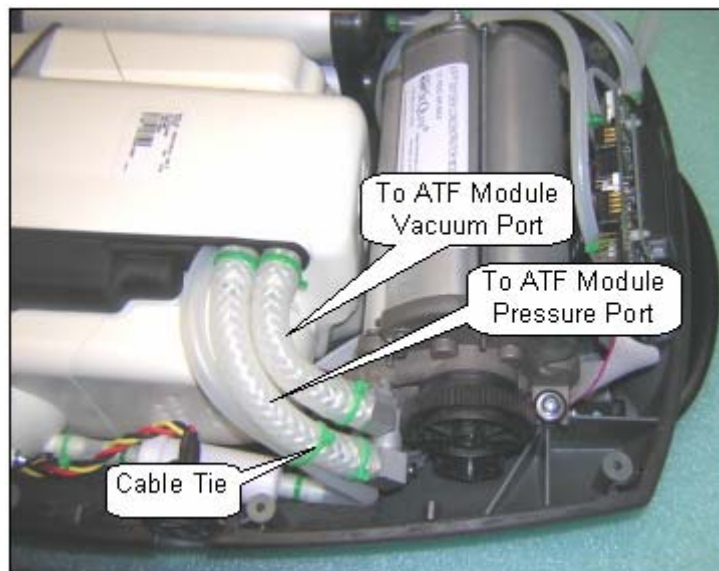


Figure 51: Removal of Compressor Pressure and Vacuum Hoses from ATF Module.

6. Turn the unit over onto a padded ESD safe surface and remove the 4 screws (M4x16 Pan Head Machine Screw , P/N 6961-420) and washers (M4 Flat Fender Washer, P/N 3568) shown in Figure 52.

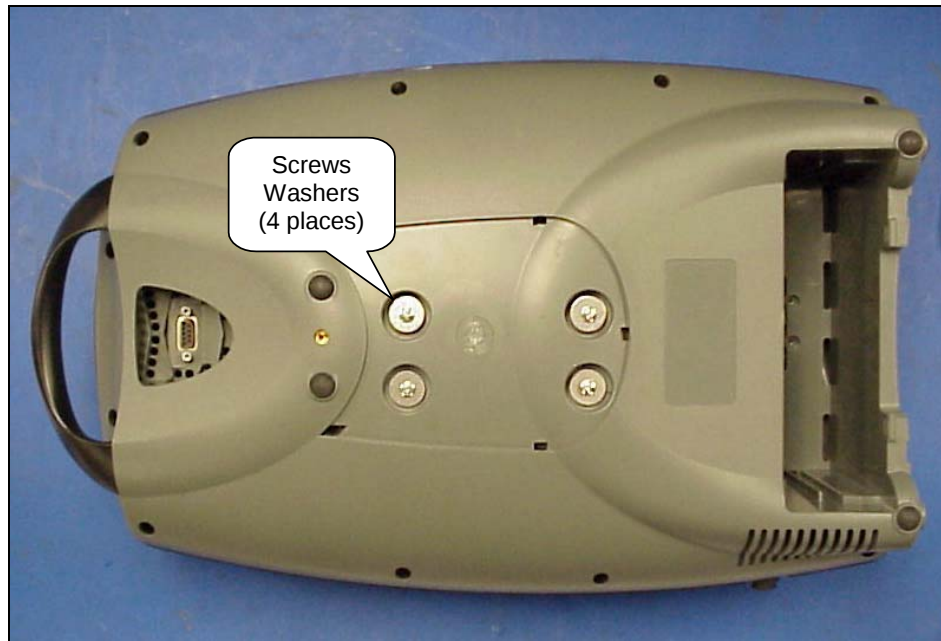


Figure 52: Remove Compressor Box screws.

7. Remove the Compressor Box.

NOTE:	There are no field serviceable parts inside the Compressor Box. Do not attempt to disassemble or modify the Compressor Box in the field.
--------------	--

8. To install the Compressor Box, Lay the new Compressor Box in the Unit. Turn over the Unit.
9. Position the Compressor Box into the Bottom Case with the compressor box screw holes aligned with the 4 brass eyelets. Screw in the 4 screws and 4 washers as shown in Figure 52. Apply small amount of Loctite 425 on the threaded tips of the screw before installing.
10. Install the braided tubes into the ATF pressure and vacuum ports as shown on Figure 51 above. Secure joints with cable ties.
11. Use a cable tie to secure the silicone tube to the braid tube to ensure that there is NO kinking on the bend as shown on Figure 51 above. Hand tightens the cable tie. Inspect the tubing to ensure the tubing is not kinked.
12. Hold onto the Compressor Box and lift the Bottom Case into a standing position. Insert the Exhaust Tube into the slot of the Exhaust Duct as shown on Figure 50 above. Ensure that it is secure without any gaps.
13. Plug the 3 harnesses into the Power Manager PCB as shown on Figure 49 above.
14. Install the Case Bottom Cover as shown in Figure 48.
15. Install the Unit Cover as described in the section Remove and Replace the Unit Cover.

Maintenance and Replacement Parts

Preventative Maintenance Parts

Description	SeQual Part Number
Preventive Maintenance Kit (includes * items)	5022
* Air Inlet Filter	7028
* Compressor Intake Filter	8069
* HEPA Filter	6986
* 9V Battery	8098
* Wire Ties (Qty 10)	5268

Replacement Parts List

Description	SeQual Part Number
AC Power Supply	4123SN
ATF Module Assembly, Eclipse 2	SP3995
Cable harness, SPI/ I2C	8076
Carton Assembly, Eclipse Oxygen System	SP3581
Case Bottom Cover	6949
Case Bottom Subassembly, Eclipse 2	SP4042
Case Top Subassembly, Eclipse 2	SP4041
Compressor Box Assembly, Eclipse 2	4135
Control Module Assembly	4043
DC Power Supply	4124SN
Foot, bottom	6956
Handle	6963
Inlet Filter	7028
Membrane Panel Overlay, Eclipse 2	SP3972
Nut, Outlet	2777
Outlet Assembly, Oxygen	3922
Power Manager PCBA, Eclipse 2	SP3986
Power Cartridge	7082
Product Tank Assembly	6138
Rubber Gasket	4106
Screw, M2x10 Pan Head Machine	6961-210
Screw, M3x10 Plastite	6950-310
Screw, M3x12 Pan Head SEM	6974-312
Screw, M4x16 Pan Head Machine	6961-416
Screw, M4x16 Pan Head Machine	6961-420
Tubing, Silicone, 3/16" ID	SP6981
Tubing, Silicone, 2mm ID	SP4101
Tubing, Braided, 5/16" ID	SP3534
Washer, M3 Flat	6950-03
Washer, M4 Flat	6985-04
Washer, M4 Flat Fender	3568
Wire harness, 9V	1076
Wire Harness, Service Port	7012
Wire Harness, External Power, Eclipse 2	4063

SeQual Customer Service Contact Information

If you need any additional assistance, contact SeQual:

By mail:

SeQual Technologies, Inc.
11436 Sorrento Valley Road
San Diego, CA 92121 USA

By telephone: 858-202-3100 or toll-free in the United States at 1-800-826-4610

By facsimile: 877-786-9943

By E-mail: techsupport@sequal.com

www.sequal.com

Authorized European Union Representative:

SEQUAL TECHNOLOGIES EUROPE BV.
VERDUNPLEIN 10
5627 SZ EINDHOVEN
THE NETHERLANDS

Tel: + 31 40 212 8606

Fax: + 31 40 211 1240

SeQual® and ATF® are registered trademarks of SeQual Technologies Inc.

Eclipse® is a trademark of Sequal Technologies Inc.

PRO₂ Check Elite™ is a trademark of Salter Labs Inc.

Lysol® is a registered trademark of Reckitt Benckiser, UK.

Loctite® is a registered trademark of Loctite Corporation, USA.