

Newport Medical Instruments, Inc.

NEWPORT e360 VENTILATOR

Service Manual

SER360 Rev. A

11/06



NEWPORT MEDICAL INSTRUMENTS, INC.
1620 Sunflower Avenue
Costa Mesa, CA 92626 USA

Tel: 714.427.5811

Tel: 800.451.3111 (USA only)

Fax: 714.427.0489

Customer Service ext. 282



www.NewportNMI.com

email: Info@NewportNMI.com

TABLE OF CONTENTS

Section 1INTRODUCTION

**Section 2MAINTENANCE, OVERHAUL
& SOFTWARE UPGRADE**

Section 3TROUBLESHOOTING GUIDE

**Section 4COMPONENT REMOVAL
& REPLACEMENT**

Section 5CALIBRATION PROCEDURES

**Section 6OPERATIONAL VERIFICATION
PROCEDURE**

Section 7CLEANING and MAINTENANCE

Appendix ATHEORY OF OPERATION

**Appendix BORDERING & CONTACT
INFORMATION**

Appendix CDIAGRAMS

1. INTRODUCTION

Introduction	1-1
Definitions	1-1
General Warnings.....	1-1
General Cautions	1-2
Warranty	1-2
Factory Service.....	1-3
Copyright Information	1-3
Contact Information	1-3

INTRODUCTION

It is very important to read and understand all of the information in this manual before attempting to service the e360 Ventilator. Please review all warnings and cautions in this manual before attempting to service the e360 ventilator.

DEFINITIONS

WARNING A WARNING describes a condition that can cause personal injury.

Caution A Caution describes a condition that can cause damage to equipment.

NOTE: A NOTE emphasizes information that is important or convenient.

Inspection: examination of actual condition.

Service: measures to maintain specified condition.

Repair: measures to restore to specified condition.

Maintenance: inspection, service, and repair where necessary.

Preventive Maintenance: maintenance performed at regular intervals.

Operational Verification: a routine verification procedure to ensure proper operation.

Overhaul Procedure: a procedure for replacing key components at regular intervals

GENERAL WARNINGS

Please review all warnings and cautions in this manual before attempting to service the ventilator.

Warnings and Cautions appear throughout this manual where they are relevant. The Warnings and Cautions listed here apply generally any time you work on the ventilator.

INTRODUCTION

WARNING

To maintain grounding integrity, connect only to a hospital grade receptacle. Always disconnect power supply before servicing the e360 ventilator.

DANGER: there is a risk of explosion if used in the presence of flammable anesthetics.

Before returning to patient use, the e360 ventilator must pass the operational verification procedure.

All e360 ventilator service or repair must be performed by a technician authorized and trained by Newport Medical Instruments.

Use extreme caution when working inside the e360 ventilator while it is connected to a power source.

GENERAL CAUTIONS

Caution

Use standard antistatic techniques when working inside the e360 ventilator or handling any electronic parts.

Clean all external parts of the e360 ventilator prior to service.

Use only dry, clean compressed air and medical grade oxygen.

Water in the air or oxygen supply can cause equipment malfunction and damage.

Mains voltage must correspond to the voltage range selected on the power module of the e360 ventilator. Always replace an open fuse with one of correct type and rating.

Do not place containers of liquids near the e360 ventilator. Liquids that get into the e360 ventilator can cause equipment malfunction or damage.

NOTE: Use the tools specified in the manual to perform specific Procedures.

WARRANTY

The e360 ventilator comes with a two (2) year conditional warranty. The warranty covers any defect or malfunction that occurs due to normal use. The warranty does not cover any

scheduled maintenance. See the e360 Ventilator Operating Manual for the conditions of this warranty.

Federal Law in the United States requires traceability of this equipment. Please fill out the self-addressed Warranty Registration Card included with the product and return it to Newport promptly. Or register online at www.NewportNMI.com.

FACTORY SERVICE

Scheduled maintenance or repair services are available from the Newport Technical Service department. See Appendix B for instructions on returning your ventilator for service. Newport's annual price list includes current pricing for scheduled maintenance and labor rates. To obtain a copy of the price list, please contact your local Newport representative or contact our Customer Service department.

COPYRIGHT INFORMATION

Copyright 2006 Newport Medical Instruments, Inc. all rights reserved. The Newport e360 Ventilator system is manufactured in accordance with Newport Medical Instruments, Inc. proprietary information and is covered by the following Patent, #6,439,229.

The information in this manual is the sole property of Newport Medical Instruments, Inc. and may not be duplicated without permission. This manual may be revised or replaced by Newport Medical Instruments at any time and without notice.

CONTACT INFORMATION

Address: Newport Medical Instruments
1620 Sunflower Avenue
Costa Mesa, California, USA 92626

Phone numbers: Toll-free within the United States: 800.451.3111
Worldwide: 1.714.427.5811

Fax numbers: Main Fax: 1.714.427.0489
Technical Service Fax: 1.714.427.0572

Website: www.NewportNMI.com/
www.Ventilators.com

Email: Customers@NewportNMI.com
TechService@NewportNMI.com

INTRODUCTION

Department extensions: Customer Service: 282
Technical Service: 500 (24-hour pager activated)
Clinical Support: 123 (24-hour pager)

Corporate Office hours: Monday through Friday, 8:00 am to 5:00 pm
(USA Pacific Time)

EU Representative: Newport Medical Instruments
Att. Robert Brink
c/o Braun & Co.
19 Pasture Rd.
Barton-on-Humber
North Lincolnshire
DN18 5 HN, England
tel: ++44.77 68 231311
Fax: ++44.1652.633399

2. MAINTENANCE, OVERHAUL & SOFTWARE UPGRADE

Maintenance & Overhaul Intervals.....	2-1
General Warnings.....	2-1
General Cautions	2-2
Parts Required / Tools Required	2-2
Maintenance Procedures	2-3
– Inlet Water Trap Filters & O-rings Assembly	2-3
– Exhalation Valve Adapter	2-4
– Exhalation Valve Diaphragm, Seal & O-Ring.....	2-5
– Emergency Relief Diaphragm	2-5
Overhaul Procedures	2-6
– Inlet Water Trap Filters & O-rings Assembly	2-6
– Air and Oxygen Inlet Regulator Rebuild	2-7
– Exhalation Valve Adapter	2-7
– Exhalation Valve Diaphragm/Poppet Assembly	2-8
– Cooling Fan Filter & Guard	2-8
– Emergency Relief Diaphragm	2-9
– Emergency Intake Diaphragm	2-9
– Inhalation Outlet Check Valve.....	2-10
– Internal Battery	2-10
– Tubing	2-10
Software Upgrade Procedure	2-11
General Information	2-11
Upgrade Procedure.....	2-11
Circuit Test & Diagnostic	2-13
Software Upgrade Form	2-19

MAINTENANCE & OVERHAUL INTERVALS

The Level I Preventive Maintenance procedure should be performed once a year or every 5000 hours, whichever comes first.

Perform the Level 2 Overhaul Procedure, every 5 years or 25,000 hours, whichever comes first.

GENERAL WARNINGS

WARNING

All servicing or repair of the e360 ventilator must be carried out off patient.

Hazardous voltages are present inside the e360 ventilator. Use extreme caution if it is necessary to work inside the ventilator while it is connected to a power source. Disconnect electrical power, air and oxygen sources before attempting any disassembly. Failure to do so could result in injury to service personnel or equipment.

To maintain grounding integrity, the e360 ventilator must be connected to a hospital grade receptacle when in use.

DANGER: There is a risk of explosion if the e360 ventilator is used in the presence of flammable anesthetics.

Before returning to patient use, the e360 ventilator must pass the Operational Verification Procedure.

All service repairs of the e360 ventilator must be performed by a service technician authorized and trained by Newport Medical Instruments.

To prevent damage from ESD and possible failure of the e360 ventilator, use standard anti-static techniques when working inside the e360 ventilator, handling circuit boards or other electronic components.

MAINTENANCE, OVERHAUL & SOFTWARE UPGRADE

GENERAL CAUTIONS

Caution

Clean all external parts of the e360 ventilator prior to service.

Use only dry, clean compressed air and medical grade oxygen. Water in the air or oxygen supply can cause ventilator malfunction or damage.

Mains voltage must correspond to the voltage range specified on the e360 ventilator Power Entry Module. Always replace fuses with those of correct type and rating.

Keep all liquids away from the e360 ventilator. Liquids in the e360 ventilator can cause malfunction or damage.

Always use standard antistatic techniques when working inside the e360 ventilator or handling any electronic parts.

TOOLS REQUIRED

NOTE: Use the tools specified in the manual to perform specific procedures.

- Large Phillips screwdriver
- Medium Phillips screwdriver
- Needle Nose pliers

PARTS REQUIRED

Preventive Maintenance Kit

The Preventive Maintenance Kit (PMK360A) includes the following items:

Part Number	Quantity	Description
JFK100P	2	JAR Filter Kit
ADP2105M	1	Exhalation Valve Adapter
DIA1800M	1	Emergency Relief Diaphragm
SEL1800M	1	Exhalation Valve Seal
ORG1200P	1	O-Ring, Exhalation Flow Sensor
DIA1810M	1	Exhalation Valve Diaphragm

Overhaul Kit

The Overhaul Kit (OVL360A) includes the following items:

Part Number	Quantity	Description
JFK100P	2	JAR Filter Kit
RRK1800P	2	Regulator Rebuild Kit
GRD1800P	1	Cooling Fan Filter & Guard
ADP2105M	1	Exh. Valve Adapter
PPT1805A	1	Exh. Valve Dia & Poppet Assy
ORG1200P	1	O-Ring, Exhalation Flow Sensor
DIA1800M	1	Emergency Relief Diaphragm
VLV100P	1	Emergency Intake Diaphragm
VLV2100M	1	Inhalation Outlet Check Valve Diaphragm
BAT1800P	1	Internal Battery

MAINTENANCE PROCEDURES

WARNING: Disconnect electrical power, air and oxygen sources before attempting any disassembly.

Inlet Water Trap Filters & O-ring Assembly



Figure 2-1 Inlet Water Trap Filter Replacement

- 1 Unscrew the collection bowl from the inlet water trap.
- 2 Unscrew the filter holder.

- 3 Remove and replace the inlet filter and O-ring.
- 4 Reinstall the filter holder and reassemble the water trap assembly.

Adapter Lip



**ADP2105M
Exhalation Valve Adapter**

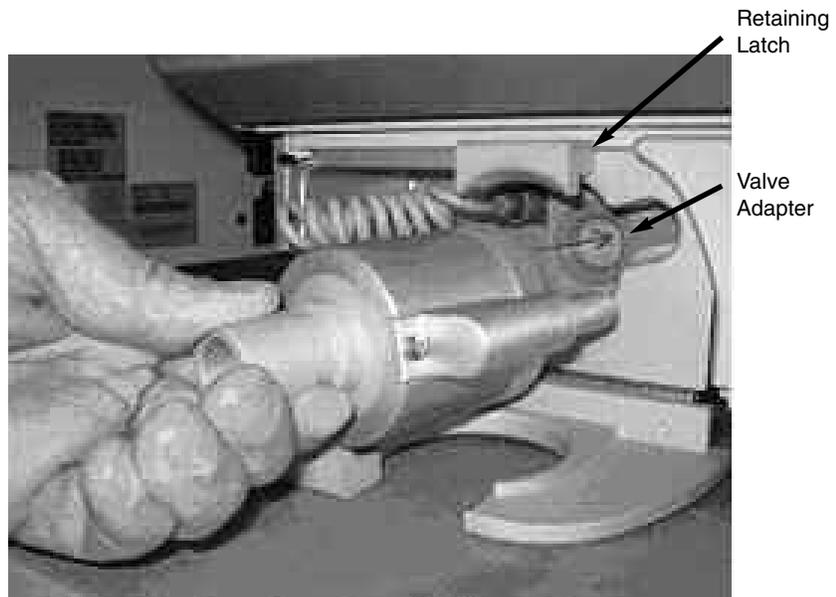


Figure 2-2 Exhalation Valve Adapter Replacement

- 1 Access the Exhalation Valve Adapter by lifting the Retaining Latch and removing the Exhalation Valve and Exhalation Flow Sensor, see Figure 2-2 above.
- 2 To remove the silicon Exhalation Valve Adapter, use your finger to grasp the Adapter and pull it straight out.
- 3 To replace the Exhalation Valve Adapter, orient the Adapter lip towards the inside of the instrument and press into place.
- 4 Ensure that the Adapter is properly seated before re-installing the Exhalation Valve and Exhalation Flow Sensor.

Exhalation Valve Diaphragm, Seal & O-Ring

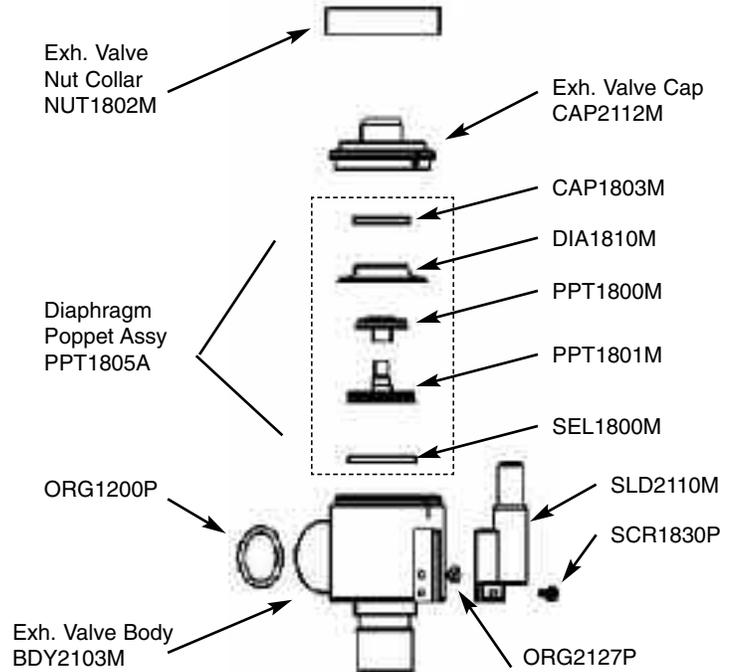


Figure 2-3 Diaphragm, Seal & O-Ring Replacement

- 1 Unscrew the Exhalation Valve Nut Collar and lift off. Then lift off the Exhalation Valve Cap and Diaphragm/Poppet Assy.
- 2 Disassemble the Diaphragm/Poppet Assy.
- 3 Reverse step 2 to install the new DIA1810M and SEL1800M.
- 4 Reverse step 1 to reassemble the Diaphragm/Poppet Assy, Exhalation Valve Cap, and Exhalation Valve Nut Collar.
- 5 Locate and replace O-ring (ORG1200P) inside the Exhalation Valve Body, see Figure 2-3.

Emergency Relief Diaphragm

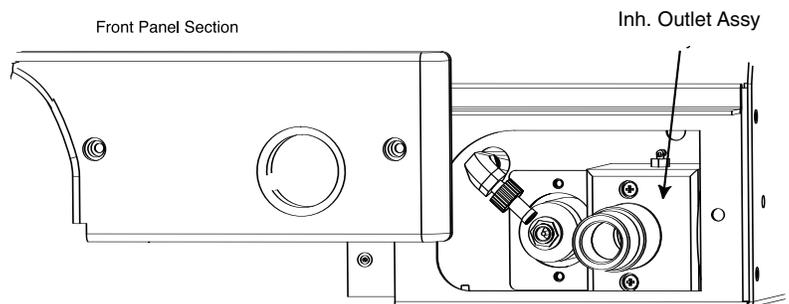


Figure 2-4 Inhalation Outlet Assembly

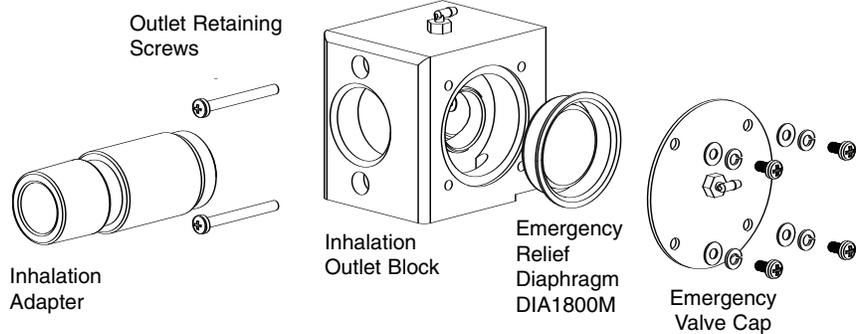


Figure 2-5 Emergency Relief Diaphragm Replacement

- 1 Access the Inhalation Outlet Assembly by removing the Lower Right Front Panel, see Figure 2-4 above.
- 2 Remove the Inhalation Outlet Assembly by removing the two retaining screws, see Figure 2-5 above.
- 3 Remove 4 screws from Emergency Valve Cap to expose the Emergency Relief Valve.
- 4 Insert finger and pull the Emergency Relief Diaphragm (DIA1800M) out of Inhalation Outlet Block.
- 5 Replace the Emergency Relief Diaphragm.
- 6 To reinstall components and assembly, reverse the above procedure.

OVERHAUL PROCEDURES

WARNING: Disconnect electrical power, air and oxygen sources before attempting any disassembly.

Inlet Water Trap Filter and O-ring Assembly

To replace the Inlet Filter and O-ring assemblies, follow the procedures given in the Preventive Maintenance at the beginning of this section.

Air and Oxygen Inlet Regulator Rebuild

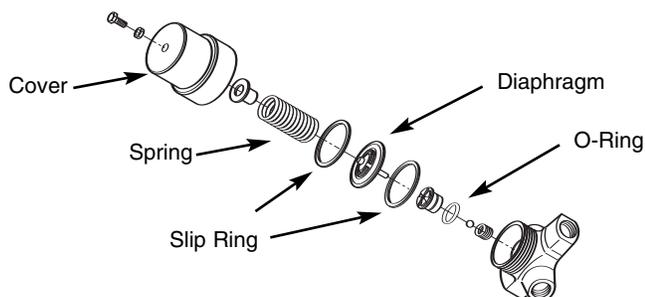


Figure 2-6 Inlet Regulator Rebuild

To remove/install the Air and Oxygen Inlet Regulator, follow the procedures in Section 4 of this manual, “Removal of Servo Valves, Regulators, Inlet Block and Flow Sensor Block”.

NOTE: Inlet Regulators must be outside of the Ventilator for disassembly and re-assembly.

To install the Air and Oxygen Inlet Regulators Rebuild Kits, refer to Figure 2-6 and do the following:

- 1 Unscrew the brass cover from the regulator (no tool should be needed) and remove the spring, diaphragm, diaphragm washer, seat with O-ring, small spring, and ball (see Figure 2-6).
- 2 Replace the used parts, reversing the disassembly, with the parts from the Regulator Rebuild Kit P/N (RRK1800P).

NOTE: The Regulator must be in a vertical position in order to reassemble the Kit components.

- 3 Install the Regulator brass cover, hand tight and ensure all components are aligned.

NOTE: This procedure is the same for both the air and the oxygen regulators.

Exhalation Valve Adapter

To replace the Exhalation Valve Adapter, follow the procedures given in the Preventive Maintenance at the beginning of this section.

MAINTENANCE, OVERHAUL & SOFTWARE UPGRADE

Exhalation Valve Diaphragm/Poppet Assembly

Refer to Drawing 2-3

- 1 Unscrew the Exhalation Valve Nut Collar and lift off. Then lift off the Exhalation Valve Cap and Diaphragm/Poppet Assembly.
- 2 Replace complete Diaphragm/Poppet Assembly (p/n PPT1805A).
- 3 Reverse step 1 to reassemble the Diaphragm/Poppet Assembly, Exhalation Valve Cap, and Exhalation Valve Nut Collar.
- 4 Locate and replace O-ring (ORG1200P) inside the Exhalation Valve Body, see Figure 2-3.

Cooling Fan Filter & Guard

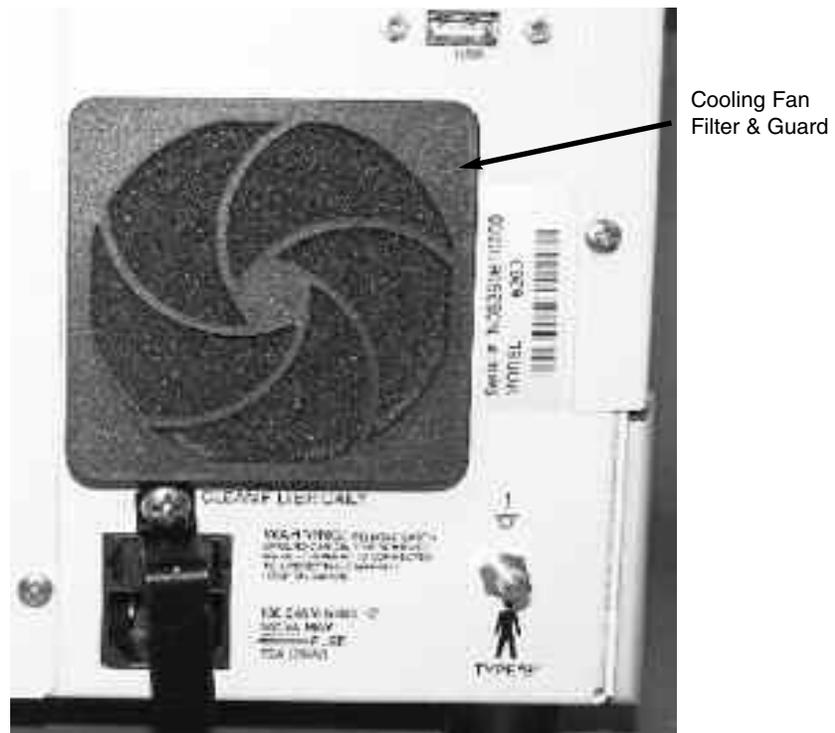


Figure 2- 7 Filter and Guard Assembly Replacement

Replace the Cooling Fan Filter and Guard Assembly (GRD1800P), see Figure 2-7.

Emergency Relief Diaphragm

To replace the Emergency Relief Diaphragm, follow the procedures given in the Preventive Maintenance at the beginning of this section.

Emergency Intake Diaphragm

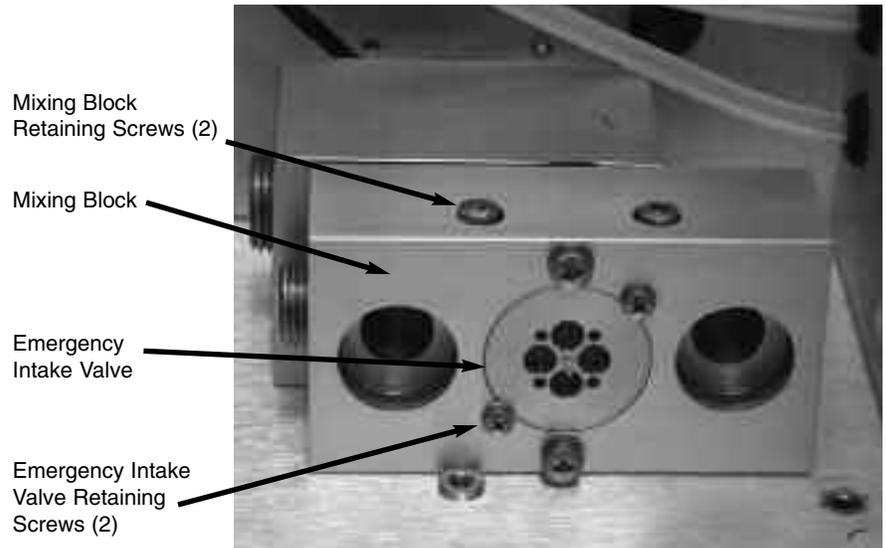


Figure 2-8 Emergency Intake Diaphragm Replacement

- 1** Remove Top Cover following procedure in Section 4 of this manual, "Removal of Top cover".
- 2** Remove Pneumatics Panel following procedure in Section 4 of this Manual, "Removal of Pneumatics Panel Assembly".
- 3** Remove Inspiratory Flow Sensors following procedure in Section 4 of this manual, "Removal of Inspiratory Flow Sensors".
- 4** Remove two Emergency Intake Valve retaining screws, see Figure 2-8 above.
- 5** Remove the Emergency Intake Valve using Needle Nose Pliers.
- 6** Replace the Emergency Intake Diaphragm (VLV100P) and reinstall assembly by reversing procedure above.

Inhalation Outlet Check Valve

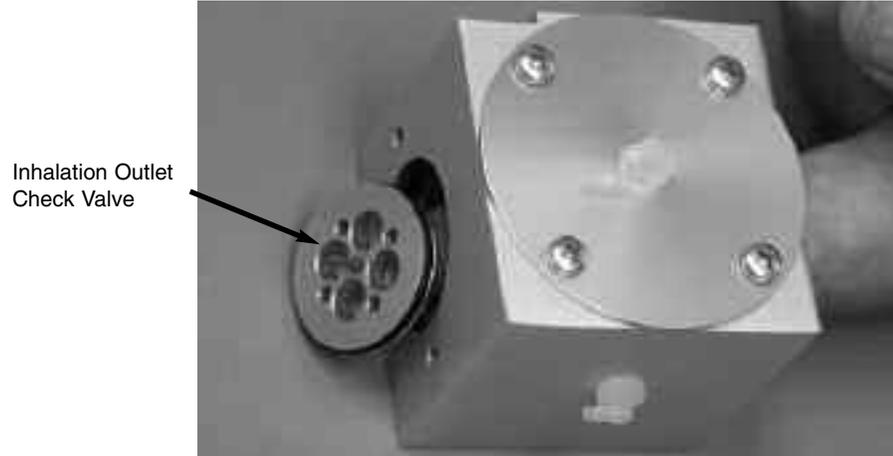


Figure 2-9 Inhalation Outlet Check Valve

- 1** Remove the Mixing Block by removing the two retaining screws, see Figure 2-8.
- 2** Remove the Inhalation Adapter from the Inhalation Outlet Assembly, see Figure 2-5.
- 3** Insert finger and push out the Inhalation Outlet Check Valve, see Figure 2-9.
- 4** Replace the Inhalation Outlet Check Valve Diaphragm (VLV2100M).
- 5** To reinstall components and assembly, reverse above procedure.

Internal Battery

To remove/install the Internal battery, follow the procedures in Section 4 of this manual, “Removal of Internal Battery”.

Caution: To avoid discharging battery voltage, do not allow any metal object (including tools) to touch battery connectors.

Warning: Observe correct polarity when reconnecting battery connectors.

Tubing

The tubing inside the e360 ventilator does not need to be replaced at any predetermined time interval; however, Newport is aware that tubing may occasionally need replacing. During the overhaul procedure, carefully inspect all tubing for degradation, cracks, or

brittleness. If the tubing indicates any of those symptoms, replace as necessary.

If tubing needs to be replaced, please contact Customer Service and order the e360 Tube Replacement Kit.

Refer to the e360 System Pneumatic Diagram (SPD2100A) located in Appendix C to cut each tube to length and replace the worn tubing in the e360 ventilator.

Upon Completion

After overhaul is completed, perform a complete electronic and pneumatic calibration as outlined in Section 5 of this manual and the Operation Verification Procedure as provided in Section 6.

e360 SOFTWARE UPGRADE PROCEDURE

GENERAL INFORMATION

The following items are required for software upgrade:

- Latest Software on USB Flash Drive
- Software Upgrade Instructions
- NMI Reusable Patient Circuit (PBC340A) or equivalent
- Cap to plug end of patient circuit (CAP100P) or equivalent

Note: Follow this procedure to reload software after performing a Main Board, Display Board or Single Board Computer component replacement.

UPGRADE PROCEDURE

- 1 Confirm the e360 ventilator is OFF and connect AC power cord to the AC wall outlet (see Figure 2-13 for Power Entry Module location).
- 2 Press and hold the “**Accept**” button and turn ON the power.
- 3 Release the “**Accept**” button when NMI Logo Screen is displayed.
- 4 Wait for few minutes until the Software Download/Diagnostics Mode screen is displayed, see Figure 2-11.
- 5 Connect USB Flash Drive (with latest software) to the USB port on the Back Panel of the e360 ventilator (see Figure 2-13 for USB port location).
- 6 Press “**Start Download**” on touch screen (Figure 2-11). The e360 ventilator will sound a short beep. “**Touch Selection to Begin**” message on screen will change to a flashing message: “**downloading....**” Wait 15 – 20 minutes for software download to complete.



Figure 2-11 Software Download/Diagnostics Mode Screen

- 7 When software download is completed, ventilator will sound a short beep. “**Download Complete**” message will appear on the screen and flashing stops.
- 8 Turn OFF the power of the e360 ventilator.
- 9 Wait at least 10 seconds and turn the e360 ventilator power back ON.
- 10 Wait until “**Ventilation Standby**” screen appears.
- 11 Press “**Start Ventilating**” to begin ventilating.
- 12 **NOTE:** Because Air/O₂ gas supplies are not connected you will get an “Air/O₂ Loss” alarm. Disregard alarm while verifying software is installed correctly.
- 13 After “**Start Ventilation**” button is pressed, confirm that “**Incompatible Software**” Message does not show up on the screen. If this message appears on the LCD touch screen, then the software download was NOT completed successfully. Repeat 1 – 6 again. If the same problem still remains, then contact NMI representative for further assistance.
- 14 Press “**Extended Functions**” button on the Front control panel.
- 15 Press “**Event History**” button on LCD touch screen.
- 16 Confirm software is properly upgraded by checking software version number (see Figure 2-12, left upper corner).

ADULT		2006-02-12 09:03	
EVENT HISTORY LOG			
SOFTWARE: RWRL3			
#	TIME	DATE	EVENT
(ID = 1000)	(12 hr)	(MM/DD/YY)	
211	07:00 A	02/12/06	LOW PAW = 3
210	05:00 A	02/12/06	HIGH PAW = 83
209	03:00 A	02/12/06	LOW VE = 0
208	03:00 A	02/12/06	HIGH VE = 60
207	03:00 A	02/12/06	VT = 500
206	03:00 A	02/12/06	PEEP = 0
205	03:00 A	02/12/06	Flow = 56
204	03:00 A	02/12/06	Pressure = 1
203	03:00 A	02/12/06	Flow = 5.0
202	03:00 A	02/12/06	DATE = 30
201	03:00 A	02/12/06	V = 32
200	03:00 A	02/12/06	FDZ = -0.21

VENTILATOR SETTINGS					
DATE: 02/12/06 TIME: 09:00 A					
MODE:	VC SIMV	PEEP:	0	FDZ:	-0.21
RATE:	30	VT:	500	THHL:	5.0 PSI
V:	32	PSUPPORT:	1	HIGH VE:	60
LOW PAW:	3	HIGH PAW:	83	LOW VE:	0

Figure 2-12 Event History Log Screen

- 17 The new Software version is now downloaded successfully.
- 18 Remove USB Flash Drive from the USB Port on the back of the e360 ventilator.

Circuit Check Test and Diagnostic

WARNING: Before returning the e360 ventilator back for patient use after the software upgrade, you must perform the following:

- 1 Turn OFF the power of the e360 ventilator.
- 2 Connect medical grade air source to Air Inlet on the Back Panel of the e360 ventilator and make sure that medical grade air source can provide at least 30 psi and does not exceed more than 90 psi. (see Figure 2-13 for Air Inlet).
- 3 Connect appropriate patient circuit to the e360 ventilator as shown in Figure 2-14. Occlude the patient circuit using a CAP. A filter and test lung are not required for this instruction.
- 4 Turn the power of the e360 ventilator back ON.
- 5 Wait until “**Ventilation Standby**” screen appears.
- 6 Follow the instructions that appear on LCD touch screen as shown in Figure 2-15.

- 7 Press “**Circuit Check**” button on LCD touch screen, and “**Circuit Check Test in Progress**” message appears on LCD touch screen as shown in Figure 2-16.
- 8 When circuit test is completed successfully, “**Circuit Check PASSED**” message appears on LCD touch screen.
- 9 If circuit test failed, “**Circuit Check FAILED**” message appears on LCD touch screen. Please check the breathing circuit for leaks and press “**Circuit Check**” button on LCD touch screen and repeat Circuit Check. If circuit check does not pass, please contact NMI representative for further assistant.
- 10 Press “**Setup & Calibration**” button on the Control Panel.
- 11 Press “**TECHNICAL**” button on LCD touch screen, see Figure 2-17.
- 12 Press “**Regional Settings**” button on LCD touch screen, see Figure 2-17.
- 13 Press “**Altitude**” button on LCD touch screen and “_ ft/ _ m” setting will start flashing.
- 14 While the numbers are flashing, rotate the Encoder Adjustment Knob to change the Altitude level to where this instruction is going to be performed. (For example if the location is at the sea level, then set Altitude setting to “**0 m / 0 ft**”).
- 15 Press “**Accept**” button to set the new Altitude setting and flashing will stop.
- 16 Wait for **15 ~ 20 seconds**.
- 17 Turn “**OFF**” the power of the e360 ventilator.
- 18 Press and hold “**Accept**” button and then turn “**ON**” the power of the e360 ventilator to enter into Software Download screen on the e360 ventilator shown in Figure 2-11. “**Accept**” button can be released once the ventilator sounds a short beep.
- 19 Press “**Start Diagnostics**” button on LCD touch screen and the Diagnostic Data screen will appear as shown in Figure 2-18.
- 20 Press “**Trig Button**” on the Control Panel. Rotate the Encoder Adjustment Knob to change value in display window to “**d9**” and press “**Accept**” button.
- 21 Occlude the breathing circuit from the y-piece using a CAP. (**Do not use test lung**).

- 22 Press “Manual Inflation” button to start Exhalation Flow Sensor calibration, d9. Wait for **30 sec ~ 1 minute** until “TSI Air flow:” and “Exhale Flow:” numbers start to increase gradually and the air flow is delivered from the e360 ventilator. It requires 6 ~ 10 minutes to complete Exhalation Flow Sensor calibration, see Figure 2-18).
- 23 When flow delivered from the e360 ventilator stops and “Message ID:” number changes to “41”, then the Exhalation Flow Sensor calibration is successfully completed, see Figure 2-18.
- 24 Turn OFF the power of the e360 ventilator.
- 25 Disconnect medical grade air source from Air Inlet on the Back Panel of the e360 ventilator.
- 26 Disconnect AC power cord from AC wall outlet.
- 27 Upon completion of the installation of software upgrade, you must complete the attached “Newport e360 Ventilator Software Update Form” with serial numbers, part numbers and signatures and return it to Newport Regulatory Department via Fax at +1.714.427. 0839.

If you have any questions please contact Newport Technical Service Department:

Tel: +1.714.427.5811 ext. 500, Fax: +1.714.427-0572

Email: TechService@NewportNMI.com

0

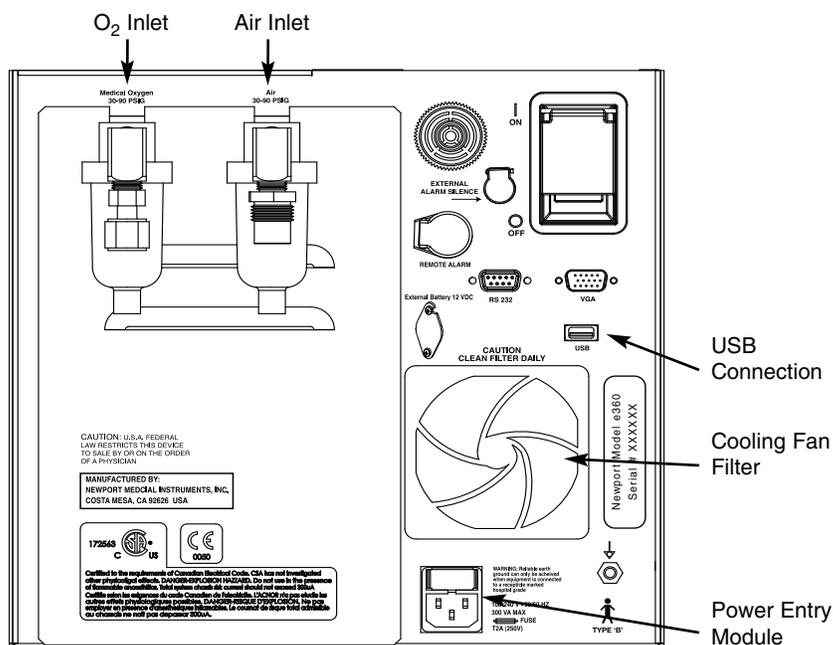


Figure 2-13 Back Panel of e360 Ventilator

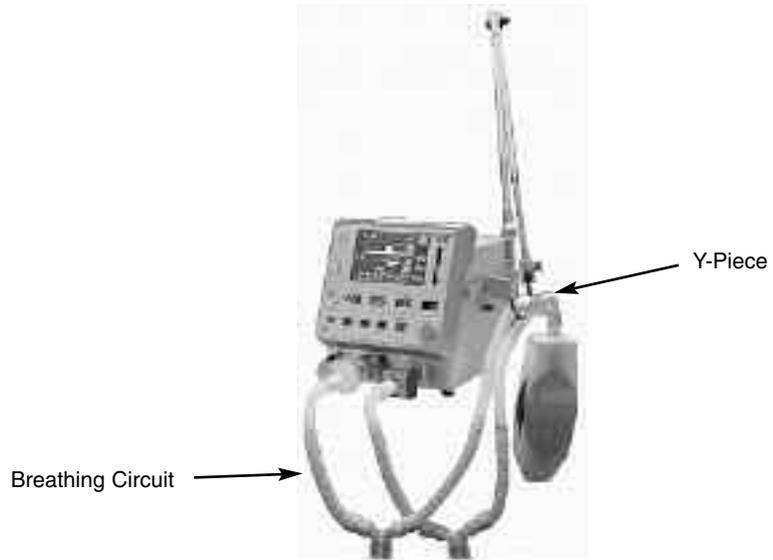


Figure 2-14 Patient Circuit Setup

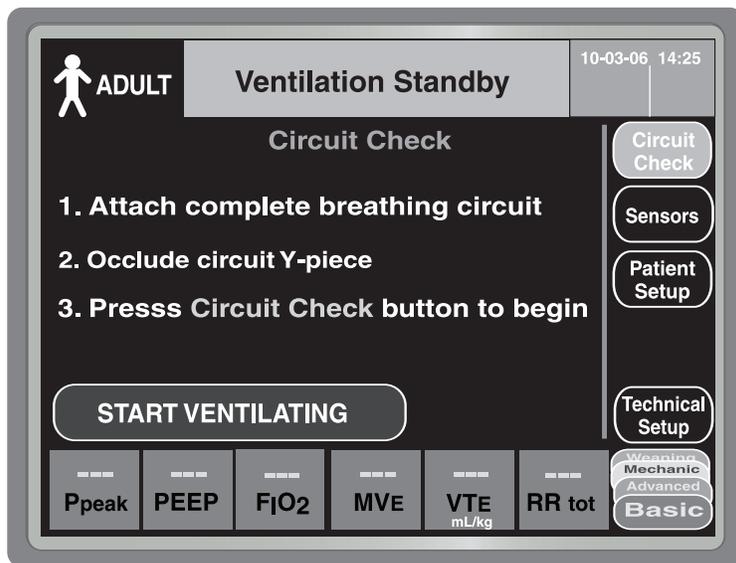


Figure 2-15 Ventilation Standby Screen

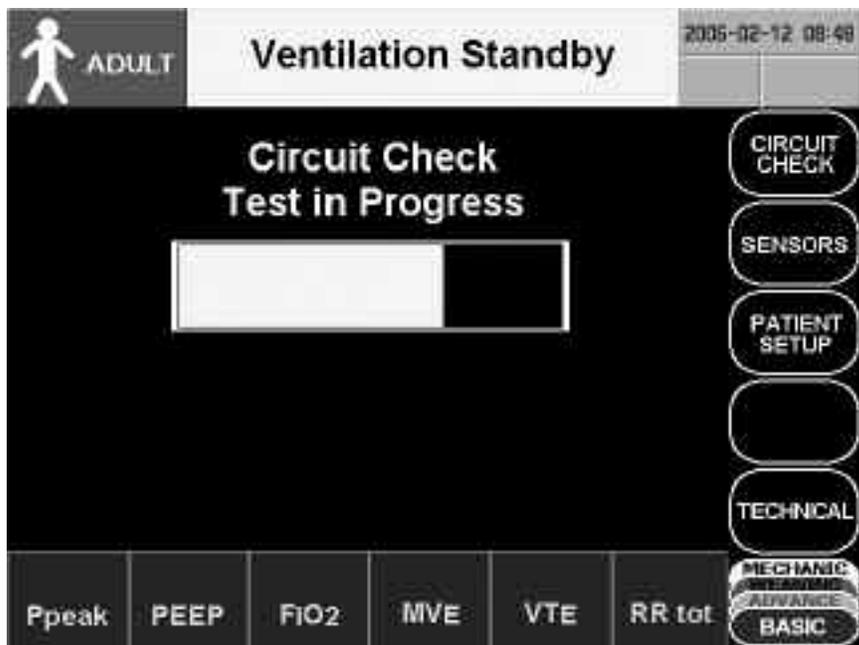
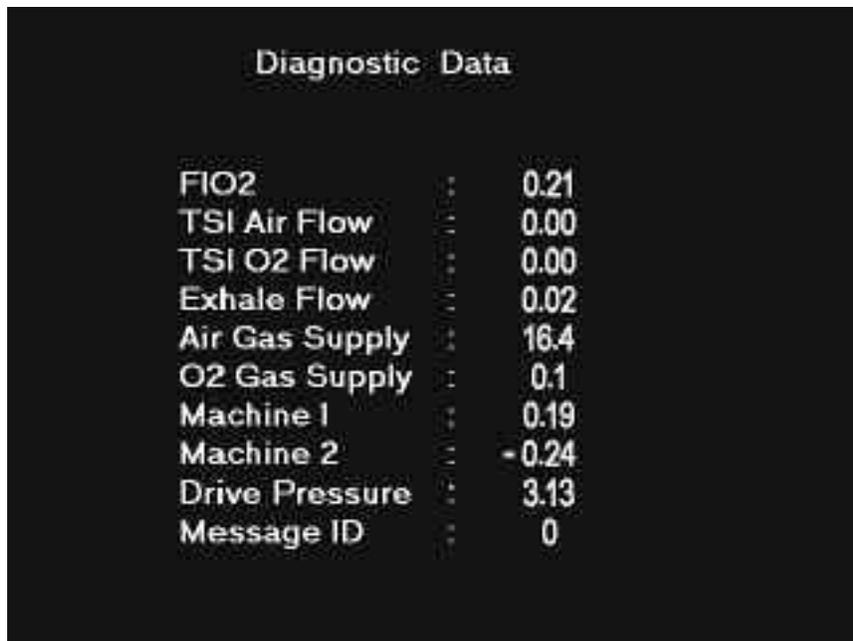


Figure 2-16 Circuit Check Screen



Figure 2-17 Technical Screen



The image shows a screenshot of a diagnostic data screen with a black background and white text. The title 'Diagnostic Data' is centered at the top. Below it, a list of parameters is displayed, each followed by a colon and its corresponding numerical value. The parameters and values are: FIO2 (0.21), TSI Air Flow (0.00), TSI O2 Flow (0.00), Exhale Flow (0.02), Air Gas Supply (16.4), O2 Gas Supply (0.1), Machine 1 (0.19), Machine 2 (-0.24), Drive Pressure (3.13), and Message ID (0).

Diagnostic Data	
FIO2	: 0.21
TSI Air Flow	: 0.00
TSI O2 Flow	: 0.00
Exhale Flow	: 0.02
Air Gas Supply	: 16.4
O2 Gas Supply	: 0.1
Machine 1	: 0.19
Machine 2	: -0.24
Drive Pressure	: 3.13
Message ID	: 0

Figure 2-18 Diagnostic Data Screen

NEWPORT e360 VENTILATOR SOFTWARE UPGRADE FORM

COMPLETE FORM MUST BE FAXED TO NEWPORT REGULATORY AFFAIRS UPON COMPLETION OF UPGRADE.

Fax completed form to: 1.714.427.0839 attention RA/QA
Or email requested information to: regulatory@NewportNMI.com

Facility Name: _____

Facility Address: _____

e360 Model: WWE WWP WWS USS Other _____

Language: _____

Current Hours: _____

e360 Model Serial Number: _____

Old software version: _____

Updated software version: _____

Company performing service: _____

Address of company performing service: _____

Software Updated

by: _____ Date: _____

Exhalation Flow Sensor Calibration, **d9** performed

by: _____ Date: _____

3. TROUBLESHOOTING GUIDE

Troubleshooting Guide	3-1
Device Alert Messages.....	3-3

TROUBLESHOOTING GUIDE

Table 3-1 may provide guidance in determining the cause and possible corrective action for ventilator problems. Newport does not guarantee that the suggested corrective action will solve the problem.

Contact Newport Technical Service Department for additional assistance.

Table 3-1 Troubleshooting Guide

Problem	Potential Cause	Suggested Action
Fail Circuit Check	Leak from patient circuit. Leak from exhalation section. Leak from inhalation section. Leak from tubing connection inside the ventilator.	Inspect patient circuit. Disassemble exhalation valve to inspect exhalation valve diaphragm and seal. Inspect exhalation valve adapter. Tighten inhalation flow outlet. Tighten oxygen sensor. Inspect emergency relief diaphragm. Inspect pneumatic tubing inside the ventilator. Inspect TSI air/oxygen flow sensors assembly. Clean or replace emergency intake diaphragm. Inspect rubber seal between inhalation outlet block and mixer block.
Flow Sensor Error/Bad	Defective exhalation flow sensor. Defective exhalation flow sensor cables, outside and inside. Defective cable from exhalation sensor board to main board. Defective exhalation sensor board.	Replace exhalation flow sensor. Replace exhalation flow sensor cables, outside and inside. Replace cable from exhalation sensor board to main board. Replace the exhalation sensor board.
Ventilator cannot achieve or maintain correct tidal volume, plateau pressure, or baseline pressure.	Pressure relief valve regulator failure. Crossover solenoid valve (solenoid PCB) failure. Machine zero solenoid (solenoid PCB) valve failure.	Perform the Operational Verification Procedure to diagnose the problem. Replace any parts that may be defective.
Pressure Bar graph does not show pressure rise.	Machine zero solenoid (solenoid PCB) valve failure. Analog board malfunction.	Replace solenoid PCB and Analog PCB.

TROUBLESHOOTING GUIDE

Problem	Potential Cause	Suggested Action
Internal battery does not charge.	Defective battery or battery charging hardware.	Replace internal battery or replace the DC-DC power supply PCB.
Loss of battery power.	Battery missing, discharged or defective. Defective battery hardware.	Recharge or replace battery. Replace DC-DC power supply PCB.
Low supply gas alarm	Supply pressure is not within specified range (30 – 90 psig).	Ensure that both gas supplies have a pressure of at least 30 psig.
No flow or low flow from inspiratory port during inspiratory phase of a mandatory breath.	Inlet regulator failure or servo valve failure.	Calibrate air and oxygen regulators; replace if calibration is not successful.
Ventilator cannot cycle, audible alarm on, and error message displayed in message window.	Based on error message.	Calibrate servo valves; replace if calibration is not successful. Refer to Table 3-2, Device Alert Messages.
Zero monitored exhaled flow.	Flow Sensor Cable disconnected. Flow sensor defective.	Reconnect cable to exhalation flow sensor. Verify that pins in cable connector are not damaged. Replace flow sensor.
Monitored values for exhaled flows or volumes differ from settings.	Occluded or missing bacteria filter. Dirty Exhalation flow sensor. Exhalation heater failure. Vent settings for “Circuit Type” humidity setup are incorrect for humidifier system in use.	Replace the bacteria filter. Disassemble and clean the Exhalation Module, replace the exhalation flow sensor. Feel the bacteria filter. If it is not warm to the touch, replace the exhalation heater. Correct “Circuit Type” selection in Patient Set-up.
Monitored F _I O ₂ values differ from setting.	Defective oxygen sensor.	Replace the oxygen sensor.
No audible alarm.	Defective alarm speaker, Sound processor board or SBC.	Replace alarm speaker or sound processor board or SBC.

DEVICE ALERT MESSAGES

Table 3-2 defines the Device Alert violations and messages that may be displayed in the message window. The first line in the message window displays the date and time of the error; the second line displays the error message.

Table 3-2 Device Alert Messages

Device Alert Violation	Violation Messages	Priority Level	Definitions
Control communications failure	Monitor μ P Failed	High	The monitor processor does not respond to a request from the control processor. The monitor processor is not running.
Control CPU failure	Control CPU Failed	High	The control processor on the main PCB is bad.
Control exception failure	M Internal System	High	The control processor has detected an abnormal operation such as illegal instruction or division by zero that was generated by the control software.
Control RAM Failure	Control RAM Failed	High	Random access memory that is used by the control processor on the main PCB is damaged.
Control ROM failure	Control ROM Failed	High	Read only memory that stores the code of the control processor has an incorrect check sum.
Control task continuity failure	Control Tasks Failed	High	Software tasks of the control processor have operated out of sequence.
Dual RAM failure	Dual RAM Failed	High	Random access memory that is shared between the control and monitor processors is damaged.
Monitor communications failure	Control μ P Failed	High	The control processor does not respond to a request from the Monitor processor. The control processor is not running.
Monitor CPU failure	Monitor CPU Failed	High	The monitor processor on the main PCB is bad.
Monitor exception failure	C Internal System	High	The monitor processor has detected an abnormal operation such as illegal instruction or division by zero that was generated by the monitor software.
Monitor RAM failure	Monitor RAM Failed	High	Random access memory that is used by the monitor processor on the main PCB is damaged.

TROUBLESHOOTING GUIDE

Device Alert Violation	Violation Messages	Priority Level	Definitions
Monitor ROM failure	Monitor ROM Failed	High	Read only memory that stores the code of the monitor processor has an incorrect checksum.
Monitor task continuity failure	Mon Task Failed	High	Software tasks of the monitor processor have operated out of sequence.
Power Failure	Power Failure	High	DC power out of tolerance. Check +12 VDC, -12 VDC and +5 VDC. (The e360 may have been powered by internal battery until it was depleted and a Device Alert resulted.)

4. COMPONENT REMOVAL & REPLACEMENT

Removal of Key Components	
– Preparation	4-1
– Tools Required	4-1
Exhalation Valve and Exhalation Flow	
Sensor	4-2
Exhalation Flow Sensor Cable (outside)	
(CBL2123P)	4-3
Top Cover (CVR2101M).....	4-3
Front Panel Assembly (DSP2102A)	4-4
Main Board (PCB2100A)	4-5
Main Board Support (CVR2103M).....	4-6
Display Board (PCB2102A)	4-7
Touch Screen Interface Board (PCB2105P)	4-8
Large LCD Cable (CBL2105A)	4-9
Front Panel Cover (CVR2104M)	4-10
Optical Encoder (ENC1800P).....	4-11
Alarm LEDs	4-11
LCD Display (DSP2105P).....	4-11
Touch Screen (PNL2105P)	4-12
Pneumatics Panel Assembly (SVO2101A)	4-13
Servo Valves, Regulators, Inlet Block and Flow	
Sensor Block	4-15
Regulator and Solenoid Assembly	
(BKT2105A)	4-16
Inspiratory Flow Sensors	4-17
Main Flow Outlet Block Assembly	
(BLK2108A)	4-18
Oxygen Sensor (R125P03-002)	4-19
Inhalation Outlet Block and Mixing Bloc	
Assembly	4-20
Analog Board (PCB2104A).....	4-21

Heater Assembly (HTR1200A)	4-22
Exhalation Manifold (MNF2110A)	4-23
Exhalation Flow Sensor Board (PCB2103P)	4-24
Battery (BAT1800P)	4-25
AC to DC Power Supply (PWR2100P).....	4-26
DC to DC Power Supply Board (PCB2101A)	4-27
Sound Processor Board (PCB2106P)	4-28
Single Board Computer (SBC2100P).....	4-28

Removal of Key Components

Unless instructed otherwise, reinstall parts by reversing the disassembly procedure.

Preparation

Before performing any repair or service on the e360 ventilator do the following:

- 1 Disconnect the power.
- 2 Shut off or disconnect the air and oxygen gas supplies.
- 3 Put on an ESD wrist strap and perform procedures in an ESD safe environment.

Tools Required

- #0 Philips Screw Driver
- #1 Philips Screw Driver
- #2 Philips Screw Driver
- #1 Flat Screw Driver
- 5/64" Hex Key
- 7/32" Nut Driver or Wrench
- 11 mm Nut Driver or Wrench
- Torque Wrench set for 8 inch/pounds
- Anti Static Wrist Strap
- Anti Static Parts Bin

WARNING To avoid possibility of electric shock, do not touch the power supply transformer when servicing the ventilator.

These instructions are intended for use only by a Newport Medical Instruments factory-trained technician. Do not perform any unauthorized modifications or repairs to the ventilator or its components.

Caution To avoid damaging equipment, always use standard electrostatic discharge (ESD) precautions, including an ESD wrist strap, when servicing the ventilator.

Note: If the Main Board, Display Board or Single Board computer components are replaced the e360 software must be reloaded. Follow the Software Upgrade Procedure in Section 2 to load software. Contact Newport Technical Service if you need a software kit.

COMPONENT REMOVAL & REPLACEMENT

Removal of Exhalation Valve and Exhalation Flow Sensor

Caution: The Exhalation Flow Sensor is a precise yet delicate instrument. Take care when handling not to disturb the measuring wires. The life cycle of the sensor is limited and will depend on observance of safe handling precautions and the ability to calibrate the sensor. Always make sure that the flow sensor is completely dry before installation.

To disconnect cable CBL2123P from Exh. Manifold MNF2110A, pull the collet of the cable straight out.

To disconnect cable CBL2123P from Exh. Flow Sensor FLS2101P, pull the connector straight up.



Figure 4-1 Exhalation Valve and Exhalation Flow Sensor

Refer to figure 4-1 and follow these steps:

- 1 Open the Front Panel Door on the lower left front of the ventilator to expose Exhalation Valve EXH2105A and Flow Sensor FLS2101P.
- 2 Remove the Exhalation Valve EXH2105A by releasing the retaining latch.
- 3 Disconnect the Flow Sensor Cable CBL2123P from the plastic body of the Flow Sensor FLS2101P by pulling cable straight up. Do not twist.
- 4 With a twisting motion, pull the plastic Flow Sensor FLS2101P away from the outlet of the Exhalation Valve EXH2105A.
- 5 To reinstall the Flow Sensor and Exhalation Valve EXH2105A, reverse the above steps.

NOTE: To reconnect the cable to the sensor body, take care to line up the sensor port to the notch in the cable connector. Press together, do not twist.

Removal and Replacement of Exhalation Flow Sensor Cable(outside) CBL2123P

- 1 Perform above steps for removal of Exhalation Valve and Exhalation Flow Sensor.
- 2 Remove the Exhalation Flow Sensor Cable (outside) CBL2123P from the Exhalation Manifold MNF2110A by pulling the collet of the cable connector.
- 3 To reinstall the cable to the Exhalation Manifold MNF2110A, align the key on the connector with the notch of the female connector on the Exhalation Manifold MNF2110A.

Note: The lock mechanism of the connector can be easily released by pulling the collet of the connector. Do NOT disconnect the connector by pulling the wire.

Removal and Replacement of Top Cover CVR2101M

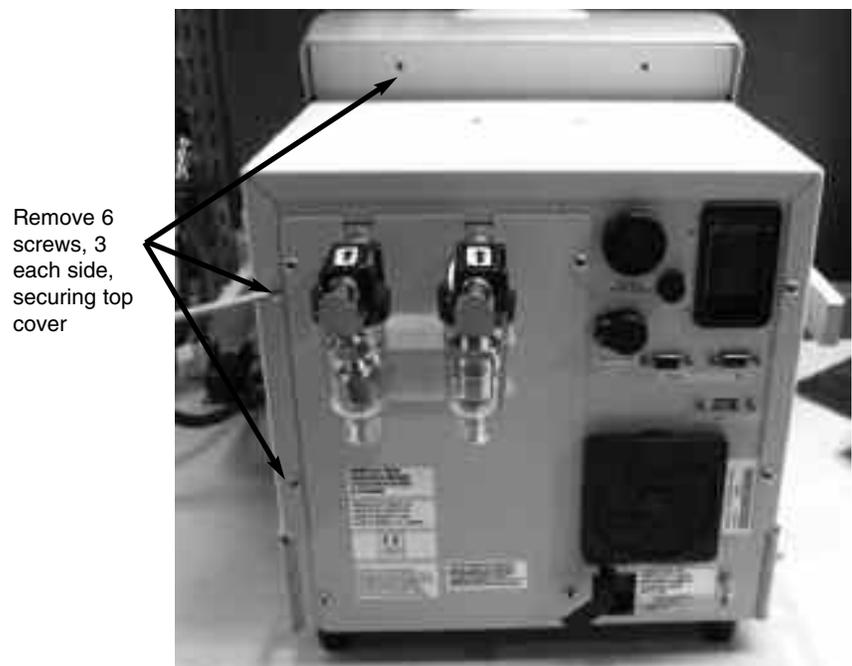


Figure 4-2 Top Cover

Refer to figure 4-2 and follow these steps:

- 1 Rotate the e360 so the rear of the ventilator is facing you.
- 2 Locate the 6 screws securing the cover to the e360 and remove.

COMPONENT REMOVAL & REPLACEMENT

- 3 Grab the handles on the sides of the e360 ventilator, pull the sides away from the chassis and slide the cover off of the e360 ventilator.
- 4 To reinstall, reverse above steps 2 and 3.

Removal and Replacement of Front Panel Assembly DSP2102A

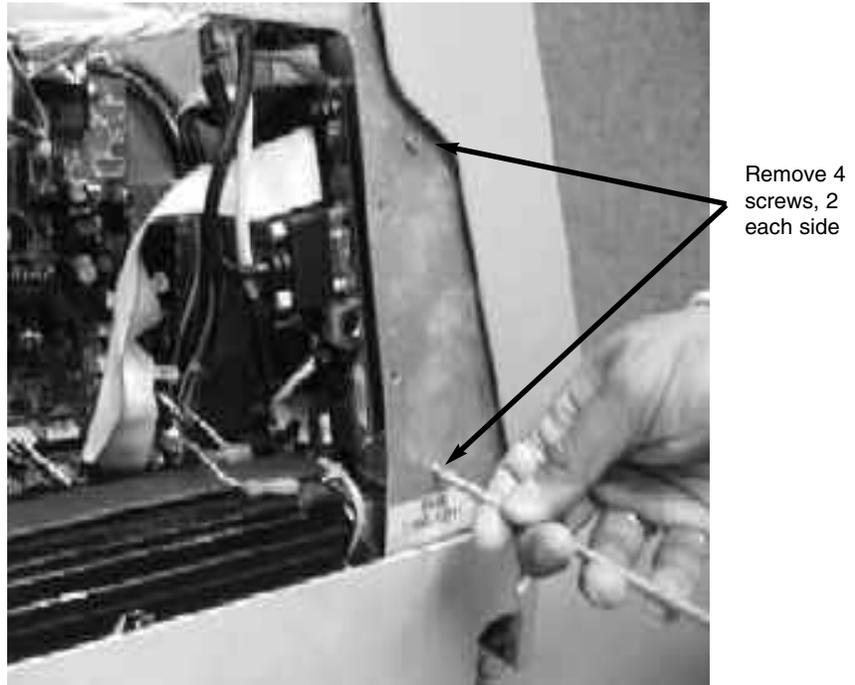


Figure 4-3 Front Panel Assembly DSP2102A

Refer to 4-3 and follow these steps:

- 1 Perform steps 1 and 2 for removal of top cover.
- 2 Locate the four screws securing the front panel assembly to the chassis of the e360 ventilator and remove.
- 3 Carefully pull forward and away the front panel assembly from the e360 ventilator chassis. Locate and remove the following cables.
 - CBL2101A from J2 on PCB2100A
 - CBL2118A from J13 on PCB2100A
 - CBL2110A from J8 on PCB2100A
 - CBL2113A from J10 on PCB2100A
 - Air and oxygen servo valve cables from J705 and J706 on PCB2100A
 - CBL2107A from J708 on PCB2100A
 - CBL2122 from J9 on PCB2100A
 - CBL2105A from connection LCD1 on SBC2100P
 - 3 wire cable of CBL2112A from connection TS1 of SBC2100P. TS1 is a 6 pin connector located adjacent to the speaker SPK1.

- 2 wire cable of CBL2112A from connection IR of SBC2100P. IR is a 5 pin connector located on the bottom of SBC2100P.
- 4 After all above cables are removed, fully remove the front panel assembly and set on a stable surface.
 - 5 To reinstall, reverse above steps 2 and 3.

Note: Cable CBL2112A splits to two connectors: 5-pin connector with 2 wires and 6-pin connector with 3 wires. Ensure the 3 wires face outside when connecting the 6-pin connector on SBC2100P.

Note: There is a small hole adjacent to J9 on PCB2100A, which is to polarize the connector.

Removal and Replacement of Main Board PCB2100A

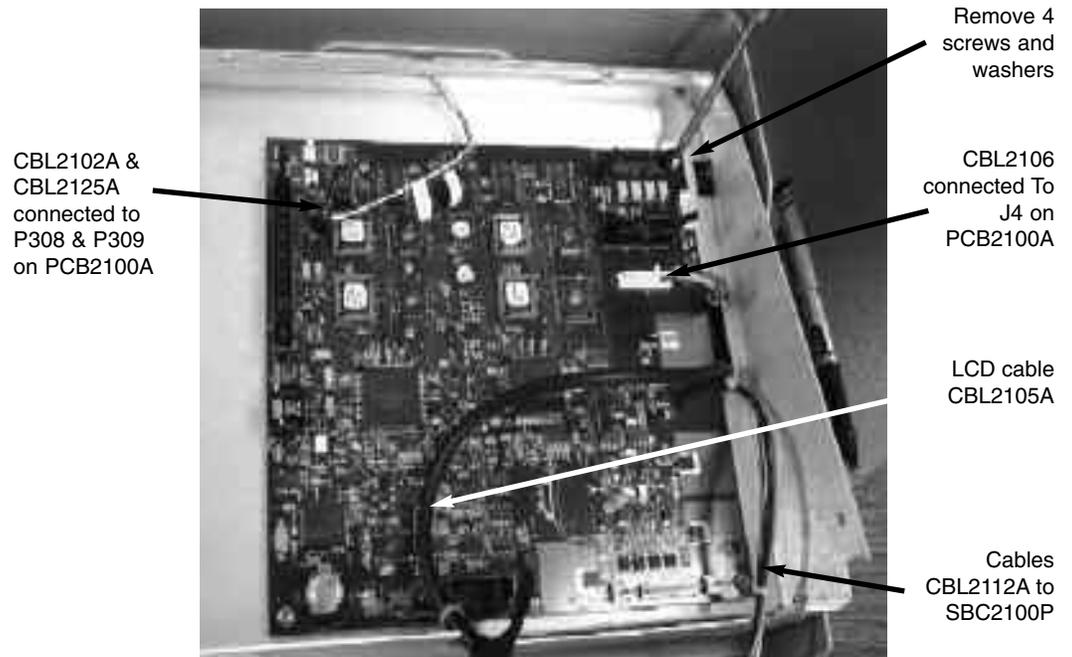


Figure 4-4 Main Board PCB2100A

Refer to figure 4-4 and follow these steps:

- 1 Perform steps above for removal of Front Panel Assembly DSP2102A.
- 2 Remove cable CBL2106A from J4 on PCB2100A.
- 3 Remove cable CBL2102A from P308 and CBL2125A from P309 on PCB2100A.
- 4 Remove 4 screws and washers securing main board to the main board support.

COMPONENT REMOVAL & REPLACEMENT

- 5 For ESD protection, place the main board in an ESD safe container.
- 6 To reinstall, reverse above steps 2 and 3.

Note: If the main board PCB2100A is replaced, the e360 ventilator will need software reloaded and D5, D1, D2, D9 and D4 calibrations performed.

Note: Refer to Section 2 for Software Upgrade Procedure. Refer to Section 5 for all the other calibrations.

Removal and Replacement of Main Board Support CVR2103M

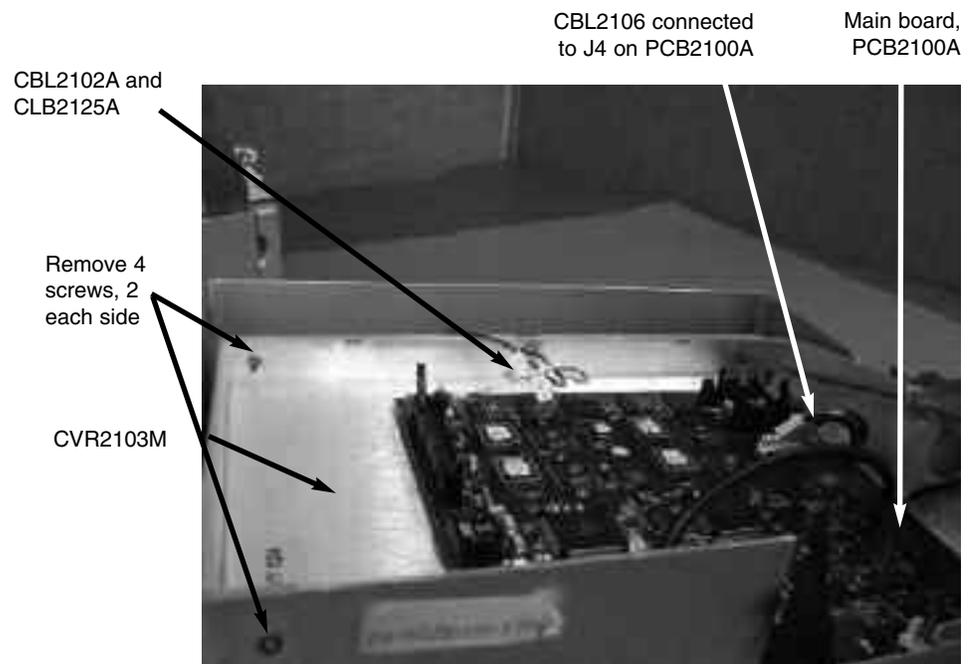


Figure 4-5 Main Board Support CVR2103M

Refer to figure 4-5 and follow these steps:

- 1 Perform steps above for removal of Front Panel Assembly DSP2102A.
- 2 Remove cable CBL2106A from J4 on PCB2100A.
- 3 Remove the cables CBL2125A and CBL2102A from the top LEDs.
- 4 Remove Qty 4 screws and washers securing the main board support to the front panel assembly.
- 5 Carefully lift up on the main board support and feed the cables CBL2105A, CBL2106A and CBL2112A through the cut out on the main board support.

COMPONENT REMOVAL & REPLACEMENT

- 1 Perform steps above for removal of Main Board Support.
- 2 Remove the 4 pin ribbon cable from header H2 on the touch screen interface board PCB2105P.
- 3 Remove cable CBL2112A from header H1 on the touch screen interface board PCB2105P.
- 4 Remove Qty 9 screws and washers securing the PCB2102A to the chassis of the DSP2102A.
- 5 Carefully lifting up on the display board from the lower left corner near the encoder, locate and remove the cable of the encoder from J209 on the PCB2102A.
- 6 Remove the lamp cable of LCD DSP2105P from JP203 on PCB2102A.
- 7 Push on the tab and remove front panel membrane cable from JP202 on PCB2102A.
- 8 Place the display board in an ESD safe container.
- 9 To reinstall, reverse above steps 2 through 7.

Note: If the Display Board PCB2102A is replaced, the e360 ventilator will need the software reloaded. Refer to Section 2 for Software Upgrade Procedure.

Removal and Replacement of Touch Screen Interface Board PCB2105P

Refer to figure 4-7 above and follow these steps:

- 1 Perform steps above for removal of Display Board PCB2102A
- 2 Locate and remove 2 screws, washers and nuts securing the PCB2105P to the display board.
- 3 To reinstall, reverse step 2.

Removal and Replacement of Large LCD Cable CBL2105A

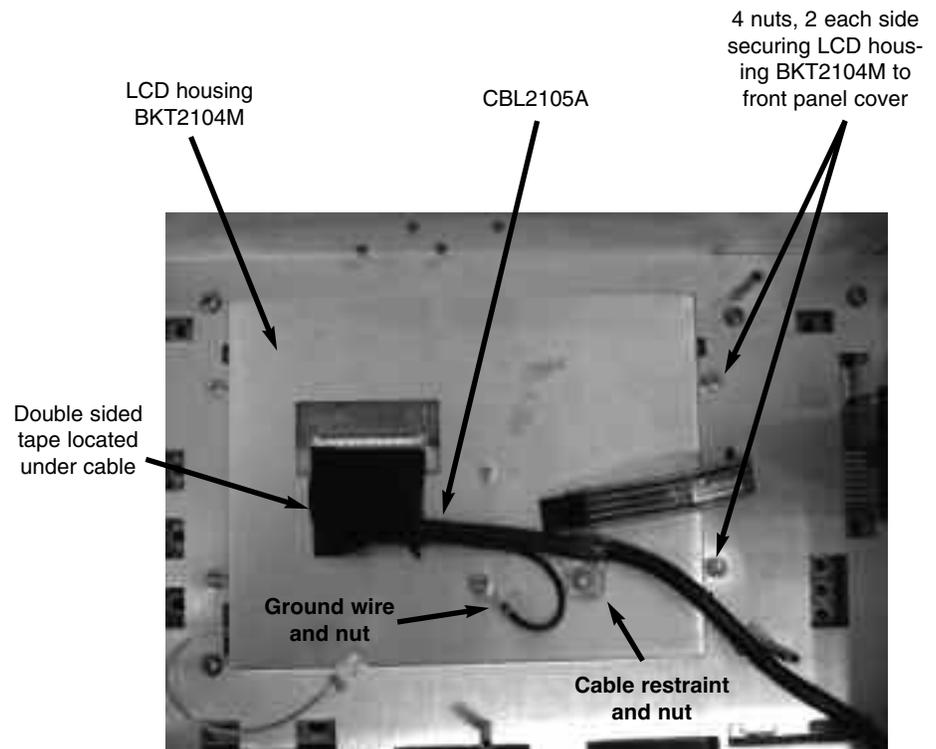


Figure 4-8 CBL2105A

Refer to figure 4-8 and follow these steps:

- 1 Perform steps above to remove Display Board PCB2102A.
- 2 Using 7/32" nut driver, remove the nut securing the ground wire of CBL2105A to the LCD housing BKT2104M
- 3 Using a 7/32" nut driver, remove the nut securing the cable restraint for CBL2105A to the LCD housing BKT2104M
- 4 Gently lift the cable away from the LCD housing, releasing it from the double sided tape.
- 5 Pull cable CBL2105A away from connector CN1 on the rear of the LCD display.
- 6 To reinstall the CBL2105A, carefully align the cable connector with CN1 on the LCD display and bend the cable up and push the connector on to CN1 then press the connector on to the double sided tape. Reverse above steps 2 and 3.

COMPONENT REMOVAL & REPLACEMENT

Removal and Replacement of Front Panel Cover CVR2104M

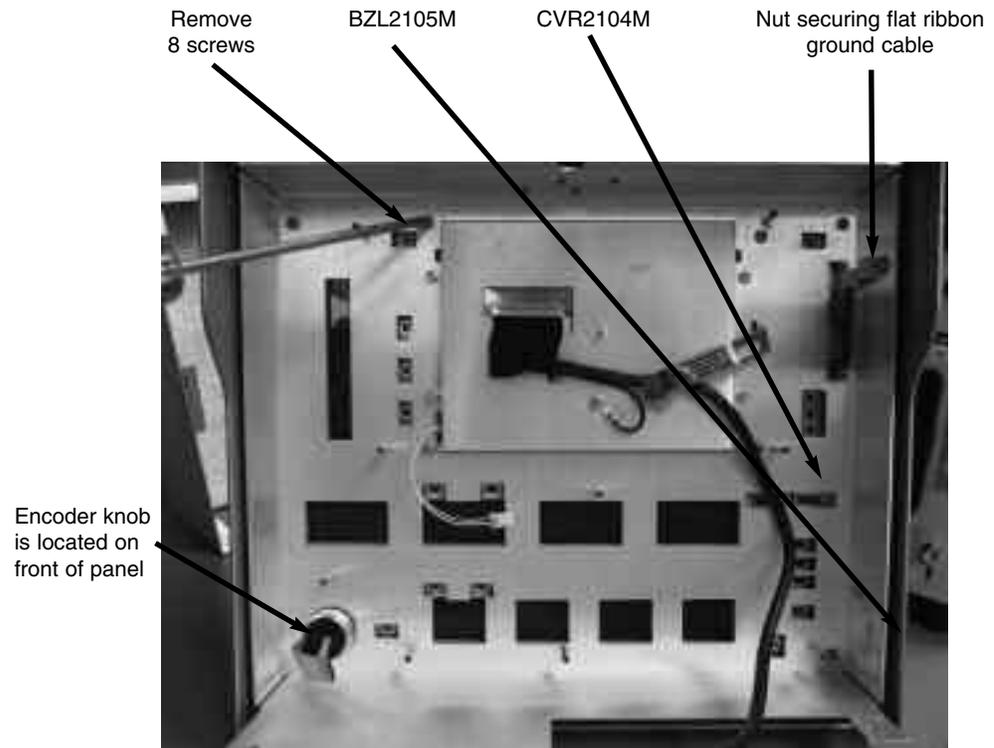


Figure 4-9 Front Panel Cover CVR2104M

Refer to figure 4-9 and follow these steps:

- 1 Perform above steps to remove the Display Board PCB2102A.
- 2 Using a 5/64" hex key, remove the set screw securing the control knob to the encoder and remove the knob.
- 3 Remove Qty 8 screws and washers securing the CVR2104M to the front panel bezel BZL2105M.
- 4 Remove the nut securing the flat ribbon cable ground to the side of front panel cover CVR2104M.
- 5 Pull the front panel cover CVR2104M away from the front bezel and place in an ESD safe container.
- 6 To reinstall, reverse above steps 2 through 5.

Removal and Replacement of Optical Encoder ENC1800P

- 1 Perform above steps for removal of the front panel cover CVR2104M.
- 2 Using an 11mm wrench, remove the nut and washer securing the encoder to the front panel cover CVR2104M.
- 3 To reinstall, reverse the above step 2.

Note: When securing the encoder with the nut and washer, tighten the nut to 8 in/lbs of torque.

Removal and Replacement of Alarm LEDS

- 1 Perform above steps for removal the front panel cover CVR2104M.
- 2 For each of the alarm LEDS, remove Qty 2 screws securing the boards to the CVR2104M.
- 3 To reinstall, reverse above step 2.

Note: The red LED is p/n LED2101P and amber LED is p/n LED2102P.

Removal and Replacement of LCD Display DSP2105P

Refer to figure 4-8 and 4-9 and follow these steps:

- 1 Perform above steps for removal of CBL2105A.
- 2 Remove the 4 nuts and washers securing the LCD housing BKT2104M to the CVR2104M.
- 3 Remove the 4 screws securing the BKT2104M to the LCD display DSP2105P.
- 4 To reinstall, reverse above steps 2 and 3.

COMPONENT REMOVAL & REPLACEMENT

Removal and Replacement of Touch Screen PNL2105P

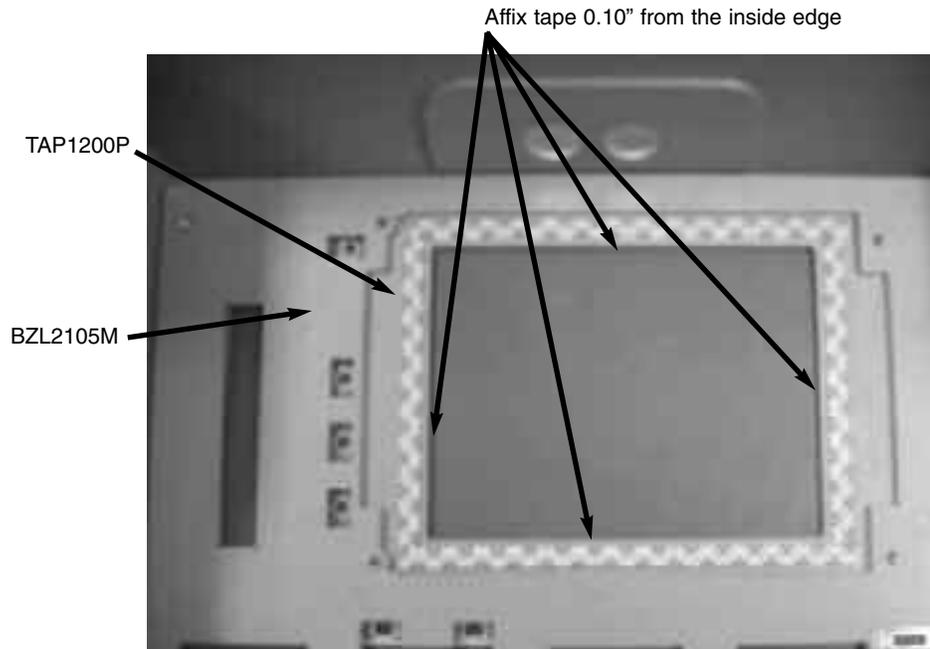


Figure 4-10 Touch Screen Panel PNL2105P

Note: Removal of the touch screen PNL2105P will destroy the screen, do not remove unless you have a replacement touch screen PNL2105P.

Refer to figure 4-10 and follow these steps:

- 1** Perform above steps for removal of the LCD display DSP2105P.
- 2** Using a flat screw driver, pry the touch screen away from the front bezel BZL2105M.
- 3** To install a new touch screen, clean all tape and adhesive from the front bezel and wipe clean with isopropyl alcohol.
- 4** Apply 4 pieces of double side tape p/n TAP1200P around the perimeter of the bezel. The tape should be placed 0.10" from the inside edge. Press the tape firmly onto the bezel.
- 5** Peel back the protective cover on the double sided tape to expose the adhesive, carefully place the new touch screen PNL2105P on to the tape and press firmly.
- 6** Clean inside panel of debris and fingerprints before reinstalling the LCD display PNL2105P.

Removal and Replacement Pneumatics Panel Assembly SVO2101A

Refer to figures 4-11, 4-12 and 4-13 and follow these steps:

4 screws, 2 each side secures PNL2102M

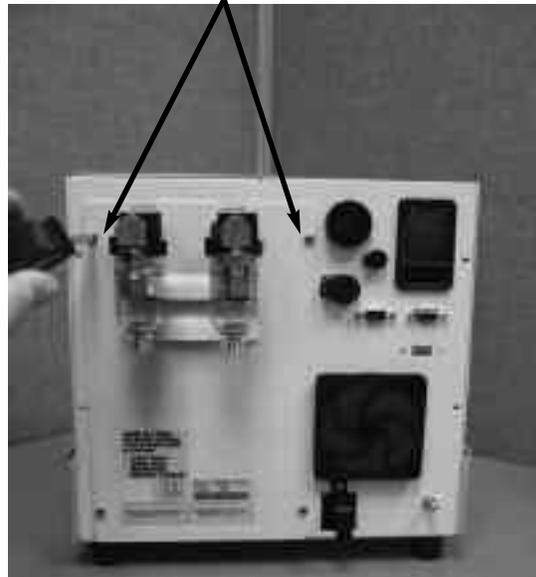


Figure 4-11 Pneumatics Panel

6 screws, 3 on each side secures CVR2106M

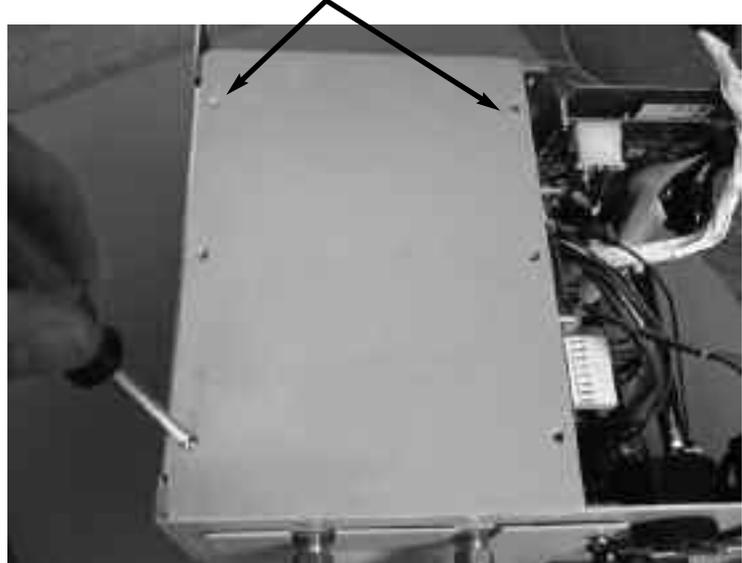


Figure 4-12 Pneumatics Cover

COMPONENT REMOVAL & REPLACEMENT

Cover CRV2115M
with Gasket GKT2101M

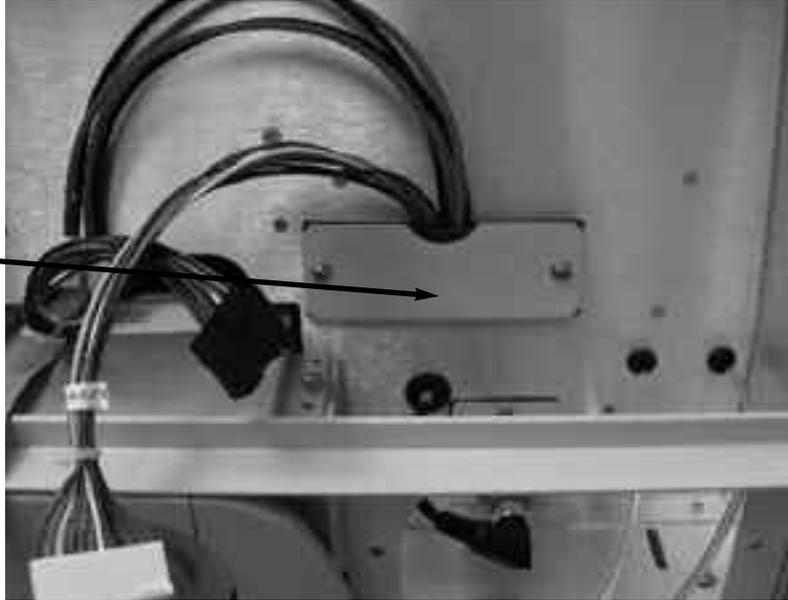


Figure 4-13 Cover CRV2115M and Gasket GKT2101M

Refer to figures 4-11, 4-12 and 4-13 and follow these steps:

- 1 Perform steps above for Removal of Top Cover and Front Panel Assembly.
- 2 Remove 6 screws securing the pneumatics cover CVR2106M.
- 3 Remove the 2 screws securing the cover CVR2115M and gasket GKT2101M.
- 4 Remove the yellow tube and blue tube from the air and oxygen inlet manifold BLK2115M
- 5 Remove the 4 screws securing the pneumatics panel PNL2102M
- 6 Remove the yellow tube and blue tube from the air and oxygen servo vales SVO2101P
- 7 While supporting the pneumatics panel, slide the panel away from the e360 ventilator.
- 8 To reinstall, support the pneumatics panel and align the air and oxygen flow sensors into the flow sensor manifold block, secure 2 screws on top for the pneumatics panel PNL2102M before releasing support. Reverse steps 2 through 7.

Removal and Replacement of Servo Valves, Regulators, Inlet Blocks and Flow Sensor Block

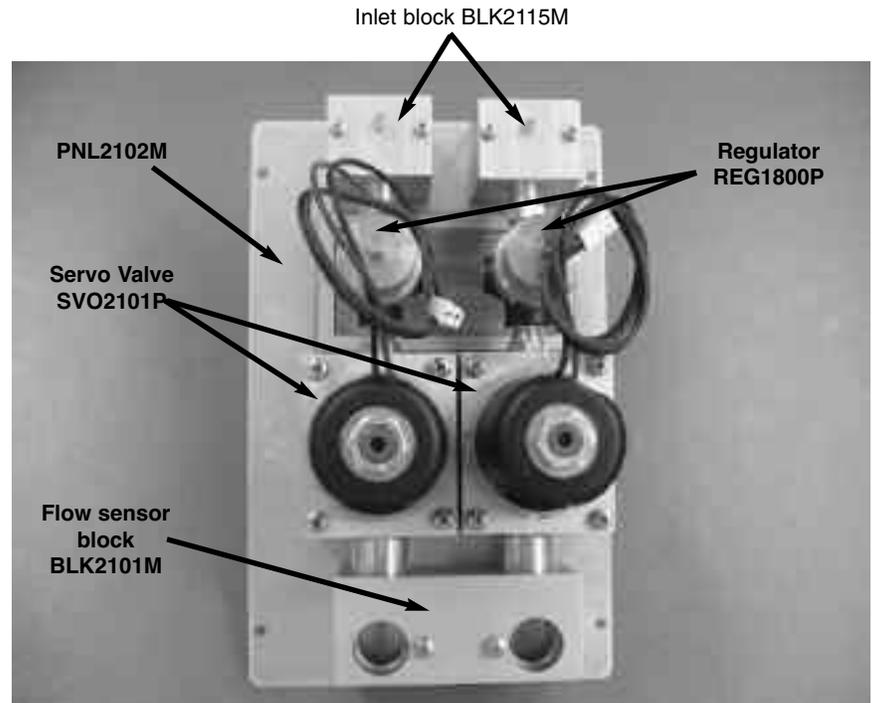


Figure 4-14 Pneumatics Panel Assembly SVO2101A

Refer to figure 4-14 and follow these steps:

- 1 Perform above steps for removal of pneumatic panel assembly SVO2101A.

Note: To replace servo valves, regulators, inlet blocks or the flow sensor block, all screws securing listed components need to be removed.

- 2 Remove 4 screws, 2 each securing the air and oxygen inlet blocks to PNL2102M.
- 3 Remove 8 screws, 4 each securing the air and oxygen servo valves to PNL2102M
- 4 Remove 2 screws securing the flow sensor block to PNL2102M.
- 5 Lift all parts away from the panel PNL2102M at the same time, then disassemble each component as needed.
- 6 To reassemble, reverse steps 2 through 5. Ensure the servo valves and regulators are aligned during reassembly.

Note: If replacing either of the servo valves or regulators, calibrations D1 and / or D2 and calibration of the regulators will need to be performed. Refer to Section 5 for D1, D2, and regulator calibration.

COMPONENT REMOVAL & REPLACEMENT

Removal and Replacement of Regulator and Solenoid Assembly BKT2105A

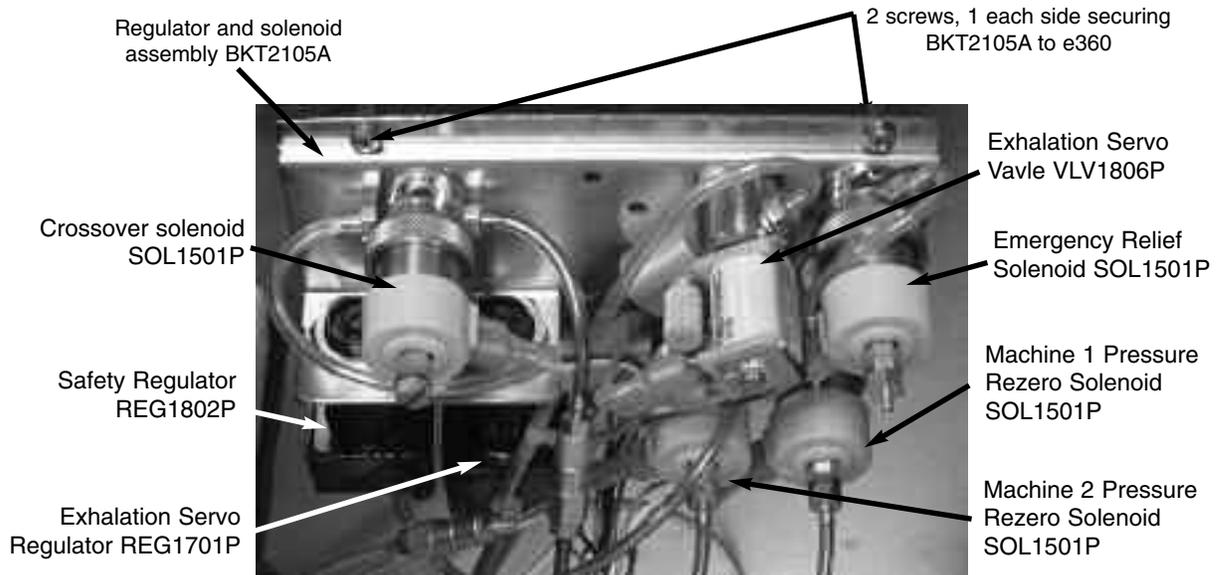


Figure 4-15 Regulator and Solenoid Assembly BKT2105A

Refer to figure 4-15 and the System Pneumatic Diagram in Appendix C, and follow these steps:

- 1 Perform steps above for removal of Pneumatics Panel Assembly SVO2101A.
- 2 Remove the yellow tubing from the Air Inlet Block BLK2115M, and remove the blue tubing from the Oxygen Inlet Block BLK2115M. Refer to Fig 4-14.
- 3 Remove the clear tubing from the top port of the pressure transducer XD105 (machine 1 pressure) on the analog board PCB2104A, and remove the clear tubing from the exhaust port of the rezero solenoid SOL1501P for machine pressure 1.
- 4 Remove the green tubing from the bottom port of the pressure transducer XD106 (machine 2 pressure) on the analog board PCB2104A, and remove the green tubing from the exhaust port of the rezero solenoid SOL1501P for machine pressure 2.
- 5 Remove the blue tubing, one end of which is connected to the Exhalation Servo Valve VLV1806P, from the other end, which is connected to a tee connector.
- 6 Remove the green tubing, one end of which is connected to the IN port of the Emergency Relief Solenoid SOL1501P, from the other end, which is connected to a cross tee connector.

- 7 Remove 2 screws and washers securing BKT2105A to the e360 ventilator.
- 8 To reinstall, reverse the above steps.

Removal and Replacement of FTD2100P and FTD2101P Inspiratory Flow Sensors

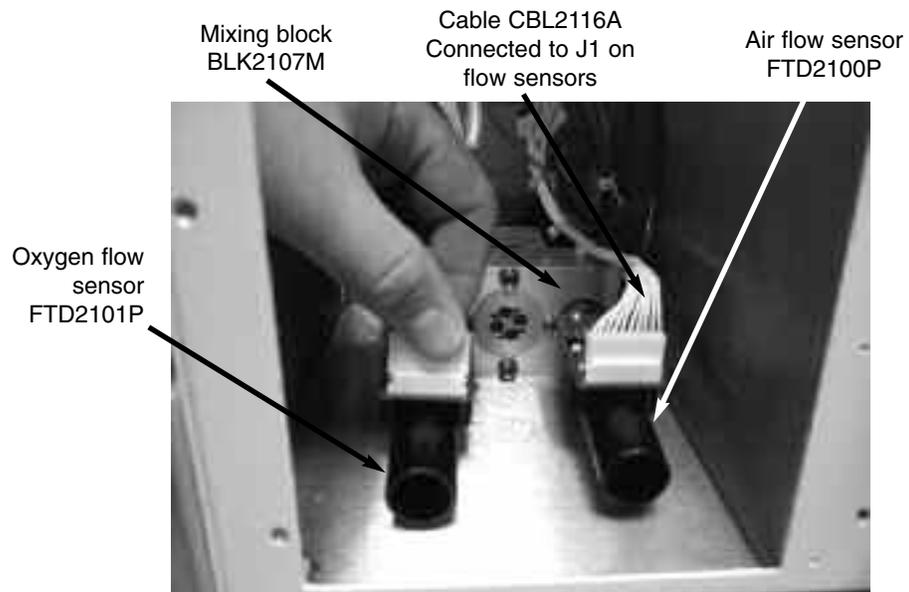


Figure 4-16 Inspiratory Flow Sensors

Refer to figure 4-16 and follows these steps:

- 1 Perform steps above for removal of pneumatics panel assembly SVO2101A.
- 2 Remove cable CBL2116A from connector J1 on the flow sensor.
- 3 Remove the flow sensors from mixing block BLK2107M by pulling the flow sensor straight out of the mixing block.
- 4 To reinstall, reverse steps 2 and 3.

Note: If either of the flow sensors are replaced, calibrations D1 and /or D2 will need to be performed.

COMPONENT REMOVAL & REPLACEMENT

Removal and Replacement of Main Flow Outlet Block Assembly BLK2108A

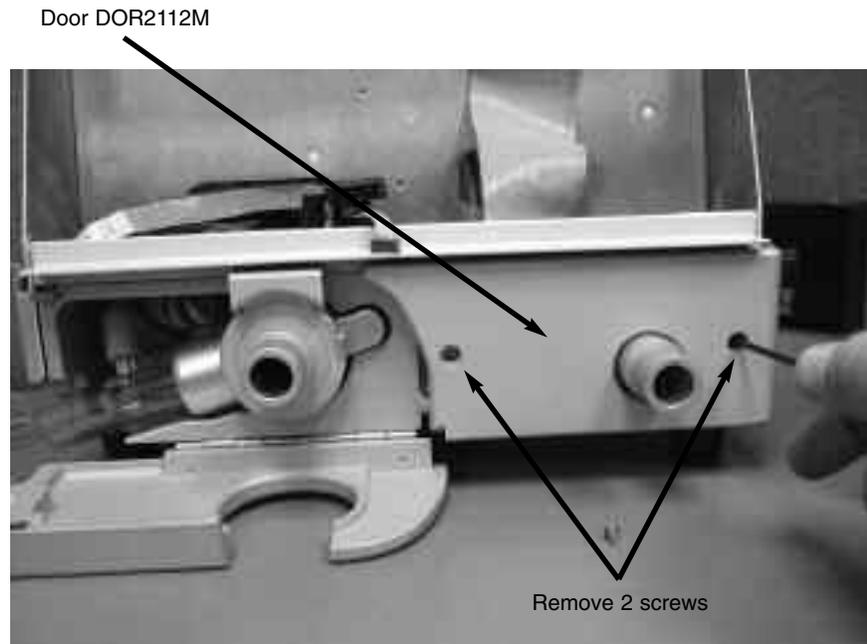


Figure 4-17 Door DOR2112M

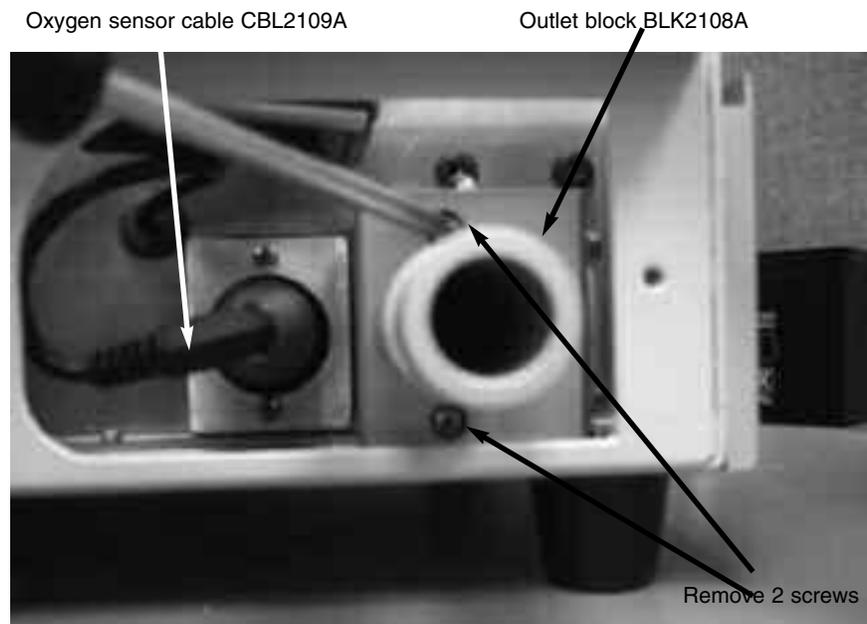


Figure 4-18 Outlet Block BLK2108A

Refer to figure 4-17 and 4-18 and follow these steps:

- 1 Remove the 2 screws securing DOR2112M to the front of the e360 ventilator.

- 2 Remove 2 screws securing BLK2108A to the e360 ventilator.
- 3 Pull the BLK2108A away from the e360 ventilator and remove 2 tubes.
- 4 To reinstall, reverse above steps 2 and 3.

Removal and Replacement of Oxygen Sensor R125P03-002

Refer to figure 4-18 and 4-19 and follow these steps.

- 1 Remove the Oxygen Sensor cable CBL2109A from the Oxygen Sensor R125P03-002 by unscrewing the connector on the cable.
- 2 Remove the Oxygen Sensor by unscrewing the Oxygen Sensor counterclockwise.
- 3 To reinstall, reverse above steps 1 and 2.

Note: If the Oxygen Sensor is installed too tightly to be removed, place a Newport reusable circuit on the oxygen sensor to obtain better friction while unscrewing the Oxygen Sensor.



Figure 4-19 Use circuit to loosen Oxygen Sensor

COMPONENT REMOVAL & REPLACEMENT

Removal and Replacement of Inhalation Outlet Block and Mixing Block Assembly

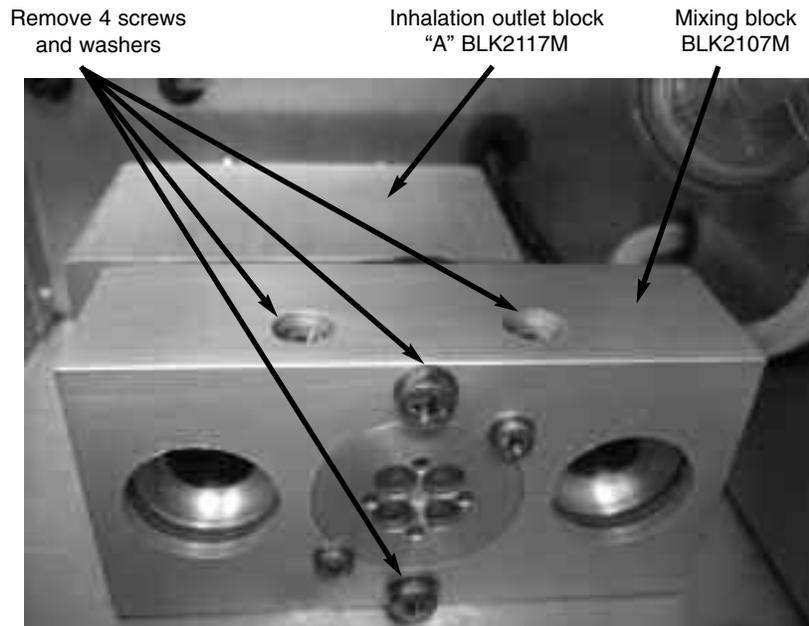


Figure 4-20 Inhalation Outlet block and mixing block

Refer to figure 4-20 and follow these steps:

- 1 Perform above steps for removal of Oxygen Sensor R125 P03-002.
- 2 Remove 2 screws on top of mixing block BLK2107M.
- 3 Remove both the mixing block and inhalation block from the e360 ventilator.
- 4 Remove 2 screws and washers securing mixing block BLK2107M to inhalation outlet block BLK2117M and separate the two.
- 5 To reinstall, reverse above steps 2 through 5.

Removal and Replacement of Analog Board PCB2104A

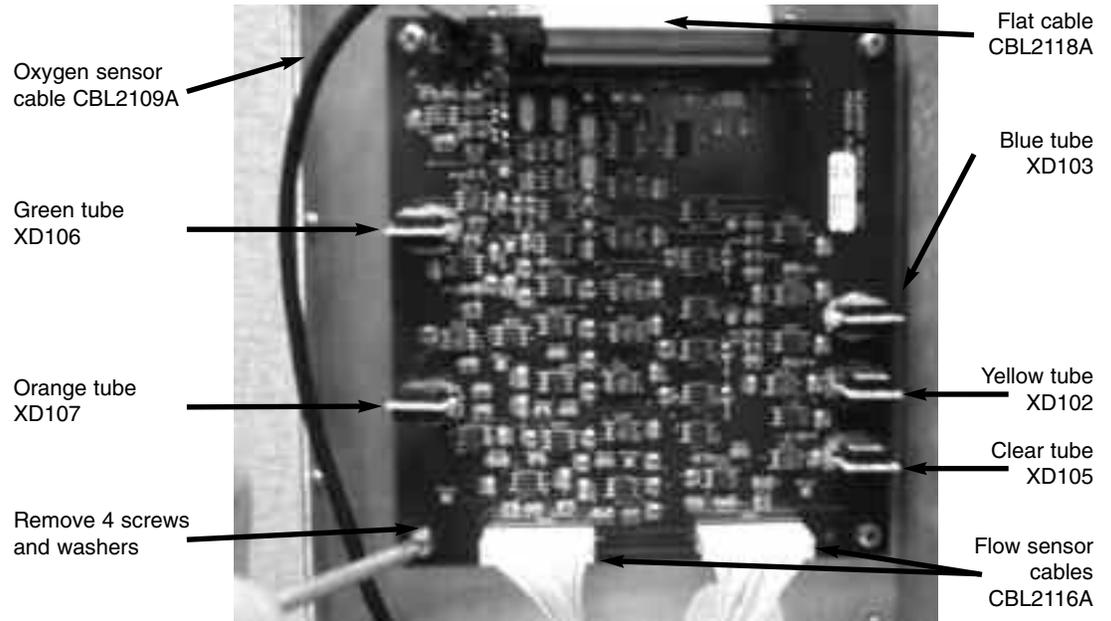


Figure 4-21 Analog board PCB2104A

Refer to figure 4-21 and follow these steps:

- 1 Perform above steps for removal of Regulator and Solenoid Assembly BKT2105.
- 2 Remove 5 tubes from PCB2104A
 - Orange tube – exhalation valve pressure from XD107
 - Green tube – Exhalation valve pressure from XD106
 - Blue tube – Regulated oxygen pressure from XD103
 - Yellow tube – Regulated air pressure from XD102
 - Clear tube – Patient breathing circuit pressure from XD105

Note: For transducers XD106 and XD107, the tubings are connected to the bottom ports of the transducers. For transducers XD102, XD103 and XD105, the tubings are connected to the top ports of the transducers.

- 3 Remove flat cable CBL2118A from J401 on PCB2104A.
- 4 Remove oxygen sensor cable CBL2109A from J404 on PCB2104A.
- 5 Remove air and oxygen flow sensor cables CBL2116A from J402 and J403 on PCB2104A
- 6 Remove 4 screws and washers securing PCB2104A to the e360 ventilator.

COMPONENT REMOVAL & REPLACEMENT

7 To reinstall, reverse above steps 2 through 6.

Note: If the analog board PCB2104A is replaced, the e360 ventilator will need D5 calibration performed. Refer to Section 5 for the D5 calibration.

Removal and Replacement of Heater Assembly HTR2100A

Remove 2 screws and washers Heater HTR2100A



Figure 4-22 Heater Assembly HTR2100A

Refer to figure 4-22 and perform these steps:

- 1 Perform above steps for removal of Front Panel Assembly DSP2102A
- 2 Remove 2 screws securing the door DOR2112M to the e360 ventilator.
- 3 Remove 2 screws securing heater HTR2100A to the MNF2110A (Exhalation Manifold).
- 4 Remove heater cables from power supply board PCB2101A connectors J107 and J108.
- 5 Remove the heater HTR2100A.
- 6 To reinstall, reverse above steps 2 through 5

Removal and Replacement of Exhalation Manifold MNF2110A

Refer to figures 4-23 and 4-24 and follow these steps:

- 1 Turn the e360 ventilator so the bottom of the unit is facing upward, remove 3 screws securing the MNF2101A to the base of the e360 and the 1 screw and washer securing the bumper BMP2100P to the bottom of the e360 ventilator.
- 2 Remove the exhalation valve drive line and the Machine 2 pressure line from the rear of the Exhalation Manifold MNF2110A (see figure 4-22).
- 3 Remove the MNF2110A from the e360 ventilator.
- 4 To reinstall, reverse above steps 2 and 3.

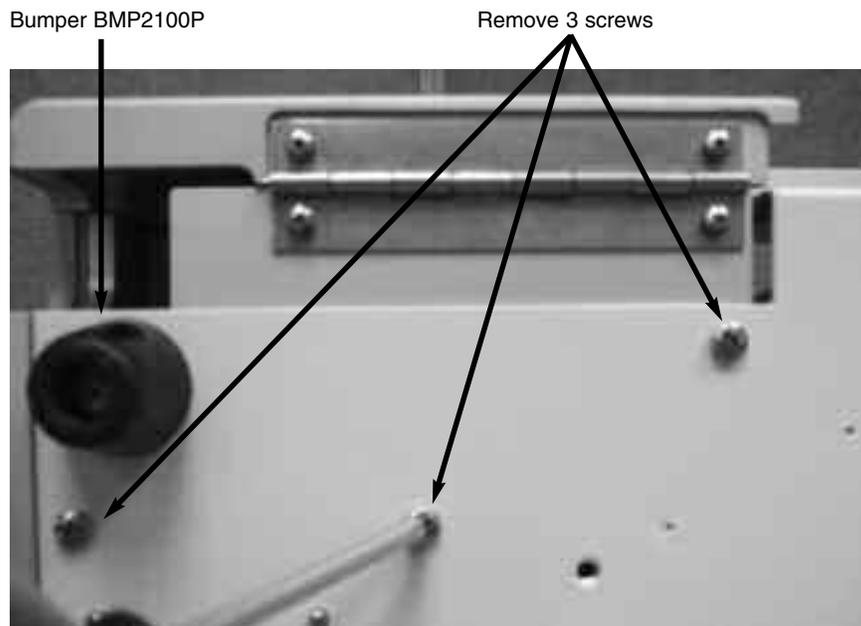


Figure 4-23 Location of 3 screws and bumper

COMPONENT REMOVAL & REPLACEMENT

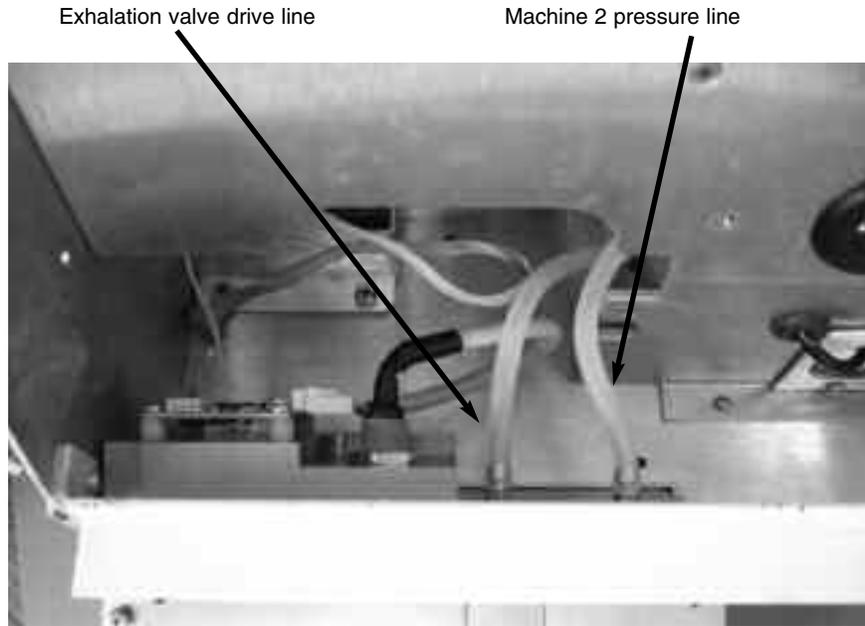


Figure 4-24 Removal of MNF2110A

Removal and Replacement of Exhalation Flow Sensor Board PCB2103P

Refer to figure 4-25 and follow these steps.

Perform above steps for removal of Exhalation Manifold MNF2110A.

- 1 Remove cable CBL2122A from K1 and CBL2124P from K5 on PCB2103P.
- 2 Remove 2 screws and washers securing PCB2103P to the Exhalation Manifold MNF2110A.
- 3 Remove PCB2103P.
- 4 To reinstall, reverse above steps 1 through 4.

Note: There is a small hole adjacent to K1 on PCB2103P, which is to polarize the connector.

CBL2124P connected to
K5 on PCB2103P

CBL2122A connected to
K1 on PCB2103P

Polarization hole for K1
on PCB2103P

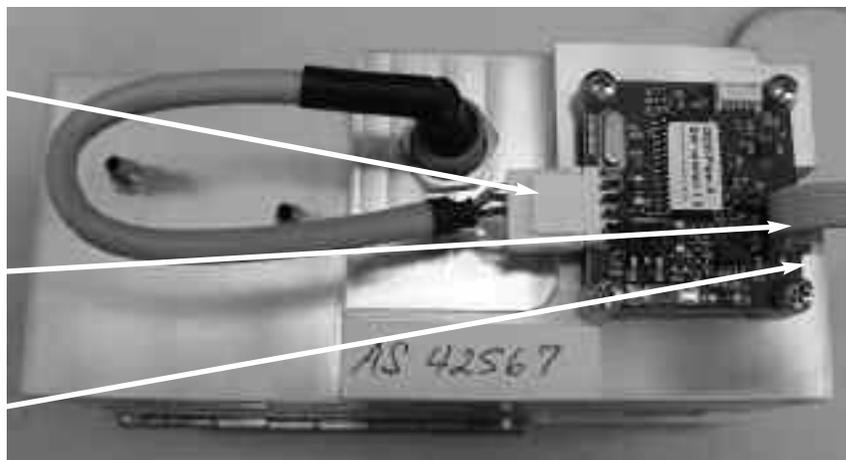


Figure 4-25 Exhalation Flow Sensor Board PCB2103A

Removal and Replacement of Battery BAT1800P

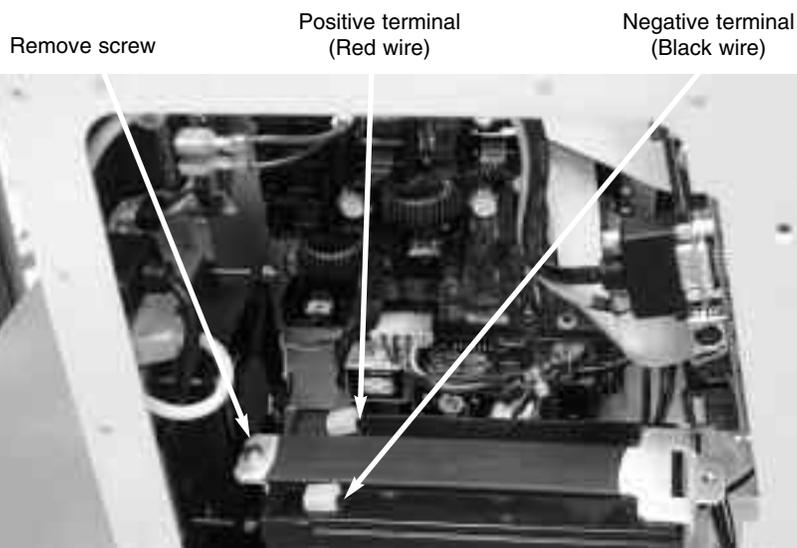


Figure 4-26 Battery removal BAT1800P

Refer to Figure 4-26 and perform these steps:

- 1 Perform steps for removal of Top Cover on Page 4-3.
- 2 Remove the battery wires from the positive and negative terminals.
- 3 Remove the screw securing the battery bracket to the e360 ventilator and life off bracket.
- 4 Remove the battery by lifting up and out.
- 5 To reinstall, reverse steps 2 through 4.

COMPONENT REMOVAL & REPLACEMENT

Removal and Replacement of AC/DC Power Supply PWR2100P

Cable CBL2115
connected to TB1

Remove 4 screws
and washers

Cable CBL2103
connected to TB2

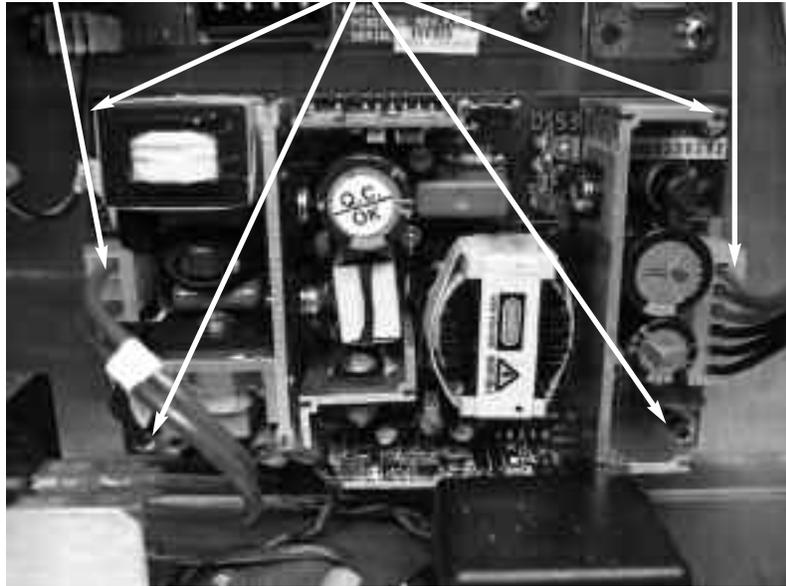


Figure 4-27 AC/DC Power Supply PWR2100P

Refer to figure 4-27 and follows these steps:

- 1 Perform above steps for removal of the battery.
- 2 Removal cables CBL2115A from connector TB1 and CBL2103A from connector TB2 on PWR2100P
- 3 Remove 4 screws and washers securing PWR2100P to the e360 ventilator.
- 4 Remove the PWR2100P.
- 5 To reinstall, reverse above steps 2 through 4.

Removal and Replacement of DC to DC Power Supply PCB2101A

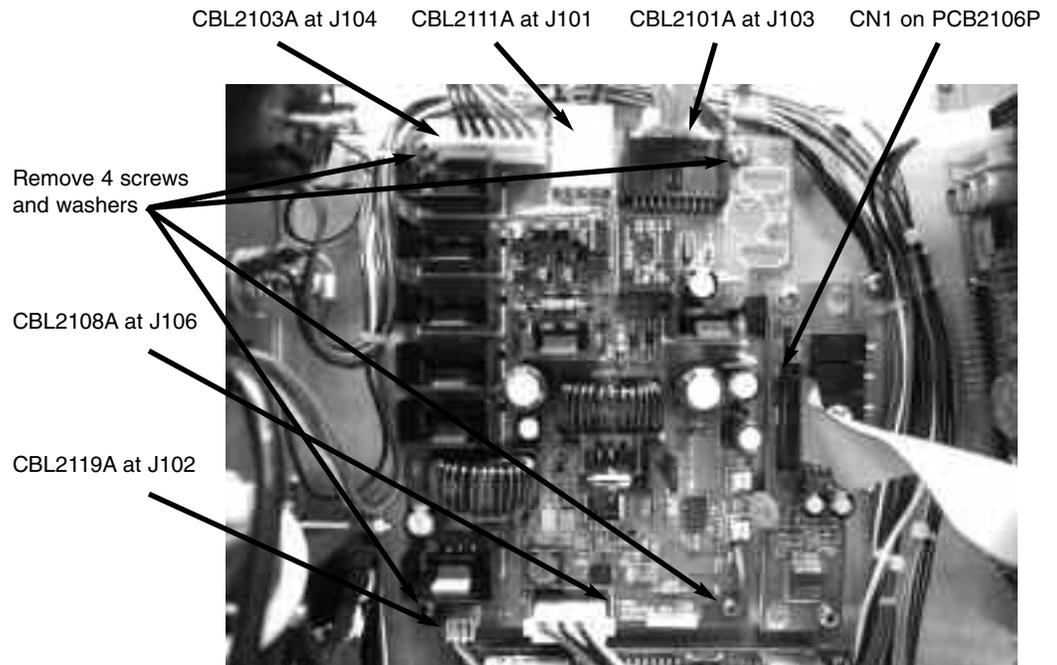


Figure 4-28 Dc to DC power supply PCB2101P

Refer to figure 4-28 and follow steps:

- 1 Perform above steps for removal of battery BAT1880P.
- 2 Remove cables from the following locations;
 - CBL2101A from J103 on PCB2101P
 - CBL2103A from J104 on PCB2101P
 - CBL2108A from J106 on PCB2101P
 - CBL2111A from J101 on PCB2101P
 - CBL2119A from J102 on PCB2101P
- 3 Remove 4 screws and washers securing PCB2101P to the e360 ventilator.
- 4 To reinstall, reverse above steps 2 and 3.

COMPONENT REMOVAL & REPLACEMENT

Removal and Replacement of Sound Processor Board PCB2106P

Refer to figure 4-28 and follow these steps:

- 1 Perform above steps for removal of the battery.
- 2 Remove flat ribbon cable from CN1 on PCB2106P
- 3 Remove 2 screws and washers securing PCB2106P to the e360 ventilator
- 4 Remove the board.
- 5 To reinstall, reverse above steps 2 through 4

Removal and Replacement of Single Board Computer SBC2100P

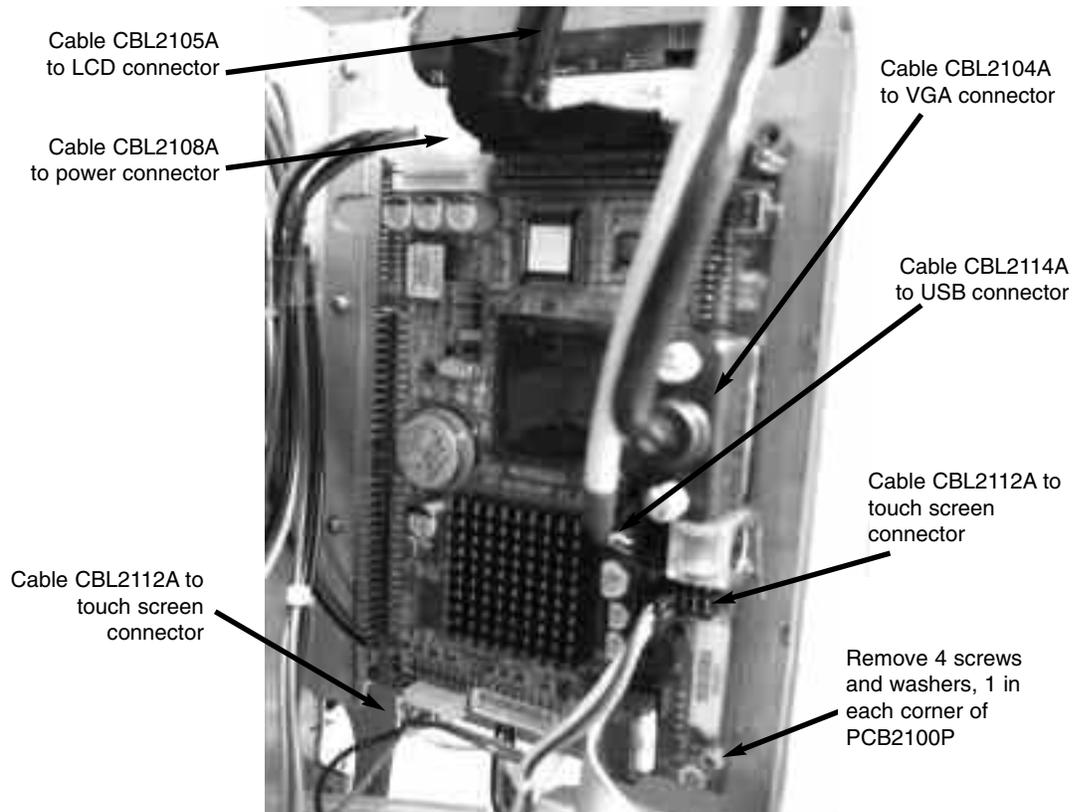


Figure 4-29 Single Board Computer SBC2100P

Refer to figure 4-29 and follow these steps:

- 1 Perform above steps for removal of battery.
- 2 Remove cables from the following locations:

- CBL2104A from VGA connector on PCB2100P
- CBL2105A from LCD connector on PCB2100P
- CBL2108A from Power connector on PCB2100P
- CBL2112A from Touch Screen connector 3 wires on PCB2100P
- CBL2100P from Touch Screen connector 2 wires on PCB2100P
- CBL2114A from USB connector on PCB2100P

3 Remove 4 screws and washers securing PCB2100P to the e360 ventilator.

4 Remove the PCB2100P.

5 To reinstall, reverse steps 2 through 4.

Note: Cable CBL2112A splits to two connectors: 5-pin connector with 2 wires and 6-pin connector with 3 wires. Ensure the 3 wires face toward the closest edge of the SBC2100P when connecting the 6-pin connector on SBC2100P.

Note: If the Single Board Computer SBC2100P is replaced, the e360 ventilator will need software reloaded. Refer to Section 2 for Software Upgrade Procedure.

5. CALIBRATION PROCEDURES

Calibration Procedures	5-1
– Calibration Equipment	5-1
Setup	5-2
Diagnostic Mode	5-3
– Entering Diagnostic Mode.....	5-3
Analog PCB Calibration	5-4
e360 Pneumatics Calibration	5-9
– Air Inlet Regulator	5-9
– Oxygen Inlet Regulator	5-11
– Exhalation Servo Regulator	5-11
– Safety Regulator	5-12
– Air Servo Valve	5-12
– Oxygen Servo Valve	5-13
– Exhalation Flow Sensor	5-14
– Exhalation Servo Valve	5-14
Descriptions of Message ID	5-15

CALIBRATION PROCEDURES

The purpose of these procedures is to provide instructions and acceptance/rejection criteria to calibrate the e360 Ventilator.

This section describes how to use the e360 Ventilator's Diagnostic Mode to calibrate the e360 ventilator. The Diagnostic Mode can also be used for troubleshooting (see Section 3 for more information on troubleshooting).

WARNING An authorized Newport Medical Instruments factory-trained service technician must perform all service and repairs on the e360 Ventilator.

WARNING Hazardous voltages are present inside the e360 ventilator. Disconnect electrical power, air, and oxygen sources before attempting any disassembly. Failure to do so could result in injury to service personnel or damage to equipment.

NOTE: To prevent damage from ESD and possible failure of the e360 ventilator, ALWAYS use standard anti-static practices when working inside the e360 ventilator, handling circuit boards or handling any other electronic components.

Calibration Equipment

Verify that all test equipment is in current calibration status. To calibrate the e360 Ventilator you will need the following:

- NMI Reusable Breathing Circuit (PBC340A) or equivalent
- Cap to plug the end of the breathing circuit (CAP100P) or equivalent
- Clean, dry regulated medical air and oxygen supplies at 50 \pm 2 psig.

NOTE: To perform the calibration procedures correctly, the gas supply pressure must be regulated to 50 \pm 2 psig. The gas supplies can support a minimum constant flow of 180L/min.

- Power Source of 100 – 240VAC, 50/60 Hz.
- High Pressure Gauge for reading from 0 – 60 psig, or equivalent.
- Low Pressure Gauge for reading from 0 – 200 cmH₂O, or equivalent.
- Calibrated pressure syringe; NMI tool (TOL1952P) or equivalent.

CALIBRATION PROCEDURES

- 1/4 inch Open-ended Wrench
- 5/16 inch Open-ended Wrench
- Medium size flat head screw driver

Caution The accuracy of all test equipment (electronic or pneumatic) used for verification or calibration procedures should be certified annually by a testing laboratory before use.

SETUP

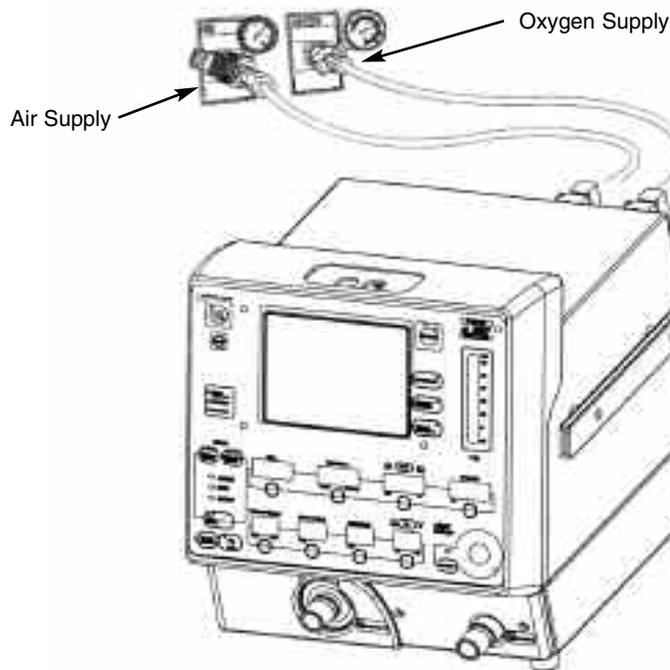


Figure 5-1 e360 Ventilator Connected to Gas Sources

- 1 Visually inspect the e360 ventilator for cosmetic defects, damage or missing items.
- 2 Before removing the Top Cover, unplug the e360 ventilator from the AC power and gas sources.
- 3 Remove the 6 screws on the Back Panel that secures the Top Cover to the e360 ventilator. Remove the Top Cover, see Section 4, "Removal of Top Cover".
- 4 Reconnect the AC power to the e360 ventilator.
- 5 Connect both air and oxygen supply gas sources to the e360 ventilator, verify supply gas sources are at 50 ± 2 psig.
- 6 Prior to starting the calibration procedure, verify that all test equipment is in current calibration status.

Diagnostic Mode

Most of the calibrations on the e360 ventilator are performed in the Diagnostic Mode. The Diagnostic Mode enables you to perform Servo Valve Calibration, Exhalation Valve Calibration, and Regulator Calibration.

Table 5-1 Diagnostic Mode

Diagnostic Mode	Calibration
D0	N/A
D1	Air Servo Valve Calibration
D2	Oxygen Servo Valve Calibration
D3	Manual Flow Adjustment
D4	Exhalation Servo Valve Calibration
D5	Analog PCB Calibration
D6	N/A
D7	N/A
D8	N/A
D9	Exhalation Flow Sensor Calibration

Entering Diagnostic Mode

To enter Diagnostic Mode use the following instructions:

- 1 Confirm the e360 ventilator is OFF and connected to AC power.
- 2 Press and hold the “**Accept**” button and turn ON the power.
- 3 Release the “**Accept**” button when NMI Logo Screen is displayed.
- 4 Wait for few minutes until the Software Download/Diagnostics Mode Screen is displayed, see Figure 2-11.
- 5 Press “**Start Diagnostics**” on the LCD touch screen, see Figure 2-11. After short beeps, Diagnostic Data Screen will be displayed.

PROCEDURES

Most calibrations rely on the Analog PCB being accurately calibrated first. The Analog PCB has five (5) Transducers and each one must be calibrated according to the procedure in this Section. After the Analog PCB has been properly calibrated, proceed with the rest of the calibrations.

To perform the calibrations successfully, it is very important that the air and oxygen gas supply are regulated to 50 \pm 2 psig and that

CALIBRATION PROCEDURES

the supply is capable of supporting a minimum of 180 L/min of constant flow.

Attach the patient circuit to the e360 ventilator.

NOTE: Observe ESD precautions throughout the following procedures for Analog PCB and Pneumatics Calibrations:

Analog PCB Calibration: d5

To locate the transducers on the Analog PCB, see Figure 5-2, below.

- 1 “**d0**” will be displayed in the “**Trig**” window on the Control Panel and “**0**” will be displayed in the “**Flow/t Insp**” window when the e360 ventilator enters into the Diagnostics Mode.
- 2 Press the button below the “**Trig**” window, then the display will start blinking.
- 3 While the display is blinking, turn the Adjustment Knob to change the setting from “**d0**” to “**d5**”. Then press the “**Accept**” button to acknowledge.

NOTE: Steps 4 to 14 are to calibrate zero pressure offset of the Exhalation drive pressure transducer **XD107**.

- 4 Remove the **ORANGE** tubing from transducer **XD107** on the Analog PCB.
- 5 Press the “**Manual Inflation**” button to start the offset calibration. The Message ID will change to “25”. Refer to Table 5-5 for the descriptions of all message ID’s.
- 6 Verify the setting of “**t Insp**” is “**0**”. If not, press the button below “**Flow / t Insp**” window, then the display will start blinking.
- 7 While the display is blinking, turn the Adjustment Knob to adjust the setting of “**t Insp**” to “**0**”, and then press the “**Accept**” button to acknowledge.
- 8 Press the button below “**Resp Rate**” window, then the display will start blinking.
- 9 While the display is blinking, turn the Adjustment Knob to change the setting to any value, and then press the “**Accept**” button to acknowledge.
- 10 After the “**Accept**” button is pressed, the value of “**Drive Pressure**” displayed on the LCD touch Screen will change.

- 11 As the setting of “**Resp Rate**” increases, the value of “**Drive Pressure**” will decrease after the “**Accept**” button is pressed.
- 12 As the setting of “**Resp Rate**” decreases, the value of “**Drive Pressure**” will increase after the “**Accept**” button is pressed.
- 13 When the setting of “**Resp Rate**” is “0”, which cannot be further decreased, consequently the value of “Drive Pressure” cannot be increased. In this case, first increase the setting of “**Resp Rate**” to a high value and then decrease it. Always press “Accept” button when the adjustment of the “**Resp Rate**” setting is made.
- 14 Repeat steps 8 to 13 to obtain drive pressure of $3.00 \text{ cmH}_2\text{O} \pm 0.05 \text{ cmH}_2\text{O}$, then press “**Manual Inflation**” button to acknowledge. The Message ID will change to “26”.

NOTE: Steps 15 to 25 are to calibrate the gain of the Exhalation drive pressure transducer **XD107**.

- 15 Press the button below “**Flow / t Insp**” window, then the display will start blinking.
- 16 While the display is blinking, turn the Adjustment Knob to set the value of “**t Insp**” to “1”, and then press the “**Accept**” button to acknowledge.
- 17 Use a pressure syringe to apply a pressure of $110 \pm 1 \text{ cmH}_2\text{O}$ to the bottom port of transducer XD107. (Tee in a pressure gauge 0 to 200 cmH_2O to insure accurate pressure delivery).
- 18 Press the “**Manual Inflation**” button to start the gain calibration. The Message ID will change to “25”.
- 19 Press the button below the “**Resp Rate**” window, then the display will start blinking.
- 20 While the display is blinking, turn the Adjustment Knob to change the setting to any value, then press the “**Accept**” button.
- 21 After the “**Accept**” button is pressed, the value of “**Drive Pressure**” displayed on the LCD touch Screen will change.
- 22 As the setting of “**Resp Rate**” increases, the value of “**Drive Pressure**” will increase after the “**Accept**” button is pressed.
- 23 As the setting of “**Resp Rate**” decreases, the value of “**Drive Pressure**” will decrease after the “Accept” button is pressed.
- 24 Repeat steps 19 to 23 to obtain drive pressure of $110.0 \text{ cmH}_2\text{O} \pm 1.0 \text{ cmH}_2\text{O}$, then press “**Manual Inflation**” button to acknowledge. The Message ID will change to “26”.

CALIBRATION PROCEDURES

- 25** Remove the pressure and then connect the **ORANGE** tubing back to the bottom port of transducer **XD107**.
- 26** To calibrate the zero pressure offset of Machine 2 pressure transducer **XD106**, repeat steps 4 to 14, except for the following difference.
- In step 4, remove **GREEN** tubing from transducer **XD106**.
 - In step 7, adjust the setting of “**t Insp**” to “**2**”.
 - In step 14, calibrate the value of “Machine 2” to 0.00 ± 0.05 cmH₂O.
- 27** To calibrate the gain of Machine 2 pressure transducer **XD106**, repeat steps 15 to 25, except for the following difference.
- In step 16, adjust the setting of “**t Insp**” to “**3**”.
 - In step 17, apply a pressure of 110 ± 1 cmH₂O to the bottom port of transducer **XD106**.
 - In step 25, connect **GREEN** tubing back to the bottom port of transducer **XD106**.
- 28** To calibrate the zero pressure offset of Machine 1 pressure transducer **XD105**, repeat steps 4 to 14, except for the following difference.
- In step 4, remove **CLEAR** tubing from transducer **XD105**.
 - In step 7, adjust the setting of “**t Insp**” to “**4**”.
 - In step 14, calibrate the value of “**Machine 1**” to 0.00 ± 0.05 cmH₂O.
- 29** To calibrate the gain of Machine 1 pressure transducer **XD105**, repeat steps 15 to 25, except for the following difference.
- In step 16, adjust the setting of “**t Insp**” to “**5**”.
 - In step 17, apply a pressure of 110 ± 1 cmH₂O to both the top port of transducer **XD105** and the bottom port of transducer **XD106**.
 - In step 25, connect **CLEAR** tubing back to the top port of transducer **XD105** and connect **GREEN** tubing back to the bottom port of transducer **XD106**.

Note: If pressure is only applied to transducer XD105 during this calibration, Device Alert will occur when the pressure to XD105 is 20cmH₂O higher than the pressure to XD106. Device Alert can be only cleared by turning OFF and ON the e360 ventilator.

- 30** To calibrate the zero pressure offset of Air Gas Supply pressure transducer **XD102**, repeat steps 4 to 14, except for the following difference.
- In step 4, remove **YELLOW** tubing from transducer **XD102**.
 - In step 7, adjust the setting of “**t Insp**” to “**6**”.
 - In step 14, calibrate the value of “**Air Gas Supply**” to 0.0 ± 0.1 psig.
- 31** To calibrate the gain of Air Gas Supply pressure transducer **XD102**, repeat steps 15 to 25, except for the following difference.
- In step 16, adjust the setting of “**t Insp**” to “**7**”.
 - In step 17, apply a pressure of 25psig to the top port of transducer **XD102**.
 - In step 24, calibrate the value of “**Air Gas Supply**” to 25.0 ± 0.1 psig.
 - In step 25, connect **YELLOW** tubing back to the top port of transducer **XD102**.
- 32** To calibrate the zero pressure offset of Oxygen Gas Supply pressure transducer **XD103**, repeat steps 4 to 14, except for the following difference.
- In step 4, remove **BLUE** tubing from transducer **XD103**.
 - In step 7, adjust the setting of “**t Insp**” to “**8**”.
 - In step 14, calibrate the value of “**Oxygen Gas Supply**” to 0.0 ± 0.1 psig.
- 33** To calibrate the gain of Oxygen Gas Supply pressure transducer **XD103**, repeat steps 15 to 25, except for the following difference.
- In step 16, adjust the setting of “**t Insp**” to “**9**”.
 - In step 17, apply a pressure of 25psig to the top port of transducer **XD101**.

CALIBRATION PROCEDURES

- c. In step 24, calibrate the value of “**Oxygen Gas Supply**” to 25.0 ± 0.1 psig.
 - d. In step 25, connect **BLUE** tubing back to the top port of transducer **XD103**.
- 34** Turn OFF the power, and then disconnect the Air and O₂ gas supplies and AC power.

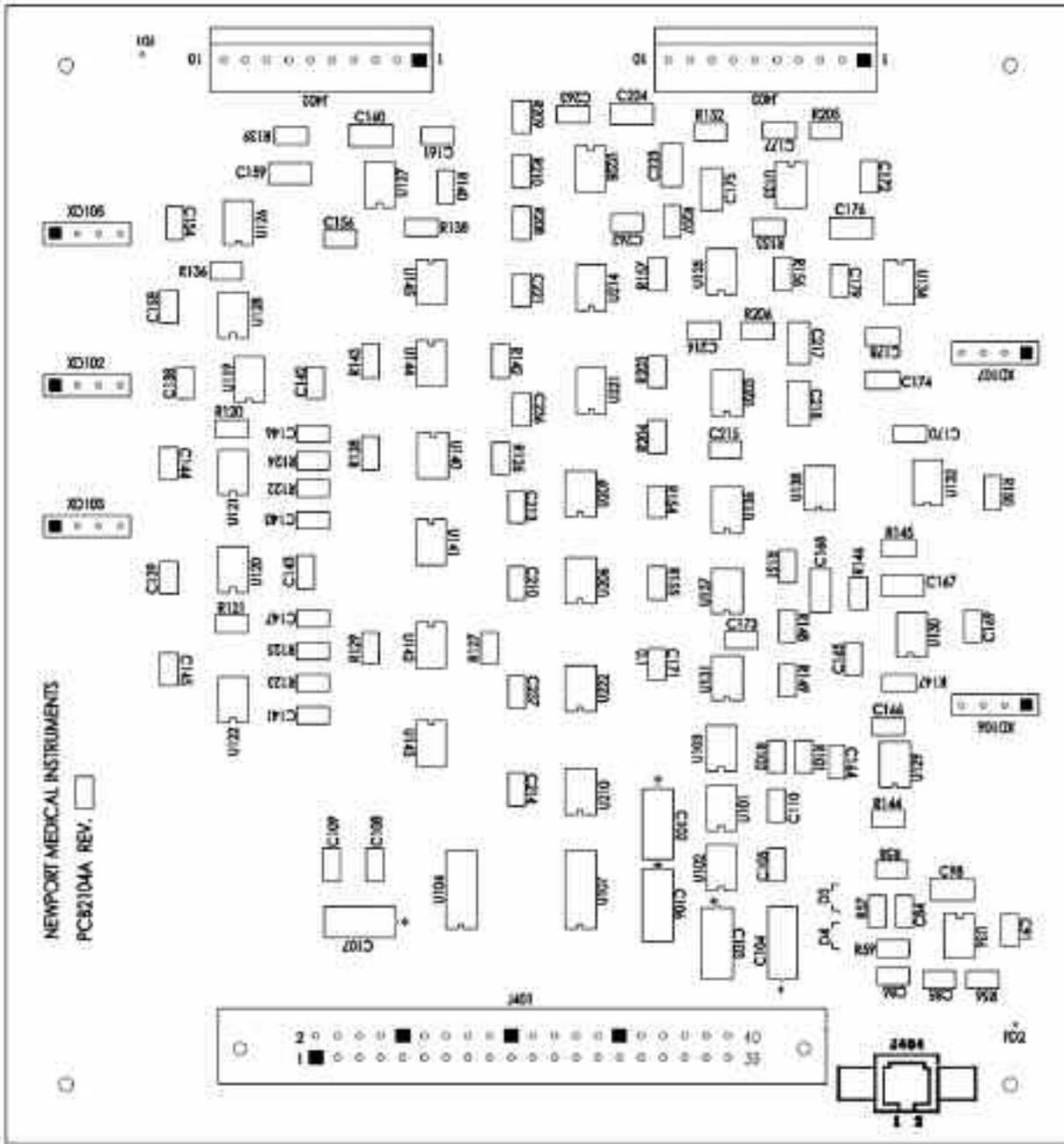


Figure 5-2 Analog PCB

Table 5-2 Zero Offset Calibration

ZERO SETTING					
TRANSDUCER ID	LCD DISPLAY	t Insp	PRESSURE	TOLERANCE	TUBE COLOR
XD107	Drive Pressure	0	3.00 cmH ₂ O	±0.05	Orange
XD106	Machine 2	2	0.00 cmH ₂ O	±0.05	Green
XD105	Machine 1	4	0.00 cmH ₂ O	±0.05	Clear
XD102	Air Gas Supply	6	0.0 psig	±0.1	Yellow
XD103	O ₂ Gas Supply	8	0.0 psig	±0.1	Blue

Table 5-3 Gain Calibration

GAIN SETTING						
TRANSDUCER ID	LCD DISPLAY	t Insp	PRESSURE	TOLERANCE	DESIGNATION	TUBE COLOR
XD107	Drive Pressure	1	110 cmH ₂ O	±1.0	Bottom Port	Orange
XD106	Machine 2	3	110 cmH ₂ O	±1.0	Bottom Port	Green
XD105	Machine 1	5	110 cmH ₂ O	±1.0	Top Port	Clear
XD102	Air Gas Supply	7	25 psig	±0.1	Top Port	Yellow
XD103	O ₂ Gas Supply	9	25 psig	±0.1	Top Port	Blue

Pneumatics Calibration

NOTE: Before proceeding with the pneumatics calibration, the Analog PCB in the e360 ventilator must be previously calibrated.

NOTE: To calibrate Air/Oxygen Inlet Regulators, and Safety Regulator, use Diagnostic Mode “d3”: Manual Flow Adjustment.

Air Inlet Regulator

- 1 Connect the Air and Oxygen gas supplies and AC power to the e360 ventilator.
- 2 Turn ON the power to the e360 ventilator.
- 3 Enter the Diagnostics Mode following the procedure “Entering Diagnostics Mode” in this Section.

CALIBRATION PROCEDURES

- 4 Press the button below the **“Trig”** window then the display will start blinking.
- 5 While the display is blinking, turn the Adjustment Knob to change the setting from **“d0”** to **“d3”**. Then press the **“Accept”** button to acknowledge. The Message ID will change to **“11”**.
- 6 Press the button **“Select”** above the **“Flow/t Insp”** window and press the **“Accept”** button to select **Flow**.
- 7 Press the **“Manual Inflation”** button to enable manual flow adjustment. The message ID will change to **“12”**.
- 8 Press the button below the **“Flow / t Inst”** window then the display will start blinking.
- 9 While the display is blinking, turn the Adjustment Knob to change the setting from **“0”** to **“3”**. Then press the **“Accept”** button to acknowledge. This is to obtain a flow of 3 L/min.
- 10 Verify the value of **“Air Gas Supply”** is 15.5 ± 0.5 psig. Adjust the Air Inlet Pressure Regulator if not within specification.
- 11 To adjust the Air Inlet Pressure Regulator, use a 5/16” open-ended wrench to loosen the bottom lock nut (see Figure 5-3). Using a 1/4” open-ended wrench, rotate the top adjustment bolt to adjust the pressure. Rotate the bolt clockwise to increase the pressure and counter clockwise to decrease the pressure. When the value of **“Air Gas Supply”** is 15.0 ± 0.5 psig, secure the bottom lock nut.

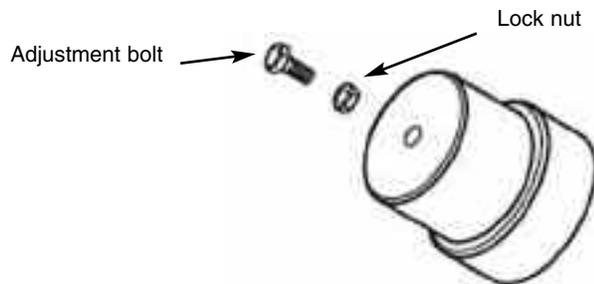


Figure 5-3 Air/Oxygen Pressure Regulators Adjustment

- 12 Adjust Flow as shown below and verify that the expected regulated pressure for each flow setting is within tolerance.

Table 5-4 Air Flow and Pressure Settings

Flow Setting	Air Inlet Pressure
3 L/min	15.0 to 16.0 psig
100 L/min	12.0 to 14.5 psig
180 L/min	> 9.5 psig

Oxygen Inlet Regulator

- 1 While still in Diagnostic Mode “d3”, adjust $F_{I}O_2$ to 100% oxygen and adjust Flow to 3 L/min.
- 2 Adjust the oxygen inlet regulator pressure to 15.5 ± 0.5 psig.
- 3 To adjust the Oxygen Inlet Pressure Regulator, refer to the above “Air Inlet Regulator”, step 9.
- 4 Adjust Flow as shown below and verify that the expected regulated pressure for each flow setting is within tolerance.

Table-5-5 Oxygen Flow and Pressure Settings

Flow Setting	Oxygen Inlet Pressure
3 L/min	15.0 to 16.0 psig
100 L/min	12.0 to 14.5 psig
180 L/min	> 9.5 psig

- 5 Adjust Flow to 0 L/min and $F_{I}O_2$ to 21% after the calibration is completed.

Exhalation Servo Regulator

- 1 Take the **ORANGE** tubing from the Exhalation Servo Valve port “IN” and connect to a high pressure gauge, see Figure 5-4.
- 2 Use a flat head screw driver to adjust the Exhalation Servo Regulator, which is located near the Exhalation Servo Valve, between 15.0 and 15.5 psig.
- 3 Reconnect the **ORANGE** tubing to the Exhalation Servo Valve port “IN”.

CALIBRATION PROCEDURES

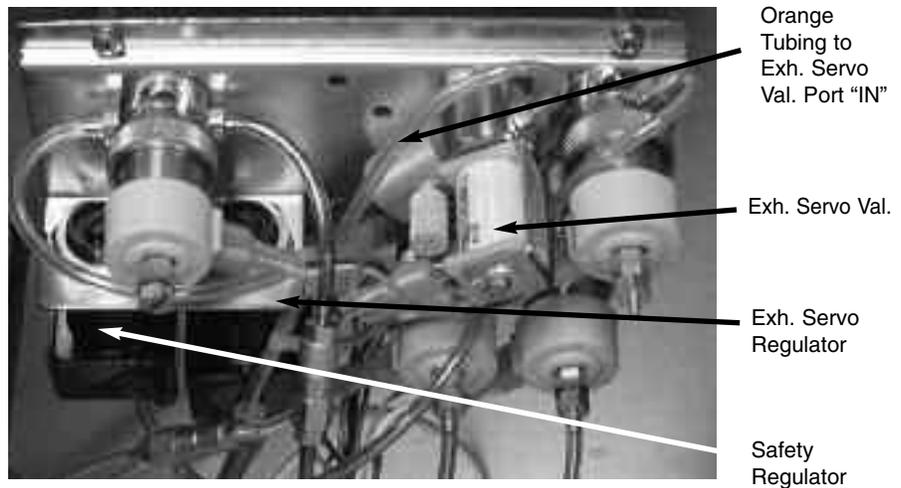


Figure 5-4 Exhalation Servo / Safety Regulators

Safety Regulator

- 1 While still in Diagnostics Mode "**d3**", adjust Flow to 3 L/min.
- 2 Connect a patient circuit to the e360 ventilator as shown in Figure 6-1. (Test lung is not needed)
- 3 Disconnect the patient circuit from the Exhalation Valve, and connect it to the Y-piece of the patient circuit, which is to form a close loop.
- 4 Tee in a low pressure gauge in the patient circuit.
- 5 Use a flat head screw driver to adjust the Safety Regulator, see Figure 5-4, to obtain 140 ± 5 cm²HO of "**Machine 1**" pressure displayed on LCD touch screen.
- 6 Verify the reading of the pressure gauge is within 2 cmH₂O of the value of "**Machine 1**" pressure.
- 7 Adjust Flow to 0 L/min after the calibration is completed. Then press "**Manual Inflation**" button to disable manual flow adjustment. The "**Message ID**" will change to "**13**".

Air Servo Valve: d1

Caution: Do not attempt to perform Air Servo Valve calibration unless instructed by NMI Representative or for one of the following conditions:

- Replacement or readjustment of Air Inlet Regulator
- Replacement of Air Servo Valve
- Replacement of Analog PCB
- Replacement of Main PCB

Caution: Do not attempt to perform Air Servo Valve calibration unless the air gas supply is regulated to 50 ± 2 psig and capable of supporting a minimum of 180 L/min of constant flow.

- 1 Set the e360 ventilator to Diagnostics Mode “**d1**”.
- 2 Disconnect the patient circuit from the e360 ventilator.
- 3 Press the “**Manual Inflation**” button to initiate Air Servo Valve calibration. The e360 ventilator will go through a calibration maneuver that slowly increases and then decreases flow twice.
- 4 The value of “**TSI Air Flow**” displayed on LCD touch screen will slowly change as the delivered flow changes.
- 5 Wait for several minutes to complete the calibration until the “**Message ID**” changes to “**6**”.

Note: If the “**Message ID**” shows “7” during this calibration, the Air Servo Valve needs to be replaced.

Oxygen Servo Valve: d2

Caution: Do not attempt to perform Oxygen Servo Valve calibration unless instructed by a NMI Representative or for one of the following conditions:

- Replacement or readjustment of Oxygen Inlet Regulator
- Replacement of Oxygen Servo Valve
- Replacement of Analog PCB
- Replacement of Main PCB

Caution: Do not attempt to perform Oxygen Servo Valve calibration unless the oxygen gas supply is regulated to 50 ± 2 psig and capable of supporting a minimum of 180 L/min of constant flow.

- 1 Set the e360 ventilator to Diagnostics Mode “**d2**”.
- 2 Disconnect the patient circuit from the e360 ventilator.
- 3 Press the “**Manual Inflation**” button to initiate Oxygen Servo Valve calibration. The e360 ventilator will go through a calibration maneuver that slowly increases and then decreases flow twice.
- 4 The value of “**TSI O₂ Flow**” displayed on LCD touch screen will slowly change as the delivered flow changes.
- 5 Wait for several minutes to complete the calibration until the “**Message ID**” changes to “**10**”.

Note: If the “**Message ID**” shows “7” during this calibration, the Oxygen Servo Valve needs to be replaced.

CALIBRATION PROCEDURES

Exhalation Flow Sensor: d9

- 1 Turn OFF the e360 ventilator.
- 2 Turn ON the e360 ventilator and wait until the “**Ventilation Standby**” screen is displayed.
- 3 Connect the patient circuit to the e360 ventilator as shown in Figure 6-1.
- 4 Occlude the patient circuit at the Y-piece using a cap. A filter and test lung is not required for this calibration.
- 5 Press “**CIRCUIT CHECK**” on LCD touch screen to perform the circuit check. Confirm that the circuit check passes.
- 6 Press “**SENSORS**” on LCD touch screen, and press “**Flow Sensor**” to start Exhalation Flow Sensor calibration. It may require performing several times in order to pass the Exhalation Flow Sensor calibration.
- 7 Turn OFF the e360 ventilator and turn ON while pressing and holding “**Accept**” button to enter Diagnostics Mode.
- 8 Set the e360 ventilator to Diagnostics Mode “**d9**”.
- 9 With patient circuit occluded, press “**Manual Inflation**” button to start Exhalation Flow Sensor calibration in Diagnostics Mode. The Message ID will change to “**63**”.
- 10 Wait for several minutes to complete the calibration until the “**Message ID**” changes to “**41**”.

Exhalation Servo Valve: d4

- 1 Set the e360 ventilator to Diagnostics Mode “**d4**”.
- 2 With patient circuit occluded, press the “**Manual Inflation**” button once. The “**Message ID**” will change to “**35**”.
- 3 Press the “**Manual Inflation**” button again to start the calibration, now the “**Message ID**” will change to “**15**”.
- 4 Wait for several minutes to complete the calibration until the “**Message ID**” changes to “**20**”.

Table 5-6 Descriptions of Message ID

D1: Air Servo Valve Calibration	
ID	Meaning
4	Hit Manual Inflation Button to Start Air Servo Valve Calibration
5	Calibrating Air Servo Valve
6	Air Servo Valve Calibration Completed
7	Calibration Failed: Valve Leaks more than 50 cc
D2: Oxygen Servo Valve Calibration	
ID	Meaning
8	Hit Manual Inflation Button to Start Oxygen Servo Valve Calibration
9	Calibrating Oxygen Servo Valve
10	Oxygen Servo Valve Calibration Completed
7	Calibration Failed: Valve Leaks more than 50 cc
D3: Manual Flow Adjustment	
ID	Meaning
11	Hit Manual Inflation Button to Enable Manual Flow Adjustment
12	Adjust Flow Setting
13	Manual Flow Adjustment Disabled
D4: Exhalation Valve Calibration	
ID	Meaning
14	Hit Manual Inflation Button to Enable Exhalation Valve Calibration
35	Occlude the Patient Circuit and Hit Manual Inflation Button Again to Start Exhalation Valve Calibration
15	Calibrating Exhalation Valve
20	Exhalation Valve Calibration Completed
16	Exhalation Valve Calibration Failed: Proximal Pressure Less than 1cmH ₂ O when Exhalation Valve Closed
17	Exhalation Valve Calibration Failed: Proximal Pressure High than 1cmH ₂ O when Exhalation Valve Opened
18	Exhalation Valve Calibration Failed: Proximal Pressure Low than Target Pressure
19	Exhalation Valve Calibration Failed: Test Flow Less than 1L/min
D5: Analog Board Calibration	
ID	Meaning
21	Hit Manual Inflation Button to Start Analog Board Calibration
25	Analog Board Calibration Enabled
26	Analog Board Calibration Disabled

CALIBRATION PROCEDURES

D9: Exhalation Flow Sensor Calibration	
ID	Meaning
2	Occlude the Patient Circuit and Hit Manual Inflation Button to Start Exhalation Flow Sensor Calibration
63	Calibration Exhalation Flow Sensor
41	Exhalation Flow Sensor Calibration Completed
59	Exhalation Flow Sensor Failed: Sensor Bad
60	Exhalation Flow Sensor Calibration Failed: No Flow Detected

Note: Proximal pressure is the average pressure of Machine 1 and Machine 2 pressure

6. OPERATIONAL VERIFICATION PROCEDURE

Operational Verification Procedure	6-1
Test Equipment.....	6-1
Setup	6-2
Electrical Safety Checks	6-2
Ground Resistance test	6-2
Current Leakage test	6-3
Operational Checks	6-3
– Front Panel LED Check	6-4
– Circuit Leak Test	6-5
– Loss of Gas Alarm.....	6-5
– F _I O ₂ Test	6-6
– Main Flow	6-6
– Bias Flow	6-8
– Inspiratory Time.....	6-8
– Respiratory Rate	6-8
– Pressure Control	6-9
– Pressure Support	6-9
– Pressure Trigger Sensitivity	6-9
– PEEP/CPAP	6-10
– Manual Inflation	6-11
– Inspiratory Tidal Volume	6-11
– Expiratory Tidal Volume	6-11
– Alarm Silence	6-12
– Loss of Power Alarm and Battery Operation	6-12
e360 Operational Verification	
Test Record Sheet	6-13

OPERATIONAL VERIFICATION PROCEDURE

The Operational Verification Procedure ensures that the Newport e360 Ventilator is in proper operating condition.

WARNING Do not use the e360 ventilator unless it passes the Operational Verification Procedure.

Test Equipment

- Electrical safety test (EST) analyzer
- Certified calibration analyzer manufactured by TSI, Inc. or equivalent
- Oxygen Analyzer
- Newport reusable patient breathing circuit (PBC340A) or equivalent
- Adult test lung (LNG800P), or adult test lung with RP20 airway resistor (LNG600A) or equivalent
- Adjustable (0-60 psig) dry clean regulated medical grade air and oxygen gas supplies
- A cap to occlude the patient circuit Y-piece (CAP100P) or equivalent

Caution The accuracy of all test equipment (electronic or pneumatic) used for verification or calibration procedures should be certified annually by a testing laboratory before use.

OPERATIONAL VERIFICATION PROCEDURE

SETUP

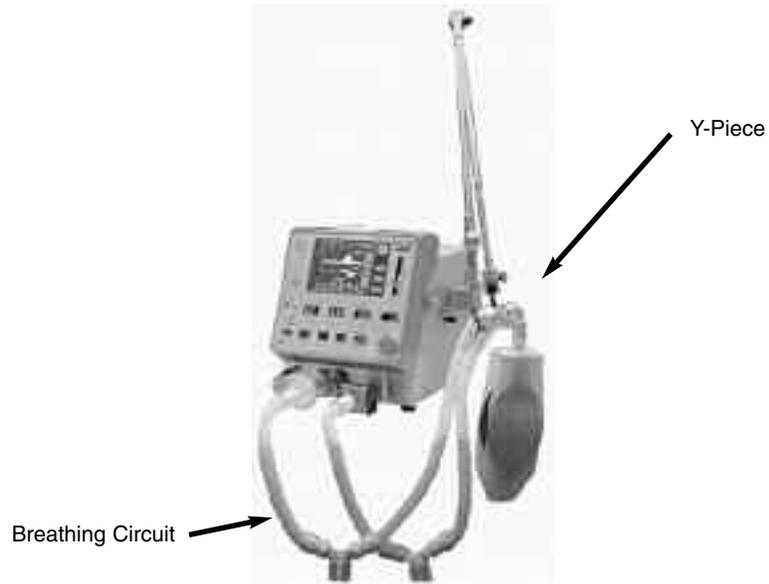


Figure 6-1 Test Setup

- 1 Connect reusable adult patient breathing circuit to the e360 ventilator to be tested. Attach a test lung to the patient breathing circuit Y-Piece.
- 2 Connect the calibration analyzer with oxygen sensor between the main flow outlet and the patient breathing circuit.
- 3 Connect regulated adjustable air and oxygen gas supplies to ventilator inlets on the back of the ventilator. Set regulators to 50 psig.
- 4 Make a copy of the e360 Test Record sheets provided at the end of this section. Check the appropriate box or record appropriate data on the record sheet after each test is performed.

ELECTRICAL SAFETY CHECKS

Ground Resistance Test

- 1 Connect the A.C. power cord to the EST analyzer.
- 2 Connect the ground lead of the EST analyzer to the labeled equipotential connection on the back of the ventilator.
- 3 Perform ground resistance check and record the results on the OVP record sheet. To pass, the ventilator ground resistance must be $\leq 0.1\Omega$.

Current Leakage test

- 1 Power the e360 ventilator ON.
- 2 Perform the current leakage check and record the result on the OVP record sheet. To pass, the measured current leakage must be $\leq 100 \mu\text{A}$.

OPERATIONAL CHECKS

Ensure the e360 ventilator Control Panel is adjusted to the settings shown in Table 6-1.

NOTE: Adjustments are made with the Touch-Turn-Accept method.

Table 6-1. Standard Test Setting

Control	Setting
Patient Type	Adult
Power	ON
Breath Type	Volume Control
Mode	A/CMV
F _I O ₂	.60
Flow	30 L/min
Tidal Volume	500 mL
Resp Rate	10 b/min
Pressure Limit	5
Pressure Support	0
PEEP	0
Trig	Pressure 3.0 cmH ₂ O
MVE Alarm	Low at 1 L/min, High at 50 L/min
Pause	0 sec
Paw Alarm	Low at 10, High at 75
Leak Comp.	OFF
Circuit Type	HVE

NOTE: Pressure readings should be set to either cmH₂O or mbar

OPERATIONAL VERIFICATION PROCEDURE

Front Panel LED Check

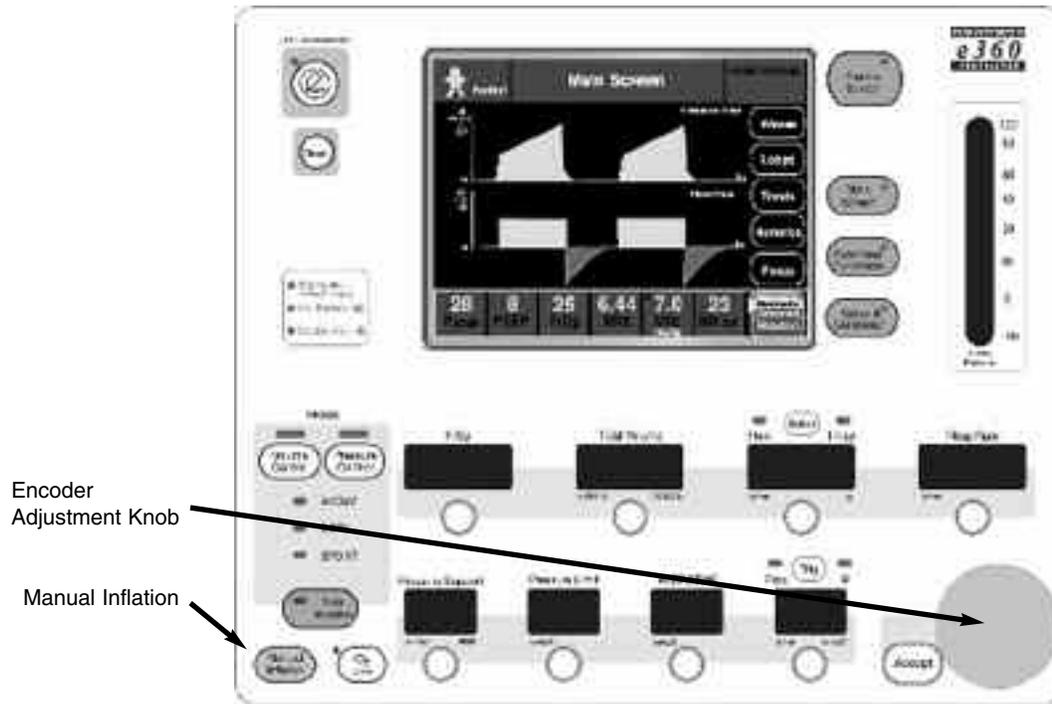


Figure 6-2 Front Panel Controls & Indicators

- 1 Toggle the power switch located on the back of the e360 ventilator, to the OFF position.
- 2 Press down the **“Accept”** button located next to the Adjustment Knob.
- 3 While pressing the **“Accept”** button, toggle the power switch **OFF** then to the **ON** position. This puts the e360 ventilator into Diagnostics Mode. Release the **“Accept”** button.
- 4 Verify that all the Control Panel display lights are lit except for the Alarm Lamp on top of the ventilator.

Circuit Leak Test

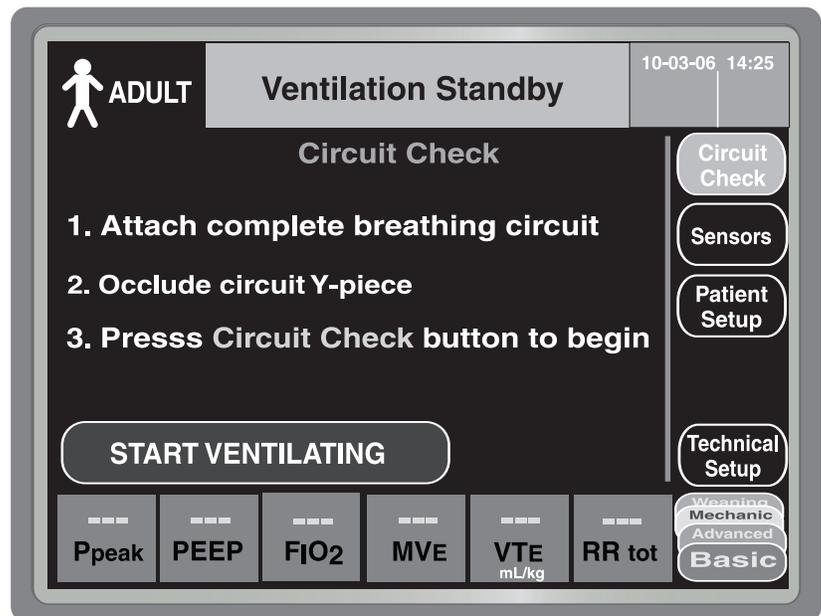


Figure 6-3 Circuit Leak Test

NOTE: Circuit Check is available in Ventilation Standby only.

- 1 Remove test lung if present and occlude the end of the patient circuit Y-Piece using CAP100P.
- 2 Power ON the e360 ventilator or press “**Setup & Calibration**” button on the Control Panel.
- 3 Press the “**Circuit Check**” button on the display and follow the screen instructions.
- 4 After the test is completed, verify that the message display window reads **PASSED**. Check off the record sheet and reattach the test lung.
- 5 To exit Ventilation Standby condition, press the “**START VENTILATING**” button on LCD touch screen.

Loss of Gas Alarm

- 1 Lower the air gas supply pressure to 20 psig. Verify that there is no Loss of Gas alarm.
- 2 Lower the air gas supply pressure to 8 psig. Verify that the audible alarm sounds, the amber LED on the top is flashing, and the message display reads Air Supply Loss.

OPERATIONAL VERIFICATION PROCEDURE

- 3 Set the air gas supply pressure to 50 psig, and clear the alarm.
- 4 Repeat steps 1-3 for the oxygen gas source.
- 5 Shut off both gas supplies. Verify that the audible alarm sounds, the amber LED on the top is solid on, the red LED on the top is flashing, and the message display reads Both Air/O₂ Supply Loss.
- 6 Turn on both gas supplies and clear the alarm.

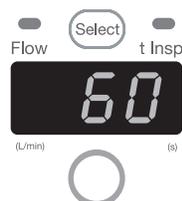
F_IO₂ Test



- 1 Set the F_IO₂ to 0.21.
- 2 Verify the value of F_IO₂ displayed on LCD touch screen, the F_IO₂ reading measured by the oxygen analyzer, and the F_IO₂ setting are within tolerance of $\pm 3\%$ among each other. Record the readings on the Test Record.
- 3 Repeat step 1 with F_IO₂ settings of 0.40, 0.60, 0.80, and 1.0. , use Touch-Turn-Accept method to adjust settings.
- 4 Set F_IO₂ to 0.21.

NOTE: Allow sufficient time for the calibration analyzer to stabilize at each setting before recording the calibration analyzer reading.

Main Flow



- 1 Remove the test lung from the patient circuit Y-Piece.
- 2 Place the calibration analyzer at the Inhalation Outlet, and set the calibration analyzer to flow measurement.
- 3 Press the button under the “**Tidal volume**” window and use the Touch-Turn-Accept method to adjust setting to 2.00 L.
- 4 Press the “**Select**” button at the top of the “**Flow/t Insp**” window to choose **Flow**.
- 5 Press “Main Screen” membrane button on control panel.
- 6 Press the “**Numeric**” button on the LCD touch screen to display *Numeric* data.
- 7 Set **Flow** to 5 L/min, verify the value of **V_{peak}** (Insp Flow) displayed on the *Numeric* screen, the flow reading measured by the calibration analyzer, and the flow setting are within tolerance of ± 1 L/min among each other. Record the readings on the Test Record.

- 8 Set **Flow** to 10 L/min, verify the value of \dot{V}_{peakI} (Insp Flow) displayed on the *Numeric* screen, the flow reading measured by the calibration analyzer, and the flow setting are within tolerance of ± 1 L/min among each other. Record the readings on the Test Record.
- 9 Set **Flow** to 50 L/min, verify the value of \dot{V}_{peakI} (Insp Flow) displayed on the *Numeric* screen, the flow reading measured by the calibration analyzer, and the flow setting are within tolerance of ± 4 L/min among each other. Record the readings on the Test Record. Record the readings on the Test Record.
- 10 Set **Flow** to 80 L/min, verify the value of \dot{V}_{peakI} (Insp Flow) displayed on the *Numeric* screen, the flow reading measured by the calibration analyzer, and the flow setting are within tolerance of ± 5 L/min among each other. Record the readings on the Test Record.
- 11 Set $F_{\text{I}}\text{O}_2$ to 100%, and set the calibration analyzer to oxygen flow measurement.
- 12 Repeat steps 7 - 10. Record the reading on the Test Record.

Note: “The flow reading measured by the calibration analyzer” mentioned in steps 7-9 shall be the actual analyzer measurement dividing by 89%. This is because the e360 ventilator automatically reduces the flow delivery by 11% of the set flow to compensate for using without a humidifier (BTPS compensation).

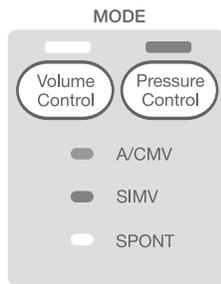
- 13 Set $F_{\text{I}}\text{O}_2$ to 21%, **Flow** to 30 L/min and **VT** (Tidal Volume) to 500; reattach the test lung.

NOTE: Because the e360 ventilator automatically compensates for use with a humidifier by lowering the flow by 11% (calibrated to BTPS) the calibration analyzer flow reading will be 11% lower than the ventilator’s set flow rate if the calibration analyzer is not BTPS compensated.

NOTE: When EMBED Equation.3 \dot{V}_{peakI} reading displayed on the *Numeric* screen is higher than expected flow, it could be caused by the peak flow delivered in the very beginning of the inspiratory phase. In this case, select flow waveform in the *Waves* screen, and then press “Freeze” button to read the actual flow value. To adjust the scale of the waveform, touch the flow axis on the screen, turn the knob, and then touch the flow axis again to accept when a proper scale is obtained.

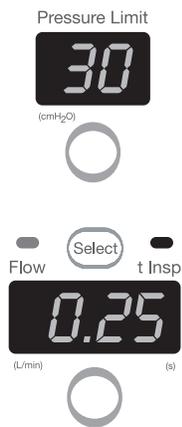
OPERATIONAL VERIFICATION PROCEDURE

Bias Flow



- 1 Set the e360 ventilator to **Volume Control SPONT** by pressing “**Volume Control**” button until **Spont** LED is lit, and then pressing “**Accept**” button to acknowledge.
- 2 Set the calibration analyzer to air flow measurement.
- 3 Verify that the calibration analyzer measures a flow rate of 2.5 to 3.5 L/min, record the reading.

Inspiratory Time



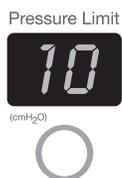
- 1 Keep the test lung unattached. Place the calibration analyzer at the patient circuit Y-Piece.
- 2 Set the calibration analyzer to inspiratory time measurement.
- 3 Set the e360 ventilator to **Pressure Control A/CMV** by pressing “**Pressure Control**” button until the **A/CMV** LED is lit, and then pressing “**Accept**” button to acknowledge.
- 4 Set **Pressure Limit** to 30 cmH₂O.
- 5 Set **t Insp** to 0.25 seconds. Verify the value of **t_i** displayed on Numeric screen, the inspiratory time reading measured by the calibration analyzer and the **t Insp** setting are within tolerance of ± 0.05 seconds among each other. Record the readings on the Test Record.
- 6 Set **t Insp** to 0.50 seconds. Verify the value of **t_i** displayed on Numeric screen, the inspiratory time reading measured by the calibration analyzer and the **t Insp** setting are within tolerance of ± 0.10 seconds among each other. Record the readings on the Test Record.

Respiratory Rate



- 1 Set the calibration analyzer to breath rate measurement.
- 2 Set **t Insp** to 0.25 seconds and attach test lung to patient circuit Y-Piece.
- 3 Set **Resp Rate** to 5 b/min. Verify the value of **f tot** displayed on Numeric screen, the breath rate reading measured by the calibration analyzer and the **Resp Rate** setting are within ± 1 b/min. Record the readings on the Test Record.
- 4 Repeat step 3 with **Resp Rate** setting of 20 b/min.
- 5 Set **Resp Rate** to 10 b/min.

Pressure Control



- 1 Set the calibration analyzer to peak pressure measurement in cmH₂O.
- 2 Set **Pressure Limit** to 10 cmH₂O, and t Insp to 3.0 seconds.
- 3 Verify that the value of **Ppeak** displayed on *Numeric* screen, the peak pressure measured by the calibration analyzer and the **Pressure Limit** setting are within tolerance of $\pm 10\%$ among each other. Record the readings on the Test Record.
- 4 Repeat step 3 with **Pressure Limit** setting of 20 cmH₂O.
- 5 Repeat step 3 with **Pressure Limit** setting of 50 cmH₂O.

Pressure Support



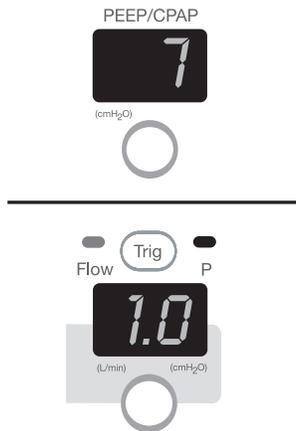
- 1 Set the e360 ventilator to **Pressure Control SPONT**.
- 2 Set **Trig** to **P** (pressure) and adjust to 0.5 cmH₂O.
- 3 Set **Pressure Support** to 10 cmH₂O.
- 4 Squeeze the test lung to trigger a breath. Verify that the value of **Ppeak** displayed on *Numeric* screen, the peak pressure measured by the calibration analyzer and the **Pressure Support** setting are within tolerance of $\pm 10\%$ among each other. Record the readings on the Test Record.
- 5 Repeat step 4 with **Pressure Support** for setting of 20 cmH₂O.
- 6 Set **Pressure Support** to 0 cmH₂O, and verify no pressure-supported breaths are delivered.

Pressure Trigger Sensitivity



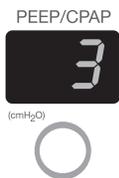
- 1 Set **Pressure Support** to 10 cmH₂O.
- 2 Set **PEEP/CPAP** to 7 cmH₂O.
- 3 Set e360 **Trig** to **P** (pressure) and set to 1.0 cmH₂O.

OPERATIONAL VERIFICATION PROCEDURE



- 4 Manually squeeze and slowly release the test lung to create a dip in the pressure bar graph. Verify that the dip equals the **P Trig** setting when a pressure support breath is triggered.
- 5 Repeat step 4 with **P_{trig}** setting of 3 cmH₂O.
- 6 Set **Pressure Support** to 0 cmH₂O. Leave the test lung connected, and proceed to the next test.

PEEP/CPAP

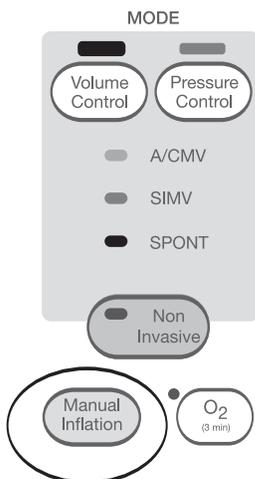


- 1 Set the e360 ventilator to the standard test settings except for **PEEP** to 3 cmH₂O. Set the calibration analyzer to **PEEP** measurement.
- 2 Verify that the value of **PEEP** displayed on *Numeric* touch screen, the pressure reading measured by the calibration analyzer, the pressure bar graph on the Control Panel, and the **PEEP/CPAP** setting are within tolerance of ± 1 cmH₂O among each other. Record readings on the e360 Test Record.
- 3 Repeat step 2 with **PEEP** setting of 10 cmH₂O.
- 4 Set Low Paw alarm to 20 cmH₂O, and repeat step 2 with **PEEP** setting of 20 cmH₂O.

NOTE: Allow three to four breaths at each setting for pressure to stabilize.

- 5 Set the **PEEP** to 0 cmH₂O and set Low Paw alarm to 10 cmH₂O.
- 6 Remove the test lung.

Manual Inflation



- 1 Set the e360 ventilator to **Volume Control SPONT**.
- 2 Press the “**Manual Inflation**” button.
- 3 Verify that a manual inflation is delivered while the button is pressed.

Inspiratory Tidal Volume



- 1 Set the e360 ventilator to **Volume Control A/CMV**.
- 2 Set **Flow** to 30 L/min.
- 3 Press “**Setup & Calibration**” button on the Control Panel, and then press “**Patient Setup**” button on the LCD touch screen.
- 4 Press “**Circuit Type**” button on the LCD touch screen, and set “**Circuit Type**” to HME by Touch-Turn-Accept method.
- 5 Press “**Main Screen**” button on the Control Panel, and then press “**Numeric**” button on the LCD touch screen.
- 6 Set the calibration analyzer to volume measurement in **BTPS** mode, and connect it in the inspiratory limb of the patient circuit.
- 7 Set **Tidal Volume** to 250 mL. Verify the value of VTI displayed on *Numeric* screen, the tidal volume reading measured by the calibration analyzer and the **Tidal Volume** setting are within tolerance of $\pm 10\%$ among each other. Record readings on the Test Record.
- 8 Repeat step 7 with **Tidal Volume** settings of 500 mL, and 1L.

Expiratory Tidal Volume

- 1 Connect the calibration analyzer in the expiratory limb of the patient circuit.

OPERATIONAL VERIFICATION PROCEDURE

- 2 Set Tidal Volume to 250 mL. Verify that the value of VTE displayed on *Numeric* screen is between 212 – 259 mL, and verify that the tidal volume reading measured by the calibration analyzer and the **Tidal Volume** setting are within tolerance of $\pm 10\%$. Record readings on the Test Record.
- 3 Set Tidal Volume to 500 mL. Verify that the value of VTE displayed on *Numeric* screen is between 423 – 517 mL, and verify that the tidal volume reading measured by the calibration analyzer and the **Tidal Volume** setting are within tolerance of $\pm 10\%$. Record readings on the Test Record.
- 4 Set Tidal Volume to 1.00 L. Verify that the value of VTE displayed on *Numeric* screen is between 840 mL – 1.03 L, and verify that the tidal volume reading measured by the calibration analyzer and the **Tidal Volume** setting are within tolerance of $\pm 10\%$. Record readings on the Test Record.

Alarm Silence

(Hold 1 sec for disconnect)



- 1 Create an alarm condition by changing the settings and wait for the alarm to sound.
- 2 Press the “**Alarm Silence**” button and verify the indicator lights up, and the audible alarm stops.
- 3 Press the “**Alarm Silence**” button again and verify the indicator turns off, and the audible alarm resumes.
- 4 Return e360 ventilator to standard test setting. Press **Reset** button to clear alarm indicators.
- 5 Check off on the record sheet.

Loss of Power Alarm and Battery Operation

- 1 Disconnect the power cord from the AC power source.
- 2 Verify that the messages AC Power Loss and Battery Back Up are displayed in the message window. Verify that the audible alarm sounds, the Power Fail indicator flashes, and the Internal Battery indicator lights.
- 3 Verify that at least 3 bars of the charge bar graph are lit.
- 4 Reconnect the power cord to the AC power source.

e360 OVP TEST RECORD SHEET

Hospital or Organization _____					
e360 Serial Number _____		Hour Meter _____		Software Rev. _____	
Service Technician _____				Date _____	
Released by _____					
Test Equipment:	ID No.	Electrical Safety Test		Tol.	Value
Calibration Analyzer		Ground resistance		<0.1?	
Oxygen Analyzer		Max leakage current		<100 μ A	
Electrical Safety Analyzer					
		F_IO₂			
Test	Pass	Set	Displayed F_IO₂	Measured F_IO₂	Tol. Range
Front Panel Visual LED Check		21			\pm 3 Variance
Pneumatic Leak Test		40			\pm 3 Variance
Loss of Gas Alarms (Air/O ₂)		60			\pm 3 Variance
F _I O ₂		80			\pm 3 Variance
Main Flow		100			\pm 3 Variance
Bias Flow		Main Flow (L/min) F_IO₂ = 21%			
Inspiratory time		Set	V_T peak^l	Measured Flow/89%	Tol. Range
Respiratory Rate		5			\pm 1 Variance
Pressure Control		10			\pm 1 Variance
Pressure Support		50			\pm 4 Variance
P _{trig} sensitivity		80			\pm 5 Variance
PEEP/CAP		Main Flow (L/min) F_IO₂ = 100%			
Manual Inflation		Set	V_T peak^l	Measured Flow/89%	Tol. Range
Insp. Tidal Volume					
Exp. Tidal volume (V _T E)		5			\pm 1 Variance
Alarm Silence		10			\pm 1 Variance
Loss of power/battery operation		50			\pm 4 Variance
		80			\pm 5 Variance
		Bias Flow (L/min)			
		Set	Bias Flow		Tol. Range
		3			2.5 - 3.5

OPERATIONAL VERIFICATION PROCEDURE

360 OVP TEST RECORD SHEET (CONTINUED)

Inspiratory Time (sec)				Ptrig Sensitivity (cmH ₂ O)				
Set	t _i	Measured Insp. Time	Tol. Range	Set	Actual	Tol. Range		
0.25			0.2 - 0.3	1		± 0 - 2		
0.5			0.4 - 0.6	3		± 2 - 4		
Respiratory Rate (b/min)				PEEP/CPAP (cmH ₂ O)				
Set	f _{tot}	Measured Resp. Rate	Tol. Range	Set	PEEP	Measured	Tol. Range Pressure	
5			± 1 Variance	3			± 1 Variance	
				10			± 1 Variance	
20			± 1 Variance	20			± 1 Variance	
Pressure Control (cmH ₂ O)				Inspiratory Tidal Volume (mL)				
Set	P _{peak}	Measured	Tol. Range	Set	VTI	Measured Volume	Tol. Range	
10			± 10% Variance	200			± 10% Variance	
20			± 10% Variance	500			± 10% Variance	
50			± 10% Variance					
Pressure Support (cmH ₂ O)				Expiratory Tidal Volume (mL)				
Set	P _{peak}	Measured Pressure	Tol. Range	Set	V _T E	Tol. Range	Measured Volume	Tol. Range
10			± 10% Variance	250		212-259		± 10% Variance
20			± 10% Variance	500		423-517		± 10% Variance
				1000		880-1030		± 10% Variance

APPENDIX A: THEORY OF OPERATION

Device Description	A-1
Breath Types	A-2
Volume Control	A-2
Pressure Control	A-2
Volume Target Pressure Control	A-3
Modes of Ventilation	A-3
A/CMV	A-3
SIMV	A-4
SPONT	A-4
Spontaneous Breath Management in SIMV and SPONT Modes	A-5
Safety Features	A-6
Description of Functional Subsystems	A-8
Inhalation System	A-8
Exhalation System	A-10
Electronics	A-11

DEVICE DESCRIPTION

The e360 ventilator employs a dual servo gas delivery system (one each for air and oxygen), a servo controlled active exhalation valve, and a combination control panel interface and touch screen interface/ graphics monitor (GUI). The electronically-controlled inlet gas mixing system is superior to traditional pneumatic mixers that must exhaust gas from the system to consistently deliver precise oxygen concentrations. The dual servos respond immediately to change the delivered $F_{I}O_2$ when requested by the control system. Approximately 60 minutes of operational backup power is available when the ventilator's internal battery is fully charged. In addition, the e360 ventilator has remote alarm, external battery, VGA and external alarm silence connections plus an RS232 interface to connect to central monitoring systems and USB port for uploading software.

When the e360 ventilator is turned on, the Power On Self-Test (POST) verifies the integrity of the software and hardware of the ventilator and the ventilator is in Standby until the user selects Start Ventilating. During operation, the ventilator performs regular pressure transducer calibrations and software tests to ensure accuracy of monitored and displayed data. A user initiated Circuit Check performs a leak test of the breathing circuit system and measures circuit compliance and resistance. User initiated sensor calibration tests allow for calibration of the O_2 and Exhalation Flow Sensors.

All breath types and modes include a range of ventilation and alarm settings appropriate for adult or pediatric/infant patients. The e360 ventilator has settable alarm limits for high and low peak airway pressure, high and low expiratory minute ventilation/ back up ventilation, high respiratory rate, disconnect threshold and apnea. There are built-in alarm limits for O_2 monitoring, low baseline pressure, high baseline pressure, sustained high baseline pressure, gas supply failure, device alert and power switchover.

The e360 ventilator monitors and displays the power source, volumes, peak flows, breath timing parameters (I:E ratio, respiratory rate, and inspiratory time), delivered oxygen concentration, and patient pressures (peak, plateau, mean airway, and baseline).

The e360 ventilator has a built in oxygen analyzer that can be calibrated with a push of a button.

During exhalation, the e360 ventilator uses a bias flow to flush exhaled CO_2 and stabilize temperature, humidity, and baseline pressure in the patient breathing circuit. A stable baseline pressure between breaths helps to minimize auto-triggering.

THEORY OF OPERATION

The exhalation system is heated to prevent moist exhaled gas from condensing in the exhalation pathway. A bacteria filter should be used at the “FROM PATIENT” port to prevent contaminants in the exhaled gas from entering the exhalation system and contaminating the exhalation valve and flow sensor. Another filter should be placed at the “TO PATIENT” port to prevent contamination of the inspiratory manifold when the emergency relief valve opens (in the case of a Device Alert alarm, Both Air/O₂ Supply Loss alarm or Sustained High Baseline Pressure alarm that is accompanied by a blockage of the exhalation valve).

The heated exhalation system features an active exhalation valve with a low exhaled flow resistance for rapid return of circuit pressure to baseline and decreased potential for auto-PEEP.

Breath Types

The e360 ventilator offers these breath types:

- Volume Control
- Pressure Control
- Volume Target Pressure Control*

Volume Control

Each Volume Control mandatory breath is delivered primarily according to the user-selected Tidal Volume and Flow/Inspiratory Time setting and is secondarily affected by Respiratory Rate, PEEP/CPAP, Pause, Sigh, and Flow Wave pattern settings. A square flow wave pattern delivers the set flow constantly until the set tidal volume is delivered. A descending ramp flow wave pattern delivers the set flow initially and then decreases at a constant rate until 50% of the initial flow is reached and then terminates when the set Tidal Volume has been delivered.

Pressure Control

Each Pressure Control mandatory breath is delivered primarily according to the user-selected Pressure Limit and Inspiratory Time settings and is secondarily affected by Respiratory Rate, PEEP/CPAP and Slope/Rise settings. A Pressure Control inspiration terminates when the set Inspiratory Time has elapsed.

** Available on specific models*

Volume Target (Volume Target Pressure Control)*

Each Volume Target Pressure Control mandatory breath is delivered primarily according to the user-selected Tidal Volume, Pressure Limit and Inspiratory Time settings and is secondarily affected by Respiratory Rate, PEEP/CPAP and Slope/Rise settings. These are much like pressure control mandatory breaths but unlike the pressure control mandatory breaths delivered. When Pressure Control breath type is selected, the pressure control level is managed breath-by-breath by the ventilator to a level that is between 5 cmH₂O above PEEP/CPAP and the Pressure Limit setting in order to try to achieve the set Tidal Volume. The set Tidal Volume is not guaranteed for each breath, it is a target. The first Volume Target Pressure Controlled mandatory breath delivered after Volume Target is turned ON is at a pressure control level equal to PEEP/CPAP + 5 cmH₂O. Spontaneous breaths in Volume Target Pressure Control SIMV and SPONT modes are Volume Target Pressure Support breaths.

Modes Of Ventilation

Each breath type includes the choice of three modes:

- Assist/Control Mandatory Ventilation (A/CMV)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Spontaneous (SPONT)

Assist/Control Mandatory Ventilation (A/CMV)

In A/CMV, all breaths delivered to the patient are mandatory breaths. The user may choose to Pressure Control, Volume Control, or Volume Target Pressure Control* the mandatory breaths. In any case the breaths may be time (ventilator-triggered) or patient-triggered. The Respiratory Rate setting determines the minimum number of time-triggered or patient triggered mandatory breaths delivered each minute. (In other words, the patient is guaranteed to receive this number of mandatory breaths per minute.) The Trig setting determines the airway pressure or airway flow threshold that the patient's effort must reach in order to trigger these and additional mandatory breaths. If the patient doesn't breathe or if the patient's efforts don't cause airway pressure or airway flow to reach the Trig threshold, the e360 Ventilator delivers the number of time triggered breaths each minute selected via the Respiratory Rate setting.

** Available on specific models*

Synchronized Intermittent Mandatory Ventilation (SIMV)

In SIMV, mandatory and spontaneous breaths may be delivered to the patient. The user may choose to Pressure Control, Volume Control, or Volume Target Pressure Control* the mandatory breaths. Mandatory breaths may be time (ventilator-triggered) or patient-triggered. In Volume or Pressure Control, the user may choose to pressure support the spontaneous breaths.

In Volume Target Pressure Control*, all spontaneous breaths are Volume Target Pressure Support breaths.

The Respiratory Rate setting determines the total number of mandatory breaths delivered each minute. The Respiratory Rate setting also establishes a timing window that determines whether a patient trigger results in a mandatory breath or a spontaneous breath.

The Trig setting determines the airway pressure or airway flow threshold that the patient's effort must reach in order to trigger mandatory breaths and also to trigger spontaneous breaths in between mandatory breaths.

If there are no patient breathing efforts or if patient efforts fail to cause enough airway pressure or airway flow change to meet the set Trig threshold, the patient receives the number of time-triggered breaths each minute selected via the Respiratory Rate setting.

Spontaneous (SPONT)

In SPONT, all breaths delivered to the patient are spontaneous breaths. When Volume Control or Pressure Control breath types are selected, the user may choose to add Pressure Support to assist spontaneous efforts. When Volume Target Pressure Control* breath type is selected, all spontaneous efforts are assisted by Volume Target Pressure Support. The Trig setting determines the airway pressure or airway flow threshold that the patient's effort must reach in order to trigger spontaneous breathing assistance from the ventilator. If there are no patient efforts or if the patient efforts fail to cause enough airway pressure or airway flow change to meet the set Trig threshold, no spontaneous breathing assistance is provided.

Spontaneous Breath Management In SIMV and SPONT Modes

There are two forms of spontaneous breath assistance on the e360 ventilator:

- Pressure Support
- Volume Target Pressure Support

In Volume Control and Pressure Control SIMV, spontaneous breaths with Pressure Support are available to the patient. In Volume Target Pressure Control SIMV, spontaneous breaths are Volume Target Pressure Support breaths.

In SPONT, when Volume or Pressure Control breath type is selected spontaneous breaths with Pressure Support are available. In SPONT Volume Target Pressure Control breath type (Volume Target is selected in Advanced Data Set on GUI), all spontaneous efforts are assisted by Volume Target Pressure Support.

Pressure Support

(SIMV and SPONT - Volume Control and Pressure Control breath types only)

For patient spontaneous efforts that trigger the ventilator, e360 delivers breaths with a constant pressure in the breathing circuit at a pressure equal to PEEP/CPAP + Pressure Support, until the end of patient inspiration. The breaths are delivered according to the user-selected settings for Pressure Support, Slope/Rise, Expiratory Threshold and PEEP/CPAP. The maximum inspiratory time is 2 seconds for Adult and 1.2 seconds for Ped/Infant patient types.

NOTE: When Pressure Support is set to zero (CPAP), the ventilator raises the pressure in the patient circuit to a target pressure of 1.5 cmH₂O/mbar above the set PEEP/CPAP until the end of inspiration.

Volume Target Pressure Support*

(SIMV and SPONT - Volume Target Pressure Control breath type only)

For patient spontaneous breaths in the Volume Target Pressure Control* SPONT and SIMV modes, the ventilator delivers breaths with a constant pressure in the breathing circuit at a pressure equal to a ventilator selected level between PEEP/CPAP + 5 cmH₂O/mbar and the Pressure Limit, until the end of patient inspiration.

Each Volume Target Pressure Support spontaneous breath is delivered primarily according to the user-selected Tidal Volume and Pressure Limit and is secondarily affected by PEEP/CPAP, Slope/Rise and Expiratory Threshold settings. These are very much like pressure support spontaneous breaths but unlike the pressure support spontaneous breaths delivered when Pressure Control or Volume Control breath type is selected, the pressure support level is managed breath-by-breath by the ventilator to a level that is between 5 cmH₂O/mbar above PEEP/CPAP and the Pressure Limit setting in order to try to achieve the set Tidal

THEORY OF OPERATION

Volume. The set Tidal Volume is not guaranteed for each breath, it is a target.

The target pressure of the first breath, when no target pressure has been established is PEEP/CPAP + 5 cmH₂O/mbar.

Safety Features

- Protection From Over Pressurization
- Protection From Re-breathing Exhaled Gases In Case of Ventilator Shutdown

The e360 Ventilator software allows the user to perform a pre-use leak, compliance and resistance tests of the patient breathing circuit, humidifier and filters. Other software based selections include: breathing circuit compliance compensation of flow/volume delivery and monitoring On or Off, circuit type in use (heated expiratory limb (high output), heated insp. expiratory limb (middle output), or HME), leak compensation On or Off, set time and date, and adjust for operation at the local altitude.

All modes of ventilation and breath types on the e360 Ventilator include a range of settings appropriate for adult or pediatric/infant patients. To maximize patient safety, the Control Panel has an Accept Button that must be pressed to activate any setting changes. This feature is to prevent accidental changes. The e360 has settable alarm limits for high and low peak airway pressure, high and low expiratory minute volume, high respiratory rate, circuit disconnect threshold and apnea. The Low Minute Volume Alarm activates Back up Ventilation which increases respiratory rate in A/CMV and SIMV and provides pressure controlled ventilation according safe basic settings in SPONT mode in order to increase ventilation back to acceptable values during the alarm condition. In addition, there are built-in alarms limits for O₂ monitoring, low baseline pressure, high baseline pressure, sustained high baseline pressure, gas supply failure, device alert and power switchover.

If a condition, such as low battery power during battery operation or component malfunction, occurs and the ventilator cannot maintain reliable operation, it declares a Device Alert alarm. This alarm cannot be silenced without first powering off the ventilator. An Alarms and Message Bar on the GUI clearly displays all alarm and informational messages. An alarm lamp on the top of the device lights with all alarms. It can be viewed from 360°. In addition, a separate control panel indicator lights in case of a Device Alert.

The exhalation system is heated to prevent moisture in the exhaled gas from being condensed in the exhaled flow monitor system. It features low exhalation flow resistance to allow rapid return to baseline pressure after a positive pressure breath, and

decreased potential for auto-PEEP. A filter is used between the expiratory limb of the breathing circuit and the expiratory (FROM PATIENT) port to prevent contaminants in the exhaled gas from entering the exhalation system.

Protection From Over Pressurization

In the case of a High Pressure alarm violation, Sustained High Baseline Pressure alarm violation with suspension of ventilation, Device Alert shutdown, Both Air/O₂ Supply Loss alarm shutdown or Power Off, the exhalation valve opens to allow the patient to exhale. The exhalation valve also opens any time breathing circuit pressure reaches 135 cmH₂O.

With exception of the High Pressure alarm, these same conditions cause the inspiratory emergency relief valve solenoid to be de-energized which allows the circuit pressure to vent if it is above the relief valve cracking pressure of 4 cmH₂O. The relief valve also opens any time breathing circuit pressure reaches 140 cmH₂O.

A bacteria filter is placed between the inspiratory limb and the inspiratory (TO PATIENT) port to prevent contaminants in the exhaled gas from entering the inspiratory manifold when the inspiratory emergency relief valve is de-energized.

Protection From Re-breathing Exhaled Gases In Case of Ventilator Shutdown

In the case of a Sustained High Baseline Pressure Alarm violation, Device Alert shutdown, Both Air/O₂ Supply Loss alarm violation or Power Off, gas delivery to the patient will cease. The inspiratory manifold and exhalation valve systems are designed to protect the patient from re-breathing exhaled gas under this condition. A mechanical emergency intake valve in the inspiratory manifold allows the patient to breathe room air into the breathing circuit. The exhalation valve acts as a one way valve allowing the patient to exhale but not inhale. This system provides fresh gas through the inspiratory limb and an easy route for exhalation through the exhalation valve in the case of ventilator shutdown. If the exhalation valve is blocked when the ventilator shuts down, the patient will exhale through the inspiratory emergency relief valve when pressure in the circuit reaches the cracking pressure of 4 cmH₂O.

THEORY OF OPERATION

Description of Functional Subsystems

The e360 Ventilator includes these subsystems:

- Inhalation system
- Exhalation system
- Electronics
- Safety mechanisms

Inhalation System

The inhalation system supplies gas according to the user-selected breath delivery settings.

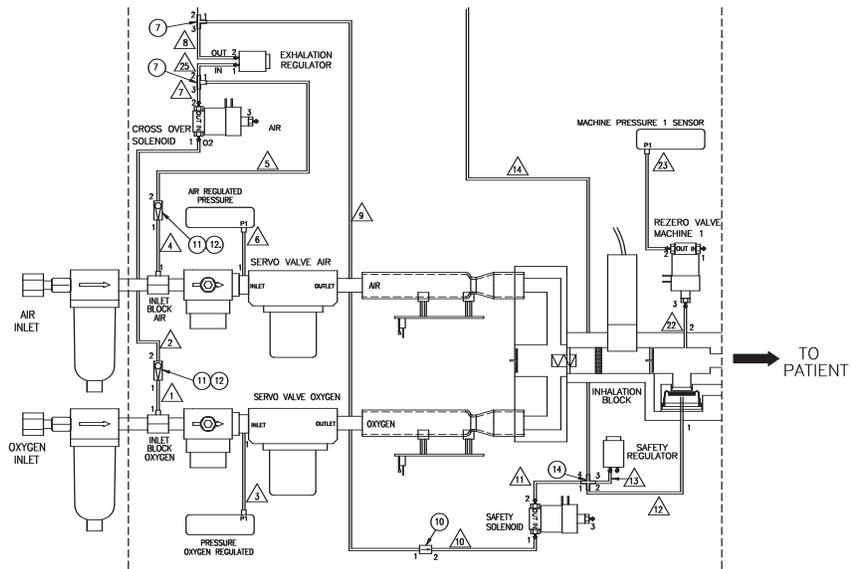


Figure A-1 e360 Ventilator Inhalation System

Supply gas enters the inlet filters (one for oxygen and one for air) at a pressure of 30 to 90 pounds per square inch gauge (psig). Each inlet filter traps particles as small as 40 microns and includes a water trap to collect any water from the supply gas.

The filtered supply gas then enters a regulator that regulates pressure from 30 to 90 psig down to 15 psi. Transducers monitor pressure at the regulators, and a pressure drop at either regulator generates a low inlet pressure alarm.

The regulated gas enters the servo valves, which are designed to supply gas to the patient circuit at the preset or ventilator managed flow. A servo valve calibration creates a lookup table of the currents required to generate the range of flows from the servo valve. The lookup table allows the ventilator to target the required flow as quickly as possible, and feedback from the flow sensor every 10 milliseconds allows the ventilator to refine flow delivery. Because the lookup table is unique to each combination of

regulator and servo valve, the servo valve calibration should be rerun when either component is replaced. Most of the gas pressure drops across the servo valves, and gas exiting the servo valves is close to patient pressure.

Check valves downstream of the servo valves prevent cross-contamination from the ventilator to the gas supplies.

The flow sensors are hot wire anemometers: as gas flows through the sensor, it cools the wire and increases its resistance. The flow sensor adjusts power to keep wire temperature constant, and the power required is directly proportional to the flow across the wire. Each flow sensor is factory-calibrated for air or oxygen.

Air and oxygen then enter the mixing chamber, where they are combined. The blended gas then exits to the patient circuit through the inspiratory manifold. The inspiratory manifold also includes the emergency intake valve and the emergency relief valve. These components are described above in item 4, Safety Features.

The oxygen sensor is mounted directly to the inspiratory manifold where it can monitor the delivered $F_{I}O_2$ and compare it to the set $F_{I}O_2$. Because the oxygen sensor is sensitive to changes in atmospheric pressure and temperature, the ventilator calibrates the oxygen sensor, each time the O_2 3 min button is activated and any time the monitored $F_{I}O_2$ is $\geq \pm .07$ from the set value. Ventilator software assigns an $F_{I}O_2$ of 1.0 to the voltage read during calibration. The user may also initiate a calibration from a menu on the GUI.

During exhalation the inhalation system supplies a bias flow of 3 L/min through the patient circuit to flush exhaled CO_2 and stabilize temperature, humidity, and baseline pressure. When either Leak Compensation or Non Invasive is turned On, the ventilator provides leak compensation by increasing flow above bias flow to maintain end expiratory flow near 3 liters per minute in the expiratory flow sensor. The maximum leak compensation level available when Leak Compensation is turned On varies for each Patient Category as follows: Ped/Infant = 8 L/min, Adult = 15 L/min. Maximum leak compensation supplied by the Non Invasive function is 25 L/min.

Transducers monitor pressure in the inspiratory manifold and expiratory system. A transducer re-zero solenoid maintains an accurate zero point for the pressure transducers by opening periodically to note the voltage that equals atmospheric (zero) pressure.

Exhalation System

The exhalation system measures the flows and volumes of gas exhaled from the patient circuit, measures pressure and controls the exhalation valve to manage pressure in the breathing circuit and allow patient exhalation.

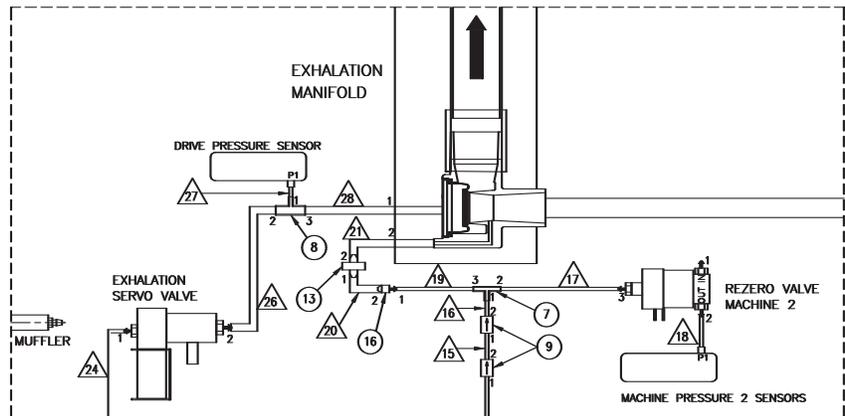


Figure A-2 e360 Ventilator Exhalation System

Because gas delivered to and exhaled from the patient is humidified to near 100% relative humidity, the expiratory block includes a heater to prevent condensate from forming as the exhaled gas passes through the exhalation system.

The heater heats the expiratory block and flow sensor to prevent condensation. The exhalation flow sensor includes a hot wire sensor and a temperature compensation wire. By measuring the temperature exchange for the hot wire in the flow sensor the ventilator calculates the flow of the exhaled gas. The exhalation flow sensor requires a short calibration before it is put into use. The calibration is performed by the user at ventilator start-up and may also be initiated by the user during ventilation if calibration is suspect.

Gas from the exhalation valve flows to the exhalation flow sensor. The exhalation valve includes a flexible silicone exhalation diaphragm, and drive pressure from the jet pump opens and closes the diaphragm to manage pressure in the breathing circuit and allow patient exhalation.

The exhalation solenoid is a small servo valve that controls pressure to the exhalation valve diaphragm by varying its outlet size. Gas from the exhalation solenoid enters the jet pump, where it flows through a jet nozzle to create drive pressure to the exhalation valve diaphragm. The low mass of the jet pump allows it to operate without the complications caused by oscillation of a larger part.

A pressure transducer at the exhalation valve provides feedback that tells the exhalation solenoid to increase or decrease its output to achieve the correct drive pressure. The exhalation solenoid associates an approximate PEEP with an approximate drive pressure. In case of a circuit disconnect, these reference pressures help avoid supplying excess pressure in the circuit after reconnection. Excess flow from the jet pump vents through the muffler.

Electronics

Power to the ventilator enters the A.C. inlet, which connects to the power supply. The power supply converts alternating current to direct current, and accepts any voltage or frequency within the specified range.

Direct current from the power supply enters the DC-DC PCB, which supplies operating voltage to other PCBs, includes circuitry for external battery connection and battery operation, and powers the fan, and heater.

The Main PCB accepts input from the oxygen sensor and servo valves, acts as “motherboard” for the ventilator including the secondary (Backup) alarm. The Main PCB powers and receives signals from the Analog PCB.

The Analog PCB accepts signals from the flow sensors and includes all ventilator transducers. The Solenoid PCB includes all valve controls (solenoids) except for the exhalation valve solenoid attached to the jet pump.

The Single Board Computer Board includes all of the video interface, USB, RS232, Primary Audio Alarm, and Touch Screen interfaces.

APPENDIX B: ORDERING & CONTACT INFORMATION

Ordering Parts and Kits	B-1
Contact Technical Support	B-3
Return e360 for Repair.....	B-3
Submit a Product Complaint	B-4

ORDERING PARTS AND KITS FROM CUSTOMER SERVICE

This section lists field-replaceable parts kits for the e360 Ventilator. For more information about parts or ordering, contact Newport Customer Service:

Telephone (voice mail):

800.451.3111, extension 282 (only in USA)

714.427.5811, extension 282

Fax:

714.427.0489

Customer Service department hours:

Monday through Friday, 8:00 am to 5:00 pm (USA Pacific Time)

Table B-1 e360 Ventilator Spare Parts List

Description	Part Number
PREVENTIVE MAINTENANCE KIT	PMK360A
OVERHAUL KIT	OVL360A
12 VOLT/7.2 AH (AMP HOUR) BATTERY	BAT1800P
ADAPTER, EXHALATION	ADP2105M
ANALOG BOARD	PCB2104A
AUDIO BOARD	PCB2106P
SAFETY REGULATOR	REG1802P
BUZZER	BZR1001P
CABLE ASSEMBLY, SPEAKER	CBL2120A
CABLE ASSY, AC POWER INPUT	CBL2115A
CABLE ASSY, ANALOG PCB	CBL2118A
CABLE ASSY, DC/DC TO BATTERY & SWITCH	CBL2111A
CABLE ASSY, DC/DC TO SBC	CBL2108A
CABLE ASSY, EXH. PCB TO MAIN PCB	CBL2122A
CABLE ASSY, INHALATION FLOW SENSOR	CBL2116A
CABLE ASSY, LCD DISPLAY TO SBC	CBL2105A
CABLE ASSY, MAIN TO BACK PANEL	CBL2113A
CABLE ASSY, MAIN TO DC/DC	CBL2101A
CABLE ASSY, MAIN TO DISPLAY BOARD	CBL2106A
CABLE ASSY, MAIN TO TOP AMBER LED	CBL2125A
CABLE ASSY, MAIN TO O2 SENSOR	CBL2109A
CABLE ASSY, MAIN TO POWER SUPPLY TO DC/DC	CBL2103A
CABLE ASSY, MAIN TO SINGLE BOARD	CBL2110A
CABLE ASSY, MAIN TO SOLENOID ASSY	CBL2107A
CABLE ASSY, MAIN TO TOP RED LED	CBL2102A

ORDERING & CONTACT INFORMATION

Table B-1 e360 Ventilator Spare Parts List, cont.

Description	Part Number
CABLE ASSY, SBC TO BACKPANEL VGA PORT	CBL2104A
CABLE ASSY, SBC TO TOUCH PANEL CONTROLLER	CBL2112A
CABLE ASSY, USB TO SBC	CBL2114A
CABLE, GROUND	CBL2144M
CABLE, OUTSIDE EXHILATION FLOW	CBL2123P
CALE ASSY, DC/DC FAN	CBL2119A
DIAPHRAGM, EXHILATION VALVE	DIA1810A
DISPLAY BOARD	PCB2102A
DISPLAY, LCD	DSP2105P
EMERGENCY RELIEF DIAPHRAM	DIA1800M
EXHALATION FLOW SENSOR	FLS2101P
EXHILATION FLOW SENSOR BOARD	PCB2103P
EXHILATION VALVE ASSEMBLY	EXH2105A
FAN FILTER, EMI	FLT2100P
FUSE – 2A SLO-BLO	FUS1802Q
HEATER ASSEMBLY	HTR2100A
INSIDE EXH. FLOW CABLE ADULT	CBL2124P
LED, AMBER, TOP	LED2102P
LED, RED, TOP	LED2101P
MAIN BOARD	PCB2100A
SPEAKER	SPK2103M
OXYGEN SENSOR	R125P03-002
MODULE, POWER ENTRY	FUH1800P
OPTICAL ENCODER	ENC1800P
POWER CORD	PWR1500P
POWER SUPPLY BOARD	PCB2101A
POWER SWITCH BOX ASSEMBLY	SWI1810A
EXHALATION SERVO REGULATOR	REG1701P
REGULATOR, INLET	REG1800P
SBC/GUI, e360 COMPACT FLASH	CF2105A
SEAL, POPPET, EXHILATION VALVE	SEL1800M
EXHALATION SERVO VALVE	VLV1806P
SERVO VALVE	SVO2101P
SINGLE BOARD COMPUTER	SBC2100P

Table B-1 e360 Ventilator Spare Parts List, cont.

Description	Part Number
SOLENOID VALVE	SOL1501P
SWITCH, POWER	SWI1800P
SWITCHING POWER SUPPLY	PWR2100P
TOUCH SCREEN CONTROLLER	PCB2105P
TOUCH SCREEN PANEL	PNL2105P
TSI FLOW SENSOR, AIR	FTD2100P
TSI FLOW SENSOR, OXYGEN	FTD2101P
EMERGENCY INTAKE DIAPHRAGM	VLV100P

CONTACT TECHNICAL SUPPORT

Contact Newport Medical Instruments Technical Support using one of the contact information numbers below.

Phone: 800.451.3111, extension 500 (US only)
714.427.5811, extension 500

Fax: 714.427.0572 (Technical Service Dept.)

Email: TechService@NewportNMI.com

For maintenance, warranty, or non-warranty repairs: dial extension 500 to reach the Technical Service department.

If you need emergent technical support after business hours, please call Technical Support and leave your name, phone number and detailed message in the voice mail. Our Technical Support Team members will be paged and return your call shortly.

For other returns: dial extension 282 to reach the Customer Service department.

RETURN e360 FOR REPAIR

Follow these steps to return your e360 Ventilator for repair:

- 1 Obtain a returned goods authorization (RGA) number from Newport Technical Support at the numbers given above. The RGA number helps to identify your repair and avoid service delays.

ORDERING & CONTACT INFORMATION

- 2 Unless requested to do otherwise, remove all accessories from the ventilator except the inlet water traps. Do not send accessories to Newport.
- 3 Package the ventilator in the original packing material, if available. If the original packing material is not available, call the Customer Service department to order a replacement box. Package parts or accessories (if requested) for safe shipping (original packing materials are not required).

SUBMIT A PRODUCT COMPLAINT

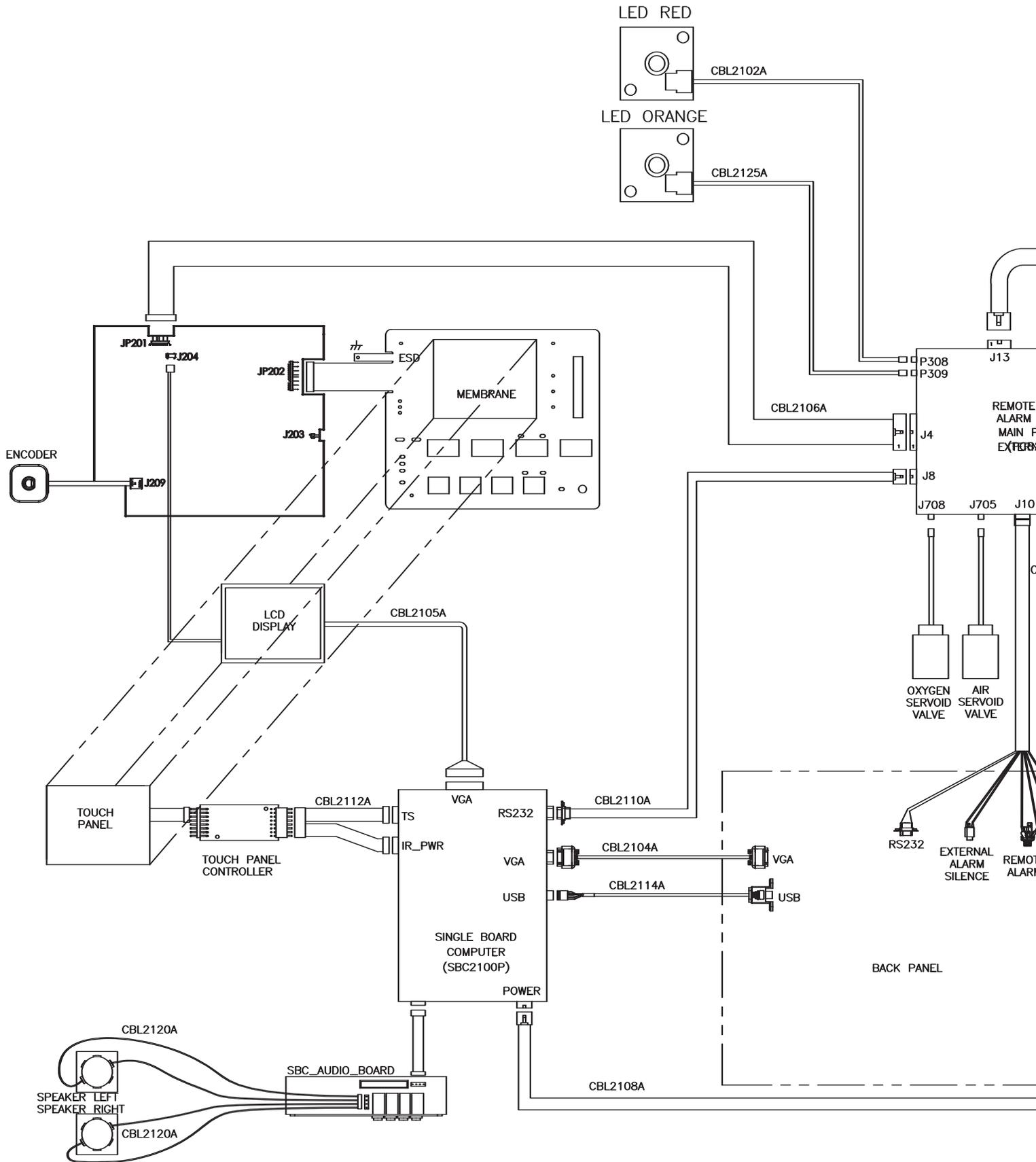
If your ventilator is not functioning properly (malfunctions) or a part of your ventilator is defective, a “Product Complaint Report” is required before any warranty replacement is authorized and/or a RGA number is issued. To submit a “Product Complaint Report”, go to the Newport website WWW.VENTILATORS.COM and click on Customer Support / Complaint Report. Fill out the form completely with as much detail as possible and submit. A Technical Support Team member will review your product complaint and contact you shortly to resolve any issues you may have.

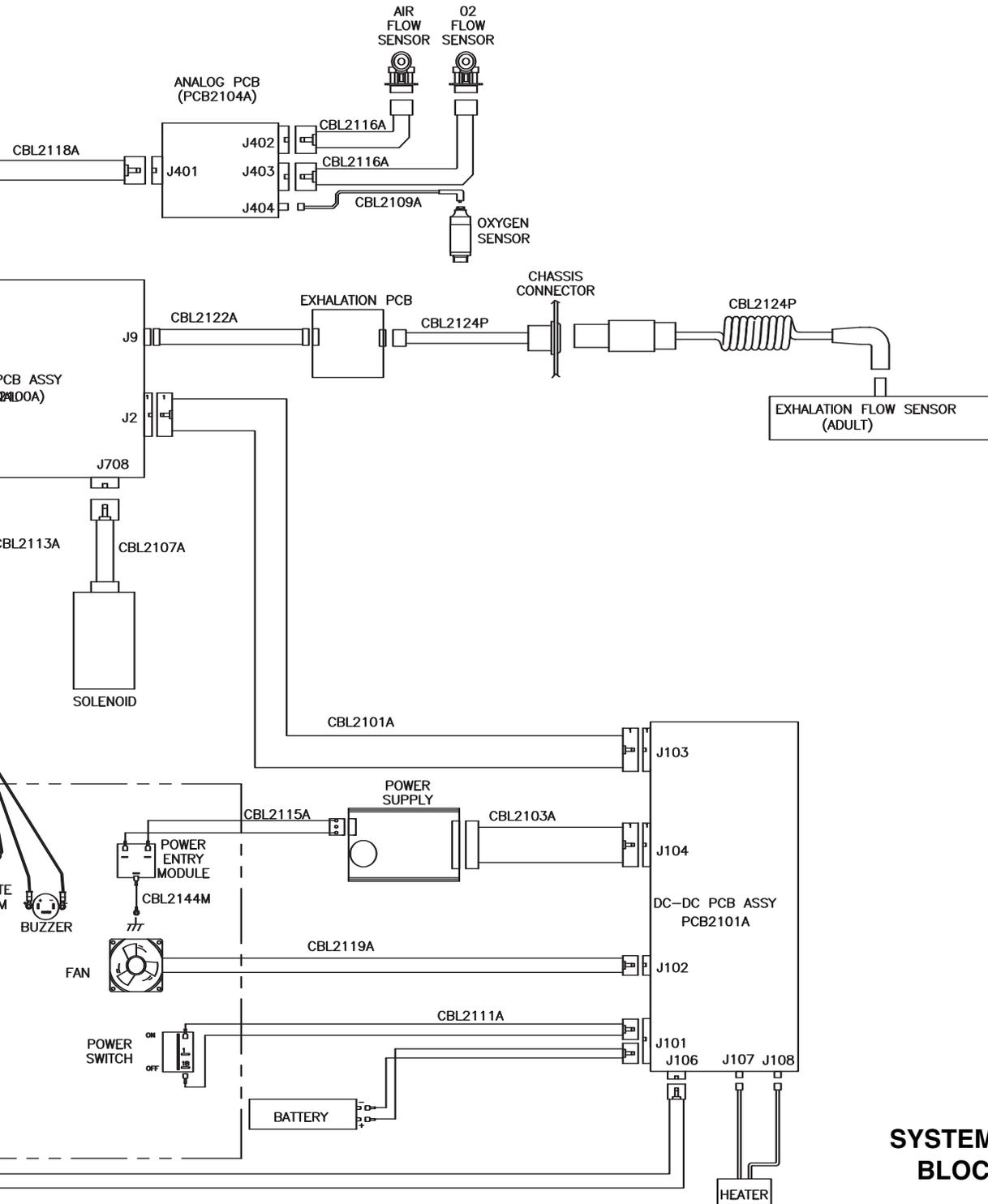
If you would like to request an RGA number for other returns or offer a product improvement suggestion, you can also use the Product Complaint Report.

APPENDIX C: DIAGRAMS

e360 System Electrical Block Diagram	C-1
e360 System Pneumatic Diagram	C-2

DIAGRAMS



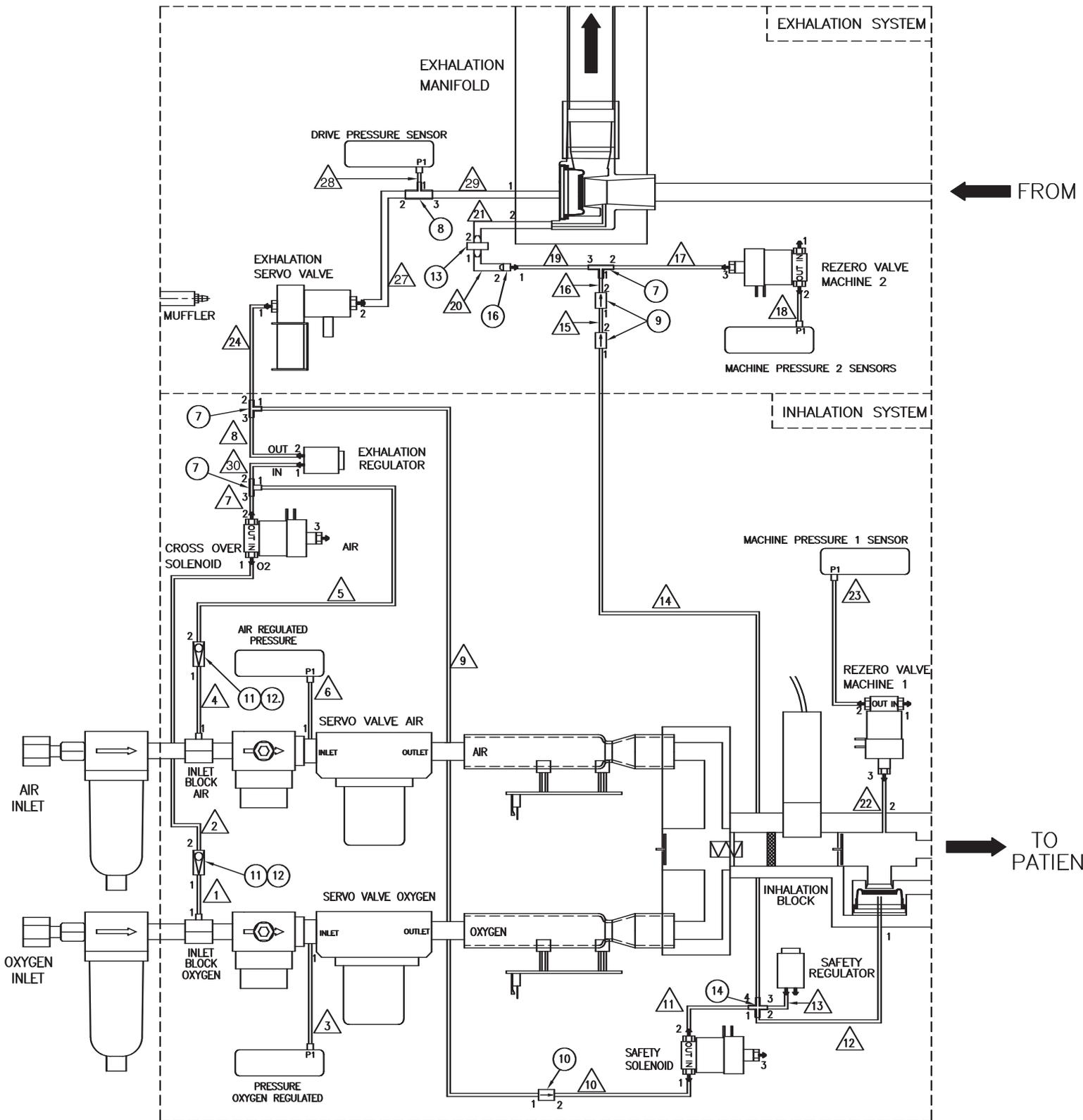


**SYSTEM ELECTRICAL
BLOCK DIAGRAM**

SWD2100A

DIAGRAMS

e360 PNEUMATIC DIAGRAM



TUBING CONNECTIONS									
△ TUBE	FROM			TO			TUBE		
	LOCATION	ITEM NO.	PORT	LOCATION	ITEM NO.	PORT	I.D. & LENGTH	ITEM NO.	COLOR
1	INLET BLOCK OXYGEN	--	1	CHECK VALVE	11, 12	1	1/16 X 3	5	BLUE
2	CHECK VALVE	11, 12	2	CROSS OVER SOLENOID	--	1	1/16 X 2	5	BLUE
3	SERVO VALVE OXYGEN	--	1	ANALOG PCB	--	XD103, P1	1/16 X 12	5	BLUE
4	INLET BLOCK AIR	--	1	CHECK VALVE	11, 12	1	1/16 X 3	3	YELLOW
5	CHECK VALVE	11, 12	2	TEE	--	1	1/16 X 2	3	YELLOW
6	SERVO VALVE AIR	--	1	ANALOG PCB	--	XD102, P1	1/16 X 12	3	YELLOW
7	CROSS OVER SOLENOID	--	2	TEE	--	3	1/16 X 1	3	YELLOW
8	EXHALATION REGULATOR	--	2	TEE	7	3	1/16 X 1	2	ORANGE
9	TEE	7	1	RESTRICTOR .009	10	1	1/16 X 2	2	ORANGE
10	RESTRICTOR .009	10	2	SAFETY SOLENOID	--	1	1/16 X 3	2	ORANGE
11	SAFETY SOLENOID	--	2	CROSS TEE	14	1	1/16 X 5.5	4	GREEN
12	CROSS TEE	14	2	INHALATION BLOCK	--	1	1/16 X 15	4	GREEN
13	CROSS TEE	14	3	SAFETY REGULATOR	--	1	1/16 X 1	4	GREEN
14	CROSS TEE	14	4	RESTRICTOR .003	9	1	1/16 X 4	4	GREEN
15	RESTRICTOR .003	9	2	RESTRICTOR .003	9	1	1/16 X 1	4	GREEN
16	RESTRICTOR .003	9	2	TEE	7	1	1/16 X 1	4	GREEN
17	TEE	7	2	REZERO VALVE MACHINE 2	--	3	1/16 X 8	4	GREEN
18	REZERO VALVE MACHINE 2	--	2	ANALOG PCB	--	XD106, P1	1/16 X 7	4	GREEN
19	TEE	7	3	REDUCER	16	1	1/16 X 1	4	GREEN
20	REDUCER	16	2	FILTER	13	1	1/8 X 1	15	SILICON
21	FILTER	13	2	EXHALATION MANIFOLD	--	2	1/8 X 4	15	SILICON
22	INHALATION BLOCK	--	2	REZERO VALVE MACHINE 1	--	3	1/16 X 18	1	CLEAR
23	REZERO VALVE MACHINE 1	--	2	ANALOG PCB	--	XD105, P1	1/16 X 8	1	CLEAR
24	TEE	7	2	EXHALATION SERVO VALVE	--	1	1/16 X 3	2	ORANGE
25	REMOVED	--	-	---	-	-	---	-	-
26	REMOVED	--	-	---	-	-	---	-	-
27	EXHALATION SERVO VALVE	--	2	TEE REDUCER	8	2	1/8 X 8	6	BLUE
28	TEE REDUCER	8	1	ANALOG PCB	--	XD107, P1	1/16 X 5	2	ORANGE
29	TEE REDUCER	8	3	EXHALATION MANIFOLD	--	1	1/8 X 8	15	SILICON
30	TEE	7	2	EXHALATION REGULATOR	--	1	1/16 X 4	3	YELLOW

e360 PNEUMATIC DIAGRAM

SPD2100A