Newport Medical Instruments, Inc.

NEWPORT e360 VENTILATOR

Operating Manual

For Model e360S and e360P

OPR360 WW Rev. B

05/06

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1. INTRODUCTION

INTENDED USE

The e360 Ventilator System is intended to provide continuous (endotracheal or tracheostomy [ET] tube) or non-continuous (mask) ventilatory support and monitoring for infant, pediatric, and adult patients requiring tidal volumes equal to or greater than 20 milliliters (mL). The device is for use by prescription only. The intended environments include hospital, hospital-type, and intra-hospital transport environments. Hospital use typically includes general care floors, operating rooms, special procedure areas, emergency rooms, and intensive and critical care areas within the hospital. Hospital-type use includes facilities such as or similar to surgicenters, sub-acute centers, and special nursing facilities outside of the hospital. Intra-hospital transport includes patient transport within the hospital or hospital-type facility.

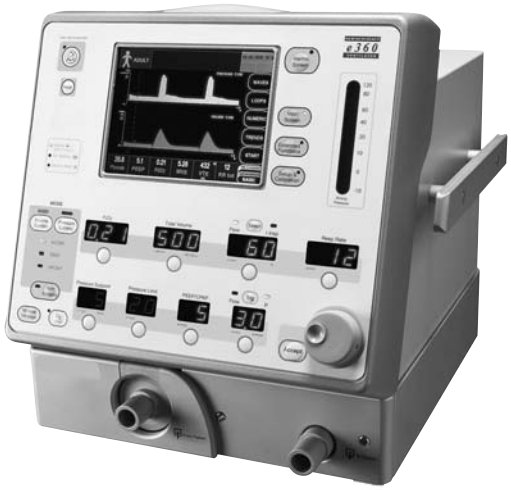

Figure 1-1.
e360 Ventilator System

WARRANTY AND RESPONSIBILITY

WARRANTY

The Newport e360 Ventilator System is guaranteed to be free of defects for a period of one (1) year from date of delivery. The following are exceptions to this warranty:

- Defects caused by misuse, mishandling, tampering, or by modifications not authorized by Newport or its representatives are not covered.

- Rubber and plastic components and materials are warranted to be free of defects at time of delivery.

- The O_2 sensor is covered for a period of one year from purchase date.

Any product, which proves to be defective in workmanship or material will be replaced, credited, or repaired with Newport holding the option. Newport is not responsible for deterioration, wear, or abuse. In all cases, Newport will not be liable beyond the original selling price.

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.

Application of this warranty is subject to the following conditions:

- Newport or its authorized representatives must be promptly notified upon detection of the defective material or equipment.
- Defective material or equipment must be returned to Newport or its authorized representative.
- Examination by Newport or its authorized representatives must confirm that the defect is covered by the terms of this warranty.

In order to assure complete protection under this warranty, the Warranty Registration Card must be returned to Newport within ten (10) days of receipt of equipment.

The above is the sole warranty provided by Newport. No other warranty expressed or implied is intended. Representatives of Newport are not authorized to modify the terms of this warranty.

RESPONSIBILITY FOR PATIENT SAFETY

To use this product correctly and effectively and to avoid hazards, carefully read and observe all sections of this manual prior to use.

Because the design, operating manual, and labeling of the e360 Ventilator System assume that its sale and use are restricted to qualified, trained professionals under the direction of a physician who understand the general operating characteristics of ventilators, this manual includes instructions, warnings, and cautions that are specific to the design of this ventilator. This manual excludes references to hazards that are obvious to medical professionals, the consequences of product misuse, or to potentially adverse effects in patients with abnormal conditions.

Product modification or misuse can be dangerous. Newport disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences that might result from the combination of this ventilator with other products, whether supplied by Newport or by other manufacturers, if such a combination is not endorsed by Newport.

Federal Law and Regulations in the United States and Canada restrict this device to sale by or on the order of a physician.

It is the responsibility of the ventilator operator to choose appropriate monitoring of equipment performance and patient condition. Electronic surveillance of equipment performance and patient condition cannot take the place of directly observing clinical signs. The ventilator operator is solely responsible for selecting the optimum level of patient monitoring.

LIMITATION OF LIABILITY

The liability of Newport, whether arising out of, or related to manufacture and sale of the goods, their installation, demonstration, sales representation, use, performance, or otherwise, including any liability based upon Newport's product warranty, is subject to and limited to the exclusive terms and conditions as set forth, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to Newport and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).

The stated expressed warranties are in lieu of all other warranties, expressed or implied, including, without limitation, warranties of merchantability, fitness for any purpose, or noninfringement.

Newport shall not be liable for, nor shall the buyer be entitled to recover, any special incidental or consequential damages or any liability incurred by buyer to any third party in any way arising out of or relating to the goods.

TYPING CONVENTIONS

Controls, buttons, and alarms are shown in this manual as italicized text, written as they appear on the ventilator (for example, *SPONT* for spontaneous mode).

WARNINGS, CAUTIONS, AND NOTES

Please review all **WARNINGS** and **CAUTIONS** outlined in this manual before operating the ventilator.

Strictly follow this Operating Manual. Any use of the product requires full understanding and strict observation of all sections of these instructions. The equipment is only to be used for the purpose specified under INTENDED USE and in conjunction with appropriate patient observation and monitoring. Observe all **WARNINGS** and **CAUTIONS** that appear in this manual and on equipment labels.

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.

GENERAL CAUTIONS

- Use only dry clean compressed air and medical grade oxygen.
- Use only fuses with the correct rating.
- Do not place liquids on or near the ventilator.

GENERAL WARNINGS

- Danger: there is a risk of explosion if used in the presence of flammable anesthetics.
- All ventilator controls and alarm limits must be appropriate for the patient's condition, according to the therapy prescribed by a physician.
- Newport cannot warrant or endorse the safe performance of third party humidifiers for use with the e360 Ventilator.
- Contact the manufacturers/distributors of third party humidifiers about the compliance and performance characteristics of their products.
- A patient connected to a ventilator requires the constant attention of medical staff to the patient's condition, and to any significant difference between monitored and set values that may indicate a fault in ventilator operation.
- Before and during the use of the e360 Ventilator, make sure that all connections in the patient circuit are secure. Ensure the integrity of each part of the patient circuit, humidifier connections, and humidifier chamber.
- Always use appropriate monitors to ensure sufficient oxygenation and ventilation (such as a pulse oximeter and capnograph) when the e360 Ventilator is in use on a patient.

- Have an alternate method of ventilation available for use when using the e360 Ventilator. If the ventilator's operation or monitoring functions are in doubt, discontinue ventilator use and employ an alternate method of ventilation.

- Have an alternate method of oxygen monitoring with high and low alarms available for use when using the e360, in the event the built-in oxygen monitor is unavailable due to a defective or missing oxygen sensor.

- Use a bacteria filter between the inspiratory (TO PATIENT) port and the inspiratory limb of the breathing circuit to prevent contaminants in the patient exhaled gas from entering the inspiratory manifold when the emergency relief valve opens (when there is a *Device Alert, Both Air/O_2 Supply Loss*, or *Sustained High Baseline Pressure* Alarm). If a filter is not used, the inspiratory manifold will have to be cleaned and sterilized between patients.

- Use of a bacteria filter between the expiratory limb of the breathing circuit and the e360 Ventilator to prevent contaminants in the exhaled gas from entering the exhalation system is recommended. If a filter is not used, the exhalation valve will have to be cleaned and sterilized and the flow sensor will have to be replaced between patients.

- Use an additional single patient use bacteria filter between the expiratory limb of the breathing circuit and the primary expiratory bacterial filter when nebulized medications are delivered through the breathing circuit. Failure to do so could lead to expiratory volume monitoring inaccuracies, damage to the expiratory flow sensor, increased resistance to patient exhalation and even exhalation system obstruction. Discard the filter at the completion of nebulized drug delivery or more frequently as needed to minimize expiratory resistance. Follow filter manufacturer's instructions.

NOTE: Install bacteria filters, water traps and/or heated wires as required. Newport recommends the use of a bacteria filter on both the inspiratory and expiratory limbs of the breathing circuit to speed ventilator turnover and protect ventilator components.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class 1 and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular

installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected.
- Consult the manufacturer or field service technician for help.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input or output parts "configures" a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the Technical Service department or your local representative.

Dispose of waste products, residue, etc., in accordance with the appropriate national requirements.

COPYRIGHT INFORMATION

CONTACT INFORMATION

For more information about parts or ordering, contact Newport Customer Service:
Telephone (voice mail): 714.427.5811 Extension: 282
Fax: 714.427.0489
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Internet: www.NewportNMI.com or www.ventilators.com

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2. VENTILATOR OVERVIEW

e360 Control Panel

The e360 Control Panel is clearly labeled with standard ventilation terminology, following ISO standards. Figure 2-1 shows the e360 Control Panel and the following table provides descriptions of each area.

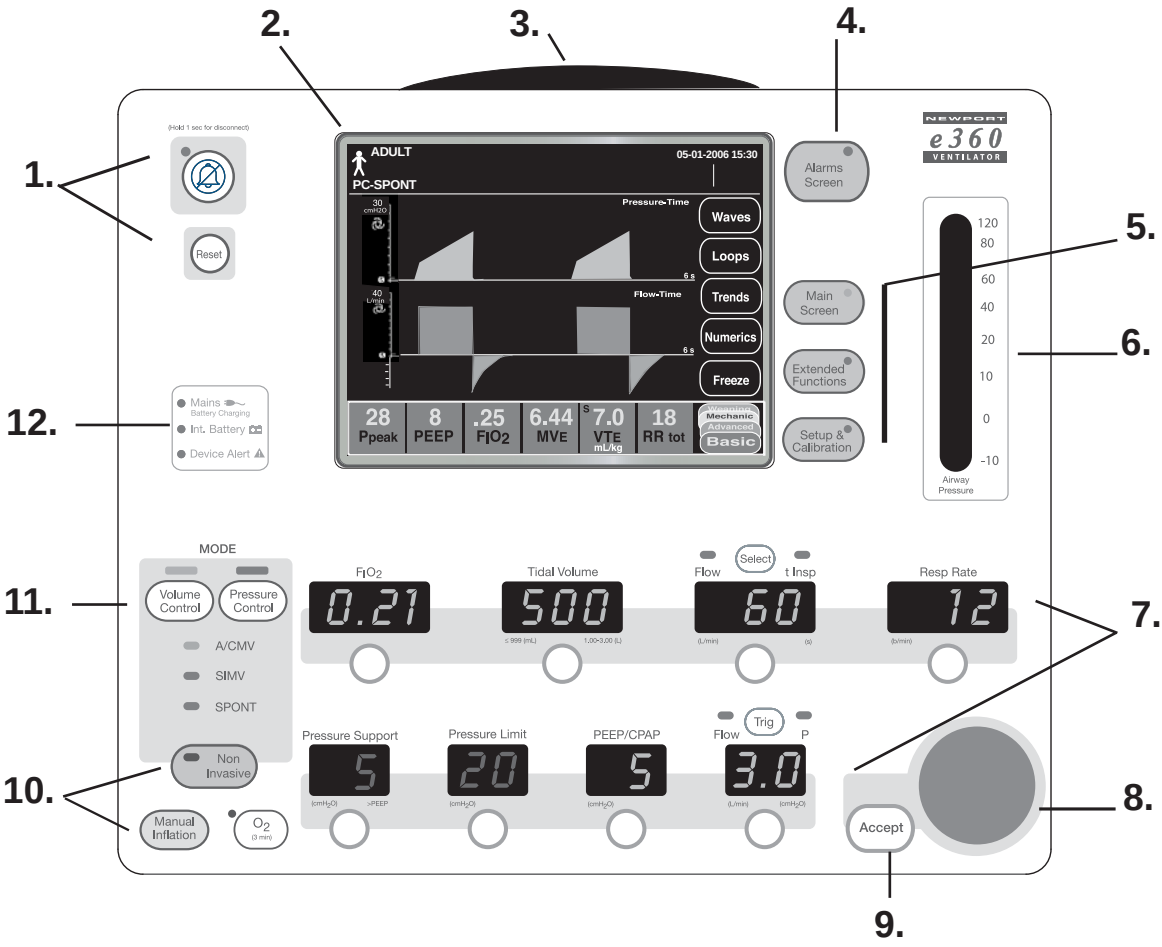


Figure 2-1. e360 Control Panel

No.	Description	No.	Description
1.	Alarm Silence and Reset Buttons	8.	Adjustment Knob
2.	Graphical User Interface (GUI)	9.	Accept Button
3.	360º Alarm Lamp	10.	Special Functions
4.	Alarms Screen Menu Button		Non Invasive Button
5.	Graphical User Interface Menu Buttons		Manual Inflation Button
6.	Pressure Bar Graph		O_2 (3 min) Button
7.	Ventilation Controls	11.	Modes/Breath Types Button
		12.	Power Indicators

Graphical User Interface Display (GUI)

The e360 Graphical User Interface allows the user to quickly navigate through a number of screens to access extensive data including monitoring, custom set-up, automated calibrations, numerics, wave forms and loops. Figue 2-2 shows the e360 GUI main screen and the following table provides a description of each area.

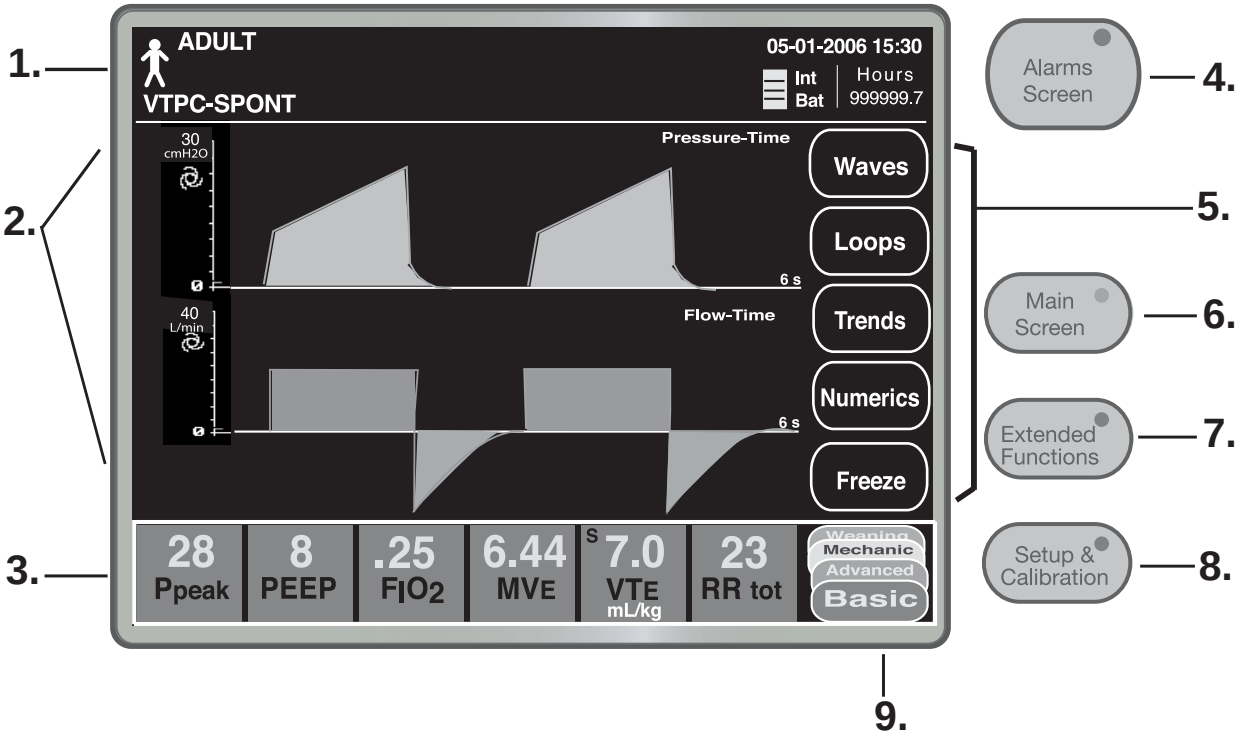


Figure 2-2. e360 GUI

Item No.	Description
1.	**GUI Status Bar**
2.	**Main Display Area**
3.	**Data Sets Bar** (4 data sets display monitored data & Advanced Settings)
4.	**Alarms Screen Menu Button** (press to access Alarms settings touch screen)
5.	**GUI Menu Touch Buttons**
6.	**Main Screen Menu Button** (press to access Waves, Loops, Trends & Numerics touch screen)
7.	**Extended Functions Menu Button** (press to access Extended Functions touch screen)
8.	**Setup & Calibration Menu Button** (press to access Circuit Check, Sensors (calibration) Patient Setup, and Technical Setup touch screen)
9.	**Data Set Touch Button**

Patient Connections Panel

The lower panel area on the front of the e360 contains patient connection ports and provides easy access to the exhalation valve and flow sensor. Figure 2-3 shows the Patient Connections Panel and the following table describes each connector.

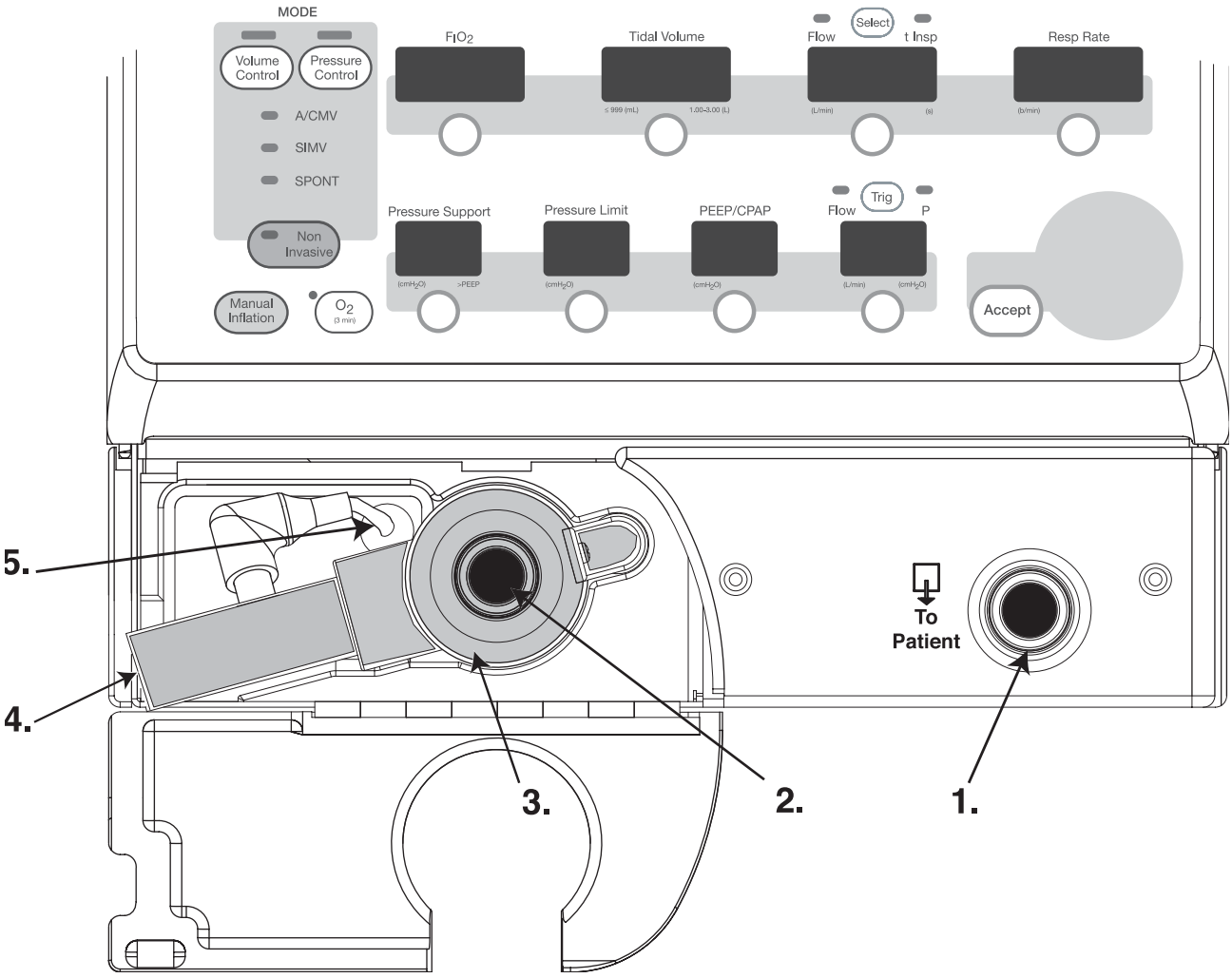


Figure 2-3. e360 Patient Connection Panel

Item No.	Description
1.	Inspiratory Port (To Patient) 22 mm OD
2.	Expiratory Port (From Patient) 22 mm OD
3.	Exhalation Valve
4.	Exhalation Flow Sensor
5.	Flow Sensor Cable connection

Rear Panel

The e360 rear panel contains the on/off power switch and other connectors to provide access to various external devices. Figure 2-4 shows the e360 rear panel and the following table provides a description of each area.

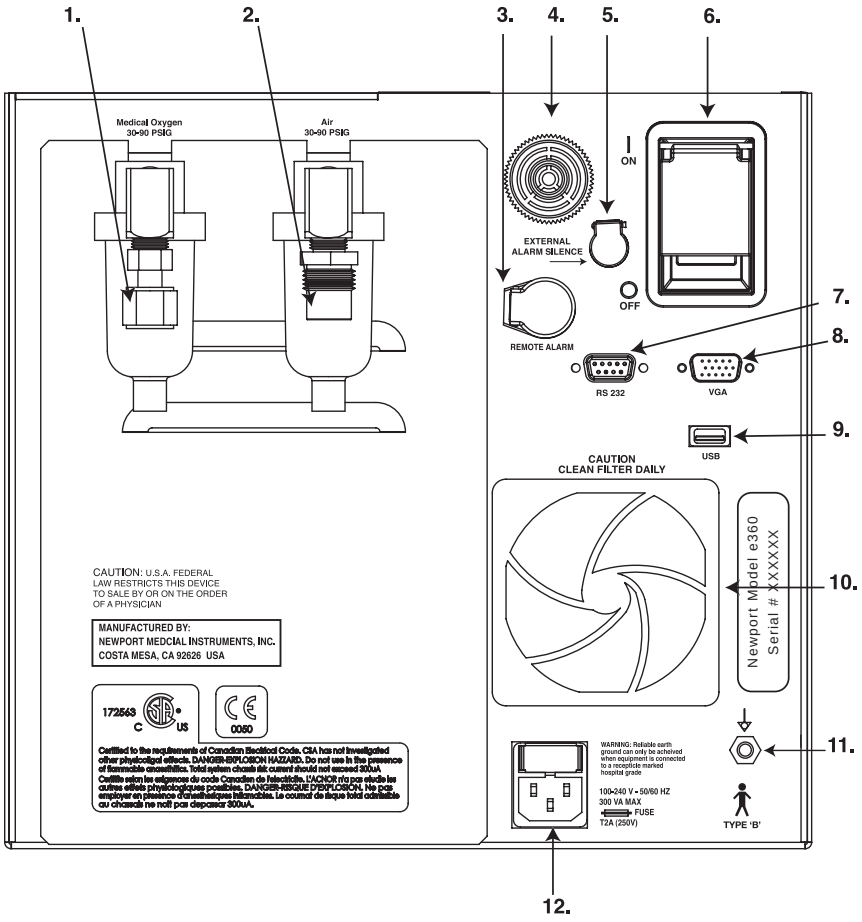
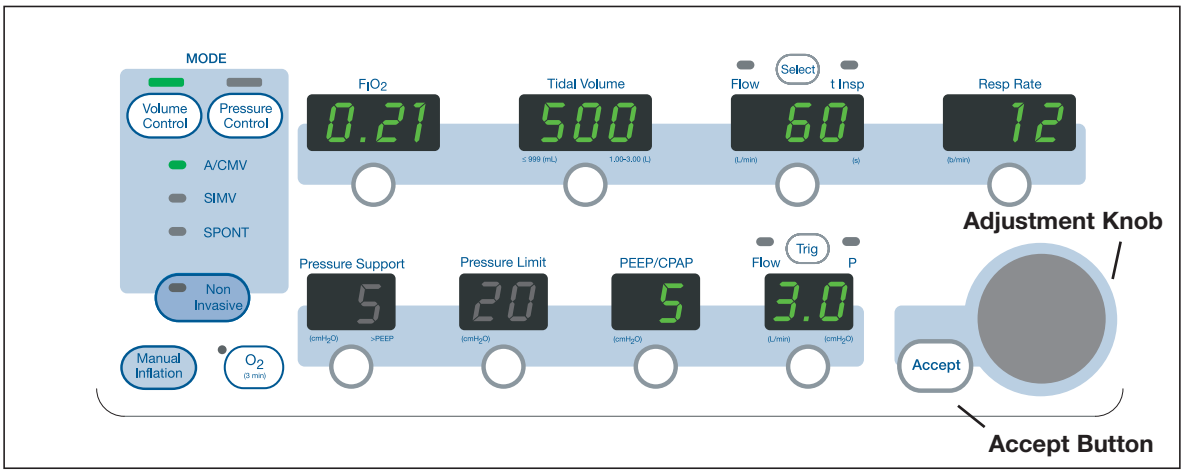


Figure 2-4. e360 Rear Panel

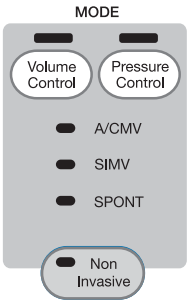
Item No.	Description
1.	Oxygen Inlet
2.	Air Inlet
3.	Remote Alarm connection
4.	Alarm speaker
5.	External Alarm Silence connection
6.	On/ Off power switch
7.	RS232 connection
8.	VGA connection
9.	USB connection
10.	Cooling Fan Filter housing
11.	Equipotential grounding stud
12.	AC power connection

This section provides an overview of the buttons, controls and functions of the ventilator and where they are located. Before using the e360 Ventilator on patients, please read and understand all of the information in this manual.

NOTE: Ventilation controls (on the Control Panel and on the GUI) are adjusted with the *Touch-Turn-Accept* method. *Touch* the desired selection, *Turn* the Adjustment Knob to make a change and press the *Accept* button to confirm or invoke the change. If the *Accept* button is not pressed within 10 seconds the setting will not be changed and will revert to the previous condition/value.



BREATH TYPE / MODE



Breath Type Selection

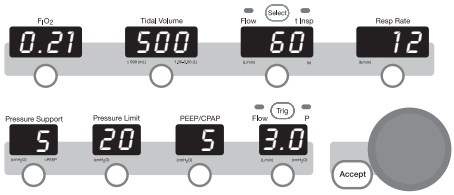
To select a breath type, press *Volume Control* or *Pressure Control*. The LED will continue to flash until the *Accept* button is pressed or 10 seconds has passed. If *Accept* is not pressed within 10 seconds the setting will not be changed and will revert to the previous condition/value.

Mode Selection

To select a mode, press the selected breath type button, *Volume Control* or *Pressure Control*, repeatedly until the desired mode indicator is flashing. Press *Accept* to invoke the change.

NOTE: On the e360 Plus model: To select a *Volume Target Pressure Control* breath type, Select Pressure Control breath type and then access the *Advanced* Data Set on the GUI. Press the *Volume Target* touch button and use the Adjustment knob to select On. Press *Accept* button to confirm. (See “Advanced Settings”).

VENTILATION CONTROLS / CONTROL PANEL



F_IO_2, Tidal Volume, Flow, Inspiratory Time (t Insp), Respiratory Rate (Resp Rate), Pressure Support, Pressure Limit, PEEP/CPAP and *Trigger (flow or pressure)* can be set via the membrane buttons on the Control Panel.

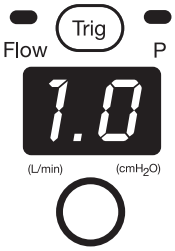
Press the button below the corresponding display to select parameter. The display will flash. Rotate the *Adjustment Knob* to adjust setting. Press the *Accept* button to invoke the change. The display will stop flashing and the setting will take effect.

Before pressing the *Accept* button to invoke the new change, the user can select and adjust multiple other controls in the same area and then press the *Accept* button, thereby accepting all of the changes.

In *Volume Control*, you can choose to set either *Flow* or *Inspiratory Time* (see t insp) for mandatory breaths.

Press the *"Select"* button above the display to toggle between *Flow* and *t Insp*. An LED above the display will indicate the current selection.

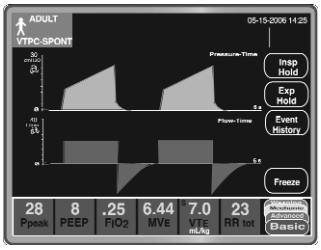
To change the *Flow* or *t Insp* setting: Press the button below the control display and use the *Touch-Turn-Accept* method.



To change the trigger sensitivity type: Press the *Trig* button at the top of the display to toggle between *Trigger Flow* or *Pressure (P)* trigger. An LED above the display will indicate the current selection.

To change the trigger setting: Press the button below the control display and use the *Touch-Turn-Accept* method.

VENTILATION CONTROLS – GRAPHICAL USER INTERFACE (GUI)



Extended Functions
Pressing the *Extended Functions* menu button on the control panel reveals new GUI menu buttons: *Insp Hold, Exp Hold, Event History* and *Freeze*. Touch and hold *Insp* or *Exp Hold* to start the maneuver for the current or following breath (the *Accept* button is not needed). Touch the *Event History* button to access the Event History log that records up to 1000 events.

*e360 Plus model

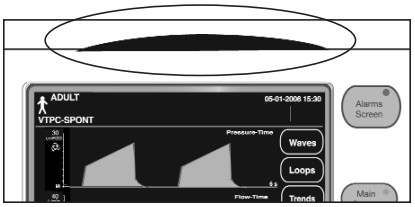
Advanced Settings
Additional ventilation controls can be found on the Graphical User Interface. Touch the button on the lower right hand corner of the screen to change the lower display "Data Set Bar" to the *Advanced Data Set*. Here the user can adjust and enable settings for *Slope/Rise, Expiratory Threshold, Pause, Flow Wave*. If you have the e360 Plus model, *Volume Target* and *Open Exhalation Valve* are also adjustable. Adjust or enable/disable these settings the same way as other ventilator controls; *Touch-Turn-Accept*.

ALARM MANAGEMENT

Alarm Silence / Reset
Pressing the *Alarm Silence* button mutes silenceable audible alarms for 120 seconds and cancels the Shutdown alarm that occurs after the power is switched to Off. (It does not silence Device Alert alarms until after power is switched off.)

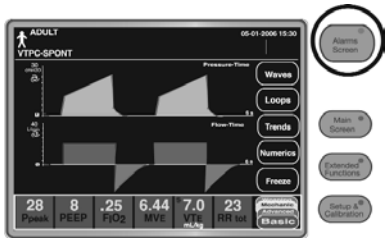
The LED lights while alarm silence is active. Press again to cancel the silence. To perform *Suction Disconnect Function*, press and hold *Alarm Silence* until two tones sound. See Section 6/Alarms for details.

Pressing the *Reset* button clears all visual indicators for alarms that are no longer violated.

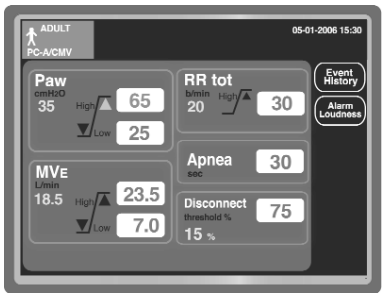


360º Alarm Lamp
The 360º *Alarm Lamp* (located on the top center of e360 bezel) flashes to indicate an alarm violation. It flashes Yellow for low and medium level alarms, Red for high level alarms.

Alarms & Messages Display Bar
The *Alarms & Messages* bar, located at the top, center of the Graphical User Interface status bar, shows user prompt messages and alarm violation messages.



Alarms Screen Menu Button
Pressing the *Alarms Screen* menu button opens the Alarm Settings screen on the Graphical User Interface. From this screen the user can modify all adjustable alarm settings, view *Event History* and adjust *Alarm Loudness*.



Alarm Settings Screen
The Alarm Settings screen allows the user to adjust high and low *Paw*, high and low MVE, high Respiratory Rate (*RRtot*), *Apnea* time and *Disconnect Threshold %* alarm limit settings in relation to a monitored displayed value.

To change an alarm setting: Press the displayed value button of the desired alarm, the number in the display will flash, rotate the Adjustment Knob to the desired setting and press the *Accept* button to invoke the change. The display will stop flashing and the setting will take effect.

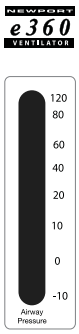
Multiple alarms can be adjusted before touching the *Accept* button as long as there is not a pause of 10 seconds or more between changes. If *Accept* button is not pressed, after 10 seconds all adjusted alarms will revert to their original values.

• Event History
Touching the *Event History* button takes you to the Event History Log where the user can view up to 1000 of the most recent events including alarm violations, setting changes and power On/Off sequences.

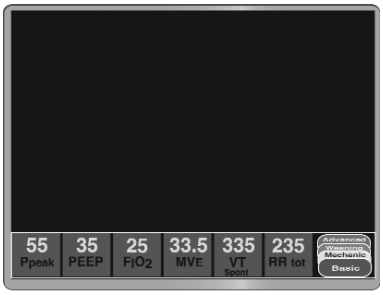
• Alarm Loudness
To adjust the alarm tone volume, touch the *Alarm Loudness* button. Use the Adjustment Knob to adjust the loudness up or down (a lower number is quieter and a larger number is louder). Press the *Accept* button to invoke the change.

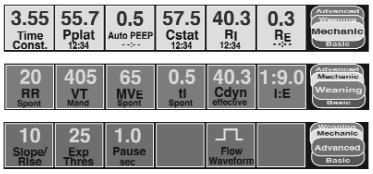
To exit either of these screens, touch any menu button on the Control Panel.

MONITORED PATIENT DATA



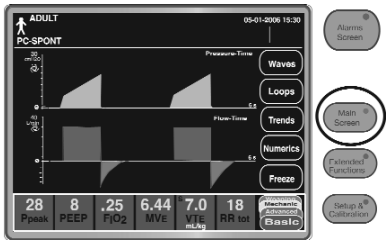
Pressure Bar Graph
The *Pressure Bar Graph* on the control panel continuously displays pressure monitored in the breathing circuit.





Data Sets
All patient monitored data (other than the pressure bar graph) is viewed on the Graphical User Interface (GUI) screen while ventilating. Four different data sub-sets are accessed by touching the lower right corner of the Display. The sets are labeled: *Basic, Mechanic, Weaning* and *Advanced*.

The *Advanced Data Set* displays the current settings for the Advanced Settings features: *Slope/Rise, Exp Threshold, Pause,* and *Flow Wave*. On the e360 Plus model, *Volume Target* and *Open Exhalation Valve* are also displayed. To adjust these settings touch the desired setting button. When the value flashes use the Adjustment Knob to change the selection and press the *Accept* button to invoke the change.



Main Screen
Pressing the *Main Screen* menu button on the Control Panel reveals GUI menu buttons:
Waves, Loops, Numeric, Trends and *Freeze*.

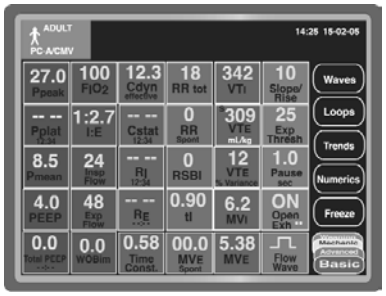
The graphic scale can be adjusted by touching the screen at the X or Y axis of the desired scale to be adjusted, turning the *Adjustment Knob* to the desired scale and pressing the *Accept* button to invoke the change.

There are five Waveform selections when the “Waves” button is touched: Pressure/Time & Volume/Time, Pressure/Time & Flow/Time, Pressure/Time, Flow/Time and Volume/Time.

Loops options include: Flow/Volume, Volume/ Pressure and Both.

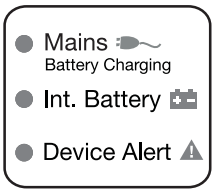
There are two Trends screens options, each with four trends:

Screen 1	Screen 2
VTE / Time	Ppeak / Time
Minute Vol / Time	Pmean / Time
RRtot / Time	Pbase / Time
VTE % Variance/ Time	RSBI spont / Time



Numerics
Pressing the *Numerics* button from the *Main Screen* menu displays all monitored and calculated numerics and *Advanced* settings on one screen.

POWER INDICATORS



Mains
The *Mains* LED on the control panel lights (Green) when the ventilator is supplied with AC power. The ventilator recharges the internal battery whenever AC power is connected (whether the power switch is ON or OFF).

Internal Battery Indicators
The LED for *Int. Battery* lights (Yellow) when the ventilator is operating on internal battery power.

Device Alert LED
The *Device Alert* LED blinks (Red) when operating on less than 10% internal battery power or when a ventilator malfunction occurs. See Section 4, Ventilator Operation for more details.

GUI MISC. INDICATORS

The top area of the Graphical User Interface provides useful information and icons that relate to ventilator settings and conditions. This is referred to as the *Status Bar* area.

Patient Selection
At the far left of the *Status Bar* bar an icon is displayed that represents which patient category is selected, *Adult* or *Ped/Infant*. See Section 4, Ventilator Operation/Patient Category for more details.

Breath Type and Mode Selection
Next to the patient selection, the initials for the current Breath type and mode in use are displayed, i.e. PC/SIMV.

Trigger Indicator
While ventilating, the patient/mode selection area flashes Green with every patient spontaneous effort.

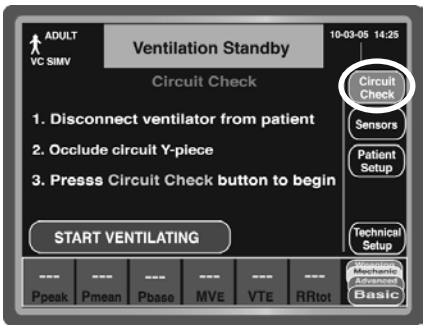
Alarms and Messages Display
Violated alarms' descriptor, such as "High Paw" or "Circuit Disconnect", and all messages are displayed in the center section of the *Status Bar*.

Int. Battery Charge Level
When the ventilator is powered by the internal battery an icon at the far right of the *Status Bar* shows the remaining battery power. Each lit bar represents approximately 25% of the total battery capacity.

Date/Time
Date and time is displayed in the far right corner of the display. The current, local date and time (and preferred format) can be set in the Technical Setup screen.

Hour Meter
Touch the area just below the Date/Time to display the total working hours of the ventilator.

SETUP & CALIBRATION – GRAPHICAL USER INTERFACE

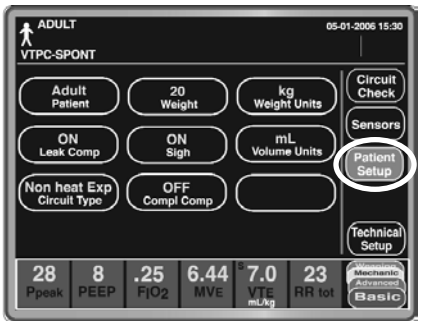


Circuit Check Screen

Pressing the *Setup & Calibration* menu button on the Control Panel reveals GUI menu buttons: *Circuit Check, Sensors, Patient Setup* and *Technical Setup*.

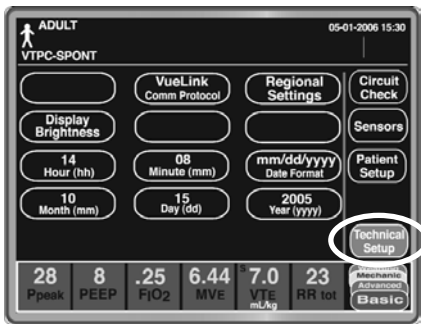
Circuit Check: Allows the user to perform a test that does background safety checks of the ventilator, checks the breathing circuit for leaks and does compliance and resistance tests of the breathing circuit. (Only available in Standby Condition.)

Sensors: Allows the user to calibrate the O_2 and Exhalation Flow sensor.



Patient Setup Screen

Patient Setup: Touch here to access the Patient Category, Weight, Units of Measure, Start Sigh, Circuit Type selection, Leak Compensation and Compliance Compensation settings.



Technical Setup Screen

Technical Setup: Settings for Communication Protocol, Display Brightness, Date/Time/Format and Regional (Altitude, Language, Pressure Units) are accessed from here.

For more details regarding the setup options see Section 4/Ventilator Operation.

3. VENTILATOR ASSEMBLY

This section describes how to:

- Assemble and set up the e360 ventilator
- Attach the humidifier and patient breathing circuit

Read and understand all of the information in this section before using the e360 Ventilator. For cart assembly, please refer to instructions provided with the cart.

WARNING The ventilator is ready for operation only when it is completely assembled and has successfully completed the Safety Check Procedure in Section 10.

UNPACK THE VENTILATOR

Take care when unpacking the e360 ventilator from its box and take note of any damage to the exterior of the box or to the ventilator itself. Ensure that all components are present before proceeding with the ventilator assembly. Fill out the Warranty Card and return it to Newport as soon as possible. You can also go online to submit the Warranty Card at www.NewportNMI.com.

The e360 ventilator includes:
Built-in heated reusable exhalation valve
Exhalation Flow Sensor – one installed and one spare
Power Cord (choice of North American standard or European style)
Operating Manual
Accessory Package
- Choice of North American standard or European style air and O_2 hoses
- Extension arm with circuit hanger and rail mount holder
- Disposable bacteria filters (2)

MOUNT e360 TO THE CART (IF USED)

The e360 cart, CRT360A, provides a stable, convenient stand for mounting the e360 ventilator. The CRT360A five wheel base includes 2 locking brakes and the durable front handle provides added protection for the patient connection area. Follow assembly instructions provided with the cart.

Figure 3-1. e360 mounted onto CRT360A

CHECK THE EXHALATION VALVE AND FLOW SENSOR

The e360 ventilator is shipped with the exhalation valve and exhalation flow sensor installed. If a replacement valve or sensor needs to be installed follow these directions. See Section 7, Cleaning and Maintenance, for further instructions.

Open the Front Door Panel on the lower left side of the ventilator to install the Exhalation Valve and the Flow Sensor. Locate the Exhalation Valve and fit the Flow Sensor into the side outlet. Connect the Flow Sensor Cable to the electrical connector in the back of the recessed panel area. Slide the Exhalation Valve into its receptacle and lock it into place with the releasable Retaining Latch.

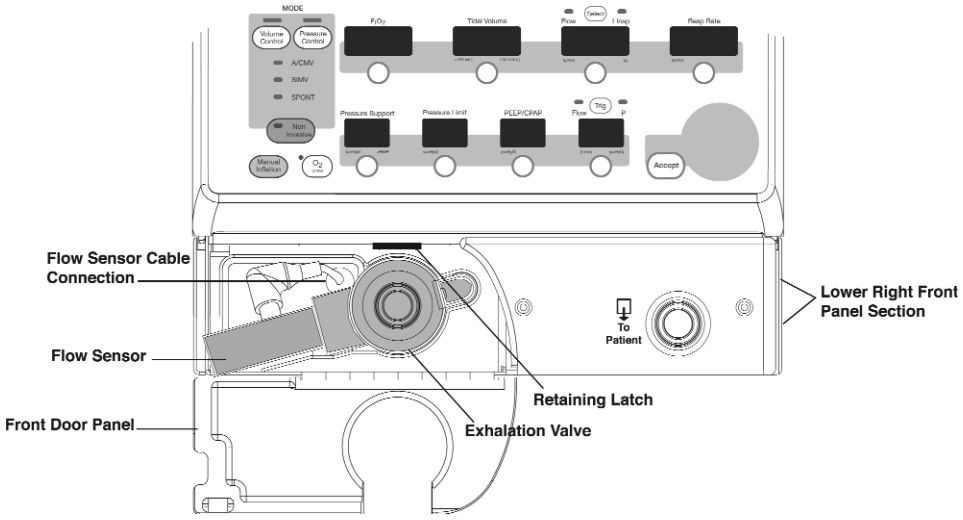


Figure 3-2. Connect Exhalation Valve and Flow Sensor

CONNECT AIR AND OXYGEN CONNECTORS TO THE VENTILATOR

Figure 3-3 shows the location of high-pressure air and oxygen DISS fittings on the rear of the e360 Ventilator. Connect the proper hoses to these fittings.

CONNECT TO AC POWER

Figure 3-3 shows the location of the AC power connection.

NOTE: The power cord for the e360 Ventilator must be hospital grade, i.e. the ventilator connection must be an IEC 320 C-13 hospital grade plug. The wall outlet connection must meet country-specific voltage standards.

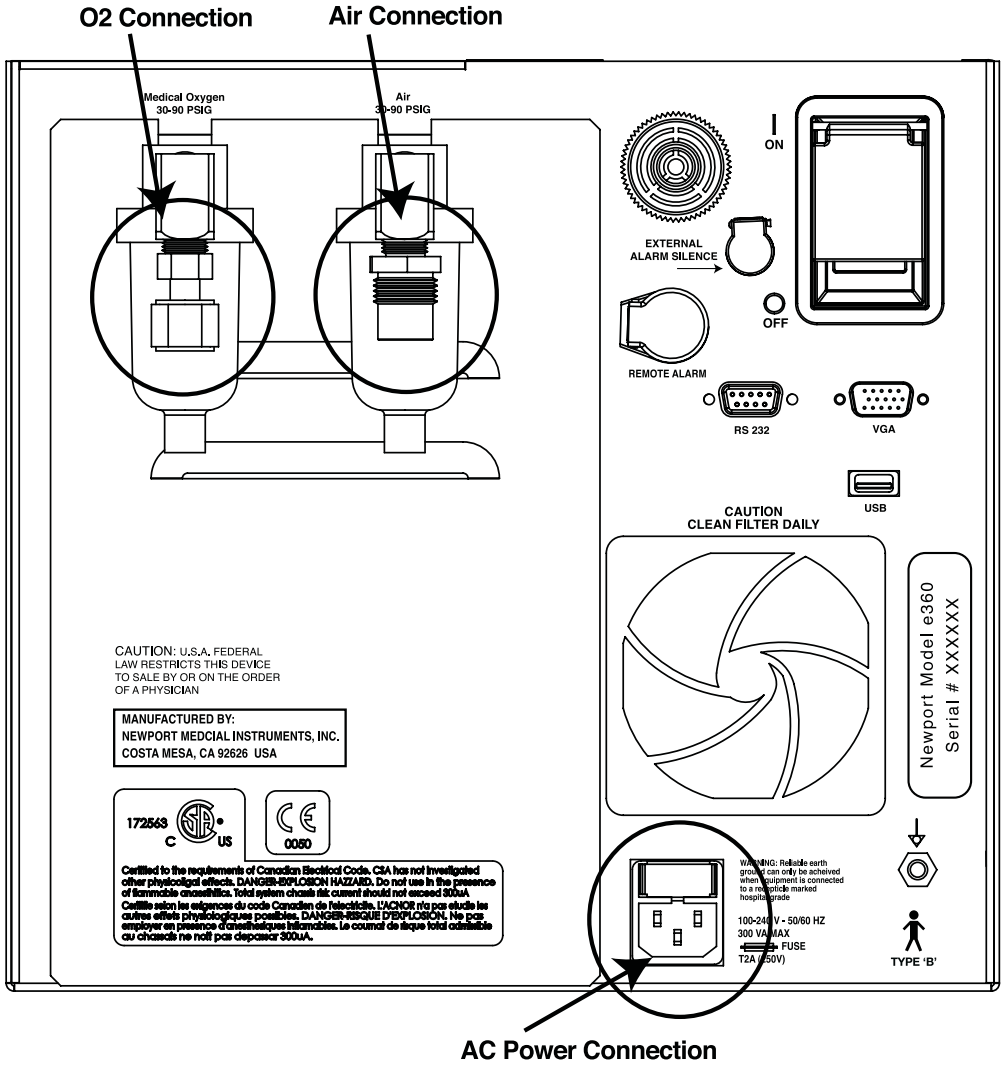


Figure 3-3. Connect Air, Oxygen & AC Power

SUPPORT ARM INSTALLATION

Figure 3-4 shows the location of the Support Arm Rail Bracket (part # EAB1001A) that can be attached to either side rail of the ventilator. The support arm threads into the top of the rail bracket.

Figure 3-4. Install Support Arm

ASSEMBLE THE PATIENT BREATHING CIRCUIT

It is important to read the following WARNINGS and CAUTIONS before assembling the components of the breathing circuit.

WARNINGS

- Do not use electrically conductive breathing circuits. Always use clean, sterile breathing circuits.
- Use water traps in appropriate locations in the breathing circuit to prevent water from draining into the patient airway or into the ventilator. Empty and clean as necessary.
- To protect ventilator components and avoid the possibility of increased expiratory resistance, use and change regularly the bacteria filters in the breathing circuit.

WARNING: The flow resistance of filters generally increases with use. Change all filters, especially those in the expiratory limb of the breathing circuit, regularly. Newport recommends changing the filter in the expiratory limb of the breathing circuit more frequently with the administration of nebulized medications inline with the breathing circuit.

Caution: Periodically inspect the air and oxygen inlet water traps and drain water from the bowls as necessary by pressing the pin at the bottom of the bowl.

The e360 can be used with a reusable or disposable two limb breathing circuit. No proximal line is required. Install bacteria filters, water traps and/or heated wires as required into the breathing circuit.

Figure 3-5 shows patient breathing circuit configuration with test lung on the e360 Ventilator. Figure 3-6 shows a breathing circuit configuration using a Fisher & Paykel-style humidifier with a heated inspiratory limb and an exhalation water trap. Figure 3-7 shows breathing circuit configuration with humidifier and heated inspiratory and expiratory limb.

NOTE: Newport recommends the use of a bacteria filter on both the inspiratory and expiratory ports of the e360.

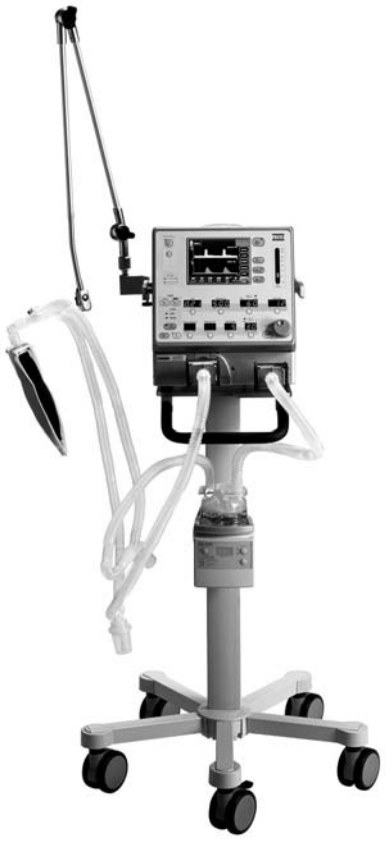


Figure 3-5. e360 Ventilator with Disposable Patient Breathing Circuit and Test lung

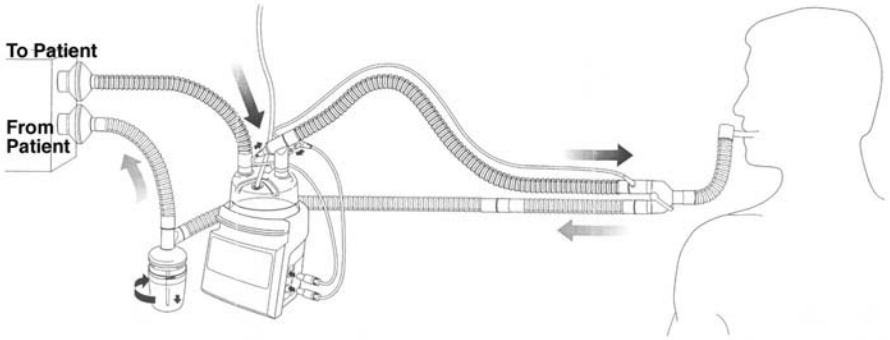


Figure 3-6. Humidifier and Water Trap Configuration (non-heated exp. limb)

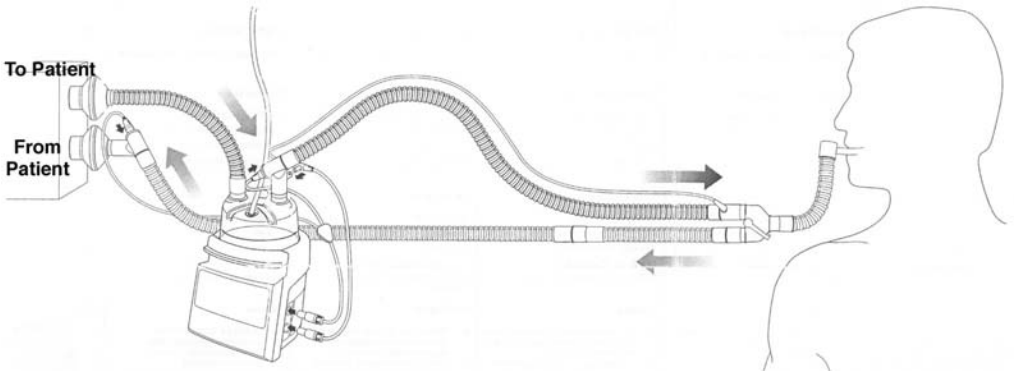


Figure 3-7. Humidifier and Heated Expiratory Limb Configuration (heated exp. limb)

4. e360 VENTILATOR OPERATION

This section provides instruction in understanding how to operate the ventilator and prepare to start ventilation. Before using the e360 Ventilator on patients, please read and understand all of the information in this manual.

WARNING The ventilator is ready for operation only when it is completely assembled and has successfully completed the Safety Check Procedure.

OPERATING PRINCIPLES

The e360 Ventilator is a high performance ventilator that is easy to use and maintain. The e360 features a dual servo gas delivery system (one each for air and oxygen), a servo controlled active exhalation valve, a simple to use interface and a touch screen graphics monitor. 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 changes in the delivered F_IO_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 has remote alarm (nurse call) and external alarm silence connections plus an RS232 interface to connect to central monitoring systems, VGA port to connect to an external monitor and USB port for uploading software or downloading to an external device.

When the e360 is turned on, the power on self-test (*POST*) verifies the integrity of the software and hardware of the ventilator. 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 ensures that there are no leaks in the breathing circuit system and measures circuit compliance and resistance. User initiated sensor calibration tests allow for calibration of the Oxygen 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 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 alarms limits for O_2 monitoring, Low Baseline Pressure, High Baseline Pressure, Sustained High Baseline Pressure, Gas Supply Failure, Device Alert and Power Switchover.

The ventilator monitors and displays the power source, exhaled 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).

During exhalation, the e360 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.

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/O_2 Supply Loss* alarm or *Sustained High Baseline Pressure* alarm).

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.

TURNING THE VENTILATOR ON

Power Switch

Follow these steps to power up the ventilator:

1. Plug the power cord into a hospital-grade AC electrical outlet.
2. Connect the air and oxygen hoses to the gas supplies.
3. Turn the power switch (on the back of the ventilator) to the **On** position.

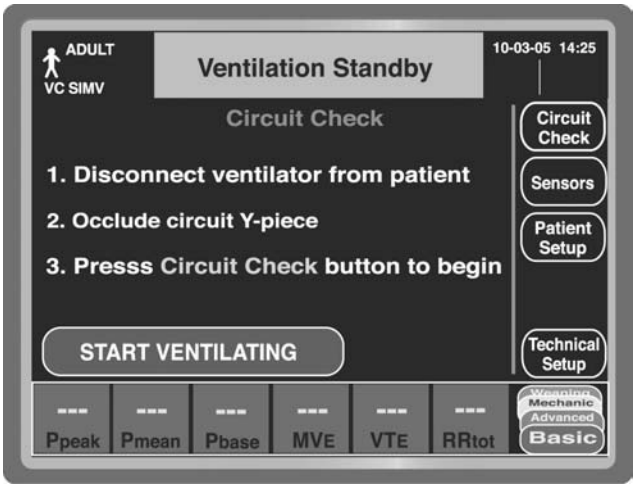
Follow these steps to power down the ventilator:

1. Set the power switch (on the back of the ventilator) to the **Off** position.
2. Press the *Alarm Silence* button to silence the Shut Down audible alarm.
3. Disconnect the air and oxygen hoses from the gas supplies.
4. When possible, leave the power cord plugged into the electrical outlet to maintain the internal battery charge level.

NOTE: When powered on, the e360 uses the previous ventilation parameters set prior to power off. (With the exception of NIV & Patient Weight which are not retained).

Standby Condition

When the ventilator is powered On, it remains in a *Standby* condition and does not start ventilating until the *Start Ventilating* button is touched on the Graphical User Interface (GUI). In *Standby*, ventilator control and alarm settings can be adjusted prior to patient connection. The *Start Ventilating* button is displayed on the GUI screen while in *Standby* condition. During *Standby*, a bias flow of 3 L/min maintains temperature stability and allows for an Oxygen Sensor Calibration.



The *Setup and Calibration* menu is the default screen when the ventilator is powered On so that the Circuit Check and Sensor Calibrations can be accessed easily.

WARNING: Always press the *"Start Ventilating"* touch button on the GUI just prior to connecting the breathing circuit to the patient. Never connect the patient breathing circuit to the patient while the ventilator is in Standby condition.

SET UP AND CALIBRATION

Setup and Calibration is the default screen at start up and can also be accessed by pressing the *Setup and Calibration* menu button on the Control Panel. There are four main selections available from the Setup and Calibration menu, located on the right side of the GUI:

- Circuit Check
- Sensors
- Patient Setup
- Technical Setup

From this menu the breathing circuit assembly can be checked for leaks, compliance and resistance, the sensors can be calibrated, and changes can be made to the Patient Setup and Technical areas. *The Circuit Check* is only available while in Standby Condition.

The following diagram shows a map of the functions and features that are available with each menu button:

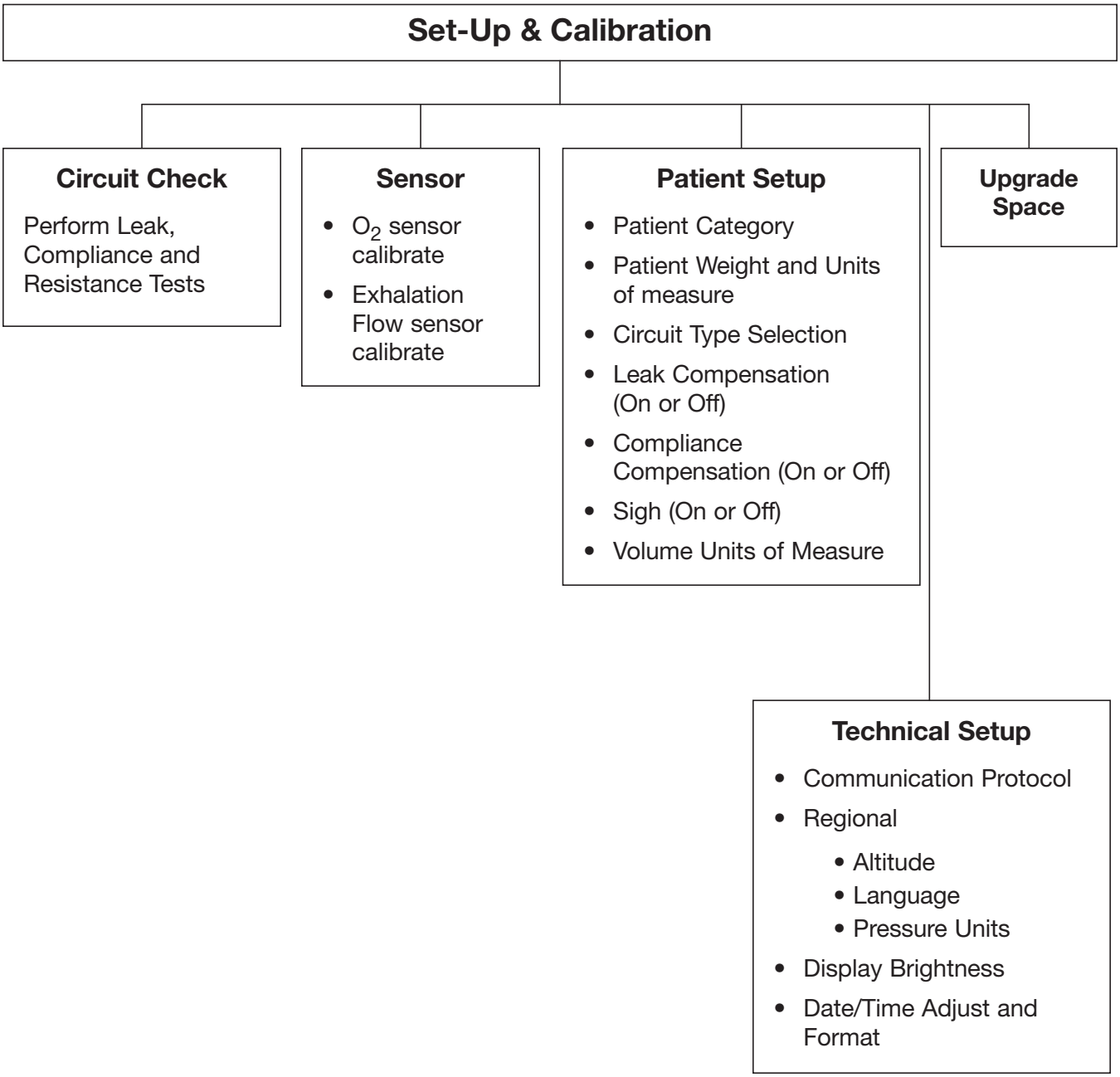


Figure 4-1. GUI Navigation Map for Setup & Calibration

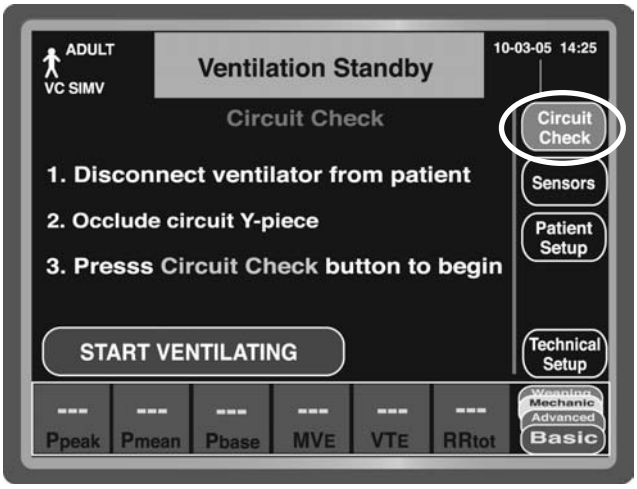
NOTE: Ventilator settings are automatically retained when the ventilator is powered down, with the exception of Non Invasive and Patent Weight. Setting changes made less than 10 seconds before power down are not retained.

Circuit Check

The *Circuit Check* tests the breathing circuit for leaks, compliance and resistance, tests the exhalation valve for leaks and does a Flow Sensor calibration. Perform the Circuit Check each time a new breathing circuit or circuit component is installed and also any time breathing circuit/filter integrity is suspect.

NOTE: The *Circuit Check* is only available in *Standby* condition (only at power on). Do not use a test lung to block the patient wye for the circuit check test.

WARNING Never connect the ventilator to the patient while in Standby condition.



Touch the *Circuit Check* button and, follow the on-screen instructions. The test is performed in one or two parts, depending on circuit size. If the test fails, confirm the integrity of all breathing circuit components and connections including all the connectors, tubings, filters and humidifier chamber, then repeat the test.

Do not use a test lung to occlude the circuit for the first part of the test. For the second part of the test, remove everything distal to the circuit wye connector. The second part of the test may not need to be performed if the ventilator reads appropriate resistance levels.

When the Circuit Check is completed successfully the screen will show “Passed” and Compl Comp, Insp and Exp Resistance values will be displayed.

Sensors

Touching the *Sensors* button opens a submenu that allows you to calibrate the Oxygen (O_2) and Exhalation Flow sensors.

• O_2 (Oxygen) Sensor Calibration

Perform an O_2 Sensor Calibration before each patient use and regularly while ventilating, according to hospital policy. The test takes 60 – 90 seconds and can be done in *Standby* condition or during ventilation.

Press the *O_2 Sensor* button to initiate the automatic calibration. The Message display will indicate if the sensor passed or failed the calibration. If the calibration fails or shows an error message, the sensor may need to be replaced. See Section 7, Cleaning and Maintenance, for instructions.

NOTE: The O_2 Sensor calibration is also initiated each time the O_2 3 min button is pressed while ventilating.

• Flow Sensor Calibration

Perform an Exhalation Flow Sensor Calibration prior to each patient use, each time you change the sensor and anytime there are suspected volume/monitoring inaccuracies. The calibration can be performed in *Standby* condition or during ventilation.

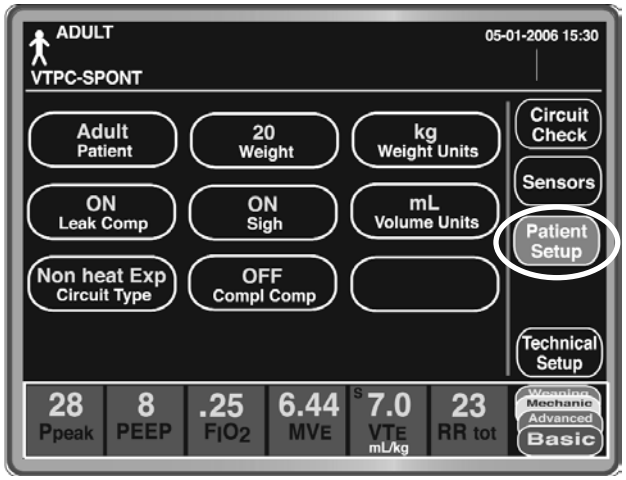
Press the *Flow Sensor* button to initiate the automatic calibration. The Message display will indicate if the sensor passed or failed the calibration. If the calibration fails or shows an error message, the sensor may need to be replaced. See Section 7, Cleaning and Maintenance, for instructions.

NOTE: Always use a bacteria/viral filter on the expiratory port to protect the exhalation pathway from airborne or liquid contaminants. See Section 7, Cleaning and Maintenance for more information.

Patient Set up

The *Patient Setup* screen allows you to: select *Patient Category*, *Patient Weight* in lbs or kg, monitored *Units of Measure*, *Sigh* On/Off, *Circuit Type*, *Leak Compensation* On/Off and *Compliance Compensation* On/Off (for *Volume Control* breaths only).

NOTE: Adjusting the settings and features in *Patient Setup* works the same as adjusting ventilator controls and alarms; Touch-Turn-Accept. Multiple adjustments can be made on the *Patient Setup* screen before touching *Accept* (as long as they are done within 10 seconds of each other).



• Patient Category

This selection allows you to choose between Adult and Ped/Infant patient category. It is important to ensure that the proper patient category is selected prior to starting ventilation.

NOTE: Always select Ped/Infant category when using a pediatric 15 mm ID or infant 12 mm ID breathing circuit.

• Weight Units of Measure

Select either Lb or kg. for the unit of measure for weight.

• Patient Weight

Enter the patient weight value, between 1 – 999 kg/2-2202 lb. The patient weight must be entered before you can choose to display exhaled volume measurements in mL/lb or mL/kg.

• Volume Units

You must enter a patient weight before making this selection. If you have not yet entered patient weight, the unit of measure for volume is mL and is not selectable.

NOTE: Selecting the volume unit affects the numeric data display for VTE only, and does not change the volume units for waveforms, loops, or trends.

• Sigh

Allows the user to turn the *Sigh* feature On or Off. When turned On, the ventilator will give a sigh breath every 100 breaths at 1.5 times the set Tidal Volume for Volume Controlled breaths only.

• Circuit Type

Select from the following three choices:

1. Heated Exp Limb = heated humidifier with dual heated wire breathing circuit.
2. Non Heated Exp Limb* = heated humidifier with no heated wire on the expiratory limb of a breathing circuit.
3. HME* = unheated circuit with heat moisture exchanger.

*Monitored expiratory volumes are adjusted appropriately for Body Temperature Pressure Saturated (BTPS).

NOTE: Circuit Type selection affects the monitored values for expiratory tidal volume and expiratory minute volume. Selecting the *Circuit Type* that matches the humidifier and circuit that is set up on the ventilator will ensure accuracy of monitored expiratory volumes.

• Leak Comp (Leak Compensation) On / Off

The Leak Compensation function allows the user to select whether or not they want the e360 to provide compensation for leaks over and above the 3 L/min bias flow that the ventilator always provides. *Leak Compensation* is factory preset to On. When *Leak Comp* is turned On, the e360 adjusts the bias flow between 3 and 8 L/min for Ped/Infant selection and 3 and 15 L/min for Adult, in order to maintain an end expiratory base flow of 3 L/min.

NOTE: Factory setting is On.

• Compl Comp (Compliance Compensation) On / Off

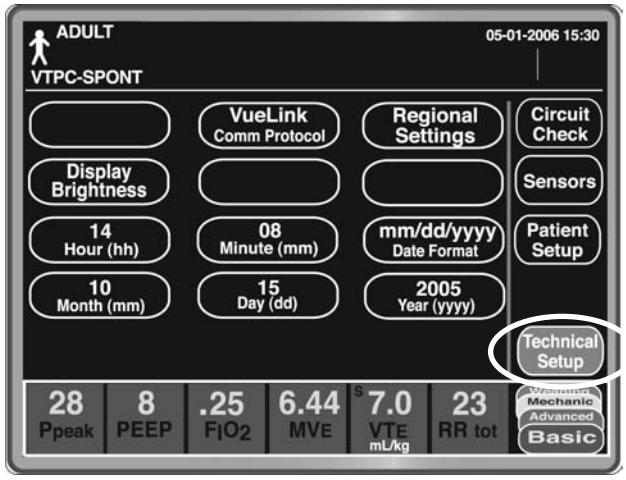
When turned On, the ventilator will compensate for delivered volume loss due to breathing circuit compressibility during every *volume controlled* mandatory breath. The most recently measured circuit compliance (obtained by performing a *Circuit Check*) will be used for the compliance compensation. Compliance compensation may be set to On or Off at any time from the Patient Setup screen. The compliance compensation value is displayed in mL/cmH_2O or ML/mbar.

NOTE: The *Compl Comp* factor is measured during the Circuit Check. When you perform Circuit Check make certain that the humidifier (including water) and breathing circuit are set up exactly as they will be used on the patient in order to ensure that the volume delivery/monitoring adjustment is accurate.

NOTE: Factory setting is On but stored compliance value is 0.

Technical Setup

Technical Setup allows the user to set ventilator specific technical settings that are appropriate for your hospital or patient.



NOTE: Most setting changes are accomplished the same way other controls are changed; *Touch-Turn-Accept*. To exit screens touch the Data Sets button on the lower right hand corner of the screen or press a Control Panel menu button.

The following submenus can be accessed from Technical Setup:

- Communication Protocol for the RS232 port (e.g. Newport, VueLink)
- Regional Settings
  - Altitude
  - Language
  - Pressure Units
- Display Brightness
- Date/Time adjustment and format

• Communication Protocol

The communication protocol refers to the protocol output by the 9-pin RS232 data connection port on the rear of the ventilator. Select the RS232 communication protocol that corresponds with the monitoring system that is connected to the e360 Ventilator.

NOTE: Contact Newport Technical Service for more details regarding the Communication Port Protocol.

• Display Brightness

The *Display Brightness* button allows adjustment of the display brightness by using *Touch-Turn-Accept* to raise or lower the light level.

• *Regional Settings*

– Altitude

The Altitude button allows adjustment of ambient altitude setting in 200-meter increments so that it corresponds with your local ambient altitude. It may be set, up to a maximum of 4,000 meters (13,124 feet). The screen shows the altitude in meters and in feet.

– Language

This menu allows you to select the language for all GUI screen text:

Selections may include:

English	Spanish	French	German
Italian	Chinese	Japanese	Portuguese
Polish			

– Pressure Units

Select from cmH2O/mbar or mbar for the units of measure for all pressure related settings and monitored values. The selection is applied to the pressure units in data, waveforms, loops, and trends.

• Date and Time Format

The *Date Format* button allows the user to select the date format: month–day–year, day-month-year or year-month-day.

- **Date and Time**

Use the Adjustment Knob on the Control Panel to set the Month, Day, Year and Time.

PREPARING TO START VENTILATION

Standby Condition

When the e360 is powered On, it is in *Standby* Condition and the *Setup and Calibration* screen is displayed.

The Standby Condition (not ventilating) allows a user to adjust all ventilation and alarm settings and prepare to connect to a patient.

Touch the *Start Ventilating* button to exit the Standby Condition and begin ventilation immediately using the current ventilation and alarm settings.

Patient Category

Select the *Patient Category* on the *Patient Setup* screen using the *Touch-Turn-Accept* method.

Available Patient Categories are *Ped/Infant* or *Adult*.

NOTE: Category selection determines the limits for ventilator settings and alarms.

NOTE: If any alarm or ventilator setting is out of range, after changing the Patient Category, the *Alarms and Messages* display shows *"[setting] out of range"* and the LED display for the parameter(s) that are out of range flashes. After 10 seconds, an audible alarm sounds.

Adjusting Ventilator Settings on the Control Panel

Except for those settings that are not retained (Non Invasive and Patient Weight), the e360 powers up using the last selected ventilator settings. Follow these steps to adjust the ventilation controls on the e360 Control Panel:

- Press the button on the Control Panel that corresponds to the parameter you want to adjust, i.e. *F_IO_2, Resp Rate, PEEP/CPAP*, etc. The numbers in the display will flash repeatedly to acknowledge your selection.
- Adjust the parameter by rotating the *Adjustment Knob* to the desired setting.
- Press the *Accept* button to invoke the setting change.

NOTE: Most ventilator settings can be adjusted by the *Touch-Turn-Accept* method. If a setting is changed using the *Adjustment Knob* and then 10 seconds elapse before pressing the *Accept* button, the new setting will not take effect and the display will revert back to the original setting.

Selecting Breath Type / Mode

To change the Breath Type, press the button for the breath type desired, *Volume Control or Pressure Control*. Press the *Accept* button to confirm the new setting.

NOTE: On the e360 Plus model, *Volume Target* breath type can be selected On for Pressure Control and Pressure Support breaths from the *Advanced* Data Set on the GUI.

To change the Mode, press the selected breath type repeatedly until the flashing indicator for the mode desired, (*A/CMV, SIMV*, or *SPONT*) lights. Press the *Accept* button to confirm the new setting.

Displays for ventilation and alarm control settings that are not available for the new mode are dimmed.

NOTE: Even though they are not currently in use, ventilator controls with dimmed displays can be adjusted with the *Touch-Turn-Accept* method to ensure that the value is at a safe level when changing modes/breath types.

Choosing Ventilation Parameters

Trigger Selection

Follow these steps to select the type and level of *Trig* (trigger sensitivity):

Press the *Trig* select button at the top of the *Trig* display to highlight the trigger type you want to select: *Flow* or *P* (pressure). Press the button under the display and use the *Touch-Turn-Accept* method to adjust the trigger setting.

A lower trigger level/number is more sensitive, a higher number is less sensitive. Adjust the Flow or Pressure trigger so that the patient can trigger easily without auto-triggering.

NOTE: Flow trigger is compensated for the flow from Leak Compensation.

Flow and Inspiratory Time Selection (Volume Control Breath Type Only)

When ventilating in Volume Control, you can choose to set either Peak *Flow* or Inspiratory Time (*t Insp*) for mandatory breaths. Press the *Select* button at the top of the display to choose *Flow* or *t Insp*. Press the button under the display and use the *Touch-Turn-Accept* method to adjust the setting.

NOTE: When *Flow* is selected, *t Insp* will vary for the breath depending on the Peak Flow setting, *Tidal Volume* setting and *Flow Wave* choice. If *t Insp* is selected, Peak *Flow* will vary depending on the *t Insp* setting, *Tidal Volume* setting and *Flow Wave* setting. When *Pressure Control* is selected, only *t Insp* can be adjusted.

Non Invasive Ventilation (NIV)

The e360 Ventilator can be used for invasive (intubated patient) or noninvasive (mask) ventilation. When the "*Non Invasive*" button is activated on the front panel, e360 tailors the ventilator's performance (described below) to meet the needs of a patient who is breathing from a mask rather than an invasive artificial airway. *Non Invasive* can be used with any mode of ventilation. It is factory preset to OFF. Non Invasive setting is not returned after power down, the e360 powers up with NIV off. See Section 9/Explanation of Modes for more details.

- **Leak Compensation (Baseline pressure management) in Non Invasive**

The *Non Invasive* function automatically provides leak compensation/baseline pressure management with a bias flow range of 3 to 25 L/min in order to accommodate the potential for bigger airway leaks around the (non-vented) mask. (When *Non Invasive* is OFF and *Leak Comp* is ON bias flow is only 3-8 L/min Ped/Infant and 3-15 L/min Adult.)

- **Alarms in Non Invasive**

The Low MV_E alarm, can be set to OFF while *Non Invasive* is activated. If the Low MV_E alarm is OFF when *Non Invasive* is

deactivated, the alarm is automatically turned back on and set to the lowest value in the range.

The Disconnect Threshold alarm can be set to Off while Non Invasive is activated. If it is set Off when Non Invasive is deactivated, the alarm is automatically turned back On and set to the highest value in the range.

NOTE: To minimize the chances of auto-triggering due to leaks, Newport recommends using Pressure trigger (start at 2 cmH_2O/mbar for *Adult* and 1 cmH_2O/mbar for *Ped*/*Infant* and then titrate for patient comfort) when using the e360 for non-invasive mask ventilation. Use a non-vented mask to ensure proper patient-ventilator synchrony.

Adjusting Ventilator Settings on the Graphical User Interface (GUI)

Adjust most ventilator settings on the GUI by the *Touch-Turn-Accept* method. If 10 seconds elapse before pressing the *Accept* button, the new setting will not take effect and will revert back to the original setting. Control Panel settings that are not available for a selected breath type/mode are dimmed.

Advanced Data Set

Advanced ventilation features such as *Slope*/*Rise*, *Expiratory Threshold*, *Pause*, and *Flow Wave* are adjustable from the *Advanced* Data Set located at the bottom of the GUI display screen. Use the *Touch-Turn-Accept* method to adjust the setting.

- **Slope/Rise** is adjustable from 1 – 19 (19 being the fastest)
- **Exp Thresh** is adjustable from 5 – 55%
- **Pause** is adjustable from 0.1 to 2.0 seconds or Off
- **Flow Wave** selections include square or descending ramp for Volume Controlled breaths.

On the e360 Plus model these selections are also available:

- **Open Exhalation Valve** can be turned On (for active exhalation valve control during mandatory Pressure Controlled breaths only) or Off.
- **Automatic** setting option available for Slope/Rise and Expiratory Threshold.
- **Volume Target** can be selected On or Off for Pressure Control and Pressure Support breaths.

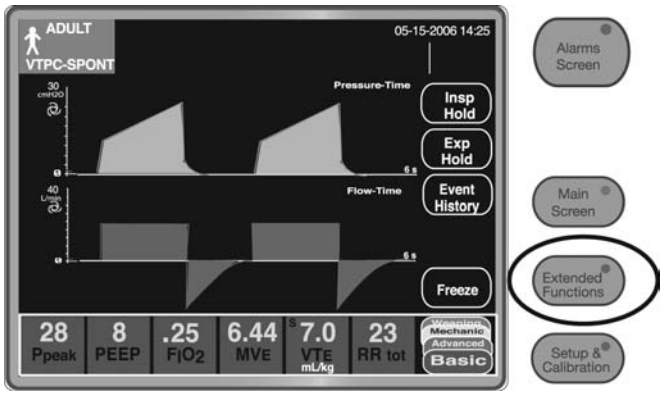
NOTE: A square wave flow pattern delivers a constant flow (the *Flow* setting) throughout a mandatory inspiration, which

terminates when the set *Tidal Volume* has been delivered. For a descending ramp flow pattern, inspiration begins at the *Flow* setting, decreases at a constant rate to 50% of the *Flow* setting, then terminates when the set *Tidal Volume* has been delivered.

For more information on these features see Section 9, Explanation of Modes and Special Functions.

Extended Functions

Press the *Extended Functions* button on the Control Panel to access the following functions on the GUI: *Insp Hold*, *Exp Hold*, *Event History* and *Freeze*.



- **Inspiratory Hold and Expiratory Hold**

To initiate an “end-inspiratory” or “end-expiratory” hold, follow these instructions:

1. Touch and hold the *Insp* or *Exp Hold* button from the *Extended Functions* menu on the right of the display.
2. When the timing is right, the e360 will perform the hold and measure the static pressure. The maneuver may be terminated at any time by releasing your finger from the button.
3. The Mechanic data set will show Plateau Pressure, Total PEEP, Static Compliance, Inspiratory and Expiratory Resistance. If the maneuver does not succeed in providing a stable static pressure (patient effort is present) a message will appear on the screen.

- **Event History**

Press the *Event History* button to access the Event History Log. This log records the 1000 most recent occurrences of alarm violations and settings, ventilator setting changes and power On/Off sequences with the date and time of each event.

Recorded events are color-coded. Alarm violations are in red, setting changes are in blue and Power On/Off is in green. Event History is retained after shutdown.

- **Freeze**

The *Freeze* function suspends plotting of graphs (waveforms, loops, or trends) and holds the current display for extended viewing. Incoming data is background-processed while *Freeze* is on. Plotting resumes with the most recent data when *Freeze* is deactivated by touching the *Start* button.

Touch the *Freeze*/ *Start* button to toggle the Freeze function On or Off. The button is labeled *Freeze* when Freeze is off, and Start when Freeze is on. Freeze is also available from the *Main Screen* menu.

Using Other Ventilation Controls

Manual Inflation

Manual Inflation delivers a manual inspiration while you press the button (located on the lower left corner of the Control Panel). The inflation is limited to five seconds or until a high *Paw* alarm violation occurs, whichever occurs first.

In *Volume Control A/CMV* and *SIMV*, the *Manual Inflation* delivers the set *Flow* (or calculated flow from the set *t Insp*).

In *Pressure Control A/CMV* and *SIMV*, the *Manual Inflation* delivers the set Pressure Limit setting.

In *SPONT* mode of either breath type, *Manual Inflation* delivers pressure at *PEEP/CPAP* + 15 cmH_2O/mbar.

O_2 (3 min) Button

O_2 (3 min) delivers 100% oxygen for three minutes, regardless of the current *F_IO_2* setting. The indicator on the *O_2 (3 min)* button lights when 100% oxygen is delivered. Pressing the button again cancels 100% oxygen delivery. The F_IO_2 high alarm is disabled during and for three minutes following the completion of 100% oxygen delivery. The ventilator also initiates the O_2 Sensor Calibration whenever the *O_2 3 min* button is pressed.

Accept Button

The *Accept* button is next to the Adjustment Knob and confirms adjusted ventilator settings when pressed.

Alarm Reset

The *Reset* button turns off all latched alarm indicators (alarms that are no longer violated) and removes the corresponding alarm message from the *Alarms & Messages* Bar.

Alarm Silence

The *Alarm Silence* button mutes silenceable audible alarms for 120 seconds and cancels the shutdown alarm that occurs when the ventilator is powered off. The indicator on the *Alarm Silence* button lights while the alarm silence is active. To cancel an active alarm silence, press *Alarm Silence* again. Pressing *Alarm Silence* does not silence a *Device Alert* alarm unless the ventilator is powered down first.

NOTE: The optional External Alarm Silence Cable provides the same function as the *Alarm Silence* button except that it does not silence a power-down alarm.

Suction Disconnect Function

Pressing down and holding the *Alarm Silence* button for one second or longer (until the ventilator sounds a short tone) silences the silenceable audible alarms for 120 seconds and enables the *Suction Disconnect* function. If the ventilator detects a circuit disconnect within 20 seconds of enabling the *Suction Disconnect* function, the ventilator displays the message "*Ventilation Suspended*", disables automatic leak compensation and delivers a bias flow of 10 L/min for *Adult* or 5 L/min for *Ped /Infant* patient type. It does not deliver breaths until the breathing circuit is reconnected or three minutes elapse. When the ventilator detects reconnection or three minutes have elapsed, the ventilator resumes normal operation.

NOTE: Both the Low Minute Volume Alarm and Back up Ventilation are suspended for 60 seconds after you reconnect the breathing circuit following *Suction Disconnect* function.

Alarms Management

See Alarms, Section 6 for complete details regarding e360 alarms. During conventional ventilation, the e360 Ventilator provides user-adjustable alarm limits for high and low minute volume (MVE), high and low airway pressure (Paw), high respiratory rate (RR tot), Disconnect threshold and Apnea.

While the Non-Invasive function is activated on the Control Panel, the Low Minute Volume alarm (*Low MVE*) can be set to off. When Non-Invasive function is deactivated the *Low MVE* alarm is automatically turned back on and set to the lowest value in the range.

The Disconnect Threshold alarm can be set to Off while Non Invasive is activated. If it is set Off when Non Invasive is deactivated, the alarm is automatically turned back On and set to the highest value in the range.

During an alarm limit violation:

- The 360º Alarm Lamp lights, Red for high or Yellow for medium and low level alerts.
- An audible alarm sounds.
- The *Alarms & Message* display shows an alarm message.

If the alarm limit is no longer violated:

- The audible alarm turns off.
- The visual indicator stops flashing and remains steadily lit (becomes latched) and the message remains in the *Alarms & Message* display until the operator presses the *Reset* button.

The operator can change alarm limits during an alarm limit violation. If the new alarm limit is not in violation, the audible alarm turns off. The visual indicator remains steadily lit and the message remains in the *Alarms & Message* display until the operator presses *Reset*.

To adjust alarm limits:

- Press the *Alarm Screen* button on the Control Panel.
- The Alarm Setting window appears which allows the user to set all adjustable alarms.
- Use the *Touch-Turn-Accept* method to change alarm limits. Multiple alarms can be changed before pressing the *Accept* button.
- The user can also choose to adjust *Alarm Loudness* or view *Event History* from this window.
- If Non Invasive function is activated *Low MVE* and Disconnect Threshold Alarm can be set to Off.
- Touch any menu button on the Control Panel to exit this screen.

NOTE: The ventilator sounds a tone if the user attempts to set alarm limits that are out of range.

Alarm Loudness

The *Alarm Loudness* is used to select the preferred alarm audio level for the ventilator environment. To adjust the alarm volume press the *Alarm Screen* menu button on the Control Panel and touch the *Alarm Loudness* touch button on the GUI screen. Use the *Adjustment Knob* to set the loudness level up or down (lower number is quieter and a higher number is louder). Press *Accept* to invoke the change.

360º Alarm Lamp

The 360º Alarm Lamp, located at the top center of the Control Panel, lights to indicate that an alarm has been violated. Yellow indicates a low or medium level alarm and Red indicates a high level alarm. See Alarms, Section 6 for more details.

Viewing Monitored Data

Pressure Bar Graph

The LED pressure bar graph on the Control Panel continuously displays patient airway pressure (Paw) that is monitored at the end of the breathing circuit.

NOTE: The e360 Ventilator adjusts monitored volumes based on Circuit Type selection (*Heated Exp Circuit*, *Non-Heated Exp Circuit* or *HME*) to account for the differences in temperature and humidity. *Circuit Type* can be changed on the Graphical User Interface: *Setup & Calibration*/*Patient Setup* screen.

Graphical User Interface (GUI)

All patient monitored data (other than the pressure bar graph) and the Advanced settings can be viewed on the GUI screens while ventilating. Groups or sets of monitored data and settings are displayed on the lower margin of the GUI in four different data sets: *Advanced*, *Weaning*, *Mechanic* and *Basic*. A full screen of numeric data is displayed when *Numerics* is selected from the *Main Screen* menu. Maneuver-based calculated values are displayed for 24 hours with a time-stamp (otherwise dashes are displayed). See Section 8, Specifications for monitored parameter specifications.

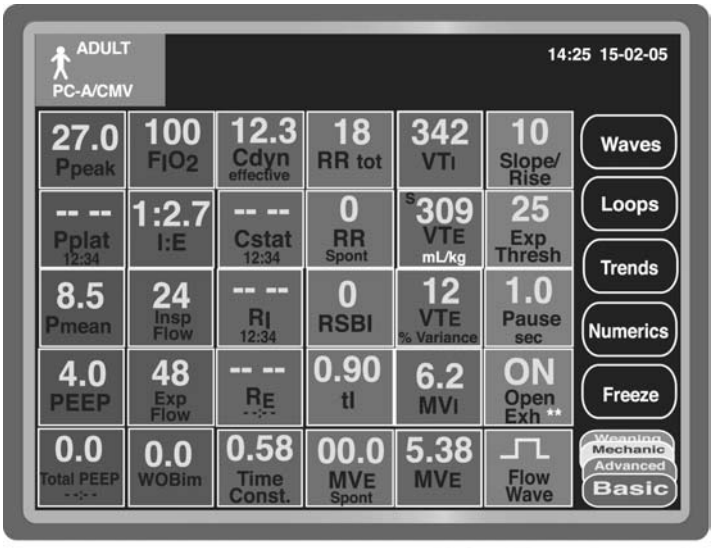
- **Data Sets**

To choose a different displayed data set, scroll through the four choices by touching the Data Sets button in the lower right corner of the GUI display.

Advanced	Slope/Rise	Exp Thresh	Pause sec	Flow Wave	Open Exhalation Valve (e360 Plus)	Volume Target (e360 Plus)
Weaning	RR Spont	VTE mL	MV_E Spont	t Insp	C_{DYN} effective	I:E
Mechanics	Time Const.	Pplat -- : --	Total PEEP --:--	Cstat --:--	R_I --:--	R_E --:--
Basic	Ppeak	PEEP	F_I0_2	MV_E	VTE mL	RR tot

- **NUMERICS**

To view all monitored, calculated and set numeric values on one screen, touch the *Numerics* button from the *Main Screen* menu.



** On e360 Plus Model only

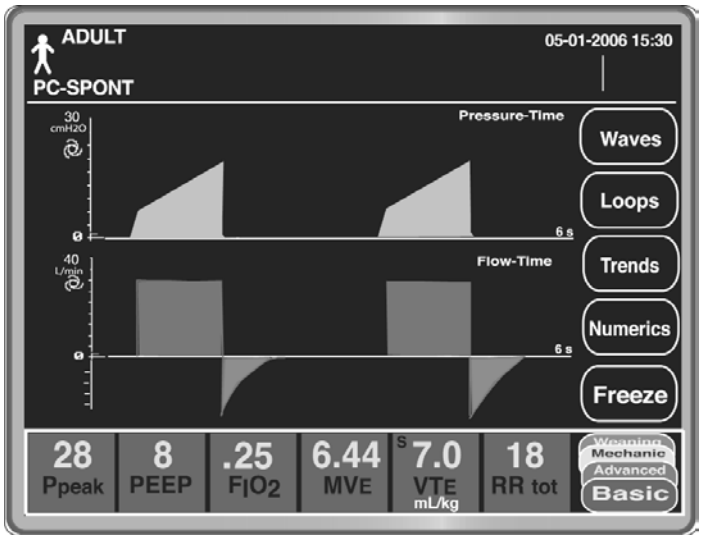
Using the Waves and Loops Display

Displaying Waveforms

From the *Main Screen* menu on the GUI, pressing the *Waves* button will allow the user to choose from several waveform combinations (Pressure, Flow or Volume over time) to be displayed with a touch of the button. When the waveform reaches

the right end of the time scale, it wraps from right to left and continues to plot, erasing a small section of the old graph as it goes. Changing the time scale causes the waveform to restart from the left.

NOTE: The *Accept* button is not needed to change the display from waveforms to loops, trends or numerics.



Displaying Loops

From the *Main Screen* menu on the GUI, pressing the *Loops* button will allow the display of either a Flow-Volume Loop, Volume –Pressure Loop or both with a touch of the button. While a Loop is displayed, it will clear before a new one is plotted. Spontaneous breath Loops are displayed in a separate color from mandatory breaths.

Trends

The e360 can display two trend screens, each displaying four trended parameters. Touch the *Trends* button from the *Main Screen* menu to allow the user to choose between the two trend screens displaying these parameters:

Screen 1	Screen 2
VTE / Time	Ppeak / Time
Minute Vol / Time	Pmean / Time
RRtot / Time	Pbase / Time
VTE % Variance / Time	RSBI / Time

Scale

To adjust scales: Touch the GUI screen at the X or Y axis of the desired scale to be adjusted. A blue indicator bar appears on the screen to identify the parameter selected for scale change. Use the Adjustment Knob to increase or decrease the scale and press the *Accept* button to confirm the change. While in *Waves* or *Loops*, pressure, volume and flow scales may be adjusted independently. The time scale applies to all displayed parameters.

Each turn of the Adjustment Knob steps to the next scale, with the Auto-scale option between the highest and lowest scales choice for parameters other than time.

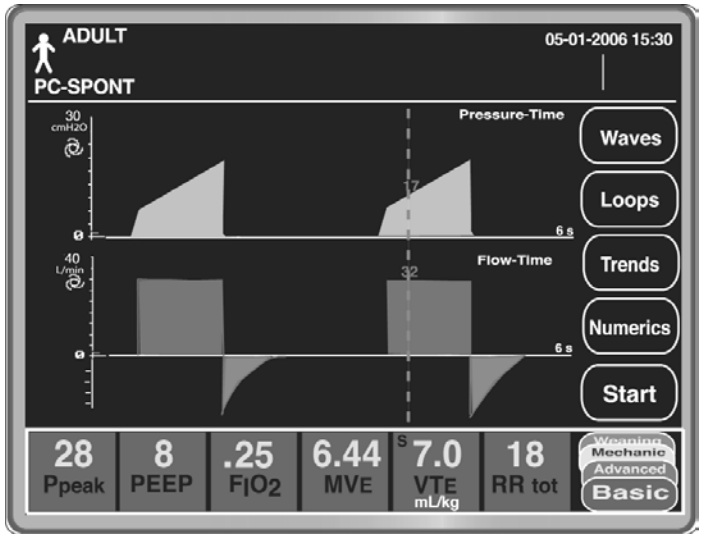
- **Auto-scale**

When Auto-scale is active, the automatic control icon appears on the automatically scaled vertical axis. Auto-scale automatically selects one of the four pre-defined manual scales that allows the best view (highest resolution) of the parameter. The selected scale range is based on the highest amplitude of the waveform for that parameter. Auto-scale switches to a higher scale range if the parameter value exceeds the current range, and switches to the lowest range that can accommodate an entire breath without exceeding the scale limit shown.

Freeze

The *Freeze* function suspends plotting of graphs (waveforms, loops, or trends) and holds the current display for extended viewing. Incoming data is background-processed while *Freeze* is on. Plotting resumes with the most recent data when *Freeze* is deactivated by touching *Start*.

Touch the *Freeze*/ *Start* button to toggle the Freeze function On or Off. The button is labeled *Freeze* when Freeze is off, and *Start* when Freeze is on.



- **Using the Cursor**

When *Freeze* is on, a green, vertical-dashed line (the cursor) appears at the center of the screen. The Adjustment Knob is used to reposition the cursor. The cursor allows user to obtain detailed numeric data for any point on a waveform, loop or trend.

Numerical values are displayed for each point on a waveform, loop or trend intersected by the cursor. Where the cursor intersects a time axis for a waveform or trend, the numerical value of the time axis is displayed once the cursor stops moving. Where the cursor intersects a loop, the values of the loop at the top and bottom intersect points are displayed.

5. STARTING VENTILATION

* Available on e360 Plus model

This section provides instruction in preparing to start patient ventilation. Before using the e360 Ventilator on patients, please read and understand all of the information in this manual.

WARNINGS

Before and during the use of the e360 Ventilator, make sure that all connections in the patient circuit are secure. Ensure the integrity of the ventilator itself.

Make sure the internal battery is fully charged to assure battery operation in case of AC failure.

Newport recommends that you perform the Circuit Check procedure in *Setup and Calibration* before connecting the ventilator to a patient.

Use a bacteria filter between the inspiratory (To Patient) port and the inspiratory limb of the breathing circuit to prevent contaminants in the patient exhaled gas from entering the inspiratory manifold when the emergency relief valve opens (as in the case of *Both Air/O_2 Supply Loss*, *Device Alert*, or *Sustained High Baseline Pressure* Alarm).

Use a bacteria filter between the ventilator expiratory port connector and the expiratory limb of the breathing circuit to prevent contaminants in the exhaled gas from entering the exhalation system.

Always use a secondary bacteria filter between the expiratory (from patient) bacteria filter and the expiratory limb of the breathing circuit any time nebulized medications are delivered through the breathing circuit. Failure to do so could lead to obstruction of the exhalation system and increased resistance to patient exhalation. Discard/change filter at the completion of nebulized drug delivery or more frequently as needed to minimize expiratory resistance. Follow filter manufacturer's instructions.

PREPARING FOR PATIENT VENTILATION

Follow these steps to begin ventilation:

1. Verify that the ventilator and the patient breathing circuit are assembled correctly.

2. Connect the air and oxygen hoses to the appropriate source gas supplies.

3. Plug the ventilator power cord into a properly grounded electrical outlet. Turn the ventilator ON.

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

4. Perform a *Circuit Check* (follow the on-screen instructions) to check for leaks, test the compliance and resistance of the circuit.

5. Calibrate the O_2 *Sensor* and Exhalation Flow *Sensor*.

6. Check and adjust all settings in *Patient Setup* (including *Patient Category*) before beginning ventilation.

7. Select the appropriate breath type/mode of ventilation, ventilation parameters plus appropriate *Advanced* settings such as *Slope*/*Rise* and *Exp Threshold*.

8. Select safe alarm limits.

9. Press the *Start Ventilating* button and connect breathing circuit to the patient to begin ventilation.

10. Observe the patient's condition and make sure the ventilation and alarm settings are appropriate.

WARNING: A patient who is connected to a ventilator requires the constant attention of medical staff to the patient's condition. Always use appropriate monitors to ensure sufficient oxygenation and ventilation (such as a pulse oximeter and capnograph) when the e360 Ventilator is in use on a patient.

WARNING Always ensure that ventilator settings that are not in use (their displays are dimmed) are set at appropriate, safe levels in case of accidental breath type or mode changes.

• Non Invasive Function

The Non Invasive Function is activated by pressing the *Non Invasive* button, located on the lower, left corner of the Control Panel. The LED is lit when it is activated. It is available for use with any breath type/mode and should be turned ON when using a (non-vented) mask or similar to ventilate a patient. See Section 9/Explanation of Modes for further description of this function.

VOLUME CONTROL BREATH TYPE

Depending on the selected mode, select ventilator settings in the order shown in Table 5-1.

NOTE: While adjusting *Flow*/Inspiratory Time (*t Insp*) or *Resp Rate*, the corresponding value for I:E Ratio is displayed in real time in the Graphical User Interface Weaning Data Set. Press the Data Set area in the lower right corner of the screen to select data for display.

Table 5-1. Volume Control Breath Settings Based on Mode

A/CMV

1. Set *Volume Control-A/CMV* on the control panel.
2. Set *Tidal Volume*.
3. Set *Flow* or *Inspiratory Time* (*t Insp*) (use the *Select* button to choose).
4. Set *Flow Wave* (square or descending ramp) pattern on the GUI.
5. Set *Respiratory Rate*.
6. Set F_IO_2.
7. Set *PEEP/CPAP*.
8. Set Trig to *Flow* or *P* (pressure), then adjust setting.
9. Set High and Low Minute Volume alarms on the GUI alarms setting screen.
10. Set High and Low Paw alarms.
11. Set High Resp Rate alarm.
12. Set Apnea alarm.
13. Set Disconnect Threshold alarm.
14. Optional: Set Non Invasive Ventilation (via button on the Control Panel)
15. Optional: Set these additional settings on the GUI screens:
    - *Pause*
    - *Sigh*

SIMV

1. Set *Volume Control-SIMV* on the control panel.
2. Set *Tidal Volume*.
3. Set *Flow* or *t Insp* (*Inspiratory Time*) (use the *Select* button to choose).
4. Set *Psupport* for spontaneous breaths.
5. Set *Flow Wave* (square or descending ramp) on the GUI.
6. Set *Respiratory Rate*.
7. Set F_IO_2.
8. Set *PEEP/CPAP*.

9. Set Trig to *Flow* or *P* (pressure), then adjust setting.
10. Set High and Low Minute Volume alarms (on GUI)
11. Set High and Low Paw alarms.
12. Set High Resp Rate alarm.
13. Set Apnea alarm.
14. Set Disconnect Threshold alarm.
15. Optional: Set Non Invasive Ventilation (via button on the Control Panel).
16. Optional: Set these additional settings on the GUI screens:
    - *Slope/Rise*
    - *Expiratory Threshold*
    - *Pause*
    - *Sigh*

SPONT

1. Set *SPONT* on the Control Panel.
2. Set *Pressure Support* (*if desired*)
3. Set F_IO_2.
4. Set *PEEP/CPAP*.
5. Set trig to *Flow* or *P* (pressure), then adjust setting.
6. Set High and Low Minute Volume alarms (on GUI)
7. Set High and Low Paw alarms.
8. Set High Resp Rate alarm.
9. Set Apnea alarm.
10. Set Disconnect Threshold alarm.
11. Optional: Set Non Invasive Ventilation (via button on the Control Panel).
12. Optional: Set these additional settings on the GUI screens:
    - *Slope/Rise*
    - *Expiratory Threshold*

PRESSURE CONTROL BREATH TYPE

Depending on the selected mode, adjust ventilator settings in the order shown in Table 5-2.

NOTE: While adjusting Inspiratory Time (*t Insp*) or *Resp Rate*, the corresponding value for I:E Ratio is displayed in real time in the Graphical User Interface Weaning Data Set. Press the Data Set area in the lower right corner of the screen to select data for display. The *I:E ratio* setting does not reflect an *Insp Hold* in progress.

Table 5-2. *Pressure Control* Breath Settings Based on Mode

A/CMV

1. Set *Pressure Control-A/CMV* on the Control Panel.
2. Set *Pressure Limit*.
3. Set *t Insp* (*Inspiratory Time*).
4. Set *Resp Rate*.
5. Set F_IO_2.
6. Set *PEEP/CPAP*.
7. Set Trig to *Flow* or *P* (pressure), then adjust setting.
8. Set High and Low Minute Volume alarms on GUI.
9. Set High and Low Paw alarms.
10. Set High Resp Rate alarm.
11. Set Apnea alarm.
12. Set Disconnect Threshold alarm.
13. Optional: Set Non Invasive Ventilation on face panel
14. Optional: Set these additional settings on the GUI screens:
    - *Slope/Rise*
    - **Volume Target (breaths will be Volume Target Pressure Control)*

SIMV

1. Set *Pressure Control-SIMV* on the Control Panel.
2. Set *Pressure Limit*
3. Set *t Insp* (*Inspiratory Time*)
4. Set *Pressure Support*
5. Set *Resp Rate*.
6. Set F_IO_2.
7. Set *PEEP/CPAP*.
8. Set Trig to *Flow* or *P* (pressure), then adjust setting.
9. Set High and Low Minute Volume alarms on the GUI.
10. Set High and Low Paw alarms.
11. Set High Resp Rate alarm
12. Set Apnea alarm
12. Set Disconnect Threshold alarm.
13. Optional: Set Non Invasive Ventilation on the Control Panel
14. Optional: Set these additional settings on the GUI screens:
    - **Volume Target* (breaths will be Volume Target Pressure Control and Volume Target Pressure Support)
    - *Slope/Rise*
    - *Expiratory Threshold*

* Available on e360 Plus model

SPONT

1. Set *SPONT* on the control panel.
2. Set *Pressure Support*
3. Set F_IO_2.
4. Set *PEEP/CPAP*.
5. Set trig to *Flow* or *P* (pressure), then adjust setting.
6. Set High and Low Minute Volume alarms on the GUI.
7. Set High and Low Paw alarms.
8. Set High Resp Rate alarm
9. Set Apnea alarm
10. Set Disconnect Threshold alarm.
11. Optional: Set Non Invasive Ventilation on the Control Panel
12. Set *Pressure Limit* (Pressure Support display will be dimmed)
13. Optional: Set these additional settings on the GUI screens:
    - *Slope/Rise*
    - *Expiratory Threshold*
    - **Volume Target* (breaths will be pressure supported)

* Available on e360 Plus model

NOTE: See Section 4 /Ventilator Operation for a description of the use of the controls listed above.

VOLUME TARGET PRESSURE CONTROL (VTPC) / VOLUME TARGET PRESSURE SUPPORT (VTPS)

(Available on e360 Plus model)

Volume Target for VTPC/VTPS is enabled on the *Advanced* data set on the GUI and can be turned to ON for use in Pressure Control breath type. The set *Tidal Volume* becomes a targeted volume after pressure control is selected. See Section 9 /Explanation of Modes for more information.

6. ALARMS

This section describes e360 Ventilator alarms and indicators as well as an Alarm Violation and Remedy Guide (see Table 6-2). A general description on how to manage alarms can be found in Section 4 and alarm specifications are located in Section 8 of this manual.

The e360 Ventilator powers up using the most recently selected alarm limits.

WARNING Failure to identify and correct alarm conditions can result in patient injury. To ensure continued ventilator operation when a Low Battery alarm occurs, substitute an alternate power source, such as AC power, immediately.

WARNING If the internal built-in oxygen monitor malfunctions or is disabled, you must have an external oxygen monitor with alarms available to ensure patient safety.

ALARM SILENCE BUTTON

Pressing *Alarm Silence* button mutes silenceable audible alarms for 120 seconds and cancels the Shutdown alarm after power down. The indicator on the *Alarm Silence* button lights while the alarm silence is activated. To cancel alarm silence, press the *Alarm Silence* again.

NOTE: Pressing *Alarm Silence* does not mute a *Device Alert* alarm until the ventilator is powered down.

NOTE: The optional *External Alarm Silence* cable provides the same function as the *Alarm Silence* button except that it does not silence a power-down alarm.

NOTE: Pressing and holding down the *Alarm Silence* button for one second or longer enables the *Suction Disconnect* function feature. See section 4/Ventilator Operation for more details.

ALARM RESET BUTTON

Alarm indicators do not automatically reset. When an alarm is no longer violated, alarm indicators will stop flashing and remain steadily lit to signal a latched alarm. Pressing the *Reset* button clears these latched alarm indicators.

ALARM INDICATORS

The 360º Alarm Lamp

Located at the top center of the e360 front panel, the 360º Alarm Lamp lights yellow or red to indicate that an alarm has been violated.

Alarms & Messages Display Bar

The *Alarms & Messages* display is located in the top center area of the Graphical User Interface and displays alarm descriptions when an alarm is violated.

NOTE: Informational messages are also displayed in the *Alarms and Messages* display area to provide the user with useful instructions and ventilator information during use.

Device Alert LED

The *Device Alert* LED, located on the left side of the Control Panel, lights and an alarm sounds when there is a device alert condition (e.g. low battery power or device malfunction). A *Device Alert* violation is not silenceable. See Table 6-2 for more information on device alert conditions.

ADJUSTABLE ALARMS

During conventional ventilation, the e360 Ventilator provides user-adjustable alarm limits for:

- High and low minute volume (MV_E) (Low MV_E activates Back up Ventilation)
- High and low airway pressure (Paw)
- High respiratory rate (RR tot)
- Disconnect Threshold
- Apnea

Pressing the *Alarms Screen* menu button on the Control Panel opens the Adjustable Alarm screen on the GUI. All adjustable alarms can be set from this screen. Like most other ventilator settings, adjustments are made with the *Touch-Turn-Accept* method. Multiple adjustable alarms can be changed before the Accept button is pushed as long as the user does not take more than 10 seconds to make the next adjustment.

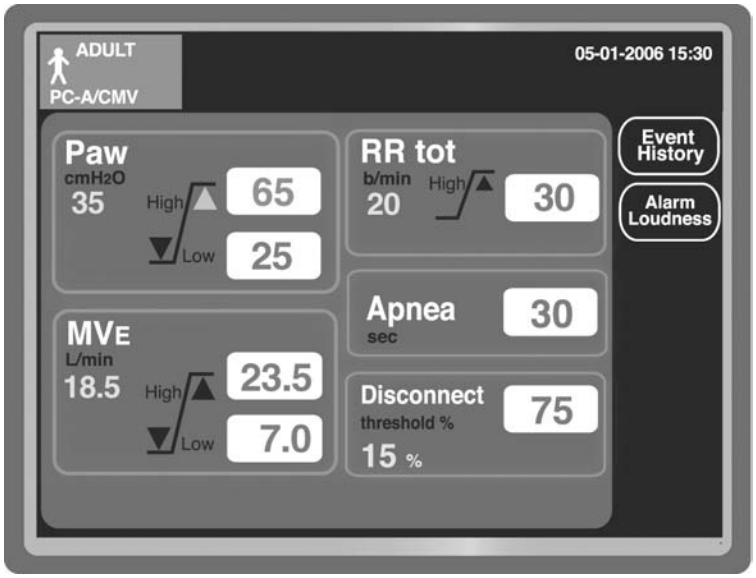


Figure 6-1. Graphical User Interface (GUI)– Alarms Setting Screen

The *Event History* log can be viewed and the *Alarm Loudness* can be adjusted from this screen. For alarm setting ranges and specifications see Section 8/Specifications. For the violation criteria of Adjustable Alarms, see Table 6-2 at the end of this section.

NOTE: When any alarm occurs the e360 ventilator makes a time-stamped entry, in red text, into the Event History Log. See Section 4/Ventilator Operation for more information on Event History.

To exit this screen press any menu button on the Control Panel.

NON ADJUSTABLE ALARMS

The following alarms may occur during ventilator operation and are non-adjustable:

High FIO2
Low FIO2
Low Baseline (PEEP) Pressure
High Baseline (PEEP) Pressure
Sustained High Baseline (PEEP) Pressure
Low Paw Below PEEP
Pressure Limit Below PEEP
Gas Supply Alarm
(Both Air/O_2 Supply loss)
Low Battery
Device Alert
O_2 Sensor Error
Flow Sensor Error
Insp. Time too long
Insp. Time too short
Volume Target Not Met
Setting out of range
Check Vent Fan
AC Power loss/Battery Backup
Power Shutdown

ALARM, VIOLATION AND REMEDY GUIDE

The following table lists alarm messages alphabetically, violation criteria (what causes the alarm limit to be violated), and Remedy (possible steps to take to correct the alarm).

Device Alert Violation Messages are listed in Table 6-3 that follows.

Table 6-2 Alarm, Violation and Remedy Guide

Alarm Message	Alarm Lamp	Violation Criteria	Remedy
[Any message not listed here]	Red	Ventilator failure that requires service.	1. Check patient and provide alternate ventilation immediately. 2. Contact a qualified service representative.
[setting/alarm limit] Out of Range Alarm	Yellow	Selected patient category conflicts with current control settings or alarm limits	1. Evaluate the patient category, ventilator settings, and alarm limits, and readjust as necessary.
AC Power Loss Battery Back Up Alarm *Int Battery* LED lights, and the battery charge level shows on GUI screen.	Yellow	Loss of mains power, which may be due to failed AC power source, a blown fuse, or disconnected power cord.	1. No action required if AC power is deliberately disconnected. 2. Verify that AC power source is securely connected and functional. 3. Prepare alternate ventilation if necessary.
Air Supply Loss Alarm	Red	Air gas inlet supply pressure has dropped below the minimum supply pressure required.	1. Check patient and provide alternate ventilation if necessary. 2. Check that air supply is connected and provide greater than or equal to 30 psig of pressure at ventilator inlet, especially during inspiration. If oxygen gas supply is connected, the ventilator continues breath delivery using the remaining oxygen gas supply.

Alarm Message	Alarm Lamp	Violation Criteria	Remedy
Apnea Alarm	Red	Ventilator has not detected a mandatory breath or spontaneous effort during the set apnea interval.	1. Check patient and make sure breathing circuit is intact and securely connected, provide alternate ventilation if necessary. 2. Evaluate ventilator settings if necessary to meet patient's needs, especially Respiratory Rate and Trigger setting. The alarm is reset when the ventilator detects a mandatory or spontaneous breath.
Back up Ventilation Alarm	Yellow	Monitored MVE ≤ Low MVE alarm limit.	1. Check patient. 2. Evaluate ventilator settings and readjust if necessary. The alarm is recovered when MVE rises to 10% above the Low MVE alarm limit. **NOTE**: Back up ventilation is suspended for 60 seconds after changing any ventilator settings such as mode, breath type, breath timing, pressure, volume, sensitivity and following circuit reconnect after a *Suction Disconnect* Alarm Function.
Both Air/O_2 Supply Loss Alarm	Red	Inlet pressure for both air and oxygen supplies has dropped below minimum supply pressure required. **WARNING** If this alarm occurs, the emergency relief valve opens. If an inspiratory bacteria filter is not in use, the inspiratory manifold must be removed, cleaned, and sterilized before use in the next patient.	1. Check patient and provide alternate ventilation immediately. 2. Check that air and oxygen supplies are connected and providing > 30 psig at ventilator inlet. The ventilator opens its emergency relief valve and exhalation valves to allow the patient to breathe room air.
Check Vent Fan Alarm	Yellow	Fan inside of the unit fails.	Contact a qualified service representative to replace vent fan. **NOTE**: Message cannot be canceled with the Alarm Silence button or Reset button.

Alarm Message	Alarm Lamp	Violation Criteria	Remedy
Device Alert Alarm (If message display is possible) Unsilencable, audible alarm Device Alert indicator flashes (if possible)	Red	Ventilator malfunction. Also activated if less than 10% of internal battery operation time remains when ventilator is battery operated. See the Table 6-3 for a list of device alert messages that require contact of a qualified service technician. **WARNING** If a Device Alert alarm occurs, ventilation ceases and the emergency relief valve opens. If a bacteria filter is not in use, the inspiratory manifold must be removed, cleaned, and sterilized before use on another patient. See Cleaning and Maintenance, Section 8 for instructions.	1. Check patient and provide alternate ventilation immediately. 2. If the alarm is due to a battery failure, plug the ventilator into a power source to allow charging. 3. Contact a qualified service representative. Ventilation ceases and the ventilator opens its emergency intake and exhalation valves to allow the circuit pressure to vent and the patient to breathe room air. The audible alarm can only be silenced after turning the ventilator off.
Circuit Disconnect Alarm	Red	Disconnect Threshold alarm level met. Alarm recovers when VTE % variance ≤ Disconnect Threshold. May be caused by large leak or disconnection of the patient circuit from the ventilator or High Pressure Alarm.	1. Reconnect circuit or check for leaks in the breathing circuit, ET tube or mask (if mask ventilating). 2. Reduce or eliminate leak as much as possible before raising alarm limit.
FIO2 High Alarm	Yellow	Measured *FIO2* is more than 0.07 above the *FIO2* setting. **NOTE**: This alarm is inactive if the e360 detects a disabled or defective oxygen sensor, or oxygen supply pressure is below 30 psig.	1. Verify that the source gas and connections are secure and functional. 2. Calibrate the O_2 sensor by pressing the O_2 3 min. button or by accessing O_2 calibrate in Setup and Calibration. 3. Replace O_2 sensor if necessary. **NOTE**: Insufficient supply inlet pressure of air may cause ventilator to be unable to deliver required high flow rate, resulting in *FIO2* alarm.

Alarm Message	Alarm Lamp	Violation Criteria	Remedy
FIO2 Low Alarm	Red	Measured *FIO2* is more than 0.07 below the *FIO2* setting. **NOTE**: This alarm is inactive if the e360 detects a disabled or defective oxygen sensor, or oxygen supply pressure is below 30 psig.	1. Verify that the source gas and connections are secure and functional. 2. Calibrate the O_2 sensor by pressing the O_2 3 min button or by accessing O_2 calibrate in Setup and Calibration. 3. Replace O_2 sensor if necessary. **NOTE**: Insufficient supply inlet pressure of O_2 may cause ventilator to be unable to deliver required high flow rate, resulting in *FIO2* alarm.
Flow Sensor Error Alarm	Red	1. Sensor is dis-connected from cable. 2. Ventilator is unable to calibrate the exhalation flow sensor or a sensor malfunction is detected.	1. Check flow sensor connection and recalibrate. 2. Replace sensor connection and calibrate. 3. Contact qualified technical service rep for repair.
High Baseline Pressure Alarm	Red	At the start of a time-triggered mandatory breath monitored baseline pressure (PEEP/CPAP) has been 5 cmH_2O/mbar above the PEEP/CPAP setting for two consecutive breaths.	1. Check breathing circuit tubing (and bacteria filter) for kinks or obstructions. 2. Evaluate ventilator settings and readjust if necessary. The alarm is recovered when monitored baseline pressure (PEEP/CPAP) is less than set PEEP/CPAP + 5 cmH_2O/mbar at the start of a time triggered breath.
High MVE Alarm (High Expiratory Minute Volume)	Red	Monitored exhaled minute volume (MVE) is ≥ set High MVE.	1. Check patient, evaluate ventilator settings and readjust if necessary. The alarm is recovered when the monitored MVE is below the High MVE alarm limit.
High Paw Alarm (High Peak Airway Pressure)	Red	Monitored breathing circuit pressure is ≥ set High *Paw* alarm limit for one breath.	1. Check patient. 2. Check the endotracheal tube. 3. Check breathing circuit tubing (and bacteria filter) for kinks or obstructions. 4. Make sure exhalation valve is functioning correctly. 5. Evaluate ventilator settings and readjust if necessary. The alarm is recovered when patient breathing circuit pressure drops 5 cmH_2O/mbar below the *High Paw* alarm limit.

Alarm Message	Alarm Lamp	Violation Criteria	Remedy
High RR tot Alarm (Respiratory Rate)	Red	When alarm is ON, monitored total breathing frequency is ≥ set alarm level. This may indicate a change in patient condition or auto triggering	1. Check patient for change in status or need for increased ventilatory support. 2. If due to autotrigger, check breathing circuit for leaks. 3. If due to autotrigger, turn Leak Compensation on (if it has been turned off). 4. Turn On Noninvasive Ventilation if mask ventilating. 5. Evaluate trigger setting/ method (Flow vs Pressure).
I:E Ratio Inverse Violation Alarm	Yellow	Ventilator settings would result in an inverse I:E ratio greater than 4:1, so ventilation is not delivered according to settings.	1. Check patient. 2. Evaluate inspiratory time, frequency, and trigger settings and readjust as necessary.
Insp Time Too Long Alarm	Yellow	Ventilator settings result in an inspiratory time greater than 5 seconds, including any pause time, so ventilation is not delivered according to settings.	1. Evaluate *Tidal Volume*, *Flow*, *Resp. Rate*, Isnp Time, flow waveform, *Pause* settings and readjust as necessary.
Insp. Time Too Short Alarm	Yellow	Ventilator settings or alarm limit violation results in an inspiratory time < 0.1 seconds, excluding any pause or inspiratory hold. While in VC, an Insp Time setting that cannot deliver the set *Tidal Volume*	1. Evaluate *Tidal Volume* and *Flow* settings and readjust as necessary. 2. Potential cause may be High Paw alarm violation. Resolve as needed.
Low Baseline Press Alarm	Yellow	Monitored airway pressure has been below the *PEEP/CPAP* setting for more than 0.5 seconds for two consecutive breaths.	1. Turn Leak Compensation On. 2. Check breathing circuit for leaks or disconnects. 3. If ventilating non-invasively, turn Non Invasive On. The alarm is inactive when *PEEP/CPAP* is set below 4 cmH_2O/mbar.

Alarm Message	Alarm Lamp	Violation Criteria	Remedy
Low Battery Alarm	Red	Internal battery operating capacity has dropped to 25% of capacity.	1. Connect the ventilator to AC power to allow the internal battery to recharge. **WARNING** To ensure continued ventilator operation, substitute an alternate power source, such as AC power, immediately when a Low Battery alarm occurs. The ventilator continues to operate normally until the battery is depleted, at which time a *Device Alert* alarm occurs.
Low MVE Alarm (Low Expiratory Minute Volume)	Red	Monitored MVE ≤ set Low MVE alarm limit.	1. Check patient, evaluate ventilation and alarm settings and readjust if necessary. The ventilator provides back up ventilation while this alarm limit is violated.
Low Paw Alarm (Low Peak Airway Pressure)	Red	Monitored airway pressure does not reach the *Low Paw* alarm limit during a mandatory inspiration for two breaths (does not apply to manual spont or pressure supported breaths.	1. Check breathing circuit for leaks or disconnects. 2. Evaluate ventilation and alarm settings and readjust if necessary. The alarm is recovered when *Ppeak* for a mandatory breath (including Back Up Ventilation) ≥ *Low Paw* alarm limit.
Low Paw Below PEEP Alarm		Low Paw alarm limit is ≤ PEEP setting	1. Check Low Paw alarm setting and adjust as needed or lower PEEP.

Alarm Message	Alarm Lamp	Violation Criteria	Remedy
O2 Sensor Error Alarm	Yellow	Ventilator cannot calibrate the O_2 sensor correctly.	1. Change the sensor as soon as possible. Note: Always use an external O_2 monitor with alarms while ventilating with this message.
O2 Supply Loss Alarm Audible alarm ALARMS indicator flashes	Red	Oxygen supply inlet pressure is below minimum supply pressure required.	1. Check that oxygen supply is connected and providing > 30 psig at the ventilator inlet, especially during inspiration. 2. Provide alternate ventilation if necessary. The ventilator continues breath delivery using the remaining air gas supply, and does not calibrate the O_2 sensor.
Pressure Limit Below PEEP Alarm		Pressure limit setting is ≤ the PEEP setting in Pressure Control and Volume Target Pressure Control	1. Check Pressure Limit and PEEP setting and adjust as needed.
Power Shutdown Alarm	Red	When ventilator is powered off an audible alarm sounds.	Press Alarm Silence button to silence alarm.
Sustained High Baseline Pressure Alarm	Red	Monitored PEEP pressure has been ≥ 8 cmH2O/mbar above set PEEP/CPAP for over 6 seconds in Ped/Infant or 10 seconds for Adult. **NOTE**: Emergency relief valve opens as needed to relieve pressure. If a bacteria filter is not in use, the inspiratory manifold must be removed, cleaned, and sterilized before use on another patient. Additional alarms may be violated due to interruption of ventilation during Sustained High Baseline Pressure Alarm.	1. Check circuit tubing for occlusions and/or fluids. 2. Check expiratory filter for blockage, replace if necessary. 3. Evaluate ventilator settings and readjust if necessary. 4. If not resolved, disconnect breathing circuit from patient and use alternate means of ventilation. Other possible causes: Malfunctioning Exhalation valve, replace if necessary.

Alarm Message	Alarm Lamp	Violation Criteria	Remedy
***Volume Target Not Met Alarm** *on e360 Plus model	Yellow	In Volume Target Pressure Control or Volume Target Pressure Support breath type, the set tidal volume cannot be delivered within the set Pressure Limit for two consecutive breaths.	1. Check patient condition for reversible cause. 2. Increase Pressure Limit, reduce Tidal Volume, increase t Insp or change Slope/Rise or Exp. Threshold if necessary. Factors that could trigger the alarm: agitation, biting of ET tube, coughing, increase in resistance or drop in compliance (eg. secretions, pneumothorax).
Informational Messages Displayed on GUI			
O2 Sensor Disconnect Alarm Message only No audible alarm	Informational message displayed on GUI	Oxygen sensor is removed or is disconnected. **NOTE**: Always use an external O2 monitor with alarms while ventilating with this message displayed	1. Install a functional sensor as soon as possible.
Ventilation Suspended Alarm No audible signal No indicator lit	Informational message displayed on GUI	Operator has enabled the *Suction Disconnect* Function after which the ventilator detects a circuit disconnect.	No action required. The ventilator resumes normal operation when it detects that the circuit is reconnected.

NOTE: When turning the power off, the ventilator will sound an audible tone that is silenceable using the Alarm Silence button.

Table 6-3 Device Alert Violation Messages

Device Alert Violation	Violation Messages	Alarm Lamp	Definition
Control communications failure	Monitor uP Failed	Red	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	Red	The control processor on the main PCB is bad.
Control exception failure	M Internal System	Red	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	Red	Random access memory that is used by the control processor on the main PCB is damaged.
Control task continuity failure	Control Tasks Failed	Red	Software tasks of the control processor have operated out of sequence.
Dual RAM failure	Dual RAM Failed	Red	Random access memory that is shared between the control and monitor processors is damaged.
Monitor communications failure	Control uP Failed	Red	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	Red	The monitor processor on the main PCB is bad.
Monitor exception failure	C Internal System	Red	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	Red	Random access memory that is used by the monitor processor on the main PCB is damaged.
Monitor ROM failure	Monitor ROM Failed	Red	Read only memory that stores the code of the monitor processor has an incorrect checksum.

Device Alert Violation	Violation Messages	Alarm Lamp	Definition
Monitor task continuity failure	Mon Task Failed	Red	Software tasks of the monitor processor have operated out of sequence.
Power Failure	Power Failure	Red	DC power out of tolerance. Check +12 VDC, –12 VDC and +5 VDC. (The e500 may have been powered by internal battery until it was depleted and a *Device Alert* resulted.)

7. CLEANING AND MAINTENANCE

INTRODUCTION

To ensure proper ventilator operation, perform the following cleaning and maintenance procedures at the recommended intervals. All procedures should be adapted to your institution's policies and procedures.

This section describes:
1. Cleaning and sterilizing
2. Preventive maintenance
3. Storage
4. Repackaging

WARNING Unqualified personnel must not attempt to service the ventilator system. Improper repair or unauthorized modification can compromise safety and result in patient injury. The regularly scheduled maintenance should only be done by a qualified service technician using the e360 Ventilator Service Manual.

NOTE: Parts removed from the ventilator during maintenance procedures should be disposed of appropriately and according to your institution's protocol. Sterilize parts before nondestructive disposal. Follow all applicable regulations for disposing of or recycling device components.

CLEANING AND STERILIZATION OF VENTILATOR COMPONENTS

Table 7-1 describes how to clean and sterilize ventilator components.

WARNINGS

Do not remove or clean inspiratory flow sensors, or flush with liquid or pressurized air.

To minimize exposure to sterilizing agents and damage to parts, follow these cleaning and sterilization instructions.

Handle filters carefully to minimize the risk of infection and damage to filters.

Follow your institution's infection control protocol.

Table 7-1. Cleaning and Sterilizing Ventilator Components

Caution Use only the cleaning and sterilization methods specifically listed for each e360 ventilator component. Consult accessory manufacturer's guidelines for specific cleaning, disinfecting and sterilizing guidelines. General guidelines for sterilization methods are provided on the pages that follow.

Ventilator/Component Accessory	Cleaning and Sterilization	Additional Information
Ventilator exterior, including control panel, cart, and support arm	Clean with a damp cloth and mild soap solution. Vacuum rear vents to remove dust.	Do not allow liquids into components or cable connections. Do not attempt to EtO sterilize or use pressurized air to clean or dry.
e360 fan filter	Wash filter in mild detergent solution, rinse thoroughly, allow to air dry.	Replace if damaged. Refer to Fig. 7-1.
Inspiratory bacteria filter	Single patient use: discard. Reusable: sterilize according to manufacturer's suggested methods.	Replace as needed or as per the filter manufacturers recommendation.
Expiratory bacteria filter	Single patient use: discard. Reusable: sterilize according to manufacturer's suggested methods.	Replace as needed or as per the filter manufacturers recommendation.
Expiratory bacteria filter (for use in addition to primary expiratory filter whenever medication is nebulized inline with the circuit)	Single patient use: discard. Reusable: sterilize according to manufacturer's suggested methods.	Monitor expiratory resistance carefully when nebulizing medications inline with the breathing circuit. Discard single patient use filter after treatment and replace reusable filter as needed.
Breathing circuit tubing	Reusable: disassemble then clean and sterilize according to tubing manufacturer's suggested methods. Single patient use: discard.	Pressurized air can be used to blow moisture from inside the component if it has been submerged in liquid. Replace if damaged. When installing a new circuit, perform a Circuit Check and Exh. Flow Sensor calibration (if replaced).

Ventilator/Component Accessory	Cleaning and Sterilization	Additional Information
Breathing circuit water traps	Reusable: disassemble then clean and sterilize according to water trap manufacturer's suggested methods. Single patient use: discard.	Monitor water traps regularly and empty as required. Replace if cracked or damaged.
Breathing circuit connectors	Reusable: disassemble then clean and sterilize according to breathing circuit connector manufacturer's suggested methods. Single patient use: discard.	Pressurized air can be used to blow moisture from inside the component if it has been submerged in liquid. Replace if damaged.
Exhalation Valve	Disassemble and clean, then autoclave to sterilize. Refer to Fig. 7-3.	After sterilization, perform the Circuit Check on the fully assembled circuit.
Inspiratory manifold	Disassemble and clean, then autoclave to sterilize. Refer to Fig. 7-2.	After sterilization, perform the Circuit Check on the fully assembled circuit.
Exhalation Flow Sensor	Limited patient use: See Flow Sensor Guidelines.	Perform the Flow Sensor Calibration after replacement.

GENERAL GUIDELINES

NOTE: Guidelines are provided for your convenience. For ventilator accessories, see manufacturer's suggested methods for cleaning.

Caution Be very careful when handling the Flow Sensor due to the sensitive wires inside. Do not poke anything inside the sensor.

Cleaning

Do not clean or reuse single patient use or disposable products. To avoid damaging part surfaces, do not use hard brushes or other instruments to clean reusable parts.

Definition of *clean*: the removal of all foreign material (for example, soil or organic matter) from objects. Cleaning is normally accomplished by washing with running water, mechanical action, or enzymatic products.

Failure to remove foreign matter from an object before sterilization is likely to render that process ineffective and may also cause permanent damage. Meticulous cleaning must precede sterilization procedures. After cleaning and before sterilization, rinse the component thoroughly with clean, running water for at least two minutes. Failure to rinse adequately may shorten the useful lifespan of the component. Follow these steps to clean a part before sterilization:

1. Wash parts in water and mild soap solution.
2. Rinse parts thoroughly in clean running water for at least two minutes and wipe dry or allow to air dry thoroughly.
3. Inspect all parts after every cleaning. Replace damaged or worn parts.
4. Make sure to perform Circuit Check and sensor calibrations if appropriate, after every breathing circuit or part replacement.

Caution Always follow soap manufacturer's instructions. Exposure to a highly concentrated soap solution can shorten the useful life of a part. Soap residue can cause blemishes or cracks, particularly on parts exposed to elevated temperatures during sterilization.

Sterilization

Do not sterilize or reuse single patient use or disposable products. Avoid kinking tubing during sterilization and make sure that the tubing lumen is visibly dry before wrapping.

Definition of *sterilize*: The complete elimination or destruction of all forms of microbial life. Sterilization is accomplished by physical or chemical processes. Steam under pressure, dry heat, low temperature sterilization processes (such as ethylene oxide [EtO], gas, or plasma sterilization) and liquid chemicals are the principal sterilizing agents used. The term *sterilization* is intended to convey an absolute (not relative) meaning.

Autoclave Sterilization: Separate components and wrap each in muslin or equivalent paper before autoclaving. Make sure to follow your steam sterilizer manufacturer's instructions. Follow these steps:

1. Disassemble
2. Clean
3. Inspect
4. Sterilize
5. Reassemble
6. Perform Circuit Check and Sensor Calibration if appropriate.

ETO: Separate components and ensure that they are completely dry before packaging for EtO sterilization. After sterilization, properly aerate to dissipate residual gas absorbed by the part. Follow the EtO sterilizer manufacturer's instructions. Follow these steps:

1. Disassemble
2. Clean
3. Inspect
4. Sterilize
5. Aerate
5. Reassemble
6. Perform Circuit Check and Sensor Calibration if appropriate.

MAINTENANCE INTERVAL SUMMARY

Table 7-2 summarizes preventive maintenance and procedures for the e360 Ventilator. See the hour meter on the GUI Technical Setup screen for total hours of operation.

Table 7-2. e360 Ventilator Maintenance Intervals

Frequency	Ventilator Component	Recommended Maintenance
Several times a day or as required by your institution's policy		
	Patient breathing circuit	Monitor for water accumulation, drain and clean as necessary.
	Expiratory Bacteria filter, disposable	Inspect and if you suspect excess resistance, replace. Always use a new secondary filter for each nebulized medication delivery.
	Breathing circuit water traps	Monitor for water accumulation, drain and clean as necessary.
Daily or as necessary		
	e360 rear panel air and oxygen high pressure inlet water traps	Monitor for water accumulation, drain and clean as necessary. Replace the bowl if there is any sign of wear/damage. If inlet water trap fills, remove ventilator from use and contact an authorized service agent.
	e360 rear panel fan filter	Check and clean as required. Wash weekly when in use.

Frequency	Ventilator Component	Recommended Maintenance
As necessary and Between patient use		
	Patient breathing circuit	Single patient use (disposable): discard and replace between every patient use, and when it malfunctions or is visibly contaminated during use. Reusable: sterilize and replace between patient use or when malfunction or visible contaminated occurs during use.
	Ventilator exterior (body, control panel, cart, and support arm)	Wipe clean with a damp cloth and mild soap solution. Vacuum dust from the vents on the rear panel. Wipe off all residues after cleaning.
	Inspiratory Bacteria filter, reusable	Reusable: sterilize and replace between every patient use and when visibly contaminated or malfunctions during use.
	Expiratory Bacteria filter, reusable	Reusable: sterilize and replace between every patient use and when visibly contaminated or malfunctions during use. Monitor expiratory resistance carefully and replace filter when you suspect increased resistance.
	Exhalation Flow Sensor	Limited patient use With **No** expiratory bacteria filter: clean and sterilize between patient use or when it is visibly contaminated. See Flow Sensor Guidelines, pg 7-13. With exp. bacteria filter in use: no requirement. Clean and sterilize as necessary. Replace sensor when it cannot pass calibration.
Between patient use		
	Inspiratory Bacteria filter, disposable	Replace between every patient use.
	Exhalation valve	With **No** bacteria filter: disassemble, clean and sterilize between every patient use, and when it is visibly contaminated during use. **With** bacteria filter in use: clean and sterilize only as necessary.
	Inspiratory manifold	With **No** bacteria filter: disassemble, clean and sterilize between every patient use **With** bacteria filters in use: no requirement

Frequency	Ventilator Component	Recommended Maintenance
At least every 6 months		
	Internal battery	Recharge the internal battery at least every six months or sooner, if necessary.
Every year or after 25 autoclave sterilization cycles or as needed.		
	Newport reusable patient breathing circuit tubing i.e., p/n PBC345A or PBC450A.	Discard and replace. Sterilize before nondestructive disposal.
Every year or 5,000 hours, whichever comes first		
	e360 various parts	Install appropriate preventive maintenance kit. Preventive maintenance must be performed by a Newport authorized service technician following the instructions found in the *e360 Ventilator Service Manual*.
Every 2 years or as required		
	e360 oxygen sensor	Discard and replace.
Every 5 years or 25,000 hours of operation		
	e360 various parts	Perform an overhaul procedure according to instructions in the *e360 Ventilator Service Manual*.

Caution Perform preventive maintenance and replace components at recommended intervals to avoid component damage from excessive wear.

MAINTENANCE PROCEDURES

Rear Panel Fan Filter

(Daily or as required)

Over time, the fan filter will collect dust since it pulls air from the room into the ventilator's interior for cooling. While in use, check the fan filter regularly and clean or replace as necessary. Follow these steps to remove and reinstall the fan filter (Figure 7-1), as required:

1. Gently pry the fan cover from the back panel of the e360 (a coin can be used).
2. Remove the fan filter from the cover.
3. Vacuum dust from filter or clean with soap and water, dry and replace.
4. Reinstall the cover by pressing it onto the back panel until it snaps into place.

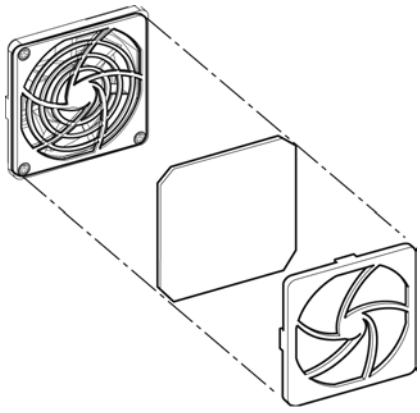


Figure 7-1.Rear Panel – Reinstalling and Replacing the Fan Filter

Reusable Patient Breathing Circuit

The reusable tubing for the Newport breathing circuit (i.e., p/n PBC345A Adult and PBC465A Ped and PBC450A Infant) is manufactured from a high-temperature polyester elastomer material. The breathing circuit tubings also incorporate a silicone rubber cuff. Newport recommends that the elastomeric components be replaced after 25 sterilizing cycles. Fully disassemble, clean, and sterilize the Newport reusable circuit between patients or if contamination occurs during use.

1. Wash the breathing (in approved full strength or diluted cleaning solution) circuit to remove all organic contaminants.

2. *Rinse thoroughly* to remove cleanser residue prior to sterilizing.

NOTE: This is extremely important since residual solution can cause crazing (cracking) or rupturing of breathing circuit components during these overlapping chemical exposures.

3. *Sterilize using the guidelines below*:

    - Autoclave at 132ºC /270ºF for 3 - 5 minutes
    - Autoclave at 126ºC / 259ºF for 10 minutes
    - Autoclave at 121ºC / 250ºF for 15 minutes
    - Ethylene Oxide 55ºC / 131ºF
    - Pasteurization 75ºC / 170ºF

Caution: To avoid damage to the tubing, attach and detach tubing by handling only the silicone cuffs. Do not pull or twist the tubing. Avoid exposing the tubing to UV light.

Caution: Breathing circuit tubing and plastic components should not come in contact with the following solutions because they may cause disintegration of the tubing:

1. Hypochlorite
2. Phenol (>5%)
3. Inorganic Acids
4. Formaldehyde
5. Ketone
6. Chlorinated Hydrocarbons
7. Aromatic Hydrocarbon

Ventilator Exterior Cleaning

(Weekly and at Every Patient Use)

Clean the exterior of the e360 ventilator using established procedures, protocols and products in your facility. Newport recommends using a hospital grade disinfectant to wipe clean the surfaces of the ventilator. Environments that have resistant strains of bacteria may require the use of a buffered bleach solution to clean the surfaces between patients (consult your facility's cleaning procedures).

After cleaning, wipe off all cleaning agent residues to prevent buildup. Vacuum the vents on the rear panel of the e360 to remove dust.

Cautions:

Do not sterilize the ventilator. Standard sterilization techniques, including EtO and formaline, may cause damage.

Do not use cleaning agents that contain phenols, ammonium chloride, chloride compounds, or more than 2.4% glutaraldehyde. These agents may damage the plastic components and front panel overlays.

Do not use harsh abrasives.

Do not immerse the ventilator in liquid sterilizing agents or liquids of any kind.

Do not spray cleaning solutions directly onto the front or rear panels of the ventilator.
Do not allow cleaning solutions to pool on the ventilator control panel or top of the ventilator.

Do not submerge bacteria filters in liquids of any kind. Reusable bacteria filters should be steam-autoclaved.

Check with the manufacturer of all cleaning chemicals and sterilizing equipment to ensure safe handling procedures are followed.

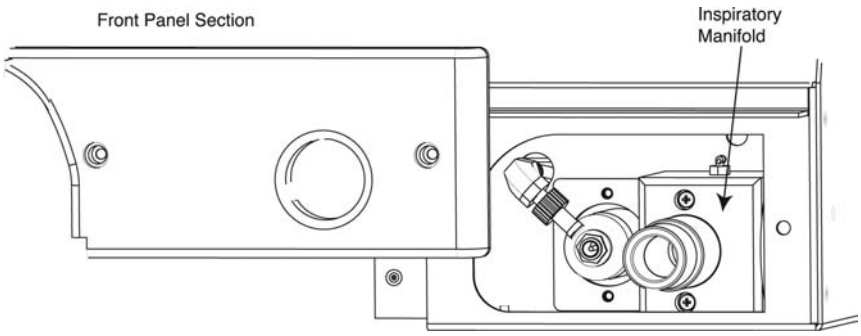
Inspiratory Manifold

If the emergency relief valve (located in the inspiratory manifold) opens during ventilator operation, the inspiratory manifold can be exposed to contaminated exhaled gas from a patient (if a bacterial/viral filter is not used to protect it). In this circumstance, it is important to fully disassemble, clean, and sterilize the inspiratory manifold between patients.

Follow these steps to remove and disassemble the Inspiratory Manifold for cleaning or repair (Figure 7-2):

1. Using a screwdriver or a coin, unscrew the two screws on the Lower Right Front Panel section and remove it to expose the Inspiratory Manifold.

2. Use a Philips screwdriver to remove the upper and lower Manifold Retaining Screws and pull the manifold away from the ventilator.



Remove Lower Right Front Panel

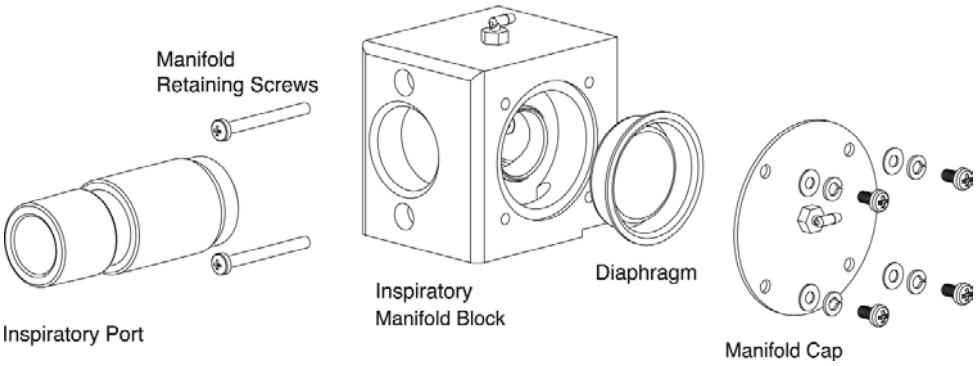


Figure 7-2. Disassembly and Reassemby of the Inspiratory Manifold

3. Remove the Manifold Cap by removing the four screws to expose the Diaphragm. Handle with care.

4. Remove the Inspiratory Port from the block by turning it counterclockwise.

5. Clean, sterilize and then replace the manifold, reversing the above steps.

Exhalation Valve

Fully disassemble, clean, and sterilize the exhalation valve between patients, unless the valve has been protected from contaminated exhaled gases with a bacterial/viral filter.

Follow these steps to remove and disassemble the exhalation valve (refer to Fig. 7-3).

1. Open the Front Panel Door to expose the Exhalation Valve.

2. Remove Exhalation Valve by releasing the latch at the top of the panel and pulling the valve away from the ventilator. Remove the Flow Sensor from the Valve.

3. Turn the Retaining Ring counter clockwise while holding valve body securely and remove it.

4. Separate the Exhalation Valve Cap from the Valve Body.

5. Remove Diaphragm and Poppet Assembly from the Valve Cap (do not disassemble the diaphragm/poppet assembly).

6. Wash the Exhalation Valve to remove all contaminants and rinse thoroughly before sterilization.

7. To re-assemble the valve, reverse these steps taking care to align the guide pin on the valve cap with the slot in the valve body (see Figure 7-4 below).

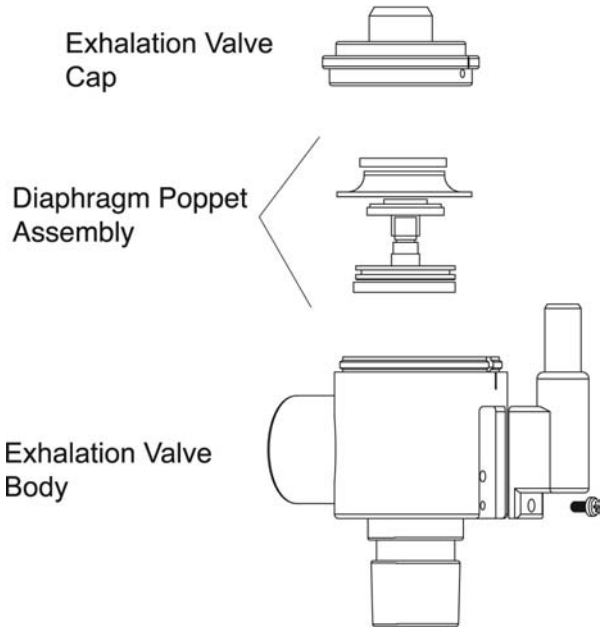


Figure 7-3. Disassembly and Reassembly of the Exhalation Valve

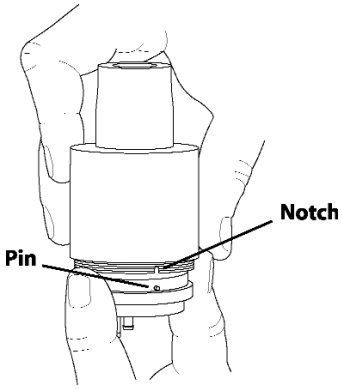


Figure 7-4. Align Exhalation Valve Cap and Body

WARNING: Disassemble, clean and sterilize the exhalation valve assembly after each patient use if no bacteria filter has been used.

WARNING: Always use a secondary bacteria filter at the expiratory side, while nebulizing medication inline with the breathing circuit. This secondary filter should be replaced after each treatment.

WARNING To reassemble the exhalation valve, proper orientation of the various components is critical. Refer to Fig. 7-3 and 7-4 for correct component orientation.

Exhalation Flow Sensor

Guidelines for Cleaning and Replacement

With expiratory filter protection:
No replacement required. If the Flow Sensor is visibly soiled or fails calibration, clean and sterilize according to instructions below. If it cannot be calibrated, discard the sensor.

Without expiratory filter protection:
Clean and sterilize between every patient use or if visibly soiled.

Cleaning: Soak the Sensor in 70% alcohol solution for approximately one hour then gently agitate the sensor while submerged. When visibly clean, remove from alcohol and fully air dry for at least 30 minutes. Do not clean inside the Sensor in a mechanical way with compressed air or jet of water as this will result in damage of the measuring wires.

Sterilization: The Sensor is not autoclaveable. Sterilize by ETO (Ethylene Oxide). If it is possible that the sensor is still contaminated, a new sensor must be used.

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.

Instructions for Removal and Reinstallation

1. If the ventilator is in use, provide alternate ventilation to patient.

2. Open the Front Panel Door on the lower left front of the ventilator to expose Exhalation Valve and Flow Sensor.

3. Remove the Exhalation Valve by releasing the retaining latch.

4. Disconnect the Flow Sensor Cable from the plastic body of the Sensor by pulling cable straight up. Do not twist.

5. With a twisting motion, pull the plastic Flow Sensor away from the outlet of the Exhalation Valve.

NOTE: Clean the Flow Sensor Cable with a damp cloth and appropriate disinfectant (do not soak) between patients and when visibly soiled.

6. To reinstall the Sensor, reverse the above steps.

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

7. To calibrate the Flow Sensor, press the *Setup and Calibration* menu button on the Control Panel, touch the *Sensors* menu button on the GUI and then touch the *Flow Sensor* button to start the automatic calibration. See Section 4, Sensors for more details.

Caution: The Flow Sensor should be calibrated whenever you suspect that the expiratory tidal/ minute volumes are significantly different than expected (example: at least 25% higher or lower). If the Sensor fails to calibrate, even after it has been cleaned and sterilized, inspect it for broken wires. Replace sensor if damaged and discard in accordance with local regulations.

Oxygen Sensor

Replace the Oxygen (O_2) Sensor every two years or when the sensor cannot calibrate (the ventilator will display the message "*O_2 Sensor Error*" when a calibration fails). Use the instructions below to disassemble/reassemble the sensor.

1. Set the Power Switch to the OFF position and disconnect the ventilator from AC power and gas supplies.

2. Using a screwdriver or a coin, remove the Lower Right Front Panel section to expose the Oxygen Sensor.

3. Locate the Sensor Cable and turn the twist collar counter clockwise to remove the cable from the sensor (as shown in Figure 7-5).

4. Rotate the Sensor counter clockwise to remove it. Discard Oxygen Sensor in accordance with local regulations.

5. To reinstall a new sensor, reverse steps.

6. To calibrate the O_2 sensor, press the *Setup and Calibration* menu button on the Control Panel and then touch the *Sensors* menu button on the GUI and then touch the *O_2 Sensor* button to start the automatic calibration. See Section 4, Sensors for more details.

The ventilator also calibrates the Sensor whenever the *O_2 3 min* button is pressed, unless:

- the oxygen supply pressure is below minimum pressure requirements
- the sensor is disconnected
- the sensor is defective.

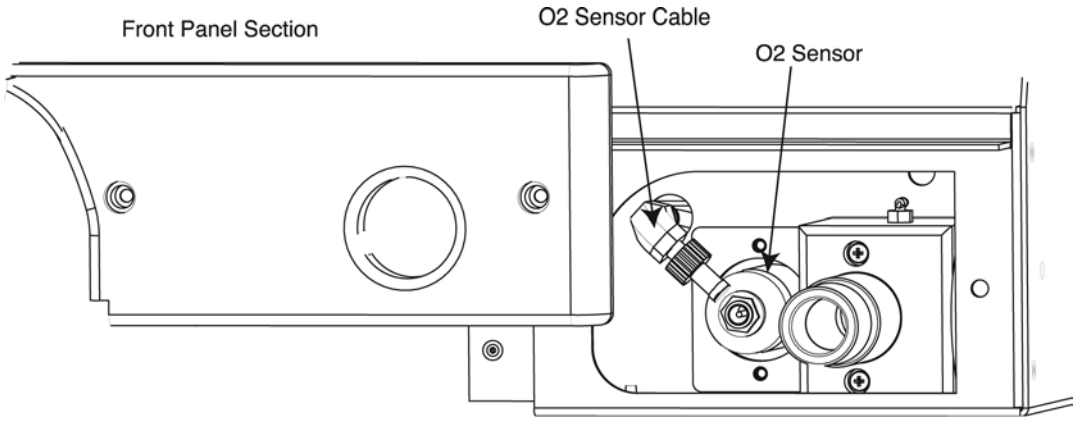


Figure 7-5. Replacing the Oxygen Sensor

Internal Battery

WARNING: To ensure that the internal battery remains functional, fully recharge the battery at least every 6 months when the ventilator is not in use.

NOTE: The internal battery recharges whenever the ventilator is connected to AC power, regardless of whether the Power switch is in the **ON** or **OFF** position. Newport recommends connecting the e360 to AC power when it is not in use in order to maintain the battery charge level.

A fully charged internal battery can support approximately 60 minutes of complete ventilator function at the following standard settings: *Adult*, *SIMV*, V_T *500*, F_IO_2 .30, *Insp Time* 1.0s, *Resp Rate* 15, *PS* 0, PEEP +5, *Pause* Off, *Sigh* Off, *Square Wave*.

The *Int Battery LED* lights and an audible signal sounds every five minutes to indicate that the ventilator is operating on internal battery power.

The Battery Charge Level icon (located in the top right area of the GUI) shows the relative level of internal battery power when ventilator is operating on internal battery power.

The internal battery requires up to 5 hours of AC power to achieve 80% charge, and is fully recharged after 14-16 hours. If internal battery voltage remains low (that is, a Low Battery alarm occurs when the ventilator is On and disconnected from AC power) after 5 hours of charging, replace the internal battery as described in the *e360 Ventilator Service Manual*.

Remove and Replace the Fuses

The fuses are located in the top of the AC power module on the rear of the e360. Refer to Figure 7-6 as you follow these steps:

1. Set the Power switch to the OFF position and disconnect the ventilator from AC power and gas supplies.

2. Using a small flathead screwdriver, squeeze the tabs on the fuse drawer to loosen it; then pull it from the AC power module.

3. Inspect and replace the fuses only if they are blown.

4. Reinstall the fuse drawer.

NOTE: Refer to the *e360 Ventilator Service Manual* for fuse specifications.

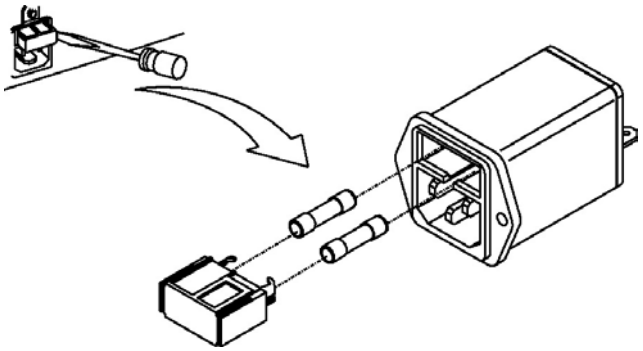


Figure 7-6. Replace the Fuses (FUS1802Q)

STORING THE VENTILATOR

When storing the ventilator for extended periods of time, plug into AC power and fully recharge the battery at least every six months.

Caution Disconnect oxygen from the ventilator for storage or if the ventilator will not be used for an extended period of time. Do not store the ventilator on its side or back.

REPACKAGING THE VENTILATOR

Use the original packing carton and material to ship the ventilator, or contact your Newport representative to order replacement packing material. See contact information in Section 1.

8. SPECIFICATIONS

CONTROL PANEL FUNCTIONS AND CONTROLS

Control Panel	Range and Resolution
Breath Type /Mode	**Breath Type:** *Volume Control, Pressure Control* or **Volume Target Pressure Control* ***NOTE:** On the e360 Plus model, *Volume Target* is accessed via the *Advanced* Settings data set on GUI. **Mode:** A/CMV (assist/control mandatory ventilation), SIMV (synchronized intermittent mandatory ventilation), or SPONT (spontaneous ventilation) **NOTE:** See Section 9/Explanation of Modes for details.
Non Invasive	Range: On or Off Available in all modes and breath types. Leak Compensation is automatically adjusted up to 25 L/min. **NOTE:** Use with non-vented masks. **NOTE:** See Section 9/Explanation of Modes for details.
FIO_2 (oxygen concentration)	Range: 0.21 to 1.00 (resolution 0.01) Accuracy: ±.03
Mains indicator	Lights when the ventilator is supplied with AC power
Internal Battery indicators	*Int Battery* LED on the control panel lights and an audible signal sounds every five minutes to indicate that the ventilator is operating on internal battery power. The Battery Charge Level icon (located in the top right area of the GUI) shows the relative level of internal battery power when ventilator is operating on internal battery power. **NOTE:** Low Battery alarm occurs when capacity is ≤ 25%. See Section 6/Alarms for more details.
Pressure Bar Graph	Displayed range: –10 to 120 cmH_2O/mbar Continuously displays the pressure in the patient breathing circuit in cmH_2O/mbar.

Control Panel	Range and Resolution
Tidal Volume * * Gas delivery is BTPS compensated: Body Temperature Pressure Saturated. Body temperature 37 ºC, steam saturated gas, ambient pressure.	Range: Ped/Infant: 20 to 100 mL (resolution 2 mL) 105-1000 mL (resolution 5 mL) Adult: 100 to 995 mL (resolution 5 mL), 1.00 to 3.00 L (resolution 0.01 L) Accuracy: ±10% or ±4 mL, whichever is greater **NOTE:** This is the set volume for mandatory Volume Control breaths and the target volume for Volume Target Pressure Control and Volume Target Pressure Support breaths. The display is dimmed but still adjustable when not in use for present mode of ventilation. **NOTE:** The e360 adjusts expiratory gas monitoring based on the Circuit Type (Heated Exp. Circuit, Non-Heated Exp. Circuit, or HME) chosen via the GUI (Setup & Calibration /Patient Setup).
Flow (inspiratory flow)	Range: Ped/Infant: 1 to 100 L/min (resolution 1 L/min) Adult: 1 to 180 L/min (resolution 1 L/min) Accuracy: ±10% or ±3 L/min, whichever is greater [Use *Select* button above the display to toggle selection to *Flow* or *t Insp*] **NOTE:** Applies to mandatory breaths and Manual Inflations when Volume Control breath type is selected.
t Insp (inspiratory time)	Range: Ped/Infant: 0.10 to 3.00 seconds (resolution 0.01 seconds) Adult: 0.10 to 5.00 seconds (resolution 0.01 seconds) Accuracy: ±0.05 seconds [Use *Select* button above the display to toggle selection to *t Insp* or *Flow*] **NOTE:** Applies to mandatory breaths only. The ventilator limits inspiratory times for all breaths to a minimum of 0.1 seconds and a maximum of 5 seconds, including any pause. The 5-second maximum does not apply to an inspiratory hold maneuver.
Resp Rate (respiratory rate)	Range: Ped/Infant: 1 to 120 b/min (resolution 1 b/min) Adult: 1 to 80 b/min (resolution 1 b/min) Accuracy: ±1 b/min or ±10% of breath period, whichever is less **NOTE:** Applies to mandatory breaths only.
Pressure Support	Range: Ped/Infant: 0 to 50 cmH_2O/mbar (resolution 1 cmH_2O/mbar) above PEEP/CPAP setting Adult: 0 to 60 cmH_2O/mbar (resolution 1 cmH_2O/mbar) above PEEP/CPAP setting Accuracy: ±10% or 1 cmH_2O/mbar, whichever is greater **NOTE:** Applies to spontaneous breaths in SIMV and SPONT modes for Volume Control and Pressure Control breath types. **NOTE**: Out of Range alarm occurs if PEEP + PS $\geq$ 60. **NOTE**: See Section 9 / Explanation of Modes for more details.

Control Panel	Range and Resolution
Pressure Limit	Range: Ped/Infant: 0 to 70 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Adult: 0 to 80 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Accuracy: ±10% or ±1 cmH_2O/mbar, whichever is greater **NOTE:** This is the set Pressure Control level for mandatory Pressure Control breaths and the maximum pressure for *Volume Target Pressure Control and *Volume Target Pressure Support breaths. The display is dimmed but still adjustable when not in use for breath management.
PEEP/CPAP (baseline pressure)	Range: Ped/Infant: 0 to 30 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Adult: 0 to 45 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Accuracy: ±10% or ±1 cmH_2O/mbar, whichever is greater
Trigger [Press *Trig* button above the display to select *Flow* or *P* (pressure)]	**P (pressure trigger sensitivity)** P range: 0.0 to -5.0 cmH_2O/mbar (resolution 0.1 cmH_2O/mbar) Accuracy: ±10%
	Flow (trigger sensitivity) Flow range: Ped/Infant: 0.1 to 2.0 L/min (resolution 0.1 L/min) Adult: 0.6 to 2.0 L/ min (resolution 0.1 L/min) Accuracy: ±10% or ±0.1 L/min, whichever is greater
Manual Inflation	Range: Up to 5 seconds Delivers a manual inspiration while the button is held down. Terminates when the button is released or when a High Pressure Alarm is violated, whichever comes first. **NOTE:** See Section 4/Ventilator Operation/Manual Inflation for more details.
O_2 (3 min)	Delivers 100% oxygen for 3 minutes Pushing the button again turns off 100 % oxygen delivery and resumes delivery of the set F_IO_2. Indicator lights when O_2 3min is in effect. An O_2 Sensor calibration begins automatically when the O_2 3 minute button is pressed.
Accept button	Use this button to confirm and implement the adjusted selection(s).

GRAPHICAL USER INTERFACE FUNCTIONS AND CONTROLS

Main Screen	Range and Resolution
Waves	Waveform combinations: Pressure / Time, Flow/ Time, Volume/Time or combination of two can be displayed on one screen
Loops	Loops combinations: Flow/Volume, Volume/Pressure or both on one screen
Trends	Accuracy: Larger of the individual parameter accuracy, or 2% of the selected full scale. Two trend screens are available each with four numeric variable trends positioned one above another. Trend parameters (all are over Time): Ppeak, Pmean, Pbase, RSBI, VTE, Min. Volume, RRtot, VTE %Variance
Numeric	The Numeric screen displays all monitored parameters on a single screen, including Advance data functions. Numeric table includes: Ppeak, Pplat, Pmean, PEEP, Total PEEP, FIO2, I:E, Peak Insp Flow, Peak Exp Flow, WOBim, Cdyn effective, Cstat, RI, RE, Time Const., RR tot, RR spont, RSBI, t Insp, MVE spont, VTI, VTE, VTE % Variance, MVI, MVE, Slope/Rise, Exp. Threshold, Pause, Flow Wave, * Open Exh. Valve *Available on e360 Plus model
Freeze / Start	Freeze: Suspends plotting of graphs (waveforms, loops, or trends) and holds the current display for extended viewing. Start: Resumes plotting of graphs. **NOTE**: A vertical-dashed line (the cursor) appears at the center of the waveforms, loops, or trends screen. Use the Adjustment Knob to reposition the cursor and obtain detailed numeric data for any point on a graph.

Extended Functions	Range and Resolution
Insp Hold	Range: Up to 5 seconds Generates an Inspiratory Hold maneuver at the end of inspiration for as long as the button is pushed.
Exp Hold	Range: Up to 20 seconds Generates an Expiratory Hold maneuver at the end of exhalation for as long as the button is pushed.
Event History	A log of the past 1000 events. Events are color coded: Power On/Off — Green Ventilation and Alarm Control settings — Blue Alarm violations and messages — Red Event History is retained after Power shutdown.
Freeze/Start	*Freeze*: Suspends plotting of graphs (waveforms, loops, or trends) and holds the current display for extended viewing. *Start*: Resumes plotting of graphs. **NOTE:** A vertical-dashed line (the cursor) appears at the center of the waveforms, loops, or trends screen. Use the Adjustment Knob to reposition the cursor and obtain detailed numeric data for any point on a graph.
Graphical User Interface Functions and Controls	
Advanced Settings	**Description**
Slope/Rise	Range: 1 – 19 (resolution 1, where 1 is the slowest pressurization and 19 is the fastest) and *Auto (ventilator automatically manages the pressurization gain).Sets pressurization gain for Pressure Control, Pressure Support, *Volume Target Pressure Control and *Volume Target Pressure Support breaths. *Auto option available on e360 Plus model
Exp. Threshold	Range: 5 – 55% and *Auto (resolution 1%) of peak flow Sets the flow cycling-off threshold for Pressure Support and Volume Target Pressure Support breaths *Auto option available on e360 Plus model
Insp. Pause	Range: Off, 0.1 – 2.0 seconds (resolution 0.1 second) Sets the duration of Pause at the end of inspiration **NOTE:** Applies to mandatory Volume Control breaths only.
Flow Wave	Range: Square or Descending Ramp Selects flow waveform for Volume Control mandatory breaths.
Volume Target Pressure Control (on e360 Plus model)	Range: On or Off Available in Pressure control A/CMV, SIMV and SPONT modes. Minimum target pressure is PEEP + 5 cmH_2O/mbar, maximum target pressure is Pressure Limit setting. **NOTE:** See Section 9, Explanation of Modes for more details.

SETUP AND CALIBRATION FUNCTIONS (GUI)

Patient Setup	Description
Open Exhalation Valve (on e360 Plus model)	Range: On or Off Activates management of a partially open exhalation valve during Pressure Control mandatory breaths for Biphasic Pressure Release Ventilation (BPRV). **NOTE**: Open Exhalation Valve is only active for Pressure Controlled mandatory breaths in A/CMV or SIMV modes. **NOTE**: See Section 9, Explanation of Modes for more details.
Patient Category	Range: Ped/Infant (pediatric/infant) Adult (An icon located on the GUI indicates category selected.) **NOTE:** Settable ranges for ventilator parameters and alarms may vary depending on the patient category selected. **NOTE:** To achieve the best ventilator performance, always select *Ped/Infant* when a pediatric (15 mm ID) or infant (12 mm ID) breathing circuit is used.
Patient Weight	Range: 2-2022 lb (2-999 kg)
Weight Units	Range: lb or kg
Volume Units	Range: mL or mL/kg or mL/lb
Sigh	Range: On or Off In Volume Control A/CMV or SIMV, delivers one sigh breath every 100 breaths, where sigh VT = 1.5 times VT setting) **NOTE:** Flow remains at the set level and inspiratory time is lengthened. The mandatory breath interval increases to twice the set interval if the Resp Rate setting is ≥ to 6 b/min (otherwise the interval does not change).
Circuit Type	Range: Heated Expiratory Circuit, Non-heated Expiratory Circuit, Heat Moisture Exchanger (HME) 1. Heated Exp. Circuit = heated humidifier with dual heated wire breathing circuit. 2. Non-heated Exp. Circuit = heated humidifier with no heated wires in the circuit or heated wire in the inspiratory limb of the breathing circuit only. 3. HME = no heated humidifier, unheated breathing circuit with passive humidification (heat moisture exchanger [HME] or hydroscopic condensing humidifier [HCH]). **NOTE:** Circuit Type selection affects the monitored values for expiratory flow, expiratory tidal volume and expiratory minute volume. Selecting the circuit/humidification device that matches the current ventilator setup will ensure accuracy of monitored expiratory flows and volumes.

Patient Setup	Description
Leak Compensation (Leak Comp)	Range: On or Off On = 3 – 8 L/min for Ped/Infant patient selection 3 – 15 L/min for Adult patient selection Off = 3 L/min regardless of leaks/ no leak **NOTE**: When Non Invasive is On, Leak Compensation is automatically adjusted from 3-25 L/min.
Compliance Compensation (Compl Comp)	Range: On or Off Volume Control mandatory breaths: flow delivery is adjusted to compensate for the effects of breathing circuit compliance and the display of monitored flows and volumes approximate effective delivered flows and volumes. **NOTE:** To ensure accurate Compliance Compensation, perform the Circuit Check with a complete breathing circuit and a filled humidifier chamber set up. **Note:** See Section 9, Explanation of Modes, for more details.
Circuit Check	Allows the user to test the breathing circuit and exhalation system for Leaks, Compliance and Resistance. The test is done in one or two phases, depending on the circuit in use. Follow the on-screen instructions. **NOTE:** Only available in Standby Condition. **NOTE**: e360 performs a Flow Sensor Calibration during the circuit check.
Sensors (Calibrate)	
O_2 Sensor Calibration	Performs an oxygen sensor calibration by delivering 100% oxygen to the system.
Exh Flow Sensor Calibration	Performs an Exhalation Flow Sensor Calibration.
Technical Setup	**Description**
Comm. Protocol	Allows user to select protocol to communicate with patient monitoring systems via the RS232 port
Display Brightness	Allows user to adjust display brightness
Date/Time/Format	Allows the user to set the date, time and format preferred.
Regional Settings	• Altitude — Range: 0 to 4,000 meters (0 to 13,124 feet) • Pressure Units — Range: mbar or cmH_20/mbar • Language — Select from available languages for GUI text

MONITORED DATA – GRAPHICAL USER INTERFACE

Monitored Data	Description
VT_E (mL) **(expiratory tidal volume)**	Displayed range: 0 to 999 mL (resolution 1 mL) 1.00 to 9.99 L (resolution .01 L) Accuracy: For set tidal volume ≥ 0.10 L , ±10% or ±0.02 L, whichever is greater. for set tidal volume < 0.10 L, ±20% The measured tidal volume exhaled by the patient for each breath as measured at the expiratory flow sensor. **NOTE:** At very low tidal volumes the exhaled volume may be significantly different than the set volume because of circuit characteristics and differences in heat and humidity. **NOTE:** VTE display is updated once the next breath starts and is accompanied by either an “S” to indicate a spontaneous breath or “M” to indicate a mandatory breath measurement. **NOTE:** The display will not be updated if the exhalation flow sensor is disconnected.
MV_E **(expiratory minute volume)**	Displayed range: Ped/Inf: 0.00 to 9.99 L (resolution 0.01 L) Adult: 10.0 to 99.9 L (resolution 0.1 L) Accuracy: ±10% or ±0.3 L, whichever is greater The measured volume per minute of gas exhaled by the patient. **NOTE:** The display will not be updated if the exhalation flow sensor is disconnected.
Exp Flow (L/min) **(peak expiratory flow)**	Displayed range: 0 to 300 L/min (resolution 1 L/min) Accuracy: ±10% or ±2 L/min, whichever is greater The peak flow exhaled by the patient.
Insp Flow (L/min) **(peak inspiratory flow)**	Displayed range: 0 to 200 L/min (resolution 1 L/min) Accuracy: ±10% of the inhaled peak flow or ±1 L/min, whichever is greater The peak inspiratory flow delivered from the ventilator. **NOTE:** e360 delivered volumes and flows are referenced to BTPS (Body Temperature Pressure Saturated).

Monitored Data	Description
I:E Ratio (inspiratory to expiratory time ratio)	Displayed range: From 99:1 to 10:1 (resolution 1) From 9.9:1 to 1:9.9 (resolution 0.1) From 1:10 to 1:99 (resolution 1) Inactive in SPONT mode ("—-" displayed). If the ventilator settings result in an inverse I:E ratio greater than 4:1, the ventilator will limit inspiratory time to deliver an I:E ratio of 4:1. Minimum exhalation times are 0.35 seconds (Adult) and 0.25 seconds (Ped/Infant).
F_IO_2 (oxygen concentration)	Displayed range: 0.21 to 1.00 (resolution 0.01) Accuracy: ±0.03 ("—-" displayed if oxygen supply pressure is below minimum, or oxygen sensor is disconnected, defective, uncalibrated since power up, or oxygen sensor calibration is in progress)
t Insp (inspiratory time)	Displayed range: 0 to 9.99 seconds (resolution 0.01 seconds) Accuracy: ±0.05 second Updated following each spontaneous or mandatory breath. The measured inspiratory time for the previous breath.
Ppeak (peak pressure)	Displayed range: 0 to 120 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Accuracy: ±3% or ±2 cmH_2O/mbar, whichever is greater Updated following each positive pressure inflation
Pplat (plateau pressure)	Displayed range: 0 to 120 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Accuracy: ±3% or ±2 cmH_2O/mbar, whichever is greater Displays time stamped numeric value (for up to 24 hours) following an inspiratory hold maneuver or following Pause that results in a stable pressure level.
Pmean (mean airway pressure)	Displayed range: 0 to 120 cmH_2O/mbar (resolution 1 cmH2O/mbar) Accuracy: ±3% or ±2 cmH_2O/mbar, whichever is greater The average pressure in the patient breathing circuit for the past 30 seconds
PEEP/CPAP (baseline pressure)	Displayed range: 0 to 120 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Accuracy: ±3% or ±2 cmH_2O/mbar, whichever is greater Measured end expiratory pressure.

Monitored Data	Description
Cdyn effective (mL/ cmH_2O/mbar) (Effective dynamic compliance)	Displayed range: 0 to 999.9 mL/ cmH_2O/mbar Accuracy: ± 1 mL/ cmH2O/mbar Cdyn effective = VTE/ (Ppeak – Pbase) Calculated for time triggered breaths only. VTE, Ppeak, and Pbase must be valid to calculate Cdyn effective.
Cstat (mL/cmH_2O/mbar) (Static compliance)	Displayed range: 0 to 999.9 mL/ cmH_2O/mbar Accuracy: ± 1 mL/ cmH_2O/mbar Cstat = VTE/ (Pplat – PEEP) The ratio of volume change to pressure change between two points in time when there is zero flow through the lung. Calculated for time-triggered breaths only. Cstat is updated immediately following an update of Pplat (Insp Hold Maneuver). It is also updated following an update of Total-PEEP (Exp Hold Maneuver) if this maneuver is performed within 5 min. following Pplat update. In this case, the Auto-PEEP measurement is substituted for the PEEP measurement in the equation.
RSBI (b/min/L) (Rapid Shallow Breathing Index)	Displayed range: 0 to 9999 b/min/L Accuracy: ± 1 b/min/L Spontaneous respiratory rate/exhaled tidal volume ratio. RR spont and MVE (spont) must be valid to calculate RSBI.
RR spont (b/min) (Spontaneous respiratory rate)	Displayed range: 0 to 999 b/min Accuracy: Larger of ± 3% or ± 2 b/min. The total number of patient triggered spontaneous breaths per minute.
RR tot (b/min) (Total respiratory rate)	Displayed range: 0 to 999 b/min Accuracy: ± 3% or ± 2 b/min., whichever is greater The total number of time, manual and patient triggered breaths per minute.
RE (cmH_2O/mbar/L/s) (Expiratory resistance)	Maneuver–based with time stamp (for up to 24 hours) Displayed range: 0 to 999.9 cmH_2O/mbar/L/s Accuracy: ± 1 cmH_2O/mbar/L/s RE = exhalation time constant/ Cstat. The exhalation time constant is the slope of volume/flow loop during exhalation. Cstat must be valid to calculate RE. Calculated for time-triggered breaths only.
RI (cmH_2O/mbar/L/s) (Inspiratory resistance)	Maneuver–based with time stamp (for up to 24 hours) Displayed range: 0 to 999.9 cmH_2O/mbar/L/s Accuracy: ± 1 cmH2O/mbar/L/s RI = (Ppeak – Pplat)/ end inspiratory flow. Calculated for volume control breaths only. Ppeak and Pplat must be valid to calculate RI. RI is updated only once immediately following update of Pplat (Insp Hold) or Pause.

Monitored Data	Description
Total PEEP	Maneuver–based with time stamp (for up to 24 hours) Displayed range: 0 to 99.9 cmH_2O/mbar Accuracy: Larger of ± 3% or 2 cmH_2O/mbar Measured static end-expiratory pressure from an expiratory hold maneuver. Total PEEP equals the sum of set PEEP + AutoPEEP. Total PEEP is updated immediately following an Exp Hold.
Time Constant	Accuracy: +/- .01 s Represents the exhalation Time Constant: slope of flow-volume loop during exhalation. Calculated for time triggered breaths only. Reliable measurements require adequate time for complete exhalation. Displayed as time in seconds.
VT_E % Variance	Displayed Range: 0 to 100% Accuracy: +10% Percent difference between inspiratory and expiratory tidal volumes. This difference may be due to a breathing circuit leak, endotracheal tube leak, or improper humidifier type setting in patient setup.
WOBim (J/min) (Imposed work of breathing)	Displayed range: 0 to 99.99 J/min Accuracy: ± 0.1 J/min Summation of imposed work of breathing for patient-initiated breathing during a one-minute interval. The work imposed on the patient by the ventilator and breathing circuit, is calculated by using the area of the negative pressure portion of the pressure volume loop.
Patient trigger indicator	The area behind the patient category icon at the top left side of the GUI lights green to indicate that a patient trigger has been activated.

SCALE

Preset scales are available for each parameter. Where available, auto-scaling allows e360 software to select the best scale for displaying monitored data.

PARAMETER (UNIT)	SCALE (RESOLUTION)
Wave time (s)	0 to 6 s (1 s) 0 to 12 s (1 s) 0 to 30 s (5 s) 0 to 120 s (10 s) Auto-scale not available.
Trend time (hr)	24 hr Auto-scale not available.
Pressure (cmH_2O/mbar)	–5 to 30 cmH_2O/mbar (5 cmH_2O/mbar) –10 to 50 cmH_2O/mbar (10 cmH_2O/mbar) –20 to 80 cmH_2O/mbar (10 cmH_2O/mbar) –60 to 140 cmH_2O/mbar (20 cmH_2O/mbar)
Volume (mL)	–10 to 50 mL (10 mL) –20 to 500 mL (50 mL) –20 to 900 mL (100 mL) –30 to 3000 mL (500 mL)
Flow (L/min)	-20 to 15 L/min (5 L/min). -80 to 40 L/min (20 L/min). -100 to 80 L/min (20 L/min). -300 to 200 L/min (100 L/min).
VTE (mL)	0 to 50 mL (10 mL). 0 to 500 mL (50 mL). 0 to 900 mL (100 mL). 0 to 3000 mL (500 mL).
MVE (L)	0 to 2 L/min (1 L/min). 0 to 10 L/min (5 L/min). 0 to 30 L/min (10 L/min). 0 to 100 L/min (10 L/min)
RR tot (b/min)	0 to 20 b/min (5 b/min). 0 to 50 b/min (10 b/min). 0 to 100 b/min (10 b/min). 0 to 200 b/min (50 b/min).
VTE % Variance (%)	0 to 10% (1%). 0 to 25% (5%). 0 to 50% (10%). 0 to 100% (10%).

PARAMETER (UNIT)	SCALE (RESOLUTION)
Ppeak (cmH_2O/mbar)	0 to 30 cmH_2O/mbar (5 cmH_2O/mbar). 0 to 50 cmH_2O/mbar (10 cmH_2O/mbar). 0 to 80 cmH_2O/mbar (10 cmH_2O/mbar). 0 to 140 cmH_2O/mbar (20 cmH_2O/mbar).
Pmean (cmH_2O/mbar)	0 to 10 cmH_2O/mbar (1 cmH_2O/mbar). 0 to 20 cmH_2O/mbar (5 cmH_2O/mbar). 0 to 40 cmH_2O/mbar (10 cmH_2O/mbar). 0 to 80 cmH_2O/mbar (10 cmH_2O/mbar).
PEEP (Pbase) (cmH_2O/mbar)	0 to 10 cmH_2O/mbar (1 cmH_2O/mbar). 0 to 20 cmH_2O/mbar (5 cmH_2O/mbar). 0 to 30 cmH_2O/mbar (5 cmH_2O/mbar). 0 to 40 cmH_2O/mbar (10 cmH_2O/mbar).

VENTILATOR ALARMS

Alarm specifications are grouped in three sections:

1. Adjustable alarms
2. Non-adjustable alarms
3. Alarm Features

A list of informational messages is provided at the end of this section. See Alarms, Section 6 for list of Device Alert violation messages.

Adjustable Alarms

Alarm	Description
Low MVE Alarm (expiratory minute volume)	Range: Ped/Infant: 0.01 to 9.99 L (resolution 0.01 L) 10.0 to 30.0 L (resolution 0.1 L) Adult: 1.00 to 9.99 L (resolution 0.01 L) 10.0 to 50.0 L (resolution 0.1 L) Accuracy: ±10% or ±0.1 L, whichever is greater **NOTE:** When Non Invasive is activated this alarm may be set to Off. **NOTE:** Violation of this alarm limit activates Back Up Ventilation (see the alarm specification for Back Up Ventilation) Low MVE alarm is suspended for 60 seconds once the breathing circuit is reconnected following pre-silencing alarms and disconnection for an intervention e.g. suctioning.

Alarm	Description
Back Up Ventilation (BUV) Alarm	An audible alarm sounds and the Alarms & Messages bar in the Graphical User Interface displays “Back up Ventilation” to indicate that the ventilator is supplying back up ventilation in response to a Low MVE alarm. If the current mode is A/CMV or SIMV: • Back Up Ventilation employs the current control panel settings except for Resp Rate • Resp Rate increases to 1.5 times the current setting (15 b/min minimum, 100 b/min maximum) If the current mode is SPONT, the ventilator delivers pressure control mandatory breaths with the following settings: • Plimit 15 cmH_2O/mbar above PEEP setting • t Insp 0.6 seconds Ped/Infant, 1.0 seconds Adult • Resp Rate 20 b/min Ped/Infant, 12 b/min Adult Changing any ventilation setting that affects mode, breath timing, flow/volume, pressure, or trigger sensitivity suspends back up ventilation for 60 seconds. It is also suspended for 60 seconds following Suction Disconnect function with breathing circuit disconnect then reconnect. (See the Suction Disconnect function description in this table.) **NOTE:** Back Up Ventilation audible and visual alarm continues while BUV is active and is cancelled when the monitored MVE exceeds the Low MVE alarm limit by 10%.
High MVE Alarm (expiratory minute volume)	Range: Ped/Infant: 0.02 to 9.99 L (resolution 0.01 L) 10.0 to 60.0 L (resolution 0.1 L) Adult: 2.00 to 9.99 L (resolution 0.01 L) 10.0 to 80.0 L (resolution 0.1 L) Accuracy: ±10% or ±0.1 L, whichever is greater
Low Paw Alarm (peak airway pressure)	This alarm is violated when the monitored circuit pressure does not reach the Low Paw alarm limit during two consecutive mandatory breaths (including Back Up Ventilation). It is not applicable during manual inflations or spontaneous breaths. Range: Ped/Infant: 3 to 75 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Adult: 3 to 95 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Accuracy: ±3% or ±2 cmH_2O/mbar, whichever is greater
High Paw Alarm (peak airway pressure)	Range: Ped/Infant: 5 to 100 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Adult: 5 to 120 cmH_2O/mbar (resolution 1 cmH_2O/mbar) Accuracy: ±3% or ±2 cmH_2O/mbar, whichever is greater A High Paw alarm violation terminates the current breath and cycles to expiration. This alarm is applicable for all breaths, including manual inflations.

Alarm	Description
High RR tot Alarm (High Respiratory Rate)	Range: OFF or 10-120 b/min Accuracy: +3% or +2 b/min, whichever is greater
Disconnect threshold Alarm (VTE% Variance)	Percent of difference between inspiratory and expiratory tidal volumes. Range: 20 to 95% Accuracy: +10% **Note**: When Non Invasive is activated this alarm may be set to Off.
Apnea Alarm	Alarm is violated when no breath or effort is detected within the set apnea interval. Range: 5 to 60 seconds Accuracy: ±1 second

Non-Adjustable Alarms

Alarm	Description
F_IO_2 High Alarm	When the monitored F_IO_2 is more than 0.07 above the set F_IO_2. Accuracy: ±0.03
F_IO_2 Low Alarm	When monitored F_IO_2 is more than 0.07 below the set F_IO_2. Accuracy: ±0.03
High Baseline Pressure Alarm	Monitored PEEP (Pbase) pressure is greater than set PEEP level by 5 cmH_2O/mbar for two consecutive breaths. Accuracy: ±1 cmH_2O/mbar
Low Baseline Pressure Alarm	When the monitored proximal pressure < low baseline pressure criteria (see Section 6/Alarms for criteria) for more than 0.5 seconds for two consecutive breaths. Accuracy: ±1 cmH_2O/mbar
Sustained High Baseline Pressure Alarm	Monitored circuit pressure Pbase has been ≥ 8 cmH_2O/mbar above set PEEP/CPAP for over 6 seconds for Ped/Infant patient or 10 seconds for Adult patient and machine pressure is also ≥ 8 cmH_2O/mbar above set PEEP/CPAP. Accuracy: ±1 cmH_2O/mbar **WARNING** Ventilation and triggering are suspended and the emergency relief valve opens to vent breathing circuit pressure until the alarm condition is no longer violated. Provide alternate means of ventilation until the alarm violation is resolved. Also, if e360 is in use on a patient and a bacterial filter is not in use on the inspiratory outlet, the inspiratory manifold must be removed, cleaned and sterilized before using e360 on another patient.
Flow Sensor Error Alarm	Flow sensor cannot calibrate or the internal wire is damaged or sensor is disconnected.
I:E Ratio Inverse Violation Alarm	Ventilator settings result in an I:E ratio greater than 4:1
Insp time too long Alarm	Ventilator settings result in an Inspiratory Time greater than 5 seconds

Alarm	Description
Insp time too short Alarm	Ventilator settings result in and Inspiratory time less than 0.1 seconds
***Volume Target Not Met Alarm** *on e360 Plus model	In Volume Target Pressure Control breath type the set tidal volume cannot be delivered within the set Pressure Limit.
Pressure Limit Below PEEP Alarm	The current Pressure Limit setting is lower than the PEEP/CPAP setting.
Low Paw Below PEEP Alarm	The current Low Paw alarm setting is lower than the PEEP/CPAP setting.
Gas Supply Alarm	If one or both gas supplies are below the operational pressure level an audible alarm sounds and the Alarms & Message bar displays alarm message. **WARNING** If Both Air/O_2 Supply Loss violation occurs, the emergency relief valve opens. If e360 is in use on a patient when this occurs and a bacteria filter is not in use on the inspiratory outlet, the inspiratory manifold must be removed, cleaned and sterilized before using e360 on another patient.
Device Alert Alarm	Unsilenceable audible alarm sounds if there is a ventilator malfunction (additional messages associated with a device alert are described in Appendix A). Also activated if less than 10% of internal battery operation time remains. **WARNING** If a Device alert occurs, the emergency relief valve opens. If e360 is in use on a patient when this occurs and a bacteria filter is not in use on the inspiratory outlet, the inspiratory manifold must be removed, cleaned and sterilized before using e360 on another patient.
O_2 Sensor Error Alarm	Alarm message is displayed and audible alarm sounds if the oxygen sensor fails.
Power Shutdown Alarm	When ventilator is powered off an audible alarm sounds. Silence by pressing Alarm Silence button.
Low Battery Alarm	Unsilenceable audible alarm sounds when internal battery capacity has dropped to 25% or less.
AC Power Loss / Battery Backup Alarm	Loss of Mains power
Check Vent Fan Alarm	Ventilator cooling fan failure
Setting/alarm limit Out of range Alarm	Alarm or setting parameter out of range for the selected patient category
Circuit Disconnect Alarm	Disconnect threshold level met. Alarm recovers when VTE % variance ≤ disconnect threshold. May be caused by large leak or disconnection of the patient circuit from the patient or ventilator.

Alarm Features

	Description
Alarm Silence	Mutes silenceable, audible alarms for 120 seconds. Pressing the Alarm Silence button again turns off the alarm silence function. This button will not silence a Device Alert alarm without first powering the ventilator OFF.
Alarm Reset	Clears visual indicators and messages for alarms that are no longer violated.
Alarm Loudness	Located on GUI. Press the Alarms Screen membrane button to display the alarms settings screen. Press the submenu button “Alarm Loudness” and use the Adjustment Knob to change the alarm volume.
Suction Disconnect Function	Holding down the Alarm Silence button for one second or longer (until the ventilator sounds a short beep) enables the Suction Disconnect Function. All silenceable alarms are silenced for two minutes. If the ventilator detects a circuit disconnect within 20 seconds it displays the message “Ventilation Suspended”. It does not deliver breaths until the breathing circuit is reconnected or three minutes elapse. See Section 4, Ventilator Operation, for more details.
External Alarm Silence Cable (optional accessory)	External Alarm Silence Cable is a 10 ft (3 m) cable with an Alarm Silence button at the end that can be connected to the back panel of the ventilator (EXTERNAL ALARM SILENCE connector). The External Alarm Silence cable is an extension of the Alarm Silence button, and differs only in that it cannot silence a power down alarm.

INFORMATIONAL MESSAGES

Messages are displayed on the GUI for the following conditions:

O_2 Sensor Disconnect	The O_2 sensor has been disconnected or disabled.
Ventilation Suspended	Displayed when the *Suction Disconnect Function* has been activated and the patient is disconnected from the ventilator (see *Suction Disconnect Function*).
All other Messages	For any message not described here see Section 6, Alarms, Device Alert Violation Messages, for more information.

PHYSICAL SPECIFICATIONS

	Description
Power Specifications	AC input range: 100 to 240 VAC, 300 VA maximum, 50/60 Hz (±10%) Internal battery: Fully charged battery can support approximately 60 minutes of complete ventilator function at the following standard settings: Adult, VC-SIMV, VT 500, FIO2 .30, Insp Time 1.0s, Resp Rate 15, PS 0, PEEP +5, Pause Off, Sigh Off, Square Wave. The ventilator recharges the internal battery whenever AC power is connected (whether the power switch is On or Off). Minimum recharge time: From Low Battery Alarm to Full = 5 hours From Empty to Full = 14 - 16 hours The ventilator indicates internal battery operation by beeping every 5 minutes. **Power Cord Requirements** In the USA, power cord must comply with UL2601. For 125 VAC, 15 A: 2-pole, 3-wire, 18 AWG, grounding-type, 5-15P hospital-grade plug cap, < 10 ft (3 m) long, CSA and UL-approved or For 250 VAC, 15 A: 2-pole, 3-wire, 18 AWG, grounding-type, 6-15P, hospital-grade plug cap, < 10 ft (3 m) long, CSA and UL-approved
Compliance	Complies with IEC 60601-1 with Amendments 1 & 2, C22.2 No 601.1-M90 and UL Std No 2601-1 Type B Applied Parts Rated battery voltage: 12 VDC Class I electrical-safety equipment Mode of operation: continuous operation (as per Clause 5.6) IPX0 rating (degree of protection against ingress of water)
Expiratory Channel Resistance	Pressure drop Less than 1.7 cmH_2O/mbar @ 50 L/min Adult Less than 1.7 cmH_2O/mbar @ 20 L/min Infant **NOTE:** Testing was performed according to ASTM F1100-90, section

	Description
Dimensions	Height: 14 in Width: 12 in Depth: 14 in
Display	6.4 in active matrix color LCD Touch screen Transparent plastic-covered glass. Pressure-sensitive surface can electronically decode touch position.
Environmental requirements	**Operating:** Temperature: 5 to 40 ºC Relative humidity: 10 to 95% Rh non-condensing Altitude: 0 to 13,124 feet (0 to 4000 meters) Pressure: 21 to 31 in. Hg (700 to 1060 hPa) **Storage:** Ambient temperature: -20 to 60º C (–68 to 140 ºF) Relative humidity: < 95% Rh non-condensing Altitude: 0 to 18,000 feet (0 to 5500 meters) Pressure: 15 to 31 in. Hg (500 to 1050 hPa) **NOTE:** Gas temperatures of > 40 ºC may adversely affect the performance of the e360.
Air and O_2 supply	inlet pressure: 30 to 90 psig, 50 psig nominal
External Alarm Silence	For connecting Newport's External Alarm Silence cable. The External Alarm Silence is an Alarm Silence button at the end of a 10 ft (3 m) cable. See Table 2-4 for more information on the Alarm Silence button and External Alarm Silence.
Remote Alarm	For attachment to a nurse call or remote alarm system. System Requirements: Normally Open Contact : 250 mA @ 100 VDC: Allowable current at maximum voltage between the relay contact < .2 ohms: Maximum initial contact resistance RS 232C: 9-pin D-shell, 38.4k baud. For use with central monitoring systems.
Patient circuit connections	Inspiratory and expiratory ports: 22-mm OD for connection to a patient breathing circuit.

	Description
Remote Alarm	Range: Normally Open (refers to the electrical continuity of the circuit) For attachment to a nurse call or remote alarm system. The purpose of the remote alarm is to alert a caregiver at a remote location (i.e. nursing station, outside of the patient's room, etc.) that there is an alarm violation on the ventilator. **System Requirements:** Normally Open Contact: Nurse call or remote system must operate as a normally open system 250 mA @ 100 VDC: Allowable current at maximum voltage between the relay contact < .2 ohms: Maximum initial contact resistance The REMOTE ALARM capability is based on a contact closure relay. The REMOTE ALARM connector located on the rear panel of the ventilator is a .25 inch (.0.64 cm) female mono phone-type connector. When an alarm violation occurs on the ventilator, the relay contact will reverse conditions, sending the signal to the nurse call or remote alarm system that there is a current alarm violation. When the alarm is no longer violated, the relay contact will go back to the original condition, canceling the alert to the nurse call or remote alarm system, i.e. the electrical circuit of a normally open contact becomes closed. The e360 Alarm Silence button will silence the audible portion of the alarm(s) from the ventilator. This will also cause the relay contact to go back to the original position, canceling the alert to the nurse call or remote alarm system. When the e360 is powered off, the relay contact will reverse conditions. This means that the interface cable between the ventilator and the nurse call or remote alarm system must be disconnected in order to reset the nurse call or remote alarm. **NOTE:** Always verify that the remote alarm function is operational following initial connection to the nurse call or remote alarm system. **NOTE:** Always use shielded cables for connection between the REMOTE ALARM and the nurse call or remote alarm system.

9. EXPLANATION OF MODES AND SPECIAL FUNCTIONS

* Available on e360 Plus model

The e360 offers a comprehensive selection of breath types and modes. This section describes each form of mandatory and spontaneous breath available within these selections.

BREATH TYPES

The e360 offers these breath types:
- *Volume Control*
- *Pressure Control*
- **Volume Target Pressure Control*

* Available on e360 Plus model

Volume Control

Each *Volume Control* mandatory breaths 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.

The *Flow Wave* pattern function is accessed via the *Advanced* Data Set. A square flow waveform pattern delivers the set flow constantly until the set tidal volume is delivered. A descending ramp flow waveform 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.

The Slope/Rise function is accessed via the *Advanced* Data Set. A pressure control inspiration terminates when the set *Inspiratory Time* has elapsed.

NOTE: On the e360 Plus model, when in Pressure Control, the Open Exhalation Valve feature can be turned ON via the Advanced Data Set on the GUI. See the end of this section for a description of the Open Exhalation Valve feature.

WARNING If the *Slope/Rise* control is set manually and is set too low, breathing circuit pressure may not reach the *Pressure Limit* value by end inspiration.

**Volume Target (Volume Target Pressure Control)*

*Available on e360 Plus model

Each *Volume Target Pressure Control* mandatory breath is delivered primarily according to the user-selected *Tidal Volume*, *Pressure Limit* and *Inspiratory Time* and is secondarily affected by *Respiratory Rate*, *PEEP/CPAP* and *Slope/Rise* (see *Pressure Control* above) 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 cmH_2O/mbar above *PEEP/CPAP* and the *Pressure Limit* setting. This is done 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 40% of the set pressure limit or *PEEP/CPAP* + 5 cmH_2O/mbar, whichever is larger.

Spontaneous breaths in *Volume Target Pressure Control* mode are *Volume Target Pressure Support* breaths.

WARNING If the Slope/Rise control is set manually and is set too low, breathing circuit pressure may not reach the target pressure by the end of inspiration.

VENTILATION MODES

Each breath type includes the choice of three modes:

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

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.

* Available on e360 Plus model

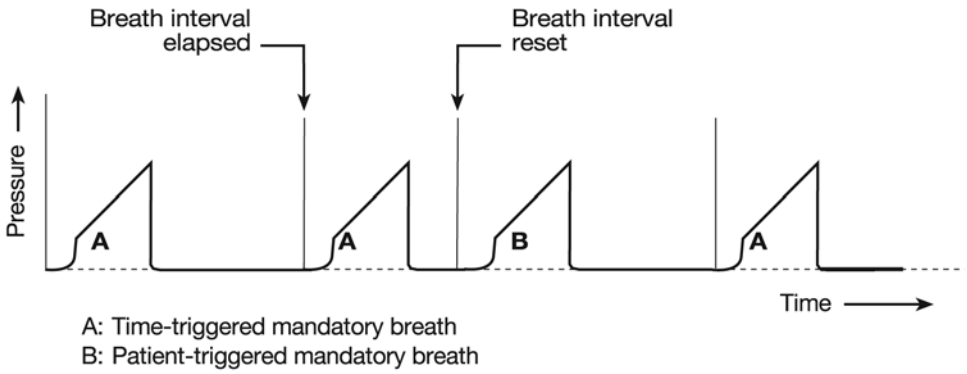


Figure 9-1. A/CMV Mode

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.

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. In any case, the 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.

* Available on e360 Plus model

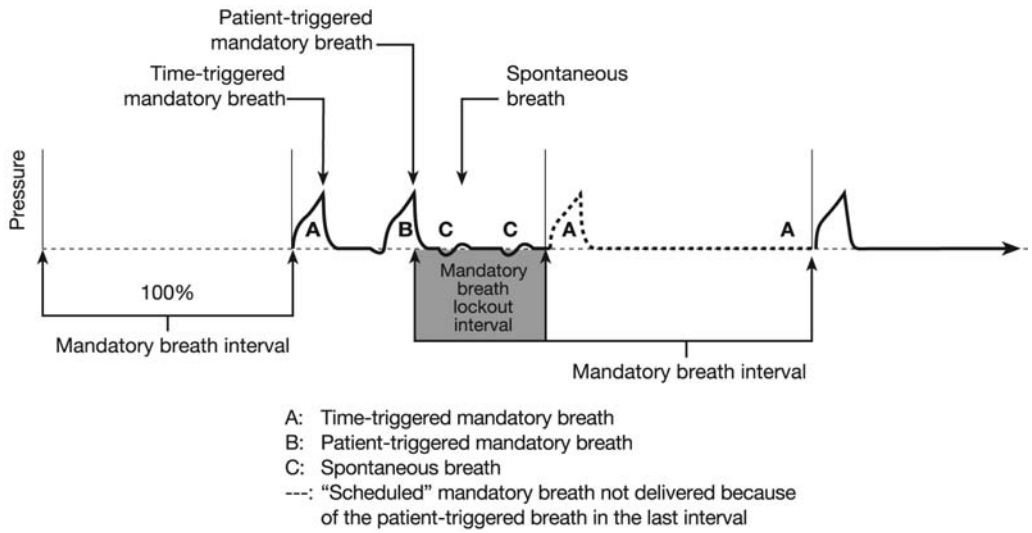


Figure 9-2. SIMV Mode

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.

* Available on e360 Plus model

SPONTANEOUS BREATH MANAGEMENT IN *SIMV* AND *SPONT* MODES

There are two forms of spontaneous breath assistance on the e360 ventilator: *Pressure Support* and **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*.

* Available on e360 Plus model

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 cmH_2O/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 cmH_2O/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 cmH_2O/mbar 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 target pressure of the first breath, when no target pressure has been established is 40% of the pressure limit or PEEP/CPAP + 5 cmH_2O/mbar, whichever is higher.

* Available on e360 Plus model

ADVANCED FEATURES & SPECIAL FUNCTIONS

- Slope/Rise
- Expiratory Threshold
- Leak Compensation
- Noninvasive Ventilation
- *Open Exhalation Valve

Slope/Rise

Slope/*Rise* is the term used to describe the e360 pressurization gain for *Pressure Control*, **Volume Target Pressure Control*, *Pressure Support* and **Volume Target Pressure Support Breaths*.

The user can choose a *Slope*/*Rise* value between 1 and 19 (resolution 1, where 1 is the slowest pressurization and 19 is the fastest). This function is accessed via the *Advanced* Data Set at the bottom of the GUI screen.

On e360 Plus model, an Auto option is available. The ventilator will automatically adjust the Slope/Rise within the established range, based on changing patient conditions, to attain target pressure quickly while preventing pressure overshoot.

The *Slope*/*Rise* selection is retained after power down.

* Available on e360 Plus model

Expiratory Threshold

Expiratory Threshold is the term used to describe the flow cycling-off threshold for *Pressure Support* and **Volume Target Pressure Support* breaths. Expiratory Threshold is expressed as a percent (%) of peak flow.

The user can choose an *Expiratory Threshold* value between 5 and 55% (resolution 1%) of peak flow. This function is accessed via the *Advanced* Data Set at the bottom of the GUI screen.

On e360 Plus model, an Auto option is available. The ventilator will automatically adjust the Expiratory Threshold within the established range, based on changing patient conditions.

The *Expiratory Threshold* selection is retained after power down.

Pressure Support and *Volume Target Pressure Support* (*VTPS*) breaths are cycled off based on attaining one of three thresholds: a percent (%) of peak flow (*Expiratory Threshold*), maximum Inspiratory Time (2.0 seconds for Adult, 1.2 seconds for Ped/Infant) or pressure overshoot, whichever comes first.

NOTE: See Figure 9-3, a graphical representation of the pressure overshoot cycling off threshold for *Pressure Support* and *Volume Target Pressure Support* breaths.

* Available on e360 Plus model

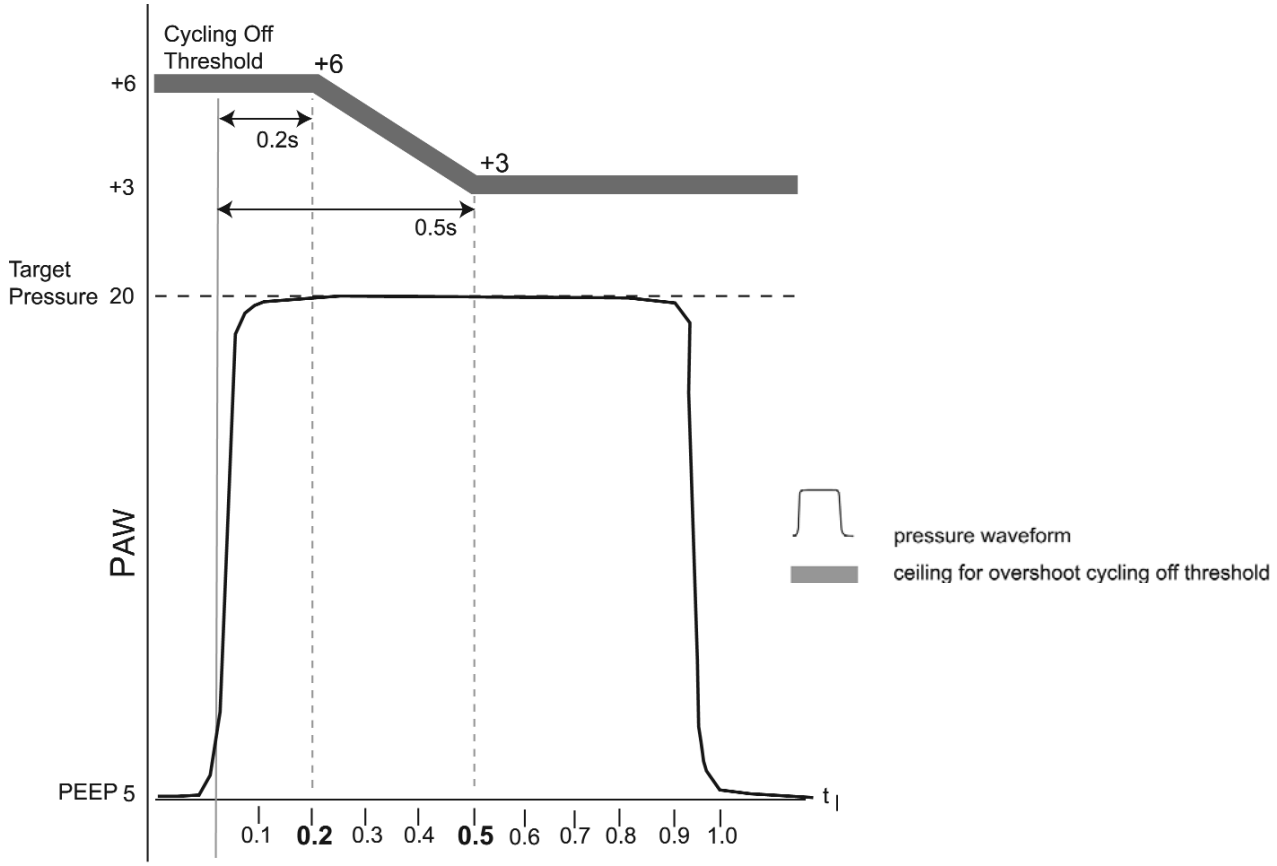


Figure 9-3. Pressure Cycling Off Threshold for Pressure Support and Volume Target Pressure Support Breaths

Leak Compensation (*Automatic Leak Compensation - Baseline Pressure Management*)

The e360 provides 3 L/min of bias flow through the breathing circuit in between breaths (i.e. during the exhalation period). This flow facilitates both flow triggering and the stabilization of baseline pressure and flow in order to minimize auto-triggering of breaths. The *LEAK COMP* (Automatic Leak Compensation/ Baseline Pressure Management) function allows the user to select whether or not they want the e360 to compensate for leaks over and above the 3 L/min bias flow. *LEAK COMP* is factory preset to ON and the selection is retained after power down.

When it is ON, e360 automatically adjusts the bias flow between 3 and 8 L/min for *Ped/Infant* selection and between 3 and 15 L/min for *Adult* selection, in order to maintain an end expiratory base flow of 3 L/min. When it is OFF, bias flow is 3 L/min regardless of leaks. If there is no leak, bias flow remains at 3 L/min whether *Leak Comp* is ON or OFF.

Compliance Compensation (Compl Comp)

Compliance Compensation (*Compl Comp*) can be selected On or OFF from the *Patient Setup* screen.

• *Volume Control Mandatory Breaths*

When *Compl Comp* is On, displayed *VTI* & *VTE* represent volume as if it were being monitored at the patient's airway. When *Compl Comp* is Off, *VTI* & *VTE* represent volume monitored at the main flow outlet and exhalation valve.

VTI & *VTE* displayed values will not look any different with *Compl Comp* On or Off even though *VTI* & *VTE* monitored values **are** different. Actual delivered/monitored values will be bigger with *Compl Comp* On. But you will not see it in the displayed value. The extra flow/volume that is added in and delivered to the patient in order to compensate for the volume that is "lost" in the tubing is subtracted from both the *VTI* & *VTE* displayed values.

Caution: The e360 circuit check determines how the much the e360 compensates for circuit compliance. If you have a bigger circuit and humidifier in place when you do the test it will result in more adjustment. A smaller circuit/humidifier will result in less adjustment. Make certain that the ventilator is set up exactly like it will be on the patient (including filters and water in the humidifier) when you do these tests or the displayed volumes will be incorrect during ventilation.

Non Invasive Ventilation (NIV)

The e360 Ventilator can be used for invasive (intubated patient) or noninvasive (mask) ventilation. When the "*Non Invasive*" button is activated on the front panel, e360 tailors the ventilator's performance (described below) to meet the needs of a patient who is breathing from a mask rather than an invasive artificial airway. *Non Invasive* can be used with any mode of ventilation. It is factory preset to OFF and the setting returns to off after power down.

Leak Compensation (Baseline pressure management) in Non Invasive

The *Non Invasive* function automatically provides leak compensation/baseline pressure management with a bias flow range of 3 to 25 L/min in order to accommodate the potential for bigger airway leaks around the non-vented mask. (When *Non Invasive* is OFF and Leak Comp is ON bias flow is only 3-8 L/min Ped/Infant and 3-15 L/min Adult.)

Alarms in Non Invasive

The Low MV_E and the Disconnect Threshold alarm, can be set to OFF while *Non Invasive* is activated. All other alarms such as the Apnea alarm remain operative and cannot be set to OFF. If the Low MV_E or Disconnect Threshold alarm is OFF when *Non Invasive* is deactivated, the alarms are automatically turned back on and the Low MV_E alarm is set to the lowest value while the Disconnect Threshold alarm is set to the highest value.

NOTE: To minimize the chances of auto-triggering due to leaks, Newport recommends using Pressure trigger (start at 2 cmH_2O/mbar for Adult and 1 cmH_2O/mbar for Ped/Infant) when using the e360 for non-invasive mask ventilation. Use a non-vented mask to ensure proper patient-ventilator synchrony.

Open Exhalation Valve
(for Biphasic Pressure Release Ventilation-BPRV)
*Available on e360 Plus Model

The Open Exhalation Valve is turned ON via the Advanced data set.

If a patient makes an expiratory effort, such as a cough, against a closed exhalation system (i.e., Open Exhalation Valve OFF) during the inspiratory phase of a pressure-controlled mandatory breath, airway pressure will rise above the target pressure. When Open Exhalation Valve is ON, the e360 Ventilator actively controls the exhalation valve so that excess pressure is vented out, the degree of pressure overshoot is minimized and airway pressure is maintained close to the target pressure.

This is referred to as “Biphasic Pressure Release Ventilation” (BPRV) and is considered more comfortable for patients on Pressure control with respiratory drive.

10. SAFETY CHECK PROCEDURE

The Safety Check Procedure is designed to help verify that the Newport e360 ventilator is operational. Newport recommends that you perform a complete Safety Check prior to the initial use of the ventilator and at least with every preventative maintenance interval. Perform the *Circuit Check* (from the Setup & Calibration screen) regularly and at the least with every patient breathing circuit change.

Use the e360 Safety Check Record at the end of this section to record the results of each Safety Check. The e360 Ventilator does a self-diagnostics test when powered on and verifies the operation of internal electronics.

Do not use the e360 ventilator if it does not pass every element of the Safety Check Procedure.

SET UP AND INSPECTION

1. Assemble the ventilator system as described in Section 3 of this manual.

2. Inspect the Newport e360 ventilator, Newport air compressor (if used), AC power cords, and verify that there is no evidence of wear or damage which might contribute to a malfunction.

3. Connect AC power cord(s) to properly grounded wall receptacles.

4. Inspect the high pressure air and oxygen inlet water traps on the back of the e360 to ensure that there is no water or debris present.

5. Ensure that the high pressure air and oxygen hoses are firmly tightened onto the ventilator inlet fittings.

6. Attach a recommended two-limb 22 mm breathing circuit and test lung. If using a humidifier, use only sterile water and fill the humidifier chamber prior to the Safety Check. Remember to choose an appropriate Circuit Type selection in *Patient Setup* prior to patient use.

7. Inspect the patient breathing circuit, humidifier/chamber, and all connections to verify that there is no evidence of wear or damage which might result in leaks and/or contribute to ventilator malfunction.

8. Choose *Adult* patient category from the *Patient Setup* screen on the GUI.

EMERGENCY INTAKE VALVE

1. Make sure the e360 power is turned Off on the back of the ventilator.

2. Verify that air can be drawn into the patient breathing circuit through the emergency intake valve. You may create a negative effort on the inspiratory limb of the patient breathing circuit by (1) using a “bellows” type test lung, or (2) inspiring through a barrier filter on the inspiratory limb of the patient circuit.

WARNING: Newport Medical Instruments strongly recommends that you use a clean/disinfected breathing circuit and bacteria filter(s) on the ventilator before breathing through the circuit.

CIRCUIT CHECK

1. Connect the high pressure oxygen hose from the oxygen inlet water trap on the back of the Newport e360 to a 50 ± 10 psig gas source provided by either a gas cylinder or a wall outlet.

2. If the Newport air compressor is the compressed air gas source, connect the high pressure air hose from the air inlet water trap on the back of the Newport e360 to the outlet of the air compressor.

3. Toggle the compressor power switch to the On position and verify its function.

4. If the Newport air compressor is not in use, connect the high pressure air hose from the back of the e360 to a 50 ± 10 psig gas source provided by a gas cylinder or a wall outlet.

5. To start a Circuit Check, locate the power switch on the back of the ventilator and push the power rocker switch to the On position.

6. When the Graphic User Interface (GUI) powers on, the ventilator will be ready to start a Circuit Check test. Follow the on-screen instructions. Do not use a test lung to occlude the circuit for the Circuit Check. Following the completion of the test, a message will show that the test has passed or failed. If the circuit test failed, resolve all circuit tubing connections and exhalation valve leaks and repeat test.

GAS SUPPLY ALARMS

Set ventilator to STANDARD TEST SETTINGS:

VOLUME CONTROL
Mode: A/CMV
Waveform: Square
Resp Rate: 10
Flow˙: 30 L/min or *t Insp* = 1.0 sec
Tidal Volume: 500 mL
FIO2: .21
Pressure Trig: 5.0 cmH_2O/mbar
PEEP: 0 cmH_2O/mbar
High/Low Paw Alarms: 70/5
High/Low MVE Alarms: 6.0/2.0
Apnea: 20 seconds
Disconnect Alarm: 75%

1. Attach a recommended test lung (LNG800P) or equivalent (500 mL test lung with embedded RP20 resistor).

2. Make certain there are no holes in the test lung and touch the "Start Ventilating" button on the GUI.

3. Adjust the F_IO_2 to .23. Disconnect the high pressure oxygen hose from the gas source. Verify that e360 provides an audible alarm and visual O_2 Supply loss alarm message.

4. Reconnect the high pressure oxygen hose to the gas source. Verify that the alarm is no longer violated. Push *Reset* to clear visual message and indicator. Return the F_IO_2 to .21.

5. Disconnect the high pressure air hose from the gas source. Verify that e360 provides an audible and visual alarm and *Air Supply Loss* alarm message.

6. Reconnect the high pressure air hose to the gas source. Verify that the alarm is no longer violated. Push *Reset* to clear visual message and indicator.

AC POWER LOSS/BATTERY BACKUP ALARM

1. While the ventilator is operating, unplug the AC power cord from the wall outlet. Verify that the ventilator continues functioning and provides both an audible and a visual alarm, the *Int Battery* (Internal Battery) indicator lights and the message *AC Power Loss Battery Back Up* appears in the window.

2. Plug the AC power cord back into the wall outlet. Verify that the ventilator continues functioning, the *Int Battery* indicator goes out and the *Mains* (*Battery Charging*) indicator lights.

3. Push *Reset* to clear visual messages and indicator.

HIGH/ LOW AIRWAY PRESSURE ALARMS / DISCONNECT / ALARM SILENCE

1. Remove the test lung. Verify that both visual and audible *Low Paw* (low airway pressure) alarms are violated after 2 mandatory breaths and after 3 breaths the *Disconnect* alarm message is displayed.

2. Press the *Alarm Silence* button and verify that the audible alarm is muted but the alarm indicator continues to blink.

3. Press the *Alarm Silence* button again and verify that the audible alarm resumes beeping and the *Low Paw* alarm message is displayed.

4. Re-attach the test lung. Verify that the audible alarm stops and the alarm indicator is steadily lit (latched).

5. Press the *Reset* button to clear the alarm message and visual indicator.

6. Remove the test lung and occlude the patient wye of the breathing circuit. Verify that both the visual and audible (high airway pressure) alarm is violated.

7. Re-attach the test lung to the wye connector. Verify that the audible alarm stops and the alarm indicator is steadily lit.

8. Press the *Reset* button to clear the *High Paw* alarm message and indicator.

MINUTE VOLUME / BACK UP VENTILATION / APNEA ALARMS

1. Adjust the *Resp Rate* to 20 b/min. Verify that both audible and visual *High MVE* (*Exhaled Minute Volume*) alarms are violated within 30 seconds.

2. Adjust the *Resp Rate* back to 10 b/min. Verify that within 30 seconds the audible alarm stops and the visual alarm indicator is steadily lit. Press the *Reset* button to clear the *High MVE* alarm message and indicator.

3. Adjust the *Resp Rate* to 1 b/min. Verify that within 30 seconds the audible and visual alarm is violated, an APNEA message is displayed, and the *Low MVE* alarm is violated. Verify that after 65 seconds, Back Up Ventilation begins and is indicated with a *Back Up Ventilation* message on the Alarms & Messages display.

4. Verify that within 30 seconds following the start of Back Up Ventilation the alarm indicators are steadily lit signifying the end of Back Up Ventilation. Adjust the Resp Rate to 10 b/min. Press the *Reset* button to clear the messages and indicators.

TRIGGER/PRESSURE SUPPORT

1. Set *High MVE* alarm to 12, Mode to *SPONT*, *Pressure Support* to 10, *PEEP* to 3, *P Trig* to 2.0.

2. Briefly squeeze the test lung to create a negative pressure in the breathing circuit. Verify that the green patient effort indicator “blinks”, and that a pressure support breath is delivered.

3. Select *Flow trig* and set to 2.0 and repeat step 2.

4. Set Mode to *A/CMV*, *PEEP* to 0 and *trig* to P = 5.0 cmH_2O/mbar. All other controls should still be at Standard Settings.

VOLUME/FLOW/RATE ACCURACY TEST

1. Change the ventilator display (GUI) to the Numeric screen (via Main Screen) to see the monitored exhaled tidal volume VTE. Verify that monitored value is within + 20% of the *Tidal Volume* setting on the front panel.

2. Observe the *Insp Flow* display and verify that the measured value is within + 5 L/min of the *Flow* setting on the front panel.

3. Observe *RRtot* (monitored total breath rate) on the Numeric Screen and verify that the monitored value is within + 1 b/min of the *Resp Rate* setting after 30 seconds.

SHUT DOWN ALARM

1. Switch the e360 power to Off. Verify that the audible Shut Down alarm activates.

2. Press the Alarm Silence button. Verify that the alarm is silenced.

The following e360 Safety Check Record can be used to record the results of each step of the safety check.

e360 SAFETY CHECK RECORD

Pre-Use Checks Results

Set Up and Inspection	Pass _____	Fail _____
Emergency Intake Valve	Pass _____	Fail _____
Circuit Check	Pass _____	Fail _____
Gas Supply Alarms	Pass _____	Fail _____
AC Power Loss/Battery Backup Alarm	Pass _____	Fail _____
Pressure Alarms, Disconnect and Alarm Silence	Pass _____	Fail _____
Minute Volume, Back Up Vent and Apnea Alarms	Pass _____	Fail _____
Trigger/Pressure Support	Pass _____	Fail _____
Volume/Flow/Rate Accuracy	Pass _____	Fail _____
Shut Down Alarm	Pass _____	Fail _____

Comments re: inspection, corrective action taken, or suggestions for further action.

_____

_____

Completed by: _____

Date: _____

Unit hours: _____

A

B

C

D

E

F

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H

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L

M

N

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P

R

S

T

V

W