Operating Manual
For Model e360S-US
OPR360US Rev. H
07/11

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The information in this manual is the sole property of Newport Medical Instruments, Inc. and may not be duplicated without permission. This manual may be revised or replaced by Newport Medical Instruments, Inc. at any time and without notice.
Figure F-1: Newport e360 Ventilator with Accessories

Figure F-2: Newport e360 Rear Panel

1. Oxygen Inlet
2. Air Inlet
3. Remote Alarm Connection
4. Alarm Speaker
5. External Alarm Silence
6. On/Off Power Switch
7. RS232 Connection
8. VGA Connection
9. USB Connection
10. Cooling Fan
11. Equipotential Ground Stud
12. AC Power Connection
13. Fuse Drawer
14. External Battery Connection

Figure F-3: GUI Navigation Map

- Alarms Screen
  - High PAw
  - Low PAw
  - High MVR
  - Low MVR
  - High RR
  - Alarm
  - Disconnected Triggers
  - Alarm History
  - Alarm Loudness
  - Alarm Tones
  - Save

- Main Screen
  - Waves
  - Logs
  - Numerics
  - Trends
  - Freeze/Save

- Extended Functions
  - Imp.Holt
  - Stay.Holt
  - Event.History
  - Save
  - Freeze

- Setup & Calibration
  - Circuit Check
  - Sensors
  - Patient Setup
  - Technical

- Patient Setup
  - Patient Type
  - Ideal Weight
  - Respiratory Rate
  - Volume Units
  - IMV, VT
  - SpO2
  - Sign
  - Great Tissue
  - Lead Comp.
  - Gauged, Comp.

- Circuit Check
  - Lack of VIOM
  - Blown Fuse
  - Resistance Test
  - Low Sensor Calibration
- Technical
  - Current Protocol
  - Display Brightness
  - Event History File
  - Data Format
  - Year Adjust
  - Month Adjust
  - Day Adjust
  - Hour Adjust
  - Minute Adjust
  - Regional
  - Units
Check power on. Do not use a test lung to block the patient wye for the circuit check test.

1. Attach complete breathing circuit
2. Occlude circuit Y-piece
3. Press Circuit Check button to begin

NOTE: The Circuit Check is only available in the 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 the Standby condition.
# Table of Contents

## 1 Introduction
- Device Description
- Intended Use Information
- About this Manual
- Typing Conventions
- Software Versions
- Service Guidelines
  - Regular Service
  - Complete Service Records
- Disclaimers
- Warnings
  - General Warnings
  - Filter Warnings
  - Power Supply Warnings
  - Gas Warnings
  - Auxiliary Equipment Warnings
- Cautions
- Warranty Information
- Responsibility for Patient Safety
- Limitation of Liability

## 2 Overview
- Ventilator System Overview
- Control Panel Layout and Labeling
- Graphical User Interface (GUI) and Controls
  - Navigation Map for GUI Menus
- Lower Front Panel Layout
- Rear Panel Layout
- Navigating the Control Panel
  - Using Touch-Turn-Accept
  - Selecting Mandatory Breath Type and Mode
- Non Invasive Function
- Patient Triggering Methods
- Basic Ventilation Controls
- Flow or Insp Time in Volume Control
- Manual Inflation Button
- O2 3 Minute Button
- Alarm Silence Button
- Suction Disconnect Function
- Alarm Reset
- Graphical User Interface (GUI) Screens
  - Alarms Screen
  - Main Screen
  - Extended Functions Screen
  - Setup & Calibration Screen
- GUI Miscellaneous Indicators
- Internal Battery
# Table of Contents

## 3 Unpacking, Assembly, and Safety Check

- Unpack the Ventilator
  - List of Package Contents
- Assembly
  - Exhalation Valve Compartment
  - Connect Air, Oxygen and AC Power
  - Install the Breathing Circuit System
- Safety Check Procedure
  - Setup and Inspection
  - Emergency Intake Valve
  - Circuit Check
  - Gas Supply Alarms
  - AC Power Loss/Battery Backup Alarm
  - High/Low Airway Pressure Alarm/Circuit Disconnect Alarm/
    Alarm Silence
  - Minute Volume/Back Up Ventilation/Apnea Alarms
  - Trigger/Pressure Support
  - Volume/Flow/Rate Accuracy Test
  - Shut Down Alarm
- Safety Check Record Sheet

## 4 Setting Up for Patient Use

- Power Conditions
  - Shutdown Alarm
- Overview: Preparing for Patient Ventilation
- Setup & Calibration Menu
  - Circuit Check
  - Oxygen and Flow Sensors
    - Exhalation Flow Sensor, Calibration
    - Oxygen Sensor, Calibration
    - Oxygen Sensor, Disable
  - Patient Setup
    - Patient Category
    - Weight Units
    - Ideal Weight
    - Volume Units
    - Sigh
    - Circuit Type
    - Leak Comp (Leak Compensation)
    - Compl Comp (Compliance Compensation)
- Technical
  - Comm (Communications) Protocol
  - Display Brightness
  - Regional Settings
    - Altitude
  - Date Format
  - Date and Time
Table of Contents

Screen Files
Event History Files
Ventilator Controls Guide
Ventilator Settings in Advanced Data Set
  Slope/Rise
  Expiratory Threshold
  Pause
  Flow Waveform
  Volume Target
  Open Exhalation Valve
Inspiratory and Expiratory Hold Maneuvers
P0.1 Measurement Function
Negative Inspiratory Force (NIF) Maneuver
Waves and Loops Display
  Adjusting Scale
  Auto Scale
  Using the Freeze Function
  Using the Cursor in Freeze
Event History Screen
Numerics Screen
Trends Screen
Data Sets
Save Feature
Download Feature

5 Alarms

Introduction
Visual Alarm Displays
  360° Alarm Lamp
  Alarm and Message Display
  Device Alert LED
GUI Alarm Screen Environment
  Alarm Settings Screen
    Saving the Alarm Settings Screen
  Adjustable Alarms
  Alarm History
    Saving the Alarm History Log
  Alarm Loudness
  Alarm Tones
  Exiting Alarm Screens
Front Panel Alarm Interface Environment
  Alarm Silence Button
  Suction Disconnect Feature
  Alarm Reset Button
Non-Adjustable Alarms
  Alarm Violation and Remedy Guide
## 6 Cleaning and Maintenance

**Introduction**

Use of Filters
- Inspiratory (To Patient) Port
- Expiratory (From Patient) Port

Disassembly and Reassembly Procedures
- Rear Panel Fan Filter
- Exhalation Manifold
  - Exhalation Flow Sensor
  - Exhalation Valve
- Inspiratory Manifold
- Oxygen Sensor
- Fuses

Cleaning

Sterilizing
- Autoclave Sterilization
- EtO Sterilization

Guide to Cleaning and Sterilizing
Guide to Preventive Maintenance
Storing the Ventilator
Repackaging the Ventilator

## 7 Explanation of Modes, Breath Types and Special Functions

**Introduction**

Settings Functions
- Timing Limitations to Ventilation Controls
- Control Retention
- Control Range

Mandatory Breath Types
- Volume Control
- Pressure Control
- Biphasic Pressure Release Ventilation
- Volume Targeted Pressure Control

Spontaneous Breath Management in SIMV and SPONT
- Pressure Support
- Volume Targeted Pressure Support

Ventilation Modes
- A/CMV
- SIMV
- SPONT (Spontaneous)

Advanced Features and Special Functions
- Bias Flow
- Slope/Rise
- Expiratory Threshold and FlexCycle
- Leak Compensation
Table of Contents

Compliance Compensation
Non-Invasive Ventilation-NIV
Leak Compensation in NIV
Alarms Settings in NIV

8 Specifications
Alarms, Controls, Monitored Data, Setup & Calibration
Physical Specifications

Foldout Diagrams

Front
F-1  e360 Ventilator System and Accessories
F-2  e360 Rear Panel
F-3  Graphical User Interface (GUI) Navigation Map
F-4  Control (Front) Panel
F-5  Circuit Check Screen

Rear
F-6  Main Screen
F-7  Extended Functions Screen
F-8  Alarms Screen
F-9  Event History Screen
F-10  Technical Screen
F-11  Patient Setup Screen
Section 1: Introduction

Device Description ................................................1-1
Intended Use Information ................................1-2
About this Manual .........................................................1-2
Typing Conventions ................................................... 1-3
Software Versions ................................................ 1-4
Service Guidelines .................................................. 1-4
   Regular Service .................................................. 1-4
   Complete Service Records .................................. 1-4
Disclaimers .............................................................. 1-4
   Warnings ........................................................ 1-5
   General Warnings ............................................... 1-5
   Filter Warnings .................................................. 1-6
   Power Supply Warnings ....................................... 1-7
   Gas Warnings .................................................... 1-8
   Auxiliary Equipment Warnings ............................. 1-8
Cautions ....................................................................... 1-8
Warranty ...................................................................... 1-9
Responsibility for Patient Safety .............................. 1-10
Limitation of Liability ................................................. 1-11
Device Description

The e360 Ventilator is a high performance ventilator that is easy to use and maintain. The e360 features a dual servo gas delivery system, 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 set FIO2. 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, an RS232 interface to connect to central monitoring systems, a VGA port to connect to an external monitor, and USB port for uploading software and downloading saved files.

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, measures circuit compliance and resistance, and calibrates the exhalation flow sensor. 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 for O2 monitoring, O2 and Flow Sensors, Low Baseline Pressure, High Baseline Pressure, Sustained High Baseline Pressure, Ventilator settings violations, Low Battery, 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, patient pressures (peak, plateau, mean airway, and baseline), and pulmonary mechanics.

During exhalation, the e360 uses a bias flow to flush exhaled CO2 and stabilize temperature, humidity, and baseline pressure in the patient breathing circuit. A stable baseline pressure between breaths helps to minimize auto-triggering.
Introduction

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.

![Figure 1-1 Newport e360 Ventilator](image)

Intended Use Information

The e360 Ventilator System is intended to provide invasive or noninvasive ventilatory support and monitoring for infant, pediatric, and adult patients with respiratory failure or respiratory insufficiency.

The e360 Ventilator System is for use by prescription only. Only those who are professional healthcare providers with training in the use of this ventilator system and experience with providing ventilator support should use it.

The e360 Ventilator System is for use in hospitals, healthcare facilities, or during intra-hospital transport.

Specific details about the intended use environment are available in Section 8 Specifications.

About this Manual

Foldout Drawings

Foldout pages containing frequently referenced diagrams are placed in the front and rear of this manual. These foldouts are designed for easy reference while reading the manual and are designated as Foldout F-X. Foldouts F-1 to F-5 are located on the front foldout page and Foldouts F-6 to F-11 are located on the rear foldout page.
Introduction

Section 1- Introduction
This section contains information about the safe use of the e360 Ventilator system, information about this manual, general warnings and cautions, and warranty information.

Section 2- Ventilator Overview
This is the road map and directions for getting where you need to go. This section summarizes the elements of the ventilator system, controls, and functions.

Section 3- Unpacking, Assembly and Safety Check
This is the “putting it together/setting it up” section-use this as a guide to setting up the ventilator for the first time and performing a safety check. A sample record sheet is provided for documenting the results of the safety check.

Section 4- Setting Up for Patient Use
This is the “how to use” section. It will guide you through setting up the ventilator for patient use and managing commonly used features during ventilation.

Section 5- Alarms
This contains information related to the alarm systems and alarm troubleshooting.

Section 6- Cleaning and Maintenance
Make sure to follow these guidelines for cleaning, reprocessing, keeping the ventilator system in working order, storing, and packaging for shipment.

Section 7- Explanation of Modes, Breath Types and Special Functions
This is the “how does it work” reference section of the manual to give you a general description of the e360 breath types, modes and special functions.

Section 8- Specifications
This is where you will find ranges, physical dimensions, and information about settings, controls, alarms, and displays.

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).

WARNING! A Warning describes a condition that can cause personal injury.
Introduction

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

NOTE: A Note emphasizes information that is important or adds convenience.

Software Version

This manual applies to software version 7.0 and later for the e360 Ventilator System. The software version is listed at the top of the Event History Log, i.e. USR7.0.

Service Guidelines

Regular Service
Service must be provided at regular intervals by professionals who have received training specific to the maintenance and repair of the Newport e360 Ventilator.

Complete Service Records
All service performed on the e360 Ventilator System must be recorded in a service log in accordance with hospital procedures and local and national regulations.

Disclaimers

Newport Medical has no responsibility for the safe operation of the e360 Ventilator System if the intended use, intended user, and intended use environment requirements specified in this document are not followed.

Newport Medical has no responsibility for the safe operation of the e360 Ventilator System if operating instructions and maintenance specified in this document are not followed or if service maintenance or repairs are performed by persons who have not received the appropriate professional training.

Newport Medical 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 Medical or by other manufacturers, if such a combination is not endorsed by Newport Medical.
Warnings

Follow these safety guidelines. Additional warnings appear in context throughout this document.

General Warnings
All ventilator controls and alarm limits must be appropriate for the patient’s condition, according to the therapy prescribed by a physician.

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.

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.

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 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 disabled, defective or missing oxygen sensor.

Always ensure that the caregiver can hear the audible alert when the alarm sounds. Do not use the ventilator in an environment where audible alarms cannot be heard by the caregivers.

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 clean breathing circuits.

Dispose of waste products, residue, etc., in accordance with the appropriate regulatory requirements and facility policy.

Follow your institutions infection control policy.

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.

Filter Warnings
At all times during patient use, keep clean, dry filters in the following locations to protect the patient and the ventilator:

1. Between the Inspiratory (To Patient) Port and the inspiratory limb of the circuit.
2. Between the expiratory limb of the circuit and the Expiratory (From Patient) Port.

If a clean, dry filter is not used on the Expiratory (From Patient) Port, sterilize the exhalation valve and the expiratory flow sensor between every patient use.

If a clean, dry filter is not used on the Inspiratory (To Patient) Port, sterilize the inspiratory manifold between patients should any of the following occur during patient ventilation:

- Device Alert Alarm
- Both Air/ O2 Supply Loss Alarm
- Sustained High Baseline Pressure Alarm

(These are alarms which cause the emergency intake relief valve and exhalation valve to open.)

Active humidification, nebulization or instillation of medications or liquids could result in moisture accumulation in the expiratory (From Patient) filter. This could result in the following:

- Ineffective filtration
- Expiratory volume monitoring inaccuracies
- Damage to the Expiratory Flow Sensor
- Increased resistance to patient exhalation
- Exhalation system obstruction

Change/discard dirty or wet filters in accordance with the recommendations of the filter manufacturer as well as the policy of your facility.

Handle filters carefully to minimize the risk of infection as well as damage to filters.
Introduction

Do not submerge filters in liquids of any kind.

Between uses, reusable filters must be steam autoclaved and then checked for resistance, according to the manufacturer’s instructions.

**Power Supply Warnings**

To maintain grounding integrity, connect the ventilator only to a hospital-grade receptacle.

Always disconnect the ventilator from power before servicing.

Do not use electrically conductive breathing circuit tubing.

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

To ensure that the internal battery remains functional, fully recharge the battery at least every 2 months when the ventilator is not in use.

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.
Introduction

Gas Warnings
Danger: There is a risk of explosion if used in the presence of flammable anesthetics. The system is not intended for use with anesthetic gases.

Use only dry clean, particle-free compressed air.

Oxygen source gas must be medical grade, 100% oxygen.

Auxiliary Equipment Warnings
Newport Medical 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.

Cautions

Follow these safety guidelines. Additional cautions appear in context throughout this document.

Use only fuses with the correct rating.

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 ventilator.

Do not place liquids on or near the ventilator.

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

The Exhalation Flow Sensor is a precise and delicate instrument. Take care when handling not to disturb the measuring wires. Do not insert any object into the flow sensor, nor direct pressurized flows of liquids or gases through the sensor during cleaning and reprocessing. 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.
Warranty

The Newport e360 Ventilator System is warranted to be free of defects for a period of two (2) years from invoice date of purchase.

The following are exceptions to this warranty:

- Defects caused by misuse, mishandling, tampering, or by modifications not authorized by Newport Medical or its representatives are not covered.
- Rubber and plastic components and materials are warranted to be free of defects at time of delivery.
- The exhalation flow sensor is warranted to be free of defects at time of delivery. After initial use, the flow sensor is not covered by this warranty.
- The O₂ sensor is covered for a period of six months from the invoice date of the e360 purchase.
- The internal battery is covered for a period of six months from the invoice date of the e360 purchase.
- Accessory items, not manufactured by Newport Medical, supplied with the ventilator are warranted in accordance with the original manufacturer’s warranty. These include (but are not limited to) items such as humidifiers, nebulizers, monitors, and patient circuits.

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

Application of this warranty is subject to the following conditions:

- Newport Medical or its authorized representatives must be promptly notified upon detection of the defective material or equipment. This can be accomplished by filling out the online complaint form at www.ventilators.com.
- Defective material or equipment must be returned to Newport Medical or its authorized representative.
- Examination by Newport Medical or its authorized representatives must confirm that the defect is covered by the terms of this warranty.
Introduction

- This warranty is applicable to the original purchaser/facility and is non-transferable.
- Repairs, maintenance or servicing of the Newport e360 Ventilator by personnel other than Newport Factory Trained Technicians or authorized representatives will void this warranty.

In order to assure complete protection under this warranty the customer must register the product within ten (10) days of receipt of the equipment by visiting the Newport Medical website and filling out the product registration form at www.ventilators.com.

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

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

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 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 Medical 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 Medical or by other manufacturers, if such a combination is not endorsed by Newport Medical.

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 Medical, 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 Medical’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 Medical 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 non-infringement.

Newport Medical 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.
Section 2: Overview
Section 2: Overview

Ventilator System Overview ........................................2-1
Control Panel Layout and Labeling ...............................2-1
Graphical User Interface Display (GUI) and Controls .................................................................2-1
  Navigation Map for GUI Menus .................................2-1
Lower Front Panel Layout ............................................2-1
Rear Panel Layout .......................................................2-2
Navigating the Control Panel ........................................2-2
  Using Touch - Turn - Accept .....................................2-2
  Selecting Mandatory Breath Type & Mode ..................2-3
Non Invasive (Ventilation) (NIV) Function ...................2-3
Patient Triggering Methods ..........................................2-4
Basic Ventilation Controls ..........................................2-4
Flow or Inspiratory Time in Volume Control ................2-4
Manual Inflation Button .............................................2-4
O2 (3 min) Button .....................................................2-5
Alarm Silence Button ................................................2-5
Suction Disconnect Function ......................................2-5
Alarm Reset ............................................................2-5
Graphical User Interface (GUI) Screens ......................2-5
  Alarms Screen ......................................................2-5
  Main Screen ........................................................2-6
  Extended Functions Screen ....................................2-6
  Setup & Calibration Screen ..................................2-6
GUI Miscellaneous Indicators ....................................2-6
Internal Battery .......................................................2-7
Ventilator System Overview

The user controls the ventilator settings by using the graphical user interface, membrane buttons and rotary adjustment knob. Ventilation delivery is continuously monitored and controlled by a servo-controlled feedback system. When there is a difference between the measured value and the target value, e360 adjusts gas delivery so that the target value is achieved. The system uses two gas modules. When air and O2 are both connected to the ventilator, the system mixes the gases according to the user adjustment for FIO2. Gases may be supplied by a medical pipeline system, a compressor, or by gas cylinders.

Control Panel Layout and Labeling

Please refer to Foldout F-4 for a sample of the e360 English language control panel.

The e360 Ventilator Control Panel is made up of a Graphical User Interface (GUI) touch screen, membrane buttons, rotary dial, and indicator LEDs/lights. The panel may be ordered with different labeling options which include various languages or an all symbols panel.

Graphical User Interface Display (GUI) and Controls

The e360 Graphical User Interface allows the user to quickly navigate through a number of screens to access monitoring, custom set-up, automated calibrations, numerics, waveforms and loops.

Please refer to Foldout F-4 for a sample of the GUI screen and description of its controls.

Navigation Map for GUI Menus

Please refer to Foldout F-3 for a flow chart of the GUI menu navigation.

Lower Front Panel Layout

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. See Figure 2-1.
Overview

Rear Panel Layout

The e360 rear panel contains the On/Off power switch, Air/Oxygen inlets, and other connections for various external devices.

Refer to Foldout F-2 for rear panel view and description of connections.

**NOTE:** Make sure that the e360 is completely shutdown before the power switch is turned on again. If the power switch is turned off and then on too quickly and the screen does not load correctly, turn the power off and wait 15 seconds before powering ON the ventilator.

Navigating the Control Panel

Refer to Foldout F-4 for a full view of the e360 Control Panel functions described here.

**Using Touch - Turn - Accept**

Most ventilation and alarm controls on the Control Panel and the GUI are adjusted with the Touch-Turn-Accept method. There are a few exceptions which are noted with the description of the control.
Touch a parameter control on the GUI or press a parameter membrane button on the Control Panel; then,

Turn the *Adjustment* knob (Foldout F-4, Item 9) to make a change; and,

Press the *Accept* button (Foldout F-4, Item 10) to confirm and 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.

**Selecting Mandatory Breath Type and Mode**

Refer to Foldout F-4, item 12.

**NOTE:** More specific information on modes and breath types is available in Section 7.

The mandatory breath type and mode are displayed in the upper left corner of the GUI. Spontaneous breath type is pre-selected based on the mandatory breath type.

Modes are selected by pressing the *Volume Control or Pressure Control* breath type buttons repeatedly until the desired mode is highlighted.

Biphasic Pressure Release Ventilation (BPRV) is selected by choosing *Pressure Control A/CMV* or *SIMV* mode and then selecting *Open Exhalation Valve* from the *Advanced* Data Set GUI screen. See Data Sets, Section 4, for more information.

Volume Target Pressure Control (VTPC) is selected by choosing a *Volume Control or Pressure Control A/CMV* or *SIMV* mode and then selecting *Volume Target ON* from the *Advanced* Data Set GUI screen. See Advanced Data Sets in Section 4 for more information.

See the Ventilation Controls Guide in Section 4 for a full list of breath type and mode combinations.

**Non Invasive (Ventilation) (NIV) Function**

Refer to Foldout F-4, item 11.

To activate the NIV function in any mode or breath type, press the *Non Invasive* button (the indicator will light) and then press *Accept*. Non Invasive always reverts to *OFF* when e360 is powered down (the setting is not retained). See Section 7 for more information on Non Invasive function.
Overview

Patient Triggering Methods

Refer to Foldout F-4, item 8.

The ventilator offers the clinician the choice of flow or pressure (P) triggering for patient-initiated breaths in all modes of ventilation. To select Flow or P, press the Trig button (LED lights) and then press Accept.

Basic Ventilation Controls

Refer to Foldout F-4, item 8.

To set FiO₂, Tidal Volume, Flow, Inspiratory Time (t Insp), Respiratory Rate (Resp Rate), Pressure Support, Pressure Limit, PEEP/CPAP and Trigger (flow or pressure (P)):

1. Press the button below the corresponding display to select a parameter.
2. Rotate the Adjustment knob to adjust the setting while it is flashing.
3. Press the Accept button to invoke the change.

Or Select and adjust multiple basic ventilation controls within 10 seconds of the last change and then press the Accept button to invoke all of the changes. The display(s) will stop flashing and the setting(s) will take effect.

Flow or Inspiratory Time in Volume Control

When ventilating in Volume Control, you can choose to set either Flow or Inspiratory Time (t Insp) for mandatory breaths. For all other mandatory breath types, only t Insp can be adjusted. Press the Select button to toggle between Flow and t Insp.

Manual Inflation Button

Refer to Foldout F-4, item 11.

Press and hold the Manual Inflation button to deliver a manual inspiration. The inflation ends when the user releases the button, five seconds elapses, or a High Paw alarm is violated, whichever occurs first.
O2 (3 min) Button

Refer to Foldout F-4, item 11.

Press the O2 (3 min) button to start a timed delivery of 100% oxygen, regardless of the current FiO2 setting. The indicator on the O2 (3 min) button lights when this function is activated. FiO2 returns to the set value and the indicator turns off after three minutes or when the button is pushed a second time, whichever comes first.

Alarm Silence Button

Refer to Foldout F-4, item 1.

Press the Alarm Silence button (LED lights) to mute silenceable audible alarms for two (2) minutes or to cancel the Shutdown alarm after the power is switched to OFF. Press again to cancel alarm silence.

Suction Disconnect Function

Prior to a planned circuit disconnect, press and hold Alarm Silence button for one second until a second tone sounds to activate the Suction Disconnect function. See Section 5, Alarms, for more details.

Alarm Reset

Refer to Foldout F-4, item 2.

Press the Reset button to clear visual indicators for alarms that are no longer violated.

Graphical User Interface (GUI) Screens

Refer to rear Foldout F-6 - F-8 for samples of these screens.

Alarms Screen

Refer to Foldout F-4, item 5.

Press the Alarms Screen menu button on the Control Panel to open the Alarm Settings screen on the GUI. From this screen the user can modify all adjustable alarm settings, view Alarm History, adjust Alarm Loudness and Alarm Tones and Save the screen image for later downloading. See Section 5, Alarms, for more details.
Main Screen
Refer to Foldout F-4, item 6.

Press the Main Screen menu button on the Control Panel to reveal five GUI menu buttons: Waves, Loops, Numeric, Trends and Freeze. When Freeze is selected the Adjustment knob will move a cursor across the screen and display data and time relevant to the point the cursor is crossing. The user can choose to “Save” the current screen or touch “Start” to deactivate the Freeze function. See Section 4 for more details.

Extended Functions Screen
Refer to Foldout F-4, item 6.

Press the Extended Functions menu button on the Control Panel to reveal five GUI menu buttons: Insp Hold, Exp Hold, Event History, Save and Freeze. Touch and hold Insp Hold or Exp Hold to start the maneuver for the current or following mandatory breath (the Accept button is not needed). Touch the Event History button to access the Event History log that records up to 1000 events. See Section 4 for more details.

Setup & Calibration Screen
Refer to Foldout F-4, item 6.

Press the Setup & Calibration menu button on the Control Panel to reveal four GUI menu buttons: Circuit Check, Sensors, Patient Setup and Technical. See Section 4 for more details.

GUI (Graphical User Interface) Miscellaneous Indicators

Refer to Foldout F-4, item A.

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

Figure 2-2 GUI Status Bar
**Patient and Breath Type/Mode Selection**
At the far left of the Status Bar an icon is displayed that represents which Patient Category and which mandatory Breath Type/Mode are selected. See Section 4 for more details.

**Patient Trigger Indicator**
While ventilating, the Patient Category and mandatory Breath Type/Mode selection area flashes green each time the patient triggers the ventilator.

**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.

**Ext. Battery Indicator**
When the ventilator is powered by an external battery “Ext Bat” is displayed on the far right of the status bar.

**Date/Time**
Date and time are displayed in the far right corner of the display. The date, time, and preferred format can be set in the Technical screen. See Section 4 for more details.

**Hour Meter**
Touch the area just below the Date/Time to display the total working hours of the ventilator. After 10 seconds the hour meter will disappear.

**Internal Battery**

The e360 Ventilator is equipped with an internal battery that when fully charged can support approximately one hour of ventilator function at the following settings: Adult, SIMV with RR 15, Vt 500, t insp 1.0 seconds, FiO2 .30, PS 0, PEEP +5, Pause OFF, Sigh OFF, Square wave form.

When the ventilator is operating on the internal battery:
- the Int Battery LED on the front panel lights and an audible alarm sounds every 5 minutes
- the Battery Charge Level icon indicates the relative charge level of the internal battery

The internal battery recharges whenever the ventilator is connected to AC power, regardless of whether the power switch is ON or OFF.
The internal battery requires up to 5 hours recharge from AC power to obtain an 80% charge and is fully charged after 14-16 hours. Recharge interval should not exceed 2 months.

If the internal battery voltage remains low (a Low Battery alarm sounds after disconnecting from AC power) after a 5 hour charge on AC power, the internal battery may need to be replaced. The standard replacement schedule for the e360 internal battery is every 24 months. Refer to the e360 Ventilator Service Manual for replacement procedure.
Section 3: Unpacking, Assembly, and Safety Check

Unpack the Ventilator and Accessories ...............3-1
  List of Package Contents ........................................3-1
Assembly ........................................................................3-1
  Exhalation Valve Compartment .......................... 3-5
  Connect Air, Oxygen and AC Power ................. 3-5
  Install the Breathing Circuit System ............... 3-6
Safety Check Procedure ............................................. 3-8
  Setup and Inspection ............................................. 3-8
  Emergency Intake Valve .......................................... 3-8
  Circuit Check.......................................................... 3-9
Gas Supply Alarms .................................................. 3-9
AC Power Loss/Battery Backup Alarm ............ 3-10
High/ Low Airway Pressure Alarms / Circuit
  Disconnect Alarm/ Alarm Silence .................. 3-10
  Minute Volume / Back Up Ventilation / Apnea
  Alarms ................................................................. 3-11
Trigger/Pressure Support ...................................... 3-11
  Volume/Flow/Rate Accuracy Test ................... 3-11
  Shut Down Alarm ................................................ 3-12
Safety Check Record .................................................. 3-13
Unpack the Ventilator and Accessories

Make note of and photograph if possible any shipping damage to the boxes. Compare the contents you received with the e360 package contents listed below. Contact Newport Customer Service to resolve any discrepancies.

Register your ventilator for warranty protection by submitting the Product Registration form online at www.ventilators.com.

List of Package Contents
- e360 Ventilator, model S
- Power Cord: NA (North American standard)
- Built-in heated reusable exhalation valve
- Two (2) Exhalation Flow Sensors – one installed and one spare
- Operating Manual
- Accessory Package
  - Air and O2 hoses
  - Extension arm with circuit hanger and rail mount extension arm bracket
  - Two (2) disposable breathing circuit filters
- Optional Accessories
  - External Monitor
  - Humidifier
  - Expiratory Filter Heater Kit and Reusable or Disposable Expiratory Filter
  - e360 Cart
  - AC Power Strip (120 VAC) for Cart
  - Dual Cylinder Holder for Cart
  - Accessory Basket for Cart

Assembly

Refer to Foldout F-1 or Figure 3-1 for complete view of e360 assembled on the cart.

1. Set aside the disposable breathing circuit filters and store the spare exhalation flow sensor in a convenient location.
2. Optional: Mount the e360 to the CRT360A Cart (assembly instructions are provided with the cart.) See Figure 3-1, A.
3. Install the extension arm bracket and extension arm on either of the side rails. See Figure 3-1, B.
4. Optional: Install a third-party humidifier. See Figure 3-1, C.
Figure 3-1 Mounting Accessories to Cart
5. Optional: Install External Monitor (instructions are provided with the monitor). See Figure 3-2.
6. Optional: Install Expiratory Filter Heater Kit (instructions are provided with the heater kit). See Figure 3-3.

**NOTE:** To install both a humidifier and heater on the cart, you will need to order a Dual Mounting Bar. The straight bar, p/n BAR1820A, mounts the filter heater next to the humidifier. The L-shape bar, p/n BAR2101A, mounts the filter heater next to and higher than the humidifier so that a shorter tubing can be used between the heater and the patient port.
Exhalation Valve Compartment
Open the Exhalation Valve Compartment and check to make sure that the exhalation valve and flow sensor are fitted securely. See Figure 3-4. Close the compartment door. Refer to Section 6 for removal and cleaning instructions.

NOTE: When fitting the flow sensor cable to the flow sensor, ensure that the pins in the cable are properly aligned with the flow sensor during insertion. Do not twist either assembly while inserting the flow sensor cable or damage to the cable may result. See Figure 3-5.

Connect Air, Oxygen and AC Power
Refer to Foldout F-2, items 3 and 4, or Figure 3-6.

Connect Air and Oxygen Hoses to their proper fittings on the back of the ventilator. See Figure 3-6, A.
Unpacking, Assembly, and Safety Check

Ensure that the AC power cord is connected to the fitting on the back of the ventilator. Tighten the retaining clamp as needed to secure the cord. See Figure 3-6, B.

**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.

**Install the Breathing Circuit System**

1. Firmly install the disposable filters on the **To Patient** port and the **From Patient** port.

Optional: If the Expiratory Filter Heater is in use, install a filter into the heated system instead of on the **From Patient** port.

2. Install a two-limb breathing circuit and humidification system according to patient requirements. See Figure 3-7, 3-8 and 3-9 for setup options.
NOTE: The e360 can be used with a reusable or disposable two limb breathing circuit. No proximal line or external exhalation valve is required.

WARNING! Do not use electronically conductive breathing circuits.
WARNING! Use water traps or heated wires in appropriate locations in the breathing circuit to prevent water from pooling in the circuit tubing, draining into the patient airway or draining into the ventilator. Empty and clean water traps as necessary. Never drain the water back into the humidifier water chamber.

Caution The ventilator is ready for operation only when it is completely assembled and has successfully completed the Safety Check and Circuit Check procedures.

Safety Check Procedure

The e360 does a self-diagnostics test when powered ON which verifies the operation of internal electronics. Newport Medical recommends that you perform a complete Safety Check prior to the initial use of the ventilator and at least with every preventative maintenance interval. Use the e360 Safety Check Record at the end of this section to record the results of each check.

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

Setup and Inspection
1. Assemble the ventilator system.
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 secured onto the ventilator inlet fittings.
6. Attach a recommended two-limb 22 mm breathing circuit and filters. Have a 500 mL (or 1L enclosed) test lung available.
7. Inspect the patient breathing circuit 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.

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 strongly recommends that you use a clean/disinfected circuit and filters on the ventilator before breathing through the circuit.

Circuit Check
1. Connect the high pressure oxygen and air hoses from the oxygen and air inlet water traps on the back of the Newport e360 to 50 ± 10 psig gas sources provided by gas cylinders, wall outlets or air compressor.
2. If an 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. Otherwise go to #4.
3. Toggle the compressor power switch to the ON position and verify its function.
4. Switch the Power Switch (on the back of the ventilator) to the ON position.
5. When the Graphical 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 two-step 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.
6. Touch the Patient Setup button and select the ADULT patient category.

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 cmH₂O/mbar
PEEP: 0 cmH₂O/mbar
High/Low Paw Alarms: 70/5
High/Low MVE Alarms: 6.0/2.0
Apnea: 20 seconds
Disconnect Alarm: 75%

1. Attach a 500 mL (or 1L enclosed) test lung.
2. Touch the “Start Ventilating” button on the GUI.
3. Adjust the FiO2 to .23. Disconnect the high pressure oxygen hose from the gas source. Verify that e360 provides an audible alarm and visual O2 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 FiO2 to .21.

5. Disconnect the high pressure air hose from the gas source. Verify that e360 provides an audible alarm and visual 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 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. The e360 issues a short beep every (5) minutes while running on internal battery.

2. Plug the AC power cord back into the wall outlet. Verify that the ventilator continues functioning, the Internal 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 / Circuit Disconnect Alarm/ Alarm Silence**

1. Remove the test lung. Verify that both visual and audible indicators for the Low Paw (low airway pressure) alarm are activated after two mandatory breaths and after three breaths the Circuit Disconnect alarm message is displayed.

2. Press the Alarm Silence button and verify that the audible alarm is muted but the alarm lamp continues to blink and the alarm message remains displayed.

3. Press the Alarm Silence button again and verify that the audible alarm resumes beeping.

4. Re-attach the test lung. Verify that the audible alarm stops and the 360° alarm lamp is steadily lit (latched).

5. Press the Reset button to clear all visual alarm indicators (lamp and messages).

6. Remove the test lung and occlude the patient wye connector of the breathing circuit. Verify that both the visual and audible indicators for High Paw (high airway pressure) alarm are activated.

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 visual indicators.

**Minute Volume / Back Up Ventilation / Apnea Alarms**

1. Adjust the Resp Rate to 20 b/min. Verify that both audible and visual indicators for High MVE (Exhaled Minute Volume) alarms are activated 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 indicators for APNEA and the Low MVE alarm are activated. Verify that after 65 seconds, Back Up Ventilation begins and is indicated with a Back Up Ventilation message on the Alarms and 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 alarm messages and indicators.

**Trigger/Pressure Support**

1. Set High MVE alarm to 12 L, Mode to SPONT, Pressure Support to 10 cmH\(_2\)O/mbar, PEEP to 3 cmH\(_2\)O/mbar, P Trig to 2.0 cmH\(_2\)O/mbar.
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 L/min and repeat step 2.
4. Set Mode to A/CMV, PEEP to 0 cmH\(_2\)O/mbar and Trig to P = 5.0 cmH\(_2\)O/mbar. All other controls should still be at standard settings.

**Volume/Flow/Rate Accuracy Test**

1. Change the GUI to the Numeric screen (via Main Screen button) to see the monitored exhaled tidal volume (VTE). Verify that the monitored value is within ± 20% of the Tidal Volume setting on the front panel.
2. Observe the Insp Flow display on the Numeric screen 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 after 30 seconds the monitored value is within ± 1 b/min of the Resp Rate setting on the front panel.
NOTE: The flow sensor should be calibrated whenever you suspect that the expiratory tidal/minute volumes are significantly different than expected (such as ± 25%). If the sensor fails to calibrate, even after it has been cleaned and sterilized, inspect it for broken wires. If damaged, discard it in accordance with local regulations and replace with a new sensor.

**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.
Newport Medical recommends that you perform a complete Safety Check prior to A) The initial use of the ventilator; and, B) At least at every Preventative Maintenance interval.

<table>
<thead>
<tr>
<th>Item</th>
<th>Pass</th>
<th>Fail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setup and Inspection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency Intake Valve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circuit Check</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gas Supply Alarms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AC Power Loss/Battery Backup Alarm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pressure Alarms/Circuit Disconnect Alarm/Alarm Silence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minute Volume/Back up Ventilation/ Apnea Alarms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trigger/Pressure Support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume/Flow/Rate Accuracy Test</td>
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<tr>
<td>Shut Down Alarm</td>
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</tbody>
</table>

Comments:

Performed by: | Date: | Unit Hours:

NOTE: Make copies of this form to record the results of safety checks.
Section 4:
Setting Up For Patient Use
Section 4: Setting Up For Patient Use

Power Conditions ................................................................. 4-1
Shutdown Alarm ..................................................................... 4-1
Overview: Preparing For Patient Ventilation ....................... 4-1
Setup & Calibration Menu .................................................. 4-2
   Circuit Check ............................................................. 4-2
   Oxygen and Flow Sensors ........................................... 4-3
      Exhalation Flow Sensor, Calibration ......................... 4-3
      O2 (Oxygen) Sensor, Calibration ............................... 4-4
      O2 Sensor, Disable ................................................. 4-4
Patient Setup ....................................................................... 4-5
   Patient Category ......................................................... 4-5
   Weight Units ............................................................. 4-5
   Ideal Weight ............................................................ 4-5
   Volume Units ........................................................... 4-5
   Sigh .......................................................................... 4-5
   Circuit Type ............................................................. 4-6
   Leak Comp (Leak Compensation) ................................. 4-6
   Compliance Compensation ........................................... 4-6
Technical ........................................................................... 4-7
   Comm (Communication) Protocol .................................. 4-7
   Display Brightness ..................................................... 4-7
   Regional Settings ........................................................ 4-7
      Altitude ................................................................. 4-7
   Date Format ............................................................... 4-7
   Date and Time ........................................................... 4-7
   Screen Files .............................................................. 4-7
   Event History Files ..................................................... 4-7
Ventilation Controls Guide .................................................. 4-8
Ventilation Settings in Advanced Data Set ........................... 4-10
  Slope/Rise ..................................................................... 4-10
  Expiratory Threshold ...................................................... 4-10
  Pause ........................................................................... 4-10
  Flow Waveform ............................................................ 4-10
  Volume Target ............................................................... 4-10
  Open Exhalation Valve .................................................. 4-10
Inspiratory and Expiratory Hold Maneuvers .......................... 4-10
P0.1 Measurement ............................................................ 4-10
Negative Inspiratory Force (NIF) ......................................... 4-10
Waves and Loops Displays ................................................ 4-14
  Adjusting Scale .............................................................. 4-14
  Auto-scale .................................................................... 4-14
  Using the Freeze Function ............................................. 4-14
  Using the Cursor in Freeze ............................................. 4-14
Event History Screen ....................................................... 4-16
Numeric Screen ............................................................... 4-17
Trends Screen ................................................................. 4-17
Data Sets ........................................................................ 4-18
Save Feature .................................................................... 4-19
Download Feature ........................................................... 4-21
Power Conditions

Off: Power switch is in the OFF position.
Ventilation Standby: Power switch is in the ON position but the ventilator is not yet in the ventilating condition.
Ventilating: Power switch is in the ON position and the user has touched the Start Ventilating button.

WARNING! Never connect the patient breathing circuit to the patient while the ventilator is in ventilation standby condition. Always touch the “Start Ventilating” button on the GUI prior to connecting the breathing circuit to the patient.

Shutdown Alarm
After powering off the ventilator it will initiate a Shutdown alarm as confirmation that the ventilator has been powered OFF. Cancel the Shutdown alarm by pressing the Alarm Silence button.

NOTE: Make sure that the e360 is completely shutdown before the power switch is turned on again. If the power switch is turned off and then on too quickly and the screen does not load correctly, turn the power off and wait 15 seconds before powering ON the ventilator.

Overview: Preparing For Patient Ventilation

1. Attach the breathing circuit and humidifier. Fill the humidifier water chamber.
2. Connect the air and oxygen hoses to the appropriate source gas supplies.
3. Plug the ventilator power cord into AC power.
4. Turn the ventilator ON. It will be in the standby condition.
5. While in standby:
   a. Perform a Circuit Check (follow the on-screen instructions).
   b. Touch Sensors and perform the O2 Sensor calibration.

WARNING! Newport Medical recommends that you perform the Circuit Check (which includes an Exhalation Flow Sensor Calibration) and O2 Sensor Calibration procedures before connecting the ventilator to a patient.

   c. Touch Patient Setup and enter selections for:
      Patient Category
      Ideal Weight and Units of Measure
      Circuit Type
      Leak Compensation (Newport recommends that you always keep Leak Compensation turned ON)
      Compliance Compensation (ON or OFF)
      Sigh (ON or OFF)
   d. Verify that ventilation parameters settings, including Advanced settings are appropriate.
Setting Up For Patient Use

e. Activate the Non-invasive button when using a noninvasive (e.g., mask) patient interface, or when ventilating with a large airway leak.

f. Verify safe alarm limits.

6. Touch the Start Ventilating button to enter ventilating condition and begin breath delivery.

7. Connect the breathing circuit to the patient.

8. Observe the patient’s condition and make sure the ventilation and alarm settings are appropriate.

Setup & Calibration Menu

Refer to Foldout F-3 for a navigation map of GUI menus, including Setup & Calibration Menu. See Foldout F-10 and F-11 to reference the Setup & Calibration menu screens.

Circuit Check

Refer to Foldout F-5.

The Circuit Check is available in Standby condition after the e360 is turned ON. It requires that the e360 be connected to a compressed air gas source.

Perform the Circuit Check:

- Each time you set up the e360 on a patient;
- With each breathing circuit or circuit component installation;
- Any time breathing circuit/filter integrity or resistance is suspect.

The check is performed in two steps. The results of the Circuit Check are logged in the Event History. Follow these instructions to perform a Circuit Check:

1. Set up the breathing circuit and humidifier (including water) as it will be used on the patient. The breathing circuit system compliance that is measured will determine the Compliance Compensation factor used during ventilation.

2. Cap off/occlude the patient connection of the circuit (don’t use a test lung).

3. Touch the Circuit Check button to initiate the first step.

4. When the first step is complete, remove everything distal to the circuit wye connector, then touch the Circuit Check button again to complete the test.

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

6. If the Circuit Check is not successful, the screen will show “Failed”.
a. Confirm the integrity and tightness of connections for all breathing circuit components such as tubing, filters and humidifier chamber, as well as the exhalation valve components.

b. Repeat the test.

7. The results of the Circuit Check are logged in the Event History.

**NOTE:** Circuit Check function is only available in the standby condition. If the ventilator is in use, ensure that an alternate method of ventilation is available if you want to perform a Circuit Check. You must power OFF the ventilator and power back ON to access Circuit Check.

**Oxygen and Flow Sensors**

Refer to Figure 4-1.

Press the Setup & Calibration menu button, then touch the Sensors button to access the screen which allows you to calibrate the Oxygen (O2) and Exhalation Flow sensors and to disable the O2 sensor.

**Exhalation Flow Sensor, Calibration**

Refer to Figure 4-1.

The Exhalation Flow Sensor calibration requires that the ventilator be connected to a compressed air gas service.

Perform an Exhalation Flow Sensor calibration each time you change the sensor and anytime there are suspected volume/monitoring inaccuracies. To calibrate the sensor:

---

**Figure 4-1 Sensors Screen**

- Flow Sensor
- O2 Sensor

- 41.1 Ppeak
- 6.4 PEEP
- 0.21 FiO2
- 5.75 MVE
- 402 VTE
- 16 RR tot
Setting Up For Patient Use

1. Touch the **Sensors** button and then touch the **Flow Sensor** button.
2. Touch **Calibrate** to start the calibration procedure or touch **Exit** to terminate the process.
3. Upon successful calibration, touch **Exit**.

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 cleaned or replaced. See Section 7 for instructions. The results of the Flow Sensor Calibration are logged in the Event History.

**NOTE:** The Exhalation Flow Sensor Calibration is automatically performed as part of the Circuit Check. Make sure to perform the Circuit Check each time you set up the e360 Ventilator for patient use.

**O2 (Oxygen) Sensor, Calibration**

Refer to Figure 4-1.

The O2 Sensor Calibration requires that the e360 be connected to a medical grade, 100% oxygen gas source. Perform an O2 Sensor Calibration before each patient use and regularly while ventilating, according to hospital policy. Pressing the **O2 3 min** button also initiates an O2 sensor calibration. To calibrate the O2 sensor:

1. Touch the **Sensors** button and then touch the **O2 Sensor** button.
2. Touch **Calibrate** to initiate the automatic calibration, or touch **Exit** to terminate the process.

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. The results of the O2 Sensor Calibration are logged in the Event History.

Newport Medical recommends that the O2 sensor be replaced every two years or sooner if it is not able to pass a calibration. See Section 6 for instructions.

**NOTE:** Gas delivery to the breathing circuit is at 100% O2 during O2 Sensor calibration.

**O2 (Oxygen) Sensor, Disable**

Disabling the O2 sensor causes the FiO2 monitoring and FiO2 alarms to be disabled and places an alarm-disabled icon in place of the monitored FiO2 value on the Basic Data Set Bar. (See Figure 4-2)

**WARNING** While this function is disabled, use an external device for FiO2 monitoring and alarms.

Ensure that an O2 sensor remains in place even while disabled.
To Disable the O₂ Sensor
1. Touch the Sensors button, then touch the O₂ Sensor button.
2. Touch Disable to disable the O₂ sensor, then touch Yes to confirm.
3. Touch Exit.

To Enable the O₂ Sensor
1. Touch the Sensors button, then touch the O₂ Sensor button.
2. Touch Enable to enable the O₂ sensor.
3. Touch Exit.

Patient Setup
Refer to Foldout F-11.

Press the Setup & Calibration menu button, then touch the Patient Setup button to access this screen.

Patient Category
Choose between Adult and Ped/Infant patient category. The setting impacts ventilation and alarm settings ranges and ventilation management algorithms. 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 and an audible alarm sounds.

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

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

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

Volume Units
Choose mL or mL/kg for the unit of measure for the VTE display. You must enter an ideal weight before selecting mL/Kg.

NOTE: Selecting the volume unit affects the numeric data display for VTE only.
Setting Up For Patient Use

**Sigh**
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 four choices:

1. *Heated Exp Limb* = heated humidifier with dual heated wire breathing circuit.
2. *Heated Insp Limb* = heated humidifier with no heated wire on the expiratory limb of a breathing circuit.
3. *HME* = unheated circuit with heat moisture exchanger.
4. *Test Lung* = no humidification, no heat (for testing and demonstration purposes)

Monitored expiratory flow and volumes are adjusted appropriately for Body Temperature Pressure Saturated (BTPS). **Circuit Type** selection affects the monitored values. Selecting the **Circuit Type** that matches the humidifier and circuit in use will ensure accuracy of monitored expiratory flow and volumes.

**Leak Comp (Leak Compensation)**
Select **Leak Comp ON** or **OFF**. When Leak Compensation is turned **ON**, the e360 automatically 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. When Leak Compensation is **OFF**, the ventilator always provides a leak compensation flow of 3 L/min during the expiratory phase of each breath cycle. Leak Compensation flow may increase to a maximum of 25 L/min with **Non Invasive ON**. See Section 7 for more information on Non Invasive Ventilation. Flow Triggering is automatically compensated for Leak Compensation flow.

**Compl Comp (Compliance Compensation)**
Select **Compl Comp ON** or **OFF**. When Compl Comp is turned **ON**, the ventilator automatically compensates for delivered volume loss due to breathing circuit compressibility during every volume controlled mandatory breath, using the Compl Comp factor that was measured during the most recent Circuit Check (the factor is stored at power down).

The **Compl Comp** factor is measured during the Circuit Check. Always perform the circuit check with the breathing circuit system and humidifier (including water), set up exactly as they will be used on the patient in order to ensure that the volume delivery/monitoring adjustment is accurate.
Technical
The Technical Screen is accessed from the Setup & Calibration screen. Refer to Foldout F-10 for a sample of the Technical screen. Set ventilator specific technical settings that are appropriate for your hospital or patient.

Comm (Communication) Protocol
Select the RS232 communication protocol that corresponds with the monitoring system that is connected to the e360 Ventilator. Touch the button to select from Newport, Newport 2, and Vuelink.

Contact Newport Technical Service for more details regarding the communication port protocol.

Display Brightness
Adjust the built-in GUI display brightness.

Regional Settings

- Altitude
  Adjust the altitude setting in 200-meter increments so that it corresponds with your local ambient altitude. The altitude setting may be adjusted up to 4,000 meters (13,124 feet).

Date Format
Select from three (3) date formats: month–day–year, day-month-year or year-month-day.

Date and Time
Set the Month, Day, Year and Time.

Screen Files
Touch this button to open the Screen Files List window which contains the last 200 saved screen images (.bmp files). Ensure that a flash drive is properly inserted into the USB port. Use the Adjustment knob to scroll to a .bmp file, then touch Download button to download the file to the flash drive. A File Storing Successful message will appear with a short two-toned beep when the download to the flash drive is complete. Repeat the process for each file to be downloaded.

Event History Files
Touch this button to open the Event History Files List window which contains the last 200 Event and Alarm History Logs (.csv files). Ensure that a flash drive is properly inserted into the USB port. Use the Adjustment knob to scroll to a file, and then touch Download button to save the file to the flash drive. A File Storing Successful message will appear with a short two-toned beep when the download to the flash drive is complete. Repeat the process for each file to be downloaded.
Setting Up For Patient Use

**NOTE**: See "Save Feature" and "Download Feature" on following pages in this section for details on saving Screen and Event History files.

## Ventilation Controls Guide

The following table shows the ventilation parameters that are active in each mode/breath type.

X = active, D = dimmed (not active but still adjustable)

<table>
<thead>
<tr>
<th>Control Display</th>
<th>VC/ACMV</th>
<th>VC/SIMV</th>
<th>VC/SPONT</th>
<th>PC/ACMV</th>
<th>PC/SIMV</th>
<th>PC/SPONT</th>
</tr>
</thead>
<tbody>
<tr>
<td>FiO2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Tidal Volume</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Flow</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>t Insp</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>D</td>
</tr>
<tr>
<td>Resp. Rate</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>D</td>
</tr>
<tr>
<td>Pressure Support</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pressure Limit</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>D</td>
</tr>
<tr>
<td>PEEP/CPAP</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Trig</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Slope/Rise</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Exp. Thresh</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pause</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Open Exh (ON/OFF)</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>D</td>
</tr>
<tr>
<td>Flow Wave</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Volume Target (ON/OFF)</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
</tr>
<tr>
<td>Mode LEDs</td>
<td>Volume Control and ACMV</td>
<td>Volume Control and SIMV</td>
<td>Volume Control and SPONT</td>
<td>Pressure Control and ACMV</td>
<td>Pressure Control and SIMV</td>
<td>Pressure Control and SPONT</td>
</tr>
</tbody>
</table>

**Table 4-1: Ventilation Controls Guide**
**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.

**NOTE:** When Freeze is activated, the Freeze button turns to “Start” and all other menu buttons are dimmed and not functional until Start is pressed.

<table>
<thead>
<tr>
<th>BPRV/ACMV</th>
<th>BPRV/SIMV</th>
<th>VTPC/ACMV</th>
<th>VTPC/SIMV</th>
<th>VTPC/SPONT</th>
<th>Control Display</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>FiO2</td>
</tr>
<tr>
<td>D</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Tidal Volume</td>
</tr>
<tr>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>Flow</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>t InsP</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>D</td>
<td>Resp. Rate</td>
</tr>
<tr>
<td>D</td>
<td>X</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>Pressure Support</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Pressure Limit</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>PEEP/CPAP</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Trig</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Slope/Rise</td>
</tr>
<tr>
<td>D</td>
<td>X</td>
<td>D</td>
<td>X</td>
<td>X</td>
<td>Exp. Thresh</td>
</tr>
<tr>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>Pause</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>Open Exh (ON/OFF)</td>
</tr>
<tr>
<td>ON</td>
<td>ON</td>
<td>D</td>
<td>D</td>
<td>D</td>
<td>Flow Wave</td>
</tr>
<tr>
<td>Must be OFF</td>
<td>Must be OFF</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>Volume Target (ON / OFF)</td>
</tr>
<tr>
<td>Pressure Control and ACMV</td>
<td>Pressure Control and SIMV</td>
<td>Volume Control, Pressure Control ACMV</td>
<td>Volume Control, Pressure Control SIMV</td>
<td>Volume Control, Pressure Control SPONT</td>
<td>Mode LEDs</td>
</tr>
</tbody>
</table>

*Table 4-1: Ventilation Controls Guide (cont.)*
Ventilation Settings in Advanced Data Set

Touch the Data Sets button in the lower right corner of the GUI to scroll to the Advanced data set.

<table>
<thead>
<tr>
<th>Slope/Rise</th>
<th>Exp Thres</th>
<th>Pause</th>
<th>Open Exh</th>
<th>Flow Wave</th>
<th>Volume Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>25</td>
<td>1.0</td>
<td>ON</td>
<td>Flow</td>
<td>OFF</td>
</tr>
</tbody>
</table>

*Figure 4-3 Advanced Data Set Options*

**Slope/Rise**: 1 (slowest) – 19 (fastest) (active for all pressure based breaths).

**Exp Thresh**: 5 – 55% or AUTO (FlexCycle) (active for Pressure Support and Volume Target Pressure Support breaths).

**Pause**: 0.1 to 2.0 seconds or OFF (active for Volume Control breaths).

**Flow Wave**: Square or Descending Ramp (active for Volume Control breaths).

**Volume Target**: ON (enables Volume Target Pressure Control and Volume Target Pressure Support breaths) or OFF.

**Open Exhalation Valve**: ON (enables Biphasic Pressure Control breaths) or OFF.

Inspiratory and Expiratory Hold Maneuvers

Refer to Foldout F-7 for a sample of the Extended Functions screen.

During ventilation, you may perform “end-inspiratory” and “end-expiratory” mandatory breath hold maneuvers in order to obtain ventilatory mechanics measurements. Follow these instructions:

1. Press the Extended Functions menu button.
2. Touch and hold the Insp Hold button on the right of the display. The e360 will perform the hold and measure the static pressure. The maneuver is terminated by releasing your finger from the button or when 15 seconds elapse.
3. Touch and hold the Exp Hold button on the right of the display. The e360 will perform the hold and measure the static pressure. The maneuver is terminated by releasing your finger from the button or when 20 seconds elapse.
The *Mechanics* 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) or other exclusion criteria is not met, the related calculated values will not be displayed.

See “Save Feature” and “Download Feature” on following pages for details on saving Extended Function screen files.

**P0.1 Measurement**

While ventilating, the P0.1 measurement function is available for assessing the patient's respiratory drive. This measurement can be used as one of the tools to predict weaning success from ventilatory support.

This function is enabled via the *P0.1* button on the Technical Screen. It is available in all modes and breath types. It is not available when Non Invasive Ventilation (NIV) is activated.

Ensure that the trigger setting is optimized before performing this function. The P0.1 measurement is the difference between the pressure at which a patient effort (trigger) is detected and the pressure 100 milliseconds later.

**To Perform a P0.1 Measurement**

Refer to Fold-out drawing F10 for a sample of Technical Screens.

1. Press the *Setup & Calibration* menu button on the control panel.
2. Touch *TECHNICAL*.
3. Touch *P0.1* to enable the function. The screen will change to the Main Screen.
4. Touch *START P0.1* to initiate the measurement. (Figure 4-4) The measurement result will be displayed after the first patient trigger is detected.
5. Touch *SAVE* to store the measurement result and the screen image. The measurement will be logged in the Event History and the screen image will be stored in the Screen Files List.
6. Touch *START* to resume normal plotting on the screen.
Setting Up For Patient Use

Explanation of P0.1 Measurement Function Conditions
After the P0.1 Measurement Function is activated the following condition occurs:

- Ventilation continues according to user settings but a 3-minute timing window opens within which the user may touch START P0.1. The function times out if the measurement is not started within this time frame.

After START P0.1 is touched the following conditions occur:

- Ventilation continues per user settings.
- Backup ventilation is disabled for one minute.
- When the e360 detects a patient trigger, it imposes a 100 millisecond delay before delivering inspiratory flow to the patient.
- Normal operation resumes after the first patient trigger or after one minute if no trigger is detected.

Negative Inspiratory Force (NIF) Maneuver
(also referred to as Maximum Inspiratory Pressure (MIP) or PIMAX)

While ventilating, the Negative Inspiratory Force (NIF) Maneuver is available for measuring airway pressure during a maximum inspiratory effort. This measurement is used to assess the patient’s inspiratory muscle strength.

This function is enabled via the NIF button on the Technical Screen.
The NIF Maneuver is available in all modes, with and without Non Invasive Ventilation (NIV) activated.

**To Perform a NIF Maneuver**

Refer to Foldout drawing F-10 for a sample Technical Screen.

1. Press the *Setup & Calibration* menu button on the control panel.
2. Touch *TECHNICAL*.
3. Touch *NIF* to enable the function. The screen will change to the main screen with a pressure waveform displayed. (See Figure 4-5)
4. Touch and hold the *NIF* (menu button) to perform the maneuver. The e360 will temporarily cease all flow delivery while the button is being touched.
5. Upon release of the *NIF* button, choose the ideal NIF value by using the adjustment knob to move the cursor to the appropriate point on the pressure waveform. The NIF value displayed is the measured value at the selected pressure point.
6. Touch the *SAVE* button to store the measurement result and the screen image. The measurement will be logged in the Event History and the screen image will be stored in the Screen Files List.
7. Touch *START* to resume normal plotting on the screen.

![Figure 4-5. Main screen showing the location of the NIF button](image)
Setting Up For Patient Use

Explanation of NIF Maneuver Function Conditions
After the NIF Measurement is turned ON the following condition occurs;

- Ventilation continues according to user settings but a 3-minute timing window opens within which the user may touch the NIF button. The function times out if the measurement is not started within this time frame.

While a NIF maneuver is in progress (while NIF button is being touched), the following conditions occur:

- PEEP is automatically set at $\leq 1\, \text{cmH}_2\text{O}$.
- No flow is delivered from the ventilator.
- Expiratory minute volume (MV$_E$) monitoring is paused.
- Backup ventilation and apnea alarms are disabled.

Normal operation resumes after the NIF button is released or 30 seconds elapse.

Waves and Loops Displays

Refer to Foldout F-6 for a sample of the Main Screen.

From the Main Screen menu on the GUI, repeatedly touching the Waves button will allow the user to scroll through the following waveform displays:

- Pressure/Time
- Flow/Time
- Volume/Time
- Pressure/Time and Flow/Time
- Pressure/Time and Volume/Time

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.

Touch the Loops button to display either a Flow-Volume Loop, Volume-Pressure Loop or both. Each loop clears before a new one is plotted. Spontaneous breath Loops are displayed in a separate color from mandatory breaths.

See “Save Feature” and “Download Feature” on following pages for details on saving Waves and Loops screen files.

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

Adjusting 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. Scale adjustments are not saved at power-off.

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.

Using the Freeze Function
Touch the Freeze button to suspend plotting of graphs (waveforms, loops, or trends) and hold the current display for extended viewing. Touch the Start button to resume plotting. Only the graphic display is suspended, numeric values continue to update.

Using the Cursor in Freeze
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.

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.

Freeze is also available from the Main Screen and Extended Function menus.
Event History Screen

Refer to Foldout F-9

From the *Extended Functions* menu touch 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, sensor calibration results and power On/Off sequences with the date and time of each event. Recorded events are color-coded - alarm violations and power *OFF* are red, setting changes and calibration results are blue, and power *ON* and *Start Ventilating* are in green. The Event History is retained after shutdown.

The software version (i.e. USR7.0) and the serial number (i.e. NXXX...) are listed at the top of the Event History Log.

See “Save Feature” and “Download Feature” on following pages in this section for details on saving Event History files.

**Numeric Screen**

Refer to Figure 4-6

![Figure 4-6 Numeric Screen](image)

Touching the *Numeric* button from the Main Screen menu displays the following information:
Setting Up For Patient Use

- All monitored data (except P0.1 and NIF)
- All calculated data
- Settings for Advanced controls (except Vol Target)

See Section 8, Specifications, for a details about the data displayed on this screen.

See “Save Feature” and “Download Feature” on following pages in this section for details on saving Numeric screen files.

Trends Screen

The e360 ventilator can display two trends screens, each screen displays four trended parameters containing up to 24 hours of trended data. Touch the Trends button from the Main Screen menu to choose between the two trend screens.

The following data is displayed on the trends screens:

<table>
<thead>
<tr>
<th>Screen 1</th>
<th>Screen 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTE/Time</td>
<td>Ppeak/Time</td>
</tr>
<tr>
<td>Minute Volume/Time</td>
<td>Pmean/Time</td>
</tr>
<tr>
<td>RRtot/Time</td>
<td>Pbase/Time</td>
</tr>
<tr>
<td>VTE % Variance/Time</td>
<td>RSBI/Time</td>
</tr>
</tbody>
</table>

Table 4-2 Trends Screens

See “Save Feature” and “Download Feature” on following pages for details on saving Trends screen files.
Setting Up For Patient Use

Data Sets

Refer to Figure 4-7

Selected sets of data may be viewed on the GUI during ventilation utilizing the Data Sets button at the bottom of the GUI screen. Three different monitored data subsets and one settings subset are accessed by touching the tabs at lower right corner of the display. The Data Sets are labeled: Basic, Mechanic, Weaning, and Advanced. The following table lists the parameters displayed in each data set. For information on a specific parameter, refer to Section 8, Specifications.
Setting Up For Patient Use

### Data Sets

<table>
<thead>
<tr>
<th>Basic</th>
<th>Mechanics</th>
<th>Weaning</th>
<th>Advanced (settings)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$P_{peak}$ (Peak Pressure)</td>
<td>$Time Constant$</td>
<td>$RR_{Spont}$ (Respiratory Rate Spontaneous)</td>
<td>$Slope$/Rise</td>
</tr>
<tr>
<td>$PEEP$</td>
<td>$P_{plat}$ (Plateau Pressure)</td>
<td>$P_{0.1}$</td>
<td>$Exp.$ Thresh (Expiratory Threshold)</td>
</tr>
<tr>
<td>$FiO_2$</td>
<td>$Total PEEP$</td>
<td>$MVE_{Spont}$ (Minute Ventilation Exhaled Spontaneous)</td>
<td>Pause</td>
</tr>
<tr>
<td>$MVE$ (Minute Volume Exhaled)</td>
<td>$Cstat$ (Static Compliance)</td>
<td>$RSBI$ (Rapid Shallow Breathing Index)</td>
<td>$Open$ Exh. (Open Exhalation Valve)</td>
</tr>
<tr>
<td>$VTE$ (Tidal Volume Exhaled)</td>
<td>$RI$ (Inspiratory Resistance)</td>
<td>$NIF$</td>
<td>$Flow$ Waveform (Shape)</td>
</tr>
<tr>
<td>$RR_{tot}$ (Total Respiratory Rate)</td>
<td>$RE$ (Expiratory Resistance)</td>
<td>$I$:E (I:E Ratio)</td>
<td>$Volume$ Target</td>
</tr>
</tbody>
</table>

### Save Feature

The **Save Feature** is available from these screens: Waves, Loops, Trends, Numeric, Extended Functions, P0.1, NIF, Alarms setting, Alarm History and Event History. Screens that have been saved can be accessed from the *Technical* screen for download.

Screen image files are saved in .bmp format and Event History files are saved in .csv format. To make them easier to identify, each saved file is assigned an 8-digit file name which includes a letter indicating the type of file (i.e., W for wave, L for loop, H for history, etc.), the last four digits of the ventilator’s serial number, and a three digit sequential number. A maximum of 200 Screen or Event (and Alarm) History files can be saved. After 200 of either type are saved, the oldest file is deleted.

When the Save function is complete, e360 emits a short, two-tone beep.
Setting Up For Patient Use

Waves, Loops, Trends, Numeric and Extended Functions Screens
(See Figure 4-7)

Touch the “Freeze” button. “Save” and “Start” buttons will appear.

Touch the “Save” button to store the screen image or touch the “Start” button to exit the Freeze screen and resume normal plotting.

Figure 4-7 Waveform Save and Start Buttons

Alarm Setting Screen
Touch the Save button to store a screen image of the current alarm settings.

Alarm History Screen
Touch the Save Alarm History button to store the Alarm/Event History Log as a spreadsheet file.

Event History Screen
Touch the Save Event History button to store the Event History Log as a spreadsheet file.

P0.1 Screen
Touch the Save button to store a screen image of the current screen and also log the P0.1 measurement to the Event History.

NIF Screen
Touch the Save button to store a screen image of the current screen and also log the NIF measurement to the Event History.
Download Feature

Touching Screen Files and Event History Files buttons on the Technical screen allows retrieval and downloading of the stored images and spreadsheet files to an external flash drive via the USB port on the rear of the ventilator (See Figure 4-8).

1. Press the Setup & Calibration button on the control panel.
2. Touch the Technical button on the GUI.
3. Touch the Screen Files (for screen image files) or the Event History Files (for Event/Alarm History files) button.

A scrollable table of the corresponding saved files will appear.

4. Install a USB compatible flash drive (level 2.0 or later) into the USB port on the back of the ventilator (located below the power switch). Ensure that the flash drive is installed securely.
5. Using the Adjustment knob, highlight a file to be downloaded.
6. Touch the Download button.
7. When the download to the flash drive is complete, a “File storing successful” message will appear with a short, two-tone beep.

![Figure 4-8 Screen and Event History Files List screens (for download)](image-url)
Section 5: Alarms
Section 5: Alarms

Introduction ........................................................................5-1
Visual Alarm Displays .........................................................5-1
   360° Alarm Lamp ..........................................................5-1
   Alarm and Message Display ...........................................5-1
Device Alert LED ..............................................................5-2
GUI Alarms Screen Environment .........................................5-3
   Alarm Settings Screen ...................................................5-3
   Saving the Alarm Settings Screen .....................................5-3
   Adjustable Alarms .........................................................5-3
Alarm History .......................................................................5-3
   Saving the Alarm History Log .........................................5-4
Alarm Loudness .................................................................5-4
Alarm Tones .........................................................................5-5
Exiting Alarm Screens ........................................................5-5
Front Panel Alarm Interface Environment .........................5-5
   Alarm Silence Button ....................................................5-5
   Suction Disconnect Feature ...............................................5-6
   Alarm Reset Button ........................................................5-6
Non-Adjustable Alarms ........................................................5-6
Alarm Violation and Remedy Guide ......................................5-7
Introduction

The e360 Ventilator is equipped with an audible and visual alarm system to help ensure patient safety. This section describes the procedure for setting alarm limits, lists all alarms and includes a Violation and Remedy Guide in Table 5-1. Alarm specifications are located in Section 8 of this manual.

Visual and audible alarms warn about:
- Patient breathing problems such as apnea or high and low airway pressure.
- Power problems such as a loss of AC power.
- Problems with gases such as low supply pressure of oxygen.
- Hardware problems such as overheating or memory failure.

NOTE: The e360 Ventilator powers up using the most recently selected alarm limits. The MVE and Disconnect Threshold alarms may be set to OFF in NIV. Those settings are not retained. See Section 7, Non Invasive Ventilation for details.

WARNING: Failure to identify and correct alarm conditions can result in patient injury. To ensure continued operation of the ventilator when a Low Battery Alarm occurs, substitute an alternate power source immediately. AC Power is always the preferred power source.

WARNING: Always ensure that the caregiver can hear the audible alert when the alarm sounds. Do not use the ventilator in an environment where audible alarms cannot be heard by the caregivers.

Visual Alarm Displays

The e360 displays the following visual information when an alarm is violated:

The 360° Alarm Lamp
Refer to Foldout F-4, item 4.

Located at the top center of the e360 front panel, the 360° Alarm Lamp flashes yellow and/or red when an alarm is violated. The lamp remains lit in a steady state to show a latched alarm until the Reset button is pressed.

Alarm and Message Display
Refer to Figure 5-1.

Descriptions of violated alarms such as Low Paw or Circuit
Disconnect as well as all messages are displayed in the center section of the status bar in the Graphical User Interface (GUI).

These messages flash while active then remain in a steady state (latched) after the alarm violation has been corrected until the Reset button is used to clear the alarm. Alarm messages are color-coded and listed in order of priority. Red messages are alarms of high priority such as Low MVE or High Paw. Messages displayed in yellow are medium priority warnings such as Back-up ventilation. Green Messages are low priority informational messages such as Ventilation Suspended or Low Paw Below PEEP setting violation.

**Device Alert LED**

Refer to Figure 5-1.

Located on the left side of the control panel, the Device Alert LED lights and a non-silenceable alarm sounds when there is a device alert condition such as an empty battery or device malfunction. Refer to table 5-2 for more information on device alert conditions.

**Figure 5-1 Alarms Screen Environment**

1. Alarm Silence/Suction Disconnect button and indicator
2. Alarm Reset button
3. Mains Power, Internal Battery, and Device Alert indicators
4. Alarm Messages display area
5. Alarms Screen button
6. Touch buttons:
   - Alarm History button
   - Alarm Loudness button
   - Alarm Tones button
   - Save button
7. Setting adjustable alarms area
**WARNING!** If a Device Alert alarm occurs, ventilation ceases and the emergency intake relief valve and exhalation valve opens.

**GUI Alarms Screen Environment**

**Alarm Settings Screen**  
See Figure 5-1 or Foldout F-8.

Press the *Alarms Screen* menu button to open the Alarm Settings screen on the GUI. From this screen you may modify all adjustable alarm settings, view Alarm History, adjust Alarm Loudness and Alarm Tones, and Save the screen for download.

**Saving the Alarm Settings Screen**  
Touch the *Save* button to capture an image of the Alarm Setting screen for later download. Refer to Section 4 for instructions on downloading files that are saved to memory.

**Adjustable Alarms**

The Alarm Setting screen allows you to adjust the following settings:

- High and Low Paw  
- High and Low MV  
- Apnea delay time  
- High Respiratory Rate (RR tot)  
- Disconnect Threshold %

To change an alarm setting touch the displayed value you want to change. The value will begin to flash. Rotate the *Adjustment* knob and press either the *Accept* button or the displayed value. The display will stop flashing and the new alarm setting will be in effect.

You may change multiple alarms before touching the *Accept* button as long as inputs occur within 10 seconds of each other. If the *Accept* button or displayed value are not pressed within 10 seconds of the last change all adjusted alarms will revert to the original values.

**Alarm History**  
See Figure 5-2.

Touch the Alarm History button to open a log of the last 1000 alarms and events including:

- Alarm Violations  
- Setting Changes  
- Circuit Check results  
- O₂ Sensor Calibration results  
- Flow Sensor Calibration results  
- Power On/Off Sequences

The ventilator settings at the time of the highlighted event are displayed.
Alarms

Saving the Alarm History Log

See Figure 5-2.

Touch the Save Alarm History button to save the Alarm History Log for later download as a spreadsheet file in comma-separated format (.csv). Refer to Section 4 for instructions on downloading files that are saved to memory.

Alarm Loudness

See Figure 5-3.

Press the Alarm Loudness button to open a new screen. Use the Adjustment knob to change the value from 1 (Quiet) to 10 (Loud). Press the Accept button to confirm the change.
Alarm Tones
See Figure 5-4.

Touch the Alarm Tones button to open the screen. Use the Adjustment knob to select one of three unique sets of sounds that will be activated when an alarm is violated. Press Accept to confirm the change.

Exiting Alarm Screens
Touch any menu button on the control panel to exit any alarm screen. See Figure 5-1

Front Panel Alarm Interface Environment

Alarm Silence Button
See Figure 5-1

Press the Alarm Silence button to mute silenceable alarms for two (2) minutes and also to cancel the Shutdown Alarm after powering down the ventilator. The indicator lamp on the Alarm Silence button is lit when alarms are silenced. To cancel Alarm Silence press the Alarm Silence button again.

Press the Alarm Silence for one (1) second or longer to enable the Suction Disconnect feature.

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

NOTE: The optional External Alarm Silence cable provides the same function as the button except that it does not silence a the Shutdown Alarm.
Suction Disconnect Feature
Press and hold the *Alarm Silence* button for one second or longer (until the ventilator sounds a short tone) to enable the Suction Disconnect feature. With this feature enabled the ventilator will automatically silence all patient and disconnect alarms, display the message *Ventilation Suspended*, disable automatic leak compensation, and deliver a bias flow of 10 L/min for Adult or 5 L/min for Ped/Infant patient types if the ventilator senses that the patient circuit has been disconnected. The ventilator will not deliver breaths until the breathing circuit is reconnected or three minutes has elapsed. When the ventilator detects reconnection or three minutes has elapsed the ventilator will resume normal function.

**NOTE:** The ventilator recognizes the reconnection of the circuit by reading the expiratory flow. Do not use the Suction Disconnect feature if the flow sensor on the ventilator is defective, failing calibration or disconnected.

Alarm Reset Button
See Figure 5-1

Audible alarms are automatically silenced when the alarm violation no longer exists; however, visual alarm indicators do not automatically reset. When an alarm violation is no longer active the alarm indicator stops flashing and remains steadily lit to signal a latched alarm. Press the *Reset* button to individually clear these alarm indicators.

Non-Adjustable Alarms
The following alarms may occur during ventilator operation and are non-adjustable:
(Priority, violation criteria, and remedies are listed in Table 5-1)

<table>
<thead>
<tr>
<th>High FiO2</th>
<th>O2 Sensor Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low FiO2</td>
<td>Flow Sensor Error</td>
</tr>
<tr>
<td>Low Baseline (PEEP) Pressure</td>
<td>Insp. Time Too Long</td>
</tr>
<tr>
<td>High Baseline (PEEP) Pressure</td>
<td>Insp. Time Too Short</td>
</tr>
<tr>
<td>Volume Target Not Met</td>
<td>Sustained High Baseline (PEEP Pressure)</td>
</tr>
<tr>
<td>Low Paw Below PEEP</td>
<td>Setting Out of Range</td>
</tr>
<tr>
<td>Pressure Limit Below PEEP</td>
<td>Check Vent Fan</td>
</tr>
<tr>
<td>Gas Supply Alarm</td>
<td>AC Power Loss/Battery Backup</td>
</tr>
<tr>
<td>Both Air/O2 Supply Loss</td>
<td>Low Battery</td>
</tr>
<tr>
<td>Power Shutdown</td>
<td>Device Alert</td>
</tr>
<tr>
<td>Data Read Failure</td>
<td>Check Flow Sensor Board</td>
</tr>
</tbody>
</table>
Alarm Violation and Remedy Guide

The following table lists alarm and informational messages alphabetically. The alarm priority, type (ventilator/patient problem differentiation), violation message or criteria (what causes the alarm to be activated) and remedy (possible corrective actions) are included in this guide. Alarm specification ranges are listed in Section 8.

**Table 5-1 Alarm Violation and Remedy Guide**

<table>
<thead>
<tr>
<th>Alarm or Device Alert Message</th>
<th>Priority • Type • Lamp Color</th>
<th>Description and/or Criteria</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>{Any Message not listed here}</td>
<td>• High • Ventilator • Red</td>
<td>Ventilator failure that requires service</td>
<td>Check patient and provide an alternate source of ventilation. Contact a qualified service representative.</td>
</tr>
<tr>
<td>AC Power Loss-Battery Back Up</td>
<td>• High • Ventilator • Red</td>
<td>Loss of main power—may be due to failed AC power source, a blown fuse, or disconnected power cord.</td>
<td>No action required if AC power is deliberately disconnected. Verify that AC power source is securely connected and functional. Prepare alternate ventilation source if needed.</td>
</tr>
<tr>
<td>Air Supply Loss (&lt; 30 psig)</td>
<td>• High • Ventilator • Red</td>
<td>Air gas inlet supply pressure has dropped to &lt; 30 psig.</td>
<td>Check patient and provide an alternate source of ventilation. Check that air supply is connected and providing equal to or greater than 30 psig at inlet, especially during inspiration. <strong>NOTE:</strong> If the oxygen supply is connected, the ventilator continues breath delivery using 100% oxygen.</td>
</tr>
<tr>
<td>Apnea (5–60 seconds)</td>
<td>• High • Patient/Ventilator • Red</td>
<td>Ventilator has not detected a mandatory breath or spontaneous effort during the set interval.</td>
<td>Check patient. Evaluate settings/readjust as necessary. Check trigger sensitivity. Check that the breathing circuit is intact and securely connected.</td>
</tr>
<tr>
<td>Alarm or Device Alert Message</td>
<td>• Priority • Type • Lamp Color</td>
<td>Description and/or Criteria</td>
<td>Remedy</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------</td>
<td>-------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Back Up Ventilation</td>
<td>• Medium • Patient • Yellow</td>
<td>Monitored MVE ≤ Low MVE alarm limit.</td>
<td>Check patient. Evaluate settings/readjust as necessary. Check trigger sensitivity. Check that the breathing circuit is intact and securely connected. The alarm is recovered when MVE rises to 10% above the Low MVE alarm limit. <strong>NOTE:</strong> Back up ventilation is suspended for 60 seconds after changing any ventilator settings and following circuit reconnect after the Suction Disconnect feature is used.</td>
</tr>
<tr>
<td>Both Air/O2 Supply Loss</td>
<td>• High • Ventilator • Red</td>
<td>Inlet pressure for both air and oxygen supplies has dropped below minimum supply pressure required.</td>
<td>Restore both gas supplies and/or provide alternate ventilation immediately. Check that air and oxygen supplies are connected and providing ≥ 30 psig at ventilator inlet. The ventilator opens the emergency intake and exhalation valves to allow the patient to breathe room air.</td>
</tr>
<tr>
<td>Check Flow Sensor Board</td>
<td>• Medium • Ventilator • Yellow</td>
<td>The flow sensor cable on the flow sensor board is disconnected from the main board. The ventilator can only detect the flow sensor cable during ventilation.</td>
<td>The flow sensor cable must be re-connected to the Main Board by a qualified service representative. <strong>NOTE:</strong> Message cannot be cleared with the Reset button.</td>
</tr>
<tr>
<td>Alarm or Device Alert Message</td>
<td>• Priority • Type • Lamp Color</td>
<td>Description and/or Criteria</td>
<td>Remedy</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------</td>
<td>----------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Check Vent Fan</td>
<td>• Medium • Ventilator • Yellow</td>
<td>Fan inside of the unit fails.</td>
<td>Contact a qualified service representative to replace vent fan. <strong>NOTE:</strong> Message cannot be cleared with the Reset button.</td>
</tr>
<tr>
<td>C Internal System</td>
<td>• High • Device Alert • Red</td>
<td>Monitor Exception Failure The monitor processor has detected an abnormal operation such as illegal instruction or division by zero that was generated by the monitor software.</td>
<td>Check patient and provide an alternate source of ventilation. Contact a qualified service representative</td>
</tr>
<tr>
<td>Circuit Disconnect</td>
<td>• High • Patient/ Ventilator • Red</td>
<td>Disconnect Threshold % alarm level met. In A/C or SIMV-VTE % variance &gt; Disconnect Threshold. In SPONT- Expiratory flow reading is less than 1 L/min for greater than 5 seconds. May be caused by large leak or disconnection of the patient circuit from the ventilator or High Pressure Alarm.</td>
<td>Reconnect circuit or check for leaks in the breathing circuit, ET tube or mask (if mask ventilating). Reduce or eliminate leak as much as possible. Check that the exhalation flow sensor is calibrated and installed correctly. Clean or replace sensor if necessary. Re-adjust alarm limit to clinically appropriate level.</td>
</tr>
<tr>
<td>Alarm or Device Alert Message</td>
<td>• Priority  • Type  • Lamp Color</td>
<td>Description and/or Criteria</td>
<td>Remedy</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------</td>
<td>-----------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Control CPU Failed</td>
<td>• High  • Device Alert  • Red</td>
<td>Control CPU Failure</td>
<td>Check patient and provide an alternate source of ventilation. Contact a qualified service representative.</td>
</tr>
<tr>
<td>Control uP Failed</td>
<td>• High  • Device Alert  • Red</td>
<td>Monitor Communications Failure The control processor does not respond to a request from the monitor processor. The control processor is not running.</td>
<td>Check patient and provide an alternate source of ventilation. Contact a qualified service representative</td>
</tr>
<tr>
<td>Control RAM Failed</td>
<td>• High  • Device Alert  • Red</td>
<td>Control RAM Failure</td>
<td>Check patient and provide an alternate source of ventilation. Contact a qualified service representative.</td>
</tr>
<tr>
<td>Control Tasks Failed</td>
<td>• High  • Device Alert  • Red</td>
<td>Control Task Continuity Failure Software tasks of the control processor have operated out of sequence.</td>
<td>Check patient and provide an alternate source of ventilation. Contact a qualified service representative.</td>
</tr>
<tr>
<td>Data Read Failure</td>
<td>• High  • Ventilator  • Red</td>
<td>Error is detected during the reading of stored data at power up.</td>
<td>Contact a qualified service representative.</td>
</tr>
<tr>
<td>Alarm or Device Alert Message</td>
<td>Priority • Type • Lamp Color</td>
<td>Description and/or Criteria</td>
<td>Remedy</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------</td>
<td>-----------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Device Alert (If message display is possible) Unsilenceable audible alarm. Device Alert indicator flashes if possible.</td>
<td>High • Device Alert • Red</td>
<td>Ventilator malfunction. Also activated if less than 10% of the internal battery operation time remains when ventilator is operating on the internal battery.</td>
<td>Check patient and provide an alternate source of ventilation. If the alarm is due to battery depletion, plug the ventilator into an alternate power source to allow charging. If not a result of a low battery, contact a qualified service representative.</td>
</tr>
<tr>
<td>Dual RAM Failed</td>
<td>High • Device Alert • Red</td>
<td>Dual RAM Failure Random access memory that is shared by the control and monitor processors has failed.</td>
<td>Check patient and provide an alternate source of ventilation. Contact a qualified service representative.</td>
</tr>
<tr>
<td>EEPROM Read Error</td>
<td>Low • Ventilator • None</td>
<td>This error is logged into the Event History Log when the software type read from the EEPROM on the main board is invalid. No audible or visual alarm is displayed, and no message appears on the GUI.</td>
<td>EEPROM Read Error is a Technical Service Message that does not affect functionality of the ventilator. Contact a qualified service representative.</td>
</tr>
<tr>
<td>FIO2 High</td>
<td>Medium • Ventilator • Yellow</td>
<td>Measured FIO2 is more than 0.07 above the FIO2 setting for 30 seconds. (cont. next page)</td>
<td>Verify that the source gases and connections are secure and functional. Verify that the oxygen source gas is providing 100% oxygen. (cont. next page)</td>
</tr>
<tr>
<td>Alarm or Device Alert Message</td>
<td>• Priority • Type • Lamp Color</td>
<td>Description and/or Criteria</td>
<td>Remedy</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>---------------------------------</td>
<td>-------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>FiO2 High (cont.)</td>
<td>• Medium • Ventilator • Yellow</td>
<td>NOTE: This alarm is inactive if the e360 detects a disabled or defective oxygen sensor, or oxygen supply pressure is below 30 psig.</td>
<td>Calibrate the O2 sensor by pressing the O2 3 min. button or by accessing O2 Sensor calibration button in Setup &amp; Calibration/Sensors. Replace O2 sensor if necessary.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Measured FiO2 is more than 0.07 below the FiO2 setting for more than 30 seconds.</td>
<td>Verify that the source gas and connections are secure and functional. Verify that the oxygen source gas is providing 100% oxygen. Verify that ventilator flow and trigger settings are adequate to meet patient’s needs. Calibrate the O2 sensor by pressing the O2 3 min button or by accessing O2 Sensor calibration button in Setup &amp; Calibration. Replace O2 sensor if necessary.</td>
</tr>
<tr>
<td>FiO2 Low</td>
<td>• High • Ventilator • Red</td>
<td>NOTE: This alarm is inactive if the e360 detects a disabled or defective oxygen sensor, or oxygen supply pressure is below 30 psig.</td>
<td>NOTE: Insufficient supply inlet pressure of O2 may cause ventilator to be unable to deliver required high flow rate, resulting in FiO2 alarm.</td>
</tr>
<tr>
<td>Alarm or Device Alert Message</td>
<td>• Priority • Type • Lamp Color</td>
<td>Description and/or Criteria</td>
<td>Remedy</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------</td>
<td>-----------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Flow Sensor Error</td>
<td>• High • Ventilator • Red</td>
<td>Sensor is disconnected from cable. Ventilator is unable to calibrate the exhalation flow sensor or a sensor malfunction is detected.</td>
<td>Check flow sensor connection and recalibrate. Clean or replace sensor and calibrate. Contact qualified technical service representative.</td>
</tr>
<tr>
<td>High Baseline Pressure</td>
<td>• Medium • Ventilator • Yellow</td>
<td>At the start of a time triggered mandatory breath, monitored baseline pressure (PEEP/CPAP) has been 5 cmH2O/mbar above the PEEP/CPAP setting for two consecutive breaths.</td>
<td>Check breathing circuit tubing and From Patient port filter for kinks or obstructions. Change the filter if resistance is suspected. Evaluate ventilator settings and readjust if necessary to allow for adequate exhalation time. The alarm is recovered when monitored baseline pressure (PEEP/CPAP) is less than set PEEP/CPAP + 5 cmH2O/mbar at the start of a time triggered breath.</td>
</tr>
<tr>
<td>High MVE</td>
<td>• High • Patient • Red</td>
<td>Monitored exhaled minute volume (MVE) is &gt;/= set High MVE.</td>
<td>Check patient, evaluate ventilator settings, check for leaks and autotriggering and readjust if necessary. The alarm is recovered when the monitored MVE is below the High MVE alarm limit.</td>
</tr>
<tr>
<td>High PAW</td>
<td>• High • Patient/ Ventilator • Red</td>
<td>Monitored breathing circuit pressure is &gt;/= set High Paw alarm limit for one breath. (cont. next page)</td>
<td>Check patient. Check the endotracheal tube. Check breathing circuit tubing and From Patient port filter for kinks or obstructions. (cont. next page)</td>
</tr>
</tbody>
</table>
## Alarms

<table>
<thead>
<tr>
<th>Alarm or Device Alert Message</th>
<th>Priority</th>
<th>Type</th>
<th>Lamp Color</th>
<th>Description and/or Criteria</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High PAW (cont.)</strong></td>
<td>High</td>
<td>High</td>
<td>Patient/Ventilator Red</td>
<td>A High Paw alarm violation terminates the current breath and cycles to exhalation. This alarm is applicable for all breaths, including manual inflations.</td>
<td>Make sure exhalation valve is functioning correctly. Evaluate ventilator settings and readjust if necessary. The alarm is recovered when patient breathing circuit pressure drops 5 cmH₂O/mbar below the High Paw alarm limit.</td>
</tr>
<tr>
<td><strong>High RR Tot</strong></td>
<td>Medium</td>
<td>Medium</td>
<td>Patient/Ventilator Yellow</td>
<td>When alarm is ON, monitored total breathing frequency is ( \geq ) set alarm level. This may indicate a change in patient condition or autotriggering.</td>
<td>Check patient for change in status or need for increased ventilatory support. If due to autotrigger, check breathing circuit for leaks. If due to autotrigger, turn Leak Compensation ON (if it has been turned to OFF). If due to airway/mask leak, turn ON Noninvasive Ventilation. Evaluate trigger setting/method (Flow vs. Pressure).</td>
</tr>
<tr>
<td><strong>I:E Ratio Inverse Violation</strong></td>
<td>Medium</td>
<td>Medium</td>
<td>Ventilator Yellow</td>
<td>Ventilator settings would result in an inverse I:E ratio greater than 4:1, so ventilation is not delivered according to settings.</td>
<td>Check patient. Evaluate inspiratory time, frequency, and trigger settings and readjust as necessary.</td>
</tr>
<tr>
<td><strong>Insp Time Too Long</strong></td>
<td>Medium</td>
<td>Medium</td>
<td>Ventilator Yellow</td>
<td>Ventilator settings result (cont. next page)</td>
<td>Evaluate Tidal Volume, Flow, Respiratory Rate, Inspiratory Time, (cont. next page)</td>
</tr>
<tr>
<td>Alarm or Device Alert Message</td>
<td>• Priority • Type • Lamp Color</td>
<td>Description and/or Criteria</td>
<td>Remedy</td>
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<td></td>
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</tr>
<tr>
<td>Insp Time Too Long (cont.)</td>
<td>• Medium • Ventilator • Yellow</td>
<td>in an inspiratory time greater than 5 seconds, including any pause time, so ventilation is not delivered according to settings.</td>
<td>and Pause settings and readjust as necessary.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insp Time Too Short</td>
<td>• Medium • Ventilator • Yellow</td>
<td>Ventilator settings or alarm limit violation results in an inspiratory time &lt; 0.1 seconds for adult or &lt; 0.05 seconds for pediatric patients, excluding any pause or inspiratory hold. While in VC, an Insp. Time setting that cannot deliver the set Tidal Volume.</td>
<td>Evaluate Tidal Volume and Flow settings and readjust as necessary. Potential cause may be High Paw alarm violation. Resolve as needed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Baseline Pressure</td>
<td>• High • Patient/ Ventilator • Red</td>
<td>Monitored airway pressure has been below the PEEP/CPAP setting for more than 0.5 seconds for two consecutive breaths.</td>
<td>Turn Leak Compensation ON. Check breathing circuit for leaks or disconnects. If there is an airway/mask leak, turn ON Noninvasive Ventilation.. The alarm is inactive when PEEP/CPAP is set below 4 cmH2O/mbar.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Battery</td>
<td>• High • Ventilator • Red</td>
<td>Internal battery operating (cont. next page)</td>
<td>Connect the ventilator to any AC power source to allow the internal battery to recharge. (cont. next page)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Alarms

<table>
<thead>
<tr>
<th>Alarm or Device Alert Message</th>
<th>• Priority • Type • Lamp Color</th>
<th>Description and/or Criteria</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low Battery</strong> <em>(cont.)</em></td>
<td>• High • Ventilator • Red</td>
<td>capacity has dropped to 25% of capacity.</td>
<td><strong>NOTE:</strong> The ventilator continues to operate normally until the battery is depleted, at which time a Device Alert alarm occurs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>WARNING!</strong> To ensure continued ventilator operation, substitute an alternate power source, such as AC power, immediately when a Low Battery alarm occurs.</td>
</tr>
<tr>
<td><strong>Low MVE</strong></td>
<td>• High • Patient • Red</td>
<td>Monitored MVE &lt; set Low MVE alarm limit.</td>
<td>Check patient, evaluate ventilation and alarm settings and readjust if necessary.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Check breathing circuit for leaks or disconnects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Check that the exhalation flow sensor is installed correctly.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The ventilator provides back up ventilation while this alarm limit is violated.</td>
</tr>
<tr>
<td><strong>Low Paw</strong></td>
<td>• High • Patient/Ventilator • Red</td>
<td>Monitored airway pressure does not reach the Low Paw alarm limit during a mandatory inspiration for two breaths (does not apply to manual, spontaneous or pressure supported breaths).</td>
<td>Check breathing circuit for leaks or disconnects.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Evaluate ventilation and alarm settings and readjust if necessary.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The alarm is recovered when Ppeak for a mandatory breath (including Back Up Ventilation) is greater than Low Paw alarm limit.</td>
</tr>
</tbody>
</table>
### Alarms

| Alarm or Device Alert Message | • Priority
• Type
• Lamp Color | Description and/or Criteria | Remedy |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Paw Below PEEP</td>
<td>Informational Message</td>
<td>Set Low Paw Alarm level is less than set PEEP</td>
<td>Change alarm limit to greater than the set PEEP level.</td>
</tr>
</tbody>
</table>
| M Internal System             | • High
• Device Alert
• Red | Control Exception Failure
The Control processor has detected an abnormal operation such as illegal instruction or divide by zero that was generated by the control software. | Check patient and provide an alternate source of ventilation. Contact a qualified service representative. |
| Monitor uP Failed             | • High
• Device Alert
• Red | Control Communications Failure
The monitor processor does not respond to a request from the control processor. The monitor processor is not running. | Check patient and provide an alternate source of ventilation. Contact a qualified service representative. |
| Monitor CPU Failed            | • High
• Device Alert
• Red | Monitor CPU Failure
The monitor processor on the main PCB is bad. | Check patient and provide an alternate source of ventilation. Contact a qualified service representative. |
| Monitor RAM Failed            | • High
• Device Alert
• Red | Monitor RAM Failure
(cont. next page) | Check patient and provide an alternate source of ventilation. Contact a qualified service representative. |
<table>
<thead>
<tr>
<th>Alarm or Device Alert Message</th>
<th>Priority • Type • Lamp Color</th>
<th>Description and/or Criteria</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor RAM Failed (cont.)</td>
<td>High • Device Alert • Red</td>
<td>Random Access Memory that is used by the monitor processor on the main PCB is damaged.</td>
<td></td>
</tr>
<tr>
<td>Monitor ROM Failed</td>
<td>High • Device Alert • Red</td>
<td>Monitor ROM Failure</td>
<td>Check patient and provide an alternate source of ventilation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Read only memory that stores the code of the monitor processor has detected an illegal checksum.</td>
<td>Contact a qualified service representative.</td>
</tr>
<tr>
<td>Mon Task Failed</td>
<td>High • Device Alert • Red</td>
<td>Monitor Task Continuity Failure</td>
<td>Check patient and provide an alternate source of ventilation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Software tasks of the monitor processor have operated out of sequence.</td>
<td>Contact a qualified service representative.</td>
</tr>
<tr>
<td>No Communication</td>
<td>High • Ventilator • none</td>
<td>Continuous audible alert. This message is recorded into the Event History Log when there is a communication failure to the touch screen.</td>
<td>If the communication is reestablished the alert will automatically reset. No Communication is a Technical Service Message that does not affect functionality of the ventilator. Contact a qualified service representative if the alert does not reset.</td>
</tr>
<tr>
<td>Alarm or Device Alert Message</td>
<td>• Priority • Type • Lamp Color</td>
<td>Description and/or Criteria</td>
<td>Remedy</td>
</tr>
<tr>
<td>------------------------------</td>
<td>--------------------------------</td>
<td>-----------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>O2 Sensor Disconnect</td>
<td>Informational Message</td>
<td>The O2 Sensor is disconnected.</td>
<td>Reconnect the O2 sensor. <strong>NOTE:</strong> Always use an external O2 monitor with alarms while ventilating with this message.</td>
</tr>
<tr>
<td>O2 Sensor Error</td>
<td>• Medium • Ventilator • Red</td>
<td>Ventilator cannot calibrate the O2 sensor correctly.</td>
<td>Change the sensor as soon as possible. <strong>NOTE:</strong> Always use an external O2 monitor with alarms while ventilating with this message.</td>
</tr>
<tr>
<td>O2 Supply Loss</td>
<td>• High • Ventilator • Red</td>
<td>Oxygen supply inlet pressure is below minimum supply pressure required.</td>
<td>Check that oxygen supply is connected and providing ( \geq 30 ) psig at the ventilator inlet, especially during inspiration. Provide alternate ventilation if necessary. The ventilator continues breath delivery using the remaining air gas supply, and does not calibrate the O2 sensor.</td>
</tr>
<tr>
<td>Out of Range</td>
<td>Informational Message</td>
<td>A setting adjustment is out of range for the patient category selected.</td>
<td>Re-adjust the setting to within range or change the patient category.</td>
</tr>
<tr>
<td>Power Failure</td>
<td>• High • Device Alert • Red</td>
<td>Power Failure DC power out of tolerance. Check +12 VDC, -12 VDC, and +5 VDC. (cont. next page)</td>
<td>Check patient and provide an alternate source of ventilation. Contact a qualified service representative.</td>
</tr>
</tbody>
</table>
### Alarms

<table>
<thead>
<tr>
<th>Alarm or Device Alert Message</th>
<th>• Priority • Type • Lamp Color</th>
<th>Description and/or Criteria</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Failure (cont.)</td>
<td>• High • Device Alert • Red</td>
<td>(The e360 may have been powered by the internal battery until it was depleted and a Device Alert resulted.)</td>
<td></td>
</tr>
<tr>
<td>Pressure Limit Below PEEP</td>
<td>Informational Message</td>
<td>The set pressure limit is less than the set PEEP.</td>
<td>Adjust either set Pressure Limit or set PEEP so that the Pressure Limit is above the PEEP level.</td>
</tr>
<tr>
<td>Pressure Support + PEEP &gt; 60</td>
<td>Informational Message</td>
<td>The sum of Pressure Support plus the PEEP Settings is greater than 60 cmH2O/mbar.</td>
<td>Adjust either Pressure Support or PEEP level to less than a combined total of 60 cmH2O/mbar.</td>
</tr>
<tr>
<td>Shutdown Alarm</td>
<td>No Indicator</td>
<td>No message is associated with this alarm. The Shutdown alarm provides confirmation that the ventilator power state has been switched to OFF.</td>
<td>Press the Alarm Silence button to cancel the Shutdown alarm.</td>
</tr>
<tr>
<td>Sustained High Baseline Pressure</td>
<td>• High • Ventilator • Red</td>
<td>Monitored PEEP pressure has been ≥ 8 cmH2O/mbar above set PEEP/CPAP for over 6 seconds in Ped/Infant or 10 seconds for Adult.</td>
<td>Check circuit tubing for occlusions and/or fluids. Check expiratory filter for increased resistance/blockage, replace if necessary. Evaluate ventilator settings and readjust if necessary. Check to verify that the Exhalation Valve is clean/free of debris. Replace if necessary. If not resolved, use alternate means of ventilation.</td>
</tr>
</tbody>
</table>

(cont. next page)
<table>
<thead>
<tr>
<th>Alarm or Device Alert Message</th>
<th>• Priority • Type • Lamp Color</th>
<th>Description and/or Criteria</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sustained High Baseline Pressure (cont.)</td>
<td>• High • Ventilator • Red</td>
<td><strong>WARNING!</strong> Ventilation and triggering are suspended, the exhalation valve and the emergency relief valve open as needed for a minimum of 5 seconds to relieve pressure and no flow is delivered until the condition is resolved.</td>
<td></td>
</tr>
<tr>
<td>Ventilation Suspended</td>
<td>Informational Message</td>
<td>The Suction Disconnect feature is enabled.</td>
<td>Informational only.</td>
</tr>
<tr>
<td>Volume Target Not Met</td>
<td>• Medium • Patient/Ventilator • Yellow</td>
<td>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.</td>
<td>Check patient condition for reversible cause. Increase t Insp, reduce Resp Rate, increase Slope/Rise, adjust Exp. Threshold, increase Pressure Limit or reduce Tidal Volume if necessary. Factors that could trigger the alarm: agitation, biting of ET tube, coughing, increase in expiratory filter or patient resistance or drop in compliance (e.g. secretions, pneumothorax).</td>
</tr>
</tbody>
</table>
Section 6: Cleaning and Maintenance
Section 6: Cleaning and Maintenance

Introduction ........................................................................................................... 6-1
Use of Filters .......................................................................................................... 6-1
    Inspiratory (To Patient) Port ........................................................................ 6-1
    Expiratory (From Patient) Port ................................................................... 6-1
Disassembly and Reassembly Procedures .......................................................... 6-2
    Rear Panel Fan Filter .................................................................................. 6-2
    Exhalation Manifold ................................................................................... 6-3
        Exhalation Flow Sensor ........................................................................ 6-3
        Exhalation Valve ................................................................................... 6-5
    Inspiratory Manifold ................................................................................... 6-7
    Oxygen Sensor ............................................................................................. 6-8
    Fuses ............................................................................................................ 6-8
Cleaning .................................................................................................................. 6-9
Sterilizing ................................................................................................................ 6-9
    Autoclave Sterilization ............................................................................... 6-10
    EtO (Ethylene Oxide) Sterilization ............................................................ 6-10
Guide to Cleaning and Sterilizing ................................................................. 6-10
Guide to Preventive Maintenance ................................................................. 6-12
Storing the Ventilator ......................................................................................... 6-14
Repackaging the Ventilator .............................................................................. 6-14
Introduction

To ensure proper ventilator operation and minimize risk of cross contamination, perform the following cleaning and maintenance procedures at the recommended intervals. All procedures should be adapted to your institution’s policies and procedures. All personnel should use precautions to minimize the risk of spreading infection when disassembling, cleaning and performing maintenance procedures on the ventilator system.

Use of Filters

Inspiratory (To Patient) Port
The gas that enters the breathing circuit through the Inspiratory (To Patient) Port of the ventilator is usually clean and dry; however, Newport Medical strongly recommends using a filter at this port for two reasons:

1. To protect the inspiratory manifold from potential contaminants in patient gases, and
2. To protect the patient from potential contaminant in the delivered gas.

By using the filter, the need for regular cleaning and sterilization of the inspiratory manifold is reduced. By replacing the filter between each patient use, the risk of infection being spread between patients is reduced.

Expiratory (From Patient) Port
Gas that enters the Expiratory (From Patient) Port on the ventilator from the breathing circuit may be moist and contain pathogens. Newport Medical strongly recommends the use of a dry, clean filter in this location for three reasons:

1. To protect the expiratory manifold from potential contaminants in exhaled gases;
2. To protect the patient from potential contaminants in the exhalation system should the patient pull gas in through the expiratory limb of the circuit;
3. To protect the staff from potential contaminants in the patient gases.

When a filter placed on the From Patient port gets wet, filtration capabilities are diminished and resistance to patient exhalation increases. By keeping a clean, dry filter in this location, the need for regular cleaning of the exhalation valve and flow sensor is reduced,
the lifetime of the flow sensor is maintained, the risk of cross contamination between patients is reduced, the risk of infection being spread to the staff is reduced and expiratory resistance is kept to a minimum.

NOTE: Any practice that adds moisture to the exhaled gas will cause the filter on the From Patient port to get wet more quickly and require that it be changed more often.

Caution For cleaning/disinfecting the exterior surface of the ventilator system, use a soft cloth that is moistened with a cleaning/disinfecting agent. Do not use harsh abrasives, hard brushes, or cleaning/disinfecting agents that contain phenols, ammonium chloride, chloride compounds, or more than 2.4% glutaraldehyde.

Caution Plastic components should not come in contact with the following solutions because they may cause disintegration of the component:

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

Caution Use only the cleaning and sterilization methods specifically listed for each ventilator component. Consult accessory manufacturer’s guidelines for specific cleaning, disinfecting, and sterilizing guidelines.

Disassembly and Reassembly Procedures

Rear Panel Fan Filter
The following diagram and instructions are for removal and reinstallation of the fan filter.

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.
Cleaning and Maintenance

Exhalation Manifold

**Exhalation Flow Sensor**
The following diagram and instructions are for the removal and reinstalltion of the exhalation flow sensor.

1. Open the front panel door on the lower left front of the ventilator to expose exhalation valve and flow sensor. See Figure 6-2

2. With a gentle twisting motion, pull the plastic flow sensor away from the outlet of the exhalation valve. See Figure 6-3.

**Figure 6-1 Fan Filter**

**Figure 6-2 Exhalation Valve and Flow Sensor**
Cleaning and Maintenance

3. Disconnect the flow sensor cable from the plastic body of the sensor by pulling the cable connector straight out. Do not twist.

4. To reconnect the cable connector to the sensor body: Take care to line up the notch in the cable connector with the notch in the connector on the sensor body. Press together. Do not twist. See Figure 6-4.

5. To reconnect the flow sensor to the exhalation valve: Push the flow sensor into the outlet port of the exhalation valve, carefully tucking the cable into the compartment behind it.

6. Close the front panel door.

7. Calibrate the sensor as described in Section 4.

Caution The exhalation flow sensor is a precise and delicate instrument. Take care when handling not to disturb the measuring wires. Do not insert any object into the flow sensor, nor direct pressurized flows of liquids or gases through the sensor during cleaning and reprocessing. 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.

**Exhalation Valve**
The following diagram and instructions are for removal and reinstallation of the exhalation valve.

1. Open the front panel door to expose the exhalation valve.
2. Remove the exhalation valve by releasing the latch at the top of the panel and pulling the valve away from the ventilator. Refer to Figure 6-5.
3. With a twisting motion, pull the plastic flow sensor away from the outlet of the exhalation valve.

![Exhalation Valve Diagram](image)

*Figure 6-5 Remove Exhalation Valve*

4. While holding exhalation valve body securely, turn the retaining ring counter clockwise and remove it. See Figure 6-6.
5. Separate the exhalation valve cap from the valve body.
6. Remove diaphragm poppet assembly from the valve cap (do not disassemble the diaphragm poppet assembly).
Caution Proper orientation of the various components is critical. Failure to reassemble the exhalation valve correctly will result in leaks in the exhalation system.

7. To re-assemble and reinstall 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 6-7.
Inspiratory Manifold
The following diagram and instructions are for removal and reinstallation of the inspiratory manifold.

1. Using a flat screwdriver or a coin, unscrew the two screws on the lower right front panel section and remove it to expose the inspiratory manifold. See Figure 6-8.
2. Use a Philips screwdriver to remove the upper and lower manifold retaining screws and pull the manifold away from the ventilator.

3. Remove the manifold cap by removing the four screws to expose the diaphragm. Handle with care. See Figure 6-9.
4. Remove the inspiratory port from the block by turning it counterclockwise.
5. To reassemble and reinstall, reverse the above steps.

Figure 6-8 Remove Panel Section

Figure 6-9 Inspiratory Manifold Block
Oxygen Sensor
The following diagram and instructions are for the removal and reinstallation of the oxygen 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, unscrew the two screws on the lower right front panel section and remove it to expose the oxygen sensor. See Figure 6-11.
3. Locate the sensor cable and turn the twist collar counter clockwise to remove the cable from the sensor.
4. Pull the sensor straight out to remove it. Discard oxygen sensor in accordance with local regulations.

NOTE: The Inspiratory Manifold may need to be removed to aid in sensor removal.

5. To install a new sensor, reverse the steps.
6. Calibrate the sensor as described in section 4.

NOTE: Before calibrating a new oxygen sensor, open the package and allow the sensor to be exposed to room air for 20 minutes.

Fuses
The following diagram and instructions are for the removal and reinstallation of fuses.

The fuses are located in the top of the AC power module on the rear of the e360.

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. See Figure 6-10.
3. Inspect and replace the fuses only if they are blown.
Cleaning and Maintenance

4. Reinstall the fuse drawer.

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

**Cleaning**

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. Follow these steps to clean a part before sterilization:

1. Disassemble (separate all components).
2. Wash part in water and mild soap solution or enzymatic cleaner.
3. Rinse part thoroughly in clean running water for at least two minutes and wipe dry or allow to air dry thoroughly.
4. Inspect part after every cleaning. Replace damaged or worn parts.

**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.

**Sterilizing**

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, and low temperature sterilization processes (such as ethylene oxide [EtO], gas, or plasma sterilization) and liquid chemicals are the principal sterilizing methods used.
Caution  Do not sterilize the entire ventilator. Standard sterilization techniques, including EtO and formalin, may cause damage.

NOTE: Follow the cleaning and sterilization instructions provided by the manufacturer of each assembly as well as your facility’s policy.

Autoclave Sterilization:
1. Clean/Inspect
2. Sterilize
3. Dry
4. Reassemble
5. Perform *Circuit Check* on fully assembled breathing circuit after installation.

EtO (Ethylene Oxide) Sterilization:
1. Clean/Inspect
2. Sterilize
3. Aerate (to dissipate residual gas absorbed by the part)
4. Reassemble
5. Perform *Circuit Check* on fully assembled breathing circuit after installation.

Guide to Cleaning and Sterilizing

*Table 6-1*

<table>
<thead>
<tr>
<th>Ventilator/Component Accessory</th>
<th>Cleaning and Sterilization Methods</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator exterior, including control panel, cart, support arm, humidifier, and exhalation filter heater</td>
<td>Clean and disinfect with a cloth dampened with a surface disinfectant cleaner, according to your facility’s infection control policy. 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 rear vents to remove dust.</td>
<td>Do not allow liquids into components or cable connections. Do not attempt to EtO sterilize or use pressurized air to clean or dry.</td>
</tr>
<tr>
<td>Ventilator/Component Accessory</td>
<td>Cleaning and Sterilization Methods</td>
<td>Additional Information</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>e360 fan filter</td>
<td>Wash filter in mild detergent solution, rinse thoroughly, allow to air dry.</td>
<td>Replace if damaged.</td>
</tr>
<tr>
<td>Inspiratory filter</td>
<td>Single patient use: discard. Reusable: dry, then autoclave.</td>
<td>Replace with each patient set up and sooner if expiratory resistance through the expiratory filter is increased or if visibly wet, soiled, or contaminated or as per the filter manufacturer’s recommendation.</td>
</tr>
<tr>
<td>Expiratory filter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exhalation Valve</td>
<td>If filters are not used during ventilation: disassemble and clean, then autoclave to sterilize. If filters are used: clean and sterilize only as needed.</td>
<td>After sterilization, perform the Circuit Check on the fully assembled circuit.</td>
</tr>
<tr>
<td>Inspiratory Manifold</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Approved cleaning and sterilization methods:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sterilization: Sterilize by EtO. The sensor cannot be sterilized in an autoclave.</td>
<td></td>
</tr>
<tr>
<td>Exhalation Flow Sensor Cable</td>
<td>Clean/disinfect the Flow Sensor Cable with a cloth dampened with an appropriate disinfectant cleaner (do not soak) between patients and when visibly soiled.</td>
<td>NOTE: Newport Medical recommends that the flow sensor be replaced after 5 cleaning or sterilizing cycles.</td>
</tr>
</tbody>
</table>
Cleaning and Maintenance

Guide to Preventive Maintenance

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

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Ventilator Component</th>
<th>Recommended Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Several times a day or as required by your institution’s policy</td>
<td>Expiratory filter, disposable</td>
<td>Replace with each patient set up and sooner if expiratory resistance through the filter is increased or if visibly wet, soiled, or contaminated or as per the filter manufacturer’s recommendation.</td>
</tr>
<tr>
<td>Daily or as necessary</td>
<td>e360 rear panel air and oxygen high pressure inlet water traps</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>e360 rear panel fan filter</td>
<td>Check and clean as required.</td>
</tr>
<tr>
<td>As necessary and between patient use</td>
<td>Ventilator exterior (body, control panel, cart, and support arm)</td>
<td>Wipe to clean/disinfect with soft cloth dampened with a surface disinfectant cleaner. Vacuum dust from the vents on the rear panel. Wipe off all residues after cleaning.</td>
</tr>
<tr>
<td></td>
<td>Inspiratory filter, disposable</td>
<td>Discard and replace.</td>
</tr>
<tr>
<td></td>
<td>Inspiratory filter, reusable</td>
<td>Sterilize and replace with each patient setup.</td>
</tr>
<tr>
<td></td>
<td>Expiratory filter, reusable heated</td>
<td>Reusable: sterilize and replace with each patient set up and sooner if expiratory resistance through the filter is increased or if visibly wet, soiled, or contaminated or as per the filter manufacturer’s recommendation.</td>
</tr>
<tr>
<td></td>
<td>Exhalation Flow Sensor</td>
<td>Calibrate: Calibrate the Flow Sensor (see Section 4) after cleaning and/or sterilizing, before every patient use and any time you suspect that the expiratory tidal/ minute volumes are significantly different than expected (example: at least 25% higher or lower).</td>
</tr>
</tbody>
</table>
## Cleaning and Maintenance

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Ventilator Component</th>
<th>Recommended Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between patient use</td>
<td>Exhalation Valve/ Inspiratory Manifold</td>
<td>If the Sensor fails to calibrate, even after it has been cleaned and sterilized, discard the sensor in accordance with local regulations and replace with a new sensor. Clean/sterilize: With no expiratory filter: clean and sterilize between patients and also when it malfunctions or is visibly contaminated during use. With exp. filter in use: clean and sterilize when it malfunctions or is visibly contaminated during use. Replace sensor when it cannot pass calibration after cleaning/sterilization.</td>
</tr>
<tr>
<td>At least every 2 months</td>
<td>Internal battery</td>
<td>With no filter in use: disassemble, clean and sterilize.</td>
</tr>
<tr>
<td>Every year or 5,000 hours, whichever comes first</td>
<td>e360 various parts</td>
<td>Install Level 1 Preventative Maintenance Kit (PMK360A). Preventive maintenance must be performed by a Newport authorized service technician following the instructions found in the e360 Ventilator Service Manual.</td>
</tr>
<tr>
<td>Every 2 years or as required</td>
<td>Oxygen sensor</td>
<td>Discard and replace the Oxygen (O2) Sensor every two years or when the sensor cannot be calibrated (the ventilator will display the message O2 Sensor Error or O2 Sensor Calibration Failed).</td>
</tr>
<tr>
<td>Internal battery</td>
<td>Discard and replace.</td>
<td></td>
</tr>
<tr>
<td>Every 5 years or 25,000 hours of operation</td>
<td>e360 various parts</td>
<td>Perform a Level 2 Preventative Maintenance (OVL360A) according to instructions in the e360 Ventilator Service Manual. This must be performed by a Newport Medical authorized service technician.</td>
</tr>
</tbody>
</table>
Storing the Ventilator

Caution Disconnect gas supplies from the ventilator for storage or if the ventilator will not be used for an extended period of time.

Caution To ensure that the internal battery remains functional, fully recharge the battery at least every 2 months when the ventilator is not in use.

Caution 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 at the front of this manual.
Section 7: Explanation of Modes, Breath Types and Special Functions
Explanation of Modes, Breath Types and Special Functions

Section 7:

Introduction ........................................................................................................ 7-1
Settings Functions ............................................................................................ 7-1
  Timing Limitations to Ventilation Controls ........................................... 7-1
  Control Retention ....................................................................................... 7-1
  Control Range .............................................................................................. 7-1
Mandatory Breath Types .................................................................................. 7-1
  Volume Control ............................................................................................ 7-2
  Pressure Control .......................................................................................... 7-3
  Biphasic Pressure Release Ventilation .................................................... 7-3
  Volume Target Pressure Control ............................................................... 7-4
Spontaneous Breath Management (SIMV/SPONT) ...................................... 7-4
  Pressure Support ......................................................................................... 7-4
  Volume Target Pressure Support ............................................................. 7-5
Ventilation Modes .......................................................................................... 7-6
  A/CMV ........................................................................................................ 7-7
  SIMV .......................................................................................................... 7-8
  SPONT (Spontaneous) ............................................................................... 7-8
Advanced Features & Special Functions ...................................................... 7-9
  Bias Flow .................................................................................................... 7-9
  Slope/Rise .................................................................................................. 7-9
  Expiratory Threshold and FlexCycle ....................................................... 7-9
  Leak Compensation (Leak Comp) ........................................................... 7-10
  Compliance Compensation (Compl Comp) ........................................... 7-10
Non Invasive Ventilation (NIV) ................................................................. 7-11
  Leak Compensation in NIV ................................................................. 7-11
  Alarm Settings in NIV .............................................................................. 7-11
Introduction

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 as well as descriptions of the operation of special functions.

Settings Functions

Timing Limitations to Ventilation Controls
While in A/CMV, SIMV, and SPONT modes, the ventilator limits the setting of any ventilation parameter so that inspiratory time and I:E ratio cannot exceed the following limits.

- Inspiratory time cannot be less than 0.01 seconds.
- Inspiratory time cannot exceed 5.0 seconds for adult and 3.0 seconds for Infant/Pediatric patients (not counting an Inspiratory Hold).
- I:E ratio cannot exceed an inverse ratio of 4:1.

Control Retention
All ventilation control settings, except Noninvasive and Scale setting, are retained when e360 is powered OFF. When the ventilator is powered ON, the control settings that are retained in memory are the initial *Start Ventilating* ventilation and alarm settings unless the user selects new settings.

Control Range
All variable ventilation controls are limited to a specified range. For some controls, the range is dependent on the selected patient category. When the patient category is changed, the selection for a variable ventilation control may be out of range.

Mandatory Breath Types
The e360 offers these breath types:

- Volume Control
- Pressure Control
- Biphasic Pressure Release Ventilation
- Volume Target Pressure Control

<table>
<thead>
<tr>
<th>Mandatory Breath Type</th>
<th>Control Panel Selection</th>
<th>Advanced Selection-Open Exhalation</th>
<th>Advanced Selection-Volume Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume Control</td>
<td>Volume Control</td>
<td>Not available</td>
<td>Off</td>
</tr>
</tbody>
</table>
### Explanation of Modes, Breath Types and Special Functions

**Volume Control**

Volume Control ventilation provides time-cycled, volume limited mandatory breaths. Volume and flow (or inspiratory time) are user-set parameters and pressure is allowed to vary. The user has the option to select between two *Flow Wave* patterns for breath delivery in volume ventilation. The *Flow Wave* pattern function is accessed via the *Advanced* Data Set.

A square flow wave pattern delivers the set flow constantly until the set tidal volume is delivered. See figure 7-1A. A descending ramp flow wave pattern delivers the set flow initially, decreases flow rate at a constant rate until 50% of the initial flow is reached and then terminates flow delivery when the set Tidal Volume has been delivered. See Figure 7-1B.

<table>
<thead>
<tr>
<th>Mandatory Breath Type</th>
<th>Control Panel Selection</th>
<th>Advanced Selection-Open Exhalation</th>
<th>Advanced Selection-Volume Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Control</td>
<td>Pressure Control</td>
<td>Off</td>
<td>Off</td>
</tr>
<tr>
<td>Volume Target</td>
<td>Volume Control or Pressure Control</td>
<td>Off</td>
<td>On</td>
</tr>
<tr>
<td>Pressure Control (VPTC)</td>
<td>Pressure Control</td>
<td>On</td>
<td>Off</td>
</tr>
</tbody>
</table>

**Table 7-1 Control Selections for Mandatory Breaths**
Explanation of Modes, Breath Types and Special Functions

Pressure Control
Pressure Control Ventilation provides time-cycled, pressure limited mandatory breaths. Inspiratory Pressure Limit and \( t_{\text{Insp}} \) (inspiratory time) are set parameters with tidal volume and flow allowed to vary to meet the set parameters. The Slope/Rise may be adjusted via the Advanced Data Set. A pressure control inspiration terminates when the set inspiratory time has elapsed.

NOTE: If the Slope/Rise control is set too low, breathing circuit pressure may not reach the pressure limit value by end inspiration.

Biphasic Pressure Release Ventilation
(Open Exhalation Valve On)
Biphasic Pressure Release mandatory breaths are similar to Pressure Control mandatory breaths except that the exhalation valve remains open during the inspiratory time. This allows the patient the option of unrestricted spontaneous breathing even while pressure in the circuit is elevated to the Pressure Limit level. This type of ventilation is referred to as “Biphasic Pressure Release Ventilation” (BPRV). It is considered to be more comfortable for patients with an active respiratory drive who are ventilated with Pressure Control. Open Exhalation Valve is turned ON via the Advanced Data Set to achieve BRPV breaths.

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.
**Volume Target (Volume Target Pressure Control - VTPC)**

Volume Targeted Pressure Control is a hybrid pressure control breath type where the ventilator attempts to achieve (target) a user-set tidal volume using the lowest pressure control level. These are much like pressure control mandatory breaths except that the pressure control level is managed breath-by-breath by the ventilator in steps of up to 3 cmH₂O/mbar. The pressure change in VTPC is limited to a level that is between 5 cmH₂O/mbar above PEEP and the Pressure limit setting in order to try to achieve the targeted (user set) tidal volume within the (user set) inspiratory time. The set tidal volume is not guaranteed for each breath, it is a target.

The first VTPC mandatory breath delivered after Volume Target is turned ON is at a pressure control level equal to PEEP/CPAP + 5 cmH₂O/mbar.

Spontaneous breaths in VTPC/SIMV mode are Volume Target Pressure Support (VTPS) breaths.

**NOTE:** If the Slope/Rise control is set too low, breathing circuit pressure may not reach the target pressure by the end of inspiration.

**Spontaneous Breath Management in SIMV and SPONT Modes**

There are two forms of spontaneous breath assistance on the e360 ventilator in SIMV and SPONT modes, Pressure Support and Volume Target Pressure Support.

In Volume Control, Biphasic Pressure Release and Pressure Control SIMV, spontaneous breaths with Pressure Support are available. In Volume Target Pressure Control SIMV, spontaneous breaths are Volume Target Pressure Support breaths.

In SPONT, when Volume, BPRV or Pressure Control mandatory breath type is selected spontaneous breaths with Pressure Support are available.

In SPONT, when Volume Target Pressure Control mandatory breath type is selected (Volume Target is ON in Advanced Data Set), all spontaneous efforts are assisted by Volume Target Pressure Support.

**Pressure Support**

Pressure Support is available in SIMV and SPONT - Volume Control, BPRV and Pressure Control mandatory breath types only. For
patient spontaneous efforts that trigger the ventilator, e360 delivers breaths with a constant pressure equal to PEEP/CPAP + Pressure Support until the end of patient inspiration which is determined by the attainment of one of the three cycling off thresholds. The breaths are delivered according to the user-selected settings for Pressure Support, Slope/Rise, and PEEP/CPAP.

Pressure Support breaths are cycled off based on attaining one of three thresholds: a percent (%) of peak flow (user set via Expiratory Threshold in Advanced Data Set), maximum inspiratory time (2.0 seconds for Adult, 1.2 seconds for Ped/Infant) or pressure overshoot, whichever comes first.

**NOTE:** See Figure 7-2 for a graphical representation of the pressure overshoot cycling off threshold for Pressure Support and Volume Target Pressure Support breaths.

![Figure 7-2 Pressure Overshoot Cycling Off](image)

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

**Volume Target Pressure Support (VTPS)**
Volume Target Pressure Support is available in SIMV and SPONT - Volume Target Pressure Control breath type only. For patient
spontaneous breaths in the Volume Targeted Pressure Control (VTPS)模式，呼吸机以恒定的气道压力，设定为上PEEP/CPAP + 5 cmH2O/mbar和压力限制之间的某个值，直到患者吸气结束，吸气末触发三个停机条件之一。每个VTPS自发呼吸的提供根据用户选择的潮气量（Tidal Volume）和压力限制（Pressure Limit），斜率/上升（Slope/Rise）和PEEP/CPAP设置。这些很像压力支持的自发呼吸，但与选择压力控制、BPRV或容控模式的自发呼吸不同。设置的潮气量在每呼吸中被尝试实现。潮气量不保证保证每次呼吸，它是一个目标。

目标压力的首次呼吸，当没有目标压力被建立是PEEP/CPAP + 5 cmH2O/mbar。

Volume Target Pressure Support (VTPS)呼吸是基于达到三个阈值之一而停机的：一个百分比（%）的峰值流量（通过Expiratory Threshold在Advanced Data Set中设置），最大吸气时间（成人为2.0秒，婴儿为1.2秒）或压力超调，无论是哪个先发生。见图7-2来说明压力超调停机功能。

Ventilation Modes

有三种通气模式可用:
- Assist/Control Mandatory Ventilation (A/CMV)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Spontaneous (SPONT)
Explanation of Modes, Breath Types and Special Functions

**A/CMV**

In A/CMV, all breaths delivered to the patient are delivered according to the parameters set by the user. These are called mandatory breaths. The user may choose to Pressure Control, Volume Control, Biphasic Pressure Release or Volume Target Pressure Control the mandatory breaths. All breaths may be time (ventilator-triggered) or patient-triggered.

The **Resp Rate** (respiratory rate) setting determines the minimum number of time-triggered or patient triggered mandatory breaths delivered each minute. The **Trig** setting determines the airway pressure or airway flow threshold that the patient’s effort must reach in order to trigger these and additional mandatory breaths.

If the patient doesn’t breathe or if the patient’s efforts don’t cause airway pressure or airway flow to reach the **Trig** threshold, the e360 Ventilator delivers the number of time-triggered breaths each minute selected via the **Resp Rate** setting.

**SIMV**

![Figure 7-3 A/CMV](image)

*Figure 7-3 A/CMV*

*Figure 7-4 SIMV*
In SIMV, mandatory and spontaneous breaths may be delivered to the patient. The user may choose to Pressure Control, Volume Control, Biphasic Pressure Release or Volume Target Pressure Control the mandatory breaths. Mandatory breaths may be time or patient-triggered. In Volume Control, Pressure Control or Biphasic Pressure Release, the user may choose Pressure Support to augment the spontaneous breaths.

When Volume Target Pressure Control mandatory breath type is selected, all spontaneous breaths are Volume Target Pressure Support breaths.

The Resp Rate setting determines the total number of mandatory breaths delivered each minute and 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 Resp Rate setting.

**SPONT (Spontaneous)**

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 mandatory 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.
Advanced Features & Special Functions

Bias Flow
When e360 is in standby or ventilating condition, it provides 3 L/min of mixed-gas (when both air and oxygen source gases are connected) Bias Flow during the exhalation period. Exceptions to this Bias Flow level are described below.

Bias Flow is at a Different Level When:

- Ventilation Suspended due to Circuit Disconnect alarm or other condition: Bias Flow 10 L/min for Adult and 5 L/min for Ped /Infant patient type;
- (Automatic) Leak Compensation is turned ON and there is a leak: Bias Flow 3-15 L/min for Adult and 3-8 L/min for Ped /Infant patient type;
- Noninvasive Ventilation is turned ON and there is a leak: 3-25 L/min for all patient types.

Bias Flow is OFF When:

- e360 is powered OFF;
- During a pause, an inspiratory hold, an expiratory hold, any alarm related to an elevated pressure, and during a Loss of Both Gas Supplies alarm.

Slope/Rise
Slope/Rise is the term used to describe the e360 pressurization gain for Pressure Control, Volume Target Pressure Control, Biphasic Pressure Release, 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.

The Slope/Rise selection is retained after power down.

Expiratory Threshold and FlexCycle
(Automatic Expiratory Threshold Management)
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% of peak flow. This function is accessed via the Advanced Data Set at the bottom of the GUI screen.

In addition to the manual selection for Expiratory Threshold, an AUTO option is also available. When Auto is selected, the ventilator automatically adjusts the Expiratory Threshold setting on a breath-by-breath basis within the established range in order to end the breath when the patient stops inhaling and prevent early or late cycling off. We refer to this automated option as FlexCycle.

The Expiratory Threshold selection is retained after power down.

**Leak Compensation (Leak Comp)**

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 Leak Comp is ON, the 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. Flow triggering is automatically compensated for changes in bias flow delivery. When Leak Comp 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) for Volume Control mandatory breaths can be selected ON or OFF from the Patient Setup screen.

When Compl Comp is ON, displayed VTI and VTE represent volume as if it were being monitored at the patient’s airway. When Compl Comp is OFF, VTI and VTE represent volume monitored at the main flow outlet and exhalation valve.

VTI and VTE displayed values will not look any different with Compl Comp ON or OFF even though VTI and 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 displayed values.

**Caution** The e360 Circuit Check determines how 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 delivered and 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 (LED lights), 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 or an uncuffed/deflated cuff trach tube. 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 in NIV**

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 or uncuffed/deflated cuff trach tube. (When Non Invasive is not activated and Leak Comp is ON bias flow is only 3-8 L/min Ped/Infant and 3-15 L/min Adult.)

**Alarm Settings in NIV**

The Low MVE and the Disconnect Threshold alarms, can be set to OFF while Non Invasive is activated. All other alarms are functional. If the Low MVE or Disconnect Threshold alarm is OFF when Non Invasive is deactivated, the alarms are automatically turned back on and the Low MVE 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 Medical recommends using Pressure trigger (start at 2 cmH2O/mbar for Adult and 1 cmH2O/mbar for Ped/Infant) when using the e360 for noninvasive mask ventilation. Use a nonvented mask to ensure proper patient-ventilator synchrony.
Section 8: Specifications
Section 8: Specifications

Alarms, Controls, Monitored Data, Setup & Calibration ........................................... 8-1
Physical Specifications .................................................................................................. 8-18
<table>
<thead>
<tr>
<th>Item</th>
<th>Location and/or Function</th>
<th>Range and Resolution or Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Other Messages</strong></td>
<td>GUI-Informational Message</td>
<td>For any message not shown here refer to Section 5, Alarms for more information.</td>
</tr>
<tr>
<td><strong>Alarm History</strong></td>
<td>GUI-Alarms</td>
<td>See Event History</td>
</tr>
<tr>
<td><strong>Alarm Loudness</strong></td>
<td>GUI-Alarms</td>
<td>Range: 1 to 10 (55 - 75 dbA) Default : 5 Accuracy: +/- 5 dbA</td>
</tr>
<tr>
<td><strong>(Alarm) Reset</strong></td>
<td>Control Panel</td>
<td>Clears visual indicators and messages for alarms that are no longer violated.</td>
</tr>
<tr>
<td><strong>Alarm Silence</strong></td>
<td>Control Panel</td>
<td>Mutes silenceable, audible alarms for two (2) minutes. 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.</td>
</tr>
<tr>
<td><strong>Alarm Tones</strong></td>
<td>GUI-Alarms</td>
<td>Range: 1-3 Default: 1</td>
</tr>
<tr>
<td><strong>Apnea</strong></td>
<td>GUI-Alarms-Adjustable</td>
<td>Alarm is violated when no breath or effort is detected within the set apnea interval. Range: 5 to 60 seconds Accuracy: ±1 second</td>
</tr>
<tr>
<td><strong>Back Up Ventilation (BUV)</strong></td>
<td>Alarms-Non-Adjustable</td>
<td>If the current mode is A/CMV or SIMV, Back Up Ventilation employs the current Control Panel settings except for Respiratory Rate which increases to 1.5 times the current setting (15 b/min minimum, 100 b/min maximum).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If the current mode is SPONT, the ventilator delivers pressure control mandatory breaths with the following settings: • Plimit 15 cmH2O/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</td>
</tr>
</tbody>
</table>

(Cont. next page)
## Specifications

<table>
<thead>
<tr>
<th>Item</th>
<th>Location and/or Function</th>
<th>Range and Resolution or Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Back Up Ventilation (BUV)</strong> (Results from low MVE Alarm Violation)</td>
<td></td>
<td>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. Back Up Ventilation terminates when MVE exceeds the Low MVE Alarm setting by 10%</td>
</tr>
</tbody>
</table>
| **Breath Type/Mode Setting**                                         | Control Panel/GUI        | Breath Type: Volume Control, Pressure Control or Volume Target Pressure Control and Biphasic Pressure Release Ventilation (BPRV)  
Mode: A/CMV (assist/control mandatory ventilation), SIMV (synchronized intermittent mandatory ventilation), or SPONT (spontaneous ventilation)  
Selected breath type and mode is displayed below the Patient Category icon on the upper left side of GUI. |
| **Monitored**                                                        | GUI-Monitored Data       | Displayed range: 0 to 999.9 mL/cmH2O/mbar  
Accuracr: ± 1 mL/cmH2O/mbar  
Cdyn effective = VTE/(Ppeak – Pbase)  
**NOTE:** Calculated for time triggered breaths only. VTE, Ppeak, and Pbase must be valid to calculate Cdyn effective. |
| **Cdyn effective** (mL/cmH2O/mbar) (Effective dynamic compliance)    | GUI-Monitored Data       | Indicates that the Disconnect Threshold % is greater than or equal to the set value.  
Range: Heated Expiratory Limb, Heated Inspiratory Limb, Heat Moisture Exchanger (HME), and Test Lung.  
(Cont. next page) |
| **Circuit Disconnect**                                               | Alarms- Non adjustable   |                                                                                                                                                                 |
| **Circuit Type**                                                     | GUI-Patient Setup        |                                                                                                                                                                 |
### Circuit Type (cont.)

<table>
<thead>
<tr>
<th>Item</th>
<th>Location and/or Function</th>
<th>Range and Resolution or Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GUI-Patient Setup</td>
<td></td>
<td>1. Heated Exp. Limb = heated humidifier with dual heated wire breathing circuit. 2. Heated Insp. Limb = 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]). 4. Test Lung = no humidification, no heat.</td>
</tr>
</tbody>
</table>

**NOTE:** Circuit Type selection affects the accuracy of monitored values for expiratory flow, expiratory tidal volume and expiratory minute volume.

### Comm. Protocol

| GUI-Technical          | Range: Newport, Newport 2, Vuelink Allows user to select protocol to communicate with patient monitoring systems via the RS232 port. |

### Compl Comp (Compliance Compensation)

| GUI-Patient Setup      | 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. |

### Cstat (mL/cmH2O/mbar) (Static compliance)

| GUI-Monitored Data     | Displayed range: 0 to 999.9 mL/cmH2O/mbar Accuracy: ± 1 mL/cmH2O/mbar \( C_{stat} = \frac{V_{TE}}{(P_{plat} - P_{PEEP})} \) Maneuver based with time stamp for up to 24 hrs. **NOTE:** 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. |
### Specifications

<table>
<thead>
<tr>
<th>Item</th>
<th>Location and/or Function</th>
<th>Range and Resolution or Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Read Failure Contact Service Alarm</td>
<td>Alarms-Non Adjustable</td>
<td>Software type is read invalid from both the EEPROM on the main board and a stored file on the compact flash card.</td>
</tr>
<tr>
<td>Device Alert</td>
<td>Control Panel-Alarms-Non Adjustable</td>
<td>LED on Control Panel lights (if possible). Unsilenceable audible alarm sounds if there is a ventilator malfunction (messages associated with a device alert are described in Section 5). Also activated if less than 10% of internal battery operation time remains. <strong>WARNING!</strong> If a Device Alert occurs, ventilation ceases and the emergency intake valve and exhalation valve opens.</td>
</tr>
<tr>
<td>Disconnect Threshold (VTE Var %)</td>
<td>GUI-Alarms-Adjustable</td>
<td>Percent of difference between inspiratory and expiratory tidal volumes. Range: 20 to 95% Accuracy: +/- 10% <strong>NOTE:</strong> When Non Invasive is activated this alarm may be set to OFF.</td>
</tr>
<tr>
<td>Display Brightness</td>
<td>GUI-Technical</td>
<td>Range: 0-100% Default: 50% Allows user to adjust display brightness of GUI.</td>
</tr>
<tr>
<td>EEPROM Read Error</td>
<td>Alarms-Non Adjustable</td>
<td>Software type is read invalid from the EEPROM on the main board. It is logged in the event history page, but no audible alarm and alarm LED indicator will be activated. No error message will be displayed on the alarm/message bar on the screen.</td>
</tr>
<tr>
<td>Event History (Alarm History)</td>
<td>GUI-Extended Functions (and Alarms)</td>
<td>A log of the past 1000 events. Events are color coded: Green: Power ON and Start Ventilating. Blue: Control settings and changes, calibration results and Circuit Checks. Red: Alarm violations and messages and Power OFF Event History is retained after Power shutdown. <strong>Save Event History</strong> button allows user to capture current event log for later downloading in .csv format.</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
</tr>
<tr>
<td>----------------------</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Event History Files</td>
<td>GUI-Technical</td>
<td>Contains a list of the last 200 saved Event and Alarm History logs (.csv files). Files are assigned an 8-digit file name that includes a letter for file type (H for history, etc), the last 4 digits of the serial number, and a 3 digit sequential number.</td>
</tr>
<tr>
<td>Expiratory Hold</td>
<td>GUI-Extended Functions</td>
<td>Range: Up to 20 seconds Generates an Expiratory Hold maneuver at the end of a mandatory breath exhalation for as long as the button is pushed.</td>
</tr>
<tr>
<td>Expiratory Threshold</td>
<td>GUI-Advanced Data Set</td>
<td>Range: AUTO 5 – 55%, (resolution 1%) of peak flow. Manually or automatically sets the flow cycling-off threshold for Pressure Support and Volume Target Pressure Support breaths</td>
</tr>
<tr>
<td>FiO2 (Set)</td>
<td>Control Panel</td>
<td>Range: 0.21 to 1.00 (resolution 0.01) Accuracy: ±0.03</td>
</tr>
<tr>
<td>FiO2 (Monitored)</td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0.21 to 1.00 (resolution 0.01) Accuracy: ±0.03 (“—” displayed if sensor is disconnected)</td>
</tr>
<tr>
<td>FiO2 High</td>
<td>Alarms-Non Adjustable</td>
<td>Monitored FiO2 is more than 0.07 above the set FiO2 for 30 seconds. Accuracy: ±0.03</td>
</tr>
<tr>
<td>FiO2 Low</td>
<td>Alarms-Non Adjustable</td>
<td>Monitored FiO2 is more than 0.07 below the set FiO2 for 30 seconds. Accuracy: ±0.03</td>
</tr>
<tr>
<td>Flow Sensor Error</td>
<td>Alarms-Non Adjustable</td>
<td>Flow sensor cannot calibrate or the internal wire is damaged or sensor is disconnected.</td>
</tr>
<tr>
<td>Flow - Inspiratory Setting</td>
<td>Control Panel</td>
<td>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 ± 0.3 L/min, whichever is greater</td>
</tr>
<tr>
<td>Flow - Inspiratory Monitored</td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 200 L/min (resolution 1 L/min)</td>
</tr>
<tr>
<td>Flow- Expiratory</td>
<td>GUI Monitored Data</td>
<td>Displayed range: 0 to 200 L/min (resolution 1 L/min)</td>
</tr>
<tr>
<td>Flow Waveform</td>
<td>GUI-Advanced Data Set</td>
<td>Range: Square or Descending Ramp Selects flow waveform for Volume Control mandatory breaths.</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
</tr>
<tr>
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</tr>
<tr>
<td>Freeze/Start/Save</td>
<td>GUI-Main and Extended Functions</td>
<td>Freeze: Suspends plotting of graphs (waveforms, loops, or trends) and holds the current display for extended viewing. Start: Resumes plotting of graphs. Save: Captures current screen image for later downloading.</td>
</tr>
<tr>
<td>Gas Supply</td>
<td>Alarms-Non Adjustable</td>
<td>If one or both gas supplies are below 30 psi.</td>
</tr>
<tr>
<td>High Baseline Pressure</td>
<td>Alarms-Non Adjustable</td>
<td>Monitored PEEP (Pbase) is greater than set PEEP level by 5 cmH₂O/mbar for two consecutive breaths. Accuracy: ±1 cmH₂O/mbar</td>
</tr>
<tr>
<td>High MVE</td>
<td>GUI-Alarms-Adjustable</td>
<td>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)</td>
</tr>
<tr>
<td>High Paw</td>
<td>GUI-Alarms-Adjustable</td>
<td>Range: Ped/Infant: 5 to 100 cmH₂O/mbar (resolution 1 cmH₂O/mbar) Adult: 5 to 120 cmH₂O/mbar (resolution 1 cmH₂O/mbar) Accuracy: ±3% or ±2 cmH₂O/mbar, whichever is greater <strong>NOTE:</strong> A High Paw alarm violation terminates the current breath and cycles to exhalation. This alarm is applicable for all breaths, including manual inflations.</td>
</tr>
<tr>
<td>High RRtot</td>
<td>GUI-Alarms-Adjustable</td>
<td>Total respiratory rate including mandatory and spontaneous breaths. Range: 10-120 b/min or OFF Accuracy: +3% or +2 b/min, whichever is greater</td>
</tr>
<tr>
<td>I:E Inverse Violation</td>
<td>Alarms-Non Adjustable</td>
<td>Ventilator settings result in an I:E ratio greater than 4:1</td>
</tr>
<tr>
<td>I:E Ratio (Monitored)</td>
<td>GUI-Monitored Data</td>
<td>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)</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
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</tr>
<tr>
<td>Ideal Body Weight</td>
<td>GUI-Patient Setup</td>
<td>Range: 2-2202 lb (1-999 kg)</td>
</tr>
<tr>
<td>Inspiratory Hold</td>
<td>GUI-Extended Functions</td>
<td>Range: Up to 15 seconds</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Generates an Inspiratory Hold</td>
</tr>
<tr>
<td></td>
<td></td>
<td>maneuver at the end of a mandatory</td>
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<td></td>
<td>breath inspiration for as long as</td>
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<td></td>
<td>the button is pushed.</td>
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<tr>
<td>Insip time too long</td>
<td>Alarms-Non Adjustable</td>
<td>Ventilator settings result in an</td>
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<tr>
<td></td>
<td></td>
<td>Inspiratory Time greater than 5</td>
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<tr>
<td></td>
<td></td>
<td>seconds</td>
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<tr>
<td>Insip time too short</td>
<td>GUI-Alarms-Non Adjustable</td>
<td>Ventilator settings result in an</td>
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<tr>
<td></td>
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<td>Inspiratory Time less than:</td>
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<td></td>
<td></td>
<td>Adult: 0.1 Seconds</td>
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<tr>
<td></td>
<td></td>
<td>Infant/Peds: 0.05 seconds</td>
</tr>
<tr>
<td>Internal Battery Indicators</td>
<td>Control Panel</td>
<td>Internal Battery LED on the Control</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Panel lights and an audible signal</td>
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<tr>
<td></td>
<td></td>
<td>sounds every five minutes to indicate</td>
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<td></td>
<td></td>
<td>that the ventilator is operating on</td>
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<tr>
<td></td>
<td></td>
<td>internal battery power. The Battery</td>
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<tr>
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<td></td>
<td>Charge Level icon (located in the</td>
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<td></td>
<td>top right area of the GUI) shows</td>
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<tr>
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<td></td>
<td>the relative level of internal battery</td>
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<tr>
<td></td>
<td></td>
<td>power when ventilator is operating on</td>
</tr>
<tr>
<td></td>
<td></td>
<td>internal battery power.</td>
</tr>
<tr>
<td>Leak Comp (Leak Compensation)</td>
<td>GUI-Patient Setup</td>
<td>Range: ON or OFF</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ON = 3 – 8 L/min for Ped/Infant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>patient selection</td>
</tr>
<tr>
<td></td>
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<td>3 – 15 L/min for Adult patient</td>
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<td></td>
<td></td>
<td>selection</td>
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<td>OFF = 3 L/min regardless of leaks/</td>
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<tr>
<td></td>
<td></td>
<td>no leak</td>
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<tr>
<td></td>
<td></td>
<td>Non-Invasive Ventilation ON- Leak</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Compensation is automatically</td>
</tr>
<tr>
<td></td>
<td></td>
<td>adjusted from 3-25 L/min.</td>
</tr>
<tr>
<td>Loops</td>
<td>GUI-Main</td>
<td>Loops combinations: Flow/Volume,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Volume/Pressure or both on one screen</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
</tr>
<tr>
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</tr>
<tr>
<td>Low Baseline Pressure</td>
<td>Alarms-Non Adjustable</td>
<td>When the monitored proximal pressure $\leq$ low baseline pressure criteria for more than 0.5 seconds for two consecutive breaths. Accuracy: $\pm 1$ cmH2O/mbar</td>
</tr>
<tr>
<td>Low Battery</td>
<td>Alarms-Non Adjustable</td>
<td>Unsilenceable audible alarm sounds when internal battery capacity has dropped to 25% or less.</td>
</tr>
<tr>
<td>Low MVE</td>
<td>GUI-Alarms-Adjustable</td>
<td>Range: Ped/Infant: 0.01 to 9.99 L (resolution 0.01 L) 10.0 to 30.0 L (resolution 0.1L) Adult: 1.00 to 9.99 L (resolution 0.01 L) 10.0 to 50.0 L (resolution 0.1 L) Accuracy: $\pm 10%$ or $\pm 0.1$ L, whichever is greater</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>NOTE:</strong> When Non Invasive is activated this alarm may be set to OFF.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>NOTE:</strong> Low MVE alarm is suspended for 60 seconds once the breathing circuit is reconnected following activation of Suction Disconnect.</td>
</tr>
<tr>
<td>Low Paw</td>
<td>GUI-Alarms-Adjustable</td>
<td>Range: Ped/Infant: 3 to 75 cmH2O/mbar (resolution 1 cmH2O/mbar) Adult: 3 to 95 cmH2O/mbar (resolution 1 cmH2O/mbar) Accuracy: $\pm 3%$ or $\pm 2$ cmH2O/mbar, whichever is greater</td>
</tr>
<tr>
<td>Low Paw Below PEEP</td>
<td>GUI-Informational Message</td>
<td>The current Low Paw alarm setting is lower than the PEEP setting.</td>
</tr>
<tr>
<td>Mains</td>
<td>Control Panel</td>
<td>Lights when the ventilator is supplied with AC power.</td>
</tr>
<tr>
<td>Manual Inflation</td>
<td>Control Panel</td>
<td>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.</td>
</tr>
<tr>
<td>MVE</td>
<td>GUI-Monitored Data</td>
<td>Displayed range: (cont. next page)</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
</tr>
<tr>
<td>----------------------</td>
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<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **MVe (cont.)**      |                          | 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  

**NOTE:** The display will not be updated if the exhalation flow sensor is disconnected. |
| **MVi**              | GUI-Monitored Data       | 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. |
| **NIF**              | GUI-Technical            | Generates NIF maneuver for measuring airway pressure during a maximum inspiratory effort. It is available in all modes, with and without Non Invasive Ventilation (NIV) activated. |
| **Non-Invasive**     | Control Panel            | Range: ON (LED lights) or OFF  
Available in all modes and breath types. Leak Compensation is automatically adjusted up to 25 L/min when Non Invasive is ON. |
| **No Communications**| Alarms-Non Adjustable    | No communications failure is a failure of the SBC to send communication to the Main Board or loss of monitor processor.  
Unsilenceable audible alarm.  
**Note:** Ventilator continues to ventilate at current control setting. |
| **Numeric**          | GUI-Main                 | The Numeric screen displays all monitored parameters on a single screen, including Advance data functions (except Volume Target).  
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, Open Exh, Flow Wave |
<table>
<thead>
<tr>
<th>Item</th>
<th>Location and/or Function</th>
<th>Range and Resolution or Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>O2 3 Min</td>
<td>Control Panel</td>
<td>When pressed delivers 100% oxygen for 3 minutes. Pressing button again turns off 100% oxygen delivery. Indicator lights when O2 3 min is in effect.</td>
</tr>
<tr>
<td>O2 Sensor</td>
<td>GUI-Sensors</td>
<td>Can perform an oxygen sensor calibration by delivering 100% oxygen to the system. O2 Sensor calibration is always performed when the O2 3 min button is pressed. Can disable O2 sensor.</td>
</tr>
<tr>
<td>O2 Sensor Disconnected</td>
<td>GUI-Informational Message</td>
<td>Notification message that the O2 sensor has been disconnected.</td>
</tr>
<tr>
<td>O2 Sensor Error</td>
<td>Alarms-Non Adjustable</td>
<td>Alarm message is displayed and audible alarm sounds if the oxygen sensor fails.</td>
</tr>
<tr>
<td>Open Exhalation Valve</td>
<td>GUI-Advanced Data Set</td>
<td>Range: ON or OFF Activates management of a partially open exhalation valve. Converts Pressure Control mandatory breath type to Biphasic Pressure Release mandatory breath type (enables BPRV).</td>
</tr>
<tr>
<td>P0.1</td>
<td>GUI-Technical</td>
<td>Generates P0.1 measurement for assessing the patient's respiratory drive. It is available in all modes and breath types but not available when Non Invasive Ventilation (NIV) is activated.</td>
</tr>
<tr>
<td>Patient Category</td>
<td>GUI-Patient Setup</td>
<td>Range: Ped/Infant (pediatric/infant) Adult (An icon located on the top left corner of the GUI indicates category selected.) <strong>NOTE:</strong> Settable ranges for ventilator parameters and alarms will vary depending on the patient category selected.</td>
</tr>
<tr>
<td>Patient Trigger Indicator</td>
<td>GUI-Monitored Data</td>
<td>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.</td>
</tr>
<tr>
<td>Pause (Inspiratory)</td>
<td>GUI-Advanced Data Set</td>
<td>Range: Off, 0.1 – 2.0 seconds (resolution 0.1 second) Sets the duration of Pause at the end of inspiration for volume control mandatory breaths.</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
</tr>
<tr>
<td>----------------------</td>
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<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **PEEP/CPAP** (Baseline Pressure-Set) | Control Panel | Range:  
Ped/Infant: 0 to 30 cmH2O/mbar (resolution 1 cmH2O/mbar)  
Adult: 0 to 45 cmH2O/mbar (resolution 1 cmH2O/mbar)  
Accuracy: ±10% or ±1 cmH2O/mbar, whichever is greater.                                                                                           |
| **Baseline Pressure-Monitored** | GUI-Monitored Data | Displayed range: 0 to 99.9 cmH2O/mbar (resolution 0.1 cmH2O/mbar)  
Accuracy: ±3% or ±2 cmH2O/mbar, whichever is greater.                                                                                                         |
| total **PEEP**       | GUI-Monitored Data      | Displayed range: 0 to 99.9 cmH2O/mbar  
Resolution: 0.1 cmH2O/mbar  
Accuracy: Larger of ± 3% or 2 cmH2O/mbar  
Maneuver–based with time stamp (for up to 24 hours)  
Total PEEP equals the sum of set PEEP + AutoPEEP. Total PEEP is updated immediately following an Exp Hold. |
| **Pmean**            | GUI-Monitored Data      | Displayed range: 0 to 140 cmH2O/mbar (resolution 0.1 cmH2O/mbar)  
Accuracy: ±3% or ±2 cmH2O/mbar, whichever is greater  
The average pressure in the patient breathing circuit for the past 30 seconds                                                                 |
| **Power Shutdown**   | Alarms-Non Adjustable   | When ventilator is powered off an audible alarm sounds. Silence by pressing Alarm Silence button.                                                                                                                               |
| **Ppeak**            | GUI-Monitored Data      | Displayed range: 0 to 140 cmH2O/mbar (resolution 0.1 cmH2O/mbar)  
Accuracy: ±3% or ±2 cmH2O/mbar, whichever is greater  
Updated following each positive pressure inflation                                                                                           |
| **Pplat**            | GUI-Monitored Data      | Displayed range: 0 to 140 cmH2O/mbar (resolution 0.1 cmH2O/mbar)  
Accuracy: ±3% or ±2 cmH2O/mbar, whichever is greater  
**NOTE:** Displays time stamped numeric value (for up to 24 hours) following a valid inspiratory hold maneuver or following Pause that results in a stable pressure level. |
<table>
<thead>
<tr>
<th>Item</th>
<th>Location and/or Function</th>
<th>Range and Resolution or Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Bar Graph</td>
<td>Control Panel</td>
<td>Displayed range: -10 to 120 cmH2O/mbar</td>
</tr>
<tr>
<td>Pressure Limit</td>
<td>Control Panel</td>
<td>Range: Ped/Infant: 0 to 70 cmH2O/mbar (resolution 1 cmH2O/mbar)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adult: 0 to 80 cmH2O/mbar (resolution 1 cmH2O/mbar)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Accuracy: ±10% or ±1 cmH2O/mbar, whichever is greater</td>
</tr>
<tr>
<td>Pressure Limit Below PEEP</td>
<td>GUI-Informational Message</td>
<td>The current Pressure Limit setting is lower than the PEEP/CPAP setting.</td>
</tr>
<tr>
<td>Pressure Support</td>
<td>Control Panel</td>
<td>Range: Ped/Infant: 0 to 50 cmH2O/mbar (resolution 1 cmH2O/mbar) above PEEP/CPAP setting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adult: 0 to 60 cmH2O/mbar (resolution 1 cmH2O/mbar) above PEEP/CPAP setting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Accuracy: ±10% or +1 cmH2O/mbar, whichever is greater</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>NOTE:</strong> Out of Range alarm occurs if PEEP + PS &gt; 60 cmH2O/mbar.</td>
</tr>
<tr>
<td>Pressure Support + PEEP &gt; 60</td>
<td>GUI-Informational Message</td>
<td>Indicates that the operator is attempting to set a Pressure Support or PEEP level that is greater than the sum of the two settings.</td>
</tr>
<tr>
<td>Pressure Units</td>
<td>GUI-Technical/Regional</td>
<td>Select cmH2O (centimeters/water pressure) or mbar (millibars).</td>
</tr>
<tr>
<td>RE (cmH2O/mbar/L/s)</td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 999.9 cmH2O/mbar/L/s</td>
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<tr>
<td></td>
<td></td>
<td>Accuracy: ±1 cmH2O/mbar /L/s</td>
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<tr>
<td></td>
<td></td>
<td>Resolution: 0.1 cmH2O/mbar/L/s</td>
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<tr>
<td></td>
<td></td>
<td>RE = exhalation time constant/ Cstat.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maneuver–based with time stamp (for up to 24 hours)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Regional</td>
<td>GUI-Technical</td>
<td>• Altitude Range: 0 to 4,000 meters (0 to 13,124 feet)</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td><strong>Resp Rate</strong></td>
<td>Control Panel</td>
<td>Range: Ped/Infant: 1 to 120 b/min (resolution 1 b/min) &lt;br&gt;Adult: 1 to 80 b/min (resolution 1 b/min) &lt;br&gt;Accuracy: ±1 b/min or ±10% of breath period, whichever is less</td>
</tr>
<tr>
<td><strong>RI</strong></td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 999.9 cmH2O/mbar/L/s &lt;br&gt;Accuracy: ±1 cmH2O/mbar/L/s &lt;br&gt;Maneuver–based with time stamp (for up to 24 hours) &lt;br&gt;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.</td>
</tr>
<tr>
<td><strong>RR spont</strong></td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 999 b/min &lt;br&gt;Accuracy: Larger of ±3% or ±2 b/min.</td>
</tr>
<tr>
<td><strong>RR tot</strong></td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 999 b/min &lt;br&gt;Accuracy: ±3% or ±2 b/min., whichever is greater.</td>
</tr>
<tr>
<td><strong>RSBI</strong></td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 9999 b/min/L &lt;br&gt;Accuracy: ±1 b/min/L &lt;br&gt;Spontaneous respiratory rate/exhaled tidal volume ratio. (RSBI = RRspont2 / MVEspont). RR spont and MVE (spont) must be valid to calculate RSBI.</td>
</tr>
<tr>
<td><strong>Screen Files</strong></td>
<td>GUI-Technical</td>
<td>Contains list of the last 200 saved screen images (.bmp files). Files are assigned an 8-digit file name that includes a letter for file type (W for Wave, L for loop, etc), the last 4 digits of the serial number, and a 3 digit sequential number.</td>
</tr>
<tr>
<td><strong>Setting/Alarm Limit out of Range</strong></td>
<td>Alarms- Non Adjustable</td>
<td>Alarm or setting parameter out of range for the selected patient category.</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>Sigh</td>
<td>GUI-Patient Setup</td>
<td>Range: ON or OFF In Volume Control A/CMV or SIMV delivers 1 sigh breath every 100 breaths at tidal volume x 1.5. During a sigh breath flow remains at set value and inspiratory time is lengthened.</td>
</tr>
<tr>
<td>Slope/Rise</td>
<td>GUI-Advanced Data Set</td>
<td>Range: 1-19 Resolution: 1, where 1 is the slowest pressurization and 19 is the fastest. Slope/Rise sets the pressurization gain for Pressure Control, Pressure Support, Volume Targeted Pressure Control, BPRV and Volume Targeted Pressure Support breaths.</td>
</tr>
<tr>
<td>Suction Disconnect</td>
<td>Alarm Feature</td>
<td>Holding down the Alarm Silence button for one second or longer (until the ventilator sounds a short beep) enables the Suction Disconnect Function.</td>
</tr>
<tr>
<td>Sustained High Baseline Pressure</td>
<td>Alarms- Non Adjustable</td>
<td>Monitored circuit pressure Pbase has been &gt; 8 cmH2O/mbar above set PEEP/CPAP for over 6 seconds for Ped/Infant or 10 seconds for Adult patients. Machine pressure is also &gt; 8 cmH2O/mbar above set PEEP/CPAP. Accuracy: ±1 cmH2O/mbar WARNING! Ventilation and triggering are suspended and the exhalation valve and emergency intake valve open to vent pressure.</td>
</tr>
<tr>
<td>t Insp (inspiratory time)</td>
<td>Control Panel GUI Monitored Data</td>
<td>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 Displayed range: 0 to 9.99 seconds (resolution 0.01 seconds) Accuracy: ±0.05 second Updated following each spontaneous or mandatory breath.</td>
</tr>
<tr>
<td>Tidal Volume *</td>
<td>Control Panel</td>
<td>Range: Ped/Infant: 20 to 1000 mL (resolution 2 mL) (cont. next page)</td>
</tr>
<tr>
<td>Item</td>
<td>Location and/or Function</td>
<td>Range and Resolution or Description</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Tidal Volume * (cont.)</td>
<td>Control Panel</td>
<td>Adult: 100 to 995 mL (resolution 5 mL), 1.00 to 3.00 L (resolution 0.01 L) Accuracy: ±10% or ±2 mL, whichever is greater</td>
</tr>
<tr>
<td></td>
<td></td>
<td>* Gas delivery is Body Temperature Pressure Saturation compensated: Body temperature 37 ºC, steam saturated gas, and ambient pressure.</td>
</tr>
<tr>
<td>Time Constant</td>
<td>GUI Monitored Data</td>
<td>Displayed range: 0 to 9.99 Accuracy: +/- 0.01 s Represents the exhalation Time Constant: slope of flow-volume loop during exhalation. Reliable measurements require adequate time for complete exhalation. Displayed as time in seconds.</td>
</tr>
<tr>
<td>Trends</td>
<td>GUI-Main</td>
<td>Accuracy: Larger of the individual parameter accuracy, or 2% of the selected full scale.</td>
</tr>
</tbody>
</table>
| Trigger [Press Trig button above the display to select Flow or P (pressure)] | Control Panel | **P (pressure trigger sensitivity):** Range: 0.0 to -5.0 cmH2O/mbar (resolution 0.1 cmH2O/mbar) Accuracy: ±10%.  
**Flow (trigger sensitivity)** 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  
**NOTE:** Automatically compensated for bias flow/leak compensation. |
| Ventilation Suspended | Informational Message      | Displayed when the Suction Disconnect feature has been activated and the patient is disconnected from the ventilator (See Suction Disconnect). |
| Volume Target         | GUI-Advanced Data Set      | Range: ON or OFF  
When enabled, turns on Volume Target Pressure Control mandatory (cont. next page) |
<table>
<thead>
<tr>
<th>Item</th>
<th>Location and/or Function</th>
<th>Range and Resolution or Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume Target (cont.)</td>
<td>GUI-Advanced Data Set</td>
<td>breath type for all mandatory breaths and Volume Target Pressure Support for all spontaneous breaths.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimum pressure control/support is PEEP + 5 cmH₂O/mbar, maximum pressure control/support is Pressure Limit setting.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>When this feature is ON, Open Exh (BPRV) is not active.</td>
</tr>
<tr>
<td>Volume Target Not Met</td>
<td>Alarms-Non Adjustable</td>
<td>In Volume Target Pressure Control breath type the set tidal volume cannot be delivered within the set Pressure Limit/Inspiratory Time.</td>
</tr>
<tr>
<td>Volume Units</td>
<td>GUI-Patient Setup</td>
<td>Range: mL or mL/kg or mL/lb</td>
</tr>
<tr>
<td>VTE (mL) (expiratory tidal volume)</td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 3000 mL (resolution 1 mL) Accuracy: For set tidal volume &gt; 0.10 L , ±10% or ±0.02 L, whichever is greater. For set tidal volume &lt; 0.10 L, ±20% or +/- 0.002L, whichever is greater.</td>
</tr>
<tr>
<td>VTI (mL) (Inspiratory tidal volume)</td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 3000 mL (resolution 1 mL) Accuracy: For set tidal volume &gt; 0.10 L , ±10% or ±0.02 L, whichever is greater. For set tidal volume &lt; 0.10 L, ±20% or +/- 0.002L, whichever is greater.</td>
</tr>
<tr>
<td>VTE % Var</td>
<td>GUI-Monitored Data</td>
<td>Displayed Range: 0 to 100% (resolution: 1%) Accuracy: +/- 10% Percent difference between inspiratory and expiratory tidal volumes.</td>
</tr>
<tr>
<td>Waveforms</td>
<td>GUI-Main</td>
<td>Waveform combinations: Pressure / Time, Flow / Time, Volume / Time or combination of two can be displayed on one screen</td>
</tr>
<tr>
<td>Weight Units</td>
<td>GUI-Patient Setup And Quick Setup</td>
<td>Range: lb or kg</td>
</tr>
<tr>
<td>WOBimp (J/min)</td>
<td>GUI-Monitored Data</td>
<td>Displayed range: 0 to 99.99 J/min</td>
</tr>
</tbody>
</table>
## Specifications

### Physical Specifications

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Power Specifications</strong></td>
</tr>
<tr>
<td><strong>AC input range</strong>: 100 to 240 VAC, 250 VA maximum, 50/60 Hz (±10%), 2A for 125 VAC, 1A for 250 VAC Internal battery: Fully charged battery can support approximately one (1) hour of complete ventilator function at the following standard settings: Adult, VC/SIMV, VT 500, FiO2 .30, Insp Time 1.0 s, 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). <strong>Minimum recharge time</strong>: From Low Battery Alarm to Full = 5 hours From Empty to Full = 14 - 16 hours <strong>Power Cord Requirements</strong>: 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, &lt; 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, &lt; 10 ft (3 m) long, CSA and UL-approved</td>
</tr>
<tr>
<td><strong>Compliance</strong></td>
</tr>
<tr>
<td>Complies with IEC 60601-1 with amendments 1 &amp; 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)</td>
</tr>
<tr>
<td><strong>Expiratory Channel Resistance</strong></td>
</tr>
<tr>
<td>Pressure drop less than 1.7 cmH2O/mbar @ 50 L/min Adult less than 1.7 cmH2O/mbar @ 20 L/min Infant <strong>NOTE</strong>: Testing was performed according to ASTM F1100-90</td>
</tr>
<tr>
<td><strong>Dimensions</strong></td>
</tr>
<tr>
<td>Height: 14 in (35.56 cm) Width: 12 in (30.48 cm) Depth: 14 in (35.56 cm) Weight: 40 lbs. (18.14 kg)</td>
</tr>
<tr>
<td><strong>Display</strong></td>
</tr>
<tr>
<td>6.4 in active matrix color LCD Touch screen transparent plastic-covered glass. Pressure-sensitive surface can electronically decode touch position.</td>
</tr>
</tbody>
</table>
## Specifications

<table>
<thead>
<tr>
<th>Environmental Requirements</th>
<th>Description</th>
</tr>
</thead>
</table>
| **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 60 ºC (–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 O₂ supply | Inlet pressure: 30 to 90 psig, 50 psig nominal |

<table>
<thead>
<tr>
<th>Remote Alarm/ Nurse Call</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Range:** Normally Open (refers to the electrical continuity of the circuit)  
For attachment to a nurse call or remote alarm system.  
250 mA @ 100 VDC: Allowable current at maximum voltage between the relay contact < .2 ohms: Maximum initial contact resistance  
**NOTE:** Always verify that the remote alarm function is operational following initial connection to the nurse call or remote alarm system and at regular intervals thereafter.  
**NOTE:** Always use shielded cables for connection between the remote alarm and the nurse call or remote alarm system. |

| RS232C | 9-pin D-shell, 38.4k baud. For use with central monitoring systems. |
| VGA | Output for external display monitor |
| USB | Output for connecting a data storage device |
| External Alarm Silence | Input for optional Newport external alarm silence cable |
| External Battery | 3-pin DIN input for external power, 10 VDC to +14 VDC |
| Patient circuit connections | Inspiratory and expiratory ports: 22-mm OD for connection to a patient breathing circuit / filters. |
A
A/CMV- See Modes
AC Power Loss/Battery Backup Alarm, 5-7
AC Power- See Power
Accept Button, 2-3, F-4 item 10
Adjustable Alarms, 5-3
Adjustment Knob, 2-3, F-4 item 10
Advanced Data Set, 4-10, F-4
Air Connection, 3-5
Air Supply Loss Alarm, 5-7
Alarms & Message Display Bar, 5-1
Adjustable, 5-3
Alarm History, Downloading, 4-17
Alarm History, Saving, 4-16
in Non-Invasive, 7-11
Indicators, Visual, 5-1
Lamp, 5-1
Loudness, 8-1
Non-Adjustable, 5-6
Settings Screen, 5-3
Tones, 5-5, 8-1
Violation and Remedy Guide, 5-7
Alarm Reset, 5-6
Alarm Screen Button, F-4
Alarm Silence, 5-5, 8-1
Altitude, 4-7
Apnea Alarm, 5-7, 8-1
Assembly
Accessories, 3-1
Cart, 3-2
External Display Monitor, 3-3
Expiratory Filter Heater, 3-4
Automatic Leak Compensation- See Leak Comp
Auto-Scale- See Waves and Loops

B
Back Up Ventilation Alarm, 5-8, 8-1
Basic Data Set, 4-15
Bias Flow, 7-9
Both Air/O2 Supply Loss Alarm, 5-8
BPRV-Biphasic Pressure Release Ventilation
Description, 7-3
Setting, 4-10

Open Exhalation Valve, 8-10
Breath Type
Description, 7-1, 7-4, 8-2
Display, 2-7
Selection, 2-3
Breathing Circuit, Installation, 3-6

C
C Internal System Alarm, 5-9
Cautions, General, 1-8
Cdyn Effective- See Compliance
Check Flow Sensor Board Alarm, 5-8
Check Vent Fan Alarm, 5-9
Circuit Check, 4-2, F-5
Circuit Disconnect Alarm, 5-9
Circuit Type Selection, 4-6, 8-2
Cleaning, 6-9
Communication Protocol, 4-7, 8-3
Communications Failure Alarm, See No Communication Alarm
Compliance
Circuit Check, 7-11
Effective Dynamic-Cdyn, 8-2
Static-Cstat, 8-3
Compl Comp (Compliance Compensation)
Description, 7-10
Setting, 4-6
Specification, 8-3
Contact Information, ii
Control µP Failed Alarm, 5-10
Control CPU Failed Alarm, 5-10
Control Panel Layout, 2-1, F-4, F-12
Control RAM Failed Alarm, 5-10
Control Task Failed Alarm, 5-10
Cstat (Static Compliance)- See Compliance

D
Data Read Failure Alarm, 5-10
Data Sets, 4-18
Date and Time
Display, 2-7
Setting, 4-7
Device Alert, 5-2, 5-11, 8-4
Device Description, 1-1
Dimensions, 8-18
Disassembly and Reassembly Procedures, 6-2
Disconnect Threshold Alarm, 8-4
Display Brightness, 8-4, F-10
Download, 4-21
Dual RAM Failed Alarm, 5-11

E
EEPROM Read Error Alarm, 5-11
Event History
  Downloading, 4-17
  Files, 4-7, 8-4
  Saving, 4-17
  Specifications, 8-4
  Screen, 4-16, F-10
Exhalation Flow Sensor
  Calibration, 4-3
  Cleaning, 6-11
  Removal, 6-3
Exhalation Valve
  Cleaning, 6-11
  Removal, 6-5
Exp Flow (peak)- See Flow
Expiratory Hold Maneuver, 4-10, F-7
Expiratory Minute Volume- See MVE
Expiratory Resistance- See RE
Expiratory Tidal Volume- See VTE
Expiratory Threshold
  Description, 7-9
  Setting, 4-10
  Specifications, 8-5
Extended Functions Screen, 2-6, F-4
External Alarm Silence Cable Port, F-2, Item 3
External Battery
  Connector F-2
  Indicator 2-7

F
Fan Filter
  Cleaning, 6-11
  Removal, 6-2
Filters
  Use of, 6-1
  Warnings, 1-6
FiO2
  Setting, 2-4
  Specifications, 8-5
FiO2 High Alarm, 5-11
FiO2 Low Alarm, 5-12
FlexCycle - see Expiratory Threshold
Flow
  Setting, 2-4
  Specifications, 8-5
Flow Sensor - See Exhalation Flow Sensor
Flow Sensor Error Alarm, 5-13
Flow Trigger, See Trigger
Flow Waveform, 4-10, 8-5
Freeze- See Waves and Loops
Fuses, Removal, 6-8

G
Gas Supply Alarm, 8-6
Graphical User Interface (GUI), 2-1
GUI Navigation Map, 2-1, F-3
GUI Screens, 2-5
GUI Status Bar, 2-6

H
High Baseline Pressure Alarm, 5-13, 8-6
High MVE Alarm (Expiratory Minute Volume), 5-13, 8-6
High Paw Alarm, 5-13, 8-6
High RR tot Alarm, 5-14, 8-6
Hour Meter, 2-7

I
I:E Ratio, 8-6
I:E Ratio Inverse Violation Message, 5-14
Ideal Body Weight, 4-5, 8-7
Imposed Work of Breathing - See WOBimp
Inspiratory Flow (peak)- See Flow
Inspiratory Hold Maneuver, 4-10, 8-7, F-7
Inspiratory Manifold, Removal, 6-7
Inspiratory Pause- See Pause, 4-10, 8-5
Inspiratory Resistance- See RI
Inspiratory Time- See t insp
Inspiratory Time Too Long Alarm, 5-14
Inspiratory Time Too Short Alarm, 5-15
Intended Use Information, 1-2
Internal Battery
  About, 2-7
  Charge Level, 2-7
  Charging, 2-7
  Indicators, 2-7, 8-7

L
Leak Comp (Leak Compensation)
  Description, 7-10
  Non-Invasive, 7-11
  Setting, 4-6
Specifications, 8-7
Loops- See Waves and Loops
Low Baseline Pressure Alarm, 5-15, 8-8
Low Battery Alarm, 5-15, 8-8
Low MVE Alarm (Expiratory Minute Volume), 5-16, 8-8
Low Paw Alarm, 5-16, 8-8
Low Paw Below PEEP Message, 5-17, 8-8
Lower Front Panel Layout, 2-1

M
M Internal System Alarm, 5-17
Main Screen, 2-6, F-4
Mains, 8-8, F-4 item 13
Maintenance Frequency Summary, 6-12
Mandatory Breath Types, 7-1
Manual Inflation Button, 2-4, 8-8, F-4 item 11
Mean Airway Pressure (Pmean)- See Pressure
Mechanics Data Set, 4-15
Modes
and Breath Types Available, 2-3
Descriptions, 7-6
A/CMV, 7-7
Selecting, 2-3
SIMV, 7-7
SPONT, 7-8
Monitor µP Failed Alarm, 5-17
Monitor CPU Failure Alarm, 5-17
Monitor RAM Failed Alarm, 5-17
Monitor ROM Failed Alarm, 5-18
Monitor Task Failed Alarm, 5-18
MVE (Expiratory Minute Volume), 8-8
MVI (Inspiratory Minute Volume), 8-9

N
Negative Inspiratory Force (NIF), 4-10
No Communication Alarm, 5-18
Non Adjustable Alarms, 5-6
Non Invasive
  Description, 7-11
  Setting, 2-3
  Specifications, 8-9
Numeric Screen, 4-17, 8-9
O
O2 (3min), 2-5, 8-9, F-4
O2 Sensor
  Calibration, 4-4
  Disable, 4-4
  Removal, 6-8
  Replacement, 6-13
  Specification, 8-9
O2 Sensor Disconnect Alarm, 5-19
O2 Sensor Error Alarm, 5-19
O2 Supply Loss Alarm, 5-19
Open Exhalation Valve- See BPRV
Operating Temperature, 8-19
Out of Range Message, 5-19
Oxygen Connection, 3-5

P
P0.1 Measurement, 4-10
Patient Breathing Circuit, 3-5
Patient Category, 4-5, 8-10
Patient Selection- See Patient Category
Patient Setup, 4-5
Patient Trigger, See Trigger
Patient Weight, See Ideal Weight
Pause (Inspiratory), 4-10, 8-10
Peak Expiratory Flow- See Flow
Peak Inspiratory Flow- See Flow
Peak Pressure (Ppeak)- See Pressure
PEEP/CPAP
  total PEEP, 8-10
  Setting, 2-4
  Specifications, 8-10
Physical Specifications, 8-18
Plateau Pressure, See Pressure
Pmean- See Pressure
Power
  Connections, 3-5
  Conditions, 4-1
  Indicators, F-4
  Shutdown Alarm, 5-20
  Specifications, 8-18
  Switch Location, F-2
Power Cord Requirements, 8-18
Power Failure Alarm, 5-19
Power Supply Warnings, 1-7
Ppeak- See Pressure
Pplat- See Pressure
Preparing for Patient Ventilation, 4-1
Pressure
Mean - Pmean, 8-11
Peak - Ppeak, 8-11
PEEP, 8-10
Plateau - Pplat, 8-11
Pressure Bar Graph, 8-11, F-4 item 7
Pressure Control Breath Type, 7-3
Pressure Limit
  In VTPC, 7-4
  In VTPS, 7-5
  Setting, 2-4
  Specifications, 8-11
Pressure Limit Below PEEP
Message, 5-20, 8-11
Pressure Support
  Description, 7-4
  Specifications, 8-12
Pressure Support + PEEP > 60
Message, 5-20, 8-12
Pressure Trigger - See Trigger

R
Rapid Shallow Breathing Index (RSBI), 8-13
RE - Expiratory Resistance, 8-12
Rear Panel Layout, 2-2, F-14
Reassembly Procedures, 6-2
Regional Settings, 4-7, 8-12
Remote Alarm, F-2, 8-19
Repackaging the Ventilator, 6-14
Reset Button, Alarm, 5-6
Respiratory Rate - Resp Rate
  Monitoring, 4-15
  RR spont, 4-17, 8-13
  RR tot, 4-15, 8-13
  Specifications, 8-12
Responsibility for Patient Safety, 1-10
RI - Inspiratory Resistance, 8-13

S
Safety Check Procedure
  AC Power Loss/Battery Back Up, 3-10
  Alarm Silence, 3-10
  Apnea Alarm, 3-11
  Back Up Ventilation Alarm, 3-11
  Circuit Check, 3-9
  Circuit Disconnect Alarm, 3-10
  Emergency Intake Valve, 3-8
  Gas Supply Alarms, 3-9
  High/Low Airway Pressure
  Alarms, 3-10
  Minute Volume Alarm, 3-11
  Setup and Inspection, 3-8
  Shut Down Alarm, 3-12
  Trigger / Pressure Support, 3-11
  Volume/Flow/Rate Accuracy Test, 3-11
Safety Check Record, 3-13
Save Feature, 4-19
Scale - See Waves and Loops
Screen Files, 4-7, 8-13
Sensors - See Exhalation Flow or O2 Sensor
Setup and Calibration Menu, 2-6, 4-2, F-4
Shutdown Alarm, 5-20
Sigh, 4-5, 8-13
SIMV - See Modes
Slope/Rise
  Description, 7-9
  Setting, 4-10
  Specifications, 8-14
SPONT - See Modes
Spontaneous Breath Management 7-4
Spontaneous Respiratory Rate - See Respiratory Rate
Static Compliance (Cstat) - See Compliance
Sterilizing, 6-9
Storage Temperature, 8-19
Storing the Ventilator, 6-14
Suction Disconnect Feature, 5-6
Support Arm Installation, 3-2
Sustained High Baseline Pressure Alarm, 5-20
Symbols Control Panel, F-12

T
t Insp (Inspiratory Time)
  Monitoring, 4-13
  Setting, 2-4
  Specifications, 8-14
Technical Setup Screen, 4-7
Tidal Volume
  Expiratory, 4-15, 8-16
  Inspiratory, 4-15, 8-16
  Setting, 2-4
  Specifications, 8-14
Time Constant, 8-15
Trends Screen, 4-17
Index

Trigger
   and Leaks, 7-8
   and Non-Invasive, 7-11
Indicator, 2-7
   Selecting Flow or Pressure, 2-4
   Specifications, 8-15

V
   Ventilation Controls, 2-4
   Ventilation Controls Guide, 4-8
   Ventilation Standby Condition, 4-1
   Ventilation Suspended Message, 5-21, 8-15
   Volume Control Breath Type, 7-2
   Volume Target, 8-15
   Volume Target Not Met Alarm, 5-21
   Volume Target Pressure Control (VTPC)
      Description, 7-4
      Settings, 4-10
   Volume Target Pressure Support (VTPS)
      Description, 7-5
      Settings, 4-12
   Volume Units, 4-5
   VTe (Expiratory Tidal Volume), 8-16
   VTe % Variance, 4-14, 8-17
   VTl, 8-16

W
   Warranty, 1-9
   Warnings
      General, 1-5
      Filter, 1-6
      Power Supply, 1-7
      Gas, 1-8
      Auxilliary Equipment, 1-8
   Waves and Loops
      Descriptions, 4-14
      Adjusting Scales, 4-14
      Auto Scale, 4-14
      Cursors, 4-14
      Freeze, 4-14, 8-6
      Saving, 4-15
      Downloading, 4-17
   Weaning Data Set, 4-15, A-6
   Weight Units, 4-5, 8-17
   WOBimp, 8-17