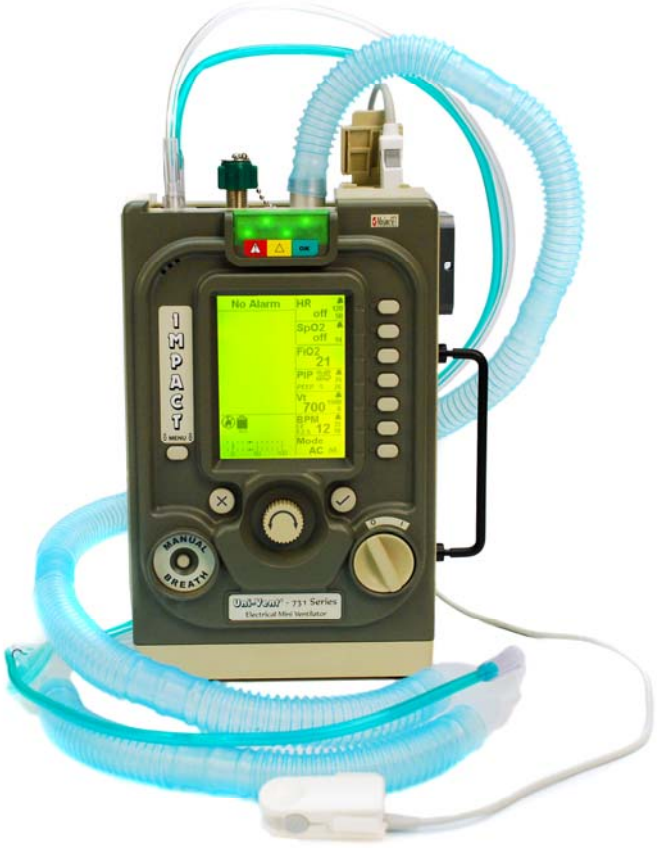
731 Series EMV

Operation Manual



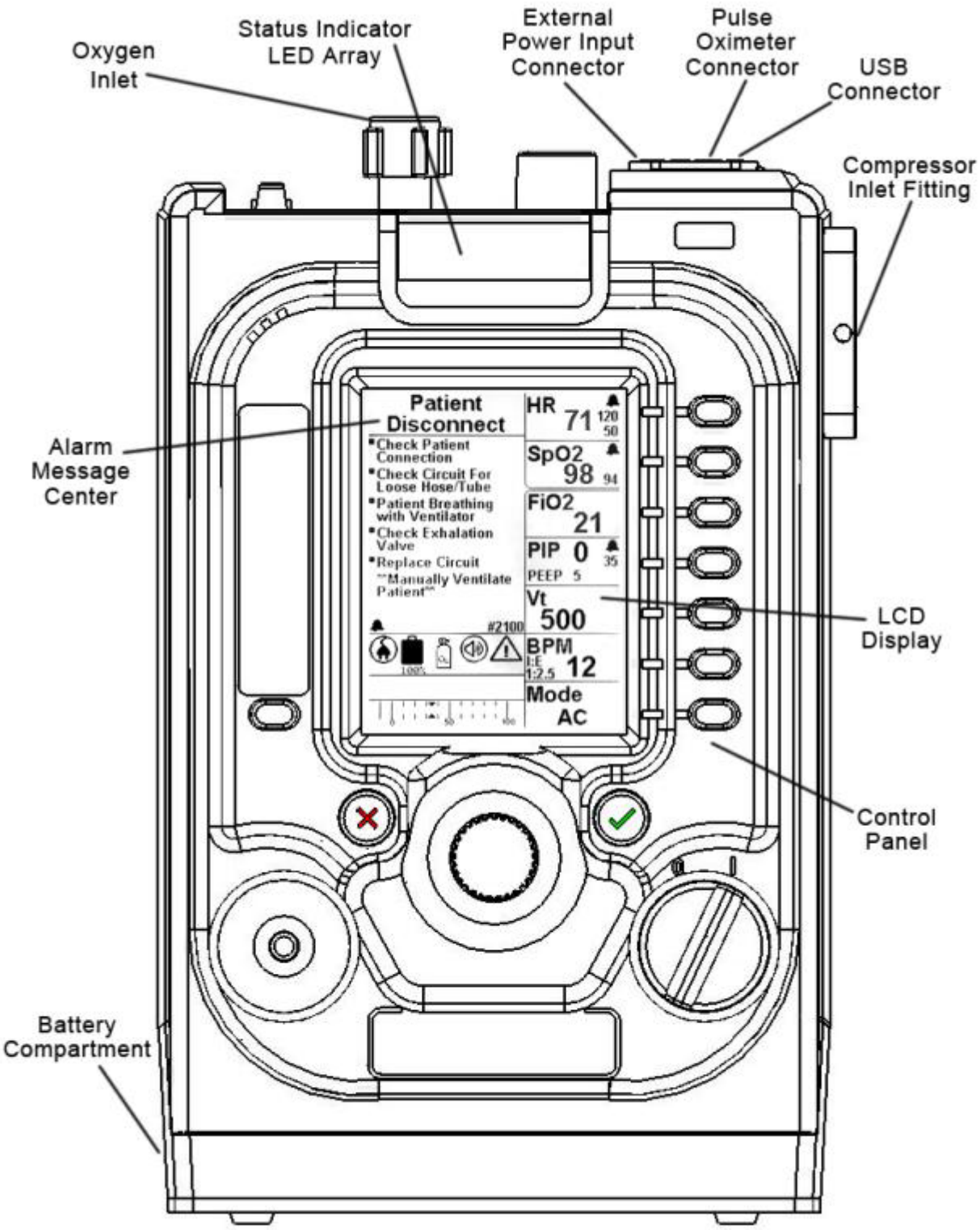
IMPACT®
instrumentation inc.

Uni-Vent®

(IMPACT P/N- 906-0EMV-01)

Revision 12.0

Impact Instrumentation, Inc. 27 Fairfield Place West Caldwell, New Jersey 07006



EMV MAIN FEATURES

TABLE OF CONTENTS

CONVENTIONS, TERMINOLOGY, AND ABBREVIATIONS

CONVENTIONS

WARNING!

A WARNING! message identifies conditions that could have an adverse effect upon the patient or operator.

CAUTION!

A CAUTION! statement identifies conditions that could damage this device.

NOTE!

NOTE! Information immediately following is of sufficient importance that emphasis is made.

TERMINOLOGY

EMV - Uni-Vent® 731EMV Series Portable Electrical Mini Ventilator

ABBREVIATIONS

A/C- Assist/Control	**LED** - Light Emitting Diode
ACV- Assist-Control Ventilation	**LPM** - Liters per Minute
ATPD - Atmospheric Temperature and Pressure, Dry	**ml** - Milliliters
BPM - Breaths per Minute	**mm** - Millimeter
B/V - Bacterial/Viral Filter	**O_2** - Oxygen
cm H_2O - Centimeters of Water	**P_{aw}** - Airway Pressure
CPAP – Continuous Positive Airway Pressure	**PEEP** - Positive End Expiratory Pressure
CPR - Cardiopulmonary Resuscitation	**PIP** - Peak Inspiratory Pressure
DISS - Diameter Index Safety System	**PS** – Pressure Support
FiO_2 . Fraction of Inspired Oxygen	**psig** - Pounds per Square Inch Gage
HME - Heat and Moisture Exchanger	**SIMV** – Synchronized Intermittent Mandatory Ventilation
HME/BV - Heat and Moisture Exchanger/Bacterial Viral filter combined	**USP** - United States Pharmacopoeia
Hz – Hertz (as in frequency, cycles per second)	**VAC** - Volts AC
ID - Internal Diameter	**VDC** - Volts DC
IR - Infrared	**V_T** - Tidal Volume
L - Liters	**WOB** – Work of Breathing

INTENDED USE

The Model 731EMV (EMV) is indicated for use in the management of adolescent and adult patients weighing ≥30 kg with acute or chronic respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. It is appropriate for use in hospitals, outside the hospital, during transport and in austere environments where it may be exposed to rain, dust, rough handling and extremes in temperature and humidity. With an appropriate third-party filter in place, it may be operated in environments where chemical and/or biological toxins are present (see External Filter Use). It is **not** intended to operate in explosive environments. The EMV is intended for use by skilled care providers with knowledge of mechanical ventilation, emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation and by first responders under the direction of skilled medical care providers.

The EMV ventilator is a small, extremely durable, full-featured portable mechanical ventilator designed to operate in hospitals or austere and under-resourced environments. It can be used in prehospital (ALS, ATLS, ACLS), field hospital and hospital settings. Easy-to-use, durable, lightweight and portable, the EMV is built with the same standard of quality, reliability and performance that all Impact® products are known for.

FEATURES

- Durable design to facilitate transport and treatment in the prehospital environment
- AC mode for use with acute or chronic respiratory failure.
- Sealed gas path for use with chemical/biological filters to assure safe breathing gas supply.
- Self-contained system that operates with or without external O_2.
- Rechargeable battery provides over 10 hours of operation (at factory default settings).
- Sealed case and control panel protects components from weather and fluids.
- Intuitive ventilation parameter and alarm limit change protocol protects existing settings from inadvertent contact and manipulation.

SHIPPING CONTENTS

Each EMV Portable Electrical Mini Ventilator is shipped with the following components:

1 ea.	Ventilator, EMV
2 ea.	Circuit, Vent, Single Limb, Wye, Adult/Pedi
1 ea.	Jasper AC/DC Power Supply (90-264 VAC, 100 Watts, 24 Volts, 4.2A, IEC320 Plug)
1 ea.	AC Power (Line) Cord
1 ea.	Power Cable, 12 VDC (Automotive type)
1 ea.	Power Cable 28 VDC (IDF type)
1 ea.	Power Cable , Saft Battery to EMV
2 ea	Filter, Disk, Fresh Gas /Emergency Air Intake
2 ea.	Removable foam inlet filter
1 ea.	Heat and Moisture Exchanger & Bacterial Viral(HME/BV) Filter
1 ea.	Bacterial Viral (BV) Filter
1 ea.	High Pressure Hose, D.I.S.S. Oxygen X D.I.S.S. Oxygen, 6' Long with Ohmeda™ Quick-Disconnect and captive chain
1 ea.	3-Liter O2 Reservoir Kit Assembly
1 ea.	Pulse Oximeter Adult, Reusable
1 ea.	Pulse Oximeter Ear Lobe Probe, Reusable
1 ea.	Pulse Oximeter Patient Cable, Reusable
1 ea.	Case, Padded, Ventilator & Accessories
1 ea.	Carry-all Case with foam inserts
1 ea.	Field Manual
1 ea.	Operation and Field Manual (on Compact Disc)

ACCESSORIES LIST

The Accessories List contains common items, required from time to time, some of them are not provided with each EMV at the time of delivery. Each item is preceded by its part number. Accessories may be ordered direct from Impact. When ordering, please include the part number, description and quantity required.

Send purchase orders to:

Impact Instrumentation, Inc.
P.O. Box 508
West Caldwell, New Jersey 07007-0508

Telephone orders: 973/882-1212
Fax orders: 973/882-4993

Email:
Government
govsales@impactii.com

Non-Government
sales@impactii.com

PART NUMBER	PART DESCRIPTION
024-0012-00	Power Supply. 90-264 VAC, 100Watts 24 Volts 4.2A, IEC320 & DT7L Plugs
402-0029-00	Case, Vent and Accessories, Model EMV
465-0024-00	Filter, Bacterial/Viral (BV)
465-0025-00	Filter, HME/BV, Heat and Moisture Exchanger
465-0027-00	Filter, Disk, Fresh Gas/Emergency Air Intake
465-0028-00	Filter, Foam, Inlet, 1.08 dia. X 1/2" Long
704-0004-00	Assembly, Kit, O2 Reservoir, 3 Liter
704-0EMV-05	Assembly, Cable, DC, External Power, 28 V
704-0EMV-06	Assembly, Cable, DC, External Power, 12 V
704-0EMV-07	Assembly, Cable, DC, External Power, SAFT
708-0036-00	Cable Assembly, 3 ft, Masimo SET Oximeter, LNCS Type DC-1, Adult Sensor to DB9 Male
708-0043-00	Cable Assembly, 3 ft, Masimo SET Oximeter, LNCS DCIP, Pediatric (10 to 50 kg) Sensor to DB9 Male
708-0037-00	Cable Assembly 4 ft, Masimo LNCS Patient Cable Type LNC-4, DB9 Female to Male
708-0039-00	Cable Assembly 3 ft, Masimo Adult Ear Sensor, LNCS Type DC-1, Adult Sensor to DB9 Male
708-0041-00	Line Cord, IEC60320-5 Female to Right Angle 3-Pronge Israeli Plug, 3 Conductor, 2.0 M Long
820-0106-00	Circuit, Vent, Single Limb, Wye, Adult/Pedi[1]
820-0106-20	Circuit, Vent, Single Limb, Wye, Adult/Pedi (case of 20)
825-0027-00	Assembly, Oxygen Hose, DISS x DISS, High Pressure, 6' Long, w/Ohmeda Q/D and Captive Chain
906-0EMV-03	Manual, Field, EMV
909-0EMV-01	CD, Manual, Operation and Field, EMV
703-0EMV-03	Carry-all Case with Foam Inserts, Rechargeable
703-0731-01	Assembly, Battery Pack, Lithium-Ion, 6.6 Ah

LIMITED COPY WRITE RELEASE

MASIMO PULSE OXIMETER

The EMV uses Masimo SET® technology[2] to provide continuous pulse oximeter and heart rate monitor and is covered under one or more of the following U.S.A. patents: 5,758,644, 5,823,950, 6,011,986, 6,157,850, 6,263,222, 6,501,975 and other applicable patents listed at www.masimo.com/patents.htm.

[1] Unit is shipped with the Wye circuit, if the standard circuit (820-006-00) is used a check valve (704-0700-01) is required when operating with a Chem/Bio filter.

WARNINGS AND CAUTIONS REGARDING USE

EMV AND PULSE OXIMETER

WARNING! Electric shock hazard: Do not remove equipment covers except to replace batteries! An operator may only perform maintenance procedures specifically described in this manual. Refer servicing to Impact or an authorized Impact Service Center in the repair of this equipment.

WARNING! The EMV is intended for use by qualified personnel only! The operator should read this manual, all precautionary information, and specifications before using the device!

WARNING! Possible explosion hazard if used in the presence of flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments or nitrous oxide!

WARNING! Measure the EMV's leakage current whenever an external device is connected to the USB port. Leakage current must not exceed 100 microamperes!

WARNING! Grounding:

- Connect the EMV only to a three-wire, grounded, hospital-grade receptacle! The three-conductor plug must be inserted into a properly wired three-wire receptacle; if a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code.
- Do not under any circumstances remove the grounding conductor from the power plug!
- Do not use extension cords or adapters of any type! The power cord and plug must be intact and undamaged.
- If there is any doubt about the integrity of the protective earth conductor arrangement, operate the oximeter on internal battery power until the AC power supply protective conductor is fully functional!

WARNING! To ensure patient electrical isolation, connect only to other equipment with electronically isolated circuits!

WARNING! Do not use antistatic or conductive hoses or tubing with this device!

WARNING! Do not connect to an electrical outlet controlled by a wall switch or dimmer!

WARNING! As with all medical equipment, carefully route the ventilator circuit hose and tubing, patient cabling, and external power cables to reduce the possibility of patient entanglement or strangulation!

WARNING! Do not place the EMV or external power supply in any position that might cause it to fall on the patient! Do not lift the EMV by the power supply cord, ventilator circuit or pulse oximeter patient cable!

WARNING! Do not use the EMV, its pulse oximeter or pulse oximetry sensors during magnetic resonance imaging (MRI) scanning! Induced current could potentially cause burns. The EMV and/or its pulse oximeter may affect the MRI image and the MRI unit may affect EMV operation or the accuracy of the oximetry measurements.

WARNING! USB Interconnection: Consult IEC-601-1-1 for system interconnection guidance. The specific requirement for system interconnection are dependent upon the device connected to the EMV and the relative locations of each device from the patient, and the relative location of the connected device to the medically used room containing the EMV. In all circumstances the Model EMV must be connected to a grounded AC power supply. The EMV and its integrated pulse oximeter are referred to as an IEC 601/F device in the summary of situations table contained in IEC-601-1-1. **NOTE!** The USB interconnection does not support automatic record keeping.

CAUTION! Federal law restricts this device to sale by or on the order of a physician.

CAUTION! Service is to be performed by qualified biomedical equipment technicians only.

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[2] Possession or purchase of this device does not convey any expressed or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within scope of one or more of the patents relating to this device.

CAUTION! Internal components are susceptible to damage from static discharge. Do not remove device covers.

WARNING! Cleaning

- Do not autoclave, pressure-sterilize or gas sterilize this device.
- Do not soak or immerse the device in any liquid.
- Use the cleaning solution sparingly. Excessive solution can flow into the device and cause damage.
- Do not use abrasive cleaning compounds, brushes or abrasive scrubbers on the device.
- Do not use petroleum-based cleaners or acetone solutions, or other harsh solvent to clean the unit.
- Do not use oil and/or grease on any surface of the unit.

PULSE OXIMETER SPECIFIC WARNINGS AND CAUTIONS

WARNING! A pulse oximeter should not be used as an apnea monitor.

WARNING! A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

WARNING! MEASUREMENTS

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.

Inaccurate measurements may be caused by:

- Incorrect sensor application or use
- Significant levels of dysfunctional hemoglobin (e.g., carboxyhemoglobin or methemoglobin)
- Intravascular dyes such as indocyanine green or methylene blue
- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material)
- Excessive patient movement
- Venous pulsations
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- The pulse oximeter can be used during defibrillation, but the readings may be inaccurate for a short time.

WARNING! Interfering Substances: Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

WARNING! ALARMS Check alarm limits each time the pulse oximeter is used to ensure that they are appropriate for the patient being monitored.

WARNING! Loss of pulse signal can occur in any of the following situations:

- The sensor is too tight
- There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight
- A blood pressure cuff is inflated on the same extremity as the one with a SpO_2 sensor attached
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
- There is arterial occlusion proximal to the sensor
- The patient is in cardiac arrest or is in shock

WARNING! Sensors:

Before use, carefully read the LNOP® sensor directions for use.

Use only Masimo oximetry sensors for SpO_2 measurements. Other oxygen transducers (sensors) may cause improper performance.

Tissue damage can be caused by incorrect application or use of an LNOP® sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity and correct positioning and adhesion of the sensor.

Do not damage LNOP® sensors. Do not use an LNOP® sensor with exposed optical components. Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam or ethylene oxide. See the cleaning instructions in the directions for reusable Masimo LNOP® sensors.

Do not use damaged patient cables. Do not immerse the patient cables in water, solvents or cleaning solutions (the patient cables are not waterproof). Do not sterilize by irradiation, steam or ethylene oxide. See the cleaning instructions in the directions for reusable Masimo patient cables.

SYMBOLS AND ICONS

(Used with the EMV and this manual)

Off		
On		
Direct Current		**Identifes the location to connect external DC power.**
Mute/ Cancel		**Identifies button which mutes the active alarm or cancels the parameter selection.**
Accept/ Confirm		**Identifies button which accepts the parameter selection.**
ESD		**Warns that connector pins should not be touched.**
Defibrillation Proof		**Indicates the degree of protection against electrical shock.**
Alarm Bell		**Identifies Alarm Limits Settings** **Identifies the on-screen alarm**
Alarm Bell Outline		**Identifies the number of off-screen alarms.**
Attention		**High Priority Alarm Active**
		**Medium Priority Alarm Active**
Warning		**Low Priority Alarm Active**
Mute		**Active Alarm Audible Signal Muted**
Speaker		**Active Alarm Audible Signal**
Oxygen Supply		**Oxygen Supply connected**
External Power		**Indicates the unit is operating using an external power source.**
No External Power		**Indicates the unit is operating without an external power source.**
Internal Battery		**Provides indication of battery capacity and charging status**
No Internal Battery		**Indicates when internal battery is not an available power source**
Heart		**Provides indication that the pulse oximeter is in use.**
Rotary Encoder		**Identifies the rotary encoder which allows adjustment of a selected parameter value**
SAFT		**Indicates the unit is operating with external SAFT Battery**

UNPACKING, ASSEMBLY AND CONNECTIONS

UNPACKING

Compare shipping case contents against Shipping Contents list. Examine instrument for any obvious signs of shipping damage. If there is no apparent sign of mechanical damage, read instructions contained within this manual before attempting operation.

ASSEMBLY

The EMV only requires that the operator attach the breathing circuit to begin ventilation using either internal or external power. Both the ventilator and breathing circuit are supplied clean and are ready for use on a patient.

The EMV batteries may not be installed within the unit (depending upon the contractual requirements or the storage environment as described in the Battery Care And Recharging section). Battery installation may be required prior to operation.

CONNECTIONS

OXYGEN INPUT – connects the unit to the output of an appropriate O_2 regulator attached to a medical-grade (USP) O_2 cylinder or other 55 psig (+20%, -25% psig) USP O_2 source. The OXYGEN IN fitting has a male oxygen Diameter Index Safety System (D.I.S.S.) thread. It is located on the Connector Panel at the top of the unit. A green, 6 foot long high-pressure oxygen hose with compatible fittings that provides for connection between the unit and the O_2 source is required (see Harsh Environment Operation sections).

NOTE! If external O_2 is connected the gas pressure must be at least 41-psig (± 2 psig) when SELF-CHECK is performed.

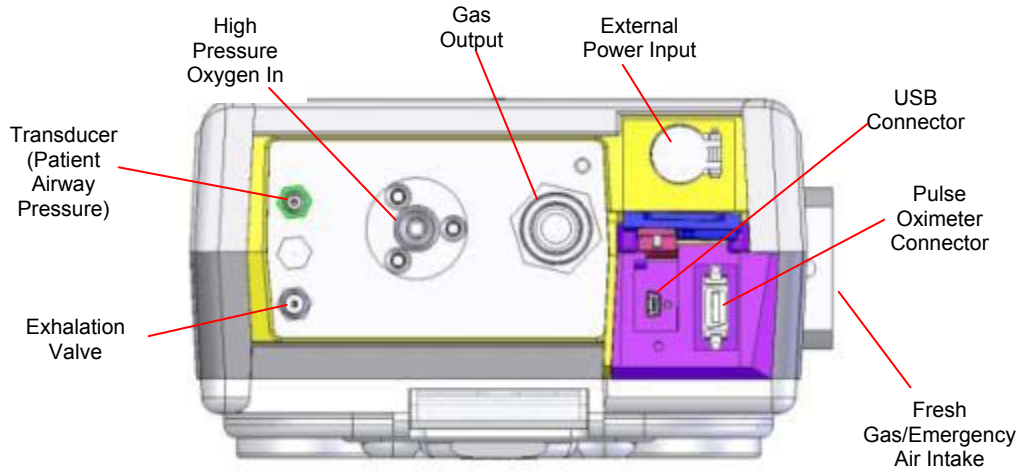
GAS OUTPUT - connects to the ventilator circuit 22 mm ID corrugated hose. The connector is a 22 mm male conical connection. It is located on the Connector Panel at the top of the unit, see figure below.

FRESH GAS/EMERGENCY AIR INTAKE – allows ambient air into the EMV's internal compressor. The port also functions as the internal antiasphyxia valve which allows the patient to breathe ambient air in the event of a ventilator failure. The intake contains a particulate filter and permits the operator to connect either a bacterial/viral or a chemical/biological filter depending on ambient conditions.

TRANSDUCER (Patient Airway Pressure) – connects to the ventilator circuit 3/16" ID transducer tubing. The barb-type connector is colored a blue/green to distinguish it from the other connectors. Note: the 3/16" ID ventilator circuit transducer tubing is a blue/green color. It is located on the Connector Panel at the top of the unit.

EXHALATION VALVE – connects to the ventilator circuit 1/4" ID exhalation valve tubing. The barb-type connector is clear anodized aluminum to distinguish it from the other connectors. Note: the 1/4" ID ventilator circuit exhalation valve tubing is clear. It is located on the Connector Panel at the top of the unit.

EXTERNAL POWER INPUT – The External Power Input connector is located on the top of the unit. It accepts DC voltages between 11 and 32 volts (negative ground). The input mates with the output connector plug of the AC/DC Power Supply, 12 and 28 VDC Power Cables (both are provided in the standard equipment set) or the external battery.



CONNECTOR PANEL

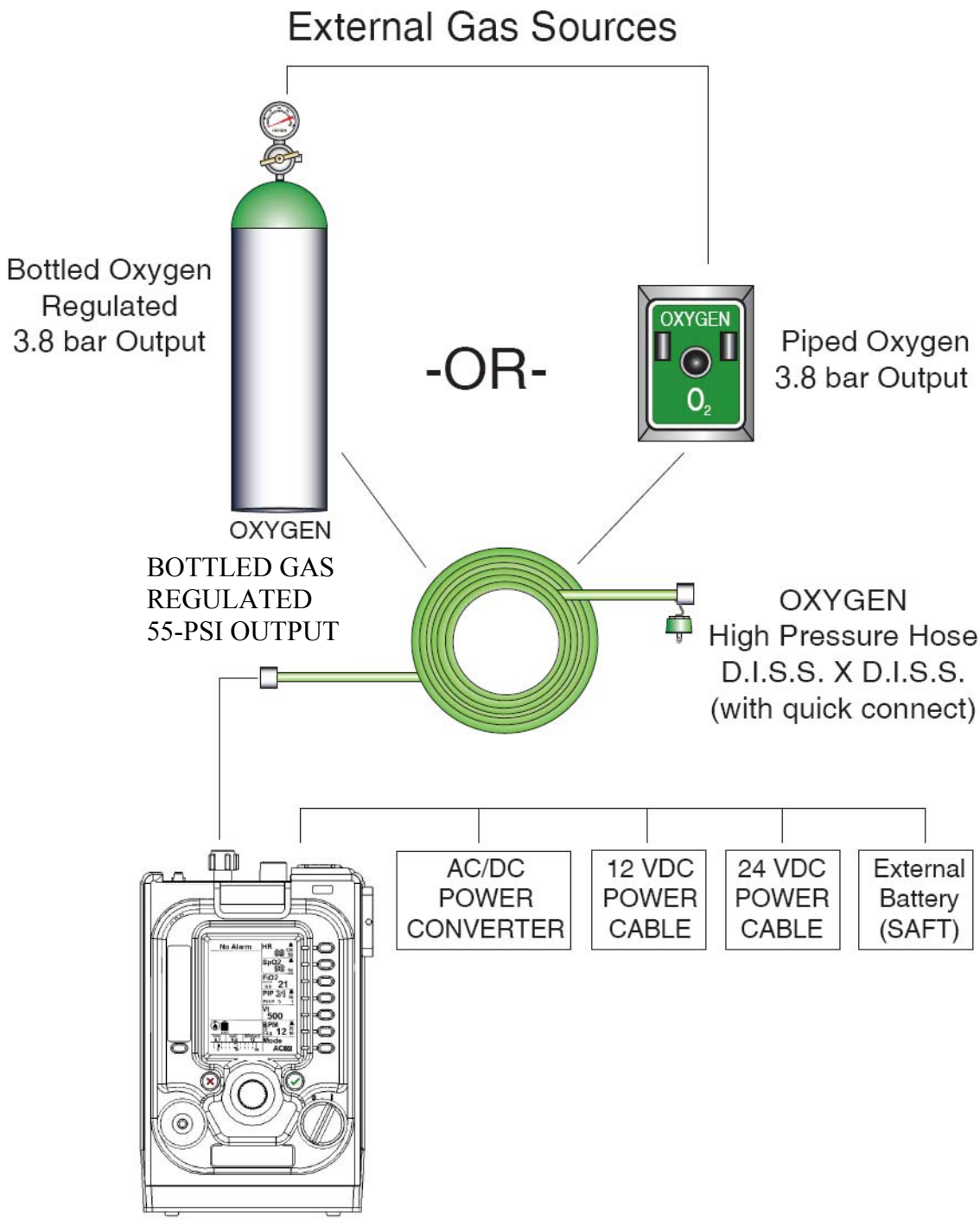
CAUTION! Follow Set Up instructions prior to placing this device into service.

SET-UP

The EMV can be configured to suit most applications. Additional hoses, fittings and adapters may be required for particular uses.

1. For use with external O_2: connect a green high-pressure O_2 hose to the OXYGEN IN fitting and a 55 psig external source. Use only with medical-grade (USP) oxygen.
2. Connect the disposable ventilator circuit to the GAS OUTPUT, TRANSDUCER, and EXHALATION VALVE connectors on EMV Connector Panel. Follow the directions included with the disposable ventilator circuit.
3. In a high-dust or biological environment, a bacterial/viral filter should be attached to the FRESH GAS/EMERGENCY AIR INTAKE to prevent entrainment of particulate or biological matter.
4. In toxic biological or chemical environments the user can attach a chemical/biological filter to the FRESH GAS/EMERGENCY AIR INTAKE. The threaded interface accommodates chemical/biological filters with an Rd 40 x 1/7 interface (see BS EN 148-1 1999 Respiratory protective devices – threads for face pieces).
5. For use with AC power: connect the AC/DC Power Supply (supplied) to the EXTERNAL POWER INPUT (see Connector Panel figure). Note: The EMV can operate from internal battery or from external AC or DC power sources. See section entitled OPERATING POWER SELECTION & STOPPING for details.

WARNING! Always assure that there is an alternate means of providing ventilation. A bag-valve resuscitator and an appropriate mask for the patient being ventilated should be immediately available.

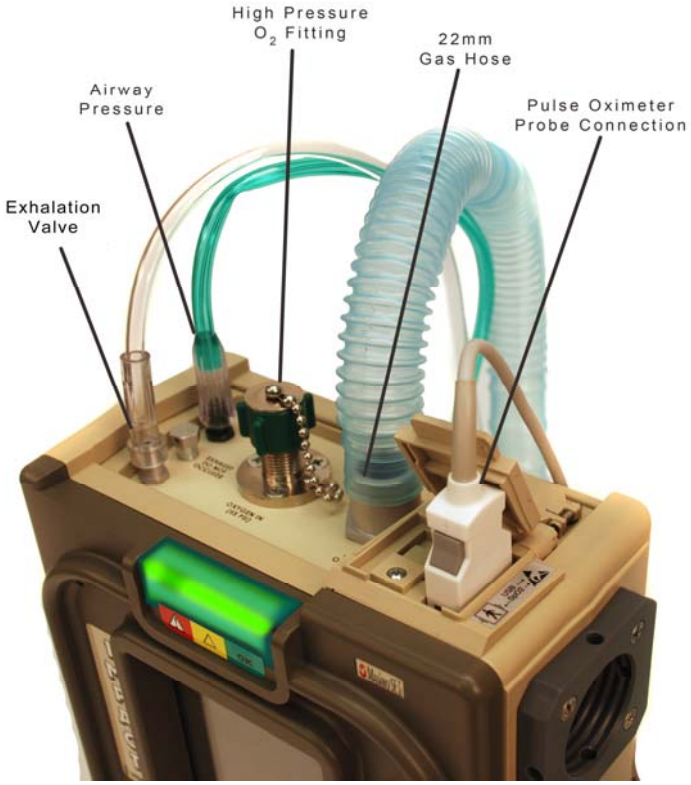


INITIAL SETUP

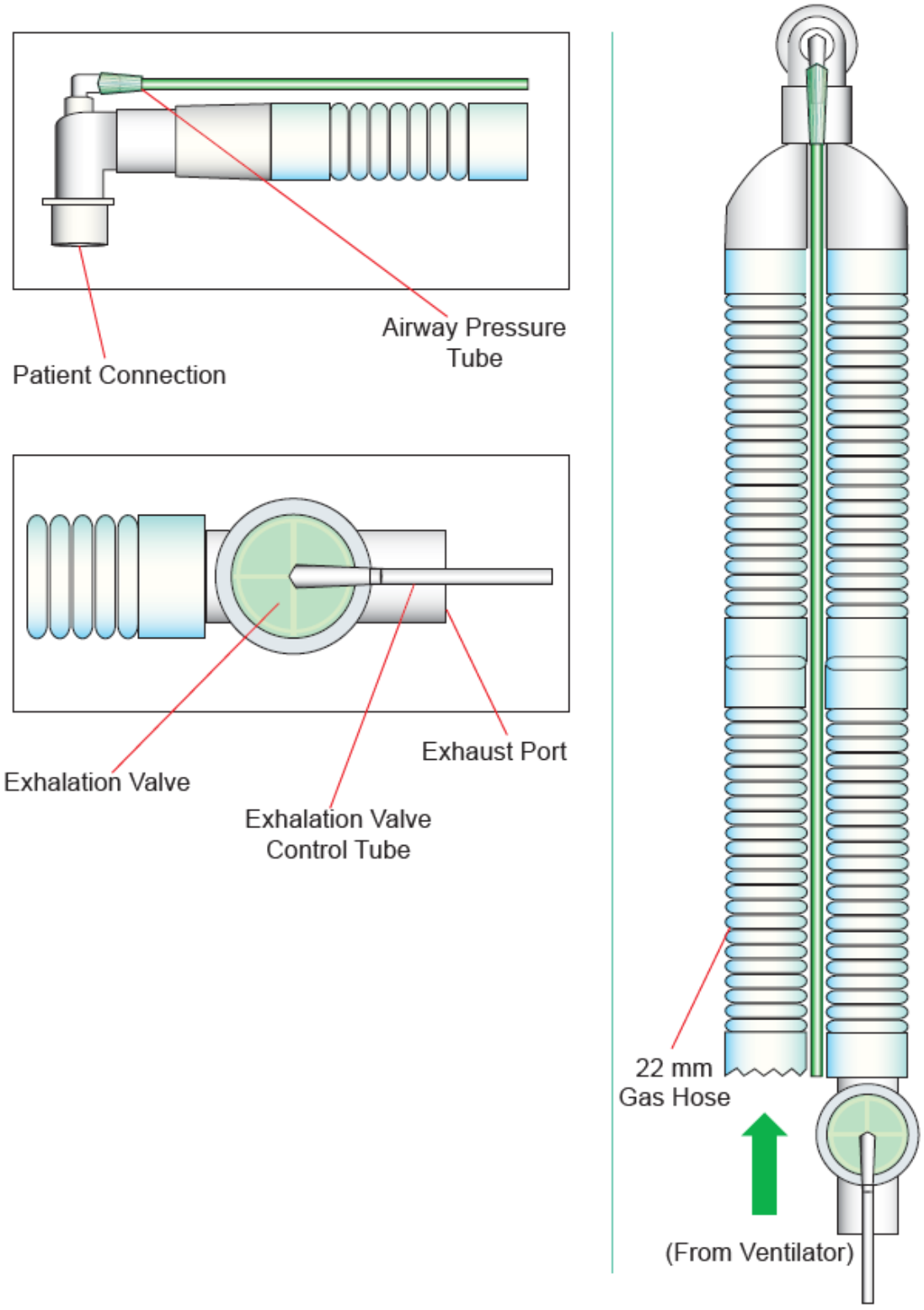
WARNING! DO NOT BLOCK FRESH GAS/EMERGENCY AIR INTAKE

VENTILATOR CIRCUIT

The EMV is designed to operate using a standard disposable single-limb circuit. The circuit is attached to the ventilator as shown in the figure below.



VENTILATOR CIRCUIT, DEVICE CONNECTIONS



CAUTION! Always dispose of the circuit after use institutional guideline for biologically contaminated material. Reusing the circuit can result in cross contamination between patients.

VENTILATOR CIRCUIT, PATIENT CONNECTION

OPERATING POWER SELECTION & STOPPING

The EMV is designed to operate using DC power supplied from 3 sources:

1. Internal 14.8V lithium ion (Li Ion) rechargeable battery with 6.6 Ah capacity (fully charged, the battery provides 10 hours of operation at factory default settings with pulse oximeter operating).
2. External AC/DC Power Supply (90 to 260 VAC 47 to 440 Hz) with IEC 320 style AC input connector (supplied). The AC/DC Power Supply provides a DC output of 24V at 4.2A.
3. External DC power from a standard vehicle DC outlet using the supplied 12 or 28 VDC Power Cables. The input connector of the EMV is designed to accept DC voltages between 11 and 32 volts, negative ground.

The POWER switch is the master power switch. Use this switch to initiate or end operation.

WARNING! Never start the ventilator with the patient connected. Always start the ventilator, select the patient settings, assure operation, and then connect the patient.

The EMV is designed to use external power when available rather than its internal battery pack. When an acceptable external power source is present, the internal battery pack is automatically charged while the unit operates. When an external power failure occurs, the EMV automatically switches to its internal battery pack for operating power and activates the EXTERNAL POWER FAILURE Alarm; there is no interruption in operation. When external power returns, operating power automatically switches from internal power to the external source.

SELF-CHECK

At start up the EMV automatically performs a self check that includes a check for pre-existing alarm conditions. Following start up, the presence of alarm conditions is checked continuously. The ventilator circuit must be open to ambient atmosphere (not connected to the patient) during start up. Ventilator operation begins immediately following the self check.

WARNING! Until the operator has determined that the ventilator is functioning properly and that the ventilator parameters are set correctly for the patient, the patient should not be connected to the ventilator.

TRANSDUCER CALIBRATION (AUTO CAL)

The ventilator circuit connects to a pressure transducer (pressure-sensing device) in the ventilator. Periodically, the transducer recalibrates itself using the ambient air pressure as a reference. This process maintains a consistent transducer baseline over a wide temperature range to assure display, monitoring, and triggering accuracy. The AUTO CAL is performed during SELF-CHECK, and then every 5 minutes thereafter. However, if a change in temperature exceeding +/- 1.5° C is sensed, the AUTO CAL time interval will be reduced automatically until temperature stability returns.

OPERATION

Operators will find the EMV easy to learn and operate. A complete understanding of its capabilities and limitations will allow you to take advantage of all its features. The EMV is a volume targeted, time cycled ventilator designed to use either oxygen (O_2) from a 55 psig source or fresh air using its internal compressor to deliver a positive pressure breath. The front panel interface allows the user to initiate operation of the EMV to begin operation at default settings values. Factory default values at start up are: Mode = AC, BPM = 12, Vt = 700 ml, PEEP = 5 cm H_2O, FIO_2 = 21%, I:E = 1:2.5 and High Paw Limit = 35 cm H_2O. If oxygen is connected to a 55 psig source, the default FIO_2 = 100%. Once operation begins, the operator may change the ventilating parameters or alarm limits by following the instructions below. When high-pressure O_2 is connected the internal blender allows the FIO_2 to be set at 21, 50 or 100%. When FIO_2 is set to 21%, operators may connect a low flow O_2 source at the Fresh Gas/Emergency Air Intake using the reservoir (see Appendix 6: Use of Low Flow Oxygen). Each time the compressor cycles, low flow O_2 will mix with ambient air to provide supplemental O_2 to the patient. While the FIO_2 value cannot be ascertained without using a separate O_2 analyzer, the operator may set the oxygen flow rate up or down to achieve the desired SpO_2 value. A suite of alarms alert the operator when conditions exceed parameter limits or when operation is affected by an external or internal fault or failure. When an alarm occurs the operator is alerted by audible and visual indicators while context sensitive help messages are displayed in the LCD's Alarm Message Center guide. Operating power is from an external AC/DC Power Supply connected to live AC mains, external DC power, or from the internal rechargeable lithium ion battery.

PULSE OXIMETER

At start up the EMV checks the pulse oximeter connection; if a sensor is connected the unit begins the pulse search and all pulse oximeter alarms (SpO_2, HR and signal) are active. If no sensor is detected the unit starts with the pulse oximeter functions turned off. The heart rate and SpO_2 parameter windows display "**off**" to remind the operator that these functions are not available. Pulse oximeter functions will automatically start when the operator connects a pulse oximeter sensor. See Appendix 3: Pulse Oximeter Principles and Specifications.

The pulse oximeter and its accessory probes and cables are intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by the SpO_2 sensor) for adult and pediatric patients. The pulse oximeter becomes operational in all ventilator modes when its cable and sensor are properly attached to the SpO_2 connector (see figure Connector Panel above).

To operate the pulse oximeter, connect its probe to its patient cable and the patient cable to the SpO_2 connector. The monitoring function will continuously display the patient's pulse rate and SpO_2 value. The operator can set low alarm limit. If an alarm occurs, the user can use this information to assess the condition of the patient and as an aide in determining what intervention is required. **NOTE!** When a functioning pulse oximeter probe is connected to the EMV the pulse oximeter functions cannot be turned off. The operator must remove the probe and then turn off the pulse oximeter.

The pulse oximeter reading can be affected by the following conditions:

1. The sensor is too tight.
2. There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.
3. A blood pressure cuff is inflated on the same extremity as the one with a SpO2 sensor attached.
4. The patient has hypertension, severe vasoconstriction, severe anemia, or hypothermia.
5. There is an arterial occlusion proximal to the sensor.
6. The patient is in cardiac arrest or is in shock.

DESCRIPTION OF CONTROLS AND DISPLAY

The EMV contains various controls, indicators and connections. Their placement has been chosen to facilitate ease of use and visibility in all operating environments. A liquid crystal display (LCD) provides continuous display of control settings, operating conditions, power, and alarm status information. The location of each control and indicator is shown in the figure (their respective location callouts are listed below in parenthesis). The core concept for operating all major functions of the EMV is pressing the PARAMETER button associated with the parameter you wish to change. Pressing the PARAMETER button highlights the primary parameter followed by the secondary parameters moving in a clockwise direction. When the parameter you wish to change is highlighted, turn the ROTARY ENCODER clockwise or counter clockwise to adjust the parameter to the desired value. Confirm that you want to operate with this new value by pressing the CONFIRM/SELECT button. Once this is done the highlight goes away and the unit begins operation using the new parameter. At any point the operator may cancel any operation and return to the primary operating screen by pressing the MUTE/CANCEL button. When a parameter is selected (highlighted) it stays active for 5 seconds; after this time the unit automatically cancels the operation and returns to the default screen.

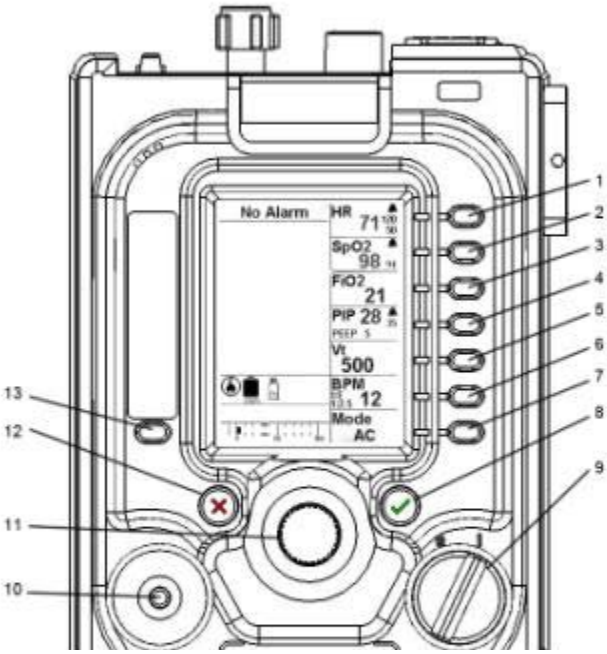
CONTROLS

The Control Panel incorporates all controls and the LCD Display. Each control is described in the following text (See EMV Controls figure).

HR (1) – Pressing the HR button will highlight the current value of the High Heart Rate Alarm Limit and enable its value to be changed. Pressing the HR button a second time will highlight the current value of the Low Heart Rate Alarm Limit and enable its value to be changed. The HR parameters are functional only when the pulse oximeter is connected. Both limits are adjustable in 1 b/min increments. The default value at start up for the high alarm limit is 120 b/min; the low alarm limit is 40 b/min.

SpO2 (2) – Pressing the SpO_2 button will highlight the current Low SpO_2 Alarm Limit value. The SpO_2 display is active only when the pulse oximeter is connected. When no SpO_2 sensor is connected during start up or the operator turns off the pulse oximeter "**off**" is displayed in the parameter window. The default value at start up is 94%.

FIO2 (3) – pressing the FIO_2 button will highlight the current FIO_2 setting. There are no adjustable secondary parameters. The default value at start up is 21%. **NOTE!** The EMV does not directly measure FIO_2. If a direct measurement is desired a third-party FIO_2 monitor can be inserted in the ventilator circuit following the manufacturer's instructions.



EMV CONTROLS

PIP (PEAK INSPIRATORY PRESSURE) (4) – pressing the PEAK INSPIRATORY PRESSURE button will highlight the high airway pressure alarm limit. The high default value at start up is 35 cm H_2O. **NOTE!** Alarm values greater than 60 cm H_2O require the user to perform a separate confirmation to assure the value is required to manage the particular patient.

Vt (TIDAL VOLUME) (5) - pressing the TIDAL VOLUME button will highlight the current value and enable its current value to be changed. The default value at start up is 700 ml.

BPM (BREATHING RATE) (6) – pressing the BPM button highlights the current value. The I:E ratio is also displayed in this window but cannot be changed by the operator. The default BPM value at start up is 12 BPM.

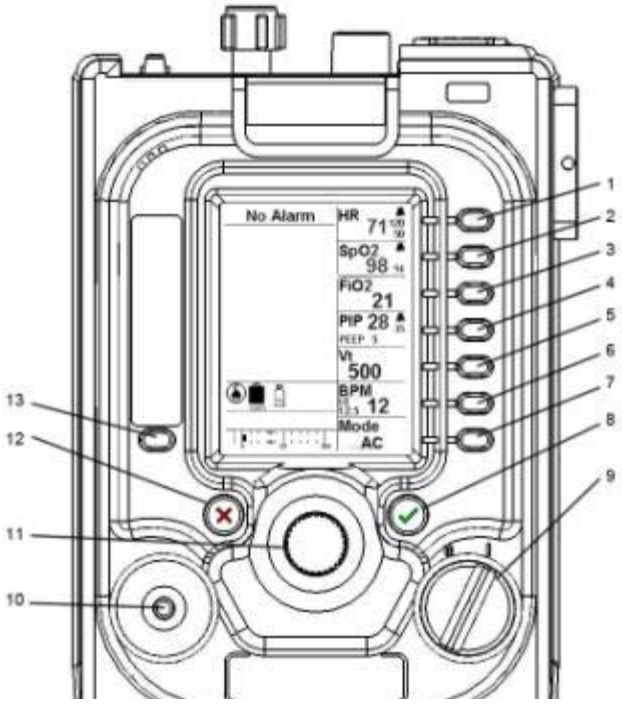
MODE (7) – Pressing the MODE button has no affect on the device. It is reserved for future use. The EMV is designed to operate only in the AC mode.

CONFIRM/SELECT (8) – press the CONFIRM/SELECT button to confirm a new control setting or to select from a menu or setting option. The CONFIRM/SELECT button switch is labeled with a check green "√".

POWER OFF/ON (9) – turn the POWER OFF/ON switch to apply or remove operating power to the EMV.

MANUAL BREATH (10) – press the Manual Breath button to deliver a single breath to the patient. Manual breaths can only be delivered during the expiratory phase of the breath after the pressure has reached baseline. This is done to prevent breath stacking.

ROTARY ENCODER (11) – turn the ROTARY ENCODER clockwise or counter clockwise to change a value or highlight a particular menu option.



EMV CONTROLS

ALARM MUTE/CANCEL (12) – press the MUTE/CANCEL pushbutton to mute most Medium Priority Alarms, to cancel/acknowledge Low Priority Alarm or to cancel an action that is no longer desired (for example a control setting change). The MUTE/CANCEL pushbutton switch is labeled with a red "X".

MENU (13) – pressing the MENU button provides access to user menus and special functions. Use the rotary encoder to scroll to the desired menu option and press the CONFIRM/SELECT button to access the menu control. Pressing CONFIRM/SELECT then accesses the parameter variable which is changed by turning the rotary encoder to the desired value. To accept the new parameter value press the CONFIRM/SELECT (the highlight moves from the parameter variable back to the parameter). For parameters with multiple options pressing CONFIRM/SELECT opens a submenu where the various parameters are selected using the rotary encoder and changed using the process described above. At any point the operator can cancel an operation, return the previous MENU level or exit of the MENU control by pressing the MUTE/CANCEL button.

1. Unit Info: lists the serial number for the unit and SPM, software version, hours of use and last calibration date.
    a. Date: the current date (day/month/year), based on the time and date where the calibration was performed.
    b. Cal Date: displays the date of the last calibration.
    c. Hours of Op: displays the hours of operation since the last calibration.
    d. EMV Soft Rev: displays the EMV software revision that is in use with the device.
    e. EMV SN: displays the serial number of the EMV.
    f. SPM Soft Rev: displays the SPM software revision that is in use with the device.
    g. SPM SN: displays the serial number of the SPM.
2. Trigger Level: allows the operator to adjust the assisted breath trigger from -6 to -1 cm H_2O to optimize the patient/ventilator interaction; the default value is -2 cm H_2O below baseline.

3. Pulse Oximeter: allows the operator to turn the pulse oximeter on and off. The operator may need to turn off the pulse oximeter when the probe is damaged after the device started with a functioning pulse oximeter probe or if the operator wishes to use the probe with another patient.
4. O2 Reservoir: allows the operator to tell the device that the 3-Liter O2 Reservoir Assembly is in use. Using the reservoir can cause the Fresh Gas Intake Fault to occur. Turning this function in disables this alarm and prevents nuisance alarms. The device is still able to detect and alarm if the Fresh Gas/Compressor Intake is blocked and not able to deliver breaths. Operation in high vibration environments can also trigger this alarm using this feature in these situations can also be used to reduce nuisance alarms.
5. Power Up Settings: allows the operator to select startup settings different from the factor default. The menu allows the operator to select the current ventilator settings for use at startup. There are 3 options: default, user 1 and user 2. Default uses the factory default setting (AC, Vt 700, Rate 12, PEEP 5, Trigger -2). User 1 and user 2 allow the operator to establish different start up settings based on the intended patient population. To establish different start up settings, other than the default, configure the ventilator to the desired setting while it is in operation, press the MENU button, select POWER UP SETTINGS, select SAVE SETTINGS and select either user 1 or user 2 and press CONFIRM/SELECT. To start with the new setting, select POWER UP WITH and select which user setting you would like to use at start up and press CONFIRM/SELECT. Assure the proper start up setting by turning the ventilator off then on again. The unit should begin operation with the new settings.
6. Contrast: allows the operator to adjust the contrast of the LCD to optimize visibility in the current lighting environment. The default is 213; increasing the value increases the contrast while decreasing the value decreases the contrast. During cold weather operation ~ 0 °C the contrast can fade. The operator can improve visibility by increasing the contrast.

VISUAL INDICATORS

LCD parameter windows present information relating to settings, menus/instructions, alarm information, pressure measurement data, pulse oximeter data, and heart rate data. When a parameter, secondary parameter or alarm limit is associated with an active alarm the parameter flashes to help the operator better understand the nature of the alarm condition.

HR (A) – displays the HR and Low/High HR alarm limits. A heart icon is also displayed in this window when the pulse oximeter is in use. The icon flashes at the patient's heart rate.

SpO2 (B) – displays the SpO_2 value and the Low SpO_2 alarm limit.

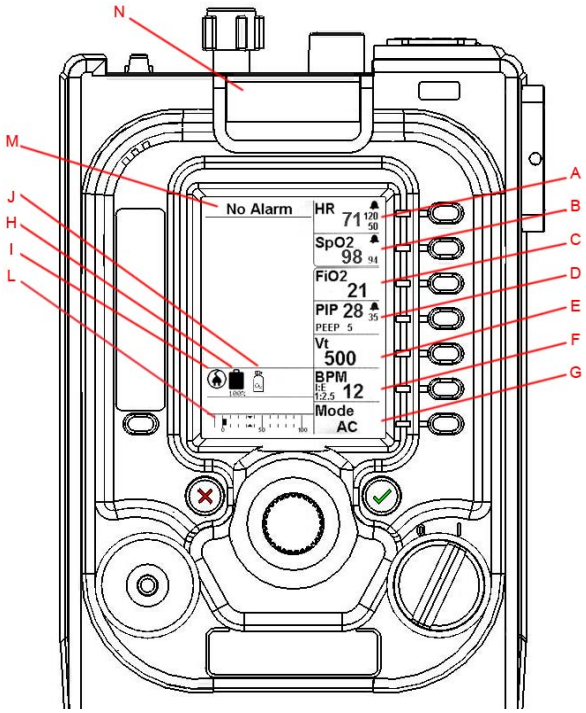
FIO2 (C) – displays the set fraction of inspired O_2.

PIP (D) – displays the peak airway pressure, PEEP and High PIP alarm limit.

V_T (E) – displays the set tidal volume.

BPM (F) – displays the set breath rate and the I:E ratio.

MODE (G) – displays the operating mode.



EMV VISUAL INDICATORS

BATTERY Icon/Indicator **(H) –** indicates (1) the presence of a functional battery, (2) when the battery is charging and (3) the current battery capacity. The BATTERY icon appears in outline form and is filled with vertical rows of lines indicating its current capacity. When the battery is charging, these vertical lines cyclically scroll vertically, one row at a time, from the bottom row to the row that corresponds with the current level of charge. When the battery is fully charged, the icon is completely filled with lines and scrolling stops. Each line represents approximately 10% of battery capacity. During internal battery operation, a vertical row "disappears" when battery capacity is reduced by a 10% increment. The BATTERY icon will flash off/on when a Battery Power Low Alarm occurs. The icon will flash off/on and present with a diagonal line when no battery is connected.

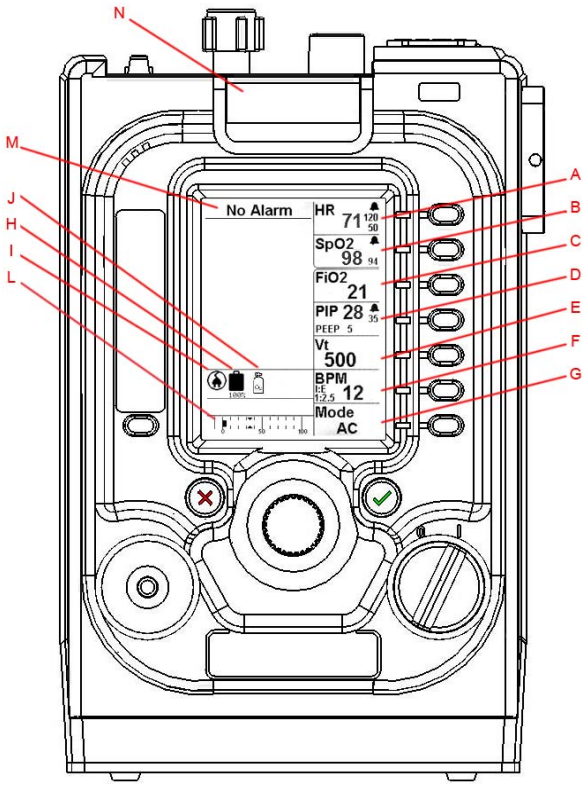
EXTERNAL POWER Icon/Indicator **(I)** – indicates the presence of external power. When no external power is sensed, the icon/indicator presents with a diagonal line. When an External Power Low or External Power Fail/Disconnect Alarm occurs, the icon flashes off/on.

OXYGEN SUPPLY Icon/Indicator **(J)** – indicates the presence of external oxygen (55 psig source). The icon only appears when no external oxygen is detected by the pressure transducer. The icon flashes off/on when the Oxygen Low/Fail Alarm occurs.

AIRWAY PRESSURE Graphic (L) - provides a continuous display of airway pressure. Its absolute range is from -10 to 100 cm H_2O with a horizontal resolution of 1 cm H_2O/pixel. The scale below the indicator is graduated in 10 cm H_2O increments with numerical markers appearing at 0, 50 and 100 cm H_2O.

ALARM MESSAGE CENTER (AMC) (M) – The AMC is a dedicated area located in the upper left-hand corner of the LCD. At the onset of an alarm, the AMC displays the alarm name and then a series of context-sensitive help messages. These messages serve to guide the operator by presenting suggestions as to the cause and resolution of a particular alarm. When no alarm is present, the AMC displays "**No Alarm**". (See Alarm Functions section for additional information)

STATUS INDICATOR LED ARRAY (N) – The STATUS INDICATOR LED ARRAY contains green, yellow, red and IR LED's. During normal operation the STATUS INDICATOR LED ARRAY is enabled. During "dark" operation only IR light is emitted.



EMV VISUAL INDICATORS

LCD ALARM INDICATORS

The EMV uses a comprehensive suite of alarms to alert the operator and guide their actions to resolve alarm conditions and assure patient safety. The primary alarm message is displayed at the top of the AMC while guidance and operator instructions are displayed below the alarm name. When multiple alarms occur they are prioritized and displayed based on the risk to the patient. Refer to the section entitled, ALARM FUNCTIONS, for a complete description of each alarm and how the EMV controls alarm conditions.

GREEN – The LED array illuminates green to indicate the presence of operating power and that all ventilator and patient parameters are within normal limits.

YELLOW – The LED array illuminates yellow to indicate the presence of a Low Priority alarm condition or a persistent alarm condition and the user has acknowledged the alarm state. The EMV will continue to operate within its safety limits while the yellow LED provides a constant reminder that although it was acknowledged, the causing condition remains. When this fault is detected, a Low Priority yellow LED alarm is triggered alerting the user to the event. When the user acknowledges the alarm by pressing the Mute/Cancel pushbutton the yellow LED displays indicating that the unit is operational but, there is a fault or failure that persists and should be recognized by the operator. As long as the fault or failure exists and the unit is operating the yellow LED will display except during Medium and High Priority Alarms.

RED – The LED array illuminates red to indicate the presence of High and Medium Priority alarm conditions. The Alarm LED flashes when the alarm occurs. When the MUTE/CANCEL pushbutton is pushed the LED illuminates continuously during the 30 seconds that the audible alarm is muted during Medium Priority alarms.

INFRARED – The infrared LED is disabled during normal operation and enabled only in the "dark" operating mode. It is visible only to those wearing night vision goggles (NVG'S). The infrared LED flashes when an alarm occurs and stays on continuously during mute periods. Silent/Dark mode may not be available in your EMV depending on the acquisition contract.

MODE OF OPERATION

The EMV has been designed to ease the learning transition commonly associated with new equipment. Turning the POWER switch starts an internal SELF CHECK and begins operation with default settings. The EMV operates in Assist Control (AC) mode. An internal blender enables the EMV to deliver O_2 concentrations of 21%, 50% and 100% using its internal compressor and/or a standard medical-grade O_2 source. Additionally, low-pressure O_2 can be entrained through the reservoir accessory except when a chemical/biological filter is connected. When using the reservoir the FIO_2 should be set to 21%. The operator should titrate the flow of O_2 to the reservoir to maintain an adequate SpO_2 value. Positive end-expiratory pressure (PEEP) can also be used to support oxygenation and prevent alveolar collapse; the range is 0 to 25 cm H_2O.

In the AC mode, breaths are delivered at the patient's spontaneous breathing rate, but never at a rate less than the set BREATHING RATE. A patient-initiated breath must generate at least -2 cm H_2O during the expiratory phase to trigger a breath at the set TIDAL VOLUME (an assisted breath). Following an assisted breath the ventilator waits

the expiratory time (which is based on the set BREATHING RATE), before another controlled breath is delivered. However, if the patient initiates another breath during the expiratory phase another assisted breath is delivered. During the inspiratory phase of a breath, the patient is not able to trigger another breath. This is done to prevent excessive pressure in the airway due to multiple breaths occurring in the same inspiratory cycle.

ASSISTED BREATH TRIGGER

The spontaneous breath trigger is preset to -2.0 cm H_2O. In order to initiate a spontaneous breath, the patient must generate -2.0 cm H_2O. When the pressure drop is detected an assisted breath is delivered. The trigger can be changed from -1 to -6 cm H2O below PEEP in the User Menu. **Note!** The trigger automatically adjusts when the PEEP is changed.

OPERATIONAL TEST PROCEDURE

1. With the breathing circuit connected, turn the POWER switch to on "1", allow ventilator to complete SELF-CHECK and begin operation with its default values.
2. The PATIENT DISCONNECT alarm should be active.
3. Press the MANUAL BREATH pushbutton, gas should flow out of the patient connection each time the button is pressed. (**Note!** the minimum period between breaths is limited by the tidal volume and the time required to complete a full exhalation based on the I:E ratio.)
4. Occlude the patient port with a clean hand or gloved hand. During inspiratory phase the HIGH AIRWAY PRESSURE LIMIT/ALARM should sound when the airway pressure reaches 35 cm H_2O.
5. If the HIGH AIRWAY PRESSURE LIMIT alarm fails to activate assure that the all of the tubing connections are secure and the exhalation valve is closing during inhalation and that the High Airway Pressure Limit is set to 35 cm H_2O.
6. After a breath or two release the patient port while allowing the ventilator to operate. During inspiration the DISCONNECT alarm should alarm.
7. If either the HIGH AIRWAY PRESSURE or DISCONNECT alarms fail to trigger replace the ventilator and send the unit for service.
8. If operating using the internal battery, verify that the BATTERY icon indicates sufficient available battery capacity remains to support the anticipated duration of operation. If not, begin ventilation and find an alternate source of power.

VENTILATE USING THE EMV

1. Attach the disposable patient circuit to the ventilator. To use a Heat and Moisture Exchanger (HME), attach it to the patient connector of the ventilator circuit.
2. Attach the AC/DC Power Supply to an appropriate AC power source if available (see **OPERATING POWER SELECTION & STOPPING** for details.
3. Turn the POWER switch to on "1" to start operation initiate self check. Upon the successful completion of self check, operation begins at default values.
4. Allow at least one breath to occur. During this time the PATIENT DISCONNECT alarm will sound as the ventilator does not detect the minimum required airway pressure.
5. Attach the ventilator circuit patient connection[3] to the patient's endotracheal tube, tracheostomy tube or other airways[4] that support positive pressure ventilation. Delivery of the first breath will automatically cancel the PATIENT DISCONNECT alarm.
    a. Noninvasive Ventilation: If you are ventilating with a mask make sure a proper seal is attained and that the patient's head is maintained in the midline position.

WARNING! During noninvasive ventilation, NEVER LEAVE THE PATIENT UNATTENDED!

WARNING! Avoid high airway pressure as this increases the risk of aspiration.

WARNING! Deadspace increases with mask ventilation. Always follow the manufacturer's directions.

[3] 22 mm OD/15 mm ID standard conical interface for use with respirator devices

[4] Other airways can include: laryngeal mask airway, esophageal obturator airway, combination esophageal-tracheal tubes though there use should be under the direction of the attending physician. See AARC Clinical Practice Guideline, Management of Airway Emergencies Respir Care 1995;40(7):749–760 Section 10.2.2.

6. Once connected to the ventilator, carefully do the following:
    a. Attach the pulse oximeter probe and begin monitoring HR and SpO_2 (See instructions provided with the pulse oximeter probe)[5].
    b. Set the high and low HR alarms appropriately for the patient.
    c. Set the low SpO_2 limit appropriately for the patient.
    d. Asses the patient's breath sounds for bilateral ventilation.
    e. If this is not possible watch the rise and fall of the chest wall to determine if there is adequate movement on both sides of the chest.

CHANGE SETTINGS

Each parameter button on the right side of the EMV is associated with a parameter window; each parameter window has a primary parameter and as many as 3 secondary parameters that can be adjusted by the operator. To adjust the primary parameter, push the parameter button one time; to adjust a secondary parameter push the parameter button a second or third time. Each time the parameter button is pushed a different parameter is highlighted in the parameter window. To change a primary or secondary parameter the following sequence is used:

1. Press the parameter button one or more times to select either the primary parameter or secondary parameters.
2. With the appropriate parameter highlighted, turn the rotary encoder clockwise or counterclockwise to raise or lower the value.
3. Press the Confirm/Select button "√"to complete the value change.
4. At anytime the operator can exit from any operation by pressing the Mute/Cancel button "X".

EXAMPLES

Example 1 - To change the ventilation rate from 12 to 16:
Step 1: Press the Set BPM button.
Step 2: Turn the Rotary Encoder clockwise to 16.
Step 3: Press the Confirm/Select button.

Example 2 - To change the Low SpO_2 Limit Alarm from 84 to 92:
Step 1: Press the SpO_2 button.
Step 2: Turn the Rotary Encoder clockwise to 92.
Step 3: Press the Confirm/Select button.

[5] If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.

BACK UP VENTILATOR

The EMV contains a built-in back up ventilator mode that is designed to provide a limited degree of operation should certain types of failures occur to the primary operating system. Depending upon the resources available at the time of failure, the backup ventilator will begin operation in one of two ways:

1. If no pre-existing alarm condition(s) exists: backup operation will continue using the current settings.
2. If a pre-existing alarm condition(s) exists: backup operation will revert to the startup default settings using pressure targeted ventilation (Mode AC, BPM 12, PIP 20 cm H_2O, FIO_2 21%, PEEP 5 cm H_2O, I:E 1:2.5, Trigger -2 cm H_2O).

HUMIDIFICATION

Heat and Moisture Exchangers (HME's) sometimes referred to as "artificial noses" can be used with the EMV. While HME's may not be suitable for all applications, they facilitate portability in a way that conventional humidifiers cannot. The EMV can be used with an optional HME or an optional HME/bacterial viral filter (HMEF). The HME provides heat and moisture to the inspired gas by recycling the heat and moisture contained in the patient's exhaled gas. Use of a HME/bacterial viral filter may help reduce the risk of cross contamination of biologic pathogens that might be transmitted in the patient's exhaled gas. It attaches between the disposable ventilator circuit and patient's endotracheal tube along with any additional instructions provided by the manufacturer.

Impact does not offer a heated humidifier option for the EMV. Users are cautioned to carefully consider the ramifications of such use and the effect it may have upon device performance and the patient's comfort. Such humidifiers have been shown to increase the work of breathing in portable ventilators. A diffuser or "cascade impactor" within the device is responsible for the increase in work of breathing[6]. In most applications, it has been recommended that if a Cascade is used, that its tower be removed. This will change the Cascade from a bubble humidifier to a pass-over humidifier, rendering it less efficient, but still capable of adding heat and moisture to the inspired gas. Any humidification device should be connected and operated only in accordance with directions provided by its respective manufacturer. Humidifiers are not recommended for transport. Observe all safety and cautionary statements.

WARNING! Use of the HME or HME/Bacterial Viral filter (HMEF) may not be indicated in patients with small tidal volumes as the dead space may be greater that 25% of the set TIDAL VOLUME. Always select an HME/HMEF that is appropriate for the patient.

WARNING! Use of the HME or HME/Bacterial Viral filter (HMEF) will cause a slight increase in the inspiratory effort to trigger an Assisted Breath (Approximately 1 cm H_2O)

EXTERNAL ENVIRONMENT FILTERS

With an appropriate third party filter in place, the EMV may be operated in environments where chemical and/or biological toxins are present. To do this, all gas delivered to the patient must come from either pressurized medical-grade O_2 or filtered ambient air entrained through the FRESH GAS/EMERGENCY AIR INTAKE. Operators can chose between a bacterial/viral filter and a chemical/biological filter based on the direction of the Medical Control Officer.

To prevent the patient from breathing contaminated ambient air in the event of a ventilator failure, the EMV contains an internal antiasphyxia valve that allows the patient to inspire gas through the external filter. While this design assures that no contaminated gas reaches the patient, it requires that the operator ensure that nothing blocks the input of the external filter.

WARNING! The Medical Control Officer and/or Incident Commander should determine which if any external filtration is used based on the potential hazard.

WARNING! The operator must assure that nothing blocks the inlet of the external filter. Failure to do so could prevent the patient from breathing in the event of a ventilator failure (see figure).

[6] Kacmarek et al (Respir Care 1990;35:405)

BACTERIAL/VIRAL FILTER USE

Bacterial/viral filters (B/V) can be used in environments where the patient is at risk to cross contamination or airborne pathogens. When used in accordance with the manufacturer's instructions these filters can help prevent inhalation of infectious matter. In dusty environments the B/V filters can also be used to prevent entrainment of particulate matter that could affect the ventilators pneumatic components. To use a bacterial/viral filter, insert the filter's male 22 mm conical fitting into the Fresh Gas/Emergency Air Intake.

CAUTION! If filters have been exposed to biological matter dispose of them following Universal Precaution procedures for your facility.

CHEMICAL/BIOLOGICAL FILTER (C2A1) USE

The EMV is designed to allow attachment of chemical/biological filter/canister (type C2A1[7]) for use in contaminated environments. The Fresh Gas/Emergency Air Intake fitting allows for attachment of standard Rd 40 x 1/7 threads. A complete description of this standard can be found in BS EN 148-1:1999 Respiratory protective devices – Threads for face pieces.

WARNING! Unit is shipped with the Wye circuit, if the standard circuit (820-0067-00) is used a check valve (704-0700-01) is required when operating with a Chem/Bio filter.

FRESH GAS/EMERGENCY AIR INTAKE

C2A1 FILTER
(RD 40 X 1/7 CONNECTION)

Bacterial Viral Filter
(22 MM MALE CONICAL CONNECTION)

External Environment Filters

[7] A 3M C2A1 canister (3M St. Paul, MN) was used in our validation testing to represent the class of filters generically known as C2A1 under the NSN number 4240-01-361-1319. These tests confirmed the performance of the ventilator when operating with these devices as a class. Use of the 3M canister does not constitute endorsement or recommendation of the 3M device. Use and selection of the appropriate filter should always be under the direction of the Incident Commander.

HARSH ENVIRONMENT OPERATION

The EMV is designed to operate in harsh prehospital environments and during air and ground transport. In order to safely manage the patient the operator must understand the operating characteristics of the ventilator and diligently monitor the patient and device in these environments. The EMV continuously monitors environmental conditions (temperature and ambient pressure) and when extreme environments are detected the operator is alerted by a low priority alarm which defines the operating condition and prompts the actions of the operator. Low priority alarms are advisory and the operator should remember that the device is operating as designed.

AIRBORNE PARTICULATES

Under normal operating conditions the internal 2-stage filtration system protects the gas flow path from particulates entrained through the Fresh Gas/Emergency Air Inlet. However, when operating in areas where fine dust or dirt is airborne due to wind or vehicle movement the operator should use a disposable bacterial/viral filter (sometimes called HEPA filter) to preserve the internal filter. Use of these filters will prevent the operator from having to change the internal filters. For extended operation in these environments the operator should change the filter as it becomes dirty (visually inspect the filter for dust/dirt build up). The primary affect of entrained particles is on the operation of the flow pneumotach used to control the gas delivered to the patient. Dirt on the pneumotach screens affects the calibration. Cleaning the screens requires a biomedical technician to disassemble the device and ultrasonically clean the screens. The best way to prevent taking the unit out of service is to use a filter in dusty environments. In addition to using the filter the operator should also keep the unit in the padded case which will protect the case and the LCD from becoming scratched or damaged. It is also easier to clean the padded case following use in a dusty/dirty environment than the device.

EXTREME TEMPERATURE ENVIRONMENTS

Traditional transport ventilators typically operate from 0° to 40° C (32° to 104° F). The EMV is designed to be capable of operating over a range of -25° to 49° C (-13° to 120° F). The primary limit to operating at low or high temperatures is the performance of commercially available Li Ion batteries which limit the charging temperature range to 0° to 45° C (32° to 113° F). However, the batteries are capable of discharging from -20° to 75° C. In addition, the device is also capable of operating over the entire range using external power. When the internal battery temperature drops below 0° or goes above 45° C a low priority alarm activates alerting the operator that the battery is no longer charging. The battery is able to discharge and power the unit. Operators can improve temperature performance by making sure that the unit is in the optional padded case when operating at low temperatures. The padded case insulates the unit and allows it to retain the heat generated by the compressor, circuit boards and AC/DC Power Supply. When operating at high temperatures the operator should remove the EMV from its padded case which will allow the unit to pass heat into the surrounding environment.

ALTITUDE

The EMV is designed to operate from -2,000 to 25,000 feet (-610 to 7620 meters). An absolute barometric pressure sensor monitors ambient conditions and this information is used to continuously correct the output of the device to maintain the ventilation parameters. When the altitude is >25,000 feet the unit activates a low priority alarm. When this occurs the operator should monitor the peak inspiratory pressure (PIP) and adjust the tidal volume to maintain the PIP and monitor breath sounds and chest excursion to assure adequate ventilation is maintained. The tidal volume increases as altitude increases so the operator should look to prevent over pressurization of the lung when the altitude increases beyond 25,000 feet. If changes are made above 25,000 the operator should revert to the initial settings once operation resumes in the compensated range (the LED will turn from yellow to green). **NOTE!** The EMV is not intended for hyperbaric operation. Use in a hyperbaric chamber can result in harm to the patient and/or damage to the EMV.

RAIN AND SNOW

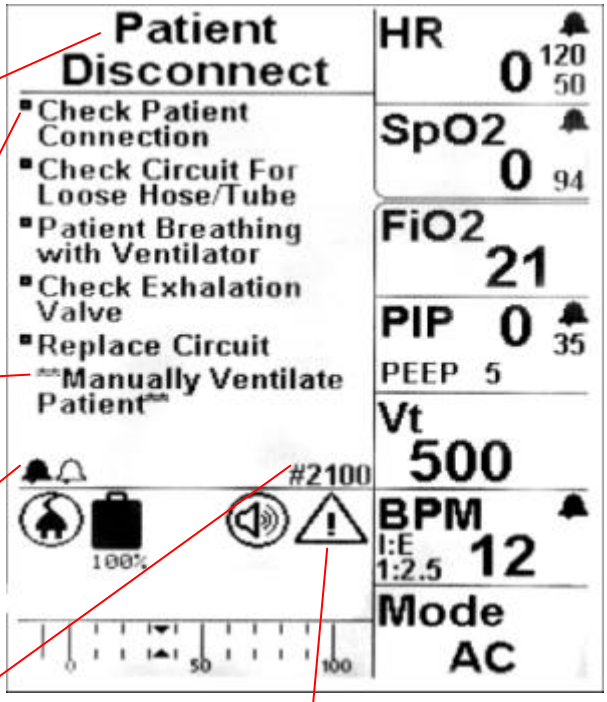
Like any electronic device the operator should attempt to prevent exposure to rain or snow. The EMV is capable of operating in these conditions but the operator should keep the device in the padded case and use the rain flap which is provided with the padded case. The padded case and rain flap prevent rain and snow from puddling on any of the device's surfaces. The EMV is certified to IP Code IPx2[8].

[8] IEC 60529 Degrees of protection provided by enclosures (IPx2), Protection against vertically falling water drops when enclosure is tilted up to 15 degrees.

ALARM FUNCTIONS

At the onset of an alarm, a multi-line message screen appears starting in the upper left-hand corner of the LCD. This screen area is called the ALARM MESSAGE CENTER (AMC). The AMC displays the alarm name with a series of messages to help the user resolve the alarm. The number of active alarms is indicated at the bottom of the AMC as a series of ALARM BELL icons with each bell indicating an active alarm. These messages are context-based and suggest what is causing the condition and/or how it can be resolved.

Alarm Messages are presented using the following format:



Alarm Message Center (AMC): contains the information and instructions to all active alarms.

Alarm Name/Description: describes the nature and/or cause of the fault or failure. The *Alarm Name/Description* appears at the top of the AMC. When more than one alarm occurs at the same time, the Model EMV prioritizes them based on patient safety.

Mitigation/Resolution Instructions: instructions for the operator as to how the alarm state may be resolved.

If Not Resolved Instruction area: instructs the operator on what to do if they cannot resolve the alarm state. The instruction always shown in the following format ***Message…***.

Alarm Number Icon: for each active alarm an alarm bell appears. When multiple alarms are active the number of bells corresponds to the number of alarms. The alarm in the AMC is demonstrated by an outline bell instead of a solid bell. To view each active alarm turn the rotary encoder to scroll through all active alarms.

Service Code: each alarm has a 4 digit number associated with it which helps the operator communicate with technical assistance or biomedical technician support. See Appendix 1 for a complete description of each service code/alarm

1###: high priority alarms
2###: medium priority alarms
3###: low priority alarms

Attention Warning Icon: Identifies the severity of the alarm, low, medium or high priority.

ALARM PRIORITIES

Alarm priorities define the operational state of the device regarding its ability to provide operator controlled mechanical ventilation. There are three priorities:

High Priority: mechanical ventilation under operator control is no longer possible. This alarm category requires immediate intervention by the operator. It also includes system failure alarms where the CPU has failed and a backup has taken over to sound the audible and visual alarms and when the device is turned on and there is no internal or external power source. Pressing the Mute/Cancel pushbutton has no affect on the high priority alarm. The alarm can only be silenced by turning off the ventilator.

Medium Priority: mechanical ventilation is active or is possible (maybe for a finite period of time) but, there is a failure/fault with the patient, ventilator circuit, a pneumatic subsystem or pulse oximeter. This alarm category requires immediate intervention by the operator. Pressing the Mute/Cancel pushbutton mutes medium priority

alarms for 30 seconds. If after 30 seconds the alarm-causing condition still exists, the audible alarm will recur until it is muted again for another 30 second period or resolves.

Low Priority: safe mechanical ventilation is active but, there is a fault that the operator must be aware of to assure safe management of the patient and/or ventilator. Low priority alarms present with both an audible and yellow LED alarm signal alerting the user to the condition. Pressing the Mute/Cancel pushbutton cancels the audible signal. If the alarm is not resolved the yellow LED remains illuminated to remind the operator of the fault or failure.

VENTILATOR ALARM CATEGORIES

Alarms are presented and grouped as categories rather than individual alarms because any given fault/failure may have a different affect on patient safety based on what operating resources are available (55 psig O_2, external power, etc), environmental conditions and the severity of the fault/failure. In each case the EMV analyzes the fault/failure and attempts to continue ventilating the patient while guiding the operator to make an appropriate intervention to resolve the condition. **NOTE!** Appendix 1 identifies all alarms based on their service code and their characteristics based on the unique service code that is associated with each alarm.

CPU Failure: alarm is associated with an unrecoverable failure of the central processor unit (CPU) that controls the user interface and SpO_2 monitoring. When this High Priority alarm occurs the user interface goes blank and the audible and red LED indicators are activated. The backup ventilation system automatically continues to provide ventilation based on the last good settings. Pressing the Mute/Cancel pushbutton has no affect on the alarm; the alarm can only be silenced by turning the ventilator off.

Compressor Fault/Failure: alarms are associated with faults or failures with the internal compressor which is used to deliver electrically powered breaths. High Priority alarms occur when the compressor is no longer able to deliver breaths based on the ventilator parameters and there is no 55 psig O_2 supply to operate the O_2 valve as a backup. When a compressor failure occurs with 55 psig O_2 available the EMV automatically begins ventilation using the O_2 valve and sounds a Medium Priority alarm. To clear the alarm the user is required to manually set the FIO_2 to 100%. Once the FIO_2 is set to 100% the Medium Priority alarm changes to a Low Priority alarm with a yellow alarm LED and persistent message. Low Priority alarms associated with the compressor system involve restrictions though the pneumotach screen or internal gas path that are detected by an internal sensor. Although outside the normal operating conditions the unit is still able to deliver breaths within the ventilator parameters. **Note!** failures of the compressor will prevent the entrainment of low flow O_2 through the Fresh Gas/Emergency Air Intake.

O2 Valve Fault/Failure: alarms are associated with faults or failures of the O_2 valve which is used to control pneumatically powered breaths. High Priority alarms occur when there is a failure of the O_2 valve and the internal compressor is not available for backup due to a secondary failure. When the O_2 Valve fails and the FIO_2 is >21%, the EMV automatically begins ventilation using the compressor and sounds a Medium Priority alarm. To clear the alarm the user is required to manually set the FIO_2 to 21%. Once the FIO2 is set to 21% the Medium Priority alarm changes to a Low Priority alarm with a yellow alarm LED and persistent message. Low Priority alarms associated with the O_2 Valve system involve restrictions through the pneumotach or internal gas path that are detected by internal sensors and that are outside normal operating conditions but still allow the unit to deliver breaths consistent with the ventilator parameters. **Note!** the user should recognize that setting the FIO_2 to 21% is acknowledging that the patient is being ventilated without supplemental O_2.

O2 Supply Pressure Low Fault/Failure: alarms are associated with faults or failures of the 55 psig O_2 supply and/or the unit's ability to detect the presence of high-pressure O_2. High Priority alarms occur when the O_2 supply pressure drops below 35 psig and the internal compressor is not available for backup due to a secondary failure. When the O_2 supply pressure drops below 35 psig and the FIO_2 is >21%, the EMV automatically begins ventilation using the compressor and sounds a Medium Priority alarm. To clear the alarm the O_2 supply pressure must >45 psig or the operator must manually set the FIO_2 to 21%. Once the FIO_2 is set to 21% the Medium Priority alarm is canceled. Note: the user should recognize that setting the FiO_2 to 21% is acknowledging that the patient is being ventilated without supplemental O_2. There are no Low Priority alarms associated with this fault/failure.

O2 Supply Pressure High Fault/Failure: alarm is associated with faults or failures of the 55 psig O_2 supply and/or the unit's ability to detect the presence of high-pressure O_2. High Priority alarm occurs when the O_2 supply pressure is greater than 80 psig. When the O_2 supply pressure is > 80 psig the EMV automatically shuts down to

prevent harm to the patient and/or damage to the EMV. When the pressure is ≥75 and ≤80 psig a low priority alarm sounds warning the operator of the potential shutdown should pressure increase beyond the current level.

Fresh Gas Intake Fault/Failure: alarms are associated with obstructions of the Fresh Gas/Emergency Air Intake. These obstructions can be the result of mechanical blockage of the intake (such as a plastic bag) or by using an inappropriate filter or when the internal or external filters become dirty or clogged. The pressure drop across the filter is continuously monitored. High Priority alarms occur when the obstruction prevents the compressor from delivering a breath that meets the ventilator settings and there is no 55 psig O_2 supply to operate the O_2 valve as a backup. Medium Priority alarms occur when O_2 supplied breaths can be delivered when the compressor is not able to deliver a breath. When this occurs the operator must set the FIO2 to 21% to acknowledge the fault. At this point, a Low Priority alarm sounds; pressing the Mute/Cancel button cancels the audible alarm while the yellow LED remains lit to remind the operator of the fault condition.

Power Fault/Failure: alarms are associated with power management and the supply of power from external sources and the internal rechargeable battery. High Priority power failure alarms occur when there is no backup power alternative or failures of the internal power management system. Low Priority alarms are associated with faults or failures that occur when a backup power source is available either by using the internal battery or through use of the external power source. Pressing the Mute/Cancel pushbutton cancels the audible alarm while a persistent message remains. **Note!** the EMV has the ability to automatically disconnect itself from external power sources that are providing power outside of the safe power range. When the unit detects that the external power supply is within range the unit automatically reconnects to the external source to power operation and recharging of the internal battery.

Low Battery Power: alarms are associated with power remaining in the internal battery and its ability to continue ventilator operation. High Priority alarms signal that the battery no longer has the power to continue ventilator operation and no external source detected. Pressing the Mute/Cancel pushbutton has no affect on the alarm; the alarm can only be silenced by turning the ventilator off. Medium Priority alarm alerts the operator that the unit has approximately 5 minutes of operating time remaining. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds. The Low Priority alarm occurs during internal battery operation when the unit determines that there is approximately 30 minutes of operating time remaining. Pressing the Mute/Cancel pushbutton cancels the audible alarm but the persistent message and yellow LED remain.

Missing Battery: alarm is associated with operating the unit without an internal battery or operation when the ventilator is not able to detect the internal battery. The Low Priority alarm alerts the user that the device is operating on external power and that the unit does not have the ability to automatically switch to internal battery power in the event of an external power failure. Pressing the Mute/Cancel pushbutton cancels the audible alarm but the persistent message and yellow LED remain.

SPM Change: alarm occurs when the CPU does not recognize the smart pneumatic module (SPM). The failure is most often associated with a mix up during servicing where the complete unit was not properly calibrated after a new SPM was installed. Pressing the Mute/Cancel pushbutton has no affect on the alarm; the alarm can only be silenced by turning the ventilator off and sending it for service.

Calibration Fault/Failure: alarm is associated with internal sensors that monitor and control breath delivery. High Priority alarms occur when there is a failure in one or more of the sensors that prevent the EMV from safely delivering breaths. Medium Priority faults occur when the sensors are not able to establish an airway pressure baseline. While the unit attempts to recalibrate the sensor the audible and visible alarms sound. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds.

Exhalation System Fault/Failure: alarms are associated with the control of the exhalation valve and airway pressure. High Priority alarms occur when the airway pressure exceeds the Pressure Limit value or 40 cm H_2O for more than 5 seconds, or when the airway pressure is >75 cm H_2O for more than 1.5 seconds. Medium Priority alarms occur when the end expiratory pressure does not reach the baseline pressure before the start of the next breath. This fault is typically associated with problems causing restrictions to the exhalation valve. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds.

Airway Pressure High: alarm is triggered when the airway pressure exceeds the High Airway Pressure Limit. Patient related causes for this Medium Priority alarm are patient coughing, ventilator dissynchrony or excess secretions in the airway. Other causes include kinks in the ventilator circuit tubing or a High Airway Pressure limit

that is too low given the airway pressure. The factory set default value at start up is 35 cm H_2O and instructions for changing the value are found above. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds.

PEEP Leak: alarm is triggered when the ventilator detects a drift of more than 2 cm H_20 in the end expiratory pressure. This Medium Priority alarm is most often associated with a loose or disconnected circuit hose or tube. The operator should also check to make sure the exhalation valve is firmly attached to the circuit and that the cap is securely attached to the body of the assembly. Leaks around the cuff of the patient's airway can also cause this alarm. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds.

Disconnect: alarm is triggered when the peak airway pressure fails to go 5 cm H_2O above the baseline pressure before the end of the inspiratory phase. This Medium Priority alarm is associated with disconnects between the patient port of the circuit and the patient airway. It can also be caused by a loose or disconnected circuit hose or tube. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds.

Calibration Due: this Low Priority alarm is triggered when the time since its last calibration has passed its next due date. Pressing the Mute/Cancel pushbutton cancels the audible alarm and yellow LED remains illuminated with the persistent message.

Ambient Pressure Fault: alarm is triggered when the ventilator senses that it is operating outside of its designed ambient pressure range (-2000 to 25,000 feet altitude). This Low Priority alarm alerts the user that there may be some affect on the delivered volume and to monitor the airway pressure and breath sounds to assure adequate ventilation of the patient. Pressing the Mute/Cancel pushbutton cancels the audible alarm and yellow LED remains illuminated with the persistent message.

Ambient Temperature Fault: alarm is triggered when the ventilator senses that it is operating outside of its designed ambient temperature range (-25 to 50° C). This Low Priority alarm alerts the operator that there may be some affect on the performance of the device. Pressing the Mute/Cancel pushbutton cancels the audible alarm and the yellow LED remains illuminated with the persistent message. (See Extreme Operating Conditions for additional details)

PULSE OXIMETER ALARMS

Low SpO_2: alarm is triggered when the SpO_2 value drops below the Low SpO_2 alarm limit. The Medium Priority alarm alerts the operator to a decrease in the patient's oxygenation status. Resolution of the alarm may involve increasing the FIO_2 or suctioning the patient. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds. The default low alarm limit at start up is 94%. To adjust the alarm limit refer to the instructions above.

High Heart Rate: alarm is triggered when the heart rate (HR) monitored by the pulse oximeter is above the High HR alarm limit. The Medium Priority alarm alerts the operator to tachycardia. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds. The default high alarm limit at start up is 120 beats/minute. To adjust the alarm limit refer to the instructions above.

Low Heart Rate: alarm is triggered when the heart rate (HR) monitored by the pulse oximeter is below the High HR alarm limit. The Medium Priority alarm alerts the operator to bradycardia. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds. The default high alarm limit at start up is 40 beats/minute. To adjust the alarm limit refer to the instructions above.

SpO_2 Shutdown: alarm is associated with a failure of the pulse oximeter. This Medium Priority alarm alerts the user to a failure of the pulse oximeter that is nonrecoverable or that communication between the CPU and pulse oximeter has failed. Pressing the Mute/Cancel pushbutton mutes the audible alarm for 30 seconds. In order to clear the alarm the user is required to use the Menu controls to turn off SpO_2 monitoring. Doing this cancels the Medium Priority alarm but the yellow LED and persistent message remain.

Pulse Ox Sensor Off Patient: alarm occurs when an operating sensor losses the patient signal. The Medium Priority alarm occurs most commonly when the sensor disconnects from the patient or is misaligned with the sensor site. This alarm can also be caused by poor perfusion at the sensor site which doesn't allow for a reading. In these cases try another site. Replace the sensor if another sensor is available. Pressing the Mute/Cancel button silences the audible alarm for 30 seconds.

No SpO_2 Sensor Connected: alarm is triggered during SpO_2 monitoring when the pulse oximeter does not detect the presence of a functioning SpO_2 sensor. The Low Priority alarm most often occurs when the SpO_2 sensor cable becomes disconnected from the ventilator. To clear the alarm, reattach the sensor cable to the ventilator. Pressing the Mute/Cancel pushbutton cancels the alarm. Note: if the EMV is started without a pulse oximeter sensor cable attached pulse oximeter monitoring does not start. At any time after start up, attaching the sensor to the ventilator automatically starts monitoring and all alarms activate.

Defective SpO_2 Sensor: alarm is triggered when the pulse oximeter detects a bad sensor. The Low Priority alarm prompts the operator to check and/or replace the sensor as needed. Pressing the Mute/Cancel pushbutton cancels the alarm. To clear the alarm, check/replace the sensor or turn off SpO_2 monitoring.

Low SpO_2 Perfusion: alarm is triggered when the pulse waveform is marginal. The Low Priority alarm alerts the operator to check the sensor site and reposition as needed. Pressing the Mute/Cancel pushbutton cancels the alarm. To clear the alarm, check/replace the sensor or turn off SpO_2 monitoring.

Poor SpO_2 Signal: alarm is triggered when the pulse waveform is marginal. The Low Priority alarm alerts the operator to check the sensor site and reposition as needed. Pressing the Mute/Cancel pushbutton cancels the alarm. To clear the alarm, check/replace the sensor or turn off SpO_2 monitoring.

SpO_2 Pulse Search: alarm is triggered whenever the pulse oximeter is not able to detect a pulse waveform. The Low Priority alarm alerts the operator check the position of the sensor, patient movement and/or the perfusion at the sensor site. Pressing the Mute/Cancel pushbutton cancels the alarm. To clear the alarm, reposition the sensor to a better site or turn off SpO_2 monitoring.

SpO_2 Interference Detected: alarm is triggered when the sensor and/or cable are exposed to significant electromagnetic interference. This Low Priority alarm can be caused by powerful radio or radar equipment. Pressing the Mute/Cancel pushbutton cancels the alarm. To clear the alarm, remove the patient from the area or shield the patient/sensor or turn of SpO_2 monitoring.

SpO_2 Sensor Off Patient: alarm is triggered when the pulse oximeter detects that it is no longer connected to the patient. The Medium Priority alarm alerts the operator to check the position of the sensor, patient movement and/or the perfusion at the sensor site. Pressing the Mute/Cancel pushbutton mutes the alarm for 30 seconds. To clear the alarm, reposition the sensor to a better site or turn off SpO_2 monitoring.

SpO_2 Light Contamination: alarm is triggered when the SpO_2 signal is corrupted by an external light signal. The Low Priority alarm alerts the operator that too much external light (sunlight, surgical light, etc) is affecting the sensor. Pressing the Mute/Cancel pushbutton cancels the alarm. To clear the alarm, shield the sensor from direct light using a cloth or paper towel.

Unrecognized SpO_2 Sensor: alarm is triggered when the pulse oximeter detects connection of an inappropriate sensor to the ventilator. The Low Priority alarm alerts the operator that the attached probe is not designed to work with the pulse oximeter in the ventilator. Pressing the Mute/Cancel pushbutton cancels the alarm. To clear the alarm, use an appropriate sensor or turn off SpO_2 monitoring.

ROUTINE CARE: CALIBRATION, CLEANING AND PREVENTIVE MAINTENANCE

CALIBRATION CHECKS

This device should be incorporated into a regular preventative maintenance program to insure compliance with operating specifications. Calibration checks should be done every 12 months. unless significant usage warrants a shorter period between preventative maintenance inspections. Following 6-months of continuous storage/non-use, or longer, this device should be examined, operationally tested, and its batteries recharged before patient-use is attempted. A complete calibration check should be made by a competent biomedical equipment technician at 12 intervals. Calibration checks should be performed as required and the results recorded. A secure record of these Calibration checks should be maintained for devices not returned to Impact for calibration/maintenance. Calibration checks should also be performed whenever the operator suspects that the EMV is not functioning properly or following mass deployment before the device is returned to storage. If the unit being tested fails the calibration check it should be returned to an authorized Impact Service Center or Impact for calibration.

Contact an authorized Impact Service Center or Impact prior to returning this instrument for scheduled maintenance, calibration or service (Telephone 973.882.1212, email service@impactii.com). A Returned-Goods-Authorization number (RGA #) will be issued. The RGA # must appear on both the packing slip and address label. This will facilitate better tracking of the returned item and result in improved scheduling and handling.

CLEANING

Keep the EMV and its accessories clean at all times. Never allow grease and/or oil to enter the system or coat its components. Exposed parts should be dried following usage in wet environments. Users are encouraged to clean this device and its accessories at regular intervals and maintain up-to-date records of maintenance and inspections. Internal pneumatic components are sealed, thus routine maintenance is not required. Pressure hose connections should be wiped with a damp, soapy cloth and thoroughly dried with a lint-free cloth. The EMV's housing should also be cleaned as necessary with a damp, soapy cloth and thoroughly dried with a lint-free cloth. Do not clean with abrasives or chlorinated hydrocarbon cleansers.

High Pressure Hoses: Examine hoses for cracking, discoloration and disfigurement. Wipe the exterior wall with a damp, soapy cloth. Dry with a lint-free cloth. Examine end connection fittings for damaged threads and sharp edges. Replace if defective, DO NOT attempt to repair.

WARNING! Never use oil or grease of any kind with O_2 or compressed gas equipment.

PREVENTATIVE MAINTENANCE

Routine maintenance should be performed on the EMV at regular intervals and prior to its being placed into service. Routine maintenance should consist of the following:

1. Storage – make sure the ventilator is stored in a clean and dry environment.

2. Operational checks – using the ventilator circuit operate the ventilator at default settings, then change various settings and confirm proper operation, test disconnect, airway pressure, and SpO_2 alarms.

3. Tubing and hose checks – replace crimped, cracked or worn tubing and hose as required.

4. Mechanical components are subject to wear and fatigue over time. Components will deteriorate more quickly when used continuously or stored in direct sunlight. Also, use in dusty environments without proper filtration will affect the compressor and pneumatic components. To insure compliance with operating specifications, it is the user's responsibility to keep the device clean and ensure that the device is used as intended and that it is sent for periodic maintenance with a qualified technician.

REMOVABLE FOAM FILTER REPLACEMENT

Removable Foam Filter: The Removable Foam Filter housing is located on the right side of the ventilator. Remove the filter using a pair of tweezers or similar tool. Examine the filter for dirt, lint, or general wear. Replace if necessary (Part # 465-0028-00). DO NOT attempt to clean this filter. Do not operate internal compressor without filter in place.

CAUTION! Do not operate the compressor without both the foam and disk filters in place.

FRESH GAS/EMERGENCY AIR INTAKE DISK FILTER REPLACEMENT

Fresh Gas/Emergency Air Intake Disk Filter: The Fresh Gas/Emergency Air Intake Disk Filter (Part #465-0027-00) is located behind the Removable Foam Filter. This filter provides a second level of filtration to the ambient air that is delivered to the patient. When the ventilator is in regular service this filter should be replaced after every 1500 hours of service or every 1 year whichever comes first. To inspect or replace the disk filter, remove the 4 screws that secure the Compressor Inlet Housing and remove the Compressor Inlet Housing. If the filter appears dirty or discolored or the replacement interval has passed replace the filter with a new one. Reinstall the Compressor Inlet Housing then secure it by tightening the 4 screws; do not forget to install the Removable Foam Filter. For complete instructions on replacing these filters see Appendix 5: INTERNAL FILTER CHANGE/INSERTION. **NOTE!** DO NOT attempt to clean this filter.

CAUTION! When used in dusty/dirty environments the foam and disk filters should be checked, and replaced as needed. This will prevent particle build up on the transducer screen and the need to take the unit out of service for maintenance by a biomedical technician.

CAUTION! If filters have been exposed to biological matter dispose of them following Universal Precaution procedures for your facility.

POST-CONTAMINATED ENVIRONMENT CLEANING

If the ventilator is operated in an environment where it may have been exposed to contamination from a hazardous materials accident, mass epidemic or weapon of mass destruction, Impact recommends that the guidelines below be followed.

1. Always follow the decontamination procedures specified by the local Incident Command Safety Officer.
2. Equipment should be cleaned and decontaminated as soon as possible after use. Consumables should be disposed of following the protocols established by the Incident Command Safety Officer. Personnel should always wear the appropriate Personal Protective Equipment while decontaminating equipment.
3. The ventilator's outer case should be cleaned with a damp soapy cloth and thoroughly dried with a lint-free cloth. Make sure that all exposed surfaces are cleaned and dried.
4. For general decontamination/cleaning situations, a 10% bleach solution applied with a damp cloth is an effective decontaminant that can be used. Since the potential amount of contaminants that our ventilators might be exposed to is so large, it is difficult to provide an appropriate cleaning method for each type of exposure. An effective cleaning agent for one type of exposure may not be effective with another and cleaning and sterilizing practices may vary between institutions. Impact Instrumentation, Inc. suggests that each facility have in place a procedure for the cleaning and disinfection of its medical equipment and that these procedures be consulted for further guidance.
5. Care must be taken to prevent liquids from entering the ventilator. Never submerge the ventilator and avoid using excessive amounts of water that might enter the unit.
6. Never use abrasives or chlorinated hydrocarbon based cleansers when cleaning the ventilator, they will damage the plastic and interface lens.

BATTERY CAPACITY, CARE AND RECHARGING

BATTERY CAPACITY

While the unit is operating on battery power, users can best determine the relative amount of charge in the internal battery by looking at the BATTERY Icon/Indicator. The BATTERY icon appears in outline form and is filled with vertical rows of lines indicating its current capacity. Each line represents approximately 10% of battery capacity.

NOTE! The operating time indicated in the Specifications section is based on laboratory testing using fully charged batteries. Operating the ventilator at extreme low or high temperatures will affect the duration of operation. Users are advised to always monitor the battery charge and identify a secondary source of external power.

BATTERY CARE AND CHARGING

If the unit was supplied without the battery installed or battery replacement is required see APPENDIX 4: INTERNAL BATTERY CHANGE/INSERTION.

The EMV uses a rechargeable lithium-ion battery which offers a wide temperature operating range, does not exhibit "memory" characteristics (reduced capacity) or vent hydrogen gas. The life of this battery depends, to a great extent, upon the care it receives. Avoid exposing it to direct sunlight or heat sources and never store the battery at temperatures above 76 °C (170 °F) for more than 2 hours. Following these simple guidelines will prevent premature charge depletion and reduction of battery life.

CAUTION! Only use the Power Supply provided with the unit. Use of any other power supply could damage cause a fire and/or destroy the battery and unit.

CAUTION! If you witness a battery or the battery compartment starting to balloon, swell up, smoke or feel excessively hot, discontinue the charging process immediately, disconnect the battery and observe it in a safe place for approximately 15 minutes and send the unit for service. Never puncture or disassemble the battery packs or cells.

CAUTION! Never attempt to completely discharge the battery by shorting or some other method and never ship the battery in a completely discharged state.

1. DO NOT charge the ventilator when the temperature range exceeds 0 °C to 45 °C (32 °F to 114 °F).
2. DO NOT store the ventilator with the batteries discharged. For maximum battery life, store the battery about 35% charged.
3. For long-term storage, the optimum storage temperature range is -15 °C to 21 °C (5 °F to 71 °F) with low humidity.

Lithium-ion batteries exhibit excellent charge retention characteristics. Prolonged periods of disuse will not substantially reduce operating capability. If long-term storage/non-use is common, recharge the unit once every six months; this will insure that battery charge is maintained at 80% capacity or better. The EMV battery rapid recharges to 90% of its capacity in approximately 2 hours. It will take approximately another 2 hours of trickle-charging to top off the battery to 100% of its capacity. Continuous charging is permissible with the supplied 12 VDC Power Cable or AC/DC Power Supply.

Operating power will always default to the external power source to preserve the internal battery charge. This assures that power is available for transport use or emergency back-up purposes. If the EXTERNAL POWER LOW/FAIL Alarm occurs, the EMV will automatically revert to its internal batteries for operating power.

The BATTERY Icon/Indicator – indicates (1) the presence of a functional battery, (2) when the battery is charging and (3) what its current capacity is. The BATTERY icon appears in outline form and is filled with vertical rows of lines indicating its current capacity. When the battery is charging, these vertical rows of lines cyclically scroll vertically, one row at a time, from the bottom row to the row that corresponds with the current level of charge. When the battery is fully charged, the icon is completely filled with lines and scrolling stops. Each line represents approximately 10% of battery capacity. During operation from its internal battery, a vertical row “disappears” as battery capacity is reduced by a 10% increment. The BATTERY icon will flash off/on when a Battery Power Low Alarm occurs. The icon will flash off/on and present with a diagonal line when no battery is connected.

SPECIAL CHARGING APPLICATIONS

For special applications using non-Impact charging equipment, the following requirements are intended to serve as guidelines:

Input Voltage:	11 to 32 VDC (28 VDC nominal)
DC Ground:	Negative
DC Power:	80 Watts (minimum, over the input voltage range)
AC Frequency:	Not applicable

IN CASE OF DIFFICULTY

TROUBLE SHOOTING

Authorization to service this instrument by other than factory-trained and certified personnel will not be given, nor does Impact Instrumentation, Inc. assume any responsibility and/or liability resulting from such unauthorized servicing.

Impact will, upon request; provide competent biomedical engineering departments with service data and schematics. There may be a charge for requested documents and documentation related to certain proprietary sub-systems may not be available. Such departments are encouraged to contact the factory for assistance when needed and it is recommended that staff members attend a factory training course. Details may be obtained by contacting the Impact Customer Service Department.

OPERATOR CORRECTABLE PROBLEMS

Common problems may be quickly rectified by operators by following the mitigation instructions that are displayed by the EMV. Should the EMV fail to operate properly, verify the integrity of all hose, tubing and fitting connections. Check all control panel settings and follow the alarm mitigations instructions provided in the AMC. Verify that the Fresh Gas/Emergency Air Intake Filter and Removable Foam Filter are not clogged or dirty. Check for operating power with internal batteries and external power source(s). Assure the supplied power and O2 supply pressure are within the specified range.

OPERATING PROBLEMS REQUIRING SERVICE

If the tests described above do not resolve an operating problem, service is required. Should servicing be necessary, contact the closest authorized Impact Service Center or the Impact Customer Service Department 973.882.1212. When calling or emailing for support be sure to have the service code number associated with the fault or failure. A Returned-Goods-Authorization number (RGA #) will be issued if the problem cannot be resolved. The RGA number must appear on both the packing slip and address label. This will facilitate better tracking of returned items, and result in improved scheduling and handling. Please have the Model and Serial Number ready and any other pertinent data you wish to include in the service request. The EMV Serial Number Label is affixed to the bottom cover. This information is also contained in the User Menu, My Ventilator Section.

STORAGE INFORMATION

For prolonged storage periods, the EMV should be stored indoors. The environment should be clean and out of direct sunlight. Storage in non-controlled environments is permissible if batteries are removed.

Short-term storage temperatures should range between -15°C to 40°C (5°F and 104°F), relative humidity should be low though the range is 0 to 95% noncondensing. For long-term storage, the optimum storage temperature range is -15°C to 21°C (5°F to 71°F). Battery life is diminished at temperatures above 35°C. It is recommended that batteries be discharged to 50% capacity if long term storage above 35°C is expected.

DO NOT store batteries in a discharged condition.

CAUTION! DO NOT store batteries in a discharged condition.

When batteries are in extended storage, it is recommended that they receive a refresh charge at recommended intervals when <u>not</u> continuously connected to an external power source:

STORAGE AMBIENT	RECHARGE INTERVAL
Below 68°F (20°C)	12-months
68°F to 86°F (20°C to 30°C)	6-months
86°F to 104°F (30°C to 40°C)	3-months

Following periods of extended storage in non-controlled environments, allow the EMV sufficient time to stabilize to a temperature within its specified operating range (see section entitled Battery Care, Capacity And Recharging).

Following 6-months of continuous storage/non-use, or longer, this device should be examined, operationally tested, and its batteries recharged before patient-use is attempted. Servicing may be required. Servicing should be performed by qualified personnel only.

SPECIFICATIONS

Parameter	Operating Range
Operating Mode	Assist Control (AC)
Breath Target	Volume
Flow Rate	0 to 100 LPM @ 40 cm H_2O
Breath Rate	6 to 30 BPM (default 12)
Tidal Volume	300 to 1200 ml (default 700)
Inspiratory Time	Varies based on 1:2.5 fixed I:E ratio and set breathing rate
FIO_2	21% with ambient air, 50 and 100% with external O_2 source
PEEP	5 cm H_2O, fixed
Oxygen Input Pressure	55 psig (-25%; + 20%)
Airway Pressure Limit	20 to 80 cm H_2O values (values >60 cm H_2O require secondary user confirmation)
Breath Trigger	-1 to -6 cm H2O (default -2.0 cm H_2O) through menu
LED Bar Graph	-10 to 100 cm H_2O
LED Status/Alarm Indicator	Red, yellow and green
Alarm Volume	82 dBA @1 ft
Noise Level	~60 dBA when measured @1-meter (compressor operating at default settings)
Operating Voltages	90 to 260 VAC (47 to 440 Hz) or 11.5 to 32 VDC
Operating Time:	
Internal Battery	10 hours at default settings (normal adult R20, C20), peak load <7A
External AC	Continuously
External DC	Continuously
Temperature Ranges:	
Operating	-25° C to 49° C (-13° F to 120° F)
Charging	0° C to 45° C (32° F to 114° F)
Long Term Storage	-15° C to 21° C (5° F to 71° F) *recommended for optimum device life
Humidity	Operating & storage: 0 to 95% noncondensing
Control Accuracy	± 10% of setting
Size	7.5" Wide X 12.5" High X 4.5" Deep (19.1 cm Wide X 31.7 cm High X 11.4 cm Deep)
Weight	9.7 lbs (4.4 kg)
Warranty	Limited, 1-year (see LIMITED WARRANTY statement)

LIMITED WARRANTY

When used in accordance with the instructions contained within this Manual, Impact Instrumentation, Inc., warrants this instrument to be free from all defects in materials and workmanship for a period of one (1) year.

Batteries, which by their nature are consumable and subjected to environmental extremes, will be warranted only for a period of ninety (90) days. Accessories, also consumable in usage, such as connecting hose and ventilator circuits, are not warranted.

Mechanical components are subject to wear and fatigue over time. They will deteriorate quicker when continuous-use applications are involved. To insure compliance with operating specifications, it is the user's responsibility to insure that periodic preventative maintenance is performed.

This warranty is neither assignable nor transferable, nor does it apply if this instrument is tampered with, misused or serviced by unauthorized personnel. All warranty repairs shall be subject to return postage billing.

APPENDIX 1: ALARMS

Service Code	Alarm Name
	Alarm description and mitigation information.
1001	**Compressor Failure (Compressor Control Fault - No Backup)** Alarm occurs when the compressor fails to operate or fails to provide the flow required to deliver a breath and high-pressure O_2 (HP O_2) is not available to provide ventilation. *Mitigation/Info: Manually Ventilate Patient, Connect 55 psig O2, Restart Ventilator With O2* ***Replace/Service Ventilator***
1002	**Compressor Failure (Compressor Signal Chain Fault - No Backup)** Alarm occurs when communication between the compressor controller and Smart Pneumatic Module (SPM) is lost and high-pressure O_2 (HP O_2) is not available to provide ventilation. *Mitigation/Info: Manually Ventilate Patient, Connect 55 psig O2, Restart Ventilator With O2* ***Replace/Service Ventilator***
1003	**Self Check Failure** Alarm occurs when the flow from the first breath is ±20% of the expected flow for the tidal volume at start up. *Mitigation/Info: Manually Ventilate Patient* ***Replace/Service Ventilator***
1010	**O2 Valve Failure (O2 Valve Failed Open)** Alarm occurs when the O_2 valve fails in the open position which results in continuous inspiratory flow. When this occurs the unit automatically opens the exhalation valve to prevent pressure from accumulating in the circuit and ventilation stops. *Mitigation/Info: Manually Ventilate Patient* ***Replace/Service Ventilator***
1011	**O2 Valve Failure (O2 Valve Control Fault – No Back Up)** Alarm occurs when the signal to the O_2 valve is not delivering the required flow rate and the compressor is not available to provide ventilation. *Mitigation/Info: Manually Ventilate Patient* ***Replace/Service Ventilator***
1012	**O2 Valve Failure (O2 Valve Signal Chain Fault – No Backup)** Alarm occurs when the communication between the O_2 valve and the SPM fails and the compressor is not available to provide ventilation. *Mitigation/Info: Manually Ventilate Patient* ***Replace/Service Ventilator***
1020	**O2 Supply Failure (O2 Tank Pressure Low - No Backup)** Alarm occurs when the O_2 supply pressure is ≤ 35 psig and the compressor is not able to support ventilation. If the O_2 source can be restored the unit should be cycled off then on to reset. By design the unit will not reestablish O_2 operation unless the supply pressure is ≥40 psig. If the supply pressure is between 40 and 80 psig the operator should check all hose connections for leaks. Occasionally, this alarm can be caused by a regulator that provides a static pressure within range but is not able to provide the flow necessary to meet the patient demand. *Mitigation/Info: Manually Ventilate Patient, Connect 55 psig O2 then Restart, Check O2 Supply for Leaks, Replace Regulator* ***Replace/Service Ventilator ***

1030 Fresh Gas Intake Failure

Alarm occurs when the Fresh Gas/Emergency Air Inlet is blocked so that the compressor is not able to deliver flow sufficient for the current settings and HP O_2 is not available to support ventilation. The operator should clear the blockage and restart the ventilator.
Mitigation/Info: Manually Ventilate Patient, Clear Blocked Intake, Connect 55 psig O2, Restart Ventilator
***Replace/Service Ventilator ***

1041 O2 Supply Pressure High Failure (O2 Tank Pressure Excessive - No Backup)

Alarm occurs when the O_2 supply pressure is >80 psig. Pressures above 80 psig could result in a catastrophic failure, harm to the patient and/or damage to the unit. While the patient is manually ventilated the operator or assistant should seek to reduce the O_2 supply pressure. Sometimes this requires changing the regulator which is not functioning as required. If the pressure cannot be reduced and a low flow device like a flow meter is available the operator can provide supplemental O_2 via the optional low flow O_2 reservoir. To clear the alarm the unit should be turned off and then restarted with supply pressure in the appropriate range (40 to 79 psig) or without HP O_2 connected.
Mitigation/Info: Manually Ventilate Patient, Decrease O2 Supply to 55 psig, Replace Regulator, Connect Low Flow O2,
*** Restart Ventilator without O2 Supply***

1051 Run-Time Calibration Failure

Alarm occurs when there is a failure of the calibration system. When this occurs the patient should be manually ventilated, the unit removed from use and sent for service.
Mitigation/Info: Manually Ventilate Patient
*** Replace/Service Ventilator ***

1052 Airway Pressure Sensing Failure

Alarm occurs when communication between the airway pressure sensor and SPM is lost. When this happens the operator should manually ventilate the patient, replace the ventilator and send the unit for service.
Mitigation/Info: Manually Ventilate Patient
*** Replace/Service Ventilator ***

1060 Exhalation System Failure (Exhalation Valve Failure)

Alarm occurs when the exhalation control valve fails to operate. When this happens the unit stops ventilating and attempts to discharge the pressure in the breathing circuit to atmosphere. This failure may be caused by a significant blockage of the exhalation valve or an occlusion/kink in the exhalation valve tube. If possible, the operator should replace the breathing circuit and restart the ventilator. If this does not resolve the problem then the operator should manually ventilate the patient, replace the ventilator and send the unit for service.
Mitigation/Info: Manually Ventilate Patient, Replace Circuit and Restart
*** Replace/Service Ventilator ***

1061 Exhalation System Failure (Excessive Airway Pressure)

Alarm occurs when the airway pressure (Paw) is above 40 cm H_2O or the PIP limit (when PIP limit is <35 cm H_2O) for >5 seconds or when the Paw is above 75 cm H_2O for >1.5 seconds. When this happens the unit stops ventilating and attempts to discharge the pressure in the breathing circuit to atmosphere. This failure may be caused by a significant blockage of the exhalation valve or an occlusion/kink in the exhalation valve tube. If possible, the operator should replace the breathing circuit and restart the ventilator. If this does not resolve the problem then the operator should manually ventilate the patient, replace the ventilator and send the unit for service.
Mitigation/Info: Manually Ventilate Patient, Replace Circuit and Restart
*** Replace/Service Ventilator ***

1420 Complete Power Failure

Alarm occurs when power is lost from both the internal battery and an external source during operation. When this occurs, the LCD blanks (no power for operation); the audible alarm pulses rapidly, and the visual alarm flashes rapidly. This alarm will last approximately two minutes.

Mitigation/Info: No LCD Display

1430 Empty Battery

Alarm occurs when the internal battery power drops below the amount required to provide ventilation and external power is not connected. When this occurs there is enough power to operate the user interface and provide information to the operator. The patient should be manually ventilated while an external source of power is sought. To cancel the alarm and begin operation, connect external power.

Mitigation/Info: Manually Ventilate Patient, Connect External Power
Replace/Service Ventilator

1172 Run-Time Self Check Alarm

Alarm occurs when the supplied voltage to the logic circuits fails to reach the required voltage. When this occurs the patient should be manually ventilated, the unit removed from use and sent for service.

Mitigation/Info: Manually Ventilate Patient, Ventilator Not Functioning
*** Replace/Service Ventilator***

1173 Internal Comm Failure

Alarm occurs when communication between the EMV and SPM fails. When this occurs the backup ventilator initiates. The patient should be manually ventilated and the unit removed from use and sent for service.

Mitigation/Info: Manually Ventilate Patient, Backup Ventilator Enabled
*** Replace/Service Ventilator ***

1174 Self Check Failure

Alarm occurs when a failure of the PGA offset control is detected during startup that will affect operation. When this occurs the patient should be manually ventilated, the unit removed from use and sent for service.

Mitigation/Info: Manually Ventilate Patient, Ventilator Not Functioning
*** Replace/Service Ventilator***

1175 Internal Comm Failure

Alarm occurs when the SPM DSP fails to write data onto the PGA registers. When this occurs ventilation stops and the high priority alarm sounds. The patient should be manually ventilated and the ventilator sent for service.

Mitigation/Info: Manually Ventilate Patient, Ventilator Not Functioning
*** Replace/Service Ventilator***

1471 Internal Communication (Comm) Failure

Alarm occurs when the device is no longer able to communicate with the User Interface Module (UIM) and the interface controls. When this occurs ventilation continues at the current settings or the backup mode settings and the high priority alarm sounds. The patient should be manually ventilated and the ventilator sent for service.

Mitigation/Info: Manually Ventilate Patient, Backup Ventilator Enabled
*** Replace/Service Ventilator***

1472 Internal Communication (Comm) Failure

Alarm occurs when the device is no longer able to communicate with the Smart Pneumatic Module (SPM). When this occurs ventilation continues at the current settings or the backup mode settings and the high priority alarm sounds. The patient should be manually ventilated and the ventilator sent for service.

Mitigation/Info: Manually Ventilate Patient, Backup Ventilator Enabled

*** Replace/Service Ventilator****

1473 **Internal Comm Failure**

Alarm occurs when no valid data is sent from the SPM within 1 second. When this occurs ventilation continues at the current settings or the backup mode settings and the high priority alarm sounds. The patient should be manually ventilated and the ventilator sent for service.

Mitigation/Info: Manually Ventilate Patient, Backup Ventilator Enabled

*** Replace/Service Ventilator****

1474 **Internal Comm Failure**

Alarm occurs when cyclic redundancy checking between the EMV and SPM fails. When this occurs ventilation continues at the current setting or the backup mode settings and the high priority alarm sounds. The patient should be manually ventilated and the ventilator sent for service.

Mitigation/Info: Manually Ventilate Patient, Backup Ventilator Enabled

*** Replace/Service Ventilator****

1475 **LCD Control Failure**

Alarm occurs when the device has lost communication with the contrast control and in most instances the content of the LCD is not visible. When this occurs ventilation continues at the current settings or the backup mode setting and the high priority alarm sounds. The patient should be manually ventilated and the ventilator sent for service.

Mitigation/Info: Manually Ventilate Patient, Backup Ventilator Enabled

*** Replace/Service Ventilator****

1480 **SPM Compatibility Failure**

Alarm occurs when the EMV and SPM software loads are not compatible. This alarm is typically associated with an SPM change where the technician failed to update the EMV and SPM to the current software revision. Ventilation is provided using the backup mode settings. The unit should be removed from use and sent for service.

Mitigation/Info: Manually Ventilate Patient, Software Compatibility Failure

*** Replace/Service Ventilator ****

1485 **Power-On Self-Check Failure**

Alarm occurs when the Smart Pneumatic Module (SPM) software fails and is shut down. Powering the unit off allows the software to reset and may allow operation to continue.

Mitigation/Info: Manually Ventilate Patient, Abnormal Reset Detected, Restart Ventilator

*** Replace/Service Ventilator ****

2001 **Compressor Fault (Compressor Control Fault – Backup Available)**

Alarm occurs when the communication between the O_2 valve and the SPM fails and HP O_2 is available to provide ventilation. The alarm will continue to sound as a medium priority alarm until the user acknowledges that ventilation is being provided using HP O_2 by setting the FIO_2 to 100%. At this time the priority changes to low priority. While operating in this state the operator should assure an adequate supply of HP O_2. Failure to maintain the HP O_2 supply will result in a high priority alarm.

***Mitigation**: Operation Switched to O2 valve, Set FIO2 to 100%*

Replace/Service Ventilator*

2002 **Compressor Fault (Compressor Signal Chain Fault – Backup Available)**

Alarm occurs when communication between the compressor controller and Smart Pneumatic Module (SPM) is lost and HP O_2 is available to provide ventilation. The alarm will continue to sound as a medium priority alarm until the user acknowledges that ventilation is being provided using HP O_2 by setting the FIO_2 to 100%. At this time the alarm priority changes to low. While operating in this state the operator should assure an adequate supply of HP O_2. Failure to maintain the HP O_2 supply will result in a high priority alarm.

***Mitigation**: Operation Switched to O_2 valve, Set FIO2 to 100%*

Replace/Service Ventilator

2011 O2 Valve Fault (O2 Valve Control Fault – Backup Available)

Alarm occurs when the signal to the O_2 valve is outside of the calibration range for the required flow rate and the compressor is available to provide ventilation. The medium priority alarm will continue until the user acknowledges that ventilation is being provided using the compressor by setting the FIO_2 to 21%. At this time the alarm priority changes to low priority. While operating in this state the operator should monitor the SpO_2 to assure that adequate oxygenation is maintained. If low flow O_2 is available it can be entrained through the Fresh Gas/Emergency Air Intake port using the optional O_2 reservoir. Maintain an acceptable SpO_2 by adjusting the O_2 supply up or down to increase or decrease the amount of O_2 delivered to the patient.

Mitigation: Operation Switched to Compressor, Set FIO2 To 21%, Connect Low Flow O2, Monitor SpO2

Replace/Service Ventilator

2012 O2 Valve Fault (O2 Valve Signal Chain Fault – Backup Available)

Alarm occurs when the communication between the O_2 valve and the SPM fails and the compressor is available to provide ventilation. The alarm will continue to sound as a medium priority alarm until the user acknowledges that ventilation is being provided using the compressor by setting the FIO_2 to 21%. At this time the alarm priority changes to low. While operating in this state the operator should monitor the SpO_2 to assure that adequate oxygenation is maintained. If low flow O_2 is available it can be entrained through the Fresh Gas/Emergency Air Intake port using the optional O_2 reservoir. Maintain an acceptable SpO_2 by adjusting the O_2 supply up or down to increase or decrease the amount of O_2 delivered to the patient.

Mitigation/Info: Operation Switched to Compressor, Set FIO2 To 21%, Connect Low Flow O_2, Monitor SpO2

Replace/Service Ventilator

2020 O2 Supply Pressure Low (O2 Tank Pressure Low)

Alarm occurs when the O_2 supply pressure is <35 psig and the compressor is able to support ventilation. When this occurs the unit begins ventilation using the compressor. The alarm will continue to sound as a medium priority alarm until the user acknowledges that ventilation is being provided using the compressor by setting the FIO_2 to 21%. Pressing the MUTE/CANCEL button cancels this alarm completely (Note: the device is designed to work with or without external O_2). If HP O_2 is connected the unit will not continue O_2 operation unless the supply pressure is ≥40 psig. This is done to prevent continuous cycling between alarms during the inspiratory phase and no alarm during the expiratory phases. If low flow O_2 is available it can be entrained through the Fresh Gas/Emergency Air Intake port using the optional O_2 reservoir. Maintain an acceptable SpO_2 by adjusting the O_2 supply up or down to increase or decrease the amount of O_2 delivered to the patient.

Mitigation/Info: Operation Switched to Compressor, Check O2 Supply Pressure, Check/Replace Regulator, Set FIO2 to 21%. Connect Low Flow O2, Monitor SpO2

***Replace/Service Ventilator ***

2030 Fresh Gas Intake Fault (Compressor Intake Blocked - Backup Available)

Alarm occurs when the Fresh Gas/Emergency Air Inlet is blocked so that the compressor is not able to deliver a breath within ±10% of the current settings and HP O_2 is available to support ventilation. When this occurs the ventilator immediately switches to HP O_2 powered ventilation. To clear the alarm first set the FIO_2 to 100% to acknowledge that the patient is being ventilated at 100%, clear the blockage and then set the FIO_2 back to the original value. If the blockage has been cleared operation with the compressor will restart. If the blockage cannot be cleared, the alarm will resound, continue ventilation with FIO_2 set to 100% and assure an adequate supply of HP O_2.

Mitigation/Info: Operation Switched to O2 Valve, Clear Blocked Intake, Set FIO2 to 100%, Monitor SpO2
***Replace/Service Ventilator ***

2053 Suspicious Triggers (False Trigger or Bad Baseline)

Alarm occurs when airway pressure sensor fails to calibrate during the expiratory phase of a breath. When this occurs the unit attempts to reestablish a baseline by momentarily setting PEEP to 0 cm H_20 and suspending triggered breaths. This interruption lasts no longer than 2 breath cycles. The operator should also check for leaks in the hose and tubes; patient airway and exhalation valve. If recalibration is successful the alarm will automatically cancel. If it cannot, the patient should be manually ventilated; the unit should be replaced and sent for service.
Mitigation/Info: Attempting Self Calibration, Momentarily Disabling Triggers and PEEP, Check Circuit For Leaks/Disconnects, Check Tube Placement/Cuff
Replace/Service Ventilator

2062 Exhalation System Fault (Gas Trapped)

Alarm occurs when the airway pressure (Paw) measured at the end of expiration is >5 cm H20 above the baseline pressure (PEEP pressure). This is typically caused by a restriction of the exhalation valve or an occlusion/kink in one or more of the breathing circuit tubes or hose. If the breathing circuit tubes appear to be intact the circuit should be replaced to eliminate the possibility of a bad exhalation valve. If the condition does not resolve the operator should manually ventilate the patient, replace the ventilator.
Mitigation/Info: Check Circuit for Kinked Hose/Tube, Check for Blocked Exhalation Valve, Replace Circuit, Replace/Service Ventilator
*** Manually Ventilate Patient***

2070 Airway Pressure High

Alarm occurs when the Paw is greater than the high airway pressure limit. When this occurs flow decelerates to maintain Paw at the high airway pressure limit for the duration of the breath (inspiratory time). The operator should check for kinks or blockage of the breathing circuit, exhalation valve or patient airway. In some instances the cause can be an accumulation of secretions in the airway which will require suctioning to clear. The operator should also assess if the patient is fighting the ventilator (dyssynchrony) or if the high airway pressure limit is set too low.
Mitigation/Info: Pressure Exceeds Limit Setting, Check Circuit for Kinked Hose/Tube, Check for Airway Obstruction, Suction Airway if Necessary, PIP Limit Set Too Low?
*** Manually Ventilate Patient***

2090 PEEP Leak

Alarm occurs when Paw drops below the PEEP setting by 2 cm H_20 during the expiratory phase of the breath. This can be caused by a leak in the breathing circuit, exhalation valve or patient airway. The operator should check the breathing circuit and exhalation valve to assure that all connections are tight. When the circuit appears damaged or is suspect it should be replaced. The operator should also check if there is a leak around the cuff of the patient's airway. If these mitigations do not resolve the alarm condition then, the ventilator should be replaced and sent for service.
Mitigation/Info: Check Patient Connection, Check Circuit For Loose Hose/Tube, Check Exhalation Valve, Check Tube Placement/Cuff
*** Replace Circuit***

2100 Patient Disconnect

Alarm occurs when the Paw fails to exceed the PEEP setting by ~7 cm H_2O. When this occurs the operator should quickly check the patient connection, breathing circuit connections and the exhalation valve. At times this alarm can be caused by the patient breathing with the ventilator during inspiration which prevents the Paw from passing the minimum pressure.

While resolving the alarm condition the operator should be sure to manually ventilate the patient.
Mitigation/Info: Check Patient Connection, Check Circuit for Loose Hose/Tube, Check Exhalation Valve, Patient Breathing With Ventilator?, Replace Circuit
Manually Ventilate Patient

2300 Pulse Ox Module Failed

Alarm occurs when the pulse oximeter module fails while in use. There is no operator intervention. When the alarm is active "-- --" will display in the HR and SpO2 windows. Pressing the Mute/Cancel button silences the audible alarm for 30 seconds. To resolve the alarm, remove the probe from the unit and turn off the pulse oximeter function. in the user menu.
Mitigation/Info: Internal Failure, SpO2/HR Not Available, Turn Off Pulse Ox
Replace/Service Ventilator

2301 Internal Comm Failed

Alarm occurs when the communication between the pulse oximeter module and unit fails. When this occurs the operator is required to turn off the pulse oximeter monitor to end the alarm condition. When this is done "off" appears in the data windows for SpO_2 and HR as those parameters are no longer available. When appropriate the operator should replace the ventilator and send it for service.
Mitigation/Info: Pulse Ox Module Failure, SpO2/HR Not Available, Turn Off Pulse Ox
Replace/Service Ventilator

2314 Pulse Ox Sensor Off Patient

Alarm occurs when an operating sensor losses the patient signal. The most common cause is when the sensor disconnects from the patient or is misaligned with the sensor site. This alarm can also be caused by poor perfusion at the sensor site which doesn't allow for a reading. In these cases try another site. Replace the sensor if another sensor is available. If the alarm condition cannot be resolved the operator should turn off pulse oximetry monitoring.
Mitigation/Info: Check Pulse Ox Sensor Site, Check Patient for Peripheral Pulse, Change Placement, Check Sensor Operation, Replace Sensor
Turn Off Pulse Ox Monitoring

2401 SpO2 Low

Alarm occurs whenever the SpO_2 value drops below the Low SpO_2 Limit. The default value for the limit is 94%. Corrective actions are increasing oxygenation by increasing the FIO_2 or PEEP settings. PEEP should only be changed based on consultation with the attending physician. When using low-flow O_2 the operator should increase the flow of O_2 into the optional low flow O_2 reservoir.
Mitigation/Info: SpO2 Below Limit, Increase FIO2, Check O2 Supply, Increase PEEP Per Physician
Consult Physician

2410 Heart Rate High

Alarm occurs when the heart rate is greater than the High Heart Rate Limit. The default value for the limit is 120 beats/minute. The operator should consult with the attending physician on how best to reduce the heart rate to an acceptable level.
Mitigation/Info: Heart Rate Above Limit
Consult Physician

2411 Heart Rate Low

Alarm occurs when the heart rate is less than the Low Heart Rate Limit. The default value for the limit is 40 beats/minute. The operator should consult with the attending physician on how best to increase the heart rate to an acceptable level.
Mitigation/Info: Heart Rate Below Limit

Consult Physician

2421 Input Protection Circuit Failed

Alarm occurs when there is a failure of the input protection circuit and the unit is able to operate. The alarm will continue until the unit is turned off. The operator can mute the alarm for 30 seconds by pushing the MUTE/CANCEL button. The operator should replace the unit and send it for service.

Mitigation/Info: Power System Needs Repair, Internal Battery Operation

Replace/Service Ventilator

2423 Power Circuit Hardware Fault

Alarm occurs when the internal power circuit has failed and external power is connected but cannot be used. The fault cannot be repaired by the operator. Pressing the Mute/Cancel button silences the audible alarm for 30 seconds.

Mitigation/Info: Power System Needs Repair, Internal Battery Operation

*** Replace/Service Ventilator***

2430 Low Battery (Low Battery - No Backup)

Alarm occurs when the unit detects that there is ≤5 minutes of battery operation remaining and external power is not connected. The operator should immediately seek a source of external power and/or plan to provide manual ventilation. Attaching external power will immediately clear the alarm though a low priority alarm will be maintained until the internal battery has recharged so that the unit can provide 30 minutes of operating time (~5 to 10 minutes).

Mitigation/Info: Less Than 5 Minutes Operation, Connect External Power, Assure Ability to Manually Ventilate

*** Replace/Service Ventilator***

2450 Battery Fault – No External Power Connected (Battery Nearly Too Hot for Discharge)

Alarm occurs when the battery temperature reaches 70 °C (158 °F) which is 5 °C from its maximum operating temperature using the internal battery and external power is not connected. When the battery temperature reaches 75 °C (167 °F) the battery will shut down to prevent failure and the unit will sound a high priority alarm and shutdown. If possible the operator should provide a source of external power which would allow operation to continue at the current and higher temperatures. In addition, the unit should be removed from the soft case which acts as insulation. Shading the patient and ventilator from direct sunlight may also help reduce the battery temperature.

Mitigation/Info: Battery Within 5 °C of High Limit, Remove Padded Case, Connect External Power, Assure Ability to Manually Ventilate, Shade Patient and Ventilator

Move To Cooler Location

2455 Battery Fault – No External Power Connected (Communication Failure)

Alarm occurs when the EMV is not able to communicate with the internal battery. When this occurs the device does not know the current charge in the batter and operation could stop at anytime. To continue operation and the operator should connect external power and assure the ability to manually ventilate the patient. When external power is connected the alarm priority decreases to Low Priority.

Mitigation/Info: Battery Comm Failure, Connect External Power, Assure Ability to Manually Ventilate Patient

Replace/Service Ventilator

3001 Compressor Fault (Compressor Control Fault – Backup Selected)

Alarm occurs when the compressor fails to operate or fails to provide the flow required to deliver a breath within ±10% of the current settings, HP O_2 is available to provide ventilation and the operator has set the FIO_2 to 100%. While operating in this state the operator should assure an adequate supply of HP O_2. Failure to maintain the HP O_2 supply will result in a high priority alarm.

***Mitigation**: Assure 55 psig O2, O2 Operation Only!*
Replace/Service Ventilator

3002 Compressor Fault (Compressor Signal Chain Fault – Backup Selected)

Alarm occurs when communication between the compressor controller and SPM is lost, HP O_2 is available to provide ventilation and the operator has set the FIO_2 to 100%. While operating in this state the operator should assure an adequate supply of HP O_2. Failure to maintain the HP O_2 supply will result in a high priority alarm.
***Mitigation**: Assure 55 psig O2 Supply, O2 Operation Only!*
Replace/Service Ventilator

3011 O2 Valve Fault (O2 Valve Fault – Backup Selected)

Alarm occurs when the signal to the O_2 valve is outside of the calibration range for the required flow rate, the compressor is available to provide ventilation and the operator has acknowledged that ventilation is being provided using the compressor by setting the FiO_2 to 21%. While operating in this state the operator should monitor the SpO_2 to assure that adequate oxygenation is maintained. If low flow O_2 is available it can be entrained through the Fresh Gas/Emergency Air Inlet port using the optional O_2 reservoir. Maintain an acceptable SpO_2 by adjusting the O_2 supply up or down to increase or decrease the amount of O_2 delivered to the patient.
Mitigation: Compressor Operation Only!, Keep FIO2 at 21%, Connect Low Flow O2, Monitor SpO2
Replace/Service Ventilator

3012 O2 Valve Fault (O2 Valve Signal Chain Fault – Backup Selected)

Alarm occurs when communication between the O_2 valve is lost, the compressor is available to provide ventilation and the operator has set the FIO_2 to 21%. While operating in this state the operator should monitor the SpO_2 to assure that adequate oxygenation is maintained. If low flow O_2 is available it can be entrained through the Fresh Gas/Emergency Air Inlet port using the optional O_2 reservoir. Maintain an acceptable SpO_2 by adjusting the O_2 supply up or down to increase or decrease the amount of O_2 delivered to the patient.
Mitigation/Info: Operation Switched to Compressor!, Keep FIO2 at 21%, Connect Low Flow O2, Monitor SpO2
Replace/Service Ventilator

3030 Fresh Gas Intake Fault (Compressor Intake Blocked - Backup Selected)

Alarm occurs when the Fresh Gas/Emergency Air Inlet is blocked so that the compressor is not able to deliver breaths within ±10% of the current settings, HP O_2 is available to support ventilation and the operator has set the FIO_2 to 100%. To clear the alarm, clear the blockage and set the FIO_2 back to the original value. If the blockage is cleared operation with the compressor will restart. If the blockage is not cleared, the alarm will resound, set the FIO_2 to 100%, continue ventilation and assure an adequate supply of HP O_2.
Mitigation/Info: O2 Valve Operation, Clear Blocked Intake & Retry Compressor, Keep FIO2 at 100%, Monitor SpO2
***Replace/Service Ventilator ***

3031 Fresh Gas Intake Fault (Compressor Intake Restricted)

Alarm occurs when the Fresh Gas/Emergency Air Inlet is blocked but is still capable of delivering breaths within ±10% of the current settings. This could be caused by an external blockage or a dirty external or internal filter (refer to instructions for changing the internal filter). If the blockage is cleared the alarm will automatically cancel.
Mitigation/Info: Clear Restricted Intake
***Replace/Service Ventilator ***

3032 Fresh Gas Intake Fault (Intake Pressure Signal Chain Failure)

Alarm occurs when communication between the Fresh Gas/Emergency Air Inlet pressure sensor has been lost. Normal operation can continue but, if the condition is not cleared by

powering off and restarting the unit should be sent for service. When used during this alarm condition the operator should be sure to keep the Fresh Gas/Emergency Air Inlet clear and assure that external filters are checked regularly.
Mitigation/Info: Intake Pressure Sensor Failure, Unable to Detect Filter Obstruction
***Replace/Service Ventilator ***

3041 O2 Supply Pressure High (O2 Tank Pressure High)

Alarm occurs when the O_2 supply pressure is ≥75 psig. The alarm automatically cancels when the supply pressure drops below 68 psig. Pressures above 80 psig could result in a catastrophic failure, harm to the patient and/or damage to the unit. The operator should seek to reduce the O_2 supply pressure, sometimes this requires replacing the regulator which is not functioning as required. If the pressure cannot be reduced and a low flow device like a flow meter is available the operator can provide supplemental O_2 via the optional low flow O_2 reservoir. If not, the operator should monitor the HP O_2 supply pressure and assure that the pressure does not rise further.
Mitigation/Info: Decrease O2 Supply Pressure, Replace Regulator, Connect Low Flow O2, Monitor SpO2
*** Monitor O2 Supply Pressure***

3110 RTC Battery Fault (RTC Battery Low)

Alarm occurs when the real-time clock (RTC) battery is < ~2.5 volts. The alarm condition is checked at start up and if this alarm occurs the unit is safe to operate but the operator should look to take the unit out of service when appropriate and send it for service. Changing the battery requires opening the unit and should only be done by a trained service technician. The RTC battery provides power for the storage of critical information used by the ventilator during startup.
Mitigation/Info: RTC Battery Low, Schedule Service Immediately
Replace/Service Ventilator

3120 Self Check Fault (Calibration Due)

Alarm occurs at start up when the preselected number of days has elapsed from the last calibration. When appropriate the unit should be sent for service. The low priority message serves as a reminder. Calibration is due every 365 days. Operators should schedule the unit for service as soon as possible.
Mitigation/Info: Calibration Due, Schedule Service Immediately
Replace/Service Ventilator

3130 Ambient Pressure Fault (Excessive Altitude Sensor Failure)

Alarm occurs when the ambient pressure transducer fails. When this occurs, the unit is no longer able to automatically compensate for changes in altitude especially in situations where the ambient pressure could change rapidly as during air transport. When used in these conditions the operator should monitor the airway pressure and reduce the tidal volume to maintain the airway pressure as altitude is increased. During descent, the tidal volume should be increased to maintain Paw if it was adjusted while at altitude. Operators should also monitor chest rise and breath sounds to assure adequate ventilation.
Mitigation/Info: Barometric Pressure Sensor, Altitude Compensation Disabled, Maintain Airway Pressure, Check Patient Chest Rise, Avoid Use At Varying Altitude
Replace/Service Ventilator

3131 Ambient Pressure Fault (Excessive Altitude)

Alarm occurs when the ambient pressure transducer detects an altitude >25,000 feet (7620 meters). Beyond this altitude compensation remains fixed at the 25,000 ft compensation level. The operator should monitor the Paw and reduce the tidal volume as altitude increases. During descent the tidal volume should be increased to its original value once the unit has returned to the compensated altitude. Where possible cabin pressure should be maintained in the compensated range.

Mitigation/Info: Excessive Altitude Detected, Beyond Altitude Compensation Limit, Maintain Airway Pressure, Check Patient Chest Rise, Monitor Ventilator/Patient
Reduce Altitude

3132 Ambient Pressure Fault (Excessive Altitude)

Alarm occurs when the ambient pressure transducer detects an altitude <-2,000 feet below sea level (610 meters, 15.8 psig or 1089 mb). This state can be caused by use in subterranean rescue operation or mistaken use in a hyperbaric chamber. Beyond this pressure level compensation remains fixed at the -2,000 ft level. NOTE: the EMV is not intended for use in hyperbaric chambers or at hyperbaric pressures.
Mitigation/Info: High Barometric Pressure Detected, Beyond Compensation Limit, Maintain Airway Pressure, Check Patient Chest Rise, Monitor Ventilator/Patient
Reduce Ambient Pressure

3140 Operational Temperature Fault

Alarm occurs when the ambient temperature exceeds the normal operating range (>131 °F, 55 °C) for the ventilator. The unit allows operation at these temperatures but alerts the operator to the condition. Operating above the specified range can affect the longevity of the internal battery and the duration of operating time. When operating at high temperatures the operator should remove the softcase which insulates and increases the ventilator's internal temperature.
Mitigation/Info: High Temperature Detected, Remove Padded Case,
Monitor Ventilator

3141 Operational Temperature Fault (Excessive Temperature Low)

Alarm occurs when the ambient temperature falls below the normal operating range (<14 °F, -10 °C) for the ventilator. The unit allows operation at these temperatures but alerts the operator to the condition. Operating below the specified range can affect the longevity of the internal battery and the duration of operating time. At extreme cold temperatures operating time can be significantly reduced. When operating at low temperatures the operator should use the softcase which insulates and increases the ventilator's internal temperature.
Mitigation/Info: Low Temperature Detected, Use Padded Case
Monitor Ventilator

3143 Self Check Fault

Alarm occurs when the failure of the internal temperature sensors. When this occurs the unit is not longer able to detect if it is operating outside of the allowable temperature range. If operating inside of the standard temperature range -25° C to 49° C (-13° F to 120° F) there is not affect on operation. If operating outside this range the operator should monitor the unit continuously. When appropriate the operator should replace the ventilator and send it for service.
Mitigation/Info: Temperature Sensor Fault, Temperature Changes Do Not Affect Autocal Cycle, Schedule Service Immediately
Replace/Service Ventilator

3300 Pulse Ox Module Failed

Alarm occurs when the pulse oximeter module fails and the operator has turned off pulse oximeter monitoring acknowledging the condition. When this is done "off" appears in the data windows for SpO_2 and HR as those parameters are no longer available. When appropriate the operator should replace the ventilator and send it for service.
Mitigation/Info: Internal Failure, SpO2/HR Not Available
Replace/Service Ventilator

3301 Internal Comm Failed (Comm Failure EMV-Pulse Ox - Monitor Not In Use)

Alarm occurs when the communication between the pulse oximeter module and unit fails and the operator has turned off pulse oximeter monitoring acknowledging the condition.

When this is done “off“ appears in the data windows for SpO_2 and HR as those parameters are no longer available. When appropriate the operator should replace the ventilator and send it for service.
Mitigation/Info: Pulse Ox Module Failure, SpO2/HR Not Available
Replace/Service Ventilator

3310 Pulse Ox Sensor Not Connected

Alarm occurs when the pulse oximeter detects that no SpO_2 sensor is connected after a period of successful operation. Note: during start up the unit automatically detects if a sensor is connected. If it is, the unit begins operation with the pulse oximeter active. If no sensor is detected the unit turns off this function. If the sensor is properly connected this failure can also be the result of a broken or defective sensor. If the alarm condition cannot be resolved the operator should remove the sensor and turn off pulse oximetry monitoring in the user menu.
Mitigation/Info: Check Pulse Ox Sensor, Check Sensor/Ventilator Connection, Reinsert Sensor, Cable/Sensor Damaged?, Replace Sensor
Turn Off Pulse Ox Monitoring

3311 Defective Pulse Ox Sensor (Defective Sensor)

Alarm occurs when the pulse oximeter cannot identify the connected sensor or the sensor has failed. Causes for this alarm include broken sensor cable, inoperative LEDs and/or faulty detector. If the alarm condition cannot be resolved the operator should turn off pulse oximetry monitoring.
Mitigation/Info: Check Pulse Ox Sensor, Check Sensor/Ventilator Connection, Reinsert Sensor, Cable/Sensor Damaged?, Replace Sensor
Turn Off Pulse Ox Monitoring

3312 Pulse Search (Pulse Search)

Alarm occurs when the pulse oximeter is searching for a pulse. If values are not displayed within 30 seconds disconnect and reconnect sensor and reapply to patient. If pulse search continues, remove sensor and replace on a better perfused site. Replace the sensor if another sensor is available. If the alarm condition cannot be resolved the operator should turn off pulse oximetry monitoring.
Mitigation/Info: Please Wait, Check Sensor Placement/Change Placement, *Minimize Patient Movement, Check Sensor Operation/Replace*
Turn Off Pulse Ox Monitoring

3313 Pulse Ox Signal Interference

Alarm occurs when an outside signal or energy source prevent accurate reading by the device. When this occurs the patient should be moved from the location or pulse oximeter turned off.
Mitigation/Info: External Signal Interfering With Measurement , Remove Patient From Location
Turn Off SpO2 Monitoring

3315 Pulse Ox Light Contamination

Alarm occurs when there is too much ambient light on the SpO_2 sensor or there is inadequate tissue covering the sensor detector. Most often this alarm condition can be resolved by shielding the sensor from ambient light.
Mitigation/Info: Too Much Ambient Light, Shield Sensor From Light, Change Sensor Placement, Check Sensor Operation, Replace Sensor
Turn Off Pulse Ox Monitoring

3316 Invalid Pulse Ox Sensor

Alarm occurs does when the pulse oximeter does not recognize the connected sensor. The alarm can also occur when there is a broken sensor cable, inoperative LEDs, a fault is detected and/or the sensor has failed. To resolve the alarm condition the sensor should be

replaced. If the alarm condition cannot be resolved the operator should turn off pulse oximetry monitoring.
Mitigation/Info: Replace Sensor
Turn Off Pulse Ox Monitoring

3317 **Low SpO2 Perfusion**
Alarm occurs whenever the amplitude of the arterial pulsation is weak. Low perfusion typically occurs in patients with poor circulation or when the sensor is applied to the same limb as the noninvasive blood pressure (NIBP) cuff. To resolve the alarm condition, move the sensor to a better perfused site or to another limb if the interference is from the NIBP cuff. *Mitigation/Info: Arterial Pulsation Weak, Check Sensor Placement, Change Sensor Placement, Check Sensor Operation*
Turn Off Pulse Ox Monitoring

3318 **Low SpO2 Perfusion**
Alarm occurs when the pulse oximeter determines the quality of the input signal is low due to excessive motion or artifact. To resolve the alarm minimize patient movement and make sure the sensor is properly applied.
Mitigation/Info: Signal Artifact, Minimize Patient Movement, Check Sensor Placement, Check Sensor Operation
Turn Off Pulse Ox Monitoring

3421 **External Power Fail/Disconnect**
Alarm occurs when the external power (either AC or DC) drops below minimum level (5 VDC as supplied by either the AC/DC Power Supply or a direct DC source) or power is intentionally disconnected. Since the unit is designed to operate with either external power or using its internal battery this is a low priority alarm that clears when the operator presses the MUTE/CANCEL button. Pressing the MUTE/CANCEL button is the operator's acknowledgement that the unit is operating on internal battery. If this alarm occurs and the operator believes that the unit is still connected to external power the operator should investigate the external power source.
Mitigation/Info: Internal Battery Operation, Check Power Connection/Supply, Monitor Battery Status
Replace/Service Ventilator

3422 **Missing Battery**
Alarm occurs when the internal battery has been removed or communication between the battery and CPU has failed. When external power is applied the unit is capable of operation however, loss of external power will result in loss of ventilation and a high priority alarm. Operating in this state should only be done when no other alternatives are available.
Mitigation/Info: No Battery Detected, DO NOT Remove External Power!, Maintain External Power
Replace/Service Ventilator

3423 **Battery Charge Circuit Failed**
Alarm occurs when battery charging circuit has failed and the unit is not able to charge the internal battery. The unit is able to operate using the remaining charge in the batter or with external power.
Mitigation/Info: Power System Needs Repair, Battery Cannot Charge, Maintain External Power!
Replace/Service Ventilator

3430 **Low Battery (Low Battery – Warning)**
Alarm occurs when the unit detects that there are ≤30 minutes of battery operation remaining and no external power is connected. The operator should seek a source of external power and/or plan to provide manual ventilation. Attaching external power will immediately clear the alarm to a low priority alarm and will be maintained until the internal

battery has recharged so that the unit can provide at least 30 minutes of operating time.
Mitigation/Info: Less Than 30 Minutes Operation, Connect External Power, Assure Ability to Manually Ventilate
*** Replace/Service Ventilator****

3431 Low Battery (Low Battery - With Backup)

Alarm occurs when operating with external power and the unit detects that there are ≤30 minutes of internal battery backup available. The unit is warning the operator that in the event of an external battery failure the unit ≤30 minutes of backup. (Note: the unit does not charge the internal battery when attached to an external battery.) To resolve the alarm condition the operator must attach the unit to a continuous external AC or DC source to recharge the internal battery. If this is not possible operation can continue as long as power is supplied by the external battery.
Mitigation/Info: Less Than 30 Minutes Internal Backup, Operating With External Power, Continue Charging With External Power, Assure Ability To Manually Ventilate
Replace/Service Ventilator*

3441 External Power Failed (External Power High)

Alarm occurs when the supplied DC power is >33 VDC. When this occurs the unit automatically switches to operation using the internal battery. If the supplied power drops to <30 VDC the unit automatically returns to operation using external power. If the external power source is known to be good then the AC/DC Power Supply may be faulty and need replacement.
Mitigation/Info: External Voltage Too High, Internal Battery Operation, Check/Replace Power Supply, Change Power Source
Replace/Service Ventilator*

3442 External Power Failed (External Power Low)

Alarm occurs when the supplied DC power is >5 and < 11.5 VDC. When this occurs the unit automatically switches to operation using the internal battery. If the DC supply returns to the normal range the unit automatically returns to operation using external power. If the external power source is known to be good then the AC/DC power supply may be faulty and need replacement.
Mitigation/Info: External Voltage Too Low, Internal Battery Operation, Check/Replace Power Supply, Change Power Source
Replace/Service Ventilator*

3444 External Power Failed

Alarm occurs when the voltage polarity is reversed when the unit is attached to an external DC source. When this occurs the unit automatically switches to operation using the internal battery. This condition is most likely caused by a faulty DC source. The operator should seek an alternate power source.
Mitigation/Info: DC Voltage Reversed, Internal Battery Operation, Disconnect Power Source
Replace Power Source

3450 Battery Fault – With External Power Connected (Battery Nearly Too Hot for Discharge)

Alarm occurs when the battery temperature reaches 70 °C (158 °F) which is 5 °C from its maximum operating temperature and external power is connected. When the battery temperature reaches 75 °C (167 °F) the battery will shut down to prevent failure. When this occurs the unit will continue operation using external power only. The unit should be removed from the soft case which acts as insulation. Shading the patient and ventilator from direct sunlight may also help reduce the battery temperature.
Mitigation/Info: Battery Within 5 °C of High Limit, Remove Padded Case, Continue External Power Operation, Shade Patient and Ventilator
Move To Cooler Location*

3451 Battery Fault – With External Power Connected (Battery Too Hot for Discharge)

Alarm occurs when the battery temperature reaches ≥75 °C (167 °F) and external power is connected. Discharging the battery beyond this temperature could destroy the battery and damage the unit. During the alarm condition the unit will continue operation using external power. The unit should be removed from the soft case which acts as insulation. Shading the patient and ventilator from direct sunlight may also help reduce the battery temperature.
Mitigation/Info: Battery Too Hot to Discharge, Do Not Remove External Power!, Remove Padded Case, Assure Ability to Manually Ventilate Patient, Shade Patient and Ventilator
Move To Cooler Location

3452 **Battery Fault (Battery Too Hot for Charging)**

Alarm occurs when the battery temperature is > 45°C (122 °F). Charging the battery above this temperature could destroy the battery and damage the unit. During the alarm condition the unit continues to operate using external power and if external power is lost the unit will operate using internal battery power. The unit should be removed from the soft case which acts as insulation. Shading the patient and ventilator from direct sunlight may also help reduce the battery temperature.
Mitigation/Info: Battery Too Hot To Charge, Remove Padded Case, Shade Patient and Ventilator
Move To Cooler Location

3453 **Battery Fault – With External Power Connected (Battery Too Cold For Charging)**

Alarm occurs when the battery temperature is ≤0 °C (32 °F). Charging the battery below this temperature could destroy the battery and damage the unit. During the alarm condition the unit continues to operate using external power and if external power is lost the unit will operate using internal battery power. The soft case should be used because it provides insulation.
Mitigation/Info: Battery Too Cold To Charge, Connect External Power, Use Padded Case
Move to Warmer Location

3455 **Battery Fault – With External Power Connected (Battery Communication Failure)**

Alarm occurs when the EMV is not able to communicate with the internal battery and external power is connected. To continue operation and the unit should remain connected external power.
Mitigation/Info: Battery Comm Failure, DO NOT Remove External Power!, Assure Ability to Manually Ventilate Patient
Replace/Service Ventilator

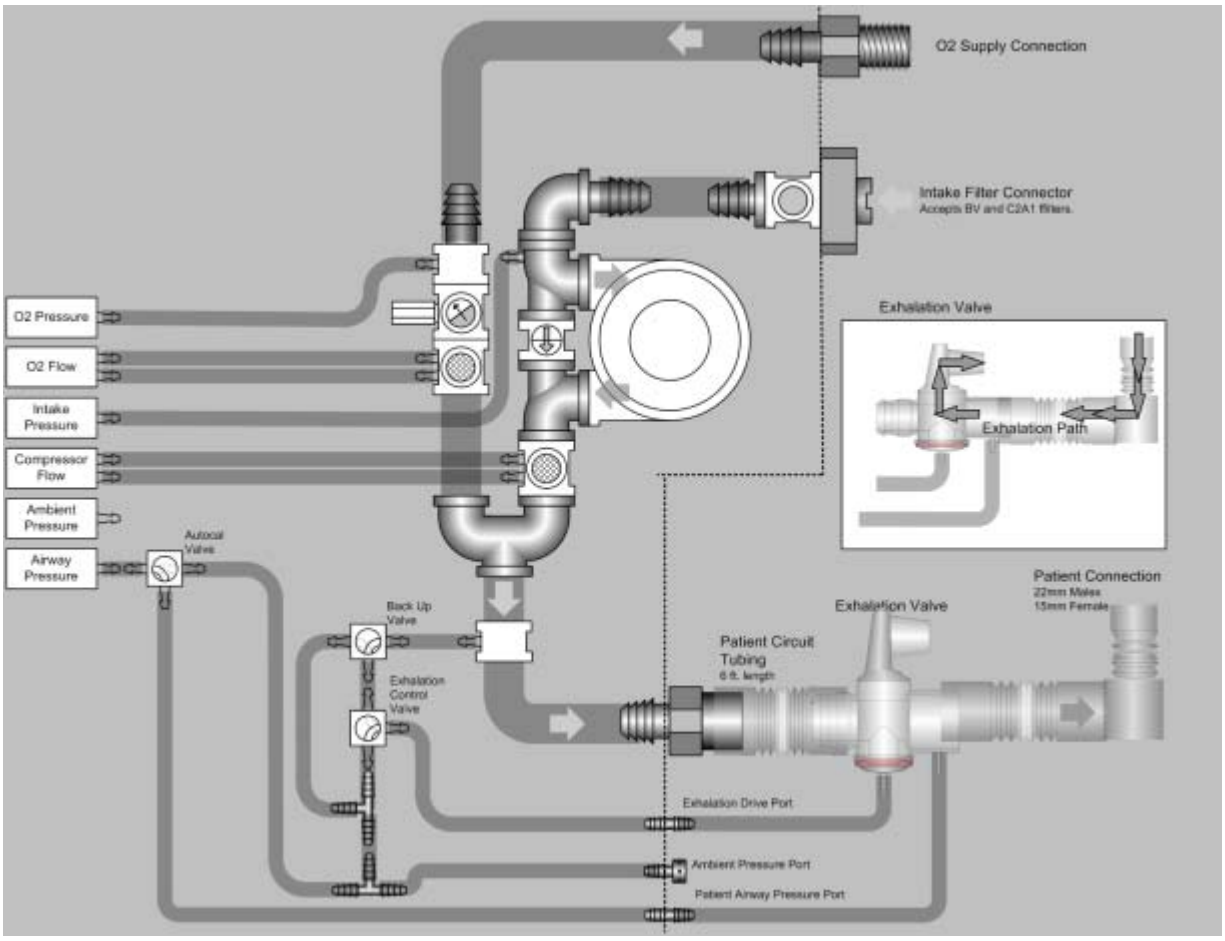
3470 **Internal Communication (Comm) Failure Fault – PIM Comm**

Alarm occurs when the EMV is not longer able to communicate with the Power Interface Module (PIM). When this occurs the operator should monitor operation continuously, seek to replace the ventilator as soon as possible and assure the ability to manually ventilate the patient.
Mitigation/Info: Power Management Failure, Assure Ability To Manually Ventilate Patient, Monitor Power Source
Replace/Service Ventilator

3480 **SPM Compatibility Fault**

Alarm occurs when the EMV software detects that it has not been calibrated with the SPM that is inside the unit. This fault occurs when the biomedical technician fails to recalibrate the unit following an SPM change or service. When this occurs the unit should be removed from use when appropriate and sent for service.
Mitigation/Info: Hardware Compatibility Failure, Update Calibration Records
*** Replace/Service Ventilator ***

APPENDIX 2: PNEUMATIC DIAGRAM



APPENDIX 3: PULSE OXIMETER PRINCIPLES AND SPECIFICATION

The Masimo SET® MS board pulse oximeter is based on three principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometer).
2. The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).
3. Arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse.

The Masimo SET MS board pulse oximeter as well as traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance (DC) at each of two wavelengths, 660 nm and 905 nm:

$$S(660) = AC(660)/DC(660)$$
$$S(905) = AC(905)/DC(905)$$

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

$$R = S(660)/S(905)$$

This value of R is used to find the saturation SpO_2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The Masimo SET MS board pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major component of noise during the pulse. The MS board decomposes S(660) and S(905) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

$$S(660) = S1 + N1$$
$$S(905) = S2 + N2$$
$$R = S1/S2$$

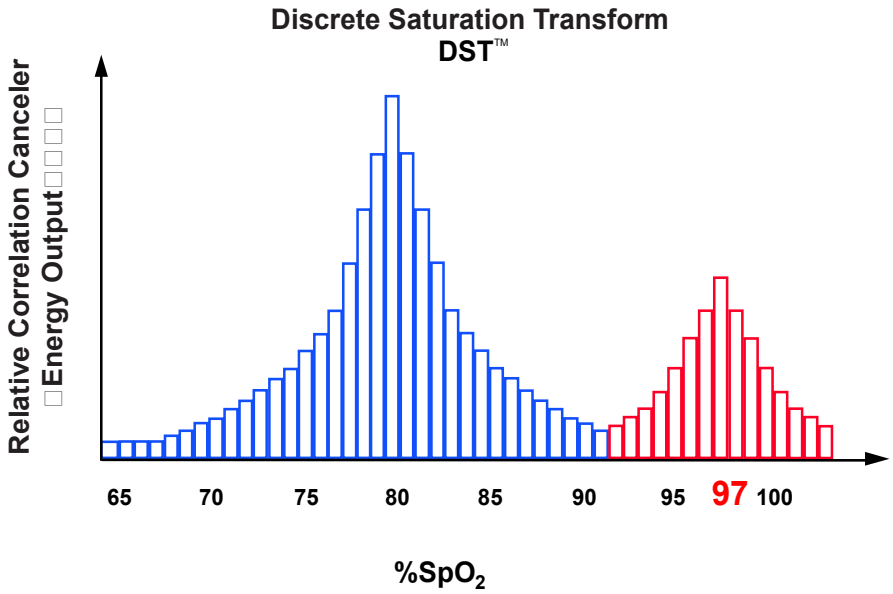
Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The above equations are combined and a noise reference (N') is determined:

$$N' = S(660) - S(905) \times R$$

If there is no noise N' = 0: then S(660) = S(905) x R which is the same relationship for the traditional pulse oximeter.

The equation for the noise reference is based on the value of R, the value being seeked to determine the SpO_2. The MS board software sweeps through possible values of R that correspond to SpO_2 values between 1% and 100% and generates an N' value for each of these R-values. The S(660) and S(905) signals are processed with each possible N' noise reference through an adaptive correlation canceler (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possible SpO_2 value as shown in the following figure where R corresponds to SpO_2 = 97%:



The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO_2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The MS board SpO_2 therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

Pulse Oximeter Specifications

Range

Saturation (% SpO_2)	1% - 100%
Pulse Rate (bpm)	25 – 240
Perfusion	0.02% - 20%

Accuracy

Saturation (% SpO_2) - During No Motion Conditions[1]

Adults, Pediatrics	70% - 100% ± 2 digits
	0% - 69% unspecified
Neonates	70% - 100% ± 3 digits
	0% - 69% unspecified

Saturation (% SpO_2) - During Motion Conditions[2,3]

Adults, Pediatrics[2]	70% - 100% ± 3 digits
	0% - 69% unspecified
Neonates[3]	70% - 100% ± 3 digits
	0% - 69% unspecified

Pulse Rate (bpm) - During No Motion Conditions[1]

Adults, Pediatric, Neonates 25 to 240 ± 3 digits

Pulse Rate (bpm) - During Motion Conditions[2,3]

Adults, Pediatric, Neonates 25 to 240 ± 5 digits

Resolution

Saturation (% SpO_2)	1%
Pulse Rate (bpm)	1

Low Perfusion Performance[4]

> 0.02% Pulse Amplitude Saturation (% SpO_2) ± 2 digits
and % Transmission > 5% Pulse Rate ± 3 digits

Interfering Substances

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

APPENDIX 4: INTERNAL BATTERY CHANGE/INSERTION

Tools needed:

Phillips Head Screwdriver

Warning:

Before attempting to replace the battery pack make sure that external power is disconnected and the EMV Power Switch is set to "OFF".

Procedure:

Remove the four (4) 6-32 x 5/16 Phillips Pan Head screws located at the bottom of the EMV. This will release the Battery Pack Compartment Cover and expose the Battery Pack and its integral mounting bracket.

Remove the four (4) 6-32 x 2 ¼ Phillips Pan Head screws that hold the Battery Pack and its integral mounting bracket to the EMV Lower Case.

The EMV Battery Pack is wired to a mating plug-and-socket connector that remains electrically-attached to the EMV. This mating connector includes a locking latch.

While holding the Battery Pack in one hand, pinch the connector plug locking latch while pulling outward. This will release the plug from its mating socket and free the entire Battery Pack.

Replace the old Battery Pack with one that is new. Dispose of the old Battery Pack in accordance with instructions contained at the end of this procedure.

Align the plug then insert into its mating socket. The plug and socket are "keyed" to protect against misconnection.

Momentarily turn the EMV Power Switch to its "ON" position to confirm operating power. A Disconnect Alarm will sound.

Turn the EMV Power Switch to its "OFF" position.

Secure the Battery Pack with its integral mounting bracket to the EMV Lower Case using the four (4) 6-32 x 2 ¼ Phillips Pan Head screws. **Warning:** Make sure that none of the Battery Pack wires get pinched between the bracket and case enclosure.

Align the Battery Pack Compartment Cover and secure it with the four (4) 6-32 x 5/16 Phillips Pan Head screws.

Momentarily turn the EMV Power Switch to its "ON" position to confirm operating power. A Disconnect Alarm will sound. Verify the charge status of the new Battery Pack. Turn the EMV Power Switch to its "OFF" position. If required place the EMV on charge.

APPENDIX 5: INTERNAL FILTER CHANGE/INSERTION

Tools needed:

Hemostat or tweezers
Phillips Head Screwdriver

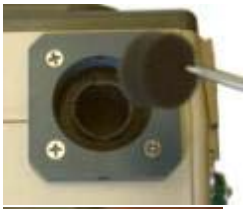
Warning:

Before attempting to replace filters make sure that external power is disconnected and the EMV Power Switch is set to "OFF".

Procedures:

Foam Filter:

The Foam Filter is located inside the Compressor Inlet Fitting.



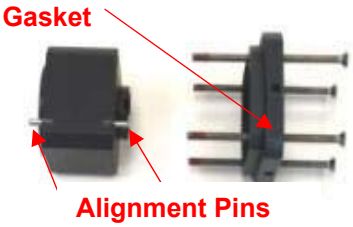
Carefully remove the Foam Filter using a hemostat or tweezers.

Do Not reuse or attempt to clean the old filter.

Replace the Foam Filter with a new filter. Lightly tap the new filter into place. The top of the filter should reside approximately ¾ to 7/8" below the height of the 22 mm female connector that is part of the Compressor Inlet Fitting.

Disk Filter:

Remove the four (4) 8-32 x 3 Phillips Flat Head screws that secure the Compressor Inlet Fitting Assembly to the SPM Chassis.

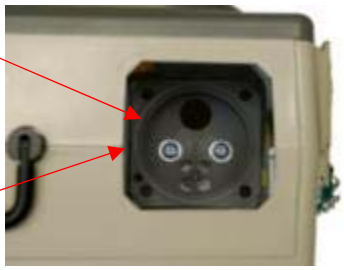


Lift the two (2) segments of the Compressor Inlet Fitting Assembly away from the EMV. If the two segments come apart, **do not** lose the gasket that seats between the parts.

The Disk Filter is now exposed. **Do Not** remove the filter at this time.

Examine the surface of the Disk Filter. **Do Not** replace the Disk Filter if it isn't discolored. If the Disk Filter is discolored, replacement is necessary.

Remove the Disk Filter using the hemostat or tweezers and replace it with a new, clean filter. Make sure that the filter sits flat on the shoulder in its recessed area.



Set the lower segment of the Compressor Inlet Fitting Assembly into the EMV making sure that its alignment pin mates.

Set the upper segment of the Compressor Inlet Fitting Assembly into the lower segment making sure that its alignment pin mates.

Secure the Compressor Inlet Fitting Assembly to the SPM Chassis by equally tightening each of the four (4) 8-32 x 3 Phillips Flat Head screws.

Momentarily turn the EMV Power Switch to its "ON" position to confirm operating power.

A Disconnect Alarm will sound.

Turn the EMV Power Switch to its "OFF" position.

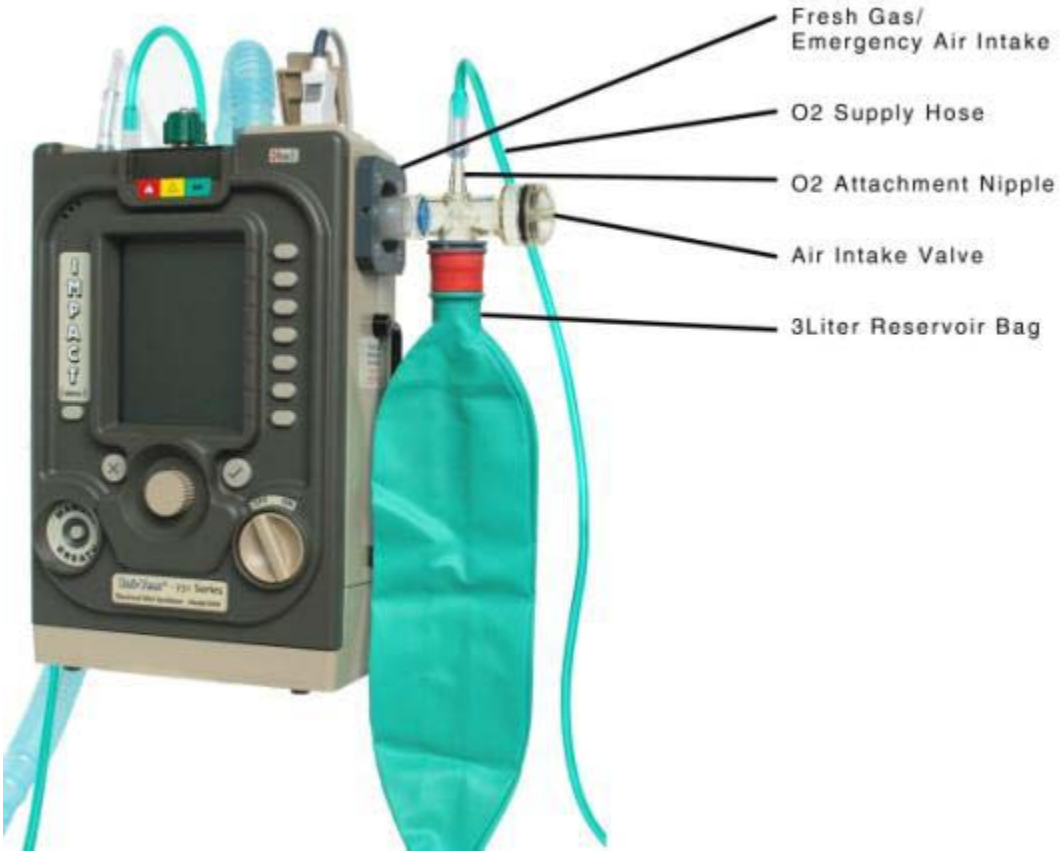
APPENDIX 6: USE OF LOW FLOW OXYGEN

Introduction

The EMV can use O_2 from low flow sources, O_2 flow meters and O_2 concentrators, to provide supplemental O_2 to patients. To do this, O_2 is entrained through the Fresh Gas/Emergency Air Intake when the EMV's internal compressor cycles to deliver a breath. In order to assure efficient O_2 delivery, Impact recommends that the operator use the Oxygen Reservoir Bag Assembly (Part # 704-0004-00). The assembly performs a number of functions: 1) it acts a reservoir collecting O_2 during the expiratory phase of ventilation, 2) provides interface to the ventilator and the attachment of the low-flow O_2 supply hose, and 3) provides an inlet for air in the event the low-flow O_2 supply fails or the tidal volume is greater than the supplied O_2.

Procedure

1. Press the Menu button and use the encoder to select O2 Reservoir "On". This tells the EMV that the reservoir is attached and prevents the Fresh Gas Intake Restricted alarm.
2. Attach the O_2 supply hose to the nipple on the reservoir assembly (see figure below).
3. Attach the O_2 Reservoir Bag Assembly to the Fresh Gas/Emergency Air Intake as shown.
    a. **Note!** The assembly will function when the reservoir bag is hanging down or lying horizontally provided the bag does not fall in such a way that occludes the neck of the bag.
    b. **Note!** The ventilator will sound a Low Priority "Fresh Gas Intake Restricted" alarm if the menu has not been changed (see #1 above). Operating with the alarm active does not affect the ability of the ventilator to deliver breaths at the current settings. It is to alert the user that a restriction has been detected at the inlet.
4. Adjust the O_2 flow to achieve an acceptable O_2 saturation.
    a. **Note!** Always allow 5 to 10 minutes between adjustments to assure the patient oxygenation has stabilized. This is very important when decreasing the O_2 supply where it may take several minutes for a patient to stabilize at the new O_2 flow.
    b. **Note!** Never use O2 flows >10-12 liters/min. Flows greater than this can cause the baseline pressure to drift.



Operating Notes

1. **Note!** When the reservoir is removed be sure that the 22 mm adapter is removed with the assembly.
2. Due to the slight difference between the densities of air and O_2 the tidal volume will decrease slightly as O_2 is entrained. The worst case is a <10% decrease in tidal volume when the entrained O_2 results in an FIO_2 of 100%. The tables below show both affect on tidal volume and the resultant FIO2 for various O_2 supply rates:

	AC 12, Vt 700, PEEP 5, I:E 1:2.5								
O2 Flow	0	1	2	3	4	5	6	7	8
FIO2	21	30	38	48	57	70	80	89	100
Vt(set)	740	732	725	718	711	703	691	689	682
Vt(actual)	700	692	685	678	671	663	651	649	642
% Chg	0	-1.1	-2.1	-3.1	-4.1	-5.3	-7.0	-7.3	-8.3

	AC 12, Vt 500, PEEP 5, I:E 1:2.5						
O2 Flow	0	1	2	3	4	5	6
FIO2	21	30	43	56	69	89	100
Vt(set)	527	523	514	506	502	493	486
Vt(actual)	500	496	487	479	475	466	459
% Chg	0	-0.8	-2.6	-4.2	-5.0	-6.8	-8.2

	AC 18, Vt 300, PEEP 5, I:E 1:2.5						
O2 Flow	0	1	2	3	4	5	6
FIO2	21	32	47	62	76	96	100
Vt(set)	312	307	303	299	298	291	287
Vt(actual)	300	295	291	287	286	279	275
% Chg	0	-1.7	-3.0	-4.3	-4.7	-7.0	-8.3

APPENDIX 7: SILENT DARK MODE

Introduction

Under normal operating conditions the audible and visual alarms are used to alert the operator to potential problems with the patient or ventilator. There are, however, occasions where the audible and visual alarms could present a hazard to both the patient and operator by alerting others to their presence. In these situations the EMV is able to operate in SILENT/DARK mode whereby the audible alarm is suppressed; the LCD, CONFIRM/SELECT and MUTE/CANCEL backlights are suppressed and the alarm LED indicator emits only infrared (IR) light. When operating in this mode the LCD remains viewable by transflecting visible light or with night vision glasses (NVG) equipment under dark conditions. The NVG equipment used in this mode of operation must be capable of detecting IR light in order to enable the operator to detect alarm conditions.

WARNING! Never use SILENT/DARK mode without the appropriate NVG equipment and always assure that the NVG equipment is capable of detecting the IR alarms prior to commencing operation.

Operating Procedure

1. Press both the MENU and MANUAL BREATH buttons while turning the device on. This configures the device to start with no visible light and no audible alarms. The device will display "Silent/Dark Mode Enabled. Press Accept Key to Enter Silent/Dark Mode Now". Starting the device in this way enables Silent/Dark mode for the duration of the power cycle (turning the unit off cancels Silent/Dark Mode; it must be enabled again the next time the unit is turned on).
    a. Pressing CONFIRM/SELECT while the message is displayed continues operation in Silent/Dark Mode.
    b. Pressing MUTE/CANCEL enables the audible and visible alarms and the LCD backlight. In addition, Silent/Dark Mode is added to the MENU so that the operator can enter Silent/Dark Mode at a later time for the duration of the current power cycle.
2. When ventilating in Silent/Dark Mode the operator should be extremely diligent in monitoring the patient and device.
3. To end Silent/Dark Mode operation press MENU, select Silent/Dark Mode, then select OFF, followed by CONFIRM/SELECT.
    a. Silent/Dark Mode can be reentered provided the device has not been turned off.
4. When a High priority alarm is detected the IR LED blinks at 2 Hz.
    a. Pressing the MUTE/CANCEL button does not affect the IR LED blink rate.
    b. The operator should begin manual ventilation immediately.
5. When a Low or Medium priority alarm is detected the IR LED blinks at 1 Hz.
    a. The IR LED continues to blink while medium priority alarms are active. Pressing MUTE/CANCEL results in the IR LEF being lit continuously for the 30 seconds.
    b. The IR LED blinks when a Low Priority alarm is detected. Pressing the MUTE/CANCEL button stops the blinking, leaving only the persistent message.

APPENDIX 8: RECHARGING GUIDELINES:

1. Do not store the ventilator at 100% battery charge in a high temperature environment (~40˚C and above) for long periods. Doing this may affect the useable life of the battery.

2. When charging in the storage case, be advised that the battery may stop charging if ambient temperature is above 40˚C. Under these conditions, battery temperature can get as high as 10˚C above ambient. When the ambient temperature drops the unit will automatically reinitiate charging.

Figure 1: EMV Storage Case

CAUTION! DO NOT apply external power to the ventilator for extended periods in a high temperature environment (~35˚C and above). Even when the unit is not charging the AC supply heats up both the ventilator (up to 15˚C above ambient) and it's power supply (up to 30˚C above ambient).