# Operation Manual

731 Series Electrical Mini Ventilator (EMV+)

Uni-Vent®

Impact P/N 906-EMVP-02
Revision 6.0
Impact Instrumentation, Inc.   27 Fairfield Place   West Caldwell, New Jersey   07006

PS
c   PS
Certified

SGS
US

CE
0470

Oxygen Inlet

Status Indicator LED Array

External Power Input Connector

Pulse Oximeter Connector

USB Connector

Compressor Inlet Fitting

Alarm Message Center

LCD Display

Control Panel

Battery Compartment

O2 Supply Pressure Low
- Operation Switched to Compressor
- Check O2 Supply Pressure
- Check/Replace Regulator
- Set FIO2 to 21%
- Connect Low Flow O2
- Monitor SpO2
Replace/Service Ventilator

#2020

HR ♥ 62 120 40

SpO2 82 80

FiO2 O2 USE 1.2 100

PIP 15 20
PEEP 0 10

Vt(del) 272 410 0

BPM I:E 1:2.5 15 25 8

Vmin 4.0   MAP 8.8   BPMt 15   TI 1.14

Mode AC (P) IV

0   50   100

EMV+ MAIN FEATURES: FIGURE 1

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CONVENTIONS, TERMINOLOGY AND ABBREVIATIONS
CONVENTIONS

WARNING!

A WARNING statement identifies conditions or information that could have an adverse effect upon the patient or operator which if not avoided, could result in death or serious injury.

CAUTION!

A CAUTION statement provides important information about a potentially hazardous situation which if not avoided may result in minor or moderate injury to the patient, operator or damage to the equipment or other property.

NOTE:

A NOTE provides additional information intended to avoid inconvenience during operation.

ABBREVIATIONS

A/C- Assist/Control

ACLS- Advanced Cardiac Life Support

ALS- Advanced Life Support

ATLS- Advanced Trauma Life Support

ACV- Assist-Control Ventilation

ATPD - Atmospheric Temperature and Pressure, Dry

BPM - Breaths per Minute

B/V - Bacterial/Viral Filter

cm H$_2$O - Centimeters of Water

CPR - Cardiopulmonary Resuscitation

DISS - Diameter Index Safety System

FIO$_2$ - Fraction of Inspired Oxygen

HME - Heat and Moisture Exchanger

HME/BV - Heat and Moisture Exchanger/Bacterial Viral filter combined

Hz – Hertz (as in frequency, cycles per second)

ID - Internal Diameter

L - Liters

LED - Light Emitting Diode

LPM - Liters per Minute

ml - Milliliters

mm - Millimeter

NPPV – Noninvasive Positive Pressure Ventilation

O$_2$ - Oxygen

P$_{aw}$ - Airway Pressure

PEEP - Positive End Expiratory Pressure

PIP - Peak Inspiratory Pressure

psig - Pounds per Square Inch Gage

USP - United States Pharmacopeia

VAC - Volts AC

VDC - Volts DC

V$_T$ - Tidal Volume

WOB – Work of Breathing

INTENDED USE

The Model 731EMV+ (EMV+) is indicated for use in the management of infant through adult patients weighing ≥5 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

- Portable critical care ventilator that can be used in the hospital, aeromedical and ground transport, mass casualty situations and extreme environments

- Multiple modes of ventilation for use with acute or chronic respiratory failure in both intubated and nonintubated patients.

- Intuitive operator interface minimizes operator training and protects existing settings from inadvertent contact and manipulation.

- Lightweight (9.7 lbs, 4.4 kg) provides for easy transport

- Rechargeable battery provides over 10 hours of operation (at factory default settings with pulse oximeter operating).

- Operating temperature range from -25° to 49°C (Impact Instrumentation validated testing) and from 10° to 40°C (SGS listed).

- Altitude compensation from -2000 to 25,000 feet

- Self-contained system that operates with or without external O_2.

- Gas manifold design allows operation with both high and low-pressure O_2 sources. . All O2 is delivered to the patient circuit, none vented or wasted to operate the device.

- Sealed gas path with chemical/biological filter connected to assure safe breathing gas supply.

- Sealed case and control panel protects components from weather and fluids.

SHIPPING CONTENTS

> **NOTE:** Shipping contents may be different for military and government customers based on contract specifications. Please refer to the packing slip enclosed with your unit.

ACCESSORIES LIST

The Accessories List contains common items, required from time to time, some of which 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 or through your local distributor. When ordering, please include the part number, description and quantity required.

Send purchase orders to:
Impact Instrumentation, Inc.
P.O. Box 508   Telephone orders: 973/882-1212
West Caldwell, New Jersey 07007-0508   Fax orders: 973/882-4993

Email:
Government   Non-Government
govsales@impactii.com   sales@impactii.com

PART NUMBER	PART DESCRIPTION
024-0012-00	AC/DC Power Supply, 110-240 VAC, 100Watts 24 Volts 4.2A, IEC320 Plug
708-0042-00	AC Power line cord, 6', (United States Version)
402-0032-00	Padded carry case, tan, material
465-0024-00	Filter, Bacterial/Viral (B/V)
465-0025-00	Filter, HME/ B/V, Heat and Moisture Exchanger
465-0027-00	Filter, Disk, B/V, Emergency Air Intake
465-0028-00	Removable foam compressor inlet filter
820-0108-00	Heat and Moisture Exchange (HME), Adult
820-0109-00	Heat and Moisture Exchange (HME), Pediatric
820-0110-00	Heat and Moisture Exchange (HME), Infant
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
708-0036-00	Pulse Oximeter Probe Sensor, Adult Reusable
708-0043-00	Pulse Oximeter Pediatric, Reusable
708-0037-00	Pulse Oximeter Patient Cable, Reusable
708-0039-00	Pulse Oximeter Adult - Ear, Reusable
708-0047-00	Pulse Oximeter Infant, Single Patient Use
820-0106-00	Circuit, Vent, Single Limb, Pediatric/Adult (disposable)
820-0106-15	Circuit, Vent, Single Limb, Pediatric/Adult (disposable) (case of 15)
820-0107-00	Circuit, Vent, Single Limb, Infant/Pediatric (disposable)
820-0107-20	Circuit, Vent, Single Limb, Infant/Pediatric (disposable) (case of 20)
825-0002-00	High pressure Oxygen Hose, DISS x DISS, oxygen, 6'
907-EMVP-01	Quick Reference Guide, laminated
906-EMVP-02	Operation Manual (Commercial)
909-EMVP-02	CD format Operation Manual (Commercial)
703-0731-03	Carry-all Case with Foam Inserts, Rechargeable
703-0731-11	Assembly, Case, Transit Carry
703-0731-12	Assembly, Case, Transit Carry, w/ AC Bulkhead Connector
703-0731-13	Assembly, Case, Transit Carry, w/ AC Bulkhead & USB Connectors
703-0731-14	Assembly, Case, Transit Carry, w/ Wheels & Pull-Out Handle

PART NUMBER	PART DESCRIPTION
703-0731-15	Assembly, Case, Transit Carry, w/ Wheels & Pull-Out Handle, AC Bulkhead Connector
703-0731-16	Assembly, Case, Transit Carry, w/ Wheels & Pull-Out Handle, AC Bulkhead & USB Connectors
703-0731-01	Assembly, Battery Pack, Lithium-Ion, 6.6 Ah
704-0EMV-XX	Extension Cord 8' US Hospital Grade Female Plug to ***
708-0041-XX	Cordset, 6', IEC 60320-C5 Plug to ***
704-0700-01	Check Valve Kit
812-0011-00	Mask, CPAP, #6, Large Adult
812-0010-00	Mask, CPAP, #5, Adult
812-0009-00	Mask, CPAP, #4, Child
812-0008-00	Mask, CPAP, #3, Small Child
812-0007-00	Mask, CPAP, #2, Infant
812-0006-00	Mask, CPAP, #1, Small Infant
334-0125-00	Harness, Mask, Universal

*** Country Specific (Contact factory for complete part # for each country)

LIMITED COPYRIGHT RELEASE

MASIMO PULSE OXIMETER

This device uses Masimo SET® technology to provide continuous pulse oximeter and heart rate monitoring 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.

QNET BV
Hommerterweg 286
6436 AM Amstenrade
The Netherlands

Manufactured by:
IMPACT Instrumentation Inc.
27 Fairfield Place, West Caldwell, NJ 07006, U.S.A
P.O Box 508, West Caldwell, NJ 07007-0508, U.S.A

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 device 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! During operation the EMV+ unit should not be stacked on top of or under other medical equipment due to the possibility of electromagnetic interference between the EMV+ and other equipment. (The EMV+ was subjected to EMC testing in accordance with Military Mil-STD-461F and Commercial IEC 60601-1-2 and FDA Reviewers Guidance specifications.)
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! The EMV+ must be connected to a grounded AC power supply when connected to AC power. The EMV+ and its integrated pulse oximeter are referred to as an IEC 601/F device in the summary situation table contained in IEC-601-1-1.
WARNING! USB Interconnection: Do not operate the device on a patient when the USB is connected to any other device.
NOTE: The USB interconnection does not support automatic record keeping.
WARNING! The Impact supplied ventilator circuit's labeling provides the resistance and compliance values for the circuits under normal operating conditions. If added accessories are used (e.g. humidification, filters etc.), the operator should assure they do not degrade the performance of the device. If non-Impact circuits are used, the operator should assure these circuits do not affect the performance of the device.
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.
CAUTION! Internal components are susceptible to damage from static discharge. Do not remove device covers. ESD

NOTE: This Operation Manual is not meant to supersede any controlling standard operating procedure regarding the safe use of assisted ventilation.
NOTE: Follow all governing regulations regarding the disposal of any part of this medical device.
NOTE: Follow all governing regulations regarding the handling of materials contaminated by body fluids.
NOTE: Follow all governing regulations regarding shipment of the Li batteries.

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 LNCS® 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 LNCS® 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 LNCS® sensors. Do not use an LNCS® 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 LNCS® 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.

CAUTION! 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 the scope of one or more of the patents relating to this device. Impact cannot assure the proper functioning of this device if it is used with unauthorized sensors or cables.

SYMBOLS AND ICONS
(Used with the EMV+ and this manual)

Off	O	
On	I	
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	O₂	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
Do Not Re-Use	②⃠	This item should not be re-used
Do Not Discard	⌦	Follow all governing regulations regarding the disposal of any part of this medical device.
Serial Number	SN	Numbers following "SN" indicates serial number
BF symbol	🧍	Protection against electric shock, Type B with floating (F-type) parts
Head w/ Mask	😷	The unit is in Non-invasive Positive Pressure Ventilation (NPPV) mode
Pleth	〜	screen will show Pleth and Pressure/Time plots instead of alarm

UNPACKING, ASSEMBLY AND CONNECTIONS

UNPACKING

Compare shipping case contents against Shipping Contents list. Examine the device and accessories 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.   (See Appendix 4 for Battery Installation.)

CONNECTIONS

OXYGEN INPUT – connects the unit to the output of an appropriate O_2 regulator attached to a medical-grade (USP) O_2 cylinder. 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 (see Figure 2). A green (white for some installations), 6 foot long high-pressure oxygen hose with compatible fittings that provides for connection between the unit and the O_2 source is required. (Also see Harsh Environment Operation section).

> **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 2).

FRESH GAS/EMERGENCY AIR INTAKE – allows ambient air into the EMV+'s internal compressor. The port also functions as the internal anti-asphyxia 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 (see Figure 2).

TRANSDUCER (Patient Airway Pressure) – connects to the ventilator circuit 3/16" ID transducer tubing. The barb-type connector is colored a green/blue to distinguish it from the other connectors (see Figure 2).

> **NOTE:** The 3/16" ID ventilator circuit transducer tubing is a green/blue (darker) 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 (see Figure 2).

> **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 available as accessories) or the external battery (see Figure 2).

HIGH PRESSURE OXYGEN INPUT
GAS OUTPUT
EXTERNAL POWER INPUT
USB CONNECTOR
TRANSDUCER (PATIENT AIRWAY PRESSURE)
PULSE OXIMETER CONNECTOR
EXHALATION VALVE
FRESH GAS/EMERGENCY AIR INTAKE
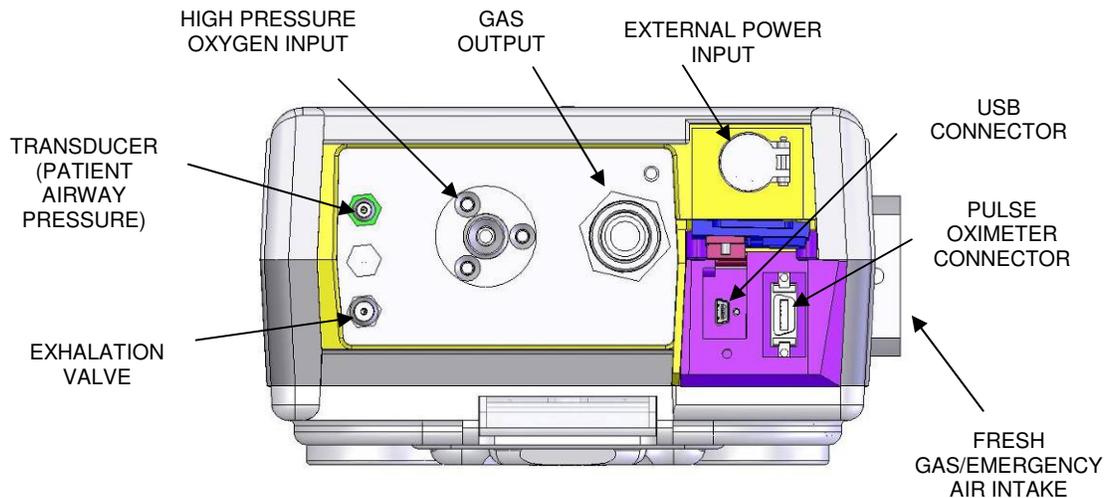
CONNECTOR PANEL: FIGURE 2

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 (white for some installations) high-pressure O_2 hose to the OXYGEN IN fitting and a 55 psig external source.

NOTE: Use only with medical-grade (USP) oxygen. When using with an oxygen cylinder, the cylinder must be secured.

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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. (See section on Hazardous Environment Filters.)
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). (See section on Hazardous Environment Filters.)
5. For use with AC power: connect the AC/DC Power Supply (supplied) to the External Power Input (see Figure 2).

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.

WARNING! This unit's USB connection (unlabelled) does not provide any signal output or input to the Operator. It is for the use of Impact Instrumentation trained personnel only. The Operator should not connect anything to the USB connection.

The EMV+ can operate using high-pressure O_2 from either bottled O_2 or piped O_2 sources, as illustrated in Figure 3.

External Gas Sources

Bottled Oxygen
Regulated
55 psig
(3.8 bar) Output

OXYGEN

-OR-

OXYGEN
O_2

55 psig
(3.8 bar) Output

OXYGEN
High Pressure Hose
D.I.S.S. X D.I.S.S.

AC/DC POWER CONVERTER

12 VDC POWER CABLE

24 VDC POWER CABLE

Low O_2 / O_2 concentrator

To Fresh Gas/ Emergency Air Intake

See Appendix for additional instructions on Low Flow O_2
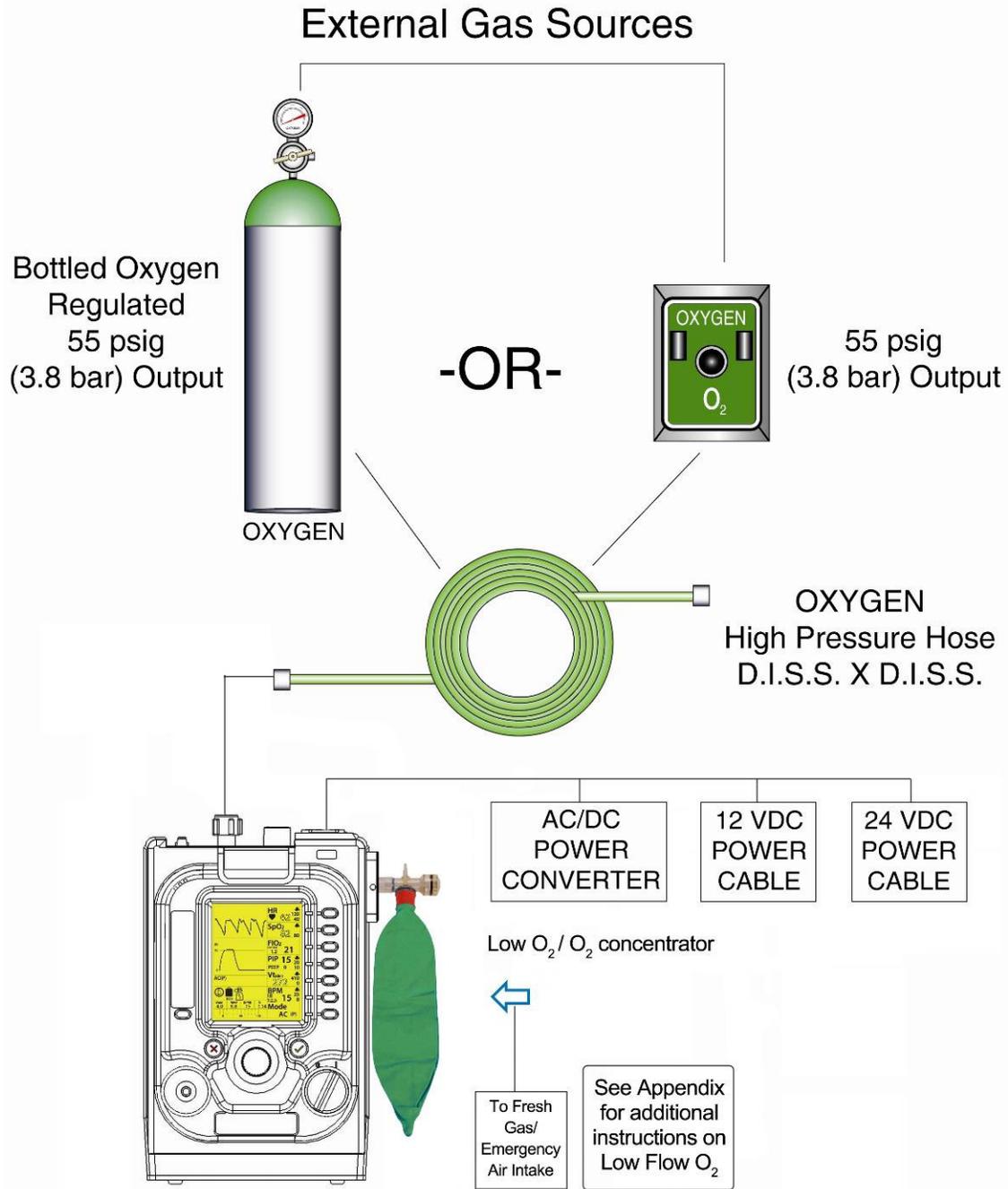
EXTERNAL GAS SOURCES: FIGURE 3

The duration of any given gas cylinder depends on the size & pressure of the cylinder, and the rate at which gas is being used to support the patient.   The formula to calculate the operating duration of any cylinder (based on the Ideal Gas Law) is given below. An example is worked out for a typical large cylinder. It is recommended that the gas cylinder pressure not be allowed to fall below 300 psi.

V_{start} = 9540 liter at 1 atm/ 70° F (21° C) : from label on cylinder

P_{start} = 2640 psig : from label on cylinder

$P_{present\ in\ cylinder}$ = 300 psig : from pressure gauge on cylinder

$V_{present\ in\ cylinder}$ = volume remaining in cylinder = ($P_{present}$/ P_{start}) V_{start} = 1084 liter at 1 atm/ 70° F (21° C)

$V_{delivered}$ = 9540 – 1084 = 8456 liter at 1 atm/ 70° F (21° C)

For a typical ventilator setting (20 BPM, Vt = 500 ml, FIO_2 =100%, I time = 1 sec, I:E = 1:2.0), the gas consumption is 10 liter/min.

NOTE: Whenever external high-pressure O_2 is used, the EMV+ automatically determines the O_2 usage and displays it in the FIO_2 parameter window. (See O_2 Use under FIO_2 in Description of Controls and Display.

Total duration of the gas cylinder in above example = $V_{delivered}$/ (10 liter/min) = 8456/10 min = ~14 hours
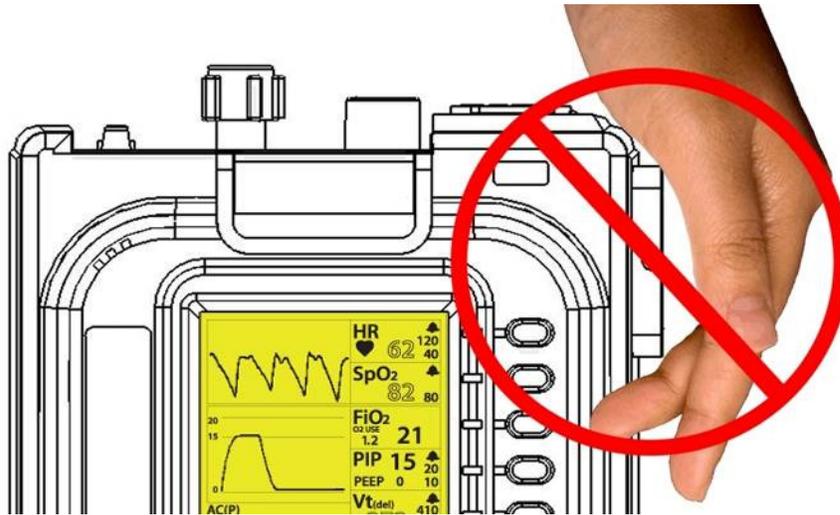
FRESH GAS/EMERGENCY AIR INTAKE: FIGURE 4

WARNING! Never block the FRESH GAS/EMERGENCY AIR INTAKE. A free flow of air is required during compressor operation or in the event of a device failure to allow spontaneous breathing. The FRESH GAS/EMERGENCY AIR INTAKE also acts as an anti-asphyxia port in the event of a ventilator failure.

VENTILATOR CIRCUIT CONNECTIONS

The EMV+ is designed to operate using a standard disposable ventilator circuit. The circuit is attached to the ventilator as shown in Figure 5.
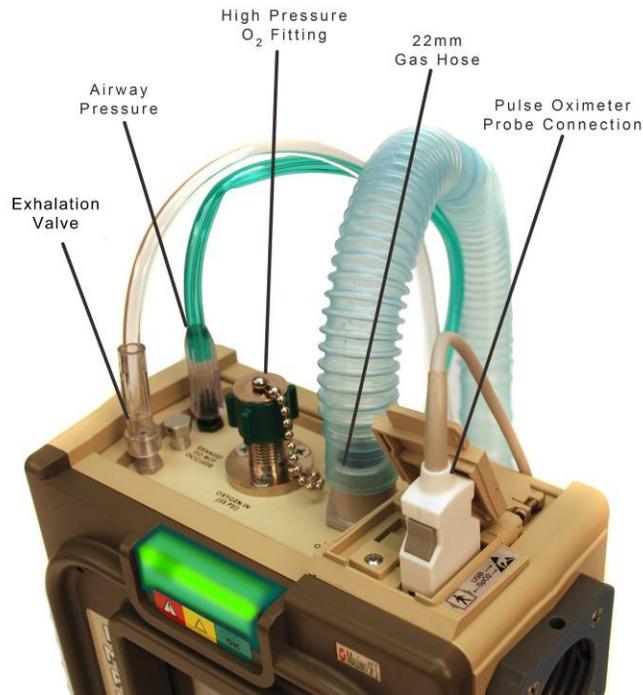
VENTILATOR CIRCUIT, DEVICE CONNECTIONS: FIGURE 5

> **CAUTION!** Always dispose of the circuit after single patient use following the institutional guidelines for biologically contaminated material. Reusing the circuit can result in cross contamination between patients.

VENTILATOR CIRCUIT, PATIENT CONNECTIONS

The EMV+ uses two different single limb vent circuits to support patients from ≥5 kg through adult: Infant/ Pediatric (Part #820-0107-00) and Pediatric/Adult (Part #820-0106-00). These are illustrated in Figure 6.

Infant/ Pediatric Circuit

10 mm Gas Hose

Exhalation Valve

Exhalation Valve Control Tube

Exhaust Port

(To patient, from ventilator)

Airway Pressure Line (Green)

Exhalation Valve Line (Clear)

Patient Connection (20 mm OD x 15 mm ID)

Airway Pressure Line

Pediatric/ Adult Circuit

22 mm Gas Hose

(To patient, from ventilator)

Exhalation Valve Line (Clear)

Airway Pressure Line

Patient Connection (22 mm OD x 15 mm ID)

VENTILATOR CIRCUIT, PATIENT CONNECTION: FIGURE 6

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VENTILATOR CIRCUITS, RESISTANCE AND COMPLIANCE

The resistance and compliance of the Impact ventilator circuits are listed in the table below:

Patient	Patient Weight (kg)	Breathing Circuit	Impact Part Number	Inspiratory Resistance (cm H_2O)	Expiratory Resistance (cm H_2O)	Resistance measured at Flow (l/min)	Compliance (ml/cm H_2O)	Dead Space (ml)
Adult	≥ 40	Ped/Adult	#820-0106-00	1.44	4.82	60	1.2	17
Pediatric	12-50	Ped/Adult	#820-0106-00	0.39	2.99	30	1.2	17
Pediatric	12-50	Infant/Ped	#820-0107-00	5.99	5.21	30	0.44	4.2
Infant	5-12	Infant/Ped	#820-0107-00	0.24	1.78	5	0.44	4.2

WARNING! If circuits with different resistance/ compliance are used or additional adjuncts are placed in line with the circuit, the Operator must make sure that the appropriate circuit resistance/ compliance factors for the new circuit is used as well as dead space volume of the added adjunct(s) is / are factored into the equation for effective tidal volume delivery to the patient.

OPERATING POWER SELECTION & STOPPING

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

The EMV+ is designed to operate using any one of three power 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 at 25° C).
2. External AC/DC Power Supply (110-240 VAC 50/60 & 400 Hz-- Impact Instrumentation validated testing, and 110-240 VAC 50/60 –SGS listed) 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 12 or 28 VDC Power Cables. The input connector of the EMV+ is designed to accept DC voltages between 12.5 to 28.0 VDC +/- 10% volts, negative ground.

CAUTION! When using the standard vehicle DC outlet, the vehicle should not be jump started during operation of the ventilator.

WARNING! Never start the ventilator with the patient connected. Always start the ventilator, select the patient settings, assure operation, and then connect the patient. Always manually ventilate the patient when they are not connected to the ventilator.

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 and/or loss of any alarms. 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 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 and altitude range to assure display, monitoring, and triggering accuracy.

The AUTO CAL affects 3 transducer systems: Compressor Flow, O_2 Flow and Airway Pressure. Its purpose is to compensate for small temperature related drifts in the transducer offset (zeroing). The AUTO CAL is performed during SELF-CHECK, and then every 5 minutes thereafter. However, if a temperature change exceeding +/- 1.5° C is sensed, the AUTO CAL time interval is reduced automatically to assure a stable pressure measurement baseline.

OPERATION OVERVIEW

INTRODUCTION

The EMV+ is a volume and pressure targeted, time or flow 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 user interface allows the operator to initiate operation of the EMV+ to begin operation at default setting values.

When high-pressure O_2 is connected the internal blender allows the FIO_2 to be set from 21 to 100%. Backpressure from the patient connection does not affect the delivered accuracy of the volume, flow, pressure or FIO_2. When the 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). 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. Operating power is from an external AC/DC power converter connected to live AC mains, external DC power, or from the internal rechargeable lithium ion battery. Fresh air is filtered using a particulate filter or, when the operating environment requires, a bacterial/viral filter or a chemical/biological filter may be attached.

When the unit is first powered up, certain patient circuit alarms are preemptively muted for 120 sec. to allow the operator time to attach the patient circuit, pulse oximeter and properly adjust the ventilator without nuisance alarms. For a list of these preemptively muted alarms, see the "Alarms Turn Off & Cancellation" section. The time remaining for the mute period is displayed on a countdown clock shown beneath the speaker icon.

PULSE OXIMETER

At start-up, the pulse oximeter is in standby (pulse oximeter on and ready to monitor). In standby, the parameter windows for SpO2 and Heart Rate read "stby" and operational alarms are suppressed. As soon as valid patient signal is detected ≥ 10 seconds, the pulse oximeter comes out of standby - the parameters are displayed, and all alarms are active. The pulse oximeter can be turned on via the "Pulse Oximeter" submenu in the main menu by changing "stby" to "on". Similarly, if the probe is removed from the patient and is no longer needed, the pulse oximeter can be placed back in standby via the "Pulse Oximeter" menu submenu. 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 O_2 saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by the SpO_2 sensor) for adult, pediatric and infant patients using the appropriate sensor for the patient. The pulse oximeter is operational in all ventilator modes when its cable and sensor are properly attached to the SpO_2 connector (see Figure 5).

To operate the pulse oximeter, connect the probe to the patient cable and the patient cable to the SpO_2 connector on the EMV+. The monitoring function will continuously display the patient's pulse rate and SpO_2 value. See the Pulse Oximeter Alarms in the Ventilator Alarm Categories section for more information on pulse oximeter alarms.

> **NOTE:** The pulse oximeter can only be placed in standby when the probe is disconnected from the patient. A valid signal will automatically bring the pulse oximeter out of standby.

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 hypotension, 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.

HR
♥ 62 ▲120
      40

SpO₂
   82 ▲
      80

FiO₂
O2 USE
1.2 21

PIP 15 ▲20
PEEP 0   10

Vt(del)
   272 ▲410
        0

BPM
I:E   ▲25
1:2.5 15 8

Mode
     AC (P)

AC(P)

20
15
0

| Vmin	MAP	BPMt	TI
4.0	8.8	15	1.14

0   50   100
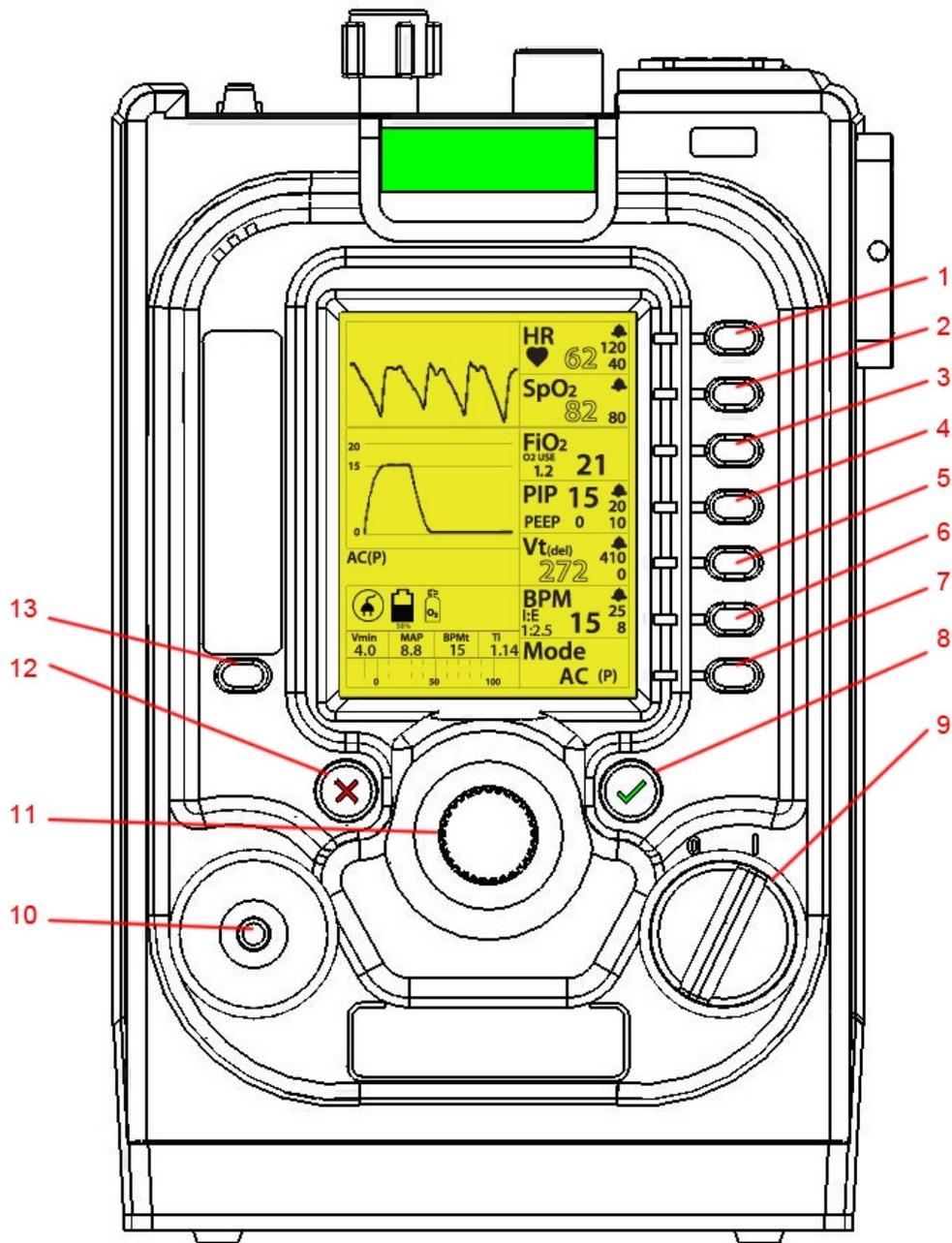
CONTROLS AND INDICATORS: FIGURE 7

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DESCRIPTION OF CONTROLS AND DISPLAY

The EMV+ contains various controls and indicators that are placed 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 Figure 7 (their respective location callouts are listed below in parenthesis). Most EMV+ functions are controlled by pressing the PARAMETER button associated with the parameter you wish to change. Pressing the PARAMETER button highlights the primary parameter. Additional presses highlight 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 and confirm the 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. The operator may cancel any operation and return to the primary operating screen by pressing the MUTE/CANCEL button. A parameter stays highlighted for 5 seconds; after this time the unit automatically cancels the operation and returns to the default screen. Additional functionality associated with a parameter is viewed in Context Menus which are accessed by pressing and holding (P&H) the parameter button for ~1 second. Parameter and their associated Context Menus are described below.

To assist the operator in recognizing parameters that can be changed and those that are dependent on the patient the EMV+ uses "Outlined" text to demonstrate patient dependent values, see Figure 8. Parameters in Outlined text cannot be adjusted. For example, during volume targeted ventilation the PIP value is displayed as outlined text because it is dependent on the patient's resistance and compliance. In pressure targeted ventilation the tidal volume is outlined text.
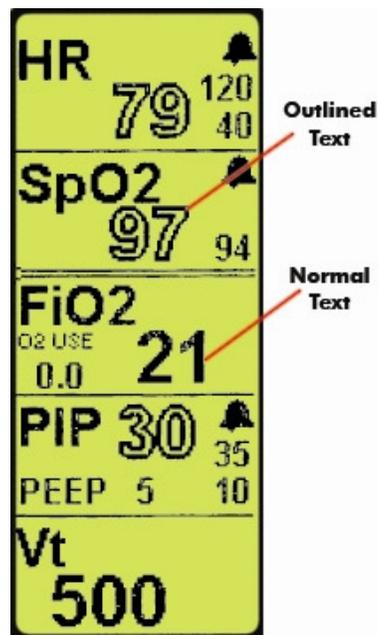
EXAMPLE OUTLINED / NORMAL TEXT: FIGURE 8

The Control Panel incorporates all controls and the LCD display. Each control is described in the following text (see Figure 7). Context Menu controls are shown in tables associated with their parameter button.

HR (1) – Pressing the HR button highlights the High Heart Rate alarm limit and enables 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. To access the HR context menu press and hold (P&H) the HR parameter button. The HR context menu provides control of the pulse oximeter settings.

Masimo Context Menu		
Menu Item	**Range**	**Description**
Averaging	2-4, 4-6, 8, 10, 12, 14, 16(t=sec)	Adjusts the SpO2 and HR averaging durations
Sensitivity	Norm, Max	Default: Norm, adjusts the pleth signal sensitivity. Max is designed to interpret and display data for even the weakest of signals. This more is recommended during procedures and when clinician and patient contact is continuous.
Fast SAT	Off, On	Default: off, Fast Sat enables rapid tracking of arterial O_2 saturation changes by minimizing the averaging. This mode is clinically applicable during procedures when detecting rapid changes in SpO_2 is paramount such induction, intubation and sleep studies.
APOD	Off, On	Default: "Off". When "On", this mode improves detection of the "probe off patient" condition, but reduces ability to acquire a reading on patients with low perfusion.
Signal Strength	0 to 20	Current signal strength value, not adjustable. A value of zero indicates that no measurement is available. This value helps clinicians place sensors on optimal sites.
Signal IQ	Bar graph	Bar graph displays the relative reliability of the pulse ox signal

SpO2 (2) – Pressing the SpO_2 button highlights the Low SpO_2 Alarm Limit and enables its value to be changed. The SpO_2 display is active only when the pulse oximeter is connected. When no SpO_2 sensor is connected or if the probe is off the patient during start up or the operator places the pulse oximeter in standby, "stby" is displayed in the parameter window. The default low SpO2 value at start up is 94%. SpO2 uses the same Context Menu as HR.

FIO_2 (3) – Pressing the FIO_2 button highlights the current value and enables it to be changed. There are no adjustable secondary parameters. The default value at start up is 21% whether O2 is present or not. If an FIO_2 value greater than 21% is saved and used for Power Up settings, the unit will start up with that saved FIO_2 value if high-pressure O_2 is present. If high-pressure O_2 is <u>not</u> present, the unit will start up with FIO_2 = 21% and *O2 SUPPLY PRESSURE LOW* alarm will <u>not </u>be activated. The secondary display in the parameter

window is O_2 Use[1]. This is the flow (liters/min) of high pressure O_2 used by the unit to support the patient at the current settings. O_2 Reservoir mode is indicated on the display with a plus "+" sign next to the FIO_2 value. (The "O_2 Use" value does not include O_2 use in the O_2 Reservoir.)

PIP (PEAK INSPIRATORY PRESSURE) (4) –   In volume targeted modes, the primary field shows the delivered PIP as outline text. In pressure target modes, the PIP target is displayed and adjustable. The PIP High Limit, PIP Low Limit, and PEEP are also available as secondary parameters.

PIP Context Menu		
Menu Item	**Range**	**Description**
Pressure Support	0 to 60	PS value is the pressure over the PEEP setting

> Pressure Support: This is the amount of pressure applied for spontaneous pressure supported breaths which are available in SIMV and CPAP. For more information, see "Additional Modes of Operation."

NOTE: PIP values greater than 60 cm H_2O require the user to perform a separate confirmation.

V_T (TIDAL VOLUME) (5) - In volume targeted modes, the primary field shows the set tidal volume. In pressure target modes, the delivered tidal volume is shown as outlined text and is based on the patient pulmonary mechanics. The V_T High and Low Limits are also available as secondary parameters.

NOTE: In the CPAP-NPPV, the V_T delivered and V_{min} may be overestimates of the true volume going to the patient when leaks are present. The O2 Use values will accurately display the O2 use though the amount used will be more than if no leak was present.

WARNING! In the CPAP-NPPV, if the V_T is lower than anticipated based on the patient's weight, this is an indication that the patient is not able to spontaneously ventilate to meet their respiratory demand.

BPM (BREATHING RATE) (6) – pressing the BPM button highlights the current value and enables it to be changed. Secondary parameters include high breath rate, low breath rate and I:E ratio which can be adjusted by pressing the PARAMETER button the appropriate number of times. When the EMV+ is operating in CPAP the patient's actual breathing rate is displayed as the BPM primary parameter in outlined text.

BPM Context Menu		
Menu Item	**Range**	**Description**
Control Parameter	I:E, TI	Allows operator to select independent variable
Rise Time	1 to 10	Determines the speed of the rise flow, low values fast rise, high values slow rise
Cycle Off %	10 to 70% (default 25%)	Allows operator to adjust Cycle Off %.

> Control Parameter: the operator can select which parameter is dependent or independent. Selecting I:E results in the ventilator maintaining the I:E Ratio while the inspiratory time (T_I) varies when the breathing rate is changed. Selecting T_I maintains a constant inspiratory time while the I:E ratio varies when the rate is changed.

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[1] O_2 Use = ((FIO_2 – 0.21)/0.79) * Minute Volume where FIO_2 is represented as a fraction and minute volume is the actual minute volume (controlled and spontaneous/assisted breaths).

Rise Time: the EMV+ allows the operator to adjust the time it takes to reach the full inspiratory flow and peak inspiratory pressure during pressure targeted breathing and when pressure support is being used. The range is 1 to 10 where 1 is the shortest rise time and 10 is the longest rise time. When the unit is turned on, either the default Rise Time (3) or a User Setting Rise Time will be used. Using the Pressure-Time waveform as reference will assist the operator in setting the Rise Time.

The Rise Time settings should be reassessed and adjusted after the patient is placed on the ventilator and initially stabilized. To minimize patient's work of breathing and potential for pressure overshoots, operators must take the following into consideration when setting the Rise Time:
- Patient's respiratory pattern
- Patient's comfort
- Patient's flow demand
- Resistance (Mechanical/ Physiological)
- Compliance characteristics

The Rise Time for a passive lung is driven primarily by airway resistance, and is fairly independent of compliance.

Resistance	Rise Time
5	1
20	3
50	5
200	10

Adult patient with high Resistance may benefit from a Rise Time setting of 3 to 4 for optimal breath delivery. Rise Times of 8-10 are optimized for infants and are flow limited. (The infant circuit is not intended for flows > 60 LPM.)

Cycle Off %: the EMV+ allows the operator to adjust the Cycle Off %. The primary purpose of this parameter is to set a fraction of maximum flow at which inspiration ends and exhalation begins. A key application for Cycle Off % is to adjust for leaks present in and around the patient circuit or the patient themselves.

NOTE: The longest duration of a spontaneous pressure supported breath is limited to 5 seconds. At the end of this time, the ventilator ends flow and opens the exhalation valve. (All other breaths are time cycled.)

- Cycle Off % is principally made available as a parameter for NPPV mode, where a much higher setting is required to cycle the breath properly in the presence of a leak. If a higher value is not used and there is a leak, the tendency will be for the system to time cycle at 5 sec instead of flow cycle. This is due to the fact that the leak flow might be higher than 25% of the peak flow, so the cycle threshold is never crossed.

- If there is no leak, increasing the Cycle Off % will cause breaths to cycle sooner, thus delivering less volume. If it is set too high, the breath will end early relative to patient effort and may lead to the triggering of a second breath.

NOTE: Clinicians must carefully assess the patient's response to the Cycle Off % application and must carefully adjust the flow cycle setting to optimize patient ventilatory support and comfort.

MODE (7) – Pressing the MODE button will highlight the current ventilation mode. Pressing the parameter buttonagain will allow for the selection of volume or pressure targeting which are shown as either"(V)" for volume or "(P)" for pressure. Selecting volume assures a constant volume is delivered to the patient in the inspiratory time using a constant flow. Pressure targeted ventilation provides a constant airway pressure for the duration of the inspiratory time using a decelerating flow pattern. See "Additional Modes of Operation" for description of how to enter the NPPV (Noninvasive Positive Pressure) adjunct in the Mode parameter window.   To access the Mode Context menu P&H the Mode parameter button.   This will permit the Apnea Back Up settings to be defined.

Mode Context Menu		
Menu Item	**Range**	**Description**
BPM	1 to 60	Allows operator to select BPM for Apnea Back Up.
PIP Target	10 to 80	Allows operator to select the PIP Target for Apnea Back Up.
I:E, TI	1:1 to 1:99, 0.3 to 3	Allows operator to select either I:E or TI for Apnea Back Up.

When going into Apnea Backup from CPAP (both NPPV and PPV), the unit will automatically return to Pressure with the following back up settings:

PIP Target	BPM	I:E OR T$_I$
20	12	1:2.5 OR 1.42

All other parameters will remain as they were previously set.   When leaving CPAP, the new operating mode will be Pressure Targeted and will use Apnea Backup settings as the new settings.

CAUTION! These Apnea Backup settings are appropriate for an adult. The Operator should adjust for pediatric and infant patients.

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 green check mark "**√**".

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

MANUAL BREATH (10) – pressing the manual breath button delivers one control breath based on the V$_T$ or PIP settings. If the Manual Breath is pressed during inspiration or before baseline is reached in the expiratory period, a manual breath will not be triggered. If there is incomplete exhalation, it will not be possible to trigger a manual breath. This is to prevent accidental breath stacking. When operating in CPAP, a breath is delivered using the PIP value from the Apnea Backup settings

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

MUTE/CANCEL (12) – press the MUTE/CANCEL pushbutton to mute most Medium Priority alarms, to cancel/acknowledge Low Priority alarms or to cancel an action that is no longer desired (for example: a parameter value change). Pressing the MUTE/CANCEL button can also be used to cancel any current operation and return to the normal operating screen. The MUTE/CANCEL button 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 label).   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 to the previous MENU level or exit the MENU control by pressing the MUTE/CANCEL button.

1. Alarm Configuration: allows the operator to disable the audible and visible alarm alerts associated with specific alarms in order to prevent nuisance alarms. While the menu shows all of the alarms that can be disabled, the design does not allow for an alarm to be disabled until it has been detected. This approach assures that the operator has been advised of the alarm and has decided that it does not affect safe and effective management of the patient. It is important to recognize that Low Priority alarms are Advisory and the patient and device are performing as configured, but there is information that could affect management of the patient. For more information, see the section "Alarm Turn Off and Cancellation".

2. Power Up Settings: allows the operator to select startup settings different from the factory 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. User 1 and user 2 allow the operator to establish different start up settings based on the intended patient population.

   Impact Instrumentation Inc. is constantly focused on providing clinically safe, effective and timely support to patients requiring ventilator support as well as ease of use to their care providers. The initial focus and area for application of the EMV+ platform is Acute Patient Care in many varied and austere environments. This patient area of need has historically been the Adult range of patients. Impact has used this historical data and experience as its rationale for the EMV+ to start-up in the Adult patient Assist-Control Volume mode and associated parameters which have been deemed as clinically safe and acceptable starting points and limits by international experts and standards committees.

   Impact also strives to provide User friendly options to our customers and allow them to setup certain USER Start-up selected modes after their acquisition of the equipment as they know best what their patient base and needs for mechanical ventilatory support are within their respective region or facilities. Realizing that varied levels of need and experience exist, as well as knowing that each patient is different and clinician assessment is required prior to application to the patient, certain mode and parameter configurations are not available as User setup options in an effort to maximize patient safety.

   To configure start up settings other than the default, 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 will begin operation with the new settings. Limits for stored parameters shown in the table below. Default startup modes are limited to AC and SIMV; CPAP cannot be stored as a startup default.

| Parameter	Limitations
Vt Setting	≤1000 ml
Vt High Limit	10ml resolution, only recalled if the target is pressure or in SIMV(V)
Vt Low Limit	10ml resolution, only recalled if the target is pressure or in SIMV(V)
Constant I time vs. constant I:E	No limit
Target (P or V)	No limit
BPM	6 to 60
BPM High Limit	No limit
BPM Low Limit	>6 bpm

I time	No limit
PIP Target	≤35 cmH2O
PIP High limit	≤35 cmH2O
PIP Low Limit	No limit
PEEP	No limit

> **CAUTION!** The Operator should set the PIP Low Limit to be at least PEEP + 5. This is to reduce the likelihood of not detecting a kinked hose. If the PIP Low Limit is set > PEEP and <PIP, the PIP Low Limit can also serve as a PEEP compensated disconnect threshold.

3. <u>Pulse Oximeter</u>: allows the operator to turn the pulse oximeter on or place it in standby.

4. <u>Trigger Level</u>: allows the operator to adjust the assisted breath trigger from -6 to -0.5 cm H_2O to optimize the patient/ventilator interaction; the default value is -2 cm H_2O below baseline. The setting is not retained when the device is powered off.

> **CAUTION!** The Operator should take care in setting the trigger level so as to minimize work of breathing and prevent auto-triggering. This is critical when ventilating infants and during NPPV operation.

5. <u>O2 Reservoir</u>: allows the operator to tell the device that the 3-Liter O2 Reservoir Assembly is in use. Using the reservoir can cause a *FRESH GAS INTAKE FAULT* alarm to occur. Turning this function on 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 the compressor is not able to deliver its contribution to the breath. Operation in extremely high vibration environments can also trigger this alarm. Using this mode in these situations can reduce nuisance alarms. The setting is not retained when the device is powered off.

6. <u>Unit Info</u>: lists the serial number for the unit and Smart Pneumatic Module (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.

7. <u>Contrast</u>: 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. During operation at temperature extremes the device may start with a contrast setting that renders the display not visible. In these situations the operator can directly access the contrast control by pressing and holding the menu and then adjusting the contrast with the Rotary Encoder.
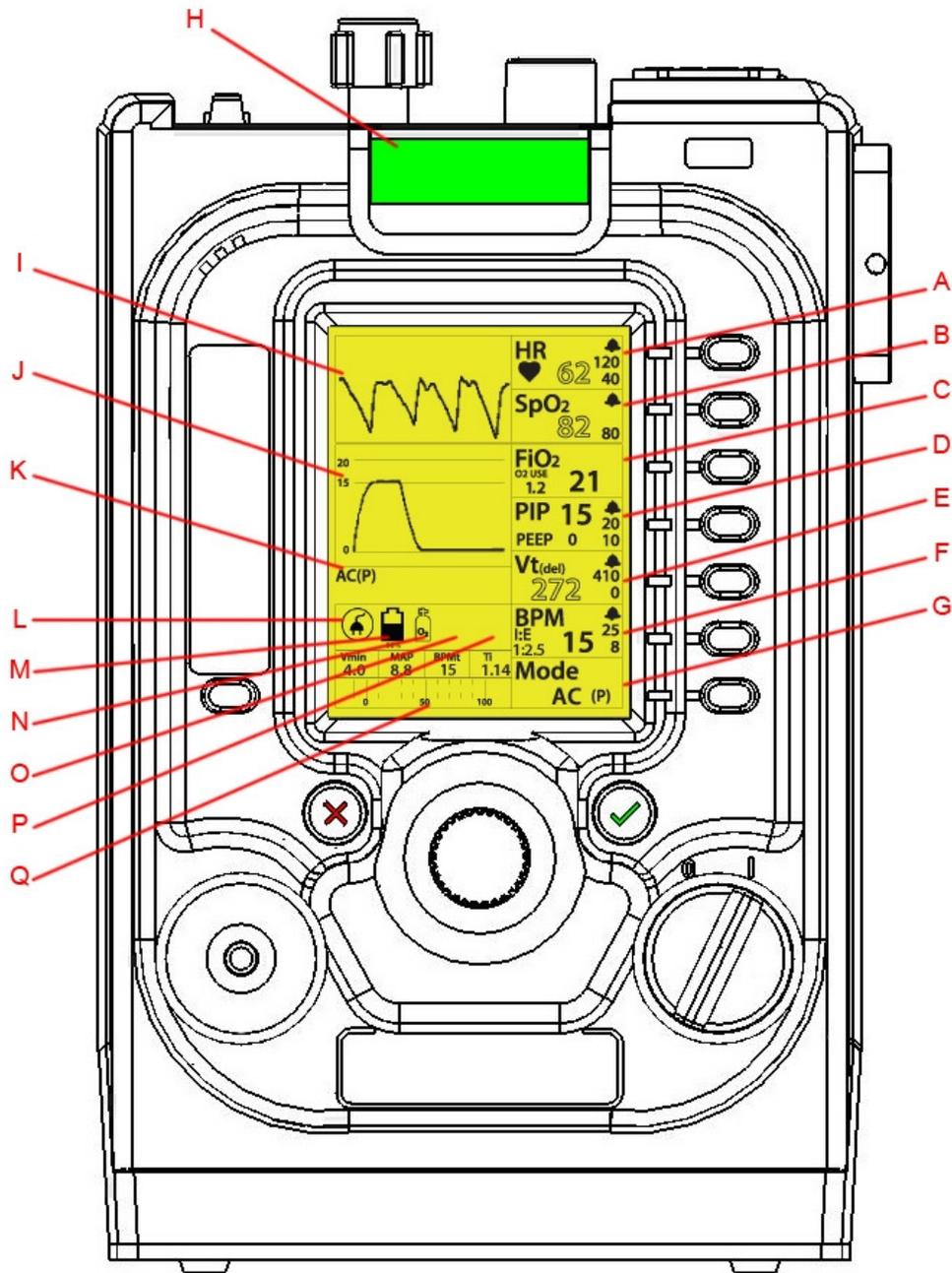
VISUAL INDICATORS: FIGURE 9

VISUAL INDICATORS

LCD parameter windows present information relating to settings, menus/instructions, alarm information, pressure measurement data, pulse oximeter data, and heart rate data (see Figure 9). 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 in sequence with the patient's heart rate. Immediately to the left of the HR and SpO_2 parameter windows is the pulse oximeter pleth display. When no alarms are present, the pleth is displayed. When alarms occur, the pleth is removed to allow room for alarm name and mitigation instructions. When a Low priority alarm is muted, the pleth is returned to the screen. For all priority alarms, the LED indication lights remain active even if the alarm information is not shown on the screen.

SpO2 (B) – displays the SpO_2 and Low/High SpO_2 alarm limits.

FIO$_2$ (C) – displays the set fraction of inspired O_2. The window also displays the O_2 Use value.

PIP (D) – displays the peak airway pressure, PEEP and Low/High PIP alarm limits. During volume targeted ventilation the PIP is displayed as outlined text to remind the operator that it is dependent on the set volume and patient's respiratory mechanics.

V$_T$ (E) – displays the set tidal volume during volume targeted ventilation. During pressure targeted ventilation it displays the delivered tidal volume. This is indicated by the outlined text and by displaying "**(Del)**" next to "**Vt**". In pressure targeted ventilation the High and Low tidal volume alarm limits are displayed.

BPM (F) – displays the set breath rate. In addition the High and Low breath rate alarm limits and either the I:E ratio or inspiratory time (depending on the operator configuration) are displayed in this window. During operation in CPAP the BPM primary parameter is the patient's actual breathing rate in outlined text.

MODE (G) – displays the operating mode and the breath target "**(V)**" for volume or "**(P)**" for pressure. The upper right corner of this window also displays if the unit is in the NPPV adjunct (Noninvasive Positive Pressure) or the default PPV adjunct (Positive Pressure Ventilation).

STATUS INDICATOR LED ARRAY (H) – The STATUS INDICATOR LED ARRAY contains green, yellow and red LED's. During normal operation the STATUS INDICATOR LED ARRAY is enabled.

PULSE/ TIME PLOT (I) – displays the Pulse Oximeter reading versus time plot if no medium/high alarms are displayed.

PRESSURE/ TIME PLOT (J) – displays the PIP pressure versus time plot if no medium/ high alarms are displayed. The numbers indicate the PIP readings, and are not displayed when the PIP is above/ below the PIP limits. This pressure information is to assist both in diagnostic evaluation and in setting the rise time.

NOTE: When no alarms are present, the pulse/ time and pressure/ time plots are displayed. When alarms occur, the plots are removed to allow room for alarm name and mitigation instructions (see Figure 10). When a Low priority alarm is muted, the plots are returned to the screen. For all priority alarms, the LED indication lights remain active even if the alarm information is not shown on the screen

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CURRENT MODE (K) – displays the current Mode plus any adjuncts that are in effect (for example, CPAP + NPPV, AC(Volume) etc.) The pressure value for the pressure support (PS) is indicated by the number in parenthesis after PS (for example, PS (40)).

EXTERNAL POWER Icon/Indicator **(L, 1st position)** – indicates the presence of external power. When no external power is sensed, the icon/indicator presents with a diagonal line. If an *EXTERNAL POWER LOW* or *EXTERNAL POWER FAIL/DISCONNECT* alarm occurs, the icon flashes off/on.
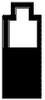
BATTERY Icon/Indicator **(M, 2nd position)** – indicates (1) the presence of a functional battery, (2) when the battery is charging and (3) the current battery capacity. The BATTERY icon appears in outline form and is filled with horizontal lines indicating its current capacity. When the battery is charging, these horizontal lines cyclically scroll vertically, one row at a time, from the bottom row to the top. The scroll rate of the rows is faster when the battery is charging faster and it slows down when slower trickle charging. The charge level is indicated numerically under the battery icon. When the battery is fully charged, the icon is completely filled and scrolling stops. Each line represents approximately 5% of battery capacity. During internal battery operation, a horizontal line is removed with each 5% decrement of battery capacity. 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.

OXYGEN SUPPLY Icon/Indicator **(N, 3rd position)** – indicates the presence of external high-pressure O_2 (55 psig source). The icon only appears when high-pressure external O_2 is detected by the pressure transducer. The icon flashes off/on when the OXYGEN LOW/FAIL alarm occurs.

SPEAKER (MUTE OR UNMUTE) Icon/Indicator **(O, 4th position)** – indicates whether the alarm sound has been muted or is active. The muted speak is present during the start up 2 minute mute, with the remaining muted time indicated under this icon.

HEAD WITH MASK Icon/ Indicator **(O, 4th position)** – indicates if the NPPV adjunct is in effect for ventilatory support of spontaneously breathing patients. This icon replaces the unmuted speaker icon and/or the muted speaker icon for Low priority alarms. (This icon does not appear if a Medium priority alarm has been muted.)

ALARM TRIANGLE Icon/Indicator **(P, 5th position)** – indicates if there is an active alarm. The priority of the alarm is indicated by the interior of the triangle. (See "Symbols and Icons" table.)

AIRWAY PRESSURE/MEASURED VALUES (Q) - provides a continuous display of airway pressure. Its absolute range is from -10 to 100 cm H_2O ATPD 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. Above the bar graph measured values for delivered minute volume, mean airway pressure (MAP) and actual breathing rate (set plus spontaneous) are displayed.

LCD ALARM INDICATORS

The EMV+ uses a comprehensive suite of alarms to alert the operator and guide their actions to resolve the alarm condition and assure patient safety. At the onset of an alarm, the screen displays the alarm name and then a series of context-sensitive help messages (see Figure 10). These messages serve to guide the operator by presenting suggestions as to the cause and resolution of a particular alarm. When multiple alarms occur they are prioritized and displayed based on the risk to the patient. Refer to Appendix 1: Alarms for a complete description of each alarm and how the EMV+ controls alarm conditions.

O2 Supply Pressure Low
- Operation Switched to Compressor
- Check O2 Supply Pressure
- Check/Replace Regulator
- Set FIO2 to 21%
- Connect Low Flow O2
- Monitor SpO2
- **Replace/Service Ventilator**

#2020
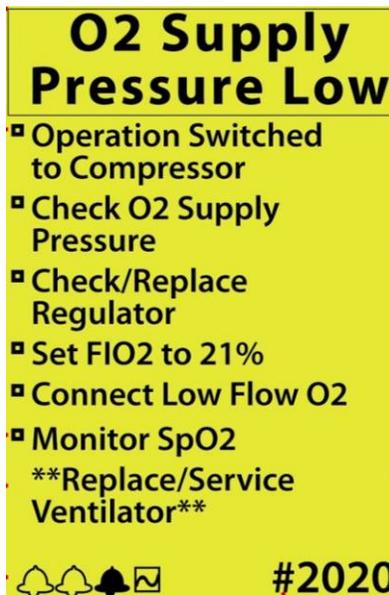
ALARM & PLOT LIST: FIGURE 10

Figure 10 is an illustration of what is seen if there are several alarms. The Alarm message refers to the alarm bell that is dark. The Operator can cycle through the various alarms by turning the encoder dial. If there are less than 5 alarms, this alarm list will also include a "plot" icon, where the alarm screen will be replaced by the Pleth and Pressure/ Time plots.

If the alarms are Low Priority, then muting these Low Priority alarms will cause the Pleth and Pressure/Time plots to appear permanently on the screen. If the alarms are Medium Priority, the unit will cycle through each Medium Priority Alarm for a 20 second period. The encoder dial can be used to select a particular Medium Priority Alarm and/or Plot for 20 seconds, after which the above cycling rotation will resume. New Alarms will overwrite the screen at any time.

The color of the LCD Alarms indicates their status:

GREEN – The LED array illuminates green to indicate operating power and that all ventilator and patient parameters are operating as intended.

YELLOW – The LED array illuminates yellow to indicate a Low Priority alarm has been detected or that a persistent alarm condition is active. The EMV+ will continue to operate within its safety limits while the yellow LED provides a constant reminder that although it was acknowledged, the condition remains. An example of a persistent alarm is when the compressor inlet filter needs to be changed but the ventilator is still able to deliver the correct tidal volume. 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   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 High and Medium Priority alarm conditions. The Alarm LED flashes when the alarm occurs.   When the MUTE/CANCEL button is pushed the LED illuminates continuously during the 30 seconds that the audible alarm is muted during Medium Priority alarms. Pressing the MUTE/CANCEL button during High Priority alarms has no effect.

ALARM TURN OFF & CANCELLATION
The Operator may decide, based on their professional judgment and the clinical conditions, either to turn off or cancel certain alarms that, in the given situation, are "nuisance" alarms and are not assisting in the safe management of the patient. Before any such alarms can be turned off or cancelled, the Operator will receive a Pop Up message asking them to confirm their understanding that the alarm will no longer be available in that session.

Alarm Preemptive Mute upon Power up
When the unit is first powered up, certain patient circuit alarms are preemptively muted for 120 sec, to allow the operator time to get the patient circuit properly adjusted without nuisance alarms. There is a countdown timer located under the muted alarm symbol, showing how much time of the 120 sec is remaining. The list of alarms that have this preemptive mute are:

Alarm Number	Alarm Name
2062	Exhalation Fault
2070	Airway Pressure High
2071	Low Airway Pressure
2072	High Tidal Volume
2073	Low Tidal Volume
2074	High Breath Rate
2075	Low Breath Rate/Apnea
2076	Apnea
2090	PEEP Leak
2095	Insufficient Flow
2100	Patient Disconnect
2170	Spontaneous Breath – PIP High
2171	Spontaneous Breath – PIP Low
2172	Spontaneous Breath – Vt High
2173	Spontaneous Breath – Vt Low
2300	Pulse Ox Module Failed
2301	Internal Communication Failed
2314	SpO2 Sensor Off Patient
2401	SpO2 Low
2410	Heart Rate High
2411	Heart Rate Low (Pulse Rate Low)
3300	SpO2 Shutdown (MS 11 Failure - Monitor Not In Use)
3301	SpO2 Shutdown (Communication Failure EMV+-Pulse Ox - Monitor Not In Use)
3310	No SpO2 Sensor Connected (No Sensor Connected)
3311	Defective Sensor
3312	SpO2 Pulse Search

Alarm Number	Alarm Name
3313	SpO2 Signal Interference
3315	Too Much Ambient Light
3316	Invalid SpO2 Sensor (Unrecognized Sensor)
3317	Low SpO2 Perfusion (Low Perfusion)
3318	Low SpO2 Perfusion (poor SpO2 signal)

Alarm Turn Off at Extreme Range Limits
If the Operator sets the below alarm limits to their extreme range, the indicated alarms will be turned off after Pop Up message confirmation. These alarms are:

1) High Breath Rate (Alarm # 2074)
2) PIP Low (Alarms # 2071, 2171)
    a. This changes automatically to "off" in NPPV.
3) V_T High (Alarms # 2072, 2172)
    a. This changes automatically to "off" in NPPV.
4) V_T Low (Alarms # 2073, 2173)
    a. This changes automatically to "off" in NPPV.
5) Low SpO2 (Alarm # 2401)
6) High Heart Rate (Alarm # 2410)
7) Low Heart Rate (Alarm # 2411)

If an alarm has been turned "off" and is then modified, but not accepted, then the alarm parameter will be set to the values indicated in the table below. This is done to assure patient safety in the event of an inadvertent value change.   These values can be changed by the operator following the parameter change procedures described above.

High Breath Rate	PIP Low	Vt High	Vt Low	Low SpO2	High Heart Rate	Low Heart Rate
99 BPM	3 cm H_2O	2000 ml	0 ml	86%	240 BPM	30 BPM

Alarm Cancellation in Alarm Configuration Menu.
There are clinical situations where an alarm occurs, and in the Operator's clinical judgment this alarm should be cancelled for the remainder of the unit's operating session.   The following constraints apply to this Alarm cancellation:

1) Only alarms that have occurred in the current operating session can be cancelled.
2) Alarms which have not occurred since turn on will be indicated with a "—".
3) Cancelled Alarms will not be saved in the User Settings for the next session.
4) All cancelled alarms will reappear (if appropriate) when the unit is next turned on. (As an example, the Self Check Fault, calibration due Alarm # 3120, will reappear in the next operating session.)

The following alarms may be cancelled in the Alarm Configuration Menu:
1) Self Check Fault, calibration due (Alarm # 3120)
2) RTC Battery Fault (Battery Low) (Alarm # 3110)
3) Incomplete Exhalation (Alarm # 3091)
4) PEEP Leak (Alarm # 2090)
5) Fresh Gas Intake Fault (Alarm # 3031)
6) Patient Inspiratory Demand not Met (Alarm # 3092)

POP UP MESSAGES
To prevent setting of unwanted or inadvertent parameter values that are outside of the typical clinical range of settings the EMV+ presents Pop Up messages that ask the operator if they are sure they would

like to set the parameter beyond the typical range. When a message occurs the operator is asked to press the SELECT/CONFIRM button before they can adjust a parameter beyond the typical range.   Pop Up messages are also used to alert the operator that certain settings are not permitted. In addition, Pop Up messages can call for the user to SELECT/CONFIRM that they are entering configurations   where certain alarms are being suppressed, turned "off" and/or cancelled. A complete list of these Pop Up Messages is given in Appendix 8. An example of a Pop Up Message is illustrated in Figure 11 where the operator is trying to set the I:E ratio to a value that exceeds the allowable range of the inspiratory time.
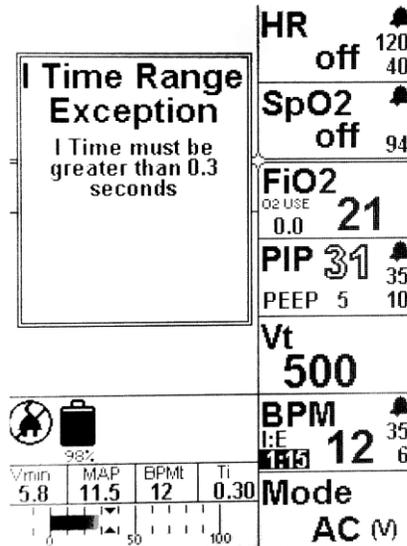
POP UP MESSAGE EXAMPLE: FIGURE 11

OPERATION

The EMV+ has been designed to ease the learning transition commonly associated with new equipment. Turning the POWER switch to "1" starts an internal SELF CHECK and begins operation with the default settings. The operator has the option of delivering volume targeted or pressure targeted breaths. An internal blender enables the EMV+ to deliver O_2 concentrations from 21 to 100% using its internal compressor and/or a standard medical-grade O_2 source. Additionally, low-pressure O_2 can be entrained through the Fresh Gas/Compressor Intake using the reservoir accessory except when a chemical/biological filter is connected. When using the reservoir the FIO_2 should be set to 21% and enable the O_2 Reservoir mode from the User Menu (enabling this avoids nuisance alarms from the compressor inlet sensors). The operator should titrate the flow of O_2 to the reservoir to maintain an adequate SpO_2 value. O_2 Reservoir mode is indicated on the display with a plus "+" sign next to the FIO_2 value.

MODES OF OPERATION

The EMV+ offers a range of modes using both pressure and volume targeting that can be selected to optimally manage the patient.

Assist/Control (AC): patient receives either controlled or assisted breaths. When the patient triggers an assisted breath they receive a breath based on either the volume or pressure target.

Synchronized Intermittent Mandatory Ventilation (SIMV): patient receives controlled breaths based on the set breathing rate. Spontaneous breaths can be either unsupported or supported using Pressure Support.

Continuous Positive Airway Pressure (CPAP): patient receives constant positive airway pressure while breathing spontaneously. Spontaneous breaths can be either demand flow or supported using Pressure Support. The minimum baseline pressure (PEEP) during CPAP is 0 cm H_2O provided the Pressure Support

is ≥3 cm H_2O. The minimum baseline pressure (PEEP) in CPAP-NPPV is 3 cm H_2O regardless of the Pressure Support setting.

NOTE: In the SIMV(P), SIMV(V) and CPAP modes, the sum (PEEP + PS) must be ≥3 cm H_2O
NOTE: In transitioning from AC to either CPAP or SIMV, if the starting PEEP value is 3 cm H_2O or less, the PEEP shall be set to 3.0 cm H_2O during the transition. (This is to assure that there is never a situation when both the PS and PEEP are zero, which would violate (PEEP + PS) ≥3 cm H_2O.)

ADDITIONAL ADJUNCTS OF OPERATION

In addition to Modes of Operation, the EMV+ also provides various adjuncts that can be used to manage the patient. Two adjuncts are Pressure Support (PS) and Noninvasive Positive Pressure (NPPV). The table below shows which adjuncts can be used with which modes. It is possible to use more than one adjunct, if the mode permits.

Mode	Breath Target	Pressure Support (PS)	Noninvasive Positive Pressure Ventilation (NPPV)
AC	V & P	No	No
SIMV	V & P	Yes	No
CPAP	N/A	Yes	Yes

Pressure Support (PS): can be used to assist spontaneous breaths in both SIMV and CPAP modes. To set pressure support, Press & Hold the PIP parameter button (while the mode is set to either SIMV or CPAP), press the Confirm/Select button to highlight the PS value then turn the Rotary Encoder to the desired value. Once the desired value is selected, press the Confirm/Select button to enable the value and then the Mute/Cancel button to return to the main screen.   The Current Mode display will denote the value of this pressure support by the number in parenthesis after PS (value).

Noninvasive Positive Pressure (NPPV): provides flow during the expiratory phase to maintain the baseline pressure (CPAP) in spontaneously breathing patients with a leaking airway or facemask. The amount of leak compensation depends on the leak flow rate during the expiratory period and ranges from 0 to 15 liters/min and is automatically adjusted by the ventilator in order to maintain the CPAP target.

CAUTION! The operator should take care in setting the trigger level so as to minimize work of breathing and prevent auto-triggering. This is critical when ventilating infants and during NPPV operation.
CAUTION! The transition into NPPV automatically sets the rise time to 3 which may be too fast for infants and small children. Before using with an infant or small child, the operator should increase rise time and monitor the pressure/time trace to assure that it is set appropriately for the patient.

To avoid nuisance alarms in patients with active leaks, operation using NPPV suppresses certain alarms. The alarms which are suppressed are:

1) Incomplete Exhalation (Alarm # 3091)
2) Insufficient Flow (Alarm # 2095)

To start NPPV:
1) Press mode button to highlight mode.
2) Select CPAP and press "Accept".
3) Press mode button until the "PPV" field is selected.
4) Adjust to NPPV.
5) Pop Up message will appear and ask for confirmation.
6) Press "Accept".

When the NPPV adjunct is in operation, the "head with mask" icon will appear in the location used by the "speaker/mute" icons. Low and Medium priority alarms will cause this "head with mask" icon to disappear. It will reappear when Low priority alarms are muted. When Medium priority alarms are muted, the "muted speaker" icon will appear.

When transitioning to NPPV mode, the following parameters/ alarm limits will automatically be adjusted to the following default values:

Alarm/ Parameter	CPAP into NPPV Default Value
High BPM Alarm	40
Low BPM Alarm	4
Low Airway Pressure Alarm	Off
PEEP	5 cm H_2O
V_T High Limit	Off
V_T Low Limit	Off
Rise Time	3
Pressure Support	2 cm H_2O

When transitioning from the NPPV mode to another mode, some of the parameters/ alarm limits will reset to the default values (below). This is done to assure appropriate patient monitoring in an active ventilating mode:

Alarm/ Parameter	NPPV into CPAP Default Value	NPPV into P Default Value
High BPM Alarm	25	25
Low BPM Alarm	8	8
Low Airway Pressure Alarm	(PIP Target = -3)	(PIP Target = -3)
PEEP	No change	No change
Vt High Limit	750	750
Vt Low Limit	250	250
Rise Time	No change	No change
Pressure Support	No change	If ACP, Pressure Support = 0

WARNING! Never use the Noninvasive Positive Pressure (NPPV) adjunct on a patient that is NOT spontaneously breathing and/or may stop spontaneously breathing. The NPPV adjunct is designed for "ventilatory support", NOT "ventilation".

SPONTANEOUS/ASSISTED BREATH TRIGGER
The spontaneous/assisted breath trigger is preset to -2.0 cm H_2O and can be adjusted from -6.0 to - 0.5 cm H_2O below the baseline (PEEP) pressure. In order to initiate a spontaneous or assisted breath, the patient must generate -2.0 cm H_2O. When the pressure drop is detected an assisted breath is delivered. The trigger value can be adjusted in the User Menu.

OPERATIONAL TEST PROCEDURE
Before attaching the patient to the ventilator, the user should perform an Operational Test to ensure that the breathing circuit is properly attached and that the primary patient safety alarms (*PATIENT DISCONNECT*, *HIGH AIRWAY PRESSURE*) are functioning properly. The test should be performed following connection of the breathing circuit.

Procedure:
1. With the breathing circuit connected, turn the POWER switch to "ON", allow the ventilator to complete SELF-CHECK and begin operation with its default values.
2. The *PATIENT DISCONNECT* alarm should be active. (The sound will be muted during the 2 minute initial mute.)
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 manual 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 activate after 2 breaths that reach the PIP High Limit.
5. If the *HIGH AIRWAY PRESSURE LIMIT* alarm fails to activate, assure that 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 or less.
6. After a breath or two release the patient port while allowing the ventilator to operate. The *DISCONNECT* alarm should activate.
7. If either the *HIGH AIRWAY PRESSURE* or *DISCONNECT* alarms fail to trigger, manually ventilate the patient, 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.

NOTE: The trigger automatically adjusts when the PEEP is changed.

TO BEGIN VENTILATING
1. Attach the disposable patient circuit to the ventilator. If you wish to use a Heat and Moisture Exchanger (HME), attach it to the patient connector of the ventilator circuit.
2. Attach the AC/DC CONVERTER to an appropriate AC power source if available.
3. Turn the Power switch on to initiate the self check and start the ventilator. When self check is complete, operation will begin at default values

Parameter	Mode	BPM	Vt	PEEP	FIO$_2$	I:E	High PIP Limit
Default Value	AC(V)[2]	12	500 ml	5 cm H_2O	21%[3]	1:2.5	35 cm H_2O

WARNING! Default settings are intended to provide basic support and prevent unintended injury. Particular care should be taken to adjust the ventilator appropriately before ventilating infants and children. The ventilator should always be adjusted before placing the patient on the ventilator.

4. Allow at least one breath to occur; during this time the *PATIENT DISCONNECT* alarm will activate as the ventilator does not detect the minimum required airway pressure.

5. Attach the ventilator circuit patient connector[4] to the patient's endotracheal tube, tracheostomy tube or other airway that supports positive pressure ventilation[5]. Delivery of the first breath will automatically cancel the *PATIENT DISCONNECT* alarm.

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[2] (V): indicates volume targeted ventilation
[3] If external O$_2$ is attached, the default FIO$_2$ will be 100%.

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 mask manufacturer's directions.
WARNING! During pressure targeted ventilation always set the high tidal volume just above the patient's maximum tidal volume. In the event of disconnect or decannulation the alarm will activate indicating more volume is required to reach the set pressure target.

6. Once connected to the ventilator, carefully assess the following:
   a. Attach the pulse oximeter probe and begin monitoring HR and SpO_2 (See instructions provided with the pulse oximeter probe)[6].
   b. Set the high and low HR alarms appropriately for the patient.
   c. Set the low SpO_2 limit appropriately for the patient.
   d. Assess 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.
   f. Check AIRWAY PRESSURE indicator to determine the peak airway pressure. Set the AIRWAY PRESSURE LIMIT/ALARM 5 to 10 cm H_2O above the peak pressure. This will prevent excess airway pressure.

WARNING! Always set the Low Airway Pressure Limit at least 5 cm H2O above PEEP. Ideally, the value should be 5 cm H2O < PIP.

7. Start a record of the date, time, ventilator settings, power source and patient status.
8. Check the patient and ventilator on a regular basis to assure adequate ventilation and device performance. Listen for, and respond to, all alarms.
9. During transport, reassess the patient and ventilator at least every hour or whenever the patient is moved. When operating on battery power always monitor the battery charge.

TO CHANGE SETTINGS

Each parameter button 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 based on the mode of operation and breath target. To adjust the primary parameter the operator pushes the parameter button one time; to adjust a secondary parameter the operator pushes 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 Pushbutton switch "**√**" to complete the value change.
4. At anytime the operator can exit from any operation by pressing the Mute/Cancel button "**X**".

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[4] 22 mm OD/15 mm ID standard conical interface for use with respirator devices.

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

[6] 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.

EXAMPLES

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

Example 2 - To change from volume targeted breaths to pressure targeted breaths:
  Step 1: Press the Mode parameter button twice
  Step 2: Turn the Rotary Encoder clockwise to switch from "**(V)**" volume to "**(P)**" pressure.
  Step 3: Press the Confirm/Enter button.

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 pre-existing conditions 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 (Mode AC (P), volume target, BPM 12, PIP 20 cm H2O, FIO_2 21%, PEEP 5 cm H2O, I:E 1:2, PIP High Limit 35 cm H2O).

PULSE OXIMETER

The pulse oximeter and its accessory probes and cables are intended for continuous noninvasive monitoring of functional O_2 saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by the SpO_2 sensor) for infant through adult patients. The pulse oximeter becomes operational in all ventilator modes when its cable and sensor are properly attached to the SpO_2 connector.

To operate the pulse oximeter, connect the sensor probe to the patient cable and the patient cable to the SpO_2 connector on the top of the ventilator. The monitoring function initiates automatically when a valid patient signal is detected for > 10 seconds and the unit will continuously display the patient's heart rate and SpO_2 value. The operator can set low and high alarm limits. If an alarm occurs, the operator can use this mitigation instructions to assess the condition of the patient and as an aid in determining what intervention is required.

HUMIDIFICATION

Heat and Moisture Exchangers (HME's) 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 an HMEF may help reduce the risk of cross contamination of biologic pathogens that might be transmitted in the patient's exhaled gas. HMEs or HMEFs attaches between the disposable ventilator circuit and patient's endotracheal tube. Be sure to follow all instructions provided by the manufacturer. The table below gives guidance on appropriate tidal volume ranges using various HMEs with both the Adult and Infant circuits.

Patient	Weight (kg)	V_T Range (ml)	HMEF Dead Space	Circuit Dead space (ml)	Total Dead space (ml)	Minimum V_T (ml)
Adult	≥ 40	≥ 400	≤ 75 ml	17 (adult)	≤ 92	360
Pediatric	12 to 50	120 to 500	≤ 25 ml	17 (adult)	≤ 42	168
Pediatric	12 to 50	120 to 500	≤ 25 ml	4 (infant)	≤ 29	117
Infant	5 to 12	50-120	≤ 10 ml	4 (infant)	≤ 14	56

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[7]. 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. For very small tidal volumes (50 to 75 ml) it may be advisable to not use an HME.

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)

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[7] Kacmarek et al (Respiratory Care 1990;35:405)

HAZARDOUS ENVIRONMENT FILTERS

The EMV+ can be used in environments where chemical and/or biological toxins are present. To do this safely, all gas delivered to the patient comes from either a pressurized medical-grade O_2 source and/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 anti-asphyxia 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 and cause a ventilator failure (see Figure 4).

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 (see Figure 13). 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 the Universal Precaution procedures for your facility. |

CHEMICAL/BIOLOGICAL FILTER USE

The EMV+ is designed to allow attachment of chemical/biological filter/canister (type C2A1[8]) 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.

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[8] 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.

CHECK VALVE ON BREATHING CIRCUIT WHEN IN HAZARDOUS ENVIRONMENT

When operating in a Hazardous Situation when Bacterial/ Viral or Chemical/ Biological filters are in use, the operator should also make sure that a Check Valve (PN# 704-0700-01) is used to prevent hazardous gas from entering the patient's breathing circuit. The exhalation valve on the breathing circuit is not adequate to protect the Patient if they are rapidly inhaling/ exhaling as the valve may not fully close in time to prevent hazardous gas entrainment. Also, if the PEEP is set low, the patient can inhale faster than the flow is being delivered, and this could also cause hazardous gas entrainment. Consequently, a Check Valve is required to protect the Patient.

WARNING! Unit is shipped with both the pediatric/ adult and infant/pediatric single limb circuits. A check valve (704-0700-01) is required with these breathing circuits when operating in a Hazardous Environment. The correct mating of the check valve with the breathing circuit is shown in Figure 12. Operators who anticipate use in these environments should also stock the Check Valve.
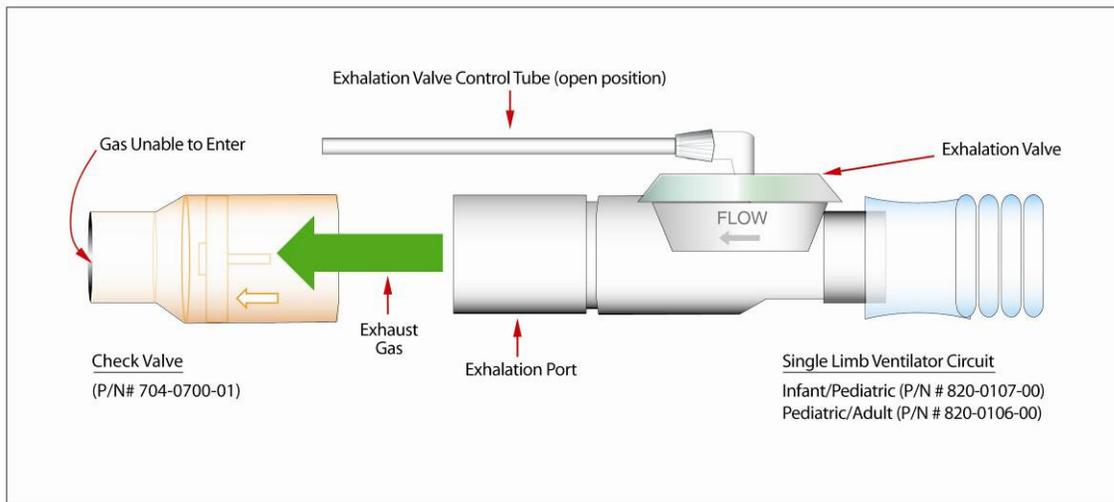

CHECK VALVE CONNECTION TO BREATHING CIRCUIT: FIGURE 12

FRESH GAS/EMERGENCY AIR INLET

BACTERIAL/ VIRAL FILTER
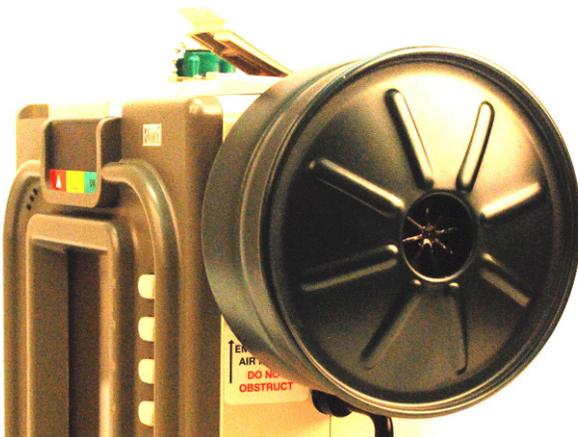
CHEMICAL/ BIOLOGICAL FILTER

HAZARDOUS ENVIRONMENT FILTERS: FIGURE 13

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 can also keep the unit in the soft case which will protect the EMV+ 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+ has been validated by Impact Instrumentation to be capable of operating over a range of -25° to 49° C (-13° to 120° F) and above when required during emergency situations. (The SGS listed operation range is 10° to 40°/ 50° to 104F.) 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 have been validated by Impact Instrumentation of being capable of discharging from -25° to 49° C (-13° to 120° F). In addition, the device has been validated by Impact Instrumentation to be 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. This prevents damage to the Li battery from charging at high temperatures, which would void the battery warranty. The battery is still able to discharge and power the unit. Operators can improve temperature performance by making sure that the unit is in the 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 pressure 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).

WARNING! 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 device.

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. In cases of driving rain, where water could possibly enter the unit's compressor, the bacterial-viral filter can be used to protect the compressor.

O2 Supply Pressure Low

- Operation Switched to Compressor
- Check O2 Supply Pressure
- Check/Replace Regulator
- Set FIO2 to 21%
- Connect Low Flow O2
- Monitor SpO2

  Replace/Service Ventilator

#2020

HR ♥ 62 120 / 40

SpO₂ 82 80

FiO₂
O2 USE 1.2 **100**

PIP **15** 20
PEEP 0 10

Vt(del) 410
272 0

BPM 25
I:E 1:2.5 **15** 8

Mode IV
AC (P)

50% O₂

Vmin 4.0 | MAP 8.8 | BPMt 15 | T 1.14

0   50   100
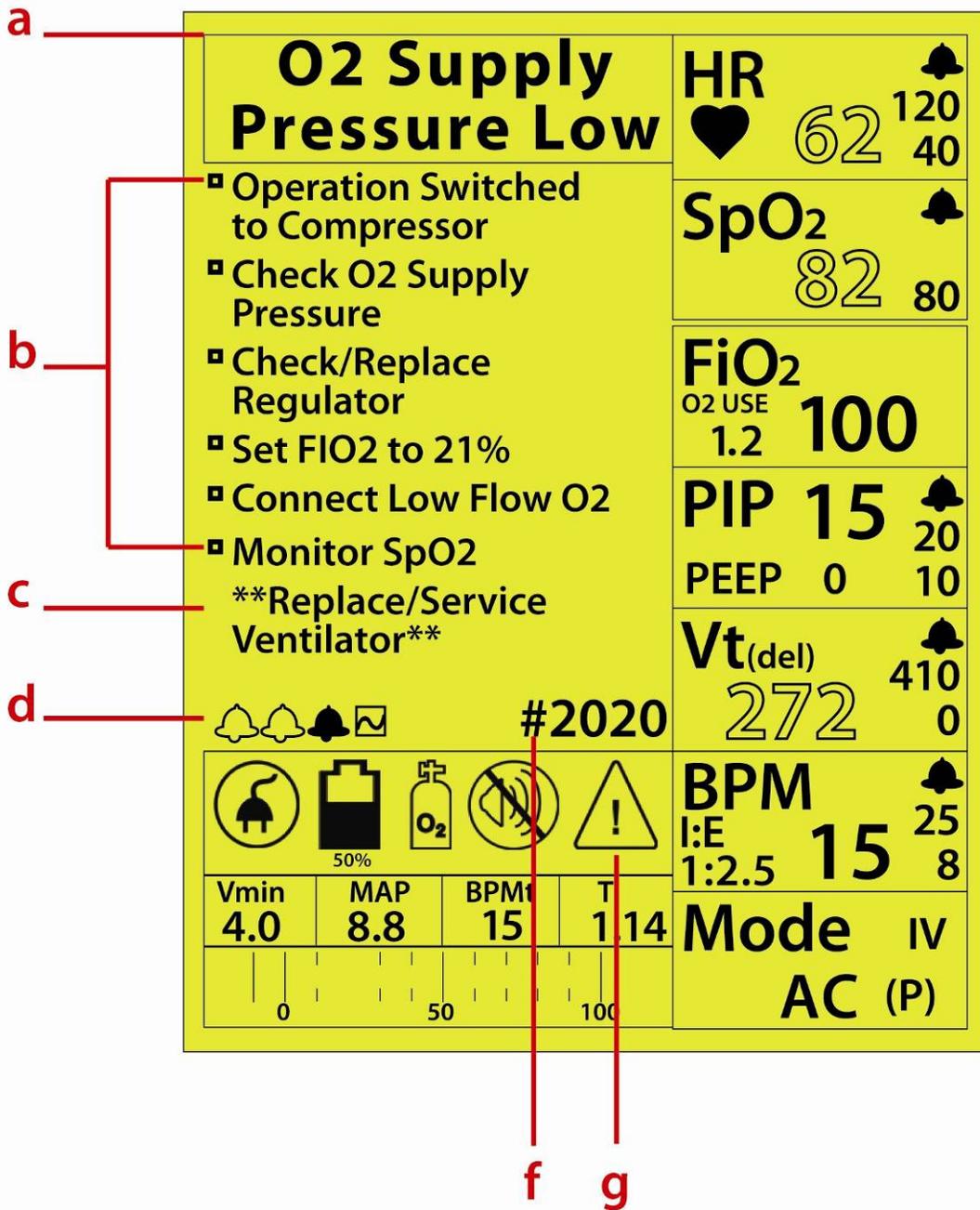
ALARM **D**ISPLAY: **F**IGURE **14**

ALARM FUNCTIONS

At the onset of an alarm, a multi-line message screen appears in the upper left-hand corner of the LCD (see Figure 14). 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. Alarms are prioritized based on the risk to the patient. The alarm with the greatest risk to the patient is always presented first. All 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) (a): contains the information and instructions for all active alarms.

Alarm Name/Description (b): 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 (c): instructions for the operator as to how the alarm state may be resolved.

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

Alarm Number Icon (e): 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 as the solid bell. To view each active alarm, turn the rotary encoder to scroll through all active alarms. If there are less than 5 alarms, the plot icon will also appear. See Figure 10 (Alarm & Plot list) for details on the appearance of these alarms and plot icon.

Service Code (f): 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 (g): identifies the severity of the alarm: low, medium or high priority. See Symbols & Icons table for appearance of the warning triangle for each of these three alarms.

ALARM PRIORITIES
Alarm priorities define the operational state of the device regarding its ability to provide mechanical ventilation. The alarm priority determines what effect pressing the Mute/Cancel button will have. There are three priorities:

High Priority: mechanical ventilation under operator control is no longer possible. This alarm category requires immediate intervention by the operator. This includes system failure alarms where the CPU has failed and a backup has taken over to sound the audible and visual alarms. It also includes when the device is turned on and there is no internal or external power source. Pressing the Mute/Cancel button 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 button 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 (Advisory): 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 button cancels the audible signal. If the alarm is not resolved the yellow LED remains illuminated to remind the operator of the fault or failure. Some Low Priority alarms may be canceled to avoid nuisance alarms, see Alarm Cancelation section above.

VENTILATOR ALARM CATEGORIES

Alarms are presented and grouped as categories rather than individual alarms because any given fault/failure may have a different effect 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 describes the activation characteristics and background information.

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 button 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 through 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/O_2 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 FIO_2 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.

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 be >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 ≥ 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, when the internal or external filters become dirty or clogged or when the low pressure O_2 reservoir is used. The pressure drop across the intake is continuously monitored. A High Priority alarm (code 1030) occurs 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. A Medium Priority alarm (code 2030) occurs when the obstruction prevents the compressor from delivering a breath that meets the ventilator settings and there is a 55 psig O_2 supply available to operate the O_2 valve as a backup. Changing FIO_2 to 100% will downgrade this alarm to a Low Priority (code 3030). A Low Priority alarm (code 3031) will occur when the intake is restricted, but the compressor can still deliver a breath that meets the ventilator settings.

Power Fault/Failure: alarms are associated with power management and the supply of power from external sources and the internal rechargeable battery. High Priority alarms alert the operator to power failures where there is no backup power alternative or failures of the internal power management system. Pressing the Mute/Cancel pushbutton has no affect on the alarm; the alarm can only be silenced by turning the ventilator off. Low Priority alarms are associated with faults or failures that occur where a backup power source is available either by using the internal battery or through use of the external power source. Pressing the Mute/Cancel button 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 there is no external source detected. Pressing the Mute/Cancel button 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 button 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 button 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 operator 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 button 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 button 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 button 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. Resolution of this fault is typically associated with problems causing restrictions to the exhalation valve. Pressing the Mute/Cancel button mutes the audible alarm for 30 seconds.

Airway Pressure High: alarm is triggered when the airway pressure exceeds the High Airway Pressure Limit value for two consecutive breaths. 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 value that is too low given the airway pressure. The default value at start up is 35 cm H_2O and instructions for changing the value are found above. Pressing the Mute/Cancel button mutes the audible alarm for 30 seconds.

PEEP Not Met/ Leak: alarm is triggered when the ventilator detects a drift of more than 2 cm H_2O in the end expiratory pressure. This Medium Priority alarm is most often associated with a loose or disconnected circuit hose or tube. The alarm can also be triggered when leaks are present during noninvasive mask ventilation or when uncuffed endotracheal or tracheostomy tubes are used. 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.   Pressing the Mute/Cancel button 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 button mutes the audible alarm for 30 seconds.   The operator can suppress the Low Priority persistent message for the current operational session using the procedures described in the Alarm Cancelation section.

RTC Battery Fault/Failure: alarm is associated with the voltage of the real-time clock (RTC) battery that powers the memory that stores calibration and service information. The operator should immediately

take the ventilator out of service. A Low Priority Alarm is sounded when RTC battery voltage drops below the replacement threshold. Pressing the Mute/Cancel button cancels the audible alarm and yellow LED remains illuminated with the persistent message.   The operator can suppress the Low Priority persistent message for the current operational session using the procedures described in the Alarm Cancelation section.

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 button cancels the audible alarm and yellow LED remains illuminated with the persistent message. The operator can suppress the Low Priority persistent message for the current operational session using the procedures described in the Alarm Cancelation section.

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 operator 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 button 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 delivered volume and to monitor the airway pressure and breath sounds to assure adequate ventilation of the patient. Pressing the Mute/Cancel button 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 button mutes the audible alarm for 30 seconds. The default low alarm limit at start up is 94%.

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 button mutes the audible alarm for 30 seconds. The default high alarm limit at start up is 120 beats/minute.

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

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 button mutes the audible alarm for 30 seconds. In order to suspend the alarm the operator is required to use the Menu controls to place SpO$_2$ monitoring in standby "stby". Doing this cancels the Medium Priority alarm but the yellow LED and persistent message remain.

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. This alarm will not occur when the pulse oximeter is in standby, "stby". 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. The alarm can also be suspended, by pressing the Mute/Cancel pushbutton, pressing the Menu pushbutton, select Pulse Oximeter, and setting the field to "stby".

> **NOTE:** If the EMV+ is started without a pulse oximeter sensor cable attached, pulse oximeter monitoring does not start and the alarms are not enabled. At any time after start up, attaching the sensor to the ventilator and patient automatically starts monitoring and all alarms are enabled.

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 button cancels the alarm. To clear the alarm, check/replace the sensor or suspendf SpO$_2$ monitoring by placing it in standby, "stby".

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 button cancels the alarm. To clear the alarm, check/replace the sensor or suspend SpO$_2$ monitoring by placing it in standby, "stby".

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 button cancels the alarm. To clear the alarm, check/replace the sensor or turn off SpO$_2$ monitoring by placing it in standby.

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 to check the position of the sensor, patient movement and/or the perfusion at the sensor site. Pressing the Mute/Cancel button cancels the alarm. To clear the alarm, reposition the sensor to a better site or suspend SpO$_2$ monitoring by placing in standby, "stby".

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 button cancels the alarm. To clear the alarm, remove the patient from the area or shield the patient/sensor or suspend SpO$_2$ monitoring by placing it in standby, "stby".

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 by placing in standby, "stby".

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 button cancels the alarm. To clear the alarm, use an appropriate sensor or suspend SpO$_2$ monitoring by placing it in standby, "stby".

ROUTINE CARE: CALIBRATION, CLEANING AND PREVENTATIVE 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 or 1500 service hours, unless significant usage warrants a shorter period between preventative maintenance inspections. The device performs a calibration check as part of the startup routine when the device is powered on. 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 month/ 1500 service hour 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.

GENERAL 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 this instrument 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 – with the ventilator not connected to a patient, power cycle the ventilator after every 1000 hours of use and using a ventilator circuit and test lung, 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. To insure compliance with operating specifications, it is the user's responsibility to insure that periodic preventative maintenance is performed. It is

recommended that the In-Field Calibration Check be performed by Impact or a certified Impact service facility.

5. Impact Instrumentation recommends that on a daily basis the operator examine the breathing circuit for damage or wear including but not limited to cracking, discoloration or disfigurement. If there is any sign of physical degradation or the unit is indicating breathing circuit problems, the Operator should replace with a new breathing circuit.

REMOVABLE FOAM FILTER REPLACEMENT

Removable Foam Filter: The Removable Foam Filter is located on the right side of the ventilator. It should be inspected and replaced if needed every 1,000 hours of operation or more frequently if used in dusty environments. 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.

CAUTION! Do not operate the compressor without a filter 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. This filter must be checked periodically and replaced when necessary. The EMV+ triggers an alarm when the combination of Removable Foam Filter and Fresh Gas/Emergency Air Intake Disk Filter become dirty. This alarm signifies that the EMV+ is still able to deliver the correct tidal volume but one or more of its filters need replacement. The Fresh Gas/Emergency Air Intake Disk Filter can be visually inspected after the Removable Foam Filter is removed. If the filter appears discolored it must be replaced. See Appendix 5: Internal Filter Change/Insertion.

CAUTION! There are no user serviceable parts except the filter components described above.
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.
NOTE: Do not attempt to clean this filter and do not operate internal compressor without filter in place.

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. 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 horizontal rows of lines indicating its current capacity. Each line represents approximately 5% of battery capacity.

BATTERY CARE AND CHARGING

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.

If the unit was supplied without the battery installed or battery replacement is required see Appendix 4: Internal Battery Change/Insertion.

CAUTION! Only use the Power Supply provided with the unit. Use of any other power supply could cause damage or create 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, turn off the unit, disconnect external power 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. Battery charging is controlled by ventilator in the temperature range of 0°C to 45°C (32F to 113°F) to provide the best life time for the battery
2. The battery has a discharge (operational) temperature range of -25° to 49° C (-13° F to 120° F) (as validated by Impact Instrumentation).
3. DO NOT store the ventilator with the batteries discharged. Always store with the battery fully charged.
4. For long-term storage, the optimum storage temperature range is -15°C to 21°C (5°F to 71°F).

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 every six months; this will insure that battery charge is maintained at 80% capacity or better. The EMV+ battery rapidly 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. 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 horizontal rows of lines indicating its current capacity. When the battery is charging, these horizontal rows of lines cyclically scroll vertically, one row at a time, from the bottom row to the top . When the battery is fully charged, the icon is completely filled with lines and scrolling stops. Each line represents approximately 5% of battery capacity. During internal battery operation a horizontal line "disappears" as battery capacity is reduced by a 5% 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.

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.

OPERATOR CORRECTABLE PROBLEMS

Common problems may be quickly rectified by operator following this instructions provided in the alarm mitigation instructions. Should this device 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).

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 back cover. This information is also contained in the User Menu, Unit Info.

STORAGE INFORMATION

For optimal 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. 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 (95°F). It is recommended that batteries be discharged to 50% capacity if long term storage above 35°C (95°F) 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 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 Modes	AC, SIMV, CPAP with and without Pressure Support and with and without Noninvasive Positive Pressure Ventilation (NPPV)
Breath Target	Volume and pressure
Flow Rate	0 to 100 LPM @ 40 cm H_2O (3922 Pa)
Breath Rate	1 to 60 BPM
Tidal Volume	50 to 1500 ml ATPD +/- 10% of setting
Inspiratory Time	0.3 to 3.0 seconds
FIO_2	21 to 100% +/- 3% of full scale +/- 10% of setting
PEEP	0 to 25 cm H_2O (0 to 2451 Pa) (The minimum PEEP in CPAP-NPPV mode is 3 cm H_2O)
Peak Inspiratory Pressure (PIP)	10 to 80 cm H_2O (980 to 7845 Pa) (values >60 cm H_2O require secondary user confirmation) +/- 5 cm H_2O +/- 10% of setting
Oxygen Input Pressure	55 psig (-25%; + 20%) (379170 Pa)
Airway Pressure High Limit	20 to 100 cm H_2O values (1961 to 9806 Pa)
Airway Pressure Low Limit	Off, 3 to 35 cm H_2O (294 to 3432 Pa)
Breath Trigger	-6.0 to - 0.5 cm H_2O (-588 to -49 Pa) below baseline/PEEP
PIP Bar Graph	-10 to 100 cm H_2O (-980 to 9806 Pa)
LED Status/Alarm Indicator	Red, yellow and green
Alarm Volume	82 dBA @1-meter
Noise Level	~60 dBA when measured @1-yard (operating at default settings using the compressor only)
Operating Voltages	100 to 240 VAC (50/60 & 400 Hz) or 12.5 to 28.0 VDC, validated by Impact Instrumentation
	100 to 240 VAC (50/60 Hz) or 12.5 to 28.0 VDC, SGS listed
Operating Time	
Internal Battery	10 hours at default settings
External AC	Continuously
External DC	Continuously
Temperature Ranges	
Operating	-25° to 49° C (-13° to 120° F) battery discharge and AC power operation based on Impact Instrumentation validation
	10° to 40° C (50° to 104° F) with battery charging, battery discharge and AC power operation (SGS listed)
Battery Charging	0° to 45° C (32° to 113° F)
Long Term Storage	-15° to 21° C (5° to 71° F) Optimal storage conditions
Control Accuracy/Precision	± 10% of setting for all measured values & controls not other specified

Parameter	Operating Range
Size	8.0" Wide X 12.5" High X 4.5" Deep(20.3 cm Wide X 31.8 cm High X 11.4 cm Deep)
Weight	9.7 lbs (4.4 kg)
Warranty	Limited, 1-year (see LIMITED WARRANTY statement)

This unit meets the Classification requirements of IEC 60601-1 (2nd edition, 1988) as indicated in the following table:

IEC 60601-1 Clause	Category	Classification
5.1 a) External Electrical Power Source 5.1 b) Internally Powered Equipment	Type of Protection against Electric Shock	Class 1: Protection against electric shock does not rely on Basic Insulation only, but includes an additional safety precaution in that means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.
5.2	Degree of protection against electric shock	BF: Type B with floating (F-type) parts
5.3	Degree of Protection against harmful ingress of water	IPX4: Splash-proof equipment (equipment protected against splashing water when enclosed in padded case/ rain flap with bacterial-viral filter protecting compressor.)
5.4	Method of Sterilization or Disinfection	Pressure hose connections should be wiped with a damp, soapy cloth and thoroughly dried with a lint-free cloth. The unit'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.
5.5	Degree of Safety of Application in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide	Equipment not suitable for use in presence of Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide
5.6	Mode of Operation	Continuous Operation

The unit was tested for the effect of pressure at the patient connection port (e.g airway pressure) on the V_T and Oxygen concentration.

The tests consisted of a core matrix of volume or pressure targets for a set of resistances and compliances, based on the ASTM F1100 guidance. These test cases were then performed at different PEEP targets, FIO_2 settings, and with different patient circuit accessories and Fresh Gas Intake accessories. The possible settings and accessories are listed below:

Setting/ Accessories	Value
PEEP Settings	0, 5, 25
FIO_2 Settings	21, 30, 50, 90, 100
Patient Circuit Accessories	No Accessory HME HME + BV HMEBV
Intake Filter Accessories	No Accessory C2A1 BV Filter O2 Reservoir

The following accuracies/ precision were observed for adult settings:

Parameter	Accuracy/ Precision
V_T, Tidal Volume	±10% of setting
Pressure Target Accuracy	± 5 cm H_2O for setting < 30, else ± 10 cmH2O
PEEP Accuracy	± 1.5 cm H_2O ±10% of setting
FIO_2 Accuracy	± 3% of full scale ± 10% of setting

LIMITED WARRANTY

Impact Instrumentation, Inc. warrants the device to be free from all defects in material and workmanship for a period of one (1) year from the date of delivery to the original purchaser.

During the warranty period, Impact will repair or replace the device or any part which upon examination is shown to be defective. At its sole discretion, Impact may choose to supply a new or equivalent replacement product or refund the amount of the purchase price (on the date sold by Impact). To qualify for such repair, replacement, or refund, the defective device must be returned to the Impact Service Center within thirty (30) days from the date that the defect is discovered. This warranty does not apply if the device has been repaired or modified without the authorization of Impact or if the damage was caused by incorrect (off-label) use, negligence or an accident

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 breathing circuits, are not warranted.

DISCLAIMER OF IMPLIED & OTHER WARRANTIES:
THE PRECEDING WARRANTY IS THE EXCLUSIVE WARRANTY AND IMPACT INSTRUMENTATION, INC. MAKES NO OTHER WARRANTY OR REPRESENTATION OF ANY KIND WHATSOEVER, EXPRESS OR IMPLIED, WITH RESPECT TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER. THE REMEDIES STATED IN THIS DOCUMENT WILL BE THE EXCLUSIVE REMEDIES AVAILABLE TO THE CUSTOMER FOR ANY DEFECTS OR FOR DAMAGES RESULTING FROM ANY CAUSE WHATSOEVER AND WITHOUT LIMITATION.

IMPACT INSTRUMENTATION, INC. WILL NOT IN ANY EVENT BE LIABLE TO THE CUSTOMER FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, WHETHER FOR DEFECTIVE OR NONCONFORMING PRODUCTS, BREACH OR REPUDIATION OF ANY TERM OR CONDITION OF THIS DOCUMENT, NEGLIGENCE, OR ANY OTHER REASON.

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 HP O_2, Restart Ventilator With HP O_2
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 HP O_2, Restart Ventilator With HP O_2
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. This unusually low RPM is a symptom of a dirty flow screen which cannot be serviced by the operator.
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 Pressure Low**
Alarm occurs when the O_2 supply pressure is ≤ 35 psig and the compressor is not available 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 flow 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 (Compressor Intake Blocked - No Backup)**

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. (A false alarm can be triggered in very high vibration environments.)

Mitigation/Info: Manually Ventilate Patient, Clear Blocked Intake, Connect 55 psig O2, Restart Ventilator

**Replace/Service Ventilator **

1041   **O2 Supply Pressure High**

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 75 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. (A false alarm can be triggered in very high vibration environments.)

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 High limit (when PIP High 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 ***

1172   5 Volt Self Check Failure

Alarm occurs when the 5 volt power bus fails to provide the required voltage. If this failure occurs, the operator should manually ventilate the patient, replace the ventilator and send the unit for service.

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

1173   Internal Communication Failure (Host Device Communication Failure)

Alarm occurs when communication fails between one of the subcomponents and the host processor. If this failure occurs, the operator should manually ventilate the patient, replace the ventilator and send the unit for service.

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

1174   Off Set Self Check Failure

Alarm occurs when the device is not able to calibrate the one or more transducers and is no longer able to operate safely. If this failure occurs, the operator should manually ventilate the patient, replace the ventilator and send the unit for service.

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

1175   Internal Communication Failure

Alarm occurs when there is a failure of the internal communication bus and the host is not able to communicate with the subassemblies. If this failure occurs, the operator should manually ventilate the patient, replace the ventilator and send the unit for service.

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

1176   Off Set Self Check Failure

Alarm occurs when the calibration file fails its integrity check. If this failure occurs, the operator should manually ventilate the patient, replace the ventilator and send the unit for service.

Mitigation/Info: Manually Ventilate Patient, Ventilator Not Functioning
*** 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 with external power the unit must be turned off and then back on.
Mitigation/Info: Manually Ventilate Patient, Connect to External Power, Restart Ventilator
Replace/Service Ventilator

1471   Internal Communication 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 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 Communication 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 Communication 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**

Alarm occurs when the communication between the compressor 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 operator 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 FIO_2 to 100%
Replace/Service Ventilator

2002 **Compressor Fault**

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 operator 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 FIO_2 to 100%
Replace/Service Ventilator

2011 **O2 Valve Fault**

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 operator 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 FIO_2 To 21%, Connect Low Flow O2, Monitor SpO2
Replace/Service Ventilator

2012 **O2 Valve Fault**

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 operator 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 FIO_2 To 21%, Connect Low Flow O_2, Monitor SpO2
Replace/Service Ventilator

2020 **O2 Supply 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%. The alarm will cancel completely when the user sets to 21%.

> **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 FIO_2 to 21%. Connect Low Flow O2, Monitor SpO2
**Replace/Service Ventilator **

2030   Fresh Gas Intake Fault
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. Once 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. A high vibration environment can trigger this alarm. If necessary, the operator can activate the O_2 Reservoir Mode while continuing to operate normally. This will suppress the alarm.
Mitigation/Info: Operation Switched to O2 Valve, Clear Blocked Intake, Set FIO2 to 100%, Monitor SpO2
**Replace/Service Ventilator **

2053   Suspicious Triggers
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_2O 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 Fault
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 and send it for service.
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 meets or is greater than the high airway pressure limit for 2 consecutive breaths. 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 (dissynchrony) 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 High Limit Set Too Low?
** Manually Ventilate Patient**

2071   Low Airway Pressure

Alarm occurs when the Paw is less than the low airway pressure limit for 2 consecutive breaths. The operator should check for leaks/disconnects in the breathing circuit, patient airway or a failure of the exhalation valve. The operator should also assess if the patient is breathing with the ventilator or if the low airway pressure limit is set too high. If a replacement is available the operator should replace the breathing circuit. 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, Is Low Limit Set Correctly?
** Manually Ventilate Patient**

2072   High Tidal Volume

Alarm occurs when operating with a pressure target and the delivered tidal volume exceeds the operator defined limit for 2 consecutive breaths. This can be caused by a leak in the patient connection or breathing circuit. When the ventilator is not able to reach the pressure target flow increases to compensate which leads to a high delivered tidal volume. It is critical to set this alarm with infant and pediatric patients given the high resistance airways used with these patients can provide a false airway pressure even when the patient has extubated or decannulated. The operator should check for leaks/disconnects in the breathing circuit, patient airway or a failure of the exhalation valve. The operator should also assess if the patient is anxious and breathing deeply or if the high tidal volume limit is set too low. If a replacement is available the operator should replace the breathing circuit.
Mitigation/Info: Check Patient Connection, Check Circuit For Loose Hose/Tube, Check Exhalation Valve, Check Tube Placement/Cuff, Is High Limit Set Correctly?
** Monitor Patient**

2073   Low Tidal Volume

Alarm occurs when operating with a pressure target and the delivered tidal volume does not reach the operator defined limit for 2 consecutive breaths. When this occurs flow decelerates to maintain the Paw at airway pressure limit for the duration of the breath (inspiratory time). If the PIP setting is set properly the breath should be greater than the low limit (provided it is set properly as well). The operator should check for kinks or blockage of the breathing circuit 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 (dissynchrony) or if the high airway pressure limit is set too low.

Mitigation/Info: Check Circuit For Kinked Hose/Tube, Check For Airway Obstruction, Suction Airway If Necessary, Is Low Limit set correctly?
*** Manually Ventilate Patient***

2074   **High Breath Rate**

Alarm occurs when the actual breathing rate (set rate plus spontaneous patient rate) exceeds the high alarm limit. This can be caused by the patient breathing too fast due to anxiety or pending respiratory failure. It can also be caused by autotriggering due to a leak or the when the spontaneous/assisted breath trigger is set too close to the baseline pressure (PEEP). The operator should check for leaks/disconnects in the breathing circuit, patient airway or a failure of the exhalation valve. The operator should also assess if the patient is anxious and breathing deeply or if the high tidal volume limit is set too low. If a replacement is available the operator should replace the breathing circuit.

Mitigation/Info: Check For Loose Hose/Tube, Is Trigger Level Too Sensitive, Is High Alarm Limit Set Correctly?
*** Consult Physician***

2075   **Low Breath Rate/Apnea**

Alarm occurs when the actual breathing rate (set rate plus spontaneous patient rate) is less than the low alarm limit. This can be caused by the patient not breathing or breathing at a rate less than the limit. If the spontaneous/assisted breath trigger is not sensitive enough the patient may not be able to trigger breaths. The operator should also determine if the low rate is set too high for the patient.

Mitigation/Info: Is Patient Breathing Spontaneously?, Is Trigger Level Sensitive Enough?, Is Low Alarm Limit Set Correctly?, Increase Ventilation Support
*** Manually Ventilate Patient***

2076   **Apnea**

Alarm occurs when the spontaneous breathing rate is less than the low alarm limit. This alarm only occurs in CPAP and CPAP-NPPV. This can be caused by the patient not breathing or breathing at a rate less than the limit. The apnea backup ventilation starts automatically. The operator should set the mode to AC or SIMV. The Rate and Tidal Volume/Pressure targets should also be set.

Mitigation/Info: Apnea Backup Ventilation Started. Set Mode to AC or SIMV, Set Rate and Tidal Volume/Pressure Target
*** Manually Ventilate Patient***

2090   **PEEP not met/ Circuit Leak**

Alarm occurs when Paw drops below the PEEP setting by 2 cm H_2O 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***

2095   **Insufficient Flow**

Alarm occurs when the pressure target is not reached during the inspiratory period during pressure targeted ventilation. Typically this can occur when the Rise Time is set too low for the patient and their respiratory mechanics. Decrease the Rise Time and check the circuit and

exhalation valve for leaks or disconnects. If the flow cannot be adjusted appropriately then the patient should be ventilated using volume targeted ventilation.

Mitigation/Info: Pressure Target Not Met, Decrease Rise Time , Press/Hold BPM Button
** Ventilate With Volume Target**

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

2170   **Spontaneous Breath – PIP High**

Alarm occurs when the Paw exceeds the High PIP Limit Setting during 2 consecutive spontaneous breaths. When this occurs, the operator should quickly check for kinked hoses/ tubes and check for airway obstruction. Patient should be suctioned if necessary. The operator should also check if the High PIP limit is set correctly. While resolving the alarm condition the operator should be sure to manually ventilate the patient.

Mitigation/Info: Pressure Exceeds Limit Setting, Check Circuit for Kinked Hose/Tube, Check for Airway Obstruction, Suction Airway if Necessary, PIP High Limit set too Low?
Manually Ventilate Patient

2171   **Spontaneous Breath – PIP Low**

Alarm occurs when the Paw exceeds the Low PIP Limit Setting during 2 consecutive spontaneous breaths. When this occurs, the operator should quickly check circuit for loose hoses/ tubes and also check the exhalation valve and the tube placement/ cuff . The operator should also check if the Low PIP Limit is set correctly. While resolving the alarm condition the operator should be sure to manually ventilate the patient.

Mitigation/Info: Check Circuit for Loose Hose/Tube, Check Exhalation Valve, Check Tube Placement/ Cuff, is Low Limit set correctly?
Manually Ventilate Patient

2172   **Spontaneous Breath – V_T High**

Alarm occurs when high V_T Limit is exceeded during 2 consecutive spontaneous breaths. When this occurs, the operator should check: the patient connection, airway placement, breathing circuit for loose hoses/ tubes and also check the exhalation valve. The operator should also check if the High V_T Limit is set correctly. While resolving the alarm condition the operator should be sure to manually ventilate the patient.

Mitigation/Info: Check Circuit for Loose Hose/Tube, Check Exhalation Valve, Check Tube Placement/ Cuff, is High Limit set correctly?
Manually Ventilate Patient

2173   **Spontaneous Breath – V_T Low**

Alarm occurs when the Low V_T Limit Setting is not achieved during 2 consecutive spontaneous breaths. When this occurs, the operator should quickly check for kinked hoses/ tubes and check for airway obstruction. The patient should be suctioned if necessary. The operator should also check if the Low V_T limit is set correctly. While resolving the alarm condition the operator should be sure to manually ventilate the patient.

Mitigation/Info: Check Circuit for Kinked Hose/Tube, Check for Airway Obstruction, Suction

Airway if Necessary, is Low Limit set correctly?
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 put the pulse oximeter in standby "stby".

Mitigation/Info: Internal Failure, SpO2/HR Not Available, Turn Off Pulse Ox
Replace/Service Ventilator

2301   **Internal Communication 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 "stby" 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   **SpO2 Sensor Off Patient**

Alarm occurs when an operating sensor loses 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 put the pulse oximetry monitor in standby "stby".

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: SpO_2 Below Limit, Increase FIO_2, Check O_2 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 (Pulse 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: Input protection circuit failure, 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**

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**

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, Assure External Power Available, Assure Ability to Manually Ventilate, Shade Patient and Ventilator

Move To Cooler Location

2455 **Battery Fault – No External Power Connected**

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 battery 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 Communication Failure!, Connect External Power, Assure Ability to Manually Ventilate Patient

Replace/Service Ventilator

3001 **Compressor Fault**

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**

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**

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 FIO$_2$ at 21%, Connect Low Flow O2, Monitor SpO2

Replace/Service Ventilator

3012   **O2 Valve Fault**

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 FIO$_2$ at 21%, Connect Low Flow O2, Monitor SpO2

Replace/Service Ventilator

3030   **Fresh Gas Intake Fault**

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. (It is possible for this alarm to be a false alarm that is triggered in a very high vibration environment.)

Mitigation/Info: O2 Valve Operation, Clear Blocked Intake & Retry Compressor, Keep FIO$_2$ at 100%, Monitor SpO2

**Replace/Service Ventilator **

3031   **Fresh Gas Intake Fault**

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, Patient Breathing with Ventilator?

**Replace/Service Ventilator **

3032   Fresh Gas Intake Fault

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

Alarm occurs when the O_2 supply pressure is ≥75 psig and < 80 psig. The alarm automatically cancels when the supply pressure drops below 66 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 O_2 Supply Pressure, Replace Regulator, Connect Low Flow O_2, Monitor SpO$_2$

** Monitor O2 Supply Pressure**

3091   Incomplete Exhalation

Alarm occurs when the exhaled flow from the patient continues throughout the expiratory period causing the expiratory control valve to cycle throughout the period to maintain the baseline pressure. When this occurs the operator should increase the expiratory period by decreasing the inspiratory time, decreasing the breathing rate or both. The physician should also be consulted as this alarm is an indication that autoPEEP is occurring.

Mitigation/Info: Incomplete Exhalation, Increase Expiratory Time, Decrease Inspiratory Time, Decrease Respiratory Rate

** Consult Physician**

3092   Patient Inspiratory Demand Not Met

Alarm occurs when the end Inspiratory Paw is < -1.0 cm H_2O for 3 consecutive breaths. (3 breaths are required to eliminate nuisance alarms when the patient takes a single deep breath.) This can occur due to changes in the patient's status, where the patient will attempt to inspire more gas than what is currently being delivered. When this occurs, the operator should note if the patient is breathing or fighting with the vent. The operator should increase the flow rate (by decreasing the inspiratory time) and/or reduce the rise time. The physician should be consulted.

Mitigation/Info: Patient Breathing/ Fighting with Vent?, Increase Flow Rate or Reduce Rise Time, Adjust Alarm Settings if Required, Consult Physician

Manually Ventilate Patient

3110   RTC Battery Fault

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**

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 or 1500 hours of service. 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**

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 (Excessive Temperature High)**

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 no effect 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 **SpO2 Shutdown (MS 11 Failure - Monitor Not In Use)**

Alarm occurs when the pulse oximeter module fails and the operator has turned off pulse oximeter monitoring acknowledging the condition. When this is done "stby" 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 **SpO2 Shutdown (Communication 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 "stby"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 Oximeter Module Failure, SpO2/HR Not Available
Replace/Service Ventilator

3310 **No SpO2 Sensor Connected (No Sensor 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 by placing it in standby.

Mitigation/Info: Check Pulse Ox Sensor, Check Sensor/Ventilator Connection, Reinsert Sensor, Cable/Sensor Damaged?, Replace Sensor

Turn Off Pulse Ox Monitoring

3311   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 suspend pulse oximetry monitoring by placing it in standby "stby".

Mitigation/Info: Check Pulse Ox Sensor, Check Sensor/ Ventilator Connection, Reinsert Sensor, Cable/Sensor Damaged?, Replace Sensor

Turn Off Pulse Ox Monitoring

3312   SpO2 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 suspend pulse oximetry monitoring by placing it in standby "stby".

Mitigation/Info: Please Wait, Check Sensor Placement, Change Placement, Minimize Patient Movement, Check Sensor Operation/Replace

Turn Off Pulse Ox Monitoring

3313   SpO2 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 Pulse Ox Monitoring

3315   Too Much Ambient Light

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: Shield Sensor From Light, Change Sensor Placement, Check Sensor Operation, Replace Sensor

Turn Off Pulse Ox Monitoring

3316   Invalid SpO2 Sensor (Unrecognized 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 by placing it in standby "stby".

Mitigation/Info: Invalid Pulse Ox Sensor, Replace Sensor

Turn Off Pulse Ox Monitoring

3317   Low SpO2 Perfusion (Low 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,, Check Sensor Operation

Turn Off Pulse Ox Monitoring

3318   **Low SpO2 Perfusion (poor SpO2 signal)**

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 (~11 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 the Battery Charge Circuit failed. Under this condition, the battery cannot be charged. 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: 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 3430 alarm. Alarm 3431 will occur in its place (see below).

Mitigation/Info: Less Than 30 Minutes Operation, Connect External Power, Assure Ability to Manually Ventilate

** Replace/Service Ventilator**

3431   **Low Battery**

This alarm occurs when external power is connected to a unit that has an internal battery that has drained to a Low Battery Status. The unit is warning the operator that in the event of an external battery failure the unit has ≤30 minutes of backup.   This alarm will resolve when the

internal battery charge has approximately >30 minutes of operation. The operator must maintain constant monitoring of the device and the patient during this period.

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 Voltage 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 voltage 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

Remove DC Connection

3442   External Power Failed (Insufficient Current)

Alarm occurs when the external power supply has insufficient current.   When this occurs the unit automatically switches to operation using the internal battery. If the external power source is known to be good then the AC/DC Power Supply may be faulty and need replacement.

Mitigation/Info: Internal Battery Operation, Check/Replace Power Supply, Change Power Source

Remove DC Connection

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 (Battery Nearly Too Hot for Discharge - w/External Power Connected)

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 (Battery Too Hot for Discharge w/External Power Connected)

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 softcase which acts as insulation. Shading the patient and ventilator from direct sunlight may also help reduce the battery temperature.

Mitigation/Info: Battery Does Not Charge when Too Hot , Assure External Power Available, Remove Padded Case, Shade Patient and Ventilator
Move To Cooler Location

3453   **Battery Fault (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, Assure External Power Available, 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 Communication Failure!, DO NOT Remove External Power!, Assure Ability to Manually Ventilate Patient
Replace Battery Soon

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
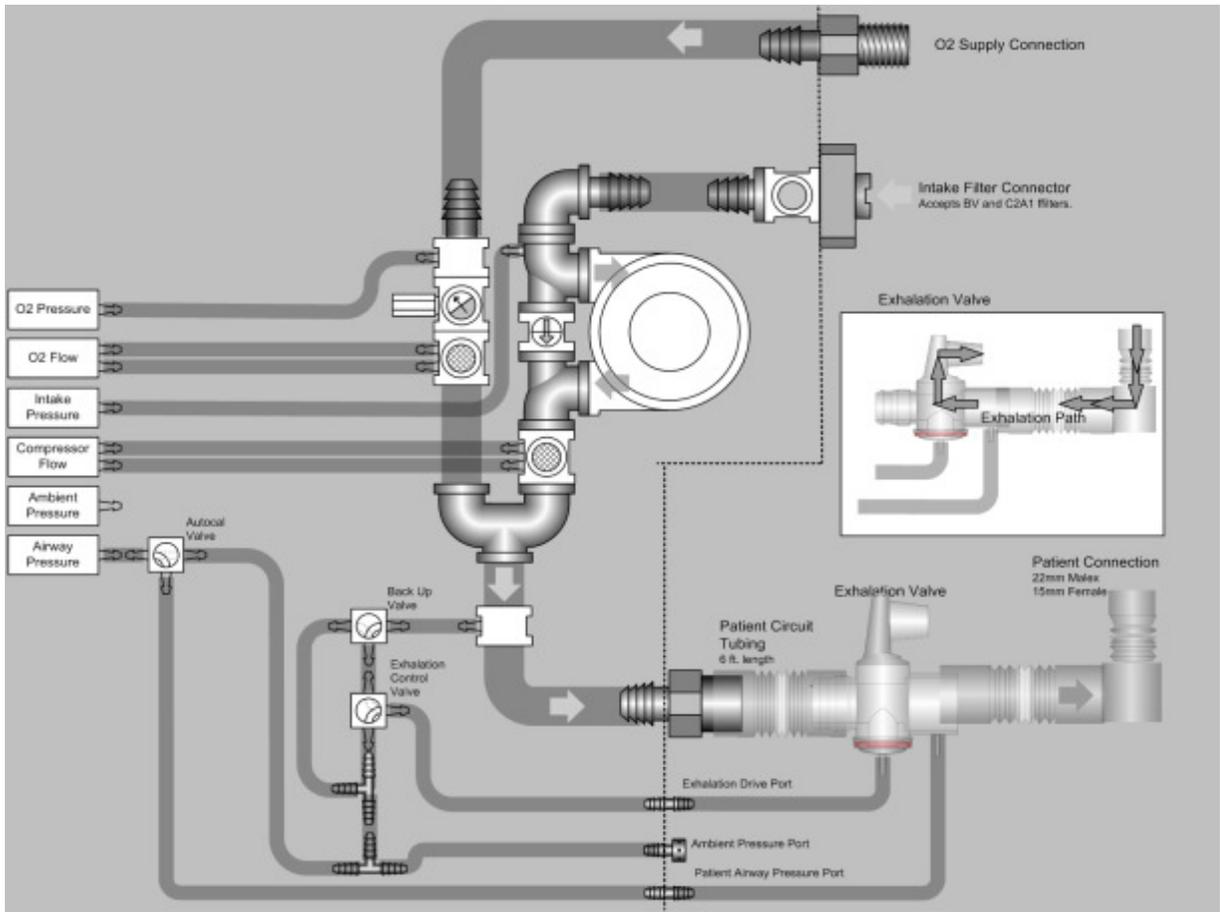
PNEUMATIC DIAGRAM: FIGURE 15

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 SpO2 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 sought 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%:
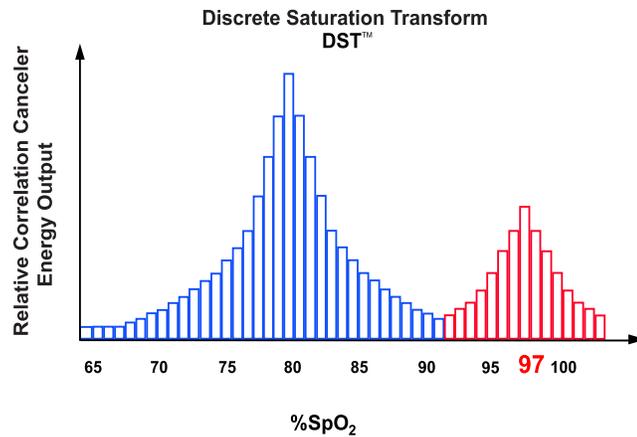
PULSE OXIMETER DISCRETE SATURATION TRANSFORM: FIGURE 16

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
                Adults, Pediatrics 70% - 100% ± 2 digits
                                0% - 69% unspecified
                Neonates   70% - 100% ± 3 digits
                                0% - 69% unspecified
Saturation (% SpO_2) - During Motion Conditions
                Adults, Pediatrics 70% - 100% ± 3 digits
                                  0% - 69% unspecified
                Neonates   70% - 100% ± 3 digits
                                0% - 69% unspecified
Pulse Rate (bpm) - During No Motion Conditions
                Adults, Pediatric, Neonates   25 to 240 ± 3 digits
Pulse Rate (bpm) - During Motion Conditions
                Adults, Pediatric, Neonates   25 to 240 ± 5 digits
Resolution
                Saturation (% SpO_2)   1%
                Pulse Rate (bpm) 1
Low Perfusion Performance
                > 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

BATTERY CHANGE INSTRUCTIONS: FIGURE 17 (A)-(E)

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.

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.

Gasket

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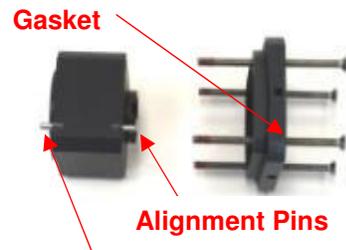
The Disk Filter is now exposed. **Do Not** remove the filter at this time.

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.

Shoulder

Alignment Hole

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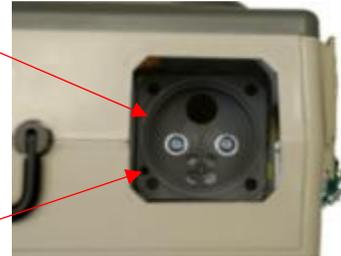
Set the upper segment of the Compressor Inlet Fitting Assembly into the lower segment making sure that its alignment pin mates.

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 18).
3. Attach the O_2 Reservoir Bag Assembly to the Fresh Gas/Emergency Air Intake as shown.

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.
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.

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.
NOTE: Never use O_2 flows greater than the patient's consumption. Flows greater than this may cause the baseline pressure to drift, wastes O_2 and may cause an *INCOMPLETE EXHALATION* alarm.

Operating Notes

NOTE: When the reservoir is removed be sure that the 22 mm adapter is removed with the assembly.

1. 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 effect on tidal volume and the resultant FIO2 for various O_2 supply rates:

	AC 12, V_T 700, PEEP 5, I:E 1:2.5								
O2 Flow l/min	0	1	2	3	4	5	6	7	8
FIO_2	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, V_T 500, PEEP 5, I:E 1:2.5						
O2 Flow l/min	0	1	2	3	4	5	6
FIO$_2$	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, V_T 300, PEEP 5, I:E 1:2.5						
O2 Flow l/min	0	1	2	3	4	5	6
FIO$_2$	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
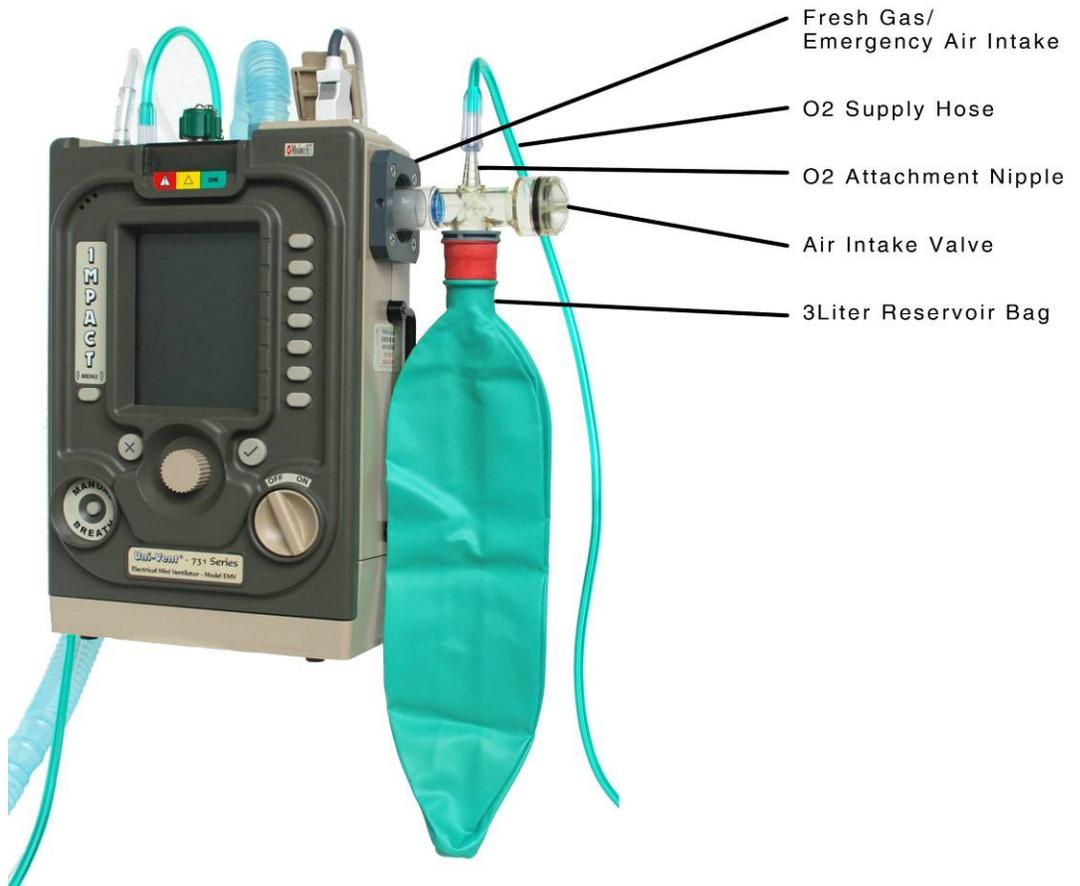
OXYGEN RESERVOIR BAG ASSEMBLY (PART #704-0004-00): FIGURE 19

APPENDIX 7: RECHARGING GUIDELINES:

1. Do not store the ventilator at 100% battery charge in a high temperature environment (~40˚C/104°F 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/104°F even though the unit is still connected to external power. Under these conditions, battery temperature can get as high as 10˚C/50°F above ambient. Charging will automatically start when the ambient temperature drops.

EMV+ STORAGE CASE (PART #703-0EMV-03): Figure 20

APPENDIX 8: POP UP MESSAGES (ALPHABETICAL LIST)

Pop Up Message	Explanation
Alarm Disable	Confirmation required—press accept key to disable alarm
BPM Limit Conflict	Cannot adjust high limit lower than low limit
BPM Limit Conflict	Cannot adjust low limit higher than high limit
BPM Setting Conflict	I Time cannot exceed 3 seconds
BPM Setting Conflict	I:E > 1:99 not allowed
CPAP + NPPV	Some Alarms Disabled! Configure Alarms for Patient!
Heart Rate Limit Conflict	Cannot adjust high limit lower than low limit
Heart Rate Limit Conflict	Cannot adjust low limit higher than high limit
High Pressure Target Setting	Confirmation required -- press accept key to exceed 60 cmH2O
High Vt Limit Setting	Confirmation required -- press accept key for values above 1500ml
High Vt Setting	Confirmation required -- press accept key to allow Vt > 1000ml
I Time Range Exception	I Time cannot exceed 3 seconds
I Time Range Exception	I Time must be greater than 0.3 seconds
I:E Range Exception	I:E > 1:99 not allowed
I:E Range Exception	Inverse I:E not allowed
Low Breath Rate Setting	Confirmation required--press accept key for values below 6 BPM
PEEP Backup Setting Conflict	Cannot adjust PEEP target to within 5 of backup PIP target
PEEP Setting Conflict	Cannot adjust PEEP target to within 5 of PIP High Limits
PEEP Setting Conflict	Cannot adjust PEEP target to within 5 of PIP target
PEEP Setting Conflict	PEEP + PS cannot be greater than PIP High Limit
PEEP + PS Setting Conflict	PEEP + PS must be ≥ 3 cm H2O, Adjust Setting to Assure Patient Safety
PIP Limit Backup Setting Conflict	Cannot adjust high limit lower than backup PIP target
PIP Limit Conflict	Cannot adjust high limit lower than low limit
PIP Limit Conflict	Cannot adjust high limit lower than PIP target
PIP Limit Conflict	Cannot adjust high limit lower than PS + PEEP
PIP Limit Conflict	Cannot adjust low limit higher than high limit
PIP Setting Conflict	Cannot adjust PIP target higher than PIP High Limit
PIP Setting Conflict	Cannot adjust PIP target to less than 5 more than PEEP
PS Conflict	Cannot adjust PS higher than PIP High Limit - PEEP
Requested Compressor Flow Too High	Cannot exceed 100 LPM total flow
Requested Compressor Flow Too Low	reduce FIO$_2$, increase BPM, reduce I Time, or increase Vt
Requested O2 Flow Too High	Cannot exceed 100 LPM total flow
Requested O2 Flow Too Low	increase FIO$_2$, increase BPM, reduce I Time, or increase Vt
Total Requested Flow Too High	Cannot exceed 100 LPM total flow
Total Requested Flow Too Low	Cannot flow less than 2 LPM total flow

Pop Up Message	Explanation
Vt Limit Backup Setting Conflict	Cannot adjust high limit lower than Backup Vt Setting
Vt Limit Backup Setting Conflict	Cannot adjust low limit higher than Backup Vt Setting
Vt Limit Conflict	Cannot adjust high limit lower than low limit
Vt Limit Conflict	Cannot adjust high limit lower than Vt Setting
Vt Limit Conflict	Cannot adjust low limit higher than high limit
Vt Limit Conflict	Cannot adjust low limit higher than Vt Setting
Vt Limit Conflict	Cannot adjust Vt Set above Vt High Limit
Vt Limit Conflict	Cannot adjust Vt Set below Vt Low Alarm

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