OPERATION MANUAL
PORTABLE VENTILATOR

Uni-Vent®
700 Series Model 73X

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

P/N 906-073X-01

REV 3.0
08/08/13

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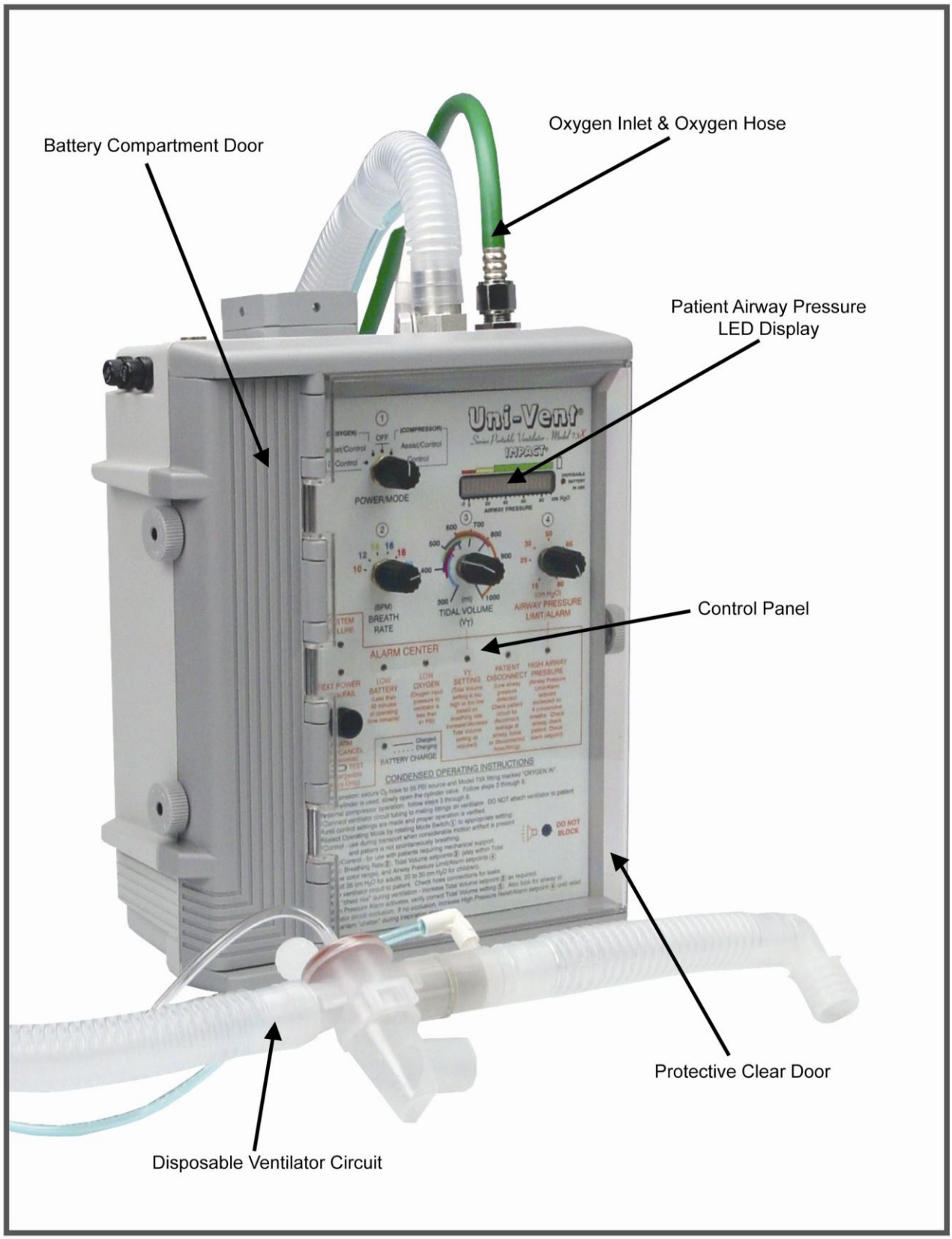


Model 73X Main Features
Figure 1

CONVENTIONS, TERMINOLOGY, DEFINITIONS AND ABBREVIATIONS AS USED IN THIS MANUAL

CONVENTIONS

WARNING

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

CAUTION

A CAUTION statement identifies conditions that could damage this device.

NOTE

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

TERMINOLOGY

Model 73X - Uni-Vent® 700 Series Model 73X Portable Ventilator

DEFINITIONS

Fresh Air – outside air that is entrained by the compressor and delivered to the patient
Gas – air or medical-grade oxygen
Setpoint - the value for any user-selectable parameter
Ventilator - any reference to the Model 73X, Uni-Vent®, Ventilator-Compressor

ABBREVIATIONS

A/C- Assist/Control	**LED**- Light Emitting Diode
ACV- Assist-Control Ventilation	**LPM**- Liters per Minute
Ah- Amp Hours	**ml**- Milliliters
ATPD - Atmospheric Temperature and Pressure, Dry	**mm**- Millimeter
BPM- Breaths per Minute	**O_2**- Oxygen
B/V- Bacterial/Viral Filter	**P_{aw}** - Airway Pressure
cm H_2O- Centimeters of Water	**PEEP**- Positive End Expiratory Pressure
CPR- Cardiopulmonary Resuscitation	**PIP**- Peak Inspiratory Pressure
DISS- Diameter Index Safety System	**psig**- Pounds per Square Inch Gage
FiO_2-Fraction of Inspired Oxygen	**USP**- United States Pharmacopeia
HME- Heat and Moisture Exchanger	**VAC**- Volts AC
HME/BV- Heat and Moisture Exchanger/Bacterial Viral filter combined	**VDC**- Volts DC
ID- Internal Diameter	**V_T**- Tidal Volume
L- Liters	**WOB**- Work-of-Breathing

A WORD ABOUT THE MODEL 73X

The Model 73X ventilator is designed to function primarily as an emergency response ventilator that can be used by emergency medical services (EMS) personnel with a basic knowledge of mechanical ventilation and by first responders under the direction of skilled medical care providers. Easy-to-use, durable, lightweight and portable, the Model 73X is built with the same standard of quality, reliability and performance that all Impact Instrumentation Inc. products are known for.

The Impact Instrumentation, Inc., Model 73X Portable Ventilator is indicated for use in the management of adult and pediatric patients weighing more than 30 kg (66 lbs) with respiratory failure or during resuscitation by providing continuous positive-pressure ventilation. It is appropriate for use in hospitals, during transport, and in austere prehospital 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. It is **not** intended to operate in explosive environments.

SHIPPING CONTENTS

Each Model 73X Portable Ventilator is shipped with the following components:

1 ea.	Ventilator, Model 73X
1 ea.	Ventilator Circuit, Disposable, Single Patient Use
1 ea.	High Pressure Hose, D.I.S.S. Oxygen X D.I.S.S. Oxygen, 6' Long
1 ea.	AC/DC Power Supply, Astec DPS54-M-401
1 ea.	AC Power Cord
1 ea.	12 VDC Power Cable
1 ea.	Case, Padded, Ventilator & Accessories
1 ea.	Operation Manual (on Compact Disc)
2 ea.	Fuse, 4A
1 ea	Fresh Gas/Emergency Air Intake filter

Model 73X Standard Equipment
Figure 2

ACCESSORIES LIST

The Accessories List contains common items, required from time to time. Each item is preceded by its part number. Accessories may be ordered directly from Impact. When ordering, please include the part number, description and quantity required.

Send purchase orders to:

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

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

Email:
Government
govsales@impactii.com

Non-Government
sales@impactii.com

PART NUMBER		PART DESCRIPTION
081-0031-00		Fuse, 4A
003-0005-00		Line Cord, 3-Cond, Shielded, IEC
490-0074-00		Exhalation Check Valve, 22mm F x 22mm M (See Warning below)
402-0027-00		Case, Padded, Ventilator & Accessories
704-0754-01		Assembly, Battery Pack, 5.0 AH
465-0024-00		Filter, Bacterial/Viral (BV)
465-0025-00		Filter, HME/BV
820-0053-00		Heat & Moisture Exchanger, Single Patient Use
820-0067-15		Ventilator Circuit, Disposable, Single Patient Use (Case/15)
825-0002-00		High Pressure Hose, D.I.S.S. Oxygen X D.I.S.S. Oxygen, 6' Long
708-073X-01		12 VDC Power Cable
024-0009-00		AC/DC Power Supply, Astec DPS54-M-401
906-073X-01		Operation Manual
909-073X-01		Operation Manual (on Compact Disc)
465-0026-00		Fresh Gas/Emergency Air Intake Filter
820-0105-00		1 Liter Test Lung

WARNING: Use only the Impact supplied Exhalation Check Valve when Model 73X is used with a chemical/biological filter. Other check valves may not offer the same degree of protection to the patient or may cause the ventilator to malfunction.

LIMITED COPYRIGHT RELEASE

CALIBRATION/PREVENTATIVE MAINTENANCE NOTICE

This device should be incorporated into a regular preventative maintenance program to insure compliance with operating specifications (see LIMITED WARRANTY statement). A calibration and maintenance check should be performed each year unless significant usage warrants a shorter period between preventative maintenance inspections . A complete calibration check should be made following each 12-month period. Following 6-months of continuous storage/non-use, this device should be examined, operationally tested, and its batteries recharged before patient use is attempted. Recommended maintenance checks can be found in the ROUTINE CARE: CALIBRATION, CLEANING, AND PREVENTATIVE MAINTENANCE section of this Manual.

UNPACKING

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

LOCATION OF USE

The Uni-Vent® Model 73X is a transportable device; therefore, its location of use will vary. When operated in a wet environment, users should take precautions and protect this device by covering it with a protective barrier (small tarp, plastic sheet, etc.). The unit should never be immersed. The unit may be used in environments where chemical and/or biological toxins are present by using the appropriate Bacterial/Viral or Chemical/Biological filter.

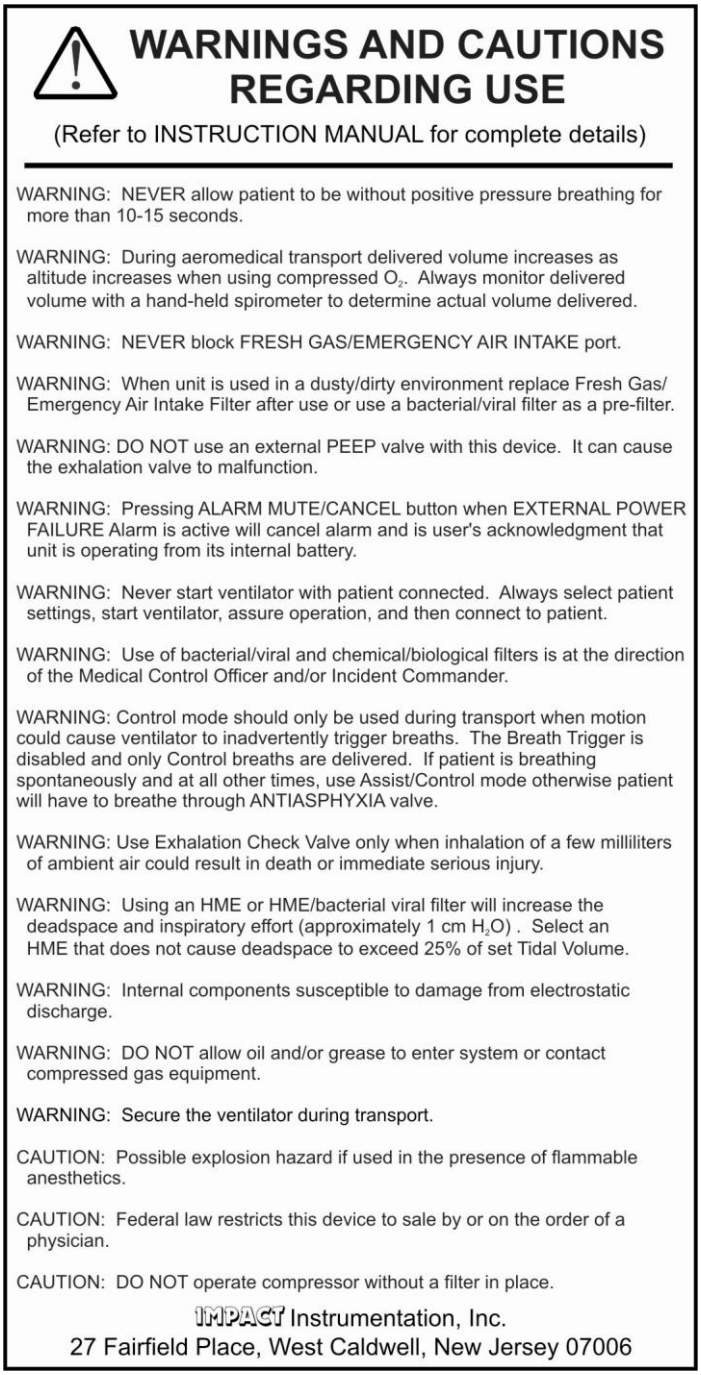
WARNING: When used in environments where chemical and/or biological toxins may be present, the local medical control officer should be consulted as to which filter, bacterial/viral or chemical/biological, should be used.

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 antiasphyxia port in the event of a ventilator failure.

WARNING: Secure the ventilator during transport.

WARNINGS AND CAUTIONS REGARDING USE

Figure 3 shows the warnings and cautions associated with the ventilator and its use. In order to highlight the context of each warning and caution, they are also listed in the relevant sections of the manual. The user should read and understand all of the warnings and cautions associated with the ventilator before operation.



Warnings & Cautions Label
Figure 3

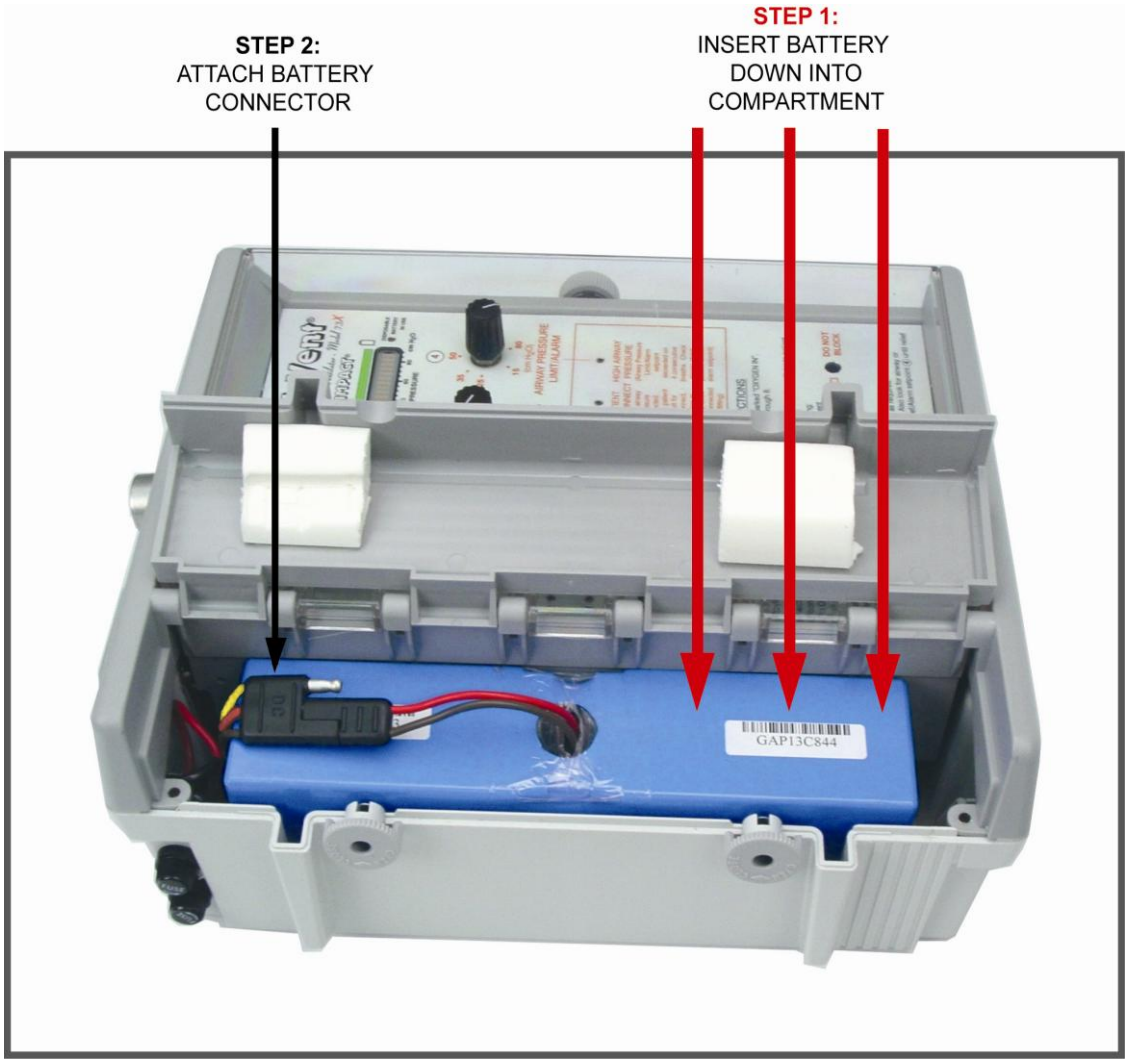
ASSEMBLY, CONNECTIONS AND INITIAL ADJUSTMENTS

ASSEMBLY

The Model 73X only requires that the user attach the breathing circuit to begin ventilation. Both the ventilator and breathing circuit are supplied clean and are ready for use on a patient.

The internal battery may or 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), so installation may be required prior to operation.

Caution: Use only Impact battery packs with this device, P/N 704-0754-01. Failure to do so can result in failure of the device and/or damage to the battery.



Battery Insertion
Figure 4

CONNECTIONS

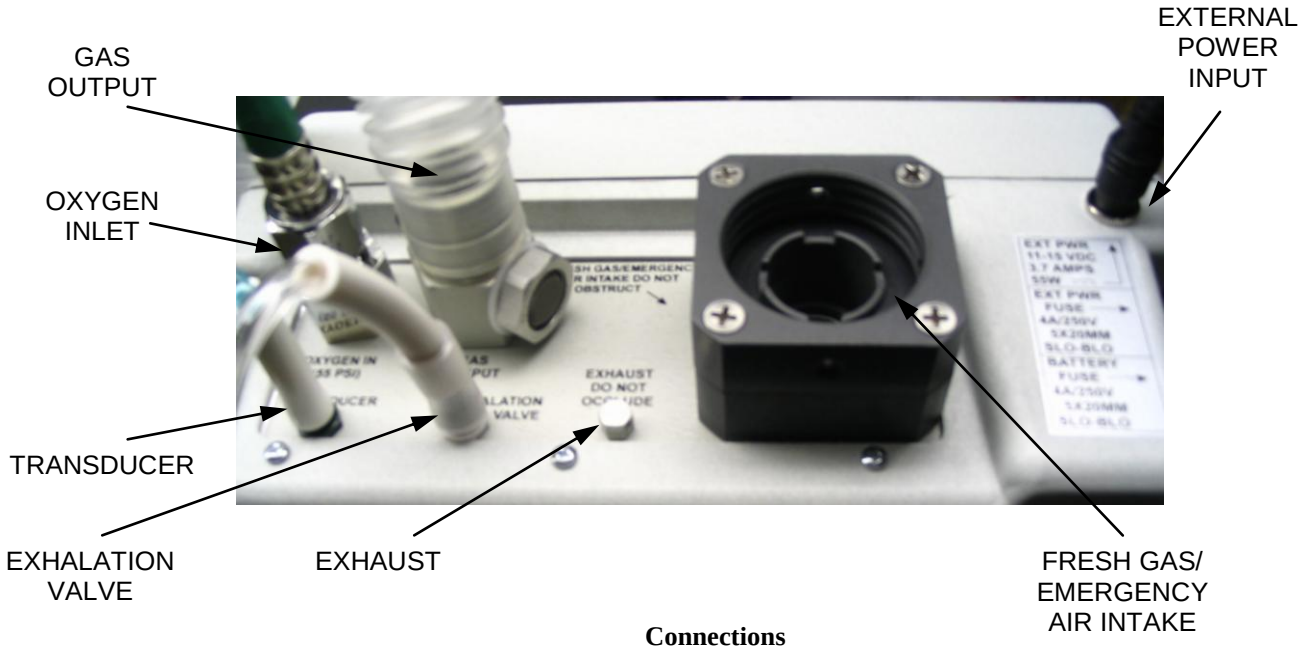
CAUTION: Follow connection instructions before placing this device into service (see Figure 4).

1. For use with external O_2: connect the green high-pressure hose to the OXYGEN IN fitting and a 55 psig external source. Use only medical-grade (USP) oxygen (see Figure 5).
2. Connect the disposable ventilator circuit to the GAS OUTPUT, TRANSDUCER, and EXHALATION VALVE connectors on Model 73X Connector Panel (see Figure 5). Observe directions included with disposable ventilator circuit.
3. In a high-dust or biological environment, a bacterial/viral filter can be attached to the FRESH GAS/EMERGENCY AIR INTAKE to prevent entrainment of particulate or biological matter. The 22 mm male end of the Bacterial/Viral filter connects directly to the fresh gas/emergency air intake, do not use any adapters.
4. In biological or chemical environments the user can attach the 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 (for more information see: BS EN 148 Respiratory protective devices – threads for facepieces). **Note:** when the chemical/biological filter is used the Check Valve, 22mm F x 22mm M (Part # 490-0074-00) should be placed on exhalation port of the disposable circuit. This valve assures that all inspired gas is through the ventilator and chemical/biological filter (see Figure 13).

WARNING: Use of the bacterial/viral and chemical/biological filters should be at the direction of the Medical Control Officer and/or Incident Commander.

WARNING: Never block the FRESH GAS/EMERGENCY AIR INTAKE port. A free flow of air is required during compressor operation or in event of a device failure to allow spontaneous breathing. The FRESH GAS/EMERGENCY AIR INTAKE also acts as an antiasphyxia port in the event of a ventilator failure (see Figure 6).

5. For use with AC power: connect the Astec DPS54-M-401 AC/DC converter to the External Power Input (see Figure 5) and attach the 110 VAC power cord to an appropriate AC receptacle. Note that the device can operate from internal battery or from AC power, see OPERATING POWER SELECTION & STOPPING section for details.



Connections
Figure 5

<u>Do Not Block</u> Fresh Gas/Emergency Air Intake Port
Figure 6

INITIAL ADJUSTMENTS

Before placing this device into service, read the section entitled OPERATION: DESCRIPTION OF CONTROLS, VISUAL INDICATORS AND CONNECTIONS. Always configure the control settings and verify device performance prior to patient use.

SECTION I. OPERATION

INTRODUCTION

Users will find the Model 73X easy to learn and operate. A complete understanding of its capabilities and limitations will allow you to take advantage of all its features. The Model 73X is a portable ventilator that is built to be extremely durable and is designed to operate in austere environments. It can be used to treat and transport adults and children in prehospital (ALS, ATLS, ACLS), field hospital and hospital settings. Its small size and weight facilitates transport, deployment and storage.

The Model 73X is a flow limited, time cycled ventilator designed to use either O_2 from a 55 psig source or fresh air using its internal compressor to deliver a positive pressure breath. The front panel interface allows the user to select the ventilation mode (Assist/Control or Control) and gas source (fresh air or medical-grade oxygen). Breaths are delivered using either O_2 or compressed air; there is no air/O_2 mixing. Controls allow the user to select the breathing rate, tidal volume and airway pressure limit. Adjustment of the tidal volume varies the inspiratory time to deliver the desired tidal volume based on the selected breathing rate. Tidal volumes are limited based on the breathing rate to a range that maintains the inspiratory to expiratory ratio (I:E) between 1:2 and 1:4. A series of alarms alert the operator to: external power low/fail, low battery power, loss of external O_2 pressure, tidal volume settings that violate the I:E ratio conditions, patient disconnect, high airway pressure and system failure. If an alarm occurs the user is alerted by audible and visual indicators. Operating power is from an external AC/DC power supply connected to 100 to 250 VAC, external 12 VDC, or from the internal 12 VDC rechargeable sealed lead-acid battery (gel cell). Fresh air is filtered using a particulate filter or, when the operating environment requires, a bacterial/viral filter or chemical/biological filter may be attached. The unit is contained in an impact resistant case with a clear polycarbonate door which protects the controls from damage and inadvertent manipulation.

FEATURES

- Durable design to facilitate transport and treatment in the prehospital environment.
- A/C and Control modes for use with acute respiratory failure and during CPR.
- Sealed gas path with chemical/biological filter connected to assure safe breathing gas supply.
- Self-contained system that operates with or without external O_2.
- Rechargeable battery provides over 6 hours of autonomous operation (based on 20 BPM, Vt=500mL, I:E 1:2, compressor mode).
- Clear polycarbonate door protects control panel components from weather, fluids and inadvertent contact.

DESCRIPTION OF CONTROLS, VISUAL INDICATORS, ALARM LED INDICATORS, AND CONNECTIONS

CONTROLS

Control descriptions are listed based on their control panel location, reading from left to right, top to bottom. Each is described in the following text (see Figure 7).

POWER/MODE (1) – the POWER/MODE control allows the user to select the mode of operation. Selecting a mode also turns the unit on (see MODES OF OPERATION for mode description).

BREATHING RATE (2) – the BREATHING RATE allows the user to select the breath delivery rate. Available rates are: 10, 12, 14, 16, 18, and 20 breaths per minute (BPM). Selection of the BREATHING RATE limits the range of tidal volume to those with an I:E ratio between 1:2 to 1:4. As a result, selecting an adult breathing rate limits the tidal volume to those values appropriate for adults.

TIDAL VOLUME (3) – the TIDAL VOLUME control allows users to select tidal volumes based on the BREATHING RATE setting. The selected BREATHING RATE and TIDAL VOLUME will always result in an I:E ratio that is between 1:2 and 1:4 (see Table A). The control display is color-coded to show the maximum and minimum values for each BREATHING RATE as well as relative values within each range.

Rate (BPM)	V_T Range (ml)
10	600 to 1000
12	500 to 825
14	425 to 710
16	375 to 625
18	330 to 550
20	300 to 500

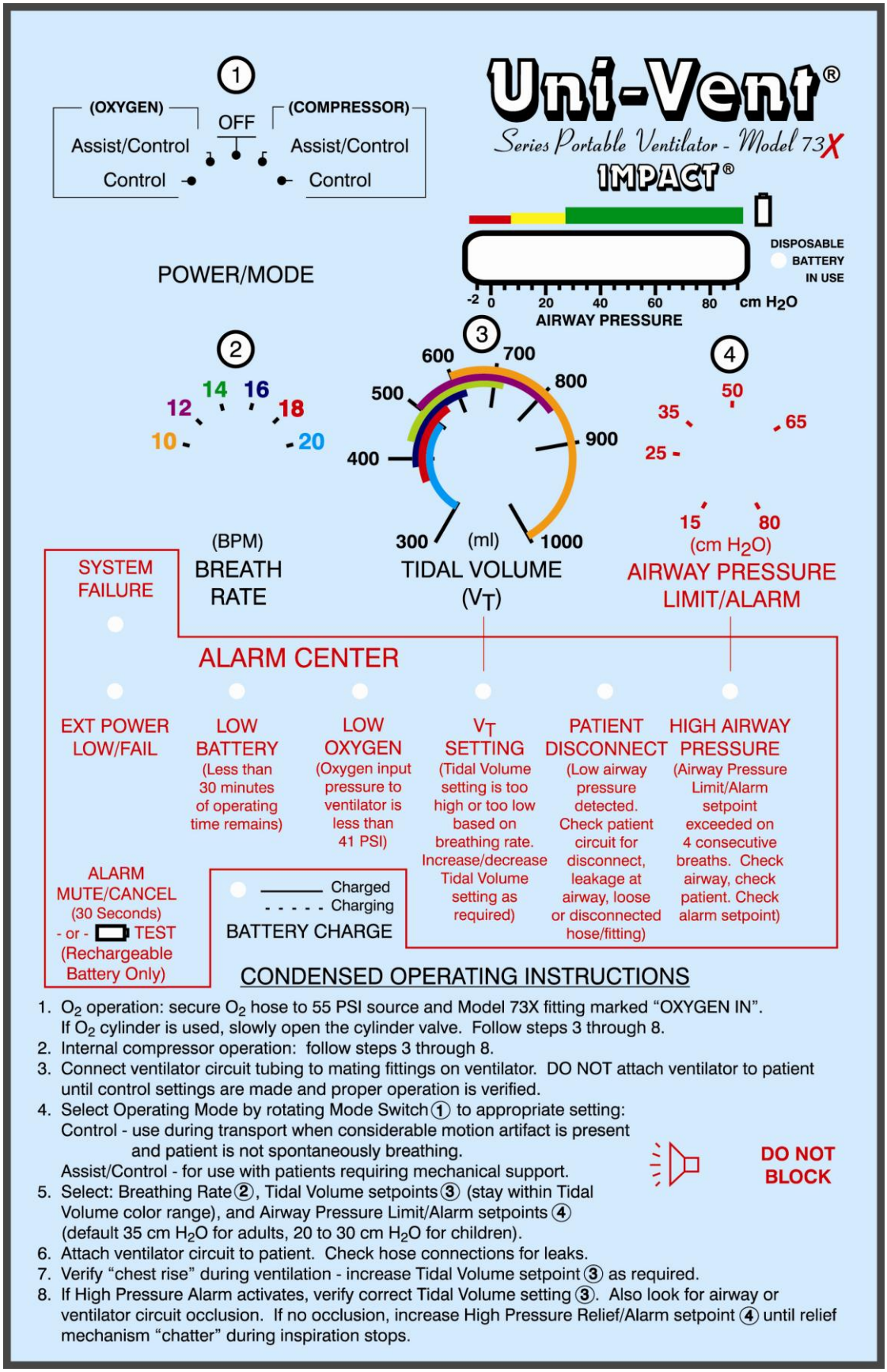
Tidal Volume Ranges
Table A

AIRWAY PRESSURE LIMIT/ALARM (4) – the AIRWAY PRESSURE LIMIT/ALARM control allows the user to select the maximum airway pressure setpoint between 15 and 80 cm H_2O. When the pressure in the patient circuit reaches the set value, the inspiratory flow pauses to maintain the airway pressure at or slightly below the AIRWAY PRESSURE LIMIT setpoint. If the limit is reached on 4 consecutive breaths, the HIGH AIRWAY PRESSURE visual and audible alarms are activated. The control display shows the maximum and minimum values as well as relative values in the range.

ALARM MUTE/CANCEL – pressing the ALARM MUTE CANCEL pushbutton allows the user to silence the audible alarm for 30 seconds and/or cancel an alarm depending on the condition. While the audible alarm is muted, the visual alarm illuminates continuously indicating that the alarm condition still exists. If a new alarm condition occurs while the audible alarm is muted, the new alarm overrides the mute and sounds the audible alarm and flashes the LED alarm indicator(s) for all active alarm conditions. If the alarm condition is not resolved during the mute period, the audible alarm re-sounds and the alarm LED flashes. When the alarm causing condition is resolved, both the audible and visual alarms are automatically cancelled.

WARNING: Never allow the patient to be without positive pressure breathing from either the ventilator or through manual ventilation for more than 10-15 seconds. If the alarm condition can not be resolved manually ventilate the patient while you or an assistant tries to resolve the problem.

Note: In the event that there are multiple alarms and the alarms have been muted, resolving one alarm condition whether through user action or spontaneous resolution will result in the audible and visible alarms for the remaining alarms reactivating to indicate the current status.



Control Panel
Figure 7

LED VISUAL INDICATORS

AIRWAY PRESSURE indicator LED array – provides a continuous display of airway pressure. Its absolute range is from -2 to +90 cm H_2O ATPD. The scale below the indicator is graduated in 5 cm H_2O increments with numerical markers appearing at -2, 0, 20 through 80 cm H_2O (20 cm H_2O major increments) (see Figure 7).

When the ALARM MUTE/CANCEL button is pressed and held during normal operation the AIRWAY PRESSURE LED display indicates the charge of the internal battery. This provides the user with an indication of the amount of charge in the battery. See the Operating Power and Selection section for additional information. During alarm states, once the alarm has been muted, pressing and holding the ALARM MUTE/CANCEL button will also activate the battery charge LED array (see Figure 7).

BATTERY CHARGE indicator LED – provides indication of battery charging. With the battery and external power connected, the BATTERY CHARGE indicator LED blinks when the battery is charging. The LED stays continuously illuminated when the battery is fully charged. The BATTERY CHARGE indicator LED will not illuminate if either the battery or external AC power are disconnected (see Figure 7).

Note: After installing a new battery, users are advised to wait as much as one minute before the BATTERY CHARGE indicator LED comes on.

ALARMS/ LED INDICATORS

EXTERNAL POWER LOW/FAIL Alarm –activates when the unit is operating using external power and the external power fails completely or the voltage goes below 10.8 VDC. When either of the conditions is detected, the unit immediately switches to internal power and audible and visual alarms are activated. Pressing the ALARM MUTE/CANCEL pushbutton cancels both the audible alarm and visual alarms. The alarm is also reset if external power returns. This condition can occur when the external AC power is absent, too low, or if there is a problem with the AC/DC power converter (see Figure 7).

WARNING: Pressing the ALARM MUTE/CANCEL pushbutton when the EXTERNAL POWER LOW/FAIL ALARM occurs is the user's acknowledgment that the ventilator is operating from internal battery power.

Note: The EXTERNAL POWER LOW/FAIL Alarm is a cancelable alarm. In the event of multiple alarms, pressing the alarm mute cancel button will mute the other alarm, and cancel the EXTERNAL POWER LOW/FAIL Alarm. If another alarm is muted and then the EXTERNAL POWER LOW/FAIL Alarm occurs, only the EXTERNAL POWER LOW/FAIL Alarm LED will flash with the audible alarm. The other alarm LED remains on solid. Resolving the EXTERNAL POWER LOW/FAIL Alarm condition during this mute period will not reactivate the audible or flashing aspect of the remaining muted alarms.

LOW BATTERY Alarm –activates when there is less than 30 minutes of operating time remaining in the internal battery. When the condition is detected, audible and visible alarms are activated. Pressing the ALARM MUTE/CANCEL pushbutton silences the audible alarm for 30 seconds while the visual alarm stays continuously illuminated. The alarm condition will continue until the battery voltage level becomes greater than 11.4 volts. The unit will continue to operate using its remaining battery power. During this time however, the user should seek a source of external power and/or assure that the means for providing manual ventilation are available (see Figure 7).

WARNING: After installing a new internal battery, users should wait until LOW BATTERY Alarm automatically resets (as much as one minute) before removing external power source.

LOW OXYGEN Alarm – activates when the unit is operating in one of its OXYGEN modes and an external O_2 pressure of less than 41 psig (± 2 psig) is detected. When the condition is detected the unit automatically switches to compressor power and audible and visible alarms are activated. Pressing the ALARM MUTE/CANCEL pushbutton silences the audible alarm for 30 seconds while the visual alarm stays continuously illuminated. The alarm condition will continue until the external O_2 pressure becomes greater than 45 psig or one of the COMPRESSOR modes is selected. If external O_2 pressure returns to greater than 45 psig and an OXYGEN mode is selected, the alarm will automatically cancel, the compressor operation will stop and breaths will be delivered using O_2 (see Figure 7) .

WARNING: During LOW OXYGEN Alarm, the internal compressor is ventilating the patient at ambient oxygen levels (usually 21% oxygen) and no longer at 100% oxygen.

V_T SETTING Alarm – activates when the selected BREATHING RATE and TIDAL VOLUME cause an I:E ratio that is outside of the 1:2 to 1:4 range. When the condition is detected the unit activates an audible and visible alarm. Pressing the ALARM MUTE/CANCEL pushbutton silences the audible alarm for 30 seconds while the visual alarm stays continuously illuminated. If the selected BREATHING RATE is appropriate for the patient, the user must increase or decrease the TIDAL VOLUME to a volume that is in the required range to correct the condition. If the set tidal volume is greater than the maximum of that range the delivered tidal volume will be the maximum value for the set BREATHING RATE. If the set tidal volume is less than the minimum value for the range, the delivered tidal volume will be the minimum value for the set BREATHING RATE. This prevents the patient from receiving a breath that is outside the range for a given BREATHING RATE (see Figure 7).

PATIENT DISCONNECT Alarm –activates when the airway pressure fails to reach at least 5 cm H_2O within 75% of the inspiratory time. While the condition is detected the unit attempts to deliver breaths based on the BREATHING RATE and TIDAL VOLUME and audible and visible alarms are activated. Pressing the ALARM MUTE/CANCEL pushbutton silences the audible alarm for 30 seconds while the visual alarm indicator stays continuously illuminated (see Figure 7).

To correct the PATIENT DISCONNECT Alarm condition the user should do the following:

1. Check the connection between the patient airway and the ventilator circuit.
2. Check that there are no significant leaks from or around the patient's airway.
3. If using a mask, assure that there is a seal against the patient's face when the breath is delivered.
4. Check that all of the breathing circuit hoses and tubes are properly connected.
5. Check that the exhalation valve is properly connected.
6. Check that there is gas flowing from the ventilator circuit.

If the user is not able to determine the cause of the PATIENT DISCONNECT Alarm within 10-15 seconds, the user should initiate manual ventilation. An assistant should evaluate the ventilator and circuit to determine the cause of the alarm and evaluate the patient as required.

WARNING: Never allow the patient to be without positive pressure breathing for more than 10-15 seconds from either the ventilator or manually using a self-inflating bag-valve ventilator.

Note: During the first breath at start up the DISCONNECT ALARM is deactivated. The alarm automatically activates at the start of the second breath.

HIGH AIRWAY PRESSURE Alarm – activates when the pressure in the patient circuit reaches the AIRWAY PRESSURE LIMIT/ALARM setpoint on 4 consecutive breaths. The ventilator attempts to deliver the patient breath, however, when the AIRWAY PRESSURE LIMIT/ALARM setpoint is reached, inspiratory flow pauses to maintain the airway pressure at or slightly below the AIRWAY PRESSURE LIMIT/ALARM setpoint. When the AIRWAY PRESSURE LIMIT/ALARM setpoint is reached on 4 consecutive breaths, the audible and visual alarms are activated. Pressing the ALARM MUTE/CANCEL pushbutton silences the audible alarm for 30 seconds while the visual alarm stays continuously illuminated. Once activated the alarm requires 4 breaths with the airway pressure below the setpoint to reset (see Figure 7).

To correct the HIGH AIRWAY PRESSURE Alarm condition the user should do the following:

1. Check the ventilator circuit for kinks or obstructions.
2. Suction the airway to clear excess secretions if present.
3. Determine if the patient is fighting the ventilator or biting the endotracheal tube.
4. Check the Exhalation Valve and Exhaust Port of the breathing circuit; assure that it is not blocked or damaged. If damaged, replace the circuit while an assistant manually ventilates the patient.
5. Verify proper V_T setting.
6. Verify proper Airway Pressure Limit Alarm setpoint.

Note: If during a HIGH AIRWAY PRESSURE Alarm condition a PATIENT DISCONNECT Alarm is activated (while suctioning or checking the circuit, etc), then the HIGH AIRWAY PRESSURE Alarm is automatically canceled.

SYSTEM FAILURE Alarm – activates and **ventilation stops** (see Compressor Failure below for exception) whenever the unit detects a failure of one of the primary subsystems. The audible and visual alarms are continuously active and can only be canceled by turning the POWER/MODE switch to OFF. When the SYSTEM FAILURE alarm occurs, all other alarm states and associated LEDs are canceled (see Figure 7).

SYSTEM FAILURE Alarms are caused by:

1. Autocal Failure – alarm initiates when the unit is not able to autocal correctly.
2. Battery Failure – alarm initiates when the battery voltage drops below 10.7 VDC and there is no external power.
3. Compressor Failure – alarm initiates when a compressor failure occurs and there is no external high-pressure O_2 present. NOTE: If a compressor failure occurs and there is external high-pressure O_2 the unit automatically switches to gas powered operation and an intermittent audible and visible SYSTEM FAILURE Alarm is initiated. The alarm can not be canceled by pressing the MUTE/CANCEL button. In order to cancel the alarm the unit must be switched to one of the OXYGEN modes of operation.
4. Excessive Airway Pressure – alarm initiates when the airway pressure is greater than 80 cm H_2O for 1.5 seconds or the airway pressure is greater than 40 cm H_2O for 5 seconds.
5. Exhalation System – alarm initiates when the airway pressure does not fall below 7 cm H_2O for 2 consecutive breath cycles.

WARNING: Never allow the patient to be without positive pressure breathing for more than 10-15 seconds from either the ventilator or manually using a self-inflating bag-valve ventilator.

DISPOSABLE BATTERY IN USE Indicator –illuminates when an internal disposable battery is in use. Currently, a compatible disposable battery is not available as an accessory. When available, users/purchasers will be notified (see Figure 7).

CONNECTIONS

OXYGEN IN: connects the unit to the output of an appropriate O_2 regulator attached to a medical-grade (USP) O_2 cylinder or other 55 psig (+20%, -25% psig) medical-grade O_2 (USP) gas source. The inlet is designed to accept O_2 using a male O_2 Diameter Index Safety System (DISS) thread. It is located on the Connector Panel at the top of the unit. The Model 73X is supplied with a green, 6 foot long high-pressure O_2 hose that provides for connection between the unit and the O_2 source (see Figure 5).

NOTE: If external O_2 is connected, the gas pressure must be at least 41 psig (± 2 psig). The source must also be capable of meeting the 30 liter/minute peak flow required during the inspiratory phase while maintaining the 41 psig pressure.

GAS OUTPUT: provides the connection for 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 5).

FRESH GAS/EMERGENCY AIR INTAKE: provides the ambient air input to the internal compressor. The port also provides an internal antiasphyxia valve that allows the patient to breath ambient air in the event of a ventilator failure. The port contains a particulate filter and permits the operator to connect either a bacterial/viral or a chemical/biological filter depending on the ambient conditions (see Figure 5).

TRANSDUCER: provides the connection for the ventilator circuit 3/16" ID transducer tubing. The barb-type connector is colored green to distinguish it from the other connectors (Note: the 3/16" ID transducer tubing is also green/blue). It is located on the Connector Panel at the top of the unit (see Figure 5).

EXHALATION VALVE: provides the connection for the ventilator circuit 1/4" ID exhalation valve tubing. The barb-type connector is clear anodized aluminum to distinguish it from the other connectors (Note: the 1/4" ID exhalation valve tubing is also clear). It is located on the Connector Panel at the top of the unit (see Figure 5).

EXTERNAL POWER INPUT: provides the connection for external power source connection. It is located next to the Connector Panel at top of the unit (see Figure 5). The connection accepts the input from the external Astec DPS54-M-401AC/DC Power Supply or an external 11-15 volt power source via the 12 VDC Power Cable (both of which are provided in the standard equipment set).

Caution: When using shore DC power to charge the device ensure that the supplied power remains between 11 to 15 VDC. Failure to do so will reduce the usable life of the battery and can damage the battery such that it will not hold a charge or support operation of the device.

OPERATING POWER SELECTION & STOPPING

The Model 73X is designed to operate using DC power supplied from 3 sources:

1. Internal 12VDC sealed lead acid battery with 5-6 Ah capacity (providing over 5 hours of operation).
2. External Astec DPS54-M-401 AC/DC Power Supply (100-240 VAC 50/60 Hz) with IEC 320 style AC input connector (supplied). The Astec DPS54-M-401 AC/DC Power Supply provides a DC output of 15V at 4A.
3. External DC power (11 to 15 volts DC) from a standard vehicle DC outlet can be used with the 12 VDC Power Cable.

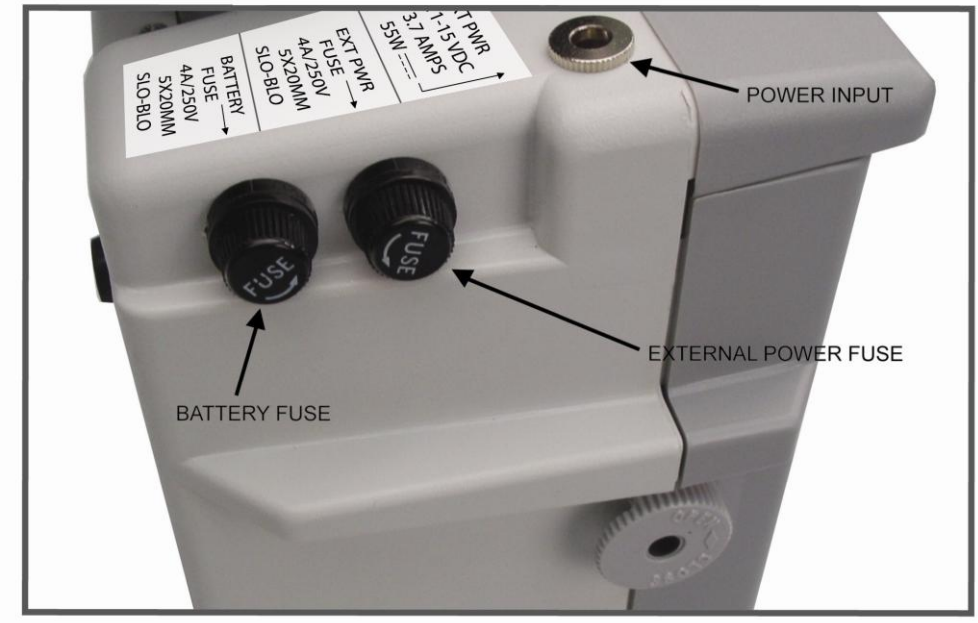
The POWER/MODE Selector Switch acts as a master power switch. Use this switch to initiate or cease operation.

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

The Model 73X is designed to use external power when available rather than its internal battery pack. When an external power source is present, the internal battery pack is automatically charged while the unit operates. When the external power fails or the unit is disconnected from external power for transport the Model 73X automatically switches to its internal battery pack for operating power and activates the EXTERNAL POWER FAILURE Alarm. When external power returns, operating power automatically switches from internal power to the external source.

WARNING: Pressing the MUTE/CANCEL button when the EXTERNAL POWER FAILURE Alarm is active will cancel the alarm. Canceling the alarm is the user's acknowledgement that the unit is operating using power from the internal batteries.

Two external fuseholders are located adjacent to the battery compartment door. Each fuseholder contains a type 5 X 20 mm, 4A SLO-BLO fuse (Part # 081-0031-00). The fuse closest to the power input protects external power operation and battery charging. The other fuse protects battery operation and charging (see Figure 8).



Fuses
Figure 8

Battery Operation

The unit can be operated using the internal sealed lead-acid battery. The battery is stored in the battery compartment which is on the side of the unit. To open the compartment turn the lock knobs so that the door tabs are visible, then open the compartment door (see Figure 9). Depending on the charge state of the battery, it may take as long as 12 to 16 hours to fully charge the battery. Typical operating time in the COMPRESSOR mode is 6 hours with a fully charged battery (A/C, Rate = 20, Vt = 500 ml, compressor powered, @ 25° C). When operating in an OXYGEN mode, typical operating time is 12 to 16 hours. User should be aware that operating time is diminished when the unit is operated at low temperatures.

Battery Compartment
Figure 9

SET-UP

INITIAL SET-UP

The Model 73X can be configured to suit most applications. Additional filters and a check valve may be required for particular uses (see Figure 10).

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

Additional Filters, HME and Exhalation Check Valve
Figure 10

SELF-CHECK

At start up, the Model 73X 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 not** be connected to the patient during SELF-CHECK. The ventilator begins operation immediately following SELF-CHECK.

NOTE: SELF-CHECK must be performed with the ventilator circuit disconnected from the patient. This insures that the TRANSDUCER connection is open to ambient atmosphere. Ignoring this requirement could cause the SELF- CHECK process to sense a residual airway pressure.

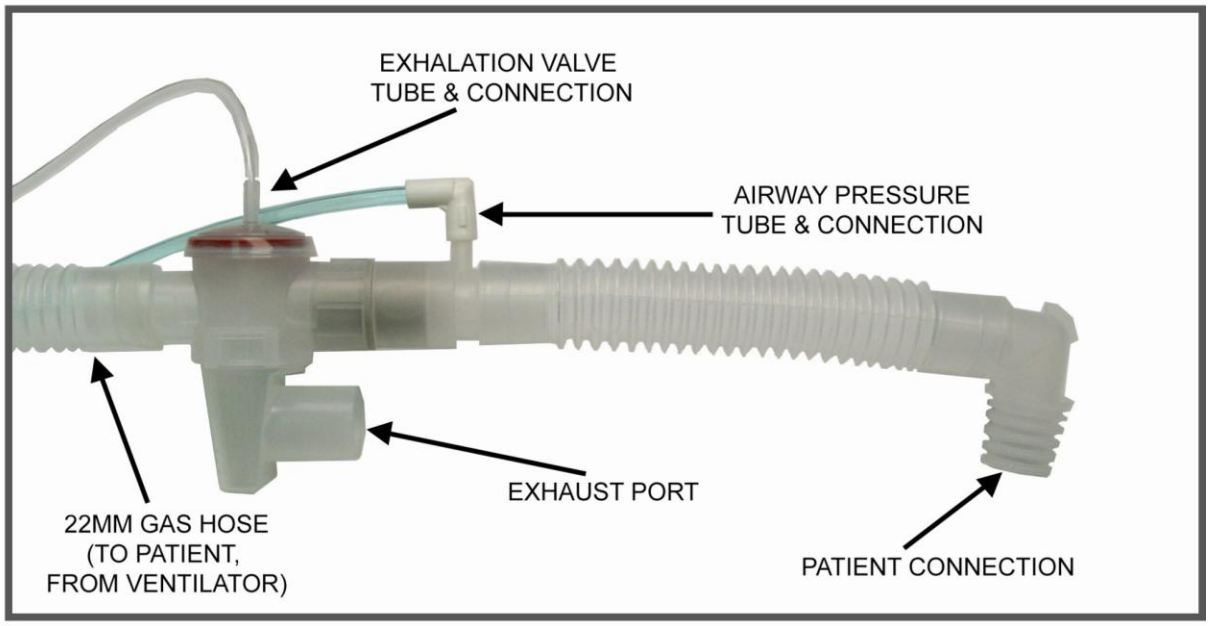
TRANSDUCER CALIBRATION (AUTO CAL)

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 range to assure display, monitoring, and triggering accuracy. AUTO CAL is automatically performed during SELF-CHECK, and then approximately every 265 seconds thereafter by the 73X's AUTO CAL function; no user intervention is required.

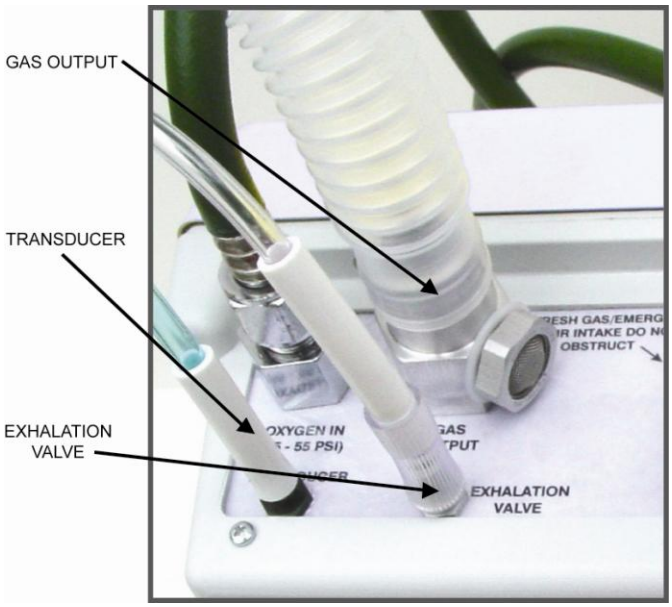
VENTILATOR CIRCUIT

The Model 73X is designed to operate using a standard disposable single-limb circuit (see Figure 11) which shows the patient connection end of the circuit. The circuit is connected to the ventilator as at the Connection Panel on the top of the unit (see Figure 12).

WARNING: DO NOT use an external PEEP valve with this device. It can cause the exhalation valve to malfunction.



Disposable Ventilator Circuit, Patient Connection
Figure 11



Disposable Ventilator Circuit, Ventilator Connections
Figure 12

OPERATIONAL TEST

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 to the ventilator.

OPERATIONAL TEST PROCEDURE:

1. Select the appropriate ventilator mode and associated settings.
2. PATIENT DISCONNECT ALARM should be active on second breath after startup.

3. Occlude the Patient Connection with a clean hand:
    a. Check the circuit and all connections for leaks.
    b. Set the AIRWAY PRESSURE LIMIT/ALARM to 15 cm H_2O, after 4 breaths the audible and visible alarms should be active.
    c. Set AIRWAY PRESSURE LIMIT/ALARM to 35 cm H_2O for adults or 20 to 30 cm H_2O for children.
4. If operating using the internal battery, make sure that the Battery Charge is in the Green Zone by pressing and holding the ALARM/MUTE CANCEL button. If not, begin ventilation and find an alternate source of power.

MODES OF OPERATION

The Model 73X has been designed to ease the learning transition commonly associated with new equipment. The Model 73X uses a 4-step method, indicated by numerical panel markings, to guide start up and operation.

Breathing gas can be from either a standard medical-grade O_2 source (55 psig +20%, -25%) or from the ventilator's internal compressor. The Model 73X features two ventilation modes, ASSIST/CONTROL and CONTROL. Each of these modes can be used with either gas source. To select the mode the operator must rotate the POWER/MODE selector switch to the appropriate gas source (OXYGEN or COMPRESSOR) and mode.

Assist/Control Mode

In the Assist/Control mode, breaths are delivered at the patient's spontaneous breathing rate, but never at a rate less than the set BREATHING RATE. To trigger the ventilator the patient-initiated breath must generate at least -2 cm H_2O during the expiratory phase of the breath. Patient triggered breaths are delivered at the set TIDAL VOLUME (an Assisted Breath). Following an Assisted Breath the ventilator waits the expiratory time, based on the set BREATHING RATE, before another Controlled Breath is delivered. However, if the patient initiates another breath during the expiratory phase another Assisted Breath is delivered. During the inspiratory phase of a breath, the patient is not able to trigger another breath. This is done to prevent excessive airway pressure from multiple breaths occurring in the same inspiratory cycle (breath stacking).

Assisted Breath Trigger

The spontaneous assisted breath trigger is permanently set to -2.0 cm H_2O. In order to trigger an Assisted Breath the patient must generate -2.0 cm H_2O. When the pressure drop is detected, and the unit is in either OXYGEN or COMPRESSOR ASSIST/CONTROL MODE, an assisted breath is delivered.

To ventilate in the ASSIST/CONTROL modes:

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 Connection of the ventilator circuit. (See Figure 11 for location)

2. Attach the Astec DPS54-M-401 AC/DC Supply to an appropriate AC power source if available (see **OPERATING POWER SELECTION & STOPPING** for details).

3. Turn the POWER/MODE switch to either OXYGEN or COMPRESSOR Assist/Control.

4. Adjust BREATHING RATE, TIDAL VOLUME and AIRWAY PRESSURE LIMIT/ALARM (set to 35 cm H_2O for adults, 20 to 30 cm H_2O for children) controls as required. Allow at least one breath to occur after all setting adjustments are complete. During this time the PATIENT DISCONNECT alarm will sound as the ventilator does not sense the minimum required airway pressure.

5. Perform the Operational Check described above in the Operational Test Procedure.

6. Attach the patient connection of the ventilator circuit to the patient's endotracheal tube, mask, tracheostomy tube or other airway that supports positive pressure ventilation. Delivery of the first breath to the patient will automatically cancel the PATIENT DISCONNECT alarm.

WARNING: If using a mask, be sure to use the proper head positioning technique and assure that a leak-free seal is maintained with the patient's face. NEVER LEAVE THE PATIENT UNATTENDED DURING FACEMASK VENTILATION!

7. Once the patient is connected to the ventilator carefully assess the following:

    a. The patient's breath sounds for bilateral ventilation.
    b. 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.
    c. The patient's airway for any indication of leaking or displacement.
    d. The AIRWAY PRESSURE indicator to determine the peak airway pressure. Set the AIRWAY PRESSURE LIMIT/ALARM 5-10 cm H_2O above the peak pressure once its value has been determined. This will prevent excessive airway pressure.

8. Record the time, ventilator settings, power source and patient status on a ventilator flow sheet or other treatment record.

9. Check the patient and ventilator on a regular basis to assure adequate ventilation and device performance.

10. Reassess the patient and ventilator every hour or whenever the patient is moved. When operating on battery power always carefully monitor the battery charge.

Control Ventilation

In Control mode, breaths are delivered at the preset BREATHING RATE and TIDAL VOLUME control settings. Control mode may be useful during extended periods of cardiopulmonary resuscitation.

WARNING: Control mode should only be used during transport and only when considerable motion is causing the ventilator to inadvertently trigger breaths. If the patient is breathing spontaneously and at all other times, the patient should be ventilated in one of the Assist/Control modes.

WARNING: In Control mode the Breath Trigger is disabled so that only Control breaths are delivered. **NO** assisted breaths are delivered and a spontaneously breathing patient will have to breathe through the ANTIASPHYXIA valve.

1. Attach the disposable patient circuit to the ventilator. If you wish to use an HME, attach it to the Patient Connection of the ventilator circuit (see Figure 11 for location).

2. Turn the POWER/MODE switch to either OXYGEN or COMPRESSOR Control.

3. Adjust BREATHING RATE, TIDAL VOLUME and AIRWAY PRESSURE LIMIT/ALARM ALARM (set to 35 cm H_2O for adults, 20 to 30 cm H_2O for children) controls as required. Allow at least one breath to occur after all setting adjustments are complete. During this time the PATIENT DISCONNECT alarm will sound as the ventilator does not sense the minimum required airway pressure.

4. Perform the Operational Check described above in the Operational Test Procedure.

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

WARNING: When using a mask, be sure to use the proper head positioning technique and assure that a leak-free seal is maintained with the patient's face. NEVER LEAVE THE PATIENT UNATTENDED DURING FACEMASK VENTILATION!

6. Once the patient is connected to the ventilator carefully assess the following:

    a. The patient's breath sounds for bilateral ventilation.
    b. 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.
    c. The patient's airway for any indication of leaking or displacement.
    d. The AIRWAY PRESSURE indicator to determine the peak airway pressure. Set the AIRWAY PRESSURE LIMIT/ALARM 5-10 cm H_2O above the peak pressure once its value has been determined. This will prevent excess airway pressure.

7. If the patient is spontaneously breathing and motion artifact is not occurring, switch to the appropriate Assist/Control MODE and follow the directions above.

8. Record the time, ventilator settings, power source and patient status on a ventilator flow sheet or other treatment record.

9. Reassess the patient and ventilator every hour or whenever the patient is moved. When operating on battery power always carefully monitor the battery charge.

AEROMEDICAL USE

The unit can be used to ventilate patients during aeromedical transport in either fixed or rotary-winged aircraft. The delivered volume is subject to change as the altitude changes. Users should always monitor the delivered volume with a hand-held spirometer to determine the delivered volume. This can be done by attaching the spirometer to the Exhaust Port of the ventilator circuit (see Figure 11). Generally the delivered tidal volume increases as altitude increases when operating using compressed O_2.

HUMIDIFICATION

Heat and Moisture Exchangers (HMEs), sometimes referred to as "artificial noses" can be used with the Model 73X. While HMEs may not be suitable for all applications, they facilitate portability in a way that conventional humidifiers cannot. The Model 73X can be used with an optional HME or an optional HME/bacterial viral filter. The HME provides heat and moisture to the inspired gas by recycling the heat and moisture contained in the patient's exhaled gas. Use of a HME/bacterial viral filter may help reduce the risk of cross contamination of biologic pathogens that might be transmitted in the patient's exhaled gas. It attaches between the Patient Connection of the ventilator circuit and patient's airway. (See Figure 11 for location) Always follow any additional instructions provided by the HME manufacturer.

Impact does not offer a heated humidifier option for the Model 73X. Users are cautioned to carefully consider the ramifications of such use: 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[1]. A diffuser or "cascade impactor" within the device is responsible for the increase in work. In most applications, it has been recommended that if a cascade is used, that its tower be removed. This will change the cascade from a bubble humidifier to a pass-over humidifier, rendering it less efficient, but still capable of adding heat and moisture to the inspired gas. Any humidification device should be connected and operated only in accordance with directions provided by its respective manufacturer. Humidifiers are not recommended for transport. Observe all safety and cautionary statements.

1Kacmarek et al (Respir Care 1990;35:405)

WARNING: Use of the HME or HME/bacterial viral filter may not be indicated in patients with small tidal volumes as the deadspace may be greater that 25% of the set TIDAL VOLUME. Always select an HME that is appropriate for the patient being ventilated. Failure to do so can cause significant rebreathing and result in hypercarbia and hypoxemia.

WARNING: Use of the HME or HME/Bacterial Viral filter may cause a slight increase in the inspiratory effort to trigger an Assisted Breath (approximately 1 cm H_2O).

WARNING: During aeromedical transport delivered volume increases as altitude increases when using compressed O_2. Always monitor delivered volume with a hand-held spirometer to determine actual volume delivered.

HAZARDOUS ENVIRONMENT FILTERS

The Model 73X is operable in environments where chemical and/or biological toxins are present. To accomplish this, all gas delivered to the patient comes from either the pressurized medical-grade O_2 source or filtered ambient air which is entrained through the FRESH GAS/EMERGENCY AIR INTAKE. Operators should choose between a bacterial/viral filter and a chemical/biological filter based on the direction of the local Medical Control Officer.

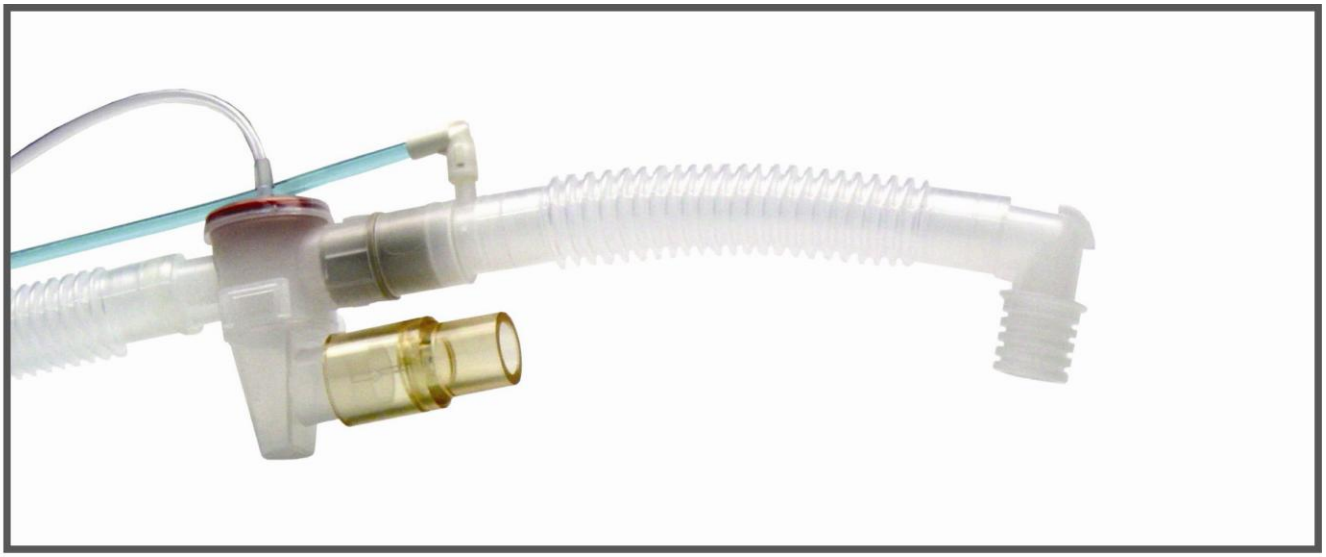
To prevent the patient from breathing contaminated ambient air in the event of a ventilator failure, the Model 73X contains an internal antiasphyxia valve that allows the patient to inspire gas through the external filter. While this design assures that no contaminated gas reaches the patient, it requires that the operator ensure that nothing blocks the input of the external filter. In order to ensure that no contaminated gas is drawn in through exhalation valve in the event of a ventilator failure the Exhalation Check Valve (490-0074-00) is added to the Exhalation Port of the breathing circuit when a chemical/biological filter is used (see Figure 13).

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 ensure that nothing blocks the inlet of the external filter. Failure to do so could prevent the ventilator from operating in COMPRESSOR mode and prevent the patient from breathing in the event of a ventilator failure (see Figure 6).

WARNING: Use Exhalation Check Valve only when inhalation of a few milliliters of ambient air could result in death or immediate serious injury.

Note: The Exhalation Check Valve is only intended for use with the chemical/biological filter. Its use prevents any ambient air from being entrained through the Exhalation Port. It is not indicated when B/V filters are used to prevent entrainment of sand, dust and dirt into the ventilator.



Exhalation Check Valve (For Use Only With The Chemical/Biological Filters!)
Figure 13

Bacterial/Viral Filter Use

Bacterial/Viral filters can be used in environments where the patient is at risk of cross contamination of airborne pathogens. When used in accordance with the manufacturer's instructions these filters can help prevent inhalation of infectious matter. In dusty environments the B/V filters can also be used to prevent entrainment of particulate matter that could affect the ventilator's pneumatic components. To use the bacterial/viral filter, insert the filter's male 22 mm conical fitting into the FRESH GAS/EMERGENCY AIR INTAKE (see Figure 14).

Installed Bacterial/Viral Filter
Figure 14

Chemical/Biological Filter Use

The Model 73X Ventilator is designed to allow attachment of an optional chemical/biological filter for use in contaminated environments. The Fresh Gas/Emergency Air Intake allows for attachment of standard Rd 40 x 1/7 threads. A complete description of this standard can be found in BS EN 148 Respiratory protective devices – Threads for facepieces. When the chemical/biological filter is used in a toxic environment the Exhalation Check Valve (Part# 490-0074-00) should always be used.

Installed Chemical/Biological Filter
Figure 15

ROUTINE CARE: CALIBRATION, CLEANING, AND PREVENTATIVE MAINTENANCE

IN-FIELD CALIBRATION CHECKS

This device should be incorporated into a regular preventative maintenance program to assure compliance with operating specifications. The Model 73X has been designed to allow users to perform calibration checks in the field. Calibration measurements should be made each year unless significant usage warrants a shorter period between preventative maintenance inspections. A complete calibration check should be made following each 12-month period. Following 6 months of continuous storage/non-use, this device should be examined, operationally tested (see Operational Check procedure above), and its batteries recharged before patient-use is attempted. Calibration checks should be performed per procedure *DMR/073X/In-FieldCalCheck* as required (contact Impact for latest version of this document, phone 973-882-1212, email service@impactii.com). The user can use calibration devices that meet the minimum standards (± 2% for pressure and ± 4% for flow/volume measurements). A secure record of Calibration Checks should be maintained for all devices owned or operated by an organization. Calibration Checks should also be performed whenever the operator suspects that the Model 73X 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 Impact or an authorized service center for calibration.

The unit can also be returned to Impact for calibration, maintenance and repair; contact Impact before returning the device, phone 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 Model 73X 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 Model 73X's housing may 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 Hose: Examine the hose for cracking, discoloration, disfigurement and excessive wear. Wipe 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 with O_2 or compressed gas equipment an explosion can result.

Fresh Gas/Emergency Air Inlet Filter: the Fresh Gas/Emergency Air Inlet filter housing is located on top of the ventilator. Remove filter using a pair of tweezers or similar tool. Examine the filter for dirt, lint, or general wear. Replace if necessary (Part # 465-0026-00). DO NOT attempt to clean this filter. Do not operate in COMPRESSOR mode without a filter in place. See filter replacement instructions below.

CAUTION: Do not operate the compressor without a filter in place.

PREVENTATIVE MAINTENANCE

Routine maintenance should be performed on the device at regular intervals and before it is placed into service. Routine maintenance should consist of the following:

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

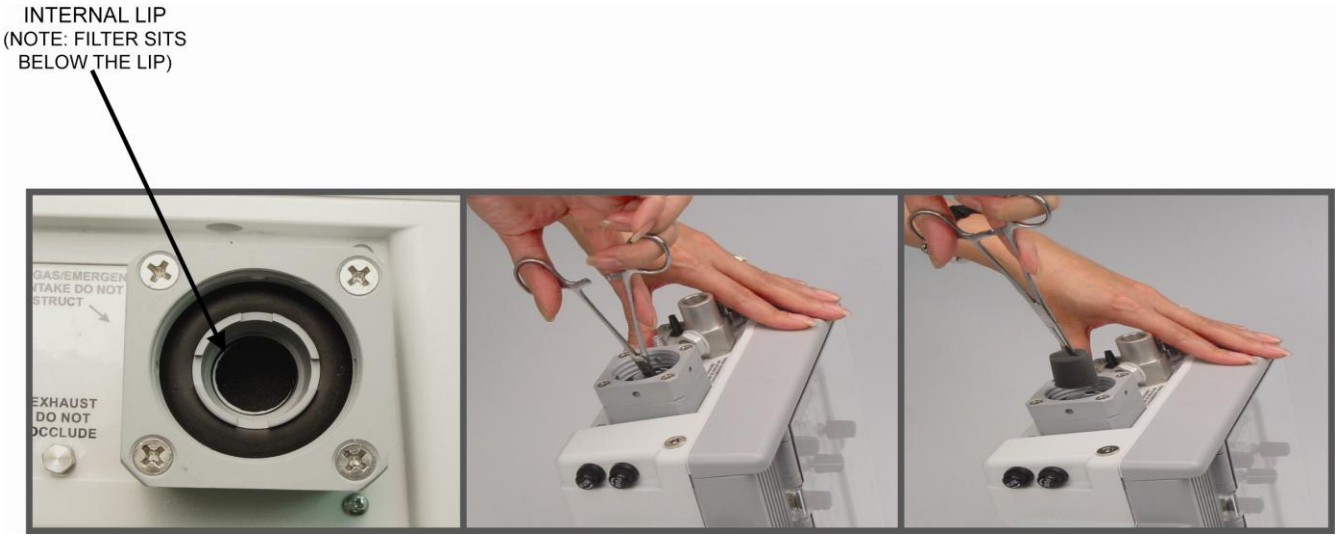
2. Operational checks – using a ventilator circuit and test lung, operate the ventilator in all of the applicable modes.

3. Tubing and hose checks – replaced crimped, cracked or worn tubing and hose as required. This applies to both the high pressure O_2 hose and the hoses and tubing associated with the ventilator circuit.

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. Following each 12-month period, it is recommended that the *DMR/073X/In-FieldCalCheck* be performed by a certified service facility or by Impact Instrumentation, Inc.

FRESH GAS/EMERGENCY AIR INLET FILTER REPLACEMENT

To protect the patient and compressor from particulate matter entrained through the FRESH GAS/EMERGENCY AIR INLET, a replaceable filter is provided. The Fresh Gas/Emergency Air Intake Filter (part # 465-0026-00) prevents particles from entering the compressor and patient breathing gas pathway. To change the filter, remove it from the FRESH GAS/EMERGENCY AIR INLET by gently pulling it using a pair of hemostats or tweezers. The filter is held in place with friction and a small internal lip on the interior face of the inlet (see Figure 16). To replace, gently insert a new filter all the way down into the cavity and allow the filter to expand to fill the area. All of the filter should be below the internal lip (see Figure 16). If it is not, simply press it into place with the tool that was used to remove the filter.



Removal and replacement of the Fresh Gas/Emergency Air Intake Filter (part # 465-0026-00).
Figure 16

WARNING: Before use or long-term storage always assure that the Fresh Gas/Emergency Air Intake Filter is clean and free of debris. When the unit is used in a dusty/dirty environment protect the inlet by using a bacterial/viral filter as a prefilter to prevent entrainment of particulate matter into the ventilator. If no prefilter was used in a dusty/dirty environment, replace the Fresh Gas/Emergency Air Intake Filter after the use. Please contact Impact for internal pneumatic cleaning procedures.

POST-CONTAMINATED ENVIRONMENT CLEANING

If the ventilator is operated in an environment where it may have been exposed to contamination from the patient, hazardous materials accident, mass epidemic or weapon of mass destruction, Impact Instrumentation, Inc. 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 (or incident specific solution) 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. Since the range of contaminants the unit might be exposed to is large, it is not possible 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.

BATTERY TESTING, CARE AND RECHARGING

BATTERY TEST

While the unit is operating on battery power, users can determine the relative amount of charge in the internal battery by pressing and holding the ALARM MUTE/CANCEL button. The amount of charge is displayed using the AIRWAY PRESSURE LED display. The scale above the LED display indicates relative zones of charge. During operation the user should seek an external source of power when the Battery Test shows the battery charge to be in the yellow or red zones.

NOTE: The operating times identified in the manual are based on laboratory testing using fully charged batteries. Operating the ventilator at extreme low or high temperatures will affect the duration of operation. Users are advised to always monitor the battery charge and identify a secondary source of external power when the battery charge moves into the yellow zone.

BATTERY CARE AND CHARGING

The Model 73X uses a sealed lead-acid battery (Part # 704-0754-01), "starved-electrolyte" type, which offers a wide temperature operating range, does not exhibit "memory" characteristics (reduced capacity) or vent hydrogen gas. The battery dimensions are 2.7" x 8.5" x 1.9" (6.9 x 21.6 x 4.8 cm) and weighs 4.5 lbs (2.0 kg). The life of these batteries depends, to a great extent, upon the care they receive. Following these simple guidelines will prevent premature charge depletion and reduction of battery life.

1. DO NOT operate the ventilator when the temperature range exceeds -25°C to 49°C (-13°F to 120°F).
2. DO NOT charge the ventilator when the temperature range exceeds 0°C to 40°C (32F to 104°F).
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 10°C to 30°C (50°F to 80°F).
5. Recharge the batteries for 6 to 12 hours every 3 to 4 months to assure maximum charge when needed for operation and to maximize the life of the internal battery.
6. Under ordinary conditions the battery can be recharged in less than 6 hours. The battery will recharge faster (3 to 4 hours) if the ventilator is not operating.
7. Replace the battery every 2 years. Batteries that undergo daily charge/discharge cycles may need to be replaced every year if they fail to hold a charge that provides 5 hours of run time.

Caution: Do not leave the battery continuously connected to external power. Charging should never take longer than 16 hours. Prolonged continuous charging will reduce the usable life of the battery and can cause damage to the battery such that it will not hold a charge or support operation of the device.

Sealed lead acid batteries exhibit excellent charge retention characteristics. Prolonged periods of disuse will not substantially reduce operating capability provided the battery is charged as described above. If long-term storage/non-use is common, recharge the unit once every six months; this will insure that battery charge is maintained at 80% capacity or better. Recharge time ranges from 6 to 12 hours, depending upon initial state of discharge.
Operating power will always default to the external power source to preserve the internal battery charge. This assures that power is available for transport use or emergency back-up purposes. If the EXTERNAL POWER LOW/FAIL Alarm occurs, the Model 73X will automatically revert to its internal batteries for operating power.

Battery Charge Indicating LED

The BATTERY CHARGE indicating LED will flash whenever there is external power and the internal battery is charging. The BATTERY CHARGE indicating LED will illuminate continuously when there is external power and the internal battery is fully charged. When there is no external power source or if the battery is disconnected, the BATTERY CHARGE indicating LED is off.

Note: After installing a new battery, users are advised to wait as much as one minute before the BATTERY CHARGE indicator LED comes on.

SPECIAL CHARGING APPLICATIONS

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

Input Voltage:	11 to 15 VDC
DC Ground:	Negative
DC Power:	55 Watts (over the input voltage range)
AC Frequency:	Not applicable

CAUTION: Users are cautioned that use of non-Impact chargers without input from a knowledgeable biomedical technician may result in destruction of the battery and/or unit, and fire. Other chargers should always be tested and certified before they are put into use with patients.

TROUBLE SHOOTING

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

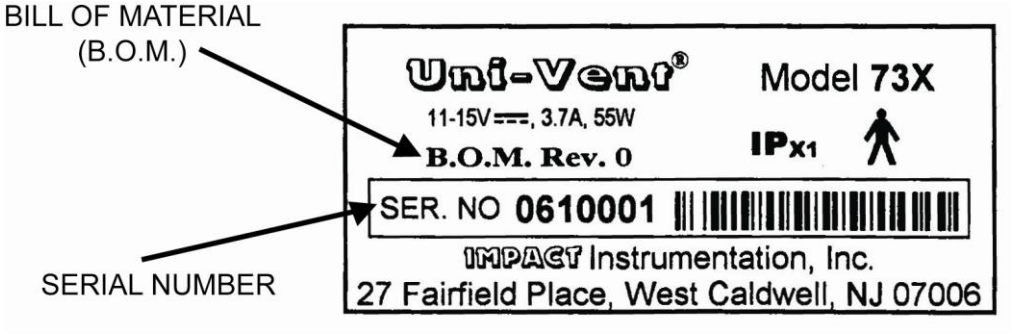
Impact will, upon request, provide competent biomedical engineering departments with service data and schematics. Such departments are encouraged to contact the factory for assistance when needed and it is recommended that staff members attend a factory training course. Details may be obtained by contacting the Impact Service Department.

OPERATOR CORRECTABLE PROBLEMS

Common problems may be quickly rectified by users. Should this device fail to operate properly, verify the integrity of all hose, tubing and fitting connections. Check all control panel settings. Verify that compressor inlet filter is not clogged or dirty. Check for operating power with internal batteries and external power source(s). Replace fuses that are blown or missing. If the device still fails to operate contact Impact 973 882-1212 or service@impactii.com.

OPERATOR PROBLEMS REQUIRING SERVICE

If the procedures described above do not resolve an operating problem, service is required. Should servicing be necessary, contact your nearest Impact Representative or the Impact Service Department 973 882-1212 or service@impactii.com. A Returned-Goods-Authorization number (RGA #) will be issued. 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, Serial Number, and B.O.M. Rev. Number ready and any other pertinent data you wish to include in the service request. The Model 73X Serial Number Label is affixed to the bottom cover (see Figure 17).



Device Serial Number Label
Figure 17

STORAGE INFORMATION

For prolonged storage periods, the Model 73X 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.

If batteries are not removed, short-term storage temperatures should range between 5°F and 104°F (-15°C to 40°C), relative humidity should be low. For long-term storage, the optimum storage temperature range is 50°F to 80°F (10°C to 30°C).

DO NOT store batteries in a discharged condition.

CAUTION: DO NOT store batteries in a discharged condition; doing so will result in the batteries losing their ability to hold a charge.

When batteries are in extended storage, it is recommended that they receive a refresh charge at recommended intervals:

STORAGE AMBIENT	RECHARGE INTERVAL
Below 68°F (20°C)	18-months
68° to 86°F (20° to 30°C)	12-months
86° to 104°F (30° to 40°C)	6-months

WARNING: Before putting the unit back into service, charge the battery using the Astec DPS54-M-401 AC/DC Power Supply or DC Power Cable. This will ensure the maximum autonomous operating time when needed.

Following periods of extended storage in non-controlled environments, allow ventilator 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 for 6 to 12 hours before patient-use is attempted. Servicing may be required. Servicing should be performed by qualified personnel only.

SPECIFICATIONS

OPERATING MODES:	OXYGEN or COMPRESSOR: Assist/Control or Control
FLOW RATE:	30 LPM, constant flow
BREATHING RATE:	Adjustable, 10, 12, 14, 16, 18, 20 BPM
TIDAL VOLUME:	300 to 1000 ml, ATPD
INSPIRATORY TIME:	Varies based on selected BREATHING RATE and TIDAL VOLUME
FiO_2:	21% using ambient air or 100% with external oxygen source
MAXIMUM AIRWAY PRESSURE:	80 cm H_2O using AIRWAY PRESSURE LIMIT/ALARM, 100 cm H_2O internal mechanical backup
OXYGEN INPUT PRESSURE:	55 PSI (-25%; + 20%)
AIRWAY PRESSURE LIMIT:	Adjustable, range of 15 to 80 cm H_2O
BREATH TRIGGER:	Fixed: -2.0 cm H_2O
LED BAR GRAPH:	Range -2 to +90 cm H_2O
LED ALARM INDICATORS:	Ext Power Low/Fail, Low Battery, Low Oxygen, Vt Setting, Patient Disconnect, High Airway Pressure, and System Failure
ALARM VOLUME:	85 dBA @1 ft
NOISE LEVEL:	Less than 75 dBA when measured @1-meter (compressor operating)
OPERATING VOLTAGE:	12 VDC (nominal)
OPERATING TIME:	
INTERNAL BATTERIES:	Compressor: approximately 6 hours @ average adult settings Oxygen: approximately 12 hours @ average adult settings
EXTERNAL 12V:	Continuous (from AC-DC converter or automotive power source)
TEMPERATURE RANGES:	
OPERATING:	-25°C to 49°C (-13°F to 120°F)
CHARGING:	0°C to 40°C (32°F to 104°F)
LONG TERM STORAGE:	10°C to 30°C (50°F to 80°F)
CONTROL ACCURACY:	± 10% of setting
SIZE:	
VENTILATOR SYSTEM:	8.87" Wide X 11.5" High X 4.5" Deep (22.55 cm Wide X 29.21 cm High X 11.43 cm Deep)
AC POWER SUPPLY:	2.38" Wide X 5.23" High X 1.60" Deep (6.05 cm Wide X 13.28 cm High X 4.06 cm Deep)
WEIGHT:	Ventilator: 11 lbs (4.5 kg) Complete Kit: 13.2 lbs. (6.0 kg)
WARRANTY:	Limited, 1-year (see LIMITED WARRANTY statement)

LIMITED WARRANTY

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

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

Mechanical components are subject to wear and fatigue over time. They will deteriorate quicker when continuous-use applications are involved. To insure compliance with operating specifications, it is the user's responsibility to insure that periodic preventative maintenance is performed. Following each 12-month period, it is recommended that this device have preventative maintenance performed by Impact or an Impact certified service facility.

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