

SIGH OFF/ON Pushbutton Switch: Default value is "OFF". When set to "ON", first breath delivered is a SIGH, then once every 100-breaths or 7-minutes thereafter (whichever occurs first). Each SIGH equals 150% of Inspiration Time setting, delivered volume is increased by 50%. Status displayed in LCD (beneath Pushbutton Switch).

PEEP OFF/ON-SET Pushbutton Switch: Sets internally-generated PEEP setpoint. Default value is "OFF". Range is from 0 to 20 cmH₂O. Value increases by 1, each time pushbutton is pressed. Value displayed in LCD (beneath Pushbutton Switch).

PRESSURE PLATEAU OFF/ON Pushbutton Switch: Default value is "OFF". When switch is pressed, PLATEAU value is automatically referenced 10 cmH₂O less than HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint. Plateau range is 5 to 90 cmH₂O. Value displayed in LCD (beneath Pushbutton Switch).

HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control: Sets threshold value for High Pressure Alarm/Peak Inspiratory Pressure Relief. Range is 15 to 100 cmH₂O. Default is current position of Control. Activates when inspiratory pressure exceeds setpoint any time during 4-consecutive ventilations. Value displayed in LCD (beneath Control).

LOW PRESSURE ALARM Control: Sets threshold value for Low Pressure Alarm. Range is 0 to 50 cmH₂O. Default is current position of Control. Activates when inspiratory pressure does not exceed setpoint at any time during 2-consecutive ventilations. Value displayed in LCD (beneath Control).

ALARM MESSAGE CENTER (AMC): A centralized location for displaying up to 4-lines of alarm message information. Up to 2-alarms with, short messages, may be displayed simultaneously. If more than 2-alarms occur simultaneously, only the name of each alarm is displayed (as shown below in boldface).

BATTERY LOW/FAIL-RECHARGE/ REPLACE BATTERY PACK
EXTERNAL POWER LOW-CHECK POWER SOURCE/CONNECTIONS
O2 LOW/FAIL-CHECK OXYGEN SOURCE/CONNECTIONS
EXT AIR LOW/FAIL-CHECK AIR SOURCE/CONNECTIONS
LOW PRESSURE-PEAK INSPIRATORY PRESSURE TOO LOW
DISCONNECT-CHECK CIRCUIT CONNECTIONS
HIGH PRESSURE-PEAK INSPIRATORY PRESSURE TOO HIGH
APNEA-CHECK PATIENT FOR SPONTANEOUS BREATHING
APNEA-CPAP AVERAGE RATE LESS THAN 6-BPM
HIGH PEEP-INSPIRATION BEGAN BEFORE END PRESSURE PLATEAU
FI02-GAS MIX ERROR. CHECK SOURCE/SETTINGS/CONNECTIONS
PRESSURE ALARM SETTINGS-ALARM SETTINGS REVERSED
VT-DELIVERED TIDAL VOLUME DOES NOT EQUAL SET TIDAL VOLUME
COMP-COMPRESSOR OUTPUT LOW/FAIL
INSPIRATION TIME TRUNCATED TO 3-SEC - NOTE I-TIME & I:E
PLATEAU VOLUME-DELIVERED VOLUME LESS THAN SET VOLUME
VT SETTINGS - I-TIME X FLOW UNABLE TO DELIVER SET VOLUME
EXT PWR FAIL/DISCONNECT - CHECK POWER SOURCE/CONNECTIONS
TOTAL FLOW BACKUP - CONTACT CUSTOMER SERVICE
INVERSE I:E-INSPIRATORY TIME LONGER THAN EXHALATION TIME
TRANSDUCER CALIBRATION ABORT RECALIBRATE TRANSDUCER

The following alarm overrides any of the above messages when activated:

VENTILATOR FAILURE DETECTED
 * this alarm is followed by one of the following *
 FAILURE CODE 1
 ● SELF-CHECK FAILURE!
 FAILURE CODE 2
 ● NO GAS AND COMPRESSOR FAILURE!
 FAILURE CODE 3
 ● EXCESSIVE AIRWAY PRESSURE!
 FAILURE CODE 4
 ● MEMORY CHECK FAILURE!
 FAILURE CODE 5
 ● EXHALATION VALVE FAILURE!
 FAILURE CODE 6
 ● EXCESSIVE NEGATIVE PRESSURE!
 FAILURE CODE 7
 ● RUN-TIME CALIBRATION FAILURE!

EXTERNAL AIR OFF/ON Pushbutton Switch: Use with nominal 50-PSI compressed gas source. Default value is "OFF". Status displayed in LCD (beneath Pushbutton Switch).

MODE Indicator: Displays current setting the MODE Selector Switch

V_{min} Indicator: Displays Minute Volume (in liters), in the A/C mode.

INSPIRATION/EXHALATION Indicator: Alternately displays the inspiration and exhalation phase of mechanical and/or spontaneous breaths.

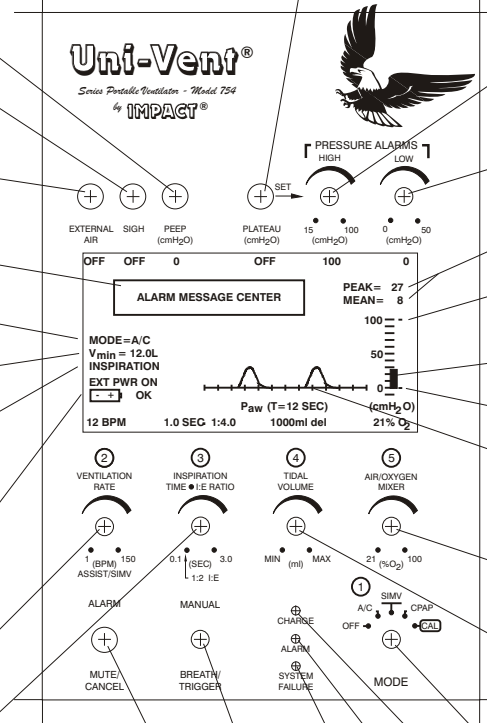
POWER INFORMATION CENTER: A 2-line area that displays current status of external power, internal power, and fuses. The EXT PWR line blinks when the ventilator is not connected to an external power source.

VENTILATION RATE Control: Sets mechanical ventilation rate for A/C and SIMV modes. Range is 1 to 150 BPM. Default is current position of Control. Value displayed in LCD (above Control).

INSPIRATION TIME I:E RATIO Control: Sets inspiratory duration for all ventilator-generated breaths. Range 0.1 to 3.0-seconds maximum. Usable range is limited by VENTILATION RATE Control setting (Inverse I:E is not permitted). Fully counterclockwise position enables fixed 1:2 I:E Ratio. Default is current position of Control. Combination of inspiration time and I:E Ratio is displayed in LCD (above Control).

ALARM MUTE/CANCEL Pushbutton Switch: The alarm category determines what effect pressing this switch will have. It will mute an audible operating alarm signal, cancel an advisory alarm signal, or cancel specific alarms such as APNEA or EXTERNAL POWER FAIL. A typical mute is 30-seconds, special alarms have longer mutes.

MANUAL BREATH/TRIGGER: Delivers a Manual Breath equal to one complete ventilatory cycle in A/C and SIMV. In CPAP, the Manual Breath delivers gas at a 30 LPM flow rate, for 1.67-seconds, pressure limited to 40 cmH₂O. The Manual Trigger is operational when a System Failure has occurred. Gas will flow at a rate of 30 LPM, pressure limited to 40 cmH₂O, for as long as the Pushbutton Switch is pressed.



PEAK and MEAN AIRWAY PRESSURE Indicators: Display the Peak and MEAN Airway Pressure of the previous breath.

HIGH AIRWAY PRESSURE ALARM Setpoint Indicator: Indicates current setting of HIGH PRESSURE ALARM Control adjacent to Digital Bar Graph.

DIGITAL BAR GRAPH Indicator: Provides continuous display of airway pressure. Range is from -10 to +100 cmH₂O, vertical resolution 2 cmH₂O/bar.

LOW AIRWAY PRESSURE ALARM Setpoint Indicator: Indicates current setting of LOW PRESSURE ALARM Control adjacent to Digital Bar Graph.

P_{aw} Indicator: Displays the most recent 12-seconds of airway pressure information. Vertical axis is calibrated to coincide with adjacent DIGITAL BAR GRAPH. Horizontal axis is calibrated in 1-second intervals.

AIR/OXYGEN MIXER Control: Sets FIO₂ when ventilator is connected to external 50-PSI oxygen source. Range is 21 to 100%. Default is current position of Control. FIO₂ value displayed in LCD (above Control).

TIDAL VOLUME Control: Sets Tidal Volume. Range is based on gas flow not exceeding 60 LPM (1000 ml/sec). Default value is current position of Control. Set and delivered Tidal Volume alternately displayed in LCD (above Control).

MODE Selector Switch: Applies operating power to ventilator for Assist-Control (A/C), Synchronized Intermittent Mandatory Ventilation (SIMV), Continuous Positive Airway Pressure (CPAP), or Transducer Calibration (CAL) modes.

CHARGE Indicator: Green LED, illuminates when battery recharging current is flowing. LED does not remain illuminated when battery is fully charged.

ALARM Indicator: Activates for all alarm conditions except a System Failure Alarm. Red LED flashes on/off when alarm is not muted; stays on continuously when alarm is muted. The LED Indicator is accompanied by a pulsing tone that remains on until the alarm is muted.

SYSTEM FAILURE Indicator: Activates when CPU is forced to stop operation or a CPU failure has occurred. Red LED illuminates continuously and is accompanied by a continuous audible tone that cannot be muted. A System Failure will cause the LCD to blank.

OPERATION MANUAL

**PORTABLE, SELF-CONTAINED VENTILATION SYSTEM
(VENTILATOR, COMPRESSOR, AIR/OXYGEN MIXER)**

**UNI-VENT[®] Eagle[®]
700 SERIES
MODEL 754**

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

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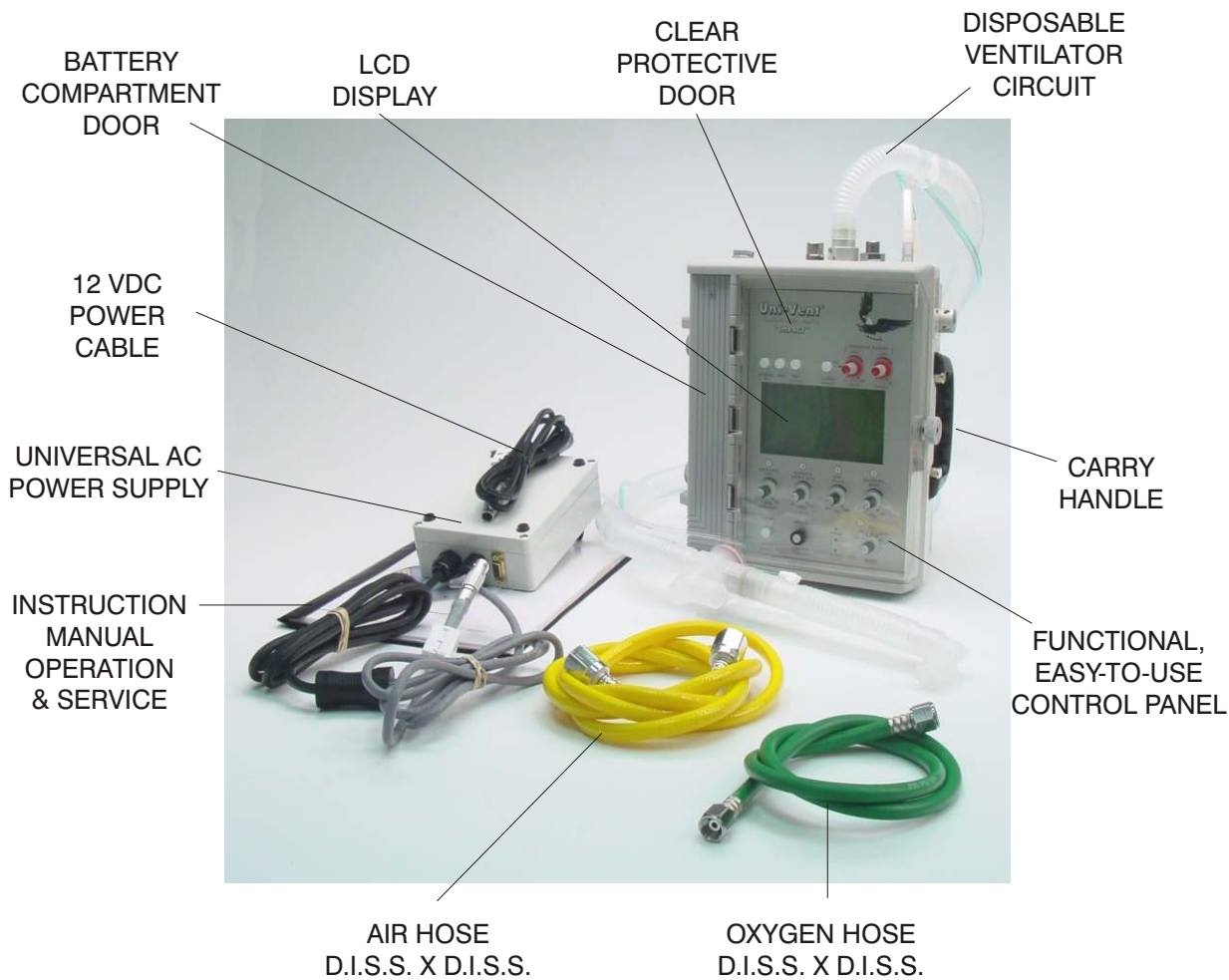


Figure 1. Model 754 Main Features

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

Air/Oxygen Mixer - Blender, Gas Blender
Model 754 - Uni-Vent[®]
Pressure Plateau - Plateau
Uni-Vent[®] - Model 754, Ventilator, Eagle[™]
Ventilator-Compressor-Air/Oxygen Mixer - Ventilator

DEFINITIONS

Gas - Air or oxygen or the resultant mixture of these two gases
Ventilator - Any reference to the Model 754, Uni-Vent[®], Ventilator-Compressor-Air/Oxygen Mixer
- Denotes that display will indicate some number between 0 and 9 for each appearance of "#"

ABBREVIATIONS

Airway Pressure - P_{aw}
Alarm Message Center - AMC
Assist-Control - A/C
Assist-Control Ventilation(s) - ACV
Breaths Per Minute - BPM
Centimeters of Water - cmH₂O
Continuous Positive Airway Pressure - CPAP
delivered - del
End Tidal Carbon Dioxide - ET_{CO}₂
Fraction of Inspired Oxygen - FIO₂
Light Emitting Diode - LED
Liquid Crystal Display - LCD
liters - L
Liters Per Minute - LPM
milliliters - ml
Oxygen - O₂
Peak Inspiratory Pressure - PIP
Positive End Expiratory Pressure - PEEP
Pounds Per Square Inch - PSI
Power Information Center - PIC
Synchronized Intermittent Mandatory Ventilation(s) - SIMV
Tidal Volume - V_T
Work-of-Breathing - WOB

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). 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 2000 hours of cumulative use or 12-month period. A pressure-sensitive Calibration label is attached to the outer case, indicating when the last calibration was performed and the next calibration is due. DO NOT remove this label. Following 6-months of continuous storage/non-use, this device should be examined, operationally tested, and its batteries recharged before patient-use is attempted. The Model 754 contains internal clocks that monitor cumulative use and storage/non-use periods. Appropriate Advisory Alarm messages will appear in the Alarm Message Center when calibration/preventative maintenance is required.

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[®] Eagle[™], Model 754, 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.).

WARNINGS AND CAUTIONS REGARDING USE

WARNING: Electric shock hazard, do not remove equipment covers.

WARNING: Do not operate this instrument prior to reading instructions contained within this Manual.

WARNING/CAUTION: Possible explosion hazard if used in the presence of flammable anesthetics.

WARNING/CAUTION: DO NOT block or connect the ventilator circuit hose to the Internal Compressor Air Filter port (see Figure 2).

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

WARNINGS AND CAUTIONS REGARDING USE, (cont'd)

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

CAUTION: Do not allow oil and grease to enter system. See ROUTINE CARE AND MAINTENANCE section entitled CLEANING for additional instructions.

CAUTION: Internal components are susceptible to damage from static discharge.

ASSEMBLY, INTERCONNECTIONS AND INITIAL ADJUSTMENTS

ASSEMBLY:

Model 754 - No assembly is required before placing this device into operation.

INTERCONNECTIONS:

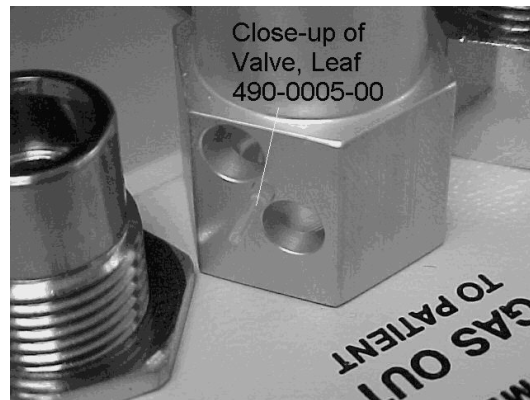
CAUTION: Follow interconnection instructions prior to placing this device into service (see Figure 2).

1. For use with external oxygen: connect high pressure oxygen hose between OXYGEN inlet port and a 50-PSI external oxygen source. Use only medical-grade oxygen (see Figures 5a and 5b).
2. For use with external air: connect high pressure air hose between AIR inlet port and a 50-PSI external air source. Use only medical-grade compressed air (see Figures 5a and 5b).
3. Connect disposable ventilator circuit to its respective gas outlet, transducer, and exhalation valve connectors on Model 754 Connector Panel. Observe directions included with disposable ventilator circuit (see Figure 4).

The gas outlet contains a leaf valve mounted flush to its inside – it has two purposes. First, should a spontaneously breathing patient require supplemental flow or the ventilator is not triggering in response to the patient’s breathing effort, the leaf valve opens allowing entrainment of ambient air (acting as an anti-asphyxia valve). Second, should the gas outlet port or the ventilator circuit become blocked, the leaf valve wedges itself into the large holes it normally blocks (acting as a protective blow-out valve) to protect the patient and ventilator from excessively high pressures. Never block (or occlude) the gas outlet port or connected ventilator circuit when the ventilator is operating. Prior to operation, verify that the leaf valve is properly seated otherwise re-seat before patient use.



Location of Leaf Valve inside Adapter



Leaf Valve in position

Should valve dislodge, use blunt end of a small diameter object to gently push wedged section(s) of leaf valve inward so it dislodges from peripheral hole(s) and re-seats itself against inner wall of gas outlet connector. Visually verify leaf valve lays flush against inner wall curvature of gas outlet connector.

Should valve detach from gas outlet connector, gently grab leaf valve “tail” with tweezers. Insert “tail” from inside of gas outlet connector through its small hole. Grab “tail” as it passes through small hole. Pull gently on “tail” until you feel it lock into position. Leaf valve and mating hole have interlocking shoulders causing valve to become locked in place when initially pulled. Visually verify leaf valve lays flush against inner wall curvature of gas outlet connector.

INTERCONNECTIONS, (cont'd)

4. Connect Universal AC Power Supply, or 12 VDC Power Cable, between EXTERNAL POWER JACK and external power source (see Figure 5b).

NOTE: The standard Universal AC Power Supply is operable from AC voltages between 100 and 240 volts, 50/60 Hz. Voltage and line frequency sensing is automatic. Output Voltage is nominally 13.0VDC.

NOTE: For 11-15 VDC operation, connect appropriate power cord between EXTERNAL POWER JACK and 11-15 VDC power source. A 12 VDC Power Cable is provided for attachment to automotive power source, negative ground.

INITIAL ADJUSTMENTS:

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

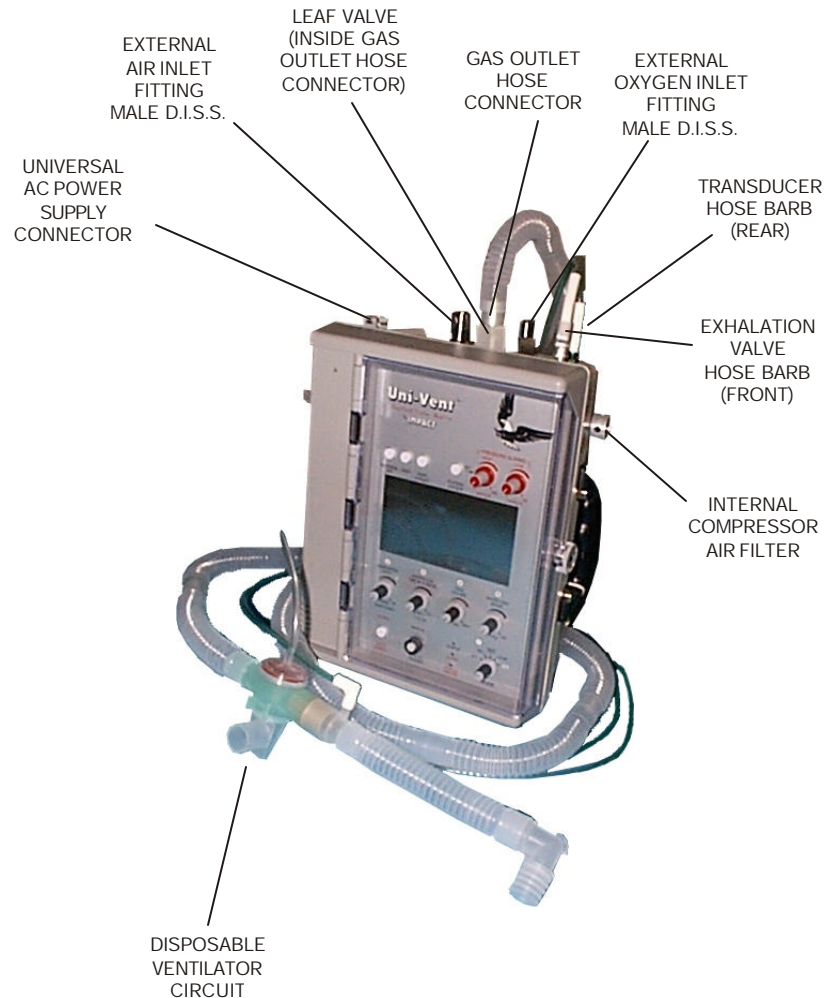


Figure 2. Interconnection Diagram

SECTION I. OPERATION

INTRODUCTION

User's will find this instrument quite easy-to-learn and operate. The following text presents a brief overview of device features. A complete understanding of its capabilities and limitations will allow you to take advantage of its many features.

Your Model 754 is a portable, electronically controlled ventilator, compressor, air/oxygen mixer. It is controlled by an internal microprocessor (CPU) which continuously monitors and displays airway pressure, control settings, alarm parameters, gas source(s), gas flows, gas blends, and power signals. ACV, SIMV and CPAP modes are operable with or without PEEP, with or without SIGH. ACV and SIMV are operable with or without Pressure Plateau. All modes are PEEP and altitude compensable to minimize your patient's work-of-breathing and automatic ventilatory backup assures continued mechanical support if the patient becomes apneic. An adjustable pressure limit control limits peak inspiratory pressures and high pressure alarm setpoint.

The Model 754 can provide gas mixtures with oxygen content ranging from 21 to 100%. Gases may be blended from external oxygen (compressed gas cylinder or PTLOX) and internal compressor, or external oxygen and external compressed air. External compressed air, delivered from an electric compressor, must be oil-less and filtered. Acceptable input gas pressures may range up to 80-PSI without effecting measurement accuracy or danger to internal componentry. It is operable in any position; upright, on its side, or lying flat.

Uni-Vent[®] is operable from internal, rechargeable batteries; 11-15 volts DC (negative ground). Its battery pack may be recharged within the range of either of the aforementioned DC voltages. A Universal AC Power Supply and 12 VDC Power Cable is provided. The Universal AC Power Supply connects directly to AC mains providing 100 to 240 volts, 50/60 Hz, Output Voltage is nominally 13.0VDC. The Model 754 does not consume gas for operating power - all gas is dedicated for patient care.

Your ventilatory system employs a comprehensive alarm system. Alarms are categorized as Operating, Non-operating, or Advisory (see section entitled ALARM FUNCTIONS for complete descriptions of each alarm).

The Model 754 is extremely durable and designed for all environments. Its case is injection molded from polycarbonate material. It is appropriate for use with adults, children and infants - in clinical, field hospital, aeromedical, homecare, and prehospital (ALS, ATLS, ACLS) settings. Its small size and weight facilitates transport, deployment and storage.

FEATURES

- Microprocessor control of all functions including automatic monitoring of internal battery and external power sources, internal compressor and external gases.
- Extensive alarm monitoring of operating, non-operating and advisory conditions.
- Contemporary design to facilitate transport and placement.
- Gas-efficient electronic control circuitry eliminates all pneumatic-logic circuits, and any dependency on gas for operating power.
- Rechargeable batteries, fully compatible with vehicular electrical systems and airborne environments.
- Self-contained system, may be operated without attachment of external gas(es).

FEATURES, (cont'd)

- Numerical panel markings that indicate sequence-of-operation steps to simplify and speed start-up.
- Graphics display includes 12-second pressure waveform, its amplitude is calibrated to the adjacent digital bar graph.
- Automatically compensates pressure transducer to altitude-related barometric pressure changes up to 25,000 ft.

DESCRIPTION OF CONTROLS, VISUAL INDICATORS AND CONNECTIONS

Uni-Vent[®] contains various controls, indicators and connectors. Their placement has been carefully chosen to facilitate ease of use, visibility, and interconnection. A large, liquid crystal display (LCD) provides continuous display of graphics, control settings, operating conditions, and alarm status information. A clear door protects control panel components from weather, fluids and inadvertent contact.

CONTROLS

Control descriptions are listed based upon their control panel location, reading from left to right, top to bottom. Where applicable, corresponding LCD information is provided. Each is described in the following text (see Figure 3).

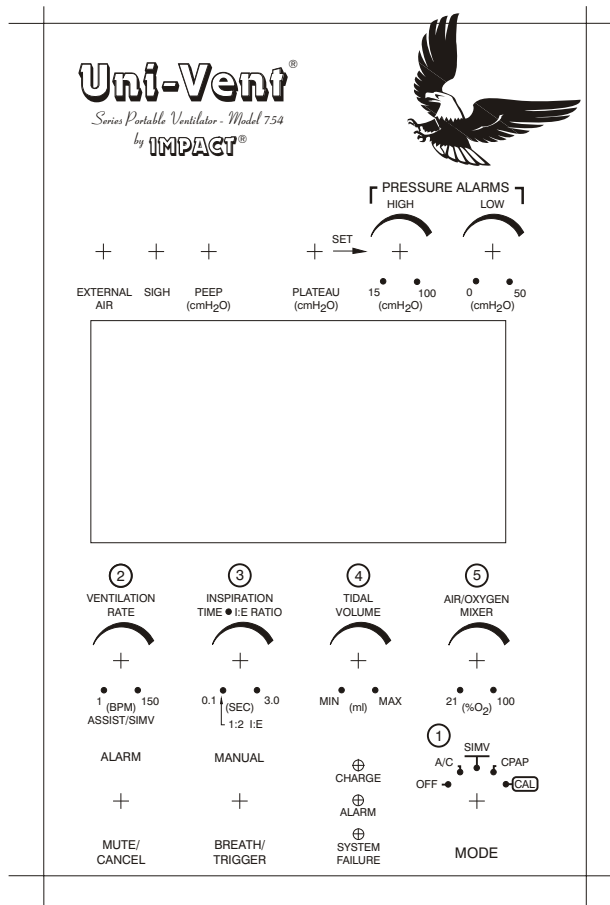


Figure 3. Control Panel

CONTROLS, (cont'd)

EXTERNAL AIR OFF/ON Pushbutton Switch: The EXTERNAL AIR Pushbutton Switch permits you to manually select external compressed air as your primary air source. When the ventilator is turned ON, its CPU "samples" the respective gas fitting and looks for an air pressure, greater than 40-PSI. If a lower pressure, or no pressure is sensed, the LCD will display "OFF" (default value), and the CPU allows operation from the internal compressor. If a pressure exceeding 40-PSI (+/- 2-PSI) is sensed, the LCD will display "ON", and allow operation from the external air supply. Manually pressing this pushbutton will toggle the display from "OFF" to "ON", or from "ON" to "OFF". Attempting to select "ON" with less than 35-PSI (+/- 2-PSI) present will cause an alarm to sound. The LCD display area for EXTERNAL AIR is on the top line, immediately below its respective pushbutton switch. The EXTERNAL AIR OFF/ON display will blank when a SYSTEM FAILURE Alarm occurs.

SIGH OFF/ON Pushbutton Switch: The SIGH OFF/ON Pushbutton Switch permits Uni-Vent[®] to operate with or without SIGH. When activated, the first ventilator generated breath will be a SIGH. Additional SIGH ventilations are delivered once every 100 ventilations or 7-minutes, whichever occurs first. Each SIGH ventilation equals 150% of the INSPIRATION TIME setting (and exhalation period), which increases delivered volume by 50%. Proportionately increasing both the inspiration and exhalation time allows Uni-Vent[®] to maintain I:E during SIGH. As a safety precaution, Uni-Vent[®] does not allow the inspiratory portion of a SIGH breath to exceed 3-seconds. Manually pressing this pushbutton will toggle the display from "OFF" to "ON", or from "ON" to "OFF". "OFF" is its default value. SIGH becomes disabled ("OFF") in the CPAP mode, or when PRESSURE PLATEAU is selected ("ON"). The LCD display area for SIGH is on the top line, immediately below its respective pushbutton switch. The SIGH OFF/ON display will blank when a SYSTEM FAILURE Alarm occurs.

PEEP OFF/ON-SET Pushbutton Switch: The PEEP OFF/ON-SET Pushbutton Switch activates Uni-Vent's internal PEEP control. When the ventilator is turned ON, PEEP has a default value of 0 cmH₂O (no PEEP). Pressing the pushbutton allows a PEEP value to be manually entered (see section entitled USING POSITIVE END EXPIRATORY PRESSURE). The LCD display area for PEEP is on the top line, immediately below its respective pushbutton switch. The PEEP OFF/ON-SET display will blank when a SYSTEM FAILURE Alarm occurs.

PRESSURE PLATEAU OFF/ON Pushbutton Switch: The PRESSURE PLATEAU OFF/ON Pushbutton Switch permits ACV or SIMV operation with a pressure plateau. When the ventilator is turned ON, PLATEAU is OFF (default value). Pressing this pushbutton activates a PLATEAU value that is referenced 10 cmH₂O below the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint. Its absolute range is 5 to 90 cmH₂O. When this pushbutton is pressed, it will toggle the display from "OFF" to its PLATEAU value, or from its PLATEAU value to "OFF". PRESSURE PLATEAU becomes disabled ("OFF") in the CPAP mode. The LCD display area for PRESSURE PLATEAU is on the top line, immediately below its respective pushbutton switch (see section entitled USING PRESSURE PLATEAU). The PRESSURE PLATEAU OFF/ON display will blank when a SYSTEM FAILURE Alarm occurs.

HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control: This control is used to select the HIGH PRESSURE ALARM and PEAK INSPIRATORY PRESSURE RELIEF setpoint. It has an absolute range from 15 to 100 cmH₂O. When the ventilator is turned ON, the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint value equals its current position. The LCD display area for HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint is on the top line, immediately below its respective control. The HIGH PRESSURE ALARM Control setting display will blank when a SYSTEM FAILURE Alarm occurs. Once the ventilator is operating on the patient, the user should set the airway pressure limit 5 to 10 cm H₂O above the patient's peak inspiratory airway pressure.

LOW PRESSURE ALARM Control: This control is used to select the LOW PRESSURE ALARM setpoint. It has an absolute range from 0 to 50 cmH₂O. When the ventilator is turned ON, the LOW PRESSURE ALARM Control setpoint value equals its current position. The LCD display area for the LOW PRESSURE ALARM Control setpoint is on the top line, immediately below its respective control. The LOW PRESSURE ALARM Control setting display will blank when a SYSTEM FAILURE Alarm occurs.

CONTROLS, (cont'd)

VENTILATION RATE Control: The VENTILATION RATE control setting determines the mechanical ventilation rate for ACV and SIMV operation. It is not operable in CPAP (RATE = 0). Its range is from 1 to 150 breaths per minute (BPM). When the ventilator is turned ON, the VENTILATION RATE Control setpoint value equals its current position. The LCD display area for VENTILATION RATE Control setpoint is on the bottom line, immediately above its respective control. During APNEA, the RATE Control setting and its LCD display will change to 12 BPM. The VENTILATION RATE Control setting display will blank when a SYSTEM FAILURE Alarm occurs, or the CPAP mode is selected.

INSPIRATION TIME/I:E RATIO Control: The INSPIRATION TIME/I:E RATIO Control sets the inspiratory duration of all ventilator-delivered breaths. It is adjustable in 0.1 second increments from 0.1 to 3.0 seconds maximum. Its usable range is limited by the VENTILATION RATE Control setting. Inverse I:E Ratio's (inspiratory time is greater than expiratory time) are not permitted. (See section entitled ALARM FUNCTIONS). A default I:E ratio of 1:2 is activated when this control is turned to its fully counterclockwise position. When the ventilator is turned ON, the INSPIRATION TIME/I:E RATIO Control setpoint value equals its current position. Setting INSPIRATION TIME causes the resulting I:E RATIO to be calculated. Setting the default I:E RATIO (1:2) causes the INSPIRATION TIME to be calculated when VENTILATION RATE settings are changed. Inspiration time and I:E ratio are simultaneously displayed in the LCD. The LCD display area for INSPIRATION TIME/I:E RATIO Control setpoint is on the bottom line, immediately above its respective control. The INSPIRATION TIME/I:E RATIO Control setting display will blank when a SYSTEM FAILURE Alarm occurs or CPAP is selected. It will blink during INVERSE I:E conditions.

TIDAL VOLUME Control: The TIDAL VOLUME Control allows gas to be delivered over a wide range. Its maximum flow is equivalent to approximately 1000ml/sec (60 LPM). TIDAL VOLUME may be obtained from any of the following gas or gas combinations:

External Air (Cylinder)

External Compressed Air (Compressor)

Internal Air Compressor

External Oxygen and External Air Cylinder or Compressor, or Internal Air Compressor

External Oxygen

Tidal volume is calculated and displayed in milliliters (ml). When the ventilator is turned ON, the TIDAL VOLUME Control setpoint value equals its current position. Uni-Vent's CPU monitors and adjusts gas flow. Its LCD initially displays "#### set" TIDAL VOLUME for the first one or two delivered breaths, while the CPU makes whatever flow corrections are required, then the LCD alternately displays "#### set" TIDAL VOLUME and "#### del" TIDAL VOLUME. The LCD display area for TIDAL VOLUME Control setpoint is on the bottom line, immediately above its respective control. The TIDAL VOLUME Control setting display will blank when a SYSTEM FAILURE Alarm occurs or CPAP is selected.

AIR/OXYGEN MIXER Control: The AIR/OXYGEN MIXER Control allows air, oxygen, or mixtures of air and oxygen to be delivered. It has a range of 21% (all air) to 100% (all oxygen) and may be obtained from the following gas or gas combinations:

21% FIO₂ from External Air (Cylinder)

21% FIO₂ from External Compressed Air (Compressor)

21% FIO₂ from Internal Air Compressor

21 to 100% FIO₂ from External Oxygen and External Air Cylinder or Compressor

21 to 100% FIO₂ from External Oxygen and Internal Air Compressor

100% FIO₂ from External Oxygen

CONTROLS, (cont'd)

When the ventilator is turned ON, the AIR/OXYGEN MIXER Control setpoint value equals its current position. Uni-Vent's CPU monitors and adjusts gas flow according to the FIO₂ and TIDAL VOLUME setpoints. In CPAP mode, FIO₂ proportions are based on gas flowing at 1000ml/sec. The CPU makes any necessary flow corrections during the first one or two delivered breaths. Delivered FIO₂ is displayed in the LCD. The LCD display area for AIR/OXYGEN MIXER Control setpoint is on the bottom line, immediately above its respective control. The AIR/OXYGEN MIXER Control setting display will blank when a SYSTEM FAILURE Alarm occurs. It will blink when an EXT AIR LOW/FAIL, O₂ LOW/FAIL, or FIO₂ Alarm occurs.

ALARM MUTE/CANCEL Pushbutton Switch: Depending upon alarm category, the ALARM MUTE/CANCEL Pushbutton Switch can either mute an audible alarm signal, or cancel a particular alarm function.

Muting: Depressing this switch mutes the audible component of an Operating Alarm condition for a predetermined period (see ALARM FUNCTIONS). Alarm muting is reset when the current alarm condition no longer applies or the predetermined mute-period is reached (audible alarm will resound). A new alarm condition overrides a "muted" pre-existing alarm.

When an alarm causing condition occurs, the LCD ALARM MESSAGE CENTER will display the pertinent alarm message. The ALARM LED alternately flashes, at the same frequency as the accompanying audible alarm. Pressing the ALARM MUTE/CANCEL Pushbutton Switch causes the ALARM LED to stay on continuously. It will resume flashing when the mute period ends.

If a new alarm condition occurs during the mute period of a previous alarm, the new alarm will have no effect upon the display of that alarm. The new alarm will cause the ALARM LED to alternately flash and respond as previously described when the ALARM MUTE/CANCEL Pushbutton Switch is pressed.

Canceling: When depressed, the ALARM MUTE/CANCEL Pushbutton Switch cancels the audible component of an Advisory Alarm condition (see ALARM FUNCTIONS). During an APNEA alarm condition, it will cancel both the audible and visual APNEA alarms and the controlled ventilations that are automatically invoked at the onset of apnea. Cancellation of an APNEA alarm allows Uni-Vent[®] to resume operation at the preset ACV, SIMV or CPAP settings.

MANUAL BREATH/TRIGGER Pushbutton Switch: The MANUAL BREATH/TRIGGER Pushbutton is operable two ways.

Pressing this control during normal CPU operation, delivers one MANUAL BREATH. Each MANUAL BREATH is equal to one complete ventilatory cycle consisting of the current INSPIRATORY TIME/TIDAL VOLUME settings and expiratory period. In the CPAP mode, a manual breath is delivered at a flow rate of 30 LPM, an inspiratory time of 1.67-seconds, and pressure limited at 40 cmH₂O. A MANUAL BREATH cannot be delivered until airway pressure has reached baseline (zero or PEEP). Each time a MANUAL BREATH is triggered, an audible beep is heard.

This control functions as a MANUAL TRIGGER backup, if a CPU failure occurs in the primary system. The MANUAL TRIGGER contains dedicated circuitry capable of providing manually triggered breaths. For as long as this pushbutton is depressed, the MANUAL TRIGGER delivers a continuous gas flow at 30 liters per minute (LPM). A pressure relieving mechanism, contained within this circuit, limits peak inspiratory pressure from exceeding 40 cmH₂O.

The MANUAL BREATH/TRIGGER Pushbutton is protected against accidental contact by a circular guard.

MODE Selector Switch (OFF-A/C-SIMV-CPAP-CAL): The MODE SELECTOR Switch provides operating power in the ACV, SIMV, CPAP, and CAL positions.

Turning the MODE SELECTOR Switch from OFF to A/C, SIMV, or CPAP causes the microprocessor to perform a "SELF-CHECK" (see section entitled SELF-CHECK) before initiating operating in the selected mode. Ventilator operation will not begin until "SELF-CHECK" is successfully completed. Calibration of the airway pressure transducer is permitted in the CAL position only (see section entitled TRANSDUCER CALIBRATION).

VISUAL INDICATORS

When activated, STATUS, and ALARM INDICATORS are continuously displayed. All indicators are displayed within the LCD except for the ALARM, SYSTEM FAILURE, and CHARGE LED's which appear elsewhere on the control panel. When activated, the ALARM and SYSTEM FAILURE LED's illuminate red, the CHARGE LED illuminates green.

STATUS

MODE Indicator: Based upon the MODE Selector Switch setting, this indicator displays, respectively, ASSIST, SIMV, CPAP, or CAL. The MODE Indicator display will blank when a SYSTEM FAILURE Alarm occurs.

V_{min} Indicator: Displays Minute Volume (in liters) in the ACV mode, blanks during SIMV, CPAP and CAL or when a PLATEAU VOLUME or SYSTEM FAILURE Alarm occurs.

INSPIRATION/EXHALATION Indicator: Alternately displays the "INSPIRATION" or "EXHALATION" phase of mechanical and/or spontaneous breaths in each operating mode, blanks during CAL. The INSPIRATION/EXPIRATION Indicator display will blank when a SYSTEM FAILURE Alarm occurs.

POWER INFORMATION CENTER: The POWER INFORMATION CENTER (PIC) occupies a 2-line area in the LCD's lower left section. It illuminates when the MODE SELECTOR SWITCH is in any position except OFF and the CPU validates a usable source of power (see OPERATING POWER SELECTION & STOPPING) during the power check portion of SELF-CHECK (see SELF-CHECK). The POWER INFORMATION CENTER display will blank when a SYSTEM FAILURE Alarm occurs.

The POWER INFORMATION CENTER can display the following messages:

Line 1: "EXT PWR ON" or,

Line 1: "EXT PWR LOW" or,

Line 1: "EXT PWR FAIL" or,

Line 1: "EXT CHK FUSE" (flashing, see description below) or,

Line 1: Blank

"EXT PWR ON" denotes operation from an external power source. "EXT PWR LOW" denotes a low external power source voltage and works in conjunction with the EXTERNAL POWER LOW/FAIL Alarm (see section entitled ALARMS). This line is blank when no external power is connected.

Line 2: Battery icon "OK" or,

Line 2: Battery icon "LOW" or,

Line 2: Battery icon "ON CHG" or,

Line 2: Battery icon "CHK FUSE" (flashing, see description below) or,

Line 2: Blank

Battery icon "OK" denotes (1) operation from internal batteries that have more than 30-minutes of remaining charge or, (2) in conjunction with external power operation, internal batteries can provide at least 30-minutes of operation. Battery icon "LOW" denotes (1) operation from internal batteries having less than 30-minutes of remaining charge (see section entitled ALARMS) or, (2) in conjunction with external power operation, internal batteries are being charged and currently have less than 30-minutes

VISUAL INDICATORS, (cont'd)

of operating time capability. Battery icon "ON CHG" is displayed, and the CHARGE LED illuminates, when charging current is flowing into the battery pack. This line will blank if no battery is sensed.

OPEN or MISSING FUSES: The POWER INFORMATION CENTER is able to identify open or missing fuses under the following circumstances:

1. During normal operation from external power, the External Power Operation & Charge Fuse opens (or is removed):
 - a. EXT PWR FAIL/DISCONNECT Alarm activates, operation continues from internal battery.
 - b. PIC Line 1 displays "EXT PWR FAIL".
 - c. When Alarm Mute/Cancel pushbutton is pressed, the EXT PWR FAIL/DISCONNECT Alarm is reset.
 - d. PIC Line 1 flashes "EXT CHK FUSE".
2. Prior to beginning operation from external power, the External Power Operation & Charge Fuse opens (or is removed):
 - a. Operation begins from internal battery.
 - b. PIC Line 1 flashes "CHK EXT FUSE".
3. During normal operation from external power, the Battery Operation & Charge Fuse opens (or is removed):
 - a. Operation continues from external power.
 - b. PIC Line 2 flashes battery icon "CHK FUSE".
4. Prior to beginning operation from internal battery (external power is not connected), and the Battery Operation & Charge Fuse opens (or is removed):
 - a. The ventilator will not operate, its LCD will not illuminate.
 - b. The SYSTEM FAILURE LED illuminates and a continuous tone sounds (non-mutable).

PEAK AIRWAY PRESSURE Indicator: Displays the PEAK AIRWAY PRESSURE of the previous breath. The PEAK AIRWAY PRESSURE Indicator display will blank when a SYSTEM FAILURE Alarm occurs.

MEAN AIRWAY PRESSURE Indicator: Displays the MEAN AIRWAY PRESSURE. Uni-Vent[®] calculates MEAN AIRWAY PRESSURE to the following algorithm:

$$(PIP-PEEP) \times \frac{I}{\text{TOTAL CYCLE TIME}} + PEEP$$

The MEAN AIRWAY PRESSURE Indicator display will blank when a SYSTEM FAILURE Alarm occurs.

DIGITAL BAR GRAPH Indicator: The DIGITAL BAR GRAPH indicator provides continuous display of airway pressure. Its absolute range is from -10 to +100 cmH₂O. Increment markings appear every 10 cmH₂O, numerical markers appear at 0, 50 and 100 cmH₂O. Vertical resolution is 2 cmH₂O/bar. The DIGITAL BAR GRAPH Indicator display will blank when a SYSTEM FAILURE Alarm occurs.

HIGH and LOW AIRWAY PRESSURE ALARM Setpoint Indicators: The HIGH and LOW AIRWAY PRESSURE ALARM Setpoint Indicators appear as small horizontal lines to the right of the DIGITAL BAR GRAPH. Setpoint indicators are positioned according to their respective alarm control settings and reposition

VISUAL INDICATORS, (cont'd)

whenever an alarm control is adjusted. Setpoint indicator vertical resolution is 2 cmH₂O. The respective HIGH or LOW AIRWAY PRESSURE ALARM Setpoint Indicator blinks when a HIGH PRESSURE or LOW PRESSURE Alarm is triggered and blanks when a SYSTEM FAILURE Alarm occurs.

P_{aw} Indicator: The P_{aw} indicator represents a continuous and updating display of airway pressure. It display's the most recent 12-second period. Airway pressure amplitude along the vertical axis is calibrated to coincide with the adjacent digital bar graph. Markings along the horizontal axis represent 1-second intervals. The P_{aw} Indicator display will blank when a SYSTEM FAILURE Alarm occurs.

CHARGE Indicator: The green CHARGE Indicator LED illuminates whenever sufficient battery recharging current is flowing.

Control Setting Indicators: All control settings, except MODE SELECTOR Switch, appear on the LCD's upper and lower lines.

ALARM INDICATORS

The LCD display allocates up to 4-lines of alarm message information in a dedicated area. This dedicated area is called the ALARM MESSAGE CENTER (AMC). Each alarm is displayed in the LCD except for the ALARM Indicator and SYSTEM FAILURE LED's. The ALARM Indicator LED illuminates, and alternately flashes ON and OFF, whenever an alarm causing condition other than SYSTEM FAILURE occurs. An audible signal accompanies each alarm. Alarms are categorized as OPERATING, NON-OPERATING, or ADVISORY (for detailed information on alarms, see section entitled ALARM FUNCTIONS). When the audible signal is muted during an OPERATING ALARM, the ALARM Indicator LED remains illuminated, but stops flashing, during the mute period. During an ADVISORY ALARM pressing MUTE/CANCEL turns the ALARM Indicator LED OFF.

OPERATING ALARMS

BATTERY LOW/FAIL Alarm: Initiates when a low battery condition is sensed. When activated the AMC displays: BATTERY LOW/FAIL - RECHARGE/REPLACE BATTERY PACK, BATTERY LOW/FAIL or BATTERY. The AMC will blank if a non-operating alarm occurs.

EXTERNAL POWER LOW Alarm: Initiates when external power (as sensed at the External Power Jack), is less than 10.9 VDC. When activated the AMC displays: EXTERNAL POWER LOW - CHECK POWER SOURCE/CONNECTIONS or EXT PWR. The AMC will blank if a non-operating alarm occurs.

LOW PRESSURE Alarm: Initiates when PIP fails to exceed the LOW PRESSURE ALARM setpoint for two consecutive breaths and causes its LCD setpoint indicator to blink. When activated the AMC displays: LOW PRESSURE - PEAK INSPIRATORY PRESSURE TOO LOW or LOW PRESSURE. The AMC will blank if a non-operating alarm occurs. The setpoint indicator will alternately blink, with the HIGH PRESSURE Alarm LCD setpoint indicator, during a PRESSURE ALARM SETTINGS Alarm.

DISCONNECT Alarm: Initiates when a disconnect is sensed in the patient circuit. When activated the AMC displays: DISCONNECT - CHECK CIRCUIT CONNECTIONS or DISCONNECT. The AMC will blank if a non-operating alarm occurs.

HIGH PRESSURE Alarm: Initiates when PIP exceeds the HIGH PRESSURE Alarm setpoint for four consecutive breaths, or 2-seconds continuously, and causes its LCD setpoint indicator to blink. When activated the AMC displays: HIGH PRESSURE - PEAK INSPIRATORY PRESSURE TOO HIGH or HIGH PRESSURE. The AMC will blank if a non-operating alarm occurs. The setpoint indicator will alternately blink, with the LOW PRESSURE Alarm LCD setpoint indicator, during a PRESSURE ALARM SETTINGS Alarm.

APNEA Alarm: ACV and SIMV: initiates when approximately 19-seconds have elapsed and no pressure deflections have been sensed. When activated the AMC displays: APNEA - CHECK PATIENT FOR SPONTANEOUS BREATHING or APNEA. CPAP: initiates when no spontaneous breathing is detected for 10-seconds (based on a 30-second moving average). When activated the AMC displays: APNEA - CPAP AVERAGE RATE LESS THAN 6-BPM or APNEA. The AMC will blank if a non-operating alarm occurs.

VISUAL INDICATORS, (cont'd)

HIGH PEEP Alarm: Initiates when the inspiratory cycle begins before end expiratory pressure plateaus. When activated the AMC displays: HIGH PEEP - INSPIRATION BEGAN BEFORE END PRESSURE PLATEAU or HIGH PEEP. The AMC will blank if a non-operating alarm occurs.

O₂ LOW/FAIL Alarm: Initiates when low pressure is sensed from an external oxygen supply. When activated the AMC displays: O₂ LOW/FAIL - CHECK OXYGEN SOURCE/CONNECTIONS, O₂ LOW/FAIL or O₂. The AMC will blank if a non-operating alarm occurs.

EXT AIR LOW/FAIL Alarm: Initiates when low pressure is sensed from an external source of compressed air. When activated the AMC displays: EXT AIR LOW/FAIL - CHECK AIR SOURCE/CONNECTIONS, EXT AIR LOW/FAIL or EXT AIR. The AMC will blank if a non-operating alarm occurs.

FIO₂ Alarm: Initiates when the oxygen component or the air component of the AIR/OXYGEN MIXER is unable to meet its proportion of the gas mixture. When activated the AMC displays: FIO₂ - GAS MIX ERROR. CHECK SOURCE/SETTINGS/CONNECTIONS or FIO₂. The AMC will blank if a non-operating alarm occurs.

PRESSURE ALARM SETTINGS Alarm: Initiates when the HIGH PRESSURE ALARM and LOW PRESSURE ALARM setpoints are reversed (i.e.: low setpoint is set higher than the high setpoint). Both Control setpoint indicators, and both indicators adjacent to the DIGITAL BAR GRAPH, alternately blink during a PRESSURE ALARM SETTINGS Alarm. When activated the AMC displays: PRESSURE ALARM SETTINGS - ALARM SETTINGS REVERSED or PRESSURE ALARM SETTINGS. The AMC will blank if a non-operating alarm occurs.

V_T Alarm: Initiates when delivered tidal volume does not equal set tidal volume. When activated the AMC displays: V_T - DELIVERED TIDAL VOLUME DOES NOT EQUAL SET TIDAL VOLUME or V_T. The AMC will blank in the CPAP mode, or if a non-operating alarm occurs.

COMP Alarm: Initiates when the internal compressor output does not produce its intended contribution to tidal volume. When activated the AMC displays: COMP - COMPRESSOR OUTPUT LOW/FAIL or COMP. The AMC will blank if a non-operating alarm occurs.

NON-OPERATING ALARMS

INVERSE I:E Alarm: Initiates when inspiratory time becomes longer than expiratory time. When activated the AMC displays: INVERSE I:E - INSPIRATORY TIME LONGER THAN EXHALATION TIME or INVERSE I:E. The AMC will blank in the CPAP mode, or if a SYSTEM FAILURE Alarm occurs.

TRANSDUCER CALIBRATION ABORT Alarm: Initiates when the TRANSDUCER CALIBRATION process is stopped prematurely. When activated the AMC displays: TRANSDUCER CALIBRATION ABORT - RECALIBRATE TRANSDUCER or TRANSDUCER CALIBRATION ABORT. The AMC will blank if a MEMORY CHECK or SYSTEM FAILURE Alarm occurs.

SYSTEM FAILURE Alarm: LED, illuminates when CPU is forced to shutdown operation or a CPU failure has occurred. This alarm is usually related to a hardware problem and will cause the LCD to blank.

VENTILATOR FAIL Alarm: Initiates when any one of seven ventilator failure causing conditions occur. These conditions will not cause the LCD to blank, and some may be operator correctable. A VENTILATOR FAIL Alarm will cause the ALARM LED to illuminate. It will not cause the SYSTEM FAILURE LED to illuminate. The LCD will display: VENTILATOR FAILURE DETECTED followed by FAILURE CODE # (a number from 1 to 7), and an abbreviated description of the failure.

ADVISORY ALARMS

INSPIRATION TIME TRUNCATED TO 3-SEC Alarm: Initiates when control settings would cause inspiration time to exceed 3-seconds. It is disabled in the CPAP mode. When activated the AMC displays: INSPIRATION TIME TRUNCATED TO 3-SEC - NOTE I-TIME & I:E. The AMC will blank if a non-operating alarm occurs. A SIGH breath that would exceed 3.0-seconds is truncated but will not activate this alarm.

VISUAL INDICATORS, (cont'd)

PLATEAU VOLUME Alarm: Initiates when delivered PRESSURE PLATEAU tidal volume is less than set tidal volume by more than 5%. When activated the AMC displays: PLATEAU VOLUME - DELIVERED VOLUME LESS THAN SET VOLUME. The AMC will blank in the CPAP mode, or if a non-operating alarm occurs.

V_T SETTINGS Alarm: Initiates whenever the sum of the flows of the selected gases would exceed a flow rate of 60 liters per minute (LPM). When activated, the AMC displays: V_T SETTINGS - I-TIME X FLOW UNABLE TO DELIVER SET VOLUME or V_T SETTINGS. The AMC will blank in the CPAP mode.

PREVENTATIVE MAINTENANCE Alarm: Initiates after 2000-hours of cumulative use, or 12-months, whichever occurs first. When activated the AMC displays: PREVENTATIVE MAINTENANCE DUE - CONTACT CUSTOMER SERVICE. The AMC will blank if a non-operating alarm occurs.

EXTENDED NON-USE/STORAGE Alarm: Initiates at power-up after 6-months of continuous non-use/storage has occurred. When activated the AMC displays: EXTENDED NON-USE/STORAGE - TEST BEFORE PATIENT USE. The AMC will blank if a non-operating alarm occurs.

EXTERNAL POWER FAILURE Alarm: Initiates whenever external power fails, or is disconnected during external power operation. When activated the AMC displays: EXT PWR FAIL/DISCONNECT - CHECK POWER SOURCE/CONNECTIONS or EXT PWR FAIL/DISCONNECT. The AMC will blank if a non-operating alarm occurs.

TOTAL FLOW BACKUP Alarm: Initiates when the backup flow sensor detects the sum of the flows (O₂, Air, and internal compressor) exceeding set flows by +/- 50% for 5-consecutive breaths. There must be a total flow rate of at least 10 LPM and a total tidal volume of at least 200ml for this alarm to operate. When activated the AMC displays: TOTAL FLOW BACKUP - CONTACT CUSTOMER SERVICE. The AMC will blank if a non-operating alarm occurs.

CONNECTIONS

OXYGEN INLET: Nominal 50 PSI input, D.I.S.S. oxygen, male -thread. Connects to output of oxygen cylinder pressure reducer (medical-grade only), PTLOX; or on-board aircraft generated source. Use the high pressure hose, D.I.S.S. Oxygen X D.I.S.S. Oxygen, 6' Long, for interconnection.

AIR INLET: Nominal 50 PSI input, D.I.S.S. air, male -thread. Connects to output of air cylinder pressure reducer (medical-grade only), or electric compressor (oil-less and filtered). Use the high pressure hose, D.I.S.S. Air X D.I.S.S. Air, 6' Long, for interconnection. Note: To protect the ventilator from dirt and condensate, use an Air Inlet Filter/Moisture Trap whenever external air is provided by an electric air compressor.

GAS OUTLET: Low pressure, 22mm male tapered connection. Connects to disposable ventilator circuit 22mm I.D. corrugated hose (see Figure 4).

TRANSDUCER: Low pressure, fits 3/16" I.D. tubing. Connects ventilator pressure transducer to disposable ventilator circuit transducer hose (see Figure 4). This connector is colored green.

EXHALATION VALVE: Low pressure, fits 1/4" I.D. tubing. Connects ventilator exhalation valve control port to disposable ventilator circuit exhalation valve (see Figure 4). This connector is colored clear aluminum.

EXTERNAL POWER JACK: External power source connection. Connects ventilator to Universal AC Power Supply or external 11-15 volt power source via 12 VDC Power Cable (provided).

CAUTION

DO NOT connect external power sources rated higher than 15 volts or lower than 11 volts (see SPECIFICATIONS).

The EXTERNAL POWER JACK includes pins containing signals for the COMMUNICATIONS PORT

CONNECTIONS, (cont'd)

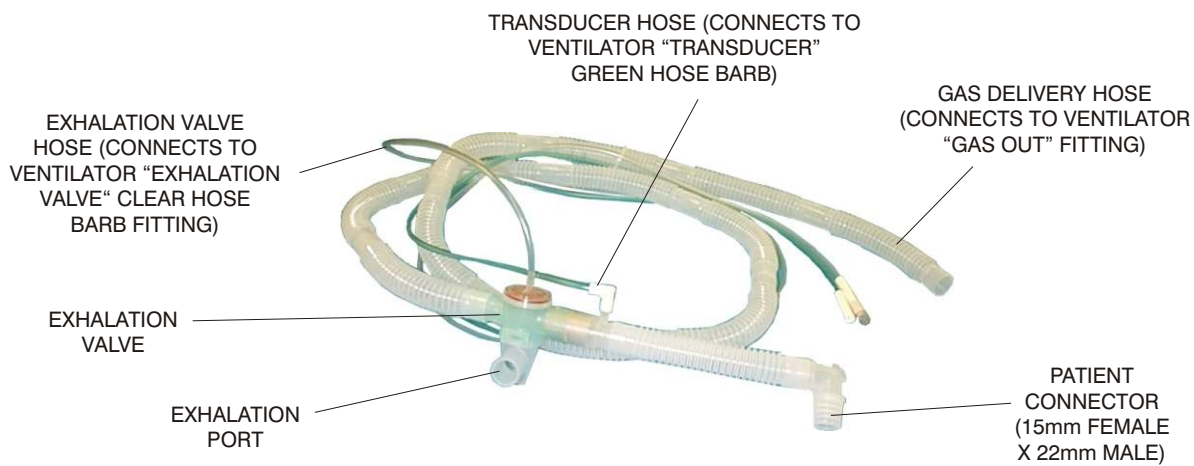


Figure 4. Disposable Ventilator Circuit

(Pins 2, 3 and 5). User's requiring communications capability during operation on battery power may special-order a DC COMMUNICATIONS CABLE from Impact's Customer Service Department.

The connector is wired as follows:

Power	Communications
Pin 1 - Power (+)	Pin 2 - Send
Pin 4 - Ground	Pin 3 - Receive
Pin 6 - Shield	Pin 5 - Ground

COMMUNICATIONS PORT: The Model 754/754M provides a communications interface port for data exchange. The port consists of a standard, 9-Pin, Sub-D, Female, RS-232C connector which is located on the side of the Universal AC Power Supply. The connector is wired as follows:

Pin 2 - Send
Pin 3 - Receive
Pin 5 - Ground

Uni-Vent's communications port permits remote monitoring of ventilator functions and capabilities, including: switches, controls, alarms, and pressure signals.

- Switch, control, and alarm information is monitored and updated every second. Pressure signals are updated every 100-milliseconds.
- Control signals allow servicing personnel to perform "factory-level" device calibrations.

Contact Impact's Customer Service Department, for additional information on communications protocols. Requests for communications protocols must be made in writing and mailed to the attention of the Customer Service Department Supervisor.

OPERATING POWER SELECTION & STOPPING

Uni-Vent[®] is designed to operate from various voltages and frequencies (see SPECIFICATIONS). Its Universal AC Power Supply automatically accepts input voltages from 100 to 240 volts AC, 50/60 Hz. Output Voltage is nominally 13.0VDC.

DC operating voltages, within the range of 11 to 15 volts (negative ground), may be connected directly to the EXTERNAL POWER JACK. A 12 VDC Power Cable is provided for operation from a vehicular source or external 12-volt battery.

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

Uni-Vent[®] is designed to give operating power priority to external power rather than its internal battery pack. When a live external power source is applied, internal batteries are automatically placed on charge. When an external power failure occurs, Uni-Vent[®] automatically switches to its internal battery pack for operating power and activates the EXTERNAL POWER FAILURE Alarm. When external power reappears, operation will switch from internal power to the external source.

Two external fuseholders are located adjacent to the battery compartment door. Each fuseholder contains a type 5 X 20mm, 10A fuse. The fuse closest to the top cover effects external power operation and battery charging. The other fuse effects battery operation and charging. POWER INFORMATION CENTER messages for "EXT PWR" and battery icon "ON CHG" will not display if their respective fuse(s) is/are blown or missing. See DESCRIPTION OF CONTROLS, VISUAL INDICATORS AND CONNECTIONS - POWER INFORMATION CENTER, for additional information.

INITIAL SET-UP, SELF-CHECK & TRANSDUCER CALIBRATION

INITIAL SET-UP: (Refer to Figures 5a and 5b).

Uni-Vent[®] is easily configurable to suit most applications. Additional hoses, fittings and adapters may be required for particular uses. Figures 5a and 5b depict common applications.

TEST ALL CONFIGURATIONS FOR CORRECT OPERATION PRIOR TO PATIENT CONNECTION.

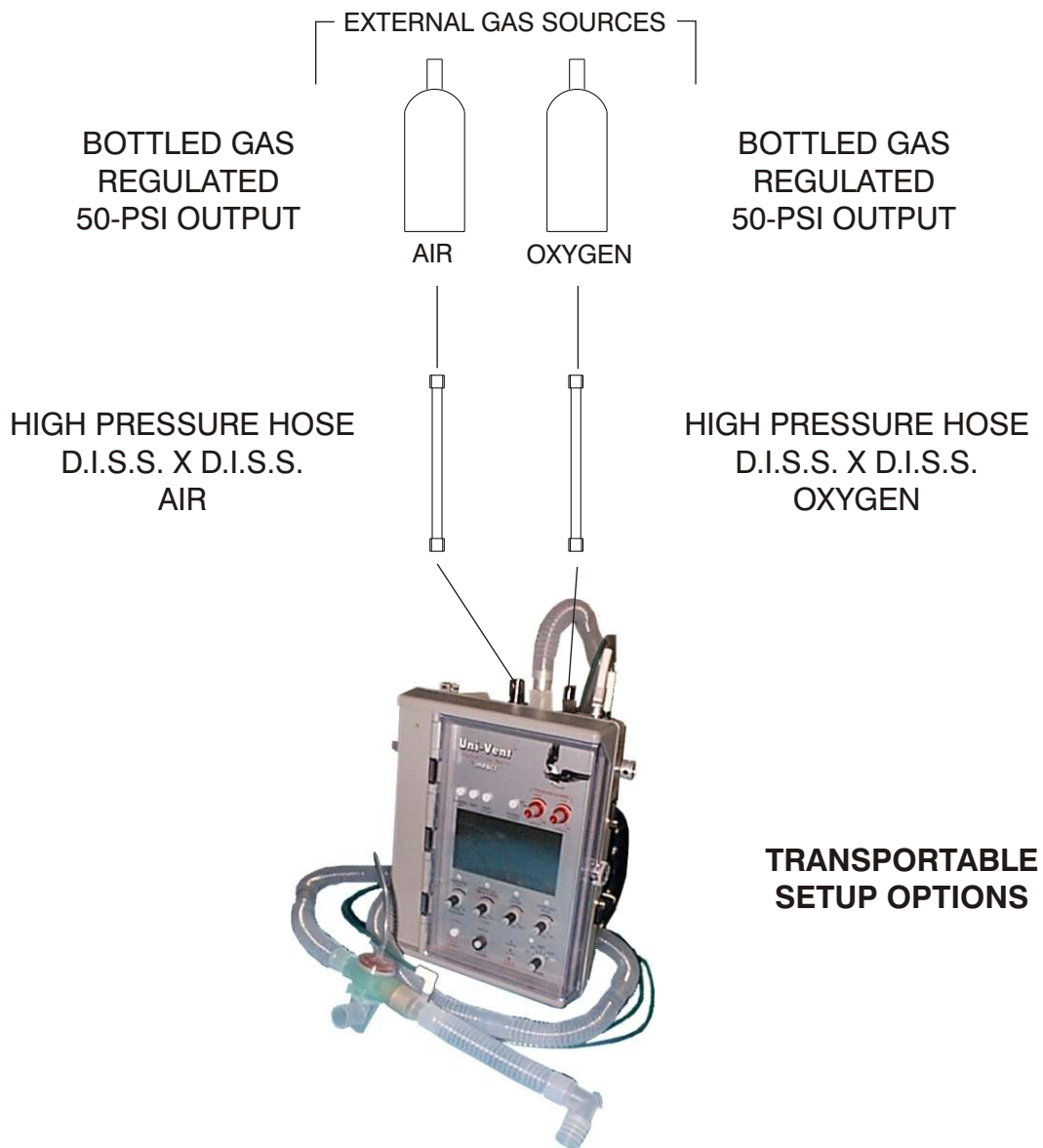


Figure 5a. Initial Setup

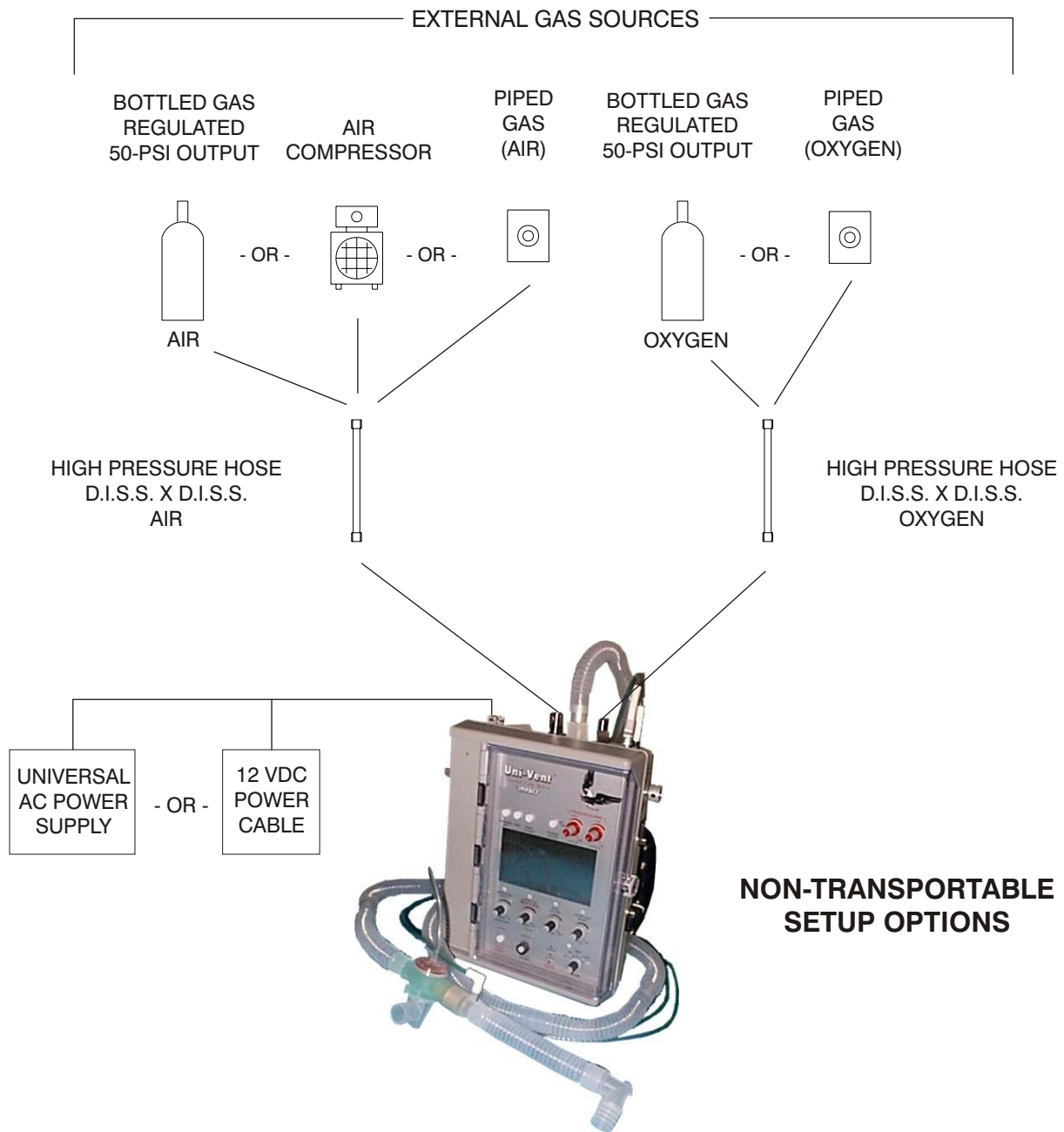


Figure 5b. Initial Setup

SELF-CHECK

Uni-Vent[®] undergoes a self-checking process every time its MODE Selector Switch is turned from "OFF" to ACV, SIMV, or CPAP; or from CAL to ACV, SIMV, or CPAP. After the initial SELF-CHECK is performed, self-checking is not repeated if the operator turns the MODE Selector Switch to another operating mode position.

The SELF-CHECK process consists of interaction between Uni-Vent's microprocessor and peripheral circuitry to verify external power/internal battery status, memory check, pressure transducer calibration and control panel settings.

NOTE

If external oxygen and/or external compressed gas is connected, each gas pressure must be at least 40-PSI (+/- 2-PSI) at the time SELF-CHECK is performed.

WARNING

SELF-CHECK must be performed with the disposable 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. Current information is compared to previous calibration information stored in memory. Accordingly, any residual pressure would result in a false reading leading to a SELF-CHECK failure.

Operation begins immediately following SELF-CHECK.

If Uni-Vent[®] fails SELF-CHECK, a VENTILATOR FAIL Alarm will occur. Return the MODE Selector Switch to its OFF position and then repeat this procedure. If SELF-CHECK fails again, contact qualified service personnel - DO NOT ATTEMPT PATIENT USE.

SELF-CHECK will automatically alert attendant personnel if the pressure transducer calibration "zero" baseline exceeds +/- 1 cmH₂O from its last calibration. A TRANSDUCER CALIBRATION Alarm activated during SELF-CHECK will cause an audible tone and the AMC to display:

TRANSDUCER CALIBRATION - CALIBRATE TRANSDUCER VENTILATOR FAILURE DETECTED	- OR - if SELF-CHECK Alarm is not related to the Transducer Calibration:	VENTILATOR FAILURE DETECTED
FAILURE CODE 1 • SELF-CHECK FAILURE!		FAILURE CODE 1 • SELF-CHECK FAILURE!

If only the pressure transducer calibration portion of SELF-CHECK fails, proceed to the section entitled TRANSDUCER CALIBRATION - DO NOT ATTEMPT PATIENT USE.

TRANSDUCER CALIBRATION

The disposable ventilator circuit connects to a pressure-sensing element (transducer) in the ventilator. The transducer, in turn, provides a stream of data to Uni-Vent's microprocessor. Transducer calibration information is stored in a serial, non-volatile EEPROM memory. This information is updated automatically during SELF-CHECK, then every 5-minutes thereafter through Eagle's AUTO CAL function, or, it can be manually updated by the user. Transducer calibration is essential for correct operation.

The TRANSDUCER CALIBRATION process calibrates Uni-Vent's internal pressure transducer to atmospheric pressure. During operation, Uni-Vent's microprocessor will respond according to pressure signals from the transducer which are compared to its control panel settings.

TRANSDUCER CALIBRATION, (cont'd)

AUTOMATIC CALIBRATION (AUTO CAL)

During operation, Eagle™ performs an automatic calibration of its pressure transducer every 5-minutes. This process maintains a consistent transducer baseline over a wide temperature range to assure display, monitoring, and triggering accuracy. If the baseline drifts significantly since the prior AUTO CAL was performed, or the baseline is unstable, Eagle™ will retry AUTO CAL 1-minute later. If AUTO CAL fails again, a VENTILATOR FAILURE Alarm, CODE 7 is activated to assure patient safety.

MANUAL CALIBRATION

WARNING

TRANSDUCER CALIBRATION, like SELF-CHECK, must be performed with the disposable ventilator circuit disconnected from the patient. This insures that the TRANSDUCER connection is open to ambient atmosphere. Ignoring this requirement would allow the procedure to sense any residual airway pressure in the patient circuit. The residual pressure becomes the new calibration reference (albeit a false reference), which will increase your patient's work-of-breathing by the residual amount.

- 1. Set MODE Selector Switch to CAL. The AMC will display:

Calibration...Please Wait

MODE = CAL

- 2. Calibration will take approximately 3-seconds. When finished, the AMC display will change to:

MODE = CAL OK

NOTE

The PIC will display information pertinent to operating power and battery charge status in addition to the above AMC messages.

A TRANSDUCER CALIBRATION ABORT Alarm will occur if the MODE Selector Switch is turned to an operating mode position before CAL is completed. The CAL procedure must be restarted by turning the MODE Selector Switch to any position other than CAL, and then returning it to CAL, and repeating the process described in steps 1, 2 and 3 above. When activated the AMC displays: TRANSDUCER CALIBRATION ABORT - RECALIBRATE TRANSDUCER or TRANSDUCER CALIBRATION ABORT. The AMC will blank if a SYSTEM FAILURE Alarm occurs.

USER PROGRAMS

The Model 754 contains a USER PROGRAMS menu that allows certain operating characteristics to be changed. Some changes can be stored in Eagle™'s memory - temporary changes are not. Program changes that get stored in memory apply each time the ventilator is operated or, until the user makes a new program change effecting that particular characteristic. Temporary changes are not stored in memory and will last until ventilator power is turned OFF. User programmable/selectable characteristics are: LCD Backlight Threshold default, can not be adjusted for units with serial number greater than 0704001, LCD Contrast default, Trigger Level Sensitivity, Set Spontaneous Flow, Demonstration Mode (DEMO), and TEST BACKUP VENTILATOR.

The bottom line of each menu in USER PROGRAMS contains the following information:

"#### Hrs" - where "####" represents cumulative hours of operation since the last Preventative Maintenance was performed.

USER PROGRAMS, (cont'd)

"### Dys" - where "###" represents cumulative days since the last Preventative Maintenance was performed

"Version #.##" - where #.## indicates the software version.

To enter the USER PROGRAMS menu, simultaneously press MUTE and MANUAL BREATH/TRIGGER Pushbutton Switches while turning the MODE Control Switch to A/C, SIMV, CPAP, or CAL.

- Follow on screen prompts.
- Press adjacent pushbutton switches to make your selections.
- Press pushbutton switch adjacent to "EXIT" to leave USER PROGRAMS menu and return to selected mode of operation:

A/C

A/C DEMO

SIMV

SIMV DEMO

CPAP

CPAP DEMO

CAL

LCD BACKLIGHT THRESHOLD DEFAULT: Backlight can not be adjusted for units with serial number greater than 0704001.

LCD CONTRAST DEFAULT: Controls the LCD's contrast setpoint. Depending upon viewing comfort, user's may choose to increase or decrease color contrast between activated LCD pixels and their background. Any increase or decrease to the setpoint is seen on the LCD. Changes can be stored in memory or temporarily used during the current operating cycle. To store changes in memory, the pushbutton switch adjacent to the on screen "SAVE" prompt must be pressed. If "SAVE" is not pressed, the previously stored setpoint remains.

TRIGGER LEVEL SENSITIVITY: Controls the inspiratory work-of-breathing setpoint for patient-triggered breaths. Eagle™'s default sensitivity is 1.5 to 2.0 cmH₂O below end pressure. This USER PROGRAM allows Trigger Level Sensitivity to be temporarily changed until operating power is turned OFF. It is adjustable from 1.0 to 6.0 cmH₂O in 0.5 cmH₂O increments. For spontaneous breaths occurring in SIMV and CPAP, the sensitivity cannot be set below 2 cmH₂O. Sensitivity adjustments to 2 cmH₂O, or higher, will affect all breaths. Adjustments made below 2 cmH₂O will only affect mandatory breaths. New settings cannot be saved in memory. Once operating power is turned "OFF" Trigger Level Sensitivity is returned to its default value.

NOTE

Under most operating conditions Eagle™'s default Trigger Level Sensitivity should be used. User's are cautioned to carefully consider their operating environment before selecting a different Trigger Level Sensitivity. If 1.0 cmH ₂ O is selected, motion artifact may cause false triggering of breaths. Conversely, selecting a sensitivity above 2.0 cmH ₂ O to compensate for excessive motion artifact, or physiologic conditions, can cause excessive inspiratory work-of-breathing.

USER PROGRAMS, (cont'd)

SET SPONTANEOUS FLOW: Eagle™'s default Spontaneous Flow is 60 LPM. This USER PROGRAM allows Spontaneous Flow (for use in SIMV or CPAP) to be temporarily changed until operating power is turned OFF. It is adjustable from 10 to 60 LPM in 5 LPM increments. New settings cannot be saved in memory. Once operating power is turned "OFF", Spontaneous Flow is returned to its default value.

DEMONSTRATION MODE (DEMO): Permits user's to operate this device in a mode that is quite helpful for demonstration/training purposes. DEMO mode allows user's to make settings, adjustments, trigger alarms, and view simulation waveforms on Eagle™'s LCD. DEMO mode does not allow Disconnect Alarm activation or Proximal Pressure Transducer operation.

WARNING

DEMO mode is not for patient use. Once operating power is turned "OFF" DEMO mode is cancelled.

TEST BACKUP VENTILATOR: Permits user to test the BACKUP VENTILATOR and MANUAL TRIGGER. Activating the BACKUP VENTILATOR will cause it to function as described in the section entitled BACKUP VENTILATOR. To leave the BACKUP VENTILATOR function and return to normal operation, turn the MODE Control Switch to "OFF" then "ON" to desired operating mode.

MODES OF OPERATION

Your Model 754 has been carefully designed to ease the learning transition commonly associated with new instruments. In addition to its clean, uncluttered appearance, Uni-Vent[®] includes numerical panel markings to simplify and speed start-up. Only the five primary controls, common to most applications, are marked. They are numbered in order of use, in a 5-step sequence. It is possible to initiate operation using as few as 3-controls.

- Step 1: Select operating mode; ACV, SIMV or CPAP
- Step 2: Set VENTILATION RATE
- Step 3: Set INSPIRATION TIME

NOTE

If your protocol calls for use only at the 1:2 I:E RATIO preset, Step 3 can be bypassed.

- Step 4: Set TIDAL VOLUME
- Step 5: Set the AIR/OXYGEN MIXER for an FIO₂ between 21 and 100

NOTE

If your protocol involves use without external oxygen, or with 100% oxygen, the AIR/OXYGEN MIXER control remains either fully counterclockwise or fully clockwise and control #5 can be bypassed.

Control panel settings may be adjusted at any time. In normal use, adjustments are typically made immediately following SELF-CHECK, however, the 1:2 I:E RATIO and extents for FIO₂ and PRESSURE ALARMS may be preset.

The Model 754 can operate in the following modes:

ASSIST-CONTROL VENTILATION: WITH/WITHOUT PEEP,
WITH/WITHOUT SIGH

ASSIST-CONTROL VENTILATION: WITH/WITHOUT PEEP,
WITH/WITHOUT PRESSURE PLATEAU

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION:
WITH/WITHOUT PEEP, WITH/WITHOUT SIGH

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION:
WITH/WITHOUT PEEP, WITH/WITHOUT PRESSURE PLATEAU

CONTINUOUS POSITIVE AIRWAY PRESSURE: WITH/WITHOUT PEEP

CONTROL VENTILATION (apnea backup of ACV, SIMV and CPAP)

CONTROL VENTILATION (backup ventilator)

WARNING

Functions which are dependent upon accurate pressure readings should only be used in conjunction with a protected airway. This will prevent "leaks" from distorting pressure signals. DO NOT use pressure dependent functions with an unprotected airway. This applies primarily to use with uncuffed endotracheal tubes, uncuffed tracheostomy tubes, and resuscitation masks where the face-to-mask-seal integrity is frequently and typically compromised.

MODES OF OPERATION, (cont'd)

IMPORTANT NOTE

The Model 754 includes preset trigger sensitivity default.

Preset trigger sensitivity default is set between 1.5 and 2.0 cmH₂O below end pressure. Triggering sensitivity determines how much negative deflection a spontaneously breathing patient must generate before Uni-Vent[®] initiates a mechanical breath or demand flow. In the Model 754, triggering sensitivity is both automatic and PEEP compensated. To change trigger sensitivity, or Spontaneous Flow for SIMV and CPAP, see section entitled (USER PROGRAMS).

During operation Uni-Vent's preset trigger looks for the next spontaneous breath to reach its trigger threshold. For whatever reason, if a spontaneous breath is in process when the trigger is activated, the following conditions prevail:

- If the patient's inspiratory pressure has not reached the trigger threshold, Uni-Vent[®] will trigger when the threshold is reached.
- If the patient's inspiratory pressure has exceeded the trigger threshold, Uni-Vent[®] will wait until the next spontaneous inspiration reaches threshold before triggering.

IMPORTANT NOTE

ACV, SIMV and CPAP ventilations are continuously monitored. Should apnea occur in one of these modes, Uni-Vent's microprocessor will activate applicable alarms and initiate control ventilations (see section entitled CONTROL VENTILATION DURING APNEA).

NOTE

Uni-Vent[®] includes built-in altitude compensation. Once you've performed a TRANSDUCER CALIBRATION, changes in altitude will have no effect upon pressure-related performance.

NOTE

Uni-Vent[®] has been certified by an independent testing laboratory to meet electromagnetic interference (EMI) and radio frequency interference (RFI) shielding requirements. Certification includes both radiated emissions and conducted susceptibility.

ASSIST-CONTROL VENTILATION (ACV)

In ACV, Uni-Vent[®] is configured to deliver a minimum ventilatory rate, preset inspiration time and preset tidal volume. Patient-initiated breaths, sensed by negative pressure deflection, cause Uni-Vent[®] to trigger an "assisted" ventilation that is equal to its INSPIRATION TIME and TIDAL VOLUME settings. Controlled ventilations are delivered when there are no spontaneous respiration's or the patients' spontaneous ventilation rate attempts to fall below the current VENTILATION RATE setting. If this occurs, controlled ventilations are delivered at the VENTILATION RATE, INSPIRATION TIME and TIDAL VOLUME settings.

Should the patient become apneic in the ACV mode, Uni-Vent[®] will activate its APNEA Alarm and automatically begin controlled ventilations at its current VENTILATION RATE/INSPIRATORY TIME/TIDAL VOLUME control settings or 12 ventilations per minute/INSPIRATORY TIME/TIDAL VOLUME control settings - whichever is greater (see section entitled CONTROL VENTILATION DURING APNEA; *APNEA DURING ACV OR SIMV OPERATION*).

ASSIST-CONTROL VENTILATION (ACV), (cont'd)

ACV operation is permitted in combination with PEEP and/or SIGH, or PEEP and/or PRESSURE PLATEAU (SIGH will become disabled whenever PRESSURE PLATEAU is selected).

The following steps are required to initiate ASSIST-CONTROL operation:

- 1. Turn MODE Selector Switch to A/C. Allow SELF-CHECK tests to complete. Perform TRANSDUCER CALIBRATION if required (see section entitled TRANSDUCER CALIBRATION).

DO NOT connect disposable patient circuit to patient during SELF-CHECK.

When SELF-CHECK is completed, ACV cycling begins automatically. The INSPIRATION/EXHALATION Indicator will toggle accordingly during the inspiratory and expiratory cycles of each ventilation.

NOTE:

When ACV cycling begins, the DISCONNECT Alarm will activate. This alarm will remain active until the disposable ventilator circuit is connected to the patient (see Step 3, below) and the pressure transducer detects a pressure rise during the next ventilator generated breath, or the ALARM MUTE/CANCEL Pushbutton Switch is pressed.
--

- 2. Adjust VENTILATION RATE, INSPIRATION TIME/I:E RATIO, TIDAL VOLUME, AIR/OXYGEN MIXER, LOW and HIGH AIRWAY PRESSURE ALARM Control settings as required. If LOW and HIGH AIRWAY PRESSURE ALARM's are not used, set their respective controls to 0 and 100.
- 3. Attach disposable ventilator circuit to patient's endotracheal or tracheostomy tube. Spontaneous breathing should cause the ventilator to trigger an assisted breath and cancel the DISCONNECT Alarm. A ventilator-generated controlled breath will also cause the DISCONNECT Alarm to cancel. The INSPIRATION/EXHALATION Indicator will continue to toggle during the inspiratory and expiratory cycles of each ventilation.
- 4. If PEEP is required, repeatedly press PEEP Pushbutton Switch until desired setting appears in LCD. (See section entitled USING POSITIVE END EXPIRATORY PRESSURE for complete instructions).
- 5. Press SIGH Pushbutton Switch if ACV operation with SIGH is required. SIGH ventilations are delivered once every 100 ventilations or 7-minutes, whichever occurs first. Each SIGH ventilation equals 150% of the INSPIRATION TIME setting, which increases delivered volume by 50%. As a safety precaution, Uni-Vent[®] does not allow the inspiratory portion of a SIGH breath to exceed 3-seconds.
- 6. Press PLATEAU Pushbutton Switch if ACV operation with PRESSURE PLATEAU is required. SIGH is automatically disabled (OFF) when PLATEAU is selected. PRESSURE PLATEAU limits peak airway pressure to the PLATEAU level for the duration of an inspiratory cycle. The PRESSURE PLATEAU value is automatically referenced 10 cmH₂O below the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setting (see section entitled USING PRESSURE PLATEAU).

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION (SIMV)

SIMV permits patients to breathe spontaneously while periodically receiving ventilator-generated assisted breaths. Microprocessor control of the disposable ventilator circuits' expiration valve determines which breaths are spontaneously entrained and which are mechanically delivered. FIO₂ is determined by the AIR/OXYGEN MIXER setting. Spontaneously breathing patients are allowed to entrain breathing gas, assuming the entire work-of-breathing for each spontaneous breath, at their own rate/inspiratory time. Assisted breaths are delivered as determined by the VENTILATION RATE, INSPIRATORY TIME/I:E RATIO, and TIDAL VOLUME control settings. Assisted breaths are synchronized to the patients ventilatory effort. However, if the patient does not breathe within the assisted breath "time window", a controlled breath is delivered to insure that the prescribed number of mandatory breaths are received.

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION (SIMV), (cont'd)

Should the patient become apneic in the SIMV mode, Uni-Vent[®] will activate its APNEA Alarm and automatically begin controlled ventilations at its current VENTILATION RATE/INSPIRATORY TIME/TIDAL VOLUME control settings or 12 ventilations per minute/INSPIRATORY TIME/TIDAL VOLUME control settings - whichever is greater (see section entitled CONTROL VENTILATION DURING APNEA; *APNEA DURING ACV OR SIMV OPERATION*).

SIMV operation is permitted in combination with PEEP and/or SIGH, or PEEP and/or PRESSURE PLATEAU (SIGH will become disabled whenever PRESSURE PLATEAU is selected).

The following steps are required to initiate SIMV operation:

- 1. Turn MODE Selector Switch to SIMV. Allow SELF-CHECK tests to complete. Perform TRANSDUCER CALIBRATION if required (see section entitled TRANSDUCER CALIBRATION).

DO NOT connect disposable patient circuit to patient during SELF-CHECK.

When SELF-CHECK is completed, SIMV cycling begins automatically. The INSPIRATION/EXHALATION Indicator will toggle accordingly during the inspiratory and expiratory cycles of each ventilation.

NOTE

When SIMV cycling begins, the DISCONNECT ALARM will activate. This alarm will remain active until the disposable ventilator circuit is connected to the patient (see Step 3, below) and the pressure transducer detects a pressure rise during the next ventilator generated breath, or the ALARM MUTE/CANCEL Pushbutton Switch is pressed.

- 2. Adjust the VENTILATION RATE (SIMV RATE), INSPIRATION TIME/I:E RATIO, TIDAL VOLUME, AIR/OXYGEN MIXER, LOW and HIGH AIRWAY PRESSURE ALARM Control settings as required. If LOW and HIGH AIRWAY PRESSURE ALARM's are not used, set their respective controls to 0 and 100.

During SIMV operation, mandatory breaths are delivered according to Uni-Vent's VENTILATION RATE, INSPIRATION TIME and TIDAL VOLUME control settings. When the mandatory breath is scheduled, Uni-Vent's trigger becomes momentarily armed so that it may synchronize with the patient's next inspiration. If there is no inspiratory effort during this period, a controlled breath is delivered regardless of patient effort.

During SIMV operation, mandatory breaths are delivered at the INSPIRATION TIME and TIDAL VOLUME settings.

- 3. Attach disposable ventilator circuit to patient's endotracheal or tracheostomy tube. Spontaneous breathing should cause the ventilator to trigger an assisted breath and cancel the DISCONNECT Alarm. A ventilator-generated controlled breath will also cause the DISCONNECT Alarm to cancel. The INSPIRATION/EXHALATION Indicator will continue to toggle during the inspiratory and expiratory cycles of each ventilation.
- 4. If PEEP is required, repeatedly press PEEP Pushbutton Switch until desired setting appears in LCD. (See section entitled USING POSITIVE END EXPIRATORY PRESSURE for complete instructions).
- 5. Press SIGH Pushbutton Switch if SIMV operation with SIGH is required. SIGH ventilations are delivered once every 100 ventilations or 7-minutes, whichever occurs first. Each SIGH ventilation equals 150% of the INSPIRATION TIME setting, which increases delivered volume by 50%. As a safety precaution, Uni-Vent[®] does not allow a SIGH breath to exceed 3-seconds.

SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION (SIMV), (cont'd)

- 6. Press PLATEAU Pushbutton Switch if SIMV operation with PRESSURE PLATEAU is required. SIGH is automatically disabled (OFF) when PLATEAU is selected. PRESSURE PLATEAU limits peak airway pressure to the PLATEAU level for the duration of an inspiratory cycle. The PRESSURE PLATEAU value is automatically referenced 10 cmH₂O below the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setting (see section entitled USING PRESSURE PLATEAU).

CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)

CPAP operation is similar to SIMV with PEEP, except the mandatory rate is "zero". There are no assisted ventilations. The VENTILATOR RATE BECOMES "zero" and its setpoint indicator blanks. CPAP permits the patient to breathe spontaneously with PEEP. Each spontaneous breath causes a negative pressure deflection. When the trigger point is reached (2.0 cmH₂O below end pressure), Uni-Vent[®] causes gas to flow at a default rate of 60 LPM until a back pressure of PEEP +5 cmH₂O is sensed (unconditional end-of-inspiration) or, 3-seconds have elapsed (time out), whichever occurs first. The Spontaneous Flow rate can be changed to a lesser flow rate, for current use, until operating power is turned OFF (see section entitled USER PROGRAMS, SET SPONTANEOUS FLOW). FIO₂ is equal to the AIR/OXYGEN MIXER setpoint. PRESSURE PLATEAU and SIGH are disabled (OFF) during CPAP operation.

An APNEA Alarm activates when there is no spontaneous breathing for 10-seconds (based on a 30-second moving average). If the spontaneous breathing rate falls to 6 BPM (or less), control ventilation during APNEA will begin (see section entitled CONTROL VENTILATION DURING APNEA; *APNEA DURING CPAP OPERATION*).

CONTROL VENTILATION DURING APNEA

When apnea is detected during ACV, SIMV, or CPAP operation, Uni-Vent's microprocessor generates an APNEA Alarm and initiates controlled ventilation breathing to protect your patient. Control settings that were displayed prior to APNEA will remain displayed, but ignored, during these CONTROL VENTILATIONS.

APNEA DURING ACV OR SIMV OPERATION: Controlled ventilation occurs when the period between positive and/or negative pressure deflections (spontaneous and/or Uni-Vent[®] generated ventilations) exceeds 19-seconds minus INSPIRATION TIME setting. Monitoring for APNEA is disabled during an INVERSE I:E Alarm. Uni-Vent[®] will provide your patient, from the following two alternatives, the one which offers the highest ventilation rate.

- 1. Control panel settings for VENTILATION RATE, INSPIRATION TIME and TIDAL VOLUME or;
- 2. A default VENTILATION RATE of 12 ventilations per minute and the control panel INSPIRATION TIME and TIDAL VOLUME Control settings.

NOTE: To prevent a potential lockout of the APNEA backup, Eagle™ will create a 1:2 I:E Ratio at the onset of APNEA if its current Inspiratory Time setting would result in an Inverse I:E condition.

APNEA DURING CPAP OPERATION: Controlled ventilation occurs when no spontaneous breathing is detected for 10-seconds. Controlled ventilations will have the following characteristics:

Mechanical rate = 12 breaths per minute

I:E ratio = 1:2

Tidal Volume = Will vary with patient. Uni-Vent[®] will deliver gas at a flow rate of 30 liters per minute until a peak inspiratory pressure of 40 cmH₂O is reached.

Depressing the ALARM MUTE/CANCEL Pushbutton Switch cancels the APNEA Alarm, stops CONTROL VENTILATION DURING APNEA and restarts ACV, SIMV or CPAP operation to current control panel settings.

USING POSITIVE END EXPIRATORY PRESSURE (PEEP)

The Model 754 is capable of internally controlling PEEP. A separate PEEP valve is not required and must not be added to the disposable patient circuit. The PEEP function provides a means of converting the transducer calibration pressure reference from atmospheric pressure to atmospheric pressure + PEEP pressure. PEEP may be used during ACV, SIMV, or CPAP operation.

When the ventilator is turned ON, PEEP has a default value of 0 (OFF). A PEEP value can be manually entered using the PEEP OFF/ON-SET Pushbutton Switch. To set a value of PEEP, simply press the PEEP OFF/ON-SET Pushbutton Switch. Each time this switch is pressed, the value of PEEP will increase by 1 cmH₂O. A maximum PEEP value of 20 cmH₂O is possible. Pressing the PEEP OFF/ON-SET Pushbutton Switch when a current value of 20 exists, returns the value to 0. The PEEP setpoint value can be made to scroll upwards by putting continuous pressure on the PEEP OFF/ON-SET Pushbutton Switch until the desired value is reached.

Default trigger sensitivity is referenced to end pressure and will trigger between 1.5 to 2.0 cmH₂O below the end pressure value (see section entitled USER PROGRAMS).

Uni-Vent's CPU monitors PEEP. If PEEP pressure attempts to rise during its plateau, Uni-Vent[®] causes the exhalation valve to open, allowing pressure to fall to zero. Should an inspiration cycle begin before end pressure plateaus, a HIGH PEEP alarm will sound.

The airway pressure waveform displayed in the LCD is an accurate representation of proximal airway pressure. Large expiratory pressure changes that occur within a short period of time create temporary pressure gradients between the patient's lungs and the proximal airway pressure sensor. Unless PEEP is used, this condition is not apparent because equalization of positive pressures does not occur with a "zero" baseline. Compliance and resistance effect exhalation time. Patient's with higher airway resistance will momentarily alter the exhalation waveform appearance by causing a greater pressure differential between the lungs and ventilator circuit. Uni-Vent's PEEP circuitry and software attempt to learn the patient's expiratory characteristic. Learning is an ongoing process and fine adjustments can be made to each breath as required. By doing so, pressure "undershoot" caused by gradient differences is minimized, or eliminated altogether. The initial learning process typically takes from 1 to 6 breaths. During this process, a temporary PEEP "baseline" is established for each breath so that triggering sensitivity is not decreased.

The LCD display area for PEEP is on the top line, immediately below its respective pushbutton switch. The PEEP OFF/ON-SET display will blank when a SYSTEM FAILURE Alarm occurs.

USING PRESSURE PLATEAU

When the ventilator is turned ON, PLATEAU is OFF (its default value). It becomes operable, only in the ACV and SIMV operating modes, by pressing the PRESSURE PLATEAU OFF/ON Pushbutton Switch. The PLATEAU value is automatically referenced 10 cmH₂O below the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setpoint. PRESSURE PLATEAU has an absolute range of 5 to 90 cmH₂O.

When a PLATEAU value is reached, gas flow is alternately cycled OFF and ON, to maintain the PLATEAU, until the inspiratory cycle is completed. If inspiratory pressure attempts to rise above the HIGH PRESSURE ALARM/PEAK INSPIRATORY PRESSURE RELIEF Control setting, Uni-Vent[®] will open the exhalation valve until pressure falls to the PLATEAU level. If Uni-Vent[®] detects a leak in its disposable patient circuit, or any of its connections, additional gas flow is allowed to maintain the PLATEAU.

The LCD display area for PRESSURE PLATEAU is on the top line, immediately below its respective pushbutton switch. The PRESSURE PLATEAU display will blank when a SYSTEM FAILURE Alarm occurs.

BACKUP VENTILATOR

Eagle™ contains a backup ventilator that is designed to provide a limited degree of operation should a CPU failure occur. A CPU failure is a hardware -detected computer failure that will trigger a SYSTEM FAILURE Alarm. Normal operation will stop, the LCD will blank, the ALARM LED illuminates (flashing), the SYSTEM FAILURE LED illuminates (non-flashing) and a pulsing tone is heard. A SYSTEM FAILURE, that is caused by a CPU failure, will illuminate the SYSTEM FAILURE LED because the causing condition cannot assure safe operation of the primary Eagle™ ventilator. In such cases, a separate ventilator circuit embedded within the Eagle™, begins automatic operation. Its operating characteristics are as follows:

Rate:	12 Breaths Per Minute
I:E Ratio:	1:2 (1.67-seconds x 3.33-seconds)
Flow Rate:	30 Liters Per Minute for duration of Inspiratory Time or until Peak Inspiratory Pressure threshold is reached
Peak Inspiratory Pressure Relief:	40 cmH ₂ O
Gas Source Prioritization:	External Air, if available; or Internal Compressor, if operable; or External Oxygen, if available
Audible System Failure Alarm Mute/Cancel:	Pressing ALARM MUTE/CANCEL pushbutton switch cancels audible alarm
Manual Trigger Override:	Yes, followed by a 6-second reset period before automatic ventilation resumes

NOTE

A SYSTEM FAILURE that is caused by patient circuit pressure exceeding 40 cmH₂O for 5-seconds, continuously, will not cause the BACKUP VENTILATOR to activate. Instead, the ALARM LED illuminates (flashing), the SYSTEM FAILURE LED illuminates (non-flashing), a non-mutable continuous tone is heard.

HUMIDIFIERS AND HEAT MOISTURE EXCHANGERS (HME'S)

A cascade humidifier option is not available for the Model 754. 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 ventilators¹. 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 use in transport. Observe all safety and cautionary statements.

HME's, sometimes referred to as "artificial noses", are not position-sensitive, and are recommended for transport applications. While HME's may not be suitable for all applications, they facilitate portability in a way that conventional humidifiers cannot. Impact's HME, part number 820-0053-00 is lightweight, has minimal dead-space and minimal resistance to flow. It attaches between the disposable ventilator circuit and patient's endotracheal tube.

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

OPERATOR PERFORMANCE CHECKS

Before placing this instrument into operation, the operator can perform various operational checks to insure proper performance.

OPERATOR PERFORMANCE CHECKS, (cont'd)

- 1. Verify operating power selections.
- 2. When using external power source (from Universal AC Power Supply, or 12 VDC Power Cable) insure that LCD display verifies presence of external power and fuses are not blown or missing.
- 3. Verify successful completion of SELF-CHECK.
- 4. Insure that all hoses, tubing and fittings are properly connected.

ALARM FUNCTIONS

Uni-Vent[®] contains numerous alarm circuits, designed to alert attendant personnel and protect the patient. Alarm messages appear in a dedicated area of the LCD display. This area is called the ALARM MESSAGE CENTER (AMC).

AMC is the centralized location for alarm information. It consists of a 4-line display area. Each alarm may be displayed with a short, accompanying message (two lines maximum); or simply as an alarm announcement that consists only of the alarm name. The number of simultaneous alarms determines how alarm information is displayed.

The AMC will display one alarm with accompanying message; or two simultaneously occurring alarms with respective messages. The first occurring alarm (name and message), occupies AMC's top two lines. If a second alarm occurs while the first alarm is still unresolved, its name and message occupies the AMC's third and fourth lines. If three or more alarms become active simultaneously, the AMC reverts to showing each alarm by name only. There are no accompanying messages. When more than four alarms occur simultaneously, the words "LOW/FAIL" are blanked from the BATTERY, O₂ and EXT AIR alarm names.

When there are two alarms with messages displayed in the AMC and one becomes resolved, the remaining alarm with message will occupy lines one and two.

When three alarm names are displayed in the AMC and one alarm becomes resolved, the AMC reverts to displaying the two remaining alarms with their respective messages.

Normally, each and every alarm is displayed in the LCD. However, a CPU problem will trigger a SYSTEM FAILURE that causes normal operation to stop and the LCD to blank. A SYSTEM FAILURE LED illuminates whenever a SYSTEM FAILURE alarm condition occurs. It is accompanied by a continuous, non-mutable tone. The SYSTEM FAILURE LED illuminates because the ALARM LED and LCD are rendered inoperable by the SYSTEM FAILURE. The ALARM Indicator LED illuminates whenever an alarm causing condition, other than SYSTEM FAILURE, occurs. It provides a supplemental alert when operating in a high noise environment or from a distance that might make LCD readability difficult. A pulsing audible signal accompanies each alarm.

Alarm conditions, depending upon type, may be temporarily muted or cancelled. Alarms are categorized as OPERATING, NON-OPERATING, or ADVISORY. An Operating Alarm may be muted successively and allows continued operation. Mutable alarms will reset automatically when the alarm condition is no longer valid. Non-operating alarms cannot be muted and do not allow operation to begin/continue. Advisory alarms permit continued operation and can be muted once. AMC display of Advisory Alarms blank if a non-operating alarm occurs or, more than four Operating Alarms are simultaneously active. A description of each alarm follows:

OPERATING ALARMS

BATTERY LOW/FAIL Alarm: The BATTERY LOW/FAIL Alarm activates when 30-minutes of operating time remains. As Uni-Vent[®] approaches its failing voltage, it will generate alerting sounds from its alarm buzzer. At the failing voltage a SYSTEM FAILURE ALARM occurs just prior to shutdown. When activated the AMC displays: BATTERY LOW/FAIL - RECHARGE/REPLACE BATTERY PACK, BATTERY LOW/FAIL or BATTERY. The AMC will blank if a non-operating alarm occurs.

WARNING

The BATTERY LOW Alarm activates based on CPU assessment of current consumption. The user is cautioned to be aware that battery power will consume faster when the internal compressor is used.
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WARNING

When a BATTERY LOW Alarm occurs during internal compressor and external oxygen use, the CPU will instruct the external oxygen supply to provide full tidal volume (at 100% FIO ₂) to prolong battery life. An FIO ₂ Alarm will be generated. It can be cancelled by turning the AIR/OXYGEN MIXER Control setpoint to 100%.

OPERATING ALARMS, (cont'd)

EXTERNAL POWER LOW Alarm: The EXTERNAL POWER LOW Alarm activates when Uni-Vent[®] senses an external power source voltage less than 10.9 VDC at the External Power Input Jack. When activated the AMC displays: EXTERNAL POWER LOW - CHECK POWER SOURCE/CONNECTIONS or EXT PWR. The AMC will blank if a non-operating alarm occurs.

LOW PRESSURE Alarm: Initiates when PIP fails to exceed the LOW PRESSURE ALARM setpoint for two consecutive breaths and causes its LCD setpoint indicator, and DIGITAL BAR GRAPH setpoint indicator, to blink. When activated the AMC displays: LOW PRESSURE - PEAK INSPIRATORY PRESSURE TOO LOW or LOW PRESSURE. The AMC will blank if a non-operating alarm occurs. The LOW AIRWAY PRESSURE Alarm setpoint indicator adjacent to the DIGITAL BAR GRAPH will alternately blink, with the HIGH PRESSURE Alarm Control LCD setpoint indicator, during a PRESSURE ALARM SETTINGS Alarm.

DISCONNECT Alarm: Initiates when a disconnect is sensed in the patient circuit. When activated the AMC displays: DISCONNECT - CHECK CIRCUIT CONNECTIONS or DISCONNECT. The AMC will blank if a non-operating alarm occurs. If a DISCONNECT Alarm occurs during a LOW PRESSURE Alarm, both alarm messages will appear in the AMC. If a DISCONNECT Alarm occurs first, the LOW PRESSURE Alarm is disabled. DISCONNECT Alarm is armed in all operating modes, however, its activating conditions are different:

ASSIST-CONTROL & SIMV modes - The microprocessor looks for a positive pressure rise of at least 3 cmH₂O to occur within 75% of the INSPIRATION TIME Control setting (applies only to ventilator-generated breaths). If a positive pressure rise does not occur within this period, the DISCONNECT Alarm activates.

ASSIST-CONTROL & SIMV modes - The microprocessor alarm circuit activates when respiration's (spontaneous and/or Uni-Vent[®] generated) are undetected for a period that is equal to 19-seconds minus INSPIRATORY TIME (range = 16.0 to 18.9 seconds); or *CPAP mode* - when no spontaneous breathing is detected for 10-seconds (based on a 30-second moving average). To qualify the alarm condition as DISCONNECT, or APNEA, the microprocessor delivers a controlled ventilation at the INSPIRATION TIME setting. If a pressure rise of at least 3 cmH₂O occurs within 75% of the INSPIRATION TIME Control setting (1-second when in CPAP mode), the APNEA Alarm is activated. If a pressure rise is not detected, Uni-Vent[®] returns to its respective mode and activates its DISCONNECT Alarm. Should no change in status occur, the controlled ventilation test is repeated every 30-seconds.

HIGH PRESSURE Alarm: The HIGH PRESSURE Alarm activates when the patient's airway pressure exceeds the HIGH AIRWAY PRESSURE ALARM Control setting for 2-seconds (continuous), or 250-milliseconds for four (4) consecutive ventilations.

The HIGH PRESSURE Alarm setting is also the safety setting for Peak Inspiratory Pressure Relief. Excessive flows and/or inspiration times, occlusion of the patient circuit or a change in the patient's physiological condition can cause a rise in peak inspiratory pressure (PIP). To safeguard the patient from high PIP, Uni-Vent[®] compares PIP against the HIGH AIRWAY PRESSURE ALARM Control setting.

When a high PIP condition occurs (exceeding the HIGH AIRWAY PRESSURE ALARM Control setting by 1 cmH₂O), Uni-Vent[®] causes the disposable ventilator circuit exhalation valve to open. This allows excess pressure to "dump" through the exhalation valve to atmosphere, while allowing the INSPIRATION TIME cycle to continue. When the patient circuit pressure falls below the trigger point (1 cmH₂O below the HIGH PRESSURE ALARM Control setting), the exhalation valve is closed and gas flow is allowed to resume for the remainder of the inspiratory cycle.

The HIGH PRESSURE Alarm initiates when PIP exceeds the HIGH PRESSURE Alarm setpoint for four consecutive breaths, or 2-seconds continuously, and causes its LCD setpoint indicator, and DIGITAL BAR GRAPH setpoint indicator, to blink. When activated the AMC displays: HIGH PRESSURE - PEAK INSPIRATORY PRESSURE TOO HIGH or HIGH PRESSURE. The AMC will blank if a non-operating alarm occurs. The HIGH AIRWAY PRESSURE Alarm setpoint indicator adjacent to the DIGITAL BAR GRAPH will alternately blink, with the LOW PRESSURE Alarm Control LCD setpoint indicator, during a PRESSURE ALARM SETTINGS Alarm.

OPERATING ALARMS, (cont'd)

APNEA Alarm: The APNEA Alarm is functional in the ACV, SIMV and CPAP modes. When activated in ACV or SIMV, the AMC displays: APNEA - CHECK PATIENT FOR SPONTANEOUS BREATHING or APNEA. When activated in CPAP, the AMC displays: APNEA - CPAP AVERAGE RATE LESS THAN 6-BPM or APNEA. The AMC will blank if a non-operating alarm occurs.

APNEA ALARM DURING ACV OR SIMV OPERATION: The APNEA Alarm activates when the period between positive and/or negative pressure deflections (spontaneous and/or Uni-Vent[®] generated respiration's) exceeds 19-seconds minus the INSPIRATION TIME setting.

APNEA ALARM DURING CPAP OPERATION: The APNEA Alarm activates when no spontaneous breathing is detected for 10-seconds (based on a 30-second moving average).

HIGH PEEP Alarm: This alarm is disabled when the PEEP OFF/ON-SET Pushbutton Switch is set to "0". Initiates when the inspiratory cycle begins before end expiratory pressure plateaus. When activated the AMC displays: HIGH PEEP - INSPIRATION BEGAN BEFORE END PRESSURE PLATEAU or HIGH PEEP, and the PEEP OFF/ON-SET LCD display area will alternately flash. The AMC will blank if a non-operating alarm occurs.

O₂ LOW/FAIL Alarm: Initiates when a pressure less than 35-PSI (+/- 2-PSI) is sensed from an external oxygen supply. If gas mixing, or 100% oxygen, was chosen, the FIO₂ Alarm will also sound, and the CPU will terminate the oxygen source. EXTERNAL AIR (if connected), or the internal compressor, will provide the tidal volume requirement (see Note below). The O₂ LOW/FAIL Alarm can be cancelled by setting the AIR/OXYGEN MIXER setpoint to 21% or, restoring the oxygen source pressure to greater than 45-PSI (+/- 2-PSI). When activated the AMC displays: O₂ LOW/FAIL - CHECK OXYGEN SOURCE/CONNECTIONS, O2 LOW/FAIL, or O₂. The AMC will blank if a non-operating alarm occurs.

EXT AIR LOW/FAIL Alarm: Initiates when a pressure less than 35-PSI (+/- 2-PSI) is sensed from an external source of compressed air and causes the EXTERNAL AIR OFF/ON LCD indicator to blink. If the AIR/OXYGEN MIXER setpoint is greater than 21%, an FIO₂ Alarm is momentarily generated as additional oxygen flow is used to make up the air deficit contribution to tidal volume. Uni-Vent's CPU terminates the EXTERNAL AIR source, and activates the internal compressor, canceling the FIO₂ Alarm (see Note below). The EXTERNAL AIR LOW/FAIL Alarm can be cancelled by pressing the EXTERNAL AIR Pushbutton Switch to "OFF" which cancels the alarm or, restoring the EXTERNAL AIR source to a pressure to greater than 45-PSI (+/- 2-PSI). When activated the AMC displays: EXT AIR LOW/FAIL - CHECK AIR SOURCE/CONNECTIONS, EXT AIR LOW/FAIL or EXT AIR. The AMC will blank if a non-operating alarm occurs.

FIO₂ Alarm: Initiates when the oxygen component, or the air component, of the AIR/OXYGEN MIXER is unable to meet its proportion of the gas mixture. If the alarm is caused by an EXT AIR LOW/FAIL condition, the CPU terminates the EXTERNAL AIR source, and activates its internal compressor, canceling the FIO₂ Alarm (see Note below). The EXTERNAL AIR LOW/FAIL Alarm remains, and the EXTERNAL AIR Pushbutton Switch LCD indicator continues blinking. The alarm is cancelled when the EXTERNAL AIR Pushbutton Switch is pressed to "OFF". When activated the AMC displays: FIO₂ - GAS MIX ERROR. CHECK SOURCE/SETTINGS/CONNECTIONS or FIO₂. The AMC will blank if a non-operating alarm occurs.

NOTE

When switching between gas sources, a V _T Alarm may occur on the first transition-breath. This alarm will self-cancel on the second breath and is due to monitoring software adjustments that occur when a gas source change is invoked (manually or automatically).

PRESSURE ALARM SETTINGS Alarm: Initiates when the HIGH PRESSURE ALARM and LOW PRESSURE ALARM setpoints are reversed (i.e.: low setpoint is set higher than the high setpoint). Both Control setpoint indicators, and both indicators adjacent to the DIGITAL BAR GRAPH, alternately blink during a PRESSURE ALARM SETTINGS Alarm. When activated the AMC displays: PRESSURE ALARM SETTINGS - ALARM SETTINGS REVERSED or PRESSURE ALARM SETTINGS. The AMC will blank if a non-operating alarm occurs.

OPERATING ALARMS, (cont'd)

V_T Alarm: Initiates when delivered tidal volume is not within 10% of set tidal volume. Its usable range is from 100 to 3000ml. When activated, the TIDAL VOLUME display will alternately flash the "#### set" and "#### del" volumes; the AMC displays: V_T - DELIVERED TIDAL VOLUME DOES NOT EQUAL SET TIDAL VOLUME or V_T. The AMC will blank in the CPAP mode, or if a non-operating alarm occurs. A momentary V_T Alarm may occur when adjustments to control settings causes a large change in V_T. This alarm will self-cancel on the second breath as monitoring software makes adjustments.

COMP Alarm: Initiates when the compressor output exceeds +/-30% of its intended contribution to tidal volume for 3-consecutive breaths (the compressor alarm monitoring range requires a total tidal volume of at least 200ml {sum of all gases if FIO₂ is greater than 21% } with the compressor delivering a flow rate of at least 10 LPM). If the alarm occurs during operation with external oxygen, Uni-Vent's CPU instructs the oxygen source to make up for any tidal volume deficit caused by the compressor. When this occurs, an FIO₂ Alarm is generated. If EXTERNAL AIR is connected but not in use, Uni-Vent's CPU instructs the EXTERNAL AIR source to take over for the internal compressor (pressing the MUTE/CANCEL Pushbutton Switch cancels the COMP Alarm). If the alarm occurs and no external air or oxygen source is connected, a TIDAL VOLUME Alarm is generated, and the TIDAL VOLUME display will alternately flash the "#### set" and "#### del" volumes. This will last momentarily because a VENTILATOR FAIL Alarm (CODE 2 or CODE 3), will cause operation to cease. The AMC displays: COMP - COMPRESSOR OUTPUT LOW/FAIL or COMP. The AMC will blank if a non-operating alarm occurs.

NON-OPERATING ALARMS

INVERSE I:E Alarm: The INVERSE I:E Alarm occurs when the INSPIRATION TIME Control is set for a period that is longer than the exhalation period. Correct by lowering the RATE Control setting or lowering the INSPIRATION TIME Control setting (or both).

When INVERSE I:E occurs, an audible tone is heard, Uni-Vent's CPU will cause the disposable ventilator circuit exhalation valve to open to atmosphere (antiasphyxia condition), the INSPIRATION TIME/I:E RATIO Display will blink, and the AMC displays: INVERSE I:E-INSPIRATORY TIME LONGER THAN EXHALATION TIME or INVERSE I:E. The AMC will blank in the CPAP mode, or if a SYSTEM FAILURE Alarm occurs. Apnea monitoring is disabled during an INVERSE I:E Alarm.

TRANSDUCER CALIBRATION ABORT Alarm: The TRANSDUCER CALIBRATION ABORT Alarm activates when the TRANSDUCER CALIBRATION procedure is stopped prematurely. When activated, an audible tone is heard and the AMC displays: TRANSDUCER CALIBRATION ABORT-RECALIBRATE TRANSDUCER or TRANSDUCER CALIBRATION ABORT. The AMC will blank if a SYSTEM FAILURE Alarm occurs. The TRANSDUCER CALIBRATION ABORT Alarm will reset itself when recalibration is performed.

SYSTEM FAILURE Alarm: The SYSTEM FAILURE Alarm activates when Uni-Vent's CPU is forced to shutdown normal operation or a CPU failure has occurred. This alarm is usually related to a hardware problem. It will cause the LCD to blank, and the SYSTEM FAILURE LED to illuminate.

VENTILATOR FAIL Alarm: Initiates when any one of seven ventilator failure-causing conditions occur: Self-Check Failure, No Gas and Compressor Failure, Excessive Airway Pressure, Memory Check Failure, Exhalation Valve Failure, Excessive Negative Pressure, or Run-Time Calibration Failure. These conditions will not cause the LCD to blank and some may be operator correctable. Messages will appear in the AMC (see below). A VENTILATOR FAIL Alarm will not cause the SYSTEM FAIL LED to illuminate.

SELF-TEST FAILURE: Occurs when the ventilator fails to successfully complete SELF-CHECK. The AMC will display:

TRANSDUCER CALIBRATION - CALIBRATE TRANSDUCER VENTILATOR FAILURE DETECTED	- OR - if SELF-CHECK Alarm is not related to the Transducer Calibration:	VENTILATOR FAILURE DETECTED FAILURE CODE 1 • SELF-CHECK FAILURE!
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NON-OPERATING ALARMS (cont'd)

NO GAS AND COMPRESSOR FAILURE: Occurs when the internal compressor has failed and no external gas(es) are available. The AMC will display:

VENTILATOR FAILURE
DETECTED

FAILURE CODE 2

- NO GAS AND COMPRESSOR FAILURE!

EXCESSIVE AIRWAY PRESSURE: Occurs when a continuous pressure, above 100 cmH₂O, is sensed in the patient circuit for more than 2-seconds. Uni-Vent[®] must be turned OFF, then restarted, to clear a SYSTEM FAILURE Alarm caused by high pressure. The AMC will display:

VENTILATOR FAILURE
DETECTED

FAILURE CODE 3

- EXCESSIVE AIRWAY PRESSURE!

MEMORY CHECK FAILURE: Occurs when the MEMORY CHECK portion of SELF-CHECK fails. The AMC will display:

VENTILATOR FAILURE
DETECTED

FAILURE CODE 4

- MEMORY CHECK FAILURE!

EXHALATION VALVE FAILURE: Occurs when a failure of the exhalation backup solenoid is sensed. The AMC will display:

VENTILATOR FAILURE
DETECTED

FAILURE CODE 5

- EXHALATION VALVE FAILURE!

EXCESSIVE NEGATIVE PRESSURE: Occurs when a continuous negative pressure exceeding -10 cmH₂O for 1.5-seconds is sensed.

VENTILATOR FAILURE
DETECTED

FAILURE CODE 6

- EXCESSIVE NEGATIVE PRESSURE!

RUN-TIME CALIBRATION FAILURE: Occurs when Eagle[™]'s pressure transducer AUTO CAL function detects excessive baseline shift.

VENTILATOR FAILURE
DETECTED

FAILURE CODE 7

- RUN-TIME CALIBRATION FAILURE!

ADVISORY ALARMS

INSPIRATION TIME TRUNCATED TO 3-SEC Alarm: Initiates when control settings would cause an inspiration time to exceed 3-seconds. It is disabled in the CPAP mode. When activated, operation is allowed to continue, an audible tone is heard and the AMC displays: INSPIRATION TIME TRUNCATED TO 3-SEC-NOTE I-TIME & I:E or INSPIRATION TIME TRUNCATED. The AMC will blank if a non-operating alarm occurs. Otherwise, pressing the ALARM MUTE/CANCEL Pushbutton Switch cancels this alarm's audible component, and turns the ALARM LED off. Only the AMC message remains. A SIGH breath that would exceed 3.0-seconds is truncated but will not activate this alarm.

PLATEAU VOLUME Alarm: Initiates when delivered PRESSURE PLATEAU tidal volume is less than set tidal volume by more than 5%. When activated, operation is allowed to continue, an audible tone is heard and the AMC displays: PLATEAU VOLUME-DELIVERED VOLUME LESS THAN SET VOLUME or PLATEAU VOLUME. The TIDAL VOLUME LCD Display will flash "#### set" volume (delivered volume is not displayed), and V_{\min} is blanked (ACV mode). The AMC will blank in the CPAP mode, or if a non-operating alarm occurs. Pressing the ALARM MUTE/CANCEL Pushbutton Switch cancels this alarm's audible component, and turns the ALARM LED off. Only the AMC message and alternating display remain. This alarm replaces the V_T Alarm during PRESSURE PLATEAU operation. It is disabled when CPAP operation is selected.

V_T SETTINGS Alarm: Initiates whenever the sum of the flows of the selected gases would exceed a flow rate of 60 liters per minute (LPM). When activated the AMC displays: V_T SETTINGS - I-TIME X FLOW UNABLE TO DELIVER SET VOLUME or V_T SETTINGS. The TIDAL VOLUME LCD Display will alternately flash "#### set" and "#### del". The AMC will blank in the CPAP mode, or if a non-operating alarm occurs. Pressing the ALARM MUTE/CANCEL Pushbutton Switch cancels this alarm's audible component, and turns the ALARM LED off. Only the AMC message and alternating display remain.

PREVENTATIVE MAINTENANCE Alarm: Initiates after 2000-hours of cumulative use, or 12-months, whichever occurs first. Preventative maintenance will insure that this device has been cleaned, tested, calibrated, and serviced to manufacturers specifications (see LIMITED WARRANTY statement). When activated the AMC displays: PREVENTATIVE MAINTENANCE DUE - CONTACT CUSTOMER SERVICE or PREVENTATIVE MAINTENANCE DUE. The AMC will blank if a non-operating alarm occurs. Pressing the ALARM MUTE/CANCEL Pushbutton Switch cancels this alarm's audible component, and turns the ALARM LED off. Only the AMC message remains.

EXTENDED NON-USE/STORAGE Alarm: Initiates at power-up after 6-months of continuous non-use/storage has occurred. Following 6-months of continuous storage/non-use, 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. When activated the AMC displays: EXTENDED NON-USE/STORAGE - TEST BEFORE PATIENT USE or EXTENDED NON-USE/STORAGE. The AMC will blank if a non-operating alarm occurs. Pressing the ALARM MUTE/CANCEL Pushbutton Switch cancels this alarm's audible component, and turns the ALARM LED off. Only the AMC message remains.

EXTERNAL POWER FAILURE Alarm: Initiates whenever external power fails, or is disconnected during external power operation. When activated, operation reverts to internal battery power, a tone is heard, and the AMC displays: EXT PWR FAIL/DISCONNECT - CHECK POWER SOURCE/CONNECTIONS or EXT PWR FAIL/DISCONNECT. The POWER INFORMATION CENTER (PIC) will display: EXT PWR FAIL. Pressing the ALARM MUTE/CANCEL Pushbutton Switch cancels the audible alarm, and the AMC and PIC messages, and resets the ALARM LED. The AMC will blank if a non-operating alarm occurs.

TOTAL FLOW BACKUP Alarm: Initiates when the backup flow sensor detects the sum of the flows (O_2 , Air, and internal compressor) exceeding set flows by +/- 50% for 5-consecutive breaths. There must be a total flow rate of at least 10 LPM and a total tidal volume of at least 200ml for this alarm to operate. When activated, operation is allowed to continue, an audible tone is heard, and the AMC displays: TOTAL FLOW BACKUP - CONTACT CUSTOMER SERVICE. The AMC will blank if a non-operating alarm occurs. Pressing the ALARM MUTE/CANCEL Pushbutton Switch cancels this alarm's audible component, and turns the ALARM LED off. Only the AMC message remains. If this alarm is not preceded by a V_T operating alarm, the causing condition is likely due to the backup flow sensing element being dirty or partially clogged.

ALARM MUTING AND CANCELLING

ALARM MUTE/CANCEL Pushbutton Switch: The ALARM MUTE/CANCEL Pushbutton Switch, deactivates the audible portion of an existing OPERATING ALARM for a 30-second period (with the exception of certain power alarm conditions). Mute periods for BATTERY Alarms last for 5-minutes. If an EXTERNAL POWER LOW Alarm occurs and is muted, the mute period will last until the internal battery depletes. At this point, a BATTERY LOW Alarm activates, in addition to the EXTERNAL POWER LOW Alarm, and muting will now last for 5-minute periods.

A new alarm condition will always override a pre-existing "mute".

The ALARM MUTE/CANCEL Pushbutton Switch will cancel an APNEA Alarm allowing Uni-Vent[®] to resume operation in the ACV, SIMV or CPAP modes. Pressing the ALARM MUTE/CANCEL Pushbutton Switch does not effect the AMC display (except for the APNEA message which is cancelled).

A NON-OPERATING ALARM cannot be muted or cancelled. It will self-cancel when its causing condition is corrected.

ADVISORY ALARMS may be muted once. The mute period will continue indefinitely or until its causing condition is corrected.

ROUTINE CARE: CALIBRATION, CLEANING, AND PREVENTATIVE MAINTENANCE

CALIBRATION

This device should be incorporated into a regular preventative maintenance program to insure compliance with operating specifications. 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 2000 hours of cumulative use or 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. The Model 754 contains internal clocks that monitor cumulative use and storage/non-use periods. Appropriate Advisory Alarm messages will appear in the Alarm Message Center when calibration/preventative maintenance is required.

A Calibration Label is affixed to the Eagle™'s exterior case. It includes the date of last calibration, the next calibration due date (based on 12-months use, however, if 2000-hours use occurs first, it shall take precedence). The LIMITED WARRANTY will become void if this label is removed or tampered with.

CLEANING

Keep Uni-Vent® and its accessories clean at all times. Never allow grease and 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. Uni-Vent'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 Hoses: Examine hoses for cracking, discoloration and disfigurement. 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.

Compressor Inlet Filter: The compressor inlet filter housing is located to the right of the connector panel on the side edge of the bottom cover. Remove filter using a pair of tweezers or similar tool. Examine the filter for dirt, lint, or general wear. Replace if necessary. DO NOT attempt to clean this filter. Do not operate internal compressor without filter in place.

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. Cleaning checks - as described above.
- 2. Operational checks - as described in OPERATOR PERFORMANCE CHECKS.
- 3. Tubing and hose checks - replaced crimped, cracked or worn tubing and hose as required.
- 4. Mechanical components have a finite life expectancy. Their cumulative wear-and-tear depends largely upon the number of cycles-during-use and their number of hours-in-use. Accordingly, this instrument should be returned to Impact®, or a certified Impact® Service Facility, after 2000 hours of cumulative use or 12-months, whichever occurs first, to insure its continued operation to specifications (see LIMITED WARRANTY statement).

Contact Impact® prior to returning this instrument for scheduled maintenance or service. 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.

BATTERY CARE AND RECHARGING

The Uni-Vent[®] Model 754 uses sealed lead-acid batteries, "starved-electrolyte" type, which offer a wide temperature operating range, do not exhibit "memory" characteristics (reduced capacity) or vent hydrogen gas. 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 this instrument where the temperature range exceeds -25°C to 49°C (-13°F to 120°F).
2. DO NOT charge this instrument where the temperature range exceeds -20°C to 50°C (-4°F to 122°F).
3. DO NOT store this instrument with the batteries discharged. Always store in a charged condition.
4. For long-term storage, the optimum storage temperature range is 10°C to 30°C (50°F to 80°F).

Sealed lead acid batteries exhibit excellent charge retention characteristics. Prolonged periods of disuse will not substantially reduce operating capability. If long-term disuse is common, it would be advisable to recharge the unit once every two months. This will insure that battery charge is maintained at 80% capacity or better. Recharge time ranges from 14 - 16 hours, depending upon initial state of discharge. Continuous charging is permissible with the 12 VDC Power Cable or Universal AC Power Supply furnished with Uni-Vent[®]. The EXTERNAL POWER Jack is located along the top edge of the Uni-Vent[®] case. The CHARGE indicating LED will illuminate whenever charging current is flowing into the battery pack. The POWER INFORMATION CENTER (PIC) will display: (Line 1) "EXT PWR ON", and (Line 2) battery icon "ON CHG". A fully charged battery pack will cause the CHARGE LED to turn off and PIC display Line 2 changes to battery icon "OK".

Uni-Vent[®] will accept a range of inputs for operating power and battery recharge purposes. Standard accessories, as mentioned in the previous paragraph, are provided. For special applications requiring non-standard accessories, the following requirements are intended to serve as guidelines:

Input Voltage:	11 to 15 VDC
DC Ground:	Negative
DC Power:	80 Watts (over the input voltage range)
AC Frequency:	Not applicable

Operating power will default to the external power source to preserve internal batteries for portable or transport use, emergency back-up or recharging purposes. If an EXTERNAL POWER LOW/FAIL Alarm occurs, Uni-Vent[®] will automatically revert to its internal batteries for operating power.

IN CASE OF DIFFICULTY

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

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

OPERATOR CORRECTABLE PROBLEMS

Common problems may be quickly rectified by users. Should Uni-Vent[®] 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 any fuse that is blown or missing. Verify successful SELF-CHECK, perform TRANSDUCER CALIBRATION if required.

OPERATOR PROBLEMS REQUIRING SERVICE

If the tests described above do not resolve an operating problem, service is required. Should servicing be necessary, contact your nearest Impact[®] Representative or the Impact[®] Customer Service Department 973/882-1212. 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 and Serial Number ready and any other pertinent data you wish to include in the service request. Uni-Vent's Serial Number Label is affixed to the bottom cover.

STORAGE INFORMATION

For prolonged storage periods, the Model 754 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.

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

Following periods of extended storage in non-controlled environments, allow Uni-Vent® sufficient time to stabilize to a temperature within its specified operating range (see section entitled BATTERY CARE AND RECHARGING).

The EXTENDED NON-USE/STORAGE Alarm will initiate at power-up after 6-months of continuous non-use/storage has occurred. 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

OPERATING MODES:	ACV - with/without PEEP, with/without SIGH ACV - with/without PEEP, with/without PRESSURE PLATEAU SIMV - with/without PEEP, with/without SIGH SIMV - with/without PEEP, with/without PRESSURE PLATEAU CPAP - with/without PEEP Control Ventilation - for APNEA backup of ACV, SIMV and CPAP
FLOW RATE:	Adjustable, 0 to approximately 60 LPM (0 to approximately 1000 ml/SEC)
VENTILATION RATE:	Adjustable, 1 to 150 breaths per minute, resolution 1 breath per minute (+/- 1 digit on the LCD)
INSPIRATION TIME:	Adjustable, 0.1 to 3.0 seconds, resolution in 0.1 second increments (+/- 1 digit on the LCD); 1:2 I:E RATIO Preset
FIO ₂ :	Adjustable, 21% to 100%, resolution in 1% increments, accurate to within +/- 10%
LOW PRESSURE ALARM:	Adjustable, 0 to 50 cmH ₂ O, resolution in 1 cmH ₂ O increments (+/- 1 digit on the LCD)
HIGH PRESSURE ALARM:	Adjustable, 15 to 100 cmH ₂ O, resolution in 1 cmH ₂ O increments (+/- 1 digit on the LCD)
PEAK INSPIRATORY PRESSURE RELIEF:	Adjustable, 15 to 100 cmH ₂ O, resolution in 1 cmH ₂ O increments (+/- 1 digit on the LCD)
PRESSURE PLATEAU:	Range, 5 to 90 cmH ₂ O (referenced to HIGH PRESSURE ALARM setpoint)
ASSIST/SIMV SENSITIVITY:	Default, 1.5 to 2.0 cmH ₂ O below end pressure (see USER PROGRAMS)
PEEP:	Program range 1 to 20 cmH ₂ O, resolution in 1 cmH ₂ O increments (+/- 1 digit on the LCD)
SIGH:	Occurs once every 100-ventilations or 7-minutes, whichever occurs first. SIGH duration = 150% of inspiration time (truncated to a combined maximum of 3-seconds)
Liquid Crystal Display:	EXTERNAL AIR, SIGH, PEEP, PRESSURE PLATEAU, HIGH PRESSURE ALARM SETTING, LOW PRESSURE ALARM SETTING, VENTILATION RATE, INSPIRATION TIME/I:E RATIO, TIDAL VOLUME, AIR/OXYGEN MIXER, MODE, INSPIRATION/EXHALATION, POWER, PEAK AIRWAY PRESSURE, MEAN AIRWAY PRESSURE, DIGITAL BAR GRAPH, HIGH/LOW, AIRWAY PRESSURE ALARM SETPOINT INDICATORS, P _{aw}

SPECIFICATIONS, (cont'd)

LED INDICATOR:	CHARGE
LCD DIGITAL BAR GRAPH:	Range -10 to 100 cmH ₂ O
LCD ALARM DISPLAY:	BATTERY LOW, EXTERNAL POWER LOW, LOW PRESSURE, O ₂ LOW/FAIL, DISCONNECT, HIGH PRESSURE, APNEA, V _T , HIGH PEEP, EXT AIR LOW/FAIL, FIO ₂ , INVERSE I/E, COMP, PRESSURE ALARM SETTINGS, TRANSDUCER CALIBRATION ABORT, SYSTEM FAILURE, VENTILATOR FAIL, INSPIRATION TIME TRUNCATED TO 3-SEC, PLATEAU VOLUME, PREVENTATIVE MAINTENANCE DUE, V _T SETTINGS, EXTENDED NON-USE/STORAGE, EXTERNAL POWER FAILURE, TOTAL FLOW BACKUP
LED ALARM INDICATORS:	ALARM, SYSTEM FAILURE
ALARM VOLUME:	80 dBA @1 ft
MANUAL BREATH/TRIGGER:	Yes
NOISE LEVEL:	Less than 80 dBA when measured @1-meter (compressor operating)
OPERATING VOLTAGES:	
Ventilator:	11-15 volts, DC (negative ground)
Universal AC Power Supply:	Model 754 (standard) - Input: 100 to 240 VAC, 50/60 HZ, autosensing 0.55-1.33A, 133W. Output Voltage is 13.0VDC, 6A, 78W. Shock Protection: Type B, Class 1
Water / Dust Resistance	IPX1
OPERATING TIME:	
Internal Batteries:	3-hours, maximum, using internal compressor 12-hours using external gas
External AC:	Continuous
External DC:	Continuous
TEMPERATURE RANGES:	
OPERATING:	-25°C to 49°C (-13°F to 120°F)
CHARGING:	-20°C to 50°C (-4°F to 122°F)
LONG TERM STORAGE:	10°C to 30°C (50°F to 80°F)

SPECIFICATIONS, (cont'd)

SIZE:

Ventilation 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 (std)	7.75" Wide X 2.62" High X 4.75" Deep (19.69 cm Wide X 6.65 cm High X 12.07

WEIGHT:

Ventilation System	13 lbs (5.8 Kg)
AC Power Supply (std)	3.00 lbs (1.36 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, 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 2000 hour preventative maintenance is performed. Following each 2000 hours cumulative use, or 12-month period, whichever occurs first, this device must have preventative maintenance performed by Impact[®] or a certified Impact[®] service facility.

A Calibration Label is affixed to the Eagle[™]'s exterior case. It includes the date of last calibration, the next calibration due date (based on 12-months use, however, if 2000-hours use occurs first, it shall take precedence). This warranty shall become void if this label is removed or tampered with.

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.