HALLOWELL EMC

Hallowell EMC Model 2024^{PRO} & Model 2024IE^{PRO}

Veterinary Anesthesia Ventilators

The latest design in precision digital ventilation.



User Manual

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MODEL 2024 ^{PRO} ™ SPECIFICATIONS

PLEASE READ THIS MANUAL BEFORE OPERATING THE VENTILATOR.

This **Model 2024**^{PRO}/**2024IE**^{PRO} equipment is designed to function, as specified in this manual, when operated and maintained in accordance with supplied instructions. This equipment must be periodically checked, calibrated, maintained and components repaired and replaced when necessary for equipment to operate reliably. Parts that have failed, in whole or in part, exhibit excessive wear, are contaminated, or are otherwise at the end of their useful life, should not be used and should be replaced immediately with parts supplied and approved by **Hallowell EMC**. Equipment that is not functioning correctly should not be used. This equipment and any of its accessories or component parts should not be modified.

The user/owner of this equipment shall have the sole responsibility and liability for any damage or injury to patients or property (including the equipment itself) resulting from operation not in accordance with the authorized maintenance instructions, unauthorized repair or modification of the equipment or accessories, or from the use of components or accessories that have either been damaged or not authorized for use with this equipment by **Hallowell EMC**.

WARNINGS AND CAUTIONS

Personnel operating the ventilator must become thoroughly familiar with the instruction manual prior to using the **Model 2024**^{PRO} /2024IE^{PRO} **Anesthesia Ventilator** with patients.

- ELECTRIC SHOCK HAZARD DO NOT remove ventilator cover. Refer all servicing to an authorized service technician.
- DANGER Possible explosion hazard if the unit is used in the presence of flammable anesthetics.
- Before using the ventilator, check that all connections are correct, and verify that there is no leak.
- Any problems arising from an improperly functioning scavenging system is solely the user's responsibility.
- OPENING THE CONTROL UNIT BY UNAUTHORIZED PERSONNEL AUTOMATICALLY VOIDS ALL WARRANTIES AND SPECIFICATIONS. THE PREVENTION OF TAMPERING WITH THE CONTROL UNIT IS EXCLUSIVELY THE USER'S RESPONSIBILITY: THE MANUFACTURER ASSUMES NO LIABILITY FOR ANY MALFUNCTION OR FAILURE OF THE VENTILATOR IF THE CONTROL UNIT'S SEAL IS BROKEN.
- Compressed Supply Gas must be clean and dry to prevent ventilator malfunction.

The **Model 2024**^{PRO} /2024IE^{PRO} Veterinary Anesthesia Ventilator is covered under the warranty expressed on the warranty card attached to the unit at the time of sale to the end user, which reads as follows:

LIMITED WARRANTY STATEMENT

WHAT THIS WARRANTY COVERS:

HEMC offers you a limited warranty that the enclosed subscriber unit and its enclosed accessories will be free from defects in material and workmanship, according to the following terms and conditions:

1. The limited warranty for the product extends for TWENTY-FOUR (24) MONTHS beginning on the date of purchase of the product with valid proof of purchase.

2. The limited warranty extends only to the original purchaser of the product and is not assignable or transferable to any subsequent purchaser. Only through a HEMC authorized Dealer the warranty can be transferred from the original end user.

3. The housing, bellows and cosmetic parts shall be free of defects at the time of shipment and, therefore, shall not be covered under these limited warranty terms.

4. Upon request from HEMC, the consumer must provide information to reasonably prove the date of purchase.

5. The customer shall bear the cost of shipping the product to the Customer Service Department of HEMC. HEMC shall bear the cost of shipping the product back to the consumer after the completion of service under this limited warranty.

WHAT THIS WARRANTY DOES NOT COVER:

1. Defects or damages resulting from use of the product in other than its normal and customary manner.

2. Defects or damages from abnormal use, abnormal conditions, improper storage, exposure to moisture or dampness, unauthorized modifications, unauthorized connections, unauthorized repair, misuse, neglect, abuse, accident, alteration, improper installation, or other acts which are not the fault of HEMC, including damage caused by shipping, blown fuses, spills of food or liquid.

3. Alleged defect or malfunction of the product during the applicable limited warranty period not reported by the end user to HEMC prior to the expiration of the warranty period as defined.

4. Products which have had the serial number removed or made illegible.

5. Damage resulting from use of non-HEMC approved accessories.

6. All plastic surfaces and all other externally exposed parts that are scratched or damaged due to normal customer use.

7. Products operated outside published maximum ratings.

8. Products used or obtained in a rental program.

9. Consumables (such as fuses).

10. This limited warranty is in lieu of all other warranties, expressed or implied either in fact or by operations of law, statutory or otherwise, including, but not limited to any implied warranty of marketability or fitness for a particular use.

WHAT HEMC WILL DO?

HEMC will, at its sole discretion, either repair, replace or refund the purchase price of any unit that does not conform to this limited warranty. HEMC may choose at its discretion to use functionally equivalent reconditioned, refurbished, or new units or parts.

STATE LAW RIGHTS:

THE DURATION OF ANY IMPLIED WARRANTIES, INCLUDING THE IMPLIED WARRANTY OF MARKETABILITY, IS LIMITED TO THE DURATION OF THE WARRANTY EXPRESSED HEREIN. HEMC SHALL NOT BE LIABLE FOR THE LOSS OF THE USE OF THE PRODUCT, INCONVENIENCE, LOSS OR ANY OTHER DAMAGES, DIRECT OR CONSEQUENTIAL, ARISING OUT OF THE USE OF, OR INABILITY TO USE, THIS PRODUCT OR FOR ANY BREACH OF ANY EXPRESS OR IMPLIED WARRANTY, INCLUDING THE IMPLIED WARRANTY OF MARKETABILITY APPLICABLE TO THIS PRODUCT.

Some states do not allow the exclusive of limitation of incidental or consequential damages or limitations on how long an implied warranty lasts; these limitations or exclusions may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from state to state.

HOW TO GET WARRANTY SERVICE:

To obtain warranty service, you may contact us by telephone, fax, or email at: Tel. 1-413-445-4263, Fax. 1-413-496-9254 or info@hallowell.com. Visit www.hallowell.com

Correspondence may also be mailed to: Hallowell EMC 35 Downing Industrial Park Pittsfield, MA 01201

Prices, terms, and product specifications are subject to change without notice.

INTRODUCTION

The **Model 2024**^{PRO} /2024IE^{PRO} Veterinary Anesthesia Ventilator are designed specifically for veterinary anesthesia use. It is a volume-cycled microprocessor-controlled ventilator with a choice of three bellows sizes, providing consistent IPPV for patients from rabbits to foals.

The **Model 2024**^{PRO} /2024IE^{PRO} from **Hallowell EMC** incorporates experience resulting from over twenty years of ventilator design and manufacture. The device is small, portable, and quiet in operation. It has been designed to be economical in its consumption of supply gas.

The ventilator consists of two main assemblies: the controller assembly, comprising all electronics, regulatory and control electronics, and pneumatics; and the bellows assembly, comprising the bellows base with pop-off valve, the bellows, and the bellows housing. The bellows assembly is easily removed to facilitate cleaning and sterilization. Equally as easily, the different size bellows and bellows housings may be interchanged on the same bellows base to minimize the ventilator's contribution to the compliance of the breathing system, and to provide increased resolution on the tidal volume scale in the 0-300 ml tidal volume range.

The bellows base is of injection molded ULTEM®, a product of General Electric Plastics. ULTEM® is a high temperature, high-impact resistant material that is unaffected by water or the presence of all state-of-the-art anesthetics. In addition, the high temperature properties of ULTEM® make it fully compatible with standard steam sterilization techniques.

The **Model 2024**^{PRO}/2024IE^{PRO} is shipped as a free-standing unit with the bellows assembly mounted on top of the controller. For custom installations such as for use in conjunction with MRI units, the bellows assembly may be separated from the controller and mounted in a location closer to the patient. As supplied, the ventilator may be located on the anesthesia machine shelf or cart, or on a tabletop. The rubber feet can be removed for installation on an optional heavy-duty stand with casters. The stand increases the mobility of the unit permitting convenient use in multiple operating rooms. Optionally, **Hallowell EMC** provides mounting hardware for the Matrx VMC and Spartan, VMS and VML anesthesia machines. Mounting hardware is also available for anesthesia machines manufactured by A.M. Bickford, Anesco, Delmarva Labs, Dispo-Med, SDI, and VetEquip (formally Omni Medical).

Important

Before attempting to use this ventilator, it is important that you first thoroughly familiarize yourself with this manual. After your review, you should complete the receiving and setup procedures, then perform the verification check with a test lung, as described herein. Become familiar with the ventilator's controls during the verification check and observe the effect of control adjustments on the breathing system.

RECEIVING PROCEDURES

1. Remove all components from the shipping carton. Retain and store the original shipping carton for use if the unit must be shipped back. (See "Returning for Service").

2. Inspect the ventilator and accessories for any signs of damage that may have occurred during shipping. If damage has occurred, immediately file a damage claim with the carrier.

Packed by	Date	_//	/	Controller SN
Received by	Date	/	/	Serial Number verified

3. Check the items against the packing slip and report discrepancies immediately.

All ventilator models include and are shipped with the following:

- Model 2024^{PRO}/2024IE^{PRO} Controller
- Bellows Base Assembly (PN 000A0510)
- Tube, Driving Gas (7¹/₂" black rubber) (PN 000A0495)
- Airway Pressure Sampling Tee (PN 000A2420B)
- 36" x 22 mm Breathing System Tube (PN 201A1615)
- External 12VDC Power Supply (PN 090A0280) w/ Country Kit (070A5174), medical safety approval: ANSI/AAMI ES60601-1/60601-1-11
- Warranty Registration Card (DOCA5967B). Complete and return to Hallowell EMC.
- Card Spin USB Flash Drive (w/ Operating Manual) (125A1845)
- Pro Series Vent. Accessory Kit (000A6557):
 - O₂, DISS Inline Pressure Gauge.
 - O₂ DISS HT Fem Inlet WYE w/ DISS Demand Outlets.
 - O2, DISS Male Coupler
 - O₂, DISS 4' Green Supply Hose (F x F)

The standard Model - 300 - 1600 ml version – PN 000A6758 (IE Model PN 000A6762) Includes one each of:

- Bellows, 300 1600 ml (PN 000A0488)
- Bellows Housing, 300 1600 ml (PN 200A2289)

The 0 - 300 ml version – PN 000A6757 (IE Model PN 000A6761) Includes one each of:

- Bellows, 0 300 ml (PN 000A0487)
- Adapter, Bellows, 0 300 ml (PN 000A0486)
- Bellows Housing, 0 300 ml (PN 200A2288)

The 1600 - 3000 ml version – PN 000A6759 (IE Model PN 000A6763) Includes one each of:

- Bellows, 1600 3000 ml (PN 000A1866)
- Bellows Housing, 1600 3000 ml (PN 200A1867)

Numerous other optional parts may have been shipped with your order also. Please refer to the packing slip for details.

SET-UP PROCEDURE

- 1. **Inspect the control unit for debris from shipping.** Inspect all three ports, the 50 psi SUPPLY GAS, EXHAUST, and DRIVING GAS ports on the back of the ventilator and remove any obstructions that may have become lodged inside during shipping and unpacking.
- 2. Inspect the bellows assembly for debris from shipping. Tilt the top of the bellows housing toward you and lift it off. Remove the accessories from within the bellows housing.
- 3. Ensure that all passages, ports, and chambers are free, clear, and unobstructed. Note that even a hair across the pop-off valve seat will produce an unacceptable leak in the breathing system.

Caution:

If removal of the pop-off valve becomes necessary, remove the bellows by gently lifting it off to the side. Unscrew the three red thumb screws. Gently lift the pop-off valve off the bellows base assembly to reveal the pop-off valve seat and red silicone O-ring. Do not damage the valve seat. Do not touch the seat with any type of hard object--even a fingernail scratch--could permanently damage the seat. Be sure the red O-ring remains in its gland in the bellows base.

- 4. **Reassemble the bellow assembly.** If removed, first install the pop-off valve with the three red thumbscrews. Next install the bellows with its <u>first</u> convolution over the bellows-mounting ring. Carefully hold the outer edge of the bellows disk (top of bellows): lift and lower it quickly several times to puff out and remove any folds in the convolutions. Place the bellows housing over the bellows, positioning the housing so that the tabs are to the immediate right of the bayonet locks. Gently press the housing down, twisting the housing clockwise at the same time until the tabs engage with the bayonet locks. The bellows assembly is now reassembled.
- 5. Connect the drive gas tube Locate the 7½" long corrugated black rubber drive gas tube, with 15 mm diameter cuffed ends. Connect the tube between the bellows assembly DRIVING GAS port and the DRIVING GAS port of the control unit. If the bellows base assembly is being mounted remotely from the control unit, a longer 15 mm tube will be needed. (A ½" garden hose works well for the long runs to MRI units, but the shorter this tube can be, the better.)
- 6. **Position the ventilator.** Place the ventilator in an accessible location, close to the area where it will be used, both for convenience, and in an effort to keep the breathing system tubing as short as possible.
- 7. Connect the ventilator to the breathing system Remove the breathing bag from the bag connector of the Anesthesia machine. Connect the 22 mm x 36" corrugated tube (PN 201A1615) to the BREATHING SYSTEM port of the bellows assembly and to the bag connector. Use of the clear breathing circuit tubing is recommended so the user can see an excessive accumulation of condensation that may interfere with gas flows within the breathing system

SET-UP PROCEDURE (Continued)

- 8. Insert the Airway Pressure Sampling Tee into the breathing system Disconnect the patient breathing hose from the INHALE VALVE of the anesthesia machine. Connect the Airway Pressure Sampling Tee (PN 000A2420B) to the INHALE VALVE and reconnect the patient breathing hose to the Airway Pressure Sampling Tee. Route the sampling tube as desired to the ventilator Pressure Transducer port on the rear panel. Trim sampling tube to length leaving enough slack for movement. Install Luer Lock fitting such that the hose barb is fully set into the tube. Attach fitting to ventilator Pressure Transducer port.
- **9.** Connect the ventilator to the scavenger Use a 19-mm corrugated tube (not provided) to connect the EXHAUST port of the bellows assembly to a properly functioning scavenger system.

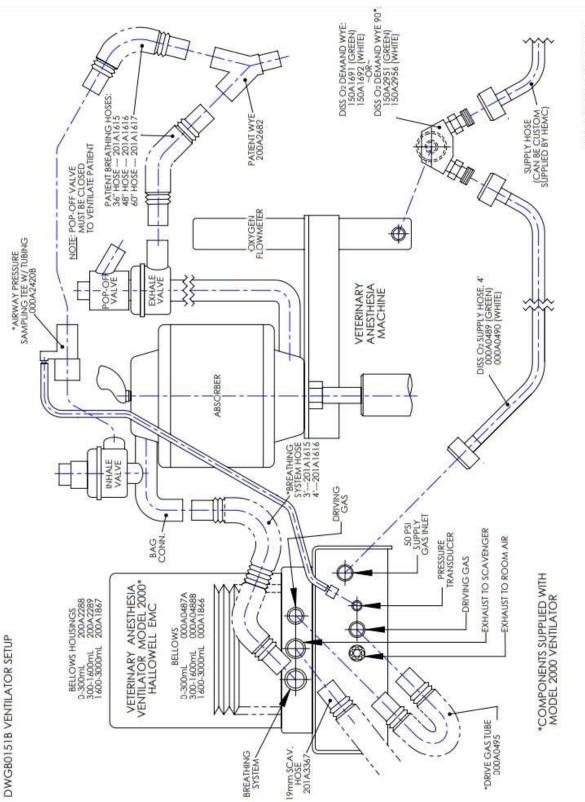
Warning:

Applying any negative or positive pressure to the EXHAUST port of the bellows base assembly will result in a more positive pressure in the patient breathing system and improper operation of the ventilator.

10. Connect the supply gas Connect the O₂, DISS Inline Pressure Gauge (Accessory Kit) to the 50 psi SUPPLY GAS INLET of the control unit and to the DISS 4' Green Supply Hose of the oxygen gas supply. The unit is provided with a DISS 1240 male oxygen bulkhead fitting. Gas consumption of the ventilator is very economical, therefore, the use of oxygen as a drive gas is recommended. Oxygen use reduces the risk of unit malfunction due to contamination of the pneumatics. Compressed air may be used, but it must be CLEAN and DRY.

The 50-psi source for the ventilator may be provided from a separate tank, wall, or ceiling drop, or from a PTO (Power-Take Off) on the anesthesia machine. Should none of the above be available, a common practice, for machines with DISS 1240 male O₂ inlets, is to remove the O₂ supply line to the anesthesia machine from the anesthesia machine, connect a demand wye (HEMC PN 150A1691 (GRN) from Accessory Kit to the inlet of the anesthesia machine and then reconnect the O₂ supply line to the anesthesia machine via one of the two remaining connections to the wye. This leaves one leg of the wye available to source the ventilator with O₂, connect HEMC PN 000A0489 (GRN) from Accessory Kit between the demand wye and the ventilator 50-psi inlet.

11. Connect the electrical power PRIOR to connecting the electrical power, confirm that the appropriate country power inlet adapter is installed on the Power Supply (090A0280). Insert the 2.1mm plug into receptacle on the rear of controller. Secure the power cable with clamp provided on the rear of the unit. Plug the Power Supply into a properly grounded power source. (*Pic.2 Rear Panel on Page 12*)



DWGB01518 VENTILATOR Setup

CONTROLS (FRONT PANEL)

Power Switch (PWR) - A maintained switch with built in green LED. Use to turn the ventilator ON and OFF. The green LED is illuminated to indicate the power is ON. (*Pic.1 Front Panel, Page 12 – Ref. #1*)

Standby/Ventilate (STBY/VENTILATE) – A toggle switch with a YELLOW LED above it.

Note: The ventilator is in **STANDBY** mode when the switch is **UP**, and the **LED** light is on. You should setup the **RATE** and the **MWPL** in this mode. The **VOLUME** valve should be completely closed (**clockwise**). (*Pic.1 Front Panel, Page 12 – Ref. #2*)

Put the switch **DOWN** to **VENTILATE** the patient or when using the artificial lungs. The **LED** light should be off. Slowly open the **VOLUME** valve until you reach the desired parameters. (*Pic.1 Front Panel, Page 12 – Ref. #3*)

Two controls, the **RATE** and **VOLUME** on the **Model 2024**^{PRO}/**2024IE**^{PRO} are used to directly set the amount of ventilation.

VOLUME Control – A multi-turn metering valve (9 rotations) regulates the inspiratory flow from 0 to 100 lpm. This valve has a lot of resolution at the low end, so adjusting small tidal volumes is much easier. The first three turns are offering fine increments of flow to set small tidal volumes (0-300ml), after the four turns, the increments of flow are coarse increments to set large tidal volumes (300-3000ml). The inspiratory volume control is used to adjust the minute volume ventilation of the patient, this is the only control that will affect minute volume ventilation because the I:E ratio is held constant at 1:2, in the model 2024PRO ventilator. (*Pic.1 Front Panel on Page 12 – Ref. #4*) If the ventilator is a 2024IE PRO ventilator, the two controls that affect the minute volume ventilation

If the ventilator is a 2024IE PRO ventilator, the two controls that affect the minute volume ventilation should be the inspiratory **VOLUME** control and the **I:E RATIO** control.

RATE Control - A potentiometer. Use to set the respiratory rate in breaths per minute (BPM). The specific setting will be read on a 2-digit RATE display window. The range of the RATE is from 2 to 80 BPM in all models, 2024PRO and 2024IE PRO. (*Pic.1 Front Panel on Page 12 – Ref. #5*) By request, the customer can choose a different range of rate:

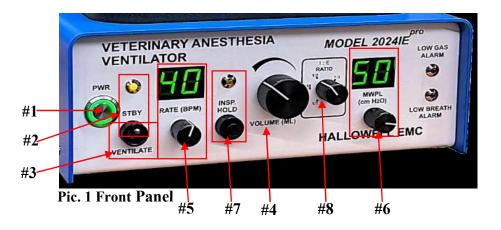
- 6 to 40 BPM
- 0.5 to 60 BPM.

Maximum Working Pressure Limit (MWPL) – A potentiometer. Use to set a safety pressure limit in cmH₂O. The MWPL is used to adjust an upper limit above which you wish the airway pressure never to exceed. The set pressure is read on a 2-digit MWPL display window. The range of MWPL is from 10 to 60 cm H₂O. (*Pic.1 Front Panel Page 12 – Ref. #6*)

Inspiratory Hold (INSP HOLD) – A momentary pushbutton. Use to pause the breathing cycle at the end of the current or next inspiration. The maximum length of the hold is 60seconds. After this time, the ventilator automatically resets the hold mode and the cycle initiates again. The inspiratory hold mode will not respond if the MWPL is exceeded. (*Pic.1 Front Panel on Page 12 – Ref. #7*)

Inspiratory/Expiratory Ratio (I: E RATIO) – A potentiometer. Use to set the duration of Inspiratory: Expiratory phases, and it can be set from 1:1, 1:1.5, 1:2, 1:3, and 1:4. (*Pic.1 Front Panel on Page 12 – Ref. #8*)

This feature only comes with the 2024IE Pro Version.



CONTROLS (REAR PANEL)

Power Supply Inlet (12Vdc @ 2A) - a 2.1mm jack for external medical safety approved (ANSI/AAMI ES60601-1/60601-1-11) power supply (PN 090A0280).

Fuse Holder (2A) – for fuse, 5x20mm 2A 250V Fast VDE (PN 053A1782).

Features that can be installed by request are:

MANUAL REMOTE INSPIRATORY HOLD. A 30ft cable connected to the back of the ventilator (Remote Ins. Hold connector) that pauses the breathing cycle from a remote place. This option is great to use when the ventilator is set to work with an MRI or CT Scanner environment.

OXYGEN FLOW INTERRUPTER BOX. Use to stop the flow from the anesthesia machine when the Inspiratory hold button is pressed from the front of the ventilator or from the remote inspiratory cable. This box is connected to the oxygen supply source, the ventilator, and the anesthesia machine. The box cable is connected to the back of the ventilator, specifically to the flow interrupter connector.



If the customer requests the installation of these features, the ventilator should come back to Hallowell

- Remote Insp. Hold Button with O₂ Flow Interrupter (000A_____
- Remote Insp. Hold Button (PN 000A______



ALARMS and LEDs

Maximum Working Pressure Limit Alarm (MWPL): The MWPL feature allows the operator to set an upper limit above which the airway pressure will not exceed. The ventilator will terminate the inspiratory phase of the breathing cycle and begin an expiratory phase when the pressure transducer senses a pressure above the MWPL setting. The MWPL is settable over a range from 10 to 60 cmH₂O. When the airway pressure reaches the set limit, the 2-digit MWPL display blinks and a short tone is heard. If the excessive pressure is not immediately relieved, cycling is paused, and the alarm sounds continuously. Note that the **INSP**iratory **HOLD** feature is designed to not function when the MWPL setting is exceeded. Therefore, a holding inspiration will be released when the MWPL setting is exceeded.

Low Breathing System Pressure Alarm (LO BSP): The LO BSP alarm is activated at the end of inspiration if the differential pressure transducer is not sensing a raise of pressure of at least 2cmH₂O. This alarm is sometimes commonly referred to as a "disconnect" alarm; however, it should be understood that a patient disconnect is not always nor the only cause of low breathing system pressure. During the alarm condition a RED LED light is illuminated on the front panel and the sound of a raspy siren is heard. The alarm is automatically resets at the end of the next inspiratory phase if minimum pressure condition has changed.

Low 50 PSI Supply Gas Alarm (LOW GAS ALARM): The Low Supply Gas alarm is activated when the supply gas pressure drops below 35 psi (2.4 bar). The sensor for this alarm is located downstream of the internal 40-micron filter and may also indicate a clogged filter condition. During an alarm condition, a RED LED light on the front panel is illuminated and a steady, continuous tone is heard. This alarm automatically resets when the pressure increases above 40 psi (2.7 bar).

Working Pressure Switch Alarm (WPS): This switch is located inside the ventilator and senses the pressure that is related to the driving gas. If that is greater than 80cmH₂O the inspiratory phase terminates, two RED LEDs are illuminated, the 2-digit MWPL display is blinking, and a continuous tone alarm is heard. This alarm resets automatically when the switch senses a pressure less than 80 cmH₂O. This feature protects the user in the case the pressure built inside the clear housing breaks the tabs and the housing detach abruptly from the bellows base assembly.







VERIFICATION OF PROPER FUNCTION

A Note on Test Lungs

The most readily available test lung will probably be the breathing bag you removed to connect the ventilator. A breathing bag is a very poor model of a lung. It can be used if one understands how poor a model of the lung it is and how to avoid using it in such a way that it creates problems that will not occur with a real patient.

A far better test lung is a ridged walled container such as a gas can, water fountain bottle, or beer keg. The compliance of these containers is equal to their volume in liters and will be linear as is that of a real lung over normal operating ranges. Most importantly they will maintain a functional residual capacity (FRC) that is hard to maintain in a breathing bag.

The breathing bag has an unpredictable FRC from breath to breath if bumped or squeezed beyond the point of relaxation, more gas than would normally be popped off at the end of exhalation escapes from the breathing system. The bellows then abnormally fails to remain at the top of the bellows housing at the end of exhalation. To use the bag successfully, connect it to the patient wye, hang it vertically, and do not disturb it.

Verification of proper ventilator operation requires that you first complete the system setup, as described on pages 8-10, and connect a test lung to the patient wye piece. During verification, you will be observing the operation of the entire system configuration, checking for leaks, and monitoring the ventilator for consistent cycling.

- Install appropriate bellows assembly. <u>Note</u>: For tidal volume requirements below 300 ml use the 0-300 ml bellows, bellows adapter, and bellows housing.
- Connect a test lung to the patient wye and close the pop-off of the anesthesia machine.
- Fill the breathing system with the O₂ flush until the bellows reaches the top of the bellows housing.
- Turn the VOLUME controls fully clockwise to the minimum setting.
- Set the STBY/VENTILATE toggle switch UP in STBY position.
- Turn ON Power by pressing PWR push button. Observe all LEDs and displays. They will be flashing during the initialization and alarm will sound. If any alarm LEDs and sound will persist after initialization done, the troubleshooting should be made to solve the issue.
- Set up the RATE and MWPL as desired.
- To start ventilation put the STBY/VENTILATE switch DOWN in VENTILATE position. The LOW BREATH ALARM LED will be flashing and alarm sounds.
- Increase the VOLUME controls by turning it counterclockwise until the bellows begin mowing and alarm sound stops.

VERIFICATION OF PROPER FUNCTION (Continued)

- Depress the INSP HOLD button. Yellow LED above will be on. Bellows stops moving. Hold it long enough, but no longer than 60 sec to verify that the breathing system is not leaking. The pressure should remain constant.
- Release the INSP HOLD button. Observe that the ventilator is continuing to cycle, and that over time, ~ten cycles, and the bellows is not falling significantly.
- Turn the VOLUME controls fully clockwise to the minimum setting, switch back to STANDBY and turn the ventilator off.

STOP HERE.

IF THE VENTILATOR IS NOT PERFORMING IN ACCORDANCE WITH THESE EXPECTED OBSERVATIONS, DO NOT USE THE VENTILATOR. REFER TO THE "TROUBLESHOOTING" SECTION.

<u>Note</u>: In the above procedure no fresh gas flow was used. During actual operation of the system, the anesthesia machine will be set to deliver enough fresh gas to compensate for minor leaks in the entire breathing system and variations in patient uptake. This fresh gas will keep bellows full between each Inspiratory cycle.

<u>A TYPICAL USAGE SCENARIO:</u>

The **Model 2024**^{PRO}/**2024IE**^{PRO} is a time cycled volume ventilator with an adjustable breathing pressure limit. The more you understand of the ventilator, how it works, and what it does in response to your settings, the more comfortable you will be with it. It will feel "right" to change a setting and get what you want from the ventilator.

Making the initial settings:

What are you going to do first? If this is your first ventilator, you have probably spent many an hour bagging patient that required IPPV. You are, by now, comfortable doing that. Let us setup the ventilator to "bag" a patient as you would bag one yourself. If you are convinced the ventilator is bagging the patient, as you would be, you can feel comfortable with what the machine is doing.

When you bag a patient, you are careful not to over inflate the lungs. You have a feeling as to how hard to squeeze the bag. Your feelings have grown out of experience: checking the chest wall excursion and correlating that with a reading from the airway pressure manometer on the anesthesia machine. In general, for a healthy patient, the peek inspiratory pressure (PIP) should be kept in the range of 15-20 cm H_2O . Patients with more compliant lungs may even require less pressure for adequate ventilation and vice versa.

After induction and intubations, when it is time to start IPPV, power ON ventilator, put it in STANDBY mode, set the VOLUME control fully clockwise to the minimum setting. This control is a needle multiturn valve regulating inspiratory flow, with no or very little flow you will deliver no or a very small tidal volume (TV). Set the maximum working pressure limit (MWPL) control to about 20 cm H_2O . The airway pressure will not exceed this setting regardless of what you do with the other controls. Connect the ventilator to the breathing system (BS) as discussed in the Set-up Procedure, fill the bellows by turning up the fresh gas flow until the bellows reaches the top of the bellows housing. Set the RATE control to an appropriate rate for the patient. Switch to VENTILATE mode.

There will be a pause before the first inspiration. Watch the chest wall excursion and the airway manometer as you would when you bag. Since we have started with the inspiratory flow very low, the first TV delivered will be too small to generate sufficient airway pressure. Consequently, the Low Breathing System Pressure Alarm ((LO BSP) will sound, and LED will be flashing -- don't be alarmed. Now, increase the VOLUME controls breath by breath, a little at a time, until the chest wall excursions and PIP reach levels that you would seek to achieve while bagging. At this point you can be comfortable that the ventilator "is squeezing the bag" as you would be.

Trimming the settings as the case proceeds:

At this point the ventilator is delivering an inspiratory flow, determined by your setting of the VOLUME controls, for a time as calculated from your setting of the RATE control. This flow for a time results in a volume delivered to the bellows assembly that "squeezes the bag", in this case bellows, displacing the mixed gas within to the patient.

This delivery to the patient, these TVs at the set rate, results in the overall minute ventilation (MV). It is the proper MV that must be delivered to the patient in order to maintain proper blood gas and pH levels.

This MV can be delivered in many ways from a few large TVs to a lot of small TVs. The most optimum combination is up to you to determine just as you would while bagging.

Our ventilator, for those of you familiar with the term, is considered a MV divider. For those unfamiliar with the term, the ventilator delivers a consistent MV to the patient and that MV is divided into different size TVs by the RATE control. You can change the RATE control all you want without changing the total ventilation delivered to the patient. Let us repeat that. You can change the RATE control all you want, and it will not affect the total ventilation delivered to the patient. **

In order to change the MV delivered you must change the VOLUME controls. This point will be quite important when you go to wean the patient from the ventilator.

Remember, when you change the VOLUME controls it is the inspiratory flow that you are changing directly. The rate and, therefore, the time that flow is delivered has not changed, thus the delivered TV will be either larger or smaller than before. Stop and think about it, you are now delivering a different volume of gas to the same compliance of the patient; it follows that the PIP will be different. This different PIP may be fine, or it may be unnecessarily high or low. In the high extreme the MWPL alarm will sound, a short steady tone, and the PIP will be limited to the set value or in the low extreme, the LO BSP alarm will sound, a warbling tone.

Back to the change being implemented, you have changed the MV as desired now, if needed, trim the delivered TV size with the RATE control to obtain a new TV that results in a more appropriate PIP, and no alarms.

Now do it and get comfortable with it. Do not just put this document away - setup the ventilator and a test lung. Read this again trying what is discussed as you read.

Note: that no discussion has been made of I-time and E-time and the need to keep them in a proper relation to each other. This relation is automatically held constant by the ventilator. The I:E ratio is a consistent 1:2, no need to think about it - there will be enough time for exhalation. For those of you that want to think about it, we offer the model 2024IE PRO with an adjustable ratio from 1:1, 1:1.5, 1:2, 1:3, and 1:4. Even when the I:E ratio is adjustable that ratio is still held constant over the full range of rate settings.

**This statement is somewhat of a simplification as you deviate greatly from the current RATE setting. There is a difference in MV delivered by the ventilator and the alveolar ventilation received by the patient. This difference is related to the dead space and BS compliance. With each TV delivered, a portion ventilates the dead space and BS, the more TVs per minute the greater the portion of the delivered MV that is not seen by the alveoli and, thus, is of no use to the patient. The significance of this difference is small unless the BS being used is severely mismatched with the patient or the deviation from the current setting is great. Similarly, the amount of variation is minimal with the small changes needed to trim the TV after adjusting the MV.

OPERATING INSTRUCTIONS

Output of the **Model 2024^{PRO} /2024IE^{PRO}** is adjusted by only two controls: a linearly calibrated RATE control (breaths per minute), and a metering VOLUME control.

Follow the setup and verification procedures and be certain the pop-off valve on the anesthesia machine is completely closed.

DETAILED OPERATING INSTRUCTIONS:

- 1. When the patient is ready, reconnect the ventilator to breathing system.
- 2. ALWAYS set the VOLUME controls to its minimum setting before turning on the ventilator. The VOLUME controls must be **fully clockwise** to be set to the minimum setting.
- 3. Turn ON the ventilator.
- 4. Put ventilator in STANDBY mode.
- 5. Set the RATE to the desired breaths per minute.
- 6. Set the maximum working pressure limit (MWPL).
- 7. Start ventilation by switching it to VENTILATE mode.

NOTE: As you proceed, continually observe the anesthesia system's breathing system pressure (*BSP*) gauge to ensure that excessive pressures are not being attained.

- 8. The volume controls, as noted above, are initially set after the appropriate RATE has been selected. Turn the VOLUME controls counterclockwise to increase the tidal volume delivered, or clockwise, to decrease the tidal volume delivered. Read the approximate tidal volume by noting the displacement of the bellows in ml as indicated on the bellows housing scale. At a given RATE setting, the tidal volume can be increased or decreased in this manner.
- 9. Slight changes in the RATE and VOLUME controls can be made as the procedure continues but never make any gross adjustments to these controls with the patient connected.

Warning:

Under no circumstances should the flush button on the anesthesia machine be used during the Inspiratory phase of the breathing cycle. There is the extreme danger of rupturing a lung. The flush button introduces 50 - 100 lpm, perhaps more, of oxygen flow into the breathing system. During inspiration the discharge valve in the control unit is closed so that flush flow is added to the inspiratory flow generated by the ventilator and has nowhere else to go except to the patient's lungs. It is recommended that the flush feature on the anesthesia machine NEVER be used with patient connected. The oxygen flow valve can be opened further than normal providing a more controllable high flow of oxygen.

CLEANING & STERILIZATION

A majority of the **Model 2024**^{PRO}/**2024IE**^{PRO} components do not come in contact with the breathing gas; consequently, they require cleaning with only a damp cloth. This includes the entire control unit as well as certain bellows assembly components. Only the bellows base interior and the inside of the bellows come in contact with the breathing system gases.

CAUTION:

NEVER use an abrasive cleaner to clean any part of the ventilator. Abrasives will scratch the transparent acrylic bellow housing and other surfaces of the ventilator. Also, DO NOT allow water from an overly-damp cloth to collect on or penetrate into the ventilator.

Cleaning the Ventilator Surfaces: The outer surface of the ventilator may be cleaned simply by using a clean, soft, slightly damp cloth. A mild detergent solution may be used to remove persistent surface dirt or grime. Be sure to use only a mild detergent, if necessary, and use care to ensure that the cloth is only slightly damp.

WARNING:

Clean bellows and bellows housing only with water and a mild detergent. Use a soft cloth. Avoid abrasives and aromatic spirits. (USE NO ALCOHOL.)

Cleaning the Bellows Housing: Remove the bellows housing for cleaning and for access to the bellows and pop-off valve. Twist the housing counterclockwise until the tabs at the base of the housing clear the bayonet locks. (This may require some degree of force because of a tight O-ring fit.) Tilt the top of the bellows housing toward you and lift it off. DO NOT attempt to steam-sterilize the bellows housing. Since it does not come in contact with the breathing gas, it needs only occasional cleaning with a clean, soft slightly damp cloth, or by immersion in a mild detergent bath, followed by rinsing. Moreover, steam sterilization may warp or deform the housing rendering it useless. USE NO ALCOHOL.

Cleaning the pop-off valve: With the bellows housing removed, it is necessary to also remove the bellows to gain access to the pop-off valve. This is easily accomplished by gently pulling the bellows to the side until it detaches from the base.

Removing the bellows exposes the pop-off valve and the three small red thumbscrews which attach it to bellows base. Loosen the three screws and remove the valve. The black, ULTEM® pop-off valve seat will now be exposed. This valve seat has a precision machined and lapped surface, which is relatively delicate: USE CONSIDERABLE CARE while cleaning the seat with a clean, soft, damp-cloth. Clean P.O.V. disk with cotton swab and alcohol.

CAUTION:

NEVER use an abrasive cleaner or hard object to clean the valve seat. Abrasives or hard objects will scratch or damage the seat, causing the pop-off valve to leak, which will result in a serious malfunction of the ventilator.

<u>NOTE</u>: EVEN A PIECE OF LINT ON THE SEAT COULD CAUSE A LEAK.

CLEANING & STERILIZATION (Continued)

After cleaning the pop-off valve seat, replace the valve taking care to ensure that the small orange O-ring (PN 180A1429) under the pop-off valve is securely in place. If this orange O-ring is dislodged or missing, the ventilator will not be able to function properly.

Sterilizing the bellows base from the controller and bellows interior surface: The bellows and its interior surface do come in contact with the breathing gas and require periodic sterilization. Sterilization is accomplished with the bellows housing and bellows removed, as described above. The pop-off valve, and the 300-ml bellows adapter, if used may remain on the base during sterilization.

To remove the bellows base from the controller for sterilization, disconnect the hoses from the base and loosen the four black thumbscrews, located at the corners. First, clean the base using a clean, soft, slightly dampened cloth. Then wrap the whole base and steam sterilize it using the same standard hospital techniques as used for any surgical apparatus.

Finally, clean and sterilize the bellows using an appropriate hospital technique for delicate latex supplies. DO NOT steam sterilize the bellows.

After completing the above sterilization procedures, complete the reassembly of the unit by first reattaching the bellows base to the ventilator control unit, reconnect the hoses, and slip the first convolution of the bellow over the bellows mounting ring. Then and finally, reattach the bellows housing to the base. This completes the cleaning and sterilization procedures.

TROUBLESHOOTING

Leaks in the circle (breathing) system are very common. Particularly, the reuse of "single use" circle systems frequently results in leaks. This reuse practice is not recommended. Circle system leaks are not as apparent when bagging a patient or when using an older style ventilator with a falling-during-exhalation bellows system. The **Model 2024**^{PRO}/2024IE^{PRO} Ventilator with its state-of-the-art standing (ascending)-during-exhalation bellows system will, more readily reveal system leaks.

The determination as to whether a leak is in the circle system and/or anesthesia machine or in the ventilator is easily accomplished. The following procedure should be conducted:

- 1. Close the anesthesia machine's pop-off valve.
- 2. Turn off the flow of fresh gas.
- 3. Disconnect the 22-mm tube from the bellows base assemblies' BREATHING SYSTEM port and connect it to the patient wye piece to produce a closed loop.
- 4. While observing the breathing system pressure, slowly increase the fresh gas flow to the system until the pressure builds to about 50 cm H_2O .
- 5. Turn the flow off.
- 6. The pressure should hold steady without falling appreciably.

If the system passes this test, refer to the following table to locate the problem with the ventilator.

Symptom	Potential Causes	Possible Remedies
Ventilator sounds as though it is cycling. I can hear the valves clicking but nothing happens.	 No supply gas pressure. VOLUME control is set at it's minimum. 	 Unkink the supply gas hose. Replace empty tank. Increase the VOLUME setting.
Ventilator hums with each inspiration.	 Supply gas pressure at the ventilator inlet is dropping to around 25 - 30 psi with O₂ flow. Pipeline or tank pressure is low. 	 Unkink supply gas hose. Anesthesia machine power outlet is incapable of supplying the required flow. Bypass it. Switch to new supply gas source.

Nothing happens when the	No electrical power.Ventilator is set at STANDBY	Plug ventilator into the properSet the ventilator to VENTILATE
ventilator is turned on. No valves are clicking, green LED not lit.	Mode.	power source.Check voltage setting.Check the outlet.Check the fuse
Pop-off valve in the Bellows Base chatters and the bellows shakes after it reaches the top during exhalation.	Excessive fresh gas flow from the anesthesia machine.	• Reduce the fresh gas flow.

Inspiratory flow chugs intermittently.	 Pressure within the bellows housing is exceeding 70 cm H₂O. Working pressure limit is shutting off the switch Inspiratory flow. 	 Inflate collapsed bellows. Unkink the drive gas tube. Unkink breathing system hose.
The ventilator operation sounds normal but the TV delivered is incorrect and or inconsistent.	Missing or damaged pop-off valve O-ring.	Replace O-ring
Irregular cycling when using cautery or another electro-surgical device. Bellows dislodges from mounting ring.	 Excessive generation of EMI and/or RFI. Partially detached or improperly 	 Locate and repair source of disturbance. Reattach or replace the bellows.
	 mounted bellows. Either pressure or vacuum is occurring at the Bellows Base EXHAUST port. 	Repair defective or poorly regulated scavenger system.
Bellows is bulging.	 P.O.V. is stuck closed. (To determine if this is the problem, temporarily disconnect scavenger to isolate problem.) 	Clean P.O.V. and seat. *
Everything seems normal, but the bellows progressively becomes less full.	 Breathing system gas is leaking from the system. (SEE THE FIRST PARAGRAPH OF THIS SECTION) Inadequate fresh gas supply from anesthesia machine. Missing or damaged pop-off valve O-ring Hole in Bellows Partially detached or improperly installed bellows. Damaged pop-off valve or valve seat. Anesthesia machines pop-off valve is not completely closed. 	 Remove obstruction. Increase flow. Replace O-ring Replace Bellows Reattach Bellows to the mounting ring. Replace damaged part. Check all tubes and tubing connections for leaks. Clean P.O.V. and seat. * Close, repair or replace valve.

*See "Cleaning the P.O.V." page 19.

RETURNING FOR SERVICE – RETURN AUTHORIZATION POLICY

NO HALLOWELL EMC PRODUCTS OR ACCESSORIES CAN BE ACCEPTED FOR REPAIR OR RETURN WITHOUT A RETURN AUTHORIZATION FROM HALLOWELL.

To obtain a Return Authorization number call 413-445-4263, fax to 413-496-9254, or email your request to info@hallowell.com. Please have the following information ready and available:

- 1. The serial number of the item to be returned, if applicable.
- 2. The nature of the problem, reason for return and action requested.
- 3. The name, phone number and extension of the party to contact should we have future questions.
- 4. The billing name, address, phone number and PO number of the responsible party.
- 5. If the item is to be returned, such as with a repair, the name of the party to whom we should ship the item, the shipping address and receiver's PO number if needed for acceptance.
- 6. AND a fax number or email address to which we can send a "Return Goods Instructions Sheet." This sheet will have the RA # at the top. Clearly mark the RA # on the outside of the box that you will be returning to Hallowell EMC.

Please follow the procedures faxed to you carefully. It is based on our experience of how best to get your items back to us without damage and delay.

Deliveries will not be accepted for packages that are not expected, i.e., that do not have a valid (on file) authorization number clearly marked on them along with a complete return address.

We thank you for your understanding and cooperation.

Model 2024^{PRO} /2024IE^{PRO} by HALLOWELL EMC SPECIFICATIONS

OPERATIONAL CHARACTERISTICS

	1
Rate2-80, (6-40 and 0.5-60 by request) bpm	
Tidal Volume	
I:E Ratio 1:2 (preset), 1:1 to 1:4 (IE version)	
Maximum Working Pressure Limit 10 - 60 cm H ₂ O	
Gas Supply Air	
Flow & Pressure 100 lpm @ 35-65 psi (3 cfm @ 2.4 - 4.4 bar)	
Power Supply12V1.5A Medical Wall Plug-In (80 ~264VAC)	

Controls

Standby/Ventilate Switch Rate Volume Inspiratory Hold I:E Ratio MWP.	Linear potentiometer
	Linear potentiometer, Rear panel, port (by request)
	Real paller, port (by request)

Indicators

PWR	Green LED
STNDBY	
RATE	2-digit LED display
MWPL	. 2-digit LED display
Alarms and Audio:	
Low Gas Alarm	Red LED & continuous tone sound
Low Breathing Alarm	. Red LED & 2-tone sound
MWPL Alarm	MWPL display is flashing & short beep
WPLS Alarm	WPLS display & 2 Red LED are flashing,
	and continuous tone sound

PHYSICAL

Unit Weight		Approximately 13 lb. [5.9 kg]
Dimensions:	ootorint	
Controller 1 C		[228 W x 254 D mm]
Configuration	n Overall Height:	
PN 000A	- 300 ml	
	1600 ml	
PN 000A	3000 ml	