Harvard Inspira

Advanced Safety Ventilator

User's Manual

Inspira Advanced Safety Ventilator, Volume Controlled	MA1 55-7058
Inspira Advanced Safety Ventilator, Pressure Controlled	MA1 55-7059





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WEEE/RoHS Compliance Statement

EU Directives WEEE and RoHS

To Our Valued Customers:

We are committed to being a good corporate citizen. As part of that commitment, we strive to maintain an environmentally conscious manufacturing operation. The European Union (EU) has enacted two Directives, the first on product recycling (Waste Electrical and Electronic Equipment, WEEE) and the second limiting the use of certain substances (Restriction on the use of Hazardous Substances, RoHS). Over time, these Directives will be implemented in the national laws of each EU Member State.

Once the final national regulations have been put into place, recycling will be offered for our products which are within the scope of the WEEE Directive. Products falling under the scope of the WEEE Directive available for sale after August 13, 2005 will be identified with a "wheelie bin" symbol.

Two Categories of products covered by the WEEE Directive are currently exempt from the RoHS Directive - Category 8, medical devices (with the exception of implanted or infected products) and Category 9, monitoring and control instruments. Most of our products fall into either Category 8 or 9 and are currently exempt from the RoHS Directive. We will continue to monitor the application of the RoHS Directive to its products and will comply with any changes as they apply.



- Do Not Dispose Product with Municipal Waste
 - Special Collection/Disposal Required

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Serial Numbers

All inquires concerning our product should refer to the serial number of the unit. Serial numbers are located on the rear of the chassis.

Calibrations

All ventilators are calibrated at rated voltage and frequency.

Warranty

Harvard Apparatus warranties this instrument for a period of two years from date of purchase. At its option, Harvard Apparatus will repair or replace the unit if it is found to be defective as to workmanship or materials. This warranty does not extend to damage resulting from misuse, neglect or abuse, normal wear and tear, or accident. This warranty extends only to the original customer purchaser.

IN NO EVENT SHALL HARVARD APPARATUS BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES. Some states do not allow exclusion or limitation of incidental or consequential damages so the above limitation or exclusion may not apply to you. THERE ARE NO IMPLIED WARRANTIES OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE, OR OF ANY OTHER NATURE. Some states do not allow this limitation on an implied warranty, so the above limitation may not apply to you.

If a defect arises within the two-year warranty period, promptly contact *Harvard Apparatus, Inc. 84 October Hill Road, Building 7, Holliston, Massachusetts 01746-1388* using our toll free number 1-800-272-2775. Goods will not be accepted for return unless an RMA (returned materials authorization) number has been issued by our customer service department. The customer is responsible for shipping charges. Please allow a reasonable period of time for completion of repairs, replacement and return. If the unit is replaced, the replacement unit is covered only for the remainder of the original warranty period dating from the purchase of the original device.

This warranty gives you specific rights, and you may also have other rights which vary from state to state.

Repair Facilities and Parts

Harvard Apparatus stocks replacement and repair parts. When ordering, please describe parts as completely as possible, preferably using our part numbers. If practical, enclose a sample or drawing. We offer a complete reconditioning service.

CAUTION

This apparatus is not registered with the FDA and is not for clinical use on human patients.

CAUTION: Not for clinical use on human patients.

Please read the following safety precautions to ensure proper use of your Inspira ventilator. To avoid potential hazards and product damage, use this product only as instructed in this manual.

TO PREVENT HAZARD OR INJURY:

Use Proper Line Cord

Use only the specified line cord for this product and make sure line cord is certified for country of use.

Ground the Product

This product is grounded through the grounding conductor of the power cord. To avoid electric shock, the grounding conductor must be connected to earth ground. Before making any connections to the input or output terminals of the product, ensure that the product is properly grounded.

Make Proper Connections

Make sure all connections are made properly and securely. Any signal wire connections to the Inspira unit must be no longer than 3 meters.

Observe all Terminal Ratings

Review the operating manual to learn the ratings on all Inspira connections.

Do Not Operate Without Cover

Make sure that the top cover is securely in place before connecting to power source to avoid injury to body and damage to the product.

Use Proper Fuse

Use only specified fuses with product.

Avoid Exposed Circuitry

Do not touch any electronic circuitry inside of the product.

Do Not Operate with Suspected Failures

If damage is suspected on or to the product do not operate the product. Contact qualified service personnel to perform inspection.

Place Product in Proper Environment

Review the operating manual for guidelines for proper operating environments.

Observe all Warning Labels on Product

Read all labels on product to ensure proper usage.





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Figure 1. Front view of Inspira Advanced Safety Ventilator



Figure 2. Rear view of Inspira Advanced Safety Ventilator

Theory of Operation

The Inspira is Harvard's first ventilator that can ventilate animals from mice to cats using the same machine. Its versatility and ease of use allow safer and superior ventilation. The Inspira Ventilator uses an advanced piston/cylinder assembly and a microprocessor controlled actuation mechanism to precisely control respiration profiles. Two interchangeable piston/cylinder assemblies are available to provide a wide range of tidal volumes. The ventilator auto-detects which cylinder, or if no cylinder, is installed. Variable flow valves control the gas flow for inhalation and exhalation.

The Inspira ASV Volume Controlled Ventilator delivers the desired tidal volume to the animal by precisely controlling the stroke of the piston. Since actual stroke length (and therefore tidal volume) may be modified for a given stroke, sigh breaths are supported. Since stroke speed is precisely controllable during inspiration and expiration, variable inspiration-to-expiration ratios are also supported. A pressure sensor continuously monitors the airway pressure to prevent over-pressure conditions. Most volume-controlled ventilators presently available do not support sigh breaths and do not provide any pressure monitoring as a safety feature.

The Inspira ASVp pressure-controlled ventilator adds pressure control capability to the ASVv volume-controlled platform. Inspiration pressure is limited to the userentered pressure setting. Flow rates are automatically adjusted by the microcontroller by changing the tidal volume while keeping the inspiration time constant. The flow rate is adjusted so that the inspiration pressure limit is reached near the end of the piston stroke, ensuring that animals with a higher airway resistance receive the majority of the expected tidal volume and that the ventilator does not prematurely terminate the piston stroke. No manual adjustment of inspiratory flow rates is required.

The ASVp also adds PEEP capability for both the volume- and pressure-control modes. The machine allows a PEEP setting up to $10 \text{cmH}_2\text{O}$.

Features

Volume Control Mode

The ventilator delivers a known volume of gas to the patient on each inspiration stroke. Respiration frequency and I:E Ratio determine amount of time for inspiration and expiration phases.

Pressure Control Mode (Inspira ASVp Only)

The ventilator delivers gas to the patient until the user-selected pressure limit is reached. Flow rate is automatically adjusted by the machine so that the pressure limit is reached near the end of the inspiration time. Respiration frequency and I:E Ratio determine the amount of time for inspiration and expiration phases.

Adjustable I:E Ratio

This option allows the user to select the ratio of inhalation to exhalation times when advanced respiratory control is needed. This feature is intended to allow greater respiratory control for research. The default I:E Ratio is 50%.

Flow-Rate Monitoring (Future Feature)

Flow-rate monitoring will allow continuous monitoring of the rate at which the gas is being delivered to the animal. This feature will also aid respiratory research.

Programmable Sigh Breath

Continuous, long-term ventilation combined with the force of gravity will cause the animal's lungs to begin to collapse. Introducing a larger than normal tidal volume over-inflates the animal's lungs, replicating a natural sigh. It allows the lungs to expand and opens the collapsed alveoli. Sigh breaths are supported in both modes. In the volume-controlled mode, a sigh tidal volume is used. In the pressure-controlled mode, a sigh pressure limit is used. The frequency and volume of the sigh breath are user selectable in volume-controlled mode. In the pressure-controlled mode, the frequency and pressure of the sigh breaths are selectable.

Respiratory Assist

The Inspira ventilator supports Respiratory Assist in both volume-and pressure-controlled modes. This feature is used to wean an animal off the ventilator. When the animal attempts to initiate a breath on its own, a pressure sensor detects the drop in airway pressure. This drop initiates a ventilation cycle. The sensitivity of the Assist Mode is adjustable from -1 to -10 cmH₂O. The ventilator lets the animal initiate breaths independently as long as its breathing rate is greater than the respiration rate set by the user or calculated by the microprocessor. If the animal does not try to initiate a breath, Inspira warns the user.

Airway Pressure Monitoring

The ventilator monitors the pressure of gas delivered to the animal being ventilated. This safety feature prevents the operator from over or under pressurizing the lungs of the animal. When Inspira detects an over-pressurization condition it sounds an alarm, stops the inspiration stroke, and then cycles to expiration. Inspira continues to ventilate but does not deliver enough gas to over-pressurize the lungs. Overpressure conditions may result from occluded or restricted airways. When Inspira detects an under-pressurization condition it sounds an alarm. This condition could result from an airway disconnect or large leaks. Once again, Inspira continues to ventilate while requesting user intervention. These features ensure that the animal is kept safe from improper ventilator setup.

PEEP (Inspira ASVp Only)

Positive end-expiratory pressure (PEEP) is settable in the Inspira ASVp in both volume -and pressure-controlled modes. The PEEP is adjustable from 0 to 10 cm H_2O .

Initial Setup

- 1. Remove unit from box.
- 2. Remove foam-packing inserts from both ends of the ventilator.
- Locate and carefully remove air cylinders and power cord from shipping material.
- 4. Visually inspect both the ventilator and the air cylinders for any damage that might have occurred in the shipping process. The unit is shipped without the air cylinder installed. Please refer to "Air Cylinder Installation" to properly install the cylinder, see pages 11 to 12.
- 5. The Inspira is shipped from the factory with a North American line cord with a U.S. three wire molded power plug on one end and an IEC320/C13 connector on the other. Use only an approved AC line cord with a molded IEC320/C13 connector certified for country of use. Only connect to grounded power receptacles to help ensure proper grounding; do not use adapter plugs.
- 6. Read the manual to become familiar with all features and functions of the Inspira.

Location Requirements

- A sturdy, level, clean, nonflammable and dry surface
- Minimum of 1 inch (2.5 cm) clearance around the pump
- · Adequate power supply
- Room temperature 4° to 40°C (40° to 104°F)
- Relative humidity of 20 to 80%
- A well ventilated room



WARNING! Do not use in the presence of explosive gasses or in a 100% oxygen environment.

Typical Operation

The Inspira ventilator is designed to respirate small animals with a body mass ranging from 15 grams to 10 kilograms. It can operate at respiration rates of 5 to 200 breaths per minute (bpm) and can deliver tidal volumes of 0.1 to 100 cc. It is designed for use in a typical laboratory, operating room, or any other well-ventilated, nonexplosive environment. The Inspira can be used to deliver all types of nonexplosive gas mixtures including, but not limited to, anesthetic gases and 100% oxygen.

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VENTILATOR CONNECTIONS

The Inspira ASV comes with connection ports located on the front and rear panels of the ventilator. These connections are shown on the following pages.





Figure 3. Airway Tubing Connections

Airway Tubing Connections: Front Panel

The Inspira ASV provides four airway-tubing connections at the front of the machine. A fifth port (Side Stream) is provided to support advanced options. These ports are standard 1/8"-27 NPT threaded ports and may accept many types of fittings including barbed and luer-lock. This allows for a wide range of tubing sizes and for accommodating air filters, if needed. The functions of these connections are as follows:

To Animal

Flow of source gas from ventilator to animal.

From Animal

Flow of expired gas from animal to ventilator.

Exhaust

Flow of expired air from ventilator. This gas may be vented to room, recirculated for rebreathing, collected, and or filtered if chemicals are present in the expired air.



CAUTION: Do not vent anesthesia gases to room air.

Source

Flow of gas used by Inspira for inspiration. Connect to the source of inspiration gas or leave disconnected to use room air.

Side Stream

Not used in this model.

CAUTION: Do not connect Inspira to pressurized gas sources unless proper pressure regulation is provided to equalize the pressure with atmospheric pressure. Failure to do so could result in excessive and unknown tidal volumes delivered to the animal.

Installation



Figure 4. Front Panel

Electrical Connections: Front Panel

Inspira provides four BNC type connectors at the front of the machine. Their functions are as follows:

Sync Out

Produces a digital pulse at the start of the respiration cycle allowing synchronization of other electronic equipment with Inspira's respiration cycle.

Trigger In

For use with equipment which uses a digital signal to start and stop respiration. An example of this type of equipment would be a footswitch.

Analog Out 1

An analog signal representing the airway pressure within the ventilator. This signal may be monitored with an oscilloscope.

Analog Out 2

Not used in this model. Note: Electrical specifications for these signals are given in Appendix A.

Electrical Connections: Rear Panel

Inspira provides power entry, RS232 communications, and User I/O (Optional) connections at the rear of the machine. Their functions are as follows:

User I/O

Not used in this model.

RS232 In

For use with a host computer to establish a communication connection between the computer and the Inspira.

- 1. No connection
- 2. Transmit Data (TXD)
- 3. Receive Data (RXD)
- 4. Data Terminal Ready Input (DTR)¹
- 5. Signal Ground (GND)
- 6. No Connection
- 7. Request to Send Input $(RTS)^2$
- 8. No Connection
- 9. No Connection



Figure 5. Rear Panel



Figure 6. RS232 Connector

¹ Used for Vpp Enable in optional flasb programming configuration; disabled in bardware.
² Used as Serial Reset in optional flasb programming configuration; disabled in bardware.

RS232 Out

Used to establish a daisy chain serial connection with other devices. Future models will support a serial printer connection through this port.

- 1. No connection
- 2. Receive Data (RXD)
- 3. Transmit Data (TXD)
- 4. No Connection
- 5. Signal Ground (GND)
- 6. No Connection
- 7. No Connection
- 8. No Connection
- 9. No Connection

Power Connection

Power in.

Note: Electrical specifications for these signals are given in Appendix A.

Installation



Figure 7. Air Cylinder Installation

Air Cylinder Installation

Key Information

- 1. Use ONLY Harvard Apparatus approved air cylinders. Any other nonapproved cylinders may damage the Inspira unit.
- Do not oil or grease the air cylinders. Inspira's special air cylinders are selflubricating, requiring no additional lubrication. Applying oil or grease may damage the air cylinders.
- 3. When switching the air cylinders, the power must be SWITCHED OFF.
- 4. Tampering with any components besides the air cylinders inside of the Inspira will void the warranty.



CAUTION: Electrostatic discharge (ESD) can damage components on the circuit boards. Avoid contact with the circuit boards when changing cylinders.

Procedure

Before the Inspira can be used for the first time, one of the two provided air cylinders (10 cc and 100 cc) must be installed. Choose the proper cylinder depending on the size of the animal to be ventilated. Remove the top cover of the ventilator by removing the four phillips head screws which hold the top cover in place, one on either side of the unit and one in each of the top two black feet. Once the top cover is removed locate the mounting area for the air cylinders as seen in figure 7. Place the small provided O-ring in the mounting groove, which is found on the valve block as illustrated. Then move Inspira's white plunger back by turning the coupling connecting the black

lead screw to the motor shaft. Turn the lead screw until the flag pin on the rear of the plunger is vertically in-line with the rear switch as illustrated. (Note: When installing the air cylinder, do not change the bends of the cylinder detection switches or else the correct cylinder will not be detected.) Now insert the cylinder by placing the plunger portion of the air cylinder on the end of Inspira's white plunger. Carefully slide the air cylinder back on the white plunger compressing the air cylinder just enough to allow the front end of the cylinder to be lowered into place. Once the air cylinder is fit in place, screw the air cylinder's threaded nipple into the valve block and hand tighten



CAUTION: Do not overtighten the cylinder. Overtightening the cylinder can cause the glass cylinder to crack.

the cylinder in place.

Now that the air cylinder is in place, rotate the lead screw to position the flag pin in between both the front and rear switches. To complete the installation, replace the top cover of the Inspira unit. When Inspira is powered on it should display the correct cylinder size after initializing.

Fuse Replacement

Key Information

- 1. Make sure the power cord is disconnected from the main supply before servicing the fuse.
- 2. Use only Type 3AG, 1/4" x 11/4", 1 amp, 250 volt, Type T (time delay) fuses (Harvard Apparatus part number 5113-033 or equivalent).

Turn off power and remove power cord from power module. Use a straight blade screwdriver to pry open the access door. Remove the fuse holder and then remove the fuses from this holder as shown in figure 8 below. Replace fuses using only 1 amp, 250 volts, Type T fuses. Then replace the fuse holder.

Note: A fuse, which is not operator replaceable, is located on the power supply. This fuse is rated 5 amps, 250 volts.



Figure 8. Fuse Replacement

Operation: Getting Started





Figure 9. Main Operating Screen, Volume-Control Mode

Turning Ventilator On

Power must be properly supplied to the ventilator, according to the power specifications. Locate the power switch on the rear of the ventilator. Toggle the switch so that the "I" side of the switch is pressed down. The ventilator is now powered on.

Volume-Controlled Ventilation

With machine powered ON, press and release the SELECT MODE key until VOL mode is selected. Press SET and WEIGHT and enter the animal's weight in kg. Press and hold parameter keys in order to verify respiration parameters. If any parameters need to be changed, press the SET key and the appropriate parameter key and enter the value to set. Press and release the RUN/STOP key to start ventilation.

Pressure-Controlled Ventilation (Inspira ASV_p Only)

With machine powered ON, press and release the SELECT MODE key until PRES mode is selected. Press SET and WEIGHT and enter the animal's weight in kg. Press and hold parameter keys in order to verify respiration parameters. If any parameters need to be changed, press the SET key and the appropriate parameter key and enter the value to set. Press and release the RUN/STOP key to start ventilation.

Main Operating Screens

The main operating screen is the default display. This screen displays the operating mode, current operating variables, such as tidal volume and respiration rate, and the status of the ventilator (stopped or running).

Main Operating Screen - Pressure Control Mode

Paw	ΧХ	сm	H ₂ O	PR	ES
Rate	ХХ	Х	ΒΡΜ	R	>>>>

Main Operating Screen – Pressure Assist Control Mode

Paw	XX	cm	HzO	ΡR	SASST
Rate	XX	X	BPM	R	>>>>

Main Operating Screen - Volume Control Mode

٧t	ΧХ	Х.	ΧХ	сс	٧0	L
RAT	E	ΧХ	Х	BPM	R	>>>>

Main Operating Screen - Volume Assist Control Mode

٧t	XX	Χ.	ΧХ	сс	۷0	LASST
RAT	E	ΧХ	X	врм	R	>>>>

Paw	Average Peak Pressure in cmH ₂ O
Vt	Tidal Volume in cc
Rate	Respiration Rate in BPM
R	Remote Mode Indication

Operation: Getting Started



Figure 10. Front Panel

Set Keys

Set

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Allows modification of a data item. To modify a data item, press the relevant key after pressing the [Set] key. Also used to toggle different options when prompted.

Rate

Displays/Sets current respiration rate.

Volume

Displays/Sets current tidal volume in volume mode.

Weight

Displays/Sets current animal weight.

Sigh

Displays/Sets sigh parameters and manually triggers a sigh breath.

I:E Ratio

Displays/Sets the current inspiration to expiration (I:E) ratio.

Pressure

Displays/Sets pressure limits.

RS232

Displays/Sets current RS232 device(s) attached.

Toggle Keys

Pressing these keys toggle through the successive states of the key's function.

Run/Stop

Starts/Stops the ventilator. When stopping, the ventilator will finish its current stroke before ceasing ventilation.

Select Mode

Toggles through available run modes with each press of the key. It is also used to select entry choices in hardware setup.

Data Entry Keys

1, 2, 3, 4, 5, 6, 7, 8, 9, 0, •

Used to enter numeric data values or access special features.

С

Clear; clears numeric data values prior to entry.

Enter

Saves and stores displayed data value in memory when setting a data item.

Safe Range[™] Respiratory Profiles

Setting up the ASV ventilator is both easy and safe thanks to the Safe Range[™] software. Once the animal's body weight has been entered the software computes the median settings for tidal volume and respiratory rate. These same equations are used to calculate a Safe Range[™] around the median values. Inspira uses the entered weight to calculate the correct tidal volume and respiratory rate for the animal. The tidal volume (in liters) is determined by the equation $0.0062 \times M_b^{1.01}$ where M_b is the animal mass in kilograms.

The respiratory rate (in min¹) is determined by the equation 53.5 x $M_b^{-0.26}$. The Safe Range^w is established by computing a range of acceptable values, which are less than or equal to ±10% of the calculated tidal volume and respiratory rate. All the default parameter settings can be overridden. If you enter a setting outside of the Safe Range^w for the body mass of the animal to be ventilated you are warned that the value is outside the Safe RangeTM and asked to confirm the setting.

SAFE RANGE – Pressure-Control Mode

Inspiration Pressure Range

Safe Range: 15 to 25 cmH₂O Full Range: 5 to 50 cmH₂O

Sigh Pressure Range

Safe Range: Insp. Pressure to (Insp. Pressure + $10 \text{cmH}_2\text{O}$) or $35 \text{cmH}_2\text{O}$, whichever is less

Full Range: Insp. Pressure to 50cmH₂O

Ventilator Graph

The graph labeled as figure 11 below shows tidal volume vs. body mass and rate for laboratory mammals in a resting state. (Apparatus dead space must be added.)

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Figure 11. Ventilator Graph

Ventilation Parameters Mammals with < 70g Body Mass					
Body Mass (g)	Vt (ml)	Rate (BPM)			
15	0.1	159			
20	0.12	148			
30	0.18	133			
40	0.24	123			
50	0.30	117			
60	0.36	111			
70	0.42	107			

Entering Animal Weight

Key Information

- The Inspira can handle animal weights ranging from 0.015 to 10.00 kilograms.
- The large cylinder can handle masses between 0.160 and 10.00 kilograms and the small cylinder can handle masses between 0.015 and 0.59 kilograms.
- Entering an animal's weight will allow Inspira to automatically choose a Safe Range[™] tidal volume and respiration rate. No extra setup is required.

To enter the animal's weight, press the [Set] key. The display should now read "Press parameter key". Press the [Weight] key. The display will now read "Enter Weight (Kg)". Simply use the numeric keypad and decimal point key to enter the proper weight (between 15 g and 10 kg). The weight must be entered in kilograms. Inspira will allow for the entry of up to three decimal places. After entering the weight press the [Enter] key. The display should read "Change SV and BPM" (stroke volume and breaths per minute). Use the [Set] key to move the bar cursor to select either "yes" or "no". Press [Enter] to select your choice. Selecting yes will change the SV and BPM to the automatically calculated Safe Range" ventilation settings. Selecting no will leave the previously used SV and BPM settings, which may not be safe for the animal.



Starts and stops ventilation

Starting and Stopping Ventilation

To start and stop ventilation simply press the [Run/Stop] key. When stopping, Inspira will finish its current stroke before stopping completely. The valve will always be in the expiration position when a STOP has been commanded.

Displaying Ventilator Parameters

Inspira allows you to easily check the current ventilation parameters by using one key commands. To display a specific parameter, simply press and hold the appropriate key.

Key	Display
Rate	Resp Rate xxxBPM
Displays current respiration rate	
Volume	Tidal Vol xxx.xxcc Sigh Vol xxx.xxcc
Displays current tidal volume and sigh volume (volume-c	control mode)
Volume	Tidal Vol xxx.xx cc
Displays current tidal volume (pressure control mode)	
Weight	Weight xx.xxxkg
Displays current weight setting	
Sigh	Sigh Vol xxx.xxcc Sigh Freq 1/xxx
Displays sigh breath settings	
Sigh	Sigh Pres xx cmH2O Sigh Freq 1/xxx
Displays sigh breath settings (pressure control mode)	
I:E Ratio	%Inspiration xx%
Displays I:E ratio settings	
Pressure	Insp P Limit xxcmH20 Assist P -xxcmH20
Displays current pressure settings	
Pressure	Paw xx EEP xx Asst-x Plim xx PEEP xx cmH2O
Displays current pressure settings (ASVp)	
RS232	Baud = xxxx Bits = 1,8,x,x
Displays current RS232 setting	

Warnings and Faults

Pump Stall



This fault indicates that the expected motion of the piston axis does not match the actual motion. This is a critical fault and requires operator intervention. The valve is set to the expiration position and the machine is commanded to STOP. The user is always notified via a visual alarm and also by an audible alarm (if enabled).

Valve Stall



This fault indicates that the expected motion of the valve axis does not match the actual motion. This is a critical fault and requires operator intervention. The machine is commanded to STOP. The user is notified via a visual alarm and audible alarm (if enabled).

Motor Drive Fault



This fault indicates a problem with the step motor drive. This is a critical fault and requires operator intervention. The machine is commanded to a STOP state.

Airway Over-Pressure



This fault indicates that an overpressure condition has been detected in the airway. The user is always notified via a visual alarm and also by an audible alarm (if enabled). An overpressure in Volume Control mode is defined as a pressure greater than the average measured peak pressure (averaged over 10 samples, not counting sigh breaths) plus 10 cmH₂O, or 67cmH₂O, whichever is smaller. This limit is adjusted during sigh breaths to 150% of the average value or 67 cmH₂O, whichever is smaller. The optional user-entered inspiration pressure limit is used as a secondary pressure check. The default limit is 35 cmH₂O. If the average pressure should rise up and exceed this value, the user is notified via a visual alarm and also by an audible alarm (if enabled).

Airway overpressure conditions cause the inspiration stroke to stop; the machine immediately cycles to expiration. After completing expiration, the machine will continue to run the current respiration profile, repeating the above steps if the overpressure condition continues. If the fault is cleared, the alarms (visual and audible) will self-clear. Otherwise, the alarms will continue, requesting operator intervention.

Occlusion Alarm

If the peak pressure limit is reached within the first 40% of the inspiration stroke, an occlusion alarm is reported. This indicates that a restriction may be present in the airway or that the airway resistance may be too high for the flow rate. Occlusions, system restrictions due small tubing and/or port diameters, or incorrect respiratory parameters could be the cause. This alarm is self-clearing on removal of the fault condition.

Assist Alarm

Assist Alarm

This fault indicates that a vacuum trigger, which is generated by an inhalation effort by the patient, has not been detected on 5 consecutive cycles. This would be a result of the patient failing to initiate breaths on its own or of improper respiration parameter settings, such as assist pressure threshold or respiration rate.

Airway Under-Pressure

Underpressure Alarm

This fault indicates that an under-pressure condition has been detected in the airway. For Volume Control mode, an under-pressure condition is defined as a pressure less than 25% of the average measured peak pressure (averaged over 10 samples, not counting sigh breaths), checked at a time approximately halfway into the inspiration stroke. This could indicate that the airway is not connected or is leaking. This is a critical fault and requires operator intervention. The machine shall continue to run at the current respiratory settings. This fault shall be self-clearing once the condition is corrected. The user is always notified via a visual alarm and also by an audible alarm (if enabled).

```
Underpressure Alarm (Inspira ASV<sub>p</sub>)
```

Underpressure Alarm

If the average airway pressure is less than 3cmH20, an underpressure alarm is reported. Underpressure conditions are generally caused by severe system leaks. This alarm is self-clearing on removal of the fault condition.

Initialization Fault

```
Initialization Fault
```

This fault indicates that the machine failed to initialize properly due to one or more reasons.

High PEEP Alarm (Inspira ASV_p Only)

High PEEP Alarm

If the actual end-expiratory pressure (EEP) exceeds the desired PEEP plus $5\text{cmH}_2\text{O}$ or $11\text{cmH}_2\text{O}$, whichever is less, a High PEEP Alarm is reported. This alarm is self-clearing on removal of the fault condition.

Entering Respiration Rate

To enter a custom respiration rate press the [Set] key followed by the [Rate] key. The display should now read "Enter Resp Rate". Enter the rate in breaths per minute (BPM) using the numeric keypad. Only whole numbers will be accepted as valid rates. Press the [Enter] key to enter the selected rate. If the selected rate is not within the Safe Range¹⁵ a prompt will ask if you would like to override the Safe Range¹⁵ value; see page 32.

Step	Кеу	Display
1	Set	Press Parameter Key
	\frown	
2	Rate	_ (BPM)
Enter	s respiration rate configuration mode	
3		Enter Resp Rate 123 (BPM)
Selec	ts rate in breaths per minute	
4	Enter	
Enter	s choice and returns to main screen	

Entering Tidal Volume (Volume-control Mode Only)

• The inspiration and expiration volumes are always the same.

To enter a custom inspiration/expiration volume press the [Set] key followed by the [Volume] key. The display should now read "Enter Tidal Vol". Use the numeric keypad to enter the inspiration/expiration volume. Press the [Enter] key to enter the selected volume. If the selected volume is not within the Safe Range[™] a prompt will ask if you would like to override the Safe Range[™] value; see page 32.



Enters choice and returns to main screen

Entering Sigh Breath (Volume-control Mode)

• A sigh tidal volume (STv) and a sigh frequency must be set in order to activate the sigh breath function in volume-control mode.

To enter a sigh tidal volume and a sigh frequency press the [Set] key followed by the [Sigh] key. The display will now read "Enter Sigh Volume" and will also show the current STv. Use the numeric keypad to enter the desired STv. Press [Enter] to enter selected STv. Inspira will now ask for the desired sigh frequency. The display should read "Enter Sigh Freq, 1sigh/__ breaths". Again, use the numeric keypad to enter the ratio of sigh breaths to regular breaths (Note: Inspira will only accept whole numbers for this ratio). Press the [Enter] key to enter the selected ratio. If the selected values are out of the Safe Range™ a prompt will ask you if you would like to override the Safe Range™ value; see page 32.

Step	Кеу	Display
_1	Set	Press Parameter Key
i i	\frown	
2	Sigh	STv: _ (cc)
Enters	s sigh configuration mode	
3		Enter Sigh Volume STv: 12.3 (cc)
Selec	ts sigh volume	
4	Enter	Enter Sigh Freq: 1 Sigh/ _ Breaths
Enters	s sigh volume; returns prompt for sigh frequency	
5		Enter Sigh Freq: 1 Sigh/ 12 Breaths
Select	s sigh frequency	
6	Enter	

Enters choice and returns to main screen

Entering Sigh Breath (Pressure-Control Mode)

A sigh pressure and sigh frequency must be set in order to activate the sigh breath function in pressure-control mode.

Disabling Sigh Breath

To disable sigh breaths, enter Sigh Volume = Tidal Volume (volume-control mode) or set Sigh Frequency to 1 sigh / 0 breaths. SIGH BREATHS ARE AUTOMATICALLY DIS-ABLED WHENEVER A NEW ANIMAL WEIGHT IS ENTERED.

Sigh Pressure (Pressure-Control Mode Only)

Step Key Display Press Parameter Key 1 Set Enter Sigh Pressure 2 Sigh (cmH20) Enters sigh configuration mode 3 Enter Sigh Pressure 3 5 35 (cmH2O) Selects sigh pressure Enter Sigh Freq: 4 Enter Breaths 1 Sigh/ _ Enters sigh pressure; returns prompt for sigh frequency 5 Enter Sigh Freq: 1 2 Sigh/ 12 Breaths Selects sigh frequency

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Entering I:E Ratio

- The I:E ratio is the ratio of the time needed for inhalation compared to time needed for exhalation. The volume of the inhalation breath is always the same as the volume of the exhalation breath.
- There are no predetermined safe range values for I:E ratios.
- The default I:E ratio is 50%

To enter a different I:E ratio press the [SET] key followed by the [I:E RATIO] key. The display should now read "Enter % Inspiration, (20%-80%)". Use the numeric keypad to enter the whole number percentage of inspiration (which must be between 20 and 80). The percent of expiration is determined from the value for inspiration. (Note: Due to electromechanical system limitations, Inspira might not accept some I:E Ratio values for certain respiration profiles. If a desired I:E ratio is not accepted when using the small cylinder, try switching to the larger cylinder. This may allow acceptance of the desired ratio.)



Enters inspiration ratio and returns to main screen

Entering Pressure Settings (Inspira ASV_v)

Inspiration Pressure

The Inspiration pressure is a pressure threshold, which is used to detect airway overpressure conditions. If the average airway pressure rises above this pressure threshold, an alarm is sounded (if enabled) and the display shows the fault. This indicates that the residual volume may be increasing in the animal's lungs and user intervention is required immediately. Ventilation will still occur after this threshold has been broken. The default Inspiration Pressure is 35 cmH₂O.To set the inspiration pressure press the [Set] key followed by the [Pressure] key. The display should now display a list of options "Press 1=Insp, 2=Asst". Press the [1] on the numeric keypad to select the inspiration pressure. The display should now read "Enter Insp Pressure" and display the current pressure setting. Using the numeric keypad, enter the inspiration pressure setting in cmH₂O. Inspira will only accept whole number values for this setting. Press [Enter] to enter the selected pressure setting.

Step	Кеу	Display
<u>1</u>	Set	Press Parameter Key
2	Pressure	PRESS 1=INSP 2=ASST
: Enter	s pressure configuration mode	
3		Enter Insp Pressure: _ (cm H2O)
Enter	s inspiration pressure setup	
4	3 0	Enter Insp Pressure: 30 (cm H2O)
Selec	ts inspiration pressure	
5	Enter	

Enters inspiration pressure and returns to main screen

Assist Pressure

The assist pressure is a sub-baseline pressure threshold which is used to trigger an inspiration stroke. Inspira looks for this trigger within the first 10% of the calculated inspiration time, which is determined by the inspiration rate. The default Assist Pressure is -5 cmH₂O.

• The ASV will always use a negative assist pressure.

To set the assist pressure press the [Set] key followed by the [Pressure] key. The display should now show a list of options "Press 1=Insp, 2=Asst". Press [2] on the numeric keypad to select the assist pressure. Now the display should read "Enter Assist Pressure" and also show the current assist pressure setting. Use the numeric keypad to enter the vacuum pressure (the negative sign does not need to be entered, Inspira assumes that this value is negative). Press the [Enter] key to enter the selected assist pressure value.

Step	Кеу	Display
<u>1</u>	Set	Press Parameter Key
: <u>2</u>	Pressure	PRESS 1=INSP 2=ASST
Enter	s pressure configuration mode	
3	2	Enter Asst Pressure: (cm H2O)
Enter	s assist pressure setup	
4	5	Enter Asst Pressure: -5 (cm H2O)
Selec	ts assist pressure	
5	Enter	

Enters assist pressure and returns to main screen

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Entering Pressure Settings (Inspira ASVp)



Note 1: Sigh pressure setting only available in pressure-control mode.

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Assist Pressure



Enters assist pressure and returns to main screen

Note 1: Sigh pressure setting only available in pressure-control mode.



Enters peep pressure and returns to main screen

Note 1: Sigh pressure setting only available in pressure-control mode.



Sigh Pressure (Pressure-Control Mode Only)

Starts and stops ventilation

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Operating Modes

The Inspira ASV_v has two operating modes, Volume Mode and Assist Mode. To toggle between the modes press the [Select Mode] key. The upper right hand corner of the display will show which mode the ventilator is currently in, either VOL or ASST.

The Inspira ASVp has four operating modes – VOLUME, VOLUME ASSIST, PRESSURE, and PRESSUREASSIST. To toggle between the modes, stop the machine by pressing the RUN/STOP key (if it is presently running) and then press the SELECT MODE key. When the mode is switched from VOLUME ASSIST to PRESSURE or PRESSURE ASSIST to VOLUME, the machine will re-initialize to place it in its "home" position for that mode. The upper right hand corner of the display will show which mode the ventilator is currently in -VOL, VOLASST, PRES, or PRSASST.

Volume Mode

When in Volume Mode the ventilator delivers a known volume of gas to the animal over a specified amount of time for each respiration stroke. This is the basic operating mode for volume-controlled ventilation.

Pressure Mode (Inspira ASVp Only)

When in Pressure Mode, the ventilator delivers gas until the desired airway pressure is reached or the end of the inspiration cycle has occurred. If the airway pressure is not reached within the inspiration time, the machine will automatically adjust the inspiratory flow rate by incrementally increasing the tidal volume until the pressure limit is achieved. If the pressure limit is reached early in the inspiratory cycle, the machine will automatically decrease the flow rate so that the limit is reached toward the end of the cycle. If the limit is reached very early in the cycle, the machine will also report an Occlusion Fault.

Volume Assist Mode

Pressure Assist Mode (Inspira ASVp only)

Assist mode is a more advanced mode used to help wean animals off of mechanical respiration. This mode detects when the animal is trying to breathe on its own via a drop in the airway pressure. This mode allows the animal to initiate the respiration strokes. The ventilator starts a respiration stroke when the airway pressure falls below a user-defined threshold. If five respiration strokes occur without the airway pressure dropping below the assist pressure threshold, the animal may not be trying to initiate a breath. The ventilator will continue to operate in the current assist mode but the assist alarm will sound to request user intervention. The user may adjust the respiration parameters and/or the assist pressure to obtain correct performance.



Toggles between available modes

User Override

The user has the option of overriding the machine's "Safe Range" "limits to allow for more advanced respiratory control. The Safe RangeTM is defined as $\pm 10\%$ of the machine's recommended tidal volume and $\pm 10\%$ of the machine's recommended respiration rate. When you would like to change a respiration parameter simply enter the value according to the steps provided in the *Getting Started* section. If the value is outside of the Safe RangeTM, Inspira will ask you if you would like to override the current Safe RangeTM parameter. On this prompt screen press [1] to select "Yes" or [2] for "No".

Note: Some parameters may not be valid due to current respiration profile, cylinder size, and electromechanical limitations.



Using Digital and Analog I/O Ports

Trigger In

This is an active low, digital signal, used to trigger the ventilator between the RUN and STOP modes. Each pulse given to Inspira through this channel will toggle the machine to the next state. This optional signal is input by the user through the use of a footswitch or other device connected to the front panel BNC connector. Minimum input pulse width = 1 ms.

Sync Out (Inspira ASV_v (version 1.13 and earlier))

This is an active-low, open-collector, digital signal generated at the start of each inspiration stroke. This signal is available at the front panel through a BNC connector. The pulse width equals 20 ms ± 10 ms. This signal can be used in conjunction with other devices, which need to operate in sync with the ventilator's respiration stroke. The falling edge must be used for sync timing.

Sync Out (Inspira ASVp & ASVv (version 1.14 and later))

The sync signal is a logic high for the duration of the inspiration time and a logic low during the expiration time. The rising edge corresponds to the start of the inspiration cycle and the falling edge corresponds to the start of expiration.

Analog Out

The analog out (ANALOG OUT 1) is used to measure the ventilator's airway pressure. This output can be monitored using a data acquisition system or by an oscilloscope. To view or record this signal, connect the data acquisition system or oscilloscope to the analog out BNC connector on Inspira's front panel.

Remote Control / Monitoring (Serial Communication)

The Inspira is equipped for serial communication through two RS232 ports. Inspira uses a Harvard Apparatus Command Line protocol as the basis of its serial commands. These serial commands can be found in Appendix C.

RS232 Cable Selection

To connect PC/At or laptop computers you will need a 9-pin male to 9-pin female shielded cable; Harvard Apparatus part number 5154-353. For PCs with a 25-pin serial port connection, use a 9-pin male to 25-pin female shielded cable; 5154-527. *Note: Do not use a "Null-Modem" type cable.*

RS232 Cable Connection

- Use correct cable.
- The recommended cable length is 3 meters maximum.
- Turn power off to Inspira and to the external device before connecting the cable into the connectors.
- Check that the Inspira signal ground (pin 5) is connected to the external device signal ground.
- Use shielded cabling to connect Inspira's chassis ground to the chassis ground of the external device.

Serial Communication Setup

To configure Inspira for serial communications, press [Set] key followed by the [RS232] key. The display should read "RS232 Setup, Enter to Continue". Press [Enter] key to display the RS232 input/output selection menu. The display should now read "Press 1=Input port, 2=Output port". Select the port you would like to configure (Input is used for serial connection to a pc; Output is used for a daisy chain setup). The display should now show the RS232 port setup menu which reads "Press 1=Baud, 2=Bits, 3=Parity, 4=Addr".



Data Transfer Rate Configuration

To configure the data transfer rate, enter the port configuration menu. Press [1] to enter the Baud rate setup screen. The display should read "Press Select Mode to toggle baud" and display current baud rate. Press the [Select Mode] key to toggle through the baud rates (38400, 19200, 9600, 2400, and 1200). Pressing the [Enter] key will accept the valve and return Inspira to the main screen. Default baud rate is 9600.



Accepts value and returns to main screen

Start, Word, and Stop Bit Configuration

To change the bit configuration, enter the port configuration menu by pressing [2]. The display should read "Define Serial Bits, STRT, WD, STP", and display the current bit settings respectively. The start bit is fixed at 1 bit and word bits are fixed at 8. Use the numeric keypad to change the number of stop bits. Press [Enter] to return to the main screen.



Accepts entry and returns to main screen

* Note: See page 33 for steps 1 through 4.

Parity Configuration

To configure the port parity settings, enter the port configuration menu. Press [3] to enter the parity configuration menu. The display should read "Define Parity: 1= Even, 2= Odd, 3= None". Choose the desired parity by pressing the corresponding numeric key. After making your selection Inspira will automatically return to the main screen. The default parity is "none".



Changes parity parameter and returns to main screen

Address Configuration (Future Feature)

To assign an address to the Inspira for use in a daisy chain, enter the port setup menu. Press [4] to enter the address configuration menu. The display should read "Enter Address" and display Inspira's current address. Use the numeric keys to enter an address between 0 and 999. Press [Enter] to enter the selected address and to return to the main screen.



Enters address and returns to main screen

Testing RS232 Communication

Once Inspira and the external device are configured with the same port settings, connect the Inspira to the external device using the proper cable. Send the VER command from the external device to Inspira. If the R\$232 connection is working properly the Inspira will return its version number. If nothing is returned, check the cable connection and the port settings to verify that they are configured correctly.

* Note: See page 33 for steps 1 through 4.

Changing Air Cylinders

The Inspira ventilators use two easily interchangeable piston/cylinder assemblies. These assemblies are available to provide 0.1 to 10 ml and 1 to 100 ml tidal volumes. Changing the piston/cylinder assembly is simple. Remove the top cover of the ventilator by removing the seven phillips head screws which hold the top cover in place. Once the top cover is removed locate the currently installed cylinder. Move Inspira's white plunger back by turning the coupling connecting the black lead screw to the motor shaft. Turn the lead screw until the flag pin on the rear of the plunger is vertically in-line with the rear switch as seen illustrated below. Remove this cylinder from the Inspira chassis. Place the O-ring from the extracted cylinder back into the mounting groove, which is found on the valve block. *(Note: When installing the air cylinder, do not change the bends of the cylinder detection switches or else the correct cylinder will not be detected.) Now insert the new cylinder by placing the plunger portion of the air cylinder on the end of Inspira's white plunger.

Carefully slide the air cylinder back on the white plunger compressing the air cylinder just enough to allow the front end of the cylinder to be lowered into place. Once the air cylinder is fit in place, screw the air cylinder's threaded nipple into the valve block and hand tighten the cylinder in place.



CAUTION: Do not overtighten cylinder. Overtightening may cause glass cylinder to crack.

Now that the air cylinder is in place, rotate the lead screw into position so that the flag pin in between both the front and rear switches. To complete the installation, replace the top cover of the Inspira unit. When Inspira is powered on it should display the correct cylinder size after initializing. The ventilator automatically detects which size cylinder is installed.



Figure 12. Changing Air Cylinders

Hardware Setup

Inspira's microprocessor based system provides hardware setup options and diagnostic tests to be run on the ventilator. Hardware setup menus allow the user to configure specific hardware in the ventilator, while the diagnostics provide some tests to help in troubleshooting faults. These options are found in the hardware settings menu which is accessed by pressing the [Set] key followed by the [Enter] key. Press [Enter] again to enter the hardware configuration menu.



Audible Alarm On/Off

To toggle the audible alarm on or off, enter the hardware configuration menu. Press [1] to enter the alarm setup. The display should read "Press Select Mode to Toggle Alarm" and display whether the alarm is currently on or off. Pressing the [Select Mode] key toggles the alarm on or off, enters the selection, and then returns to the main screen. WHEN YOU TURN OFF THE AUDIBLE ALARM, IT IS OFF FOR ALL FAULT FUNCTIONS.



Accepts value and returns to main screen

* Note: See above for steps 1 through 3.

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I/O Setup

To review or modify the I/O settings, enter the hardware configuration menu. Press [2] to enter the I/O setup. The display should now read "Set I/O: Press 1= Digital, 2= Analog". Pressing [1] selects Digital I/O configuration. This feature is a future option and is not presently available. Pressing [2] selects the Analog I/O menu. The display should now read "Analog 1= Arwy Pres". This indicates that the airway pressure analog signal is connected to Analog Out 1. This is the only analog signal available in this model. Inspira then returns to the main display screen.



Displays current analog setting and returns to the main screen

Display Brightness Level

To change the display brightness level, enter the hardware configuration menu. Press [3] to enter the display configuration. The display should now read "Set Brightness Level 100%" (default setting). There are four options for the display brightness, 25, 50, 75, and 100%. Use the [Select Mode] key to toggle through the different levels of brightness. The [enter] key selects the brightness level and then returns to the main screen.



Accepts value and returns to main screen

* Note: See page 37 for steps 1 through 3.

Diagnostics

To enter the Inspira diagnostic menu, first enter the hardware configuration menu and press [4] to advance to the next menu. The display should read "Press 5= Diagnostics". Press [5] to enter the diagnostics menu. The display should read "Press 1= Dsply, 2=Key, 3=Alarm, 4=Next".



Display Diagnostics

To perform the display diagnostic, enter the diagnostic menu. Press [1] to perform the display test. The display should read "Display Test", then illuminate all pixels and return to the diagnostics menu.



Keypad Diagnostics

To run the keypad diagnostic, enter the diagnostics menu. Press [2] to start the keypad diagnostic. The display should momentarily read "Keypad Test, Press Enter to Exit". Then the display will show a cursor in its upper left-hand corner. This test echoes keystrokes on the display. Press each key and verify that the display echo matches the key pressed. Press [Enter] to exit this test and return to the diagnostics menu.



* Note: See page 37 for steps 1 through 3. [†] Note: See above for steps 4 and 5.

Audible Alarm Diagnostics

To test the audible alarm, enter the diagnostics menu. Press [3] to perform the alarm test. The display should read "Press set to test, Press enter to exit". Press the [Set] key to sound the alarm. When finished press the [Enter] key to return to the diagnostics menu.



Fault Log

To read fault log information, enter the diagnostics menu and press [4] to advance to the next menu of tests. Press [1] to momentarily display fault code information and an error count. The fault code is a hexadecimal code indicating faults and warnings detected since the fault log was last cleared. The error count tracks the number of events which have occurred and caused the machine to re-initialize. The machine will re-initialize automatically three times before requiring user intervention. Events such as valve stalls and end-of-travel faults trigger the automatic re-initialization in an attempt to restore the machine to normal operation. If the fault occurs more than three times, a more serious problem may exist and the machine will no longer automatically re-initialize. In this case, the user should contact the manufacturer for assistance. Power cycling clears the fault and error count. Fault log information is retained until the fault log is cleared.



Displays Fault Log and Error Count Returns to previous screen after a few seconds

Clearing Fault Log

To clear the information in the fault log, press [2]. The fault log will be cleared to 0x0000 but the error count will be retained.

Step*	Кеу	Display
6	(4)	1=FLT LOG 2=CLR FLT 3=PRES 4=NEXT 5=BACK
Adva	nces to next menu of diagnostic tests	
7	2	Fault Log=0x0000 Error Count=0
Clea previ	rs Fault Log and returns to ous screen after a few seconds	

Pressure Test (Future Feature)

A pressure test for testing the internal pressure transducer is planned for future versions. It is not yet implemented.



Returns to previous screen after a few seconds

Advancing / Returning to Other Diagnostic Tests

Pressing [4] will advance to the next menu of tests. Pressing [5] will return to the previous menu of tests.



Returns to previous menu of diagnostic tests

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Pump Diagnostics

To check the pumping mechanism functionality, enter the diagnostics menu. Press [4] and press [4] again to advance to the next menu of tests. Press [1] to perform the pump test. The display should read "Pump Test". Once the test has completed successfully, the display will read Piston Test Success and return to the diagnostic menu.



Valve Diagnostics

To check the respiration valve's functionality, enter the diagnostics menu. Press [4] and press [4] again to advance to the next menu of tests. Press [2] to perform the valve test. The display should read "Valve Test". Once the test has completed successfully, the display will read Valve Test Success and return to the diagnostic menu.



Non-Volatile Memory Diagnostics

To check the non-volatile memory (NVRAM) for errors, enter the diagnostics menu. Press [4] and press [4] again to advance to the next menu of tests. Press [3] to perform the memory test. The display should read "No errors yet...".When done, the display should read NVRAM test done and return to the diagnostic menu.



7	(4)	1=PUMP 2=VALVE 3=NVRAM 4=BACK
81	(4)	1=FLT LOG 2=CLR FLT
	\bigcirc	3=PRES 4=NEXT 5=BACK

Returns to previous menu

Exiting the Diagnostics

Pressing the [Enter] key while in the diagnostic menus will exit and return to the main operating screen.

Power Failure

The Inspira ventilator may be connected to an uninterruptable power source (UPS), such as a battery backup, to protect against power failures. Choose a UPS that has an output power capacity sufficient to power a 75 watt load for the desired length of time to protect. A UPS rated at 650 VA will typically provide more than 1 hour of operation on a fully charged battery. If a UPS is not used, the machine will stop ventilating for the duration of the power failure. When the power is restored, the machine will power up in its last commanded state. If that state was RUN, it will continue ventilation with the last entered respiratory parameters. Harvard Apparatus recommends use of a UPS device or other backup power source when performing unmonitored ventilation.

Note: There are many manufacturers of UPS devices. Some examples are American Power Conversion (<u>www.apc.com</u>) and Belkin (<u>www.belkin.com</u>). Contact the UPS manufacturer for help in choosing the right sized unit.

General Maintenance and Cleaning

To ensure that your Inspira operates correctly only use the ventilator according to the guidelines provided in this operating manual. If the ventilator does not work properly contact Harvard Apparatus for appropriate instructions.

To clean the exterior surfaces, use a lint-free cloth to remove loose dust. Use care to avoid scratching the clear display window. For more efficient cleaning, use a soft cloth dampened with water or an aqueous solution of 75% isopropyl alcohol.

Appendix A

General Specifications

Specifications	
Animal Size	15 g to 10 kg
Volume	0.1 to 100 ml
Port Sizes	1/8"-27 NPT threaded nylon barbed ports, accommodates 1/16", 1/8", 3/16" ID Tubing (Default = 1/8" ID Tubing)
Control Modes	Volume or Assist
Breathing Rate	5 to 200 bpm
Resolution	1 breath/min
% Inspiratory Time	20 to 80% of cycle time (Default = 50%)
I:E Ratio	4:1 to 1:4 (Default = 1:1)
Inspiratory Flow	0 to 12 SLPM
Gas Supply	Room air or nonflammable mixed gas
Inspiration Pressure:	
Full Range	5 to 50 cmH $_2$ O
Safe Range	15 to 25 cmH ₂ O
Accuracy	+/- 1 cmH ₂ O
Resolution	$1 \text{ cmH}_2\text{O}$
Sigh Frequency	1 in 5 to 1 in 250 breaths (Default = No Sigh)
Sigh Pressure:	
Safe Range	Insp. Pressure to 50 CriH_2O Insp. Pressure to (Insp. Pressure + 10 cmH_2O) or 35 cmH_2O , whichever is less
Respiratory Assist	Available
Assist Trigger	-1 to -10 cmH ₂ O (Default = -5 cmH ₂ O)
Signal Inputs:	Σ. (
External Trigger Input	0 to +5 V digital pulse, active low
Signal Outputs:	
Sync Out (ASV _v)	0 to +5 V digital pulse, 20 ±10 ms wide, active low
Sync Out (ASV _p)	V _{0H} for Inspiration Duration
AmelowOutd	V _{OL} for Expiration Duration
	0 to +5 v analog (Detault = Alrway Pressure Signal)
Pressure Range	±67 cmH ₂ O (±50 mm Hg)
Sensitivity	30 mV/cmH2O, typical (40.0 mV/mmHg, typical)
Signal Level	+0.5 to +4.5 V
Offset	+2.5 V ±0.05 V
Hesponse	1 ms max
Analoguuiz	
	NJ2J2
Display	2 line x 20 character vacuum Fluorescent Display (VFD)
Power	AU 100 10 240 V, 50/60 HZ, 75 Watts
Dimensions, H X W X D	17.8 x 25.4 x 40.6 cm (8 x 10 x 17.25 in)
Weight	9.1 kg (20 lb)

Appendix B

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Specifications			
Analog Out 1, Analog	Out 2:		
Signal Type	Analog Output		
V _{OH} (max)	+10.5 V @ R _L = 1 MΩ		
V _{OL} (typical)	0 V		
V _{OL} (max)	50 mV @ I _{OL} = 0		
IOUT	0.5 mA @ V _O = 5V, R _L = 10 KΩ		
^I OUT ^(max)	30 mA		
Protection	Short Circuit, Duration Indefinite, ESD Protected		
Connector Type	BNC		
Cable Length	3 m max		
Sync Out:			
Signal Type	Digital Output		
V _{OH} (typical)	5 V		
V _{OH} (min)	2.5 V @ I _{OH} = 2.5 mA		
V _{OL} (max)	0.3 V		
l _{OL} (min)	1 mA		
l _{OL} (typical)	15 mA		
Pulse Width	20 ms ±10 ms (Inspira ASV _V Only)		
Pulse Width (Inspi	ra ASV _p)		
	V _{0H} for Inspiration Duration		
	V _{OL} for Expiration Duration		
Protection	Short Circuit, Duration Indefinite, ESD Protected		
Connector Type	BNC		
Cable Length	3 m max		
Trigger In:			
Signal Type	Digital Input; Input pulled up to +5 V through a 330 Ω resistor.		
	Drive with open collector or switch closure.		
V _{IH} (min)	2.4 V		
V _{IH} (max)	/ V		
v _{IL} (max)	0.8 V		
IL(typical)	13.5 MA		
Puise width	i ms minimum Obact Oinseit Dunction Indefinite, EOD Ductostad		
Protection	Short Circuit, Duration Indefinite, ESD Protected		
Connector Type			
Cable Length	3 m maximum		
RS232 Input/Output:			
Signal Type	Digital Input / Output to EIA RS232C Standard		
Protection	Short Circuit, Duration Indefinite, ESD Protected		
Connector Type	9-pin D-Sub		
Cable Length	3 m maximum		

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SERIAL COMMANDS, QUERIES, AND RESPONSES

Each command sent to the Inspira is a string of ASCII characters. Commands are not case sensitive and spaces are optional. After a transmission to the Inspira terminating with a <cr> character, the Inspira enters remote mode and responds with the three character sequence:

ASCII 42 decimal

<cr></cr>	carriage retur	n ASCII 13 decimal
<lf></lf>	line feed	ASCII 10 decimal
Prompts		
:	Stopped	ASCII 58 decimal
>	Running	ASCII 62 decimal

The following symbols are used in describing the commands.

Commands

*

Format: command<cr> Response: <cr><lf>prompt

Fault

KEY	Return to keyboard control, exit remote mode
RUN	Start ventilation
STP	Stop ventilation
SIGH	Commands SIGH Breath
OVRD	Override Safe Range [™] checking
SAFE	Enable Safe Range [™] checking

Commands with Input Data

Format: command data<cr>

r	
CETD AT	 Cote and institute and a la DDM (handle and a la la

SEIKAI	nnn	sets respiration rate in BPM (breaths per min)
SETVOL	nnn.nn	Sets tidal volume in cc
SETIE	nn	Sets I:E Ratio as % inspiration
SETSTV	nnn.nn	Sets sigh tidal volume in cc
SETSFREQ	nnn	Sets sigh frequency as 1 breath per nnn breaths
SETPRS	nn	Sets inspiration pressure limit in cmH ₂ O
SETWGT	nn.nnn	Sets animal's weight in kg
SELMOD	mode	Selects operation mode (<i>mode</i> = VOL or ASST)

Commands with Input Data (Inspira ASVp Only)

Format: command data<cr>

Response: <cr><lf>prompt

SETPRS	nn	Sets inspiration pressure in cmH_2O (Pressure-control
		mode) or pressure limit in cmH_2O (Volume-control
		mode)
SETSPRS	nn	Sets Sigh pressure in cmH ₂ O (Pressure-control mode only)

Appendix C

SETPEEP	nn	Sets PEEP pressure in cmH ₂ O	
SELMOD	mode	Selects operation mode (mode = VOL, VOLASST, PRES, or PRESASST)	
Queries			
Format: query<	cr>		
Response: <cr></cr>	<lf>value<cr< td=""><td>r><lf>prompt</lf></td></cr<></lf>	r> <lf>prompt</lf>	
RAT	Return respiration rate in BPM (breaths per min) as integer value		
VOL	Return tidal volume in cc to 2 decimal places		
IE	Return I:E Ratio as % inspiration		
STV	Return Sigh Tidal Volume in cc to 2 decimal places		
SFREQ	Return Sigh Frequency as 1 breath per xxx breaths		
PRS	Return ins	Return inspiration pressure limit in cmH ₂ O	
MOD	Return operation mode (VOL,AST)		
WGT	Return animal weight in kg to three decimal places of precision		
VER	Return model (ASVv,ASVp,ARV) and firmware version number		
AIRPRS	Returns airway pressure in cmH ₂ O		
FLT	Returns a 2 digit fault code (xx), defined as follows:		
00	No Fault		
01	Overpressure		
02	Under pressure		
03	Motor Drive Fault		
04	Pump Stall		
05	Valve Stall		

Queries (Inspira ASVp Only)

Format: query<cr>

Response: <cr><lf>value<cr><lf>prompt

Value is a string of characters of varying length.

PRS	Returns requested inspiration pressure (Pressure-control mode) or pressure limit (Volume-control mode) in $\rm cmH_2O$
SPRS	Returns requested sigh pressure (Pressure-control mode only) in $\mbox{cm}\mbox{H}_2\mbox{O}$
PEEP	Returns requested PEEP pressure in cmH2O
MOD	Returns operation mode (VOL, VOLASST, PRES, or PRESASST)
BSLNPRS	Returns actual baseline pressure (EEP) in cmH ₂ O
AVGPRS	Returns actual average peak pressure in cmH ₂ O

Error Responses:

<cr><lf>?<cr><lf>prompt</lf></cr></lf></cr>	Unrecognized command
<cr><lf>OOR<cr><lf>prompt</lf></cr></lf></cr>	Out Of Range

Harvard Apparatus Inspira Advanced Safety Ventilator User's Manual

Glossary of Terms

Assist

Respiratory assist mode, whereby a subject is aided in regaining normal breathing after artificial respiration (weaning), or for respiration of a non-paralyzed, anesthetized subject. Ventilation is triggered when the device detects a slight vacuum in the airway.

Expiration

The process of breathing out (exhaling) a gas or gasses.

Flow Rate

The rate of gas flow, expressed in L/min or mL/min.

I:E Ratio

The ratio of inspiration to expiration times. As used in this context, however, it is expressed as the percent of inspiration time to total respiration period. An I:E Ratio of 1:1 is equivalent to 50% inspiration time. An I:E Ratio of 1:4 is equivalent to 20% inspiration time.

Inspiration

The process of breathing in (inhaling) a gas or gases.

Inspiration Pressure

The pressure to which the subject's lungs are inflated during inspiration.

PEEP

Positive End-Expiratory Pressure.

Residual Volume

The smallest volume to which the subject's lungs can slowly be deflated.

Respiration Rate

Breathing rate, expressed in breaths per minute (BPM).

Sigh

A deeper than usual breath, which expands the lungs to a greater capacity and redistributes the lung surfactant that tends to puddle in the alveoli during normal respiration.

Sigh Volume

The inspiration volume during a sigh breath (some percentage greater than normal tidal volume for the subject).

Sigh Pressure

The inspiration pressure during a sigh breath (some percentage greater than normal inspiration pressure for the subject).

Appendix E

Sample Waveforms





Figure 13. Sample Waveforms

Frequently Asked Questions

1. When I start ventilation, why is underpressure constantly displayed?

If no connection is made to the "To Animal" port, this is the proper indication. The fault will clear when airway pressure is detected.

If proper connections have been made, there is most likely a leak in the system. Make sure that the O-ring has been installed properly before installing the glass cylinder. Verify that the cylinder has been tightened properly.

If barbed ports at the front of the machine have been replaced make sure that they are fully tightened to be flush with the front bezel.

Finally, check for leaks in the tubing and at the animal's airway.

If you are using the Inspira ASVp in pressure-control mode and the average airway pressure is greater than 3 cmH₂O, the machine will attempt to adjust the flow rate to increase the airway pressure. If an underpressure condition continues (Paw much less than desired) and the tidal volume is larger than expected, check for system leaks.

2. When I change or install a cylinder, why is it not detected properly?

The Inspira uses two micro-switches to detect the two different cylinder sizes. The rear-most switch actuates when the 10cc cylinder is installed. Both switches actuate when the 100cc cylinder is installed. If the 10cc cylinder is not being detected, first make sure that the rear-most actuator arm is resting against the side of the cylinder. If it isn't, just reposition the actuator arm. Next, make sure that the switches are actuating. Gently pull back on the actuator arm(s) contacting the installed cylinder and listen for a click. If the switch clicks it had not been actuated. This indicates that the actuator arm's bend angle has not been set properly. This may be easily corrected by gently increasing the bend angle of the actuator arm(s).

3. Why does it seem like the volume delivered is too low?

It is possible that there is a system leak. Check for leaks as described in the answer to question 1.

In volume-control mode, if the inspiration pressure limit is reached the machine will cycle to expiration before total tidal volume is delivered. Make sure that restrictions in the airway circuit are minimized and make sure that the pressure limit isn't set too low.

If you are using side-stream gas monitoring, tidal volume will need to be adjusted (increased) to account for the sample volume.

If system dead space is high, tidal volume will need to be adjusted to account for it.

Please note that the machine's calculations for tidal volume and respiration rate based on the animal's weight are for healthy mammals in a resting state and do not account for additional dead space which may be introduced by the user's system set-up. Deadspace volume should be calculated and the tidal volume should be increased accordingly. The animal's respiratory health must also be considered when adjusting respi-

ratory parameters.

4. How do I create a PEEP pressure with the Inspira ASVv?

To create a PEEP pressure when using the Inspira ASVv, simply connect a length of tubing to the "Exhaust" port and submerge the other end in a column of water. The depth of the end of the tubing (in cm) below the water surface will give the PEEP pressure in cmH₂O. See Appendix J.

5. How do I connect the Inspira to pressurized gas sources?

When connecting any volume-controlled, piston/cylinder type ventilator to a pressurized gas source, that gas must be equalized with atmospheric pressure before being drawn into the ventilator. If it is not, unknown and possibly lethal tidal volumes will be delivered to the animal. A set-up as shown in Appendix I may be used for this purpose.

6. How do I use anesthetic gases with the Inspira?

Refer to Appendix I for setting up the Inspira with a vaporizer and pressurized gasses. When using anesthetic gasses, keep in mind that total system volume will impact delay times in getting a change in gas mixtures to the animal. Vent or scrub expired gasses; do not vent to room air.

WARNING: Do not vent anesthetic gasses to room air!

7. How do I use the Inspira with MRI equipment?

Since the Inspira has a ferrous metal chassis and components, it will be attracted to the MRI's magnetic field. Also, the machine will create its own electromagnetic fields, which could impact measurements made with the MRI. It is therefore highly recommended that the machine be located far from the MRI equipment (more than ten feet). If the machine is located in the same room as the MRI system, tying the unit down to the floor or other immovable object may be required. Long lengths of tubing will be required to connect with the animal's airway, so total system volume, compliance, and flow restrictions must be considered when choosing the tubing diameter, wall thickness, and adapters. If anesthetic gasses are to be used, delay times in getting an adjusted gas mixture to the animal will be significant and should be determined.



Appendix H

Recommended Port Size vs. Tidal Volume & Rate 100 Tidal Volume (cc) 10 1 0.1 5 20 50 100 125 150 175 200 25 75 Rate (BPM) Max Tidal Volume Large Ports (cc) (Large Ports) **Medium Ports** Min Tidal Volume (cc) (Large Ports) Small Ports <u>-Δ</u> Max Tidal Volume (cc) (Med Ports) Min Tidal Volume (cc) (Med Ports) Max Tidal Volume (cc) (Small Ports) Min Tidal Volume (cc) (Small Ports)

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Using Inspira with Pressurized and/or Anesthetic Gasses



Notes:

- 1. Set flow rate into vaporizer per manufacturer's specification.
- Flow into breathing bag should be equal to or slightly greater than flow out of bag. Gas pressure must be equalized with atmospheric pressure before drawing into ventilator. An optional bleed circuit may be used to prevent pressurization of breathing bag.



Anesthesia Connection Kit

Catalog No. 73-3076



Appendix J



Declaration of Conformity

Application of Council Directive(s):

73/23/EEC, 89/336/EEC

Harvard Apparatus, Inc.

Standard(s) to which conformity is declared:

EN61010, EN61326:1998, Class B

Manufacturer's Name:

Manufacturer's Address:

84 October Hill Road Holliston, Massachusetts 01746 U.S.A.

Type of Equipment:

Œ

IARVARD

APPARATUS

Animal Ventilator

Model No.:

Inspira ASV

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).

Place:

United States of America

Date:

July 11, 2000

Robert D. Bohre

Signature)

Robert D. Bohne (Full Name)

VP Engineering / Operations

(Position)