

Model: AHP300

Electrically Controlled Ventilator



Distributed & Marketed by



**12 Madden St. Auckland, CBD 1010
New Zealand, Australia and Pacific Islands
Phone : +64 21 798 394
E-mail : service@mangomedtech.co.nz**




Covered by U.S.A. Patent #9,022,746

Rev. L1 2020

Table of Contents

1.	Intended Use:	3
2.	Product Description:	4
3.	Explanation of Warnings:	4
4.	Explanation of Abbreviations:	5
5.	Symbols:	5
6.	Controls and Connections:	6
7.	Operating the AHP300:.....	8
8.	Ventilation Modes:	15
9.	Breath Types:	18
10.	Programmable Presets:	19
	Quick Start Modes:	19
	Custom Modes:	22
11.	O2 Conserve Mode:	25
12.	Manual Breaths:	26
13.	Measured Parameters:	26
14.	Alarms:	27
15.	External Alarm Connection:	30
16.	Battery Parameters:	31
17.	AC Power Inlet and Auxiliary Power Connection:	32
18.	Cleaning:	34
19.	Check Out Procedure:	35
20.	Pneumatic Diagram:	36
21.	Maintenance:	37
22.	Specifications:	44
23.	Accessories and Replacement Parts:	48
24.	NBR Filter:	49
25.	Oxygen Cylinder Depletion Times:	50
26.	Approximate Tidal Volume Settings based on Height:	51
27.	Warranty:	52
28.	Applicable Standards:	53

Models covered by this manual: Transport Ventilator with Internal Air Compressor

	Warning: The AHP300 Ventilator should not be used on children with a weight of 5 kg (11 lbs) or less.
	Warning: This device should only be operated by qualified personnel under approved medical direction.
	Warning: Use only as directed. Improper usage or unauthorized modification of this product may result in user or patient injury or death.

1. Intended Use:

The AHP300 is intended to be used as an electrically controlled emergency ventilator that can use an external compressed gas source or its internal compressor. This ventilator is designed to provide emergency respiratory support by means of a face mask or tube inserted into the patient's airway. The ventilator is intended for use on patients weighing greater than 5kg (11lbs). The ventilator is intended to be used in the environments associated with emergency medical services (EMS), inter-hospital transport and hospital facility usage by qualified, trained personnel under the direction of a physician. The ventilator is intended to be used in temperatures of -18°C to 50°C (0°F to 122°F) and 5% to 95% RH non-condensing.

Prior to use, first read and understand the instruction manual, charge the battery and then follow the check out procedure in Section 19.

Each AHP300 ventilator includes the following:

- 1 Ventilator
- 1 Power Cord
- 1 Oxygen Hose
- 1 Instruction Manual



Warning: Use only as directed. Always have an alternate means of ventilation available when using the ventilator in case of a mechanical or system problem.

This product has been designed and tested to have a 6 year product life.

Caution: To ensure the ventilator performs reliably to specifications, the maintenance schedule in section 21 must be followed.

Latex Free: This product does not contain latex.


Intended "users" of this device are: **doctors, respiratory therapists, nurses and EMTs**

2. Product Description:


The Ventilator (AHP300) is an electrically controlled, portable emergency ventilator, which is designed to provide emergency respiratory support by means of a face mask or tube inserted into a patient's airway. The AHP300 is capable of supporting the patient's respiratory efforts in a variety of modes. The modes are Volume assist control (Volume AC), Volume synchronized intermittent mandatory ventilation (Volume SIMV), Pressure control with assist control (Pressure AC), Pressure control with synchronized intermittent mandatory ventilation (Pressure SIMV), and continuous positive airway pressure (CPAP). The AHP300 can deliver breaths to the patient using internal compressors as well as external gas sources.

The AHP300 is intended for use on patients weighing greater than 5kg (11 lbs.). This ventilator is intended to be used in the environments associated with emergency medical services (EMS), inter-hospital transport and hospital facility usage, by qualified, trained personnel under the direction of a physician. The ventilator is intended to be used in temperatures of -18°C to 50°C (0°F to 122°F) and 5% to 95% RH non-condensing. The AHP300 is intended to be used on one patient at a time. The unit can be reused after it has been cleaned and the single use patient circuit has been replaced.

Biocompatibility testing has proven this unit safe for periods up to 24 days of continuous use. Results beyond this time are not known.

	Warning: The AHP300 is not MRI compatible.
Caution:	The AHP300 should not be used on children with a weight of 5kg (11 lbs) or less.

3. Explanation of Warnings:



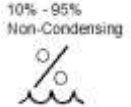
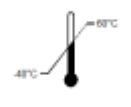


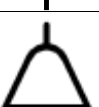


 Warning:	Potential injury to the patient or operator exists.
Caution:	Potential damage to the ventilator, breathing circuit or other equipment may result.

Warnings and cautions should be read and understood before operating the ventilator.

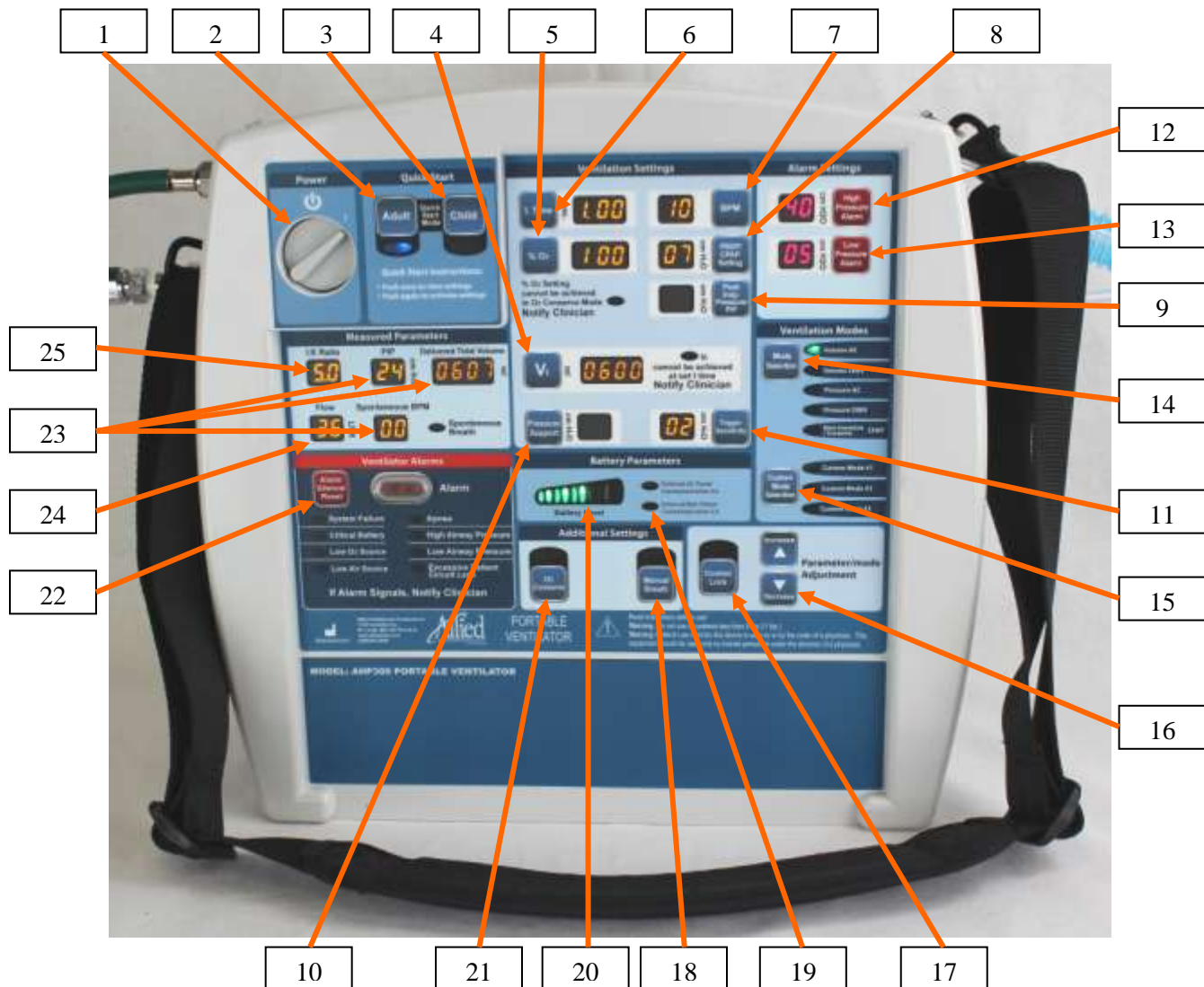
4. Explanation of Abbreviations:

V_t	Delivered Tidal Volume
BPM	Breaths per Minute (Respiratory Frequency)
RF	Respiratory Frequency
T_i	Inspiratory Time
Psi	Pounds per Square Inch
cm H ₂ O	Centimeters of Water
kpa	Kilopascal
ml	Milliliters
LPM	Liters per minute
mm	Millimeters
LED	Light emitting diode
CPR	Cardio Pulmonary Resuscitation
LPA	Low pressure alarm
HPA	High pressure alarm
RH	Relative Humidity
PIP	Peak Inspiratory Pressure
I:E	Inspiratory to Expiratory

5. Symbols:

	Degree of protection against electric shock: Type BF
	Caution, Consult accompanying documents
	% Relative Humidity: 5 to 95% Non-Condensing
	Temperature Range: -18°C to 50°C (0°F to 122°F) Operating -40°C to 60°C (-40°F to 140°F) Storage
	Off
	On
	External Alarm
	Do not Occlude
	Shock Hazard

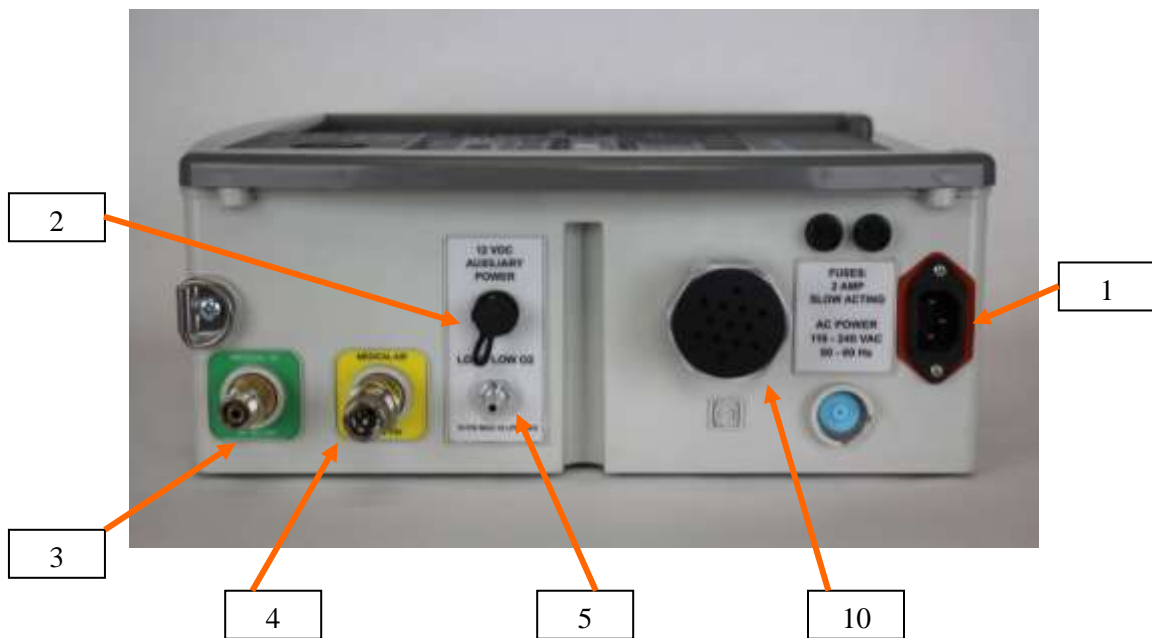
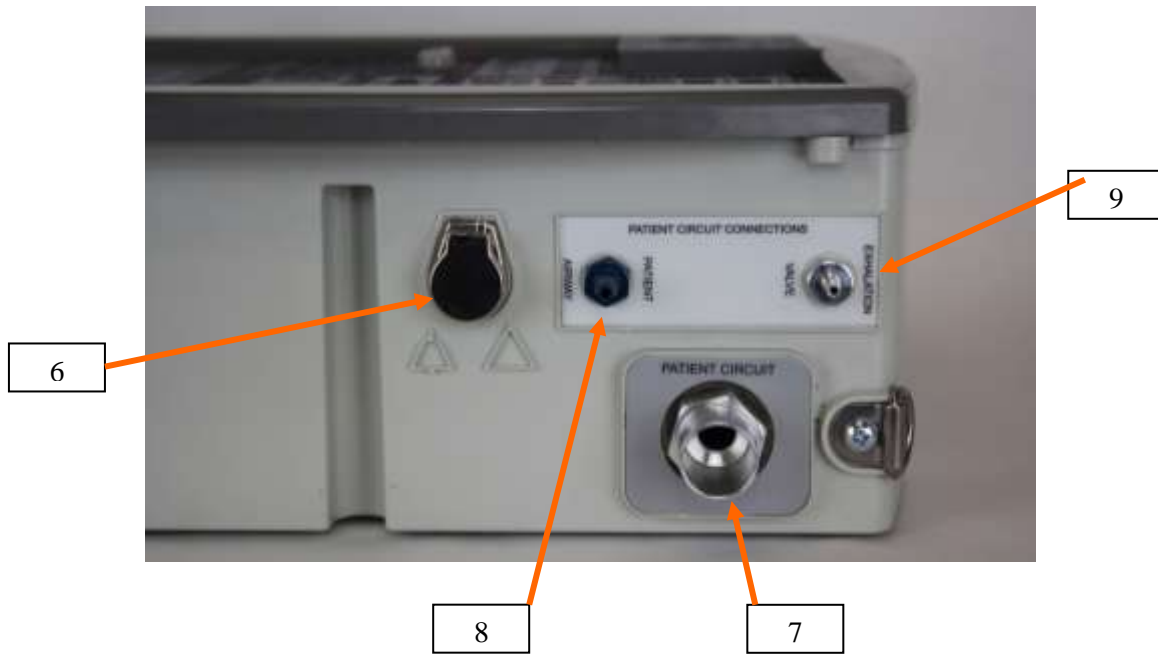
6. Controls and Connections:



Control Panel

Item #	Description	Item #	Description
1	Power On/Off	13	Low Airway Pressure Alarm Setting
2	Quick Start Adult Button	14	Ventilation Mode Selection
3	Quick Start Child Button	15	Custom Mode Selection
4	Tidal Volume Setting	16	Parameter Adjustment Buttons
5	O2 % Setting	17	Control Lock Button
6	I time Setting	18	Manual Breath Button
7	BPM Setting	19	External Power Indicators
8	PEEP / CPAP Setting	20	Battery Status Indicator
9	Peak Inspiratory Pressure	21	O2 Conserve Mode
10	Pressure Support Setting	22	Alarms / Silence Reset Button
11	Breath Trigger Sensitivity	23	Measured Parameters
12	High Airway Pressure Alarm Setting	24	Flow Setting (Volume Modes)
		25	I:E Ratio (Based On Vent Settings)

Ventilator Connections:



Item #	Description
1	AC Power
2	External Battery
3	O2 Source (Fresh Gas)
4	Air Source (Fresh Gas)
5	Low Pressure O2 Source (Fresh Gas)

Item #	Description
6	Remote Alarm Connection
7	Patient Circuit Connection Port
8	Patient Airway Pressure (blue)
9	Exhalation Valve Control
10	Air Intake Port

7. Operating the AHP300 Ventilator :

The following steps will guide a person through the setup and operation of the AHP300 ventilator.

- **Connecting to an Oxygen Source:**

Located on the left side of the AHP300 are 2 diameter index safety system (DISS) fittings, one for Oxygen and one for Medical Air. Connect the appropriate 3.4 bar (344 kPa) (50 psi) gas source with a minimum of 80 LPM flow capacity to these fittings. The AHP300 may be used without an external gas source. The AHP300 has an internal compressor that can be used to supply ambient air to the patient.

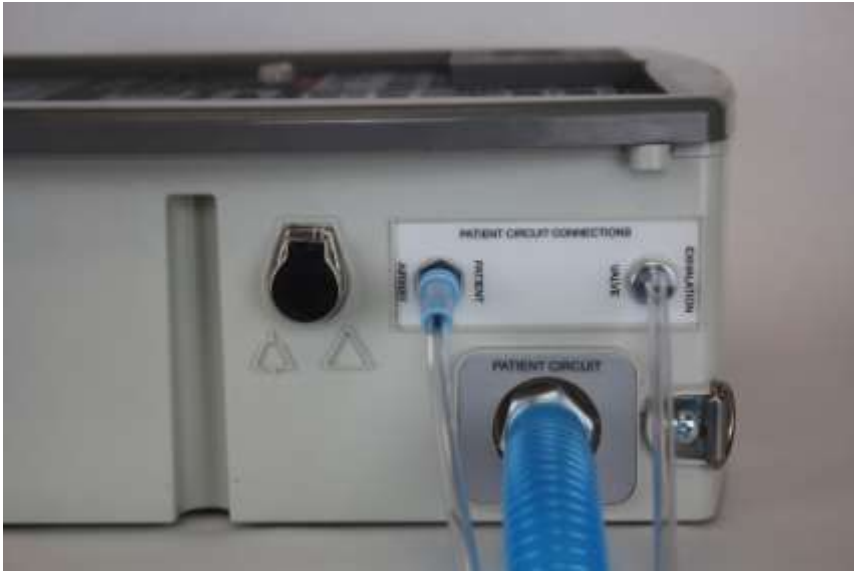


	Warning: Proper tidal volumes may not be provided with a gas source not providing a minimum of 80 LPM at 2.8 bar (280 kPa) (40 psi).
	Warning: This device operates with medical gases under pressure, including oxygen. Do not use this device while smoking or near open flames. Do not use this device or operate near flammable materials.
	Warning: Do not use on this device in the presence of flammable anesthetics.
	Warning: Verify that there are no noticeable leaks after connection to the 3.4 Bar (344 kPa) (50 PSI) Medical O2 or Medical Air source.
	Caution: In order to provide optimal performance, check all gas supplies to assure only medical grade gas is used.

- **Connecting the patient breathing circuit:**



Located on the right side of the unit is a 22mm patient connection port for a patient breathing circuit. Install the corrugated tubing over the connector so that it is on securely. The tubing will not pull off easily when properly installed. Connect the small tube without a connector to the small barb labeled Exhalation Valve. Connect the tube with a connector to the blue barb labeled Patient Airway.

	Warning: Do not use unapproved patient circuits as loss of performance may result.
---	---



Ventilator Patient Circuit


The AHP300 uses a universal single limb ventilator patient circuit (pictured below).

	
<p>Adult Circuit Part number L599-600 Dead space = 64.1 ml* Exhalation resistance < 6 cmH2O ^ (Approximately 4 at 60 LPM) (Approximately 3 at 30 LPM)</p>	<p>Pediatric Circuit Part number L599-650 Dead space = 9.2 ml* Exhalation resistance < 6 cmH2O ^ (Approximately 4 at 60 LPM) (Approximately 3 at 30 LPM)</p>

*Too large of an apparatus dead space can affect the oxygen and other gas levels delivered to the patient. The addition of accessories may impact the dead space and must be considered when they are used.

^Addition of accessories may impact the exhalation resistance.

Do not use circuits with “anti-static” or electrically conductive tubing or hoses.

	Warning: Ventilator patient circuits may become contaminated during use. To prevent cross contamination do not reuse patient circuits without proper disinfecting. Never reuse a “single patient use” ventilation circuit.
---	---

Always verify the ventilator circuit is not leaking by checking the connections to ensure they are pushed on completely. Verify the exhalation valve is on tight and not leaking during breath delivery.

Installation of a mask to the patient circuit is done by pushing the mask onto the end of the 90degree elbow at the patient end of the circuit as shown below.



Another option is use an exhalation filter to limit the spread of bacteria. L599-200 exhalation filters may be used as shown below.



Additional exhalation resistance will be experience when using an exhalation filter. The resistance based on flows is listed below.

Flow Condition (Lpm)	Exhalation Resistance (cm H2O)
15	1.45
30	3.15
45	5.07
60	7.30
80	10.61

Turn the ventilator “ON” by rotating the knob in the “Power” section of the control panel to the “|” position.



- **Select the Desired Ventilation Mode:**

If the control lock is activated as shown below it must be deactivated before any adjustments can be made. This is done by pushing the control lock button and the light will turn off to signify control lock is no longer active. Pushing the control lock button when the control lock is not active will activate the control lock as indicated by the light above the button.



Push the Mode Selection button and the current mode (for example Volume AC) will begin to flash. Using the Parameter/Mode adjustment buttons you can move the flashing light to the mode you desire. Push the mode selection button a second time and that mode will become the active mode of ventilation. If you do not push the mode selection button a second time after selecting a mode the ventilator mode change will time out in 5 seconds and exit the mode selection process. The ventilator will stay in the current mode of operation.


- Select the Required Parameters:



The ventilator will automatically populate the required fields with the current values.

The table below shows the parameters that must be set in each mode.

	Volume Control	Pressure Control	CPAP
Ti (Inspiratory Time)	Required	Required	N/A
BPM (Frequency)	Required	Required	N/A
%O2	Required	Required	Required
PEEP/CPAP	Optional	Optional	Required
PIP	N/A	Required	N/A
Vt (Tidal Volume)	Required	N/A	N/A
Pressure Support	Optional	Optional	Optional
Trigger Sensitivity	Required	Required	Required
High Pressure Alarm	Required	Required	Required
Low Pressure Alarm	Required	Required	Required
O2 Conserve	Optional	Optional	Optional

 **Warning: A CBRN Filter is required when the ventilator compressor is used in an environment where the air is not safe to breath.**

You can then change the ventilation parameters by pushing the button next to the parameter you want to change and then use the parameter/mode adjustment buttons to change the value.

For example the inspiratory time can be adjusted by pushing the button labeled “I. Time”. When you push the button the display will begin to flash, the value will change each time one of the parameter adjustment buttons is pushed. The inspiratory time may be adjusted from .5 to 2.0 seconds. If the ventilator is in a volume mode and the new inspiratory time is too short or long for to achieve the set tidal volume the light next to the tidal volume setting will come on and the inspiratory time will not be changed to a setting that does not allow the current tidal volume setting. The tidal volume must be changed if that inspiratory time is desired.

The following table lists the tidal volumes and BPMs that may be used based on the set inspiratory time.

Inspiratory Time	Tidal Volume Range	BPM Range
.5	40 to 500 ml	0 and 5 to 60
.75	60 to 750 ml	0 and 5 to 45
1.0	80 to 1000 ml	0 and 5 to 30
1.25	100 to 1250 ml	0 and 5 to 20
1.5	125 to 1500 ml	0 and 5 to 20
1.75	150 to 1750 ml	0 and 5 to 20
2.0	175 to 2000 ml	0 and 5 to 20

The AHP300 has a flow range from 5 to 60 LPM in volume control mode.

In pressure control mode a Peak Inspiratory pressure (PIP) from 15 to 55 cm H₂O is set. In this mode the peak flow may be greater than 80 LPM and the flow will vary during the breath. The flow rate will be higher in the beginning of the breath and lower as the airway pressure approaches the peak inspiratory setting. See section 8 for more detail on breath types.

As the BPM or Inspiratory time is adjusted the I:E ratio will be updated on the ventilator display. This is the calculated ratio of the inspiratory time to the expiratory time. The number displayed indicates how much longer or shorter the expiratory time is compared to the inspiratory time. For example if a 2 is displayed it means the expiratory time is 2 times as long as the inspiratory time. See section 14 for more detail.

The % O₂ indicates the percentage of oxygen in the gas delivered to the patient. For example, “100” indicates that the delivered gas is all oxygen, while “21” indicates that it is all air. This value is adjustable from 21 to 100 with an accuracy of 12% of the setting. For example a %O₂ setting of 50 would have a tolerance of ±6 giving a potential range of 44 to 56%. If you select a value that cannot be achieved due to a gas supply not being connected or having low pressure, a gas source alarm will sound. If only oxygen is connected, the AHP300 will use the internal compressor to supply air and there will not be an alarm. If you select a %O₂ of 70 when only oxygen is available, the ventilator will activate the internal compressor to provide the required air flow so that the set tidal volumes can be delivered.

Rapid adjustment of the %O₂ setting can be made by pressing the %O₂ button. This will cause the %O₂ display to flash indicating it can now be adjusted. If you hold down the Alarm Silence/Reset button and press one of the Parameter Adjustment buttons the %O₂ will change by 10 instead of 1.

PEEP may be used in any volume or pressure mode. PEEP (positive end expiratory pressure) will hold a set pressure at the end of exhalation portion of a breath. This pressure keeps the lungs partially inflated to help the exchange of oxygen through the alveoli. The PEEP setting may be set from 0 to 25 cm H₂O.

The PEEP/CPAP setting also controls the pressure level for CPAP (Continuous Positive Airway Pressure). See section 9 for more detail.

The AHP300 is **not** PEEP compensated and therefore changing the PEEP setting will not change the inhalation pressure in pressure modes.

Safety Pressure Relief:

This ventilator has a mechanical pressure relief set at ≤ 85 cm H₂O (maximum limited pressure). When the airway pressure reaches this limit the valve will open and gas will be vented to prevent the pressure from continuing to build. This is a redundant safety device as the high airway alarm limits the maximum pressure.



Warning: Preset tidal volumes may not be delivered when the pressure relief setting is reached. Inspiratory times will remain constant, however no additional tidal volume will be delivered after the pressure relief limit is reached.

- **Connect the patient breathing circuit to the patient:**

The patient breathing circuit has been designed to fit with an oxygen mask (22mm outside diameter) or endotracheal tube (15mm inside diameter). Follow the established guidelines for maintaining the patient's airway.

- **Verify the patient is receiving good ventilation:**

Once the patient is connected to the ventilator the patient should be observed to make sure they have adequate chest rise and fall. The chest rise should be even and should return to a normal position. If the patient does not have adequate chest rise check the tidal volume or pressure control setting, patient connections and examine the patient for a possible obstruction of the airway or other injury. The patient should be monitored to make sure they are receiving proper ventilation.

The airway pressure display "PIP" should be observed to make sure the patient is receiving adequate positive pressure ventilation. If the airway pressure display reading is low during the delivery of a breath and the chest rise is also low, check the tidal volume setting, patient connections and examine the patient for a possible obstruction of the airway or other injury. The airway pressure display reading should also be observed to make sure it is not too high. Common numbers used in practice are a maximum of 20 cm H₂O for an unprotected airway and 30 cm H₂O for a protected airway. Higher pressures may be required based on the patient's condition and you should always follow the physician's instructions. A high reading with pressure limit alarm may indicate a blocked airway or a stiff lung.

- **Spontaneous Breathing by the Patient:**

Should the patient begin to breathe spontaneously the AHP300 will sense this breath and deliver the breath per the ventilator setting. The LED (light) indicating a spontaneous breath

by the patient will come on after the spontaneous breath is delivered by the ventilator. The ventilator will also display the number of spontaneous breaths delivered in the past minute.

The trigger pressure level for a spontaneous breath may be adjusted using the trigger level setting. The adjustment range is from 1 to 5 and represents a range from 1 to 5 cm H₂O.

See assist control and synchronized intermittent mandatory ventilation sections for more detail on how the ventilator reacts to a spontaneous breath.

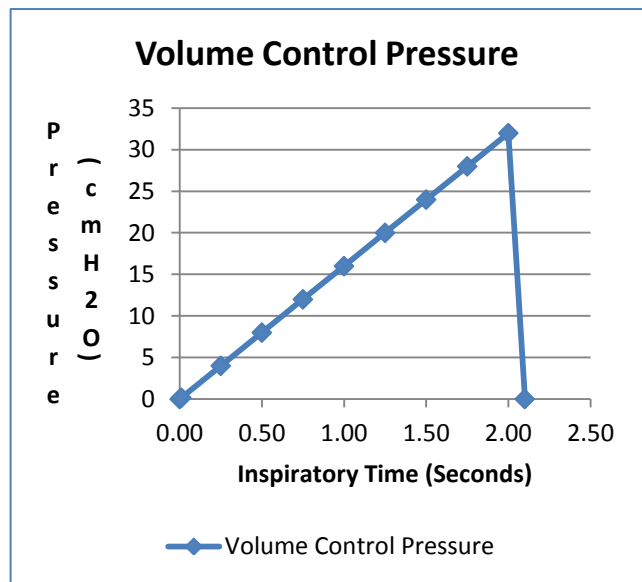
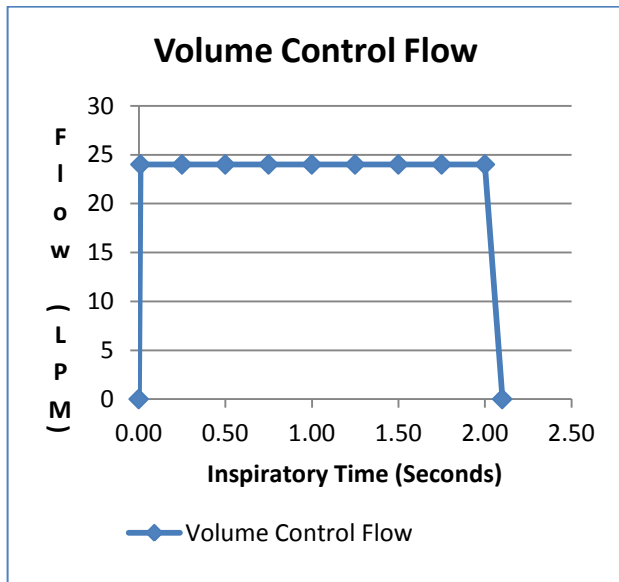
For safety, the ventilator contains an internal anti-suffocation valve.

	<p>Warning: A CBRN Filter is required when the ventilator compressor is used in an environment where air is not safe to breath.</p>
---	--

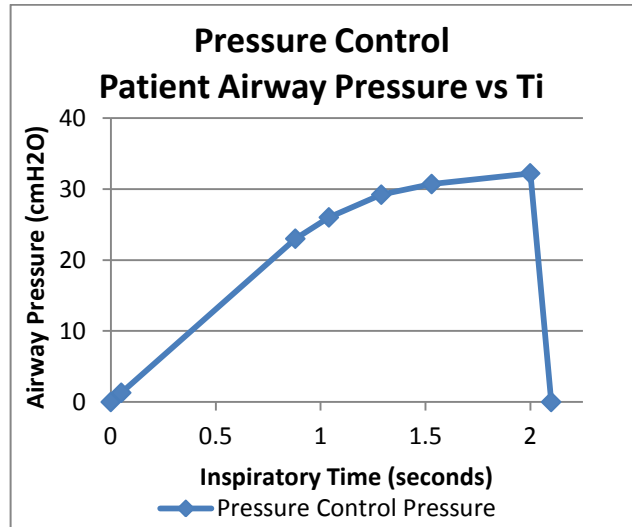
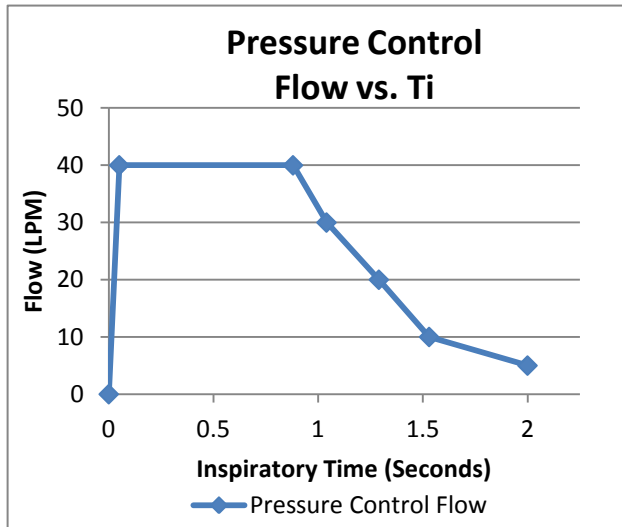
8. Ventilation Modes:

Volume Control: In volume control the ventilator will deliver a set tidal volume at a time cycled interval determined by the inspiratory time and respiratory frequency (BPM) settings. The breath will have a constant flow rate. The flow rate required is a function of the tidal volume (V_t) and the inspiratory time (T_i). The patient's airway pressure will steadily increase during the breath delivery.

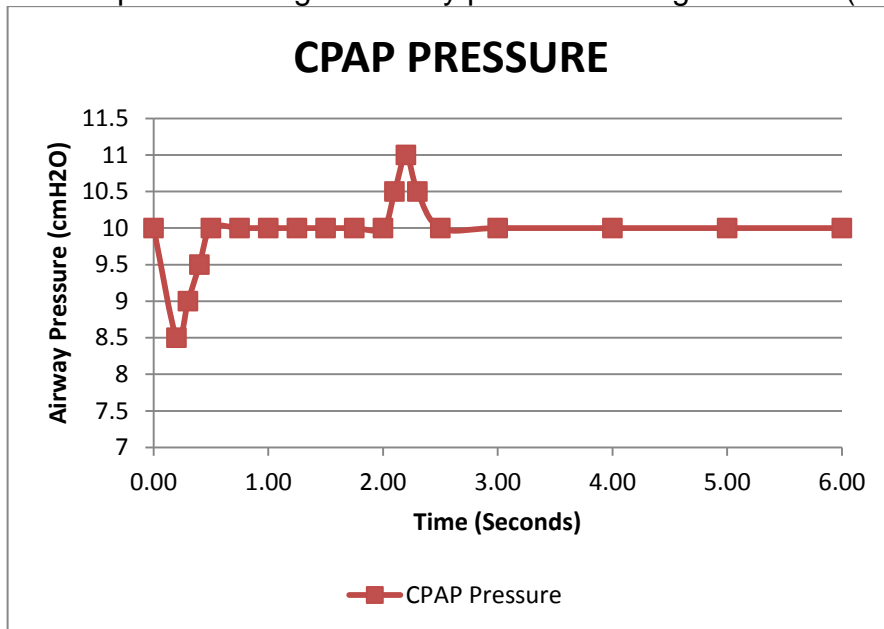
The graphs below shows a typical flow versus inspiratory time graph for a volume controlled breath. The second graph shows a typical patient airway pressure versus inspiratory time pattern.



Pressure Control: In this mode the ventilator will deliver flow to the patient until a set pressure is reached. The flow rate will be variable and will slow down as the airway pressure approaches the set pressure. The ventilator will measure the time and pressures at various points in the breath and then adjust the flows automatically to achieve the pressure curve shown below. If the set pressure is not reached the breath will terminate based on the inspiratory time selected. If the set peak inspiratory pressure is reached before the end of the inspiratory time the, the flow will stop but exhalation will not happen until the end of the inspiratory time. The rate of breathing will be time cycled based on the BPM rate and inspiratory time settings.



Continuous Positive Airway Pressure (CPAP) Mode: The ventilator will maintain the set pressure through inhalation and exhalation. There will be a slight drop in pressure at the start of inhalation and a slight increase at the start of exhalation. The rate of breathing will be based on the patient’s spontaneous respiratory rate. Pressure support may be used to produce a higher airway pressure during inhalation (BI-PAP).



Pressure Support:

In this mode the ventilator will deliver flow to elevate the **inhalation** pressure to the pressure support setting and maintain it at that pressure until the flow required to maintain the pressure is less than 2 LPM . This breath has a maximum inspiratory time per the Inspiratory time setting in the volume or pressure control mode. Pressure support is only activated on patient initiated breaths that are not receiving volume or pressure control. Pressure Support may be used with Volume SIMV, Pressure SIMV and CPAP.

Bilevel Positive Airway Pressure (BIPAP): BIPAP may be achieved on this ventilator by using pressure support in combination with CPAP. To achieve BIPAP the Pressure Support setting would be 15 and the CPAP setting would be 10 as an example. This would produce an airway pressure of 15 cmH₂O during inhalation and 10 cmH₂O during exhalation. The Pressure Support setting must be set higher than the CPAP setting.

Seamless Transition between Volume and Pressure Modes

To facilitate rapid and safe adjustment of therapy by respiratory care professionals the AHP300 incorporates what we call “Seamless Mode Transition”.

When moving from a pressure regulated mode to a volume regulated mode, the prior settings for BPM and Inspiratory Time remain the same and the Tidal Volume that has been measured for the last breath in pressure control mode becomes the initial Tidal Volume for the new volume control mode. Likewise, when the practitioner moves from a volume controlled mode to a pressure controlled mode, the measured Peak Inspiratory Pressure in the volume mode will become the PIP setting for the pressure control mode. In short, the patient sees no change in the ventilator parameters delivered until further adjustment by the RCP, and in that sense, we term the transition seamless.

9. Breath Types:

Assist Control (AC): The ventilator will guarantee that the numbers of breaths given will be equal to or greater than the BPM setting. The patient may trigger additional breaths. When the ventilator detects a spontaneous breath it will deliver a breath per the volume or pressure control settings.

The ventilator will allow a minimum exhalation time of .5 seconds and will not allow a spontaneous breath to be triggered during this time. The ventilator will include a light to signify the delivery of a spontaneous breath and display the number of spontaneous breaths taken during the last minute.

Pressure support is not allowed with this breath type because each spontaneous breath receives full ventilator support per the volume or pressure control settings.

Synchronized Intermittent Mandatory Ventilation (SIMV): The ventilator will deliver only the set number of breaths per minute per the volume or pressure control settings. If the patient is breathing more rapidly than the BPM setting the additional breaths will be demand flow or pressure support (if enabled) breaths.

For example if the BPM is set to 10 the breath period will be set to 6 seconds. During the 6 second period the first breath will be to ventilator settings. Additional breaths will be demand flow or pressure support (if enabled) breaths. The maximum time from the start of one breath to the start of the next breath will also be 6 seconds. If the patient is breathing at a rate slower than the BPM setting, the ventilator will deliver breaths at the set BPM.

The ventilator will allow a minimum exhalation time of .5 seconds and will not allow a spontaneous breath to be triggered during this time. The ventilator will include a light to signify the delivery of a spontaneous breath and display the number of spontaneous breaths taken during the last minute.

10. Programmable Presets:

The ventilator has 2 different programmable presets, Quick Start and Custom modes. The Quick Start modes are for adult and child and have a button for each mode. There are 3 Custom modes that can be set up. One must use the Custom Mode button and the parameter adjustment buttons to select the desired Custom Mode.

Quick Start Modes:

These modes allow the care giving facility or agency to program and store ventilator settings for quickly establishing initial patient ventilation.

There are 2 Quick Start Mode buttons (Adult/Child) for which the settings may be customized based on the direction of a physician. The location of the buttons is shown on the panel below.



Table 1 shows the Quick Start Mode settings as supplied from the factory. **However**, before these buttons can be used, the settings must be confirmed or modified by qualified, trained medical personnel under the direction of a physician. To determine whether the Quick Start Modes have been confirmed or modified by facility medical personnel, press the desired Quick Start Mode button (Adult or Child). If the Quick Start Mode button has been confirmed or modified the settings selected and stored by the qualified medical personnel will be displayed; if not, the light below the button will flash and the unit will beep.

Initial Confirmation or Modification of Default Settings:

To begin the initial confirmation/modification process (Initialization), first push down both Quick Start mode buttons and hold for 3 seconds. The lights below both buttons will begin to flash. Then press the button for the mode (Adult/Child) you wish to confirm or modify. The light below that button will now flash rapidly and the other will turn off. The ventilator will now show the default settings for this button (see Table 1, below).

Table 1

Adult Button		Child Button	
Ventilation Mode:	Pressure AC	Ventilation Mode:	Pressure AC
BPM Setting:	10	BPM Setting:	15
T _i Setting:	2 seconds	T _i Setting:	1.0 seconds
% O ₂	100%	% O ₂ :	100%
PIP:	15 cmH ₂ O	PIP:	15 cmH ₂ O
PEEP:	3 cm H ₂ O	PEEP:	3 cm H ₂ O
Low Pressure Alarm:	10 cm H ₂ O	Low Pressure Alarm:	10 cm H ₂ O
High Pressure Alarm:	30 cm H ₂ O	High Pressure Alarm:	30 cm H ₂ O
Trigger Sensitivity:	2 cm H ₂ O	Trigger Sensitivity:	2 cm H ₂ O

To modify the settings for the selected mode select the parameter to be adjusted and then use the parameter adjustment buttons to revise the setting. (These settings may be changed to any mode on the ventilator.) Once all parameters have been modified to conform to physician directives, the settings must be stored. To store the settings for the selected mode (Adult/Child) Quick Start Mode, press **and hold** the button until the ventilator beeps, about three seconds. (In the event that you decide to use the factory default values, you must still store the settings to confirm and to activate the Quick Start buttons for use.) Once the settings have been stored the button will be initialized and is ready for use.

Storing New Settings:

To store new settings, hold the Quick Start button you are programming down until you hear a beep indicating the settings have been stored. This will take approximately 3 seconds. The light below the button will stop flashing and the ventilator will now operate with the Quick Start settings you just programmed.

If you are in the process of changing the setting of a Quick Start button and decide to abandon the changes one may either press the “Alarm Silence/Reset” button or cycle power. This will exit the Quick Start mode programming or revision process and restore the Quick Start mode button to its previously saved settings.

The process of modifying and storing the settings for a Quick Start button will have to be done twice, once for button #1 and once for button #2.

These buttons should not be initialized while the ventilator is in use on a patient. The ventilator will change to the stored settings at the end of the initializing sequence.



Warning: Do not Initialize the “Quick Start mode” while in use on a patient. Unwanted setting changes may occur.

Using the Quick Start Buttons:

To use the Quick Start mode push one of the Quick Start buttons and the light below the button will blink and the stored settings will be displayed. Push the button a second time and these settings will be activated. If you do not push the button a second time in 10 seconds the displays will revert back to the current ventilator settings and you will need to start the process over.

When the settings are activated the light under the Quick Start button will remain lit until you make a change to one of the settings. Once you make a change to one of the settings the light will go out indicating the operating settings of the ventilator no longer match the stored settings. Any of the ventilation parameters may be changed as directed by the physician. Quick Start serves as a way to quickly recall stored settings and does not impact the operation of the ventilator.

Revising the Stored Quick Start Settings:

The stored settings may be changed if desired. (If you have not initialized the Quick Start button see the section on **Initial Confirmation or Modification of Default Settings** for the Quick Start buttons above.) To revise a Quick Start Mode the ventilator must be operating in the mode (Adult/Child) you wish to revise. To do this, push and release the Quick Start button you want to revise. The stored settings will be displayed and the light under the button will blink. Push the button a second time and the light under the button will turn on and the ventilator will be operating per the settings of the selected Quick Start button you have selected. Hold the same Quick Start button down for 3 seconds. The light below the active button will now flash rapidly and you may revise the stored settings for the button.

To modify the settings for the selected Quick Start mode, select the parameter to be adjusted and then use the parameter adjustment buttons to revise the setting. (Quick Start allows the use of all ventilation modes and associated settings) Once all parameters have been modified to conform to physician directives, the settings must be stored. To store the settings for the selected mode (Adult/Child) Quick Start Mode, press and hold the button until the ventilator beeps, about three seconds. The ventilator will be operating with the stored settings.

Note for CPAP and BIPAP; because the ventilator is operating, it will go into apnea ventilation mode in 20 seconds. If the adjustment is taking longer than 20 seconds, use the test lung to trigger a spontaneous breath or breathe with the circuit. In Pressure Control and Volume Control the use of a test lung is also recommended to prevent alarms from activating.

Custom Modes:

The end user will have the ability to create and recall three Custom Modes. Custom Modes allow the user to preprogram the ventilation modes and settings so they can be quickly recalled. These custom modes allow a common treatment options to be preprogrammed on all AHP300 ventilators that a hospital or EMS service may use based on the physician's direction. For example custom mode #1 could be CPAP at 10 cmH2O. The Custom Modes are in the ventilation mode portion of the control panel. This section is shown below.



Table 2 shows the Custom Mode settings as supplied from the factory. **However**, before these modes can be used, the settings must be confirmed or modified by qualified, trained medical personnel under the direction of a physician. To determine whether the Custom Modes have been confirmed or modified by facility medical personnel, press the Custom Mode button a light by one of the custom modes will begin to flash. If this mode has not been modified or confirmed the ventilator will beep indicating you cannot use this mode. In a couple of seconds the ventilator will return to the previous mode. The parameter adjustment arrows must be used to move between the 3 custom modes.

Initial Confirmation or Modification of Default Custom Mode Settings:

To begin the initial confirmation/modification process (Initialization), select the custom mode (1, 2 or 3) the unit will beep and briefly show the default settings. Now hold the Custom Mode Selection button down for 3 seconds and the Custom Mode light will flash rapidly. The ventilator will now continuously show the default settings for this button (see Table 2, below).

Table 2 Default Custom Modes

Ventilation Mode:	Volume Control
Breath Type:	Assist Control
BPM Setting:	12
T _i Setting:	1 seconds
% O ₂ :	100%
Tidal Volume:	500 ml
PEEP:	0 cm H ₂ O
Low Pressure Alarm:	10 cm H ₂ O
High Pressure Alarm:	30 cm H ₂ O
Trigger Sensitivity:	2 cm H ₂ O

The ventilator will begin operating in the stored default settings. To change a setting select the parameter you want to change and use the parameter adjustment arrows to make the adjustment. To store these settings in the current custom mode, the user will depress the “Custom Mode Selection” button first and then press the “Mode Selection” button. The ventilator will sound a short beep to indicate the custom mode has been saved.

Using the Custom Modes:

To recall a custom mode, the user must deactivate the Control Lock function (if on) and select one of the three custom modes by pushing the Custom Modes button and using the Parameter/Mode Selection button to select the desired custom mode. When a custom mode is selected the light next to the custom mode will flash slowly and the parameters associated with that custom mode will appear in the parameter display windows. If the ventilator beeps when selecting the custom mode see Initial Confirmation or Modification of Default Custom Mode Settings above.

To change the ventilator to operate with these settings as the new ventilator settings the custom mode button must be pushed a second time. The light next to the custom mode will become solid to indicate the mode is now active.

You may change any parameter as needed per the patient’s needs. As soon as a parameter is changed the custom mode light will turn off indicating that the ventilator settings no longer match the stored settings. Any of the ventilation parameters may be changed as directed by the physician as Custom Modes serves as a way to quickly recall stored settings and does not impact the operation of the ventilator.

Revising a Custom Mode

To revise a Custom Mode select the custom mode you wish to revise by pushing the Custom Mode button and using the parameter adjustment arrow to select the mode you wish to revise. The stored settings will be displayed and the light by the Custom Mode will flash. Push the Custom Mode button a second time and the ventilator will now operate with these settings and the light by the Custom mode will stay on. Now that the ventilator is operating in the Custom Mode you wish to revise push the “Custom Mode Selection” button down hold it down for three seconds. The light by the custom mode selection will

now flash rapidly. You may now adjust the mode and any applicable parameter. To store these settings in the current custom mode, the user will depress **and hold** the “Custom Mode Selection” button first and then press the “Mode Selection” button. The ventilator will sound a short beep to indicate the custom mode has been saved.

If you are in the process of changing the setting of a custom mode and decide to abandon the changes one may either press the “Alarm Silence/Reset” button or cycle power. This will exit the custom mode revision process and restore the custom mode to its previously saved settings. The ventilator will continue to operate with the settings that were on the ventilator at the time you exited the programming mode, however the custom mode light will not be on. This is done because the ventilator operates with the settings shown during programming and exiting the programming mode will not revert back to a previous setting.

Note for CPAP and BIPAP; because the ventilator is operating, it will go into apnea ventilation mode in 20 seconds. If the adjustment is taking longer than 20 seconds, use the test lung to trigger a spontaneous breath or breathe with the circuit. In Pressure Control and Volume Control the use of a test lung is also recommended to prevent alarms from activating.

11. O2 Conserve Mode:

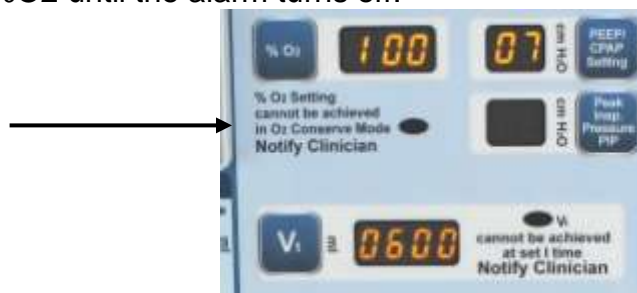
O2 Conserve Mode: This mode allows the use up to 10 LPM of oxygen at .2 to 2.8Bar (20.7 to 275kPa), (3 to 40 psi) through the DISS port or .2 to 2.8Bar (20.7 to 68.9kPa) (3 to 10 psi) through the low pressure, low flow O₂ connection.



Low Pressure, Low Flow O₂ Connection (barb fitting)

O₂ Conserve Mode is activated by pushing the O₂ Conserve button on the control panel. The ventilator will detect if oxygen is available by checking to see if there is greater than .2Bar (20.7 kPa) (3 psi) pressure in the DISS port or Low Pressure, Low Flow O₂ port. If the O₂ source meets the above requirement and an air source (or internal compressor) meeting the normal, greater than 2.7Bar (275kPa) (40 psi) pressure requirement is present, the ventilator will switch to O₂ Conserve mode. If either source is missing the ventilator will not allow O₂ Conserve mode. When the O₂ conserve button is pushed without proper gas sources the O₂ conserve light will turn on, an alarm will beep and the O₂ conserve mode will turn back off.

The ventilator will use oxygen through the DISS port if available and then automatically switch to the Low Pressure, Low Flow O₂ connection. The ventilator will supply the %O₂ per the ventilator setting until the oxygen requirement has exceeded 10 LPM or the available flow from the O₂ source. At that point the light below the %O₂ button will begin to flash and an audible beep will occur. This will be a medium level alarm with a different flashing and sound pattern from the other critical alarms. The operator will need to decrease the %O₂ until the alarm turns off.



If the pressure in the DISS port is below the pressure in the low pressure O₂ port the ventilator will switch to the low pressure barb inlet.

When O₂ conserve has been activated the low pressure alarm point will shift from 2.7 Bar (275kPa), (40 psi) to .2Bar, (20.7kPa) (3 psi). In O₂ conserve mode, if the available O₂ flow drops below 2 LPM the Low O₂ Source Alarm will sound. This alarm will sound, even if the O₂ pressure meets the greater than .2Bar (20.7kPa), (3 psi) requirement.

12. Manual Breaths:

Manual breaths may be delivered using the manual breath button. Each time this button is pushed the ventilator will deliver one breath with the set tidal volume. The unit will deliver only one breath per the ventilator settings when the button is pushed. The button must be released and pushed again to deliver a second breath. The ventilator has a minimum exhalation time of .5 seconds and will not deliver a breath during this time. The ventilator breath timing is reset when the button is pushed.

13. Measured Parameters:

Measured Parameters: The ventilator will measure and display certain ventilation parameters. These parameters are calculated based on the ventilator settings or measured during a breath.

I:E Ratio is the ratio of inspiratory time (T_i) to the expiratory time. This number is calculated based on the selected T_i and the BPM settings. For example if the BPM is set to 10 and the T_i is set to 2 the I:E ratio would be 1:2. This is calculated by determining the breath time. The time for one breath is 60 seconds / BPM ($60/10 = 6$). The expiratory time is the time for one breath minus the inspiratory time. ($6 - 2 = 4$). The I:E ratio is $4/2 = 2$

PIP (Peak Inspiratory Pressure) The Airway Pressure is measured in the patient circuit near the connection to the mask or ET tube. The ventilator will show the current airway pressure except at the end of a delivered breath (inspiration), it will show the peak inspiratory pressure for a brief amount of time.

Delivered Tidal Volume is measured inside the ventilator. When the airway pressure exceeds 80 cmH₂O, this reading will not be accurate. The safety pressure relief will start to actuate and release gas flow outside the vent circuit.

Spontaneous BPM is the number of spontaneous breaths taken in the last minute.

Flow is the flow rate that will be delivered during volume controlled breaths. The flow number shown is approximate as the decimal place is not shown. The flow rate during CPAP and pressure control is not constant and will not be displayed.

14. Alarms:

Electronic Alarms:

Alarm Sound Level is greater than 70 decibels. A large general alarm indicator light will light when any alarm is detected. The light next to the specific alarm will also turn on. Alarms will clear the audible alarm when the alarm condition is cleared but not the visual indicators next to the specific alarm. The silence/reset button will need to be pushed to clear the visual indicator.



System Failure Alarm: This alarm will activate if critical components of the ventilator fail. This alarm has an audible and visual signal. This alarm may not be silenced. You will not be able to adjust the ventilator when this alarm occurs and the system may not be operating to the displayed settings. The alarm activates under the following conditions:

- This alarm will activate if communication between processors in the ventilator fail. Multiple processors have been used so that the failure of one processor can be detected.
- This alarm will also activate if one of its critical sensors fails. If the pressure sensors fail the processor will detect a shift in its 0 pressure signal level and set a system failure alarm.
- If a failure occurs reading from either of the flow sensor's analog or digital signals a system failure alarm will be indicated. This indicates the ventilator is not operating or may not be operating per the settings.



Warning: The ventilator must be taken out of service immediately when a system failure alarm occurs.

Critical Battery Alarm: Activates when there is about 20 minutes of battery life remaining. This alarm may not be silenced. The ventilator will need to be connected to an AC power source or external battery when this alarm sounds. If running on an external battery it will indicate the status of the external battery. This alarm will clear 10 seconds after adequate power is restored. . **If the battery has been allowed to run completely dead (units stops operating) there may be permanent damage to the battery, reducing battery life.** These batteries should be replaced. See Section 21 for instructions. If the ventilator is allowed to shut down due to a low battery, multiple alarms

may occur including system failure. The ventilator's processors may randomly reboot due to the low battery power. This will appear as if the ventilator is turning on and off.

Low O₂ Source Alarm: Activates at 275 to 255kPa (40 to 37 psi) source pressure. Clears 8 seconds after pressure is restored. The alarm is an indication that the unit may stop operating soon and the gas source should be replaced immediately. The AVG-AAH-VENT will automatically switch to 100% air when the ventilator can no longer operate on the compressed O₂ source.

Low Air Source Alarm: Activates at 275 to 255kPa (40 to 37 psi) source pressure. Clears 8 seconds after pressure is restored. The alarm is an indication that the unit may stop operating soon and the gas source should be replaced immediately. The AVG-AAH-VENT will automatically switch to 100% air using its internal compressor when the ventilator can no longer operate on the compressed Air source.



Warning: Set tidal volumes may not be delivered when the low source gas pressure is reached.

Apnea Alarm: Activates if the ventilator does not detect a spontaneous breath or deliver a machine breath in 20 seconds. The ventilator will operate in **Apnea Ventilation Mode** once an apnea has been detected. The Apnea ventilation settings are as follows:
Ventilation Mode = Pressure AC Peak Inspiratory Pressure = 20 cmH₂O
BPM = 10 Inspiratory Time = 2.00 seconds PEEP = 3 cmH₂O

The ventilator displays will show the apnea settings. The ventilator will revert to previous settings if silence/reset button is pushed twice or if the patient has 2 consecutive spontaneous breaths. One may exit Apnea mode and use current settings by changing the Mode in one of the following ways: by pushing the "Mode Selection" button twice, using the Mode selection button to change mode, or going to a stored "Quick Start" or "Custom Mode".

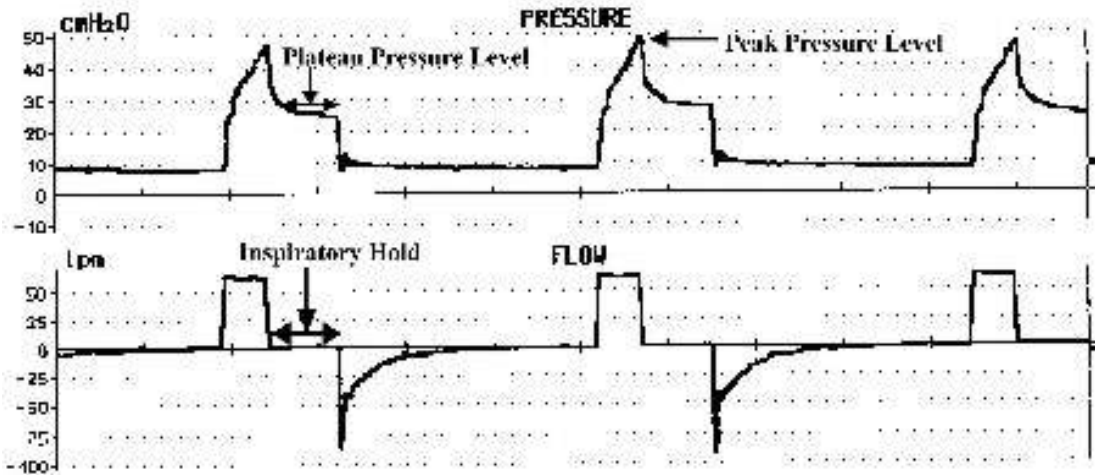
High Airway Pressure Alarm: The High Airway Pressure Alarm setting ranges from 15 to 80 cm-H₂O with an accuracy of $\pm 5\%$ or ± 1.0 cm-H₂O, whichever is greater. The High Airway Pressure alarm is activated when the pressure in the airway exceeds the High Airway Pressure Alarm setting. When this alarm is activated during breath delivery the flow will be terminated and the pressure will be held for the remainder of the inspiratory time. When the pressure in the airway drops below the High Airway Pressure Alarm setting, the High Airway Pressure Alarm will clear in approximately 25 seconds as long as the alarm set point is not exceeded again. The audible alarm can be silenced by pressing the Alarm Silence/Reset button and will reactivate in approximately 110 seconds.



Warning: Preset tidal volumes will not be delivered when the High Airway Pressure Alarm limit is reached. No additional tidal volume will be delivered after the pressure limit is reached.

The airway pressure is measured near the end of the patient ventilation circuit. Restrictions in the patient airway may result in this pressure being higher than the pressures in the lungs. The actual pressure in the lungs is called the **plateau pressure**.

The plateau pressure is measured by not allowing exhalation for a short period (inspiratory hold) after inspiratory flow has stopped. The graph below shows this relationship.




The plateau pressure may be measured by temporarily occluding the outlet of the patient valve during and for a short period at the end of inspiration. The PIP display will show the peak inspiratory pressure for a short time at the end of inspiration and then show the current pressure which in this case will be the plateau pressure.

Low Airway Pressure Alarm: The Low Pressure Alarm setting ranges from 5 to 30 cm-H₂O with an accuracy of $\pm 5\%$ or 1.0 cm-H₂O, whichever is greater. The Low Airway Pressure alarm is activated when the pressure in the airway drops below the Low Pressure Alarm setting for a period of approximately 12 seconds. If a spontaneous breath occurs the ventilator will deliver a breath at the set tidal volume and reset the 12 second period. When the pressure in the airway rises above the Low Pressure Alarm setting, the Low Pressure Alarm clears instantly. The audible alarm can be silenced by pressing the Alarm Silence/Reset button and will reactivate in approximately 110 seconds.

Excessive Patient circuit Leak Alarm: A Leak Alarm is indicated in pressure control mode if on 3 consecutive breaths the pressure fails to reach 75% of the PIP setting and the initial flow is greater than 60 lpm. In CPAP a Leak Alarm is indicated if the flow exceeds 10 lpm for more than 5 seconds.

Silence/Reset Button: Silences existing audible alarms for 110 seconds but does not silence any new alarms. In addition it clears the visual indicator for cleared alarms.

The pneumatic pressure relief is set to limit the maximum system pressure to ≤ 85 cmH₂O. This is a backup system in case the high pressure alarm does not function properly.

	<p>Warning: Preset tidal volumes may not be delivered when the pressure relief setting is reached. Inspiratory times will remain constant, however no additional tidal volume will be delivered after the pressure relief setting is reached.</p>
---	--

15. External Alarm Connection:



An external alarm connection is provided. This connection uses a standard ¼ inch phono jack. This jack is commonly used as an auxiliary connection in nurse call systems. The connection is normally open and closes when an alarm occurs. The connection will be capable of handling a maximum of .5 amps @ 125 volts AC or 1 amp at 30 volts DC signal. The minimum signal required is 1 ma @ 5 volts.



Warning: Use only insulated connectors for the external alarm connection. The use of non-insulated connectors will result in a shock hazard if using high voltages.

16. Battery Parameters:

Battery Level

The battery level is shown in the Battery Parameters of the control panel. The ventilator will monitor battery voltage and display the current battery voltage.



When the battery level has reached a low level the left 2 lights will turn red indicating the ventilator should be connected to an external power source. This indicator will blink and an alarm will sound when the battery reaches a critical level and must be connected to an external source immediately.

Battery Charging

When the ventilator is connected to an external AC power source the “External AC Power” light will come on and the battery will charge if necessary. This will be indicated by the right most light of the battery level indicator flashing.

To maintain optimum battery life, this unit should be plugged in at all times when not in use. If unable to do so, the unit should be fully charged once a week. Failure to do so will degrade the capacity of the battery. This will result in a battery life of less than 7 hours.

If the internal battery has run down and the unit stops operating, (runs past the Critical Battery Alarm) the unit may be connected to an AC power source to restore operation. If the battery has been allowed to run completely dead (the units stops operation) there will be permanent damage to the battery, reducing battery life. These batteries should be replaced.

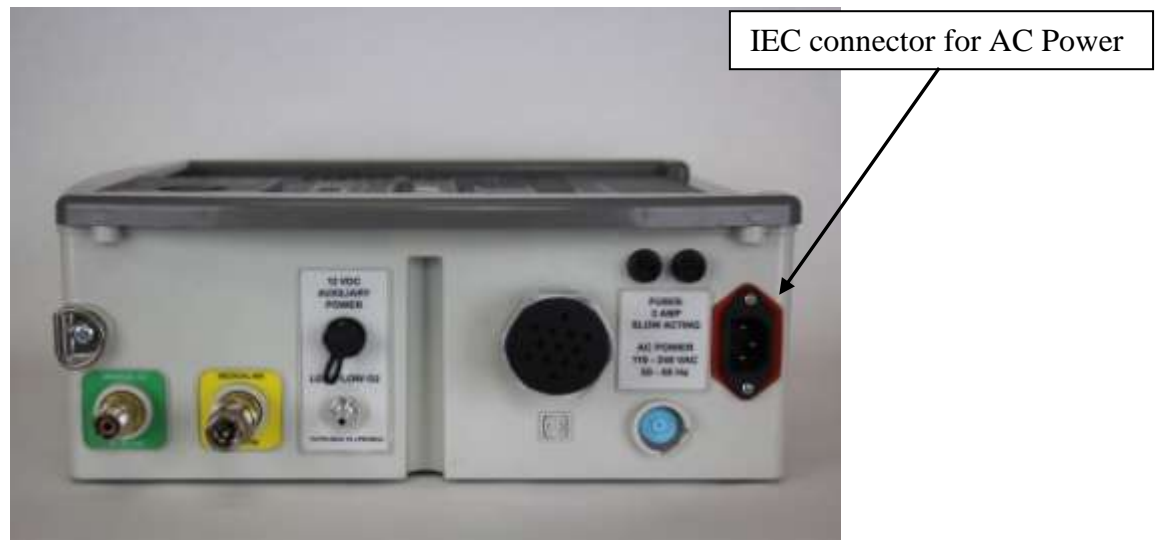
The unit will charge automatically when connected to an AC power source. The unit will charge the battery only when necessary and can be left plugged in at all times. If the battery does not recharge in 7 hours all the lights on the battery indicator will blink letting the user know the battery does not have full capacity and should be replaced. The recharge time for the internal battery is less than 5 hours when the unit is off (the recharge time is approximately 10 hours when in use.)

If the auxiliary battery is plugged in the “External Battery Power” light will come on. If the auxiliary battery is plugged in the unit will show the level of the external battery and will only charge the auxiliary battery when connected to AC power.



Warning: Grounding reliability can only be achieved when the equipment is connected to a hospital grade receptacle.

17. AC Power Inlet and Auxiliary Power Connection:




A 110/240 Volt 50/60 Hz AC power source may be connected to the unit using the connector as shown above. The unit has a switching power supply inside it and automatically compensates to cover the full range of voltage and power frequencies. The unit will automatically charge the internal battery when connected to an AC power source. Plugging in the unit during breath delivery may affect the volume of the breath delivered. Plug the unit in between breaths.

Connecting the auxiliary power source MCV-AUXBAT is done by first aligning the keyed connector with the keyed inlet on the unit and then inserting the connector into the inlet. Twisting the ring on the connector clockwise will then lock the connector to the unit. To remove the auxiliary power supply, twist the connector counterclockwise and then pull the connector straight out of the socket. Contact manufacturer for information on an approved auxiliary power source.

The MCV-AUXBAT contains batteries capable of delivering 10 amp-hours of power. This is approximately twice as much power as contained in the internal battery of the AVG-AAH-VENT. Use of this device can approximately triple the battery run time.



AHP300 with Auxiliary Power Source MCV-AUXBAT

	<p>Warning: Auxiliary power connection is keyed. Make sure that connectors are properly aligned before insertion, do not force. Damage to the ventilator may occur making the ventilator unavailable for use.</p>
	<p>Caution: Use only the MCV-AUXBAT external battery pack, damage to the ventilator may occur with a non-approved battery pack.</p>

The auxiliary battery pack will charge through the ventilator if the external power supply is also plugged in at the same time. Remove the auxiliary battery pack to charge the ventilator's internal battery.

Do not plug the auxiliary battery pack into an AC power source when connected to the ventilator. The auxiliary battery pack's internal charging system is disabled when connected to a ventilator.

18. Cleaning:

The AHP300 should be cleaned after each use. To clean the ventilator, keep the gas supply hose on the unit to prevent contamination of the oxygen circuit.



Warning: Cleaning procedures should be performed in an environment free of oil and petroleum based products.

The AHP300 has been designed to be water resistant but the unit cannot be submerged or sprayed down for cleaning.

Wipe the unit down with a damp rag containing a mild cleaning solution to remove any residue from the surface. Once the residue has been removed the unit should be wiped with isopropyl alcohol or a cold disinfecting solution to kill bacteria. The unit should then be wiped down with water to remove any film left by the cold disinfecting solution. Make sure the unit is dry before putting the unit away. The following is a list of tested cleaning solutions:

1. Isopropyl Alcohol: 70% IPA
2. Cetylcide: 30ml Cetylcide to 3.8 liters H₂O
3. Bleach: 10% Bleach in H₂O



Warning: Do not attempt to clean and re-use single patient ventilation circuits as loss of performance may occur.

Dispose of single patient use items per local biohazard standards.

19. Check Out Procedure:

The unit should be checked for proper operation before each use. This can be done after cleaning to prepare the unit for the next use.

Set the ventilator to the following settings:

Mode = Volume AC
BPM = 10
Inspiratory Time = 2 seconds
Tidal Volume = 800 ml
%O₂ = 100

General Operation Check:

1. Connect a 3.4 Bar (344kPa), (50 psi) oxygen source to the unit, turn the power on and it should begin to cycle.
2. Using a watch count the number of breaths delivered in 1 minute (60 seconds).
 - a. Confirm that between 9 and 11 breaths have been delivered.
 - b. Confirm that the inspiratory time is significantly shorter than the expiratory time. (At the settings noted above, ventilator should provide a 2 second inspiratory time and a 4 second expiratory time.)
 - c. You will be receiving a low airway pressure alarm.
 - d. Occlude the ventilator outlet and you should see the high airway alarm and the PIP should read nearly the same as the alarm setting.
3. Repeat for Air (%O₂ = 21)
4. Press and release the manual breath button and confirm that a breath is triggered.

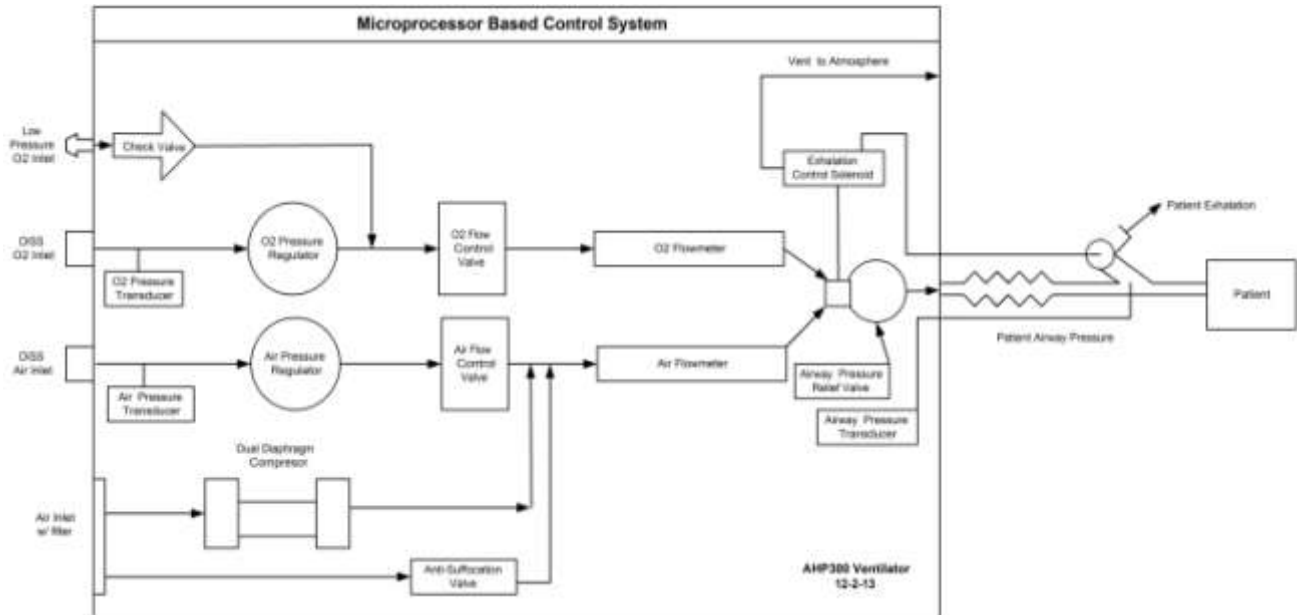
Alarm Mode Check:

1. Turn the source gas off and wait for the pressure to drop.
 - a. Confirm that the low gas LED indicator is on and the main alarm light is on.
 - b. Confirm that the low source gas alarm sounds

Should the unit fail any of the tests contact Modi Innovations Service Department
at Phone : +91 240 247 8855 / +91 8888885665 / +91 9673478855

Always store the ventilator in a clean dry place.

20. Pneumatic Diagram:



21. Maintenance:

The following section provides information on basic maintenance as well as annual maintenance schedules and procedures for this ventilator. Performing the Verification of Calibration and Function annually is required to ensure the ventilator performs to specifications. Maintenance is required to ensure ventilator performance and reliability.

Routine Maintenance:

Between Patients

- Clean the ventilator after each patient. Cleaning should be performed as described in section 18 of the manual. Before use of a cleaning agent follow manufacturer's instructions and confirm that it is compatible with ABS plastic and Polyester plastics. If the cleaning agent causes crazing (fine cracks on the surface) discontinue the use of the ventilator and contact your authorized distributor for repair.
- Follow the checkout procedure described in section 19.

Every 4 Months

- Particle Filter Replacement:



The AHP300 contains a particle filter located inside the air inlet on the side of the unit. This filter cleans the ambient air drawn in by the compressor. This filter should be checked every 4 months and changed if visibly dirty. Stockpiled ventilators that are not being used may skip this step as no dirt will collect when not in use.

To replace the filter, remove the protective screen by prying off with a dull flat tool. Once the screen is removed the filter can be removed and replaced.

The Air intake port is connected to the internal ground and may be used when testing for electrical leakage currents.

Charge battery as described in section 16. (This 4 month battery charge protocol is only necessary if the ventilator is stored without continuous charging.)

Yearly maintenance

- Yearly Verification of Calibration and Function
Perform Yearly Verification of Calibration and Function as described on page 40.

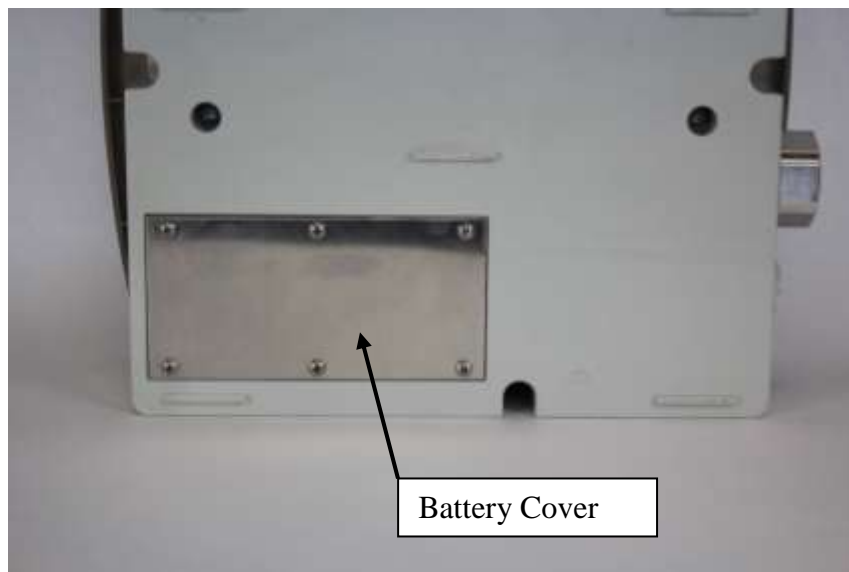
Every 3 years maintenance

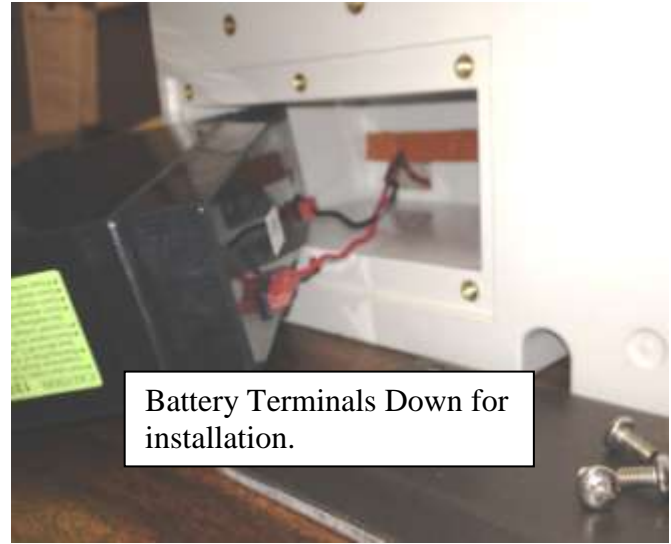
- Calibration and Battery Replacement.

Calibration and Battery Replacement must be performed by factory trained personnel.

- Battery Maintenance/ Replacement:

The AHP300 battery level should be checked every four months. If not kept on continuous charge, charge the battery at this time. If the battery does not reach full charge within 5 hours, the battery should be replaced at that time. If the battery does not recharge in 7 hours all the lights will blink on the battery indicator letting the user know the battery does not have full capacity and should be replaced. **If the battery has been allowed to run completely dead (units stops operating) there may be permanent damage to the battery reducing battery life.** These batteries should be replaced as soon as possible. Every three years, the lead acid battery in the unit should be replaced. This battery must be disposed of as required by local ordinances.





To remove the battery, remove the screws from the aluminum panel on the back of the ventilator as shown above. Use a pair of pliers to remove the connectors from the battery terminals. Do not pull the connectors off using wires as this may damage the ventilator.

Move the piece of foam from the old battery to the new battery. Connect the red wire to the “+” side of the battery first. The terminals are different sizes and the “+” red wire terminal will only fit in the “+” side of the battery. When reinstalling the battery, the terminals should be towards the bottom of the unit so they line up with the cutouts inside the battery compartment.



Warning: Use only a 12volt HC1221W battery or equivalent. Improper function or damage to the ventilator may occur with the wrong battery.

Every 6 Year Maintenance

- Comprehensive Maintenance:

Every six years, the unit should be sent to a qualified service center for a comprehensive maintenance. This maintenance includes replacement of battery, all seals in the ventilator including internal regulators, replacement of compressor, replacement of flow sensors and plastic tubing and fittings. This maintenance also includes calibration and performance testing of the ventilator. This maintenance must be performed by personnel trained by manufacturer on how to maintain this ventilator.

Maintenance Requirements For AHP300 Ventilators

Every 4 Months Charge Battery or keep on continuous charge if not in use

Year 1 Maintenance Check List

Verification of Calibration and Function	Time Required 30 Minutes
Charge Battery	

Year 2 Maintenance Check List

Verification of Calibration and Function	Time Required 30 Minutes
Charge Battery	

Year 3 Maintenance Check List

Manufacturer Maintenance* Calibration and Battery Replacement <ul style="list-style-type: none"> • Replace Battery • Calibrate & Performance Test Unit 	Time Required 4 Hours
---	-----------------------

*** Must be performed by by factory trained personnel.**

Year 4 Maintenance Check List

Verification of Calibration and Function	Time Required 30 Minutes
Charge Battery	

Year 5 Maintenance Check List

Verification of Calibration and Function	Time Required 30 Minutes
Charge Battery	

Year 6 Maintenance Check List

Manufacturer Maintenance * <ul style="list-style-type: none"> • Replace Seals • Replace flow sensors • Replace Battery • Replace compressor Calibrate Unit and Performance Test	
---	--

***Manufacturer Maintenance must be performed by by factory trained personnel.**

Yearly Verification of Calibration and Function:

Equipment Required

- Respicap, RT200 or equivalent ventilator calibrator
- 50 psi regulated Oxygen and Air source
- 110 VAC, 60 Hz or 220 VAC, 50 Hz
- Power Cord
- Ventilator Patient Circuit
- Test lung or restrictor

Procedure

- Connect the Oxygen source to the AHP300.
- Use the power cord and connect the unit to 110 VAC, 60 Hz, or 220 VAC, 50Hz power source.
- Connect the ventilator circuit to the AHP300 outlet and the ventilator calibrator.
- Set the tidal volume to 300 setting and turn the AHP300 on. Readjust the gas source to 50 psi if necessary.
- Set the gas selection to 100% O₂.
- Adjust the BPM rate, inspiratory time and tidal volume per the following table and verify the output is in the acceptable range:

BPM	Acceptable Range BPM	Tidal Volume	Acceptable Range Tidal Volume	Flow (ref)
10 (Ti = 2)	9 to 11	2000	1800 to 2200	60
20 (Ti = 1.5)	18 to 22	1250	1125 to 1375	50
30 (Ti = 1)	27 to 33	675	607 to 743	40.5
40 (Ti = .75)	36 to 44	375	337 to 413	30
40 (Ti = .75)	36 to 44	250	225 to 275	20
50 (Ti = .5)	45 to 55	100	90 to 110	12
60 (Ti = .5)	54 to 66	40	30 to 50	4.8

Note, the airway pressure needs to reach a minimum of 5 cmH₂O during this test, adjust the test lung as necessary to maintain pressure between 5 and 25 cmH₂O. Read the tidal volume after 5 - 10 breaths.

- Set the %O₂ to 60 O₂ Retest the tidal volumes per the above table.
- Set the %O₂ to 21 (Air). Retest the BPM and tidal volumes per the above table.
- Turn the ventilator off and disconnect the compressed gas sources. Turn the ventilator back on and test the compressor function.
- To test the high airway pressure alarm, set the alarm to 40 cm H₂O. The alarm LED and the buzzer should turn on and the HPA setting should flash on the LCD. To silence the alarm, hold the Alarm Silence button down for 3 seconds.
- To test the low airway pressure alarm, set the alarm to 5 cm H₂O. Open the patient outlet and the alarm/light will turn on in about 15 seconds.
- Turn off the gas supply and the low gas alarm/light will turn on and the pump will automatically activate in one minute.

If the ventilator fails this test it must be repaired by factory trained personnel before use. If problems are noted with this product, contact the manufacturing representative.

The following is a sample log that may be used for recording test records during Yearly Verification of Calibration and Function.

Test Log

Test Date:

BPM	Acceptable Range	Reading			
10	9 to 11				
20	18 to 22				
30	27 to 33				
40	36 to 44				
50	45 to 55				
60	54 to 66				
Tidal Volume	Acceptable Range	100% O2	60% O2	Air	Int Comp
40	30 to 50				
100	90 to 110				
250	225 to 275				
375	417 to 412				
675	607 to 743				
1250	1125 to 1375				
2000	1800 to 2200				
Pressure Relief High Pressure Alarm	NO higher than 60 cmH2O Light Buzzer				
High Airway Pressure Alarm	Light Buzzer				
Low Airway Pressure Alarm	Light Buzzer				
Low Source Gas	Light Buzzer				

AC Inlet Fuse Replacement

The AC power inlet is protected by 2 fuses. If a fuse is blown the unit will not charge the battery. Should one of the fuses need to be replaced it can be replaced as follows;

Remove the fuse by turning the fuse holder ¼ turn counter-clockwise. Replace the fuse with a 2 amp 250VAC slow acting fuse (5mm x 20mm).



Warning: Use only the specified fuse. Improper fuse rating may result in damage to the ventilator or electrical shock to the user.



Specifications:

Power/Gas Supply

A. Gas Supply Pressure:

High Pressure: 280 kPa (40.6 psi) to 600 kPa (87.0 psi) Oxygen DISS and Air DISS or 69 kPa (10 psi) to 275 kPa (40.0 psi) Oxygen DISS in O2 conservation mode.

Connections: CGA V5 O2 and Air DISS Inputs
ISO 5356 22 mm Output

Low Pressure O2: Up to 10 LPM at less than 10 PSI

Connections: 1/8" Barb

B. Gas Flow: 5 to 60 LPM in Volume Mode and peak flows > 80 LPM in Pressure Control, CPAP and demand flows.

C. Electrical Rating:

Operating Voltage: 12 volts DC 5.0 amp current draw at 12 volts

Input Voltage AC: 110 to 240 volts AC, 50 to 60 HZ <1 Amps max current draw. (55 watts)

Input Voltage DC: 11 to 15 volts DC, 5.0 Amps max current draw.

Replacement Fuses 2 amp 250 volt rating

Control Settings

D. Inspiratory Time (T_i): Accuracy: ±10%

.5 to 2.0 seconds in increments of .25 seconds

E. Breaths per Minute (BPM) or Frequency: Accuracy: ±10%

BPM Range: .50 sec Inspiratory Time = **0 and 5 to 60**

BPM Range: .75 sec Inspiratory Time = **0 and 5 to 45**

BPM Range: 1.0 sec Inspiratory Time = **0 and 5 to 30**

BPM Range: 1.25 sec Inspiratory Time = **0 and 5 to 20**

BPM Range: 1.50 sec Inspiratory Time = **0 and 5 to 20**

BPM Range: 1.75 sec Inspiratory Time = **0 and 5 to 20**

BPM Range: 2.00 sec Inspiratory Time = **0 and 5 to 20**

F. O2 Blending Capability: The vent will be capable of O2 blending in mixtures from 21% to 100% O2 in 1% increments. O2 mixture will have an accuracy of 12%

G. CPAP/PEEP Range; 0 to 25 cm H2O

Inadvertent PEEP: ≤ 2 cm H2O

H. Peak Inspiratory Pressure: 15 to 55 cm H2O Accuracy ±2 cm H2O or 10% whichever is greater.

I. Tidal Volume (V_t):

Accuracy: $\pm 10\%$ with 100% Oxygen or 100% Air, $\pm 12\%$ for blended gases
For temperatures below 15F:

Accuracy: $\pm 12\%$ with 100% Oxygen or 100% Air, $\pm 14\%$ for blended gases

Flows from 5 to 60 LPM produce the following tidal volumes

Tidal Volume Range .5 Second Inspiratory Time = 40ml to 500ml

Tidal Volume Range .75 Second Inspiratory Time = 60ml to 750ml

Tidal Volume Range 1 Second Inspiratory Time = 80ml to 1000ml

Tidal Volume Range 1.25 Second Inspiratory Time = 100ml to 1250ml

Tidal Volume Range 1.50 Second Inspiratory Time = 125ml to 1500ml

Tidal Volume Range 1.75 Second Inspiratory Time = 150ml to 1750ml

Tidal Volume Range 2.00 Second Inspiratory Time = 175ml to 2000ml

J. Trigger Sensitivity Adjustment; 1 to 5 (approximately 1 to 5 cm H₂O) The level of effort to trigger an assisted breath.

K. Pressure Support Range; 0 to 25 cm H₂O The level of pressure support given on a spontaneous breath that is not receiving a pressure control or volume control breath.

L. High Airway Alarm Range; Adjustable from 15 to 80 cm H₂O with an accuracy of $\pm 5\%$ or ± 1 cm H₂O whichever is greater. Audible and visual alarm sounds when pressure is exceeded.

M. Low Airway Alarm Range; Adjustable from 0 to 20 cm H₂O. Audible and visual alarm sounds when pressure is not exceeded during a 15 second time span.

N. Safety Pressure Relief: Fixed at 88 cm H₂O Accuracy: $\pm 10\%$ cm H₂O.

Additional Settings

O. Manual Breath; Delivers one breath per ventilator settings with a minimum exhalation time of .5 seconds. (Not available in CPAP mode)

P. O₂ Conserve Mode; Allows the use of oxygen at 10 to 40 psi through the DISS fitting or low pressure oxygen 10 to 3 psi through the barbed fitting. Gas flows are limited to 10LPM in this mode. If gas is connected to the DISS port the ventilator will not use gas through the barb fitting.

Q. Control Lock: When this button is pushed a LED will turn on and the control panel will not recognize any button pushes. Pushing the button a second time will turn off the LED and resume normal operation of control panel.

R. Ventilation Modes

- Volume Control w/ Assist Control
- Volume Control with SIMV
- Pressure Control w/ Assist Control
- Pressure Control with SIMV
- CPAP

- S. Custom Ventilation Modes:** The ventilator allows 3 custom modes to be stored and recalled. The custom modes may be any of the ventilation modes and the appropriate parameters.
- T. Battery Parameters:** A battery level indicator shows the battery status for the battery in use. When the battery gets low the battery level indicators will flash yellow to alert the user that the battery is low.
- External AC Power Connected when lit: This light indicates that the ventilator has been connected to AC power. When connected the battery will charge and battery level indicators will flash to indicate the unit is charging. The ventilator may be operated and charged at the same time.
 - External Battery Power Connected when lit: This light indicates that a battery pack or other 12 volt source has been connected to the ventilator. The internal battery will be disconnected and the battery level indicators will show the level of the external battery.

Alarms

U. Electronic Alarms:

Alarm Sound Level is greater than 70 decibels. A large general alarm indicator light will light when any alarm is detected. Alarms will clear the audible alarm when the alarm condition is cleared but not the visual indicators. The silence/reset button will need to be pushed to clear the visual indicator.

- * **System Failure Alarm:** This alarm will activate if communication between the processors fail. This indicates the ventilator is not operating or may not be operating per the settings. When the processor fails the alarm sounds and a light will turn on. This alarm may not be silenced.
- * **Critical Battery Alarm:** Activates when there is about 20 minutes of battery life remaining. This alarm may not be silenced.
- **Low O2 Source Alarm:** Activates at 2.7 to 2.5 Bar (275 to 255kPa) (40 to 37 psi) source pressure. Clears 8 seconds after pressure is restored. This alarm does not activate if the %O2 setting is 21%(Air only)
- **Low Air Source Alarm:** Activates at 2.7 to 2.5 Bar (275 to 255kPa) (40 to 37 psi) source pressure. Clears 8 seconds after pressure is restored. This alarm does not activate if the %O₂ setting is 100%(O₂ only)
- **Apnea Alarm:** Activates if the ventilator does not detect a spontaneous breath or deliver a machine breath in 20 seconds. The vent will operate in apnea ventilation mode once an apnea has been detected.
- **High Airway Pressure Alarm:** 15 to 80 cm H₂O Accuracy \pm 5 %
Stops flow when activated. High airway alarm clears in 25 seconds if pressure is not exceeded.
- * **Low Airway Pressure Alarm** Activates if the Airway pressure does not go above the set point of 5 to 30 cm H₂O during a span of 15 seconds. Clears when pressure exceeds the set point. The low airway alarm will also clear if a spontaneous breath is detected.
- * **Silence/Reset Button:** Silences existing audible alarms for 110 seconds but does not silence any new alarms. In addition it clears the visual indicator for cleared alarms.

- * **External Alarm Connection:** A ¼ Phono style jack connection will be provided. This connection will provide a normally open switch that will close when an alarm occurs. The connection will be capable of handling a maximum of .5 amps @ 125 volts AC or 1 amp at 30 volts DC signal. The minimum signal is 1 ma @ 5 volts.

Measured Parameters:

- V. I to E ratio (Inspiratory time to Expiratory time)** This will be calculated based on the Inspiratory time and BPM selected.
- W. Airway Pressure;** 0-99 cm H₂O (0 – 5.9 kPa) accuracy ± 5% or ±1 cm H₂O whichever is greater.
- X. Delivered Tidal Volume:** This is calculated based on inspiratory flows over time and displayed to an accuracy of 10%.
- Y. Spontaneous Breaths per Minute:** This is the number of spontaneous breaths in the last minute.

Other Information

- Z. Battery Life:** Run time at room temperature 21°C (70±5°F), BPM=10, and Tidal Volume=600ml.
 - a. 100% O₂: 7.5 hours (Approx 5 hours at 0°F (-18°C))
 - b. 100% Air: 7.5 hours (Approx 5 hours at 0°F (-18°C))
 - c. 100% Air Compressor: 7 hours (Approx 4 hours at 0°F (-18°C))

AA. Oxygen Inlet Filter: 65 Micron sintered bronze.

BB. Burst Pressure: 145 psig (1000kPa) minimum through oxygen inlet.

CC. Inspiratory and Expiratory Resistance: 5 cm H₂O (.5kPa) maximum

DD. Dead Space: ≤ 5.5% of minimum tidal volume

EE. Peak Inspiratory Flow: >80 LPM

FF. Weight: 8.5 kg (18.8 lbs)

GG. Size: 135 x 338 x 350 mm (5.3 x 13.3 x 13.8 inches)

HH. Operating Conditions: -18°C to 50°C (0°F to 122°F)

5% to 95 % non-condensing relative humidity

IP22 Protected from touch from fingers greater than 12 mm and water spray less than 15 degrees from vertical.

II. Storage Conditions: -40 to 60°C (-40 to 140°F)

10% to 95 % non-condensing relative humidity

JJ. Shipping Conditions: -40 to 60°C (-40 to 140°F)

5% to 95% non-condensing relative humidity

KK. Sound Level: < 40dBA with compressed gas tested per ISO 80601-2-12.

< 50 dBA with internal compressor and flows less than 36 LPM

Max sound level with internal compressor is <55 dBA.

Note:

This ventilator has been tested (life cycle testing) to meet the specifications over the life of the product. The worst case mode of operation is volume control as any drift in the flow control mechanisms may impact the ability to meet specifications. Maintenance schedules must be followed to ensure the product can reliably meet specifications.

22. Accessories and Replacement Parts:

Part Number	Description	Qty per Package	Usage	See page for instructions
L599-600	6' Adult Single Limb Vent Circuit (22mm Corrugated Tubing)	10	Disposable Single Patient use	9
L599-650	6' Pediatric Single Limb Vent Circuit (15mm Corrugated Tubing)	10	Disposable Single Patient use	9
L595161-10	Disposable Cuffed Oxygen Mask, Adult	10	Disposable Single Patient use	10
L595162-10	Disposable Cuffed Oxygen Mask, Child	10	Disposable Single Patient use	10
L599-200	Exhalation Filter	10	Disposable Single Patient use	10
L535026	Replacement Oxygen Hose 6ft W/ DISS	1	Reusable	8
83-90-0113	Replacement Air Hose 6ft W/ DISS	1	Reusable	8
MCV-AUXBAT	External Battery Pack	1	Reusable	30
801163	Battery 12volt	1	3 year life	38

23. NBR Filter:

NBR Hazardous Environment Filter (not included):

This filter should be used when a patient may breath spontaneously in a hazardous environment.

The air inlet fitting on the AHP300 has an internal 40 mm threaded connection per EN 148-1:1999. This is the standard thread connection for respiratory protective devices typically used by industry, law enforcement, and the military. This connection will accept air filters used in hazardous environments. To install, remove the air inlet screen and dust filter. The AHP300 will perform within manufacturer's specifications when used with filters that are in compliance with requirements as specified in NIOSH-42 CFR Part 84. Refer to filter manufacturer's specifications for gas type, filter life, and all other properties of the filter. Filter model FR-15-CBRN manufactured by 3M has been tested with this ventilator



Warning: Use of any filter with flow capacity of less than 40 LPM can degrade performance of the ventilator and may not provide filtration against the toxic environment for its intended use. Refer to manufacturer specifications for filter life.



Warning: Tighten filter in place securely to insure that the seal is air tight. Failure to tighten the filter may allow dangerous chemicals into the patient's lungs.

24. Oxygen Cylinder Depletion Times:

These times are approximate and assume full cylinder capacity. Always monitor the cylinder pressure and low pressure alarm to make sure you do not run out of oxygen.

**E Cylinder Capacity = 682 Liters Oxygen Capacity
(4.6 Liters Water Capacity)**

Breaths per Minute

Tidal Volume ml	Breaths per Minute							
	8	9	10	12	14	15	18	20
1200	67	60	54	46	39	37		
1000	80	72	65	54	47	44		
800	98	88	80	67	58	54		
600	127	115	104	88	76	72	60	54
500	149	135	123	104	90	85	72	65
400	180	163	149	127	111	104	88	80
300	225	206	189	163	143	135	115	104
200	293	274	256	225	200	189	163	149

**Jumbo D Cylinder Capacity = 637 Liters Oxygen Capacity
(4.0 Liters Water Capacity)**

Breaths per Minute

Tidal Volume ml	Breaths per Minute							
	8	9	10	12	14	15	18	20
1200	63	56	51	43	37	34		
1000	75	67	61	51	44	41		
800	92	82	75	63	54	51		
600	119	107	97	82	71	67	56	51
500	139	126	115	97	85	79	67	61
400	168	152	139	119	104	97	82	75
300	210	192	177	152	134	126	107	97
200	274	256	239	210	187	177	152	139

**D Cylinder Capacity = 414.6 Liters Oxygen Capacity
(2.8 Liters Water Capacity)**

Breaths per Minute

Tidal Volume ml	Breaths per Minute							
	8	9	10	12	14	15	18	20
1200	41	37	33	28	24	22		
1000	49	44	39	33	29	27		
800	60	54	49	41	35	33		
600	77	70	63	54	46	44	37	33
500	91	82	75	63	55	52	44	39
400	109	99	91	77	67	63	54	49
300	137	125	115	99	87	82	70	63
200	178	166	155	137	122	115	99	91

25. Approximate Tidal Volume Settings based on Height:

APPROXIMATE SETTINGS BASED ON PATIENT HEIGHT

Tidal Volume (ml) @10 ml/Kg	50	100	200	300	400	500	600	700	800	900	1000	1100	1200
Tidal Volume (ml) @8 ml/Kg	40	80	150	250	325	400	475	550	650	725	800	875	950
Tidal Volume (ml) @6 ml/Kg	40♦	60	120	175	250	300	350	425	475	550	600	650	725
Height Male inches (cm)	22.5* (57)	35* (89)	45* (114)	53* (134)	58* (147)	60• (152)	64 (163)	69 (175)	73 (185)	77 (196)	82 (208)	86 (218)	90 (229)
Height Female inches (cm)	22.5* (57)	35* (89)	45* (114)	53* (134)	59* (150)	62 (158)	66 (168)	71 (180)	75 (190)	79 (201)	84 (213)	88 (224)	92 (234)
Ideal Body Weight Kg	5	10	20.0	30.0	40.0	50.0	60.0	70.0	80.0	90.0	100.0	110.0	120.0

Tidal Volumes are show at the closest ventilator setting allowed

- Dr. Devine formula for heights of 60 inches (152 cm) or taller.
Male Height (inches) = $((IBW-50)/2.3)+60$
Female Height (inches) = $((IBW-45.5)/2.3)+60$
- * CDC Growth Charts Ages 2 to 20 Boys and Girls Charts(modified 11/21/00) and CDC Growth Charts Ages Birth to 36 Months Boys and Girls Charts (modified 4/20/01)
- ♦ 40 ml is the minimum tidal volume delivered by the AHP300

26. Warranty:

Limited One (1) Year Warranty

AHPI warrants this product to be free from defects in material and workmanship for a period of one (1) year from the date of manufacture. This Warranty is expressly conditioned on compliance with all inspection and preventative maintenance requirements as set by applicable government agencies and as specified by AHPI.

This warranty is extended by AHPI only to the first purchaser of this product from either AHPI or its authorized distributor.

AHPI's OBLIGATIONS AND PURCHASER'S REMEDIES UNDER THIS WARRANTY ARE LIMITED AS FOLLOWS: In the event of a defect, malfunction or failure to conform to this warranty, purchaser shall return this product to AHPI, with shipping charges prepaid, within a reasonable time after discovery of such defect, malfunction or failure to conform. AHPI shall repair or replace (at AHPI's option) this product if it is defective, malfunctions or fails to conform to this warranty, and shall return it to the purchaser with shipping charges prepaid and without any additional charges due to the costs of repair or replacement.

In the event the product returned by the purchaser is not defective, has not malfunctioned and does conform to this Warranty, AHPI shall not be obligated to repair or replace the product and shall not be obligated for shipping charges for return of the product to the purchaser.

AHPI shall in no event be liable for consequential damages, nor for loss, damages or expenses directly or indirectly arising from the use of the product.

Disclaimer of Other Warranties

THIS WARRANTY IS IN PLACE AND IN LIEU OF ALL OTHER WARRANTIES OR REPRESENTATIONS, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A SPECIFIC PURPOSE, BY OPERATION OF LAW OR OTHERWISE.

This warranty does not apply to malfunction or damage resulting from accident, alteration, misuse, abuse of the product, improper prev

entative maintenance, storage at extreme temperatures or extreme environments beyond design limits, or where appropriate, improper use of the product by untrained persons. This warranty does not cover batteries other than those failing during initial use. This warranty does not apply to any plastic or rubber components since they can be affected adversely by undue exposure to heat, sun, water, ozone or to other deteriorate elements.

AHPI has not authorized any other firm or person to make any representations concerning this product nor to assume on AHPI's behalf any liability in any way concerned with the sale or use of this product.

This Warranty becomes void immediately should any repairs of, or alterations to this warranted product be made without authorization by AHPI.

27. Applicable Standards:

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/ECN (EN 55011 and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- *Reorient or relocate the receiving device*
- *Increase the separation between the equipment*

Consult the manufacturer or field service technician for help

The AHP300is intended to provide emergency respiratory support for children and adults. The product is intended to meet the following safety and performance standards:

Performance and Safety Requirements

- ASTM F920 – Performance and Safety Requirements for Resuscitators Intended for Use with Humans
- ISO 10651-3 Lung Ventilators for Medical Use

Electrical Safety Requirements

- IEC 60601-1

Electromagnetic Compatibility

- IEC 60601-1,-2

Biocompatibility Requirements

- ISO 10993 – Biocompatibility Tests – Part 1, 10, 11

Transport and Storage Requirements

- IEC 60068-2-27 – Shock
- IEC 60068-2-6 – Sinusoidal Vibration
- IEC 60068-2-31 – Rough Handling Shocks
- IEC 60068-2-64 – Random Broadband Shocks

The above listing of standards is not intended to be a complete listing of standards reviewed and tested during the development of this product. It may also not reflect latest versions as standards change.

CE
0413



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands