EPV100 Portable Ventilator

Battery Powered Ventilator With Oxygen Source Required





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Models: EPV100

<u>1 Product Description:</u>

The EPV100 is an internal battery powered, electronically controlled, portable ventilator that requires a 50 psi oxygen source. The EPV100 has selectable Tidal Volume, BPM and Inspiratory Times, based on the intended Patients' respiratory requirements.

2 Product Intended Use:

The EPV100 is intended to be used as an electronically controlled gas powered emergency ventilator, which 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 20kg (44 lbs). This ventilator is intended to be used in the environments associated with emergency medical services (EMS), inter-hospital transport and hospital facility usage. The ventilator is intended to be used in temperatures of -9 to 50°C (15 to 122°F) and 5% - 95% relative humidity, non condensing.

Biocompatibility testing has proven this unit safe for periods up to 14 days of continuous use. Results beyond this length of time are not known.

CAUTION: Federal law restricts this device to sale by or on the order of a physician. CAUTION: The EPV100 should not be used on children with a weight of 20 kg (44 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:

Tidal Volume
Breaths per Minute
Inspiratory Time
Pounds per Square Inch
Centimeters of Water
kilopascal
Milliliters
Liters per minute
Millimeters
Light emitting diode
Cardio Pulmonary Resuscitation
High pressure alarm
Relative Humidity

5 Specifications:

- A. Gas Supply Pressure: 280 kPa (40.6psi) to 600 kPa (87 psi) Oxygen DISS
- Breaths per Minute (BPM): Accuracy: ±10%
 BPM Range: 1 sec Inspiratory Time = 8 to 30
 BPM Range: 2 sec Inspiratory Time = 8 to 20
- **C. Tidal Volume (Tv):** Accuracy: ±10% with 100% Oxygen Tidal Volume Range 1 Second Inspiratory Time = 200ml to 600ml Tidal Volume Range 2 Second Inspiratory Time = 400ml to 1200ml
- **D.** Inspiratory Time (I_t): Accuracy: ±10%
 1 second or 2 second selection
- E. Safety Pressure Relief: Fixed at a maximum of 60 cm H2O.
- F. Low Source Gas Alarm: Activates at 275 to 241kPa (40 to 35 psi) source pressure.
- **G. High Airway Pressure Alarm Electronic:** Activates at 45 cm H2O Alarm Sound Level is greater than 58 decibels
- **H. Breath Delivery Alarm**: Activates if the Airway pressure does not go above 9 cm H2O during a span of 15 seconds.
- I. Battery Life: Greater than 48 hours at room temperature (10 BPM & 2 sec It)
- J. Oxygen Inlet Filter: 65 Micron sintered bronze.
- **K.** Leakage: The unit shall be designed so that pressurized oxygen is not allowed to leak through any seals or fittings.
- L. Gauge: 0-99 cm H2O accuracy \pm 5% or 1 cm H₂O whichever is greater
- M. Inspiratory and Expiratory Resistance: 5 cm H2O (.5kPa) maximum
- N. Inadvertent PEEP: <a> 2 cm H2O
- **O.** Inadvertent Continuing Expiratory Pressure: < 2 cm H2O
- P. Dead Space: < 5.5% of minimum tidal volume
- Q. Weight: 1.4 kg (3.1 lbs.) with batteries
- **R.** Size: 3.5 x 7.0 x 9.3 (88.9 x 177.8 x 236.2 mm)
- **S. Operating Conditions:** -9 to 50°C (15 to 122°F) 5% 95% RH non condensing
- T. Storage Conditions: -40 to 60°C (-40 to 140°F) 5% 95% RH non condensing
- U. Shipping Conditions: -40 to 60°C (-40 to 140°F) 5% 95% RH non condensing

Latex Free: This product does not contain latex.



ltem #	Description		
1	Tidal Volume Control		
2	Inspiratory Time Control		
3	BPM Control		
4	Oxygen Inlet		
5	Airway Pressure Display		
6	Power On/Off Switch		
7	Battery Compartment		

ltem #	Description	
8	Anti-Suffocation Valve	
9	Patient Circuit Connection	
10	High Airway Pressure Alarm	
11	Low Source Gas Alarm	
12	Low Battery Alarm	
13	Breath Delivery Alarm if	
	Flashing	
14	BPM Display	

7 Operating the Ventilator:

\triangle	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.
	Warning: Unit is not MRI compatible.
	Warning: Not for use in Toxic Environment or in the presence of flammable anesthetics.

Connecting to an Oxygen Source:

Located on the right side of the ventilator and marked with text is a diameter index safety system (DISS) fitting. Connect a 50 psi oxygen source with a minimum of 40 LPM flow capacity to this fitting. The unit comes with a <u>single use</u> supply hose made of PVC. A rubber reusable hose may be purchased and is recommended. See accessories.

\triangle	Warning: Proper tidal volumes may not be provided with a gas source not meeting the specified requirements on page 4.
\triangle	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 on this device or operate near flammable materials.
	Caution: In order to provide optimal performance, check all gas supplies to assure only clean, dry gas is used, free of contaminants and/or liquids.

The gas source may also be a high flow air/oxygen blend meeting the flow and pressure requirements.

• Select the proper inspiratory time:

Press the ON/OFF button to activate the unit. The EPV100 has the options of a 2 second inspiratory time (this is used on adults with tidal volume requirements of more than 600ml) and a 1 second inspiratory time (this is used on children or adults). Push the appropriate Inspiratory time button and a green LED will show the selected Inspiratory time

• Select the desired Breaths per Minute, BPM:

The EPV100 has a BPM range of 8 to 20 with a 2 second inspiratory time and a BPM range of 8 to 30 with a 1 second inspiratory time. Use the up and down arrows above or below the text "BPM" to set the desired BPM. The BPM setting will be displayed in the window above the selection arrows.

The American Heart Association Guidelines 2005 recommend a BPM rate of 8 to 12 for an adult and 12 to 20 for a child. These are recommendations and you should always follow your physicians or medical directors' instructions.

• Select the desired Tidal volume, T_v:

Turn the tidal volume knob to desired tidal volume. The flow to the patient is different for each tidal volume.

Tidal Volume Setting		Approximate Flow (LPM)
$I_t = 1$ second $I_t = 2$ second		
200	400	12
240	480	14.4
280	560	16.8
320	640	19.2
360	720	21.6
400	800	24
440	880	26.4
480	960	28.8
520	1040	31.2
560	1120	33.6
600	1200	36

• Verify the Pressure Relief Setting:

This unit has a factory set pressure relief setting of less than 60cm H2O. The 60 cmH2O setting is a maximum regardless of vent settings. The pressure relief setting will vary slightly with tidal volume setting. Lower tidal volumes will have a slightly lower pressure relief point. Always verify the relief pressure after the vent settings have been selected. To check the actual relief pressure, block the end of the ventilator breathing circuit and observe the reading on the airway pressure gauge. This will be the maximum airway pressure. You should hear an audible alarm and see a flashing light as this maximum pressure is reached.



• Connecting the patient breathing circuit:

Located on the left side of the unit is a 22mm connection for a patient breathing circuit. The patient breathing circuit has been design to fit with an oxygen mask (22mm outside diameter) or endotracheal tube (15mm inside diameter). Install the corrugated tubing over the connector so that it is on securely. 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 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 gauge should be observed to make sure the patient is receiving adequate positive pressure ventilation. If the gauge 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 gauge 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 and 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. If you are using a PEEP valve with the ventilator circuit the PEEP pressure will not be displayed on the gauge (airway pressure display).

Spontaneous Breathing by the Patient:

Should the patient begin to breathe spontaneously the EPV100 will allow ambient air to be pulled in through an anti-suffocation valve located in the breathing circuit connection fitting. The EPV100 ventilator will not adjust its breath delivery if the patient breathes spontaneously.

	Warning: Do not cover or block Anti-suffocation valve.
\triangle	Warning: Should a mechanical problem develop or the patient appears to be experiencing difficulty breathing while connected to the unit, disconnect the unit immediately and ventilate by other means.

• Cold Temperature Operation

Operating time will be significantly reduced if the batteries are stored at low temperatures. At 15°F (-9°C) the battery life will be approximately 9 hours (10 BPM and 2 second I_t) before the low battery indicator turns on. The low battery indicator will still give about a 2 hour low battery warning. Batteries should be replaced when the low battery indicator appears as run times are reduced at low temperatures. When the unit stops operating you will receive a breath delivery alarm.



Warning: Batteries stored at temperatures below 15°F (-9°C) may not have enough power to properly operate the solenoid valve in the unit resulting in tidal volumes that are not the indicated value.

8 Alarms:

This ventilator contains several alarms. These alarms are high airway pressure, low source gas, low battery and a breath delivery failure alarm.

The high airway alarm is an audible alarm with a red LED that is actuated when the airway pressure during inspiration reaches 45 cm H2O. The safety pressure relief will actuate at pressures between the alarm setting and 60 cm H2O.



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

This alarm is automatically cleared when 25 seconds pass without a high airway pressure being detected.

Low source gas alarm is an audible alarm with a red LED that activates when the source gas pressure drops below 40 to 35 psi. This is an indication that the unit will stop functioning soon and that the unit may not be delivering proper tidal volumes.

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

This alarm clears when proper source gas pressure is restored for 15 seconds.

The low battery alarm is a red LED that indicates the battery is running low. The unit will operate about 2 hours after the alarm first turns on. The batteries should be replaced when the low battery alarm turns on.



Warning: The displays on the unit will stay on after the unit has stopped delivering breaths. Batteries should be replaced when a low battery condition is encountered.

This alarm clears when the batteries have proper battery voltage.

The breath delivery alarm is a flashing red LED. This alarm uses the same light as the high airway pressure alarm. The breath delivery alarm will sound when the airway pressure does not reach 9 cm H2O in 15 seconds. This alarm may indicate that the patient has become disconnected from the unit or the unit has stopped delivering breaths. This alarm clears when airway pressure exceeds 9 cm H2O.

Silence Button – When there is an alarm, the user may press the button for the currently selected inspiratory time for 3 seconds to silence the alarm. This will turn off the buzzer for 110 seconds as long as there are no other alarms. Pressing this button will not clear the alarm LED's.

9 Battery Replacement:



The batteries are replaced by loosening the 4 thumbscrews on the battery door located on the front of the unit. The batteries should be removed by gently prying the top (+) of the battery up and towards the bottom of the unit. Replace the batteries with 2 "D" size alkaline batteries only. Do not mix new and old batteries when installing in unit. The batteries must be inserted with the positive (+) end of the battery towards the top of the unit. For ease of installation, install the bottom (-) of the battery first. Replace the battery door and tighten the 4 thumbscrews.

Turn the unit on and verify that the displays turn on. Connect a 50 psi oxygen source to the unit and verify that the unit does deliver breaths. The breath delivery alarm will sound if the unit is not connected to a test lung. This is normal and not a concern. The ventilator is now ready for use. Always turn the ventilator off when not in use to preserve battery life. The ventilator does not turn off automatically.

10 Cleaning:

The EPV100 should be cleaned after each use. To clean the EPV100 keep the gas supply hose on the unit to prevent contamination of the oxygen circuit.

Λ	Warning: Cleaning procedures should be performed in an environment
$\langle ! \rangle$	free of oil and petroleum based products.

The EPV100 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 detergent to remove any residue from the surface. Once the residue has been removed the unit may be wiped with isopropyl alcohol or a cold disinfecting solution to kill bacteria. The unit should 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. Alconox: 1 Tablespoon Alconox to 1 Gallon H_2O
- 3. Cetylcide: 2 Tablespoon Cetylcide to 1 Gallon H_2O
- 4. Bleach: 10% Bleach in H₂O

Dispose of single patient use items per local biohazard standards.

11 Maintenance and Schedule:

The EPV100 should be checked annually to insure proper function. Batteries should be replaced if they are beyond the expiration date on the battery. Replace with "D" sized alkaline batteries.

Year 1:

Perform Yearly Verification and Calibration procedure, check battery expiration date, replace as necessary.

Year 2:

Perform Yearly Verification and Calibration procedure, check battery expiration date, replace as necessary. Replace disposable O₂ inlet hose with 6 ft Oxygen hose, see accessories.

Replace main valve with piston, o-ring, and spring for units manufactured before April 2009. The manufacturing date is coded into the serial number for each unit. The first four digits identify the year of manufacture, the next two digits identify the month of manufacture. As an example, the serial number <u>200904</u>03001 was manufactured in the year 2009 and in the month of April. All repairs should be performed by Allied Healthcare Products trained and certified technicians.

Year 3:

Perform Yearly Verification and Calibration procedure, check battery expiration date, replace as necessary

Year 4:

Perform Yearly Verification and Calibration procedure, check battery expiration date, replace as necessary

Year 5:

Perform Yearly Verification and Calibration procedure, check battery expiration date, replace as necessary.

The unit has a life expectancy of 5 years based on normal usage and proper maintenance. A comprehensive rebuild will be necessary at this time, and should be performed by Allied Healthcare Products trained and certified technicians.

Yearly Verification and Calibration:

Equipment Required

- Certified gas flow analyzer, capable of measuring, BPM, Inspiratory time and Tidal volume.
- Regulated 50 PSI Oxygen source
- New batteries
- 36 inches of 22 mm Corrugated tubing, or the allied patient circuit provided.

Procedure

- Connect the 50 PSI Oxygen source to the Oxygen inlet connector.
- Connect the 22mm corrugated tubing to the Patient circuit connection valve, and the other end to the gas analyzer.
- Turn the tidal volume, Inspiratory time and BPM to the values indicated in the table below. Monitor the values to evaluate acceptability of the unit.

Inspiratory	Inspiratory	BPM	BPM	Tidal	Tidal
Time	Time acceptable	setting	Acceptable	Volume	Volume
setting	Values		value	Setting	Acceptable
(seconds)	(seconds)			(ml)	Value
					(ml)
2.0	1.8 - 2.2	20	18 -22	400	360 - 440
2.0	1.8 - 2.2	10	9 - 11	800	720 - 880
2.0	1.8 - 2.2	10	9 - 11	1200	1080 -1320
1.0	0.9 – 1.1	30	27 - 33	200	180 - 220
1.0	0.9 – 1.1	20	18 - 22	400	360 - 440
1.0	0.9 – 1.1	20	18 - 22	600	540 - 660

- To test pressure relief, turn tidal volume to 640 ml, block the patient end of the 22 mm corrugated tubing or patient circuit while monitoring the airway pressure display. The airway pressure should not exceed 60 cm-H₂O. The *High Airway Pressure* alarm should sound and a red LED should be activated.
- To test the *Breath Delivery Alarm*, remove all obstructions from the Patient circuit connection valve and allow the ventilator to cycle. The *Breath Delivery Alarm* should sound, and a red LED should be flashing.
- To test the Low Source Gas alarm, reduce the inlet pressure source below 35 PSI. The Low Source Gas alarm should sound and a red LED should be flashing.

Should the unit fail any of these tests contact Allied Healthcare Products, Inc., technical support center at 1-800-411-5136

12 Check-out Procedure :

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

Set the ventilator to the following settings:

- BPM = 10
- Tidal Volume = 640
- Inspiratory time = 2 seconds

General Operation Check:

- 1. Connect a 50 PSI Oxygen source to the unit, turn the power on and it should begin to cycle.
- 2. Using a stop watch count the number of breaths delivered in 1 minute (60 seconds).
 - Confirm that between 9 and 11 breaths have been delivered.
 - Confirm that the inspiratory time is significantly shorter than the expiratory time. (At the settings noted above, ventilator should provide a 2.0 second inspiratory time and a 4.0 second expiratory time)
- 3. Connect the 22 mm tubing or the allied patient circuit provided, to the patient circuit connection port. (See Item 9 Under Features Page 5). Block the patient end of the corrugated tubing.
 - Confirm that the airway pressure does not exceed 60 cm-H₂O, by monitoring the "Airway pressure display" on the face of the EPV100 ventilator.
 - An alarm will sound at approximately 45 cm-H₂O
- 4. Visually inspect the anti-sufficiation valve in the patient circuit connection port to verify that the valve is flush to the contour of the round inner surface and no gap exists.

Alarm Mode Check

- 1. Low source gas:
 - Reduce the source gas pressure below 35 PSI and monitor the red LED display turns on and an audible alarm sounds. Return the source gas pressure to 50 PSI, and the alarm should clear in 15 seconds
- 2. High Airway pressure:
 - Block the patient circuit connection port, and monitor the red LED display for "High airway Pressure" and an audible alarm will sound. The mechanical pressure relief should limit the airway pressure to less than 60cm-H₂O
- 3. Breath Delivery:
 - Clear the patient circuit connection port and allow the EPV to cycle for at least 20 seconds. The Airway Pressure display should not exceed 9 cm-H2O for 15 seconds. Monitor that the red LED is flashing on the "Breath delivery Alarm" and an audible alarm will sound.

Should the unit fail any of these tests contact Allied Healthcare Products, Inc., technical support center at 1-800-411-5136.

13 Accessories:

Description	Part Number
6 ft Oxygen Hose	L535026
Oxygen Regulator	L270-220
3 ft Ventilator Circuit	L599-130
with Swivel, adult	
mask and filter	
case of 10	
Adult Oxygen Mask	L595161-10
Case of 10	
Child Oxygen Mask	L595162-10
Case of 10	
PEEP Valve*	LPEEP
Case of 12	
Hook and Loop Strap	L770-CPR-VEL
Case of 15	

*When using a PEEP valve the airway pressure display will not show the PEEP pressure.

14 Warranty:

LIMITED ONE (1) YEAR WARRANTY

Allied Healthcare Products, Inc.(Allied) warrants this product to be free from defects in material and workmanship for a period of (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 Allied.

This Warranty is extended by Allied only to the first purchaser of the product from either Allied or from an authorized Allied distributor.

ALLIED'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 Allied with shipping charges prepaid, within a reasonable time after discovery of such defect, malfunction or failure to conform. Allied shall repair or replace (at Allied's option) this product if it is defective, malfunctions or fails to conform to this Warranty, and shall return it to purchaser with shipping charges prepaid and without any additional charges due to costs of repair or replacement.

In the event the product returned by purchaser is not defective, has not malfunctioned and does conform to this Warranty, Allied 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.

Allied shall in no event be liable for any consequential damages, nor for loss, damages or expenses directly or indirectly arising from the use of this 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 SPECIFIC PURPOSE, BY OPERATION OF LAW OR. OTHERWISE.

This Warranty does not apply to malfunction or damage resulting from accident, alteration, misuse of the product, improper preventative 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 apply to any plastic or rubber components since they can be affected adversely by undue exposures to heat, sun, water, ozone, or to other deteriorative elements.

Allied has not authorized any other firm or person to make any representations concerning this product nor to assume on Allied's behalf any liability in any way connected 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 Allied.

15 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		Сарас	ity =	682 Breath	Liters (4.6 Li ns per M	s Oxyge ter Wat linute						
	8	9	10	12	14	15	18	20	22	24	26	28	30
1200	67	60	54	46	39	37	1	1		1	1 1 1	1	1
1000	80	72	65	54	47	44					1		
800	98	88	80	67	58	54	1 1 1	1 1		1 1 1	1 1 1	1 1 1	1 1 1
600	127	115	104	88	76	72	60	54	50	46	42	39	37
500	149	135	123	104	90	85	72	65	59	54	50	47	44
400	180	163	149	127	111	104	88	80	73	67	62	58	54
300	225	206	189	163	143	135	115	104	96	88	82	76	72
200	293	274	256	225	200	189	163	149	137	127	119	111	104
Tidal Volume													

Jumbo D Cylinder Capacity = Liters Oxygen Capacity (4.0 Liters Water Capacity) **Breaths per Minute** ÷ ÷ ÷ Tidal Volume

		(2.8 Liters Water Capacity)											
	Breaths per Minute												
	8	9	10	12	14	15	18	20	22	24	26	28	30
1200	41	37	33	28	24	22		- - - -				- - - -	
1000	49	44	39	33	29	27							
800	60	54	49	41	35	33	1 1 1	1 1 1	1 1 1	1 1 1	1 1 1	1 1 1	1 1 1
600	77	70	63	54	46	44	37	33	30	28	26	24	22
500	91	82	75	63	55	52	44	39	36	33	31	29	27
400	109	99	91	77	67	63	54	49	44	41	38	35	33
300	137	125	115	99	87	82	70	63	58	54	50	46	44
200	178	166	155	137	122	115	99	91	84	77	72	67	63
Tidal Volume													

Capacity = 414.6 Liters Oxygen Capacity (2.8 Liters Water Capacity)

16 Symbols:

D Cylinder

X	Degree of protection against electric shock: Type BF
	Caution, Consult accompanying documents
5 to 95% Non-condensing	
~~~	% Relative Humidity: 5 to 95%
-40'F	Storage Temperature Range: -40°F to 140°F
ON/OFF	On/Off

#### 17 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
- Connect the equipment into an outlet on a circuit different from that which the other device(s) is connected.

Consult the manufacturer or field service technician for help

The EPV100 is 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 Medial Use Particular Requirements for Emergency and Transport Ventilators

Electrical Safety Requirements

• *IEC* 60601-1 – *Medical Electrical Equipment* – *General Requirements for basic safety and Essential Performance* 

Transportation and Storage Requirements

MIL-STD-810E – Shock, Vibration and Storage Requirements

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 also may not reflect latest versions as standards change. Allied Healthcare Products, Inc. regularly reviews the standards and updates the products to ensure compliance as necessary.

For the latest revision of the instruction manual, please refer to the company website at <u>www.alliedhpi.com</u>

This manual is also available in other languages. Please call 314-771-2400 for more information on obtaining this manual in other languages.

#### Flow Rates and I : E Ratios By Tidal Volume and Breaths per Minute

## 2 Second Inspiratory Time

	Tidal Volume	400	480	560	640	720	800	880	960	1040	1120	1200
	Height Male =((IBW-50)/2.3)+60 inch @10 ml/Kg (cm)	56 4"8" (142.2)	59 4'11" (149.9)	63 5'3" (160.0	66 5'6" (167.6)	70 5'10" (177.8)	73 6'1" (185.4)	77 6'5" (195.6)	80 6'8" (203.2)	83 6'11" (210.8)	87 7'3" (220.9)	90 7'6" (228.6)
	Height Female =((IBW-	50	61	GE	69	70	75	70	00	05	80	00
	(2.3)+00 m/Ka	; 00 // 10	' 01 5'1"	00 5' 5"	00 5' 8"	12 6' 0"	75 6'5"	0/ 6' 8"	O∠ 6' 10"	CO 7'1"	09 7'5"	92 7'8"
	(cm)	(147.3)	(154.9)	(165.1)	(172.7)	(182.9)	(190.5)	(198.1)	(208.3)	(215.9)	(226.1)	(233.7)
	Flow Rate	12	14.4	16.8	19.2	21.6	24	26.4	28.8	31.2	33.6	36
8	BPM = I:E (1 TO - )	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8
9	BPM = I:E (1 TO - )	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
10	BPM = I:E (1 TO - )	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
11	BPM = I:E (1 TO - )	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
12	BPM = I:E (1 TO - )	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
13	BPM = I:E (1 TO - )	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
14	BPM = I:E (1 TO - )	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
15	BPM = I:E (1 TO - )	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
16	BPM = I:E (1 TO - )	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
17	BPM = I:E (1 TO - )	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
18	BPM = I:E (1 TO - )	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
19	BPM = I:E (1 TO - )	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
20	BPM = I:E (1 TO - )	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Ideal Body Weight Kg	10.0	10.0	50.0	24.0	70.0				404.0	440.0	400.0
	@10 ml/Kg	40.0	48.0	56.0	64.0	72.0	80.0	0.88	96.0	104.0	112.0	120.0

### 1 Second Inspiratory Time

	Tidal Volume	200	240	280	320	360	400	440	480	520	560	600
	Height Male =((IBW-50)/2.3)+60 inch	47	49	50	52	54	56	57	59	61	63	64
	@10 ml/kg	3' 11"	4' 1"	4' 2"	4' 4"	4' 6"	4' 8"	4' 9"	4' 11"	5' 1"	5' 3"	5'4"
	(cm)	(119.4)	(124.9)	(127.0)	(132.1)	(137.2)	(142.2)	(144.8)	(149.9)	(154.9)	(160.0)	(162.6)
	Height Female =((IBW-											
	45.50)/2.3)+60 inch	49	51	52	54	56	58	59	61	63	65	66
	@10 ml/kg	4'1"	4'3"	4'4"	4'6"	4'8"	4' 10"	4' 11"	5'1"	5'3"	5'5"	5'6"
	(cm)	(124.5)	(129.5)	(132.1)	(137.2)	(142.2)	(147.3)	(149.9)	(154.9)	(160.0)	(165.1)	(167.6)
	Flow Rate	12	14.4	16.8	19.2	21.6	24	26.4	28.8	31.2	33.6	36
8	$\frac{\text{BPM} = \text{I:E}(1 \text{ IO} -)}{\text{DPM} = \text{IE}(4 \text{ TO} -)}$	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5
9	$\frac{BPM = I:E(1 IO -)}{DPM = I:E(4 TO -)}$	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7
10	BPM = I:E(1 IO -)	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
11	$\frac{BPM = I:E(1 IO -)}{DPM = I:E(4 TO -)}$	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5	4.5
12	BPM = I:E(1 IO -)	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
13	$\frac{\text{BPM} = \text{I:E}(1 \text{ IO} -)}{\text{DPM} + \text{E}(4 \text{ TO} -)}$	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6
14	BPM = I:E (1 TO - )	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3
15	BPM = I:E (1 IO - )	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
16	BPM = I:E (1 TO - )	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8
1/	BPM = I:E(1 IO -)	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
18	BPM = I:E (1 IO - )	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
19	BPM = I:E(1 IO -)	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2	2.2
20	BPM = I:E(1 IO -)	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
21	BPM = I:E(1 IO -)	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9	1.9
22	$\frac{\text{BPM} = \text{I:E}(1 \text{ IO} -)}{\text{DPM} = \text{IE}(4 \text{ TO} -)}$	1.7	1./	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
23	$\frac{BPM = I:E(1 IO -)}{DPM = I:E(4 TO -)}$	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
24	$\frac{\text{BPM} = \text{I:E}(1 \text{ IO} -)}{\text{DPM} = \text{IE}(4 \text{ TO} -)}$	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
25	BPM = I:E(1   U - )	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
26	$\frac{BPM = I:E(1 IO -)}{DPM = I:E(4 TO -)}$	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
27	BPM = I:E(1 IO -)	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
28	BPM = I:E(1 IO -)	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
29	BPM = I:E (1 IO - )	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
30	BPM = I:E (1 TO - )	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	Ideal Body Weight											
	@10 ml/Kg	20.0	24.0	28.0	32.0	36.0	40.0	44.0	48.0	52.0	56.0	60.0

### 19 Attaching EPV100 to equipment

Using two Hook and Loop straps, see accessories, the EPV100 can be looped around hospital or other equipment as shown.



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