pNeuton® Ventilator Model A-E

User Manual

REF 5514218

The ventilator has not been cleared or approved by the FDA. The ventilator has been authorized by FDA under an Emergency Use Authorization (EUA). The ventilator is authorized only for the duration of the U.S. declared health emergency.

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Manufactured by Ford Motor Company for

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Distributed by GE Healthcare

For Customer Service, call GE Healthcare at (800) 345-2700.

Do not contact Airon. Direct all inquiries to GE Healthcare.

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Revision History

| Date | Rev | Change Description | |
|--------------|-----|--------------------|--|
| 7 April 2020 | 1 | Initial release | |
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Chapter 1 General Description

pNeuton Model A-E (pronounced "new-ton") is a small, lightweight ventilator designed for use on patients from pediatric to adult in size, 23 Kg (50.7 pounds) or greater. It is a time cycled, flow limited ventilator providing Intermittent Mandatory Ventilation (IMV). In this mode of ventilation, an adjustable respiratory rate and tidal volume are delivered to the patient. The patient is allowed to breath spontaneously between the mandatory breaths with minimal work of breathing. A built-in PEEP / CPAP system can be set to provide expiratory positive pressure. The delivered oxygen is adjustable to 65% or 100%, with oxygen as the driving source gas.

pNeuton Model A-E is a pneumatic ventilator. Electrical power is not required for patient ventilation. **pNeuton Model A-E** has been specifically designed for patient ventilatory support and critical care mechanical ventilation. It may be used during intra and inter-hospital transport, in aircraft, on ambulances, in emergency rooms, and radiology suites.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Chapter 2 Warnings, Cautions, Notes

The **pNeuton Model A-E** Ventilator is intended for use by properly trained personnel under the direct supervision of licensed medical Physician or Practitioner only. Personnel must become thoroughly familiar with this Operator Manual prior to using the **pNeuton Model A-E** Ventilator on a patient.

The various safety and cautionary notes throughout this manual are defined as follows:



Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.

⚠ CAUTION

Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.

Note:

Used for instructions to the operator to prevent damage to property.

Warnings

This manual serves as a reference. The instructions in this manual are not intended to supersede the physician's instructions regarding the use of the **pNeuton Model A-E** Ventilator.

The operator should read and understand this entire manual before using the **pNeuton Model A-E** Ventilator.



DO NOT use the **pNeuton Model A-E** Ventilator in conjunction with anesthetics or in contaminated (hazardous, explosive) atmospheres. Only compressed oxygen may be used.



DO NOT use conductive (anti-static) patient breathing circuits. The <u>only</u> approved patient circuits for use with **pNeuton Model A-E** Ventilator are the **pNeuton** circuits listed in *Chapter 5* of this manual. Any other patient circuit should **NOT** be used and may lead to patient harm.

The Operational Verification tests as described in this manual (*Chapter 4*) must be performed prior to connecting a patient to the ventilator. If the ventilator fails any of the tests, it <u>must</u> be removed from clinical use. **DO NOT** return the unit to clinical use.



The pNeuton Model A-E Ventilator has been designed for use on <u>adult and pediatric</u> patients. The pNeuton Model A-E cannot deliver operator adjusted tidal volumes less than 360 ml. DO NOT use the pNeuton Model A-E on neonatal or infant patients, or small children.

To protect the patient from high airway pressures, ensure that the Peak Pressure control is adjusted appropriately.

Due to the design of the ventilator (see *Chapter 7 - Theory of Operation*), the Tidal Volume and Respiratory Rate controls are interdependent. The Tidal Volume control is a calibrated control. The Respiratory Rate control is calibrated for a set tidal volume between 500 ml and 900 ml. Lower tidal volumes will have higher rates, higher tidal volume will have lower rates. Once the tidal volume is set, it will not vary as the respiratory rate is changed. However, if the Tidal Volume control setting is changed, the respiratory rate may change. Always recheck the patient's mandatory breath rate after changing the tidal volume to assure the patient is receiving the proper respiratory rate.



The **pNeuton Model A-E** Ventilator is not intended for use under hyperbaric pressure conditions. If used in these conditions, tidal volume delivery will significantly decrease. Careful patient monitoring of tidal volume with a hyperbaric compatible external spirometer is mandatory.

The Low Gas Supply Alarm will occur if the driving gas supply drops below safe levels (30 psi, 200 kPa). The alarm activates as long as driving gas is available or until supply pressure returns to normal. The alarm will only activate for a very short period of time if the gas supply abruptly ceases as can happen if the supply gas becomes disconnected. Always ensure that the supply gas is secure and operating at the proper pressure.

Cautions



DO NOT attempt to service the unit. Service may only be performed by authorized engineers.

Any attempts to modify the hardware of this device without the express written approval of the manufacturer will void all warranties and liabilities.

Do not immerse the **pNeuton Model A-E** Ventilator or allow any liquid to enter the case or the inlet filter. Clean as directed in *Chapter 9, Cleaning and Maintenance*.

Notes

In the USA the **pNeuton Model A-E** Ventilator is a restricted prescription medical device intended for use by qualified medical personnel under the direction of a physician.

During the transport of patients, it is recommended that an alternate source of ventilation be available in the event of driving gas supply failure or ventilator malfunction.

Note:

The ventilator will operate normally at altitudes up to 15,000 feet. Changes in altitude will not affect pressure settings but will cause the delivered tidal volume to increase and the respiratory rate to decrease as altitude increases. To compensate for the effect of changing altitude on tidal volume and respiratory rate, use an external spirometer to verify tidal volume accuracy.

Special note on the presence of latex:

The components, devices, accessories, and packaging that make up the **pNeuton Model A-E** Ventilator system do not contain any dry natural rubber or natural rubber latex, which may cause allergic reactions.

Special note on the presence of di (2-ethylhexyl) phthalate (DEHP):

The components, devices, accessories, and packaging that make up the **pNeuton Model A-E** Ventilator system do not contain any phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC.

Additional Warnings, Cautions, and Notes are located throughout this manual.

Indicatons for use

The **pNeuton Model A-E** Ventilator is intended for continuous mechanical ventilation of patients in the following patient populations and use locations:

Patient population: adult OR pediatric patients 23 Kg and greater who require the following general types of ventilatory support:

- positive pressure ventilation delivered invasively (via an ET tube) or non-invasively (via a mask)
- CMV and IMV modes of ventilation.
- with or without PEEP / CPAP
- with oxygen or a mixture of air and oxygen

The ventilator is suitable for use in:

- Hospitals and alternate care units to meet the needs for mechanical ventilation
- Pre-hospital transport applications including accident scene, emergency rescue vehicles
- Hospital ICU transport applications including emergency, radiology, surgery and post- anesthesia/recovery
- Air transport via helicopter or fixed wing

Contraindications

The following conditions contraindicate the use of the **pNeuton Model A-E** Ventilator:

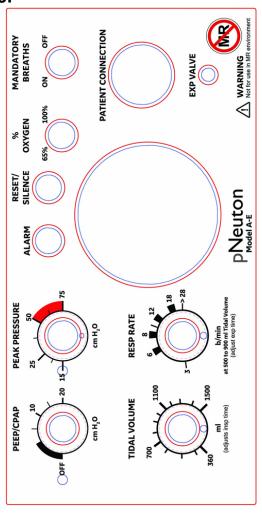
- Patients undergoing procedures with flammable anesthetic gases
- Patients undergoing hyperbaric treatment
- Infants and neonatal patients requiring tidal volumes less than 360 ml

Medical Symbol Key

| <u> </u> | Consult Instructions of Use |
|--------------|---|
| MR | Not for use in MR environment |
| REF | Model (Part) Number |
| LOT | Lot Number |
| SN | Serial Number |
| ② | Do Not Reuse |
| | Manufacturer |
| M | Manufactured Date |
| Σ | Use by Date |
| * | Keep Dry |
| <u></u> | Caution, serious injury or device damage may occur by disregarding the instructions accompanying this warning symbol. |

Chapter 3 Controls and Patient Safety Systems

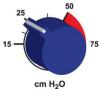
Front Panel





Pressure gauge, patient circuit pressure





Peak Pressure control of mandatory breaths calibrated, range 15 to 75 cm H₂O

PEEP / CPAP

cm H₂O

PEEP / CPAP control, calibrated, range 0 to 20 cm H₂O

TIDAL VOLUME



Tidal Volume control, calibrated, range 360 to 1,500 ml



b/min at 500 to 900 ml Tidal Volume (adjusts exp time) Respiratory Rate control, calibrated, range 3 to >28 bpm dependent on tidal volume setting

ALARM



Alarm visual indicator

RESET/ SILENCE



Alarm Reset / Silence, 1 minute

MANDATORY BREATHS



Mandatory Breath control, turns on or off mandatory breath system

OXYGEN



Oxygen control, select either 100% or 65%



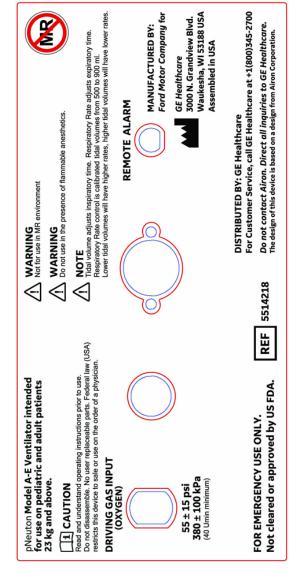
Patient Circuit connection, see *Chapter 5* for a complete description of the patient circuit and its attachment to the front panel

EXP VALVE



Expiratory Valve connection

Rear Panel



| Driving Gas Input (Oxygen) 55 ± 15 psi 380 ± 100 kPa (40 L/min minimum) | Driving Gas Input (oxygen), DISS connection, requires 55 <u>+</u> 15 psi (380 <u>+</u> 100 kPa), (40 liter/minute minimum) |
|---|--|
| | Alarm, Low Driving Gas |
| | Ambient Air Inlet Filter |
| REMOTE ALARM | Remote Alarm output |

Internal Patient Safety Systems

The ventilator has several internal safety systems. These systems ensure patient safety in the event of ventilator malfunction.

High Pressure Release

The patient circuit peak pressure is adjustable using the Peak Pressure control. This control can be set from 15 to 75 cm H_2O . The factory preset value is 50 cm H_2O . In addition to this control, there is an internal safety pressure release valve. This valve will automatically limit circuit pressure to approximately 80 cm H_2O , regardless of the setting of the Peak Pressure control.

Anti-Suffocation System

An internal safety system will allow the patient to breathe on his or her own in the event of ventilator malfunction. At approximately 2 cm H_2O negative pressure an internal valve will open allowing unimpeded ambient air to enter the patient circuit for the patient. This system is always available to the patient, irrespective of control settings, including PEEP / CPAP.

Low Gas Supply Pressure Alarm

Whenever the driving gas supply pressure drops below the safe operating pressure the visual alarm indicator will illuminate and an internal pneumatic audible alarm will sound. This low-pressure alarm will occur when the source gas pressure drops below 30 psi (200 kPa). The alarm will continue to sound until all pressure has been lost in the system or when pressure is re-established to at least 35 psi (250 kPa).



The Low Gas Supply Alarm will only activate for a very short period of time if the gas supply abruptly ceases as can happen if the supply gas becomes disconnected. Always ensure that the supply gas is secure and operating at the proper pressure.

Disconnect Alarm

The ventilator automatically monitors patient pressure at all times. If there is a disconnection in the patient circuit, the visual alarm indicator will illuminate, and the audible alarm will sound. The alarm activates when either of the following conditions occur:

- With Mandatory Breaths "ON" if a circuit pressure of at least 5 cm H₂O is not sensed within 22 seconds after the last breath
- With Mandatory Breaths "OFF" if the circuit pressure is less than 5 cm H₂O for 22 seconds.

Note:

Setting the CPAP level less than 5 cm H₂O with mandatory breaths off will cause the alarm to sound continuously.

The Disconnect alarm may be silenced for 1 minute by pressing the alarm "Reset / Silence" button.

Note:

Always use an external oxygen monitor to ensure the desired oxygen percentage is delivered to the patient.

Chapter 4 Operating Instructions

Ventilator Setup

The following equipment is needed (obtained locally):

- 1. **pNeuton Model A-E** Ventilator with breathing circuit (see *Chapter 5* for a list of compatible circuits)
- 2. Test lung (1 Liter rigid wall)
- 3. Spirometer
- 4. Watch

When ready:

- 1. Attach the breathing circuit to the ventilator as described in *Chapter 5*.
- 2. Attach the test lung to the patient side of the breathing circuit.
- 3. Set the controls as follows:
 - a. Mandatory Breath control to On
 - b. % Oxygen to 65%
 - c. PEEP / CPAP to Off
 - d. Peak Pressure to 50 cm H₂O
 - e. Tidal volume to 700 ml
 - f. Respiratory Rate to 12 bpm
- 4. Attach Oxygen Input on rear panel of the ventilator to a high-pressure oxygen source and turn on the oxygen.

Note:

The ventilator will begin operation at the above settings when the oxygen is turned on. The alarm will sound. You may press the "Reset / Silence" button to silence the alarm or wait for the unit to begin ventilating.

Operational verification

| Verification Step | Acceptable Range | Result |
|---|---------------------------------|-----------|
| Attach a spirometer to the expiratory valve using the elbow included in the circuit packaging. After 3 breaths measure the delivered tidal volume. | 700 ± 70 ml | Pass/Fail |
| Count the respiratory rate with a stopwatch. Measure the number of breaths in one minute. | 12 ± 2 breaths per minute | Pass/Fail |
| Remove the test lung and occlude the patient connection on the circuit. Read the circuit pressure from the pressure gauge on the front of the ventilator. | 50 ± 5 cm H2O | Pass/Fail |
| Remove the occlusion and allow the breathing circuit to remain open. Using a stopwatch, measure the time until the alarm sounds | 22 ± 3 seconds | Pass/Fail |

If the ventilator has passed all the above steps it is ready to return to clinical use. If the ventilator fails to pass any of the following tests, do not apply it to patients. Call your GE Healthcare Customer Support at (800) 345-2700. **Do not attempt to service the unit.** Do not contact Airon Corporation.

⚠ CAUTION

Do not disassemble the **pNeuton Model A-E** Ventilator. No internal user replaceable parts. Opening the device will negate the warranty.

Patient Ventilation

The ventilator operates with the following modes:

- CMV Continuous Mechanical Ventilation
- IMV Intermittent Mandatory Ventilation
- CPAP Continuous Positive Airway Pressure

Using the Intermittent Mandatory Ventilation (IMV) mode, the ventilator provides an adjustable number of breaths per minute. The tidal volume of these breaths is also adjustable. The patient may breathe spontaneously between ventilator breaths as desired.

- 1. Set the % Oxygen control to the desired F₁O₂.
- 2. Set the Mandatory Breath control to On.
- 3. Set the Tidal Volume control to the appropriate level.
- 4. Adjust the Respiratory Rate control to achieve the desired mandatory breath frequency.
- Adjust the Peak Pressure control to the desired level by turning the control while occluding the patient circuit and observing the level of pressure generated during a mandatory breath.
- Attach the patient circuit to the patient and observe for appropriate ventilation. Adjust as required. External measurement devices should be used to verify ventilation parameters.
- Adjust the PEEP / CPAP control to the desired level. There is no adjustment for spontaneous breath trigger sensitivity as this is automatically set by the ventilator.
- 8. Observe and monitor the patient and the ventilator per your institution's standards. If using a portable gas supply, monitor the supply level to insure there is enough gas for ventilation.

Interrelationship of Volume and Rate Controls

There is an interrelationship between the Tidal Volume control and the Respiratory Rate control which must be considered while operating this ventilator. The Tidal Volume control is a calibrated control and will not vary from its setting during normal operation. It will not change if the Respiratory Rate control is changed. The Respiratory Rate control is calibrated and will not vary the patient's mandatory breath rate unless changed. However, if the Tidal Volume control setting is changed the actual respiratory rate may change even if the Respiratory Rate control is not moved.

The ventilator operational characteristics define the reason the rate changes when the tidal volume is changed. See *Chapter 7* for a detailed description of the ventilator's Theory of Operation.

The Respiratory Rate control is calibrated for tidal volumes between 500 to 900 ml. This allows the rate control to be preset with initial set-up of the ventilator on a patient.

Always count the patient's mandatory breath rate when first setting up the ventilator and after any changes to the tidal volume to assure the patient is receiving the proper respiratory rate.

The mandatory breath inspiratory flow is fixed at 36 L/min. Due to this preset flow rate, it is possible that desired combinations of high tidal volume and respiratory rates may not be available. In other words, combinations of high tidal volumes and high mandatory breath rates are limited by the fixed mandatory breath flow rate. If a high respiratory rate is required, a lower tidal volume may be necessary. Likewise, if a high tidal volume is required, a lower respiratory rate may be needed.

Oxygen Control

The ventilator uses internal venturi systems which provide the oxygen concentration delivered to the patient. See Chapter 7 for a complete description of these systems. It is recommended that an external oxygen analyzer always be used to verify oxygen delivery.

Hypobaric Operation

The ventilator will operate normally at altitudes up to 15,000 feet. Changes in altitude will not affect pressure settings. However, delivered tidal volume increases and respiratory rate decreases with increasing altitude. This is due to lower barometric pressure than ventilator calibration at standard sea level.

To compensate for the effect of changing altitude on tidal volume and respiratory rate, use an external spirometer to verify tidal volume accuracy. Adjust the Tidal Volume and Respiratory Rate controls to the desired value as measured by the spirometer rather than the markings on the control panel.

Disconnect Alarm

The ventilator has a patient circuit disconnect alarm system. This system cannot be turned off. If a circuit disconnect is sensed, the visual indicator on the front panel will illuminate and the audible alarm will sound.

The alarm will activate as soon as an oxygen source is turned on to the ventilator. You may silence the alarm for approximately 1 minute by pressing the Reset / Silence button. Attaching the ventilator to a patient and starting ventilation will automatically reset the alarm system and turn off the audible and visual indicators.

A patient circuit disconnect is sensed when any of the following conditions occur:

- Mandatory Breaths "ON" circuit pressure does not rise above 5 cm H₂O within 22 seconds of the last time at least 15 cm H₂O was sensed.
- Mandatory Breaths "OFF" a pressure of less than 5 cm H₂O is sensed for 22 seconds

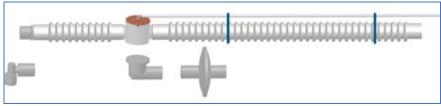
Note:

Setting a CPAP level of less than 5 cm H₂O with Mandatory Breaths OFF will cause a continuous alarm. If this occurs, either set CPAP to at least 5 cm H₂O or turn on the mandatory breaths.

The alarm system can be momentarily silenced by pressing the Reset / Silence button on the front panel. Pressing this button turns off the visual and audible indicators for 1 minute. Each time the Reset / Silence button is pressed, the alarm system restarts the 1-minute silence time delay. This delay is NOT cumulative. In other words, repeatably pressing the Reset / Silence button will not increase the silence time by more than 1 minute.

Chapter 5 Patient Circuit

Adult / Pediatric Circuit



(5514234)

The patient circuit designed for use with the **pNeuton Model A-E** is disposable and has a compression volume of 1ml per cm H₂O.

Patient circuits other than the specific circuits listed above may alter the ventilator's CPAP / PEEP characteristics and / or expiratory flow resistance. They should **NOT** be used and may lead to patient harm.

⚠ WARNING

Do not use air filters on the **expiratory port** of the patient circuit except those with the patient circuit kit. Some filters may alter the ventilator's CPAP / PEEP characteristics and / or expiratory flow resistance. They should **NOT** be used and may lead to patient harm.

If the bacterial/viral filter must be replaced, GE Healthcare recommends using a filter with the following specification:

- Resistance @ 30 LPM: equal or below 75.5 pa (0.77 cm H₂O)
- Connector: 22M/15F 22F

⚠ CAUTION

The **pNeuton Model A-E** ventilator requires the use of a non-vented full-face mask for proper device operation.

Ventilator Connection

The patient circuit must be attached to the ventilator properly. Incorrect attachment could result in failure to provide adequate ventilation.

| PATIENT CONNECTION | The main breathing hose (22 mm) is connected to the "Patient Connection" port. |
|--------------------|---|
| EXP VALVE | The small tubing (3 mm) connects the expiratory valve to the "Expiratory Valve" port. |

Note:

The specific **pNeuton Model A-E** patient circuit is a single use, disposable device. Cleaning, reprocessing and / or reuse of this device must not be performed.

Single-Use only. The circuit and all components are sold clean and non-sterile.

Single-Use only Medical Devices/Accessories

How do I know if a device is Single-Use?

This symbol will be identified on the packaging and User's Manual of the device.

What does Single-Use mean?

Do not reuse. A single-use device is used on an individual patient during a procedure or mechanical ventilation, and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

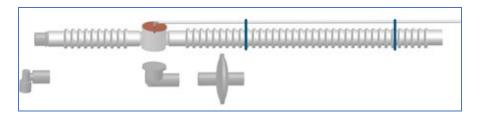
What is the concern with reused device labeled Single-Use? The use of reprocessed devices may present serious incidents relating to the health and safety of patients and healthcare professionals. Reuse can be unsafe because of risk of:

- Cross-infection inability to clean and decontaminate due to design, device components are not manufactured for disassembly and reassembly
- Endotoxin reaction excessive bacterial breakdown products, which cannot be adequately removed by cleaning
- Patient injury device failure from reprocessing or reuse because of fatigue or material alteration
- Chemical burns or sensitization residues from chemical decontamination agents on materials that can absorb chemicals

Note:

If you reuse a single-use device, you may be legally liable for the safe performance of the device.

Chapter 6 Accessories



Adult/pediatric patient circuit

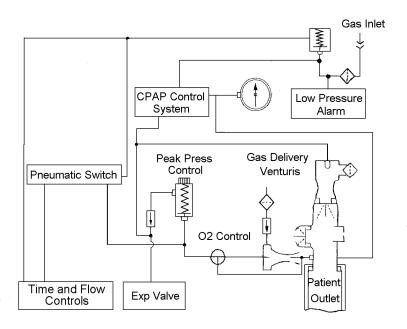
- Disposable, single patient use.
- 6-foot (1.8m)
- Bacterial/Viral Filter for exhalation valve
- Part Number: 5514234

Patient Circuit other than the specific circuit listed above may alter the ventilator's CPAP / PEEP characteristics and / or expiratory resistance.

Chapter 7 Theory of Operation

pNeuton Model A-E is a pneumatic ventilator based upon the Intermittent Mandatory Ventilation (IMV) principle. As such, adjustable respiratory rate and tidal volume breaths are delivered to the patient between which the patient may breathe spontaneously. This chapter describes how the ventilator operates.

Pneumatic System Diagram



Pneumatic System Description

The major components of the pneumatic system and the control of gas flow through the ventilator are as follows:

- 1. High pressure gas (oxygen) enters the ventilator and is filtered (5 micron) and reduced to a lower working pressure (35 psi 240 kPa).
- The timing circuit uses two precision control valves to control inspiratory and expiratory time. These valves charge (or reduce) pressure to a pneumatic timing cartridge. This timing cartridge turns on or off the ventilator's main flow valve.
- 3. The main flow valve controls gas flow from the internal regulator to the % Oxygen control, which in turn delivers it to the patient. The % Oxygen control setting determines whether flow goes directly to the patient or through the high flow venturi. If gas is directed to the patient, a restrictive orifice limits the flow to a specific flow rate (36 L/min). If gas is directed to the high flow venturi, ambient air is entrained to provide precisely the same flow to the patient, but at a reduced F₁O₂ (approximately 65%). The high flow venturi provides stable performance (no stall) up to the maximum operating pressure (75 cm H₂O) of the ventilator.
- 4. The pressure generated by the main flow valve also powers the Peak Pressure control system. This system sends an adjustable pressure to the patient circuit expiratory valve. The pressure in this system determines the peak pressure that can be generated in the patient circuit.
- 5. The adjustable PEEP / CPAP system directs a pressure signal to the expiratory valve to generate PEEP and provides flow on demand for spontaneous breaths.

Tidal Volume and Rate Control System

pNeuton Model A-E Tidal Volume and Respiratory Rate controls function to determine mandatory breath inspiratory and expiratory time.

Since the ventilator provides a fixed flow (at 36 L/min or 600 ml/sec) during a mandatory breath, setting a specific inspiratory time also sets a specific tidal volume. This tidal volume is so precise that the inspiratory time control is calibrated to reflect the range of tidal volumes available (360 to 1,500 ml).

The ventilator's tidal volume output will not change in the face of increasing patient circuit pressure. The only change that may occur to actual patient delivered tidal volume will be caused by compression of gas based upon the compliance of the patient circuit used. The compression volume of the ventilator itself is negligible. With the specific disposable patient circuit (part number 5514234), the following tidal volume / patient circuit pressure relationships can be expected:

| Patient Pressure | <u>Tidal Volume</u> | | |
|------------------------|---------------------|--------|---------|
| | 360 ml | 800 ml | 1200 ml |
| 5 cm H₂O | 360 | 800 | 1,200 |
| 15 cm H₂O | 350 | 785 | 1,180 |
| 30 cm H ₂ O | 340 | 775 | 1,165 |
| 60 cm H₂O | 320 | 750 | 1,145 |

The Respiratory Rate control adjusts expiratory time with a range 0.6 to 20 seconds. Rate is controlled by increasing or decreasing expiratory time. With a set tidal volume, a slower respiratory rate will equate to a longer expiratory time. Tidal volume is not affected by changes to the Respiratory Rate control.

The Respiratory Rate control is calibrated for set tidal volumes between 500 and 900 ml.

The calibrated Respiratory Rate range optimizes the interdependence between the expiratory and inspiratory time for ease of operation. If the tidal volume is changed and the rate is not changed, the number of breaths that can occur in one-minute changes. For example:

```
Volume = 600, Respiratory Rate = 12
(I time = 1 sec, E time = 4 sec, total time = 5 sec)
Change the volume to 900
(I time changes to 1½ sec)
Resultant Respiratory Rate is now 11
(total time for inspiration and expiration = 5½ sec)

Volume = 600, Respiratory Rate = 12
(I time = 1 sec, E time = 4 sec, total time = 5 sec)
Change the volume to
1200 (I time
changes to 2 sec)
Resultant Respiratory Rate is now 10
(total time for inspiration and expiration = 6 sec)
```

Tidal volumes below 500 ml will result in **faster** rates than marked on the Respiratory Rate control. Tidal volumes higher than 900 ml will result in **slower** rates than marked on the Respiratory Rate control. The marks on the Rate Control are wide to reflect the range of control position that will provide the desired rate over the range of tidal volume. Always count the respiratory rate when first placing the ventilator on a patient and whenever changing tidal volumes.

As when using any mechanical ventilator, careful attention to detail is required. It is suggested that independent validation of tidal volume and rate be performed using external spirometers and timing devices.

Mandatory Breath Pressure Control System

During normal mandatory breath inspiration, the expiratory valve functions to prevent gas from escaping through the expiratory valve. The pressure used to close the expiratory valve is set with the Peak Pressure control. The range is 15 to 75 cm H_2O .

The Peak Pressure adjustment can be used to manipulate the highest pressure applied during mandatory breaths.

- If volume limited ventilation is the goal, set the Tidal Volume control to the desired volume and the Peak Pressure control to at least 10 cm H_2O above the pressure required to deliver that tidal volume.
- If pressure limited ventilation is the goal, set the Tidal Volume control to the desired inspiratory time and the Peak Pressure control to the desired peak pressure.

During pressure limited ventilation any excess flow will be released by the expiratory valve while maintaining the desired peak pressure. This flow release may cause a "honking" sound as gas escapes through the partially closed valve.

The Peak Pressure control can be tested by occluding the patient port of the patient circuit during a mandatory breath. During the breath the pressure will rapidly rise to the set peak pressure. Turn the Peak Pressure control until the desired peak pressure is achieved.

CPAP Demand Flow Breathing System

The ventilator's internal CPAP demand flow system provides gas for spontaneous breathing at adjustable CPAP pressures up to 20 cm H_2O . This system has several key features:

- When turned on, the system supplies a continuous flow of gas at approximately 10 L/min during the expiratory time of the ventilator. This flow of gas helps to establish the desired CPAP level by balancing flow with the pressure generated on the expiratory valve by the CPAP system.
- 2. The continuous flow of gas also establishes the flow sensitivity to spontaneous breathing efforts. If the patient's inspiratory flow demand exceeds the continuous flow of gas, additional flow will be added to meet patient demand. There is no sensitivity adjustment to this system. The CPAP system will automatically meet the needs of the patient, greater than 100 L/min, by attempting to maintain the balance between flow and pressure at the expiratory valve.
- 3. The PEEP / CPAP control is calibrated to the dynamics of the pNeuton specific disposable patient circuit. Using this circuit will insure proper operation and the full 0 to 20 cm H_2O PEEP / CPAP range.

Oxygen Delivery System

With the ventilator driven by 100% oxygen as the source gas, the ventilator can be set to deliver 65% or 100% oxygen. There are two independent systems within the ventilator that determine oxygen concentration. The following section describes how these systems operate.

Mandatory Breaths

The % Oxygen control determines the oxygen concentration of the mandatory breaths that enter the patient circuit at the Patient Connection. When set for 65%, an internal high flow venturi system entrains ambient air to decrease the F_1O_2 while maintaining the correct tidal volume. The high flow venturi provides stable performance up to the maximum operating pressure (75 cm H_2O) of the ventilator

Spontaneous Breaths

Spontaneous breaths are available from the internal CPAP system which uses a venturi mechanism separate from the mandatory breath high flow venturi. When turned on by the PEEP / CPAP control, the system delivers approximately 10 L/min baseline flow during the expiratory time of the ventilator.

The F_1O_2 of this system is set by the % Oxygen control. When set for 65%, the actual oxygen percentage and baseline flow is related to the level of CPAP in use. Up to 10 cm H_2O CPAP will provide a F_1O_2 of approximately 0.65 ± 0.10 . As the CPAP level raises to 20 cm H_2O , the F_1O_2 can be expected to increase to as high as 0.75 ± 0.10 .

This is due to a drop off in efficiency (stalling) of the CPAP venturi system at higher CPAP levels. The actual F_1O_2 of spontaneous breaths will be approximately the same as the baseline flow. Whether set for 65% or 100%, extremely high inspiratory flow demand may decrease the desired F_1O_2 .

It is always recommended that an external oxygen monitor be used to measure and display the delivered oxygen concentration.



Never operate the ventilator without proper oxygen gas supply at the required pressure.

Factors Effecting the Operating Time of Oxygen Tanks

There are several factors that affect the length of time the ventilator will operate from a tank of oxygen. The ventilator uses very little gas for its own operation (less than 4 L/min) and is not a major factor in oxygen tank consumption.

The major factors are:

- Volume of oxygen in the tank
- Patient's tidal volume and rate
- Position of the % Oxygen control
- If the PEEP / CPAP system is on or off

Setting the % Oxygen control to 65% will decrease the amount of oxygen used from the tank, nearly doubling the time an oxygen tank lasts.

Note:

Always use full oxygen and air tanks before the start of any transport. The calculation of any expected run time becomes unreliable as tank pressure is reduced.

Example of expected operating time using a full "E" size cylinder (660 liters) PEEP/CPAP off

| <u>Minute Volume</u> | <u>100% Oxygen</u> | <u>65% Oxygen</u> |
|----------------------|--------------------|-------------------|
| 5 l/m | 77 min | 80 min |
| 10 l/m | 40 min | 76 min |
| 15 l/m | 33 min | 60 min |

The PEEP / CPAP system, when turned on, uses approximately 5 L/min oxygen from the tank to provide the 10 L/min baseline flow of the system. The patient's own spontaneous tidal volume and rate will use additional oxygen from the tank, based upon the tidal volume of those breaths.

Example of expected operating time using a full "E" size cylinder (660 liters) PEEP/CPAP on

| Minute Volume | <u> 100% Oxygen</u> | 65% Oxygen |
|---------------|---------------------|------------|
| 5 l/m | 29 min | 37 min |
| 10 l/m | 26 min | 33 min |
| 15 l/m | 23 min | 30 min |

Low Gas Supply Alarm

The Low Gas Supply Alarm will occur if the driving gas supply drops below safe levels (30 psi, 200 kPa). The alarm activates as long as driving gas is available or until the supply pressure returns to normal.

When operating from an oxygen cylinder the ventilator will gradually use up the gas in the cylinder and tank pressure will fall. Once the cylinder pressure reaches approximately 500 psi, most portable tank regulators will start to decrease pressure to the ventilator during mandatory breaths. As this happens that Low Gas Supply Alarm will sense the decreased pressure and begin to intermittently alarm each time the pressure drops during inspiration. As pressure in the cylinder falls to lower values, the amount of time the regulator is delivering low pressure increases and the alarm sounds longer. Eventually the regulator is unable to maintain pressure and the alarm will sound continuously until all gas in the cylinder is used.



The Low Gas Supply Alarm will only activate for a very short period of time if the gas supply abruptly ceases. This can occur if operating from a wall source and the gas supply hose is disconnected from the gas supply outlet.

In fact, the Low Gas Supply Alarm may not sound at all when the ventilator is disconnected from a wall source. This is because all gas in the high-pressure hose immediately exits out from where the hose was connected to the outlet and there is no gas pressure to power the ventilator's alarm. When using the ventilator on a patient always ensure that the supply gas is secure and operating at the proper pressure.

Chapter 8 Troubleshooting

This troubleshooting guide lists common problems that may be encountered and possible solutions. If none of the corrective actions seem to work, contact GE Healthcare.

| Indication | Meaning | Corrective Action |
|---|--|--|
| Ventilator does not operate – no patient ventilation | Missing or insufficient driving gas supply | Check gas source, 55 psi (380 kPa) at 40 L/min is required |
| | Patient circuit disconnection | Reconnect patient circuit |
| | Internal malfunction | Contact GE Healthcare for replacement |
| Ventilator seems to "want" to operate, but no breaths are | Peak Pressure control set too low | Increase Peak Pressure control |
| generated | Respiratory Rate set too low | Increase Respiratory Rate |
| | Expiratory valve drive line disconnected | Ensure tubing is properly connected |
| | Expiratory Valve is malfunctioning | Replace patient circuit |
| | Insufficient driving gas supply | Check gas source, 55 psi (380 kPa) at 40 L/min is required |
| | Internal malfunction | Contact GE Healthcare for replacement |
| Ventilator appears to be stuck in inspiration | CPAP may be turned on high | Check CPAP control |
| шърнацоп | Internal malfunction | Contact GE Healthcare for replacement |
| Ventilator stops and starts | Insufficient driving gas supply | Check gas source, 55 psi (380 kPa) at 40 L/min is required |

| Indication | Meaning | Corrective Action |
|-----------------------------------|--|--|
| Lower minute volume than desired | Insufficient driving gas supply | Check gas source, 55 psi (380 kPa) at 40 L/min is required |
| | Leak in the Patient Circuit or Expiratory Valve | Replace patient circuit |
| | Obstruction of gas output | Check or replace patient circuit |
| | Use in hyperbaric condition | Ventilator should not be used in hyperbaric conditions |
| | Tidal volume control is out of calibration | Contact GE Healthcare for replacement |
| | Internal malfunction | Contact GE Healthcare for replacement |
| Higher minute volume then desired | Use at higher altitude then calibration | Use external spirometer to verify tidal volume |
| | Tidal volume control is out of calibration | Contact GE Healthcare for replacement |
| | Internal malfunction | Contact GE Healthcare for replacement |
| Tidal volume inaccurate | Leak in the patient ET-Tube, mask, breathing circuit or expiratory valve | Check patient interface. Replace patient circuit if at fault |
| | Ventilator is operating at an altitude different then calibration | Tidal volume should be measured by an external spirometer |
| | Tidal volume control is out of calibration | Contact GE Healthcare for replacement |

| Indication | Meaning | Corrective Action |
|---|---|---|
| Rate control inaccurate | Tidal volume set below 500 ml or above 900 ml | This is normal. Rate will be faster when tidal volume is set lower than 500 ml. Rate will be slower when tidal volume is set higher than 900 ml |
| | Rate control out of calibration | Contact GE Healthcare for replacement |
| Patient pressure too high | Tidal Volume set too high | Decrease Tidal Volume or Peak Pressure setting |
| | Patient response | ET-Tube may be occluded, or patient may be biting tube |
| | Expiratory Valve malfunctioning | Replace patient circuit |
| | Internal malfunction | Contact GE Healthcare for replacement |
| Can't get the PEEP / CPAP desired | Expiratory Valve malfunctioning | Replace patient circuit |
| | Using a circuit not recommended by the manufacturer | Replace patient circuit |
| | Internal malfunction | Contact GE Healthcare for replacement |
| | Excessive "chattering" of CPAP system | Occurs when using some test lungs but will not when connected to a patient. If problem persists, contact GE Healthcare for replacement |

| Indication | Meaning | Corrective Action |
|-------------------------------|---|---|
| Ventilator using too much gas | PEEP / CPAP system turned "on" | Turn off PEEP / CPAP system |
| | Leak at source gas | Check hoses and tank regulator for leaks |
| | Internal leaks | Contact GE Healthcare for replacement |
| Oxygen concentration too low | Source gas not 100% oxygen | Ensure source gas is 100% oxygen |
| | High patient spontaneous ventilation | Decrease spontaneous ventilation |
| | Internal malfunction | Contact GE Healthcare for replacement |
| Alarm activated | Patient circuit disconnection | Reattach circuit or locate leak |
| | Alarms at start-up when gas is supplied to ventilator | Normal operation. To silence alarm, attach patient (or test lung) or press Reset / Silence button |
| | Expiratory valve tubing disconnected | Ensure tubing is connected properly |
| | Leak in the Patient Circuit or Expiratory Valve | Replace patient circuit |
| | Insufficient driving gas supply – alarm sounds briefly during each mandatory breath | Tank may be low. Check gas source, 55 psi (380 kPa) at 40 L/min is required |

| Indication | Meaning | Corrective Action |
|---|---|---|
| | Mandatory Breaths OFF and CPAP set to less than 5 cm H2O | Set CPAP to at least 5 cm H2O or Mandatory Breaths ON |
| | Excessive patient effort | If peak pressure does not reach 15 cm H2O due to patient insp effort during mandatory breaths, alarm will sound. This is normal operation |
| | Internal malfunction | Contact GE Healthcare for replacement |
| Alarm does NOT activate | Patient circuit occluded | Check circuit |
| | Expiratory valve drive line kinked or occluded | Check / replace patient circuit |
| | Internal malfunction | Contact GE Healthcare for replacement |
| Visual alarm activates but audible does not | Reed Cap Malfunction | Replace reed cap on back of unit |

Chapter 9 Cleaning and Maintenance

Cleaning the Ventilator

- Use only mild detergent or disinfectant and water with a soft cloth.
- Do not immerse the ventilator in water.
- Do not attempt to sterilize the ventilator with autoclave or ethylene oxide. Severe damage to the ventilator may occur.

Cleaning / Disinfecting the Patient Circuit

The **pNeuton Model A-E** specific patient circuit is a disposable, single use device. This circuit <u>must not</u> be cleaned, disinfected or reused. See Single-Use only Medical Device information, page 31.

Routine Maintenance

The manufacturer recommends that an Operational Verification Test (see *Chapter 4*) be performed at initial installation and prior to use on each patient. Institution's standards may require additional biomedical surveillance. No additional routine maintenance is required.

Chapter 10 Specifications

The product should only be used during the duration of the U.S. declared health emergency or 2 years from the date of manufacture, whichever is less.

General Description

- Pneumatically operated ventilator provides automatic mechanical ventilation with a built-in PEEP / CPAP demand flow system for spontaneous breathing
- Patient ranges: pediatric to adult, ≥ 23 Kg (50.7 lbs.)
- Equipment not suitable for use in the presence of flammable anesthetics
- Rated for continuous operation

Ventilator System Performance

Controls

| 0 | Mandatory Breaths | On or Off |
|---|-------------------|-----------------------------------|
| 0 | Respiratory Rate | from 3 to > 28 bpm |
| 0 | Tidal Volume | from 360 to 1,500 ml |
| 0 | Peak Pressure | from 15 to 75 cm H ₂ O |
| 0 | PEEP / CPAP | from 0 to 20 cm H ₂ O |
| 0 | % Oxygen | 100% or 65% |

Operating Ranges

| 0 | Inspiratory Time | 0.6 to 2.5 seconds |
|---|------------------|------------------------------|
| 0 | Expiratory Time | 0.6 to 20.0 seconds |
| 0 | Minute Volume | 0.2 to 30 L/min |
| 0 | Flow Pattern | square, 36 L/min |
| 0 | Internal P Limit | 70 to 84 cm H ₂ O |

- Accuracy of Controls
 - Respiratory Rate <u>+</u> 2 bpm (V_T between 500-900)
 - Tidal Volume <u>+</u> 15% of setting at the following clinically relevant representative nominal settings:
 - PEEP 10 cm H₂O, RR 18 bpm, Resistance 20 cm H₂O/l/sec, Compliance 20 ml/cm H₂O, F₁O₂ 100%
 - Note: Changing any one of these nominal values over their setting ranges will not change the delivered tidal volume by more than + 10%
 - Peak Pressure Less than + 10% of setting (Peak 25 to 50 cm H₂O)
 - o PEEP / CPAP + 3 cm H₂O of setting
 - o F_IO₂, <u>+</u> 15% (mandatory breaths set to ON)
- Precision breath to breath repeatability of controls
 - Respiratory Rate <u>+</u> 10%
 - Tidal Volume + 25ml
 - Peak Pressure + 5 cm H₂O
 - PEEP / CPAP + 2 cm H₂O
 - o F₁O₂ + 5%
- Specificity effect of one control on another
 - Respiratory Rate if tidal volume is constant, + 5%
 - Tidal Volume + 10%
 - Peak Pressure + 5%
 - o PEEP / CPAP +5% or + 1 cmH₂O, whatever is greater
 - $_{\circ}$ F₁O₂ + 5%
- Internal Compliance 0.1 ml/cm H₂O
- Ventilator Resistance to Flow
 - o Inspiratory, 60 L/min: less than 2 cm H₂O/I/sec
 - Expiratory, 50 L/min: less than 6 cm H₂O/l/sec

Alarm System

- Patient Disconnect
 - Pressure:
 - mandatory breath OFF, less than 5 cm H₂O
 - mandatory breath ON, less than 5 cm H₂O
 - o Alarm delay: 22 seconds
 - o Alarm silence: approx. 60 seconds
- Low Gas Supply
 - Input supply pressure: less than 30 psi (2.1 bar)
 - Cannot be silenced

Environmental and Physical Characteristics

- Hypobaric (high altitude) compatible up to 15,000 feet (4,600 meters)
- Weight and Size: 9 pounds (4.1 kg),
 5.1"H x 10.5"W x 7.3"D (13.0 cm x 26.7 cm x 18.5 cm)
- Storage Temperature Range: -20 to 60 °C (-4 to 140 °F),
 15 to 95 percent humidity, noncondensing
- Operating Temperature Range: -5 to 40 °C (23 to 104 °F),
 15 to 95 percent humidity, noncondensing

Power Sources

- Driving gas requirement
 - 55 psi + 15 psi (380 kPa + 100 kPa)
 - 100% oxygen. Do not use the ventilator with other types of gases.
 - The gas supply must be capable of delivering at least 40 liters per minute at 55 psi. If input pressure drops less than 30 psi due to insufficient gas flow, the ventilator will alarm and begin to malfunction.

Note:

Driving gas consumption at 10 L/min minute volume;

- o PEEP / CPAP off: 4 L/min
- o PEEP / CPAP on, 65%: 9 L/min
- o PEEP / CPAP on, 100%: 15 L/min

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