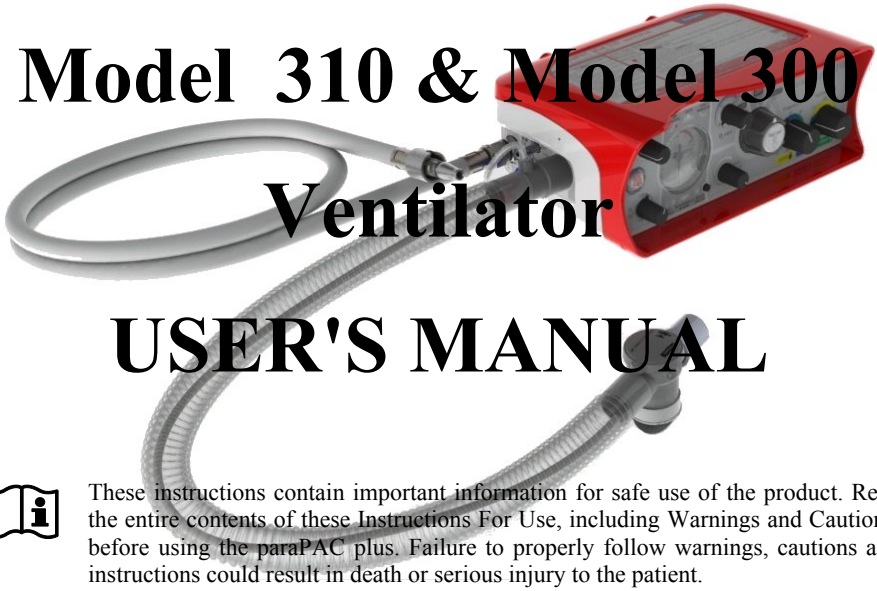
Pneupac™

paraPAC plus

Model 310 & Model 300 Ventilator

USER'S MANUAL



These instructions contain important information for safe use of the product. Read the entire contents of these Instructions For Use, including Warnings and Cautions, before using the paraPAC plus. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

smiths medical

CE 0473

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paraPAC plus Ventilator User's Manual
Model 310 & Model 300

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Smiths Medical International Ltd. reserves the right to make changes, without notice, which may affect the information contained in this manual.

Additional copies of this User's Manual can be obtained from Smiths Medical International Ltd.

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SECTION: 1 SAFETY INSTRUCTIONS

(a) Summary Statement

The paraPAC plus ventilators are portable devices intended for the ventilation of adults, children and infants (above 10kg) during transportation and emergency situations. They consist of a control module and a remote patient valve, connected by means of a breathing hose. Both pneumatic and electronic alarms are incorporated.

Warning: Failure to read this user's handbook before first use of this device may result in death or serious injury

Before use for the first time, all potential users must read the complete User's Manual and should familiarise themselves with the machine and its operation to enable them to use it effectively. They should study the contents of this Manual to the extent required to supplement their training. Special attention must be paid to warnings and precautions that are summarised in section 1(b). Failure to observe these warnings and precautions could compromise patient and/or user safety. Special guidance on the operation and use of the ventilator is given in section 3 of this manual and basic operating instructions are provided on the label affixed to the control module.

Warning: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Warning: To avoid harm to the patient, this equipment should only be used by personnel trained in the use of automatic ventilation.

The equipment should only be used by medical personnel who have a full understanding of the techniques required for its use, or paramedical personnel who have received full and proper initial and 'refresher' instruction from a qualified person, both on resuscitation and on detailed use of the equipment in the situations in which it is likely to be employed. Information given in this manual beyond the basic operation of the ventilator is only intended as a guide to supplement proper medical training and to indicate the specific operational requirements of the paraPAC plus ventilator.

Warning: Failure to constantly monitor the patient whilst using this equipment may lead to death or serious injury.

Warning: To avoid harm to the patient, blood oxygenation and expired carbon dioxide levels should be monitored independently using pulse oximetry and capnography as part of due clinical diligence. Correct operation of the ventilator will not necessarily achieve the required blood gas levels.

The paraPAC plus ventilator is intended only for use in transport and emergency situations where the patient is being constantly monitored by the carer. The integrated alarm unit is intended to alert the carer to changes in the patient's ventilation but it cannot ensure that the patient's blood gases are maintained at the required level. Therefore, patient monitoring devices e.g. a pulse oximeter and other recommended devices should additionally be used where appropriate.

(b) Warnings, Cautions and Precautions

(i) WARNINGS

Warnings are given to make you aware of dangerous conditions, that could lead to death or serious injury to the user or patient, that can occur if you do not obey all of the instructions given in this manual.

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1. Warning: user's handbook (Sect. 1(a)).

Failure to read this user's handbook before first use of this device may result in death or serious injury.

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2. Warning: Federal (U.S.A.) law Restrictions (Sect. 1(a)).

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

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3. Warning: personnel trained (Sect. 1(a)).

To avoid harm to the patient, this equipment should only be used by personnel trained in the use of automatic ventilation.

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4. Warning: Constant monitoring of the patient (Sect. 1(a) & 4(d)).

Failure to constantly monitor the patient whilst using this equipment may lead to death or serious injury.

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5. Warning: blood gas levels (Sect. 1(a)).

To avoid harm to the patient, blood oxygenation and expired carbon dioxide levels should be monitored independently using pulse oximetry and capnography as part of due clinical diligence. Correct operation of the ventilator will not necessarily achieve the required blood gas levels.

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6. Warning: Use of Oxygen (Sect. 2(a) and 3(b)13)

To avoid the risk of ignition, do not smoke or have naked flames in the vicinity of oxygen. Do not allow oil, grease or combustible lubricants (only those approved for oxygen use) to come into contact with any part of the ventilator, regulator or cylinder.

7. Warning: Use in Aircraft (Sect. 2(a))

To avoid the risk of explosion or interference, where used on aircraft, the use of this equipment must be authorised by the Aviation Authority and the Aircraft Operator.

8. Warning: Tidal Volumes Below 150mL (Sect. 2(b))

Use of the ventilator and Patient breathing Circuit at Tidal Volumes below 150ml may result in a CO_2 build up and inadequate ventilation of the patient. For tidal volumes below 150ml the Smiths Medical Hyperinflation Bag system, in conjunction with the CPAP / O_2 L/min connector on the ventilator may be used.

9. Warning: Use of CMV with Demand inhibit Facility (Sect. 2(b) and 4(d))

Because this function has characteristics specific to this range of ventilators it is important that the sections of the operating instructions describing this facility (Sections 2(b) and 4(d)) are read before this version of the paraPAC plus ventilator is used so that the operator understands how the ventilator interacts with the patient during spontaneous breathing.

10. Warning: Direct Proximal Pressure Sensing (Sect. 2(b) #9)

Ventilators must never be used without the sensing line attached as this will result in a loss of 'delivered volume' to the patient.

Although there is no net flow in the sensing line it is recommended that the microbio filter is always fitted to ensure that no patient contamination can enter the manometer circuit within the control module.

11. Warning: Battery for MRI Use (Sect. 2(d)15)

To prevent possible risk of projectile injury within a MRI environment, routinely check for magnetic attraction.

To avoid projectile risk in a MRI environment, use only the approved MRI conditional battery, Part No: W269-023. Do not attempt to remove the battery from the ventilator (or take a loose battery) in a MRI environment.

12. Warning: Potential Unsatisfactory Performance with Alternative Ventilator Patient Circuits (Sect. 2(d)18 and 6(d))

Ensure that only approved circuits supplied by Smiths Medical are used with the paraPAC plus range of ventilators. Failure to use the approved circuits could result in death or serious injury.

To avoid cross contamination please be aware that the patient circuit is a single use device and should be disposed of after each use.

13. Warning: Provision of Accessories, Ancillaries and Spares for CE marked products (Sect. 2(f), 6(d) & 7).

The paraPAC plus ventilator is manufactured and 'CE' marked to the requirements of 93/42/EEC. To ensure that this equipment functions as intended, use only the manufacturer's authorised spares and accessories.

14. Warning: Pre-Use Checks

To avoid harm to the patient, pre-use checks must be performed (See Section 3(a) and 3(b) Points #1 to #8 inclusive) before each use.

15. Warning: Functional Check (Sect. 3(b)13)

Deviations noted at functional check should be reported immediately to Smiths Medical and the unit must be taken out of service to avoid the risk of death or serious injury.

16. Warning: Release of Cylinder Pressure (Sect. 3(b)13)

To avoid ignition by adiabatic compression, connect the ventilator to the regulator before opening the cylinder valve slowly. Similarly, prior to changing cylinders, turn off the cylinder valve, switching on the ventilator. When the ventilator stops, it is safe to release the pin index yoke.

17. Warning: Provision of Alternative Means of Ventilation (Sect. 4)

Always ensure that an alternative means of ventilation is available in the event of ventilator failure or malfunction.

18. Warning: Adequacy of Gas Supply (Sect. 4(b)(ii))

To avoid harm to the patient, ensure that ventilation can be maintained without interruption, keep a constant check on the adequacy of gas supply by observing the gas cylinder contents indicator and the gas failure visual alarm.

19. Warning: Interpreting of 'Spontaneous Breath' Indicator (Sect. 4d)

Actuation of the 'Spontaneous Breath' indicator only indicates that spontaneous breathing has been detected and that the low-pressure alarm has been reset as a consequence. The operator must still ensure that patient minute ventilation is adequate.

20. Warning: Heat Moisture Exchanger (HME) filter

If a Heat Moisture Exchanger (HME) filter is used and the patient is experiencing breathing difficulties, or there are mechanical ventilation problems, or decreases in gas exchange, always ensure that there are no blockages in the breathing system. If a blockage is found, immediately replace the breathing system or HME filter. To prevent such problems occuring, filters and HME's should be routinely replaced in accordance with the manufacturer's instructions.

21. Warning: Use in Extreme Environments (Sect. 4 and Appdx. B)

Extreme environments may impair ventilator performance (see Appendix B), operator vigilance is required to monitor the patient.

22. Warning: Patient Transportation (Sect. 3)

To avoid harm to the patient, inter- or intra-hospital transport should only be undertaken according to established medical practice and under medical supervision.

23. Warning: Projectile Risk (Sect. 4 and Appdx. B)

To reduce the risks of potential projectile injury to the user or patient, the normal routine of checking the ventilator system for magnetic attraction should be followed whenever the equipment is taken into an MRI environment to ensure that magnetically attracted parts have not been added to the system inadvertently.

24. Warning: Use in Contaminated Atmosphere (1) (Sect. 4(g))

The paraPAC plus ventilator models are suitable for use in contaminated and toxic atmospheres subject to certain limitations as described below and these should be clearly understood by those likely to use the equipment in such environments so that it is only used where appropriate.

In any situations where the respirable qualities of the immediate environment are suspect, ventilation should only be carried out in the 100% oxygen (no air mix) mode. This ensures that only a minimum of ambient gas can enter the breathing system.

25. Warning: MRI Use (Sect. 4(h))

To prevent possible risk of projectile injury within a MRI environment, routinely check for magnetic attraction.

When in use in a MRI environment, to prevent injury to the patient, check the pressure manometer to confirm unchanged ventilation. Also, test the high-pressure relief/alarm system by temporary circuit disconnection and occlusion of the ventilator outlet connector, both whenever the system is taken into a MRI environment, and every time the patient is positioned within the magnetic field.

26. Warning: Training Requirements (Sect. 4(i))

All operators who are not medically qualified should receive full and proper instruction from a qualified person, both on resuscitation and on detailed use of the equipment in the particular situations in which it might be employed (see Section 1(a))

27. Warning: Regular functional checks for devices in storage (Sect. 4 (a))

To avoid harm to the patient, if the device remains unused for a period exceeding three months, conduct a functional check.

28. Warning: Approved Accessories (Sect. 5 (d))

Failure to use approved circuits and accessories may lead to unsatisfactory ventilator performance.

29. Warning: Lithium batteries (Appendix A)

Lithium batteries are of the primary type and are NOT designed to be recharged. Attempts to recharge these batteries can lead to leakage and possibly an explosion.

30. Warning: Use in very confined spaces

Do not use this ventilator in very confined spaces, as oxygen concentration will be affected, due to expired gas from the expiration valve entering the fresh gas intake port. Where fitting in a confined space is necessary, consult Smiths Medical for installation advice.

31. Warning: Storage in Low Temperatures (Appendix B)

After storing at temperatures below -18°C set controls to 40 bpm and tidal volume 150mL and connect to gas at higher than 0°C before CMV operation and reset controls as desired once ventilator is cycling.

Warnings specific for the Patient Breathing Circuit

Note: The warnings specific for the Patient Breathing Circuit are listed here for information only. Refer to Instructions for Use part number 100/905/340 and 100/905/341 for the latest information.

A. Users must ensure that they are knowledgeable and proficient in the use of the ventilator and circuit before use to allow them to be used safely.

B. Ensure that the circuit is undamaged, complete, assembled correctly and fully functional before use. Failure to do so could lead to inadequate ventilation.

C. Ensure that all connections are secure. Failure to do so could lead to inadequate ventilation.

D. Ensure that the inline filter is securely attached to the ventilator and that the pressure monitoring line is not kinked. Failure to do so could lead to incorrect or misleading readings on the ventilator's manometer.

E. Pressure test the circuit before use to verify leak resistance. Failure to do so could lead to inadequate ventilation.

F. Ensure that the PEEP valve is set to the minimum pressure before connecting the circuit to the patient. Failure to do so could lead to patient injury.

(ii) CAUTIONS

Cautions warn of dangerous conditions that can occur and cause damage to the ventilator or its accessories, if you do not obey all of the instructions given in this manual.

1. **Caution: Do not allow any oil or grease to come into contact with the module or, in particular, with the input and output fittings because of the potential fire risk when oxygen is being used.**
2. **Caution: When storing for long periods, to avoid the risk of possible corrosion or drain of the battery, ensure that the ventilator is left in the 'Demand' (Off) (ventilator off) position and the battery is removed from its holder (Sect. 2(d) # 15).**
3. **Caution: To ensure that the cylinder contents are not lost during storage due to small leakages, it is recommended that the valve on the gas cylinder is turned off after use. (Sect. 2(d)15).**

4. **Caution: Do not attempt to sterilise the paraPAC plus or to clean it by immersion in any fluid. Do not use any cream cleanser. Do not allow any petrochemical or its derivative (petrol, diesel, paraffin etc.) come into contact with the device. Do not autoclave the paraPAC plus.**

5. **Caution: If the device is accidentally immersed in water or any liquid, it should no longer be operated and an alternative means of ventilation used (see Warning** #17**).**

6. **General Precautions Relating to Battery Safety, Transportation and Disposal. See Appendix A.**

7. **CAUTION : To avoid risk of of internal corrosion within the device, use only dry, filtered gas (Sect. 2(b) & 4(b) ii).**

Cautions specific for the Patient Breathing Circuit

Note: The cautions specific for the Patient Breathing Circuit are listed here for information only. Refer to Instructions for Use part number 100/905/340 and 100/905/341 for the latest information.

a. The PEEP valve has been determined to be MR Conditional ref. (ASTM) F2503-08. There is no projectile risk or change in PEEP performance in a static magnetic field of 3 Tesla or less with spatial gradient magnetic field of 7.5 T/m (750 G/cm) or less.

Special care should be taken as follows: MR image quality may be compromised if the area of interest is close to the position of the PEEP Valve. Therefore it should be secured away from the area of interest for the scan. Optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

b. If circuit 100/905/341 is used with Model 310 and the circuits PEEP valve is set higher than the value set by the ventilator's separate PEEP control, the value indicated on the mechanical PEEP valve will be the calibration to follow. At all times, use the ventilator's manometer to accurately monitor the set PEEP.

SECTION: 2 GENERAL INFORMATION

(a) Intended Use

Warning: To avoid the risk of ignition, do not smoke or have naked flames in the vicinity of oxygen. Do not allow oil, grease or combustible lubricants (only those approved for oxygen use) to come into contact with any part of the ventilator, regulator or cylinder.

The ParaPAC plus range are gas-powered emergency and transport portable ventilators that are primarily intended for use in transport applications in vehicles including fixed and rotary wing aircraft. They are suitable for emergency use at the accident scene, intra and inter-hospital transport and within medical facilities including magnetic imaging systems to 3 Tesla. They should only be used under the constant supervision of trained healthcare professionals. The devices are intended to provide ventilatory support for adults, children and infants (above approx. 10 kg). The devices also provide free flow oxygen therapy and CPAP therapy for spontaneously breathing patients.

The paraPAC plus ventilators and associated equipment described in this manual conform to International Standard ISO 10651-3 "Emergency and Transport Ventilators" and comply with the requirements of the European Directive for Medical Devices 93/42/EEC.

Warning: To avoid the risk of explosion or interference, where used on aircraft, the use of this equipment must be authorised by the Aviation Authority and the Aircraft Operator.

The paraPAC plus model 310 has been determined to be MR Conditional ref. (ASTM) F2503-08. There is no projectile risk or change in ventilator performance within an open bore shielded magnet with a static magnetic field of 3 Tesla or less with spatial gradient magnetic field of 7.5 T/m (750 G/cm) or less. Special care should be taken as follows:

If the ventilator is placed at a distance less than 30cm from the area of interest it will affect image quality and could affect the ventilator's electronic alarms. Therefore it should be secured away from the area of interest for the scan. Optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

(i) Variants Covered by this Manual

This manual addresses both the paraPAC plus variants – model 310 and 300. Features that are not applicable to the model 300 are annotated (Model 310 Only), as model 310 is enhanced variant of the model 300. The majority of the illustrations in this User's Manual are of the model 310.

(ii) Variant Features

Feature	Model 300	Model 310
8 to 40 bpm Frequency Control	✓	✓
70 to 1500 ml Tidal volume control	✓	✓
Air mix control 100% or 50% oxygen concentration	✓	✓
Manual breath button	✓	✓
Demand oxygen therapy function	✓	✓
Demand inhibit of CMV	✓	✓
Electronic alarm	✓	✓
PEEP Control on ventilator		✓
II FLOW control		✓

* See Terms and Definitions, Section 7 (d).

Figure 1: General views of the paraPAC plus 310

(b) General Description

The paraPAC plus ventilator consists of a control module and a remote patient valve, connected by means of a corrugated hose (See Fig 1). A description of controls and features on the paraPAC plus ventilator is given in Section 2 (d), the number reference against each description corresponds to the number shown in Figure 2.

The paraPAC plus ventilator is a gas powered (use only dry filtered gas), time cycled ventilator which depends solely on the pressure of the supply gas for its operation. The models described in this Manual additionally incorporate an integrated electronic pressure alarm unit to alert the user to certain significant changes that may occur in the patient's ventilation. Loss of battery power for the alarm is signalled to the user but will have no effect on the ventilation performance of the paraPAC plus ventilator, nor affect the mechanically operated alarms and protection systems.

CAUTION: To avoid risk of internal corrosion within the device, use only dry, filtered gas.

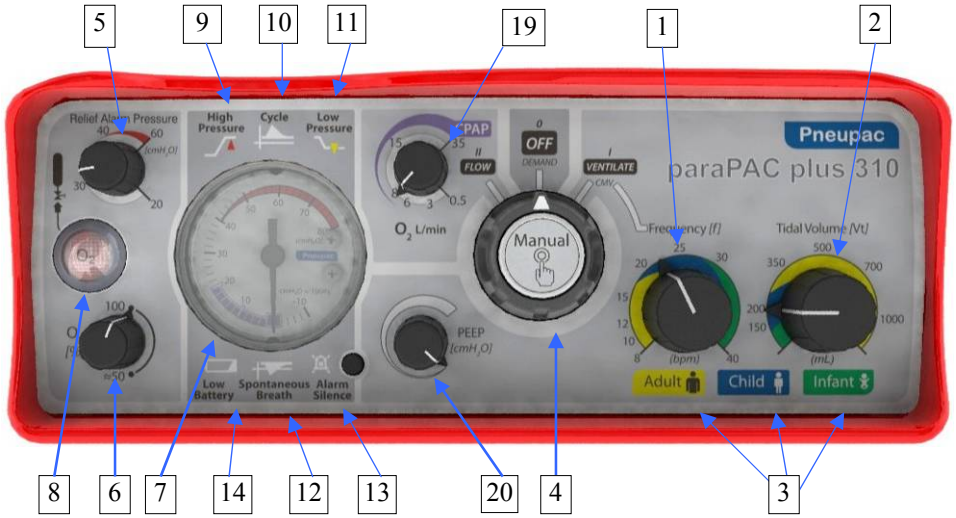
The control module of the paraPAC plus ventilator is rugged by virtue of the design of case, internal pneumatics and electronics. The controls are recessed to minimise the possibilities of damage.

Calibrated frequency and tidal volume controls are provided to set the required ventilation pattern and these are clearly colour coded to indicate the recommended settings for adults, children and infants.

Used in conjunction with the patient pressure manometer, the PEEP control (Model 310 Only) is provided to set PEEP between 0 and 20 cm H_2O.

An air mix control gives a FiO_2 option of 0.50 or 1.0. For longer term ventilation the 0.50 FiO_2 setting will normally be used and in this setting gas consumption is significantly reduced - by almost 70% - giving greatly extended cylinder duration or allowing the use of a much smaller compressor if compressed air is used as the driving gas.

On the paraPAC plus ventilator, selection can be made between O OFF DEMAND, I VENTILATE CMV & II FLOW (Model 310 only). When I VENTILATE CMV is selected, the ventilator cycles at the set frequency but if a spontaneous breath is taken during an exhalation phase then this is taken from an internal demand valve. If breathing is at an adequate level for an adult, cycling will be inhibited as long as this breathing level is maintained. If breathing becomes inadequate, CMV will be restored, synchronised with the last breath.



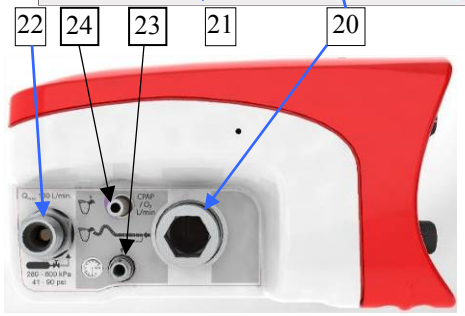


Figure 2.1: Controls, Features & Interfaces of the paraPAC plus 310

When O OFF DEMAND, is selected, only the internal demand valve is energised by the gas supply. When the patient is connected to the patient valve, any spontaneous breathing effort is satisfied by flow from the demand valve. This provides a very gas efficient method of treating a victim with an unprotected airway where enhanced oxygen [tidal volume dependent see table in Appendix C] is recommended as the approved therapy. It can also be used to protect a spontaneously breathing patient during rescue from a contaminated atmosphere.

The control module is designed to be mounted in a variety of ways as described under Section 2 (e) (ii) 'Mounting Options'. A wide range of attachments and brackets are also available. The paraPAC plus ventilator may be driven by oxygen from a compressed gas cylinder or pipeline system.

(c) Contraindications – none known

(d) Controls and Features (Figure 2)

1. Frequency Control

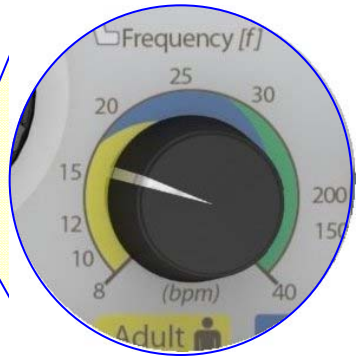


Fig. 2a: Frequency Control

This calibrated rotary control knob gives simultaneous continuous adjustment of the frequency of ventilation over the range 8 to 40 breaths per minute.

The frequency range on the paraPAC plus ventilator extends beyond that required by the AHA* guidelines in order to give flexibility of use in a wide range of situations.

*See Terms and Definitions, Section 7(d)

2. Tidal Volume Control (T_{DEL})

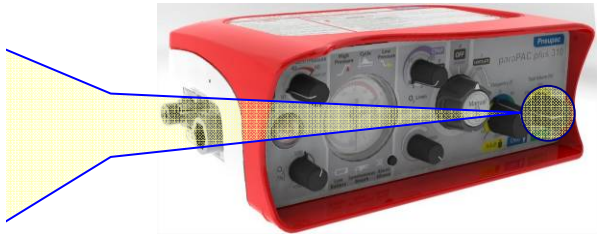


Fig. 2b: Tidal Volume Control

This rotary control knob gives continuous adjustment of the flow to the patient over the range 8 & 39 litres per minute. For ease of use in the emergency situation, it is calibrated in terms of tidal volume (V_T=T_I x Flow).

Variations of inspiratory time with frequency setting mean that this calibration can only be an approximation but in practice, because the two adjustments will normally be made in unison, and because the variations of inspiratory time are limited, the resultant accuracy is sufficient for the intended application of the ventilator. Colour coding is used on both this and the frequency control to give guidance as to the combination of settings, which should normally be used. For further details refer to Technical Data, Section 7(b).

Warning: Use of the ventilator and Patient breathing Circuit at Tidal Volumes below 150ml may result in a CO_2 build up and inadequate ventilation of the patient. For tidal volumes below 150ml the Smiths Medical Hyperinflation Bag system, in conjunction with the CPAP / Flow connector on the ventilator may be used (Model 310 only).

3. Body Mass Symbols

Fig. 2c: Body Mass Symbols

The colour coded symbols correspond to the Frequency and Tidal Volume controls. These symbols and markings on the controls are for guidance only and are intended to aid in identifying the most appropriate combinations of frequency and tidal volume that the user requires for the particular patient.

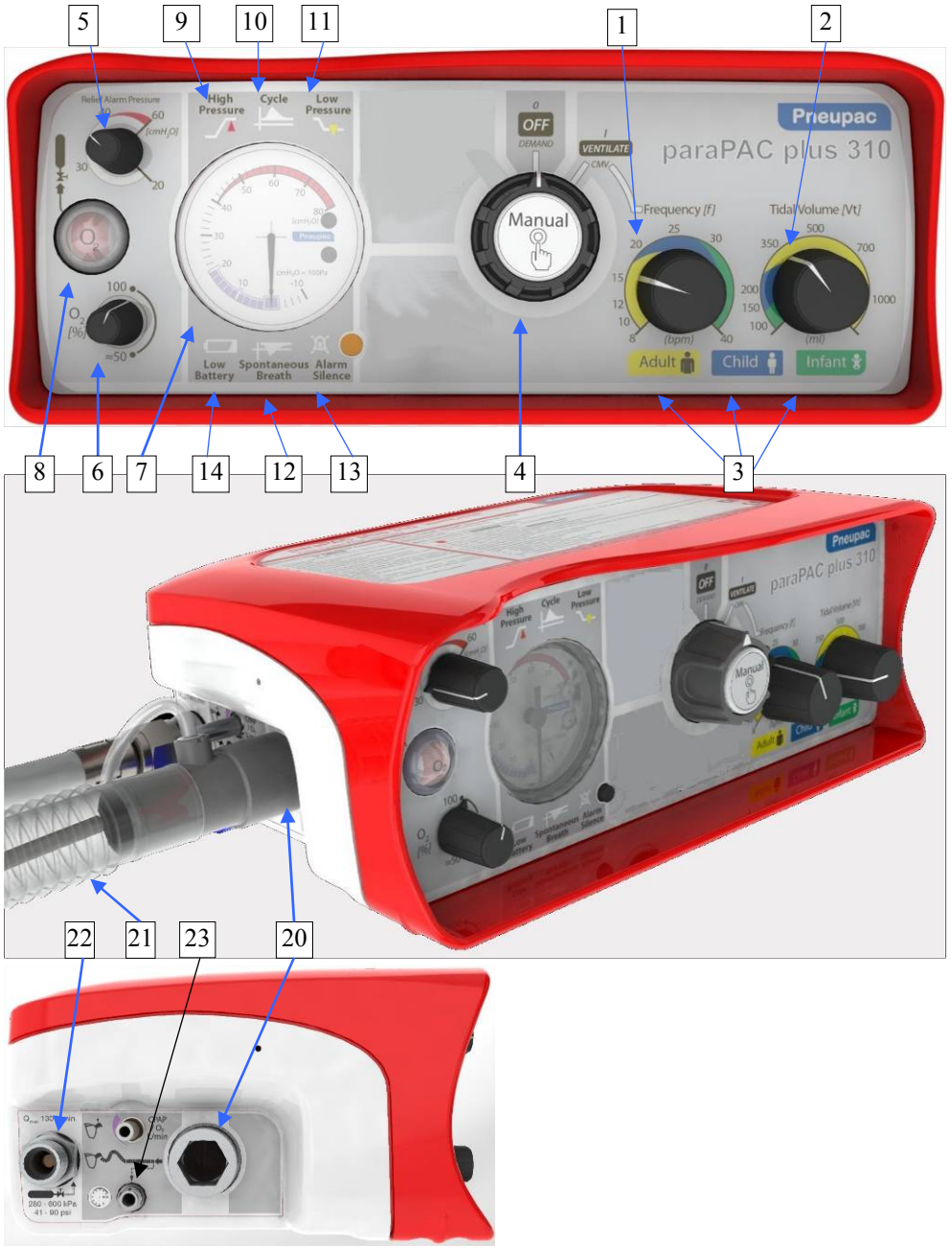


Figure 2.2: Controls, Features & Interfaces of the paraPAC plus 300

4. Function Switch & Manual Push-button

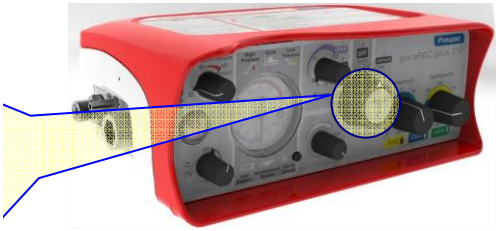


Fig. 2d: Function Switch

This knob operates a rotary switch to select O OFF DEMAND or II FLOW (this function is only available on Model 310 only, see items 19 and 20 below for details of this function) or I VENTILATE CMV which provides continuous mandatory ventilation to non breathing patients but allows inhibition of the CMV function if an adult patient commences spontaneous breathing to an adequate level.

Warning: Because this function has characteristics specific to this range of ventilators it is important that the sections of the operating instructions describing this facility (Sections 2(b) and 4 (d)) are read before this version of the paraPAC plus ventilator is used so that the operator understands how the ventilator interacts with the patient during spontaneous breathing.

Selection of I VENTILATE CMV also switches on the visual electronic alarms but for the first 60 seconds of the ventilator operation, the electronic audible is automatically suspended in order to allow time to apply the ventilator to the patient. Selection of O OFF DEMAND switches off the alarm unit.

5. Relief Pressure Control

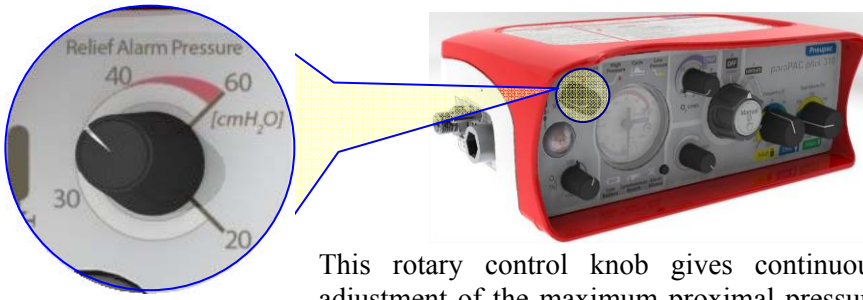


Fig. 2e: Relief Pressure Control

This rotary control knob gives continuous adjustment of the maximum proximal pressure by setting the relief valve spring loading. When the proximal pressure reaches this setting, any additional gas is allowed to escape to atmosphere via the relief valve. Also both the electronic (visual and audible) and the pneumatic audible alarms will be activated.

6. Air mix Control

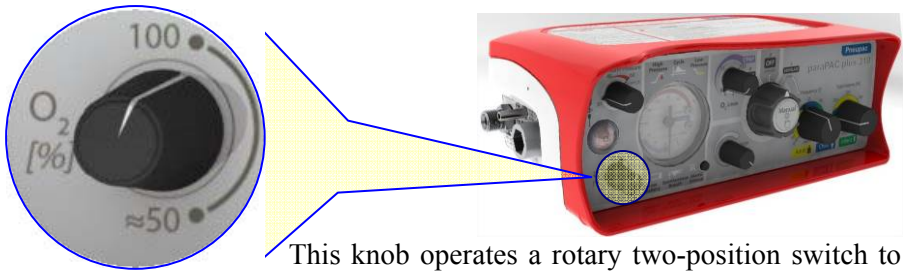


Fig. 2f: Air Mix Control (O2 %)

This knob operates a rotary two-position switch to select the ≈50% oxygen (air mix) or the 100% oxygen (no air mix) mode.

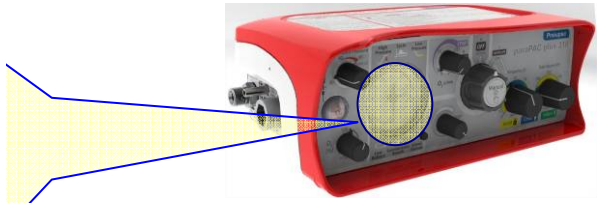
In the 100% oxygen (no air mix) position the gas supplied to the ventilator is passed undiluted to the patient.

In the 50% oxygen (air mix) mode the ventilator uses a high efficiency entrainment device to mix ambient air with the supply gas in the ratio of approximately 2:1. When supplying oxygen, this means that a mixture containing 50% oxygen is generated and supplied to the patient.

Different lung inflation pressures and the use of the paraPAC plus PEEP control can change the ≈50% oxygen concentration. See Appendix B.1.1.& B.1.2.

7. Pressure Monitor

Fig. 2g: Inflation Pressure Monitor (O2 %)



This pressure manometer displays the proximal pressure, as measured at the patient valve connection port. It will give an indication of the actual proximal pressure under all normal settings of the ventilator.

Warning: Ventilators must never be used without the sensing line attached as this will result in a loss of 'delivered volume' to the patient.

Although there is no net flow in the sensing line it is recommended that the microbio filter is always fitted to ensure that no patient contamination can enter the manometer circuit within the control module.

Note : The patient circuit is supplied with the microbio filter attached. The circuit is single use only.

8. Supply Gas Failure Alarm

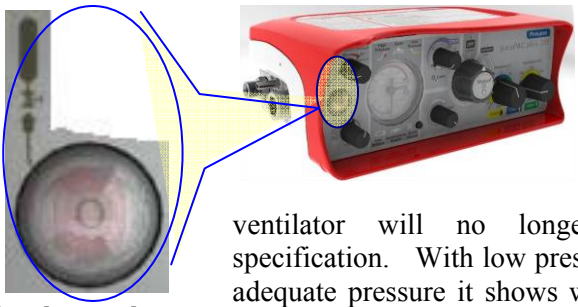


Fig. 2h: Supply Gas Failure Alarm

This mechanically operated visual alarm gives a warning that the supply gas has dropped to a pressure at which the ventilator will no longer be operating to specification. With low pressure it shows red, with adequate pressure it shows white. Any visible red indicates that the supply should be changed. In most cases the display will begin to oscillate from white to partial red as the supply pressure falls to the lower threshold level. The visual indication will be accompanied by an electronically generated medium priority* audible warning. In order to conserve the battery, if this audible alarm is ignored for more than 60 seconds the alarm system will ultimately switch itself off.

* See section 7(e) & (f) for explanation of symbols and description of alarm priorities.

9. High Inflation Pressure Alarm

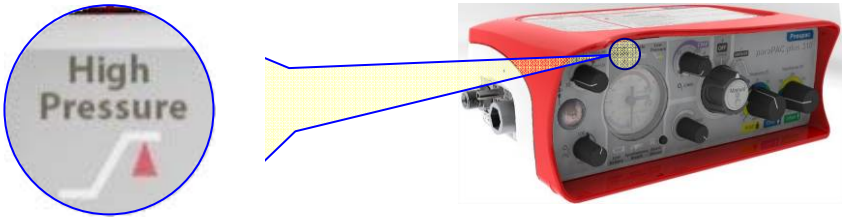


Fig. 2j: High Inflation Pressure Indicator / Alarm

An audible alarm is provided to signal that the relief pressure has been achieved and that gas loss is occurring through the relief valve. The alarm is pneumatically operated by means of gas vented through the relief valve.

Note: The alarm may also be triggered if the PEEP is set above 13cmH_2O (Model 310 only).

The pneumatically operated alarm is backed up by a high priority* electronically generated audible and visual alarm. The electronic audible alarm only sounds after alarm pressure has been maintained for a period of 1.0 second in order to avoid the simultaneous sounding of both alarms during transient pressure events. Initially the visual alarm only indicates each time the pressure reaches the preset limit but if high pressure conditions persist the alarm latches to give continuous flashing.

Both the audible and visual alarms reset automatically after 10 seconds when the condition is no longer present.

10. Cycle Indicator

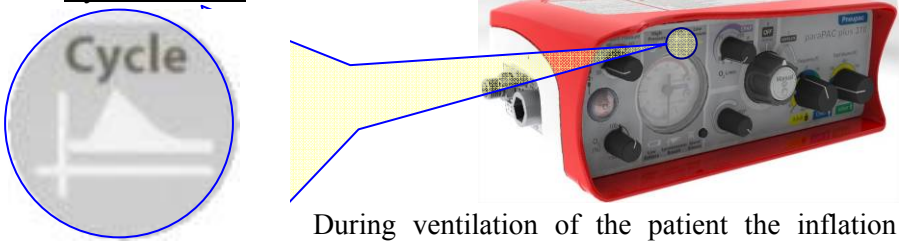


Fig. 2k: Cycle Indicator

During ventilation of the patient the inflation pressure is continuously monitored by a positive pressure detector pre-set to 10cmH_2O (10 x100Pa). Each time the inflation pressure rises through this set pressure level the green Cycle Indicator* flashes for 1/10 second to indicate to the user that, at least, this inflation pressure is being achieved each cycle.

Note: If the PEEP set above 13cmH_2O, this indicator may be disabled (model 310 only).

* See section 7(e) & (f) for explanation of symbols and description of alarm priorities.

11. Low Inflation Pressure (Disconnect) Alarm

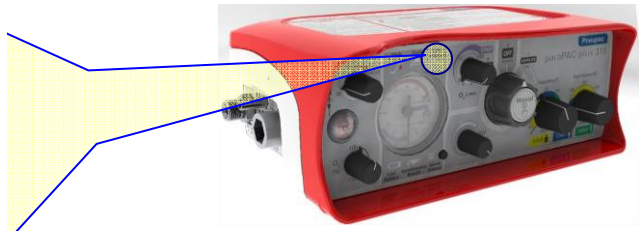
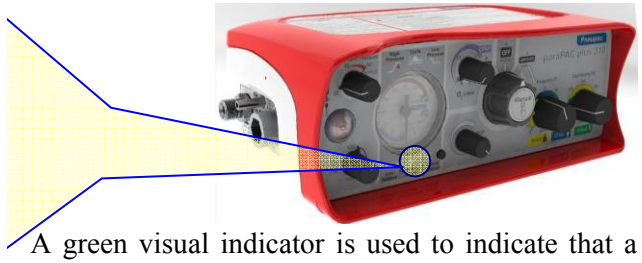


Fig. 2l: Low Pressure Indicator

A medium priority* audible and visual alarm will operate to warn the user of a possible disconnection in the ventilator breathing system or that the ventilator is not cycling correctly if the inflation pressure generated by the ventilator does not rise through the pre-set level of 10cmH_2O (10 x100Pa) at least once in any 10 second period. Both the audible and visual alarms reset when the alarm condition no longer exists.

12. Breathing Detect Indicator



2m: Spontaneous Breath Indicator

A green visual indicator is used to indicate that a spontaneous breathing effort has been detected by the demand detector in the paraPAC plus ventilator. Each time detection occurs the low inflation pressure (disconnect) alarm is reset in the same way as a positive pressure resets the alarm in normal ventilation. This ensures that nuisance alarms do not occur due to the absence of positive ventilation when the patient is breathing spontaneously.

* See section 7(e) & (f) for explanation of symbols and description of alarm priorities.

13. Silencing and Muting of Electronic Audible Alarms

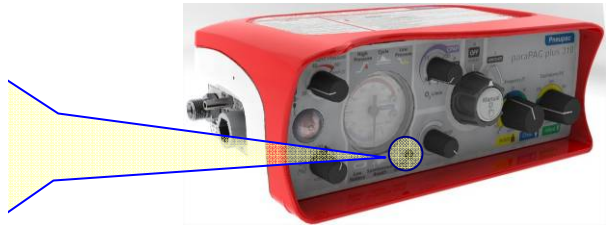


Fig. 2n: Alarm silenced indicator and button

A visual signal, consisting of an orange light flashing every 3 seconds, is used to indicate when an electronically generated audible alarm has been silenced. For the first 60 seconds after switching on the ventilator when I VENTILATE CMV is selected, all alarms, except the supply gas failure alarm, are automatically suspended although high priority visual alarms will still operate. Any audible alarm can be silenced for a 60 second period, subsequently, by depressing the silencing button but if a new alarm condition occurs during this period it will be immediately annunciated.

If the silencing button is depressed before any alarm sounds, then only a new high priority alarm condition will cause an alarm to sound during the following 60 seconds.

14. Low Battery Alarm

Fig. 2p: Low Battery Indicator

A yellow visual indicator is used to indicate that the internal battery used to power the alarm unit is giving reduced voltage. The flashing rate will increase to twice every second, accompanied by a medium priority audible alarm, for the final few minutes of the battery life.

When operating at very low temperature the life of the battery will be reduced.

When the alarm is operating normally, as indicated by flashing of either the silencing indicator or one of the two green indicators, the absence of any signal from the low battery indicator confirms that the battery voltage is adequate to operate the alarm system correctly. Refer to Section 5(c) for recommendations concerning battery replacement.

Warning: To prevent possible risk of projectile injury within a MRI environment, routinely check for magnetic attraction.

Warning: To avoid projectile risk in a MRI environment, use only the approved MR Conditional battery, Part No: W269-023. Do not attempt to remove the battery from the ventilator (or take a loose battery) in a MRI environment.

The electronic alarm unit is powered by means of a single cell lithium battery retained in a battery holder on the right hand side of the ventilator. Only use the special low ferrous content battery, supplied by Smiths Medical and marked "For use in MR Conditional ventilators". This is an AA size battery but provides 3.6V and has a non-metallic casing. It has been specially selected as having minimal ferrous content such that when installed in the ventilator it produces no noticeable effect.

It must be noted that no battery of this type, commercially available, is completely free of ferrous content and must never be removed from the battery compartment of the ventilator in the presence of a magnetic field.

Lithium batteries have an expected shelf life of 10 years and there is no current drain on an installed battery when the paraPAC is switched off . Under general use conditions the specified batteries will give at least one year's service before requiring replacement.

Caution: When storing for long periods, to avoid the risk of possible corrosion or drain of the battery, ensure that the ventilator is left in the 'Demand' (Off) (ventilator off) position and the battery is removed from its holder (Sect. 2(d) # 15).

15. Basic Operating Instructions

This panel on the ventilator gives basic operating instructions to assist the infrequent user of the paraPAC plus ventilator. It is not intended to replace, in any way, the more comprehensive instructions and information given in this handbook.

16. Alarm Information Label

This label provides visual alarm information and a key to alarm signals.

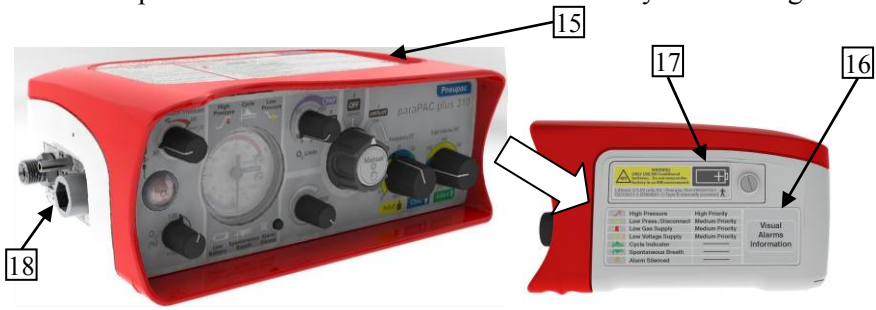


Fig. 2r: Label Information

17. Battery Information Label

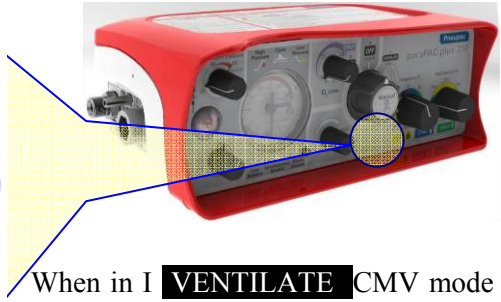
This label on the ventilator has the information regarding the battery

18. Patient Outlet Connection

This outlet to the patient from the ventilator is intended for the attachment of the patient circuit supplied by Smiths Medical for this purpose.

19. PEEP Control (Model 310 only)

Fig. 2s: PEEP Control



When in I VENTILATE CMV mode the control gives continuous adjustment of the PEEP pressure. The PEEP value will be slightly affected by the particular patient and ventilator settings and the patient pressure manometer must be used as the reference for the set pressure.

20. CPAP & Flow Control (Model 310 only) (T_{DEL})

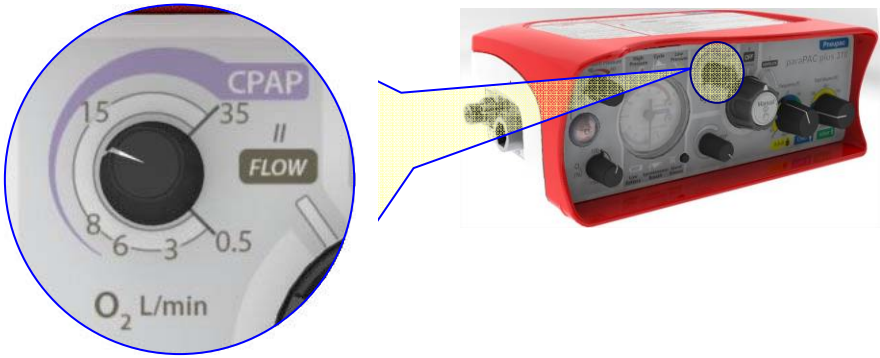


Fig. 2t: CPAP & Flow Control

Warning: Use of the ventilator and Patient breathing Circuit at Tidal Volumes below 150ml may result in a CO_2 build up and inadequate ventilation of the patient. For tidal volumes below 150ml the Smiths Medical Hyperinflation Bag system, in conjunction with the CPAP / Flow connector on the ventilator may be used (model 310 only).

- Rotary control
- Controls oxygen flowrate of 0.5 – 35 L/min.
- Can be used to power oxygen therapy device (tubes, masks etc.)
- Can be used to power CPAP therapy devices
- Output flow from a taper connector

Fig. 2u: CPAP & Flow Connector

21. Patient Breathing Circuits

Warning: Ensure that only approved circuits supplied by Smiths Medical are used with the paraPAC plus range of ventilators. Failure to use the approved circuits could result in death or serious injury.

To avoid cross contamination please be aware that the patient circuit is a single use device and should be disposed of after each use.

There are two variants of breathing circuits both with a patient valve fitted to the circuit. The corrugated tubing houses the pressure monitoring line that interconnects the ventilator to the monitoring devices at the patient proximal end.

The patient valve directs the inspiratory flow from the ventilator into the lungs during the inspiratory phase and allows expiration to the atmosphere. The connection to the patient is by means of a 22mm taper fitting so that face masks or endotracheal tubes conforming to the requirements specified in BS EN ISO 5356-1:2004 may be used. The patient valve contains an non-return valve to minimize entrainment from atmosphere. See table in Appendix C for concentration of oxygen at different inspired tidal volumes.

Warnings:

1. **Users must ensure that they are knowledgeable and proficient in the use of the ventilator and circuit before use to allow them to be used safely.**
2. **Ensure that the circuit is undamaged, complete, assembled correctly and fully functional before use. Failure to do so could lead to inadequate ventilation.**
3. **Ensure that all connections are secure. Failure to do so could lead to inadequate ventilation.**
4. **Ensure that the inline filter is securely attached to the ventilator and that the pressure monitoring line is not kinked. Failure to do so could lead to incorrect or misleading readings on the ventilator's manometer.**
5. **Pressure test the circuit before use to verify leak resistance. Failure to do so could lead to inadequate ventilation.**
6. **Ensure that the PEEP valve is set to the minimum pressure before connecting the circuit to the patient. Failure to do so could lead to patient injury.**

CAUTIONS:

1. **The PEEP valve has been determined to be MR Conditional ref. (ASTM) F2503-08. There is no projectile risk or change in PEEP performance in a static magnetic field of 3 Tesla or less with spatial gradient magnetic field of 7.5 T/m (750 G/cm) or less.**

   Special care should be taken as follows: MR image quality may be compromised if the area of interest is close to the position of the PEEP Valve. Therefore it should be secured away from the area of interest for the scan. Optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

2. **If circuit 100/905/341 is used with Model 310 and the circuits PEEP valve is set higher than the value set by the ventilator's separate PEEP control, the value indicated on the mechanical PEEP valve will be the calibration to follow. At all times, use the ventilator's manometer to accurately monitor the set PEEP.**

21 (a) Standard Circuit

The circuit (Ref 100/905/340) has been designed for use with the paraPAC plus ventilator. A Single Limb Circuit with Internal Pressure Monitoring Line with In-Line Filter and Expiratory Port Flow Diverter.

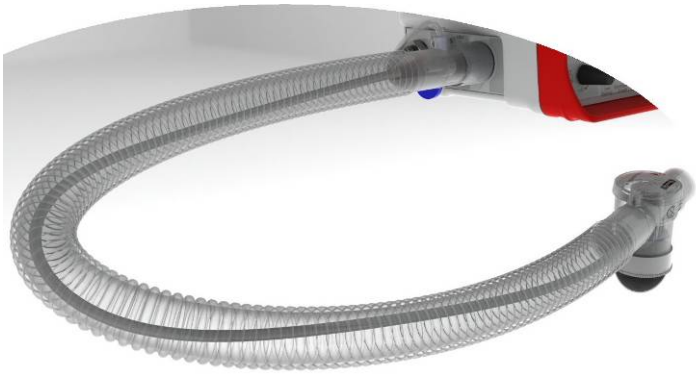


Fig. 2v: Patient Breathing Circuit with Patient Valve & Sensing Line

21 (b) Standard Circuit with Mechanical PEEP valve. (Model 300 only)

The circuit (Ref 100/905/341) has been designed for use with paraPAC plus ventilator.

A Single Limb Circuit for Pneupac ParaPAC plus Ventilators with 0-20 cmH_2O PEEP Valve and Internal Pressure Monitoring Line with In-Line Filter. PEEP setting is by means of a calibrated adjustment knob.

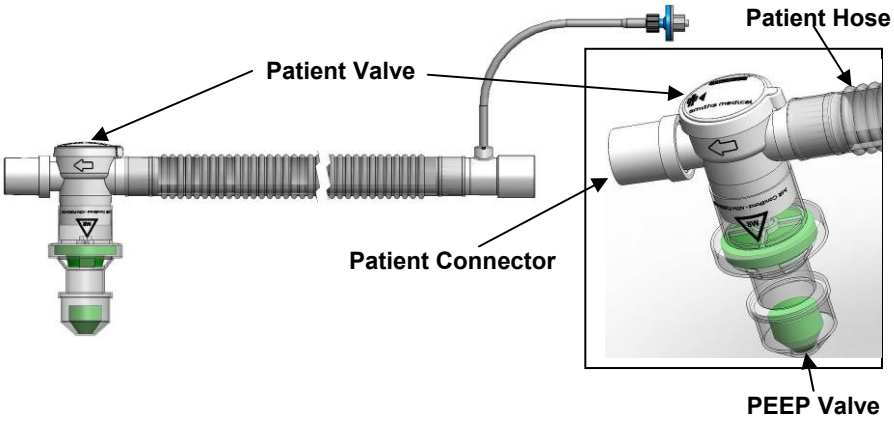


Fig. 2w: As With 2v above with a Mechanical PEEP valve

22. O_2 Input Connection

A compact, screw type input connection is provided which is specifically designed to take the input hose provided by Smiths Medical to make a permanent connection. Alternative, gas specific, user detachable connections can be provided by Smiths Medical if specified at the time of ordering.

23. Flow / CPAP Connection (Model 310 only)

A tapered connector suitable for connection to oxygen therapy accessories including entrainment type CPAP accessory.

24. Pressure monitoring Connection

This is a Luer lock connector that allows connection of the Pressure Monitoring Line with an In-Line Filter from the patient circuit. This means that inflation pressure is measured at the patient connection port and PEEP is therefore displayed on the inflation pressure monitor

Fig. 2x: Fixtures & Interfaces of the paraPAC plus 310

25. Mounting Attachment Points

Six M6 x 7mm deep female threaded bushes on the back of the control module may be used for the attachment of brackets for direct mounting.

26. Input Hose

A range of input hoses are available with alternative connections and probes to suit different geographic locations and requirements by different Standards (see Appendix D).

(e) Options Covered by this Manual

(i) Model Option

Feature	Model 300	Model 310
8 to 40 bpm Frequency Control	✓	✓
70 to 1500 ml Tidal volume control	✓	✓
Air mix control 100% or 50% oxygen concentration	✓	✓
Manual breath button	✓	✓
Demand oxygen therapy function	✓	✓
Demand inhibit of CMV	✓	✓
Electronic alarm	✓	✓
PEEP Control on ventilator		✓
II FLOW control		✓

(ii) Device Orientation and Installation Options

The paraPAC plus ventilator has been designed to be installed and carried with a wide range of options as shown in Fig. 2y & Fig. 2z.

It may be used with its base or back on a flat surface as shown in Fig. 2y.

Fig. 2y: Orientation Options

Figure 2z: Installation Options

For more permanent installations paraPAC plus ventilators can be fitted with a rail or pole-mounting bracket as shown in Fig. 2z. The brackets are attached to the back of the control module by means of two M6 socket head fixing screws supplied with the bracket. The rail bracket is of the universal type and attaches to 35/30 mm rails of either 6.5 or 10 mm thickness and of the form shown in Fig 2z. A quick release clamp with a screw back up is used.

The pole mounting bracket attaches to the module in the same way and accommodates vertical pole diameters of 1/2 - 1" (12 - 26 mm). A screw with a T-handle is used for clamping.

(f) Accessories

Warning: The paraPAC plus ventilator is manufactured and 'CE' marked to the requirements of 93/42/EEC. To ensure that this equipment functions as intended, use only the manufacturer's authorised spares and accessories.

(i) Gas Cylinders

Lightweight aluminium compressed gas cylinders are available from Smiths Medical International Ltd. for use with portable ventilators. The 'D' sized version is suitable for use with the Carrying Case (if used), but it is flat based which permits free standing use also.

(ii) Cylinder Regulators

The Pneupac brass body regulator is designed to reduce the pressure of high pressure gas cylinders from 137 x100kPa (137 bar) to 400kPa (4 bar) as required by the paraPAC plus ventilator. It will deliver flow in excess of 60 L/min at this nominal pressure. Pin index or other standard inlet connectors are available for air or oxygen. The regulator is equipped with a protected contents gauge and a gas specific quick-release outlet connector which accepts the BS probe on the paraPAC input hose.

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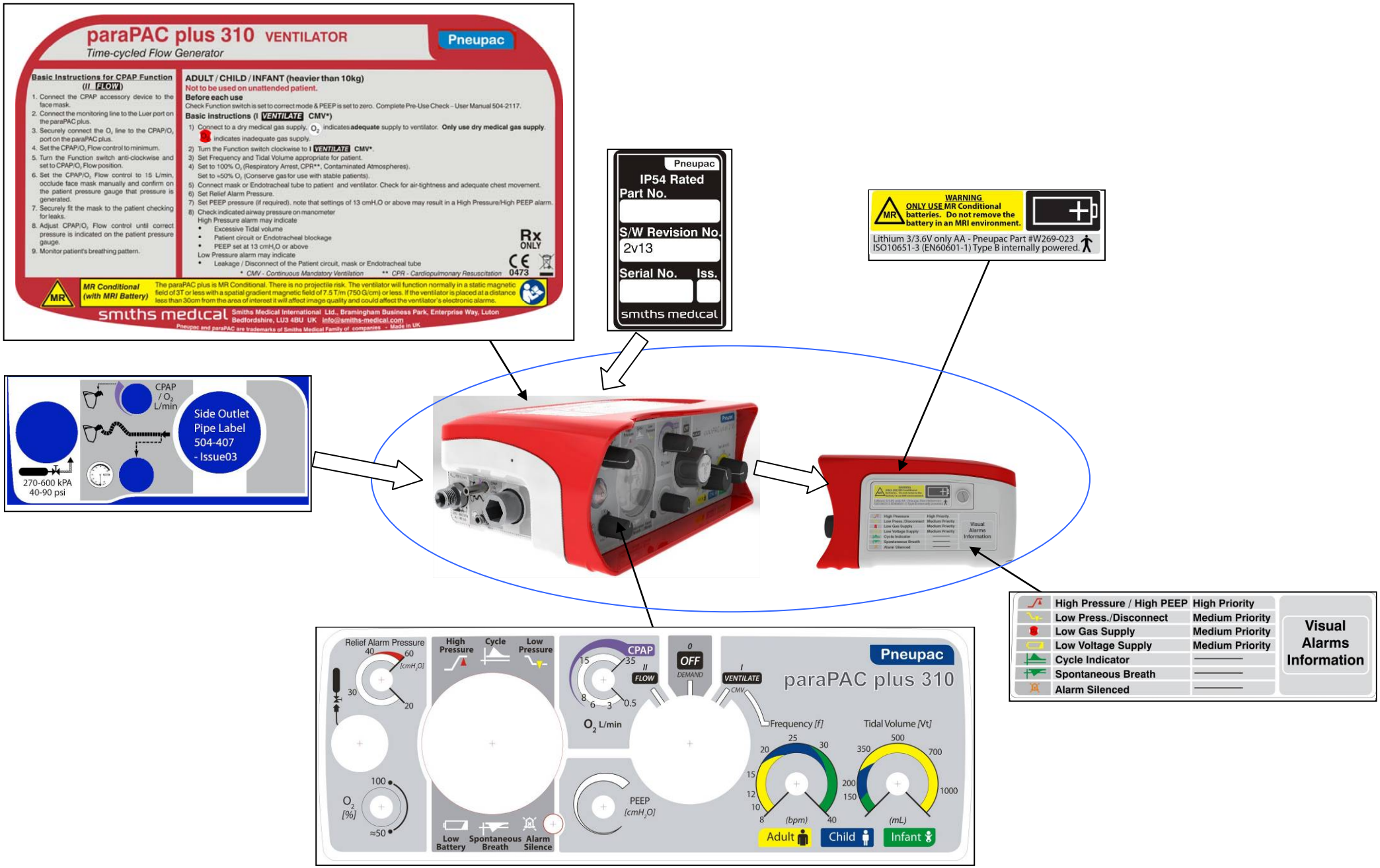


Figure 3: paraPAC plus Model 310 Labels and Their Locations

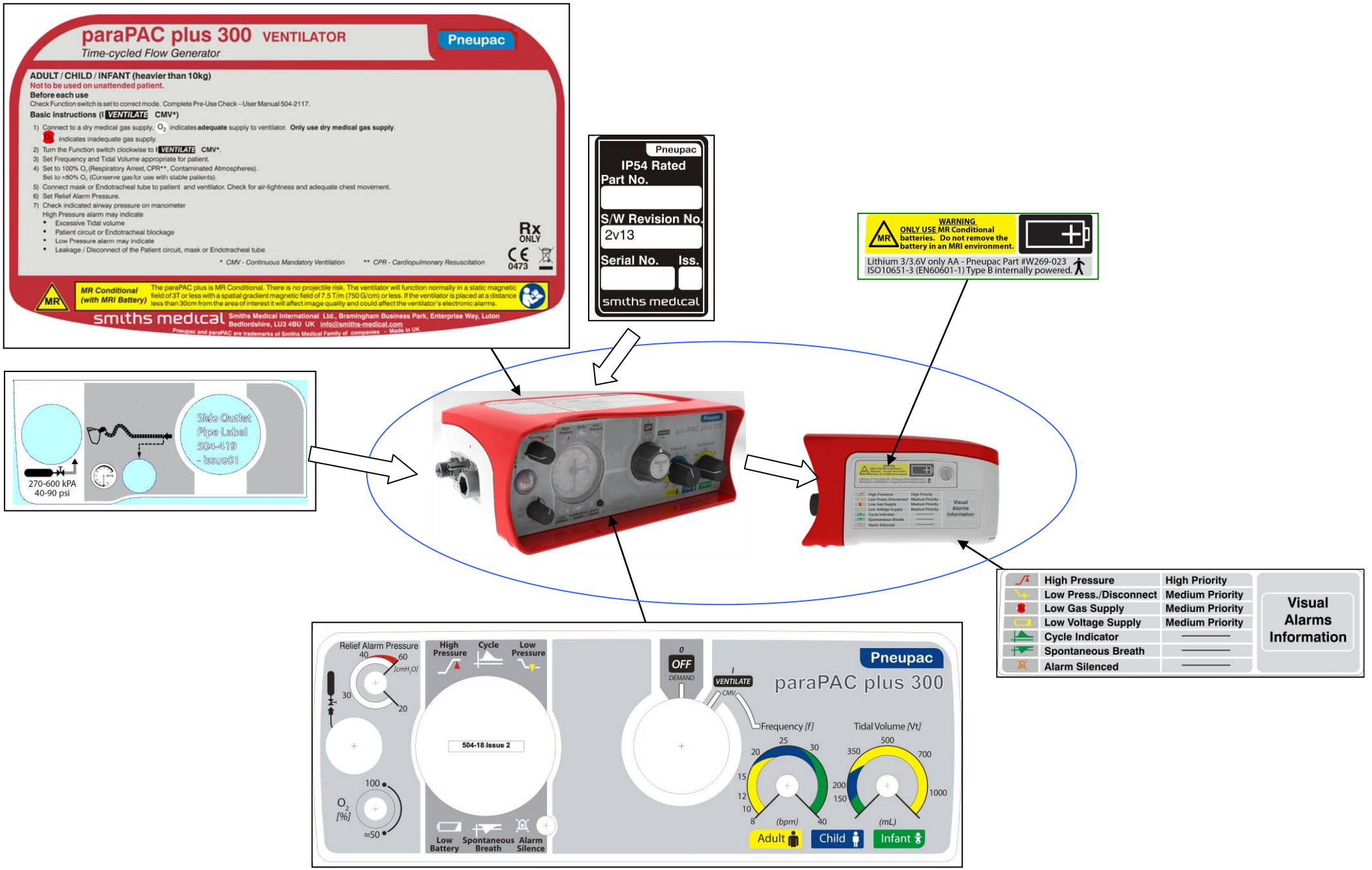


Figure 4: paraPAC plus Model 300 Labels and Their Locations

SECTION: 3 SET-UP, FUNCTIONAL CHECK and USE

(a) Set Up

(i) paraPAC plus ventilator

Unpack the paraPAC plus control module and accessories and check all items against the contents checklist. If any items are missing or incorrect or have become damaged notify your supplier immediately.

Insert the battery into the module battery holder as described in Section 5(c). Connect the breathing circuit to the control module as shown in Fig 1 (a). Connect the input hose to the inlet connector as shown in Figure 1(a) and tighten the securing nut lightly using a spanner (wrench).

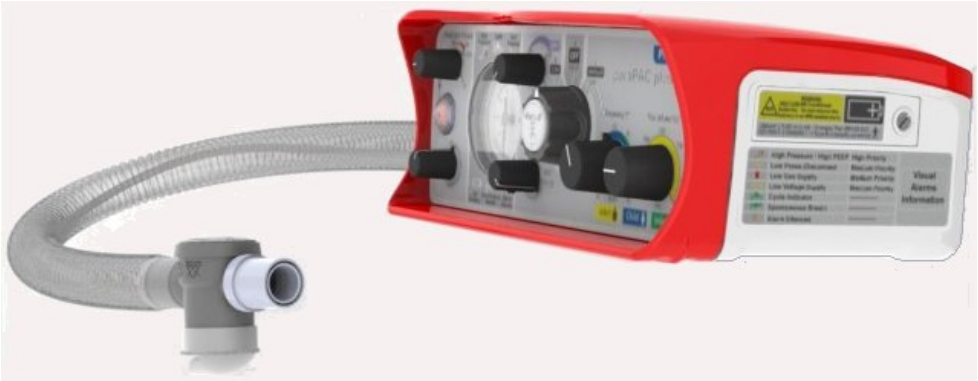


Figure 5: paraPAC plus and Breathing Circuit

The probe on the input hose is gas specific to the standard specified when ordering. Any of the Smiths Medical hoses listed in the paraPAC Accessories and Spare Parts List can be used with the ventilator provided the same inlet connection is specified.

Warning: To avoid harm to the patient, pre-use checks must be performed before each use (See Section 3(a) and 3(b) Points #1 to #10 inclusive).

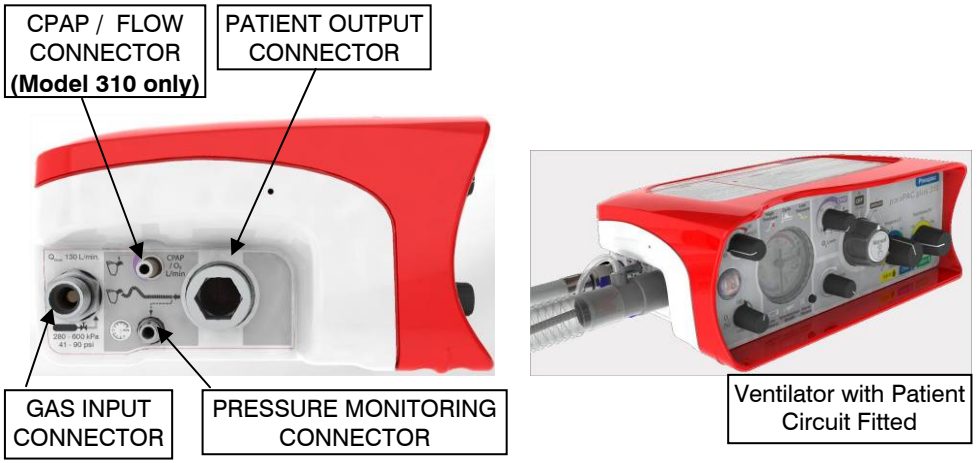
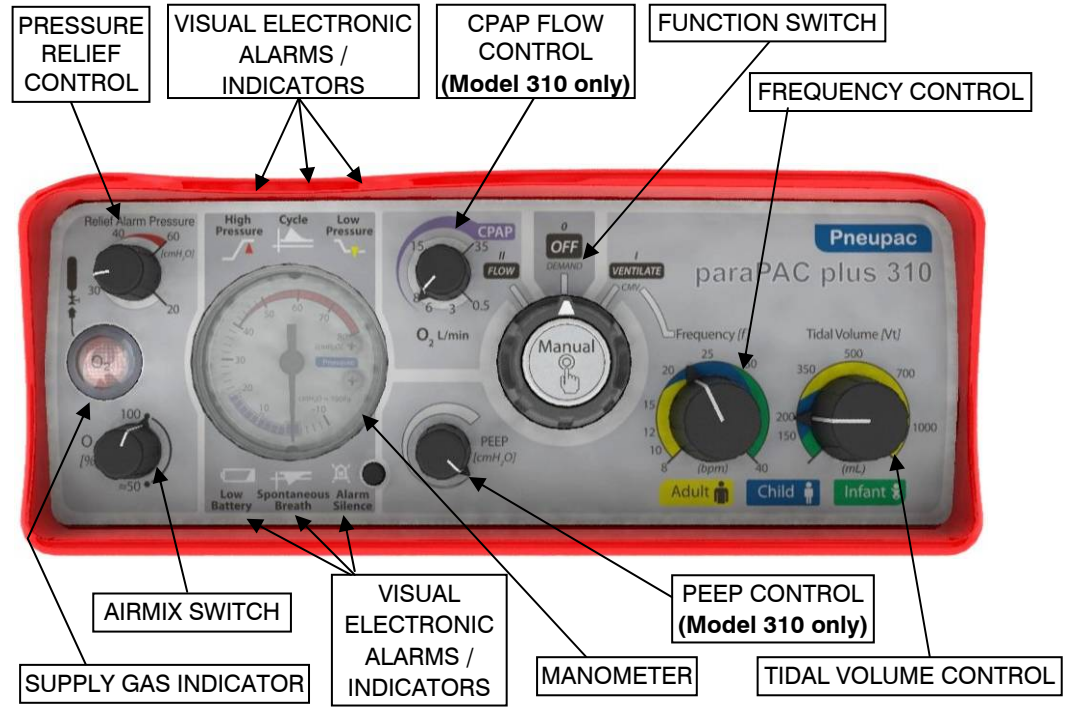


Figure 6: paraPAC plus User Interfaces



(b) Functional Check

The following procedure should be followed when first setting up the ventilator to check that it has been assembled correctly and is operating safely. It should be repeated periodically as specified under 'Maintenance'.

1. Check the ventilator controls as follows:-

Function Switch	O **OFF** DEMAND.
Frequency	12 bpm
Tidal Volume:	700mL
Air mix Switch (O_2 %)	≈ 50
Relief Pressure:	40 cmH_2O (40 x100Pa)
CPAP / O_2 Therapy (Model 310 only)	Fully counter-clockwise
PEEP (Model 310 only)	Fully counter-clockwise

Caution: Ensure the Filter is securely connected to the sensing line.

2. Connect the pressure monitoring Filter on the patient circuit to the pressure monitoring connector on the ventilator.
3. Connect a breathing circuit to the output connector on the ventilator.
4. Connect the gas input hose to the input connector on the ventilator and secure in place with a spanner (wrench).
5. Connect the probe on the input hose to an appropriate dry filtered gas outlet.
6. If connected to a cylinder regulator turn on cylinder valve **slowly**.

NOTE: The gas source must be capable of maintaining a pressure of at least 280 kPa (≈2.8 bar) whilst delivering a flow of 40 L/min.

7. Check that the visual alarm for supply gas failure indicator has changed from red to white.
8. Set the Function Switch to **I** / **VENTILATE** / **CMV**.
   The ventilator should commence cycling and all the visual alarms will flash in turn. A single burst of the high priority audible alarm is given at the same time. The orange silencing indicator should flash for 60 seconds.
9. Allow the ventilator to cycle with no obstruction at the output port and check that the low inflation pressure (disconnect) alarm operates after 10 seconds.
10. Occlude the outlet of the patient valve and check that the manometer gives a reading of between 30 and 50 cmH_2O during each inspiratory phase. The pneumatic audible alarm should also sound, accompanied by the high inflation pressure visual alarm. After occlusion for one second and once the silencing period has elapsed, the high priority electronic audible alarm will also sound. Check that the unit cycles regularly about every 5 seconds.

11. Set O_2 (%) switch to 100 and repeat step 10. The difference in the manometer reading should not be more than 5cmH_2O (5 x100Pa) from the reading taken in step 10 above.

NOTE: After the 60 second initial silenced period the electronic audible alarms will operate if an alarm condition persists. These can be silenced for as long as required by depressing the silencing button each time the silencing indicator switches off.

12. Set the 'Tidal Volume' control to its minimum setting and ensure that the O_2 % switch is set to 100. Occlude the output port and check that at least 20 x100 cmH_2O pressure is attained on the manometer. Gradually increase the Tidal Volume setting and observe that the pressure increases until the relief pressure is reached.
13. Reset the 'Tidal Volume' control to its minimum setting and set O_2 (%) switch to ≈ 50. Occlusion of the output port should now cause the manometer to rise sharply to between 30 and 50 x100Pa and the alarms should operate.
14. Set the Frequency control knob to the extreme of its range. By listening to the gas flow, check that the ventilator is responding to the controls and that no irregularities of performance can be observed. It will be audibly noticeable as the frequency is reduced from 40 down to 8.
15. Finally, set the controls as specified in step 1 so that the ventilator is left set for emergency use.

(i) Pre use function test of the PEEP Function (Model 310 only)

16. With settings as specified in step 1, except the relief pressure which should be set to maximum (fully clockwise), connect patient hose to a 1 Litre Test Lung (not supplied)
17. Turn Function Switch control to **I VENTILATE CMV** and observe functioning of the test lung.
18. Turn PEEP control fully clockwise and observe the patient pressure manometer which should read between 16 to 24 during the expiratory phase.
19. Return PEEP control to the fully counter clockwise position and the test lung should collapse during expiratory phase and patient pressure manometer should read 0.
20. Turn Function Switch control to **O OFF DEMAND.**

(ii) Pre use function test of the CPAP Function (Model 310 only)

21. With settings as specified in step 1
22. Turn Function Switch control to **II FLOW** (Model 310 only).
23. Turn CPAP control from minimum to maximum then back to minimum and observe increasing then decreasing sound of flow from the CPAP outlet port.
24. Turn Function Switch control to **O OFF DEMAND.**
25. Finally, set the controls as specified in step 1 so that the ventilator is left set for emergency use.

Warning: Deviations noted at functional check should be reported immediately to Smiths Medical and the unit must be taken out of service to avoid the risk of death or serious injury.

Warning: To avoid the risk of ignition, do not smoke or have naked flames in the vicinity of oxygen. Do not allow oil, grease or combustible lubricants (only those approved for oxygen use) to come into contact with any part of the ventilator, regulator or cylinder.

Warning: To avoid ignition by adiabatic compression, connect the ventilator to the regulator before opening the cylinder valve slowly. Similarly, prior to changing cylinders, turn off the cylinder valve, switching on the ventilator. When the ventilator stops, it is safe to release the pin index yoke.

Caution: To ensure that the cylinder contents are not lost during storage due to small leakages, it is recommended that the valve on the gas cylinder is turned off after use.

(c) User's Skill

See Summary Statement (Section 1(a))

Warning: All operators who are not medically qualified should receive full and proper instruction from a qualified person, both on resuscitation and on detailed use of the equipment in the particular situations in which it might be employed (see Section 1(a))

Warning: Always ensure that an alternative means of ventilation is available in the event of ventilator failure or malfunction

Warning: Extreme environments may impair ventilator performance. Operator vigilance is required to monitor the patient.

Warning: Failure to constantly monitor the patient clinically, whilst using this equipment may lead to death or serious injury.

Warning: To avoid harm to the patient, blood oxygenation and expired carbon dioxide levels should be monitored independently using pulse oximetry and capnography as part of due clinical diligence.

Warning : To avoid harm to the patient, inter- or intra-hospital transport should only be undertaken according to established medical practice and under medical supervision.

(d) Setting of Ventilator

The ventilator should always be left with the controls set in the position specified in the functional check (Section 3(b)) to enable it to be brought into use with a minimum of re-adjustment. It should be stored with a suitable gas source or suitable wall outlets must be known to be available. At least one patient circuit should also be kept available for emergency use.

(e) Ventilating the Patient in | VENTILATE CMV.

CAUTION : To avoid risk of internal corrosion within the device, use only dry, filtered gas.

1. Connect supply hose probe to dry filtered gas supply.
2. Turn on gas supply (if relevant).
3 Check that the visual alarm for supply gas failure has changed from red to white.
4. Turn Function switch to | VENTILATE CMV.
5. Check that the alarm indicators flash in sequence, to indicate correct function.
6. Set ventilation parameters to suit the patient.
7. Briefly occlude the patient connection port of the patient valve with the thumb. Check that the peak inflation pressure reading on the manometer is appropriate for the patient and that the pneumatic audible alarm sounds and the high inflation pressure indicator shows red.
8. Connect face mask or endotracheal tube (ET tube) to patient valve.
9. Check chest movement and Inflation Pressure Manometer to ensure correct ventilation.
10. Check that the green cycle indicator light flashes when inflation pressure rises above 10cmH_2O.

11. Make adjustments to the ventilator based upon clinical observation and measurement of expired CO_2 and pulse oximetry.

The patient's condition and chest movements as well as the inflation pressure monitor should be kept under constant observation so that changes in airway resistance and lung compliance can be detected and corrected before the patient is put at risk. Repeat step 11, above, if the tidal volume setting is increased at any time during the ventilation procedure. When ventilating with a mask, the peak inflation pressure should ideally be kept below 20cmH_2O (20 x100Pa) to minimise the risk of inflation of the stomach.

If the pressure jumps excessively at the commencement of inspiration, an airway obstruction is indicated and this must be rectified. If the airway is clear the flow rate may be too high and this should be reduced by decreasing the tidal volume setting.

Excessive pressure at the end of inspiration may be the result of a too high setting of tidal volume. This may be reduced by either reducing the tidal volume setting or increasing the frequency setting.

When ventilating with an ET tube a sudden increase in patient airway pressure may indicate kinking of the tube or other obstruction.

If the inflation pressure is too low, particularly if the low pressure alarm operates;

- check for leaks
- check the ventilation parameters
- check the patient valve for proper functioning.

Warning: Always ensure that an alternative means of ventilation is available in the event of ventilator failure or malfunction

Warning: To avoid harm to the patient, ensure that ventilation can be maintained without interruption, keep a constant check on the adequacy of gas supply by observing the gas cylinder contents indicator and the gas failure visual alarm.

If you are in **any** doubt about the function or setting of the ventilator the patient should be immediately transferred to another ventilation device (such as a bag – valve device) until the problem has been resolved.

(f) Use of CMV & Demand inhibit

Warning: Failure to constantly monitor the patient whilst using this equipment may lead to death or serious injury.

Warning: Because this function has characteristics specific to this range of ventilators it is important that this section is read before use so that the operator understands how the ventilator interacts with the patient during spontaneous breathing

Warning: Actuation of the 'Spontaneous Breath' indicator only indicates that spontaneous breathing has been detected and that the low-pressure alarm has been reset as a consequence. The operator must still ensure that patient minute ventilation is adequate.

(i) Demand breathing system

The demand breathing system allows a spontaneous breathing patient to draw oxygen 'on demand' from the gas supply, in any mode and in some cases, cause the ventilator cycling to inhibit.

When I VENTILATE CMV is selected, the ventilator delivers the preset tidal volume and frequency according to the setting on the Tidal Volume/Frequency control. However, if the patient starts to breath spontaneously with an inspiratory effort of below -2 cmH_2O, oxygen from the gas supply can be drawn up to a flow of 120 L/min.

If the demand breath volume exceeds approximately 450ml, the ventilator cycling will also be inhibited. At the end of spontaneous breathing, the ventilator recommences cycling after the expiratory time.

The demand breathing system does not inhibit cycling of the ventilator if the patient takes frequent small panting breaths. Volumes demanded by a child may be insufficient to inhibit the ventilator.

When O OFF DEMAND is selected, the ventilator functions as an oxygen delivery system, delivering 100% oxygen to the patient during each spontaneous breath.

Notes:
1. *The unit delivers ≈100% oxygen regardless of O_2 % (Airmix) setting.*
2. *Under certain circumstances, when the patient is drawing flow from the demand breathing system, the demand valve may 'flutter'. This does not affect operation of the device.*
3. *At ambient temperature between 0ºC and -18 ºC, the demand tidal volume required to inhibit the automatic cycling can be expected to increase outside the normal limits. Additional user vigilance should be applied in these conditions.*

(ii) Spontaneous breathing under power failure

Should the oxygen supply fail, the ventilator will not cycle, but the patient can breath spontaneously through the ventilator since a separate internal 'spontaneous breathing' valve opens to atmosphere.

(iii) Manually Ventilating the patient in O OFF DEMAND mode

To use the Manual ventilation facility the function switch must be set to O OFF DEMAND position

Figure 7: Selection for Manual Ventilation

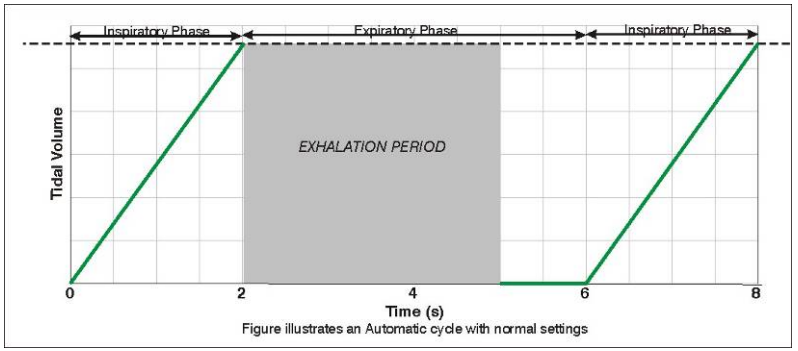
1. Select the appropriate mask or airway (Endotracheal tube or LM) and connect the breathing circuit. Select the required tidal volume and frequency appropriate for the size of patient and adjusting if necessary.

Note The first cycle of delivered volume is 20% more than the selection.

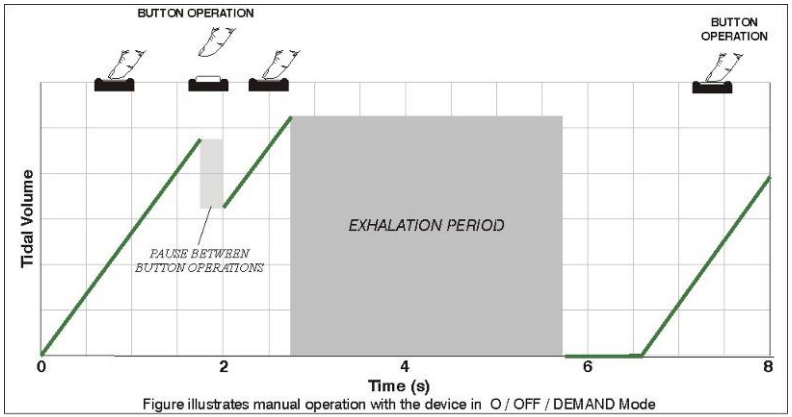
2. With the Airmix switch select the required oxygen concentration 100% O2 or 50% O_2 .
3. Set the function switch to O OFF DEMAND position.
4. Ensure a clear airway and correct head position.
5. Depress the MANUAL button on the function switch and listen for flow whilst the button is held, up to the duration set by the tidal volume and frequency.
6. Check patient's chest movement to ensure correct ventilation,.
7. Make adjustments to the controls as necessary.

Pressing down the 'MANUAL' button is a means by which a series of single breaths, as set by the tidal volume and frequency controls, can be delivered to the patient. It is NOT a purge action; it cannot stack breaths and is therefore inherently much safer to the patient.

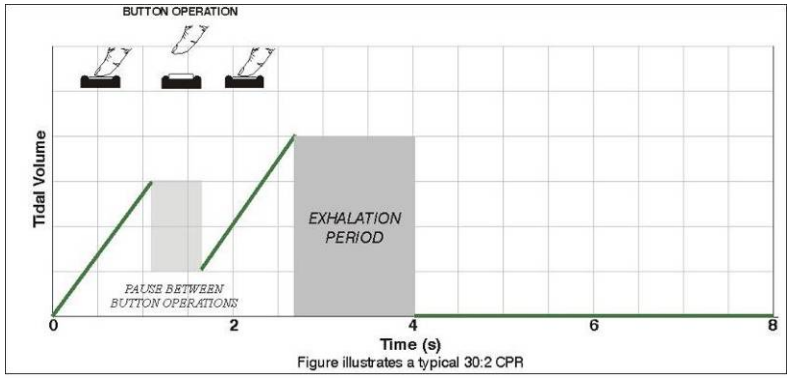
If the user delivers a total tidal volume, the ventilator will 'lock out' until the appropriate E-time has elapsed. If a shorter breath is delivered, then further breaths can be delivered until the total tidal volume has been delivered. The unit will then 'lock out' again for the E-time".



a: Automatic Ventilation



b: Manual Ventilation



c: Manual Ventilation (30:2 CPR)

Figure 8: Manually Ventilating the patient in O OFF DEMAND mode

(iv) Use of CPAP (Model 310 only)

Connect the CPAP accessory supply tubing to the O2 Therapy / CPAP Therapy barbed connector on the side of the ventilator. Connect the CPAP accessory pressure monitoring tube to the Luer lock manometer connection on the side of the ventilator

Connect the ventilator to a suitable supply of oxygen

Set the function switch to the O2 therapy / CPAP function

Use the Oxygen therapy / CPAP control to adjust the level of the CPAP which is displayed on the inflation pressure monitor (Manometer). Please refer to the CPAP accessory user manual for more detailed connections and instructions for use

(v) O_2 Therapy (Model 310 only)

Connect the oxygen therapy accessory supply tubing to the O2 Therapy / CPAP Therapy barbed connector on the side of the ventilator.

Connect a suitable supply of oxygen to the ventilator

Set the function switch to the CPAP FLOW function

Use the CPAP FLOW control to adjust the level of oxygen flow to the accessory. The range 0.5 to 15 L/min is calibrated for use with free flow oxygen therapy accessories

(g) Ventilating Intubated Patients

Warning: If a Heat Moisture Exchanger (HME) filter is used and the patient is experiencing breathing difficulties, or there are mechanical ventilation problems, or decreases in gas exchange, always ensure that there are no blockages in the breathing system. If a blockage is found, immediately replace the breathing system or HME filter. To prevent such problems occuring, filters and HME's should be routinely replaced in accordance with the manufacturer's instructions.

When the patient is intubated, the operator must be concerned with the implications of bypassing the patient's upper airway. In particular, the use of the 50% oxygen (air mix) in a dust filled environment could introduce contamination into the patient's lungs and the drying effects of medical gas must also be considered.

Both of these potential problems can be effectively overcome by the use of bacterial filters, which also acts as heat and moisture exchangers (HMEs). Smiths Medical would therefore strongly recommend the use of such devices when ventilating intubated patients, at least for longer term ventilation. Only HMEs conforming to EN ISO 9360 are recommended.

(h) Positive End Expiration Pressure (PEEP)

(i) PEEP on Model 300 (Patient Circuit Part No. 100/905/341)

PEEP can be applied using the patient circuit with mechanical PEEP valve as shown in Figure 2w. The exhaust port shown is fitted with a mechanical type PEEP valve.

Warning: To reduce the risks of potential projectile injury to the user or patient, the normal routine of checking the ventilator system for magnetic attraction should be followed whenever the equipment is taken into an MRI environment to ensure that magnetically attracted parts have not been added to the system inadvertently.

The patient pressure manometer will indicate exhalation pressure so the setting of the PEEP control can be carefully observed. The patient pressure manometer will show the sum of the PEEP and the airway pressure drop as a step change at the commencement of inspiration and the effect of PEEP changes can be observed in this way.

(j) Use in Contaminated Atmospheres

Warning: The paraPAC plus ventilator models are suitable for use in contaminated and toxic atmospheres subject to certain limitations as described below and these should be clearly understood by those likely to use the equipment in such environments so that it is only used where appropriate.

In any situations where the respirable qualities of the immediate environment are suspect, ventilation should only be carried out in the 100% oxygen (no air mix) mode. This ensures that only a minimum of ambient gas can enter the breathing system.

If the victim is breathing weakly or intermittently the tidal volume should be adjusted to ensure that the ventilator controls the entire breathing pattern.

If the victim is breathing strongly, ideally, the paraPAC plus ventilator should be used with the Off (Demand) mode selected.

Some of the surrounding atmosphere may enter the breathing system during spontaneous breathing as a result of venting ports within the ventilator. This dilution is minimal but will be worst at low breathing levels - particularly below the level at which inhibition occurs - and therefore under these conditions the paraPAC plus ventilator should be set to take control of the breathing.

(k) Use in a Magnetic Resonance Imaging (MRI) environment

WARNING: To prevent possible risk of projectile injury within a MRI environment, routinely check for magnetic attraction.

WARNING: When in use in an MRI environment, to prevent injury to the patient, check the pressure manometer to confirm unchanged ventilation. Also, test the high pressure relief/ alarm system by temporary circuit disconnection and occlusion of the ventilator outlet connector, both whenever the system is taken into an MRI environment, and every time the patient is positioned within the magnetic field.

The paraPAC plus model 310 has been determined to be MR Conditional ref. (ASTM) F2503-08. There is no projectile risk or change in ventilator performance within an open bore shielded magnet with a static magnetic field of 3 Tesla or less with spatial gradient magnetic field of 7.5 T/m (750 G/cm) or less. Special care should be taken as follows:

If the ventilator is placed at a distance less than 30cm from the area of interest it will affect image quality and could affect the ventilator's electronic alarms. Therefore, the ventilator should be secured at least 30cm away from the area of interest for the scan. Optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

All tests were undertaken on a Siemens MAGNETOM Verio 3T 70 cm open bore whole body system with a Field Strength at centre of bore of 3 Tesla. Maximum spatial gradient of 7.5 T/m (750 G/cm).

(l) Use of Air mix

The O_2 % (Airmix) control allows for the selection of ventilation of the patient with supply gas or with the supply gas diluted by ambient air in the ratio 1:2.

Where high oxygen concentrations are required, such as during initial resuscitation, use the 100% (no air mix) setting and oxygen as the supply gas.

Where ≈50 % oxygen concentration is required, use an oxygen supply and select ≈50 (air mix). In this setting a bottled gas supply will last longer and therefore this setting is preferred wherever possible once the patient is stabilised.

When the tidal volume control is set to its lower settings with ≈50 % (air mix) selected the actual tidal volume and oxygen concentration delivered to the patient will become increasingly dependent upon the inflation pressure being generated. The use of the paraPAC plus PEEP control can also change the ≈50% oxygen concentration.

The ventilator is calibrated such that at normal inflation pressures the tidal volume calibration accuracy is maintained. At high or low inflation pressures the calibration accuracy should not be relied on when ≈50 % (air mix) is selected and low tidal volumes are being delivered. However, in most cases the operator will be using additional indicators to assess adequate ventilation (eg. inflation pressure and pulse oximetry). If it is required to set the ventilation more accurately then this can be achieved by first setting the ventilation to the calibration using the 100% (no air mix) setting. If the peak inflation pressure is noted the tidal volume control can be adjusted to achieve the same inflation pressure after selecting 50% oxygen (air mix). The calibrated tidal volume will now be delivered.

At low tidal volume settings with ≈50 % (air mix) selected and oxygen as the supply gas the delivered oxygen concentration will be higher than 50%. The exact rise will be dependent upon the tidal volume setting and the patient compliance and resistance, but if the concentration requirement is critical oxygen monitoring equipment should be used.

See Appendix B.1.1 for Affects Of Inflation Pressure On Delivered Tidal Volume & Oxygen Concentration.

NOTE: 60 cm H_2O is not shown because there is a 100% flow drop due to relief valve being fully open.

See Appendix B.1.2. for Increase of delivered nominal FiO_2 (≈50%) due to the entrainment of the paraPAC plus PEEP control waste oxygen.

(m) User Information Label (Figure 9)

Warning: All operators who are not medically qualified should receive full and proper instruction from a qualified person, both on resuscitation and on detailed use of the equipment in the particular situations in which it might be employed.

The paraPAC may be used by fully trained personnel in life support. Basic information is provided on the control module (see Figures 9.1 and 9.2.).

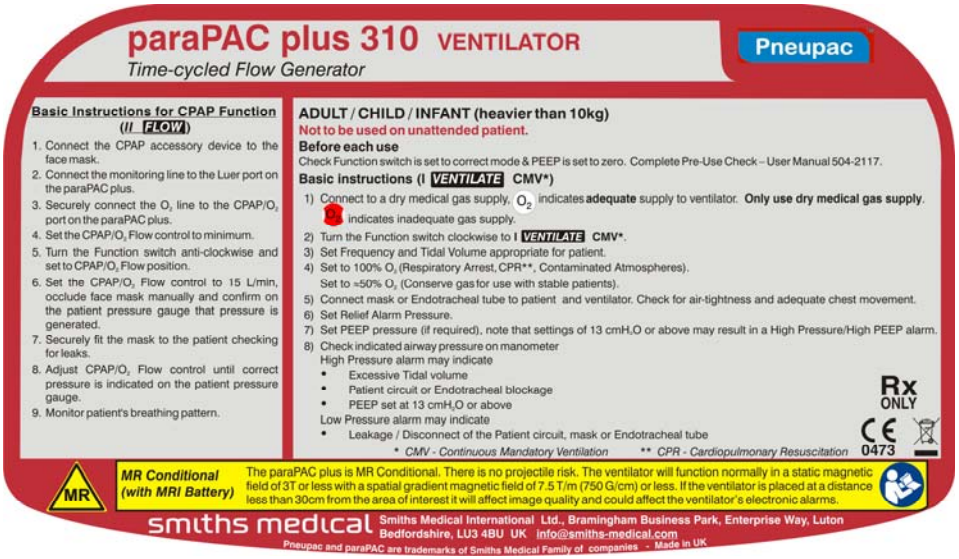


Figure 9.1: paraPAC plus Model 310 User information Label

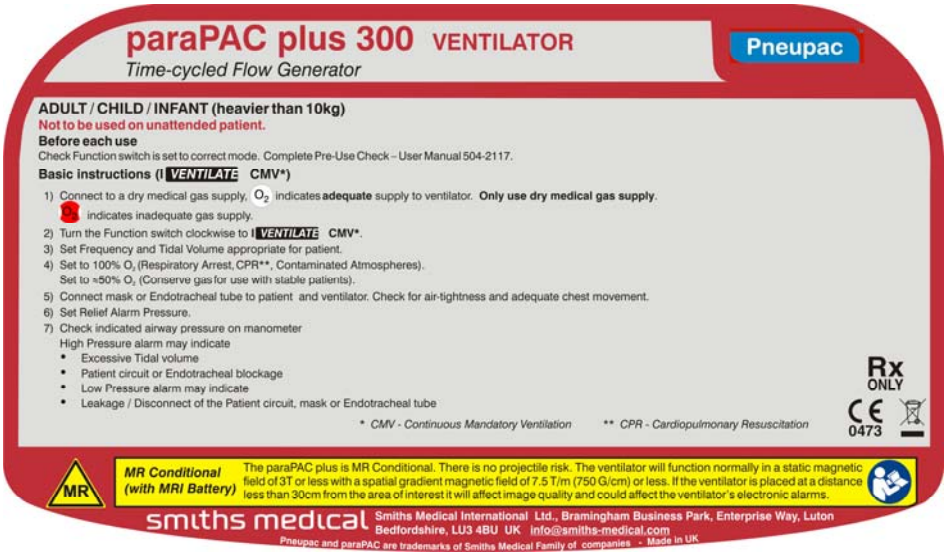


Figure 9.2: paraPAC plus Model 300 User information Label

SECTION: 4 CARE, CLEANING & STERILIZATION

a) Care

The paraPAC plus is designed to operate in harsh conditions during its intended use, but to prolong its life and retain its appearance, basic care should be taken between uses. In particular the following steps are recommended after each use;

- Carefully inspect the complete system for damage or contamination and discard single use accessories.
- Check that sufficient oxygen is available for next use.
- Clean, disinfect or sterilise parts as described in this Section 4 (b) below.
- Reassemble the system and carry out the functional check in Section 3(b).
- Store the system in a clean, dry area, away from excessive heat or intense light. If it is stored in conditions that exceed the operating temperature / humidity limits (refer to the table on page 70), then the unit will require a climatization period of at least 90 minutes prior to use.

Warning: To avoid harm to the patient, if the device remains unused for a period exceeding three months, conduct a functional check.

The paraPAC plus is rated to IP54. After use in a severe dust environment or after heavy wetting or immersion, see Sections 4 b) 3., 4 b) 4. and 4 b) 5. for instructions regarding returning to use.

b) Cleaning , disinfection and sterilisation

4 b) 1. Ventilator

Caution: Do not attempt to sterilise the paraPAC plus or to clean it by immersion in any fluid. Do not use any cream cleanser. Do not allow any petrochemical or its derivative (petrol, diesel, paraffin etc.) come into contact with the device. Do not autoclave the paraPAC plus.

The paraPAC plus should only be cleaned with a damp cloth. For obstinate marks a mild soap may be used. Wipe dry immediately with a soft clean cloth.

Caution: Do not allow any oil or grease to come into contact with the module or, in particular, with the input and output fittings because of the potential fire risk when oxygen is being used.

The paraPAC plus may be wiped with a disinfectant but it must not be immersed. The paraPAC plus cannot be sterilized.

4 b) 2. Oxygen Input hose

The oxygen input hose should not come into contact with any solvents, but may be cleaned in the same manner as the ventilator taking the same care to keep free from grease.

4 b) 3. Care after device is subjected to dust

If the device is adversely affected by dust, return to use as follows;

1. Protecting the Gas Inlet and patient outlet from further dust ingress, remove the dust from the device.
2. If a breathing circuit is fitted, protecting the patient outlet from further dust ingress, remove the breathing circuit and dispose.
3. If the oxygen input hose is not attached, protect inlet connection from further ingress of dust.
4. If necessary, replace the inlet filter as described in the service manual part no. **504-2049.**
5. Wipe around the patient outlet port taking care not to cause dust to enter the device.
6. Fit a new patient breathing circuit.
7. Clean device in accordance with Section 4 (b)
8. Carry out the functional check and pre-use check as described in Section 3 (b) and run the device for 10 minutes.

4 b) 4. Care after device is heavily wetted

If the device is heavily wetted, return to use as follows;

1. Protecting the Gas Inlet and patient outlet from further ingress of water, dry down the device.
2. If a breathing circuit is fitted, protecting the patient outlet from further water ingress, remove the breathing circuit and dispose.
3. If the Oxygen Input Hose is not attached, protect inlet connection from further ingress of water.
4. If necessary, replace the inlet filter as described in the service manual part no. **504-2049.**
5. Fit a new patient breathing circuit.

6. Clean device in accordance with Section 4 (b) then leave the device and hose assembly in a warm (≈30º) and dry environment for 12 hours (approx.). Then run device in I VENTILATE CMV mode for 10 minutes.
7. Carry out the functional check and pre-use check as described in Section 3 (b).

4 b) 5. Care after device immersed in water

Caution: If the device is accidentally immersed in water or any liquid, it should no longer be operated and an alternative means of ventilation used (see Warning **#17**).

If the device is immersed in water, it should be prepared as follows to be returned to the manufacturer for a full safety evaluation;

1. If the oxygen input hose is not attached, protect inlet connection from further ingress of water
2. Remove input hose, shake dry and blow through with oxygen from gas supply
3. Shake the device to remove excess water.
4. Protecting the patient outlet from further water ingress, dry down the device.
5. Remove (if connected) and discard patient breathing circuit.
6. Leave the device and hose assembly in a warm (≈30º) and dry environment for 12 hours (approx.).
7. Place the device in a polythene bag and seal. Label the bag with all relevant information to assist the manufacturer with any investigation.
8. Dispatch the package to the manufacturer via normal channels.

4 b) 6. Actions after contamination with vomitus

If the device is adversely affected by vomitus, return to use as follows;

1. If a replacement breathing circuit is available, remove and discard contaminated breathing circuit.
2. Fit the new breathing circuit. Proceed to step 4.
3. If a replacement breathing circuit is **not** available;
   i) Remove the patient circuit from the patient
   ii) Shake for approximately 20 seconds to remove the vomitus.
   iii) Inspect to ensure the majority of contamination has been removed from the patient circuit.
   iv) Proceed to step 4.
4. Confirm device is functioning correctly as described in Section 3 (b) & 3 (c).

Warning : To avoid cross contamination please be aware that the patient circuit is a single use device and should be disposed of after each use.

5. Use of this circuit is only permitted on the same patient in its current status.

c) Reassembly and Function Testing

After cleaning or sterilisation, parts must be carefully dried and then reassembled.

Before putting the system back into service the functional check described in Section 3(b) should be carried out.

SECTION: 5 MAINTENANCE

(a) General

The ventilator is enclosed in a tamper-evident enclosure and is serviced as described in Section 5(b) below. Intervention inside the device is only possible by return to a Smiths Medical service centre.

The user should perform regular functional checks in accordance with Section 3(b) to identify faults or damage and a log of the results maintained for each device.

Smiths Medical recommends a regular performance check and service by a Smiths trained and certificated engineer as described in Section 5 (b).

Users should return faulty or damaged product to Smiths Medical service centres for repair and calibration.

During the warranty period, users should contact Smiths Medical regarding faults. An extended warranty and maintenance service contracts are available from Smiths Medical.

(b) Performance Checking

Performance checking of the paraPAC plus ventilator must be carried out on a regular basis with equipment calibrated to ensure accuracy under the flow patterns generated by the machine. It should be carried out by suitably trained personnel. If suitable personnel or equipment are not available it should be checked by Smiths Medical as part of a service contract or its authorised representative.

Recommended performance checking procedures and suitable equipment are detailed in the product maintenance manual, which is available to suitably trained personnel.

The frequency of performance checking is annually.

(c) Changing of Battery

The specified batteries will give several years of service under normal use conditions but to avoid the need to locate a spare battery whilst the ventilator is in field service it is recommended that the battery is replaced as a matter of routine at the same time as the performance checking as specified in Section 5(b) above. The procedure for changing the battery is as follows (see section 2 (c) 15 for precautions in MRI use): -

(i) Ensure ventilator is off by selecting O OFF Demand on the main function switch.

(ii) Remove the battery cover, situated on the left hand side of the control module, by removing the retaining screw.

(iii) The battery can be removed by pulling on the ribbon.

(iv) Fit the replacement battery, with positive on the right hand side, trapping the ribbon underneath the battery to ease removal on next replacement. Also ensure that the battery removal ribbon is not trapped between battery and battery holder contact pad.

(v) Replace the battery retaining cover by locating the left hand side tab to the ventilator case first and then refitting the screw.

(vi) Select I VENTILATE CMV on the function switch and check that the alarm system runs through the start-up self checking procedure (See section 3(b) 5).

If the battery low alarm operates (indicated by a medium priority audible and visual alarm) whilst ventilating a patient and it is considered necessary to maintain the electronic alarm monitoring then the above procedure should be followed but care should be taken to minimise the time that electronically alarmed ventilation is interrupted. Be aware that battery failure does not affect the operation of the ventilation functions nor the effective operation of the pneumatic alarms and safety devices, therefore at the user's discretion, the ventilation can be continued whilst replacing the battery, providing there are no hazards associated with battery replacement eg. MRI environment, flammable environment, static sensitive areas etc.

(d) Servicing

If the paraPAC plus ventilator shows a malfunction during operation or testing or if its performance is measured to be outside the tolerance stated in the specification (see Section 7(b) & (c)) during its performance checking, then the unit must be withdrawn from operation and an appropriate service must be carried out.

Servicing or adjustment of the paraPAC plus ventilator should only be carried out by competent personnel who have been trained for such work.

Warning: Failure to use approved circuits and accessories may lead to unsatisfactory ventilator performance.

Warning: The paraPAC plus ventilator is manufactured and 'CE' marked to the requirements of 93/42/EEC. To ensure that this equipment functions as intended, use only the manufacturer's authorised spares.

SECTION: 6 ACCESSORIES AND SPARE PARTS

Warning: The paraPAC plus ventilator is manufactured and 'CE' marked to the requirements of 93/42/EEC. To ensure that this equipment functions as intended, use only the manufacturer's authorised spares.

Description		Order Code
Battery	MRI	W269-023
Control Module	paraPAC plus 310	530A1167
	paraPAC plus 300	530A1166
Standard Breathing Circuit		100/905/340
Standard Breathing Circuit with mechanical PEEP valve		100/905/341
Pneupac® paraPAC™ plus Disposable CPAP Circuit with Medium Adult Mask		100/905/360
Pneupac® paraPAC™ plus Disposable CPAP Circuit with Large Adult Mask		100/905/361
BS DISS White 6mm Oxygen input hose, 1.5 metres long *		500A4997
Smiths Medical Hyperinflation System with 0.5L bag, Double swivel elbow, manometer and infant face mask		008432DM
Mounting, Clamp for Medical Rail (30/35mm)		500-A4843
Mounting, Clamp for Pole 12-26mm		500-A4844
User's Manual (this document)		504-2117

* Refer to Appendix D for alternative country specific Oxygen input hoses

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SECTION: 7 TECHNICAL INFORMATION

(a) Principle of Operation

The principle of operation of the ventilator is illustrated by the block diagram in figure 6(a). Compressed gas enters the ventilator from the input hose at the inlet connection (1) and this is fed to the pressure regulator (2) where it is regulated to 2.86 bar before being fed to the Timer valve (3), the function switch (4), the demand valve (5) & the spontaneous breathing valve (6). The demand valve (5) is constantly supplied with oxygen and can be activated by spontaneous breathing via the patient circuit. The spontaneous breathing valve (6) is closed by the supply pressure but will open to atmosphere when the pressure supply decays below minimum operating pressure to allow patient to breathe from atmosphere.

The timer valve (3) is an integrated miniature pneumatic device which switches the flow on and off at a frequency controlled by the setting of the frequency control (7). If the function switch (4) is in the Off or Oxygen flow position the output of the timer valve (3) is blocked by the closed bi-stable valve (8). When the function switch (4) is switched to CMV the bi-stable valve (8) opens and feeds the output of the timer valve (3) to the tidal volume control (9). The tidal volume control (9) contains two tapered grooves that feed oxygen to either the entrainment device (10) or the oxygen concentration switch (11)

If the 50% oxygen (air mix) mode is selected the oxygen concentration switch (11) is in the off state and gas is passed from the tidal volume control (9) to the entrainment device (10). Ambient air is entrained and drawn in through non-return valve (12) and the resultant gas mixture is fed to the patient circuit through the output connection (13).

When the 100% oxygen (no air mix) mode is selected, switch (11) is open and 100% oxygen passes through from the tidal volume control to the output connection (13).

The frequency of breaths is controlled by the timer valve (3) & frequency control (7) & the flow of gas in both oxygen concentration settings is controlled by the setting of the tidal volume control (9). The tidal volume control is calibrated as tidal volume to give a more helpful presentation although, as explained in Section 2(d) 2, this is only an approximation.

Proximal pressure is limited by the setting of the spring-loaded variable relief valve (14) and is measured and displayed by the inflation pressure monitor (15).

During the expiratory phase the patient circuit is vented to atmosphere by

means of the normally open patient dump valve (16). Its function is to vent the patient circuit to avoid patient valve lock-up due to trapped pressure.

The demand detector (17) is connected to the demand valve and automatically senses the demand flow being taken by the patient whilst breathing spontaneously. It operates in conjunction with the timer valve (3) to integrate this signal and to extend the expiratory phase, as a function of the spontaneous tidal volume, up to a maximum time dictated by the frequency setting of the ventilator. The cumulative effect of successive spontaneous breaths by the patient is that the ventilator appears to become inhibited although in fact this is only on a breath by breath basis.

In order to avoid inhibition by weak breathing or panting, very low flows are ignored and no action is taken in response to very short breaths.

The level of spontaneous breathing required to inhibit the oscillator is fixed at that of a typical adult. Higher spontaneous ventilation rates can readily be taken and will result in complete inhibition of the ventilator.

The multifunction electronic alarm (22) built into the paraPAC plus ventilators is electrically powered by a replaceable single cell lithium battery but the ventilatory functions of the paraPAC plus ventilators are completely independent of the alarm functions and its power source. It is switched on by selection of CMV using the function switch (4)

The alarm unit is microprocessor controlled and has four preset pressure level detectors which monitor, respectively, the gas supply pressure, the inflation pressure, operation of the pneumatic pressure relief valve and operation of the demand breathing detector.

The gas supply pressure detector is built into the pneumatically operated pressure indicator (23) and is used to operate a medium priority audible alarm if the supply pressure drops to a level where the indicator shows red.

The inflation pressure detector is a pressure switch (24) which senses the inflation pressure at the patient connection port. The inflation pressure monitor (15) senses the pressure at the proximal end of the patient circuit. An output signal is given to the alarm control unit whenever the inflation pressure is greater than 10 x100Pa. The signal is used to determine if the pressure has passed through this threshold at least once in any 10 second period. If not, an alarm is provided in order to warn either of inadequate inflation pressure due to a leakage or failure to cycle or that the pressure is constantly above the threshold.

The relief valve pressure switch (25) is used to sense if gas is being vented

from the patient circuit by the variable relief valve at the pressure set by the relief pressure control.

The demand breathing detector is used to sense whenever the demand detector (17) gives a signal to the ventilator control unit causing it to interact with the patient's breathing. The signal is used to suppress the alarm in the same manner as the cycle detect signal. The 'breathing detect' visual indicator is operated to alert the operator that a spontaneous breath has occurred and that the low pressure alarm has, therefore, been temporarily inhibited.

The alarm unit is designed to operate from 3 volts and therefore only lithium batteries can be used. Other batteries will fail to operate the alarm system.

Model 310 Only

When the function switch (4) is in the CMV position it also supplies oxygen to the PEEP switch (18) which is normally open during expiratory time to supply the PEEP control (19). The PEEP Control supplies a user controlled small flow of oxygen to the output connection which is used in conjunction with the correct recommended patient circuit to set Positive End Expiratory Pressure. The PEEP switch is closed during inspiration by the action of the timer valve (3)

If the function switch (4) is switched to Oxygen flow/CPAP, oxygen is supplied to the Oxygen flow/CPAP control (20). The PEEP Control supplies a user controlled flow of oxygen to the Oxygen flow/CPAP connection (21) which is used in conjunction with the correct recommended circuit to supply either free flow oxygen or CPAP therapy.

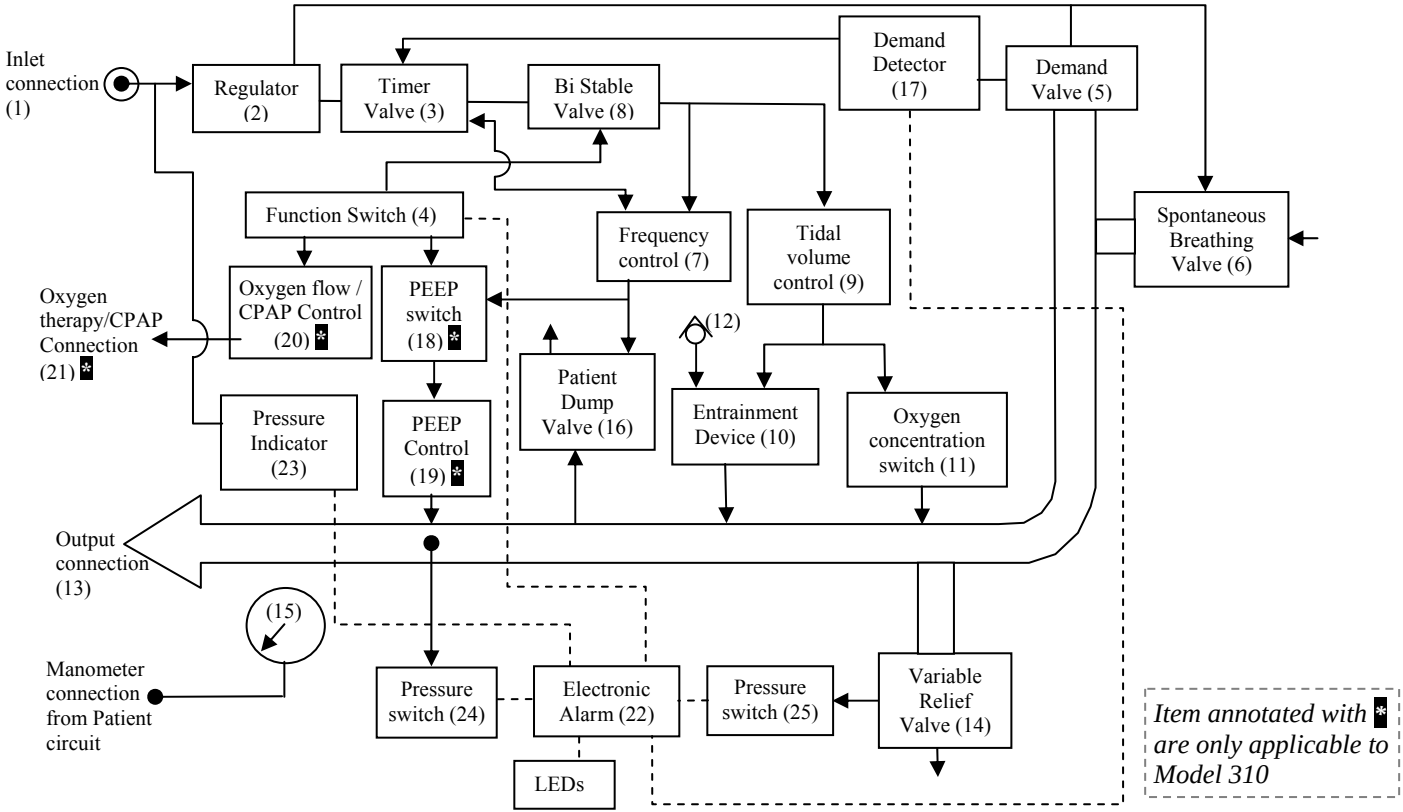


Figure 10: Principles of operation of the paraPAC plus ventilator

(b) Technical Data

Principle of operation: The ventilator is a time cycled, volume preset, pressure limited, flow generator.

All the paraPAC plus models incorporates a patient demand valve and a ventilation inhibit function which becomes operative when an adult patient breathes at an adequate level.

Power Source:	Gas specific terminal outlet providing dry, oil free, filtered gas within the pressure range 280 to 600 kPa at 65 L/min. As standard the ventilator is calibrated for use with oxygen.
Frequency Range:	8 to 40 bpm (12 bpm at detent position)
Flow Range:	8 to 39 L/min
Inspiratory Time Range: At 12 bpm: At 20 bpm:	0.6 to 2.4 sec 1.65 sec 1.0 sec
Tidal Volume Control:	See table below for nominal values

Calibration of Tidal Volume Control

Actual tidal volume in millilitres delivered at combinations of BPM & Vt knob settings									
Set Tidal volume ► Set Frequency▼	**1500**	**1000**	**700**	**500**	**350**	**200**	**150**	**100**	**Min**
8	**1500**	1235							
10	1215	**1000**	832						
12		842	**700**	619					
15			566	**500**	458				
20				383	**350**	255			
25					275	**200**	171		
30						175	**150**	**108**	82
40							139	92	70

Actual Frequencies are within ± 20%
Actual 100% FiO_2 Tidal volumes are within ± 20% or ± 50mL whichever is the greater
Actual 50% FiO_2 Tidal volumes are within ± 25% or ± 50mL whichever is the greater

All tidal volumes are referenced to Standard Temperature and Pressure (STP) i.e. 1013mbar and 21°C for a normal lung of compliance of 0.05 L/cm H_2O (C50) and resistance 5cmH_2O / L /sec (Rp 5).

Colour Coding:

Colour	Frequency (bpm)	Tidal Volume Calibrations (mL)	Approx. Flow (L/min)
Yellow	8 – 20	220 – 1500	16 – 39
Blue	17- 35	130 – 300	12 – 19
Green	28 – 40	70- 150	8 – 13

PEEP Control Model 310 only	Nominal range of 0-20 cmH_2O
Oxygen flow / CPAP control. Range: 0.5 to 35 L/min Model 310 only	Actual oxygen therapy flows less than 8 L/min are within ±20% or 0.3 L/min whichever is the greater Actual oxygen flows for CPAP greater than 6 L/min are within ±25%. Maximum Flow 35 to 45 L/min.
Duration of Gas Supply:	1. In 100% O2 and at detent position (700ml, 12BPM) an 'E'-size cylinder (680L) will last approximately 75 minutes at ISO STP (15°C and sea level). Note that higher tidal volume settings or lower ambient temperatures can reduce the running time of the device. 2. At a minute volume of 10L ventilation an 'E'-size cylinder (680L) will last approximately 60 minutes at same conditions as above when set in 100% O2. 3. At a minute volume of 10L ventilation an 'E'-size cylinder (680L) will last approximately 160 – 180 minutes at same conditions as above when set in 50% O_2. Refer to the tables below for variation of the above.

No Air-Mix (NAM) Endurance (mins.) 100% O_2 (680L)

		Frequency (bpm)						
		8	**10**	**12**	**15**	**20**	**25**	**40**
Tidal Volume (mL)	**100**	No PEEP				213	170	106
	200				174	131	105	65
	350			138	111	83	66	41
	500		121	101	81	61	49	
	700	112	89	75	60	45		
	1000	80	64	53	43			
	1500	54	44	36				

Air-Mix (AM) Endurance (mins.) 50% O_2 (680L)

		Frequency (bpm)						
		8	**10**	**12**	**15**	**20**	**25**	**40**
Tidal Volume (mL)	**100**	**No PEEP**				**373**	**298**	**186**
	200				**370**	**278**	**222**	**139**
	350			**335**	**268**	**201**	**161**	**100**
	500		**314**	**262**	**210**	**157**	**126**	
	700	**305**	**244**	**203**	**163**	**122**		
	1000	**228**	**183**	**152**	**122**			
	1500	**161**	**129**	**107**				

NAM PEEP Endurance (mins) 100 O_2 (680L) (Model 310 only)

		Frequency (bpm) & Tidal Volume (mL)						
		8&1500	**10&1000**	**12&700**	**15&500**	**20&350**	**25&200**	**40&100**
PEEP (cm H_2O)	**0**	**54**	**64**	**75**	**81**	**83**	**105**	**106**
	5	49	57	65	70	72	88	84
	10	46	53	60	64	65	80	75
	15	44	50	56	60	62	74	69
	20	42	48	53	56	58	69	64

AM PEEP Endurance (mins) 100 O_2 (680L) (Model 310 only)

		Frequency (bpm) & Tidal Volume (mL)						
		8&1500	**10&1000**	**12&700**	**15&500**	**20&350**	**25&200**	**40&100**
PEEP (cm H_2O)	**0**	**161**	**183**	**203**	**210**	**201**	**222**	**186**
	5	122	134	146	149	146	160	132
	10	104	113	121	123	122	133	111
	15	94	102	108	110	109	119	99
	20	86	92	97	99	98	107	89

Note: The times indicated on these tables are for an O2 cylinder of nominal capacity of 680L.(E Size). At temperatures above 15°C the nominal capacity is likely to be greater. The times are indicative only, & due diligence must be paid to both the patient & the paraPAC plus Gas Supply Failure Alarm at all times. A 340L (D size) will last approx. half these.

<table>
<tr><td>I:E Ratio</td><td colspan="2">Max Limit at 8bpm</td><td>Min Limit at 40bpm</td></tr>
<tr><td></td><td colspan="2">1:2.500</td><td>1:1.400</td></tr>
<tr><td>Relief Pressure Range:</td><td colspan="3">Relief pressure is flow dependent and falls within the tolerances detailed below</td></tr>
<tr><td></td><td>Nominal pressure cm H_2O</td><td>Max Limit</td><td>Min Limit</td></tr>
<tr><td></td><td>20</td><td>23</td><td>17</td></tr>
<tr><td></td><td>30</td><td>25.5</td><td>34.5</td></tr>
<tr><td></td><td>40</td><td>46</td><td>34</td></tr>
<tr><td></td><td>60</td><td>66</td><td>54</td></tr>
<tr><td>Maximum single fault Limited Pressure:</td><td colspan="3">80 cmH_2O (80 x100Pa *)</td></tr>
<tr><td>Patient Pressure Monitor:</td><td colspan="3">Indicates from -10 to +80 cmH_2O (-10 to + 80 x100Pa *).</td></tr>
<tr><td>Sensing Line Filter</td><td colspan="3">21.5mm diameter GORE™ Medical Membrane with 0.2µm pore size.</td></tr>
<tr><td>Air mix:</td><td colspan="3">Selectable switch, providing nominally 100 or ≈50%, when using oxygen as gas source.</td></tr>
<tr><td>Oxygen concentration</td><td>O_2 % setting</td><td>Max Limit</td><td>Min Limit</td></tr>
<tr><td></td><td>100</td><td>100</td><td>95</td></tr>
<tr><td></td><td>50**</td><td>60</td><td>40</td></tr>
<tr><td>Gas Consumption:</td><td colspan="3">Delivered tidal volume plus approximately 60mL per breath</td></tr>
<tr><td>Output Connection:</td><td colspan="3">22mm taper</td></tr>
<tr><td>Patient Breathing Circuit: ⊗</td><td colspan="3">Single Limb Circuit for Pneupac paraPAC plus Ventilators with Internal Pressure Monitoring Line with In-Line Filter and Expiratory Port Flow Diverter. All circuits have a nominal hose length of 1.5m.</td></tr>
<tr><td></td><td colspan="2">Inspiratory Resistance:</td><td rowspan="2"><6cm H_2O at 60 L/min</td></tr>
<tr><td></td><td colspan="2">Expiratory Resistance:</td></tr>
<tr><td></td><td colspan="2">Compliance:</td><td>14.4 mL/kPa</td></tr>
<tr><td></td><td colspan="2">Internal volume:</td><td>600 mL</td></tr>
<tr><td></td><td colspan="2">Deadspace</td><td>10mL</td></tr>
<tr><td>Demand Parameters:</td><td colspan="3">Demand Flow commences at - 2cmH_2O (2 x100Pa*)
100 L/min at - 8.5cmH_2O (8.5 x100Pa *)
maximum > 120 L/min.
These demand sensitivities are with 400 kPa supply pressure. Higher supply pressures will slightly decrease the sensitivities.</td></tr>
</table>

* 1.02 cmH_2O = 1 x100Pa (or 1 x100Pa = 1 cmH_2O -2%).

** O_2 % Nominal declared at zero inflation pressure at STP. See Figure 11 for changes due to increasing inflation pressure. See Appendix B.1.2. for changes due to the use of the PEEP control.

Minimum demand to inhibit ventilator	Tidal volume 425ml nominal at 12 bpm.
Power Source:	Replaceable 3.6 volt lithium battery. Size AA special low magnetic battery for MRI and general use, Pneupac part number W269-023.
Battery Life:	Shelf life – 10 years. In general use – in excess of 1 year.
Supply Gas Input Connectors:	9/16" DISS connection intended for the permanent connection of the input hose. Gas-specific connectors, for use with user interchangeable hoses, are available if specified
Input Hoses, Standard:	1.5m long, 6mm bore with probe to BS 5682 oxygen as standard. (Alternatives available).
Dimensions:	93H x 235W x 165D mm
Weight of Control Module:	2.4 kg
Threaded Bushes for Mounting Brackets:	M6 x 7mm deep.
High Pressure / High PEEP Alarm	An alarm signal is generated if the inflation pressure matches the relief alarm pressure setting or the PEEP pressure exceeds 13cmH_2O (13 x100Pa*) (Model 310 only)
Low Pressure (Disconnect) Alarm:	An alarm signal is generated if inflation pressure does not rise through the low pressure setting of 10cmH_2O (10 x100Pa*) at least once in 10 seconds.
Alarm silenced:	Alarm silenced for 60 seconds duration - visually indicated
Weight of Patient Breathing Circuit with Patient Valve, sensing line & Microbio Filter:	100/905/340 = 131g
Patents:	This product is covered by the following patents; UK 2,174,760B EP 0343818, EP 0343824, EP 0342883
Standards:	International Standard ISO 10651-3 "Emergency and Transport Ventilators" The unit follows the International Standard for alarm sounds and indication: BS EN 60601-1-8:2007 Electrical Safety to IEC 601-1 Internally powered Type 'B' equipment. EMC to EN60601-1-2

* 1.02 cmH_2O = 1 x100Pa (or 1 x100Pa = 1 cmH_2O -2%)

Environmental Resistance	
Feature	**Specification**
Enclosure	PC+ABS blend, injection moulded with colourant
Operating environment	-10°C to +50°C with relative humidity 0 to 95%
Storage environment	-40°C to +60°C with relative humidity 0 to 95%
Temperature & Temperature variation	RTCA[2] DO160-F Section 4 & 5
Barometric pressure (altitude) - Refer to the table in Appendix B for deviations	EN794-3:1998 Sect. 10 & RTCA DO160-F Sect. 4 700 to 1100mbar (10000ft to –1000ft) Barometric pressure (altitude) 465 mbar to 1100 mBar for operating 465 to 1700 mBar. storage
Vibration[1]	ISO10651-3:1997, BS EN1789:2007 & BS EN13718-1:2008 (RTCA[2] DO160-F section 8 profile C[4])
Mechanical shock (drop)	EN794-3 Section 21.102, ISO10651-5:2006
Crash Safety & Sustained Shock Tests	RTCA[2] DO160-F section 7
Impact	EN60601-1 Section 21b
Driving sand and dust[1]	RTCA[2] DO160-F section 12
Salt fog[3]	RTCA DO160-F section 14 category S
Waterproofing.	ISO10651-5:2006, JIS T 7206
Condensing and drip tests	RTCA DO160-F Section 10
MRI compatibility	3 Tesla (refer to section 7 (g))
IP rating to EN ISO 60529	IP54
EMC compliance (Also refer to the tables on the next 3 pages)	ISO 10651-3:1997, BS EN 13718-1:2008 (RTCA/DO-160F), BS EN 60601-1-2:2007, Mil Std 461D:1993 RE101 Radiated Magnetic Field - 30Hz- 100KHz, Mil Std 461D:1993 RS101 Magnetic Field Immunity - 30Hz-100KHz & FDA Guidance November 1993 Quasi-Static Electric Field 0.5Hz @ 2kV pk (2kV/m)

1 These tests have been conducted in order to demonstrate suitability for carry-on aircraft use.

2 Radio Technical Commission for Ae

3 Use of this device is not recommended in adverse marine conditions. Place the device in a re-sealable bag during storage or transport in marine environments. Consult the manufacturer if the device is subjected to abnormal salt fog.

4 Always support the paraPAC plus via its base and the mounting attachment points when used as a transport ventilator.

Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacturers Declaration – Electromagnetic Emissions[3]		
The paraPAC plus Model 300/310 ventilators are intended for use in the following electromagneti environment specified below. The customer or the user of the paraPAC plus model 300/310 ventilators should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions BS EN 60601-1-2:2002 BS EN 55011:2007 CISPR 11	Group 1	The paraPAC plus Model 300/310 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model 001 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	
RTCA/DO-160F[1] Section 21 Category M (Radiated RF, aero medical)	Complies	
MIL STD 461D[2] RE101 (Radiated Magnetic Field, FDA)	Complies	

[1] Frequency range 100MHz to 6GHz [2] Frequency range 30Hz to 100kHz, 7cm distance [3]Data taken from ETR973

Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
The paraPAC plus Model 300/310 ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the paraPAC plus Model 300/310 ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level (ISO 10651/RTCA)**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2:1995 (amended 1998) ISO 10651-3:1997 RTCA/DO-160F (Section 25)	± 6 kV contact ± 8 kV air (± 15 kV air) (± 15 kV air)	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4		Not applicable	
Surge IEC 61000-4-5		Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11		Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8		Not applicable	

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for LIFE-SUPPORTING ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The paraPAC plus Model 300/310 ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the paraPAC plus Model 300/310 ventilator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level (RTCA)**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF BS EN 60601-1-2:2002 IEC 61000-4-3:2002 CISPR 24	10 V/m 80MHz to 2.5 GHz	30V/m	Portable and mobile RF communications equipment should be used no closer to any part of the paraPAC plus Model 300/310 ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0.40\sqrt{P}$ 80 MHz to 800 MHz $d = 0.77\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
RTCA/DO-160F[1] Section 20 Category T (Radiated RF, aero medical)	(5V/m 100MHz to 8GHz)	Complies	
Conducted RF IEC 61000-4-6:2002	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	Not applicable (battery operation, no cable network involved in normal operation)	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the paraPAC plus Model 300/310 ventilator is used exceeds the applicable RF compliance level above, the paraPAC plus Model 300/310 ventilator should
be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the paraPAC plus Model 300/310 ventilator.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 30 V/m.

(c) Accuracies

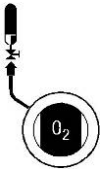
The accuracies to which the ventilation parameters of the paraPAC plus ventilator are factory calibrated and how these are affected by operating and ambient conditions are tabulated in Appendix B.

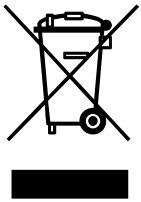
(d) Terms and Definitions

Airway Resistance:	Pressure drop across airway per unit flow.
AHA:	American Heart Association
CMV:	Continuous Mandatory Ventilation
CPR:	Cardiopulmonary Resuscitation. Comprehensive standards and guidelines for this procedure are given by the American Heart Association Guidelines CPR EC 2005 in the Journal of the American Medical Association (JAMA), 6th June 1986 Vol 255 No 21.
Deadspace	This represents the volume on the patient side of the patient valve which the patient can re-breathe.
Demand Valve:	A valve which delivers gas to the patient at a flow related to the inspiratory efforts of the patient
Expiratory Phase:	Interval from the start of expiratory flow to the start of inspiratory flow.
Expiratory Time (T_E):	Duration of the expiratory phase.
FiO_2:	The oxygen content of the gases inspired by the patient expressed as a fraction.
Frequency (f):	The number of ventilation cycles per minute (breaths/min).
HME	Heat Moisture Exchange
Inspiratory Flow:	The flow passing to the patient during the inspiratory phase. This flow will always be less than the flow through the breathing circuit and will be determined by the patient's airway resistance and lung compliance and by the set inspiratory pressure.
Inspiratory Phase:	Interval from the start of inspiratory flow to the start of expiratory flow.
Inspiratory Time (T_I):	Duration of the inspiratory phase.
I/E Ratio:	The ratio of the Inspiratory Time to the Expiratory Time.
JAMA	See CPR.
Lung Compliance:	Volume added per unit pressure increase when is added to a human or artificial lung.

Maximum Proximal pressure:	The maximum pressure that can be delivered by the ventilator to the patient.
Minute Volume ($\dot{V}$DEL):	Delivered Total Ventilation or the volume per minute of gas delivered through the patient connection port during the inspiratory phases.
MRI:	Magnetic Resonance Imaging.
Mouth Pressure:	The proximal pressure as measured at the patient's mouth.
Patient Valve:	Valve that directs gas into the lungs during the inspiratory phase and allows expiration to atmosphere during the expiratory phase.
PEEP Valve:	A valve which is attached to the exhalation port of the patient valve in order to hold a positive expiration pressure at the patient's mouth at the end of the expiratory phase. (Positive End Expiration Pressure - PEEP).
PEEP:	Positive End Expiratory Pressure. Pressure in the breathing circuit is maintained at a set positive pressure throughout the expiratory phase.
Pressure Generator:	The ventilator delivers ventilation by establishing a constant set pressure at the patient connection throughout the inspiratory phase. The resultant flow into the lungs is determined by the compliance of the patient's lungs and the resistance of the airways.
Relief Valve:	Valve which limits the maximum proximal pressure by venting excess gas to the atmosphere.
Tidal Volume (VTDEL):	Volume of gas delivered to the patient during an inspiration phase.
VBS:	Ventilator Breathing System. The breathing system connected to the patient connection port and bounded by the exhaust port and the air entrainment device.

(e) Explanation of Symbols and Alarm Condition Indicated

	**Inflating Gas Input Port Connector.** Compressed gas entering this port is delivered to the patient after its pressure energy has been used to power the ventilator.
	**Gas Output Port Connector** The paraPAC plus ventilator breathing system, supplied with the ventilator, is attached to this connector to transfer ventilating gas from the ventilator to the patient connection.
	**Connection Points for EP Option** This symbol shows connection point for the pressure sensing line (See section 2(d)(i) 2 and Figure 1)
	**Supply Gas Failure Alarm** This symbol identifies the pneumatically operated supply-gas failure visual alarm. Any visible red indicates a low supply pressure or a restrictive supply. This is accompanied by a medium priority audible alarm.
O_2	**Chemical symbol for oxygen**
 **IEC 601-1 Internally Powered Type B**	Type 'B' equipment defines the degree of electric shock regarding allowable leakage currents
	Caution Refer to User's Manual before use
	**Audio Alarm Silenced Indicator** This orange light flashes once every 3 seconds during the 60 second silenced period, to indicate that the electronic alarm is in its silenced state.
	**Low Battery Indicator** This yellow light indicates that battery voltage is low. Initially it flashes every 10 seconds. This indicates that the battery is low although monitoring will continue. The flashing rate increases to twice every second, accompanied by a medium priority alarm, for the final few minutes at the end of the battery life.
	**RF Transmitter**

	**High Inflation Pressure Visual Alarm** This red light flashes at 2 times per second after the high pressure relief valve has operated and whenever it is venting inflation gas to the atmosphere. It is accompanied by a pneumatically generated audible alarm. If the relief valve has operated for 3 successive cycles, or for at least one second, then the high priority audible alarm sounds and the visual alarm flashes continuously. Both persist until 10 seconds after the condition is last detected. They then automatically reset. The same alarm signals are also given if on Model 310 a PEEP greater than 13cmH_2O (13 x100Pa*) is detected for 10 seconds or more.
	**Low Pressure/Disconnect Visual Alarm** This yellow light flashes 30 times per minute if 'cycle detect' or 'breathing detect' has not been activated for 10 seconds. It is accompanied by a medium priority alarm.
	**Breathing Detect Indicator** This green light flashes for 1/10th second to indicate when a demand breath has been registered by the demand detector within the ventilator.
	**Cycle Indicator** This green light flashes once, for 1/10th second, every time the inflation pressure rises through the pre-set threshold pressure of 10cmH_2O (10 x100Pa). This indicates normal operation.
Q_{max}	**Maximum Flow Requirement** This symbol denotes the maximum flow requirement at the minimum input pressure
	**Collect Separately** This product contains electronic and other components (such as batteries) that may contain materials which, if disposed of with general household waste, could be damaging to the environment. In accordance with Directive 2/96/EC Waste Electrical and electronic Equipment, Smiths Medical International Ltd. requires that residents of the European Union return this product for proper disposal at the end of its useful life. Contact your local distributor for specific instructions on how to return the product for disposal.
Rx ONLY	**Warning: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician**

	**Caution**
	**Consult instructions for use**
	**MR Conditional**
	**Temperature limit**
	**Atmospheric pressure limitation**
	**Humidity limitation**
	**Atmospheric pressure limitation**
	**This way up**
	**Fragile, handle with care**
	**Keep away from sunlight**
	**Keep dry**
	**Serial No.**
	**Manufacturing Date**
	**Manufacturer**

(f) Indicated Priority of Audible Alarm Sounds

High Priority	Two bursts of five pulses of sound repeated at the rate of 6 times per minute, while the alarm condition persists, in accordance with ISO 9703.
Medium Priority	One burst of three pulses of sound repeated at the rate of 6 times per minute for 60 seconds. During the next 60 seconds the rate increases progressively to 12 times per minute.

(g) MR Conditional Tests

Although the paraPAC plus ventilator has been assessed to be MR Conditional under the conditions specified in the labeling, the following detailed test information is provided to assist the user in ensuring suitability of the device for their specific environment with a minimum of additional testing.

Test information:

(i) Equipment

All tests were undertaken at the Wolfson Brain Imaging Centre, Cambridge, UK on an actively shielded Siemens MAGNETOM Verio 3T 70 cm open bore whole body system with a Field Strength of 3 Tesla.

(ii) Assessment of Projectile Risk of the paraPAC Plus ventilator.

The paraPAC plus ventilator was suspended from a string attached to the 0° indicator on the test fixture protractor. The test fixture was then positioned so that the centre of mass of the device was at the location where the deflection was a maximum. The location of the maximum deflection was marked so all test repetitions could be conducted at the same location. The device was held so that the string was vertical and then released. The deflection of the device from the vertical direction to the nearest 1° was recorded and repeated three times. At no point within the magnetic field up to a maximum spatial gradient of 7.5 T/m (750 G/cm) was the paraPAC Plus ventilator a projectile risk.

(iii) Assessment of any effects on the paraPAC Plus ventilator by the static magnetic field.

The ventilator was set to its minimum frequency and corresponding tidal volume setting, providing a peak inspiratory pressure of approximately 40cmH_2O. It was placed, in turn, 4 meters from the bore entrance of the scanner, 1 meter from the bore entrance of the scanner, at the bore entrance of the scanner bore and at the point of maximum spatial gradient, 7.5 T/m (750 G/cm).

At no point could any change in the delivered ventilation be detected. The electronic alarms and manometer operated consistently and correctly. Trial circuit disconnections and airway obstructions were always indicated correctly.

(iv) Assessment of any effects by the paraPAC plus ventilator on the quality of the image generated by the scanner

The paraPAC plus ventilator was placed along the central bore of the scanner varying the distance from the scanning area of interest to determine the minimum safe distance from the scanning region of interest.
In these positions, FLASH gradient echo sequences are used acquiring axial images to test for any interference due to the presence of the ventilator. Indications of interference could be a significant reduction in SNR (signal to noise ratio), frequency artefacts, contrast change or image distortion.
If the ventilator is placed at a distance less than 30cm from the area of interest it will affect image quality and could affect the ventilator's electronic alarms. Therefore, the ventilator should be secured at least 30cm away from the area of interest for the scan. Optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

(v) Assessment of any effects on the paraPAC Plus ventilator by the pulsed RF fields and the pulsed gradient magnetic fields

The scan sequences chosen for these tests are:

- EPI (Echo Planar Imaging) & DTI (Diffusion Tensor Imaging) sequences. The sequences are chosen for their fast gradient switching characteristics which would maximise the chances of induced electric fields & currents.
- FLAIR (FLuid Attenuation Inversion Recovery) sequence to be used because of its high RF load & Specific Absorption Rate (SAR).

Both sequences were run continuously whilst observing the ventilator's electronic alarms for failed or spurious conditions. No effect due to

dB/dT, RF & SAR values per scan sequence type

	EPI	DTI	FLAIR
dB/dT	44.25 T/s (1885Hz/μs)	44.25 T/s (1885Hz/μs)	-
RF	1 μT	1.4 μT	2.2 μT
SAR	0.0 W/Kg Whole Body 0.2 W/Kg Head	0.1 W/Kg Whole Body 0.3 W/Kg Head	0.2 W/Kg Whole Body 0.8 W/Kg Head

dB/dt – time rate of change of the magnetic field.
RF – Radio Frequency
SAR – Specific Absorption Rate.

All sequences were run continuously whilst observing the ventilator's electronic alarms for failed or spurious conditions.

Electronic alarms may reset if the ventilator is positioned closer than 30cm to the scanning area of interest. Therefore, the ventilator should be secured at least 30cm away from the area of interest for the scan.

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APPENDIX A

Product Safety, Transportation and Disposal of Recommended Batteries

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Appendix A: Lithium Batteries – Product Safety, Transportation and Disposal

PRECAUTIONS FOR HANDLING AND USE

Lithium battery cells as recommended for use with this device will provide long, reliable and safe service when used correctly. To achieve optimum performance and trouble-free operation, the following precautions should be observed.

ALWAYS take care to fit batteries correctly, observing the 'plus' and 'minus' signs on the battery and appliance.

ALWAYS replace batteries in your equipment with the type and size of battery specified by the manufacturer.

ALWAYS remove dead batteries from equipment and all batteries from equipment your know you are not going to use for a long time.

ALWAYS keep batteries away from small children. If swallowed seek medical advice immediately and contact the subsidiary of the battery manufacturer in you country.

NEVER deliberately short-circuit batteries.

NEVER take apart, crush, puncture or mutilate lithium batteries.

NEVER bring a damaged cell in contact with water. Lithium metal reacts vigorously with water producing flammable hydrogen gas which can cause a fire.

PRECAUTIONS FOR STORAGE

Batteries should be stored at temperatures between 10°C and 25°C with relative humidity not exceeding 65%. To maximise shelf life excessive temperature cycling and storage at temperatures greater than 25°C should be avoided. Storage of lithium batteries at lower temperatures is possible, providing care is taken in returning the batteries to room temperature prior to use.

Store unused batteries in their packaging and keep away from metal objects which may cause short-circuit resulting in possible leakage, or in extreme cases an explosion.

CHARGING

Warning: Lithium batteries are of the primary type and are NOT designed to be recharged. Attempts to recharge these batteries can lead to leakage and possibly an explosion.

No responsibility is accepted by the manufacturer for injury or damage resulting from the cells having been recharged or otherwise abused.

IF PART OR WHOLE OF THE BATTERY IS SWALLOWED SEEK MEDICAL ADVICE IMMEDIATELY

Note: Lithium batteries are not subject to EC requirements on the classification, packaging and labelling of dangerous substances or preparations (directives 67/548/EEC and 88/379/EEC as amended).

TRANSPORTATION

AIR TRANSPORTATION

Lithium batteries are exempt from IATA/ICAO transport regulations under special provision A45, provided that they meet criteria given below.

ROAD TRANSPORTATION

Lithium batteries are exempt from the ADR regulations under Marginal 2901a, provided that they meet the criteria given below.

RAIL TRANSPORTATION

There are no special requirements for the transportation of lithium batteries under the RID regulations.

SEA TRANSPORTATION

Lithium batteries are exempt from the IMDG code under the special provisions of Page 9033, provided that they meet the criteria given below.

CRITERIA FOR EXEMPTION OF LITHIUM BATTERIES FROM TRANSPORTATION REGULATIONS.

1. Each cell contains not more than 1 gram of lithium or lithium alloy.
2. Each battery contains not more than an aggregate quantity of 2 grams of lithium or lithium alloy.
3. Cells are separated so as to prevent short-circuit.
4. Batteries are separated so as to prevent short-circuit and are packed in strong packaging, except when installed in electronic devices.

5. If a battery contains more than 1 gram of lithium or lithium alloy, it does not contain a liquid gas that is considered dangerous, unless the liquid or gas, if free, would be completely absorbed or neutralised by other materials in the battery.

The lithium batteries recommended in this Manual are covered by this exemption from the above international regulations. For restrictions applying to individual countries, the relevant regulatory authority should be consulted.

REFERENCES

1. Dangerous Goods Regulations. Montreal: International Air Transport Association, 1993.
2. European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR). 1993 Edition. London: HMSO, 1992.
3. Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID). 1990 Edition. London: HMSO, 1989.
4. International Maritime Dangerous Goods Code. London: International Maritime Organisation, 1992.

DISPOSAL PROCEDURES

As they contain no mercury, lead or cadmium, the disposal of the lithium batteries recommended in this manual is not regulated by European Community Directive 91/157/EEC on “Batteries and Accumulators Containing Certain Dangerous Substances”.

However, individual countries may also establish regulations that cover the disposal of waste batteries. These may be more stringent that EC requirements. Thus, local regulatory authorities should be contacted for their disposal guidelines.

In the absence of specific regulations or guidelines the following is recommended for the disposal of lithium batteries.

Up to five lithium batteries can be disposed of with other general waste.

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APPENDIX B

Calibration accuracies and deviations due to change in ambient conditions

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Appendix B: Calibration accuracies & deviations due to change in ambient conditions

Warning: is essential that, where this equipment is used in extreme environmental conditions outside those specified in this manual, the operator must exercise particular patient vigilance, although this may not lead to a safety hazard, performance will become more uncertain as conditions become more extreme.

Further deviations due to changes in ambient conditions. (Typical healthy lung in 100% oxygen setting)							
Parameter		**Ambient temp.- 18°C**	**Ambient temp. -10°C**	**Ambient temp. +50°C / 95% R.H.**	**Ambient pressure 1100 mBar**	**Ambient pressure 700 mBar Equivalent altitude 3048m (10,000 ft)**	**Ambient pressure 465 mBar Equivalent altitude 6096m (20,000 ft)**
Frequency	Adult	-2%	Note 3	Note 3	Note 3	Note 3	-5%
	Child	-15%	-5%	Note 3	Note 3	Note 3	Note 3
Tidal Volume	Adult	+20.5%	Note 3	Note 3	Note 3	Note 3	Note 3
	Child	+51%	+23%	Note 3	Note 3	Note 3	Note 3
I:E ratio		Note 3	Note 3	Note 3	Note 3	Note 3	Note 3
FiO_2		Note 3	Note 3	Note 3	Note 3	Note 3	Note 3
PEEP (Model 310 only)		Note 3	Note 3	Note 3	Note 3	+10%	+60%

Warning: After storing at temperatures below -18°C set controls to 40 bpm and tidal volume 150mL and connect to gas at higher than 0°C before CMV operation and reset controls as desired once ventilator is cycling.

Notes: 1. Nominal values are at local conditions of 20°C and 1013 mBar.
2. At ambient temperature between 0ºC and -18 ºC, the demand tidal volume required to inhibit the automatic cycling can be expected to increase outside the normal limits. Additional user vigilance should be applied in these conditions.
3. Changes are within the general ventilator accuracy stated in this manual

B. 1. 1. Effects Of Inflation Pressure On Delivered Tidal Volume & Oxygen Concentration

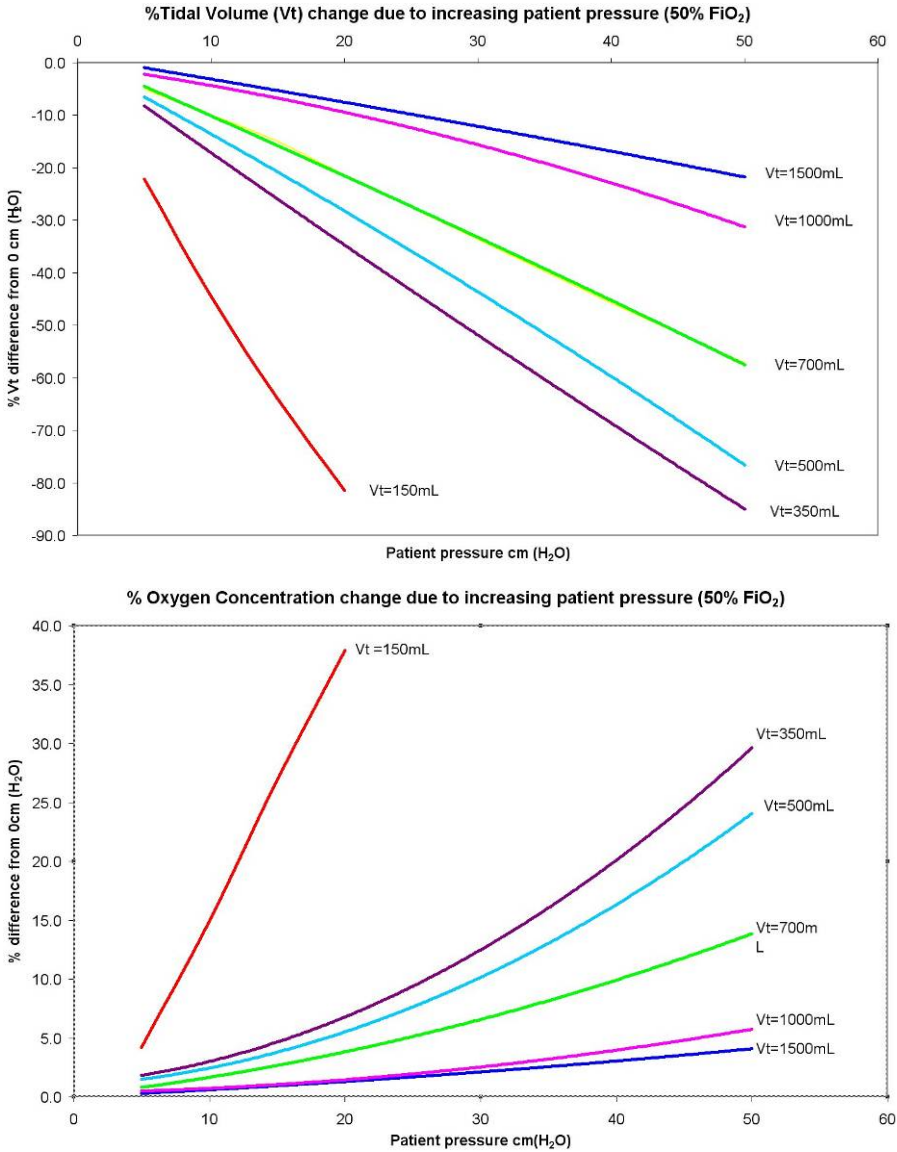

Figure 11: Charts Illustrating the Effects Of Inflation Pressure On Delivered Tidal Volume & Oxygen Concentration

B. 1. 2. Increase of delivered nominal FiO2 (≈50%) due to the entrainment of the paraPAC plus PEEP control waste oxygen when ventilating a normal healthy adult lung of airway resistance R5 & lung compliance C50.

Increase of delivered nominal FiO_2 (≈50%) due to the entrainment of the paraPAC plus PEEP control waste oxygen when ventilating a normal healthy adult lung of airway resistance R5 & lung compliance C50.										
	2.5 cm H_2O PEEP		5 cm H_2O PEEP		10 cm H_2O PEEP		15 cm H_2O PEEP		20 cm H_2O PEEP	
Tidal Volume setting mL	Peak inflation pressure cm H_2O	% Oxygen	Peak inflation pressure cm H_2O	% Oxygen	Peak inflation pressure cm H_2O	% Oxygen	Peak inflation pressure cm H_2O	% Oxygen	Peak inflation pressure cm H_2O	% Oxygen
Maximum	35	58	36	60	40	64	44	68	46	69
1000	28	57	30	61	34	64	38	67	41	69
700	23	58	25	62	29	66	34	70	37	72
500	17	59	20	62	24	68	29	73	32	75
350	14	61	16	66	21	72	26	77	29	80
150	8	72	10	77	16	86	20	91	23	94
Minimum	6	91	7	92	11	96	17	97	20	97

Increase of delivered nominal FiO_2 (≈50%) due to the entrainment of the paraPAC plus PEEP control waste oxygen when ventilating a diseased adult lung of airway resistance R20 & lung compliance C20.										
	2.5 cm H_2O PEEP		5 cm H_2O PEEP		10 cm H_2O PEEP		15 cm H_2O PEEP		20 cm H_2O PEEP	
Tidal Volume setting mL	Peak inflation pressure cm H_2O	% Oxygen	Peak inflation pressure cm H_2O	% Oxygen	Peak inflation pressure cm H_2O	% Oxygen	Peak inflation pressure cm H_2O	% Oxygen	Peak inflation pressure cm H_2O	% Oxygen
Maximum	59	67	59	71	60	76	60	80	60	82
1000	56	62	56	66	58	72	59	76	59	78
700	46	62	47	66	51	72	54	76	55	77
500	34	64	36	68	40	75	43	79	45	80
350	26	68	28	72	32	79	35	83	38	86
150	15	80	16	85	20	91	24	96	26	97
Minimum	7.5	95	9	96	12	97	17	98	20	98

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Appendix C

Delivered Oxygen concentrations when used for spontaneously breathing patients

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Appendix C: Inspired Oxygen concentrations when using the ventilator in the O OFF DEMAND mode for spontaneously breathing patients

Tidal Volume (mL) of Inspired Breath	BPM	Oxygen concentration (% points)
100	12	61
150	12	72
300	12	88
500	12	92
1000	12	93
1500	12	95

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APPENDIX D

Alternative Input Hoses

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Appendix D: Alternative Input Hoses

D.1 Alternative Input hoses

The table below lists input hoses that are available from Smiths Medical International Ltd. for use with the paraPAC plus in different parts of the world.

WARNING: There is a risk of unacceptable performance when alternative ventilator patient circuits or accessories are used. Failure to use patient circuits and accessories recommended in this User's Manual may lead to unacceptable device performance.

Probe	Connector	Hose Ø (mm)	Gas	Colour	Country	Part No.	Length*
BS5682	DISS	6	O_2	White	British	500A4997	1.5m
DIN	DISS	6	O_2	White	German	500A4931	1.5m
AFNOR	DISS	6	O_2	White	French	500A4944	1.5m
AGA	DISS	6	O_2	White	Scandanavian	500A4968	1.5m
DISS	DISS	6	O_2	Green	USA/Japan	TBA	1.5m
Mini Schrader	DISS	6	O_2	White	British	500A4971	1.5m
Ohmeda Style	DISS	6	O_2	White	Canada	TBA	1.5m

* These hose lengths are standard, alternative lengths are also available on request.

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Appendix E

Cleaning and inspection record

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Appendix E: Cleaning and inspection record

Contents Complete	Cleanliness Checked	Functional Performance Check (Sect. 3 (b))	Cylinder contents	Date	Signature	Comments

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