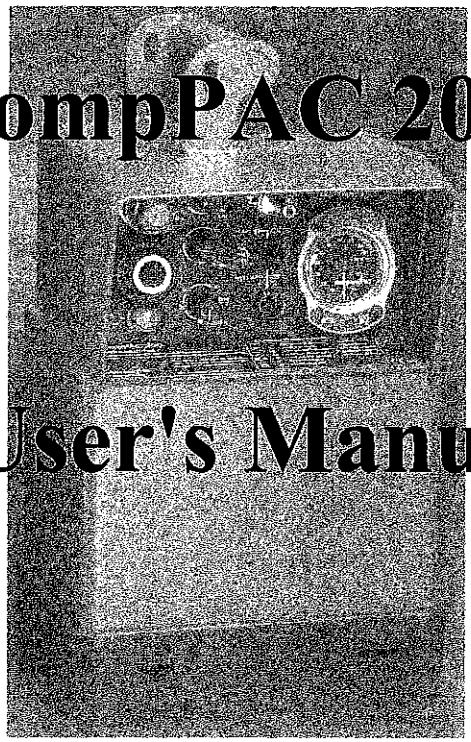
Pneupac™

compPAC 200®



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 compPAC 200. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

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compPAC 200 User's Manual

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FIGURES

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

SECTION 1

(a) Summary Statement

The Pneupac® compPAC 200® ventilator is a self contained portable gas powered automatic ventilator intended to provide emergency ventilation, in a battlefield environment only, to adult and pediatric patients greater than 20 kg (44 lb). The compPAC 200 is suitable for emergency and transport use in situations where conventional portable ventilators are not suitable.

The primary role of the Pneupac® compPAC 200® ventilator is a Portable Gas-Powered Ventilator (PGPV) that can be powered by compressed oxygen or by an electrically operated compressor. The reasons for this rationale is that in battlefield use, the supply or re-supply of compressed oxygen in cylinders is difficult or impossible. Therefore to be as versatile as possible, the ventilator has various selectable front panel options and can be driven in various ways. Each option delivering different concentrations of oxygen as follows;

i) Oxygen from a nominal 60psi supply ('No Air Mix') which can be powered by;

- Regulated compressed cylinder, or
- Wall-mounted outlets

This provides delivered oxygen concentration of 100%.

ii) Oxygen from a nominal 60psi supply with 'Air Mix'. Power sources as in i) above.

This provides delivered oxygen concentration of 45%.

iii) Internal compressor providing compressed, fresh air. This can be powered by;

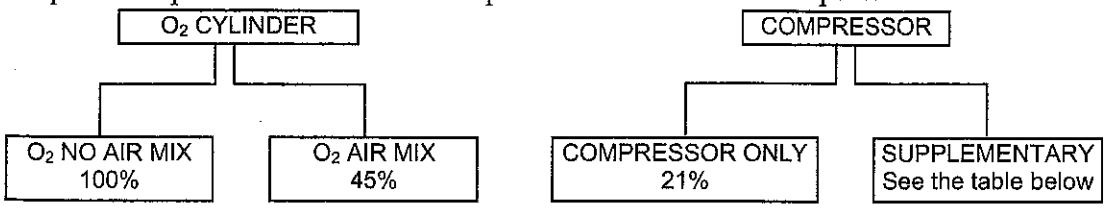
- internal 24V battery, or
- external 24/28V d.c. supply, or
- external 115V a.c. supply (via PS12 or PS11 power supply), or
- external 240V a.c. supply (via PS12 or PS11 power supply)

This provides delivered oxygen concentration of 21%.

iv) Internal compressor providing compressed, fresh air with low-pressure supplementary oxygen. Power sources as in iii) above.

This provides delivered oxygen concentration in accordance with the supplementary oxygen concentration table below.

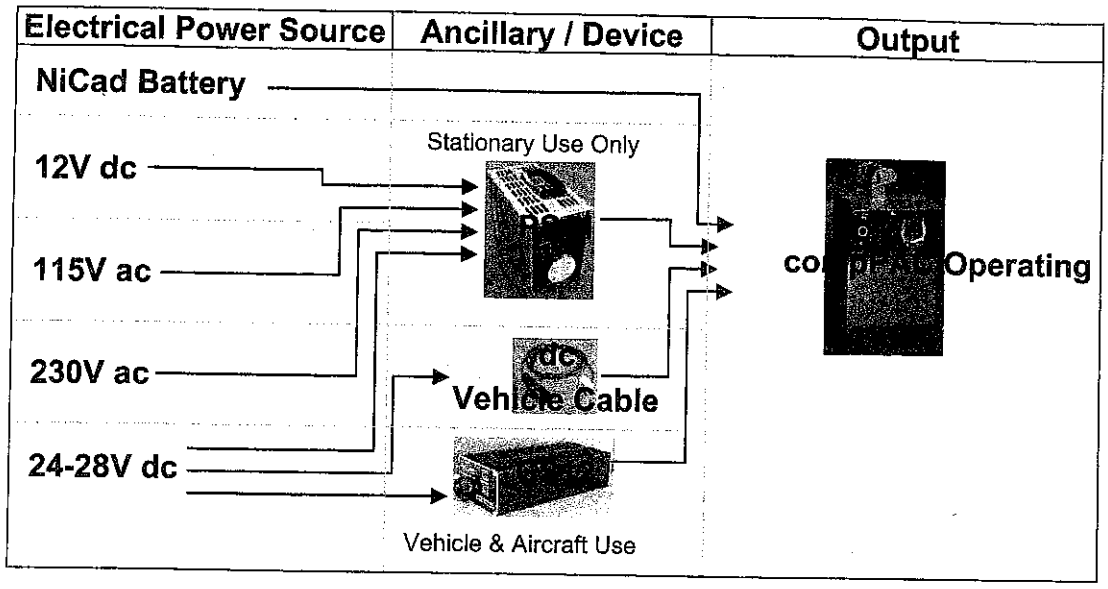
Graphical Representation of source inputs and their relevant outputs.



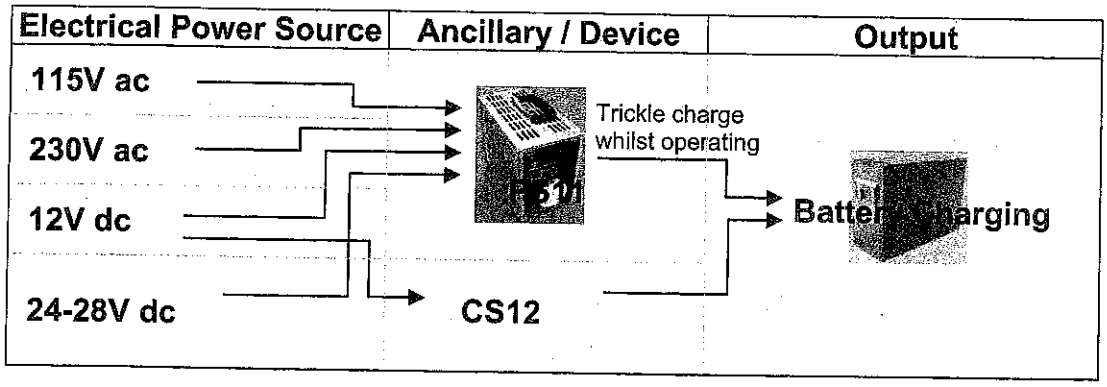
	Supplementary Oxygen Flow (L/min)						
Minute Volume (L/min)	0	0.5	1.0	2.0	3.0	4.0	
6	21	29	35	47	56	64	O_2 %
9	21	26	29	37	44	50	
12	21	25	28	34	40	45	
14	21	24	27	33	38	43	

Graphical representation of electrical power source inputs, their relevant interfaces / devices and outputs.

To run the compPAC



To charge the NiCad battery



The Pneupac® compPAC 200® ventilator is a robust self-contained portable device comprising of the following standard kit parts:

- Control Module –
  — Green case variant: Part No - 510A2433
  OR
  — Yellow case variant: Part No - 510A2434
- Rubber Boot: Part No – 510A2271
- NBC Filter: Part No – W7265
- Patient Valve and Hose assembly: Part No – 510A1082
- O_2 Auxiliary gas input lead, Schrader probe (BS5682): Part No – 510A2600
- Support ramp: Part No – 510A2372
- 24/28 volt open-ended Vehicle Supply lead to compPAC: Part No – 510A2564
- compPAC C200 User Manual: Part No – 504-2055/A

And the following fitted labels:

- Valance Panel Label: Part No – 504-228
- Instrument Panel Label: Part No – 504-227
- Supplementary O_2 Table Label: Part No – 504-224
- Battery fitting and removal instruction Label: Part No – 504-223
- Alarm Bezel Label (set of 2): Part No – 504-222
- Adjustable Relief Valve Label: Part No – 504-236

The Pneupac® compPAC 200® ventilator is a self contained portable gas powered automatic ventilator intended to provide emergency ventilation, in a battlefield environment, to adult and pediatric patients greater than 44 lb (20 kg). The Pneupac® compPAC 200® is suitable for emergency and transport use in situations where conventional portable ventilators are not suitable.

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

WARNING: **To avoid harm to the patient, pre-use checks must be performed in accordance with section 4 of this manual before each use.**

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

All operators should receive a full and proper initial and 'refresher' 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.

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

Information given in this manual beyond the basic operation of the compPAC ventilator is only intended as a guide to supplement proper training and to indicate the specific operational requirements of the compPAC.

The compPAC ventilator is intended for use in emergency or transport situations by users who are appropriately trained and where the patient is being constantly monitored by the rescuer. It may be used by qualified anaesthetists as an adjunct to anaesthetic procedures. ***(Not for use in the US).***

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

Although use of this ventilator outside the environmental conditions specified in this Manual will not directly lead to a safety hazard the performance will become increasingly uncertain as the conditions become more extreme. Therefore the operator must exercise constant patient vigilance under these conditions.

WARNING: **Blood gas levels must be monitored independently, correct operation of the ventilator will not necessarily achieve the required blood gas levels. Also, when used at moderate altitude, it is essential that the user closely monitors delivered tidal volume, and measures end-tidal CO_2 using suitable capnography.**

(b) WARNINGS AND CAUTIONS

(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.

The following Warnings highlight aspects of the use of the compPAC ventilator that require particular emphasis. The section of this manual referenced in each clause provides the relevant context:

1. **WARNING: Failure to read this user's handbook before first use of this device may result in death or serious injury (Section 1(a)).**

2. **WARNING: To avoid harm to the patient, this equipment should only be used by personnel trained in the use of automatic ventilation (Sections 1(a), 3(a), 4(a), & 4g)).**

3. WARNING: **Blood gas levels must be monitored independently, correct operation of the ventilator will not necessarily achieve the required blood gas levels. Also, when used at moderate altitude, it is essential that the user closely monitors delivered tidal volume, and measures end-tidal CO_2 using suitable capnography (Section 1(a)).**

4. WARNING: **Avoid smoking or naked flame. To avoid the risk of ignition, do not use oil, grease or combustible lubricants (only those approved for oxygen use) in contact with any part of the ventilator, regulator or cylinder (Sections 2(e) & 3(a)).**

5. 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 (Section 3(a)).**

6. **WARNING: Failure to use approved circuits and accessories may lead to unsatisfactory ventilator performance (Section 7).**

7. WARNING: **To avoid the risk of harm to the patient from an incorrectly set ventilator, servicing or adjustment of this equipment should only be carried out by competent personnel who have been trained by Smiths Medical to carry out such work (Section 6c).**

8. WARNING: **To ensure protection against electrical shock, any mains driven power supply connected to the compPAC ventilator MUST conform to the safety requirements for medical electrical equipment specified in IEC 60601-1 (Section 2(b)).**

9. WARNING: **To avoid the risk of contamination of the ventilator airways when in a potentially contaminated environment and also avoid the loss of performance (reduced tidal volume). When the supplementary oxygen connector is not being used, the blanking cap MUST be securely in place to prevent any intake air from by passing the filter (Section 4(c)).**

10. WARNING: **Deviations noted at the 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 (Sections 3b)#9 & 6b)).**

11. WARNING: To avoid the risk of fire or explosion or impaired ventilator performance, always observe the correct polarity of the auxiliary supply. Ensure the supply is a stable voltage of between 23 to 28 Volts, capable of supplying at least 2.3 Amperes and does not contain excessive interference (Section 2e) iii).

12. WARNING: To prevent transmission of any contaminants to both user and patient after use in a contaminated environment, be aware that the compPAC outer case is NOT hermetically sealed against ingress of gas or liquids. Decontamination, if necessary, should involve removal of the module from its case by a suitably trained person (Sections 4f) & 5g)).

13. WARNING: To avoid harm to the patient, pre-use checks must be performed in accordance with section 4 of this manual before each use (Sections 1a) & 3b)).

14. WARNING: Always ensure that an alternative means of ventilation is available in the event of ventilator failure or malfunction (Section 4).

15. WARNING: To avoid the risk of over inflation of the patient it is important for the operator to constantly monitor the patient pressure manometer during manual ventilation (Section 4).

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

17. WARNING: To avoid the potential risk of explosion associated with re charging the Lithium version of battery, ensure that only a Ni Cad battery (Part No: 510-A1490/CE, NATO No: 6140-99-620-8057) is installed. UNDER NO CIRCUMSTANCES SHOULD THE LITHIUM BATTERY (NATO No: 6135-99-840-0109), OR ANY OTHER PRIMARY BATTERY, BE FITTED'. (Sections 2c), 2d) #14, 2d #15, 2e) iii), 3a), & 5b)).

18. WARNING: If uncontrolled oxygen flow is connected to the supplementary oxygen connector there is a risk of the patient valve locking up, causing harm to the patient. Therefore only flow controlled oxygen sources of up to 4L/min. should be attached to the supplementary oxygen connector (Sections 2(b), 2(c), & 4c)).

19. WARNING: Failure to constantly monitor the patient whilst using this equipment, may lead to death or serious injury (Sections 1(a) & 4b)ii)).

20. WARNING: When using the ventilator and ALL of the following settings and conditions are present simultaneously, there is a risk that the ventilator may begin to provide inadequate tidal volume when the gas bottle becomes exhausted. This will be indicated by a lower peak pressure on the manometer :-
    - Minute volumes above 6 L/min
    - The On / Off switch on the front panel is pushed fully down to Ext 24 / 28Vdc and an external electrical power source is connected or the On / Off switch on the front panel is pushed fully up to Int Batt and a charged battery is fitted.
    - No Air Mix is selected on the front panel.
    - External oxygen is supplied by gas cylinder but the cylinder is almost empty (N.B: Ample warning of this particular condition is given by the gas supply indicator eyeball).

    In the event of this occurring, disconnect the external gas supply, and the tidal volume will be restored (See Section 2d) # 1).

21. WARNING: To avoid the risk of cross contamination all re usable components in the patient circuit, that can come into contact with the patient or the patient's exhaled gas (Patient Valve and Patient Hoses) should be sterilized or disinfected as per instructions detailed in Sections 5d) and 5e) of this user manual.

22. **WARNING: Only operate the compPAC with a NBC filter fitted. Filteration ensures that dirt does not penetrate the sensitive areas e.g. valve seats which could cause malfunctions.**

23. **WARNING: To avoid the risk of over inflating the patient, because the adjustable relief valve (where fitted) is uncalibrated, initial settings of the relief pressure should always be checked by occluding the patient connection port and observing the pressure displayed on the inflation pressure manometer BEFORE attaching the ventilator to the patient. (See SETION 2d) #4).**

24. **WARNING: To avoid the risk of electric shock, when using the compPAC ventilator in conjunction with the PS12 or PS11 Power Supply/ Charger, the PS12 or PS11 should be located outside the patient environment (ie: ≥ 1.5 Metres from the patient) (Section 2d) #15 and 3a)).**

25. **WARNING: To avoid malfunction of the ventilator when using the battery as a power source, periodically check the battery to ensure that there is sufficient charge to power the ventilator. The battery may be trickle or fast charged using the PS12 or PS11 power supply/ charger unit (see section 2e) iii), however, this should be undertaken in advance of use and, where necessary (ie: battery does not retain its charge), the battery may need replacing (Sections 2e ii) and 5b).**

26. **WARNING: To avoid the risk of harm to the patient, when using Oxygen as the driving gas, the user should be aware that in the event of the oxygen source becoming exhausted, the ventilator would switch over to using the compressor to deliver Air (provided that the battery is fitted, as recommended, at all times, or the auxiliary power supply lead is connected) (Section 2d) 12).**

27. **WARNING: When in use in a contaminated atmosphere, to avoid the risk of harm to the patient, the NBC filter must be fitted (Section 2e iv)).**

28. **WARNING: Both the long patient hose (part no. W7483/CE) and the short patient hose (part no. W6861/CE) contain a natural rubber latex which may cause allergic reactions (Section 2e and 7).**

29. **WARNING: To avoid the risk of harm to the patient, the user should be aware that, under power failure conditions, the inspiratory resistance can be as high as 5.8 cm H_2O at 30 l/min. and could cause respiratory fatigue in certain individuals (Section 2c).**

30. **WARNING: The Non-Return Valve elements in the flowblock within the gas pathway of this device contain a natural rubber latex which may cause allergic reactions (Section 2a).**

31. **WARNING: where a PEEP Valve is being used, to avoid risk of harm to the patient, the User should be aware that PEEP and any malfunction in the PEEP Valve, Breathing Circuit or Exhalation Port cannot be reliably detected by observing the Pressure Manometer (Section 2e) ix)).**

32. **WARNING: To avoid the risk of chemical / environmental hazards, disposal of a contaminated / used NBC filter must be in accordance with local regulations (Section 3b #11).**

33. **WARNING: To avoid the risk of under inflation of the patient, it is important for the operator to monitor tidal volumes. This is especially important with a combination of ventilator minute volume settings of 12L and above, power supply voltages below 24 Vdc and patients with low compliance lungs and highly resistive airways (Section 4).**

(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: To ensure that cylinder contents are not lost during storage due to small leaks, it is recommended that the valve on the gas cylinder is turned off after use. (Section 3b)#9).**

2. **CAUTION: It is recommended that the compPAC ventilator is only used with a battery installed, even if the ventilator is being powered by gas only, as the battery is used to power the electronic alarm system. The ventilator will work without a battery or external electrical supply, since it operates as a conventional gas powered device with the patient protection devices and the high inflation pressure pneumatic alarm operating normally. However, the user must be aware that in these circumstances, the electrically operated alarms will NOT function. (Section 2e).**

3. **CAUTION: To avoid a sudden release of pressure when changing gas cylinders, turn off the cylinder valve and then switch on the ventilator. After one or two cycles, the ventilator will stop and it is then safe to unclamp the pin index yoke. (Sections 2(e), 3(a), & 3b)#9).**

4. **CAUTION: To avoid accidental disconnection of the power supply unit (PS12 or PS11) when it is connected to the compPAC unit, the power supply mains lead should always be locked in position. (Section 2e).**

5. **CAUTION: Avoid fast charging batteries outside the temperature range of +10°C to +30°C. The batteries will not accept a full charge outside this range and, in certain circumstances, the capacity of the battery may be permanently impaired. At low temperature, the electrolyte may be electrolysed, and small quantities of hydrogen released, which in extreme circumstances present an explosive risk. (Section 2e).**

6. **CAUTION: If the ventilator is in use at elevated altitude where the barometric pressure is at or below 525 mmHg (700mBar), and the ventilator is set at 40 Litres per minute output, there is a risk that the reduced pressure of gas within the reservoir will result in the indicator 'eyeball' turning to red (see table in Appendix A 'Table showing calibration inaccuracies and deviations due to changes in ambient conditions).**

7. **CAUTION: The protective bung fitted to the NBC Filter should always be removed before fitting it to the compPAC ventilator (Sections 2e) iv) & 3b) #11.**

8. **CAUTION: The external supply power connector must only be connected with a SELV(Safety (or Separated) extra-low source) power source. (Section 2d) #15).**

9. **CAUTION :When using supplementary oxygen connector, the user should be aware that the delivered oxygen concentration quoted on the label (See Fig 4) for 14, 12 & 8 V_{DEL} settings are nominals with a potential variation of up to 5%. However the nominal delivered oxygen concentration shown on the label for the 4 V_{DEL} setting is subject to a potential variation of up to 13%. (Section 2d) #17).**

10. **CAUTION: Excessive ingress of moisture could result in deterioration of internal components, if the device is unlikely to be used regularly (ie more than once a week). This could also result in the ventilator failing to start. To avoid this, ensure that the compPAC is properly dried after each use. The compPAC ventilator must be dried internally as detailed in Section 5 a) iv), powered by the compressor alone (i.e. delivering 21% oxygen).**

11. **CAUTION: A maximum of 4 L/min. supplementary oxygen is recommended, as once usage goes above this level there is no benefit of oxygen conservation. The conservation of oxygen during ventilation is a major design feature of this ventilator therefore at supplemental flow of above 4 L/min. we would advise users to revert to driving the ventilator from an oxygen supply rather than compressor with supplementary oxygen (Section 2d) #17).**

12. **CAUTION: Although this ventilator has been fully tested to withstand water spray from all directions, it is not designed to be immersed in water. In the event that the module is accidentally immersed, it should no longer be operated and an alternative means of ventilation used (see also WARNING #16 in this User Manual). The ventilator should then be returned to the manufacturer for rectification (Section 4(g)).**

SECTION 2: GENERAL INFORMATION

(a) Intended Use

The Pneupac® compPAC 200® ventilator is an autonomous self contained portable gas powered automatic ventilator suitable for emergency and transport use in situations where conventional portable ventilators are not suitable. In particular it has been designed to function using a NATO approved NBC filter (NATO No: 4240-21-912-5397), and is therefore suitable for use in chemically laden environments that are likely to be encountered on the battlefield. It can be operated from a range of power sources to provide maximum flexibility of operation in remote areas, in military campaigns and in disaster relief. It is suitable for ventilating adults and children (above 20 kg). Where hospital equipment is not available the compPAC ventilator may be used with basic anaesthetic equipment, such as used in the Military Tri-Services sets, to administer anaesthesia. ***(Not for use in the US).***

WARNING: **The Non-Return Valve elements in the flowblock within the gas pathway of this device contain a natural rubber latex which may cause allergic reactions.**

The compPAC ventilators and associated equipment described in this manual conform to European Standard EN794-3 "Particular Requirements for Emergency and Transport Ventilators" and comply with the requirements of the European Directive for Medical Devices 93/42/EEC.

(b) Contraindications – None Known.

(c) General Description

The Pneupac® compPAC 200® ventilator is gas powered and is housed in an easily carried, chemically hardened housing. The housing is designed to accept the long endurance battery that is used to drive a small compressor, which in turn provides the inflating gas, through an 'oscillator', to the casualty. All ambient air for the ventilation of the casualty passes into the system through a standard *NBC filter. About 1/3 of the volume is compressed to drive the ventilator before expansion in an entrainment mixing device, which entrains the other 2/3 by creating a sub-atmospheric pressure.

WARNING: **To avoid the risk of harm to the patient, the user should be aware that, under power failure conditions, the inspiratory resistance can be as high as 5.8 cm H2O at 30 l/min. and could cause respiratory fatigue in certain individuals.**

The NiCad rechargeable battery specified for fitting inside the unit will provide approximately 2 hours continuous ventilation (also dependent on the ventilator setting during use). The ventilator has a socket to accept an external 24V d.c. supply from e.g. a vehicle electrical circuit. This enables the system to be used for extended periods wherever a 24-28V d.c. supply is available. The power requirement is less than 50 watts. If the Pneupac PS12 or PS11 power supply is connected to this socket, simultaneous trickle charging of internal battery will occur whilst the ventilator is running. When not required as a power supply it can be switched, to fast charge the battery whilst it is in situ inside the ventilator. (See Section 2(d)15).

WARNING: **To avoid the potential risk of explosion associated with re charging the Lithium version of battery, ensure that only a Ni Cad battery (Part No: 510-A1490/CE, NATO No: 6140-99-620-8057) is installed. UNDER NO CIRCUMSTANCES SHOULD THE LITHIUM BATTERY (NATO No: 6135-99-840-0109), OR ANY OTHER PRIMARY BATTERY, BE FITTED'.**

An input gas connector is provided to allow the compPAC ventilator to be connected to a 400 kPa gas supply so that it can be operated independently of its internal battery electrical supply. In this way, if oxygen cylinders or NBC filtered oxygen supply is available, 100% or 45% oxygen can be supplied to the casualty and the internal battery can be conserved. This facility also allows connection to air compressor systems.

Alternatively, there is a supplementary oxygen intake connector, in parallel with the NBC filter, enabling 21-72 % oxygen to be supplied to the casualty, from e.g. an oxygen concentrator, when the ventilator is operating on its compressor.

Calibrated controls for frequency and tidal volume are provided to set the required ventilation pattern. A fixed or adjustable pressure relief device limits the peak inspiratory pressure and provides a pneumatically operated audible high-pressure alarm. In addition an electronic high-pressure alarm sounds if the inflation pressure exceeds 60 x100Pa (60 cm H_2O). There is negligible interdependence of these controls.

Most of the controls and input and output connections are mounted on the front panel, which is deeply shrouded to give maximum protection from chemical "rain". The layout is shown on Figure 1.

The electronic alarm unit not only gives warning of high inflation pressure but also of patient circuit disconnection, failure to cycle and low voltage. It is powered from the internal battery and will operate even if the battery power is too low to operate the compressor.
There is no specific control switch on the alarm system. With the main battery in place it is energised automatically whenever the ventilator is switched 'On', either by means of the main electrical 'On/Off' switch, or by the application of gas pressure to the gas supply port.

The alarm is turned off by removing the gas supply if an external source is being used or by returning the main selector switch to "OFF".

The compPAC ventilator module is connected to the patient by means of a corrugated hose and remote patient valve.

(d) Controls and Features (Figure 1)

1 Minute Volume Control (See Figure 1)

This calibrated rotary control knob gives continuous adjustment of the minute volume delivered to the patient over the range 4 to 14 L/min.

WARNING: When using the ventilator and ALL of the following settings and conditions are present simultaneously, there is a risk that the ventilator may begin to provide inadequate tidal volume when the gas bottle becomes exhausted. This will be indicated by a lower peak pressure on the manometer :-

- **Minute volumes above 6 L/min**
- **The On / Off switch on the front panel is pushed fully down to Ext 24 / 28Vdc and an external electrical power source is connected or the On / Off switch on the front panel is pushed fully up to Int Batt and a charged battery is fitted.**
- **No Air Mix is selected on the front panel.**
- **External oxygen is supplied by gas cylinder but the cylinder is almost empty (N.B: Ample warning of this particular condition is given by the gas supply indicator eyeball).**

In the event of this occurring, disconnect the external gas supply, and the tidal volume will be restored (See Section 2d) # 1).

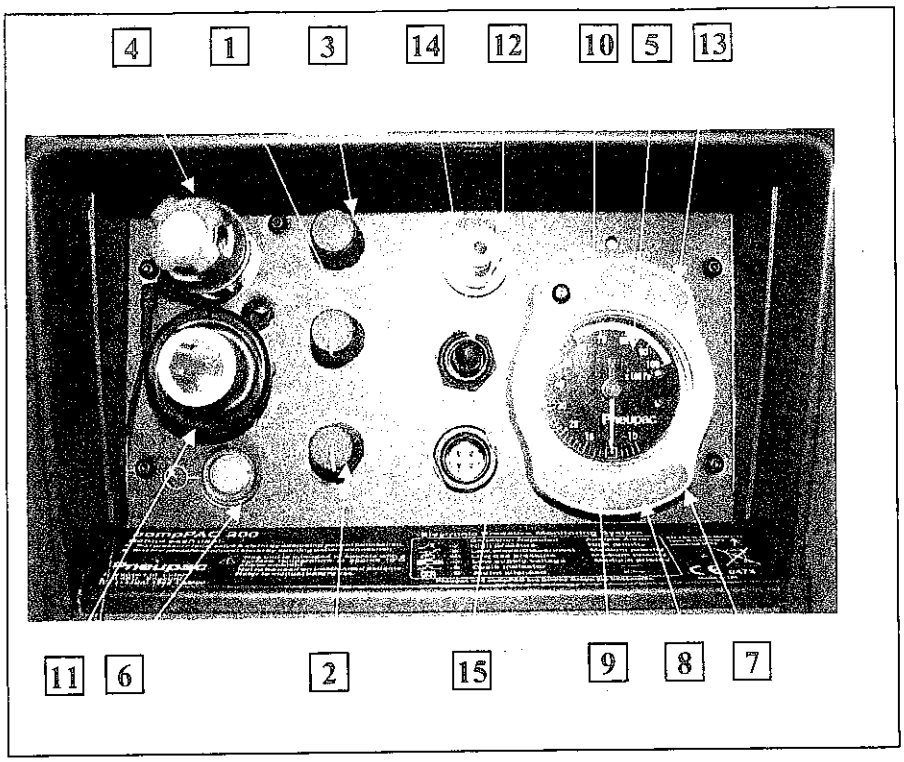


FIGURE 1: compPAC Control Panel

2 Frequency Control (See Figure 1)

This rotary control knob gives continuous adjustment of frequency over the range 10 to 30 breaths per minute. There is a detent and a heart symbol at 13 breaths per minute to aid selection of the optimum setting for adult cardiopulmonary resuscitation (CPR*).
The I:E ratio is nominally constant at 1:1.8 throughout the range of frequency.

3 Oxygen Concentration Control (See Figure 1)

This two-position rotary control knob selects either the 100% or 45% inspired oxygen concentration when an oxygen supply is connected to the gas-input connector. When no external gas is connected this switch is disabled internally.

In the 45% O_2 position the driving gas requirement is reduced by 66% and the balance of the gas supplied to the patient is entrained from atmospheric air which is drawn through the filter canister.

4 Pressure Relief Valve (See Figure 1) **(Fixed relief valve is shown)**

WARNING: **To avoid the risk of over inflating the patient, because the adjustable relief valve (where fitted) is uncalibrated, initial settings of the relief pressure should always be checked by occluding the patient connection port and observing the pressure displayed on the inflation pressure manometer BEFORE attaching the ventilator to the patient.**

The relief valve is connected inside the ventilator directly into the patient circuit and protects the patient from being delivered pressures in excess of the set level.
Note : Cycling pressure will be up to that set by the pressure relief valve.

Either a fixed relief valve set at 60 cm H_2O, or an uncalibrated adjustable relief valve, may be fitted to the compPAC ventilator. The adjustable valve enables the relief pressure to be set to pressures between 20 x100Pa and 70 x100Pa (20 and 70 cm H_2O). It has a pneumatic audible alarm that sounds when the set pressure is reached and gas is being relieved from the patient circuit. Because this adjustment is uncalibrated, initial settings of the pressure should always be checked by occluding the patient connection port and observing the pressure displayed on the inflation pressure manometer before attaching the ventilator to the patient. If there is a battery in place, or an external electrical supply is connected, the independent electronically operated high-pressure alarm will sound whenever the inflation pressure exceeds 60 x100Pa (60 cm H_2O). (See Section 2d #7)

The fixed relief valve can be unscrewed from the control panel but this is only advised for cleaning and maintenance. Always use the wings on the body of the valve for tightening and untightening.

5. Inflation Pressure Monitor (See Figure 1)

This pressure manometer displays the patient inflation pressure, as measured at the ventilator outlet. It will give an accurate indication of the actual patient proximal inflation pressure under all normal settings of the ventilator. It will not display exhalation pressure although this will only be relevant if attachments such as a PEEP valve are added to the patient valve.

This arrangement is to be preferred for emergency use because it requires the simplest patient circuit and there is less probability of disconnection occurring as a result of snagging of the circuit.

6. Supply Gas Failure (See Figure 1)

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 if operating from a compressed gas supply. 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 low threshold level. The visual indication will be accompanied by an electronically generated medium priority[1*] 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.

7. High Inflation Pressure Alarm (See Figure 1)

In addition to the audible alarm described in Section 2(d)#4 an independent electronically generated audible and visual alarm is provided which operates when the inflation pressure rises above 60 x100Pa (60 cm H_2O) irrespective of the setting or operation of the relief valve. The electronic audible alarm only sounds after the alarm pressure has been maintained for a period of one second in order to avoid the sounding of the alarm during transient pressure events. Initially the visual alarm only indicates each time the pressure exceeds the preset limit but if high pressure conditions persist the alarm latches to give continuous flashing.

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

[1*] See section 9(e) for explanation of symbols and description of alarm priorities

8. Cycle Indicator (See Figure 1)

During ventilation of the patient the inflation pressure is continuously monitored by a positive pressure detector pre-set to 8 x100Pa (8 cm H_2O). 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 the least, this inflation pressure is being achieved each cycle.

9. Low Inflation Pressure (Disconnect) Alarm (See Figure 1)

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 8 x100Pa (8 cm H_2O) at least once in any 10 second period. Both the audible and visual alarms reset when the alarm condition no longer exists.
It should be noted that during normal functioning of the ventilator the generated pressure is always zero during the expiratory phase even if PEEP is applied at the exhalation port of the patient valve.

10. Silencing of Electronic Audible Alarms (See Figure 1)

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 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 pre-emptively, i.e. before any alarm sounds, then only a new high priority alarm condition will cause an alarm to sound during the following 60 seconds.

11. Patient Outlet Connection (See Figure 1) – GAS OUTPUT

This outlet to the patient from the ventilator is intended for the attachment of the patient circuit supplied by Smiths Medical for the purpose. A locking ring is provided to allow the circuit to be secured against accidental disconnection. The ring is turned clockwise (looking at the panel) for disconnection.

12. Gas Input Connector (See Figure 1) – DRIVING GAS INPUT

WARNING: **To avoid the risk of harm to the patient, when using Oxygen as the driving gas, the user should be aware that in the event of the oxygen source becoming exhausted, the ventilator would switch over to using the compressor to deliver Air (provided that the battery is fitted, as recommended, at all times, or the auxiliary power supply lead is connected).**

This panel connector is used to connect a compressed gas supply, when available, in order to power the compPAC. This gas may be air or oxygen. If oxygen is used 100% oxygen or oxygen enriched air (45%O_2) will be supplied to the patient, depending upon the setting of the oxygen concentration control.

** See section 9(e) for explanation of symbols and description of alarm priorities.*

If compressed air is used as the supply the 45%O_2 setting should be selected wherever gas economy is important because in this mode the gas usage is reduced by approximately 70%; although it is self evident that the patient will only receive 21% oxygen in either setting.

NOTE: The use of dry compressed gas is the preferred method of driving the compPAC.

The gas source should be at 305-600 kPa (44-87 psi) and be capable of supplying 13 litres/min at this pressure when 45%O_2 is selected and 42 litres/min when 100%O_2 is selected.

When not in use, this connector must be protected by the push-on rubber cap provided.

The mini schrader connector on the Drive Gas Supply Hose should be pushed onto this connector for connection. The white collar should be pushed towards the front panel to release the hose connection.

NOTE: When compressed gas is supplied to this connector the pressure automatically overrides any electrical power selected such that the compPAC ventilator will be powered by the gas source.

13 Electrical Power Indicator (See Figure 1)

A yellow visual indicator is used to indicate the state of the electrical power supplies to the ventilator.

When the internal battery has been selected as the power source or when a gas supply has been connected, the absence of any signal from this indicator, coupled with normal operation the alarm system indicators, confirms the internal battery is providing adequate voltage. When the alarm system detects that the battery charge has dropped to the level where approximately 30 minutes running time remains the yellow power indicator will commence to flash once every 30 seconds to give advanced warning of battery failure. As the charge reaches the point where it can no longer ensure full performance of the ventilator the flashing rate of the power indicator will increase to twice every second, accompanied by a medium priority* audible alarm. Although the ventilator may continue to operate whilst the battery failure alarm is annunciating, ventilator operation will become increasingly uncertain and damage may be caused to the battery.

When an external electrical power source has been selected to power the ventilator and the internal battery is installed and charged then, again, absence of any signal from the power indicator, coupled with normal operation of the alarm system indicators, confirms that both the external supply and internal battery are providing adequate voltage for correct ventilation operation.

With an adequate external power supply and no internal battery, or a discharged battery, the yellow power indicator will be constantly illuminated. A drop in voltage of the external power supply will be indicated by the indicator flashing off once every 30 seconds. If the supply voltage drops to the level where correct ventilator operation cannot be assured the power indicator flashes off twice a second and this is accompanied by a medium priority* audible alarm.

14. On/Off Switch (See Figure 1)

The On/Off switch is used to start the ventilator when it is required to operate the ventilator electrically. It is pushed upwards to run off the internal battery and pushed downwards to run off the auxiliary supply when this is connected. The mid position is 'Off'

* *See section 9(e) for explanation of symbols and description of alarm priorities.*

Charging of the internal battery will take place whenever an appropriate voltage is supplied to the charging circuit of the auxiliary supply connector (see Item No 15 below and Section 2e) iii)) irrespective of the position of the On/Off switch.

WARNING: **To avoid the potential risk of explosion associated with re charging the Lithium version of battery, ensure that only a Ni Cad battery (Part No: 510-A1490/CE, NATO No: 6140-99-620-8057) is installed. UNDER NO CIRCUMSTANCES SHOULD THE LITHIUM BATTERY (NATO No: 6135-99-840-0109), OR ANY OTHER PRIMARY BATTERY, BE FITTED'.**

NOTE: The compPAC is intended to run with a surface temperature of approximately 15°C above ambient when operating from its internal compressor.

15 Auxiliary Electrical Supply Connector (See Figure 1)

WARNING: **To avoid the risk of electric shock, when using the compPAC ventilator in conjunction with the PS12 or PS11 Power Supply/ Charger, the PS12 or PS11 should be located outside the patient environment (ie: ≥ 1.5 Metres from the patient).**

CAUTION: The external supply power connector must only be connected with a SELV (Safety (or Separated) extra-low source) power source.

This panel connector enables an auxiliary electrical supply, when available, to be connected to the unit to conserve the internal battery. The external source should be at 23-28V d.c. with a current capability of at least 2.3 Amperes When not in use this connection is protected by a twist-to-lock/unlock cap.

Four pins are used in the connector to allow for the connection of three independent circuits; one for powering the compressor and two for charging the battery whilst in situ (trickle or fast charge see Section 2(c)). For this reason, only connecting leads specifically supplied for this purpose should be used.

NOTE: *An external power supply used to power the ventilator will not simultaneously charge the internal battery unless it also has a charging system, which is connected to the charging circuit within the connector. The Pneupac PS12 or PS11 power supply has been specially designed to provide both functions and, therefore, will trickle charge the battery at the same time as powering the ventilator.*

WARNING: **To avoid the potential risk of explosion associated with re charging the Lithium version of battery, ensure that only a Ni Cad battery (Part No: 510-A1490/CE, NATO No: 6140-99-620-8057) is installed. UNDER NO CIRCUMSTANCES SHOULD THE LITHIUM BATTERY (NATO No: 6135-99-840-0109), OR ANY OTHER PRIMARY BATTERY, BE FITTED'.**

WARNING: **To ensure protection against electrical shock, any mains driven power supply connected to the compPAC ventilator MUST conform to the safety requirements for medical electrical equipment specified in IEC 60601-1.**

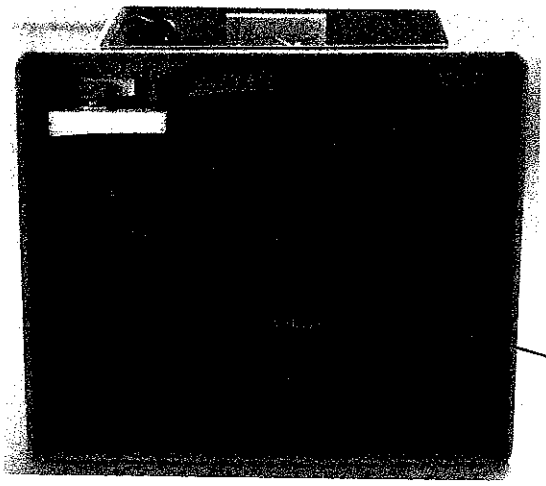


Figure 2a – Battery in installed position

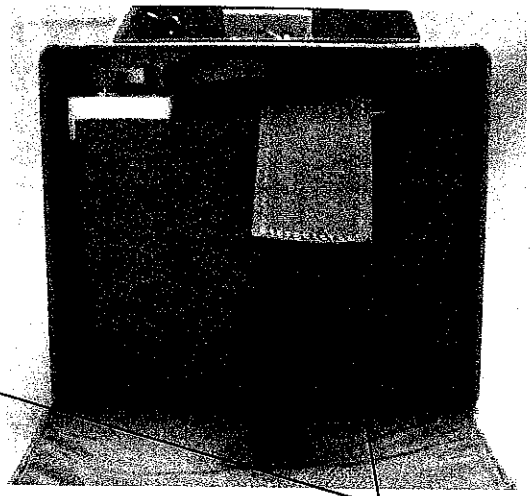


Figure 2b – Undo the main velcro strap

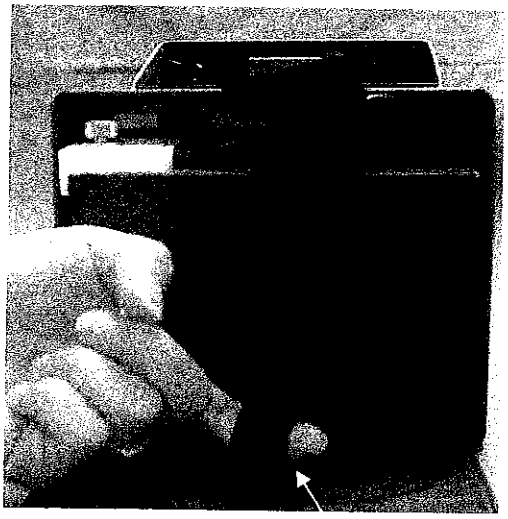


Figure 2c – Place finger in loop and gently pull to extract battery

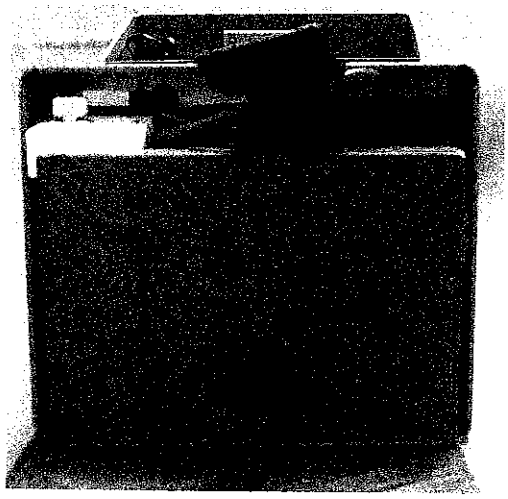


Figure 2d – Disconnect the Battery

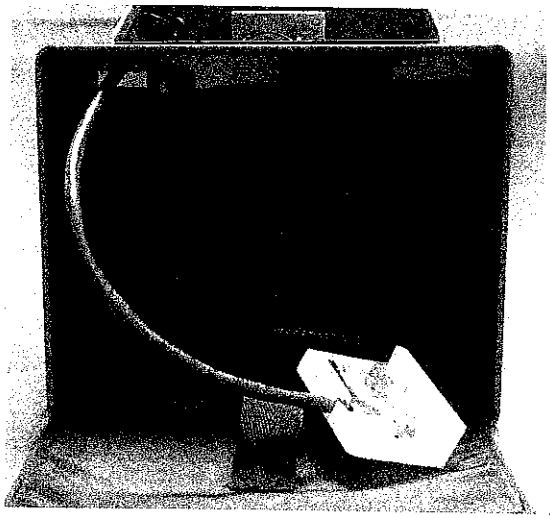


Figure 2e –Battery Removed.

Also refer to figure 7, installation is the reverse of removal

FIGURE 2: Removal of the Battery (installation is reverse [See also Figure 7])

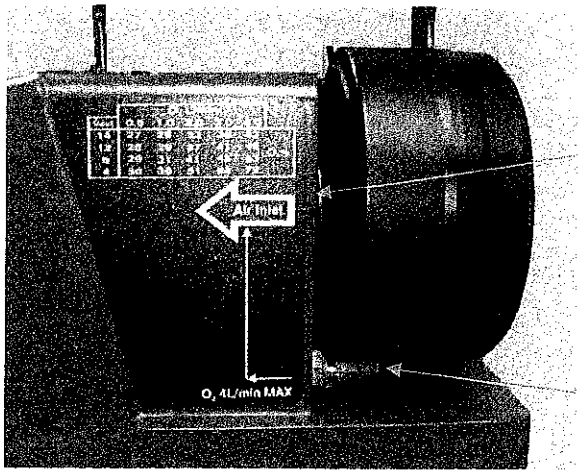


FIGURE 3: NBC Filter & Supplementary Oxygen Connector

16 NBC Canister Adaptor (See Figure 3)

This threaded adaptor is to a standard military specification for the connection of NBC filters. The filter should always be screwed in fully so that it seals against the sealing washer at the base of the adaptor thread.
The compPAC should not be operated without a filter; other than its obvious need when protecting the patient's air supply; its presence ensures that dust and dirt do not enter the patient circuit, valves and other internal sensitive areas.

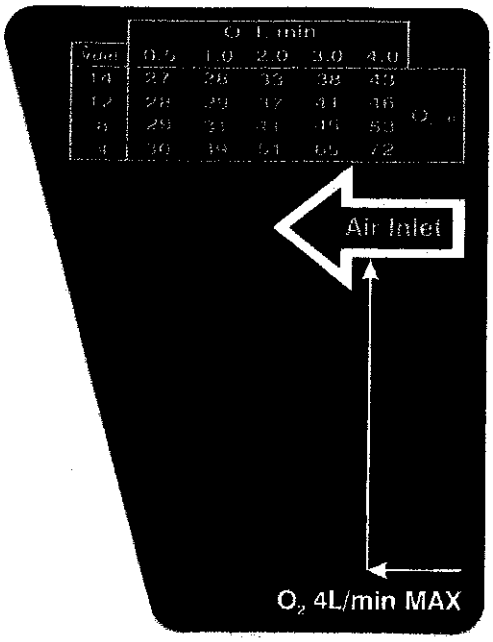
17 Supplementary Low Pressure Oxygen Connector (See Figure 3)
SUPPLEMENTARY FRESH GAS

This connector is situated on the rear of the compPAC ventilator, in the NBC filter recess, parallel with the filter. If a constant flow of oxygen is supplied to this connector this flow supplements the flow of air through the filter. The resultant concentration of oxygen supplied to the casualty is determined by the ratio of the flow supplied to the minute volume selected (See Fig 4), e.g. if the supplementary flow is 1 L/min O_2 and the minute volume is set at 14 L/min, then the delivered concentration will be 28%. The set flow should not be greater than 50% of the minute volume setting (giving 60% O_2 and in no case greater than 4 L/min. If higher flows are used, most of the additional oxygen will pass to atmosphere through the front panel vents and in certain failure conditions increases the risk of an oxygen fire.

When not in use, the connector-blanking cap should be replaced to prevent any intake air by-passing the NBC filter.

WARNING: If uncontrolled oxygen flow is connected to the supplementary oxygen connector there is a risk of the patient valve locking up, causing harm to the patient. Therefore only flow controlled oxygen sources of up to 4L/min. should be attached to the supplementary oxygen connector.

al **Caution :** When using supplementary oxygen connector, the user should be aware that the delivered oxygen concentration quoted on the label (See Fig 4) for 14, 12, 8 & 4 V_{DEL} settings are nominals with a potential variation of up to ±10% of this nominal value. However the nominal delivered oxygen concentration shown on the label for the 4 V_{DEL} setting is subject to a potential variation of up to 13%.



NBC Filter Inlet

Supplementary oxygen connector

FIGURE 4: Label (Part No: 504-224) Showing Supplementary Oxygen Table

(e) Accessories

(i) Patient Circuit

WARNING: **Both the long patient hose (part no. W7483/CE) and the short patient hose (part no. W6861/CE) contain a natural rubber latex which may cause allergic reactions.**

This consists of a Patient Valve, an Inline Filter and two sections of patient hose.

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 an ISO 22/15mm co-axial taper fitting so that face masks or endotracheal tubes conforming to British Standards and ISO requirements may be used. It may be autoclaved at temperatures up to 134°C.

The silicone annular disc on the patient valve ensures that, if spontaneous breathing should occur, all breathing gas passes through the NBC filter. If the applications of the compPAC ventilator will not involve its use in contaminated environments this disc may be removed.

The In Line Filter serves to ensure that no particulate matter originating due to the use of a compressor in the system will pass through to the patient. The filter is not contaminated by the patient because it is upstream of the patient valve. It is therefore acting as a particulate filter for relatively dry gas passing in one direction. It should be replaced after each use.

The patient hose is a 22 mm corrugated hose. For mechanical security the connection to the ventilator is by means of a twist-to-lock connector. Also, the connection to either side of the filter is secured by means of a ratchet clip and the connection to the patient valve by an oversized taper.

(ii) Batteries

The compPAC ventilator is designed to operate from the NiCad rechargeable version of a widely stocked military 24V battery which was originally introduced to power the "Clansman" communications pack; NATO No. 6140 - 99 - 620 - 8057. It is packaged in either a plastic or metal casing but the compPAC ventilator only accepts the plastic casing - there are wider fixing lugs on the metal casing.

The Ni-Cad battery has an 85°C internal thermal cut out.

WARNING: **To avoid malfunction of the ventilator when using the battery as a power source, periodically check the battery to ensure that there is sufficient charge to power the ventilator. The battery may be trickle or fast charged using the PS12 or PS11 power supply/ charger unit (see section 2e) iii), however, this should be undertaken in advance of use and, where necessary (ie: battery does not retain its charge), the battery may need replacing.**

This battery needs to be recharged within a month before use. Battery life will depend on ventilator settings, the table below shows typical battery durationfor given settings:-

Ventilator settings	Battery Life (min.)
4MV, 30BPM	189
12MV, 13BPM	134
14MV, 10BPM	53

The batteries are field exchangeable.

CAUTION: It is recommended that the compPAC ventilator is only used with a battery installed, even if the ventilator is being powered by gas only, as the battery is used to power the electronic alarm system. The ventilator will work without a battery or external electrical supply, since it operates as a conventional gas powered device with the patient protection devices and the high inflation pressure pneumatic alarm operating normally. However, the user must be aware that in these circumstances, the electrically operated alarms will NOT function.

(iii) Power Supply/Charger

WARNING: **To avoid the potential risk of explosion associated with re charging the Lithium version of battery, ensure that only a Ni Cad battery (Part No: 510-A1490/CE, NATO No: 6140-99-620-8057) is installed. UNDER NO CIRCUMSTANCES SHOULD THE LITHIUM BATTERY (NATO No: 6135-99-840-0109), OR ANY OTHER PRIMARY BATTERY, BE FITTED'.**

The Pneupac PS12 or PS11 Mains Power Supply/Charging Unit is specially designed for use with the compPAC ventilator. Its 6 pin input socket will accept leads for connection to supplies of 200/250V 50Hz, 100/120V 60Hz or 24/28V d.c. respectively. Each lead is wired to connect to a different pair of pins.

The PS12 or PS11 / compPAC supply cable assembly (510A2421) connects between the 4-pin socket on the power supply output and the Auxiliary Electrical Supply connector on the panel of the compPAC ventilator.

WARNING: **To avoid the risk of fire or explosion or impaired ventilator performance, always observe the correct polarity of the auxiliary supply. Ensure the supply is a stable voltage of between 23 to 28 Volts, capable of supplying at least 2.3 Amperes and does not contain excessive interference.**

When switched to 'On & Trickle Chg' the PS12 or PS11 power supply provides the correct voltage and current to drive the ventilator through one of the circuits and to simultaneously trickle charge the internal battery through a second circuit. This trickle charging will provide about 8 minutes running time for every hour of charging.

When the power supply is switched to the 'Fast Charge' position it will only energise the third, fast charging, circuit. In this mode the rate of charge is increased by about 4 times such that the internal battery will become fully charged in 4-5 hours. Fast charging will only take place when the 'On/Off' switch on the panel of the ventilator is in the 'Off' position.

Alternatively, if the battery charging lead (510A2422) is connected to the output socket of the power supply it can be used to fast charge a spare battery directly – outside the ventilator.

Plug-in supply leads can be supplied to suit most mains outlet sockets used World-wide.

CAUTION: To avoid accidental disconnection of the power supply unit (PS12 or PS11) when it is connected to the compPAC unit, the mains lead should always be locked in position.

CAUTION: Avoid fast charging batteries outside the temperature range of +10°C to +30°C. The batteries will not accept a full charge outside this range and, in certain circumstances, the capacity of the battery may be permanently impaired. At low temperature, the electrolyte may be electrolysed, and small quantities of hydrogen liberated, which in extreme circumstances present an explosive risk.

An auxiliary power supply lead, part number 510A2582, is available from Smiths Medical to which the user can fit specific connectors to suit alternative 24/28V d.c. power supplies. This lead has only a single circuit so simultaneous battery charging will not occur with its use.

(iv) NBC Filter

WARNING: When in use in a contaminated atmosphere, to avoid the risk of harm to the patient, the NBC filter must be fitted.

The compPAC ventilator is designed to accept any NBC filter with a NATO Stanag 4155 thread, in order to filter NBC contaminants from gas being drawn from the atmosphere for supply to the patient. The selection and usage of a suitable filter for a particular environment must be the judgement of a person trained in the use of such a filter but, in principle, the criteria for selection, use and replacement will be identical to those which would be appropriate to protect the spontaneous breathing of the rescuer. Smiths Medical can supply Avon L12A1 NBC Filter Canisters which are registered as NATO No. 4240 – 99 – 132 – 0941.

CAUTION: The protective bung fitted to the NBC Filter should always be removed before fitting it to the compPAC ventilator.

For use in non-NBC environments it is recommended that the Avon L12A1 filter is always used to act as a dust/particle filter. It will also act as a silencer. For non-NBC use the filter only need be replaced at service intervals, and then only if it has been in normal emergency use.

(v) Drive Gas Supply Hose

As standard an oxygen Gas Supply Hose is provided in order to drive the ventilator from a compressed gas source. This hose has an oxygen probe complying with BS 5682 at the supply end and a proprietary quick connect socket at the ventilator-input connection. The hose connector is pushed onto the ventilator connector probe for connection and the white sleeve is pushed forward towards the panel in order to disconnect.

Note: Where an air specific input hose is used, the Oxygen Mini Schrader to Air probe extension adaptor Part Number 510A2472 is required to connect the hose to the oxygen specific male connector on the compPAC control panel

(vi) Accessories Bag

A multi-purpose bag, which will contain the accessories for use with the compPAC ventilator, is available. This has an exterior pocket with elasticated loops for organising trauma supplies, a large windowed pocket inside the lid and an exterior pocket on the lid.

(vii) Carrying Case

For ease of transportation and to protect the equipment, a robust carrying case designed to contain the compPAC ventilator and all its accessories, is available. The case is made out of plastic, with the interior segmented and lined using foam. The following features are also an advantage:-

- Quick release fasteners
- Two solid wheels
- Three fixed handles
- One extendable pulling handle

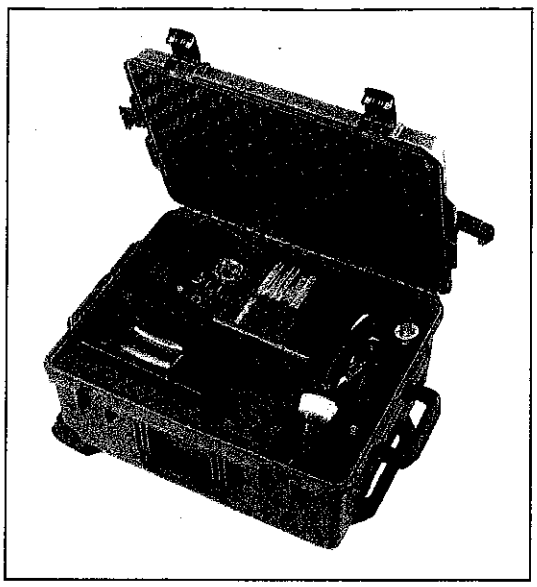


FIGURE 5: Carrying Case

(vii) Gas Cylinders

Lightweight aluminium compressed gas cylinders are available from Smiths Medical for use with portable ventilators. The 'C'/'D' sized version is flat based which permits free standing use also.

(viii) Cylinder Regulators

The Pneupac lightweight aluminium regulator is designed to reduce the pressure of high-pressure gas cylinders from 137-200 x100 kPa (137-200 bar) to 400 kPa (4 bar) as required by the compPAC 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 compPAC Supply Hose. A version is available with an additional, constant flow, outlet for oxygen therapy.

This can be used to supply oxygen to the supplementary oxygen connector on the rear face of the compPAC ventilator. Flows of up to 15 L/min can be selected for oxygen therapy use **but only flows of 4 L/min or less should be used to supply the compPAC.**

WARNING: If uncontrolled oxygen flow is connected to the supplementary oxygen connector there is a risk of the patient valve locking up, causing harm to the patient. Therefore only flow controlled oxygen sources of up to 4L/min. should be attached to the supplementary oxygen connector.

WARNING: Avoid smoking or naked flame. To avoid the risk of ignition, do not use oil, grease or combustible lubricants (only those approved for oxygen use) in contact with any part of the ventilator, regulator or cylinder.

CAUTION: To avoid a sudden release of pressure when changing gas cylinders, turn off the cylinder valve and then switch on the ventilator. After one or two cycles, the ventilator will stop and it is then safe to unclamp the pin index yoke.

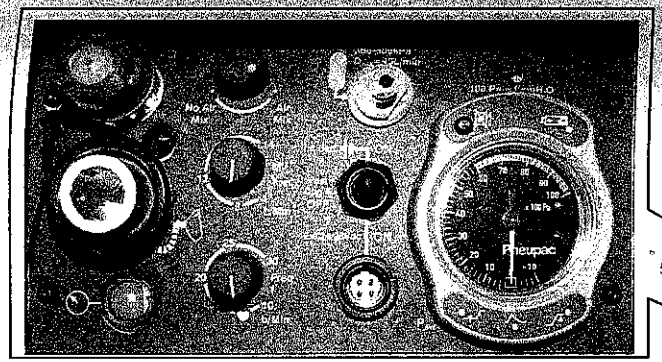
(ix) PEEP Valves

WARNING: **where a PEEP Valve is being used, to avoid risk of harm to the patient, the User should be aware that PEEP and any malfunction in the PEEP Valve, Breathing Circuit or Exhalation Port cannot be reliably detected by observing the Pressure Manometer.**

The Pneupac patient valve supplied with the compPAC ventilator can be fitted with a PEEP valve by means of an exhaust collector (see Fig. 8). This collector is a push fit onto the body of the patient valve and connects the exhalation ring to a 30 mm male taper connection port without interfering with the function of the valve. Smiths Medical can supply a compact PEEP valve to fit onto this port with an adjustment range of 0-20 x100Pa (0-20 cm H_2O). PEEP setting is by means of a calibrated adjustment knob. Before using PEEP with the compPAC ventilator refer to Section 4(e) of this Manual.

(x) Mask

An inflatable cuff mask is supplied with the compPAC ventilator as standard. The cuff should be inflated when the compPAC ventilator is first set up and should be checked for adequate inflation at periodic intervals. It should be sufficiently pliable that it will seal to the face without undue pressure applied to the mask.



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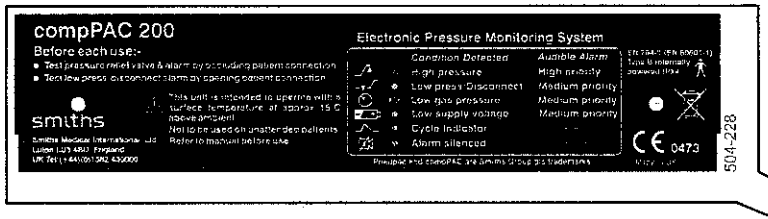

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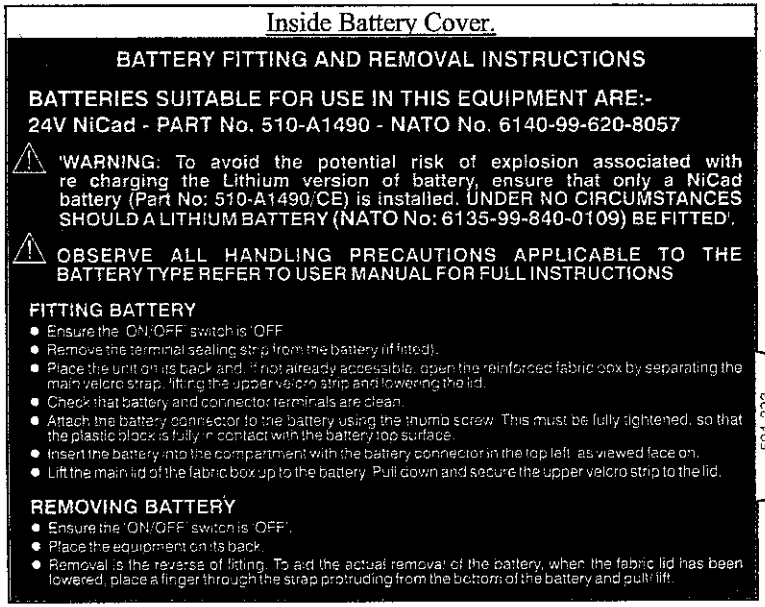

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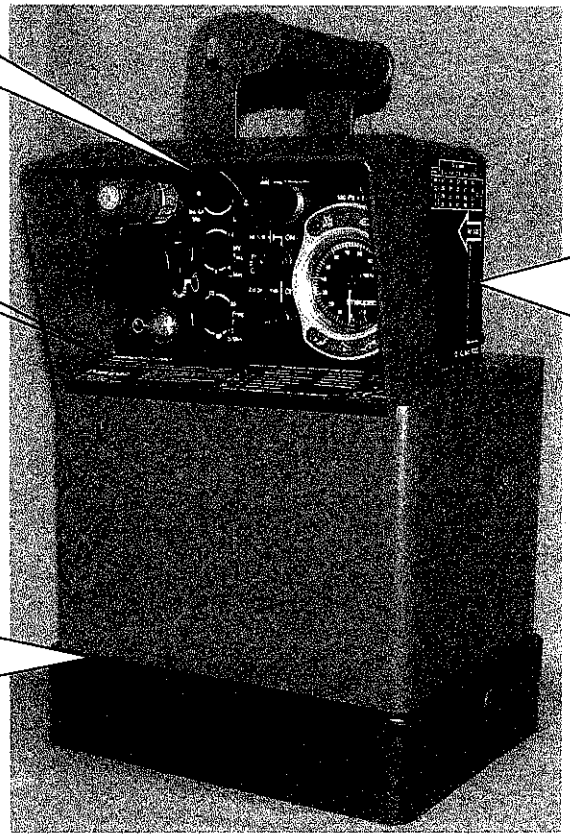

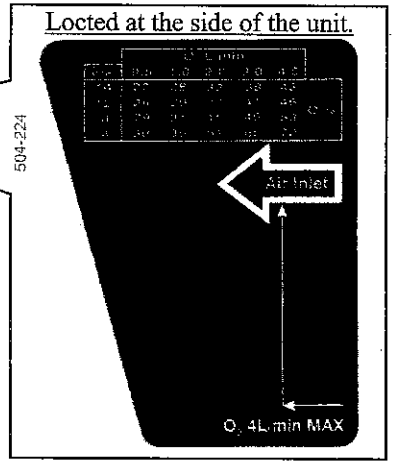

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FIGURE 6: Labels And Their Locations

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SECTION 3: SET-UP, USE and FUNCTIONAL CHECK

(a) Set Up

(i) compPAC Ventilator

Unpack the compPAC ventilator and its accessories and check all items against the contents checklist. If any items are missing or incorrect, or have become damaged, notify your supplier immediately.

WARNING: **To avoid the risk of electric shock, when using the compPAC ventilator in conjunction with the PS12 or PS11 Power Supply/ Charger, the PS12 or PS11 should be located outside the patient environment (ie: ≥ 1.5 Metres from the patient).**

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

If a new NiCad battery is supplied it will need to be charged initially for 14 hours using the PS12 or PS11 Mains Power Supply with the recharging lead connected to the battery terminals by means of the dedicated Charger to Battery recharging lead Pt. No: 510A2422

WARNING: **To avoid the potential risk of explosion associated with re charging the Lithium version of battery, ensure that only a Ni Cad battery (Part No: 510-A1490/CE, NATO No: 6140-99-620-8057) is installed. UNDER NO CIRCUMSTANCES SHOULD THE LITHIUM BATTERY (NATO No: 6135-99-840-0109), OR ANY OTHER PRIMARY BATTERY, BE FITTED'.**

After charging the battery fit it to the ventilator, by following the instructions shown on the upper face of the rubber boot, when removed from the compPAC which are reproduced in Fig. 7.

Fit an NBC filter canister to the ventilator by means of the specially threaded adapter in the recess of the rear face. Screw it in fully until sealing contact is made with the sealing washer at the internal base of the adapter.

If the support ramp is required, fit in the following manner:-

- Place the bottom of the ramp into the slots in the rubber boot (making sure the boot is fitted to the compPAC, with the ramp positioned at the rear of the ventilator).
- Remove the protective backing from the adhesive pads.
- Offer the support ramp up to the rear of the compPAC case, holding in position for approx. 30 seconds for the pads to bond.

To remove the ramp:

- Hold one side of the ramp and using thumb (on case) and fingers (on ramp), prise one side of the ramp from the back of the compPAC case.

- The other side can then be prised free in a similar manner.

Assemble the patient circuit and connect it to the connector on the ventilator control panel using the twist lock nut for retention. Note that the hose is attached to the fixed taper limb of the patient valve which is at an angle to the body. The mask is attached to the swivel taper.

NOTE: *If the ventilator output hose is, incorrectly, connected to the swivel connector the ventilator will not deliver tidal volumes and the alarm will not sound during the functional occlusion test (See Section 3(b), 4(b)(ii) and 4(g)(iii) 5).*

Connect the Gas Supply Hose to the Gas Input Connector by pushing the body of the connector towards the panel until it clicks. The probe on the Supply Hose is gas specific to the standard specified when ordering. Any of the Pneupac hoses listed in the compPAC Accessories and Spare Parts list can be used with the ventilator.

(ii) Oxygen System

If a Pneupac cylinder regulator and oxygen gas cylinder have been provided, proceed as follows:

WARNING: **Avoid smoking or naked flame. To avoid the risk of ignition, do not use oil, grease or combustible lubricants (only those approved for oxygen use) in contact with any part of the ventilator, regulator or cylinder.**

CAUTION: To avoid a sudden release of pressure when changing gas cylinders, turn off the cylinder valve and then switch on the ventilator. After one or two cycles, the ventilator will stop and it is then safe to unclamp the pin index yoke.

Remove any packaging from the cylinder valve. Momentarily turn on cylinder using cylinder valve key/wheel to blow out any dust in cylinder valve. Fit regulator and yoke to the cylinder valve, making sure the sealing washer is in position and the two foolproofing locating pins are entered in the side of the square cylinder valve. Tighten the T screw in the yoke making sure that the pointed end of the screw is in the recess of the cylinder valve. Where a regulator with a threaded cylinder connection fitting is provided, screw the fittings onto the threaded connection of the cylinder, tightening with the regulator in the required orientation.

Slowly open the cylinder valve anti-clockwise using the cylinder valve key/wheel. Once the contents gauge pointer has stabilised, open the cylinder fully then close the valve one quarter of a turn to enable subsequent users to distinguish between an open and closed valve. Check that gas does not leak audibly from the connection or from the gland nut on the cylinder valve. If leaking, check that the previous fitting instructions have been carried out properly and that the sealing washer is in position and is not damaged. If leaking from gland nut, replace the cylinder and refer the faulty cylinder via the normal reporting channel.

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.**

A pressure gauge is provided to check the contents of the cylinder. Check level of charge. If the gauge indicates empty, check that the connection has been made according to above; otherwise replace with new cylinder. Close cylinder valve.

(b) Functional Check

WARNING: To avoid harm to the patient, pre-use checks must be performed in accordance with section 4 of this manual before each use.

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:-

Electrical Switch:	Off (Middle – position)
Frequency:	12 b/min (detent position)
Minute Volume:	10 L/min
Air Mix Switch:	100% O_2
Adjustable Relief Valve:	Minimum (fully anti-clockwise)

2. Connect the probe on the input hose to an appropriate gas outlet. 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 305 kPa (≈ 3 bar) whilst delivering a flow of 55 L/min.

3. The ventilator should commence cycling and all the alarm lights flash in turn. A single burst of the high priority audible alarm is given at the same time. The orange silenced indicator should flash for 60 seconds. Check that flow is coming from the patient connection port by feeling the flow when placed close to the back of the hand or to the face.

4. If the Fixed Relief Valve is fitted, occlude the output port on the patient valve and check that the manometer gives a reading of 60 x100Pa during each inspiratory phase. Check that the audible alarm sounds when the output port is occluded.

   If the variable relief valve is fitted, occlude the output port on the patient valve, adjust the relief valve and check that the manometer gives a reading of between 60-70 x100Pa during each inspiratory phase. Check that the audible alarm sounds when the output port is occluded. Adjust relief valve to give 40 x100Pa reading on the manometer.

5. Switch over to 45% O_2 and again occlude output port. The change in the manometer reading should not exceed 5 x100Pa (5 cm H_2O).

6. Set the 'Minute Volume' control to its minimum setting. Occlude the output port and check that at least 20 x100Pa pressure is attained on the manometer. Gradually increase the minute volume setting and observe how the pressure rises - demonstrating the pressure generator principle.

7. Set the 'Frequency' and 'Minute Volume' control knobs to the extremes of their range. By listening to the gas flow, check that the ventilator is responding to the controls and that no irregularities of performance can be discerned.

8. Disconnect or switch off the oxygen supply. Set the 'On/Off' switch to the 'On' position (upwards if using the internal battery or downwards if using an external auxiliary power source). Repeat step 7.

   - To test the disconnect alarm conduct the following:
   - Low **patient** pressure disconnect alarm – Disconnect the patient hose from the outlet; the low pressure/ disconnect alarm denoted by the ⚠ symbol on the alarm bezel will activate a yellow LED flashing at Medium Priority accompanied by an audible alarm.
   - Low **supply** pressure disconnect alarm – Switch off the compressor by selecting the mid position on the 'On/ Off' switch and remove the auxiliary gas supply pipeline from the input fitting, the low pressure/ disconnect alarm denoted by the ⚠ symbol on the alarm bezel will activate a yellow LED flashing at Medium Priority accompanied by an audible alarm.

NOTE: Short runs using the compPAC compressor should be kept to a minimum in order to minimise the requirement to dry the unit after use.

9. 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.**

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

CAUTION: To avoid a sudden release of pressure when changing gas cylinders, turn off the cylinder valve and then switch on the ventilator. After one or two cycles, the ventilator will stop and it is then safe to unclamp the pin index yoke.

10. Battery Replacement

If the battery needs replacing follow the instructions shown on label Part Number 504-223 located on the inside face of the rubber boot which is reproduced in Fig 7.

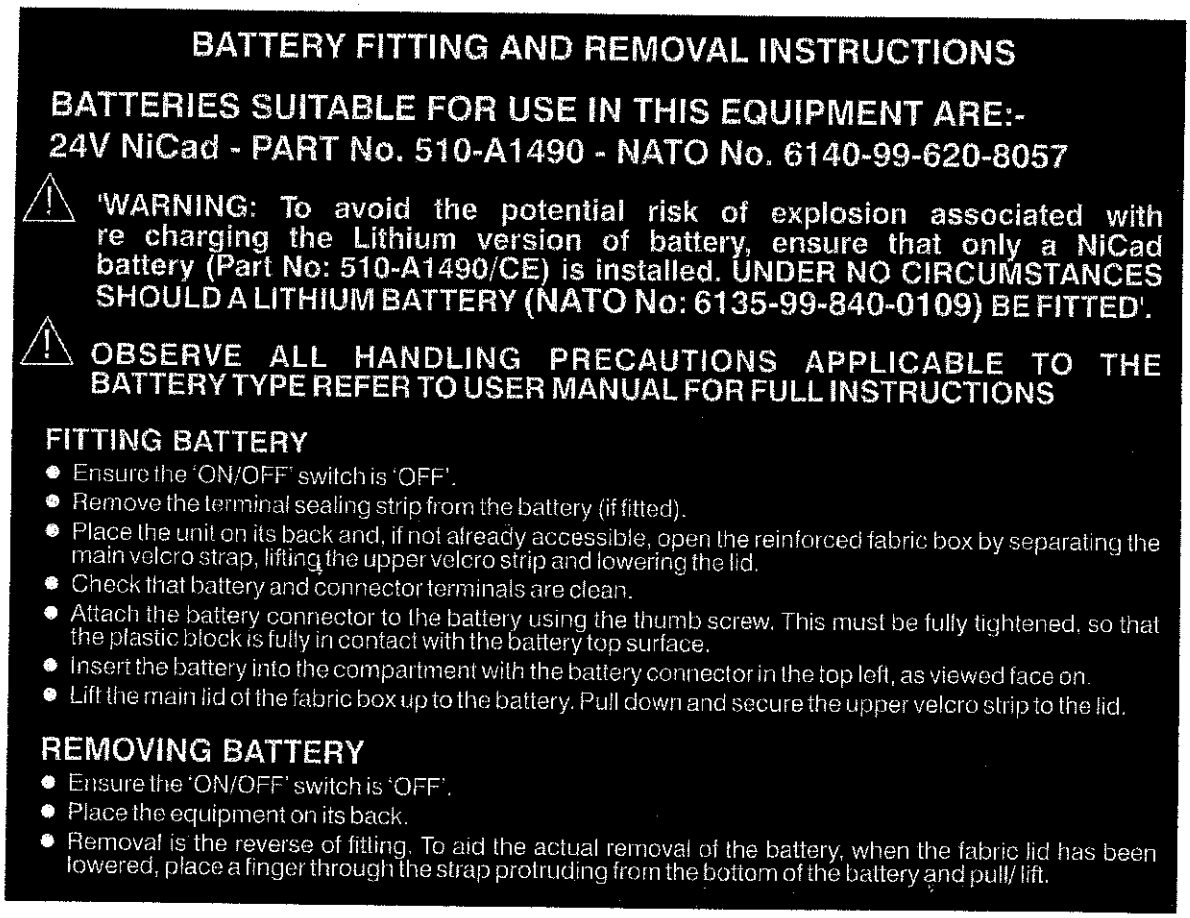

FIGURE 7: Battery Installation and Removal Instructions (See also Figure 2)

11. NBC Filter Replacement

WARNING: **To avoid the risk of chemical / environmental hazards, disposal of a contaminated / used NBC filter must be in accordance with local regulations**

CAUTION: The protective bung fitted to the NBC Filter should always be removed before fitting it to the compPAC ventilator.

The ventilator should always be run with a NBC filter in place as this reduces the operating noise as well as filtering the air entering the compressor. Other than the protection provided to the patient's air supply, the filter also prevents ingress of dust and dirt into the ventilator circuit, which could cause deterioration of ventilator performance.

If there is no NBC filtration requirement the filter need only be replaced if there is a visible accumulation of dirt in the inlet grid.

If the ventilator is being used in a NBC environment then the NBC filter should be replaced as would be required by procedures for normal use. No additional service load is placed on the filter other than that imposed by a resting person breathing normally.

Note: Ensure that the filter is fully tightened before use.

12. Carrying

The compPAC ventilator is intended to be carried by its handle. It can be installed in vehicles and aircraft by means of special mounting brackets attached to the wall.

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SECTION 4: OPERATION

WARNING: **To avoid the risk of over inflation of the patient it is important for the operator to constantly monitor the patient pressure manometer during manual ventilation.**

WARNING: **To avoid the risk of under inflation of the patient, it is important for the operator to monitor tidal volumes. This is especially important with a combination of ventilator minute volume settings of 12L and above, power supply voltages below 24 Vdc and patients with low compliance lungs and highly resistive airways.**

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

(a) User's Skill

The compPAC ventilator is designed to be used by medically qualified personnel with a general training in ventilation and resuscitation and by paramedic personnel specifically trained in emergency techniques. If to be used in hazardous environments all users should be trained in the use of the compPAC ventilator in these environments.

All potential users 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 by their training.

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

(b) Setting of the Ventilator

(i) General

The ventilator should be left with the controls set in the position specified in the functional check (Section 3(b)1) 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.

Where the compPAC ventilator is likely to be used away from gas sources it should be stored with a fully charged known good battery and/or connection leads for use with an outside power source. At least one mask should also be kept available for emergency use.

(ii) Ventilating the Patient

1. Where a suitable gas source is available connect the gas supply hose between the front panel connector and the gas supply.
2. Turn on the gas supply (if relevant)
3. If no suitable gas source is available switch the On/Off Switch to 'Int' to run on internal battery or to '24/28V d.c.' if connected to outside power source.
4. Set ventilation parameters to suit the patient.
5. Occlude the end of the patient hose with the thumb and check that the peak inflation pressure reading on the Inflation Pressure Monitor is limited by the relief valve (accompanied by a pneumatically generated audible alarm. After occlusion, gradually increase the setting of the adjustable relief valve (if fitted) and check that correct peak pressure control is achieved and that the electronic audible alarm sounds above approximately 60 x100Pa.

6. Decrease the relief valve setting of the adjustable valve to minimum.
7. Apply the face mask to the patient, ensuring that the airway is free, or connect Patient Valve to endotracheal tube.
8. Check Inflation Pressure Monitor to ensure correct ventilation. Make adjustments as necessary.

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

The Inflation Pressure Monitor should be kept under constant observation so that adverse ventilation conditions can be detected and corrected before the patient is put at risk. When ventilating with a mask the peak inflation pressure should ideally be kept below 20 x100Pa (20 cm H_2O) 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 is reduced by decreasing the minute volume setting.

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

When ventilating with an endotracheal tube a higher pressure will normally be observed but if abnormally high either kinking of the tube or excessive ventilation should be suspected.

If the inflation pressure is too low, firstly check for leaks, secondly check the ventilation parameters, thirdly, check the patient valve for proper functioning.

NOTE *At all times check the adequacy of the gas source or the power supply/battery as indicated by the electrical power indicator.*

(c) Oxygen Concentration

When using oxygen as the supply gas, the Oxygen Concentration control will allow for the selection of ventilation of the patient with 100% supply gas or with the supply gas diluted by ambient air in the ratio of 1:2.

When using the internal compressor to drive the ventilator, other oxygen concentrations are available by connecting a flow-controlled oxygen supply to the supplementary oxygen connector as detailed in Section 2.

WARNING: WARNING: **To avoid the risk of contamination of the ventilator airways when in a potentially contaminated environment and also avoid the loss of performance (reduced tidal volume). When the supplementary oxygen connector is not being used, the blanking cap MUST be securely in place to prevent any intake air from by passing the filter.**

WARNING: **If uncontrolled oxygen flow is connected to the supplementary oxygen connector there is a risk of the patient valve locking up, causing harm to the patient. Therefore only flow controlled oxygen sources of up to 4L/min. should be attached to the supplementary oxygen connector.**

Where high oxygen concentrations are required, such as during initial resuscitation, use the '100% O_2' setting and oxygen as the supply gas.

Where 45% oxygen concentration is required, use an oxygen supply and select the '45% O_2' setting. In this setting a bottled gas supply will last three times as long and therefore this setting is preferred, wherever possible, once the patient is stabilised.

If air is used as the supply gas, the '45% O_2' setting should be used at all times except when in contaminated or toxic atmospheres (See Section 4(f)).

(d) Ventilating Intubated Patients

When the patient is intubated, the operator must be concerned with the implications of by-passing the patient's upper airway. The drying effects of medical gas must also be considered.

Potential problems can be effectively overcome by the use of bacterial filters, which also act 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.

(e) Positive End Expiratory Pressure (PEEP)

PEEP can be applied to the patient circuit by the means shown in Figure 8. The exhaust collector adaptor shown allows a pop-off type PEEP valve to be attached to the exhalation port of the Patient Valve.

As stated earlier, the Inflation Pressure Monitor will not indicate exhalation pressure, so the setting of the PEEP control should be carefully observed. The Pressure Monitor will show the sum of the PEEP and the airway pressure drop at the commencement of inspiration and the effect of PEEP changes can be observed in this way.

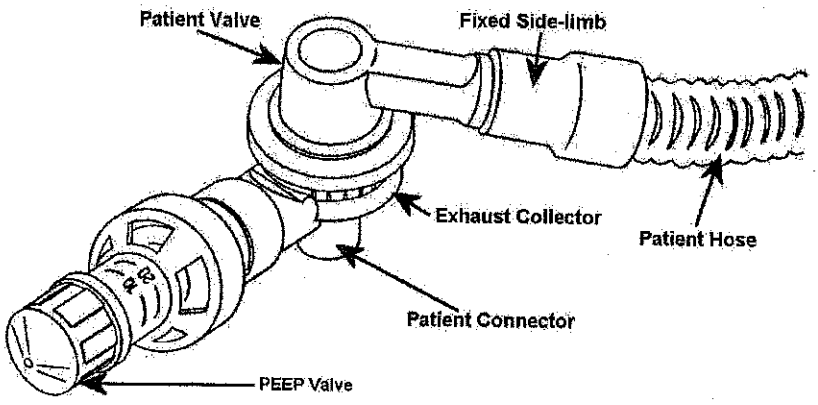

FIGURE 8: Correct Assembly Of PEEP Valve & Exhaust Collector

(f) Use in Contaminated Atmospheres

WARNING: **To prevent transmission of any contaminants to both user and patient after use in a contaminated environment, be aware that the compPAC outer case is NOT hermetically sealed against ingress of gas or liquids. Decontamination, if necessary, should involve removal of the module from its case by a suitably trained person.**

The compPAC is suitable for use in contaminated and toxic atmospheres subject to certain limitations and these should be clearly understood by those likely to use the equipment in such environments.

In any situation where the respirable qualities of the immediate environment are suspect, ventilation can be carried out with either the '45% O_2' or '100% O_2' Oxygen Concentration setting selected provided the supplementary oxygen connector blanking cap is fitted to ensure that no ambient gas can enter the breathing system except through the NBC filter. It is essential, however, that the filter canister selected is suitable for eliminating the contaminant suspected. If oxygen (or an external air source) is used as the gas supply (compressor off) and the 100% Oxygen Concentration setting is selected, no air will enter the system through the filter from the atmosphere and hence with this setting there is no dependence on the correct functioning of the filter.

If the patient is breathing weakly or intermittently the Minute Volume and Frequency controls should be adjusted to ensure that the ventilator controls the entire breathing pattern.

(g) Inadvertent Immersion in Water

CAUTION: Although this ventilator has been fully tested to withstand water spray from all directions, it is not designed to be immersed in water. In the event that the module is accidentally immersed, it should no longer be operated and an alternative means of ventilation used (see also WARNING #16 in this User Manual). The ventilator should then be returned to the manufacturer for rectification.

Should the compPAC be accidentally immersed in water, it should no longer be operated and an alternative means of ventilation used. Immediately disconnect the patient hose at the compPAC outlet and the filter then drain water from the hose, compPAC and filter followed by shaking to remove excess water. The compPAC should then be returned to the manufacturer for rectification. Prior to return, wash down the outside of the compPAC with clean water and discard the filter, the patient mask and the patient hose with biological filter.

The battery fitment, battery, battery terminals, battery connector, and any exposed surfaces / parts / controls should be dried and the compPAC returned to Smiths Medical for repair.'

SECTION 5: CARE, CLEANING and STERILISATION

(a) Care

The compPAC ventilator is designed to operate in the face of the tough treatment it may receive during its intended use but to prolong its life and retain its appearance, basic care should be taken in its cleaning and stowage between uses. In particular the following steps are recommended to be taken after every use:-

i) Carefully inspect the complete system and make note of what actions should be taken. In particular check for damage to hoses or masks, contamination of any component, evidence of any part having been subjected to excessive force and missing parts.
ii) Remove, discard and replace the in line filter.
iii) Clean or sterilise the parts of the patient circuit adjacent to the patient, as necessary.

CAUTION: **Excessive ingress of moisture could result in deterioration of internal components, if the device is unlikely to be used regularly (ie more than once a week). This could also result in the ventilator failing to start. To avoid this, ensure that the compPAC is properly dried after each use. The compPAC ventilator must be dried internally as detailed below, powered by the compressor alone (i.e. delivering 21% oxygen).**

iv) If the compPAC ventilator has been running powered by its internal compressor and with no oxygen input, humidity in the ambient air drawn in by the compressor may have condensed in parts of the internal pneumatic circuit. The design of the compPAC ventilator is configured to minimise this effect and to dissipate any excess water but some dampness may remain after the unit is switched off. To avoid any internal deterioration due to this condensation, after each use perform the following shutdown actions if the device is unlikely to be used more than once a week. Run the compPAC powered only by the compressor (i.e. delivering 21% oxygen), internally dry the compPAC ventilator using the following procedure:

Pneumatic Circuit Drying Procedure

Connect the oxygen supply hose to the supply gas connector on the panel of the compPAC ventilator and to a source of dry oxygen, e.g. cylinder or pipeline. Turn the supply on and set the ventilator to 30 breaths per minute and 14 L/min volume. Select Air-Mix. Run for 15-60 minutes, depending on the ambient humidity under which the ventilator has been running. If a humidity meter is available place it in the ventilator output connector and run the unit until a dew point of about the 0°C is achieved.

Additional instructions for the maintenance (only applicable to suitably trained personnel) of the compressor reservoir are detailed in section 6 (d).

v) Reassemble the system and carry out the function check specified in Section 3.

vi) Stow the system in a clean area, away from heat and intense light.

(b) Battery Care

The NiCad battery recommended for use with the compPAC ventilator should be periodically charged to ensure it remains at full capacity. The battery should be removed for storage periods greater than one month. Charging of the battery can be carried out, both inside and outside of the compPAC, using a recommended charger.

WARNING: To avoid the potential risk of explosion associated with re charging the Lithium version of battery, ensure that only a Ni Cad battery (Part No: 510-A1490/CE, NATO No: 6140-99-620-8057) is installed. UNDER NO CIRCUMSTANCES SHOULD THE LITHIUM BATTERY (NATO No: 6135-99-840-0109), OR ANY OTHER PRIMARY BATTERY, BE FITTED'.

WARNING: To avoid malfunction of the ventilator when using the battery as a power source, periodically check the battery to ensure that there is sufficient charge to power the ventilator. The battery may be trickle or fast charged using the PS12 or PS11 power supply/ charger unit (see section 2e) iii), however, this should be undertaken in advance of use and, where necessary (ie: battery does not retain its charge), the battery may need replacing.

(c) Cleaning

(i) compPAC Control Module – the module should normally be cleaned by means of a damp cloth. For obstinate marks a mild soap or non-abrasive cleaner may be used. Wipe dry immediately with a soft clean cloth.

Do not attempt to sterilise the Control Module or to clean it by immersion in any fluid

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

WARNING: Both the long patient hose (part no. W7483/CE) and the short patient hose (part no. W6861/CE) contain a natural rubber latex which may cause allergic reactions.

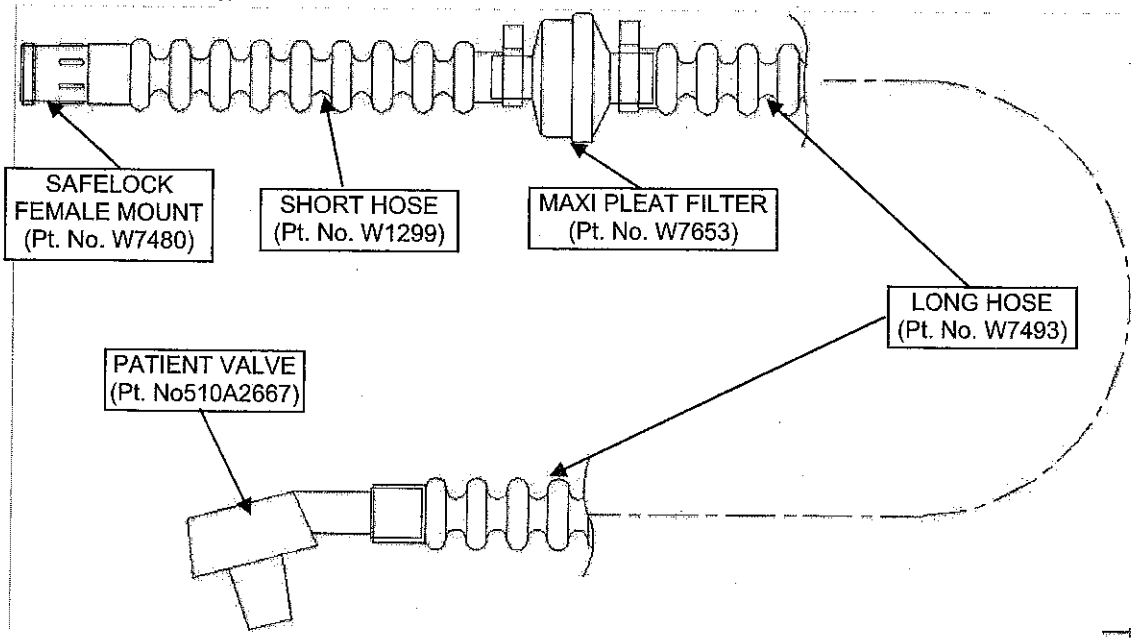

FIGURE 9: Patient Hose And Valve Assembly

(ii) Patient Valve – Disassemble the Patient Valve by unscrewing the two parts of the body and carefully removing the silicone valve element. Remove also the silicone annular disc surrounding the patient connector.

Thoroughly clean each of the parts either in running hot water or in a detergent solution, followed by thorough rinsing under running water. Scrub the rigid plastic parts if necessary but not the silicone parts.

Dry all parts thoroughly and check them for damage before reassembly. Ensure that the silicone valve element is inserted the correct way round and is not distorted when the valve halves are re-screwed together. Replace the silicone annular disc.

(iii) Hoses – The Gas Supply Hose may be cleaned in the same manner as the Control Module taking the same care to keep free from grease.

The Patient Hose may be cleaned in the same manner as the Patient Valve parts. The In Line Filter should be replaced after every use.

WARNING: **To avoid the risk of cross contamination all re usable components in the patient circuit, that can can come into contact with the patient or the patient's exhaled gas (Patient Valve and Patient Hoses) should be sterilized or disinfected as per instructions detailed in Sections 5d) and 5e) of this user manual.**

(d) Disinfection

After cleaning, the Patient Valve components and the Patient Hose may be disinfected by immersion in a cold solution of disinfectant or germicide. Always follow the manufacturer's instructions. Rinse and carefully dry all components before assembly.

The Control Module may be wiped with a disinfectant but must not be immersed.

(e) Sterilisation

The following components of the compPAC Patient Circuit may be steam sterilised after disassembly:

- 510-A2667 Patient Valve
- W6861 Short corrugated hose (ventilator side of the particulate filter)
- W7483 Long corrugated hose (patient side of the particulate filter)

The Patient Valve can be treated up to 134°C. These components may also be sterilised by means of gas sterilisation, carefully following the steriliser manufacturer's recommendations.

No parts of the compPAC Control Module come in contact with the casualty's expired gases and therefore this unit is not designed to be sterilised.

(f) Assembly and Function Testing

After cleaning or sterilisation, parts must be carefully dried and then reassembled. Before putting the system back into stores or service the functional check described in Section 3 should be carried out.

(g) Decontamination

WARNING: To prevent transmission of any contaminants to both user and patient after use in a contaminated environment, be aware that the compPAC outer case is NOT hermetically sealed against ingress of gas or liquids. Decontamination, if necessary, should involve removal of the module from its case by a suitably trained person.

The compPAC ventilator is chemically hardened and is designed to be decontaminated by approved methods.

The casing is completely sealed, apart from the control panel and the battery compartment which are protected by heavy shrouding. The canister connector is protected in use by the NBC canister.

For NBC decontamination, the rubber boot, the battery and the battery fixings should be completely removed (see Figure 2). The casing can then be decontaminated using the shroudings to protect the panel and the internal parts of the battery compartment. Light contamination of the controls on the shrouded panel should be decontaminated by a method suitable for instrumentation e.g. light dusting with Fullers Earth.

SECTION 6: MAINTENANCE

(a) General

The compPAC ventilator requires checking for calibration settings at least annually. Service is only required if calibration needs to be restored, if component failure occurs or if damage is incurred.

It is recommended that maintenance of units in service is carried out at two levels. At the first level, the procedure specified in section 3 (b) should be followed at regular intervals, typically once a month, irrespective of use, and a record kept by the use of the log sheet at the back of this manual. At the second level, the performance of the ventilator should be checked as specified in Section 6(b).

Before the unit is put into storage, it is recommended that it is run for about one hour on dry bottled gas as detailed in Section 5 (a)(iv).

(b) Performance Checking

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.

Performance checking of the compPAC ventilator must be carried out with equipment calibrated to ensure accuracy under the flow patterns generated by the machine. It should only 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 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 should be determined by the user. Normally, this would be not more often than once every 6 months but at least once every two years.

(c) Service

Information will be made available to suitably qualified personnel upon request.

WARNING: To avoid the risk of harm to the patient from an incorrectly set ventilator, servicing or adjustment of this equipment should only be carried out by competent personnel who have been trained by Smiths Medical to carry out such work.

If the compPAC ventilator shows a malfunction during operation or testing or if its performance is measured to be outside the acceptable tolerance before re-calibration stated in the specification during its performance checking, then the unit should be withdrawn from operation and an appropriate service must be carried out.

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

(d) Compressor Reservoir Maintenance

During routine calibration/ servicing of the compPAC ventilator, it is advisable to also clean the Compressor Reservoir. The cleaning procedure detailed below may also be performed if there is suspicion that reservoir may be dirty or wet..
To carry out cleaning of the resevoir, proceed as follows:-

1. Remove the rubber boot from the bottom of the compPAC. The boot is retained in place using retaining studs.

2. Remove the battery in accordance with the instructions detailed inside the rubber boot.

3. Remove the battery retaining jacket from the battery compartment by separating the velcro fastenings.

4. Remove the reservoir access plate retaining screws and detach the access plate.

5. Drain out any excess residual moisture from the inside of the reservoir.

6. Wipe clean all the inside surfaces of the reservoir with an absorbent lint free cloth.

7. Carefully remove the rubber 'O' ring seal from the groove in the access plate.

8. Wipe clean the 'O' ring seal and all the surfaces of the access plate, including the seal groove, with an absorbent lint free cloth.

9. Using a clean absorbent lint free cloth, apply a disinfectant such as Ethyl or Iso Propyl Alcohol (70% to 90%) to the inside surfaces of the reservoir, the rubber 'O'ring seal and the access plate and leave for a duration of at least 10 minutes.

10. Rinse off the disinfectant with sterile water and fully dry the inside of the reservoir, 'O' ring seal and access plate. This may be done with a lint free cloth or a clean forced air supply.

Note: If no sterile water is available, use tap water, followed by alcohol and then dried by means of forced air.

11. Inspect the rubber 'O' ring seal for any sign of damage or deterioration. If it is in good condition carefully place it into the groove of the access plate. If there is any doubt about the condition of the rubber 'O' ring seal discard it and fit a replacement.

12. Re-fit the access plate to the compPAC and securely tighten the 10 screws (supplied as a kit Part No. 510A2956).

13. Perform a leak test and any rectification as follows:-
    (i) Temporarily reconnect the battery or a suitable d.c. supply to the compPAC.
    (ii) Set the controls to 6mV and 10 b/Min.
    (iii) Switch on the compPAC.
    (iv) Apply soap solution around the access plate and to the screw heads to check for any air leakage.
    (v) If an air leak is detected, switch off the compPAC, disconnect the power source and remove the access cover.

(vi) Re-check the condition of the rubber 'O' ring seal, replace if necessary. Also check the reservoir plate surface for any particles of matter or scratches which could prevent the 'O' ring seal sealing. After any corrective action, repeat the steps (i) to (iv) above.

14. On successful completion of the Leak test, replace the battery retaining jacket, battery and boot. Carry out the pre use checks as recommended in Section –3b 'Functional Check' of the user manual before deploying the compPAC.

(e) Storage

If the compPAC ventilator is to be stored for prolonged periods, it should be located in a cool dry place out of direct sunlight. Remove the internal battery prior to any prolonged periods of storage. Prior to use, following any prolonged storage, ensure that the compPAC ventilator has stabilised to a temperature within its specified operating range (-10°C to +40°C).

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SECTION 7: ACCESSORIES and SPARE PARTS

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

WARNING: Both the long patient hose (part no. W7483/CE) and the short patient hose (part no. W6861/CE) contain a natural rubber latex which may cause allergic reactions.

(Only parts with an Order Code incorporating /CE may be sold to countries bound by the European Medical Devices Directive for use with compPAC ventilators bearing a CE mark (see Section 1)).

Description			Order Code
Airway, Guedel, Disposable	Size 1 Child		W6875
	Size 2 Adult		W6876
	Size 3 Adult		W6877
Bag, Accessories			W1356
Battery, NiCad			510-A1490
Cylinder, Lightweight Aluminium, 'D' size (2.7 Litre)		full	W6837
		empty:	W6838
Electrical Leads	PS12 or PS11 to Battery Recharging Lead		510A2422
	24V / 28V dc supply to compPAC Lead		510A2564
	PS12 or PS11 to compPAC 24V / 28V dc lead		510A2421
Exhaust Collector, 30mm Male			W1434
Filter,NBC			W7265
Particulate Filter (Ventilator Breathing Circuit)			W7653
Hook Ring			W6872
Hose, input 1.5m long quick connect	O_2 mini Schrader to Air probe extension adaptor		510A2472
	O_2 mini Schrader female probe to O_2 mini Schrader male probe		510A2601
	Air mini Schrader female probe to Air mini Schrader male probe		510A2602
	Air mini Schrader female probe to Air (4 Bar) mini Schrader male probe		510A2603
Hose lengths of up to 15 metres are available			
Hose,	Oxygen Therapy with BS5682 Probe (6 L/min flow):		500-A254/6
	Constant Flow Oxygen		500-A928
	Patient, Long		W7483
	Patient, Short		W1299
	Clip (for Hose/Filter to compPAC)		W6709
	Clip (for Hose/Filter patient valve)		W6710
Lightstick	Pack of 10		W6858/10
	Pack of 50		W6858/50
Masks,	Oxygen Therapy Disposable (Pack of 5)		500-A369/5
	Adult Clear		W6807
	Child/Small Adult Clear		W6806

Description			Order Code
Oxygen Therapy Unit with BS5682 Probe (6L/min)			500-A253/6
Patient Circuit (complete)			510-A1082
PS12 Power Supply & Battery Charger			525A1034
PS11 Power Supply/Charger			510-2408
Regulator,	Pin-Index Cylinder connection (O_2) with Outlet for BS5682 Probe		500-A162/CE
	Pin-Index Cylinder connection (O_2) with Outlet for BS 5682 Probe and Variflow Outlet for O_2 Therapy & Supplemental Oxygen for ventilator		500-A162CE/Z43
	With Outlet for BS5682 Probe	DIN	500-A166
	and Oxygen cylinder connection	Bullnose	500-A166/Z2
Support Ramp			510A2372
User's Manual			504-2055/A
Valve, Patient			510A2667
Valve, PEEP (5 - 20 cm H_2O)			W1433
Fixed (60 cm H_2O) Relief Valve, (with audible alarm)			500A247CE-60
Wheel, Cylinder, Valve			500-A171/MRI
Bodoc Seal (pack of 3)			500-276/3
Service Manual - Level One			504-2042

SECTION 8: CLEANING and INSPECTION RECORD

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

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SECTION 9: TECHNICAL INFORMATION

(a) Principle of Operation

The principle of operation of the compPAC is illustrated by the circuit diagram in Fig. 10. The compressor (P1) draws ambient air through the NBC filter (Z6) and passes compressed air into the reservoir (Z7). This stores compressed air during the expiratory phase. The compressed gas is regulated to a nominal constant pressure of 207 kPa by the regulator (V4) before passing to the oscillator unit (V3). This generates the breathing cycles at a rate determined by the setting of the control knob (Z2).

The output from the oscillator supplies the nozzle of the entrainment mixing device (V8) by way of a series of needle valves which control the gas flow according to the setting of the minute volume knob (Z3). The entrainment mixing device draws atmospheric air via the filter (Z6), and a non return valve, to make up 66% of the air which is delivered to the casualty during the inspiratory phase.

A dump valve (V5) is provided to vent the patient during the expiratory phase. It is energised shut by the output of the oscillator during the inspiratory phase.

The relief valve (V7) protects the patient from excessive airway pressure by limiting the inspiratory pressure and gives an audible warning if gas loss occurs through the valve. There is an additional back up provided by a secondary relief valve (V6).

If compressed gas is available from an external source this can be fed into the primary oxygen supply (Z9). This will drive the system in the same way as the compressor.

If an external gas supply is connected, the applied pressure cuts off the electrical supply to the compressor by means of the pressure switch (S2). It also opens valve (V2) to enable the mixture control valve attached to switch (Z4). Therefore, if switch (Z4) is in the 100% O_2 position, 100% of the selected flow rate is fed from the needle valve through (V2) to the entrainment port of the entrainment mixing device (V8). If oxygen is used as the supply gas 100% oxygen flows to the patient. If the 45% O_2 mode is selected the 100% O2 flow from the needle valve is fed to the nozzle of entrainment mixing device which takes atmospheric air through the filter.

If oxygen is supplied to the supplementary oxygen connector (Z8) at a constant flow this supplements the air drawn through the filter and increases the inspired oxygen concentration in accordance settings shown on product label.

The supply gas pressure, either from the compressor or from an external supply is monitored by the gas supply indicator (Z5). This eyeball type indicator shows White when the supply pressure is sufficient to power the ventilator. The indicator starts to show red when the gas supply pressure falls below the minimum operating pressure

Whenever the compressor is switched on, the valve V9 opens for a brief period to ensure that the compressor starts under a no load condition. The valve closes again once the compressor has started and allows the compressor to pressurise the reservoir (Z7)

CompPAC Electronics Description

Key to parts: [to be used in conjunction with electronics functional diagram figure 10]

M1	Brushed 24 V D.C. Motor
V1	Water Dump Solenoid Valve (N/C)
V9	Compressor head pressure dump valve (N/C)
S1	Conditioned Pressure Transducer (5V output at 100psi)
S2	O_2 Pressure Switch (N/C)
S3	Reservoir 'Eyeball' Operated Pressure Switch (N/O)
S4	'Patient Pressure High' Pressure Switch (N/O)
S5	'Patient Pressure Low and Cycle' Pressure Switch (N/O)

LED Indicators:	Misc Features:
High Patient Pressure	Gas Failure
Disconnect Alarm	Silencing Button
Battery Low	Piezo Sounder
Patient Pressure Cycle	
Silencing	

Compressor Control System:

The compressor control system can only be activated when the Primary (external) Oxygen Supply is not present or has fallen to less than 24 psi.

The system comprises control electronics with a Motor (M1) directly coupled to a compressor (P1) that charges a reservoir used as the source of the patients' breathing gas supply. The reservoir pressure is monitored by an electronic 100 psi gauge Pressure Transducer (S1) that provides an analogue output signal for the control system feedback. The level of feedback is 'set' to maintain over 50 psi in the reservoir by controlling the motor's speed. This is accomplished by driving the motor with a variable pulse width modulated (pwm) signal that is proportional to the difference between the monitored pressure and the required 'set' level.

The reservoir monitored pressure is sampled by the control system in time with the breath given to the patient. As the breath is given, the reservoir pressure falls. When the breath stops, an electronic circuit detects this 'low' point in the reservoir and samples the pressure for comparison with the required 'set' level. Hence, the control system becomes synchronised with the pneumatic oscillator and relies on it during normal operation.

To prevent 'lockup' of the compressor, the motor is not turned ON until the pressure on compressor head is less than 15 psi provided by activation of valve (V9). Once started, it is not allowed to be reduced too low or turned OFF again until the unit is either powered down or the pressure in the reservoir exceeds 108 psi. If the pressure exceeds 108 psi a specific operation of the control system is initiated. This mode of operation turns the motor back ON when the reservoir pressure has fallen below 44 psi and OFF again when the pressure exceeds 108 psi.

To prevent any water build up in the reservoir, a solenoid valve (V1) has been provided to dump any water present to atmosphere. The valve is actuated by an electronic timer for approximately 100mS every 4 to 5 minutes. This 'dump' feature is not activated until the pressure in the reservoir has reached 40 psi and is disabled again if the pressure falls below 29 psi.

Disconnect Alarm:

The Disconnect Alarm is turned ON with the compressor control system. It is also automatically turned ON whenever the Primary (external) Oxygen Supply is present, regardless of the state of the front panel ON/OFF switch.

As the microprocessor based Disconnect Alarm supplements the primary pneumatic alarms and performs no control function, the equipment is safe to operate with or without the Disconnect Alarm. The pneumatic system provides visual indication of supply failure with the 'eyeball', patient system over-pressure with a pneumatic whistle. A low battery condition is indicated by low or slowing compressor speed, in addition to the audible electronic alarm.

Five LED indicators are located on the front panel bezel which provide the following functions:

High Patient Pressure
An alarm to show the patient pressure is higher than 60 cm H_2O or has NOT fallen back below the Cycle pressure switch level of 8 cm H_2O for over 10 seconds.

Disconnect Alarm
An alarm to show the patient pressure has not risen above the Cycle pressure switch level of 8 cm H_2O for over 10 seconds.

Battery Low

An alarm to show the battery voltage is failing. Prior to battery failure, this indicator will give a brief flash every 10 seconds when the battery voltage falls to about 21 Vdc to indicate impending failure. Below 20 Vdc a full alarm condition will be activated.

If the internal battery is not fitted when the unit is powered from an external source. The indicator will be turned ON permanently with no accompanying audio.

Note: Both the internal battery and any connected external supply must both fail for this alarm to operate.

Patient Pressure Cycle

An indicator to show the patient pressure is cycling. Every time the pressure rises above the Cycle pressure switch level of 8 cm H_2O, the indicator will give a brief flash.

Silencing

An indicator to show that the audio warning has been silenced.

Miscellaneous Features:

Gas Failure

An alarm to show that the reservoir gas supply has fallen below 24 psi. The Disconnect Alarm is automatically turned OFF after this alarm has continually operated for 60 seconds. Only the audio warning is provided by the Disconnect Alarm as visual indication is provided by the pneumatic 'eyeball'..rrence of certain alarms.

Piezo Sounder

All audio warnings are provided by a Piezo sounder and prioritised into High, Medium, Low and information patterns generally conforming to EN475.

Additional details on the Disconnect Alarm operation can be seen in Appendix C Alarm Parameters.

Power Supply:

Internal power is derived from a 24 Vdc 4 Ampere / Hour rechargeable Ni-Cad battery which nominally provides 2 hours use (according to settings and with a battery of normal capacity) when running the compressor. With an external gas supply, only the Disconnect Alarm is powered which extends battery life to potentially thousands of hours depending on how long alarms are left active.

The battery can be charged in-situ via the front panel external power connector using a Pneupac PS12 or PS11 charger. A 90% charge is provided in 4 hours with the remainder being 'topped up' over another 4 hours. After that, the charger provides a permanent trickle charge to maintain the battery while connected. The front panel power switch should be in the OFF (midway) position during charging.

An 'automotive' compatible supply can also be used to power the Disconnect Alarm and Compressor. This should have a nominal voltage of 24/28 Vdc.

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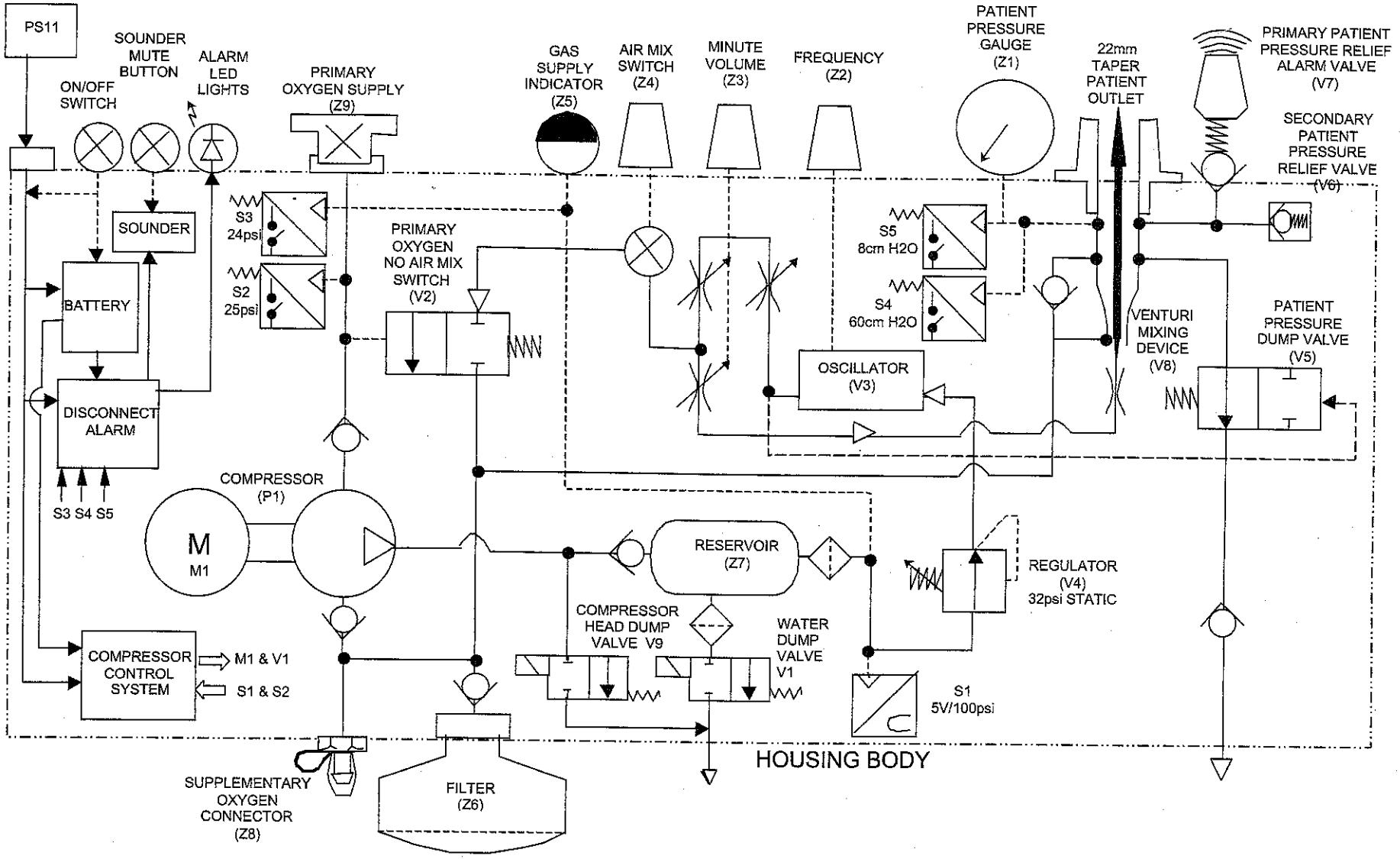

FIGURE 10: Diagram Showing compPAC Pneumatic and Electronic Circuit

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(b) Technical Data

Principle of operation: The ventilator is a time cycled, volume preset, pressure limited, flow generator. It operates increasingly as a pressure generator at lower Minute Volume settings with '45% O_2' selected.

Power Sources:	**(i) Gas:** Gas specific terminal outlet providing dry, oil free filtered gas (Oxygen or medical air) within the pressure range 305 to 600 kPa at 45 L/min (this ensures a min pressure of 280 kPa at the ventilator input port with allowance for supply hose pressure drop) **(ii) Internal Battery** NiCad rechargeable; NATO No. 6140-99-620-8057 Field exchangeable. Fitted with an 85°C internal thermal cut out . Weight: 3000g (6.6 lb.) **(iii) External Electrical:** External 23V-28 Vd.c. supply at 50W. When connecting an external supply ensure that contact 'A' is positive and contact 'B' is negative. A separate voltage converter is available to run from 12 Vd.c. If the ventilator is to be run from 240/115 V a.c. 50/60 Hz. the recommended Pneupac power supply must be used to ensure this unit complies with the requirements of IEC 601-1.
Frequency Range:	10 ±20% to 30 ±20% b/min (13 b/min at detent position)
Minute Volume Range:	4 ±20% to 14 ±20% L/min
Flow Range:	10 – 40 L/min
I:E Ratio (Fixed)	1:1.8 (nominal) ±20%
Relief Pressure (Fixed Valve)	60 x100Pa (60 cm H_2O *) +10% / -20% with audible alarm
Relief Pressure Range: (Adjustable Valve)	20-70 x100Pa (20 to 70 cm H_2O *) with audible alarm
Inflation Pressure Monitor	Indicates from –10 to +100 x100Pa (-10 to +100 cm H_2O *)
Exhalation Breathing Resistance	@ 60 L/min = <3.2 cm H_2O (0.314 kPa)
Inspiratory Breathing Resistance Under Power Failure	5.8cm H_2O @ 30 l/min.
Inspiratory Breathing Resistance under power failure	1.0 cm H_2O @ 30 L/min. 2.0 cm H_2O @ 50 L/min.
Air Mix:	0 or 70% air mix, selectable, providing 100% or 45% O_2 when using oxygen as gas source. Reduces gas consumption by 70% with oxygen or air as gas source.
Gas Consumption:	'100% O_2' – V_{DEL} plus 20 ml/cycle '45% O_2' – 30% V_{DEL} plus 20 ml/cycle
Output Connection:	22/15 mm co-axial taper with locking
Patient Circuit:	1.4 m long, 15mm single bore EPDM corrugated hose with autoclavable patient valve and 0.5 µm particulate filter. Weight: 454g.
Volume of Patient Circuit:	740 mL
Supply Gas, Input Connection:	Mini-Schrader male probe to BS 4272

Input Hose:	2.0 m long, 6mm bore with probe to BS 5682 (oxygen) as standard (alternatives available). Weight: 250g (0.55 lb.)
Dimensions:	350mm H x 210mm W x 210mm D
Weight:	Complete with NiCad Battery: 8½ kg (18.7 lb.)
Weight of Patient Valve:	50g (0.09 lb.)
Autoclaving Temperatures:	Patient Valve: +134°C
Noise Level:	Less than 65 dBA at 1 metre (greatest noise in line with NBC filter)
NBC Filter Connection:	Threaded in accordance with NATO Stanag 4155
Filter Connection:	Threaded in accordance with NATO Stanag 4155 Connector size is 40mm DIN NATO compatible threads.
Pressure Conversion:*	1 x100Pa = 1.02 cm H_2O (or 1 x100Pa = 1 cm H_2O –2%)
Environmental Resistance	
(a) Casing	Two-part epoxy painted aluminium. Labels screen-printed with epoxy ink.
(b) Operating temperature range:	-10°C to +40°C
(c) Storage temperature range:	-15°C to +50°C
(d) Humidity range:	20 – 95% RH
(e) Barometric Pressure range:	700 to 1100 mbar (700 mbar ≅ 3,000 metres altitude)
(f) Vibration and bump:	Conforms to EN 794 – 3.
(g) EMC:	The ventilator conforms to the electromagnetic compatibility requirements specified in EN 794-3 which invoke testing in accordance with EN 60601-1 but set a tighter specification for conformance.
Transport Environmental conditions	
(a) Temperature range:	- 40°C to +70°C
(b) Humidity range:	20% to 95% RH
(c) Barometric Pressure range:	700 to 100 mbar.
Patents:	This product is covered by the following patents UK 2,174,760B EP 0343818 EP 0342883
Filter, NBC Particulate:	Filter mounted externally. 0.5 µm breathing circuit filter with 22mm male conical connectors.
Electrical Protection	**There are no user serviceable parts inside (with the exception of the fuse in the battery connector)**
Safety:	The compPAC meets the requirements of EN 60601-1. It is designated 'internally powered' when run from its own battery. When powered from the PS12 or PS11 power supply it is run from a SELV (Safe Electrics Low Voltage) compliant source.
Fuses:	All fuses are self-resetting with the exception of the fuse in the battery connector.

Table showing Tidal Volume, Oxygen Concentration, Minute Volume and Flow performance with increasing Back Pressure on 'AIR MIX' Setting.

Frequency BPM	Minute Vol. (L)	Parameter	Typical measured value	% difference to typical measured value at zero back pressure					
			0 cmH_2O	5 cmH_2O	15 cmH_2O	20 cmH_2O	30 cmH_2O	40 cmH_2O	60 cmH_2O
10	14	Tidal volume	1.4 L	-1.43	-4.29	-5.71	-8.57	-11.43	-16.43
		Minute volume	16.2 L	-1.85	-4.94	-6.17	-8.64	-12.35	-18.52
		Flow	40.2 L/min	-1	-3.71	-4.98	-7.71	-10.45	-15.92
13	12	Tidal volume	0.94 L	-2.13	-6.38	-9.57	-12.77	-18.09	-30.85
		Minute volume	13.3 L	-1.50	-6.02	-7.52	-12.78	-17.29	-30.83
		Flow	33 L/min	-1.82	-6.36	-8.18	-11.82	-17.27	-30
20	9	Tidal volume	0.51 L	-3.92	-9.8	-13.73	-23.53	-35.29	-54.9
		Minute volume	10.6 L	-3.77	-10.38	-15.09	-24.53	-35.85	-54.72
		Flow	25.6 L/min	-2.73	-10.55	-14.84	-24.61	-34.77	-54.69
30	6	Tidal volume	0.26 L	-11.54	-30.77	-42.31	-61.54	-76.92	-76.92
		Minute volume	7.7 L	-10.39	-29.87	-41.56	-61.04	-75.32	-75.32
		Flow	17.2 L/min	-8.72	-31.98	-40.12	-62.21	-74.42	-74.42

Table of back pressure performance for oxygen concentration

Frequency BPM	Minute volume L	% Oxygen concentration to backpressure						
		0 cm H_2O	5 cm H_2O	15 cm H_2O	20 cm H_2O	30 cm H_2O	40 cm H_2O	60 cm H_2O
10	14	43.4	44.8	45.3	45.5	46.2	46.9	48.9
13	12	42.5	43.1	43.7	44	45.2	46.6	51.4
20	9	42.2	43.3	44	45.2	48	51.8	63.9
30	6	41	45	48.5	53	69.2	96	96

Table showing recommended minute volume and frequency settings for patient population

MV Setting	Frequency Setting	Patient Population
6	25 to 30	CHILD
6 to 9	20 to 25	SMALL ADULT
9 to 14	10 to 20	ADULT
10	13	CPR

Table showing approximate duration of a 'd' size (365 litre capacity) oxygen cylinder charged at 2000 psi

Ventilator Setting	AIR MIX or NO AIR MIX	Duration (Minutes)
6MV, 30 BPM	AIR MIX	125
6MV, 30 BPM	NO AIR MIX	55
12MV, 13 BPM	AIR MIX	101
12MV, 13 BPM	NO AIR MIX	30

NOTE: The gas cylinder should be changed as soon as the gas pressure indicator begins to show red, indicating low supply input pressure.

compPAC INPUT CONNECTIONS (See item#15 Figure 1)

Connects with Amphenol C16-1 Free Plug compPAC Input Connects with FCI Metalok Bantam Free Plug 6-way+PE plug PG9 with Solder Contacts 4-way housing + PG Hood + Tin Plated 0.75mm² Crimp Sockets (Pneupac W255-016 & RS 452-013) (FEC 105-335+105-588+105-490 = Pneupac W256-045/047/046)

Pin 1:	Battery Charge	+35V/1A	----------	Pin A:	Battery Charge
Pin 5:	Trickle Charge	+28V/0.15	----------	Pin C:	Trickle Charge
Pin 6:	Line Output	+28V/3A	----------	Pin D:	Resuscitator Power
Pin 7:	(PE) Common	0V	----------	Pin B:	Common (-ve)

(c) Accuracies

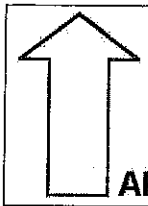
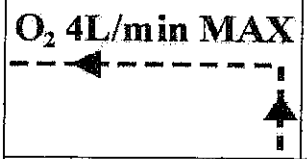
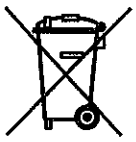
The accuracies to which the ventilation parameters of the compPAC ventilator are factory calibrated and how these are affected by operating and ambient conditions are tabulated in Appendix A.

(d) Terms and Definitions

Airway Resistance:	Pressure drop across airway per unit flow
CMV:	Controlled Mandatory Ventilation
CPR:	Cardiopulmonary Resuscitation. Comprehensive standards and guidelines for this procedure are given by the American Heart Association in the Journal of the American Medical Association (JAMA), 6th June 1986 Vol 255 No 21.
Expiratory Phase:	Interval from the start of expiratory flow to the start of inspiratory flow.
Expiratory Time (T_E):	Duration of the expiratory phase.
F_iO_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).
Inspiratory Flow: (v_{DEL})	The flow delivered to the patient by the ventilator during the inspiratory phase.
Inspiratory Phase:	Interval from the start of inspiratory flow to the start of expiratory flow.
Inspiratory Time (T_I):	Duration of the inspiratory phase.
JAMA	See CPR.
Lung Compliance:	Volume added per unit pressure increase when gas is added to a human or artificial lung.
Maximum Patient Inflation Pressure:	The maximum pressure that can be delivered by the ventilator to the patient.
Minute Volume (V_{DEL}):	Delivered Total Ventilation or the volume per minute of gas delivered through the patient connection port during the inspiratory phases.
Mouth Pressure:	The patient inflation 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).
Relief Valve:	Valve which limits the maximum patient inflation pressure by venting excess gas to the atmosphere.
Tidal Volume (V_{TDEL}):	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

	**Audio Silencing Indicator** This orange light flashes once every 3 seconds for 54 seconds of the 60 second 'silencing' period to indicate that the alarm is in its silenced state.
	**Cycle Indicator** This green light flashes once, for $1/10^{th}$ second, every time the patient inflation pressure rises through the pre-set threshold pressure of 10 x100Pa ($10cmH_2O$). This indicates normal operation.
	**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.
	**High inflation pressure alarm** The red light flashes at 2 times per second, after the high pressure relief valve has operated and whenever it is venting inflation gas to atmosphere. It is accompanied by both a pneumatically generated audible alarm, and, after 1 second or 3 successive cycles, a high priority electronically generated audible alarm. It gives the same alarm if a continuous positive pressure greater than 10x100Pa is detected for 10 seconds or more.
	**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. The pneumatic high pressure alarm and gas supply alarm visual indicator will however continue to function.
	The symbol designates a battery and the abbreviation 'Int' indicates that a downward movement of the switch switches the unit 'On' using the internal battery.
24/28 V dc	This designates external power source and indicates that an upward movement of the switch switches the unit 'On' using the external supply.
	**Gas Output Port Connector** The compPAC ventilator breathing system, supplied with the ventilator, is attached to this connector to transfer ventilating gas from the ventilator to the patient connector.
P_{aw}	Is the symbol for airway pressure. This symbol is placed adjacent to the manometer which displays this pressure
	**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.
$\dot{V}_{DEL}$	This symbol identifies the minute volume control knob and is the international symbol used to designate minute volume. The DEL suffix indicates that the calibrations refer to the volume delivered by the ventilator.
Freq.	This is an abbreviation for frequency and identifies the frequency control knob.

	This symbol indicates the ambient air intake point.
	This symbol indicates the auxiliary inlet to which a controlled oxygen 0-4 L/min flow may be supplied to increase the oxygen content of the delivered gas to between 21 and 45%.
 **IEC 601-1 Internally Powered Type B**	Type 'B' equipment defines the degree of electric shock in terms of allowable leakage currents.
	This symbol indicates the suggested setting for performing Cardiopulmonary Resuscitation (CPR).
	This symbol calls for the attention of the operator and advises that a knowledge of the accompanying documents is required.
	**DRIVING GAS INPUT** This symbol designates the connector to which compressed gas must be supplied to operate the compPAC as a gas powered ventilator. Gas entering this connector is delivered to the patient after its pressure energy has been used to power the ventilator.
	**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 2002/96/EC Waste Electrical and electronic Equipment, Smiths Medical 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.

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Appendix A

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Appendix A: Calibration accuracies and deviations due to change in ambient conditions

WARNING: Extreme environments may impair ventilator performance, operator vigilance is required to monitor the patient.

Factory calibrated to within +/- 15%

Parameter		Deviations due to changes in ambient conditions			
		Ambient temperature - 15°C	**Ambient temperature +50°C**	**Ambient pressure 700 mBar**	**Ambient pressure 1100 mBar**
Frequency	(NAM)	-14.5 %	No change	-19.3 %	+ 5.7%
	(AM)	-22 %	-15 %	-16.8 %	No change
Minute Volume	(NAM)	+2.4 %	-5.5 %	-15 %	+ 3.6%
	(AM)	-5%	-18 %	- 23 %	+ 3.2%
Relief Pressure		+4 (x100) Pa @ 60 (x 100) Pa	No change @ 60 (x 100) Pa	-1 (x100) Pa @ 60 (x 100) Pa	+1 (x100) Pa @ 60 (x 100) Pa
Oxygen concentration	(AM)	+3 O_2 % Points	No change	No change	No change

Note: Volumes are quoted as measured at local conditions referenced to STP conditions of 20°C and 1013 mBar. 35% RH.

AM - refers to Air Mix setting.

NAM - refers to No Air Mix setting

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Appendix B

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Appendix B: Nickel Cadmium Battery Management

The following guidance is given to aid customers in the care of their Nickel – Cadmium batteries. If these guidelines are followed, Pneupac Nickel – Cadmium batteries will give their best performance and have a long and useful life.

General treatment

- Protect the batteries from severe shock and vibration.
- Keep the batteries away from intense heat.
- Do not immerse batteries in water or expose them to driving rain, steam or high humidity.
- **Never** short circuit Nickel Cadmium Batteries. They are capable of delivering very large currents which could result in fire.

Maintenance

- Nickel Cadmium Batteries need little routine maintenance in normal use.
- If a battery should get wet, shake out any excess water and allow it to dry naturally in a warm, dry place. Do not attempt to use the battery until it has fully dried.

Charging

- Nickel Cadmium Batteries can be re-charged repeatedly, providing constantly restored power and long service; but as with all rechargeable batteries, they will eventually need to be replaced.
- Nickel Cadmium Batteries should only be charged using a constant current charger. This type of charger maintains the correct charging current irrespective of mains voltage and battery condition. Under no circumstances should a charger intended for lead-acid batteries be used. The uncontrolled current could cause permanent damage to the battery cells.

Disposal

- At the end of their useful life these Nickel Cadmium batteries should be disposed of in accordance with the requirements of Council Directive 91/157/EEC.
  They may be returned to Smiths Medical for disposal, but a charge will be levied for this service.

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Appendix C

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APPENDIX C: Table detailing operation of electronic alarms

compPAC Parameters	Priority	Audio Note 1	Visual Note 2	Duration	Mute Note 3	Silence 60 Sec	Comments
1. High Patient Pressure (Pat Pres > High Pres Sw) (& Mech adjust)	High Alarm Red Led	Y, after 1 sec. of alarm or 3 'blips consecutive'	High Pres led Flash 2 Hz Duty 30%	Indefinite Reset after 10 secs of no alarm	N/A	Y	If NOT the first 'power-on' auto silence period, the first instance of a 'new' High Priority alarm will terminate any current silencing underway.
2. High PEEP (Pat Pres > Cycle Pres Sw) (for 10 secs & Mech adjust)	High Alarm Red Led	Y	High Pres led Flash 2 Hz Duty 30%	Indefinite Reset when Pres < Cycle Sw	N/A	Y	If NOT the first 'power-on' auto silence period, the first instance of a 'new' High Priority alarm will terminate any current silencing underway.
3. Disconnect Alarm (Pat Pres < Cycle Pres Sw) (for 10 secs)	Medium Alarm Yel Led	Y	Disconnect led Flash 0.5 Hz Duty 22%	Indefinite Reset when Pres > Cycle Sw or High Prior Alm	N/A	Y	The alarm is disabled during the first 'power-on' auto silence period. An alarm also clears the High Pat Pres 'consecutive blip' counter.
4. Gas Failure (Gas supply < 24 psi)	Medium Alarm	Y, after delay of 2 to 3 secs	Pneumatic Eyeball Goes from white to red	60 Secs Unit is then automatically turned off	N/A	Y	The first instance of this alarm will terminate any current silencing underway. An alarm also clears the High Pat Pres 'consecutive blip' counter.
5. Microprocessor Failure (Watchdog 0.88 sec) (timeout)	Yel Led	N	Low Bat led Fast 1mS blip every second	Indefinite Reset when 5v supply > 4v35	N/A	N	This alarm is purely a function of the electronic watchdog and can not be altered. Indication changes as battery expires.
6. Battery Low Alarm (Battery < 19v9 for 5 secs)	Medium Alarm Yel Led	Y	Low Bat led Flash 0.5 Hz Duty 22%	Indefinite Reset when Battery > 22	N/A	Y	This will continue as the battery voltage decreases until there is a Microprocessor Failure
7. Battery Low Caution (Battery < 21v for 5 secs)	Info Indicator Yel Led	N	Low Bat led Short blip every 10 secs	Indefinite Reset when Battery > 23	N/A	N/A	This caution signal converts to a Battery Low Alarm as the battery voltage reduces
8. Internal Battery Missing (Internal Battery test floats) (Battery -Ve line to > 32V)	Info Indicator Yel Led	N	Low Bat led Turned on permanently	Indefinite Reset only after Battery fitted	N/A	N/A	This exclusively hardware test is only performed during the first several seconds of 'power-on' to show internal battery is not fitted.
9. Patient Pressure Cycling (Pat Pres rises past) (Cycle Pres Sw)	Info Indicator Grn Led	N	Cycle Pres led 111mS blip	Indefinite Blips while Pat Pres Cycling	N/A	N/A	Each 'blip' resets/initialises Disconnect Alarm
10. Silencing (Whenever Silence button) (pressed)	Info Indicator Amb Led	OFF For all audible indication	Silence led 111mS blip every 3 secs	60.5 secs Silence of audio indicator	N/A	N/A	Silencing can also be terminated by the first occurrence of certain alarms. Typically High Priority Alarms or Gas Failure

Note 1: The Standards for Medical Alarms, EN 475 and ISO 9703-3, specify a burst of audible alarm of 20 secs minimum period for Medium priority. The Pneupac devices repeat every 10 ecs, eventually reducing to 5 secs after a minute has occurred at 10 secs. The Requirements for the 'rise time' of the sound envelope may not be met. (Technicality)

Note 2: LED alarm flash periods and duty cycle are individually software programmable, so relatively easy to change if necessary.

Note 3: Mute function is only available on babyPAC's.