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HELIX ADULT - PAEDIATRIC PORTABLE VENTILATOR

Part Reference - HELIX VENT A/P

INSTRUCTIONS FOR USE MANUAL

For ventilation support in challenging environments

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CE 1639

UKCA 0120

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Read this page first.

INTENDED USE

This device is designed for, and suitable for, use in hospital settings with limited resources or in any field or outreach location and is suitable for adult and paediatric patients.
The Helix Adult Paediatric Portable Ventilator is not intended for use in The EU. It is suitable for use in dry non-condensing atmospheres and should be kept free of surface liquid.

The HELIX ADULT - PAEDIATRIC PORTABLE VENTILATOR provides effective and efficient ventilation in difficult environments. It can be used as standalone equipment or in conjunction with Diamedica's Portable Anaesthesia systems to facilitate the administration of inhalational anaesthesia and respiratory support in difficult environments, humanitarian emergency situations and low resource settings.

FOREWORD

This manual is intended to provide guidance on the function, performance, and user maintenance of the Diamedica Helix Adult-Paediatric Portable Ventilator (HAPPV). The information given in this manual is correct at the date of publication.

The policy of Diamedica (UK) Ltd is to continuously improve its products. Changes may be made to this manual without notice being given.

Users of the Diamedica Helix Adult-Paediatric Portable Ventilator must read, understand, and follow the guidance given in this manual before using the system.

THE NEED FOR PATIENT MONITORING

WARNING

The Diamedica Helix Adult-Paediatric Portable Ventilator delivers mixtures of gases to the patient and the patient should be monitored at all times.

Do not operate at altitudes above 2000M
Ensure unit is suitably situated on a level surface free from standing and dripping liquid.
Unit is not suitable for transport ventilation.

Do not cover the ventilator or place in a position that affects proper operation e.g., do not obstruct air inlet

Do not add any attachments or accessories to the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of a serious deterioration of health of the patient.

The only relative contraindication is if non-invasive ventilation is available, and its use is expected to resolve the need for mechanical ventilation. This should be started first as it has fewer complications than mechanical ventilation.

Pressure readings indicated on the gauge on top of the Helix screw indicate the pressure inside the

bellows at the point of delivery. Downstream pressures at the patient interface may be less than this due to length and elasticity of the circuit.
It is essential that the patient's respiration and other vital functions are also monitored.

The ultimate responsibility for patient safety remains with the operator, who should always have a secondary means of maintaining ventilation.

Do not initiate use if the green power light is flashing (Battery life less than 2 hours). Connect unit to power source to recharge.

Mains power supply isolation: Disconnect the mains supply cable from the socket (see Section 4).

The Helix Adult Paediatric Portable Ventilator does not include patient monitoring for ETCO2 FIO2, Patient airway pressure, expired volume, or PEEP. It is the responsibility of the clinician in charge to ensure suitable monitoring is in place for the patient and procedure being performed and in the environment in which it is being completed. Scales for Tidal volume, BPM and pressure are for indication (+/-10%) of delivery from the ventilator.

Observations of the patient must take precedence over machine settings in judging the condition of the patient.

The Diamedica Helix Adult-Paediatric Ventilator utilizes atmospheric air within the delivered mixture to the patient. It is therefore recommended, particularly in areas at risk of atmospheric contamination, that a single use bacteria filter is used within the patient circuit. HME and breathing system filters should be medically compliant with recognized standards for use within the region of operation.

The ventilator has a breathable casing and must be kept dry and free from standing moisture (IP20) When not in use, ensure unit is stored in a manner free from dripping liquids.

This User Manual must be stored near the product, protected from anything, which could compromise its integrity and legibility.

NO MODIFICATION OF THIS EQUIPMENT IS PERMITTED.

The ventilator is only intended to be used by qualified medical personnel

Classification and Electromagnetic Conformity

Classifications

The Helix Adult Paediatric Portable Ventilator has the following classifications (EN 60601-1:2006 +A12:2014

Protection against shock.

When connected to a mains AC source via the supplied lead for charging, the ventilator is Class II ME Equipment.

When not connected to a mains supply it is considered as Internally Powered ME Equipment.

Protection against harmful ingress of water or particulate matter

IP20

Method(s) of sterilization

The Helix Adult Paediatric Portable Ventilator is a non-sterile device and is not intended to be sterilized by the user.

Suitability for use in an OXYGEN RICH ENVIRONMENT

Intended for use in an Oxygen rich environment

Mode of operation

The Helix Adult Paediatric Portable Ventilator is suitable for continuous operation subject to a power supply for recharging and drive gas supply.

Electromagnetic conformity

The Helix Adult / Paediatric Portable Ventilator is a 12V portable device that complies with the requirements of the 93/42/EEC European directive and has been assessed against the applicable requirements of EN 60601-1-2:2015

Standard	Description	Outcome
BS EN 55011:2009+A1	Radiated Emissions Class B	Pass
EN 61000-4-2:2009	Electrostatic Discharge (UKAS)	Pass
EN 61000-4-3:2006 + A2	Radiated RF Immunity Table 9 (UKAS)	Pass

Whilst every precaution has been taken to prevent the effect on or effect from other devices the following precautions should be adhered to ensure continued normal operation.

Always ensure that the device is used in accordance with the Instructions for Use.

Use of this equipment adjacent to or stacked with other equipment should be avoided. If such use cannot be avoided, both items should be observed to verify that they are operating normally.

Only use the charger lead supplied.

The implementation of accessories or spares, other than those specified, provided, or

advised by the manufacturer of this equipment should not be used. Failure to follow this could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

If this equipment is found to cause interference or be affected by interference from other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate either device to Increase the separation between the

equipment. If the unit is charged disconnect from the power supply and remove

power lead.

Do not leave the charger connected to the battery for long periods after the battery is fully charged and the unit is not in use.
Consult the manufacturer for help when required.

DIAMEDICA HELIX ADULT - PAEDIATRIC PORTABLE VENTILATOR

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1. INTRODUCTION

DIAMEDICA HELIX ADULT - PAEDIATRIC PORTABLE VENTILATOR

This is a time cycled, volume limited pressure generator. Delivered pressure is limited via a pressure regulator. It is a gas driven ventilator and can therefore function largely independently of the supply of electricity. There is however a small battery in the base of the ventilator which is required to power the electronic circuitry. **This battery should be kept fully charged by keeping the ventilator connected to the mains supply when available.**

The ventilator bellows section consists of a set of bellows and a helix screw above the bellows that is used to control the tidal volume adjustment.

A drive piston is mounted below the bellows and is driven upwards by the driving gas. This piston pushes the top of the bellows upwards causing the bellows to expand and fill with the gas mixture (carrier air and supplementary oxygen). When the control solenoid switches the gas flow, the piston is driven downwards, collapsing the bellows. A valve directs the gas mixture towards the patient.

2. SPECIFICATIONS

The Diamedica HAPPV is suitable for adult and paediatric use. The specifications for HAPPV are provided in the table below. Helix Adult-Paediatric Portable Ventilator specifications

Feature		Specification
Height		40 cm (Helix Screw closed) 48 cm (Helix Screw Open)
Diameter		26 cm (Inclusive of valve)
Weight		9.1 kg (Unpacked weight inclusive of circuit)
Tidal Volume **		100 – 1200ml
Inspiratory/Expiratory Ratio		1:2
Inspiratory pressure range **		8 – 50cm H_2O
Triggered breathing control **		1 – 5cm
Breaths per minute **		6 - 40
Alarms		High Pressure >60cmH_2O (LED/Audible) Low pressure / Disconnect <2cmH_2O (LED/Audible) Low Battery life <2 hours (Flashing Green LED) Battery failure (Flashing Green LED / Intermittent audible)
Pressure relief		>66cmH_2O
Drive pressure/volume		> 20psi /<75psi @ >5l/min
PEEP; circuit dependant		0 – 20 cm H_2O
Power Supply		12volt Lithium battery (Rechargeable from mains power A/C or vehicle D/C)
Internal rechargeable battery		>100 hours
Ingress protection (IP)		IP20 Protected from touch by fingers and objects greater than 12 millimeters. No protection against ingress of liquid
Electrical Safety classification		⧈ Class II Equipment, double insulated (When connected to power via PSU) Internally powered when not connected to mains
Operating Environment	Temperature Humidity Altitude	5 - 40° C 35% - 90% RH 79 – 106 kpa
Storage Environment	Temperature Humidity Altitude	-10 - +45° C 15% - 93% RH 79 – 106 kpa
Maximum operational altitude		< 2000m

The gas flow and volume specifications are represented as STAP it should be noted that the use of alternative patient circuitry and extreme atmospheric conditions can have an effect on the delivered values.

** Control scales are indicative. Delivered condition accurate within +/-10%

3. CLEANING, GENERAL MAINTENANCE AND DISPOSAL

Ventilator usage should be clearly logged and recorded to assist maintenance and cleaning activities. This can be done in a format suitable to the user or in a format as shown below.

Date	Task ① Patient use ② Maintenance ③ Cleaning	Time on	Time off	Comments

Suggested usage log for Helix adult-paediatric portable ventilator

a) **Cleaning**

The ventilator should be cleaned daily by wiping down with a damp cloth**. Ensure unit is dry free from moisture after wiping**

Patient safety is the primary concern of the Clinician, and infection control is critical to ensuring the safety of medical procedures. Appropriate cleaning and disinfection is essential after each patient's usage. The Helix Ventilator is supplied with a breathing circuit that, subject to usage and inspection, may be cleaned and reused. It is recommended that a bacteria filter is always used between the circuit and the patient to minimize contamination. If no bacteria filter is used, then the entire circuit should be cleaned and disinfected where possible or replaced if deemed necessary by the clinician. This should be evaluated after each patient or after any contamination event involving the breakdown of the completed circuit. Refer to table below.

Component	Image	cleaning requirements	Frequency	Comments
		Disassemble and Autoclave 134° - 137°C for 3 mins. Or Wash in bleach solution, thoroughly rinse and dry in line with hospital's infection control procedures	After each patient.	Examine for damage, replace if necessary. Reassemble and test function

Patient limb		Silicone reusable circuit is autoclavable up to 134℃. Or Wash in bleach solution, rinse and dry in line with hospital's infection control procedures	Weekly if patient filters are used or as per hospitals infection control guidance and procedures	Examine for damage, replace if necessary.
Self-inflating bag		Wash in bleach solution, rinse and dry in line with hospital's infection control procedures	Weekly if patient filters are used or as per hospitals infection control guidance and procedures	Examine for damage, replace if necessary. Ensure function on reassembly
Limb to self-inflating bag		Silicone reusable circuit is autoclavable up to 134℃. Or Wash in bleach solution, rinse and dry in line with hospital's infection control procedures	Weekly if patient filters are used or as per hospitals infection control guidance and procedures	Examine for damage, replace if necessary.
Ventilator outlet block and Patient circuit inlet valve		Wash in bleach solution, rinse and dry in line with hospital's infection control procedures	Weekly if patient filters are used or as per hospitals infection control guidance and procedures	Examine for damage, replace if necessary. Ensure function on reassembly

Any bacteria filters and other single-use items provided should be discarded after one use since they are not designed to be reprocessed.

If the Clinician has any concerns relating to cleaning or maintenance or the function of the Ventilator, they should contact the manufacturer.

b) **Maintenance**

The Helix Ventilator is designed to require minimal maintenance.

Patient circuit components should be inspected after each use and cleaning operation to ensure their integrity. If any degradation of a component is observed, then it should be replaced. It is recommended that at least one full set of patient circuit components is available to eliminate the need for any downtime of the ventilator.

WARNING

The patient circuit tubing is Non-conducting (Applied Part). DO NOT replace with conducting/anti-static tubing.

A full list of spares is available by contacting Diamedica – support@diamedica.co.uk

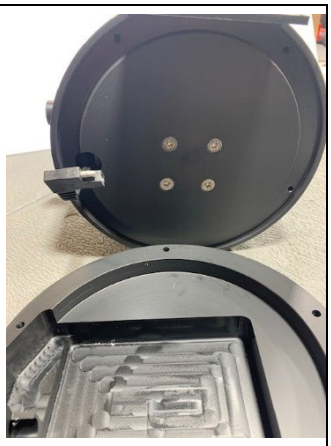
Replacement of Lithium Battery.

In the event that a new battery is required, this must be done by a suitably competent service technician.

The battery is a 'Tracer' 12V 4ah Lithium Polymer Battery. This is available by contacting Diamedica – support@diamedica.co.uk

To remove the ventilator battery.

a) Lay the ventilator on its back with the panel facing up. Unscrew the 2 screws at the bottom of the panel.	
b) Remove the 5 screws that secure the base.	
c) Carefully part the base from the body taking care not to put to pull on the battery connection lead	

d) Remove the battery from the base and disconnect the lead	 
e) Connect the new battery. **Type - 'Tracer' 12V 4ah Lithium Polymer Battery Ref No. BP2541 When replacing the battery ensure the battery orientation is correct and that the charging point is aligned with the hole in the base. ** available by contacting Diamedica support@diamedica.co.uk	 
f) Carefully replace base back onto body section, ensuring that cable does not become trapped when doing so. Re-attach base (5 screws) and front panel (2 screws) **CHARGE BATTERY FULLY BEFORE USING**	

Replacement of control board fuse.
If it is identified that the onboard fuse protection for the control board has blown then please contact Diamedica

✉ Email: support@diamedica.co.uk
WhatsApp: +44 (0) 7716 503156

The Fuse must be replaced by a technician under guidance from Diamedica – Replacing the fuse with an incorrect type may lead to malfunction, fire, and or injury.

Non serviceable components.
The PC Control board and loom contained within the unit are non-serviceable please contact Diamedica for any enquiries relating to these components – support@diamedica.co.uk

c) **Accessories and spares**

All accessories used with the Helix Ventilator must:

- Be oxygen compatible,
- Be biocompatible,
- Comply with the general requirements of the 93/42/EEC European Directive

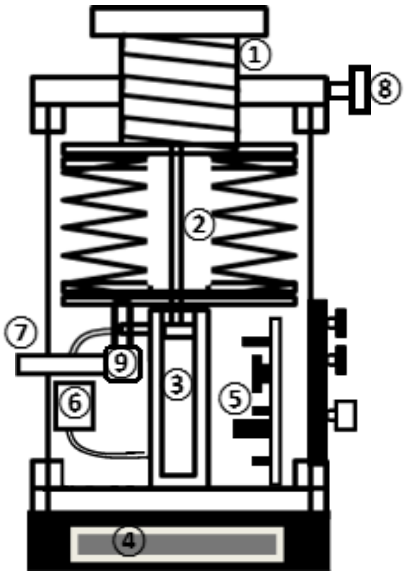
A full list of available spares is available by contacting Diamedica – support@diamedica.co.uk

d) **Method for disposing of the device**

If the product is returned to the manufacturer at the end of its life the company will ensure disposal in line with the Waste Electrical and Electronic Equipment Directive (WEEE) 2012/19/EU

4. COMPONENT PARTS OF THE VENTILATOR

Diagram of the ventilator showing major components



1. Helix screw
2. Bellows
3. Pneumatic piston
4. Battery
5. Electronics board
6. Solenoid valve
7. Patient circuit connection
8. Tidal volume lock
9. Pressure relief valve

The Power supply / Charging lead.

The Helix Ventilator is supplied with a Medically certified charging lead. This lead must be kept safe with the unit at all times. Please refer to the Leads IFU for details on safety and information regarding charging status information.

General Input / Output

Input voltage:	100-240 VAC
Line Frequency:	50 – 60Hz
Output	12.6 VDC
Temperature range	
• Operating:	+5 °C - +40 °C
• Storage:	-25 °C - +85 °C

In the event that the supplied charging lead becomes lost or damaged DO NOT substitute with an alternative, contact Diamedica – support@diamedica.co.uk / WhatsApp +44 (0) 7716 503156

The Control Panel.

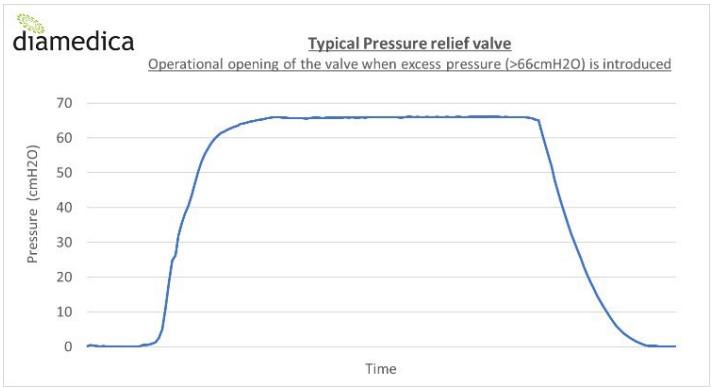
This contains the following features from left to right:

- On /off power switch with illuminated `power on` indicator above.
- Trigger level control (top).
- Respiratory rate control (centre).
- Patient pressure control (bottom).

Down the right-hand side:

- Alarm Mute (top)
- High pressure warning light, this is illuminated if the airway pressure exceeds 60 cm H_2O (middle)
- Low pressure warning light (bottom), this is illuminated if the airway pressure fails to reach 3 cm H_2O during IPPV. After twenty seconds this is accompanied by an audible warning.

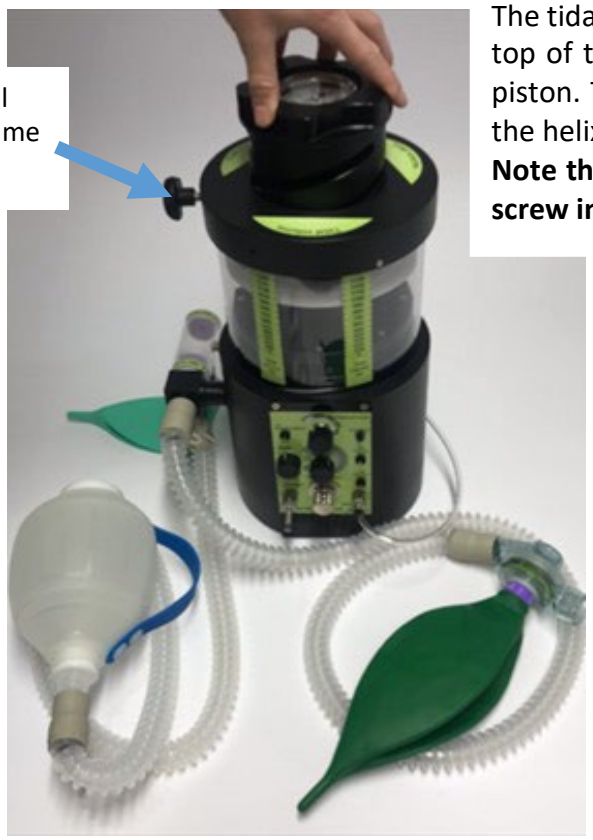
At the bottom of the panel there are the drive gas connections and return (recycled O_2).



Patient circuit protection.
Relief valve characteristics

The circuit may contain pressure up to 66 cmH2O (This will be under alarm conditions at greater than 60cmH2O) After which point the relief valve will crack and vent.

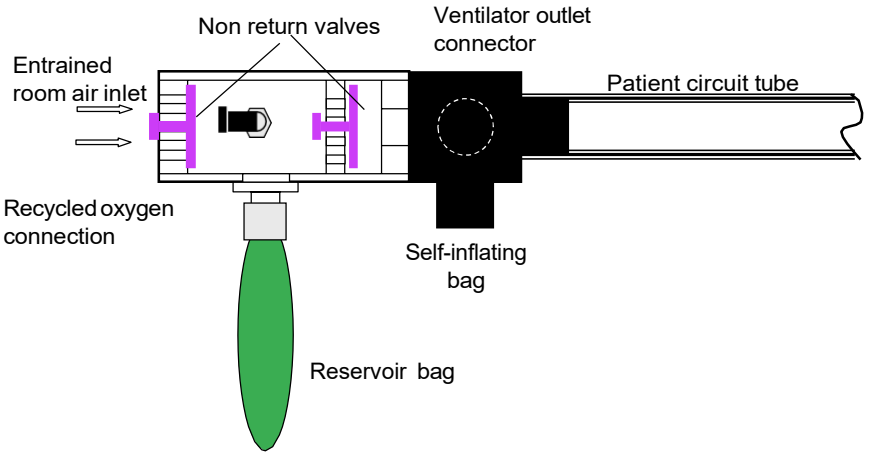
Diamedica Helix Portable Ventilator Tidal Volume Control



The tidal volume is adjusted by turning the helix screw on top of the bellows, restricting the movement of the drive piston. The set tidal volume limit is read at the bottom of the helix screw in the position indicated by the arrow. **Note the tidal volume lock must be used to lock the screw in the set position after each adjustment.**

The gauge showing the delivered patient pressure is set into the top of the ventilator helix control screw.

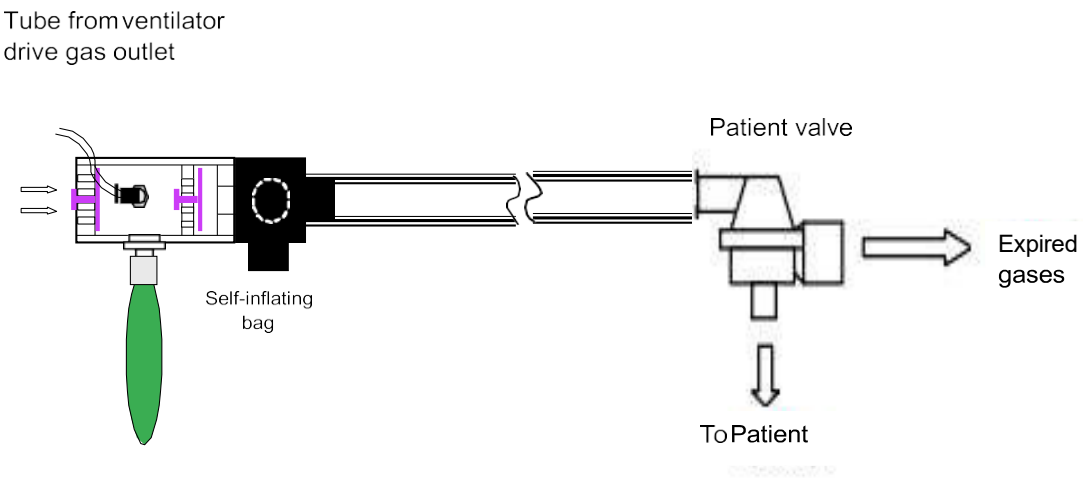
The Patient Circuit and Outlet Block



Recycled Drive Gas Connection

The recycled drive gas connection tube is connected between the recycled O_2 port on the control panel and the ventilator outlet block.

Patient Circuit

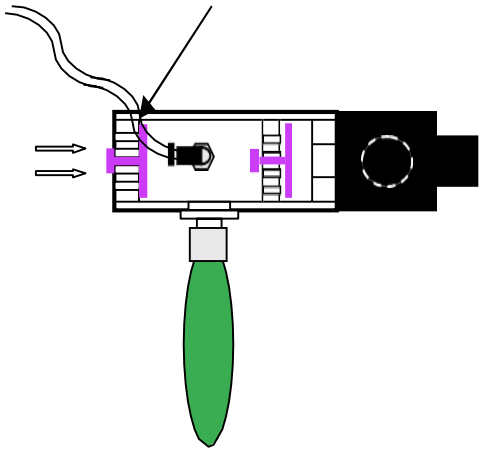


The ventilator has been designed to minimize the volume of driving gas required. This is possible because the piston diameter is much smaller than the bellows.

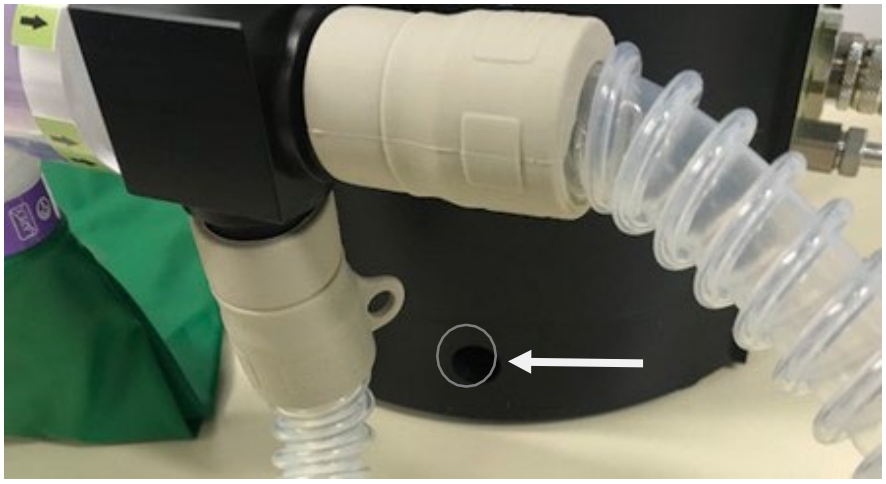
The volume of driving gas required is less than 1/4 of the tidal volume set for the patient. If the drive gas is oxygen this can then be recovered and put back into the patient circuit, increasing the FiO_2 to approximately 40%.

If higher oxygen concentrations are required, additional oxygen can be added by removing the recycled drive gas connection identified below and applying a separate oxygen source to the tube marked below. **Note: Do not over inflate the green reservoir bag – Risk of barotrauma.**

Refer to section 7. USE OF SUPLEMENTARY OXYGEN.

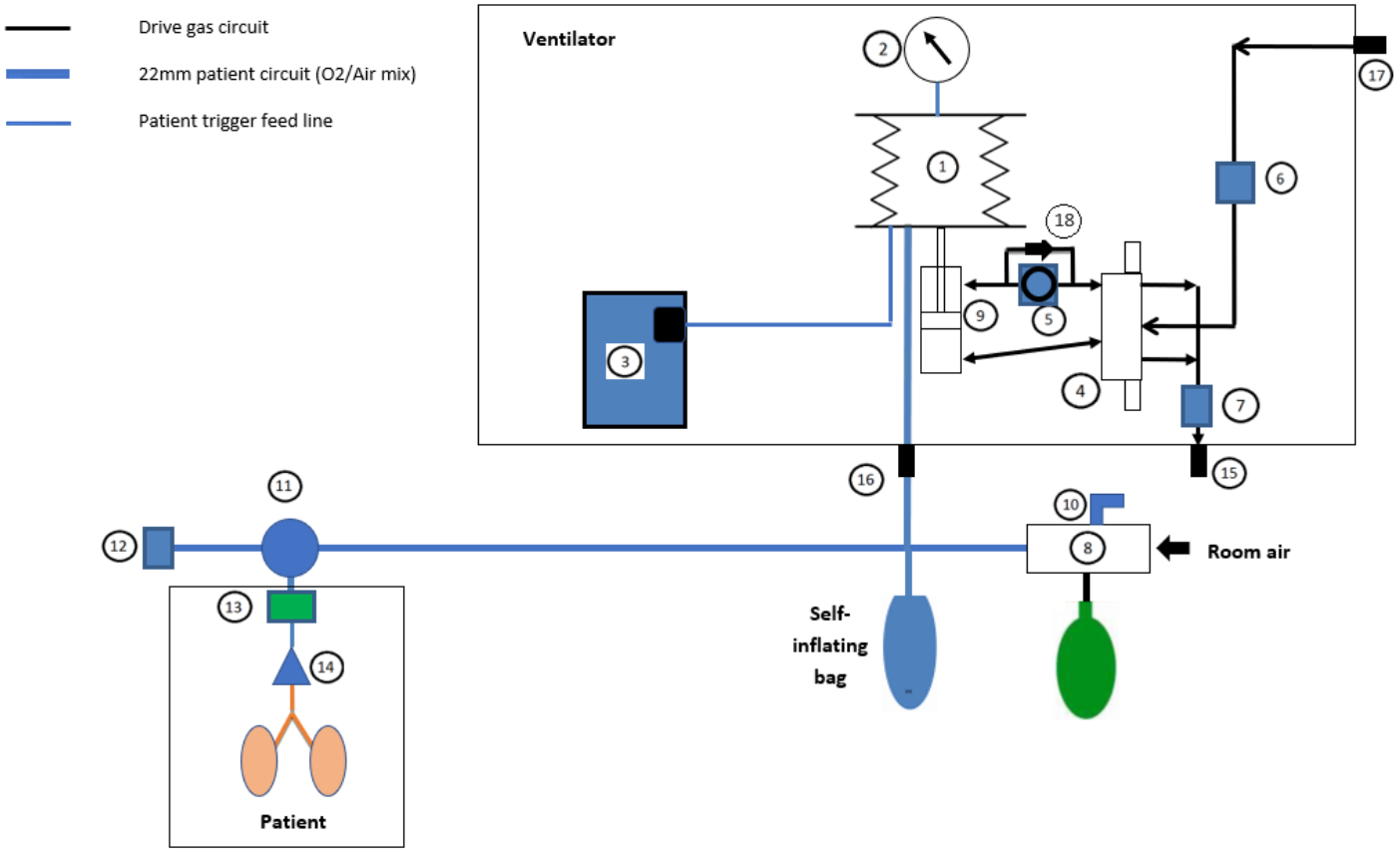


The Battery Recharge Socket



The battery recharge socket is marked above. The charger should be connected whenever power is available. When fully charged the battery should operate for more than 100 hours.

Pneumatics and gas circuit



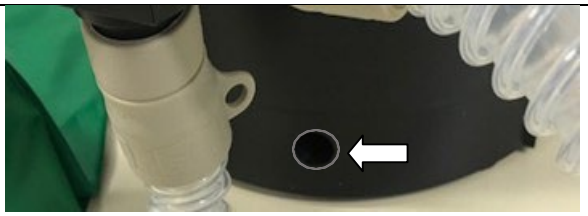
Key

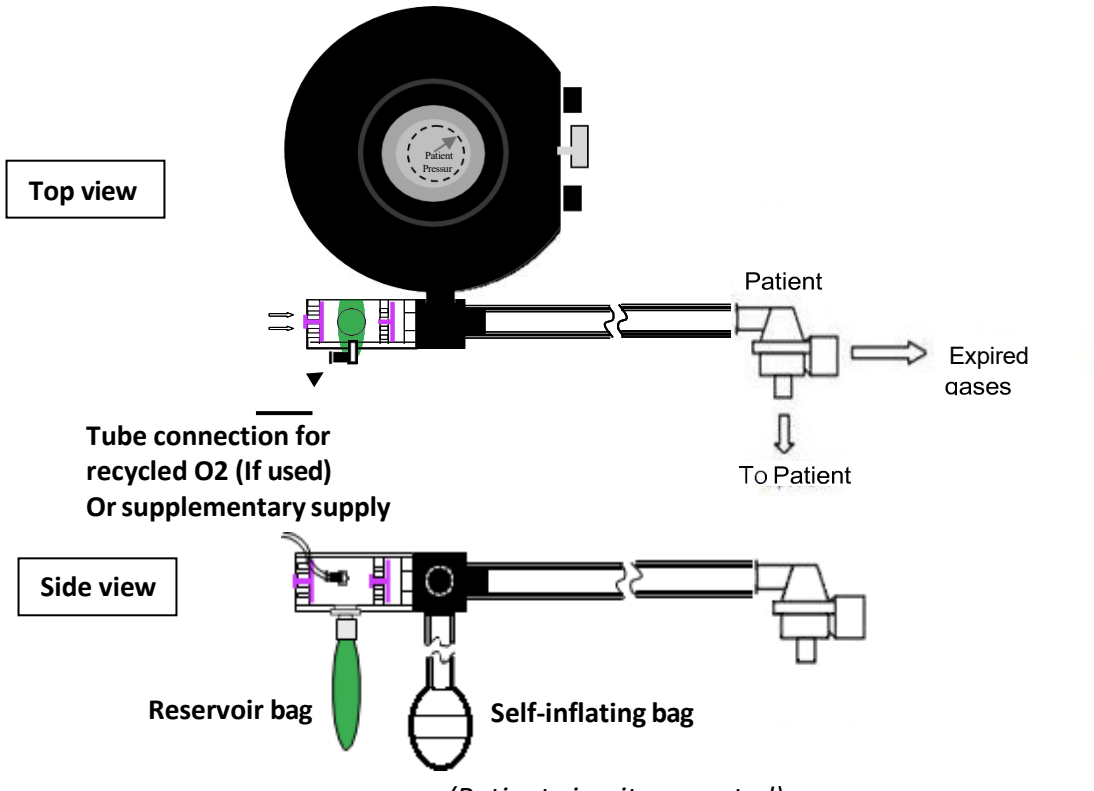
1. Bellows.
2. Pressure gauge.
3. Printed Circuit Board.
4. Solenoid valve.
5. Patient pressure controller.
6. Pressure regulator.
7. Flow regulator.
8. Inspiratory valve.
9. Piston.
10. Supplemental Oxygen inlet.
11. Laerdal valve.
12. Peep valve.
13. HME filter (Not supplied with Ventilator).
14. Patient interface (Mask / Tube).
15. Drive gas outlet (If O2 is used this can be connected to supplemental input to increase FIO2 to 40% approx.)
16. Patient circuit connection block.
17. Drive gas input.
18. One-way Valve

5. USE OF THE VENTILATOR

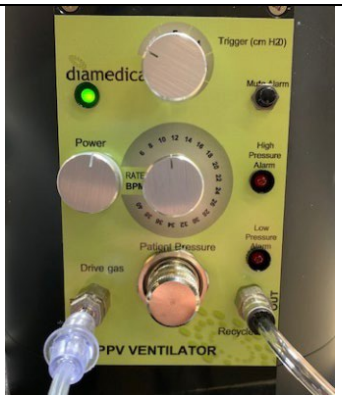
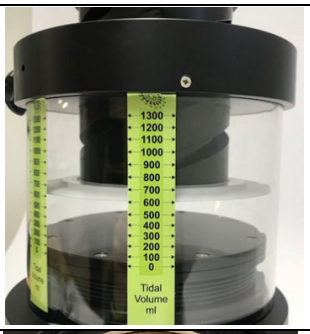
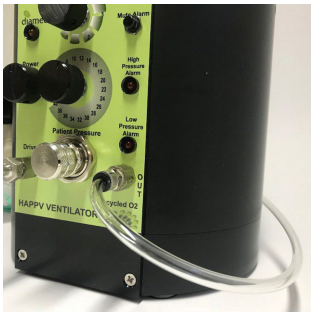
A. SET UP AND TEST

Set the ventilator on a flat surface and connect the gas source from an oxygen concentrator (nominal recommended pressure 1.5bar - 20psi) or (regulated oxygen cylinder 4bar-60psi).

① Connect the battery charger to the ventilator, plug into the mains power.	
② Connect the patient circuit tube to the end connection on the patient circuit block. ③ Connect the self-inflating bag limb to the lower connection on the patient circuit block. ④ Attach the patient valve to the end of the patient circuit limb. ⑤ Affix the reservoir bag to the underside of the inspiratory valve. ⑥ If using O2 as the drive gas the connection tube can be connected from the recycled gas connection on the front right of the ventilator to the connector on the clear section of the patient circuit block.	



(Patient circuit connected)

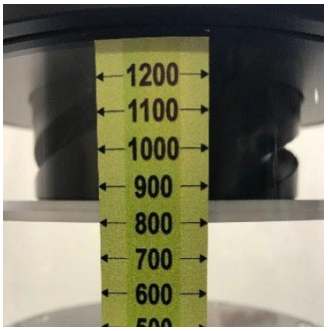
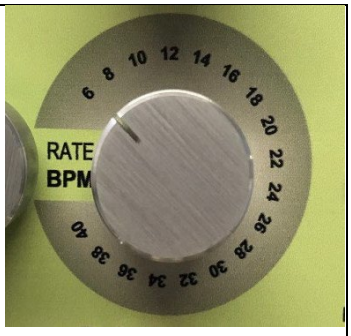
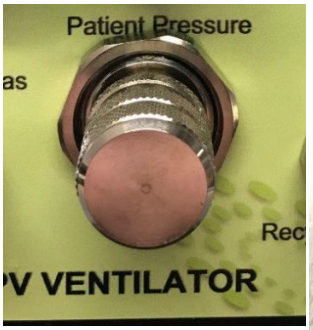
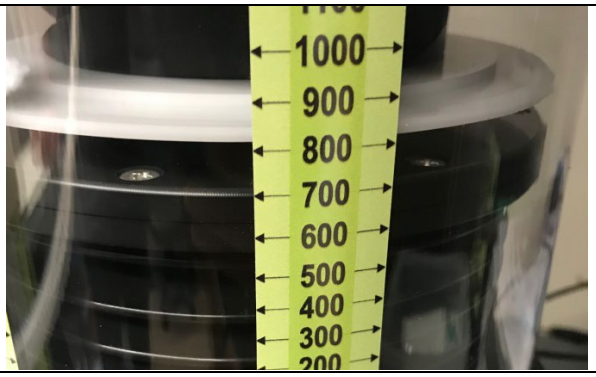
⑦Set the breaths per minute to 10-12 (BPM) and ensure the 'Trigger' control is off.	
⑧ Set the tidal volume screw to 600ml and switch on the ventilator. <u>Observe</u> Ensure bellows move freely through this range and that the gas is delivered correctly through the patient valve and that there are no obstructions.	 
⑨ Occlude the patient connection on the patient valve (Laerdal valve) and observe the pressure gauge on the top of the ventilator. Adjust the silver patient pressure control on the front of the ventilator anti-clockwise until the inspiratory pressure reaches 25cmH2O.	 
⑩ Connect a 1 litre reservoir bag to the patient valve as a test lung and ensure the bag inflates. Initially the 'Low Pressure' warning light will illuminate, and an audible alarm may be heard. When there is pressure in the test lung the 'Low Pressure' warning light should go out.	
⑪ If utilizing recycled oxygen, ensure that O2 tube is connected from the recycle port to the inlet connection on the Patient (Inspiratory) Circuit Valve (PCV)	 

Refer to section 6 for Alarms testing.

The ventilator is now ready to use. Reset the parameters to the appropriate settings for the next patient.

B. PERIODIC (Monthly) CIRCUIT INTEGRITY CHECK

The following check should be made once a month to ensure integrity of the internal gas lines. The completion and result of this test should be recorded on the usage log (Refer to section 3)

Set the ventilator to. ❶ 800 tidal volume ❷ 6 BPM	 
❸ Wind the pressure valve in (clockwise) fully and then back (anti-clockwise) 2 turns. ❹ Remove the inspiratory valve from the side of the ventilator	 
❺ When the bellows have completed the up cycle, occlude the outlet completely	 
❻ On the down cycle check the bellows do not fall below 500 tidal volume.	

C. USE OF THE HELIX VENTILATOR IN ADULTS

VENTILATOR SET-UP

Set the ventilator on a flat surface adjacent to the patient and ensure the following.

The unit is placed within the reach length of the patient circuit but not within the patients arm length to the ventilator.

The unit is within easy connection length of the drive gas source.

If the unit is connected to the mains power via the PSU. ensure that it is easy to access should the device need to be disconnected.

Connect the gas source from an oxygen concentrator (nominal recommended pressure 1.5bar - 20psi) or (regulated oxygen cylinder 4bar-60psi).

Connect the battery charger to the ventilator, plug into the mains power.

Connect the patient circuit block and the circuit tube and patient valve (Laerdal valve). Connect the outlet gas connection tube from the recycled gas connection on the front right of the ventilator to the connector on the clear section of the patient circuit block.

Set the breaths per minute to 10-12 (BPM) and ensure the 'Trigger' control is off. Set the tidal volume screw to 600ml, switch on the ventilator, occlude the patient connection on the patient valve (Laerdal valve) and observe the pressure gauge on the top of the ventilator. Adjust the silver patient pressure control knob on the front of the ventilator until the inspiratory pressure reaches 25cmH_2O.

Connect a 1 litre reservoir bag to the patient valve as a test lung and ensure the bag inflates. Initially the 'Low Pressure' warning light will illuminate, and an audible alarm may be heard. When there is pressure in the test lung the 'Low Pressure' warning light should go out.

The ventilator is now ready to use. Reset the parameters to the appropriate settings for the next patient.

MONITORING RESPIRATION

If gas analysis and oximetry are not available, monitoring of respiration depends on good clinical observation of the patient and breathing system.

In ventilated patients a minute volume of 70-90ml/kg (approximately 6 litres/min in a 70 kg patient) is generally satisfactory to maintain normocarbia. This can usually be achieved by setting the tidal volume to 600 ml, the respiratory rate to 10 breaths per minute and the ventilator pressure to 25cmH_2O. If the bellows of the ventilator do not completely empty at this pressure it may mean that the compliance of the lungs is reduced (the lungs are stiff) and the pressure may need increasing.

Always check the patient – a rise in inflation pressure may also indicate bronchospasm, anaphylaxis, fluid overload, bronchial intubation. Seek and treat the cause first, do not immediately turn the ventilation pressure up.

D. USE OF THE HELIX VENTILATOR IN PAEDIATRICS

For use in paediatric patients above 10kg the circuit and valve are still suitable. Following the set-up instructions above the parameters need to be set to the appropriate levels for the size, weight and requirements of the patient based on the clinical judgement of the qualified clinician.

E. INSPIRED OXYGEN CONCENTRATION

When using oxygen as a drive gas with the recycling connection attached and room air (containing 21% oxygen) as the carrier gas, the resulting concentration of oxygen will be approximately 40%-50% depending on the patient's minute volume.

If alternative greater levels of supplementary oxygen are added, concentrations can reach 95%. Ensure that the reservoir bag is not overextended with excessive flows as this could lead to a **risk of barotrauma.**

F. LONG TERM VENTILATION

The ventilator has been designed to work either with a suitable anaesthetic machine or it can function as a ventilator in a recovery room or intensive care unit for longer term ventilation. No adaptation is required for long term ventilation.

To assist with weaning a patient from long term respiratory support a triggering mechanism can be activated by a manual control located on the front of the ventilator. This indicates the inspiratory effort required to initiate compression of the bellows and effectively provides some respiratory support.

Positive end expiratory pressure (PEEP) is occasionally required in some forms of lung dysfunction, and this can be applied by attaching a PEEP valve to the (30mm) expiratory limb of the patient valve.

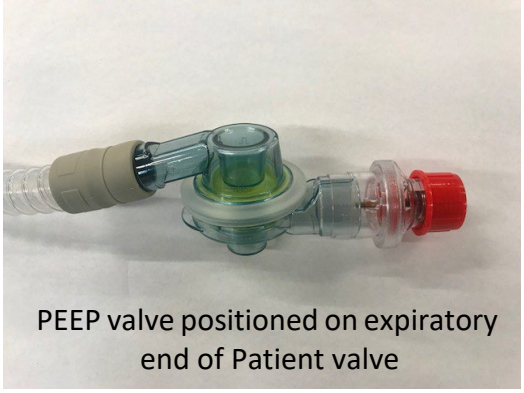
G. AFTER USE

At the conclusion of the session:

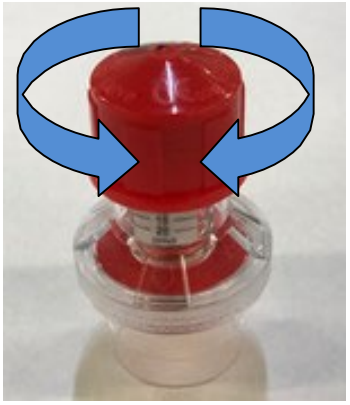
1. Turn off the concentrator or
2. Turn off the oxygen cylinder
3. Ensure that the mains electricity supply is connected so that the battery is kept fully charged.
4. Remove the patient circuit valves and tubing, and clean as per details in section 3.

H. USE OF PEEP (POSITIVE END EXPIRATORY PRESSURE)

The PEEP valve can be fitted to the expiratory end of the patient valve as shown in the picture below



PEEP valve positioned on expiratory end of Patient valve



To adjust the level of PEEP, turn the cap clockwise to increase and turn anti clockwise to reduce.

6. Alarms

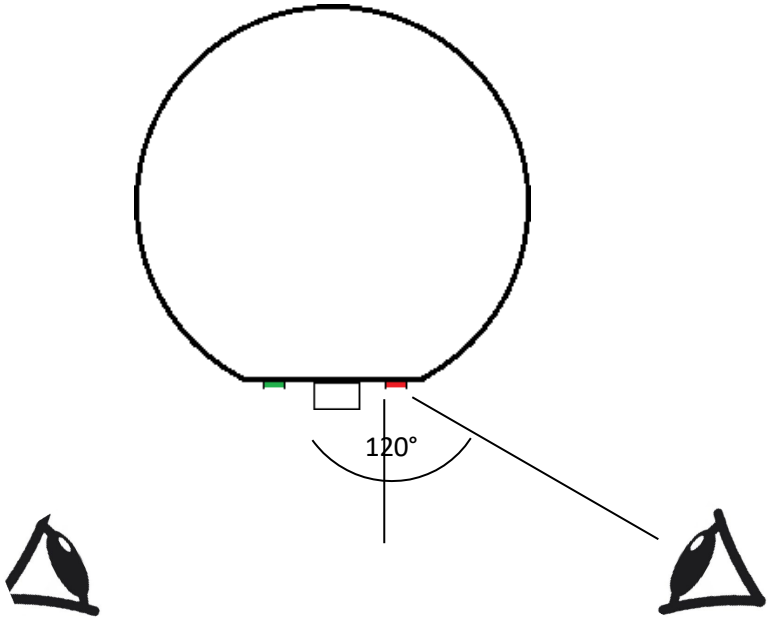
The Helix ventilator has the following alarm modes.

	Alarm Priority*	Audible (Constant or intermittent)	Sound level (db)**	LED Colour	Constant or Flashing	Comments
Low pressure / disconnect	Medium	Audible following 20 seconds (See comments)	>45db	Red	Intermittent for 20 seconds Constant after 20 seconds	The Low pressure disconnect alarm has a 5 second delay this is to avoid activation between breath cycles.
High pressure	Medium	Constant	>45db	Red	Constant	
Battery level low	Low	None	N/A	Green	Flashing	LED flashes when level @ < 2 hours running time
Battery failure	Medium	Constant	>45db	None	None	Activated when battery capacity is no longer sufficient to run the solenoids. Bellows ceases to operate. Nominal 15 minutes activation.

*Manual ventilation option built into patient circuit for immediate use.

**Audible alarm may be silenced by the mute button for 30 seconds. Visual warning remains on.

Unit should be positioned adjacent to the patient such that the operators eyeline is within a 120°sweep angle to the front of the ventilator control panel to ensure clear vision of the warning lights.



Testing alarms

With unit connected to a suitable drive gas source and patient circuit connected switch on the unit. Set the rate to 10 – 12 BPM and adjust the tidal volume to approximately 600. Ensure the ventilator is running correctly.

Low pressure disconnect

Disconnect the patient circuit block from the side of the ventilator and observe the control panel. The low-pressure warning light should illuminate after 5 seconds.

After a further 20 seconds the constant audible alarm should start.
Press the mute alarm button at which point the audible alarm should silence, the warning light will remain on. After a further 30 seconds the audible alarm should restart.
Reconnect patient circuit block and ensure that alarm goes off (audible and warning light). This may take a few seconds.

High pressure

Occlude the patient connection on the patient valve (Laerdal valve) and observe the pressure gauge on the top of the ventilator. Adjust the silver patient pressure control on the front of the ventilator clockwise fully until it reaches its stop, observing the pressure gauge whilst completing this to ensure that it increases. Ensure that on reaching 60cmH2O that the high-pressure alarm LED illuminates and the alarm sounds.

Battery level low (Flashing green light indicates < 2 hours operation left)

Not tested. Low level battery warnings should be recorded on usage log comments (Refer to Section 3) Battery life > 100 hours if indications of low battery levels occur at lesser intervals than this, a new battery should be considered. This is available by contacting Diamedica – support@diamedica.co.uk

Battery failure

Not tested.

7. USE OF SUPLEMENTARY OXYGEN.

As stated in section 4 when using oxygen as a drive gas, this can be recycled to achieve an inspired concentration of approximately 40%.

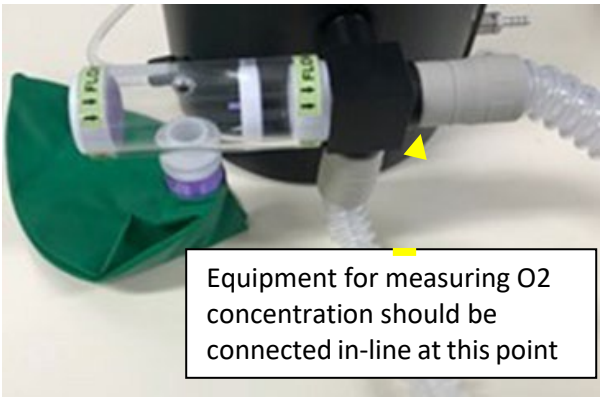
If higher concentration levels are required, this can be done by connecting a flow- controlled oxygen source to the supplementary port on the patient circuit valve. This can only be connected instead of the recycled connection.

O2 concentration will be dependent on the ventilator settings and supplementary flow rate from the external source. Tables for O2 flow rate setting are shown below to assist this process.

The tables below indicate the required supplementary oxygen flow rate required to achieve 60%, 70% and 80% delivered concentration. These tables are for indicative assistance only and the actual delivered concentration must always be checked by a suitable oxygen monitoring equipment.

The Oxygen monitor / measuring device should be connected in-line between the Patient Connection Valve (PCV) and the silicon Patient breathing limb.

<u>The patients oxygen saturation should also be monitored during use, via a pulse oximeter.</u>



First select the correct table for your required delivered concentration.

TABLE 1 – Indicated settings for 60% delivered concentration.
TABLE 2 – Indicated settings for 70% delivered concentration.
TABLE 3 – Indicated settings for 80% delivered concentration.

Read across from your set Tidal volume to the blue column beneath your set BPM this will give you the flow rate of supplementary oxygen required to give the resultant delivered concentration for that table (60%, 70% or 80%)
For any intermediate settings that are not detailed on the table an appropriate adjustment should be made between the two adjacent values above and below your requirement.

<u>PLEASE NOTE.</u>
It is the user's responsibility to ensure continuous suitable supply is in place and effective warning in case of failure.
It is the user's responsibility to ensure that the delivered concentration and resultant patients SATs are monitored at all times.

TABLE 1

Indicated supplementary oxygen (@95%) flow rate required to achieve 60% supply concentration

BPM →	10		15		20		25		30		35		40	
Tidal volume ↓	Minute volume (l/min)	**Reqd Supp. O2 for 60% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 60% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 60% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 60% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 60% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 60% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 60% (l/min)**
100	1	**0.53**	1.5	**0.79**	2	**1.06**	2.5	**1.32**	3	**1.59**	3.5	**1.85**	4	**2.12**
200	2	**1.06**	3	**1.59**	4	**2.12**	5	**2.65**	6	**3.18**	7	**3.71**	8	**4.24**
300	3	**1.59**	4.5	**2.38**	6	**3.18**	7.5	**3.97**	9	**4.77**	10.5	**5.56**	12	**6.36**
400	4	**2.12**	6	**3.18**	8	**4.24**	10	**5.30**	12	**6.36**	14	**7.42**	16	**8.48**
500	5	**2.65**	7.5	**3.97**	10	**5.30**	12.5	**6.62**	15	**7.95**	17.5	**9.27**	20	**10.6**
600	6	**3.18**	9	**4.77**	12	**6.36**	15	**7.95**	18	**9.54**	21	**11.13**	24	**12.72**
700	7	**3.71**	10.5	**5.56**	14	**7.42**	17.5	**9.27**	21	**11.13**	24.5	**12.98**	28	**14.84**
800	8	**4.24**	12	**6.36**	16	**8.48**	20	**10.60**	24	**12.72**	28	**14.84**	32	**16.96**
900	9	**4.77**	13.5	**7.15**	18	**9.54**	22.5	**11.92**	27	**14.31**	31.5	**16.69**	36	**19.08**
1000	10	**5.3**	15	**7.95**	20	**10.60**	25	**13.25**	30	**15.90**	35	**18.55**	40	**21.2**
1100	11	**5.83**	16.5	**8.74**	22	**11.66**	27.5	**14.57**	33	**17.49**	38.5	**20.40**	44	**23.32**
1200	12	**6.36**	18	**9.54**	24	**12.72**	30	**15.90**	36	**19.08**	42	**22.26**	48	**25.44**

TABLE 2

Indicated supplementary oxygen (@95%) flow rate required to achieve 70% supply concentration

BPM →	10		15		20		25		30		35		40	
Tidal volume ↓	Minute volume (l/min)	**Reqd Supp. O2 for 70% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 70% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 70% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 70% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 70% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 70% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 70% (l/min)**
100	1	**0.66**	1.5	**0.99**	2	**1.32**	2.5	**1.65**	3	**1.98**	3.5	**2.31**	4	**2.64**
200	2	**1.32**	3	**1.98**	4	**2.64**	5	**3.3**	6	**3.96**	7	**4.62**	8	**5.28**
300	3	**1.98**	4.5	**2.97**	6	**3.96**	7.5	**4.95**	9	**5.94**	10.5	**6.93**	12	**7.92**
400	4	**2.64**	6	**3.96**	8	**5.28**	10	**6.6**	12	**7.92**	14	**9.24**	16	**10.56**
500	5	**3.3**	7.5	**4.95**	10	**6.6**	12.5	**8.25**	15	**9.9**	17.5	**11.55**	20	**13.2**
600	6	**3.96**	9	**5.94**	12	**7.92**	15	**9.9**	18	**11.88**	21	**13.86**	24	**15.84**
700	7	**4.62**	10.5	**6.93**	14	**9.24**	17.5	**11.55**	21	**13.86**	24.5	**16.17**	28	**18.48**
800	8	**5.28**	12	**7.92**	16	**10.56**	20	**13.2**	24	**15.84**	28	**18.48**	32	**21.12**
900	9	**5.94**	13.5	**8.91**	18	**11.88**	22.5	**14.85**	27	**17.82**	31.5	**20.79**	36	**23.76**
1000	10	**6.6**	15	**9.9**	20	**13.2**	25	**16.5**	30	**19.8**	35	**23.1**	40	**26.4**
1100	11	**7.26**	16.5	**10.89**	22	**14.52**	27.5	**18.15**	33	**21.78**	38.5	**25.41**	44	**29.04**
1200	12	**7.92**	18	**11.88**	24	**15.84**	30	**19.8**	36	**23.76**	42	**27.72**	48	**31.68**

TABLE 3

Indicated supplementary oxygen (@95%) flow rate required to achieve 80% supply concentration

BPM →	10		15		20		25		30		35		40	
Tidal volume ↓	Minute volume (l/min)	**Reqd Supp. O2 for 80% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 80% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 80% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 80% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 80% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 80% (l/min)**	Minute volume (l/min)	**Reqd Supp. O2 for 80% (l/min)**
100	1	**0.8**	1.5	**1.2**	2	**1.6**	2.5	**2**	3	**2.4**	3.5	**2.8**	4	**3.2**
200	2	**1.6**	3	**2.4**	4	**3.2**	5	**4**	6	**4.8**	7	**5.6**	8	**6.4**
300	3	**2.4**	4.5	**3.6**	6	**4.8**	7.5	**6**	9	**7.2**	10.5	**8.4**	12	**9.6**
400	4	**3.2**	6	**4.8**	8	**6.4**	10	**8**	12	**9.6**	14	**11.2**	16	**12.8**
500	5	**4**	7.5	**6**	10	**8**	12.5	**10**	15	**12**	17.5	**14**	20	**16**
600	6	**4.8**	9	**7.2**	12	**9.6**	15	**12**	18	**14.4**	21	**16.8**	24	**19.2**
700	7	**5.6**	10.5	**8.4**	14	**11.2**	17.5	**14**	21	**16.8**	24.5	**19.6**	28	**22.4**
800	8	**6.4**	12	**9.6**	16	**12.8**	20	**16**	24	**19.2**	28	**22.4**	32	**25.6**
900	9	**7.2**	13.5	**10.8**	18	**14.4**	22.5	**18**	27	**21.6**	31.5	**25.2**	36	**28.8**
1000	10	**8**	15	**12**	20	**16**	25	**20**	30	**24**	35	**28**	40	**32**
1100	11	**8.8**	16.5	**13.2**	22	**17.6**	27.5	**22**	33	**26.4**	38.5	**30.8**	44	**35.2**
1200	12	**9.6**	18	**14.4**	24	**19.2**	30	**24**	36	**28.8**	42	**33.6**	48	**38.4**

All tables are indicative, and the resultant delivered concentrations must always be verified
Observations of the patient must take precedence over machine settings in judging the condition of the patient.
Any adjustment of the TV or BPM settings on the ventilator will alter the delivered O2 as such the supplementary flow rate setting should be reviewed and adjusted accordingly.

8. TROUBLE SHOOTING

Situations requiring the immediate attention of the clinician.

N.B. in the event of any other malfunction the ventilator must be taken out of service immediately and advice sought from Diamedica. Under no circumstances should there be any unauthorized tampering with the inside of the ventilator by untrained personnel.

1. Low pressure alarm sounds on ventilator and warning light illuminated.

Cause: There is a leak or complete disconnection of the breathing tubing. Alternatively, the tidal volume setting is too low for the size of patient.
Response: Depress the mute button to silence the alarm. Look for obvious source of leaks and or disconnections and restore integrity. If no leak is immediately evident turn off ventilator and commence manual ventilation with a self-inflating bag. Look carefully for source of leaks and or disconnections and restore integrity. Re-start ventilator. If low pressure alarm continues to sound, increase tidal volume setting until sufficient pressure is generated.

2. Failure of bellows to fill completely.

Cause: Loss of drive gas pressure due to oxygen concentrator failure or empty cylinder.
Response: Continue ventilation manually while cylinder is changed.

3. Failure of bellows to empty completely.

Cause: There may be an increased resistance to breathing due to an obstruction to the breathing tubing (e.g. kinking) or an obstruction to the patient's airway (e.g. bronchospasm, secretions). Alternatively, the patient pressure may be set too low, or the tidal volume too high.
Response: Change to manual ventilation, seek and relieve any cause of obstruction. If the bellows still do not empty completely, increase the patient pressure.

4. Sudden failure of bellows. No movement possible in either direction.

Cause: There is a mechanical fault inside the ventilator.
Response: Turn the ventilator off and continue with manual ventilation with a self- inflating bag. Consult the manufacturer for advice. DO NOT TAMPER WITH THE INSIDE OF THE VENTILATOR.

5. The supply of drive gas fails

Cause: Whatever the cause the response must be immediate as there is no supplementary oxygen for the patient to breathe and no driving gas for the ventilator.
Response: Ventilation is maintained using atmospheric air as the carrier gas. Manually controlled ventilation via a self-inflating bag should be used.

6. Power light is flashing

Cause: Low battery life. Battery has less than 2 hours operation until failure.
Response: Connect to Power source immediately until battery is fully charged.

9. FREQUENTLY ASKED QUESTIONS

Q. How long can the ventilator function in the complete absence of electricity?

A. Providing oxygen or air is available the limiting factor is the charge in the battery needed for the electronic circuitry. A fully charged battery will last for 100 hours. It is therefore important to keep the battery fully charged.

Q. Can positive end expiratory pressure (PEEP) be used?

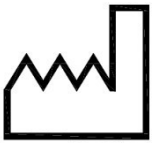
A. Yes, by applying an adjustable PEEP valve to the expiratory valve, PEEP of 20cmH_2O can safely be applied.

Q. Is humidification of the inspired gas required?

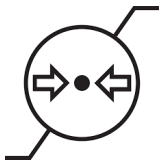
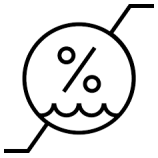
A. For long term ventilation as in an intensive care unit humidification is advisable using a filter/ humidifier at the patient's airway or by passing the inspired gases over a container of water.

10. SYMBOLS GLOSSARY

Some or all the following symbols may be used within this manual or found on the product or packaging labels. Please familiarize yourself with them:

Symbol	Description	Comment
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Batch code	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device that needs to be protected from moisture.

	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Refer to the Instruction Manual	Indicates the user must read the instructions for use before using the equipment.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Class II equipment	
	Type BF applied part	
	Recycling symbol	Products with this symbol should not be disposed of in the bin
	The battery recycling symbol	Chemical symbol for battery type included beneath
	Does not contain or presence of natural rubber latex	
	Indicates that an object is capable of being recycled	

	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	Medical device	Indicates the item is a medical device
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information

