ENG

DPA-03

Twin Vaporiser Portable Anaesthesia System

INSTRUCTIONS FOR USE MANUAL

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Read this page first

INTENDED USE

The DPA 03 facilitates the administration of inhalational anaesthesia and respiratory support in difficult environments and low resource settings. The units are contained in a protective Peli-case and are portable for deployment to field operations or humanitarian emergency situations.

This device is suitable for use in hospital settings with limited resources or in any field or outreach locations and is suitable for adult and paediatric patients.
The DPA Anaesthesia Series is not intended for use in The EU (With the exception of supervised training by qualified personnel)

FOREWORD

This manual is intended to provide guidance on the function, performance, and user maintenance of the DPA03 Anaesthesia System. 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 DPA03 Anaesthesia System must read, understand, and follow the guidance given in this manual before using the system.

THE NEED FOR PATIENT MONITORING. WARNING

The DPA03 Anaesthesia System delivers mixtures of gases and vapours which could cause injury or death to the patient. The effect of anaesthesia drugs on individual patients can vary so that “typical” device settings for concentrations delivered to the patient do not necessarily ensure patient safety.

The DPA, Diamedica Portable Anaesthesia Systems are designed for use in remote areas with limited logistical support and emergency situations where ideal medical conditions are unlikely. The ultimate responsibility for patient or procedure contraindication lies with the anaesthetist, and will be situation dependent.

Medical conditions which contraindicate the use of a DPA Series Portable Anaesthesia Systems, and its associated applications include any medical conditions which may contraindicate the medical procedure itself.

The DPA series 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.

Daily set up and test instructions should be successfully carried out to ensure that the DPA Series of anaesthetic machines are in operating condition. If any parameter or test is found to deviate from the instructions the machine should not be used, until the issue is resolved.

The Diamedica Portable Anaesthesia Series 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.

It is essential that the patient's respiration and cardiovascular status are frequently checked by the anaesthetist.

The anaesthetist is ultimately responsible for patient safety and should always have a secondary means of maintaining patient safety.

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

If ether is the only volatile agent available, it must be vaporised in a different vaporiser.

The Diamedica Portable Anaesthesia systems are transportable devices. The vaporiser must be emptied of agent (Refer to section 11) and secured within the case prior to transportation.

Drawover anaesthesia is contraindicated for patients below 10kg, for these patients the machine should be used in continuous flow (see section 9).

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 system is only intended to be used by Qualified Anaesthetists.

Method(s) of sterilization

The DPA series 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.

THE DPA 03 MANUAL

1. INTRODUCTION.

In many parts of the world anaesthetics are administered in situations far removed from those found in modern, well-equipped hospitals in wealthy countries. There may,for example, be no oxygen, electricity, or technical support. In these circumstances, the latest sophisticated anaesthetic machines with their delicate monitoring devicesare unable to function and are rapidly consigned to the graveyard of anaesthetic equipment which litters the developing world.

Anaesthetists working in such environments need equipment which goes beyond the standards of those required for hospitals in rich countries. Equipment is needed that has been specifically designed to meet the additional requirements of harsh environmental conditions and limited infrastructure and that will continue to function in those prevailing conditions. When advice has been sought from anaesthetists working in these areas the following properties have been most frequently requested:

The anaesthetic machine should be:

1. Easy to understand and operate.
2. Robust and not easily damaged
3. Inexpensive to purchase and economical to run.
4. Maintained using locally available skills.
5. Safe to use in the absence of expensive electronic monitoring equipment.
6. Versatile, so that the same machine can be used on any size of patient, with a variety of volatile agents, in either draw over or continuous mode.
7. Able to continue operating without interruption in the absence of oxygen or electricity.
8. Be resilient to unstable or intermittent mains power supplies.

The DPA series of anaesthetic machines has been developed to meet these requirements and the needs of anaesthetists working in difficult environments.

The DPA 03 is a free-standing anaesthetic machine in a transport case suitable to be carried by a single individual. It has been specifically designed to facilitate the administration of inhalational anaesthesia in difficult environments. It is easy to understand and operate, economical to run and can be maintained and serviced using locally available skills. Above all, it does not require compressed gases or electricity.

This manual has been prepared to provide practical guidance for those using the DPA series. It should only be operated by experienced anaesthetists who have received specific training in its use and are fully competent in its operation.

2. SPECIFICATIONS.

The DPA 03 is suitable for adult and paediatric use. The specifications are listed below:

Component / Feature		Specification
Dimensions (Closed case)	Height	32cm
	Width	53cm
	Depth	33cm
Weight		14kg
Operating Environment	Temperature Humidity Altitude	5 - 40° C 35% - 90% RH 79 – 106 kpa
Storage Environment	Temperature Humidity Altitude	-10 - +45° C 15% - 90% RH 79 – 106 kpa
Maximum operational altitude		< 2000m
Oxygen concentrator Regulated external gas supply (Cylinder or wall)		0.5 Bar Min. 5 Bar Max.
PEEP; circuit dependent		0 – 20 cm H_2O
Vaporisers		
Low inspiration resistance		<0.6kpa
Suitable for Drawover and continuous flow		Yes
Anaesthetic agent		Isoflurane, Halothane or Sevoflurane
Capacity		150ml
Agent concentration range. **		ISO / HAL 0-5 % SEV 0 – 8%

** Delivered concentration accurate within ±20 % of set value for concentrations (volume fraction) greater than 1 % and ±50 % of set value for concentrations of 1 % or below.

3. CLEANING, GENERAL MAINTENANCE AND DISPOSAL.

The anaesthesia machine 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.

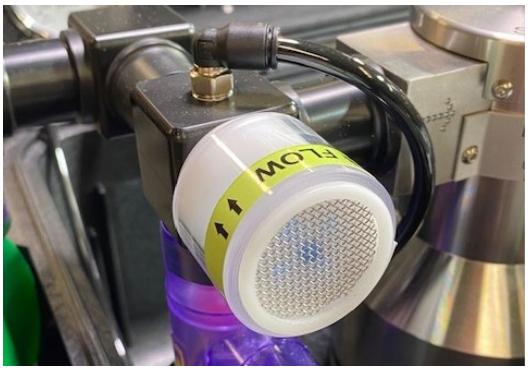
Date	Task ① Patient use ② Maintenance ③ Cleaning	Time on	Time off	Agent	Comments / Completed tasks

Suggested usage log for DPA series

The anaesthesia machine should be cleaned daily by wiping down with a damp cloth, care should be taken to ensure that any sharps have been removed and disposed of safely before this is done.

Ensure unit is dry free from moisture after wiping.

The ambient air intake grille should be inspected for any particulate matter which should be removed if present.



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 usage.

(i) Breathing circuit

Each DPA is supplied with a reusable breathing circuit, as these items may come in contact with the patient and can therefore potentially pass infectious agents from one patient to another if used improperly, the reusable breathing tubing and patient valve provided with the anaesthesia machine should be cleaned and disinfected according to your hospital's infection control procedures. If no bacteria filter is used, then the entire circuit should be cleaned and disinfected 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
Patient limb		Wash in bleach solution, rinse and dry in line with hospital's infection control procedures	Weekly	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	Examine for damage, replace if necessary.
Limb to self-inflating bag		Wash in bleach solution, rinse and dry in line with hospital's infection control procedures	Weekly	Examine for damage, replace if necessary.
Patient 'Y' Piece		Wash in bleach solution, rinse and dry in line with hospital's infection control procedures	Weekly	Examine for damage, replace if necessary.

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

(iii) Vaporiser

Halothane decomposes over time causing the release of halides, which can corrode metal components, particularly in the presence of moisture. For this reason, a stabilizing agent, thymol, is added to prevent decomposition. Since thymol does not volatilize along with halothane, it can accumulate in the vaporizer, making the control lever stiff.
If the control lever is stiff it may be the result of accumulated thymol. You can perform the following to try to loosen the lever:

1. Set the Halothane vaporiser to maximum.
2. Fill a 10ml syringe with fresh Halothane.
3. Direct the Halothane into the slot that the lever moves in.
4. Move the lever back and forwards.
5. Repeat until the leaver is clear.

The vaporiser should not require recalibration. Any Operational calibration should only be done following consultation with manufacturer.

Accessories and spares

The patient circuit tubing is Non-conducting (Applied Part). DO NOT replace with conducting/anti-static tubing.
All accessories used with the DPA-03 must:

- Be oxygen compatible,
- Be biocompatible,

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

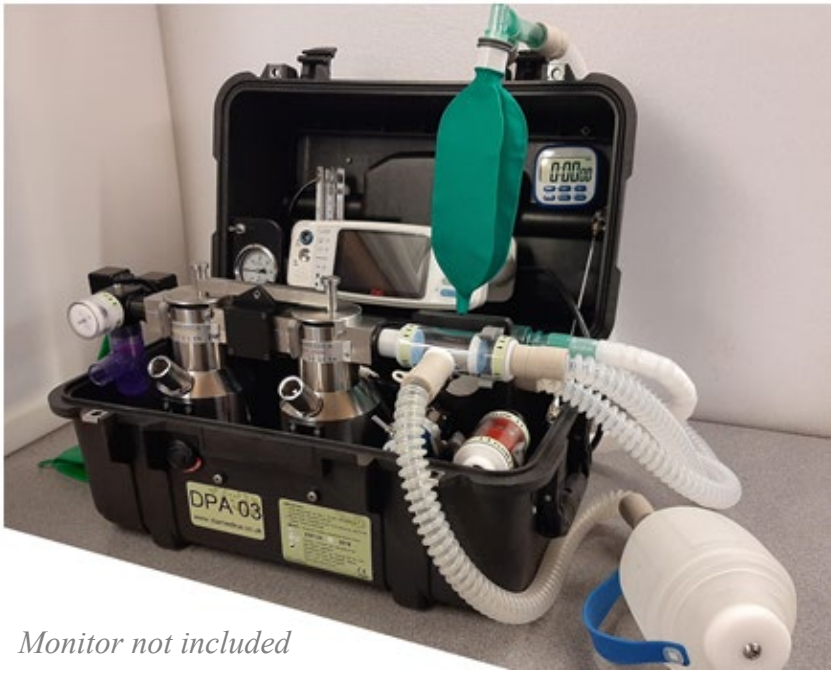
Technical data enquiries

For all technical, performance or component related enquiries please contact Diamedica - support@diamedica.co.uk

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 relevant disposal regulations

4. THE COMPONENT PARTS OF THE DPA 03.



Monitor not included

The Diamedica Portable Anaesthetic system DPA-03 has four principal components;

- Protective Peli case.
- Reservoir.
- 2 vaporisers.
- Breathing system.

These are configured as follows:

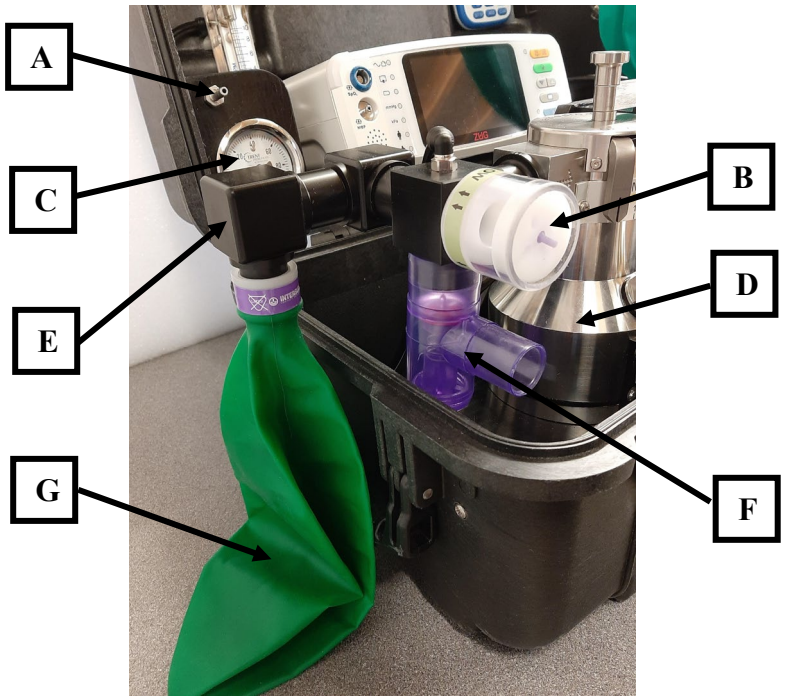
Peli case.

The Peli case has 2 easy open double-step latches and 3 carrying handles. The case protects against the elements and accidental damage when latched shut for transportation.

Ensure labelling is not damaged or removed and always store in an upright condition.

The reservoir.

A. The oxygen supplementation port (metallic nozzle).
B. The air entry one-way valve with arrows indicating direction of air flow.
C. Patient pressure gauge.
D. Vaporiser.
E. Reservoir block.
F. The pressure relief valve with outlet pressure set at 7.5cm water.
G. The 2-litre reservoir bag.



Vaporiser

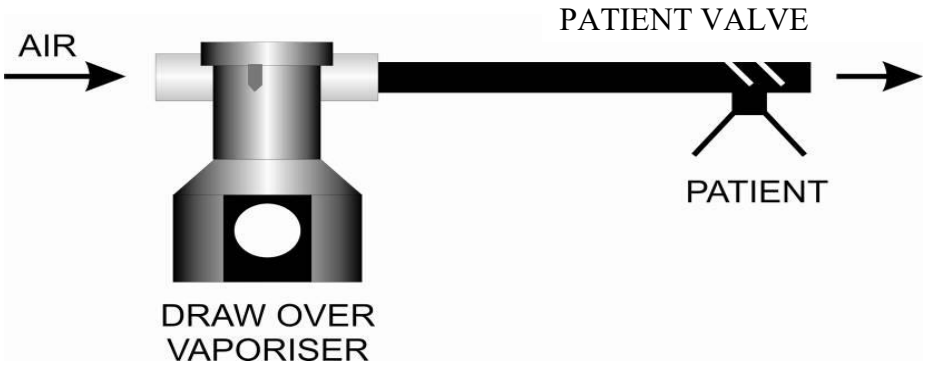
Before a volatile anaesthetic agent can be administered to a patient it must first be vaporised. A carrier gas containing oxygen passes through the chamber of a vaporiser where vaporisation occurs, and the resulting mixture is delivered to the patient.

Pressure Gradient

In order for the carrier gas to pass through the vaporiser there must be a pressure gradient between entry and exit ports of the vaporiser. The carrier gas must therefore either be PUSHED through by positive pressure from upstream or DRAWN through by negative pressure from downstream.

By contrast in DRAWOVER anaesthesia the carrier gas is DRAWN over the vaporiser by negative pressure generated by the patient's inspiration. The great advantage of draw over anaesthesia is that it can still be administered EVEN IF THE OXYGEN SUPPLY FAILS. In this situation room air, containing 21% oxygen, can be used as the carrier gas for the volatile agent which is supplemented with oxygen if available.

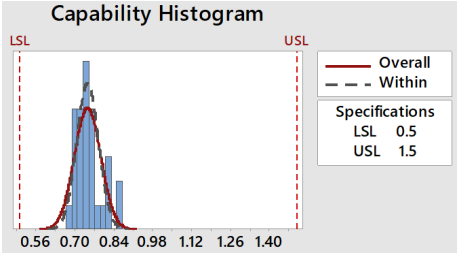
The DPA 03 can function as a continuous flow machine when gases are provided by an Oxygen concentrator or an auxiliary source. However, if these sources fail the system will default to a drawover machine in order for anaesthesia to continue safely.



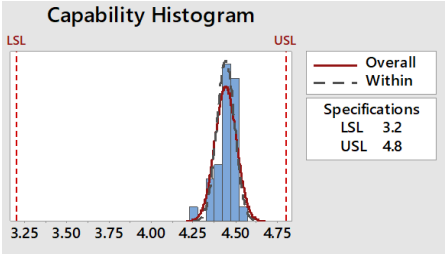
This conversion happens automatically in the event of gas failure or Drawover can be used in order to conserve both oxygen and anaesthetic agent. This is described further in later sections of the manual.

The Diamedica vaporisers output is consistent in both modes, the output from otherDrawover vaporisers may not be suitable for both these modes.

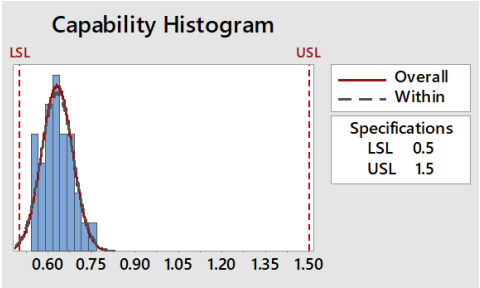
The flow capabilities of the draw-over vaporizer meet the requirements of ISO 18835:2015 and can operate consistently up to an intermittent peak inspiratory draw of 35 L/min
Typical capabilities @ 6l/min are represented in the graphs below.



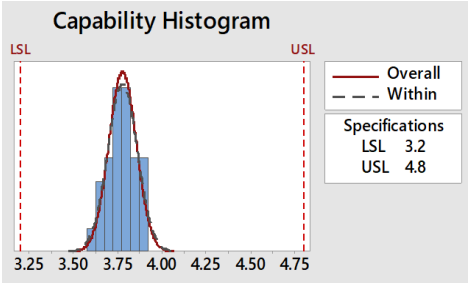
1% Continuous



4% Continuous



1% IPPV



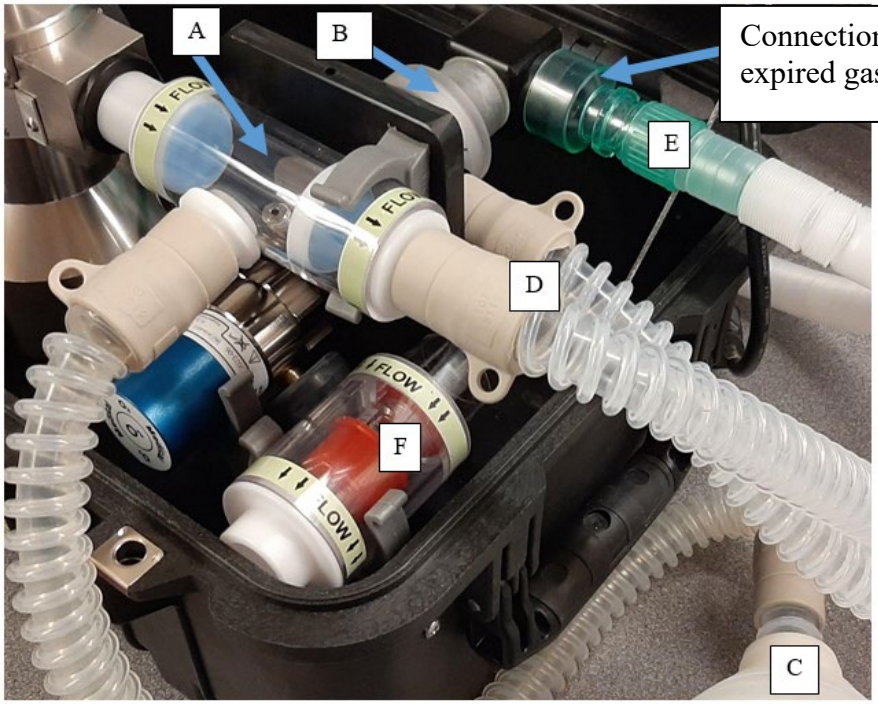
4% IPPV

These vaporizers are designed to be used with isoflurane (0 to 5% output) and sevoflurane (0 to 8% output)

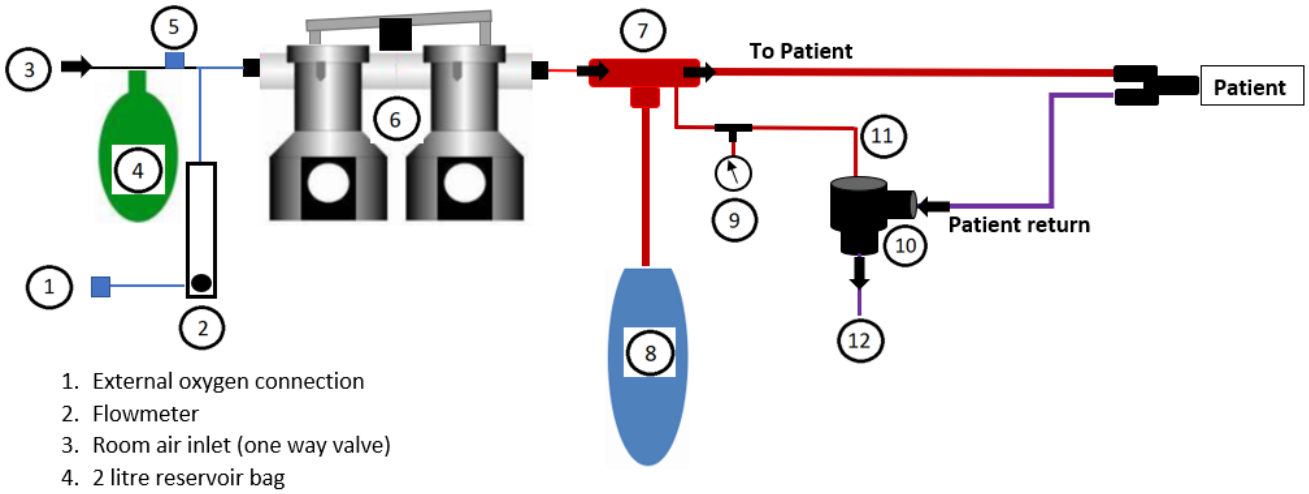
The breathing system.

The following parts of the breathing system are identified;

1. The valve unit. This consists of two separate clear cylindrical valves known as inspiratory (A) and expiratory (B) valves, connected by 4mm diameter length of clear tubing.
2. Self-inflating bag (C) (a smaller size is available for paediatrics)
3. A dual limb of 22mm silicon respiratory tubing (D) ending in a standard 'Y' piece and 1 litre bag to act as a test lung.
4. A length of standard respiratory tubing for scavenging of expired gases (E).
5. PEEP valve (F) in storage location. (Refer to Chapter 11 for use and fitting)



Gas circuit diagram



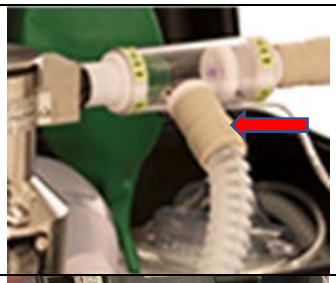
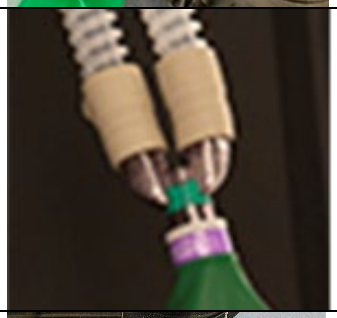
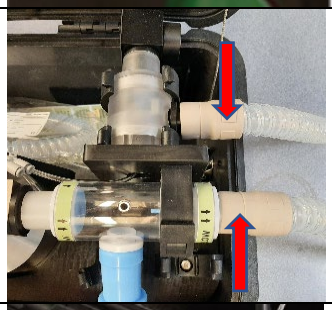
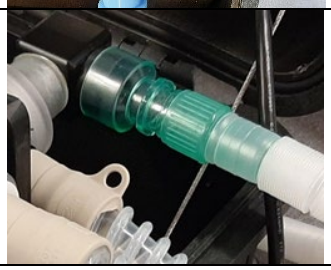
1. External oxygen connection
2. Flowmeter
3. Room air inlet (one way valve)
4. 2 litre reservoir bag
5. Over pressure valve (7.5cmH20)
6. Dual vaporiser with pivot interlock
7. Inspiratory valve
8. Self-inflating bag
9. Patient pressure gauge
10. Expiratory valve
11. Pressure stabilisation tube
12. Expired gases

KEY

- One-way valves (Direction of flow)
- Agent / carrier gas mix (Patient circuit)
- Agent / carrier gas mix (Machine circuit)
- Oxygen
- Room air
- Patient expired gases

5. CONTROL AND OPERATION.

Assembly of the breathing system

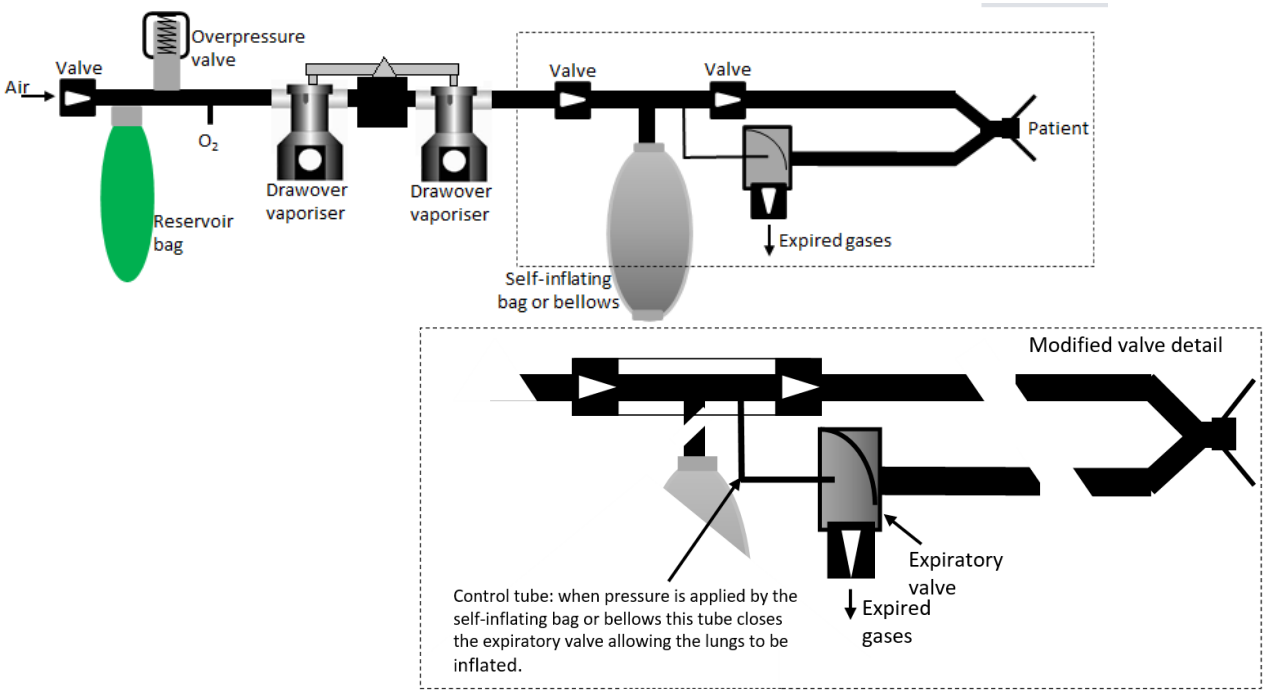
1. Open the case and remove the patient circuit and self-inflating bag	
2. Attach the self-inflating bag and tube to the port between the two valves on the inspiratory valve.	
3. Rotate the fitting holding the green reservoir bag so the bag hangs outside the case. Ensure that Reservoir bag is unrestricted and free to expand.	
4. Take the 2-limb corrugated patient circuit with Y piece and 1 litre test lung (Test lung required for circuit integrity testing only – See below)	
5. Attach one off the tubes to the outlet of the inspiratory valve and the other tube to the inlet of the Expiratory valve.	
6. Affix corrugated scavenging tube to outlet port of expiratory valve at rear of unit.	

See Circuit diagrams

To test the assembly:

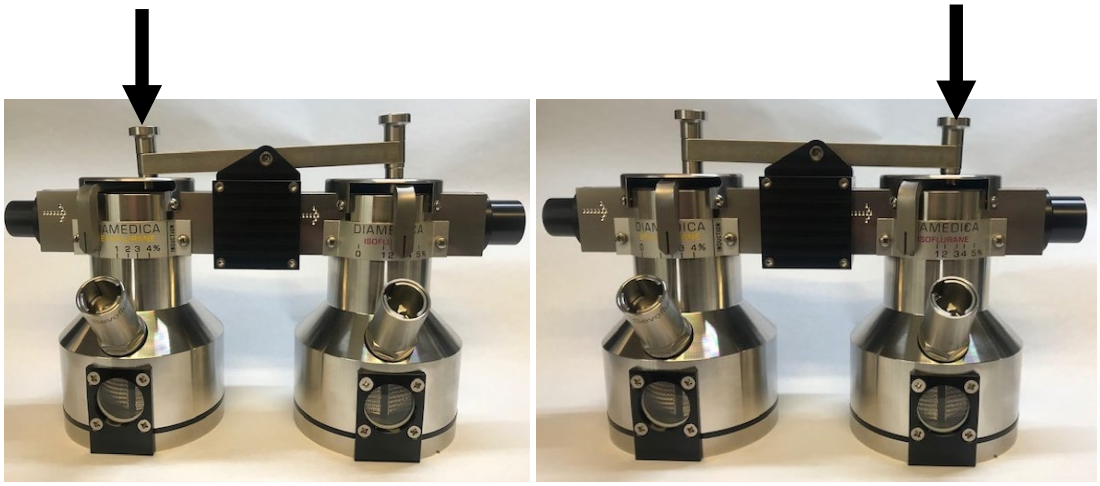
Test the integrity of the system using the self-inflating bag. The test lung (1 litre green reservoir bag) should fill and hold pressure as the Self inflating bag is compressed and release pressure when the Self inflating bag is released. The reservoir bag will indicate flow/breathes when connected to a supplementary oxygen supply, as it will inflate between breathes and release on the inspiratory cycle.

Circuit diagrams



Vaporiser selection

Set both levers to zero and push down on pivot bar to select vaporiser



The DPA 03 has two vaporisers fitted with a pivot interlock system. To select a vaporiser, first you must set both vaporisers to zero and then to select which vaporiser you require push down on the opposite pivot arm. Once selected the vaporiser lever should move freely. The opposite vaporiser will be locked in place until the selected vaporiser has been set to zero.

The vaporisers are designed to be used with specific anaesthetic agents and are equipped with filling systems to enforce the same. The filler tubes are agent specific. The fittings on the vaporiser and the collar of the bottles are specific to the agent too. This precaution is built into the design to prevent mixing of the anaesthetic agents.

Vaporisers must not be overfilled or underfilled to prevent failure of the vaporizer systems.

Only fill the Vaporisers with the agent indicated on the display.

FILLING CAPS ARE AGENT SPECIFIC AND SHOULD NOT BE REMOVED

Note

If the pivot bar is straight, you will not be able to move either vaporiser lever until one is selected.

Circuit pressure indication

During operation, the generated pressure can be observed on the pressure gauge.

Pressure readings indicated on the gauge indicate the pressure inside the machine circuit prior to delivery to the patient circuit. 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.

Flow meter - Supplementary oxygen

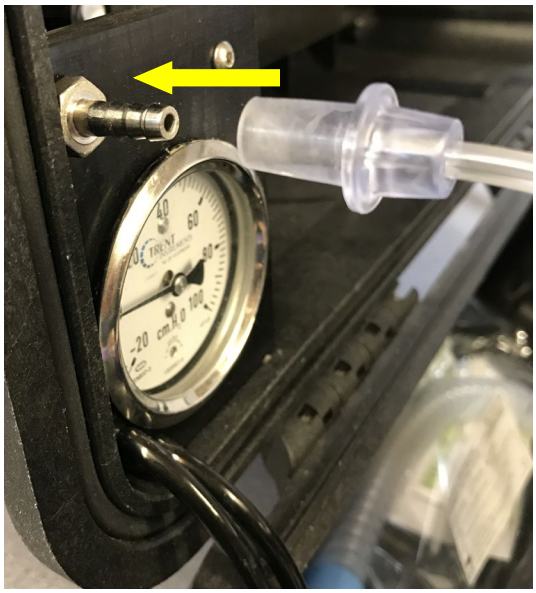
The flow meter situated behind the pressure gauge and supplemental oxygen connection port controls the flow of oxygen being released into the reservoir which is then taken into the circuit on the inspiratory cycle.

Please note that this is an open draw over circuit actual inspired O2 levels will vary depending on the overall minute volume of the patient.

Patient observations and Fio2 monitoring must take precedence over machine settings

6. SUPLEMENTRY OXYGEN SOURCES.

The DPA series will accept oxygen directly from an oxygen concentrator or an oxygen cylinder by use of the supplied oxygen regulator.



Insert supplied Oxygen tube onto barbed connection as shown above, ensuring that connection is fully inserted

The opposite end of the oxygen tube must be connected to the barbed connector on the supplied regulator (as shown) or directly to the relevant output port of an oxygen concentrator.

NOTE

The Dial regulator flow setting MUST be set to 10 minimum to ensure accuracy of the downstream flow meter

If using an alternative source of supplementary Oxygen this must also be supplied at a minimum 10l/min to ensure accurate setting of the unit's flowmeter.

7. TEST PROCEDURE BEFORE USE.

Confirm vaporiser contains the correct volatile agent and that concentration lever moves freely. Refill vaporiser if required.

Turn on oxygen supply if available. Always ensure that the cylinder has sufficient content prior to use.

Test oxygen flow meter over full range.

Ensure gas scavenging tube is connected to the 30mm outlet of the Expiratory valve and that tail end of tube is suitably positioned away from the operational area.

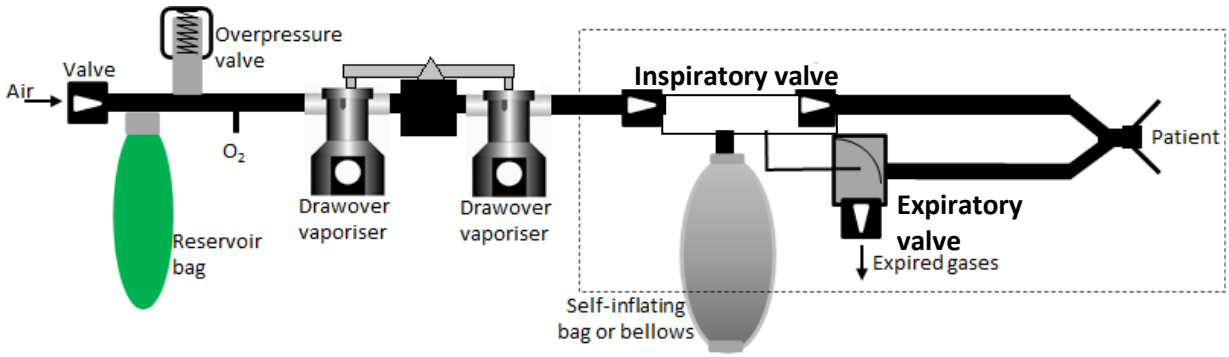
Test anaesthetic circuit. Attach a one litre reservoir bag to the end of the patient circuit to act as test lung. Compress the self-inflating bag to demonstrate expansion of test lung and simultaneous movements of reservoir bag.

Remove test bag and affix patient interface (and filter – recommended)

Unit is now ready for use

8. USE OF THE DPA 03 ON ADULTS.

In Adult patients (and paediatric patients above 10 kg) the standard Y piece dual limb circuit is used (Refer to Section 6 – Control and operation).

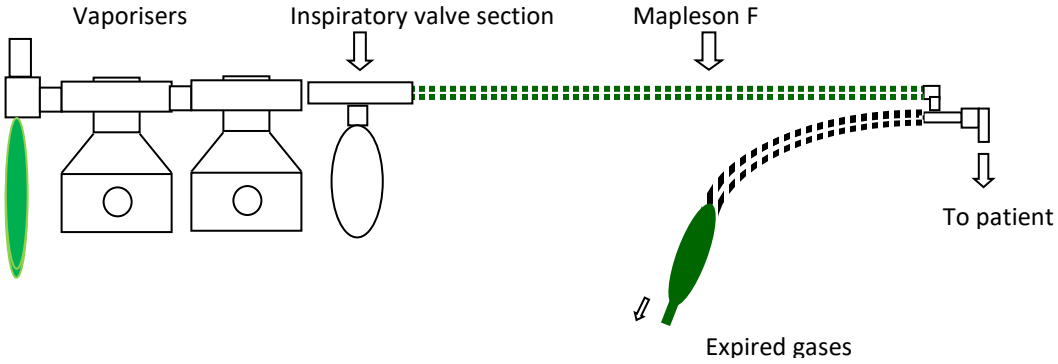


Correct vaporiser settings for induction and maintenance of anaesthetised stated are clinical decisions based on patient evaluation and ongoing monitoring.

9. USE ON PAEDIATRIC PATIENTS.

In patients less than 10 kg the continuous flow paediatric circuit (Mapleson F – Ayres T piece) should be used with a flowrate of at least 3 times the patients minute volume.

Ayres 'T' Piece paediatric circuit
The circuit can be connected directly to the inspiratory valve section as below. It is recommended that this circuit should be used with a minimum fresh gas flow from concentrator or cylinder of at least 3 x the patient's minute volume.



The self-inflating bag and inspiratory valve can stay in position.

10. PEEP (Positive end expiratory pressure).

The PEEP valve is located in the case next to the oxygen cylinder regulator and should be connected between the expiratory valve outlet and the scavenging tube, as shown in the picture below ensuring the correct direction of flow.

To adjust the PEEP valve

The PEEP valve can be removed by pulling the valve from the clear case. To adjust the valve, turn cap clockwise to increase pressure and anti-clockwise to reduce pressure. The PEEP valve pressure ranges from 0-20 cmH20.

11. FREQUENTLY ASKED QUESTIONS.

Q. Which volatile agents can be used with the Diamedica vaporiser?

A. The DPA-03 is supplied with a Sevoflurane vaporiser and an Isoflurane vaporiser.

Important

If ether is the only volatile agent available, it must be vaporised in a different vaporiser. It should also not be used in conjunction with the mechanical ventilator due to the risk of explosion.

Q. How is the vaporiser filled?

A. The vaporisers are filled by pushing the agent bottle into the agent specific filler, this should be done with the vaporiser set to 2% to avoid vapour lock and spattering.

Q. How can the vaporiser be emptied?

A. Remove the agent specific filler then draw up the agent using a syringe. Once emptied replace filler cap. NOTE. Only complete on one vaporiser at a time replacing filler cap before repeating with second vaporiser to prevent mixing of fillers

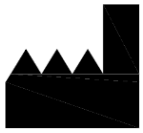
To remove the residual contents, the dial must be turned on fully and gas/air blown through the chamber for several minutes until the vapour can no longer be detected.

Q. What regular maintenance is required for the Diamedica vaporiser?

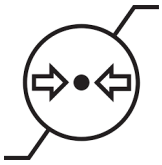
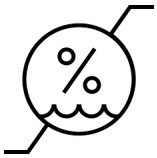
A. The vaporisers have been designed to require minimal maintenance. Refer to Section 3

12. SYMBOLS GLOSSARY.

Some or all the following symbols may be used within this manual or found onthe 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 medicaldevice 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 tothe 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 canbe broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device thatneeds 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

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