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DPA 02™

Diamedica Portable Anaesthesia System

INSTRUCTIONS FOR USE MANUAL

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Read this page first

INTENDED USE

The DPA02 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 DPA02 Anaesthesia System. The information given inthis 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 DPA02 Anaesthesia System must read, understand, and follow the guidance given in this manual before using the system.

THE NEED FOR PATIENT MONITORING. WARNING

The DPA02 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 02 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 devices are 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 02 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 02 is suitable for adult and paediatric use. The specifications are listed below:

Component / Feature		Specification
Dimensions (Closed case)	Height	17cm
	Width	47cm
	Depth	35cm
Weight		9.8kg
Operating Environment	Temperature Humidity Altitude	5 - 40° C 35% - 90% H 79 – 106 kpa
Storage Environment	Temperature Humidity Altitude	-10 - +45° C 15% - 93% H 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 H2O
Vaporiser		
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 unit and case 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 / after emergency field usage	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 / after emergency field usage	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 / after emergency field usage	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 / after emergency field usage	Examine for damage, replace if necessary.

(ii) Any bacteria filters and other single-use items provided 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. Remove the vaporiser from the stand and set to zero.
2. Turn it upside down, and shake it vigorously followed by moving the lever until it becomes loose.
3. When the lever loosens, it should be drained and rinsed with fresh agent.
4. Attach the vaporiser to the control panel and fill with fresh halothane.

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-02 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 02

The Diamedica Portable Anaesthetic system DPA-02 has four principal components.

- Protective Peli case.
- Reservoir.
- vaporiser.
- Breathing system.

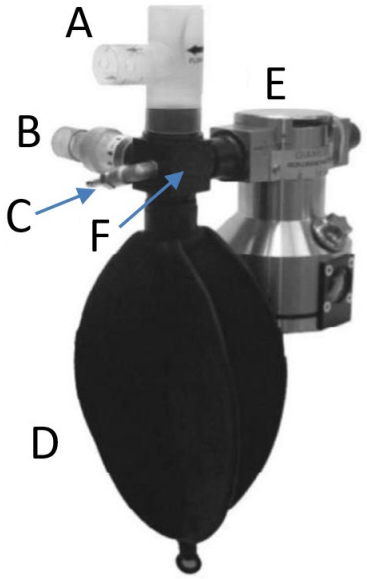
These are configured as follows:

Peli case.

This carrying case features a soft-grip handle and two easy-open press-and-pull latches. The case protects against the elements - it is dustproof, crushproof, and waterproof, rated IP67 when latched shut for transportation.

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

The Reservoir.



A. The pressure relief valve with outlet pressure set at 7.5cm water.

B. The air entry one way valve with arrows indicating direction of air flow.

C. The oxygen supplementation port (metallic nozzle).

D. The 2-litre reservoir bag.

E. Vaporiser.

F. Connecting block.

Vaporiser.

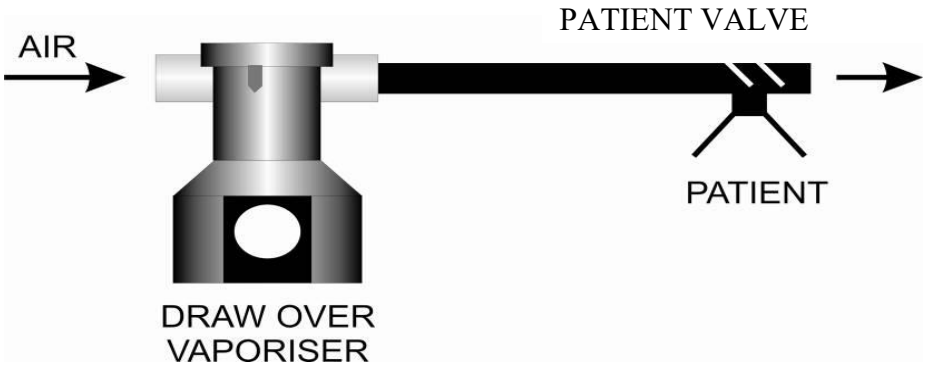
Before a volatile anaesthetic agent can be administered to a patient it must first be vaporised. A carrier gas containing oxygen passes through the chamber of a vaporiser where vaporisation occurs, and the resulting mixture is delivered to the patient.

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.

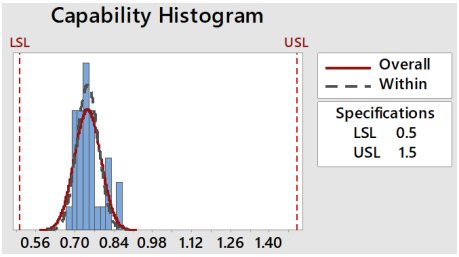
The DPA 02 can function as a continuous flow machine when gases are provided by an Oxygen concentrator or an auxiliary source. However, if these sources fail the system will default to a drawover machine in order for anaesthesia to continue safely.



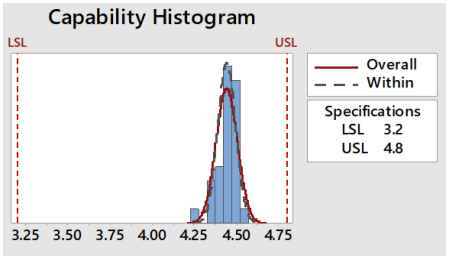
This conversion happens automatically in the event of gas failure or Drawover can be used in order to conserve both oxygen and anaesthetic agent. This is described further in later sections of the manual.

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

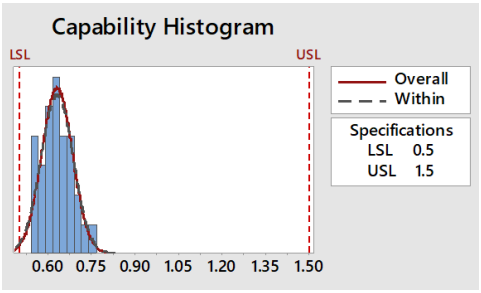
The flow capabilities of the draw-over vaporizer meet the requirements of ISO 18835:2015 and can operate consistently up to an intermittent peak inspiratory draw of 35 L/min
Typical capabilities @ 6l/min are represented in the graphs below.



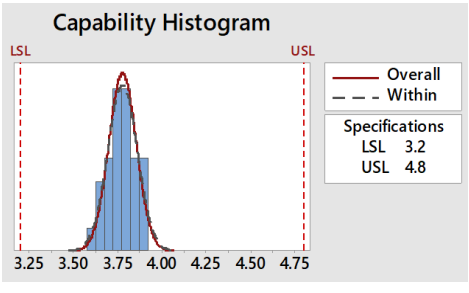
1% Continuous



4% Continuous

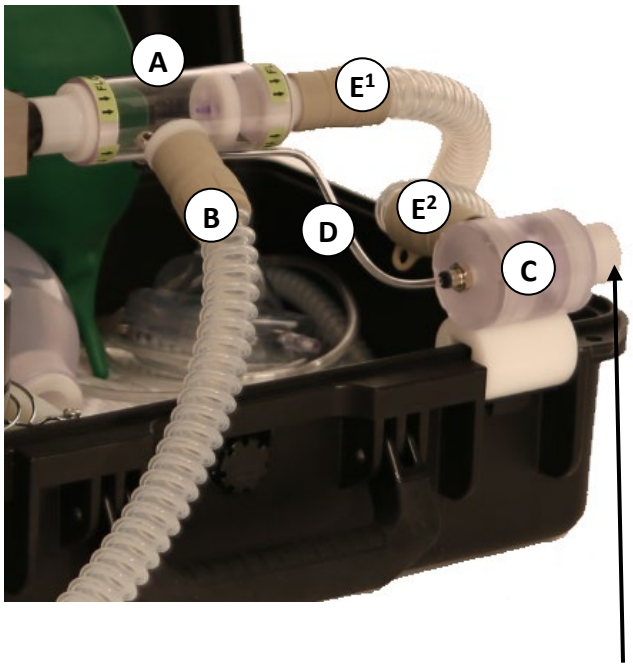


1% IPPV



4% IPPV

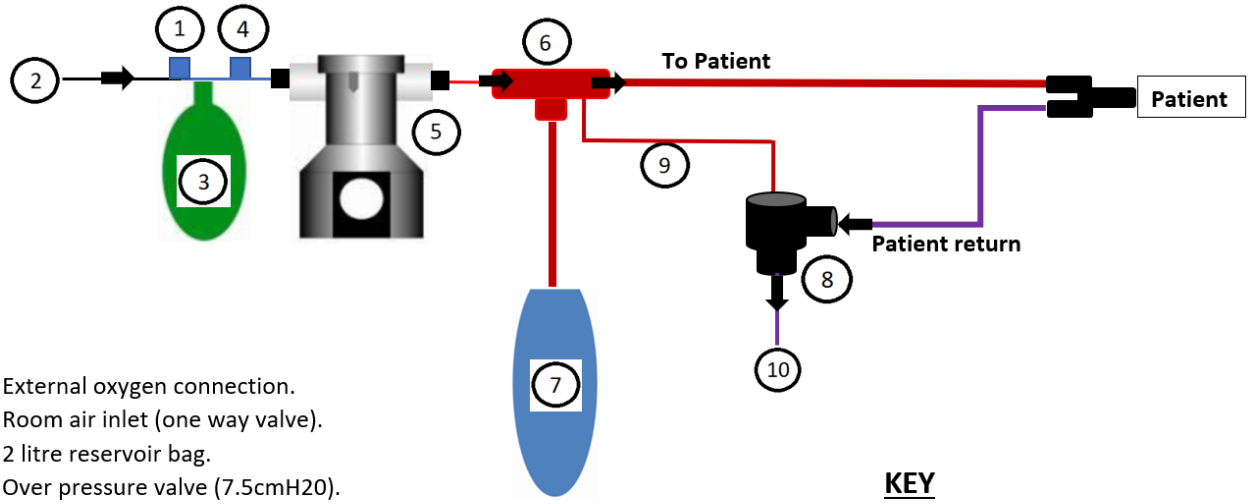
The breathing system.



A length of standard respiratory tubing (supplied) for scavenging of expired gases away from the operational area to be attached here.

1. The Inspiratory valve **(A).** This consists of a one-way valve at either end of a clear cylindrical tube to control the direction of flow. The side wall of the tube has 2 further connections as
2. A Self-inflating bag **(B)** is connected to a connection port on the side wall of the inspiratory valve. This is used to induce flow across the vaporiser and on to the patient when not breathing spontaneously.
3. The Expiratory valve **(C).** PEEP valve can be affixed to the vent port of this valve – Refer to section 10.
4. Pressure stabilization tube **(D)** between inspiratory and expiratory valves. This closes the expiratory valve during the inspiratory phase to allow the lungs to fill
5. 22mm silicon respiratory tubing **(E^1 & E^2)** is connected to the Inspiratory and expiratory valves with the opposite ends joined together with a standard 'Y' piece and 1 litre bag to act as a test lung.

Gas Circuit diagram



1. External oxygen connection.
2. Room air inlet (one way valve).
3. 2 litre reservoir bag.
4. Over pressure valve (7.5cmH20).
5. Vaporiser.
6. Inspiratory valve.
7. Self-inflating bag.
8. Expiratory valve
9. Pressure stabilisation tube
10. 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

The Diamedica Portable Anaesthetic machine DPA 02 must be assembled as follows.

Position and secure the vaporiser

(1) Remove the vaporiser from the storage location and place it on the wire grill.

(2) Secure the back of the vaporiser to the upright partition of the stand using the supplied screw.

Assemble and attach the reservoir block

(1) Take reservoir block and affix the reservoir bag to the connection port on the opposite side to the pressure relief valve.

(2) Attach the assembled reservoir block to the input port on the left side of the vaporiser.

(3) If using a supplementary Oxygen supply connect this to the supply port on the end of the block with the other end connected to the regulator if using a cylinder or directly to the supply port of an oxygen concentrator. Refer to Section 6.

Assembly of breathing system.

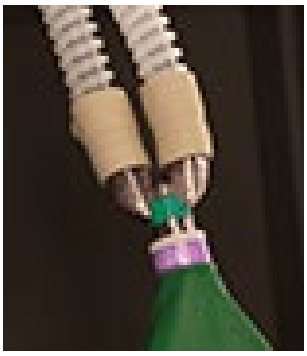
1. Attach the Inspiratory valve to the vaporiser outlet ensuring the direction of flow is correct (Arrows pointing away from the vaporiser).

2. Attach the self-inflating bag and tube to the port between the two valves on the inspiratory valve.

3. Fix the expiratory valve to the case

4. Assemble the two corrugated tubes to the Y piece and fit the 1 litre test lung

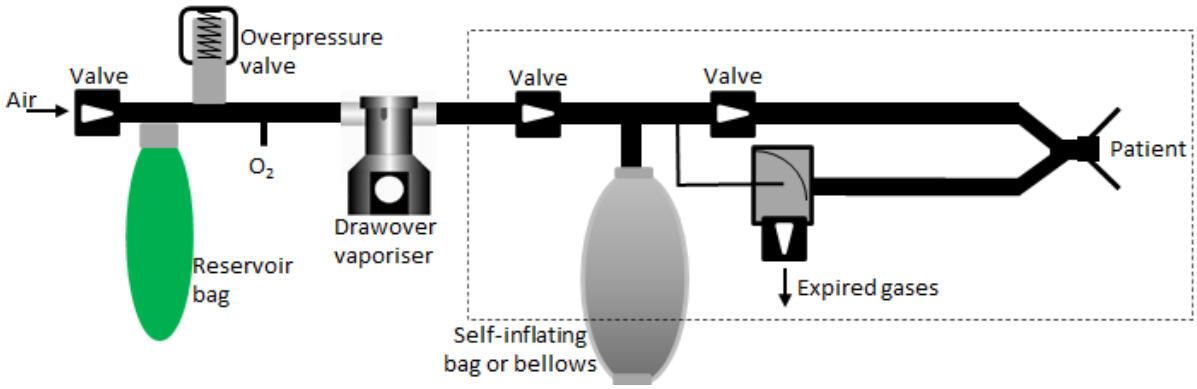
   NOTE
   Test lung to be replaced with patient interface once correct circuit set-up is confirmed.

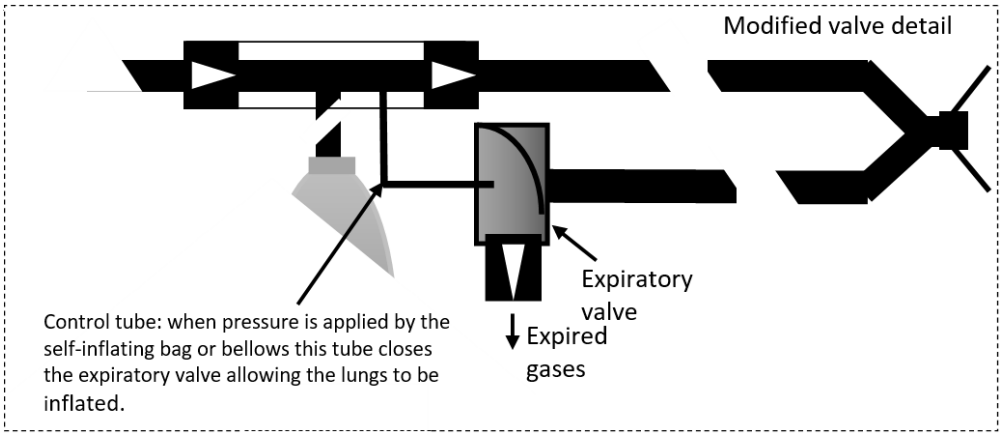


5. Attach one off the tubes to the outlet of the inspiratory valve and the other tube to the Expiratory valve.

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.





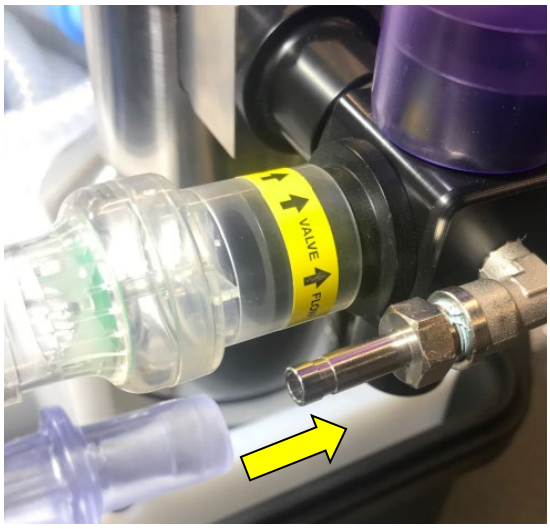
The vaporisers are designed to be used with specific anaesthetic agents as clearly labelled. Where dual agents are permitted it is the users' responsibility to ensure that only same agent is added to the vaporiser or that the chamber is emptied before filling with fresh agent. In the case of single agent vaporisers, 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.

Ensure that only a single agent as specified on the scale is used.

6. SUPPLEMENTRY OXYGEN SOURCES

The DPA series will accept supplemental oxygen from an oxygen concentrator.
It will also accept supplemental oxygen from a regulated cylinder (the regulator flowmeter below is supplied), or from a regulated central oxygen supply.



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.

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.

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.

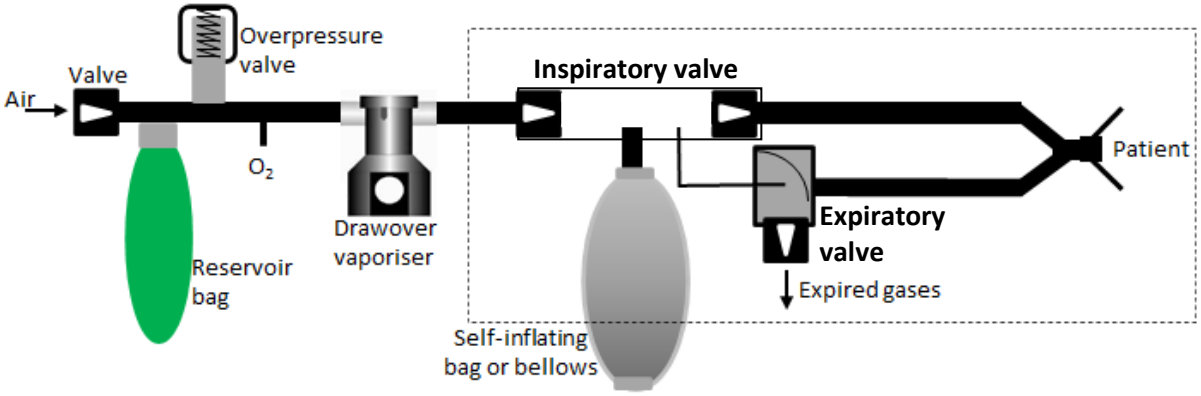
Test anaesthetic circuit. Attach a one litre reservoir bag to the end of the patient circuit to act as test lung. Compress the self-inflating bag to demonstrate expansion of test lung and simultaneous movements of reservoir bag.

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

Unit is now ready for use

8. USE OF THE DPA 02 ON ADULTS

In Adult patients (and paediatric patients above 10 kg) the standard Y piece dual limb circuit is used (Refer to Section 5 – Control and operation).

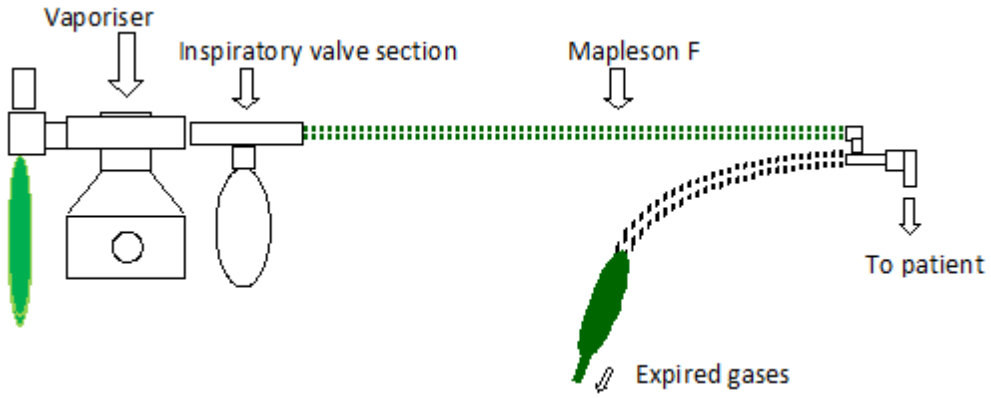


Correct vaporiser settings for induction and maintenance of anaesthetised stated are clinical decisions based on patient evaluation and ongoing monitoring.

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.

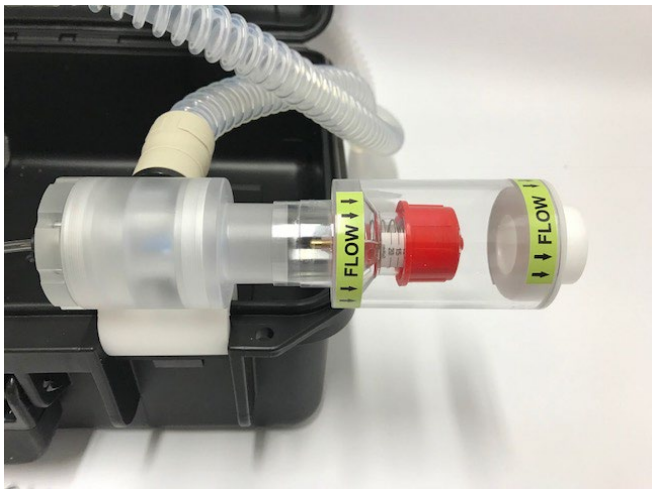
Ayres 'T' Piece paediatric circuit
The circuit can be connected directly to the inspiratory valve section as below. It is recommended that this circuit should be used with a minimum fresh gas flow from concentrator or cylinder of at least 3 x the patient's minute volume.



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

10. PEEP (positive end expiratory pressure)

PEEP can be fitted to the DPA 02 by connecting to the expiratory valve 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 red 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 scale is correct for both Halothane and Isoflurane. A Sevoflurane version of the vaporiser is also available.

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 vaporiser is filled by unscrewing the filler cap and pouring the agent directly from the bottle into the chamber. No special filling device is required although a funnel is available if needed. If the vaporiser requires filling during anaesthesia, then the vaporiser must be turned off while being filled.

If fitted with a Sevoflurane vaporiser filling is carried out 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 completely?

A. This can be done by one of two methods.

1. Remove the vaporiser from the standby releasing the captive screw at the back of the upright section. The filler cap is removed, and the vaporiser inverted over the bottle until fully drained using the funnel if required.
2. Remove the filler cap / agent specific filler then draw up the agent using a syringe.

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?

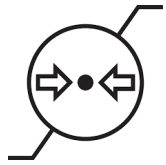
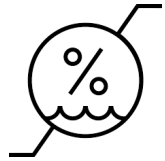
A. The vaporisers have been designed to require minimal maintenance. Refer to Section 3

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 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 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, handlewith care	Indicates a medical device that canbe 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

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