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DPA 02™

Diamedica Portable Anaesthesia System

INSTRUCTIONS FOR USE MANUAL

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Read this page first

INTENDED USE

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 DPA02 facilitates 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 DPA02 Anaesthesia System.

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 01, DPA 02 and DPA 03 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 System and its associated applications include any medical conditions which may contraindicate the medical procedure itself.

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 during anaesthesia.

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

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

The system is only intended to be used by Qualified Anaesthetists

Fig. 1

The Diamedica Portable Anaesthetic machine DPA 02™ has three principal components; vaporiser, reservoir, and breathing system. It can be rapidly assembled ready for use as follows:

(1) The vaporiser

Remove the vaporiser from the container and place it on the wire grill. Fix the vaporiser to the stand using the captive screw at the back of the upright section.

(2) The reservoir. See Fig 2

The following parts of the reservoir are identified;
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. A solid block with four openings and a metallic nozzle.

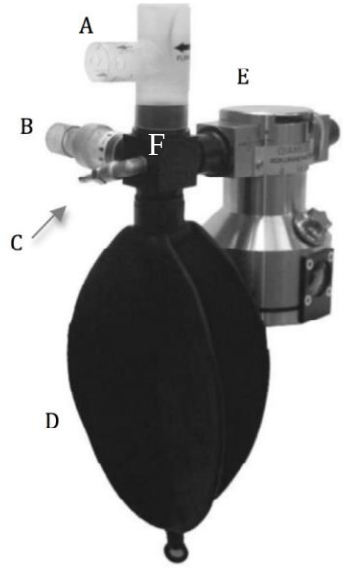

Fig. 2

Assembly of reservoir:

1. While standing in front of the vaporiser and facing the DPA 02 anaesthetic machine, hold the reservoir block so that the metallic nozzle (C) is on the left and pointing away from you.
2. Attach the reservoir block to the input port on the left side of the vaporiser
3. With the reservoir block firmly in place attach as follows:
4. To the rear port attach the air entry valve with the arrows pointing forward
5. To the top port attach the pressure relief valve so that it stands vertically.
6. To the bottom port attach the green reservoir bag

7 To the metallic nozzle attach the clear oxygen tubing from the oxygen source.

(3) The breathing system (See Fig. 3)

The following parts of the breathing system are identified:

1. The valve unit. This consists of two separate clear cylindrical valves known as the inspiratory (A) and expiratory (B) valves, connected by a 20cm length of clear narrow tubing (C). The inspiratory valve is long, narrow and has a side port. The expiratory valve is short, wide and has a fixing bracket.
2. Self-inflating bag (D) (a smaller size is available for children)
3. A dual limb of 22mm Silicon tubing (E) ending in a standard 'Y' piece
4. A 1 litre reservoir bag to act as test lung.
5. A length of standard respiratory tubing for scavenging of expired gases.

Assembly of breathing system:

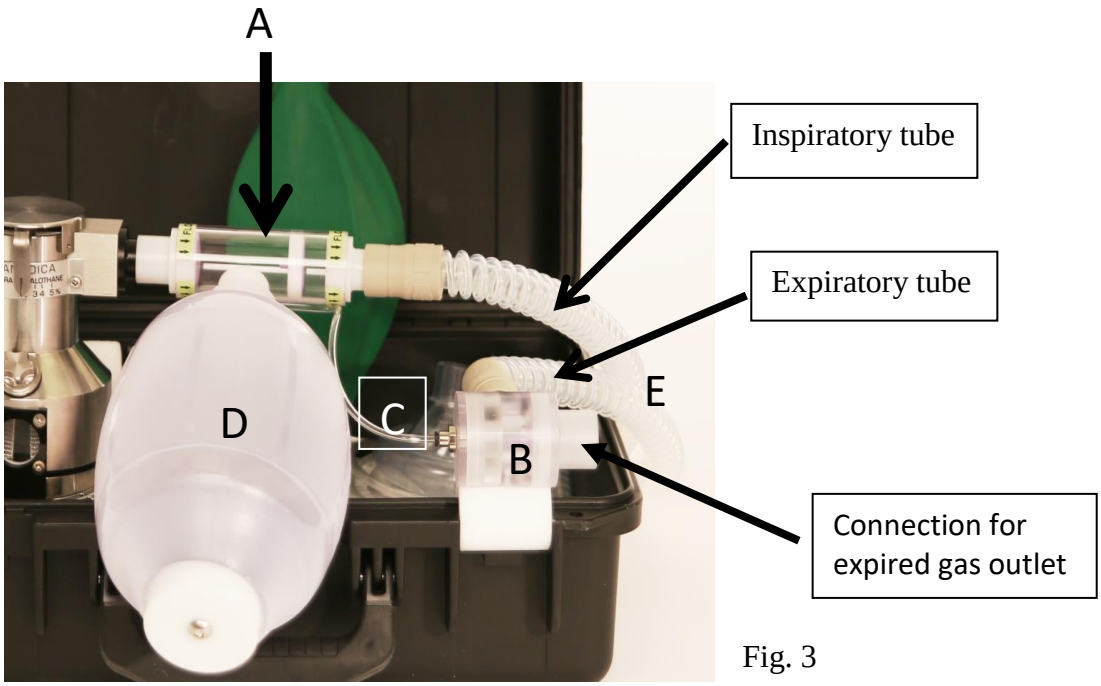

Fig. 3

1. Attach the narrow inspiratory valve (A) to the exit port of the vaporiser. Rotate the valve so that the side port points downwards and forwards at an angle of approx. 45 degrees.
2. Attach the self inflating bag (D) to the side port of the inspiratory valve so that it lies in front of the case pointing downwards (this can also be connected by the additional supplied 22mm silicone tube).
3. Take the expiratory valve (B) and insert the on to the case. Tighten the metallic screw located below the expiratory valve to secure it in position.
4. Attach one side of the dual limb respiratory tubing to the inspiratory valve and the other to the expiratory valve.
5. Attach scavenging tube to expiratory valve 30mm outlet.

To test the assembly: Attach the test lung (1 litre green reservoir bag) to the patient end 'Y' piece of the respiratory tubing and confirm the integrity of the system using the self inflating bag.

Main Circuit

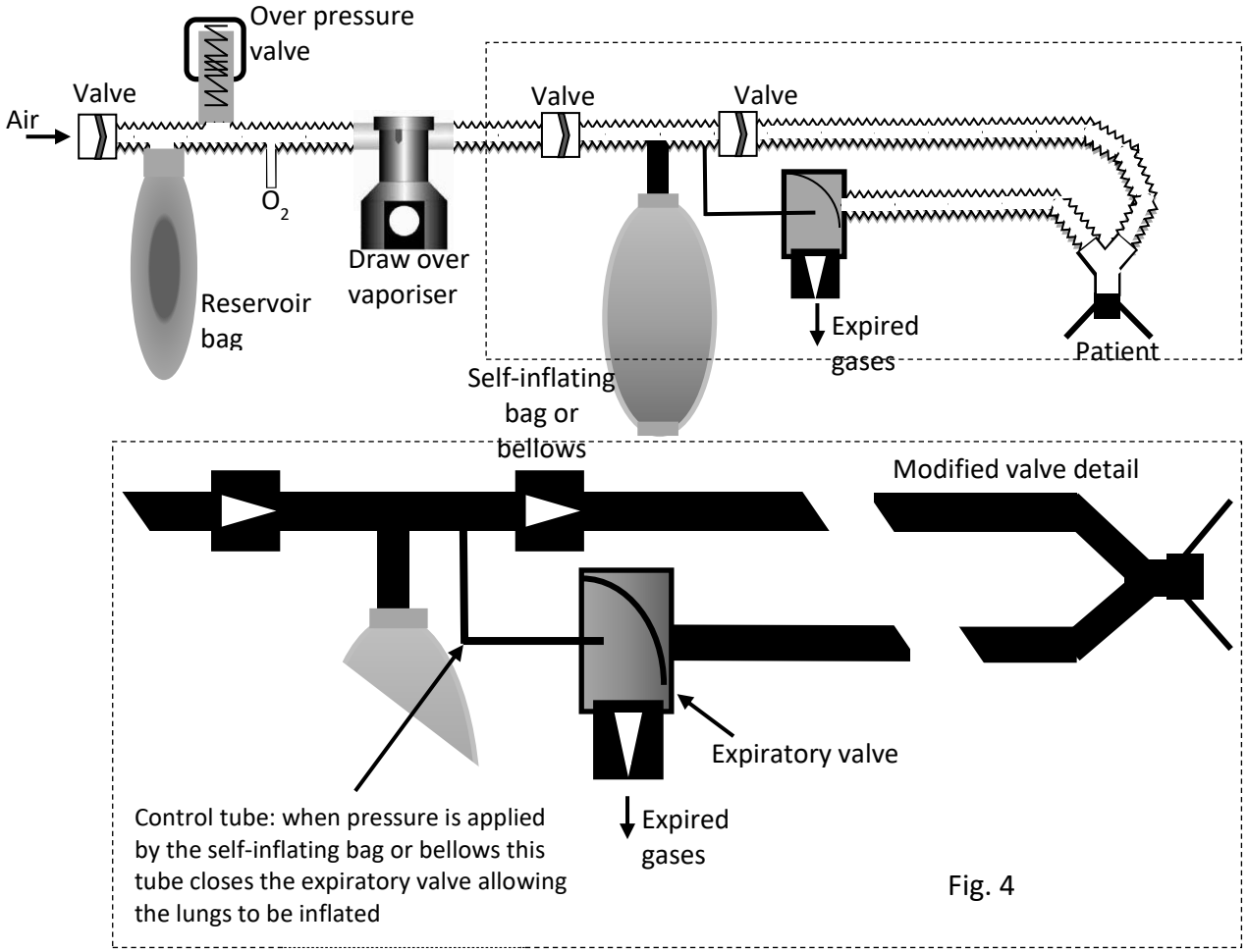

Fig. 4

Note: The self-inflating bag or bellows may be replaced by a suitably designed ventilator

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 flow capabilities of the draw-over vaporiser are 1 – 35 L/min

If the supplementary flow rate is greater than 4 lt/min the patient circuit can be replaced with a paediatric circuit (Mapleson F) suitable for continuous flow / assisted ventilation with small children.

ALWAYS ENSURE THAT YOUR ASSEMBLED UNIT IS SECURELY POSITIONED AND THAT THE VAPORISER IS AS LEVEL AS IS PRACTICABLE. IN ANY CASE THIS SHOULD ALWAYS BE LESS THAN 30° FROM THE HORIZONTAL.

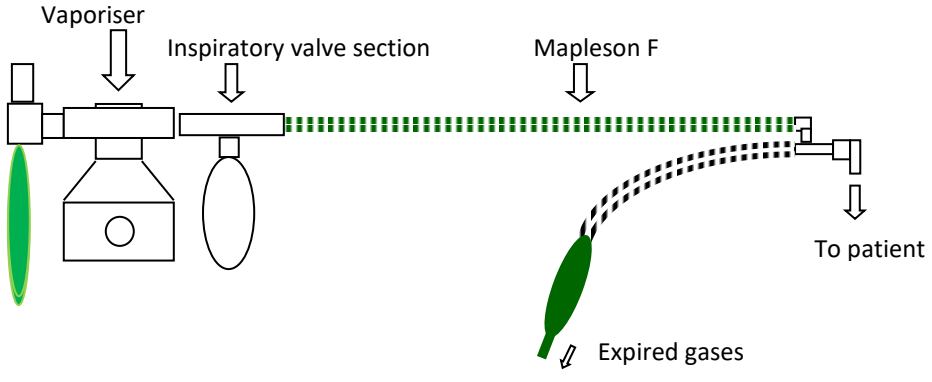

Fig. 5

Inspiratory arm of valve for DPA Portable

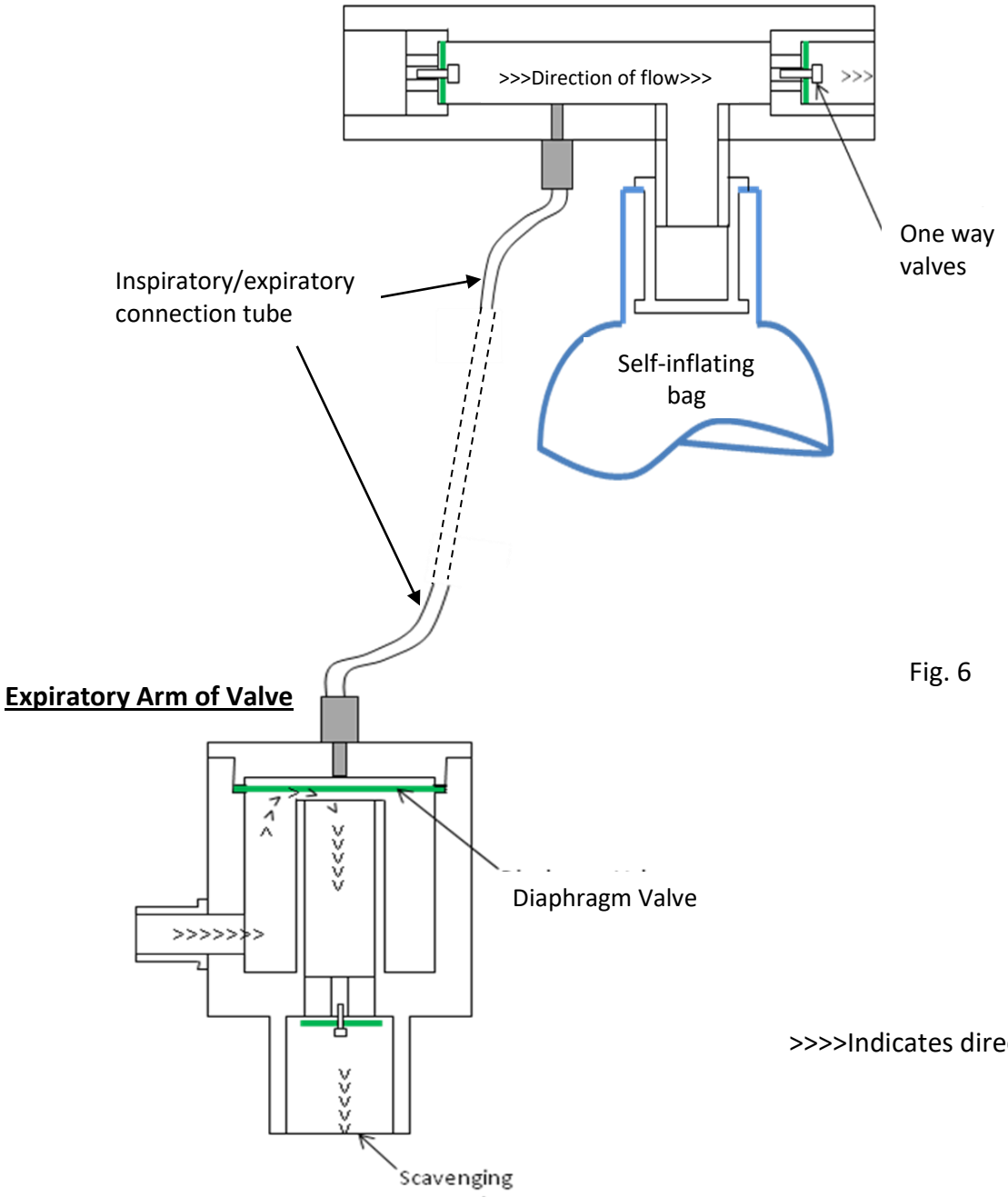

Fig. 6

>>>>Indicates direction of flow >>>>

Valve and Patient Circuit

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.

Fig. 7

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.

Fig. 8

CLEANING AND GENERAL MAINTENANCE

Cleaning and maintenance

The DPA 02 is designed to require minimal maintenance and cleaning, however some basic cleaning is identified below.

Patient safety is the primary concern of the anaesthetist and infection control is critical to ensuring the safety of surgical procedures.

Each DPA02 is supplied with a breathing circuit and as these items may come in contact with the patient they can therefore potentially pass infectious agents from one patient to another if used improperly.

The breathing tubing provided with the DPA 02 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.

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

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 vaporiser, 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. Set to zero.
2. Turn it upside down, and shake it vigorously followed by turning the lever until it becomes loose.
3. When the lever loosens, the vaporiser should be drained and rinsed with fresh agent.
4. Attach the vaporiser to the stand and fill with fresh halothane.

If the anaesthetist has any concerns relating to cleaning or maintenance or the function of the DPA 02 they should contact the manufacturer.

Ensure that agent is removed from vaporiser before securing in Peli-case for transportation

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

Accessories and spares

All accessories used with the DPA 02™ 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

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 industry practice.

Frequently asked questions on the breathing system.

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

A. The scale is calibrated for both Halothane and Isoflurane. A Sevoflurane version of the vaporiser is also now available. If ether is the only volatile agent available it must be vaporised in a different vaporiser.

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.

Q. How can the vaporiser be emptied completely before a different agent is used?

A. Remove the vaporiser from the stand by 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. 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 vaporiser has been designed to require minimal maintenance. If movements of the dial lever become stiff, the shuttle casing should be cleaned. A small quantity of Halothane is poured into the chamber which is inverted and shaken several times before being discarded.

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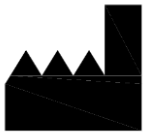
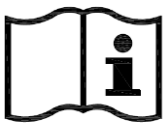
SYMBOLS GLOSSARY

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.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	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 have the presence of natural rubber latex	
	Indicates that an object is capable of being recycled	