ENG

GLOSTAVENT® ECO2 ANAESTHESIA SYSTEM

INSTRUCTIONS FOR USE MANUAL

For anaesthesia in difficult circumstances

Diamedica (UK) Ltd
Grange Hill Industrial Estate
Bratton Fleming, Barnstaple,
Devon, EX31 4UH, United
Kingdom

Tel: +44 (0)1598 710066
WhatsApp: +44 (0) 7716 503156
Email: support@diamedica.co.uk
Web: www.diamedica.co.uk

EC REP Alphamed Consulting Ltd, Knock, Barnaderg, Tuam,
Co. Galway, H54 W220

CE 1639

Revision D 08/03/2022 DCN-0152

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 Glostavent® ECO2 Anaesthesia machine is not intended for use in The EU (With the exception of supervised training by qualified personnel). It is suitable for use in dry non-condensing atmospheres and should be kept free of surface liquid.

The Glostavent® **ECO2** facilitates the administration of inhalational anaesthesia andrespiratory 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 Glostavent® ECO2 Anaesthesia System. The information given inthis manual is correct at the date of publication.

Separate IFU Manuals for the UPS and Oxygen Concentrator are also included andmust be reviewed for specific Safety and maintenance requirements before use.

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

Users of the Glostavent® ECO2 Anaesthesia System must read, understand, and follow the guidance given in this manual before using the system.

THE NEED FOR PATIENT MONITORING.WARNING.

The Glostavent® ECO2 Anaesthesia System delivers mixtures of gases and vapours which could cause injury or death to the patient. The effect of anaesthesia drugs onindividual patients can vary so that “typical” machine settings for concentrations delivered to the patient do not necessarily ensure patient safety.

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

Do not cover the device whilst in use or place in a position that affects its effective operation e.g., do not obstruct air inlets or equipment ventilation grilles.

Do not add any attachments or accessories that contravene the instructions for use, as this may cause the unit to function incorrectly, leading to the risk of a serious deterioration of health of the patient.

Medical conditions which contraindicate the use of a Glostavent® ECO2 Anaesthesia System and its associated applications include any medical conditions which may contraindicate the medical procedure itself.

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.

The ultimate responsibility for patient or procedure contraindication lies with the anaesthetist.

Pressure readings indicated on the gauge on the front panel 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.

Mains power supply isolation:

1. Switch off UPS.
2. Disconnect the mains supply cable from the UPS to the power socket (see Section 4).

The Glostavent ECO2 is not a ventilator and 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 Glostavent® 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 Glostavent ECO2 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 havea 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. It must not be used with a mechanical ventilator due to the risk of explosion.

Drawover anaesthesia is contraindicated for patients below 10kg, for these patientsthe 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.

Classification and Electromagnetic Conformity

Classifications

The Glostavent ECO2 Anaesthesia machine has the following classifications (EN 60601-1:2006 +A12:2014

Protection against shock.

When connected to a mains AC source via the supplied lead, the machine is Class I 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

IPXX

Individual components have identified protection as below.

Oxygen Concentrator -IP21

Battery recharger – IP67

UPS – IP20

Method(s) of sterilization

The Glostavent ECO2 Anaesthesia machine 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 Glostavent ECO2 Anaesthesia machine is suitable for continuous operation subject to a power supply. Time limited operation if removed from power.

Electromagnetic conformity

The Glostavent ECO2 Anaesthesia machine is a mains powered mobile 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**	UKAS/non-UKAS	Pass / Fail
EN 60601-1-2: 2015	**Medical electrical equipment - General requirements for basic safety and essential performance – collateral standard: Electromagnetic compatibility – Requirements and tests**	**UKAS**	
EN 61000-4-2: 2009	Electrostatic Discharge	UKAS	Pass
EN 61000-4-3: 2006 + A2	Radiated RF Immunity Table 9	UKAS	Pass
EN 61000-4-4: 2012	Fast Transient and Burst Immunity	UKAS	Pass
EN 61000-4-11: 2004	Mains Dips and Interruptions	UKAS	Pass

In addition to the above evaluations the independent components listed below have also been subjected to compliance approval and this is noted in their respective IFUs supplied with this device.

Oxygen Concentrator

UPS

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 power leads 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.

Consult the manufacturer for help when required.

THE GLOSTAVENT ECO2 ANAESTHESIA SYSTEM

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 flow mode
7. Able to continue to function without interruption in the absence of oxygen or electricity.

In response to these suggestions the ECO2 ANAESTHESIA SYSTEM anaesthetic machine has been designed to meet the requirements of anaesthetists working in difficult environments in situations where surgery is limited to spontaneously breathing patients or those requiring only assisted or intermittent ventilation.

This manual has been prepared to provide practical guidance for those using the ECO2 ANAESTHESIA SYSTEM anaesthetic machine. It should only be operated by experienced anaesthetists who have received specific training in its use and are fully conversant with its operation.

2. SPECIFICATIONS

The Glostavent ECO2 Anaesthesia machine is suitable for adult and paediatric use. The specifications for Glostavent ECO2 are provided in the table below.

Component / Feature		Specification
Dimensions	Height	145cm
	Width	66cm
	Depth	54cm
Weight		74kg
Ingress protection (IP)		IPXX Individual components are assessed as follows;
		Oxygen Concentrator IP21 UPS IP20 12v Charger lead IP40
Electrical Safety classification		Class I Equipment. (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
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%
Oxygen Concentrator		
Flow rate oxygen (l/m)		0 – 10 l/m
Flow rate air (l/m)		0 – 10 l/m
Alarms		High/Low pressure Low flow Low oxygen Power fail

Power Supply	230 VAC, 50 Hz
Power consumption	600 Max
Conforms to	CE marked. IEC 60601-1:2005
UPS	
Type	2 KVA double on-line
Circuit breaker	16 A
Standard operating input range	230VAC 50Hz
Input tolerance	110-330VAC 45/65Hz
Onboard Batteries	4 x 12v 12ah
Conforms to	EN62040-1 EN62040-2

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%

*** 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	Concentrator hours	Agent	Comments / Completed tasks

Suggested usage log for Glostavent ECO2 Anaesthesia machine

a) Cleaning

The anaesthesia workstation 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. Pay attention to warning labels (As shown below).

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 Glostavent ECO2 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.

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

(ii) Filters

It is very important to check the condition of the particulate filters on the rear of the Glostavent panel and on the rear of the concentrator, at least once every week, and more often if the environment is very humid and dusty. If the air filter is dirty then it must be cleaned with by washing in clean soapy water and then rinsed, removing as much water as possible and replacing.

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 control panel and 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, 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.

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

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

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.

✉ Email: support@diamedica.co.uk

WhatsApp: +44 (0) 7716 503156

a) Accessories and spares

All patient circuit accessories used with the Glostavent anaesthesia machine 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

b) Method for disposing of the device.

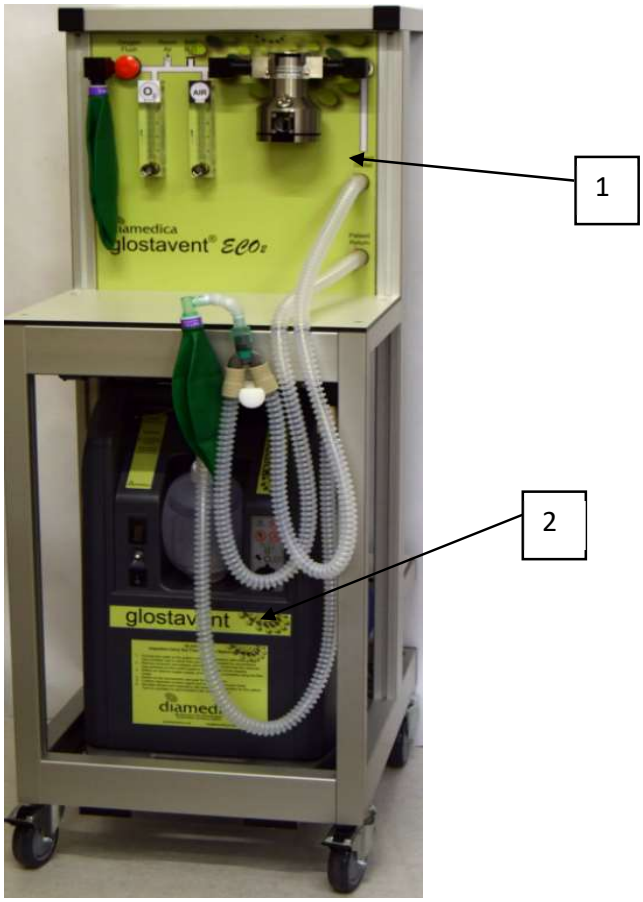
If the product is returned to the manufacturer at the end of its life the company will ensure disposal in line with the Waste Electrical and Electronic Equipment Directive (WEEE) 2012/19/EU

4. THE THEORY OF THE GLOSTAVENT ECO2 ANAESTHESIA SYSTEM

The ECO2 ANAESTHESIA SYSTEM is a free-standing anaesthetic machine which 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 can continue to function, without interruption, if either the oxygen or electricity supply fails.

The ECO2 ANAESTHESIA SYSTEM has two principal components which make this possible. These are:

1. A breathing system which can function in the absence of pressurised oxygen.
2. An oxygen concentrator which produces both oxygen and air for the patient to breathe.



THE BREATHING SYSTEM

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

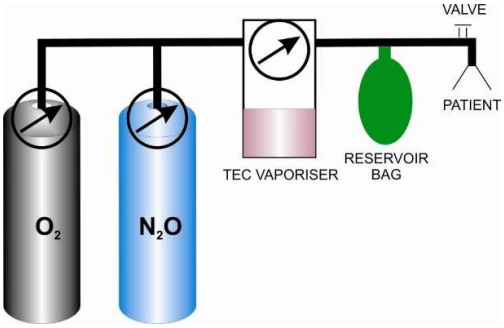
Flow →  **→ Flow**

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 (Fig 2).

In the standard continuous flow type of anaesthesia machine, the carrier gas is PUSHED through the vaporiser by gases under pressure (Fig 3). Under normal conditions, i.e. when oxygen is available, this system works well but there is one serious disadvantage. It is entirely DEPENDENT ON AN UNINTERRUPTED SUPPLY OF PRESSURISED OXYGEN. If the oxygen supply fails, as it frequently does in many parts of the world, a continuous flow type of anaesthetic machine cannot function.

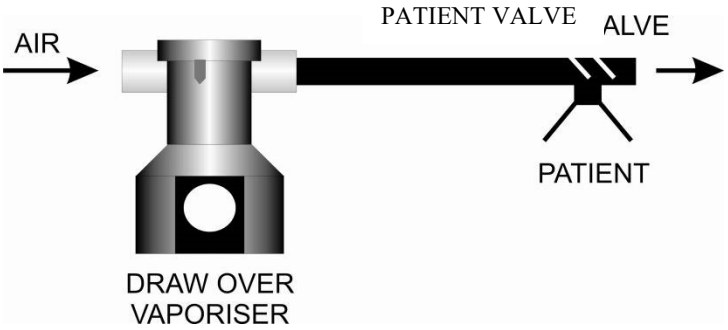
The ECO2 ANAESTHESIA SYSTEM will function as a continuous flow machine when gases are provided by the concentrator or an auxiliary source. However, if the electricity fails and there is no auxiliary 'cylinder; oxygen available it will default to a drawover machine in order for anaesthesia to continue safely.

CONVENTIONAL CONTINUOUS FLOW SYSTEM



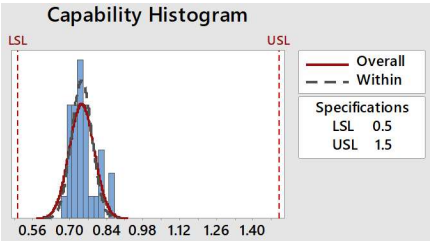
By contrast, in DRAWOVER anaesthesia the carrier gas is DRAWN over the vaporiser by negative pressure generated by the patient's inspiration (Fig 4). The great advantage of draw over anaesthesia is that it can still be administered EVEN IF THE OXYGEN SUPPLY FAILS. In this situation room air, containing 21% oxygen, can be used as the carrier gas for the volatile agent which is supplemented with oxygen if available.

DRAWOVER SYSTEM

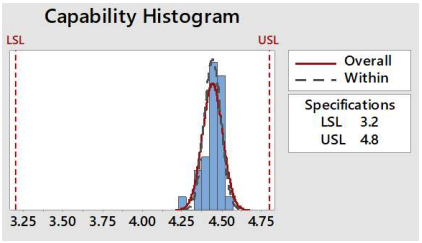


Because of the frequency of failure of the oxygen supply in some parts of the world the ECO2 ANAESTHESIA SYSTEM can use either a continuous flow or a drawover breathing system. This conversion happens automatically in the event of gas failure or drawover can be used in order to conserve both oxygen and anaesthetic agent. This is described further in later sections of the manual.

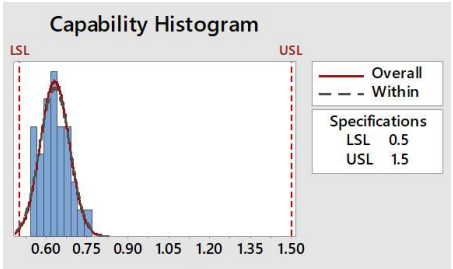
The flow capabilities of the draw-over vaporizer meet the requirements of ISO 18835:2015 and can operate consistently up to an intermittent peak inspiratory draw of 35 L/min
Typical capabilities @ 6l/min are represented in the graphs below.



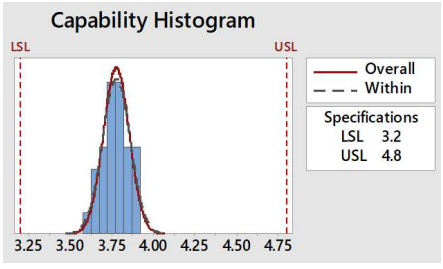
1% Continuous



4% Continuous



1% IPPV

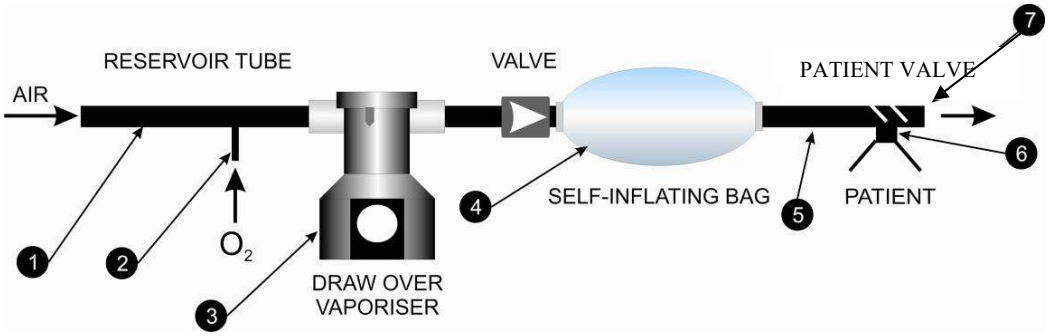


4% IPPV

FEATURES OF THE DRAWOVER SYSTEM

In its simplest form, a drawover system has the following features (Fig 5):

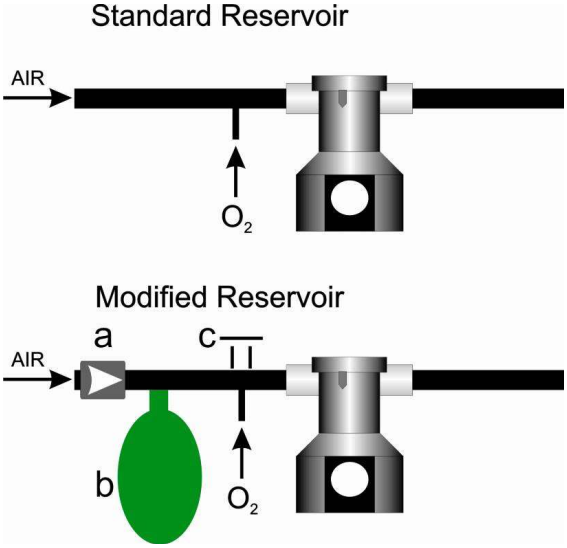
1. A reservoir tube with an open end through which air is entrained during inspiration
2. A side port for supplementary oxygen, if available.
3. A vaporiser with a low resistance to breathing, such as the ECO2 ANAESTHESIA SYSTEM vaporiser above. (The standard plenum type vaporiser, such as the Selecta-tec, is unsuitable for drawover anaesthesia because the resistance is too high).
4. A self-inflating bag or bag for I.P.P.V. with a valve to ensure the anaesthetic mixture moves towards the patient and cannot re-enter the vaporiser.
5. Inspiratory tubing leading to the patient.
6. A non-rebreathing valve system either at the patient's airway. e.g. Laerdal or Ambu valve or in the case of the ECO2 ANAESTHESIA SYSTEM a new valve system allowing a conventional circuit with no valve required at the patient airway. This ensures that, during inspiration, the anaesthetic mixture is not diluted by atmospheric air and that, during expiration, the expired gas cannot re-enter the system and lead to re-breathing. The valve can function with either spontaneous or controlled ventilation.
7. Expiratory port leading to a scavenging system if available.



The function of the reservoir tube is to store the supplementary oxygen during the phase of expiration so that it is not wasted and is included in the patient's next breath. This enables satisfactory inspired oxygen concentrations to be achieved with minimal flows of supplementary oxygen (Fig 6).

In a simple drawover system, the reservoir consists of a one metre length of corrugated anaesthetic tubing. While this is satisfactory during normal breathing it is less satisfactory during hyperventilation, for example as occurs during pre-oxygenation. This is because, when respiration is increased, more air is drawn into the reservoir and the oxygen is diluted. To increase the efficiency of the drawover system the reservoir has been modified for the ECO2 ANAESTHESIA SYSTEM by three additions.

To further enhance the system the circuit has been replaced by a 'Y' circuit allowing the Patient valve at the end of the circuit to be modified by a new valve and relocated away from the patient in the control panel. This leaves access to the patient's airway much improved (Fig 8).



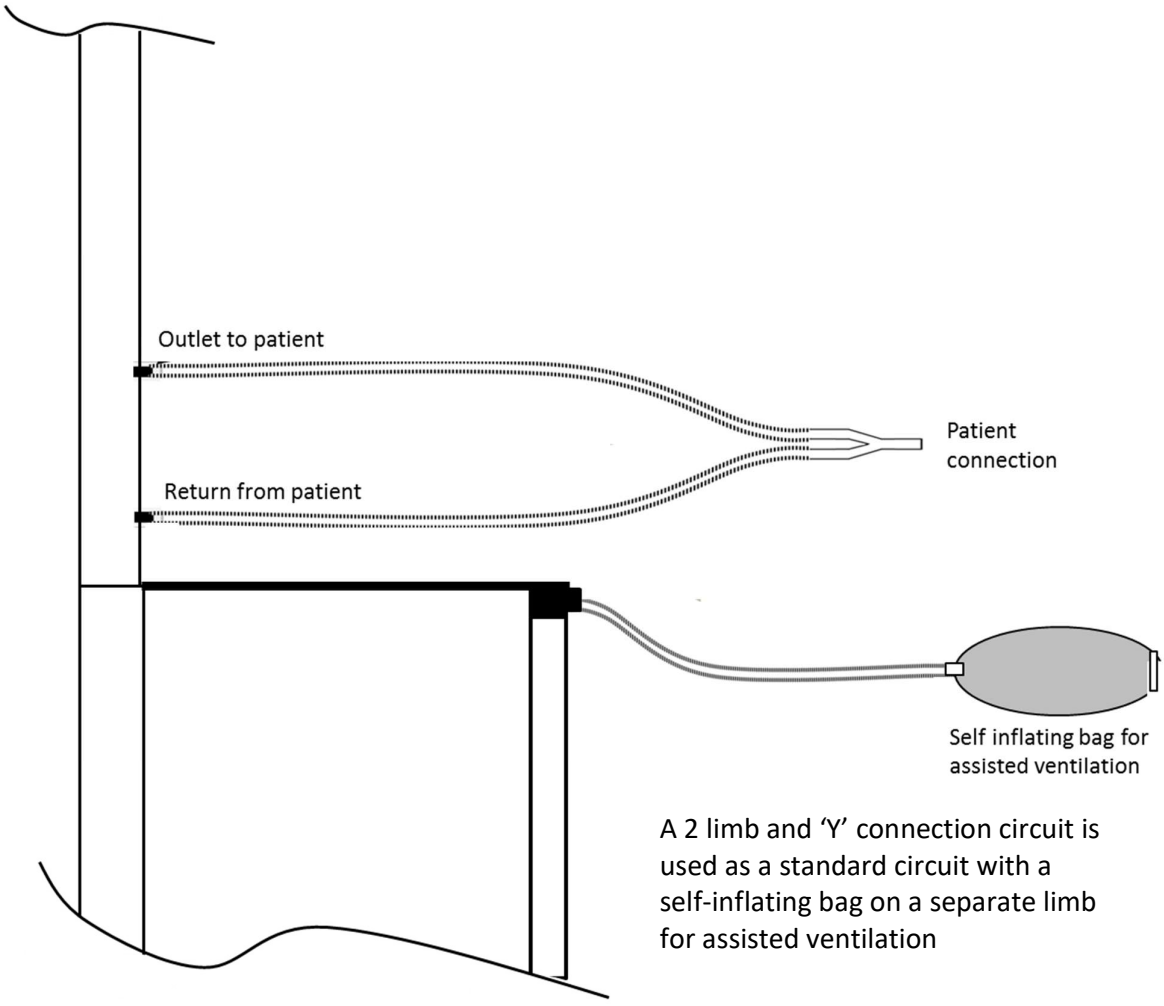
(a) A valve at the open end to prevent spillage of oxygen
(b) A reservoir bag to increase the volume of the reservoir. Movement of the reservoir bag also provides an indication of the rate and depth of respiration.
(c) A blow-off valve set at 5 cm H_20 to prevent over-distension of the reservoir bag.

The modified reservoir conveys one other important advantage. It enables the ECO2 ANAESTHESIA SYSTEM to be used for both *continuous flow* and *drawover* anaesthesia simply by adjusting the rate of gas flow in relation to the patient's minute volume.

DRAWOVER MODE. If the patient's minute volume leaving the reservoir exceeds the supplementary oxygen flow entering the reservoir, the pressure in the reservoir falls below atmospheric, air is drawn in through the open end of the reservoir tube and the system is in drawover mode.

CONTINUOUS FLOW MODE. If the supplementary oxygen flow rate is increased until it exceeds the patient's minute volume, the pressure in the reservoir rises and the system automatically transfers to continuous flow mode. A one-way valve after the vaporiser on the ECO2 ANAESTHESIA SYSTEM prevents backflow through the system when these circuits are in use.

STANDARD PATIENT CIRCUIT



A 2 limb and 'Y' connection circuit is used as a standard circuit with a self-inflating bag on a separate limb for assisted ventilation

FREQUENTLY ASKED QUESTIONS ON THE BREATHING SYSTEM

Q. What are the disadvantages of the drawover system?

A. (1) In earlier systems it was difficult to achieve high FiO2 levels during hyperventilation such as during pre-oxygenation. This is because additional air is sucked into the reservoir, diluting the oxygen. This problem has been largely alleviated by the introduction of the modified reservoir.
(2) Gaseous induction requires an airtight seal at the facemask so that sub-atmospheric pressure can be generated. This may be difficult in uncooperative children or in the presence of facial injury. With the modified reservoir this problem can be solved by conversion to continuous flow mode.

Q. How is the draw over system flushed with oxygen in an emergency situation?

A. The vaporiser is turned off while the oxygen flush button on the ECO2 ANAESTHESIA SYSTEM control panel is depressed for 10 seconds to purge the circuit of the anaesthetic mixture. The oxygen flowmeter is set to maximum, and the lungs ventilated with oxygen.

Q. Does the ECO2 ANAESTHESIA SYSTEM vaporiser have any advantage over a standard plenum type vaporiser?

A. (1) It has a low resistance allowing patients to breathe spontaneously through it.
(2) The same vaporiser can be used for two volatile agents.
(3) It is less expensive.
(4) It has a simple design and can be serviced and maintained by local hospital personnel.

Q. Which volatile agents can be used with the ECO2 ANAESTHESIA SYSTEM vaporiser?

A. The scale is calibrated for both Halothane and Isoflurane. A Sevoflurane version is also available.

Q. How is the vaporiser filled?

A. The halothane/ isoflurane 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 supplied. If the vaporiser requires filling during anaesthesia, then the vaporiser must be turned off while being filled.

The Sevoflurane vaporiser is filled using a key fill connection specific for sevoflurane, this is done by sliding the bottle filler into the vaporiser and pushing down to fill. The vaporiser must be switched on while being filled.

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

A. The door on the back of the control panel is opened and the screw supporting the vaporiser is located so that the vaporiser can be unscrewed and removed (see fig 12 item 5). 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 vaporiser is replaced, the dial turned on fully and gas is blown through the chamber for several minutes until the vapour can no longer be detected.

Q. How is the breathing circuit cleaned between patients?

A. If no patient filter is available the circuit should be washed in warm soapy water between patients as required.

Q. How can respiratory movements be monitored in drawover anaesthesia?

A. Movements of the reservoir bag can be used as a guide to the depth and rate of respiration, additionally the ECO2 ANAESTHESIA SYSTEM has a rotating expired breath indicator.

Q. What is the most effective way of pre-oxygenation of patients?

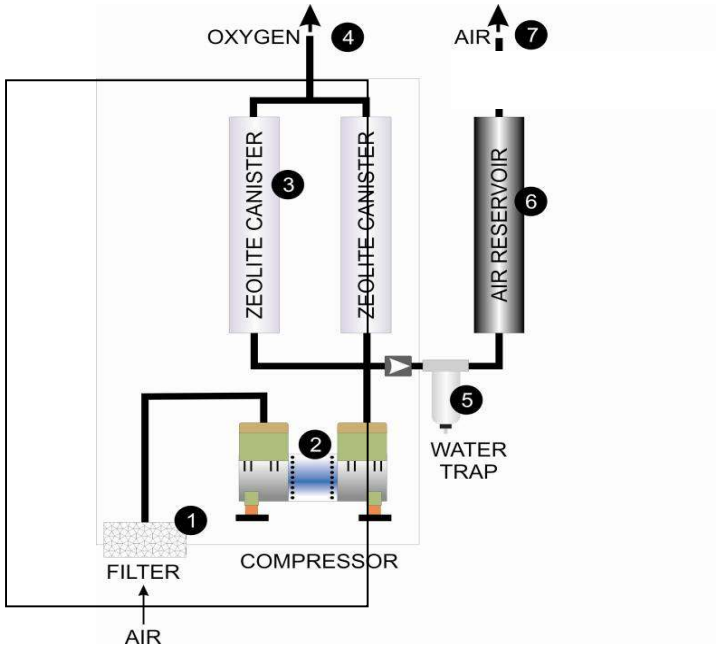
A. Satisfactory pre-oxygenation can be achieved with the ECO2 ANAESTHESIA SYSTEM drawover circuit using an oxygen flow rate of 10 L/min.

Q. What regular maintenance is required for the ECO2 ANAESTHESIA SYSTEM 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.

THE OXYGEN CONCENTRATOR

Cylinders of oxygen are expensive and may run out whereas atmospheric air costs nothing and does not run out. For this reason, atmospheric air is used as the principal source of oxygen for the ECO2 ANAESTHESIA SYSTEM, delivered by means of an oxygen concentrator.



The oxygen concentrator is a device that can produce a supply of oxygen from atmospheric air. The air is drawn into the concentrator through a filter (1) and then compressed (2) to a pressure of 20 psi (140 KPa). Some of this compressed air then passes through canisters containing granules of zeolite (3) where the nitrogen is absorbed, and the residual oxygen delivered to the patient (4). The remainder of the compressed air passes through a water trap (5) which enables the water formed by condensation to be released at regular intervals so that it cannot obstruct the flow. This water is released automatically from the water trap drain. The air then enters the compressed air reservoir (6) from which it is available for the breathing circuit (7).

The concentrator is able to deliver simultaneously up to 10 litres/min of oxygen and 10 litres/min of air for the patient. The electricity consumption is only 590 Watts (equivalent to four electric light bulbs) and is the same regardless of the flow of gases.

FREQUENTLY ASKED QUESTIONS ON THE OXYGEN CONCENTRATOR

Q. How often does the zeolite need changing?

A. Unlike soda lime, zeolite does not need changing as the granules are constantly being re-charged. The same canisters can be used for many years dependant on usage hours.

Q. Can the concentrator function at high altitude?

A. Yes. It functions in the same way whatever the altitude within specification.

Q. Can the concentrator function when the humidity is high?

A. Yes. There is a water trap in the compressed air tubing to prevent condensation causing obstruction of the tubes.

Q. Can the concentrator function in the presence of high voltage fluctuations?

A. The Concentrator is connected to the mains via a UPS system which incorporates a voltage stabiliser enabling the Glostavent® to function in the presence of the following fluctuations dependant on load.
(40% load) 100V~300V AC
(100% load) 176V~300V AC

Q. Is there any advantage in using the concentrator if cylinders are available?

A. Yes. Cylinders of oxygen are expensive and may run out. In contrast atmospheric air costs nothing and does not run out. Therefore, whenever possible air should be the source of oxygen via the concentrator and cylinders of oxygen kept in reserve.

Q. **What are the servicing requirements of the concentrator?**

A. The concentrator requires minimal operational servicing. Refer to section 3 and the Concentrator IFU for specific details.

5. THE COMPONENT PARTS OF THE GLOSTAVENT ECO2 ANAESTHESIA SYSTEM

The individual components of the Glostavent® ECO2 ANAESTHESIA SYSTEM are interconnected on a mobile workstation with a flow meter control panel above the central work surface, and an oxygen concentrator below.

THE FLOW METER CONTROL PANEL

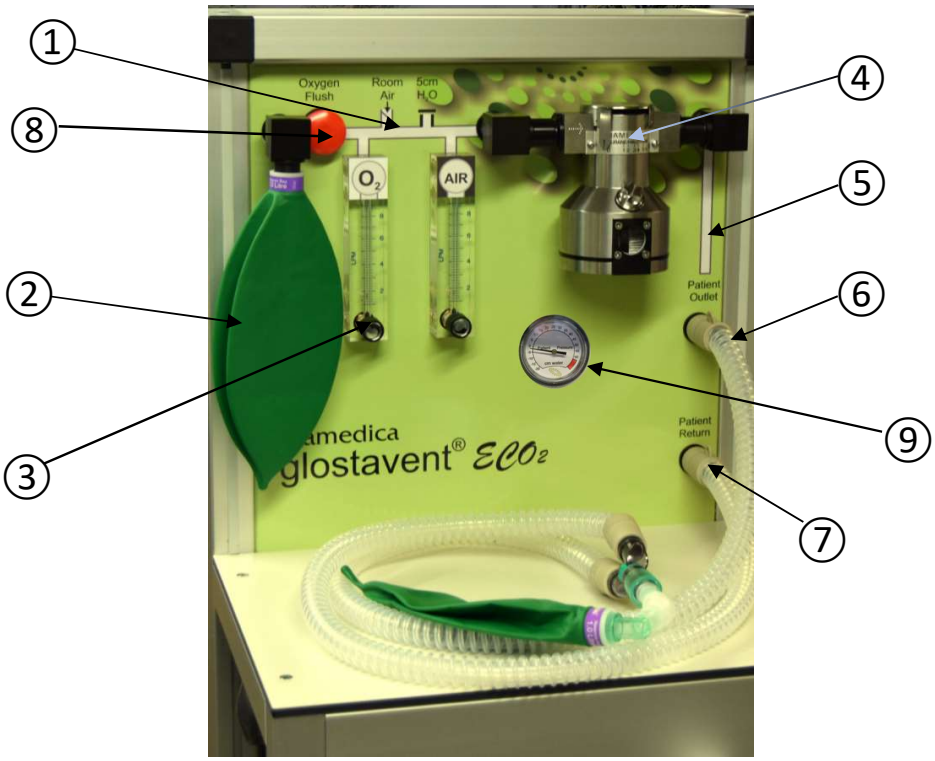
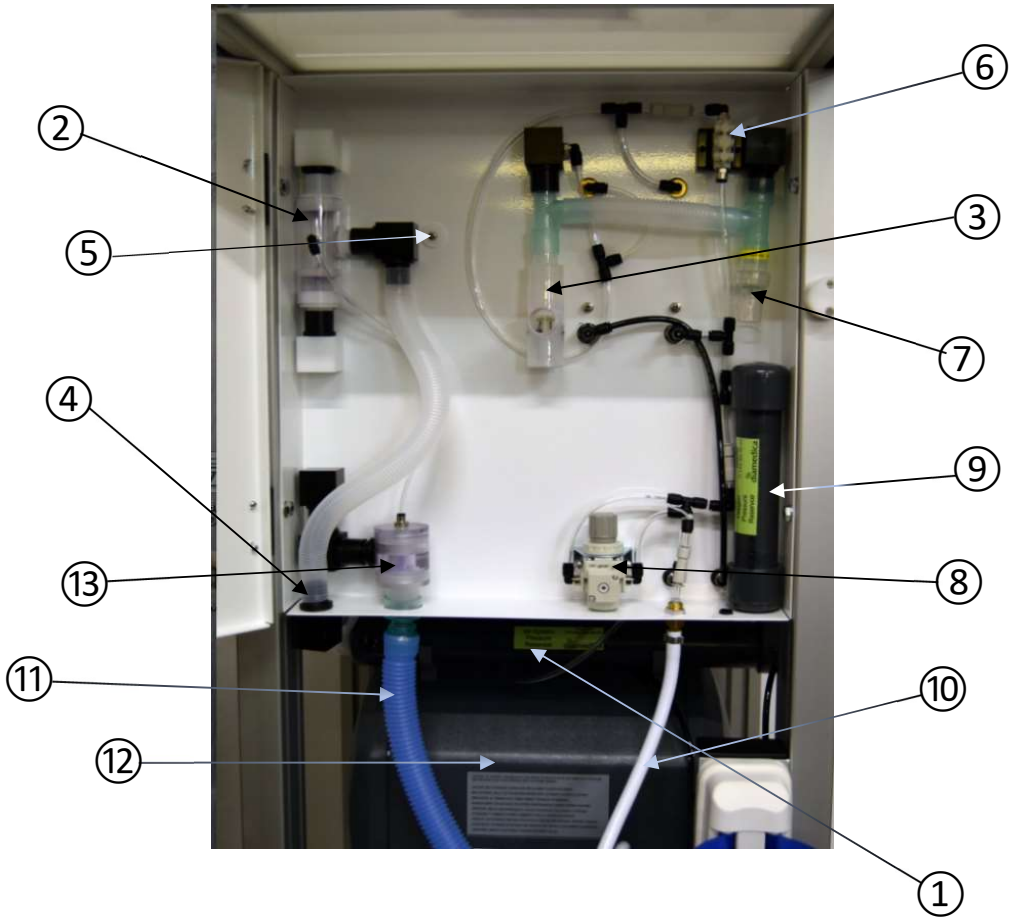


Diagram on panel indicating gas pathway ① Reservoir bag on left of panel ②. The function of this is to increase the volume of the reservoir and provide an indication of the rate and depth of respiration. It is not used to control or assist respiration.
Bank of flow meters ③ left: oxygen from concentrator or backup (10L/min maximum)
right: air from concentrator (10L/min maximum). Vaporiser ④ with concentration scale, filling port and glass window. ⑤ Indicates the position of the tube connecting the vaporiser to patient outlet on the panel. Note that this tube is behind the panel and therefore not visible. It contains a one-way valve to prevent back flow of the anaesthetic gases. A corrugated tube connects the patient outlet on the panel to the patient ⑥. The tube below ⑦ is the return from the patient.
Oxygen flush button ⑧. To flush the patient circuit, first switch off the vaporiser and depress the flush button for 10 seconds. This will flush with oxygen at a rate of 50 L per minute for the required period.
Patient pressure gauge ⑨.

INSIDE VIEW OF CONTROL PANEL

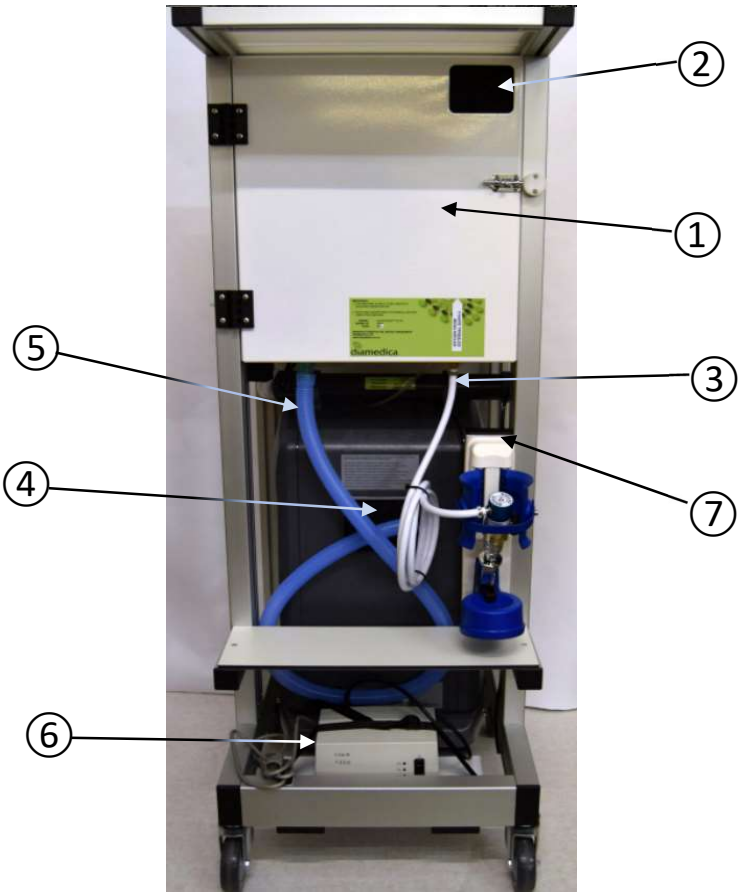


① Compressed air reservoir.
② Inspiratory patient circuit valve.
③ 5cmH2O overpressure valve.
④ Connection to assisted ventilation self-inflating bag.
⑤ Vaporiser fixing screw location.
⑥ Flush valve.
⑦ One way air inlet valve.
⑧ Oxygen changeover system.
⑨ Oxygen reservoir.
⑩ External oxygen hose.
⑪ Waste Gas outlet.
⑫ Oxygen concentrator.
⑬ Expiratory patient circuit valve.

THE OXYGEN CONCENTRATOR

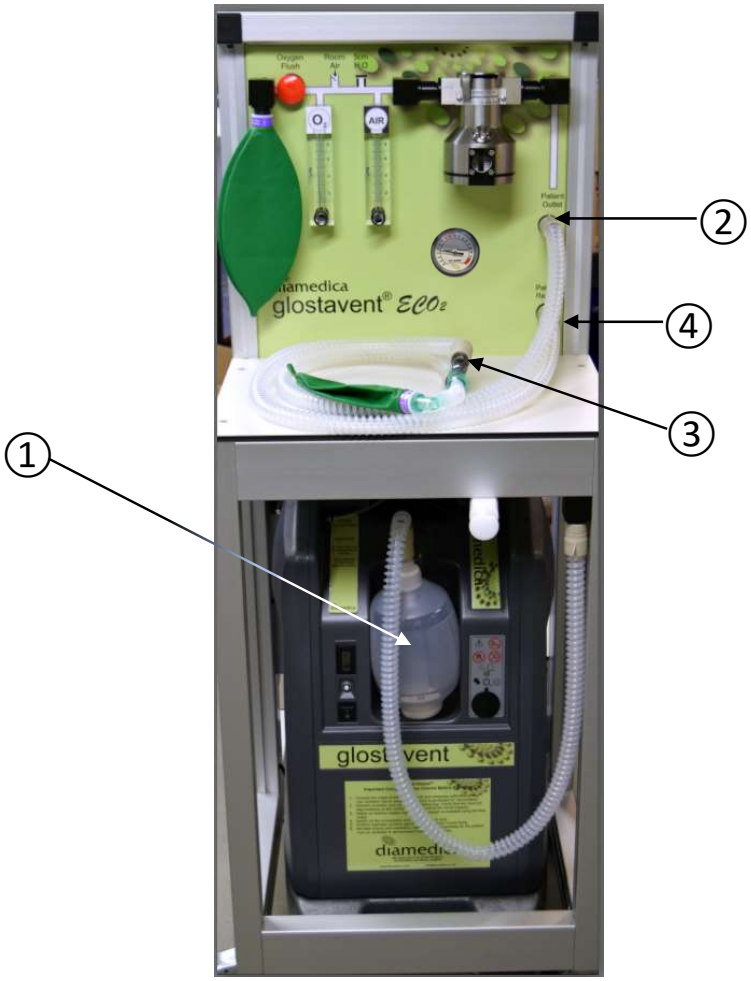
① On off switch.
② Reset button.
③ Hour counter.
④ Oxygen outlet.
⑤ Air outlet.
⑥ Low oxygen light.
⑦ Power failure light.
⑧ Maintenance light.

AT REAR OF ECO2 ANAESTHESIA SYSTEM



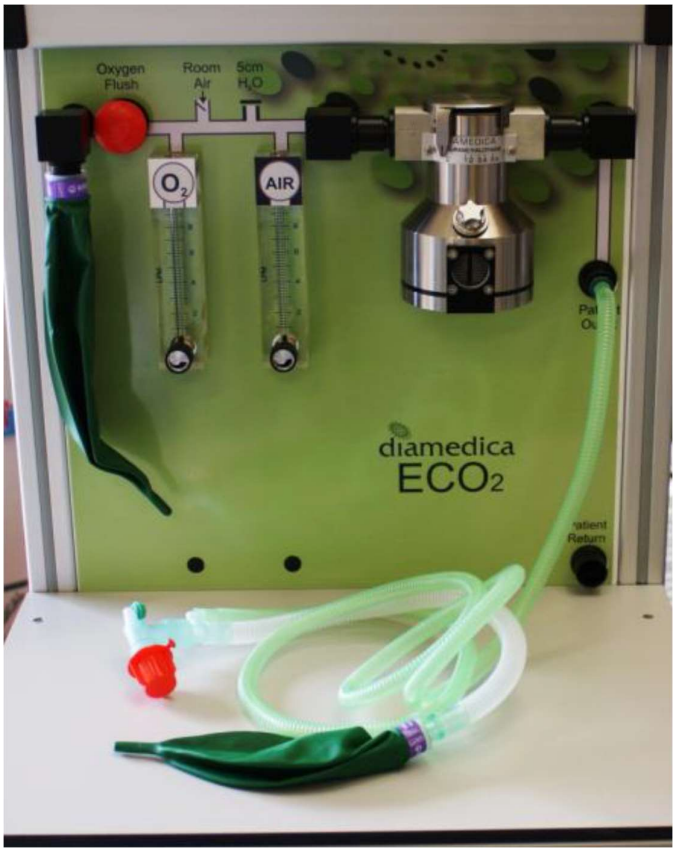
① The door on the rear of the control panel.
② Filter for inspired air.
③ Auxiliary oxygen connection.
④ Filter at rear of concentrator.
⑤ Waste gas (expired breath) outlet pipe.
⑥ Main's power lead and Voltage Stabiliser/UPS. *Appearance may differ*
⑦ Water trap location. The Water trap is located behind the cylinder bottle holder. Note the water trap is automatic and requires no intervention.

THE ADULT BREATHING CIRCUIT



The self-inflating bag ① on the separate limb of tubing. The patient outlet ②. The expiratory limb runs from the patient connection ③ back to the patient return ④ at the bottom of the control panel.

THE PAEDIATRIC BREATHING CIRCUIT (AYRES T PIECE)



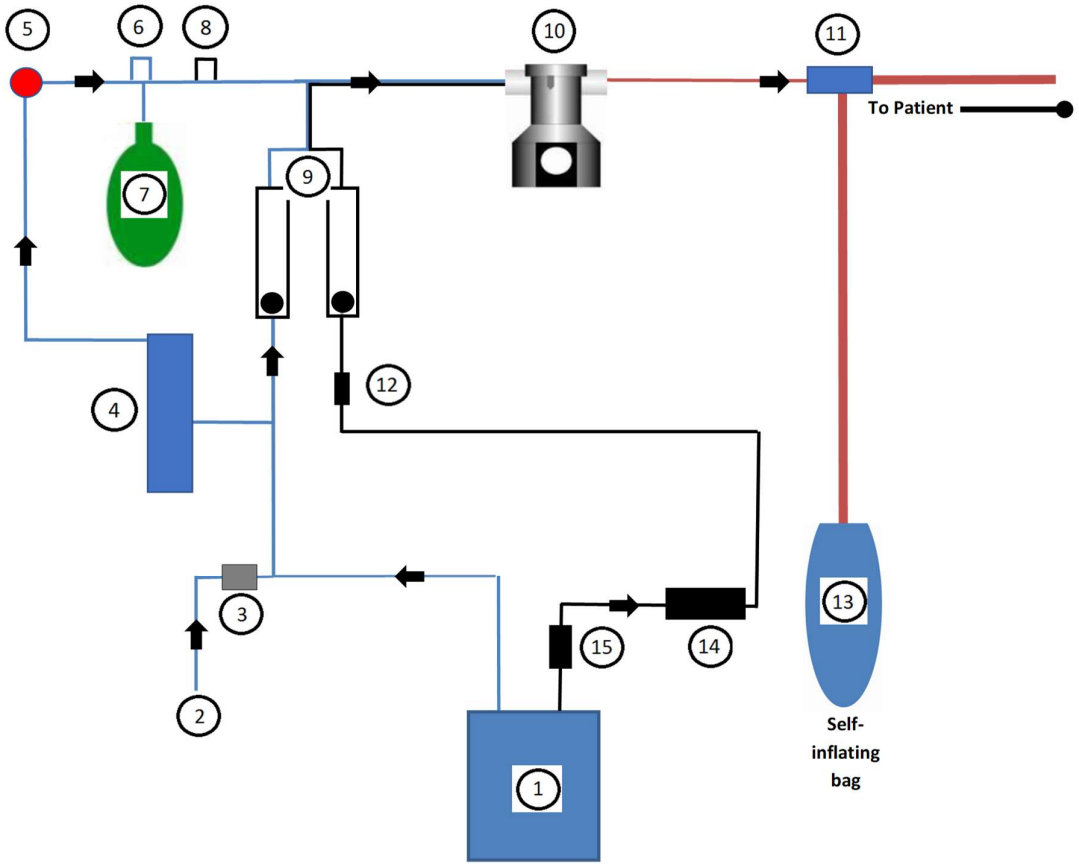
The Paediatric Ayres T piece circuit attaches directly to the Patient Outlet.

Note: the recommended flowrate for this circuit is at least 3 times the patient's minute volume.

6. THE ECO2 - CONTROL AND OPERATION

INTER-RELATION OF COMPONENT PARTS

The oxygen concentrator ① provides both oxygen to supplement the inspired mixture and also compressed air.
An oxygen cylinder ② should be available as a reserve to act as a source of oxygen for the patient in the event of power failure. The patient circuit valves ⑪ are located inside the control panel.
Under normal conditions, i.e. when electricity is available, the concentrator supplies the oxygen for the patient to breathe and air via the air flowmeter.



1. Oxygen Concentrator
2. Cylinder connection
3. Oxygen regulator
4. Oxygen reservoir
5. Oxygen Flush
6. Over pressure valve (5cmH20)
7. Reservoir bag
8. Room air inlet
9. Oxygen and Air flowmeters
10. Vaporiser
11. Inspiratory Valve
12. Air regulator
13. Self-inflating bag
14. Air reservoir
15. Water trap

The oxygen concentrator power supply is protected by a voltage regulator/ UPS on the back of the machine.

If the electricity supply fails and the UPS battery back-up is exhausted, the concentrator is no longer able to function. The reserve oxygen cylinder (if attached) takes over as the source of oxygen for the patient. This change-over occurs when valve ③ opens automatically. **No intervention is required by the anaesthetist.**

When the reserve oxygen cylinder is in use, conservation of oxygen assumes great importance. It should be noted that with an adult patient spontaneously breathing 2 litres of supplementary oxygen from the flowmeter would provide the patient with approximately 50% oxygen.

Manual ventilation

The final back up level if all other sources are exhausted and the patient requires breathing assistance is to manually ventilate the patient using the self-inflating bag until another source of power is available.

7. TEST PROCEDURE BEFORE USE

1. Confirm vaporiser contains the correct volatile agent and that concentration lever moves freely. Refill vaporiser if required.
2. Turn on reserve oxygen cylinder if available and confirm contents on pressure gauge. Test oxygen and air flow meter over full range.
3. Connect mains electricity and turn on. Switch on the UPS
4. After connecting to the power supply the display on the UPS will show 'Bypass' mode. Hold down the right-hand button until a signal is heard. Wait until the display shows 'Line;' mode. The UPS is now set for the Glostavent® ECO2 to be used.
5. Turn on oxygen concentrator. Alarm sounds and all 3 lights illuminate for 2 seconds. If the concentrator does not start check the relay trip on the circuit breaker. This is located in the electrical power line. The oxygen monitor light, located on the right side of the front of the concentrator, this will illuminated for approximately ten minutes then goes off automatically as oxygen production rises to peak efficiency. Turn on flowmeters from concentrator for air (on right) and for oxygen (on left). Turn off air flow meter. Leave oxygen flow meter turned on and set to 2 litres/min (to prevent build up of oxygen in concentrator).
6. Test anaesthetic circuit. Attach a one litre reservoir bag to the patient connection (Y piece) to act as test lung. Compress the blue self-inflating bag to demonstrate expansion of test lung and simultaneous movements of reservoir bag on control panel.

The ECO2 ANAESTHESIA SYSTEM is now ready for use

Note - After use:

1. Ensure all flow meters are turned off.
2. Remove and wash filters at back of concentrator and control panel and leave to dry.

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8. USE OF THE ECO2 ANAESTHESIA SYSTEM IN ADULTS

(For use in adults and children over 10 Kg)

1. SELECTION OF BREATHING SYSTEM

The ECO2 ANAESTHESIA SYSTEM can be operated in continuous flow or drawover mode. If a greater flow rate than the patient's minute volume is selected then the machine will operate in continuous flow mode. If the flow rate is set below the patient's minute volume then atmospheric air is also drawn into the circuit and the machine will operate in drawover. In the event of a power failure the machine will automatically switch to battery back-up from the UPS for 30 min and then to the backup cylinder if attached. If no back up is available then the machine will operate on atmospheric air alone. This is not recommended, except in emergency situations, and ventilation should be supported by using the self-inflating bag.

2. SOURCE OF OXYGEN

Under normal circumstances, i.e. when electricity is available, it is more economical to use the concentrator rather than any reserve oxygen cylinder. *The oxygen cylinder, however, should always be present and turned on,* so that oxygen supplementation can continue without interruption if the electricity supply fails and the oxygen concentrator is unable to function.

3. TEST PROCEDURE

Before commencing the anaesthetic, the drawover breathing system is first attached to the common gas outlet of the inflating bag and the routine pre use test procedure is carried out.

4. PRE-OXYGENATION

Pre-oxygenation is best achieved using a flow of oxygen of 10 l/min. An airtight seal at the face mask is desirable in order to avoid dilution with room air (but is not essential) in order to create the negative pressure normally required in drawover techniques. This is because at this high flow rate the ECO2 ANAESTHESIA SYSTEM automatically operates in continuous flow mode.

5. TYPE OF RESPIRATION

Conversion from spontaneous to controlled ventilation is very simple with the drawover system. If respiration has to be assisted or controlled during the course of an anaesthetic this can be achieved by compression of the self-inflating bag on the inspiratory tubing rather than the reservoir bag on the control panel. This is because the latter can only generate a pressure of 5 cm water before the blow off valve opens.

6. VOLATILE ANAESTHETIC AGENT

At the commencement of an anaesthetic the uptake of the volatile agent is rapid after which it is gradually reduced. A dialled concentration of approximately 2 MAC for the first 15 minutes followed by 1.5 MAC thereafter is generally satisfactory.

MAC stands for minimal anaesthetic concentration required to produce surgical anaesthesia and is specific to each anaesthetic agent. e.g. the value of 1 MAC for halothane is 0.75% and for isoflurane 1.1%. Thus, in the above example, if halothane is being used the dialled concentration would be 1.5% for 15 minutes and 1.0% thereafter, adjusting this according to the patient's response.

7. AGENT MONITORING

In situations in which the electricity supply is unreliable or when there is no technical support capable of maintaining delicate monitoring devices in good working order the use of monitors, normally considered indispensable for the conduct of safe anaesthesia, may be impossible.

Their presence is however not essential during open circuit anaesthesia since the concentration of the agent being inhaled is the same as the concentration setting on the vaporiser. It is delivered directly to the patient and not diluted by the lower concentration in expired gases as occurs with a circle system using low fresh gas flows.

8. ANALGESIA

The analgesic component of the anaesthetic can be achieved satisfactorily using intravenous analgesics incrementally according to the patient's response. For example, morphine increments of 0.03 mg/kg at 15-minute intervals is usually satisfactory in ventilated patients. In patients breathing spontaneously the respiratory rate is a useful guide to the requirements and the rate of administration can be adjusted to achieve a respiratory rate between 10 and 20 breaths per minute (in small children a rate of 20-30 breaths per minute is satisfactory). The alternative is to use local or regional anaesthesia as the analgesic component. This has the advantage that analgesia continues beyond the end of the anaesthesia.

9. 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 spontaneously breathing patient's movement of the reservoir bag on the control panel and the movement of the self-inflating bag gives an indication of the depth and rate of respiration. The patient's colour and movement of the chest and diaphragm must be kept under close observation throughout the administration of the anaesthetic.

Provided the rate and depth of respiration is satisfactory, rebreathing and hypercarbia should not occur with the drawover system as the expired gases are completely ducted away from the circuit by the valves in the patient circuit.

10. INSPIRED OXYGEN CONCENTRATION

When using the ECO2 ANAESTHESIA SYSTEM there is no danger of delivering a hypoxic mixture since oxygen is ADDED to room air (containing 21% oxygen) so the resulting concentration of oxygen will go up rather than down.

The inspired oxygen concentration depends on the ratio of the flow rate of added oxygen to the patient's respiratory minute volume (see fig 6).

In practice, a flow rate of oxygen of 2 litres/minute in a patient breathing 5 litres/min will give an oxygen concentration of approximately 50 %. If higher concentrations are required the flow rate is increased accordingly.

IMPORTANT NOTE: In the unlikely event of a simultaneous failure of both oxygen and electricity the anaesthetic can still continue safely using atmospheric air as the carrier gas. In these circumstances it is advisable to assist or control respiration to counter the respiratory depressive effects of the anaesthetic agents.

11. AFTER USE.

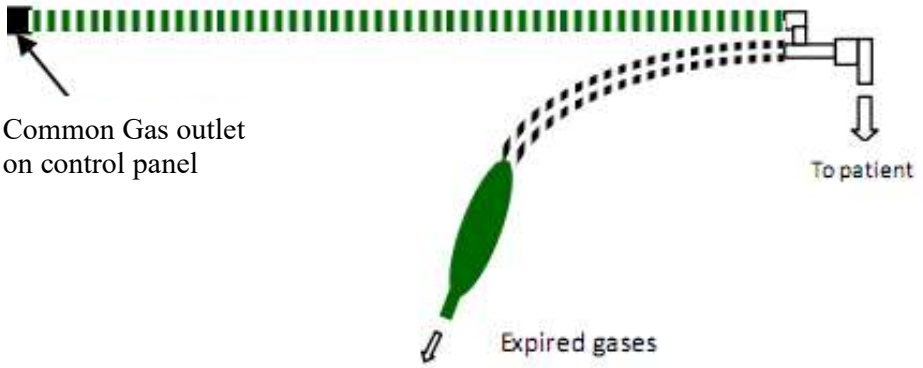
At the conclusion of the operating session:

1. Turn off the concentrator
2. Turn off the oxygen cylinder
4. If a patient filter is not being used remove the patient circuit, wash in soapy water, rinse and leave to dry.

9. USE WITH PAEDIATRIC PATIENTS

The Mapleson F Paediatric circuit (Ayres T Piece) is supplied with the ECO2 ANAESTHESIA SYSTEM and is connected directly into the patient outlet on the control panel (see Fig 16).

Small children breathing spontaneously may have difficulty in generating enough inspiratory flow to produce the necessary pressure gradient across the vaporiser, which therefore fails to deliver enough anaesthetic. For this reason, many anaesthetists may prefer to use the continuous flow mode for children weighing less than 20 Kg.
The recommended flowrate for this circuit is at least 3 times the patient's minute volume.



10. TROUBLE SHOOTING

Situations requiring the immediate attention of the anaesthetist

N.B. in the event of any other malfunction the ECO2 ANAESTHESIA SYSTEM must be taken out of service immediately and advice sought from Diamedica. Under no circumstances should there be any unauthorised tampering with the inside of the ECO2 ANAESTHESIA SYSTEM by untrained personnel.

1. The alarm on the UPS sounds

Cause: The electricity supply to the UPS has been interrupted.

Response: Turn off the UPS to silence the alarm, ensure that the electrical connections from the mains are intact. If the supply is off at the mains, then the UPS will continue to supply electricity for the next twenty minutes after which the oxygen concentrator will stop working (see 2 below). The principal function of the UPS is to remove voltage fluctuations from the electrical power supplies.

2. Continuous alarm from the oxygen concentrator

Cause: the electricity supply has been interrupted and the UPS batteries have depleted due to a failure of the mains supply or activation of the safety cut off mechanism caused by a surge in the voltage. Alternatively, the oxygen flow meter has been set too high i.e. beyond the maximum capacity of 10 litres/min.

Response: Turn off the concentrator to silence the alarm. Check electrical connections. If mains electricity failure is confirmed the oxygen cylinder automatically takes over the supply of oxygen to the patient. Supplementary oxygen from the cylinder can be added via the flow meter if required. If the reset button has been activated it should be depressed to restore function.

3. Intermittent alarm from the oxygen concentrator.

Cause: The oxygen flow meter is turned off leading to a build up of oxygen pressure in the concentrator.

Response: Turn off concentrator to silence alarm. Turn on flow meter to say 2 l/min to enable oxygen to leave the concentrator. Turn on concentrator.

4. Low oxygen warning light on concentrator becomes illuminated.

Cause: This is normal for the first ten to fifteen minutes of use as the concentrator is warming up and approaching maximum efficiency. No action is required at this stage. If the warning remains illuminated after this time it means the filter may be obstructed.

Response: The filter must be changed or washed.

5. Failure to generate pressure during manual compression of self-inflating bag.

Cause: There may be a disconnection between the bag and the common gas outlet of the ECO2 ANAESTHESIA SYSTEM allowing the contents of the bag to be discharged into the atmosphere rather than into the patient.

Response: Re-connect the tubing and continue to compress the bag.

6. The patient unexpectedly shows signs of light anaesthesia.

Cause: The patient may not be receiving the anaesthetic.

Response: Check that the vaporiser contains the anaesthetic agent and that it is turned on to the desired concentration. Confirm that the reservoir bag moves in time with respiration. Failure of the reservoir bag to move in time with respiration indicates a disconnection on the patient side of the vaporiser so that the patient is receiving atmospheric air instead of the anaesthetic! Check all connections to ensure the circuit is intact.

7. The supply of both oxygen back up and electricity fail simultaneously.

Cause: Whatever the cause the response must be immediate as there is no supplementary oxygen for the patients to breathe.

Response: The anaesthetic is maintained using atmospheric air as the carrier gas. Because of the depressant effect on respiration of the anaesthetic agents, controlled ventilation via the self-inflating bag is advised.

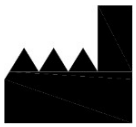
DIAMEDICA (UK) LTD
Grange Hill Industrial Estate, Bratton Fleming
Barnstaple, Devon, EX31 4UH, U K
Tel: +44(0)1598 710066
Email: support@diamedica.co.uk
www.diamedica.co.uk

EC REP **Alphamed Consulting Ltd, Knock, Barnaderg, Tuam, Co. Galway, H54 W220**

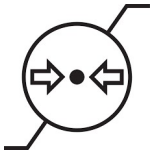
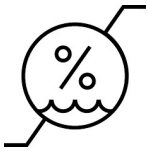
CE
1639

11. 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 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 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 hasnot been subjected to a sterilization process.
	Class II equipment	
	Type BF applied part	
	Recycling symbol	Products with this symbol should notbe disposed of in the bin
	The battery recycling symbol	Chemical symbol for battery type included beneath
	Does not containor presence of natural rubber latex	
	Indicates that an object is capableof 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