For anaesthesia and ventilation in difficult circumstances

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

Tel: +44 (0)1598 710066       Fax: +44 (0)1598 710055
Email: support@diamedica.co.uk   www.diamedica.co.uk
Read this section first.

INTENDED USE.

This device is suitable for use in hospital settings and is suitable for adult and paediatric patients.

The Glostavent® Helix 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 Glostavent® Helix Anaesthesia System. The information given in this manual is correct at the date of publication, January 2017.

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

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 Glostavent® Helix 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® Helix 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” machine settings for concentrations delivered to the patient do not necessarily ensure patient safety.

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 and the manufacturer should be informed immediately.

The Diamedica Glostavent Helix 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.

Medical conditions which contraindicate the use of a Glostavent® Series Anaesthesia System and its associated applications include any medical conditions which may contraindicate the medical procedure itself. The ultimate responsibility for patient or procedure contraindication lies with the anaesthetist.
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. It must not be used with the mechanical ventilator due to the risk of explosion.

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

The system is only intended to be used by Qualified Anaesthetists.
1. INTRODUCTION

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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, both as an anaesthetic machine in the operating room and a ventilator in a recovery or intensive care unit  
7. able to continue operating without interruption in the absence of oxygen or electricity.

The Glostavent® Helix anaesthetic machine has been developed to meet these requirements and the needs of anaesthetists working in difficult environments.

This manual has been prepared to provide practical guidance for those using the Glostavent® Helix 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. CLEANING, GENERAL MAINTENANCE AND DISPOSAL

2.1 Cleaning and maintenance

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

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 off safely before this is done.

It is very important to check the condition of the air filter on the Glostavent 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 water, removing as much water as possible and replacing.

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

Each Glostavent Helix 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 Y piece provided with the Glostavent Helix 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 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.

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

The vaporiser should not require recalibration. Any Operational calibration should only be done following consultation with manufacturer.
NOTE More detailed instructions for servicing by trained technicians can be available upon request.

2.2 Accessories and spares

All accessories used with the Glostavent® Helix 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

2.3 Technical data enquiries

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

2.4 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
3. THE PRINCIPLE OF THE GLOSTAVENT® HELIX

The Glostavent® Helix (Figure 1) 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 Glostavent® Helix principal components which make this possible are:
1. A low resistance breathing system and vaporiser which can function in the absence of pressurised oxygen.
2. A ventilator which is gas driven and can function in the absence of electricity.
3. An oxygen concentrator which produces oxygen and air for the patient to breathe and oxygen to drive the ventilator.
4. An integrated method of manual assisted ventilation that can be taken to the patient’s side.

Figure 1
4. **THE COMPONENT PARTS OF THE GLOSTAVENT HELIX**

4.1. **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](image)

*Figure 2*

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.

![Flow Diagram](image)

*Figure 3*
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.

The Glostavent® Helix can 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.

![PATIENT VALVE SYSTEM](image)

Because of the frequency of failure of the oxygen supply in some parts of the world the Glostavent® Helix 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 Diamedica vaporisers output is consistent in both modes, the output from other drawover vaporisers may not suitable for both these modes.

<table>
<thead>
<tr>
<th>Ambient Temperature</th>
<th>IPPV</th>
<th>Spontaneous Breathing</th>
<th>Continuous Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SET %</td>
<td>1% 2% 3% 4%</td>
<td>1% 2% 3% 4%</td>
</tr>
<tr>
<td>Flow Rate L/min</td>
<td>Delivered %</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 L/min</td>
<td>1.0 1.7 2.9 4.0</td>
<td>1.2 1.8 3.0 3.9</td>
</tr>
<tr>
<td></td>
<td>6 L/min</td>
<td>1.1 2.9 3.1 4.1</td>
<td>1.9 3.0 3.1</td>
</tr>
</tbody>
</table>

The flow capabilities of the draw-over vaporizer are 1 – 35 L/min
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 Diamedica 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 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 that 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 Glostavent® by three additions (Fig 7).

![Standard Reservoir](image1)

(a) A non return valve at the open end to prevent spillage of oxygen
(b) A 2ltr 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) An over pressure valve set at 5 cm H₂O to prevent over-distension of the reservoir bag.

The modified reservoir conveys one other important advantage. It enables the Glostavent® Helix 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. In this mode any of the standard anaesthetic breathing systems (e.g. Mapleson A, D, etc.) can be used by substituting them for the drawover system at the common gas outlet and using the fresh gas flow recommended for the particular system selected. A one way valve after the vaporiser on the Glostavent® Helix prevents backflow through the system when these circuits are in use.

![Patient Circuit relief characteristics](image2)

**Patient circuit protection**
**Relief valve characteristics**
Circuit may contain pressure up to 50 cmH₂O at which point the relief valve will crack and vent.
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 unco-operative 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. There are two methods of achieving this:

a) The vaporiser is turned off and the oxygen flow meter is set to deliver the maximum flow rate. The inspiratory limb of the circuit is briefly disconnected from the patient while the self-inflating bag provided in the patient circuit is compressed rapidly several times to purge the circuit of the anaesthetic mixture. It is then re-connected and the lungs ventilated with oxygen.

b) The vaporiser is turned off and the inspiratory limb of the circuit is briefly disconnected from the patient while the oxygen flush button on the Glostavent® control panel is depressed for 10 seconds to purge the circuit of the anaesthetic mixture. The inspiratory limb is then re-connected, the oxygen flowmeter is set to maximum and the lungs ventilated with oxygen.

Q. Does the Diamedica 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 a variety of 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 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. It should not be used 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.
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. 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. The risk of contamination of the anaesthetic tubing is diminished by virtue of the open circuit system, although bacterial filters should be used if available. The circuit should be washed in warm soapy water between patients. For other circuits and valves please seek the advice of the manufacturer.

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 when using the Glostavent® Helix.

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

A. Satisfactory pre-oxygenation can be achieved with the Glostavent® Helix drawover circuit using an oxygen flow rate of 10 l/min.

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.
4.2. 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 Glostavent® Helix delivered by means of an oxygen concentrator. (Figure 8)

![Figure 8](image)

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 or used to drive the ventilator (4). The remainder of the compressed air passes through a water trap (5) which enables the water formed by condensation to be automatically released at regular intervals so that it cannot obstruct the flow. It 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 and some of the oxygen is also used to drive the ventilator before recycling this drive oxygen into the patient circuit. 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.

Q. Can the concentrator function at high altitude?
A. Yes. It functions in the same way whatever the altitude.

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 UPS system incorporates a voltage stabiliser which enables the Glostavent® to function in the presence of fluctuations of +/- 30 %.

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 is the comparative cost of using oxygen cylinders as opposed to the oxygen concentrator?
A. The cost of running the concentrator is approximately 1% of the cost of cylinder oxygen.

Q. What are the servicing requirements of the concentrator?
A. The concentrator has been designed to require minimal servicing. The only regular maintenance required is the cleaning of the gross particle filter located at the air entry site at the rear of the concentrator, by washing it in warm soapy water and leaving it to dry. This should normally be carried out every 3-4 days but more frequently in dusty conditions.
4.3. THE GLOSTAVENT® HELEX VENTILATOR (Figure 9)

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

![Diagram of the Glostavent Helix Ventilator](image)

The ventilator bellows section consists of a set of bellows and a helix screw above the bellows for tidal volume adjustment.

A drive piston is mounted below the bellows and is driven upwards by the driving gas. This piston pushes the top of the bellows upwards causing the bellows to expand and fill with the gas mixture. When the control solenoid switches the gas flow the piston is driven closed compressing the bellows; a valve directs the gas mixture towards the patient.

The tidal volume range on the Glostavent Helix is 35ml to 1200ml, the displaced volume over this range is accurate to +/- 10% over the full range of possible BPM (4-40)
5. THE GLOSTAVENT HELIX - CONTROL AND OPERATION

INTER-RELATION OF COMPONENT PARTS (Fig 10)

Below the ventilator is the oxygen concentrator (1) which provides both oxygen (2) to supplement the inspired mixture and to drive the ventilator. It also provides air (3) to add gas flow for continuous flow operation if required. An oxygen cylinder (4) should be available as a reserve to act as a source of oxygen (5) for the patient (6) and to drive the ventilator in the event of failure of the concentrator. The piston requires a driving pressure of 20 PSI (140 KPa) and can therefore utilise either oxygen from the concentrator or oxygen from the cylinder. Under normal conditions, i.e. when electricity is available, the concentrator supplies both the oxygen for the patient to breathe and to drive the ventilator.

![Diagram](image)

If the electricity supply fails, the concentrator is no longer able to function. The reserve oxygen cylinder then takes over as the source of both the oxygen for the patient and to drive the ventilator. This change-over occurs when valves (7) and (8) open automatically. **No intervention is required by the anaesthetist.**

When the reserve oxygen cylinder is in use, conservation of oxygen assumes great importance. This is achieved in two ways;

1. Recycling of oxygen. After the oxygen has been used to drive the ventilator it is collected and returned to the breathing circuit via the supplementary oxygen tube (9). In other words, the same oxygen is used twice, first to drive the ventilator and then to supplement the inspired gas mixture. In this way the resulting oxygen concentration delivered to the patient is elevated to 35% without the need for any other supplementation.

2. The ventilator has been designed to minimise the volume of driving gas required. This is possible because the piston diameter is much smaller than that of the bellows.
The volume of driving gas required is therefore only $\frac{1}{6}$th of the tidal volume set for the patient. 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. However, because of the respiratory depressive effects of the anaesthetic agents, controlled ventilation is required to prevent hypoxia. This can be achieved by utilising the self-inflating bag (11) supplied as part of the breathing circuit.

**Frequently asked questions on the ventilator**

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

A. Providing oxygen is available the limiting factor is the life of the battery needed for the electronic circuitry. A fully charged battery will last for 100 hours. It is therefore important to keep the battery fully charged when the Glostavent® Helix is not in use.

**Q. Does the compression caused by the bellows cause distension of the self-inflating bag and thus a decrease in tidal volume?**

A. No. The self inflating bag is sufficiently rigid to resist significant expansion during inflation of the lungs.

**Q. How does the Glostavent® Helix ventilator differ from other similar ventilators?**

A. (1) The tidal volume control is absolute, so the tidal volume can be determined accurately by the setting. This is not possible with some other similar ventilators. 
(2) The bellows is suitable for adult and paediatric patients. 
(3) The Helix control on the top of the bellow gives accurate volume control. 
(4) There is a triggering facility to assist weaning.

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

A. Yes, by applying an adjustable PEEP valve to the expiratory limb of the circuit.

**Q. How much does it cost to drive the ventilator for 24 hours?**

A. When the ventilator is being powered by oxygen from the concentrator, the cost of driving the ventilator is the cost of electricity for the concentrator. In the UK this is approximately £0.05 per hour or £1.20 per day. Oxygen supplementation can also be provided by the concentrator at no extra cost. This would compare to a conventional gas driven ventilator running cost of approximately £80.00 per day when running from oxygen cylinders.

**Q. Is humidification of the inspired gas required?**

A. It is preferable but not essential for short term ventilation e.g. the duration of surgery. For long term ventilation as in an intensive care unit humidification is advisable using either a filter or humidifier at the patient’s airway. The individual components of the Glostavent® Helix are interconnected on a mobile workstation with a flow meter control panel above a shelf and has an arm supporting the ventilator, and an oxygen concentrator below.
THE FLOW METER CONTROL PANEL  Fig 11

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 ventilator (6). Oxygen flush button (7). To flush the patient circuit, first switch off the vaporiser, then disconnect circuit close to the patient and depress the flush button for 10 seconds. This will flush with oxygen at a rate of 30 l per minute. Self-inflating bag (8) for manual/assisted ventilation. Helix screw (9) for tidal volume adjustment. Ventilator drive gas and return (10). Oxygen and Air connections from the oxygen concentrator (11). Tidal volume lock (12).
Inside View of Control Panel

Figure 11 b.

Inside View of Control Panel

1. Compressed air reservoirs
2. One way valve (after vaporiser)
3. 5cmH₂O overpressure valve
4. Water trap
5. Ventilator tidal volume control
6. Flush valve
7. One way air inlet valve
8. Battery
9. Oxygen changeover system
10. Oxygen reservoir
11. Reserve oxygen hose
12. External oxygen hose
13. Cylinder bracket
14. Scavenger
15. Oxygen concentrator
16. Ventilator bellows
17. Ventilator connections
18. Bull nose and pin index connections
Identify:

The front panel.

This contains the following features from left to right:

On /off switch with illuminated ‘power on’ indicator above. (top) Airway pressure gauge, (bottom) Trigger level control. (top) Patient pressure control, (bottom) Respiratory rate control. (top) High pressure warning light this is illuminated if the airway pressure exceeds 50cmH₂O. (middle) Alarm Mute. (bottom) Low pressure warning light. This is illuminated if the airway pressure fails to reach 5cm water during IPPV. After twenty seconds this is accompanied by an audible warning. On the right hand side are the patient outlet and return.
**THE OXYGEN CONCENTRATOR** (Figure 13)

![Diagram of the Oxygen Concentrator](image)

**Figure 13**

Identify:

- On/off switch on left of the front panel (1)
- White reset switch immediately above this (2), (to restore current if circuit interrupted by a surge of electricity)
- Meter showing total hours of machine use (3)
- Oxygen tube to flowmeter and ventilator (4)
- Compressed air tube to air flowmeter (5)
- Low oxygen warning light (6). This is illuminated when the concentration of oxygen leaving the concentrator is below 85% and is accompanied by an audible alarm. This is normal for the first few minutes after the concentrator is turned on while the oxygen concentration is gradually building up. Once the concentration reaches 70% the alarm stops automatically. If it alarms at other times it either means that the air filter needs cleaning or that the flow meter of oxygen leaving the concentrator has been set too high, i.e. beyond the capacity and must be reduced.
- Expired gases tube (7)
- Scavenger (8)
Figure 14

Identify:

The door on the rear of the control panel and key (1)
Filter for inspired air (2)
Ventilator (3)
Ventilator swivel arm (4)
Filter at rear of concentrator (5)
Reserve oxygen cylinder holder (6)
Auxiliary oxygen connection and hose (BS 5682) (7)
The Uninterruptible Power Supply (8)
Oxygen regulator (4 bar)
(Bull Nose BS 341-1 no. 3 supplied with adaptor for Pin Index ISO 407) (9)
THE LOW PRESSURE BREATHING CIRCUIT

Identify:

The fresh gas inlet valve (1)
The over-pressure valve (2)
The self-inflating bag (3) on the ventilator limb (4)
The valves on the patient circuit (5)
The expiratory limb (6) between the valve and the scavenging system
The patient circuit Connections for circuit are standard 22mm to fit all common circuits (7)
6. THE GLOSTAVENT HELIX ALTERNATIVE POWER SOURCES

Due to the likely difficult operating environments of the Glostavent® Helix a number of alternative methods of driving the anaesthetic machine; both for the oxygen supply and the ventilator have been incorporated into the design. There are essentially 4 back-up systems.

**UPS:** The main first line back up for electrical power failure is a UPS (Uninterruptable Power Supply) which is fitted to the rear of the machine, this will provide voltage stabilisation, surge protection, and will supply a battery back to the oxygen concentrator of approximately 30 minutes without any interruption to the machines general running. If the UPS batteries become discharged the alarm on the concentrator will alarm continuously. Electrical connections on the UPS are IEC C13 and IEC C14 standard connections.

**Figure 16**

**OXYGEN CYLINDER BACK UP**

This should overcome short power interruptions that are common in many LMIC (Low and Middle Income Countries) while power is either restored or a generator is started. However if those 30 minutes are not long enough an oxygen cylinder can be used to provide a source of oxygen for the patient and a means of driving the ventilator.

**ADDITIONAL VENTILATION BACK UP**

If the UPS batteries have discharged and there is no oxygen cylinder available then there is an emergency Ventilation Back Up compressor which will run the ventilator on room air only for approximately twelve hours. This is operated by pushing the silver button on the bottom right hand corner of the control panel and a blue light appears when running.

When you start this you should allow 20 seconds for the compressor to charge the system and start moving the ventilator. Once the power has been restored and the UPS has sufficient charge you must switch on the concentrator and then manually switch the Ventilation backup off.
MANUAL VENTILATION

The final back up level if all other sources are exhausted 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 volatile agent and that concentration lever moves freely. Refill vaporiser if required.

2. Turn on oxygen cylinder if available and confirm contents on pressure gauge. Test oxygen flow meter over full range. This is located on the left of the two flow meters. Then turn off flow meter but leave cylinder on.

3. Turn on gas scavenger if required.

4. Connect mains electricity to UPS and turn on electricity.

5. 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® Helix to be used.

6. Turn on oxygen concentrator. Alarm sounds for five seconds then stops automatically. The oxygen monitor light, located on the right side of the front of the concentrator, is 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).

7. 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 on control panel.

8. Test performance of ventilator. Set tidal volume to 600 ml (by turning the helix screw on top of the bellows), set respiratory rate to 10 breaths/min. Turn on the ventilator and confirm filling of test lung. Adjust pressure to 25 cm of water (by turning the pressure control on the front panel). Disconnect test lung. Confirm that low pressure alarm flashes within 5 seconds and audible alarm sounds approximately ten seconds later. Reconnect test lung and wait for alarm to stop.

9. Test emergency power source.
   a. fit reserve oxygen cylinder and turn on.
   b. turn off electricity at mains.
   c. UPS alarm sounds (high pitched notes every 30 seconds).
   d. turn off UPS by holding down the off button until a signal is heard.
   e. oxygen concentrator stops working and alarm sounds.
   f. turn off oxygen concentrator to silence alarm.
   g. confirm ventilator continues to function (now powered by oxygen cylinder).
   h. switch off ventilator.

After completing test procedure turn on mains and UPS
The Glostavent® Helix is now ready for use

Note - After use:

1. Ensure all flow meters are turned off. Ensure UPS is connected to the mains and turned on (to keep battery charged).

2. Remove and wash filters at back of concentrator and control panel and leave to dry.

3. Inspect water trap and empty if autodrain has not emptied.

4. Cleaning and general maintenance. After use clean with a damp cloth, removing all sharps carefully. Refer to ‘Daily set up and test’ document for routine testing.

8. USE OF THE GLOSTAVENT® HELIX IN ADULTS

(For use in children under 10 Kg see section 9)

1. SELECTION OF BREATHING SYSTEM

The Glostavent® Helix is normally operated in drawover mode using the drawover breathing system described previously. This is safe, reliable and economical and enables the anaesthetic to continue without interruption in the event of a failure in the supply of oxygen or electricity or both. It can, however, also be operated as a continuous flow machine.

2. SOURCE OF OXYGEN

Under normal circumstances, i.e. when electricity is available, it is more economical to use the concentrator rather than the reserve oxygen cylinder, both as a source of oxygen for the patient and of pressure to drive the ventilator. The oxygen cylinder, however, should always be present and turned on so that ventilation can continue without interruption if the electricity supply fails and the oxygen concentrator is unable to function. The cylinder is fully opened by the key at the top of the cylinder but the oxygen flow meter on the control panel remains off to avoid wastage.

3. TEST PROCEDURE

Before commencing the anaesthetic the drawover breathing system is first attached to the common gas outlet and return of the Glostavent® Helix 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 or more. An air tight 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 Glostavent® Helix 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 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.
If longer term ventilation is required the ventilator is turned on and the tidal volume and respiratory rate controls set as required. No other adjustment is required. The self-inflating bag on the inspiratory limb remains in place at all times.

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 drawover 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 patients movement of the reservoir bag on the control panel 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 valve at the patient airway.

In ventilated patients a minute volume of 70 ml/kg (approximately 5 litres/min in a 70 kg patient) is generally satisfactory to maintain normocarbia. This can usually be achieved by setting the tidal volume to 500 ml, the respiratory rate to 10 breaths per minute and the ventilator pressure to 20 cm of water. If the bellows of the ventilator does not completely empty at this pressure it may mean that the compliance of the lungs is reduced (the lungs are stiff) and the patient pressure needs adjusting to increase the pressure on the bellows.

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

10. INSPIRED OXYGEN CONCENTRATION
When using the drawover 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
3. Ensure that the mains electricity supply is connected and the UPS is turned on so that the battery is kept fully charged.
4. Remove the patient circuit, wash in soapy water, rinse and leave to dry.

12. LONG TERM VENTILATION
Although the Glostavent® Helix was designed as an anaesthetic machine it can also function as a ventilator in a recovery room or intensive care unit. No adaptation is required for long term ventilation. The tidal volume and respiratory rate are set to the desired levels and the vaporiser is turned off.

Room air is supplemented with oxygen from the concentrator to give the required inspired oxygen concentration.
To assist with weaning a patient from long term respiratory support a triggering mechanism can be activated by a manual control located on the front of the control panel. This indicates the inspiratory effort required to initiate compression of the bellows and is gradually increased as the patient regains muscle power. Positive end expiratory pressure (PEEP) is occasionally required in some forms of lung dysfunction and this can be applied by attaching a PEEP valve to the expiratory limb of the breathing system.

9. **Use in Paediatric patients.**

Children weighing 10 Kg and above are able to use the Glostavent® Helix as described above for adults.

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 10 kg.

When using the Glostavent® Helix in these children the standard breathing circuit is first removed from the common gas outlet of the Glostavent® Helix and replaced by a ‘T’ piece paediatric system (Mapleson F). The reservoir bag is used to indicate respiratory movements during spontaneous respiration and, with the expiratory port partially occluded, to facilitate controlled ventilation. This paediatric ‘T’ piece system is used with the recommended fresh gas flows i.e. 3 times the patient’s estimated respiratory minute volume down to a minimum of 3 l/min.

To enable the 'T' piece circuit to be used in this way the pressure at the common gas outlet must be positive. This occurs automatically when the dialled gas flows exceed the patient’s minute volume and normally requires no additional action by the anaesthetist.

**N.B The open end of the ‘T’ piece reservoir BAG must NOT be completely occluded as this is the port for expired gases.**

Both spontaneous and controlled respiration can be used with this arrangement as if using a standard continuous flow anaesthetic machine. However, it should be noted that the maximum pressure that can be applied during controlled ventilation is limited to the pressure set by the control on the ventilator panel.
PEEP (positive end expiratory pressure)

PEEP can be fitted to the Glostavent Helix by connecting it to the patient return 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.
10. TROUBLE SHOOTING

Situations requiring the immediate attention of the anaesthetist.

N.B. in the event of any other malfunction the Glostavent® Helix 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 Glostavent® Helix 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 either 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 and driving gas to the ventilator. 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. If the oxygen output at the flow meter has been set too high (i.e. beyond the capacity of the concentrator of 10 l/min) the flow meter is re-set at a lower level and the concentrator restarted.

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 is obstructed.

**Response:** The filter is changed or washed.

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

**Cause:** There is a leak or complete disconnection of the anaesthetic tubing. Alternatively, the tidal volume setting is too low for the size of patient.

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

6. Failure of bellows to fill completely.

**Cause:** Loss of drive gas pressure.

**Response:** Continue ventilation manually until a further source of drive gas is available.

7. Failure of bellows to empty completely.

**Cause:** There may be an increased resistance to breathing due to an obstruction to the anaesthetic tubing (e.g. kinking) or an obstruction to the patient’s airway (e.g. bronchospasm, secretions).

**Response:** Change to manual ventilation, seek and relieve any cause of obstruction. If the bellows still do not empty completely increase the patient pressure control.

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

**Cause:** There is a mechanical fault inside the ventilator.

**Response:** Turn the ventilator off and continue with manual ventilation via the self-inflating bag. Consult the manufacturers for advice. **DO NOT TAMPER WITH THE INSIDE OF THE VENTILATOR.**

**Cause:** The bellows in the ventilator may need to be closed, turn the helix screw on the ventilator clockwise until the bellows is closed. There may be a disconnection between the bag and the common gas outlet of the Glostavent® Helix 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.

10. There is a low-pitched rumbling noise from the valve system on expiration.

**Cause:** The total flow rate dialled exceeds the patient’s minute volume, causing distension of the reservoir bag and a build up of pressure. This leads to fluttering of the valve flap which is audible during expiration.

**Response:** The flow rates are reduced till they are below the patient’s minute volume. When this occurs, the rumbling noise disappears and the reservoir bag moves with respiration.

11. 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.

12. The supply of both oxygen and electricity fail simultaneously.

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

**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.
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:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
<td>Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.</td>
</tr>
<tr>
<td><img src="image" alt="Authorized representative in the European Community" /></td>
<td>Authorized representative in the European Community</td>
<td>Indicates the Authorized representative in the European Community.</td>
</tr>
<tr>
<td><img src="image" alt="Date of manufacture" /></td>
<td>Date of manufacture</td>
<td>Indicates the date when the medical device was manufactured.</td>
</tr>
<tr>
<td><img src="image" alt="Use-by date" /></td>
<td>Use-by date</td>
<td>Indicates the date after which the medical device is not to be used.</td>
</tr>
<tr>
<td><img src="image" alt="Batch code" /></td>
<td>Batch code</td>
<td>This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.</td>
</tr>
<tr>
<td><img src="image" alt="Catalogue number" /></td>
<td>Catalogue number</td>
<td>Indicates the manufacturer's catalogue number so that the medical device can be identified.</td>
</tr>
<tr>
<td><img src="image" alt="Serial number" /></td>
<td>Serial number</td>
<td>Indicates the manufacturer's serial number so that a specific medical device can be identified.</td>
</tr>
<tr>
<td><img src="image" alt="Fragile, handle with care" /></td>
<td>Fragile, handle with care</td>
<td>Indicates a medical device that can be broken or damaged if not handled carefully.</td>
</tr>
<tr>
<td><img src="image" alt="Keep dry" /></td>
<td>Keep dry</td>
<td>Indicates a medical device that needs to be protected from moisture.</td>
</tr>
<tr>
<td>Do not re-use</td>
<td>Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.</td>
<td></td>
</tr>
<tr>
<td>Consult instructions for use</td>
<td>Indicates the need for the user to consult the instructions for use.</td>
<td></td>
</tr>
<tr>
<td>Caution</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Non-sterile</td>
<td>Indicates a medical device that has not been subjected to a sterilization process.</td>
<td></td>
</tr>
<tr>
<td>Class II equipment</td>
<td></td>
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</tr>
<tr>
<td>Type BF applied part</td>
<td></td>
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</tr>
<tr>
<td>Recycling symbol</td>
<td>Products with this symbol should not be disposed of in the bin</td>
<td></td>
</tr>
<tr>
<td>The battery recycling symbol</td>
<td>Chemical symbol for battery type included beneath</td>
<td></td>
</tr>
<tr>
<td>Does not contain or presence of natural rubber latex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indicates that an object is capable of being recycled</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>