HEALTHCARE EQUIPMENT

Patient Oxygen & Suction Transfer System (POST)

Instructions for Use

Made in the UK

The Oxylitre S8 Series Patient Oxygen & Suction Transfer System are designed specifically for medical use and comply with BS EN ISO 10079-4, BS EN ISO 15002, BS EN ISO 14971, BS EN ISO 15001 and the 93/42/EEC European Directive. Products are available for use with Oxygen.

1 Intended Purpose

MD This product is a medical device. The Patient Oxygen & Suction Transfer System intended to be connected to a nominally 4 kPa Oxygen source allowing the clinician to apply controlled variable suction, via the venturi effect, for the collection of body fluid aspirations (blood, secretions, vomitus etc).

It is also to control the medical gas flow Oxygen to a patient e.g., via attached tubing and facemask. To control the medical gas flow Oxygen to a patient e.g., via attached tubing and facemask.

They are used in conjunction with Receiver Jars to collect the fluids drained from a patient. The Patient Oxygen & Suction Transfer System is ideal for portable use and for use in areas where vacuum pipeline installations or Electrical Suction units are not available.

2 Description

The venturi Suction Unit operates from a 400 kPa gas supply. By opening the unit's Control Knob the gas is jetted through the main body creating a vacuum. This provides a vacuum source from 0 to -65 kPa (-500mmHg) on High Suction Units and 0 to -20 kPa (-150mmHg) on Low Suction Units. Suction values are indicated on the unit's vacuum gauge. The waste gas is vented through a silencing filtration system before it is dispensed into the atmosphere.

The venturi Suction Unit are available in controllable High and Low Suction and can be operated directly from an Oxygen gas supply. Units are available to fit to a cylinder or a gas supply outlet point. The venturi Suction Unit is ideal for portable use and for use in areas where vacuum pipeline installations or Electrical Suction units are not available. The Injector Suction unit can be used for most types of aspiration requirements.

The venturi Suction Unit has an outlet designed to accept vacuum tubing and connection to a collection container.

The Flowmeter is constructed with a and selective orifices in a barrel arrangement between the inlet on the Patient Oxygen & Suction Transfer System and outlet through which the gas flows. The inlet port is a BS Probe attached to a hose which is Oxygen to engage with the appropriate gas Terminal Unit. Including the zero (off) setting. There are 12 settings which

can be selected by turning the cap which has a slot indicating the numerical flow setting.

The Flowmeter is available for the delivery of Oxygen with a flow range of 0 – 15, 0 – 3, 0 – 1 l/min. The main barrel of the flowmeter is constructed from Acetal.

The Flowmeter has a Tubing Nipple attached which accepts tubing to supply the gas to the patient through a face mask or similar.

Clinical Benefit
There is no direct clinical benefit from the use of this device.

3 Indications

The Patient Oxygen & Suction Transfer System venturi suction is intended as the name implies: to control the vacuum by opening the unit's control knob so that the gas is jetted through the main body thus creating a vacuum and draining bodily fluids / secretions. They are used in conjunction with receiver jars to collect the fluids drained from a patient.
The Patient Oxygen & Suction Transfer System is intended for the administration of medical oxygen or air to patients connected to medical gas supply.

4 Contraindications

Continuous drainage is contraindicated.

5 Patient Group

The general patient population (any gender / age).

6 Warnings and Cautions

Warnings

- Do not use for any purpose other than that described within this instruction for use.
- DO NOT attempt to connect to a vacuum gas supply.
- This equipment is NOT for continuous drainage.
- This piece of equipment is fragile, please handle with care, avoid excessive force.
- Keep away from the rain.
- Keep away from sunlight.
- To be strictly operated by personnel that have received adequate instructions in its use.
- The device cannot operate without gas supply.
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- DO NOT attempt to connect to a pipeline gas supply.
- Do not drop the device, it may inadvertently damage.
- When operating the suction from an Oxygen supply, ensure the area is well ventilated to prevent high levels of Oxygen accumulation.

- Do not use any grease or oil within Oxygen filled environment, as these substances are combustible in the presence of Oxygen. 
- Do not use an Oxygen Flowmeter within an environment where Oxygen may be exposed to any naked flames, sparks, cigarettes/cigars or any open electrical appliances. This precaution applies during and after a reasonable period of patient administration.
- Stop using the device if there is any change in performance.
- No leaks are permissible on the device.
- Don't use alkaline disinfectants.
- Under no circumstances are inlet or outlet connectors to be changed.
- Do not use at higher pressures than those described
- Do not use if markings are illegible, it could lead to over or under dosage
- Exercise care when cleaning the device so as not to allow ingress of materials or contaminants entering inlets, outlets and orifices, this could lead to patient's bacterial or chemical contamination.
- Do not use if orifices, inlets / outlets show signs of blockage / obstruction.
- To be used only by trained healthcare professionals.
- Flow is available only at the numbered increments. There is NO FLOW between increments (and at 0). The indicating pointer must point to a specific number on the dial and the number to be centrally located in the window to obtain flow.

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7 **Cautions**

- Upon receipt check the package and its contents for integrity, in the event it has been tampered with or something is missing please do not use and return to Oxylitre.
- Never use faulty equipment
- Operating at higher pressures than those described there may be annoyance due to vibration.
- Inspect the condition of the Patient Oxygen Transfer System for any sign of damage or blockage i.e., pressure gauge indicator (giving wrong readings), damaged inlets / outlets, etc.
- Stop operation when the collection jar becomes full.
- Replacement of parts must be provided by and the replacement conducted by Oxylitre Holdings Ltd.
- Ensure that the device has been fully maintained to ensure safety of the user/patient when in use and to the environment.
- Do not tamper with device
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8 Side effects

There are no known side effects related to the use of the Patient Oxygen Transfer System when used in accordance with the instructions herein and all warnings and cautions are observed.

9 Notice

In the event of any serious incident having occurred which may be related to the device please report it to any or all of the following:

Oxylitre  (quality@oxylitre.co.uk) Morton House, Skerton Road, Old Trafford, Manchester, M16 0WJ, England	**The Authorised Representative** EC REP (in the EU for manufacturers not situated within Europe) Medical Device Management, Block B, The Crescent Building, Northwood, Santry, Dublin 9, D09 C6X8, Ireland	Your local Competent Authority.

All feedback including complaints regarding the appearance and performance of our products and packaging is welcome. If you have any comments you wish to make, please contact us by writing to or e-mailing us at our address or our Authorised Representative above. Please communicate the Serial Number and date of purchase of your device in all correspondence.

10 Accessories

Each device is fitted with an easy to use Flow Selector Switch in corporate with an easy to read flow indicator. Flowmeters are available in calibrated ranges of 0 - 1.1, 0 - 3, 2-4-6 and 0 - 15 LPM with a patient tubing Outlet Connector.

Accessories & replacement parts

Description	**Product code**
Adult Oxygen face mask	IS1106
Pediatric Oxygen face mask	IS1140
Oxygen Connecting tube (2m)	IS1174

Receiver Jars and Tubing

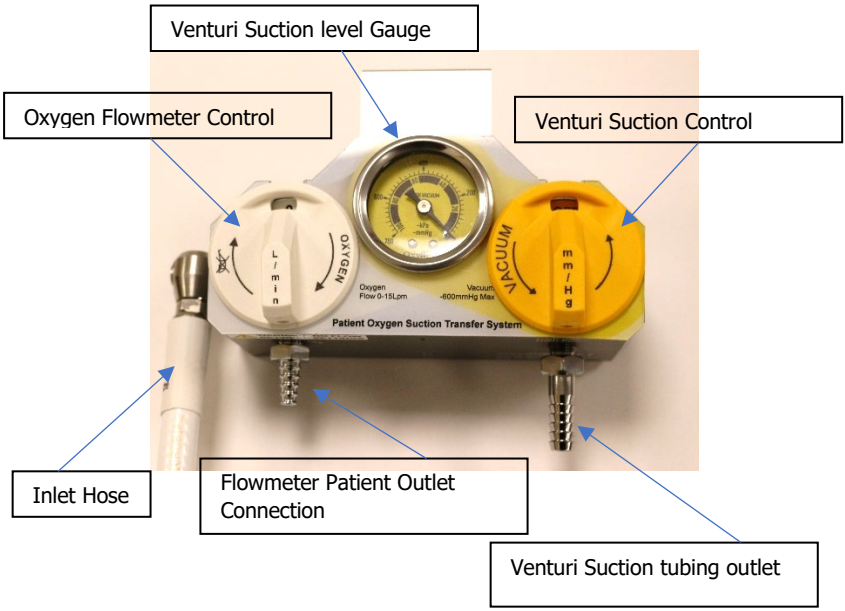
Description	**Product Code**
Oxylitre 1000ml Receiver Jar	S8701 (Rail Mounted)

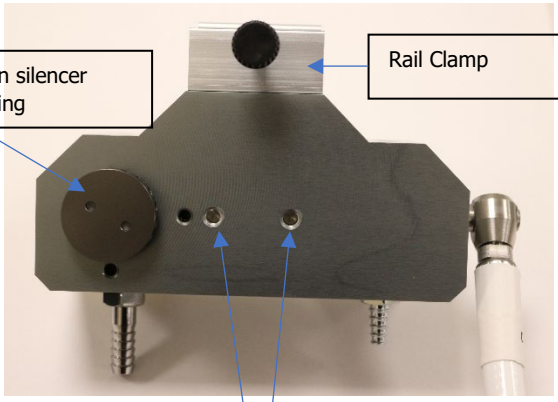
Oxylitre 1000ml Receiver Jar	S8702 ("V" Bracket Mounted)
Oxylitre 1800ml Receiver Jar	S7500B (Rail Mounted)
Oxylitre 1800ml Receiver Jar	S7500A ("V" Bracket Mounted)
Oxylitre A/S Suction Tubing	VAC101 (per 1 m length) - Clear
Oxylitre A/S Suction Tubing	VAC201 (per 1 m length) - Yellow

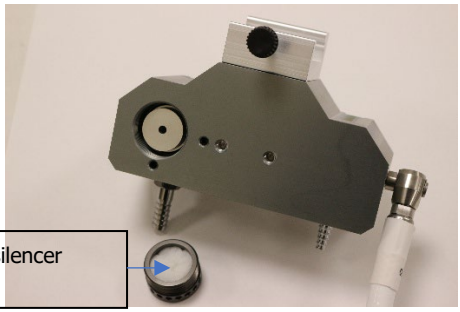
Receiver Jars with Hydrophobic Filter protected Disposable Liners may be used.

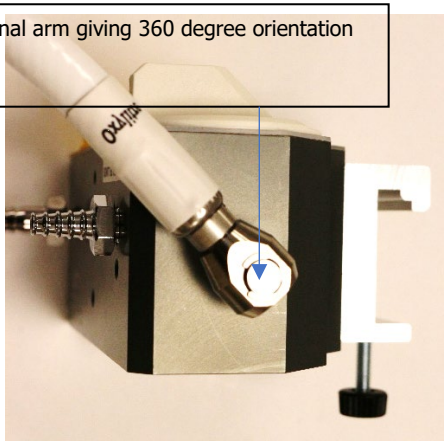
Note: The Injector Suction Controller, when connected to a gas source, does not have to be connected to another device to supply suction (i.e., intended use), but the convention is to connect it to a Receiver Jar to collect aspirated fluids.

11 User Interface of S800 Patient Oxygen Transfer System




Venturi Suction silencer wadding housing
Rail Clamp
Alternative rail clamp fixing holes


Venturi Suction silencer wadding housing


Inlet Hose rotational arm giving 360 degree orientation of the Inlet Hose

12 Using the Select-a-Flow Flowmeter

Preparing the device
(Always carry out before patient use)

Flowmeter set up
Prior to use, inspect flowmeter for obvious signs of damage such as cracks and / or broken parts.

Make sure flowmeter has been tested for any detectable leaks, this must be only done by qualified servicing personnel. NO leaks are permissible.

Before connecting the Flowmeter to a pressurised gas supply, ensure that the Flowmeter Selector Control Knob has been turned to the "0" position which Shuts Off the device.

13 Inspection & test procedures

The following Flowmeter inspection and test procedure must be carried out prior connection to a patient therapy device.
a. Connect the pressure Flowmeter into the appropriate gas outlet (Identified on the Flow Selector Control Knob) and ensure that the unit is securely locked in position.
b. With the Flowmeter fully shut off ensure that the Flowmeter Bobbin rests on the bottom of the Inner Tube without any movement.
c. Connect a calibrated Test Flowmeter to the Output Connector (via tubing) at the base of the Flowmeter, and then turn the Selector Control Knob clockwise until it clicks into first gas flow selection. Check that the Flowmeter reading calibrates with the Test Flowmeter and that it is within ± 10% full scale. Carry out this test at each flow selection to ensure the Flowmeter is fully operational.

14 Patient treatment

a. Ensure that the Flowmeter test and inspection procedure has been carried out, as stated in section 5.1, prior to use.
b. Before use, ensure that the correct sized Mask/Nasal Cannulae and Delivery Tube is used. For Oxylitre Recommendations, see "Accessories" Section 4.
c. Connect the Delivery Tube to the Mask/Nasal Cannulae and connect the other end of the Tube to the Multi-sized Tubing Outlet/Humidifier Bottle on the Flowmeter. The Mask or Nasal Cannulae is ready for Patient use. From the "0" position, rotate the Flowmeter Selector Control Knob clockwise until it fully "CLICKS" into the required Litre Flow position for therapy administration (Note: any position in between numbers is effectively "0").
d. The Litre Flow is indicated in the window of the Flowmeter Control Knob. Due to possible in-line restrictions check that the gas flow is flowing at regular intervals.
e. When the user/patient has finished, rotate the Control Knob anti-clockwise to the "0" position.

15 Using the Venturi Suction

Operating the unit

Please Note: Oxylitre S8 Series Injector Suction Controllers and Oxylitre Receiver Jars are not fitted with Hydrophobic/Bacterial protective Filters. Please ensure a protective Filter is fitted in either a non-Oxylitre Type Receiver Jar (if used) or inline between the Suction Controller and Receiver Jar prior to use. (Inline Filter Part No: S750).

a. Before connecting the equipment to a Gas Supply, check the unit for any visual damage and ensure that the unit is shut off by turning the Control Knob fully clockwise. Make sure that the correct gas has been selected.
b. Ensure the Receiver Jars' "Float Assembly" is operational, i.e. the float moves up/down freely. (Liner type Receptacles may be fitted with a Filter/Fluid Trap). Inspect all Receiver Jar components for wear or damage. Do not use and replace damaged components if necessary.
c. Connect the Vacuum Tube to the Injector Suction Unit's outlet (check for using correct diameter tubes) and the other end to the "Vacuum" input on the Receiver Jar Lid. Fit an in-line Filter in-between if necessary. Then connect a Catheter Connecting Tube (Part No: 180FFM) to the "Patient" output connector on the Receiver Jar and connect the required Catheter to the male end of the tube. (If required, use Anti-frothing agent as per the manufacturer's instructions).
d. Connect the Unit to a gas supply
e. Use the Control knob to adjust the amount of suction required. With the Patient Tube fully occluded (squeeze or fold tubing), turn the Control Knob anti-clockwise to increase the suction or turn the Control Knob clockwise to decrease. The vacuum indicator gauge will give an accurate indication of the suction being applied. Note: Occluding the Patient Tube when setting the suction level is very important and ensures that the patient does not receive excessive suction.
f. Aspiration should be stopped when fluid has reached the top graduation. In the event of an accidental overflow, the Float Valve will operate by shutting off the vacuum supply to the Receiver Jar.
g. When the 1000 ml type Jar is full, carefully unscrew and dispose of the contents. Pull the Float Assembly from the Jar Top then the Float Assembly, Jar and Jar Top must be thoroughly cleaned and re-assemble in the reverse order. When an 1800 ml type Jar is full, pull the male adapter probe from the top of the Jar lid and unhook the retaining spring clips. Remove the Jar carefully from the cradle and dispose of the contents appropriately. Unscrew the Float Assembly from the base of the Jar Lid, then Float Assembly, Jar Lid, and Jar must be thoroughly cleaned and re-assembled in the reverse order.

Note: In the event liquids or solids have been drawn into the vacuum pump proceed to immediate removal and servicing of the suction equipment. (if necessary contact manufacturer or authorised representative)

16 Maintenance & cleaning

A Patient Oxygen Transfer System forms part of an essential support system. Flowmeters must be treated with care and be serviced on a regular basis, (i.e. preventative maintenance) to ensure the unit's reliability and quality for the intended purpose. Clean outer surfaces with a propriety diluted mild (non-alkaline) disinfectant, such a Dettol, Disifin etc (always follow manufacturer's instructions), especially noting material compatibility).

Inspection
Recommended at least annually by a Service Engineer and consist of:
Leak Test
Calibration Check

Service/Repair
Fully qualified technicians should only carry out servicing.
Attention: A Major Service is recommended every 5 years. For service/repair enquiries and information, please contact our sales office.

NEVER USE FAULTY EQUIPMENT. Preventative maintenance ensures safety for the patient and user.

Cleaning

Clean surfaces of the Flowmeter by using a damp cloth soaked in a diluted mild, non-alkaline, disinfectant such as Dettol, Disifin, or similar as per container recommendations.
Avoid cleaning fluid from entering into any assembly orifices i.e. probes, outlets, etc.
DO NOT use any oil based cleaning fluids (note: some soaps are oil based).
Strong cleaning agents may cause sensitive parts and lead to loss of performance or injury / contamination of handling personnel and patient.

Use appropriate personal protective equipment to minimise risk of contamination or injury from sharps.
Improper cleaning may lead to cross contamination of users & patients.

The user is responsible for cleaning the device in accordance with this instruction.

Calibration

The Flowmeters are factory calibrated to an accuracy of ± 10% of full scale for each graduation on readings greater than 1.5 LPM at a temperature of 20ºC.
The readings are calibrated with a pressure source 400 kPa (58 psi).
Calibration tolerance

All Flowmeters are factory calibrated to:± 10% of each graduation readings (± 20% for 0.1 to 1.5 LPM range).
The accuracy of the flow rate may be affected if there are any restrictions either at the inlet or outlet.

17 Performance

Inlet Connection	Flowmeters are fitted with gas probe connectors which comply with the BS Standards for the Safety Prevention of connecting an incorrect gas. (BS 5682 Probe Type fittings)
Gas supply	Oxygen (400 kPa)
Flow range:	0 to 15 LPM 2-4-6 LPM 0 to 3 LPM 0 to 1.1 LP
Required testing pressure:	400 kPa (58psi / 4 bar)
Calibration tolerance:	± 10%
High Vacuum High Flow	0 to - 66.5 kPa (0 to -500mmHg)
Flow rate	≤25 LPM
Low Vacuum High Flow	0 to -20 kPa (0 to -150mmHg)
Gas Dispersion	80 Lpm at 66.5 kPa

18 Dimensions (excluding hose assembly)

Height:	75 mm
Width:	165 mm
Depth (with probe):	130 mm
Weight inclusive of standard 1.5m hose assembly (with probe):	1.7kg

19 Warranty

Each unit comes complete with a manufacturer's 7 Year warranty. Units are to be withdrawn from use after their "use by" date. 

Storage & transportation

- Store between 0°C to +40°C . 
- During transportation (especially through postage/carrier), ensure that the equipment is well packed and protected. Oxylitre will not be liable for any damage to the equipment.
- Store in an oil and grease-free environment.
- Always handle this equipment with care. This is a vital piece of medical equipment.
- Always transport & store the equipment within a dry environment. Keep away from excessive heat or dampness.

20 Disposal

Disposal should be in accordance with site and local/national requirements, for general guidance:

- Unless contaminated the devices may be disposed of to metal recycling.
- If biologically contaminated dispose of as clinical waste.
- In the event a device or items are to be returned to Oxylitre, ensure all contaminated and/or potentially contaminated items have been appropriately and effectively cleaned (accompanied by a decontamination certificate) and are suitably packaged. Returns shall only be made with the agreement of the person responsible for regulatory compliance at Oxylitre.

21 Explanation of symbols on label

Symbol	Explanation	Symbol	Explanation
	Manufacturer		Caution
	Keep dry		Consult instructions for use
	Temperature Limit		Medical Device
	Authorised Representative		Fragile
	Serial Number		Use no oil
	Distributor		Catalogue number
	Unique Device Identifier		Importer
	Keep away from sunlight		Not MRI compatible
	Use by date		Date of manufacture
	Warning		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EC REP