Instructions For Use

OASIS

Oxygen and Suction Integrated System

702-0012.3

Manufacturer
BPR Medical Ltd, 22 Hamilton Way
Mansfield, NG18 5BU, United Kingdom

Tel: +44 0) 1623 628281
Fax: +44 (0) 1623 628289

Approvals

OASIS is a CE Marked device in accordance with the Medical Device Directive (93/42/EEC) and meets the requirements of the following Harmonised Standards:

EN738-1 .....Pressure Regulators and Pressure Regulators with Flowmetering Devices
EN10079-3 ....Suction Equipment Powered from Vacuum or Pressure Source

Index

8.0 Specification

General	
Operating, Storage and Transport Temperature Range	*-20°C to 60°C*
Warranty	*1 Year*
Flowmeter	
Nominal Flow Rate	*0, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8,10, 15*
Flow Accuracy	*±10% of setting at 1 lpm and above, ±20% of setting below 1 lpm across the full input range*
Effect on accuracy as a result of:	
i) varying inlet pressure	*Typically less than 15% change across the input pressure range*
ii) varying outlet resistance	*Less than 1% of reading up to 5kPa (50cmH_2O) back pressure*
iii) varying temperature	*Less than 0.2% of reading per degree Celsius*
Delivery Hose	*6.0 mm inside diameter*

Suction	*Medium Suction Option (Blue Venturi Cartridge)*	*Medium/High Suction Option (Gold Venturi Cartridge)*	*High Suction Option (Silver Venturi Cartridge)*
Vacuum Range	*0 to –60 kPa (+5kPa/-30kPa)*	*0 to –55 kPa (+5kPa/-30kPa*	*0 to –50 kPa (+5kPa/-30kPa)*
Vacuum Flow	*10 – 16 lpm*	*15-25 lpm*	*38 – 60 lpm*
Gas consumption (typical)	*20 lpm*	*30 lpm*	*85 lpm max*
Recommended Suction Hose	*7.5mm inside diameter*	*7.5mm inside diameter*	*7.5mm inside diameter*
ISO EN 10079-3 Rating	*Medium Vacuum Equipment*	*Medium Vacuum equipment*	*Medium Vacuum Equipment*

Regulator	
(P_1) Maximum Input Pressure [kPa]	20 000 kPa
(P_3) Minimum Input Pressure [kPa]	900 kPa
Outlet Pressure [kPa] *Stated at 10 000 kPa Input Pressure and flow of 1 lpm*	400 kPa
Minimum Flow Capacity [lpm]	100 lpm
(Q_1) Standard Discharge [lpm]	30
(P_2) Outlet Pressure [kPa] *Stated at Input Pressure P_3 and flow Q_1*	400

7.0 Servicing

7.1 Frequency of Servicing

OASIS and its oxygen pressure regulator require servicing every 4 years. A Service Due date is given on the OASIS and pressure regulator rating label as a reminder.

7.2 Service Manual

A service manual is available for the OASIS Plus, which provides further information on spare parts and service procedures.

7.3 Decontamination Certificate

A valid decontamination certificate must accompany equipment returned for servicing. For reasons of Health & Safety, equipment returned for service without a valid decontamination certificate will be returned without further processing.

1.0 General Safety Warnings

IMPORTANT: Please ensure that all personnel who may use the OASIS have read this User Instruction Manual, are fully conversant with the Safety Warnings included within it and have received adequate general instruction on the clinical application of oxygen and suction equipment.

W1 Before using this equipment read through the entire instruction manual. Attempting to use this equipment without an appreciation of its correct operation, its limitations and the general safety warnings associated with compressed oxygen may result in patient or user injury.

W2 Oxygen therapy may be a critical treatment. A flowmeter should be used in strict accordance with the prescription and instructions of a qualified clinician. The effectiveness of supplemental oxygen therapy can only be determined by continuous monitoring of blood oxygen levels. It is essential that PaO2 or SpO2 monitoring is carried out when supplemental oxygen is prescribed.

W3 Ensure that the oxygen cylinder is securely fastened to the trolley base.

W4 When the flowmeter is turned off isolate the patient from the equipment by disconnecting the delivery tube from either the patient or the flowmeter.

W5 Only appropriately trained service personnel working in controlled conditions must perform disassembly, assembly and testing of this equipment.

W6 Do not submerge in water or allow any fluid to enter the equipment. If you have reason to suspect that fluid or other ingress has occurred remove the device from use and contact the manufacturer.

W7 The performance of the device may be affected if it is stored or transported in temperatures outside of the range -20^{o}C to +60^{o}C.

W8 Check the cylinder contents before use and at regular intervals during use as low cylinder pressure may result in poor or non-performance of the equipment. Always change the oxygen cylinder when the oxygen cylinder contents gauge is showing red.

W9 Hydrophobic filters for re-useable suction jars and disposable liner systems are designed for single use only and must be replaced after every patient use. Single Use products should be disposed of in accordance with hospital protocols. Do not attempt to clean and re-use disposable filters or liners.

W10 OASIS has been tested with the suction jar systems indicated in this manual. The use of suction jar systems other than those listed and/or approved by the manufacturer may result in poor or non-performance of the equipment.

W11 The accuracy of the flowmeter and suction device may be affected if the input pressure is other than that stated in the specifications.

2.0 Specific Safety Warnings Concerning Oxygen

W12 Oxygen is not flammable, but the presence of oxygen will drastically increase the rate and severity of combustion. Hydrocarbons such as oil or grease become highly combustible in the presence of oxygen. Oxygen must never be allowed to contact oil, grease or other petroleum-based substances.

W13 Never administer oxygen while smoking or when near an open flame.

W14 Oxygen cylinders have fill pressures up to 20 000 kPA (200 Bar). Never use medical oxygen from a cylinder without first reducing the pressure to a safe level through a suitable pressure regulator.

W15 Ensure that the threaded fittings or indexing pins on the regulator are properly mated and tightened before opening the cylinder valve.

W16 Never install a pin index regulator with more than one Yoke Seal between the cylinder and the regulator. Before attaching the regulator verify that the post valve is not already fitted with a Yoke Seal. Never add a second Yoke Seal to the regulator inlet while one is in place.

W17 Make sure that the pin-indexed or threaded fittings on the regulator inlet are compatible with the gas cylinder on which it is to be fitted. Never attempt to force an incompatible connection.

W18 The threaded bullnose connection on a UK medical oxygen cylinder may be the same as that for a UK medical air cylinder. Ensure that you have the correct cylinder for the application. OASIS and its regulator are intended for use with oxygen only and must not be connected to an air cylinder.

W19 Before removing a regulator from a cylinder fully close the cylinder valve and release all gas from the regulator.

W20 Never use oxygen as a pressure medium to purge obstructed pipelines or equipment, to operate pneumatic tools, or to build up any pressure in tanks.

W21 Never permit compressed medical gases to enter a regulator suddenly. Always open the cylinder valve slowly. Do not stand in front of a regulator outlet when opening the cylinder valve.

W22 Do not use or store oxygen equipment near excessive heat (>50^{o}C or 125^{o}F) or an open flame.

W23 Use only lubricants recommended by the manufacturer when servicing the OASIS. The use of lubricants other than those recommended by the manufacturer may result in fire or explosion.

W24 OASIS must always be used in an upright position. When fitting OASIS to a patient trolley ensure that the front membrane panel is vertical.

6.0 Maintenance

The following safety warnings apply. Please read them carefully before you proceed: W1, W5, W6, W7, W10, W11, W12, W14, W15, W16, W17, W18, W19, W20, W21, W22, W23 & W24

6.1 Frequency of Maintenance

Undertake Inspection every 6 months or when there is reason to believe that the device has sustained damage or may not be working correctly.

6.2 Inspection

Regulator Checklist:-
Input seal integrity (o-ring or dowty seal)
Cylinder contents gauge in good condition. Needle registers in the green area of the gauge on a full cylinder and zero when not connected to a cylinder
Sintered bronze filter in place and not blocked by debris
Labels intact and legible
Service due in the next 6 months?

OASIS Manifold Checklist:

Vacuum gauge in good condition
Low Pressure indicator shows when system pressure is removed and disappears when system pressure is restored
High pressure hose between regulator and manifold is in good condition.
OASIS is securely fixed to the trolley, no movement
Service due in the next 6 months?

6.3 Cleaning

Use a mild disinfectant soap solution and hot water to clean external parts in accordance with hospital procedures.

6.4 Leak Tests

Flowmeter Leak Through - Connect and charge the system to a full cylinder in accordance with Section 5. Check that the oxygen and suction control knobs are at zero (fully clockwise) and the OASIS low-pressure indicator is not showing red. Connect one end of a length of hose to the flowmeter outlet barb and place the other end into a container of water. Check that there are no bubbles coming from the end of the tube, which would indicate leak through.

External Leak – Following on from the test above, turn off the cylinder and leave the system charged for 1 hour. At the end of this time ensure that the system pressure hasn't dropped such that the low-pressure indicator has come forward and is now showing red.

Note:- If the low pressure indicator does come forward, re-charge the system and check each joint for leaks using a proprietary leak detector spray until the leak is found.

6.5 Flow Rate Test

Verify oxygen flow rates at all flow settings against specification (i.e. within ±10% at 1 l/min and above or ± 20% below 1 l/min).

6.6 Suction Test

Verify maximum suction capability by occluding the suction outlet, turning the control knob fully anticlockwise and checking the suction gauge.

3.0 Description of Symbols

Attention, see Instructions for Use

Use no oil

Ascending diagonal line on the decal label indicates increase in flow.

CE Marking

4.0 Product Description

OASIS is an oxygen flowmeter and a suction regulator integrated into one device, driven by a single oxygen cylinder.

It is designed to provide controllable delivery of supplemental oxygen and suction in emergency situations or when patients are being moved on patient trolleys.

OASIS is intended to be fitted to the head end of patient trolleys to provide easy access to both oxygen and suction where and when it is needed most. The integrated, sturdy design provides protection from damage in a harsh environment.

The oxygen flowmeter is of fixed orifice type, providing eleven pre-set flow rates selectable by turning the control knob to the required position. The flow rate at each position is shown through a window in the body of the flowmeter and is given in units of litres per minute (lpm). The patient or outlet connection barb is situated underneath the OASIS directly below the flowmeter control knob.

The suction device comprises a variable vacuum source to which a proprietary suction jar system can be connected. Vacuum is generated using the venturi principle. On turning the control knob, oxygen is fed to the venturi generator, which in turn provides a vacuum at the suction barb. The amount of vacuum is indicated by the vacuum gauge indicated in units of minus Kilo Pascals (-kPa) and minus Bar (-Bar). Vacuum is only noticeable on the gauge when an obstruction is perceived by the system, occluding the output port or hose with your finger is a simple way of testing system performance.

To provide early indication that a cylinder is empty or has been turned off, a low pressure indicator is included. The indicator, situated on the front panel, shows red when there is no gas present. A pressure regulator is provided with the OASIS to reduce the high cylinder pressure to a safe working level. The regulator is permanently connected to the OASIS manifold.

Suction Jar Systems

		Suction Jar Size			
		0.8 / 1.0 Litre	1.2 / 1.5 Litre	2.0 Litre	
Abbott					
Receptal	*Re-useable suction jar for disposable liner*	W064	E124	~~E423~~	
	Disposable liner	L212	F807	~~F906~~	
	Acupal cradle type	A	A		
Allegiance					
Medi-Vac Guardian	*Disposable canister*				
	Acupal cradle type		1212CE	~~4220CS~~	
Medi-Vac Flex Advantage	*Re-useable suction jar for disposable liner*	65652-611	65652-616		
	Disposable liner	65651-910	65651-920		
	Acupal cradle type	B	B		
Medi-Vac CRD	*Re-useable suction jar for disposable liner*	65652-511	65652-516		
	Disposable liner	1510CE	1515CE		
	Acupal cradle type	B	B		
Tyco					
Sep-T-Vac	*Disposable canister*	8888-310003	8888-310052		
	Acupal cradle type	B	B		
	Re-useable suction jar for disposable liner		8888-310839	~~8888-310843~~	
	Disposable liner		8888-310821	~~8888-310905~~	
	Acupal cradle type		B		
VacSax					
	Re-useable suction jar for disposable liner	3833-132		3833-090	
	Disposable liner	9910-340		9910-208	
	Acupal cradle type	B		B	
Flowmeter Spa					
Monokit Autoclavable	*Autoclavable suction jar*	MAK1000			
	Acupal cradle type	A			
Monokit Disposable	*Re-useable suction jar for disposable liner*				
	Disposable liner	5113080			
	Acupal cradle type	B			

5.0 User Instructions

The following safety warnings apply. Please read them carefully before you proceed: W1, W2, W3, W4, W6, W7, W8, W9, W10, W11, W12, W13, W14, W15, W16, W17, W18, W19, W20, W21, W22, W23 & W24

5.1 Connection of the Gas Pressure Regulator to a Cylinder

Check that the cylinder type and regulator inlet connector are compatible.

Check the presence and condition of the input connector seal on the regulator.

Note: For pin index regulators this is a washer type seal (Yoke Seal) and for bull-nose regulators an o-ring.

Fit the regulator to the cylinder ensuring that it is properly mated and the connectors are done up. Hand tight is sufficient.

Open the cylinder valve with a suitable cylinder key. Check the regulator cylinder contents gauge to verify that there is sufficient gas available.

Check that the 'Low Pressure' indicator on the front face of the OASIS manifold does not show red (i.e. indicator fully forwards).

5.2 Oxygen Delivery

Connect a sufficient length of oxygen tubing (not supplied) to the outlet barb. Connect the other end of the oxygen tubing to the patient or patient enclosure using the appropriate connector (not supplied).

Determine the appropriate oxygen flow rate in l/min required for the patient. Turn the control knob anticlockwise until the required rate is visible in the viewing window.

Continue to monitor the patient as advised by the clinician. Continue to check the cylinder contents gauge on the regulator.

Upon completion of the therapy turn the control knob to zero and disconnect the delivery hose from the patient.

5.3 Suction Delivery

Prepare the suction jar system in accordance with the manufacturer's instructions.

If you are intending to use an autoclavable suction jar system ensure that a hyrdophobic filter and overflow protection device is fitted.

Note:- Autoclavable suction jar systems have single use hydrophobic filter/overflow protection devices, which should be replaced with each new use/patient. The disposable liner systems recommended for OASIS (refer appropriate table) have an integral hydrophobic filter and overflow protection device.

Connect the suction hose (supplied) between the suction barb on the Acupal manifold and the barb on the suction jar marked 'Vacuum'.

Connect suction hosing and wand (not supplied) to the barb on the suction jar marked 'Patient'. This tubing is used for removing fluids from the patient and will deposit into the suction jar.

Note:- If these hoses are reversed the suction device will not operate correctly.

Fit the suction jar into the cradle provided on the bottom of the trolley.

To activate the suction unit turn the control knob anticlockwise. The level of suction (vacuum pressure) can be adjusted by turning the control knob as required.

5.4 Removing the Regulator from the Cylinder

To remove the regulator from the cylinder, first ensure the cylinder valve is closed. Bleed off any residual gas pressure in the system by turning on either the oxygen or suction delivery systems until flow ceases. Undo and remove the regulator from the cylinder.

5.5 Suction Jar Systems

Suction jar systems can generally be broken down into autoclavable and disposable types.

Autoclavable systems have a rigid suction jar with a sealable lid. Following cleaning and sterilisation they may be reused. A disposable hydrophobic filter is fitted to such systems and should be replaced after every use.

Disposable systems comprise either a rigid suction jar into which a disposable liner is fitted (the rigid jar being reusable) or a rigid or semi-rigid canister requiring no other components and being wholly disposable. The disposable systems recommended for use with the OASIS (refer appropriate table) have integrated hydrophobic filters and overflow protection devices and no other provision need be made in this regard.

Components from single use or disposable systems should never be re-used and no attempt should be made to clean or sterilise them.

5.6 Suction Jar Compatibility

OASIS has been tested and found to be compatible with the suction jar systems detailed in the table provided.

Some 2 Litre size jars shown in the table, whilst compatible with the OASIS suction regulator, are too tall and are liable to be broken should the trolley be lowered or put into the Trendelenberg position. These suction jar systems are therefore considered incompatible with OASIS and are shown with the manufacturer's part number crossed out (e.g. ~~XXX XXXX~~). For the same reason all 3 Litre and larger suction jar systems are incompatible with OASIS.