mediTECH
EMERGENCY RESUSCITATION SYSTEMS

USER INSTRUCTIONS

THREADED INPUT OXYGEN REGULATOR

PLEASE READ THESE INSTRUCTIONS BEFORE USING THE EQUIPMENT.

THREADED INPUT OXYGEN REGULATOR USER INSTRUCTIONS

This manual refers to B.N.O.S. Meditech 55B and 55SL oxygen regulators with threaded input fittings.

55B Range regulators are designed for mobile use in demanding conditions. The main material of manufacture is brass. They are also suitable for use in static conditions.

55SL Range regulators are designed for mobile use where light weight is important. The main material of manufacture is aluminium alloy, but with a brass high pressure oxygen path for safety. They are also suitable for use in static conditions.

B.N.O.S. Meditech Ltd. is an ISO 9001 & ISO 13485 registered company

EC – DECLARATION OF CONFORMITY CE 0086
These products have been either manufactured or supplied under ISO 9001 and BS EN 13485 and in accordance with the Medical Devices Regulations 2008 (No 2936). BNOS Meditech Oxygen Regulators are supplied in conformity under a quality system to meet Annex II of the Medical Devices Directive 93/42/EEC, as amended by Directives 98/79/EC, 2000/70/EC, 2001/104/EC & 2007/47/EC and Regulation (EC) No 1882/2003. Oxygen Regulators are classified as Class IIb Medical Devices. They are CE marked in accordance with the directive.

The above quality system has been inspected by the Notified Body Ref: CE 0086 being BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.

Other Standards
The following National & International Standards apply to the device:

EN738-1:1997,
ISO 10524-1:2006
BS EN ISO 407:2004,
EN980:2008
ISO 15223-1:2012
EN62366-1:2015
ISO 5359:2014
BS5682:2015,

DIN 13260-2:2004-06 (Germany)
SS8752430 (Sweden)
NFS90-116 (France)
UNI9507 (Italy)

FDA Class II Medical Device.

It is also certified that the equipment listed above fully complies with all the required mandatory standards and the performance, specifications, standards and sources agreed and contracted for this order.

CONTENTS

This Oxygen Regulator is to be used by adequately trained personnel only

Caution:

The User should ensure that no grease, oil or other contaminants come into contact with the cylinder, valve, regulator, gauge(s), flow selector or connections.

Always open the cylinder valve slowly to minimise pressure shocks.

The connectors fitted to the Regulator are designed specifically for this device. If replacements are needed, they must be approved parts supplied by B.N.O.S. Meditech Ltd.

The Regulator must not be disassembled when it is under pressure, as serious injury could result.

The Therapy Outlet Flow Selector (if fitted) must be set at the defined settings shown on the dial. It must not be set between adjacent settings, as this may result in no flow from the outlet.

The accuracy of the Therapy Outlet Flow selector (if fitted) will be affected if the input pressure is varied from the nominal value shown in the Performance section of this document.

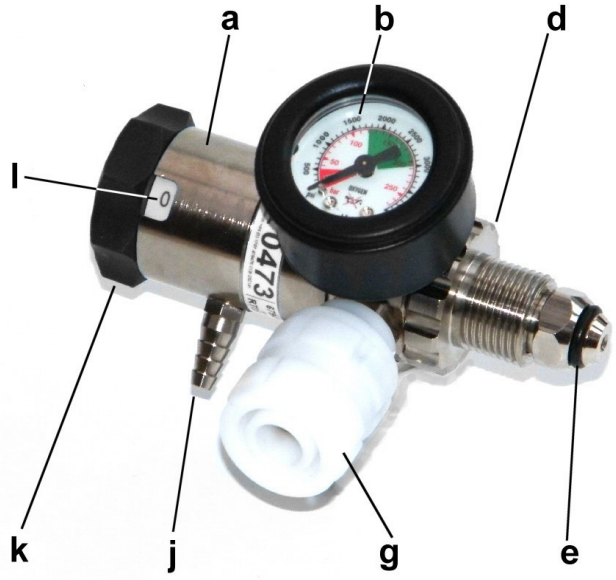
Note that increasing output flow is obtained from the Therapy Outlet Flow selector (if fitted) if the control is turned clockwise.

The setting of the Therapy Outlet Flow selector (if fitted) does not indicate that a flow is occurring. The User must check that oxygen is flowing to the patient by another means.

Attention is drawn to the accuracies stated in the Performance section of this document.

TECHNICAL DESCRIPTION

This Oxygen Regulator is designed for use with oxygen cylinders fitted with a gas specific threaded input connection for medical oxygen.
The type of connection may vary with the national standards



Key to components:

a. Regulator body
b. Pressure Gauge
d. Handwheel (BS Bullnose type illustrated)
e. O-ring seal
g. Power Output quick connection (BS Shrader type illustrated)
j. Therapy Outlet from regulator
k. Therapy Outlet Flow Selector
l. Therapy Outlet flow display window

Figure A: Regulator

1. INSTRUCTIONS FOR USE

1.1. ATTACHING TO A CYLINDER

1.1.1 Inspect the Regulator (Fig: A) and check that the o ring seal (e) is in place and in serviceable condition. Check that the Pressure Gauge (b) reads zero.

1.1.2 Check your oxygen cylinder to ensure that it is correctly labelled as medical oxygen. Ensure that any new gas cylinders are fitted with a tamper evident seal. Remove all traces of the seal. The thread and diameter of the regulator to cylinder valve connection prevent incorrect attachment of the wrong type of gas cylinder and will locate only into the same standard oxygen cylinder valve.

1.1.3 Position the Regulator and attach the regulator hand wheel to the oxygen cylinder valve outlet. Ensure the regulator is carefully lined up ensuring that the Pressure Gauge (b) and Power Output and Therapy Outlet (g and j) are in the correct orientation before tightening the handwheel securely. We recommend the orientation where the Power Output quick connection (g) is close to the oxygen cylinder body. During assembly ensure the Pressure Gauge (b) or Power Output (g) is not compressed against the cylinder valve, which can damage the gauge and prevent the sealing o-ring (e) functioning. When used with a portable cylinder the assembled regulator and cylinder is placed in the kit bag, the Pressure Gauge (b) and Therapy Outlet flow display window (l) can be easily seen and the Power Output quick connection (g) and Therapy Outlet Flow Selector (k) operated.

1.1.4 Open the cylinder valve slowly (i.e. facing away from the operator or other personnel) by means of a cylinder valve key (or cylinder valve hand wheel control). If gas escapes around the o-ring seal, turn off cylinder, depressurise the Regulator, and loosen and re-tighten the Regulator Handwheel (d). Again slowly open the cylinder valve, if no gas leak is heard, open the cylinder valve one full turn and check that the Pressure Gauge (b) shows that the cylinder is full.

1.1.5 If a leak of gas is still heard, turn off the cylinder valve and remove the Regulator. Remove and replace the o-ring (e) and repeat from step 1.1.1. If a leak is still heard then the Regulator should be taken out of service.

1.1.6 To attach an oxygen powered resuscitator or other equipment to the Regulator, insert the fitting on the equipment supply hose into the Power Output. The fittings on the Power Output are designed to meet national standards. These fittings are designed to be gas specific, so only equipment designed to operate from medical oxygen should attach to a medical oxygen regulator. This is a safety feature. Do not try and force equipment to attach.

1.1.7 To attach equipment to the Therapy Outlet (j), connect with elastomeric tubing. When connected select the required flow rate by rotating the Therapy Outlet Flow Selector (k) and observing the flow rate selected in the Therapy Outlet flow display window (l).

1.1.8 After use the cylinder valve should always be turned off. With emergency equipment it is possible to leave the regulator assembled to the cylinder valve and the resuscitator hose and medical oxygen fitting attached to the regulator Power Output (g). This enables the user to quickly turn on the oxygen supply to the equipment when required in an emergency.

1.1.9 The Therapy Outlet Flow Selector (k) should always be left in the off position (“0” indicated in the Therapy Outlet flow selector window (l)) when the Therapy Outlet is not in use. This prevents oxygen escaping un-noticed from the outlet (j) when the oxygen bottle is turned on.

1.2 TO CHANGE A USED CYLINDER

1.2.1 Turn off the cylinder valve by the cylinder key or cylinder valve handwheel.

1.2.2 De-pressurise the regulator by operating the therapy flow or equipment connected to the Power Output (g). The Pressure Gauge (b) reading will move to zero. Turn the Therapy Outlet Flow Selector (k) to the off position (“0” indicated in the Therapy Outlet flow selector window (l)). Disconnect any equipment connected to the Power Output or Therapy Outlet.

1.2.3 Unscrew the Regulator Handwheel (d) and remove the empty cylinder ensuring the o-ring seal (e) remains in place on the regulator.

1.2.4 Repeat the instructions for "Attaching to a cylinder”. (Section 1.1)

2. ACCESSORIES AND SPARE PARTS

2.1. No specific accessories are listed for the Regulator

2.2. Spare parts that are replaceable by the end user are as follows:

Protective boot for pressure gauge 633-0027-00
O-ring seal – type varies according to national standard
Please contact B.N.O.S. Meditech Ltd. with details of part number and serial number of the regulator.

2.3. Additional parts are available to medical engineers. Contact B.N.O.S. Meditech Ltd. for details.

3. PERFORMANCE

3.1. Rated maximum upstream pressure (P1): 200 bar
3.2. Rated outlet pressure (P2): 4 bar
3.3. Test inlet pressure (P3): 8 bar
3.4. Standard discharge (Q1): 50 lpm (litres per minute)
3.5. Variation of outlet pressure (P2) when inlet pressure is varied from P1 to P3 at a flow of Q1: 4%
3.6. For regulators with a Therapy Outlet, the figures represent the flow rate from the Therapy Outlet in litres per minute (lpm). These figures are subject to a tolerance of ±10% of the shown value or ±0.5 lpm whichever is the greater. If the Therapy Outlet Flow Selector has a MAX setting, this has a nominal flow rate of 25 lpm.
3.7. Temperature ranges:
3.7.1 Storage: -40°C to +60°C
3.7.2 Operating: -20°C to +60°C

4. CLEANING

4.1. Surface cleaning of the regulator should be carried out using soap flakes in solution.
4.2. For disinfection purposes a chlorine dioxide based product (eg the Tristel Wipes System) should be used, at a nominal concentration of 0.02% wt/vol. The concentration refers to chlorine dioxide in water. The regulator should be wiped clean only and should not be submerged in any fluids.
4.3. After cleaning or disinfection the regulator should be wiped with clean water to remove any residue and then allowed to dry before returning to use.

5. INSPECTION AND USER CHECKS

5.1. INSPECTION

5.1.1 The Regulator should be inspected for damaged or broken components and contamination after each use. Check that the Pressure Gauge (b), Power Output (g) and Therapy Outlet (j) (if fitted) are all tight and undamaged. Check that any controls operate correctly and that the Handwheel (d) is not binding.
5.1.2 If contaminated, the Regulator should be cleaned in accordance with Section 4.
5.1.3 If damaged, the Regulator should be withdrawn from service and returned to B.N.O.S. Meditech for assessment and repair.

5.2. USER CHECKS (to be carried out before use and after cleaning)

5.2.1 Connect the Regulator to a suitable oxygen cylinder. Check that the Pressure Gauge (b) reads zero. Slowly open the cylinder valve. Check that the Pressure Gauge indicates that there is pressure in the cylinder. If it continues to read zero, use a cylinder known to contain oxygen at a minimum pressure of 50 bar.
5.2.2 Check for audible leaks when the therapy outlet flow selector (k), if fitted, is in the off position ("0" indicated in the therapy outlet flow selector window (l)).
5.2.3 If the Regulator is fitted with a therapy outlet, check that the operation of the selector has distinct stops at all settings but can be operated smoothly between settings without undue force. Check that the flow increases as the therapy outlet flow selector (k) is operated from 0 to 15 (or MAX). Check there is no flow when the selector is returned to 0.
5.2.4 Connect an appliance (e.g. a resuscitator) to the Power Output (g). Check that the appliance is capable of being operated from the Power Output (i.e. oxygen is being supplied to it) and that there is no audible leakage from the connector. Disconnect the appliance. Check that the connector operates correctly during the connection and disconnection process.
5.2.5 Close the cylinder valve.
5.2.6 If the Regulator fails any of these checks, it should be withdrawn from service and returned to B.N.O.S. Meditech Ltd. for assessment and repair.

6. MAINTENANCE

6.1. Maintenance must be carried out on the unit on a five yearly basis by B.N.O.S. Meditech or engineers certified by B.N.O.S. Meditech. This activity involves dismantling the unit and replacing all internal seals. Inspection for broken or unserviceable components due to wear and tear or physical damage should be carried out and these components replaced as necessary.

6.2. Performance should also be checked on a five yearly basis, using suitable test equipment. The dynamic and static regulator pressure should be measured at the Power Output, using an oxygen cylinder with a minimum content of 75 bar. Verify that the flow rates on all settings are within specification at room temperature. If required, B.N.O.S. Meditech Ltd. can advise on suitable test equipment.

6.3. A leak test should also be performed by applying an oxygen compatible leak test solution to all outlets, fittings and joints, where applicable.

6.4. B.N.O.S. Meditech Ltd. offers training and certification on the service, repair and preventative maintenance of Meditech products.

7. SERIAL NUMBER

7.1. The Serial No. is to be found on the “barrel” label of the regulator. It consists of four sections the first letters expressing the general type of device, followed by numbers for the month and year of manufacture and lastly a set of up to five numbers representing the “number” of the unit and differentiating units built in the same month.

7.2. Example:

RT	**10**	**02**	**12345**
Regulator Therapy	**Month of manufacture**	**Year of Manufacture**	**Number of unit**

8. PRODUCT LIFE SPAN

8.1. This Regulator has been designed for the demands of the pre-hospital emergency medical market to give many years of reliable service. The regulator is manufactured from the finest quality materials with individual components subject to strict quality control tests to ensure high standards under ISO 9001. The regulator is designed to have a product life span of 10 years, excluding abuse to the instrument.

8.2. We reserve the right to change design without prior notice.

IMPORTANT NOTICE
Manufacturer’s Warranty is for a period of 5 years and includes parts and labour. It does not include transport costs. The responsibility and cost of returning and collecting the unit from the manufacturer or their authorised representative is the owners.
Any disassembly of the regulator beyond that detailed in this manual will invalidate the warranty and the manufacturers disclaim any liability for products that have undergone unauthorised repair.

9. COMPANY CONTACT DETAILS

9.1. This regulator is designed and manufactured by:

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CE 0086

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