mediTECH
EMERGENCY RESUSCITATION SYSTEMS

USER INSTRUCTIONS

PIN INDEX OXYGEN REGULATOR

PLEASE READ THESE INSTRUCTIONS BEFORE USING THE EQUIPMENT.

PIN INDEX OXYGEN REGULATOR USER INSTRUCTIONS

This manual refers to B.N.O.S. Meditech 55B and 55SL oxygen regulators with pin index 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 0473
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.

The above quality system has been inspected by the Notified Body Ref: CE 0473 being Amtac Certification Services Ltd, Davy Avenue, Knowlhill, Milton Keynes, MK5 8NL

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

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

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 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.

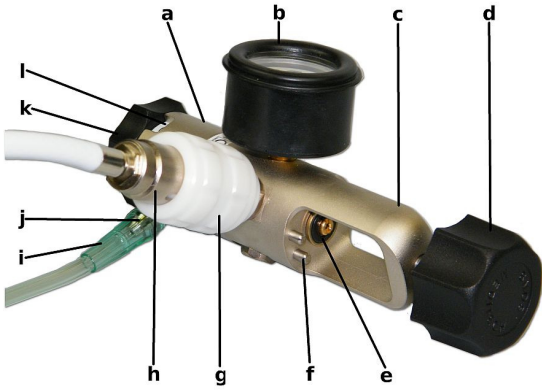
Note that increasing output flow is obtained from the Therapy Outlet Flow selector (if fitted) if the control is turned clockwise.

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 twin pin index valve of the correct offset for medical oxygen.

Figure A: Pin Indexed Regulator.

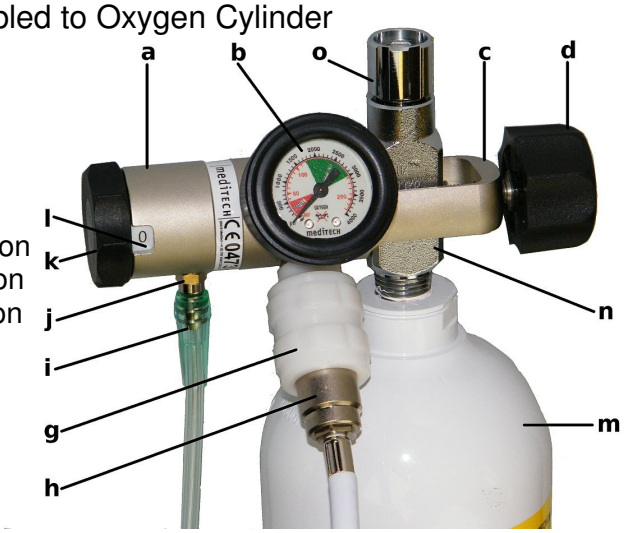


Key to components
a. Regulator body
b. Pressure gauge
c. Yoke
d. Yoke Screw
e. Yoke sealing washer
f. Pin index
g. BS 5682:1998 output quick connection
h. BS 5682:1998 probe quick connection
i. Therapy mask elastomeric connection
j. Therapy outlet from regulator
k. Therapy outlet flow selector
l. Therapy outlet flow display window

Figure B: Pin Indexed Regulator assembled to Oxygen Cylinder

Key to components

a. Regulator body
b. Pressure gauge
c. Yoke
d. Yoke screw
g. BS 5682:1998 output quick connection
h. BS 5682:1998 probe quick connection
i. Therapy mask elastomeric connection
j. Therapy outlet from regulator
k. Therapy outlet flow selector
l. Therapy outlet flow display window
m. Oxygen cylinder
n. Oxygen cylinder valve body
o. Oxygen cylinder valve



1. INSTRUCTIONS FOR USE

1.1. ATTACHING TO A CYLINDER

1.1.1 Inspect the Pin Indexed Regulator (Fig: A) and check that the Yoke sealing washer (e) is in place and in serviceable condition.

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 Index Pins (f) prevent incorrect attachment of the wrong type of gas cylinder and will locate only into the two matching holes on the face of the oxygen cylinder valve.

1.1.3 Position the Regulator Yoke (Fig: B) (c) over the Cylinder valve body (n), having first loosened the Yoke Screw (d). Positions the Index Pins (f) into their locating holes and tighten Yoke Screw (d) securely, ensuring that the Pressure Gauge (b) and Outlets (g and j) are in the correct orientation. We recommend the orientation shown in Figure B where the BS 5682: 1998 output quick connection (g) is close to the oxygen cylinder body (m). During assembly ensure the regulator gauge is not compressed against the cylinder valve, which can damage the gauge and prevent the Yoke sealing washer functioning. When the assembled regulator and cylinder is placed in the kit bag, the cylinder gauge (b) and therapy outlet flow display window (l) can be easily seen and the cylinder valve key (o), BS 5682: 1998 output quick connection (g) and Therapy outlet flow selector operated.

1.1.4 Open the Cylinder Valve (k) slowly (i.e. facing away from the operator or other personnel) by means of the Cylinder Valve Control (o). If gas escapes around the Yoke sealing washer, turn off cylinder with the Cylinder Valve Control (o) and tighten the Yoke Screw (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 Yoke sealing washer (Fig: A) (e) and repeat from step 1.1.1.

1.1.6 To attach an oxygen powered resuscitator or other equipment to the Regulator, insert male BS 5682:1998 Probe (fig A) (h) which is attached to the supply hose into the female BS 5682:1998 Outlet (g) by pushing firmly into the orifice. The coupling will lock automatically.

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 be turned off. With emergency equipment it is possible to leave the regulator assembled to the cylinder valve and the resuscitator hose and BS 5682: 1998 probe (h) attached to the regulator outlet (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 (Fig: B) by the Cylinder Valve Control (o)

1.2.2 De-pressurise the regulator by operating the therapy flow or equipment connected to the BS 5682:1998 Outlet (e). The pressure gauge (b) reading will move to zero. Turn the therapy flow to the off position ("0" indicated in the Therapy outlet flow selector window (l)) Uncouple the BS 5682:1998 Probe by twisting the knurled collar on the female BS5682:1998 Outlet (e) in a clockwise direction. The male probe will automatically disconnect.

1.2.3 Unscrew the Regulator Yoke Screw (d) and remove the empty Cylinder ensuring the Yoke sealing washer (Fig: B) (e) remains in place on a 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
Yoke sealing washer (also known as bodock seal)	033-1021-00

2.3 Additional parts are available to medical engineers. Contact the manufacturers 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 Flow Selector, 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℃ to +60℃

3.7.2 Operating: -20℃ to +60℃

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 Yoke Screw (d) operates smoothly.

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 For regulators with a Therapy Outlet Flow Selector, check that the operation of the selector (k) has distinct stops at all settings but can be operated smoothly between settings without undue force. Check that the oxygen output increases progressively as the control 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 and any components which show significant wear and tear.

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	**02**	**15**	**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 0473

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