mediTECH
MEDICAL GAS EQUIPMENT

INSTRUCTIONS FOR USE
THREADED INPUT MEDICAL GAS REGULATOR

READ THESE INSTRUCTIONS BEFORE USING EQUIPMENT

1. SYMBOLS

	Indicates a potentially hazardous situation which could result in injury to the user or others, if not avoided.
	Read these instructions before using the equipment
	Do not use any form of grease or oil
	No Smoking
	Do not use this device near any source of ignition
	Product part number
	Serial Number
	Manufactured by
	Next Maintenance or Service Due date
	Medical device
	Authorised representative details

2. INTENDED USE OF DEVICE

There are two main uses for the Meditech range of Medical Gas Regulators.

Units fitted with a pressure outlet, typically 4 bar, are used to provide gas to a device which requires an input at this pressure. Primarily, pneumatically powered medical devices such as a ventilator or Demand Valve. The pressure outlet is supplied in accordance with a national or international standard and there is the potential for a second pressure outlet for use with another item. The second outlet may be to the same national or international standard as the first, or it may be different.

Units fitted with a flow outlet are used to deliver variable flow rates of gas to a patient who requires gas therapy. The patient will be breathing on his own but may have a need for support perhaps to supply oxygen enriched air to increase blood oxygen levels. The flow outlet will be either a ‘fir tree connector’ for use with standard oxygen tubing fitted to a therapy mask, or canula or a threaded outlet for use with a humidifier. Flow outlets can be switched between different rate in the range of 0.5lpm (litres per minute) to 15 lpm, with an optional ‘MAX’ setting of approximately 25lpm used for system purging.

Units are available with both a pressure outlet and a flow outlet and these can be used for either purpose of both simultaneously.

3. TECHNICAL DESCRIPTION

This manual refers to B.N.O.S. Meditech 55B and 55SL medical gas 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 Medical Gas path for safety. They are also suitable for use in static conditions.

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.

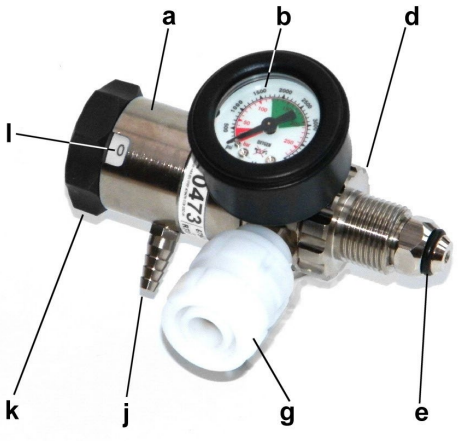

Figure A: Threaded Input Regulator.

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

4. WARNINGS!

THIS MEDICAL GAS REGULATOR IS TO BE USED BY ADEQUATELY TRAINED PERSONNEL ONLY.

4.1 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.

4.2 Do not use this device near any source of ignition e.g. naked flame, electrically powered heaters, cigarettes etc.

4.3 Always open the cylinder valve slowly to minimise pressure shocks.

4.4 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.

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

4.6 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.

4.7 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.

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

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

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

5. INSTRUCTIONS FOR USE

5.1. ATTACHING TO A CYLINDER

5.1.1 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.

5.1.2 Check your medical gas cylinder to ensure that it is correctly labelled as the required gas. 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 prevents incorrect attachment of the wrong type of gas cylinder and will locate only into the same standard medical gas cylinder valve.

5.1.3 Position the Regulator and attach the regulator hand wheel to the medical gas 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 medical gas 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.

5.1.4 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.

5.1.5 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 5.1.1. If a leak is still heard then the Regulator should be taken out of service.

5.1.6 To attach a medical gas-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, for example, 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.

5.1.7 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).

5.1.8 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 gas fitting attached to the regulator Power Output (g). This enables the user to quickly turn on the medical gas supply to the equipment when required in an emergency.

5.1.9 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 medical gas escaping un-noticed from the outlet (j) when the medical gas bottle is turned on.

5.2. TO CHANGE A USED CYLINDER

5.2.1 Turn off the Cylinder Valve (Fig: B) by the Cylinder Valve Control (o)

5.2.2 De-pressurise the regulator by operating the therapy flow or equipment connected to the BS 5682:2015 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 BS5682:2015 Outlet (e) in a clockwise direction. The male probe will automatically disconnect.

5.2.3 Unscrew the Regulator Yoke Screw (d) and remove the empty Cylinder ensuring the Yoke sealing washer (Fig: B) (e) remains in place on the regulator.

5.2.4 Repeat the instructions for "Attaching to a cylinder”. (Section 5.1)

6. CLEANING AND DISINFECTION

6.1 Surface cleaning of the regulator should be carried out using soap flakes in solution.

6.2 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.

6.3 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.

7. INSPECTION AND USER CHECKS

7.1 INSPECTION

7.1.1 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.

7.1.2 If contaminated, the Regulator should be cleaned in accordance with Section 6.

7.1.3 If damaged, the Regulator should be withdrawn from service and returned to B.N.O.S. Meditech for assessment and repair.

7.2 USER CHECKS (to be carried out before and after cleaning)

7.2.1 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.

7.2.2 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)).

7.2.3 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.

7.2.4 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.

7.2.5 Close the cylinder valve.

7.2.6 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.

8. MAINTENANCE

8.1 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.

8.2 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 a Medical Gas 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.

8.3 A leak test should also be performed by applying a Medical Gas compatible leak test solution to all outlets, fittings and joints, where applicable.

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

9. ACCESSORIES AND SPARE PARTS

No specific accessories are listed for the Regulator. 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 the manufacturer with details of part number and serial number of the regulator. Additional parts are available to medical engineers. Contact the manufacturers for details.

10. PERFORMANCE

Rated maximum upstream pressure (P1): 200 bar
Rated outlet pressure (P2): 4 bar (7 bar variant available for Medical Air)
Test inlet pressure (P3): 8 bar
Standard discharge (Q1): 50 lpm (litres per minute)
Variation of outlet pressure (P2) when inlet pressure is varied from P1 to P3 at a flow of Q1: 4%
For regulators with a Therapy Outlet Flow Selector (in accordance with the requirements of 5.4.14 of ISO 10524-1:2019), the figures represent the flow rate from the "Therapy outlet" in litres per minute (lpm). These figures are subject to a tolerance of ±20% of each stated value or ± 30% of each stated value for flows of 1,5l/min or less. If the Therapy Outlet Flow Selector has a MAX setting, this has a nominal flow rate of 25 lpm.

Temperature ranges:

Storage: -40°C to +60°C
Operating: -20°C to +60°C

11. SERIAL NUMBER

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.

Example for Therapy Regulators:

SN

RT	03	18	12345
Regulator Therapy	**Month of Manufacture**	**Year of Manufacture**	**Number of unit**

Example for Non Therapy Regulators:

SN

R	03	18	12345
Regulator	**Month of Manufacture**	**Year of Manufacture**	**Number of Unit**

12. PRODUCT LIFE SPAN

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 13485. The regulator is designed to have a product life span of 10 years, excluding abuse to the instrument.

We reserve the right to change design without prior notice.

13. RELEVANT APPLICABLE STANDARDS

B.N.O.S. Meditech Ltd. is an ISO 13485:2016 registered company.

EC – DECLARATION OF CONFORMITY CE 2797
These products have been either manufactured or supplied under ISO 13485:2016. B.N.O.S. Meditech Regulators are supplied in conformity under a quality system to meet Annex II of the Medical Devices Directive 93/42/EEC as amended 2007/47/EC, Regulators are classified as Class IIb Medical Devices.

The above quality system has been inspected by the Notified Body Ref: CE 2797 being BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands. EC Certificate No. 662942 refers.

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

ISO 13485:2016
ISO14971:2019
ISO 10524-1:2019
BS EN ISO 407:2004,
ISO 15223-1:2016
EN62366-1:2015
ISO 5359:2014+A1 2017
BS5682:2015

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.

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.

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MEDICAL GAS EQUIPMENT

CE 2797

COMPANY CONTACT DETAILS

This regulator is designed and manufactured by:

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EC REP

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