mediTECH
EMERGENCY RESUSCITATION SYSTEMS

OXYGEN FLOW SELECTOR USER INSTRUCTIONS

PLEASE READ THESE INSTRUCTIONS BEFORE USING THE EQUIPMENT.

OXYGEN FLOW SELECTOR USER INSTRUCTIONS

This manual refers to the Meditech Oxygen Flow Selector (Model No)

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

EC – DECLARATION OF CONFORMITY CE0473

These products have been either manufactured or supplied under ISO 9001:2008 and BS EN 13485 and in accordance with the Medical Devices Regulations 2002 (SI 2002, No 618) & Medical Devices (Amendment) Regulations 2008 No 2936. B.N.O.S. Meditech microVENT Resuscitators are supplied in conformity under a quality system to meet Annex II of the Medical Devices Directive 93/42/EEC 20/11/03, as amended by Directive 2007/47/EC. Oxygen Flow Selectors are classified as Class IIb Medical Devices.

The above quality system has been inspected by the Notified Body Ref: CE0473 being Amtac Certification Services Ltd, Davy Avenue, Knowlhill, Milton Keynes, MK5 8NL

Other Standards

The following National & International Standards apply to the device:

ISO 15002:2008
BS5682:1998
ISO 5359:2000
EN980:2008

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.

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Cautions:

The User should ensure that no grease, oil or other contaminants come into contact with the Flow Selector or connections.

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

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

The Flow Selector 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 Flow selector will be affected if the input pressure is varied from the nominal value shown in the Specification section of this document.

Note that increasing output flow is obtained from the Flow Selector if the control is turned clockwise.

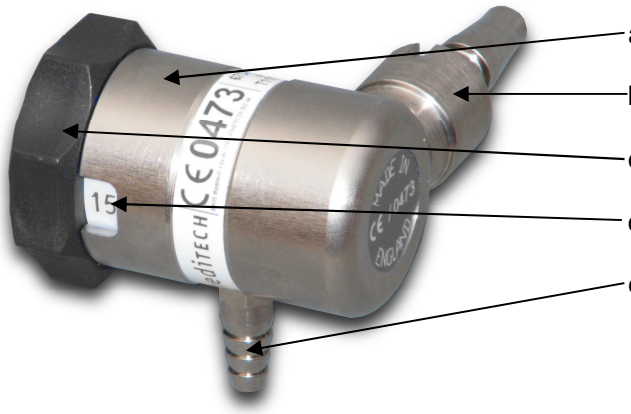
The Flow Selector device does not indicate that a flow is occurring. The User must check that oxygen is flowing to the patient by another means.

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

This Oxygen Flow Selector is to be used by adequately trained personnel only.

TECHNICAL DESCRIPTION

This Oxygen Flow Selector is designed for use with oxygen supplies at a nominal pressure of 4 bar, from a cylinder fitted with a suitable pressure regulator or from a compatible wall outlet. It consists of a brass or aluminium body with a suitable inlet connector and push fit hose outlet, for connection to an oxygen mask. The inlet connector is fitted with a filter. The principle of operation is that the oxygen passes through one of a number of selectable orifices before it reached the outlet fitting.



a. Flow Selector Body

b. Inlet Connection

c. Therapy outlet flow selector

d. Therapy outlet flow display window

e. Therapy outlet elastomeric connection

Figure A Key to Components

1 INSTRUCTIONS FOR USE

1.1 Use with an Oxygen Cylinder, fitted with a Pressure Regulator

1.1.1 Check your Oxygen Cylinder to ensure that it is correctly labelled as medical oxygen. Ensure that the Pressure Regulator is correctly attached to the Oxygen Cylinder, in accordance with its instructions. Check that the Cylinder and Regulator combination is not leaking by briefly opening the Cylinder Valve slowly. Close the Cylinder Valve.

1.1.2 Ensure the Flow Selector is set to '0'. Insert male probe of the Flow Selector (b) into the female outlet of the Oxygen Regulator by pushing firmly into the orifice. It may be necessary to lock the connector in place using a nut, depending on the type of connection in use. For outlets and probes to BS 5682:1998, it is necessary only to ensure that it clicks home and locks automatically. Other fittings are available for specific markets and these will have different connections.

1.1.3 Open the Cylinder Valve slowly. If a leak of gas is heard, turn off the Cylinder Valve and check all connections.

1.1.4 To attach equipment to the therapy outlet (e), connect with elastomeric tubing. When connected select the required flow rate by rotating the therapy outlet flow selector (c) and observing the flow rate selected in the therapy outlet flow display window (d). Note that flow rate increases as the control is turned clockwise.

1.1.5 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 Flow Selector attached to the regulator outlet. This enables the user to quickly turn on the oxygen supply to the equipment when required in an emergency.

1.1.6 The therapy outlet flow selector (c) should always be left in the off position ("0" indicated in the therapy outlet flow selector window (d)) when the therapy outlet is not in use. This prevents oxygen escaping un-noticed from the outlet (e) when the oxygen bottle is turned on.

1.2 Use with an Oxygen Wall Outlet

1.2.1 Check your Wall Outlet to ensure that it is correctly labelled as medical oxygen. Ensure the therapy outlet flow selector (c) is set to '0'. Insert male probe of the Flow Selector (b) into the female wall outlet by pushing firmly into the orifice. It may be necessary to lock the connector in place using a nut, depending on the type of connection in use. For outlets and probes to BS 5682:1998, it is necessary only to ensure that it clicks home and locks automatically. Other fittings are available for specific markets and these will have different connections.

1.2.2 To attach equipment to the therapy outlet (e), connect with elastomeric tubing. When connected select the required flow rate by rotating the Therapy outlet flow selector (c) and observing the flow rate selected in the Therapy outlet flow display window (d).

1.2.3 The therapy outlet flow selector (c) should always be left in the off position ("0" indicated in the therapy outlet flow selector window (e)) when the therapy outlet is not in use. This prevents oxygen escaping un-noticed from the outlet (d). If possible, remove the Flow Selector from the Wall Outlet when it is not in use.

2 ACCESSORIES & SPARE PARTS

2.1 No specific accessories are listed for the Flow Selector.

2.2 No spare parts are available for the Flow Selector.

3 PERFORMANCE

3.1 Nominal Inlet Pressure: 4 bar (400kPa)

3.2 Minimum Inlet Pressure: 3.5 bar (350kPa)

3.3 Maximum Inlet Pressure: 4.5 bar (450kPa)

3.4 Test Inlet pressure: 10 bar (1000kPa). The unit will remain mechanically sound at this input pressure.

3.5 Therapy Outlet Settings: 0, ½, 1, 2, 3, 4, 6, 8, 10, 15 litres per minute (lpm). The figures represent the nominal flow rate from the outlet. These figures are subject to a tolerance of ±10% of the shown value or ±0.5 lpm whichever is the greater. Units are also available with an extra outlet setting labelled MAX, with a nominal flow of 25 lpm.

3.6 Variation of outlet flow when inlet pressure is varied from Minimum to Maximum: There will be less than 12.5% variation from the indicated value with a variation in input pressure from the Minimum value stated above to the Maximum value stated above (ie ± 0.5 bar(50kPa)).

3.7 Variation of outlet flow when Outlet Resistance is varied up to 40 cm H_2O: 2%.

3.8 Temperature ranges:

3.8.1 Storage: -40°C to +60°C

3.8.2 Operating: -20°C to +60°C

3.9 Typical variation of outlet flow when temperature is varied from 0°C to +40°C: 5%

3.10 For units having multiple flow selector outlets, the flow from one outlet shall not vary by more than 2.5% when all the other outlets are adjusted to their maximum and minimum values.

4 CLEANING

4.1 Surface cleaning of the Flow Selector 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 Flow Selector should be wiped clean only and should not be submerged in any fluids.

4.3 After cleaning or disinfection the Flow Selector should be wiped with clean water to remove any residue and then allowed to dry before returning to use.

5 INSPECTION & USER CHECKS

5.1 Inspection

5.1.1 The Flow Selector should be inspected for damaged or broken components and contamination after each use.

5.1.2 If contaminated, the Flow Selector should be cleaned in accordance with Section 4.

5.1.3 If damaged, the Flow Selector 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 Plug the Flow Selector into a Wall Outlet or suitable regulator. With the supply to the wall outlet switched on, check for audible leaks when the therapy outlet flow selector (c) is in the off position (“0” indicated in the therapy outlet flow selector window (e)).

5.2.2 Check that the flow increases as the therapy outlet flow selector (c) is operated from 0 to 15 (or MAX). Check there is no flow when the selector is returned to 0.

5.2.3 Unplug the Flow Selector from the supply if it is not immediately needed. If the Flow Selector fails any of these checks or is very difficult to connect or disconnect, it should be withdrawn from service and returned to B.N.O.S. Meditech Ltd. for assessment and repair.

6 MAINTENANCE

6.1 Maintenance on the Flow Selector should be performed on a five yearly basis. It must be returned to B.N.O.S. Meditech Ltd. or a certified repair centre for this maintenance to be carried out. B.N.O.S. Meditech Ltd. offers training and certification on the service, repair and preventative maintenance of Meditech products.

6.2 Performance should also be checked on a five year basis, using suitable test equipment. Verify that the flow rates on all settings are within specification at room temperature, using an accurate 4 bar (400 kPa) supply. If required, B.N.O.S. Meditech Ltd. can advise on suitable test equipment. A leak test should also be performed by applying an oxygen compatible leak test solution to all outlets, fittings and joints, where applicable.

7 SERIAL NUMBER

7.1 The Serial No. is to be found on the "barrel" label of the Flow Selector or, for multiple units, on a label on the frame. 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. For a unit with multiple outlets, each outlet unit will carry the main serial number of the overall unit, with a letter suffix (eg A, B, C or D).

7.2 Example:

MCFM	12	11	12345
Regulator Therapy	**Month of manufacture**	**Year of Manufacture**	**Number of unit**

8 PRODUCT LIFE SPAN

8.1 This Flow Selector has been designed to give many years of reliable service. It is manufactured from the finest quality materials with individual components subject to strict quality control tests to ensure high standards under ISO 9001. It 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
Manufacturers 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 Flow Selector will invalidate the warranty and the manufacturers disclaim any liability for products that have undergone unauthorised repair.

9 COMPANY CONTACT DETAILS

9.1 This Flow Selector is designed and manufactured by:

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