

INSTRUCTIONS FOR USE OXYGEN DEMAND VALVE


















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READ THESE INSTRUCTIONS BEFORE USING THE EQUIPMENT

1. SYMBOLS

	Indicates a potentially hazardous situation which could result in injury to the user or others, if not avoided.
	Do not use any form of grease or oil
	No Smoking
	Do not use this device near any source of ignition
	Product part number
	Authorised Representative
	Medical device
	Serial Number
	Date of manufacture and country of manufacturer.
	Manufactured by
	Next Maintenance or Service Due date
	Read these instructions before using the equipment
	Unique Device Identifier
	Distributor (If applicable)
	Importer (If applicable)

2. INTENDED USE

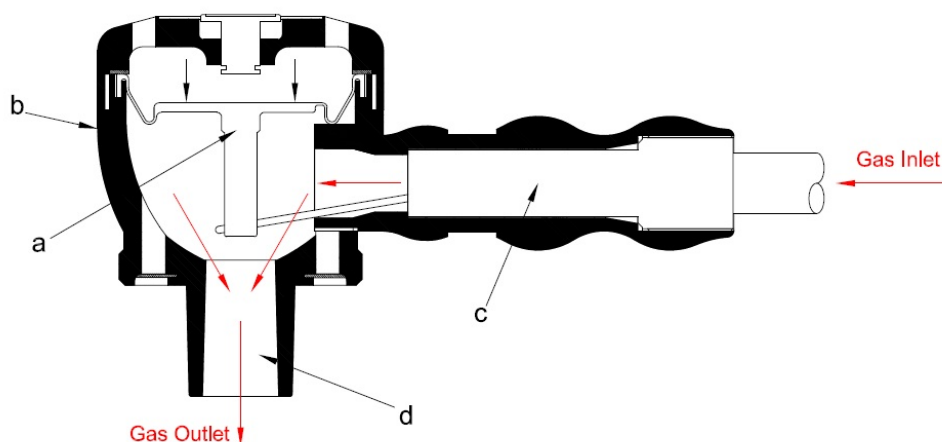
The B.N.O.S. Meditech Oxygen Demand Valve is intended for the self-administration of Medical Oxygen. Oxygen should only be used for short-term/temporary therapy by self-administration of the Demand Valve user and under supervision of suitably qualified medical personnel. Please refer to any rules or restrictions that may cover the use of Oxygen in the specific country of use of the device.

The B.N.O.S. Meditech demand valve is designed for use with either reusable (autoclavable) patient inhalation masks or single use patient inhalation masks/mouthpieces. It is highly recommended that a single use filter is used between the demand valve and the facemask/mouthpiece to minimise the risk of contamination of the device and subsequent cross contamination between users. Please ensure that single use filters/facemasks/mouthpieces are correctly specified for use with Oxygen. Filters/facemasks/mouthpieces require a 22mm female connection complying with BS EN ISO 5356-1:2015.

3. TECHNICAL DESCRIPTION

The principle of operation of the demand valve is similar to the original design of equipment used in the diving market. A diaphragm (a) contained within the demand valve housing (b) acts upon a tilt valve assembly (c). When the user exerts a negative pressure at the patient connection port (d) by inhaling, the diaphragm actuates the tilt valve due to the negative pressure created within the housing subsequently supplying a flow of gas at the patient connection of the device. (See Fig 1) The greater the negative pressure exerted on the device, the higher the flow rate available at the patient connection port. The flow rate is entirely related to the inspiratory effort of the user.




Fig 1



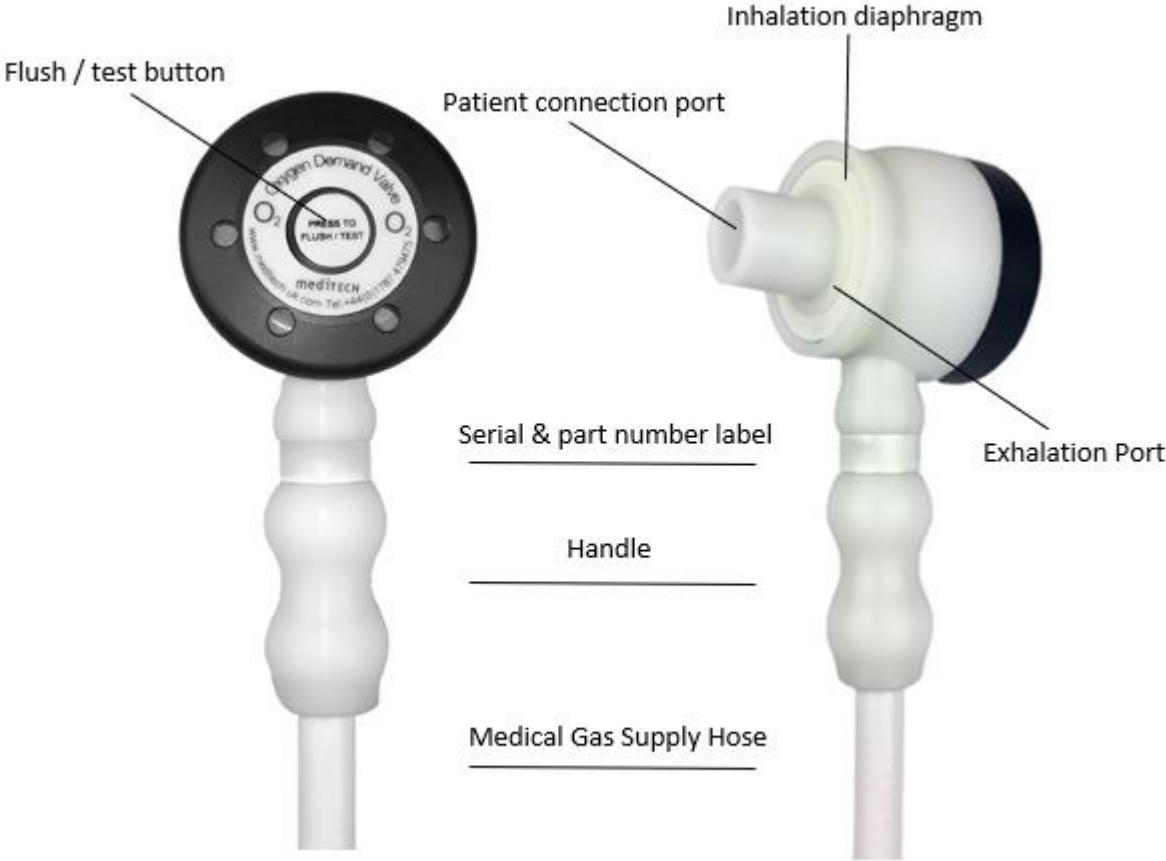
The demand valve has been specifically designed to be used with low-cost single use generic mouthpiece and filter systems that are widely available using standard connections that conform to BS EN ISO 5356-1

4. WARNINGS!



- 4.1 Please read these instructions before use. Do not use the demand valve if you do not understand the instructions detailed in this user guide.
- 4.2  Do not use any form of grease or oil (hydrocarbon-based substances) with this device.
- 4.3  Do not use this device near any source of ignition e.g., naked flame, electrically powered heaters, cigarettes etc.
- 4.4  Do not smoke any products including tobacco when using this device.
- 4.5 Medical Oxygen is a medicinal gas, and its use must be supervised by correctly trained medical staff and/or prescribed for use where applicable by a suitably authorised medically trained individual e.g., Doctor.
- 4.6 Do not use the “Press to Flush/Test” button when the device is in use.
- 4.7 Ensure sufficient Oxygen is available for use before using the product.
- 4.8 If using medical gas cylinders, ensure that they are adequately secured or stowed at all times.
- 4.9 The demand valve hose is fitted with medical gas specific connectors. Do not interfere or modify the connector. Particular attention must be paid during any form of maintenance to ensure that the correct medical gas specific connector is fitted to the device.
- 4.10 If used with a medical gas regulator, always ensure that the regulator cylinder valve is opened slowly.
- 4.11 The device must not be used with harness or retained face mask.
- 4.12 When using a regulator/cylinder, make sure that the regulator is capable of providing the Demand Valve with a flow of at least 100 l/min @ 4 bar of gas, to ensure that the device functions as intended. If in any doubt as to the suitability of the medical gas regulator to be used with the device, please contact the manufacturer.
- 4.13 When the demand valve is not in use, turn off the regulator where appropriate and disconnect the valve from the medical gas supply.
- 4.14 Check the demand valve and supply hose regularly for leaks. Remove any leaking device from service immediately.
- 4.15 Ensure that the hose is always arranged in such a way that it cannot be damaged and does not cause any form of obstruction or hazard.

5. INSTRUCTIONS FOR USE



- 5.1 Before connecting to a pressurised gas source, please ensure the unit is clean and in good condition. If you have any doubts about the condition, please do not connect or use the device. Please check that the inhalation diaphragm is fitted to the device and seated correctly (laying flat against the body of the device).
- 5.2 Ensure that the supply hose attached to the demand valve is connected to an Oxygen Medical Gas supply that uses the correct respective Medical Gas fitting.
- 5.3 If using an Oxygen regulator, please check that the cylinder has adequate gas and that the cylinder valve is turned on. It is suggested that the portable cylinder is at least half full and that additional cylinders are available if required.
- 5.4 Before administering Oxygen to the patient, please check the availability of gas by briefly pressing the 'Flus/test' button, located on the top of the Demand Valve. Please check that there are no audible sounds of gas flow once the 'Flush/Test' button has been released.
- 5.5 It is strongly advised to use a single use filter with the Demand Valve to minimise the risk of contamination of the device and a subsequent cross contamination between users. Connect a universal patient inhalation mask or single use patient inhalation mask/mouthpiece to the single use filter.
- 5.6 The Demand Valve is now ready for use. The user should be instructed to inhale through the mouthpiece or face mask connected to the patient connection port fitted to the Demand Valve. Doing so will create a negative pressure on the patient connection port which will activate the supply of Medical Oxygen. The larger the breath taken by the user, the greater the supply of Oxygen. Please advise the user not to press the 'Flush/Test' button whilst the device is in use.
- 5.7 The user is able to exhale through the mouthpiece or face mask.
- 5.8 The Demand Valve will stop supplying gas when the user stops inhaling. The exhaled gas will exit through the Demand Valve via the exhalation port.
- 5.9 The device should continue to be used under the supervision of medically trained professionals.
- 5.10 The duration of use of the device is to be determined by the medically trained professionals who are supervising the use of the Demand Valve.

6. CLEANING AND DISINFECTION

- 6.1 Ensure demand valve is disconnected from the gas supply before cleaning.
- 6.2 Clean the device before first use and then subsequently after every use, ensure the Demand Valve, including the handle is wiped over thoroughly with a disinfecting wipe. For disinfection purposes a chlorine dioxide-based product (e.g., the Tristel Wipes and solution system) can be used, at a nominal concentration of 0.02% wt/vol. The concentration refers to chlorine dioxide in water. Follow the manufacturer's directions for safe use.
- 6.3 The Demand Valve is not suitable for autoclaving.
- 6.4 The Demand Valve should be thoroughly dried before storage.

7. MAINTENANCE

- 7.1 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, diaphragm, medical gas supply hose and any components which show significant wear and tear.
- 7.2 Performance should also be checked on a five yearly basis, using suitable test equipment. The negative pressure required to generate specific flows from the device must be tested. If required, B.N.O.S. Meditech Ltd. can advise on suitable test equipment.
- 7.3 For Demand Valves in frequent use, for example, an Ambulance Service or a Maternity Unit, personnel trained to supervise the use of a Demand Valve should refer to 5.4 of this Instruction for Use document and carry out the check as described on a regular basis. For less frequent users, i.e., industrial safety use, a leak test should be periodically performed by applying an oxygen compatible leak test solution to all medical gas supply hose fittings and joints, where applicable. The suggested period is annually.
Caution must be taken when cleaning not to bend the needle and the diaphragm must be fitted and realigned correctly.
- 7.4 The medical gas supply hose MUST be changed every five years. Please contact the manufacturer to determine the age of the hose fitted to the demand valve.
- 7.5 B.N.O.S. Meditech Ltd. offers training and certification on the service, repair and preventative maintenance of its products.

SN 8. SERIAL NUMBER

The Serial No. is to be found on the handle label of the demand valve. 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 individual "number" of the unit and differentiating units built in the same month.

Example: ODV121700001

ODV	12	17	00001
Oxygen Demand Valve	Month of Manufacture	Year of Manufacture	Number of Unit

9. INTENDED LIFE

The Demand Valve is designed to have a product life span of 10 years, excluding abuse and/or damage to the device.

10. SPECIFICATION

Inspiratory Resistance	<1.5 kPa @ 200 l/min <0.25 kPa @ 10 l/min
Expiratory Resistance	<0.1kPa @ 12 l/min <0.6kPa @ 120 l/min
Transport and Storage Temperature:	-20°C to 60°C
Operating Temperature:	5°C to 40°C
Supply Pressure @ 100l/min	Nominal 400 kPa Maximum 600 kPa Minimum 280 kPa

11. SPARE PARTS

Description	Part Number
Inhalation Diaphragm	033-1031-00

12. APPLICABLE STANDARDS

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

B.N.O.S. Meditech Demand Valves are supplied in conformity under a quality system to meet Medical Devices Directives 93/42/EEC and Medical Devices Regulations UK MDR 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).

The above conformity routes have been inspected by the Notified Body Ref: CE 2797 being BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and for UKCA by UK Approved Body UKCA 0086 being BSI, Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP

Demand Valves are classified as Class IIa Medical Devices.

The following National & International Standards apply to the device:

Standard:	Title:
BS EN ISO 5356-1:2015	Anaesthetic and respiratory equipment, cones and connectors, cones and sockets.
BS EN ISO 15001:2011	Anaesthetic and respiratory equipment. Compatibility with Oxygen.
BS EN ISO 5359:2014+A1:2017	Low pressure hose assemblies for use with medical gases.
BS 5682:2015	Probes (quick connectors) for use with medical gas pipeline systems.
BS 4272-2:1996	Anaesthetic and Analgesic machines. Specification for intermittent (demand) flow analgesic machines for use with 50/50% V/V Nitrous Oxide and Oxygen.
BS EN ISO 14971:2019/A11:2021	Medical Devices. Application of risk management to medical devices.
BS EN ISO 15223-1:2021	Medical Devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.

IMPORTANT NOTICE

Manufacturer's Warranty is for a period of 7 years (excluding the hose which is 5 years intended use only) and includes parts and labour. It does not include transport costs.

This is under the condition that the demand valve device is sent to Meditech for service at the 5-year period. The responsibility and cost of returning and collecting the unit from the manufacturer or their authorised representative is the owners.

B.N.O.S. Meditech Ltd reserves the right to change design without prior notice.

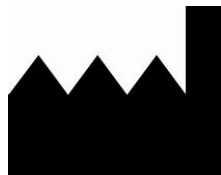
Any disassembly of the device beyond that detailed in this manual will invalidate the warranty and the manufacturers disclaim any liability for products that have undergone unauthorised repair.

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COMPANY CONTACT DETAILS

This device is designed and manufactured by:



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