mediTECH
MEDICAL GAS EQUIPMENT

INSTRUCTIONS FOR USE
ANALGESIC DEMAND VALVE

PLEASE READ THESE INSTRUCTIONS BEFORE USING THE EQUIPMENT
A COPY OF THESE INSTRUCTIONS CAN BE FOUND ON OUR WEBSITE (WEB ADDRESS STATED ON THE BACK PAGE OF THIS BOOKLET

CHECK THERE IS NO DAMAGE TO THE DEVICE PRIOR TO OPENING AND USING. IF ANY DEFECTS FOUND PLEASE NOTIFY THE MANUFACTURER OR AUTHORISED REPRESENTATIVE.

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
	Medical Device
	Authorised representative
	Serial Number
	Date of manufacture
	Manufactured by
	Next Maintenance or Service Due date

2. INTENDED USE OF DEVICE

The B.N.O.S. Meditech Analgesic Demand Valve is intended for the self-administration of N_2O/O_2 50/50% V/V, an analgesic gas, sold in the UK under the trade mark of Entonox®. N_2O/O_2 should only be used for short-term/temporary pain relief by self-administration of the demand valve user and under supervision of suitably qualified/trained medical personnel. Please refer to any rules or restrictions that may cover the use of N_2O/O_2 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 N_2O/O_2 50/50% V/V. Filters/facemasks/mouthpieces require a 22mm female connection complying with BS EN ISO 5356-1:2015.

Fig 1

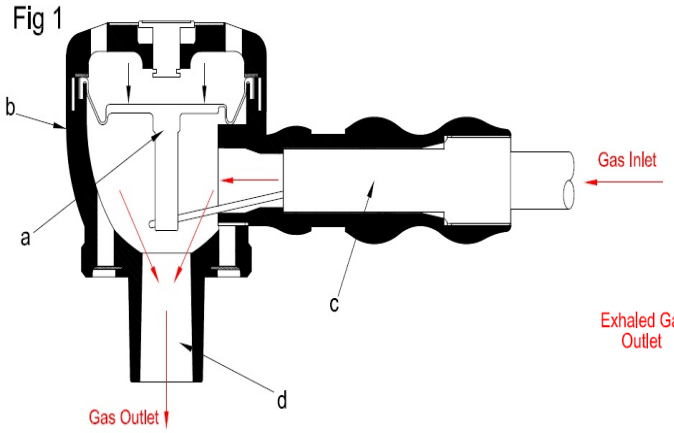
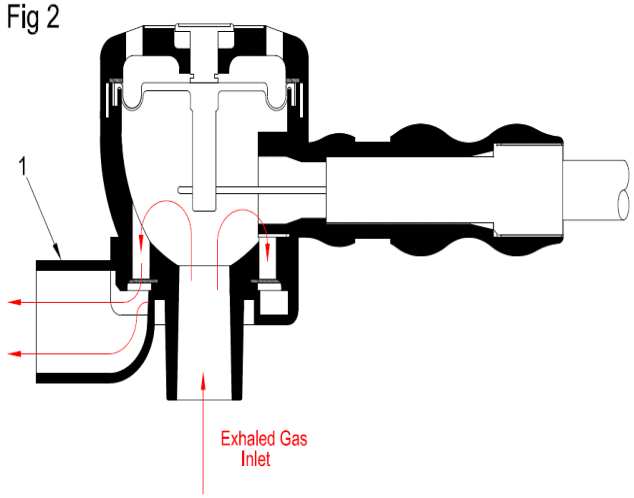


Fig 2



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.

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

An Accessory (1), the AGSS Fitting Part No.673-9023-00 is available to attach to the demand valve for use with Anaesthetic Gas Scavenging Systems. (See Fig 2)

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 N_2O/O_2 50/50% V/V 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 Continuous exposure to Nitrous Oxide can be harmful. Where applicable consult available standards relating to exposure levels to Nitrous Oxide. A gas scavenging accessory is available for the demand valve (AGSS fitting) for use in environments where adequate ventilation is not available i.e., indoors, inside an ambulance. The AGSS should be used where applicable.

4.8 Ensure sufficient N_2O/O_2 50/50% V/V is available for use before using the product.

4.9 If using medical gas cylinders, ensure that they are adequately secured or stowed at all times.

4.10 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.

4.11 If used with a medical gas regulator, always ensure that the regulator cylinder valve is opened slowly.

4.12 The device must not be used with harness or retained face mask.

4.13 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.

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.

4.16 Do not use the device in conjunction with a gas supply from a cylinder which is at sub-zero temperatures, because the gas mixture in the cylinder will separate at these low temperatures.

4.17 Important information regarding the storage of cylinders containing pre-mixed cylinders of oxygen and nitrous oxide.

For Domiciliary use (up to and including 5.5 L water capacity). Before use, ensure that the cylinder has been adequately warmed by retaining it in a warm place (above 10°C) for at least 2h, or by placing it in warm water at body temperature for 5min. Then agitate the contents by inverting the cylinder three times. Never use hot water. Avoid wetting the valve.

4.18 For Hospital use. On receipt, the cylinders shall be date marked and stored horizontally for 24h in a room maintained at a temperature above 10°C, but not exceeding 38°C, before being used. During delivery from the store room to the final destination in the hospital, it is essential that the cylinder shall not be exposed to freezing temperatures for more than 2min to 3min. If exposure to freezing temperatures occurs for any longer period, carry out the procedure in k)[1)] of BS 4272-2:1996. Special instructions for hospitals shall be displayed where O_2 and N_2O mixtures are stored and the attention of all personnel handling the cylinders should be directed to them.

5. INSTRUCTIONS FOR USE

5.1 Before connecting to a pressurised gas source, please ensure 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 N_2O/O_2 Medical Gas supply that uses the correct respective Medical Gas specific fitting.

5.3 If using a N_2O/O_2 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 When using an AGSS, ensure that the AGSS fitting is correctly attached and seated on the demand valve and that the scavenging pipe is correctly and firmly attached.

5.5 Before administering N_2O/O_2 to the patient, please check the availability of gas by briefly pressing the 'Flush/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.

5.6 It is strongly advised to use a single use filter with the demand valve to minimise the risk of contamination of the device and subsequent cross contamination between users. Connect a universal patient inhalation mask or single use patient inhalation mask/mouthpiece to the single use filter.

5.7 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 Analgesic Gas. The larger the breath taken by the user, the greater the supply of N_2O/O_2. Please advise the user not to press the 'Flush/Test' button whilst the device is in use.

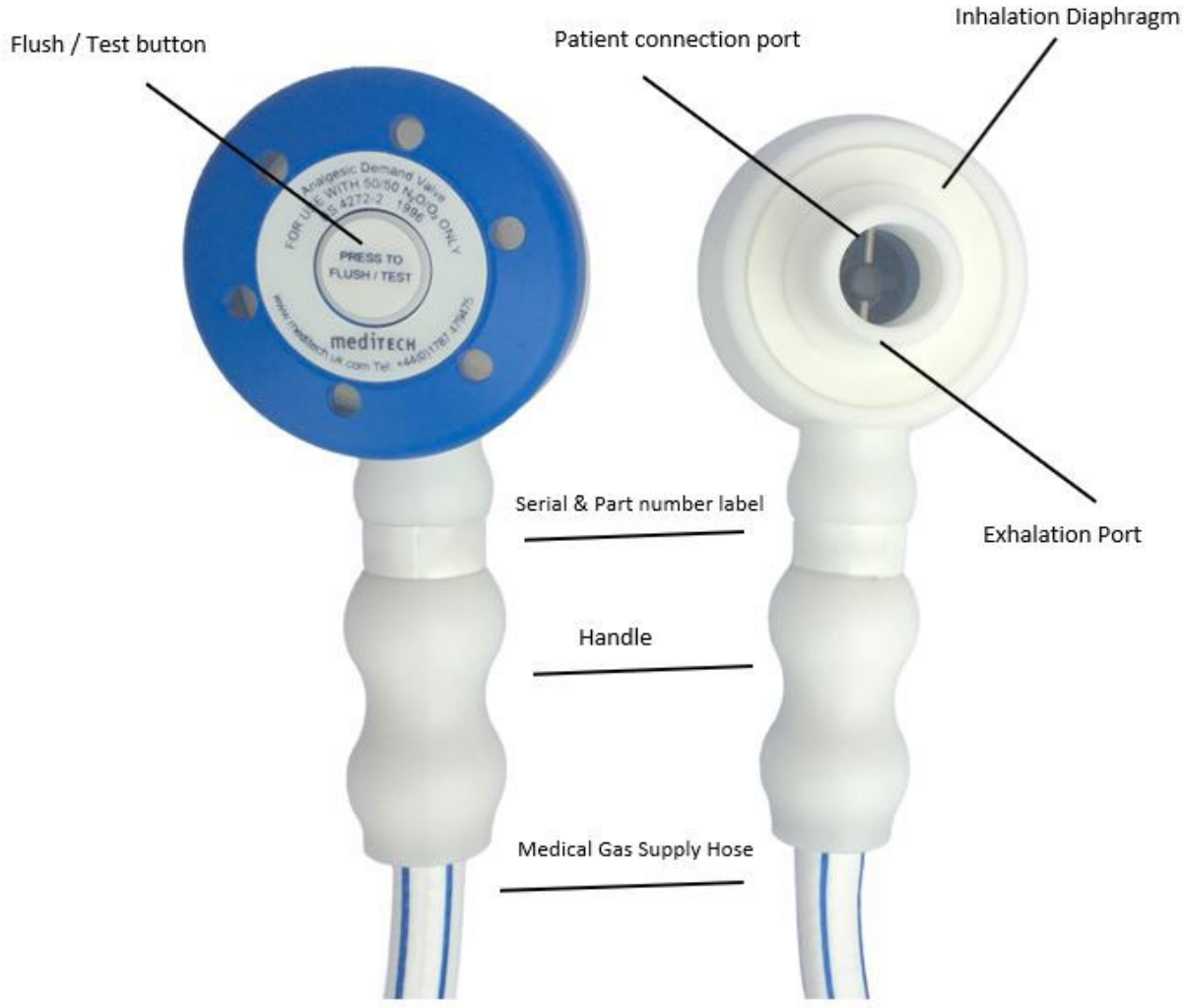
5.8 The user is able to exhale through the mouthpiece or face mask.

5.9 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.

5.10 The device should continue to be used under the supervision of medically trained personnel.

5.11 Stop use of the demand valve if the suitably trained supervisor or user detects a change in performance of the device.

5.12 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. ACCESSORIES

Part No. 673-9023-00 Description: AGSS Fitting

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, diaphragm, medical gas supply hose 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 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.

8.3 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 5.5 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.

8.4 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.

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

9. 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: SN EDV122100001

EDV	12	21	00001
Entonox® Demand Valve	Month of Manufacture	Year of Manufacture	Number of Unit

10. INTENDED LIFE

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

11. 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

12. SPARE PARTS

Description	Part Number
Inhalation Diaphragm	033-1030-00

13. 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

Demand Valves are classified as Class IIa 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.

The following National & International Standards apply to the device:

Standard Number:	**Title:**
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 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 EN ISO 14971:2019	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 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.

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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CE 2797

COMPANY CONTACT DETAILS
This device is designed and manufactured by:

B.N.O.S. MEDITECH LTD
9 FIFTH AVENUE, BLUEBRIDGE IND EST
HALSTEAD, ESSEX, CO9 2SZ, ENGLAND
Tel: +44 (0)1787 479 475
Fax: +44 (0)1787 477 747
E-mail: sales@meditech.uk.com
Website: www.meditech.uk.com

EU REPRESENTATIVE:
MEDICAL DEVICE MANAGEMENT LTD
BLOCK B, THE CRESCENT BUILDING
NORTHWOOD, SANTRY
DUBLIN 9, D09 C6X8
IRELAND