mediTECH
MEDICAL GAS EQUIPMENT

INSTRUCTIONS FOR USE
LOW PRESSURE MEDICAL GAS HOSE ASSEMBLIES

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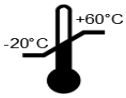
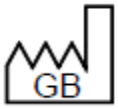
READ THESE INSTRUCTIONS BEFORE USING THIS EQUIPMENT
A COPY OF THESE INSTRUCTIONS FOR USE CAN BE FOUND ON OUR WEBSITE (THE WEB ADDRESS CAN BE FOUND ON THE BACK PAGE OF THIS BOOKLET).

CHECK THERE IS NO DAMAGE TO THE DEVICE PACKAGING PRIOR TO OPENING. IF THERE IS PLEASE REPORT THIS TO THE MANUFACTURER OR AUTHORISED REPRESENTATIVE AND DO NOT USE UNTIL ADVISED OF ACTIONS TO BE TAKEN.

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
REF	Product part number
	Storage and operating temperatures.
	Date of manufacture and country of manufacturer.
SN	Serial Number
	Manufactured by
	Next Maintenance or Service Due date
MD	Medical Device
EC REP	Indicates the authorised representative in the European Community.

2. INTENDED USE OF DEVICE

The manufacturer of this device is BNOS Meditech, England.
Low Pressure Medical Gas Hose assembly is intended for use to provide a safe method for transferring low pressure medical gases to various medical devices. The hose is categorised as an accessory used in conjunction with a medical device to achieve the intended use of administering medical gases by connecting the gas pathway to the patient.
The hoses are intended for use in the pressure range 2.8 Bar to 6 Bar (Max Pressure 10 bar) for compressed medical gases. Medical gases covered by this range are Oxygen, Medical Air (MA4 and MA7), N2O/O2 50/50% VV (Entonox), Nitrous Oxide and carbon dioxide. The hoses can be used for vacuum systems at pressures no greater than 60 kPa.

3. TECHNICAL DESCRIPTION

BNOS Meditech Low Pressure Medical Gas Hose Assemblies are available to suit gas specific medical gas systems that conform to the National /International Standard used in a number of different countries. The main product variants are compliant with British (BS) System, German DIN, French AFNOR, Scandinavian AGA, Czech CZ System, Italian UNI9507 System, USA DISS System.

The device is fitted with a probe or gas specific input fitting relevant to the specific standard used i.e., British Standard BS Schrader Probe. The probe or input fitting and the corresponding outlet fitting is attached permanently to the gas specific supply hose by means of a crimped / swaged ferrule at both ends. Critically the gas input fitting type and the gas output fitting type for instance British Standard and Medical Oxygen or British Standard and Medical air will be the same.
There is no interchangeability between medical gas types, for example a medical oxygen hose will have a medical oxygen compatible fitting attached to both ends of the hose to mitigate risk of administering a medical gas other than medical oxygen.

Devices are available in a range of Medical Gases including oxygen, medical air (MA4), Medical air (MA7), Nitrous Oxide and Nitrous Oxide and Oxygen blend 50/50% VV otherwise known as Entonox, Carbon dioxide and for use with vacuum.
Fittings are composed of metal and the medical gas hose from phthalate free anti-static medical graded plastic. The device is intended for use (but not limited to) within medical gas pipeline / supply systems rated at a nominal 4 bar and vacuum no greater than 60 kPa.

This gas hose assembly is an accessory and is intended specifically to be used together with another medical device to specifically enable and assist those medical device(s) to be used in accordance with their intended use. It is intended for multiple patients, multiple use.

4.0 WARNINGS!

Please read these instructions before use. Only appropriately trained healthcare professionals can use this device.

4.1  Do not use any form of grease or oil (hydrocarbon-based substances) with this device.

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

4.3  Do not smoke any products including tobacco when using this device.

4.4 Medical 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.

4.5 If using in conjunction with medical gas cylinders, ensure that they are adequately secured or stowed at all times.

4.6 The Low-Pressure Medical Gas 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.

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

4.8 Check the Low-Pressure Medical Gas Hose regularly for leaks. Remove any leaking device from service immediately.

4.9 Ensure that when used, a medical gas hose is always arranged in such a way that it cannot be damaged and does not cause a potential hazard.

4.10 Please report immediately any **serious** incidence that has occurred in relation to this device to the manufacturer and the authority having jurisdiction in your locale.

4.11 Ensure to clean and maintain as in the guidelines in section 6. Do not autoclave.

5. INSTRUCTIONS FOR USE

5.1 Before connecting to a pressurised gas source, please ensure the device is clean and in good condition. If you have any doubts about the condition and observe material degradation, please do not connect or use the device.

5.2 Plug the input probe side of the device into a single wall medical gas outlet which must be of both a compatible medical gas type for example oxygen and a compatible medical gas fitting type for example British Standard BS Schrader Probe.

5.3 Plug into the outlet fitting of the device compatible medical equipment of the correct medical gas type and fitting type. For instance, the device could be used to supply oxygen to a pair of medical oxygen flowmeters.

5.4 The device is designed to be used by suitably trained and qualified staff who understand the requirements of low-pressure medical gas hose specific fittings and medical equipment which uses medical gas. Users should have knowledge of medical gas flow rates required by equipment connected to the medical gas supply and understand the limitations and capabilities of flow rates within the entire system.

5.5 Always connect and disconnect the device with caution.

6. CLEANING AND DISINFECTION

6.1 Ensure that the Low-Pressure Medical Gas Hose is disconnected from the gas supply before cleaning.

6.2 Clean the device before first use and then periodically after every use, ensure the Low-Pressure Medical Gas Hose, 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 Low-pressure Medical Gas Hose is not suitable for autoclaving.

6.4 The Low-pressure Medical Gas Hose should be thoroughly dried before storage.

6.5 The hose assembly can be disposed of via the biohazard waste in a clinical setting. Alternatively, if end of life this can be returned to MediTECH for replacement and discarding.

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 any components which show significant wear and tear.

7.2 Performance should also be checked on a yearly basis, using suitable test equipment.

7.3 Where applicable a medical gas supply hose MUST be changed every five years (regardless of its condition). This date is indicated on the label directly applied to the hose. Or MediTech can be contacted if unsure.

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

8. SERIAL NUMBER

The Serial No. is to be found on the label affixed along the length of the device. 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 HA122100001

HA	12	21	00001
Hose Assembly	Month of Manufacture	Year of Manufacture	Number of Unit

9. INTENDED LIFE

The Low-Pressure Medical Gas Hose is designed to have an expected life time of 5 years, excluding abuse and/or damage to the device and whilst the gas specific fittings of the device remain the recognised local / national standard. All fittings have a 15-year lifetime expectancy. All hose assemblies must be replaced, regardless of condition, when the product life date is reached.

10. SPECIFICATION

Mechanical Strength	Capable of axial tensile forces of at least 600N
Gas Specificity	Low-Pressure Medical Gas Hoses are fitted with gas specific connectors for each individual gas type.

Lubricants	Lubricants where used are compatible with medical oxygen and other medical gas and their mixtures.
Transport and Storage Temperature:	-20°C to 60°C
Operating Temperature:	-10°C to 40°C
Supply Pressure	Nominal 400 kPa to 600kPa Maximum 1000 kPa Vacuum no greater than 60kPa

11. APPLICABLE STANDARDS

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

B.N.O.S. Meditech Medical Gas Hose assemblies are supplied in conformity under a quality system to meet Medical Devices Directive 93/42/EEC and The 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

Medical Gas Hose assemblies are Class IIa Medical Devices.

The following National & International Standards apply to the device:

Standard Number:	**Title:**
BS EN ISO 5359:2014+A1:2017	Low pressure hose assemblies for use with medical gases.
BS EN ISO 15001:2011	Anaesthetic and respiratory equipment. Compatibility with Oxygen.
BS EN ISO 15223-1:2021	Medical Devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
BS EN ISO 20417:2021	Medical Devices-Information to be supplied by the manufacturer.
BS EN ISO 5356-1:2015	Anaesthetic and respiratory equipment, cones and connectors, cones and sockets.
BS EN 18082:2014+A1:2017	Anaesthetic and respiratory equipment. Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases
BS 5682:2015 (or international fittings if applicable).	Probes (quick connectors) for use with medical gas pipeline systems.
SS8752430	(Sweden)
DIN 13260-2:2004-06	Supply systems for medical gases – Part 2: Dimensions and allocation of probes and gas specific connection points for terminal units (German)
NFS90-116	(AFNOR)
UNI 9507	Medical Gas outlet

IMPORTANT NOTICE
Manufacturer's Warranty is for a period of 2 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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COMPANY CONTACT DETAILS

This device is designed and manufactured by:

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EC REP

EU REPRESENTATIVE:

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