

INSTRUCTIONS FOR USE LOW PRESURE MEDICAL GAS HOSE ASSEMBLIES



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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.
	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
	Indicates the authorised representative in the European Community.

2. INTENDED USE OF DEVICE

BNOS Meditech 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 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. The hoses can be used for vacuum systems at pressures no greater than 60 kPa. BNOS Meditech Low Pressure Medical Gas Hose Assemblies are medical devices classified as Class IIA according to the Medical Device Directive 93/42/EEC-MDD2007/47/EC and conform to the Essential Requirements of the MDD 93/42/EEC-MDD2007/47/EC.

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 ensure there is no chance 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 and for use with Vacuum.

All components in the medical gas path are metal, other than the internal bore of the medical gas hose which is made from phthalate free anti-static correctly 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.

4.0 WARNINGS!

Please read these instructions before use. Do not use the Low Pressure Medical Gas Hose if you do not understand the instructions detailed in this user guide.

- 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 e.g. Doctor.
- 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 any form of obstruction or hazard.

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, 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 (eg 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.

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. Please contact the manufacturer to determine the age of the hose fitted to the device.
- 7.3 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 HA121700001

HA	12	17	00001
Hose Assembly	Month of Manufacture	Year of Manufacture	Number of Unit

9. PRODUCT LIFE SPAN

The Low Pressure Medical Gas Hose is designed to have a product life span 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.

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:	-18°C to 40°C
Supply Pressure	Nominal 400 kPa to 600kPa Maximum 1000 kPa Vacuum no greater than 60k

11. RELEVANT APPLICABLE STANDARDS

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

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 15223-1:2016 Medical Devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.

EN62366-1:2015 Application of usability engineering to medical devices

BS EN 15908:2010 Anaesthetic and respiratory equipment. Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases

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.

Entonox® is a registered trademark of The Linde Group.



CE 2797

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