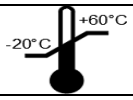
INSTRUCTIONS FOR USE
MEDICAL GAS SUPPLY SPLITTER

CONTENTS

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
	Storage and operating temperatures.
REF	Product part number
EC REP	Authorised Representative details
MD	Medical device
SN	Serial Number
	Date of manufacture and country of manufacturer.
	Manufactured by
	Next Maintenance or Service Due date

2. INTENDED USE OF DEVICE

BNOS Meditech Medical Gas Supply Splitter is intended for use in splitting a single medical gas wall outlet supply in a hospital or ambulance setting into two independent supplies. The intended purpose of the device is to provide two individual medical gas supplies from one main wall mounted supply. BNOS Meditech Medical Gas Supply Splitter are medical devices classified as Class IIa according to the Medical Device Directive 93/42/EEC

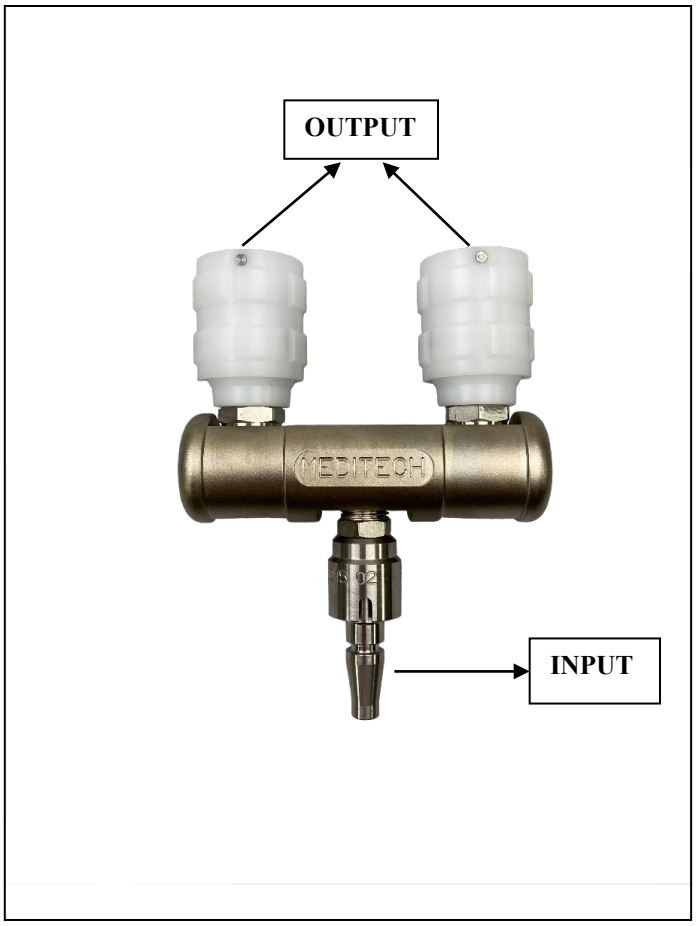
3. TECHNICAL DESCRIPTION

BNOS Meditech Medical Gas Supply Splitter is available to suit gas specific medical gas systems of 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 is attached permanently to a metal bar with an internal gas path that feeds two outlets at either end as the below. The outlets are medical gas specific and match the medical gas input fitting. i.e., if a British standard probe is fitted as the input fitting, then the outlet fittings will be British Standard Schrader Outlet Couplings. 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.

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.

All components in the medical gas path are metal. The device is intended for use (but not limited to) within medical gas pipeline / supply systems rated at a nominal 4 bar.



4. WARNINGS!

Please read these instructions before use. Do not use the Medical Gas Supply Splitter 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 Medical Gas Splitter 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 When the Medical Gas Supply Splitter is not in use disconnect from the medical gas supply.

4.9 Check the Medical Gas Supply Splitter regularly for leaks. Remove any leaking device from service immediately.

4.10 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 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 medical gas 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 splitter 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 Medical Gas Supply Splitter is disconnected from the gas supply before cleaning.

6.2 Clean the device before first use and then periodically after every use, ensure the Medical Gas Supply Splitter, 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 Medical Gas Supply Splitter is not suitable for autoclaving.

6.4 The Medical Gas Supply Splitter 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 SN

The Serial No. is to be found on the label affixed to the underside 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: MGS122200001

MGS	12	22	00001
Medical Gas Splitter	Month of Manufacture	Year of Manufacture	Number of Unit

9. INTENDED LIFE

The Medical Gas Supply Splitter is designed to have a product life span of 15 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	Medical Gas Splitters 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

11. APPLICABLE STANDARDS

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

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 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.
BS EN ISO 18082:2014+A1:2017	Anaesthetic and respiratory equipment: Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases.

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.

COMPANY CONTACT DETAILS

This device is designed and manufactured by:

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