INSTRUCTIONS FOR USE (IFU) – MEDICAL GAS HOSE ASSEMBLY

WARNINGS AND IMPORTANT NOTES

- Medical gases may be considered a critical treatment and should be prescribed in accordance with clinical guidance. As oxygen is most common medical gas, we recommend the British Thoracic Society guidelines; only appropriately trained practitioners should use the device to administer to patients; before administering to a patient, the practitioner must confirm the identity of the gas, check the expiry date of the gas and ensure adequate supplies of gas are available to maintain the flow rate prescribed; the effectiveness of medical gases can only be determined by continuous monitoring by the user.
- Medical gases are not flammable but an oxygen enriched atmosphere will increase the rate and severity of combustion. To avoid risk of fire or explosion do not use any form of oil / grease to lubricate connectors or any part of the device.
- Do not use near sources of ignition or near an excessive heat source likely to exceed 60°C. Always follow recommended procedures including the guidance given in HSE document 'Take Care with Oxygen'.
- Do not use or store near any heat sources. Elevated temperatures will soften the hose and may cause premature failure.
- Do not autoclave or submerge the device in any fluid and ensure that no fluid is allowed to enter the device.
- Ensure all connections are tight and leak free. Do not change the gas specific connector on the device.
- Do not allow the device to rest or be scraped across the floor.
- Avoid the hose being stretched or trailed along the floor during use. This could cause damage resulting in loss of gas flow.
- Due to the possible loss of pressure, it is not recommended to connect multiple Medical Gas Hose Assemblies together.
- Do not subject the device to pressures greater than 1400 kPa.
- Do not disassemble the device while under pressure.

INTRODUCTION

- This document provides instructions for the safe use and maintenance of the device.
- Read through this entire instruction guide before using.
- Personnel handling and operating the device must be authorised and appropriately trained.
- Do not use the device if you do not understand the information provided.
- Attempting to use the device without a thorough understanding may result in patient or user injury.
- Before installation, verify the device is compatible with the devices connected, especially if supplied by different manufacturers.

INTENDED USE AND DESCRIPTION

- The device comprises a length of flexible tube crimped at either end used to provide a safe method for transferring low pressure medical gas for use with various medical devices in a medical environment.
- It is the responsibility of the end user to ensure that the correct device with correct fittings has been selected. MEC Medical Limited accepts no responsibility for the selection of an incorrect device.
- There are no indications, contra-indications and the device is suitable for all patient groups.

FITTING INSTRUCTIONS

- Remove the device from the packaging and inspect for damage. If the device is damaged on receipt, do not use.
- The device can carry relatively high pressure and care should be taken to ensure that the device is sound and clean every time before connecting the device to the gas source.
- Check the gas specific connector matches the requirements of the equipment.
- Connect the equipment end connector first and tighten as required. Connect the probe end of the hose to the pressure source and give a light pull on the hose to ensure properly connected.
- Check that there is a flow being delivered through the hose. With a vacuum hose, check that suction is present.
- Undertake a performance function check of the equipment in accordance with the manufacturer's instructions to ensure that the device is performing as required.
- Because of the amount of pressure contained in the device, removal from the device should be a two-handed operation to prevent causing damage or personal injury. This is especially important on surgical air which carries higher pressure.

INSPECTION AND PREVENTATIVE MAINTENANCE:

- The device is maintenance free but it is recommended that the entire device is visually inspected at regular intervals, at least every 6 months, to check for any signs of damage or wear and tear. Pay particular attention to the surface of the hose, crimps and condition of the gas specific connectors.
- Where the device is in environments where it could be damaged, for example by having heavy equipment knocked into them, a full examination of the device should be made every week.
- Users should be especially aware of possible damage when attached to a portable device.
- Any visible damage would necessitate the device being replaced.
- It is recommended that all Medical Gas Hose Assemblies are replaced five years' after the date of manufacture regardless of condition. A manufacture date is printed on the device label.

CLEANING AND DISINFECTION

- Clean the device using only a dry lint-free cloth, distilled water or detergent wipe.
- Where a detergent wipe proves insufficient an isopropyl alcohol wipe may be used.
- Do not use any solvents as this may cause the hose to start deteriorating.
- It is not practical or economical to internally clean or disinfect due to the nature and complexity of the internal components.

DECONTAMINATION

- Decontamination of the device should be managed in accordance with national or local legislation, UK Department of Health Guideline HTM 01-01 Part A and/or other policies applicable to your organisation.
- Devices suspected of bio-contamination should be removed from service and destroyed by incineration according to proper medical and environmental protocols. Vacuum hoses should always be treated as a bio-hazard.

DISPOSAL

- To be disposed as per user's country disposal regulations and hospital/clinic protocol.

RETURN OF EQUIPMENT

- If for any reason it is necessary to return equipment to MEC Medical Limited, either directly or through a distributor, the equipment must be decontaminated first and a Decontamination Certificate signed by a Competent Person enclosed.

STORAGE:

- Storage temperature between -20ºC and 60ºC with operational temperatures between -10ºC and 40ºC
- Protect from contamination and deterioration, including protection from excessive heat or undue exposure to direct sunlight.
- Adequate precautions should be taken against spillage or breakage, attack by micro-organisms, contamination and cross-contamination.
- Store off the ground and suitably spaced to permit cleaning and inspection. Should not be stacked when stored.
- Ensure that identification is not lost.
- Packaging should be maintained until used and stored with identification visible.
- Do not use or store near any heat sources. Elevated temperatures will soften the hose and may cause premature failure.

SPECIFICATIONS

Gas Compatibility	Oxygen (O_2) Oxygen/Nitrous Oxide (O_2/N_2O) Nitrous Oxide (N_2O) Medical Air (Air) Surgical Air (Air-800) Vacuum (Vac) Heliox (He/O_2) Carbon Dioxide (CO_2) Nitrogen (N_2-800) Nitric Oxide (NO) Anaesthetic Gas Scavenging (AGSS)	**Intended range of use**	Maximum Tested Pressure gases: 1400 kPa Working Pressure gases: 400 kPa Working Pressure Air-800: 800 kPa Vacuum: 10 – 100 kPa absolute AGSS: 20 kPa absolute
		Hose ID	Gas Hoses 6.3mm Vacuum Hose 6.3mm / 8mm Disposal Hoses 16mm / 12mm
		Materials	Hose: Anti-static, non toxic PVC or PU Connector: Stainless Steel or Brass Seals: EPDM, Viton or Nitrile Rubber

REGULATORY

- This is a medical device built to comply with MDD 93/42/EEC, MDR 2017/745 and BS EN ISO 5359 standard.
- Any serious incident in relation to the device that might lead to death or serious deterioration in the health of a patient should be reported to the manufacturer and competent authority in the country.
- Is neither for single use, nor sterile.
- Does not incorporate medicinal substances, nor biological or animal tissues, nor human blood, nor phthalates.
- Contains the Biocidal Antimicrobial Product Silver Ion technology as an additive to inhibit bacterial growth.
- The biocompatibility risk assessment indicates that the likelihood of adverse effects from the device is considered low but the device is a conduit for the gas pathway and the devices upstream must consider the combined biocompatibility effect.

WARRANTY

- The medical device is guaranteed free from manufacturing defects for 12 months from the date of delivery. The replacement or repair of the parts covered by this warranty does not extend the validity of the warranty itself.

PRODUCT IDENTIFICATION

This IFU is applicable to the following stock series:

2035	*2185*	*2199*	107000*	008HA#*	009HA#	3208*	3210035
438-031*	BHA#*	CS-CU*	EKH#*	FPH#*	FXS543*	H4020#*	HA#*
KSHA#*	JIC716*HA*	MEHA#*	OXAH*	WAGD8MM*	1280001*	12800101	3210292*
BH*AGS*	FPH*AGS*	11619#*	11620#*	116192N	AP0000*	11640#*	20621#*HA*
6015#*HA*	602HA#*	60120#*HA*	1922#*HA*	20190#*HA	60120#*B*	60120#S*	*6816#H*
*231720H	16363*	R4020#*	W4020#*				

SYMBOLS

CE 1639	EC REP				LOT	SN	REF	
CE mark with Notified Body number	Authorised representative in the EU	Manufacturer	Date of manufacture	Use-by date	Batch code	Serial Number	Catalogue number	Caution, consult accompanying documents

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ILHose Assy R15/2022
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