WARNINGS AND IMPORTANT NOTES

- Medical gases may be considered a critical treatment and should be prescribed in accordance with current clinical recommendations. As oxygen is the most common medical gas, we recommend the British Thoracic Society guidelines; only appropriately trained practitioners should use the device to administer medical gas to patients; before administering medical gas 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.
- Pressured gas from the medical gas pipeline system may cause personnel injury or property damage if the device is incorrectly operated or maintained.
- 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 give in HSE document 'Take Care with Oxygen'.
- Do not autoclave or submerge the device in any fluid and ensure that no fluid is allowed to enter the device.
- Do not subject the device to pressures greater than as identified in the specification section.
- Do not disassemble the device under pressure.
- Only use probes in accordance with BS5682. Using any other probes would be dangerous and could lead to an accident.
- Terminal units designed for use with medical devices include an anti-swivel device to maintain the vertical orientation of the device. If the anti-swivel device is removed then the probe may rotate which will reduce the force required to disconnect.
- This device is designed to be part of a system complying with EN ISO 1789 and HTM 2022 Supplement 2 "Piped medical gases in ambulance vehicles". Installers should ensure that any system components comply with the required standards.

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 use, verify the device is compatible with the devices connected, especially if supplied by different manufacturers.

INTENDED USE AND DESCRIPTION

- The device is used to provide a safe supply of medical gas from a supply system and are designed to accept gas specific probes to prevent cross-connection.
- The device features a positive action of rolling pin latch mechanism, which hold the probe securely. An integral check valve and retaining ring allow removal of the second fix assembly only without depressurising the system for maintenance.
- 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.

OPERATION INSTRUCTIONS FOR CONNECTION AND DISCONNECTION OR PROBES

- 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 terminal unit matches the requirements of the equipment.
- The device contains an anti-swivel function and the cut-out slot in the probe guard ring must be uppermost before connection. When fixed equipment such as a flowmeter is connected the equipment remains upright.
- Connect the equipment end connector first and tighten as required. Insert the gas specific equipment to be used in to the centre hole of the terminal unit and push in firmly until an audible click is heard. Lightly pull on the inserted equipment to ensure that the equipment is retained.
- Check that there is a flow being delivered through the device to the connected equipment.
- Undertake a performance function check of the equipment in accordance with the manufacturer's instructions.
- To release the inserted equipment from the unit, push the interlock ring on the front of the socket assembly whilst holding the inserted equipment being removed in the other hand.
- 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.

INSPECTION AND PREVENTATIVE MAINTENANCE:

- Inspection and maintenance should be carried out in accordance with EN ISO 1789 and 2022 Supplement 2.
- The user should inspect the device during normal operation for any signs of damage, audible leaks or stiffness in operation.
- The device is designed to operate with the minimum of maintenance 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.
- 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.
- Any visible damage would necessitate the device being replaced.
- The device contains rubber seals which must be replaced as a service item. ISO 9170-1 allows for a probe O ring replacement every 1000 cycles in order to maintain the leakage rate. Because of the wide variation of usage and probe condition MEC cannot recommend a period to cover all circumstances but O rings should be replaced at least every five years. See the spares and accessories section overleaf.
- It is recommended that the terminal unit is replaced 15 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 damage to the device.
- 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.

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 -30ºC and 70ºC 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.
- Ensure that identification is not lost.
- Packaging should be maintained until used and stored with identification visible.
- Should not be stacked.

SPECIFICATIONS

Gas Compatibility	Oxygen (O_2) Oxygen/Nitrous Oxide (O_2/N_2O) Nitrous Oxide (N_2O) Medical Air (Air) Surgical Air (Air-800)	**Intended range of use**	Maximum Tested Pressure gases: 1200 kPa Working Pressure gases: 400 kPa Working Pressure Air-800: 800 kPa
		Materials	First Fix: Brass Box, Plate, Second Fix: Plastic Seals: EPDM Rubber Connector: Steel and Brass

REGULATORY

- This is a medical device built to comply with 93/42/EEC European directive and BS EN ISO 9170:2008 standard.
- Is neither for single use, nor sterile.
- Does not incorporate medicinal substances, nor biological or animal tissues, nor human blood, nor phthalates.
- 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 7 years 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:

202230AMB	2022302AMB	2022303AMB	2022304AMB	2022305AMB	2022306AMB

SYMBOLS

CE 1639			LOT	SN	REF	
CE mark with NB number	Date of manufacture	Manufacturer	Batch code	Serial Number	Catalogue number	Caution, consult accompanying documents

ILTUAR02/2020

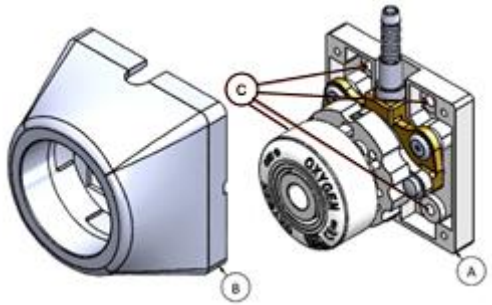
INSTRUCTIONS FOR USE (IFU) –TERMINAL UNIT AMBULANCE

INSTALLATION NOTES

- The user should receive a fitted device from their supplier (i.e. Ambulance Builder, Medical Engineering Department).
- The fitted device should be equipped with medical gas supply hoses fitted to the input connecting to the supply system.
- The connected gas must match the gas specific terminal unit.
- The completed supply system should be certified to show that it has been inspected and pressure tested and the certificate show details of the organisation who carried out the work.
- Installation should be completed and tested in accordance with EN ISO 1789 and HTM 2022 Supplement 2 “Piped medical gases in ambulance vehicles”.

TERMINAL UNIT AMBULANCE VARIANT

- The terminal unit for ambulances is a surface mount variant. Other versions available include flush mounted, bedhead trunking and boom.
- The terminal unit comprises two principal components:
  - First fix and second fix – supplied assembled with a tail for connection to the pipeline system.
  - Cover – cover plates suitable for ambulance applications. The cover plate fits over the first and second fix.



Exploded diagram of Surface Mounted Ambulance Oxygen Terminal Unit assembly, part number 202230AMB

A	First and Second Fix Assembly		C	Mounting points	
B	ORB Ambulance Cover	202107A			

INSTALLATION INSTRUCTIONS

- Remove the device from the packaging and inspect for damage. If the device is damaged on receipt, do not use.
- Physically install the first fix and second fix assembly as appropriate using the correct fixings for the wall.
- Mark the position of the terminal unit on the wall and secure to the wall using the four mounting points (C).
- The terminal unit can be installed with top, bottom, left or right side entry configuration.
- Ensure locating pin (8) is fitted in the 12 o’clock position. Relocate the pin if needed.
- Push fit the ORB Ambulance Cover (B) fully in place.

COMMISSIONING

- Commissioning ensures that all major components are serviceable and takes place in full after initial installation, after a major component change, and as part of planned preventative maintenance.
- Testing and commissioning should be completed by qualified personnel in accordance with EN ISO 1789 and HTM 2022 Supplement 2 “Piped medical gases in ambulance vehicles”.
- The device is component and the test procedures must test the complete supply system once installed.
- Commissioning typically consists of a visual check of labelling, marking, sleeving, support and performance tests for leakage and cross-connection, flow, pressure drop, mechanical function, correct identity and particulate contamination/odour/taste.
- Purging and testing the medical gas pipelines must be carried out with clean, oil-free, dry air or nitrogen, except for those tests where medical air or the specific working gas is prescribed e.g. gas identification, quality and purity check.

PERIODIC TESTING

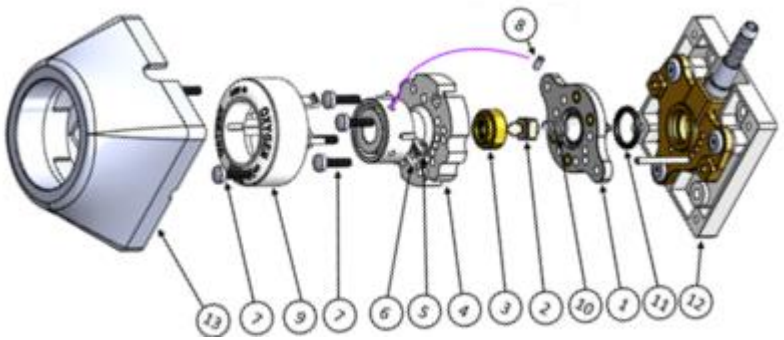
- Periodic testing should be completed in accordance with HTM 2022 Supplement 2 “Piped medical gases in ambulance vehicles”.
- Testing should be completed a minimum of every 12 months or following any repair to the system.
- The test protocol is specified in the standard and should be followed.
- The device forms part of a supply system and is subject to the periodic testing.
- MEC recommend testing using a medical air cylinder (with a pin index or bullnose cylinder valve outlet) and MEC Part number 116205 Vehicle Pressure and Flow Test Set.
- Apply a test pressure of 10.5 bar to the pipeline system and allow the volume of the system to stabilise (allowing the flexible hose time to expand). The medical air supply is turned off and over a 15 minute test period no visible pressure drop should be apparent on the analogue gauge of the test equipment. If a pressure drop is identified then the source of the leak must be identified and rectified.
- The flow at each terminal unit should then be tested with a supply pressure to the system of medical air at 4 bar. The test “gun” with a flow of 40 lpm should show a pressure of 3.8 bar or greater at the terminal unit.
- With the test gun in the no-flow condition apply a slight force side-to-side and up-and-down to the probe to check there are no audible leaks. Turn off the supply gas and repeat the test checking there are no leaks by observing the pressure reading on the test gun.
- While testing the terminal unit flow and pressure, use the probe to assess the operation of the catch and release of the terminal unit. The (correct gas specific) probe should insert easily and be caught and retained by the terminal unit. When the release collar is pressed the probe should be released and withdrawn easily.
- Check that the gas specific collar is in place and check using the probe for another gas type that this cannot be inserted into the terminal unit.
- Check that the marking identifying the type of medical gas which is printed on the release ring is distinct and legible.

MAINTENANCE

- Maintenance engineers must fully understand the MEC terminal unit and be familiar with these instructions.
- Sub-standard or inappropriate parts and materials may damage the terminal unit and invalidate the warranty. Only use genuine MEC Medical spare parts.
- All hand tools used must be clean, completely free of oil and grease and checked for serviceability before use.
- A leaking terminal unit is normally caused by an internal seal failure/wear with the cartridge assembly. The cartridge assembly is a sealed unit and should be replaced. It is also recommended that the cartridge O ring is replaced.

CARTRIDGE AND O RING REPLACEMENT

- Remove the cover plate (13), then remove the release collar (9) by releasing the clips on each side.
- Undo the four screws (7) and remove the body (4) from the housing (1). As the body is released the check seal valve assembly will be pushed from the first fix until the integral valve behind the seal plate operates.
- Do not loose Locating Pin (8).
- Remove the cartridge assembly (3) and renew replace with the new cartridge assembly.
- To replace O Ring (11), remove two screws (7) from the First Fix and remove Housing (1). Replace O Ring and reassemble.
- Reassemble the unit. Take care not to overtighten screws and check for leaks when complete.



- **Exploded diagram of Surface Mounted Ambulance Oxygen Terminal Unit assembly, part number 202230AMB**

1	Housing	N202200	8	Locating Pin	N202169
2	Valve Seal	202187	9	Release Collar	N202181
3	Cartridge Assembly	202210	10	Coil Spring	202189
4	Body	N202191	11	O Ring for First Fix	202148
5	Retaining Pin Spring	N202177	12	First Fix Assembly	N/A
6	Retaining Pin	N202179	13	ORB Ambulance Cover	202107A
7	Screws	163603			

SPARES AND ACCESSORIES

- For all service spares and accessories please check the latest catalogue or contact MEC Medical.

ORB Cartridge Assembly	202210	ORB Cartridge Assembly + First Fix O Ring	202210/S
ORB O2 Second Fix	202211N	ORB Release Collar O2	N202181
ORB O2/N2O Second Fix	202212N	ORB Release Collar O2/N2O	N202182
ORB N2O Second Fix	202213N	ORB Release Collar N2O	N202183
ORB Air4 Second Fix	202215N	ORB Release Collar Air 4	N202185
ORB O Ring (pkt 25)	202148P		

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INSTRUCTIONS FOR USE (IFU) –TERMINAL UNIT AMBULANCE