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.
- 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.
- Please refer to the manufacturer for device specific guidance on AGSS, Pendant, CO2 and Nitrogen variants.

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, vacuum and AGSS from a central supply system and are designed to accept gas specific probes to prevent cross-connection. Various formats allow flexibility of installation.
- 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. This is especially important on surgical air in theatres.

INSPECTION AND PREVENTATIVE MAINTENANCE:

- Inspection and maintenance should be carried out in accordance with EN ISO 7376-1 and HTM 02-01.
- 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.
- Any visible damage would necessitate the device being replaced.
- 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.
- 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 second fix unit is replaced 15 years' after the date of manufacture regardless of condition. A manufacture date is printed on the device label. The first fix unit is installed as a part of the medical gas pipeline system and will last the length of the installation.

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. Vacuum terminal units 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.
- Packaging should be maintained until used and stored with identification visible. Ensure that identification is not lost.
- 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) Vacuum (Vac) Heliox (He/O_2) Carbon Dioxide (CO_2) Nitrogen (N_2-800) Anaesthetic Gas Scavenging (AGSS)	**Intended range of use**	Maximum Tested Pressure gases: 1000 kPa Working Pressure gases: 400 kPa Working Pressure Air-800: 800 kPa Vacuum: 40 kPa absolute AGSS: 20 kPa absolute
		Materials	First Fix: Brass Box, Plate, Second Fix: Acetal Seals: Nitrile 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 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:

S20210*N	T20210*N	F20210*N	B20210*N	R20210*N	20223*AMB
A20210*	202230/*NN	202230/*TN	202230/*RAN		

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

ILTUR03/2020

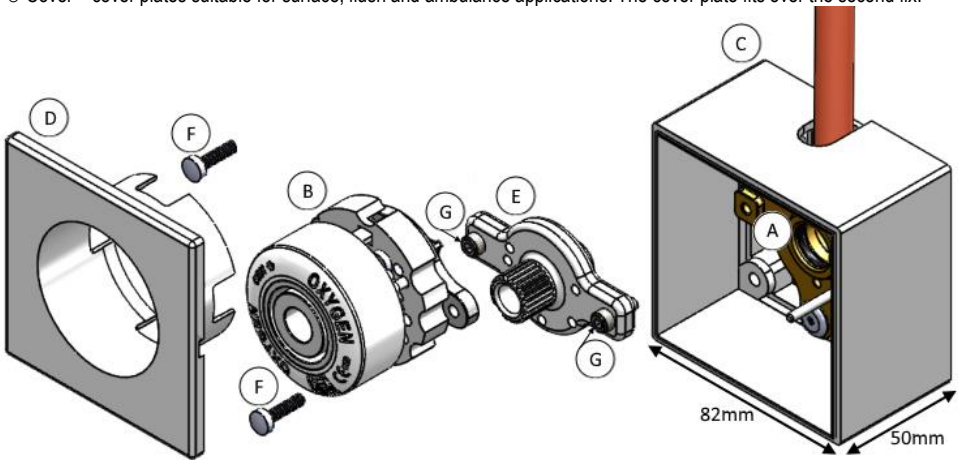
INSTRUCTIONS FOR USE (IFU) –TERMINAL UNIT

INSTALLATION NOTES

- The user should receive a fitted device from their supplier (i.e. Medical Engineering Department).
- 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 7396-1 and HTM 02-01.

TERMINAL UNIT VARIANTS

- The terminal unit is available as surface mount, flush mounted, bedhead trunking and boom variants.
- The terminal unit comprises four principal components:
  - First fix – supplied assembled with a length of copper stub pipe or NIST for connection to the pipeline system
  - Second fix – supplied assembled
  - Box – base plate and box assembly, complete with fixing screws to secure both first fix and box to base plate
  - Cover – cover plates suitable for surface, flush and ambulance applications. The cover plate fits over the second fix.



Exploded diagram of Surface Mounted Oxygen Terminal Unit assembly, part number S202101N

A	First Fix	A202119121
B	Second Fix	202211N
C	Box	202107
D	Cover Plate	N202167

E	Blanking Plate	202130M
F	Screws	163603
G	Screws	202149STST

FIRST FIX INSTALLATION

- 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 as appropriate using the correct fixings for the wall, which are typically as follows:
  - Surface mounted – when the wall has been plastered and decorated, mark the position of the terminal unit on the wall and secure to the wall.
  - Flush mounted – fix to a depth of 50mm plus an allowance for final plastering. Upon satisfactory completion of the pressure test, fit the cover box and plaster cover to protect the unit from building debris. When the wall is finished, remove and discard the plaster cover.
  - Bedhead trunking – mounting plates and/or studs should be provided in the trunking. The terminal unit can be installed with top, bottom, left or right side entry configuration. Assemble the installation plate to the back of the first fix using the screws provided, with the stub pipe in the required position. Locate the first fix assembly over the studs in the trunking, and secure with the nuts and spring washers provided.
- Braze the copper stub pipe to the distribution pipeline system. If it is necessary to shorten the copper stub pipe then remove the installation back box and terminal unit seal plate, with O-ring, to prevent heat damage.
- Fit a blanking plate and retaining strip using the screws provided and pressure test the pipeline.
- Boom mounted terminal units are normally supplied fully assembled and pressure tested. Connection to the distribution pipeline is by means of a flexible hose connected to the integral NIST connector. Tighten all NIST connections, but do not over-torque. Ensure that NIST connections are tightened before use.

SECOND FIX INSTALLATION

- Remove the blanking plate from the first fix installation.
- Install the second fix assembly, with the anti-swivel pin (if fitted) in the 12 o'clock position.
- Secure with the screws provided. Do not over-tighten the screws.
- Pressure test and purge the pipeline.
- Where required, locate the cover plate over the location lip on the rear of the fascia.

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 7396-1 and HTM 02-01.
- Commissioning is typically carried out in two parts:
  - Part 1 is performed after installation of the pipeline carcass but before concealment and consists of visual check of labelling, marking, sleeving, support and performance tests for leakage and cross-connection.
  - Part 2 is carried out after complete installation and includes tests for leaking, 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.

AGSS SETTING PROCEDURE

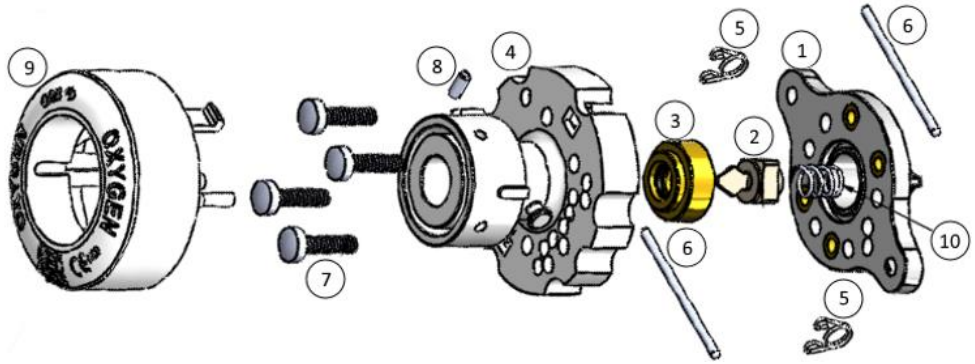
- AGSS flow rate at any terminal unit shall not exceed 130 l/min when a resistance of 1 kPa is applied nor be less than 80 l/min when a resistance of 4 kPa is applied. The performance of the disposal system may vary and require adjustment.
- Adjustments should only be made as part of the installation or setting of the complete system.
- The AGSS terminal unit can be adjusted using the AGSS Adjusting Tool (part number 231747/8). The flow can be adjusted by screwing in to increase flow, or screwing out to decrease flow.
- The AGSS Test & Commissioning set (part number 19031100) is suitable for performance testing of terminal units.

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.

O RING REPLACEMENT

- Remove the cover plate if fitted, then remove the release collar (9) by releasing the clips on each side.
- Undo the 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.
- Remove the cartridge assembly (3) and renew the O ring or the cartridge assembly complete.
- Reassemble the unit. Take care not to overtighten screws and check for leaks when complete.



Exploded diagram of Oxygen Second Fix assembly, part number 202211N

1	Housing	N202200
2	Valve Seal	202187
3	Cartridge Assembly	202210
4	Body	N202191
5	Retaining Pin Spring	N202177

6	Retaining Pin	N202179
7	Screws	163603
8	Locating Pin	N202169
9	Release Collar	N202181
10	Coil Spring	202189

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 O Ring (pkt 25)	202148P
ORB Pendant Cartridge Assembly Valve	202210A

AGSS Adjusting Tool	231747/8
AGSS Blanking Plug	231713P
Terminal Unit Blanking Plug	2022BP

MEC Medical Limited ▌ Unit 3 Trust Estate, Wilbury Way, Hitchin, England, SG4 0UZ
Tel: +44 (0) 1462 436 396 ▌ Email: sales@mecmedical.com ▌ Web www.mecmedical.com

ILTUR03/2020

INSTRUCTIONS FOR USE (IFU) –TERMINAL UNIT