

**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.
- 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.
- Ensure all connections are tight and leak free. Testing prior to use is critical to patient safety and it is essential that the device is not used until full testing in accordance with ISO 7396-1 has been completed.
- Do not subject the device to pressures greater than 850 kPa

**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 an inlet connector and a Schrader quick acting coupler which is used to provide a safe connection transferring low pressure medical gases to various medical devices in a medical environment.
- Every device is checked for burst pressure before dispatch.
- 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.

**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 inserting a probe into the device.
- Check the gas specific connector matches the requirements of the equipment.
- Connect the equipment end connector first and tighten as required. Insert gas specific equipment to be used in to the orifice of the adapter and push in firmly until an audible click is heard. Lightly pull on the inserted equipment to ensure that the equipment is retained within the Schrader coupler.
- Check that there is a flow being delivered through the device.
- Undertake a performance function check of the equipment in accordance with the manufacturer's instructions to ensure that the device is performing as required.
- To release the inserted equipment from the unit, twist the white cover clockwise 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 7 bar surgical air in theatres.

**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.
- 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 Gas Specific Schrader Adapters are replaced seven 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.
- 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 organization.
- 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 -20°C and 60°C with operational temperatures between -10°C and 40°C
- 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	Intended range of use	
Oxygen (O <sub>2</sub> ) Oxygen/Nitrous Oxide (O <sub>2</sub> /N <sub>2</sub> O) Nitrous Oxide (N <sub>2</sub> O) Carbon Dioxide (CO <sub>2</sub> ) Medical Air (Air) Surgical Air (Air-800) Vacuum (VAC)	Materials	Maximum Tested Pressure gases: 1000 kPa Working Pressure gases: 300 – 850 kPa Vacuum: 10 – 100 kPa absolute
		Schrader: Aluminium, Steel and Brass Shroud: 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 9170-1:2008 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:

1922*	1932*	1922***SP	20229*	191412*	20231*
19221*TL	2019**S	2019**B	2019**NB	2019**	2019**P
20190**N	321028*				

**SYMBOLS**

CE mark with NB number	Date of manufacture	Manufacturer	Batch code	Catalogue number	Serial number	Caution, consult accompanying documents

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