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 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.
- Do not subject the device to pressures greater than 850 kPa.
- Do not change the gas specific connector on the device.
- Do not disassemble the device while under pressure.
- Varying the inlet pressure or outlet resistance may affect the accuracy of the flowrate indicated by the device.
- Variations in ambient temperature from 0 °C to 40 °C may affect the accuracy of the flowrate indicated by the device.

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 results 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 is used to provide a pressure limited connection with quick release for various medical devices in a medical environment. The fixed variant limits the outlet pressure to 4 bar and adjustable variants allow line pressure down to zero.
- 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 connecting the device to the gas source.
- Check the gas specific connector matches the requirements of the equipment.
- If using the adjustable variant then ensure the device is turned off by turning the knob fully anticlockwise.
- Insert the regulator into the gas source socket and push in firmly until an audible click is heard. Lightly pull on the regulator to ensure that the equipment is retained within the gas source.
- Gently pull the knob on the bottom of the regulator in a downward plane and, whilst looking at the pressure gauge, adjust the output pressure to the required setting. Push the knob in an upward plane to lock the setting.
- Insert your intended gas specific equipment into the Schrader adapter (white cover) firmly until an audible 'click' is heard. Lightly pull on the connected equipment to ensure that it is retained within the Schrader adapter.
- 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 connected 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 pressure reducing regulators 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 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 -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.
- 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) Medical Air (Air) Surgical Air (Air-800)	**Intended range of use**	Maximum Inlet Pressure: 850 kPa Minimum Inlet Pressure: 50 kPa Adjustable Outlet Pressure: Nil to 700 kPa Fixed Outlet Pressure: 400 kPa
Gauge Accuracy 2.5% of reading	**Materials**	Regulator: Aluminium, Brass Schrader: Aluminium, Steel and Brass Gauge: Brass Shroud: Acetal Seals: Nitrile Rubber Connector: Steel and Brass
Inlet Filtration 40 µm		

REGULATORY

- This is a medical device built to comply with 93/42/EEC European directive and BS EN ISO 10524-4:2008 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:

161818	161818/1	161818/4	161818/5	F161818	

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

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INSTRUCTIONS FOR USE (IFU) – PRESSURE REDUCING REGULATOR