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. Do not change the gas specific connector on the device.
- Do not subject the device to pressures greater than 1000 kPa.
- 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.
- The Flowmeter will deliver restricted to zero flow between flow settings. Ensure the dial clicks into the required setting and that the flow is indicated in the window below the dial.
- Variations in ambient temperature from 0 °C to 40 °C may effect 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 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 controls & indicates the rate of flow of gas passing through it from a regulated gas source to 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.

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.
- Ensure the device is turned off by turning the dial to the zero setting.
- Connect the device to the gas source and tighten as required. Lightly pull on the device to ensure that it is retained.
- Check that there is a flow being delivered through the device.
- To adjust the flow, turn the dial counter clockwise to increase flow and turn the knob clockwise to decrease the flow.
- Turn the dial completely counter clockwise to achieve maximum flush.
- 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.

INSPECTION AND PREVENTATIVE MAINTENANCE:

- To ensure there are no blockages the device should be checked on a weekly basis by opening the dial to give maximum flow rate and then closing the dial to zero.
- 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 Dial Flowmeters 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 -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		**Intended range of use**	Maximum Tested Pressure gases: 1200 kPa Working Pressure gases: 400 kPa +-50kPa High Flow Rates: 0 - 25 l/min Low Flow Rates: 0 - 15 l/min Max Flush Flow: 15 l/min or 25 l/min
Oxygen (O_2) Medical Air (Air)			
Accuracy		**Materials**	Body: Aluminium Dial Insert: Polyoxymethylene (POM) Dial: Polycarbonate Seals: EPDM Rubber Connector and outlet: Stainless Steel
Flow: +- 0.5 l/min or 20% of reading			
Inlet Filtration			
40 µm			

REGULATORY

- This is a medical device built to comply with MDD 93/42/EEC, MDR 2017/745, UKMDR 2002/618 and BS EN ISO 15002.
- 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.
- 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:

2515#	2525#					

SYMBOLS

CE 1639	UKCA 0120	EC REP				LOT	SN	REF	
CE mark with Notified Body number	UKCA mark with Approved 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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ILDFLM R01/2022

INSTRUCTIONS FOR USE (IFU) –DIAL FLOWMETER