MEDISELECT® II, MEDIREG® II

HIGH PRESSURE REGULATORS

INSTRUCTION FOR USE

COMWELD Healthcare

CONTENTS

FIG. 1

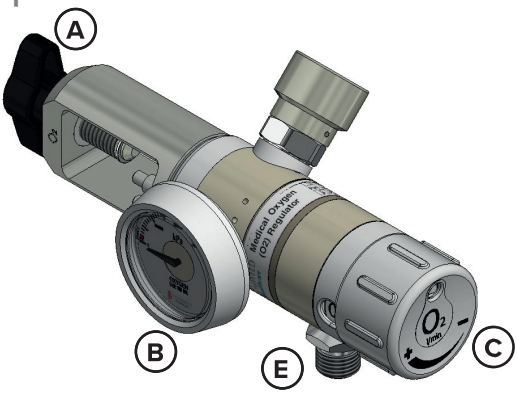
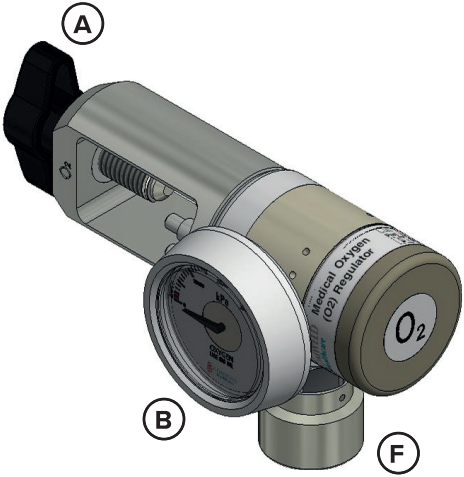

A
B
E
C
Medical Oxygen
(O2) Regulator
O2
L/min

FIG. 2


A
B
F
Medical Oxygen
(O2) Regulator
O2

ENGLISH

INSTRUCTION FOR USE: MEDIREG® II, MEDISELECT® II

1. FOREWORD

Comweld Healthcare Medical Regulators are medical devices classified as class IIb according to the Medical Device Directive 93/42/EEC.
Their Compliance with essential requirements of 93/42/EEC Medical Device Directive is based upon EN 10524-1 standard.

2. INTENDED USE

Comweld Healthcare Medical Regulators are designed for use with high-pressure medical gas cylinders equipped with a medical cylinder valve. They regulate pressure and flow of medical gases to the patient. They are intended for the administration of the following medical gases in the treatment, management, diagnostic evaluation and care of the patient:

- Oxygen;
- Nitrous oxide;
- Air for breathing;
- Helium;
- Carbon dioxide;
- Xenon;
- Specified mixtures of the gases listed.
- Air or nitrogen to power surgical tools.

3. OPERATIONAL, TRANSPORT AND STORAGE SAFETY REQUIREMENTS

⚠ **Keep the product and its associated equipment away from:**

- **All sources of heat,**
- **Flammable materials,**
- **Oil or grease (including all hand creams),**
- **Water,**
- **Dust.**

⚠ **The product and its associated equipment must be prevented from falling over.**

⚠ **Always maintain oxygen cleanliness standards,**

⚠ **Use only the product and its associated equipment in a well ventilated area.**

Before initial use the product should be kept in its original packaging. Comweld Healthcare recommends use of the original packaging (including internal sealing bag and caps) if the product is withdraw from operation (for transport, storage).
Statutory laws, rules and regulations for medical gases, accident prevention and environmental protection must be observed.

OPERATING CONDITIONS	STORAGE AND TRANSPORT CONDITIONS
-20/+60 °C	-30/+60 °C
10/100%	10/100%
600/1200 mbar	600/1200 mbar

⚠ In case of storage at a temperature below -20 °C, d o not operate the regulator until it has been allowed to increase its temperature to a minimum of -20 °C.

⚠ At regulators intended for use with mixture of medical gases O_2+N_2O is lower operation temperature limit +5°C. During normal use the flow outlet and pressure outlet will sometimes have a frosty appearance. This is a normal physical reaction in the valve, due to that the gas is going from high pressure to low pressure (Joule Thompson effect). Ensure that all equipment that is connected to the valve by at least a 2 metre hose.

4. PERSONNEL INSTRUCTIONS

The Medical Devices Directive 93/42/EEC states that the product provider must ensure that all personnel using the product are provided with the instructions & performance data.

⚠ Do not use the product without properly familiarization of the product and its safe operation as defined in this Instruction for use. Ensure user is aware of particular information and knowledge required for the gas in use.

5. PRODUCT DESCRIPTION

FIG. 1: Typical configuration of MediSelect® II regulator
FIG. 2: Configuration of MediReg® II regulator.
The regulator acts as a pressure-reducer, gas from the cylinder valve passes through the pressure regulator to the user outlets.

A - Inlet stem

Regulator is fitted to the medical cylinder valve by mean of an inlet stem. The stem can be bull nose type (male thread), nut type (female thread) or pin index type. The inlet stem includes a filter.

B - Inlet pressure indicator or sensor

The regulator is fitted with a pressure indicator or sensor which is intended for cylinder gas content indication only, not for measuring purposes. The pressure indicator or sensor can be equipped with output of electric signal. The connection of pressure indicator with output of electric signal must be carried out by trained personnel in accordance with national regulations pertaining to the electric device and standard EN ISO 7396-1.

Output of electric signal shall be connected only to device which is in accordance with standard EN ISO 60601-1 and 60601-1-2.

C, E – Flow-metering device and flow outlet

Comweld Healthcare regulators can be supplied with a flow-metering device - flow control head "C" or flowmeter "D". This function is used to supply a gas flow (l/min) at atmospheric pressure directly to the patient through the flow outlet "E", e.g. through a cannula or a facemask.

The flow outlet "E" can be hose nipple (for cannula or mask) or outlet with thread (for humidifier).

F - Pressure outlet

The regulator may be fitted with a pressure outlet. The pressure outlet is the outlet directly from the low-pressure chamber. Two types of the pressure outlet can be used:

Pressure outlet I - is fitted with a gas specific Sleeve Indexed System to AS 2896. The user can connect another piece of equipment to this outlet with a gas specific handwheel. The connector self seals when the handwheel is disconnected. This outlet is for supplying gas at a controlled pressure to power medical devices, e.g. medical ventilator.

Pressure outlet II – is fitted with a threaded connector. The regulator with this type of pressure outlet shall be only an integral part of a medical equipment (e.g. emergency ventilators, anaesthesia devices, etc.)

⚠ **If the regulator is fitted with two pressure outlets, do not use both of them at the same time. If you use both of them in the same time the performance of the regulator will not be according to specification (see appendix 1) !!!**

Note also that the product colour (especially flow control knob) might not be gas specific colour coded.

6. OPERATIONS

6.1. BEFORE USE

6.1.1. VISUAL INSPECTION BEFORE USE

- Check if there is visible external damage to the product (including product labels and marking) and on the gas cylinder. If it shows signs of external damages, remove it from service and identify its status.
- Visually check if the product or the medical gas cylinder is contaminated; if needed, for the regulator, use the cleaning procedure detailed in this section (if required for the cylinder, refer to the gas cylinder manufacturer cleaning recommendation).

- Check that the total life time of the product and the gas cylinder has not been exceeded, (refer to Comweld Healthcare or owner's date coding system). If life time has been exceeded, remove the product (or the gas cylinder) from service & suitably identify its status.
- Ensure that the product inlet stem is compatible with the medical cylinder valve (gas/ thread type).
- Check the presence & the integrity of inlet stem seals / correct size of seal. Always make sure the inlet stem o-ring is in good status, without damage.

⚠ **Remove caps from inlet and/or flow outlet. Keep caps in a safe place for reuse during transport or storage.**

⚠ **The product is dedicated only for use with the gas specified on its labelling. Never try to use for another gas.**

6.1.2. FITTING TO MEDICAL CYLINDER VALVE

- Secure the gas cylinder stand.

Screw connection (bull nose or nut type)

- Connection equipped with rubber sealing - tighten by hand!
- Connection equipped with metal to metal sealing or plastic sealing - tighten by means of a torque wrench (max. tightening torque is 50 Nm).
- Turn the regulator into the correct position for use and tighten the nut by hand - do not use tools.

Pin index connection

- Position the pin-index over the cylinder valve with the pin(s) on the pressure regulator pointing towards the cylinder valve connector holes on the cylinder valve.
- Press the regulator inlet connection pins into the cylinder valve connector holes - do not use force, otherwise the pins or holes may be damaged.
- Tighten the screw on the regulator onto the cylinder valve connector via the T-bar handle. Do not use tools.
- Position the equipment so that the regulator user outlets point away from personnel or patient.

⚠ **Fitting the regulator with too high a torque to the cylinder valve may result in damage.**

⚠ **During fitting to the cylinder valve, do not apply torque/load to any other parts of the product.**

6.1.3. LEAKAGE CHECK BEFORE USE

- For regulators fitted with a flow-metering device, set the flow control knob on the "ZERO" position - Ensure the flow control knob engages correctly.
- Open the cylinder valve slowly by turning the hand wheel in anticlockwise direction approx 1 to 1½ turns.

⚠ **Sudden opening of the cylinder valve could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the cylinder valve could reduce actual flow delivered.**

- Perform visual and audible check for possible leakages:
  - regulator inlet connection to cylinder valve
  - pressure indicator/sensor to regulator body
  - pressure relief valve vent hole(s)
  - flowmeter (if any)
- Turn off the cylinder valve by turning the hand wheel in an clockwise direction to stop position. Do not use excessive force.

⚠ **If any leakage is detected, use the procedure in chapter 6.3 and return the product to Comweld Healthcare for service.**

6.1.4. FUNCTIONAL CHECKS BEFORE USE

- Ensure the flow control knob is on the “ZERO” position.
- Ensure the cylinder valve is open – in the “ON” position.
- Check that the gauge indicates pressure/contents. If the pointer reaches the red area send the cylinder for the filling
- For regulators fitted with a flow-metering device check that there is gas flow at each setting (for instance, by listening for the sound of gas flow or checking presence of bubbles in a humidifier).
- Turn off the shut off cylinder valve by turning the hand wheel in a clockwise direction to the stop position. Do not use excessive force.
- Reset the flow control knob to on the “ZERO” position once the gas flow stops and the regulator is vented..
- For regulators fitted with a pressure outlet, ensure it is functional by connecting and disconnecting a male QC probe.

6.2. USER OUTLET(S) CONNECTION & USE

6.2.1. LIST OF RECOGNISED ACCESSORIES

To be connected to the flow outlet:

Humidifiers, breathing masks or cannulas, gas savers, nebulizers.

To be connected to the pressure outlet:

Flexible hoses, flow meters, Venturi suction ejectors.

⚠ **At regulators fitted with pressure outlet together with ejector outlet don´t use quick coupler and ejector outlet in the same time. Especially when inlet pressure is bellow 50 bar it may negatively affect performance of the regulator.**

⚠ **Before connecting any accessory or medical device to the regulator, always check that it is fully compatible with the product connection features & the product performances.**

6.2.2. PRESSURE OUTLET CONNECTION

Pressure outlet I

- Ensure the male quick coupler is compatible with the pressure outlet feature.
- Connect the male quick coupler.
- Check if the male quick coupler is fully engaged.

⚠ **Regulator with threaded connector as pressure outlet shall be only an integral part of medical equipment. Do not use it for other purposes!**

Pressure outlet II

- Ensure the counterpart is compatible with the pressure outlet features.
- Screw the counterpart.
- Check the counterpart is fully screwed.

⚠ **When is pressure outlet used by medical product with high flow consumption (for example lung ventilator with request of source flow 100 l/min at minimal pressure 2,8 bar) check the required capacity of source device with regulator pressure outlet performance listed in appendix 1. To obtain enough performance of the regulator is recomended replace cylinder when gauge reach the red area.**

6.2.3. FLOW OUTLET CONNECTION

⚠ **When connecting any accessory to the flow outlet make sure that it is not connected to the patient before operating the product.**

- Ensure the hose/humidifier is compatible with the flow outlet feature.
- Push the hose onto the regulator flow outlet/outlet for humidifier.
- Ensure the hose/humidifier is well engaged.

6.2.4. USE OF PRODUCT THROUGH THE FLOW OUTLET (FLOW SETTING)

- Ensure that the flow control knob is on the ZERO position.
- Ensure that the accessory is connected to the flow outlet.
- Slowly open the cylinder valve by turning the hand wheel in anticlockwise direction approx. 1 to 1½ turns.

⚠ **Sudden opening of the cylinder valve could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the cylinder valve could reduce actual flow delivered.**

- Set the flow control knob on the required one of the available flow rates.

⚠ **Always ensure that the flow control knob has engaged and not placed between two settings otherwise the flow selector will not deliver the correct flow of medical gas.**

⚠ **Do not try to apply an excessive torque on the flow control knob when it stops on the maximum flow position or in zero position.**

⚠ **The oxygen flow rate must be prescribed and administered by a clinically trained user.**

After completion of the therapy

- Turn off the cylinder valve by turning the hand wheel in a clockwise direction to stop position. Do not use excessive force.
- Vent gas pressure from downstream equipment.
- Reset flow control knob on the ZERO position when gas venting has ceased.
- Disconnect the tube/humidifier from the flow outlet.

6.2.5. USE OF PRODUCT THROUGH THE PRESSURE OUTLET.

- Ensure that the flow control knob is on the ZERO position (if any).
- Ensure the accessory IS NOT connected to the pressure outlet.
- Slowly open the cylinder valve by turning the hand wheel in anticlockwise direction approx 1 to 1½ turns.

⚠ **Sudden opening of the cylinder valve could result in a danger of fire or explosion arising from oxygen pressure shocks. Insufficient opening of the cylinder valve could reduce actual flow delivered.**

- Connect the accessory to the pressure outlet.

After completion of the therapy

- Turn off the cylinder valve by turning the hand wheel in a clockwise direction to the stop position. Do not use excessive force.
- Vent gas pressure from downstream equipment.
- Disconnect the male QC probe from the pressure outlet.

6.3. AFTER USE

- Turn off the cylinder valve by turning the hand wheel in a clockwise direction to the stop position. Do not use excessive force.
- Reset the flow control knob on the “ZERO” position – when the gas venting has ceased (valid for version with flow-metering device only).
- Ensure the pressure indicator does not show any residual pressure.
- Remove connections from user outlets.
- Refit pressure outlet and flow outlet protection caps. Before refitting the caps, ensure they are clean.

7. CLEANING

Remove dirt with a soft cloth damped in oil free soap water & rinsed with clean water. Disinfection can be carried out with an alcohol-based solution (with damped wipes). If other cleaning solutions are used, check that they are not abrasive and they are compatible with the product materials (including labels) and gas (convenient cleaning solution - i.e. Meliseptol)

⚠ **Do not use cleaning solutions containing ammonia!**

⚠ **Do not expose to water or any other liquid.**

⚠ **Do not expose to high temperature (such as autoclave).**

⚠ **To apply the cleaning solution do not spray it as the spray may enter into the inner parts of product and cause contamination or damage.**

⚠ **Do not use pressure wash as it could damage or contaminate the pro-duct.**

⚠ **If the inner parts of the product have been contaminated do not continue to use the product under any circumstances. It must be withdrawn from service.**

8. MAINTENANCE

8.1. SERVICE AND PRODUCT LIFE TIME

8.1.1. SERIAL NUMBER AND DATE OF PRODUCTION

Form of nine digit serial number stamped on the product is following:
YY MM XXXXX
YY: year of production;
MM: month of production;
XXXXX : sequence number
Example: serial number 090300521 shows the regulator produced in March 2009, with sequence number 521.

8.1.2. MARKING UDI CODING IMPLEMENTATION

There are 3 marked identifiers on the surface of body regulator:
13 numbers with prefix (01): GTIN - Global Trade Identification Number (identification of type regulator)
11 numbers with prefix (10): batch number (LOT)

6 numbers with prefix (17): the end of the product´s life time in format YYMMDD

Example: marking number (17) 290227 shows the regulator produced on the 27th of February 2019 with maximum life time 10 years from the date of manufacture.

8.1.3. MAINTENANCE

To ensure that the regulator is always in a safe, reliable, useable condition it is recommended that the unit be placed on a preventative maintenance program. The preventative maintenance program should include as a minimum fixed bi-yearly servicing. Depending on usage, an additional more frequent service (e.g. twelve monthly or six monthly) is recommended.

8.1.4. MAXIMUM LIFE TIME AND WASTE MANAGEMENT

Maximum life time of the product is 10 years from the manufacturing date.
At the end of the product's life time (10 years maximum), the product must be withdrawn from service. The provider of the device shall prevent the reuse of the product and handle the product in compliance with local regulations. In accordance with Article 33 of REACH Comweld Healthcare, shall inform all customers if materials containing 0.1% or more of substances included in the list of Substance of Very High Concern (SVHC). The most commonly used brass alloys used for bodies and other brass components contain 2-3% of lead (Pb), EC no. 231-468-6, CAS no. 7439-92-1. The lead will not be released to the gas or surrounding environment during normal use. After the lifetime has expired, an authorized metal recycler shall scrap the product to ensure efficient material handling with minimal impact to environment and health.

8.2. REPAIRS

8.2.1. REPAIRS

Repairs activities cover the replacement of the following damaged or missing components:

- Inlet stem,
- Flow-metering device,
- Indicator,
- Piston,
- Pressure relief valve,
- Quick coupler.

The repairs shall be carried out by a Comweld Healthcare authorised person only.

Any product sent back to a Comweld Healthcare authorised person for maintenance shall be properly packaged. The purpose of the maintenance has to be clearly specified (repair, overall maintenance). For product to be repaired a short description of fault and any reference to a claim number might be helpful.

Some repair activities concerning to the replacement of the damaged or missing components can be carried out by the owner of the product. The following parts can be replaced only:

- Caps,
- Flow knob and stickers,
- Hose nipple (including o-ring)
- Inlet stem o-ring.

⚠ Contact our customer service for appropriate component number

⚠ All labels on the equipment must be kept in good, legible condition by the owner and the user during the entire product life time.

⚠ All seals and o-rings must be kept in dry, dark and clean environment by the owner and the user during the entire product life time.

⚠ Use only components provided by Comweld Healthcare!

9. GLOSSARY

	Consult instruction for use		Suitable for Home care use
	Caution		Suitable for Hospital care use
	Keep away from heat and flammable material		Suitable for Emergency care use
	Keep away from oil and grease	SN	Serial number
	Humidity limit	REF	Catalogue number
	Temperature limit	LOT	Batch code
	Keep dry		Fragile, handle with care
	Date of manufacture		Manufacturer
	Use by date		Weight of product
	Inlet parameter		Outlet parameter
P_1	Inlet pressure range	P_2	Outlet pressure
P_4	Max outlet pressure (closing pressure)	Q	Outlet flow
	Take back equipment for recycling. Do not dispose into unsorted municipal waste.		Ambient pressure limit

10. WARRANTY

LIMITED WARRANTY: CIGWELD Pty Ltd, An ESAB Brand, hereafter, “CIGWELD” warrants to customers of its authorized distributors hereafter “Purchaser” that its products will be free of defects in workmanship or material. Should any failure to conform to this warranty appear within the time period applicable to the CIGWELD products as stated below, CIGWELD shall, upon notification thereof and substantiation that the product has been stored, installed, operated, and maintained in accordance with CIGWELD’s specifications, instructions, recommendations and recognized standard industry practice, and not subject to misuse, repair, neglect, alteration, or accident, correct such defects by suitable repair or replacement, at CIGWELD’s sole option, of any components or parts of the product determined by CIGWELD to be defective.

CIGWELD MAKES NO OTHER WARRANTY, EXPRESS OR IMPLIED. THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHERS, INCLUDING, BUT NOT LIMITED TO ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

LIMITATION OF LIABILITY: CIGWELD SHALL NOT UNDER ANY CIRCUMSTANCES BE LIABLE FOR SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, SUCH AS, BUT NOT LIMITED TO, LOST PROFITS AND BUSINESS INTERRUPTION. The remedies of the Purchaser set forth herein are exclusive and the liability of CIGWELD with respect to any contract, or anything done in connection therewith such as the performance or breach thereof, or from the manufacture, sale, delivery, resale, or use of any goods covered by or furnished by CIGWELD whether arising out of contract, negligence, strict tort, or under any warranty, or otherwise, shall not, except as expressly provided herein, exceed the price of the goods upon which such liability is based. No employee, agent, or representative of CIGWELD is authorized to change this warranty in any way or grant any other warranty.

PURCHASER’S RIGHTS UNDER THIS WARRANTY ARE VOID IF REPLACEMENT PARTS OR ACCESSORIES ARE USED WHICH IN CIGWELD’S SOLE JUDGEMENT MAY IMPAIR THE SAFETY OR PERFORMANCE OF ANY CIGWELD PRODUCT. PURCHASER’S RIGHTS UNDER THIS WARRANTY ARE VOID IF THE PRODUCT IS SOLD TO PURCHASER BY NON-AUTHORIZED PERSONS.

The warranty is effective for the time stated below beginning on the date that the authorized distributor delivers the products to the Purchaser. Notwithstanding the foregoing, in no event shall the warranty period extend more than the time stated plus one year from the date CIGWELD delivered the product to the authorized distributor.

Any claim under this warranty must be made within the warranty period which commences on the date of purchase of the product. To make a claim under the warranty, take the product (with proof of purchase from a Cigweld Accredited Seller) to the store where you purchased the product or contact

Cigweld Customer Care 1300 654 674 for advice on your nearest Service Provider. CIGWELD reserves the right to request documented evidence of date of purchase. CIGWELD or our Accredited Distributor must be notified in writing of its claim within seven (7) days of becoming aware of the basis thereof, and at its own expense returning the goods which are the subject of the claim to CIGWELD or nominated Accredited Distributor/Accredited Service Provider.
This warranty is given.
Cigweld Pty Ltd
A.B.N. 56007226815
71 Gower Street, Preston
Victoria, Australia, 3072
Phone: 1300 654 674
Email: enquiries@cigweld.com.au
Website: www.cigweld.com.au

This warranty is provided in addition to other rights and remedies you have under law: Our goods come with guarantees which cannot be excluded under the Australian Consumer Law. You are entitled to replacement or refund for a major failure and to compensation for other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.
Cigweld Pty. Ltd. warrants this product for a period of two years from the date of purchase.

APPENDIX:

Nr 1- Technical and performance data

Nr 2 - Quick coupling feature and connecting/disconnecting procedure

MANUFACTURER:

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