SUMMARY

ONLY THOSE PERSONS WHO HAVE READ THESE TECHNICAL INSTRUCTIONS THOROUGHLY AND UNDERSTAND THEM COMPLETELY SHALL BE AUTHORIZED TO USE THIS PRODUCT.

IMPORTANT NOTICE

If this product is being purchased or used for incorporation into another product (for example, a compressed gas valve for incorporation into a compressed gas cylinder), then *Ceodeux SA - Meditec* reminds the end product manufacturer that any and all product user warning, instructions or product labels are the responsibility of the end product manufacturer. If the valve is "CE" Marked it means that this product complies with European Directive 93/42/CEE and if the product is marked "π" it means that the product complies with European Directive 2010/35/CEE.

Failure to follow the installation instructions and handling instructions may cause an accident or personal injury for which CEODEUX S.A. Meditec declines any responsibility.

CONTENT

1. DESCRIPTION

Alpinox regulators are medical pressure regulators, flow meters for oxygen therapy in hospitals, for home care and in deambulation.

Regulator name: ALPINOX® regulator

High-pressure regulator for standardised fixed regulation, with cylinder or pin-index flow meter.

Optionally, this regulator can be fitted with a low-pressure medical connector.

This product is not intended for any other installation or purpose. If the product user has any question regarding this product's proper application or purpose, the product user should call ***+00352-32-78-32-1***. Any non-approved use or application and/or any non-approved modification of the product or its use or application may result in a serious accident or personal injury for which ***Ceodeux SA*** - ***Meditec*** will not be responsible.

2. GENERAL SAFETY REQUIREMENTS

- All users must comply fully with all national or local laws, rules or regulations in force.
- Anyone using this product must be thoroughly familiar with these instructions and other applicable product instructions and manuals.

! WARNING	This product is a component part designed for use with a gas supply system. The final manufacturer is responsible for preparing appropriate and adequate instructions and warnings for the ultimate product user.

- The maintenance instructions outlined below should be incorporated into any product manual or instruction label.
- Failure to follow any instruction or warning within this instruction manual or on any product label may result in a serious accident involving either personal injury, property damage or both.
- The regulator must not be exposed to any violent shock: a deformed or damaged regulator must not be used.
- Keep this equipment out of the reach of children.
- Do not immerse in any liquid and do not expose to high temperature.
- Do not use a flow outlet for driving any medical equipment
- The customer is responsible for any accident and bodily injury, material or immaterial, direct or indirect, resulting from improper assembly or inadequate maintenance.

This regulator is CE marked. This involve:

- The compliance with this instruction of use
- The management of the traceability by the final manufacturer
- The duty of communicate any incident relative to this product to Ceodeux S.A.-Meditec. Involved products must be sent back to our manufacture.

3. OXYGEN REQUIREMENTS

The use of oxygen can be very hazardous linked with the intrinsic property of this gas. Although oxygen does not burn it does support combustion. An increase of oxygen concentration in contact with a spark, a flame or another heat source like a sudden rise of oxygen pressure in contact with other materials can generate ignition of oxygen. That is why the cleanliness of the cylinder valve and its manipulation has to be followed scrupulously.

- Before using the first time, check the condition of the product (cleanliness, condition of the threads), and familiarize yourself with the standards and safety regulations governing regulator and gas.
- Most malfunctions are caused by the intrusion of particles, dust or other contamination.
- Do not grease, oil a valve or touch it with greasy or dirty fingers.
- Never heat a valve on a naked flame.
- The regulator must not be exposed to sparks (electrical equipment, etc.).
- Do not smoke near the pressurized regulator.
- Gas company personnel will attend to the cleanliness of the gas supply system. The cylinder must be kept free of grease, plastic or metallic particles and dust. (EN ISO 15001)

- The connection of the downstream medical device must be compatible with oxygen and should be able to withstand at least two times the outlet pressure.

4. TECHNICAL DATA

All the significant characteristics (tightening torque) are to be boldfaced, as for all the references to standards.

Pressure of use	According country standard 200 bar 2000 PSI 14.7 MPa
Operating temperature	- 20°C to + 65°C
Storage temperature	- 40°C to + 65°C
Pressure outlet	According country standard 4.5 bar or 50 PSI (USA) 50 Psi
Flow outlet	Flow selector 12 positions 0-2 Lpm, 0-6 Lpm, 0-15 Lpm or 0-25 Lpm
Pressure gauge	According country standard 0 – 315 bar 0 - 3000 PSI 0 – 24.5 MPa
Material: Body Internal parts Regulator seat O-ring Springs	 Brass Brass PA 6.6 EPDM Stainless steel or Copper Beryllium
Inlet connection	CGA 540 UNI 11144-2 MIE TIPO-F DIN 477-9 DIN 477-6 NF E29-650 Type F JIS B 8246 BS 341 N°3 NBN 226 According standard of each country
Gas	Medical OXYGEN, OXYGEN mixtures and AIR
Standard conformity	EN ISO 10524-1
Outlet	Hose barb Medical connector (optional)

Subject with modification without preliminary opinion

5. INSTALLATION AND HANDLING INSTRUCTIONS

A. Connections:

Inlet connection: The regulator is fitted to the gas cylinder valve by an inlet thread. The thread could be parallel or taper, and have different size according the cylinder valve standard. Most of the time, the inlet connection includes a filter.

Outlet connection: The regulator could have the variable flow outlet or a pressure outlet or both of them. Most of the time the flow outlet is a dial flow with. The outlet pressure is fitted with a specific medical quick connector according to the local standard. Nasal canula and oxygen mask can be connected to the hose barb.

B. Mounting the regulator on the gas bottle

NOTE: Carefully place the bottle so as to avoid any risk of it falling, and secure it in place if possible. Before connecting the regulator, check that the high-pressure valve connector is free of dust or foreign bodies (see figures D and E ref. 8).

ATTENTION: Make sure that hands are grease free when manipulating the regulator and the gas valve.

1. Remove the bottle valve protection.
2. Remove the high-pressure connector protection stopper from the regulator. Store it away in a clean location.
3. Ensure that the bottle valve and the regulator connector are clean (no dust or foreign bodies).
4. Check that the O-ring on the regulator inlet connector is in good condition, and is not scratched, torn or creased. The O-ring must always be maintained in perfect position.
5. Hand-tighten the regulator inlet connector in the bottle valve so as to obtain a sealed connection (tightening using a tool is strictly prohibited for O-ring seals).

NOTE: If a seal gasket is faulty, maintenance must be carried out by a certified technician in accordance with the instructions provided in the Ceodeux SA Meditec maintenance documentation.
Only use original parts provided by Ceodeux SA Meditec.

6. Connecting to the user device
- either to the oxygen therapy cylinder nipple outlet
- or to the pressure outlet (medical connector in compliance with country specific standards)

ATTENTION: The flow meters must be at position 0 when connecting to the bottle and when slowly opening the high-pressure valve of the bottle. The cylinder outlet must never be used for supplying machines or other devices.

C. Using the regulator

1. In accordance with recommendations for oxygen application, open the bottle valve slowly. You are recommended not to stand opposite the regulator or high-pressure gas flow. Check the quantity of gas

remaining in the bottle by means of the regulator manometer.

IMPORTANT: In the event of a leak between the regulator and the bottle close the bottle valve immediately and wait for the leak to stop. Open the chamber outlet to ensure that there is no remaining pressure in the regulator. Under no circumstances should the connector be unscrewed or retightened if the manometer indicates a positive pressure. Remove the regulator from the bottle and call a Ceodeux SA Meditec certified technician to carry out maintenance.

2. Adjust the desired gas flow using the flowrate selector switch. Do not try to place the selector switch between the flowrates indicated on the control wheel. Do not use simultaneously the pressure outlet and the flow outlet.

3. After use, close the bottle valve then:
- Disconnect the cylinder hose and wait for the leak to stop.
- Ensure that the pressure reading on the manometer is 0.
- Set the cylinder to position 0.

If you were using the pressure outlet:
- Disconnect the hose from the medical connector.
- Set the cylinder to max. position and wait for the leak to stop.
- Ensure that the pressure reading on the manometer is 0.
- Set the cylinder to position 0.

D. Disconnecting the bottle from the regulator.

1. Unscrew by hand the regulator inlet connector (do not use any tool and do not force).
2. Store the regulator in a dry and clean location after replacing the protective stopper on the inlet connector.

E. Cleaning and disinfection.

The Alpinox regulator should only be cleaned with a damp cloth. Disinfect with an alcohol-based solution (CE).

ATTENTION: It is strictly prohibited to use products containing ammonia or triethanolamine in whatever concentrations.

6. MAINTENANCE

The warranty foreseen in our general conditions of sale does not cover the following:
- Repair or replacement due to normal wear or damage during routine maintenance.
- Damage to components whose fragility is for technical reasons unavoidable and determined by product design.
- Damage from not following recommended maintenance and procedures, as outlined in this instruction manual.
- Damage arising from modifications not included in the procedures in this instruction

manual.

- Damage resulting from the use of an unauthorised part, supplied, manufactured or modified by procedures not included in this instruction manual.

! WARNING	Failure to follow the installation instructions and handling instructions may cause an accident or personal injury, for which ***Ceodeux SA – Meditec*** declines any responsibility.

Maintenance, repairs and reconditioning of the product are under the responsibility of the user or the operator. Anyone attempting to maintain, repair or conditioning the product must be thoroughly familiar with ***the ISO 10524-1 standard*** and all other standards and regulations referenced therein.

According to *CGA V-9* and EN ISO 22434, maintenance, properly trained personnel shall perform repairs and/or reconditioning.

Product is designed for 10 years lifetime from manufacturing date under normal conditions of use as mentioned in the instruction for use. No preventive maintenance is requested during lifetime under normal conditions of use. Regular controls are required. Frequency depends on intensity of use but must not exceed 5 years. Ceodeux S.A. Meditec recommends annual controls (visual inspection, operational check, checks for leaks and of cleanliness). In case of failure or damage, repairs are to be performed by Ceodeux S.A. Meditec or by certified and trained agents and with spare parts from the original manufacturer, Ceodeux S.A. Meditec

In case of incident or complaint, the user has to send back the supposed defective product to the manufacturer ***Ceodeux SA Meditec*** securely packed. In order to preserve the warranty, the user will not execute any intervention on the product (disassembling, repair, modification…) without our written agreement.

7. STORAGE

Recommended storage condition

- Between -40°C and +65°C
- Relative humidity between 45% and 70%
- Keep away from equipment producing ozone
- Keep away from any magnetic source
- The pressure regulator should be stored indoor in its original packaging

Storage time

- The maximum storage time is 2 years.

8. GENERAL CONDITIONS

8.1. Because of a policy of continuous product improvement, ***Ceodeux SA - Meditec*** reserves the right to change designs and materials as well as specifications and product informations without notice.

8.2. ***Ceodeux SA - Meditec*** preserves completely the intelectual property of their projects, studies and in

general on all documents forwarded to their customers : it is not permitted to communicate, to execute or to use these documents in any way without their written authorisation.

8.3. This instruction manual is a part of the sales contract and is subject to the general terms of sale.

Symbol

CE 0476 in compliance with European Directive 93/42/EEC of June 14 1993 amended 2007/47/CE of September 5 2007 on medical devices, established by notified body 0476

Regulations / Reference standard

- ISO 10524-1, ISO 15001
- Directive 93/42/CEE
- Directive 2007/47/CE

9. GLOSSARY

	Consult instruction for use		Product serial number YY MM XXXX
	Caution		Batch number
	Upper and lower humidity limit		Keep away from oil and grease
	Ambient pressure limit		Fragile
	Upper and lower temperature limit		Manufacturer
	Keep dry		Use by date

10.PRODUCT DETAILS

Key

No.	View A	No.	View B	No.	View C Pin Index configuration
2	Flow selector	**3**	Pressure outlet (Medical connector)	**6**	Pressure gauge
4	Pressure gauge	**1**	Flow outlet	**7**	Inlet connexion
5	Inlet connexion				

View F:

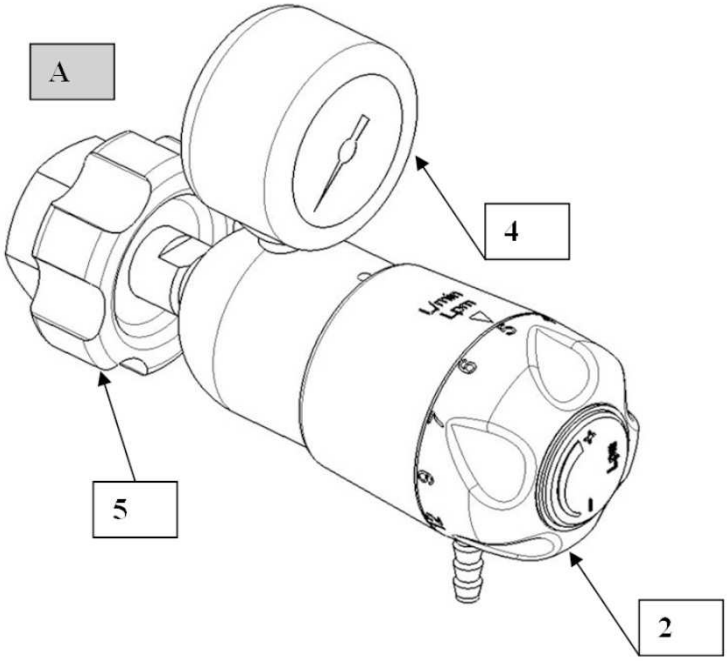
Fixed pressure regulator with ball rotameter 0 – 15 Lpm O2 (No. 9).
These devices are fitted with a removable nipple assembly (view G).

View G:

Removable nipple assembly option:

- No.10: O-ring
- No.11: Hose nipple
- No.12: Screw nut in compliance with national standards

Drawings for illustration purposes only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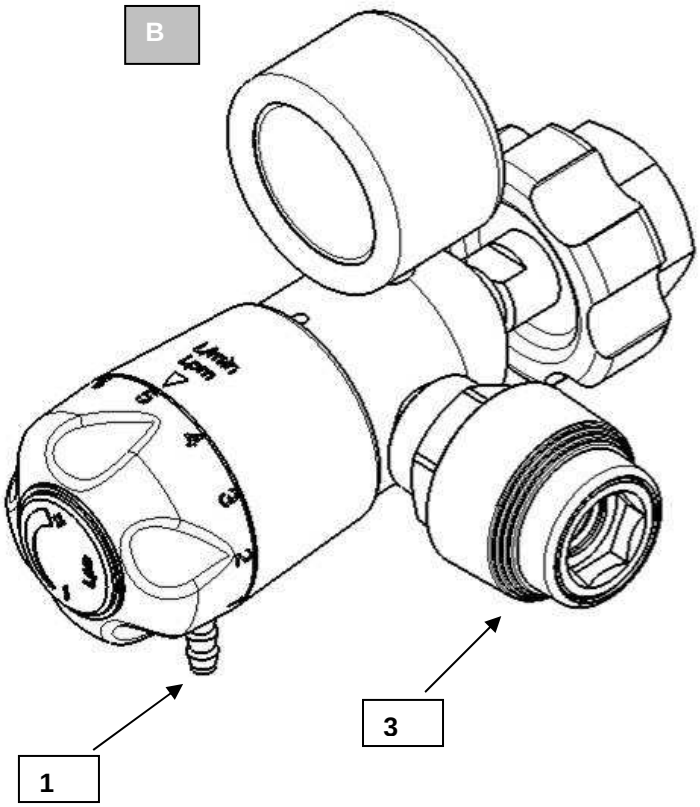
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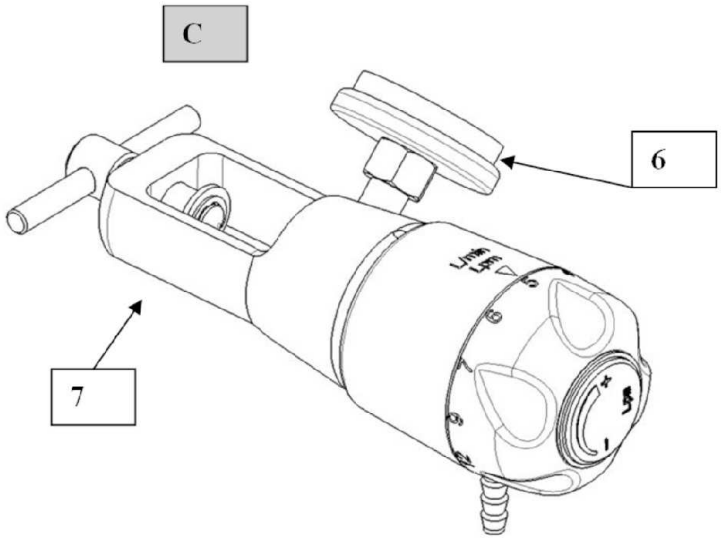

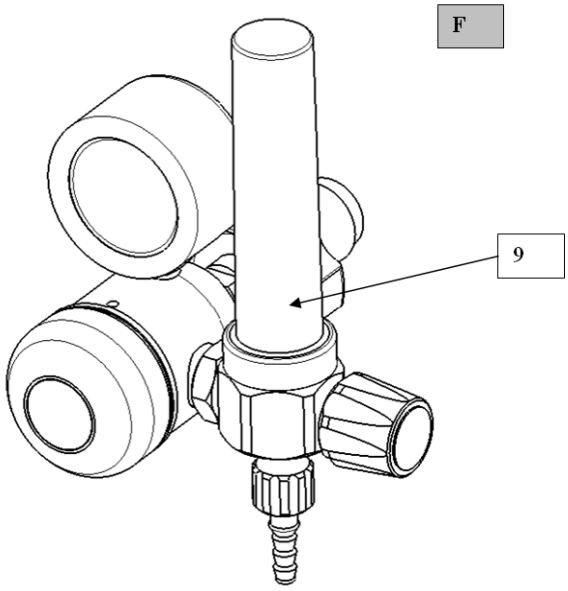

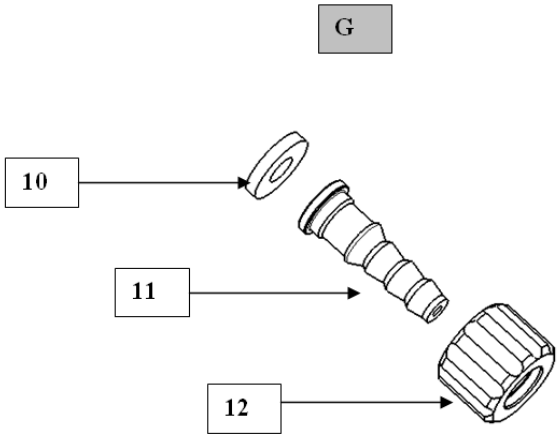
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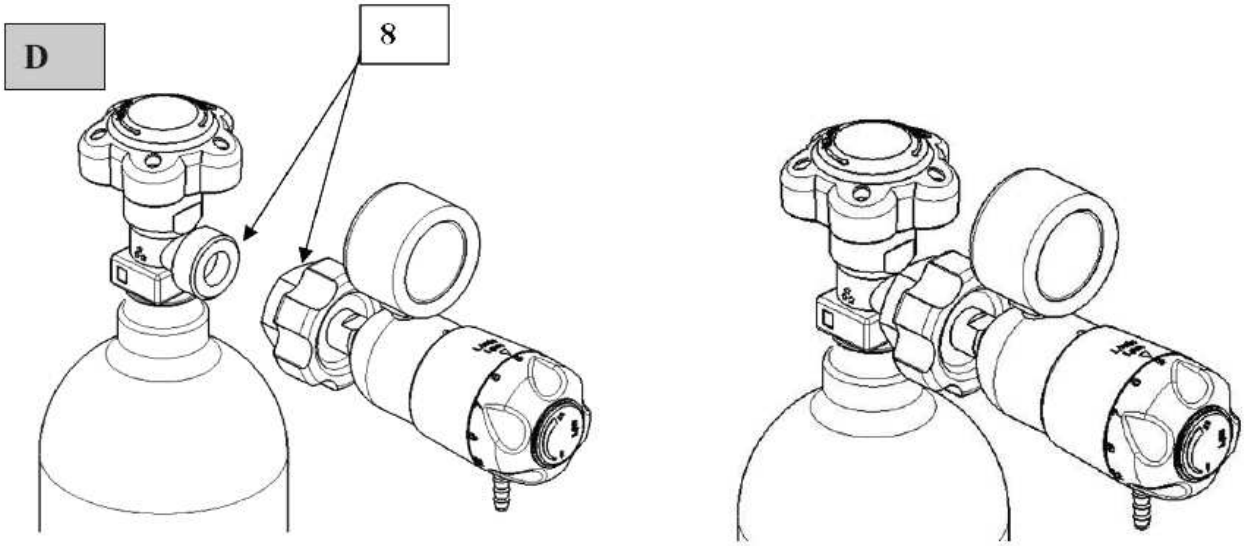
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