



H) REGULATORY AND REFERENCE STANDARDS

- ISO 10524-1
- EN 15001
- AS 3840.1
- Directive 93/42/EEC
- Directive 99/36/EEC

I) KEY

VIEW A	VIEW B
1 High pressure inlet connection	5 Flowrate selector knob (ball rotameter 0-15 l/min O ₂)
2 Yoke connection: wing screw	6 Barbed outlet connection
3 Barbed outlet connection	7 Yoke connection wing screw
4 Pressure gauge	

The ALPINOX™ regulator is manufactured by **Ceodeux SA** and is supplied in Australia by: **Air Liquide Healthcare Pty. Ltd.**



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ALPINOX™
INSTRUCTION MANUAL

ALPINOX™ regulators are medical pressure regulators for oxygen therapy in hospitals, for home care and in ambulatory applications. They provide a regulated gas flow from a high pressure gas source to patients.

NOTE: Please read these instructions carefully before using the ALPINOX™

A. MOUNTING THE REGULATOR ON THE GAS CYLINDER



Carefully place the cylinder so as to avoid any risk of it falling; secure it in place if possible. Before connecting the regulator, check that the high pressure valve connector is free of dust or foreign matter (see figure A ref. 1).

Make sure that hands and equipment are oil and grease free when handling the regulator and the cylinder valve.

- 1) Ensure the cylinder valve is closed and remove the cylinder valve protection (if fitted).
- 2) Remove the stopper from the yoke connection of the regulator (if fitted). Store it away in a clean location.
- 3) Ensure the cylinder valve and the regulator yoke connections are clean (no dust or foreign matter).
- 4) Check that the bodok seal on the regulator yoke connection is present and in good condition (free of nicks, marks, etc).
- 5) Place the regulator yoke connection over the cylinder valve. Check that the pins match the cylinder valve connection.
- 6) Hand-tighten the regulator to the cylinder valve using the yoke connection wing screw (see figure A ref 2).

DO NOT overtighten or tighten THE REGULATOR using a tool, as this may damage the bodok seal.



If the bodok seal is missing or damaged, DO NOT use the regulator. The bodok seal shall be replaced by an authorised person. Only use original parts provided by AIR LIQUIDE Healthcare.

- 7) Open the cylinder valve SLOWLY. Ensure the system is gas tight and leak free.
- 8) If leaks are present, remove the regulator from the cylinder valve (see Section C), and repeat steps 4 – 6. If leaks persist, DO NOT use the regulator. Contact AIR LIQUIDE Healthcare
- 9) Connect the patient device (tubing, canular, mask, etc) to the barbed outlet of the regulator (see figure A ref 3).

The flow setting on the regulator must be in the “0” position before connecting it to the cylinder and when slowly opening the cylinder valve.



The regulator barbed outlet must never be used for connecting and supplying other equipment or devices other than those mentioned in these instructions. Only use equipment that is compatible with medical oxygen.

B. USING THE REGULATOR

- 1) Regularly check the pressure gauge on the regulator (see figure A ref 4) to ensure there is sufficient quantity of medical oxygen gas remaining in the cylinder. The coloured sections on the gauge are an indication of the available contents:

- **GREEN:** Sufficient contents
- **AMBER:** Contents are getting low
- **RED:** Contents are low. Discontinue use and replace cylinder with a full one



In the event of a leak between the regulator and the cylinder valve, close the cylinder valve immediately and wait for the leak to stop. Ensure that there is no remaining pressure in the regulator; the pressure gauge should read “0”. Under no circumstances should the yoke connection be unscrewed or retightened if the pressure gauge indicates a positive pressure. Follow step 7 in Section A).

- 2) Adjust to the desired gas flow rate using the flow rate selector knob (see figure B ref 5).



Ensure that the position shown on the selector knob is not in-between the available flow rate settings. Doing so may interrupt the supply of medical oxygen.

Flow inaccuracies can be caused by back-pressure created by equipment connected downstream of the regulator.

- 3) After use, slowly close the cylinder valve.
 - Disconnect the tubing from the barbed outlet of the regulator (see figure B ref 6) and wait for the leak to stop.
 - Ensure that the pressure reading on the pressure gauge is “0”.
 - Set the flow rate position to “0” using the flow rate selector knob (see figure B ref 5).



Always use the regulator in well ventilated areas and away from oil and grease and sources of heat and ignition. DO NOT smoke and keep away from combustible materials.

C. DISCONNECTING THE REGULATOR FROM THE GAS CYLINDER

- 1) Unscrew by hand the regulator from the cylinder valve using the yoke connection wing screw (see figure B ref 8).
- 2) Store the regulator in a dry and clean location after replacing the protective stopper on the yoke connection (if available).

D. MAINTENANCE

1. USER OPERATIONAL CHECKS AND INSPECTIONS

The following checks should be performed each time the ALPINOX™ regulator is used;

- Check the condition of the inlet and outlet connections for secureness and signs of damage.
- Check that the bodok seal is present, free of nicks and marks and in good condition.
- Check that the pointer on the pressure gauge reads zero when the regulator is unpressurised.
- Check for any other physical damage to any part of the regulator.
- Check to ensure that the regulator is within its service date.

Note: If the regulator fails any of these checks, it must be removed from service. Contact AIR LIQUIDE Healthcare for support.

2. CLEANING AND DISINFECTION

The ALPINOX™ regulator should only be cleaned with a damp cloth. Disinfect using an instrument grade disinfectant – Instrumax Pink ARTG No. 135544 (Whitely Medical) or equivalent as approved by the manufacturer. In performing these tasks, be careful to avoid the ingress of moisture or cleaning solution into the outlet and inlet connections.



It is strictly prohibited to use products containing ammonia or triethanolamine in any concentration. DO NOT sterilize the ALPINOX™ regulator

3. STORAGE

Should the regulator not be required to be used for a period of time, it should be stored in a clean, dry and secure place to prevent accidental damage. Ensure a dust free environment is maintained to prevent the ingress of dust borne contamination to the inlet and outlet connections.

4. SCHEDULED MAINTENANCE

The frequency of this maintenance depends on the intensity of use. In any case, the interval between scheduled maintenance shall not exceed five years. Scheduled maintenance shall only be carried out by authorized persons that have been trained and certified by Ceodeux SA. Contact AIR LIQUIDE Healthcare for support.

SERVICE PERIOD	5 years	3 years	1 year
USE	Low or shelf	8hr / day	Continuous

In case of ad-hoc repairs (due to accidental damage, abnormal variation in performance, etc.), the ALPINOX™ regulator can be returned to AIR LIQUIDE Healthcare for service.

The ALPINOX™ regulator has a service life of 10 years. It shall be removed from service once its period of use has reached this stage.

E. SAFETY CONDITIONS

- 1) Follow safety and handling instructions given on the gas cylinder label and gas SDS.
- 2) Do not use lubrication or any other sealing material on the regulator to aid connection or to stop leaks.
- 3) Do not use the regulator if it has been or suspected to have been exposed to extreme environmental conditions (temperature, humidity, etc.)

Failure to respect these and the other cautions given within these instructions may result in severe injury.

F. TROUBLESHOOTING GUIDE

Type of malfunction	Cause	Remedy
Gas flow inadequate or non-existent	Valve closed or insufficiently opened	Open the cylinder valve
	Cylinder not full or insufficiently filled	Check the filling level of the cylinder. Change the cylinder
	Valve does not function	Change the cylinder
	Pressure regulator does not function	Call your Rotarex technical support
	Downstream equipment does not function	Change the downstream equipment
Connection not possible	Wrong selected flow	Turn the flow selector of the pressure regulator
	Connection incompatible with the valve	Check the compatibility between the cylinder valve and the pressure regulator
Gas exists from vent holes	Connection damaged	Call your AIR LIQUIDE Healthcare for support
	Leak on seat	Close the valve. Call AIR LIQUIDE Healthcare for support

G. SYMBOLS

CE 0029 in compliance with European Directive 93/42/EEC of June 14 1993 on medical devices, established by notified body 0029

TT 0029 in compliance with European Directive 99/36/EEC of June 29 1999 on transportable pressure equipment, established by notified body 0029