Air Liquide
HEALTHCARE | ALIZE

Régulateur de vide Manuel d'utilisation	FR	Vacuum regulator Use manual	EN
منظم التفريغ دليل الاستخدام	AR	Vakuumregler Bedienungsanleitung	DE
Regulador de vacío Manual de uso	ES	Regolatore di vuoto Instruzioni per l'uso	IT
Vacuümregelaar Handleiding	NL	Regulador de vácuo Manual de utilização	PT

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1 Introduction

User Alerts

⚠ **Caution:** Warns the user of the risks associated with the use or misuse of the device:
- occurrence of a technical problem or device malfunction,
- slight or serious injury to the patient.

If the risk to the patient is very high, the warning will appear in bold lettering

ⓘ **Note:** Highlights a particular item of information.

⚠ **Caution:** Handle with caution, to avoid damaging the vacuum gauge in particular

Intended Use

The ***ALIZE***™ vacuum regulator is a medical suction device for professional use in hospitals and A&E departments. This device is used for precise adjustment and regulation of vacuum pressure from a standard vacuum outlet, supplied by a vacuum source. It can be used to suction patients' body fluids and secretions during surgical procedures, to clear the upper airways and for gastric drainage.

ⓘ **Note:** The ***ALIZE***™ vacuum regulator range is not recommended for use in direct thoracic drainage. The tube recommended by Air Liquide Medical Systems must have a minimum length of 1.3 m. Do not use ***ALIZE***™ devices to remove anaesthetic gases.

Instructions for Hospital Staff and Required Training

Hospitals and health care centres which bring in the ***ALIZE***™ vacuum regulator must ensure that the medical personnel handling it have read and understood this user manual and have been shown how to use this type of medical device.

Description of *ALIZE*™ vacuum regulator

The range of ***ALIZE***™ vacuum regulators comprises four regulator types:

- ***ALIZE***™ 250 20L (blue front panel) has a low suction level (adjustment range < 200 mbar) and a low flow rate (< 20 l/min), and is equipped with a safety relief valve restricting the maximum vacuum pressure to -300 mbar,
- ***ALIZE***™ 250 20L (grey front panel, blue screen-printed overlay) has a low suction level (adjustment range < 200 mbar) and a high maximum flow rate (< 40 l/min), and is equipped with a safety valve restricting the maximum vacuum pressure to -300 mbar,
- ***ALIZE***™ 600 (grey front panel, violet screen-printed overlay) has an adjustment range of 0 to -500 mbar for medium-vacuum pressure and high-flow suction,
- ***ALIZE***™ 1000 (grey front panel, orange screen-printed overlay) has an adjustment range of 0 to -800 mbar for high-vacuum pressure and high-flow suction.

ⓘ **Note:** The vacuum pressure levels shown are valid only if the vacuum network of the hospital can supply the maximum vacuum pressure level. Otherwise, the maximum suction level provided by the ***ALIZE***™ vacuum regulator will be equal to the capacity of the vacuum network.

ⓘ **Note:** ***ALIZE***™ vacuum regulators are not recommended for use in MRI rooms.

ⓘ **Note:** ***ALIZE***™ does not contain any natural rubber latex components.

The vacuum regulators in the ***ALIZE***™ range have a one-piece ABS body with the following functions:

- a knob for adjusting vacuum pressure value (4) and thus the level of medical suction. The suction level is increased by turning the adjustment knob counter-clockwise; the suction level is decreased by turning the knob clockwise.

- a vacuum gauge (1), clearly indicating the available adjustment range
- a sliding on/off button (2 and 3) connected to a window (6) indicating the status of the device (Green = on; Red = off)
- a connector system incorporated into the body of the regulator, for connecting to the suction circuit. This system is designed for connecting the emergency nozzle (9) the 2 in 1 filter (7) or the reusable safety jar (e) before attaching the suction tube connected to the collection system.
- a “push” button (5) for releasing the emergency nozzle (9), the 2 in 1 filter (7) or the reusable safety jar (e) from the regulator in a single action

⚠ **Caution:** Do not use the 2-in-1 filter to suction fumes produced using an cautery knife. This could prematurely block the filter medium.

- a system for connecting the regulator to the medical vacuum outlet or to the rail, located at the back of the device
- an access panel (8) for replacing the vacuum gauge, located at the back of the device
- an emergency nozzle (9) fixed to the back of the regulator

They can be used together with an emergency nozzle (9) a single use 2 in 1 filter (7) or a reusable safety jar (e) comprising a non-return valve (13) and a bacteria filter (11).

The models ***ALIZE***™ 250 and ***ALIZE***™ 250 20L are equipped with a safety relief valve restricting vacuum pressure to -300 mbar (discharge of excessive vacuum pressure).

2 Correct Function Controls

There are pre-use and recommended in-use controls to ensure correct functioning.

2.1 Pre-use Controls

- Check that the end-of-life date of the ***ALIZE***™ vacuum regulator has not passed (the end-of-life date is shown on the back of the device).
- Check the condition of the inlet fitting (10).
- Check that the vacuum gauge needle (1) is at zero before connecting to the vacuum network. If it is not at zero, isolate the vacuum regulator for curative maintenance of the vacuum gauge. Check the presence and condition of the emergency nozzle (10) or 2 in 1 filter (7), depending on the configuration of the ***ALIZE***™ vacuum regulator.
- If using the reusable safety jar, check that the seal is in good condition, that the non-return valve (13) and bacteria filter (12) are present, and that the whole unit is working correctly (fig. e).

Note: *Air Liquide Medical Systems*strongly recommends using a safeguard to protect the vacuum regulator and vacuum network against bacterial contamination and fluid backflow in the event of failure of the collection system located upstream of the regulator. For this purpose, *Air Liquide Medical Systems* recommends using a 2 in 1 filter (7) or a reusable jar (e). This is indispensable if the patient secretion collection device has no safeguards against bacteria and reflux.

Note: If the vacuum regulator is used with the nozzle alone, and no upstream protection measures are present, the device and the vacuum network are no longer protected.

Caution: Do not use the ***ALIZE***™ vacuum regulator if the vacuum gauge needle is not at zero when the device is off (indicator window Red). Risk of incorrect adjustment of medical suction level.

2.1.1 Connection

1. Connect the 2 in 1 filter or the safety jar to the regulator (fig. c). You will hear a “click” when the filter, nozzle or jar is correctly connected.
2. Attach ***ALIZE***™ to the vacuum outlet.
    1. For models connected with EASYCLIC NF connector (fig. g):
        1. Push the device fully into the outlet (notches together)
        2. Rotate clockwise are far as possible.
        3. Rotate anticlockwise to a vertical position.
    2. For models connected with the rail attachment (fig. d):
        - clip the rail attachment to the rail then insert the leg at the back of ***ALIZE***™ into this attachment.

    Check that it is locked in place by pulling gently.

    Check that there is no leakage at the point of connection.
3. Connect the nozzle, 2 in 1 filter or safety jar to the suction containers with a suction tube measuring 8 x 14 or 9 x 16 (2 m max.).
4. In case of emergency, if no safety jar is available, connect the nozzle (9) found at the back of the device (release by pulling the bottom part upwards).

Caution: Do not use this device without at least one safeguard against bacteria and reflux between the patient and the vacuum network. Risk of contamination of the vacuum regulator and vacuum network.

2.1.2 Use and Related Controls

1. Start: push the button on the side (2) from left to right. Check that the window indicating the status of the device changes from red to green.
2. Adjustments:
    1. Close the suction outlet (for example, by stopping the vacuum or completely clamping the suction tube).
    2. Turn the central knob (4), checking that the needle moves accordingly, until the desired vacuum pressure value is reached. The adjusted value is displayed on the vacuum gauge (1). The coloured markings on the vacuum gauge dial show the available vacuum level adjustment range.

       If the maximum level is exceeded, the button is disengaged.

       If the adjusted vacuum pressure is too high, begin the adjustment process again as follows:
    3. Reset the system by pressing the button on the side (3) from right to left and check that the window indicating the status of the device (6) changes from green to red.
    4. Turn the knob (4) clockwise as far as it will go.
    5. Begin the operating procedure again.
3. Suction: When the suction tube is opened, the vacuum regulator suctions air or fluid: the needle on the vacuum gauge swings between 0 and the adjusted level according to the nature and quantity of the fluid suctioned.
4. Stop: press the button on the side (3) from right to left and check that the window indicating the status of the device (6) changes from green to red. The patient circuit adjusts to atmospheric pressure.

⚠ **Caution:** Ensure that with each use, vacuum pressure is perfectly stable after adjustment (at zero flow, i.e. tube fully clamped or vacuum off). If the vacuum gauge needle fluctuates, the vacuum regulator has not been stopped. Check that the device is properly connected to the outlet and the accessories are properly fitted, then repeat the test.

If there are any irregularities, isolate the vacuum regulator for review by the technical personnel of the centre or by the manufacturer.

The device must be switched off when not in use.

Suction stops when the overflow protection device is triggered. In this case, the vacuum regulator should be stopped and the collection containers and tubes should be replaced or emptied, as should the ***ALIZE™*** overflow protection device if it has been contaminated, before restarting the MD.

2.1.3 Maintenance

The user must replace and remove the bacteria filter used in accordance with the protocol of the centre. There are two types of bacteria filter:

- the 2 in 1 filter (fig. f), which is a single-use hydrophobic bacteria filter. It must be replaced after each patient, or in the event of visible damage or fluid backflow.
- The bacteria filter (12) located in the reusable safety jar. This must be replaced every 2 to 4 days when used on a single patient, depending on how many times it is used, and must also be replaced after each patient.

2.2 Changing the 2 in 1 filter or the safety jar (fig. c)

Disconnecting: press the “push” button (5) and pull the jar or 2 in 1 filter downwards.

Connecting: place the 2 in 1 filter or safety jar under the device, engage the connector and push until is clicks into place

Changing the bacteria filter (fig. e).

The bacteria filter is located inside the reusable jar. Each time the filter is changed, clean and disinfect the jar or sterilise it in an autoclave if necessary (depending on the model, see *Correct Function Controls* on page 7).

Disconnect the reusable jar, remove the cover (12) by turning it 90 degrees anticlockwise, remove the filter (13), place a new filter (13) on the support (14), replace the cover, press down firmly and turn 90 degrees clockwise.

In order for the device to operate correctly, only accessories and filters supplied by *Air Liquide Medical Systems* should be used.

3 Cleaning/Disinfection

- Wash with soapy water and rinse with clean water.
- No not use abrasive products.
- Do not immerse the device.
- Disinfect the outer panels of Alize with one of the following CE certified solutions: Schülke Mikrozid, Schülke Esemfix, Anios Surfa Safe Premium.

Models with rail holders

- If necessary, clean the hose externally using water and the usual types of detergent, without excessive scrubbing that would affect the markings.
- Do not use solvents.

ALIZE™ 250 20L includes a flow limit upstream of the connection for the 2 in 1 filter or safety jar. After releasing the filter or jar, check that this opening, located in the body of the regulator, is clean.

Sterilise the reusable safety jar in an autoclave at 134°C (yellow jar) for 18 minutes.

The nozzle (9) can be sterilised in an autoclave at 121°C for 30 minutes. These components are designed for a maximum of 30 autoclave sterilisations.

The jar suitable for cold disinfection (blue jar) is not autoclavable.

After these cleaning operations, check the overall condition of the jar, especially the presence and condition of the seals and the functioning of the non-return valve, which must be mobile. If any of these components is not working correctly, it must be replaced.

4 Maintenance

Control of proper functioning and sealing once per year and every time the device is accidentally knocked or dropped.

Models with rail holders

Note: Factors contributing to hose damage: crushing, bending, excessive curvature, prolonged exposure to ultraviolet rays.

Note: The vacuum gauge is the most fragile component of the MD and may be damaged if the device is dropped.

No preventive maintenance is required during the lifetime of the device (10 years).

In case of operational problems (I/O button blockage, lost or broken buttons, vacuum gauge blockage, etc.) a trained technician must perform corrective maintenance. Consult the ***ALIZE™*** maintenance manual.

Only use parts supplied by Air Liquide Medical Systems.

Perform an annual check to ensure that the hose is in good condition, without bulges, cracking, leak (all along the hose and at crimping locations), and that the connector catches are not worn out. Replace the hose if any such defects are found.

5 Technical Description

Standards and Regulations

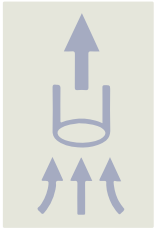
Medical suction devices: EN ISO 10079-3

Standard connectors: NFS 90 116 or other national standards (according to model).

European directive 93/42/EEC.

Year of marking CE : 2015

Symbols

BATCH YYMM : batch no. on packaging (YY=year, MM=month),			
SN YYMMxxxx: serial number of the product (YY = year, MM = month, xxxx= device no.)			
	YYYY-MM: year-month use-by date (UBD)		For releasing the safety jar or the nozzle
	Single-use		For disposal according to hospital protocol
	This device has a vacuum function.		Vacuum pressure adjustment
	Consult the accompanying documents	CE 0459	complies with European directive 93/42/EEC relating to medical devices - notified body no. 0459

Technical characteristics

Specification	*ALIZE*™ 250 20L	*ALIZE*™ 250	*ALIZE*™ 600	*ALIZE*™ 1000
	Low vacuum pressure Low flow	Low vacuum pressure High flow	Medium suction High flow	High suction High flow
Main uses	Neonatology and paediatrics	Gastric drainage and suction	Tracheal and pharyngeal suction	Surgery
Max flow in l/min of regulator + nozzle (9)* Models with rail holder	< 20 l/min at -200 mbar	75 l/min at -200 mbar	80 l/min at 500 mbar	80 l/min at -800 mbar
	< 20 l/min at -200 mbar	60 l/min at -200 mbar	65 l/min at -500 mbar	65 l/min at -800 mbar
Max flow in l/min of regulator + safety jar (e)*	< 20 l/min at -200 mbar	60 l/min at -200 mbar	75 l/min at 500 mbar	75 l/min at -800 mbar

Models with rail holder	< 20 l/min at -200 mbar	50 l/min at -200 mbar	65 l/min at -500 mbar	65 l/min at -800 mbar
Max flow in l/min of regulator + 2 in 1 filter (7)*	< 20 l/min at -200 mbar	45 l/min at -200 mbar	65 l/min at 500 mbar	65 l/min at -800 mbar
Models with rail holder	< 20 l/min at -200 mbar	40 l/min at -200 mbar	50 l/min at -500 mbar	50 l/min at -800 mbar
Adjustment range**	0/-200 mbar (0/-150 mmHg) Safety valve at < 300 mbar		0/-500 mbar 0/-375 mmHg	0/-800 mbar 0/-600 mmHg
Button disengagement	< 200 mbar		Between -500 and -600 mbar	from 800 mbar
Reading scale	0 / -250 mbar - 0/187 mmHg		0/-600 mbar 0/-450 mmHg	0/-1000 mbar - 0/-750 mmHg
Accuracy of vacuum gauge	2.5% of the full scale			

Dimensions	233 (H) x 105 (W) x 125 (D) mm	Network entry vacuum pressure**(Recommended Pressure Pr)	-400~-950 mbar/ (-300 ~-710 mm Hg (- 40 000 ~ -95 000 Pa)
		Mass	347 g (NF version)
Working temperature	+5°C to + 40°C	Storage temperature	0 to + 55°C

*value measured upstream of the regulator at maximum vacuum pressure level of the regulator

**The adjustment range can only be accessed if the network entry vacuum pressure is sufficiently high: the network vacuum pressure must be higher than the desired vacuum pressure adjustment; otherwise, vacuum pressure and suction will be limited by the hospital’s vacuum network.

Air Liquide Medical Systems S.A.
Parc de Haute Technologie
6 rue Georges Besse
92182 ANTONY CEDEX – FRANCE
Tel. +33 (0)1 40 96 66 00
Fax +33 (0)1 40 96 67 00
Hotline hors France métropolitaine
+33 (0)1 79 51 70 01
Hotline France
0820 146 359
0,12 € / min TTC depuis un poste fixe

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