flow-meter™

INSTRUCTIONS MANUAL

EASYVAC® - EASYVAL VACUUM REGULATOR

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⚠ CAUTION

THIS DOCUMENT IS INTENDED FOR THE INSTALLER AND THE SERVICE ENGINEER. IT IS INTEGRATED WITH THE INSTRUCTIONS CONTAINED IN THE INSTRUCTIONS FOR USE IU 002 THAT MUST ACCOMPANY THE EQUIPMENT THROUGH TO THE FINAL USER.

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Contents

⚠ Important

CAUTION: DANGER INDICATION

Attention: Important indication

General information

- **THE INFORMATION IN THIS DOCUMENT MUST BE READ CAREFULLY BEFORE INSTALLING OR PERFORMING MAINTENANCE ON THE EASYVAC-EASYVAL SERIES VACUUM REGULATORS.**
- **AFTER UNPACKING AND CONNECTION, CHECK THE DEVICE IS INTACT AND CARRY OUT THE FUNCTIONAL TEST AS DESCRIBED IN THE CHAPTERS "INSTALLATION" AND "START-UP PROCEDURE".**
- **EACH TIME BEFORE USING THE DEVICE CARRY OUT THE OPERATIONS DESCRIBED IN THE CHAPTER "START-UP PROCEDURE".**
- **INSTALLATIONS THAT ARE NOT ENVISAGED BY THIS MANUAL MAY REDUCE THE SAFETY LEVEL OF THE DEVICE.**
- **BEFORE EACH USE, ENSURE THAT THE EASYVAC-EASYVAL VACUUM REGULATOR IS DIRECTLY OR INDIRECTLY CONNECTED TO A COLLECTION SYSTEM FITTED WITH AN OVERFLOW VALVE AND ANTIBACTERIAL FILTER AND THAT THE CONNECTOR HOSES USED CONFORM WITH THE STANDARD EN ISO 10079-3.**
- **The company will not accept any responsibility if the instructions in this manual are not observed, if original spare parts and/or authorized technicians are not used.**
- **The device and its components or accessories do not include parts in natural rubber latex.**

Connections

- **THE DEVICE MUST NOT COME INTO CONTACT WITH OIL OR GREASE.**
- **The vacuum supply connector is positioned on the rear of the appliance and can be identified by referring to the drawing on page 5 of this manual (pos.7).**

Operation

- **THE EASYVAC-EASYVAL VACUUM REGULATOR MUST ALWAYS BE USED WITH CARE AND ONLY BY PERSONNEL WHO ARE AWARE OF THE CONSEQUENCES OF THE ONGOING THERAPY.**
- **Disconnect the vacuum supply by switching push button switch I-0 to "0" (green visible) when the unit is not in use.**
- **The device must be used in a hospital or equivalent structure in the environmental conditions of use indicated here and is not intended for applications in environments where electromagnetic fields, combustion sources, electrical or electrostatic discharge generators, sources of ionising and non-ionising radiation are present.**

Service

- **All the modifications and repairs must only be performed by personnel authorized by FLOW METER S.p.A., or by hospital technicians approved by the same company.**
- **Only if original spare parts, indicated in the service manual, area used for the maintenance operations, FLOW METER can guarantee the intended functioning of the device.**
- **Check the EASYVAC-EASYVAL vacuum regulator every three years in accordance with the chapter "Periodic controls" of Instructions Manual MO002.**
- **Due to periodic updates, the construction of the device may vary. On this point, it is guaranteed the availability of spare parts for a minimum period of 5 years from the date of manufacture.**
- **Any modifications to the device must be approved by FLOW METER S.p.A., and carried out in accordance with the procedures prescribed.**

Your local dealer and service center

Your local dealer and service centre for FLOW METER S.p.A. products is:

Sponsor: ICU Medical Australia Pty Ltd
Unit U, 10 – 16 South St, Rydalmere NSW 2116, Australia
Tel: +61 2 9466 5300
www.clements.net.au

The equipment described in this publication is designed and manufactured by:

FLOW METER S.p.A. - Via del Lino, 6 - 24040 LEVATE (Bg) – Italy – Tel. +39-035-594047 – Fax +39-035-594821 – e-mail: info@flowmeter.it - http://www.flowmeter.it

Applications

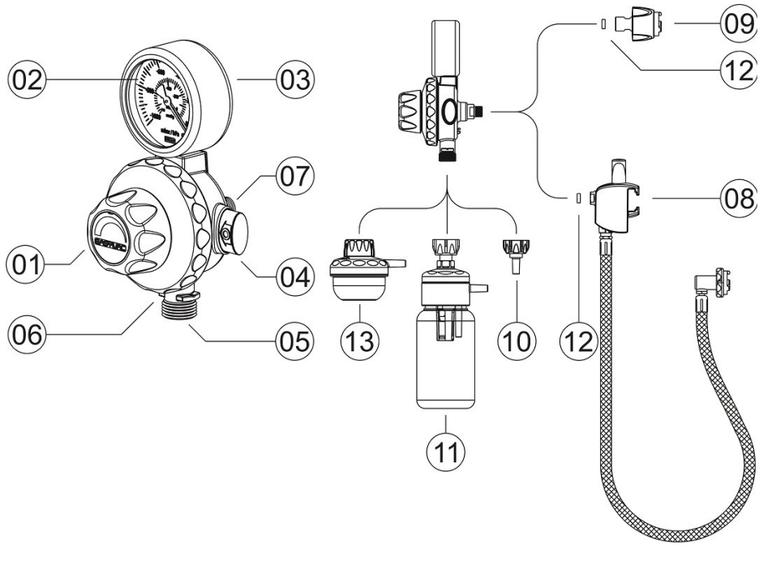
The EASYVAC-EASYVAL series vacuum regulator is particularly suitable for all medical suction applications in hospitals. Basically this device consists of a technopolymer body which houses a quick I-0 push button switch, a suction adjustment knob and a control vacuum gauge with double-scale indication (mbar / hPa + mmHg), protected by a silicon shell to avoid damage caused by possible blows during transport or use and with a different full-scale depending on the model (-250 mbar / hPa for low vacuum/high flow or low vacuum/low flow applications, -600 mbar / hPa for medium vacuum applications, -1000 mbar / hPa for high vacuum/high flow applications). The EASYVAC-EASYVAL series vacuum regulator can also be fitted, using the outlet connector, for direct or indirect connection to the collection system for suctioned liquids. The extremely rational and essential design, together with the sophisticated technical execution, makes it possible to operate under the maximum safety conditions for both the operators and the patients. Different versions can be produced on request.

EASYVAC-EASYVAL/1000 VACUUM REGULATOR

Controls and connections

LEGEND

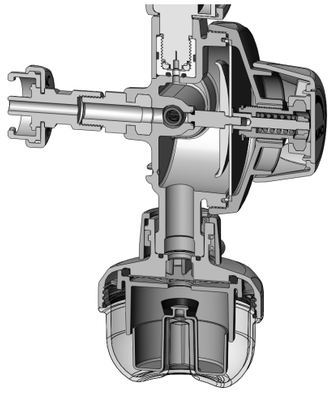
1 – Vacuum adjustment knob
2 – Controlling vacuum gauge
3 – Silicon protection shell
4 – Quick I-0 push button switch to start and stop suction
5 – Threaded fitting for the regulated vacuum use
6 – Quick coupling system for EasySAFE – EasySAFE Plus safety collection jar
7 – Vacuum supply connector
8 – Clip for bar with flexible hose and specific gas coupling
9 – Specific gas rapid coupling
10 – Hose connector
11 – MAK series safety or fluid collection container
12 – Specific gas rapid coupling and clip for wall rail
13 – EasySAFE – EasySAFE PLUS safety container



Working principle

⚠ CAUTION

THE EASYVAC-EASYVAL SERIES VACUUM REGULATOR CAN WORK CORRECTLY WHEN SUPPLIED WITH A MAXIMUM DEPRESSION OF –950 mbar / hPa. THE DEVICE OFFERS MAXIMUM EFFICIENCY BELOW THIS DEPRESSION RANGE.

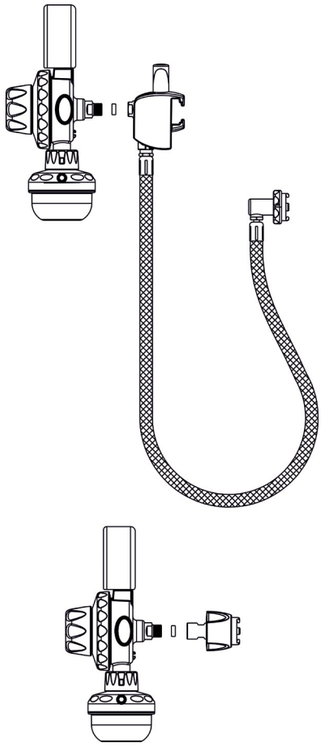


The EASYVAC-EASYVAL series vacuum regulating unit consists mainly of:

- A technopolymer body on which a control vacuum gauge is mounted to display the degree of suction applied, with double-scale indication (mbar / hPa + mmHg) and protected by a silicon shell to avoid damage caused by possible blows during transport or use.
- A threaded fitting to supply the vacuum.
- A fitting integrated in the body, with threaded coupling for connection to the collection device or to the hose connection, and with quick coupling system to allow connection to the EasySAFE – EasySAFE Plus safety jar.
- Quick I-0 push button switch, which allows the operator to stop or start suction simply by pressing.
- A suction adjusting knob, that makes it possible to set the amount of vacuum necessary for treatment.
- A pre-set safety valve to discharge excess vacuum pressures (only for models EASYVAC-EASYVAL/250 and EASYVAC-EASYVAL/600).

Suction adjustment takes place by means of a dynamic balance between a contrast spring and a membrane, attached to a shutter valve, that is subjected to a force generated by the suction supply.
The dimensions of the depression balancing system make it possible to achieve precise and constant adjustments during all the stages in which the vacuum regulator is used.

Installation



Check the functioning of the unit every day or in accordance with the hospital routine. A description is given below of some of the most commonly used methods for connecting the EASYVAC-EASYVAL vacuum regulator.

Alternative 1: fixing to rail and suction supplied unit

This alternative makes it possible to fix the EASYVAC-EASYVAL vacuum regulator to a wall rail with an appropriate bracket.

suitable for a wall rail (e.g. for a 30x10 rail), with an ISO G 1/4" F threaded inlet connection.

on the rail bracket and secure it with an appropriate hose clamp.

quick coupling designed for central hospital systems (e.g. type AFNOR NF-S 90-116) with a hose inlet connector, securing it with an appropriate permanent hose clamp.

connection with a coupling of suitable dimension to the fitting for use of the regulator device.

the hospital central pipeline system.

Alternative 2: direct connection to the vacuum

This alternative makes it possible to connect the EASYVAC-EASYVAL Vacuum Regulator directly to the hospital distribution pipeline system terminal units.

- Connect the suction regulating device to a coupling that fits the hospital central system (e.g. type AFNOR NF-S 90-116) with an ISO G 1/4" F threaded inlet connection.

  connection with a coupling of suitable dimension to the fitting for use of the regulator.

  the hospital central pipeline system.

Start-up procedure

To start-up the device, proceed as follows:

- Ensure that a collection system has been directly or indirectly connected to the fitting for use of the device and that the float of the overflow valve is able to move freely in its container.
- Connect the suction hose to the PATIENT hose fitting on the collection jar.
- Check that the quick I-0 push button switch is pressed in position 0 (green button visible).
- Connect the vacuum supply to the wall terminal unit on the hospital central pipeline system.
- Start suction by pressing the quick I-0 push button switch to position I (red button visible).
- Set the degree of suction needed and check it on the control vacuum gauge, after closing the regulated vacuum outlet coupling (or the hose connector from the collection container to the patient, if used), using the regulation knob (turn anti-clockwise to increase suction and clockwise to decrease or halt suction). The system is now ready for use.

After using the device, it is essential to proceed as follows:

- Press the quick I-0 push button switch to position 0 to stop operation (green button visible).
- Disconnect the vacuum supply from the hospital pipeline system terminal unit.
- The collection container must now be removed, disconnecting it from the suction regulation unit and disconnecting the PATIENT circuit.

CAUTION

- **BEFORE EACH USE, ENSURE THAT THE EASYVAC-EASYVAL VACUUM REGULATOR IS DIRECTLY OR INDIRECTLY CONNECTED TO A COLLECTION SYSTEM FITTED WITH AN OVERFLOW VALVE.**
- **IT IS ADVISABLE TO USE A COLLECTION CONTAINER WITH ANTIBACTERIAL FILTER TO PROTECT THE DEVICE AND THE VACUUM DISTRIBUTION PIPELINE SYSTEM, AS WELL AS THE ENVIRONMENT, FROM ACCIDENTAL CONTAMINATION.**
- **BEFORE USE, MAKE SURE THAT THE SUCTION UNIT IS SECURELY FIXED AND IN A VERTICAL POSITION (THIS IS FUNDAMENTAL FOR THE CORRECT FUNCTIONING OF THE OVERFLOW VALVE).**
- **THE LIQUIDS COLLECTED MUST ONLY BE DRAINED OUT IN AREAS ASSIGNED TO THE DISPOSAL OF HOSPITAL WASTE AND/OR STRICTLY FOLLOWING THE INSTRUCTIONS OF THE ORGANIZATION FOR THE TREATMENT OF THESE LIQUIDS.**
- **CLEAN AND DISINFECT THE VACUUM GAUGE BEFORE USING IT AGAIN, FOLLOWING THE INSTRUCTIONS IN THE CHAPTER "CLEANING AND DISPOSAL".**
- **IT IS ADVISABLE TO USE A SAFETY COLLECTION JAR COMPLETE WITH OVERFLOW VALVE TO PROTECT THE SYSTEM AGAINST ANY OVERFLOW OF FLUIDS WHICH COULD OCCUR FROM THE PRIMARY COLLECTION SYSTEM (E.G. OF THE EASYSAFE TYPE).**

Maintenance

EASYVAC/1000 vacuum regulator withEasySAFE safety vessel (optional) (example of application)

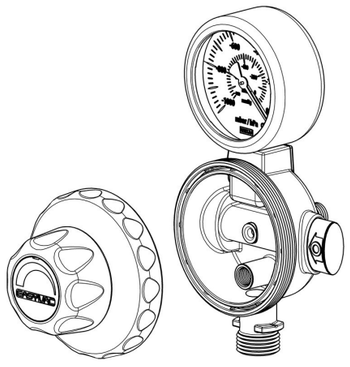
The EASYVAC-EASYVAL vacuum regulating unit is designed and manufactured with materials that ensure a long working period without requiring maintenance.
However, when the periodic controls made by the user indicate the need for repairs (e.g. replacement of components), this must be done by FLOW METER S.p.A. authorized technicians and according with instructions described in the product Service Manual.
Whatever the circumstances, to ensure a prolonged efficiency of the system described in this publication it is necessary to:

- Clean the surfaces regularly and accurately as described in the chapter "Cleaning and disposal".
- Replace any worn, damaged or faulty parts using original spare parts only and following the instructions provided by the manufacturer.
- Always use the EASYVAC-EASYVAL vacuum regulator in combination with a safety container, in order to protect the device from accidental contamination.
- Carry out the periodic checks described in the chapter "Periodic controls".

⚠ CAUTION

- **THE USE OF NON-ORIGINAL SPARE PARTS MAY INTERFERE WITH THE FUNCTIONING AND SAFETY OF THE DEVICE, REPRESENTING A HAZARD FOR THE USER AND THE PATIENT.**

Cleaning and disposal



- Clean the device every day or in accordance with the hospital routine.
- Carefully clean all the surfaces of the device using a soft damp cotton cloth rinsed in neutral detergent diluted 10% in water.
- Unscrew the lid, complete with the regulating knob and the membrane, and remove it from the regulator body and check that the suctioned liquids have not accidentally contaminated the inside surfaces. If they have, carry out the operations described in the important instructions below.

⚠ CAUTION

DO NOT USE SOLVENTS OR ABRASIVE PRODUCTS FOR CLEANING: THESE CAN SERIOUSLY DAMAGE THE SURFACES OF THE EQUIPMENT AND THE PLASTIC PARTS.

- **DO NOT IMMERSE THE UNIT IN DISINFECTANT;**
- **DO NOT PLACE THE UNIT IN AN AUTOCLAVE;**
- **DO NOT USE INFLAMMABLE PRODUCTS.**

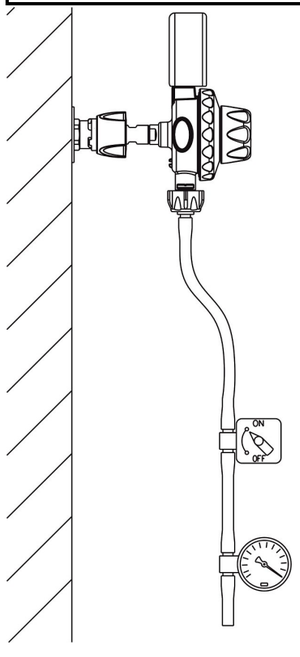
IF THE EQUIPMENT IS ACCIDENTALLY CONTAMINATED BY SUCTIONED LIQUIDS, IT MUST BE ISOLATED AND THE NECESSARY CLEANING AND DISINFECTION OPERATIONS CARRIED OUT BY QUALIFIED PERSONNEL.

IF NECESSARY, STERILISE THE EASYVAC-EASYVAL VACUUM REGULATOR WITH A VALIDATE ETHYLENE OXIDE STERILIZATION CYCLE (e.g. 14% EO 12 h. / 50 kPa / 37 °C).

⚠ CAUTION FOR DISPOSAL

IF THE DEVICE IS DAMAGED AND CANNOT BE REPAIRED, DISPOSE AND DISCARD IT ACCORDING TO THE INTERNAL PROCEDURES OF THE HOSPITAL. DO NOT RECYCLE OR REUSE ANY COMPONENT.

Periodic controls



Check the device every three years or in accordance with hospital procedures to guarantee adequate operation and perfect efficiency of the EASYVAC-EASYVAL vacuum regulator.

1. Functioning control

Check functioning following the instructions in the chapter "Start-up procedure".

2. Control of the maximum depression value

• Connect a suitable size hose fitting to the outlet connector.
• Connect a control vacuum gauge with a suitable full-scale depending on the model to be checked (-250, -600 or -1000 mbar / hPa) and an ON-OFF tap to the hose connection described above.
• Connect the vacuum source to the terminal unit of the centralized hospital distribution pipeline system and start suction by switching the quick I-0 push button switch to position I (red button visible).
• After closing the ON-OFF tap, turn on the suction adjustment knob completely, turning it counter-clockwise, and check that the maximum vacuum value reached corresponds to the value indicated in the chapter "Technical features". Moreover, make sure that the controlling vacuum gauge shows the same value as the one indicated on the device.

3. Control of the maximum suction rate

• Connect a suitable size hose fitting to the suction connector.
• Connect the above hose fitting to the outlet of a control AIR flowmeter with a calibration of 100 L/min. at 1013 mbar / 23 °C.
• Connect the vacuum source to the terminal unit of the centralized hospital pipeline distribution system and start suction by pressing the quick I-0 push button switch to position I (red button visible).
• Fully open the suction adjusting knob by turning it anticlockwise and check that the maximum flow value reached corresponds to the one indicated in the chapter "Technical features".

Check the device every three years following the instructions in the section "Periodic controls".
Useful lifetime upon first installation: 10 years.
Warranty: the manufacturer provides a two-year warranty for concealed defects which are not caused by wear and tear of materials, starting from the date when the device is first placed on the market.

Technical features

Sales description	EASYVAC-EASYVAL vacuum regulator
Dimensions	Height: 170 mm Width: 92 mm Depth: 103 mm
Weight	- Kg. 0.37 (EASYVAC-EASYVAL/600 – EASYVAC-EASYVAL/1000) - Kg. 0.42 (EASYVAC-EASYVAL/250)
Vacuum gauge with indication of the suction	With double scale indication (mbar / hPa + mmHg) Accuracy class 2.5 (2.5% V.L.): - 0 ÷ -1000 mbar (EASYVAC-EASYVAL/1000) - 0 ÷ -600 mbar (EASYVAC-EASYVAL/600) Accuracy class 1.6 (1.6% V.L.): - 0 ÷ -250 mbar (EASYVAC-EASYVAL/250)
Maximum suction rate	EASYVAC-EASYVAL/1000: 80 L/min. ± 5 L/min. to –950 mbar / hPa EASYVAC-EASYVAL/600: 72 L/min. ± 5 L/min. to –550 mbar / hPa EASYVAC-EASYVAL/250: 50 L/min. ± 5 L/min. to –220 mbar / hPa
Maximum adjustable depression	EASYVAC-EASYVAL/1000: -950 mbar / hPa EASYVAC-EASYVAL/600: -550 mbar / hPa EASYVAC-EASYVAL/250: -220 mbar / hPa
Maximum supply depression	-950 mbar / hPa
Performance of the suction/flow level	EASYVAC-EASYVAL/1000: high vacuum / high flow EASYVAC-EASYVAL/600: medium vacuum EASYVAC-EASYVAL/250: low vacuum / high flow low vacuum / low flow
Suction adjusting system	Membrane
Standard vacuum supply connection	ISO G. ¼" M.
Regulated vacuum outlet connection	ISO G. ½" M. + quick coupling system for EasySAFE – EasySAFE Plus safety collection jar
I-0 switch	Quick push button type
Valve protecting against excessive negative pressures (only for EASYVAC-EASYVAL 250 and EASYVAC-EASYVAL 600 models)	Pre-set with anti-clogging system
Environmental storage conditions	-40 °C ± 2 °C / +60 °C ± 5 °C and 40%÷70% relative humidity
Environmental working conditions	-18 °C ± 2 °C / +50 °C ± 5 °C