

POLIVAC B4/SLT30 2 (2 bottles) Version with piston pump - INSTRUCTION MANUAL

(Edition Sept. 2004)

This unit is manufactured by ALSA APPARECCHI MEDICALI S.R.L.- CASTEL MAGGIORE - BOLOGNA - ITALY which guarantees its safety, reliability and performances only if the installation, recalibrations and repairs are performed by personnel authorized by ALSA and if the unit is used in compliance with given instructions in an area that meets all the applicable IEC requirements.

The Manufacturer will supply, on demand, the electric diagrams and any further information needed.

This manual must be kept with the unit.

Please read this entire manual carefully to become familiar with each of the controls and features before making any attempt to use the equipment clinically and ask for it again if it is missing.

If any questions arise regarding the information contained in this manual regarding your specific needs, please contact the Manufacturer directly or through the local distributor, before using the unit.

VERY IMPORTANT

In accordance with the requirements of the European directive for medical devices 93/42 CEE and with the procedures of Company Quality System for the after-sale control of the production, the users will be pleased to inform the Manufacturer about every, however small, problem of this unit.

INDICATIONS AND GUIDELINES FOR POWER SETTINGS

According to the international rules EN 10079/1, this equipment is a mobile suction unit with high vacuum/high flow for hospital and emergency care use (for every kind of purpose except breast milk aspiration and low vacuum/low flow drainage).

In detail:

- For operating theatres, first aid departments, health care facilities (starting from setting of 300 mmHg)
- For pharyngeal suction (starting from setting of 300 mmHg)
- For O.R.L. suction (starting from setting of 400 mmHg)
- For neonatal mucous extraction (starting from setting of 100 mmHg)
- For every kind of need in gynaecological field (starting from setting of 500 mmHg)
- For extremely delicate suction (starting from setting of 150 mmHg)
- For endoscopic suction (starting from setting of 400 mmHg)
- For permanent tracheotomy suction (starting from setting of 400 mmHg)
- For plastic surgery (starting from setting of 400 mmHg)

In any case this suction unit must be used under direct control of personnel thoroughly trained in the techniques and problems of medical suction and it is advisable, before using the equipment, to check carefully its performances (for ex. aspirating liquids) without trusting blindly to previous experiences with other similar units.

VERY IMPORTANT:

1. Use rigid suction tips (tube, curettes) only when the field is under direct visual control, otherwise use only soft catheter tubes.
2. For suction on delicate tissues use only suction tips with finger vacuum regulation (this system grants more safety, intermittent suction and, if necessary, the immediate reduction of suction power).
3. **Emergency:** if necessary you can obtain quick stop of suction power by disconnecting from the bottle the connector (please see "A" in paragraph "Changing over and emptying of the bottles") of intermediate tubing.

CANNULAS OR SUCTION TIPS: use always cannulas or suction tips according to ISO 10993/1 Rules

PRELIMINARY INSTRUCTIONS (please see details on last page)

Install (if supplied) the supplementary over-fill device as follows ("A"):

1. Fix the device on the back side of the central column (using the specific screws) and connect the black nipple (on the device) with the white nipple (on the column) through the intermediate tubing ($\varnothing 6 \times 11$ length about 15 cm)
2. Check the transparent pot (should be well screwed) and the inside floating (must freely work).


Furthermore you have to:

- a. Check that power input corresponds to the technical data label on the back of the unit, plug the power cord into the appropriate grounded wall outlet, ensuring that the main switch (1) (green) is in the "0" position (switched off).
- b. Put the bottles on the unit checking every cap (should be well inserted and well pressed) and the relative over-fill device (the floating must freely work).
Connect the unit to one bottle by using the relative intermediate tubing (please see par. "Changing over and emptying of the bottles", "Bacteriological filter"), then connect also the "patient" tubing.
- c. In order to use the pedal switch STOP/PN (please see "2" on the front panel) you have to insert in the tubing (of the pedal) the ring nut "O" and the gasket "N" (during the transport screwed in the plastic part "M") and so, without activating the pedal, you have to insert the tubing and the gasket in the plastic part "M" screwing tightly the ring nut.

INSTRUCTIONS FOR USE

(the unit must be used in vertical position without obstructing the air cooling areas - not less of 20 cm from the walls)

Never switch off the unit at the maximum vacuum, first you must reduce the vacuum (by the regulator on the front panel or by disconnecting the intermediate tubing) (see par. "Changing over and emptying of the bottles")

1. Switch on the unit by the main switch "1"
2. Select the mode of activation (selector "3") as follows:
(Position ON) activation without pedal switch
(Position ON - ) activation by pressing the pedal switch only
3. Set the vacuum power as indicated in the paragraph "Suction setting"

SUCTION SETTING

To set the desired suction power use the manual control "4" (rotary multi-turn, maximum vacuum clockwise) with the relative vacuum gauge "5" and, according to the same way but with the patient tubing closed, you can preset the maximum vacuum not to be exceeded, before using the unit.

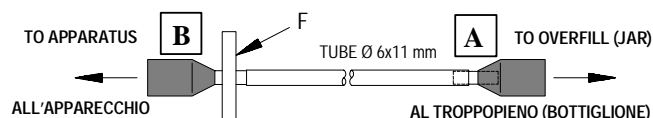
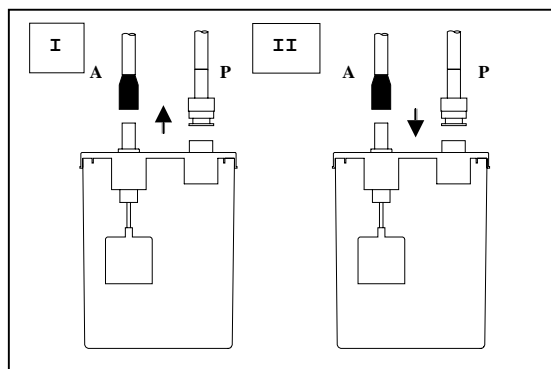
OVERFILL DEVICE

Every bottle has a specific overflow device which prevents the aspiration of liquid into the pump without stopping the unit but interrupting the connection between bottle and vacuum pump.

This overflow device must be in good condition, well cleaned and efficient, with floating freely working.

The overflow device on the central column is only for safety's sake.

CHANGING OVER AND EMPTYING OF THE BOTTLES



To change over the aspiration between the bottles you must:

1. Disconnect from the cap of the first bottle:
 - * The blue elastic connector (side "A" of the connection intermediate tubing between bottle and unit)
 - * The connector of patient tubing (P)
2. Insert them into the same points of the cap on the next bottle

To empty the full bottle you have to take it up in a vertical position (don't take it on the cap) and then start emptying the liquid through the hole for the connection of patient tubing.

Take away the cap only at the end for the final emptying.

BACTERIOLOGICAL FILTER WITH FUNCTION OF SUPPLEMENTARY OVERFILL

The bacteriological filter, able to stop even liquids and usable as a second safety overflow device, is a in-line filter device, reusable and sterilizable (30 times by autoclave at 121°C for 20 min.) with retention rating of 99,97% of all particules ≥ 0.3 micron.

The filter must be connected according to detail "F" and indications on the filter: **it has a specific side to the vacuum**, all the group connections/tubing is made of silicon rubber, sterilizable, and so it can be assembled and disassembled very easily by means of a simple pressure. During the cleaning the filter can't be wet. Anyway, if the device works, the internal media filter must be dry because otherwise stops completely the suction power.

When the filter is new (working at the maximum vacuum with the patient tubing opened) on the vacuum gauge you can see a vacuum of 10-15 cmHg which raises while the media filter is getting obstructed (at the same time the suction power decreases). The filter must be replaced after about 30 times (they can be more or less, according to the material aspirated, but in any case don't exceed 50 times).

QUICK CHECKING OF TUBINGS, BOTTLES, GASKETS AND SO ON

To check tubing, bottles, caps, gaskets, and so on (not damaged or obstructed) it is advisable, each time you use the unit, to switch it on reaching the maximum vacuum with patient tubing closed.

CLEANING, STERILIZATION, MAINTENANCE AND TRANSPORT

Attention: at the moment of sale the accessories (even reusable suction accessories – on request) are not sterile. Bottles with caps (both unbreakable), tubing with connectors, gaskets, suction accessories, are sterilizable (by autoclave at 121°C for 20 min.) or by means cold sterilizer solutions (i.e. Cydex). The bacteriological filter is sterilizable (by autoclave at 121°C for 20 min.) but can't be wet when cleaning. The supplementary overflow device, if necessary, can be sterilized by means cold sterilizer solutions (i.e. Cydex), obviously you have to remove it first.

The unit may be cleaned with mild soap solution, but take great care that fluid does not enter the system. Wipe dry. When the unit is not used keep it in a dry, dust-free area at room temperature and take care not to spill any liquid onto the system.

It is advisable to submit the unit for a periodic (annual) inspection, better to the manufacturer.

Move the equipment around the working area keeping it in vertical position and, for shipping or transport.

Check overflow device

Before using the equipment you have to verify the overflow device with the floating freely working and the inside gasket (better if changed after a working period of 500 hours) well cleaned and in good conditions (to perform this control you can unscrew the ring nut floating holder).

ATTENTION: REMEMBER THAT THE ASPIRATION GROUP COULD BE VERY HOT

Never operate on the pump: please, contact trained technical assistance.

DISPOSAL: all the materials, including consumer materials must be disposed off according to the different National Rules

TECHNICAL FEATURES

- Unit meets Safety Rules CEI EN 60601-1 and CEI EN 10079-1.
- Classification CEI EN 10079-1: mobile unit for medical suction (high vacuum/high flow)
- Classification: I type BF
- Input voltage, absorption, fuses: please see technical data label on the back of the unit
- Working mode: discontinuous - max 9h (15 sec. max vacuum/15 sec. no vacuum)
- Aspiration pump with thermal protection (max vacuum 720 mmHg \pm 5%, about -0.9 bar, -95 kPa)
- Vacuum setting: rotary regulator on front panel with vacuum gauge
- Pedal switch: pneumatic, water and explosion proof
- Working noise: less than 60 dB
- Casing protection against liquids: common, not protected
- Cooling: convention cooling with fan on vacuum pump
- Dimensions: cm 40x34x75 – Weight: kg 22
- Collection container (bottle) VMLT 3, capacity ml 3000: 2 pcs.
- Tubing (silicon rubber made):(patient: length m 2 - \varnothing 7x12 mm), (intermediate: cm 30 - \varnothing 6x11 mm)
- Power cord: length mt 3, section \varnothing 3x1 mm²

ATMOSPHERIC CONDITIONS

of use

Temperature (°C)	+10 ÷ +35
Humidity	30% 75%
Pressure (hPA)	700 ÷ 1060

of transport and storage

Temperature (°C)	-40 ÷ +70
Humidity	10% 95%
Pressure (hPA)	500 ÷ 1060

STANDARD ACCESSORIES

- STOP/PN pedal switch: pneumatic, water and explosion proof

CONTROLS

1. Main switch
2. Pedal switch socket
3. Working selector (with or without pedal switch)
4. Vacuum control
5. Vacuum gauge

On the back: socket with fuses holder for power cord

