# Vario

## SUCTION PUMP

- EN Instructions for use
- DE Gebrauchsanweisung
- FR Mode d’emploi
- IT Istruzioni per l’uso
- NL Gebruiksaanwijzing
- SV Bruksanvisning
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Vario 18 AC / DC

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# Congratulations

By choosing the Vario, you have acquired a high-quality suction pump which is adaptable to your needs. The QuatroFlex suction aggregate is the innovative continuation of the proven Medela piston/cylinder system. As all Medela suction pumps, this pump provides reliable and simple suction. Its simple handling and cleaning as well as the safety features are additional advantages you receive. A comprehensive range of accessories makes the Vario ideally suited to a wide range of medical applications and can be used for continuous operation. Contact us – we will be pleased to advise you.

# 1 Warnings and safety instructions

**WARNINGS**
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

**CAUTIONS**
Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

**Safety related tip**
Indicating useful information about the safe use of the device.

The Vario is approved exclusively for the use as described in these instructions for use. Medela can only guarantee the safe functioning of the system when the Vario is used in combination with the original Medela accessories (collection system, tubings, filters etc. – see chapters 19/20).

**Please read and observe these warning and safety instructions before operation. These instructions for use must be kept with the device for later reference.**

Please note that these instructions for use are a general guide for the use of the product. Medical matters must be addressed by a physician.

Medela considers herself only responsible for the effect on BASIC SAFETY, reliability and performance of the Vario if it is used in accordance with the instructions for use.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Subject to change.

**WARNINGS**

- For use only by medically trained persons who have been adequately trained in suction procedures and in the use of aspirators.
- For patients for whom a breakdown of the device can lead to a critical situation (e.g. patients with acute dyspnoea or severe catarrhal congestion), a replacement device must always be available.
- Gastric suction: When the device is used for gastric suction, the patient's condition and correct functioning of the pump (on the basis of acoustic and visual signs) must be checked at least once every four hours.
- The device must not be used for suctioning explosive, easily flammable or corrosive liquids
- The connecting tubing supplied with the device must never come into direct contact with the suction area. A sterile suction catheter must always be used (risk of infection).
- Before cleaning the device, pull the plug out of the fixed mains socket.
- No modification of this equipment is allowed.
- Do not connect this device to a passive drainage tube.
- Consult the indications for use and consider risk factors and contraindications before using the Vario. Failure to read and follow all instructions in this manual prior to use may result in serious or fatal injury of the patient.
- The Vario pump may shortly shut down with electrostatic discharge (ESD) events at the DC port of 15kV.

**CAUTIONS**

- Incorrect use can cause pain and injury to the patient.
- Do not use sterile accessories when the sterile packaging is damaged.
- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walki-talkie can affect the Vario and should be kept at least a distance 1ft (30 cm) away from the equipment.
- Portable and mobile RF communications equipment can affect medical devices.
- The patient should be monitored regularly according to the physicians instructions and facility guidelines. Objective indications or signs of a possible infection or complication must be met immediately (e.g. fever, pain, redness, increased warmth, swelling or purulent discharge). Non-observance can lead to considerable danger of the patient. Monitor the Vario frequently for operating status.

**Safety related tip**

- The Vario suction pump is Magnetic Resonance (MR) unsafe. Do not take the pump into the MR environment.
- For safety tests, it is assumed that the device is serviced and repaired throughout its service life in accordance with the service manual. Because the Vario is a device of safety class II (EN IEC 60601-1, A1, A2:1995), the safety tests are confined to visual inspection of the housing and power cord. This test must be carried out before each use.
- Testing the patient leakage current: Please see service manual for details.
- The protection of the Vario against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.

- Separation from the mains is only assured through the disconnection of the mains plug and the fixed mains socket.
- Before you plug in the device, please check that your local power supply is the same as the voltage given on the specification plate.

**Safety instructions**

- The Medela Vario is a medical device that requires special safety measures in regard to EMC. It must be installed and put into operation in accordance with the attached EMC information.
- In the case of overflow, inform the internal technical service immediately and perform the tasks in the service manual.
- In each of the following cases, the device must not be used and it must be repaired by Customer Services:
  - if the power cord or the plug are damaged
  - if the device is not functioning perfectly
  - if the device is damaged
  - if the device shows clear safety defects.
- Keep the power supply cord away from hot surfaces.
- The mains plug and the on/off switch must not come into contact with moisture.
- Never pull the mains plug out of the fixed mains socket by pulling on the power supply cord!
- Never leave the device unattended when it is switched on.
- The pump must stand upright during use.
- Never place the power supply cord around your neck.
- Never use the device at high room temperatures, while bathing or showering, if you are very tired or in an environment where there is a risk of explosion.
- Never place the device in water or other liquids.
- When using single use, sterile products, please note that they are not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.
- Contact your local Medela customer service representative for assistance with product operations.
- Do not place a 2l suction jar in the lateral adaptor.
- The overflow protection/bacteria filter protects the pump against overflow. Caution: Suctioning is interrupted when the filter is wet/moist or clogged. Test the filter before each use and during use periodically (see chapter 17).

These instructions for use must be kept for later reference.

# 2 Power supply and battery operation

The Vario is a mains-powered suction pump. Before you plug in the device, please check that your local power supply is the same as the voltage given on the specification plate. If the Vario AC/DC versions are running continuously, a maximum of 30 minutes of battery time is expected before it is necessare to recharge. If the Vario AC/DC version is not in use, the battery must be calibrated every 60–90 days.

**Battery low** (only AC/DC versions)
During battery operation a slow blinking of the LED indicator and an acoustic signal (beep - beep - beep) indicates, that the rechargeable battery is soon discharged. The function of the Vario is maintained for 10 minutes (20 minutes Vario low vacuum versions), but the battery must be recharged as soon as possible.

**Battery empty** (only AC/DC versions)
As soon as the rechargeable battery is empty, the pump comes to a stop. The proper function of the pump is no longer maintained. The rechargeable battery must be recharged.

# 3 Description

**Introduction**
The Vario is a high-quality suction pump. It is powered by the well-proven QuatroFlex system and guarantees maximum suction performance for many suctioning needs. It ideally combines easy handling and cleaning with safety features to ensure optimal operation. You can choose from a comprehensive range of accessories from Medela to configure the pump to many medical applications. The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

**Intended use**
The Vario 8/18/ci suction pumps are indicated for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids (including vomit) or infectious materials from a patient's airway or respiratory support system, either during surgery or at the patient's bedside. Generally the Vario 8/18/ci is intended to be used for a variety of suctioning procedures including nasopharyngeal, tracheal, surgical, gastrointestinal suctioning either in «constant» or «intermittent» mode. Please make sure you have a correct Vario version for the required application.

**Contraindications**
None known.

**Intended user**
The Vario should only be operated by properly trained staff. These persons must not be hard of hearing or deaf and must have adequate visual faculty. The training has to be refreshed at least once a year.

**Intended Patient Population**
The Vario is intended to be used on patients only exhibiting conditions as described in the indications for use.

**Important note**
Compliance with proper surgical procedures and techniques is the responsibility of the physician. Each physician must evaluate the appropriateness of the treatment based on his own knowledge and experience.

# 4 Overview

**Definition of vacuum**

By the application of medical aspiration devices, vacuum is normally given as the difference (in absolute figures) between absolute pressure and atmospheric pressure or as negative values in Kilopascal (kPa). In this document, the indication of -10 kPa for example always refers to a pressure range in kPa below atmospheric ambient pressure (according to EN ISO 10079:1999).

**Versions of the pump**


Vario 8 AC


Vario 8 AC/DC


Vario 8 c/i AC/DC


Vario 18 AC

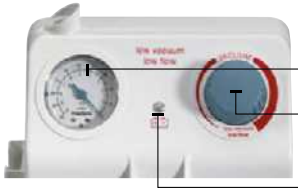

Vario 18 AC/DC


Vario 18 c/i AC/DC

**Front of the pump**

**Bottom of device**


**Operating elements and battery status**




| | |
|---|---|
| **not lit** | Battery is fully charged |
| **lit up** | – Battery is being charged<br>– Pump is connected to the mains |
| **blinks slowly** | Battery is soon empty |
| **blinks rapidly** | Battery is defective |

**Acoustic indicator**

During battery operation an acoustic signal (beep - beep - beep) indicates that the rechargeable battery is soon discharged.

**On/off switch not c/i versions**


**On/off switch c/i versions**

# 5 Installation

**Check initial delivery**

Check the delivery package of the Vario for completeness and general condition.

Vario portable version

| | | |
|---|---|---|
| REF | Vario 8 AC | 026.XXXX |
| | Vario 8 AC/DC | 026.XXXX |
| | Vario 8 c/i AC/DC | 026.XXXX |
| | Vario 18 AC | 026.XXXX |
| | Vario 18 AC/DC | 026.XXXX |
| | Vario 18 c/i AC/DC | 026.XXXX |

Silicone Tubing ø 7 x 12 mm, 25 cm with 2 coupling pieces

REF 077.0931

5 x Disposable overflow protection/bacteria filter with Medela connections

REF 077.0571


Instructions for use

REF 177.2604

# 6 Preparation for use

**WARNINGS**

For use only by medically trained persons who have been adequately trained in suction procedures and in the use of aspirators.

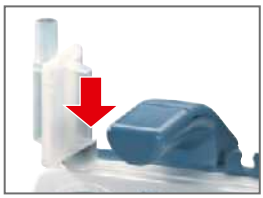
**CAUTIONS**

- The Vario must remain in an upright position during use.
- Sterile accessories must be checked on the integrity of the packaging before use.
- Non sterile and reusable accessories must be cleaned, disinfected and/or sterilized according to the Medela cleaning guide (product code 200.2391).

## 6.1 Checks before use

- **Check the Vario system before use for damage of the power cord or plug, obvious device damage or safety defects and proper functioning of the device.**
- **Check for completeness and general condition of the Vario delivery package.**
- **Only for AC/DC versions: make sure that the rechargeable battery is calibrated according to chapter 16.**
- **Check all accessories prior to use:**
  - **suction jars, lids and liners for cracks, brittle and flawed spots. Replace if necessary.**
  - **Tubing for cracks, brittle areas and that connectors are firmly attached. Replace if necessary.**
  - **As an additional safety test, evacuate the system (including jars) to maximum vacuum several times before actual use.**

## 6.2 Assembly of the basic configuration

1. 

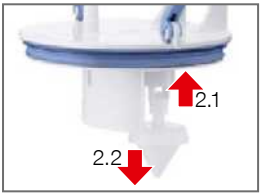
1.1 Attach the overflow protection bacteria filter to the Vario with the arrow pointing in the flow direction.

2. Attach all necessary accessories according to your needs. See the system overview for more details.

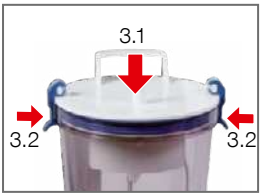
## 6.3 Assembly of the REUSABLE collection system

positions for jars:

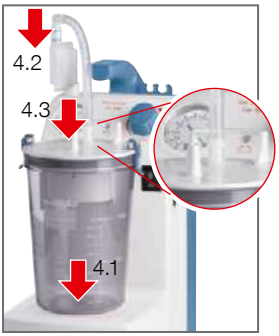
1. **If you use a DISPOSABLE collection system proceed with step 6.4.**

2. 


2.1 Attach mechanical overflow protection to lid.
2.2 Pull gently downwards to make sure it is open/deactivated.

3. 


3.1 Attach the lid to the jar.
3.2 Lock with the two lid clamps.

4. 


4.1 Attach the jar to the Vario.
4.2 Connect tubing to the filter.
4.3 Connect tubing to the lid of the jar (marked with «vacuum»).

5. 

5.1 Connect patient tubing to the lid of the jar (marked with «patient»).

## 6.4 Assembly of the DISPOSABLE collection system

1. **If you use a REUSABLE collection system proceed with step 6.3.**

positions for jars:

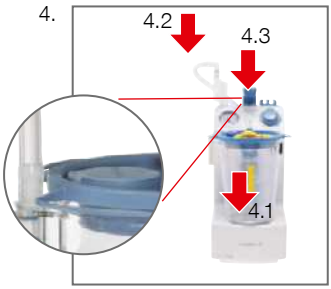
2. 

2.1 Attach the Vario jar adapter to the Vario.

3. 

3.1 Choose the 1.5l size (yellow code) for the Vario.

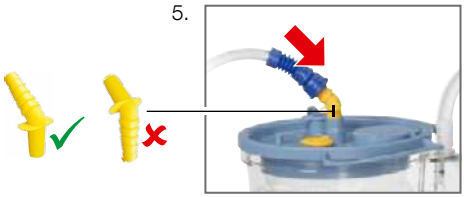
3.2 Prepare and insert corresponding liner size (yellow) according to instructions delivered with liners. The disposable liner has an integrated overflow protection filter. No action is necessary to activate it.

4. 


4.1 Attach the jar to the Vario.

4.2 Connect tubing to the filter.

4.3 Connect tubing to the jar. The tubing connector is on top of the jar.

5. 

5.1 Connect patient tubing to the lid of the liner using either the coloured angle piece or the patient port directly (depending on tubing size).

# 7 Operating instructions

**CAUTIONS**
The Vario is to be set up in such a way, that a separation from the mains supply can be easily managed.

## 7.1 Connect Vario to mains power

1. Check the pump before use following the instruction in chapter 6.1.
2. **All versions: if the pump is connected to a fixed mains socket:** Plug in the mains plug of the power cord to a fixed mains socket.

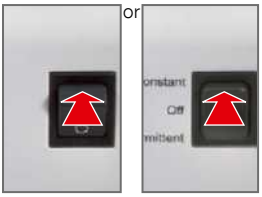
   or

   **AC/DC versions: if the pump is operated with a 12 V DC power source:** Connect the optional 12 V DC connection cable to the socket on the side of the pump and connect it to the 12 V DC power source.

   or

   **AC/DC versions: if the pump is operated with the rechargeable battery:** No connection to a power source is needed. Make sure that the battery was charged for five hours.

## 7.2 Check maximal vacuum for functional check

1. 


   1.1 Switch on the Vario. The pump will start running. Caution: **c/i versions** must be switched on in «constant» mode.

2. 


   2.1 Press and turn the vacuum regulator to the right to set maximum vacuum.

3. 

   3.1 Seal the end of the patient tubing with your thumb.

   3.2 Compare the maximum vacuum according to the specification. See chapter 10 if the maximum vacuum is not reached.

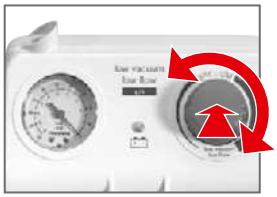
**Specifications:**

| Altitude above sea level: | Vario 8 / Vario 8 c/i Max. Vacuum: low vacuum | Vario 18 c/i Max. Vacuum: medium vacuum | Vario 18 Max. Vacuum: high vacuum |
|---|---|---|---|
| + 2000 m | – 7.0 kPa | – 43 kPa | – 59 kPa |
| + 1000 m | – 7.9 kPa | – 48 kPa | – 66 kPa |
| + 500 m | – 8.5 kPa | – 51 kPa | – 70 kPa |
| 0 m | – 9.0 kPa | – 55 kPa | – 75 kPa |

(Tolerance +/- 10 %)

## 7.3 Changing vacuum level

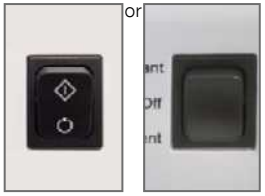
1.



1.1 Clamp patient tubing
1.2 Push and turn vacuum regulator to select the correct vacuum according to the particular application.
1.3 Check vacuum gauge for setting.

## 7.4 Placing out of operation after use

1.



or

1.1 Switch the on/off switch of the Vario to position «0» (c/i-versions: «Off»).

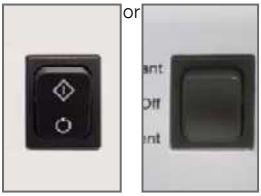
2. **If the pump is connected to a fixed mains socket:** Disconnect the mains plug from the fixed mains socket.

   or

   **If the pump is connected to a 12 V DC power source:** Disconnect the 12 V DC plug from the 12 V DC power source.

3. Clean and desinfect the Vario. See chapter 18.

# 8 Changing reusable jar

1. 


1.1 Switch the on/off switch of the Vario to position «0» (c/i-versions: «Off»).

1.2 Remove patient and vacuum tubings from the lid.

2. 

2.1 Remove full jar from the Vario.

3. 

3.1 Prepare new jar and unpack it.

3.2 Secure new jar to the Vario

3.3 Reconnect vacuum tubing and new patient tubing firmly.

4. Empty jar and dispose of patient tubing in accordance with local guidelines and inhouse guidelines.

5. Switch on the Vario. The pump will start running.

6. Set vacuum according to the particular application.
See chapter 7.3.

# 9 Changing disposable liner

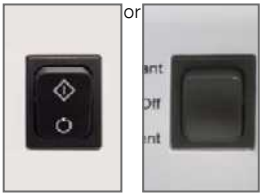
**WARNINGS**

Disposable liners are not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics.


1. 

1.1 Remove patient tubing with colored angle piece from lid.

1.2 Plug patient port.

2. 

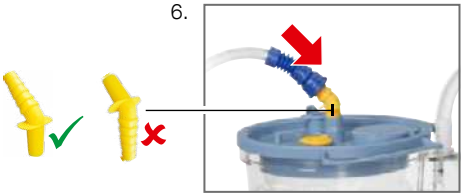

2.1 Switch the on/off switch of the Vario to position «0» (c/i-versions: «Off»). Reduce vacuum to minimum by pressing and turning vacuum regulator to the left.

3. 

3.1 Remove full liner from the jar.

4. Dispose of the liner and patient tubing in accordance with local guidelines and inhouse guidelines.

5. Prepare new liner, unpack it and insert it in the jar. Press down lid.

6. 

6.1 Connect new patient tubing firmly.

7. Switch on the Vario. The pump will start running.

8. Set vacuum according to the particular application. See chapter 7.3.

# 10 Troubleshooting

**Motor not running**
Check if:
– the Vario is switched on.
– the mains voltage is correct and if the mains plug is inserted correctly into the fixed mains socket.
– the internal battery is charged (only AC/DC version under battery operation)
– the fuse on the bottom of the Vario is not defective. For replacing the defective fuse see chapter 11.

**Insufficient vacuum**
Check if:
– the vacuum regulator is set correctly.
– the tubings are not defective or broken. If necessary, replace.
– all plug-in connections are tight.
– the overflow protection is deactivated/open. If the overflow protection is activated, deactivate as shown under 6.3a/2.2.
– the suction jar/lid have no cracks, brittle areas, discolouration. Replace if necessary.
– the disposable system has no cracks, brittle areas, discolouration. Replace if necessary.
– filter is not clogged. To test if the filter is clogged see chapter 17.
– the QuatroFlex is defective. To replace the QuatroFlex see chapter 13.

**No LED lit** (AC/DC version only)
The rechargeable battery is fully charged.

**LED lit up** (AC/DC version only)
– The rechargeable battery is being charged.
– The pump is connected to the mains.

**LED blinks slowly** (AC/DC version only)
The rechargeable battery is soon empty.

**LED blinks rapidly** (AC/DC version only)
The rechargeable battery is defective. For replacing the defective battery see chapter 14.

# 11 Replacing defective fuse

**WARNINGS**
Before replacing the fuse, pull the mains plug from Vario out of the fixed mains socket.

1. Disconnect the Vario from the mains.

2. 

   2.1 Open (turn left) the fuse holder on the bottom of the Vario.

3. Replace the defective fuse(s). Make sure that the technical specification are corresponding.

   | | |
   |---|---|
   | AC-versions: | **T 0.8 AL, 5 x 20, 230–240 V** |
   | | **T 1.25 AL, 6.3 x 20, 120 V** |
   | AC/DC-versions: | **T 1.0 AL, 5 x 20, 100–240 V** |

4. 

   4.1 Close (push back and turn right) the fuse holder.

5. Reconnect the Vario to the mains again.

6. Switch on the Vario again.

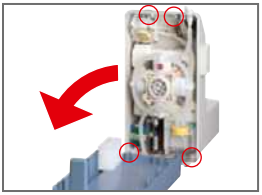
# 12 Setting interval times

(c/i versions only)

**WARNINGS**

Before setting the interval times, switch off the Vario and pull the mains plug from Vario out of the fixed mains socket.

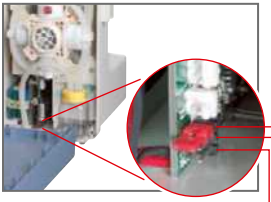
1.



1.1 Unscrew the 4 screws on the back of the Vario.

1.2 Open the Vario by removing the back cover.

2.



2.1 Determine the location of the red jumper.

2.2 Place the red jumper according to the desired interval:

| On-time | Off-time |
|---|---|
| 8 sec. | 4 sec. |
| 16 sec. | 8 sec. |
| 32 sec. | 16 sec. |

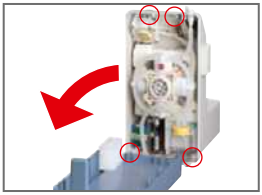
3. Reattach the back cover to the Vario and tighten the 4 screws.

4. Plug the Vario to a fixed mains socket and test the correct functioning of the Vario (see chapter 7).

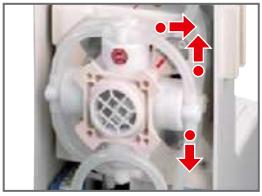
# 13 Replacing the QuatroFlex

**WARNINGS**

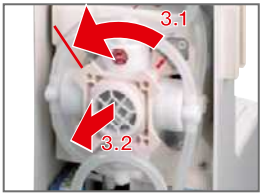
Before replacing the QuatroFlex, switch off the Vario and pull the mains plug from Vario out of the fixed mains socket.

1. 

1.1 Unscrew the 4 screws on the back of the Vario.
1.2 Open the Vario by removing the back cover.

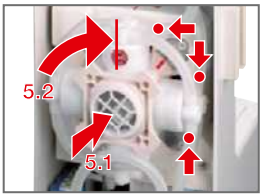
2. 

2.1 Remove the 3 marked tubings from the QuatroFlex.

3. 


3.1 **Turn** the QuatroFlex 45° to the left.
3.2 **Pull out** the QuatroFlex and remove it from the Vario.

4. Clean inside of the Vario.

5. 


5.1 **Insert** new QuatroFlex.
5.2 **Turn** it 45° to the right.
5.3 **Reattach** the 3 tubings to the QuatroFlex.

6. Reattach the back cover to the Vario and tighten the 4 screws.

7. Plug the Vario to a fixed mains socket and test the correct functioning of the Vario (see chapter 7).

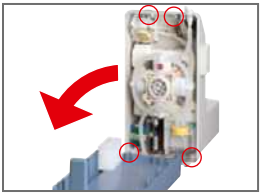
# 14 Replacing the rechargeable battery

(AC/DC versions only)

**WARNINGS**

Before replacing the rechargeable battery, switch off the Vario and pull the mains plug from Vario out of the fixed mains socket.

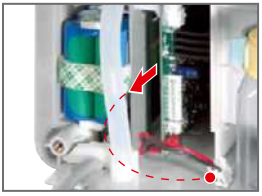
1.



1.1 Unscrew the 4 screws on the back of the Vario.

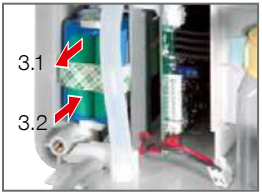
1.2 Open the Vario by removing the back cover.

2.



2.1 Detach the battery cable by pulling the plug.

3.




3.1 Remove the old rechargeable battery.

3.2 Insert the new rechargeable battery.

4.

4.1 Reattach the battery cable.

5. Reattach the back cover to the Vario and tighten the 4 screws.

6. Plug the Vario to a fixed mains socket and calibrate the rechargeable battery (see chapter 16).

# 15 Battery data and test

(AC/DC versions only)

**CAUTIONS**

Only charge the rechargeable battery when the acoustic signal sounds and the charging indicator blinks slowly. The rechargeable battery is charged during mains operation.

**Duration of pumping**

If the battery is fully charged, the operating time is about:

- low vacuum versions: approx. 120 minutes
- high and medium vacuum versions: approx. 30 minutes.

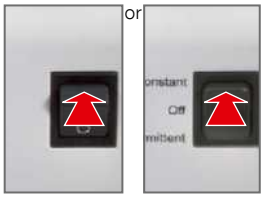
**Charging time** (charged up to 100 %)

- low vacuum versions: approx. 5 hours
- high and medium vacuum versions: approx. 5 hours.

**Testing the rechargeable battery**

1. Make sure that the rechargeable battery is fully charged.
2. Pull out the mains plug from the fixed mains socket.
3. 


   3.1 Press vacuum regulator and turn it to the right to select maximum vacuum.

4. 


   4.1 Switch on the Vario. The pump will start running. Caution: **c/i versions** must be switched on in «constant» mode.

5. Measure the time until the pump comes to a stop. The battery is ok, when the following values are reached:
   - low vacuum versions: > 120 min.
   - high and medium vacuum versions: > 30 min.

   **If the values are not reached, repeat test or calibrate the battery (see next page).**

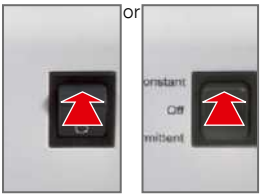
# 16 Battery calibration

(AC/DC versions only)

**CAUTIONS**

Calibrate rechargeable batteries before the first use, or after a storage period >2 months. Replace the battery if the calibration process fails.

**Calibrating NiMH rechargeable battery**

1. Make sure that the battery is fully charged.
2. Pull out the mains plug from the fixed mains socket.
3. 


   3.1 Switch on the Vario. The pump will start running. Caution: **c/i versions** must be switched on in «constant» mode.
4. Let the pump run until the rechargeable battery is empty and the pump comes to a stop.
5. Plug the mains cable into a fixed socket. The rechargeable battery is beeing charged.
6. Wait until the charging indicator goes out.
7. Repeat step 1 to 6. The Vario AC/DC is then ready to use.

**Storage of the rechargeable battery**

In order to keep the self-discharge at a minimum, store the Vario and the replacement rechargeable batteries at temperatures below 25 °C (77 °F). Repeat the calibrating process every 60–90 days.

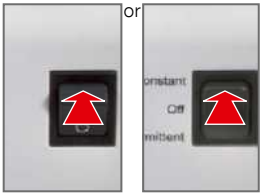
# 17 Filter test

1. 

1.1 Remove tubing from filter.

2. 


2.1 Select maximum vacuum.

3. 


3.1 Switch on the Vario. The pump will start running. Caution: **c/i versions** must be switched on in «constant» mode.

4. 


4.1 Read the vacuum.

4.2 Replace the filter if the vacuum exceeds the values given in the following table:

| | |
|---|---|
| **Vario 8 / Vario 8 c/i**<br>low vacuum | **– 3 kPa** |
| **Vario 18**<br>high vacuum | **– 10 kPa** |
| **Vario 18 c/i**<br>medium vacuum | **– 10 kPa** |

# 18 Cleaning guidelines

**WARNINGS**
After each use, the parts that had been in contact with the aspirated secretions are to be cleaned, disinfected, sterilised or disposed of **according to the table on the next page**.

**Before cleaning the device, pull the mains plug out of the fixed mains socket.**

**General notes**
- These are general recommendations only that may be adjusted individually, based on the hospital's specific directives and cleaning practices and policies.
- Detailed information according to Medela cleaning instructions (product code 200.2391).
- Wear protective gloves for cleaning/disinfection.
- Dispose of fluids such as blood and secretions and the parts contaminated with them in accordance with internal hospital guidelines.

**Medela recommended surface cleaning agents for pump housing**
- CaviWipes, Metrex Research, www.metrex.com
- Mikrozid AF Wipes**,** Schülke & Mayr, www.schuelkemayr.com

**Water**
Use only the purest quality of water for cleaning. Water hardness is a serious consideration since deposits left on medical products may not be properly decontaminated. Use deionised water in order to reduce this problem. The final rinse water is bacterial free and contains no endotoxins.

**Cleaning/disinfection machines**
Can be used to desinfect parts from the table on the next page. A hot water rinse (maximum temperature 100 °C) may provide a medium-to high level of disinfection. Every section of the constituent parts must be accessible in order to ensure efficient cleaning. We recommend using a cleaning/disinfecting machine that has been approved by the Robert Koch- Institute and complies with ISO 15883. Recommended temperature for noncritical medical devices (i.e. those that only come into contact with uninjured skin) is 90 °C for 1 minute. The time is increased to 5 minutes for all medical devices that are considered to be critical.

**Disposable products**
These are single use products not intended to be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

| PSU* jars, lids | PC** jars | Silicone tubing | Pump housing Mains cable | Plastic accessories | Legend:<br><br>* Polysulfone<br>** Polycarbonate |
|---|---|---|---|---|---|
| x | x | x | x | x | **1. Disassembly**<br>Separate all individual parts before cleaning, disinfecting and sterilising. |
| x | x | x | | | **2. Cleaning**<br>Clean components in hot water (60–70 °C) containing a detergent with a pH range between 6.0 and 8.0 only, in order to avoid damaging the instruments and containment devices. Enzymatic detergents help with the removal of organic matter, such as blood. Detergents should be used according to their manufacturer's recommended concentration levels. Some alkaline detergents have been formulated to be safe for reprocessing medical devices. The manufacturers of these detergents should provide information about specific materials that may be damaged by their detergents.<br>Soak all parts thoroughly with warm, soapy water or in enzymatic detergent for 1–5 minutes.<br>**1.** Remove visible dirt with a cleaning tool – general purpose cleaning brushes, such as pipe cleaners or non-abrasive lint cloths. Brushes and pipe cleaners should fit snugly but still be able to be moved around easily within the area to be cleaned. Rinse thoroughly in clear water. Allow to dry<br>**2.** Check the instruments for visible dirt and repeat these steps if necessary. |
| | | | x | x | **3. Cleaning**<br>Wipe with detergent mentioned above. Use clean cloth to dry. |
| x | x | x | | x | **4. Disinfect**<br>Soak at room temperature for 30 minutes in a disinfection/cleaning solution (A). After the reaction time, use water to rinse the solution residue from the individual parts and rinse the tubing. Rinse for at least 2 minutes with the cleaning solution (B).<br><br>(A) fluid aldehyde-free disinfection solution with cleaning effect for use as a soaking bath, bactericide, fungicide, limited virucide, with good material compatibility for stainless steel, non-ferrous material and plastics including silicone, slightly alkalic. e.g. 2 % neodisher® Septo MEDsolution<br><br>(B) Fluid, pH-neutral, enzymatic cleaning solution for the treatment of instruments by machine or manually with very good material compatibility for stainless steel, non-ferrous material and plastics including silicone.<br><br>or use cleaning/desinfecting machine.<br>or use your dishwasher at home. |
| x | | x | | | **5. Sterilise**<br>Remove any chemical disinfectant residue before autoclaving. Do not stack during autoclaving. In the autoclave at 134 °C for 10 minutes. The sterilisation device must comply to ISO 17665:2003. The following procedures are acceptable: In the autoclave with saturated steam at 132 °C, with triple pre-evacuation, sterilisation time of 6 minutes, or at 135–137 °C in an porous load vacuum autoclave for 3–3.5 minutes |
| x | x | x | | x | **6. Storing components**<br>After disinfection/sterilising, store the components in sterile foil until required for use. |

# 19 Accessories overview

**WARNINGS**

Vario was verified in combination with the accessories listed below. For a correct and safe operation use Vario with these accessories only. Further information is supplied on the instruction sheet of the individual accessory.

**Patient tubings/tubing connectors**



077.1020

077.1017

with funnel connectors:
077.0952 180 cm
077.0191 300 cm

without coupling pieces, 7x12mm

077.0900: 25 m
077.0901: 1 m
077.0902: 2 m
077.0905: 5 m

with 1 coupling piece, 7x12mm

077.0912: 0.6m
077.0913: 1m

*

**Liners**

077.0083/84

**Reusable lids**

077.0440

077.0420/30

Fingertip tubing

077.0951

with 2 coupling pieces, 7x12mm

077.0921: 0.3m
077.0922: 0.6m
077.0931: 0.25m

**PC jars**

077.0082

077.0105

**Reusable jars**

077.0125: 0.25l
077.0155: 0.5l
077.0110: 1l

**Reusable sets**

077.0715: 1l

**Connectors and Tubings** *(max. length 60cm)*

077.1019

077.1018

077.1015/16

with 2 coupling pieces, 7x12mm

077.0921: 0.3m
077.0922: 0.6m
077.0931: 0.25m, 1 coupling piece 90°

**Filters**

077.0092

077.0571

077.0577

* **Drainage valve**

077.1022

* **Specimen cups**

077.0562/64 077.0094

**Foot control**

077.0731

**Additional accessories**

077.0823

077.0825

077.0821

077.0831

077.0832

| | |
|---|---|
| Vario 8 AC | 026.XXXX |
| Vario 8 AC/DC | 026.XXXX |
| Vario 8 c/i AC/DC | 026.XXXX |
| Vario 18 AC | 026.XXXX |
| Vario 18 AC/DC | 026.XXXX |
| Vario 18 c/i AC/DC | 026.XXXX |

**Safety related tip**

If the pump is used together with non-Medela applied parts, they must:

- have CE mark and (if necessary) local registration
- be able to be attached to Medela accessories safely without impacting the performance of the pump.

**Note:** when combining Medela parts and non-Medela parts, you take over the responsibility of the entire system.

# 20 Accessories legend

| | REF | |
|---|---|---|
| | *026.XXXX* | Vario 8 AC |
| | *026.XXXX* | Vario 8 AC/DC |
| | *026.XXXX* | Vario 8 c/i AC/DC |
| | *026.XXXX* | Vario 18 AC |
| | *026.XXXX* | Vario 18 AC/DC |
| | *026.XXXX* | Vario 18 c/i AC/DC |
| **Filters** | *077.0092* | Disposable overflow protection/bacteria/odour filter with Medela connections |
| | *077.0571* | Disposable overflow protection/bacteria filter with Medela connections |
| | *077.0577* | Disposable overflow protection/bacteria filter with Medela and conical connections |
| **Reusable jars** | *077.0110* | Suction jar, polysulfone, 1l |
| | *077.0125* | Suction jar, polysulfone, 0.25l |
| | *077.0155* | Suction jar, polysulfone, 0.5l |
| **Drainage valve** | *077.1022* | Drainage valve (for vacuum ports of reusable jars) |
| **Liners** | *077.0083* | Disposable suction liner 1.5l |
| | *077.0084* | Disposable suction liner 1.5l with solidifier |
| **Reusable sets** | *077.0715* | Reusable 1l set with PSU suction jar |
| **PC jars** | *077.0082* | Suction jar PC, 1.5l |
| | *077.0105* | Vario jar adapter |

| | | |
|---|---|---|
| **Specimen cups** | *077.0094* | Specimen cup for disposable system. Can be attached to lid of liner (patient port) of Disposable Collection System |
| | *077.0562* | Disposable specimen cup, Ø 6–10 mm |
| | *077.0564* | Disposable specimen cup, Ø 10–14 mm. Attach to lid of Reusable Collection System (patient port) |
| **Reusable lids** | *077.0440* | Small lid with conical patient connection, Ø 6–10 mm and overflow protection device |
| | *077.0420* | Large lid with conical patient connection Ø 6–10 mm and overflow protection device |
| | *077.0430* | Large lid with conical patient connection Ø 10–14 mm and overflow protection device |
| **Patient tubings/tubing connectors** | *077.0902* | Silicone tubing Ø 7 x 12 mm, w/o coupling pieces, 2 m |
| | *077.0912* | Silicone tubing Ø 7 x 12 mm with 1 coupling piece, 60 cm |
| | *077.0900* | Silicone tubing Ø 7 x 12 mm, w/o coupling pieces, 25 m |
| | *077.0901* | Silicone tubing Ø 7 x 12 mm, w/o coupling pieces 1 m |
| | *077.0905* | Silicone tubing Ø 7 x 12 mm, w/o coupling pieces, 5 m |
| | *077.0913* | Silicone tubing Ø 7 x 12 mm with 1 coupling piece, 100 cm |
| | *077.0951* | Disposable (PVC) tubing, 180 cm, with fingertip, sterile (applied part) |
| | 077.0952 | Disposable tubing with funnel connector (non-sterile), 180 cm |
| | 077.0191 | Disposable tubing with funnel connector (non-sterile), 300 cm |
| | *077.1017* | Double conical coupling piece. For connecting 2 tubings to each other |
| | *077.1020* | Y-Piece. For connecting 3 tubings to each other |
| | *077.0921* | Silicone tubing Ø 7 x 12 mm with 2 coupling pieces, 30 cm |
| | *077.0922* | Silicone tubing Ø 7 x 12 mm with 2 coupling pieces, 60 cm |
| | *077.0931* | Silicone tubing Ø 7 x 12 mm, 25 cm, with 1 coupling piece and 1 coupling piece 90° |
| | *077.1015* | Angle piece Ø 6–10 mm |
| | *077.1016* | Angle piece Ø 10–14 mm. Attaches to lid of Reusable Collection System (patient port) |
| | *077.1018* | Coupling piece. Used to connect tubing to vacuum port of pump |
| | *077.1019* | Coupling piece 90 °. Used to connect tubing to vacuum port of pump |
| **Additional accessories** | *077.0821* | Rail holder |
| | *077.0823* | Universal holder |
| | *077.0825* | Rail holder |
| | *077.0831* | Carrying bag |
| | *077.0832* | Car connection cable for 12 V DC |
| **Foot control** | *077.0731* | Foot vacuum regulator |

# 21 Technical specifications


**Vario 8 / Vario 8 c/i:**
low vacuum, - 9 kPa / - 68 mmHg (Tolerance: +/- 10 %)
**Vario 18 c/i:**
medium vacuum, - 55 kPa / - 413 mmHg (Tolerance: +/- 10 %)
**Vario 18:**
high vacuum, - 75 kPa / - 563 mmHg (Tolerance: - 10 %)

Measured at 0 m, atmospheric pressure: 1013.25 hPa Please note: vacuum levels may vary depending on location (meters above sea level, atmospheric pressure and temperature).


Vario 8: 8 l/min. (+/- 10 %)
Vario 18: 18 l/min. (+/- 10 %)


AC 3.5 kg
AC / DC 4.2 kg
Without jar


230–240 V, 50 Hz, 90 VA
230–240 V, 60 Hz, 90 VA
120 V, 60 Hz, 70 VA


100–240 V
50 / 60 Hz
80 VA

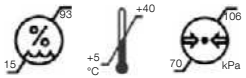
§

ISO 9001
ISO 13485
CE (93/42/EEC), IIa
CE 0123

h x w x d
380 x 170 x 285 mm


Transport / Storage Conditions


Transport / Storage
Rechargeable battery




Operating Conditions


**IP21**

# 22 Signs and symbols

CE 0123 This symbol indicates the compliance with the essential requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

This symbol indicates the compliance with additional USA and Canada safety requirements for medical electrical equipment.

§ This symbol indicates the legal specifications of the pump.

This symbol indicates to follow instructions for use.

This symbol indicates to consult instructions for use.

This symbol indicates a CAUTION or WARNING associated with the device.

This symbol indicates safety related tip.

This symbol indicates the class of the pump.

This symbol indicates a class II device.

IP21 This Symbol indicates the protection against ingress of solid foreign objects and against harmful effects due to the ingress of water.

This symbol indicates a type CF applied part.

MR This symbol indicates MR UNSAFE.

This symbol indicates that interferences may occur in the vicinity of equipment marked with this symbol.

This symbol indicates the manufacturer.

This symbol indicates the date of manufacture (four digits for the year and two digits for the month).

This symbol indicates that the device should not be used after the end of the year and month shown.

This symbol indicates a single use device. Do not reuse the device.

REF This symbol indicates manufacturer's catalogue number.

SN This symbol indicates manufacturer's serial number.

LOT This symbol indicates manufacturer's batch code.

STERILE EO This symbol indicates the device is sterilized using ethylene oxide.

This symbol indicates the temperature limitation for operation, transport and storage.

This symbol indicates the humidity limitation for operation, transport and storage.

This symbol indicates the atmospheric pressure limitation for operation, transport and storage.

This symbol indicates do not use the device if package is damaged.


This symbol indicates the number of items n that the content is sufficient for.

This symbol indicates do not dispose the device together with unsorted municipal waste (for EU only).

This symbol indicates that the material is part of a recovery/ recycling process.


This symbol indicates a carton package.

This symbol indicates to keep the device away from sunlight.

This symbol indicates to handle the fragile device with care.

This symbol indicates to keep the device dry.


This symbol indicates the maximum vacuum level of the pump.


This symbol indicates the flow levels of the pump.



This symbol indicates the electrical specifications of the pump.

This symbol indicates alternating current.

This symbol indicates direct current.


This symbol indicates the weight of the pump.

This symbol indicates the dimensions (h x w x d) of the pump.


This Symbol indicates a Prescription Device. CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician. (for US only).

**pcs** This symbol indicates number of items.

This symbol indicates the fuse

# 23 Warranty and servicing

**Warranty**
Medela AG warrants the device will be free from defects in materials and workmanship for a period of 2 years (6 month for the rechargeable battery and the QuatroFlex) from the date of delivery. Faulty material will be replaced free of charge during this period if not resulting from abuse or misapplication. This will not apply to parts subject to wear and tear in use. To ensure compliance with this warranty as well as optimum service from Medela products, we recommend the exclusive use of Medela accessories with our appliances.
In no event shall Medela AG be liable for claims which exceed the scope of warranty described including liability for consequential damages, etc. The right to the replacement of faulty parts will not be recognized by Medela if any work has been carried out on the pump by unauthorized persons. This warranty is subject to the appliance being returned to a Medela service centre.

**Servicing/routine check**
Routine checks and service work are only to be carried out by positions authorised by Medela. The routine check is to be carried out 1 x per year (see service manual). The Medela service manual is available upon request.

# 24 Disposal

The Vario comprises metals and plastics and should be disposed of in accordance with the European directives 2011/65/EU and 2012/19/EU. Additional, local guidelines must also be observed. With the AC/DC versions, the electronic components and the rechargeable battery must be disposed of separately, in accordance with the local regulations.
Please take care that you dispose the Vario and its accessories in accordance with your local disposal guidelines.

**User information for the disposal of electrical and electronic equipment**
This symbol means that the electrical and electronic equipment must not be disposed as normal household refuse. A correct disposal of this device protects and prevents possible damage to the environment or human health. For more information about the disposal contact the manufacturer, your local caregiver or healthcare provider. This symbol is only valid in the European Union. Please respect the relevant state laws and rules in your country for the disposal of electrical and electronic equipment.

# 25 Technical documentation

**WARNINGS**

Do not use other accessories than those specified or sold by the manufacturer as replacement parts for internal components as it may result in increased emissions or decreased immunity of the Vario pump.

HF (high-frequency) surgical equipment, radio networks or the like can influence the operation of the device and may not be operated in combination with the system.

**EMC**

Vario is EMC-tested in conformity with the requirements of IEC 60601-1-2:2007 and IEC 60601-1-2:2014 4th Edition according to clause 7 and 8.9. Vario is suitable for use in home and clinical environments. Vario is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the attached EMC information.