

# Basic

## SURGICAL SUCTION PUMP

EN Instructions for use



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# Congratulations

By choosing the Basic, you have acquired a high-quality suction pump which is adaptable to your needs. 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 Basic 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 Basic 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 Basic is used in combination with the original Medela accessories (collection system, tubings, filters etc. – see annex “II List of accessories”).

The Basic 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 and can be used in the vicinity of other EMC-tested devices that fulfil the requirements as outlined in the IEC 60601-1-2 standard. 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 Basic pump.

**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 is only responsible for the effect on BASIC SAFETY, reliability and performance of the Basic 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.
- To avoid risk of electric shock, this equipment must only be connected to a fixed mains socket with protective earth.
- 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.
- Consult the indications for use and consider risk factors and contraindications before using the Basic. Failure to read and follow all instructions in this manual prior to use may result in serious or fatal injury of the patient.
- Do not connect this device to a passive drainage tube.
- Not suitable for setting at a low vacuum, as needed for example for thoracic drainage without specialized accessories. Not approved for outdoor use or transport applications.
- The Basic 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 Basic pump and should be kept at least a distance 1ft (30 cm) away from the equipment.
- The rack version requires a minimum distance of 5 cm to the enclosure to prevent overheating of the device.
- 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 Basic frequently for operating status.
- To prevent the device from overheating, the exhaust at the bottom of the unit must be unobstructed when the unit is operational.

**Safety related tip**

- The Basic Suction Pump is Magnetic Resonance (MR) Unsafe. Do not take the pump into the MR environment.
- For safety tests, the device requires service and repair throughout its service life in accordance with the service manual.
- The protection of the Medela Basic 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 Basic 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 EMC information in annex “I Technical documentation (EMC).”
- 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 Medela Customer Service:
  - 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 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 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.

These instructions for use must be kept for later reference.

## 2 Power supply

The Basic 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.

### **Plugging in the pump**

Take the power supply cord and plug into the appliance inlet port at the back of the device. Use the mounting bracket to secure the cord in the inlet port.

# 3 Description

## Introduction

The Basic is a high-quality suction pump. It is powered by a piston/cylinder system and provides 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/indications

Intended Use of the Basic suction pump is the creation of a constant vacuum in the range of 0 to -90 kPa. This vacuum can be used for all applications in the hospital, clinic and doctors practice which require a vacuum in this setting such as: general surgery, liposuction, endoscopy, epicardial ablation, nasopharyngeal suction, neurosurgery, OPCAB, vacuum assisted cesarian/delivery and wound drainage.

## Intended user

The Basic 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 should be refreshed at least once a year.

## Intended patient population

The Basic is intended to be used on patients only exhibiting conditions as described in the indications for use.

## Important note

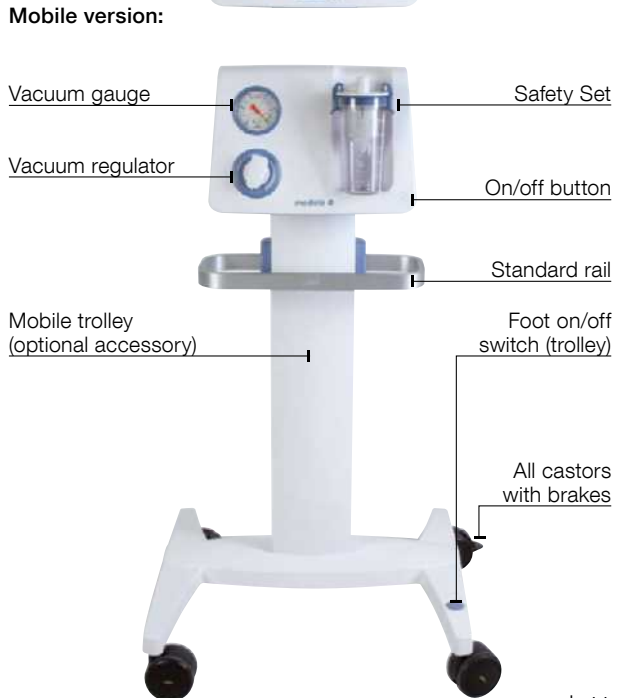
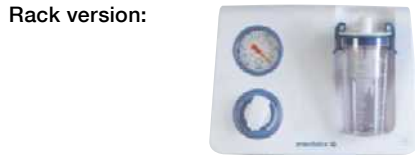
Compliance with proper surgical procedures and techniques is the responsibility of the physician. Each physician must evaluate the appropriateness of the treatment based on his own knowledge and experience.

# 4 Overview

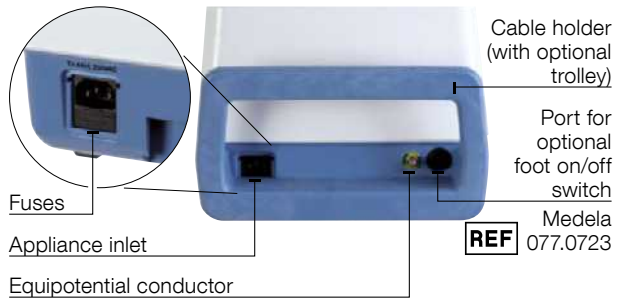
## Definition of vacuum

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 -10kPa for example always refers to a pressure range in kPa below atmospheric ambient pressure (according to EN ISO 10079:1999).

## Versions and main elements of the pump



**Back of device**



**Operating elements and indicators**

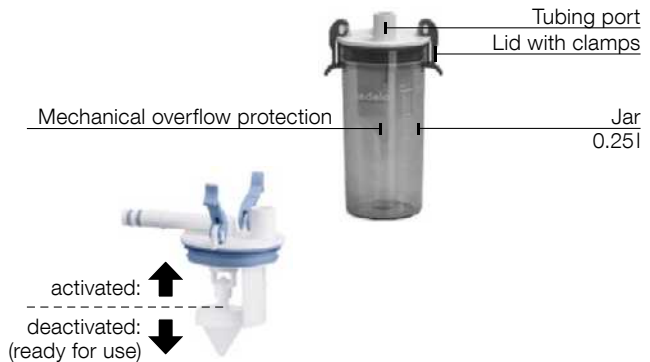


**green light** Pump is plugged in

**yellow light** Pump has an error. Refer to chapter 11

**white light** Pump is running

**Safety Set**



# 5 Installation

## 5.1 Check initial delivery

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



Basic portable version

**REF** 071.0000

or



Basic rack version

**REF** 071.0001



Mains plug

**REF** See service manual



Safety Set

**REF** 077.0711



Silicone Tubing  $\varnothing 7 \times 12$  mm with 2 coupling pieces

**REF** 077.0922

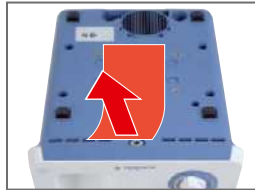


Instructions for use

**REF** 200.5524

## 5.2 Remove transport lock

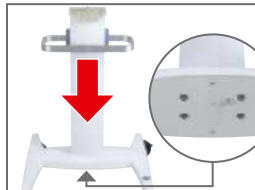
1.



- 1.1 Remove the red note
- 1.2 Remove 3 screws and store them for later use.

## 5.3 Set up mobile version (if available)

1.



- 1.1 Position top part of trolley on bottom part, making sure the tubing fits as shown.
- 1.2 Connect parts with 4 screws.

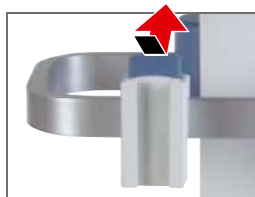
2.



- 2.1 Position pump on trolley. Make sure that the front of the pump and the standard rail point forward.
- 2.2 Connect pump with 4 screws.
- 2.3 Attach the cable holder with the two screws to the pump.

## 5.4 Assembly of the optional clampholder (when using the trolley)

1.



- 1.1 Press and hold the blue release knob.
- 1.2 Attach the clampholder to the standard rail by releasing the blue knob.

## 5.5 Set up the Safety Set

1.



- 1.1 Attach the mechanical overflow protection to the lid. Pull gently downwards to make sure it is open/deactivated.
- 1.2 Attach the lid to the jar.
- 1.3 Close the two lid clamps.

2.



- 2.1 Attach the Safety Set to the pump.

# 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 Basic must remain in an upright position during use.
- The rack version requires a minimum distance of 5 cm to the enclosure to prevent from overheating of the device. The back of the enclosure must be open.
- Sterile accessories must be checked to ensure 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 Basic 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 Basic delivery package.
- 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 before actual use.

### 6.2 Assembly of the basic configuration



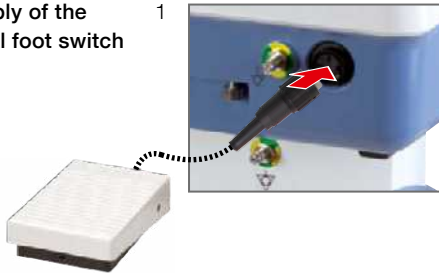
1.1 Make sure that the Safety Set is attached to the Basic. See chapter 5.5.



2.1 Attach a filter (if required) to the Safety Set with the arrow pointing in the flow direction.

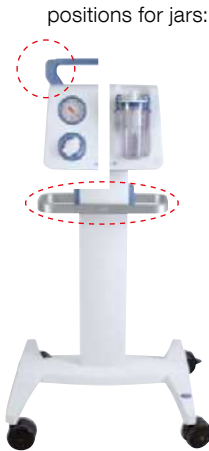
3. Attach all necessary accessories according to your needs. See annex "II List of accessories".

**6.3 Assembly of the optional foot switch**



- 1.1 Connect the optional foot switch to the pump by plugging in the plug.
- 1.2 Test the correct functioning of the foot switch.

**6.4a Assembly of the REUSABLE collection system**



positions for jars:

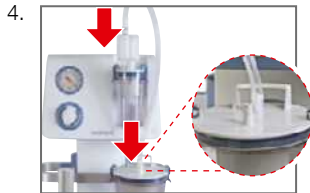
**1. If you use a DISPOSABLE collection system proceed with step 6.4b**



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



- 3.1 Attach the lid to the jar and lock with the two lid clamps.
- 3.2 Attach the jar to the carrying handle (portable version only) or to the optional clampholder on the rail (see step 5.4).



- 4.1 Connect tubing from the Safety Set to the lid of the jar (vacuum port).



- 5.1 Connect patient tubing to the lid of the jar (patient port).

## 6.4b Assembly of the DISPOSABLE collection system



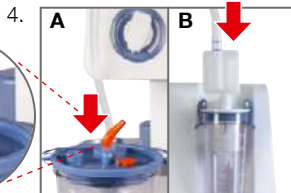
1. If you use a REUSABLE collection system proceed with step 6.4a



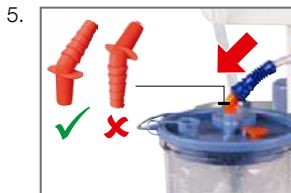
- 2.1 Choose the size necessary for the application.  
Yellow colour code: 1.5l,  
Orange colour code: 2.5l.
- 2.2 Attach the jar to the carrying handle (portable version only) or to the optional clampholder on the trolley (see step 5.4).



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



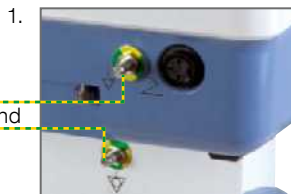
- 4.1 Connect tubing from the jar (A) to the Safety Set (B).



- 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).

## 6.5 Install equipotential bonding

to bus bar and



- 1.1 Connect the equipotential conductor at the back of the Basic with the bus bar as advised by your technician and according to inhouse directives. The respective cable is not supplied from Medela.

The equipotential conductor and connecting cables are used to equalise the potential between equipment placed in the hospital environment.

# 7 Operating instructions

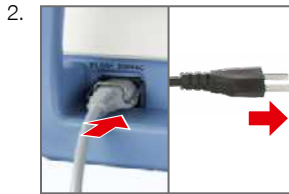


## CAUTIONS

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

### 7.1 Connect Basic to mains power

1. Check the pump before use following the instruction in chapter 6.1.



2.1 Connect the power cord to the appliance inlet at the back of the Basic.  
2.2 Plug in the mains plug of the power cord to a fixed mains socket.



3.1 An internal self-test is performed. When the green LED lights up, the device is ready for use.

### 7.2 Check maximal vacuum for functional check



1.1 Switch on the Basic.



2.1 Turn the vacuum regulator to the right to set maximum vacuum



3.1 Seal the end of the patient tubing with your thumb.  
3.2 Compare the maximum vacuum according to the specification (on left). See chapter 11 if the maximum vacuum is not reached.

#### Specifications:

Altitude  
above  
sea level:

Max. Vacuum:

+ 2000 m	- 70 kPa - 525 mmHg
+ 1000 m	- 79 kPa - 592 mmHg
+ 500 m	- 85 kPa - 638 mmHg
0 m	- 90 kPa - 675 mmHg

(Tolerance: +/- 15%)



**CAUTIONS**

When the Basic is used for wound drainage, the negative pressure should be set according to instruction of the specialist and not cause any wound damage.

**7.3 Changing vacuum level**

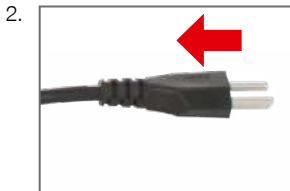


- 1.1 Clamp patient tubing
- 1.2 Turn vacuum regulator to select the correct vacuum according to the particular application.
- 1.3 Check vacuum gauge for setting.

**7.4 Placing out of operation after use**



- 1.1 Touch on/off button to switch off the Basic.



- 2.1 Disconnect the mains plug from the fixed mains socket.

- 3. Clean and disinfect the Basic. See chapter 14.

# 8 Vacuum Assisted Delivery setup



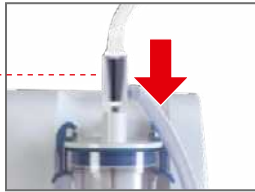
## CAUTIONS

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



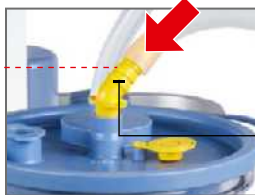
1. Set up pump and accessories according to chapter 6.

2.



2.1 Connect the foot vacuum regulator: the silver adapter must be fully seated in the Safety Set of the suction pump.  
2.2 Attach tubing to top of metal adapter.

3a



3.1 Attach tubing from suction cup to patient connection on the lid of the liner.

3b



3.1 Attach tubing from suction cup to patient connector on suction jar of the reusable collection system.

4.



4.1 Switch on pump, turn to max. vacuum, clamp tubing from suction cup and fully depress the vacuum regulator (forward and down, using ball of foot).  
4.2 Compare maximum vacuum according to specification (on left).

5.



5.1 If OK, release vacuum by returning foot vacuum regulator to resting «zero pressure» state (rear and down using heel of foot).  
5.2 The pump is now ready for use.

## Specifications:

Altitude above sea level:

Max. Vacuum:

+ 2000m	- 70 kPa - 525 mmHg
+ 1000m	- 79 kPa - 592 mmHg
+ 500m	- 85 kPa - 638 mmHg
0m	- 90 kPa - 675 mmHg

(Tolerance: +/- 15%)

# 9 Changing reusable jar



- 1.1 Switch pump off by touching the on/off button.
- 1.2 Remove patient and vacuum tubings from the lid.
- 1.3 Remove full jar from the Basic.



- 2.1 Prepare new jar and unpack it.
- 2.2 Secure new jar in the clampholder or directly to the Basic carrying handle.
- 2.3 Reconnect vacuum tubing and new patient tubing firmly.

- 3. Empty jar and dispose of patient tubing according in accordance with local guidelines and inhouse guidelines.



- 4.1 Switch pump on by touching the on/off button. Vacuum is built up.
- 4.2 Set vacuum according to the particular application. See chapter 7.3.

# 10 Changing disposable liner

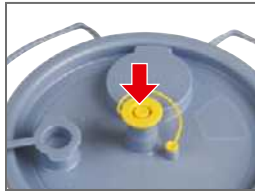


## WARNINGS

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 coloured angle piece from lid.

1.2 Plug patient port.

2.



2.1 Switch pump off by touching the on/off button.

3.



3.1 Reduce vacuum to minimum by turning vacuum regulator to the left.

4.

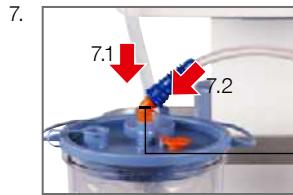


4.2 Remove full liner from the jar.

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



- 6.1 Prepare new liner and unpack it.
- 6.2 Insert new liner in the jar and press down lid.



- 7.1 Connect tubing from the jar to the Safety Set.
- 7.2 Connect new patient tubing firmly.



- 8.1 Switch pump on by touching the on/off button. Vacuum is built up.
- 8.2 Set vacuum according to the particular application. See chapter 7.3.

# 11 Troubleshooting

## **No LED lit**

The Basic is not connected to the mains or the fuse needs replacement.

## **Yellow LED indicator lit**

### **Minor case**

yellow LED indicator lit but the pump can be switched on and off:

- contact the internal technical department or your authorised service center at next possible occasion.

### **Major case**

yellow LED indicator lit and pump cannot be switched on and off:

- contact the internal technical department or your authorised service center for repairs / maintenance.

## **Motor not running**

Check to ensure:

- the Basic is switched on. The standby LED must be illuminated.
- the mains plug is inserted correctly into the fixed mains socket and into the appliance inlet.
- the fuse on the back of the Basic is not defective. For replacing the defective fuse see chapter 12.

If the fault cannot be rectified, please contact the internal technical department.

## **Insufficient vacuum**

Check if:

- the vacuum regulator is set correctly.
- the tubing is 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 it as shown under 6.4a/2.2.
- the suction jar / lid have no cracks, brittle areas, discolouration. If necessary, replace.
- the disposable system has no cracks, brittle areas, discolouration. If necessary, replace.
- the filter is not clogged. To test if the filter is clogged see chapter 13.

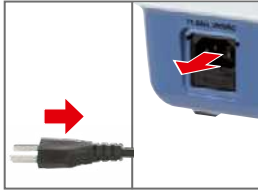
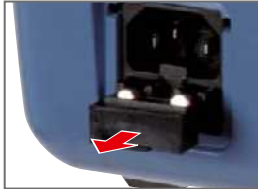
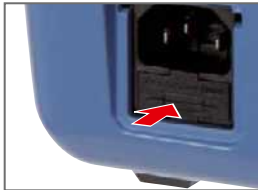
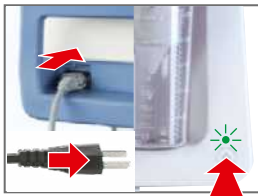
If the fault cannot be rectified, please contact the internal technical department.

# 12 Replacing defective fuse



## WARNINGS

Before replacing the fuse, pull the mains plug from Basic out of the fixed mains socket.

1.
 
  - 1.1 Disconnect the Basic from the mains.
  - 1.2 If attached, remove the cable holder (2 screws on bottom).
  
2.
 
  - 2.1 Open (pull out) the fuse holder on the back of the Basic.
  
3. Replace the defective fuse(s). Make sure that the technical specifications are correct.  
**T 1.6AH, 250VAC, 5x20mm**
  
4.
 
  - 4.1 Close (push back) the fuse holder.
  
5.
 
  - 5.1 Reconnect the Basic to the mains again.
  - 5.2 Switch on the Basic again.

# 13 Filter test

1.



1.1 Remove tubing from filter.

2.



2.1 Select maximum vacuum.

3.



3.1 Switch on Basic by pressing the on/off button.

4.



4.1 Read the vacuum.  
4.2 Replace the filter if the vacuum exceeds -20kPa.

# 14 Cleaning guidelines



## WARNINGS

After each use, the parts that have 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.**



## Safety related tip

Avoid contact of fluids with the ends of the mains plug or appliance inlet port.

## General notes

- These are general recommendations only that may be adjusted individually, based on the hospital's specific directives and cleaning practices and policies.
- Also refer to 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

- **Perform** [concentrate], Schülke & Mayr, [www.schuelkemayr.com](http://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 should be 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	Reusable suction cups	Pump housing Mainscable	Plastic accessories	Legend: * Polysulfone ** Polycarbonate
x	x	x	x	x	x	<b>1. Disassembly</b> Separate all individual parts before cleaning, disinfecting and sterilising.
x	x	x	x			<b>2. Cleaning</b> 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. Soak all parts thoroughly with warm, soapy water or in enzymatic detergent for 1–5 minutes. <b>1.</b> 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. <b>2.</b> Check the instruments for visible dirt and repeat these steps if necessary.
				x	x	<b>3. Cleaning</b> Wipe with detergent mentioned above. Use clean cloth to dry.
x	x	x	x		x	<b>4. Disinfect</b> 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).  (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 alkaline. e.g. 2% neodisher® Septo MEDsolution  (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.  or use cleaning/disinfecting machine.
x		x	x			<b>5. Sterilise</b> 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		x	<b>6. Storing components</b> After disinfection/sterilising, store the components in sterile foil until required for use.

## 15 Warranty and servicing

### Warranty

Medela AG warrants the device will be free from defects in materials and workmanship for a period of 5 years 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 pumps. 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. Medela recommends to carry out the routine check 1x per year (see service manual). The Medela service manual, is available upon request.

## 16 Disposal

The Basic is made of 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. Please take care that you dispose of the Basic 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 together with unsorted municipal waste. 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.

# 17 Accessories overview



## WARNINGS

Basic was verified in combination with the accessories listed in annex “II List of accessories”. For correct and safe operation, use Basic with these accessories only. Further information is supplied on the instruction sheet of the individual accessory.



## Safety related tip

If the pump is used together with third party patient interfacing devices (e.g. cannulas, catheters), they must:

- have CE mark (within the European Union) and local registration (outside the European Union)
- be able to be attached to Medela accessories safely without impacting the performance of the pump.

    Tubing connection on reusable lids of jars: Ø6–10mm, Ø10–14 mm

    Tubing connection on disposable liners: Ø6.5–11 mm

**Note:** when combining Medela parts and a new patient interfacing device, you take over the responsibility of the entire system and should test the combination to ensure the vacuum levels are properly maintained.

# 18 Technical specifications



high vacuum  
- 90 kPa / - 675 mmHg  
Tolerance: +/- 15%

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



high flow  
30l/min.  
+/- 5l/min.



9.3 kg  
20.5 lbs  
Rack version



100-240V, 50/60Hz  
50 W



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



0123



HxWxD (rack version)  
210x305x375 mm  
8.2x 12.0x 14.8 inches



Transport/Storage Conditions



Operating Conditions



IP21

# 19 Signs and symbols



**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 class of the pump.



This symbol indicates the date of manufacture.



This symbol indicates protective earth (ground).



This symbol indicates that the device should not be used after the date shown.

**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 single use device. Do not reuse the device.



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



This symbol indicates a type CF applied part.

**REF**

This symbol indicates manufacturer's catalogue number.



This symbol indicates the legal specifications of the pump.



This symbol indicates MR UNSAFE.

**SN**

This symbol indicates manufacturer's serial number.



This symbol indicates to follow instructions for use.



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

**LOT**

This symbol indicates manufacturer's batch code.



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



This symbol indicates the equipotential conductor connection.

**STERILEEO**

This symbol indicates the device is sterilized using ethylene oxide.



This symbol indicates safety related tip.



This symbol indicates the connection port for the foot switch.



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



This symbol indicates earth (ground).



This symbol indicates the manufacturer.



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



This symbol indicates to handle the fragile device with care.



This symbol indicates the fuse



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



This symbol indicates to keep the device dry.



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



This symbol indicates the maximum vacuum level of the pump.



This symbol indicates the flow levels of the pump.



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



This symbol indicates the electrical specifications of the pump.



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



This symbol indicates the weight of the pump.



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



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



This symbol indicates a carton package.



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



This symbol indicates to keep the device away from sunlight.



This symbol indicates number of items.