medela
THE SCIENCE OF CARE™

Dominant Flex
Surgical Suction Pump

EN

INSTRUCTIONS FOR USE

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 Dominant Flex 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 Dominant Flex is used in combination with the original Medela accessories (collection system, tubings, filters etc. – see chapter "Accessories overview").

IMPORTANT NOTE
- Please read and observe these warnings and safety instructions before operation. Please also familiarize yourself with associated information signals and troubleshooting instructions before operation (see chapter "Installation" and "Troubleshooting").
  These instructions for use must be kept with the device for 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. 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. Medela is only responsible for the effect on basic safety, reliability and performance of the Dominant Flex if it is used in accordance with the instructions for use.
- 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.
- Any serious incident that has occurred in relation to the device must be reported to Medela AG and the relevant Competent Authority.

WARNINGS

⚠ *Warning: To reduce the risk of potential cross-contamination or exposure to biological hazards*
- After each use, the parts that have been in contact with the aspirated secretions are to be cleaned, disinfected, sterilized or disposed of according to reprocessing instructions.
- 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).

⚠ *Warning: To reduce the risk of potential injury due to incorrect use*
- For use only by medically trained persons who have been adequately trained in suction procedures and in the use of aspirators.
- Consult the indications for use and consider risk factors and contraindications before using the Dominant Flex. Failure to read and follow all instructions in this manual prior to use may result in serious or fatal injury of the patient.
- 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.

⚠ *Warning: To reduce the risk of potential injury during setup or operation*
- No modification of this equipment is allowed.
- Do not connect this device to a passive drainage tube.
- The Dominant Flex was verified in combination with the accessories listed in "Accessories overview". For correct and safe operation, use the Dominant Flex with these accessories only. Further information is supplied on the instruction sheet of the individual accessory.

⚠ *Warning: To reduce the risk of potential injury due to interference with other devices*
- The Dominant Flex should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Dominant Flex should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories or cables other than those provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this suction pump and result in improper operation.
- Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Dominant Flex pump including cables (power cord, foot switch, trolley) specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ *Warning: To reduce the risk of potential electric shock or exposure to heat, fire, explosion*
- To avoid risk of electric shock, this equipment must only be connected to a fixed mains socket with protective earth ground.
- The device must not be used for suctioning explosive, easily flammable or corrosive liquids.
- Before reprocessing the device, remove the plug from the fixed mains socket.
- Disconnect mains plug from electrical power source before replacing the fuse.
- The Dominant Flex is a mains-powered suction pump. Before you connect the suction pump to power, please verify that your local power supply complies with the power rating on the specification plate.

CAUTIONS

⚠ *Caution: To reduce the risk of potential cross-contamination or exposure to biological hazards*
- Visually inspect sterile packaging of the device for damage before opening.
- Devices with a damaged packaging system must not be used.
- Reusable devices are delivered non-sterile and must be reprocessed before first use and after each use according to the chapter "General Reprocessing Guidelines".
- When reprocessing devices, always wear personal protective equipment (PPE): disposable gloves and other PPE as per local guidelines and regulations.
- Point-of-use treatment with tap water (≤40 °C, ≤104 °F). Violation of this may result in the fixation of residue and thus inhibit disinfection.

⚠ *Caution: To reduce the risk of potential injury due to incorrect use*
- Incorrect use can cause pain and injury to the patient.
- 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 to the patient. Monitor the Dominant Flex frequently for operating status.
- When the Dominant Flex is used for wound drainage, the negative pressure should be set according to instruction of the specialist and not cause any wound damage.

⚠ *Caution: To reduce the risk of potential injury during setup or operation*
- The rack version requires a minimum distance of 5 cm from the enclosure to prevent overheating of the device.

⚠ *Caution: To reduce the risk of potential injury due to interference with other devices*
- Wireless communication equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the Dominant Flex pump and should be kept at a distance of at least 30 cm away from the equipment (suction pump, mains cable, foot switch, trolley).

⚠ *Caution: To reduce the risk of potential electric shock or exposure to heat, fire, explosion*
- To prevent the device from overheating, the exhaust at the bottom of the suction pump must be unobstructed when the suction pump is operational.

☛ SAFETY RELATED TIP
- For safety tests, the suction pump requires service and repair throughout its service life in accordance with the service manual.
- The protection of the Dominant Flex against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.
- Separation from electrical power is only assured through the disconnection of the mains plug and the fixed mains socket.
- Third party interfacing devices (e.g. cannulas, catheters) must be able to be attached without impacting the performance of the pump.
- Ensure proper performance of the suction pump prior to use, see section on preparation for use.
- Avoid contact of fluids with the ends of the mains plug or appliance inlet port.

SAFETY INSTRUCTIONS

- Please consult the IFU of the devices for use with the Dominant Flex for any contraindications in the specific indications for use.
- Wear gloves for all operations.
- The Dominant Flex 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 chapter "Technical documentation".
- The Dominant Flex is Magnetic Resonance (MR) Unsafe. Do not take the pump into the MR environment.
- 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 is 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, 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.
- Use the Medela suctioning equipment for the removal of bodily fluids only. Do not use Medela suctioning equipment for the administration of bodily fluids.

These instructions for use must be kept for later reference.

DESCRIPTION

Introduction
The Dominant Flex is a high-quality suction pump, which provides maximum suction performance for many suctioning needs. The Dominant Flex's option of three selectable flow rates gives flexibility depending on the surgeon's preference. It ideally combines easy handling and reprocessing 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.

Intended use/purpose
The intended use of the Dominant Flex suction pump is the creation of a constant vacuum in the range of 0 to –95 kPa.

Indications for use
The Dominant Flex suction pump is indicated for all applications requiring vacuum such as general surgery, liposuction, endoscopy, epicardial ablation, nasopharyngeal suction, neurosurgery, OPCAB, vacuum assisted cesarian/ delivery and wound drainage in hospital, clinic and doctors practice settings.

Contraindications
There are no known contraindications for the Dominant Flex suction pump.

Intended user
The Dominant Flex should only be operated by healthcare professionals familiar with suctioning procedures and staff dedicated to reprocessing. These persons must not be hard of hearing or deaf and must have adequate visual faculty.

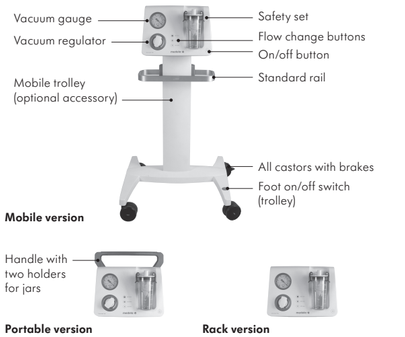
Intended patient population
The Dominant Flex is intended to be used on patients only exhibiting conditions as described in the indications for use.

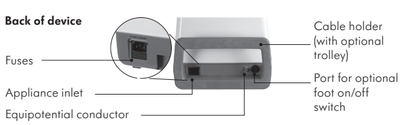
Undesirable side effects
There are no known undesirable side effects associated with the Dominant Flex suction pump.

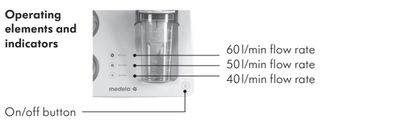
OVERVIEW

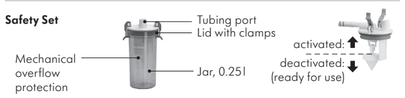
Definition of vacuum
In the application of medical aspiration devices, vacuum is normally given as the difference (in absolute figures) between absolute pressure and atmospheric pressure or as negative values in Kilopascal (kPa). In this document, the indication of –10 kPa for example always refers to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

Versions and main elements of the suction pump









INSTALLATION

1 Check initial delivery
Check the delivery package of the Dominant Flex for completeness and general condition.


Dominant Flex portable version
REF 071.0002
REF 101046575*
REF 101046576*
*for global accounts only


Dominant Flex rack version
REF 071.0003


Power cord, Allen key
REF See service manual


Reusable jar 0.25 l
REF 077.0125


Lid for safety jar, overflow protection device
REF 077.0450

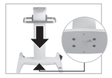

Silicone Tubing ø 7x12 mm with 2 coupling pieces
REF 077.0922


Instructions for use

2 Remove transport lock

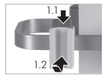

1.1 Remove the red note.
1.2 Remove 3 screws and store them for later use.

3 Set up mobile version (if available)


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


2.1 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.

4 Assembly of the optional clampholder (when using the optional trolley)



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

5 Set up the Safety Set

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.

2.1 Attach the safety set to the pump.

3.1 For reprocessing, remove the safety set from the pump and disassemble by reversing steps 1.3, 1.2, and 1.1

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.

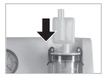
Note
- Wear gloves for all operations.

⚠ CAUTIONS
- The Dominant Flex 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.

1 Check before use
- Check the Dominant Flex 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 Dominant Flex delivery package.
- Check all accessories prior to use:
  1. suction jars, lids and liners for cracks, brittle and flawed spots. Replace if necessary.
  2. Tubing for cracks, brittle areas and that connectors are firmly attached. Replace if necessary.
  3. As an additional safety test, evacuate the system (including jars) to maximum vacuum before actual use.

2 Assembly of the basic configuration


1.1 Make sure that the Safety Set is attached to the Dominant Flex. See chapter "Installation" and "Set up the Safety Set".


2.1 If required attach a filter to the Safety Set with the arrow pointing in the flow direction.
3. Attach all necessary accessories according to your needs. See "Accessories overview".

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.

4 Assembly of collection systems
Please refer to the instruction sheets of the Medela Disposable Collection System, Medela Reusable Collection system and Medela Disposable filter provided with the associated articles to find the assembly instructions and all information related to the use of the accessories and collection system.

OPERATING INSTRUCTIONS

⚠ WARNING
- The Dominant Flex is a mains-powered suction pump. Before you connect the suction pump to power, please verify that your local power supply complies with the power rating on the specification plate.

Note
- The Dominant Flex is to be set up in such a way, that a separation from the mains supply can be easily managed.
- Wear gloves for all operations.

1 Connect the Dominant Flex to electical power


1. Check the pump before use following the instruction in chapter "Preparation before use".
2.1 Connect the power cord to the appliance inlet at the back of the suction pump. Use the mounting bracket to secure the cord in the inlet port.
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.

2 Verify maximum vacuum


1.1 Switch on the Dominant Flex. The pump will indicate a flow rate of 50 l/min.


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 (below). See chapter "Troubleshooting" and "Insufficient vacuum" if vacuum is not reached.

Vacuum specifications:

Altitude above sea level:	Max. Vacuum:
+ 3000 m	– 64 kPa – 480 mmHg
+ 2000 m	– 74 kPa – 555 mmHg
+ 1000 m	– 84 kPa – 630 mmHg
+ 500 m	– 89 kPa – 668 mmHg
0 m	– 95 kPa – 713 mmHg

(Tolerance: +/– 15 %)

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

3 Changing flow rate


1.1 Change flow rate according to operator's preference. After switching on the pump (with either the foot switch or the button on the pump), it will start running in the 50 l/min. mode.
1.2 Touch to change to:
60 l/min
50 l/min
40 l/min

4 Changing vacuum level

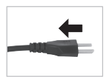

2.1 Clamp patient tubing.
2.2 Turn vacuum regulator to select the correct vacuum according to the particular application. To increase vacuum turn regulator clockwise.
2.3 Check vacuum gauge for setting.

⚠ WARNING
- After each use, the parts that have been in contact with the aspirated secretions are to be cleaned, disinfected, sterilized or disposed of according to reprocessing instructions.

⚠ CAUTION
- Reusable devices are delivered non-sterile and must be reprocessed before first use and after each use according to the chapter "General Reprocessing Guidelines".

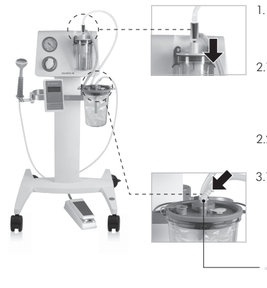
5 Placing out of operation after use


1.1 Touch on/off button to switch off the suction pump.


2.1 Disconnect the mains plug from electrical power source.
3. Clean and disinfect the Dominant Flex. See chapter "General Reprocessing Guidelines".

VACUUM ASSISTED DELIVERY SETUP

Note
- The Dominant Flex is to be set up in such a way, that a separation from the electrical power supply can be easily managed.


1. Set up pump and accessories according to chapter "Preparation before use".
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.
3.1 a) Attach tubing from Medela VAD cup to patient connection on the lid of the liner of the disposable collection **OR**


b) Attach tubing from Medela VAD cup to patient connector on suction jar of the reusable collection system.


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


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

TROUBLESHOOTING

Insufficient vacuum
Verify that:
- 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 chapter "Installation" and "Set up the Safety Set".
- the suction jar and lid have no cracks, brittle areas, discoloration. If necessary, replace.
- the disposable system has no cracks, brittle areas, discoloration. If necessary, replace.
- the filter is not clogged. To test if the filter is clogged, refer to instruction sheet provided with the filters.

If the issue cannot be resolved, contact the internal technical department.

No LED lit
The Dominant Flex is not connected to electrical power 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
Verify that:
- the Dominant Flex 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 Dominant Flex is not defective. For replacing the defective fuse follow chapter "Replacing defective fuse".

If the issue cannot be resolved, contact the internal technical department.

REPLACING DEFECTIVE FUSE

⚠ WARNING
- Disconnect mains plug from electrical power source before replacing the fuse.

Please follow the instruction in the service manual [REF 200.6365], how to replace fuses (T 1.6AH, 250 VAC, 5x20 mm) of the Dominant Flex pump.

GENERAL REPROCESSING GUIDELINES

	PSU jars, reusable lids, clamps, overflow protection, O-rings (in case of spill thereon), wall holders and PC jars (in case of a spill), connectors (disassembled from tubing), holders, locking clasp	Silicone tubing (up to 200 cm only), change over valve (in case of a spill)	Pump housing, cables, foot switch, foot vacuum regulator, wall holders, trolley, PC jars	
Additional information	x	x	x	– Per ISO 17664-2, these instructions have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility,achieves the desired result. This requires verification and/or validation and routine monitoring of the process. – For specification of water qualities see AAMI TIR34.
	x	x		– The washer-disinfector shall be qualified according to ISO 15883 series; cleaning and disinfection was validated in an ISO 15883 certified washer- disinfector of an accredited lab. – All disassembled parts must be safely fixed in the carriers/on fixation points. – Do not overload the washer-disinfector. Arrange the disassembled parts in such a way that no areas are left unwashed and inner and outer surfaces are reached by the cleaning liquids.
Limitations	x	x	x	– Discard or service the device (or component as applicable) if it shows visible signs of wear or damage.
Warnings/cautions	x	x	x	– Always wear personal protective equipment (PPE): disposable gloves and other PPE as per local guidelines and regulations. – Point-of-use treatment with tap water (≤40 °C, ≤104 °F). Violation of this may result in the fixation of residue and thus inhibit disinfection.
General safety instructions	x	x	x	– If the device is used on a patient who suffers from a disease, and whose pathogens cannot be eliminated with procedure outlined below, the device must be disposed of. – Consult the cleaning and disinfection agent manufacturer's instruction for use regarding, including but not limited to exposure times and safety measures. – Perform point-of-use treatment directly after use of the device (before soil can dry onto the device).
			x	– Disconnect the power cord from the electrical power source. – Avoid contact of fluids with the ends of the mains plug or appliance inlet port. – Never immerse the device in or rinse with water or other liquids. Do not spray cleaning agent and disinfectant directly on the device.
Preparation before cleaning		x	x	– Wipe external surfaces of the device to remove all gross soil with a soft, lint-free wipe moistened with tap water. Take care to wipe away from difficult-to-clean (and disinfect) areas, such as crevices, dead ends, and complex geometry.
		x		– In case of contamination on the lumen of the tubing with connectors or on the mating area between connector piece and hose (if the connector cannot be removed), or in the channels of the change-over-valve, dispose of the device per applicable procedures for contaminated material.
	x		x	– Disassemble into individual parts before proceeding (see installation instructions). – Remove connector piece(s) from hose of tubing if they are soiled. – Remove O-rings from connector piece if they are soiled. – Carefully open the Torx Screw on the holder, compress the spring by pressing the button. After removing the screw, slowly release the push button. Next, remove the push button and the spring. Then remove the lower claw by closing the clamp and then pulling.
	x			– If necessary, and for the removal of gross soil, place the disassembled components in tap water for 10 minutes and wipe off visible staining with a soft, lint-free wipe soaked in tap water.
	x	x		– If residual soil has dried onto the device, the soil must be rehydrated before the enzymes can be effective.
Manual cleaning			x	– Wipe all external surfaces of the device with CaviWipes™ or Incidin OxyWipe S™. – Wipe away from difficult-to-clean areas (e.g., where components that cannot be disassembled meet). – Use a new cleaning and disinfectant wipe when the wipe is contaminated. – Clean until all visible soil is removed.
Manual disinfection			x	– Take a new CaviWipes™ or Incidin OxyWipe S™ wipe and wipe all external surfaces of the equipment. – Pay special attention to the difficult-to-clean areas of the device. – After 3 minutes, take a new CaviWipes™ or Incidin OxyWipe S™ wipe and wipe all external surfaces of the equipment. – Make sure all surfaces of the device remain visibly moistened at room temperature for the time specified in the wipe manufacturer's instructions for use. If the used wipe is getting too dry to moisten the surface use a new wipe. – To aid exposure of difficult-to-clean areas, a new CaviWipes or Incidin Oxy Wipe S wipe may be wrapped around a spatula or a similar utensil. – After the prescribed exposure, remove any residuals using a soft, lint-free wipe moistened with purified water.
Automated cleaning	x	x		– Connect tubes to the active rinsing system of the load carrier to ensure the rinsing of the inside and outside. – Place lids on straight nozzle through inlet (patient side). – Position all other devices in the load carrier. – If applicable, position the carrier for small parts on the load carrier. – Do not use any drying aids (rinsing agents) as these could remain on the surface with a detrimental effect to the device and its biocompatibility. The cleaning program of the washer-disinfector should adhere to the following: – 1 minute pre-cleaning with tap water – 5 minutes cleaning at 55 °C with 0.5 % solution of neodisher® MediClean forte in tap water – 1 minute rinsing with purified cold water
Automated disinfection	x	x		– Thermal disinfection with purified water (without an additional agent) at 90 °C for 1 minute (A_0=600) or adapt A_0 values per local guidelines and regulations.
Drying	x	x		– Dry disassembled components in washer-disinfector at 110 °C for at least 45 minutes.
	x	x	x	– If drying in the washer-disinfector is not possible or in case of residual moisture, wipe external surfaces dry using a dry, soft lint-free wipe, or carefully dry with medical grade compressed air. – Pay special attention to the dryness of hard to reach areas.
Inspection	x	x	x	– Visually inspect the device or disassembled components for any remaining soil or disinfectant solution. If necessary, repeat the cleaning and disinfection. – Visually inspect the device or disassembled components for damage. In case of any damage to one or more parts, replace them with new ones.
	x		x	– Consult the installation section in this IFU for guidance on reassembly.
			x	– Perform full service or routine check as indicated in this IFU.
Storage	x	x	x	– Always store device in a dry, clean, and dust free environment.
Transport			x	– Reprocess the device before sending it in for service. If this is not possible or can only be done in parts, the package shall indicate the potential biohazard. Local procedures and guidelines apply.
	x	x	x	– Take appropriate measures to ensure intactness of the device or the components and to safeguard against re-contamination until use as per local guidelines and regulations.

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, caused by incorrect operation, inappropriate use, unauthorized repairs or inappropriate assembly or disassembly.
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 device being returned to a Medela service centre.

Servicing/routine check
Maintenance and service work on the suction pump, its modules or accessories must only be performed by authorised maintenance personnel who have been trained. Medela recommends to carry out the routine check 1x per year according to the Medela service manual [REF 200.6365], which is available in English upon request.

DISPOSAL

- Handle and dispose of all products in accordance with accepted medical practice and with applicable local guidelines and regulations.
- Reprocess reusable devices prior to disposal. Autoclave accessories that are contaminated with body fluids.

Pump and electrical parts
- Inquire at the point of sale or contact your local authority for appropriate collection points for waste equipment.
- The Dominant Flex should be disposed of in accordance with the European directive 2012/19/EU WEEE.
- Do not dispose of electrical or electronic equipment together with unsorted municipal waste, collect it separately instead.
- In the European Union/Switzerland/UK the manufacturer or its vendor must take back waste equipment. Other countries may have similar collection and recycling systems. Please respect the relevant state laws and rules in your country for the disposal of electrical and electronic equipment.
- The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

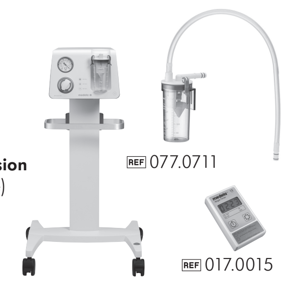
ACCESSORIES OVERVIEW

⚠ WARNING
- The Dominant Flex was verified in combination with the accessories listed on this page. For correct and safe operation, use the Dominant Flex with these accessories only. Further information is supplied on the instruction sheet of the individual accessory.

☛ SAFETY RELATED TIP
- Third party interfacing devices (e.g. cannulas, catheters) must be able to be attached without impacting the performance of the pump. Ensure proper functioning and maintenance of vacuum levels prior use.

REF **071.0003, rack version**

REF **071.0002, portable version**
(not shown in this picture)



REF 077.0711
REF 017.0015
REF **071.0034**

Patient tubing (from collection system to patient applied part)

Disposable Sterile Tubing STERILE EO

REF 077.0170: 150 cm
REF 077.0184: 150 cm
REF 077.0951: 180 cm
REF 077.0193: 300 cm (for global account only)

Disposable tubing, non sterile

REF 077.0952: 180 cm

*Silicone, 7x12 mm**
REF 077.0053: 32 cm
REF 077.0054: 50 cm
REF 077.0055: 120 cm
REF 077.0056: 150 cm
REF 077.0051: 200 cm
REF 077.0052: 2500 cm
* may be used with VAD cups (for reprocessing see instructions for use of VAD cups)

Silicone, 5x10 mm
REF 077.0970: 2500 cm

Silicone, 6.5x11.7 mm
REF 077.0961: 180 cm

Connectors

REF 077.0161
REF 077.1017
REF 077.1020
REF 077.0100
REF 077.0101
REF 077.0097
REF 077.0098
REF 077.1019
REF 077.1018

Liners

1.5 L
REF 077.0083/84
REF 077.0194 (for global account only)
REF 101035340 (for global account only)

2.5 L
REF 077.0086/87

Reusable lids

REF 077.0450
REF 077.0440
REF 077.0420/30
REF 077.1021
REF 077.1013

PC jars (max. 4x 2.5 l)
REF 077.0082 (1.5 l)
REF 077.0085 (2.5 l)

PSU Reusable jars (max. 4x 5 l)
REF 077.0125: 0.25 l
REF 077.0155: 0.5 l
REF 077.0110: 1 l
REF 077.0120: 2 l
REF 077.0130: 3 l
REF 077.0150: 5 l

Locking clasp
REF 077.0102

Reusable sets

REF 077.0701: 1 l (with clampholder)
REF 0770715: 1 l (without clampholder)
REF 077.0702: 2 l (with clampholder)
REF 077.0716: 2 l (without clampholder)
REF 077.0703: 3 l
REF 077.0705: 5 l

REF 077.0704: 2 x 3 l
REF 077.0706: 2 x 5 l
REF 077.0707: 2 x 2 l

Vacuum tubing (from suction pump to collection system)

Silicone, 7x12 mm

REF 077.0054: 50cm
REF 077.0901: 100 cm
REF 077.0902: 200 cm
REF 077.0905: 500 cm
REF 077.0900: 2500 cm

REF 077.0931: 25 cm
REF 077.0185: 60 cm

REF 077.0921: 30 cm
REF 077.0922: 60 cm
REF 077.0189: 300 cm

REF 077.0154: 25 cm
REF 077.0911: 33 cm
REF 077.0912: 60 cm
REF 077.0913: 100 cm

Filters**
REF 077.0571
REF 077.0572
REF 077.0573
REF 077.0575
REF 101035263
REF 101035264
REF 101035265
** single patient use, see respective IFU

Foot controls
REF 077.0723
REF 077.0731

Holders
REF 077.0521
REF 077.0751/52
REF 077.0651

Accessories for high volume setups
REF 077.0563
REF 077.0561
REF 077.0188
REF 077.0542
REF 077.0158
REF 077.0160
REF 077.0095

Specimen cups
REF 077.0562/64
REF 077.0194 (for global account only)
REF 077.0094

Wall holders
REF 077.0523
REF 077.0192

Vacuum Assisted Delivery cups

Reusable (for reprocessing see instructions for use of VAD cups)

REF 077.0175/76
REF 077.0080
REF 077.0171/72
REF 077.0173/74
REF 077.0761/62
REF 077.0078

Single use/sterile STERILE EO

REF 077.0792
REF 077.0791

TECHNICAL SPECIFICATIONS

vacuum	high vacuum –95 kPa/–713 mmHg Tolerance: ± 15 %	Measured at sea level (0 m), atmospheric pressure: 1013.25 hPa Please note: vacuum level varies depending on location (atmospheric pressure, humidity, and temperature).
flow	high flow 40, 50 or 60 l/min. Tolerance: + 10 l/min.	Measured at sea level (0 m), atmospheric pressure: 1013.25 hPa Please note: flow varies depending on location (atmospheric pressure, humidity, and temperature).
kg	9.3 kg 20.5 lbs Rack version	
AC	100–240 V, 50 / 60 Hz 120 W	
§	ISO 13485 CE (93/42/EEC), IIa	CE 0123
	H x W x D (rack version) 210 x 305 x 375 mm 8.2 x 12.0 x 14.8 inches	
20 % – 95 %; -20 °C – +55 °C		Transport/Storage conditions
30 % – 75 %; +5 °C – +40 °C; 70 kPa – 106 kPa		Operating conditions
CLASS; IP22		

SIGNS AND SYMBOLS

CE 0123 Indicates compliance with the EU requirements concerning medical devices.	TÜV SÜD C US Indicates the compliance with additional USA and Canada safety requirements for medical electrical equipment.	§ Indicates the legal specifications of the system.
Read and follow the instructions for use.	General safety alert symbol, points to information related to safety.	Indicates safety related tip.
Indicates earth (ground).	CLASS Indicates the class of the system related to electrical safety.	Indicates protective earth (ground)
IP22 Indicates the protection against harmful effects due to the ingress of solid foreign objects and water.	Indicates a type CF applied part.	MR MRI Unsafe keep away from magnetic resonance imaging (MRI) equipment.
Indicates that interferences may occur in the vicinity of equipment marked with this symbol.	Indicates the equipotential conductor connection.	Indicates the connection port for the foot switch.
Identifies the manufacturer.	Indicates the date of manufacturing.	Indicates that the device should not be used after the date shown.
Indicates a medical device that is intended for one single use only.	REF Indicates the part number of the device.	SN Indicates the serial number of the device.
LOT Indicates manufacturer's batch code.	Defines a temperature range (e.g. for operation, transport or storage).	Defines a relative humidity range (e.g. for operation, transport or storage).
Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	Indicates do not use the device if package is damaged.	Do not dispose of electrical or electronic devices together with unsorted municipal waste (dispose of the device in accordance with local regulations).
Keep away from sunlight.	Contains fragile goods. Handle with care.	Keep away from rain. Keep in dry conditions.
vacuum Indicates the maximum vacuum level of the system.	flow Indicates the flow levels of the system.	AC Indicates the electrical specifications of the system.
kg Indicates the weight of the system.	Indicates the dimensions (h x w x d) of the system.	pcs Indicates number of items.
MD Indicates the item is a medical device.	YY XXX Indicates recycling of the packaging material defined with the code "XX" and the abbreviation "YYY".	Indicates that the package is capable of being recycled.
Indicates this side up.	Indicates the fuse.	# Indicates model number.
X Indicates the quantity (x) of individual devices in pack.	i Indicates to consult instructions for use.	STERILE EO Indicates the device is sterilized using ethylene oxide.
Indicates a single sterile barrier system.	Indicates a single sterile barrier system with protective packaging outside.	UDI Indicates a carrier that contains unique device identifier information.
RFID This symbol identifies a radio frequency identification tag.	Indicates the authorized representative.	Indicates the entity distributing the medical device into the locale.

TECHNICAL DOCUMENTATION

EMC
The Dominant Flex is EMC-tested in conformity with the requirements of IEC 60601-1-2:2014/AMD1:2020 Edition 4.1 according to clause 7 and 8.9. The Dominant Flex is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the EMC information. The Dominant Flex does not have an essential performance as defined in IEC 60601-1.

⚠ WARNINGS
- The Dominant Flex should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Dominant Flex should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories or cables other than those provided by the manufacturer of this device could result in increased electromagnetic emisions or decreased electromagnetic immunity of this suction pump and result in improper operation.

⚠ CAUTION
- Wireless communication equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, RFID can affect the Dominant Flex pump and should be kept at a distance of at least 30 cm away from the equipment (suction pump, power cord, foot switch, trolley).

Electromagnetic emissions
The Dominant Flex is only approved for the following electromagnetic environments: professional healthcare facility environment and home healthcare environment.

Emission Tests	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Dominant Flex uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The Dominant Flex is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity
The Dominant Flex is only approved for the following electromagnetic environments: professional healthcare facility environment and home healthcare environment.

Immunity Tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV line-to-earth	± 1 kV differential mode ± 2 kV line-to-earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle 70 % U_T for 25 cycles at 50 Hz single phase: at 0° and for 30 cycles at 60 Hz single phase: at 0° 0 % U_T for 250 cycles at 50 Hz and for 300 cycles at 60 Hz	0 % U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T for 1 cycle 70 % U_T for 25 cycles at 50 Hz single phase: at 0° and for 30 cycles at 60 Hz single phase: at 0° 0 % U_T for 250 cycles at 50 Hz and for 300 cycles at 60 Hz	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dominant Flex requires continued operation during power mains interruptions, it is recommended that the Dominant Flex be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels of a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	8 A/m 30 kHz – CW 65 A/m 134.2 kHz – PM 2.1 kHz 7.5 A/m 13.56 MHz – PM 50 kHz	8 A/m 30 kHz – CW 65 A/m 134.2 kHz – PM 2.1 kHz 7.5 A/m 13.56 MHz – PM 50 kHz	Magnetic field intensity should be that of a typical or commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.
CW: Continuous Wave
PM: Pulse Modulation

⚠ WARNING
- Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Dominant Flex pump including cables (power cord, foot switch, trolley) specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic immunity
The Dominant Flex is only approved for the following electromagnetic environments: professional healthcare facility environment and home healthcare environment.

Immunity Tests	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the Dominant Flex, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 0.15–80 MHz 6 Vrms in ISM and amateur radio bands between 0.15 and 80 MHz	3 Vrms 6 Vrms	$d = 1.2\sqrt{P}$ $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 0.7\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
NOTE 3 Proximity fields from RF wireless communication equipment were tested according to Table 9 of IEC 60601-1-2:2014/AMD1:2020

[a] Field strengths from fixed RF transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Dominant Flex are used exceeds the applicable RF compliance level above, the Dominant Flex should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the Dominant Flex.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table of frequencies
Table of frequencies of portable and mobile transmitters for which the recommended separation distance is 30 cm (12 inches):

Band (MHz)	Service
380–390	TETRA 400
430–470	GMRS 460, FRS 460
704–787	LTE Band 13, 17
800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5
1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS
2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7
5100–5800	WLAN 802.11 a/n

ADDRESSES

Medela AG
Lättichstrasse 4b
6340 Baar, Switzerland
www.medela.com

International Sales
Medela AG
Lättichstrasse 4b
6340 Baar
Switzerland
Phone +41 41 562 51 51
Fax +41 41 562 51 00
customercare@medela.ch

Australia
Medela Australia Pty Ltd,
Medical Technology
3 Arco Lane
Heatherton, Vic 3202
Australia
Phone +61 3 9552 8600
Fax +61 3 9552 8699
contact@medela.com.au

Netherlands & Belgium
Medela Benelux BV
Uilenwaard 31
5236 WB's-Hertogenbosch,
Netherlands
Phone +31 73 690 40 40
Fax +31 73 690 40 44
info@medela.nl
info@medela.be

India
Medela India Private Limited
602-603 | 6th Floor,
JMD Megapolis | Sohna Road,
Sector – 48 | Gurgaon 122 001
India
Phone +91 124 4832069
Fax +91 124 4832066
info@medela.in

United Kingdom
Medela UK Ltd.
Huntsman Drive
Northbank Industrial Park
Irlam, Manchester M44 5EG
United Kingdom
Phone +44 161 776 0400
Fax +44 161 776 0444
info@medela.co.uk

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