Trolley optional (standard version w/o trolley)

ergo vac

(incl. LT-Version)

Operating Manual

ergo vac LT version
(different Cable
Arm only)

Art.-Nr.: 360 188 Ver.: g

mbnet engineering

Sales and Service Information

The latest version of this instruction for use can be found at www.mbnet.de.

Sales information can also be obtained from: **info@mbnet.de**

ergo vac bears the CE mark, indicating its compliance with the essential general safety and performance requirements of Annex I of the Medical Device Regulation 2017/745/EU. The requirements apply to patients, users and third persons who come into contact with this device within the scope of its intended use.

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Original

Table of Contents

1 Safety Notes

1.1 Responsibility of the User

- The device must be used only by qualified physicians or trained medical professionals.
- The responsibilities of the staff for operating and maintaining the device must be specified by the operator.
- Ensure that the staff has read and understood the user guide. This applies in particular to this section Safety notes.
- The device must not be stacked at any moment.
- Damaged or missing parts must be replaced immediately.
- The safety, reliability and performance of the device can only be guaranteed when the maintenance intervals as stated in Chapter 7: “Maintenance and Care” are observed.
- Do not modify this equipment without authorization of the manufacturer.

1.2 Organisational Measures

- Keep this user guide in an accessible place for reference purposes.
  Make sure that it is always complete and legible.
- Observe the operating and maintenance instructions.

1.3 Indications for Use

- The device is an ECG vacuum and is operated in combination with normal ECG devices. The device is suitable for both recording resting as well as exercise ECG and is used for patients of both genders as well as all ancestries and age groups (preferably as of the age of seven, also dependent on body size).
- The device is only to be operated in a professional healthcare environment.
- The device is suitable for use inside hospitals, cardiology centres, outpatient clinics and medical practices.
- The device can safely be used with pacemaker patients.
- Always operate the device in line with the technical data indicated.
- The device is not intended for sterile use or use outdoors.
- This is a device of type BF. It is not defibrillation protected. As a safety precaution, remove the electrodes before defibrillation!

1.4 Contra-indication

- The device is not intended for sterile use.
- The device must not be used in potentially explosive areas or in the presence of flammable gases such as anaesthetic agents.
- The device is not for use in an MRI suite.

1.5 Safety-conscious Operation

- Make sure that the staff has read and understood the operating instructions, in particular this section Safety Notes.
- Do not touch the housing of the device during defibrillation.
- To ensure patient safety, none of the electrodes, including the neutral electrode, nor the patient or any person with simultaneous patient contact, must come in contact with conductive parts, even when these are earthed.
- Immediately report any changes that impair safety (including operating behaviour) to the responsible person.
- Only use accessories and disposables recommended or supplied by **mbnet Engineering GmbH**. The use of accessories or disposables from other manufacturers may result in injury, inaccurate information and/or damage to the unit.

1.6 Safe Use with Electronics

- Operating the device without the correctly rated fuse or with defective cables constitutes a danger to the life and limb of the patient or the operator!
  Therefore take note of the following:
  - The device must not be used if the power cable is damaged or suspected of being damaged.
  - Damaged cable connections and connectors must be replaced immediately.
  - Electrical safety devices, such as fuses, must not be modified.

1.7 Operation with other Devices

- If the device is part of a medical system, only the original suction hoses from **mbnet Engineering GmbH** must be connected to the device.
- Portable communication devices, HF radios and devices labelled with the symbol: (non-ionic electromagnetic radiation) can affect the operation of this device.

1.8 Maintenance

- Danger of electric shock - do not open the device! It contains no parts, which can be repaired by the user. Servicing must only be performed by qualified technicians authorised by **mbnet Engineering GmbH**.
- Switch off the device before cleaning and disconnect it from the mains.
- Do not use high-temperature sterilisation processes (such as autoclaving). Do not use e-beam or gamma radiation sterilisation.
- Do not use aggressive or abrasive cleaners.
- Do not, under any circumstances, immerse the device or cable assemblies in cleaning liquid.

1.9 Terms of Warranty

Your device is warranted against defects in material and manufacture, as stated in the Terms and Conditions. Excluded from this warranty is damage resulting from negligence or improper use. The warranty covers the free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

In case the device is defective, send it to your local **mbnet Engineering GmbH** representative or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability and performance of the apparatus if:

- assembly operations, extensions, readjustments or repairs are carried out by persons authorized by the manufacturer, and
- the device and approved attached equipment is used in accordance with the manufacturer's instructions, and
- the maintenance intervals as stated in Chapter 7: “Maintenance and Care” have been complied with.

No further guarantees are assumed. **mbnet Engineering GmbH** makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

1.10 Symbols and Pictograms

1.10.1 Symbols Used in this Document

The safety level is classified according to ISO 3864-2. The following overview shows the safety symbols and pictograms used in this user guide.

For general safety notes as listed in this section.

For electrical hazards, warnings or precautionary measures when dealing with electricity.

For possibly dangerous situations which could lead to damage to property or system failure. Important or helpful user information.

DANGER **For a possibly dangerous situation which could lead to severe personal injury or to death.**

Warning For a direct danger which could lead to severe personal injury or to death.

Caution For a possibly dangerous situation which could lead to slight personal injuries. This symbol is also used to indicate possible damage to property.

1.10.2 Symbols Used on the Device

BF-symbol, no protection against defibrillation current

Dispose of as electronic waste

Manufacturer

Date of manufacture

CE label

Refer to instruction manual

Serial number

Catalogue number

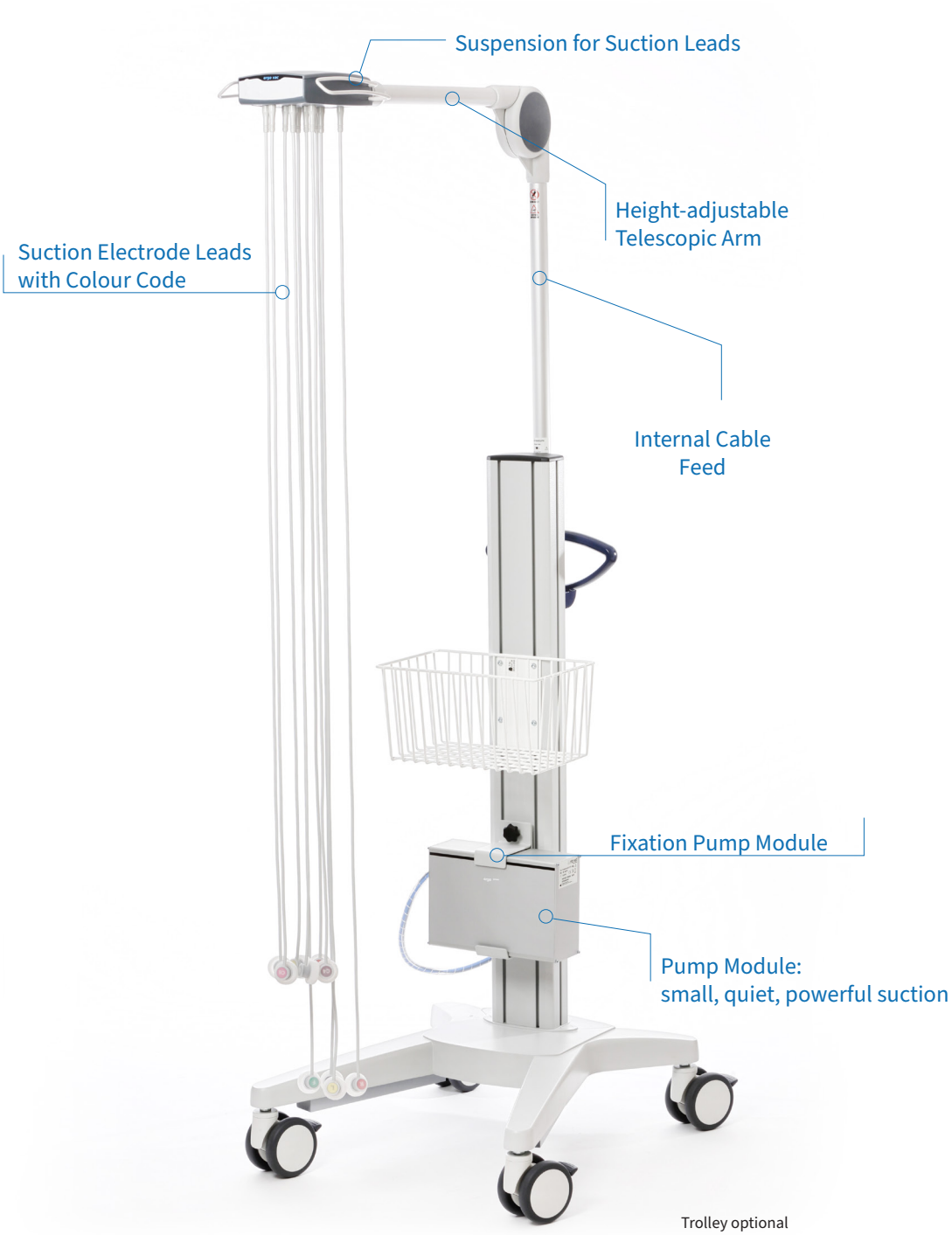
Medical Device

2 Introduction

The ergo vac is an ECG suction device for recording heart potentials during resting and stress ECGs and sending the data to the ECG device. The built-in control panel allows for easy operation and efficient configuration of the device.

2.1 Elements of the Suction Device

2.1.1 Overview



Trolley optional
(standard version w/o trolley)

2.1.2 Scope of Delivery

Standard Model

- Resting and stress ECGs
- Mains operation

Options

- Battery operation
- Trolley (with grounding cable)
- Fixation pump module on trolley

2.2 Control Box with Control Panel

What makes the control box stand out is its optimal user ergonomics. It consists of a control panel and control electronics. The control panel features white and green backlighting as well as push buttons. The control panel is easy to operate and to clean.

2.3 Suction Electrode Leads

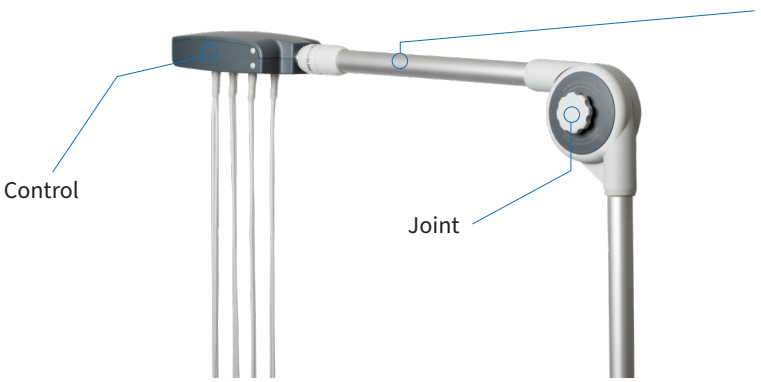
The ten shielded, interference-free electrode lines are trouble-free and stand out by virtue of their low abrasion and high flexibility.

Caution Please pay attention on the careful handling of suction leads (see 7.2.3 page 27)

2.4 Cable Arm

2.4.1 Cable arm ergo vac

The special feature of the cable arm is its hidden cable routing as well as its movable and horizontal telescopic arm.

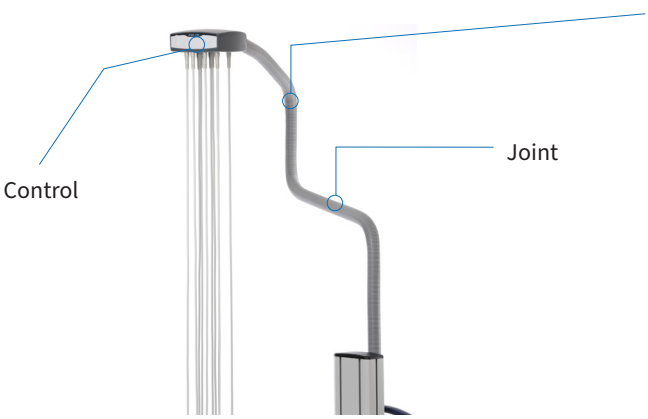


Telescopic arm Closure

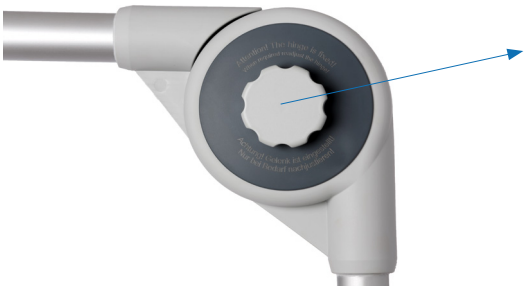
Opening and closing to insert and remove the telescopic arm.

2.4.2 Cable arm ergo vac^{LT}

As a special feature, the cable arm has a hidden cable guide as well as a swivel arm.



2.5 Joint



Caution The joint is set at the factory! Adjust only if necessary!

2.6 Pump Module

Caution

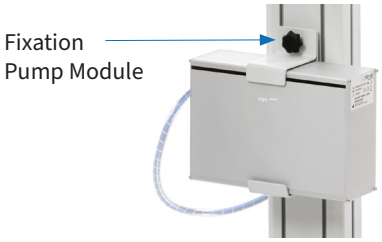
The unit may only be connected to the following devices:

- ECG devices that meet IEC 60601-1 standards.
- ECG monitors that meet IEC 60601-1 standards.
- The unit must not be connected to Class B ECG devices.
- Any connection to unauthorized hardware is at your own risk. It may also void the warranty.

2.7 Fixation Module Pump

Bracket for Pump Module ergo vac with Trolley vexio-cart.

Comment: We have a large selection of brackets (bracket can be created according to customer requirements), incl. table and wall mounts.

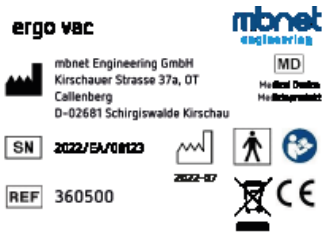


2.8 Label

2.8.1 ergo vac

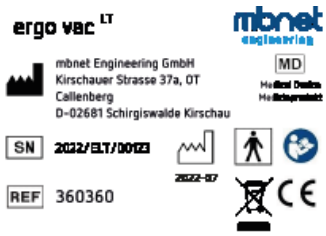
Option Mains powered

Option Battery powered



2.8.2 ergo vac[LT]

Option Mains powered



Option Battery powered

2.9 Supplied accessories for ergo vac mains, battery or ergo vac[LT]

- Cable arm with patient module
- Electrode suction hose (6 x 1.30 m / 4 x 1.50 m)
- Spacers (2 pcs with 3 rows / 2 pcs with 2 rows)
- Pump unit
- ECG-connection cable 3.7m (15pol D-Sub)
- Power cable for mains connection
- ECG Spray 250 ml
- Standard bracket
- Screw set consisting of:
  - 2 x cable ties 200mm
  - 1 x D-sub connection kit
  - 1 x cable clip, small
  - 1 x 5 mm and 1 x 2.5 mm Allen key
  - 4 x each of M6x12 / M6x16 / M6x20 Allen screw
  - 4 x each of M6 nut / M6 self-locking / M6 square nut
  - 4 x 6.3 washer / 4 x 6.37 spring washer / 4 x rubber feet
  - Operation manual

3 Operation

3.1 Getting Started

HAZARD

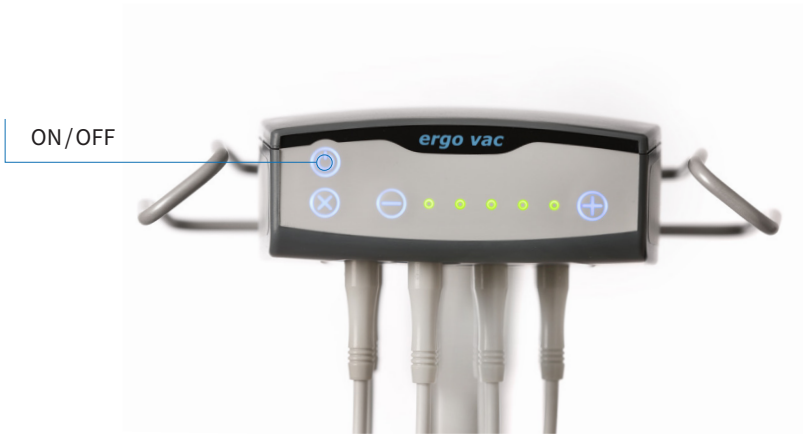
Electric shock hazard. The device must not be used if it is not properly grounded or the power cable is damaged or suspected to be damaged.

Location

- The device must not be stored or operated in a wet, humid or dusty area. It must also not be exposed to direct sunlight or heat from other sources.
- The device must not come into contact with acids or acidic fumes.
- The device should not be placed in the vicinity of X-ray, hf surgical equipment, diathermy units, large transformers or electric motors.

3.2 On / Off

- The unit is switched on and off with the ⏻ button. When pressing the ON button, the electrode can be sucked to the skin of the patient by applying light pressure with the fingers.



- Turn off the unit when not in use for a longer time.

Warning

Never apply suction when the electrodes are in a cleaning fluid.

- When pressing the ⊗ button, the suction pump creates a vacuum for about 5 seconds and then turns off automatically.

3.3 Power Supply

3.3.1 Displays for Mains or Battery Power

The unit can be connected to the mains or be supplied from the built-in battery (option).
In both modes the ⏻ button on the control panel will light up.

- **Battery Life (Option):**
  - The internal battery provides power for up to 2 hours of continuous use.
- **Battery being charged:**
  - A completely depleted battery takes about 3,5 hours to fully charge (when power is off). If the device is switched on during charging, the charging time may be around 4 hours.

    The battery is charged when the device is connected to the mains. The device can remain connected to the power grid without causing damage to the device or battery.
- **Recharging Times:**
  - Battery recharging time if depleted: about 3,5 hours if the unit is not in use
  - Charging time when in use: about 3,5 hours

3.3.2 Isolation from Power Grid

To isolate the device and the power supply from the mains, pull the power plug.

⚠ Caution

To prevent a deep discharge of the battery (battery charge level below 10 %), the pump is automatically deactivated. This protective function is carried out in battery mode -> mains switch off / battery charging switch on.

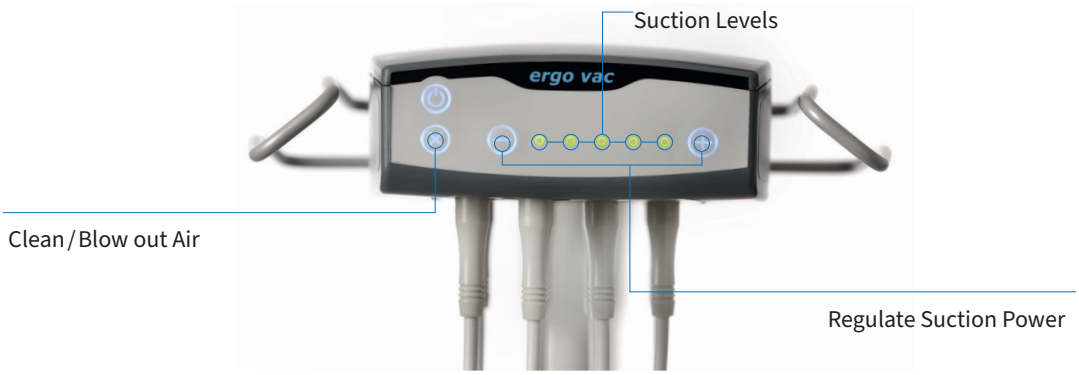
- Please note that the LED indicators on the display continue to light up when the battery charge level is at a minimum. However, the corresponding functions of the keys can no longer be carried out due to the low charge state of the battery!
- For this reason, connect the unit to the mains supply when the battery is low in order to ensure that the battery is charged and the suction system functions via mains operation. Ensure that both the battery charging switch and the mains switch on the pump module are switched on.

In the event of a battery defect, the system can continue to operate in mains operation. To do this, switch off the battery charging switch. The mains switch must be switched on in this case.

Contact the service department to rectify the battery fault!

4 Controls

The controls are located on the front of the control box and control the entire suction system.



4.1 Suction Levels

The system‘s suction lines can be individually adjusted for each patient using 5 suction levels. When the unit is turned on, it activates an average default level. The current suction level is indicated by the green LEDs on the control panel. The highest level should only be used in extreme cases (a lot of body hair).

The suction level must in each case be adjusted to the patient‘s skin type!

Warning

- The device must not be used in case of injured skin. Strong suction or long-term exposure to suction may result in hematomas! Particular caution is especially required with older patients. The operator of the unit should ask the patient how he or she feels!
- The electrodes should not be applied to the skin of the patient for more than **25 minutes.**

4.2 Blowing out Air

When pressing the ⊗ button, the suction unit will be blown out with compressed air for about 5 Minutes and then turned off automatically.

4.3 Cleaning

When the system is in standby mode, it can blow out the air from the suction lines by pressing the cleaning button. The cleaning is stopped by pressing the ⏻ button or automatically after 5 MInutes. The system then reverts back to standby mode.

Warning

- Never apply suction when the electrodes are in a cleaning fluid.

5 Possible Errors during Operation

Warning

- Ensure that neither the patient nor the leading parts of the patient connection nor the electrodes (including the neutral electrodes) come in contact with other persons or conductive objects (even when these are earthed.).

5.1 Placement of Electrodes

Careful application of the electrodes and good electrode contact is important for a good transmission of the heart electrical currents.

Therefore, please note the following points:

5.1 Placement of Electrodes

1 Only use electrodes that are recommended by **mbnet Engineering GmbH.**

2 To increase the electrode's conductivity and adherence:

- Shave the areas where the electrodes are to be placed, if necessary.
- Thoroughly clean the areas with alcohol or soapy water
  (skin cream is often applied above all during the winter as this will increase electrode resistance enormously(!) – Always COMPLETELY remove skin cream at the application sites!).
- Let the skin dry thoroughly before you apply the electrodes.

3 Check the electrode resistance.

4 If the electrode contact is higher than the acceptable level:

- Remove the electrode and use an abrasive cleaning pad or abrasive cleaning gel to remove the uppermost layer of epidermis.
- Apply the electrode.

5 After the recording, remove the electrodes by pressing on the cleaning button.
Clean the suction or vacuum electrodes according to the manufacturer's instructions.

* Dedicated abrasive cleaning gel gives very good results in reducing the skin-electrode resistance.

5.2 Possible Sources of Errors with the ECG Recording

5.2.1 Preparation

If you are using new electrodes or those, which have not been used for a long time and have therefore dried out, first stabilise the electrodes by placing them for at least three hours in a 1% salt solution (NaCl solution).

IMPORTANT: Use only pure NaCl and distilled or deionised water for this. No tap water! Do not use physiological salt solution from a pharmacy! This contains additives, which can damage the electrodes!

5.2.2 Application of Electrodes

The areas of skin to which the electrodes will be applied must be clean and dry. Use an electrolyte ECG spray, which contains soluble chloride.

- Do not use ECG gel! Only ECG spray!
- Remove any skin cream!

5.2 Possible Sources of Errors with the ECG Recording

5.2.3 During the Recording

Suction hoses must under no circumstances pull/tear/stretch the electrodes, but must hang freely!

Under no circumstances must the electrodes be applied on the patient's skin for longer **than 25 minutes** (risk of blisters forming)!

5.2.4 Removal of Electrodes from the Skin

Do not pull on the electrode cables, but touch the electrode carefully at the edge or activate the blow-out function at the suction unit (⟶ The electrodes will then fall off on their own accord)!

5.3 Electrode Identification and Colour Code

The electrode colour codes in this section correspond to Code 1 (IEC).
Below you will find the corresponding colour codes in accordance with Code 2 (AHA).

	IEC		AHA	
	IEC label	Colour	AHA label	Colour
Extremity	R L F	red yellow green	RA LA LL	white black red
Chest according to Wilson	C1 C2 C3 C4 C5 C6	white/red white/yellow white/green white/brown white/ black white/purple	V1 V2 V3 V4 V5 V6	brown/red brown/yellow brown/green brown/brown brown/black brown/purple
Neutral	N	black	RL	green

6 Application

Caution

- Do not take an ECG picture until you have read and understood the safety instructions at the beginning of these instructions for use.
- The device is a BF type device.
- During ECG recording, make sure that neither the patient- nor the conductive parts of the patient connection or the electrodes (including the neutral ones) come into contact with other persons or conductive parts (even if they are grounded).
- The device must not be used if the mains connection cable is damaged or there is a suspicion of damage.

6.1 Operating Conditions

Caution

- The device is not suitable for continuous operation; switch off again after use.
- High-frequency fields and radiation can influence the quality of ECG leads..

The device can be operated under the following environmental conditions:

- Ambient temperature: +10 °C and +50 °C
- Relative humidity: between 30 % and 75 % (non-condensing)
- Air pressure: between 700 hPa and 1060 hPa

6.2 Starting a Recording

1 Preparing the patient

2 Switch on device and apply electrodes ⏻

3 Ask the patient about their well-being (note the suction strength of the electrodes)

4 Determine and adjust suction strength ⊕ / ⊖

- The lower the pressure level, the better the skin tolerance!

  Level 1 & 2: for smooth skin **Level 4:** for medium-hairy skin

  Level 3: for lightly-hairy skin **Level 5:** for very hairy skin

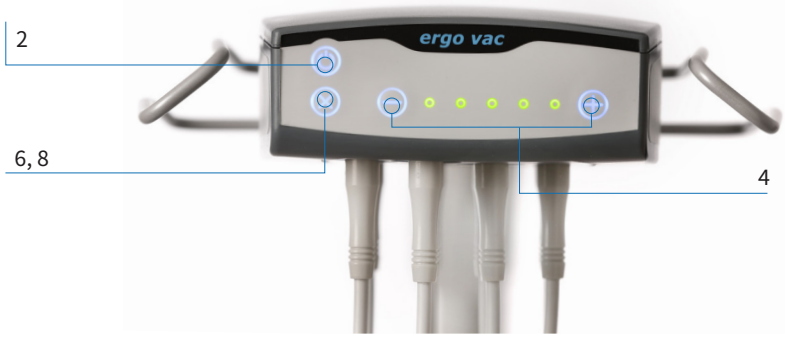
5 Performing a measurement

6 Switch off the vacuum pump with the ⏻ button, the electrodes detach from the patient.

7 The system switches off automatically after 30 seconds.

8 (Optional) After long periods of use and/or heavy perspiration by patients, the system can blow out air for a longer time by the pressing of the cleaning button. ⊗

9 Cleaning the electrodes (See Chapter 7.2.1 page 21)



7 Maintenance and Care

The device requires regular checks (Chapter 7.5). The test results must be recorded in writing and compared to the values in the accompanying documents.

Maintenance work not described in this section may only be performed by a qualified, authorised technician.

The following table indicates the intervals and responsibilities of the maintenance work required. Local regulations in your country may stipulate additional or different inspection intervals and tests.

Interval	Maintenance step	Responsible
Before every use	■ Visual inspection of the device and ECG electrodes	User
Every 6 months	■ Visual inspection of the device (see page 29, 7.5 Inspection report) - Cables and accessories - Mains cable ■ Functional tests according to the instructions (see page 29, 7.5 Inspection report)	User

The useful life of the device electrodes is estimated to be 2 years.

7.1 Visual Inspection

Visually inspect the unit and cable assemblies for the following:

- Device, housing and mains cable (not damaged or cracked)
- Keypad (not damaged or cracked)
- Electrode cable sheathing and connectors (undamaged)
- No cracks, abrasion or wear in any cable assembly
- Input/output connectors (not damaged or cracked)

In addition to the visual inspection, the device should be switched on and the functions of the operating field should also be checked. In this way, you can check that:

- the device performs faultlessly
- the display works

Warning Defective units or damaged cables must be replaced immediately.

7.2 Cleaning the Housing and Cables

Warning

Switch off the device before cleaning and disconnect it from the mains. Do not, under any circumstances, immerse the device in cleaning liquid and do not sterilise it with hot water, steam or air.

Caution

- Do not autoclave the unit or any accessories.
- Do not immerse the device in liquid.
- The use of detergents with a high acid content or detergents that are otherwise unsuitable can damage the device (i.e. cracks and wear of the plastic housing).
- Always follow the dilution instructions provided by the manufacturer of the cleaning solution.
- Never use any of the following or similar cleaning products: Ethyl alcohol, ethanol, acetone, hexane, abrasive or scouring powder or material, any cleaning material that damages plastic.
- The patient cable and other cable assemblies must not be exposed to excessive mechanical stress. Whenever disconnecting the leads, hold the plugs and not the cables. Store the leads in such a way as to prevent anyone stumbling over them or any damage being caused by the wheels of medical equipment carts.
- When cleaning, ensure that all labels and safety statements, whether etched, printed or stucked to the device, remain in place and remain readable.

Thoroughly inspect the device and the accessories before cleaning.

- Look for any signs of damage and make sure that the buttons and connectors work correctly from a mechanical perspective.
- Gently bend and flex cables, inspecting them for damage or extreme wear, exposed wires and bent connectors.
- Confirm that all connectors engage securely.

The housing of the device and the cable assemblies can be cleaned with a cloth slightly moistened (not wet) on the surface only. If necessary, a domestic non-caustic cleaner or a 70 % alcohol solution can be used to remove grease stains and finger prints.

Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions (see Chapter 7.2.5 page 27). Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, switches or gaps. If liquid gets into connectors, dry the area with warm air and then check that the device operates properly.

7.2.1 Cleaning and Storing the Electrodes

Caution

- NEVER use metallic or sharp items to clean the electrodes.
  This could damage them irreparably.
- Make absolutely sure that the suction unit is operating in cleaning mode when you immerse the electrode into the cleaning liquid ⊗.
  Incorrect operation and vacuuming of cleaning liquid could mean that the device is irreparably damaged.
- Remove all impurities on the surface of the electrode immediately after use. You can use a dry handkerchief or soft toothbrush for this (or the **product SaniCloth**®).

Do not let any impurities dry on the electrode!

Do not use any 100% alcohol!

Do not use any tap or bottled drinking water!

Do not use any other soap solutions or abrasive cleaning products!

- Light will cause a brown to black coating on the surface of the electrode as a result of the oxidation of the silver. This can be wiped off with a mild ammonia solution or by gentle rubbing with a microfibre cloth or an extremely fine sandpaper (at least 200 grain).

Store the electrodes somewhere dry and dark when they are not being used!

Do not expose the electrodes permanently to the light because otherwise they will turn black!

- Electrodes can be damaged or soiled with only small quantities of bromides, sulphides and a few other metallic ions.

No contact with metals (bromides, sulphides etc.)!

7.2.2 Recommended Cleaning and Disinfection Methods for Electrodes

- **Wiping disinfection / cleaning:** to be carried out after every use
- **Intensive wiping disinfection / cleaning:** 1x daily after the last use (**OR: when required)**
- **Immersion disinfection, cleaning / drying:** 1x weekly after the last use (**OR: when required)**

⚠ Caution This cleaning method can damage the suction unit if not carried out correctly.

Instructions for Wiping Disinfection / Cleaning

1. Use only the disinfectants mentioned in Point 7.3.1.
2. Clean / disinfect all areas of the electrode, which have come into contact with the patient.

Electrode suction dome outside, grip area / suction area

Diagram 1:
Suction dome cleaning outside

Cleaning of the electrode contact surface

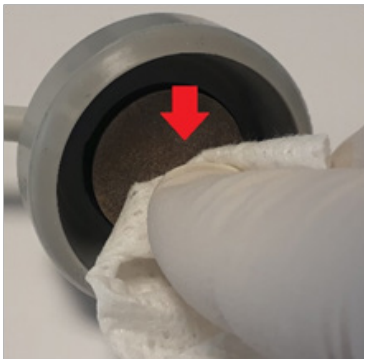


Diagram 2:
Clean contact surfaces

Electrode suction dome inside, sealing lip, electrode body / suction dome, suction area

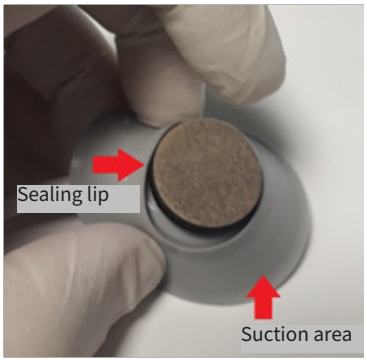


Diagram 3:
Suction dome cleaning inside

Attention: if the inside is cleaned incorrectly, particles (skin flakes, contact product residues) can remain in the area of the sealing lip (see Diagram 3).

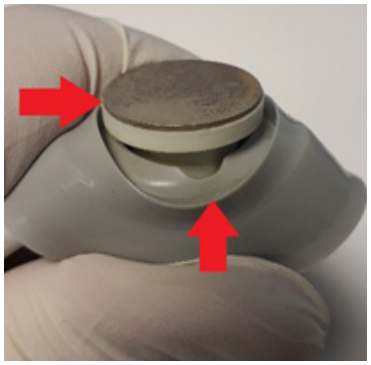


Diagram 4:
Impurities (electrode)

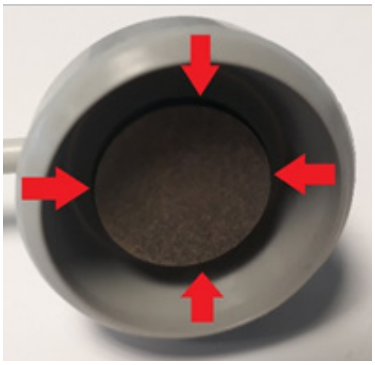


Diagram 5:
Check the position of the suction dome on the electrode housing

i After cleaning, check the optimal fit of the suction dome on the electrode housing to ensure the suction electrode functions optimally.

Instructions: Intensive Wiping Disinfection / Cleaning

1. Use only the disinfectants mentioned in Point 7.3.1.
2. Clean / disinfect all areas of the electrode, which have come into contact with the patient.

Electrode suction dome outside, grip area / suction area

Diagram 6:
Suction dome cleaning outside

Cleaning of the electrode contact surface

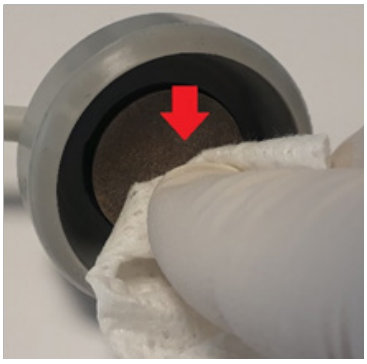


Diagram 7:
Clean contact area (electrode)

Cleaning the inside of the electrode suction dome, sealing lip, electrode body / suction dome / suction area

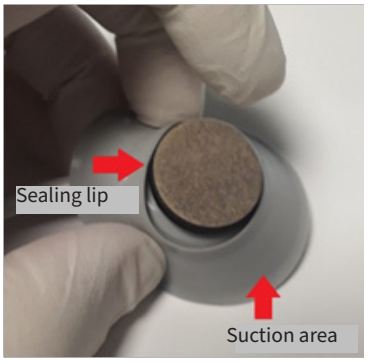


Diagram 8:
Suction dome cleaning inside

Pull off the silicone suction dome from the electrode housing (in the direction of the arrow). Then clean the inside of the suction dome and the electrode housing.

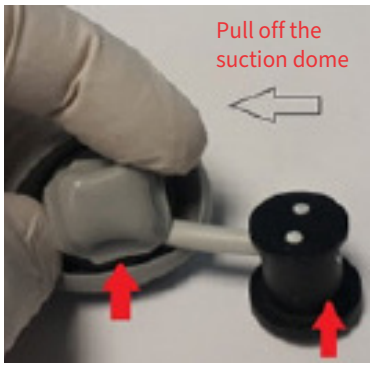


Diagram 9:
Remove the suction dome

Replace the suction dome after it has been cleaned back on the electrode housing.

After cleaning, check the optimal fit of the suction dome on the electrode housing to ensure the suction electrode functions optimally.

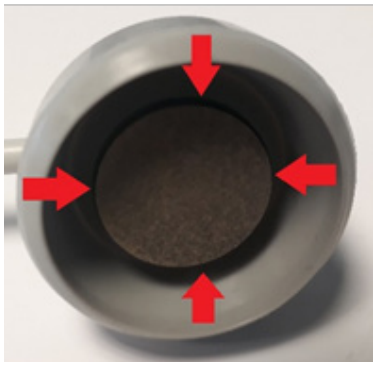


Diagram 10:
Check the position of the suction dome on the electrode housing

Immersion Disinfection and Subsequent Cleaning and Drying

Caution

This cleaning method can damage the suction unit if not carried out correctly.

1. Switch off the suction unit. ⏻
2. Position the container for the cleaning liquid in such a way that no medical equipment can be become wet from drops of liquid.
3. Pull off the silicone suction dome from the electrode housing.

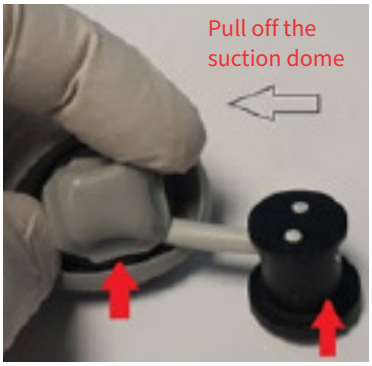


Diagram 11:
Remove the suction dome

4. ONLY immerse the electrode and the suction dome in a container with an admissible disinfectant (Point 7.3.1 page 28)

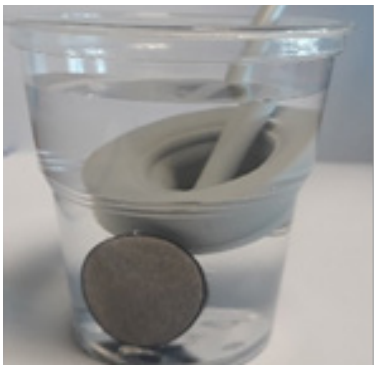


Diagram 12:
Immersion disinfection

5. Prevent any cleaning liquid from dripping by taking suitable measures (cloth, container to catch drips).
6. Activate the blow-out button on the suction unit. ⊗

Activate this function twice in a row. If the blow-out function is not activated correctly, it cannot be ruled out that cleaning liquid will flow over the electrode suction hose into the suction device.

Diagram 13:
Blow-out/ cleaning key

7. Remove any cleaning liquid that has spilt with a suitable cloth.

If some cleaning liquid remains on the electrode, it can discolour the contact surface.

Diagram 14:
Error image -
discolouration of the electrode

8. Replace the suction dome back onto the electrode housing after cleaning.

After cleaning, check the optimal fit of the suction dome on the electrode housing to ensure the suction electrode functions optimally.

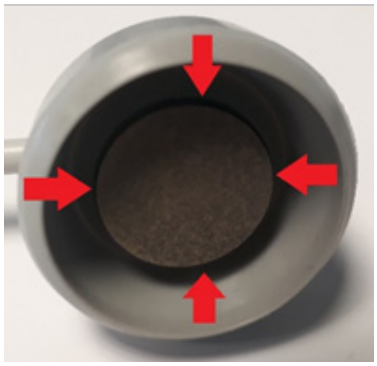
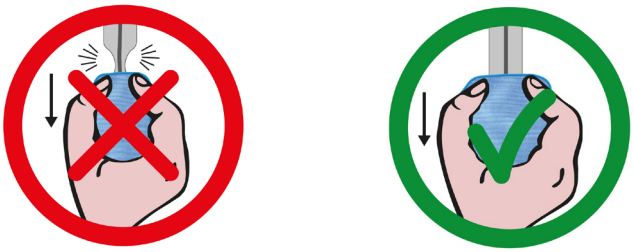


Diagram 15:
Check the position of the suction dome on the electrode housing

7.2.3 Cleaning the Suction Hoses

UNDER NO CIRCUMSTANCES pull on the suction hoses during cleaning (risk of breaking the cable)!



You MUST also instruct your temporary staff and the responsible cleaning staff on this matter!

7.2.4 Cleaning Connection Cables

1 Check the cable before cleaning for any damage. Gently bend all the parts of the cable. Inspect the cable insulation for cracks, damage or extreme wear, exposed wires and bent connectors.

2 Wipe the equipment with a cloth slightly moistened (not wet) with one of the approved cleaning solutions; the approved cleaning solutions are listed below.

3 Hold the cable with the cloth in the middle of the cable; wipe 20 cm of the cable at a time with the cloth until the entire cable is clean. Never clean the cable along its entire length at once as this can lead to damage to the cable insulation.

4 Thoroughly wipe off any excess cleaning solution. Do not let the cleaning solution run into or accumulate in connector openings, switches or gaps. If liquid still reaches the connector openings, dry them with hot air.

7.2.5 Admissible Detergents

- 50 % isopropanol (Isopropyl alcohol)
- neutral, mild detergent (for example: "**SaniCloth**®" and "**mikrozid universal wipes**®")
- all products designed for cleaning plastic

7.2.6 Non-admissible Detergents

Never use products containing the following:

- Pure, 100 % aliphatic, monovalent alcohols, such as ethyl alcohol, ethanol, ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

7.3 Disinfection

Disinfection removes certain bacteria and viruses. Please refer to the manufacturer's information. Use commercially available disinfectants intended for clinics, hospitals and medical practices.

Disinfect the device in the same way as described for cleaning the device in Chapter 7.2 page 22.

7.3.1 Admissible Disinfectants

- Isopropanol (50 %)
- Propanol (35 %)
- Aldehyde (2 – 4 %)
- Ethanol (50 %)
- all products that are suitable for sensitive surfaces, such as:
- Bacillol® 30 foam / Bacillol® 30 Tissues (10% Propanol-1, 15% Propanol-2, 20% Ethanol)
- Mikrozid® AF (25% Ethanol, 35% 1Propanol-1)

7.3.2 Non-admissible Disinfectants

- Organic solvents
- Ammonia-based detergent
- Abrasive cleaning agents
- 100% alcohol, Virex, Sani-Master
- HB Quat®
- Conventional detergents (e.g. Fantastic®, Tilex® etc.)
- Conductive solutions
- Solutions or products containing the following ingredients:
    - Acetone
    - Ammonium chloride
    - Betadine
    - Chlorine, wax or wax compound
    - Ketone
    - Sodium salt

7.4 Battery

- No maintenance is required for the battery.
- Depending on use, the battery should be replaced about every 4 years or if the battery life falls significantly below 1 hour.
- As long as the device is not in use, you should make sure that the battery is not completely depleted. Should the device not be used for more than three months, the battery must be protected from complete discharge by recharging it.

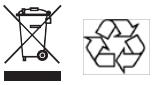
7.4.1 Charging the Battery

A completely depleted battery takes about 3.5 hours to fully charge (when power is off). If the device is switched on during charging, the charging time may be longer.

The device can stay connected to the power grid without risk to the battery.

Connect the device to the power grid.

7.4.2 Battery Disposal



The battery must be brought to a recycling center in accordance with the relevant regulations of a country or sent back to **mbnet Engineering GmbH**.

Warning

- Danger! Risk of explosion! The battery must not be incinerated or treated as municipal waste.
- Danger! Acid-burn risk! Do not open the battery under any circumstances.

7.5 Inspection Report

- The user guide must be read before the inspection
- Recommended **inspection interval: every 6 months**

Test	Results	Date				
Serial number:						
Visual inspection (external condition)	■ Housing not damaged	☐	☐	☐	☐	☐
	■ Electrode connector port not damaged	☐	☐	☐	☐	☐
Availability & condition of accessories	■ ECG suction hoses	☐	☐	☐	☐	☐
	■ User guide	☐	☐	☐	☐	☐
	■ Mains cable	☐	☐	☐	☐	☐
Functional test ■ Switch on device	■ Mains cable	☐	☐	☐	☐	☐
■ Suction strength control	■ Functions properly	☐	☐	☐	☐	☐
Remarks:						
Inspection carried out by:						

* In case of a defect, please contact the service department of your hospital, your **mbnet Engineering GmbH** representative or the local after-sales service:

(Name) ..... (Telephone) .....

Replacement of Parts with a Limited Life, every 3 – 5 years

Inspection	Results	Replacement				
Internal battery Replace the internal battery if its operating time falls significantly below 1 hour.	Device sent to **mbnet Engineering GmbH** to replace the battery.	☐	☐	☐	☐	☐
	Replaced on:					
	The controller					

7.6 Accessories and consumables

Warning

Always use **mbnet Engineering GmbH** spare parts and disposables or products approved by **mbnet Engineering GmbH**. Failure to do so may invalidate the warranty.

Your local representative stocks all the disposables and accessories available for the ergo vac. In case of difficulty, contact our head office. Our staff will be pleased to help process your order or to provide information on all **mbnet Engineering GmbH** products.

Art. no.:	Article
303 230	ECG Leads, Set of 10 leads (6 x 1.30 m / 4 x 1.50 m)
303 220	C1, 1.30 m
303 221	C2, 1.30 m
303 222	C5, 1.30 m
303 223	C4, 1.30 m
303 224	C5, 1.30 m
303 225	C6, 1.30 m
303 207	F, 1.30 m
303 208	L, 1.30 m
303 209	N, 1.30 m
303 210	R, 1.30 m
303 231	C1, 1.50 m
303 232	C2, 1.50 m
303 233	C3, 1.50 m
303 234	C4, 1.50 m
303 235	C5, 1.50 m
303 236	C6, 1.50 m
303 226	N, 1.50 m
303 227	L, 1.50 m
303 228	N, 1.50 m
303 229	R, 1.50 m
300 109	ECG Label for ECG Single Lead C1 - C6, F, N, L, R (set)
300 301	Spreader for ECG Single Leads (set)
300 400	ECG electrode contact spray
303 216	Suction Lead, Neutral, 1.30 m
303 217	Suction Lead, Neutral, 1.50 m

7.7 Replacement of ECG Leads

The ECG leads may be replaced as a whole (10 leads in total) or as single lead. When replacing the whole set of 10 ECG leads into the connector of the head the sequence of connecting the ECG leads (C1, C2, …., N, F, L, R) does not matter.

8 Troubleshooting

8.1 Possible Errors

Error	Possible Causes & Indications	Error Localization & Troubleshooting
Pump is not working (no audible noise)	■ Loose connecting plug at pump ■ No Power	■ Firmly push in connecting plug
Pump is working, but there is no suction	■ Loose hose connection at pump or leaking hose ■ Hoses are kinked or pinched	■ Check hose connection for tight fit ■ Eliminate cause
Weak suction	■ Leaking hose connection at pump ■ Loose suction line in control box ■ Leaking suction line	■ Check hose connection for tight fit ■ Eliminate cause
Pump is working, but there is no or little suction, electrodes are falling off during cardiac stress test	■ Suction cups not seated properly on electrode element ■ Suction cup hose attachment twisted or rolled up ■ Dirty electrode elements or suction cups	■ Firmly seat suction cup over electrode element ■ Electrode elements and suction cups
Battery is totally depleted	■ Prolonged time of non-use	■ Device minimum: 3.5 hours connected to power grid
Battery is defective and / or doesn‘t work	■ Battery life has been exceeded	■ Contact customer service

Should these tips be of no help in fixing the problem, please call your **mbnet Engineering GmbH** dealer or directly contact **mbnet Engineering GmbH**.

Please have your model name and serial number ready. They are listed on the type label on the pump housing.

8.2 Preventing Electromagnetic Interference

The user can help avoid electromagnetic disturbances by keeping the recommended minimum distance between portable and mobile HF telecommunication devices (transmitters) and the unit. The distance depends on the output performance of the communication device as indicated in the table below.

* “Non ionising electromagnetic radiation”

HF source Wireless communications devices	Transmitter frequency (MHz)	Testing frequency [MHz]	max. power P (W)	Distance d (m)
Various radio services (TETRA 400)	380-390	385	1.8	0.3
Walkie-talkie (FRS) Rescue service, police, fire brigade, servicing (GMRS)	430-470	450	2	0.3
L TE band 13/17	704 – 707	710 / 745 / 780	0.2	0.3
GSM800 / 900 LTE band 5 Radio telephone (micro cellular) T1+, CT2,CT3	800-960	810 / 870 / 930	2	0.3
GSM1800/1900 DECT (radio telephone) LTE band 1/3/4/25 UMTS	1700 – 1990	1720 / 1845 / 1970	2	0.3
Bluetooth, WLAN 802.11b/g/n LTE band 7 RFID 2450 (active and passive transponders and reading devices)	2400 – 2570	2450	2	0.3
WLAN 802.11a / n	5100 – 5800	5240 / 5500 / 5785	2	0.3

Caution

- Portable HF telecommunication devices must not be used within a radius of 0.3 m from the device and its cables.
- Do not place the device on top of other electric/electronic devices - i.e. maintain a sufficient distance to other devices (this includes the patient cables).

For permanent HF telecommunication devices (e.g. radio and TV), the recommended distance can be calculated using the following formula:

$d = 1.2 \times \sqrt{P}$ for 150 kHz up to 800 MHz and $d = 2.3 \times \sqrt{P}$ for 800 MHz up to 2.5 GHz

d = recommended minimum distance in metres
P = transmitting power in Watts

The user can take the following measures to prevent electromagnetic interference:

- Increase the distance to sources of interference
- Turn the device and thereby change the angle of the radiation
- Connect a potential equalisation cable
- Connect the device with another network connection
- Use only original accessories

Near strong electromagnetic fields (MRT, radio, etc.) it is possible that the device will turn off by itself or change the suction strength.

Then simply switch the device on again and / or regulate the suction strength again according to your needs.

9 Technical Data

9.1. Pump Module

Dimensions	245 x 170 x 82 mm
Weight	Pump Module without accumulator: 2.4 kg Pump Module without accumulator: 3.5 kg
Power Supply Power Consumption Fuse	100 – 240 VAC 30 VA 2 x T1.6A/250V
Battery (Option) Lifetime Charging time to 100 % Charging time in use	lead battery approx. 800 charging cycles approx. 3.5 hrs. (if device is out of operation) approx. 3.5 hrs.
Ambient conditions Operating temperature Relative air humidity Air pressure during operation	10 to 50 °C, storage 10 to 40 °C 30 to 75 % (non-condensing) 700 to 1060 hPa
Low pressure	0 - 500 mbar
Air flow	0 - 5.5 l/min

9.2 System Cable

System cable	1.9 m
ECG connection	15-channel in accordance with IEC Standard Norm
Control cable	1.5 m
Hose	1.5 m

9.3 Electrodes

Material	sintered Ag/AgCI, silicone suction cup

9.4 Cable Arm ergo vac and (ergo vac^{LT})

Length	760 to 1060 mm (between 505 bis 945 mm)
Height	620 mm (835 mm)
Pivot range	300° (270°)

9.5 Safety Standards

Safety standard	IEC/EN 60601-1
EMC	IEC/EN 60601-1-2
Compliance / Classification	CE/I in accordance with Regulation 2017/745/EU
Protection	This device is not intended for outdoor use (IPX0)

10 EMC information

The unit meets the Collateral Standards of Electromagnetic compatibility – Requirements and tests IEC/EN 60601-1-2 the limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical radio frequency equipment.

Medical electrical equipment is subject in regard to the electromagnetic compatibility (EMC) and its special precautionary measure. The unit must in reference to the mentioned EMC-hints in the accompanying documents be installed and operated.

This medical device is intended for use in the electromagnetic environment specified in the following tables. The user of this device should ensure that it is used in such an environment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The ergo vac is intended for use in the electromagnetic environment specified below. The customer or the user of the ergo vac should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ergo vac uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ergo vac 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	Complies inherently	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies inherently	

10.1 Table 1: Immunity (all devices): electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic immunity			
The ergo vac is intended for use in the electromagnetic environment specified below. The customer or the user of the ergo vac should assure that it is used in such an environment.			
Immunity test standard	**IEC 60601 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 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 lines IEC 61000-4-11	<5% U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	<5% U_T (0,5 cycle) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A / m	200 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

10.2 Table 2: Immunity: electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The ergo vac is intended for use in the electromagnetic environment specified below. The customer or the user of the ergo vac should assure that it is used in such an environment.			
Electromagnetic environment - guidance			
Portable and mobile RF communications equipment should be used no closer to any part of the ergo vac, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity test standard	**IEC 60601 test level**	**Compliance level**	**Recommended separation distance [c]**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1 = 10 Vrms 150 kHz to 80 MHz	$d = 0.35\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	E1 = 10 V/m 80 MHz to 800 MHz	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 0.8 to 2.5 GHz	E2 = 10 V/m 800 MHz to 2.7 GHz	$d = 0.7\sqrt{P}$ 0.8 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 metres (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.			
a Field strengths from fixed 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 ergo vac is used exceeds the applicable RF compliance level above, the ergo vac should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ergo vac.			
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			
c Possible shorter distances outside ISM bands are not considered to have a better applicability of this table.			

10.3 Table 3: electromagnetic immunity

Recommended separation distances (not life-supporting devices)

Recommended separation distances between portable and mobile RF communications equipment and the ergo vac

The ergo vac is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ergo vac can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ergo vac as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2500 MHz $d = 0.35\sqrt{P}$
0.01	0.04 m	0.04 m	0.07 m
0.1	0.12 m	0.12 m	0.22 m
1	0.35 m	0.35 m	0.7 m
10	1.2 m	1.2 m	2.2 m
100	3.5 m	3.5 m	7 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for 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: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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