Small.
Easy to use.
Powerful.

The compact all-in-one solution

handy vaq

User guide

Art.-no.: 350 327 Ver.: h

mbnet engineering

Sales and Service Information

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

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

handy vaq 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.

Date of issue: 19.09.2025

mbnet Engineering GmbH
Kirschauer Strasse 37a
OT Callenberg
D-02681 Schirgiswalde-Kirschau

Telefon +49 (0)3592 34
Telefax +49 (0)3592 34
E-Mail info@mbnet.de
Internet www.mbnet.de

Art.-no.: 350 327 Ver.: h
Date of issue: 19.09.2025
Original

Table of Contents

1 Safety Notes ... 4

1.1 Responsibility of the User ... 4
1.2 Organisational Measures ... 4
1.3 Indications for Use ... 4
1.4 Contra-indication ... 4
1.5 Safety-conscious Operation ... 5
1.6 Safe Use with Electronics ... 5
1.7 Operation with other Devices ... 5
1.8 Maintenance ... 5
1.9 Terms of Warranty ... 6
1.10 Serious incidents ... 6
1.11 Symbols and Pictograms ... 7
1.11.1 Symbols Used in this Document ... 7
1.11.2 Symbols Used on the Device ... 8

2 Introduction ... 9

2.1 Components of the Suction Device ... 9
2.2 Suction Device ... 10
2.3 Suction Hoses ... 10
2.4 Label ... 10
2.5 Scope of Delivery handy vaq ... 11

3 Operation ... 11

3.1 Initial Operation and Location ... 11
3.2 Connection ... 12
3.3 Application ... 12
3.4 Operating Conditions ... 13
3.5 Operation and Operating Components ... 13
3.5.1 Display ... 13
3.5.2 Application of the Suction Electrodes ... 13
3.5.3 Suction Settings ... 14
3.5.4 Ending the Measurement ... 14
3.5.5 Cleaning and Disinfecting ... 14
3.5.6 Blow-out Function ... 14

4 Possible Errors during Operation ... 15

4.1 Electrode Placement ... 15
4.2 Possible Sources of Errors with the ECG Recording ... 16
4.2.1 Preparation ... 16
4.2.2 Application of Electrodes ... 16
4.2.3 Before the Recording ... 16
4.2.4 Removal of Electrodes from the Skin ... 16
4.3 Electrode Identification and Colour Code ... 17

5 Maintenance and Care ... 17

5.1 Visual Inspection ... 18
5.2 Cleaning the Housing and Cables ... 18-19
5.2.1 Cleaning and Storing Electrodes ... 19
5.2.2 Recommended Cleaning and Disinfection Methods for Eletrodes ... 20
5.2.3 Cleaning Suction Hoses ... 25
5.2.4 Cleaning Connection Cables ... 25
5.2.5 Admissible Detergents ... 25
5.2.6 Non-admissible Detergents ... 25
5.3 Disinfection ... 26
5.3.1 Admissible Disinfectants ... 26
5.3.2 Non-admissible Disinfectants ... 26
5.4 Inspection Report ... 27
5.4.1 Accessories and Consumables ... 28
5.4.2 Replacement of ECG Leads ... 28

6 Trouble Shooting ... 29

6.1 Possible Problems ... 29
6.2 Preventing Electromagnetic Interference ... 29-30

7 Technical Data ... 31

7.1 Technical Data ... 31
7.2 Safety standards ... 31

8 EMC information ... 32

8.1 Table1: Immunity (all devices): ... 33
8.2 Table 2: Immunity: (devices that are not life-supporting) ... 34
8.3 Table 3: electromagnetic immunity ... 35

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 have 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 5: "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.
- Do not use the device in immediate proximity to strong electromagnetic sources (e.g., RFID gates).
- This is a device of type BF. It is not defibrillation protected. As a safety precaution, remove the electrodes before defibrillation!
- The device is intended for use only with power supply networks of 220–240 V AC. Use outside this range is not permitted. EMC compliance has been assessed for this voltage range.

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 have 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 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 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 5: "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 Serious incidents

If a serious incident occurs in connection with the handy vaq, it must be reported to both mbnet engineering GmbH and the competent national authority of the country in which the user and/or patient is located.

1.11 Symbols and Pictograms

1.11.1 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.

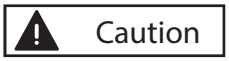
For general safety notes as listed in this section.

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.

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

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



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

1.11.2 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

Lot number

Catalogue number

Medical Device

2 Introduction

The handy vaq is probably the smallest ECG suction device on the market. The quiet, high-performance and maintenance-free pump is integrated directly into the compact control housing.

The light device can be held securely in one hand owing to the side anti-slip inserts.

Despite its compact design, if offers an impressive range of functions. Handy vaq has just three buttons to ensure it is easy and convenient to operate and to control its five vacuum power settings.

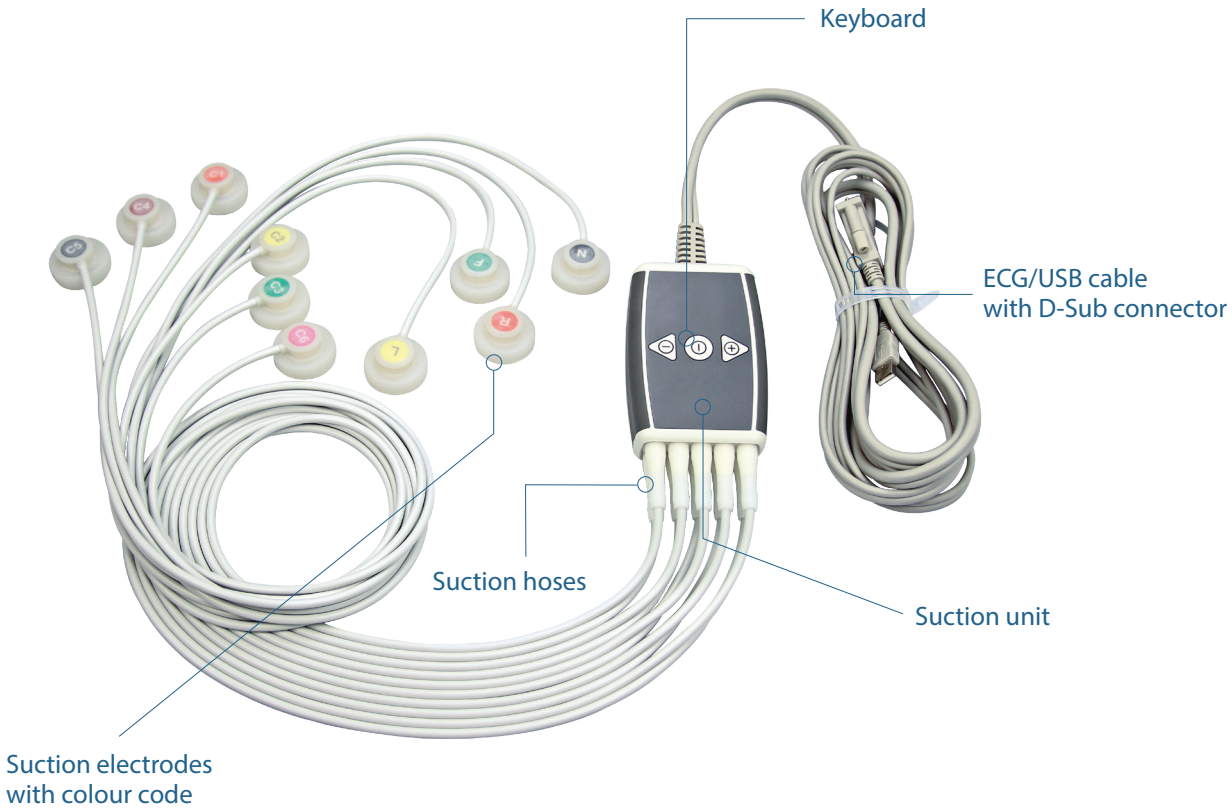
The universal holder enables it to be attached to the medical equipment carttrolley and therefore provides a broad range of uses.

Thanks to the blow-out function, the device is also easy to clean as an assembled unit.

As a result of the fact that the design has been reduced to just a few components, handy vaq is particularly easy to service.

If necessary, the sturdy plug-in components can be exchanged quickly and inexpensively. handy vaq is the user-friendly, flexible all-in-one solution that will facilitate your work. You will be impressed by its excellent price-performance ratio.

2.1 Components of the Suction Device



2.2 Suction Device

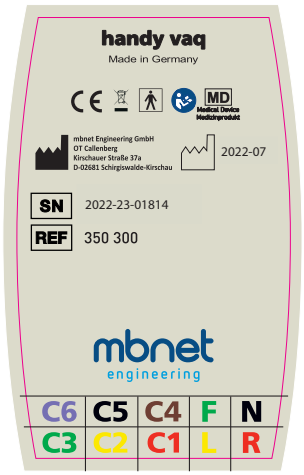
The suction device is characterised by optimal user ergonomics. It consists of a keyboard, control electronics and vacuum pump. The keyboard consists of white push buttons with green background lighting and is easy to use and clean.

2.3 Suction Hoses

The ten shielded electrode cables are interference-free and are characterised by low abrasion and high flexibility.

Caution Please ensure that the suction hoses are handled carefully (see 5.2.3, page 25)

2.4 Label



2.5 Scope of Delivery handy vaq

- handy vaq suction device
- Electrode suction power set (6x1.10m /4x1.30m)
- Spacer (2 items 3-rows / 2 items 2-rows)
- 2 m connection cable (USB/15-pol D-Sub)
- Removal tool Extractor for suction lines
- Medical power supply unit
- Operating Instructions

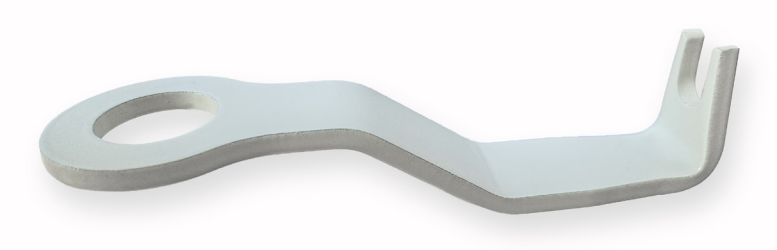


Illustration: Removal tool extractor for suction lines

3 Operation

3.1 Initial Operation

⚠ DANGER

Danger of electric shock. The device must not be used if the power cable is damaged or suspected of being damaged.

Location

- Do not keep or operate the unit in a wet, moist or dusty environment. Also avoid exposure to direct sunlight or heat from other sources.
- Do not allow the unit to come into contact with acidic vapours or liquids.
- The device should not be placed in the vicinity of X-ray, hf surgical equipment, diathermy units, large transformers or electric motors.

3.2 Connection

WARNING

Electricity supply is provided only and exclusively with the medical network adapter supplied with the unit (Protection rating class II). No other network adapter other than the "GlobTek GMT96180-1807-2.0-T3" must be used.

Attention! Danger to patients from too large leakage current! Never connect USB to another device other than the ECG device being used.

1 The ECG cable (A) is first to be connected to the ECG device. Take note of the operating instructions of the ECG device.

2 USB cable (B) is to be connected to the network adapter (C) and subsequently to the electricity supply (same multi-way connector as the ECG device).

3 As soon as the device is connected to the electricity network, both outer LEDs (D) will illuminate.

3.3 Application

Caution

- Only make an ECG recording when you have read and understood the safety information at the beginning of this user guide.
- The device is a device of type BF.
- During an ECG recording, 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).
- The device must not be used if the mains lead is damaged or suspected of being damaged.

3.4 Operating Conditions

Caution

- The device is not intended for permanent operation so switch it off after use.
- High frequency fields and radiation can influence the quality of the ECG recordings.
- Do not keep or operate the unit in a wet, moist or dusty environment. Also avoid exposure to direct sunlight or heat from other sources.
- Do not allow the unit to come into contact with acidic vapours or liquids.
- The device should not be placed in the vicinity of X-ray or diathermy units, large transformers or electric motors.

3.5 Operation and Operating Components

3.5.1 Display

Device without power

Device in stanby mode / OUT

Device in blow-out mode

Device in suction mode (here suction setting 3)

3.5 Operation and Operating Components

3.5.1 Attachment of the Suction Electrodes

1 The suction function will be switched on and off with the button ⏻. The suction strength starts at level III (middle LED lights up).

2 Moisten the application sites for the electrodes on the skin with an ECG spray. (Do not use ECG gel!) Do not spray the ECG spray onto the electrode!

3 Fix the electrodes with slight pressure on the skin.

4 As soon as you have attached all the electrodes to the patient, reduce the suction strength with the buttons ⊕ / ⊖ so that there are as few suction marks as possible on the skin.

Caution

- The device must not be used if the skin is injured. There is a risk of haematoma with a high power or a long period of application! Take special care with elderly patients. The operator of the device should ask the patient how they are feeling!
- The electrodes should not be applied for longer than 25 minutes on the patient's skin.

3.5.2 Suction Settings

The suction hose of the device can be adjusted individually for every patient using the five suction settings. When the device is switched on, the middle setting is activated. The current suction setting is displayed in the operating field with the green LEDs. The highest level should only be used in extreme cases (lots of body hair).

Caution

The suction strength must be adjusted to the patient's skin type in each case!

3.5.3 Ending the Measurement

1 The suction function will be switched off with the button ⏻.

2 The suction function will be reversed automatically and air will be blown for 30 seconds into the suction electrodes. The electrodes will fall off.

3 After 30 seconds in the blow out function the device will switch off automatically.

3.5.4 Cleaning and Disinfecting

Clean the electrodes with a lint-free, damp cloth and mild detergent and then it dry thoroughly.

Disinfect the electrodes as required with a soft, lint-free cloth, soaked in 70% alcohol solution. Then dry the electrodes thoroughly.

3.5.5 Blow-out Function

In order to avoid moisture remaining between the membrane and the electrode after cleaning/ disinfecting, start the blow-out function with the corresponding key for approx. 30 seconds.

Now switch off the device with the key ⏻.

4 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.).

4.1 Electrode Placement

For a good transmission of the electrical currents a careful application of the electrodes and good electrode contact is important.

Therefore, please note the following points:

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.

4.2 Possible Sources of Errors during Operation

4.2.1 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!

4.2.2 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!
- Never spray the ECG spray onto the electrodes, only directly onto the skin!

4.2.3 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)!

4.2.4 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)!

4.3 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

5 Maintenance and Care

The device requires regular checks (Chapter 5.4). 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 27, 5.4 Inspection report) - Cables and accessories - Mains cable ■ Functional tests according to the instructions (see page 27, 5.4 Inspection report)	User

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

5.1 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.

5.2 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 stuck to the device, remain in place and remain readable.

5.2 Cleaning the Housing and Cables

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 5.2.6). 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.

5.2.1 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.)!

5.2.2 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: by request)
- Immersion disinfection, cleaning / drying: 1x weekly after the last use (OR: by request)

Caution

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

Do not spray disinfectant directly into the electrodes!

Instructions for Wiping Disinfection / Cleaning

1. Use only the disinfectants mentioned in Point 5.3.1.
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

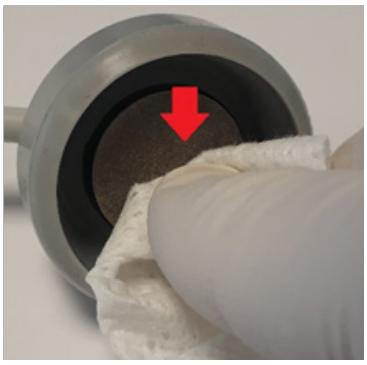


Diagram 2:
Clean contact surfaces

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

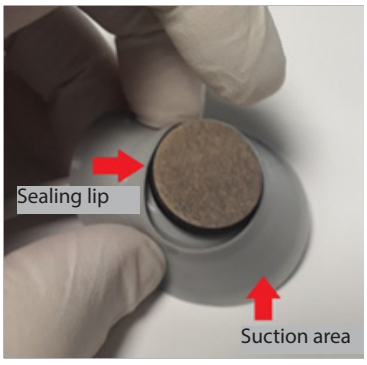


Diagram 3:
Suction dome cleaning inside

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)

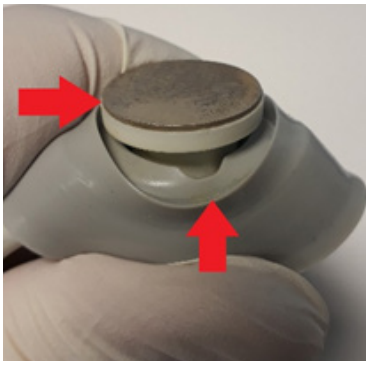


Diagram 4:
Impurities (electrode)

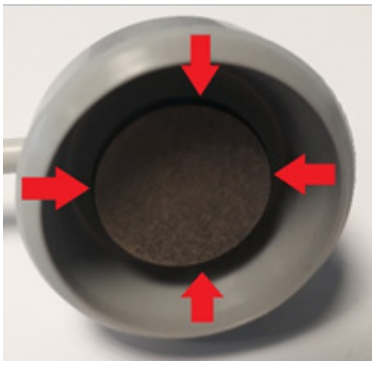


Diagram 5:
Check the position of the suction dome on the electrode housing

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 5.3.1.
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

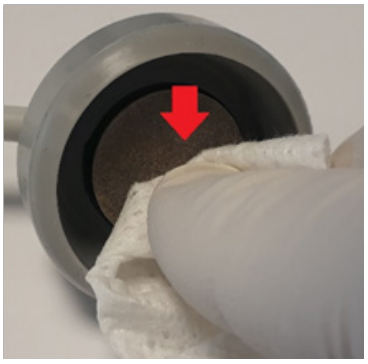


Diagram 7:
Clean contact area (electrode)

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

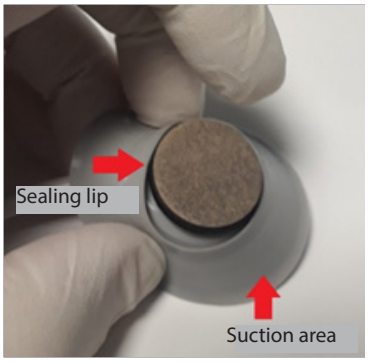


Diagram 8:
Suction dome cleaning inside

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.

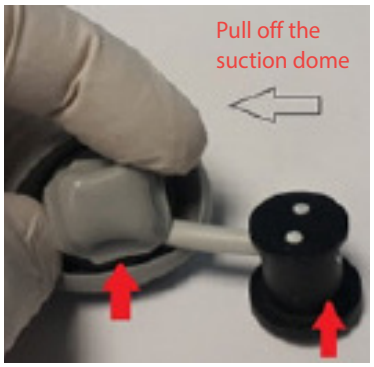


Diagram 9:
Remove the suction dome

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

i

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

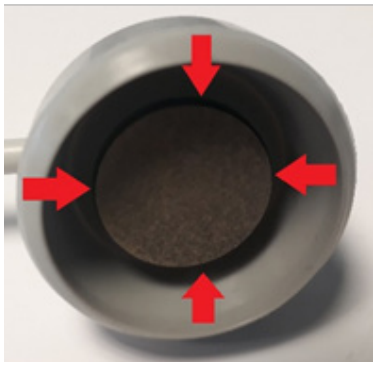


Diagram 10:
Check the position of the suction dome on the electrode housing

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.

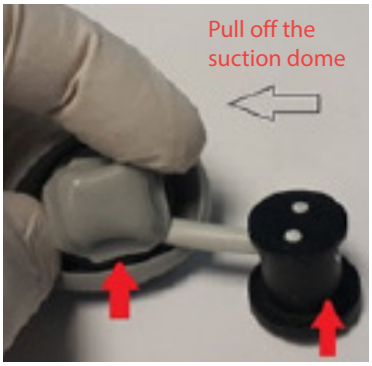


Diagram 11:
Remove the suction dome

4. ONLY immerse the electrode and the suction dome in a container with an admissible disinfectant (Point 5.3.1)

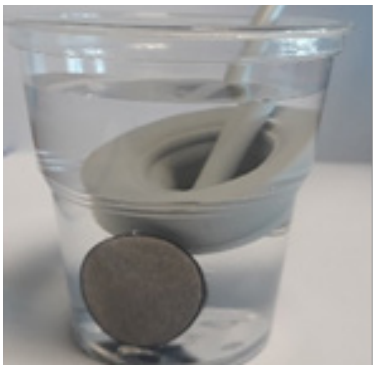


Diagram 12:
Immersion disinfection

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.

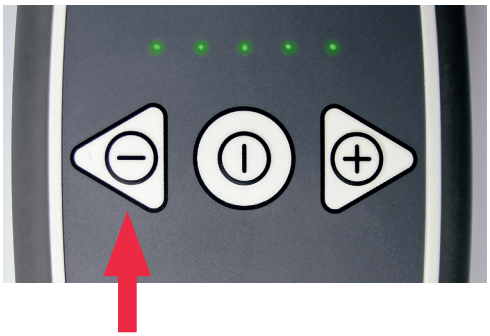


Diagram 13:
Blow-out/ cleaning key

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.

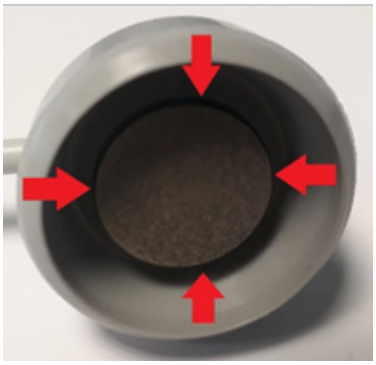
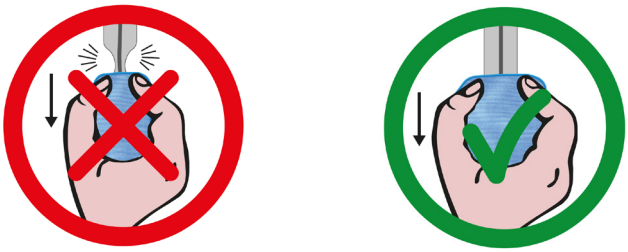


Diagram 15:
Check the position of the suction dome on the electrode housing

5.2.3 Cleaning the Suction Hoses

Caution

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!

5.2.4 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.

5.2.5 Admissible Detergents

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

5.2.6 Non-admissible Detergents

Never use products containing the following:

- Ethyl alcohol
- Acetone
- Hexane
- Abrasive cleaning powder
- Plastic-dissolving products

5.3 Disinfection

Disinfection removes certain bacteria and viruses. Permitted and non-permitted disinfectants are listed below. Disinfect the device in the same way as described for cleaning the device in Chapter 5.2.

5.3.1 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)

5.3.2 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

5.4 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	☐	☐	☐	☐	☐
■ Blow-out mode	■ Functions properly	☐	☐	☐	☐	☐
Remarks:						
■ Recurrent test in line with the ECG manufacturer		☐	☐	☐	☐	☐
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) .....

5.4.1 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 handy vaq. 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
303 200	ECG Leads, Set of 10 leads (6 x 1.10 m / 4 x 1.30 m)
303 201	C1, 1.10 m
303 202	C2, 1.10 m
303 203	C5, 1.10 m
303 204	C4, 1.10 m
303 205	C5, 1.10 m
303 206	C6, 1.10 m
303 211	F, 1.10 m
303 212	L, 1.10 m
303 213	N, 1.10 m
303 214	R, 1.10 m
303 220	C1, 1.30 m
303 221	C2, 1.30 m
303 222	C3, 1.30 m
303 223	C4, 1.30 m
303 224	C5, 1.30 m
303 225	C6, 1.30 m
303 207	N, 1.30 m
303 208	L, 1.30 m
303 209	N, 1.30 m
303 210	R, 1.30 m
300 109	ECG Label for ECG Single Lead
300 301	Spreader for ECG Single Leads
300 400	ECG Spray
303 215	ECG Lead, Neutral, 1.10m
303 216	ECG Lead, Neutral, 1.30m

5.4.2 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 (V1, V2, …., N, F, L, R) does not matter.

Caution

Please note that when replacing the suction lines, a removal tool must be used to prevent damage to the electrodes and the distributor (see page 11, 2.5 Scope of delivery).

6 Trouble Shooting

6.1 Possible Problems

Error	Possible causes and indicators	Error localisation and Trouble shooting
Pump not working (no audible noise)	■ Connector loose ■ No mains power	■ Insert the connector firmly
Pump is working, but no suction power	■ Hose connection to the pump is loose or not sealed ■ Hoses are bent or jammed	■ Check hose connection for tight fit ■ Rectify cause
Weak suction power	■ Hose connection to the pump is not sealed ■ Suction hose in the distributor is loose ■ Suction hose is not sealed	■ Check suction hoses for tight fit ■ Replace suction hose
Pump is working, but no or low suction power, electrodes fall off during ergometry	■ Suction domes are not placed correctly on the electrode body ■ Hose application over-wound or rolled together ■ Electrode body and suction dome soiled	■ Fasten the suction dome over the electrode body ■ Replace the electrode body and suction dome

If you cannot rectify the problems with this information, then please contact your mbnet Engineering GmbH dealer or mbnet Engineering GmbH directly.

Have the model designation and your serial number ready for this. You can find them on the identification plate on the pump housing.

6.2 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

HF source Wireless communications devices	Transmitter frequency (MHz)	Testing frequency [MHz]	max. power P (W)	Distance d (m)
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 tran-sponders 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

7 Technical Data

7.1. Technical Data

Ambient temperature	10 to 50 °C
Relative humidity	30 to 75% (non-condensing)
Air pressure	700 to 1050 mbar
Storage temperature	10 to 40 °C
Transport temperature	-10 to +40 °C
Partial vacuum - Maximum vacuum	250 mbar
Volume	2.6 l/min
Dimensions	78 x 117 x 27 mm (without cables)
Weight	950 g, with set of cables
Power supply	GlobTek GMT96180-1507-2.0-T3
Input	100-240 VAC, 50/60 Hz 0.6A
Output	5VDC 3.6A
ECG connection	15-pol. D-Sub, 2 m long
Patient cables	Chest (6x) Extremities (4x) 1.1 m 1.3 m
Electrodes	Ag/AgCl, cup material silicone

7.2 Safety standards

Safety standard	IEC/EN 60601-1
EMC	IEC/EN 60601-1-2, 4. Edition
Conformity/classification	Class I in accordance with regulation 2017/745/EU
Protection	This device is not designed for outdoor use (IPX0)

8 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 handy vaq is intended for use in the electromagnetic environment specified below. The customer or the user of the handy vaq should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The handy vaq 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 handy vaq 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	

8.1 Table 1: Immunity (all devices)

Guidance and manufacturer's declaration – electromagnetic immunity			
The handy vaq is intended for use in the electromagnetic environment specified below. The customer or the user of handy vaq hould 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.

8.2 Table 2: Immunity: (devices that are not life-supporting)

Guidance and manufacturer's declaration – electromagnetic immunity			
The handy vaq is intended for use in the electromagnetic environment specified below. The customer or the user of the handy vaq 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 handy vaq, 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 handy vaq is used exceeds the applicable RF compliance level above, the handy vaq should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the handy vaq.		
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.		

8.3 Table 3: electromagnetic immunity

Recommended separation distances (not life-supporting devices)

Recommended separation distances between portable and mobile RF communications equipment and the handy vaq

The handy vaq is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the handy vaq can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the handy vaq 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.