

Manual



Auroria MD

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Foreword

The Auroria MD foot care unit was produced according to strict quality criteria and uses the latest technology in its design. The images in this manual may vary slightly from the product you have bought as we are constantly developing our products.

This user manual includes a detailed description and explanation of how to use the Auroria MD unit. If you have any questions or suggestions, you can contact us by telephone or email.

This user manual belongs with the Auroria MD unit. Keep it somewhere safe. If you give this product to someone else, please include this document as it includes important information on how to correctly use the product.

Short description of functions

The Auroria MD is a medical device for the treatment of callus and nails. The hand-piece is compatible with rotating tools such as diamond polishers, steel cutters and ceramic cutters. These can reach at speeds up to 40,000 rpm and therefore provide an efficient way of removing tissue. The direction of rotation can be changed by pressing a button. The integrated filtered suction function effectively sucks up any dust particles. The rotation speed and suction function can be adjusted using the keyboard. The device display will notify you when the filter needs to be changed and when the device is due for inspection.

Safety Instructions



The equipment should only be used by trained operators.



The installation of the working area has to correspond to the relevant regulations. Set up the unit in such a way, that the air slits are not blocked and the extracted air can escape well.



To avoid the risk of electrocution only connect the device to the mains power supply.



If you pull the power plug, it will stop the connection to the mains power supply. Set up the unit so that the power plug is always accessible. The power switch should also always be easily accessible.



Only switch on the unit if the handpiece rests secured in the handpiece holder, or if you hold it safely in your hand.



Prevent any liquids from entering into the control unit, since this could damage the electronic elements. Clean the outside of the box only with a damped cloth. Make sure, that you have unplugged the unit before.



Only when pulling the mains cable, you can ensure that the device will be completely disconnected from mains. Check the mains cable regularly for damages and in case of such,

Safety Instructions

have it changed or repaired by an authorized service center.



Prevent your hair from wrapping itself around moving parts. If applicable, wear a hair net.



When working with materials, which might create dust or moisture, use a drilling unit with suction or spray technique. Wear a nose and mouth protection. Always follow the safety instructions provided by the manufacturer of the materials being formed and used.



For safety reasons, always wear disposable gloves and protective glasses when operating this device. In addition, a face mask conforming to EN 14683 type IIR or EN 149 FFP 2 must also be worn.



Ensure that the patient's foot and the hand-piece are held firmly in place during the operation. To prevent injury, work with extreme caution on the foot of the patient and use only light pressure.



To ensure that the bur/tool sits firmly in the chuck, do not work with tools which

- have an oily shaft,
- are worn,
- are bent.

Safety Instructions



Before using the equipment, assure that

- the tool can be pushed far enough into the chuck (test this with a dipstick and clean if necessary),
- the inserted tool sits properly in the chuck and will not cant/jam while clamping it,
- the tool is approved for using it at the max speed (see manufacturer's instructions), or
- only use the speed required by the instrument,
- the tool is absolutely dry.



For safety reasons do not change the tool while the motor is running.



Switch off the unit immediately if

- the bur comes off during the treatment itself.
- the motor blocks during the treatment.



While doing any foot care, only operate the unit with the suction turned on.



Only use the suction function if you have installed the suction filter. Check this filter every 10 operating hours. If it is full, please exchange it. A filter should be exchanged at least after 50 operating hours. When changing the filter, it is advisable to wear a face mask conforming to

Safety Instructions

EN 14683 type IIR or EN 149 FFP 2.



The light on the handpiece is for lighting the area being treated. Do not look directly into the light.



Never use the suction to vacuum any liquids or air/water fog which contains particles of liquids.



Always follow the operating instructions. Do not carry out any repairs, modifications or maintenance work yourself. This is only to be accomplished by an authorized specialist. The mains cable may also only be changed by the manufacturer, or an authorized specialist. Maintenance records may be supplied to repair workshops and trained technicians upon request. Never remove the housing, especially not while the equipment is plugged into the socket, since some components are under electric voltage. Any unauthorized or improper handling (e.g. trying to repair the unit) of the equipment will immediately nullify the guarantee/warranty, and any other liabilities of the manufacturer.



Attention! Only use burs/tools which are permitted for speed level saved under m1 – m3!

Safety Instructions



When the device is brought out of standby mode it will run with the rotation speed and suction power used last. Take care to not start the mill at an overly high rotation speed. Select the required rotation speed before changing the milling tool.

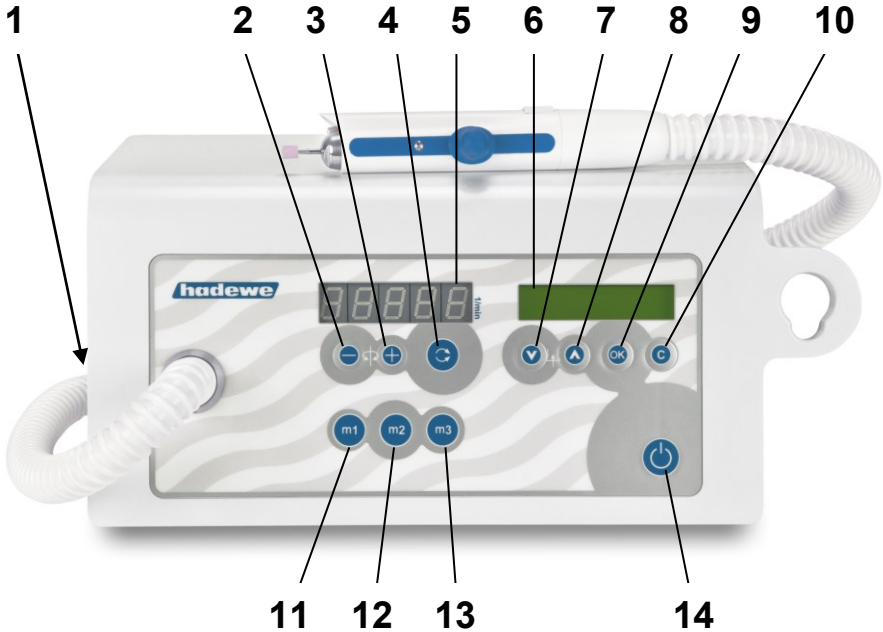
Cleaning & Disinfection



The device is designed to be compatible with rotating instruments which do not penetrate the skin or mucosal or inadvertently may still cause injuries. For this application please adhere to the cleaning and disinfection instructions provided below. After every treatment please carry out the following steps:

- Remove the rotating tool (e.g. bur, capper etc.) first. Then handle the tool according to the instructions of its manufacturer.
- Remove tissue remains by wiping off the unit with a mildly moistened paper cloth. Afterwards clean all surfaces with disinfection cloth (e.g. Mikrozyd AF Tücher of Schülke and Mayr) There is no limit to the number of times this device can be cleaned and disinfected during its recommended lifespan.

Getting to Know the Unit



- 1 power switch
- 2 decrease speed
- 3 increase speed
- 4 change direction of speed
- 5 display for speed [rpm]
- 6 display for suction level, time, change of the filter bag etc.
- 7 menu button down ∇ and reducing the suction level
- 8 menu button up \blacktriangle and increasing the suction level
- 9 menu button OK
- 10 menu button stop
- 11 memory button m1 for speed/suction level
- 12 memory button m2 for speed/suction level
- 13 memory button m3 for speed/suction level
- 14 ON/OFF button (standby)

Before First Use

Please read through the instructions carefully before using the unit and carefully note the safety advice. Always keep this manual accessible to any users of the drill.


Area of Application


This device should only be used by people who have completed a foot care qualification. Before use the operator should make themselves familiar with the device by reading this manual or being instructed by another.

The device must only be used in closed spaces. It may be used in hospitals, in a commercial environment or in homes. The device is not intended for use in operating rooms.

The control unit can be set up in a cabinet or can be used as a portable unit, e.g. in a carry case. It is suitable for the following scopes:

- foot care (milling, trimming and polishing),
- manicure (grinding, milling and polishing works).

 The device is determined of operating rotating instruments, which will not penetrate the skin or mucous membrane if used appropriate, but could evoke damages accidentally.

 Caution: In the area of pedicure you have to work with suction techniques.

Operation

The working area must conform to the conditions described. Set up the unit in such a way, that the air slits are not blocked and the extracted air can escape well. To guarantee unhindered air flow there must a gap of at least 12cm to the right of the device.

Position the device so that the operating buttons are easy to reach and the outlet of the hose is a maximum distance of 60cm from the patient's foot. The unit should be 30-90cm from the floor.

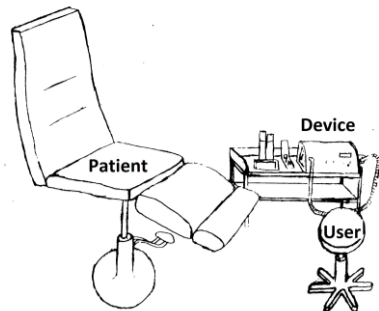


Image: Example of positioning of foot care unit in treatment room

Before First Use

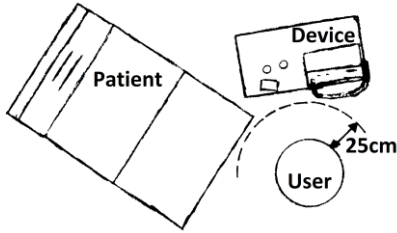


Image: Bird's eye view of work area

If you have a foot switch, insert its plug into the port on the right of the device which displays this symbol



Check that the filter bag and dust filter are correctly fitted. Ensure that the tool is fixed.

On the left side of the device you will find the main power switch. Press this switch to turn the unit on.



The word "Language?" will appear on the display. Use the buttons \vee and \wedge to select a language and press OK to confirm.

On the display will appear "Press OK". By pressing the OK button, the counter which calculates the time until the next inspection is due is set to 0.

The device is now on standby. As soon as the LCD display (6) is active the device is ready to use.

Pick up the handpiece. Should the handpiece be twisted by the hose you can adjust that at the control unit.



To use the handpiece and suction function press the button (14) on the front of the unit.

Operating Steps

In the following section the order in which you should use the device is described. Additionally, the individual steps will be explained in detail. Read the complete manual before use.

After connecting the device to the power press the standby button (14) to make it start rotating. Use the buttons (2) and (3) to select a rotation speed. Manufacturers often provide recommendations for optimal rotation speeds. However, it is important that you never exceed the maximum recommended rotation speed.

You can now choose the rotation direction using the button (4). The most commonly used direction is clockwise. Most milling instrument (steel instruments with steel cutters) are optimised for clockwise use. The rotation direction is irrelevant for diamond cutters and high-grade corundum sanders in terms of efficiency. Working anti-clockwise can be beneficial if, for example, the dust obscures your field of vision when working clockwise.

Now switch on the suction with button (8). Using buttons (7) and (8) you can adjust the intensity of the suction. Frequently used rotation speeds and suction power settings can be saved. First select the desired rotation speed and suction power. Save these settings by pressing the memory button m1 for 4 seconds. To use your custom

settings simply press m1. Other values can be saved using memory buttons m2 and m3.

After choosing rotation speed and suction power you can start working. If you want to take a break or finish the job, press the standby button (14). The handpiece motor and suction will turn off. The handpiece can now be placed in its holder on the right of the unit. Alternatively, you can switch the device to standby by pressing and holding the button on the handpiece or by pressing the button on the foot switch.

We recommend to disconnect the device from the mains power supply if it is not going to be used for a while. This will save electricity. The mains plug must also be removed when it comes to retiring the device.

Use

Work Positioning

The following images are examples of how to work on various parts of the foot. Always make sure that the foot is firmly gripped and that you can work freely and without strain.



Use



Use

Suction

Switch on the suction with button (8). The suction power can be regulated in 5 levels. You will see the selected level in the display. Level 0 would mean that the suction is turned off.

In case the suction motor overheats, the unit will switch off automatically. Leave the unit to cool off for a while before starting it again. Should the same failure appear again, please return the unit to your supplier for inspection.

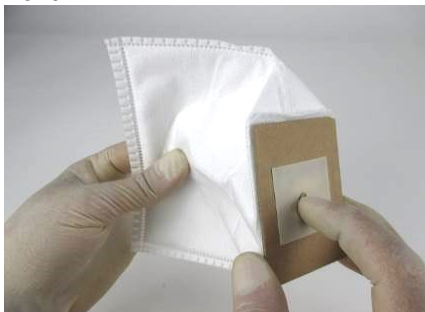
Exchange Micro Filter



When changing the filter, it is advisable to wear a face mask conforming to EN 14683 type IIR or EN 149 FFP 2.

Only operate the unit with a suction filter assembled. Control the bag after every 10 operating hours. Exchange a full filter bag immediately. A filter should be exchanged at least after 50 operating hours.


At first, unfold the paper of the micro filter bag (art. 5179) and push your finger into the opening in the front.



Pull out the lid of the dust chamber and remove the old filter.

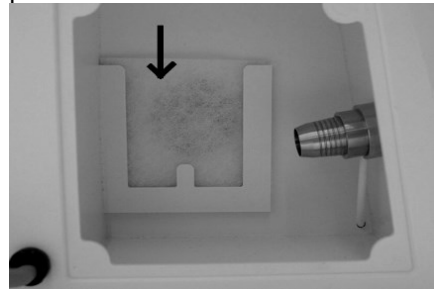
Hold the filter in the middle to prevent it from bending and sliding off (see picture below). Therefore, you avoid it from coming off again.



 The dust filter (art. 5179) must be used. The paper filter (art. 5115) must NOT be used.

Exchange Control Unit Filter

This filter (art. 3752) has to be exchanged after every 200 operating hours. Remove the old filter and place the new one in its holder.



Use

Clamping the Bur/Tool

The handpiece is equipped with a chuck, which can hold all burs with a diameter of 2.35 mm. This is the diameter usually used for tools in podiatry. To open the chuck, push the knob forward with your thumb and leave it there. Now insert the tool as far as possible. Pull back the knob and the tool will be firmly clamped.



For security reasons, only change the tool if the handpiece is turned off.

Setting up the Speed

Hold the handpiece (incl. tool) in your hand or store it in the handpiece holder attached to the side of the control unit. Switch on the unit with button (14). Now you can also set the speed with buttons (2) and (3). Choose the direction of rotation with button (4).

Memory Buttons m1, m2, m3

Frequently used speed or suction levels can be saved. Therefore, three memory buttons are available. At first, choose your speed/suction

level, and then save it by pushing the memory button m1 for 4 seconds. To recall the above combination of speed/suction level, simply press button m1 again. Further combinations can be saved with m2 and m3.



Attention! Only use burs/tools which are permitted for speed level saved under m1 – m3!

Button on the Handpiece


If you press this button once (for a short time), you can recall the memorised combination of speed and suction you saved under m1. By pressing the button once again (shortly), you recall the m2 setting. You can switch between settings m1 and m2 (not m3 though) by using this button. If you press the button on the handpiece for a longer period, you will switch on/off the complete control unit.



When the device is brought out of standby mode, it will run with the rotation speed and suction power used last. Take care to not start the mill at an overly high rotation speed. Select the required rotation speed before changing the milling tool.

Foot Switch (art. 0970)

Operation of the foot switch

Only use the original hadewe foot switch, to avoid any damages. Insert the plug of the foot switch into the socket with the symbol .

Function of the foot switch

If you press on the foot switch once, you can recall the memorized combination of speed and suction you saved under m1. By pressing the switch once again, you recall the m2 setting. You can switch between settings m1 and m2 (not m3 though) by using the foot switch this way. If you press the foot switch for a longer period, you will switch on/off the complete control unit.



Attention! Only use burs/tools which are permitted for speed level saved under m1 – m3!

LCD Display

The LCD display shows you information about the operating mode of the control unit, such as direction of rotation (left/right rotation), suction level (level 1 – level 5) or date and time. A warning notice to exchange the filter bag will appear in the display. It will also show, when the unit should be brought to a maintenance (after approx. 1 year).

By pressing the OK button, you will access the selective list for settings of the device. With the buttons \vee and \wedge you can go through the list and select a setting by pressing OK.

With “C” you can stop a function to return to the main menu.

The following functions are available:

- verification of changing the filter bag (the date of the last exchange will be displayed),
- turn light on/off at handpiece,
- show date of last maintenance,
- setting the time,
- setting the date,
- choose your language.

Change of filter bag approval

After every 50 operating hours during suction mode, you will read the note „Check the filter bag”. When this message appears, you have to confirm the date of the exchange. Choosing “Change filter” from the selective list and then press OK. Now the date of the last change will be shown in the display. Press \wedge and then OK to confirm the change.

Turn ON/OFF light

To turn on the light on the handpiece, take the following steps: Select “light” from the selective list. Approve by pressing OK. Press \wedge to choose between “light on” or “light off”. Then press OK.

Display date of maintenance

Select from the list “maintenance”. Approve with the button OK. The date of the last service will appear. If you send in the device for maintenance, hadewe or an approved service agent will update the date of service for you.

Use

Setting the time

Select from the menu list “time”. Confirm with the button OK. With the button - and + you can set the hours. With the buttons \wedge and \vee you can set the minutes. Press OK to save the setting.

Setting the date

Select from the list “date”. Confirm with OK. With the button - and + you can set the day. With the button \vee and \wedge you can set the month. With the button m1 and m2 you can set the year. Press OK to save the setting.

Choose your language

Select from the list “language”. Confirm with the button OK. With the button \wedge and \vee you can select the language. Press OK to save the setting.

Messages

CHECK FILTER BAG

→ Change the filter bag (see page 166).

HS CHECK

→ No handpiece is connected or the handpiece is faulty.

MAINTENANCE RECOMMENDED

→ After longer operation of the unit (approx. 1 year, depending on how much the unit is used), the exchange of moving parts, e.g. ball bearings, washers and other parts that will wear down in time will become necessary. A maintenance by an approved hadewe service agent is recommended after a year.

The control system will determine the period between the last maintenance and shows a recommendation for a new service. Please contact your distributor or an authorized repair service, when this occurs.

In the display appears "Maintenance recommended". Press OK. The display shows "Note off?". If the message should still appear, select NO and the OK. If you do not want this message to appear again during the next 2 months, press YES and then OK.

ERROR 1

→ The unit switches off when the rotational speed of the handpiece cannot be maintained.

ERROR 2

→ The unit switches off when the speed of the suction motor cannot

be maintained.

ERROR 3

→ The unit switches off when if the handpiece has been very heavily used for a long period of time.

Maintenance & Care

Cleaning the Chuck

In the process of time, some dirt might collect itself within the hand-piece and might affect its functions. Therefore, the chuck has to be cleaned monthly.

How to remove the chuck

Screw off the top of the handpiece with the spanner shown in the picture.



Now clean the inside of the hand-piece and the top with the brush.

For opening the chuck, push the button forward.



Set the screw spanner (wrench) on the axle and hold it tight. Now use the front of the second spanner to unscrew the chuck.



To assemble the chuck, follow the steps in reverse order. Make sure that the chuck is opened during the assembly (the handpiece button must be in forward position) and is firmly applied afterwards.

How to clean the chuck

Soak the chuck in ethyl alcohol or a cleaning liquid for tools. Clean the slits of the chuck with the brush.



Use the brush to remove all dirt residues from the drill-hole of the chuck:




Maintenance & Care


Rinse the chuck very well, and make sure you let it dry well afterwards. Cover your index finger with a very little amount (just a drop) of oil and rub in between your thumb and index finger. Dab off the oil until your fingers is only covered with a very thin film of oil. Now move the chuck in between your thumb and index finger. There should be only a very thin film of oil left on the chuck. Please act according to the saying: Less is more.


Maintenance Overview


| What has to be done? | How often? Done by whom? |
|--|---|
| cleaning the chuck | monthly by user |
| changing the filter bag | every 50 hours of operation by user (check after each 10 hours) |
| changing the control unit filter | every 200 hours of operation by user |
| maintenance by repair workshop (changing worn parts, housing, cleaning, check leakage current) | every 500 hours of operation by repair workshop |

Handling Instructions


 Never put the handpiece into any kind of liquid, and never oil or grease the handpiece. Clean its surface with a damp cloth. Pay attention, that no moisture or liquid enters the handpiece. Never use spray disinfection.


 Never put any wet burs or instruments into the handpiece. Its moisture could damage the interior parts of the handpiece.


 Any materials used by hadewe prevent a formation of rust. In cases in which a rust infestation was found within the handpiece, thorough inspections and examinations always have proved that the rust had a foreign origin (which was usually caused by the tools used in these circumstances). Even in high-grade steel instruments of well known manufacturers, formation of rust can appear, e.g., through wrong treatment with chemical cleaning and disinfection liquids. This extraneous rust affects internal parts of the handpiece in form of rust bloom and causes pitting. Therefore, when you not working with the handpiece, always remove the bur/tool from it.


 Always make sure that you do not let the handpiece fall down or exposes it to any shocks. The ballbearings and the motor could be damaged by this. Only work with tools, which are flawless. Do not work with tools which

- are bent or out of balance
- whose shaft is worn out or
- are rusty.

 Working with faulty tools will cause a stronger vibration of the handpiece. A damage of the ball bearings, clamping technique or motor could be the consequence.

 Working with high pressure will not improve the outcome of your work, since the motor will even be slowed down. A second disadvantage is the stronger impact on the ball bearings and the motor, which will shorten their life span in the long run.

 In case of sending the device by mail remove the dust filter before.

 Only suck up dust or milling waste, never suck up larger particles such as small bits of cotton wool as this may be get caught in the handpiece and lead to blockages.

Troubleshooting

Handpiece vibrates, is very noisy or becomes warm in the front part.

Use of bent burs/tools. → Use a different bur/tool to test this. The bur/tool itself can be tested with the hadewe Bur Shaft Tester (art. 4990) to see if it is bent.

Maximum allowed speed of the tool was exceeded, which caused a stronger vibration. → Pay attention to the tool (e.g. bur, capper and instrument) manufacturers handling details.

Bur/tool can be inserted only with difficulty or not at all.

Use of bent burs/tools. → Use a different bur/tool to test this. The bur/tool itself can be tested with the hadewe Bur Shaft Tester (art. 4990) to see if it is bent.

Chuck is dirty. → Clean the chuck according to the instructions in the manual.

Bur does not clamp or does not spin.

Chuck is not tightened well. → Tighten the chuck firmly according to the instruction in the manual.

Knob of the handpiece cannot be moved easily.

Chuck is dirty. → Clean the chuck according to the instructions in the manual.

Unit does not work at all.

Check, if the main switch of the unit is turned on at the side of the unit.

Foot switch is used constantly or faulty. → Pull out the socket of the foot switch to see if this is the cause.

Pull out the mains plug to reset the device.

The unit shows different sound levels at different sites of use.

The sound level varies according to the surroundings of the unit. If you set up the unit directly in front of a wall, the sound is reflected stronger, as if it would, while standing further away from a wall.

Handpiece motor stutters shortly (approx. 1 sec) when turning unit on.

In very rare cases this effect did appear. It will not harm or damage the device.

Suction function doesn't work.

The suction motor will turn off automatically if it overheats. Let the device cool down before using it again. Send the device off for inspection if this occurs repeatedly.

For descriptions of the messages on the device display, see page 20.

Technical Data

0776 Auroria MD

total weight: 2,7 kg
dimension: W273xH142xD186 mm
input: 100-240 V~, 50/60 Hz
power consumpt.: 1A(100V)-0,5A(240V)
fuse primary:
F1, F2: 4A time delayed safety fuse
fuse sec.: thermal fuse
protection class I
accuracy of speed display: $\pm 10\%$

handpiece:

type B applied part
diameter: 19 - 25 mm
length: 144 mm
speed: 6.000 - 40.000 rpm

Ambient Conditions

The device is intended for use in dry closed rooms.

Operation:

Temp.: +10°C to +26°C
Rel. humidity: 25% to 75%
(not condensed)
Air pressure: 700 hPa to 1060 hPa

Storage:

Temp: -5°C to +55°C
Rel. humidity: 10% to 95%
(not condensed)
Air pressure: 500 hPa to 1060 hPa

Transport (up to 4 weeks):

Temp: -5°C to +55°C
Rel. humidity: 10% to 95%
(not condensed)
Air pressure: 500 hPa to 1060 hPa

Operating Time

The device is designed for extended usage.

Accessories & Spare Parts

| art. no. | |
|----------|----------------|
| 5179 | micro filter |
| 3752 | filter |
| 0970 | foot switch |
| 6158 | cleaning brush |



The dust filter (art. 5179) must be used. The paper filter (art. 5115) must NOT be used.

The clamping system is designed for rotating instruments, which have a shaft of 2,35 mm in accordance with DIN EN ISO 1797-1.

Compulsory Registration

Operators, distributors and retailers who were informed about the occurrences regarding §29 of the Medical Devices law must report this. The method of reporting is detailed in the Medical Devices Safety Plan Ordinance. Outside of Germany the corresponding local conditions apply.

Safety Check

A safety check must be done in compliance with the regulations of the country where the device is used. The inspection interval is once a year.

Repeated control and control after repair (DIN EN 62353, VDE 0751-1)

Inspection interval for repeated control: 1 year

Technical Information:

Safety class: I

Application: Type B (separate measuring of discharge current not necessary)

Power connection: NPS (non-detachable power connection)

The protective ground conductor is not connected to touchable conductive parts.

Necessary function inspection: speed, display, on/off, suction/spray, clamping system.

Inspection before use

During the production control the following inspections as per DIN EN 62353 (VDE 0751-1) are conducted among others:

Optical control, protective ground conductor resistance $<0,3 \text{ Ohm}$, equivalent device leakage current $<1000 \mu\text{A}$, functional inspection of display, on/off-button, suction/spray, speed and clamping system. Safety and function deficiencies have not been found. By providing this information an inspection before use can be renounced as per DIN EN 62353, which otherwise would have to be ordered by the user.

Disposal



The device and filter may contain infectious material such as residual sanding dust or skin particles. Therefore, please bear in mind the following disposal instructions.

Disposing of the device

Old devices bought in Germany that correspond to the electronic device law should be sent directly to the manufacturer (hadewe). We will dispose of the device free of charge. The devices should not be taken to public disposal plants (WEEE Reg. No. DE20392713, b2b device). For disposal of this unit out of Germany, please contact the site where you bought this hadewe product.

Note for the disposal of the device/treatment system

Wear protecting gloves of the class 2 in accordance with DIN 374-2 during the disassembling of the device. Also, wear a protective mask for your face according EN 14683 version IIR or EN 149 FFP2.

Disposal of dust filter and coarse dust filter

The filter bag and the coarse dust filter are considered low contaminated waste. Dispose those in intransparent, liquid-tight, resistant plastic sacks and to not dispose them compressed in the regular household garbage.

Technical Data

Symbols



Caution!



Important Note!



Follow instructions for use!



temperature limit
(indicates the lower and
upper temperature limit)



air pressure: permissible range



air humidity: permissible range



Keep dry!



ON/OFF button (standby)
(no disconnection from main
power supply)



enter menu/
confirm with OK



go back in menu/cancel



change direction



suction

m1, m2, m3

memory buttons for
speed/suction output



rotation



alternating current



direct current



safety fuse



type B applied part



socket foot switch



date of manufacture,
name and address
of the manufacturer

Technical Data


Information on electromagnetic compatibility in accordance with DIN EN 60601-1-2

| Guidance and Manufacturer's Declaration – Electromagnetic Emissions | | |
|--|----------------|---|
| The device is suitable for use in the specified electromagnetic environment. The customer and/or the user of the pa-on should assure that it is used in an electromagnetic environment as described below: | | |
| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
| RF emissions according to CISPR 11 | Group 1 | The device 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 according to CISPR 11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions IEC 61000-3-3 | Not Applicable | |

Technical Data

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity IEC 60601-1-2 | | | |
|---|---|------------------------------|--|
| The device is suitable for use in the specified electromagnetic environment. The customer and/or the user of the device should assure that it is used in an electromagnetic environment as described below: | | | |
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact discharge method ± 8 kV air discharge method | ± 6 kV contact ± 8 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 according to IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | Not applicable | Mains power quality should be that of a typical commercial and/or hospital environment |
| Surge according to IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | Not applicable | Mains power quality should be that of a typical commercial and/or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | < 5 % UT (>95 % dip in UT) for ½ cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 seconds | Not applicable | Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Mains power quality should be that of a typical commercial and/or hospital environment. |
| NOTE UT is the a.c. mains voltage prior to application of the test level. | | | |

Technical Data

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity IEC 60601-1-2 | | | |
|--|--|------------------|---|
| The device is suitable for use in the specified electromagnetic environment. The customer and/or the user of the device should assure that it is used in an electromagnetic environment as described below: | | | |
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
| Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 | 3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz | 3 Veff 3 V/m | <p>Portable and mobile RF communications equipment should be used no closer to any part of the pa-on, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.</p> <p>Recommended Separation Distance: $d = 1,17 \sqrt{P}$ $d = 2,3 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment:</p>  |
| 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. | | | |

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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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the pa-on Parometer IEC 60601-2

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

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter m | | |
|---|---|---------------------|--------------------|
| | 150 kHz to 80 MHz in ISM bands | 80 MHz to 800 MHz | 800 MHz to 2,5 GHz |
| | $d = 1,17 \sqrt{P}$ | $d = 1,17 \sqrt{P}$ | $d = 2,3 \sqrt{P}$ |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,38 | 0,38 | 0,73 |
| 1 | 1,2 | 1,2 | 2,3 |
| 10 | 3,8 | 3,8 | 7,3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, 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.

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