



Manual



Hyperios⁴ PLUS

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Foreword

The Hyperios⁴ Plus 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 Hyperios⁴ Plus unit. If you have any questions or suggestions, you can contact us by telephone or email.

This user manual belongs with the Hyperios⁴ Plus 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 Hyperios⁴ Plus 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 spray function emerges reliably bundles emerging dusts. The speed of the bur and the spray function can be adjusted by the membrane keypad. The amount of spray liquid is adjusted via knob.

Safety Instructions



The equipment should only be used by trained operators, who know the function of the unit well.



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



To avoid the risk of an electric shock, this device might only be connected to a power supply with protective conductor.



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 the permeation of liquids into the control unit. The electronic elements could be damaged. Clean the outside of the box only

Safety Instructions

with a dampened cloth. Be sure you unplug 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, let it change or repair from 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.



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

Safety Instructions



Ensure the patient's foot and the handpiece (e.g. material) are held firmly in place during operation. To avoid injury, work on the foot of the patient with extreme caution, and light pressure.



If water leaks from the unit, then a disturbance is present. The unit has to be separated from the socket and cannot be used any longer.



Only use distilled water plus a sterilizing additive (e.g. hadewe AquaHy, art. 8555). If you use other brands, pay attention to their manuals if you can use them for this purpose. Never use tap water or alcoholic fluid, or other burnable liquids. In case, you are working with an alcoholic fluid, or other burnable liquids, there is always the danger of fire or explosion hazards. Never refill the tank directly over the unit to avoid in case you accidentally spill water, this will flow into the unit.

Safety Instructions



Change the spray liquid everyday. Always add disinfection additive to the distilled water. Rinse the tank daily and fill it with fresh water everyday.



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

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



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 will not can while clamping it,
- the tool stuck properly in the chuck the tool is approved for using it at the max. speed (see manufacturer's instructions),
- the tool is absolutely dry.



Switch off the unit immediately if

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

Safety Instructions



Empty the unit if it is not in use for a longer period of time (e.g. before vacations). Clean out the tank. Set the spray function on maximum. Now start the spray function, and the water will spray for approx. 3 min. The fluid will be blown out of the complete spray system and handpiece.



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, while the equipment is plugged in as some components are live. A spare parts list may be supplied to qualified persons (repair workshops). No responsibility can be accepted for unauthorized or improper tampering with the unit, which nullifies the guarantee and any other liabilities.

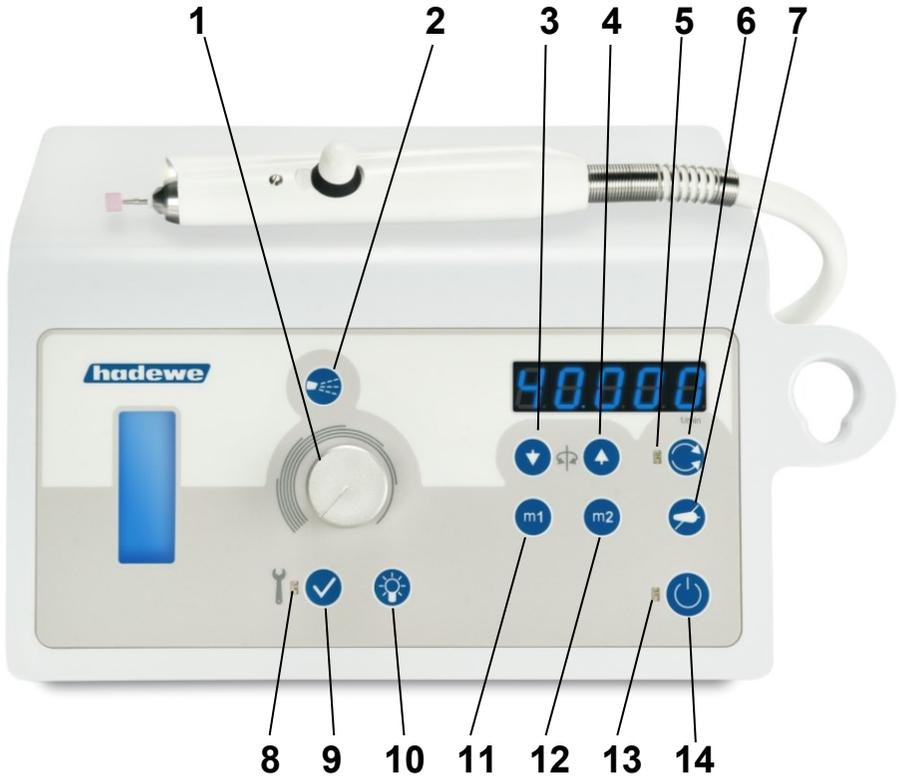
Cleaning & Disinfection



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 these steps:

- Remove the rotating tool (e.g. bur) first. To do so, pay attention to the instructions of its manufacturer.
- Remove clothing remains through wiping off easily the unit with a moistened paper cloth. Afterwards clean all surfaces with a disinfection cloth (e.g. Mikrozyd AF cloths of Schülke and Mayr).

Getting to Know the Unit



- 1 spray regulator knob
- 2 turn OFF/ON spray
- 3 decrease speed
- 4 increase speed
- 5 LED lights up during anticlockwise operation
- 6 button to change the direction of rotation
- 7 turn off handpiece & spray/turn on airflow
- 8 LED lights up when the washer change necessary
- 9 button to confirm the changing the washer
- 10 handpiece light ON/OFF
- 11 memory button m1 for speed
- 12 memory button m2 for speed
- 13 LED lights up in standby mode
- 14 ON/OFF switch (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 familiarize 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 spray 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 12 cm to the back-side 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 60 cm from the patient's foot. The unit should be 30 – 90 cm from the floor.

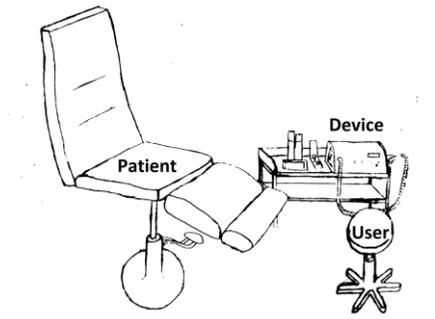


Image: Example of positioning of foot care unit in treatment room

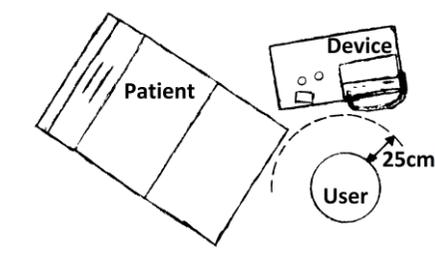


Image: Bird's eye view of work area

Before First Use

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



Make sure, that the tank is filled with spray liquid. Ensure that the tool is fixed.

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



Take up the handpiece. To use the handpiece and spray function, press the button (14) on the front of the unit.

Application

Operation 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 (3) and (4) 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 a rotation direction using the button (6). The most commonly used direction is clockwise. Most milling instrument (steel instruments with steel cutters) are optimized 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, you can turn on the spray by pushing button (2). By using the adjusting knob (1), you can set the amount of the spray liquid.

After setting the speed and the spray amount, you can start with working. If you want to take a break or finish the job, press the standby button (14). The handpiece motor

and spray 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 you 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.

Application

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.



Application



Application

Infilling the Spray Liquid

Switch off the device. Pull out the spray tank on its handle. Hold the cover of the tank in hand and unscrew the tank. Now fill it with distilled water and anti-germ liquid, e.g. AquaHy (art. 8555).



Do not exceed the maximum level when filling the tank.

Now turn the tank cover back on the tank. While screwing back the cover on the tank, make sure that is closed correct. Otherwise there will no pressure be built up. Put the tank back in the housing. Switch on the power switch in the rear of the unit.



Attention: Never use tap water (Danger of calcification!). Also, do not use explosive or combustible liquids, e.g. alcohol.

Note: The filter in the tank (art. 3479) should be fully under pressure, otherwise no water will be sucked in.



The water filter has to be fully under water, otherwise no water will be sucked in.

Insert Bur

The handpiece is equipped with a chuck which can hold all burs with a diameter of 2.35 mm and usually are used in the fields of podiatry. To open the chuck, push the black knob forward with your thumb and leave it there.



Now insert the tool as far as possible. Pull back the black knob and the tool will be clamped.



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

Application

Adjusting the Speed

Put the handpiece back in the handpiece holder or keep it in your hand. Switch ON the unit with switch (14). Now you can adjust the requested speed with the switch (3) and (4). Choose the direction with switch (6).

Memory Buttons m1, m2

Frequently used speed levels can be saved. Therefore, two memory buttons are available. At first, choose your speed level and then save it by pushing button m1 for 4 seconds. To recall the above speed level simply press button m1 (11) again. Further speeds can be saved with m2 (12).

Spray

Turn on the spray function while pushing switch (2). Now the spray system will be filled automatically and a strong spray stream will be blown out of the handpiece for the first 15 sec. Then you can adjust the requested spray stream while turning knob (1).

When turning off the unit or the spray function, the spray liquid is pumped back completely into the tank from the hoses. With this process, a bubbling can be heard in the tank.

Drying Function/ Changing the Bur

Press key (7) and the handpiece

and spray will be turned off. Now only air will come out of the top of the handpiece, which you can use to dry the spot of the recent treatment. When you push button (7) again, the spray and handpiece are working again.



This function can also be used to change your tools while the handpiece is not running.

Foot Switch (art. 0970)

Commencement of foot switch

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

Function of the foot switch

Press foot switch long time:
Switch device ON/OFF

Press foot switch short time:

While the spray is on, and you push the switch once, the spray stream will stop. If you push it a second time, the handpiece will stop. Pushing the switch, a third time, both functions will start to work again.

When working with a foot switch, take care that you only use instruments that are approved for use at the maximum speed of the device.

Maintenance & Care

Washer

The top of the handpiece is equipped with a white washer (art. 4571). This washer has to be replaced by a new one **every 50 operation hours**, unless exchanging it, water could enter the handpiece and cause of damages of the internal parts. The LED (8) will light if a change of the washer is necessary.

Exchanging the washer

Screw off the top of the handpiece. Pull out the washer with some tongs. Look for little parts of the washer in the top and around if you find some, remove such eventually. Push the new washer in the top. Now press button (9) to make the LED (8) go out.

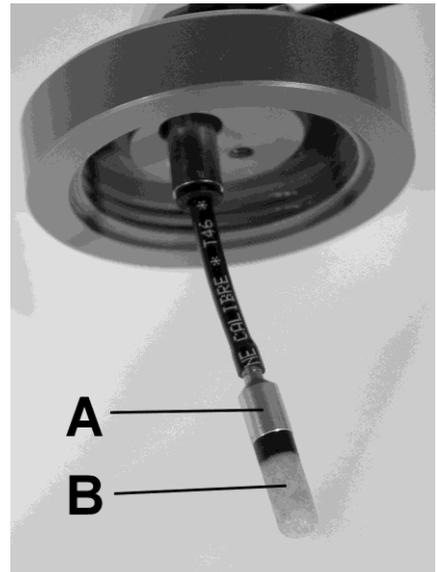


Water Filter

Even smallest parts of dirt could block the nozzle, which sits in the top. Avoiding such blockages, there is a water filter installed in the cap of the tank. We recommend to change this every time, when it is covered with some dirt, at least twice a year. Still make sure, no parts of dirt enter the tank and rinse it quite regularly.

Changing the water filter

Take off the cap of the tank. Hold the metal piece (A) in one hand and screw off the water filter (B). Now you can screw on the new filter.



Maintenance & Care

Cleaning Function

Use the cleaning function if the nozzle is blocked. Turn the unit off using button 14 (Standby). Remove the water filter at first. (For its instructions see paragraph above.) Fill the tank with distilled water. Close the tank and put it back into the unit.

Adjust the amount of spray (button (1) on maximum). Now press button (2) and hold it, until in the display shows "CLEAN". If requested, you could cancel the process by pushing button (14). The complete cleaning process will last three minutes.

During the cleaning process, the water will be washed out of the whole spray system. Parts of dirt are rinsed into the tank. Do not use this water again but clean the tank immediately after realizing a blockage in the nozzle. Otherwise the dirt parts might stick together.

Clean the water filter carefully and put it back in the adapter. Refill the tank with new water.



Use the cleaning function only if the nozzle is blocked. Do not use the function if the unit works properly.

Cleaning the Chuck

Because of the washer, very little dirt might enter the handpiece. In the course of the time, dirt can appear and might interrupt the perfor-

mance of the handpiece. Therefore, clean the chuck monthly.

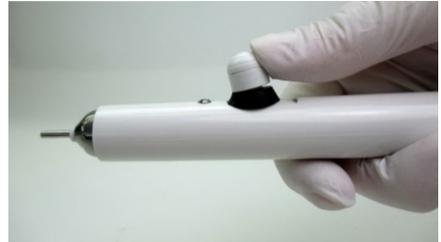
How to remove the chuck

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



Now clean the inside of the handpiece 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:



Maintenance & Care

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:



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 washer	monthly by user
changing the filter	every 6 months
maintenance by repair workshop (changing worn parts, housing, cleaning, check leakage current)	every 500 hours of operation by repair workshop

Handling Instructions

 Always deposit the handpiece with the top downwards. Therefore, you can avoid liquid from entering the handpiece.

 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 ball bearings 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.

 Always working with maximum speed might have a similar effect. Please make sure that the speed setting you use is according to the work you are doing and the instruments you are working with.

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.

Rubber ring under the knob twists while using it. → Twist it of 180°.

It does not spray.

Pressure cannot be set up in the tank, because the lid is not tightened well.

There are parts of dirt in the spray system. → Cleaning the spray system according to page 19.

The blue water filter (art. 3497) in the tank is blocked. → Change the water filter.

Unit does not work at all.

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

Footswitch 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.

Troubleshooting

After lengthy use unit does not spray.

Unit is overheated. → Slots of the unit should not be covered or blocked. Let cool down the unit for a while.

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.

The motor of the handpiece stutters (e.g., 1 sec.) while switching it on.

Very seldom this error might occur. It would not damage the motor at all.

HS, EE in Display

The motor does not start, because the chuck is still open. → Insert the bur and tighten it well (pull the black button backwards). Then start the handpiece at max. speed.

Spray stream stutters.

There is air in the spray system. After 5 min running, this effect will disappear.

Acceleration of the spray stream.

Note: To reduce the starting time of the spray, turn the spray regulator on Max. After the spray started, adjust the stream to the requested amount of water.

Fluid leaks out of the unit.

Please be aware of the maximum filling level of the tank: Do not exceed the maximum level when filling the tank.

Technical Details

0586 Hyperios⁴ Plus

total weight: 3,5 kg
dimension: W245xH133xD190 mm
power supply: 230 V~, 50 Hz
rated current: 0,5 A
fuse primary:
F1, F2: 500 mA delay action fuse
fuse sec. thermo fuse
protection class I
accuracy of speed display: $\pm 10\%$

handpiece:

type B applied part
diameter: 17-22 mm
length: 143 mm
speed: 6000-40000 rpm

Accessories & Spare Parts

art.

0970	foot switch
3497	spray filter
4571	washer
8555	AquaHy
6158	cleaning brush

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

Operating Time

The device is designed for extended usage.

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

Technical Details

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, 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, unit discharge current $<1000\mu\text{A}$, discharge current at applied part $<1000\mu\text{A}$

Functional inspection of display, on/off button, 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.

Technical Details

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)



change direction



spray ON/OFF



spray regulation



turn off handpiece & Spray /
turn on airflow



light ON/OFF



rotation

m1, m2 memory buttons for speed



Washer change is necessary.



confirm



alternating current



direct current



safety fuse



type B applied part



socket foot switch



date of manufacture,
name and address
of the manufacturer

Technical Details

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 Details

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 Details

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	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. Recommended Separation Distance: $d = 1,17 \sqrt{P}$ $d = 1,17 \sqrt{P}$ 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 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: 
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.			
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.			

Technical Details

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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