Variosuc 0624

EN

Installation and Operating Instructions

CE 0297

9000-606-40/30

DÜRR DENTAL

1707V001

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1 About this document

These installation and operating instructions form part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

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1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:


General warning symbol


Warning – dangerous high voltage


Warning – hot surfaces


Warning - automatic start-up of the unit


Biohazard warning

The warnings are structured as follows:

SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

– **DANGER**
  Immediate danger of severe injury or death
– **WARNING**
  Possible danger of severe injury or death
– **CAUTION**
  Risk of minor injuries
– **NOTICE**
  Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.


Comply with the Operating Instructions.


CE labelling with the number of the notified body


Manufacturer

Serial number

Order number


Do not reuse


Type BF application part


Wear hand protection.


Do not climb onto the unit


Do not sit on the unit


Fuses


Unit operation interrupted


Audible signal/melody sounds


Unit in operation


Aspirating cold water

1.2 Copyright information

2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose

The moveable spray mist suction unit generates a vacuum and a volume flow for dental treatment.

2.2 Intended use

The moveable spray mist suction unit removes the media which develops during dental treatment (e. g. water, saliva, dentine and amalgam). This is collected in a container or disposed.

If the the waste water from the device is disposed of directly, it must be able to run off with a slope.

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.

- Do not use this device to aspirate flammable or explosive mixtures.
- Do not use the unit as a vacuum cleaner.
- Do not use chemicals containing chlorine or foaming chemicals.
- Operation in operating theatres or explosive areas is not permissible.

2.4 General safety information

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.

› Prior to each use, check condition of the device and make sure it is in perfect working order.

› Do not convert or modify the units.

› Observe the Installation and Operating Instructions.

› Make the Installation and Operating Instructions available to the person operating the device at all times.

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2.5 Qualified personnel

Operation

Persons who operate the units must ensure safe and correct handling based on their training and knowledge.

› Instruct or have every user instructed in handling the unit.

Installation and repairs

› Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.6 Protection from electric shock

› When working on the units observe all the relevant electrical safety regulations.

› Never touch the patient and unshielded plug connections on the device at the same time.

› Immediately replace any damaged lines and connections.

Observe the EMC rules concerning medical devices

› Observe the special precaution measures concerning electromagnetic compatibility (EMC) for medical devices. "EMC information in accordance with EN 60601-1-2 for devices from Dürr Dental" (order number 9000-606-67) is available from Dürr Dental and in the download area at www.duerrdental.com.

2.7 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.

› Only use only genuine working parts and spare parts.

2.8 Transport

The original packaging provides optimum protection for the device during transport.

If required, original packaging for the unit can be ordered from Dürr Dental.

Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

› Only transport the device in its original packaging.

› Keep the packing materials out of the reach of children.

2.9 Disposal

Unit

The unit must be properly disposed of. Within the European Union, the unit must be disposed of in accordance with EU Directive 2012/19/EU (WEEE).

› If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

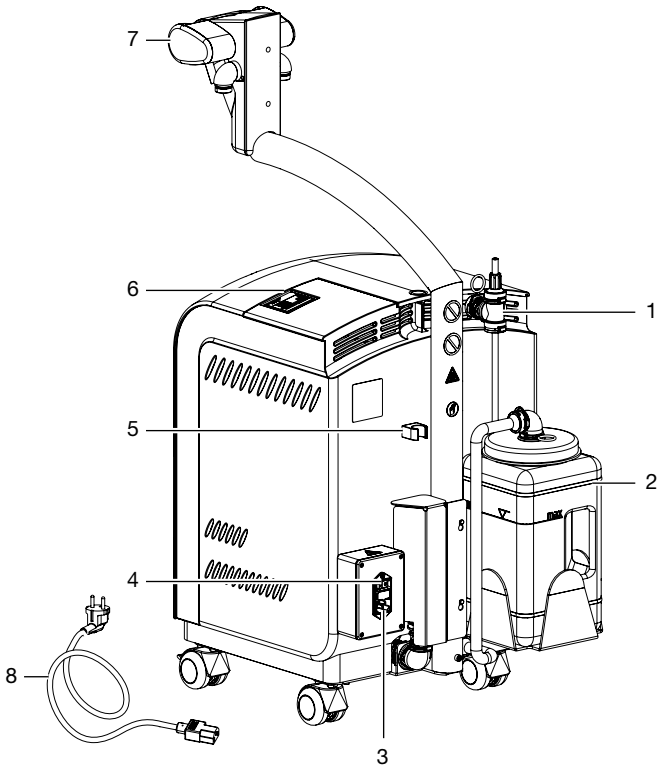
The unit may be contaminated. Instruct the company disposing of the waste to take the relevant safety precautions.

› Decontaminate potentially contaminated parts before disposing of them.

› Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.

› If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

3 Overview



1 Rinsing hose
2 Fluid container
3 Mains connection
4 On/off switch
5 Mount for water water connection
6 Display panel (optional)
7 Comfort hose manifold
8 Mains cable

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):

Variosuc VSA. 0624-100-50

Variosuc VSA with funnel element 0624-100-51

Variosuc VS 0624-100-55

Variosuc VS with funnel element 0624-100-56

- OroCup
- Cannulae set
- Disposable filter
- Rotary adaptor, grey
- Saliva extractor hose, grey
- Suction hose, grey
- Suction handpiece large, grey
- Suction handpiece small, grey
- Swivel joint, grey
- Waste water hose
- Dürr Recycling-Box (optional)
- Mains cable
- Saliva cannula (optional)

3.2 Accessories

The following articles are necessary for the operation of the unit, depending on the application:

Disposable filter 0725-041-00
Universal cannula (double set) 0700-003-00
OroCup care system 0780-350-00
Disposable amalgam container . . .7110-033-00
Saliva cannula. 7068-003-05

3.3 Disposable materials

The following materials are consumed during operation of the device and must be ordered separately:

Orotol plus
4 x 2.5 l bottles/carton CDS110P6150
MD 555 cleaner
4 x 2.5 L bottle / carton CCS555C6150
Disposable filter for suction systems 0725-041-00
Bacteria filter. 7119100010
Universal cannula, grey 20 pieces 0700-054-00
Surgical suction cannula, sterile Ø 2.5mm, 20 pieces 0700-007-50
Surgical suction cannula, sterile Ø 2.5 mm, 100 pieces 0700-007-51

4 Technical data

Electrical data for the device		
Nominal voltage	V AC	230
Voltage fluctuation	%	±10
Nominal current	A	2.9
Frequency	Hz	50
Type of protection		IP20
Protection class		I
Duty cycle	%	100 (S1)
G-fuse link IEC 60127-2		T6.3 AH
Unit plug		1/N/PE

General technical data		-50 -51	-55 -56
Dimensions (W x H x D)	mm	360 x 1000 x 625	
Weight	kg	38	37
Water temperature	°C	max. 35	
Noise level	dB(A)	54	
Exhaust air connection		DürrConnect	
Waste water connection		DürrConnect	
Mesh size, sieve of theCombination Suction Unit	mm	3	

Classification		
Medical Devices Directive (93/42/EU)		Class IIa

Ambient conditions during storage and transport		
Temperature	°C	-10 to +60
Relative humidity	%	max. 95

Ambient conditions during operation		
Temperature	°C	+10 to +40
Relative humidity	%	< 70

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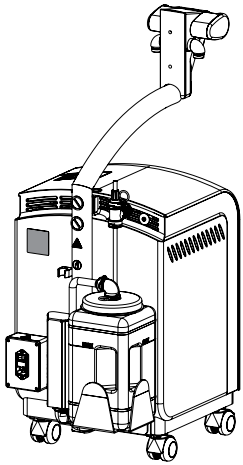
4.1 Type plate

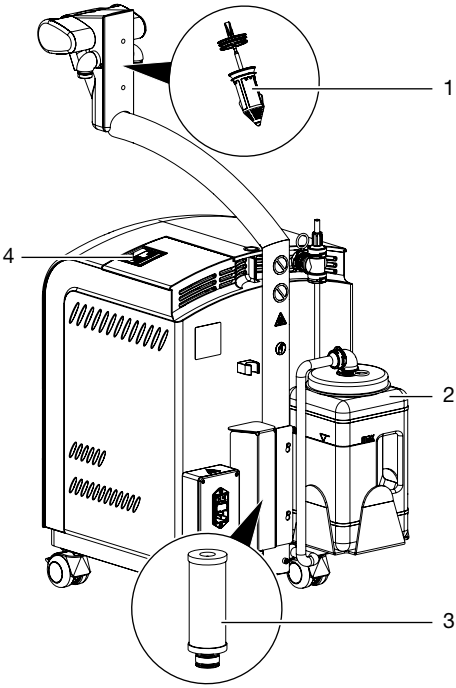
The type plate is located on the rear of the unit.



4.2 Conformity assessment

This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Operation



1 Disposable filter
2 Fluid container
3 Bacteria filter
4 Display panel (optional)

The mobile treatment unit aspirates spray mist, fluids and particles during dental treatment.

The unit is optionally available with amalgam separation. The fluid-air-mixture is flows through disposable filter in the hose manifold and is aspirated to the combination suction unit. In the combination suction unit, the fluid is separated from the air and is then transported either to the fluid container or directly into the waste water outlet via the waste water hose. The exhaust air is passed through the air bacteria filter or, as an alternative for a fixed system installation, via an exhaust air hose. Once the maximum filling level height has been reached, the fluid container must be emptied.

In a unit with amalgam separation, a display panel is integrated in the cover of the mobile treatment unit which displays the filling level of the amalgam collecting container.

6 Requirements

6.1 Installation/setup room

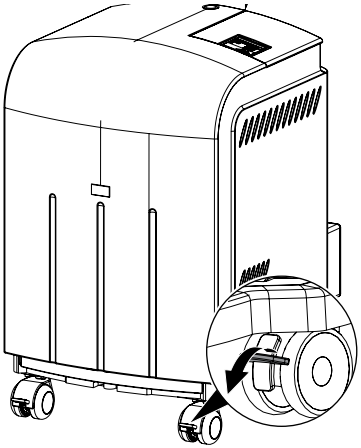
The room chosen for set up should fulfil the following requirements:

– Closed, dry room
– It should not be a room made for another purpose (e.g. boiler room or wet cell).
– Refer to the requirements for environmental conditions in "4 Technical data".
– Do not cover cooling slots or openings with housing installations; ensure sufficient clearance to the openings to permit sufficient cooling.

7 Installation

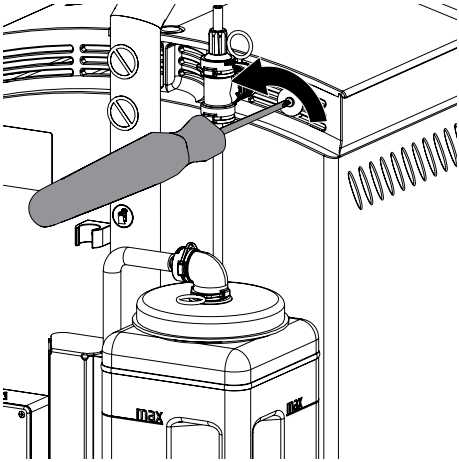
7.1 Setting up the unit

› Where a waste water connection is available, lead the fluids directly via the waste water hose into the waste water outlet.
› Secure the unit against rolling away.

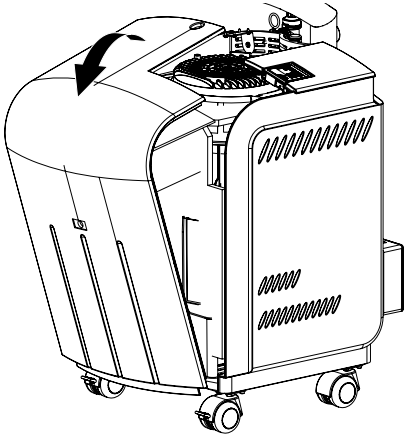


7.2 Remove the transport locks

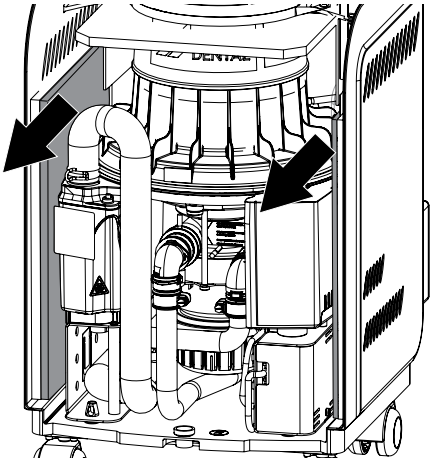
› Open the screw cap.



› Remove the protective cover.



› Remove the transport locks.



› Fit the protective cover.

7.3 Electrical safety when making connections

› The unit must only be connected to a correctly installed power outlet.

› Do not place non-fixed multi-socket units on the floor. Follow the requirements in section 16 of IEC 60601-1 (EN 60601-1).

› Do not operate any other systems using the same multiple socket.

› Make sure that none of the electrical cables leading to the unit are under any mechanical tension.

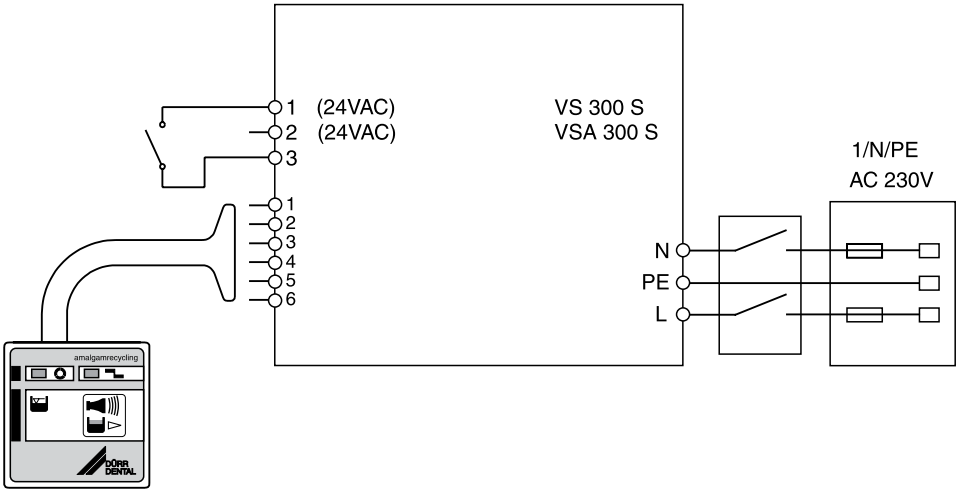
› Before initial start-up check that the mains supply voltage and the voltage stated on the type plate match (see also "4. Technical data").

7.4 Connecting the unit to the mains

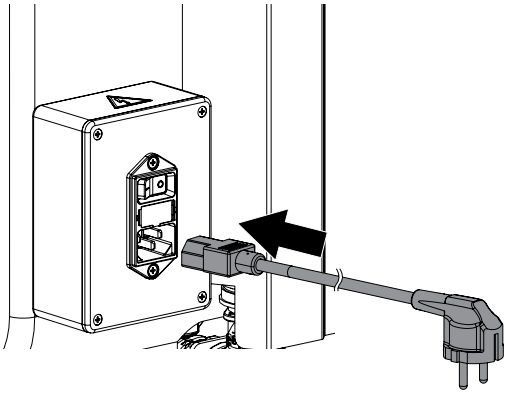
Requirements:

- Properly installed power outlet close to the unit (max. mains cable length 2.5 m).
- Easily accessible power outlet.
- Mains voltage must match the information shown on the type plate.

Further information is provided in the installation and operating instructions of the combination suction units VS 300 S and VSA 300 S.



› Plug in the mains cable connecting plug into the device socket connection.



› Plug the mains plug into the power outlet.

8 Commissioning and first start-up

NOTICE
Short circuit due to the build up of condensation
› Do not switch on the unit until it has warmed up to room temperature and it is dry.

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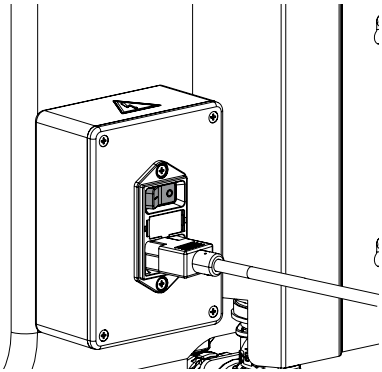
Two labels are included in the scope of delivery of the bacteria filter.
› Inscribe both labels.
› Apply the label to the bacteria filter.
› Stick the label in the practice handbook.

8.1 Switch on the unit



9 Operation

9.1 Aspirate fluid

› Remove the hose from the hose manifold to aspirate.

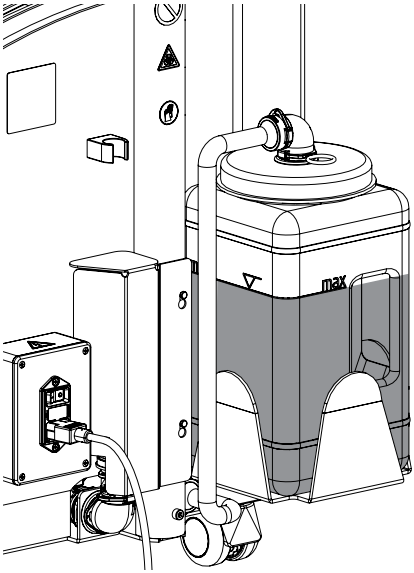
The combined suction unit is started.

› Aspirate fluid from the patient's mouth.

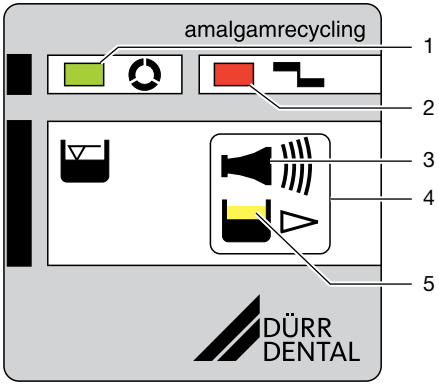
The fluid is collected in the fluid container.

› After treatment, check the filling level of the fluid container.

› Once the maximum filling level has been reached, empty the fluid container.



10 Display panel



1 GREEN LED
2 RED display
3 Audible signal/melody
4 Reset/service key
6 YELLOW LED

10.1 Ready for operation

GREEN LED illuminates

10.2 Amalgam collector vessel is 95% full

Yellow LED is on

GREEN LED illuminates

Audible signal melody sounds

– At a fill level of 95%, the signal melody can be switched off by pressing the reset button. The device is then ready for operation again.
– The yellow LED comes on as a reminder that the amalgam collector vessel is due to be changed. The level display is repeated every time the unit is switched on at the main power switch.

We recommend changing the amalgam collector vessel when it reaches 95% full.

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10.3 Amalgam collector vessel is 100% full

Yellow LED is on

Red display flashes

Audible signal melody sounds

– At a fill level of 100% the signal melody can no longer be switched off by pressing the reset button.
– The collector vessel needs to be replaced.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

– The separator will not be ready for operation again until the amalgam collector vessel has been replaced

10.4 Amalgam collector vessel not in position

Red display flashes

Audible signal

– Press the reset button briefly to switch off the audible signal.
– Switch off the device.
– Insert the collector vessel.
– Switch on the unit.
– Green LED lights up – "Ready for operation“

If this error message occurs when the collector vessel is correctly inserted, this indicates that there is a technical defect – inform your Service Technician.

10.5 Motor fault

Red display and

green LED flash alternately

Audible signal

Occurs during the start-up of the amalgam separator.

– Press the reset button briefly to switch off the audible signal.
– If the reset button is pressed for longer than 2 seconds the unit can be restarted.

If this problem happens again on the same day, the amalgam separator will no longer be operational - notify the service technician.

10.6 Brake monitoring

Red display and

green LED flash alternately

Occurs upon braking action of amalgam separator.

– The amalgam separator is still operational.

If this problem occurs on several consecutive days, the braking must be checked by a service technician.

11 Cleaning and disinfection

The reprocessing of the handpieces and the cleaning of the hose manifold is described in the installation and operating instructions "Comfort hose manifold" order no. 9000-606-18/.

NOTICE
Device malfunctions or damage due to use of incorrect media
Guarantee claims may become invalid as a result.
- › Do not use any foaming agents, e.g. household cleaning agents or instrument disinfection agents.
- › Do not use abrasive cleaners.
- › Do not use agents containing chlorine.
- › Do not use any solvents like acetone.

11.1 Fluid container

NOTICE
Equipment damage from over-filling of the fluid container
- › Comply with the tank volume.
- › Empty the fluid container before cleaning and disinfection and also during this process if necessary.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

If amalgam is extracted during treatment, dispose of it in accordance with the nationally-valid rules and regulations.

› Empty, clean and disinfect the fluid container on a daily basis

11.2 After every treatment

› Aspirate a glass of cold water through the large and the small suction hoses. Do this even if only the small suction hose was actually used during treatment.

Suction through the large suction hose causes a large amount of air to be drawn up, thereby considerably increasing the cleaning effect.

› Disinfect and clean the unit surface with a non-aggressive surface disinfectant, e. g. FD 350 disinfection wipe or a comparable product.

11.3 Daily after the end of treatment

After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:
- – Material-compatible, non-foaming disinfection/cleaning agents with Dürr Dental approval, e. g. Orotol plus.
- – Unit care system, e.g. OroCup

› To pre-clean, suck up 2 litres of water with the care system.

› Aspirate the disinfection/cleaning agent with the care system.

11.4 Once or twice a week before the midday break

Under harsher conditions (e.g. hard water or frequent use of prophylaxis powders) 1x daily before the midday break

The following are required for cleaning:
- – Material-compatible, non-foaming special cleaning agents that have been approved by Dürr Dental, e.g. MD 555 Cleaner
- – Unit care system, e.g. OroCup

› To pre-clean, suck up 2 litres of water with the care system.

› Aspirate the cleaning agent with the care system.

› Rinse with ca. 2 l water after the application time.

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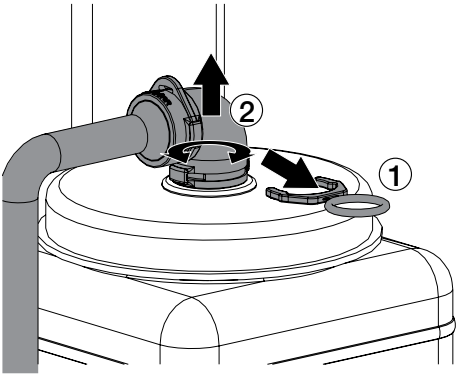
11.5 Weekly and before longer treatment interruptions

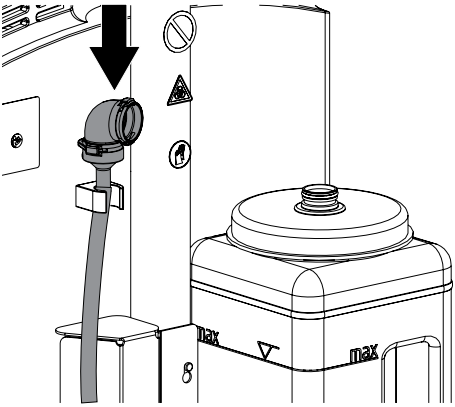
Flush the unit at least weekly and before longer treatment interruptions.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

› Remove the yellow holding clip and disconnect the waste connection from the cover of the fluid container by turning slightly.



› Insert the waste connection in the mount.

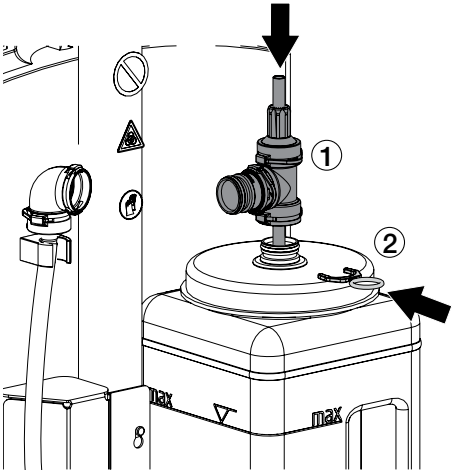


› Empty the fluid container and rinse with water.

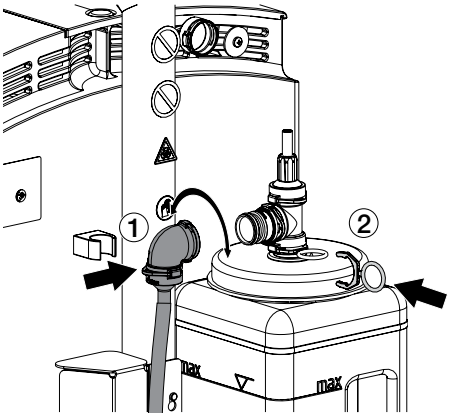
› Fill the fluid container to the maximum level with water.

› Add 60 ml Orotol plus suction unit disinfection to the filled water.

› Place the rinsing hose onto the connector on the cover of the fluid container and secure with the clip.



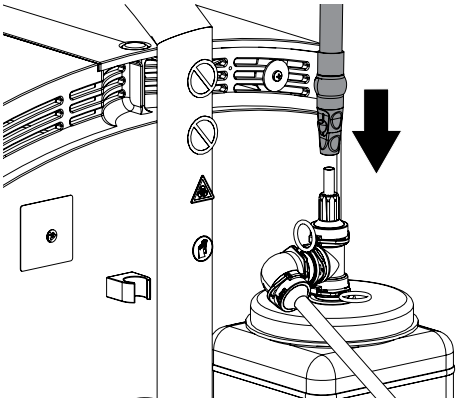
› Connect the waste water connection to the rinsing hose.



› Switch on the unit.

› Remove the cannula from the large suction handpiece.

› Place the large suction handpiece onto the rinsing hose.



› After c. 20 min. remove the suction handpiece slowlyfrom the connection of the rinsing hose,and place in the hose manifold.
› Remove the rinsing hose from the fluid container and clean and disinfect using a suitable instrument disinfectant, e.g. ID 212 forte or ID 213.
› Replace the waste water hose on the empty and disinfected fluid container.

12 Maintenance

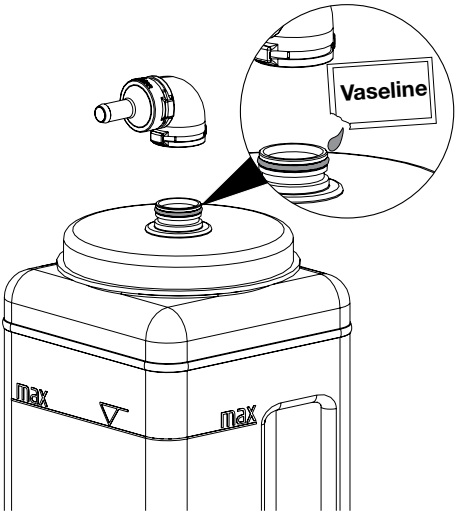
Only trained specialists or personnel trained by Dürr Dental may service the unit.

Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

Maintenance interval	Maintenance work
Weekly	› Change disposable filter.
Annually	› Replace the bacteria filter.

12.1 Grease the seal

› Grease the seal if required.



Result:
Light reduction and insertion of rinsing hose and waste water connection.

12.2 Replace the disposable filter

NOTICE
Risk of equipment damage
Do not operate the unit without the disposable filter.

Wear hand protection.

› Open the cover and remove the disposable filter.

12.3 Replace the bacteria filter

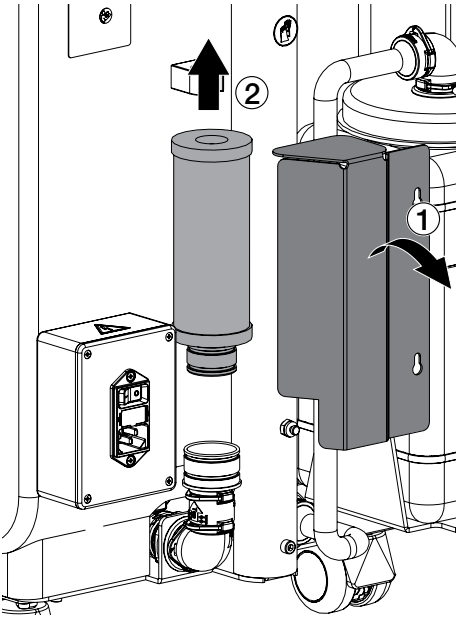
Two labels are included in the scope of delivery of the bacteria filter.

› Inscribe both labels.
› Apply the label to the bacteria filter.
› Stick the label in the practice handbook.

Wear hand protection.

› Lift the cover plate upwards out of its mounting.

› Disconnect the bacteria filter from the connecting sleeve.



13 Information about EMC in accordance with EN 60601-1-2

13.1 General information

The information in this leaflet includes excerpts from the relevant European standards for electrical, medical devices. It must be observed when installing Dürr Dental devices or combining them with products of other manufacturers. If you are uncertain about anything, please refer to the complete standard.

13.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
U_T	Rated voltage of the device (supply voltage)
V_1, V_2	Compliance level for the test in acc. with IEC 61000-4-6
E_1	Compliance level for the test in acc. with IEC61000-4-3
P	Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer
d	Recommended safety distance in metres (m)

13.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

The device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the device should ensure that the device is operated in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment - guidelines
HF emissions in accordance with CISPR 11	Group 1	The suction unit uses HF energy exclusively for internal functions. For this reason, HF transmissions are very low and it is unlikely that any interference will be caused to neighbouring electronic devices.
HF emissions in accordance with CISPR 11	Class B	The suction unit is suitable for use in all facilities including those in living areas and areas that are directly connected to the public mains electricity supply that also supplies buildings used for residential purposes.
Harmonics in acc. with IEC 61000-3-2	Class A	
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	Compliant	

Resistance to electromagnetic interference (immunity) for all devices and systems

The device is designed for use in electromagnetic environments specified below. The customer or operator of the device should ensure that the device is operated such an environment.

Interference immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or cement, or covered with ceramic tiles. If the floor is covered by synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage surge in accordance with IEC 61000-4-5	±1 kV voltage outer conductor/outer conductor ±2 kV voltage outer conductor/earth	±1 kV push-pull voltage ±2 kV common mode voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage in accordance with IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for 1/2 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for 1/2 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the operator of the device needs the unit to continue working even if the mains power supply is interrupted, we recommend powering the device from an uninterruptible power supply (UPS) or from a battery.
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	30 A/m	The magnetic fields at mains frequency should be within the range of typical values encountered in a commercial or hospital environment.

Table 1: Resistance to electromagnetic interference (immunity) for all devices and systems

Electromagnetic interference immunity for devices or systems that are not life-sustaining

Portable and mobile communication devices should not be used any closer to the unit (including cables) than the recommended safety distance, which is calculated based on the applicable formula for the transmission frequency.

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ = 10 V	$d = 0.35 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	10 V/m 80 MHz up to 2.7 GHz	$[E_1]$ = 10 V/m	$d = 0.35 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 0.7 \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz

Table 2: Electromagnetic interference immunity for units or systems operated in healthcare facilities

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

d Recommended safety distance in metres (m)

The field strength of stationary communication devices should be lower than the compliance level for all frequencies based on inspections on site[a,b].

Interference is possible in the environment of units that have the following symbols.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic radiation is affected by absorption and reflection on the building, objects and people.

[a] The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters, for example, cannot be accurately predicted. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the unit is used exceeds the compliance levels stated above, the unit should be monitored to verify that it works as intended. If unusual performance characteristics are observed additional measures may be required, such as a changing the orientation of the unit or moving it to a different location.

[b] Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than $[V_1]$ V/m.

Recommended safety distance between portable and mobile HF communication devices and the unit

The device is designed for use in the electromagnetic environments specified below, in which the HF disturbance variables are controlled. The customer or the operator of the device can help to prevent electromagnetic interference by maintaining the minimum distances between mobile HF communication equipment (transmitters) and the device as recommended below in accordance with the maximum output line of the communication equipment.

Keep a minimum distance of 30 cm between the device and mobile communication devices.

EN

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz $d = 0.35 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \cdot \sqrt{P}$
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.11	1.11	2.21
100	3.5	3.5	7

Table 3: Recommended safety distance between portable and mobile HF communication devices and the unit

For transmitters whose maximum rated power is not specified in the table shown above, the recommended safety distance d in metres (m) can be determined from the formula that belongs to the respective column where P is the maximum rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection on the building, objects and people.

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