

Variosuc

EN



Installation and operating instructions

CE 0297

9000-606-40/30



 **DÜRR
DENTAL**

2011V002

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! Important information

1 About this document

These installation and operating instructions represent 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.


The German version of the installation and operating instructions is the original manual. All other languages are translation of the original manual. These installation and operating instructions apply to:

Variosuc

Order number:

- 0642-100-50
- 0642-100-51
- 0642-100-55
- 0642-100-56

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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.

 SGS-tested product safety

 Switch off and de-energise the device (e. g. unplug from mains).



 Refer to Operating Instructions.

 CE labelling with the number of the notified body

 Manufacturer

 Medical device

 Serial number

-  Order number
-  Health Industry Bar Code (HIBC)
-  Do not reuse
-  Type BF application part
-  Protective ground connection
-  Wear protective gloves.
-  Do not climb onto the unit
-  Do not sit on the unit
-  Do not push or slide the unit.
-  Comply with the lower and upper temperature limits
-  Lower and upper humidity limits
-  Fuses
-  Unit operation interrupted
-  Audible signal/melody sounds
-  Unit in operation
-  Aspirating cold water

1.2 Copyright information

All circuits, processes, names, software programs and units mentioned in this document are protected by copyright.

The Installation and Operating Instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from Dürr Dental.

2 Safety

Dürr Dental has designed and constructed this unit so that when used properly and for the intended purpose it does not pose any danger to people or property.

Despite this, the following residual risks can remain:

- Personal injury due to incorrect use/misuse
- Personal injury due to mechanical effects
- Personal injury due to electric shock
- Personal injury due to radiation
- Personal injury due to fire
- Personal injury due to thermal effects on skin
- Personal injury due to lack of hygiene, e.g. infection

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

2.3 Improper use

Any use of this appliance / these appliances above and beyond that described in the Installation and Operating Instructions is deemed to be incorrect usage. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The operator will be held liable and bears all risks.

- 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

- › Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.
- › Check the function and condition of the unit prior to every use.
- › Do not convert or modify the unit.
- › Comply with the specifications of the Installation and Operating Instructions.
- › The Installation and Operating Instructions must be accessible to all operators of the unit at all times.

2.5 Specialist personnel

Operation

Unit operating personnel 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 Notification requirement of serious incidents

The operator/patient is required to report any serious incident that occurs in connection with the device to the manufacturer and to the competent authority of the Member State in which the operator and/or patient is established/resident.

2.7 Electrical safety

- › Comply with all the relevant electrical safety regulations when working on the unit.
- › Never touch the patient and unshielded plug connections on the device at the same time.
- › Replace any damaged cables or plugs immediately.

Observe the EMC rules concerning medical devices

The unit complies with the requirements according to IEC 60601-1-2:2014.

- › The unit is intended for use in professional healthcare facilities (in accordance with IEC 60601-1-2). If the appliance is operated in another environment, potential effects on electromagnetic compatibility must be taken into account.
- › Do not operate the unit in the vicinity of HF surgical instruments or MRT equipment.
- › Maintain a minimum distance of at least 30 cm between the unit and other electronic devices.
- › Note that cable lengths and cable extensions have effects on electromagnetic compatibility.
- › No maintenance measures are required to maintain the EMV basic safety.

**NOTICE****Negative effects on the EMC due to non-authorized accessories**

- › Use only Dürr Dental parts or accessories specifically approved by Dürr Dental.
- › Using any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an erroneous operation mode.

**NOTICE****Erroneous operation mode due to use immediately adjacent to other devices or with other stacked devices**

- › Do not stack the unit together with other devices.
- › If this is unavoidable, the unit and other devices should be monitored in order to ensure that they are working correctly.

**NOTICE****Reduced performance characteristics due to insufficient distance between unit and portable HF communication devices**

- › Keep a distance of at least 30 cm between the unit (including parts and cables of the unit) and portable HF communication devices (wireless units) (including their accessories such as antenna cables and external antennas).

2.8 Only use original parts

- › Only use accessories and optional items that have been recommended or specifically approved by Dürr Dental.
- › Only use only original wear parts and replacement parts.

2.9 Essential performance characteristics

The unit does not have any essential performance characteristics as set out in IEC 60601-1 section 4.3.

2.10 Transport

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

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



Dürr Dental will 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 unit in its original packaging.
- › Keep the packing materials out of the reach of children.

2.11 Disposal



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

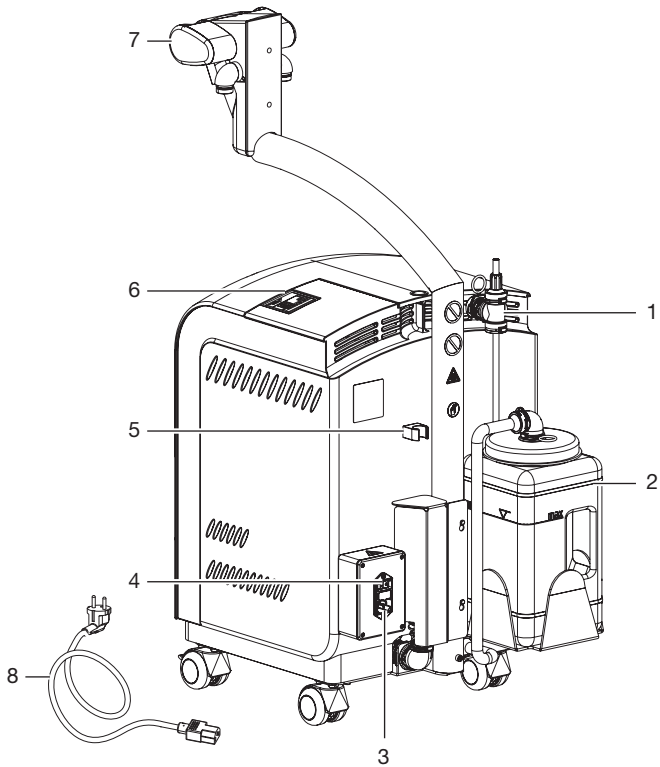
- › Decontaminate potentially contaminated parts before disposing of them.

- › 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.



An overview of the waste keys for Dürr Dental products can be found in the download area at www.duerdental.com (document no. P007100155).

3 Overview



- 1 Rinsing hose
- 2 Fluid container
- 3 Mains connection
- 4 On/off switch
- 5 Mount for 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
- Disposable amalgam container
- Mains cable
- Saliva cannula (optional)

3.2 Accessories

The following items are required for operation of the device, depending on the application:

Universal cannula (double set) 0700-003-00

Saliva cannula 7068-003-05

Prophylaxis cannula 0700-000-50

3.3 Consumables

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

Orotol plus (2.5 litre bottle) CDS110P6150

MD 555 cleaner (2.5 litre bottle) . CCS555C6150

Disposable filter for suction systems (12 pieces) 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

Disposable amalgam container . . . 7110-033-00

4 Technical data

Electrical data for the unit		VSA	VS	VS
Frequency	Hz	50	50	60
Nominal current	A	2.9	2.9	3.7
Rated voltage	V AC		230	
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		VSA	VS	VS
Dimensions (H x W x D)	mm	900 x 365 x 640		
Weight 0624-100-50	kg	32		
Weight 0624-100-51	kg	32.5		
Weight 0624-100-55	kg	31		
Weight 0624-100-56	kg	31.5		
Water temperature	°C	Max. 35		
Noise level*	dB(A)	50	50	52
Exhaust air connection		DürrConnect		
Waste water connection		DürrConnect		
Mesh size, sieve of the Combination Suction Unit	mm	3		
*Noise level in accordance with EN ISO 3744				

Classification	
Medical Device Class	Ila

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

Electromagnetic compatibility (EMC) Interference emission measurements	
Interference voltage at the power supply connection CISPR 11:2015/AMD1:2016	Group 1 Class B
Electromagnetic interference radiation CISPR 11:2015/AMD1:2016	Group 1 Class B

**Electromagnetic compatibility (EMC)
Interference emission measurements**

Intermittent interference voltage at the power supply connection CISPR 14-1:2016	Group 1 Class B
Emission of harmonics IEC 61000-3-2:2018	Compliant
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3:2013/AMD1:2017	Compliant

**Electromagnetic compatibility (EMC)
Interference immunity measurements cover**

Immunity to interference, discharge of static electricity IEC 61000-4-2:2008 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant
Immunity to interference, high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010 3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	Compliant
Immunity to interference from power frequency magnetic fields IEC 61000-4-8:2009 30 A/m at 50 Hz	Compliant
Immunity to interference, near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010	Compliant

**Electromagnetic compatibility (EMC)
Interference immunity measurements supply input**

Immunity to interference, rapid transient bursts – AC voltage grid IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition frequency	Compliant
Immunity to interference, surges IEC 61000-4-5:2014/AMD1:2017 ± 0.5 kV, ± 1 kV, L - N ± 0.5 kV, ± 1 kV, ± 2 kV, L/N - PE	Compliant

Electromagnetic compatibility (EMC)

Interference immunity measurements supply input

Immunity to interference, line-conducted disturbances induced by high-frequency fields – AC voltage grid

IEC 61000-4-6:2013

3 V

0.15 - 80 MHz

6 V

ISM frequency bands

6.765 - 6.795 MHz

13.553 - 13.567 MHz

26.957 - 27.283 MHz

40.66 - 40.70 MHz

80 % AM at 1 kHz

Compliant

Immunity to interference due to voltage dips, short interruptions and voltage variations

IEC 61000-4-11:2004/AMD1:2017

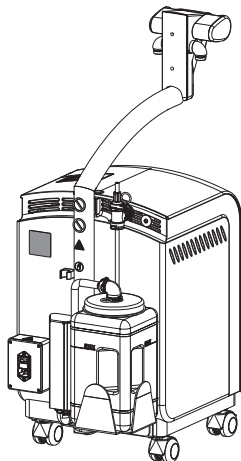
Compliant

Immunity to interference table, near fields of wireless HF communication devices

Radio service	Frequency band MHz	Test level V/m
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	1700 - 1990	28
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	2400 - 2570	28
WLAN 802.11 a/n	5100 - 5800	9

EN 4.1 Type plate

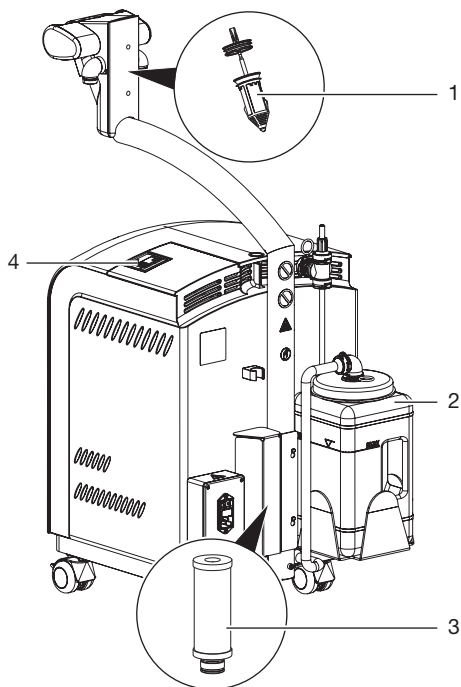
The type plate is located on the rear of the unit.



4.2 Evaluation of conformity

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

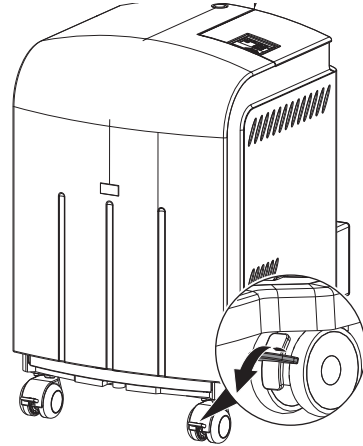
The room chosen for set up should fulfil the following requirements:

- 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

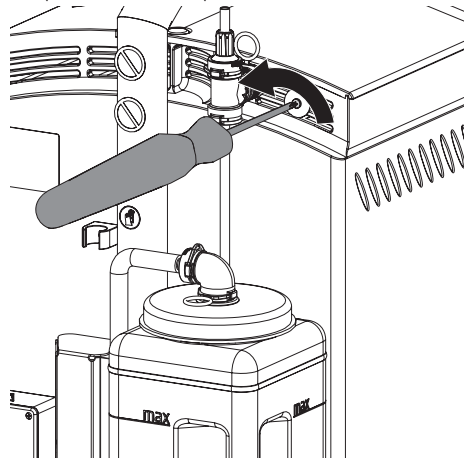
7.1 Setting up the unit

- › 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.



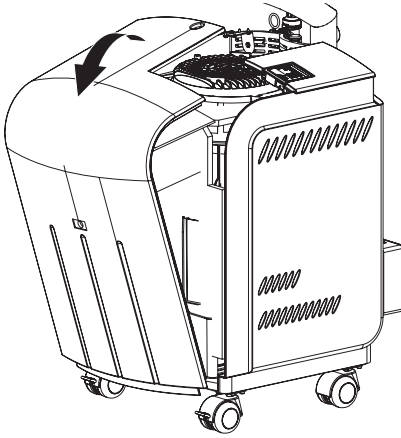
7.2 Remove the transport locks

- › Open the screw cap.

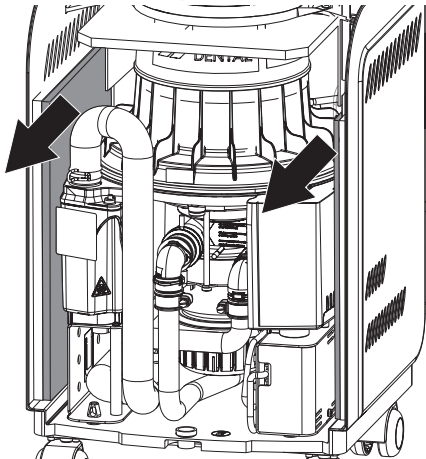


- › Remove the protective cover.

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



- › Remove the transport locks.



- › Fit the protective cover.

7.3 Safety when making electrical connections

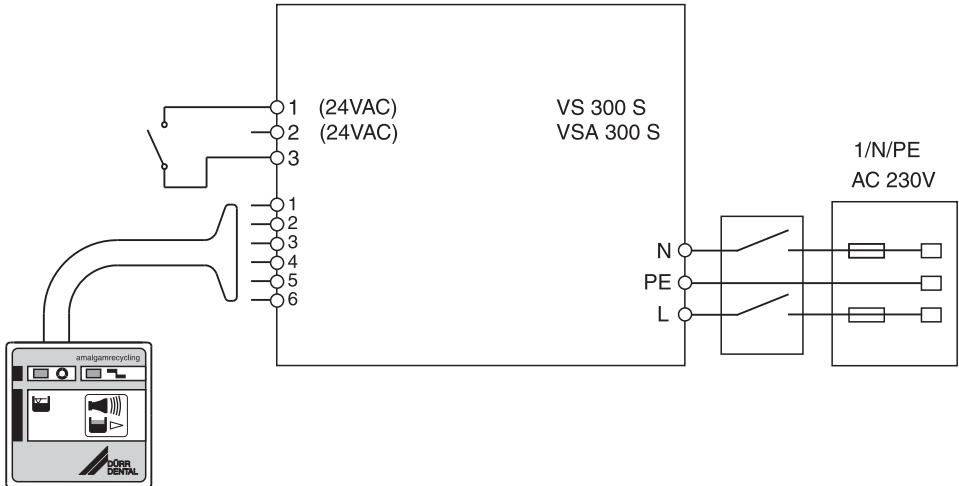
- › The device must only be connected to a correctly installed power outlet.
- › Do not place non-fixed multi-socket units on the floor. Follow the requirements in section 16 of IEC 60601-1 (EN 60601-1).
- › Do not operate any other systems using the same multiple socket.
- › Make sure that none of the electrical cables leading to the unit are under any mechanical tension.

7.4 Connecting the unit to the mains supply

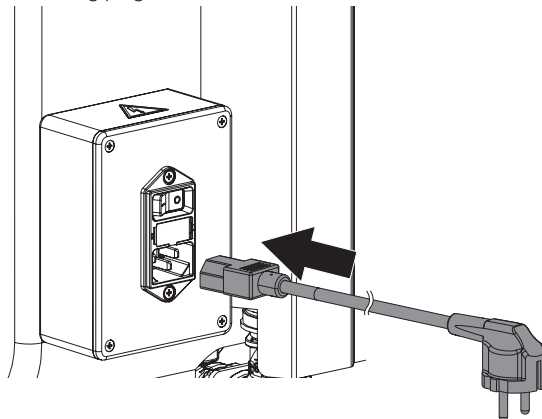
Requirements:

- ✓ 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



NOTICE

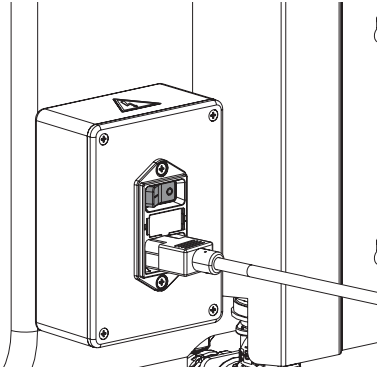
Short circuit due to the build up of condensation

- › Do not switch on the unit until it has warmed up to room temperature and it is dry.

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.

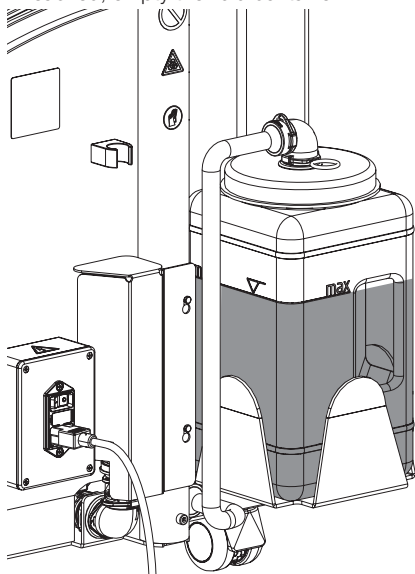


 Usage

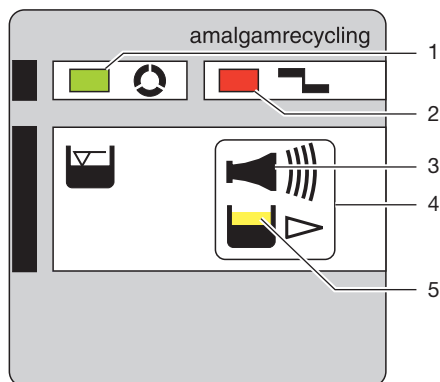
9 Operation

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
- 5 YELLOW LED

10.1 Ready for operation

-  GREEN LED lights up

10.2 Amalgam collector vessel is 95% full

-  Yellow LED lights up
-  GREEN LED lights up
-  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 collecting container 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 collecting container when it reaches 95% full.

10.3 Amalgam collector vessel is 100% full

-  Yellow LED lights up
-  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 collecting container 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 collecting container 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 collecting container.
- Switch on the unit.
- Green LED lights up – "Ready for operation"



If this error message occurs when the collecting container 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



Audible signal



Occurs upon braking action of amalgam separator.

- Press the reset button briefly to switch off the audible signal.
- 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 such as household cleaning agents or instrument disinfectants.
- › Do not use abrasive cleaners.
- › Do not use agents containing chlorine.
- › Do not use any solvents like acetone.

Dürr Dental recommends

- For disinfection and cleaning:
Orotol plus or Orotol ultra
- For cleaning:
MD 555 cleaner

Only these products have been tested by Dürr Dental.

When using prophylaxis powders, Dürr Dental recommends the water-soluble Lunos prophylaxis powders in order to protect the Dürr Dental suction systems.

11.1 Surfaces

Clean the surfaces if there is any visible soiling.

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

11.2 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.



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.

11.3 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.

11.4 Daily after the end of treatment



After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:

- ✓ Non-foaming disinfectant/cleaning agent that is compatible with the materials.
- ✓ 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.

11.5 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:

- ✓ Special non-foaming detergent for suction units that is compatible with the materials.
- ✓ 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.

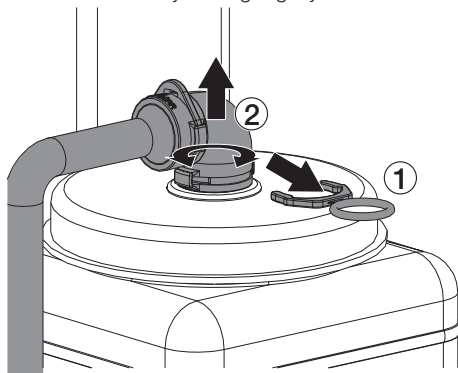
- › Rinse with ca. 2 l water after the application time.

11.6 Weekly and before longer treatment interruptions

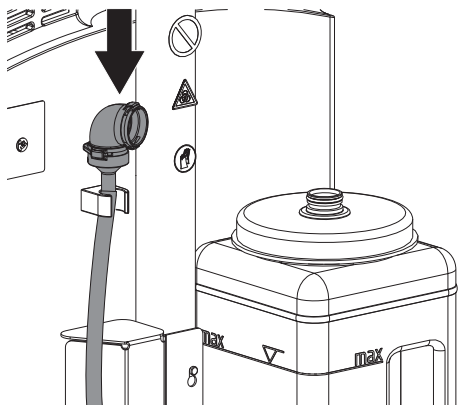
Flush the unit at least weekly and before longer treatment interruptions.

 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.

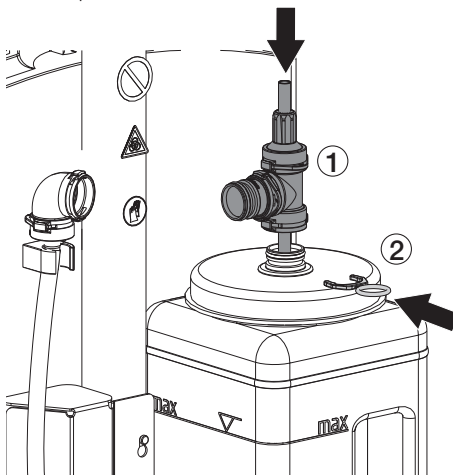


- › Insert the waste connection in the mount.

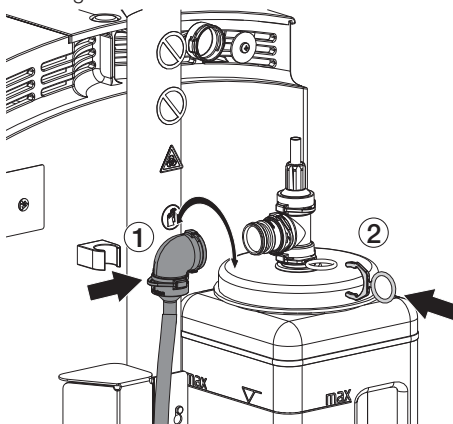


- › Empty the fluid container and rinse with water.
- › Fill the fluid container to the maximum level with water.
- › Add 60 ml Orotol plus suction unit disinfection to the filled water.

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

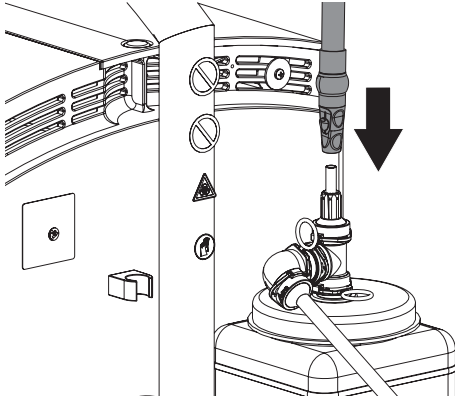


- › Connect the waste water connection to the rinsing hose.



- › 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 slowly from 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.

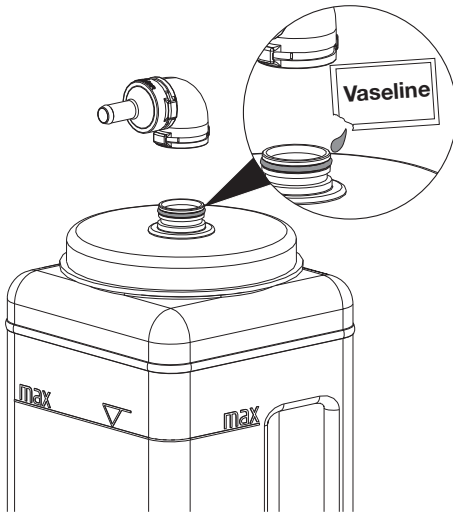


Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

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

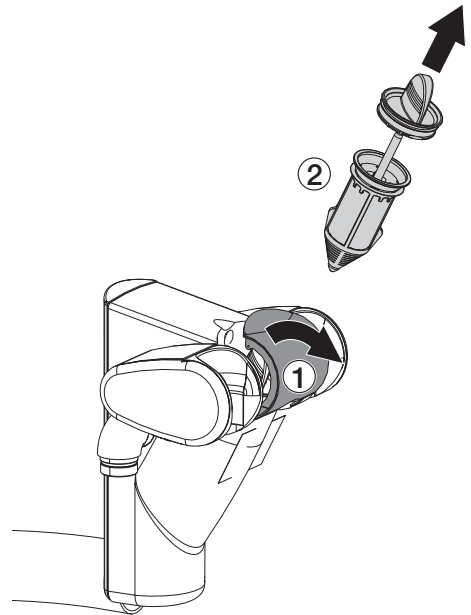
Risk of equipment damage

- › Do not operate the unit without the disposable filter.



Wear protective gloves.

- › 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.

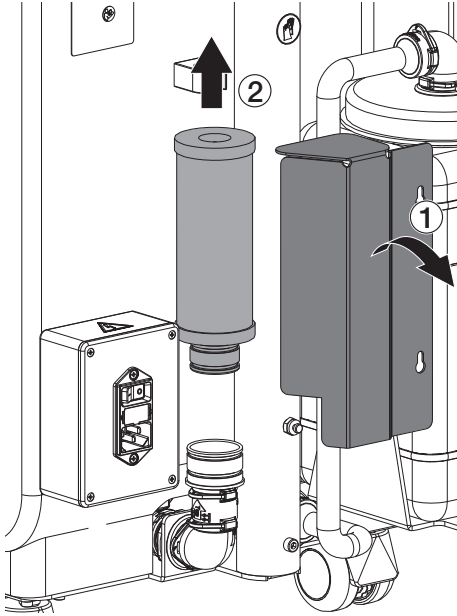
- › Inscribe both labels.
- › Apply the label to the bacteria filter.
- › Stick the label in the practice handbook.



Wear protective gloves.

- › Lift the cover plate upwards out of its mounting.

› Disconnect the bacteria filter from the connecting sleeve.



 Appendix

13 Handover record

This document confirms that a qualified handover of the medical device has taken place and that appropriate instructions have been provided for it. This must be carried out by a qualified adviser for the medical device, who will instruct you in the proper handling and operation of the medical device.

Product name	Order number (REF)	Serial number (SN)

- Visual inspection of the packaging for any damage
- Unpacking the medical device and checking for damage
- Confirmation of the completeness of the delivery
- Instruction in the proper handling and operation of the medical device based on the operating instructions

Notes:

Name of person receiving instruction:**Signature:**

Name and address of the qualified adviser for the medical device:

Date of handover:**Signature of the qualified adviser for the medical device:**

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Hersteller/Manufacturer:

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