Variosuc

EN Installation and operating instructions

CE 0297

DÜRR DENTAL

9000-606-40/30 2502V004

The current version of the installation and operating instructions is available in the Download Center:
Variosuc

http://qr.duerrdental.com/9000-606-40
VSA 300 S

http://qr.duerrdental.com/9000-606-31
VS 300 S

http://qr.duerrdental.com/7119100007
Hose Holder

http://qr.duerrdental.com/9000-606-18

Contents

Important information

Product description

Assembly

Usage

Troubleshooting

Appendix

Important information

1 About this document

These installation and operating instructions represent part of the unit.

The manufacturer and the distributor will not offer any guarantee or accept any liability for the safe operation and the safe functioning of the unit if the instructions and information in these installation and operating instructions are not complied with.

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

Variosuc

REF: 0624-100-50; 0624-100-51; 0624-100-55; 0624-100-56

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.


Observe the operating instructions.

Product for the disinfection and cleaning of suction units


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


Wear protective gloves.


Wear protective goggles.


Use a face mask.


Use protective clothing.


Do not reuse


Do not climb onto the unit


Do not push or slide the unit.


Do not sit on the unit


Aspirating cold water


Unit in operation


Unit operation interrupted

Audible signal/melody sounds


Protective ground connection


Fuses

Comply with the lower and upper temperature limits

Lower and upper humidity limits


Type BF application part

SN Serial number

REF Order number

MD Medical device

HIBC Health Industry Bar Code (HIBC)

CE xxxx CE labelling with the number of the notified body

CH REP Authorised representative for Switzerland


Manufacturer

1.2 Copyright information

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

2 Safety

The unit has been developed and designed in such a way that dangers are effectively ruled out if used in accordance with the Intended Use. 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 electrical 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 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 operator instructed in handling the unit.

Installation and repairs

– The manufacturer recommends that installation, readjustments, alterations, upgrades and repairs be carried out either by the manufacturer itself or by a qualified specialist authorised by the manufacturer.

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 unit 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 EMC basic safety.

NOTICE

Negative effects on the EMC due to non-authorised accessories

› Use only those accessories named or approved by the manufacturer.
› 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 Essential performance characteristics

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

2.9 Applied part

The applied parts of type BF in accordance with IEC 60601-1 are:
– Universal cannula
– Prophylaxis cannula
– Surgical suction cannula
– Saliva cannula

2.10 Only use original parts

– Only use accessories and optional articles named or authorised by the manufacturer.
– Only use only original wear parts and replacement parts.

2.11 Transport

The original packaging provides optimum protection for the unit during transportation.
If required, the original packaging for the unit can be ordered.

The manufacturer and the distributor do not accept liability, even during the warranty period, for damage during transportation due to improper packaging.

– Only transport the unit in its original packaging.
– Keep the packing materials out of the reach of children.

2.12 Disposal

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

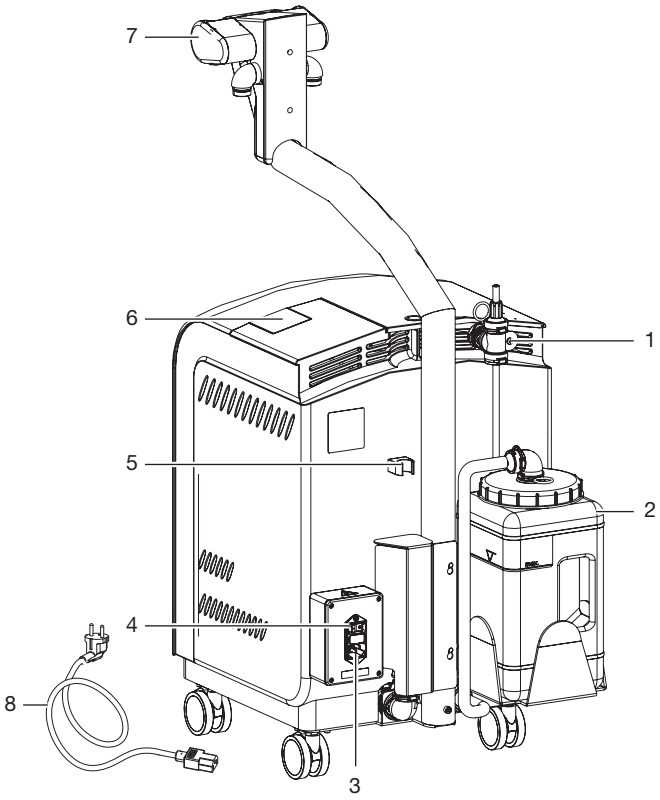
– Decontaminate potentially contaminated parts before disposing of them.
– Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
– If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

An overview of the waste keys for Dürr Dental products can be found in the download area:

http://qr.duerrdental.com/P007100155

Product description

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 variant-specific deviations 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
Orotol plus pH 7 (2.5-litre bottle) . CDS117A6150
MD 555 cleaner (2.5 litre bottle) . CCS555C6150
MD 555 cleaner organic (2.5-litre bottle) CCS556A6150
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	
Rated voltage	V AC	230, 1~	230, 1~	
Frequency	Hz	50	50	60
Nominal current	A	2.9	2.9	3.7
Starting current, approx.	A	12		
Motor protection		Motor winding overheat protector 160 °C (±5 °C)		
Type of protection		IP20		
Protection class		I		
G-fuse link IEC 60127-2		T 6.3 AH, 250 V		
Unit plug		1/N/PE		

Media				
Max. flow rate with unimpeded flow	l/min	700	710	800
Suction system pressure, max. *	mbar/hPa	-200		
Flow rate min. max.	 l/min l/min	 0.1 4	 - 4	
Water temperature, max.	°C	35		
Usable volume of collecting container, approx.	ccm	150	-	
Replacement interval	Months	6 - 9	-	

* Depending on unit type

General technical data				
Number of users, max.		1		
Duty cycle	%	100 (S1)		
Dimensions (H x W x D) *	mm	900 x 365 x 640		
Weight, max.	kg	34		
Noise level **	dB(A)	53	51	54
Exhaust air connection		DürrConnect		
Waste water connection		DürrConnect		

* Values without accessories and add-on parts
** Noise level in accordance with EN ISO 3744

Classification	
Medical Device Class (MDR)	IIa

Ambient conditions during storage and transport		
Temperature	°C	-10 - +60

Ambient conditions during storage and transport		
Relative humidity	%	< 95
Ambient conditions during operation		
Temperature	°C	+10 - +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
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

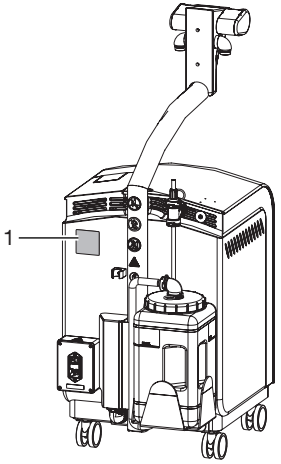
Electromagnetic compatibility (EMC) Interference immunity measurements supply input	
Immunity to interference, surges IEC 61000-4-5:2014/AMD1:2017 ± 0.5 kV, ± 1 kV, L - N ± 0.5 kV, ± 1 kV, ± 2 kV, L/N - PE	Compliant
Immunity to interference, line-conducted disturbances induced by high-frequency fields – 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

4.1 Type plate

Variosuc

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



1 Type plate

4.2 Evaluation of conformity

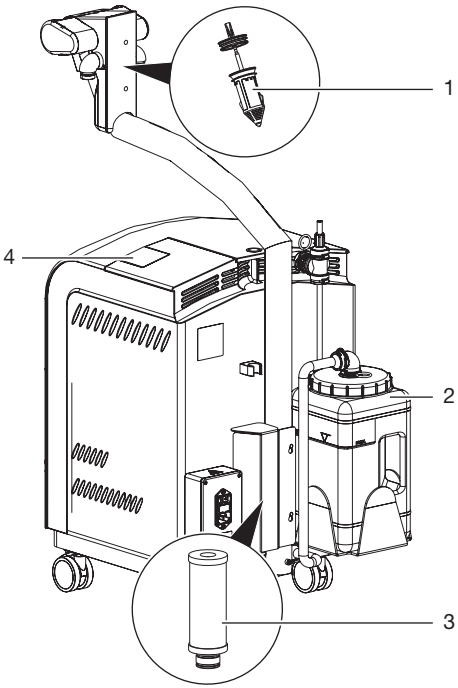
This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

4.3 Amalgam separator approval VSA 300 S

Centre of Competence in Civil Engineering, Berlin	
Test number	Z-64.1-15

Separation method compliant with standard	
ISO 11143	Type 1

5 Function



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

The mobile treatment unit sucks out spray mist, fluids and particles during a 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.

Assembly

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.

6.2 Information about electrical connections

– Ensure that the electrical connections to the mains power supply are established in accordance with current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.
– Observe the current consumption of the devices that are to be connected.

Electrical fusing

LS switch 16 A, characteristic B, C and D in accordance with 60898.

6.3 Information about connecting cables

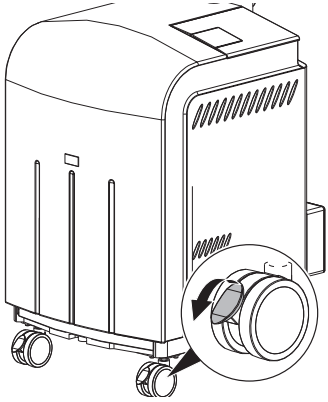
Mains supply cable

Only use the supplied mains cable to connect the device.

7 Installation

7.1 Setting up the unit

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



7.2 Safety when making electrical connections

DANGER

Electric shock due to missing protective earth

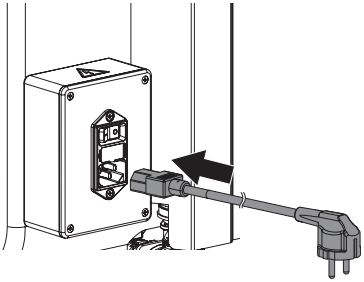
› Connect the unit to the protective earth (PE) connection.

– 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.
– Before initial start-up, check the nominal voltage with the voltage information on the type plate (see Technical data).

7.3 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.

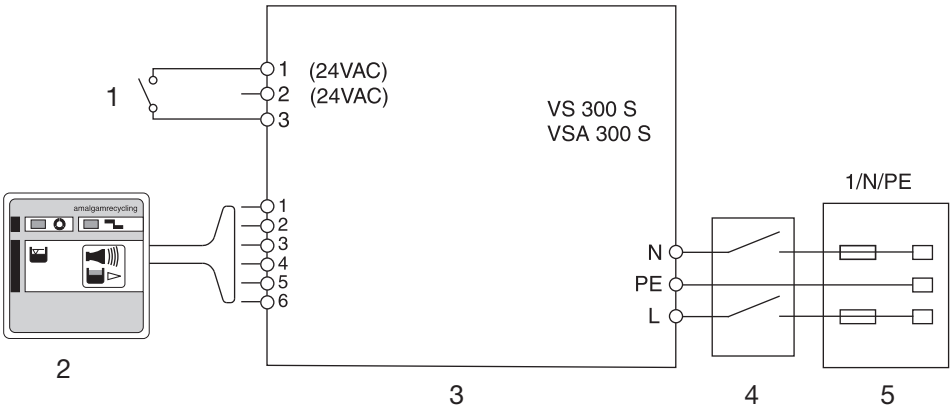
1. Plug in the mains cable connecting plug into the device socket connection.



2. Plug the mains plug into the power outlet.

8 Electrical installation

8.1 Connection overview



1 Hose manifold
2 Display panel VSA 300 S
3 Suction unit
4 On/off switch
5 Mains connection with fuses

9 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.

In many countries technical medical products and electrical devices are subject to regular checks at set intervals. The owner must be instructed accordingly.

1. Switch on the unit.
2. Carry out a function check of the device.
3. Check all connections for leak tightness.
4. Carry out an electrical safety check in accordance with applicable regulations (e.g. regulations concerning set up, operation and application of medical devices) and record the results as appropriate, e.g. in the technical log book.
5. Carry out and document the instruction and handover for the unit.

A sample handover report is included in the attachment.

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

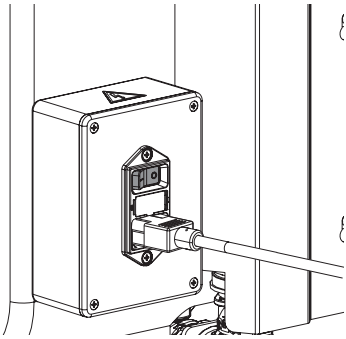
6. Inscribe both labels.
7. Apply the label to the bacteria filter.
8. Stick the label in the practice handbook.

Usage

10 Operation

Do not use the suction unit with closed suction hoses for longer than 30 minutes. Insufficient cooling can cause the motor to heat up, causing the winding overheating protector to switch off the suction unit.

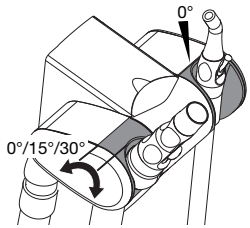
10.1 Switch on the unit



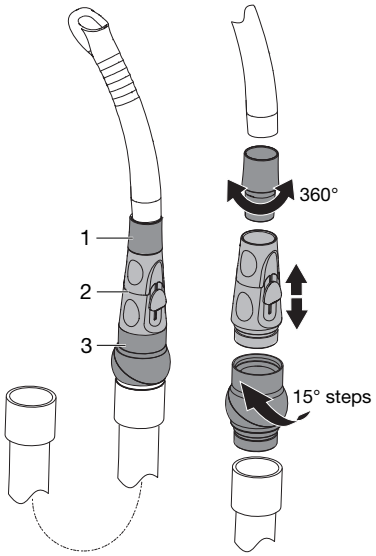
10.2 Tips on ease of operation

Adjustable inserts in the elements, depending on function

1. Initial position 0°.
   Turn the inserts to the desired position 0° / 15° / 30°.



Operation of the rotating cover, suction handpiece and swivel joint



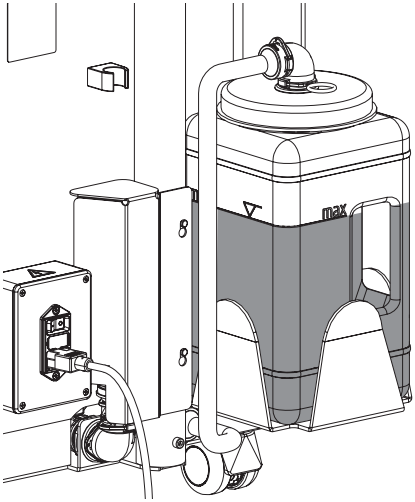
1 Rotary adaptor
2 Suction handpiece
3 Swivel joint

– A rotating cover (1) can be added to the large suction handpiece. This enables the cannula to be turned more easily.
– The slider fitted in the large and small suction handpieces (2) can be used to control the flow rate or to switch off the suction flow while working.
– A swivel joint (3) can be added to the large suction handpiece.
  The swivel joint is rotatable in 15° steps. This helps to achieve a smoother, better hose supply.

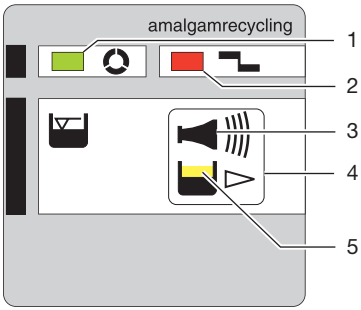
10.3 Aspirate fluid

1. Remove the hose from the hose manifold to aspirate.
   The combined suction unit is started.
2. Aspirate fluid from the patient's mouth.
   The fluid is collected in the fluid container.
3. After treatment, check the filling level of the fluid container.

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



11 Display panel (for VSA 300 S)



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

11.1 Ready for operation

GREEN LED lights up

11.2 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.

11.3 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

11.4 Fill level measurement fault

Red display and

yellow display flash synchronously

Audible signal

– Press the reset button briefly to switch off the audible signal. The device is then ready for operation again.
– The red and yellow displays flash as a reminder that the fault needs to be rectified.

If this fault occurs on several consecutive days, the fill level measurement must be checked by a service technician.

11.5 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.

11.6 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.

11.7 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.

12 Disinfection and cleaning

The following tasks are required for the disinfection and cleaning of the suction system:

"12.1 Suctioning water"	After every treatment
"12.4 Disinfection"	Daily in the evening after the end of treatment, With increased workloads, before the midday break and after the end of treatment
"12.5 Cleaning"	Allow to act for at least 2 x per week before the start of treatment or during the midday break Alternatively, 5 x per week, with short reaction times

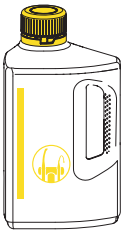
NOTICE

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.

The following should always be used:



- For disinfection and cleaning:
  - Orotol plus
  - Orotol plus pH 7
- For cleaning:
  - MD 555 cleaner
  - MD 555 cleaner organic

Only these products have been tested by Dürr Dental.

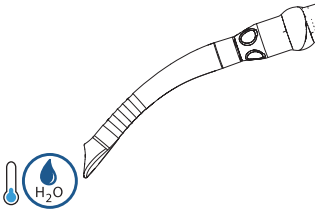
Comply with the instructions for use of the cleaning agent and disinfectant.

12.1 Suctioning water

After every treatment:

1. Suction up cold water (min. 0.5 litres) with the large and 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.



12.2 Fluid container

WARNING

Infection due to contaminated unit

- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

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.

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

12.3 Surfaces

Clean the surfaces if there is any visible soiling.

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

12.4 Disinfection

Disinfect and clean the suction system every evening after the end of treatment.

With increased workloads, clean and disinfect twice per day, e.g. before the midday break and after the end of treatment.

The following is required for the disinfection and cleaning of the suction system:

Non-foaming disinfectant/cleaning agent that is compatible with the materials
- Orotol plus
- Orotol plus pH 7

care system
- e.g. OroCup

Disinfection and cleaning are described below with OroCup and Orotol plus.

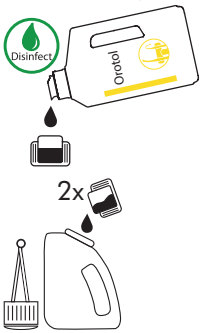
Wear protective gloves.

Wear protective goggles.

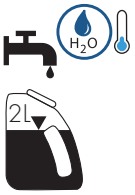
1. To pre-clean, suction up 2 litres of water with the care system.

Using the solution in the care system:

1. Pour 2 sealing caps (40 ml) of Orotol plus into the OroCup.



2. Fill the OroCup with 2 litres of cold water.

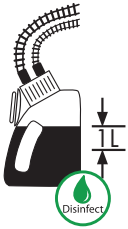


3. Close the lid of the care system.

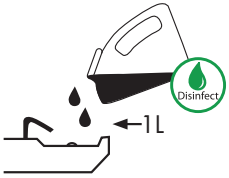
4. Mix the solution.

Using the solution:

1. Attach suction hoses to the care system and suction up 1 litre of solution.



2. Pour the remaining solution into the spittoon.



3. Allow to work for a minimum of one hour or leave overnight.

4. When placing the system back into operation, suction up 2 litres of water.

The instructions are also available as a video:

12.5 Cleaning

Clean the suction system regularly:
- Allow to act for at least 2 x per week in the morning before the start of treatment or during the midday break, reaction time 30–120 minutes
- Alternatively: 5 x per week before the start of treatment, reaction time 5–15 minutes

The following is required for cleaning the suction system:

Special non-foaming detergent for suction systems that is compatible with the materials
- MD 555 cleaner
- MD 555 cleaner organic

care system
- e.g. OroCup

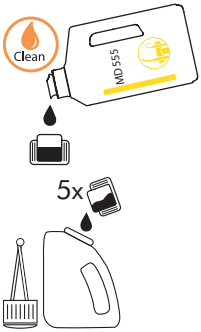
Cleaning is described below with OroCup and MD 555 cleaner.

Wear protective gloves.

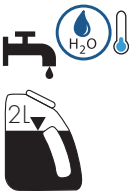
Wear protective goggles.

1. To pre-clean, suction up 2 litres of water with the care system.

2. Use the solution in the care system.
Pour 5 caps (100 ml) of MD 555 cleaner into the care system.



3. Fill the OroCup with 2 litres of cold water.



4. Close the lid of the care system.

5. Mix the solution.

6. Attach suction hoses to the care system and suction up one litre of solution.

7. Pour the remaining solution into the spittoon.

8. Allow the solution time to act.
For 2 x per week: 30–120 minutes
For 5 x per week: 5–15 minutes

9. Suction up 2 litres of water after the reaction time has elapsed.

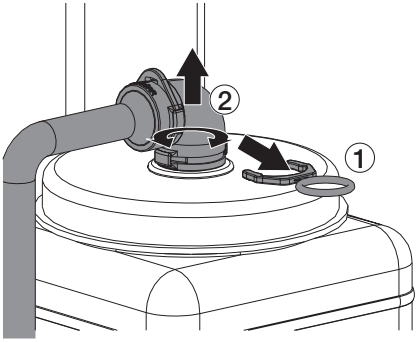
The instructions are also available as a video:

12.6 Weekly and before longer treatment interruptions

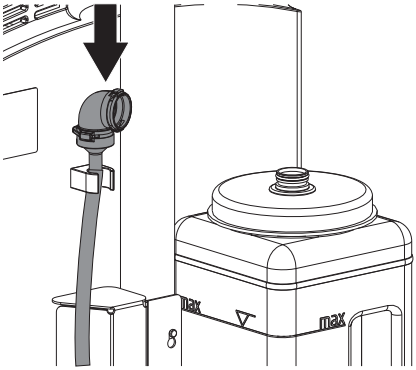
Flush the unit at least weekly and before longer treatment interruptions.

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

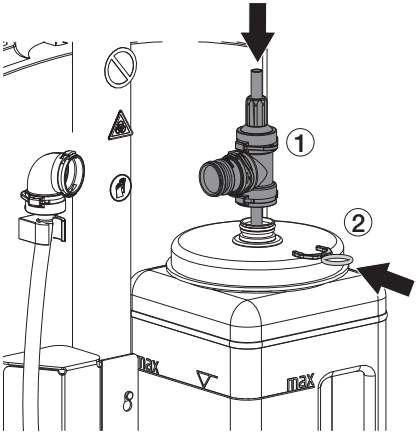
1. Remove the yellow holding clip and disconnect the waste connection from the cover of the fluid container by turning slightly.



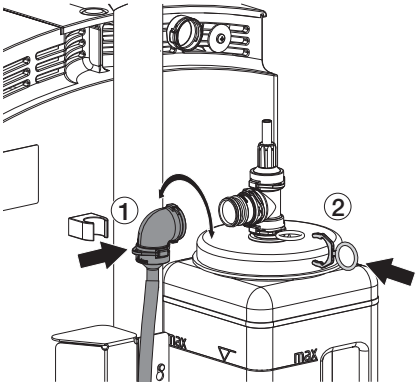
2. Insert the waste connection in the mount.



3. Empty the fluid container and rinse with water.
4. Fill the fluid container to the maximum level with water.
5. Add 60 ml Orotol plus suction unit disinfection to the filled water.
6. Place the rinsing hose onto the connector on the cover of the fluid container and secure with the clip.



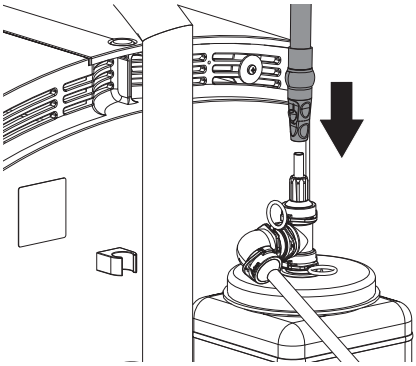
7. Connect the waste water connection to the rinsing hose.



8. Switch on the unit.

9. Remove the cannula from the large suction handpiece.

10. Place the large suction handpiece onto the rinsing hose.



11. After approx. 20 minutes pull the suction handpiece slowly off
the connection of the rinsing hose
and hang it in the hose manifold.

12. 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.

13. Replace the waste water hose on the empty and disinfected fluid container.

13 Reprocessing

13.1 Reprocessing of the suction handpieces

Risk analysis and categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator. Comply with all national directives, standards and specifications such as e. g. the "Recommendations from the Commission for Hospital Hygiene and Infection Prevention".
Accessories of the medical device are also subject to reprocessing.
Classification recommendation given intended use of the product: **semi-critical B**
Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically affected skin.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

Reprocessing procedure

Carry out the procedure for reprocessing after every treatment in accordance with the preparation process set out in ISO 17664.

Important information!

The reprocessing notes in accordance with ISO 17664 have been independently tested by the manufacturer for preparation of the device and its components for reuse.

The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.

Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially influenced by the amount of wear and tear or damage resulting from its use.

The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing procedure was validated as follows:

- **Pre-cleaning**
  - FD 350 disinfection wipes (Dürr Dental)
- **Manual cleaning**
  - ID 215 enzymatic instrument cleaner (Dürr Dental)
  - Cleaning brush
- **Manual disinfection**
  - ID 213 Instrument disinfection (Dürr Dental)
- **Automatic cleaning and disinfection**
  Was performed in accordance with EN ISO 15883 with tested efficacy.
  - Cleaning agent: Neodisher MediClean Forte
  - Washer-disinfector: PG 8535 (Miele)
  - Programmes: "Cleaning without neutralisation" and "THERMAL DES"
- **Steam sterilisation**
  was performed in accordance with EN ISO 17665 with the fractionated vacuum procedure.
  - Pre-vacuum: 3 x
  - Sterilisation temperature: 134 °C
  - Sterilisation time: 2 minutes (half-cycle)
  - Drying time: min. 20 minutes
- **Cleaning brush**
  Cleaning brush with nylon hairs, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 25 and 35 mm
  - Brush length: 5 and 10 mm

  Example: Interlock cleaning brush, double-sided, green REF 09098

General information

1. Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.
2. When selecting the cleaning and disinfectant agents to be used, the information provided (see above) must be followed.
3. Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
4. Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.

5. Only use disinfectants that are aldehyde-free and display material compatibility with the product.
6. Only use freshly-produced solutions.
7. Only use distilled or deionised water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. legionella bacteria).
8. Use clean, dry, oil and particle-free compressed air.
9. Do not use any rinse aid (danger of toxic residue on the components).
10. Subject all devices used (ultrasonic bath, cleaning and disinfection device (washer-disinfector), sealing device, steam steriliser) to regular maintenance and inspections.

Preparation at the operating location

Wear protective gloves.

Wear protective goggles.

Use a mask.

Use protective clothing.

WARNING

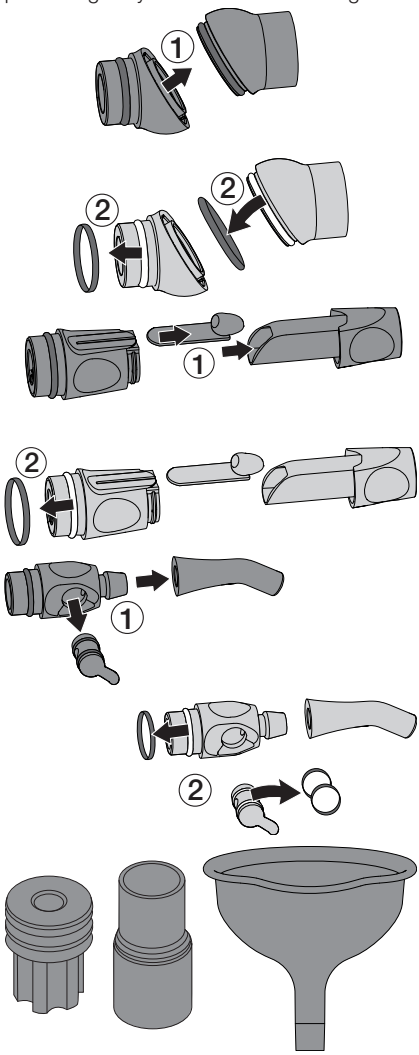
Risk of infection from contaminated products

Danger of cross contamination

› Reprocess the product correctly and promptly before its first use and after every subsequent use.

1. Directly after the treatment, aspirate at least 200 ml cold water.

2. Disassemble the ball joint and suction handpieces regularly and remove the O-rings.



3. Wipe down the exterior surfaces of all components completely with cleaning cloths to remove coarse organic and inorganic soiling:
1 Cleaning wipe for the small components, e. g. the individual parts of suction handpieces and
2 Cleaning wipes for larger components, e. B. the funnel.
4. Note the action time of the cleaning agent.

5. Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

Manual cleaning, final rinsing, drying

A disinfectant or combined cleaning and disinfectant agent is required for manual disinfection. It must have the following properties:
– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)

For further information, see: "General information".

Cleaning

1. Place the individual components in a disinfectant bath (non-fixing/aldehyde-free, see "General information") so that all parts are covered.
2. Comply with the reaction times of the cleaning agent and disinfectant (see "General information").
3. If you notice any further contamination, brush all exterior and interior surfaces completely with a hygienic brush under the surface of the ready-to-use solution.

Intermediate rinsing

After the action time prescribed by the manufacturer:

1. Rinse off all components under water for at least 1 minute (temperature < 35°C).

Disinfection

1. Place individual components in a cleaning and disinfectant bath so that all parts are covered.
2. Note the action time for the disinfectant.

Final rinse

After the action time prescribed by the manufacturer:

1. Rinse off all components under water for at least 1 minute (temperature < 95 °F (35 °F)).

Drying

1. If necessary, re-dry at a clean location using a hygienic, lint-free cloth.
2. Blow dry the components with compressed air in a clean location.

Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:
– Corresponds to and tested in accordance with ISO 15883
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 93°C)
– Programme is suitable for the components and provides sufficient rinsing cycles.
For more information: "General information".

Selection of the machine cleaning agents and disinfectants

The following properties are required:
– Material compatibility with the product
– Corresponds with the manufacturer's specifications of the CD

For further information, see: "General information".

Automatic cleaning and disinfecting

When arranging the parts in the washer-disinfector, make sure there are no areas missed by rinsing.

1. Place components in the basket for small parts.

Check for function

1. After the end of the cleaning and disinfection cycle, check the components for any residual soiling and residual moisture. If necessary, repeat the cycle.
2. If necessary, replace any damaged parts.
3. The components should be packaged as soon as possible after drying and checking.

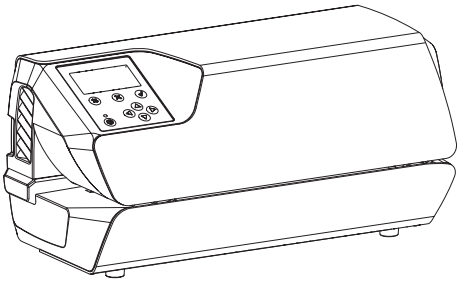
Packing

WARNING

Endangering the sterilisation success

The fitted components are not reached by the steam and as such are not sterilised.

› Do not fit the components before packaging.



For packaging of the components, use only sterile barrier systems made of transparent paper film that are approved for use in steam sterilisation according to the manufacturer information. This includes:

– Temperature resistance up to 138°C
– Standards ISO 11607-1/2
– Applicable parts of the series of standards EN 868

The sterile barrier system must be large enough. Once it is loaded, the sterile barrier system must not be under any strain.

Steam sterilising

WARNING

Health risk due to incorrect sterilisation

If the sterilisation not performed correctly, it may not be effective. The use of instruments that have not been properly sterilised can pose a health risk to the patient..

› Only steam sterilisation must be used.
› Comply with all of the specified process parameters.
› Comply with the manufacturer‘s instructions regarding use of the steam steriliser.
› Do not use any other methods.

NOTICE

Damage to equipment due to incorrect sterilisation

If the sterilisation process is not performed correctly, this can cause damage to the product.

› Comply with the manufacturer‘s instructions regarding use of the steam steriliser.
› Comply with all of the specified process parameters.

Requirements placed on the steam steriliser:

– Corresponds to EN 13060 or EN 285 and/or ANSI AAMI ST79
– Suitable programme for the products listed (e. g. with hollow bodies, fractionated vacuum procedure in three vacuum steps)
– Sufficient product drying
– Validated process in accordance with ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ))

Perform the following steps:

1. Sterilise the parts for sterilisation(at least 20 minutes at 121°C, at least 4 minutes at 270°F or at least 5 minutes at 134°C).
   Do not exceed 138°C.

Marking

1. Mark the packaged, treated medical product in such a way as to ensure safe application.

Issue clearance for the parts for sterilisation

The reprocessing of the medical products ends with the documented clearance for storage and renewed use.

1. Document the clearance of the medical product after reprocessing.

Storage

1. Comply with the stated storage conditions:
   - Store the parts protected against contamination
   - Dust-protected, e.g. in a locked cabinet
   - Protected against moisture
   - Protected against excessive temperature fluctuations
   - Protected against damage

   Packaging for a sterile medical device can suffer damage as a result of a particular incident and the passage of time.
   Potential external contamination of the sterile barrier system should be taken into account in terms of aseptic preparation when establishing the storage conditions.

13.2 Reprocessing of the cannula

Risk analysis and categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator. Comply with all national directives, standards and specifications such as e. g. the "Recommendations from the Commission for Hospital Hygiene and Infection Prevention".
Accessories of the medical device are also subject to reprocessing.
Classification recommendation given intended use of the product: **semi-critical B to critical B**
Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically affected skin.
Critical medical product:
a medical product which also comes into contact with injured skin and blood.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

Reprocessing of the cannula

Important information!
The reprocessing notes in accordance with ISO 17664 have been independently tested by Dürr Dental for the preparation of the device and its components for their reuse.

The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.
Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially influenced by the amount of wear and tear or damage resulting from its use.

The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing procedure was validated as follows:

- **Pre-cleaning**
  - FD 350 disinfection wipes (Dürr Dental)
- **Manual cleaning**
  - ID 215 enzymatic instrument cleaner (Dürr Dental)
  - Cleaning brush
- **Manual disinfection**
  - ID 213 Instrument disinfection (Dürr Dental)
- **Automatic cleaning and disinfection**
  Was performed in accordance with EN ISO 15883 with tested efficacy.
  - Cleaning agent: Neodisher MediClean Forte
  - Washer-disinfector: PG 8535 (Miele)
  - Programmes: "Cleaning without neutralisation" and "THERMAL DES"
- **Steam sterilisation**
  was performed in accordance with EN ISO 17665 with the fractionated vacuum procedure.
  - Pre-vacuum: 3 x
  - Sterilisation temperature: 132°C
  - Sterilisation time: 2 minutes (half-cycle)
  - Drying time: min. 20 minutes
- **Cleaning brush**
  Cleaning brush with nylon hairs, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 25 and 35 mm
  - Brush length: 5 and 10 mm

  Example: Interlock cleaning brush, double-sided, green REF 09098, Interlock cleaning brush round REF 09318

General information

1. Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.
2. When selecting the cleaning and disinfectant agents to be used, the information provided (see above) must be followed.
3. Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
4. Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.
5. Only use disinfectants that are aldehyde-free and display material compatibility with the product.
6. Only use freshly-produced solutions.
7. Only use distilled or deionised water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. legionella bacteria).
8. Use clean, dry, oil and particle-free compressed air.
9. Do not use any rinse aid (danger of toxic residue on the components).
10. Subject all devices used (ultrasonic bath, cleaning and disinfection device (washer-disinfector), sealing device, steam steriliser) to regular maintenance and inspections.

Preparation at the operating location


Wear protective gloves.


Wear protective goggles.


Use a mask.


Use protective clothing.

WARNING

Risk of infection from contaminated products

Danger of cross contamination

› Reprocess the product correctly and promptly before its first use and after every subsequent use.

1. Directly after the treatment, suck out at least 200 ml of cold water.

2. Wipe down the exterior surfaces of all components completely with two cleaning cloths to remove coarse organic and inorganic soiling.
3. Note the action time of the cleaning agent.
4. Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

Manual cleaning, final rinsing, drying

A combined cleaning and disinfectant agent is required for manual cleaning and disinfection. It must have the following properties:
– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)
– without chlorine, without solvent, no strong alkaline solutions (pH > 11), no strong oxidising agents

For further information, see: "General information".

Cleaning

1. Place the components in a cleaning and disinfectant bath (non-fixing/aldehyde-free) so that all parts are covered.
2. Comply with the action times of the cleaning agent and disinfectant.
3. Brush all exterior and interior surfaces with a hygienic brush under the surface of the ready-to-use solution.

Intermediate rinsing

After the action time prescribed by the manufacturer:

1. Rinse off all components under water for at least 1 minute (temperature < 35°C).

Disinfection

1. Place individual components in a cleaning and disinfectant bath so that all parts are covered.
2. Note the action time for the disinfectant.

Final rinse

After the action time prescribed by the manufacturer:

1. Rinse off all components under water for at least 1 minute (temperature < 35°C).

Drying

1. If necessary, re-dry at a clean location using a hygienic, lint-free cloth.
2. Blow dry the components with compressed air in a clean location.

Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:
– Corresponds to and tested in accordance with ISO 15883
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 93°C)
– Programme is suitable for the components and provides sufficient rinsing cycles.
For more information: "General information".

Selection of the machine cleaning agents and disinfectants

The following properties are required:
– Material compatibility with the product
– Corresponds with the manufacturer's specifications of the CD

For further information, see: "General information".

Automatic cleaning and disinfecting

When arranging the parts in the washer-disinfector, make sure there are no areas missed by rinsing.

1. Place components in the basket for small parts.

Check for function

1. After the end of the cleaning and disinfection cycle, check the components for any residual soiling and residual moisture. If necessary, repeat the cycle.
2. If necessary, replace any damaged parts.
3. The components should be packaged as soon as possible after drying and checking.

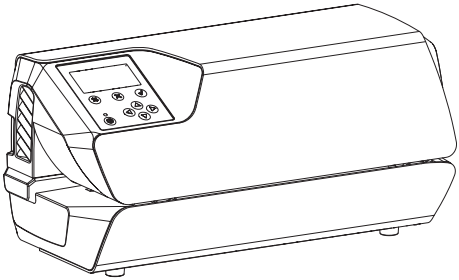
Packing

WARNING

Endangering the sterilisation success

The fitted components are not reached by the steam and as such are not sterilised.

› Do not fit the components before packaging.



For packaging of the components, use only sterile barrier systems made of transparent paper film that are approved for use in steam sterilisation according to the manufacturer information. This includes:

– Temperature resistance up to 138°C
– Standards ISO 11607-1/2
– Applicable parts of the series of standards EN 868

The sterile barrier system must be large enough. Once it is loaded, the sterile barrier system must not be under any strain.

Steam sterilising

WARNING

Health risk due to incorrect sterilisation

If the sterilisation not performed correctly, it may not be effective. The use of instruments that have not been properly sterilised can pose a health risk to the patient..

› Only steam sterilisation must be used.
› Comply with all of the specified process parameters.
› Comply with the manufacturer‘s instructions regarding use of the steam steriliser.
› Do not use any other methods.

NOTICE

Damage to equipment due to incorrect sterilisation

If the sterilisation process is not performed correctly, this can cause damage to the product.

› Comply with the manufacturer‘s instructions regarding use of the steam steriliser.
› Comply with all of the specified process parameters.

Requirements placed on the steam steriliser:

– Corresponds to EN 13060 or EN 285 and/or ANSI AAMI ST79
– Suitable programme for the products listed (e. g. with hollow bodies, fractionated vacuum procedure in three vacuum steps)
– Sufficient product drying
– Validated process in accordance with ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ))

Perform the following steps:

1. Sterilise the parts for sterilisation(at least 20 minutes at 121°C, at least 4 minutes at 270°F or at least 5 minutes at 134°C).
   Do not exceed 138°C.

Marking

1. Mark the packaged, treated medical product in such a way as to ensure safe application.

Issue clearance for the parts for sterilisation

The reprocessing of the medical products ends with the documented clearance for storage and renewed use.

1. Document the clearance of the medical product after reprocessing.

Storage

1. Store the product protected against contamination.
2. The storage time depends on the sterile packaging used – refer to the instructions for the sterile packaging.

3. Comply with the stated storage conditions:
   - Store the parts protected against contamination
   - Dust-protected, e.g. in a locked cabinet
   - Protected against moisture
   - Protected against excessive temperature fluctuations
   - Protected against damage

   Packaging for a sterile medical device can suffer damage as a result of a particular incident and the passage of time.
   Potential external contamination of the sterile barrier system should be taken into account in terms of aseptic preparation when establishing the storage conditions.

14 Maintenance

All maintenance work must be performed by a qualified expert or by one of our Service Technicians.

WARNING

Infection due to contaminated unit

- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Prior to working on the unit or in case of danger, disconnect it from the mains.

14.1 Variosuc

Maintenance interval	Maintenance work
Weekly	Replace the yellow single-use filter in the hose manifold.
As required	Replace the suction hoses Grease the O-rings
Annually	Replace the exhaust air filter.

14.2 VS 300 S

Maintenance interval	Maintenance work
Every 4 weeks	Check the filter on the suction connection of the device and clean or replace it as required.
Annually	Check the inlet and outlet hoses for signs of deposits/blockage or cracks and replace where necessary. * Check the outflow valve and replace if necessary. *

* Only to be performed by service technicians.

14.3 VSA 300 S

Maintenance interval	Maintenance work
Every 4 weeks	Check the filter on the suction connection of the device and clean or replace it as required.
Dependent upon the level of usage of the device	Replace the amalgam collecting container when a fill level of 95% or 100% is indicated on the display panel **Notes concerning prophy powders:** The function of the amalgam separator is not adversely affected by conventional prophy powders. Under certain circumstances however, increased soiling of lines and hoses and a more frequent changing of the amalgam collecting container can be expected.
Annually	Check the inlet and outlet hoses for signs of deposits/blockage or cracks and replace where necessary. * Check the outflow valve and replace if necessary. *

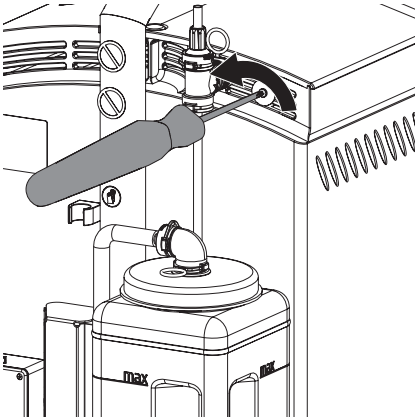
Maintenance interval	Maintenance work

* Only to be performed by service technicians.

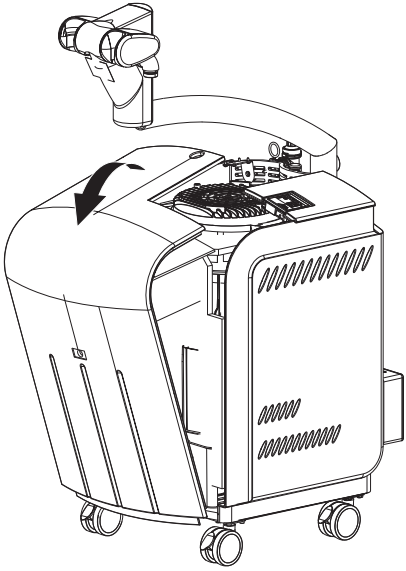
14.4 Open the protective cover

For standard safety reasons, the suction units must be protected against unauthorised access. The screw cap must therefore be removed for maintenance (e.g. filter cleaning, container change).

1. Remove the screw cap.



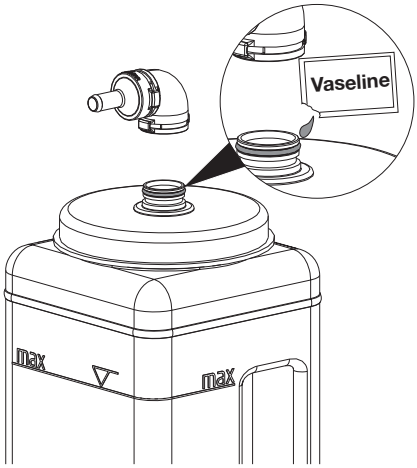
2. Slightly lift up the protective cover at the rear and swivel it forwards.



3. Perform maintenance.
4. Close the protective cover.
5. Attach the screw cap.

14.5 Grease the seal

1. Grease the seal if required.



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

14.6 Replace the disposable filter

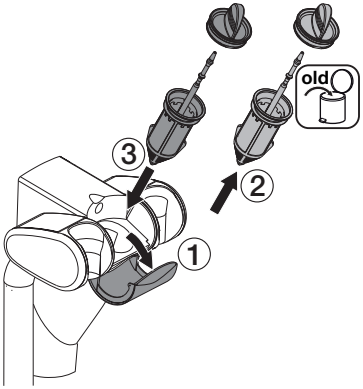
NOTICE

Faulty function when working without a disposable filter

Working without a disposable filter creates the risk that deposits or particles will accumulate in unsuitable locations within the hose manifold and hinder efficient function.

› The yellow disposable filter must inserted.

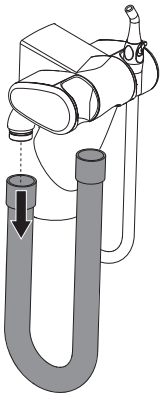
1. Open the cover of the filter element and change the yellow disposable filter.



14.7 Changing the suction hose

The suction hoses are subject to wear and tear.

1. Check the suction hose regularly for bends, change if required.
2. Pull the suction hose off the hose manifold.

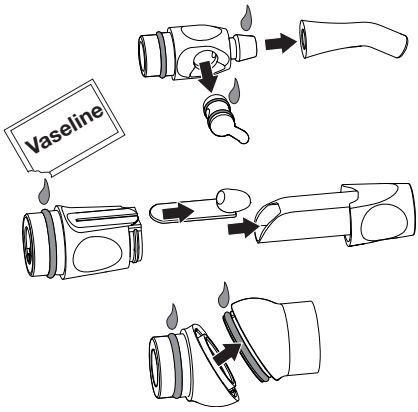


3. Connect new suction hose.

14.8 Lubricating the o-rings

The suction handpiece, suction hoses etc. are easier to handle when the O-rings have been treated with a little Vaseline.

1. Disassemble the suction handpiece regularly and lubricate the O-rings.



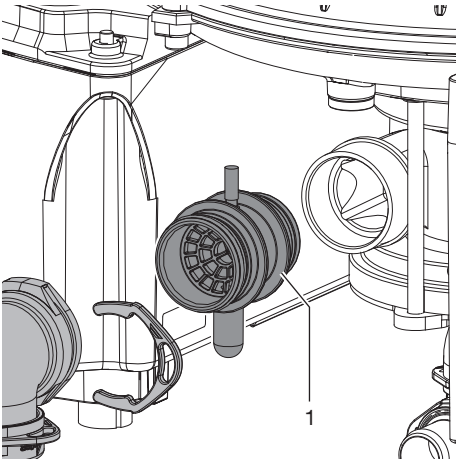
14.9 Clean the filter at the device suction connection.

WARNING

Infection due to contaminated unit

- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

1. Pull the suction hose off the filter.
2. Pull off any hoses connected to the connection piece on the filter.
3. Pull out the filter from the connection piece on the separation housing.
4. Clean the filter.
5. Push the filter into the connection piece on the separation housing.
6. Reconnect all hoses that have been pulled off.



1 Filter

14.10 Intensive cleaning

Intensive cleaning can be carried out during the self-clean process of suction systems that are heavily contaminated with biofilms or if the suction power is greatly reduced.
Carry out this intensive cleaning at least twice a week.
Exposure time: 1 – 2 hours

The following is required for intensive cleaning of the suction system:

Special non-foaming detergent for suction systems that is compatible with the materials
- MD 555 cleaner
- MD 555 cleaner organic

care system
- e.g. OroCup

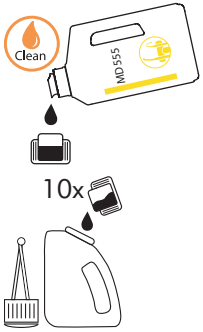
Cleaning is described below with OroCup and MD 555 cleaner.

Wear protective gloves.

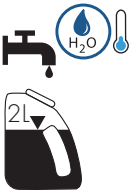
Wear protective goggles.

1. To pre-clean, suction up 2 litres of water with the care system.

2. Use the solution in the care system.
Pour 10 caps (200 ml) of MD 555 cleaner into the care system.



3. Fill the OroCup with 2 litres of cold water.



4. Close the lid of the care system.

5. Mix the solution.

6. Attach suction hoses to the care system and suction up one litre of solution.

7. Pour the remaining solution into the spittoon.

8. Allow the solution to act for 1 – 2 hours.

9. Suction up 2 litres of water after the reaction time has elapsed.

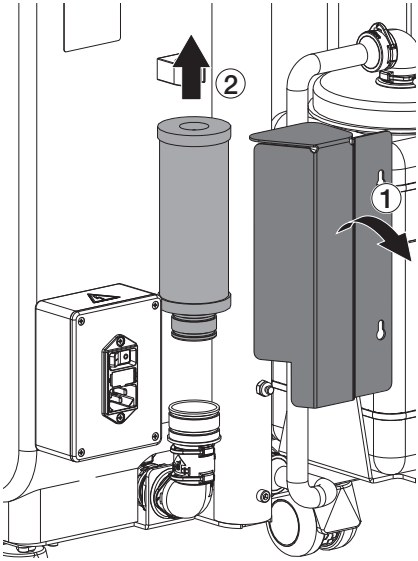
14.11 Replace the exhaust air filter

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

1. Inscribe both labels.
2. Apply the label to the bacteria filter.
3. Stick the label in the practice handbook.

Wear protective gloves.

4. Lift the cover plate upwards out of its mounting.
5. Disconnect the bacteria filter from the connecting sleeve.



14.12 Replace the amalgam collector vessel

NOTICE

Risk of contamination if the amalgam collector vessel is reused since the collector vessel is not water-tight.

› Do not use the collecting container more than once (disposable item).

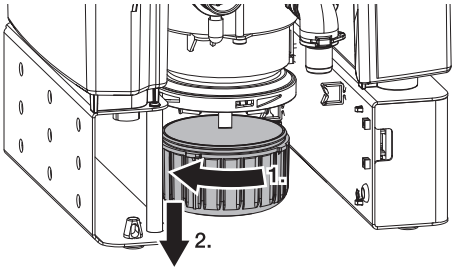
Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

We strongly recommend that the amalgam collecting container should only be changed in the morning before the start of work. This will prevent fluid from dripping out of the drum while it is being changed.

1. Disconnect all power from the unit.
2. Remove the full amalgam collecting container and from the device.
3. Close and secure the full amalgam collecting container using the cap. Observe the markings on the cap and on the collecting container.
4. Place the securely closed amalgam collecting container into its original packaging and seal.
5. Insert a new amalgam collecting container in the unit and lock it in position with the vessel lift.

Only use original amalgam collecting container.

6. Switch on the power supply. The unit is ready for operation again.



Disposal of amalgam collecting container

The contents of the amalgam collecting container are contaminated with heavy metals and must not be disposed of as household waste or the environment.

– Collection and waste disposal by a waste management company specialised in surgery waste.
– Collection and waste disposal by an approved waste management company.

14.13 Tests

WARNING

Infection due to contaminated unit

› Clean and disinfect the suction before working on the unit.
› Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

In some countries the owner is required to keep an operating handbook. This operating handbook must document all maintenance work, service work, checks and amalgam disposal.

Annual inspection

This inspection should only be carried out by suitably trained staff.

Work steps to be performed:

1. General functional check (e.g. aspiration, spittoon inlet)
2. During the sediment fill level measurement, visually inspect the operability of the sediment sensor.
3. Service program

Inspection of the general operating condition every 5 years

This inspection must be carried out every 5 years (in accordance with the German Waste Water Regulations, Annex 50, Dental Treatment) by an inspector in accordance with national regulations. For inspection, the following are required:

✓ Test vessel
✓ Measuring beaker

Work steps to be performed:

1. Remove the collector vessel. Here, the red LED on the display panel must flash and an audible signal must sound.
2. Insert the test collector vessel.
3. Press the service key on the display panel.
4. Suck up c. 1 L water.
5. Once the device has switched off, remove the test vessel and measure the remaining amount of water.

The unit is working correctly if:

– there is at minimum content of 70 ml in the test vessel.

If there is less fluid, clean the centrifuge drum or check the operation of the unit.

Troubleshooting

15 Tips for operators and service technicians

Any repairs exceeding routine maintenance may only be carried out by qualified personnel or our service.

WARNING

Infection due to contaminated unit

- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Prior to working on the unit or in case of danger, disconnect it from the mains.

Error	Possible cause	Remedy
Reduced suction performance	Disposable filter in the hose manifold is full	Change disposable filter.
	Blockage in the suction hose	Remove and clean suction hose.
	Blockage in the suction handpiece	Disassemble and clean suction handpiece.
	Suction hose is bent or twisted	Change the suction hose.
	Selective membrane does not completely open	Remove the filter cover. Remove dirt particles, e.g. using blunt tweezers or jet of water. Do not damage the **selective membrane!**
No suction power	Suction handpiece slider is closed	Open the handpiece slider.
	Suction machine is not functioning	Check the suction machine function.
	Selective membrane does not open	Remove the filter cover. Remove dirt particles, e.g. using blunt tweezers or jet of water. Do not damage the **selective membrane!**
	Control hose of one element is bent or twisted	Check the control hose, e.g. in element for large suction hose and filter element, for signs of twisting.

Error	Possible cause	Remedy
Device does not start	No mains voltage	› Check the mains voltage. * › Check the fuses and replace if necessary. *
	Undervoltage	› Measure the supply voltage; call an electrician if necessary. *
	No start signal	› Check the control voltage at the signal input. *
	Capacitor defective	› Measure capacitance and replace if necessary. *
	Turbine is blocked by solid particles or sticky soiling	› Disassemble the unit and clean the turbine. *
	Control electronics defective	› Replace the electronics. *
Motor fault	Rotational speed sensor not working	› Check that the Hall sensor is correctly seated. * › Check the plug connections of the sensor cable. * › Check the magnets in the fan wheel. *
The unit generates unusual noises	Solid particles in the turbine chamber	› Disassemble the unit and clean the turbine and housing. *
Water leaking from the exhaust air connection	Membrane valve blocked	› Check the membrane valve at the waste water connection and if necessary clean or replace. *
	Foam in turbine due to use of incorrect cleaning and disinfectant agents	› Use non-foaming cleaning and disinfectant agents.
	Build-up of condensate in the exhaust air line	› Check the pipe system; avoid over-cooling. *
	Waste water line/siphon trap blocked	› Clean the waste water line/ siphon trap. *
Suction performance too low	Filter blocked	› Clean the filter at the inlet connection.
	Leak in the suction pipe	› Check and if necessary establish leak-tightness of suction pipe and connections. *
	Mechanical sluggishness of turbine caused by soiling	› Disassemble the unit and clean the turbine. *

* Only to be done by service technicians.

Appendix

16 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:**

Hersteller / Manufacturer:

DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerrdental.com

DÜRR DENTAL