VC 65



Operating Instructions





Contents

					6.1	Installation/setup room	14
				7	Instal	lation	14
lm	porta	nt information			7.1	Remove the transport locks	14
1	About	this document	3		7.2	Setting up the unit	14
	1.1	Warnings and symbols	3		7.3	VC 65 Cart	15
	1.2	Copyright information	4		7.4	Safety when making electrical	
2	Safety	/	4		7.5	connections	15
_	2.1	Intended purpose	4		7.5	Connecting the unit to the mains supply	15
	2.2	Intended use	4		7.6	Preparation of the device	16
	2.3	Improper use	4				
	2.4	General safety information	4	8	8.1	missioning	18 18
	2.5	Information about infection pro-			0.1	Electrical safety checks	10
		tection	5				
	2.6	Specialist personnel	5		3		
	2.7	Electrical safety	5	Us	age		
	2.8	Only use original parts	5	9	•	ation	19
	2.9	Essential performance charac-	0	·	9.1	Setting up the unit	19
	0.40	teristics	6		9.2	Suction	19
	2.10	Notification requirement of serious incidents	6		9.3	Replace the fuse	19
	2.11	Transport	6	10	Clean	ing and disinfection	20
	2.12	Disposal	6		10.1	Preparation at the operating	
	_					location	20
E					10.2	Device surface and hose mani-	
						fold	20
Pr	oduct	description		11	Repro	ocessing	21
3	Overv	iew	7		11.1	Risk analysis and categorisation.	21
	3.1	Scope of delivery	8		11.2	Preparation process in accord-	
	3.2	Optional items	8			ance with ISO 17664	21
4	Techn	ical data	9		11.3	Preparation at the operating location	22
	4.1	Type plate	12		11.4	location	22
	4.2	Evaluation of conformity	12		11.4	rinsing, disinfection, final rinse,	
5	Opera	ition	12			drying	23
	5.1	Foot switch	13		11.5	Automatic cleaning, intermediate	
	5.2	Suction handpiece	13			rinsing, disinfection, final rinse,	
	5.3	Suction cannula	13			drying	23
	5.4	Adapter	13		11.6	Check for function	24
					11.7	Steam sterilising	24
					11.8	Issue clearance for the parts for sterilisation	24
		I			11.9	Storing parts for sterilisation	25
AS	semb	ory		40		•	
6	Requi	rements	14	12	iviaint	enance	26

	12.1	Lubricating the o-rings	27
Tro	ouble	shooting	
13		or operators and service techni-	
	cians		28
//	\mathcal{D}		



Appendix

14	Handove	er record					29
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Important information

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:

VC 65

Order number: 0672500000: 0672500900

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



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.



Refer to Operating Instructions.



(€ xxx CE labelling with the number of the notified body



Manufacturer



Dispose of correctly in accordance with EU Directive 2012/19/EU (WEEE).

SN

Serial number

REF

Order number

MD

Medical device

HIBC

Health Industry Bar Code (HIBC)



Do not sit on the unit



Do not climb onto the unit



Disconnect all power from the unit.



Application part type B



Wear protective goggles.





Use a mask.



Use protective clothing.



Wear protective gloves.

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 suction unit provides the user in dental surgery, orthodontic practice, dental clinic and / or oral and maxillofacial surgery with vacuum and volume flow.

2.2 Intended use

Working in combination with the suction unit with treatment unit, suction handpiece and cannula. the media used in dental treatment are removed. by suction.

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this.

In these cases, the user/operator will bear the sole risk.



WARNING

Risk of explosion due to ignition of combustible materials

Do not operate the unit in any rooms in which inflammable mixtures may be present, e.g. in operating theatres.

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 Information about infection protection

The national accident prevention regulations, as well as the biological agent regulations that apply for dental practices and dental hospitals, must be observed during work with the VC 65 and during disposal.

2.6 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.

The following groups are not permitted to operate or use a commercially operated unit:

- People without the necessary experience and knowledge
- People with reduced physical, sensory or mental capabilities
- Children

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.

2.7 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 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.
- Xeep a minimum distance of 30 cm between the unit and mobile radio 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-authorised 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.

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.





Dürr Dental accepts no liability for damages or injury resulting from the use of non-approved accessories or optional accessories, or from the use of non-original wear parts or replacement parts.

The use of non-approved accessories, optional accessories or non-genuine wear parts / replacement parts (e.g. mains cables) can have a negative effect in terms of electrical safety and EMC.

2.9 Essential performance characteristics

The VC 65 unit does not have any essential performance characteristics as set out in IEC 60601-1 (EN 60601-1) section 4.3. The unit complies with the requirements according to IEC 60601-1-2:2014.

2.10 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.

2.11 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 quarantee.

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

2.12 Disposal

Unit



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

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



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

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



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

www.duerrdental.com

Document no.: P007100155

Disposable bag

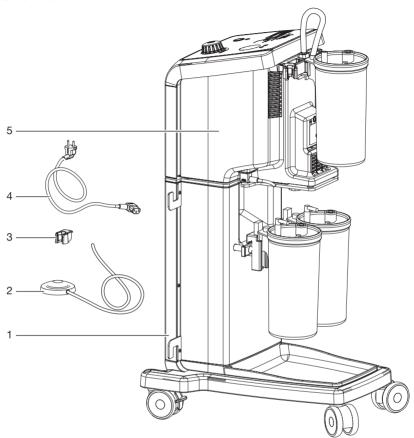
In Europe, dispose of disposable bags in accordance with waste code 18 01 03* "Waste products, the collection and disposal of which involves special requirements in order to prevent risk of infection".

* If the waste code is marked with an asterisk (*), this indicates that the waste is hazardous in the sense of the List of Waste.



Product description

3 Overview



- 1 VC 65 cart
- 2 Foot switch
- 3 Hose manifold
- 4 Mains cable
- 5 surgical suction unit



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):

- Mains cable 5 m
- Hose manifold
- Foot switch

3.2 Optional items



Electrical data			
Rated voltage	V	230	220-240
	Hz	50	60
Nominal current	А	0.8	
Type of protection	IP 22		
Protection class	II		
Mains frequency	Hz	50 / 60	
Fuse	T 2.5 AH/250 V IEC 60127-2/V		

lassi	

Medical Device Class (MDR)

lla

General technical data			
Dimensions (W x H x D)	mm	325 x 3	49 x 372
Dimensions with cart (W x H x D)	mm	454 x 10	50 x 571
Weight	kg	1	6
Weight with cart and foot switch	kg	2	7
Duty cycle	%	10	00
Noise level*	dB(A)	44	
Air flow rate	l/min Hz	65** 50	75** 60
Pressure	mbar (hPa)	-9	10

^{*} Noise level in accordance with ISO 3746 at 50 Hz

^{**} Measurement in accordance with EN EN 10079-1 (with a silicone hose with a diameter of 10 mm and a length of 1.3 m).

Ambient conditions during operation*		
Temperature	°C	+5 to +40
Relative humidity	%	≤ 70
Air pressure	hPa	800 - 1030

^{* 2000} m above MSL

Ambient conditions during storage and transport				
Temperature	°C	-20 to +60		
Relative humidity	%	≤ 95		
Air pressure	hPa	750 - 1060		

Electromagnetic compatibility (EMC) Interference emission measurements	
High-frequency emissions in accordance with CISPR 11	Group 1 Class B



Product description		
Electromagnetic compatibility (EMC) Interference emission measurements		
Interference voltage at the power supply connection CISPR 11:2009+A1:2010	Compliant	
Electromagnetic interference radiation CISPR 11:2009+A1:2010	Compliant	
Electromagnetic compatibility (EMC) Interference immunity measurements on the cover		
Immunity to electrostatic discharge IEC 61000-4-2:2008 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant	
Immunity to 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 near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010 Refer to the table with immunity to interference levels for near fields of wireless HF communication devices.	Compliant	
Electromagnetic compatibility (EMC) Interference immunity measurements on the supply input		
Immunity to fast electrical transients/bursts – AC mains voltage IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition rate	Compliant	
Immunity to surges, line-to-line IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV	Compliant	
Immunity to surges, line-earth IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV, ± 2 kV	Compliant	

variations

IEC 61000-4-11:2004

Immunity to voltage dips, short interruptions and voltage

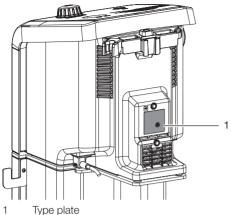
Compliant



Immunity to interference levels, 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		



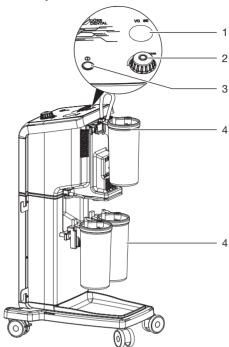
4.1 Type plate



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 Pressure gauge
- 2 Pressure regulator
- 3 On/off switch
- 4 Disposable container

The unit is used to suck secretions, blood, tissue and bone fragments, as well as fluids accumulating during drilling, from the patient's oral cavity. The unit is used particularly in oral, orthodontic and maxillofacial surgery, e.g. in implantology, where a lot of bleeding occurs.

To adjust the pressure, close the suction hand-piece and adjust the pressure on the control knob. After insertion of a surgical suction cannula into the suction handpiece the VC 65 is ready for operation. The aspirated material passes directly to the collecting container. Inside the collecting container, the air is separated from the aspirated fluids and other particles. After finishing work, switch off the device. Before the collecting container can be removed for emptying, wait a short time until the pressure indicator shows normal pressure.

ΕN

5.1 Foot switch

To switch on the unit, briefly press the foot switch once. Pressing the foot switch again will switch off the unit. The foot switch operates pneumatically.

5.2 Suction handpiece

A suction cannula and a disposable hose can be plugged onto the curved suction handpiece.

5.3 Suction cannula

The suction cannula is used during dental treatments to aspirate media (e. g. water, saliva, polishing powder, solid materials like fillers, etc.) from the patient's mouth. The suction cannula is connected to the suction hose via a suction handpiece.

The applied parts in accordance with IEC 60601-1 are:

- Suction cannulas

5.4 Adapter

Connecting piece, which, when plugged on, connects the suction cannula $d=6.5\ \text{mm}$ to the disposable hose.



6 Requirements

6.1 Installation/setup room

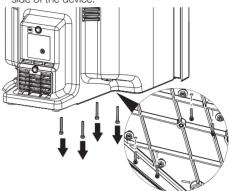
The room chosen for installation must satisfy the following requirements:

- Closed, dry room.
- Should not be a room made for another purpose (e.g. boiler room or wet cell).
- The required environmental conditions are satisfied (refer to the "Technical Data" in the operating instructions).

7 Installation

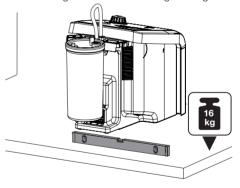
7.1 Remove the transport locks

> Remove the transport protection on the underside of the device.



7.2 Setting up the unit

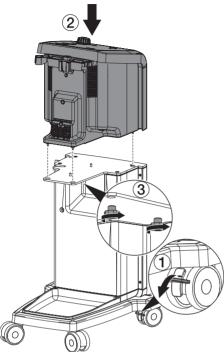
Place the unit on a horizontal table. The loadbearing capacity of the table must be suitable for the weight of the unit including its filling.





7.3 VC 65 Cart

> Place the unit on the VC cart and secure it.



7.4 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.
- Defore initial start-up check that the mains supply voltage and the voltage stated on the type plate match (see also "4. Technical data").

7.5 Connecting the unit to the mains supply

Requirements:

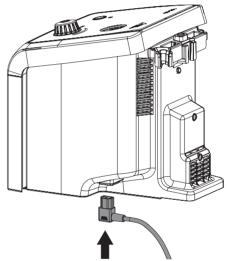
- ✓ Properly installed power outlet close to the unit (max. mains cable length 5 m)
- ✓ Easily accessible power outlet
- Mains voltage must match the information shown on the type plate of the power supply unit



WARNING

Electric shock

- The device may only be connected to a supply system with a earthed power outlet.
- Plug the connecting plug into the socket connection of the device.



> Plug the mains plug into the power outlet.



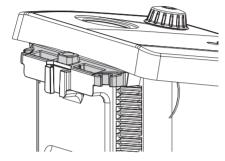
7.6 Preparation of the device

Attach the hose manifold

Attach the hose manifold to the housing until it snaps into place.

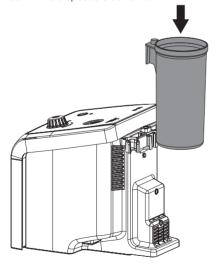






Disposable container

> Hook in the disposable container.

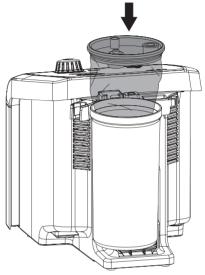


<u>^</u>

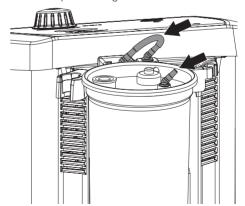
WARNING

Risk of cross contamination when reusing the disposable bag

- Do not use the disposable bag more than once (disposable item).
- Insert the disposable bag in the disposable container.



Push the connecting hose and the connecting sleeve on the standard rail mount adapter and on the container. Insert the connecting sleeve in the disposable bag.



> Switch on the unit.



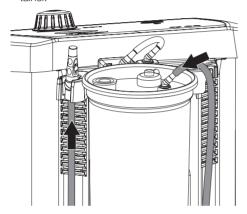
Close the connecting sleeve on the disposable bag and press the cover slightly down in the middle until the disposable bag has completely unfolded.

A

WARNING

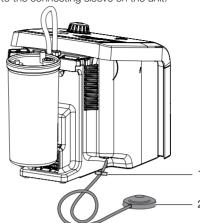
Danger of cross-contamination when reusing the disposable bag and the suction cannula for single use

- Do not reuse the suction hose and the suction cannula (disposable items).
- > Connect the suction hose to the suction handpiece and the connecting sleeve to the container.



Connecting the foot switch

Connect the hose coming from the foot switch to the connecting sleeve on the unit.



- Knurled nut
- 2 Foot switch
- Use the knurled nut to secure hose coming from the foot switch.



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.



If reusable items are used, comply with the reprocessing instructions of the manufacturers.

Regarding reusable components, the components that contact the patient directly, e. g. suction cannulas, need to be reprocessed before each use. For reprocessing instructions, see the operating instructions of the manufacturer.

- > Check the hose connections for leak-tightness.
- > Check the integrity of the collecting container.

8.1 Electrical safety checks



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

- Perform the electrical safety check according to national law.
- Document the results.



The applied parts in accordance with IEC 60601-1 are the suction cannulas (see "5.3 Suction cannula").



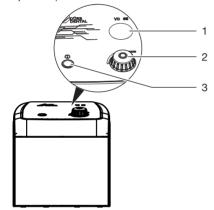
9 Operation

Requirements:

- Suction hoses and collecting container are free of damage (no leaks)
- Surface (including collecting container) cleaned and disinfected
- Components amenable to reprocessing are reprocessed
- The unit is positioned horizontally.

9.1 Setting up the unit

- > Switch on the unit.
- > Adjust the pressure.



- 1 Pressure gauge
- 2 Pressure regulator
- 3 On/off switch

9.2 Suction



NOTICE

Pump damage due to ingress of fluid

During suction, the collecting container can overflow.

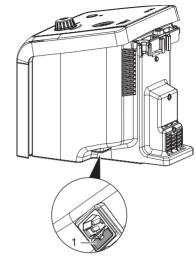
- Change the collecting container in good time.
- If the max. fill level is reached, replace the disposable container with a new one.

9.3 Replace the fuse



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

> Pull out the fuse shaft.



- 1 Fuse shaft
- Take out the fuse.

1

10 Cleaning and disinfection



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



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).

10.1 Preparation at the operating location



Wear protective gloves.



Wear protective goggles.



Use a mask.



Use protective clothing.

10.2 Device surface and hose manifold

The unit surface must be cleaned and disinfected of any contamination or visible soiling. Dürr Dental recommends the disinfectants FD 322, FD 333, FD 350 and FD 366 sensitive.



NOTICE

Liquid can cause damage to the unit.

- Do not spray the unit with cleaning and disinfectant agents.
- Make sure that liquid does not get inside the unit.
- Remove any soiling with a soft, lint-free cloth that has been dampened with cold tap water.

- Disinfect the surfaces using a disinfection wipe. Alternatively, use disinfectant on a soft, lint-free cloth.
- (i)

The hose manifold can be disinfected by heat and sterilised (at up to 134°); it can be reprocessed as described in section "11 Reprocessing".



11.1 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.

11.2 Preparation process in accordance with ISO 17664

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 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 using the fractionated vacuum procedure.

- Pre-vacuum: 3 x
- Sterilisation temperature: 134 °C
- Sterilisation time: 4 minutes
- 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 doublesided greenREF 09098

General information

- 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.
- Comply with the specifications (see "11.4 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying" and "11.5 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying") when selecting the cleaning and disinfectant agents to be used.
- Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.

- Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.
- Only use disinfectants that are aldehyde-free and display material compatibility with the product.
- Do not use any rinse aid (danger of toxic residue on the components).
- > Only use freshly-produced solutions.
- 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).
- Use clean, dry, oil and particle-free compressed air.
- > Do not exceed temperatures of 138 °C.
- Subject all devices used (ultrasonic bath, cleaning and disinfection device (CD), sealing device, steam steriliser) to regular maintenance and inspections.

11.3 Preparation at the operating location



Wear protective gloves.



Wear protective goggles.



Use a mask.



Use protective clothing.



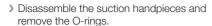
WARNING

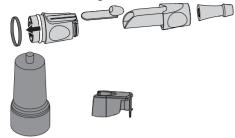
Risk of infection from contaminated products

Danger of cross contamination

- Reprocess the product correctly and promptly before its first use and after every subsequent use.
- Directly after the treatment, aspirate at least 200 ml cold water.







- 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.
- > Note the action time of the cleaning agent.
- Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

11.4 Manual cleaning, intermediate rinsing, disinfection, final rinse, 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

- Place the individual components in a disinfectant bath (non-fixing/aldehyde-free, see "General information") so that all parts are covered.
- > Comply with the reaction times of the cleaning agent and disinfectant (see "General information").
- 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:

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

Disinfection

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

Final rinse

After the action time prescribed by the manufacturer:

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

Drying

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

11.5 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 (A₀ 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 washerdisinfector, make sure there are no areas missed by rinsing.

- 1
- Place components in the basket for small parts.
- Attach cannula to suitable holders in the washer-disinfector.

11.6 Check for function

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

11.7 Steam sterilising

Packing

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 EN ISO 11607-1/2
- The applicable sections of the standard series FN 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:

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).
Time Do not exceed 138°C.

Marking

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

11.8 Issue clearance for the parts for sterilisation

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

Document the clearance of the medical product after reprocessing.



11.9 Storing parts for sterilisation

- > 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.



12 Maintenance



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).

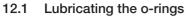


Only trained specialists or personnel trained by Dürr Dental may service the device.



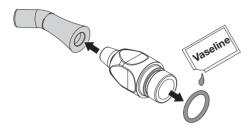
Prior to working on the unit or in case of danger, disconnect it from the mains.

Inspection interval	Inspection work
Daily	Visual check of the unit including hoses and container. Is there any damage to the hoses, handpiece or container?



Suction handpieces are easier to handle when the O-rings have been lubricated with Vaseline.

Disassemble the suction handpieces regularly and lubricate the O-rings.



IN

Troubleshooting

13 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).

Error	Possible cause	Remedy
Unit does not switch on	No mains voltage	 Check the mains cable and plug connection and replace if necessary. Check the fuse of the unit and replace it if required.
No suction from the unit	Hose leaking	Check that the hoses are securely seated and not leak- ing.
	Container cover leaking	Check the seal of the container cover.Check that the container cover is securely seated.



14 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		Serial number (SN)	
☐ Visual inspection of the packa	aging for any dam	age		
☐ Unpacking the medical device				
☐ Confirmation of the complete				
☐ 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:				

cal device:

0672100006L02 2205V008

Date of handover:

Signature of the qualified adviser for the medi-



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Hersteller / Manufacturer:

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