Operating Instructions

D2-SOLO





Manufacturer: DKL CHAIRS GmbH An der Ziegelei 3 D-37124 Rosdorf Germany +49 (0)551-50060 info@dkl.de www.dkl.de

D2-SOLO-S



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Symbols in the Operating Instructions



WARNING! (risk of injury)



CAUTION! (to prevent damage occurring)



General explanations, without risk to persons or objects



Thermodisinfectable

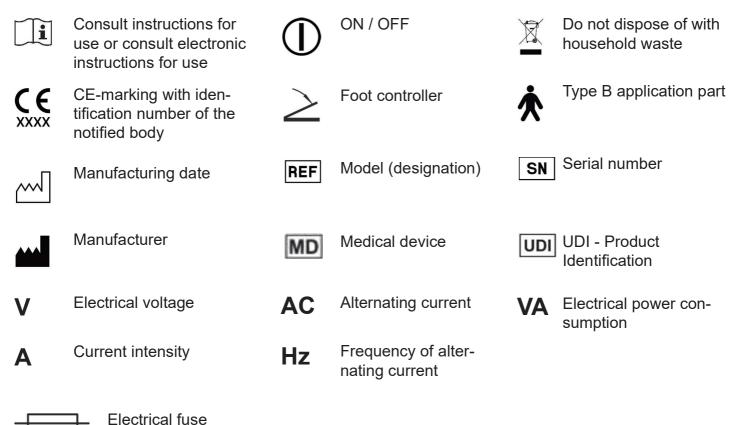


Sterilisable up to the specified temperature



Call customer service!

Symbols on the unit





Symbols inside the Unit





Ν

Earth conductor connection -Protective earth Functional earth Connection point for neutral conductor

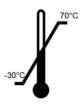
Symbols on the packaging



Air humidity, limitation



Atmospheric pressure limitation



Permissible temperature range



Transport upright; top



Protect from moisture!



Do not stack!



Fragile

Introduction



For your safety and the safety of your patients

These operating instructions are intended to explain how to use your product. However, we must also warn of possible dangerous situations. Your safety, the safety of your team and, of course, the safety of your patients are very important to us.



Please observe the safety instructions!

Intended purpose

This treatment unit is used for the diagnosis and therapy of children and adults in the field of dentistry.

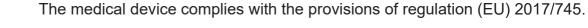


Improper use can damage the treatment unit and thus pose risks and hazards to the patient, user and third parties.

Qualification of the user

The DKL treatment unit may only be used after medically, professionally and practically trained personnel have been instructed. The development and design of the treatment unit were geared towards the target group of dentists, dental hygienists, qualified dental employees (prophylaxis) and dental assistants.







Responsibility of the manufacturer

Production according to EU directive

The manufacturer can only be held responsible for the impact on the safety, reliability and performance of the treatment unit if the following instructions are observed:

- > The dental unit must be used in accordance with these operating instructions.
- If assembly, additions, new settings, changes or repair work is carried out by DKL or trained technicians authorised by DKL or personnel of authorized dealers trained by DKL.
- > The electrical installation of the room must comply with the regulations of the IEC 60364-7-710 standard ("Erection of electrical installations in rooms used for medical purposes") or comply with the regulations applicable in your country.
- > The recommended annual maintenance is carried out and any repair work in this context meets the requirements of EN 62353.
- » "Repeat tests and pre-commissioning tests of medical electrical equipment and systems – general regulations" are fully complied with.
- > The national legal regulations are observed when using the device, in particular the applicable health and safety regulations and accident prevention measures.

Electromagnetic Compatibility (EMC)



Medical electrical equipment is subject to special precautions with regard to EMC and must be installed and commissioned in accordance with the EMC instructions. DKL guarantees that the dental unit complies with the EMC guidelines only if original DKL accessories and spare parts are used. The use of accessories and spare parts not approved by DKL may lead to an increased emission of electromagnetic interference or to a reduced resistance to electromagnetic interference.



The EMC manufacturer declaration can be found on page 27.



HF communication equipment

Do not use portable and mobile HF-communication equipment (such as mobile telephones) during operation. These can affect medical electrical devices.



Risks due to electromagnetic fields

The functionality of implantable systems, such as cardiac pacemakers and implantable cardioverter defibrillators (ICD), can be influenced by electric, magnetic and electromagnetic fields.

- > Before using the product, ask the patient and user about implanted systems and check the use.
- > Perform a risk-benefit analysis.
- > Do not place the product near implanted systems.
- > Do not place the instruments on the patient's body.
- > Take appropriate emergency precautions and respond immediately to health changes.
- > Symptoms such as increased heart rate, irregular pulse, and dizziness may be signs of problems with a pacemaker or ICD.

Safety Notes – General



- > Before being put into initial operation, the treatment unit must be kept at room temperature for 24 hours.
- > Before each application, check the treatment unit and the instruments with cables for damage and loose parts.
- > Do not operate the treatment unit if it is damaged.
- > Check the set parameters each time you restart the unit.
- > Carry out a test run before each application.
- > The application and timely shutdown of the system is the user's responsibility.
- > Make sure that in the event of a device or instrument failure, the treatment can be completed safely.
- > Use only original DKL fuses.
- > Never touch the patient and the electrical connection at the treatment unit at the same time.
- > Do not lean on the tray or the operating lamp.
- > When moving the treatment chair, the doctor's device, the assistant's device, the tray or the operating lamp, pay attention to the patient and the practice personnel.
- > Always switch off the treatment unit before leaving the practice.



- Hygiene and care before using the device
- > Clean and disinfect the device immediately before or after each treatment!
- > Wear protective clothing.



 Observe your country-specific guidelines, standards and specifications for cleaning, disinfection and sterilisation.



The treatment unit is classified as an "ordinary device" (closed device without protection against water ingress).



The treatment unit is not suitable for use in an explosive atmosphere or in explosive mixtures of anaesthetics with oxygen or nitrous oxide.



The treatment unit is not suitable for use in rooms with an oxygen enriched atmosphere.

Safety Notes – Patient Chair



- > Not suitable for patients who cannot remain in a resting position due to mental or physical disabilities.
- > The patient's arms and legs must rest on the upholstered parts of the chair.
- > Do not exceed the maximum patient weight of 150 kg.
- > Do not sit on the head or foot rest of the horizontally aligned patient chair.
- > Position changes must always be carried out under the surveillance of the person giving treatment.
- > Watch patients while moving the treatment chair.
- > Make sure that there are no objects under the treatment chair.

Technical Specifications



The motors of the treatment unit are designed for intermittent operation in accordance with the dental treatment method.

Driving motors for patient chair and backrest: duty cycle (max. 25 s "ON" / 400 s "OFF").

Supply voltage	230V AC
Nominal voltage	max. 3 A
Frequency	50/60 Hz
Fuse	T 6.3 A H 250 V primary
Maximum power consumption	625 VA
Device class according to MDR (EU) 2017/745	lla
Protection class	Device of protection class I
Contamination level	2
Over voltage category	II
Power cable	3x1,5 mm ²
Suction control lines to the suction device	5x1,5 mm ²
Potential equalisation	1x 4 mm ²
Relay control line optional special function	3x1,5 mm ²
Free end electrical cables above floor	500 mm
Fuse for domestic installation	Circuit breaker: 16 A medium-lag Recommendation: circuit breaker type C
Degree of protection against ingress of water	Ordinary device (without protection against water ingress).



Permanently connected device. In order to avoid the risk of electric shock, this device may only be connected to a power supply with an earth conductor.

Weight	
D2-SOLO	max. 165 kg
D2-SOLO-S	max. 210 kg
Transport and storage conditions	
Ambient temperature	-30 to +70 °C
Relative humidity	10 to 80 %
Atmospheric pressure	500 hPA to 1060 hPa
Operating conditions	
Quality and load-bearing capacity of the floor	The floor must be level and horizontal according to EN 18202. Unevenness of the floor along the total length of the chair base up to 2 mm is acceptable. The minimum load-bearing capacity of the floor must be 0.5 N/cm ² (equivalent to approx. 500 kg/m ²).
Ambient temperature	10 to 35 °C
Relative humidity	15 to 80 %
Atmospheric pressure	700 hPA to 1060 hPa
Installation site	≤ 3,000 m above sea level The treatment unit is not suitable for operation in hazardous areas.

Media Requirements

Media water	
Water hardness	1.5 to 2.14 mmol/l = 8,4-12 dH
ph-value	6,5 to 8,5
Water filtration on site	≤ 100 μm
Water inflow	Pipe 10x1mm, angle valve outlet 3/8"
Water connection above floor	min. 40 mm, max. 60 mm
Water inlet pressure	2.0 to max. 6.0 bars
Water quality	Cold water in accordance with local and national drinking water regulations.
Minimum flow rate	3 l/min

• Perform the installation according to the national installation requirements (e.g. EN 1717).

- For the reduction of microorganisms in the water supply pipe, please observe the following when laying this pipe to the treatment unit:
 - Avoid long stub lines to the treatment unit.
 - Select the installation in such a way that other essential consumers (e.g. washbasin) are as far as possible behind the connection of the treatment unit can be supplied from the same pipe.
 - Avoid laying the hot water supply pipes in parallel.
- Recommendation: For the water supply of the treatment unit, install an angle valve with 2 outlets and 2 stop cocks. The second outlet allows easy sampling of water for microbiological analysis.

Connection to the public drinking water supply

When the treatment unit is equipped with a cuspidor, the bowl rinser ensures the free outlet with a separation distance \geq 20 mm.



Before the treatment unit is installed, the microbiologically perfect water quality of the domestic water supply should be ensured and documented in the form of a microbial count.

Sampling and microbial count should be carried out by a competent laboratory.

Media air	
Air inlet pressure	max. 7 bars
Air consumption	80 NI/min
On-site air filtration	\leq 100 particles size 1 - 5 µm referred to one m ³ of air
Oil content	≤ 0.5mg/m ³ ,oil-free compressors; the compressor must suck in hygienically perfect air.
Humidity	Pressure dew point ≤ -20 °C at atmospheric pressure
Compressed air supply	Pipe 10x1 mm, angle valve outlet 3/8"
Air connection above the floor	min. 40 mm, max. 60 mm



Clean air and water pipes before installing the unit.

Chips and other foreign substances could be flushed or blown into the treatment unit.

Metal chips can interfere with the function of pneumatic components. Filters are clogged by foreign substances.

• When assembling, make sure that there are no chips or other foreign substances in the pipes.

- Flush the water pipes.
- Blow out the air ducts.

• Make sure that no further foreign substances get into the pipes and ducts after rinsing or blowing out.

Requirements for the suction system	
Vacuum at supply connection	min. 0,12 bar, max. 0,18 bar
Minimum suction power at supply connection	≥750NI/min
Suction system	Type 1: high flow rate wet or dry suction
Suction pipe	DN40 HT-PP (polypropylene, inside diameter approx. 36.5 mm)
Water drain	DN40 HT-PP (polypropylene, inside diameter approx. 36.5 mm)
Gradient	Min. 10 mm per metre
Wastewater volume	3 I/min

Filter in the treatment unit		maintenance interval	Article number
Particle filter water inlet	80 µm	Replace annually	200095-E2
Particle filter compressed air inlet	50 μm	Replace annually	200095-E1
Solid particle filter for the suction system	Mesh size 1 mm	In case of damage, replace at least annually.	514100

Requirements for Supply Connections

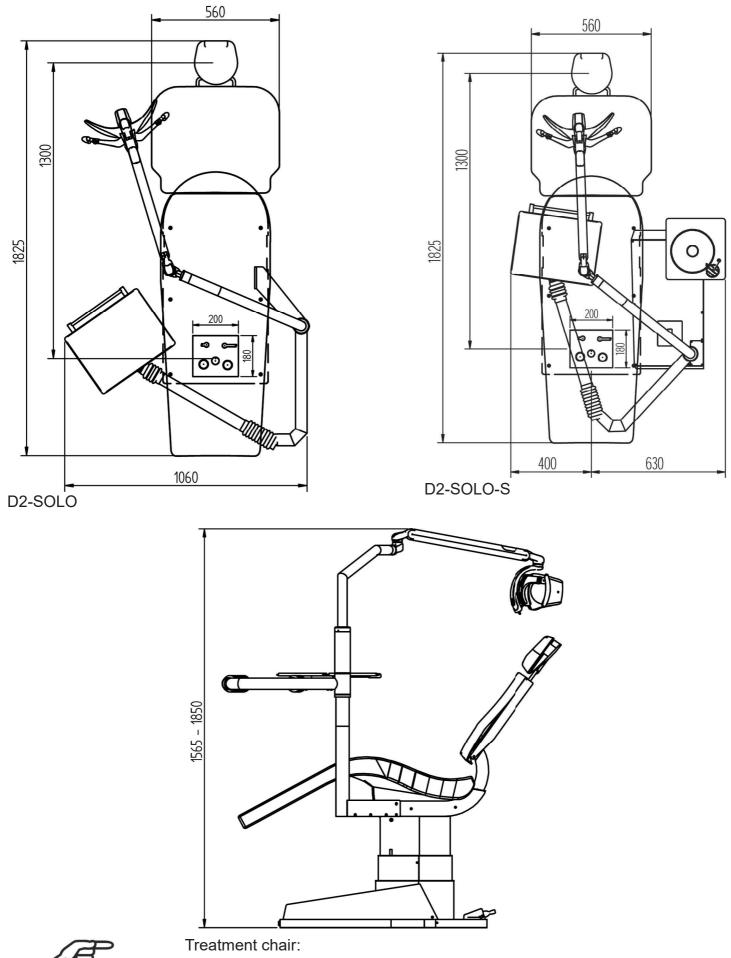
① Air: pipe min. 10x1 mm, angle valve outlet 3/8" ② Water drain DN40 HT-PP ③ Suction line DN40 HT-PP ③ Suction line DN40 HT-PP		
	10x1 mm, angle valve outlet 3/8"	1
3 Suction line DN40 HT-PP (2) (3)	N40 HT-PP	2
	N40 HT-PP	3
Power cable 3x1.5 mm ²	x1.5 mm ²	4
Equipotential bonding 1x 4 mm ²	ponding 1x 4 mm ²	4
Control line to suction device 5x1.5 mm ²	suction device 5x1.5 mm ²	4
Water: pipe min. 10x1 mm, angle valve outlet 3/8" (2 outlets with 2 stopcocks)		5



• With the D2-SOLO the connections 1, 2, 3, 5 and the control line to the suction device are not needed.

200

Dimensions in Millimetres



lowest position 395 mm highest position 730 mm



Product Description





1	Treatment chair, seat
2	Treatment chair, back rest
3	Treatment chair, double-jointed headrest
4	Treatment chair, joystick
5	Treatment chair, arm rest
6	Tray
7	Operating Lamp LED.light EVA
8	Cuspidor

Moving the Treatment Chair

Joystick at the chair base

Move the joystick downwards

- > Treatment chair moves downwards.
- Move the joystick upwards
- > Treatment chair moves upwards.
- Move the joystick to the left
- > Back rest tilts backwards.
- Move the joystick to the right
- > Back rest moves to an upright position.



Joystick

- Tap the JoystickTwice
- > Treatment chair moves to the entry /exit position.
- Tap the joystick twice downwards
- > Treatment chair moves to the treatment position p2.
- Tap the JoystickTwice to the Left
- > Treatment chair moves to the rinsing position and back to the last position when tapping twice again.

Tap the Joystick Twice to the Right

> Treatment chair moves to the treatment position p1.

Programme keys at the back rest

Press "p0"

- > Treatment chair moves to the position for getting on/off.
 Press "p1"
- > Treatment chair moves to treatment position p1.
 Proce "n2"
- Press "p2"
- > Treatment chair moves to treatment position p2.
 Press "p3"
- > Treatment chair moves to treatment position p3.
 Briefly press "lp"
- > Treatment chair moves to the rinsing position and after renewed pressing back to the "last position".

Saving programme keys p0 - p3

For programming the keys, move to the desired programme position manually and then keep the respective programme key pressed for about 3 seconds until you hear a signal tone. Now you have successfully saved your individual treatment position.

Saving programme key lp

Press the "lp" key to move the chair to the rinsing position. By pressing the key "lp" once again, the chair moves back to the previous programme position or to the manually set position. In order to programme the chair, move it manually to the desired rinsing position and then keep the key "lp" pressed for about 3 seconds until you hear a signal tone. Now you have successfully saved your rinsing position.



Moving the Treatment Chair



Emergency-Stop System

Briefly tap the joystick or any programme key at the back rest to stop the active programme immediately.



Programme Run

Press the programme keys "0" and "lp" simultaneously for about 3 seconds until you hear a signal tone. The treatment chair then moves the seat and the back rest into the lowest position. The motion sequence has been reset now.



You can find an application film at www.youtube DKL Germany. Video: DKL CHAIRS D2 SERIES FUNKTIONEN UPHOLSTERY POSITIONS

LINK: https://youtu.be/o307-rWGp5A



When moving the back rest, there is a risk of injury or crush. The patient's hands and arms must always rest on the chair upholstery.

To facilitate getting on or off the chair, the right arm rest (optional) can be swivelled by 90°.

Pull the release lever up to freely adjust the doublejointed head rest. Press the lever down to fix the position of the double-jointed head rest. The release lever must always be pulled up completely to move the head rest.

Manually extractable double-jointed head rest.

Putting the Treatment Unit into Operation



- > Before putting the device into initial operation and after downtimes (weekends, (public) holidays etc.), flush the water lines intensively.
- > Press the cup fill button several times before starting work.

Activating / Deactivating the Treatment Unit



The treatment unit is equipped with a power switch 0 on the chair base. The power switch connects the treatment unit with the power supply.

In the event of longer downtimes, the treatment unit should be disconnected from the power supply. The treatment unit contains a device fuse 2.

Switch on the treatment unit at the power switch. The power switch lights up green.

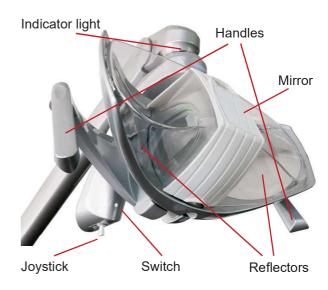
Operating Lamp LED.light EVA



For the intended use, please observe the operating instructions issued by FARO: USER MANUAL EVA

When swivelling and moving the operating lamp, always make sure that no objects or persons are in the swivelling range of the arm system. Otherwise, personal injury or property damage may occur.

In order to move the operating lamp only touch its handles!

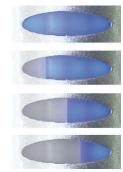


Switching on/off on the joystick: Push right or left

Decrease the light intensity on the joystick: Push right and keep pushed until desired intensity is reached.

Increase the light intensity on the joystick: Push left and keep pushed until desired intensity is reached.





light intensity indicator

change in light intensity



Operating Lamp LED.light EVA

Changing the color temperature via the switch:

Indicator light

yellow

4000 Kelvin

Every time a double click is performed, the colour temperature in Kelvin (Tk) of the light changes. Repeat the procedure until the desired colour temperature is shown on the indicator light. 2 beeps will inform the user that Tk is changing.



Indicator light blue 5700 Kelvin



Composave setting



Composave setting on the joystick: Push forwards or backwards.



Indicator light

white

5000 Kelvin

Composave setting on the switch: Single Click.



Acoustic signal and indicator light switches to orange.

Mirror

Loosen the plastic cover at the front of the protective cap by lightly pressing on its upper end. On the back of the cover there is a mirror. Attach the mirror to the plastic cover.





You can find an application film at www.youtube DKL Germany. Video: DKL CHAIRS L2-D2 SERIES FUNCTIONS LED.LIGHT OPERATING LAMP EVA

LINK: https://youtu.be/vaKW9RdjtLM

Cleaning and disinfection of the Operating Lamp LED.light EVA

Pull the protective cap towards you to remove it for cleaning.



Cleaning and care

The reflectors must be cleaned with cotton wool and ethyl alcohol. Do not use detergents that contain surfactants or water-repellent substances (staining).



Cleaning, disinfection and Sterilisation of the handles

To remove the handles, turn the handle lock on the handles and pull off the handles. To mount the handles, reattach them and push them to the limit. Then lock the handle lock.



Cleaning and Disinfection of the handles Before sterilising the handles, they must be decontaminated and disinfected.



The handles cannot be disinfected by thermodisinfection.



Sterilisation of the handles:

The handles must be packaged in compliance with EN 868-5. The handles can be sterilised with standard cycles 121°/134° C up to two hundred (200) cycles or however up to loss of the mechanical performance.





Cycle EN 13060	Temperature	Pressure	Holding time minimum
В	121°C	207 kPa	15 min.
В	134°C	308 kPa	3 min.



Warning against danger of wear and corrosion and falling suspended mass.

For all metal or plastic parts it is strictly forbidden to use substances that are abrasive, corrosive, acids, substances containing chlorine or chloride ions, phosphorous or phosphorous ions or detergents with Trilene base, petrol, white spirit, chlorine or similar.

Do not use detergents-disinfectants containing the following substances to clean plastic parts:

Ammonium Hydroxide, Sodium Hydroxide, Hydrogen peroxide, Ammonium Chloride, Methylene Chloride, Methyl Alcohol, acids and corrosive substances of all kinds.

It is forbidden to directly spray any chemical substance on the device.



The tray should be set correctly for your standard equipment and thus remain in its desired position. The maximum load of the tray is 2 kg. Do not lean on the tray.

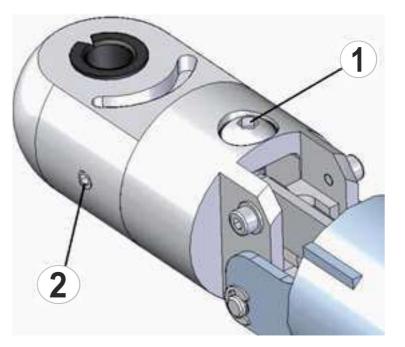
Pull back the bellows until the adjusting screw (1) is visible. Place your standard equipment on the tray (max. 2 kg) and move the tray into ahorizontal position.

Set the adjusting screw (1) so that the arm remains in the horizontal position (with a slight upward tendency).

Turn the adjusting screw in the ", + ", direction = high weight.

Turn the adjusting screw in the " - " direction = low weight

Secure the 3 grub screws (2) with safety lacquer (blue).

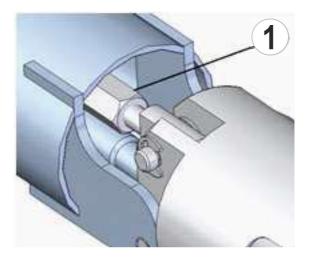


With the adjusting screw, the tray can be aligned in its radially horizontal position.

Pull back the bellows until the adjusting screw (1) is visible.

Move the tray into a horizontal position.

Secure the adjusting screw (1) for the inclination with thread locking fluid (blue).





You can find an application film at www.youtube DKL Germany. Video: DKL CHAIRS L2-D2-RANGE TRAY SETTINGS

LINK: https://youtu.be/r-Y14eEYtql

Cuspidor



1	Operating status with installed water separation unit
2	Bowl rinser
3	Glass filler



The factory setting for the bowl rinser is 7 seconds. The glass filler is factory-set to 3 seconds.



Activate the bowl rinser at the display of the doctor's device or at the cuspidor.



Activate the cup filler at the display of the doctor's device or at the cuspidor.

Changing the bowl rinsing time.



Keep the bowl rinser key at the display of the doctor's device or at the cuspidor pressed. After 2 seconds, a short signal is audible. Keep the key pressed until the desired rinsing time has been reached. Successful storage is confirmed with another signal tone. Maximum rinsing time: 25 seconds.

Changing the Filling Time for the Cup



Keep the cup filler key at the display of the doctor's device or at the cuspidor pressed. After 2 seconds, a short signal is audible. Keep the key pressed until the desired fill level has been reached in the glass. Successful storage is confirmed with another signal tone. Maximum filling time: 10 seconds.



After switching on the treatment unit, the bowl rinsing process starts automatically for the saved duration and rinses the bowl.



You can find an application film at www.youtube DKL Germany. Video: DKL CHAIRS L2-D2 SERIES FUNCTIONS CUSPIDOR CUP FILLER & BOWL RINSER

LINK: https://youtu.be/SsFSKDpJI_I

Cleaning the Sieve

Clean the sieve in the cuspidor bowl once a day under running water.



To reduce the risk of infection, liquid-tight gloves must be worn during maintenance work.



Never work without a filter, otherwise there is a risk that parts will settle in the suction system and thus impair its function.



Suction System



For the intended use, please observe the operating instructions issued by DÜRR Dental: > Cuspidor valve, Version 3

> CAS 1 operating instructions issued by DÜRR Dental

> CS 1 operating instructions issued by DÜRR Dental,

depending on the equipment and design of the suction system.





Open the door of the cuspidor fountain by pulling the handle. Depending on the equipment and design of the suction system, you will find the following in the cuspidor: > Cuspidor valve, Version 3 (wet suction)

- > CAS 1 operating instructions issued by DÜRR Dental (dry suction)
- > CS 1 operating instructions issued by DÜRR Dental (dry suction)

Cleaning and Disinfection of the Surfaces

Hygiene and Care of the Stainless-Steel Surfaces

The regular cleaning of stainless-steel surfaces is recommended for hygienic as well as aesthetic reasons and serves to remove grease stains or finger marks. These can be easily removed with commercially available chlorine- and acid-free stainless-steel cleaners. We recommend applying Prestan to the surface in question.

Most stainless-steel care products contain silicone oil. Using these products can make your work a lot easier. They effortlessly remove any finger marks, but do not necessarily prevent new ones. Depending on the intensity of use, the protective layer remains in place for a few days. Microfibre cloths slightly moistened with water have also provento be very effective.

Never use abrasive agents such as scouring powder, scouring milk or steel wool as these may cause scratches. Brushed surfaces must always be wiped in the direction of the finish. For this purpose, we recommend using a microfibre cloth. After cleaning, we recommend always wiping stainless-steel surfaces dry with a lint-free cloth to remove water stains or residual cleaning agent.

Disinfection of Stainless-Steel Surfaces

Do you put emphasis on a germ-free surface? Here, too, stainless steel proves to be extremely robust. Any commercially available chlorine-free disinfectant can be used.

Tests have shown that stainless steel is considerably easier to disinfect thanother materials and even a lot less disinfectant is required in order to meet hygiene requirements.

The Most Important Facts at a Glance:

Effective and generallysafe to use on surfaces are

- Soft sponges or microfibre cloths,
- Soapy water (to remove greasy stains),
- Diluted vinegar (to remove lime),
- Sodium bicarbonate (to remove coffee stains),
- Soda (to remove tea stains),
- Alcoholic solvents (to removeglue) and
- Special stainless-steel care products (for cleaning and conservation).



Caution is called for with

• Disinfectants containing chlorine and cleaning agents containing bleach (risk of corrosion).



Never use:

- Scrubbing sponges (scratches and extraneous rust),
- Scouring powder (scratches)
- Silver polish (corrosive).

Cleaning and Disinfection of the Surfaces

DentaClean: cleaning agent for imitation leather and plastic surfaces



Properties

DentaClean gently and easily cleans soiled imitation leather and plastic surfaces. **Use**

Test on a hidden area first. We recommend cleaning the chair upholstery at the end of every treatment day. This is particularly important with light colours; any visible soiling must be removed immediately. Use the provided sponge to apply DentaClean in circular motions to the surfaces to be cleaned. Then remove moisture and dirt with a soft, absorbent cloth. For a thorough cleaning, use a cleaning brush instead of the sponge twice a week. Finally, seal with DentaProtect. Upholstery that is treated regularly and properly with DentaProtect is easier to clean!

DentaProtect: Care and protection for your imitation leather upholstery



Properties

DentaProtect is a product for caring and protecting heavy-duty imitation leather upholstery. Sealing the surface, it acts as a micro-binding agent and protects the upholstery from damage due to abrasion, soiling and also discolouration by non-fixed colourants in clothes.

Application

After the thorough end of the day cleaning cycle, apply the DentaProtect sealing evenly to the dry upholstery. You need 1 - 2 wipes for the complete upholstery set of your treatment chair. Close the box immediately after taking out the wipes.

Disinfection of medical artificial leather



Products:Wipe disinfection for plastics.What:Upholstery, Covers (trays, panels etc.).When:After every patient.

Cleaning and Disinfection of the Surfaces



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Cleaning and Care

Care set 1 x DentaClean 200 ml spray foam cleaner (article DC200) 1 x DentaProtect wipe dispenser box (article DP100) 1 x cleaning brush, 3 x cleaning sponges	Article number PSET
DentaClean 1000ml Refill bottle for spray foam cleaner	Article number DC1000
DentaClean 200ml Spray foam cleaner incl. 2 x cleaning sponges	Article number DC200
DentaProtect wipe dispenser box 100 wipes in a disposable sealing bag	Article number DP100
DentaProtect wipe dispenser set 6 wipe dispenser boxes with 100 wipes each in a disposable sealing bag	Article number DP600
Cleaning brush set, 4 pieces	Article number RB4
Cleaning sponge set, 8 pieces	Article number RS8



You can find an application film at www.youtube DKL Germany. Video: MEDICAL UPHOLSTERY – CLEANING DISINFECTION PROTECTION

LINK: https://youtu.be/kM2E0kM6J1M

Maintenance and Inspection



In order to ensure the operational and functional reliability of your treatment unit and to avoid damage due to wear and tear it is necessary to perform maintenance once a year. Maintenance is carried out by an authorised technician of your specialist dealer or a DKL CHAIRS technician.

The work steps to be performed and the parts to be replaced are specified in the document "Maintenance Log". The tasks that were performed have to be entered in the maintenance log, which is part of the medical devices logbook.

Safety Inspections



Dental units are designed in such a way that a first fault does not present a hazard to patients, operators or third parties. Therefore, it is important to detect such faults before a second fault occurs, which may result in a hazard.

For this reason, safety inspections should be carried out every 3 years to detect electrical faults in particular (e.g. faulty electrical insulation). These checks are carried out by an authorised technician of your specialist dealer or a DKL CHAIRS technician.

The work steps to be performed are specified in the document "Safety Inspections". The measured values have to be documented.

Safety inspections have to be carried out when putting your treatment unit into initial operation, after expansion or retrofitting activities on your treatment unit and after repair jobs. The safety inspections are carried out in accordance with DIN EN 62353.



The treatment unit may only be operated when the safety checks have been passed.

Warrantee Declaration



12 Months Warranty

This DKL medical product has been manufactured with the utmost care by highly qualified specialists. Multifarious checks and inspections ensure faultless performance. Please note that warranty claims will only be accepted if all the instructions in this operating manual have been observed.

DKL as the manufacturer shall be liable for material and manufacturing faults within a warranty period of 12 months from the date of purchase. Accessories and consumables (seals, filters, lamps and suction tubes) are excluded from this warranty. We do not accept liability for damages caused by improper treatment or repair work carried out by third parties that are not authorised by DKL!

Any warranty claims must be filed with the supplier or an authorised DKL service partner and the sales slip must be enclosed. Any performance of this warranty does not extend the warranty period.

To protect your warranty claims and guarantee safe operation, medical devices must be installed properly, and staff must be instructed. To be able to proof this, information for assembly, initial start-up and instructions must be documented. For this purpose, please use our L2-D2 series certificate of delivery. After putting the device into operation, please return the completed certificate to us as proof.

Waste Disposal



Make sure that the parts that are being disposed of are not contaminated.



Observe your local and national laws, guidelines, standards and regulations for disposal.

- > Medical devices
- > Waste electrical and electronic equipment



Further information on disposal can be found at http://dkl.de



Disposal and recycling of DKL transport packaging is carried out within the scope of the Dual System via the local waste disposal and recycling companies. DKL transport packaging returned by customers at their own expense is supplied by DKL to the recycling companies set up for this purpose without further costs and without reimbursement.

EMC - Manufacturer's Declaration for the Model D2-SOLO

- WARNING: The use of accessories that do not conform to the manufacturer's specifications may result in higher interference levels and/or lower interference immunity.
- Operate the equipment in a location as far away as possible from equipment that emits electrical and magnetic disturbances. If it is necessary to operate the device in the immediate vicinity of other devices, make sure that the system functions correctly.

BASIC SAFETY

BASIC SAFETY is ensured if it meets the safety requirements of the IEC 60601-1 standard, in particular the requirements against: electrical shock, mechanical hazards and hazards due to excessive temperatures.

ESSENTIAL PERFORMANCE

The dental unit has no direct clinical function or essential performance according to IEC 60601-1, IEC 80601-2-60, 201.4.3 ESSENTIAL PERFORMANCE.

Performance limitations are permitted according to the following criteria. This is considered in the risk analysis of the system.

Criterion A

The dental unit will withstand the test without damage or other interference. During and after the test, the device will operate perfectly within the specified limits. Basic safety is guaranteed throughout.

Criterion B

The dental unit will withstand the test without damage or other interference. After the test, the device will operate perfectly within the specified limits. Basic safety is guaranteed throughout.

Criterion C

A temporary malfunction is permitted if the function resets itself or if it can be restored by user intervention. Basic safety is guaranteed throughout.

Intended operating environment

Intended operating environments are typical professional health care facilities and areas of home health care.

Technical description

This dental unit has been tested and developed to meet the EMC behaviour in the specified environment. This includes special EMC-filters to reduce the radiation of electromagnetic waves as defined in IEC 60601-1-2.

Please read and follow all technical documentation to avoid adverse events for the patient or user.

IEC STANDARD 60601-1-2:2014, 4th Edition

This device is approved for use in a specific electromagnetic environment. The customer or user of the device must ensure that it is used in an electromagnetic environment in accordance with the description given below.

Emission Measurement	Agreement	Guidelines Regarding the Electromagnetic Environment
RF-emission according to CISPR 11	Group 1	This device uses RF-energy for internal functions only. RF- emissions are therefore very low, and it is unlikely that other nearby electronic equipment will be disturbed.
RF-emission according to CISPR 11	Class B	The device is suitable for use in all environments, including residential areas, and approved for direct connection to the public low-voltage network for residential areas.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker according to IEC 61000-3-3	met	

Interference Immunity Test	IEC 60601- test level	Compliance level	Electromagnetic Environment - Guidelinesf
Electrostatic Discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ±2, 4, 8, 15 kV air discharge	± 8 kV contact discharge ±15 kV air discharge	The floor should be wood, concrete or tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%. Criterion B
Fast transient electrical dis- turbances/bursts according to IEC 61000-4-4 (only for V 300/600)	± 2 kV for mains 100 kHz repeat rate	± 2 kV for mains 100 kHz repeat rate	The quality of the mains power supply should meet the requirements for a normal commercial or clinical environment. Criterion B
Surge voltages according to IEC 61000-4-5 (only for V 300/600)	± 0,5 kV , ± 1 kV L to N ± 0,5 kV , ± 1 kV ± 2 kV L to GND	± 1 kV L to N ± 2 kV L to GND	The quality of the mains power supply should meet the requirements for a normal commercial or clinical environment. Criterion B
Voltage dips, short-term interruptions and voltage fluctuations of the mains supply lines according to IEC 61000-4-11 (only for V 300/600)			The quality of the mains power supply should meet the requirements for a normal commercial or clini- cal environment. If the user of the product requires continuous operation even with interruptions of the power supply, the product should be connected to an uninterruptible power supply.
	0 % UT 0°,45°,90°,135°,180°,2 25°,270°,315°	0 % UT for 1/2 Period	Criterion A (max. mains voltage) Criterion B (min. mains voltage)
	0 % UT 0° 0%	1 Period 25 /30 Periods	Criterion A (max. mains voltage) Criterion B (min. mains voltage) Criterion A (max. mains voltage)
	70 % UT 0 % UT 0%	(50/60Hz) 250/300 Periods (50/60Hz) for 5 s	Criterion B (min. mains voltage) Criterion A (max. mains voltage) Criterion B (min. mains voltage)
Magnetic field at the mains frequency (50/60 Hz) accor- ding to IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency should have levels typical of an application in a commercial or clinical environment.
Note: UT is the alternating ma	ains voltage prior to the a	pplication of the test level.	1

Specifications for Enclosure Port Immunity

Immunity Test	Test condition		IEC 60601 level of conformity	Electromagnetic Environmental Recommendation
Radiated electromagnetic fields from high-frequency wireless communication de	10 V/m 80 MHz – 2,7 GHz 80% AM 1kHz		10 V/m 80 MHz – 2,7 GHz	The quality of the main power supply should correspond to the one for a professional health care facility and be appropriate regarding the environment in areas of
vices IEC 61000-4-30-4-3	385MHz (18Hz pulse modulation)		27 V/m	domestic health care.
			28 V/m	Criterion A
	710MHz (217Hz P	M)	9 V/m	
	745MHz (217Hz P	M)	9 V/m	
	780MHz (217Hz P	M)	28 V/m	
	810MHz (18Hz PM	1)	28 V/m	
	870MHz (18Hz PM	1)	28 V/m	
	930MHz (18Hz PM	1)	28 V/m	
	1720MHz (217Hz	PM)	28 V/m	
	1845MHz (217Hz	PM)	28 V/m	
	1970MHz (217Hz	PM)	28 V/m	
	2450MHz (217Hz	PM)	28 V/m	
	5240MHz (217Hz	PM)	9 V/m	
	5500MHz (217Hz	PM)	9 V/m	
	5785MHz (217Hz	PM)	9 V/m	
, , , , , , , , , , , , , , , , , , , ,	IEC 60601-test level	Compliance level	Electromagnetic er	nvironment - guidelines
bance variables accor- ding to IEC 61000-4-6 (only for V 300/600)	3 Veff 150 kHz to 80 MHz 10 V/m 80 MHz to 2,7 GHz	10 Veff 10 V/m	equipment and parts less than the recomme equation applicable to Recommended prote $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ for 80 MHz to 800MF $d = 2,3\sqrt{P}$ for 800 MHz to 2.7 G Here P is the maximum watts (W) according to and d is the recomme The field strength of p was determined by a exceed the level b pe	łz

equency range

Note 2: These guidelines may not apply to all situations. The propagation of electromagnetic waves is affected by the absorption and reflection of structures, objects, people and animals.

^a The field strength of permanently installed transmitters, such as base stations for radio telephony (cordless or mobile phones), mobile radio stations, amateur radio transmitters, AM and FM radio and television transmitters, cannot theoretically be calculated with absolute accuracy. To determine the electromagnetic fields generated by fixed RF-transmitters, an electromagnetic site inspection should be carried out. If the measured field strength at the location where the device is used exceeds the permissible RF-field strength specified above, the instrument should be observed. Additional measures may be necessary, e.g. reorientation or change of location of the device.

^b In the frequency range between 150 kHz and 80 MHz, the field strength should be less than 3 V/m.

Manufacturer's Declaration - Electromagnetic Interference Immunity III

The device is approved for use in a specific electromagnetic environment.

The customer or user of the device must ensure that it is used in an electromagnetic environment as described below.

Interference Immunity	IEC 60601-	Compliance level	Electromagnetic environment –
Test	test level		guidelines
Fluctuations in the mains frequency and mains volta- ge according to IEC 601-1, section 10.2.2. a (only for V 300/600)	Nominal frequency: up to 100 Hz: variationsof ± 1 Hz of the nominal frequency; variations of ± 10%Hz of theno- minal voltage	Nennfrequenz: bis zu 100 Hz: Schwankungen von± 1 Hz der Nennfrequenz; Schwankungen von± 10%Hz der Nennspannung	The quality of the mains voltage supply should meet the requirements of a normal commercial or clinical environment.

Manufacturer's Declaration - Recommended Protective Distances between Portable or Mobile RF-Communication Equipment and the Device

The device is intended for use in an electromagnetic environment where the radiated RF-disturbance variables are checked. The customer or user of the device can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF-communication equipment (transmitters) and the device in accordance with the following recommendations, which are based on the maximum output power and frequency of the communication device.

Maximum nominal power of the transmitter in watts (W)	Protective distance as a function of the frequency of the transmitter in metres (m)			
	150 kHz to 80 MHz d = 1,2√P	80 MHz to 800 MHz d = 1,2√P	800 MHz to 2,5 GHz d = 2,3√P	
0,01	0,12	0,12	0,23	
0,1	0,38	0,38	0,73	
1	1,2	1,2	2,3	
10	3,8	3,8	7,3	
100	12	12	23	

For transmitters with a maximum output power not specified above, the recommended safety distance d in meters (m) can be calculated with an equation from the transmitter frequency and the maximum nominal output power P of the transmitter in watts (W) based on the transmitter manufacturer's specifications.

Note 1: At 80 MHz and 800 MHz respectively, the larger frequency range applies.

Note 2: These guidelines may not apply to all situations. The propagation of electromagnetic waves is affected by the absorption and reflection of structures, objects, people and animals.

ATTENTION: The use of this device directly adjacent to or coupled to another unit should be avoided as it may lead to unintentional behaviour. However, if this arrangement is unavoidable, both devices must be observed to verify that they are functioning normally.

CAUTION: Portable RF-communication equipment (including antenna cables or external antennas) should not be closer than 30 cm to the ME-equipment or ME-system, including those cables specified by the manufacturer. Otherwise, a power limitation of the device could be caused.



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Spittoon valve 3



Installation and operating instructions





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Important information

1 About this document

These installation and operating instructions represent part of the unit.

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

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

1.1 Warnings and symbols

Warnings

EN

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.



Wear protective gloves.



Wear protective goggles.



Use a face mask.



Refer to the accompanying electronic documents.



Cleaning button



- Air



Vacuum



Manufacturer



SN Serial number

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 spittoon valve is designed for installation in a treatment unit in dental surgeries or dental clinics.

The installation of the spittoon valve into a treatment unit helps to avoid suction noises emanating from the spittoon.

2.2 Intended use

The device is designed to be installed between the spittoon and the suction line. The spittoon valve may only process media (e.g. water, saliva, polishing powder, solid materials like fillers, etc.) from the the spittoon.

The spittoon valve can operate max. 1 dental work place.

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.

This includes:

- > Use of silicones, sludge, gypsum or similar substances from the practice.
- Cleaning and disinfection with chlorine-containing chemicals (such as, e. g., sodium hypochloride).

EN 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 Systems, connection with other devices

Additional devices connected with medical electrical devices must be proven to conform with their corresponding IEC or ISO standards. All configurations must continue to comply with the standard requirements for medical systems (see IEC 60601-1).

Whoever connects additional devices to medical electrical devices automatically becomes the system configurator and is responsible for ensuring that the system corresponds with the standard requirements for systems. Local laws take priority over the requirements outlined above.

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.

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.

2.8 Only use original parts

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

2.9 Transport

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

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



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

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

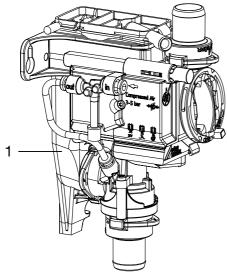
2.10 Disposal

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.

Product description

3 Overview



1 Spittoon valve

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):

Spittoon valve 3 7560700xxx

> Spittoon valve

3.2 Optional items

The following optional items can be used with the device:

Switch control panel 7560-520-00

3.3 Wear parts and replacement parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

Protective strainer 0700-702-06E



Information about replacement parts is available from the portal for authorised specialist dealers at: www.duerrdental.net.

Technical data

Electrical data		
Safety low voltage	V	24 AC/DC
Frequency	Hz	50/60
Nominal current	А	0.1
Rated power	W	2.4
Type of protection		IP 21

Electrical data, suction unit relay

Switching voltage		
min.	V	0.03 DC
max.	V	30 DC
Switching current		
min.	mA	10
max.	A	2
Connections		
Supply and waste water connection		

DürrConnect	mm	Ø 20
Collection vessel vent connection	mm	Ø 9
Compressed air connection	mm	Ø 4

Media			
Compressed air min. max.	bar / MPa bar / MPa	3 / 0.3 5 / 0.5	
Fluid flow rate, max.	l/min	3.5	
Fluid temperature, max.	°C	35	
Suction system pressure max. Absolute	mbar/hPa mbar/hPa	-200 800	

General data			
Duty cycle	%	40	
Weight	g	240	
Dimensions (H x W x D)	mm	143 x 74 x 112	

Ambient conditions during storage and transport			
Temperature	°C	-30 to +60	
Relative humidity	%	< 95	
Ambient conditions during operation			
Temperature	°C	+10 to +40	

%

< 70

Relative humidity

Air pressure	hPa	700 - 1060	
Electromagnetic compatibility (EMC) Interference emission measurements			
High-frequency emissions in accordance wit	h CISPR 11	Group 1 Class B	
Interference voltage at the power supply cor CISPR 11:2009+A1:2010	nnection	Compliant	
Electromagnetic interference radiation CISPR 11:2009+A1:2010		Compliant	
Emission of harmonics IEC 61000-3-2:2005+A1:2008+A2:2009		N/A	
Voltage changes, voltage fluctuations and fliv sions IEC 61000-3-3:2013	cker emis-	N/A	
N/A = not applicable			
Immunity to fast electrical transients/bursts - voltage IEC 61000-4-4:2012 ± 2 kV	- AC mains	Compliant	
100 kHz repetition rate			
Immunity to surges, line-to-line IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV		Compliant	
IEC 61000-4-5:2005		Compliant N/A	
EC 61000-4-5:2005 ± 0.5 kV, ± 1 kV mmunity to surges, line-earth EC 61000-4-5:2005	ed by radio-	·	

_		

Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP

Immunity to electrical fast transients/bursts - I/O, SIP/SOP ports IEC 61000-4-4:2012 Compliant $\pm 1 \, \text{kV}$ 100 kHz repetition rate Immunity to impulse voltages, conductor to earth IEC 61000-4-5:2005 N/A + 2 kV Immunity to conducted disturbances, induced by radiofrequency fields - SIP/SOP ports IEC 61000-4-6:2013 ЗV 0.15-80 MHz Compliant 6 V ISM frequency bands 0.15-80 MHz 80% AM at 1 kHz N/A = not applicable

Electromagnetic compatibility (EMC) Interference immunity measurements on the cover

Immunity to electrostatic discharge IEC 61000-4-2:2008 \pm 8 kV contact \pm 2 kV, \pm 4 kV, \pm 8 kV, \pm 15 kV air

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

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.

Immunity to power frequency magnetic fields IEC 61000-4-8:2009 30 A/m 30 Hz or 60 Hz

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

Compliant

Compliant

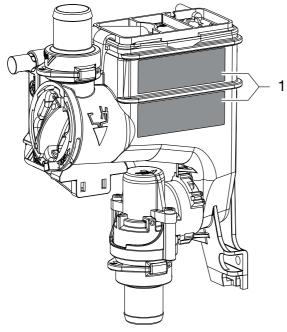
Compliant

Compliant

Immunity to interference table, near fields of wireless HF communication devices		
Radio service	Frequency band MHz	Test level V/m
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	1700 - 1990	28
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	2400 - 2570	28
WLAN 802.11 a/n	5100 - 5800	9

EN 4.1 Type plate

The type plates are located on the side of the fluid collector.



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.

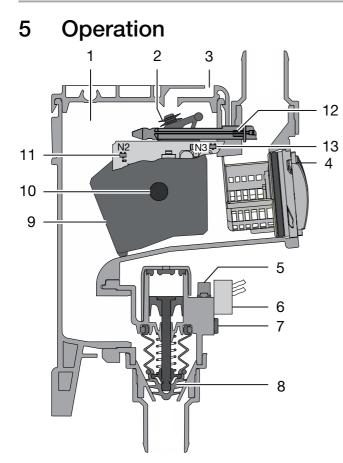


Fig. 1: Idle phase

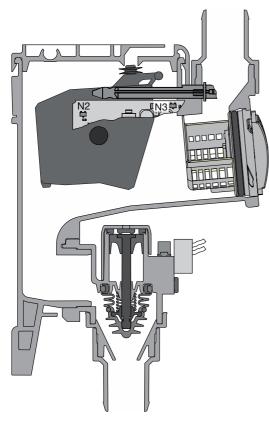


Fig. 2: Operational phase

1 Fluid collector

- 2 Air extraction seal
- 3 Vent
- 4 Protective strainer
- 5 Exhaust air damper
- 6 Solenoid valve
- 7 Compressed air connection
- 8 Shut-off valve
- 9 Float sensor
- 10 Magnet in float sensor
- 11 Float sensor detection
- 12 Magnet in cleaning button
- 13 Cleaning button detection sensor

5.1 Operating function

The waste water from the spittoon flows through the coarse filter into the collector vessel. If enough fluid is present then the magnet in the float sensor is detected by the control electronics. The control electronics start up the suction unit with the suction unit relay and actuate the solenoid valve for the compressed air supply. The inflowing compressed air opens the shut-off valve via a piston. The fluid from the collector vessel is then sucked into the suction pipe. As soon as the fill level in the collector vessel has dropped, this is detected by the control electronics and the solenoid valve is switched off. While waste water continues to flow in from the spittoon the collector vessel refills and the process starts again from the beginning.

5.2 Cleaning function

The cleaning function is activated by permanent pressure on the yellow cleaning button on the spittoon valve or on the cleaning button on the switch control panel (if present). As a result the solenoid valve for the compressed air supply, and therefore the shut-off valve, is opened and the suction unit relay is actuated in order to start up the suction unit.

The cleaning and disinfection solutions can now be aspirated without hindrance through the spittoon valve into the suction pipe and into the suction unit. A suction noise can be heard at the spittoon.

Assembly

6 Requirements

6.1 Setup options

Installation in treatment units in dental surgeries or dental clinics.

6.2 Preparing for the installation

Prior to installation of the spittoon valve the following media should be checked and if necessary adjusted; refer also to "4 Technical data":

- > Vacuum of the suction system
- > Compressed air supply
- > Water amount from the spittoon



Do not remove the gold collector or the coarse sieves from the spittoon.

6.3 Hose materials

For waste connections and suction lines only use the following hose types:

- Flexible spiral hoses made of PVC with integrated spiral or equivalent hoses
- > Hoses that are resistant to dental disinfectants and chemicals



Plastic hoses will display signs of ageing over time. Therefore, they should be inspected regularly and replaced as necessary.

The following types of hoses must not be used:

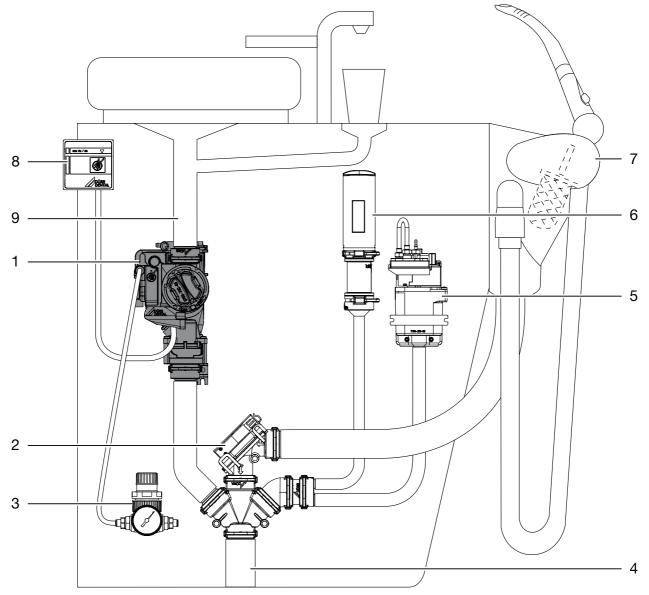
- > Rubber hoses
- Hoses made completely of PVC
- > Hoses that are not sufficiently flexible

6.4 Information about electrical connections

- The supply voltage to the device must satisfy the requirements for two means of patient protection (MOPP) as set out in IEC 60601-1 in relation to the supply network.
- The supply voltage must satisfy the following voltage/power requirements: 24 V AC/DC, 50/60 Hz, min. 2.4 VA

7 Installation

7.1 Installation overview



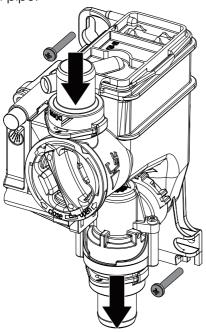
- 1 Spittoon valve
- 2 Station selection valve
- 3 Pressure reducer
- 4 Suction pipe connection
- 5 Rinsing unit
- 6 Auxiliary air nozzle
- 7 Hose manifold
- 8 Switch control panel
- 9 Spittoon outlet



EN 7.2 Installation of the spittoon valve

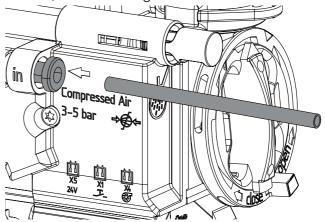
The cleaning function can be activated via the yellow button. For this reason the spittoon valve should be positioned in an easily accessible location. If this is not possible, a separate switch control panel can be used as an optional accessory.

- Disconnect the treatment unit from the power supply and secure it so that it cannot be switched back on again.
- > Firmly screw the spittoon valve onto a suitable place on the treatment unit.
- > Connect the drain hose from the spittoon to the inlet of the spittoon valve.
- > Connect the outlet of the spittoon valve to the suction pipe.



- 7.3 Establishing the compressed air connection
- > Disconnect a suitable compressed air line from the treatment unit.
- > Install a T-piece with 4 mm branch in the compressed air line.
- > Connect a compressed air hose to the T-piece.

Route the compressed air hose to the spittoon valve, cut it off straight and insert it.



To pull off the compressed air hose from the spittoon valve, press the black sleeve on the compressed air connection inwards.

7.4 Electrical connections



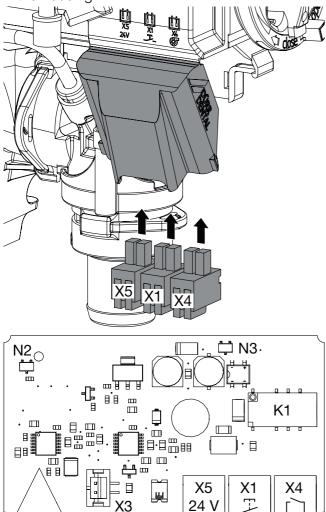
Prior to working on the unit or in case of danger, disconnect it from the mains.



The requirements of IEC 60601-1 must be satisfied during installation.

- > Open the cover of the control electronics.
- Route the power supply and control line to the spittoon valve.
- Attach the connector to the connection lines.
- > Plug in the connector at the corresponding positions on the control electronics.

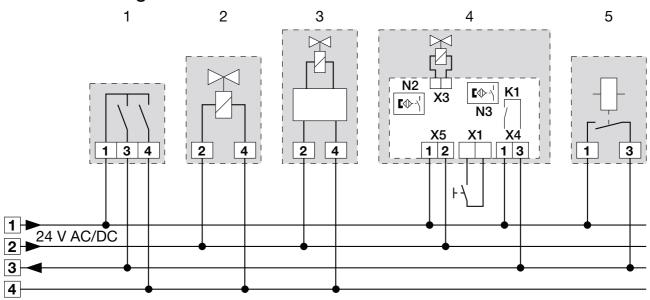
Secure the connection lines with cable ties to the housing.



- X1 Cleaning button for switch control panel
- X3 Solenoid valve
- X4 Control line for suction unit
- X5 Power supply
- K1 Suction unit relay
- N2 Float sensor detection
- N3 Cleaning button detection sensor



Circuit diagram EN 7.5



- 1 Hose manifold
- 2 Station selection valve
- З Rinsing unit
- 4 Spittoon valve
- X1 Cleaning button for switch control panel
- ΧЗ Solenoid valve
- Χ4 Control line for suction unit
- Χ5 Power supply
- K1 Suction unit relay
- N2 Float sensor detection
- NЗ Cleaning button detection sensor
- 5 Suction machine relay in the treatment unit

8 Commissioning

- > Turn on the unit power switch or the main surgery switch.
- > Carry out a function check of the system.
- > Check all connections for leak tightness.
- 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.

9 Disinfection and cleaning

NOTICE

Device malfunctions or damage due to use of incorrect media

Guarantee claims may become invalid as a result.

- Do not use any foaming agents such as household cleaning agents or instrument disinfectants.
- > Do not use abrasive cleaners.
- > Do not use agents containing chlorine.
- > Do not use any solvents like acetone.

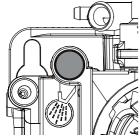
Dürr Dental recommends

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

Only these products have been tested by Dürr Dental.

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

9.1 Spittoon valve





- > Switch on the rinsing for the spittoon.
- Keep pressing the yellow cleaning button of the spittoon valve or the cleaning button on the switch control panel (if present) until rinsing of the spittoon is finished.
- Pour disinfection solution into the spittoon and at the same time press the yellow cleaning button of the spittoon valve or the cleaning button on the switch control panel (if present) until the disinfection solution has been aspirated.

9.2 Suction system

After every treatment

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



(i)

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

Daily after the end of treatment



After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:

- ✓ Non-foaming disinfectant/cleaning agent that is compatible with the materials.
- ✓ Unit care system, e.g. OroCup
- > To pre-clean, suck up 2 litres of water with the care system.
- Aspirate the disinfection/cleaning agent with the care system.

Once or twice a week before the midday break



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

The following are required for cleaning:

- ✓ Special non-foaming detergent for suction units that is compatible with the materials.
- ✓ Unit care system, e.g. OroCup
- > To pre-clean, suck up 2 litres of water with the care system.
- Aspirate the cleaning agent with the care system.
- Rinse with ca. 2 I water after the application time.

10 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.
--	--

Maintenance interval	Maintenance work
Monthly	> Press the yellow cleaning button to empty the collection vessel.> Clean the yellow coarse filter or replace it if required.
Annually	 Check compressed air supply. * Perform a functional test.
Every 3 years	 Clean the float monitor in the collection vessel. * Clean the seal on the float sensor for ventilation and replace if required. *

* Only to be performed by service technicians.

Troubleshooting

11 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
Spittoon valve not working	No power supply	Check power supply and restore. *
	Faulty connections	> Check the plug connections. *
	Relay not switching	Check the switching function of the relay. *
	No compressed air present	Check the compressed air supply of the spittoon valve. *
	Sensor defective	> Check the function of the sen- sor with the aid of the button.
		Check the function by man- ually moving the float sensor.
Suction unit does not start up or runs continuously	Float sensor does not move in its housing	Clean the housing and float sensor. *
		Insert the float sensor cor- rectly. *
Fluid does not drain off	Drain blocked	 Clean the drain line. * Check whether the filter is blocked, clean if necessary.

* Only to be done by service technicians.

12 Transporting the unit



WARNING

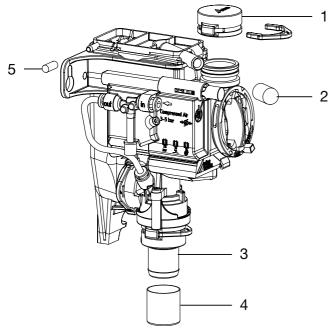
Infection due to contaminated unit

- > Disinfect the unit before transport.
- > Close all media connections.



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

- Before disassembly, clean and disinfect the suction unit and the unit using a suitable disinfectant approved by Dürr Dental.
- > Disinfect a defective unit using a suitable surface disinfection agent.
- > Seal all connections with sealing caps.
- > Pack the unit securely in preparation for transport.



- 1 DürrConnect dummy bushing (order no. 0700-700-10E)
- 2 Protective cap (order no. 9000-412-85)
- 3 DürrConnect hose connector socket Ø 20 mm (order no. 0700-700-20E)
- 4 Protective cap (order no. 9000-412-98)
- 5 Sealing cap (order no. 9000-310-002)



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



CAS 1 Combi-Separator



Installation and operating instructions





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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:

CAS 1 REF: 7117-100-51

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



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.



Wear protective gloves.



Disconnect all power from the unit.



Hose manifold connection



Spittoon connections



Suction unit connection



Drain connection



Unit in operation



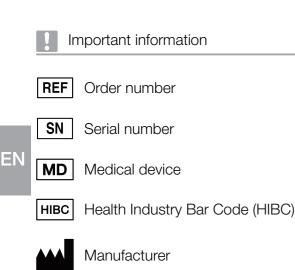
Unit operation interrupted





Do not reuse

CE labelling



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 CAS 1 Combi-Separator is designed for continuous separation of liquids and air and for separation of amalgam from the entire waste water from dental treatment units.

2.2 Intended use

The Combi-Separator is designed for installation in the suction line of a dry suction system after the hose manifold and spittoon.

Service, maintenance, recurring tests and cleaning must be performed in accordance with the manufacturer's information.

The permissible flow rate must be observed. A rinsing unit is required for surgical procedures and for procedures using prophy powders. The disposable amalgam containers must only be used once.

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.

This includes:

- Use for separation of dust, sludge, plaster or similar.
- Use in conjunction with flammable or explosive mixtures.
- Installation in a manner that does not comply with the installation instructions, in particular installation in rooms containing a potentially explosive atmosphere.
- Cleaning and disinfection with agents containing sodium hypochlorite or potassium hypochlorite.

2.4 Systems, connection with other devices

Additional devices connected with medical electrical devices must be proven to conform with their corresponding IEC or ISO standards. All configurations must continue to comply with the standard requirements for medical systems (see IEC 60601-1).

Whoever connects additional devices to medical electrical devices automatically becomes the system configurator and is responsible for ensuring that the system corresponds with the standard requirements for systems. Local laws take priority over the requirements outlined above.

2.5 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.

2.6 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.

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 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.

2.8 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.
- > Keep 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.

NOTICE

Ù

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.

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.

2.9 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 MEDICAL 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.

2.10 Transport

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

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



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

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

2.11 Disposal

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

> Decontaminate potentially contaminated parts before disposing of them.

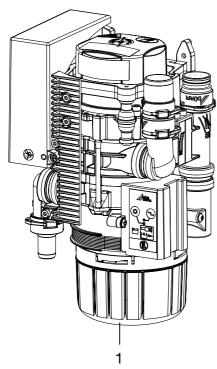
- Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
- If you have any questions about the correct disposal of parts, please contact your dental trade supplier.



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

Product description

3 Overview



1 CAS 1 Combi-Separator

3.1 Scope of delivery

The scope of delivery can vary slightly depending on the version.

The following items are included in the scope of delivery:

CAS 1 7117-100-51

- Combi-Separator
- Replacement disposable amalgam container
- Installation and operating instructions
- Operating Handbook

3.2 Accessories

The following items are required for operation of the device, depending on the application: Disposable amalgam container . . . 7117-033-00

3.3 Optional items

The following optional items can be used with the device:

Various installation sets are available on request. Display panel 7805-116-00E

Cable for display panel, 1 m 9000-119-043 Cable for display panel, 3 m 9000-119-042

Station selection valve	7560-500-60
Station selection valve for CAS 1 /	
CS 1	7560-500-80
Vario rinsing unit	7100-260-50
OroCup care system	0780-350-00
Test vessel	7117-064-00
Rinsing unit II	7100-250-50
Safety transformer 24 V, 100 VA	9000-150-46
Housing	7117-800-51

3.4 Consumables

The following materials are consumed during operation of the device and must be ordered separately: Disposable amalgam container . . . 7117-033-00 DürrConnect protective strainer, 5 pieces 0700-700-18E

DürrConnect protective strainer,	
5 pieces	0700-700-28E
Orotol plus (2.5 litre bottle)	CDS110P6150
MD 550 spittoon bowl cleaner	
(750 ml bottle)	CCS550C4500
MD 555 cleaner (2.5 litre bottle) .	CCS555C6150

3.5 Wear parts and replacement parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

Bellows	7117-420-25E
Service kit (3-year interval)	7117-980-32
Service kit (5-year interval)	7117-980-30



Information about replacement parts is available from the portal for authorised specialist dealers at: www.duerrdental.net.

4 Technical data

4.1 CAS 1 Combi-Separator

Electrical data – centrifuge motor

Electrical data – centrifuge motor		
Rated voltage	V	24 AC
Frequency	Hz	50 / 60
Rated power	VA	100
Current consumption in stand-by	mA	200
Signal input from hose manifold	V Hz	24 AC 50/60
Signal output	V mA	24 DC 300

Media		
Air flow volume	l/min	≤ 350
Flow rate		high
The suction system must be suitable for a h	igh flow rate in ac	ccordance with EN ISO 10637.
Max. pressure	hPa/mbar	-160
Min. volume of aspiration fluid max.	I/min I/min	≥ 0.1 ≤ 1.0
Water supply, spittoon	l/min	≤ 3
Total flow of waste liquids	l/min	<i>≤</i> 4
Usable volume in amalgam collecting con- tainer	ccm	approx. 90
Replacement interval		4 - 6 months
General data		
Drive motor nominal speed	rpm	2800
Operating mode		S5 95% duty cycle*
Type of protection		IP 20
Protection class		ll
Noise level ** approx.	dB(A)	55
Dimensions (H x W x D)	mm	255 x 157 x 110
Weight, approx.	kg	2.7
Separation rate	%	≥ 95

* DC = duty cycle

** Noise level in accordance with EN ISO 3746

Ambient conditions during storage and transport		
Temperature	С°	-10 to +60
Relative humidity	%	< 95

Temperature	O°	+10 to +40
Relative humidity	%	< 70
Classification		
Medical Device Class		I
Electromagnetic compatibility (El Interference emission measureme	•	
High-frequency emissions in accord	lance with CISPR 11	Group 1 Class B
nterference voltage at the power su CISPR 11:2009+A1:2010	upply connection	Compliant
Electromagnetic interference radiation	on	Compliant
Emission of harmonics EC 61000-3-2:2005+A1:2008+A2:	2009	Compliant
Voltage changes, voltage fluctuatior sions EC 61000-3-3:2013	ns and flicker emis-	Compliant
Electromagnetic compatibility (El Interference immunity measurem	•	
mmunity to electrostatic discharge EC 61000-4-2:2008		Compliant
mmunity to high-frequency electror EC 61000-4-3:2006+A1:2007+A2:	8	Compliant
mmunity to near fields of wireless H devices EC 61000-4-3:2006+A1:2007+A2:		Compliant
mmunity to fast electrical transients voltage EC 61000-4-4:2012	s/bursts – AC mains	Compliant
mmunity to electrical fast transients SIP/SOP ports EC 61000-4-4:2012	s/bursts – I/O,	Compliant
mmunity to interference, surges EC 61000-4-5:2005		Compliant
mmunity to conducted disturbance frequency fields – AC mains voltage EC 61000-4-6:2013	-	Compliant
mmunity to conducted disturbance frequency fields – SIP/SOP ports	es, induced by radio-	Compliant
EC 61000-4-6:2013		

Electromagnetic compatibility (EMC)
Interference immunity measurements

Immunity to voltage dips, short interruptions and voltage variations

Compliant

Vanationio	
IEC 61000-4-11:2004	

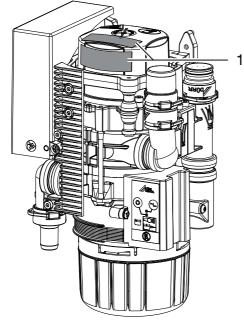
Immunity to interference levels, near fields of wireless HF	communication device	es
Radio service F	requency band MHz	Test level V/m
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 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
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	t
Immunity to surges, line-earth IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV, ± 2 kV	N/A	

Electromagnetic compatibility (EMC) Interference immunity measurements on the supply input	
Immunity to conducted disturbances, induced by radio- frequency fields – AC mains voltage IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz	Compliant
Immunity to voltage dips, short interruptions and voltage variations IEC 61000-4-11:2004	Compliant
N/A = not applicable	
Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP	
Immunity to electrostatic discharge IEC 61000-4-2:2008 ± 8 kV contact ± 2kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012 ± 1 kV 100 kHz repetition rate	Compliant
Immunity to impulse voltages, conductor to earth IEC 61000-4-5:2005 ± 2 kV	N/A
Immunity to conducted disturbances, induced by radio- frequency fields – SIP/SOP ports IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz	Compliant
N/A = not applicable	

4.2 Type plate

EN

The type plates are located on the cover of the motor.



1 Type plate

4.3 Evaluation of conformity

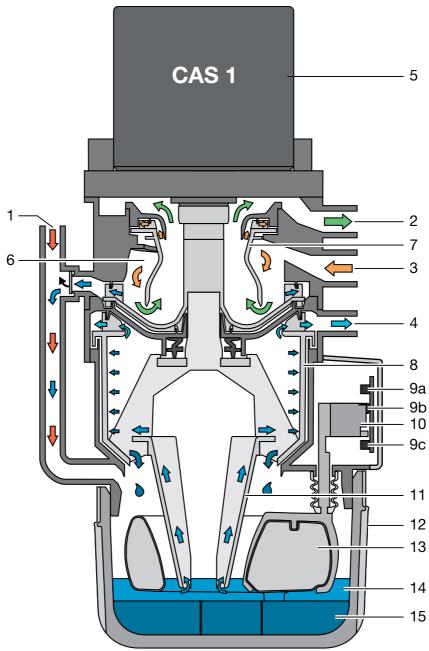
This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

4.4 Approvals

Centre of Competence Berlin	e in Civil Engineering,
Test number	Z-64.1-20
Separation method co	mpliant with standard

ISO 11143	Type 1
	51

5 Operation



- 1 Fluid intake
- 2 Vacuum, to suction unit
- 3 Aspiration input
- 4 Fluid output
- 5 Motor
- 6 Separation
- 7 Separation rotor
- 8 Centrifuge
- 9 Light barriers (3x)
- 10 Sensor enclosure
- 11 Cone pump
- 12 Amalgam collector vessel
- 13 Float sensor
- 14 Fluids
- 15 Amalgam particles

5.1 Operation

CAS 1 Combi-Separator

The task of the CAS 1 combi-separator is to provide continuous separation of secretions and air as well as the amalgam separation of all the waste water from the treatment unit.

The waste water flows through the connection (1) from the spittoon directly into the centrifuge (8) and amalgam separation.

During the suction phase the aspirated secretions are separated from the aspirated air in the separation unit (6). The secretions accumulating in the separation unit are continuously transported to the centrifuge (8), where the amalgam particles are then separated.

Underneath the centrifuge is a replaceable amalgam collector vessel (12), into which the separated amalgam particles (15) are rinsed once the centrifuge (8) is switched off. A float sensor (13) checks the level within the collector vessel and sends a signal to the display panel when it needs replacing. In combination with a light barrier (9c), this float sensor also monitors whether a collector vessel is in use.

The compact size of the CAS 1 Combi-Separator allows it to be installed in dental treatment units. This results in short secretion carrying lines. After the centrifuge is switched off, the braking cycle triggers a self-cleaning process. This self-cleaning process also leads to smooth and silent running, as well as providing a separation efficiency of more than 95%, even under heaviest loads.

5.2 Separation

At the inlet connection (3) of the CAS 1, the aspirated fluid/air mix is accelerated and set into a spiral motion in the separation unit (6). The resulting centrifugal forces sling the aspirated particles against the outer wall. The air is continuously separated from the fluid and escapes via the spinning separation rotor (7) to the suction unit. The aspirated air is subject to high centrifugal forces by the separation rotor (7), which is driven by the motor (1), which ensures that no fluid or blood foam can be carried into the suction unit. The spiral motion feeds the separated fluid continuously to the pump wheel, which transports the fluid into the collector vessel. The fluid is transported to the centrifuge (8) via a pump cone (11).

An external station selection valve connects the CAS 1 with the suction unit via the vacuum connection (2).

5.3 Spittoon connections

The waste water from the spittoon flows through a protective strainer on the fluid inlet (1) and into the collector vessel (12). Once sufficient fluid has been collected, the float sensor (13) activates a light barrier (9a) and (9b) via a sensor housing (10) and switches on the motor (1). The fluid is transported to the centrifuge (8) via a pump cone (11).

5.4 Station selection valve / safety valve

The station selection valve has 2 tasks: 1st task:

The station selection valve interrupts the suction flow between the hose manifold and the suction unit. As soon as a suction hose is removed from the hose manifold, a solenoid valve opens the station selection valve and suction flow is enabled.

2nd task:

The station selection valve also acts as a safety valve. If the CAS 1 is over-full or not functioning properly, the system will perform a safety shutdown. This safety shutdown prevents fluids from being drawn into the dry suction pipe.



For single station suction systems, the station selection valve takes over the function of the safety valve.

In various types, a station selection valve is already integrated in the CAS 1. The station selection valve is on the connection (2) of the CAS 1.

5.5 Amalgam separation

The switches in the hose manifold or the light barrier of the sensor system switch on the motor and the associated centrifuge (8).

The fluid containing amalgam particles flows continuously to the collector vessel (12). The fluids ejected by the centrifuge are pumped through the fluid output (4) to the central waste water system.

As soon as no further fluid is fed to the amalgam separator, e.g. when the suction hose is placed back in the hose manifold, the centrifuge drum is switched off after a short delay time. This switchoff brakes the motor, as a result of which the ring of water, which continues to rotate due to inertia, rinses the separated particles out of the centrifuge (8) downwards into the collector vessel. The separated amalgam particles form a sediment in the replaceable collector vessel. The level of fluid in the collector is regulated by the pump cone so that the risk of fluid escaping when the collector vessel is changed can be avoided.

5.6 Sediment level measurement

The fill level in the collector vessel (12) is checked by a float sensor (13) every time the main power switch is switched on.

The centrifuge motor starts, fluid is transported via the pump cone to the centrifuge drum (8) and provides a constant level of fluid (underside of the cone pump) in the collector vessel. The float sensor sinks. Two light barriers (9a) and (9b) measure the fluid level. Once the level reaches 95% in the collector vessel, this is displayed on the display panel.

5.7 Operating problems

If the unit is not ready for operation due to a fault, this will be indicated on the display panel via illuminated LEDs and an audible signal.

5.8 Service key

On the display panel there is a service key that can be used to switch off the audible signal in the event of a fill level warning or if a fault message is indicated. This button can also be used to start the device manually. To do this, press the button for longer than 2 seconds until the drive motor starts up. 6

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Assembly

Requirements

6.1 Installation/setup room

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

- Closed, dry, well-ventilated room
- Should not be a room made for another purpose (e. g. boiler room or wet cell)

6.2 Setup options

CAS 1 Combi-Separator

- Directly in the treatment unit.
- In a special housing in an extension of the treatment unit.

6.3 Hose materials

For waste connections and suction lines only use the following hose types:

- Flexible spiral hoses made of PVC with integrated spiral or equivalent hoses
- Hoses that are resistant to dental disinfectants and chemicals



Plastic hoses will display signs of ageing over time. Therefore, they should be inspected regularly and replaced as necessary.

The following types of hoses must not be used:

- Rubber hoses
- Hoses made completely of PVC
- Hoses that are not sufficiently flexible

6.4 Installation and routeing of hoses and pipes

Execute the on-site pipe installation in accordance with the applicable local regulations and standards. Lay the hose installation of the drains to or from the unit at a sufficient incline.



If incorrectly laid, the hoses can become blocked with sedimentation.

6.5 Information about electrical connections

- Ensure that electrical connections to the mains power supply are carried out in accordance with current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.
- Install an all-pole disconnect switch with a contact opening width of at least 3 mm in the electrical connection to the mains power supply.
- Observe the current consumption of the devices that are to be connected.
- > Install electrical lines without mechanical tension.
- Make the electrical connection via the main power switch of the treatment unit or via the main power switch of the practice.

6.6 Information about connecting cables

Mains supply cable

Installation type	Line layout (minimum requirements)
Fixed installation	 Plastic sheathed cable (e.g. type NYM-J)
Flexible	 PVC flexible line (e.g. H05 VV-F)
	or – Rubber connection (e.g. H05 RN-F or H05 RR-F)

Control cable

Installation type	Line layout (minimum requirements)
Fixed installation	 Shielded sheathed cable (e.g. (N)YM (St)-J)

 PVC data cable with shielded cable sheath- ing, as used for tele- communications and IT processing systems (e.g. type LiYCY)
or – Lightweight PVC control cable with shielded cable sheathing

Wire cross-section

Unit feed:

- 0.75 mm²
- Connection external valves / units:
- 0.5 mm²

7 Installation

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

7.1 Combining devices safely

Take care when connecting units together or to parts of other systems as there is always an element of risk (e.g. due to leakage currents).

- Only connect units when there can be no question of danger to operator or to patient.
- Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings.
- If it is not 100% clear from the unit data sheet that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the manufacturer) to verify that the setup is safe.

7.2 Installation of the CAS 1 in treatment units

The CAS 1 Combi Separator for KaVo treatment units must be set up in a defined installation setup in order to meet the relevant safety standards. For this reason it must only be installed in the treatment units that have been designed and approved for this purpose by KaVo.

KaVo-approved treatment units:

New units delivered from 01/2016 onwards: E50, E50 Life, E70/E80, E70/E80 Vision, 1058, 1058 Life

Spare parts requirements for old units such as 1078 and 1080 among others.

WARNING

Infection due to contaminated unit

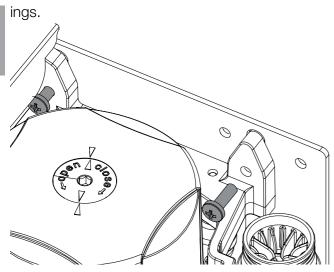
- Clean and disinfect the suction before working on the unit.
- Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Attach the unit vertically at a suitable position in the treatment unit. The unit is mounted on rubber pads and suspended in a metal frame. This mounting arrangement prevents the transmission of any vibrations to the treatment unit while the



device is running. Vibrations may occur if the unit is not positioned vertically. A minimum distance of 3 mm must be maintained to the surround-

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Station selection valve

In various types, the station selection valve is directly mounted on the CAS 1. The station selection valve (for separate installation) should be fitted in the suction pipe in the treatment unit, preferably near the end connection in the floor socket. In some installation setups the station selection valve also functions as a safety valve, so its actuation must be implemented via the CAS 1.

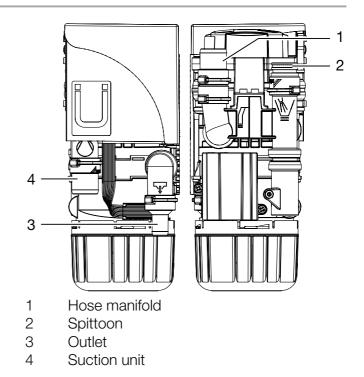
For further information, refer to the station selection valve installation and operating instructions

Inlet and outlet hoses

Connect and attach the inlet and outlet hoses with DürrConnect connectors to the relevant connections on the unit. Route the hoses at an incline.

Recommended diameter of the connection hoses: \varnothing 25 mm.

The minimum nominal width for the outlet hose is 15 mm.



Spittoon connections

In some dental units it is possible that noises can be heard at the spittoon, which are amplified by the funnel shape of the spittoon itself. In this case, the outlet between spittoon and CAS 1 should be bled. A corresponding siphon trap with ventilation is available as a special accessory.

Rinsing unit

It is recommended that the suction system is equipped with a rinsing unit, e.g. in the treatment unit. The rinsing unit provides a small amount of water during aspiration. This dilutes the aspirated fluids (blood, saliva, rinsing water etc.), which can then be transported more effectively.

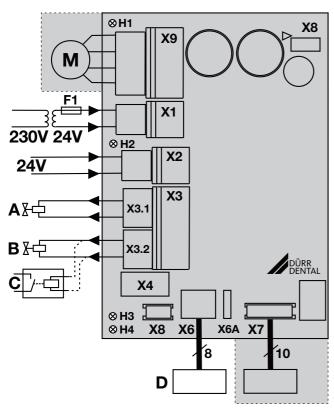
7.3 Electrical connections, controller

Power supply:

 Safety transformer order number: 9000-150-46

or

 Safety transformer 24 V AC with a with an isolator consisting of two means of patient protection (MOPP) between the mains circuit and secondary circuit, min. 100 VA, secondary fuse T 4 AH (or IEC 60127-2/V T 4 AH, 250 V)



- X1 Power supply in accordance with EN 60601-1, 24 V AC
- X2 Signal input 24 V AC/DC
- X3.1 Place selection valve / safety valve (only CAS 1, max. output 8 W)
- X3.2 Rinsing unit (CAS 1 only)
- X4 CAN bus
- X6 Display panel, external (X6A = connection for predecessor model)
- X7 Sensor technology
- X8 Production interface
- X9 Motor
- H1 Motor control display
- H2 Manifold control display
- H3 Place selection valve control display
- H4 Control display, collecting container missing
- A Place selection valve
- B Rinsing unit
- C Suction unit relay (alternative)
- D Display panel, external

7.4 Electrical connections

Station selection valve / safety valve

Connect the station selection valve / safety valve using a 2-core wire with connector to the X3 connection of the control.

Rinsing unit

- Connect the rinsing unit using a 2-core wire with connector to the X3 connection of the control.
 - At the connection for the rinsing unit, a suction unit relay, for example, can be connected if there is no isolation present between the suction unit signal and station selection valve in the treatment unit. Note the power consumption of the suction unit relay.

Display panel

The display panel is used to indicate messages acoustically and visually (via LEDs).

A display panel is already integrated in the unit and should be visible/audible at all times. If the display panel is not visible/audible, fit an additional display panel in an easily visible location. The display panel is connected to the X6 socket (RJ-45 socket). An existing Dürr Dental display panel with a 6-pin connector can be connected to the X6A connector when replacing an older device.

If the installation of the amalgam separator in a neighbouring room or in the basement results in distances of more than 3 m, we recommend installing a shielded network cable with RJ-45 sockets. EN

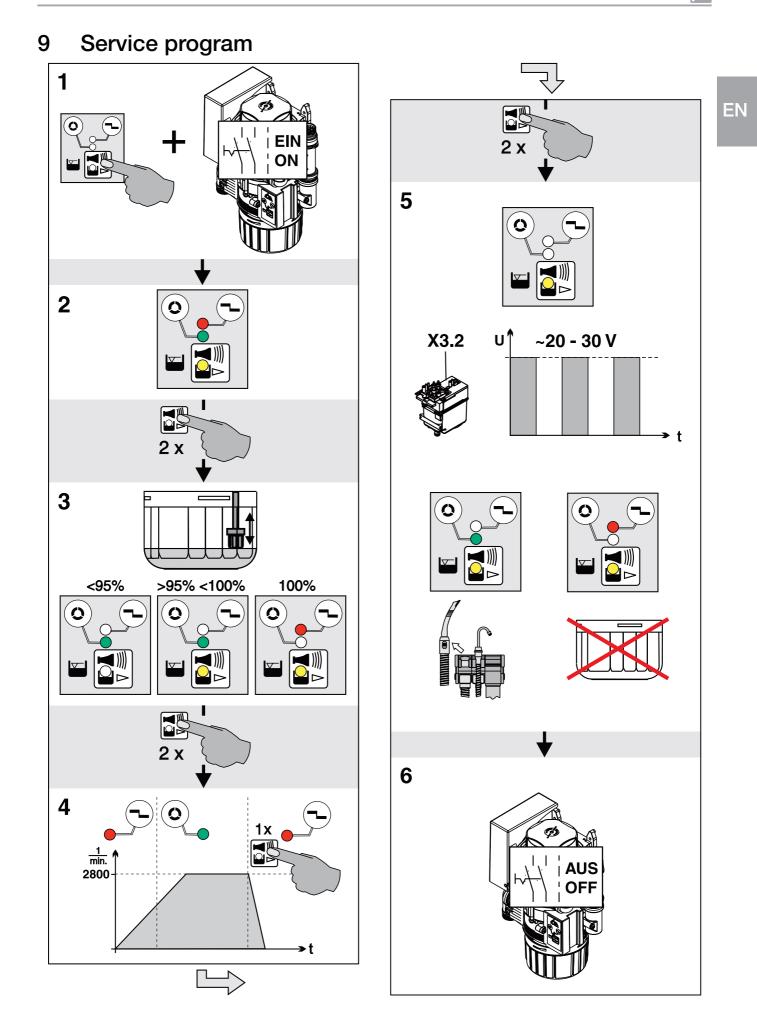
8 Commissioning

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

- > Turn on the unit power switch or the main surgery switch.
- Carry out an electrical safety check in accordance with applicable local regulations (e.g. the German Ordinance on the Installation, Operation and Use of Medical Devices / Medizinprodukte-Betreiberverordnung) and record the results as appropriate, e.g. in the technical log book.
- > Check the aspiration function.
- > Check the start function via the spittoon.
- > Check the connections, hoses and device for leaks.

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10 Description of the service program

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

The various unit functions can be checked with the aid of the service program.

The individual program steps are:

- Display test
- Sediment level measurement
- Motor start and motor braking with rpm check
- Input and output signals
- Function of the service key:
- By pressing the service key twice the next individual program step is called up.
- By pressing the service key once that program step is repeated.

A press of the service key is confirmed by an audible signal.

10.1 Service program ON/OFF On

- Press the service key and switch on the voltage supply to the unit.
- As soon as a signal melody can be heard, release the service key.

The green, yellow and orange LEDs on the display panel light up (display test) and the service program is activated.

Off

Switch off the main supply to the unit.

10.2 Display test

The display test is activated as soon as the service program is started.

The LEDs on the display panel are checked. All three LEDs must come on. There is also an audible signal, which can be switched off by pressing the service button.

10.3 Sediment level measurement



While the service program is activated, the safety check for the collector vessel is deactivated.

The sediment level measurement can be used to check the function of the sediment sensor and the function of the LEDs.

Every time the service key is pressed, the sediment level is checked. If a test collector vessel is used for this, the different levels can be scanned and made visible on the display panel. While changing the collectors (collector vessel -

test collector vessel) in the service program the unit remains in the ON state.

10.4 Motor start - motor braking

The drive motor starts and, after approx. 5 seconds, braking is applied. If the service key is pressed during these 5 seconds, the motor will immediately be braked.

This procedure can be repeated by pressing the service key 1x again.

The drive motor starts up.

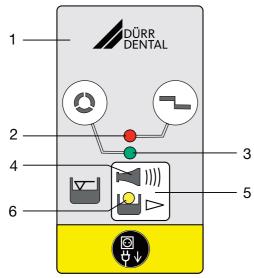
As a result of the rpm monitoring, the LED will change from orange to green upon start-up and from green to orange upon braking.

10.5 Input and output signals

- After this program item is activated, the yellow LED flashes and a cycled DC voltage (approx. 22-30 V) can be measured at the terminal for the rinsing unit.
- If the suction hose is lifted off the hose manifold the green LED will also come on.
- Removal of the collecting container causes the red LED to illuminate.

Usage

Display/handling 11



- 1 **Display** panel
- 2 **RED** display
- **GREEN LED** З
- 4 Audible signal/melody
- 5 Reset/service key
- YELLOW LED 6

11.1 Ready for operation

Green LED is on

11.2 Amalgam collector vessel is 95% full



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



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

11.3 Amalgam collector vessel is 100% full

- Yellow LED is on
- Red display flashes
- Audible signal melody sounds
- At a fill level of 100% the signal melody can no longer be switched off by pressing the reset button.
- The 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 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.

11.5 Motor fault

Red display and



green LED flash alternately

Audible signal

- 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.
- Green LED lights up "Ready for operation"

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If, after pressing the reset button repeatedly, the fault report reappears again each time, this indicates a technical defect - inform your Service Technician.

12 Disinfection and cleaning



Device malfunctions or damage due to use of incorrect media

Guarantee claims may become invalid as a result.

- > Do not use any foaming agents such as household cleaning agents or instrument disinfectants.
- > Do not use abrasive cleaners.
- > Do not use agents containing chlorine.
- > Do not use any solvents like acetone.

Dürr Dental recommends

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

Only these products have been tested by Dürr Dental.

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

12.1 After every treatment

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



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

12.2 Daily after the end of treatment



After higher workloads before the midday break and in the evening

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The following are required for disinfection/cleaning:

- ✓ Non-foaming disinfectant/cleaning agent that is compatible with the materials.
- ✓ Unit care system, e.g. OroCup
- > To pre-clean, suck up 2 litres of water with the care system.
- Aspirate the disinfection/cleaning agent with the care system.

12.3 Once or twice a week before the midday break



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

The following are required for cleaning:

- ✓ Special non-foaming detergent for suction units that is compatible with the materials.
- ✓ Unit care system, e.g. OroCup
- To pre-clean, suck up 2 litres of water with the care system.
- Aspirate the cleaning agent with the care system.
- Rinse with ca. 2 I water after the application time.

13 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).

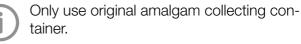


Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).



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.

- > Disconnect all power from the unit.
- Remove the full amalgam collecting container and from the device.
- Pour disinfectant for suction units (e. g. Orotol plus, 30 ml) into the full amalgam collecting container.
- Close and secure the full amalgam collecting container using the cap. Observe the markings on the cap and on the collecting container.
- Place the securely closed amalgam collecting container into its original packaging and seal.
- Insert a new amalgam collecting container in the unit and clamp it in position.



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

13.1 Disposal of the collector vessel



Used amalgam collector vessels must not be sent in the post!

Dürr Dental is not a waste management company and is not allowed by law to accept any filled amalgam collector vessels.

- Arrange to have filled amalgam collector vessels collected from the surgery by a local waste management company.
- New amalgam collector vessels should be ordered from your specialist dental equipment retailer.
- Document the replacement and legally compliant disposal of the filled waste amalgam collector vessel in the Operating Handbook.



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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.

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14 Maintenance

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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.

Maintenance interval	Maintenance work		
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 Clean or replace protective sieves during replacement of the amalgam collecting container. At the latest, do this when the suction or draining power of the device decreases. 		
Annually	 > Cleaning of the suction unit in accordance with the operating instructions. > Clean the float. * > Replace the bellows. * 		
Every 3 years	 Replace the rubber grommets on the connections. * Replace the float. * 		
Every 5 years	 > Replace the centrifuge drum and seal. * > Replace all O-rings (from the replacement parts kit) in the device. * > Replace the rubber grommets on the connections. * > Replace the float. * 		
* to be done by service technicians only			

14.1 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).

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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.

For inspection, the following are required:

✓ Test vessel

Work steps to be performed:

- General functional check (e.g. aspiration, spittoon inlet)
- > Service program

The following measurement times apply to fill level measurements with a test vessel:

- For a fill level of 95%, the measurement result is displayed after approx. 30 sec, whereby the drive motor is briefly switched off during the measurement.
- At a fill level of 100% the measurement result is displayed after approx. 90 sec continuous running.

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:

- > Fill the test vessel with water and insert it into the unit.
- > Start the device and wait until it switches off again.

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 140 ml in the test vessel.

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

P Troubleshooting

15 Tips for operators and service technicians

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

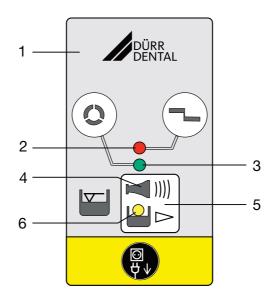
WARNING

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.



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

Error	Possible cause	Remedy
Device not "ready for opera- tion" No display on the display	The main power switch of the treatment unit or surgery is not switched on	Main power switch ON
panel.	If an external display panel is fit- ted: cable not correctly connec- ted	Check cable connections

Error	Dessible squas	Pamadu
Error	Possible cause	Remedy
Yellow display is on GREEN LED illuminates	Amalgam collecting container is 95% full	Change the amalgam collect- ing container.
Audible signal melody sounds	Float sensor dirty or blocked	If this display occurs repeat- edly even when the collecting container is empty, check that the float sensor can move freely.
Yellow display is on Red display flashes Audible signal melody sounds	Amalgam collecting container is 100% full	Change the amalgam collect- ing container. Audible signal can no longer be switched off.
	Float sensor dirty or blocked	If this display occurs repeat- edly even when the collecting container is empty, check that the float sensor can move freely.
	Waster water line/siphon trap dirty	Clean the waste water line/ siphon trap. *
The RED and GREEN displays flash alternately Audible signal	Motor is dirty or defective	 Check motor for smooth running; replace the centrifuge if necessary. * Replace the device. *
	Contact problems at X9	 > Plug in the connector correctly. * > Replace the PCB main board and connector on the motor. *
Orange LED flashes Audible signal		Press the service key briefly to switch off the audible signal
	Amalgam collecting container not correctly in position	 Switch OFF the device. Insert the amalgam collecting container in the correct position. Switch ON the device.
	Float sensor missing	Insert the float sensor. *
Water accumulating in the spittoon	Coarse sieve in the fluid inlet blocked	Clean the coarse sieve.
	Outlet ineffective or not vented	Check or retrofit the ventila- tion. *
Suction power too weak or interrupted	Coarse sieve is blocked on the inlet of the aspiration	> Clean the coarse sieve.
	Place selection valve not or incompletely open	 Check the control voltage. * Clean the place selection valve. *

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Error	Possible cause	Remedy
Device running continuously	Float sensor blocked in water start position	 Clean the float. * Free up the float sensor link- age so that it can move freely.
	Start signal at the signal input (X2)	Check the control voltage. *
	Waster water line/siphon trap dirty	Clean the waste water line/ siphon trap. *
Noise at the spittoon	Outlet ineffective or not vented	Check or retrofit the ventila- tion. *
Increased vibration of the device	Pump cone dirty	Clean or replace the pump cone. *
	Centrifuge dirty	Clean or replace the centri- fuge. *
	Water supply too low	 > Introduce water into the suction pipe. > Retrofit the rinsing unit. * > Check the rinsing unit for its correct installation position. * > Check the function of the rinsing unit. *
Water cannot be pumped away or only insufficiently	Centrifuge dirty	Clean or replace the centri- fuge
	Waster water line/siphon trap dirty	 Clean the waste water line/ siphon trap

* Only to be done by service technicians.

16 Transporting the unit

WARNING

Infection due to contaminated unit

- > Disinfect the unit before transport.
- > Close all media connections.

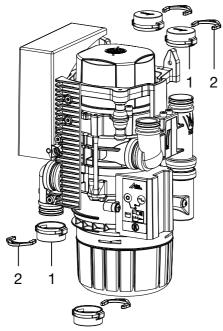


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Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

- Before disassembly, clean and disinfect the suction unit and the unit using a suitable disinfectant approved by Dürr Dental.
- > Disinfect a defective unit using a suitable surface disinfection agent.
- > Seal all connections with sealing caps.
- > Pack the unit securely in preparation for transport.

16.1 Close CAS 1



- 1 Dummy bushing
- 2 Ring clamp

Appendix

17 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:

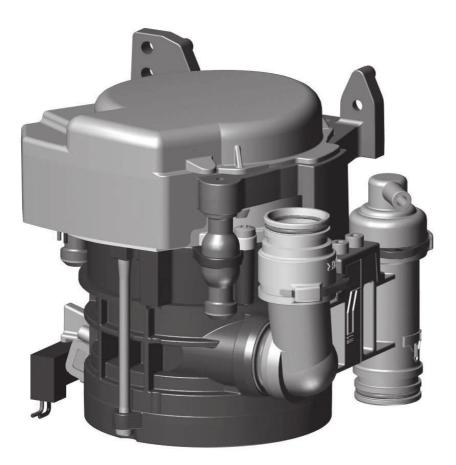


Hersteller/Manufacturer:

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



CS 1 Combi-Sepamatic 24 V AC



Installation and operating instructions





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Important information

About this document 1 EN

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:

CS 1

7117-100-70; 7117-100-70E; 7117-100-74; 7117-100-74E; 7117-100-76; 7117-100-77; 7117-100-78; 7117-100-79; 7117-100-80; 7117-100-80E

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



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.



Wear protective gloves.



Disconnect all power from the unit.



Hose manifold connection



Suction unit connection



Drain connection



Order number



- MD Medical device
- HIBC Health Industry Bar Code (HIBC)



CE labelling



Protection class II



Manufacturer

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 separation system is designed for the continuous separation of air and liquids in the suction flow of dental treatment units.

2.2 Intended use

The separation system is intended for installation in the suction line of a dry suction system after the manifold.

Service, maintenance, recurring tests and cleaning must be performed in accordance with the manufacturer's information.

The permissible flow rate must be observed. A rinsing unit is required for surgical procedures and for procedures using prophy powders.

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.

This includes:

- Use for separation of dust, sludge, plaster or similar.
- Use in conjunction with flammable or explosive mixtures.
- Installation in a manner that does not comply with the installation instructions, in particular installation in rooms containing a potentially explosive atmosphere.
 - Cleaning and disinfection with agents containing sodium hypochlorite or potassium hypochlorite.

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 Combining devices safely

Take care when connecting units together or to parts of other systems as there is always an element of risk (e.g. due to leakage currents).

- Only connect units when there can be no question of danger to operator or to patient.
- Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings.
- If it is not 100% clear from the unit data sheet that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the manufacturer) to verify that the setup is safe.

Where applicable, the requirements for medical products have been taken into account in the development and construction of the device. As a result, this device is suitable for installation within medical supply equipment.

Where this device is integrated in other medical supply equipment, the requirements of European Union Medical Device Regulation 2017/745 and the relevant standards must be observed.

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.

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 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.

2.8 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.
- > Keep 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.

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.

2.9 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 MEDICAL 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.

2.10 Transport

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

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

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

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

2.11 Disposal

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

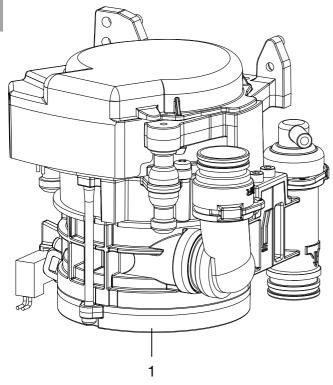
- Decontaminate potentially contaminated parts before disposing of them.
- Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
- If you have any questions about the correct disposal of parts, please contact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

An overview of the waste keys for Dürr Dental products can be found in the download area at: *www.duerrdental.com* Document no.: P007100155

Product description

3 Overview

EN



1 CS 1 Combi-Sepamatic

3.1 Scope of delivery

The scope of delivery can vary slightly depending on the version.

The following items are included in the scope of delivery:

CS 1 7117-100-7x

or

- CS 1 7117-100-8x
- Combi-Sepamatic
- or Combi-Sepamatic inc. station selection valve
- Rinsing unit
- Installation and Operating Instructions

3.2 Optional items

The following optional items can be used with the device:

Various installation sets are available on request Safety transformer 24 V, 100 VA . . 9000-150-46 Station selection valve for CAS 1 /

CS 1	7560-500-80
Station selection valve	7560-500-60
Vario rinsing unit	7100-260-51
Rinsing unit II	7100-250-50
OroCup care system	0780-350-00

3.3 Consumables

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

DürrConnect protective strainer,

5 pieces	0700-700-18E
Orotol plus (2.5 litre bottle)	CDS110P6150
MD 550 spittoon bowl cleaner	
(750 ml bottle)	CCS550C4500
MD 555 cleaner (2.5 litre bottle) .	CCS555C6150

3.4 Wear parts and replacement parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

- Protective strainer
- Rubber grommets
- O-rings



Information about replacement parts is available from the portal for authorised specialist dealers at: *www.duerrdental.net*

4 Technical data

Electrical data – centrifuge motor		7117-100-7x 7117-100-8x	
Rated voltage	V	24 AC	
Frequency	Hz	50 / 60	
Rated power	VA	70	
Nominal current in standby	mA	80	
Signal input from the hose manifold	V Hz	24 AC 50/60	
Signal output	V	24 DC	
	mA	300	
Media			
Fluid volume			
min.	l/min	≥ 0.1 ≤ 2.0	
Max.	l/min		
Air flow volume	l/min	≤ 350	
Flow rate	interference in a second	high	
The suction system must be suitable for a h	•		
Max. pressure	hPa/mbar	-160	
General data			
Operating mode	%	100 (S1)	
Type of protection		IP 20	
Protection class		II	
Noise level, approx.*	dB(A)	45	
Dimensions (H x W x D)	cm	15 x 16 x 12	
Weight, approx.	kg	1.4	
* in accordance with EN ISO 3746			
Ambient conditions during storage and t	transport		
Temperature	°C	-10 to +60	
Relative humidity	%	< 95	
Ambient conditions during operation			
Temperature	°C	+10 to +40	
Temperature Relative humidity	°C %	+10 to +40 < 70	
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	Electromagnetic compatibility (EMC) Interference emission measurements	
l	High-frequency emissions in accordance with CISPR 11	Group 1 Class B
	Interference voltage at the power supply connection CISPR 11:2009+A1:2010	Compliant
	Electromagnetic interference radiation CISPR 11:2009+A1:2010	Compliant
	Emission of harmonics IEC 61000-3-2:2005+A1:2008+A2:2009	N/A
	Voltage changes, voltage fluctuations and flicker emis- sions IEC 61000-3-3:2013	N/A
	N/A = not applicable	
	Electromagnetic compatibility (EMC) Interference immunity measurements	
	Immunity to electrostatic discharge IEC 61000-4-2:2008	Compliant
	Immunity to high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010	Compliant
	Immunity to near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010	Compliant
	Immunity to fast electrical transients/bursts – AC mains voltage IEC 61000-4-4:2012	Compliant
	Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012	Compliant
	Immunity to interference, surges IEC 61000-4-5:2005	Compliant
	Immunity to conducted disturbances, induced by radio- frequency fields – AC mains voltage IEC 61000-4-6:2013	Compliant
	Immunity to conducted disturbances, induced by radio- frequency fields – SIP/SOP ports IEC 61000-4-6:2013	Compliant
	Immunity to power frequency magnetic fields IEC 61000-4-8:2009	Compliant
	Immunity to voltage dips, short interruptions and voltage variations IEC 61000-4-11:2004	Compliant

Ν

Radio service	Frequency band Test leve	
Immunity to interference table, near fields of wireless H	IF communication devices	
ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz		
frequency fields – SIP/SOP ports IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V	Compliant	
Immunity to conducted disturbances, induced by radio-		
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012 ± 1 kV 100 kHz repetition rate	Compliant	
Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP		
Immunity to voltage dips, short interruptions and voltage variations IEC 61000-4-11:2004	Compliant	
ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz		
Immunity to conducted disturbances, induced by radio- frequency fields – AC mains voltage IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V	Compliant	
Immunity to surges, line-to-line IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV	Compliant	
Immunity to fast electrical transients/bursts – AC mains voltage IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition rate	Compliant	
Interference immunity measurements on the supply inp		

minutivity to interference table, near near of whereas the 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

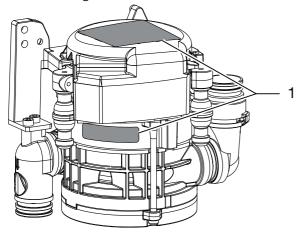
ΕN

Immunity to interference table, near fields of wireless HF communication devices		
Radio service	Frequency band MHz	Test level V/m
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	1700 - 1990	28
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	2400 - 2570	28
WLAN 802.11 a/n	5100 - 5800	9

EN

4.1 Type plate

The type plates are on the motor cover and on the motor flange.

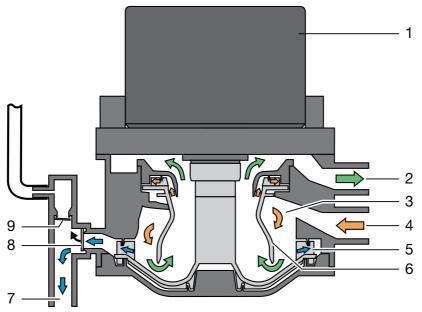


1 Type plate

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 Motor
- 2 Vacuum, to suction unit
- 3 Separation
- 4 Aspiration input
- 5 Pump wheel
- 6 Separation rotor
- 7 Fluid output
- 8 Waste valve
- 9 Relief valve

5.1 Separation

Every time the suction hose is taken out of the hose manifold, the CS 1 Combi-Sepamatic and the suction unit are started.

The mixture of liquid and air drawn up is accelerated in the intake connection and then set in spiral motion in the separation. The resulting centrifugal forces sling the aspirated particles against the outer wall. The air is continuously separated from the fluid and escapes to the suction unit via the spinning separation rotor.

The aspirated air is subject to high centrifugal forces by the separation rotor, which ensures that no fluid or blood foam can be carried into the suction unit.

The spiral motion serves to continuously transport the separated liquid to the pump wheel, this then pumps the liquid into the central waste water drainage system via the waste water valve.

The air bleed is carried out via the relief valve. If fluid escapes upwards into the air bleed area following a fault, the relief valve closes automatically.

5.2 Station selection valve

The station selection valve interrupts the suction flow between the hose manifold and the suction unit. As soon as a suction hose has been removed from the hose manifold, the station selection valve is opened and suction flow is enabled.

A station selection value is already integrated in various versions of the CS 1. An external station selection value can be electrically controlled via the CS 1.

Assembly

6 Requirements

6.1 Setup options

CS 1 Combi-Sepamatic

- Directly in the treatment unit.
- In a special housing in an extension of the treatment unit.

6.2 Hose materials

For waste connections and suction lines only use the following hose types:

- Flexible spiral hoses made of PVC with integrated spiral or equivalent hoses
- Hoses that are resistant to dental disinfectants and chemicals



Plastic hoses will display signs of ageing over time. Therefore, they should be inspected regularly and replaced as necessary.

The following types of hoses must not be used:

- Rubber hoses
- Hoses made completely of PVC
- Hoses that are not sufficiently flexible

6.3 Installation and routeing of hoses and pipes

- Execute the on-site pipe installation in accordance with the applicable local regulations and standards.
- > Lay the hose installation of the drains to or from the unit at a sufficient incline.



If incorrectly laid, the hoses can become blocked with sedimentation.

6.4 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.

- Install an all-pole disconnect switch with a contact opening width of at least 3 mm in the electrical connection to the mains power supply. It must be possible to secure the disconnect switch so that it cannot be inadvertently switched back on again.
- Install electrical lines without mechanical tension.
- Make the electrical connection via the main power switch of the treatment unit or via the main power switch of the practice.

6.5 Information about connecting cables

Mains supply cable

Installation type	Line layout (minimum requirements)
Fixed installation	 Plastic sheathed cable (e.g. type NYM-J)
Flexible	 PVC flexible line (e.g. H05 VV-F)
	or
	 Rubber connection (e.g. H05 RN-F or H05 RR-F)

Control cable

Installation type Line layout (minimum requirements)	
Fixed installation	 Shielded sheathed cable (e.g. (N)YM (St)-J)
Flexible	 PVC data cable with shielded cable sheath- ing, as used for tele- communications and IT processing systems (e.g. type LiYCY)
	or – Lightweight PVC control cable with shielded cable sheathing

Wire cross-section

Unit feed: – 0.75 mm² Connection external valves / units:

– 0.5 mm²

WARNING

Infection due to contaminated unit

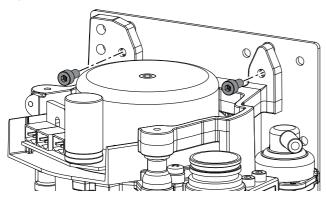
- Clean and disinfect the suction before working on the unit.
- > Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).



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

Installation of the CS 1 in 7.1 treatment units

Attach the unit vertically at a suitable position in the treatment unit. The unit is mounted on rubber pads and suspended in a metal frame. This mounting arrangement prevents the transmission of any vibrations to the treatment unit while the device is running. Vibrations may occur if the unit is not positioned vertically. A minimum distance of 3 mm must be maintained to the surroundings.



Station selection valve

In various types, the place selection valve is directly mounted on the CS 1. The station selection valve (for separate installation) should be fitted in the suction pipe in the treatment unit, preferably near the end connection in the floor socket. The electrical connection should then also be carried out on the CS 1.

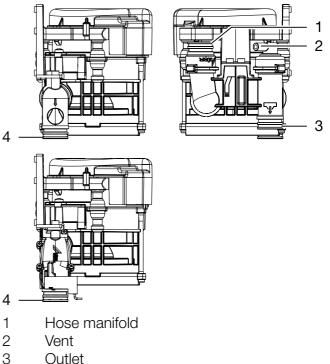
For further information, refer to the station selection valve installation and operating instructions

Inlet and outlet hoses

Connect and attach the inlet and outlet hoses with DürrConnect connectors to the relevant connections on the unit. Route the hoses at an incline.

Recommended diameter of the connection hoses: Ø 25 mm.

The minimum nominal width for the outlet hose is 15 mm.



4 Suction unit

Rinsing unit

It is recommended that the suction system is equipped with a rinsing unit, e.g. in the treatment unit. The rinsing unit provides a small amount of water during aspiration. This dilutes the aspirated fluids (blood, saliva, rinsing water etc.), which can then be transported more effectively.

Installation sets

Installation sets and detailed documentation for various installation situations are available from the manufacturers.



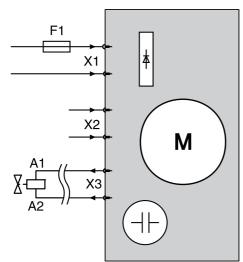
When installed in a housing, ventilation slits should be provided to avoid heat build-up in the housing.

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7.2 Power supply

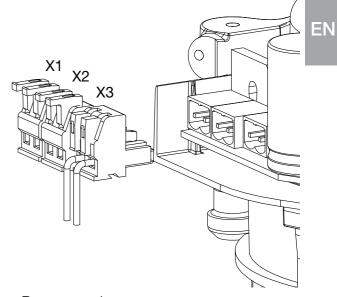
- Safety transformer order number: 9000-150-46
- Safety transformer 24 V AC with an isolator consisting of two means of patient protection (MOPP) between the mains circuit and secondary circuit, min. 100 VA, secondary fuse T 4 AH (or IEC 60127-2/V T 4 AH, 250 V)

7.3 Electrical connections, controller



- X1 Power supply in accordance with EN 60601-1
- X2 Signal input / start signal
- X3 Place selection valve and/or rinsing unit 24 V DC (max. output: 8 W)
- F1 T 4 AH, 250 V in accordance with IEC 60127-2

7.4 Electrical connections



- X1 Power supply
- X2 Hose manifold start signal
- X3 Outgoing signal station selection valve and/or rinsing unit
- > Remove the motor cover of the CS 1.
- > Attach the connector to the connection lines.

To open, lift the terminal lever upwards.

- > Plug the connector onto the control.
- > Put the motor cover on.

8 Commissioning

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

- > Turn on the unit power switch or the main surgery switch.
- Carry out an electrical safety check in accordance with applicable local regulations (e.g. the German Ordinance on the Installation, Operation and Use of Medical Devices / Medizinprodukte-Betreiberverordnung) and record the results as appropriate, e.g. in the technical log book.
- > Check the aspiration function.
- > Check the connections, hoses and device for leaks.

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ΕN

👤 Usage

9 Disinfection and cleaning

NOTICE

Device malfunctions or damage due to use of incorrect media

Guarantee claims may become invalid as a result.

- Do not use any foaming agents such as household cleaning agents or instrument disinfectants.
- > Do not use abrasive cleaners.
- > Do not use agents containing chlorine.
- > Do not use any solvents like acetone.

Dürr Dental recommends

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

Only these products have been tested by Dürr Dental.

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

9.1 After every treatment

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





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

9.2 Daily after the end of treatment



After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:

- ✓ Non-foaming disinfectant/cleaning agent that is compatible with the materials.
- ✓ Unit care system, e.g. OroCup
- > To pre-clean, suck up 2 litres of water with the care system.
- Aspirate the disinfection/cleaning agent with the care system.

9.3 Once or twice a week before the midday break

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

The following are required for cleaning:

- ✓ Special non-foaming detergent for suction units that is compatible with the materials.
- ✓ Unit care system, e.g. OroCup
- > To pre-clean, suck up 2 litres of water with the care system.
- Aspirate the cleaning agent with the care system.
- Rinse with ca. 2 I water after the application time.

10 Maintenance

-			-	
	-		1	
		1	h	J

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).



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

Maintenance interval	Maintenance work
Dependent upon the level of usage of the device	<text></text>
Annually	 > Cleaning of the suction unit in accordance with the operating instructions. > Clean or replace the protective sieves at the aspiration inlet. > If a rinsing unit is present: clean the sieve in the water supply. * > Perform a functional test. *
Every 3 years	Replace the rubber grommets on the connections. *
Every 5 years	 Replace the rubber grommets on the connections. * Replace all o-rings in the device. *

* Only by customer services service technicians.

Troubleshooting

11 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
Device does not start	No power supply	 Check power supply. * Check the fuses and replace if necessary. *
	No start signal	Check the control voltage at the signal input. *
Suction power too weak or interrupted	Coarse sieve is blocked on the inlet of the aspiration	> Clean the coarse sieve.
	Place selection valve not or incompletely open	 Check the control voltage. * Clean the place selection valve. *

* Only to be done by service technicians.

EN

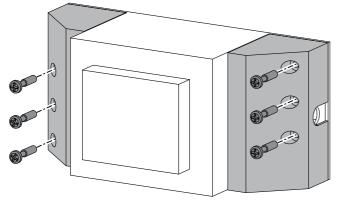
Replacing the fuse



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

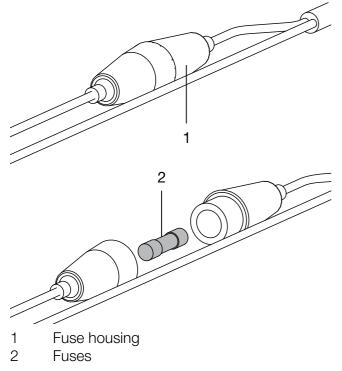
Transformer

- > Unscrew and remove the safety cover.
- > Replace the fuse.



Fuse housing

- > Turn the fuse housing to open it.
- > Replace the fuse.



12 Transporting the unit

WARNING

Infection due to contaminated unit

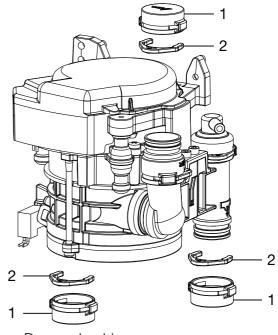
- > Disinfect the unit before transport.
- > Close all media connections.



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

- > Before disassembly, clean and disinfect the suction unit and the unit using a suitable disinfectant approved by Dürr Dental.
- > Disinfect a defective unit using a suitable surface disinfection agent.
- > Seal all connections with sealing caps.
- > Pack the unit securely in preparation for transport.

12.1 Close the CS 1



1 Dummy bushing

2 Ring clamp

Appendix

13 Handover record

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

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

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

Name of person receiving instruction:

Signature:

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

Date of handover:

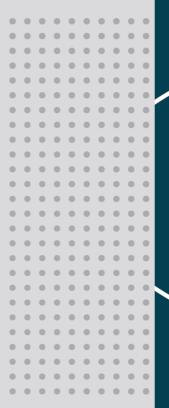
Signature of the qualified adviser for the medical device:





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







EVA



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Dear Customer, FARO wishes you success with the new high quality EVA Dental Lamp.

To work safely and to take full advantage of the product's performance, please read this manual carefully before using the device. In particular, please follow all warnings and notes described in the Safety Recommendations included in the package.

Warranty Conditions:

FARO offers the end customer a 24-month warranty from the date of installation up to a maximum of 30 months from the date of manufacture. Warranty repairs must be carried out by FARO or its approved service network.

The guarantee is considered valid only when:

- the user has sent the duly completed Certificate of Warranty to the following e-mail address: service@faro.it

- the user registered the guarantee via the Faro website or the Faro Tech APP;

The guarantee covers manufacturing and engineering defects; in the event of a valid claim, the guarantee only covers the free replacement of parts. Manual work is not included in the guarantee.

The guarantee shall not be considered valid, at FARO's sole discretion, if the defect is due to tampering, damage, unauthorised modifications to the product, improper use, incorrect maintenance and normal wear and tear.

This product has a service life of: 10 years.

Any serious accident occurring in connection with the device must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

1 SYMBOLS USED

1.1 SYMBOLS USED IN THIS MANUAL

1	WARNING
Sections ma or patient.	arked with this symbol contain instructions that must be followed carefully to avoid damaging the device, causing harm to the operator
	ATTENTION
This icon w	varns that care must be taken to avoid situations that could damage the device.
	PROHIBITION
This icon h	ighlights what not to do to avoid damaging the device and causing harm to user and patient.
i	NOTES
This icon p	rovides information that allows you to use the device more efficiently.

1.2 SYMBOLS USED IN LABELLING AND ON PACKAGING

The main nameplate is affixed:

- for the lamp or complete arms: on the rear arm

- for the lamp head: under the heat sink cover

Serial Number Description

- For dental lamp YYLDNNNN (YY: last two digits of year of manufacture, NNNNN: progressive year counter)

- For the dental lamp head YYTENNNN (YY: last two digits of the year of manufacture, NNNN: progressive year counter)

for example: 21LD000001 represents the serial number of the first device manufactured in 2021.

The following harmonised symbols are also present:

Symbol	Description	Symbol	Description	Symbol	Description
CE	European Conformity Mark	135°C \$\$\$	Can be steam sterilised at 134°C	Ţ	Fragile
MD	Medical Device according to Reg (EU) 2017/745 of 5 April 2017 .	40°C	Use the device at a temperature between 10°C and 40°C	Ť	Protect packaging from rain and high humidity
	Read the instructions for use. Supplied electronically.	1060 mbar 800 mbar	Use the device at a pressure between 80 kPa and 106 kPa	×	Do not roll
	Manufacturer symbol according to Regulation (EU) 2017/745	75% F	Use the device at a relative humidity between 30 RH and 75RH	¥	Do not use hooks
Â	Instructions for use include safety warnings		Symbol for switching the light on/off	500 Kg max	Maximum stackable weight
X	WEEE equipment according to Directive 2012/19/EC.	ጉ	Light on/off symbol on the rear arm (Theia Tech)	-24°C	Storage and transport temperatures
	Double insulation. Class 2 device against electrical hazards		Symbol for adjusting light intensity	JEL RI	Relative humidity during storage and transport
SN	Serial number	<u>††</u>	High		Storage and transport atmospheric pressure
CH REP	Swiss Mandate for the MedDo Medical Devices Regulation			0	Recyclable cardboard

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2 INTENDED USE

The device is used in the dental office and is intended to illuminate the oral cavity and oral structures of dental patients. In normal use, the device is positioned at a distance of 700 mm from the operating area, the distance for which the lighting features were designed. Patients can be of all ages with typical dental pathologies.

2.1 INTENDED USER

The intended users are dentists, dental practitioners (all specialisations) or dental assistants

2.1.1 Professional qualification:

Medical degree with specialisation in dentistry Degree in Dentistry Degree in dental hygiene

2.1.2 Minimum skills

Those envisaged for the professional qualification Language comprehension: Those acquired for the professional qualification

2.1.3 Experience

Those outlined for carrying out the profession

2.1.4 Possible user disabilities

At least one upper limb is required for use; Visual faculty compatible with the profession; The user with these characteristics requires no special training

3 PRODUCT DESCRIPTION

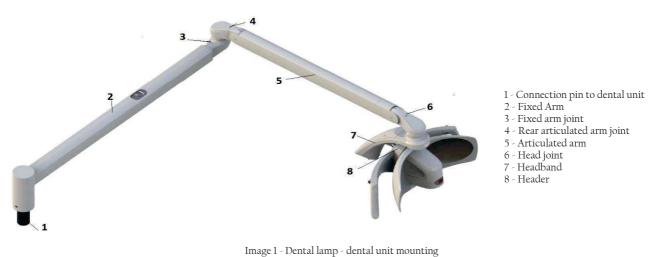


Image 2 - Dental lamp - Ceiling mounting

The device is available in two main product variants:

- EVA with 5000 K light source with 'Sunlight' spectrum

- EVA with variable white colour temperature light source (4000 K, 5000 K, 5700 K, Composave setting (2700 K)) selectable by the operator (Tunable White).

- These main variants can be supplied with:
- different Assembly:
- Different arm length combinations
- Canbus technology
- Remote cable to bring the control to the dental unit
- Automatic switch-on setting;
- Theia technology (secondary light source under the fixed arm);
- Integrated 4K camera;
- stud diameter

All variants can be ordered with dedicated product codes as shown in the table below:

	sembly 2 DIGIT	,		Fixed Arm 4TH DIGIT		Light source / Integrated camera		Command / Rediofrequency			Tring		om ⁽¹⁾
1-1	DIGIT	GIT 3°DIGIT 4TH D		fi DIGI I	5THDIGIT		(RF) 6°DIGIT		7TH DIGIT		8TH-9TH DIGIT		
5	U	0	Header only No Arm	0	Header only No Arm	0	Tunable White	0	Joystick	0	Power supply	00	Std lighthou se
5	С	1	550 mm column ø 45 mm	1	600 mm	1	Sunlight 5000K	2	Sensor	1	Power supply Remote Cable Bus cable	JJ	(4)
5	Т	2	855 mm column ø 45 mm	3	820 mm	4	cNus Tunable White ⁽²⁾⁽³⁾						
		6	550mm column ø 60 mm	4	820 mm Theia	5	cNus Sunlight 5000K ^{(2) (3)}						
		7	855mm column ø 60 mm	5	960 mm	6	CE Tunable White 4K Camera						
				6	960 mm Theia	7	CE Sunlight 4K Camera						

U: UNIT MOUNTING C: CEILING MOUNTING T: HEADER ONLY

(1) Customised codes only include aesthetic customisations that do not impact on Safety and EMC requirements

(2) The cNus mark for North America cannot be combined with the following variant codes:

Digit 1-2: 5T

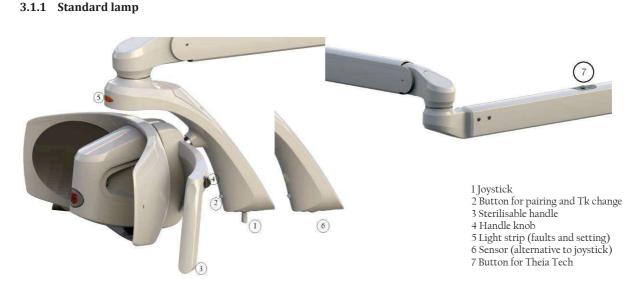
Digit 3:0

Digit 5: 6 and 7

(3) Ceiling-mounted versions with the cNus mark are considered fixed applications and must be connected to earth protection. These devices are Insulation Class I according to IEC 60601-1.

(4) Aesthetic customisation and branding do not affect safety and performance requirements

3.1 DESCRIPTION OF THE USER INTERFACE



3.1.2 Lamp with Camera



1 - Focus adjustment ring Camera

4 **INSTRUCTIONS FOR USE**

The device must be cleaned before use (see section Cleaning the device).

	WARNING
	Do not use the device in flammable or explosive environments
_ _	Simultaneous use of the lamp with electrosurgical devices may cause malfunctions (flickering, lack of control, etc.).
	PROHIBITION
	The joystick must be handled with care to avoid breakage.
	Never move the lamp using the socket switch.
	NOTE
	When switched on, the device does a self-diagnosis, and the light strip starts flashing in different colours: blue, green and red.
i	The following parameters are stored by the lamp and made available each time it is switched on:
	- last light intensity setting
	- Setting the light colour temperature (for the Tunable White variant)
	WARNING
	Do not use the device if parts or enclosures are damaged or if there is play or breaks between:
	- Header joint / Header bow
	- Fixed arm joint / Articulated arm joint

SensorE

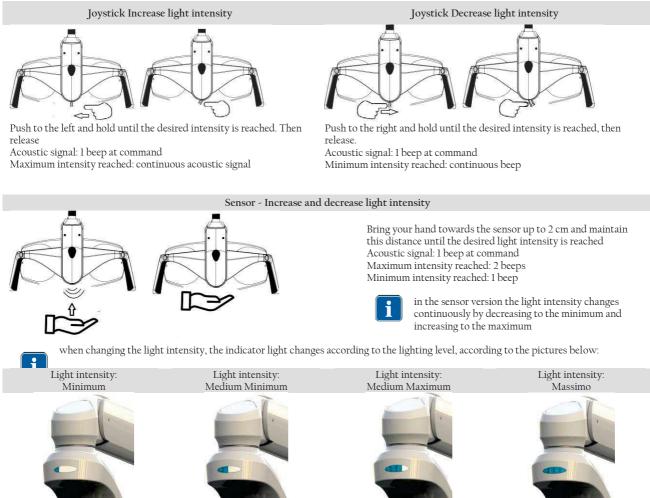
Bring your hand towards the sensor up to 2 cm and move it downwards

4.1 ON/OFF



Press right or left and release Acoustic signal: 1 beep

4.2 ADJUSTING LIGHT INTENSITY



Acoustic signal: 1 beep

4.3 CHANGING THE COLOUR TEMPERATURE ON THE TUNABLE WHITE VERSION

case repeat the operation

Joystick and Sensor

Each time a double-click is performed, the Tk of the light changes.





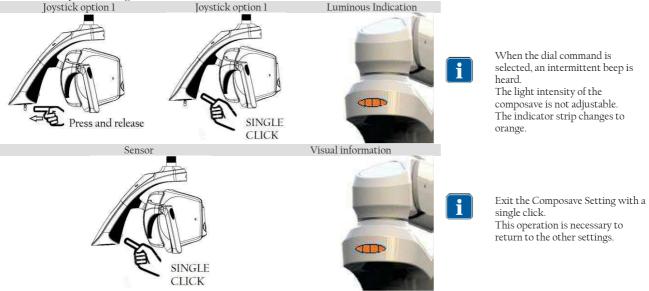
2 beeps will inform the user that the Tk is changing. If the double click is too fast, the lamp may not take the colour temperature change command. In

Repeat the procedure until the desired colour temperature is displayed on the indicator light.



COMPOSAVE SETTING ON TUNABLE WHITE VERSION 4.4

The composave setting allows the user to work while avoiding the polymerisation of composite materials. Select the composave setting as described below:



4.5 MINIMUM INTENSITY SETTING ON SUNLIGHT VERSION

Joystick	Sensor	Visual information						
Press and release	SINGLE CLICK							
Press and release the joystick Forward	Press and release the button on the	Minimum intensity sector						
or Reverse	headband	illuminated.						

To exit the setting, a single click takes you back to the previous lighting

4.6 **AUTO-ON SETTING**

When the switch-on mode is set to Auto-on, the lamps switch on automatically (without a specific command from the user) in the presence of power from the dental unit.

The function can be activated via the FARO Tech APP, available on the Play Store and Apple Store.

SWITCHING THEIA ON/OFF 4.7 arm

The light on the fixed arm (secondary light) can be switched on/off and adjusted synchronously with the operating light and its control. The secondary light can be operated manually via the button (7) on the fixed

If the secondary light is switched on after the operating light, it will be automatically synchronised.

If the secondary light is switched on with the operating light switched off, it will automatically be set to maximum intensity.



The light on the fixed arm is adjusted synchronously with the operating light, it cannot be adjusted independently.

Synchronisation can be disabled via the FARO Tech APP, available on the Play Store and Apple Store.

4.8 **REMOTE CONTROL**

Refer to the dental unit instructions for operating the dental lamp via the dental unit control panel.

4.9 SYNCHRONOUS MODE WITH LIGHTHOUSE LAMPS

When present, the device can be connected by radio frequency (RF) to Faro's Ambient Lamps to create a synchronised lighting system. The procedure for creating this connection is called 'pairing'. If more than one ambient lamp is installed in the dental office, please ensure that the others are switched off or have not been switched on for more than 60 seconds. To activate 'Pairing', proceed as follows: 1. 1. Switch on the ambient lamp. This will start to seek input from the dental lamp for a duration of 60 seconds. 2. Within 60 seconds, press the 'Pairing' button on the dental lamp. The button should be held down between 4 and 6 seconds. Attention: If the button is held down for more than 6 seconds, the procedure will be cancelled. On the Ambient Lamp, the blue LED on the aluminium housing is activated. If the blue LED does not light up, another attempt can be made within 60 seconds of the first one. If 60 seconds elapse after the Ambiete lamp is switched on, the procedure from step 1 must be repeated. 3. After the blue LED lights up, there are 60 seconds to confirm 'Pairing' by pressing the programming button on the room light remote control. At this point, the blue LED on the room light flashes twice and then goes out. If the button on the remote controls is not pressed within 60 seconds, the blue LED goes out and the procedure must be repeated from step 1. After 'Pairing', synchronisation between the 2 lamps (dental lamp and room lamp) is enabled. To DEACTIVATE THE SYNCHRONIZATION FUNCTION, proceed as follows: Press the Synchro button for 2 to 4 seconds, then release it. Upon release, an audible signal will be heard and the blue LED of the Room Light lamp will turn off to

indicate that synchronisation has been deactivated.

When the Room Lamp is synchronised with the Dental Lamp the blue LED on the Room Lamp is lit steadily. If the LED goes out, this indicates that synchronisation is not active.

The remote control is always enabled, so it is possible to change the lighting value in manual mode.

If the Dental Lamp is switched off, the Room Lamp remains switched on.

4.10 IMAGE FOCUS ADJUSTMENT

The image can be focused manually by adjusting the camera focus via the ring nut. Zoom in: turn the bezel anti-clockwise (blue arrow in the picture)

Zoom out: turn the dial clockwise (red arrow in the picture)



WARNING Do not force rotation beyond the limit switch to avoid damage to the rotation system



i

5 PREVENTIVE MAINTENANCE AND ROUTINE CHECKS

Only a trained technician is authorised to perform corrective maintenance and replacement of any part of the device, according to the manufacturer's service manual.

Control	Frequency	Procedure	Responsibility
No play or gap between the joining points (points 1, 2, 3, 4)	12 months		specialist technician
The screws of the connection	12 months		specialist
points must be tight and undamaged: - screw 5 - Screw 6.			technician
The ferrules under casings 1, 2 must be well secured and the safety screws must be intact. The screws under casing 3 must be tight and undamaged.	12 months	Carter 3 Carter 3	specialist technician
		Carter 3 Carter 1	
Check joints, arms or plastic parts for oxidation. Check that the main label is legible	12 months 12 months	Visual inspection Visual inspection	specialist technician specialist
			technician
Absence of damage to the casing and verification of the integrity of plastic and metal parts	12 months	Visual inspection	specialist technician
Electrical safety according to EN 62353	24 months	Use the parameters defined in IEC 60601-1	specialist technician
Light quality controls	24 months	Using a spectroradiometer, check the values for: Maximum luminance: >35000 lux CRI > 85 Radial power on blue light: <100 W/m2	specialist technician

6 CLEANING AND DISINFECTION

	Warning against corrosion due to the risk of falling masses			
	For all metal or plastic parts, it is strictly forbidden to use substances that are			
	- abrasive,			
	 corrosive, 			
	- acids,			
	 substances containing chlorine or chloride ions, phosphorus or phosphorous ions, 			
	- Trilene-based detergents, petrol, white spirit, chlorine or similar.			
	Do not use detergent-disinfectants containing the following substances to clean plastic parts:			
	- Ammonium hydroxide			
<u> </u>	- Sodium hydroxide			
	- Hydrogen peroxide			
	- Ammonium chloride			
	- Methylene chloride			
	- Methyl alcohol			
	- Acids and corrosive substances of all kinds.			
	It is forbidden to spray any chemical substance directly onto the device.			
	The use of wet wipes without rinsing is prohibited.			
	Faro has tested and recommends the use of the following disinfectants for plastic and metal parts:			
i	- Durr FD366 Sensitive			
	- Perflex Advanced Lighthouse			
	 Disinfectants based on water and alcohol with 70% isopropyl alcohol or ethanol are suitable. 			

6.1 CLEANING THE REFLECTORS

Cleaning should be done with a soft cotton cloth or absorbent cotton with ethyl alcohol. Alcohol-water disinfectants are suitable with 70% isopropyl alcohol or ethanol.



Caution - risk of damage to reflectors

Never spray the cleaner directly onto the dishes. Cleaning of dishes must be carried out wearing gloves to avoid leaving marks on surfaces. Never use cleaning agents containing surfactants or water repellents, which can leave streaks when deposited. Slight streaks do not impair the quality of light. Products other than those suggested could damage the dishes. In case of doubt, please contact FARO customer service.

6.2 HEAD CLEANING AND DISINFECTION

Cleaning should be done with a soft cotton cloth moistened with a disinfectant solution. Always wring out the cloth to remove all excess liquid.

6.3 CLEANING AND DISINFECTION OF ARMS

Always use a cloth soaked in approved disinfectant to disinfect surfaces and wipe with it. Always wring out the cloth to remove all excess liquid.

7 STERILISATION OF HANDLES

Danger of cross-contamination warning



The handles are not supplied sterile, they must therefore be sterilised before use. The handles must be sterilised before each patient.

7.1 REMOVAL OF HANDLES

To remove the handle, unscrew knob 'A' and pull the handle out of the holder.

7.2 DECONTAMINATION AND DISINFECTION

Bef Before sterilising handles, they must be decontaminated and disinfected. For disinfection, Faro tested the following products: Faro Perflex Advance





WARNING - danger of breaking plastic Handles cannot be disinfected by thermodisinfection.

7.3 STERILISATION

Handles must be bagged in accordance with EN 868-5.

Handles can be sterilised with standard $121^{\circ}/134^{\circ}$ C cycles up to two hundred (200) cycles or until loss of mechanical performance. The parameters of the sterilisation cycle are as follows:

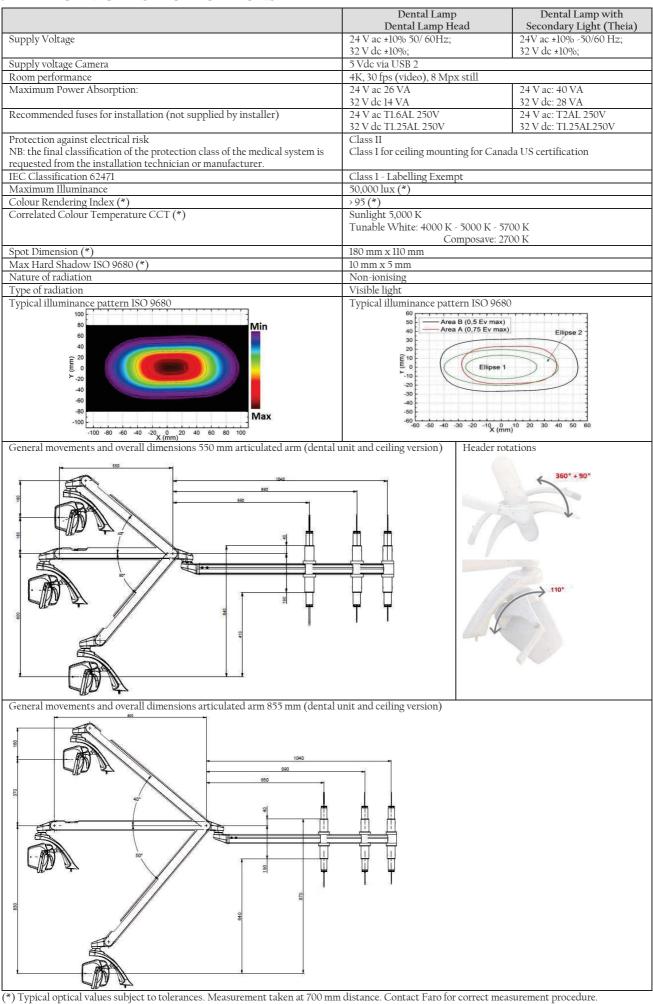
Cycle EN 13060	Temperature	Pressure	Minimum Holding Time
В	121°C	207 kPa	15 min
В	134°C	308 kPa	3 min

8 TROUBLESHOOTING

8.1 LIST OF ERRORS

Error	Description	Indicator light	Strip light colouring	Acoustics Information
El	Active overtemperature protection	First sector flashing. Colour set: VIOLET		3 prolonged beeps
E2	High temperature on the board	All sectors flash in sequence. Colour set: VIOLET	-	3 prolonged beeps
E5	Open Led circuit channel 1	First sector flashing. Set colour: RED	*	3 short beeps
E6	Open Led Circuit Channel 2	First and second sector flashing Set colour: RED	***	repeated 3 times
E8 E9	Low input voltage High input voltage	All sectors flash together Set colour: RED		5 prolonged beeps
E10	Communication with RGB board	The luminous gem is extinguished	-	Switch off the lamp for 60 s and switch it on again
Ell	Open LED circuit channel 1 and channel 2	First. Second and third sector flashing. Set colour: RED		3 short beeps repeated 3 times
N,C.	None	The luminous gem remains stuck on a colour		Switch off the lamp for 60 s and switch it on again

9 TECHNICAL SPECIFICATIONS



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9.1 STORAGE AND TRANSPORT: ENVIRONMENTAL CONDITIONS

The device in its original packaging can be transported and stored for up to 15 weeks if the following environmental conditions are met:

- Ambient temperature -20°C to +70°C

- Relative humidity from 10% to 90%.

- Atmospheric pressure from 50 kPa to 106 kPa

9.2 USE: ENVIRONMENTAL CONDITIONS

- The device must be used under the following environmental conditions:

- Temperature from 10° to 40°C
- Maximum altitude: 2000 m
- Relative humidity 30% to 75%



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EVA Dental Operating Light Medical Device Class I

