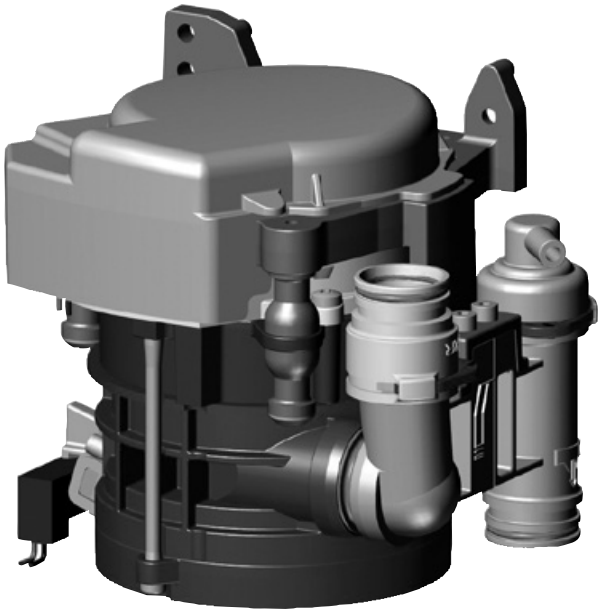
CS 1 Combi-Sepamatic

EN



Installation and Operating Instructions

CE

9000-606-39/30

DÜRR DENTAL

1709V004

Contents

Important information

Product description

Installation

Operation

Troubleshooting

Appendix

EN

1 About this document

These installation and operating instructions form part of the unit.

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

EN

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.


Comply with the Operating Instructions.


Wear hand protection.


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


Hose manifold connection


Suction unit connection


Drain connection


CE labelling

Order number

Serial number


Manufacturer

1.2 Copyright information

2 Safety

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

2.1 Intended purpose

The CS 1 Combi-Sepamatic is designed for the continuous separation of liquids in the suction flow of dental treatment units in dry suction systems.

2.2 Intended use

Installation in accordance with the requirements of the water authorities in the German Federal States or in accordance with local regulations.

Installation in dental treatment units and in practice rooms (housing version).

Positioned in the suction line of a dry suction system after the spittoon and manifold.

The CS 1 Combi-Sepamatic is designed for the continuous separation of liquids in the suction flow of an individual dental treatment unit in a dry suction system.

The The CS 1 Combi-Sepamatic can be operated in continuous operation.

The permissible volume of supply water amounts to min. 0.1l/min, but must not exceed 2.0l/min.

A rinsing unit with fresh water can be installed upstream of the the CS 1 Combi-Sepamatic.

For surgical treatment and when using the Airflow, the CS 1 Combi-Sepamatic requires a rinsing unit to be installed, which feeds a small amount of water to the device during aspiration. This thins any liquid (e.g. saliva, blood) that occurs so it can be transported more easily.

Installation, servicing and repairs must only be performed by qualified personnel specifically approved and authorized by Dürr Dental.

The CS 1 Combi-Sepamatic is unable to separate amalgam. The treatment of waste water containing amalgam requires the connection of an amalgam separator to the CS 1 Combi-Sepamatic.

2.3 Improper use

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

The Combi-Sepamatic must only be used to process liquids emerging from the oral cavity and not any other substances such as dust, sludge, plaster or similar.

Only chemicals and disinfectants that will not damage the materials, e.g. OrotolPlus or equivalent, must be used.

The unit is not suitable for installation downstream of 2 or more workplaces. The max. water volume of 2.0l/min must not be exceeded.

The device must not be installed with the drain higher than the connection piece on the device.

Do not use any risers. All pipes must have a downward gradient.

Not suitable for wet rooms. Do not use this device to aspirate flammable or explosive mixtures. Do not use the unit in a potentially explosive environment.

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 60601-1-1 or section 16 of the 3rd edition of IEC 60601-1 respectively).

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.

EN

2.5 General safety information

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
› Prior to each use, check condition of the device and make sure it is in perfect working order.
› Do not convert or modify the units.
› Observe the Installation and Operating Instructions.
› Make the Installation and Operating Instructions available to the person operating the device at all times.

2.6 Qualified personnel

Operation

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

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

Installation and repairs

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

2.7 Protection from electric shock

› When working on the units observe all the relevant electrical safety regulations.
› Never touch the patient and unshielded plug connections on the device at the same time.
› Immediately replace any damaged lines and connections.

Observe the EMC rules concerning medical devices

› Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "13 Information about EMC in accordance with EN 60601-1-2".

2.8 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
› Only use only genuine working parts and spare parts.

DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.

The use of non-approved accessories, special accessories or non-genuine working parts / spare parts (e.g. mains cable) can have a negative effect in terms of electrical safety and EMC.

2.9 Transport

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

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

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

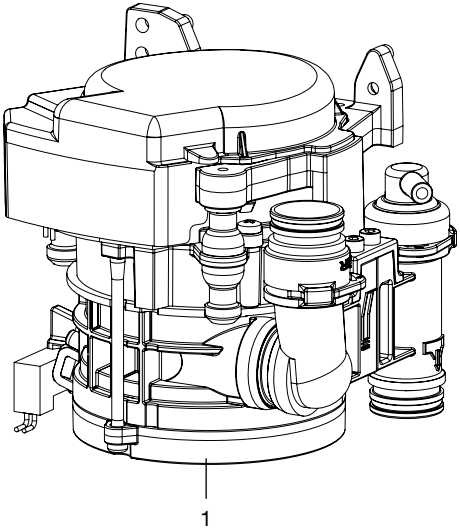
› Only transport the device in its original packaging.
› Keep the packing materials out of the reach of children.

2.10 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.

3 Overview



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 Accessories

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

Various installation sets are available on request
Safety transformer 24 V, 100VA. . . 9000-150-46
Station selection valve for
CAS 1 / CS 1 7560-500-80

3.3 Special accessories

The following optional items can be used with the device:

Station selection valve. 7560-500-60
Rinsing unit II 7100-250-50
OroCup care system. 0780-350-00

3.4 Disposable materials

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
4 x 2.5 l bottles/carton CDS110P6150
MD 550 spittoon bowl cleaner
6 x 800 ml bottles / cardboard box. CCS550A4750
MD 555 cleaner
4 x 2.5 L bottle / carton CCS555C6150

3.5 Wear parts and spare parts

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

– Protective strainer
– Rubber grommets
– O-rings

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

EN

4 Technical data

4.1 CS 1 Combi-Sepamatic

Electrical data – centrifuge motor		
Nominal voltage	V	24 AC
Frequency	Hz	50 / 60
Rated power	VA	70

Media		
Fluid volume		
min.	l/min	≥ 0.1
max.	l/min	≤ 2.0
Air flow volume	l/min	≤ 350
Flow rate		high
The suction system must be suitable for a high flow rate in accordance with EN ISO 10637.		
Max. pressure	hPa/mbar	-160

General data		
Drive motor nominal speed	min^{-1}	2800
Operating mode		S1 100% DC*
Type of protection		IP 20
Protection class		II
Noise level ** approx.	dB(A)	49
Dimensions (H x W x D)	cm	12.5 x 15 x 12
Weight, approx.	kg	1.4
Medical device (class)		I

* DC = duty cycle

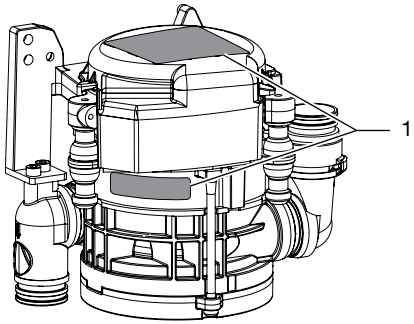
** Noise levels in acc. with EN ISO 1680 "airborne noise emissions"; measured in a sound-proofed room. The levels are average values with a tolerance of ±1.5 dB(A). Higher values may be obtained in rooms with reverberating sound characteristics.

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

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

4.2 Type plate

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

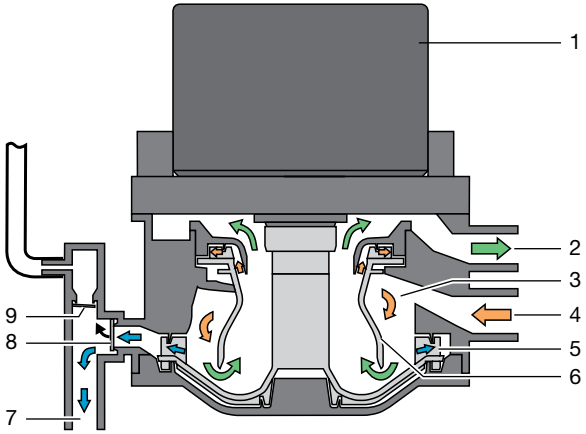


1 Type plate

4.3 Conformity assessment

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

5 Operation



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

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
– Completely PVC hoses
– 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 sheathing, as used for telecommunications 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

EN

7 Installation

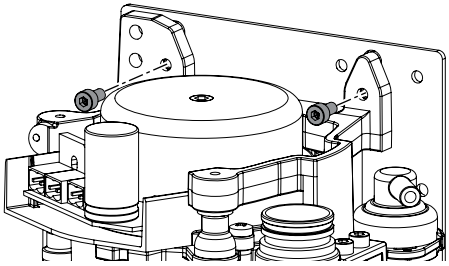
Prior to working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

7.1 Installation of the CS 1 in treatment units

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 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.

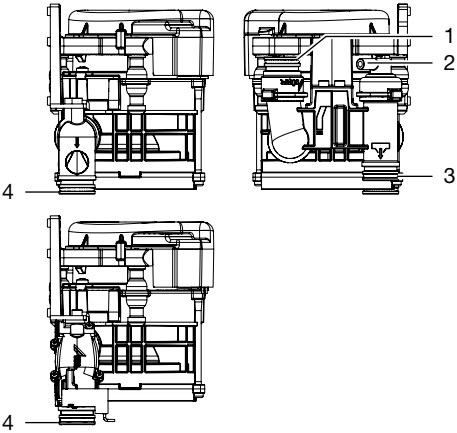
For further information, refer to the station selection valve installation and operating instructions

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: ∅ 25 mm.

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



1 Hose manifold
2 Vent
3 Outlet
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.

For further information, refer to the rinsing unit installation and operating instructions

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.

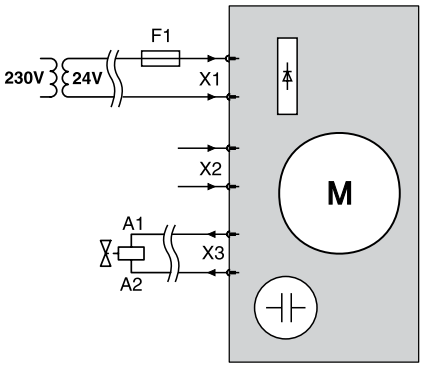
7.2 Electrical connections, controller

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)



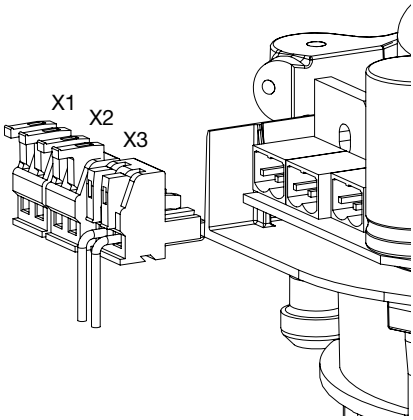
X1 Power supply in accordance with EN 60601-1, 24 V AC

X2 Signal input 24 V AC/DC

X3 Place selection valve and/or rinsing unit (max output 8 W)

F1 T 4 AH, 250 V in accordance with IEC 60127-2

7.3 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.

EN

8 Commissioning and first start-up

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.

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, e.g. household cleaning agents or instrument disinfection agents.
› Do not use abrasive cleaners.
› Do not use agents containing chlorine.
› Do not use any solvents like acetone.

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:
– Material-compatible, non-foaming disinfection/cleaning agents with Dürr Dental approval, e. g. Orotol plus.
– Unit care system, e.g. OroCup
› To pre-clean, suck up 2 litres of water with the care system.
› Aspirate the disinfection/cleaning agent with the care system.

9.3 Once or twice a week before the midday break

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

The following are required for cleaning:
– Material-compatible, non-foaming special cleaning agents that have been approved by Dürr Dental, e.g. MD 555 Cleaner
– Unit care system, e.g. OroCup
› To pre-clean, suck up 2 litres of water with the care system.
› Aspirate the cleaning agent with the care system.
› Rinse with ca. 2 l water after the application time.

EN

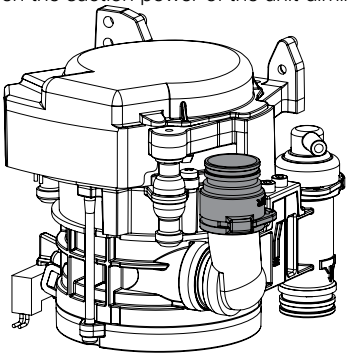
10 Maintenance

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

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

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).

EN

Maintenance interval	Maintenance work
Dependent upon the level of usage of the device	› Clean or replace the protective sieves at the aspiration inlet. At the latest, however, when the suction power of the unit diminishes. 
Annually	› Cleaning of the suction unit in accordance with the operating instructions. › Clean or replace the protective sieves at the aspiration inlet. › Where a rinsing unit is present: Clean the sieve/coarse filter in the water intake. * › Perform a function 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 unit. *

* Only by customer services service technicians.

11 Tips for operators and service technicians

Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.

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

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).

EN

Fault	Probable cause	Solution
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 by customer services service technicians.

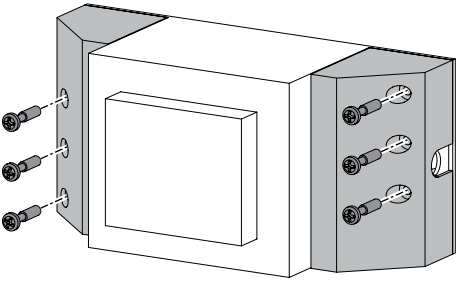
EN

11.1 Replacing the fuse

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

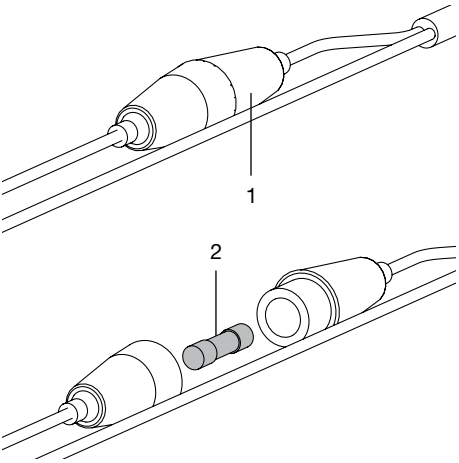
Transformer

› Unscrew and remove the safety cover.
› Replace the fuse.



Fuse housing

› Turn the fuse housing to open it.
› Replace the fuse.



1 Fuse housing
2 Fuses

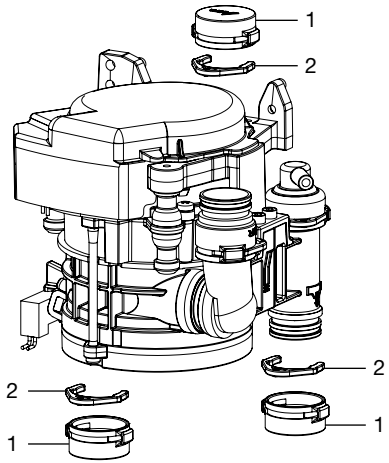
12 Transporting the unit

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

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

13.1 General information

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

13.2 Abbreviations

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

13.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

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

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

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

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

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

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

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

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ V	$d = [3.5 / V_1] \cdot \sqrt{P}$ $d = 1.2 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	$[E_1]$ V/m	$d = [3.5 / E_1] \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$ for 80 MHz to 800 MHz $d = [7 / E_1] \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz $d = 2.3 \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz

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

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

d Recommended safety distance in metres (m)

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

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

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

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

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

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

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

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

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
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

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

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

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

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

13.4 Calculation table

If the measured values deviate from the standard, the values are specified in chapter "4 Technical data".

The safety distances can then be calculated in the tables shown below.

P: .....

V_1: .....

E_1: .....

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

V_1 Compliance level for the test in acc. with IEC61000-4-6

E_1 Compliance level for the test in acc. with IEC61000-4-3

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distances
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	[V_1] V	d = [3.5 / V_1] · √P
Emitted HF disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	d = [3.5 / E_1] · √P for 80 MHz to 800 MHz
			d = [7 / E_1] · √P for 800 MHz to 2.5 GHz

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz d = [3.5/V_1] ·√P	80 MHz to 800 MHz d = [3.5/E_1]·√P	800 MHz to 2.5 GHz d = [7 / E_1] ·√P
0.01			
0.1			
1			
10			
100			

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

DÜRR DENTAL