CA 4 amalgam separator

EN

Installation and operating instructions

CE

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DÜRR DENTAL

2011V003

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Important information

1 About this document

These installation and operating instructions represent part of the unit.

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

The German version of the installation and operating instructions is the original manual. All other languages are translation of the original manual. These installation and operating instructions apply to:
CA 4
Order number: 7805-100-50; 7805-100-50E; 7805-200-50; 7805-200-60

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.
The following warning symbols are used:


General warning symbol


Warning – dangerous high voltage


Biohazard warning

The warnings are structured as follows:


SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

– **DANGER**
Immediate danger of severe injury or death
– **WARNING**
Possible danger of severe injury or death
– **CAUTION**
Risk of minor injuries
– **NOTICE**
Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.


Unit can be used with Tyscor Pulse


Refer to Operating Instructions.


Wear protective gloves.


Disconnect all power from the unit.


Do not sit on the unit


Do not climb onto the unit


Do not reuse


Unit in operation


Unit operation interrupted

Audible signal/melody sounds


Mark of conformity from the Deutsches Institut für Bautechnik


CE labelling

EN

REF Order number

SN Serial number

MD Medical device

HIBC Health Industry Bar Code (HIBC)

 Manufacturer

1.2 Copyright information

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 amalgam separator is designed for the separation of amalgam out of all waste water collected from dental treatment units.

2.2 Intended use

The amalgam separator is designed for installation downstream of an air/water separation system.
Service, maintenance, recurring tests and cleaning must be performed in accordance with the manufacturer's specifications.
The permissible flow rate must be observed.
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 or plaster or similar substances.
– Use in conjunction with flammable or explosive mixtures.
– Installation in a manner that does not comply with the installation instructions, in particular set-up 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.
› Maintain a minimum distance of at least 30 cm between the unit and other electronic devices.
› 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.

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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).

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Product description

3 Overview

CA 4 amalgam separator

Model with 230 V / 1~, 50 Hz 7805-100-50
Model with 230 V / 1~, 50 Hz, replacement unit 7805-100-50E
Model with 230 V / 1~, 50 Hz, for installation in a PTS 7805-200-50
Model with 230 V / 1~, 60 Hz 7805-200-60

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):

CA 4 amalgam separator . . . . . 7805-..

- Amalgam separator
- Set of connection fittings
- Hose ø 20 mm
- Display panel
- Cable for display panel, 1 m
- Cable for display panel, 5 m
- Amalgam collecting 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 for CA 4 7805-033-00

3.3 Optional items

The following optional items can be used with the device:

Noise reduction hood 7122200000
Rinsing unit II 7100-250-50
OroCup care system 0780-350-00
Adapter PCB for remote display . . 7805-993-00
Surge tank 7130-991-51
Wall bracket 7130-190-00
Console for floor-mounted installation 7130-191-00
Test set CA 4 7805065001

3.4 Consumables

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

Disposable amalgam container for CA 4 7805-033-00
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):

Pump propeller 7805-100-20
Fluid sensor 7805-104-00E
Centrifugal drum 7805-100-10E
Nonreturn valve (pack of 3) 7128-100-03E

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

4 Technical data

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Electrical data		7805-100-50 7805-200-50	7805-200-60
Voltage	V	230	230
Mains frequency	Hz	50	60
Rated power	W	210	260
Nominal current	A	1.0	1.2
Fuses* (2x)		T 4.0 AH	
Type of protection		IP 21	
Protection class		I	
Over-voltage category		II	

* in accordance with IEC 60127-2

Electrical data – electronics		
Switching performance signal output Max. voltage Max. nominal current	 V mA	 24 AC/DC 120
Signal input from the hose manifold	V	24 AC/DC

Media and connections		
Fluid volume min. max.	 l/min l/min	 0.1 16
Usable volume, disposable amalgam container	ccm	approx. 600
Replacement interval	Months	9 - 12
Dürr Connect inlet and outlet connection		Hose, 20 mm (inside)

General data			
Speed	rpm	2900	3470
Duty cycle	%	95 (S 5 min)	
Dimensions (H x W x D)	cm	41 x 25 x 32	
Weight	kg	10	
Noise level* without housing; approx. with housing; approx.	 dB(A) dB(A)	 57 47	 65 56
Separation rate **	%	≥ 95	≥ 95

* Noise level in accordance with EN ISO 3746
** in accordance with ISO 11143

Network connection	
LAN technology	Ethernet

EN

Network connection		
Standard		IEEE 802.3u
Data rate	Mbit/s	100
Connector		RJ45
Type of connection		Auto MDI-X
Cable type		≥ CAT5
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
Classification		
Medical Device Class		I
Electromagnetic compatibility (EMC) Interference emission measurements		
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		Compliant
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3:2013		Compliant
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

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Electromagnetic compatibility (EMC) Interference immunity measurements	
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

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

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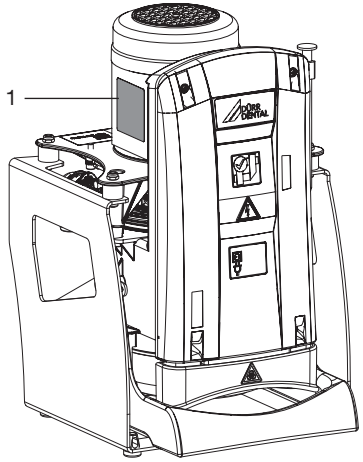
Electromagnetic compatibility (EMC) Interference immunity measurements on the supply input	
Immunity to fast electrical transients/bursts – AC mains voltage IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition rate	Compliant
Immunity to surges, line-to-line IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV	Compliant
Immunity to surges, line-earth IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV, ± 2 kV	Compliant
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

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

Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP
N/A = not applicable

4.1 Type plate

The type plate can be found on the side of the amalgam separator motor.



1 Type plate

4.2 Evaluation of conformity

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

4.3 Approvals

Centre of Competence in Civil Engineering, Berlin	
Test number	Z-64.1-22

Separation method compliant with standard	
ISO 11143	Type 1

5 Operation

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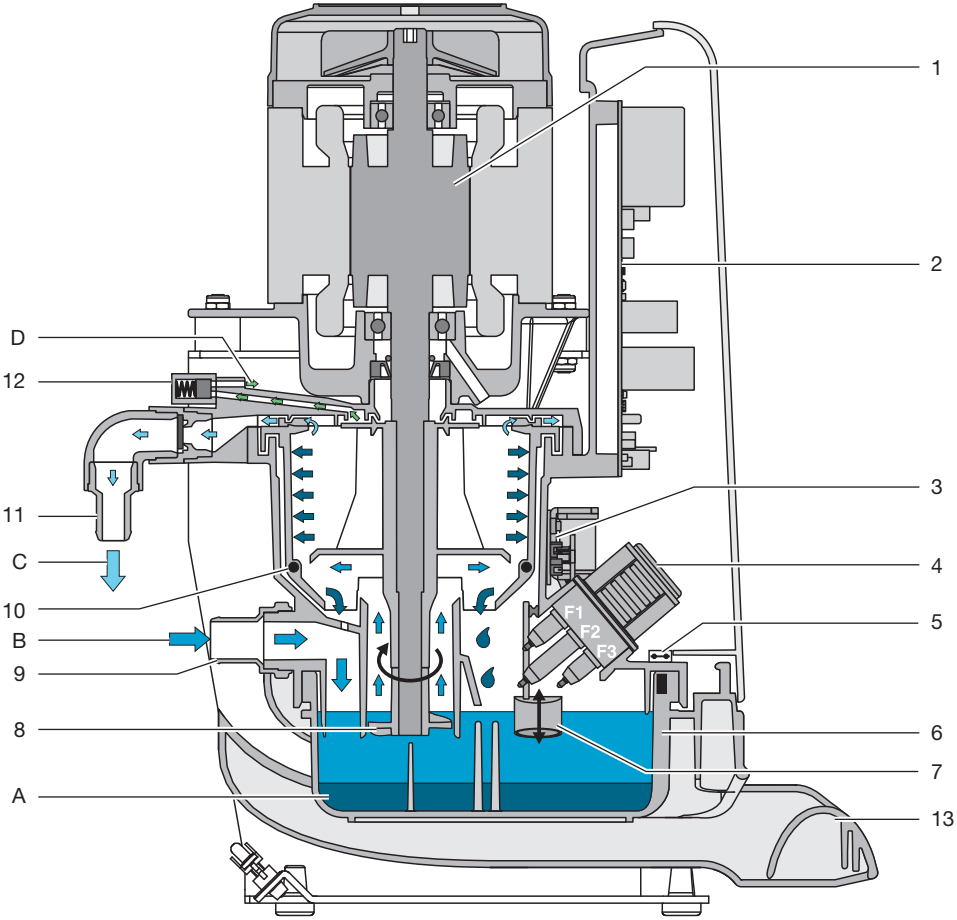

1 Motor
2 Electronics
3 Sediment PCB with sediment sensor and light barriers
4 Sensor block
F1 Emergency start sensor
F2 Reference sensor
F3 Water start sensor
5 Safety end switch on sediment PCB
6 Collecting container
7 Sediment sensor
8 Levelling pump
9 Inlet connecting piece
10 Magnets for RPM monitoring
11 Waste water outlet
12 Relief valve

13 Vessel lift
A Amalgam sludge
B Fluid with amalgam
C Waste water, cleaned
D Vent

The amalgam separator works according to the centrifugal principle and is driven by an electromotor. Each time the unit is supplied with power, the amalgam separator performs level measuring using the sediment sensor. The level detected then appears on the display panel. Where the power supply to the amalgam separator is not switched off (e.g. in hospitals), an integrated timer ensures that a sedimentation scan is carried out every 24 hours.
If the water sensor (conductivity sensor) is immersed in fluid when the amalgam separator is activated, the drive motor will start up first and the sedimentation scan will take place during the next idle phase. If the fluids in the collecting container are not recognised by the sensors, the sensitivity of the sensors can be increased via the electronics.
Fluid from the treatment unit flow through directly into the amalgam collecting container via the water inflow. A coarse filter with a mesh of max. 3 mm must be fitted upstream of the amalgam separator (e.g. in the treatment unit). Coarse particles are immediately separated out in the amalgam collecting container. When the water start sensors are bridged by fluid, the drive motor, after an initial delay, starts the centrifugal drum and the levelling pump, which is also situated on the drive shaft. The level pump pumps the fluid from the amalgam collecting container to the centrifuge drum. The amalgam floating in the fluid will then be separated using centrifugal force.
If the water start sensor is unable to detect any fluids for approx. 30 seconds, the drive motor is switched off and the brake is applied. The gravity-induced rotation of the water ring rinses the particles separated from the centrifuge drum downwards towards the amalgam collecting container.
Where there is a steady flow of fluids to the amalgam separator (e.g. if it is installed downstream of VS suction units or water ring pumps), a timer is used to briefly switch off, brake and then restart the drive motor every 15 minutes. This braking moment rinses the centrifuge drum clear. The separation rate is maintained here up to the max. nominal flow rate of 16 l/min.
If the amalgam separator is installed downstream of a VS suction unit, it can be started simultaneously with the suction unit using external start signal input.
The cover of the centrifuge housing is equipped with a solenoid valve. It remains open as long as the amalgam separator is ready for operation but closes in the event of a fault. This ensures sufficient air intake and venting of the amalgam separator during operation. If the water start sensor is defective, then the amalgam separator is monitored by a further sensor (emergency start-up sensor) and started. If the emergency start sensor is not pumped free within a set period of time, an LED will flash on the display panel. The amalgam separator is still operational. The flashing LED will switch off when the emergency start sensor is free again.
The amalgam separator is monitored and emits both an audible and an optical signal in the event of a motor breakdown, malfunction or blockage of the drainage outlet. The drive motor is switched off. It is possible to start the motor three more times using the service key. After that the motor will no longer be operational.
To restart it, the service key must be pressed for more than 2 seconds.
A hose empties the amalgam separator in the case of a malfunction, so that no water can escape when opening the amalgam collecting container.

Assembly

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6 Requirements

6.1 Installation/setup room

The room chosen for set up must fulfil the following requirements:
- Closed, dry, well-ventilated room.
- Installation in purpose built rooms, e.g. in boiler rooms, must be checked with local building regulations first.
- Ambient temperatures are compliant with "4 Technical data".

NOTICE

Risk of overheating due to insufficient ventilation

The units generates heat. Possibility of heat damage and/or reduced service life of the unit.

› Do not cover the unit.

› Install a fan for auxiliary ventilation in rooms where ambient temperatures exceed ≥40 °C while the unit is in operation.

6.2 Setup options

The following options for setting up the unit are available:
- In a side room, in conjunction with a combination suction unit or in conjunction with a suction unit in a wet suction system with downstream separation.
- As a central amalgam separator in a dry suction system.
- In a ventilated cabinet (e.g. Power Tower) or noise reduction hood.
- Upright on a level surface.
- Mounted upright on a Dürr wall holder.
- Mounted upright on a Dürr console for floor-mounted installation.

6.3 Pipe materials

Only use vacuum-sealed HT-waste pipes manufactured from the following materials:
- Polypropylene (PP),
- Chlorinated polyvinyl chloride (PVC-C),
- Unplasticized polyvinyl chloride (PVC-U),
- Polyethylene (PE).

The following materials must not be used:
- Acrylonitrile-butadiene-styrene (ABS),
- Styrene copolymer blends (e.g. SAN + PVC).

6.4 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

6.5 Pipe/hose installation

› 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.

6.6 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.

The diameter of the connections depends on the current consumption, length of line and the ambient temperature of the unit. Information concerning the current consumption can be found in the Technical Data supplied with the particular unit to be connected.

The following table lists the minimum diameters of the connections in relation to the current consumption:

Current consumption of unit [A]	Cross-section [mm²]
> 10 and < 16	1.5
> 16 and < 25	2.5
> 25 and < 32	4
> 32 and < 40	6
> 40 and < 50	10
> 50 and < 63	16

6.7 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)

Display panel

Installation type	Line layout (minimum requirements)
Fixed installation	– CAT5.e network cable
Flexible	– ISDN standard cable with connectors or – Network patch cable

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

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7 System components

7.1 Rinsing unit

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For surgical procedures and for procedures using powder jet devices, a rinsing unit must in all cases be installed 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

7.2 Surge tank

If the suction unit is combined with an amalgam separator, this requires the installation of a surge tank. The surge tank reduces pressure peaks caused by the waste water pump of the suction unit and acts as a buffer against temporary rises in the volume of water.
The surge tank can also be used if the waste water is fed directly into the building waste water system. this case the waste water from the suction unit is diverted to the building drainage system under zero pressure.

8 Installation

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

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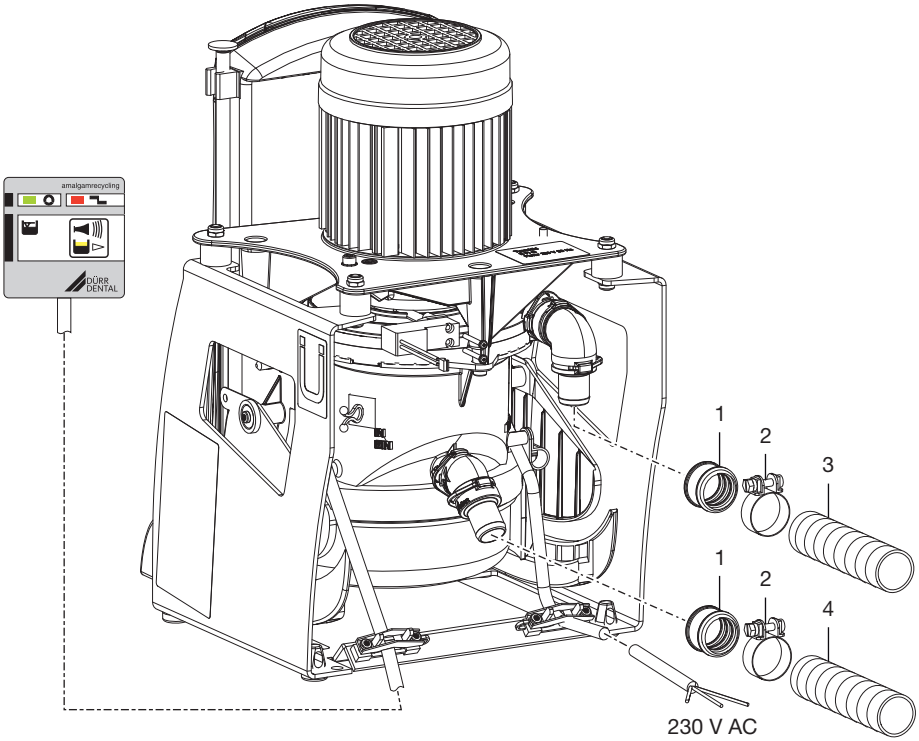
8.1 Connect the hoses and lay correctly

Install the hoses so they are as short as possible and with sufficient incline.
Downstream of separation units, a positive suction head of 150 mm must be maintained in order to prevent backflow.

› Cut the hoses to the required length.
› Screw hose sleeves onto the hose ends.
› Connect the hoses to the DürrConnect connections and secure them with hose clips.
› Connect the hoses on the inlet and outlet sides.



1 Hose sleeve
2 Hose clamp
3 Outlet hose ø 20 mm
4 Inlet hose ø 20 mm

8.2 Electrical connections

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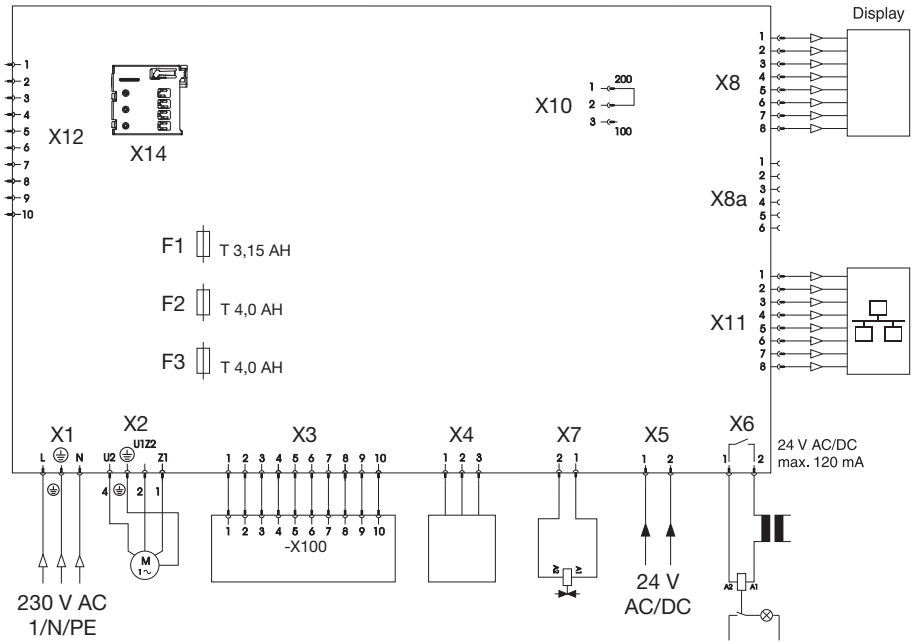
WARNING

Electric shock

› The device may only be connected to a supply system with a earthed power outlet.

› Establish the electrical connection to the supply network (230 V).
  – To a Dürr control box.
  – Connected to a power outlet via the surgery's main power switch.
› Connection the display panel.
› Connect external start (optional).
› Connect external alarm (optional).
› Connect the network (when monitoring via the network).



X1	230 V AC power supply
X2	Motor connection
X3	Sensor system connection
X4.1	Emergency start sensor
X4.2	Reference sensor
X4.3	Water start sensor
X5	External start (optional input, protective low voltage 24V, AC/DC)
X6	External alarm (switching capacity max. 24V, 120mA, AC/DC)
X7	Relief valve connection
X8	Display panel connection (RJ45 connector)

X8a	Display panel connection (6-pin connector)
X10	Sensitivity of the sensor conductance 100/200 µS
X11	100 Mbit network connection
X12	Diagnostic connector
X14	Micro SD card holder
F1	Brake fuse T 3.15 AH (IEC 60127-2)
F2	Fuse T 4.0 AH (IEC 60127-2)
F3	Fuse T 4.0 AH (IEC 60127-2)

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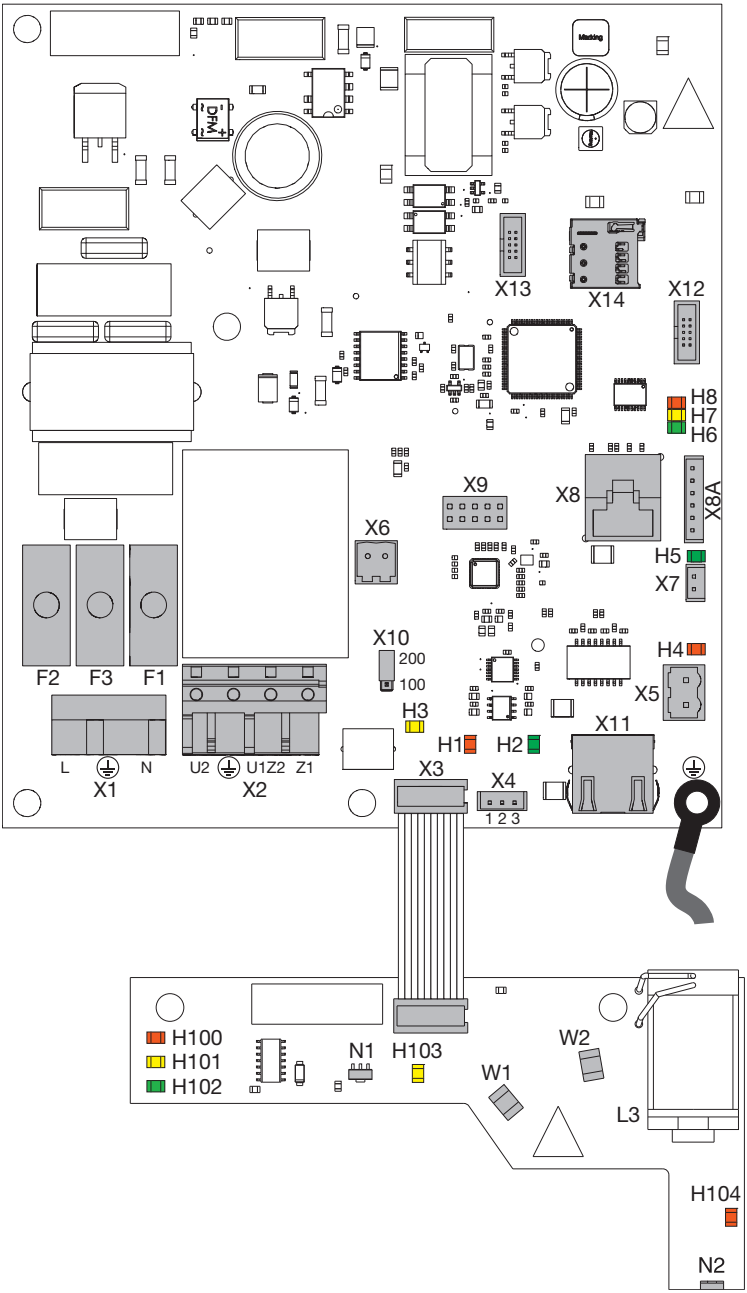
8.3 Connections and displays of the control



X1 230 V AC power supply

X2	Motor connection
X3	Sensor system connection
X4.1	Emergency start sensor
X4.2	Reference sensor
X4.3	Water start sensor
X5	External start (optional input, protective low voltage 24V, AC/DC)
X6	External alarm (switching capacity max. 24V, 120mA, AC/DC)
X7	Relief valve connection
X8	Display panel connection (RJ45 connector)
X8a	Display panel connection (6-pin connector)
X9	Bus module
X10	Sensitivity of the sensor conductance 100/200 µS
X11	100 Mbit network connection (when using a monitoring programme)
X12	Diagnostic connector
X13	Programming connector (J link)
X14	Micro SD card holder for data logger and update
F1	Brake fuse T 3.15 AH (IEC 60127-2)
F2	Fuse T 4.0 AH (IEC 60127-2)
F3	Fuse T 4.0 AH (IEC 60127-2)
H1	Emergency water start (red)
H2	Normal water start (green)
H3	Sediment coil (yellow)
H4	External start (red)
H5	Relief valve (green)
H6	Display panel (green)
H7	Display panel (yellow)
H8	Display panel (red)
W1	Sediment scan light barrier
W2	Sediment scan light barrier
N1	Hall sensor, RPM monitoring
N2	Hall sensor, RPM monitoring
H100	100% fill level W1+2 interrupted
H101	95% fill level W1 interrupted
H102	Ready for operation W1+2 free
H103	Display, motor rotation frequency
H104	Display, container monitoring

EN

8.4 Display panel connection

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

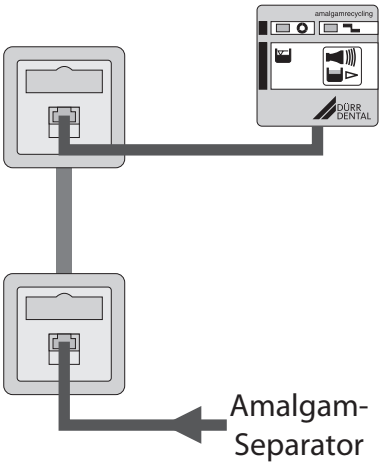
If the amalgam separator is set-up at a larger distance from the treatment chairs (e. g. in the basement), the display panel must be installed appropriately such that the status messages of the amalgam separator can be monitored at all times.

New installation with network sockets

There must be a direct line connecting the RJ-45 socket on the unit and the RJ-45 socket on the display panel. Do not toggle network units (e. g. switch or router).

Pay attention to the resistance of the network cable between the RJ-45 sockets. The maximum length should not exceed 50 m.

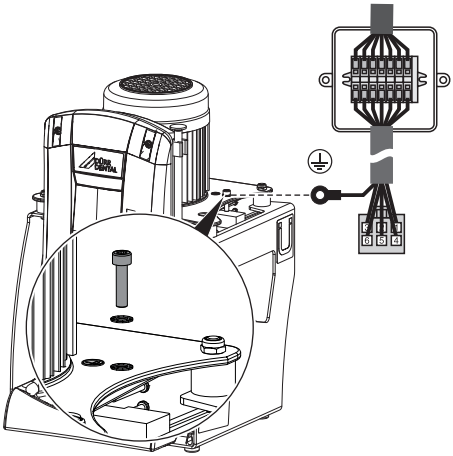
› Remove the cover from the electronics.
› Connect cable with RJ-45 socket to electronics (X8) and in RJ-45 socket.
› Fix the cable to the unit.
› Connect display panel and RJ-45 socket using the ISDN cable supplied.



Replacement of an existing amalgam separator

Where a model 7801 amalgam separator is being replaced by a CA 4 unit, the display panel can be connected using the adapter cable provided. The shielding of the existing display panel cable MUST always be reconnected.

› Connect the yellow adapter cable to X8a on the electronics.
› Connect the yellow adapter cable to the existing display cable.
› Connect the shielding of the display cable to the ground point on the motor carrier.
› Fasten the cable to the strain relief on the floor plate of the amalgam separator.



Replacement of large display panel with the new, smaller display panel

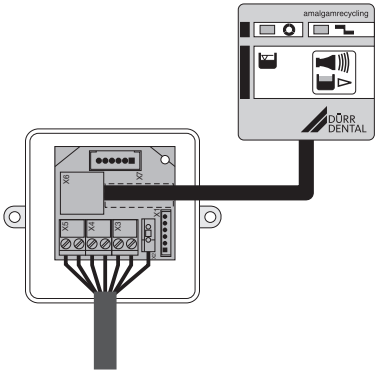
Where a model 7801 amalgam separator is being replaced by a CA 4 unit and the smaller display panel supplied is to be used, this can be connected with the help of an adapter PCB (7805-993-00).

› Disconnect the wiring of the large display panel in the terminal box and remove the terminal strip (note colour coding).

› Connect the existing display cable to the terminals of the adapter PCB.
  – Ground terminal X2
  – Screw terminals X3, X4, X5
    (WH = white, YE = yellow, BU = blue, BN = brown, PK = pink, GY = grey)

The colour coding complies with the standard connection line system used by Dürr.

› Plug the ISDN connecting cable of the display panel into connector X6 on the adapter PCB.
› Mount the display panel in a suitable position.



8.5 Network connection

All connected IT units must correspond to the currently-valid edition of IEC 60950.

Purpose of the network connection

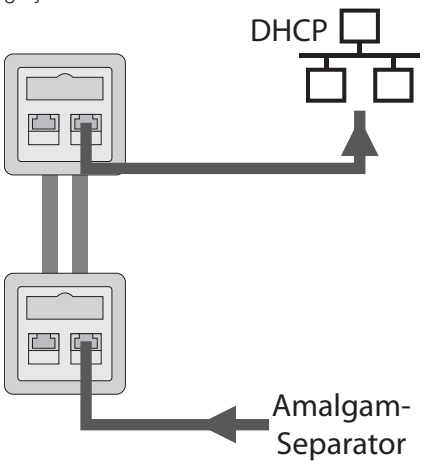
The network connection is used to exchange information or control signals between the unit and a software installed on a computer, in order to, e. g.:

– Display parameters
– Select operating modes
– Indicate messages and error situations
– Change unit settings
– Activate test functions
– Transmit data for archiving
– Provide documents concerning the units

Connecting the device to the network

During initial installation, a router or server with DHCP is recommended so the unit is detected in the network.

› Remove the cover from the electronics.
› Plug the network cable into the electronics and into a network socket.
› Attach the network cable to the device.
› Create a connection to the network in the surgery with the network cable.



9 Commissioning

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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 that coarse filters are installed in the units upstream of the amalgam separator.
› Carry out a functional test.
› Check the unit and connections for leak tightness.
› Fill out the Operating Handbook.

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.

9.1 Monitoring the unit via the network

The following requirements must be met in order to monitor the unit on the computer:
– Unit connected to the network
– Current monitoring software installed on the computer

As the monitoring system of the device, the software must deliver acoustic signals. Audio output on the computer must be activated.

Combining devices safely

– The overall safety of the unit and its main performance features are independent of the network. The device is designed for operation independent of a network. However, some of the functions are not available in this case.
– Incorrect manual configuration can lead to significant network problems. The expert knowledge of a network administrator is required for configuration.
– The data connection utilises part of the bandwidth of the network. Interactions with other medical devices cannot be completely ruled out. Apply the IEC 80001-1 standard for risk assessment.
– The device is not suitable for direct connection to the public internet.

Network configuration

Various options are available for network configuration:
✓ Automatic configuration via DHCP (recommended).
✓ Automatic configuration via Auto-IP for direct connection of unit and computer.
✓ Manual configuration.
› Configure the network settings of the unit using the software or, if available, the touch screen.
› Check the firewall and release the ports, if applicable.

Network protocols and ports

Port	Purpose	Service
45123 UDP, 45124 UDP	Unit recognition and configuration	
1900 UDP	Service indicator	SSDP / UPnP
502 TCP, 8080[1)] TCP, 2005 TCP	Device data	
514[1)] UDP	Event log data	Syslog
22 TCP, 23 TCP	Diagnosis	SSH, Telnet
123 UDP	Time	NTP
2006	Diagnosis	

1) The port may vary depending on the configuration.

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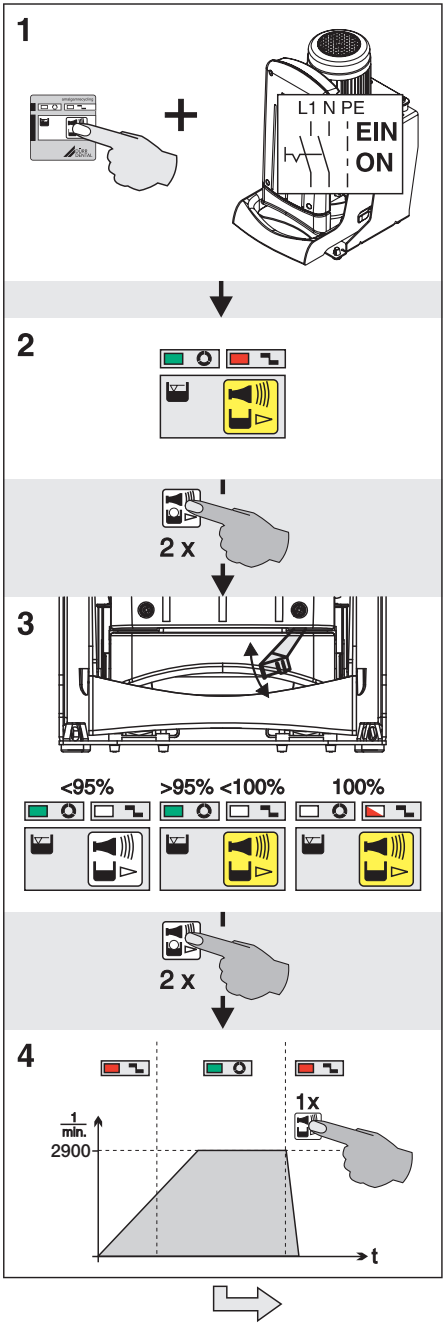
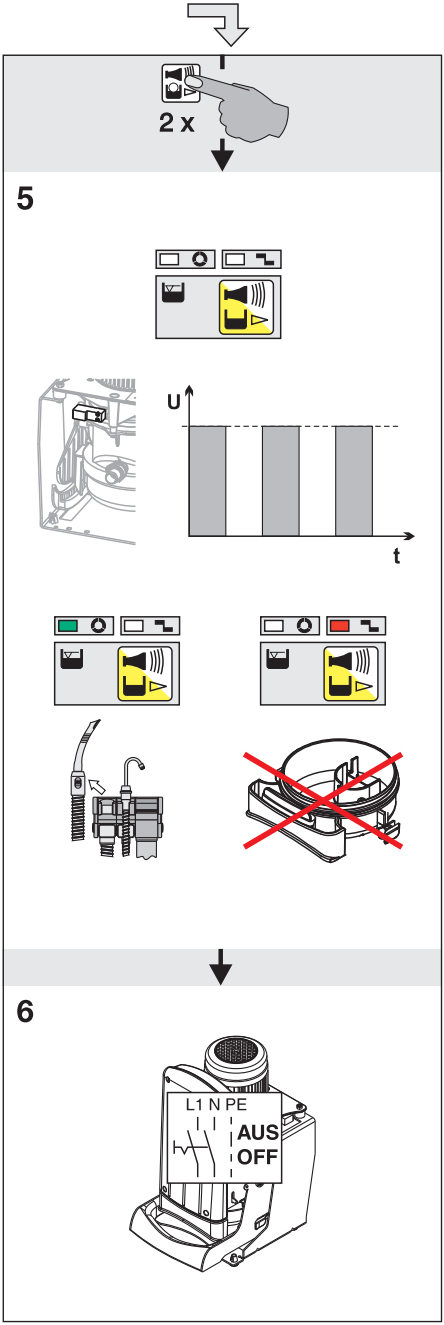
10 Service program





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11 Description of the service program

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.

11.1 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.

11.2 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.

11.3 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. Lifting the sediment level check wire strip allows the simulation of various sediment levels. The various fill levels are shown by LEDs H100 - H102 on the sediment measuring PCB (main board):
H100 = 100% fill level
H101 = >95% fill level
H102 = <95% fill level
Check:
- Lift the wire strap on the sediment scanner until H100 illuminates (red LED = 100% fill level). Hold onto the wire strap.
- Press the service key on the display panel.
- Wait briefly until the appropriate LED illuminates on the display panel.
- Repeat procedure with H101 and H102.

11.4 Motor start - motor braking

The drive motor starts and is then braked approx. 30 seconds. If the service key is pressed within this time period, the motor will be braked immediately.
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.

11.5 Input and output signals

- After activating the program point, the yellow LED on the display panel flashes. In addition, H5 and H7 will flash on the main PCB.
- A cycled DC voltage (approx. 22-30 V) can be measured on the ventilation solenoid valve connection (X7).
- If the collecting container is opened, the red LED on the display panel lights up, as do H8 on the main board and H104 on the sedimentation scan PCB.
- If voltage is applied to connector X5 (external start), the green LED on the display panel lights up together with H4 and H6 on the main PCB.

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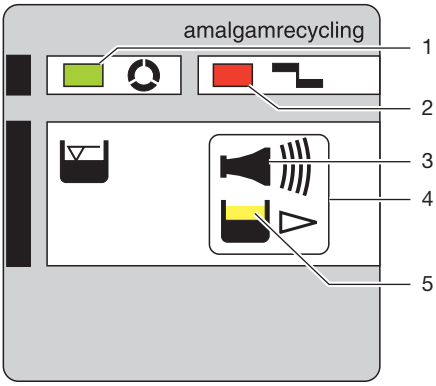
Usage

12 Display/handling



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

12.1 Ready for operation

GREEN LED lights up

12.2 Amalgam collector vessel is 95% full

Yellow LED lights up

GREEN LED lights up

Audible signal melody sounds

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

We recommend changing the amalgam collecting container when it reaches 95% full.

12.3 Amalgam collector vessel is 100% full

Yellow LED lights up

Red display flashes

Audible signal melody sounds

– At a fill level of 100% the signal melody can no longer be switched off by pressing the reset button.
– The collecting container needs to be replaced.

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

– The separator will not be ready for operation again until the amalgam collecting container has been replaced

12.4 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.

12.5 Motor fault

Red display and

green LED flash alternately

Audible signal

Occurs during the start-up of the amalgam separator.

– Press the reset button briefly to switch off the audible signal.
– If the reset button is pressed for longer than 2 seconds the unit can be restarted.

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If this problem happens again on the same day, the amalgam separator will no longer be operational - notify the service technician.

12.6 Brake monitoring

Red display and

green LED flash alternately

Audible signal

Occurs upon braking action of amalgam separator.

– Press the reset button briefly to switch off the audible signal.
– The amalgam separator is still operational.

If this problem occurs on several consecutive days, the braking must be checked by a service technician.

12.7 Emergency start sensor in overfill position

Yellow LED flashes

GREEN LED illuminates

– The yellow LED extinguishes when the emergency start sensor is free again.

If the yellow LED flashes for a prolonged period, check whether any foam is present in the collecting container.

13 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.

13.1 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.

13.2 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.

13.3 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 l water after the application time.

14 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.

Only use original amalgam collecting container.

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

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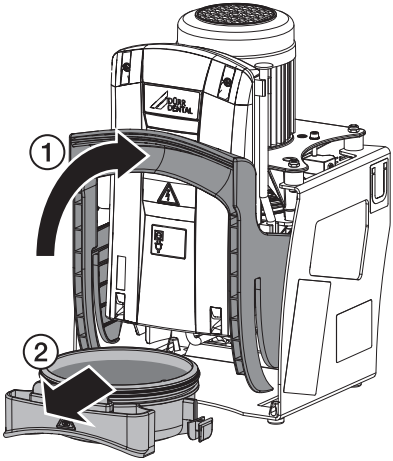
14.1 Remove the amalgam collecting container from the device

› Swivel the vessel lift upwards and remove the full amalgam collecting container from the unit.



14.2 Disposal of amalgam collecting container

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

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

15 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
Dependent upon the level of usage of the device	› Replace the amalgam collecting container when a fill level of 95% or 100% is indicated on the display panel **Notes concerning prophy powders:** The function of the amalgam separator is not adversely affected by conventional prophy powders. Under certain circumstances however, increased soiling of lines and hoses and a more frequent changing of the amalgam collecting container can be expected.
Annually	› Cleaning of the suction unit in accordance with the operating instructions. › Check the fluid sensors for soiling and clean if necessary. * › Check the inlet and outlet hoses for signs of deposits/blockage or cracks and replace where necessary. * › Check the pump propeller for damage and replace if necessary. * › Check the non-return valve and replace it if necessary. *
Every 3 years	› Replace the fluid sensor. *
Every 5 years	› Check that the centrifugal drum is seated tightly on the shaft, check for soiling and replace if necessary. *

* to be done by service technicians only

15.1 Tests

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WARNING

Infection due to contaminated unit

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

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

Annual inspection

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

Work steps to be performed:

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

Inspection of the general operating condition every 5 years

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

✓ Empty collecting container
✓ Measuring beaker

Work steps to be performed:

› Fill the collecting container with water (min. 900 ml) and insert it into the unit.
› Start the device and wait until it switches off again.
› Once the device has switched off, remove the collector vessel and measure the remaining amount of water.

The unit is working correctly if:

– There is at least 610 ml left in the amalgam collecting container.

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

Troubleshooting

16 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 mains voltage	› Check the mains supply voltage. * › Check the fuses and replace if necessary. *
	Undervoltage	› Measure the supply voltage; call an electrician if necessary. *
	Control electronics defective	› Replace the electronics. *
Device not "ready for operation" **No display on the display panel.**	The main power switch of the treatment unit or surgery is not switched on	› Main power switch ON.
	If an external display panel is fitted: cable not correctly connected	› Check cable connections. *
	Fuses have tripped	› Replace the fuses on the control PCB. *
Unit does not start when fluid enters it	Fluid is not detected by sensors (occurs mainly if water is very soft)	› Adjust the sensitivity of the sensors (connector X10) * or add approximately 20-30 ml of Orotol or other similar disinfectant to improve the conductance of the fluid in the collecting container.
	Soiled sensor	› Clean the sensor. *

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Error	Possible cause	Remedy
The unit does not switch off	Start signal from sensor, e.g. due to soiling	› Clean the sensor. *
	Fluid in the collecting container is not pumped out	› Check that the pump propeller is seated tightly and look for signs of damage. Replace if necessary. *
	Waster water line/siphon trap dirty	› Clean the waste water line/ siphon trap *
Water escapes from the relief valve when the unit is switched on	The unit is flooded by water from the outlet	› Check that the outlet has sufficient incline and is not blocked. *
	The unit is flooded by water from the suction unit	› Check the suction unit for leakage. *
Display panel working improperly or not at all	Terminals swapped	› Check the terminal assignment and connect correctly. *
	Cable too long (line resistance too high)	› Replace the existing cable with one of greater cross-section. *

* Only to be done by service technicians.

17 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).

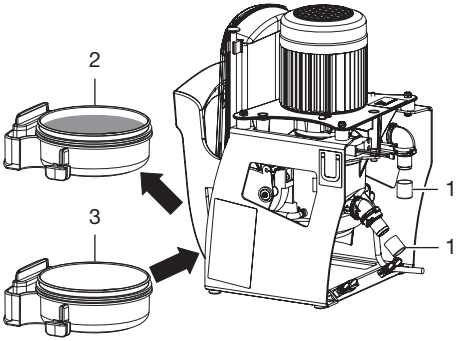
› Before disassembly, clean and disinfect the suction unit and the unit using a suitable disinfectant approved by Dürr Dental.

› Disinfect a defective unit using a suitable surface disinfection agent.

› Seal all connections with sealing caps.

› Pack the unit securely in preparation for transport.

17.1 Close CA 4



1 Sealing cap (order no. 9000-412-98)
2 Filled collecting container
3 Empty collecting container

Appendix

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18 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:

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