SepaStar amalgam separator

EN-US Installation and Operating Instructions

CE

Rx Only

AIR TECHNIQUES equipped for life

780520004OL29 2601V002

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

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Important information

1 About this document

These installation and operating instructions are an integral part of the unit.

The manufacturer and the distributor accept no responsibility or liability for safe operation and reliable functioning of the device if the information and instructions contained in these installation and operating instructions are not observed.

The German version of the installation and operating instructions is the original manual. All other languages are translations of the original manual. These installation and operating instructions apply to:
CA 4 (SepaStar)
REF: 7805200060 (A1700)

1.1 Warnings and symbols

Warnings

The warning notes in this document highlight possible injury to persons or damage to machinery.
They are marked with the following warning symbols:


General warning symbol


Warning – risk of dangerous electric voltages


Warning - biohazard

The warnings are structured as follows:

SIGNAL WORD

Description of 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 different levels of danger:

– **DANGER**
  Direct 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

Miscellaneous symbols

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

Note, e.g. specific instructions regarding the efficient use of the unit.

Take note of the accompanying electronic documents.


Disconnect all power from the unit.


Wear hand protection.


Wear eye protection.


Use a face mask.


Do not sit on the unit


Do not climb onto the unit


Water


Sunrise / morning

Lower and upper temperature limits

Lower and upper humidity limits


Do not reuse


Device in operation


Operation of the unit is interrupted


Audible signal/melody is issued


Protective ground connection


CE mark


SGS-tested product safety

Rx Only Caution: By virtue of Federal Law (US-FDA 21CFR801.109), the device may only be sold to dentists or bought on behalf of a dentist.

REF Part number

SN Serial number

HIBC Health Industry Bar Code (HIBC)


Manufacturer


Distributor

1.2 Copyright information

All circuits, processes, names, software programs, and devices mentioned in this document are protected by copyright.
Any reprinting of the installation and operating instructions, in whole or in part, is only permitted with the written approval of the owner of the corresponding rights.

2 Safety

The unit has been developed and designed appropriately such that hazards are largely excluded if the unit is used in accordance with its Normal Use.
Despite this, the following residual risks can remain:

- Personal injury due to incorrect use/misuse
- Personal injury due to mechanical effects
- Personal injury due to electric shock
- Personal injury due to radiation
- Personal injury due to fire
- Personal injury due to thermal effects to skin
- Personal injury due to lack of hygiene, e.g. infection

2.1 Intended use

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

2.2 Normal 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 consequence, this device is suitable for installation within medical supply equipment.
– Where this device is integrated in other medical supply equipment, the requirements of EU Medical Devices Regulation 2017/745 and the relevant standards must be observed.

2.6 Specialist 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

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

2.7 Notification requirement of serious incidents

The operator/patient has to report any serious incident related the product to the manufacturer and the competent authority of the Member State, in which the operator and/or patient is established/resident.

2.8 Protection from electric shock

– Comply with all the relevant electrical safety regulations when working on the unit.
– Never touch the patient and unshielded plug connections of the device at the same time.
– Replace damaged cables or plugs immediately.

Comply with the EMC rules concerning medical devices

Non-compliance with the EMC instructions can have a negative impact on the service life of the product, meaning that the service life declared by the manufacturer is then no longer guaranteed.

– The unit is intended for use in professional healthcare facilities (in accordance with IEC 60601-1-2). If the unit is operated in any other environment, potential effects on the electromagnetic compatibility must be taken into account.
– Do not operate the unit in the vicinity of RF surgical instruments or MRT equipment.
– Maintain a minimum distance of at least 12 inches between the unit and other electronic devices.

– Keep a minimum distance of 12 inches between the unit and portable 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-authorized accessories

› Only use accessories that have been specified or approved by the manufacturer.
› The use of any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an faulty 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 genuine parts

– Only use accessories and optional items that have been recommended or specifically approved by the manufacturer.
– Only use original working parts and spare parts.

Manufacturer and distributor accept no liability for damage 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 items or non-genuine wear parts / replacement parts (e. g. mains cable) can adversely affect the 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.

Manufacturer and distributor shall not accept any responsibility or liability for damage occurring during transport due to the use of faulty 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 disposal company to take the relevant safety precautions.

– Decontaminate potentially contaminated parts before disposal.
– 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.

Scan the QR code for more information on replacement and disposal.

Product description

3 Overview

SepaStar amalgam separator
Model with 220 V / 1~, 60 Hz A1700

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations may apply due to country-specific requirements and/or import regulations):

SepaStar amalgam separator A1700

- Amalgam separator
- Set of connection fittings
- Flow restrictor set
- Hose ø 20 mm
- Display panel
- Cable for display panel, 1 m
- Quick installation guide

3.2 Optional items

The following optional items can be used with the device:

Wall bracket 7130-190-00
Bracket for floor-mounted installation 7130-191-00

3.3 Consumables

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

Disposable amalgam container for SepaStar A1702
Monarch CleanStream Evacuation System Cleaner (2.5 liter bottle) 57850

3.4 Wear parts and spare parts

The following wear 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
Non-return valve (pack of 3) 7128-100-03E
Sediment sensor 7805-009-55
Ventilation 7805980008
Flow restrictor set 7805980010

Information on replacement part is available at the portal for specialist dealers: *www.airtechniques.com*.

4 Technical data

Electrical data		A1700
Voltage	V	220
Mains frequency	Hz	60
Rated power	W	310
Nominal current	A	1.4
Fuses* (2x)		T 4.0 AH
Type of protection		IP 20
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	12-24 AC/DC

Media and connections		
Fluid volume min. max.	 l/min l/min	 0.1 9
Usable volume, disposable amalgam container, approx.	cu in	36.6
Replacement interval	Months	9 - 12
Dürr Connect inlet and outlet connection	inch	Hose 0.79 (internal)

General data		
Speed	rpm	3470
Duty Cycle		S1 (100%)
Dimensions (H x W x D)	cm inch	41 X 25 X 32 16.14 x 9.84 x 12.6
Weight	kg lbs	11 24.24
Separation rate *	%	≥ 99

* according to ISO 11143

Network connection		
LAN technology		Ethernet
Standard		IEEE 802.3u
Data rate	Mbit/s	100
Connector		RJ45

Network connection		
Type of connection		Auto MDI-X
Type of cable		≥ CAT5
Ambient conditions during storage and transport		
Temperature	°F	+14 – +140°F
Relative humidity	%	< 95
Ambient conditions during operation		
Temperature	°F	+50 – +104°F
Relative humidity	%	< 70
Classification		
Medical Device Class (MDR)		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: 2015, modified + A1:2016 + A2:2019		Compliant
Electromagnetic interference radiation CISPR 11: 2015, modified +A1:2016 +A2:2019		Compliant
Emission of harmonics IEC 61000-3-2:2018 + A1:2020 + ISH1:2021		Compliant
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3:2013 + A1:2017 + A2:2021 + A2:2021/COR1:2022		Compliant
Electromagnetic compatibility (EMC) Interference immunity measurements		
Immunity to interference,discharge of static electricity IEC 61000-4-2:2008		Compliant
Immunity to interference, high-frequency electromagnetic fields IEC 61000-4-3:2020		Compliant
Immunity to interference by near fields of wireless HF communication devices IEC 61000-4-3:2020		Compliant
Immunity to interference by rapid transient bursts – AC voltage grid IEC 61000-4-4:2012		Compliant
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012		Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements	
Immunity to interference, surges IEC 61000-4-5:2014 + A1:2017	Compliant
Immunity to interference, line-conducted disturbances induced by high-frequency fields – AC voltage grid 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 interference due to voltage dips, short interruptions and voltage fluctuations IEC 61000-4-11:2020 + COR1:2020	Compliant
Electromagnetic energy in close proximity IEC 61000-4-39:2017	Compliant

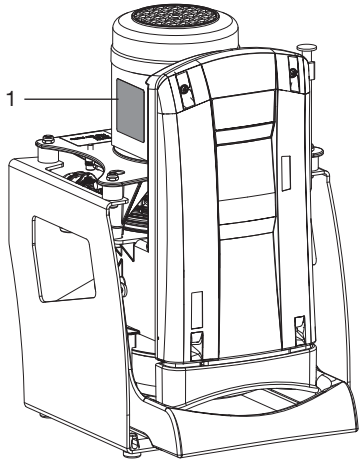
Immunity levels with respect to near fields of wireless HF communication devices		
Radio service	**Frequency band MHz**	**Test level V/m**
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE bands 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 supply input	
Immunity to interference by rapid transient bursts – AC voltage grid IEC 61000-4-4:2012 ± 2kV 100 kHz repetition frequency	Compliant
Immunity to interference, line-line IEC 61000-4-5:2014 + A1:2017 ± 0.5 kV, ± 1 kV	Compliant
Immunity to interference by surges, line-earth IEC 61000-4-5:2014 + A1:2017 ± 0.5 kV, ± 1 kV ± 2 kV	Compliant
Immunity to interference, line-conducted disturbances induced by high-frequency fields – AC voltage grid IEC 61000-4-6:2013 3 V 0.15 - 80 MHz 6 V ISM frequency bands 0.15 - 80 MHz 80 % AM at 1 kHz	Compliant
Immunity to interference due to voltage dips, short interruptions and voltage fluctuations IEC 61000-4-11:2020 + COR1:2020	Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP	
Immunity to interference,discharge of static electricity IEC 61000-4-2:2008 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012 ± 1kV 100 kHz repetition frequency	Compliant
Immunity to impulse voltages, conductor to earth IEC 61000-4-5:2014 + A1:2017 ± 2kV	not applicable
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

4.1 Model identification plate

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



1 Type plate

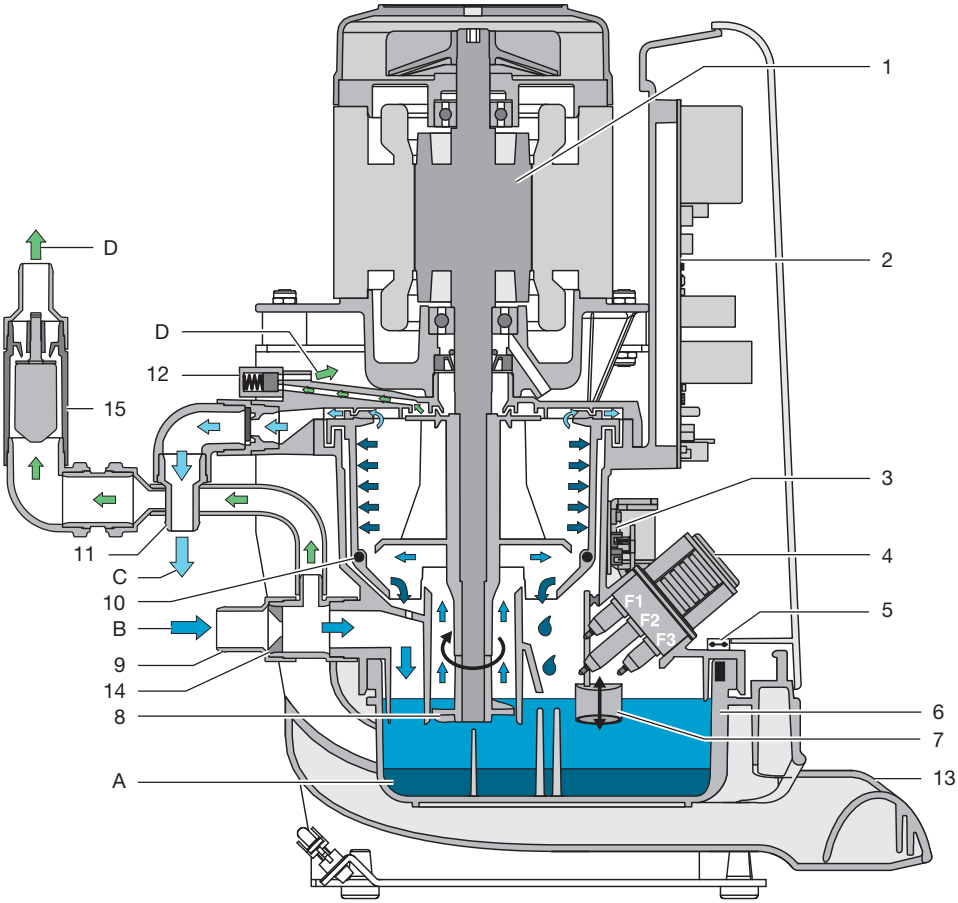
4.2 Conformity assessment

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

4.3 Approvals

Separation method compliant with	
ISO 11143 standard	Type 1

5 Function



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 Leveling pump
9 Inlet connecting piece
10 Magnets for RPM monitoring
11 Waste water outlet

12 Relief valve
13 Vessel lift
14 Flow restrictor
15 Ventilation
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 detected by the sensors, the sensitivity of the sensors can be increased via the electronics.
Fluid from the treatment unit flows directly into the amalgam collecting container via the water inlet. 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 leveling 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.
When installed in a suction system with a separating tank, the amalgam separator should be started via the input for an external starting signal at the same time as the signal for emptying the separating tank.
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 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 extinguishes when the emergency start sensor is free again.
The amalgam separator is monitored and emits both an optical and audible 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.

Installation

6 Requirements

6.1 Installation/setup room

The room chosen for set up should 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:
- As a central amalgam separator in a dry suction system with separating tank
- Upright on a level surface
- Mounted upright on a wall holder
- Mounted upright on a 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),
- Plasticizer-free 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 pipes 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

Separation from mains power supply:
The device does not have a main switch and must be disconnected from the power supply via an external isolating switch.

- Make sure 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.
- Note the current consumption of the devices that are to be connected.

The wire cross-section depends on the current consumption, line length and ambient temperatures of the units. For information concerning the current consumption, see the Technical Data enclosed with the units 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

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)

Control line

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

Connect the shielding of the cables in accordance with the regulations.

Display panel

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

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.

7 Installation

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

Separation from mains power supply:
The device does not have a main switch and must be disconnected from the power supply via an external isolating switch.

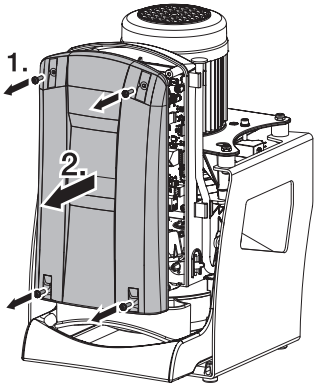
7.1 Important information for installation

Please read and apply the following information. This is an essential part of ensuring trouble-free operation.

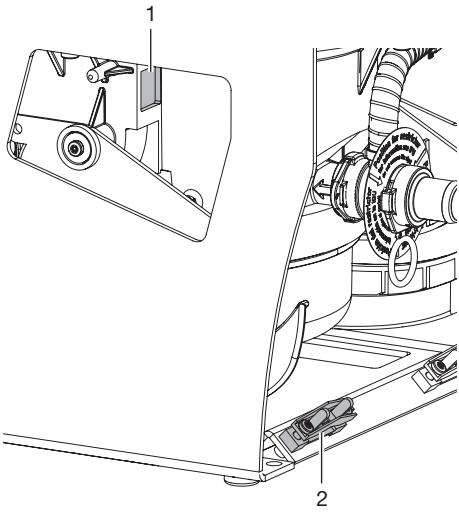
- At the water inlet of the SepaStar install a suitable flow restrictor that is appropriate for the installation conditions.
  For information about choosing the correct flow restrictor, please refer to the quick installation guide or the installation and operating instructions.
- Install the SepaStar as closely as possible to the Mojave Tank.
- The connecting hoses should be installed to be as short as possible. If necessary, shorten the hoses to the required length.
- Route the hoses with a continuous downward gradient towards the SepaStar. Avoid the formation of a siphon.
- The display must be mounted in such a way that the surgery personnel can see the signals at all times.

7.2 Connecting the external start and display panel to the SepaStar

1. Undo the four screws.
2. Remove the cover towards the front.



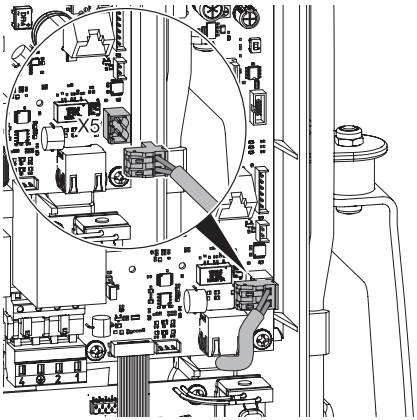
Cable entry and strain relief



1 Cable entry to the electronics
2 Strain relief

External start connection

1. Guide the connection cable with the connector for external starting through the conduit to the electronics on the housing of the SepaStar.
2. Connect the plug to connector X5.



3. Fix the connection cable with strain relief.

Connecting the display panel to the SepaStar

1. Connect the cable with RJ-45 connector to the SepaStar electronics (X8) and plug it into the RJ-45 socket for direct connection to the display panel.
2. Fix all cables with strain relief.
3. Close the electronics cover of the SepaStar properly.

7.3 Connecting the display panel

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.

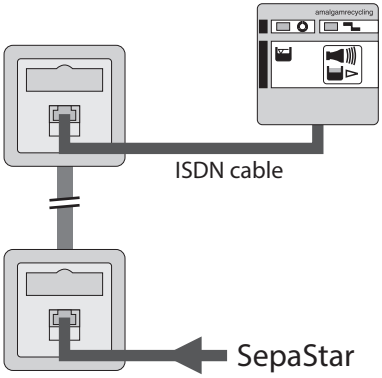
Installation, for example, on the wall next to or near low-voltage remote switches in the office.

Important: The LEDs on the display panel must be visible at all times.

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.

1. Connect display panel and RJ-45 socket using the ISDN cable supplied.



7.4 Electrical connection

WARNING

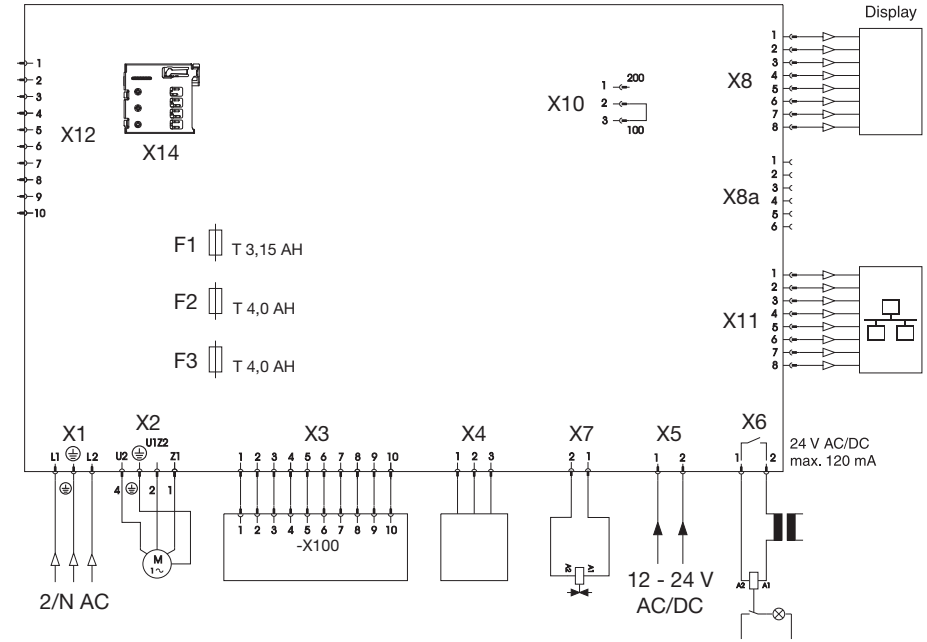
Electric shock

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

1. Check conductivity setting (jumper position X10) and adjust as necessary.
2. Establish the electrical connection to the supply network.

Separation from mains power supply:
The unit has no main power switch. An external mains disconnect must be installed upstream of the unit.

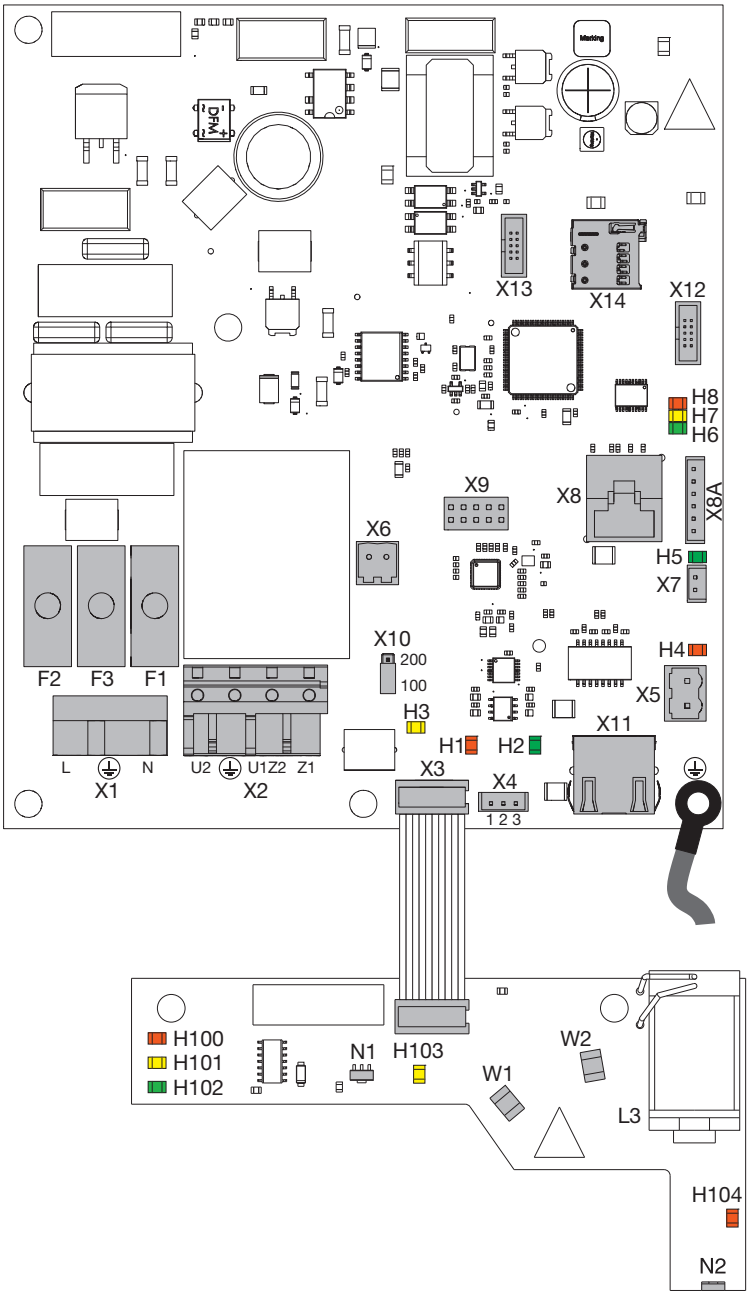
3. Connect the display panel.
4. Connect external start (optional, recommended for systems with separating tank).
5. Connect external signal (optional).
6. Connect the network (when monitoring via the network).



X1 Mains AC power connection
X2 Motor connection
X3 Sensor system connection
X4.1 Emergency start sensor
X4.2 Reference sensor
X4.3 Water start sensor

X5	External starting (optional input, safety extra-low voltage 12-24 V, AC/DC)
X6	External signal (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	Sensor sensitivity, conductivity value 100/200 µS
X11	Network connection 100 Mbit
X12	Diagnostic connector
X14	Micro SD card holder
F1	Fuse, brake, 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)

7.5 Connections and displays of the control panel



X1 Mains AC power connection

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 signal (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 program)
X12	Diagnostic connector
X13	Programming connector (J link)
X14	Micro SD card holder for data logger and update
F1	Fuse, brake, 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

7.6 Network connection

All connected IT units must demonstrably comply with the current edition of IEC 62368.

Purpose of the network connection

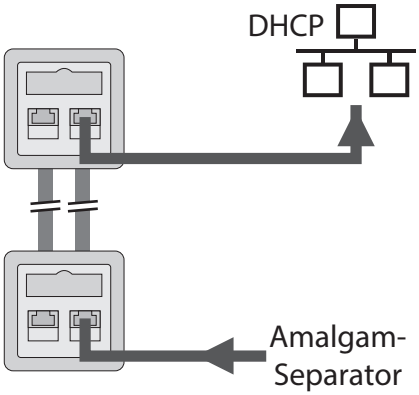
The network connection is used to exchange information or control signals between the unit and a software installed on a computer, in order to, e. g.:

- Display parameters
- Select operating modes
- Indicate messages and error situations
- Change device settings
- Activate test functions
- Transmit data for archiving
- Provide documents concerning the devices

Connecting the unit to the network

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

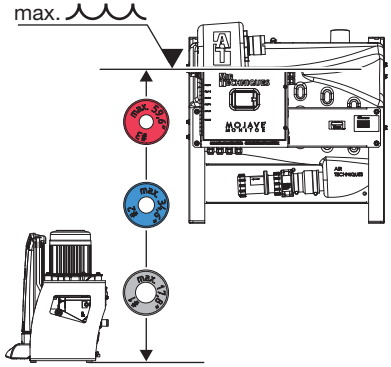
1. Remove the cover from the electronics.
2. Plug the network cable into the electronics and into a network socket.
3. Attach the network cable to the device.
4. Create a connection to the network in the practice with the network cable.



7.7 Installing the flow restrictor

To maintain a separation rate of at least 99%, the maximum flow rate of the liquid supplied must be reduced to 9 l/min.

The amount of fluid that flows into the amalgam separator depends on the height difference between the intake on the amalgam separator and the maximum water level of the connected devices. To limit the amount of fluid, an appropriate flow restrictor must be installed at the intake of the amalgam separator. Refer to the table below for help with selecting the required flow restrictor.



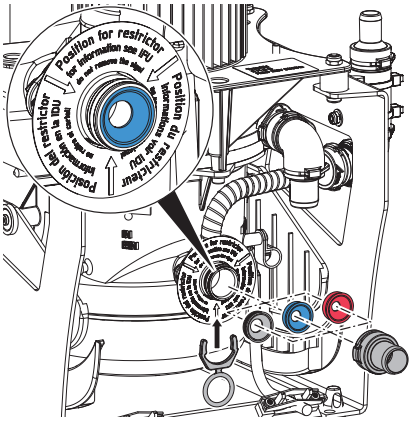
Height difference	Flow restrictor	
Min – 17.8"	#1	
17.9" – 34.6"	#2	
34.7" – 59.6"	#3	
> 59.7"	Not supported	

Device combinations with corresponding flow restrictor can be found in the attachment.

Flow restrictor #2 is already pre-installed, but it may need to be replaced by a suitable flow restrictor.

1. Select the required flow restrictor to suit the installation conditions.

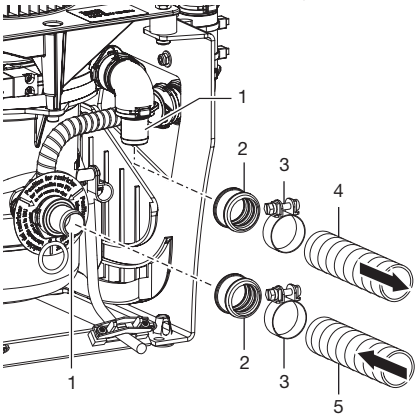
2. Insert the flow restrictor into the fitting of the ventilation.
3. Push the hose bushing onto the fitting and secure with a fixing ring.



7.8 Connecting and routing hoses

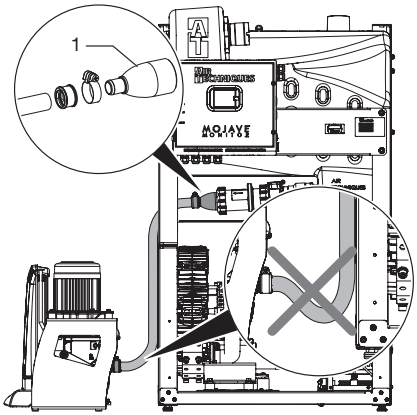
Install the hoses so they are as short as possible and with a gravity drain, without a siphon. This is the only way to avoid deposits in the hoses and ensure proper operation.

1. Position the SepaStar as close as possible to the tank module.
2. Cut the hoses to the required length.
3. Screw hose sleeves onto the hose ends.
4. Connect the hoses to the hose connectors and secure them with hose clamps.



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

5. Attach the tank connection for the outlet hose to the Mojave tank.

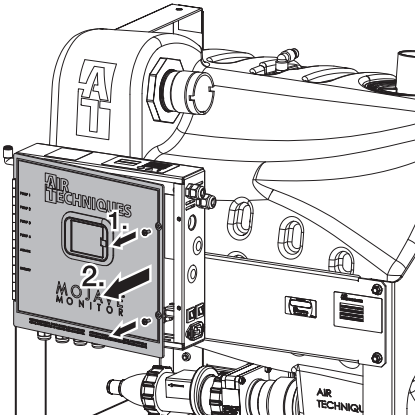


1 Tank connection

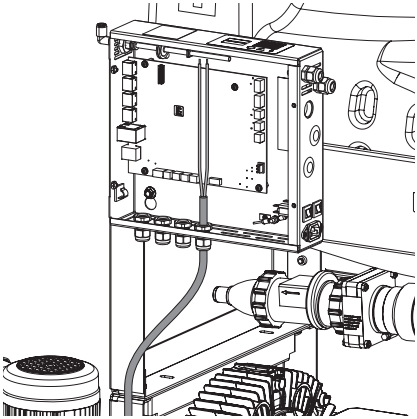
6. Check the hose length and shorten if necessary.
7. Tighten hose sleeves onto the hose ends.
8. Attach the hose to the tank connection and secure with a hose clamp.
9. Run the outlet hose from the SepaStar with an incline to the outlet and connect it there.

7.9 Connecting the external start to the Mojave

1. Loosen the two screws on the MMC-M cover.
2. Open the housing door.



3. Guide the connection cable for the external start to the MMC-M and through the strain relief for Aux/Alarm of the Mojave.
4. Connect the plug (X2) labeled “MMC-M” on the connection card into the plug connector (J18) of the MMC-M.
5. Plug the two flying leads of the connection cable into the plug connector (X1) labeled “START” at the top of the connection card and screw them together.
6. Secure the strain relief. Ensure that the cable is connected without mechanical tension.



7. Close the electronics cover of the Mojave properly.

8 Commissioning and first start-up

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

1. Turn on the unit power switch or the main surgery switch.
2. Carry out the electrical safety check in accordance with national and local regulations.
3. Check that coarse filters are installed in the units upstream of the amalgam separator.
4. Check that the ventilation is installed and the correct flow restrictor has been used.
5. Carry out a functional test.
6. Check the unit and connections for leak tightness.
7. Check that electronic covers are correctly mounted.

8.1 Measuring the conductivity of tap water

We recommend measuring the conductivity of the tap water at the installation site and adjusting the sensitivity of the conductivity sensor.

The sensitivity of the conductivity sensor for the water start can be adjusted using jumper X10 on the control panel.
Jumper X10 is set by default on delivery to “100”.
Recommended set value:
– For conductivity > 320 µS: set jumper to position “200”.
– For conductivity ≤ 320 µS: set jumper to position “100”.

When the jumper is initially set to “200”:
If the unit does not start after a period of time despite water supply, reduce the sensitivity of the conductivity sensor (jumper position “100”) and check the unit starts safely. This can be caused by seasonal fluctuations in the water supply or contamination deposits on the sensor.

8.2 Monitoring the unit via the network

The following requirements must be met in order to monitor the device on the computer:
– Device 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

– Safety and essential performance features are independent of the network. The device is designed appropriately for operation independent of a network. However, some of the functions are not available in this case.
– Faulty manual configuration can lead to significant network problems. The expert knowledge of a network administrator is required for configuration.
– The data connection utilizes part of the bandwidth of the network. Interactions with other medical devices cannot be completely excluded. Apply the IEC 80001-1 standard for risk assessment.
– The device is not suitable to be connected directly 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.

1. Configure the network settings of the unit using the software or, if applicable, the touch screen.
2. Check the firewall and release the ports, if applicable.

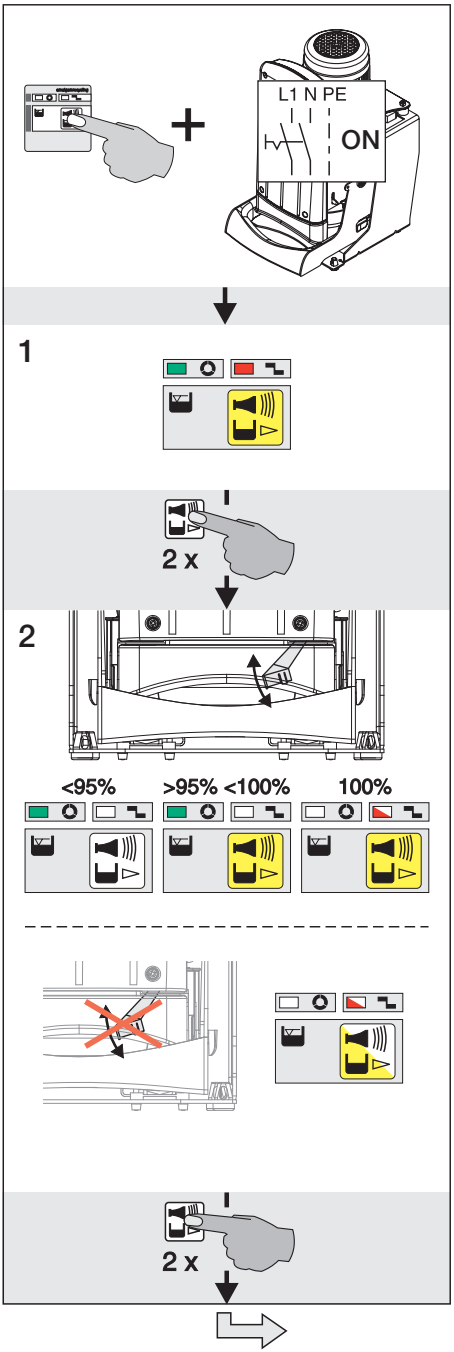
Network protocols and ports

Port	Purpose	Service
45123 UDP, 45124 UDP	Device recognition and configuration	

Port	Purpose	Service
1900 UDP	Service indicator	SSDP / UPnP
502 TCP, 8080[1] TCP, 2005 TCP	Unit data	
514[1] UDP	Event protocol data	Syslog
22 TCP, 23 TCP	Diagnosis	SSH, Telnet
123 UDP	Time	NTP
2006	Diagnosis	

1) The port can vary depending on the configuration.

9 Service program



10 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 functions of the unit can be checked with the aid of the service program.
The individual program steps are as follows:
– Display test
– Measurement of the sediment filling level
– Motor start and motor brake with speed check
– Input and output signals

Function of the service key:
– Pressing the service key twice calls up the next individual program steps.
– Pressing the service key once causes the present program step to be repeated.

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

10.1 Service program ON/OFF

On
– Press and hold 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 voltage 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 being checked. All three LEDs must light up. There is also a signal melody that can be switched off by pressing the service key.

10.3 Measurement of the sediment filling level

While the service program is activated, the safety check for the collecting container is deactivated.

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

Every time the service key is pressed, the sediment filling 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:
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.

Fill level measurement fault
If no level measurement is carried out due to a fault or defect, the red and yellow LEDs flash synchronously.

10.4 Motor start - motor brake

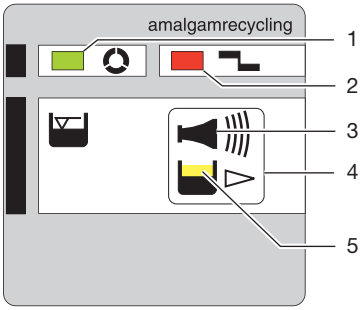
The drive motor starts and is then braked after approx. 30 seconds. If the service key is pressed within this time period, the motor will be braked immediately.
This procedure can be repeated by pressing the service key 1x again.
The drive motor starts up.
As a result of the rpm monitoring, the LED will change from orange to green upon start-up and from green to orange upon braking.

10.5 Input and output signals

– After activation of this program item, 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.

Usage

11 Display / operation



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

11.1 Ready for use

Green LED lights up

11.2 Amalgam collecting container is 95% full

Yellow LED lights up

Green LED lights up

Audible signal melody is issued

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

We recommend replacing the amalgam collecting container at a filling level of 95 %.

11.3 Amalgam collecting container is 100% full

Yellow LED lights up

Red LED flashes

Audible signal melody is issued

– At a filling 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 use" again until the amalgam collecting container has been replaced

11.4 Fill level measurement fault

Red LED and

yellow LED flash simultaneously

Audible signal

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

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

11.5 No amalgam collecting container inserted

Red LED flashes

Audible signal

– Press the reset button briefly to switch off the audible signal.
– Switch off the unit.
– Insert the collecting container.
– Switch the device on.
– Green LED lights up – "Ready for use“

If this error message occurs when the collecting container is correctly inserted, this indicates that there is a technical defect – notify your Service Technician.

11.6 Motor fault

Red LED and

green LED flash alternately

Audible signal

Occurs during the start-up of the amalgam separator.

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

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

11.7 Brake monitoring

Red LED 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 action must be checked by a service technician.

11.8 Emergency start sensor in overfill position

Yellow LED flashes

Green LED lights up

– 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.

12 Cleaning

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

"12.1 Suctioning water"	After each treatment
"12.2 Daily cleaning"	Daily in the evening after the end of treatment, After higher workloads, before the midday break and after the end of treatment for the day

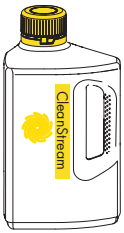
NOTICE

Device malfunction or damage due to the use of incorrect media

Guarantee claims may become invalid as a result.

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

The following must be used:



– For cleaning:
  – Monarch Evacuation System Cleaner

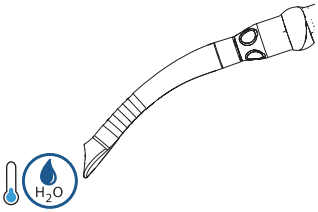
Observe the usage information of the cleaning agent.

12.1 Suctioning water

After each treatment:

1. Suction up cold water (min. 0.5 liters) with the large and small suction hoses. Do this even if only the small suction hose was actually used during treatment.

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



12.2 Daily cleaning

Clean the suction hose daily in the evening after the end of treatment.

After higher workloads, clean twice a day, e.g. before the midday break and at the end of treatment.

The following are required for cleaning the suction system:

Non-foaming cleaning agent that is compatible with the materials
– Monarch Evacuation System Cleaner

Care system
– e.g. Monarch Dispenser System

The cleaning process is described below with the Monarch Evacuation System Cleaner and Monarch Dispenser System.

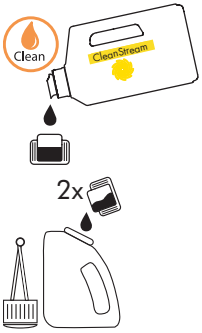
Wear hand protection.

Wear eye protection.

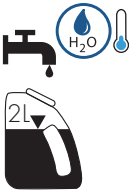
1. For pre-cleaning, suction up approx. 2 liters of water with the care system.

Adding solution to the care system:

1. Pour 2 sealing caps (40 ml) of Monarch Evacuation System Cleaner into the Monarch Dispenser System.



2. Fill up the Monarch Dispenser System with 2 liters of cold water.



3. Close the care system.

4. Mix the solution.

Using the solution:

1. Attach the suction hose to the care system and suction up 1 liter of solution.

2. Pour the remaining solution into the spittoon.

3. Allow to work for a minimum of one hour or leave overnight.
4. When placing the system back into operation, suction up 2 liters of water.

13 Replace the amalgam collecting container

NOTICE

Contamination hazard if the amalgam collecting container is reused if the collecting container is not water-tight.

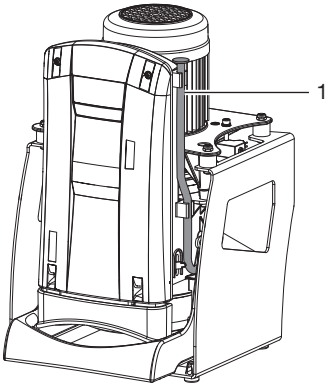
› Do not re-use the collecting container (disposable item).

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

We recommend changing the amalgam collecting container only in the morning before you commence working. This prevents fluid from dripping out of the drum while it is being changed.

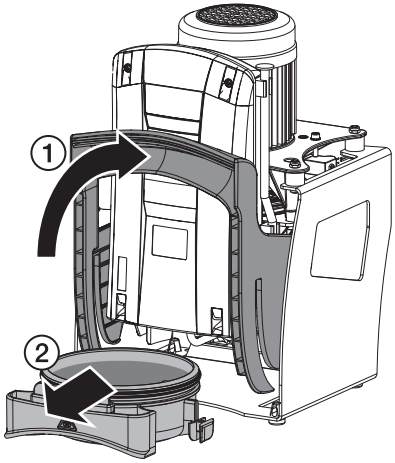
Depending on the work processes in the practice, it is recommended to start the suction machine. This prevents water from flowing out of the separating tank, as the outflow check valve is closed due to negative pressure.

1. Disconnect all power from the SepaStar.
2. Before opening the vessel lift, check whether the unit is flooded.
   To do this, take the transparent hose from the holder, remove the cap and check whether water can be removed.



1 Transparent hose

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



4. Close and secure the full amalgam collecting container using the cap. Note the markings on the cap and on the collecting container.
5. Place the securely closed amalgam collecting container into its original packaging and seal it.
6. Insert a new amalgam collecting container in the unit and clamp it in position.

Only use original amalgam collecting container.

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

13.1 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 into the environment!

– Dispatch to an authorized waste disposal company. More information is available at www.airtechniques.com

14 Maintenance

All maintenance work must be performed by qualified personnel or a Service Technician.

WARNING

Infection due to contaminated unit

- Clean and disinfect the suction system before working on the unit.
- Wear protective equipment during your work (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 power.

Separation from mains power supply:
The device does not have a main switch and must be disconnected from the power supply via an external isolating switch.

Maintenance interval	Maintenance work
Dependent upon the level of usage of the device	› Change the amalgam collecting container when a fill level of 95% or 100% is indicated on the display panel or annually per local regulations **Notes concerning prophy powders:** The amalgam separator is not functionally affected by conventional prophy powders. Under certain circumstances however, increased soiling of lines and hoses and a more frequent need to change the amalgam collecting container can be expected.
Annually	› 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 them where necessary. * › Check the pump propeller for damage and replace as required. * › Check the non-return valve and replace as required. * › Check the sediment sensor for damage and replace as required. * › Check the flow restrictor and ventilation at the fluid intake for soiling and damage and clean or replace as required. *
Every 3 years	› Replace the fluid sensor. * › Replace the flow restrictor. * › Replace the ventilation. *
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

14.1 Recommended tests

WARNING

Infection due to contaminated unit

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

We recommend regular inspection of the amalgam separator to ensure that it functions properly.

Annual inspection

Work steps to be performed:

1. General functional check (e.g. suction, spittoon inlet)
2. During the measurement of the sediment filling level, inspect the operability of the sediment sensor by eye.
3. Service program

Device with network connection

This test should be performed as an additional test if the device is monitored with software via the network.
Requirements for the test:

✓ Device connected to the network.
✓ Monitoring software running.

Work steps to be performed:

1. Check whether any messages are displayed on the PC monitor.
2. Check the acoustic signal.

Inspection of the general operating condition every 5 years

For inspection, the following are required:

✓ Empty collecting container
✓ Measuring beaker

Work steps to be performed:

1. Fill the collecting container with water (min. 900 ml) and insert it into the unit.
2. Start the device and wait until it switches off again.
3. 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

15 Tips for operators and service technicians

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

WARNING

Infection due to contaminated unit

- Clean and disinfect the suction system before working on the unit.
- Wear protective equipment during your work (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.

Separation from mains power supply:
The device does not have a main switch and must be disconnected from the power supply via an external isolating switch.

Error	Possible cause	Remedy
Device does not start-up	No mains voltage	› Check the mains supply voltage. * › Check the fuses and replace them, 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 practice 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. *

Error	Possible cause	Remedy
Fill level measurement fault	Cable connection to main board not plugged in or interrupted	› Plug in the cable connection to the main board. * › Check the cable connection for damage and replace if necessary. *
	Fill level monitoring PCB defective	› Replace level monitoring PCB. *
	Sediment sensor coil defective	› Replace level monitoring PCB. *
	Light barrier defective	› Replace level monitoring 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). *
	Soiled sensor	› Clean the sensor. *
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. *
	Unit is flooded by water from the suction unit	› Check the suction unit for leakage. *
Display panel not working properly or not at all	Cable too long (cable resistance too high)	› Replace the existing cable with one with a larger cross-section. *

* May be done by Service Technicians only

16 Transporting the unit

WARNING

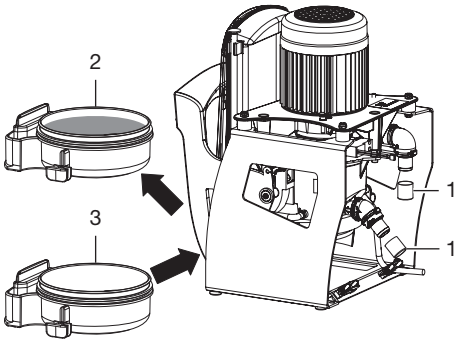
Infection due to contaminated unit

- 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)

1. Prior to disassembly, clean and disinfect the suction unit and the device via by aspirating a suitable disinfectant that has been approved by the manufacturer.
2. Disinfect a defective unit using a suitable surface disinfection agent.
3. Seal all connections with sealing caps.
4. Pack the unit securely in preparation for transport.

16.1 Close device



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

Appendix

17 Unit combinations

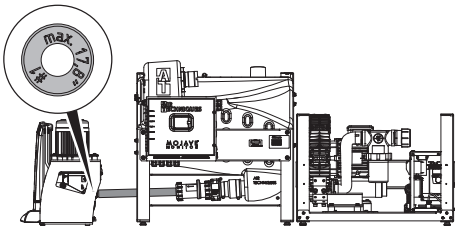


Fig. 1:

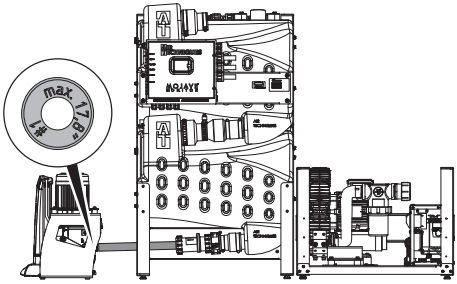


Fig. 2:

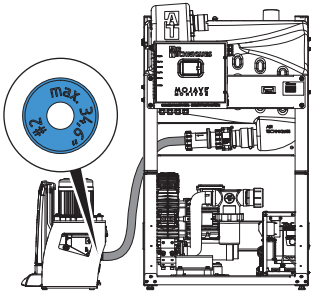


Fig. 3:

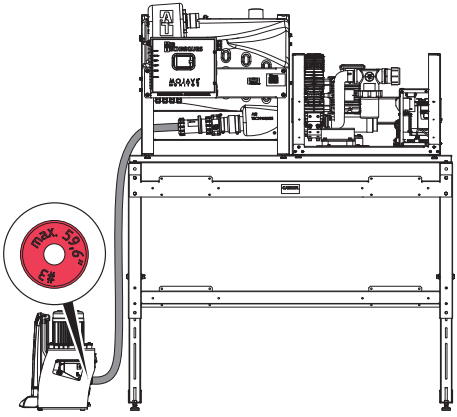


Fig. 4:

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