Sepamatic

EN

Installation and operating instructions

9000-605-04

DÜRR DENTAL

1904V001

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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.

1.1 Warnings and symbols

Warnings

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

General warning symbol

Biohazard warning

The warnings are structured as follows:

> **SIGNAL WORD**
>
> **Description of the type and source of danger**
>
> Here you will find the possible consequences of ignoring the warning
>
> › Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

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

Other symbols

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

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

Refer to Operating Instructions.

Wear protective gloves.

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

CE labelling

REF Order number

SN Serial number

Fuses

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. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose

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

2.2 Intended use

The separation system is intended for installation in the suction line of a dry suction system after the manifold.
Service, maintenance, recurring tests and cleaning must be performed in accordance with the manufacturer's information.
The permissible flow rate must be observed.

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damage resulting from improper usage. In such cases, the user/operator will bear the sole risk. This includes:

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

2.4 Systems, connection with other devices

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

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

2.5 General safety information

› Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.
› Check the function and condition of the unit prior to every use.
› Do not convert or modify the unit.
› Comply with the specifications of the Installation and Operating Instructions.
› The Installation and Operating Instructions must be accessible to all operators of the unit at all times.

2.6 Specialist personnel

Operation

Unit operating personnel must ensure safe and correct handling based on their training and knowledge.

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

Installation and repairs

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

2.7 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.

NOTICE

Negative effects on the EMC due to non-authorised accessories

- Use only Dürr Dental parts or accessories specifically approved by Dürr Dental.
- Using any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an erroneous operation mode.

NOTICE

Erroneous operation mode due to use immediately adjacent to other devices or with other stacked devices

- Do not stack the unit together with other devices.
- If this is unavoidable, the unit and other devices should be monitored in order to ensure that they are working correctly.

2.8 Only use original parts

- Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
- Only use only original wear parts and replacement parts.

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

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

2.9 Transport

The original packaging provides optimum protection for the unit during transport.
If required, original packaging for the unit can be ordered from Dürr Dental.

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

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

2.10 Disposal

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

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

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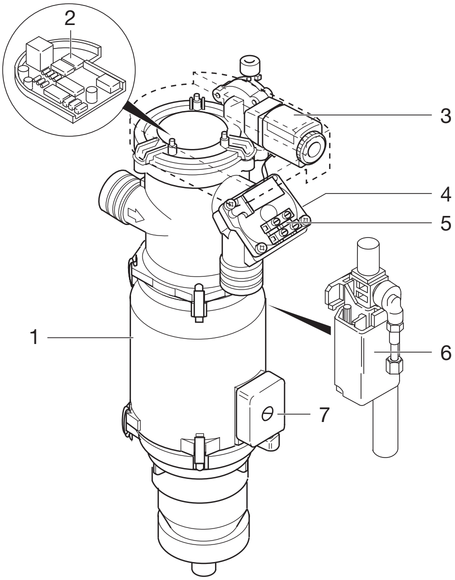
Product description

3 Overview



1 Sepamatic
2 Electronics module with fuse
3 Working valve
4 Shut-off valve
5 Connection terminals 24 V
6 Rinsing unit
7 Sensor connector

3.1 Scope of delivery

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

The following items are included in the scope of delivery:

Sepamatic 7100-100-5x
or
Sepamatic 7100-xx
or
Sepamatic 7101-xx

- Sepamatic
- or Sepamatic incl. rinsing unit
- Rinsing unit
- Installation and operating instructions

3.2 Accessories

The following items are required for operation of the device, depending on the application:
Safety transformer 24 V, 100 VA . . 9000-150-46

3.3 Optional accessories

The following optional items can be used with the device:
Rinsing unit 7100-120-00E
OroCup care system 0780-350-00

3.4 Consumables

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

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

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4 Technical data

4.1 Sepamatic

Electrical data		
Rated voltage	V	24 AC/DC
Frequency	Hz	50 / 60
Rated power without rinsing unit with rinsing unit	 VA VA	 6 8.4
Fuse IEC 60127-3T	mA	630

Media		
Fluid volume min. max.	 l/min l/min	 ≥ 0.1 ≤ 1.5
Air flow volume	l/min	≤ 300
Flow rate		high
The suction system must be suitable for a high flow rate in accordance with EN ISO 10637.		
Max. pressure	hPa/mbar	-160

General data		
Operating mode		S1 100% DC*
Dimensions (H x W x D)	cm	15 x 9 x 36
Weight, approx.	kg	1.0
Medical device (class)		I

* DC = duty cycle

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

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

Electromagnetic compatibility (EMC) Interference emission measurements	
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 on the cover	
Immunity to electrostatic discharge IEC 61000-4-2:2008 ± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant
Immunity to high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010 3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz	Compliant
Immunity to near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010 Refer to the table with immunity to interference levels for near fields of wireless HF communication devices.	Compliant
Immunity to power frequency magnetic fields IEC 61000-4-8:2009 30 A/m 30 Hz or 60 Hz	Compliant

Immunity to interference levels, near fields of wireless HF communication devices

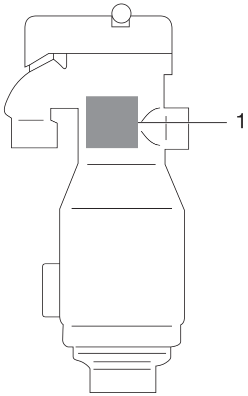
Radio service	Frequency band MHz	Test level V/m
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	1700 - 1990	28

Immunity to interference levels, near fields of wireless HF communication devices Radio service	Frequency band MHz	Test level V/m
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	2400 - 2570	28
WLAN 802.11 a/n	5100 - 5800	9

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

4.2 Type plate

The type plate is located on the rear side of the unit, to the left of the secretion inlet connection.



1 Type plate

4.3 Evaluation of conformity

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

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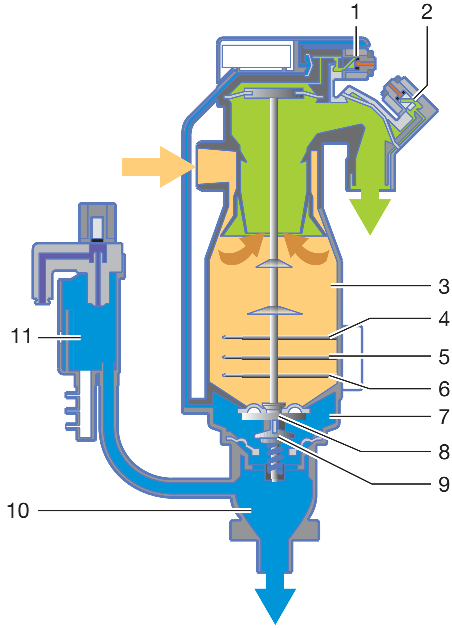
5 Operation



1 Working valve
2 Shut-off valve to the suction unit
3 Secretion chamber
4 Fluid level indicator sensor 3
5 Fluid level indicator sensor 2
6 Fluid level indicator sensor 1
7 Unit chamber
8 Lock valve
9 Waste valve
10 Outlet
11 Rinsing unit

Controller

The fill level of the secretion collector is detected via three fluid level indicator sensors. The clock frequency for opening and closing the lock valve and the outlet valve of the lock chamber is switched depending on the fill level via an electronic controller.

Basic clock rate

The clock frequency is approx. 6 cycles per minute.
(Lock throughput capacity: approx. 0.33 l/min).

Rapid cycle

If the fill level of the secretion chamber reaches the sensor F2, the system switches to the rapid cycle. The clock frequency is approx. 30 cycles per minute.
(Lock throughput capacity: approx. 1.5 l/min).

Overfill position

As soon as the fill level of the secretion chamber reaches the sensor F3, the separation process is temporarily interrupted. The shut-off valve to the suction unit is closed so that no secretion can pass into the suction line.

The lock valve and outlet valve of the lock chamber are opened simultaneously and all of the secretion drains off.
Once the lock chamber has been emptied, the separation process resumes and the shut-off valve is opened again. The valves of the lock chamber open and close again at the basic clock rate.

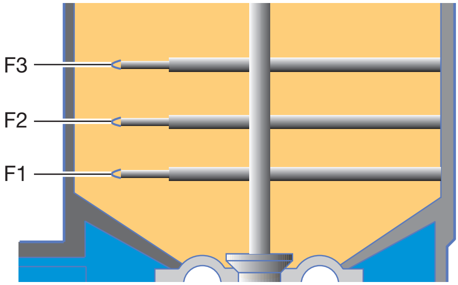


Fig. 1: Fluid level indicator sensors

F1 Sensor 1
F2 Sensor 2
F3 Sensor 3

5.1 Separation

Every time the suction hose is taken out of the hose manifold, the Sepamatic and the suction unit are started.
At the inlet connection, the aspirated secretion/air mixture is accelerated and set into a spiral motion in the cyclone separator. The resulting centrifugal forces sling the solid components against the outer wall. This separates the air from the secretion, and the air then escapes through the opened shut-off valve to the suction unit. The secretion collects in the secretion chamber.

5.2 Transfer through the lock

Atmospheric pressure passes via the working valve into the membrane chamber and actuates the valve tappet.
If the valve tappet is moved downwards, first the outlet valve is closed and then the lock valve is opened. The separated secretion flows into the lock chamber.
If the valve tappet is moved upwards, first the lock valve is closed and then the outlet valve is opened. The secretion flows out from the lock chamber and into the outlet.
The cycle frequency for opening and closing the valves is set by the electronic controller as a function of the fill level in the secretion chamber.

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Assembly

6 Requirements

6.1 Setup options

- In a dental treatment unit
- In the treatment room

6.2 Hose materials

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

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

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

The following types of hoses must not be used:

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

6.3 Installation and routeing of hoses and pipes

❯ Execute the on-site pipe installation in accordance with the applicable local regulations and standards.

❯ Lay the hose installation of the drains to or from the unit at a sufficient incline.

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

6.4 Information about electrical connections

❯ Ensure that the electrical connections to the mains power supply are established in accordance with current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.

❯ Install an all-pole disconnect switch with a contact opening width of at least 3 mm in the electrical connection to the mains power supply. It must be possible to secure the disconnect switch so that it cannot be inadvertently switched back on again.

❯ Install electrical lines without mechanical tension.

❯ Make the electrical connection via the main power switch of the treatment unit or via the main power switch of the practice.

6.5 Information about connecting cables

Mains supply cable

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

Wire cross-section

Unit feed:

– 0.75 mm²

Connection external valves / units:

– 0.5 mm²

7 Installation

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

7.1 Installation of the Sepamatic in treatment units

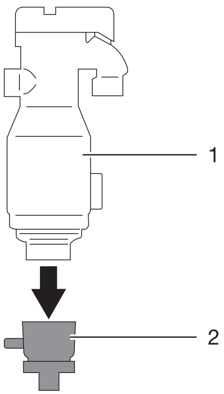
WARNING

Infection due to contaminated unit

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

Attach the unit vertically at a suitable position in the treatment unit.

› Push the Sepamatic into the mounting flange of the outlet.



1 Sepamatic
2 Outlet

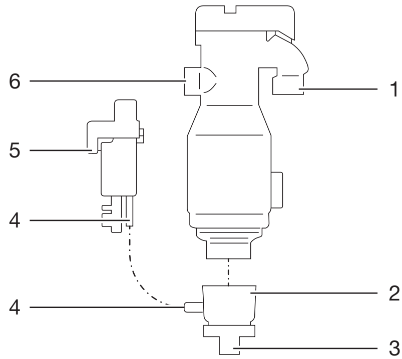
Inlet and outlet hoses

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

Recommended diameters of the connection hoses:

– Shut-off valve connection ∅ 32 mm
– Mounting flange ∅ 50 mm
– Outlet ∅ 22 mm
– Rinsing unit connection ∅ 10 mm
– Water inlet valve connection ∅ 4 mm
– Water inlet valve connection ∅ 4 mm

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



1 Shut-off valve connection
2 Mounting flange
3 Outlet
4 Rinsing unit connection
5 Water inlet valve connection
6 Secretion inlet connection

Rinsing unit

A rinsing unit with fresh water is to be installed before the Sepamatic if rinsing is not already provided by the treatment unit.

A rinsing unit is required for the suction system, e.g. in the treatment unit. The rinsing unit provides a small amount of water during aspiration. This dilutes the aspirated fluids (blood, saliva, rinsing water etc.), which can then be transported more effectively.
For further information refer to the rinsing unit installation and operating instructions

7.2 Electrical connections, controller

Power supply:

– Safety transformer order number: 9000-150-46

or

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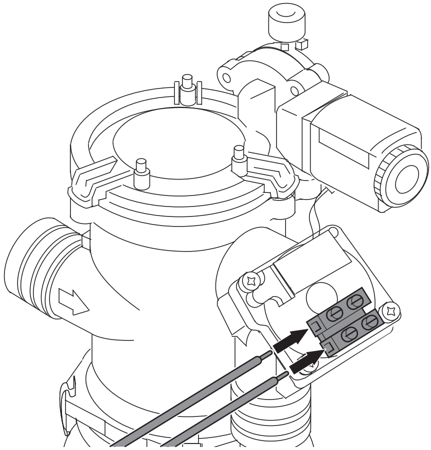
- Safety transformer 24 V AC with an isolator consisting of two means of patient protection (MOPP) between the mains circuit and secondary circuit, min. 100 VA, secondary fuse T 4 AH (or IEC 60127-2/V T 4 AH, 250 V)
- parallel to the manifold signal e.g. from the Dürr control box.

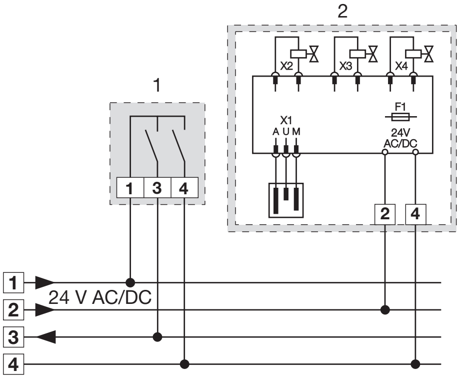
7.3 Electrical connections

› Connect the power supply to the connection terminals.



1 Connection terminals

7.4 Circuit diagram



1 Hose manifold
2 Sepamatic
F1 Fuse (IEC 60127-3T 630 mA)
X1 Fluid level indicator sensors
X2 Working valve
X3 Place selection/overfill valve
X4 Rinsing unit

8 Commissioning

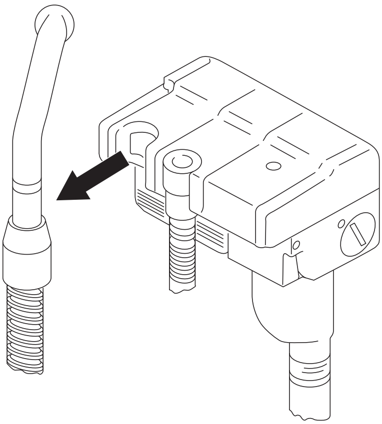
In many countries technical medical products and electrical devices are subject to regular checks at set intervals. The owner must be instructed accordingly.

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

8.1 Function test

Checking the basic clock rate

- Take a suction hose from the manifold.

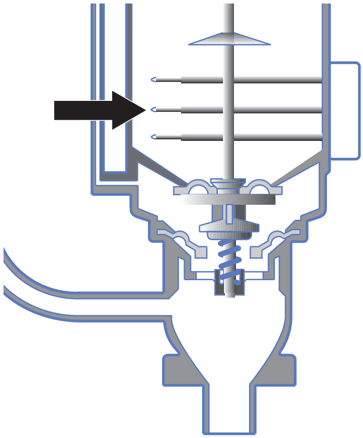


The suction unit starts up.
The Sepamatic is now running at its basic clock rate. The clock frequency is approx. 6 cycles/min.

- Visual inspection: through the semi-transparent separation container.
- Noise test: switching noises due to movement of the valve tappet.

Checking the rapid cycle

- Take a suction hose from the manifold.
  The suction unit starts up.
  The Sepamatic is now running at its basic clock rate. The clock frequency is approx. 6 cycles/min.
- Push on the cannula.
- Aspirate water from a vessel until the system switches from the basic clock rate into the working cycle.



The Sepamatic runs in the rapid cycle. The clock frequency is approx. 30 cycles/min.

- Perform a visual inspection and noise test in the same way as for "Checking the basic clock rate".

Checking the overfill position

- Take a suction hose from the manifold.
  The suction unit starts up.
  The Sepamatic is now running at its basic clock rate. The clock frequency is approx. 6 cycles/min.
- Push on the cannula.

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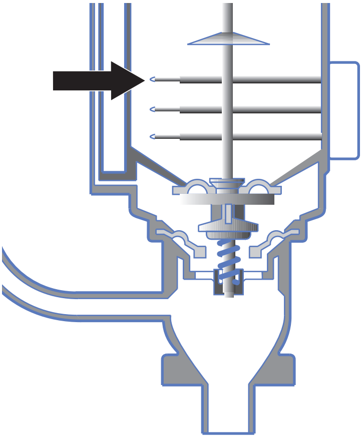
› Aspirate water from a vessel until the system switches through the working cycle into the overfill position.



All valves switch off.

– The overfill valve interrupts the suction pipe.
– The rinsing unit is no longer supplied with water.
– The working valve switches off.

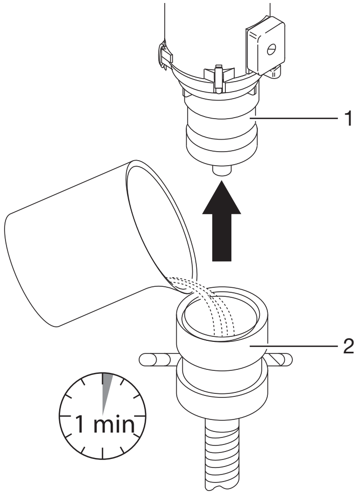
› Visual inspection: the overfill position occurs if the fluid level reaches the top fluid level indicator sensor.

Checking the outlet

The Sepamatic can transfer up to 1.5 l/min of fluid through the lock and into the outlet. The outlet needs to be checked to ensure that this is possible.

› Take out the Sepamatic from the mounting flange of the outlet.

› Pour 2 l of water continuously into the outlet. The outlet must be designed in such a way that 2 l of water can drain off within 1 minute.



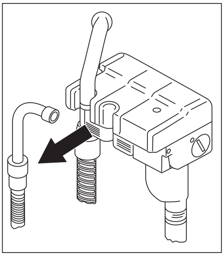
1 Sepamatic
2 Outlet mounting flange

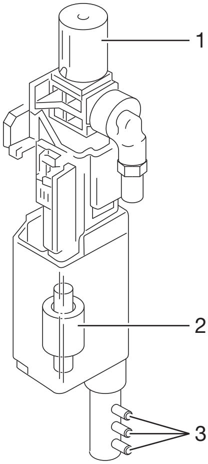
If the water does not drain off in the specified time:

– Clean the outlet.
– If the time is still exceeded, check the installation and make changes as required.

Checking the rinsing unit

› Take a small suction hose with saliva ejector hose from the manifold.





1 Water inlet valve
2 Level sensor
3 Rinsing hoses

The suction unit starts up. The switching frequency of the water inlet valve should be 10-20 cycles/min.

Check:

› Check the switching noises of the water inlet valve.

› Hold the rinsing hoses closed.
No more water can be taken from the rinsing unit.

› Check whether the level sensor switches off the water inlet valve.

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Usage

9 Disinfection and cleaning

NOTICE

Device malfunctions or damage due to use of incorrect media

Guarantee claims may become invalid as a result.

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

9.1 After every treatment

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

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

9.2 Daily after the end of treatment

After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:

✓ Non-foaming disinfectant/cleaning agent that is compatible with the materials.

✓ Unit care system, e.g. OroCup

- To pre-clean, suck up 2 litres of water with the care system.
- Aspirate the disinfection/cleaning agent with the care system.

9.3 Once or twice a week before the midday break

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.

10 Maintenance

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

WARNING

Infection due to contaminated unit

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

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

Maintenance interval	Maintenance work
Depends on the level of usage of the device.	Clean or replace the sieve on the secretion inlet connection. At the latest when the suction power of the unit starts to deteriorate.
Annually	› Cleaning of the suction unit in accordance with the operating instructions. › Clean or replace the protective sieves at the aspiration inlet. › If a rinsing unit is present: clean the sieve in the water supply. * › Perform a functional test. *

* Only by customer services service technicians.

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Troubleshooting

11 Tips for operators and service technicians

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

WARNING

Infection due to contaminated unit

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

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

Error	Possible cause	Remedy
Device does not start	No power supply	› Check the power supply. * › Check the fuses and replace if necessary. *
Deterioration in the suction performance at the cannula	Sieve at the secretion inlet connection is dirty	› Pull off the secretion hose at the inlet connection, clean the sieve and replace if required.
	Replacement filter in the corner filter (optional accessories) dirty	› Insert a new filter.
Suction process is temporarily interrupted, automatic separator goes into the overfill position	Outlet blocked	› Check the outlet and clean it if necessary. Do not patch any hoses. *
	Installation position of the automatic separator	– Check the installation and adjust as required. *
Suction power too weak or interrupted	Coarse sieve is blocked on the inlet of the aspiration	› Clean the coarse sieve.
	Place selection valve not or incompletely open	› Check the control voltage. * › Clean the place selection valve. *
No basic clock rate, although the suction unit is running	Working valve defective	› Replace the working valve. *
No switching from basic clock rate to work cycle	Fluid level indicator sensor dirty	› Remove, clean and if necessary replace the fluid level indicator sensor. *
No switching to the overfill position	Fluid level indicator sensor dirty	› Remove, clean and if necessary replace the fluid level indicator sensor. *

* Only to be done by service technicians.

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12 Transporting the unit

WARNING

Infection due to contaminated unit

› Disinfect the unit before transport.
› Close all media connections.

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

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

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