Comfort hose manifold

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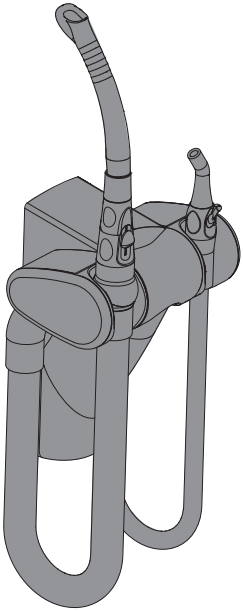

Installation and operating instructions

CE

9000-606-18/30

DÜRR DENTAL

2010V004

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Important information

1 About this document

These installation and operating instructions represent part of the unit.

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

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

Hose manifold Comfort type FG
Order number: 7602G01
Comfort hose manifold type GFK
Order number: 7603G01; 7603G01/21; 7603G51; 7603G52
Hose manifold Comfort type GFG
Order number: 7603G02
Hose manifold Comfort type SGFK
Order number: 7604G01; 7604G02; 7604G02/021
Hose manifold Comfort type GFGK
Order number: 7604G02
Hose manifold Comfort type KGFG
Order number: 7604G03
Hose manifold Comfort type SGFKK
Order number: 7605G51
Hose manifold Comfort type SGFKS
Order number: 7605G52

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.

Manufacturer

REF Order number

SN Serial number

MD Medical device

HIBC Health Industry Bar Code (HIBC)

CE labelling

Refer to Operating Instructions.

Refer to the accompanying electronic documents.

Disconnect all power from the unit.

Wear protective gloves.

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1.2 Copyright information

2 Safety

Dürr Dental has designed and constructed this unit so that when used properly and for the intended purpose it does not pose any danger to people or property.
Despite this, the following residual risks can remain:

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

2.1 Intended purpose

The product is designed to hold the suction hoses and to activate the suction unit.

2.2 Intended use

Suction hoses can be hung in place in the hose manifold when not being used even with the cannula fitted in position. The hose manifold with its suction hoses and handpieces is suitable for both wet and dry suction systems. It supplies a control signal for the suction unit.

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.
Do not aspirate any liquids and solid materials that are unsuitable for the suction system.

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

› Observe the special precaution measures concerning electromagnetic compatibility (EMC) for medical devices.
› 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 Combining devices safely

Where applicable, the requirements for medical products have been taken into account in the development and construction of the device. As a result, this device is suitable for installation within medical supply equipment.
› Where this device is integrated in other medical supply equipment, the requirements of European Union Medical Device Regulation 2017/745 and the relevant standards must be observed.

2.7 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.

The following groups are not permitted to operate or use a commercially operated unit:
– People without the necessary experience and knowledge
– People with reduced physical, sensory or mental capabilities
– Children

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.

2.8 Electrical safety

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

2.9 Essential performance characteristics

The unit does not have any essential performance characteristics as set out in IEC 60601-1 section 4.3.
The unit complies with the requirements according to IEC 60601-1-2:2014.

2.10 Notification requirement of serious incidents

The operator/patient is required to report any serious incident that occurs in connection with the device to the manufacturer and to the competent authority of the Member State in which the operator and/or patient is established/resident.

2.11 Only use original parts

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

2.12 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.

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› Keep the packing materials out of the reach of children.

2.13 Disposal

The unit may be contaminated. Inform the waste management company so that they can take all necessary safety steps.

› Prepare accessory parts before disposal, then dispose of according to local and national regulations.

› If you have any questions concerning the correct disposal of parts please contact your dental trade supplier.

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

Product description

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3 Overview

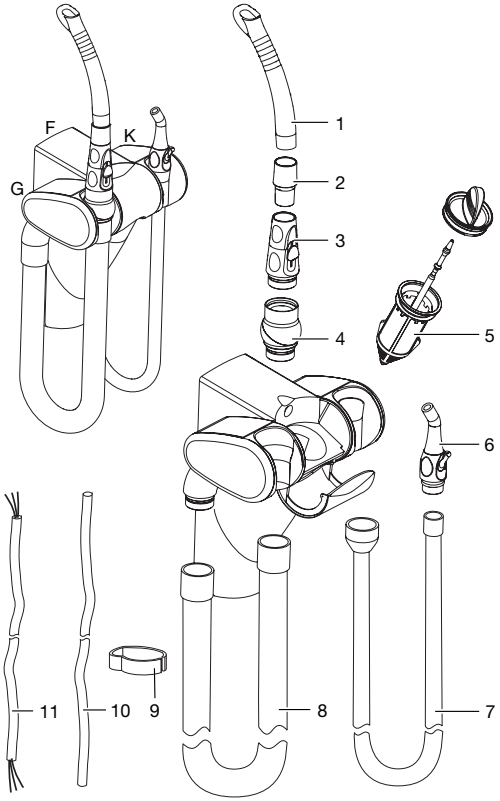

Fig. 1: Comfort hose manifold type GFK

1	Cannula, e. g. Dürr Dental universal cannula / Protect / Petito, prophylaxis cannula	8	Large suction hose
2	Rotary adaptor	9	Clip for routing electric cable and rinsing hose
3	Suction handpiece for large suction hose	10	Rinsing hose
4	Swivel joint	11	Electric cable
5	Disposable filter	G	Element for larger suction hose
6	Suction handpiece for small suction hose	F	Filter element
7	Small suction hose	K	Element for small suction hose

For further articles, refer to the information leaflet (order number 9000-606-16) supplied and "3.4 Optional items"

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3.1 Variants

G = Element for larger suction hose
K = Element for small suction hose
S = Element for air and water spray
F = Filter element

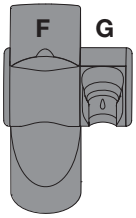

Fig. 2: Double hose manifold Comfort, type FG

1 Elements FG, 7602G01

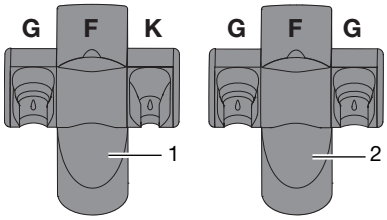

Fig. 3: Triple hose manifold Comfort

1 Type GFK, 7603G01
2 Type GFG, 7603G02

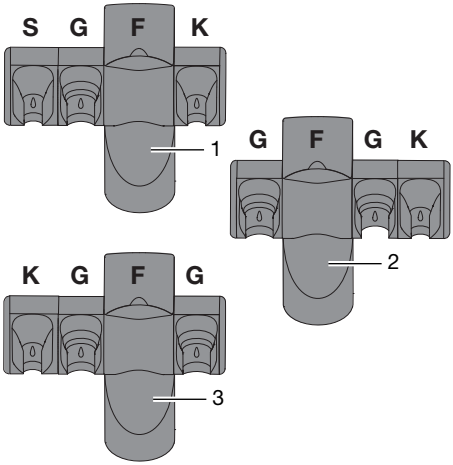

Fig. 4: 4-fold hose manifold Comfort

1 Type SGFK, 7604G01
2 Type GFGK, 7604G02
3 Type KGFG, 7604G03

3.2 Scope of delivery

Standard parts in scope of delivery of suction hoses and suction handpieces, etc. are grey.

The following items are included in the scope of delivery:

Double hose manifold Comfort
type FG 7602G01

- Large suction handpiece
- Large suction hose, 160 cm
- Central suction hose
- Rinsing hose, PVC, 3 x 1.5 x 6 mm
- Disposable filter, yellow (12 pieces)
- Universal cannula set (2 pieces)
- Drill template
- Swivel joint
- Rotating cover, 16 mm
- Hose manifold installation set
- Installation and operating instructions
- Quick start instructions Suction Handpieces

Triple hose manifold Comfort
type GFK 7603G01

- Small suction handpiece
- Large suction handpiece
- Large suction hose, 160 cm
- Small suction hose, 160 cm
- Central suction hose
- Rinsing hose, PVC, 3 x 1.5 x 6 mm
- Disposable filter, yellow (12 pieces)
- Universal cannula set (2 pieces)
- Drill template
- Swivel joint
- Rotating cover, 16 mm
- Hose manifold installation set
- Installation and operating instructions
- Quick start instructions Suction Handpieces

Triple hose manifold Comfort
type GFG 7603G02

– Large suction handpiece, 2x
– Large suction hose, 160 cm, 2x
– Central suction hose
– Rinsing hose, PVC, 3 x 1.5 x 6 mm
– Disposable filter, yellow (12 pieces)
– Universal cannula set (2 pieces)
– Drill template
– Swivel joint
– Rotating cover, 16 mm, 2x
– Hose manifold installation set
– Installation and operating instructions

Four-fold hose manifold Comfort type SGFK 7604G01

– Small suction handpiece
– Large suction handpiece
– Large suction hose, 160 cm
– Small suction hose, 160 cm
– Central suction hose
– Rinsing hose, PVC, 3 x 1.5 x 6 mm
– Disposable filter, yellow (12 pieces)
– Universal cannula set (2 pieces)
– Drill template
– Swivel joint
– Rotating cover, 16 mm
– Hose manifold installation set
– Inserts for air and water spray element
– Installation and operating instructions

4-fold hose manifold Comfort type GFGK 7604G02

– Small suction handpiece
– Large suction handpiece
– Large suction hose, 160 cm
– Small suction hose, 160 cm
– Central suction hose
– Rinsing hose, PVC, 3 x 1.5 x 6 mm
– Disposable filter, yellow (12 pieces)
– Universal cannula set (2 pieces)
– Drill template
– Swivel joint
– Rotating cover, 16 mm
– Hose manifold installation set
– Saliva cannula
– Installation and operating instructions

4-fold hose manifold Comfort type KGFG 7604G03

– Small suction handpiece
– Large suction handpiece
– Rinsing hose, PVC, 3 x 1.5 x 6 mm
– Large suction hose, 160 cm
– Small suction hose, 160 cm
– Central suction hose
– Disposable filter, yellow (12 pieces)
– Universal cannula set (2 pieces)
– Drill template
– Swivel joint
– Rotating cover, 16 mm
– Hose manifold installation set
– Saliva cannula
– Installation and operating instructions

5-fold hose manifold Comfort type SGFKK 7605G51

The five-fold hose manifold Comfort can be configured to meet any requirements.

3.3 Accessories

An overview of Dürr Dental suction handpieces, swivel joints, rotating covers, adapters and cannula can be found in the information leaflet supplied: "Cleaning and disinfection of suction handpieces". (Order number 9000-606-16)
or in the download area: www.duerrdental.com

The following items are required for operation of the device, depending on the application:

Universal cannula . . . . . 0700-000-27?
Petito universal cannula d=11 mm . . . . . 0700-000-26?
Universal cannula . . . . . 0700-000-27?
Protect universal cannula . . . . . 0700-000-28?
Saliva cannula (fits large suction handpiece) 7068-003-05
Saliva cannula universal 7068100001
Saliva ejector Mikrona 7600A020-51
Surgical suction cannula, sterile Ø 2.5mm, 20 pieces 0700-007-50
Surgical suction cannula, sterile Ø 2.5 mm, 100 pieces 0700-007-51

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3.4 Optional items

For the order no, ? must be replaced by A = grey or S = black.
Example: 7600A010-50 for grey or 7600S010-50 for black

The following optional items can be used with the unit:

Large suction hose, 160 cm . . . . . 7600?010-50
Small suction hose, 160 cm . . . . . 7600?020-50
Central suction hose . . . . . 7600?350-00
Swivel joint 7600G150-00
Adapter plate for
triple hose manifold, grey 7600-163-01
Adapter plate for
four-fold hose manifold, grey 7600-164-01
Adapter plate for
five-fold hose manifold, grey 7600-165-01
Adapter plate suitable, for example, for
Cattani connection bore holes . . . 7600-166-01

Further elements for hose manifolds

Element for air and water spray with
4 inserts 7600G980-50
Element VistaCam
with insert for Dürr Dental intraoral cameras (VistaCam model 2106) 7600G980-54

3.5 Consumables

The following materials are consumed during operation of the unit and must be reordered separately:

Disposable filter for suction systems (12 pieces) 0725-041-00
Disposable filter for suction systems (36 pieces) 0725-041-60
Orotol plus (2.5 litre bottle) CDS110P6150
MD 555 cleaner (2.5 litre bottle) . CCS555C6150

3.6 Wear parts and replacement parts

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

Large suction hose, grey,
160 cm 7600A010-50
Large suction hose, black,
160 cm 7600S010-50
Small suction hose, grey,
160 cm 7600A020-50
Small suction hose, black,
160 cm 7600S020-50
Large suction hose, 145 cm . . . . . 7600?010-51
Small suction hose, 145 cm . . . . . 7600?020-51
Filter cover for disposable filter, yellow,
1 piece 0725-041-03

Information concerning spare parts can be found in the Spare Parts Catalogue under:
www.duerr.de/etk.

4 Technical data

Electrical data for the unit		
Switching voltage	V AC/DC	5-24
Switching current	A max	0.005-4
Mains frequency	Hz	50-60
Operating pressure (min.)	mbar/hPa	-200
Type of protection	IP	23
Medical Device Class		
Unit		Class I
Handpieces		Class I
Cannulas		Class IIa
General technical data		
Dimensions (W x H x D)	cm	16 - 23 x 19 x 12
Weight	kg	approx. 1
Suction rating		
Universal cannula on large suction hose	l/min	250 - 350
Surgical suction cannula on small suction hose	l/min	50 - 80
Saliva cannula on small suction hose	l/min	30 - 60
Hose diameter		
Large suction hose	mm	LW 19
Small suction hose	mm	LW 10
Central suction hose	mm	LW 25
Ambient conditions during operation		
Temperature	°C	+10 to +40
Relative humidity	%	< 70
Ambient conditions during storage and transport		
Temperature	°C	-10 to +60
Relative humidity	%	< 95

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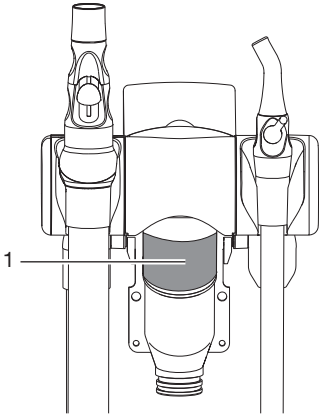
4.1 Type plate

The type plate of the hose manifold is located under the filter element cover.



1 Type plate

4.2 Evaluation of conformity

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

5 Operation

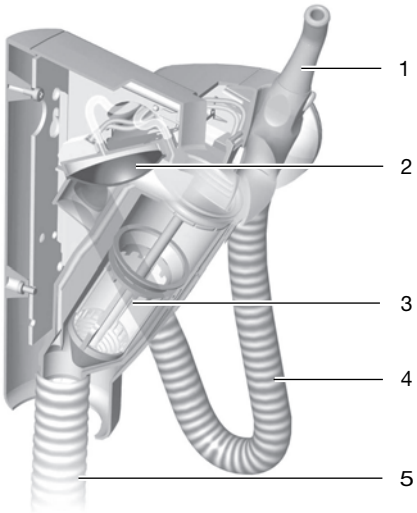


Fig. 5: Suction hose in position

1 Suction handpiece
2 Membrane
3 Disposable filter
4 Suction hose
5 Suction hose, central

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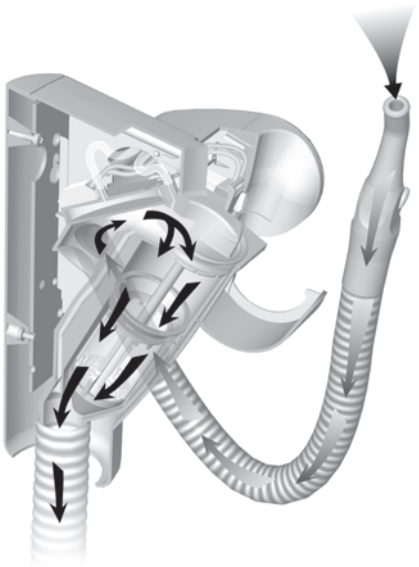


Fig. 6: Suction hose removed

5.1 Module set-up

Due to its modular design the Comfort hose manifold can be individually set up to meet your needs, depending on types of treatment, or personal suction style and handling. Between 2 and 4 elements, in special cases even 5 elements, can be configured for one hose manifold.

For other versions of the Comfort hose manifold see "3.1 Variants"

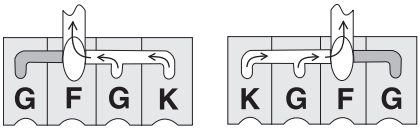
Individual elements are adjustable and can be adapted to three different ergonomic angles of application (0°, 15°, 30°).

5.2 Triple hose manifold

The triple hose manifold has a selective function, i.e. the suction hose actually being used at any moment is supplied with vacuum.

5.3 Four-fold hose manifold

The selective function for the four-fold hose manifold is restricted to the single element next to the filter element.
As soon as two further elements are used next to the filter element then both are supplied with vacuum.



5.4 Suction hose in position

When the suction hose is placed into the hose manifold the switch is pressed and the valve is thus closed.
Atmospheric pressure is present in the upper section of the selective membrane. Due to the arrangement of the selective membrane the path between suction hose and suction pipe is interrupted.

5.5 Suction hose removed

On removal of the suction hose, a valve and two microswitches are activated. One microswitch activates the suction machine, the other regulates the station selection valve or the separation, for example. The valve opens. he membrane rises and opens the path between suction hose and suction pipe due to the vacuum created by the suction machine.

Both the large and small suction handpieces are fitted with a slider to control the flow rate or to switch off the suction flow while working.

5.6 Filter function

During the aspiration of spray mist, saliva and other particles from the patient's mouth, these are then conveyed through the suction hose via the open membrane and filter and into the suction pipe. The integrated yellow filter retains the coarse particles.

5.7 Rinse function

Where a rinsing unit has been connected, water is fed into the suction system during suction. This prevents drying out and therefore the build-up of deposits that would be difficult to dissolve.

5.8 Suction handpiece

The slider fitted in the large and small suction handpieces can be used to control the flow rate or to switch off the suction flow while working.

5.9 Rotary adaptor

A rotating cover can be added to the large suction handpiece. This enables the cannula to be turned more easily.

5.10 Swivel joint

A swivel joint can be attached to the large suction handpiece.
The swivel joint is rotatable in 15° steps. This helps to achieve a smoother, better hose supply.

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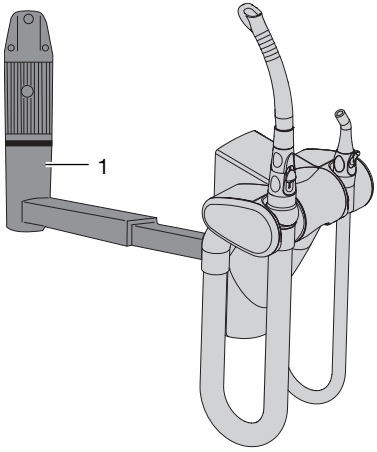
Assembly

Only qualified specialists or employees trained by Dürr Dental are permitted to install, connect and start using the unit.

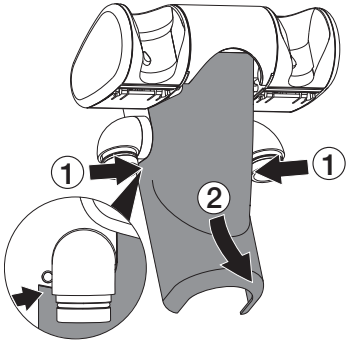
6 Assembly

The hose manifold can be fixed **with** or **without** the swivel arm (1) as follows:

– on the wall
– on or under a work surface



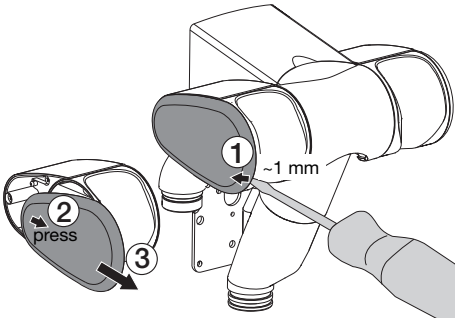
› Remove the front cover, pressing the sides, and lifting towards the front.



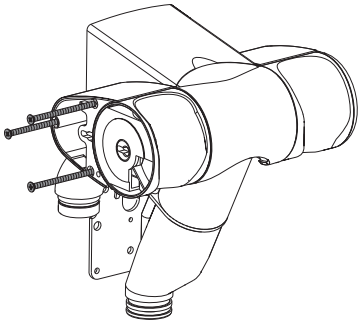
6.1 Changing the hose manifold element

This section is only required in the case of changing an element of the hose manifold or where a different element is required.

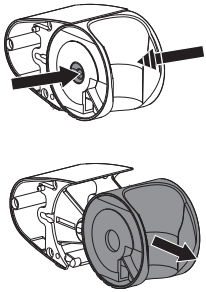
› Remove the side cover.



› Undo 3 screws.



› Pressed the section marked from both sides in order to take the element apart.



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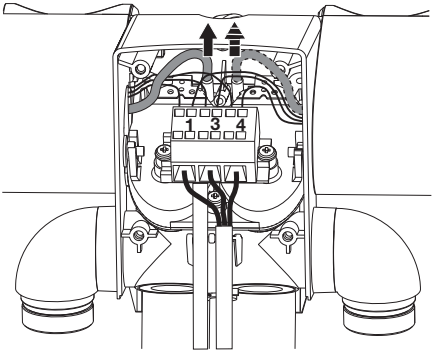
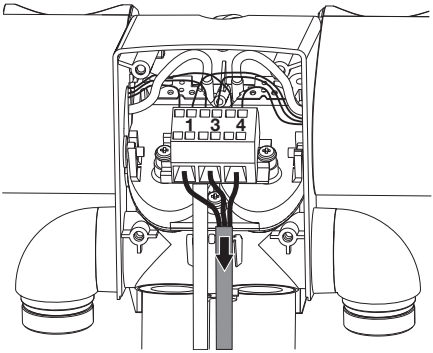
› Remove both the red and the white hoses from the filter element.



› Disconnect the cable in the filter element.



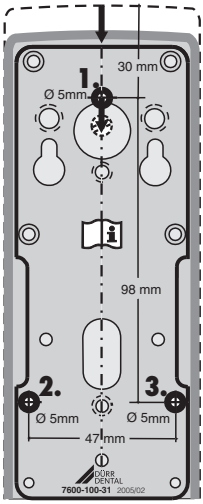
› Install the new element in reverse sequence.

6.2 Wall mounting without swivel joint

› Choose a suitable location on the wall for mounting.

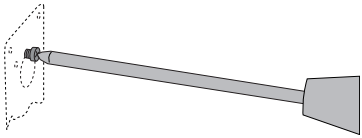
› Check that there are no cables or supply lines under the plaster.

› Use the drill template (7600-100-31) supplied to mark 3 bore positions on the wall.

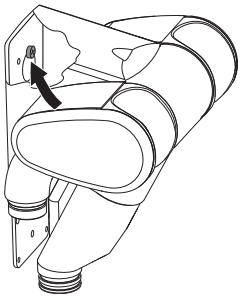


› Bore 3 holes, 5 mm in diameter. Depending on the material, pre-bore and / or use dowels.

› Screw the supplied screw **half way** into the upper bore hole.



› Hang the Comfort hose manifold in position.



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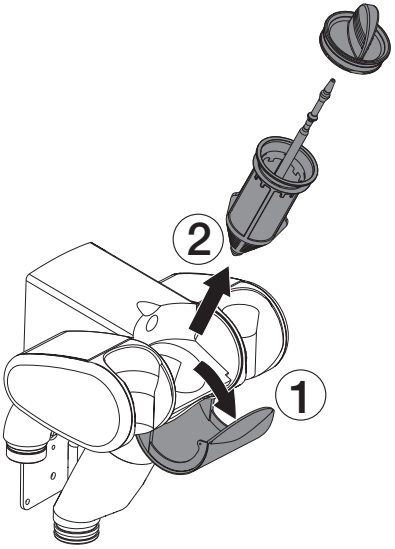
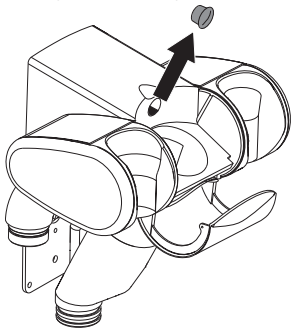
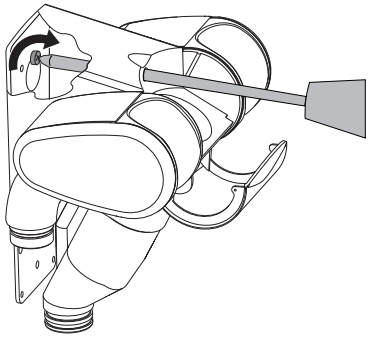
› Open the filter flap and remove the yellow filter.



› Remove the protective cap.

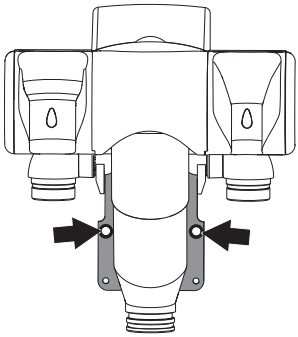


› Insert the screwdriver horizontally through the opening and tighten the screw.



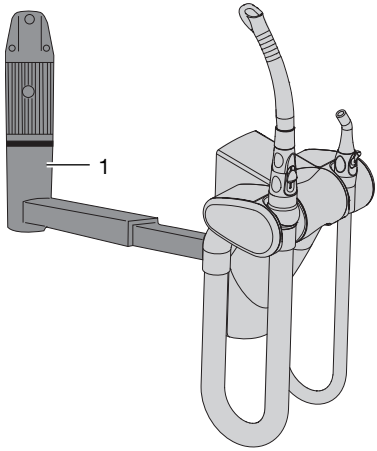
› Replace filter and protective cap.

› Fix the mounting plate with the two screws.



6.3 Fixing with the swivel slide

Instructions on installing the Comfort hose manifold in combination with the swivel slide are contained in the instruction leaflet (order no. 7600-150-00).



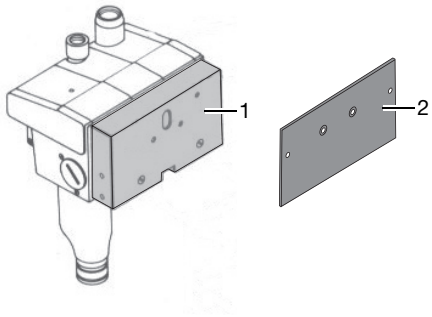
1 Swivel joint

6.4 Fixing to the Dürr Dental mounting plate

Previous versions of the Dürr Dental hose manifold were fitted with the aid of a "mounting plate" to the wall, to a swivel arm or swivel slide.

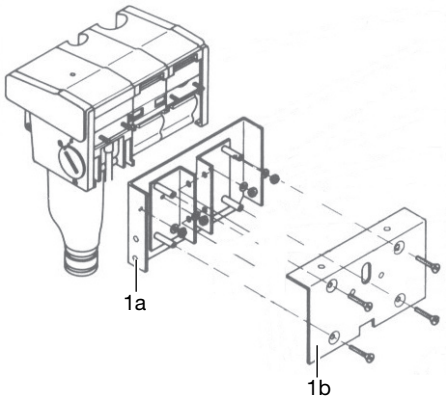
When a new Comfort hose manifold is replacing an older, previous version, then we recommend that an "adapter plate" is used between the Comfort manifold and mounting plate.

Adapter plates are available in various sizes, depending on the type of hose manifold, see Special accessories.



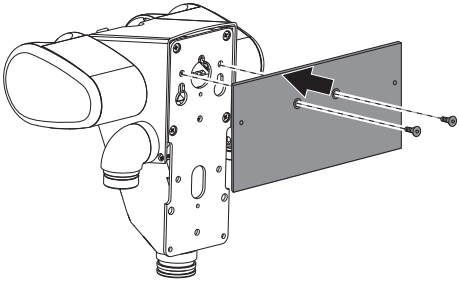
1 Mounting plate
2 Adapter plate

› Disconnect parts 1a and 1b of the mounting plate.

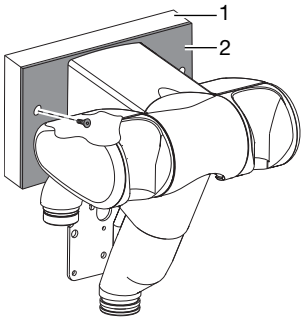


› Unscrew the older hose manifold from part 1a.
› Attach plate part 1b again to part 1a.

› Mount the adapter plate using two screws M5 x 12 to the Comfort hose manifold.



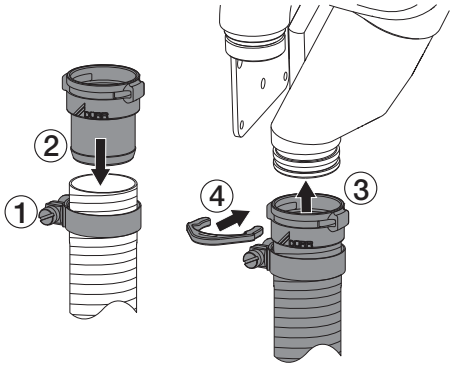
› Mount the adapter plate with the Comfort hose manifold using a countersunk screw M4 x 12 and M4 hex nut to the mounting plate.



6.5 Connect the hoses and lay correctly

Connect the central suction hose and lay correctly:

› Connect the central suction hose to the hose manifold.



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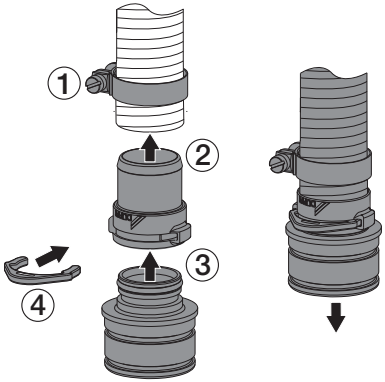
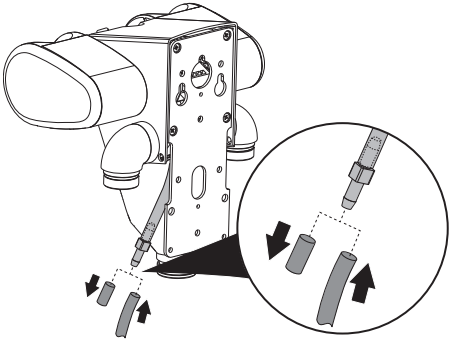
› Measure the length of the central suction hose, between hose manifold and waste water drain, e.g. to the floor waste pipe.
› Shorten the central suction hose to the required length.
› Connect the central suction hose on waste water side, using the connecting sleeved supplied where necessary.



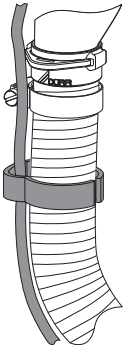
Connect the rinse hose and lay correctly:

› Remove the blue protective cap and slide the rinse hose into place.



› Lay the rinsing unit hose, ensuring as far as possible that it is parallel to the central suction hose.

› Attach the hose with the clip to the central suction hose.



6.6 Electrical connections

› The supply voltage to the unit must satisfy the requirements for two means of patient protection (MOPP) of IEC 60601--1 in relation to the supply network.
› The max. alternating current of 4 A may not be exceeded. This can be secured by:
a secondary fuse T 4 AH
or
IEC 60127 - 2/V T 4 AH, 250 V
or
< 4A

NOTICE

Fault due to cable being laid under mechanical tension

› Route the cable without mechanical tension.

› Route the cable parallel to the central suction hose and to rinse hose and connect to the floor socket.

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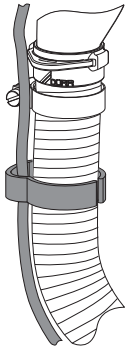
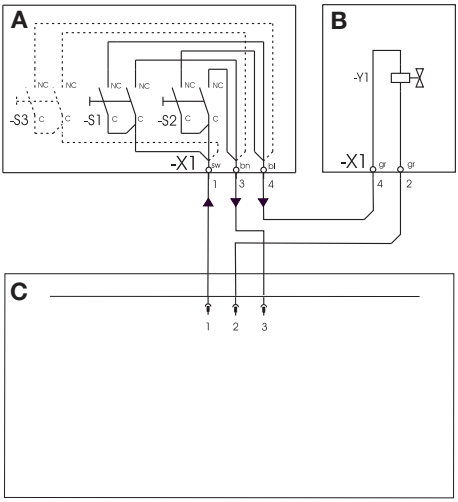
› Clip the cable to the central suction hose.

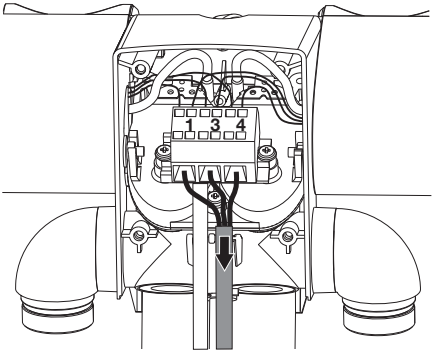


Example of connection



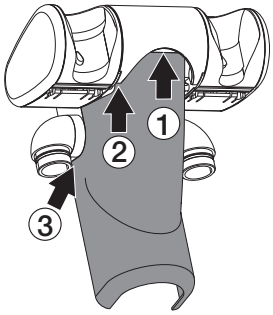
A Comfort hose manifold
B Place selection valve
C Control box, e. g. 0732-.. or 0700-..

Connection in the filter element



6.7 Installation of the cover

› Replace cover again, noting the sequence:
1. Slide the cover under the edge.
2. and 3. Snap clips in place.



6.8 Position and fit out suction hoses

› Connect suction hose or suction hoses.

Fit out suction hoses, depending on version and according to needs, e.g.:

› Large suction hose fitted with: swivel joint, large suction handpiece, rotating cover and universal cannula.

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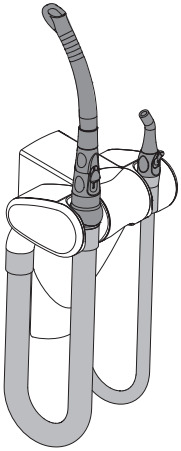
› Small suction hose fitted with: small suction handpiece and e.g. saliva cannula.



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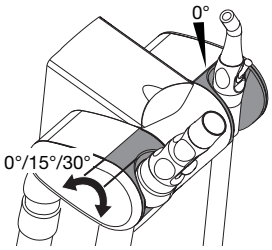
Usage

7 Operation

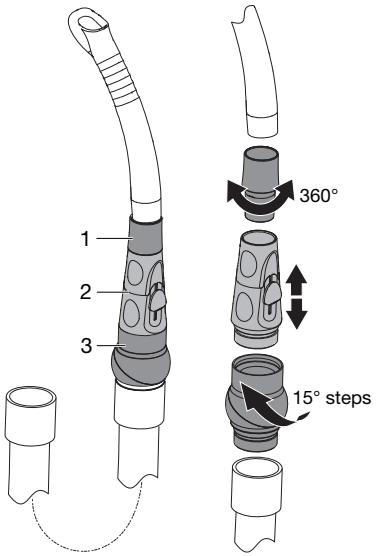
7.1 Tips on ease of operation

Adjustable inserts in the elements, depending on function

› Initial position 0°.
Turn the inserts to the desired position 0° / 15° / 30°.



Operation of the rotating cover, suction handpiece and swivel joint



1 Rotary adaptor
2 Suction handpiece
3 Swivel joint

› A rotating cover (1) can be added to the large suction handpiece. This enables the cannula to be turned more easily.

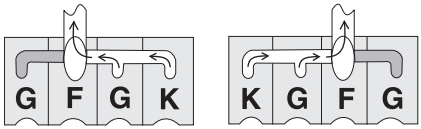
› The slider fitted in the large and small suction handpieces (2) can be used to control the flow rate or to switch off the suction flow while working.

› A swivel joint (3) can be added to the large suction handpiece.
The swivel joint is rotatable in 15° steps. This helps to achieve a smoother, better hose supply.

7.2 Tips on working with the four-fold hose manifold

Vacuum supply

When using a four-fold hose manifold (e.g. GFGK, KGFG) and two further elements have been connected next to the filter element, then both elements will be supplied with vacuum.



Optimising suction performance

Using as an example a hose manifold with the layout GFGK:
If the large suction hose **G** is being used, then close the slider on the small suction hose **K**.

EN

8 Disinfection and cleaning

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).

NOTICE

Device malfunctions or damage due to use of incorrect media

Guarantee claims may become invalid as a result.

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

Dürr Dental recommends
– For disinfection and cleaning: Orotol plus or Orotol ultra
– For cleaning: MD 555 cleaner

Only these products have been tested by Dürr Dental.
When using prophy powders, Dürr Dental recommends the water-soluble Lunos prophy powders in order to protect the Dürr Dental suction systems.

8.1 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.

8.2 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.

Disinfecting and cleaning the surfaces

› Disinfect and clean all surface areas of the Comfort hose manifold and all hoses regularly, e.g. using FD 350 disinfection wipes.

8.3 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.

9 Reprocessing

9.1 Risk analysis and categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator. Comply with all national directives, standards and specifications such as e. g. the "Recommendations from the Commission for Hospital Hygiene and Infection Prevention".
Accessories of the medical device are also subject to reprocessing.
Classification recommendation given intended use of the product: **semi-critical B**
Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically affected skin.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

9.2 Reprocessing procedure in accordance with EN ISO 17664

The reprocessing procedure after each patient treatment is carried out according to the reprocessing procedure established by EN ISO 17664.

EN

Important information!

The reprocessing notes in accordance with EN ISO 17664 have been independently tested by Dürr Dental for the preparation of the device and its components for their reuse.

The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.

Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially influenced by the amount of wear and tear or damage resulting from its use.

The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing procedure was validated as follows:

- **Pre-cleaning**
  - FD 350 Disinfection wipes (Dürr Dental)
- **Manual cleaning**
  - ID 215 Enzymatic instrument cleaner (Dürr Dental)
  - Cleaning brush
- **Manual disinfection**
  - ID 213 Instrument disinfection (Dürr Dental)
- **Automatic cleaning and disinfection**
  was performed in accordance with EN ISO 15883 with tested efficacy.
  - Cleaning agent: Neodisher MediClean Forte
  - Washer-disinfector: PG 8535 (Miele)
  - Programmes: "Cleaning without neutralisation" and "THERMAL DES"
- **Steam sterilisation**
  was performed in accordance with EN ISO 17665 using the fractionated vacuum procedure.
  - Pre-vacuum: 3 x
  - Sterilisation temperature: 134 °C
  - Sterilisation time: 4 minutes
  - Drying time: min. 20 minutes
- **Cleaning brush**
  Cleaning brush with nylon hairs, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 25 and 35 mm
  - Brush length: 5 and 10 mm

  Example: Interlock cleaning brush double-sided greenREF 09098

General information

› Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.

› Comply with the specifications (see "9.4 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying" and "9.5 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying") when selecting the cleaning and disinfectant agents to be used.

› Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.

- Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.
- Only use disinfectants that are aldehyde-free and display material compatibility with the product.
- Do not use any rinse aid (danger of toxic residue on the components).
- Only use freshly-produced solutions.
- Only use distilled or deionised water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic micro-organisms (e.g. legionella bacteria).
- Use clean, dry, oil and particle-free compressed air.
- Do not exceed temperatures of 138 °C.
- Subject all devices used (ultrasonic bath, cleaning and disinfection device (CD), sealing device, steam steriliser) to regular maintenance and inspections.

9.3 Preparation at the operating location


Wear protective gloves.


Wear protective goggles.


Use a mask.


Use protective clothing.

WARNING

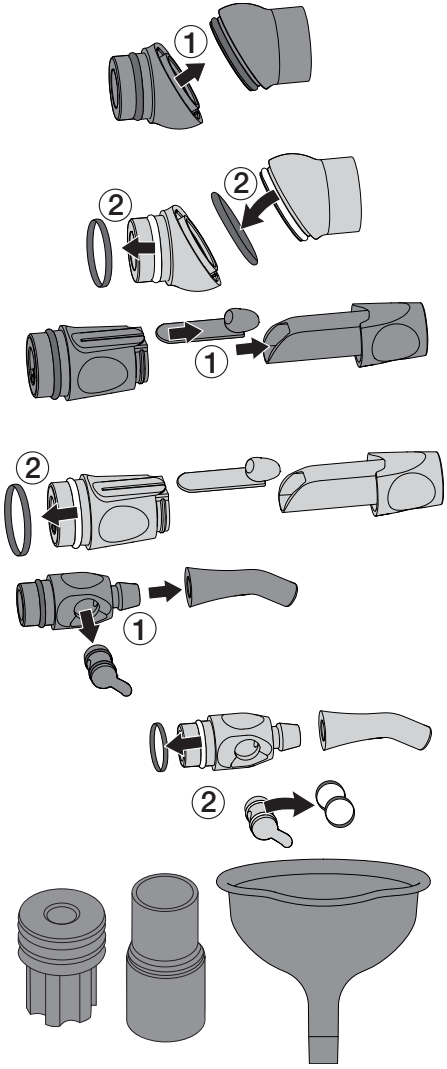
Risk of infection from contaminated products

Danger of cross contamination

- Reprocess the product correctly and promptly before its first use and after every subsequent use.

- Directly after the treatment, aspirate at least 200 ml cold water.

- Disassemble the ball joint and suction handpieces regularly and remove the O-rings.



- Wipe down the exterior surfaces of all components completely with cleaning cloths to remove coarse organic and inorganic soiling:
  1 Cleaning wipe for the small components, e. g. the individual parts of suction handpieces and
  2 Cleaning wipes for larger components, e. B. the funnel.
- Note the action time of the cleaning agent.

EN

› Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

9.4 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying

A disinfectant or combined cleaning and disinfectant agent is required for manual disinfection. It must have the following properties:
– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)

For further information, see: "General information".

Cleaning

› Place the individual components in a disinfectant bath (non-fixing/aldehyde-free, see "General information") so that all parts are covered.
› Comply with the reaction times of the cleaning agent and disinfectant (see "General information").
› If you notice any further contamination, brush all exterior and interior surfaces completely with a hygienic brush under the surface of the ready-to-use solution.

Intermediate rinsing

After the action time prescribed by the manufacturer:
› Rinse off all components under water for at least 1 minute (temperature < 35°C).

Disinfection

› Place individual components in a cleaning and disinfectant bath so that all parts are covered.
› Note the action time for the disinfectant.

Final rinse

After the action time prescribed by the manufacturer:
› Rinse off all components under water for at least 1 minute (temperature < 35°C).

Drying

› If necessary, re-dry at a clean location using a hygienic, lint-free cloth.
› Blow dry the components with compressed air in a clean location.

9.5 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:
– Corresponds to and tested in accordance with EN ISO 15883
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 93°C)
– Programme is suitable for the components and provides sufficient rinsing cycles.
For more information: "General information".

Selection of the machine cleaning agents and disinfectants

The following properties are required:
– Material compatibility with the product
– Corresponds with the manufacturer's specifications of the CD

For further information, see: "General information".

Automatic cleaning and disinfecting

When arranging the parts in the washer-disinfector, make sure there are no areas missed by rinsing.

› Place components in the basket for small parts.
› Attach cannula to suitable holders in the washer-disinfector.

9.6 Check for function

› After the end of the cleaning and disinfection cycle, check the components for any residual soiling and residual moisture. If necessary, repeat the cycle.
› If necessary, replace any damaged parts.
› The components should be packaged as soon as possible after drying and checking.

9.7 Steam sterilising

Packing

For packaging of the components, use only sterile barrier systems made of transparent paper film that are approved for use in steam sterilisation according to the manufacturer information. This includes:

– Temperature resistance up to 138°C
– Standards EN ISO 11607-1/2
– The applicable sections of the standard series EN 868

The sterile barrier system must be large enough. Once it is loaded, the sterile barrier system must not be under any strain.

Steam sterilising

WARNING

Health risk due to incorrect sterilisation

If the sterilisation not performed correctly, it may not be effective. The use of instruments that have not been properly sterilised can pose a health risk to the patient..

› Only steam sterilisation must be used.
› Comply with all of the specified process parameters.
› Comply with the manufacturer‘s instructions regarding use of the steam steriliser.
› Do not use any other methods.

NOTICE

Damage to equipment due to incorrect sterilisation

If the sterilisation process is not performed correctly, this can cause damage to the product.

› Comply with the manufacturer‘s instructions regarding use of the steam steriliser.
› Comply with all of the specified process parameters.

Requirements placed on the steam steriliser:

– Corresponds to EN 13060 or EN 285 and/or ANSI AAMI ST79
– Suitable programme for the products listed (e. g. with hollow bodies, fractionated vacuum procedure in three vacuum steps)
– Sufficient product drying
– Validated process in accordance with ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ))

Perform the following steps:

› Sterilise the parts for sterilisation (at least 20 minutes at 121°C, at least 4 minutes at 132°C or at least 5 minutes at 134°C).
Do not exceed 138 °C.

Marking

› Mark the packaged, treated medical product in such a way as to ensure safe application.

9.8 Issue clearance for the parts for sterilisation

The reprocessing of the medical products ends with the documented clearance for storage and renewed use.

› Document the clearance of the medical product after reprocessing.

9.9 Storing parts for sterilisation

› Comply with the stated storage conditions:
– Store the parts protected against contamination
– Dust-protected, e.g. in a locked cabinet
– Protected against moisture
– Protected against excessive temperature fluctuations
– Protected against damage

Packaging for a sterile medical device can suffer damage as a result of a particular incident and the passage of time.
Potential external contamination of the sterile barrier system should be taken into account in terms of aseptic preparation when establishing the storage conditions.

EN

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).

10.1 Change the disposable filter

Change the disposable filter once a week

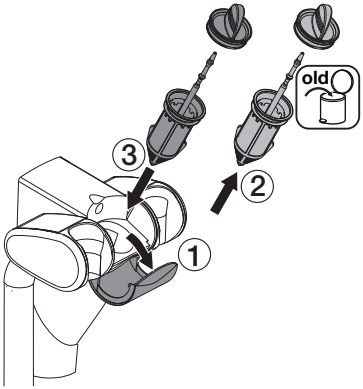
NOTICE

Faulty function when working without a disposable filter

Working without a disposable filter creates the risk that deposits or particles will accumulate in unsuitable locations within the hose manifold and hinder efficient function.

› The yellow disposable filter must inserted.

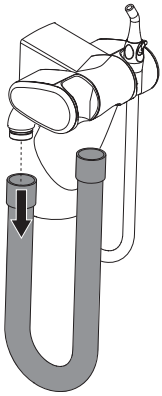
› Open the cover of the filter element and change the yellow disposable filter.
Disposable filter (12 pieces) order number 0725-041-00



10.2 Changing the suction hose

The suction hoses are subject to wear and tear.

› Check the suction hose regularly for bends, change if required.
› Pull the suction hose off the hose manifold.

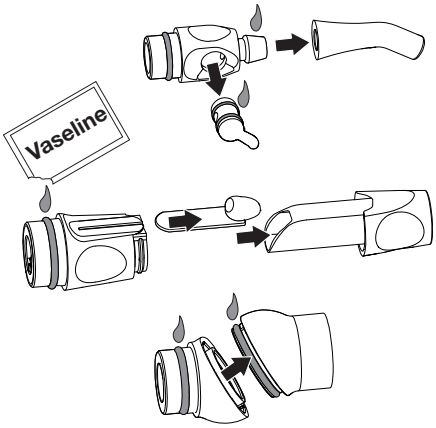


› Connect new suction hose.

10.3 Lubricating the o-rings

The suction handpiece, suction hoses etc. are easier to handle when the O-rings have been treated with a little Vaseline.

› Disassemble the suction handpiece regularly and lubricate the O-rings.



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).

Error	Possible cause	Remedy
Reduced suction performance	Disposable filter in the hose manifold is full	Change disposable filter.
	Blockage in the suction hose	Remove and clean suction hose.
	Blockage in the suction handpiece	Disassemble and clean suction handpiece.
	Suction hose is bent or twisted	Change the suction hose.
	Selective membrane does not completely open	Remove the filter cover. Remove dirt particles, e.g. using blunt tweezers or jet of water. Do not damage the **selective membrane!**
No suction power	Suction handpiece slider is closed	Open the handpiece slider.
	Suction machine is not functioning	Check the suction machine function.
	Selective membrane does not open	Remove the filter cover. Remove dirt particles, e.g. using blunt tweezers or jet of water. Do not damage the **selective membrane!**
	Control hose of one element is bent or twisted	Check the control hose, e.g. in element for large suction hose and filter element, for signs of twisting.
Fluid escapes from the suction handpiece slider	Dirt or accumulated deposits in the suction handpiece	Disinfect suction handpiece, clean and then prepare, see "9 Reprocessing"

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Appendix

12 Handover record

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

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

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

Notes:

Name of person receiving instruction:	Signature:

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

Date of handover:	Signature of the qualified adviser for the medical device:

Hersteller/Manufacturer:

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

DÜRR DENTAL