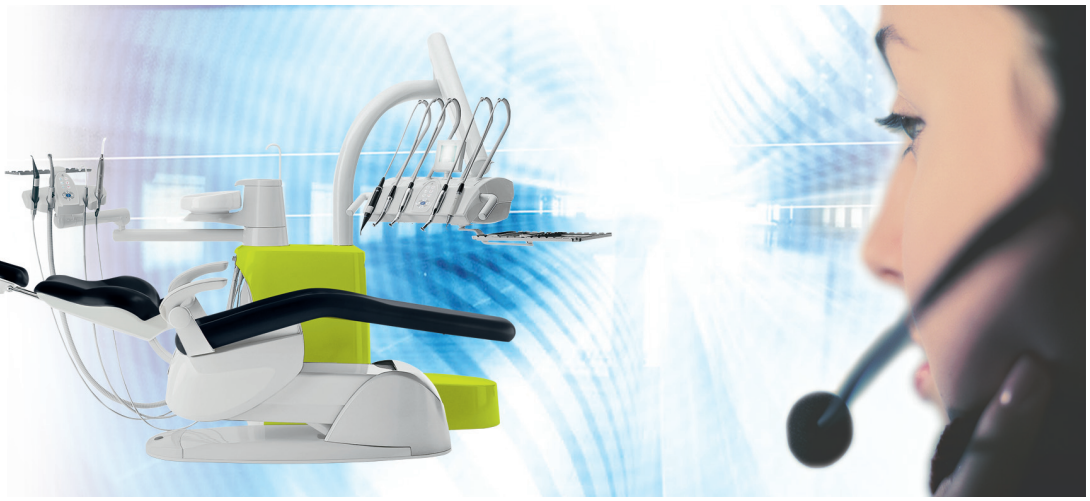
Instructions for use

KaVo Primus® 1058 S/TM/C



Always be on the safe side.

KaVo. Dental Excellence.

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CE 0124

Contents

1 User instructions

1.1 User guide

Requirement
Read these instructions prior to first use to avoid misuse and prevent damage.

1.1.1 Abbreviations

Abbre-viation	Explanation
IfU	Instructions for use
CI	Care instructions
AI	Assembly instructions
TI	Technician's instructions
SC	Safety checks
IEC	International Electrotechnical Commission
RI	Repair instructions
RK	Retrofitting kit
AS	Assembly set
EP	Enclosed parts
EMC	Electromagnetic compatibility
PI	Processing instructions

1.1.2 Symbols

	See the Safety/Warning Symbols section
	Important information for users and technicians
CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EU directive.
▶	Action required

1.1.3 Target group

This document is for dentists and dental office staff.

1.2 Service

KaVo Customer Service:
+49 (0) 7351 56-1000
Service.Einrichtungen@kavo.com
Please refer to the serial number of the product in all inquiries!
For further information, please visit: www.kavo.com

1.3 Terms and conditions of warranty

KaVo provides the final customer with a warranty that the product cited in the hand-over certificate will function properly and guarantees zero defects in the material or processing for a period of 12 months from the date of purchase, subject to the following conditions:
Upon justified complaints of flaws or a short delivery, KaVo will make good its warranty by replacing the product free of cost or repairing it according to the customer's wishes. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default and gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
KaVo cannot be held liable for defects and their consequences due to natural wear, improper cleaning or servicing, non-compliance with operating, servicing or connection instructions, calcification or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with factory specifications.
The warranty does not usually cover bulbs, glassware, rubber parts and the colour-fastness of plastics.
Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party are excluded from the warranty.
Claims from this warranty can only be asserted when the transfer form (copy) belonging to the product has been sent to KaVo, and the original can be presented by the operator or user.

1.4 Transportation and storage

1.4.1 Currently valid packaging regulations

Note
Only valid for the Federal Republic of Germany.

Dispose of and recycle the sales packaging appropriately in accordance with current packaging regulations, employing waste management or recycling companies. Comply with the comprehensive return system. KaVo has had its sales packaging licensed for this purpose. Please comply with the regional public waste-disposal system.

1.4.2 Damage in transit

In Germany

If the packaging is visibly damaged on delivery, please proceed as follows:

1. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use the product.
4. Report the damage to the shipping company.
5. Report the damage to KaVo.
6. Consult with KaVo first, before returning a damaged product.
7. Send the signed delivery receipt to KaVo.

If the product is damaged but there was no discernable damage to the packaging upon delivery, proceed as follows:
1. Report the damage to the shipping company immediately and no later than 7 days after delivery.
2. Report the damage to KaVo.
3. Leave the product and packaging in the condition in which you received it.
4. Do not use a damaged product.

Note
If the recipient fails to comply with any of the above-mentioned obligations, the damage will be considered to have arisen after delivery
(in accordance with the General German Freight Forwarders´ Terms and Conditions, Art. 28)
.

Outside Germany

Note
KaVo shall not be held liable for damage arising from transportation.
The shipment must be checked on arrival.

If the packaging is visibly damaged on delivery, please proceed as follows:
1. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
   Without this evidence, the recipient will not be able to assert a claim for damages against the shipping company.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use the product.

If the product is damaged but there was no discernable damage to the packaging upon delivery, proceed as follows:
1. Report any damage to the shipping company either immediately or no later than 7 days after delivery.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use a damaged product.

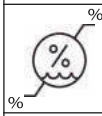
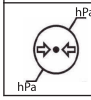
Note
If the recipient fails to comply with any of the above-mentioned obligations, the damage will be considered to have arisen after delivery
(in accordance with CMR law, Chapter 5, Art. 30).

1.4.3 Information on the packaging: Storage and transportation

Note
Please keep the packaging in case you need to return the product for servicing or repair.

The symbols printed on the outside are for transportation and storage, and have the following meaning:

	Transport upright with the arrows pointing upwards!
	Fragile - protect against impact!

	Protect from moisture!
	Permissible stacking load
	Temperature range
	Humidity
	Air pressure

2 Safety

2.1 Description of safety instructions

2.1.1 Description of danger levels

The safety instructions listed here, together with the three levels of danger will help avert property damage and injury.

⚠ CAUTION

CAUTION
indicates a hazardous situation that can cause damage to property or mild to moderate injuries.

⚠ WARNING

WARNING
indicates a hazardous situation that can lead to serious or fatal injury.

⚠ DANGER

DANGER
indicates a maximal hazard due to a situation that can directly cause death or fatal injury.

2.1.2 Warning symbol

	Warning symbol

2.1.3 Structure

⚠ DANGER

The introduction describes the type and source of the hazard.
This section describes potential consequences of non-compliance.
- The optional step includes necessary measures for hazard prevention.

2.2 Purpose – Proper use

2.2.1 General information

The user must ensure that the unit works properly and is in satisfactory condition before each use.
The KaVoPrimus® 1058 S/TM/C equipment system is a dental treatment unit in accordance with ISO 7494 with a dental chair in accordance with ISO 6875. This KaVo product is designed only for use in dentistry and may only be used by trained medical personnel. Any other type of use is not permitted.
"Proper use" includes following all the instructions for use and ensuring that all inspections and service tasks are performed.
The overarching guidelines and/or national laws, national regulations and the rules of technology applicable to medical devices for start-up and use of the KaVo product for the intended purpose must be applied and followed.

KaVo accepts liability for the safety, reliability, and performance of components supplied by KaVo, provided:

- installation, instructions, expansions, adjustments, changes or repairs were carried out by technicians trained by KaVo or third parties authorised by KaVo, or by the personnel of authorised distributors.
- the unit was operated in accordance with the instructions for use, care and installation.
- the IT components supplied by the operator meet the technical requirements in these instruction for use for hardware and software, and they are installed and set up according to the descriptions of these components.
- in the case of repairs, the requirements of IEC 62353 (DIN VDE 0751-1) "Repeat tests and tests before start-up of electrical items of medical equipment and systems - general regulations" are met in full.

Users have a duty to:

- Only use equipment that is operating correctly
- to protect himself, the patient and third parties from danger.
- to avoid contamination from the product

The applicable national legal regulations must be observed during the use of the device, in particular the following:

- Applicable regulations governing the connection and start-up of medical devices.
- Current occupational safety regulations.
- Current accident prevention regulations.

In Germany, operators, equipment managers and users are obliged to operate their equipment in accordance with the MPG regulations.
The services encompass all the test tasks required in accordance with § 6 of the medical devices operator ordinance (Medizinprodukte-Betreiberverordnung, MPBetreibV).
Regular performance of maintenance and safety checks is essential for the permanent assurance of the operating and functional safety of the KaVo product and for the prevention of damage and hazards.
Testing and maintenance intervals: Maintenance must be performed once a year, the safety check (STK) at intervals of 2 years. Shorter intervals for the safety check may be specified by the tester if necessary.

The following persons are authorised to repair and service the KaVo product:

- Technicians of KaVo branch offices after appropriate product training.
- Specifically KaVo-trained technicians of KaVo franchised dealers.

Note

The product must be cleaned and serviced according to instructions if it is not to be used for an extended period of time.

Note

The MULTIflex couplings, the current K/KL motors, and the ultrasonic scaler hoses of KaVo are equipped as standard with a protective device to prevent treatment water from being drawn back into the treatment centre via the handpieces. If products from other manufacturers are used at the standardised interfaces, it must be ensured that they are equipped with an appropriate protective device! If this is not the case, they may not be used!

Information on electromagnetic compatibility

Note

Based on IEC 60601-1-2 (DIN EN 60601-1-2) concerning the electromagnetic compatibility of electrical medical devices, we must draw your attention to the following points:

• Medical electrical devices are subject to special precautions concerning the electromagnetic compatibility and must be installed and operated in accordance with the KaVo assembly instructions.

• High-frequency communications devices may interfere with electrical medical devices.

Note

KaVo cannot guarantee the compliance of accessories, cables, and other components not supplied by KaVo with the EMC requirements of IEC 60601-1-2 (DIN EN 60601-1-2).

Disposal

Note

Any waste which is generated must be recycled or disposed of in strict compliance with all applicable national regulations in a manner which is safe both for people and the environment.

If you have any questions regarding proper disposal of the KaVo product, please contact the KaVo branch.

Disposal of electronic and electrical devices

Note

According to EC directive 2002/96 concerning used electrical and electronic devices, this product is subject to the cited directive and must be disposed of accordingly within Europe.

For more information, please visit www.kavo.com or contact your specialised dental supplier.

For final disposal, please contact:

In Germany

To return an electrical device, you need to proceed as follows:

1. On the homepage www.enretec.de of enretec GmbH, you can download a form for a disposal order under the menu item eom. Download the disposal order or complete it as an online order.
2. Enter the corresponding information to complete the order, and submit it as an online order or by fax +49 (0) 3304 3919-590 to enretec GmbH.
   The following contact options are also available for questions and for initiating a disposal order:
   Phone: +49 (0) 3304 3919-500
   Email: eom@enretec.de and
   Postal address: enretec GmbH, Geschäftsbereich eomRECYCLING®
   Kanalstraße 17
   D-16727 Velten
3. A unit that is not permanently installed will be picked up at the office.
   A permanently installed unit will be picked up at the curb at your address on the agreed date.

The owner or user of the device will have to bear the cost of disassembly, transportation and packaging.

International

For country-specific information on disposal, contact your dental supplier.

2.2.2 Product-specific

Use and target group

KaVoPrimus® 1058 S/TM/C is designed for dental treatment of children and adults. The KaVoPrimus® 1058 S/TM/C equipment system is a dental treatment unit in accordance with ISO 7494 equipped with a dental chair in accordance with ISO 6875. KaVo three-way and multifunction handpieces are dental instruments in accordance with EN 1639. They support the dental application in the mouth of the patient by supplying air, water or spray. In addition, the multifunctional handpiece supplies light and heated media. This KaVo product is designed for use in dentistry only and may only be used by trained medical personnel.
For technician jobs that require greater pressure than when working in the oral cavity such as grinding prostheses, etc., a special technician's machine must be used. The bearings of these machines are correspondingly stronger.

2.3 Safety instructions

2.3.1 General

Note
The safety and reliability of the system can only be ensured when the described procedure is followed.

⚠ DANGER

Explosion hazard.
Risk of fatal injury.
- Do not use KaVo product in areas subject an explosion hazard.

⚠ WARNING

Inappropriate operating conditions.
Impairment of the electrical safety of the device.
- It is essential to comply with the operating conditions specified in the "Technical Specifications" chapter and not to exceed those conditions.

⚠ WARNING

Use of un-authorised accessories or un-authorised modifications of the product.
Accessories that have not been approved and/or inadmissible modifications of the product could lead to hazards and/or personal injury or material damage.
- Only use accessories that have been approved for the combination with the product by the manufacturer or are equipped with standardised interfaces (e. g. MULTIflex couplings, INTRAmatic).
- Do not make any modifications to the device unless these have been approved by the manufacturer of the product.

⚠ WARNING

Injury or damage from damaged functional parts.

Damage to functional parts can cause further damage or personal injury.

- Check the device, electrical cables and any accessories for possible damage to the insulation and replace if necessary.
- If functional parts are damaged: discontinue your work and repair the damage or notify a service technician!

⚠ WARNING

Disposal of the product in the appropriate manner.

Prior to disposal, the product and accessories must be appropriately prepared or sterilised if this is necessary.

⚠ CAUTION

Health hazard and property damage due to non-compliance with servicing schedule.

Infection hazard to users and patients.

Product damage.

- Comply with servicing schedule.

⚠ CAUTION

Risks from electromagnetic fields.

Electromagnetic fields might interfere with the functions of implanted systems (such as pacemakers).

- Ask patients if they have a cardiac pacemaker or other system implanted before you start the treatment!

⚠ CAUTION

Malfunctions due to electromagnetic fields.

The product meets the applicable requirements regarding electromagnetic fields. Given the complex interactions between equipment and cell phones, the product may be influenced by a cell phone that is in use.

- Do not use cell phones in medical offices, hospitals or laboratories!
- Put electronic devices such as e.g. computer storage media, hearing aids etc. down during operation!

⚠ CAUTION

Damage by liquids.

Faults on electric components.

- Protect openings of the product from any ingress of liquids.
- Have a service technician remove liquids from the interior of the device.

⚠ CAUTION

Damage from liquids.

Residual liquids of any type can cause stains on or damage to cushions and parts of the housing.

- Remove any residual liquids without delay.

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.

Reduced product life.

- Perform regular proper care and maintenance!

2.3.2 Product-specific

⚠ WARNING

Injury or infection hazard from laid down instruments.

Given the arrangement of the instruments, injury or infections in the hand and underarm can arise when reaching for the tray holder or operating device. Increased risk of infection from diseased patients.

- Be aware of the arrangement of the instruments when accessing the tray holder or operating device.

⚠ WARNING

Health impairment due to reverse suction via the instruments.

Infection hazard.

Products from other manufacturers, which are not equipped with a protective device to prevent the drawing of treatment water into the treatment unit via the instruments, may be used at standard interfaces

- If you are using products from other manufacturers at the standardised interfaces, ensure that the products are equipped with the corresponding protective devices.
- Do not use products without a protective device.

⚠ WARNING

Electrical power.

Electrical shock from operating electrical accessory devices in the vicinity of the patient.

- Make sure that accessory devices do not compromise the safety level and that these devices comply with the requirements of IEC 60601-1 (DIN EN 60601-1) .
- Make sure that accessory devices comply with the requirements of IEC 60950-1 (DIN EN 60950-1) and are rendered compliant with the safety level of IEC 60601-1 (DIN EN 60601-1) through appropriate protective measures.
- Carry out a safety check of all devices in the vicinity of the patient in accordance with IEC 62353 (DIN VDE 0751-1) as specified by the manufacturer.

⚠ CAUTION

Electrical power

Electrical shock can result from incorrectly connecting a non-medical system to the interfaces of the device.

- When connecting an IT device to the medical system, follow IEC 60601-1 (DIN EN 60601-1) (system document).
- The USB interface on the dentist or assistant element may only be used in combination with the appropriate KaVo multimedia system.
- The USB interface must not be used for other devices.

⚠ CAUTION

Sitting down on a dental chair that is in horizontal orientation is associated with a risk of injury.

- Do not sit on the head or foot end of the patient chair when it is in a horizontal position.

⚠ CAUTION

The swinging arm may fall and cause injury.

If the swinging arm is overloaded, it can become damaged and injure the patient or user.

- Never load the swinging arm, spring arm or dentist's unit by using it as a support.

⚠ CAUTION

Risk of injury by suspended instruments (S table).

Patients may get injured by sharp instrument tips.

- When you move the dentist's unit, make sure that nobody is injured.
- Alert patients and care providers to the risk of injury.

⚠ CAUTION

Risk of injury during cleaning of the treatment unit.

Lack of instructions to the cleaning staff and lack of preparation of the treatment unit can lead to the cleaning personnel sustaining injuries.

- Only trained professionals and instructed cleaning personnel may be present in the treatment rooms.
- Position the chair for cleaning and turn the device off.

⚠ CAUTION

Third party device connection kit (optional): Hazard of reinfection from standing water.

Infections.

When a water-using unit is connected to the third-party connection kit, always perform the following tasks on the device:

- Before starting, rinse all the water drain lines without instruments (if applicable).
- Before startup and after the device has not been used for a while (weekends, holidays, vacations, etc.), rinse or purge the air and water lines.
- Make sure that the water-using unit is resistant to H_2O_2 since the water is sterilised with OXYGENAL 6 (at a concentration up to 0.02%).

⚠ CAUTION

Health damage due to germ formation.

Infection hazard.

- Before starting, rinse all the water drain lines without instruments.
- Before start-up and after the device has not been used for a while (weekends, holidays, vacations, etc.), rinse or purge with air the air and water lines.
- Carry out an intensive germ reduction.
- Actuate the tumbler filler repeatedly.

⚠ CAUTION

Long stay in the patient chair.

Decubitus formation.

- Take precautions against the formation of decubitus in long treatments.

⚠ CAUTION

Danger of injury from tipping the treatment unit.

Injury to the patient and user.

- Do not support yourself on the swinging arm.
- Do not sit on the head or foot end of the patient chair when it is in a horizontal position.

⚠ CAUTION

Danger of injury from overload or dynamic load.

The patient chair might collapse.

- Do not subject the patient chair to a load exceeding its limit (135 kg).
- Do not subject the patient chair to dynamic loads.

⚠ CAUTION

Risk of injury when the dental chair or headrest is moved.

Hair of the patient or practice personnel may get caught when the headrest of the dental chair is moved.

- Mind the hair of the patient or practice personnel when moving the dental chair or the headrest.

⚠ CAUTION

Risk of injury when the dentist or assistant element is moved.

The patient or office staff may be injured or bruised.

- Monitor the patient and office staff when moving the dentist or assistant element.

⚠ CAUTION

Danger of crushing during automatic chair movement.

The patient or treatment personnel can be clamped.

- Monitor the patient and treatment personnel when changing the chair position.

⚠ CAUTION

Damage to the handpiece hoses from stickers.

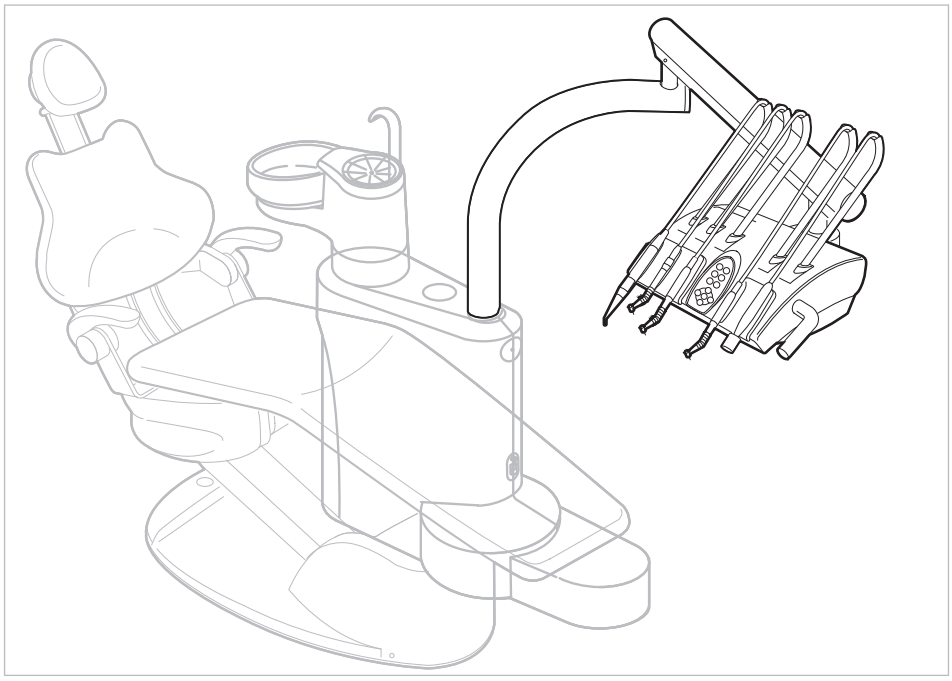
Handpiece hoses can burst.

- Do not affix stickers or adhesive tape.

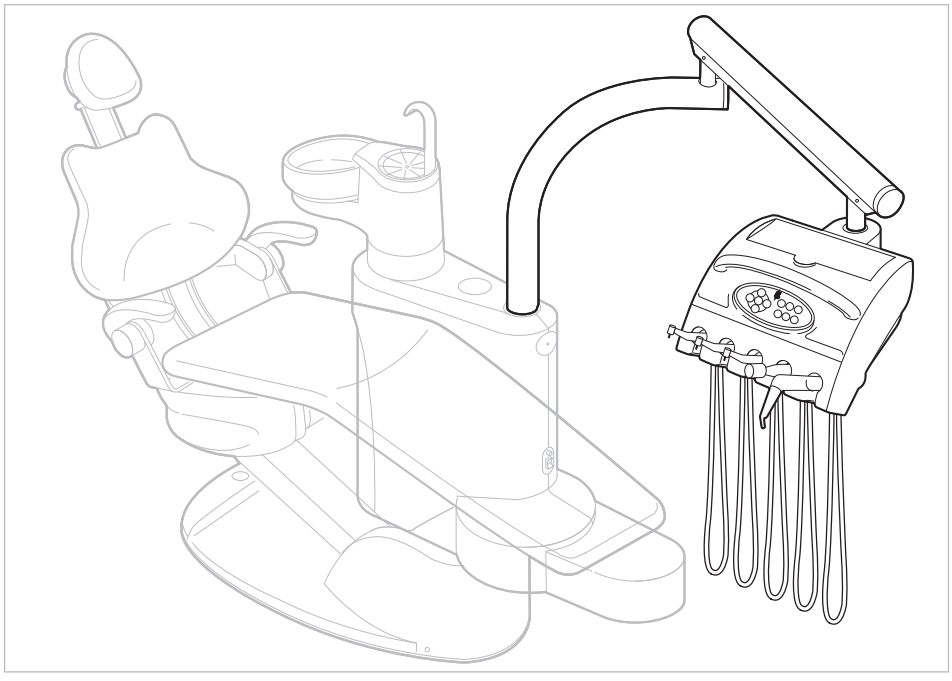
3 Product description

3.1 Treatment unit versions

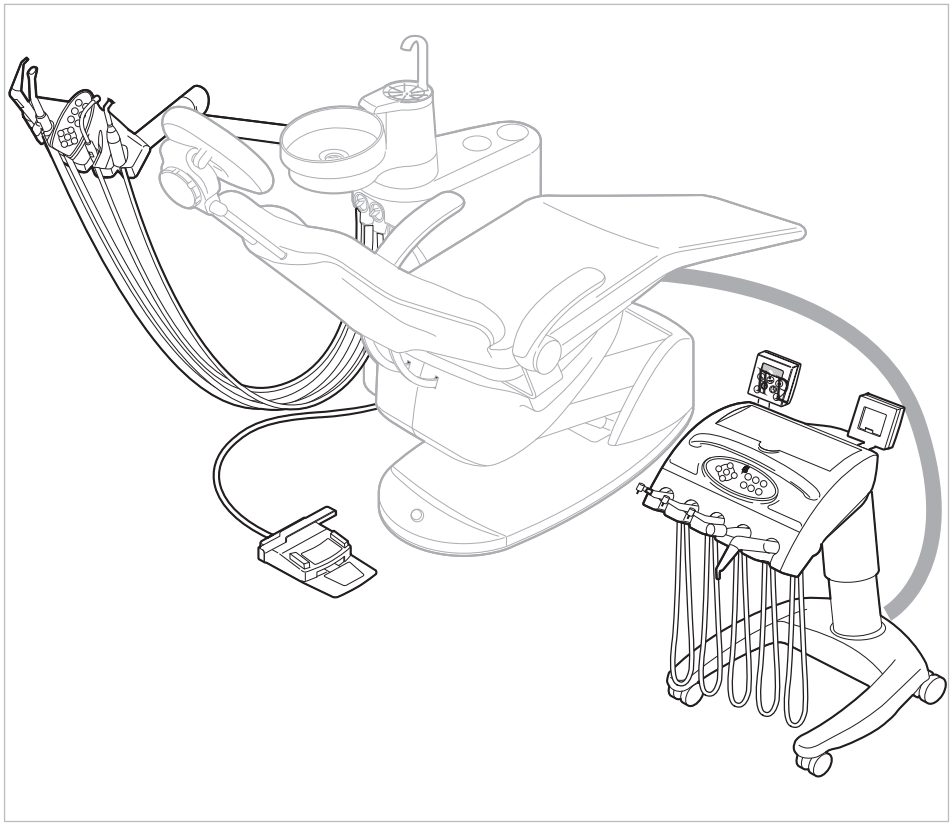
3.1.1 KaVo Primus® 1058 S



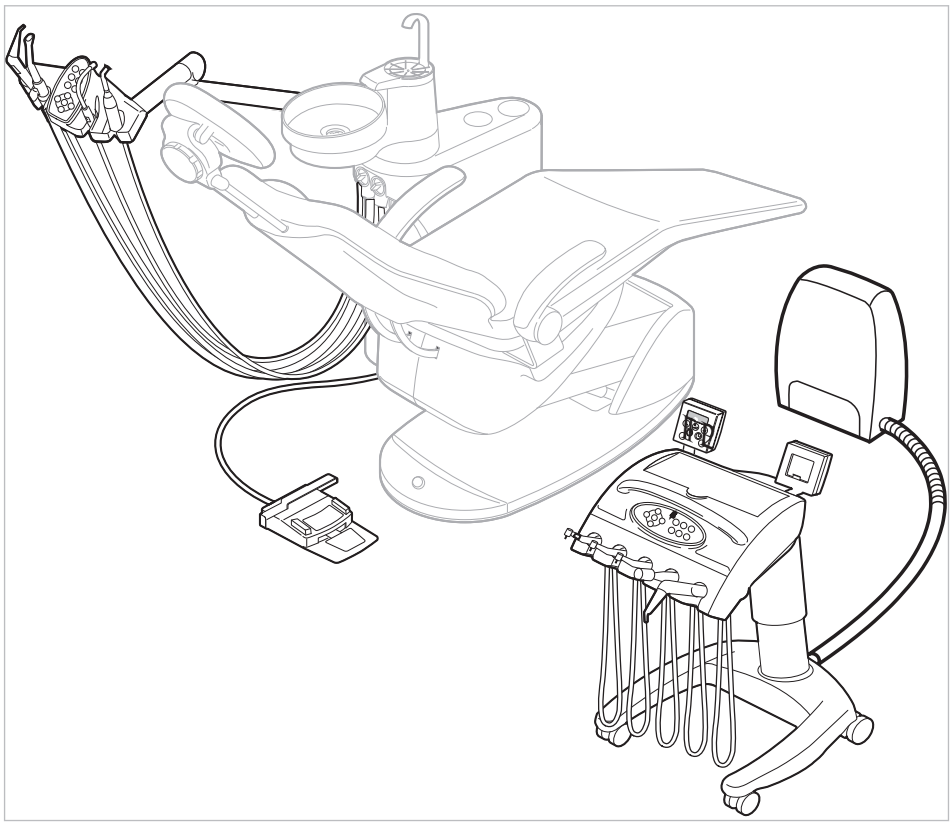
3.1.2 KaVo Primus® 1058 TM



3.1.3 KaVo Primus® 1058 C



3.1.4 KaVo Primus® 1058 C with right-side set-up kit.



3.2 Configuration options for the 1058 S/TM/C

	1058			1058 from SN 101*		
	TM	S	C	TM	S	C
Dentist element	●	●	●	●	●	●
1st Turbine tubing	●	●	●	●	●	●
1st KL motor 701	X	X	X	X	X	X
1st KL motor 703 LED	X	X	X	X	X	X
Three-function handpiece	●	●	●	●	●	●
Multifunctional handpiece	○	○	○	○	○	○
2nd Turbine tubing	○	○	○	○	○	○
2nd KL motor 701	○	○	○	○	○	○
2nd KL motor 703 LED	○	○	○	○	○	○
Smart drive	–	–	–	●	●	●
COMFORT drive	○	○	○	○	○	○
PIEZOsoft ultrasonic scaler	–	–	–	○	○	○
PiezoLED ultrasonic scaler	–	–	–	○	○	○
Memospeed display indicator or	○	○	○	○	○	○*
X-ray viewer 5x5	○	○	○	○	○	○*
X-ray viewer 1440 (mounted on light mounting pole)	○	○	○	○	○	○
X-ray viewer 1440 (mounted on table element)	–	–	○	–	–	○*
Tray holder for US tray	X	X	X	X	X	X
Tray holder for single standard tray	X	–	X	X	–	X
Tray holder for 2x standard tray	○	○	–	○	○	–
Spray heating for instruments	○	○	○	○	○	○
Physiological saline solution	○	–	–	○	–	–
ERGOcam	○	○	○	○	○	○
Satelec Mini LED	○	○	○	○	○	○
Combi separator / Combi Amalgam separator	○	○	○	○	○	○
Assistant element right/left kit	○	○	○	○	○	○

Legend:

● Standard equipment

○ Optional equipment

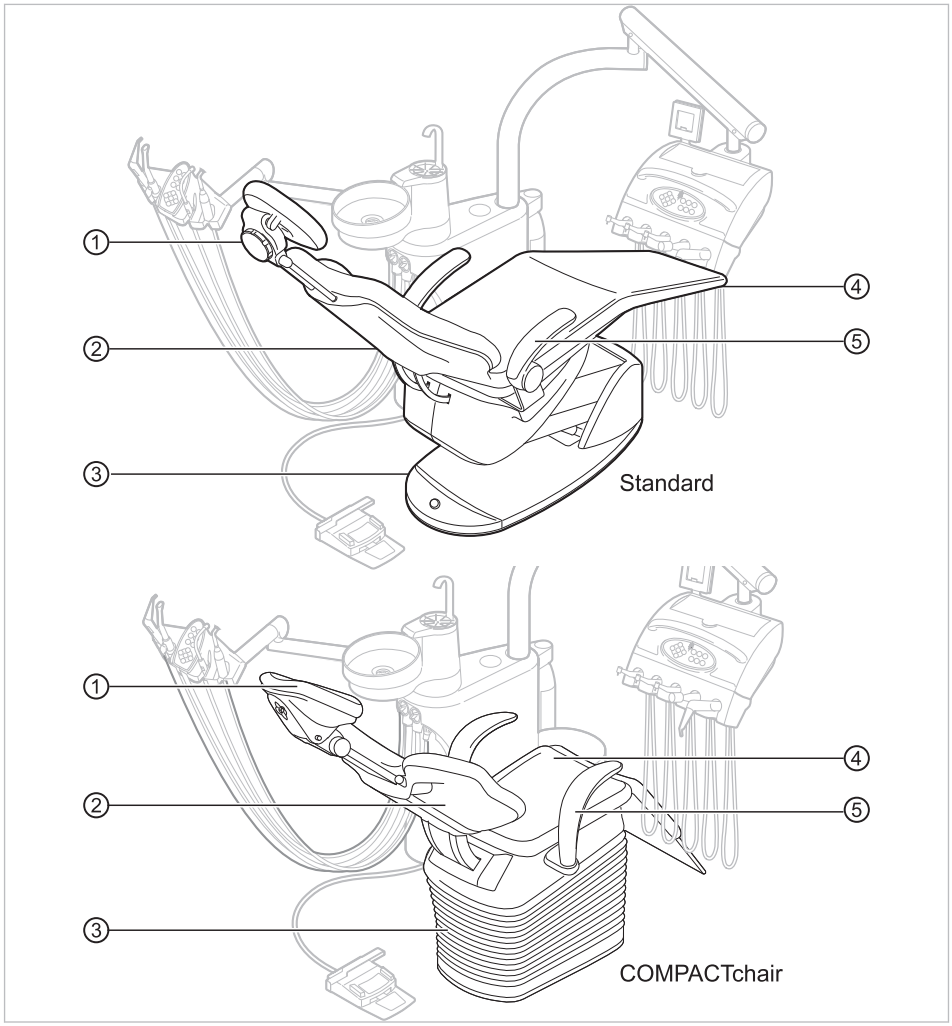
X Needs to be selected

– Not available for delivery

○* Optional equipment, not suitable in combination with kit for installation on the right, under-table

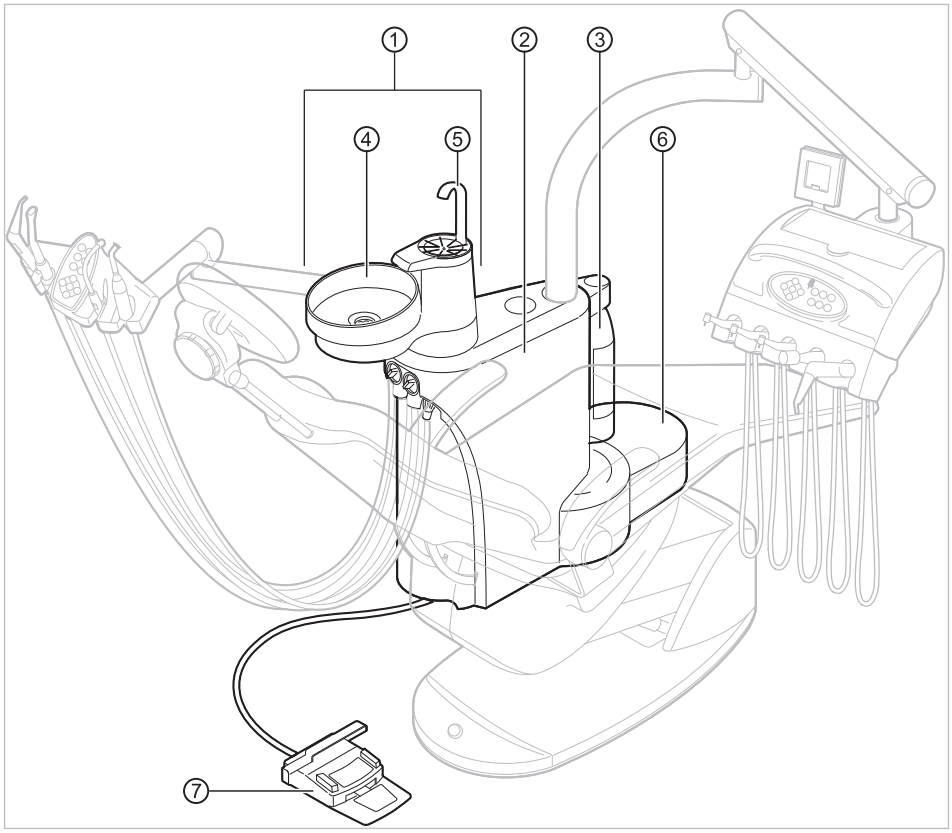
[2] Available in Chinese market only

3.3 Patient chair (standard and COMPACTchair)



① Headrest
② Backrest
③ Chair base
④ Seat
⑤ Arm rest

3.4 Device body with patient unit



Device body with patient unit

① Patient unit

② Device body
The central control is in the device body.

③ Pressurised water bottle (extra)

④ Spittoon bowl

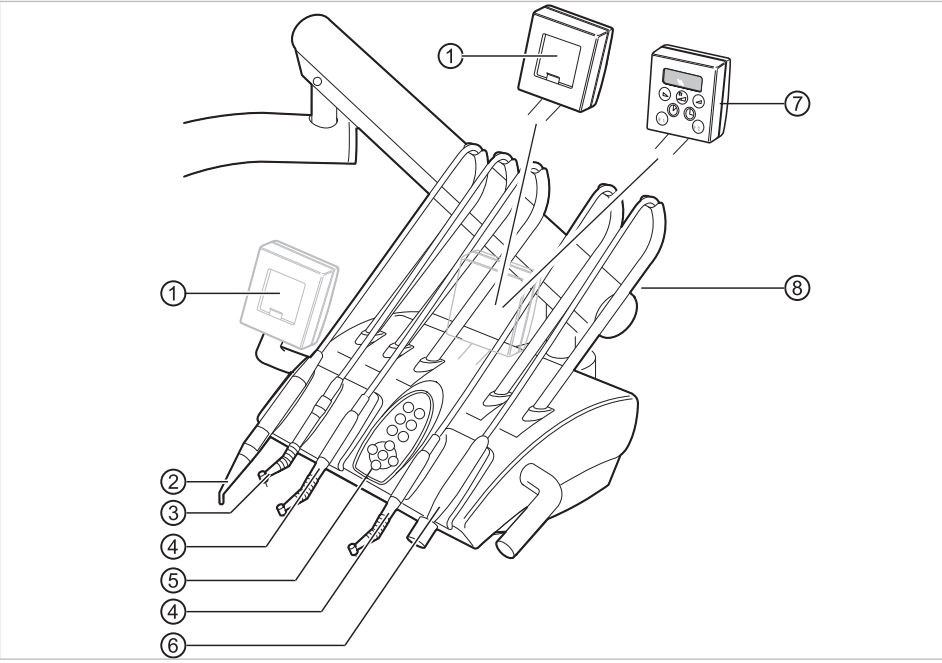
⑤ Tumbler filler

⑥ Supply element
Customer connection of power, water, compressed air, wastewater and suction air

⑦ Foot control

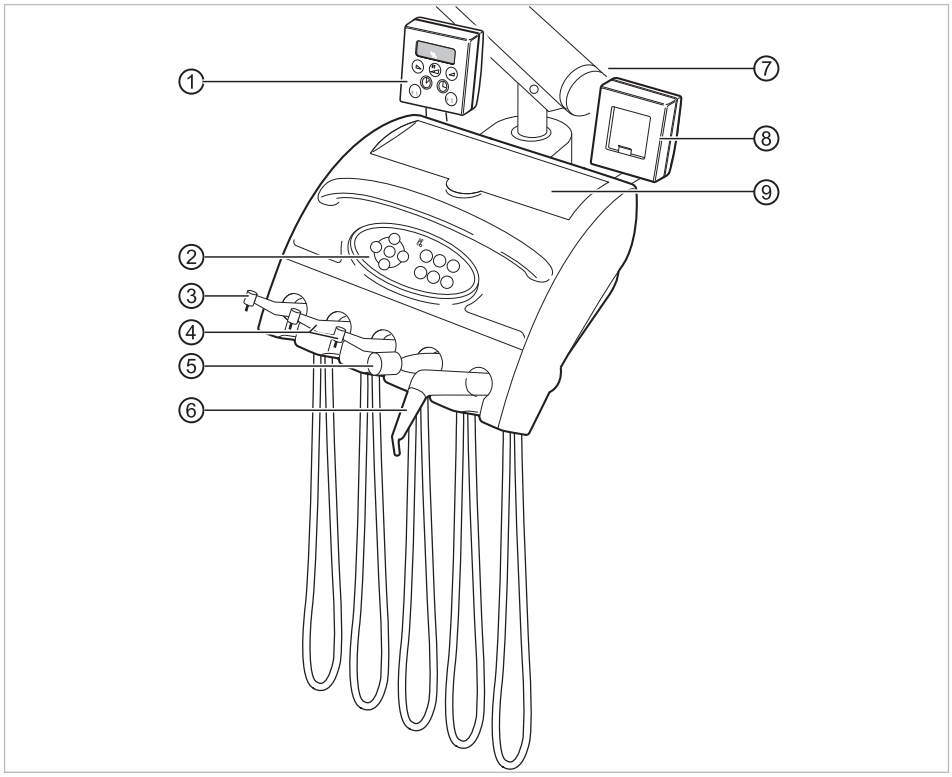
3.5 Dentist unit

Note
The arrangement of the instruments can be changed if needed.



1058 S

① X-ray viewer 5x5	② Three-function handpiece or multi-functional handpiece
③ Turbine	④ Either the INTRA LUX KL 701/703 motor or the COMFORTdrive 200XD
⑤ Button and display field	⑥ Ultrasonic scaler
⑦ Memospeed	⑧ Brake



1058 TM/C

① Memospeed	② Button and display field
③ Turbine	④ Either the INTRA LUX KL 701/703 motor or the COMFORTdrive 200XD
⑤ Ultrasonic scaler	⑥ Three-function handpiece or multi-functional handpiece
⑦ Brake	⑧ X-ray viewer 5x5
⑨ Tray holder	

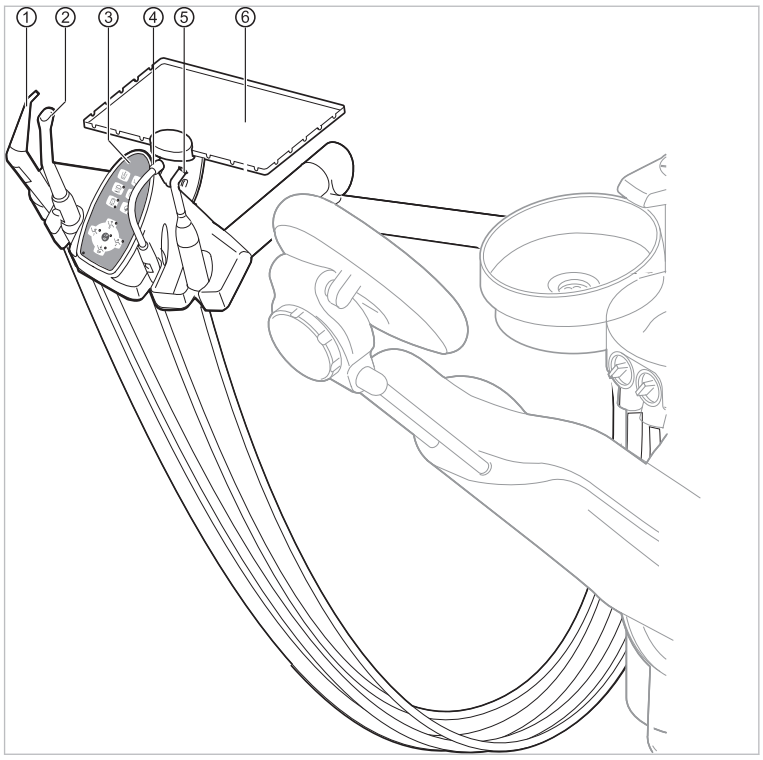
Note

When you push the 1058 Cart, installed on the right side, underneath the tabletop, objects and installed parts, such as, e.g., Memospeed ① or X-ray viewer 5x5 ⑧, may be damaged. In order to prevent any damage, the 1058 Cart needs to be moved to its lowest position before pushing it underneath the tabletop.

KaVo recommends only using the tablet tray (**Mat. no. 0.228.3016**) on the tray holder ⑨ to protect the painted parts on the dentist unit.

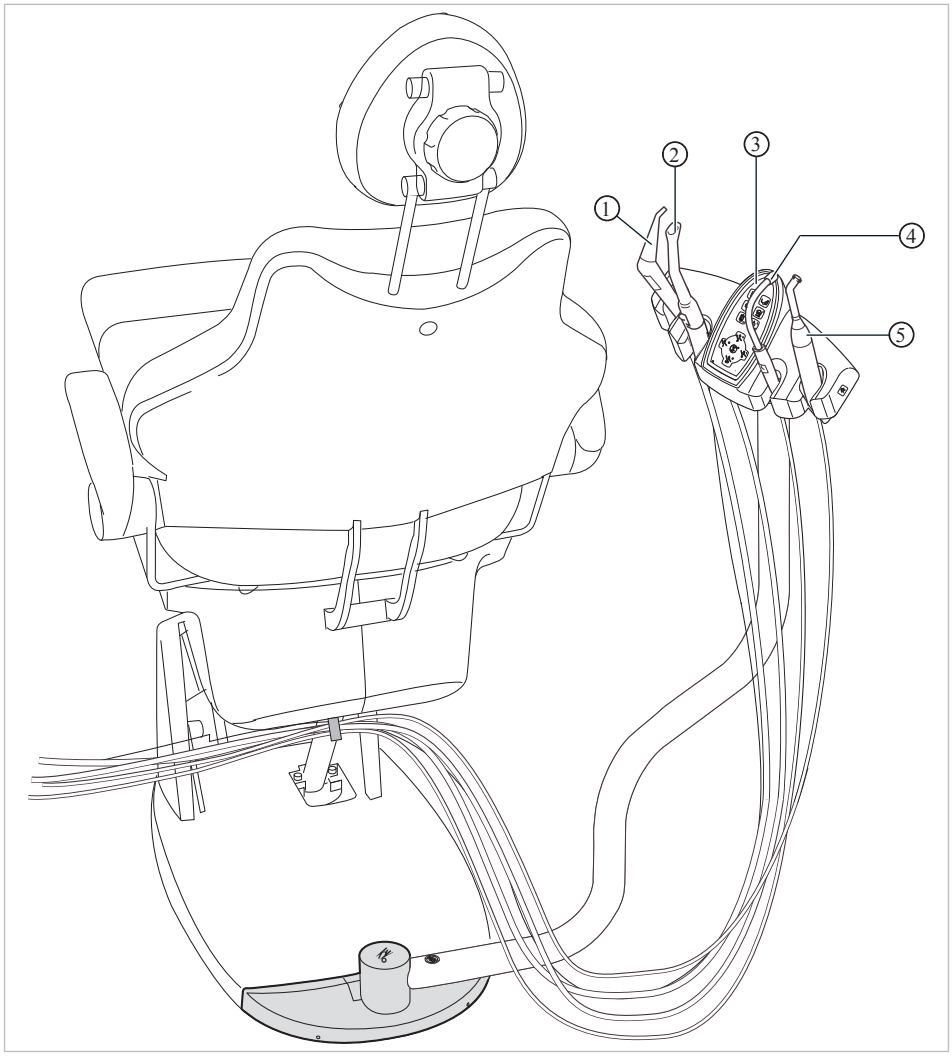
3.6 Assistant element – Versions

3.6.1 Standard assistant unit



① Three-function or multifunctional handpiece
② Spray mist ejector
③ Control element
④ Saliva ejector
⑤ Satelec Mini LED (polymerisation handpiece)
⑥ Tray holder for assistant

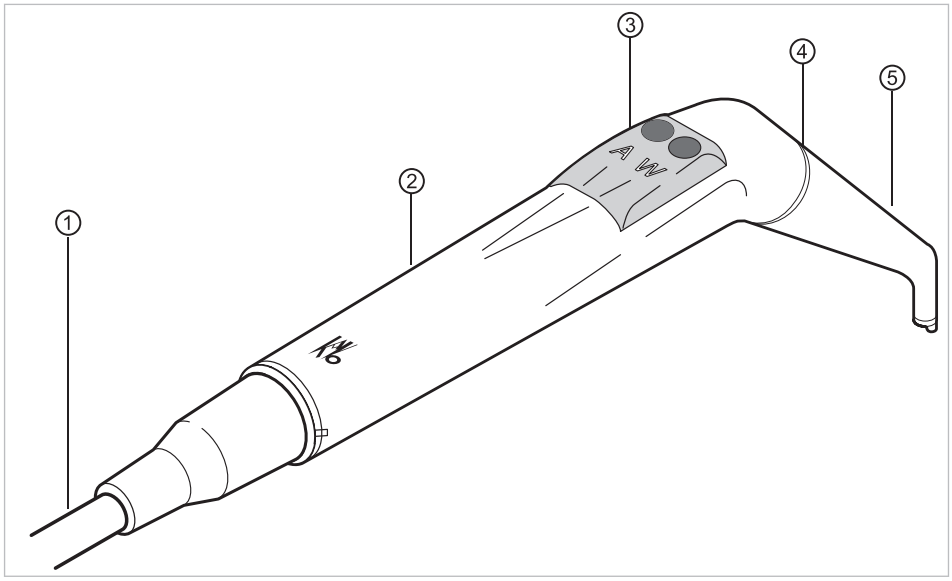
3.6.2 Assistant element right, left (optional)



Assistant element right, left with/without height adjustment (optional)

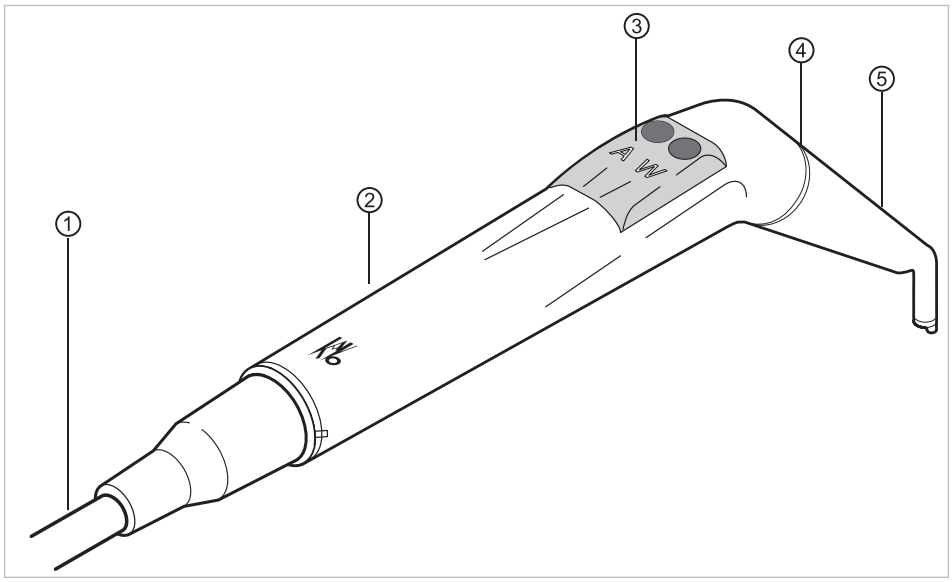
① Three-function handpiece
② Spray mist ejector
③ Control element
④ Saliva ejector
⑤ Satelec Mini LED (polymerisation handpiece)

3.7 Three-function handpiece (3F handpiece)



① MF handpiece hose
② Gripping sleeve
③ Media buttons
④ Labelled blue: Three-function handpiece (3F handpiece)
⑤ Cannula

3.8 Multifunctional handpiece (MF handpiece)

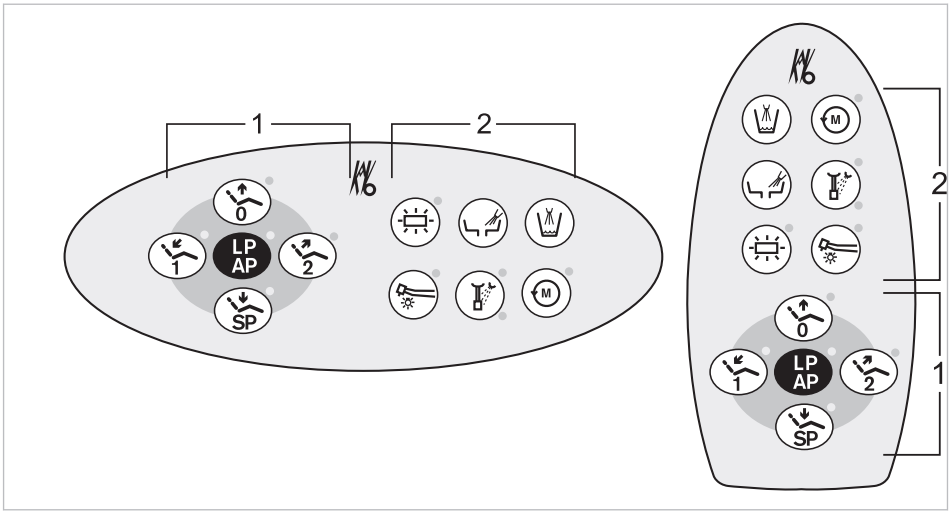


① MF handpiece hose
② Gripping sleeve
③ Media buttons
④ Labelled gold: Multifunctional handpiece (MF handpiece)
⑤ Cannula

3.9 Key fields

Note
The key functions on the 1058 S/TM/C dentist unit and Comfort assistant element are the same. The key fields are arranged differently due to the different shape.

3.9.1 with Comfort dentist unit and assistant unit



① Patient chair ② function keys

Group of keys for the patient chair

button	Designation	Display LED
	Seat up/AP 0 (automatic position 0)	green
	Seat down/rinsing position	green
	Backrest down/ AP 1 (automatic position 1)	green
	Backrest up/ AP 2 (automatic position 2)	green
	Last position/automatic position	green

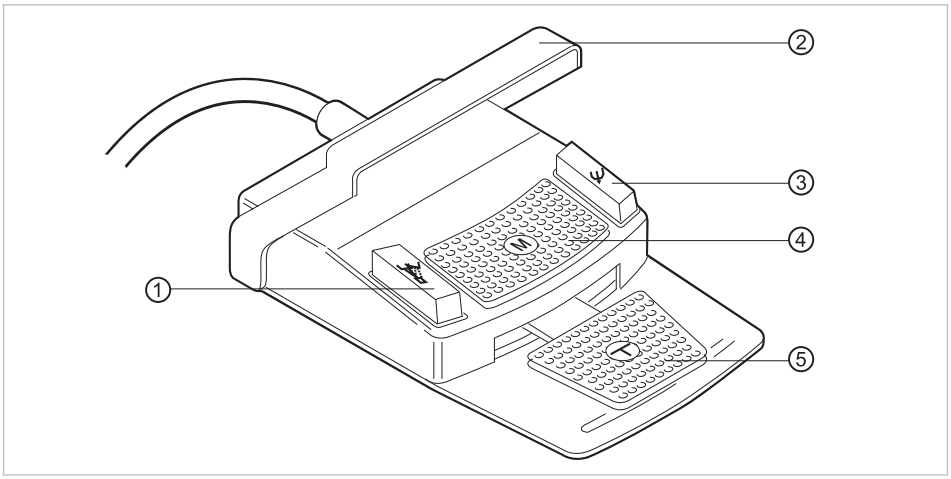
Group of function keys

Key	Designation	Display LED
	X-ray viewer	green
	Rinsing the spittoon	

Key	Designation	Display LED
	Tumbler filler	
	Cold light (on instruments)/ Treatment unit ON when the instruments are mounted	green
	Spray preselection (on removed instruments)	green/yellow
	Counterclockwise motor rotation	red

3.10 Foot control

The footswitches of the foot control have two functions. The functions of the footswitches depend on if an instrument is mounted or removed.

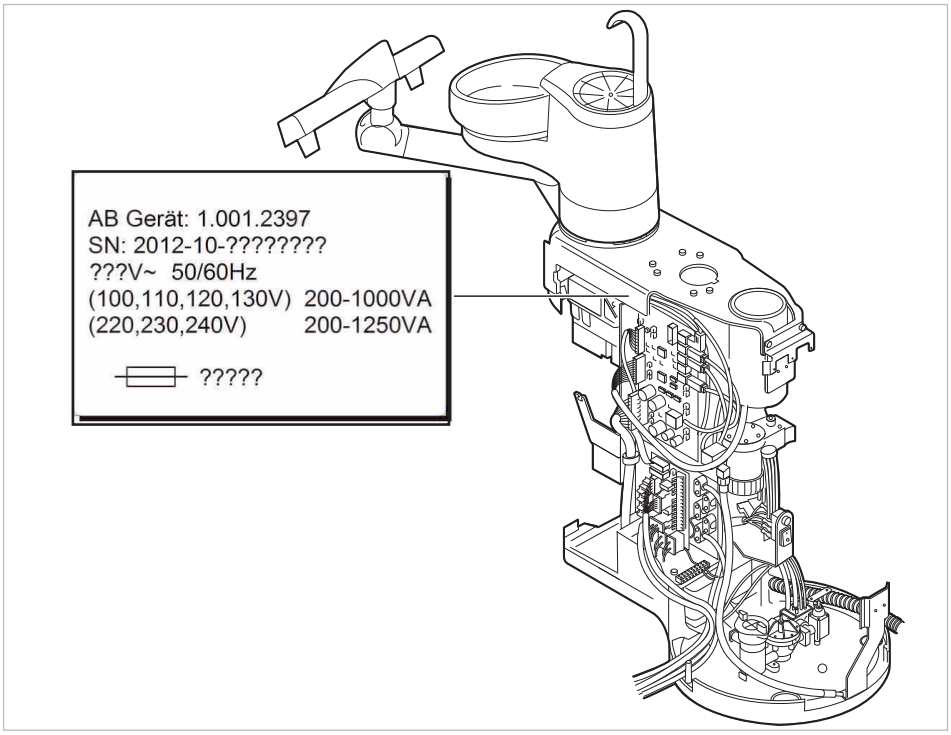


Item	Name	Function with handpiece mounted	Function with handpiece removed
①	"Spray pre-selection/AP" footswitch	Moves the dental chair into automatic position.	Sets the spray pre-selection.
②	U-shaped switch	Turns the safety shutoff On.	Switches the foot-operated buttons to the "Chair motion" function.
③	"Blown air/AP" footswitch	Moves the dental chair into automatic position.	Sets the preset blown air (chip blower).
④	Cross-switch: "Counterclockwise motor rotation"	Changes the position of the dental chair.	Selects the direction of motor rotation (for INTRA LUX motor KL 701/703 or COMFORTdrive 200XD).
⑤	"Handpieces" foot-pedal	Generates a video freeze frame if ERGOcom is installed.	Starts the motor and controls the speed/ intensity of the handpieces.

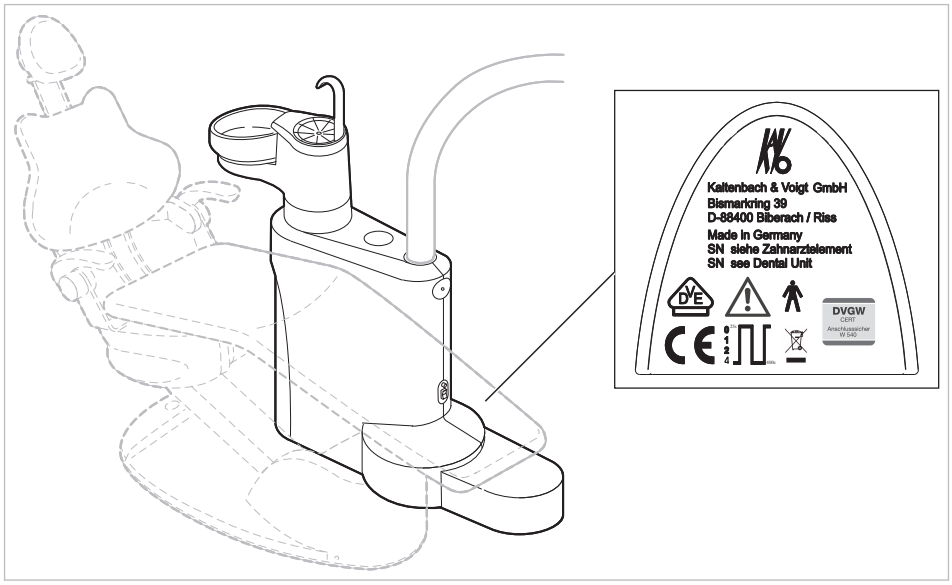
3.11 Rating plate and identification plate

Rating plate

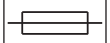
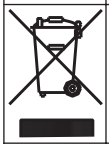
Rating plate



Inside attachment site for rating plate



Outside attachment site for rating plate

SN	Serial number
	Read and take note of the content of accompanying documents
	Type B application part
	Type BF application part
	Operating mode: Operating time of the patient chair: 25 seconds Pause time of the patient chair: 400 seconds (The permissible operating times correspond to common dental procedure.)
	Fuse ratings: The "?????" depend on the mains voltage and are either T10 H or T6.3H. 100 V~ ,110 V~, 120 V~, 130 V~ = T10H 220 V~ , 230 V~, 240 V~ = T6.3H
	For disposal information, see also: Purpose - Intended use
	CE mark according to Medical Devices Directive EC 93/42
	VDE mark
	DVGW certification DVGW CERT registration number AS-0630BT0111

Identification plates

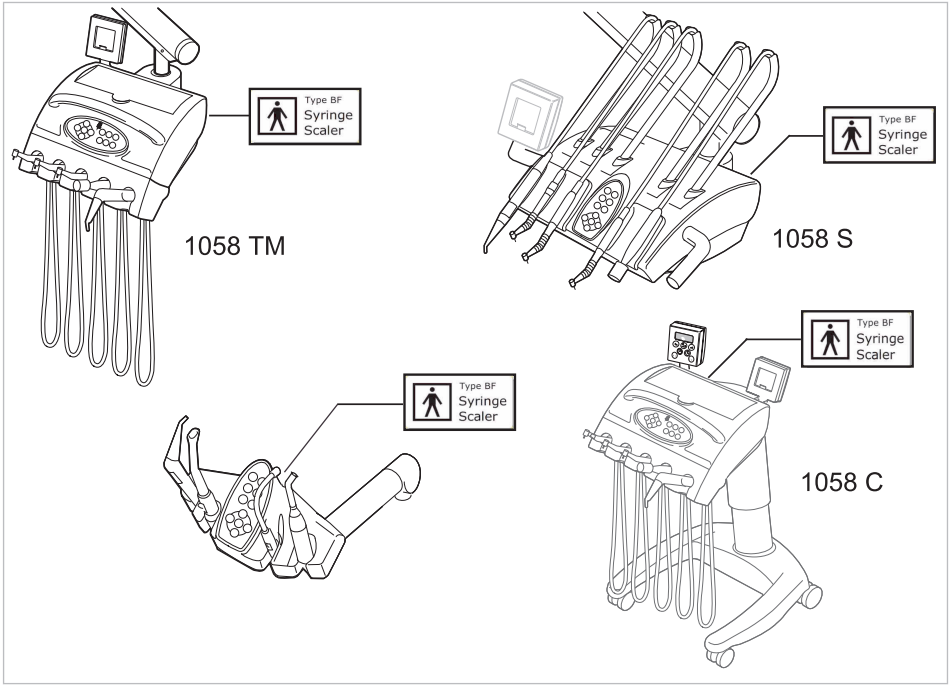
Identification plate example 1058 S

① Year and month of manufacture

② Serial number

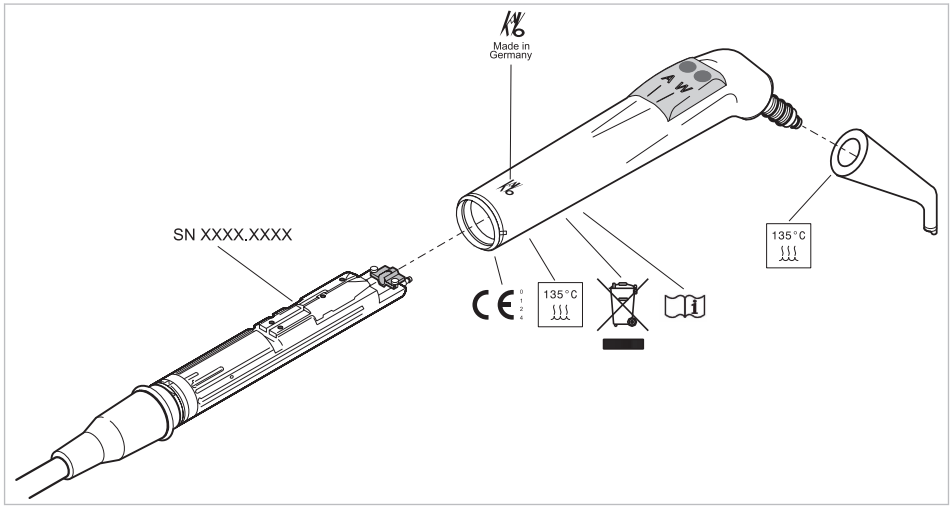
③ HIBC Code

Rating plate and labelling on dentist and assistant elements



Attachment locations for rating plates and BF labelling

Labelling and marking of the three-function handpiece and multifunctional handpiece



Made in Germany	Company logo of the manufacturer
SN	Serial number
CE 0124	CE mark according to 93/42/EEC medical devices
135 °C	Sterilisable up to 135 °C
	Disposal instructions according to Directive WEEE 2002/96/EG Annex N
	Follow instructions for use

3.12 Technical data

Drilling template and setup plan

Drilling template (**Mat. no. 1.001.4755**)	Right-handed (Rh): sheet 001, Left-handed (Lh): sheet 002
Includes COMPACTchair (**Mat. no. 1.003.6767**)	Page 001 to 004
Layout plan (**Mat. no. 1.001.4755**)	Page 003 to 006 and 011 to 013
1058 TM	Rh: Page 003, Lh: Page 004
1058 S	Rh: Page 005, Lh: Page 006
1058 C	Rh: Page 011, Lh: Page 012
Includes COMPACTchair (**Mat. no. 1.003.6767**)	Page 005 to 008 and 013 to 015

Electrical system

Electrical lead	3 x 1.5 mm^2 (customer-provided fuse protection 10 A) 3 x 2.5 mm^2 (customer-provided fuse protection 16 A)
Electrical lead	3 x 1.5 mm^2
Free end above the floor	1 000 mm
Input voltages	100/110/120/130/220/230/240 V AC
Frequency	50/60 Hz
Input voltage set by the manufacturer	See rating plate
Factory-set mains input voltage	See nameplate
Power consumption at 100, 110, 120, 130 V	200 to 1,000 VA
Power consumption at 220, 230, 240 V	200 to 1,250 VA
Customer-provided fuse protection	Automat C 16 or screw-plug fuse 10 A
Protective conductor above floor	See DIN VDE 0100-710, 1000 mm
Heat emission	360 to 3240 kJ/h
Heat emission	Ø 900 kJ/h
Degree of soiling	2
Installation category	II
Power consumption	100 to 900 VA
Customer-provided fuse protection	Auto-mat C16 or screw-plug fuse 10 A
Mark of approval	CE / DVGW / VDE
Foot control	IPX1 (moisture protection)

Triple-function handpiece and multifunctional handpiece

Flush the water and air passages for 20 to 30 seconds before working at the beginning of the day.

Water pressure	1.5 ± 0.3 bar; Flow pressure; 4 x manometer
Max. static pressure water	2.5 ± 0.3 bar
Water flow	80 ± 10 ml/min
Air pressure	3.3 ± 0.1 bar; Flow pressure; 4 x manometer
Max. dynamic pressure air	4 + 0.5 bar
Air flow	14 ± 2 Nl/min
Operating time (multifunctional handpiece only)	1 minute
Interval (multifunctional handpiece only)	3 minutes

Electrical multifunctional handpiece

Safety extra-low voltage according to DIN EN 60601-1:	24 V AC ± 10% (non-grounded voltage)
Frequency	50/60 Hz
Type of use	BF
Heat output for water	approx. 90 W
Heat output for air	approx. 20 W
Electrical resistance of the heating cartridge	6.4 ± 0.4 Ω
Lamp voltage	max. 3.2 V ± 0.15 V
High pressure lamp output	max. 2.5 W

Water supply

Note

If the water is very hard (above 12 dH), a water softening device must be fitted in the ion-exchange process.
Insufficient water hardness (below 8.4 dH) can promote the formation of algae.

Note

The "water inlet block" assembly kit does not include a separation between the treatment water and water supplied by the local mains. The operator must observe and adhere to relevant national directives concerning the prevention of backflow. If these rules are not adhered to, the manufacturer can assume no liability for the quality of the treatment water and the microbial re-contamination of the public drinking water network.

Note

A water sterilisation unit is installed in all dental units from KaVo in connection with the "Waterblock DVGW with an integrated water sterilisation system. To maintain the quality of the treatment water, the sterilising agent OXYGENAL 6 is continually in fed to the water, a hygienically effective concentration that is harmless to the patients (3.2 ml / litre). The handling is described in the maintenance instructions for the treatment units. Supplementary measures such as rinsing the water tubes and intensive germ reduction must be carried out according to the instructions of the manufacturer.

⚠ WARNING

Danger of infection if the national guidelines are not observed.

Contamination of the treatment water or the drinking water network.

- Observe and adhere to the national guidelines concerning the quality of water for human consumption (potable water) – if available.
- Observe and adhere to the national guidelines concerning the prevent of reflux (flow of water from the treatment unit to the public water network) – if relevant.

⚠ WARNING

Risk of infection if the "Water block, compact" is used without additional safeguards.

Contamination of the treatment water and/or drinking water supply with germs.

- With regard to the "Water block, compact" assembly kit, please note that no disinfection facility is installed in the unit, and take appropriate safeguards. KaVo recommends to use the "Water block DVGW with integrated water disinfection facility in combination with KaVo OXYGENAL 6 (**Mat. no. 04893451**).
- If the Water bottle kit is used with the enclosed dosing attachment (**Mat. no. 10020287**), add the proper amount of KaVo OXYGENAL 6 (**Mat. no. 04893451**) with each filling. For the correct amount, please refer to the Instructions of the dosing attachment for water disinfection.

According to DIN EN 1717, each unit that is not listed by DVGW must be provided with an upstream type AA, AB or AD safety device. (The DVGW water bottle kit is certified; see the following list.)

When establishing a water connection, prevent brackish water pools with standing water (also in the house plumbing).

You can find additional information at www.dvgw.de

Free drainage according to DIN EN 1717 - DVGW certified	Water block DVGW, water bottle DVGW, register no.: AS-0630BT0111
Water quality	Tap water
Water hardness	1.5 to 2.14 mmol/l ≙ 8.4 to 12 °dH
pH	7.2 to 7.8
Customer water filtering	80 µm
Water connection	Shut-off valve with brass cone compression screw connection 3/8" to Ø 10 mm provided
Above-floor water connection	min. 40 mm, max. 160 mm with valve opened
Water inlet pressure	2.0 to 6.0 bar
Water inlet pressure	4 l/min
Diameter of the drain connection	40 mm
Above-floor drain connection	20 mm
Outflow quantity	max. 4 l/min
Slope of water drain pipe	downstream from device: at least 10 mm per metre

Air supply

⚠ WARNING

Danger of infection due to non-adherence to the national guidelines concerning the quality of dental air.

- Observe and adhere to national guidelines concerning the quality of dental air - if available.

Air inlet pressure	5.2 to 7 bar
Air consumption	max. 80 Nl/min.
Customer air filtration	50 µm
Air connection	Shut-off valve with brass cone compression screw connection 3/8" to Ø 10 mm provided
Air connection above floor level	min. 40 mm, max. 160 mm with valve opened

Suction

	Suction vacuum at device intake	
Suction air quantity at spray mist cannula	**with wet suction**	**with dry suction**
minimal V~250 Nl/min	> 60 mbar	> 85 mbar

	Suction vacuum at device intake	
Suction air quantity at spray mist cannula	**with wet suction**	**with dry suction**
recommended V~300 Nl/min	> 80 mbar	> 120 mbar
Suction vacuum static max.	< 180 mbar	< 180 mbar

Note

If the negative dynamic pressure is > 180 mbar, the unit must be equipped with the negative pressure regulating valve assembly kit.

The values apply to the KaVo measuring set (**Mat. no. 04118500**)

Operating environment

⚠ WARNING

Inappropriate operating conditions.

Impairment of the electrical safety of the device.

- It is essential to comply with the operating conditions specified in the "Technical Specifications" chapter and not to exceed those conditions.

Floor quality	The quality of the flooring must meet the load bearing ability for buildings DIN 1055 page 3 and have a pressure resistance in accordance with DIN 18560 T 1.
Ambient temperature	+10 to +40 °C
Relative humidity	30 to 75%
Air pressure	700 hPa to 1,060 hPa
Max. elevation for operation	up to 3000 m

Maximum loads

Patient chair (lifting movement)	135 kg
Dentist unit tray holder/care provider part - loadable up to	2 kg
Assistant unit tray holder - loadable up to	1 kg
Dentist unit /care provide part - loadable up to	2 kg

Transportation and storage conditions

Ambient temperature	-20 to +55°C
Relative humidity	5% to 95% non-condensing
Air pressure	700 to 1,060 hPa

Weight

Treatment unit with Standard patient chair	279 kg gross, 224 kg net
Including steel set-up plate and ERGOcom	344 kg gross, 289 kg net
Treatment unit with COMPACTchair	255 kg gross, 200 kg net
with steel setup plate and ERGOcom	320 kg gross, 265 kg net

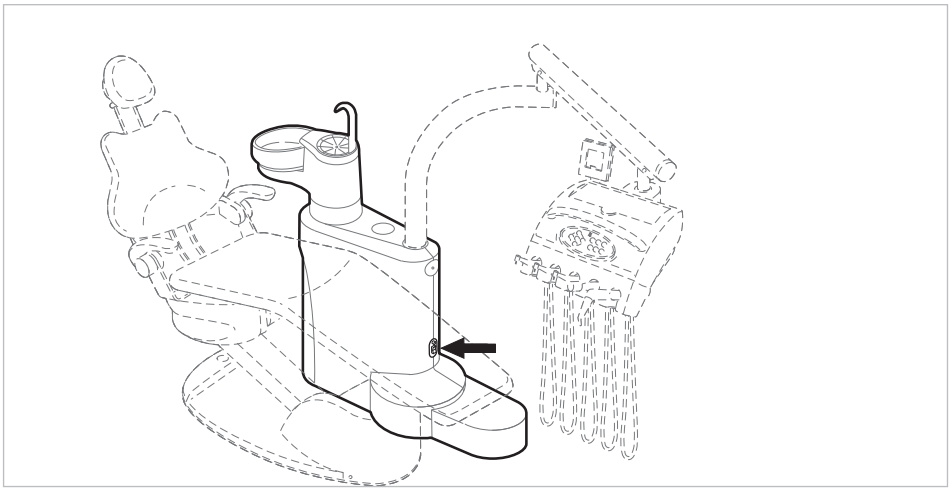
For more information on the packages, see assembly instruction, section B 3

4 Operation

4.1 Turn the unit on and off

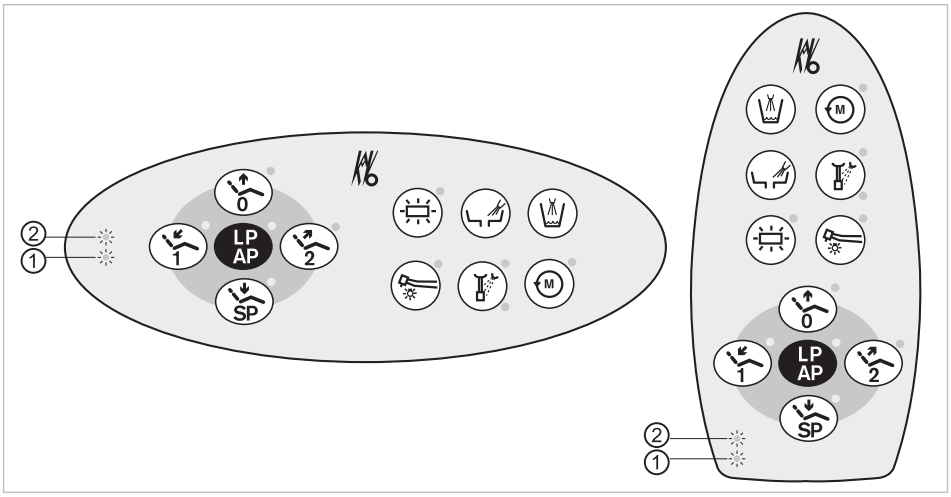
The main switch has the following tasks:

- Plug in or disconnect all the pins of the unit's plug into the customer's power supply.
- The customer's compressed air and water supplies are connected and disconnected using the solenoid valves and compressed air control installed in the device.



▸ Switch on the device using the main switch.

⇨ When the unit is ready to operate, the green LED ① shines (memory level Dentist 1) or the yellow LED ② (memory level Dentist 2).



Note

To prevent water damage, the main switch must be turned off before leaving the dental practice.

4.2 Adjusting the patient chair

4.2.1 Adjust the arm rest

Arm rest for the standard patient chair

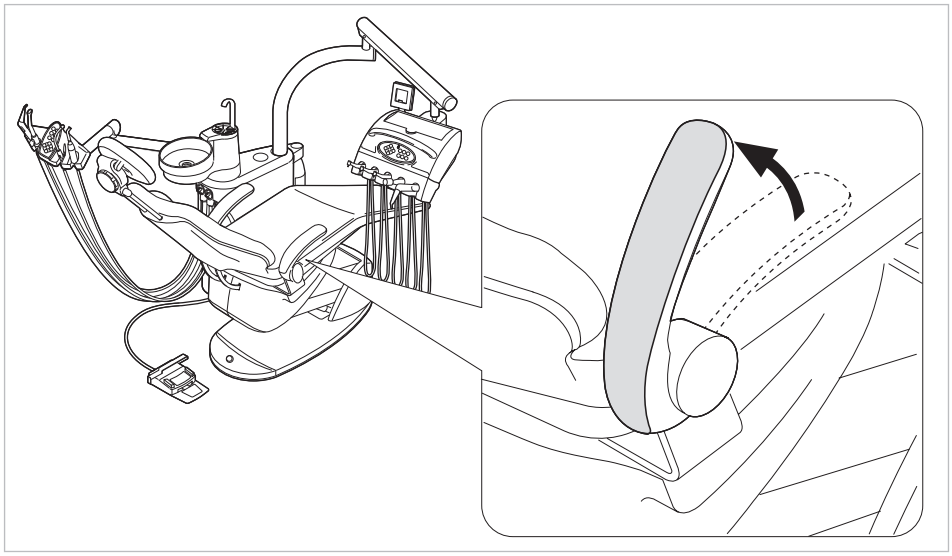
To make it easier for the patient to sit in the chair, the armrest can be swung up.

⚠ CAUTION

The patient's hands are in a bad position when the chair is rising

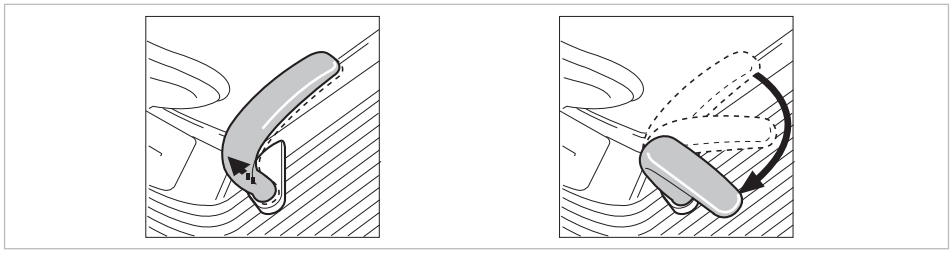
Danger of crushing fingers between the backrest and armrest.

- Make sure that the patient is sitting in the right position (especially children).



Armrest for the COMPACTchair patient chair (extra)

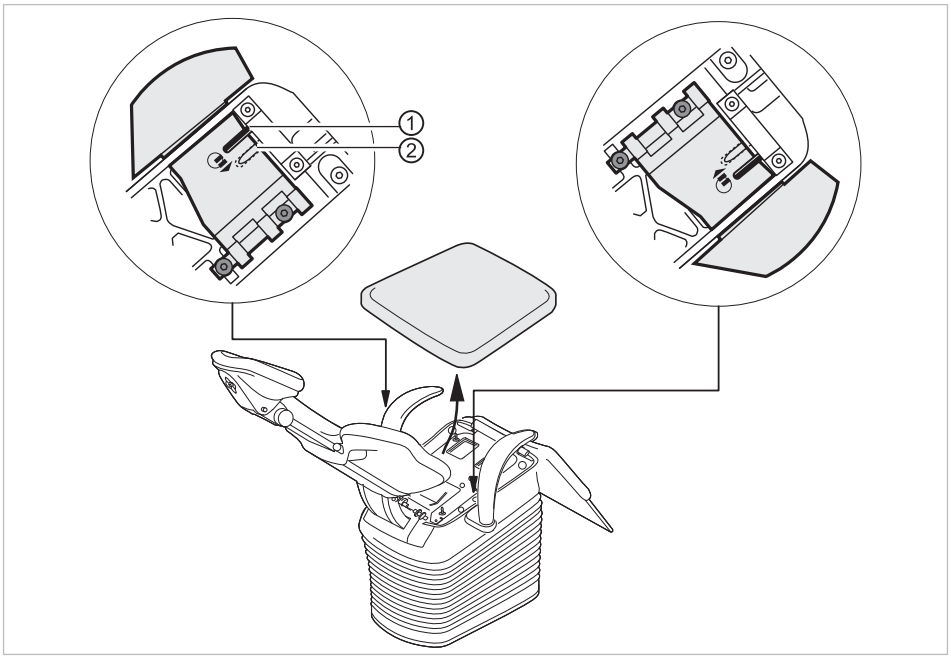
To make it easier for the patient to sit in the chair, the armrest can be swung out.



- Pull the arm rest up and swing it out.
- Then swing the armrest back until it locks in place.

To prevent the armrest from swinging out unintentionally, it can be fixed in place.

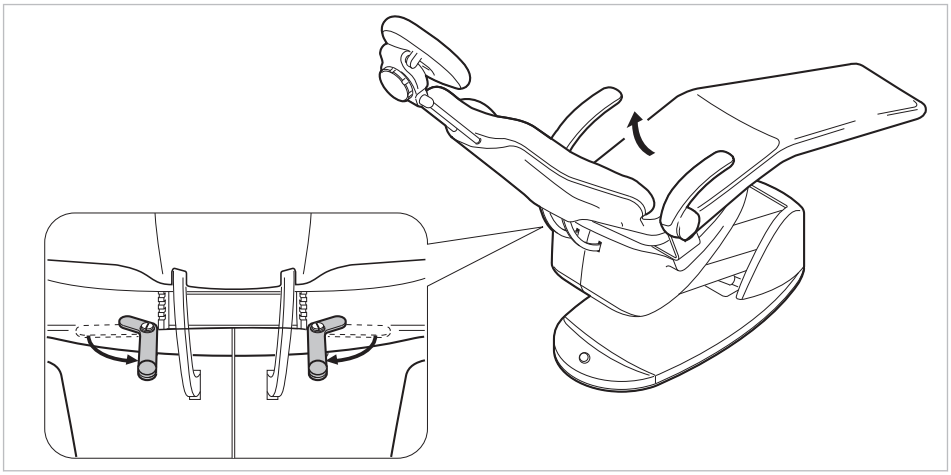
Note
The armrest on the side of the device body must be fixed to prevent collisions.



- Release the clips and remove the seat cushion.
- Move the safety lever into position ① to fix the armrest.
- Move the safety lever into position ② to allow the armrest to swing.

4.2.2 Adjust the seat

The seat can be tipped into four different positions to provide a lying surface for treating the maxilla for children of different sizes.



- Release the lock lever and tip the seat into the required position.
- Make sure that the lock lever fully locks into place.

4.2.3 Adjust head rest

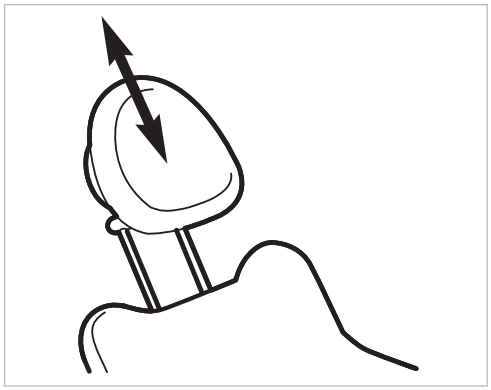
Adjust double-jointed knob headrest with knob

⚠ CAUTION

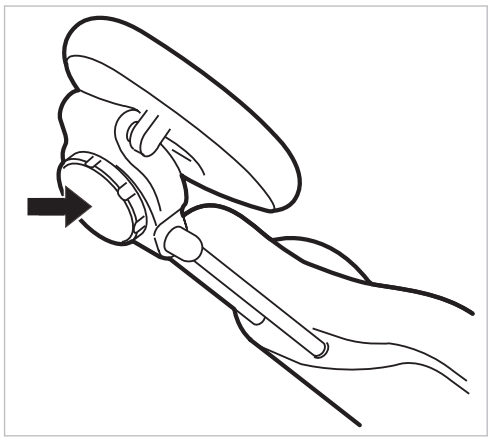
Adjusting the headrest.

Injury of neck muscles.

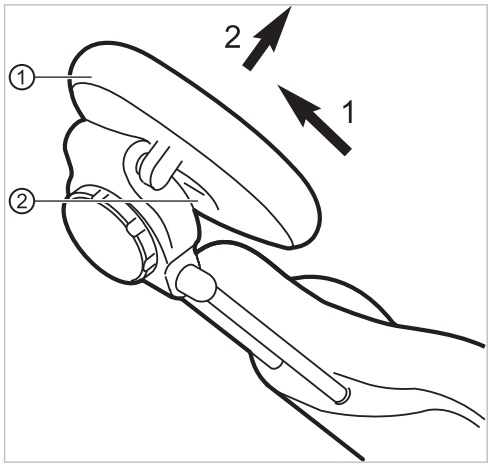
- Make sure that the patient is aware of the headrest setting.
- Patients need to raise their head slightly during adjustment.



- Push in or pull out the headrest depending on the patient's size.



- To swing the headrest, turn the locking dial to the left, move the headrest into position, and turn the dial to the right to lock it.



- To remove the headrest cushion, remove the screw ②, pull the cushion ① up slightly, and remove it to the front.

Adjust double-jointed headrest with push button

⚠ CAUTION

Adjusting the headrest.

Injury of neck muscles.

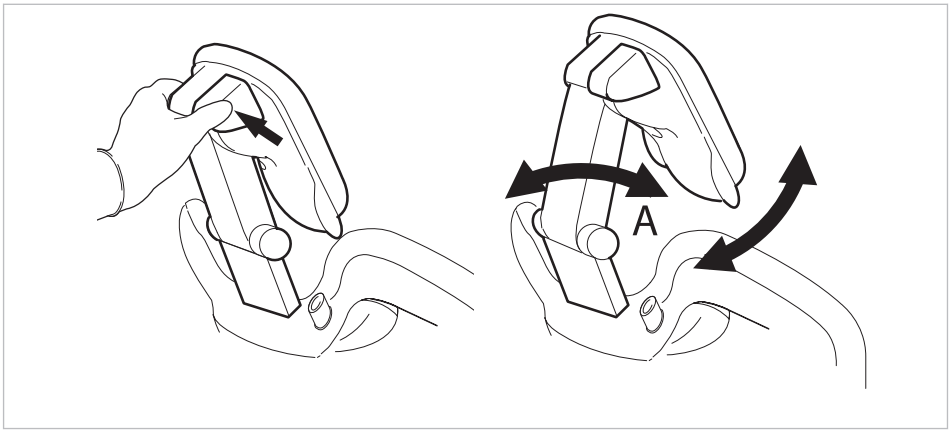
- Make sure that the patient is aware of the headrest setting.
- Patients need to raise their head slightly during adjustment.

The bar length and angle of the headrest can be adjusted.

- Press the lock button and push in or pull out the headrest depending on the patient's height.

Note

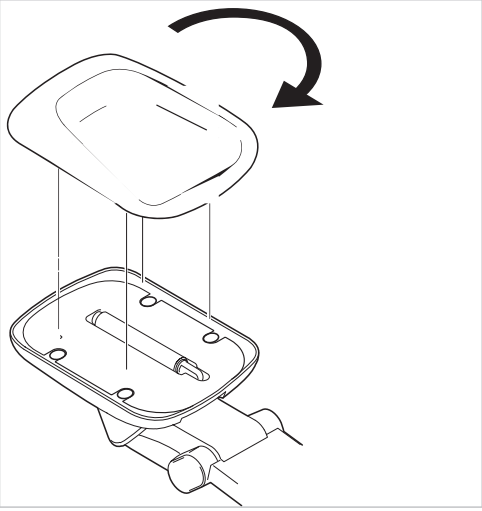
The service technician can adjust the braking force.



- Press the lock button and swing the headrest into the desired position.
  When swinging the headrest back into position, make sure that there is nothing between the area A and head cushion.

Turning the head cushion

The head rest cushion is a rotating cushion. It can be turned to offer better neck support, for example when treating children.



- Evenly pull the cushion up and rotate it 180°.
- Then mount and push the head cushion back on.

4.2.4 Adjust chair position

⚠ CAUTION

Danger of injury from overload or dynamic load.
The patient chair might collapse.
- Do not subject the patient chair to a load exceeding its limit (135 kg).
- Do not subject the patient chair to dynamic loads.

The chair position can be adjusted continuously.
Automatic positions can be saved, and the saved positions can be recalled by the push of a button.
The chair and backrest movements are simultaneous in the automatic program.
Exception: When the operating voltage for the standard patient chair is below 200 V, the movements in the automatic program or sequential. In this case, a service technician must change the program.

Automatic chair motor shutoff

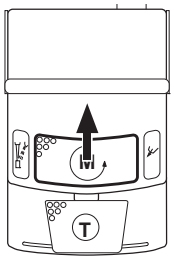
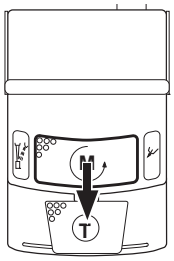
The chair motors automatically shut off when they reach an operating temperature of 140°C. This high temperature is only reached when they are frequently actuated, e.g. in demonstrations. This temperature is never reached in normal work.
After the motors automatically shut off, they will be operable again after about 15 minutes.

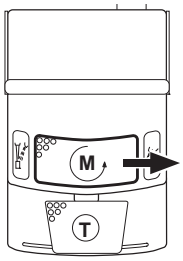
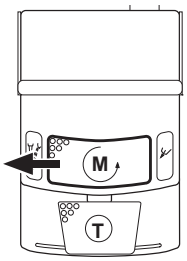
Gradually adjust the chair position

The standard patient char and COMPACTchair are adjusted in the same manner.

Note
The functions of the control keys on the dentist unit and assistant unit are the same.

The chair position can be selectively adjusted with:
- Keys on the control unit
- Cross switch on the foot control

Dentist unit key	Cross-switch: "Counter-clockwise motor rotation"	function
		The seat moves upward.
		The seat moves down.

Dentist unit key	Cross-switch: "Counter-clockwise motor rotation"	function
		The backrest moves upward.
		The backrest moves downward.

- Press the desired button, or press the cross switch in the desired direction.

⇨ The seat/backrest moves in the desired direction.

Note
If an instrument is removed, the chair functions of the foot control are blocked. The blocking can be removed by briefly pressing the stirrup switch. The functions are then available.

Note
The seat and backrest can be moved at the same time. Exception: When the operating voltage of the standard patient chair is below 200 V, only sequential movements are possible.

Special features of the COMPACTchair

Note
If the backrest is moved, the foldable foot piece also moves. The foot section cannot be moved separately.

The backrest can be moved vertically up to 85° to make it easier for patients to get in and out.
When the backrest is horizontal, the chair can be moved lower than when the backrest is vertical.

Save chair positions

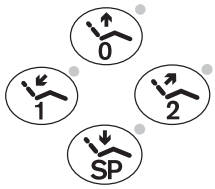
The chair positions can be saved and retrieved at any time by the press of a button. Win the position is retrieved, the chair automatically moves to the saved position (the so-called "automatic position," or "AP" for short).
The four chair positions can be saved on the control panels. Two of these four positions can be saved with the foot control.
It is for example recommendable to save the sitting down and getting up position using the "AP 0" key and the rinsing position with the "SP" key.

- Move the chair into the position that is to be saved.

Save on the Comfort dentist or assistant unit

- Briefly press the LP/AP button.

⇨ The LEDs of the buttons "AP 0", " AP 1", " AP 2" and "SP" flash for about four seconds.



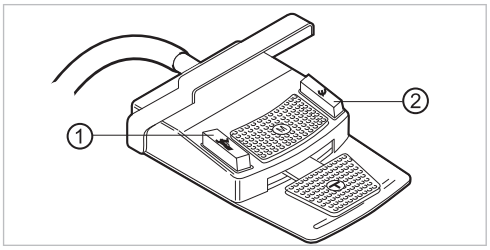
- During these four seconds, press the "AP 0", " AP 1", " AP 2" or "SP" buttons until you hear a beep.

⇨ The chair position is saved on the button.

Note

The automatic position "Last position" is saved on the "LP" button. Press the "LP" button for the chair to automatically move to the last position before the rinsing position. The "LP" button cannot be assigned to another automatic position.

Save with foot control



① Spray preselection/AP footswitch ② Blown air/AP footswitch

The chair positions can be saved on two footswitches; the standard setting is as follows:

- "Spray default" footswitch: "LP" automatic position (last position)
- "Blown air" footswitch: "SP" automatic position (rinsing position)
- Simultaneously press the foot pedal and the "Pre-selected spray" or "Blown air" foot switch.
- Press the "AP 0", " AP 1", " AP 2", "SP" or "LP" buttons on the control element until you hear a beep.

⇨ The selected automatic position is saved to the footswitch.

Retrieve saved chair positions

The saved positions of the chair (so-called automatic positions) can be retrieved by pressing a button. Five automatic positions can be retrieved with the control unit on the assistant element, and two automatic positions can be retrieved with the foot control.

⚠ CAUTION

Danger of crushing during automatic chair movement.

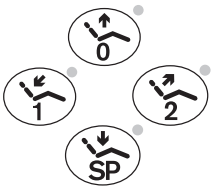
The patient or treatment personnel can be clamped.

- Monitor the patient and treatment personnel when changing the chair position.

Retrieve the chair positions using the control element

- Briefly press the LP/AP button.

⇨ The LEDs of the buttons "AP 0", " AP 1", " AP 2" and "SP" flash for about four seconds.

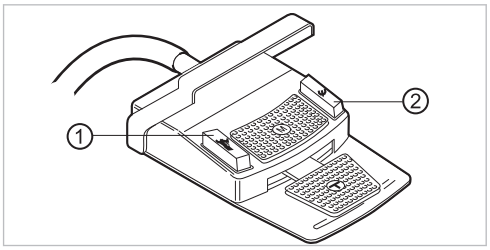


- During these four seconds, briefly press the "AP 0", " AP 1", " AP 2" or "SP" buttons.

⇨ The chair moves into the automatic position.

Retrieve the chair positions using the foot control

Note
If an instrument is removed, the chair functions of the foot control are blocked. The blocking can be removed by briefly pressing the stirrup switch. The functions are then available.

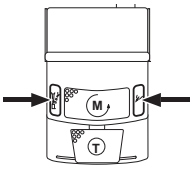


① Spray preselection/AP footswitch ② Blown air/AP footswitch

The chair positions can be recalled with two foot switches; the standard setting is as follows:

- "Spray selection" foot switch: automatic position "LP" (last position)
- "Blown air" foot switch: automatic position "SP" (rinsing position)

Move the chair when the instrument is mounted

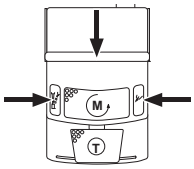


- Press the "Preselected spray" or "Blown air" foot switch.

⇨ The chair moves into the automatic position.

Move the chair when the instrument is mounted

Note
If an instrument is removed, the chair functions of the foot control are blocked. The blocking can be removed by briefly pressing the stirrup switch. The functions are then available.



- Press the stirrup switch and then the "Preselected spray" or "Blown air" foot switch.

⇨ The chair moves into the automatic position.

4.2.5 Safety shut-off

To prevent collisions arising from the movement of the patient chair, safety shutoff switches are installed to protect the patient and practice personnel from injury and the treatment unit from damage.

⚠ CAUTION

Damage to the assistant element and dental chair.

Despite some safety shut-downs being present, certain positions of the assistant unit may collide with the dental chair.

- Keep the assistant unit out of the range of motion of the patient chair.
- Always monitor the chair movement.

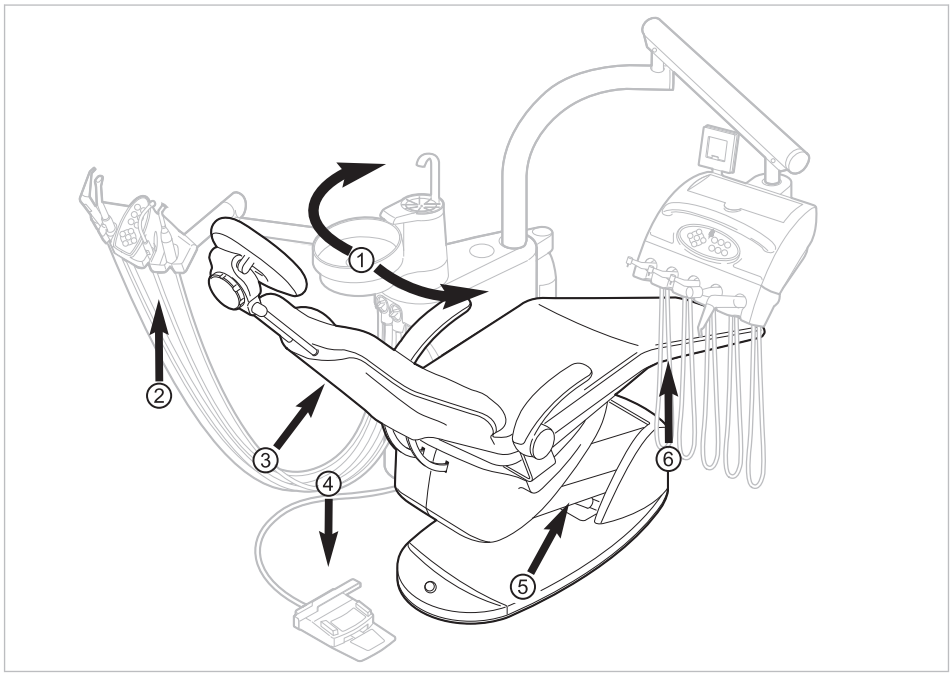
⚠ CAUTION

Pinching from the treatment chair.

The safety shutoff of the treatment chair is activated by lifting the respective component. Depending on the patient's body weight and the leverage, more force can be exerted on the object to be triggered than is necessary to trigger the switching function.

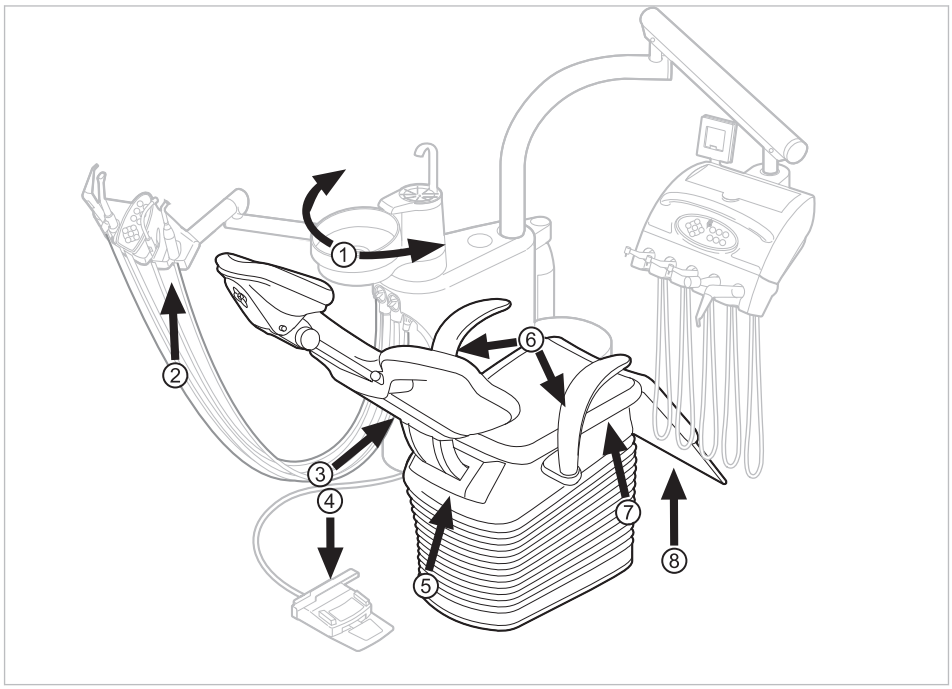
- The treatment personnel must move outside of the chair's swinging range whenever the chair moves.

The safety cut-offs can be found at the following places on the treatment unit.



Safety shutoff for the standard patient chair

① Patient unit swung over the patient chair
② Assistant element
③ Backrest
④ Bracket on the foot control
⑤ Bottom of the chair parallelogram
⑥ Seat



Safety shutoff for the COMPACTchair patient chair

① Patient's part pivoted over dental chair
② Assistant element
③ Backrest
④ Bracket on the foot control

⑤ Cover on the curved segment of the backrest
⑥ Arm rests
⑦ Seat
⑧ Foldable part of the seat

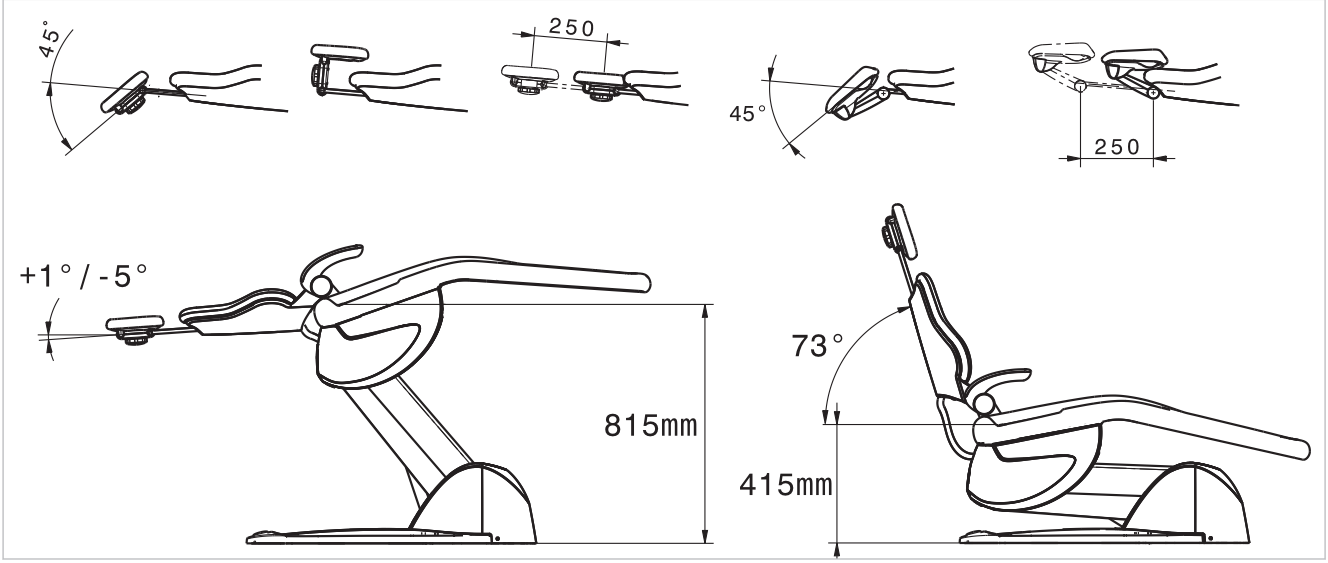
The safety shutoff occurs went a movement angle has been exceeded, or part of the treatment unit collides with an object.
If a person or object actuates a safety shutoff, the chair immediately stops moving.
The fact that the safety shutoff has been activated is displayed by the corresponding display flashing on the dentist or assistant unit.

Display LED	Safety shut-off
	Assistant unit
	Seat, backrest, vacuum stop, bottom chair program Armrest (only COMPACTchair) Bendable part of seat (only COMPACTchair)
	Foot control
	Tilt sensor for dentist unit cart (no longer mounted)
	Patient unit

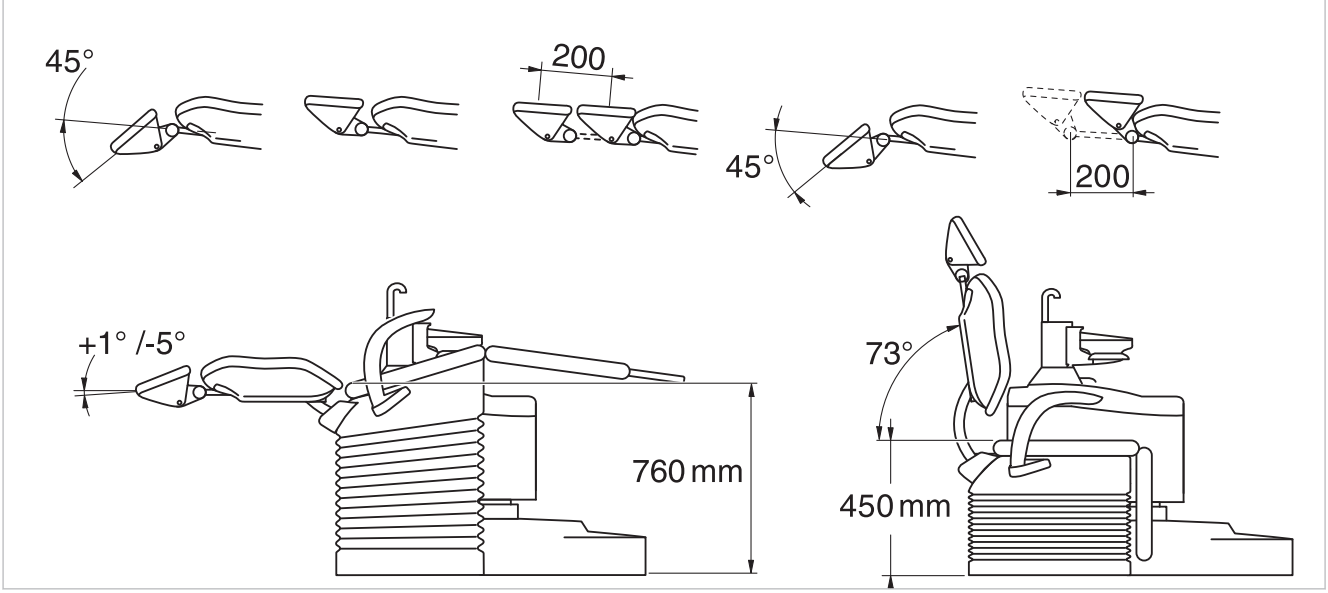
Note

The chair's position cannot be changed with the key wheels when a safety shutoff is activated.
Exception: The patient unit safety switch only stops the upward and downward movement of the patient chair. The backrest can be moved up and down.

4.3 Moving the patient chair



Patient chair Standard



Patient chair COMPACTchair

4.4 Move the dentist's unit

⚠ CAUTION

Damage from overloading the dentist element.

Exceeding the maximum weight of more than 2 kg by adding handpieces, accessories, etc., can cause damage.

- Do not overload the dentist element!

⚠ CAUTION

Risk of injury when the dentist or assistant element is moved.

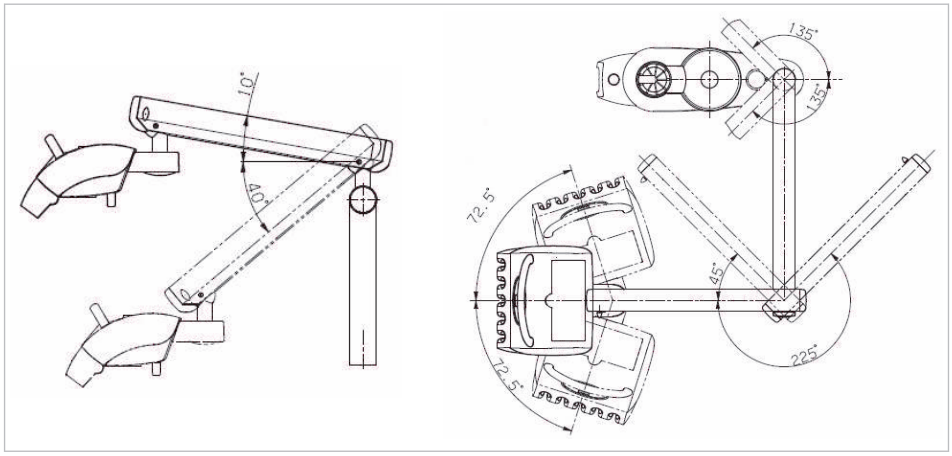
The patient or office staff may be injured or bruised.

- Monitor the patient and office staff when moving the dentist or assistant element.

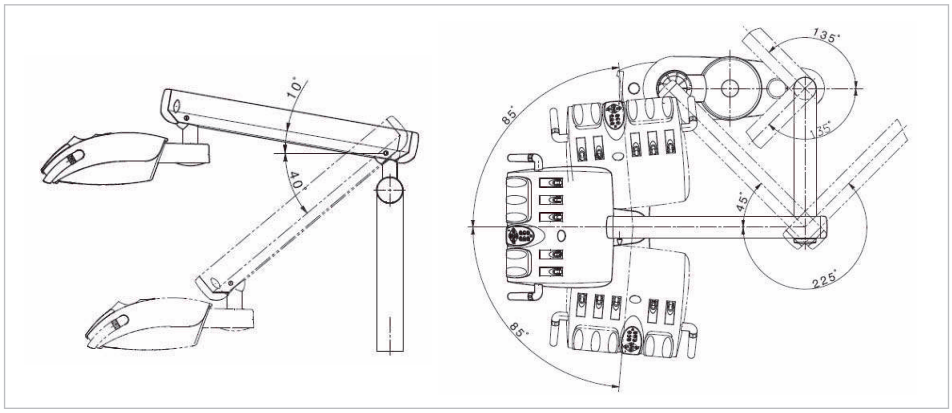
The swinging range of the dentist unit is limited by stops.

Note
Do not pull the dentist unit by the instrument hose.

- To adjust the dentist unit height, release the brake, adjust the height, and reset the brake.



dentist unit TM



Dentist unit S

4.4.1 Move the cart

⚠ CAUTION

Moving and overloading the cart.

Danger of tipping and damaging the cart.

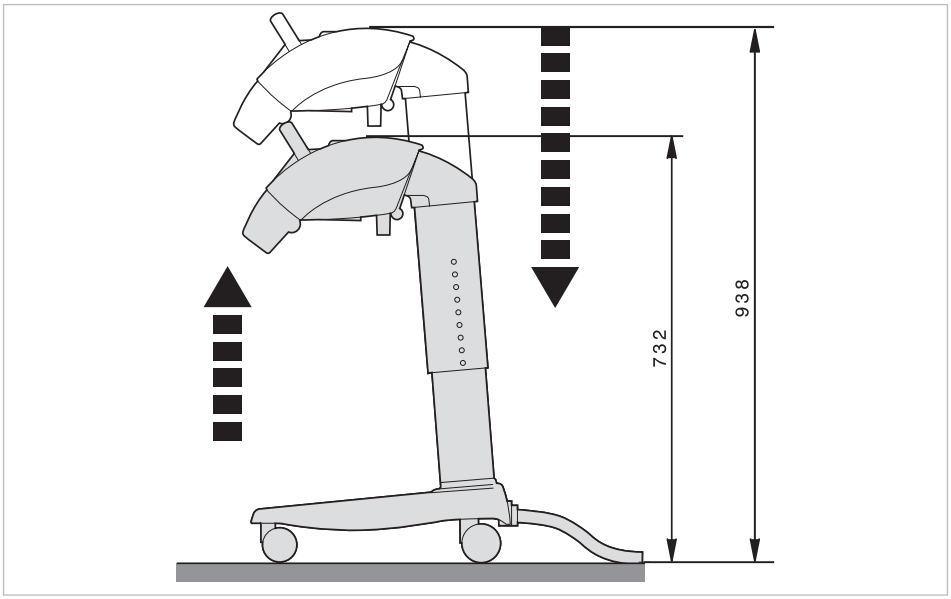
- Only use the card on a continuously smooth floor.
- Do not overextend the supply hose for the cart.
- Make sure that there are no obstructions on the floor.
- Do not sit on the dentist element or step on the castor.

Note
The area in which the cart can be move is restricted by the length of the lines and hoses that connect the cart to the base of the device. Only move the cart within this range.

- To change the position of the cart, hold the cart by the bow-type handle and move it to the desired position. Make sure that there are no obstructions on the floor.

The top part of the dentist's unit can be positioned in 9 levels.

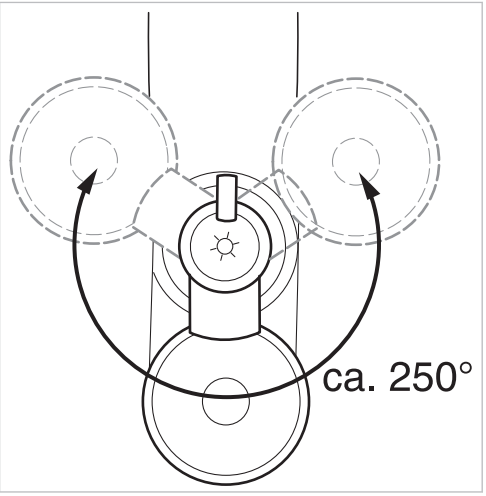
Note
Do not lift the dentist's unit using the handle. The handle is only for horizontally positioning the dentist unit.



- Lift the top part of the dentist's unit until it locks into place.
- To release the lock, move the top part all the way up and then move it down.

4.5 Move the patient unit

4.5.1 Swing the patient unit by hand



The swinging range is about 250°.

⚠ CAUTION

The left armrest can collide with the manually adjusted patient's unit when the chair moves.

Injury hazard.

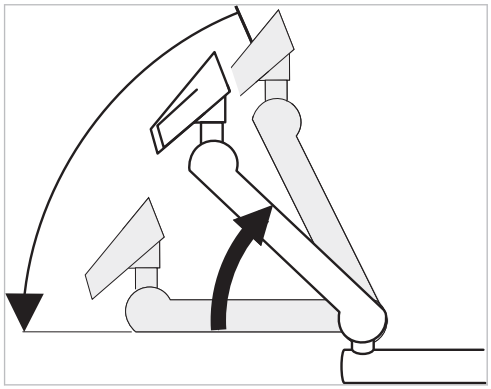
- Each time before the chair is adjusted (automatic and manual), swing the manually adjusted patient's unit into resting position.

Note
When the patient unit is swung over the patient chair, the safety shutoff is activated.

4.6 Moving the assistant element

4.6.1 Adjusting the height of the standard assistant element (optional)

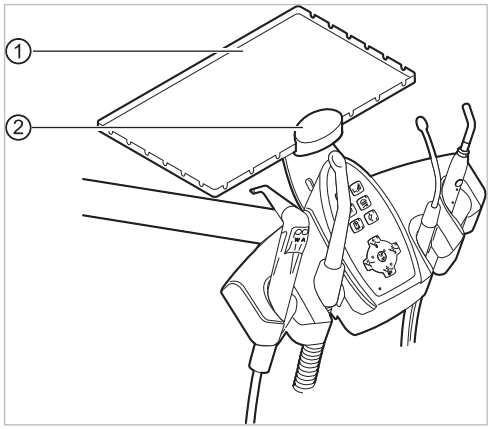
The assistant unit can be vertically positioned in four levels.



- To set a higher level, pull the assistant unit upward gently until it audibly locks in place.
- To set a lower level, pull the assistant unit all the way up until the lock releases, and then lower the assistant unit.

Mounting the tray holder

- Mount the tray holder on the assistant's unit.



① Tray holder ② Holder

The support ② for the tray holder ①is an optional accessory.

4.6.2 Moving the assistant element right, left (optional)

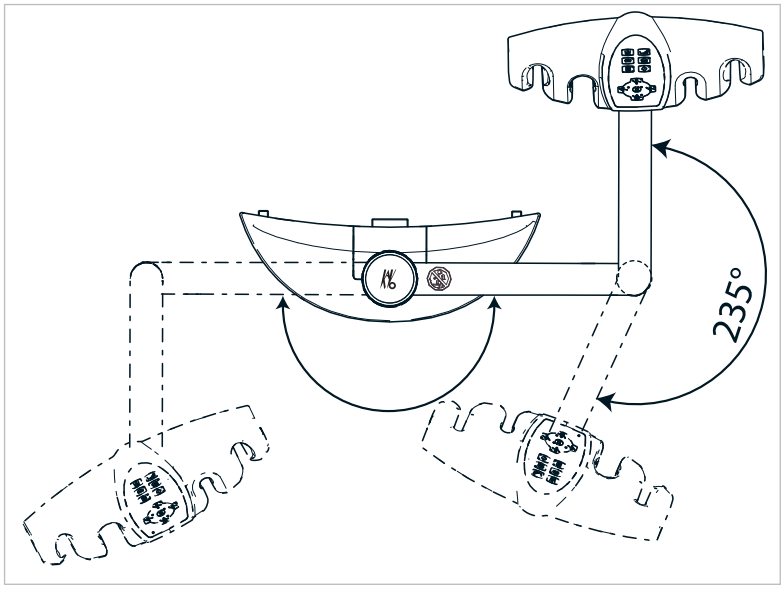
⚠ CAUTION

Pinching from the treatment chair.
The treatment staff can get pinched or crushed.
- The treatment personnel must move outside of the chair's swinging range whenever the chair moves.

⚠ CAUTION

Material damage caused by overloading.

- Do not rest your foot near the pivot point and/or transverse arm of the assistant element.



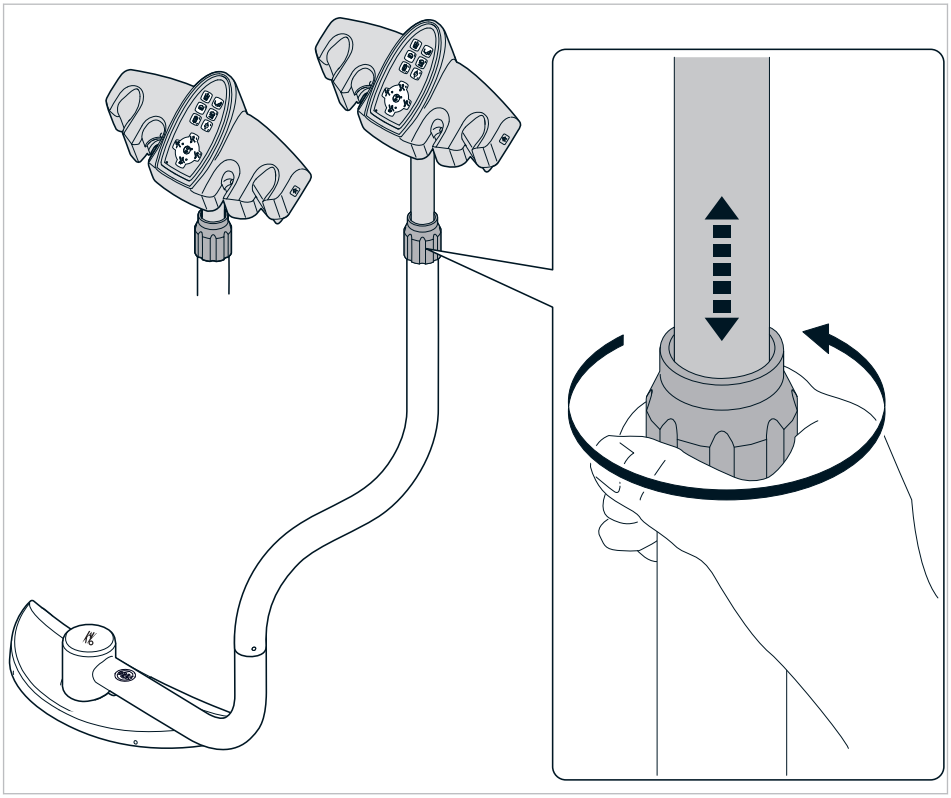
Swinging range of assistant element r, l (optional)

- Move the backrest up before swinging the assistant element.
- Move the assistant element to the desired position in its swinging range.

Adjusting the height of the assistant element right, left (optional)

Note

Handpieces may drop out of the holders while the assistant element is being moved, especially during adjustment of the height. In order to prevent handpieces from being damaged, make sure that no handpiece drops down while you move the assistant element.



- Undo the clamping screw and push the assistant element into the desired position.
- Re-tighten the clamping screw.

4.7 Setting functions

4.7.1 Select memory level Dentist 1 or Dentist 2

Note

To individually adjust instruments for different types of treatment, two dentist levels can be selected.

- Set down the instruments.
- Hold down the foot pedal and press the stirrup switch.

or

- With the Memospeed (extra), press the "Preselect level" button until you hear a signal.

⇨ Green LED comes on: Dentist level 1 is selected.
⇨ Yellow LED comes on: Dentist level 2 is selected.

4.7.2 Fill the tumbler and rinse the spittoon

The time for filling the tumbler and rinsing the bowl can be adjusted.

Adjust at the time for bowl rinsing and tumbler filling

Beeps sound when adjusting the time. Each beep corresponds to one second. The maximum time is 51 seconds.

- Press the button for filling the tumbler or rinsing the bowl and hold it until the desired number of beeps have sounded.

Filling the tumbler

- Press the "Tumbler filler" button.

⇨ The tumbler is filled.

- To stop rinsing before the set time, press the "Spittoon" button again.

Rinsing the spittoon

Note
Do not pour any liquid into the spittoon when the device is turned off.

- Press the "Spittoon" button.

⇨ The spittoon is rinsed.

- To stop rinsing before the set time is elapsed, press the "Spittoon" button again.

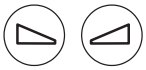
4.7.3 Turn the x-ray image viewer on and off

- Press the "X-ray viewer" button.

4.7.4 Set the time and use the timer (only with Memospeed)

Adjusting the clock time

- Press the "Clock" button until you hear a beep.



- Press the "Increase value" or" Decrease value" button until the desired number of hours is displayed.
- Briefly press the "Clock" button, and set the minutes by pressing the "Reduce value" and "Increase value" buttons.
- Press the Clock" button again to set the seconds in the same manner.
- Then press the "Clock" button until you hear a beep.

⇨ The time is now saved.

Using the timer

Setting the timer

The minimum timer time is 30 seconds, and the maximum timer time is 8 minutes.

- Press the "Timer" button until you hear a beep.

- Press the "Increase value" or" Decrease value" button until the desired timer time is displayed.
- Press the "Timer" button again until you hear a beep.

⇨ The timer time is now saved.

Starting the timer

- Press the "Timer" button.

⇨ The set timer time runs. A tone sounds after the timer time is over.

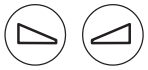
4.7.5 Use the function keys (only with the Memospeed)

From the 14 functions, you can select two that can be retrieved using the function keys.

Select and save the function

- Press "F1" or "F2" until you hear a tone.

⇨ The programming mode is started.



- Press the "Increase value" or" Decrease value" button until the desired function is displayed.
- Press the "F1" or "F2" button again until you hear a tone.

⇨ The function is saved on the button.

Calling up a function

Requirement
A function has been saved for the "F1" or "F2" key.

- Briefly press the "F1" or "F2" button.

⇨ These saved function is triggered.

4.7.6 HYDROclean function

See also:
Servicing Instructions Primus® 1058 S/TM/C, Page 0

4.7.7 Intensive cleaning/rinsing programme

See also:
Servicing Instructions Primus® 1058 S/TM/C, Page 0

4.8 Using instruments

The following sections describe the use and setting of the instruments.
A distinction is drawn between operation with and without the installed Memospeed.
The instruments are prevented from simultaneous use by software that determines when they are mounted.
To make use easier, specific instrument settings can be saved.

Holder logic

Only the instrument that was removed first is ready for operation with the exception of the three-function handpiece. All other handpieces are not ready for operation; the drill bits or ultrasonic scaler tips of these handpieces can be changed.

Note
Consult the separate instructions for the installation, use and servicing of the individual handpieces (e.g. turbine, COMFORTdrive, ultrasonic scaler, camera, Satelec Mini LED, etc.) for pertinent information.

4.8.1 Save instrument-specific settings

The following settings can be individually:saved for the instruments:

Handpiece	Setting
Turbine	Cold light intensity Spray on/off
Motor INTRA LUX KL 701/703, COMFORTdrive	Cold light intensity Spray on/off Speed range and intensity Direction of rotation
Ultrasonic scaler	Spray on/off* Intensity
Multi-functional piece	Cold light and heating On/off

*Only with a corresponding setting in service mode, group 9.

- To save a set value without the Memospeed, press the "LP/AP" button when the instrument is removed until you hear a beep.

- To save a set value with the Memospeed, press the "Preselect level" button when the instrument is removed until you hear a beep.

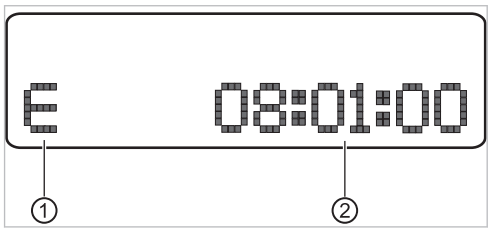
Note
Changed values are lost when the changes are not saved before the unit is turned off.

Select a memory level when the Memospeed is mounted

- Press the "Preselect level" several times until the desired level is displayed.

or

- Press the foot pedal several times when the instrument is mounted until the desired level is displayed.



Memospeed Display

① Level display ② Time

4.8.2 Using the turbine

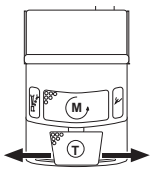
Note
Follow the instructions for use and assembly in the instrument packaging.

The following settings can be changed:
- Speed
- Preset spray
- Cold light preselection and intensity

Adjust the turbine without Memospeed

- Remove the turbine from the holder.

Setting the speed



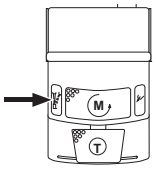
- To reduce or increase the speed, move the foot pedal to the left or right.

Note
The speed cannot be stored.
The minimum and maximum speed depends upon the type of used turbine.

Setting the cooling condition

- Press the "Preselected spray" button.

or



- "Preselected spray" footswitch.

⇨ Two LEDs shine when the spray cooling level is activated.

Setting cold light intensity

- To preset the cold light, press the "Cold light" button.

⇨ The LED shines at the preset cold light.
The cold light intensity can be set in 10 levels. When you are setting the intensity, the intensity is signalled by the number of beeps ranging from one beep (minimum intensity) to 10 beeps (maximum intensity).

- To set the cold light intensity, press the "Cold light" button until you hear the desired number of beeps.

Storing values

- Press the "LP/AP" button until you hear a beep.

Adjust the turbine with Memospeed

The spray preset is selected in the same way as without the Memospeed.

- Remove the turbine from the holder.
- Setting the level.

See also:
4.8.1.1 Select a memory level when the Memospeed is mounted, Page 61

Setting the speed

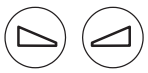
Note
The speed can be set at level E only with the foot pedal.

Two modes are available:

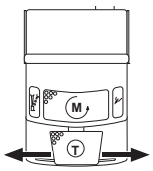
- "Manual" mode: These speed can be adjusted gradually using the foot pedal.

- "Maximum" mode: The speed remains at the maximum level independent of the foot pedal setting.

- Press the "Level selection" button until you hear a beep.



- To switch between maximum and minimum mode, press the "Increase value" or "Reduce value" button.

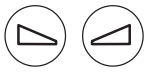


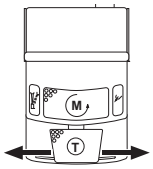
- To reduce or increase the speed in manual mode, move the foot pedal to the left or right.

Setting cold light intensity

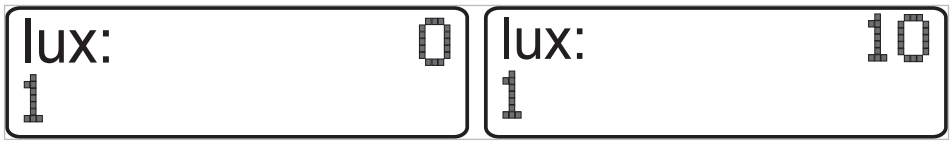
The cold light intensity can be set in 10 levels.

- Press the "Level selection" button.





- Set the desired intensity from 1 to 10 by pressing the "Reduce value" or "Increase value" buttons, or by moving the foot pedal to the left or right.



Storing values

- Press the "Level selection" button until you hear a beep.

⇨ The set values are saved for the set memory level and the set dentist level.

4.8.3 Using the INTRA LUX motor K 701/703 and COMFORTdrive 200XD

Note
Follow the instructions for use and assembly in the instrument packaging.

The following settings can be changed:
- Speed
- Preset spray
- Cold light preselection and intensity
- Direction of motor rotation

Note
The minimum and maximum speed depends on the motor and the attached hand-piece or contra-angle handpiece.
The speed cannot be stored.

Note
The motor mode is equivalent to 2 minutes operating time and 5 minutes pause.
This represents the possible maximum load of the motor (full load at maximum speed).
In practice, pulse loads lasting seconds or pause times lasting seconds or minutes are realistic given that the maximum possible motor current is not normally reached.
This equates to the dentist's normal way of working.

Adjust the motor without Memospeed

The speed, spray preset and cold light are set and the values are saved in the same manner as with the turbine.

Setting the rotational direction of the motor

Note
Only change the rotary direction of the motor when the motor is not running.

- Remove the motor from the holder.

- Press the "counter-clockwise motor" button.

or

- Press the "Counterclockwise motor rotation" cross-switch.

⇨ The LED shines when CCW motor rotation is set.

Adjust the motor with Memospeed

- Remove the motor from the holder.
- Press the Preselect level button to select the level.

See also:
4.8.1.1 Select a memory level when the Memospeed is mounted, Page 61

Adjust the speed and cold light intensity

On levels 1 to 2, the speed range can be individually changed. Reducing the speed range allows finer adjustment with the foot control.
The preset minimum cannot be reduced, and the preset maximum cannot be increased.

Note
The speed range cannot be preset in level E.

	Motor KL 701/KL 703	COMFORTdrive 200XD
Minimum	100 rpm	30,000 rpm (Display 1)

	Motor KL 701/KL 703	COMFORTdrive 200XD
Maximum	40,000 rpm	200,000 rpm (Display 10)

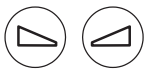
- Press the "Level selection" button until you hear a beep.

⇨ The display switches to the setting menu for minimum.

- Press the "Increase value" or" Decrease value" button until the desired value is displayed.

- Press the "Level selection" button.

⇨ The display switches to the setting menu for maximum.



- Press the "Increase value" or" Decrease value" button until the desired value is displayed.

- Press the "Preselect level" key.

⇨ The display changes to the setting for the cold light intensity.

- Set the cold light with the "Cold light" button.

- To save the values, press the "Preselect level" button until you hear a beep.

Setting the rotational direction of the motor

The motor rotary direction is selected in the same way as without the Memospeed.

See also:
4.8.3.1.1 Setting the rotational direction of the motor, Page 64

Setting the cooling level

The cooling is adjusted in the same manner as with the turbine.

4.8.4 Using the ultrasonic scaler

Using the PIEZOsoft (optional accessories)

⚠ CAUTION

The operating mode P3 for ultrasonic scalers cannot be changed in this treatment unit.

Risk of injury.

- For the selection of the ultrasonic scaler tips, please ensure that the tips are suitable for the operating mode P3.
- Do not use inappropriate tips, e.g. the tips ENDO 220 and ENDO 221 as well as all ENDO files.
- For information about the use of the tips, please refer to the Instructions for Use of the Ultrasonic Scaler.

⚠ CAUTION

Sharp-edged tips.

Risk of injury.

- Keep the enclosed torque wrench on the handpiece when the handpiece is not in use!

⚠ CAUTION

Risk of confusing tips from different manufacturers.

- Please note the labelling on the tips.
- Please note the characteristic feature of KaVo tips, i.e. the low-positioned thread.

⚠ CAUTION

Product damage and personal injury due to tips from other manufacturers.

The use of tips from other companies can lead to injuries to users and patients as well as to the destruction of the product.

- Only use KaVo PIEZO Scaler tips.

Note

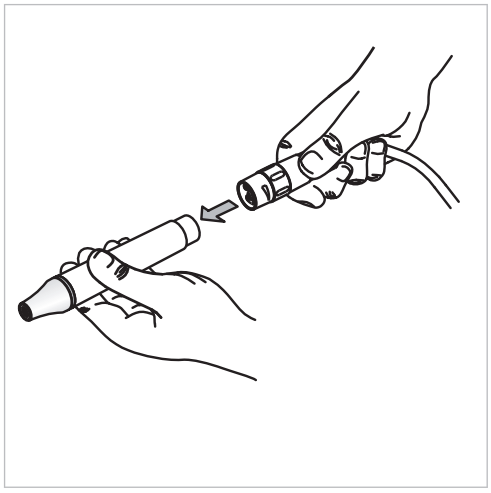
The torque wrench is subject to natural wear and should be changed when it no longer works properly (**Mat. no. 10073004**).

The following settings can be changed:

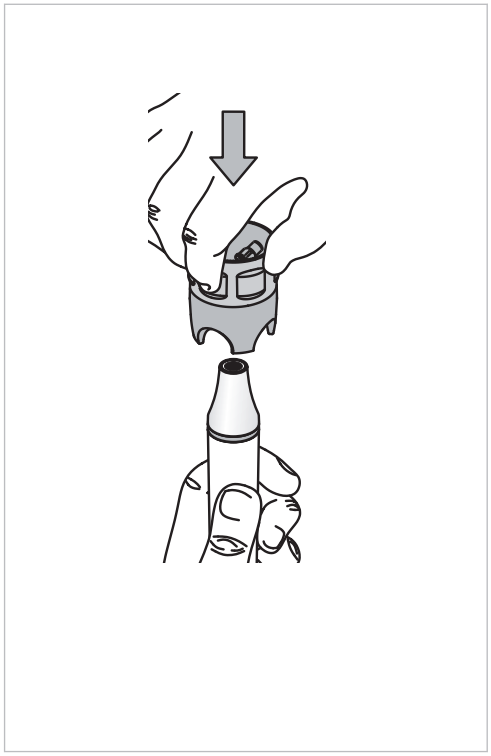
- Adjust spray water by means of adjustment ring on the handpiece
- Control the output power by means of the foot control

Attaching the handpiece insert

- Mount the handpiece on the coupling.



- Screw-on the tips.



- Tighten the tips with the torque wrench by another quarter of a turn.

⇨ This ensures that the appropriate torque is applied.

Adjust the water discharge

- Adjust the amount of spray water using the regulating ring.

Adjusting the PIEZOsoft without MEMOspeed

Note

The illumination level cannot be set in the PIEZOsoft.

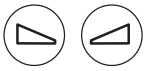
Set the intensity the same way you set the speed of the turbine.

Adjusting the PIEZOsoft with MEMOspeed

Setting the intensity

The intensity is set in steps of 0.25; the minimum intensity is 1.0, and the maximum is 10.0.

- Press the "Preselect level" button until you hear a tone.



- Press the "Increase value" or" Decrease value" button until the desired value is set.

Using the PiezoLED (optional accessories)

⚠ CAUTION

The operating mode P3 for ultrasonic scalers cannot be changed in this treatment unit.

Risk of injury.

- For the selection of the ultrasonic scaler tips, please ensure that the tips are suitable for the operating mode P3.
- Do not use inappropriate tips, e.g. the tips ENDO 220 and ENDO 221 as well as all ENDO files.
- For information about the use of the tips, please refer to the Instructions for Use of the Ultrasonic Scaler.

⚠ CAUTION

Sharp-edged tips.

Risk of injury.

- Keep the enclosed torque wrench on the handpiece when the handpiece is not in use!

⚠ CAUTION

Risk of confusing tips from different manufacturers.

- Please note the labelling on the tips.
- Please note the characteristic feature of KaVo tips, i.e. the low-positioned thread.

⚠ CAUTION

Product damage and personal injury due to tips from other manufacturers.

The use of tips from other companies can lead to injuries to users and patients as well as to the destruction of the product.

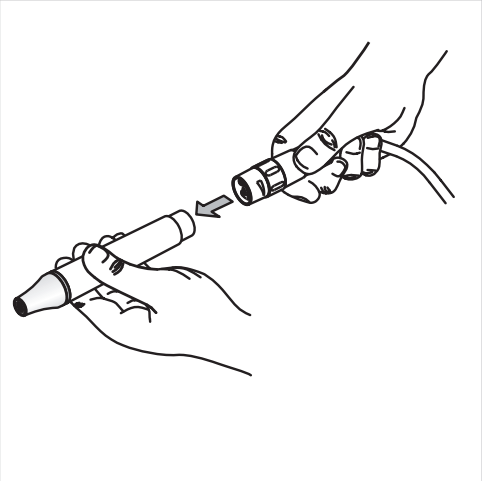
- Only use KaVo PIEZO Scaler tips.

Note
The torque wrench is subject to natural wear and should be changed when it no longer works properly (**Mat. no. 10073004**).

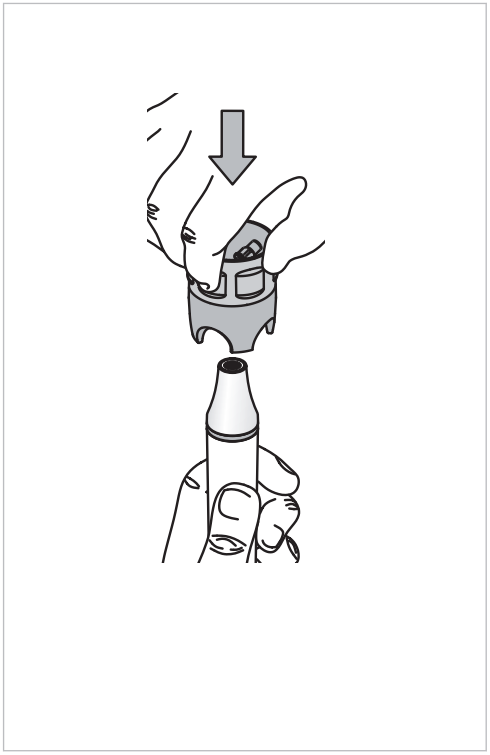
The following settings can be changed:
- Adjust spray water by means of adjustment ring on the handpiece
- Control the output power by means of the foot control
- LED illumination on/off via dentist element

Attaching the handpiece insert

▸ Mount the handpiece on the coupling.



▸ Screw-on the tips.



▸ Tighten the tips with the torque wrench by another quarter of a turn.

⇨ This ensures that the appropriate torque is applied.

Adjust the water discharge

- Adjust the amount of spray water using the regulating ring.

Adjusting the PiezoLED without MEMOspeed

Note

The illumination intensity cannot be set in the PiezoLED.

Set the light and save the settings the same way as with the turbine.
Set the intensity the same way you set the speed of the turbine.

See also:
4.8.2.1 Adjusting the turbine without Memospeed, Page 61

Adjusting the PiezoLED with MEMOspeed

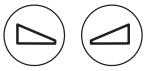
Set the light and save the settings the same way as with the turbine.

See also:
4.8.2.2 Adjusting the turbine with Memospeed, Page 62

Setting the intensity

The intensity is set in steps of 0.25; the minimum intensity is 1.0, and the maximum is 10.0.

- Press the "Preselect level" button until you hear a tone.



- Press the "Increase value" or" Decrease value" button until the desired value is set.

4.8.5 Use the COMFORTdrive 200 XD/COMFORTbase 405L (optional accessory)

General use

⚠ CAUTION

Non-observation of the instructions for use of the COMFORTdrive 200 XD

Injury to persons and property damage

- The operating instructions for the COMFORTdrive 200 XD are found in separate instructions for use. These must be read before starting up the COMFORTdrive 200 XD and COMFORTbase 405L.

The KaVo COMFORTdrive 200 XD is a dental instrument for the high-speed range up to 200,000 rpm. It may only be mounted on the KaVo COMFORTbase 405L coupling. The hose of the KaVo COMFORTbase 405L is part of the coupling and cannot be removed.
Operation and changing the settings via the control element is identical to the INTRA LUX motor KL 701/703.

Fitting the motor hose on the dentist's element

- Connect the motor hose of the COMFORTbase 405L to the connector for the motors and pneumatic instruments.

Change the high-pressure bulb of the COMFORTbase 405L

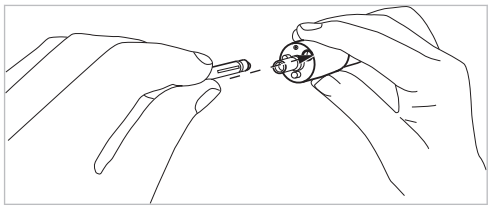
⚠ CAUTION

Danger of burns from hot high-pressure lamp.

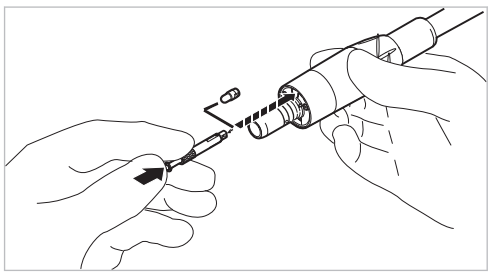
- Switch main device switch off.
- Let the COMFORTbase cool down after long use.

Requirement
The COMFORTdrive is pulled off from the COMFORTbase.

- Push the accompanying lamp changer on the lamp and pull out the lamp axially.



- Insert the new lamp into the lamp changer, and introduce it into the hole in the face of the supply hose. Carefully press the lamp into the socket by twisting slightly.
- Carefully press out the lamp by activating the ejector.



Replace O-rings

⚠ CAUTION

Missing or damaged O-rings.
Malfunctions and premature failure.
- Make sure that all O-rings are on the coupling and undamaged.

Number of available O-rings: 3
- Press the O-ring between your fingers to form a loop.
- Shove the O-ring to the front, and remove it.
- Insert new O-rings (**Mat. no. 10050327**) into the grooves.

Note
The O-ring on the COMFORTbase may only be lubricated with cotton ball wet with KAVOspray.

Adjust the COMFORTdrive with Memospeed

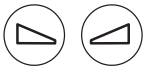
The cold light is set and saved as with the turbine.

Set intensity

Note
The intensity can be set in level E only with the foot pedal.

The intensity is set in increments of 0.25; the minimum is 1 (1=30,000 rpm), and the maximum is 10 (10=200,000 rpm).

- Press the "Preselect level" button until you hear a tone.



- Press the "Increase value" or" Decrease value" button until the desired value is set.

4.8.6 Using the three-function handpiece

⚠ CAUTION

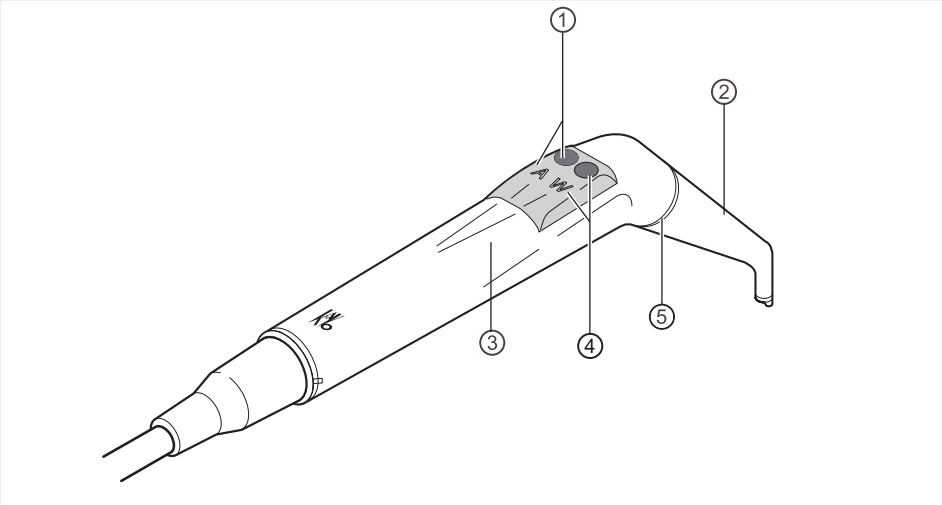
Cannulas that are worn or not locked into place.
Injury from swallowing the cannula.
- Before each treatment, ensure that the cannula is locked into place and firmly seated.
- Only use original KaVo cannulas.

⚠ CAUTION

Risk of injury from touching the cheek with the handpiece.

Irritation of the mucosa.

- Rotate the cannula of the handpiece into an operating position where there is no contact of the mucosa.



① Air button (A)
② Cannula
③ Gripping sleeve
④ Water button (W)
⑤ Ring blue

Note

The cannulas can be rotated 360°..

- Remove the turbine from the holder.
- Press the air button ① and continuously increase or decrease the exiting air flow by applying more or less pressure on the air button ①.

or

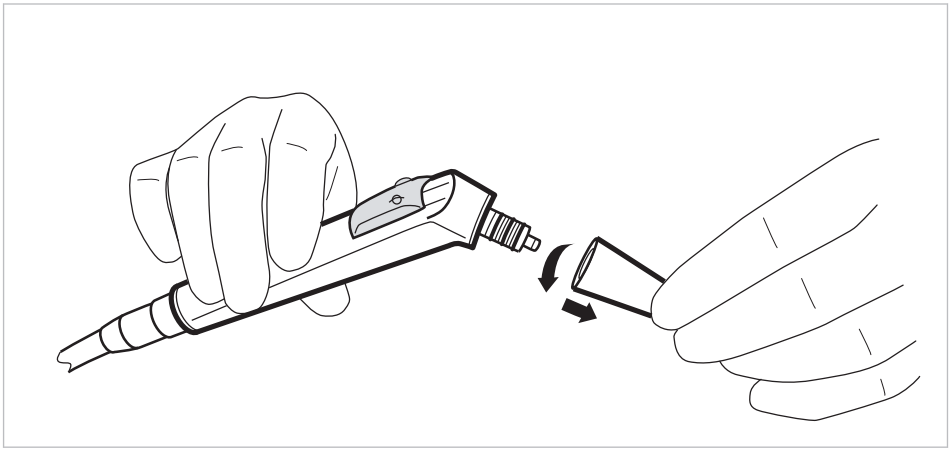
- Press the water button ④ and continuously increase or decrease the exiting water jet by applying more or less pressure on the water button ④.

or

- Simultaneously press the air button ① and water button ④ and continuously increase or decrease the exiting spray by applying more or less pressure on the two buttons.

Removing the cannulas

- Hold the handpiece at the taper sleeve and take off the cannula with a slight twisting motion.



4.8.7 Using the multifunctional handpiece

⚠ CAUTION

Risk of injury from touching the cheek with the handpiece.

Irritation of the mucosa.

- Rotate the cannula of the handpiece into an operating position where there is no contact of the mucosa.

⚠ CAUTION

Cannulas that are worn or not locked into place.

Injury from swallowing the cannula.

- Before each treatment, ensure that the cannula is locked into place and firmly seated.
- Only use original KaVo cannulas.

⚠ CAUTION

Insufficient clearance between cannula and surface of gums or gingiva.

Injury hazard.

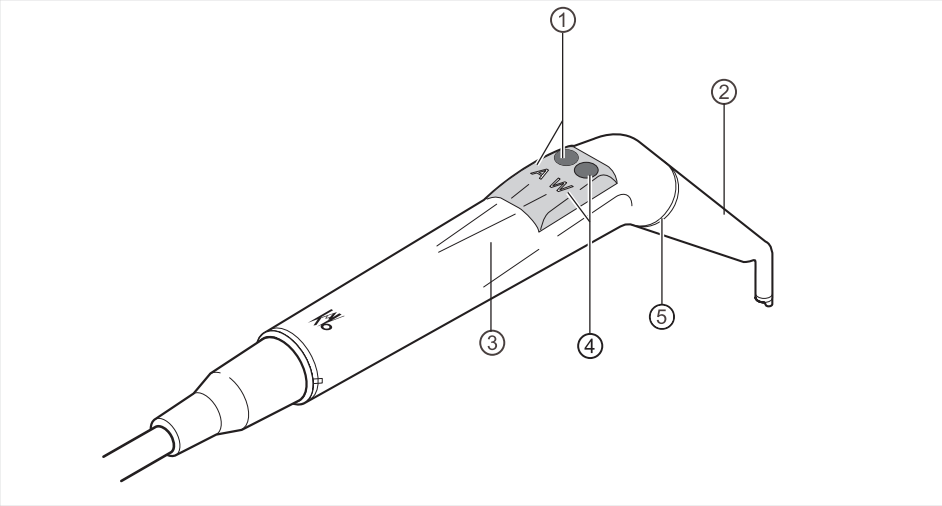
- Adhere to a minimum clearance of 10 mm between cannula and surface of gums or gingiva.

⚠ CAUTION

Damage due to missing media.

Air and water heating systems are destroyed.

- Check if the air and water are connected.
- Check the air and water supply!
- If possible, switch the heating off at the unit when putting into operation for the first time or after servicing! Press the buttons carefully several times until the media are available. Then activate heating and check its operation.



① Air button (A)
② Cannula
③ Grip sleeve
④ Water button (W)
⑤ Ring gold

Note

Cannulas can be rotated by 360°.
The "on" time for the handpiece with heating is 5 minutes with a resting time of 3 minutes.

Note

If only the cold light is preselected (heater: off), the multifunctional handpiece shines when it is removed from the holder.

- Remove the turbine from the holder.
- Adjusting the air/water heating.
- Check the passage for the media in the cannula ② each time before using it on a patient.
- Press the air button ① and continuously increase or decrease the exiting air flow by applying more or less pressure on the air button ①.

or

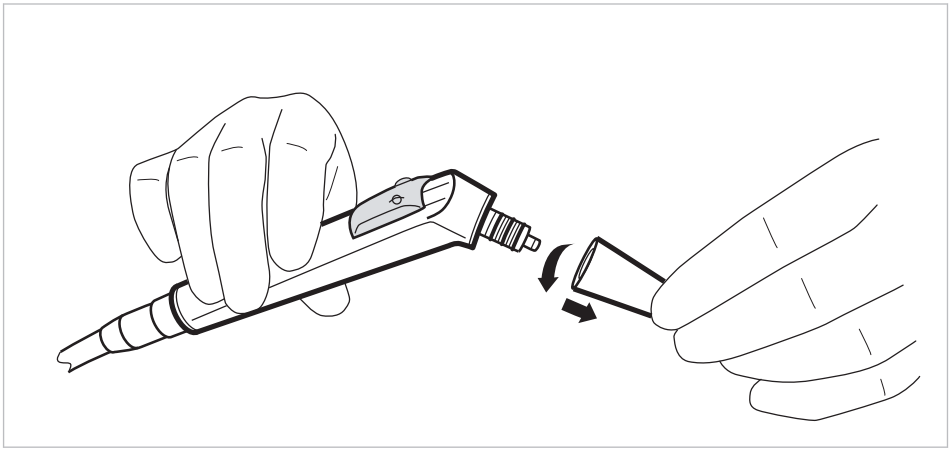
- Press the water button ④ and continuously increase or decrease the exiting water jet by applying more or less pressure on the water button ④.

or

- Simultaneously press the air button ① and water button ④ and continuously increase or decrease the exiting spray by applying more or less pressure on the two buttons.

Removing the cannulas

- Hold the handpiece at the taper sleeve and take off the cannula with a slight twisting motion.



Setting the multifunctional handpiece functions

The following settings can be changed:

- Cold light (multifunctional handpiece only)
- Heating (multifunctional handpiece only)

Note
Afterglow time and cold light intensity are constant.

The settings can be made separately on the Comfort dentist unit and assistant unit.

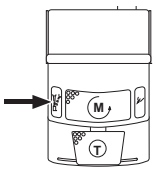
Make the settings on the dentist unit

- Remove the turbine from the holder.

⇨ The holder switch is actuated.

- Press the "Preselected spray" button.

or



- "Preselected spray" footswitch.

⇨ LED shines: Heating and cold light for the dentist unit handpiece have been preselected.

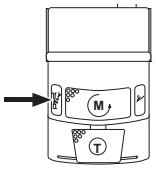
- To save the setting, press the "LP/AP" button until you hear a beep.

Enter settings on the Comfort assistant unit

- Remove the turbine from the holder.
- Briefly press the "Air" ① or "Water" ③ button.

- Press the "Preselected spray" button.

or



- "Preselected spray" footswitch.

⇨ LED shines: The heating for the assistant unit handpiece is preset.

- Press the "Cold light" button.

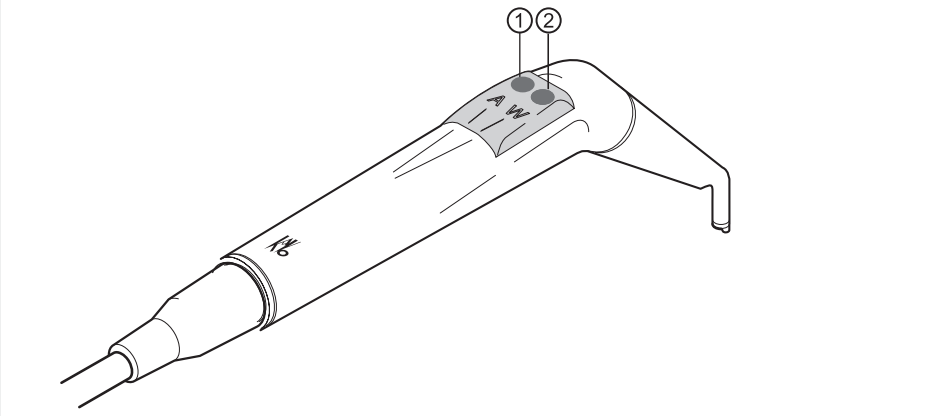
⇨ LED shines: The cold light for the assistant unit handpiece is preset.

- To save the setting, press the "LP/AP" button until you hear a beep.

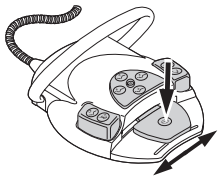
Using the cold light

Requirement
The light and heating are preselected.

- Setting the cold light intensity.
- Press the air button ① and/or the water button ②.



or



- Press the "Handpieces" foot pedal.

⇨ The light turns on.

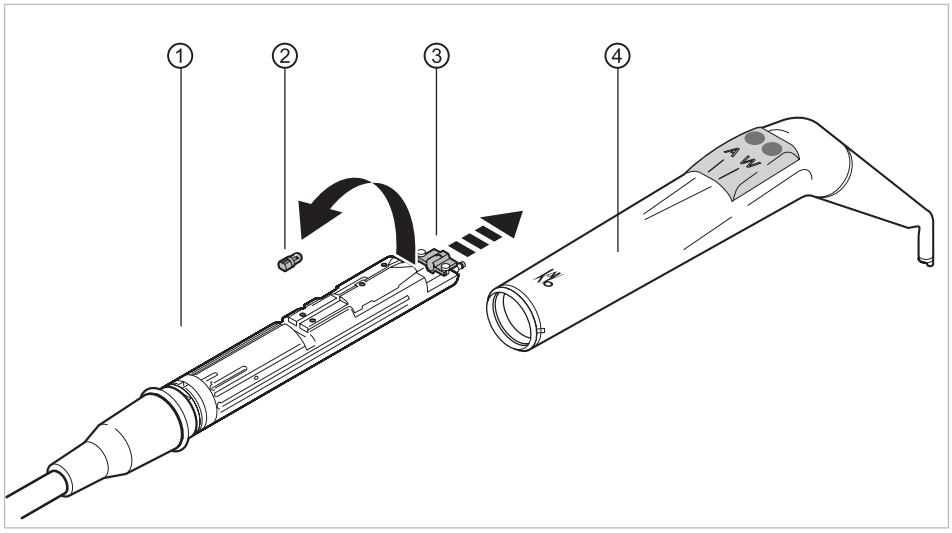
Replacing the lamp

⚠ CAUTION

Danger of injury from a hot valve body.

Risk of burn injury.

- Switch main device switch off.
- Allow the instrument to cool down after extended use.



- Pull off the grip sleeve ④ together with the cannula from the valve body ①.

Replacing the high-pressure lamp

- Push the holder ③ towards the front and draw and remove the defective high pressure lamp ② from its holder.
- Install a new high pressure lamp (**Mat. no. 1.002.2928**).

Replacing the KaVo MULTI LED lamp

Note

The KaVo MULTI LED bulb is a semiconductor element and may only be operated with direct current. To ensure proper function, the poles need to be inserted correctly.

- Push the holder ③ forward and pull the defective KaVo MULTI LED lamp ② out of the socket.
- Insert new Kavo MULTI LED lamp (**Mat. no. 1.007.5372**).

The following may happen after you turn on the KaVo MULTI LED lamp:

- Case 1: KaVo MULTI LED lamp is on.
- Case 2: KaVo MULTI LED lamp is faint.
- - Increase the cold light intensity on the unit until the desired light intensity is reached.
- Case 3: KaVo MULTI LED lamp is red or off.
- - Take KaVo MULTI LED lamp out of its socket as described above and re-insert it after rotating it 180° about its axis.

4.8.8 Adjusting the suction

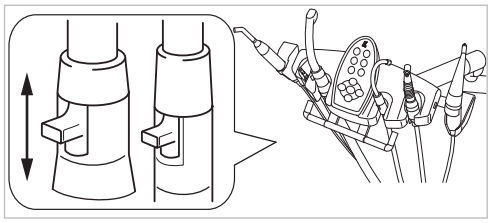
⚠ CAUTION

Unintentionally activating the saliva ejector or spray fog suction.

Injury in the area of the mouth.

- When using the vacuum stop to interrupt suction, do not leave the saliva ejector or spray fog suction in the patient's mouth.

Adjusting the suction strength



- To set the suction or block it, move the slides that are integrated in the conical pieces of the saliva ejector and spray fog suction.

Start/stop the suction on the Comfort assistant unit

⚠ CAUTION

Unintentionally activating the saliva ejector or spray fog suction.

Injury in the area of the mouth.

- When using the vacuum stop to interrupt suction, do not leave the saliva ejector or spray fog suction in the patient's mouth.

- Remove the saliva ejector or spray mist suction device from the holder.

⇨ The suction automatically turns on.

- To interrupt the suction, press and hold the "vacuum stop" button.

Note

The function of the "Vacuum stop" button can be adjusted in service mode (group 9, index 11). The suction can be stopped as long as the "Vacuum stop" button is held, or the suction can be turned on or off by pressing the "Vacuum stop" button ("Vacuum stop and go").

5 Preparation methods DIN EN ISO 17664

Note
The preparation methods can be found in the care instructions.

HYDROclean function

See also:
Servicing Instructions Primus® 1058 S/TM/C, Page 0

Intensive cleaning/rinsing programme

See also:
Servicing Instructions Primus® 1058 S/TM/C, Page 0

6 Troubleshooting

Note
In case of malfunctions, consult the separate instructions for the use and care of the individual instruments (such as the turbine, motor, camera, Satelec Mini LED, etc.).

Malfunction	Cause	Remedy
Nothing works.	Main switch is off.	▸ Turn on main switch.
	Main service fuse interrupted the electric circuit.	▸ Unplug the unit from the mains. ▸ Check and replace, if required, the main service fuse. The main service fuse is situated next to the master switch. ▸ For this purpose, open the bayonet closure with a screwdriver and replace the fine-wire fuse. (220, 230, 240 V AC: T 6,3 H **Mat. no. 0.223.2783**); (100, 110, 120, 130 V AC: T 10 H **Mat. no. 1.007.2529**). ▸ The re-close the bayonet closure with the screwdriver.
No cold light in the instruments.	Cold light not preselected.	▸ Preselect cold light.
	The high-pressure lamp or Multi LED on the instrument is defective.	▸ Replace the high-pressure lamp or Multi LED. **See also:** Instructions for Use of the handpiece
No heating function on the multifunctional handpiece.	Spray heating not preselected.	▸ Pre-select spray heating.
No cold light on the multifunctional handpiece.	Cold light not preselected.	**Requirement** The heating function is preselected. ▸ Preselect cold light.
	High pressure lamp faulty.	▸ Replace the high-pressure lamp.
No spray in the instruments.	No spray preselected.	▸ Preselect spray.
	Close the ring for controlling the spray on the instruments.	▸ Open the ring for controlling the spray on the instruments.

Malfunction	Cause	Remedy
Spray at the instruments is insufficient.	The spray nozzles are dirty/clogged.	▸ Clean the spray nozzles according to the accompanying instrument operating instructions.
Turbine making loud running noises.	Turbine wheel faulty.	▸ Replace turbine wheels. Follow the operating instructions for the turbine.
Leaks in instruments.	O-rings at MULTIflex or motor coupling, gripping sleeve or cannula of the triple-function handpiece are damaged.	▸ Replace O-rings.
Ultrasonic scaler not functional.	Ultrasonic scaler does not vibrate.	
The suction hoses do not have any suction.	Slides on the conical sections are closed.	▸ Open the slide valve.
	Sieves in suction connector are blocked.	▸ Replace sieves.
	Foot switch for vacu-stop has been pressed.	▸ Release the foot switch.
	Suction machine not running.	▸ Turn on the suction machine. ▸ Check the suction machine fuse.
	The amalgam separator does not work correctly.	▸ See the Operating Instructions of the amalgam separator.
Water in the return air filter.	O-rings of the MULTIflex coupling are damaged.	▸ Replace all O-rings of the MULTIflex coupling.
Signal sounds as continuous signal, and the "Service" LED (yellow) flashes.	Warning about the amalgam separator.	▸ See the Operating Instructions of the amalgam separator.
A beep is issued every ten seconds and the "Intensive germ reduction" LED (green) flashes.	The Oxygenal container is empty.	▸ Refill the Oxygenal container.
Ten beeps are issued.	The Oxygenal container is too full.	▸ Stop filling the Oxygenal container.
A melody sounds.	The amalgam separator CAS1 s 95% full.	▸ Exchange the amalgam container.
	The CAS1 amalgam separator is defective.	▸ Call a Service technician.

Malfunction	Cause	Remedy
The Satelec Mini LED does not work.	**See also:** Instructions for use for the Satelec Mini LED	
The patient chair does not move.	The safety shutoff is activated. (The LED on the control panel flashes.)	▸ Check the safety shutoff and eliminate the reason for the shutoff.
The patient chair does not move, or only moves upward slightly.	The spittoon is swung toward the patient chair (the safety shutoff is activated).	▸ Swing the spittoon bowl into resting position.
The "Device on" LED (green) flashes.	Internal error.	▸ Call a technician.
The "Service" LED (yellow) flashes.	Malfunction in the amalgam separator.	▸ Call a technician.
	Emergency shut off of the bowl valve (only when external suction is installed)	▸ Call a technician.
The "Service" LED (yellow) shines.	There is no error; when the LED shines continuously, and it only indicates that Dentist level 2 is selected.	▸ To select Dentist level 1, press the foot pedal and hold it down, and press the stirrup switch.
The LEDs on buttons AP0, AP1, AP2 and SP shine for three seconds after the patient chair has been actuated.	The position pickup is defective or is incorrectly addressed.	▸ Call a technician.
The LED on the LP/AP button flickers.	The data connection to the foot control is faulty.	▸ Call a service technician.
The LED on the SP button flickers.	The data connection to the position pickup is faulty.	▸ Call a service technician.
The LED on the AP0 button flickers.	The data connection to the dentist unit is faulty.	▸ Call a service technician.
The motor anticlockwise LED flashes when instruments are mounted. (only with the intensive germ reduction kit)	Intensive germ reduction request.	▸ Run intensive germ reduction.
Operating light KaVoLUX 540 LED is not functional.	The lamp is defective.	

Malfunction	Cause	Remedy
Operating light MAIA LED not functional.	The lamp is defective.	
Operating light EDI not functional.	The lamp is defective.	

7 Safety checks - testing instructions

7.1 Introduction

7.1.1 General instructions

Note

The safety checks may only be carried out by one or more electricians (as defined in IEC 61140) who have received appropriate training for the device to be inspected.

Note

The contents and specified tests in this document are based on the international standard IEC 62353 (DIN VDE 0751-1). This standard applies to testing and inspections of medical electrical devices or medical electrical systems, which are defined in IEC 60601-1 (DIN EN 60601-1).

Note

In order to evaluate the safety of medical devices, systems or components of medical devices or systems, the safety checks must be carried out at the times specified below:

- Prior to first use
- during servicing
- during inspections and maintenance
- following service and maintenance
- on the occasion of repeat testing

Note

In the case of devices that have not been manufactured in accordance with IEC 60601-1, (DIN EN 60601-1) these requirements can be employed taking the mandatory safety standards for the production of these devices into consideration.

Note

If the unit comprises several electrical devices or electrical devices from several manufacturers that are connected to a system in connection with the KaVo dental unit, the manufacturer data contained in the instructions for use for all products subject to safety controls must also be observed.

Note

Accessories to ME devices that could have an impact on the safety of the device to be tested or the measured results must be included in the safety checks.

Note

All tests concerning the included safety checks of accessories must be documented.

Note

Furthermore, the manufacturer data contained in the instructions for use must be adhered to in all products to be tested and inspected.

Note

KaVo offers a medical device book for keeping an inventory and recording essential master data on the medical device. The medical device book is only available in German (**Mat. no. 0.789.0480**).

Note

The following tests and measurements must be documented, for example in the medical device book. We recommend using the templates at the end of the document

Note

The sequence of testing recommended by the manufacturer must be followed.

7.1.2 Notes for medical electrical systems

Note

An ME System is the combination of individual devices (as defined by manufacturers) that must meet the following conditions:

- At least one of these devices must be a medical electrical device.
- The devices must be functionally connected or at least they should be connected by the application of a multiple socket outlet.

Note

With ME systems, the person responsible for putting the system together must employ the necessary measuring parameters and measuring procedures defined in IEC 60601-1 (DIN EN 60601-1).

Note

Each individual device in an ME system, which has a separate connection to the power supply network, or which can be connected to or separated from the power supply network without the aid of a tool, must be checked individually. Moreover, the ME system must be checked as one unit to avoid the situation, in which the „aging“ of individual devices lead to unacceptable values in sum.

Note

An ME system that is connected to the supply network by means of a multiple socket outlet must be treated as one device during checks and testing.

Note

If the ME system or part of the system is connected to the supply network by means of a isolating transformer, the transformer must be included in the measurements.

Note

In ME systems, in which more than one ME device are interconnected via data lines or otherwise, e. g. via electrically conductive attachments or coolant tubes, the earth wire resistance of every single device must be checked.

Note

If it should be impossible to check single ME devices that are functionally connected to an ME system individually for technical reasons, the ME-System must be checked as a whole.

7.1.3 Essential parts of the safety check

Visual inspection

Optical appraisal of the safe and usable condition of the medical device and its accessories.

Measurements

- Measurement of the earth wire resistance in accordance with IEC 62353 (DIN VDE 0751-1)
- Measurement of the leakage current of the device EUL in accordance with IEC 62353 (DIN VDE 0751-1)
- Measurement of the leakage current of the user part EPL in accordance with IEC 62353 (DIN VDE 0751-1)

Note

A measurement of the isolation resistance in accordance with IEC 62353 (DIN VDE 0751-1) need not be carried out. This check is covered by the measurement of the leakage current on application of a prescribed safety tester defined in IEC 62353 (DIN VDE 0751-1) Annex C!

Functional test

Medical device function test as well as testing of all safety shutdowns with reference to accompanying documentation/ instructions for use.

7.1.4 Testing intervals

- Testing interval every 2 years according to device type IIa (without HF surgery)

7.1.5 Notes on the test method in accordance with IEC 62353 (DIN VDE 0751-1)

- Protection class 1
- Type BF
- The device is firmly connected / threshold: SL < 0,3 Ω
- Measurement according to EUL / threshold: < 10mA*
- Measurement according to EGA / threshold: < 5 mA

*The EUL threshold is compatible with the value defined in IEC 60601 (DIN EN 60601), taking comment 2 from table 2 into consideration.

7.1.6 Notes on repeat testing

Note

The value determined in these tests must be documented and evaluated together with the measuring processes. The measured values may not overshoot the specified values.

Note

Comparisons with previous measurements must be carried out if the measured values undershoot the threshold values by more than 10 %. The test intervals should be reduced if a deterioration in values is determined!

7.2 Instructions for safety checks

7.2.1 Preparatory measures to be undertaken on the device

⚠ WARNING

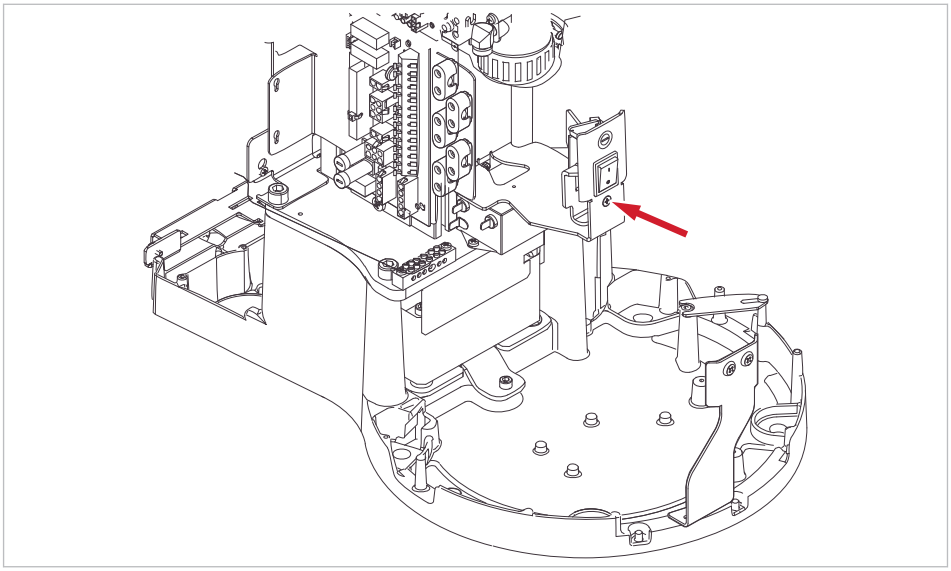
Electrical power.

Death or injury from electric shock.

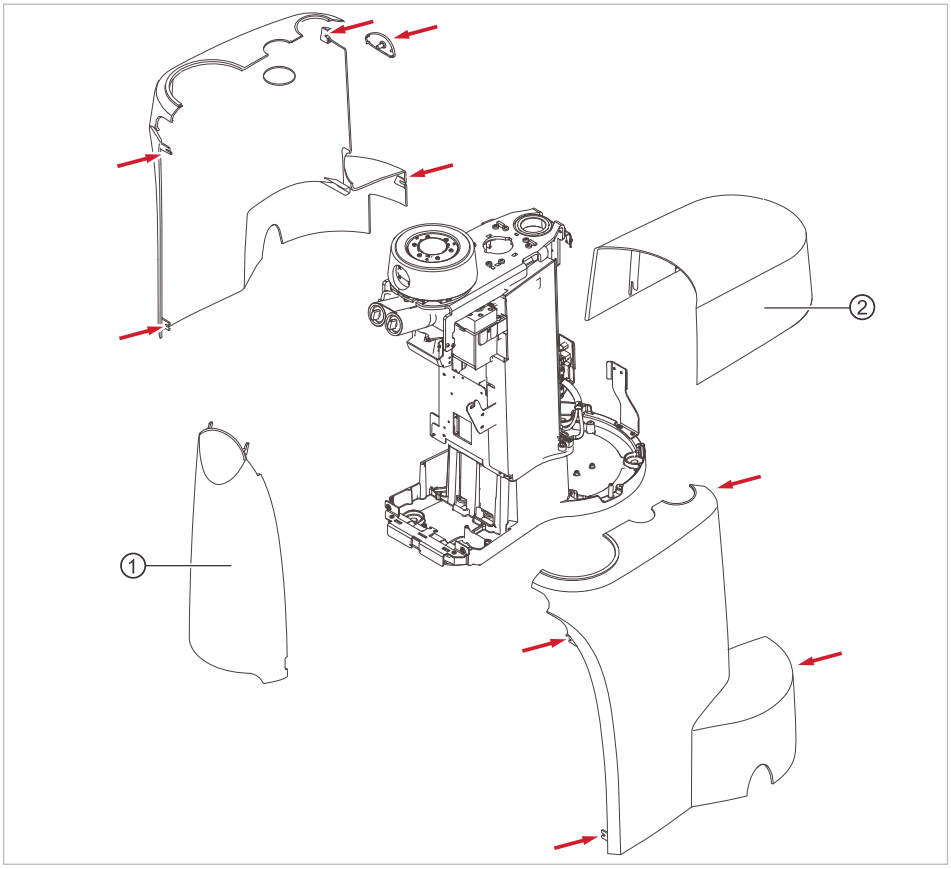
- ▸ Before servicing, pull the mains plug out of the socket or completely disconnect the device from the power to de-energise it!
- ▸ After conversion, check the electrotechnical safety in accordance with IEC 62353 (DIN VDE 0751-1).

- ▸ Turn off the main switch before any servicing work.

- Loosen the fastening screw on the bracket master switch.



- Take off the cover ② in upward direction.
- Release the rear cover ① below and remove it.
- Unscrew the fastening screws (see: arrows) of the cladding and take off the covers.



7.2.2 Visual inspection (inspection by examination)

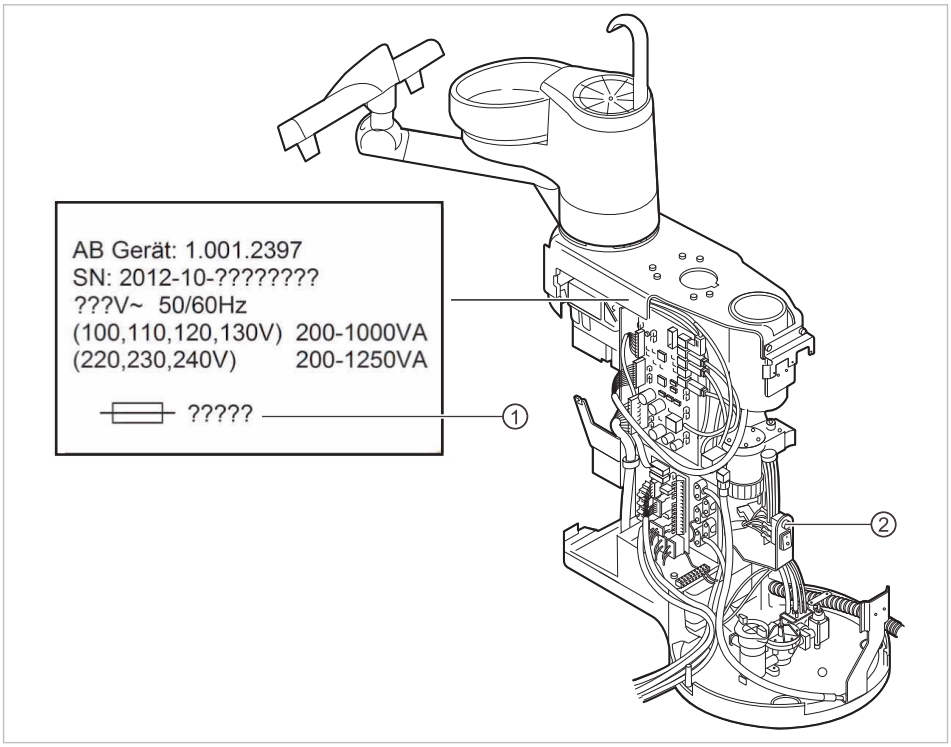
Check the following points in advance:

- Has the equipment of the ME device or the ME system been changed since the last inspection?

- Was the change documented and approved (test protocol, STK)?
- Are there any indications of insufficient safety?

Check the ratings of fuses that are accessible from outside

- Verify whether the main fuse on the main switch ② of the unit complies with the specified nominal data ①.



Visual inspection and appraisal of the medical device and accessories

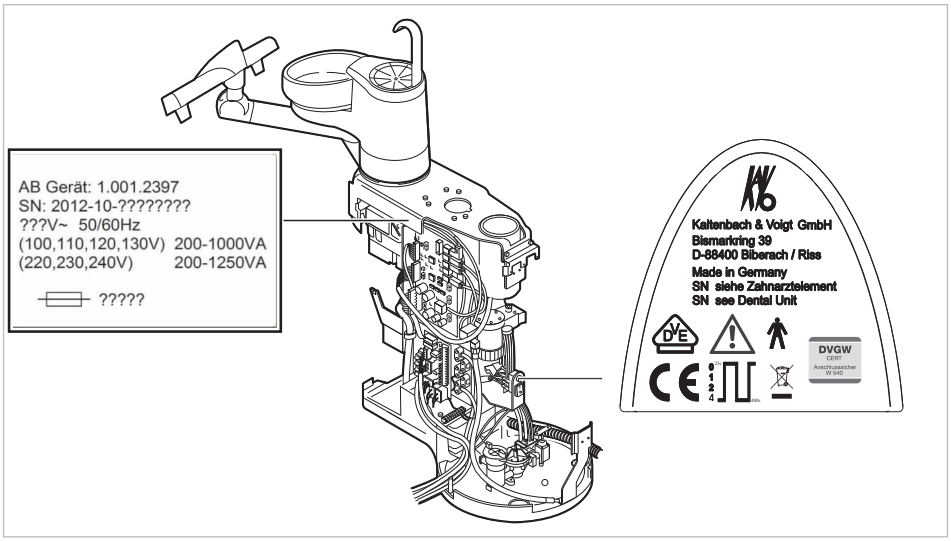
The following list is an example and makes no claim of being complete.

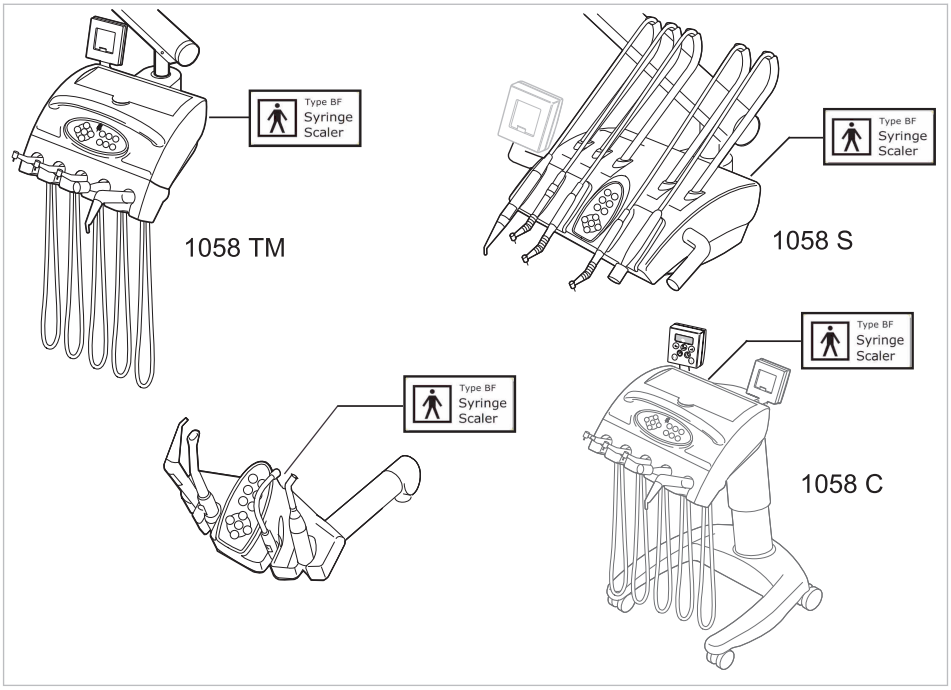
Check the following items:

- Stability of the device
- No damage to the cladding or casing (cracks, breakage)
- Firm seating of the PE headless screw of the lamp pole
- Functioning of the carrier systems on dentist and assistant side, treatment lamp, and display (brakes, height adjustment, etc.)
- Condition of the handpiece and suction hoses
- Condition of all installed application parts
- Condition of the control panels
- Condition of the threads for the fitting of tips to the scaler handpiece
- Condition of the treatment lamp (splinter guard, seating of reflectors, etc.)
- Permeability of the body of the device
- Connection of the power connection provided by the treatment centre
- Condition of air and water connections
- Any damage on the sight window and the casing of the camera ERGOcam
- Expiry date of the water bottle inserted in the BS water bottle not exceeded

Check of legibility and completeness of the safety-related labels

- Check if all safety-related markings (plates and labels) are present and legible.
- Check if the rating plate and serial number plates are present and legible.





Attachment locations for rating plates and BF labelling

Control of the availability of the necessary documents

- Verify whether the required instructions for use and care instructions are available in the surgery.

Note

Any irregularities determined in the visual inspection must be recorded in the test protocol. It is essential to determine whether defects and deficiencies could have an adverse impact on the safe operation of the unit. If the determined irregularities present a safety hazard and cannot be rectified directly, the unit must be closed down until the safe operation is restored.

7.2.3 Measurements

⚠ WARNING

Danger to persons due to a lack of care exercised during the safety checks and testing.

- Prior to connecting the treatment centre to the sight window, disconnect from the mains supply network.
- Carry out all safety checks and tests in a manner that will ensure that there will be no danger to the testing personnel, patients or other persons.

Note

The safety tester must comply with the requirements defined in IEC 62353 (DIN VDE 0751-1), Annex C.

Note

If no other specifications have been made, all values relating to voltage and current are effective values of alternating voltage, direct voltage or pulsating voltage res. alternating current, direct current or pulsating current.

Note

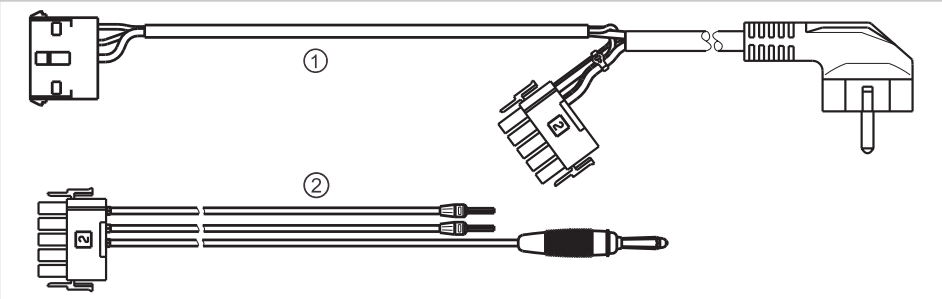
Connection cables such as data cables and cables for the functional earth could simulate protective conductor connections. These types of supplementary but unintentional protective earth connections could lead to erroneous measurements.

Note

Cables and wires e.g. supply cables, measuring circuits and data lines must be arranged in such a manner that will ensure that their influence on measurements will be restricted to a minimum.

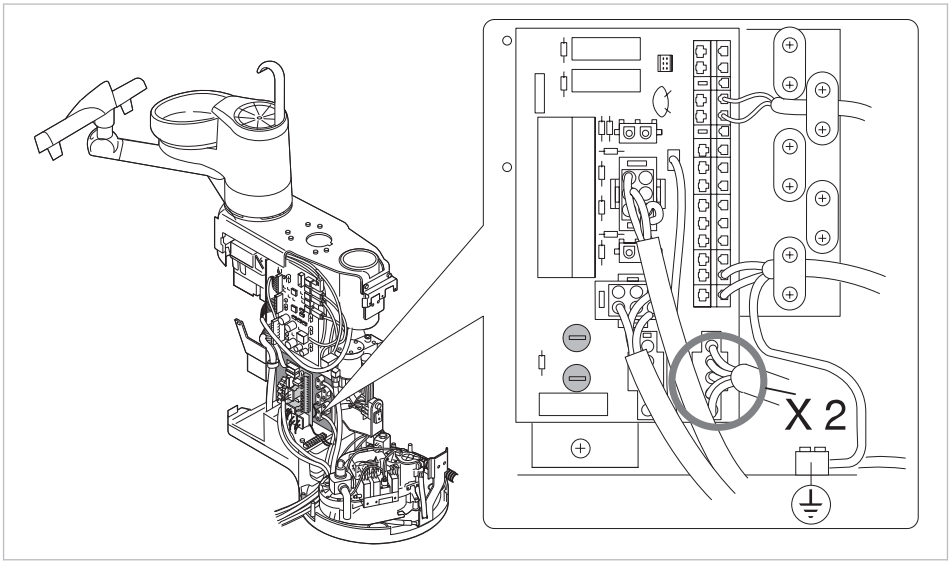
Note

The following measuring aids can be ordered from KaVo to assist in the measurements:
KaVo measuring cable (**Mat. no. 0.411.8811**)
EPL measuring cable (**Mat. no. 1.001.9904**)



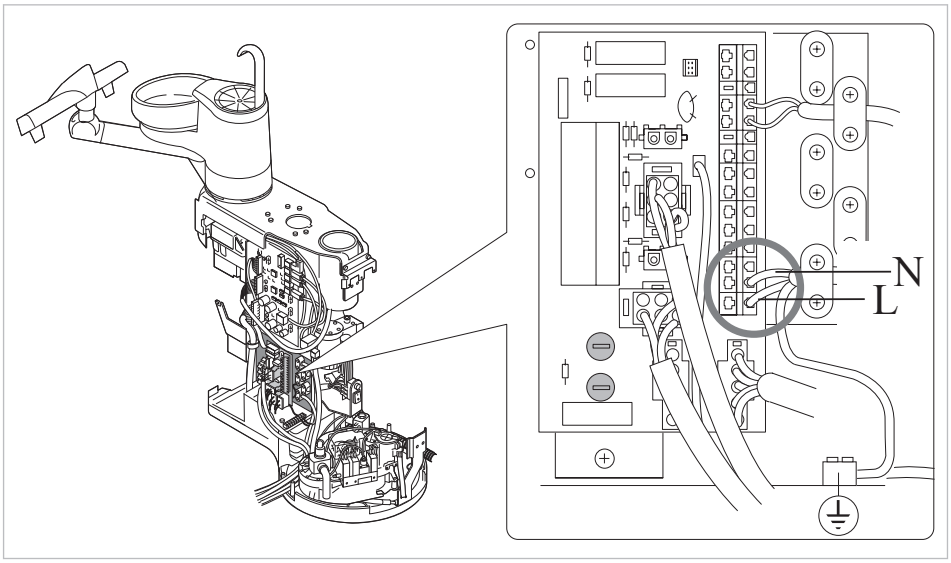
Using the measuring cable ① the unit is disconnected from the mains supply and connection of the treatment centre to the sight window is enabled. Hence, the customer-provided mains supply L & N on the power input board need not be disconnected. The adapter cable ② is included in the delivery of the KaVo measuring cable and is required for older treatment centres that are not equipped with an X2 connector.

Connecting the safety tester with KaVo measuring cables to the treatment centre



- Remove plug X2 from the power input board and plug into the matching connector X2 of the KaVo- measuring cable (**Mat. no. 0.411.8811**).
- Plug the second plug X2 of the KaVo measuring cable into the network card (X2).
- Insert the protective contact plug of the KaVo measuring cable into the sight window.

Connecting the safety tester without the KaVo measuring cable to the treatment centre



- Switch L + N of the on-site power supply cord to be voltage-free.
- Disconnect L + N on terminals X1.1 and X1.2.

- Connect the safety tester directly to terminals X1.1 (L) and X1.2 (N) and protective earth conductor terminal (PE).

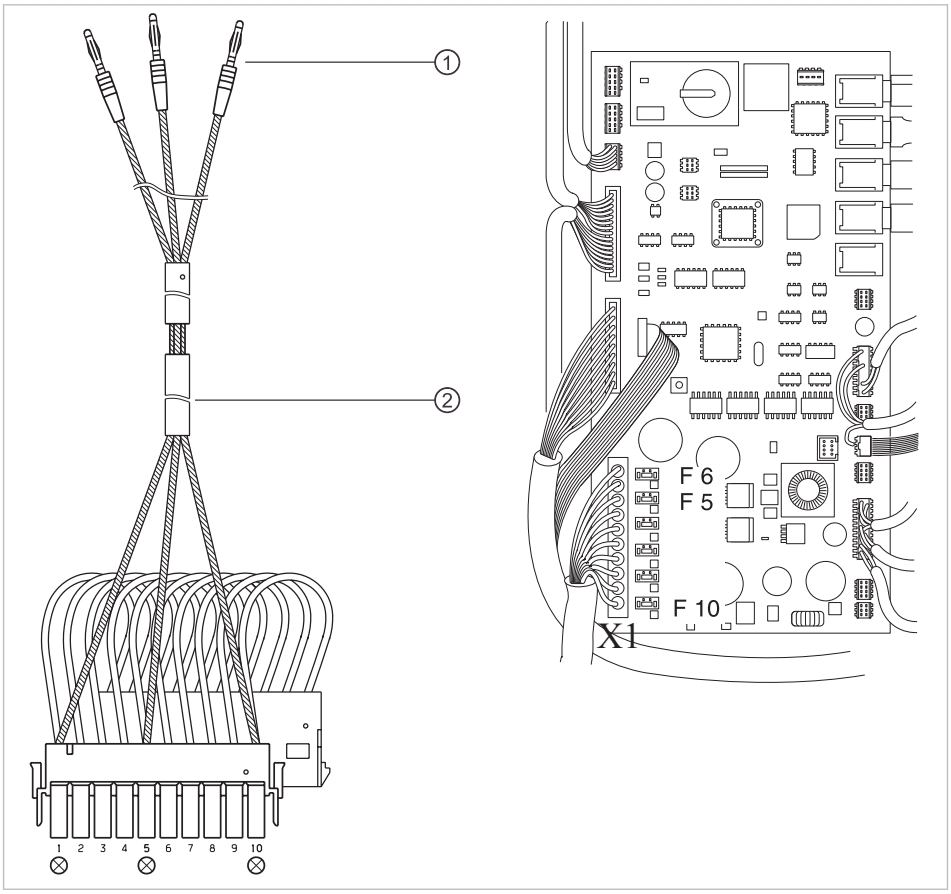
Note

The main switch of the ME device / ME system must be turned on during measurement.

Connect the application parts [AP] to the safety tester:

For the EUL and EPL measurement, the safety tester must be connected to fuses F5, F6, and F10. Measuring cable ② (**Mat. no. 10019904**) can be used for this purpose.

- Unplug plug X1 on the central control board and plug it into the proper plug of the KaVo measuring cable.
- Plug the second plug X1 of the KaVo measuring cable into the network card (X1).
- Plug the three plugs ① into the safety tester.



- Connect the safety tester to additional measuring points AP X.

Note

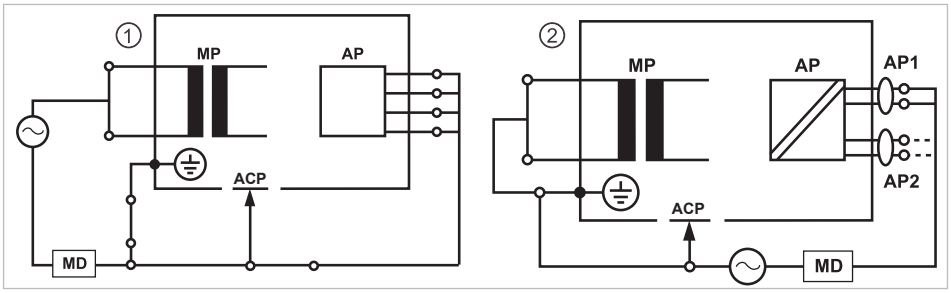
Additional measuring points AP X must be taken into consideration in the presence of accessories: e.g. accessories such as PIEZO ultrasound scaler, HF surgery etc.

See also:

8 Annex - Additional measuring points, Page 107

Connect accessible conductive parts [ACP] with PE

ACP = accessible conductive parts



Note

Additional measuring points ACP X must be taken into consideration in the presence of accessories: e.g. accessories such as saline pump etc.

See also:

8 Annex - Additional measuring points, Page 107

ACPs on the treatment centre

No ACPs need to be connected to the protective conductor (PE) during the measurement on the treatment unit Primus® 1058 S/TM/C, as all relevant parts are connected to the PE and included in the test before they leave the factory.

ACPs on treatment lamps

No ACPs need to be connected to the treatment lights during the measurement with the protective conductor (PE) because all relevant parts have already been connected with the protective conductor (PE) in the factory and are included in the test.

Measure protective conductor resistance

Threshold:	< 0,3 Ω (maximum value!)

Note

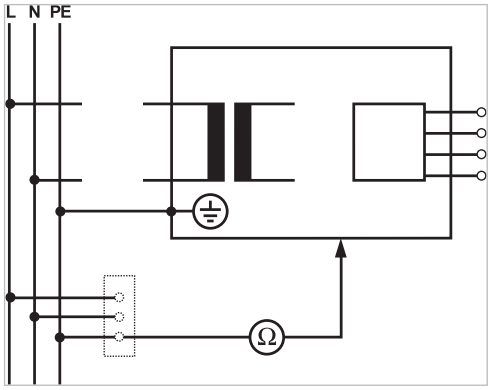
The integrity of the power supply cable, in particular the protective earth wire of the power cable must be ensured. As this is a fixed installation, the evaulation can be conducted by means of a visual inspection. If damage is determined, the further procedure to be taken is specified in the general instructions.

Note

In this measurement the resistance of the protective earth connection of the supply network can be taken into consideration.

Note

If applicable: all removable supply connection lines, which are retained for use, should be taken into consideration and the respective PE measured.



Protective earth measurement

The protective conductor resistance must be measured at the following parts of the device:

- Treatment centre
- Treatment lamp
- Accessories

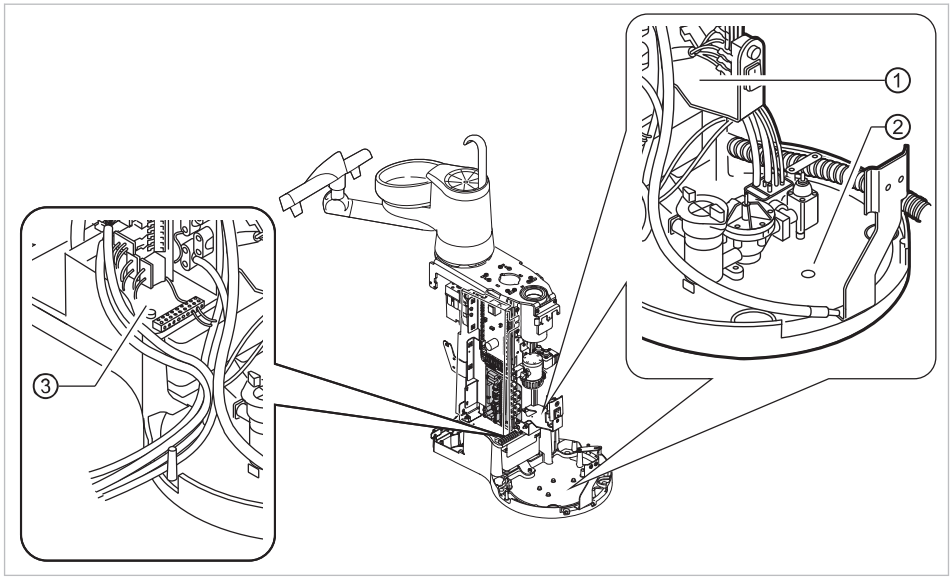
Note

Additional measuring points SL X need to be taken into consideration in the presence of accessories: e.g. if third-party devices are connected, cameral module of the multimedia system, etc.

See also:

8 Annex - Additional measuring points, Page 107

Scan the treatment centre with the test tip



Measuring points on the device base

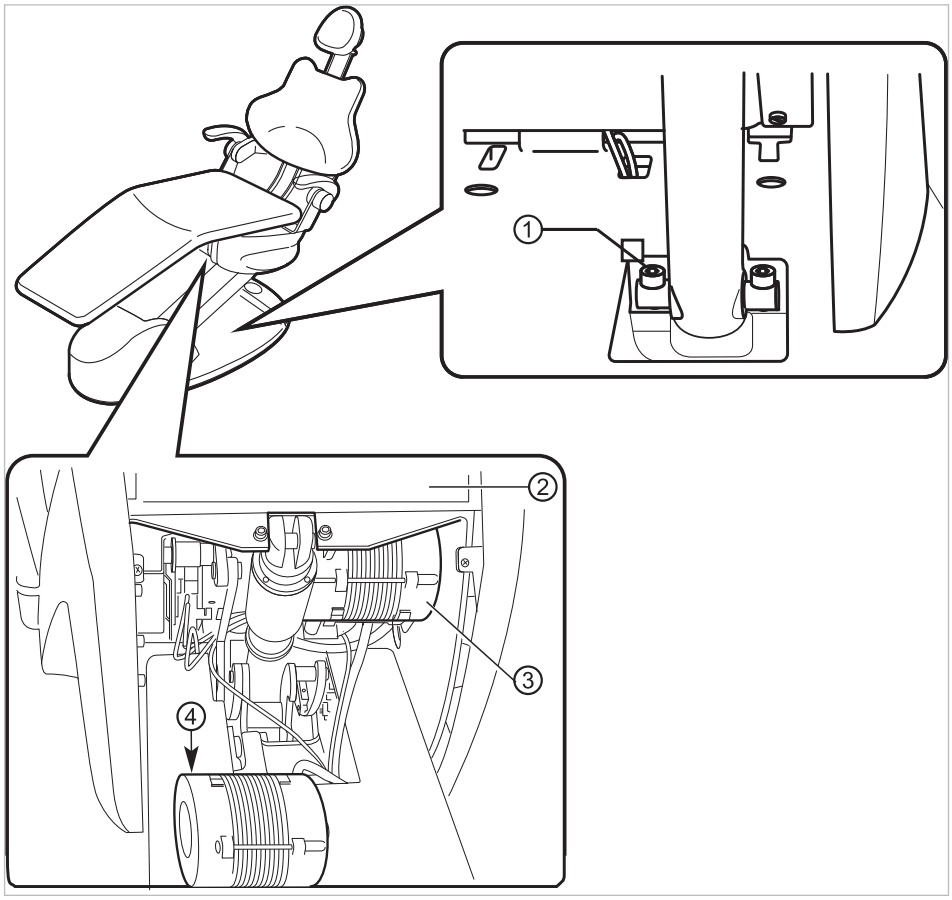
① Main switch holding plate

② Stand cover base plate

③ Surroundings of the protective conductor terminal

Scanning the patient chair with the test tip

Standard patient chair



Standard dental chair measuring points

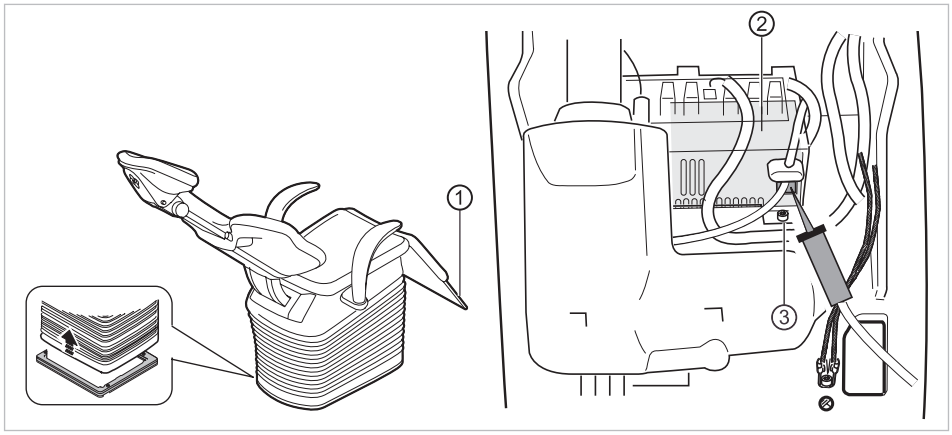
① Patient chair base plate

② Support plate for the top part of the chair

③ Backrest spindle motor

④ Lift motion spindle motor

COMPACTchair patient chair



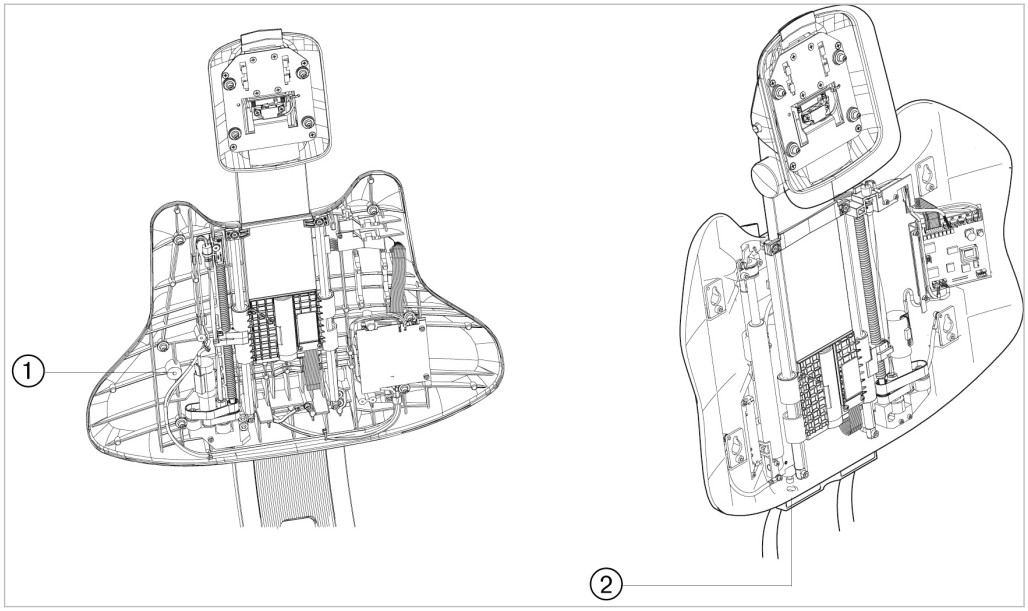
COMPACTchair measuring points

① Leg rest

② Chair power supply

③ Chair base plate

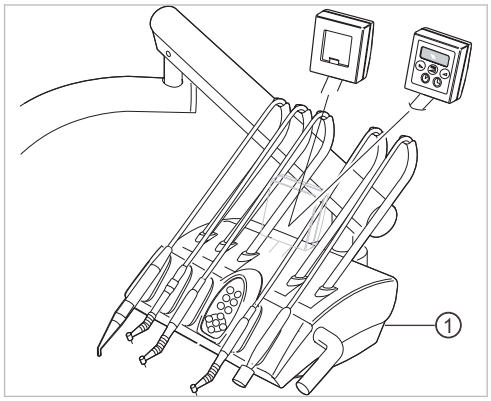
Backrest



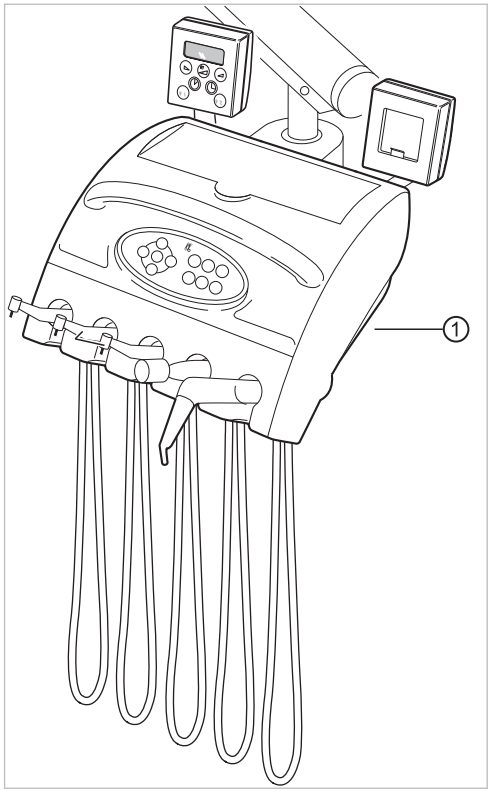
① Backrest progress: backrest with the upholstery removed

② Comfort backrest: fastening screw

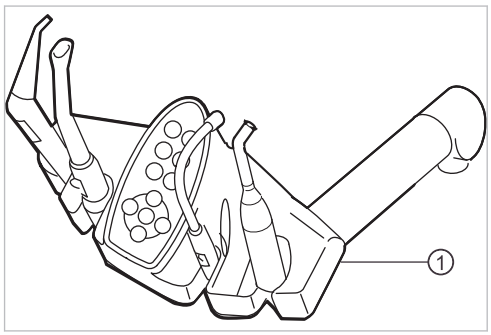
Scanning the operating elements with the test tip



① Dentist unit S: table bottom



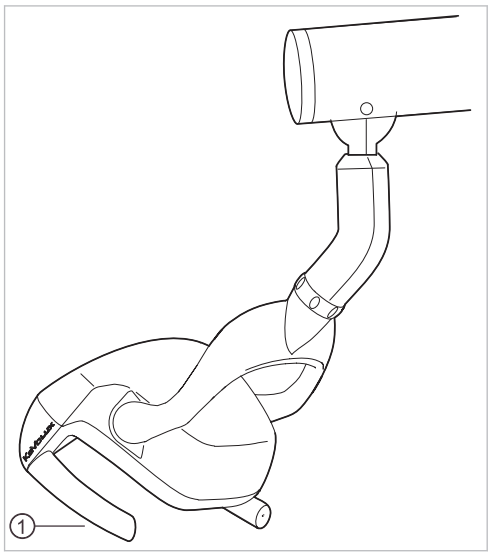
① Dentist unit TM/C fastening screw of the upper part of the table



① Assistant element: paint-free threaded bore hole on the underside

Scan the treatment lamp with the test tip

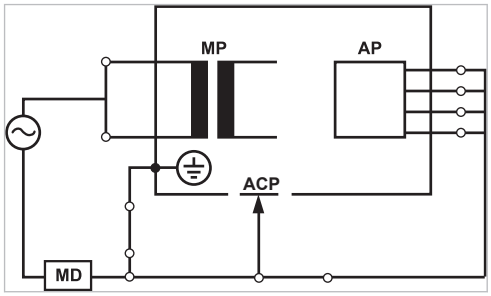
Operating light KaVoLUX 540 LED



① Fastening screw of the handle support when the gripping sleeve has been removed

Measure equivalent unit leakage current

Threshold:	< 10 mA (maximum value!)



Protection class 1

⚠ WARNING

Electrical power.

Death or injury from electric shock.

- Conduct test for leakage current in devices of Protection Class 1 only after the protective earth test has been passed.

⚠ WARNING

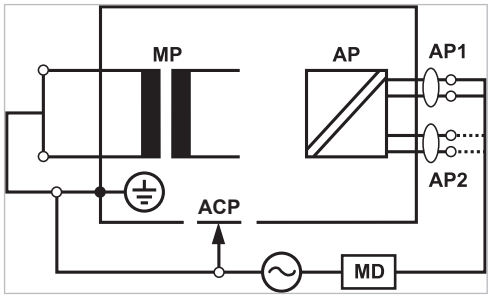
Electrical power.

Death or injury from electric shock.

- Prior to connecting the treatment centre to the sight window, disconnect the treatment unit from the mains supply network.

Measure equivalent patient leakage current

Threshold:	< 5 mA (maximum)



Protection class 1

⚠ WARNING

Electrical power.

Death or injury from electric shock.

- Conduct test for leakage current in devices of Protection Class 1 only after the protective earth test has been passed.

⚠ WARNING

Electrical power.

Death or injury from electric shock.

- Prior to connecting the treatment centre to the sight window, disconnect the treatment unit from the mains supply network.

Note

In the testing of ME devices with several application parts, the parts must be connected in succession. The measured results must be evaluated using the threshold values. Application parts, which are not included in the measurement, remain open.

Note

An additional measurement of the leakage current from type B application parts need only be carried out if this is specified by the manufacturer (see accompanying documents).

Note

A separate measurement is not usually required for type B application parts. The application parts are connected to the casing (see diagram) and included in the measurement of the leakage current of the casing, whereby the same reliable values are applicable.

7.2.4 Functional test

The following conditions must be fulfilled in all function tests:

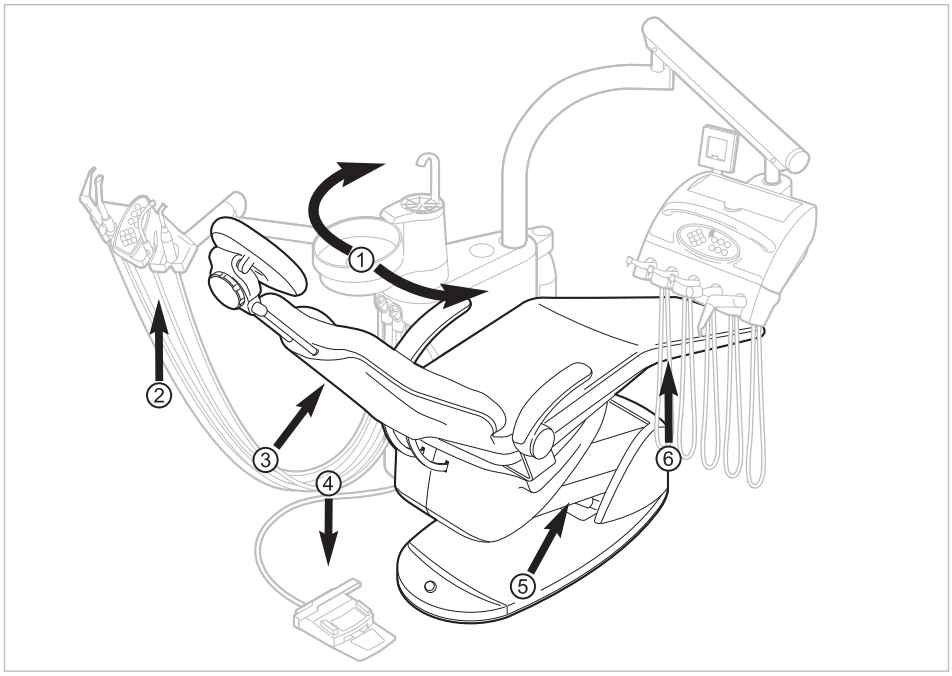
- The basic function of the treatment centre must be guaranteed.
- The treatment centre must be fit for use.
- It must not exhibit any irregularities, noise or abrasion etc.

The following list is an example and makes no claim of being complete.

- Function test of the safety circuits (see diagram below)
- Functioning of the master switch of the device
- Functioning of the displays

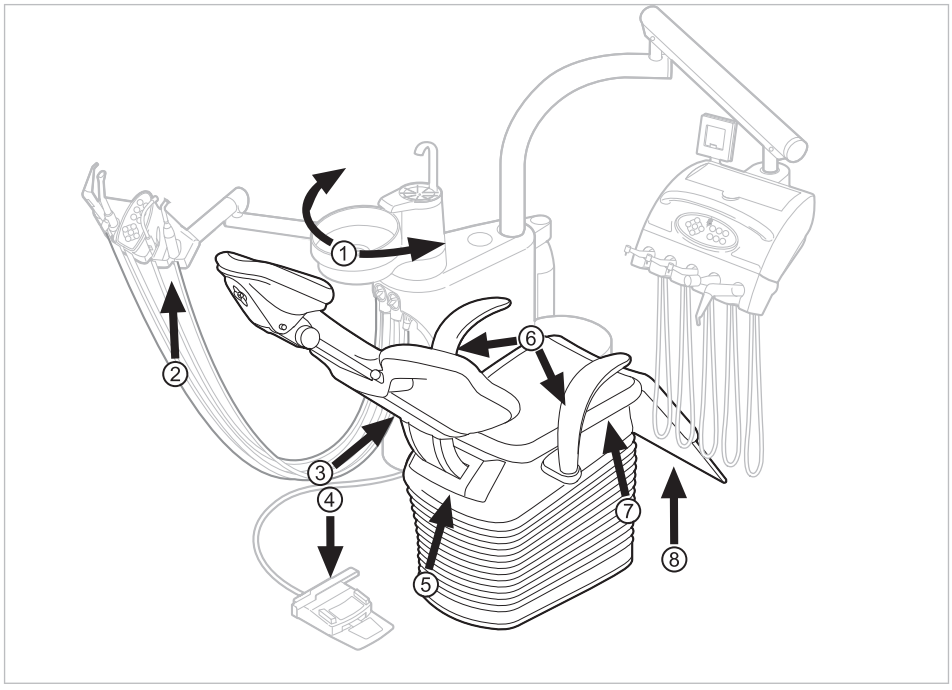
- Function test of the holder switch of the dentist and assistant element
- Functional test of the 3F/MF handpiece – seating of the cannula
- Functional test of operating light
- Function test of the suction hoses
- Function test of the foot control
- Function of the chair:
  - Travel on all axes
  - Testing of the limit switches

- Functional test ...



Safety shutoff for the standard patient chair

① Patient unit swung over the patient chair	② Assistant element
③ Backrest	④ Bracket on the foot control
⑤ Bottom of the chair parallelogram	⑥ Seat



Safety shutoff for the COMPACTchair patient chair

① Patient's part pivoted over dental chair	② Assistant element
③ Backrest	④ Bracket on the foot control

⑤ Cover on the curved segment of the backrest
⑥ Arm rests
⑦ Seat
⑧ Foldable part of the seat

If a person or object actuates a safety shutoff, the chair immediately stops moving. The fact that the safety shutoff has been activated is displayed by the corresponding display flashing on the dentist or assistant unit.

Display LED	Safety shut-off
	Assistant unit
	Seat, backrest, vacuum stop, bottom chair program Armrest (only COMPACTchair) Bendable part of seat (only COMPACTchair)
	Foot control
	Tilt sensor for dentist unit cart (no longer mounted)
	Patient unit

7.2.5 Assessment and documentation

Note

All tests conducted must be documented comprehensively. The documents must contain at least the following particulars:

- Name of the test centre
- Name of the test engineer
- Name of the tested device (e. g. type, serial number)
- Tests and measurements
- Data, type and measured results of the visual inspections
- Data, type and measured results
- Data, type and measured results of function tests
- Measuring/test equipment including SN/test equipment number and calibration period
- Final evaluation
- Name, date and signature of test engineer

There is a copy of a test report template at the end of chapter STK. KaVo recommends the use of this template.

Note

Following testing, maintenance or adjustment, it must be verified whether the ME device or ME system has been restored to the state that is required for the intended usage before it is employed once again.

Note

If the safety of the tested ME device or ME system has not been established, e.g. the tests have not been completed with positive results, the device or system must be marked accordingly and the potential hazard emanating from the device or system must be communicated in writing to the RESPONSIBLE ORGANISATION (to the operator, as a rule). This action is not required if the cause of the malfunction could be determined and rectified. The defect must be recorded in the protocol.

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Test protocol - Safety check [SC]

Operator	**Testing organisation** Name of the test engineer

❒ Test before start-up

❒ Recurrent test

❒ Test after repair

Date of testing:

Manufacturer:	
Device:	
Serial number:	
Ident. no.:	

next recurrent test required in

6	12	18	24	months

Test in accordance with:	**IEC 62353**	
Protection class.:	**I**	**II**
Power connection:	fixed connection	
Application part type:	**B**	**BF**

Measuring equipment used:

Make:

Type:

Test:

		passes test	
		yes	no
Visual inspection:		❒	❒
Measurements:	**Measured value**		
Protective conductor resistor		❒	❒
Equivalent unit leakage current EUL (according to figure 3)		❒	❒
Equivalent patient leakage current EPL (according to figure 6)		❒	❒
Insulation resistance		❒	❒
Functional test (according to manufacturer instructions)		❒	❒

Defect / Comment / Assessment

Overall assessment:

❒ No safety or functional defects detected

❒ No immediate risk, detected defects can be remedied in the short term.

❒ Device must be taken out of commission until defects are remedied!

❒ Device fails to meet requirements - Modification / replacement of of components / Withdrawal from service recommended.

Date / Signature

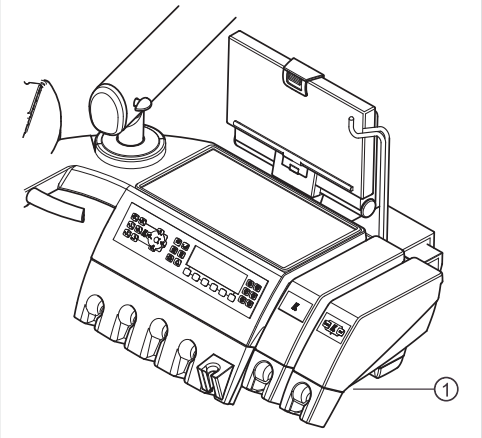
8 Appendix - Additional measuring sites

Note

With reference to accessories, which are not listed here, the specifications of the relevant instructions for use must be observed. Example: ERGOcam 5.

8.1 Additional scanning sites SL X in the protective conductor measurement

Module HF surgery and module ERGOcam 5

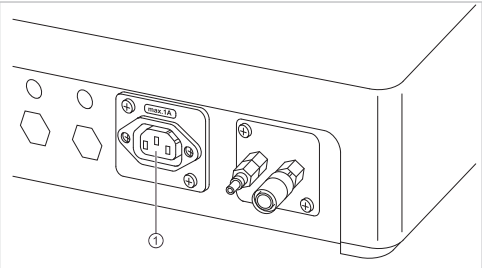


① Screw bottom section of casing

Note

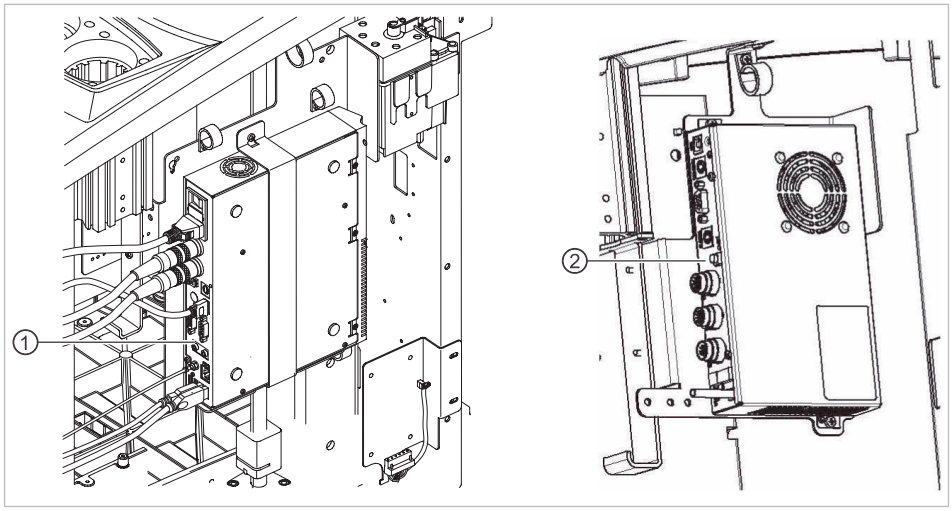
The modules are not earthed with a safety conductor. In the case of excessive PE resistance, the electrical connection between the module and the dentist element must be improved. This can be accomplished, for example, by means of a serrated lock washer on the fastening screw.

Connecting third-party equipment



▸ Position the test tip on the middle contact ①.

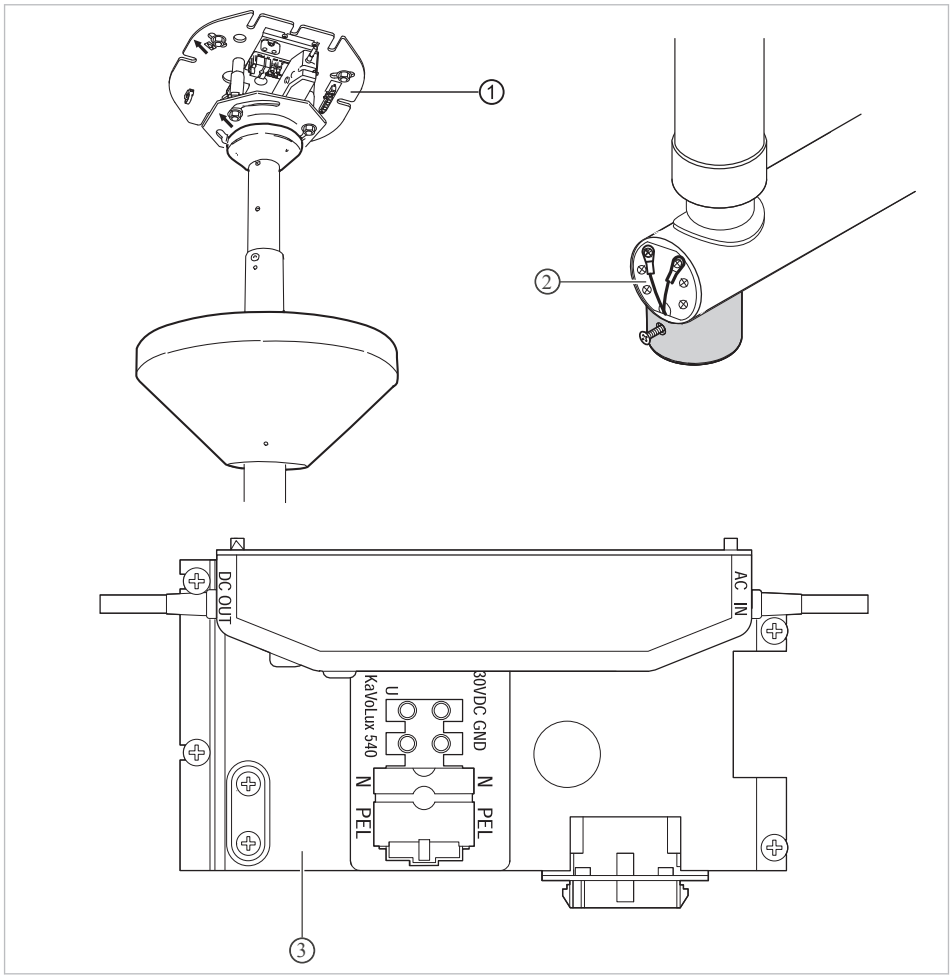
ERGOcom 4 and ERGOcom light



① ERGOcom 4: rear connection plate

② ERGOcom light: rear connection plate

BS ceiling adapter operating light



① Base plate for the ceiling adapter

② Surroundings of the protective conductor connector

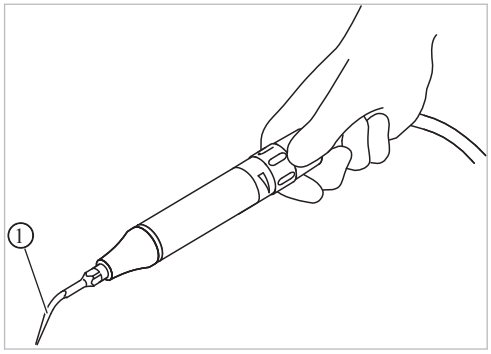
③ Surroundings of the protective earth conductor terminal

8.2 Additional measuring sites AP X for EUL/EPL measurement

Scan the PIEZO ultrasonic scaler with test probe

Note

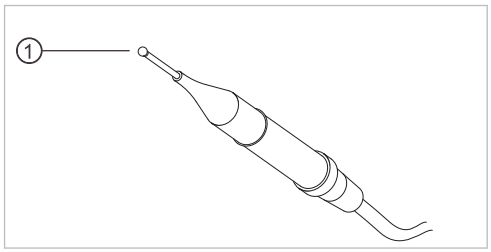
Measuring points must be connected on the following ultrasonic scalers:
- PiezoLED ultrasonic scaler
- PIEZOsoft ultrasonic scaler



Exemplary presentation of the measuring point on the PiezoLED ultrasonic scaler

① Test probe on ultrasonic scaler tip in ultrasonic scaler handpiece

HF surgery AUTOsurge



① Test tip on ball electrode in HF handpiece

Note

The switch on the handpiece must be activated during the EPA measurement

Note

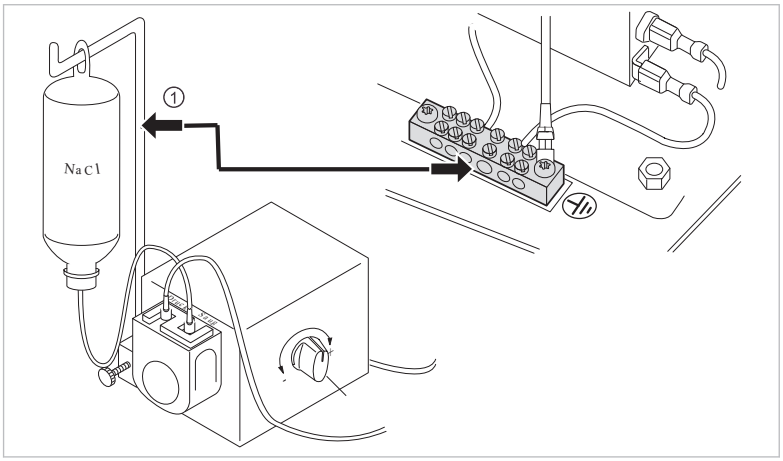
Determination of the high frequency output power:
As there is no appropriate validated testing procedure for HF surgical handpieces of this performance grade (< 50 Watt) on customer premises, the performance measurement is not specified by the manufacturer.
This does not result in a disadvantage or hazard for the user or patient. If the HF surgical handpiece exhibits an inadequate performance, KaVo recommends having the HF surgical handpiece with module tested in the factory.

Note

Additional measuring points AP X need to be taken into consideration in the presence of accessories: e.g. if third-party devices are connected, cameral of the multimedia system, etc.

8.3 Additional connection sites ACP X (additional earth connections)

Touch the saline pump with the test tip



① Test tip on bottle holder

Note

A fixed connection from ACP to the PE terminal must be established for the EUL and EPL measurement. This can be accomplished with a measuring cable and connection terminals.

9 Information concerning the electromagnetic compatibility in accordance with IEC 60601-1-2 (DIN EN 60601-1-2)

9.1 Electromagnetic Transmissions

The Primus® 1058 S/TM/C treatment unit is for use in an environment like the one cited below. The customer or user of the Primus® 1058 S/TM/C should ensure that it is used in the correct environment.

Measurements of emitted interference	Conformance	Electromagnetic environment - Guidelines
HF emissions according to CISPR 11	Group 1	The Primus® 1058 S/TM/C device uses HF energy for its internal functions exclusively. Therefore, the HF emission of the device is very low and interference with adjacent electronic devices is unlikely.
HF emissions according to CISPR 11	Class B	The Primus® 1058 S/TM/C device is suitable for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.
Emission of harmonics according to EN 61000-3-2	Class A	The Primus® 1058 S/TM/C device is suitable for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.
Emission of voltage fluctuations/ flicker according to EN 61000-3-3	Conforms	The Primus® 1058 S/TM/C device is suitable for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.

9.2 Resistance to electromagnetic interference

The Primus® 1058 S/TM/C treatment unit is for use in an environment like the one cited below. The customer or user of the Primus® 1058 S/TM/C should ensure that it is used in the correct environment.

Interference immunity tests	EN 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to EN 61000-4-2	± 6 kV contact discharge ± 8 kV atmospheric discharge	± 2/4/6 kV contact discharge ± 2/4/8 kV atmospheric discharge	Floors should be made of wood or concrete or be fitted with ceramic tiles. If the floor is fitted with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical interference / bursts according to EN 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.

Interference immunity tests	EN 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Surges according to EN 61000-4-5	± 1 kV push-pull voltage ± 2 kV common mode voltage	± 1 kV push-pull voltage ± 2 kV common mode voltage	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage interruptions, short-term interruptions and fluctuations of the supply voltage according to EN 61000-4-11	< 5% U_T (> 95% interruption) for ½ period 40 % U_T (60% interruption) for 5 periods 70 % U_T (30% interruption) for 25 periods < 5% U_T (> 95% interruption) for 5 s (250 periods)	< 5% U_T (> 95% interruption) for ½ period 40 % U_T (60% interruption) for 5 periods 70 % U_T (30% interruption) for 25 periods < 5% U_T (> 95% interruption) for 5 s (250 periods)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user needs the Primus® 1058 S/TM/C to work even if the power supply is interrupted, we recommend supplying energy to the Primus® 1058 S/TM/C from an uninterruptible power supply or battery.
Magnetic field at a supply frequency (50/60 Hz) according to EN 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to typical values in a business and hospital environment.

NOTE: V_T is the alternating mains voltage before the test level is used.

9.3 Recommended safe distance between portable and mobile HF telecommunications equipment and the treatment device

The Primus® 1058 S/TM/C is intended for use in an electromagnetic environment in which the HF interference parameters are controlled. The customer or user of the Primus® 1058 S/TM/C can help prevent electromagnetic interference by maintaining the minimum clearance between portable and mobile HF telecommunication devices (transmitters) and the Primus® 1058 S/TM/C depending on the output of the communication device as indicated below.
Safe distance depending on the transmission frequency:

Rated power of the transmitter in W	150 kHz to 80 MHz $d=1.17\sqrt{P}$ m	80 MHz to 800 MHz $d=1.17\sqrt{P}$ m	800 MHz to 2.5 GHz $d=2.33\sqrt{P}$ m
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters whose maximum rated power is not in the above table, the recommended safe distance d in meters (m) can be calculated using the equation for the respective gap, where P is the maximum rated power of the transmitter in Watts (W) according to the manufacturer's information.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

9.4 Immunity to electromagnetic interference

The treatment unit Primus® 1058 S/TM/C is designed for operation in an environment as specified below. The customer or the user of the Primus® 1058 S/TM/C should ensure that the device is operated in an environment of this type.

Interference immunity tests	EN 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Wire-based HF interference according to EN 61000-4-6 Wireless HF interference according to EN 61000-4-3	3 V_{eff} 150 kHz to 80 MHz outside the ISM bands[a] 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 3 V/m	Handheld and mobile wireless devices should not be used at a shorter distance from thePrimus® 1058 S/TM/C including cables than the recommended safe clearance calculated using the appropriate equation for the emission frequency. Recommended safe distance: $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximal nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and d is the recommended safe clearance in metres (m). [b]The field strength of stationary wireless radio transmitters as measured locally[c]should be lower than the conformance level at all frequencies. [d]Interference is possible in the vicinity of devices bearing the following icon.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

[a]The ISM frequency bands (for industrial, scientific, and medical applications) between 150 kHZ and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz.

[b]The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz are intended to reduce the probability of mobile/handheld communications facilities causing interference when they are inadvertently introduced into the patient area. For this reason, the additional factor of 10/3 is applied in the calculation of the recommended safe clearances in these ranges of frequencies.

[c]The field strength of stationary transmitters, such as, e.g. base stations of mobile phones and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and television transmitters, cannot be determined exactly based on theoretical considerations. A site study should be considered to determine the electromagnetic environment in terms of stationary transmitters. If the measured field strength at the site, at which the Primus® 1058 S/TM/C is used, exceeds the compliance levels shown above, the Primus® 1058 S/TM/C should be monitored to demonstrate proper func-

tion. If any uncommon performance characteristics are observed, additional measures may be required, such as, e.g., changing the orientation or using a different location for the Primus® 1058 S/TM/C.

[d] In the frequency range of 150 kHz to 80 MHz, the field strength should be less than $3V_{eff}$ V/m.

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