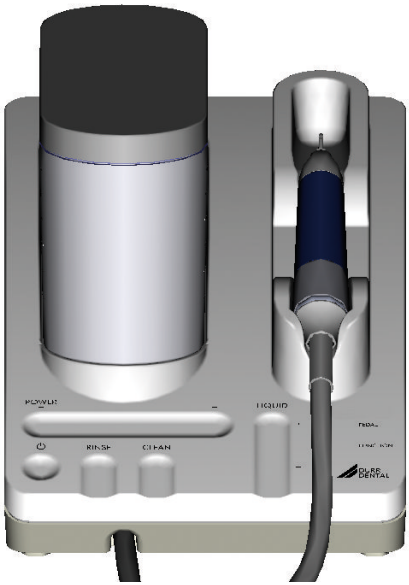
Vector scaler

EN



Installation and operating instructions

CE 0297

9000-615-32/02

DÜRR DENTAL

2012V003

EN

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Important information

1 About this document

These installation and operating instructions represent part of the unit.

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

The German version of the installation and operating instructions is the original manual. All other languages are translation of the original manual. These operating instructions apply to Vector Scaler:
Order number:
– 2032-50

1.1 Warnings and symbols

Warnings

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


General warning symbol

The warnings are structured as follows:


SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:
– **DANGER**
Immediate danger of severe injury or death
– **WARNING**
Possible danger of severe injury or death
– **CAUTION**
Risk of minor injuries
– **NOTICE**
Risk of extensive material/property damage

Other symbols

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

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


Refer to Operating Instructions.


Protection class II


CE labelling with the number of the notified body


Manufacturer

Health Industry Bar Code (HIBC)

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MD Medical device

SN Serial number

REF Order number

LOT Lot designation

Dispose of correctly in accordance with EU Directive 2012/19/EU (WEEE).

Type BF application part

Steam sterilise at 134 °C

Steam sterilise at 135°C

Not sterile

Recycling

The device contains a battery.

Use suitable tools.

The seal must only be removed by a qualified expert.

On/off switch

Amplitude reduction

Amplitude increase

Disconnect all power from the unit.

Wear protective gloves.

Wear protective goggles.

Use a face mask.

Use protective clothing.

Rinse with water.

Rinse with instrument cleaner.

Rinse with instrument disinfectant.

1.2 Copyright information

2 Safety

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

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

2.1 Intended purpose

This device is a piezo-operated ultrasonic device for use in dental applications. It is mainly used for the treatment of periodontal defects. In addition, the device is used in the area of prophylaxis, peri-implantitis treatment as well as dental hygiene.

2.2 Indications

› Periodontal conditions
› Peri-implantitis
› Hard supragingival and subgingival deposits (calculus or concrement)
› Soft supragingival and subgingival deposits (plaque or biofilm)

2.3 Contraindication

Ultrasound vibrations can interfere with the function of heart pacemakers and defibrillators. Patients with heart pacemakers or defibrillators should not be treated with these instruments.

2.4 Intended use

The ultrasonic device is designed for use in periodontology, for the removal of plaque and for the cleaning of tooth surfaces. This is done via cavitation, polishing, grinding and scraping. Further assistance for the treatment can be provided by using hydroxyl and/or fluorapatite as a polishing agent in periodontology. Only agents approved by the manufacturer may be used. Application with hydroxyapatite and/or fluoroapatite as polishing agent is not intended for Vector Easy, Vector Easy Pro or Vector Scaler.

Scaler handpiece applications

– Subgingival and supragingival removal of dental calculus and concrement

The piezo-ceramic drive of the Vector Scaler allows efficient removal of deposits while providing the best and gentlest possible protection of sensitive tissue structures. The ergonomic design of the handpiece offers six long-lasting high performance LEDs to provide the best possible illumination even into areas that are difficult to see.

2.5 Improper use

Any use of this appliance / these appliances above and beyond that described in the Installation and Operating Instructions is deemed to be incorrect usage. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The operator will be held liable and bears all risks.

2.6 General safety information

WARNING

Contraindication

Ultrasound vibrations can interfere with the function of heart pacemakers and defibrillators.

› Patients with heart pacemakers or defibrillators should not be treated with these instruments.

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

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2.7 Specialist personnel

Operation

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

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

Installation and repairs

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

2.8 Electrical safety

› Comply with all the relevant electrical safety regulations when working on the unit.

› Never touch the patient and unshielded plug connections on the device at the same time.

› Replace any damaged cables or plugs immediately.

Observe the EMC rules concerning medical devices

› The unit is intended for use in professional healthcare facilities (in accordance with IEC 60601-1-2). If the appliance is operated in another environment, potential effects on electromagnetic compatibility must be taken into account.

› Do not operate the unit in the vicinity of HF surgical instruments or MRT equipment.

› Maintain a minimum distance of at least 30 cm between the unit and other electronic devices.

› Keep a minimum distance of 30 cm between the unit and mobile radio devices.

› Note that cable lengths and cable extensions have effects on electromagnetic compatibility.

The following accessories can have an effect on the electromagnetic compatibility:

Mains cable 9000100846

Flexible foot switch cable 9000-119-130E

NOTICE

Negative effects on the EMC due to non-authorised accessories

› Use only Dürr Dental parts or accessories specifically approved by Dürr Dental.

› Using any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an erroneous operation mode.

2.9 Essential performance characteristics

The unit does not have any essential performance characteristics as set out in IEC 60601-1 section 4.3.

2.10 Notification requirement of serious incidents

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

2.11 Only use original parts

› Only use accessories and optional items that have been recommended or specifically approved by Dürr Dental.

› Only use only original wear parts and replacement parts.

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

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

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2.12 Transport

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

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

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

2.13 Disposal

Unit

The unit must be disposed of properly. Within the European Union, the unit must be disposed of in accordance with EU Directive 2012/19/EU (WEEE).

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

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

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

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

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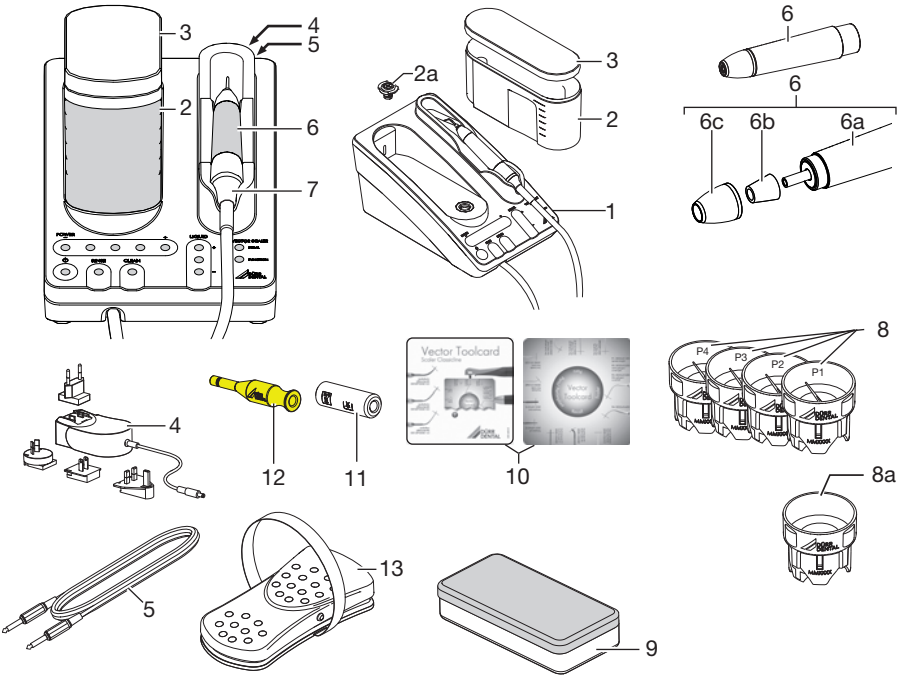
Product description

3 Overview

3.1 Vector scaler



1	Unit base
2	Fluid container
2a	Valve
3	Cover for fluid container
4	Mains cable
5	Flexible foot switch cable
6	Scaler handpiece
6a	Handpiece
6b	Light conductor
6c	Cover
7	Handpiece hose
8	Scaler tool kit torque wrench with integrated PREMIUMLINE instrument P1 - P4
8a	Torque wrench for PREMIUMLINE instruments P1 - P4
9	Scaler steri-box
10	Vector Toolcard
11	Rinsing adapter for scaler instruments
12	Rinsing adapter for handpieces (yellow)
13	Flexible foot switch

3.2 Accessories

The following items are required for operation of the device, depending on the application:
Scaler handpiece 2032-200-00

Instruments for Scaler handpiece

PREMIUMLINE
Tool-Kit Scaler P1, straight 2032-411-00
Tool-Kit Scaler P2, right curved . . . 2032-412-00
Tool-Kit Scaler P3, left curved 2032-413-00
Tool-Kit Scaler P4, supra 2032-414-00

3.3 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):
Vector Scaler 2032-50

- Unit base
- Scaler handpiece
- Scaler instrument P1
- Power supply unit
- Flexible foot-switch (including cable)
- Battery for flexible foot switch 3 V lithium CR 2032
- Scaler steri-box
- Combination wrench
- Vector Toolcard
- Vector cleaner, special cleaner
- Vector/RinsEndo disinfection, first application, 120 ml
- Installation and operating instructions for Vector Scaler
- Quick start instructions

3.4 Consumables

The following materials are consumed during operation of the device and must be ordered separately:
Vector/RinsEndo Disinfection . . . CDZ501C6150
Vector cleaner, special cleaner for hose system, 4 x 2.5 l CCA531A6150
FD 322 rapid surface disinfection CDF322C6150
FD 350 Classic disinfection wipes CDF35CA0140
FD 370 cleaner - for medical practices CCF370C6150
FD 366 sensitive rapid surface disinfection CDF366C6150

3.5 Wear parts and replacement parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):
Instruments for Scaler handpiece, see "3.2 Accessories"
Light conductor for Scaler handpiece (4 pcs.) 2032-200-03E
Flexible foot switch 2031-600-00
Scaler steri-box (cover: blue) 2032-330-00
Vector toolcard 2031-400-01
Combination wrench 2030-137-01E
Rinsing adapter set (rinsing adapter for scaler instruments and rinsing adapter for handpieces (yellow)) 2032100008
Scaler instrument torque wrench 2032100004

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

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4 Technical data

Electrical data – power supply unit		
Rated voltage	V AC	100 - 240
Mains frequency	Hz	50 - 60
Current consumption	A	1 - 0.5
Protection class		II
Type of protection		IP 20
Electrical data – basic unit and handpieces		
Voltage	V DC	24
Electrical power of Scaler handpiece	W	22
Type of protection		IP 20
Classification		
Medical Device Class		IIa
General technical data – basic unit and handpieces		
Operating frequency:	kHz	approx. 27–32
Amplitude of Scaler handpiece	µm	20-120
Duty cycle	%	100
Fluid container fill capacity	ml	600
Scaler handpiece water consumption	ml/min	approx. 30–45
Max. surface temperature of instruments	°C	58
Weight		
Basic unit	kg	1.4
Scaler handpiece	g	approx. 56
Dimensions (W x H x D)		
Basic unit	cm	15.3 x 25.2 x 16
Scaler handpiece	cm	Ø 2.1 x 9.4
Battery for flexible foot switch		
Voltage	V	3
Type		Lithium CR2032
Ambient conditions during operation		
Temperature	°C	+10 to +40
Relative humidity	%	Max. 80
Air pressure	kPa	75 - 106

Ambient conditions during transport and storage		
Temperature	°C	-15 to +60
Relative humidity	%	Max. 95
Air pressure	kPa	75 - 106

Electromagnetic compatibility (EMC) Interference emission measurements	
Interference voltage at the power supply connection CISPR 11:2009+A1:2010	Compliant
Electromagnetic interference radiation CISPR 11:2009+A1:2010	Compliant
Emission of harmonics IEC 61000-3-2:2005+A1:2008+A2:2009	Compliant
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3:2013	Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements on the cover	
Immunity to electrostatic discharge IEC 61000-4-2:2008 8 CD, 2 kV AD, 4 kV AD, 8 kV AD, 15 kV AD, evaluation criterion: B	Compliant
Immunity to high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010 80 MHz... 2.7 GHz 3 V/m 80% AM, 1 kHz sine, evaluation criterion: A	Compliant
Immunity to near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010 Refer to the table with immunity to interference levels for near fields of wireless HF communication devices.	Compliant
Immunity to power frequency magnetic fields IEC 61000-4-8:2009 50 Hz, 30 A/m, in x-y-z-direction	Compliant

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

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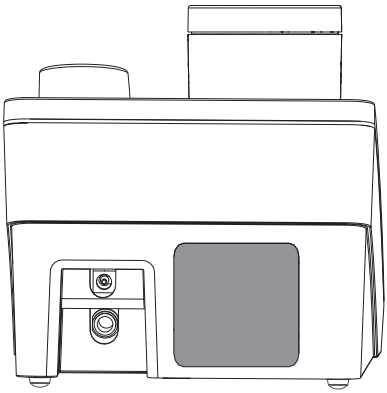
Electromagnetic compatibility (EMC) Interference immunity measurements on the supply input	
Immunity to conducted disturbances, induced by radio-frequency fields – AC mains voltage IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz	Compliant
Immunity to voltage dips, short interruptions and voltage variations IEC 61000-4-11:2004	Compliant

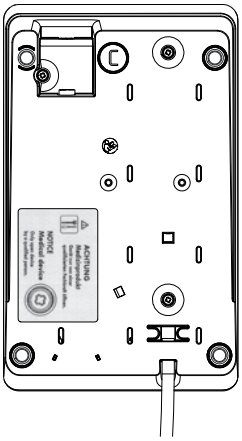
Immunity to interference table, near fields of wireless HF communication devices		
Radio service	**Frequency band MHz**	**Test level V/m**
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900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

4.1 Type plate

The type plate is located on the rear of the device.



The seal is located on the base of the device.



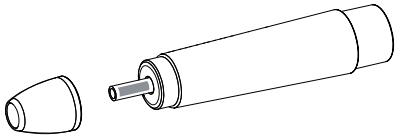
Incorrectly performed work can endanger the correct operation and safety of the device.

The seal must only be removed by a qualified expert.

The device must only be opened by a qualified expert.

4.2 Order number and serial number for the handpieces

The serial number SN of the handpieces is located in the area marked in grey.



4.3 ID number for tool kits

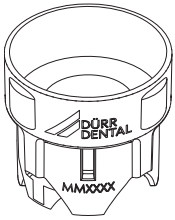
There is an ID number on the Scaler tool kits. The ID number serves to document the reprocessing.

These parts may no longer be used after a certain number of reprocessing cycles, or after the end of the service life.

The ID number is made up of the following marking: MMXXXX

MM	Date of manufacture: year and month
XXXX	Consecutive alphanumerical ID number

Scaler tool kit



4.4 Evaluation of conformity

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

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5 Operation

5.1 Handpiece

On the Scaler LED handpiece, the Vector basic unit generates a spatial vibration of the instrument tip (transverse to the instrument axis) with an amplitude of approx. 20–120 µm.
During treatment using the Scaler handpiece, fluid is applied as a constant stream. The amount of water that comes out can be adjusted via the operating panel.
6 LEDs are integrated into the front section of the handpiece. As soon as the flexible foot switch is switched on and "Power" is selected on the operating panel, the LEDs light up.
The LEDs go out approx. 4 seconds after the flexible foot switch is released.

5.2 Fluid container

The fluid level is monitored via a sensor. When the level drops to a minimum level, the LEDs in the area of the fluid container flash and a warning signal sounds (3x).

5.3 Instrument change

The instrument can be screwed in or out using the torque wrench integrated in the Scaler tool kit.

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Assembly

6 Requirements

The room chosen for installation must satisfy the following requirements:

– Closed, dry room
– Clean, level and sufficiently stable subsurface
– There should be no large interference fields present (e.g. strong magnetic fields) that could interfere with correct operation of the unit.
– The required ambient conditions are satisfied (refer to the "Technical Data").

7 Installation

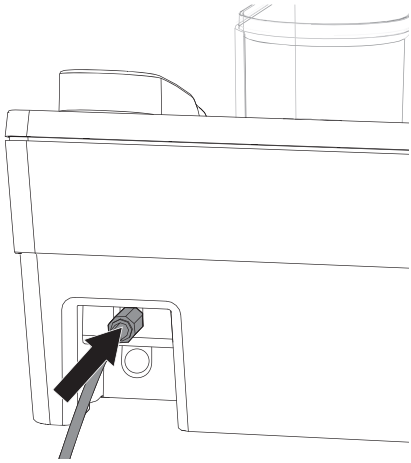
7.1 Establishing the electrical connections

The connection ports are located in the recess on the rear of the unit.

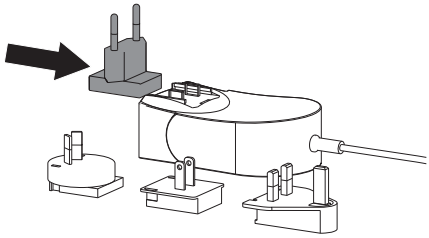
Requirements:

✓ Correctly installed power outlet in the vicinity of the unit (max. length of mains cable 3 m)
✓ The plug connection of the power supply is freely accessible so that it can be quickly disconnected in the event of danger.
✓ Mains voltage must match the information shown on the type plate of the power supply unit
✓ The supply voltage of the power supply unit matches the data on the type plate.

› Plug in the connecting plug of the connecting cable into the connecting socket of the unit.



› Fit the correct country-specific adapter.



› Plug the mains plug into the power outlet.

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7.2 Connecting the flexible foot switch

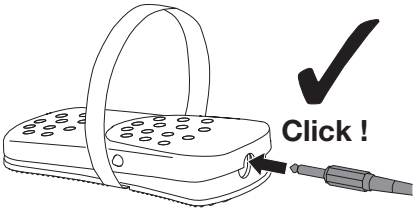
The flexible foot switch can be operated using a foot switch cable or wirelessly.

LED PEDAL flashes in orange after the unit is switched on:
- No cable connection between the unit and the foot switch.
- Pairing not performed for wireless operation.

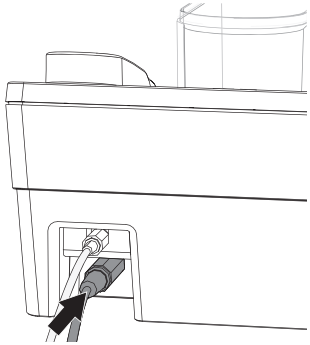
The LED will keep flashing until a cable connection is established or pairing is performed.

Operation with a cable

› Plug the connector of the foot switch cable into the connecting socket on the flexible foot switch.



› Plug the connector of the foot switch cable into the connecting socket on the unit.



Wireless operation

If the flexible foot switch is to be operated wirelessly, pairing (synchronization/coupling) of the flexible foot switch and the unit needs to be performed during initial start-up.

In order to avoid interference in wireless operation, we recommend that a maximum of 4 flexible foot switches is used wirelessly within a single surgery.

If interference does occur during wireless operation, we recommend using the flexible foot switch with foot switch cables.

Wireless operation is not possible if the foot switch cable is connected to either the unit or the flexible foot switch.

CAUTION

Risk of injury

Mixing up flexible foot switches can cause malfunctions such as the accidental operation of a different handpiece. This can cause injuries.

› If multiple devices are used simultaneously in wireless operation, make sure that the flexible foot switch that is paired with the relevant device is always used.

› Make sure they are stored together as well.

Performing pairing

✓ Place the flexible foot switch ready.

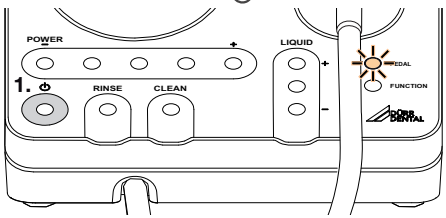
✓ Insert a battery in the flexible foot switch, "15.4 Inserting or changing the battery in the flexible foot switch".

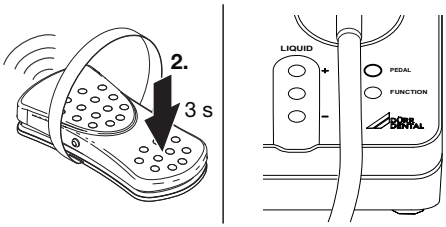
✓ Disconnect the foot pedal cable from the unit and foot switch (if previously connected).

Before carrying out the pairing process, make sure that no other Vector device with a flexible foot switch is running during the process within a range of around 10 m. Otherwise the connection may be established incorrectly.

Performing pairing between the flexible foot switch and the device:

› Switch on the device ⏻.





› LED PEDAL flashes in orange.

› Press the flexible foot switch for around 3 seconds until the orange PEDAL LED goes out.

Result:

After successful pairing the unit is immediately ready for operation.

If nothing happens when the flexible foot switch is operated, it is possible that the foot switch being used is paired with a different device. In this case cancel the pairing and repeat the process.

Cancelling a pairing

Requirements:

✓ No foot switch cable must be connected to the device or to the flexible foot switch.

✓ The orange PEDAL LED is not on or is not flashing.

› Switch off the device ⏻.

› Touch the LIQUID operating panel, keep touching it and switch on the device ⏻.

Result:

When the orange PEDAL LED flashes, this shows that the current pairing has now been cancelled.

8 Commissioning

8.1 Function check

To finish the initial start-up process, all of the connections must be checked to make sure they are securely seated and leak-tight.

Check for correct operation:

– Operating panel

– Flexible foot switch

– Visual and acoustic signals

8.2 Handover record

› Carry out and document the instruction and handover for the unit.

A sample handover report is included in the attachment.

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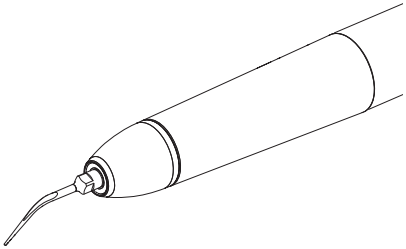
Usage

9 Components

9.1 Scaler handpiece

Overview

The Vector Scaler handpiece is suitable for the efficient removal of dental calculus and of concrement.

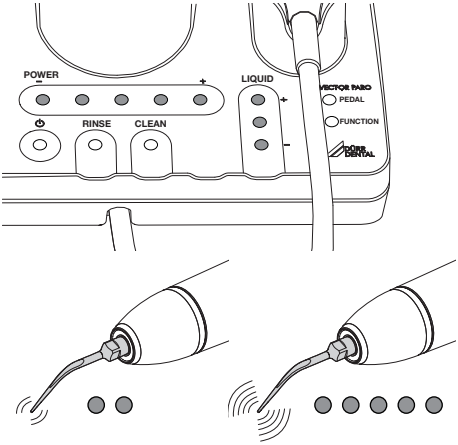


The cooling channel runs to a point just before the instrument tip. This offers the following advantages:

- Less water used, therefore less aerosol formation.
- Less contamination.
- Better clarity.
- Easier aspiration.
- Better cooling, as the fluid flows directly over the working tip.

During treatment using the Scaler handpiece, fluid is applied as a constant stream.

Settings



POWER

The power is adjusted in the POWER operating panel.

The Vector Scaler handpiece enables optimum adjustment of the ultrasonic power according to the medical indication in conjunction with the corresponding instrument.

The power can be adjusted between 5 settings on the Scaler handpiece, "POWER".

Operating frequency:

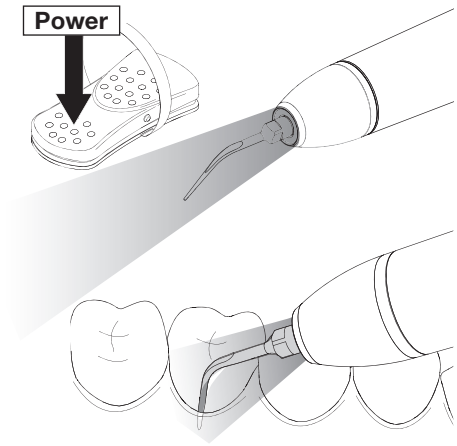
The operating frequency of the Scaler handpiece is in the range between 27–32 kHz (20–120 µm)

LIQUID

On the Scaler handpiece the water amount can be selected from 3 settings:

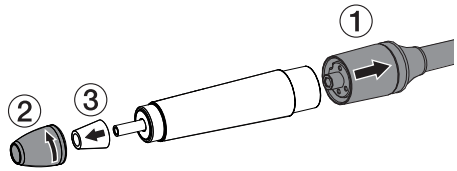
LED display	Water amount
1	30 ml/min
2	37–40 ml/min
3	45 ml/min

Illumination



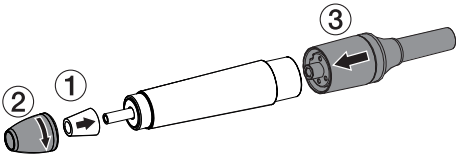
6 LEDs are integrated into the front section of the handpiece. The light conductor is located under the front cover. As soon as the flexible foot switch is operated and "Power" is selected on the operating panel, the LEDs light up. The LEDs go out approx. 4 seconds after the flexible foot switch is released.
The LEDs are actuated individually so that if one LED stops working the light source remains lit.

Disassembly



› Dismantle the instrument.
› Pull off the hose connection from the handpiece.
› Unscrew the front cover from the handpiece working anti-clockwise.
› Disconnect the light conductor.

Assembly



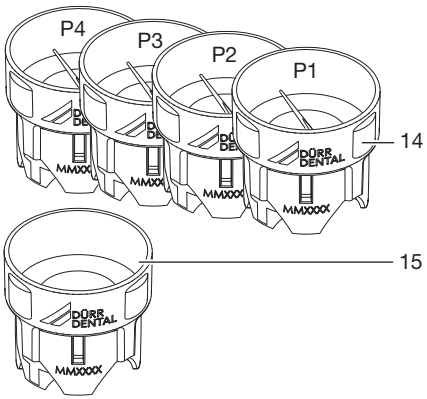
› Connect the light conductor.
› Screw the front cover onto the handpiece working clockwise.
› Connect the hose connection at the handpiece.

9.2 Instruments and tool kits

Overview

Instruments of various shapes, lengths and materials are available. These are grouped according to their different applications and arranged in the tool kits.

These instruments are specially designed for use with the Vector Scaler device. No other instruments must be used.



14 Scaler tool kit torque wrench with integrated PREMIUMLINE instrument
15 Torque wrench for all PREMIUMLINE instruments (P1 - P4)

The tool kits are designed for the storage, cleaning, disinfection and sterilisation of the instruments.
The use of metal instruments enables a higher application of energy.
Application areas:
– Periodontal initial treatment
– Removal of concrement and dental tartar

PREMIUMLINE instruments

Each instrument is contained in its own tool kit. The tool kit cover serves as a torque wrench for changing the instrument.

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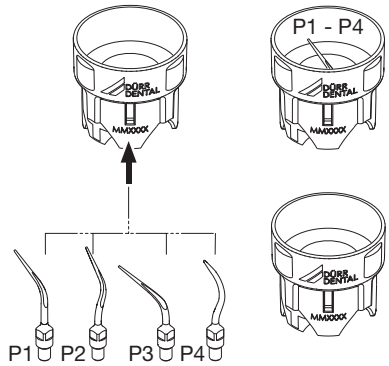
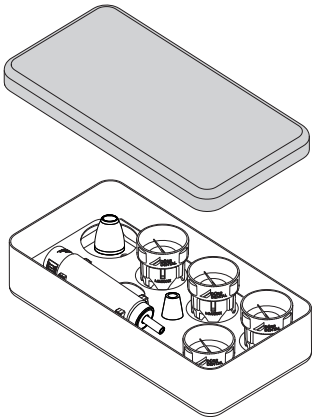


- **Scaler tool kit P1**
  30 µm, straight, for the removal of subgingival deposits with a pocket depth of up to 4 mm
- **Scaler tool kit P2**
  60 µm curved right, for the removal of subgingival deposits
- **Scaler tool kit P3**
  60 µm curved left, for the removal of subgingival deposits
- **Scaler tool kit P4**
  120 µm, for supragingival removal of coatings on smooth surfaces and for interdental areas

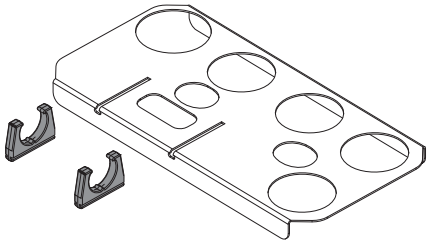
9.3 Steri-box

Scaler steri-box (cover: blue)



All parts which can be sterilised are optimally stored in the special Vector Scaler steri-box.
For steam sterilisation the steri-boxes are placed in the small steam steriliser, "13 Reprocessing".

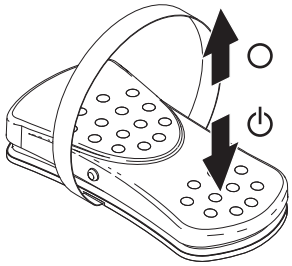
If sterile storage is required, wrap the steri-box in suitable sterilisation packaging in accordance with DIN11607-1 and seal.



The rubber clips on the carrier plate can be replaced if necessary.

9.4 Flexible foot switch

The handpieces are operated with the flexible foot switch.

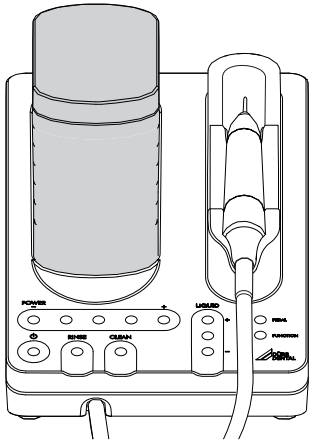


In wireless operation the flexible foot switch is supplied with voltage from a battery. If the battery power starts to fail, the orange PEDAL LED on the unit lights up.

Interference can occur in wireless operation if the battery power is low, so it is important to change the batteries in good time.

The service life of the battery is around 1 year or approx. 900 treatments.
If the battery is empty or not present then the flexible foot switch can be connected with a cable to the unit so that the treatment can be continued. The battery can then be inserted later on.
Changing the battery – "15.4 Inserting or changing the battery in the flexible foot switch".

9.5 Fluid container



The fluid container can hold up to approx. 600 ml of water or water-based fluids.

› The fluid container should be emptied and cleaned every evening and descaled as required, "12.3 Cleaning the fluid container".

The fluid container is not suitable for thermal disinfection or sterilisation.

Water quality

The water quality must meet the general requirements for water supply systems in a dental surgery and all applicable standards.

Watery active ingredients

In order to widen the range of possible treatments, additional active ingredients can be added to the water.
Possible active ingredients include e.g. chlorhexidine digluconate solutions up to a total concentration of 0.2 %; other solutions may damage the system and can lead to unsuccessful treatment.

› After using a water-based active ingredient the unit should be thoroughly rinsed using warm water.

9.6 Cleaning components

Vector/RinsEndo Disinfection

Ready-to-use aldehyde-free solutions for fast action disinfection and cleaning of Vector hose systems. The undiluted solution is poured into the fluid container. These measure must be carried out before breaks in treatment of more than 24 hours, "12.2 Activating the cleaning process of the device".

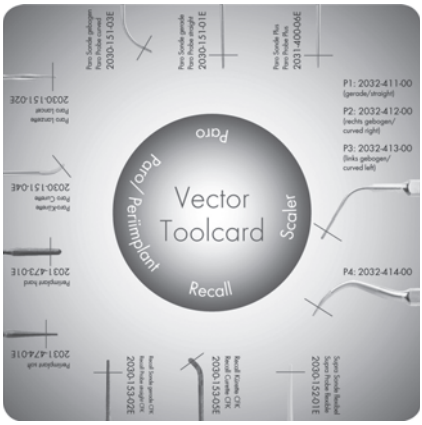
Vector cleaner

Ready-to-use solution for the removal of acid-soluble deposits in the hose system and in the handpieces of the Vector system. Special cleaner with intensive cleaning effect and very good material compatibility.

9.7 Vector toolcard

Instrument wear

The instruments are subject to wear which will depend on their material,
the surfaces being treated and length of time in use.



All instruments must be regularly checked with the Vector toolcard in order to check the degree of wear, "15.2 Checking instrument wear".

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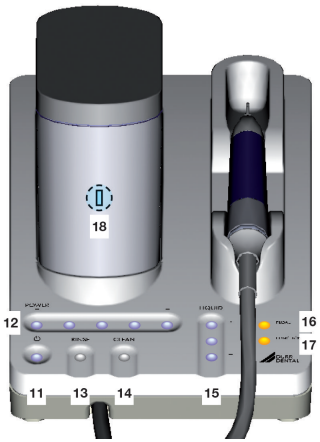
10 Operation

10.1 Display/handling

Scaler handpiece inserted:
POWER and LIQUID adjustment possible
No handpiece inserted:
The settings cannot be changed.
The LEDs are only active and light up when a handpiece is inserted.
The last settings set up for the handpiece that is inserted remain active after the unit is switched off and back on again.
Any running cleaning or rinsing processes can be stopped by touching the corresponding button again.



○ LED off

● LED on

☼ LED flashing

11	**ON / Standby**
⏻	For switching on or off; touch the button for at least 2 seconds.
○	Standby, unit switched off.
●	ON, unit switched on. If no function is used for a period of 30 minutes, the unit will automatically switch off (standby).

12	**POWER** (power setting)
●	1 – 5 LEDs light up depending on the power setting selected (5 LEDs = maximum power) **Tip:** The power setting can also be adjusted during treatment.
13	**RINSE** (rinsing/disinfecting)
☼	To start the rinsing process: touch the button for at least 2 seconds. The blue LED flashes during the rinsing process.
14	**CLEAN**
●	After approx. 30 operating hours the blue LED will light up continuously – this shows that it is time for cleaning.
☼	To start the cleaning process: touch the button for at least 2 seconds. The blue LED flashes during the cleaning process. **Recommendation:** Clean the unit every four weeks or, at the latest, as soon as the LED lights up continuously.
15	**LIQUID** This display is only active when the Scaler handpiece is inserted.
●	1 LED on = minimum fluid consumption (30 ml/minute) 3 LEDs on = maximum fluid consumption (45 ml/minute)
16	**PEDAL** (flexible foot switch)
●	LED on: low battery power – change the battery of the flexible foot switch.
☼	LED flashing: no flexible foot switch connected (cable operation) or assigned (wireless operation).
17	**FUNCTION**
●	LED lights up: The operation has been interrupted. Clean the instrument chuck with the air and water syringe and dry it, then continue the treatment.

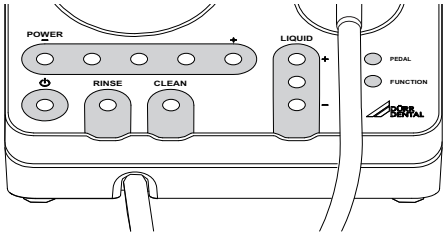
	LED flashing: the vibration behaviour of the instrument is impaired. – Contact pressure of the instrument is too high during treatment – reduce the contact pressure. – Check the instrument for signs of wear or bending.
18	**LED in the fluid container**
	LED on: normal operation, fluid container filled enough.
	LED flashing: Fluid level low. If the minimum fluid level is reached, the LED of the fluid container will start to flash and an acoustic warning signal will sound (3x high-pitched sound).

Acoustic signals

Audible signals	Trigger/situation
Clicking noise	– Touching of the operating panel – Function activated, e.g. RINSE, CLEAN
Long, low audible signal	– Function cannot be performed
Warning signal, 3x high-pitched audible signal	– Fluid level at minimum – Waiting for fluid during the cleaning process

10.2 Adjustment options

Operating panel



Settings on operating panel
The settings are changed by touching but without applying pressure.

The LEDs for POWER and LIQUID are only active and light up when a handpiece is inserted.
If no handpiece is inserted, the settings for POWER and LIQUID cannot be adjusted.

ON/Standby
The unit can be switched on or into standby mode via the operating panel ⏻ON / Standby. The unit is equipped with an automatic standby mode in order to save electricity. When the unit is left unused for 30 minutes it switches off automatically.

POWER
The power is adjusted from 1 to 5; the settings are displayed via the 5 LEDs:

LED display	Power in %
1	20
2	40
3	60
4	80
5	100

The power is set to level 5 as the default factory setting on delivery.
The adjustable operating frequency for the Scaler handpiece is 20 - 120 µm

LIQUID
The water amount can be selected from 3 settings and is displayed via 3 LEDs:

LED display	Water amount in ml/min
1	approx. 30
2	approx. 37-40
3	approx. 45

RINSE
After every treatment the system must be rinsed with water.
The rinsing process is started by touching the RINSE button; it ends automatically after approx. 30 seconds.
If a rinsing process is running it can be interrupted at any time by touching the RINSE button.

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CLEAN

The cleaning process lasts around 10 minutes. During this step *Vector cleaner* cleaning fluid is pumped through the lines, whereby these are is cleaned of any deposits.
Cleaning can be started whenever required.
Once the process is started it runs automatically until the program is finished.
We recommend that cleaning is performed every 4 weeks.
After an operating time of approx. 30 hours the blue LED on the operating panel lights up to show that cleaning needs to be performed.
The blue LED goes out when the cleaning process is completely finished.
If the cleaning process is not properly completed, the blue LED will light up every time the unit is switched on.

PEDAL (flexible foot switch)

Operating the flexible foot switch will activate the handpiece.
If the orange LED lights up, the battery power must be checked, "15.4 Inserting or changing the battery in the flexible foot switch".
If the orange LED flashes then no flexible foot switch is connected or paired.

FUNCTION

If the orange LED lights up, the contact pressure of the instrument is too high or the handpiece needs to be checked.

10.3 Preparing the device for treatment

Switch on the unit.

WARNING

Risk of cross contamination

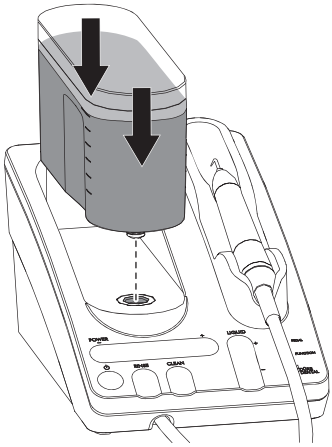
- All parts must be reprocessed before every treatment.
- If there has been no treatment for more than 24 hours then the complete fluid system must be disinfected.

› Switch on the unit.

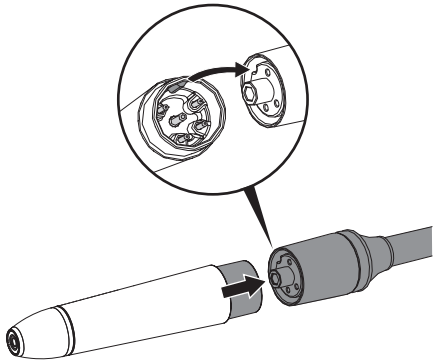
Result:
Blue LED is on – unit is ready for operation.

Inserting the fluid container

› Check whether the fluid container is full. If necessary top up the fluid container to the upper marking with lukewarm water (approx. 30 °C).
› Insert the fluid container vertically in the correct position into the unit and press downwards until you feel it lock into position.



Attach Scaler handpiece



› Attach the Scaler handpiece to the hose connection.

Inserting/changing instruments

CAUTION

If an attempt is made to perform a treatment with a damaged or worn instrument, this can cause injury and may result in an unsuccessful treatment.

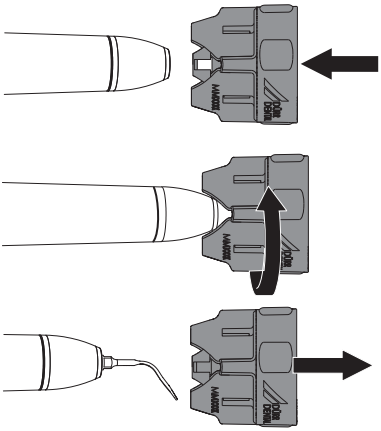
› Worn or bent instruments should be replaced immediately and not reused!

The tool kit cover of the instrument is used as a torque wrench for tightening the union nut of the instrument chuck.

› Select a suitable instrument for the corresponding treatment.

To prevent the instrument from being overtightened, the torque wrench slips when the required torque is reached. No ratcheting sound can be heard.

› Always use the torque wrench to screw the instrument on and off.
When screwing the instrument on, slowly turn the torque wrench approx. a quarter turn beyond the resistance point.



EN

11 Treatment

11.1 Preparation

Perform the following steps before every treatment:

› Make sure that only handpieces and instruments are used that have been reprocessed since the last treatment.
› Check that the instrument is correctly seated and in perfect condition, "Inserting/changing instruments".
› Check the fill level of the fluid container.
› Adjust the power on the operating panel as required, "POWER".

CAUTION

Health risks for the patient due to contraindications

› Before using the unit on the patient, check that none of the contraindications listed exist.

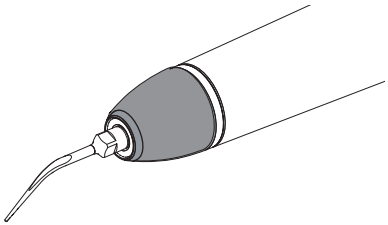
11.2 Treatment with a Scaler handpiece

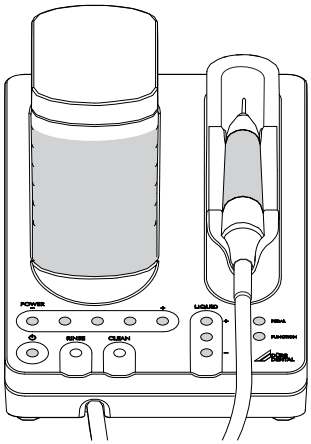
CAUTION

Risk of injury due to burns

During operation some of the components inside the handpiece heat up. Contact with hot parts can cause burns.

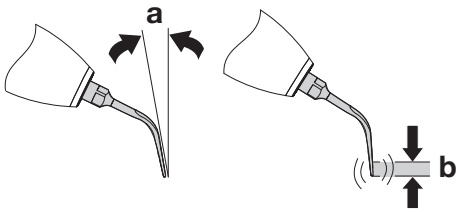
› Only operate the Scaler handpiece with the cover fitted and intact.





During treatment using the Scaler handpiece, fluid is applied as a constant stream.

11.3 Use of the Scaler instruments



a Contact angle approx. 10°
b Working area 2 mm

The active working area of the instrument is in the area of the front 2 mm.
Thanks to the minimal pain generation, treatment with the Vector Scaler can also be carried out on acute, painful parodontopathies.

WARNING

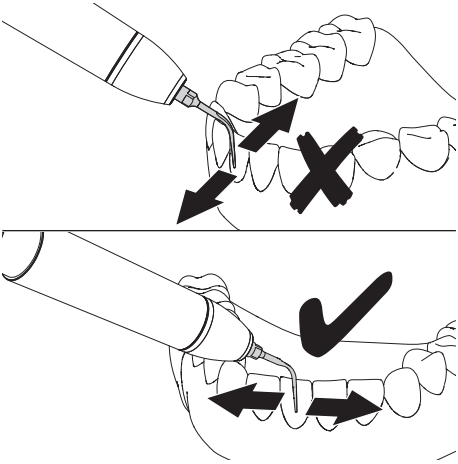
Risk of infection due to lack of aerosol suction

Breathing in aerosol or already removed soiling.

› Use suitable spray mist suction.
› For use only by trained personnel.

› Activate the handpiece by operating the flexible foot switch.

› Hold the instrument at an angle of approx. 10° against the tooth and work away from the tooth.



› Keep the instrument constantly in motion: in the longitudinal direction of the tooth or transversely across the approximal surface lingually or buccally away from the tooth.
› Guide the instrument with minimal pressure in such a way that the movements of the tip are always parallel to the tooth surface.
› Make sure that only the side surfaces of the instruments are used. Never use the front or rear surface of the instruments.
› Perform effective and targeted suction to provide good visibility of the field of treatment.

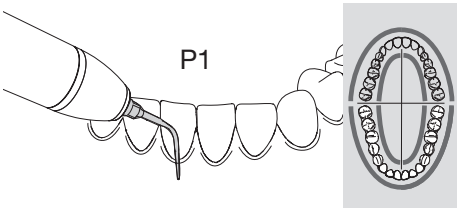
Application areas

CAUTION
Risk of injury

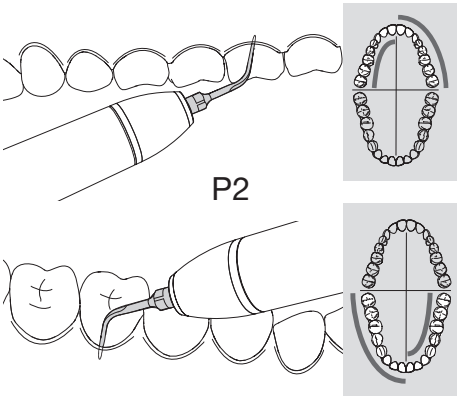
Accidental activation or uncontrolled activities of the handpiece can cause injuries.

› Insert the handpiece in the handpiece holder when it is not in use.
› Dismantle the instrument or push on the torque wrench.

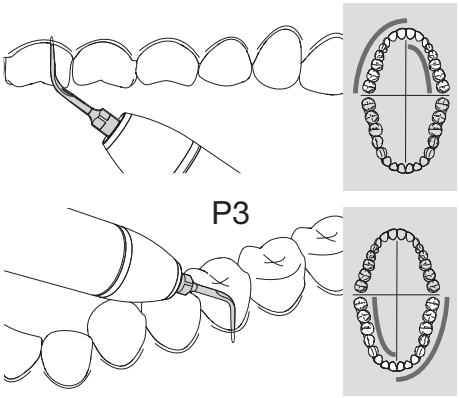
– **Scaler instrument P1**, 30 µm, straight, for the removal of subgingival deposits in deep gingival pockets (up to 4 mm).
POWER
2 LEDs: 40 % operating performance



– **Scaler instrument P2**, 60 µm, curved right, for the removal of subgingival deposits
POWER
2–4 LEDs: 40 % - 80 % operating performance



– **Scaler instrument P3**, 60 µm, curved left, for the removal of subgingival deposits
POWER
2–4 LEDs: 40 % - 80 % operating performance



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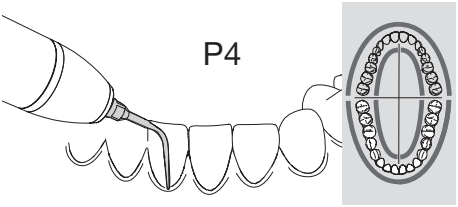
– **Scaler instrument P4**, 120 µm, for the removal of supragingival coatings on smooth surfaces and for interdental areas.
POWER
2–3 LEDs: 40 % - 60 % operating performance



11.4 After every treatment

End of treatment

› Dismantle the instrument with the tool kit cover.
› After every treatment, all parts used must be cleaned, disinfected and, if necessary, sterilised, "13 Reprocessing".

12 Cleaning

12.1 Cleaning of the outside surfaces

All outside surfaces must be cleaned and disinfected if they are contaminated or soiled.
– Surface of the device
– Handpiece hose
– Fluid container
– Tool kit for Scaler without instruments

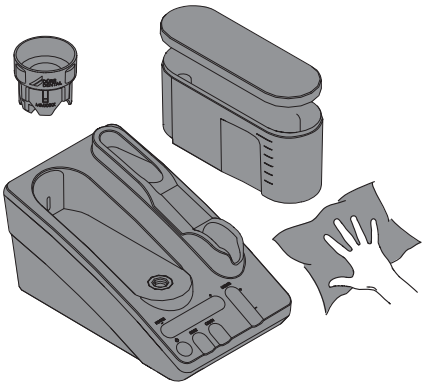
As the surface disinfectant, we recommend using a disinfectant that is compatible with the materials and meets the general dental hygiene standards, e.g.:
– Dürr Dental FD 322 rapid surface disinfectant
– Dürr Dental FD 350 disinfection wipes
– Dürr Dental FD 366 sensitive rapid surface disinfectant

NOTICE

Liquid can cause damage to the unit.

› Do not spray the unit with cleaning and disinfectant agents.
› Make sure that liquid does not get inside the unit.

› For pre-cleaning, remove coarse organic soiling with a paper towel.
› Clean the surfaces with a moist, soft, lint-free cloth.



12.2 Activating the cleaning process of the device

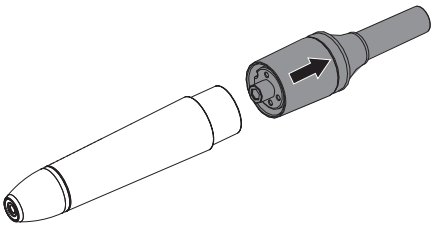
We recommend that cleaning is performed every 4 weeks. The cleaning process can be started at any time as required.

After approx. 30 operating the CLEAN LED will light up on the operating panel to show that cleaning is required.
A cleaning cycle comprises two steps that need to be started one after the other:
✓ CLEAN
✓ RINSE (rinsing/disinfecting)

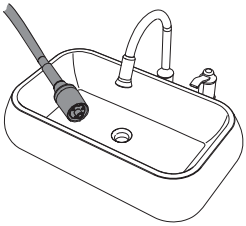
The cleaning process is not finished until both steps have been successfully performed one after the other.

CLEAN:

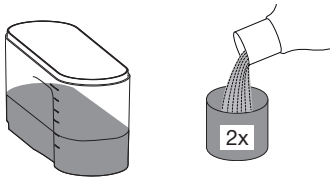
› Pull off the hose connection from the handpiece.



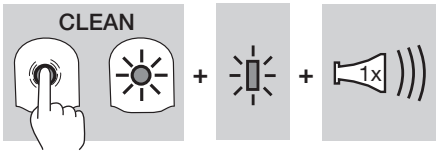
› Place the handpiece hose in a sink or in a suitable container.



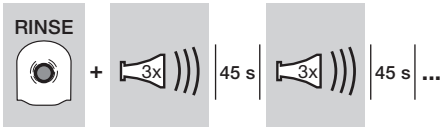
› Pour 2 sealing caps (approx. 40 ml) of ***Vector cleaner*** undiluted into the empty fluid container.



› Touch the CLEAN button for at least 2 seconds.



LED CLEAN and the LED in the fluid container flash and a clicking sound is heard.
The device is cleaned for approx. 10 minutes with ***Vector cleaner*** until the fluid container is empty. The process ends automatically.
LED RINSE lights up and a cyclically repeating warning signal sounds as an indication that the device must be rinsed with water after the cleaning with ***Vector cleaner***.



LED CLEAN and the LED in the fluid container flash and a clicking sound is heard.
The device is cleaned for approx. 10 minutes with ***Vector cleaner*** until the fluid container is empty. The process ends automatically.
LED RINSE lights up and a cyclically repeating warning signal sounds as an indication that the device must be rinsed with water after the cleaning with ***Vector cleaner***.

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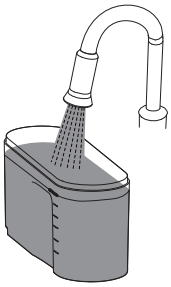
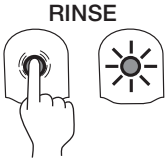
RINSE (rinsing/disinfecting):

As a result of the rinsing with water the special cleaner ***Vector cleaner*** is removed from the system. Any residue of the cleaning agent could cause irritation in the patient.

› Top up the fluid container to the upper marking with water.



› Touch the RINSE (rinsing/disinfecting) button for at least 2 seconds.
LED RINSE flashes.



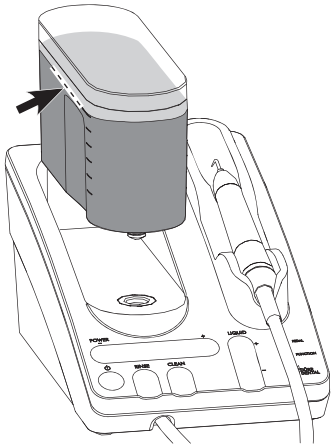
The device is rinsed with water for 30 seconds. The process ends automatically.
After the end of the complete cleaning process (CLEAN + RINSE) the CLEAN LED goes out again and an acoustic signal sounds (3x high-pitched audible signal).
If the cleaning process is not performed in full or it is stopped prematurely, then the blue CLEAN LED will come on every time the device is switched on.

12.3 Cleaning the fluid container

The fluid container should regularly cleaned and descaled.
How soon descaling is required depends primarily on the hardness of the water used. However, at the latest descaling must be performed when first signs of limescale become apparent.

Cleaning:

› Fill up the fluid container to the upper marking with cleaning solution.



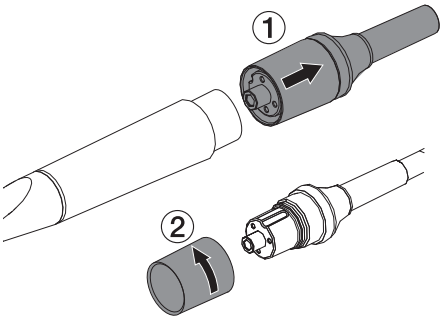
› Allow the cleaning agent to soak as directed in the manufacturer's information.
› Completely empty the fluid container.
› Thoroughly rinse the fluid container with water and dry.

Descaling:

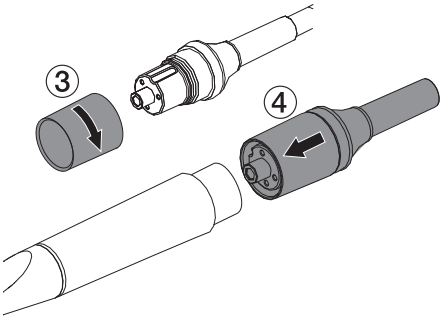
› Fill up the fluid container to the upper marking with e.g. 10% citric acid solution.
› Allow the descaler to soak in; follow the manufacturer's instructions if necessary.
› Completely empty the fluid container.
› Thoroughly rinse the fluid container with water and dry.

12.4 Cleaning the sleeve part and adapter of the handpiece hose

› Pull off the handpiece hose from the handpiece.
› Unscrew and remove the sleeve part.



› Clean the sleeve part and the adapter of the handpiece hose with a hygienic, soft brush and a moist, lint-free cloth.
› Screw sleeve back in place.
› Push the handpiece hose onto the handpiece.



EN

13 Reprocessing

13.1 Risk analysis and categorisation

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

13.2 Preparation process in accordance with ISO 17664

Carry out the procedure for reprocessing after every treatment in accordance with the preparation process set out in ISO 17664.

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

The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.
Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially influenced by the amount of wear and tear or damage resulting from its use.

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

The reprocessing method was validated as follows:

- **Pre-cleaning**
  - FD 350 Disinfection wipes (Dürr Dental)
  - Cleaning brush
- **Manual cleaning**
  - ID 215 Enzymatic instrument cleaner (Dürr Dental)
  - Cleaning brush
- **Manual disinfection**
  - ID 213 Instrument disinfection (Dürr Dental)
- **Automatic cleaning and disinfection** was performed in accordance with EN ISO 15883 with tested efficacy.
  - Cleaning agent: Neodisher MediClean Forte
  - Washer-disinfector: PG 8535 (Miele)
  - Programmes: "Cleaning without neutralisation" and "THERMAL DES"
  - Rinsing adapter: Miele 68551101 D
  - Cleaning brush
- **Steam sterilisation** was performed in accordance with EN ISO 17665 using the fractionated vacuum procedure.
  - Pre-vacuum: 3 x
  - Sterilisation temperature: 132°C
  - Sterilisation time: 2 minutes (half-cycle)
  - Drying time: min. 20 minutes
- **Cleaning brush**
  Cleaning brush with nylon hairs, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 25 and 35 mm
  - Brush length: 5 and 10 mm

  Example: Interlock cleaning brush double-sided green REF 09098

General information

NOTICE

Equipment damage due to unsuitable products

Oils and care products containing oil will damage the device.

› The handpiece must not be maintained with oil or with a care system that contains oil.

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

› Comply with the specifications (see "13.6 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying in ultrasonic bath" and "13.7 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying") when selecting the cleaning and disinfectant agents to be used.

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

› Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.

› Only use disinfectants that are aldehyde-free and display material compatibility with the product.

› Do not use any rinse aid (danger of toxic residue on the components).

› Only use freshly-produced solutions.

› Only use distilled or deionised water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. legionella bacteria).

› Use clean, dry, oil and particle-free compressed air.

› Do not exceed temperatures of 138 °C.

› Subject all devices used (ultrasonic bath, cleaning and disinfection device (CD), sealing device, steam steriliser) to regular maintenance and inspections.

EN

13.3 Preparation at the operating location

Wear protective gloves.

Wear protective goggles.

Use a mask.

Use protective clothing.

WARNING

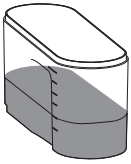
Risk of infection from contaminated products

Danger of cross contamination

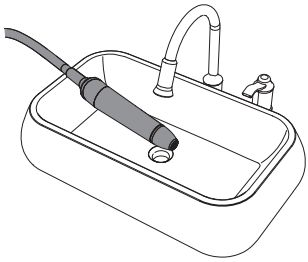
› Reprocess the product correctly and promptly before its first use and after every subsequent use.

Rinsing the handpiece with water

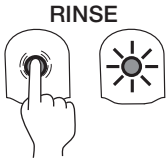
› Fill the fluid container to approx. 1/3 with water.



› Place the handpiece in a sink or in a suitable container.



› Start the rinsing process:
Press the RINSE button for at least 2 seconds.

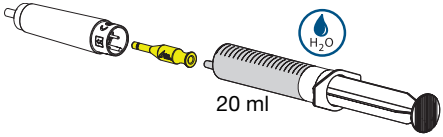


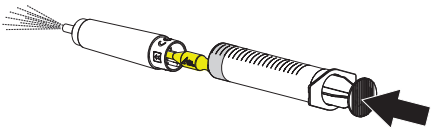
› The LED flashes – the rinsing process takes around 30 seconds and ends automatically.

Pre-cleaning

Do pre-cleaning of handpiece and accessories no more than 15 minutes after the unit has been used.

› Clean the exterior surfaces completely with two cleaning cloths. Make sure that the surfaces are sufficiently moistened.
› Note the action time of the cleaning agent.
› Perform the procedure twice.
› Draw 3 x 20 ml cold water (temperature < 20 °C) into a conventional sterile 20-ml disposable pipette with Luer connection and rinse the inner lumen of the handpiece.





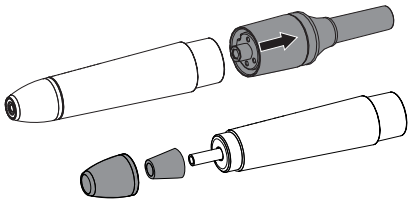
Transport

› Protect the device from contamination when you transport it from the treatment chair to the reprocessing location.

13.4 Dismantling the handpiece

› Unscrew the instrument, "Inserting/changing instruments".
› Take off the removable parts of the handpiece, "Disassembly".

› Check the Scaler handpiece light conductor for its light transmission, replace if necessary.



13.5 Manual cleaning, intermediate rinsing, disinfection, final rinsing, drying in the cleaning and disinfection bath

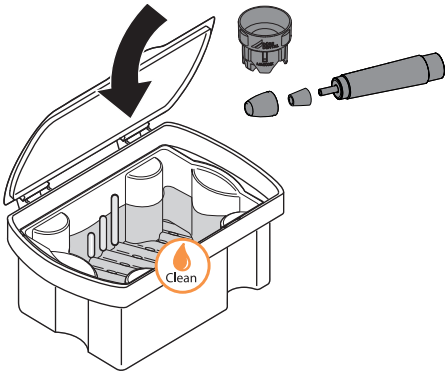
A disinfectant or combined cleaning and disinfectant agent is required for manual disinfection. It must have the following properties:

– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)

For further information, see: "General information".

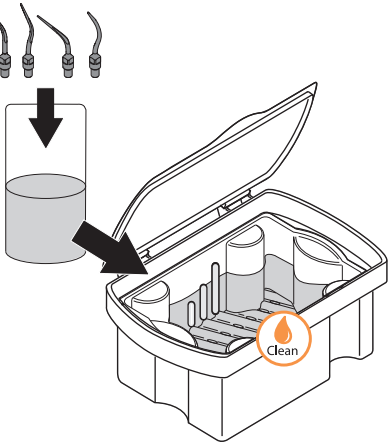
Cleaning

› Place the removable parts of the handpiece (Scaler cover, light conductor), instrument holders of the tool kits (without instruments) and the disassembled handpiece in the cleaning bath for the required reaction time, so that all parts are covered.

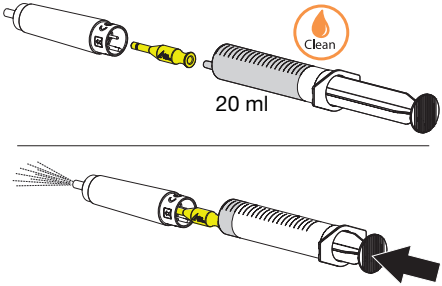


› Clean all accessible external surfaces and internal surfaces below the surface for 5 minutes with a hygienic cleaning brush until all visible soiling has been removed.

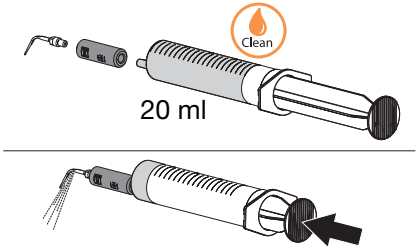
› Place instruments in small parts baskets into the cleaning bath.



› Rinse handpiece through at least 3 times using a 20-ml disposable syringe.



› Screw Scaler instruments onto the rinsing adapter one after another and rinse through each of the instruments at least 3 times using a 20-ml disposable syringe.



› Remove all rinse adapters.

› Comply with the cleaning agents' action times specified by the manufacturer.

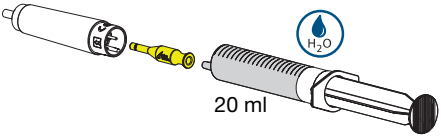
EN

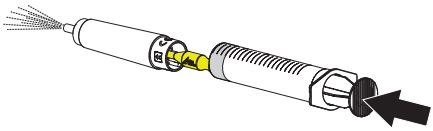
Intermediate rinsing

After the action time prescribed by the manufacturer:

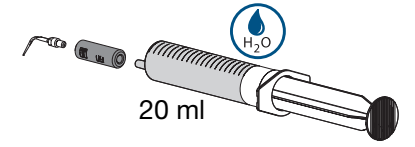
› Rinse all components under running water for at least 1 minute (temperature < 20 °C).

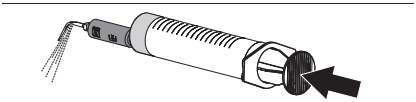
› Rinse handpiece through at least 3 times using a 20-ml disposable syringe.





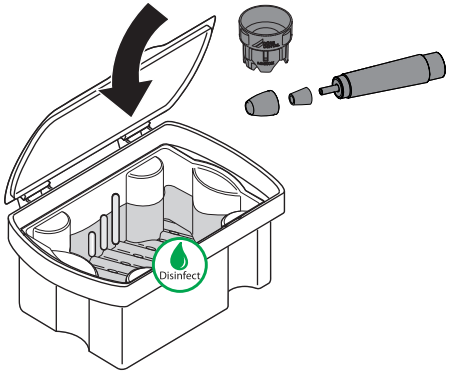
› Screw scaler instruments onto the rinsing adapter one after another and rinse through each of the instruments at least 3 times with water using a 20-ml disposable pipette.





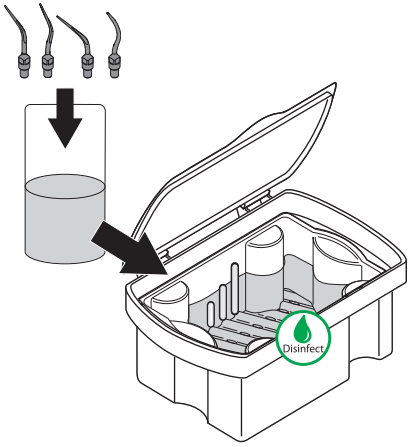
Disinfection

› Place the removable parts of the handpiece (Scaler cover, light conductor), instrument holders of the tool kits (without instruments) and the disassembled handpiece in the cleaning bath for the required reaction time, so that all parts are covered.

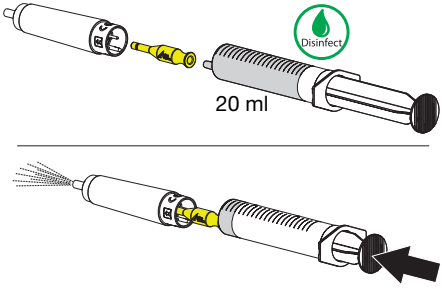


› Clean all accessible external surfaces and internal surfaces below the surface for 5 minutes with a hygienic cleaning brush until all visible soiling has been removed.

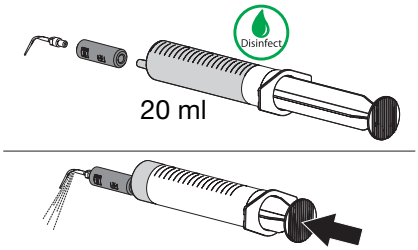
› Place instruments in small parts baskets into the cleaning bath.



› Rinse handpiece through at least 3 times using a 20-ml disposable syringe.



› Screw Scaler instruments onto the rinsing adapter one after another and rinse through each of the instruments at least 3 times using a 20-ml disposable syringe.



› Remove all rinse adapters.

› Comply with the cleaning agents' action times specified by the manufacturer.

Final rinse

After the action time prescribed by the manufacturer:

› Rinse all components under running water for at least 1 minute (temperature < 20 °C).

Drying

› If necessary, re-dry at a clean location using a hygienic, lint-free cloth.

› Blow dry the components with compressed air in a clean location.

13.6 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying in ultrasonic bath

A combined cleaning and disinfectant agent is required for manual cleaning and disinfection. It must have the following properties:

– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)

– without chlorine, without solvent, no strong alkaline solutions (pH > 11), no strong oxidising agents

For further information, see: "General information".

Cleaning in an ultrasonic bath

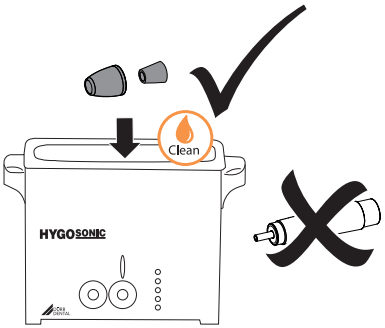
NOTICE

Malfunctions in the handpiece due to improper handling during cleaning or disinfecting

› The handpieces of the Vector must only be cleaned or disinfected in a suitable container in an ultrasonic bath.

› The handpieces must NOT be fully submerged in fluid.

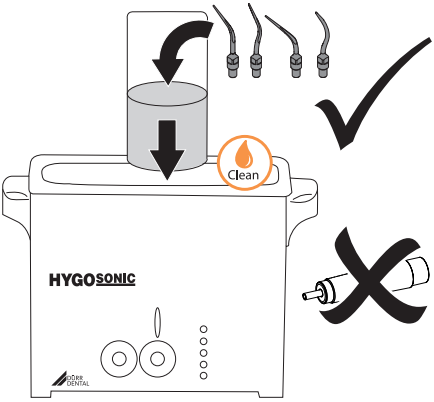
› Place the removable parts of the handpiece (Scaler cover, light conductor), tool kit Scaler (without instruments) in the ultrasonic bath for the required reaction time, so that all parts are covered.



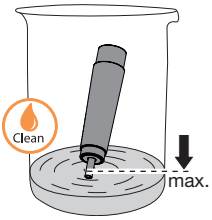
› Clean all accessible external surfaces and internal surfaces below the surface for 5 minutes with a sterile cleaning brush until all visible contaminants have been removed.

EN

› Place instruments in small parts baskets into the ultrasonic bath.

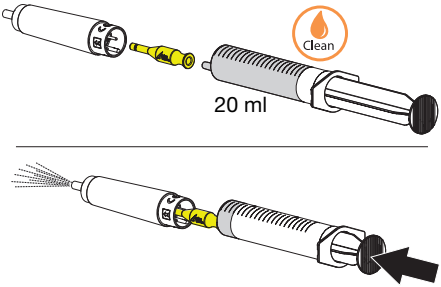


› Place the handpiece without covers in a container with fluid. The drive mechanism of the handpiece must not lie in the fluid (malfunction). Therefore observe instructions concerning maximum fluid level for the Scaler handpiece.



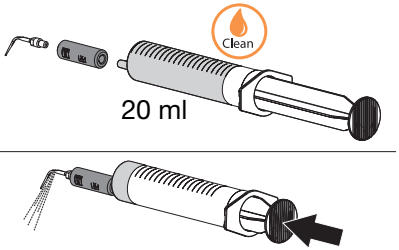
› Place container with the handpieces in the ultrasonic bath with a suitable carrier.

› Rinse handpieces through at least 3 times using a 20-ml disposable pipette.



› Remove all rinse adapters.

› Screw Scaler instruments onto the rinsing adapter one after another and rinse through each of the instruments at least 3 times using a 20-ml disposable syringe.



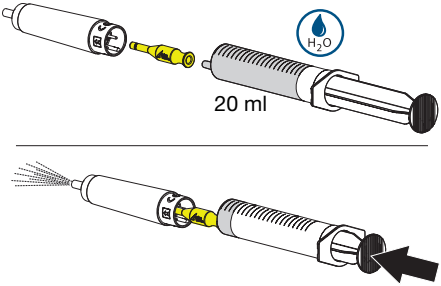
› Comply with the cleaning agents' action times specified by the manufacturer.

Intermediate rinsing

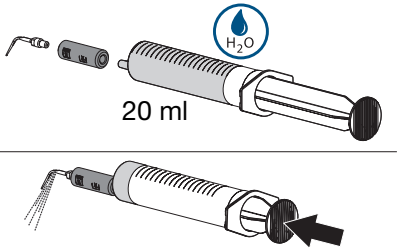
After the action time prescribed by the manufacturer:

› Rinse all components under running water for at least 1 minute (temperature < 20 °C).

› Rinse handpiece through at least 3 times using a 20-ml disposable syringe.



› Screw scaler instruments onto the rinsing adapter one after another and rinse through each of the instruments at least 3 times with water using a 20-ml disposable pipette.



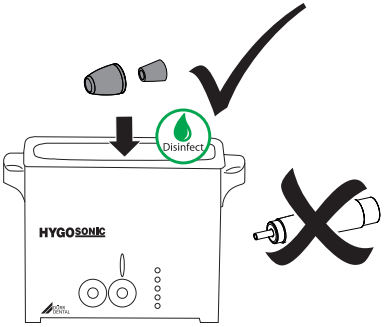
Disinfection in an ultrasonic bath

NOTICE

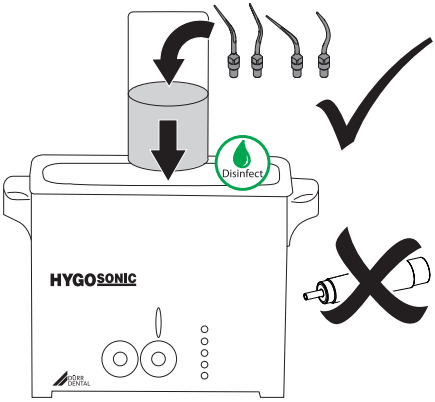
Malfunctions in the handpiece due to improper handling during cleaning or disinfecting

- The handpieces of the Vector must only be cleaned or disinfected in a suitable container in an ultrasonic bath.
- The handpieces must NOT be fully submerged in fluid.

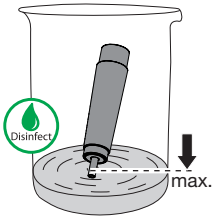
- Place the removable parts of the handpiece (Scaler cover, light conductor), tool kit Scaler (without instruments) in the ultrasonic bath for the required reaction time, so that all parts are covered.



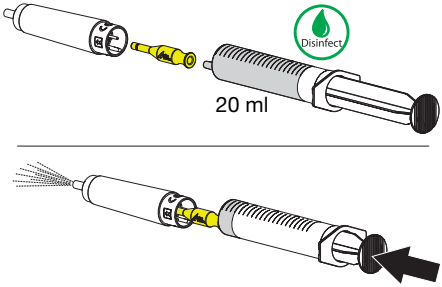
- Clean all accessible external surfaces and internal surfaces below the surface for 5 minutes with a sterile cleaning brush until all visible contaminants have been removed.
- Place instruments in small parts baskets into the ultrasonic bath.



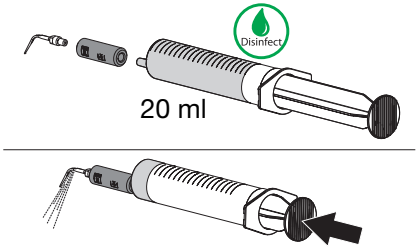
- Place the handpiece without covers in a container with fluid. The drive mechanism of the handpiece must not lie in the fluid (malfunction). Therefore observe instructions concerning maximum fluid level for the Scaler handpiece.



- Place container with the handpieces in the ultrasonic bath with a suitable carrier.
- Rinse handpieces through at least 3 times using a 20-ml disposable pipette.



- Remove all rinse adapters.
- Screw Scaler instruments onto the rinsing adapter one after another and rinse through each of the instruments at least 3 times using a 20-ml disposable syringe.



- Comply with the cleaning agents' action times specified by the manufacturer.

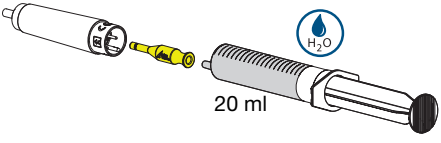
Final rinse

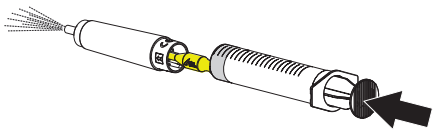
After the action time prescribed by the manufacturer:

- Rinse all components under running water for at least 1 minute (temperature < 20 °C).

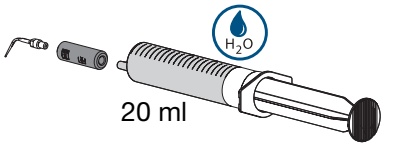
EN

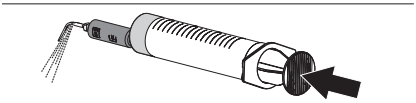
› Rinse handpiece through at least 3 times using a 20-ml disposable syringe.





› Screw scaler instruments onto the rinsing adapter one after another and rinse through each of the instruments at least 3 times with water using a 20-ml disposable pipette.





Drying

› If necessary, re-dry at a clean location using a hygienic, lint-free cloth.

› Blow dry the components with compressed air in a clean location.

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

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:

– Corresponds to and tested in accordance with ISO 15883
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 93°C)
– Programme is suitable for the components and provides sufficient rinsing cycles.
For more information: "General information".

Selection of the machine cleaning agents and disinfectants

The following properties are required:

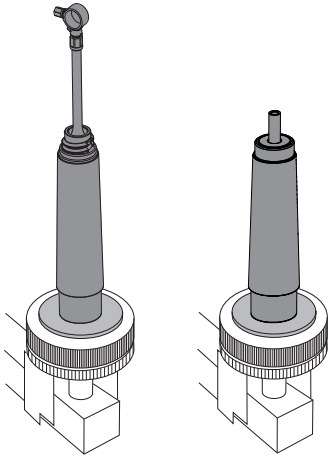
– Material compatibility with the product
– Corresponds with the manufacturer's specifications of the CD

For further information, see: "General information".

Automatic cleaning and disinfecting

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

› Attach the handpiece to the special mountings for transmission instruments (e.g. Miele: ADS 2 (for AUF1 and AUF2), ∅ approx. 16 mm, item no. 68751401D or MELAG universal adapter for MELAtherm 10, item no. 73904) in the washer-disinfector.



› Attach the scaler instruments to the special mountings for instruments (e.g. Miele: A 814, item no. 68681400D or MELAG tip adapter for MELAtherm 10, item no. 80760) in the washer-disinfector.

› Place Paro instruments in the instrument tray and place in the basket for small parts.

› Fix removable parts of the handpiece (ring cover, rotary adaptor, scaler cover, light conductor), instrument holders of the tool kits (without instruments) and torque wrench with a suitable washer-disinfector holder.

13.8 Check for function

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

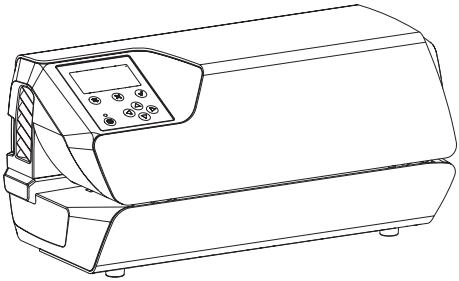
13.9 Packing

WARNING

Endangering the sterilisation success

The fitted components are not reached by the steam and as such are not sterilised.

› Do not fit the components before packaging.



For packaging of the components, use only sterile barrier systems made of transparent paper film that are approved for use in steam sterilisation according to the manufacturer information. This includes:
– Temperature resistance up to 138°C
– Standards ISO 11607-1/2
– Applicable parts of the series of standards EN 868

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

13.10 Steam sterilising

WARNING

Health risk due to incorrect sterilisation

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

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

NOTICE

Damage to equipment due to incorrect sterilisation

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

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

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

Perform the following steps:
› Sterilise the parts for sterilisation(at least 20 minutes at 121°C, at least 4 minutes at 270°F or at least 5 minutes at 134°C).
Do not exceed 138°C.

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

EN

13.11 Issue clearance for the parts for sterilisation

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

› Document the clearance of the medical product after reprocessing.

13.12 Storing parts for sterilisation

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

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

14 Treatment breaks for more than 24 hours

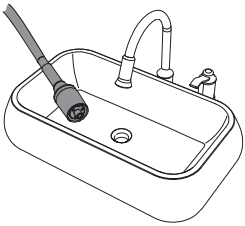
If no treatment is carried out for a period of 24 hours or more, reprocessing of the hose system must be performed.

14.1 Cleaning and disinfecting the hose system

The hose system is disinfected using a ready-to-use, aldehyde-free solution of *Vector/RinsEndo Disinfection*.

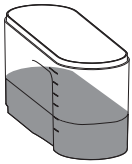
› Pull off the hose connection from the handpiece.

› Lay the handpiece hose in the sink.

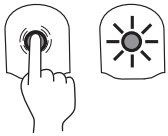


Rinsing with water:

› Fill the fluid container to approx. 1/3 with water.



› Touch the RINSE (rinsing/disinfecting) button for at least 2 seconds.



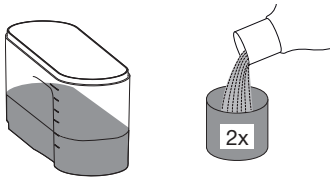
› LED flashes – the rinsing process takes around 30 seconds and ends automatically.

› Rinsing with water will flush out any remaining blockage.

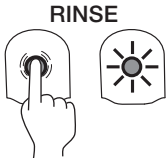
› After the end of the rinsing process drain any remaining fluid in the system.

Disinfect using Vector/RinsEndo Disinfection:

› Pour 2 sealing caps (approx. 40 ml) of ***Vector/RinsEndo disinfection*** into the fluid container.



› Touch the RINSE (rinsing/disinfecting) button for at least 2 seconds.



› LED flashes – the ***Vector/RinsEndo Disinfection*** is rinsed into the system and the process ends automatically. The ***Vector/RinsEndo Disinfection*** remains in the system until the next treatment.

› Empty any remaining ***Vector/RinsEndo Disinfection*** from the fluid container.

› Thoroughly rinse the fluid container with water and dry.

14.2 Initial start-up after a break in treatment for more than 24 hours

The initial start-up process will depend upon whether the hose system was reprocessed before the break in treatment. Proceed as follows depending on the situation:

1. Reprocessing performed before the treatment break:

› Rinse the system with water.

Thorough rinsing with water will flush out any disinfectant remaining in the hoses, and any irritation to the patient caused by the taste of residual disinfectant will be avoided.

› Pull off the hose connection from the handpiece.

› Lay the handpiece hose in the sink.

› Fill the fluid container with water.

› Touch the RINSE (rinsing/disinfecting) button for at least 2 seconds.
LED flashes – the rinsing process takes around 30 seconds and ends automatically.

2. Decontamination process was not carried out before surgery break:

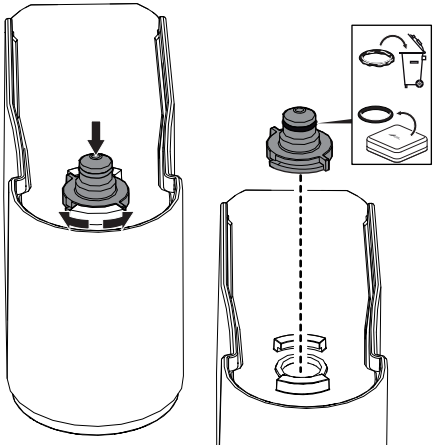
› Perform reprocessing before initial start-up of the unit, "13 Reprocessing".

EN

15 Maintenance

15.1 Changing the valve in the fluid container

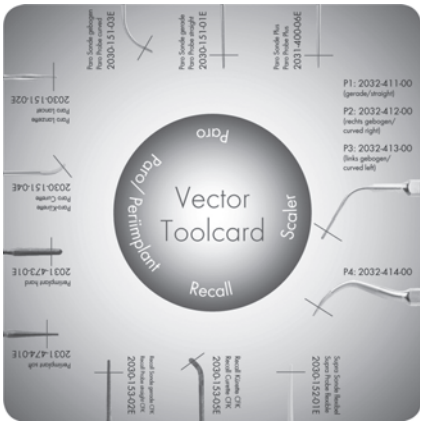
The valve on the underside of the fluid container must be cleaned regularly and checked for blockages and leaks.



› Press the valve lightly against the fluid container and unscrew it anti-clockwise.
› Clean the valve.
If cleaning is not possible, e.g. if the filter in the valve is blocked, then the valve needs to be replaced.
› Check the O-ring.
In the event of leaks, loose seating or visible damage the O-ring must be replaced.
› Insert the valve in the holder and tighten it clockwise as far as it will go.

15.2 Checking instrument wear

Instrument wear can be checked using the Vector toolcard:



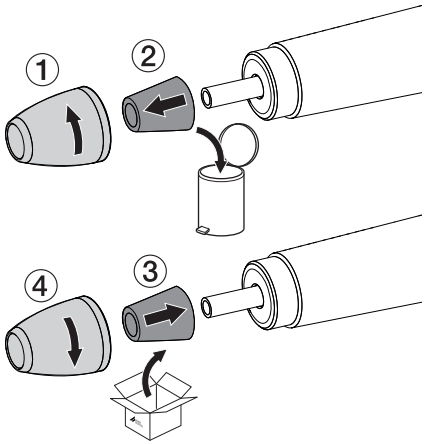
– Place the handpiece against the toolcard. If the instrument tip extends beyond the red marking then the instrument can still be used.
– If the instrument tip just reaches the red marking then the instrument shows signs of wear but can still be used.
– If the instrument tip does not reach the red marking then the instrument must be replaced.

15.3 Replacing the light conductor in the Scaler handpiece

The light conductor must be checked regularly for light transmission. Over the course of time it becomes opaque or takes on a milky colour. This impairs its ability to function and means that it needs to be replaced.

The light conductor can be sterilised several times. As soon as it starts to become opaque or take on a milky colour, light transmission begins to decrease.

› Unscrew the cover.
› Disconnect the light conductor.
› Connect a new light conductor.
› Screw on the cover.



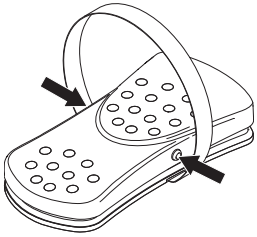
15.4 Inserting or changing the battery in the flexible foot switch

A new battery should be inserted in the flexible foot switch prior to initial start-up in wireless operation or if the power of the existing battery is low.

EN

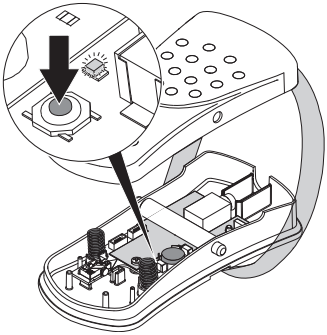
Opening the cover:

› Press both pins on the flexible foot switch together at the same time and lift the cover off.



Checking the battery:

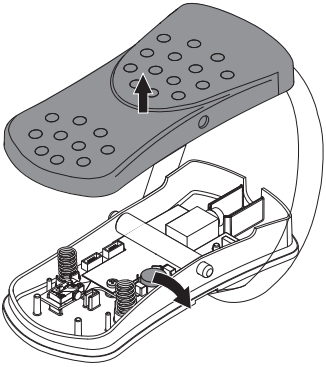
› Press the button to the left of the battery. Green LED lights up: battery power is OK. Green LED does not light up: change the battery.



Taking out the battery:

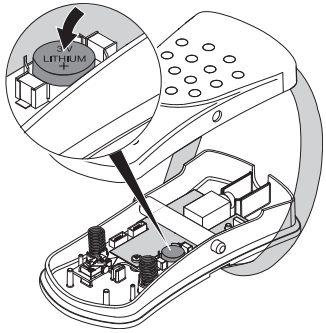
The old battery must be properly disposed of in accordance with applicable national and regional guidelines for environmentally friendly disposal. Do not throw batteries away with domestic waste.

› Take out the battery from the holder and dispose of it in an environmentally friendly way.



Inserting the battery:

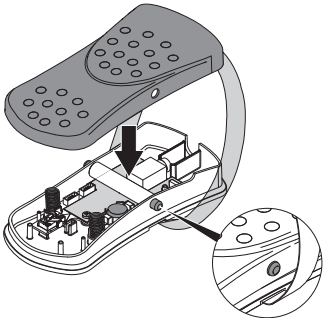
› Insert the battery in the holder. Make sure that the battery is inserted with the correct polarity.



Closing the cover:

› Make sure that the two pedal return springs are present and correctly positioned. If they are not, the function of the unit may be impaired.

› Fit the cover in such a way that the two pins on the side of the flexible foot switch snap into the holes in the cover.



Troubleshooting

16 Tips for operators and service technicians

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

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

Error	Possible cause	Remedy
Device does not start	Unit is not switched on.	› Touch the On / Standby button for at least 2 seconds.
	The flexible foot switch cable is not connected.	› Connect the flexible foot switch cable.
	The flexible foot switch is defective.	› Replace the flexible foot switch and send in the defective flexible foot switch for repairs.
	Handpiece is defective.	› Replace the handpiece and send in the defective handpiece for repairs.
Unit runs with interruptions in wireless operation or wireless operation with the flexible foot switch is not possible.	The battery in the flexible foot switch is empty.	› Check battery performance and insert a new battery if necessary.
	Interference caused by external wireless signals.	› Operate the flexible foot switch using the foot switch cable.
	The wireless module in the flexible foot switch is defective.	› Operate the flexible foot switch using the foot switch cable or call a Service Technician.
	The wireless module in the basic unit is defective.	› Operate the flexible foot switch using the foot switch cable or call a Service Technician.
	Pairing of the flexible foot switch has not been performed.	› Before using it for the first time, pairing (i.e. synchronisation/coupling) must be performed between the flexible foot switch and the unit.
Operating the flexible foot switch does not activate the handpiece.	Unit is not switched on.	› Switch on the unit.
	The connector of the flexible foot switch cable is not plugged in correctly.	› Plug in the connector correctly.
	The flexible foot switch cable is defective.	› Replace the foot switch cable.

Error	Possible cause	Remedy
Pulsed application of fluid is not clean, or fluid drips out afterwards	Grey rubber seal is missing or defective.	› Mount a new rubber seal.
	Fluid container is empty.	› Fill the fluid container.
	The O-ring on the valve of the fluid container is not leak-tight.	› Replace the O-ring or the valve of the fluid container.
	Overall system is not correctly bled.	› Fill the fluid container with water. › Touch the RINSE (rinsing/ disinfecting) button for at least 2 seconds.
	Hose coupling of one of the pumps has become loose.	› Call a Service Technician.
Fluid leaks between handpiece and handpiece hose during operation	Handpiece is not correctly attached to the handpiece hose.	› Correctly attach the handpiece to the handpiece hose.
	Sealing screw in handpiece hose leaks.	› Pull off the handpiece from the handpiece hose. › Replacing the sealing screw.
Fluid leaks out between Scaler handpiece and instrument.	Scaler instrument was not screwed on with the full torque.	› Screw on the Scaler instrument correctly.
	Scaler instrument has become loose.	› Screw the Scaler instrument in place correctly. › If there are signs of wear, replace the instrument.
Fluid leaks between handpiece and handpiece hose during operation.	Air in the fluid system.	› Fill the container with water. › Touch the FLUID button for at least 2 seconds.
Fluid leaks from the underside of the basic unit.	Hose connections within the unit have become loose or are defective.	› Call a Service Technician.
Handpiece cannot be attached to the handpiece hose.	The O-ring of the sealing screw has dried out or is defective.	› Grease the O-ring and replace the sealing screw if required (replacement part in the service kit).
	Contact pins are bent.	› Send in the handpiece.
	Water connector is bent.	› Send in the handpiece.

Error	Possible cause	Remedy
Orange "FUNCTION" LED lights up or flashes	The treatment was interrupted as water may be present in the following areas: between the handpiece and the handpiece hose.	› Clean the affected areas and dry using the air and water syringe.
	Instrument contact pressure too high during treatment.	› Reduce the contact pressure and press the flexible foot switch, the LED will go out. › If necessary, the instrument might require spraying and drying using the air and water syringe.
	Instrument defective.	› Replace the instrument.
	Handpiece defective	› Replace the handpiece. Send in the defective handpiece for repairs.
Orange "PEDAL" LED lights up	The power of the battery in the flexible foot switch is low.	› Check battery performance and insert a new battery if necessary.
Orange "PEDAL" LED flashes,	No flexible foot switch connected (cable operation) or paired (wireless operation).	› Connect a flexible foot switch (cable operation) or perform pairing (wireless operation).
Blue "CLEAN" LED continues to light up after a cleaning program has been carried out.	The CLEAN function of the cleaning process was not fully completed, or it was stopped early.	› Carry out the cleaning process CLEAN in full.
The blue "POWER" and "LIQUID" LEDs fail to light up after the unit is switched on.	Handpiece is not recognised by the basic unit.	› Attach a different handpiece in position. If the "POWER" and "LIQUID" continue to fail to light up, call a Service Technician.
	Handpiece is defective.	› Attach a different handpiece in position. If the "POWER" and "LIQUID" continue to fail to light up, call a Service Technician.
The illumination in the Scaler handpiece becomes increasingly dimmer.	The light conductor has become opaque or has become milky.	› Replace the light conductor.
	Illumination LEDs are defective.	› Send in the defective Scaler handpiece for repairs.

EN

Appendix

17 Handover record

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

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

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

Notes:

Name of person receiving instruction:	Signature:

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

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

Hersteller/Manufacturer:

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