VistaCam iX

EN

Installation and operating instructions

CE

9000-618-176/30

DÜRR DENTAL

1812V009

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.

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible risks of personal injury or material damage.
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.


Wear protective gloves.


CE labelling


Application part type B


Comply with the Operating Instructions.


Refer to the accompanying electronic documents.


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


Do not reuse

REF Order number

SN Serial number

1.2 Copyright information

All circuits, processes, names, software programs and units mentioned in this document are protected by copyright.
The Installation and Operating Instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from Dürr Dental.

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2 Safety

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

2.1 Intended purpose

The intraoral camera generates an optical image of the oral cavity or face of the patient.

Intraoral camera with Cam interchangeable head

The intraoral camera with Cam interchangeable head is used in or next to the oral cavity of the patient. The images aid with diagnosis, provide information for the patient and are used for instruction.

Macro Interchangeable head:

The intraoral camera with Macro interchangeable head is used in the oral cavity of the patient. The images aid with diagnosis, provide information for the patient and are used for instruction.

Intraoral camera with Proof interchangeable head

The intraoral camera with Proof interchangeable head is intended to assist with the detection and diagnosis of caries.

Intraoral camera with Proxi interchangeable head

The intraoral camera with Proxi interchangeable head enables the detection of approximal caries based on the translucence of healthy tooth enamel to light waves in the infrared range.

2.2 Intended use

The camera handpiece can be used in combination with a variety of interchangeable heads. This enables different applications in healthcare facilities, dental practices, dental clinics, orthodontic surgery, and oral and maxillofacial surgery.
With the aid of a computer, monitor and imaging software, this digital system can be used to create and store images and videos. The following accessories must always be used: a spacer (not for the Cam interchangeable head) and hygienic protective covers.

2.3 Improper use

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.
Do not operate the device in any rooms in containing flammable mixtures, e.g. in operating theatres.
Do not use the camera directly on the eye.

2.4 Indication

Intraoral camera with Cam interchangeable head

The images aid diagnosis, patient communication and patient instruction, and are used for instruction and documentation purposes.

Intraoral camera with Proof interchangeable head

The intraoral camera with Proof interchangeable head is intended to assist with the detection and diagnosis of caries.

Intraoral camera with Proxi interchangeable head

The intraoral camera with Proxi interchangeable head is a diagnostic aid for recognition of approximal caries above the gingiva and for monitoring of the progress of this type of lesions.

2.5 Contraindication

Intraoral camera with Proof interchangeable head

Large-scale tooth restorations can falsify the displayed caries value.

Intraoral camera with Proxi interchangeable head

The Proxi head is not designed for use on artificial teeth, teeth with crowns or teeth with excessively large fillings. The device only works together with natural enamel in the mouth of the patient. After extraction, teeth can no longer be analysed with the Proxi head.

2.6 General safety information

› Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.

- Check the function and condition of the unit prior to every use.
- Do not convert or modify the unit.
- Comply with the specifications of the Installation and Operating Instructions.
- The Installation and Operating Instructions must be accessible to all operators of the unit at all times.

2.7 Combining devices safely

Take care when connecting units together or to parts of other systems as there is always an element of risk (e.g. due to leakage currents).

- Only connect units when there can be no question of danger to operator or to patient.
- Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings.
- If it is not 100% clear from the unit data sheet that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the manufacturer) to verify that the setup is safe.
- Observe the specifications of IEC 60601-1 (EN 60601-1) when connecting the appliance with other appliances, e.g. a PC system, both in and outside the patient environment.
- Only connect peripheral units (e.g. computer, monitor, printer) that conform at least to the requirements set out in IEC 60950-1 (EN 60950-1).

A copy of the system manufacturer's declaration in accordance with Article 12 of Directive 93/42/EEC can be found in our download section at www.duerrdental.com (document no. 9000-461-264).

2.8 Qualified personnel

Operation

Operating personnel are dentists and dental personnel.

They must ensure safe and appropriate handling on the basis of their training and know-how.

- 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.

2.9 Electrical safety

- Comply with all the relevant electrical safety regulations when working on the unit.
- Never touch the patient and open connectors/contacts of the appliance at the same time.
- Replace any damaged cables or plugs immediately.

Observe the EMC rules concerning medical devices

- Electro-magnetic interference or ESD impulses can cause image artefacts in the images or unit malfunction. Restart the appliance, the software or the computer if necessary.
- The appliance is designed for the use in health care establishments (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:

USB connection cable for
VistaCam iX (2.5 m) 2108-150-50

USB connection cable (2.5 m) with
12-V mains adapter 2108-150-52

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NOTICE

Negative effects on the EMC due to non-authorised accessories

› Use only Dürr Dental parts or accessories specifically approved by Dürr Dental.
› If other accessories are used, note any negative consequences to the function of the unit.

2.10 Only use original parts

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

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

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

2.11 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.

2.12 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.

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Product description

3 Overview

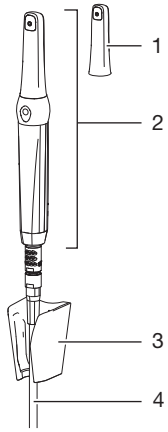

Fig. 1: VistaCam iX

1 interchangeable head
2 Handpiece with interchangeable head
3 Handpiece holder
4 USB connecting cable (to computer)

3.1 Scope of delivery

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

VistaCam iX with Cam + Proof package 2108-01

– Handpiece
– Cam interchangeable head
– Proof interchangeable head
– Storage box
– Handpiece holder
– USB connection cable (2.5 m)
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD
– Hygienic protective covers (20 pieces)
– Proof spacers (5x)
– Quick start instructions

VistaCam iX with Cam package 2108-02

– Handpiece
– Cam interchangeable head
– Handpiece holder
– USB connection cable (2.5 m)
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD
– Hygienic protective covers (20 pieces)
– Quick start instructions

VistaCam iX with Cam, Proof and Proxi package 2108-05

– Handpiece
– Cam interchangeable head
– Proof interchangeable head
– Proxi interchangeable head
– Storage box
– Handpiece holder
– USB connection cable (2.5 m)
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD
– Hygienic protective covers (20 pieces)
– Proxi disposable protective covers (20x)
– Proof spacers (5x)
– Proxi spacers (3x)
– Quick start instructions

VistaCam iX with Cam and Proxi package 2108-06

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- Handpiece
- Cam interchangeable head
- Proxi interchangeable head
- Handpiece holder
- USB connection cable (2.5 m)
- VistaSoft imaging software DVD
- DBSWIN imaging software DVD
- Hygienic protective covers (20 pieces)
- Proxi disposable protective covers (20x)
- Proxi spacers (3x)
- Quick start instructions

3.2 Accessories

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

Cam interchangeable head 2108-130-50
Proof interchangeable head 2108-130-51
Macro Interchangeable head: 2108-130-54
Proxi interchangeable head 2108-130-56
Handpiece holder for VistaCam iX HD 2108-105-50
USB connection cable for VistaCam iX (2.5 m) 2108-150-50
Storage box for interchangeable heads 2108-135-50
Disposable protective covers for VistaCam iX for Cam, Macro and Proof interchangeable heads (500x) 2108-010-50
Disposable protective covers for VistaCam iX for Cam, Macro and Proof interchangeable heads (100x) 2108010052
Disposable protective covers for VistaCam iX for Proxi interchangeable heads (500x) .2108-010-60
Disposable protective covers for VistaCam iX for Proxi interchangeable heads (100x) .2108010053
Spacer for VistaCam iX for Cam and Proof interchangeable heads (5x) 2108-132-50
Spacer for VistaCam iX for Proxi interchangeable heads (3x) . . 2108-132-52

3.3 Optional accessories

The following optional articles can be used with the unit:

Foot switch control set for PC-USB 2100-770-09
Cable-operated foot switch USB . . 2100-770-17
USB repeater 4.8 m 2106-155-63
USB connection cable (2.5 m) with 12-V mains adapter 2108-150-52

3.4 Consumables

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

Disposable protective covers for VistaCam iX for Cam, Macro and Proof interchangeable heads (500x) 2108-010-50
Disposable protective covers for VistaCam iX for Cam, Macro and Proof interchangeable heads (100x) 2108010052
Disposable protective covers for VistaCam iX for Proxi interchangeable heads (500x) .2108-010-60
Disposable protective covers for VistaCam iX for Proxi interchangeable heads (100x) .2108010053
FD multi wipes compact Surface disinfection CDF33FW0150
FD 333 forte wipes Quick-acting disinfection CDF33FW0150
FD 322 premium wipes Quick-acting disinfection CDF322A0140
ID 215 Enzymatic instrument cleaner CDI215A6150
ID 213 Instrument disinfection CDI213C6150
Cleaning set for VistaCam optical element 2101-025-50
Cleaning set for VistaCam optical element without cleaner 2109025050

3.5 Wear parts and replacement parts

The following wear parts must be replaced at regular intervals:

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

4 Technical data

4.1 Handpiece

Electrical data	
Voltage	5 - 12 V DC
Signal output	USB 2.0
Type of protection	IP20
Protection class	Applied part Type B
Operating mode*	T1/T2 = 27% 1.5 min / 5.5 min (switch-on/switch-off time)

* At an ambient temperature of max. 40 °C and while observing the switch-on/off time, the handpiece/the interchangeable head reaches a maximum surface temperature of 60 °C.

Classification	
Medical Devices Directive (93/42/EU)	Class I

Electromagnetic compatibility (EMC) Interference emission measurements	
High-frequency emissions in accordance with CISPR 11	Group 1 Class B
Harmonics in acc. with IEC 61000-3-2	Not applicable
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	Not applicable

Electromagnetic compatibility (EMC) Interference immunity tests	
Static electricity discharge in accordance with IEC 61000-4-2	Compliant
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	Compliant

Electromagnetic compatibility (EMC) Interference immunity tests	
Emitted HF disturbance variables in accordance with IEC 61000-4-3	Compliant

Camera electronics	
Image sensor	1/4" Colour Interline Transfer CCD
Number of image points sensor	470000
Effective image points (PC) YUV	704 x 576
Brightness control	Automatic
White balance	Permanently set

Dimensions and weights Handpiece with Cam interchangeable head		
Length	mm	190
Diameter	mm	26
Weight with cable	g	175
Weight without cable	g	50
Cable length	cm	250

4.2 Cam interchangeable head

Technical data		
Illumination	8 LEDs, white light	
Sharpness level	mm	12
Depth of field	mm	5 - 40
Opening angle		68°
Protection class		Applied part Type B

4.3 Macro Interchangeable head:

Technical data		
Illumination	8 LEDs, white light	
Sharpness level	mm	3
Depth of field	mm	2
Opening angle		56°
Protection class		Applied part Type B

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4.4 Proof interchangeable head

Technical data		
Illumination		4 LEDs
Wavelength	nm	405
Sharpness level	mm	12
Opening angle		68°
Protection class		Applied part Type B

4.5 Proxi interchangeable head

Proxi interchangeable head		
Light source		2 LEDs
Wavelength	nm	850
Sharpness level	mm	7
Protection class		Applied part Type B

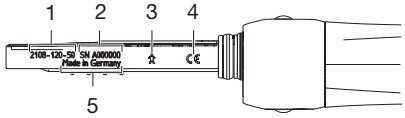
4.6 Ambient conditions

Ambient conditions during operation		
Temperature	°C	10 to 40
Relative humidity	%	20 to max. 75
Air pressure	hPa	700 - 1060

Ambient conditions during storage and transport		
Temperature	°C	-15 to +60
Relative humidity	%	max. 90
Air pressure	hPa	700 - 1060

4.7 Type plate

There is a laser inscription on the handpiece.



1 Order number
2 Serial number
3 Applied part Type B
4 CE labelling
5 Country of origin

4.8 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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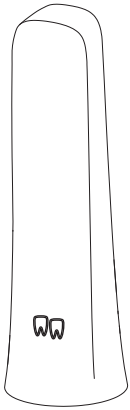
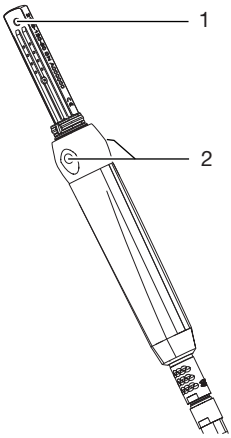
5 Operation

VistaCam iX is an intraoral camera system and consists of a handpiece and various interchangeable heads. The function of the camera depends on the function of the interchangeable head. The interchangeable head is recognisable from the symbol on the rear.



Cam interchangeable head	Intraoral images
Macro Interchangeable head:	Intraoral close-ups
Proof interchangeable head	Intraoral images for the detection of caries, plaque and calculus
Proxi interchangeable head	Intraoral images for the diagnostics of caries in the proximal region



1 Image sensor
2 Exposure switch with two points

If you click on a point of the capture ring, the VistaCam iX changes between Live mode (moving image) and Freeze mode (stationary image). The pressure point of the capture ring is tangible. The camera vibrates slightly when the mode changes. Optionally, the camera can also be operated by a foot switch.

The image sensor in the handpiece digitises the image. The camera transmits the image to a computer via the USB connection cable.

The optics and the illumination are in the interchangeable head. The optics focusing range is fixed.

The power supply of the camera to the computer is realised via the USB connection cable.

The camera switches off automatically if it is not moved for 2 minutes. As soon as the camera is moved, it switches on again.

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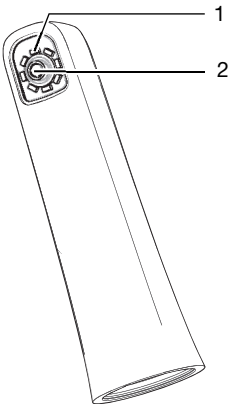
5.1 Cam interchangeable head



1 LED
2 Fixed-focus optical element

The Cam interchangeable head has a fixed-focus optical element with a focus range that enables intraoral imaging.
Eight LEDs are arranged around the optical element to ensure uniform illumination.

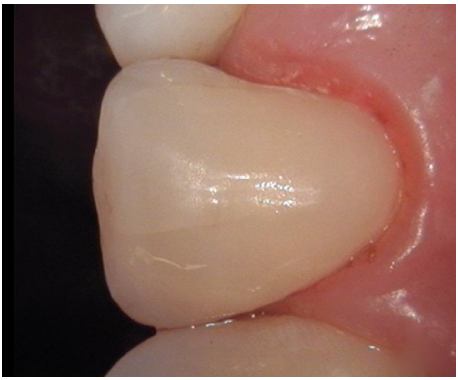


Fig. 2: Recording with Cam interchangeable head

5.2 Macro Interchangeable head:

The Macro interchangeable head can be used to take intraoral close-up images with an approx. 120 x magnification to identify e.g. edge gaps or fusion fractures.
Eight LEDs are arranged around the optical element to ensure uniform illumination.

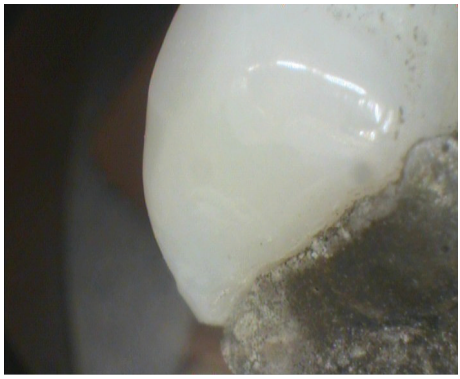
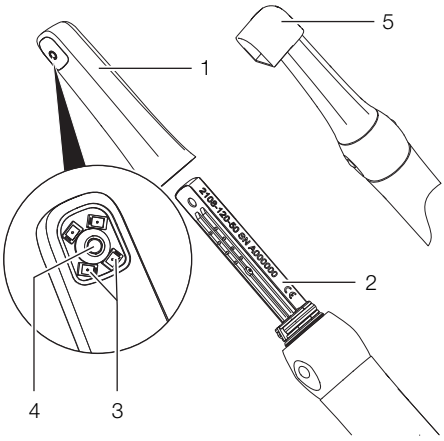


Fig. 3: Mounting with Macro interchangeable head

5.3 Proof interchangeable head



1 Interchangeable head
2 Handpiece
3 LEDs
4 Optical system
5 Spacer

The Proof interchangeable head is used to create intraoral images for the detection of caries, plaque and calculus.
Four LEDs with blue-violet light (wavelength 405 nm) are arranged around the optical element. The energy-rich light causes the tooth structure (enamel, dentine) and the metabolites cariogenic bacteria (porphyrins) to fluoresce. The substances emit different colours. This makes it possible to analyse caries activity and detect potential tooth disease.

Substance	Fluorescent colour
Tooth structure (enamel, dentine)	Green
Metabolites of cariogenic bacteria (porphyrins)	Red

The spacer enables optimum analysable images. The position and the distance of the image are reproducible. In addition, the spacer screens off the image area and minimises the penetration of external light.
Application areas of the Proof interchangeable head:

- Detecting plaque and calculus
- Detecting caries at an early stage
  - Fissure caries that are difficult to detect
  - Precise location of carious lesions on smooth surfaces
  - Optically-supported check during excavation
- Checking, documenting and archiving the progress of dental illnesses in the imaging software.

Evaluation

The images are analysed by the imaging software with the help of a filter.
The prophylaxis view shows the original image.

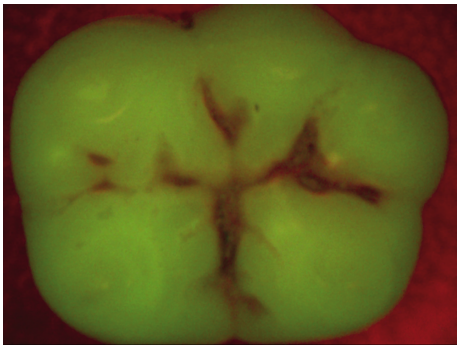


Fig. 4: Prophylaxis view

The caries view analyses the fluorescence of the substances with the caries filter.

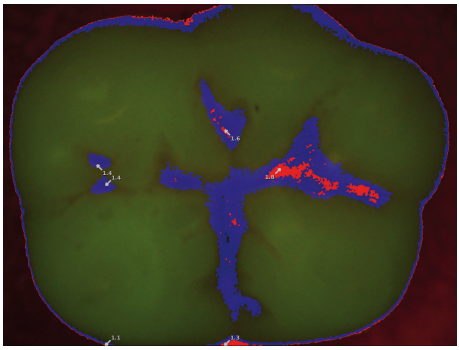


Fig. 5: Caries view

The colour scale and the numeric values provide reliable information on carious lesions:

1.0 Healthy tooth enamel

1.5 Initial caries, early stages of enamel caries

2.0 Enamel caries up to the enamel/dentine junction

2.5 Dentine junction already exceeded

Deep dentine caries

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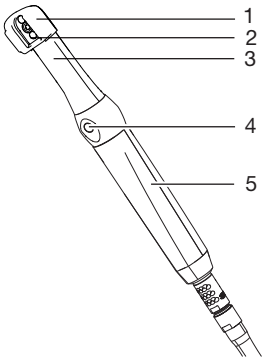
5.4 Proxi interchangeable head



1 Spacer
2 Optical system
3 Proxi interchangeable head
4 Capture ring
5 Handpiece

The VistaCam iX handpiece with the Proxi interchangeable head creates a black and white image for detecting caries in the approximal region.
The optical system is placed on the row of teeth and an image is created by actuating the capture ring. The spacer facilitates the placement of the optical element on the row of teeth. In addition, the spacer screens off the image area and minimises the penetration of external light.
Two powerful infra-red LEDs are installed in the optical system. The infra-red light illuminates the tooth and is reflected with varying intensity depending on the translucence (light transmission) of the dental structures. The reflected light is detected by the optical system and is evaluated as a black and white image by the DBSWIN imaging program (from Version 5.6) or VistaEasy (from Version 5.6).

Evaluation

The black and white image shows structures with varying translucency as different levels of brightness. The lower the translucency, the higher the reflection of the infra-red light and the brighter the structure. It is possible to make out to following structures:

- Healthy enamel appears very dark, high translucency
- Approximal caries appears bright, low translucency
- Dentine appears bright, low translucency
- Several restorations appears bright, no translucency

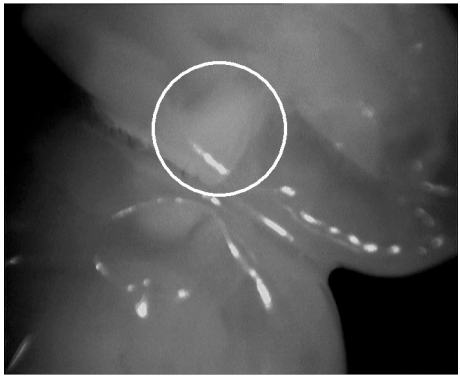


Fig. 6: Case example 1 – Lesions in the mesial area are visible as a wide bright strip up to the enamel/dentine boundary.

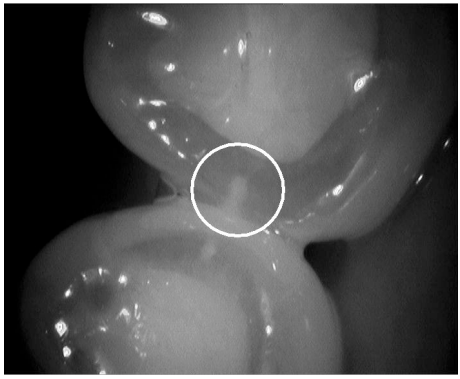


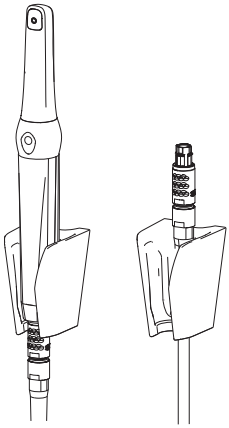
Fig. 7: Case example 2 – Enamel lesions can be seen as wedge-shaped structures within the dark translucent tooth enamel. The lesions reach to the inner half of the enamel.

The system cannot distinguish between structures with the same amount of translucency. Thus it is not suitable for the diagnosis of:

- Secondary caries under restorations
- Dentine caries
- Central occlusal caries

The enamel appears brighter in patients with highly opaque enamel. The caries diagnosis is complicated here by the low difference in contrast.

5.5 Handpiece holder

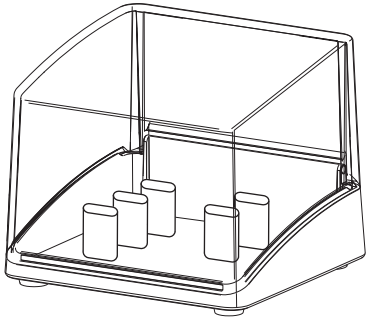


Whenever the camera is in the handpiece holder, it is switched off. When you remove the camera from the handpiece holder, it switches on automatically.
If the camera is used at a different treatment chair, it is also possible to only hang the connection cable in the handpiece holder.

5.6 Connection to computer

Using the connecting cable, you can connect the camera directly to the USB port on the computer. The camera requires the VistaEasy, DBSWIN or Image Bridge software from Dürr Dental.

5.7 Storage box



The storage box protects the interchangeable heads not placed on the camera from soiling and scratches. Up to five interchangeable heads can be stored in it.

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Assembly

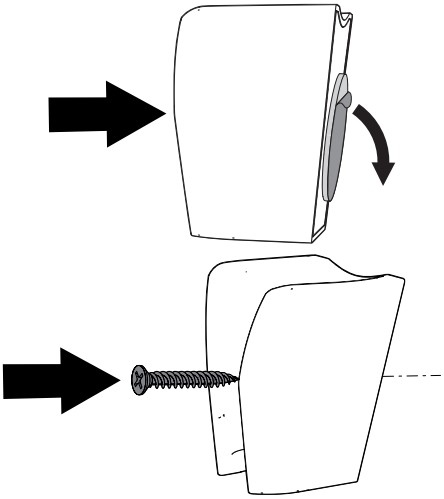
6 Installation

6.1 Installing the handpiece holder

The handpiece holder can be glued or screwed.

› Choose suitable fastening material.

› Install the handpiece holder close to the handpiece.
The USB cable is 2.5 m long.



7 Commissioning

NOTICE

Short circuit due to the build up of condensation

› The unit can only be put into operation once it has warmed up to room temperature and is dry.

The unit supports the following imaging programs:

– VistaSoft from Dürr Dental
– VistaConnect from Dürr Dental
– DBSWIN from Dürr Dental
– VistaEasy from Dürr Dental
– ImageBridge from Dürr Dental
– Third-party software on request

7.1 Connecting the unit

The unit has no main power switch. Therefore, it is important that the USB connection on the PC and, if necessary, the socket-outlet for the power supply are easily accessible and that the appliance can be unplugged if necessary.

› Carry out the installation and configuration in accordance with the accompanying instruction (document no. 9000-618-179).

A copy of the system manufacturer's declaration in accordance with Article 12 of Directive 93/42/EEC can be found in our download section at www.duerrdental.com (document no. 9000-461-264).

7.2 System requirements

The system requirements for the computer systems can be found in the download area at www.duerrdental.com (document no. 9000-618-148).

Proper operation of the Dürr Dental hardware and software is coordinated.

› Based on the *system requirements for computer systems*, check whether the device is compatible with the installed hardware/software.

7.3 Acceptance tests

Electrical safety checks

› Perform the electrical safety check according to national law.

› Document the results.

The interchangeable heads in the various versions (see "5 Operation") are application parts in accordance with IEC 60601-1.

EN

Usage

8 Operation

NOTICE

Damage to the camera from falling down or scratching

- Always place the camera in the handpiece holder.
- Do not place the camera on a storage shelf.
- Do not place the camera between other treatment instruments.

8.1 Changing the interchangeable head

The function of the camera depends on the interchangeable head. The following interchangeable heads are available:

- Cam interchangeable head
- Macro Interchangeable head:
- Proof interchangeable head
- Proxi interchangeable head

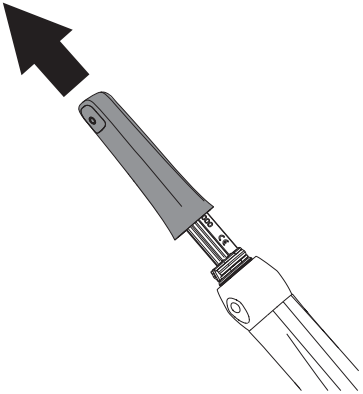
CAUTION

Leakage currents possibly too high when touching open contacts

- Never come into contact with patients and open contacts on the handpiece at the same time.

Remove the interchangeable head

- Pull the interchangeable head off the handpiece upwards.

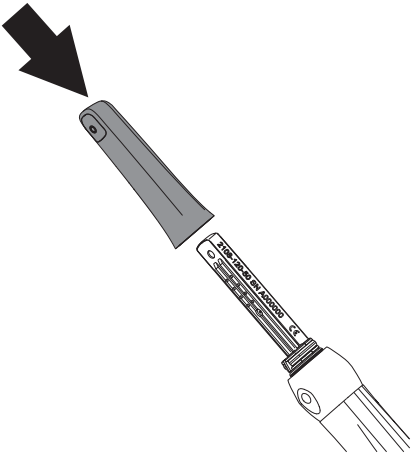


Place on the interchangeable head

Requirements:

✓ The handpiece and interchangeable head are completely dry.

- Hold the interchangeable head and handpiece so that the optical element is on the side of the image sensor.
- Slide the interchangeable head onto the handpiece until it clicks into place.



8.2 Switch on the unit.

- Using the connection cable, connect the camera to the USB port on the computer.

› Start the imaging program, refer to the software instruction (DBSWIN 2100-725-91, VistaEasy 9000-618-137).

8.3 Using the hygienic protective cover

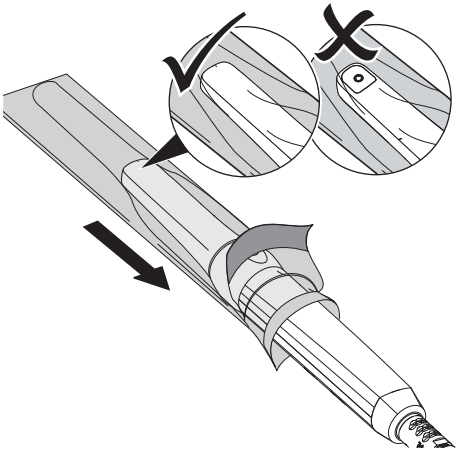
WARNING

Danger of cross contamination with failure to use or repeated use of a disposable hygienic protective cover

› Do not use the unit without a hygienic protective cover.
› Do not use the hygienic protective cover more than once (disposable item).

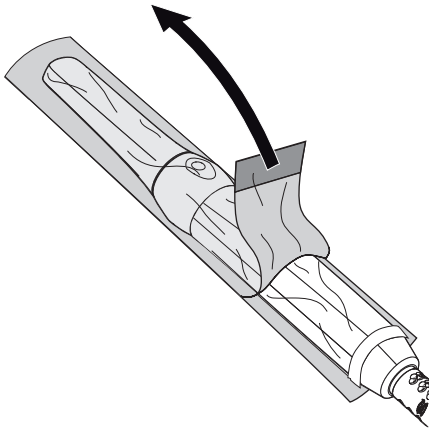
Wear protective gloves when applying the disposable hygienic protective cover.

› Hold the camera so that the optical element faces down.
› Lift the white edge of the disposable hygienic protective cover and slide the camera head carefully into the cover. The transparent plastic side must face upwards.



› Stretch the disposable hygienic protective cover an extra 2 - 3 mm so that the cover presses tightly against the optical element.
› Carefully press the disposable hygienic protective cover against the optical window using your fingers. Ensure that there are no air bubbles between the optical window and the disposable hygienic protective cover.

› Hold the disposable hygienic protective cover firmly on the white edge and pull off the transparent plastic side in the direction of the camera head.



› Pull off the paper underside from the camera head in the direction of the handpiece.

8.4 Place on the spacer

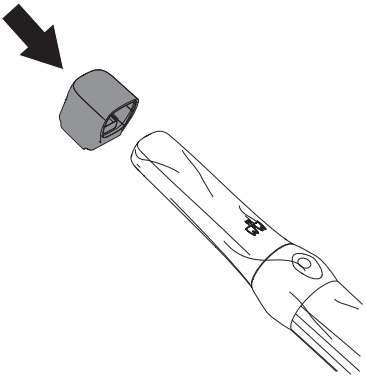
WARNING

Danger of cross-contamination when used without reprocessing or following incorrect reprocessing

› Sterilise the light protection in the steam steriliser (see "10 Reprocessing the spacer") before each use.

EN

› Place the spacer onto the interchangeable head from above. Ensure that the spacer does not cover the optical element of the interchangeable head.



8.5 Taking an image with Cam and Macro interchangeable heads

If the camera is taken out of the handpiece holder, the camera shows a moving image (Live mode). Each time the mode is switched between Live mode and Freeze mode, the handpiece vibrates slightly.
Still images and video can be recorded with the camera. The possible recording modes are dependent on the imaging software.
Requirements:

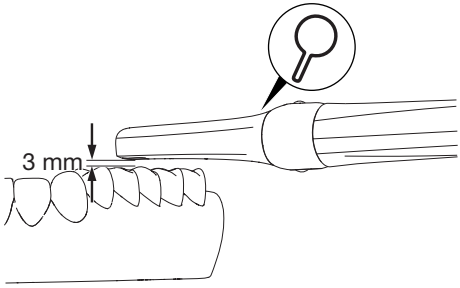
✓ Camera connected with the computer

✓ Imaging software started

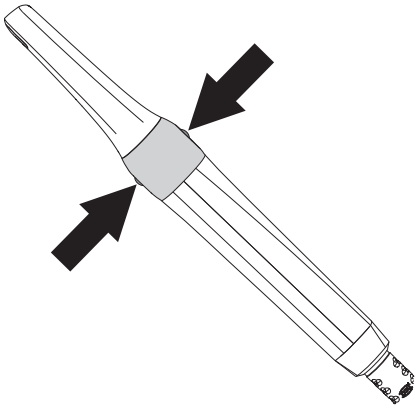
› Take the camera out of the handpiece holder.

› Select the desired image section in Live mode.

› With the Macro interchangeable head, maintain a distance of approx. 3 mm to the object.



› Press on one point of the capture ring.



The camera switches to "Freeze" mode. The freeze frame will be displayed in the imaging program / transmitted to the monitor.

› Edit the image using the imaging program and save. (For further information, refer to the software manual.)

› To return to "Live" mode, press on a point on the capture ring again.

8.6 Record an image with the Proof interchangeable head

When imaging with the Proof interchangeable head, two views are possible in the imaging software.

Prophylaxis view
This provides an informative overview of the status of oral hygiene.

Caries view
It evaluates the fluorescence of the substances and provides a reliable diagnosis of carious lesions based on the colours.
The following factors can affect the fluorescence and hence the caries analysis:

– Soiling and food remains
– Calculus, concrement
– Aid for staining plaque
– Prophylaxis/fluoride pastes
– Tooth/polishing pastes

Preparation

The teeth must be prepared differently depending on the required analysis.

For prophylaxis view:

› Do **not** clean the teeth professionally.

For caries analysis:

› Carry out professional teeth cleaning.

› Remove polishing paste using the air/water spray.

› Dry the teeth.

Record an image

CAUTION

The UV light of the camera can dazzle

› Do not peer into the light source.

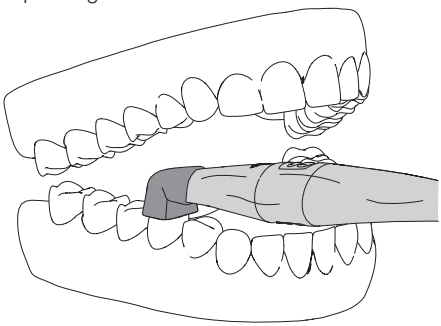
› Do not use the camera directly on the eye.

Requirements:

✓ Camera connected with the computer
✓ Imaging software started
✓ Camera in hygienic protective cover
✓ Spacer placed on

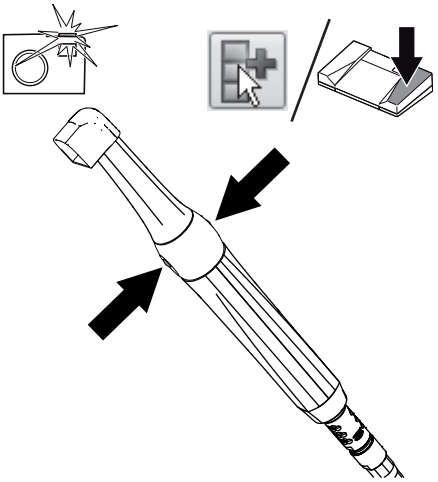
› Reduce the penetration of external light. Turn off or dim sources of external light (e.g. operating lights).

› Place the camera with spacer onto the corresponding tooth.



EN

› Press on one point of the capture ring.



› Alternatively, press the foot switch or the button in the software.
The camera switches to "Freeze" mode. The freeze frame will be displayed in the imaging program / transmitted to the monitor.
› Edit the image using the imaging program and save. (For further information, refer to the software manual.)
› To return to "Live" mode, press a point on the capture ring again.

Analyse the image

The **prophylaxis view** shows the original image. Red areas indicate caries-causing bacteria. The healthy enamel is shown as green areas.

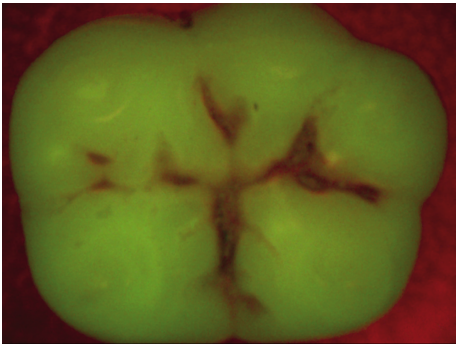


Fig. 8: Prophylaxis view

The **caries view** evaluates the fluorescence of the substances with the caries filter.

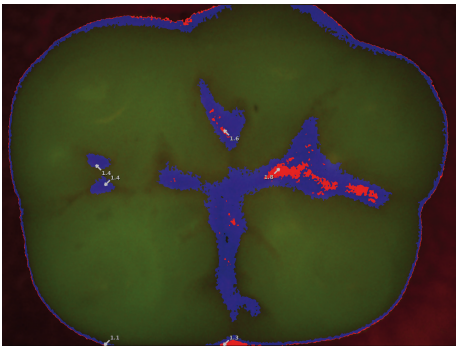


Fig. 9: Caries view

The colour scale and the numeric values provide reliable information on carious lesions:

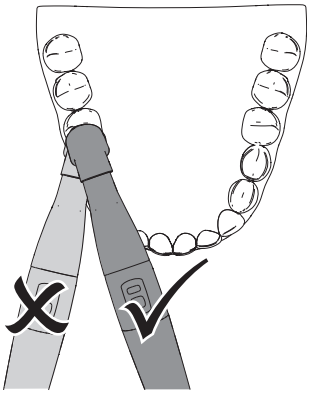
1.0	Healthy tooth enamel
1.5	Initial caries, early stages of enamel caries
2.0	Enamel caries up to the enamel/dentine junction
2.5	Dentine junction already exceeded
	Deep dentine caries

8.7 Record an image with Proxi interchangeable head

Positioning the unit correctly

The camera must be positioned correctly to achieve a good picture quality.

› Position the camera in a line with the teeth.



› Place the spacer vertically on the tooth surface. The spacer must come into contact with the teeth.

› Ensure that the relevant approximal area is located in the centre of the image section.

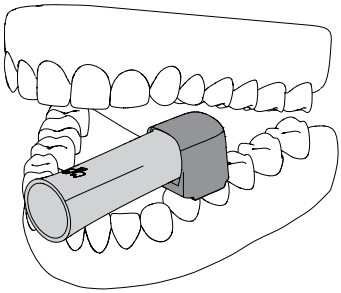
› If the structure underneath the enamel is not visible, change the angle of the camera slightly.

Record an image

› Reduce the penetration of external light. Turn off or dim sources of external light (e.g. operating lights).

› Dry the row of teeth with compressed air.

› Place the camera with spacer on the row of teeth above the approximal area. The two infrared LEDs illuminate the respective mesial and distal enamel area of the two adjacent teeth.



› Press on one point of the capture ring. The camera switches to "Freeze" mode. The freeze frame will be displayed in the imaging program / transmitted to the monitor.

› Edit the image using the imaging program and save. (For further information, refer to the software manual.)

› To return to "Live" mode, press a point on the capture ring again.

Analyse the image

The black and white image shows structures with varying translucency as different levels of brightness. The lower the translucency, the higher the reflection of the infra-red light and the brighter the structure. It is possible to make out to following structures:

– Healthy enamel appears very dark, high translucency
– Approximal caries appears bright, low translucency
– Dentine appears bright, low translucency
– Several restorations appears bright, no translucency

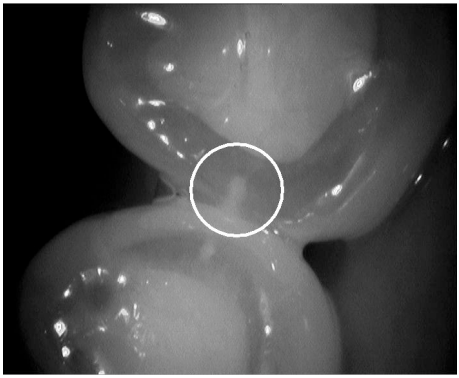


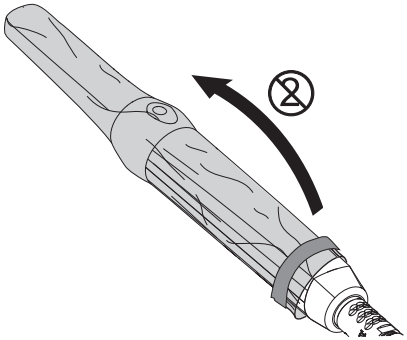
Fig. 10: Enamel lesions can be seen as wedge-shaped structures within the dark translucent tooth enamel. The lesions reach to the inner half of the enamel.

The enamel appears brighter in patients with highly opaque enamel. The caries diagnosis is complicated here by the low difference in contrast.

EN

8.8 Switching off the camera

› Carefully pull off the hygienic protective cover and dispose of it.



› Disinfect the camera (see "9 Reprocessing of the device").

› Place the camera in the handpiece holder.

Result:

The camera switches off automatically.

Always store the camera with the interchangeable head plugged on.

9 Reprocessing of the device

9.1 Risk analysis and categorisation

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

9.2 Reprocessing procedure in accordance with EN ISO 17664

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

Important information!
The reprocessing notes in accordance with EN ISO 17664 have been independently tested by Dürr Dental for the preparation of the device and its components for their reuse.
The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.
Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially influenced by the amount of wear and tear or damage resulting from its use.
The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The validation of the reprocessing method was performed based on the assumption that, in the worst case scenario, a disposable protective cover could be damaged while it is being pulled on or during use.
In accordance with IEC 80601-2-60, the application part of the intraoral camera is limited to a length of 80 mm, starting with the tip of the interchangeable head. During the validation of the reprocessing method, only the application part was looked at for this reason.
The reprocessing method was validated as follows:

- **Pre-cleaning**
  - FD multi wipes compact (Dürr Dental)
- **Manual cleaning**
  - FD 333 forte wipes (Dürr Dental)
- **Manual disinfection**
  - FD 333 forte wipes (Dürr Dental)

EN

General information

› Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.
› When selecting the cleaning and disinfectant agents to be used, the information provided (see "9.4 Manual pre-cleaning, cleaning, disinfection and drying") must be followed.
› 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.
› 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.

9.3 Preparation at the operating location


Wear protective gloves.


Wear protective goggles.


Use a mask.


Use protective clothing.

› Clean the disposable protective cover (with integrated camera) with a disinfection wipe.
› Carefully pull off the hygienic protective cover and dispose of it.
› Clean the device with a disposable wipe soaked in cold tap water until no more dirt or contamination can be seen.
› Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

9.4 Manual pre-cleaning, cleaning, disinfection and drying

NOTICE

Damage to the device due to incorrect cleaning and disinfection

› Only clean the surface of the unit.
› Only use disinfection and cleaning agents specifically approved by Dürr Dental.
› Do not use any aggressive or abrasive cleaning materials.
› Only clean the unit using wipe disinfection.
› Do not clean the unit by submerging or spraying in combination with disinfectant.
› Do not steam sterilise the unit.

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, solvents, strong alkaline solutions (pH >11) or oxidising agents

For further information, see: "General information".

Cleaning

› Thoroughly wipe down the outer surfaces for 1 minute with a cleaning wipe.
› Repeat this process with a new cleaning cloth. This means that the entire cleaning step is performed for 2 minutes.

Disinfection

› Thoroughly wipe down the outer surfaces for 2 minutes with a cleaning wipe.
› Repeat this process with a new cleaning cloth. This means that the entire disinfection step is performed for 4 minutes.

Drying

› Allow the device to air-dry.
The device must be completely dry before a new disposable protective cover is pulled on.

10 Reprocessing the spacer

10.1 Risk analysis and categorisation

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

10.2 Reprocessing procedure in accordance with EN ISO 17664

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

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

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

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

EN

The reprocessing procedure was validated as follows:

- **Pre-cleaning**
  - FD 322 premium wipes for quick-acting disinfection (ready-to-use disinfection wipes, Dürr Dental)
- **Manual cleaning**
  - ID 215 enzymatic instrument cleaner (Dürr Dental)
  - Cleaning brush
- **Manual disinfection**
  - ID 213 Instrument disinfection (Dürr Dental)
- **Automatic cleaning and disinfection**
  Was performed in accordance with EN ISO 15883 with tested efficacy.
  - Cleaning agent: Neodisher MediClean Forte
  - RDG: G 7836 CD (Miele, Gütersloh)
  - Programs: "Cleaning without neutralisation" and "D-V-MEDFORTE"
- **Steam sterilisation**
  was performed in accordance with EN ISO 17665 with the fractionated vacuum procedure.
  - Pre-vacuum: 3 x
  - Sterilisation temperature: 134 °C
  - Sterilisation time: 4 minutes
  - Drying time: min. 20 minutes
- **Cleaning brush**
  Cleaning brush with nylon hairs, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 25 and 35 mm
  - Brush length: 5 and 10 mm

  Example: Interlock cleaning brush, double-sided, green REF 09098

General information

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

› Comply with the specifications (see "10.4 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying" and "10.5 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying") when selecting the cleaning and disinfectant agents to be used.

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

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

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

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

› Only use freshly-produced solutions.

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

10.3 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.

› Clean the spacer with a disposable wipe soaked in cold tap water until no more dirt or contamination can be seen.

› Note the action time of the cleaning agent.
› Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

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

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

For further information, see: "General information".

Cleaning

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

Intermediate rinsing

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

Disinfection

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

Final rinse

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

Drying

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

EN

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

Selection of the washer-disinfector

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

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

Selection of the machine cleaning agents and disinfectants

The following properties are required:

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

For further information, see: "General information".

Automatic cleaning and disinfecting

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

› Place components in the basket for small parts.

10.6 Check for function

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

10.7 Steam sterilising

Packing

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

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

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

Steam sterilising

WARNING

Health risk due to incorrect sterilisation

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

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

NOTICE

Damage to equipment due to incorrect sterilisation

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

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

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

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

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

10.8 Issue clearance for the parts for sterilisation

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

10.9 Storing parts for sterilisation

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

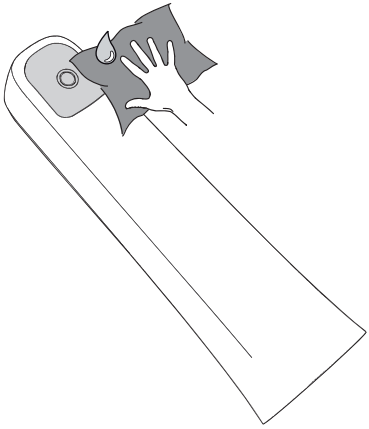
Packaging for a sterile medical device can suffer damage as a result of a particular incident and the passage of time.
Potential external contamination of the sterile barrier system should be taken into account in terms of aseptic preparation when establishing the storage conditions.

11 Cleaning

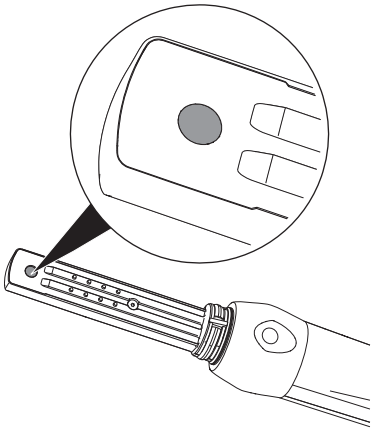
11.1 Cleaning the optical element

NOTICE
Damage of the optical element from incorrect cleaning
› Only use the cleaning set for VistaCam optical element. Disinfectant residues soil the optical element.

› Clean the window of the optical window of the interchangeable head from outside using the microfibre cloth with a drop of VistaCam optical element cleaner or alcohol.



› With the interchangeable head removed, clean the surface of the image sensor using the cleaning set for VistaCam Optik.



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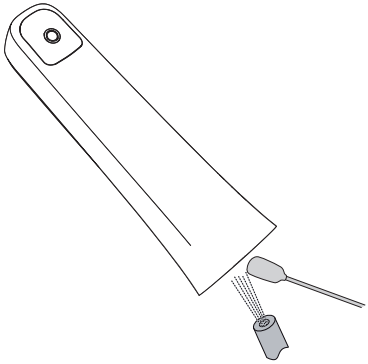
› If particles can still be seen on the image, dry clean the interchangeable head from the inside with compressed air or with a foam rod (from the cleaning set).



11.2 Storage box

Clean the surface of the storage box and the internal shelf in the event of contamination or visible soiling and disinfect.

Use the following cleaning materials for the storage box:

✓ FD 366 sensitive disinfectant for sensitive surfaces

Use the following cleaning materials for the shelf:

✓ FD 350 disinfectant wipes

› Clean the surface of the storage box and the shelf with a dampened, soft, lint-free cloth.

› Disinfect the storage box with spray disinfectant on a soft, lint-free cloth. Comply with the operating instructions for the disinfectant when doing this.

› Disinfect the shelf using a disinfection wipe.

12 Maintenance

The appliance is maintenance-free.

Troubleshooting

13 Tips for operators and service technicians

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

Error	Possible cause	Remedy
Image cloudy, milky	Hygienic protective cover not placed correctly on the optical window	› Place the hygienic protective cover on the optical window correctly.
	Optical window soiled	› Clean the optical window (see "11.1 Cleaning the optical element").
	Image sensor soiled	› Clean the image sensor (see "11.1 Cleaning the optical element").
	Optical element scratched	› Replace the interchangeable head.
	Handpiece defective	› Send the handpiece for repair.
Image too dark	LEDs defective	› Replace the interchangeable head.
No image	USB connection cable not connected	› Connect the USB connection cable.
	USB connection cable defective	› Replace the USB connection cable.
	Computer not switched on, software not started	› Switch on the computer and start the software.
	Camera driver not correctly installed	› Check the driver installation and software settings.
When the capture ring is pressed, the camera vibrates, but no stationary image is displayed	Interchangeable head has not been detected by the software	› Remove the interchangeable head. › Replace the interchangeable head.
The image is blurred	Resolution set incorrectly	› Working in *VistaConfig* > *Camera configuration* > *Settings* select a resolution with width-to-height ratio 4:3.

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13.1 Proof interchangeable head

Error	Possible cause	Remedy
Image contains a high amount of red; healthy tooth substance is not properly green	Penetration of external light	› Check the position of the spacer (directly on the tooth). › Turn off or dim source of external light (e.g. operating light); darken the room.

13.2 Proxi interchangeable head

Error	Possible cause	Remedy
Image is tool light in a specific region	The angle of the camera to the tooth is not ideal	› Change the holding angle of the camera to the tooth.
Snow effect on the image	Clearance of the camera to the tooth is too high, no optimum illumination	› Ensure that the spacer does not come into contact with the teeth.
	Camera used without spacer	› Always use a spacer for imaging using the Proxi interchangeable head.
Dark shadow in the dentine	Hygienic protective cover or optical element soiled	› Check the hygienic protective cover, clean or replace if necessary. › Check the optical element and clean if necessary (see "11.1 Cleaning the optical element").
Image is too light or too dark	Incorrect settings in the imaging software	› Alter the brightness of the image in the imaging software. › Adapt the brightness in the configuration of the imaging software to change the brightness settings.
Too many reflections in the image	Saliva in the mouth	› Dry the row of teeth with a cloth or compressed air. › Change the holding angle of the camera lightly.
	Teeth with large-surface fillings and a small surface with intact enamel in the image section	› This image does not permit exact analysis.

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