VistaCam iX HD

EN

Installation and Operating Instructions

CE

2109100005L02

DÜRR DENTAL

1609V007SE

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1 About this document

These installation and operating instructions form part of the unit.

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

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:

General warning symbol

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

Type BF application part

Comply with the specification in the accompanying documents.

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

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1.2 Copyright information

2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended purpose

The camera can be operated both in or on the oral cavity of the patient and outside their mouth. The images support diagnosis, patient communication and information, and are used for instruction and documentation purposes. They can also be used to document the progress monitoring of a range of dental diseases.

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. Working with a computer, monitor and an imaging software, this digital system can be used to create and store images and videos.

Possible applications:

1. Cam interchangeable head:
   For the recording of images and videos for a lifelike view of teeth and the oral cavity, from facial images up to macro images.
2. Proof interchangeable head:
   For improved detection of occlusal and surface caries, plaque and calculus. Fluorescence-based images are marked in colour and labelled with arrows and values.
3. Proxi interchangeable head:
   Enables the detection of approximal caries by virtue of the translucence of the healthy tooth enamel to light waves in the infra-red range.

2.3 Improper usage

WARNING
Risk of explosion due to ignition of combustible materials

› Do not operate the unit in any rooms in which inflammable mixtures may be present, e.g. in operating theatres.

CAUTION
The light of the camera is very bright and can dazzle

› Do not use the camera directly on the eye.

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.

2.4 General safety information

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
› Prior to each use, check condition of the device and make sure it is in perfect working order.
› Do not convert or modify the units.
› Observe the Installation and Operating Instructions.
› Make the Installation and Operating Instructions available to the person operating the device at all times.

2.5 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 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).

2.6 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.

2.7 Protection from electric shock

› 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

› Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "13 Information concerning EMC in accordance with IEC 60601-1-2".
› 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.

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› 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:

Handpiece holder with USB hub . . 2109105051

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.

2.8 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
› Only use only genuine working parts and spare parts.

DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.

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

2.9 Transport

The original packaging provides optimum protection for the device during transport.

If required, original packaging for the unit can be ordered from Dürr Dental.

Dürr Dental does 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 device in its original packaging.
› Keep the packing materials out of the reach of children.

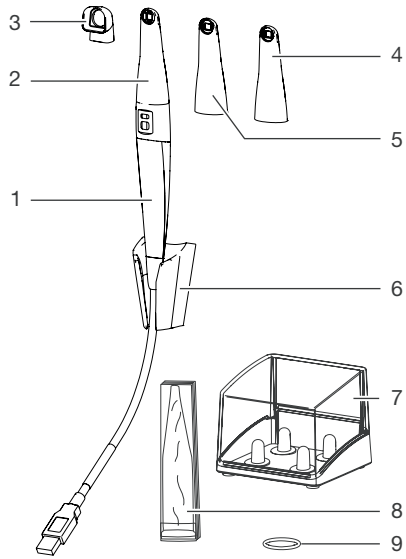
2.10 Disposal

Unit

The unit must be properly disposed of. 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.

3 Overview



1 Handpiece
2 Cam interchangeable head
3 Spacer
4 Proof interchangeable head
5 Proxi interchangeable head
6 Handpiece holder
7 Storage box for interchangeable heads
8 Hygienic protective covers
9 O-ring

3.1 Scope of delivery

The following items are included in the scope of delivery:

VistaCam iX HD with Cam, Proof and Proxi package 2109100001
– Handpiece
– Cam interchangeable head
– Proof interchangeable head
– Proxi interchangeable head
– Storage box for interchangeable heads
– Handpiece holder
– Hygienic protective covers (20 pieces)
– Spacers (2 x 5 pieces)
– O-ring, 17 x 1.5 mm (2 pieces)
– Microfibre cloth
– Quick start instructions
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD

VistaCam iX HD with Cam and Proof package. 2109100002
– Handpiece
– Cam interchangeable head
– Proof interchangeable head
– Storage box for interchangeable heads
– Handpiece holder
– Hygienic protective covers (20 pieces)
– Spacers (5 pieces)
– O-ring, 17 x 1.5 mm (2 pieces)
– Microfibre cloth
– Quick start instructions
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD

VistaCam iX HD with Cam and Proxi package. 2109100003
– Handpiece
– Cam interchangeable head
– Proxi interchangeable head
– Storage box for interchangeable heads
– Handpiece holder
– Hygienic protective covers (20 pieces)
– Spacers (5 pieces)
– O-ring, 17 x 1.5 mm (2 pieces)
– Microfibre cloth
– Quick start instructions
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD

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VistaCam iX HD with Cam package 2109100004
– Handpiece
– Cam interchangeable head
– Storage box for interchangeable heads
– Handpiece holder
– Hygienic protective covers (20 pieces)
– O-ring, 17 x 1.5 mm (2 pieces)
– Microfibre cloth
– Quick-start instructions
– VistaSoft imaging software DVD
– DBSWIN imaging software DVD

3.2 Accessories

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

Proof interchangeable head for VistaCam iX HD 2109130051
Proxi interchangeable head for VistaCam iX HD 2109130052
Handpiece holder for VistaCam iX HD 2109105050
Storage box for interchangeable heads 2109135050
Hygienic protective covers (500 pieces) 2109101050
Hygienic protective covers (100 pieces) 2109010052
Spacers (5 pieces) 2109132050

3.3 Special accessories

The following optional items can be used with the unit:

Handpiece holder with USB hub . . 2109105051
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
VistaSoft imaging software DVD . . 2110100002
DBSWIN imaging software DVD . . 2100-725-02

3.4 Disposable materials

The following materials are used when operating the unit and must be ordered separately:

Hygienic protective covers (500 pieces) 2109101050
Hygienic protective covers (100 pieces) 2109010052
FD 350 Classic disinfection wipes CDF35CA0140
FD 333 rapid surface disinfectant CDF333C6150
Cleaning set for VistaCam optical element 2101-025-50
Cleaning set for VistaCam optical element without cleaner . . . 2109025050

3.5 Wear parts and spare parts

O-ring, 17 x 1.5 mm (2 pieces) . . . 2109124050

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

4 Technical data

4.1 Handpiece

Electrical data		
Nominal voltage	V DC	5
Communication interfaces		USB 2.0
Type of protection		IP20
Protection class		Type BF application part
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	Fulfilled
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	Fulfilled
Emitted HF disturbance variablesin accordance withIEC 61000-4-3	Fulfilled

*See also: "13 Information concerning EMC in accordance with IEC 60601-1-2"

Camera electronics		
Image sensor		1/3" CMOS
Number of image points sensor	MPixel	1.37
Max. pixels effective (PC)		1280 x 1024
Video codec		Motion JPG
Brightness control		Automatic
White balance		Fixed

Dimensions and weights Handpiece with Cam interchangeable head		
Length	mm	200
Diameter	mm	24
Weight with cable	g	190
Weight without cable	g	70
Cable length	cm	250

4.2 Cam interchangeable head

Technical data		
Light source		2 LEDs, white light
Wavelength	nm	400 - 780
Irradiance	W/m²	0.8
Sharpness level	mm	1 - ∞
Focus level, preset	mm	17
Opening angle		64°
Protection class		Type BF application part

4.3 Proof interchangeable head

Proof interchangeable head		
Light source		2 LEDs
Wavelength	nm	380 - 460
Dominant wavelength	nm	405
Irradiance	W/m²	0.5
Sharpness level	mm	1 - ∞
Focus level, preset	mm	8
Opening angle		64°
Protection class		Type BF application part

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4.4 Proxi interchangeable head

Proxi interchangeable head		
Light source		2 LEDs
Wavelength	nm	780 - 880
Dominant wavelength	nm	850
Irradiance	W/m²	0.34
Sharpness level	mm	1 - ∞
Focus level, preset	mm	8
Opening angle		64°
Protection class		Type BF application part

4.5 Handpiece holder with USB hub (optional)

Electrical data		
Nominal voltage	V DC	12

General technical data		
Dimensions (W x H x D)	mm	58 x 83 x 123
Weight	g	190

Power supply type	
Manufacturer	GlobTek Inc.
Model	GTM41076-0612-X.X

Electrical data for the power supply unit		
Nominal voltage	V AC	100 - 240
Electrical frequency	Hz	47 - 63
Max. nominal current	A	0.5
Output voltage	V DC	12
Max. output voltage fluctuations	%	±1
Output current	A	0.5
Rated power	W	6

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	Compliant

Electromagnetic compatibility (EMC)* Interference immunity tests	
Static electricity discharge in accordance with IEC 61000-4-2	Fulfilled
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	Fulfilled
Voltage surge in accordance with IEC 61000-4-5	Fulfilled
Voltage dips, short interruptions and voltage variations in accordance with IEC 61000-4-11	Fulfilled
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	Fulfilled
Emitted HF disturbance variablesin accordance with- IEC 61000-4-3	Fulfilled

*See also: "13 Information concerning EMC in accordance with IEC 60601-1-2"

Connection cable		
Cable length	cm	250

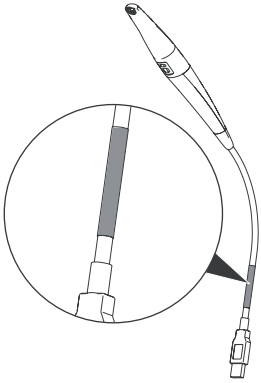
4.6 Ambient conditions

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

The type plate is located on the cable:

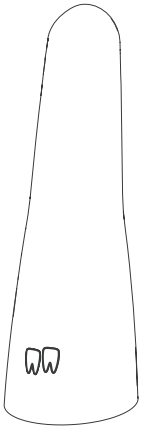


4.8 Conformity assessment

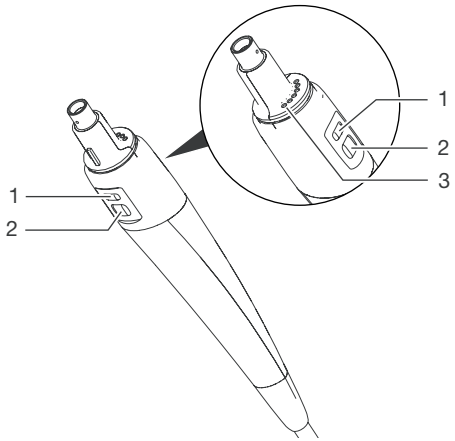
This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Operation

The intraoral camera 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
	Proof interchangeable head	Intraoral images for the detection of caries, plaque and calculus
	Proxi interchangeable head	Intraoral images for the detection of caries in the approximal region



1 Focus button
2 Trigger button
3 Contacts for interchangeable head

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The interchangeable head is plugged onto the handpiece and connected via the contacts. A guide prevents incorrect placement of the interchangeable head.

There are two buttons on each side of the handpiece: the focus button and trigger button. The pressure point of the buttons is noticeable.

The focus button is used to focus the camera sharply on the object. The focal plane is preset on the spacer during placement of the Proof or Proxi interchangeable head, but can be changed with the focus button.

Still images and video recordings can be created with the camera. The function of the trigger button is dependent of the recording mode in the imaging software (still image or video). In the Still Image mode, the camera switches between Live mode (moving image) and Freeze mode (still image). In Video mode, the recording starts or stops. Pressing the trigger button causes the camera to vibrate slightly. Optionally, a foot switch can also be used for triggering.

The illumination is incorporated in the interchangeable head. The optical element is divided: One part is in the handpiece, the other part is in the interchangeable head.

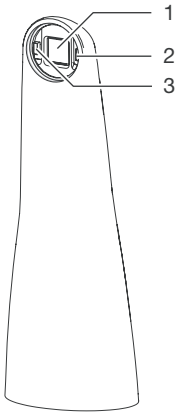
The image sensor in the handpiece digitises the image. The camera transmits the image to a computer via the USB connection cable.

The connection cable is used to connect the camera directly to the USB connection of the computer or, optionally, to the handpiece holder with USB hub. The camera needs imaging software from Dürr Dental.

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 one minute. As soon as the camera is moved, it switches on again.

5.1 Cam interchangeable head



1 Optical system
2 LED
3 LED

The Cam interchangeable head has an optical element with autofocus with a focal range for intraoral recordings. When placing on the interchangeable head, the focus level is preset to two molars. Two LEDs are positioned around the optical element for even illumination.

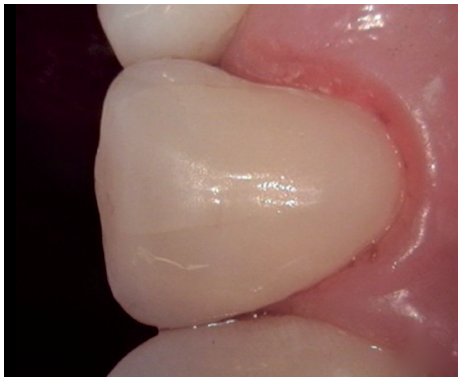
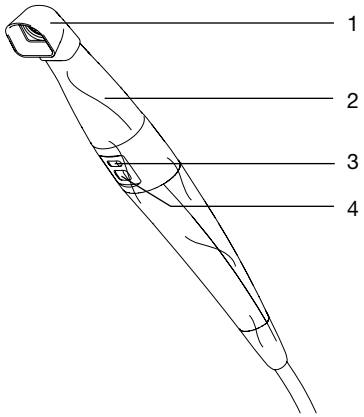


Figure 1: Recording with Cam interchangeable head

5.2 Proof interchangeable head



1 Spacer
2 interchangeable head
3 Focus button
4 Trigger button

The Proof interchangeable head is used to create intraoral images for the detection of caries, plaque and calculus.

Two LEDs are positioned around the optical element with blue/violet light (wavelength 405 nm). The energy- rich light causes the tooth structure (tooth enamel, dentine) and the metabolites cariogenic bacteria (porphyrins) to fluoresce. The substances emit different colours (intrinsic biofluorescence). This makes it possible to analyse caries activity and detect potential tooth disease.

Substance	Colour of intrinsic biofluorescence
Tooth structure (tooth 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.

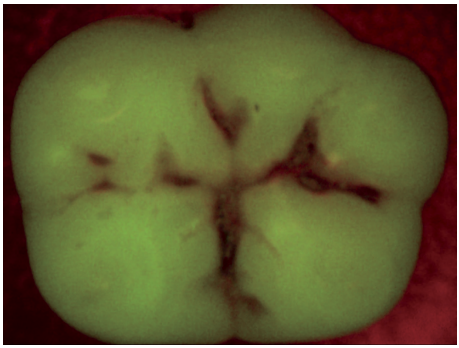


Figure 2: Prophylaxis view

The caries view analyses the intrinsic biofluorescence of the substances with the caries filter.

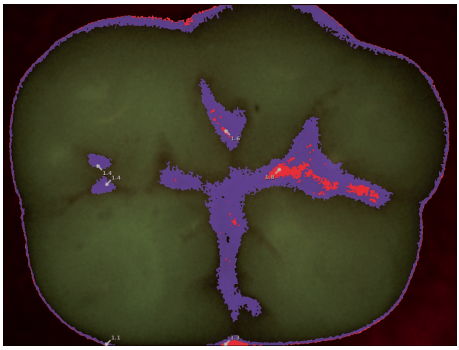


Figure 3: Caries view

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

Healthy tooth enamel

1.0

Initial caries, early stages of enamel caries

1.5

Enamel caries up to the enamel/dentine junction

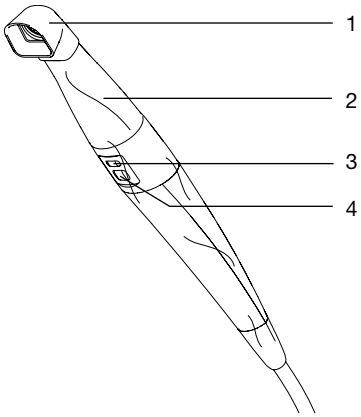
2.0

Dentine junction already exceeded

2.5

Deep dentine caries

5.3 Proxi interchangeable head



1 Spacer
2 interchangeable head
3 Focus button
4 Trigger button

The handpiece with the Proxi interchangeable head creates a black and white image for detecting caries in the approximal region.

The optical element is placed on the row of teeth. An image is created by actuating the trigger button. 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 recorded by the optical element and is analysed as a black and white image in the VistaSoft imaging software.

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

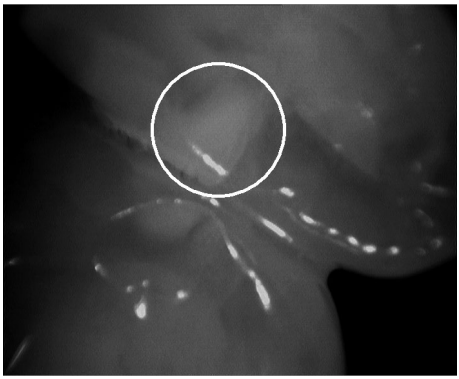


Figure 4: Any lesions on the mesial surface can be recognised as a wide bright strip up to the enamel/dentine limit.

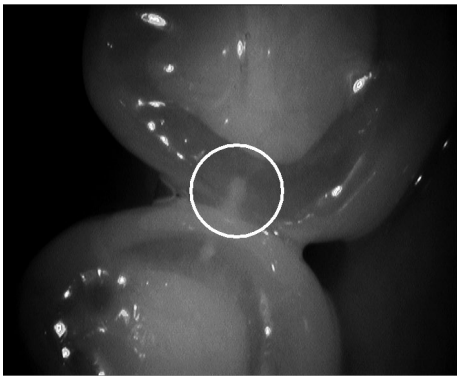


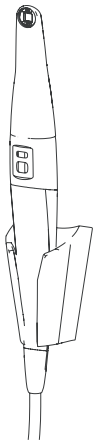
Figure 5: Enamel lesions on the mesial surface can be seen as wedge-shaped structures within the dark translucent tooth enamel. The lesions reach to the inner half of the enamel.

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

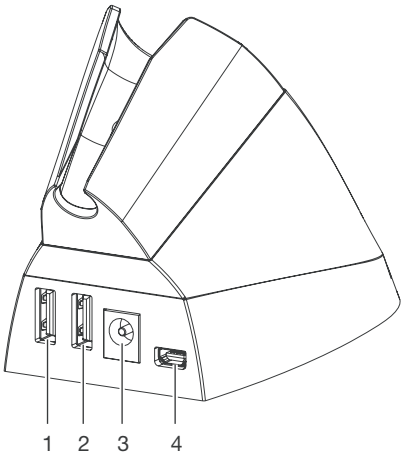
5.4 Handpiece holder



The camera is automatically switched off when placed in the handpiece holder. The camera switches on automatically when taken out.

5.5 Handpiece holder with USB hub (optional)

The camera can also be connected to the computer via the handpiece holder with USB hub. This enables a greater distance between the camera and computer.

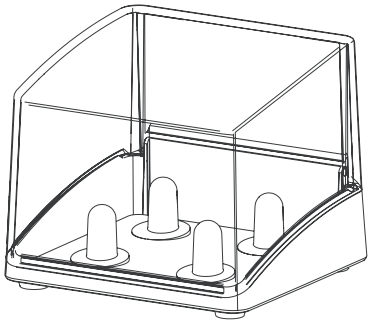


1 USB connection (for camera or USB stick)
2 USB connection (for camera or USB stick)
3 Connection for power supply unit
4 Micro USB connection for computer

The camera is connected to the handpiece holder. An additional USB connection is available, e.g. to connect a USB stick.

The camera switches off automatically when placed in the handpiece holder. The camera switches on automatically when taken out.

5.6 Storage box



The storage box protects the interchangeable heads not placed on the camera from soiling and scratches. It can store up to four interchangeable heads.

6 Installation

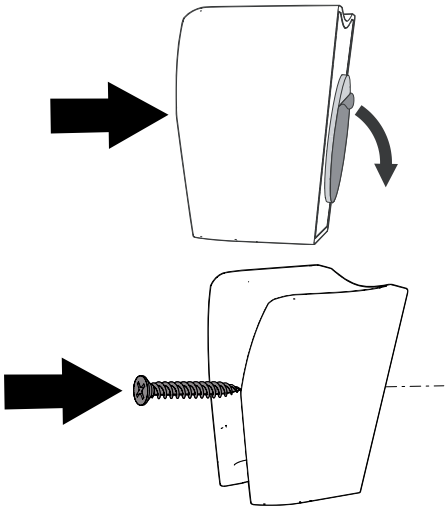
6.1 Installing the handpiece holder

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 and first start-up

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 Installing the unit

The camera can be used directly after connection. The installation of a device driver is not necessary.

The unit has no main power switch. Ensure that the USB connection on the computer and, if necessary, the handpiece holder with USB hub are easily accessible and that the unit can be unplugged if necessary.

› Connect the USB connection cable to a computer USB connection socket.

› If the USB cable is to be extended, use an USB repeater (order number 2106-155-63) or handpiece holder with USB hub (2109-105-51).

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).

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7.2 Configuring the unit in VistaSoft

The camera is preconfigured in the imaging software and can be used directly.

The following unit settings can be made in the configuration of the imaging software:

Standby settings

Standby time	Time until automatic switch-off if the camera is not moved. Preset: 2 minutes

Acquisition settings

Camera triggering	The time at which the focus and the image acquisition are executed when pressing the focus button or the trigger button: – Upon pressing (preset) – Upon releasing

› Select > *units* > *VistaCam iX HD* > *Configuration* > *Unit Settings*.

› Changing the settings.

7.3 Configuring the appliance in DBSWIN

› Start DBSWIN.

› In the *Options* > *menu, select* > *Display Configuration*.

The *Configuration* registration card opens.

› Click on the *Modules* button.

› Double click on *Video*.

The *Video Properties* window opens.

› Select the registration card *Video source 1*.

› Working under *Control type*, select the camera connected.

The following settings can be made:

Video source

WDM driver	The WDM driver is selected automatically.
Noise reduction	If noise reduction is active, the set number of images are captured one after the other for each imaging operation. The system uses these images to generate a new image that eliminates interference to the greatest possible extent.
Capture ring Operation	– *Trigger the function during release* – Trigger the function when pressing (pre-set)

Settings

Image export	Each image is automatically copied to a defined path. The path, file format and other settings are set in the *Light Table* module.

7.4 Configure the appliance in VistaConfig for VistaEasy

› Start VistaConfig via *Start* > *All Programs* > *Duerr Dental* > *VistaConfig* > *VistaCamConfig*.

The camera is detected and activated automatically.

The registration card *Settings* opens. The following settings can be made:

Display

Resolution	The resolution of the camera image can be selected
Interlaced	Full screen view (preset)

WDM driver

Driver	The WDM driver "VistaCam iX HD" is selected automatically.

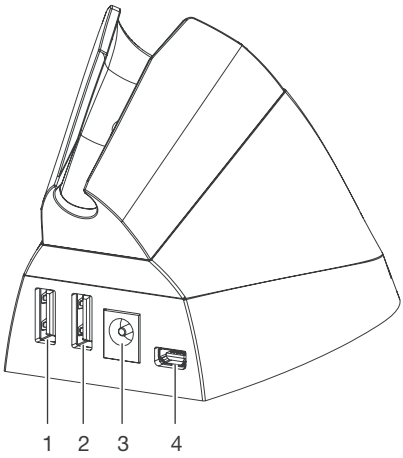
Capture ring

Operation	The function of the capture ring can be selected. *Record* + *Pause* is preset.
Trigger event	Time at which the image is created if the trigger button is pressed: – Upon pressing (preset) – Upon releasing

› To change the configuration, click .

› To save the configuration, click on .

7.5 Connect the handpiece holder with the USB hub (optional)



1 USB connection (for camera or USB stick)
2 USB connection (for camera or USB stick)
3 Connection for power supply unit
4 USB connection for computer

Requirements:

– Mains voltage must match the information shown on the type plate of the power supply unit

› Connect the power unit to the connection socket on the handpiece holder.

› Plug the mains plug into the power outlet.

› Connect the handpiece holder with the USB cable with the computer.

› Connect the connection cable of the camera in the USB connection of the handpiece holder.

8 Acceptance tests

8.1 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.

9 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.

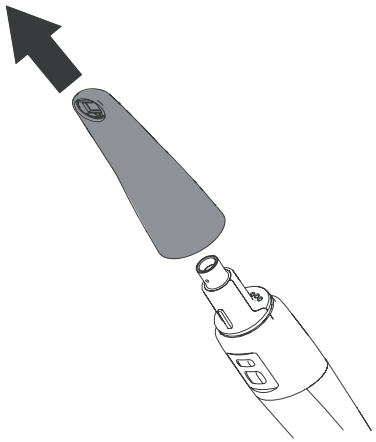
9.1 Changing the interchangeable head

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

- Cam interchangeable head
- Proof interchangeable head
- Proxi interchangeable head

Remove the interchangeable head

› Pull the interchangeable head off the handpiece upwards.

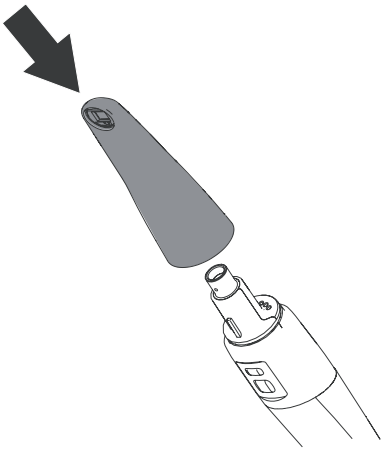


Place on the interchangeable head

Requirements:

– The handpiece and interchangeable head are completely dry.

› Slide the interchangeable head onto the handpiece (rotate if necessary) until it engages.
A guide on the handpiece ensures that the interchangeable head is placed on correctly.



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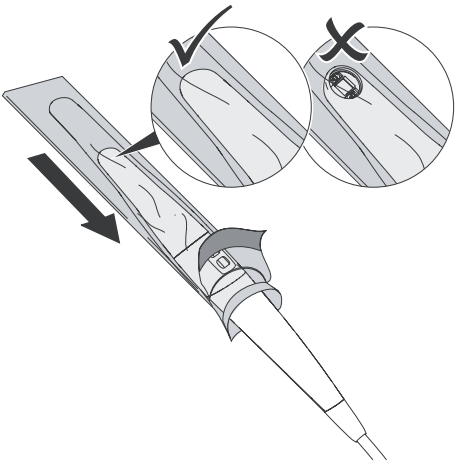
9.2 Using the hygienic protective cover

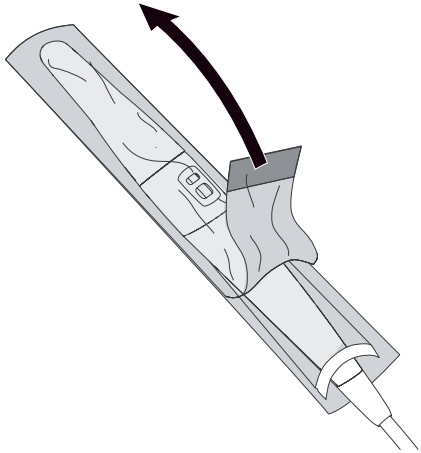
WARNING
Danger of cross contamination with failure to use or repeated use of a disposable hygienic protective cover
- › Do not use the unit without a hygienic protective cover.
- › Do not use the hygienic protective cover more than once (disposable item).

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.



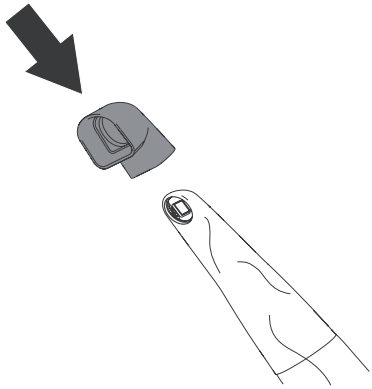
- › Pull off the paper underside from the camera head in the direction of the handpiece.

9.3 Place on the spacer

The spacer is required for imaging with the Proof and Proxi interchangeable heads.

WARNING
Danger of cross-contamination when used without reprocessing or following incorrect reprocessing
- › Sterilise the spacer in the steam steriliser (see "10.3 Reprocessing the spacer") before each use.

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



9.4 Record an image with the Cam interchangeable head

Still images and video can be recorded with the camera. The possible recording modes are dependent on the imaging software.

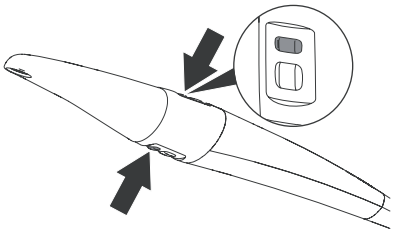
Requirements:

– Camera connected with the computer
– Imaging software started

› Take the camera out of the handpiece holder.

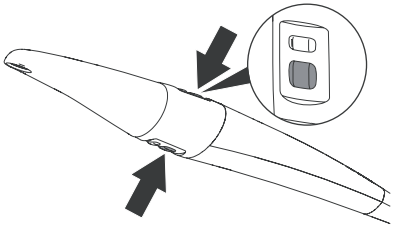
A moving image can be seen (Live mode) in the recording window of the imaging software.

› Select the desired recording mode (still image or video) in the imaging software.
› Select the image section.
› Press one of the two focus buttons.



The camera focuses.

› Press one of the two trigger buttons.



The camera switches to Freeze mode or video recording starts. The still image/video is transferred to the imaging software.

› To switch back to Live mode or to stop video recording, press the trigger button again.
› Edit and save the image/video in the imaging software. (For further information, see the software help.)

9.5 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
This analyses the intrinsic biofluorescence of the substances and provides reliable information on carious lesions by means of 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).
› Dry the row of teeth with compressed air.

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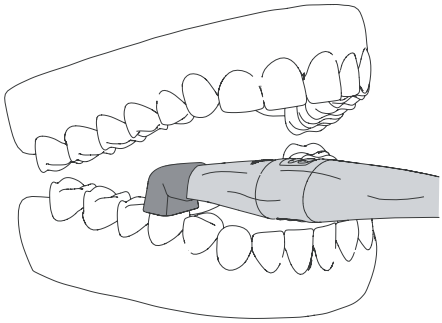
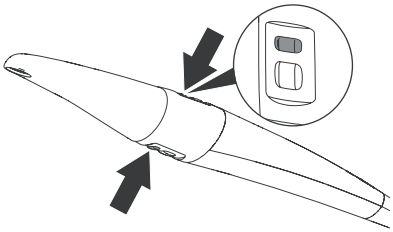
› Place the camera with spacer onto the corresponding tooth.

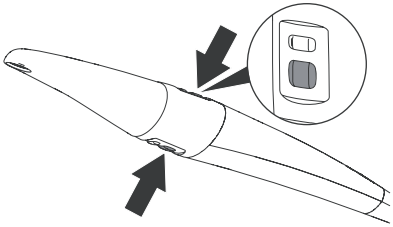


› If the image is not sharp, press one of the two focus buttons.



The camera focuses.

› Press one of the two trigger buttons.



The camera switches to "Freeze" mode. The still image is transferred to the imaging software.

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

› Analyse the image (see "Analyse the image").

› To switch back to Live mode, press the trigger buttonagain.

Analyse the image

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

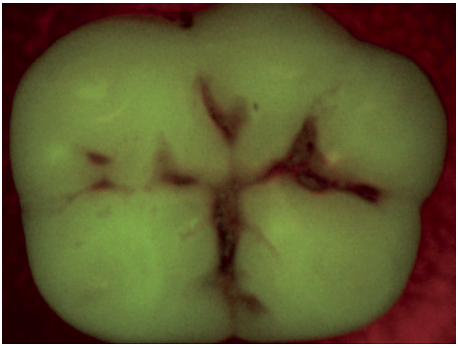


Figure 6: Prophylaxis view

The **caries view** analyses the intrinsic biofluorescence of the substances with the caries filter.

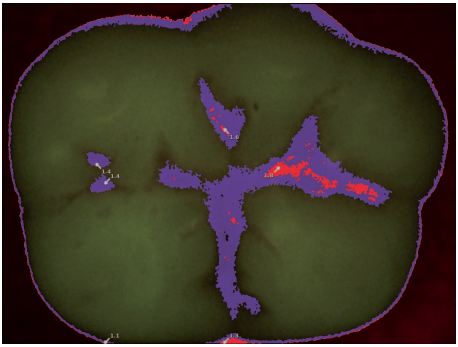


Figure 7: Caries view

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

Healthy tooth enamel

1.0

Initial caries, early stages of enamel caries

1.5

Enamel caries up to the enamel/dentine junction

2.0

Dentine junction already exceeded

2.5

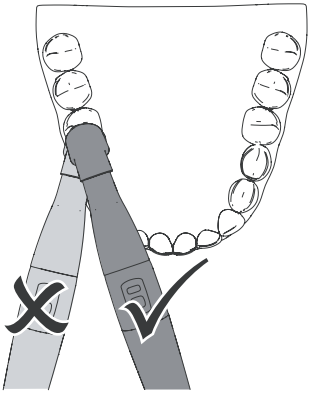
Deep dentine caries

9.6 Record an image with Proxi interchangeable head

Positioning the camera 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

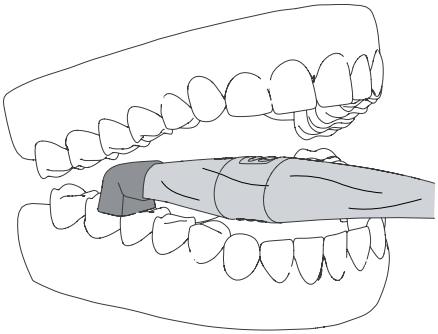
Requirements:

– 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).

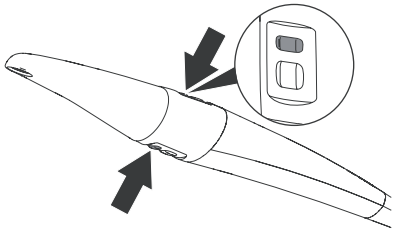
› Dry the row of teeth with compressed air.

› Place the camera with spacer on the row of teeth above the approximal area.



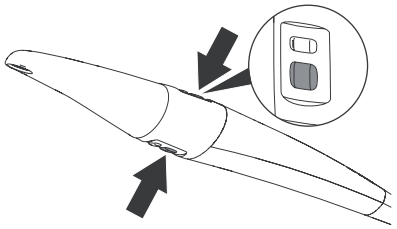
The infra-red LEDs illuminate the respective mesial and distal enamel area of the two adjacent teeth.

› If the image is not sharp, press one of the two focus buttons.



The camera focuses.

› Press one of the two trigger buttons.



The camera switches to "Freeze" mode. The still image is transferred to the imaging software.

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

› Analyse the image (see "Analyse the image").

› To switch back to Live mode, press the trigger buttonagain.

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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

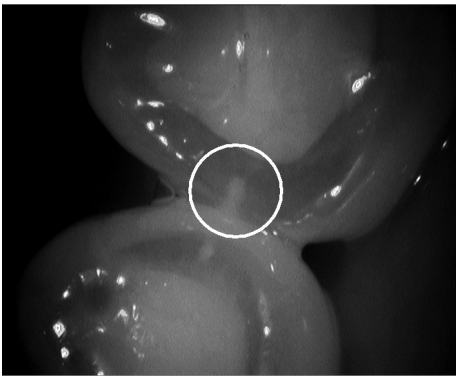


Figure 8: Enamel lesions on the mesial surface can be seen as wedge-shaped structures within the dark translucent tooth enamel. The lesions reach to the inner half of the enamel.

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

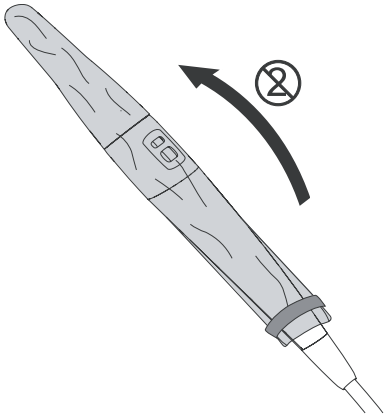
9.7 Switching off the camera

If the camera is not moved, it automatically switches itself off after the set stand-by time (preset 2 minutes).

Placing the camera in the handpiece holder, results in automatic switch-off.

Always store the camera with the interchangeable head plugged into the handpiece holder.

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



› Disinfect the camera (see "10.1 Clean and disinfect the handpiece and interchangeable head").
› Place the camera in the handpiece holder.

Result:

The camera switches off automatically.

10 Cleaning and disinfection

10.1 Clean and disinfect the handpiece and interchangeable head

NOTICE
Incorrect cleaning and disinfection can damage the unit

- 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.

› Wipe off the surface of the camera (handpiece with interchangeable head) with a disinfection wipe (e.g. FD 333 or FD 350).

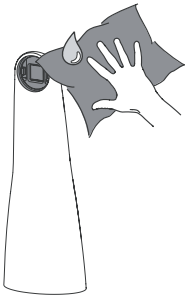
10.2 Cleaning the optical element

The optical element is located partly in the interchangeable head and partly in the handpiece.

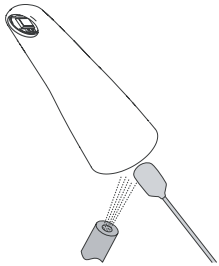
NOTICE
Damage of the optical element from incorrect cleaning

- Only use the cleaning set for VistaCam optical element. Disinfectant residues soil the optical element.

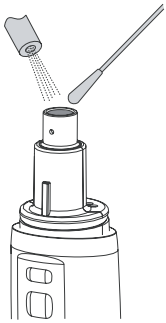
› Clean the window of the optical window of the interchangeable head from outside using the microfibre cloth with a drop of VistaCam optical element cleaner or alcohol.



› 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).



› Dry clean the lens in the handpiece with compressed air or with a cotton bud (from the cleaning set).



10.3 Reprocessing the spacer

The following instructions have been validated by Dürr Dental in order to prepare the product for reuse.

Reprocessing procedure:

1. Cleaning and disinfecting (automatic or manual)
2. Sterilising in the steam steriliser

The person performing the reprocessing is responsible for ensuring that the reprocessing carried out with the utilised equipment, materials and personnel achieve the desired results. Given any deviation from the validated reprocessing, the person performing the reprocessing is responsible for the effectiveness and for any potential adverse consequences of the reprocessing.

› Carry out the validation and routine monitoring of the reprocessing process.

› Follow the applicable national regulations during cleaning, disinfection, sterilisation and storage.

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Automatic cleaning and disinfecting

Use cleaning and disinfecting equipment in accordance with the manufacturer's instructions.

› Remove heavy soiling with a disposable disinfection wipe (e.g. FD 350).
› Place the product in the unit in such a way that it is rinsed thoroughly and the water can run off.
› Carry out the cleaning and disinfection cycle in accordance with the manufacturer's instructions.
› After the end of the cleaning and disinfection cycle, check the product for any remaining soiling. If necessary, repeat the cycle.

Manually clean and disinfect using the wet chemical process

When manually cleaning using the wet chemical process, use a VAH/DGHM listed disinfectant. Comply with the reaction times stated in the disinfectant manufacturer information.

› Remove heavy soiling with a disposable disinfection wipe (e.g. FD 350).
› Immerse the product in an instrument disinfection and cleaning solution (e. g. ID 212, ID 212 forte, ID 213).
› After the end of the cleaning and disinfection cycle, check the product for any remaining soiling. If necessary, repeat the cycle.
› Rinse parts thoroughly with water.
› Dry the spacer with hygienically clean disposable wipes or with compressed air.

Steam sterilising

WARNING
Incorrect sterilisation reduces effectiveness and can damage the product.
› Only steam sterilisation is permitted.
› Comply with the specified process parameters.
› Do not use any other methods.

Process parameters
Temperature: 134 °C
Gauge pressure above that of environment: 2.16 bar / 0.216 MPa
Holding time: 5 min

› Parts for sterilisation must be sterilised before each use in a small steam steriliser according to EN 13060 with a type B sterilisation cycle and final drying.
› Comply with the manufacturer information regarding usage of the steam steriliser and the correct placement of parts for sterilisation.
› Comply with all national and local guidelines and standards regarding the sterilisation of medical devices.

Storage

› Store the product protected against contamination.

10.4 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

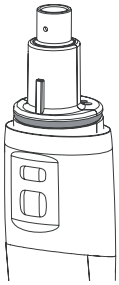
› Clean the surface of the storage box and the shelf with a dampened, soft, lint-free cloth.
› Disinfect the storage box with spray disinfectant on a soft, lint-free cloth. Comply with the operating instructions for the disinfectant when doing this.
› Disinfect the shelf using a disinfection wipe.

11 Maintenance

11.1 Replace the O-ring

If the interchangeable head does not engage properly when placed on, the O-ring on the handpiece can be replaced.

› Replace the O-ring.



11.2 Firmware update

Do not break the connection between the unit and computer while updating the firmware.

› Click on *Select firmware file*.

Result:

The firmware is updated. The process can take several minutes.

12 Tips for operators and service technicians

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Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.

Problem	Probable cause	Solution
Image cloudy, milky	Hygienic protective cover not placed correctly on the optical window	› Place the hygienic protective cover on the optical window correctly.
	Hygienic protective cover pulled on the wrong way round: do not place the transparent side on the optical window	› Pull on the hygienic protective cover correctly (see "9.2 Using the hygienic protective cover").
	Optical window soiled	› Clean the optical window (see "10.2 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 incorrectly lengthened	› Use the USB repeater or handpiece holder with USB hub to lengthen the connection cable, see "3.3 Special accessories".
	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.
	Interchangeable head not placed on correctly, no contact between the handpiece and the interchangeable head	› Ensure that the interchangeable head has been placed on to its fullest extent, no gap between the handpiece and the interchangeable head
		› Grease the o-ring with a little Vaseline, replace if necessary (see "11.1 Replace the O-ring")
The interchangeable head does not lock	Defective O-ring on the handpiece	› Replace the O-ring.
Moving image judders	Insufficient computing power	› Reduce the image resolution. › Use the computer in accordance with the system requirements (9000-618-148).

Problem	Probable cause	Solution
Camera is not detected by the software	USB driver not up to date	› Install the up-to-date USB driver.
Camera is not correctly detected by the software under Windows 7	Outdated chipset driver (especially for chipsets from Intel, type C216 or C220)	› Download and install the respective Windows 7 chipset driver from the manufacturer. (The correct driver is supplied for Windows 8 and higher)
The image is blurred	Resolution set incorrectly	› Working in *VistaConfig* > *Camera configuration* > *Settings* select a resolution with width-to-height ratio 4:3.

12.1 Proof interchangeable head

Problem	Probable cause	Solution
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.

12.2 Proxi interchangeable head

Problem	Probable cause	Solution
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 "10.2 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.

13 Information concerning EMC in accordance with IEC 60601-1-2

13.1 General information

This information contains excerpts from the international standards for electrical medical devices. It must be observed when installing Dürr Dental devices or combining them with products of other manufacturers. If you are uncertain about anything, please refer to the complete standard.

For details concerning electromagnetic compatibility, see "4 Technical data".

13.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
U_T	Rated voltage of the device (supply voltage)
V_1, V_2	Compliance level for the test in acc. with IEC 61000-4-6
E_1	Compliance level for the test in acc. with IEC61000-4-3
P	Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer
d	Recommended safety distance in metres (m)

13.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

The device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the device should ensure that the device is operated in such an environment.

EN

Interference emission measurements	Compliance	Electromagnetic environment - guidelines
HF emissions in accordance with CISPR 11	Group 1	The device uses HF energy exclusively for internal functions. As a result, HF-transmissions are very low and it is highly unlikely that any interference will be caused to neighbouring electronic devices.
HF emissions in accordance with CISPR 11	Group 2	The device needs to emit electromagnetic energy in order to perform its intended function. Neighbouring electronic devices could be affected.
HF emissions in accordance with CISPR 11	Class [A or B]	The device is suitable for use in all facilities including those in living areas and areas that are directly connected to the public mains electricity supply that also supplies buildings used for residential purposes.
Harmonics in acc. with IEC 61000-3-2	[Class A, B, C, D or Not Applicable]	
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	[Compliant or Not Applicable]	

Table 1: Electromagnetic emissions for all devices and systems

Resistance to electromagnetic interference (immunity) for all devices and systems

The device is designed for use in electromagnetic environments specified below. The customer or operator of the device should ensure that the device is operated such an environment.

Interference immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be made of wood or cement, or covered with ceramic tiles. If the floor is covered by synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage surge in accordance with IEC 61000-4-5	±1 kV voltage outer conductor/outer conductor ±2 kV voltage outer conductor/earth	±1 kV push-pull voltage ±2 kV common mode voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage in accordance with IEC 61000-4-11	0% U_T for 1/2 period 0% U_T for 1 period 70% U_T for 25/30 periods 0% U_T for 250/300 periods	< 5% U_T (> 95% drop in U_T) for 1/2 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the operator of the device needs the unit to continue working even if the mains power supply is interrupted, we recommend powering the device from an uninterruptible power supply (UPS) or from a battery.
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields at mains frequency should be within the range of typical values encountered in a commercial or hospital environment.

Table 2: Resistance to electromagnetic interference (immunity) for all devices and systems

Electromagnetic interference immunity for units or systems operated in healthcare facilities

Portable and mobile communication devices should not be used any closer to the unit (including cables) than the recommended safety distance, which is calculated based on the applicable formula for the transmission frequency.

EN

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ V	d = [3.5 / V_1] · √P d = 1.2 · √P
Emitted HF disturbance variables in accordance with IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	$[E_1]$ V/m	d = [3.5 / E_1] · √P for 80 MHz to 800 MHz d = 1.2 · √P for 80 MHz to 800 MHz d = [7 / E_1] · √P for 800 MHz to 2.7 GHz d = 2.3 · √P for 800 MHz to 2.7 GHz

Table 3: Electromagnetic interference immunity for units or systems that are operated in healthcare facilities

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

d Recommended safety distance in metres (m)

The field strength of stationary communication devices should be lower than the compliance level for all frequencies based on inspections on site[a].[b]

Interference is possible in the environment of units that have the following symbols.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic radiation is affected by absorption and reflection on the building, objects and people.

[a] The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters, for example, cannot be accurately predicted. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the unit is used exceeds the compliance levels stated above, the unit should be monitored to verify that it works as intended. If unusual performance characteristics are observed additional measures may be required, such as a changing the orientation of the unit or moving it to a different location.

[b] Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than $[V_1]$ V/m.

Test frequency (MHz)	Transmission frequency[a] (MHz)	Service	Modulation[b]	Max. performance (W)	Safety distance (m)	Compliance level (V/m)
385	380 - 390	TETRA 400	Impulse modulation[b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM[c] ±5 kHz fluctuation 1 kHz sinus	2	0.3	28
710	704 - 787	LTE band 13, 17	Impulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Impulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Impulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE band 7	Impulse modulation[b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11a/n	Impulse modulation[b] 217 Hz	0.2	0.3	9

Table 4: Test specifications for the interference immunity factor for units to mobile radios

[a] Some services only contain the uplink frequencies.

[b] The carrier frequency should be modulated with a square-wave signal with a 50% duty cycle.

[c] 50% pulse modulation with 18 Hz can be used as an alternative to FM modulation, even though it does not correspond to the actual modulation. This would be the worst case.

Recommended safety distance between portable and mobile HF communication devices and the unit

The device is designed for use in the electromagnetic environments specified below, in which the HF disturbance variables are controlled. The customer or the operator of the device can help to prevent electromagnetic interference by maintaining the minimum distances between mobile HF communication equipment (transmitters) and the device as recommended below in accordance with the maximum output line of the communication equipment.

EN

Keep a minimum distance of 30 cm between the device and mobile communication devices.

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 5: Recommended safety distance between portable and mobile HF communication devices and the unit

For transmitters whose maximum rated power is not specified in the table shown above, the recommended safety distance d in metres (m) can be determined from the formula that belongs to the respective column where P is the maximum rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection on the building, objects and people.

13.4 Calculation table

If the measured values deviate from the standard, the values are specified in chapter "4 Technical data".

The safety distances can then be calculated in the tables shown below.

P: .....

V_1: .....

E_1: .....

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

V_1 Compliance level for the test in acc. with IEC61000-4-6

E_1 Compliance level for the test in acc. with IEC61000-4-3

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distances
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	[V_1] V	d = [3.5 / V_1] · √P
Emitted HF disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	d = [3.5 / E_1] · √P for 80 MHz to 800 MHz
			d = [7 / E_1] · √P for 800 MHz to 2.5 GHz

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz d = [3.5/V_1] ·√P	80 MHz to 800 MHz d = [3.5/E_1]·√P	800 MHz to 2.5 GHz d = [7 / E_1] ·√P
0.01			
0.1			
1			
10			
100			

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