EN US

CamX Triton HD



Installation and Operating Instructions

Manufactured in Germany for





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Important information

1 Concerning this documentation

These Installation and Operating Instructions form an integral part of the unit. They correspond to the particular version of the unit and the technical standards valid at the time when it was sold.



Air Techniques cannot be held liable and cannot offer guarantees for safe and smooth operation of this unit if notes and instructions contained in these Installation and Operating Instructions are not observed.

1.1 Warnings and symbols

Warning notes

The warning notes in this document highlight possible injury to persons or damage to machinery.

They are marked with the following warning symbols:



General warning symbol

The warnings are structured as follows:



SIGNAL WORD

Description of type and source of danger

Here you will find the possible consequences of ignoring the warning

Measures to be taken to avoid the danger.

The signal word differentiates between different levels of danger:

- DANGER

Direct 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

Further symbols

These symbols are used within the documentation and on the appliance itself:



Notes, e.g. special instructions concerning economic use of the appliance.



Wear protective gloves.



CE mark



Application type BF



Observe the accompanying documentation



Take note of the accompanying electronic documents.



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



Single use only.

Rxonly US-FDA Regulated Medical Device



Sterilize at 250 °F



Serial number



Part number



1.2 Copyright and property rights information

All electronic drawings, processes, names, software, and appliances mentioned here are protected under copyright.

Printing or copying these Installation and Operating Instructions, including excerpts thereof, may only be carried out with the written approval of Air Techniques.

2 Safety

The unit has been developed and designed in such a way that dangers are effectively ruled out if used in accordance with the intended use. However, some hazards may remain. Please therefore observe the following notes.

2.1 Indication for use / Intended use

The camera handpiece of the CamX Triton HD can be used in combination with a variety of interchangeable heads. This enables different applications.

Possible applications:

- Cam interchangeable head:
 - The intraoral camera with Cam interchangeable head is inserted in or near to the oral cavity of the patient. The images support diagnosis, patient information and are used for instruction.
- Spectra interchangeable head:
 The intraoral camera with Spectra interchangeable head is intended to be used as an aid in the detection and diagnosis of dental caries.

The device is designed for use in healthcare facilities.

2.2 Contraindication



WARNING

Risk of explosion due to inflammation of combustible materials

Do not use the appliance in rooms in which combustible mixtures may be present, e.g. in operating rooms.



CAUTION

The light from the camera is very bright

Do not point the light directly into the eve.

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

2.3 General safety notes

US Federal law restricts this device to sale by or on the order of a dentist or licensed practitioner. This device should be used only under the continued supervision of a dentist or licensed practitioner.

Rxonly US-FDA Regulated Medical Device

- When operating the appliance, be sure to observe all local guidelines, laws, rules and regulations.
- > Before each use check the function and condition of the appliance.
- Do not convert or change the appliance in any way.
- Observe the Installation and Operating Instructions precisely.
- > Keep the Installation and Operating Instructions in an accessible place so that the operator has instant access to them.

2.4 Connecting appliances securely

Danger can arise when connecting appliances to each other or to parts of systems (e.g. through leakage currents).

- Only connect appliances together when there can be no danger to the operator or to the patient.
- > Only connect appliances when there can be no environmental impairment through such interconnection.
- If it is not clear from the appliance data sheets 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 relevant specifications of IEC 60601-1 (EN 60601-1) when connecting the appliance to other appliances,e.g. to a PC system, both inside as well as outside the vicinity of the patients.
- Only connect peripheral units (e. g. computer, monitor, printer) which conform to IEC 60950-1 (EN 60950-1) as a minimum standard.

2.5 Qualified personnel

Handling

Persons that operate the appliance are dentists and dental personnel.

As a result of their training and know-how, they must ensure safe and appropriate handling.

Each operator using the appliance must be trained in its handling.

Installation and repair

All installation, resetting, alteration, expansion, and repair work must be carried out either by Air Techniques personnel or by a suitably qualified person approved by Air Techniques.

2.6 Protection against electric shock

- When using the appliance, observe the relevant electrical safety procedures.
- Never touch the patient and open connectors/ contacts of the appliance simultaneously.
- Damaged supply lines and connecting devices must be replaced immediately.

Pay attention to the EMC for medical products

- Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medicinal products, see "14 Information concerning EMC in accordance with IEC 60601-1-2".
- As a result of electromagnetic radiation or ESD pulses, image artifacts can occur in the images or the device may experience a malfunction. If necessary, restart the device, software or computer.
- The appliance is designed for operation in healthcare facilities (in accordance with IEC 60601-1-2). If the appliance is operated in another environment, observe possible effects on the electromagnetic compatibility.
- Do not use the device near HF surgical devices and MRI equipment.
- > Keep a minimum distance of 11.8 inch between the device and other electronical devices.
- > Keep a minimum distance of 11.8 inch between the appliance and mobile radio devices.
- Note that cable lengths and cable extensions have effects on electromagnetic compatibility.



The following accessories can have an effect on electromagnetic compatibility:

Handpiece holder with USB hub J2560



NOTICE

Negative effects on the EMC due to non-authorized accessories

- Only Air Techniques accessories or accessories approved by Air Techniques may be used.
- If other accessories are used, observe any negative consequences to the function of the appliance.

2.7 Only use original parts

- Only Air Techniques accessories and special accessories or those approved by Air Techniques may be used.
- Only use original spare and replacement parts.



Air Techniques accepts no liability for damage resulting from the use of nonapproved accessories, special accessories or any parts other than original spare and replacement parts.

2.8 Transport

Only the original packaging ensures optimum protection for the unit during transport.

If necessary, the original packaging for this unit can be ordered from Air Techniques.



Air Techniques cannot be held responsible for any damage resulting from transport in unsuitable packaging, even during the warranty period.

- Only transport the unit in its original packaging.
- > Keep all packaging away from children.

2.9 Disposal

Appliance

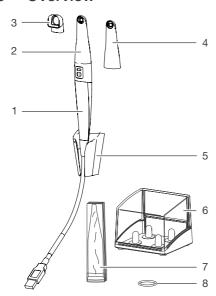


The unit must be properly disposed of. Within the European Union, the unit must be disposed of in accordance with EU Directive 2012/19/EU (WEEE).

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

Product description

3 Overview



- 1 Handpiece
- 2 Cam interchangeable head
- 3 Spacer
- 4 Spectra interchangeable head
- 5 Handpiece holder
- 6 Storage box for interchangeable heads
- 7 Disposable protective covers
- 8 O-ring

3.1 Scope of delivery

The following items are included in the scope of delivery:

CamX Triton HD with Cam and Spectra package......J2500

- Handpiece
- Cam interchangeable head
- Spectra interchangeable head
- Storage box for interchangeable heads
- Handpiece holder
- Disposable protective covers (20 pieces)
- Spacers (5 pieces)
- O-ring, 0.67 x 0.06 in (2 pieces)
- Microfiber cloth
- Quick reference quide
- Imaging software DVD
- Manuals CD

CamX Triton HD with Cam package... J2600

- Handpiece
- Cam interchangeable head
- Storage box for interchangeable heads
- Handpiece holder
- Disposable protective covers (20 pieces)
- O-ring, 0.67 x 0.06 in (2 pieces)
- Microfiber cloth
- Quick reference guide
- Imaging software DVD
- Manuals CD

3.2 Accessories

The following articles are necessary to operate the appliance (depending on particular application):

tion).		
	Part no.	As sold
Cam interchangeable head for CamX Triton HD	J2610	non sterile
Spectra interchange- able head for CamX Triton HD	J2710	non sterile
Handpiece holder for CamX Triton HD	J2540	non sterile
Storage box for inter- changeable heads	J2550	non sterile
Spacer (5 pieces)	J2720	non sterile, to be steril- ized by user*
Spacer (25 pieces)	J2721	non sterile, to be steril- ized by user*

^{*}spacer is reusable, must be sterilized before use (see "11.3 Preparing the spacer").

3.3 Special accessories

The following items can be optionally used with the unit:

Handpiece holder with USB hub	J2560
USB repeater 15.75 ft	J2060
DBSWIN imaging software DVD	E7200
Microfiber cloth	J2050

3.4 Disposable materials

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

Disposable protective covers	
(500 pieces)	 J2530
Disposable protective covers	
(100 pieces)	 J2525
Disposable protective covers	

3.5 Disposable parts and spare parts

(20 pieces) . .



4 Technical data

4.1 Handpiece

Electrical data			
Voltage	V DC	4.75 - 5.25	
Signal output		USB 2.0	
Type of protection		IP20	
Protection class	A	pplied part Type BF	
Operating mode*		T1/T2 = 27%	
		1.5 min / 5.5 min	
	(s	switch-on/-off time)	

^{*} At an ambient temperature of max. 104 °F and while observing the switch-on/off time, the hand-piece reaches a maximum surface temperature of 140 °F.

Classification	
Medical device (IEC 60601-1)	Class I
Medical device (FDA)	Class I

Electromagnetic compatibility (EMC)* Interference emission measurements	
HF emissions in accordance with CIS-	Group 1
PR 11	Class B
Harmonic oscillations in accordance with	
IEC 61000-3-2	Not applicable
Voltage fluctuations/flicker in accordance	
with IEC 61000-3-3	Not applicable

Electromagnetic compatibility (EMC)* Interference immunity tests	
Discharge of static electricity 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 variables in accordance with IEC 61000-4-3	Fulfilled

^{*}See also "14 Information concerning EMC in accordance with IEC 60601-1-2" $\,$

Camera electronics		
Image sensor		1/3" CMOS
Number of pixel sensor	MPixel	1,37
Effective image resolution on PC display (PC)		1280 x 1024
Video codec		Motion JPG
Brightness control		automatic
White balance		permanently set



Dimensions and weights Handpiece with Cam interchangeable head			
Length	in	7.87	
Diameter	in	0.94	
Weight with cable	OZ	6.7	
Weight without cable	OZ	2.47	
Cable length	ft	8.2	

4.2 Cam interchangeable head

Technical data		
Illumination	2	LEDs, white light
Wavelength	nm	400 - 780
Irradiance	W/m²	0.8
Focus level	in	0.04 - ∞
Focus level, preset	in	0.67
Opening angle		64°
Protection class		Applied part type BF

Classification	
Medical device (IEC 60601-1)	Class I
Medical device (FDA)	Class I

4.3 Spectra interchangeable head

Technical data		
Illumination		2 LEDs
Wavelength	nm	380 - 460
Dominant wavelength	nm	405
Irradiance	W/m²	0.5
Focus level	in	0.04 - ∞
Focus level, preset	in	0.31
Opening angle		64°
Protection class		Applied part type BF

Classification	
Medical device (IEC 60601-1)	Class I
Medical device (FDA)	Class II

4.4 Handpiece holder with USB hub (optional)

Electrical data			
Nominal voltage	V DC	12	
General technical data			
Dimensions (W x Hx D)	in	2.28 x 3.27 x 4.84	
Weight	OZ	6.7	

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

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

Group 1 Class B
Not applicable
Conforms completely

Electromagnetic compatibility (EMC)* Interference immunity tests	
Discharge of static electricity in accordance with IEC 61000-4-2	Fulfilled
Quick transient electric disturbance variables/bursts in accordance with IEC 61000-4-4	Fulfilled
Surges in accordance with IEC 61000-4-5	Fulfilled
Voltage dips, short interruptions and supply 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 variables in accordance with IEC 61000-4-3	Fulfilled

^{*}See also "14 Information concerning EMC in accordance with IEC 60601-1-2"

Connection cable		
Cable length	ft	8.2



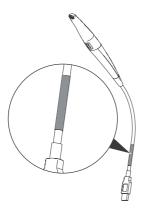
4.5 Ambient conditions

Ambient conditions during operation			
Temperature	°F	50 to 104	
Rel. humidity	%	20 to max. 75	
Air pressure	inHg	20.67 - 31.30	
Ambient conditions for storage and transport			
Temperature	°F	-13 to +158	
Rel. humidity	%	10 - 95	
Air pressure	inHg	20.67 - 31.30	

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4.6 Model identification plate

The model identification plate is located on the cable:



4.7 Evaluation of conformity

This equipment has undergone a test of conformity as prescribed under the relevant European Union directive. This equipment conforms to all requirements.

5 Function

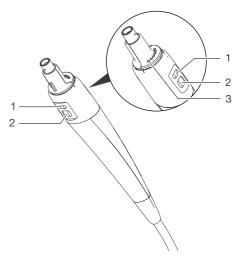
The intraoral camera consists of a handpiece and various interchangeable heads. The function of the camera depends on the function of the interchangeable head. The interchangeable head is recognizable from the symbol on the rear.



Cam interchangeable head Intraoral imaging

Spectra
interchangeable
head

Intraoral images for the detection of caries, plaque and tartar



- Focus button
- 2 Capture 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.

On each side of the handpiece there are two buttons: the focus button and the capture button. The pressure point of the buttons is noticeable.

The focus button is used to focus the camera sharply on the object. If the Spectra interchangeable head is put on, the focal plane is preset on the spacer 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 depends on 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. Releasing 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 digitizes 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. To run the camera an imaging software is necessary. The Spectra interchangeable head require imaging software from Air Techniques or a TWAIN compatible imaging software.

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

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

5.1 Cam interchangeable head



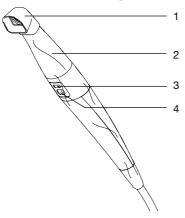
- 1 Optical system
- 2 LED
- 3 LED

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. Positioned around the optical element are two LEDs that ensure uniform illumination.



Figure 1: Recording with Cam interchangeable head

5.2 Spectra interchangeable head



- 1 Spacer
- 2 Interchangeable head
- 3 Focus button
- 4 Capture button

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

Positioned around the optical element are two LEDs with blue/violet light (wavelength 405 nm). The energy rich light causes the tooth structure (tooth enamel, dentin) and the metabolites of cariogenic bacteria (porphyrins) to fluoresce. The substances emit different colors (intrinsic biofluorescence). This makes it possible to analyze caries activity and detect potential tooth disease.

Substance	Color of intrinsic bio-fluorescence
Tooth structure (tooth enamel, dentine)	Green
Metabolites of cariogenic bacteria (porphyrins)	Red

The spacer enables optimum analyzable images. The position and the distance of the image are reproducible. In addition, the spacer screens off the image area and minimizes the penetration of external light.

Application areas of the Spectra interchangeable head:

- Detecting plaque and tartar
- 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 excava-
- Checking, documenting and archiving the progress of dental illnesses in the imaging software.

Analysis

The images are analyzed by the imaging software with the help of a filter.

The prophylaxis view shows the original image.

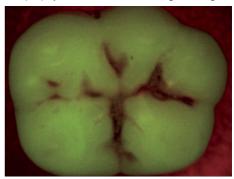


Figure 2: Prophylaxis view

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

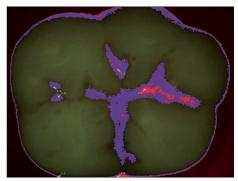
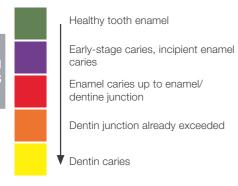


Figure 3: Caries view

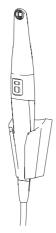


The color scale provides information on carious lesions:



Use gold standard techniques to examine for potential caries.

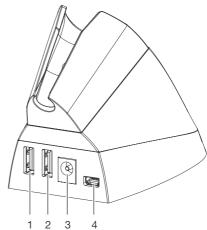
5.3 Handpiece holder



If the camera is placed in the handpiece holder, it is automatically switched off. When the camera is taken out, it automatically switches on.

5.4 Handpiece holder with USB hub (optional)

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

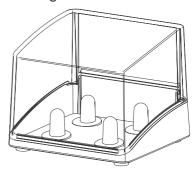


- 1 USB connection (for camera or USB stick)
- 2 USB connection (for camera or USB stick)
- 3 Connection for power unit
- 4 Micro USB connection for computer

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

If the camera is placed in the handpiece holder, it is automatically switched off. When the camera is taken out, it automatically switches on.

5.5 Storage box



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



6 System requirements

CPU:	≥ Intel Core i3
RAM:	≥ 4 GB
Operating systems:	Microsoft Windows 7, 32-bit (Home Premium and higher) Microsoft Windows 7, 64-bit (Home Premium and higher)
	Microsoft Windows 8, 64-bit (not Windows RT)
	Microsoft Windows 10, 64-bit (Pro and higher), compatible with DBSWIN version 5.10 or higher
	Microsoft Windows Server 2012
Hard disk:	Workstation (without database) ≥ 50 GB
	The database memory requirements depend on the number of images taken at the surgery in question. (Camera image: approx. 1 MB / X-ray image: approx. 2 MB - 10 MB)
Drive:	DVD-ROM
Interface:	USB 2.0 USB 3.0
Graphics card:	Resolution ≥ 1280 x 1024 Depth of colour 32-bit, 16.7 million colours
Total maximum	Up to 5 m with USB extension cable
cable length:	Up to 20 m with additional USB repeater / active USB hub (max. 5 m each) - details available on request
Software:	DBSWIN version 5.9 or higher, VistaEasy, Image Bridge

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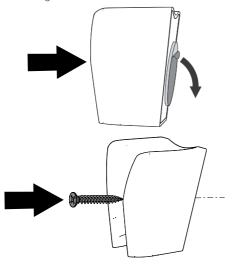
7 Installation

7.1 Assembling the handpiece holder

The handpiece holder can be attached using the adhesive or screws.

- > Use suitable mounting materials.
- Mount the handpiece holder near to where the handpiece will be used.

The length of the USB cable is 8.2 ft.



8 Initial start-up



NOTICE

Short circuit due to build up of condensation

Do not put the appliance into operation until it has warmed up to room temperature and it is dry.

The unit supports the following imaging programs:

- DBSWIN
- VistaEasy
- ImageBridge
- TWAIN compliant third party dental imaging softwares on request

8.1 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. Therefore, it is important 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 in a USB connection socket of the computer.
- If the USB cable is to be extended, use a USB repeater (order number J2060) or handpiece holder with USB hub (J2560).

8.2 Configuring the unit in DBSWIN

- > Start DBSWIN.
- > In the menu select Options > Show Configuration.

The Configuration tab opens.

- > Click on the Modules Nutton.
- > Double click on Video.

The Video Properties window opens.

- > Choose the tab Video source 1.
- In Control method select the camera CamX Triton HD.

The following settings can be made:

Video source

WDM driver

The WDM driver is selected automatically.

tion

Noise reduc- If noise reduction is activated, the set number of images are recorded for each recording. A new image is calculated from these images where interferences are compensated to the greatest possible extent.

Capture ring **Function**

Time when the image is created if a capture button is pressed:

- Trigger function on release (default)
- Trigger function on press

Settings

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

8.3 Configuring the device in Vista-Config for VistaEasy

Start VistaConfig via Start > All Programs > Air Techniques > VistaEasy > VistaConfig.

The camera is detected and activated automatically.

The Settings tab opens. The following settings can be made:

Display

Resolution The resolution of the camera

image can be selected

Interlaced Full screen view (default)

Driver

WDM driver

The WDM driver is selected

automatically.

Pressure sensitive release

Function

The function of the capture buttons can be selected.

Record + Pause is default.

Trigger event

Time when the image is created if the capture button

is pressed:

- By pressing

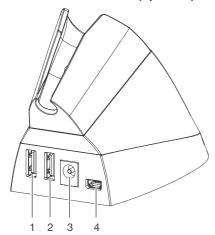
By releasing (default)

To change the configuration, click on .





8.4 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 unit
- 4 USB connection for computer

Prerequisite:

- Rated current to conform with the information on the model identification plate on the power unit
- > Connect the power unit to the connection socket on the handpiece holder.
- > Now connect the plug to the socket-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.

9 Acceptance tests

9.1 Electrical safety check

- Carry out an electrical safety check according to all national regulations.
- Document the results.



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



10 Handling



NOTICE

Damage to the camera by dropping or scratching

- Always store the camera in the handpiece holder.
- Do not place the camera on a storage surface.
- > Do not place the camera between other instruments.

10.1 Changing the interchangeable head

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



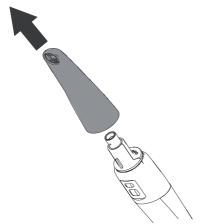
Cam interchangeable head



Spectra interchangeable head

Removing the interchangeable head

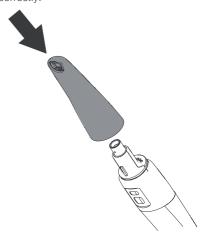
> Pull the interchangeable head off the handpiece upwards.



Attaching the interchangeable head

Prerequisite:

- 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 can only be placed on correctly.



10.2 Using the disposable protective cover



WARNING

There is a danger of cross-contamination when disposable protective covers are not used or are used more than once

- > Do not use the appliance without fitting a disposable protective cover.
- > Do not use the disposable protective cover more than once (disposable

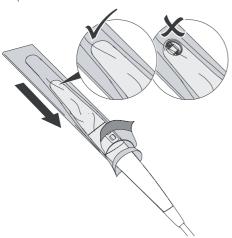


Do not use the disposable protective cover more than once (disposable item).



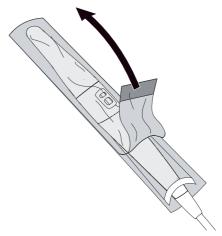
When fitting the disposable protective cover, wear protective gloves.

- > Hold the camera so that the optical element is facing down.
- > Lift the white edge of the disposable protective cover and slide the camera head into the cover. The transparent plastic side must face upwards.

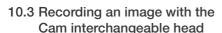


- > Stretch the disposable protective cover approximately an extra 1/8 of an inch so that the cover presses tightly against the optical ele-
- > Carefully press the disposable protective cover against the window of the optical element itself with your fingertips. Make sure there are no air bubbles between the window of the optical element itself and the disposable protective cover.

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



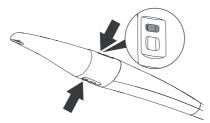
> Pull off the paper underside from the camera head in the direction of the handpiece.



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

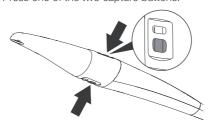
Prerequisites:

- 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 capture 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 capture button again.
- Edit and save the image/video in the imaging software. (For further information, see the software help.)

10.4 Recording an image with the Spectra interchangeable head

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



Prophylaxis view

This provides an informative overview on 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 colors.

The following factors can affect the fluorescence and hence the caries analysis:

- Soiling and remains of food
- Tartar, concrement
- Aid for staining plaque
- Prophylaxis/fluoride pastes
- Tooth/polishing pastes

Preparation

Depending on the favored analysis, the teeth must be prepared differently.

For prophylaxis view:

> Do **not** carry out professional teeth cleaning.

For caries view:

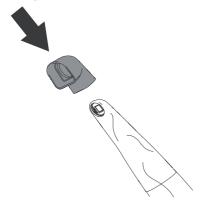
- > Carry out professional teeth cleaning.
- > Remove prophy paste using the air-water spray.
- > Dry the teeth.

Putting on the spacer



WARNING

- Danger of cross-contamination when used without preparation or following incorrect preparation
- Sterilize the spacer in the steam sterilizer (see "11.3 Preparing the spacer") before each use.
- Place the spacer onto the interchangeable head from above. Make sure that the spacer does not cover the optical element of the interchangeable head.



Taking a picture



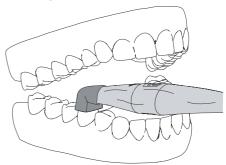
CAUTION The blue-violet LED light

- > Do not peer into the light source.
- Do not use or point the camera directly at the eyes.

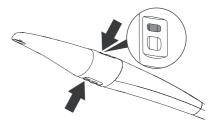
Prerequisites:

- 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 onto the corresponding tooth.

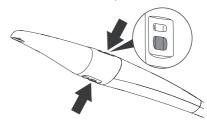


If the image is not sharp, press one of the two focus buttons.



The camera focuses.

> Press one of the two capture 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.)
- Analyze the image (see "Analysis").
- To switch back to Live mode, press the capture button again.

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Analysis

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



Figure 4: Prophylaxis view

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

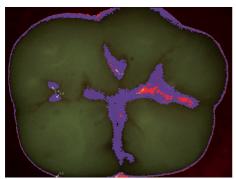


Figure 5: Caries view

The color scale provides information on carious lesions:



Use gold standard techniques to examine for potential caries.

10.5 Switching off the camera

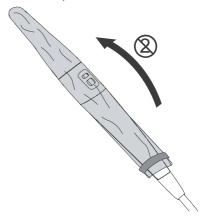
If the camera is not moved, it automatically switches itself off after the set stand-by time (preset 2 minutes).

When the camera is placed in the handpiece holder, it is immediately switched off.



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

> Carefully pull off the disposable protective cover and dispose of it.



- Disinfect the camera (see "11.1 Clean and disinfect the handpiece and interchangeable head").
- > Place the camera in the handpiece holder. Result:

The camera switches off automatically.

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11 Disinfection and cleaning



NOTICE

Unsuitable agents and methods can damage the device and accessories

Using non-approved chemicals may dearade the finish of the unit surface.

- Only use the disinfection and cleaning agents specified or approved by Air Techniques.
- Observe the instructions for use of the disinfection and cleaning agents.

For cleaning and disinfecting CamX products, Air Techniques recommends Monarch disinfecting wipes. For a full list of approved cleaning chemicals, contact Air Techniques.

11.1 Clean and disinfect the handpiece and interchangeable head



NOTICE

The wrong cleaning and disinfection can damage the camera

- > Only clean the surface of the camera.
- Do not use any aggressive or abrasive cleaning agents.
- Only use disinfectant wipes to clean the camera.
- Do not clean the camera by submerging in or spraying with disinfectant.
- > Do not put the camera in an autoclave.



The disposable protective cover must be used for only one patient and disposed of properly in accordance with locale code.



Unplug camera components before performing cleaning.

Wipe the surface of the camera with an EPA registered surface dinsinfectant.

11.2 Cleaning the camera lens

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



NOTICE

Damage of the optical element from incorrect cleaning

Residues of disinfectant will contaminate the optical element.

- Clean the window of the optic using the provided microfiber cloth, cotton buds and alcohol.
- Clean the window of the optic itself of the interchangeable head from outside using the microfiber cloth with a drop of alcohol.



If particles can still be seen on the image, dry clean the interchangeable head from the inside with compressed air or with a cotton bud.



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> Dry clean the lens in the handpiece with compressed air or with a cotton bud.



11.3 Preparing the spacer

The following instructions are verified as suitable for preparing the product for further use. Preparation process:

Sterilization in steam sterilizer

The person responsible for preparation must ensure that the process and the equipment, materials, and personnel used achieve the required results. If there is any deviation from the validated preparation process, the person responsible for the preparation is responsible for the effectiveness of the process and for any adverse consequences.

- > Carry out validations and routine monitoring of the preparation process.
- > Observe any national and local regulations that apply to the cleaning, disinfection, sterilization and storage.

Steam sterilization



WARNING

Incorrect sterilization inhibits the effectiveness, and can damage the product

- > Only use steam sterilization.
- Observe the process parameters.
- > Do not use any other process.

Process parameters

250 °F

Sterilizer type: Gravity

Minimum temperature: 250 °F

Exposure time: 30 min Dry time: 20 min



Wear protective gloves.

> Steam sterilize the spacer in a gravity steam sterilizer at 250 °F for 30 minutes and dry time of 20 minutes before use.

Use a new replacement spacer as needed.

Storage

- > Store the product protected against contamination.
- After sterilization, store the parts in a sterilization packaging cleared by FDA under 21 CFR 880.6850 product code FRG.
- > Shelf life is determined and identified per instruction for use of sterilization packaging used.

12 Maintenance

12.1 Replacing the o-ring

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

> Replacing the O-ring.



Troubleshooting

13 Tips for operators and service technicians

(i)

Repairs, above and beyond standard maintenance, may only be carried out by a suitably qualified technician or one of our service technicians.

Problem	Probable cause	Solution
Image cloudy, milky	Disposable protective cover not placed correctly on the window of the optic itself	Place the disposable protective cover correctly on the window of the optic itself.
	Disposable protective cover pulled on the wrong way round: Do not turn the transparent side towards the window of the optic itself	> Pull on the disposable protective cover correctly (see "10.2 Using the disposable protective cover").
	Window of the optic itself soiled	> Clean the window of the optic itself (see "11.2 Cleaning the camera lens").
	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 for lengthening the connection cable, see "8.4 Connect the handpiece holder with the USB hub (optional)".
	Computer not switched on, soft- ware not started	> Switch on the computer and start the software.
	Camera driver not correctly installed	Check the driver installation and software settings.
	Interchangeable head is not completely attached, no contact between handpiece and interchangeable head	> Pay attention that the inter- changeable head is slid on as far as possible, no gap between handpiece and interchangeable head
		> Grease the o-ring with very little petrolatum, replace it if necessary (see "12.1 Replacing the o-ring").



Problem	Probable cause	Solution
Moving image judders	Computing power of the computer too low	 Reduce the image resolution. Use the computer in accordance with the system requirements (E7201).
Camera is not detected by the software	USB driver not up to date	> Install an 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)
Interchangeable head not engaging	Defective O-ring on the hand- piece	> Replace the O-ring.
Image is shown distorted	Wrong resolution settings	> Choose an aspect ratio of 4:3 in VistaConfig > Video proper- ties> Display

13.1 Spectra 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.



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

14.1 General information

This information contains excerpts from the international standards for electrical, medical appliances. It must be observed during the installation and combination of Air Techniques appliances with products made by other manufacturers. In the event of uncertainties, the complete standard must be consulted.

14.2 Abbreviations

EMC Electromagnetic compatibility

HF High frequency

U_τ Rated voltage of the appliance (supply voltage)

V₁, V₂ Compliance level for the test according to IEC 61000-4-6 E₁ Compliance level for the test according to IEC 61000-4-3

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

transmitter manufacturer

d Recommended safety distance in meters (m)



14.3 Guidelines and manufacturer declaration

Electromagnetic emissions for all appliances and systems

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

Interference emission measurements	Compli- ance	Electromagnetic environment - guidelines
HF emissions in accordance with CISPR 11	Group 1	The appliance uses HF energy exclusively for its internal function. Its HF emissions are therefore very low and unlikely to interfere with nearby electronic appliances.
HF emissions in accordance with CISPR 11	Group 2	The appliance must emit electromagnetic energy in order to guarantee its intended function. Nearby electronic appliances may be influenced.
HF emissions in accordance with CISPR 11	Class [A or B]	
Harmonic oscillations in accordance with IEC 61000-3-2	[Class A, B, C, D or not applicable]	The appliance is suitable for use in all facilities including
Voltage fluctuations/flicker in accordance with IEC 61000-3-3	[Complies or not applica-ble]	those in the living area and areas that are directly con- nected to the public mains electricity supply that also supplies buildings used for living purposes.

Table 1: Electromagnetic emissions for all appliances and systems



Electromagnetic interference immunity factor for all appliances and systems

The appliance is designed for operation in the electromagnetic environments specified below. The customer or operator of the appliance should ensure that the appliance is operated in such environ-

Interference immunity tests	IEC 60601 – test level	Compliance level	Electromagnetic environment – guidelines
Static electricity discharge (ESD) in accordance 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 with synthetic material, the relative humidity must be at least 30 %.
Quick transient elec- tric disturbance vari- ables/bursts in ac- cordance with IEC 61000-4-4	±2 kV for mains lines ±1 kV for input and output lines	±2 kV for mains lines ±1 kV for input and output lines	The quality of the supply voltage should correspond to a typical business or hospital environment.
Surges in accordance with IEC 61000-4-5	±1 kV voltage (outer conductor/outer conductor) ±2 kV voltage (outer conductor/earth)	±1 kV (differential mode) ±2 kV (common mode)	The quality of the supply voltage should correspond to a typical business or hospital environment.
Voltage dips, short- term interruptions and fluctuations of the supply voltage in accordance with IEC 61000-4-11	0 % $\rm U_T$ for 1/2 period 0 % $\rm U_T$ for 1 period 70 % $\rm U_T$ for 25/30 periods 0 % $\rm U_T$ for 250/300 periods	$<5~\%~U_{T}~(>95~\%)$ dip of the U_{T}) for 1/2 period 40 % U_{T} (60 % dip of the U_{T}) for 5 periods 70 % U_{T} (30 % dip of the U_{T}) for 25 periods $<5~\%~U_{T}~(>95~\%)$ dip of the U_{T}) for 5 s	The quality of the supply voltage should correspond to a typical business or hospital environment. If the operator of the appliance also requires further functions for the occurrence of interruptions of the energy supply, it is recommended to feed the appliance from an interruption-free power supply or a battery.
Magnetic field for a supply frequency (50/60 Hz) in accor- dance with IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields in the electrical frequency should correspond to the typical values, as can be found in the business and hospital environment.

Table 2: Electromagnetic interference immunity factor for all appliances and systems



Electromagnetic interference immunity factor for appliances or systems that are operated in healthcare facilities

Mobile radios should not be used closer to the unit (including the lines) than the recommended safety distance that is calculated according to the formula that applies to the transmission frequency.

Interference immunity tests	IEC 60601 – test level	Compliance level	Recommended safety distance
Conducted HF disturbance vari- ables in accor- dance with IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	[V ₁] V	$d = [3.5 / V_1] \cdot \sqrt{P}$ $d = 1.2 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3		[E₁] V/m	d = $[3.5 / E_1] \cdot \sqrt{P}$ for 80 MHz to 800 MHz d = 1.2 · \sqrt{P} for 80 MHz to 800 MHz d = $[7 / E_1] \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz d = 2.3 · \sqrt{P} for 800 MHz to 2.7 GHz

Table 3: Electromagnetic interference immunity factor for appliances 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 meters (m)



The field strength of stationary radio transmitters for all frequencies should be lower than the compliance level $^{\rm p}$ in accordance with inspections on-site $^{\rm a}$

Interferences are possible in the vicinity of appliances that have the following symbols.

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

Note 2: These guidelines may not apply in all cases. The spreading of electromagnetic

field sizes is influenced by absorptions and reflections of the building, objects

and people.

^a The field strength of stationary transmitters, such as the base stations of mobile phones and mobile landline wireless devices, amateur radio stations, AM and FM radio and television broadcasters, cannot be predicted theoretically with accuracy. To determine the electromagnetic environment with regard to stationary transmitters, a study of the electromagnetic phenomena of the location should be considered. If the measured field strength at the location where the unit is used exceeds the compliance level mentioned above, the unit should be observed to verify the intended function. If unusual performance characteristics are observed, additional measures may be required, such as a changed alignment or relocation of the unit.

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

Test frequency (MHz)	Transmis- sion fre- quency ^a (MHz)	Service	Modula- tion ^b	Max. per- formance (W)	Safety distance (m)	Compli- ance 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° ±5 kHz fluc- tuation 1 kHz sinus	2	0.3	28
710 745 780	704-787	LTE band 13, 17	Impulse modulation ^b 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Impulse modulation ^b 18 Hz	2	0.3	28
1720 1845 1970	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
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 appliances to mobile radios

^a For some services, only the uplink frequencies are contained.

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

 $^{^{\}circ}$ As an alternative to the FM modulation, 50 % pulse modulation with 18 Hz can be used, even though it does not correspond to the actual modulation. This would be the worst case.



Recommended safety distances between mobile HF communication appliances and the appliance

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



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

Rated power of the transmitter (W)	Safety distance depending on the transmission frequency (m)			
	150 kHz to 80 MHz d = 1.2 \cdot VP	80 MHz to 800 MHz d = $1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz d = 2.3 ·√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 distances between mobile HF communication appliances and the appliance

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

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

Note 2: These guidelines may not apply in all cases. The spreading of electromagnetic

waves is influenced by absorptions and reflections of the buildings, objects and

humans.

14.4 Calculation table

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

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

P: V₁: E₁:

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

V₁ Compliance level for the test according to IEC 61000-4-6 E, Compliance level for the test according to IEC 61000-4-3

Interference im- munity 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	$d = [3.5 / V_1] \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E₁] V/m	d = $[3.5 / E_1] \cdot \sqrt{P}$ for 80 MHz to 800 MHz d = $[7 / E_1] \cdot \sqrt{P}$ for 800 MHz to 2.5 GHz

Rated power of the	Safety distance depending on the transmission frequency (m)				
transmitter (W)	150 kHz to 80 MHz $d = [3.5 / V_1] \cdot \sqrt{P}$	80 MHz to 800 MHz d = $[3.5 / E_1] \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = [7 / E_1] \cdot \sqrt{P}$		
0.01					
0.1					
1					
10					
100					

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