CamX Triton HD

EN-US Installation and Operating Instructions

Rx Only

CE

AIR TECHNIQUES equipped for life®

2109100018L29 J2505 2301V012

Contents

Important information

1 About this document 3
1.1 Warnings and symbols 3
1.2 Copyright information 4

2 Safety 4
2.1 CE certification 4
2.2 FDA registration 5
2.3 General safety information 6
2.4 Combining devices safely 6
2.5 Specialist personnel 6
2.6 Protection from electric shock . . 6
2.7 Essential performance characteristics 7
2.8 Notification requirement of serious incidents 7
2.9 Only use genuine parts 7
2.10 Transport 7
2.11 Disposal 7

Product description

3 Overview 8
3.1 Scope of delivery 8
3.2 Accessories 9
3.3 Optional items 9
3.4 Consumables 9
3.5 Wear parts and spare parts 9

4 Technical data 10
4.1 Handpiece 10
4.2 Cam interchangeable head 11
4.3 Spectra interchangeable head . . 11
4.4 Proxi interchangeable head 12
4.5 Handpiece holder with USB hub (optional) 13
4.6 Ambient conditions 14
4.7 Model identification plate 15
4.8 Conformity assessment 15

5 Function 16
5.1 Cam interchangeable head 17
5.2 Spectra interchangeable head . . 18
5.3 Proxi interchangeable head 20
5.4 Handpiece holder 21
5.5 Handpiece holder with USB hub (optional) 21
5.6 Storage box 21

Installation

6 System requirements 22

7 Installation 23
7.1 Assembling the handpiece holder 23

8 Commissioning and first start-up . . . 23
8.1 Installing the unit 23
8.2 Configuring the unit in VisionX . . 23
8.3 Configuring the unit in DBSWIN . 24
8.4 Configuring the device in VistaConfig for VistaEasy 25
8.5 Connect the handpiece holder with the USB hub (optional) 25

9 Commissioning tests 26
9.1 Electrical safety checks 26
9.2 Handover record 26

Usage

10 Operation 27
10.1 Changing the interchangeable head 27
10.2 Use the hygienic protective cover 28
10.3 Recording an image with the Cam interchangeable head 29
10.4 Recording an image with the Spectra interchangeable head . . 29
10.5 Recording an image with the Proxi interchangeable head 32
10.6 Switching off the camera 34

11 Reprocessing of the device 35
11.1 Risk analysis and classification . 35

11.2 Reprocessing procedures 35
11.3 Preparation at the operating location 36
11.4 Manual cleaning, disinfection and drying 36
12 Reprocessing the spacer 37
12.1 Risk analysis and classification . 37
12.2 Reprocessing procedures 37
12.3 Preparation at the operating location 38
12.4 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying 39
12.5 Steam sterilization 40
12.6 Storage 40
13 Cleaning 40
13.1 Cleaning the camera lens 40
14 Maintenance 41
14.1 Replacing the o-ring 41

Troubleshooting

15 Tips for operators and service technicians 42
15.1 Spectra interchangeable head . . 43
15.2 Proxi interchangeable head 43

Appendix

16 Handover record 45

Important information

1 About this document

These installation and operating instructions are an integral part of the unit.

Air Techniques shall not be held liable and offers no guarantees of the safe and smooth operation of this unit if you fail to comply with notes and instructions contained in these Installation and Operating Instructions.

The German version of the installation and operating instructions is the original manual. All other languages are translations of the original manual. These operating instructions apply to CamX Triton HD:
Order number:
- J2500 (2109300001)
- J2600 (2109300002)
- J2700 (2109300004)
- J2900 (2109300005)

1.1 Warnings and symbols

Warnings

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

› Follow these measures 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

Miscellaneous symbols

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


Note, e.g. specific instructions regarding the efficient use of the unit.


Refer to Operating Instructions.


Wear hand protection.


Wear eye protection.


Use a face mask.


Wear protective clothing.


Manufacturer


Date of manufacture


CE mark


Type BF applied part


Take note of the accompanying electronic documents.


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


Do not reuse

Rx Only	Caution: By virtue of Federal Law, the device may only be sold to dentists or bought on behalf of a dentist.
250 °F	Sterilize at 250 °F
SN	Serial number
REF	Part number
HIBC	Health Industry Bar Code (HIBC)
MD	Medical device

1.2 Copyright information

2 Safety

The unit has been developed and designed appropriately such that hazards are largely excluded if the unit is used in accordance with its Intended use.
Therefore, please note the following.
Despite this, the following residual risks can remain:

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

2.1 CE certification

Intended purpose (CE)

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

CamX Triton HD Cam

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

CamX Triton HD Spectra

The intraoral camera with interchangeable head Spectra is intended to be used as an aid in the detection and diagnosis of dental caries.

CamX Triton HD Proxi

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

Indications

CamX Triton HD Cam

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

CamX Triton HD Spectra

The intraoral camera with interchangeable head Spectra is intended to be used as an aid in the detection and diagnosis of dental caries.

CamX Triton HD Proxi

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

Contraindications

CamX Triton HD Cam

None.

CamX Triton HD Spectra

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

CamX Triton HD Proxi

The Proxi head is not designed for use on artificial teeth, on teeth bearing crowns and on teeth with excessively large fillings. The device functions only in the context of natural enamel in the mouth of the patient. After extraction, teeth can no longer be analyzed with the Proxi head.

Intended use (CE)

CamX Triton HD

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.
In combination with a computer, monitor and an imaging software, this digital system can be used to create and store images and videos. It is mandatory to use the following accessories: spacer (only with interchangeable heads Spectra and Proxi) and hygienic protective covers.

Improper use (CE)

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.
Do not operate the device in any rooms containing flammable mixtures, e.g. in operating theatres.
Do not use the camera directly on the eye.

2.2 FDA registration

Indications for use

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

CamX Triton HD Cam

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

CamX Triton HD Spectra

The CamX Triton HD Spectra is intended to be used as an aid in the detection and diagnosis of dental caries.

CamX Triton HD Proxi

The CamX Triton HD Proxi Head is a diagnostic aid for the detection of interproximal caries lesions above the gingiva and for monitoring the progress of such lesions.

Contraindications

CamX Triton HD Cam

None.

CamX Triton HD Spectra

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

CamX Triton HD Proxi

The Proxi head is not designed for use on artificial teeth, on teeth bearing crowns and on teeth with excessively large fillings. The device functions only in the context of natural enamel in the mouth of the patient. After extraction, teeth can no longer be analyzed with the Proxi head.

Intended use

CamX Triton HD Cam / CamX Triton HD Spectra

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.
In combination with a computer, monitor and an imaging software, this digital system can be used to create and store images and videos. It is mandatory to use the following accessories: spacer (only with interchangeable heads Spectra and Proxi) and hygienic protective covers.

CamX Triton HD Proxi

Working in combination with a computer, a monitor and an imaging software, this digital system can be used to create and store images and videos. The following accessories have to be used for the operation of the device: The hygienic protective covers and the spacers.

Improper use

CamX Triton HD Cam / CamX Triton HD Spectra / CamX Triton HD Proxi

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.

Do not operate the device in any rooms containing flammable mixtures, e.g. in operating theatres.

Do not use the camera directly on the eye.

2.3 General safety information

The sale or prescription of this device by a medical practitioner is subject to the restrictions of the applicable Federal Acts. The device may be used only under permanent supervision by a dentist or licensed medical practitioner.

$\mathbf{Rx}_{\text{Only}}$ Caution: By virtue of Federal Law, the device may only be sold to dentists or bought on behalf of a dentist.

- Comply with the guidelines, laws, rules and regulations applicable at the site of operation when you use this unit.
- Prior to each use, check the function and proper condition of the device.
- Do not convert or modify the unit.
- Comply with the Installation and Operating Instructions.
- Make the Installation and Operating Instructions always available to the operator in the vicinity of the device.

2.4 Combining devices safely

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

- Only connect units when there can be no question of danger to operator or to patient.
- Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings.
- If it is not completely clear from the data sheet of the unit that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the relevant 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 Specialist personnel

Operation

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 repairs

- 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 from 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.

Comply with the EMC rules concerning medical devices

- Comply with the special precautionary measures concerning electromagnetic compatibility (EMC) for medical devices.
- 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 unit is intended for use in professional healthcare facilities (in accordance with IEC 60601-1-2). If the unit is operated in any other environment, potential effects on the electromagnetic compatibility must be taken into account.
- Do not use the device near HF surgical devices and MRI equipment.

› Maintain a minimum distance of at least 12 inches between the unit and other electronic devices.
› Maintain a minimum distance of 12 inches between the unit and portable and mobile radio devices.
› Note that cable lengths and cable extensions have effects on electromagnetic compatibility.

The following accessories can have affect the electromagnetic compatibility:
Handpiece holder with USB hub J2560

NOTICE

Negative effects on the EMC due to non-authorized accessories

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

2.7 Essential performance characteristics

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

2.8 Notification requirement of serious incidents

The operator/patient has to report any serious incident related the product to the manufacturer and the competent authority of the Member State, in which the operator and/or patient is established/resident.

2.9 Only use genuine parts

› Only use accessories and optional items specified or approved by Air Techniques.
› Only use original working parts and spare parts.

Air Techniques accepts no liability for damage resulting from the use of non-approved accessories, optional items or any parts other than original spare and wear parts.

The use of non-approved accessories, optional items or non-genuine wear parts / replacement parts (e. g. mains cable) can adversely affect the electrical safety and EMC.

2.10 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.

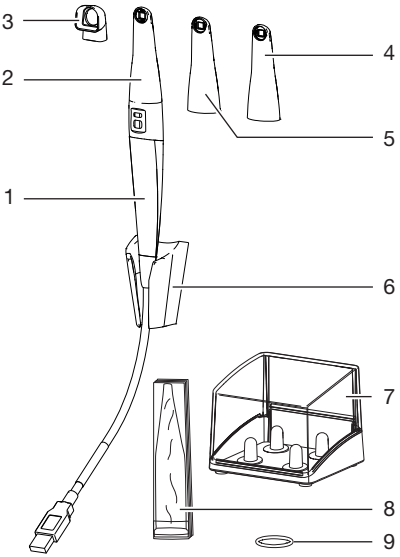
› Only transport the unit in its original packaging.
› Keep all packaging away from children.

2.11 Disposal

Devices and electronic components must be disposed of by a suitable disposal and recycling facility. It must be ensured that the items are disposed of in accordance with the locally applicable legislation at national/regional/local level.

Product description

3 Overview



1 Handpiece
2 Cam interchangeable head
3 Spacer
4 Spectra 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 (possible variations due to country-specific requirements and/or import regulations):

CamX Triton HD
with Cam and Spectra package J2500

- Handpiece
- Cam interchangeable head
- Spectra interchangeable head
- Storage box for interchangeable heads
- Handpiece holder
- Hygienic protective covers (qty. 20)
- Spacers (qty. 5)
- O-ring, 0.67 x 0.06 in (qty. 2)
- Microfiber cloth
- Cable holder
- Quick start guide
- Voucher for VisionX imaging software

CamX Triton HD
with Cam package J2600

- Handpiece
- Cam interchangeable head
- Storage box for interchangeable heads
- Handpiece holder
- Hygienic protective covers (qty. 20)
- O-ring, 0.67 x 0.06 in (qty. 2)
- Microfiber cloth
- Cable holder
- Quick Start Instructions
- Voucher for VisionX imaging software

CamX Triton HD
with Cam, Spectra and Proxi package . J2700
– Handpiece
– Cam interchangeable head
– Spectra interchangeable head
– Proxi interchangeable head
– Storage box for interchangeable heads
– Handpiece holder
– Hygienic protective covers (qty. 20)
– Spacers (2 x 5 pieces)
– O-ring, 0.67 x 0.06 in (qty. 2)
– Microfiber cloth
– Cable holder
– Quick start guide
– Voucher for VisionX imaging software

CamX Triton HD
with Cam and Proxi Package J2900
– Handpiece
– Cam interchangeable head
– Proxi interchangeable head
– Storage box for interchangeable heads
– Handpiece holder
– Hygienic protective covers (qty. 20)
– Spacers (qty. 5)
– O-ring, 0.67 x 0.06 in (qty. 2)
– Microfiber cloth
– Cable holder
– Quick start guide
– Voucher for VisionX imaging software

3.2 Accessories

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

	Order no.	As sold
Cam interchangeable head for CamX Triton HD	J2610	Not sterile
Spectra interchangeable head for CamX Triton HD	J2710	Not sterile
Proxi interchangeable head for CamX Triton HD	J2910	Not sterile
Handpiece holder for CamX Triton HD	J2540	Not sterile
Storage box for interchangeable heads	J2550	Not sterile
Spacers (qty. 5)	J2720	Not sterile, must be sterilized by therapist
Spacers (qty. 25)	J2721	Not sterile, must be sterilized by therapist

*The spacer is reusable and needs to be sterilized before each use (see "12 Reprocessing the spacer").

3.3 Optional items

The following optional items can be used with the device:
Handpiece holder with USB hub J2560
USB repeater 15.75 ft J2060
Microfiber cloth J2050

3.4 Consumables

The following materials are consumed during the operation of the unit and must be re-ordered separately:
Hygienic protective covers (qty. 500)
(K 132953) J2530
Hygienic protective covers (qty. 100)
(K 132953) J2525
Hygienic protective covers (qty. 20)
(K 132953) J2535

3.5 Wear parts and spare parts

The following wear parts need to be changed at regular intervals (refer to the "Maintenance" section):
O-ring (2 pieces) J2570

4 Technical data

4.1 Handpiece

Electrical data		
Nominal voltage	V DC	4.75 - 5.25
Communication interfaces		USB 2.0
Type of protection		IP20
Protection class		II
Operating mode*		T1/T2 = 27% 1.5 min / 5.5 min (On/off time)

* At an ambient temperature of max. 104 °F and while observing the on/off time, the handpiece/the interchangeable head reaches a maximum surface temperature of 140 °F.

Classification	
Medical Device Class	I
FDA classification (CFR Title 21)	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/flicker in acc. with IEC 61000-3-3	Not applicable

Electromagnetic compatibility (EMC) Interference immunity tests	
Discharge of static electricity in accordance with IEC 61000-4-2	Conforms
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	Conforms
Emitted HF disturbance variables in accordance with IEC 61000-4-3	Conforms

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

Dimensions and weights Handpiece including Cam interchangeable head		
Length	in	7.87
Diameter	in	0.94
Weight including cable	oz	6.7
Weight not including cable	oz	2.47
Cable length	ft	8.2

4.2 Cam interchangeable head

Technical data		
Light source		2 LEDs, white light
Wavelength	nm	400 - 780
Irradiance	W/m^2	0.8
Focus level	in	0.16 - ∞
Focus level, preset	in	0.67
Aperture angle		64°

Classification	
Medical Device Class	I
FDA classification (CFR Title 21)	I

4.3 Spectra interchangeable head

Technical data		
Light source		2 LEDs
Wavelength	nm	380 - 460
Dominant wavelength	nm	405
Irradiance	W/m^2	0.5
Focus level	in	0.16 - ∞
Focus level, preset	in	0.31
Aperture angle		64°

Classification	
Medical Device Class (MDR)	I
FDA classification (CFR Title 21) Class	II

4.4 Proxi interchangeable head

Proxi interchangeable head		
Light source		2 LEDs
Wavelength	nm	780 - 880
Dominant wavelength	nm	850
Irradiance	W/m^2	0.34
Focus level	in	0.16 - ∞
Focus level, preset	in	0.31
Aperture angle		64°

Classification	
Medical Device Class (MDR)	I
FDA classification (CFR Title 21) Class	II

4.5 Handpiece holder with USB hub (optional)

Electrical data		
Nominal voltage	V DC	12
General technical data		
Dimensions (W x H x 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 the power supply unit		
Nominal voltage	V AC	100 - 240
Mains 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/flicker in acc. with IEC 61000-3-3		Conforms
Electromagnetic compatibility (EMC) Interference immunity tests		
Discharge of static electricity in accordance with IEC 61000-4-2		Conforms
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4		Conforms
Voltage surges in accordance with IEC 61000-4-5		Conforms
Voltage dips, short interruptions and voltage variations in accordance with IEC 61000-4-11		Conforms
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8		Conforms

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

Connection cable		
Cable length	ft	8.2

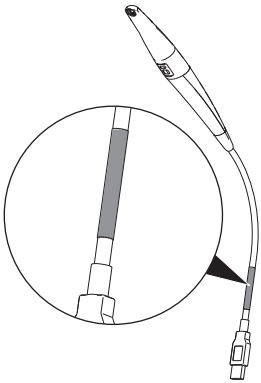
4.6 Ambient conditions

Ambient conditions during operation		
Temperature	°F	50 to 104
Rel. humidity	%	20 to max. 75
Air pressure	inHg	20.67 - 31.30

Ambient conditions during storage and transport		
Temperature	°F	-13 to +158
Relative humidity	%	10 - 95
Air pressure	inHg	20.67 - 31.30

4.7 Model identification plate

The model identification plate is located on the cable:

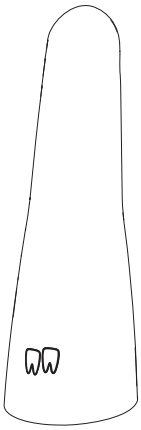


4.8 Conformity assessment

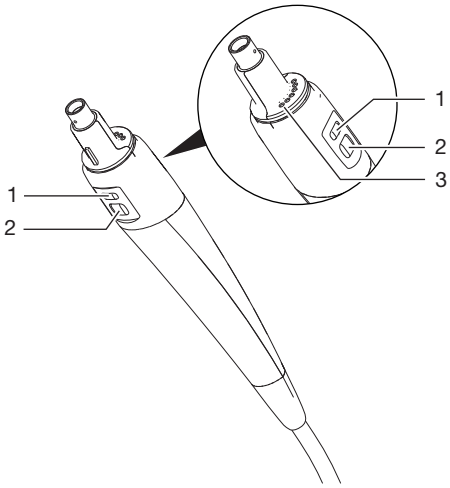
This device has been subjected to conformity acceptance testing in accordance with the current relevant guidelines of the European Union. This equipment conforms to all relevant requirements.

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 by the icon on the rear.



Cam interchangeable head	Intraoral images
Spectra 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 space



1 Focus button
2 Trigger button
3 Contacts for interchangeable head

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 Spectra 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 image 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 digitizes the image. The camera transmits the image to a computer via the USB connection cable.

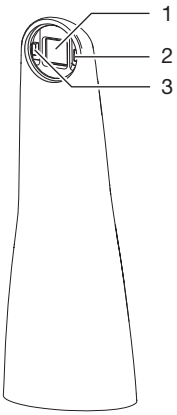
The connection cable is used to connect the camera directly to the USB port of the computer or, optionally, to the handpiece holder with USB hub.

The camera needs an imaging software. The Spectrum interchangeable head needs an imaging software from Air Techniques or a compatible TWAIN imaging software.

The camera is supplied with power via the USB connection cable to the PC.

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. Two LEDs are positioned around the optical element for even illumination.

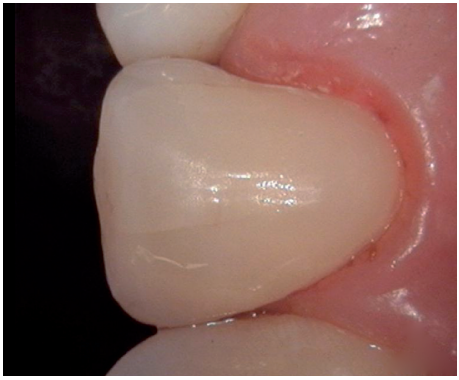
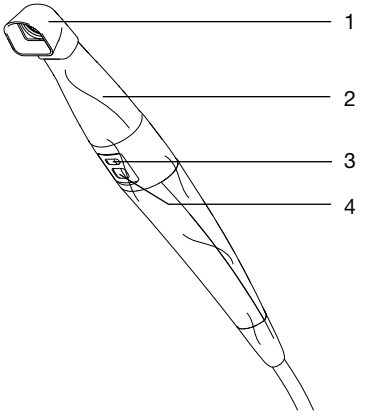


Fig. 1: Recording with Cam interchangeable head

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, dentine) and the metabolites of cariogenic bacteria (porphyrins) to fluoresce. The substances emit different colors. This makes it possible to analyze caries activity and detect potential tooth disease.

Substance	Color of 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 excavation
- 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.
All images captured with the Spectra inter-changeable head are stamped with the Spectra symbol top right.
The prophylaxis view shows the original image.

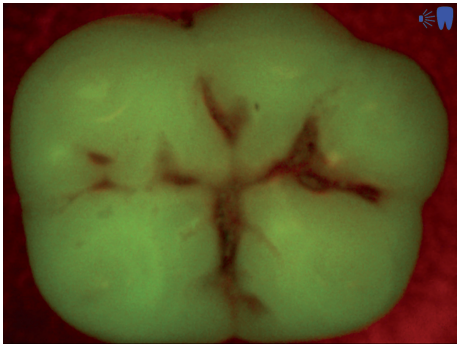


Fig. 2: Prophylaxis view

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

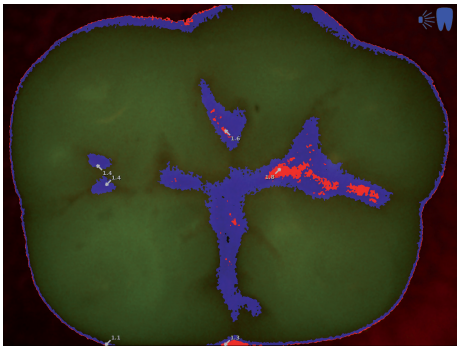


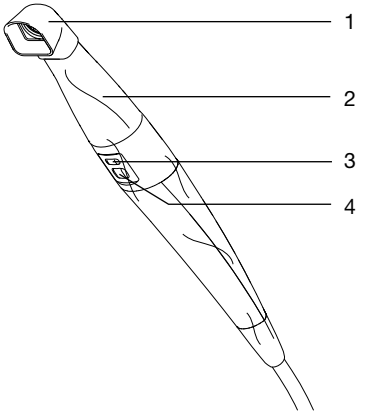
Fig. 3: Caries view

The color scale provides information on carious lesions:

	Healthy tooth enamel
	Early-stage caries, incipient enamel caries
	Enamel caries up to enamel/dentine junction
	Dentine junction already exceeded
	Dentine caries

Use gold standard techniques to examine for potential caries.

5.3 Proxi interchangeable head



1 Spacer
2 Interchangeable head
3 Focus button
4 Capture button

The handpiece with the Proxi interchangeable head creates a black and white image for detecting caries in the interproximal region.
The optical element is placed on the row of teeth. An image is created by pressing the capture 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 minimizes 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 analyzed as a black and white image in the imaging software.

Analysis

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
- Interproximal caries appears bright, low translucency
- Dentine appears bright, low translucency
- Several restorations appears bright, no translucency

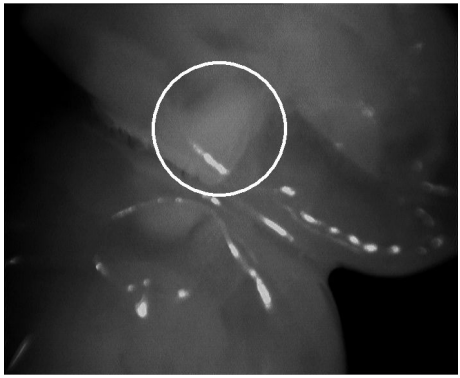


Fig. 4: Example case 1 - A lesion in the mesial area can be recognized as a wide bright strip up to the enamel/dentin limit

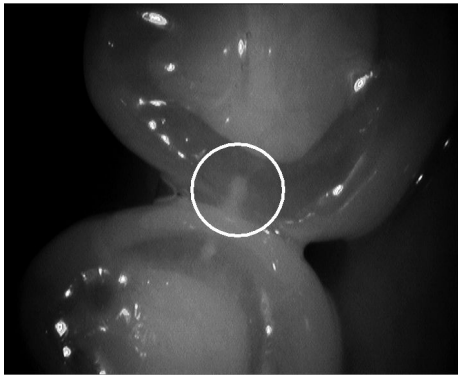


Fig. 5: Example case 2 - Interproximal enamel lesions can be seen as wedge-shaped structures within the dark translucent tooth enamel. The lesions reach to the inner half of the enamel.

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

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

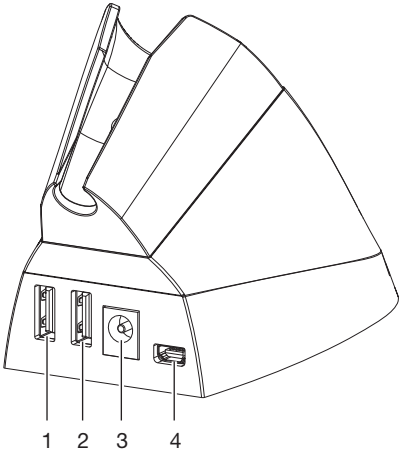
The tooth enamel appears brighter in patients with highly opaque tooth enamel. The caries diagnosis is complicated here by the low difference in contrast.

5.4 Handpiece holder

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 Handpiece holder with USB hub (optional)

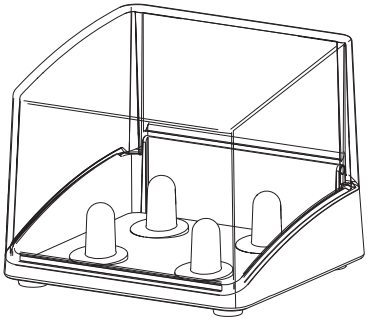
The camera can also be connected with the computer via the handpiece holder with USB hub. This makes it possible to have a greater distance between the camera and computer.



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.

5.6 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.

Installation

Only qualified specialists or persons trained by Air Techniques may install, connect, and commission the unit.

6 System requirements

The system requirements of the software being used to operate the device must always be met during its operation.
It is recommended to use the latest version of the software.
If third-party software is being used to operate the device, compliance with its system requirements must be assured.
The following additional system requirements must also be met:

Interface:	USB 2.0 USB 3.0
Total maximum cable length:	up to 5 mwith USB extension cable up to 20 m with additional USB repeater / active USB hub (max. 5 m each) - details available on request
Software:	VisionX version 2.3 or higher (order number: E7300) VisionX Connect version 3.0 or higher DBSWIN version 5.10 or higher (order number: E7200A), VistaEasy, Image Bridge

For the system requirements of the computer systems, visit the download area at www.airtechniques.com (document no. E7201).

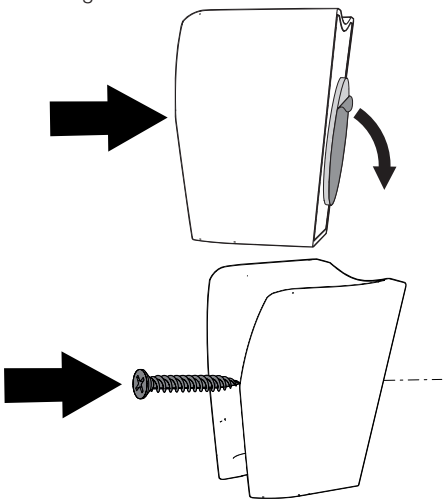
7 Installation

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 Commissioning and first 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:

– VisionX
– DBSWIN
– VistaEasy (ImageBridge, TWAIN compatible dental imaging software from third-party providers)

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 VisionX

Requirements:

✓ Additional CamX component installed in VisionX

› Connect the device to the computer.
The connection to the software is established automatically.

› In VisionX click ⚙.

› Click *Devices*.

› Click the device in the device list.

› Click *Configure*.

All device settings that are available on the selected device are listed under *Device settings*. In the tree directory, various settings can be adjusted. They vary depending on the connected device and can depend on the installed firmware version.

Acquisition settings	
Camera triggering	Time when the still image is created if the trigger button is pressed: – Upon pressing (preset) – On releasing

Standby settings	
Standby time	Time until automatic switch-off if the camera is not moved. Preset: 2 minutes
Automatic wake-up	The camera switches on as soon as the image acquisition window is opened in the software.

8.3 Configuring the unit 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 *CamX Triton HD*.

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 recording. The system uses these images to generate a new image that eliminates interference to the greatest possible extent.
Capture ring Function	Time at which the image is created when a trigger button is pressed: – *Trigger the function during release* (default) – Trigger the function when pressing

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.

8.4 Configuring the device in VistaConfig for VistaEasy

› Start VistaConfig using *Start* > *All Programs* > *Air Techniques* > *VistaEasy* > *VistaConfig*.
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 (default)

WDM driver

Driver	The WDM driver is selected automatically.

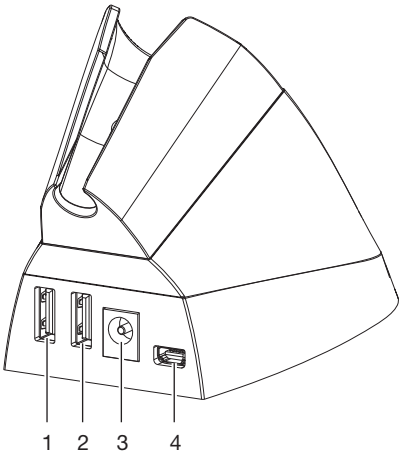
Capture ring

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

› To change the configuration, click on .

› To save the configuration, click on .

8.5 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 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 Commissioning tests

9.1 Electrical safety checks

› 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.

9.2 Handover record

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

A sample handover report is included in the attachment.

Usage

10 Operation

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.

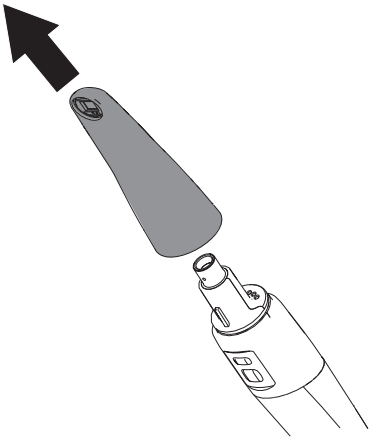
10.1 Changing the interchangeable head

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

- Cam interchangeable head
- Spectra interchangeable head
- Proxi interchangeable head

Removing the interchangeable head

- Pull the interchangeable head off the handpiece upwards.

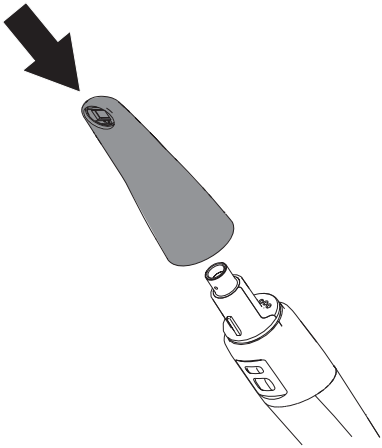


Attaching the interchangeable head

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 Use the hygienic protective cover

WARNING

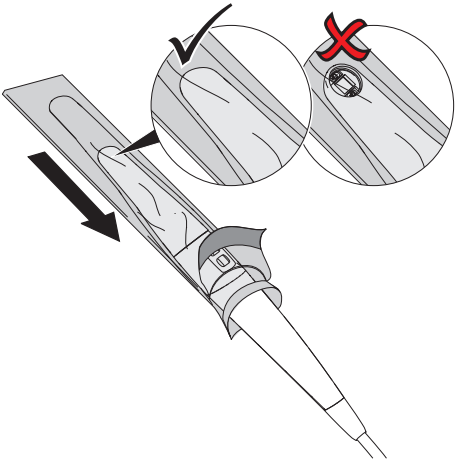
Danger of cross contamination when not using the hygienic protective cover or when using the hygienic protective cover more than once

- › Do not use the unit without the hygienic protective cover.
- › Do not re-use the hygienic protective cover (disposable item).

Do not re-use the hygienic protective cover (disposable item).

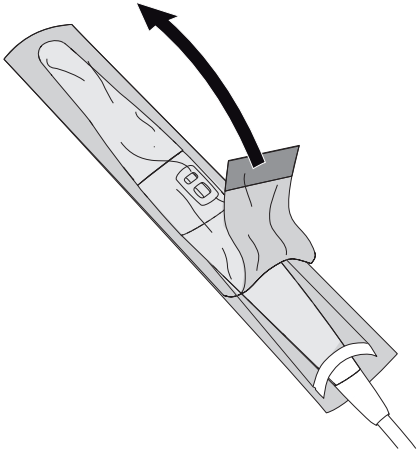
Wear protective gloves when applying the hygienic protective cover.

- › Hold the camera with the optical element facing downwards.
- › Lift the white edge of the hygienic protective cover and slide the camera head into the cover. The transparent plastic side must face upwards.



- › Stretch the hygienic protective cover by approx. 1/8 so that the cover presses tightly against the optical element.
- › Carefully press the hygienic protective cover against the optical window using your finger tips. Make sure that there are no air bubbles between the optical window and the hygienic protective cover.

- › Hold the 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.

10.3 Recording 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.

Prerequisites:

✓ Camera connected with the computer

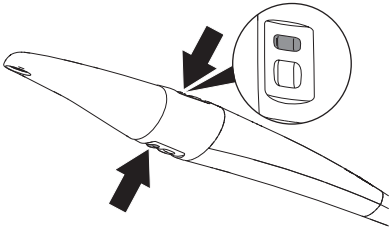
✓ Imaging software started

› 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.

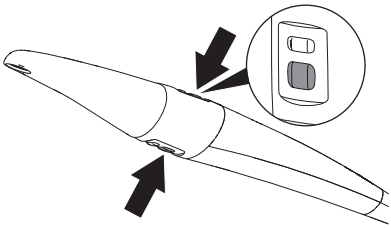
› Select the image section.

› 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 of the status of oral hygiene.

Caries view
It evaluates the fluorescence of the substances and provides a reliable diagnosis of carious lesions based on the colors.
The following factors can affect the fluorescence and hence the caries analysis:
- Soiling and food remains
- Calculus, concrement
- Aids for staining plaque
- Prophylaxis/fluoride pastes
- Tooth/polishing pastes

CAUTION

Health risks for the patient due to contraindications

› Before taking an X-ray image, check the present tooth restorations.

› see "Contraindications".

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.

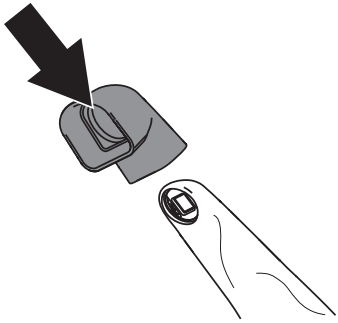
Putting on the spacer

WARNING

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

› Sterilize the spacer in the steam sterilizer (see "12 Reprocessing the spacer") before each use.

› Plug 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.

Requirements:

✓ Camera connected to computer

✓ Imaging software started

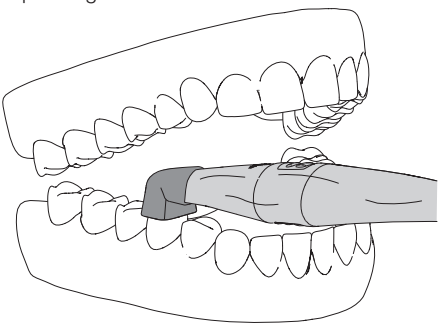
✓ Camera in hygienic protective cover

✓ Spacer plugged on

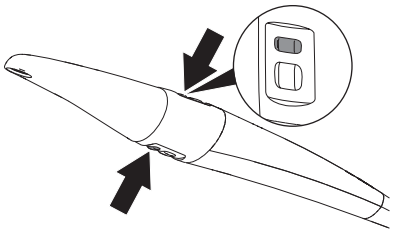
› Reduce incident external light. Turn off or dim sources of external light (e.g. operating lights).

› Dry the row of teeth with compressed air.

› Place the camera with spacer onto the corresponding tooth.

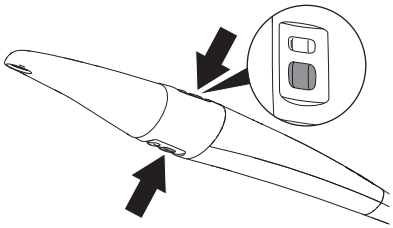


› If the image is not sharp, press one of the two focus buttons.



The camera focuses.

› Press one of the two 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 it. (For further information, refer to the software manual)

› Analyze the image (see "Analysis").

› To return to Live mode, press the trigger button again.

Analysis

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

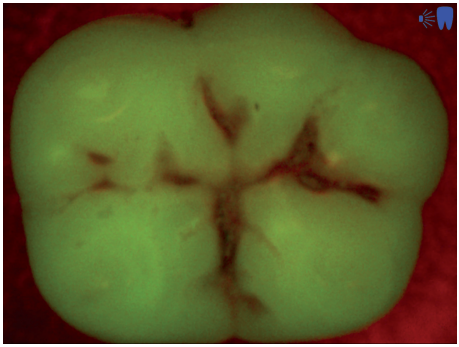


Fig. 6: Prophylaxis view

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

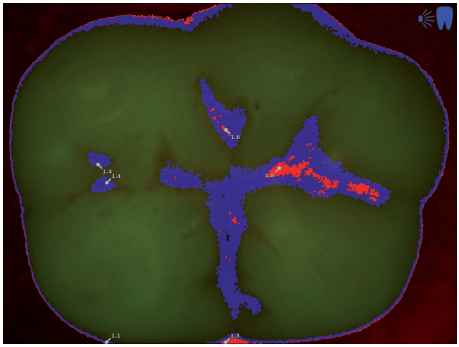


Fig. 7: Caries view

The color scale provides information on carious lesions:

	Healthy tooth enamel
	Early-stage caries, incipient enamel caries
	Enamel caries up to enamel/dentine junction
	Dentine junction already exceeded
	Dentine caries

Use gold standard techniques to examine for potential caries.

10.5 Recording an image with the Proxi interchangeable head

CAUTION

Health risks for the patient due to contraindications

› Before taking an X-ray image, check the present tooth restorations.

› see "Contraindications".

Putting on the spacer

WARNING

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

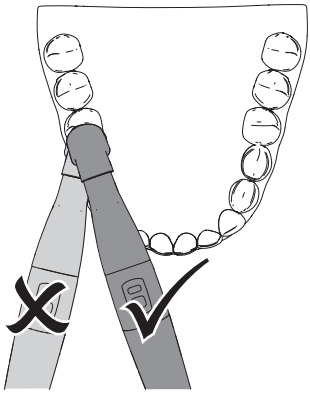
› Sterilize the spacer in the steam sterilizer (see "12 Reprocessing the spacer") before each use.

› Plug the spacer onto the interchangeable head from above. Make sure that the spacer does not cover the optical element of the interchangeable head.

Positioning the camera correctly

The camera must be positioned correctly to achieve a good image 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.

› Make sure that the relevant approximal space is located in the center of the image section.

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

Taking a picture

Requirements:

✓ Camera connected to computer

✓ Imaging software started

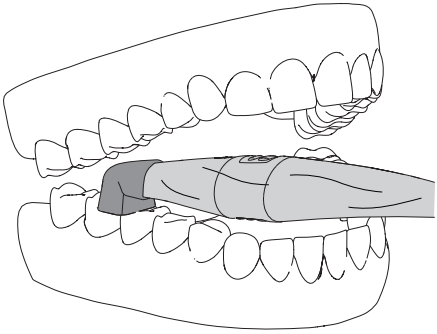
✓ Camera in hygienic protective cover

✓ Spacer plugged on

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

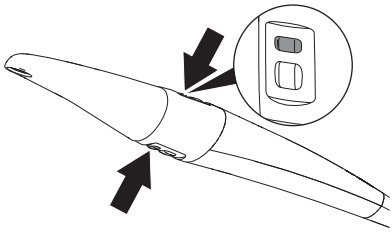
› Dry the row of teeth with compressed air.

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



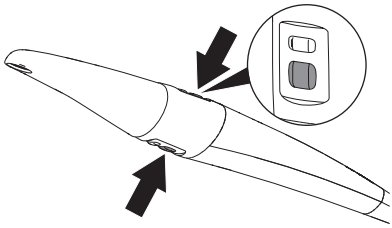
The infra-red LEDs illuminate the respective mesial and distal enamel area of the two adjacent teeth.

› 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 it. (For further information, refer to the software manual.)

› Analyze the image (see "Analysis").

› To return to Live mode, press the trigger button again.

Analysis

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
– Interproximal caries appears bright, low translucency
– Dentine appears bright, low translucency
– Several restorations appears bright, no translucency

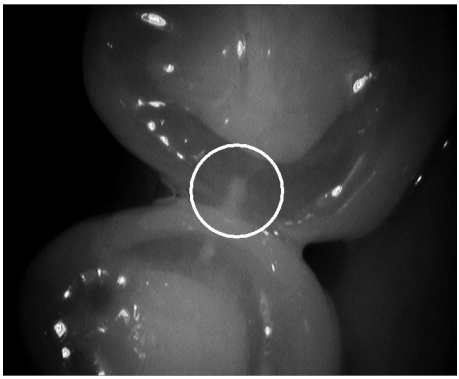


Fig. 8: Interproximal enamel lesions can be seen as wedge-shaped structures within the dark translucent tooth enamel. The lesions reach to the inner half of the enamel.

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

10.6 Switching off the camera

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

Always store the camera in the handpiece holder with the interchangeable head plugged on.

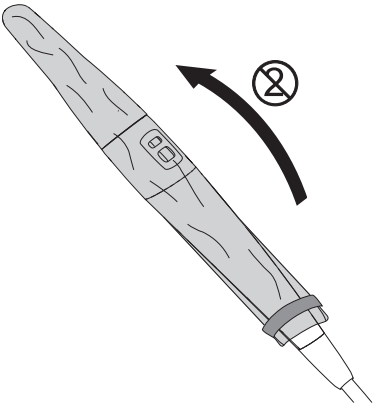
WARNING

Danger from the re-use of products intended for single use

Single-use article is damaged after use and cannot be reused.

› Dispose of single-use articles after use.

› Carefully pull off the hygienic protective cover and discard it.



› Disinfect the camera (see "11 Reprocessing of the device").
› Place the camera in the handpiece holder.

Result:
The camera switches off automatically.

11 Reprocessing of the device

11.1 Risk analysis and classification

A risk analysis and classification of medical devices that are common in dentistry must be performed before they are reprocessed by the operator. Comply with all national directives, standards and specifications such as e.g. the "Guidelines for Infection Control in Dental Health-Care Settings from the Centers for Disease Control and Prevention".
Accessories of the medical device are also subject to reprocessing.
Classification recommendation based on proper use of the product: **Semi-critical A**
Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically changed skin.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

11.2 Reprocessing procedures

Perform the reprocessing procedure after each patient treatment and according to the reprocessing procedure:
- Pre-cleaning and manual cleaning in accordance with AAMI TIR 30
- Manual disinfection in accordance with USFDA (21 CFR sections 58, 201, 211 and 820)

Important information!
The reprocessing instructions in accordance with FDA Guidance "Reprocessing Medical Devices in Health Care Settings - Validation Methods and Labeling" have been independently tested by the manufacturer for the preparation of the device and its components for their reuse.
The person conducting the reprocessing is responsible for ensuring that the reprocessing is performed using equipment, materials and personnel that attains the desired results. This requires validation and routine monitoring of the reprocessing process. Any negative consequences resulting from deviation from these instructions by the person conducting the reprocessing are the responsibility of the member of staff performing the reprocessing.
Frequent reprocessing has little effect on the components of the device. The end of the product life cycle is mainly influenced by the amount of wear and tear or damage resulting from its use.
The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The validation of the reprocessing method was performed based on the assumption that, in the worst case scenario, a hygienic protective cover could be damaged while it is being applied or during use.
In accordance with IEC 80601-2-60, the applied part of the intraoral camera is limited to a length of 80 mm, starting on the tip of the interchangeable head. For this reason, only the applied part was considered during the validation of the reprocessing method.
The reprocessing procedure was validated as follows:
- **Pre-cleaning**
  - Lint-free disposable wipe
- **Manual cleaning**
  - Monarch disinfection wipes (Air Techniques)
- **Manual disinfection**
  - Monarch disinfection wipes (Air Techniques)

General information

- Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilization of medical devices as well as the specific specifications for dental practices and clinics.
- When selecting the cleaning and disinfectant agents to be used, the information provided (see "11.4 Manual cleaning, disinfection and drying") must be followed.
- Comply with the concentrations, temperatures, residence times and post-rinsing specifications issued by the manufacturer of the cleaning agent and disinfectant.
- Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.
- Only use disinfectants that are aldehyde-free and display material compatibility with the product.
- Only use freshly-produced solutions.
- Only use distilled or de-ionized water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. Legionella bacteria).
- Use clean, dry, oil- and particle-free compressed air.

11.3 Preparation at the operating location


Wear hand protection.


Wear eye protection.


Use a mask.


Wear protective clothing.

- Clean the hygienic protective cover (with integrated camera) with a disinfection wipe.
- Carefully pull off the hygienic protective cover and discard it.
- Clean the device for 1 minute with a lint-free disposable wipe soaked in cold tap water until no more dirt or contamination can be seen.
- Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

11.4 Manual cleaning, disinfection and drying

NOTICE

Damage to the device due to incorrect cleaning and disinfection

- Only clean the surface of the unit.
- Only use disinfection and cleaning agents specified or approved by Air Techniques and the EPA.
- Use combined cleaning agents and disinfectants which do not contain chlorine, solvents, strong bases (pH >11), or oxidizing agents.
- Do not use any aggressive or abrasive cleaning agents.
- Only clean the unit using wipe disinfection.
- Do not clean the unit by submerging or spraying in combination with disinfectant.
- Do not subject the unit to steam sterilization.

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

– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)
– free of chlorine, free of solvents, no strong alkaline solutions (pH > 11), no strong oxidizing agents

For further information refer to "General information".

The outer surfaces of the applied part can be cleaned and disinfected manually using cleaning and disinfection wipes.

Cleaning

- Thoroughly wipe down the outer surfaces for 1 minute with a cleaning wipe.
  Then allow for 1 minute exposure to the agent.
- Check to make sure that no soiling is visible any longer.

Disinfecting

- Thoroughly wipe down the outer surfaces for 1 minute with a disinfection wipe.

› Repeat this step with a new disinfection wipe for 2 minutes.
This means that the entire disinfection step is performed for 3 minutes.

Drying

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

12 Reprocessing the spacer

12.1 Risk analysis and classification

A risk analysis and classification of medical devices that are common in dentistry must be performed before they are reprocessed by the operator. Comply with all national directives, standards and specifications such as e.g. the "Guidelines for Infection Control in Dental Health-Care Settings from the Centers for Disease Control and Prevention".
Accessories of the medical device are also subject to reprocessing.
Classification recommendation given Intended Use of the product: **semi-critical B**
Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically changed skin.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

12.2 Reprocessing procedures

Perform the reprocessing procedure after each patient treatment and according to the reprocessing procedure:

– Pre-cleaning in accordance with AAMI TIR 30.
– Steam sterilization in accordance with ANSI/AAMI/ISO 17665-1, Annex D and ANSI/AAMI/ISO 14937, Annex D.

Important information!

The reprocessing instructions in accordance with FDA Guidance "Reprocessing Medical Devices in Health Care Settings - Validation Methods and Labeling" have been independently tested by the manufacturer for the preparation of the device and its components for their reuse.

The person conducting the reprocessing is responsible for ensuring that the reprocessing is performed using equipment, materials and personnel that attains the desired results. This requires validation and routine monitoring of the reprocessing process. Any negative consequences resulting from deviation from these instructions by the person conducting the reprocessing are the responsibility of the member of staff performing the reprocessing.

Frequent reprocessing has little effect on the components of the device. The end of the product life cycle is mainly influenced by the amount of wear and tear or damage resulting from its use.

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

The following instructions have been validated as being suitable for preparation of the product for reuse.

Reprocessing procedure:

- **Pre-cleaning**
  - Lint-free disposable wipe
- **Automatic cleaning and disinfection**
  - Cleaning agent: Neodisher MediClean Forte
  - RDG: G 7836 CD (Miele, Gütersloh, Germany)
  - Programs: "Cleaning without neutralization" and "D-V-MEDFORTE"
- **Steam sterilization**

  Process parameters:
  - Type of sterilization: Gravity
  - Min. temperature: 250 °F
  - Holding time: 30 min
  - Drying time: 20 min

General information

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

› When selecting the cleaning and disinfectant agents to be used, the information provided (see above) must be followed.

› Comply with the concentrations, temperatures, residence times and post-rinsing specifications issued by the manufacturer of the cleaning agent and disinfectant.

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

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

› Only use freshly-produced solutions.

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

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

12.3 Preparation at the operating location


Wear hand protection.


Wear eye protection.


Use a mask.


Wear protective clothing.

WARNING

Risk of infection from contaminated products

Risk of cross contamination

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

› Clean the spacer with a disposable wipe soaked in cold tap water until no more dirt or contamination can be seen.
› Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

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

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:
– Satisfies ISO 15883, with verified efficacy
– Certified program for thermal disinfection (A_0 value ≥ 3000 or a minimum of 5 minutes at 93 °C)
– Program is suitable for the components and includes sufficient rinsing cycles.
Further information: "General information".

Selection of the machine cleaning agents and disinfectants

The following properties are required:
– Material compatibility with the product
– Compliance with the washer-disinfector manufacturer's specifications

For further information, see "General information".

Automatic cleaning and disinfecting

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

› Place components in the baskets for small parts.

12.5 Steam sterilization

WARNING

Health risk due to improper sterilization

If the sterilization is not performed correctly, it may not be effective. The use of insufficiently sterilized instruments can be a health risk to the patient.

- Only steam sterilization is permissible.
- Comply with all process parameters.
- Comply with the manufacturer's instructions regarding the use of the steam sterilizer.
- Do not use any other procedures.

NOTICE

Damage to equipment due to improper sterilization

Product damage may be caused if the sterilization process is not performed correctly.

- Comply with the manufacturer's instructions regarding the use of the steam sterilizer.
- Comply with all process parameters.

Process parameters
Type of sterilization: Gravity
Min. temperature: 250 °F
Holding time: 30 min
Drying time: 20 min

Wear hand protection.

- Prior to use, subject the spacer to steam sterilization in a gravity steam sterilizer at 250 °F for 30 minutes with 20 minutes drying time. Replace the spacer, if required.

12.6 Storage

- Store the product protected against contamination.
- Shelf life is determined and identified per instruction for use of sterilization packaging used.

13 Cleaning

13.1 Cleaning the camera lens

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

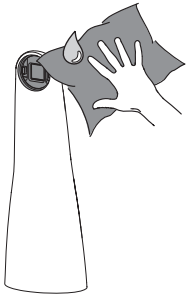
NOTICE

Damage of the optical element from incorrect cleaning

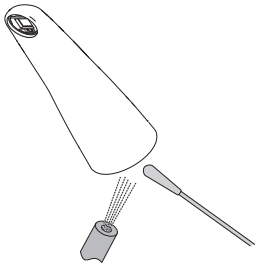
Residues of disinfectant will contaminate the optical element.

- Clean the window of the optic using the provided microfiber cloth, cotton buds and alcohol.

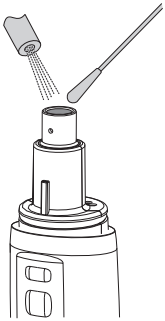
- Clean the window of the optical window of the interchangeable head from outside using the microfiber cloth with a droplet of alcohol.



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



› Dry clean the lens in the handpiece with compressed air or a cotton swab.

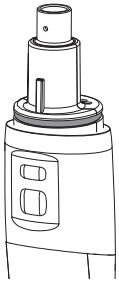


14 Maintenance

14.1 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

15 Tips for operators and service technicians

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

Error	Possible cause	Remedy
Image cloudy, milky	Hygienic protective cover not properly placed on optical window	› Place the hygienic protective cover properly on the optical window.
	Hygienic protective cover pulled on the wrong way round: do not place the transparent side on the optical window	› Pull the hygienic protective cover on correctly (see "10.2 Use the hygienic protective cover").
	Optical window is soiled	› Clean the optical window (see "13.1 Cleaning the camera lens").
	Optical element is scratched	› Replace the interchangeable head.
	Handpiece is defective	› Return the handpiece for replacement.
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 "8.5 Connect the handpiece holder with the USB hub (optional)".
	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 is not completely attached, no contact between handpiece and interchangeable head	› Pay attention that the interchangeable 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 "14.1 Replacing the o-ring")

Error	Possible cause	Remedy
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 handpiece	› Replace the O-ring.
Image is shown distorted	Wrong resolution settings	› Choose an aspect ratio of 4:3 in *VistaConfig* > *Video properties*> *Display*

15.1 Spectra interchangeable head

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

15.2 Proxi interchangeable head

Error	Possible cause	Remedy
Image is tool light in a specific region	The angle of the camera to the tooth is not ideal	› Change the holding angle of the camera to the tooth.
Snow effect on the image	Clearance of the camera to the tooth is too high, no optimum illumination	› Ensure that the spacer does not come into contact with the teeth.
	Camera used without spacer	› Always use a spacer for imaging using the Proxi interchangeable head.
Dark shadow in the dentine	Hygienic protective cover or optical element soiled	› Check the hygienic protective cover, clean or replace if necessary. › Check the optical element and clean if necessary (see "13.1 Cleaning the camera lens").

Error	Possible cause	Remedy
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.

Appendix

16 Handover record

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

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

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

Notes:

Name of person receiving instruction:	Signature:

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

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

Manufactured for / Distributed by:
Air Techniques, Inc.
1295 Walt Whitman Road
Melville, New York 11747-3062, USA
Phone: 800-247-8324
Fax: 888-247-8481
www.airtechniques.com

Hersteller / Manufacturer:
DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
www.duerrdental.com

AIR TECHNIQUES equipped for life®