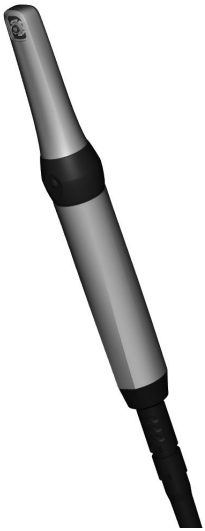
# CamX Elara / CamX Spectra



EN-US Installation and Operating Instructions

Rx Only

CE

AIR TECHNIQUES equipped for life®

2108100003L29 J2001 2301V013

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## Product description



## Installation



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# 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 Elara / CamX Spectra:
Order number:
- J2100 (2108200002)
- J2300 (2108200003)

### 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


Applied part Type B


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 Elara*

The CamX Elara intraoral camera is inserted in or near to the oral cavity of the patient. The images support diagnosis, patient information and are used for instruction.

*CamX Spectra*

The intraoral camera CamX Spectra is intended for the detection and diagnosis of caries.

**Indications**

*CamX Elara*

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

*CamX Spectra*

The intraoral camera with interchangeable head Spectra is intended for the detection and diagnosis of caries.

**Contraindications**

*CamX Elara*

None.

*CamX Spectra*

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

**Intended use (CE)**

*CamX Elara / CamX Spectra*

The intraoral camera is used in or next to the oral cavity of the patient. 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 (Spectra only) 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 Elara*

The CamX Elara is inserted in or near to the oral cavity of the patient. The images support diagnosis, patient information and are used for instruction.

*CamX Spectra*

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

**Contraindications**

*CamX Elara*

None.

*CamX Spectra*

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

**Intended use**

*CamX Elara / CamX Spectra*

The intraoral camera is used in or next to the oral cavity of the patient. 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 (Spectra only) and hygienic protective covers.

**Improper use**

*CamX Elara / CamX Spectra*

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.

**Rx**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

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 units when it is safe to do so and there is no risk of damage or harm to the surroundings.
- 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 clinical training, 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:
USB connection cable for
CamX Elara/Spectra (8.2 ft) . . . . . J2020

**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

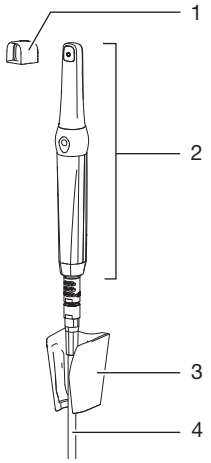



*Fig. 1: CamX*

1 Spacer (CamX Spectra only)
2 Handpiece
3 Handpiece holder
4 USB-connecting cable (to computer)

### 3.1 Scope of delivery

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

**CamX Elara . . . . . J2100**

– Handpiece
– Handpiece holder
– USB connection cable (8.2 ft)
– Hygienic protective covers (qty. 20)
– Microfiber cloth
– Voucher for VisionX imaging software

**CamX Spectra package . . . . . J2300**

– Handpiece
– Handpiece holder
– USB connection cable (8.2 ft)
– Hygienic protective covers (qty. 20)
– Spacers (qty. 5)
– Microfiber cloth
– Voucher for VisionX imaging software

### 3.2 Accessories

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

| | Part no. | As sold |
|---|---|---|
| Handpiece holder for CamX | J2040 | non sterile |
| USB connection cable for CamX (8.2 ft) | J2020 | non sterile |
| Spacer, for CamX Spectra only (5 pieces) | J2320 | non sterile, to be sterilized by user* |

*spacer is reusable, must be sterilized before use (see "12 Reprocessing the spacer").

### 3.3 Consumables

The following materials are consumed during the operation of the unit and must be re-ordered separately:

Hygienic protective covers (qty. 500) . . . . J2030
Hygienic protective covers (qty. 100) . . . . J2025
Hygienic protective covers (qty. 20) . . . . . J2035

# 4 Technical data

## 4.1 CamX Elara

| Electrical data | | |
|---|---|---|
| Voltage | V DC | 4.75 - 5.25 |
| Signal output | | USB 2.0 |
| Type of protection | | IP20 |
| Protection class | | II |
| Operating mode* | | T1/T2 = 27%<br>1.5 min / 5.5 min<br>(On/off time) |

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

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

| Electromagnetic compatibility (EMC)<br>Interference emission measurements | |
|---|---|
| High-frequency emissions in accordance with CISPR 11 | Group 1<br>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)<br>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 | 1/4" Color Interline Transfer CCD |
| Number of sensor pixels | 470000 |
| Effective pixels (PC) YUV | 704 x 576 |
| Brightness control | Automatic |
| White balance | Permanently set |

| Optical system | |
|---|---|
| Illumination | 8 LEDs, white light |

| Optical system | | |
|---|---|---|
| Focus level | mm | 12 |
| Depth of field | mm | 5 - 40 |
| Aperture angle | | 68° |

| Dimensions and weights | | |
|---|---|---|
| Length | in | 7.48 |
| Diameter | in | 1.02 |
| Weight including cable | oz | 6 |
| Weight not including cable | oz | 1.7 |
| Cable length | ft | 8.2 |

## 4.2 CamX Spectra

| Electrical data | | |
|---|---|---|
| Voltage | V DC | 4.75 - 5.25 |
| Signal output | | USB 2.0 |
| Type of protection | | IP20 |
| Protection class | | II |
| Operating mode* | | T1/T2 = 27%<br>1.5 min / 5.5 min<br>(On/off time) |

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

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

| Electromagnetic compatibility (EMC)<br>Interference emission measurements | |
|---|---|
| High-frequency emissions in accordance with CISPR 11 | Group 1<br>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)<br>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 |

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

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

| Optical system | | |
|---|---|---|
| Illumination | | 4 LEDs |
| Wavelength | nm | 405 |
| Focus level | mm | 8 |
| Aperture angle | | 68° |

| Dimensions and weights | | |
|---|---|---|
| Length | in | 7.48 |
| Diameter | in | 1.02 |
| Weight including cable | oz | 6 |
| Weight not including cable | oz | 1.7 |
| Cable length | ft | 8.2 |

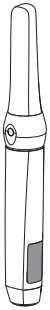
## 4.3 Ambient conditions

| Ambient conditions during operation | | |
|---|---|---|
| Temperature | °F | 50 to 104 |
| Rel. humidity | % | 20 to max. 75 |
| Air pressure | inHg | 22.15 - 31.30 |

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

## 4.4 Model identification plate

The model identification plate is on the handpiece.

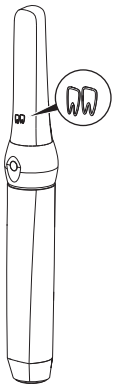


## 4.5 Conformity assessment

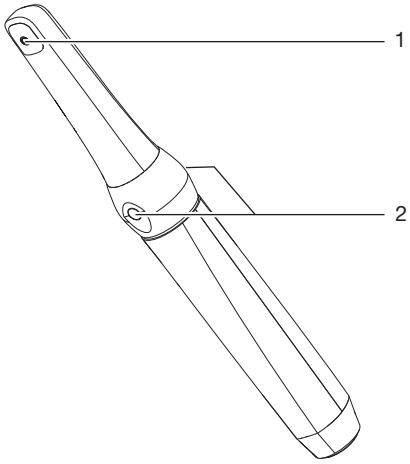
This device has been subjected to conformity acceptance testing in accordance with the current relevant guidelines of the European Union. This equipment conforms to all relevant requirements.

# 5 Function

CamX Elara and Spectra are intraoral cameras. The function of the camera is identified by the symbol on the rear.



| | | |
|---|---|---|
| | Elara | Intraoral images |
| | Spectra | Caries detection aid |




1 Optical system
2 Capture ring with two points

If you click on a point of the capture ring, the camera toggles between Live image and Still image. The pressure point of the capture ring is tangible. The camera vibrates slightly when the mode changes. Optionally, the camera can also be operated by a foot switch.
The image sensor in the handpiece digitizes the image. The camera transmits the image to a computer via the USB connection cable.

The optics focusing range is fixed.
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 2 minutes. As soon as the camera is moved, it switches on again.

## 5.1 CamX Elara

The camera has a fixed-focus optical lens with a depth of field appropriate for intraoral imaging. Eight LEDs are arranged around the optical lens which provide even illumination.

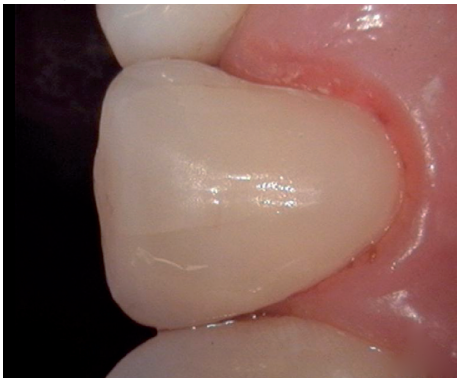


*Fig. 2: CamX Elara*

## 5.2 CamX Spectra

You can create intraoral images with the camera for the detection of caries, plaque and calculus. It has a fixed-focus optical element for intraoral imaging.
Four LEDs with blue-violet light (wavelength 405 nm) are arranged around the optical element. The energy-rich blue-violet light induces the tooth structure (enamel, dentine) and the metabolites of cariogenic bacteria (porphyrins) to fluoresce. The substances emit different colors. This allows you to analyze caries activity and detect potential tooth disease.

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

Application areas:
- Detecting plaque and calculus
- Detecting caries at an early stage
  - Fissure caries that is difficult to detect
  - Precise localization of carious lesions on smooth surfaces
  - Visually-supported check during excavation

**Analysis**

The images are analyzed by the imaging software with the aid of a filter.
All images recorded with the CamX Spectra are identified by a Spectra icon on the top right.
The **prophylaxis view** shows the original image.

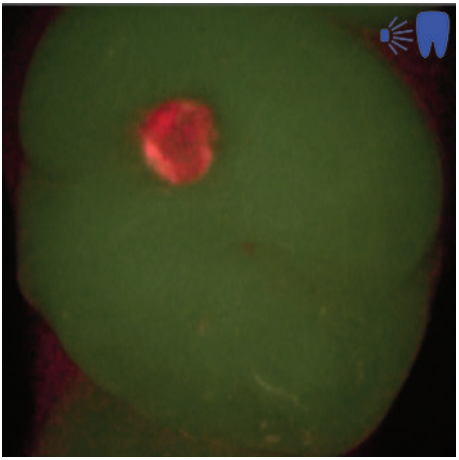


*Fig. 3: Prophylaxis view*

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

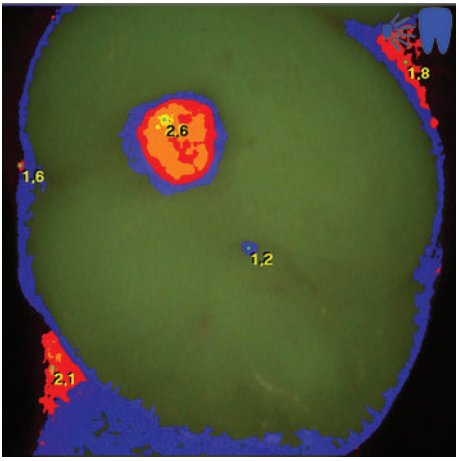


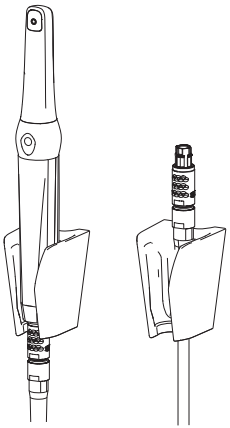

*Fig. 4: Caries view*

The color scale provides evidence of carious lesions:

| | |
|---|---|
| | Healthy tooth enamel |
| | Initial caries, early stages of enamel caries |
| | Enamel caries up to the enamel/ dentine junction |
| | Dentine junction already exceeded |
| | Dentine caries |

Use standard tests to examine potential carious lesions.

## 5.3 Handpiece holder



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

## 5.4 Connection to computer

Connect the camera directly to the USB port of the computer.
The camera requires imaging software from Dürr Dental or approved imaging software from another manufacturer, which must be connected via a TWAIN interface.

# 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<br>USB 3.0 |
| Total maximum cable length: | up to 5 m with USB extension cable<br>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)<br>VisionX Connect version 3.0 or higher<br>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).

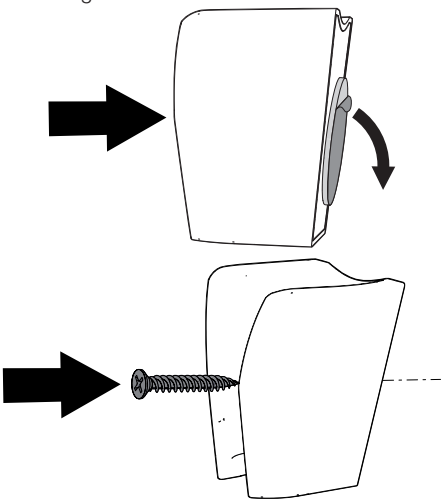
# 7 Installation

## 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 Connecting the device to a computer

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

When using a tower or desktop PC, always use one of the USB ports on the rear connector panel of the PC. Do not connect the camera to a USB port on the front.

The time when the camera needs to be connected for the first time depends on the imaging software used.

› Connect the camera as directed in the relevant section.

## 8.2 Using the device in VisionX

**Install the additional component**

If the device was not selected during the initial installation process, this additional component will need to be installed afterwards.
To do this, proceed in the same way as for the initial installation (refer to the imaging software manual).

› During the course of the installation, select the device you wish to reinstall.

› Perform the installation.
The missing additional component is then installed retrospectively.
The required device driver is installed automatically.

**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:<br>– Upon pressing (preset)<br>– On releasing |

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

## 8.3 Using the device in DBSWIN or VistaEasy

**Installing the driver(s)**

Before connecting the camera to the computer for the first time, wait until you are prompted to do so by the installation wizard.

› Close all programs.
› Call up https://www.airtechniques.com/en/drivers/.
› Select the camera driver.
› Download *CamX-Camera-Drivers-and-Utilities-G1415-Rev-...*. Run *.exe*.
› Click *Next* to acknowledge the message.
› Select the driver type.
› Follow the instructions of the installation wizard.

**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 Elara* or *CamX Spectra*.

*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:<br>– *Trigger the function during release* (default)<br>– 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. |

**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.<br>*Record* + *Pause* is preset. |
| Trigger event | Time at which the image is created when the trigger button is pressed:<br>– On pressing<br>– Upon release (default) |

› To change the configuration, click on  .

› To save the configuration, click on  .

# 9 Commissioning tests

## 9.1 Electrical safety checks

› Carry out an electrical safety check according to all national regulations.

› Document the results.

The handpiece is applied part 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 Switch the device on

- Connect the camera to a USB port of the computer using the connection cable.
- To start the imaging program, see software manual.

### 10.2 Use the hygienic protective cover

**WARNING**

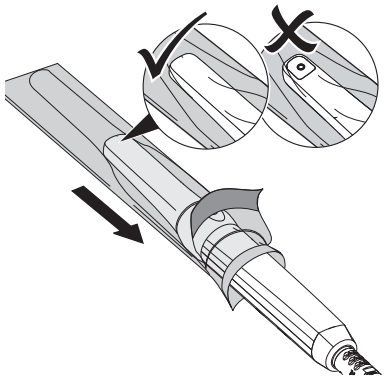
**Danger of cross contamination when not using the hygienic protective cover or when using the hygienic protective cover more than once**

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

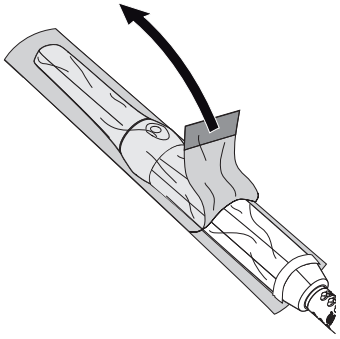
Do not re-use the hygienic protective cover (disposable item).

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 an extra 2 - 3 mm 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 Taking an image using CamX Elara

### 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.

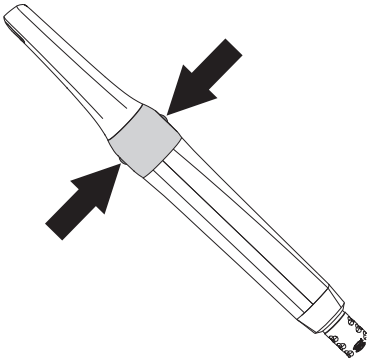
When you take the camera out of the handpiece holder, the camera shows a moving image (Live mode). Each time the mode is switched between Live mode and Freeze mode, the handpiece vibrates slightly.

› Starting the imaging program.

› Take the camera out of the handpiece holder.

› Select the desired image detail in "Live" mode.

› Press on one point of the capture ring.



The camera switches to "Freeze" mode. The still image will be transmitted to the imaging program and/or the monitor.

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

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

## 10.4 Taking an image using CamX Spectra

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.

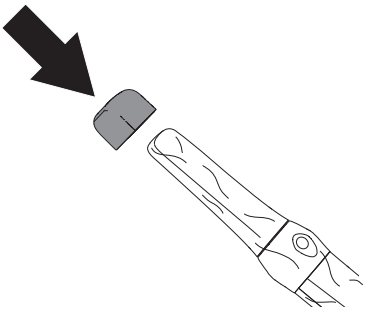
### Putting on the spacer

**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.

› Hold the camera with the properly applied hygienic protective cover and insert the tip of the interchangeable head into the round opening of the spacer.
› Push the camera into the spacer until the tip resides fully in the spacer.
› Check to make sure that the spacer does not cover the optical element of the interchangeable head.



### Taking a picture

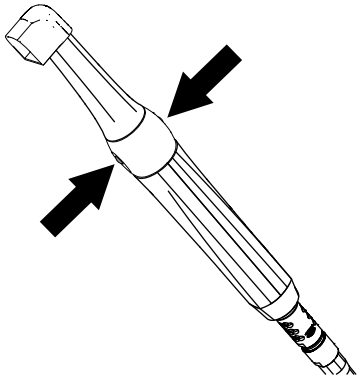
**CAUTION**

**The blue-violet LED light**

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

When you take the camera out of the handpiece holder, the camera shows a moving image (Live mode). Each time the mode is switched between Live mode and Freeze mode, the handpiece vibrates slightly.

› Start imaging program.
› Remove the camera from the handpiece holder.
› Select the required image section in Live mode.
› Press on one of the capture buttons.



The camera switches to "Freeze" mode. The freeze frame will be transmitted to the imaging program, i.e. the monitor.

› Edit the image using the imaging program and save. (For further information, refer to the software instruction.)
› To return to "Live" mode, press on one of the capture buttons again.

### Analysis

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

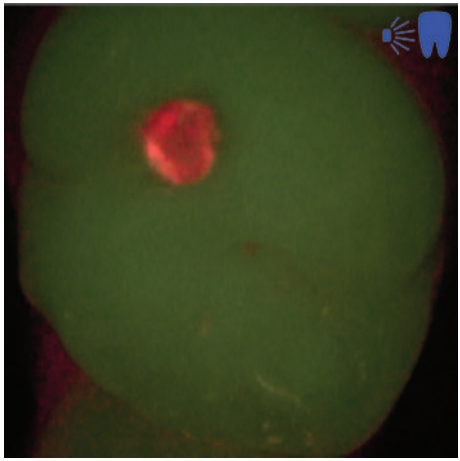


*Fig. 5: Prophylaxis view*

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

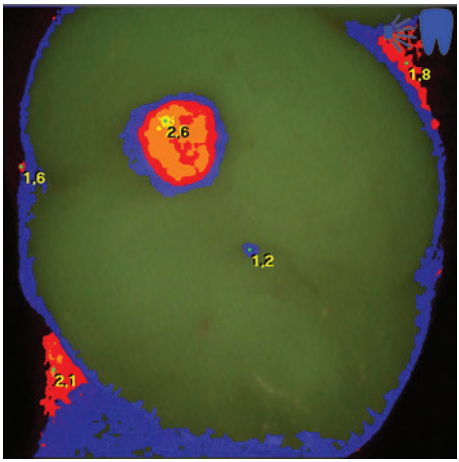



*Fig. 6: Caries view*

The color scale provides evidence of carious lesions:

| | |
|---|---|
| | Healthy tooth enamel |
| | Initial caries, early stages of enamel caries |
| | Enamel caries up to the enamel/ dentine junction |
| | Dentine junction already exceeded |
| | Dentine caries |

Use standard tests to examine potential carious lesions.

## 10.5 Switching off the camera

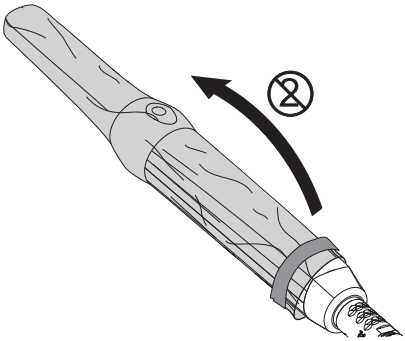
**WARNING**

**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.



› Reprocess 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)

## 11.3 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 "11.5 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 micro-organisms (e.g. Legionella bacteria).
- Use clean, dry, oil- and particle-free compressed air.

## 11.4 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.

## 11.5 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 "11.3 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

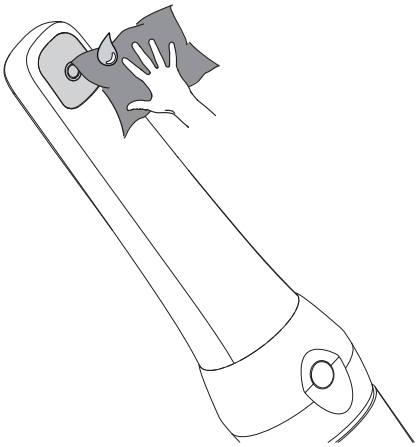
**NOTICE**

**Damage to the optical element from incorrect cleaning**

Disinfectant residues soil the optical element.

› Only use the enclosed microfiber cloth and alcohol.

› Clean the window of the optical window using the microfiber cloth with a droplet of alcohol.



# 14 Maintenance

The unit is maintenance-free.

# 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 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).<br>› Turn off or dim source of external light (e.g. operating light); darken the room. |
| **Image cloudy, milky** | Hygienic protective cover not properly placed on optical window | › Place the hygienic protective cover properly on the optical window. |
| | Optical window is soiled | › Clean the optical window (see "13.1 Cleaning the camera lens"). |
| | Handpiece is defective | › Submit the handpiece for repair. |
| **Image too dark** | LEDs defective | › Send handpiece for repair. |
| **No image** | USB connection cable is not connected | › Connect the USB connection cable. |
| | USB connection cable is defective | › Replace the USB connection cable. |
| | Computer not switched on, software not started | › Switch on the computer and start the software. |
| | Camera driver not correctly installed | › Check the driver installation and software settings. |
| **Image is shown distorted** | Wrong resolution settings | › Choose an aspect ratio of 4:3 in *VistaConfig* > *Video properties*> *Display* |

# 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:**
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