Instructions for use

DIAGNOcam Vision Full HD



KAVO
Dental Excellence

Distributed by:
KaVo Dental Technologies, LLC
11727 Fruehauf Drive
Charlotte, NC 28273 USA
Phone: 847 550 6800
Fax: 847 550 6825

Manufacturer:
KaVo Dental GmbH
Bismarckring 39
88400 Biberach
Germany
www.kavo.com

CE 0124

Table of contents

1 User instructions 5
1.1 Transport and storage 7
1.1.1 Damage in transit 7
1.2 Product Disposal 8
1.3 Terms and conditions of warranty 9

2 Safety 10
2.1 Infection hazard 10
2.2 Technical condition 10
2.3 Accessories and combination with other equipment 10
2.4 Qualification of personnel 11
2.5 Electrical shock 11
2.6 Aspiration and danger of suffocation 11
2.7 Laceration 11
2.8 Electromagnetic fields 11
2.9 LED light 11
2.10 Service and repair 12
2.11 Ingress of liquids 12
2.12 Cybersecurity 12

3 Product description 13
3.1 Intended use 14
3.2 Symbols on product and rating plate 15
3.3 Product configurations 16
3.4 Technical Specifications 16
3.5 Delivery content 18
3.6 System components 19
3.7 Control panel 20

4 Installation of the wall mount 21
4.1 Screwing the wall mount to a wall 21
4.2 Gluing the wall mount to a wall 21

5 Startup and shut-down 23
5.1 Recommended PC requirements 23
5.2 Installation and software start up 23

6 Operation 24
6.1 Start up of the camera 24
6.2 Use a sheath 24
6.2.1 Applying the sheath 24
6.2.2 Remove the sheath 26
6.3 Snap-in and detach the tip 26
6.3.1 Attach the tip to the camera 26
6.3.2 Detaching the tip from the camera 27
6.4 Recording images 27
6.4.1 Intraoral mode 27
6.4.2 Fluorescence mode 29
6.4.3 Transillumination mode 30
6.4.4 Combined Intraoral + Fluorescence mode 32
6.4.5 Combined mode Intraoral + Fluorescence + Transillumination 32
6.4.6 Monitoring cracks and carious lesions 34
6.5 Switching the camera off 34

Table of contents

7 Processing steps in accordance with ISO 17664-1 / ISO 17664-2 35
7.1 Overview of the processing options 35
7.2 Preparations at the site of use 35
7.3 Disassembly 36
7.4 Manual processing 36
7.4.1 Manual external cleaning 36
7.4.2 Manual internal cleaning 36
7.4.3 Manual external disinfection 36
7.4.4 Manual internal disinfection 37
7.4.5 Manual drying 37
7.5 Automated processing 37
7.5.1 Pre-cleaning 37
7.5.2 Automated internal and external cleaning and internal and external disinfection 37
7.5.3 Automated drying 38
7.6 Care products and systems - Servicing 38
7.7 Sterilization 38
7.8 Storage 39

8 Tools and consumables 40

9 Information concerning the electromagnetic compatibility in accordance with EN IEC 60601-1-2 42
9.1 Electromagnetic emissions 42
9.2 Electromagnetic immunity 43
9.3 Electromagnetic immunity 44
9.4 Recommended safe distance between portable and mobile HF telecommunications equipment and the treatment unit 45

1 User instructions

Dear User,
Congratulations on purchasing this KaVo quality product. By following the instructions below you will be able to work smoothly, economically and safely.

© Copyright by KaVo Dental GmbH

DIAGNOcam is a registered trademark of KaVo Dental GmbH.

All other trademarks are property of their respective owners.



KaVo Technical Service
Please direct all questions regarding the product, service and maintenance to the KaVo Technical Service:
Toll-free: 1-888-KAVO-USA (1-888-528-6872)
Email: techservice@kavo.com
Please refer to the serial number of the product in all inquiries.

KaVo Repair Service
For repairs, please contact the KaVo Repair Service. For scheduling or if you have any questions, please contact:
KaVo Dental Technologies, LLC
11729 Fruehauf Drive
Charlotte, NC 28273 USA
Toll-free Direct Customer Service: 1-888-KAVO-USA (1-888-528-6872)
Email: techservice@kavo.com
www.kavo.com

Target group

The instructions for use are intended for medical professionals, in particular dentists and office personnel.

The section on startup is also intended for the service staff.

Abbreviations

IEC	International Electrotechnical Commission
MPDG	Medical Devices Law Implementation Act

Camera	DIAGNOcam Vision Full HD
Tip	Tip Vision Full HD
Fluorescence cover	Fluorescence Cover Vision Full HD
Sheath	Sheath Vision Full HD
Table holder	Cradle Vision Full HD
Wall mount	Wall Mount Vision Full HD

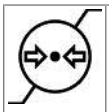
General marks and symbols

	See Chapter on User Instructions/Hazard Levels
	Important information for users and service technicians
▶	Action request

CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
MD	Medical device, labeling of medical devices
135 °C	Sterilizable by steam
	Thermodisinfectable

Information on the packaging

REF	Material number
SN	Serial number
UDI	Unique Device Identifier
	Legal manufacturer
	Manufacturing date
	Attention: Please consult the accompanying documents
	Follow Instructions for use
	Follow the electronic instructions for use
	HIBC Code
CE 0124	CE mark for medical devices
DVE	VDE mark
MET	MET mark
EAC	EAC conformity mark (Eurasian Conformity)
MD	Medical device, labeling of medical devices
	Transportation and storage conditions (temperature range)

	Transportation and storage conditions (air pressure)
	Transportation and storage conditions (humidity)
	Protect from moisture
	Protect from impact
	Original language German
	Do not dispose of with household waste

Hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and property damage. The warning notes are designated as shown below:



⚠ HAZARD

In cases which – if not prevented – directly lead to death or severe injury.



⚠ WARNING

In cases which – if not prevented – can lead to death or severe injury.



⚠ CAUTION

In cases which – if not prevented – can lead to minor or moderate injury.

NOTICE

In cases which – if not prevented – can lead to property damage.

1.1 Transport and storage

1.1.1 Damage in transit

In Germany

If the packaging is visibly damaged on delivery, please proceed as follows:

1. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use the product.
4. Report the damage to the shipping company.
5. Report the damage to KaVo.
6. Consult with KaVo, before returning a damaged product.
7. Send the signed delivery receipt to KaVo.

If the product is damaged but there was no discernable damage to the packaging on delivery, proceed as follows:

1. Report the damage to the shipping company immediately and no later than 7 days after delivery.
2. Report the damage to KaVo.
3. Leave the product and packaging in the condition in which you received it.
4. Do not use a damaged product.

NOTE
Failure on the part of the recipient to comply with any of the above-mentioned obligations will mean that the damage will be considered to have arisen only after the time of delivery (in accordance with the General German Freight Forwarders' Terms and Conditions, Art. 28).

Outside Germany

NOTE
KaVo shall not be held liable for damage arising from transportation. The shipment must be checked on arrival.

If the packaging is visibly damaged on delivery, please proceed as follows:

1. The recipient of the package must record the loss or damage on the delivery receipt. The recipient and the representative of the shipping company must sign this delivery receipt.
   Without this evidence, the recipient will not be able to assert a claim for damages against the shipping company.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use the product.

If the product is damaged but there was no discernable damage to the packaging on delivery, proceed as follows:

1. Report any damage to the shipping company immediately and no later than 7 days after delivery.
2. Leave the product and packaging in the condition in which you received it.
3. Do not use a damaged product.

NOTE
If the recipient fails to comply with any of the above-mentioned obligations, the damage will be considered to have arisen only after the time of delivery (in accordance with CMR law, Chapter 5, Art. 30).

1.2 Product Disposal

NOTE
Contact your local authorized dealer for proper disposal of the device to ensure compliance with your local environmental regulations.

1.3 Terms and conditions of warranty

KaVo provides the final customer with a warranty that the product cited in the handover certificate will function properly and guarantees zero defects in the material or processing for a period of 12 months from the date of purchase, subject to the following conditions:

Upon justified complaints of flaws or a short delivery, KaVo will make good its warranty by replacing the product free of charge or repairing it according to the customer's wishes. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default and gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.

KaVo shall not be held liable for defects and their consequences due to natural wear, improper cleaning or servicing, non-compliance with operating, servicing or connection instructions, calcification or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with factory specifications.

The warranty does not usually cover bulbs, glassware, rubber parts and the colorfastness of plastics.

Defects or their consequences that can be attributed to interventions on or changes made to the product by the customer or a third party are excluded from the warranty.

Claims from this warranty can only be asserted when the transfer form (copy) belonging to the product has been sent to KaVo, and the original can be presented by the operator or user.

2 Safety

NOTE
All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority of the member state, in which the user and/or patient resides.

The instructions for use are a component of the product and must be read carefully prior to use and be accessible at all times.
The device may only be used in accordance with the intended use, any other type of use is not permitted.

Individual warning notes must be observed in the corresponding chapters.

2.1 Infection hazard

Patients, users or third parties may get infected by contaminated medical devices.

- Take suitable personal protective measures.
- Follow the instructions for use of the components.
- Before initial startup, after each repair and after each use, process the product and accessories appropriately.
- Carry out the processing as described in the instructions for use. The procedure has been validated by the manufacturer.
- If you deviate from this validated procedure, make sure that the processing procedure is effective.
- Process the product and accessories appropriately before disposal.

2.2 Technical condition

A damaged product or damaged or NOT KaVo original components could injure patients, users or third parties.

- Visually inspect the device to ensure there is no discoloration and/or cracking of the device/components. Ensure that all functions of the device are given.
- Use the device and components only if there is no damage on the outside.
- Check the proper working order and proper condition of product and accessories before each use.
- Have parts with sites of breakage or surface changes checked by the Service.
- Do not pull on the USB cable and do not kink the cable.
- If product irregularities occur, immediately shut down the product and have the service personnel carry out repair work.
- If image faults occur, immediately shut down the product and have the service personnel carry out repair work.

2.3 Accessories and combination with other equipment

Use of un-authorized accessories on the device or un-authorized modifications to the device can lead to injury.

- Only use accessories that have been approved for combination with the product by the manufacturer.
- Only use accessories that are equipped with standardized interfaces.
- Only use consumables that have been approved for combination with the product by the manufacturer.
- Do not make any modifications to the device unless these have been approved by the manufacturer of the product.
- The USB cable of the camera must not be changed or extended.

This may damaged the tips.

- Attach the tip carefully to the camera.
- Do not attach or remove the tip in a straight line.
- Position the tip on one side of the housing and carefully snap-in into the opposite side.
- Check on the stable positioning of the tip.

2.4 Qualification of personnel

Application of the product by users lacking appropriate medical training can injure the patient, the user or third parties.

- Make sure that the user has read and comprehends the instructions for use.
- Only employ the device if the user has the appropriate medical training.
- Make sure that the user has read and comprehends the national and regional regulations.

2.5 Electrical shock

Damage or connection to external devices can lead to electrical shock and injury to patient, user and third parties.

- Make sure that the product is undamaged. Do not use it again if it dropped.
- Connect the product to a laptop/PC approved in accordance with IEC 60601-1, IEC 60950-1 or IEC 62368-1.

2.6 Aspiration and danger of suffocation

Inserting the medical device too deeply into the throat and pharynx can lead to vomiting and aspiration of the vomit.

- Do not insert the medical device too deeply into the throat and pharynx.

2.7 Laceration

Improper use can lead to laceration.

- Check the medical product and accessories for external damage before use.

2.8 Electromagnetic fields

Electromagnetic fields might interfere with the functions of implanted systems (such as cardiac pacemakers).

- Ask patients if they have a cardiac pacemaker or other system implanted and counsel them about the risks before you start the treatment.
- Switch off the medical device in treatment rooms that use other forms of energy (e.g. X-ray, laser, rotating instruments).

2.9 LED light

LED light is associated with the risk of eye damage.

- Do not direct LED illumination towards the eyes and do not look directly into the light.
- Do not operate the product when the housing is damaged or opened.

2.10 Service and repair

Repairs and servicing may only be performed by trained service personnel. The following persons are authorized to do this:

- Service technicians of KaVo branches after the appropriate product training
- Service technicians of KaVo authorized dealers after the appropriate product training

▸ Only use spare parts that comply with the specification for repair; original manufacturer spare parts comply with the specification.

NOTE

Repairs done using NON-KaVo original spare parts may constitute a product modification that leads to the loss of CE conformity. In the event of damage, the responsibility is with the service company or the operator.

The introduction into the market of a modified product, where there is reasonable suspicion that the safety and health of patients or users may be jeopardized, is prohibited by the German Medical Devices Law Implementation Act (MPDG, Section 12) and therefore requires a separate conformity check in accordance with MPDG, Section 15.

Cleansers and disinfectants that have not been approved can damage the plastic housing leading to hairline cracks and other damage which can ultimately lead to hazards.

2.11 Ingress of liquids

Liquids inside the device can cause it to malfunction.

▸ Make sure that no liquid enters the inside of the device.

2.12 Cybersecurity

The camera uses common open standards for image transfer and device interaction in order to work with the application software.

The camera device does not have any internal functions to interact with any network services.

▸ Please read the manual of your application software for further information.

3 Product description

The camera enables various applications in health facilities/dental offices, dental clinics, orthodontics and oral and maxillary surgery. Connected to a computer, a monitor and imaging software such as CONEXIO, the DIAGNOcam Vision Full HD can be used to create and save images.

The device is used as an intraoral camera to capture images in the oral cavity of the patient. The camera combines three different known applications from available intraoral cameras in one device. These applications are standard camera functionality, transillumination and fluorescence caries detection. Therefore, the camera uses different light colors for each of the three applications to illuminate the tooth. In combination with an optical system, CMOS sensor, and an internal image processing unit, a digital image of the tooth is generated. The live images are transferred as a standard mjpg video stream via USB interface to a running computer and can interface with a dental imaging software, such as CONEXIO, for basic intraoral camera management functionality.

The device may be used as an aid for monitoring caries lesion size and shape by comparing images taken with the DIAGNOcam Vision Full HD over time, by using different reference points, such as tooth contour and position, to position the device to optimize capturing tooth features previously recorded in a freeze frame. For easy use the camera is equipped with an autofocus mechanism which will provide a sharp representation of the tooth which is placed in the center of the image. The autofocus provides the ability to have sharp images from close distances of about 2 mm to about 120 mm distance.

The different operation modes are described as follows:

1. **Color mode**:
   For normal color images, white LED illumination is used. This is the light the camera uses to produce colored images.
   The camera can be used with or without a Tip Vision Full HD, which is required for illumination in Transillumination mode.
2. **Fluorescence mode**:
   Blue LED illumination is used for Fluorescence mode. The blue light excites bacterial porphorines as an aid to detect caries. To enhance the image quality and to minimize external light influence on the fluorescence effect, the Fluorescence Cover Vision Full HD accessory can be used with the camera as an option. The Fluorescence Cover Vision Full HD is a rubber cap which can be slipped onto the front camera head and prevent or minimize external light on the images surface of the tooth. After each use, the Fluorescence Cover Vision Full HD is processed and sterilized separately.
   The camera can be used with or without a Tip Vision Full HD, which is required for illumination in Transillumination mode. This mode is used to record images to aid in the diagnosis of caries (mainly in the occlusal area) and plaque by means of fluorescent effect.
3. **Transillumination mode (by the use of near-infrared light)**:
   This Transillumination mode produces images to aid in the detection of caries. Near-infrared light is used for this mode. Near-infrared light penetrates into the surface and enamel to produce a gray scale image in which intact enamel appears bright, and defects such as caries or cracks result in diffusion of light path and create an area of dark appearance.
   To use this mode, the Tip Vision Full HD must be attached to the device as the LEDs for illumination are located inside the Tip Vision Full HD. The Tip Vision Full HD touches the side of the tooth and gingiva and illuminates it from two sides while the image is captured from above.

The DIAGNOcam Vision Full HD is available in different models. All critical components within the DIAGNOcam Vision Full HD are common. A sheath is used with the device to mitigate the potential for cross contamination.

Contraindications

- The ability to diagnose is strongly limited or even made impossible by a denture (e.g. crowns) and very large fillings.
- Subgingival caries cannot be diagnosed.
- The DIAGNOcam Vision Full HD is designed solely to confirm diagnoses. The DIAGNOcam Vision Full HD is intended to aid in the diagnosis of caries, especially in the early detection of caries.

3.1 Intended use

Indications for use:

The DIAGNOcam Vision Full HD captures patient images as a diagnostic aid for detection of smooth surface caries, occlusal caries, proximal caries, initial caries, secondary caries, and tooth cracks. The DIAGNOcam Vision Full HD is designed for use by a trained professional in the field of dentistry.



⚠ CAUTION

Qualification of personnel.

US Federal law restricts this device to sale by or on the order of a healthcare professional / dentist.

- For dental use only.

Proper Use:

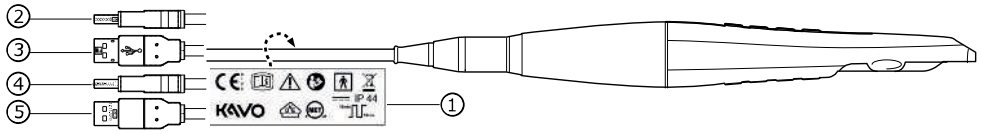
According to these regulations, this product may only be used for the described application by a properly trained user. You need to comply with the following:

- the applicable health and safety regulations
- the applicable accident prevention regulations
- these Instructions for use

In accordance with these regulations, the user is required to:

- only use equipment that is operating properly
- comply with the specified intended use
- protect himself or herself, the patient and third parties from hazards
- prevent contamination by the product

3.2 Symbols on product and rating plate



① Type plate
② Serial number
③ HIBC Code
④ Manufacturing date
⑤ Material number

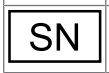
Accompanying documents

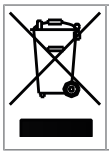
	Follow the electronic instructions for use
	Follow the instructions for use
	Follow Instructions for use
	HIBC Code

Certification

	CE mark according to Medical Devices Regulation 2017/745 MDR
	VDE mark
	MET mark
	Medical device, labeling of medical devices

Product characteristics

	Legal manufacturer
	Manufacturing date
	Serial number
	Material number
	Type BF applied part
	Direct current
	Operating mode: continuous operation with intermittent load
IP 44	Degree of protection against ingress of solid and liquid substances

	Do not dispose of with household waste

3.3 Product configurations

The camera is available with two different lengths of cable:

Standard configuration **(1.011.1213, 1.015.3700**)	Cable length: 2.5 m
Used in combination with treatment unit (**1.013.1500**)	Cable length: 1.30 m

3.4 Technical Specifications

Complete system

Power consumption	max. 0.5 A
Supply voltage	5 V
Cable length (standard)	2.5 m
Weight	190 g
Length (standard)	255 mm
Diameters	approx. 30 mm
Interface	USB 2 / USB 3

Mode: intermittent operation

Operating time	10 minutes
Pause time	10 minutes

Illumination

In the handpiece	2x LEDs for Fluorescence mode 2x LEDs for Intraoral mode
In the tip	2x LEDs for Transillumination mode

Optical system

Image size	1920 × 1080 px
Working area	2 mm (macro) to 120 mm (facial)

Operating conditions

Ambient temperature	+10°C to +30°C (+50°F to +86°F)
Air pressure	800 hPa to 1060 hPa (11 psi to 15 psi)
Relative humidity	5% to 95% non-condensing

Operating altitude	max. 2000 m

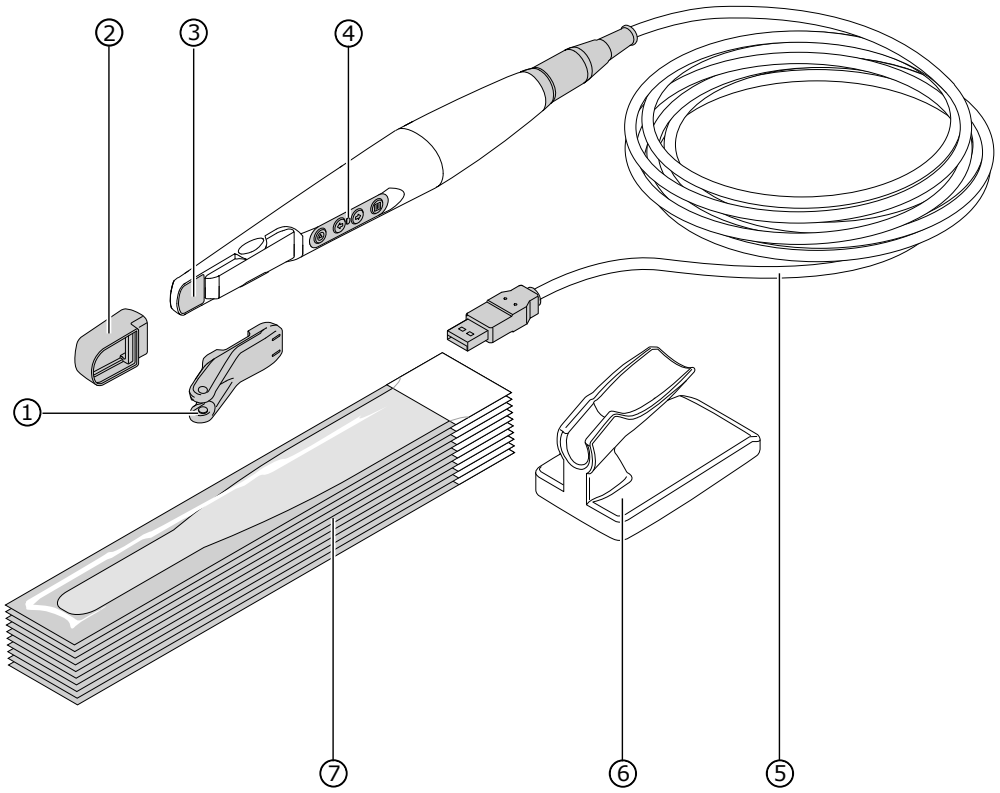
Operating environment

Permissible installation sites	Indoor premises, portable
Degree of soiling	2

Transportation and storage conditions

Ambient temperature	-10°C to +55°C (+14°F to +131°F)
Air pressure	700 hPa to 1060 hPa (10 psi to 15 psi)
Relative humidity	5% to 95% non-condensing

3.5 Delivery content

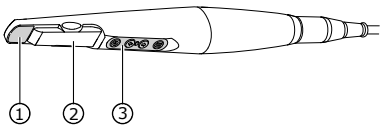
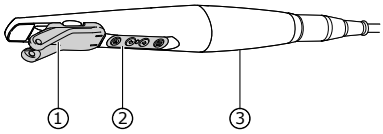
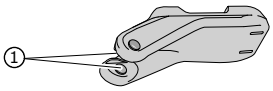
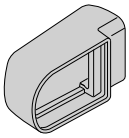
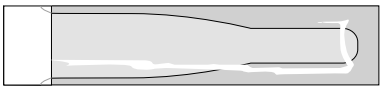
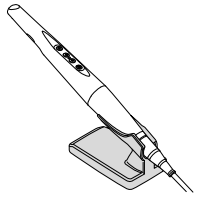
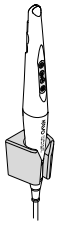


① Tip (4 pieces)
② Fluorescence cover (1 piece)
③ Camera
④ Control panel
⑤ USB cable
⑥ Table holder*
⑦ Sheath (100 pieces)

*Only available in combination with material numbers **1.011.1213** and **1.013.1500**.

The USB cable is used to connect the camera to the computer and to send the captured image to the imaging software. The DIAGNOcam Vision Full HD needs imaging software that is approved for connection to the camera. The function of the camera depends on the mode, which can be selected using the control panel.

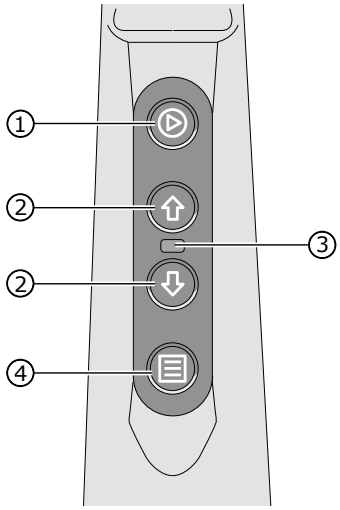
3.6 System components

Camera	
	① Window with 2 LEDs each for Intraoral mode and Fluorescence mode ② Tip holder ③ Control panel **Also refer to:** 6 Operation, Page 24
Camera with tip attached	
	① Tip ② Control panel ③ Camera **Also refer to:** 6 Operation, Page 24
Tip	
	① 2x light exit for Transillumination mode **Also refer to:** 6.3 Snap-in and detach the tip, Page 26
Fluorescence cover	
	Fluorescence Cover is used in Fluorescence mode. **Also refer to:** 6.4.2 Fluorescence mode, Page 29
Sheaths	
	The sheaths are used for infection prevention.
Table holder*	
	The table holder is to be placed on the dentist element and can be used to store the camera. When the camera is placed in the table holder, it shuts off automatically. Once the camera is taken out of the table holder, it switches on automatically.
Wall mount*	
	The wall mount is used for storing the camera and can be attached to vertical surfaces. When the camera is placed in the wall mount, it shuts off automatically. Once the camera is taken out of the wall mount, it switches on automatically.

*Only available in combination with material numbers **1.011.1213** and **1.013.1500**.

3.7 Control panel

The control panel is situated on the top and bottom side of the camera.



① Trigger button for capturing an image
② Buttons for navigation in the imaging software, e.g. numbered tooth chart (if available)
③ Status LED indicating the current status of the camera:
- Blue: Standby mode
- White: Camera is active
- Red: Error

④ Menu button, e.g. for selection of the respective mode

▸ The camera can also be operated with the PC software (keyboard or mouse).

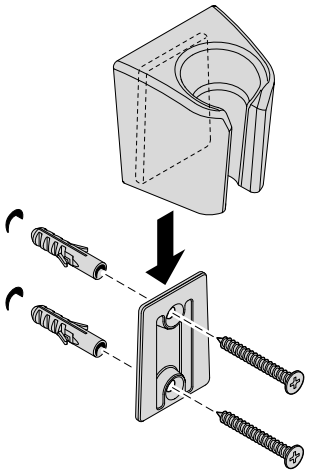
Depending on the available imaging software, the control buttons can be re-configured allowing the dentist to set an economic configuration.

4 Installation of the wall mount

The wall mount can either be screwed to the wall or glued to the treatment unit or to another surface.

4.1 Screwing the wall mount to a wall

- Mark the holes in the desired position using the wall mount.
- Drill holes with a diameter of 6 mm, insert the dowels and screw the wall mount tight with screws.



4.2 Gluing the wall mount to a wall

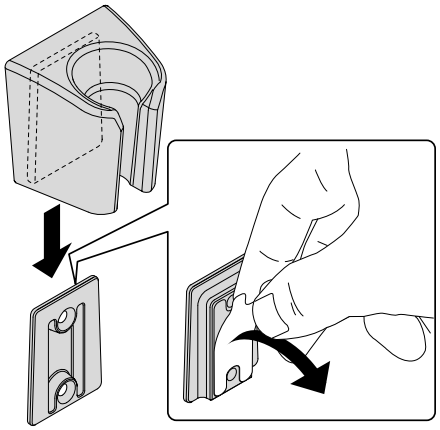
NOTICE

No secure hold of camera and wall mount.
Material damage.
- Check to make sure that the wall mount and camera are securely held.

Requirement

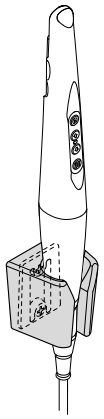
✓ The surface to which the wall mount is glued must be level, smooth, clean and free of grease.

- Remove the adhesive tape from the back of the mounting rail and stick the mounting rail in the desired position.



- Slide the wall mount onto the mounting rail.

- Place DIAGNOcam Vision Full HD HD in wall mount.



5 Startup and shut-down



⚠ WARNING

Hazard from contaminated products.

Patients, users or third parties may get infected by contaminated medical devices.

- Before initial startup, after each repair and after each use, process the product and accessories appropriately.



⚠ WARNING

Dispose of the product in the appropriate manner.

Patients, users or third parties may get infected by contaminated medical devices.

- Process the product and accessories before disposal.

5.1 Recommended PC requirements

	PC	MAC
Operating system	Windows® 64-bit (Windows® 10)	"macOS® High Sierra, macOS® Sierra,OS X® El Capitan"
Processor	A quad-core CPU of 2.8 GHz or more (such as Intel Core i5 or i7)	A quad-core CPU of 2.8 GHz or more (such as Intel Core i5 or i7)
Memory	8 GB memory	8 GB memory
Hard disk	16 GB of free disk space is recommended.	16 GB of free disk space is recommended.
Display	Full HD (1920 × 1080) or higher	Full HD (1920 × 1080) or higher, e.g. 1920 × 1200
Graphic card	A graphics card with optimal 3D support (OpenGL® 3.3) and 2 GB memory or more is recommended (such as AMD or NVIDIA). For 4K displays, 4 GB memory or more is recommended.	A graphics card with optimal 3D support (OpenGL® 3.3) and 2 GB memory or more is recommended (such as AMD or NVIDIA). For 4K displays, 4 GB memory or more is recommended.
Interface	USB 2.0	USB 2.0

- For the recommended PC requirements of the software used, follow the installation instructions of the software used, e.g. CONEXIO or any other software that complies to the USB UVC requirements.

5.2 Installation and software start up



NOTE

For software installation and start up note the installation instructions and the instructions for use of the software in use, e.g. CONEXIO or any other software that complies to the USB UVC requirements.

6 Operation

6.1 Start up of the camera

- Use the USB cable to connect the camera to the computer.
- Start up the imaging software.
- Switch on camera via one of the following options:
  - At the system start of the imaging software.
  - By pressing any button on the control panel.
  - By removing the camera from the table holder or wall mount

6.2 Use a sheath

⚠ WARNING

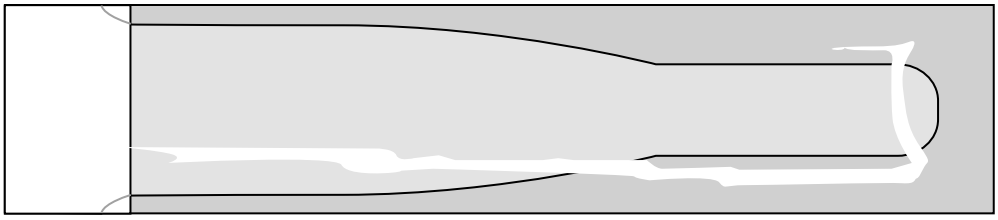
Hazard from contaminated products.

Patients, users or third parties may get infected by contaminated medical devices.

- Always use the camera with a sheath.
- Renew the sheath after each patient.
- Do not use damaged sheaths.
- Wipe the camera down with disinfectant after use.

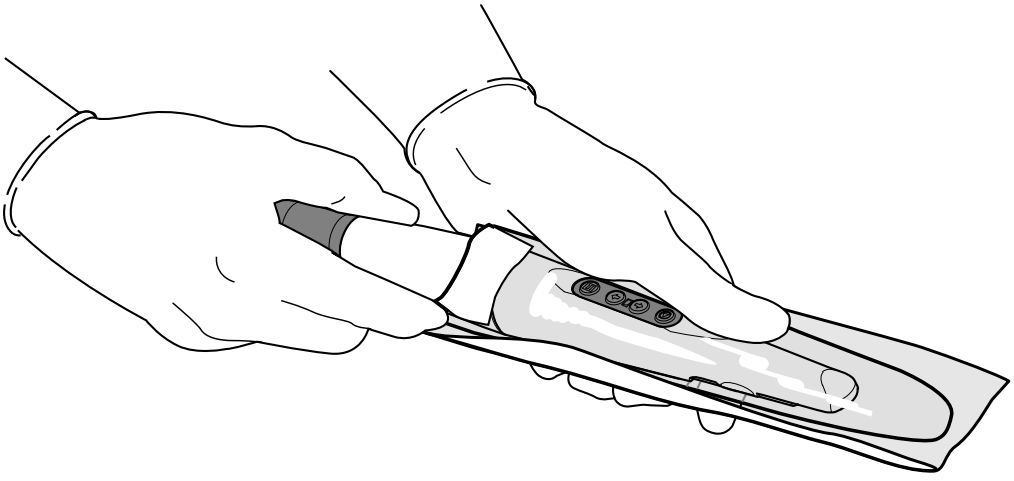
NOTE

Sheath (100 pcs.) can be ordered under **Mat. No. 1.013.5711**.

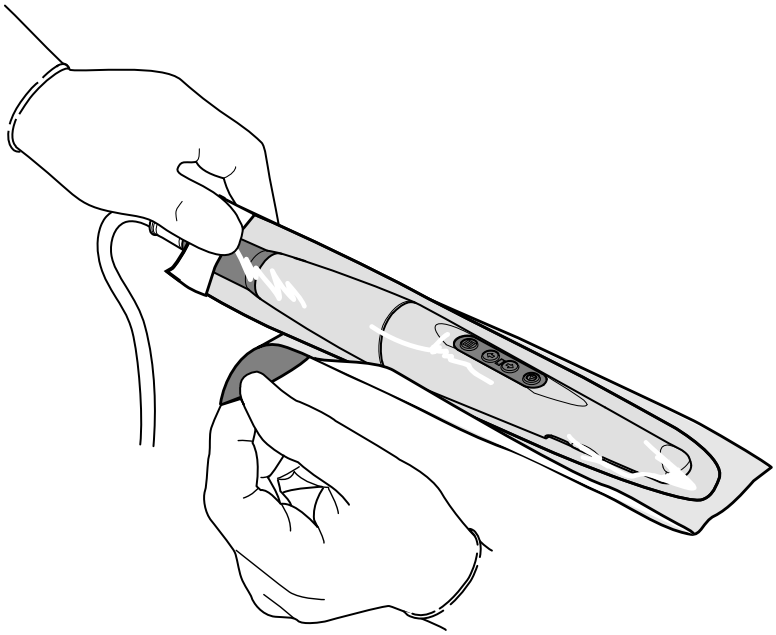


6.2.1 Applying the sheath

- Remove the camera from the camera holder.
- Slowly put the sheath on the camera to allow the air to escape.

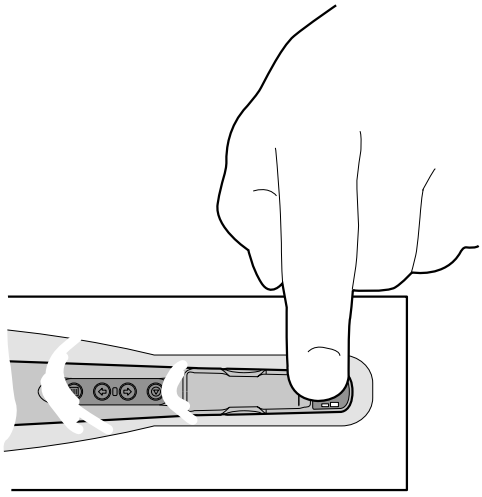


- Remove the outer protective paper.



NOTE
For optimum image quality of the system, there must be no air present between the clear view window of the sheath and the exposure window of the camera.

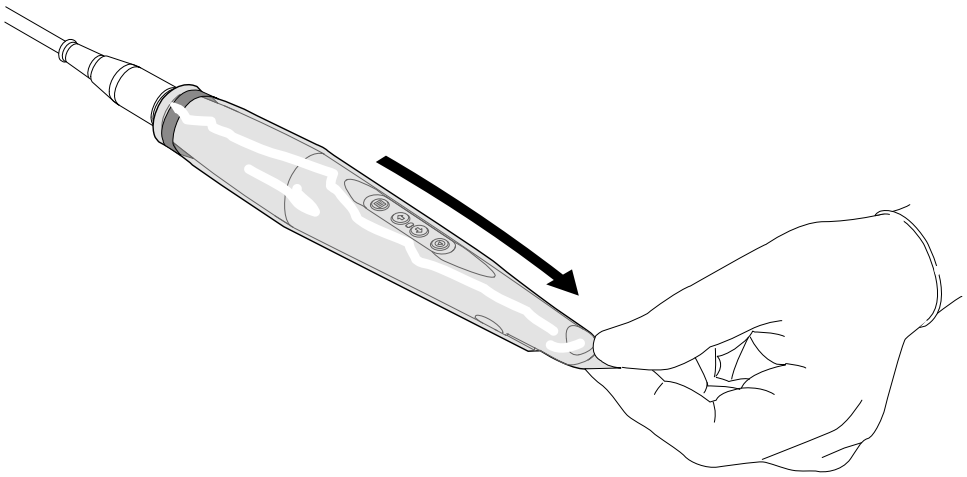
- To ensure a sharp image, the clear view window of the sheath must be situated exactly over the exposure window of the camera.
- Tighten the clear view window in front of the exposure window of the camera.



NOTE
If the image is poor quality or appears cloudy, the clear view window in the sheath is not positioned exactly over the exposure window. To achieve optimum image quality, the clear view window of the sheath must be positioned exactly over the exposure window of the camera.

6.2.2 Remove the sheath

- Carefully remove the sheath after each treatment and dispose of it.



- Then process the camera and accessories according to recommendations.

Also refer to:
7 Processing steps in accordance with ISO 17664-1 / ISO 17664-2, Page 35

6.3 Snap-in and detach the tip

6.3.1 Attach the tip to the camera

NOTICE

Damage from inaccurate attachment of the tip.
The camera and tip may be damaged if the tip is not accurately attached.
- Make sure that the contours of the camera align with the contours of the tip.
- Do not force the tip to snap-in.
- Do not slide the tip in the axial direction.

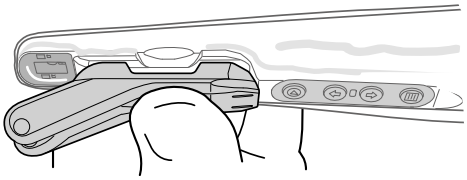
- Before the first use process the tip in accordance with the instructions for use.

Also refer to:
7 Processing steps in accordance with ISO 17664-1 / ISO 17664-2, Page 35

- Apply the sheath first before you attach the tip to the camera.

Also refer to:
6.2 Use a sheath, Page 24

- Position the tip on one side of the housing and carefully snap-in into the opposite side.
- Check on the stable positioning of the tip.

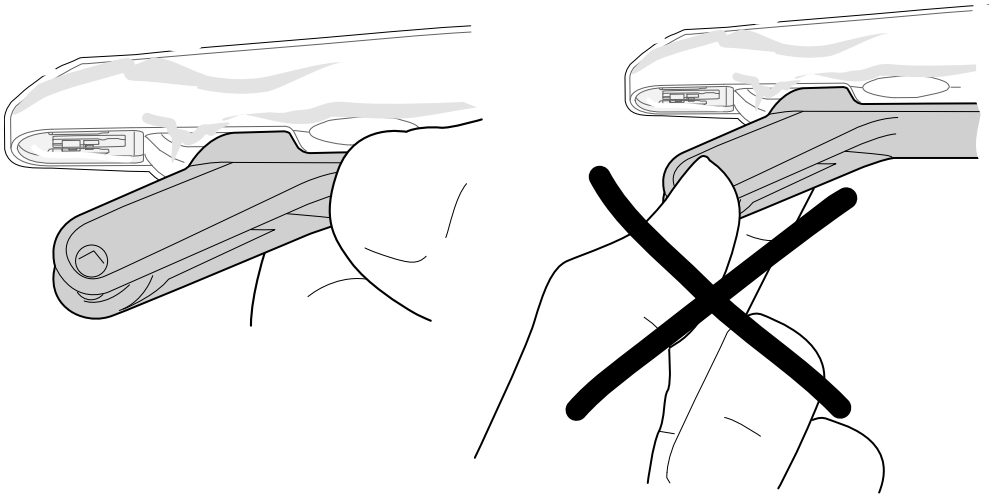


6.3.2 Detaching the tip from the camera

NOTICE

Damage from inappropriate detachment of the tip.
The camera and tip may be damaged if the tip is detached inappropriately.
- Do not pull the tip in the axial direction.
- Detach the tip only by rotating it.

- Carefully detach the tip by rotating it on one side. Then press the tip at the predetermined recess and do not touch it by the soft silicone legs.



6.4 Recording images

6.4.1 Intraoral mode

⚠ CAUTION

Hazard from optical radiation.

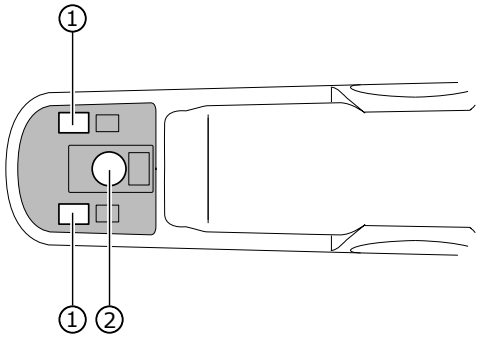
The medical device emits optical radiation that could injure patients, users or third parties.

- Do not stare into the active light source.

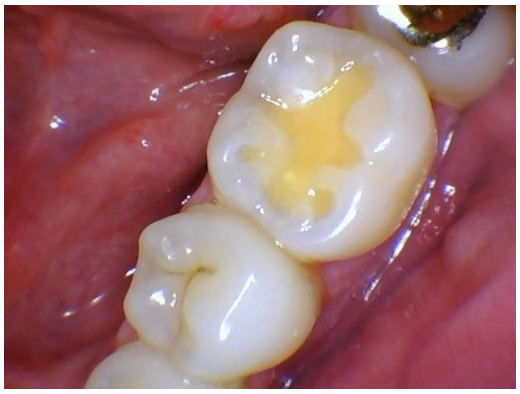
The DIAGNOcam Vision Full HD camera houses a lens system with a permanent autofocus, which focuses permanently between the macro range and facial images.

NOTE
In this mode, it is advisable to switch off the light of the treatment unit.

LEDs that illuminate white in Intraoral mode are attached to the lens system for homogenous illumination.



① LEDs ② Lens system



Example: Intraoral image

Recording an image in Intraoral mode

The DIAGNOcam Vision Full HD can be used to record images. The possible recording modes depend on the imaging software.

- Use the USB cable to connect the camera to the computer.
- Start up the imaging software.
- Remove the camera from the camera holder.
- Pull on the sheath before using the camera.

Also refer to:
6.2 Use a sheath, Page 24

The recording window of the imaging software shows a live image.

- Select Intraoral mode in the imaging software or with the menu button.
- Select an image detail.

⇨ The camera automatically focuses the selected image detail (permanent autofocus).

- Press a trigger button.

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

- Press the trigger button again to return to Live mode.
- Process and save the image in the imaging software.

6.4.2 Fluorescence mode

⚠ CAUTION

Hazard from optical radiation.

The medical device emits optical radiation that could injure patients, users or third parties.

- Do not stare into the active light source.

⚠ CAUTION

Burning hazard from hot camera.

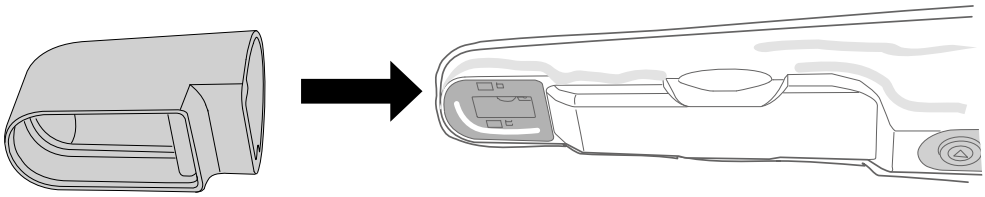
The camera can reach a temperature of up to 48° C in Fluorescence mode.

- Avoid prolonged operating times.

⚠ CAUTION

UV emitted from this product.

In Fluorescence mode, it is advisable to attach the fluorescence cover to the camera to be able to record optimally illuminated images.

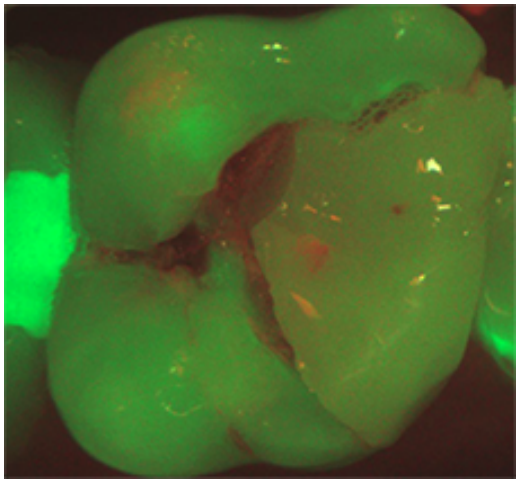


In this mode, the DIAGNOcam Vision Full HD camera records images in the fluorescence range for the detection of occlusal caries. LEDs that illuminate blue in this mode are attached to the lens system for homogenous illumination.

The blue light excites the enamel and the metabolic products of cariogenic bacteria. These substances emit different colours (fluorescence), which allows the user to detect carious activity and to diagnose possible pathological findings. This mode can be used to record images in the fluorescence range for the diagnosis of occlusal caries and plaque. The permanent autofocus can create consistently sharp images, as in Intraoral mode.

NOTE

In this mode, it is advisable to switch off the light of the treatment unit.



Example: Fluorescent image

Analysis:

- The enamel is shown in a greenish colour.
- Metabolic products of cariogenic bacteria are shown in a reddish colour.

Recording an image in Florescence mode

- Use the USB cable to connect the camera to the computer.
- Start up the imaging software.
- Remove the camera from the camera holder.
- Before first use, process the fluorescence cover in accordance with the instructions for use.

Also refer to:
7 Processing steps in accordance with ISO 17664-1 / ISO 17664-2, Page 35

- Pull on the sheath before you attach the fluorescence cover to the camera.

Also refer to:
6.2 Use a sheath, Page 24

To capture an optimum image, the fluorescence cover needs to be fully attached to the camera. This prevents the ingress of extraneous light and is an additional aid for simple positioning of the camera on the tooth.

The recording window of the imaging software shows a live image.

- Select Fluorescence mode in the imaging software or with the menu button.
- Select an image detail.
- ⇨ The camera automatically focuses the selected image detail (permanent autofocus).
- Press a trigger button.
- ⇨ The camera switches to Freeze mode. The image is transferred to the imaging software.
- Press the trigger button again to return to Live mode.
- Process and save the image in the imaging software.

6.4.3 Transillumination mode



⚠ CAUTION

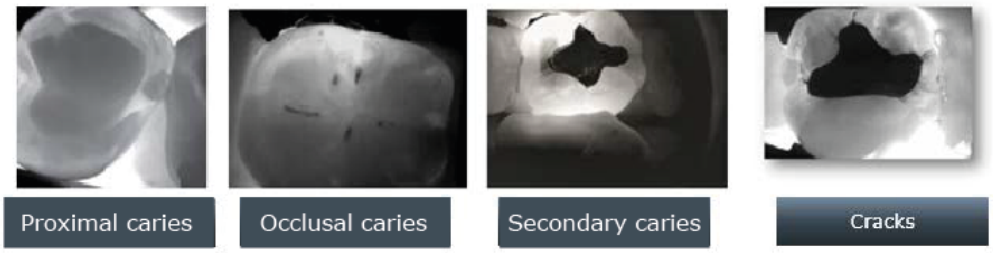
Hazard from optical radiation.

The medical device emits optical radiation that could injure patients, users or third parties.

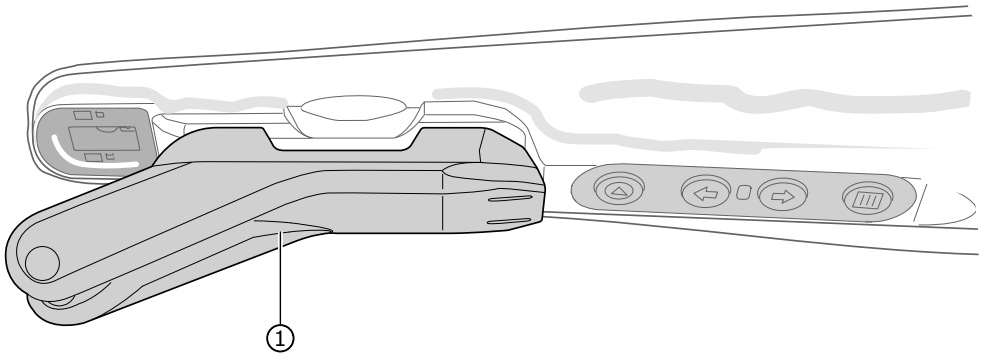
- Do not stare into the active light source.

The DIAGNOcam Vision Full HD produces images reminiscent of X-ray images, but which are completely radiation free. The light is especially adapted to this examination method. The tooth structures allow the passage of light from the entry site to the camera. Areas that block light transmission (e.g. carious lesions) show up clearly as well delimited, dark areas. The camera captures the actual situation and visualizes it in real-time on the screen.

In this mode, the DIAGNOcam Vision Full HD camera records images in transillumination for the detection of occlusal caries, proximal caries, secondary caries and cracks.



The DIAGNOcam Vision Full HD can detect caries in the enamel, but not in the dentin. Healthy dental enamel is shown bright in the image, whereas carious sites are shown as dark spots. The tip must be attached in Transillumination mode. The LEDs in the tip (attached to the camera) are situated on the left and right and emit near-infrared light.



① Tip

Recording images in Transillumination mode

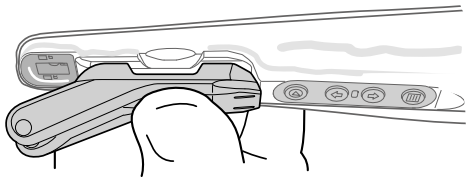
- Use the USB cable to connect the camera to the computer.
- Start up the imaging software.
- Remove the camera from the camera holder.
- Apply the sheath first before you attach the tip to the camera.

Also refer to:
6.2 Use a sheath, Page 24

- To use Transillumination mode, attach the tip to the camera.

⇨ The tip connects to the camera automatically and switches it to Transillumination mode.

NOTE
Do not damage the sheath when you attach the tip.



The recording window of the imaging software shows a live image.

- Select an image detail.

⇨ The camera has a fixed focus.

- Press a trigger button.

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

- Press the trigger button again to return to Live mode.
- Process and save the image in the imaging software.

6.4.4 Combined Intraoral + Fluorescence mode



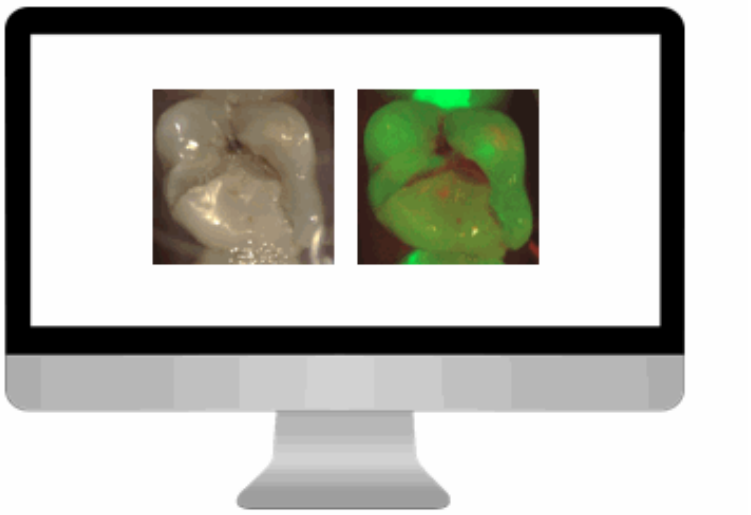
⚠ CAUTION

Hazard from optical radiation.

The medical device emits optical radiation that could injure patients, users or third parties.

- Do not stare into the active light source.

- Use the USB cable to connect the camera to the computer.
- Start up the imaging software.
- Remove the camera from the camera holder.



- Select Intraoral + Fluorescence combi mode (freeze frame) in the imaging software or with the menu button.
- Select an image detail.

⇨ The camera automatically focuses the selected image detail (permanent autofocus).

- Press a trigger button.

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

- Press the trigger button again to return to Live mode.
- Process and save the image in the imaging software.

6.4.5 Combined mode Intraoral + Fluorescence + Transillumination



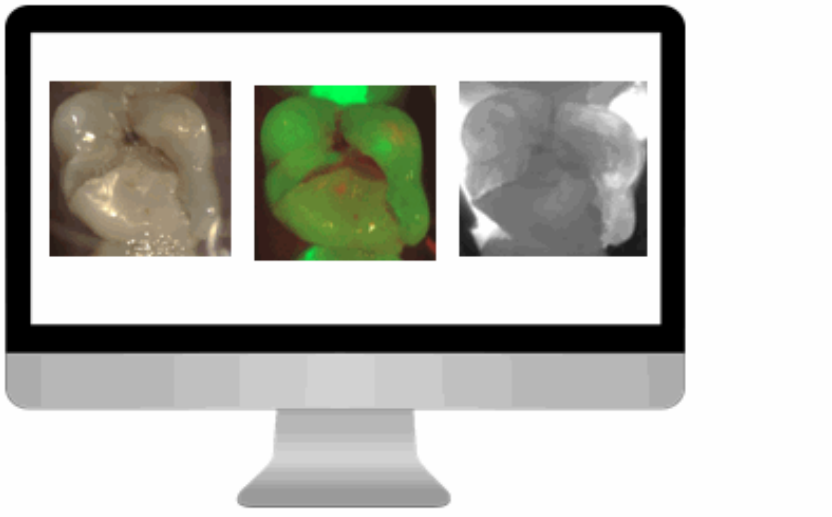
⚠ CAUTION

Hazard from optical radiation.

The medical device emits optical radiation that could injure patients, users or third parties.

- Do not stare into the active light source.

- Use the USB cable to connect the camera to the computer.
- Start up the imaging software.
- Remove the camera from the camera holder.



The recording window of the imaging software shows a live image.

- Select Intraoral + Fluorescence + Transillumination combi mode (freeze frame) in the imaging software or with the menu button.
- ⇨ The live image shows Intraoral mode exclusively.
- Select an image detail.
- ⇨ The camera automatically focuses the selected image detail (permanent autofocus).
- Press a trigger button.
- ⇨ The camera switches to Freeze mode. The image is transferred to the imaging software.
- Press the trigger button again to return to Live mode.
- Process and save the image in the imaging software.

6.4.6 Monitoring cracks and carious lesions

The monitoring of cracks and carious lesions is dependent on the progression of lesion activity over time. The camera allows the actual size and shape of cracks or carious lesions to be visualized. Monitoring is possible by comparing previous images with current images of the lesion in question.
Please check for signs on the tooth (e.g. tooth cusps, fissures, sharpness) and angle the camera until the image shows the same size and position as the tooth image already captured.
Resting the tip on the tooth or adjacent teeth in combination with the friction of the light exit windows stabilizes the DIAGNOcam Vision Full HD. A position very close to the image previously captured must be achieved.

The following step-by-step instructions help to achieve a comparable visualization of the tooth:

- View a previous image of the tooth.
- Select the same tooth that is to be visualized by the camera.
- Position the camera to capture an image of the tooth.
- Move the device horizontally to search for a similar horizontal alignment of the tooth (move the device mesial/distal and lingual/buccal in alternation).
- Make sure the device is at a similar distance to achieve a similar tooth size (adjust the device position up/downwards).
- Make sure the tooth is at the same angle as in the previous images (turn the device mesial/distal and lingual/buccal in alternation).
- Capture images of the current tooth status.

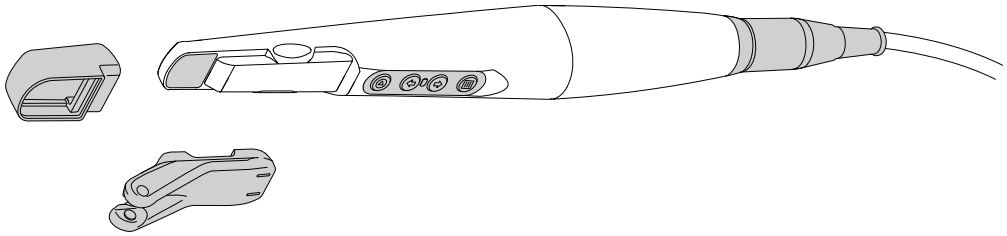
Monitoring can be done by comparing the current image with the previously stored images to identify changes in the size or structure of the lesions.

6.5 Switching the camera off

- Switch off camera via one of the following options:
  - By placing it in the table holder or wall mount.
  - Leaving it unused for a prolonged period of time.

7 Processing steps in accordance with ISO 17664-1 / ISO 17664-2

7.1 Overview of the processing options



Components	Single use or reusable product	Manual Cleaning	Manual Dis-infection	Automated Cleaning	Automated Disinfection	Steril-ization
DIAGNOcam Vision Full HD	Reusable product	Yes	Yes	No	No	No
Tip Vision Full HD	Reusable product	Yes	No	Yes	Yes	Yes
Fluorescence Cover Vision Full HD	Reusable product	Yes	No	Yes	Yes	Yes
Cradle Vision Full HD	Reusable product	Yes	Yes	No	No	No
Wall Mount Vision Full HD	Reusable product	Yes	Yes	No	No	No
Sheath Vision Full HD	Single Use	No	No	No	No	No

7.2 Preparations at the site of use



⚠ WARNING

Hazard from contaminated products.

Patients, users or third parties may get infected by contaminated medical devices.

- Take suitable personal protective measures.

- Pull out the USB plug of the medical device.
- Process the medical device as soon as possible after treatment.
- The medical device must be dry when transported to processing.
- To minimize the risk of infection during processing, always wear protective gloves.
- Remove gross soiling immediately.
- Do not immerse in solutions or the like.

7.3 Disassembly



⚠ WARNING

Incomplete processing.

Patients, users or third parties may get infected by contaminated medical devices.

- To ensure complete processing of all parts, the medical device needs to be disassembled before processing.

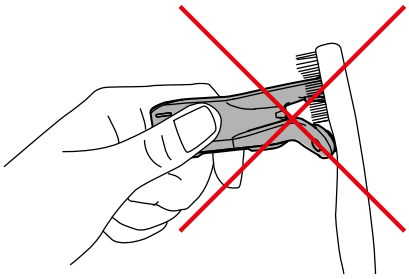
7.4 Manual processing

NOTICE

Do not process the medical device in an ultrasonic device.
Malfunction and material damage.

7.4.1 Manual external cleaning

- Clean the DIAGNOcam Vision Full HD, the tip and the fluorescence cover with a medium-hard toothbrush for at least 1 minute, or until the part looks clean, per item under running potable water at a flow rate 2l/min and a temperature of 30°C ± 5°C (86°F ± 9°F).
- Clean gently, since excessive force may damage the device.
- Do not bend the silicone legs of the tip apart during manual cleaning.



- Visually inspect the parts for cleanliness and wear.
- Repeat the cleaning steps if the parts are not clean.
- Repair or replace worn parts.

7.4.2 Manual internal cleaning

This product is not designed for manual internal cleaning.

7.4.3 Manual external disinfection

NOTICE

Do not process the medical device in an ultrasonic device.
Malfunction and material damage.

KaVo recommends the following products based on the compatibility of the materials. The microbiological efficacy must be ensured by the disinfectant manufacturer and proven by an expert opinion.

- CaviWipes and CaviCide made by Metrex

Requisite consumables:

- Cloths for wiping the medical device.

- Spray the disinfectant on a cloth, then wipe down the medical device and allow the disinfectant to act in accordance with the instructions of the disinfectant manufacturer.
- Comply with the instructions for use of the disinfectant.

7.4.4 Manual internal disinfection

This product is not designed for manual internal disinfection.

7.4.5 Manual drying

This product is not designed for manual drying.

7.5 Automated processing

NOTICE

Never process the medical device with chloride-containing products.
Malfunction and material damage.

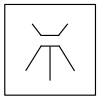
NOTICE

Do not process the medical device in an ultrasonic device.
Malfunction and material damage.

7.5.1 Pre-cleaning

- Clean the DIAGNOcam Vision Full HD, the tip and the fluorescence cover with a medium-hard toothbrush for at least 1 minute per item under running potable water at a flow rate 2l/min and a temperature of 30°C ± 5°C (86°F ± 9°F).
- Clean gently, since excessive force may damage the device.
- Do not bend the silicone legs of the tip apart during manual cleaning.
- Visually inspect the parts for cleanliness and wear.
- Repeat the cleaning steps if the parts are not clean.
- Repair or replace worn parts.

7.5.2 Automated internal and external cleaning and internal and external disinfection



KaVo recommends washer disinfectors in accordance with ISO 15883-1, operated with alkaline cleaning agents.

The validations were performed in a Miele washer disinfector using the "VARIO-TD" program and a mild alkaline cleaner made by Dr. Weigert.

In addition, KaVo recommends the use of a rinsing agent.

- For program settings as well as cleansers and disinfectants, please refer to the Instructions for Use of the washer disinfector.
- For adaptations, unless otherwise specified, refer to the Instructions for Use of the washer disinfector.

The washer disinfector should at least provide the following program steps:

Automated cleaning procedure

- Step 1: Pre-cleaning with cold tap water for 1 min
- Step 2: Cleaning 0.5% cleaner 55 °C for 5 min with demineralized water
- Step 3: Rinsing with demineralized water for 1 min

Automated disinfection procedure

- Step 1: Pre-cleaning with cold tap water for 1 min
- Step 2: Cleaning 0.5% cleaner 55 °C for 5 min with demineralized water

- Step 3: Rinsing with demineralized water for 1 min
- Step 4: Thermal disinfection with demineralized water at 93 °C for 5 min

The drying procedure is usually part of the cleaning program of the washer disinfector. In order to prevent impairment of the medical device, make sure that the inside and outside of the device is dry after the end of the cycle.

7.5.3 Automated drying

The drying procedure is usually part of the cleaning program of the washer disinfector.

NOTE
Please comply with the instructions for use of the washer disinfector.

- In order to prevent impairment of the KaVo medical device, make sure that the inside and outside of the device is dry after the end of the cycle.

7.6 Care products and systems - Servicing

NOTICE

Improper care.
Malfunction or property damage.
- Do not service the medical device with oil or maintenance spray.

7.7 Sterilization

Sterilization in a steam sterilizer (autoclave) in accordance with ISO 17665-1

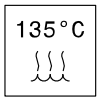
Sterilization has to be performed using a steam sterilizer (autoclave) approved by the U.S. Food and Drug Administration (FDA).

NOTE
The sterile goods package must be large enough to accommodate the product without stretching the packaging. The quality and use of the sterilization packaging must comply with applicable standards and be suitable for the sterilization procedure!

- Seal each medical device individually in a wrap/pouch when sterilizing in a steam sterilizer (autoclave).
- The components/accessories of the DIAGNOcam Vision Full HD are to be wrapped in an FDA-approved sterilization wrap/pouch when sterilizing in a steam sterilizer (autoclave).

NOTICE

Contact corrosion due to moisture.
Damage to the product.
- Remove the product from the steam sterilizer immediately after the sterilization cycle.



The medical device has a maximum temperature resistance up to 138 °C (280.4 °F).

Sterilization parameters:

Sterilization of the product is approved for the following "wrapped" steam sterilization cycles:

- Sterilizer with triple pre-vacuum:

  - 3 minutes at 135 °C (275 °F)
    Drying time: 16 min.
- Sterilizer with gravity displacement method:
  - 10 minutes at 135 °C (275 °F)
    Drying time: 30 min.
- Use in accordance with the manufacturer's Instructions for Use.

7.8 Storage

Processed products must be stored, protected from bacteria, to the extent possible, and dust, in a dry, dark, cool room.

NOTE
Observe the expiration date of the sterilized item.

8 Tools and consumables

Product	Material number
Tip Vision Full HD (pack of 1) The Tip Vision Full HD can be attached to the main device to enable the device for use in Transillumination mode. The main device with the attached Tip Vision Full HD is placed on top of a tooth so that the two arms lay laterally against the tooth. Each of the two flexible silicone arms is equipped with an LED which illuminates the tooth from the sides. The Tip Vision Full HD is fully processable. The Tip Vision Full HD is offered in packs of 1 or 4.	1.013.5708
Tip Vision Full HD (pack of 4) The Tip Vision Full HD can be attached to the main device to enable the device for use in Transillumination mode. The main device with the attached Tip Vision Full HD is placed on top of a tooth so that the two arms lay laterally against the tooth. Each of the two flexible silicone arms is equipped with an LED which illuminates the tooth from the sides. The Tip Vision Full HD is fully processable. The Tip Vision Full HD is offered in packs of 1 or 4.	1.013.5709
The Fluorescence Cover Vision Full HD (pack of 1) The Fluorescence Cover Vision Full HD can be attached to the front part of the main device. It can be optionally used with the effect to minimize stray light from the surroundings and environment which can improve the image quality. The Fluorescence Cover Vision Full HD is made of a soft rubber material for ease of use. This is also fully processable. The Fluorescence Cover vision Full HD is offered in packs of 1 or 4.	1.013.5712
The Fluorescence Cover Vision Full HD (pack of 4) The Fluorescence Cover Vision Full HD can be attached to the front part of the main device. It can be optionally used with the effect to minimize stray light from the surroundings and environment which can improve the image quality. The Fluorescence Cover Vision Full HD is made of a soft rubber material for ease of use. This is also fully processable. The Fluorescence Cover vision Full HD is offered in packs of 1 or 4.	1.013.5715
Cradle Vision Full HD* The Cradle Vision Full HD is a table holder for the main device which can be placed on flat horizontal surfaces. It ensures easy handling and provides a secure parking position for the main device. There is also a built-in magnet inside the Cradle Vision Full HD. This magnet can be detected by the main device to identify the parking position so the main device can be put into sleep mode.	1.013.5500

Product	Material number
Wall Mount Vision Full HD* The Wall Mount Vision Full HD is a tray for the main device which can be mounted on vertical surfaces. The Wall Mount Vision Full HD has a back plate which can be fixed to a surface using the adhesive tape supplied or by screws. The main body is also equipped with a magnet inside. This magnet can be detected by the main device to identify the parking position so the main device can be put into sleep mode.	1.013.0400
Sheath Vision Full HD (pack of 100) The Sheath Vision Full HD is a plastic sheath to be put over the main device to prevent infection. It consists of a transparent front area through which the camera has an uninterrupted view. The Sheath Vision Full HD is provided on paper backing for ease of handling. The paper backing is separated when it is put on the device and the Sheath Vision Full HD takes on the circular shape of the main device. The Sheath Vision Full HD is for one time use and must be removed after each treatment.	1.013.5711

*Only available in combination with material numbers **1.011.1213** and **1.013.1500**.

9 Information concerning the electromagnetic compatibility in accordance with EN IEC 60601-1-2

9.1 Electromagnetic emissions

This product is designed for use in an environment like the one cited below. The customer or the user should ensure that the device is used in an environment of the type specified.

Measurements of emitted interference	Conformance	Electromagnetic environment - guidelines
HF emissions according to CISPR 11	Group 1	This device uses HF energy exclusively for its internal functions. Therefore, the HF emission of the device is very low and interference with adjacent electronic devices is unlikely.
HF emissions according to CISPR 11	Class B	This product is suitable for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.
Emission of harmonics according to IEC 61000-3-2	Class A	This product is suitable for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.
Emission of voltage fluctuations/ flicker according to IEC 61000-3-3	Conforms	This product is suitable for use in all facilities including residential ones, and facilities that are directly connected to a public power supply that also supplies residential buildings.

9.2 Electromagnetic immunity

This product is designed for use in an environment like the one cited below. The customer or the user should ensure that the device is used in an environment of the type specified.

Interference immunity tests	EN 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to EN 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 2/4/8/15 kV air discharge	Floors should be made of wood or concrete or be fitted with ceramic tiles. If the floor is fitted with synthetic material, the relative humidity must be at least 30 %.
Fast transient electrical interference / bursts according to EN 61000-4-4	± 1 kV for input and output cables	± 1 kV for input and output cables	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Magnetic field at a supply frequency (50/60 Hz) according to EN 61000-4-8	30 A/m	30 A/m	Magnetic fields at the mains frequency should correspond to typical values in a business and hospital environment.

NOTE: V_T is the alternating mains voltage before the test level is used.

9.3 Electromagnetic immunity

This product is designed for use in an environment like the one cited below. The customer or the user should ensure that the device is used in an environment of the type specified.

Interference immunity tests	IEC 60601 test levels	Compliance level	Electromagnetic environment - Guidelines
Wireless HF interference according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile radio devices should not be used closer to this product, including the wires, than the recommenced safe distance calculated using the equation for the transmission frequency. Recommended safe distance: $d = 1.17 \sqrt{P}$ $d = 1.17 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended safe distance in meters (m). [b]The field strength of stationary radio transmitters determined in an on-site check[c] should be less than the conformance level[d] at all frequencies. Interference is possible in the vicinity of devices that bear the following symbol. 

Comment 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Comment 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

[a]The ISM frequency bands (for industrial, scientific, and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.7 MHz.

[b]The conformance level in frequency ranges between 150 kHz and 80 MHz and 80 MHz up to 2.5 GHz is determined to reduce the probability of a mobile/portable communication device causing interference if it is introduced unintentionally into the patient area. For this reason, the additional factor of 10/3 is incorporated into the formula and taken into account for transmitters in these frequency ranges.

[c]The field strength of stationary transmitters, such as base stations of mobile phones and mobile terrestrial radio devices, amateur radio stations, AM and FM radio and television transmitters, cannot be determined exactly based on theo-

retical considerations. To determine the electromagnetic environment resulting from stationary high frequency transmitters, the location should be investigated. If the determined field strength at the location where this product will be used exceeds the above cited conformance level, the product should be monitored to see if it is operating normally in every location. If unusual performance characteristics are observed, it may be necessary to undertake additional measures such as reorienting or moving the product.

[d]In the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3V $_{eff}$ V/m.

9.4 Recommended safe distance between portable and mobile HF telecommunications equipment and the treatment unit

This product is intended for use in an electromagnetic environment in which HF interference is controlled. The customer or user of the product can help prevent electromagnetic interference by maintaining minimum distances between portable and mobile HF communication devices (transmitters) and the product as recommended below corresponding to the maximum output of the communication device.

Safe distance depending on the transmission frequency:

Rated power P of the transmitter in W	150 kHz to 80 MHz d=1.17 $\sqrt{P}$ in m	80 MHz to 800 MHz d=1.17 $\sqrt{P}$ in m	800 MHz to 2.5 GHz d=2.3 $\sqrt{P}$ in m
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters whose maximum rated power is not given in the above table, the recommended safe distance d in meters (m) can be calculated using the equation for the respective column, with P being the maximum rated power of the transmitter in Watts (W) according to the manufacturer's information.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not be applicable in every case. The spread of electromagnetic waves is absorbed and reflected by buildings, objects and people.

1.013.7129 · bd · 20250827 · 09 · en-US

KAVO
Dental Excellence