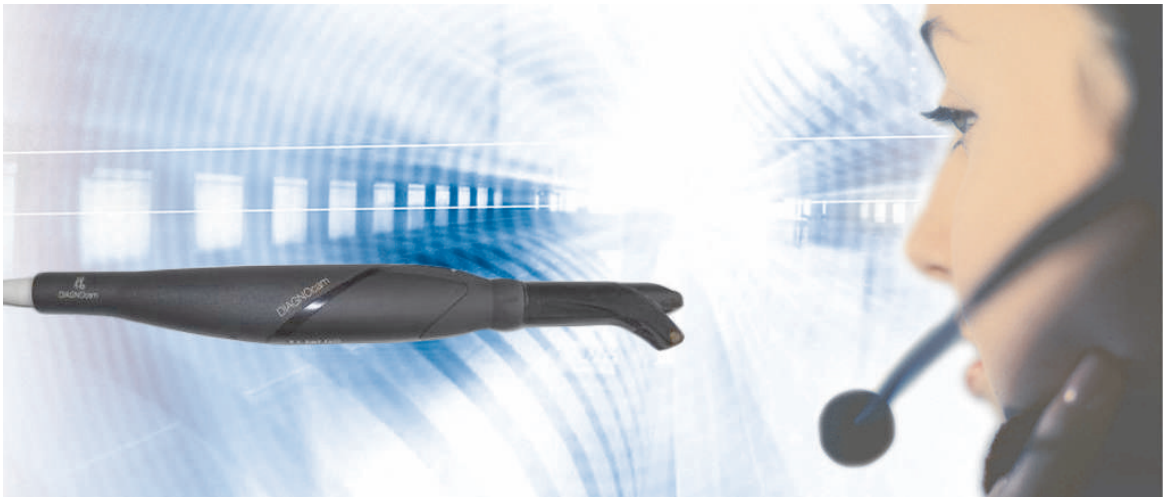
Instructions for use
DIAGNOcam 2170



Always be on the safe side.

KaVo. Dental Excellence.

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CE 0124

Table of contents

1 User instructions

1.1 User guide

Requirement
Read these instructions prior to first use to avoid misuse and prevent damage.

1.1.1 Abbreviations

Abbre-viation	Explanation
IfU	Instructions for Use
CI	Care instructions
AI	Assembly instructions
TI	Technician's instructions
SC	Safety checks
IEC	International Electrotechnical Commission
RI	Repair instructions
EMC	Electromagnetic compatibility
PI	Processing instructions

1.1.2 Symbols

	See the Safety/Warning Symbols section
	Important information for users and technicians
CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EU directive.
▶	Action required

1.1.3 Target group

This document is for dentists and dental office staff.

1.1.4 Service

Service hotline:
+49 7351 56-2700
Service.Multimedia@kavo.com
Please indicate the product serial number in all requests.
Additional information can be obtained at: www.kavo.com

Technical customer service

The technical support for KaVo products is primarily offered by the dental supplier.

KaVo provides ongoing training and special courses for dealer technicians.

To guarantee constant readiness for use and maintenance of value of the KaVO products, the products must be regularly serviced.

2 Safety

2.1 Protective equipment

Note
Since this is a class 1 laser medical device, no personal protective equipment needs to be worn according to the EC directive.

2.2 Description of safety instructions

2.2.1 Warning symbol

	Warning symbol

2.2.2 Structure

⚠ DANGER

The introduction describes the type and source of the hazard.
This section describes potential consequences of non-compliance.

- ▸ The optional step includes necessary measures for hazard prevention.

2.2.3 Description of hazard levels

Safety instructions with three hazard levels are used in this document to prevent personal and property damage.

⚠ CAUTION

CAUTION
indicates a hazardous situation that can cause damage to property or mild to moderate injuries.

⚠ WARNING

WARNING
indicates a hazardous situation that can lead to death or fatal injury.

⚠ DANGER

DANGER
indicates a maximal hazard due to a situation that can directly cause death or fatal injury.

2.3 Purpose – Intended use

2.3.1 General information

The overarching guidelines and/or national laws, national regulations and the rules of technology applicable to medical devices for start-up and use of the KaVo product for the intended purpose must be applied and followed.

This KaVo product is intended for use in dentistry only. Any other type of use is not permitted.
"Proper use" includes compliance with all instructions for use and the inspection and maintenance intervals.

The user must ensure that the unit works properly and is in satisfactory condition before each use.

During use, national legal regulations must be observed, in particular:
- the applicable health and safety regulations
- the applicable accident prevention regulations

Users have a duty to:
- Only use equipment that is operating correctly
- to protect himself, the patient and third parties from danger.
- to avoid contamination from the product

Note

The product must be cleaned and serviced according to instructions if it is not to be used for an extended period of time.

Note

Any waste which is generated must be recycled or disposed of in a manner which is safe both for people and for the environment. This must be done in strict compliance with all applicable national regulations.
Questions on proper disposal of the KaVo product can be answered by the KaVo branch.

2.3.2 Product-specific

The DIAGNOcam is designed exclusively to support the identification of open or incipient carious lesions above the gingiva and for monitoring the progress of such lesions.

Indications:
- Detection of smooth surface caries
- Detection of occlusal carries
- Detection of proximal caries
- Detection of initial caries
- Detection of secondary caries
- Detection of cracks

Contraindications:
- Diagnosability is strongly limited or restricted by a restorations (such as crowns) and very large fillings.
- Subgingival caries cannot be diagnosed.
- The DIAGNOcam is designed solely for use to confirm diagnoses (the DIAGNOcam is intended for supportive caries diagnosis, especially for the early detection of caries).

The device is for use in a dentist's office or dental clinic.

The device is a class IIa medical device according to EC Directive 93/42/EEC.

The illumination corresponds to laser class 1 according to EN 60825-1.

Note

Only a dentist may diagnose pathological changes in the tooth substance.

2.4 Disposal of electronic and electrical devices

Note

According to EC directive 2002/96 concerning used electrical and electronic devices, this product is subject to the cited directive and must be disposed of accordingly within Europe.
Before disassembling / disposing of the product, it must be completely processed (disinfected, sterilized) according to the section "Preparation methods"
Additional information can be obtained from KaVo (www.kavo.com) or your dental supplier.

For final disposal, contact:

Germany

To return an electrical device, proceed as follows:
1. At the homepage www.enretec.de of enretec GmbH, you can download a form for a disposal request under the menu item `eom`, or you can use it as an online request.
2. Fill out the request with the corresponding information, and send it as an online request or by fax (+49(0)3304 3919 590) to enretec GmbH.
   The following avenues are also available for questions and for initiating a disposal request:
   Telephone: +49 (0) 3304 3919 500
   E-mail: pickup@eomRECYCLING.com and
   Post: enretec GmbH, eomRECYCLING Department
   Kanalstraße 17
   16727 Velten
3. Your**movable**device will be picked up in your practice, and your**permanently installed**unit will be picked up at the curb at your address on the agreed deadline.
   The owner or user of the device will bear the costs for disassembly, transportation and packaging.

International (EU)

For country-specific information on disposal, contact your dental supplier.

2.5 Safety instructions

⚠ WARNING

Danger of injury from electric current.
Electric shock.

- Stop working if the device becomes damaged.
- Connect the device only to a PC/laptop that is approved according to IEC 60950.
- Do not use the device on patients or place it near patients with the probe removed.
- Do not use the device after it has been dropped.

⚠ WARNING

Danger of suffocation.
Vomiting can be triggered by inserting the device too far.
Aspiration of vomit.

- Keep the device away from the patient's throat!

⚠ WARNING

Blinding hazard from invisible laser.
Eye damage.

- Do not point the device toward the eyes when the laser is active!
- Do not operate the device when the housing is damaged or opened.
- Do not use the handpiece on the patient when the tips are not attached.
- Do not look into the handpiece's aperture for the light when the tip is removed.

⚠ WARNING

Hazard from electromagnetic radiation.
Interference with other devices.

- Do not use the device on patients with pacemakers!
- Turn off devices situated in the treatment room that are sources of hazardous energy (such as x-ray machines, lasers, and rotating instruments)!

⚠ CAUTION

The product may be damaged by kinking or pinching the USB cable.
Irreversible breakage of the electrical lines in the USB cable.

- Do not pull on the USB cable!

⚠ CAUTION

Damage from improper handling.
Destruction of the DIAGNOcam housing and internal components.

- Do not use the DIAGNOcam to move the dentist element!
- Do not lean on the DIAGNOcam while it is situated in the holder.
- Use the handpiece on the patient only when the probe is attached!

⚠ CAUTION

Risk of infection due to soiled or contaminated DIAGNOcam.
Infection.

- Recondition the DIAGNOcam handpiece and tips after use.

⚠ CAUTION

Risk of laceration from improper use
Laceration

- Do not use the handpiece on the patient without an adapted probe.
- Do not use a damaged device on a patient.
- Do not use the device on a patient when the probe is damaged.

⚠ CAUTION

Powerful laser
The pulp cavity may become heated

- Restrict use to a maximum of 1 minute per tooth.

⚠ CAUTION

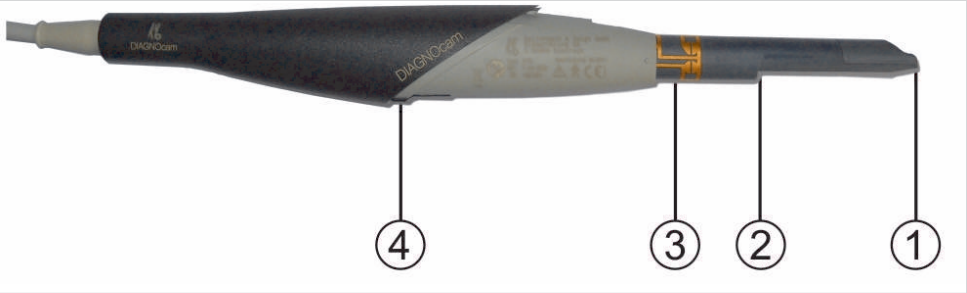
Biological contamination
Infection

- Do not use the device on wounds / exposed tissue.

3 Product description

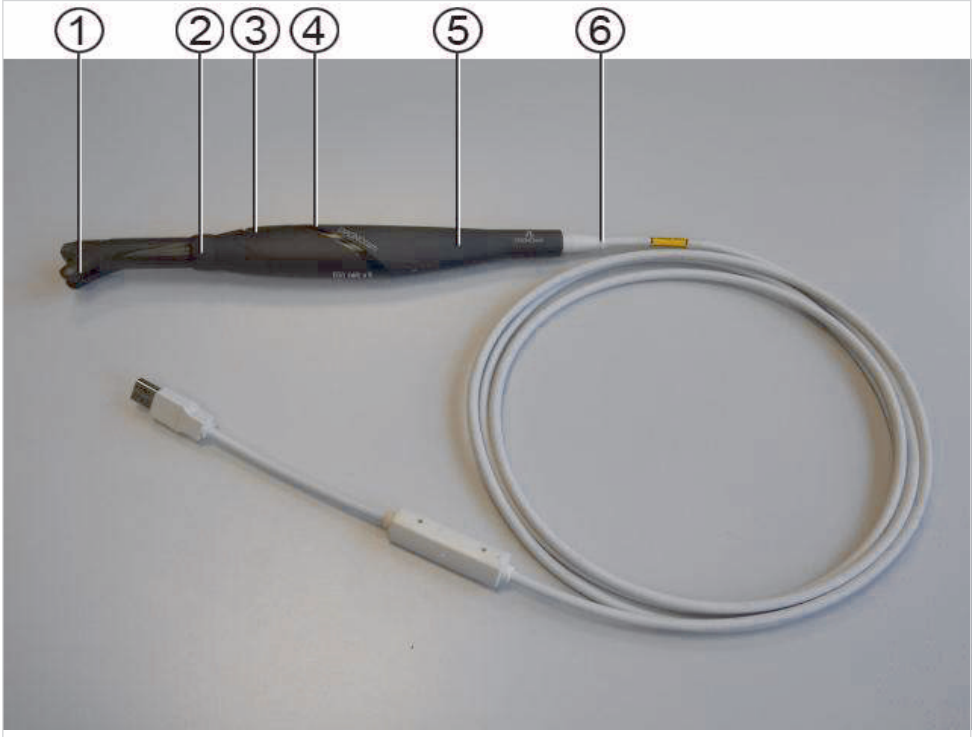
3.1 System components

3.1.1 Handpiece



① Window for camera lens system
② Aperture for the laser
③ Contact surface for the ring switch
④ Forked light barriers for probe identification

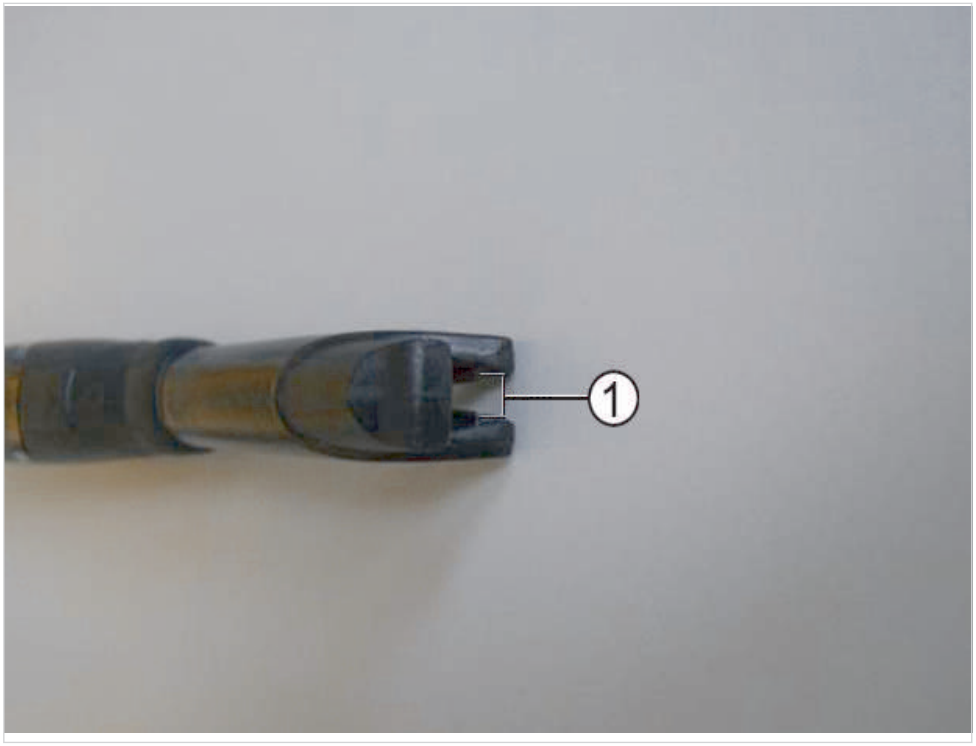
3.1.2 Handpiece with attached tip



① Occlusal tip
② Ring switch
③ Control button 1
④ Control button 2
⑤ Handpiece
⑥ USB 2.0 cable with anti-kink sleeve and DC/DC voltage transformer

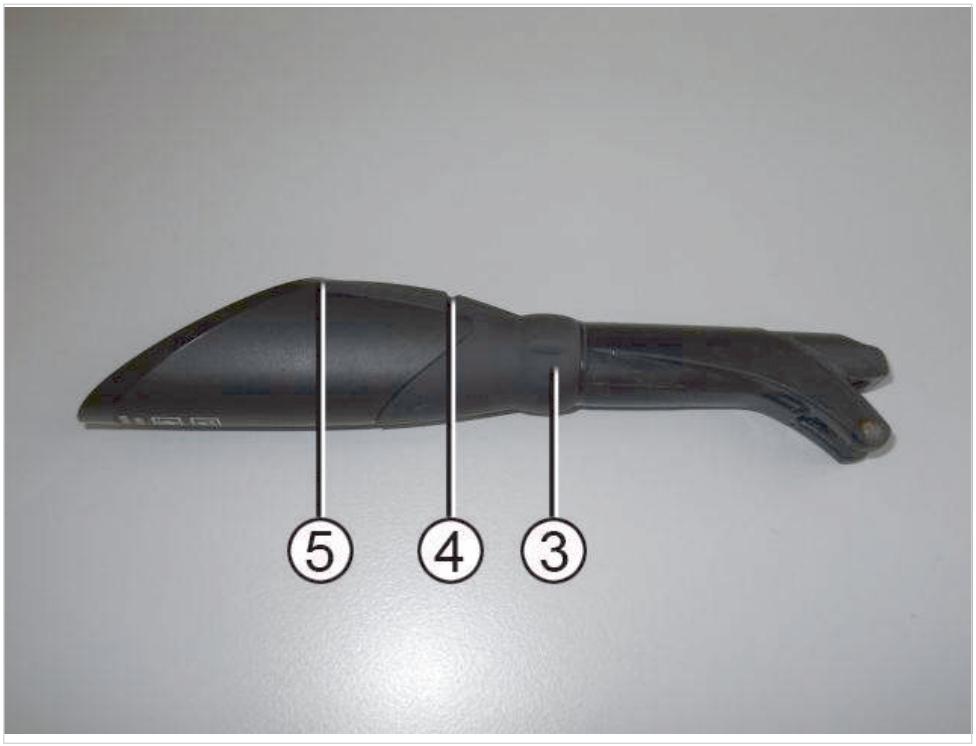
3.1.3 Occlusal tip (Tip large, Tip small)

① Opening for camera window



① Aperture for laser beam

3.2 Operating buttons and ring switch



The ring switch ③ with six positions can be used to generate still in all relevant positions.

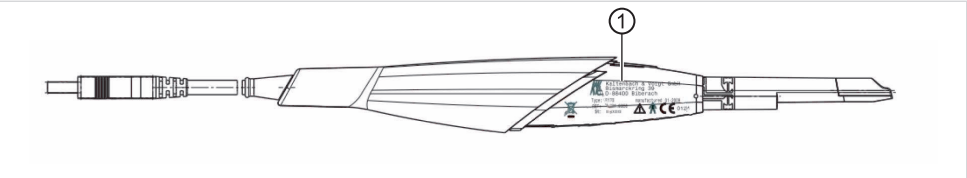
Actuation Ring switch ③	Function
Briefly when the device is turned off	Laser and camera turn on (= the device is ready to use)
Briefly when the device is turned on	Create still images that are automatically saved
Long	Laser and camera are being turned off

Actuation Control button 1 ④	Function
Brief	Select the next tooth in the tooth diagram (in a clockwise direction)
Long	Quick run through of the tooth diagram (clockwise)

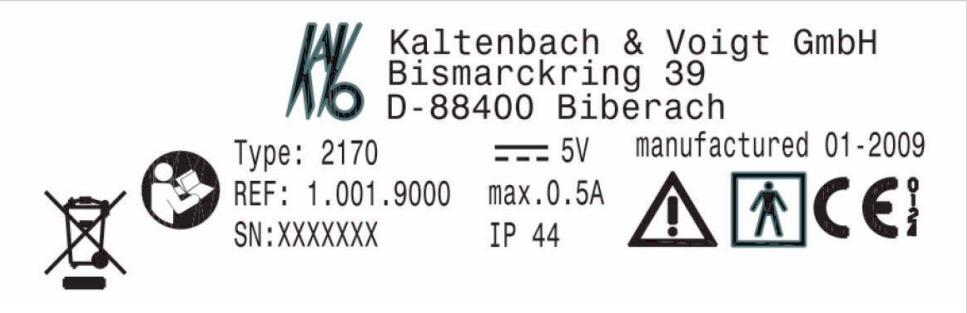
Actuation Control button 2 ⑤	Function
Brief	Select the next tooth in the tooth diagram (anticlockwise direction)
Long	Quick run through of the tooth diagram (in an anticlockwise)

3.3 IDs and labels

3.3.1 Rating plate



① Rating plate



Made in Germany	
Type	Device type DIAGNOcam – Month produced/year produced
REF	Material number
SN	Serial number
	Note: please note accompanying documents!
	Classification (application part type BF)
	CE mark according to 93/42/EEC medical devices
	Labelling according to 2002/96/EC
	Follow the instructions for use

3.4 Technical Specifications

Complete system

Power consumption: max.	0.5 A
Supply voltage	5 V
Hose length	2.5 m
Weight	190 g

Protection class	IP 44
Length	approx. 245 mm
Diameter	30 mm

Protection class IP indicates the scope of protection by a housing against the ingress of solid foreign matter and against the ingress of water.
The first number 4 means protection against ingress of solid foreign matter ≥ 1 mm in diameter.
The second number 4 indicates protection against splashing water.

Image detector

Type	CMOS
Format	¼“
Monochrome	8 Bit
Resolution	640 (H) x 480 (H)

Illumination

Type	Laser diode
Number	2
Wavelength	780 nm
Opt. power	15 mW
opt. power according to DIN EN 60825-1 downstream of the occlusal tips	max. 1 mW

Optical system

Image angle	105°
Viewing direction	80°
Focusing distance	4.5 mm

Operating conditions

Ambient temperature	+10 to + 30° C
Air pressure	800 to 1060 hPa
Rel. humidity	5 to 95% non-condensing
Max. elevation for operation	max. 2000 m

Storage and transportation conditions

Ambient temperature	-10 to +55 °C
Air pressure	700 to 1060 hPa
Rel. humidity	5 to 95% non-condensing

4 First use

4.1 Hardware requirements

- Connect the device only to a PC/laptop that is approved according to IEC 60950.

The system requirements are as follows:
- PC with at least 1 GHz processor power
- 256 MB RAM for single-user station or workstation
- 512 MB RAM for SQL database server
- 50 MB free hard disk space on system drive
- depending on data volume, 5 to 50 GB hard disk space on the data drive (may tally with system drive)
- Min. screen resolution 1024x768, min. colour depth 32 bits
- Operating system: Microsoft Windows XP from Service-Pack 3 or Win7 32/64bit

Note

Windows Media Player 11 with express settings must be installed and have been started once.
Please make sure to comply with the system requirements of other software and hardware systems to be run in conjunction with KiD!

4.2 Software installation

Using the KaVo Integrated Desktop (KiD)

It is recommended to use the DIAGNOcam in combination with the KaVo KiD software.

The software offers comfortable options for
- Recording images
- Evaluating images
- Image processing
- Archiving the images with a tooth diagram for each patient

4.2.1 Start the installation routine

- Insert the DIAGNOcam CD in the disk drive
- Double click the file, DIAGNOcam.... .exe in the root directory of the CD.

  This starts the installation.

4.2.2 Installing a single-user system

- Click on "Next" in the setup start window to start the installation.

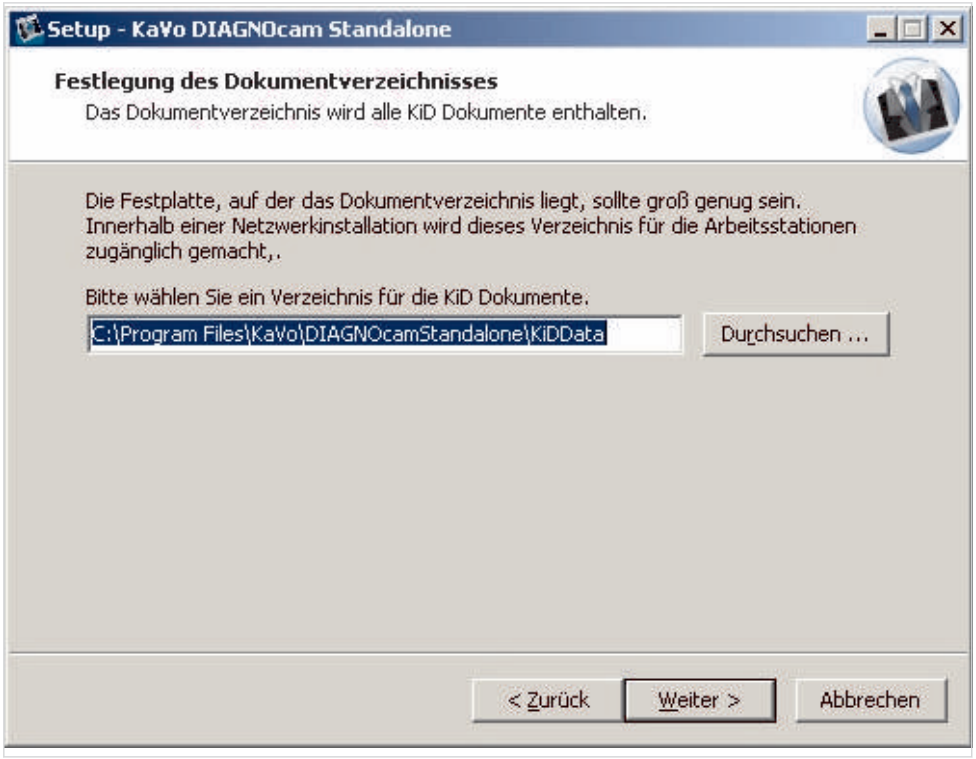
- Read the license agreements and select the option "I accept the agreements", and click "Next".

- Select the target folder for the program directory, and click "Next".

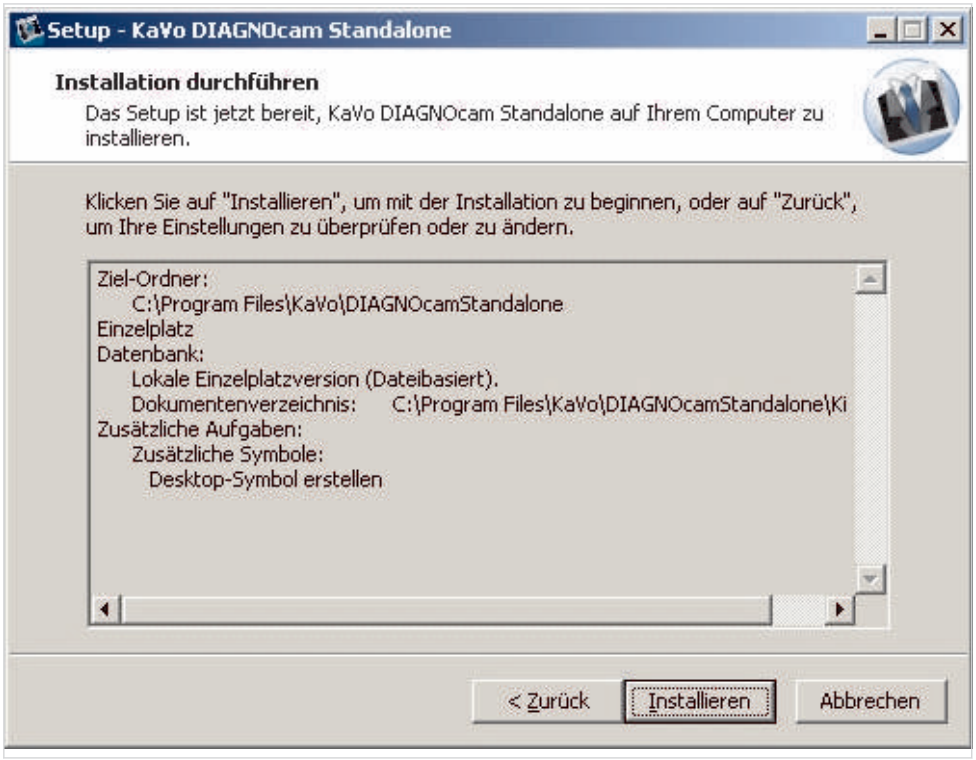
Note

The program files are saved to the target directory. The target directory must be on a local hard disk. It is recommended to use the suggested directory path (C:\Programs\KaVo\KiD). A target directory on a network drive can cause malfunctions.

- Define the document directory

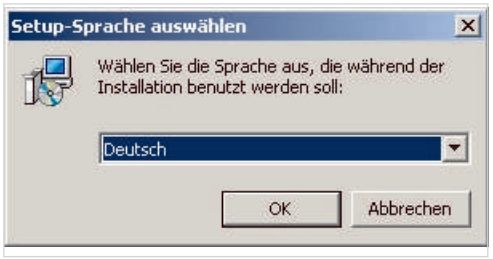


- Continue the installation



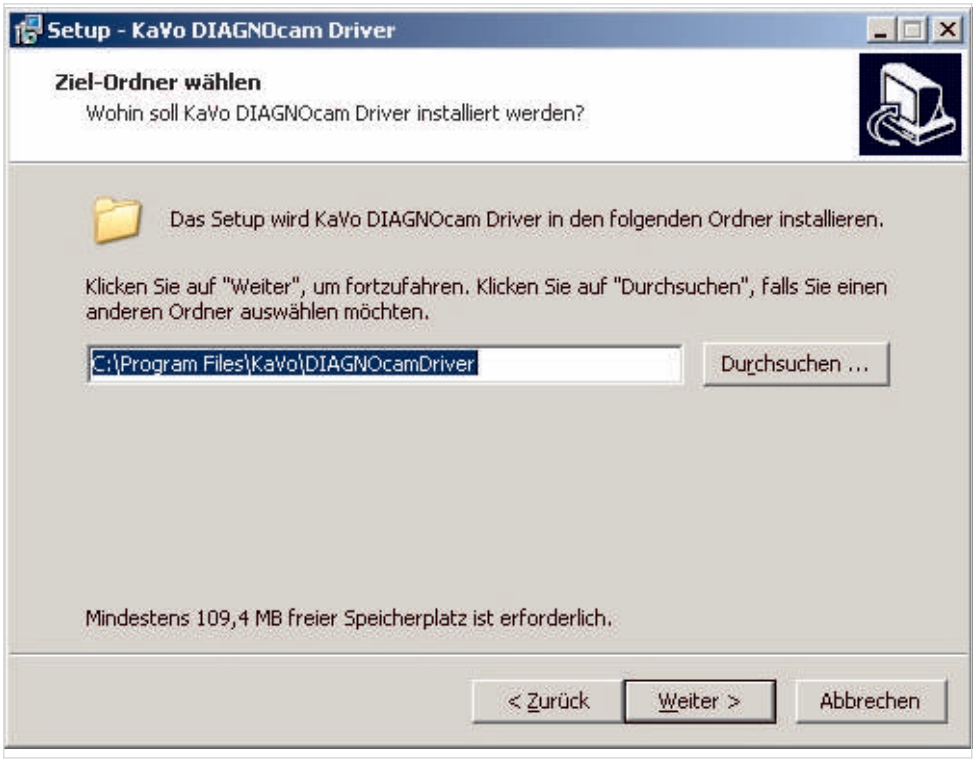
- Complete the installation clicking on Finish.

- Select the language (German or English)

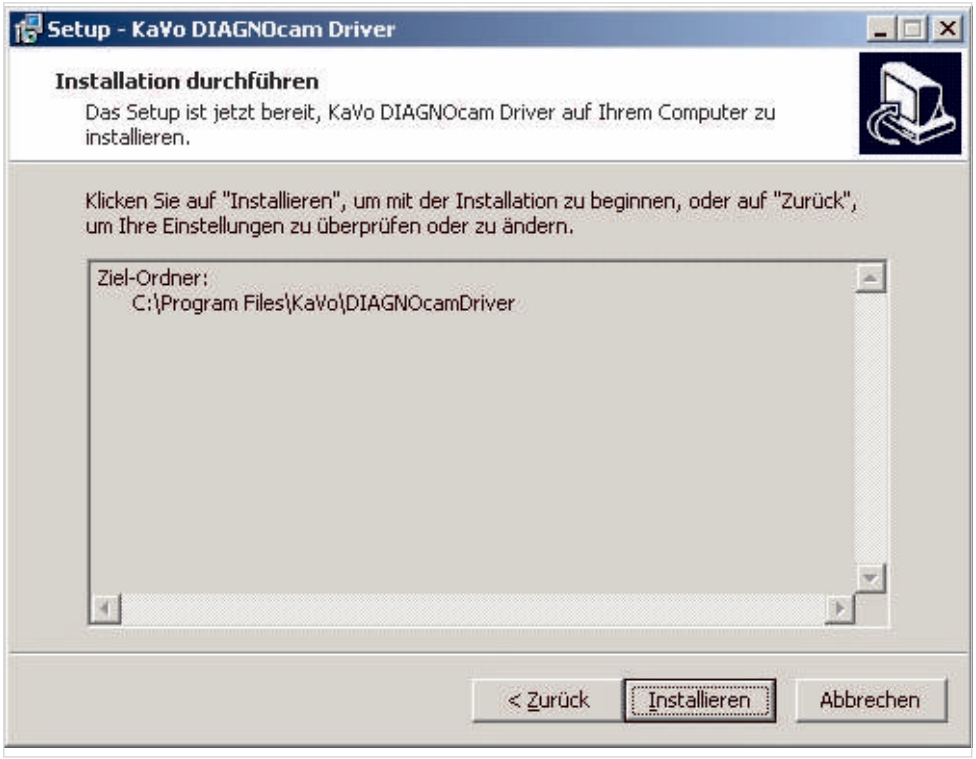


- Click Next to install the drivers

- Program files are stored in the target directory.



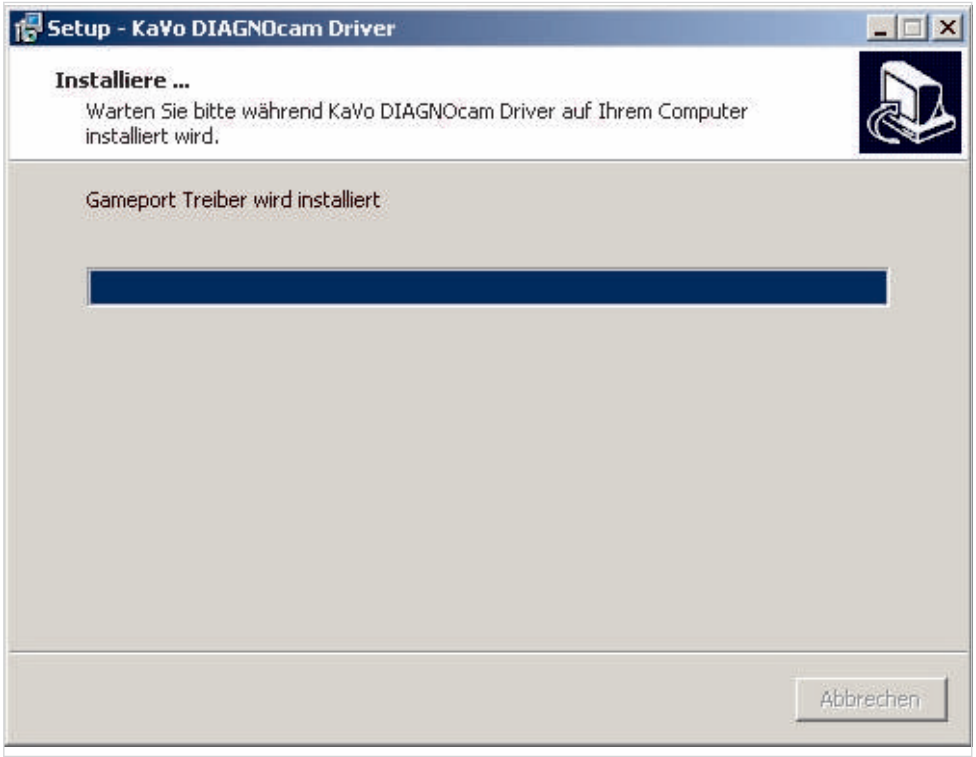
- Click Install to install them



- Click Continue installation to install the software

- Click Continue installation to install the hardware

- Wait for the installation to be completed.



- It is recommended to re-start the computer

4.2.3 Installing a multiple-user system

When KiD is installed on a network, several workstations on which KiD is installed can access a common database.
A computer in the network must be configured as the database server in this case. This computer must always be booted up before all the other computers and turned off after all other computers are turned off (for example in the evening if at all).

Note

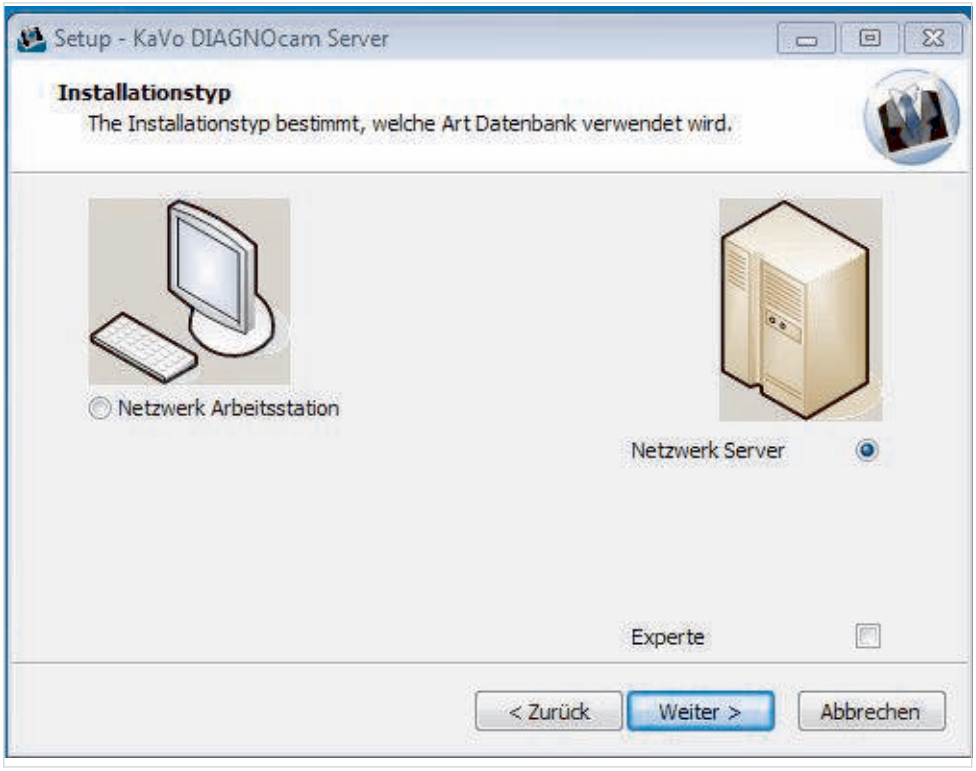
If you intend to install KiD on the network, the network server needs to be installed first.

Installing the network server

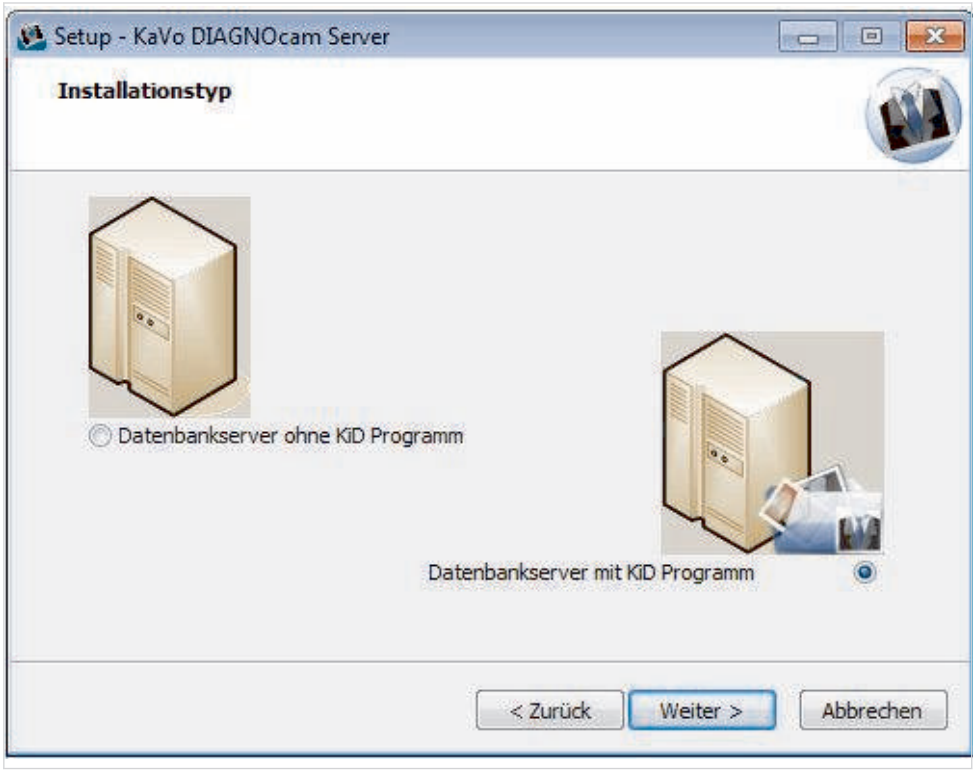
Note

In a multi-user system, all the associated workstations must access the same database server, the same database and the same document path; otherwise inconsistencies in the data can arise.

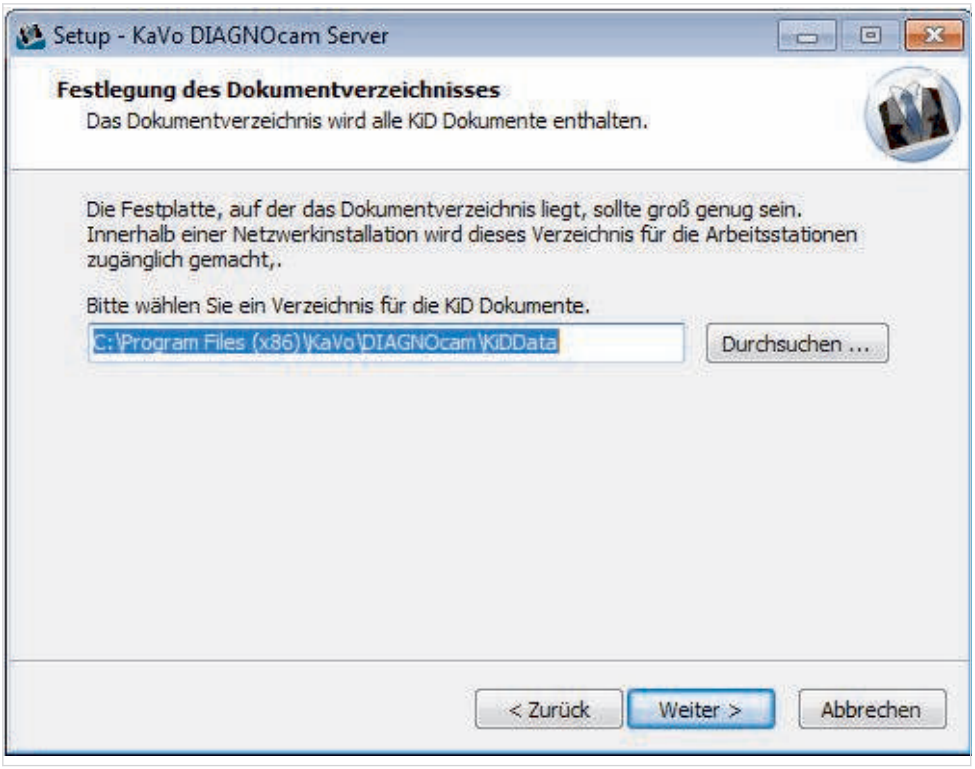
- Select "Network server" on the server.



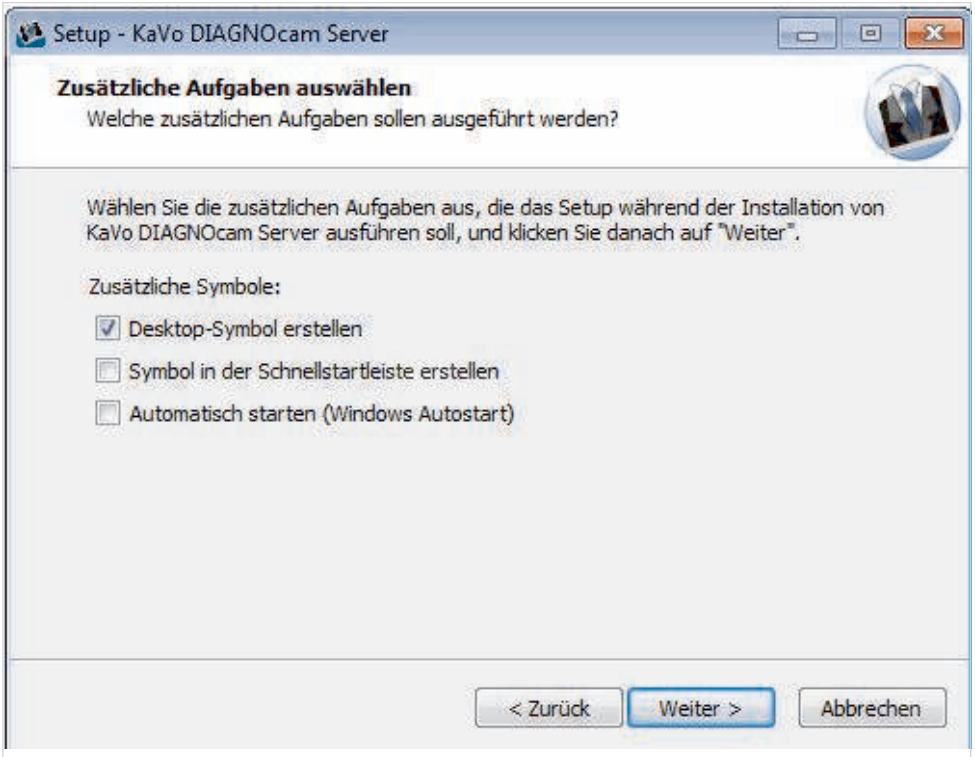
- A database server can be installed without the KiD software. This is necessary in case of a Windows 2000 server, since KiD does not support this system.



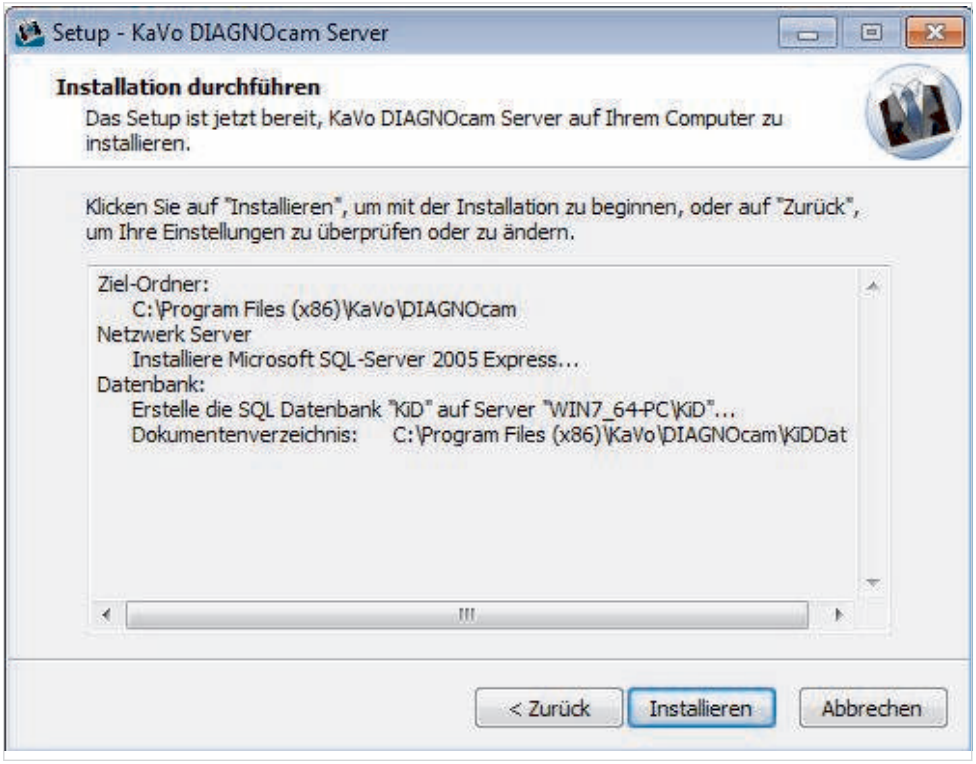
- When installing the database server or if the server release is not found, select a document directory.



- Select Additional Tasks.



- Confirm the installation settings.



- Conclude installation.

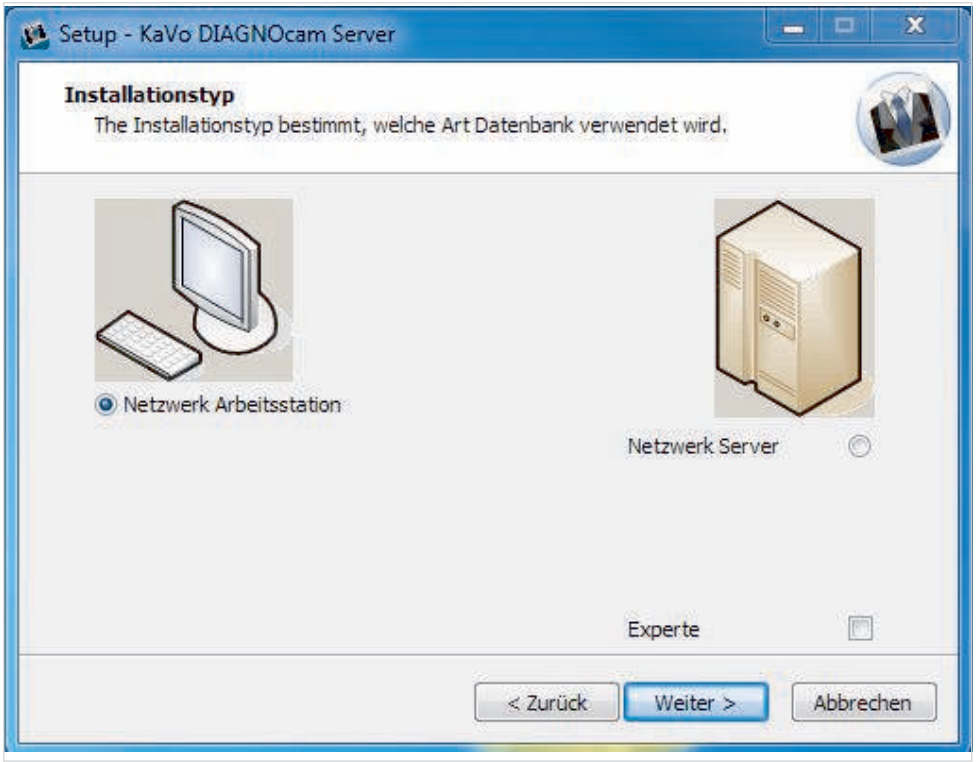
KiD must first be installed on the database server in a multi-user system. Microsoft SQL Server 2005 Express has to be installed only on this computer. The checkbox must be deactivated at all other workstations.

Note

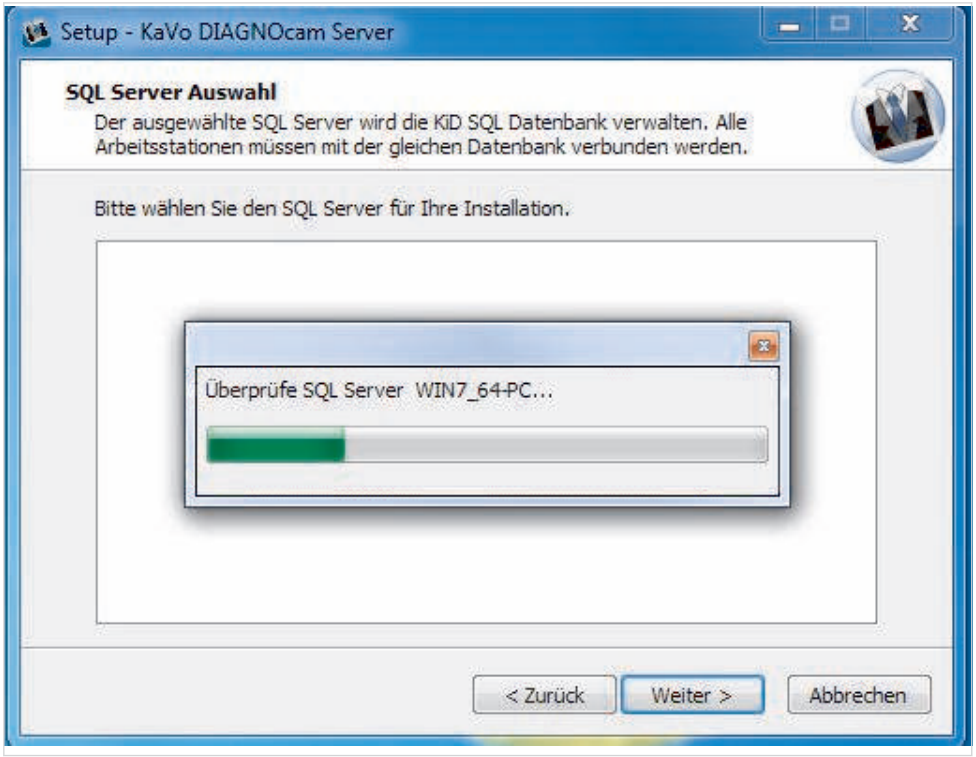
If Microsoft SQL Server is already installed on this computer, this version can be used. The user account used for installation must have administrator rights.

Installing the network workstation

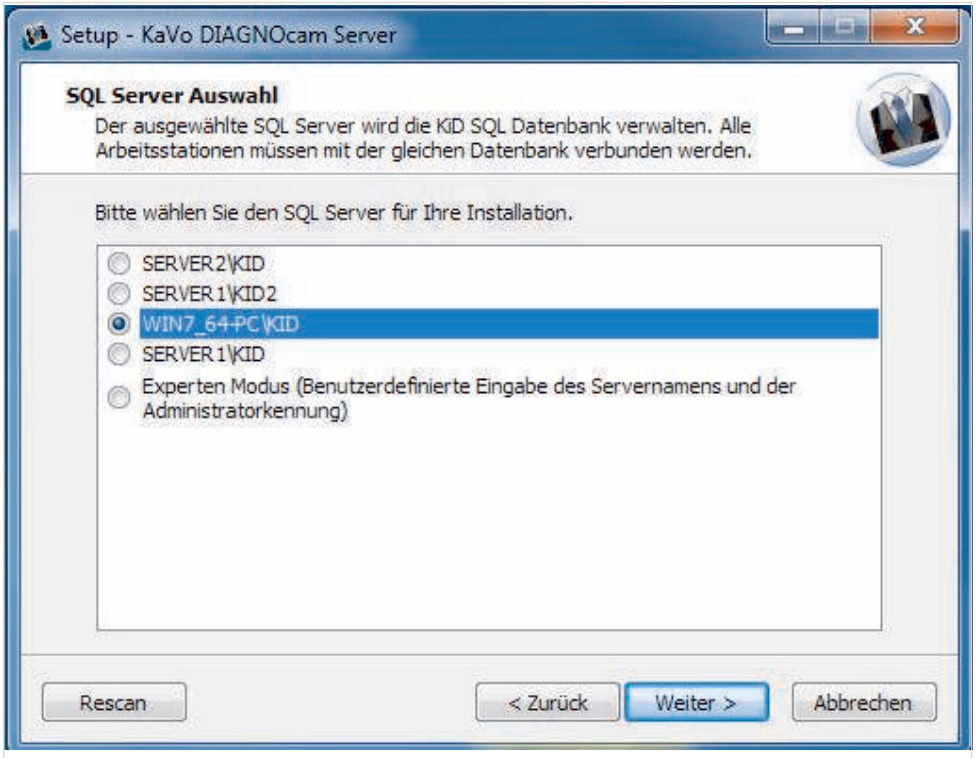
- Select the network workstation and click on Next



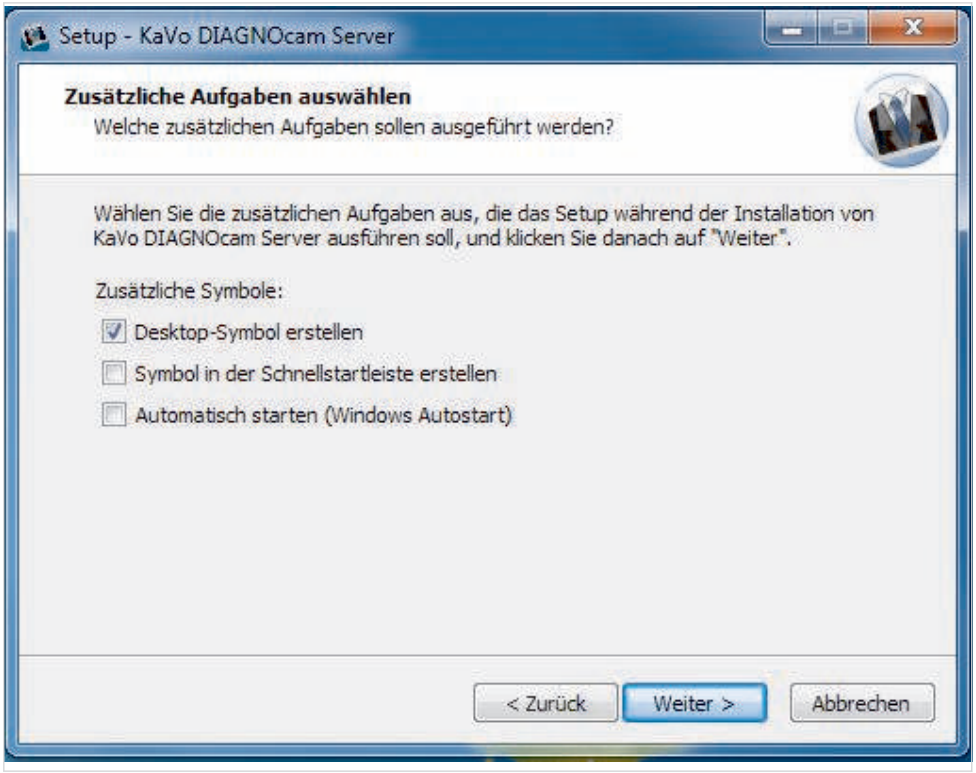
- Network is being scanned for SQL databases with authorisations



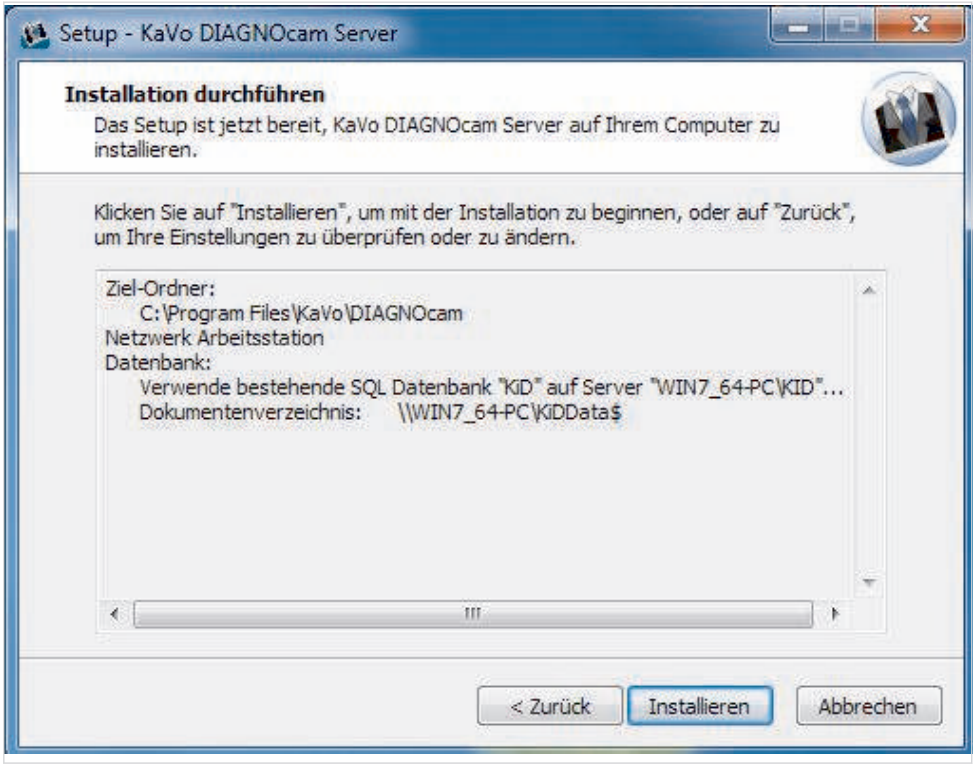
- Make the selection and click on Next



- Create a desktop icon and click on Next



- To install, click on Install



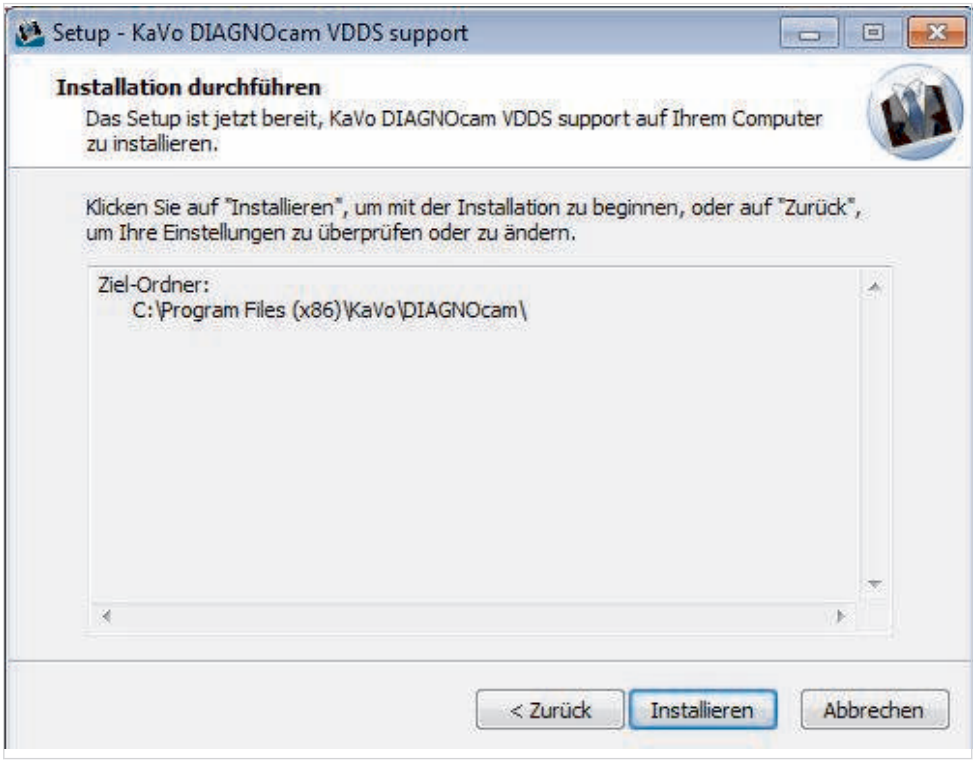
- Click on Finish to complete the installation

- Re-start the computer and click on Finish.

4.2.4 Installing a VDDS interface

- Start setup, click on Next

- Carry out the installation



- Complete the installation

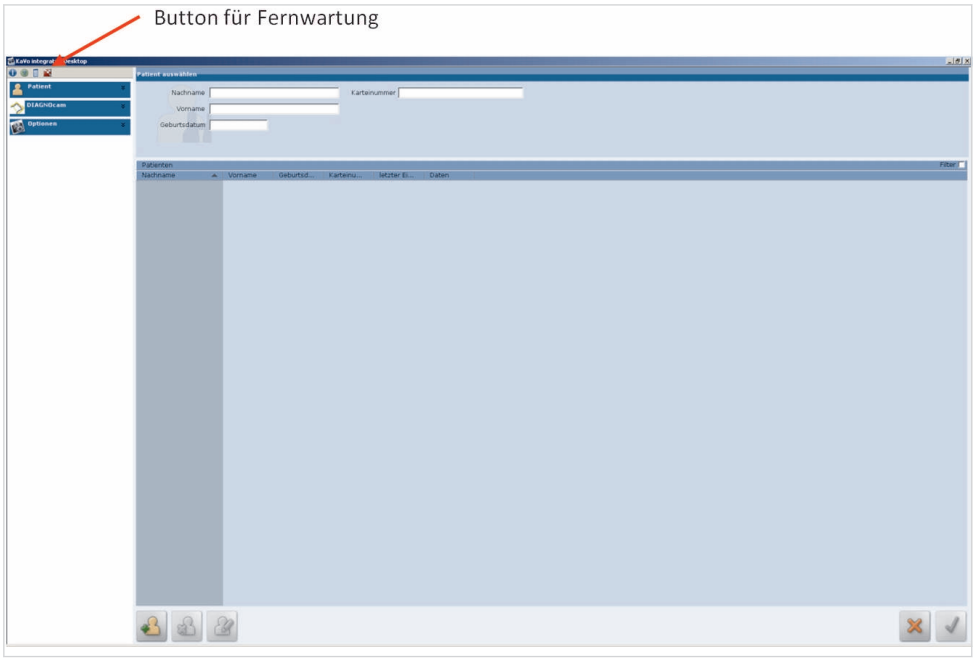
4.3 Remote maintenance by means of Netviewer

Service hotline:
+49 7351 56-2700
Service.Multimedia@kavo.com
Please indicate the product serial number in all requests.
Additional information can be obtained at: www.kavo.com

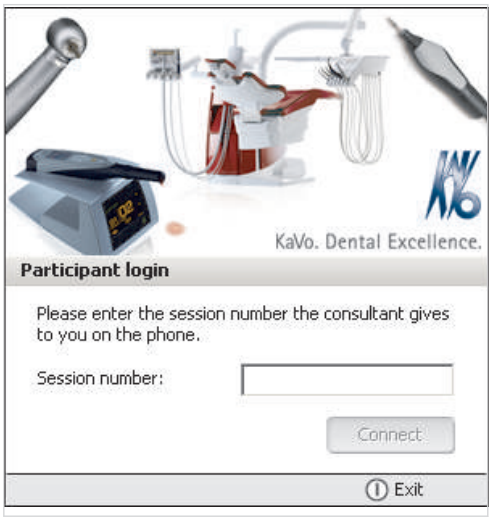
The remote service software, Netviewer, is installed automatically during installation of KiD. Moreover, Netviewer can also be run by means of the Internet site: support.kavo.com. You need to call the Technical Service by phone concurrently to receive a session number.

4.3.1 Starting Netviewer directly through button in KiD

- Press button for remote service



- Call our Technical Service (phone: +49 7351 56-2700) to request a session number for Netviewer.
- Enter the session number and click on "Connect".



This starts up the remote service.

Note

The Technical Service can access the remote maintenance only if the customer confirms the access. Access without confirmation is not feasible!

- The Remote control window shows that the KaVo Service is connected to your system.

- The Netviewer window was closed, click close to disconnect.

5 Operation

5.1 Attach and remove a tip

Slide the tip onto the handpiece

	**⚠ CAUTION** **Attaching the tip misaligned** Damage to the unit ▸ When attaching the probe, make sure that the inner lug of the tip mates with the opening in the forked light barriers.

Note

Tips must not be forced or twisted while attaching them!
Tips must be slid to the limit stop on the handpiece. Otherwise, areas within the picture may remain covered.

▸ Evenly slide the tip to the stop. Make sure that the lug ① on the inside of the tip mates with the opening in the forked light barriers.

Pulling the tip off the handpiece

Note

Tips must not be removed by being twisted.
Removing the tip, do not touch the control buttons.

- Pull the tip off the handpiece by applying a moderate amount of force; pull with your left hand and push slightly with your right thumb. Do not touch the control buttons.

5.2 Turning on/off

⚠ WARNING

Blinding hazard from invisible laser.
Eye damage.

- Do not point the device toward the eyes when the laser is active!
- Do not operate the device when the housing is damaged or opened.
- Do not use the handpiece on the patient when the tips are not attached.
- Do not look into the handpiece's aperture for the light when the tip is removed.

⚠ CAUTION

Product damage from misuse
Damage to the contacts

- Do not actuate the ring switch and control buttons when removing and mounting the tips.

Note

An internal safety check is carried out automatically if no tip is attached: Each time the device is used, upon inserting the USB plug in the computer, and when the computer is turned on.
If a tip is attached when the handpiece is turned on, the safety check does not run.
The laser light is not activated if there is no safety check. In this case, the tip must be pulled off. The safety check then runs automatically.

Note

If the tip is removed during use, it deactivates the video picture and the illumination. After attaching the tip again, the video image and illumination are turned on again.

Start up

- Briefly press ring switch.

Switch off

Note

If no function key is pressed or if the tip is not changed over a period of 10 minutes, the laser and camera are automatically shut off.

- Hold down the ring switch for 10 seconds.

5.3 Occlusal use

⚠ CAUTION

Property damage from improper use
Damage to the light guide

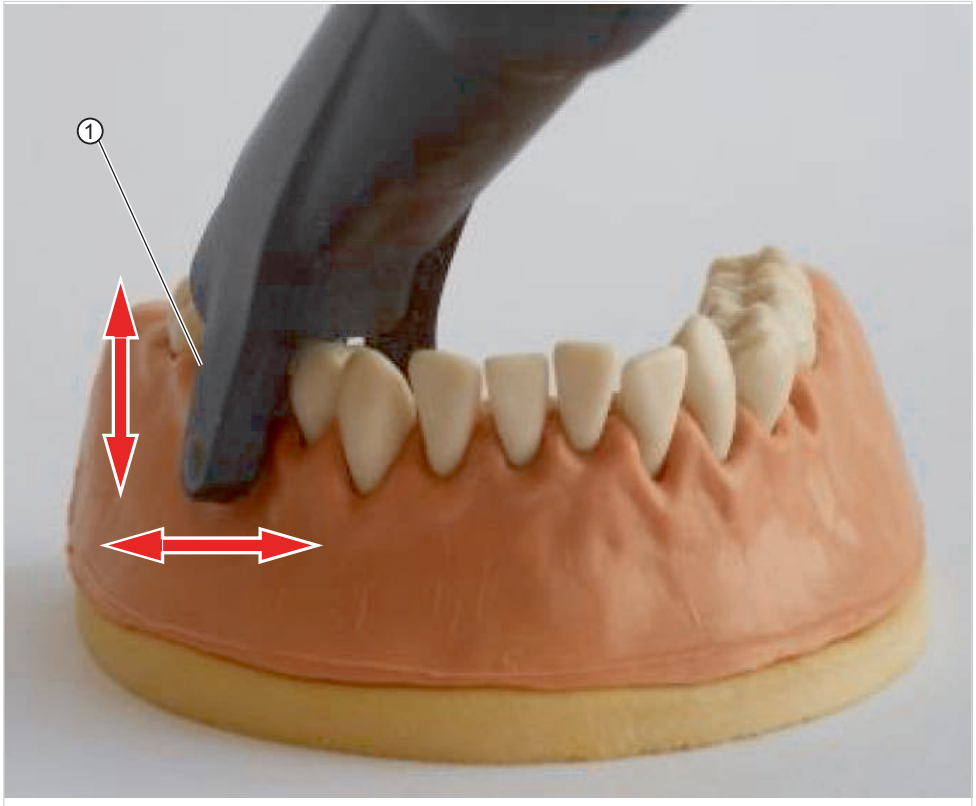
- ▸ Do not kink the light guide in the flexible part of the probe.

Note

The live picture varies depending on the following factors:
– Type of tooth defect.
- Position of the feed surface.
– Type and position of tooth fillings.

The indication range includes premolar and molar teeth.

The occlusal probe comes with a spacer. For optimal high contrast images, the spacer is to be placed on the neighbouring tooth. This way, light is fed through the gingiva into the tooth and glare is avoided.



① Light aperture (inner)

Requirement
Professionally cleaned teeth.

- ▸ Attach the occlusal tip to the handpiece.

- Contact the light apertures ① to the gingiva.
- Place the spacer of the occlusal probe on the neighbouring tooth, and monitor the live picture.
- Tip the probe slightly if needed.
- Use control buttons 2 and 3 to select the tooth in the tooth diagram for which a picture will be saved.
- Press the ring switch to create a still picture and save it.

5.4 Brief instructions for the KiD

- Start the KiD.
- Create/select patients.
- Start the DIAGNOcam viewer.
- With the probe removed, connect the DIAGNOcam to the PC/laptop.
- Attach the probe.
- Briefly actuate the ring switch to turn on the laser and camera.
- Select the tooth in the tooth diagram using control buttons 2 and 3.

  The selected tooth is shown dark blue.

- Create a freeze frame using the ring switch.

  The freeze frame is assigned to the selected tooth in the tooth diagram.

Note

Teeth having assigned pictures are light blue in the tooth diagram.

- To switch to review mode, remove the probe and click on the "File Symbol" in the live picture window.
- To return to KiD from viewer mode, click the red cross at the top right.

5.5 Determining findings and diagnosis

Note

Before the examination, the teeth must be clean. A professional tooth cleaning is recommended.

Note

Carious changes are displayed as dark shades in contrast to the healthy tooth substance.

Note

Residual cleaning agent, restoration material, calculus and discoloration on the tooth surface can change the scatter of the light and hence also be displayed as shade.

The dark shades in the picture may be interpreted as carious changes.

- To secure the diagnosis, use additional diagnostic means such as the **DIAGNOdent pen 2190**.

5.6 DIAGNOcam Function

Note
The software must always be closed, before unplugging the **DIAGNOcam**.

Start the DIAGNOcam

- Turn on the PC/laptop.
- Plug the **DIAGNOcam** without tip into the PC/laptop and wait until three acoustical signals are emitted.
- Start-up the **DIAGNOcam** software.

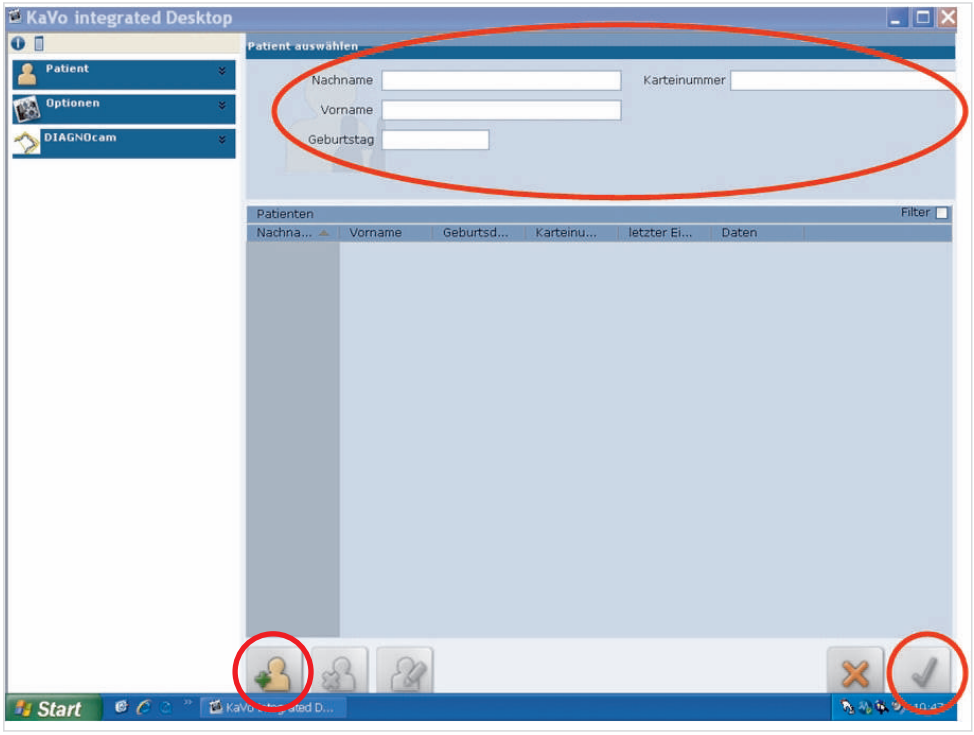
Step 1:

- Select patient.

- Click on the "Select patient" field and open it.

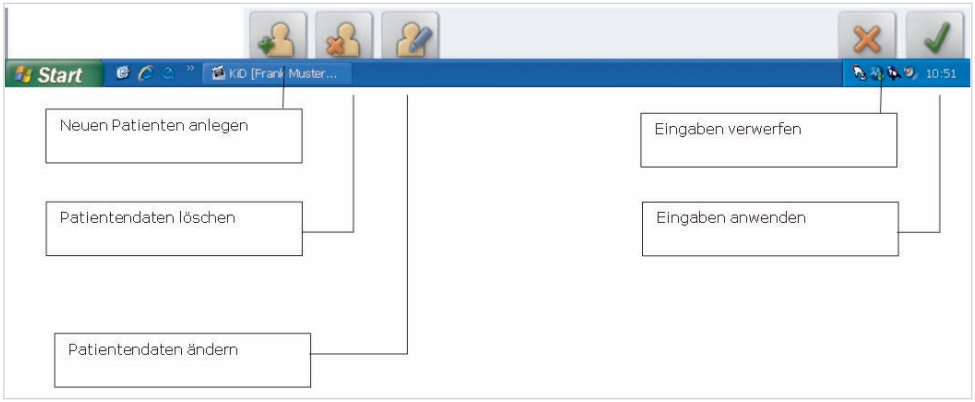
Step 2:

- Create patient.



- Click on the "Create new patient" symbol.

- Enter name of the patient and save it by clicking on the "OK" symbol.

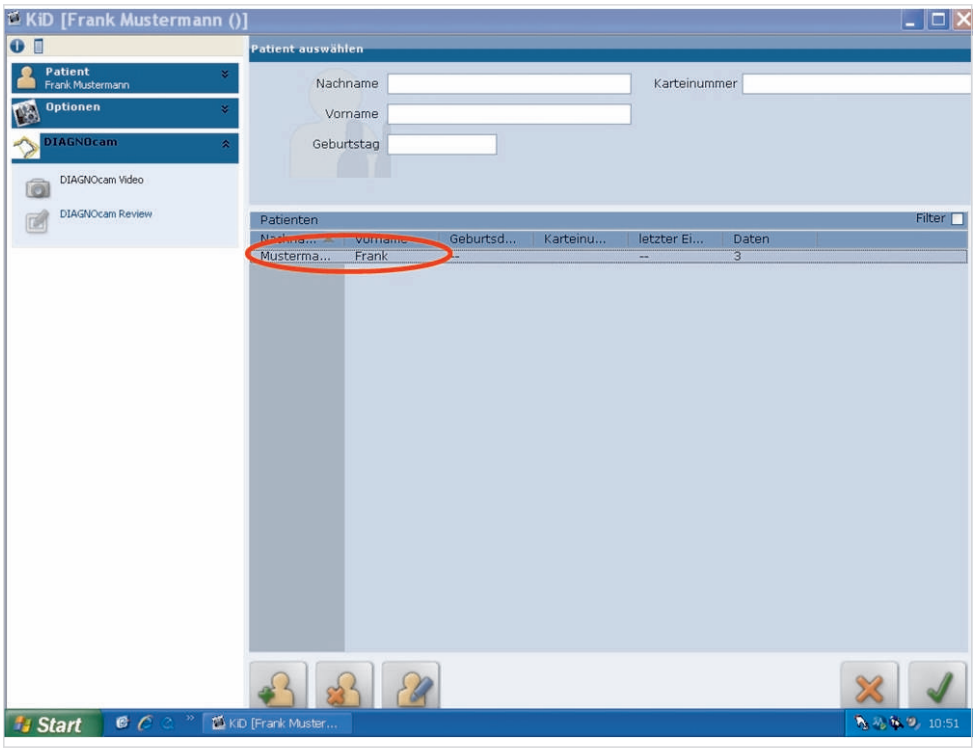


Tool bar

Step 3:

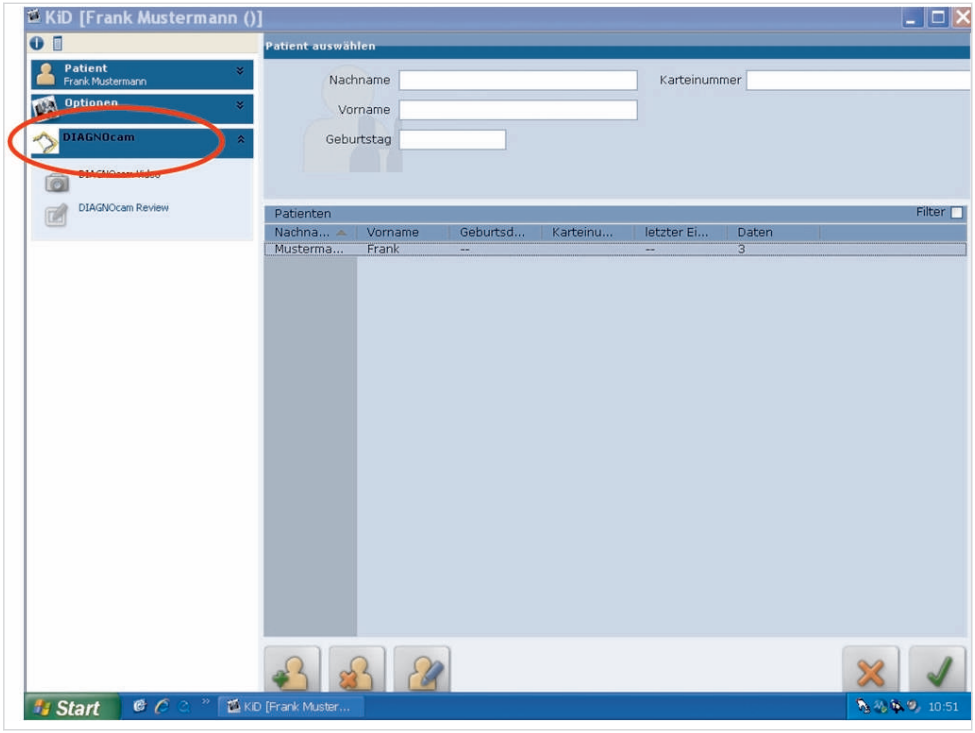
- Select patient.

- Double-click on patient name or confirm by clicking on "OK".



Step 4:

- Start-up the camera.



- Firstly, click on the "DIAGNOcam" field and open it.

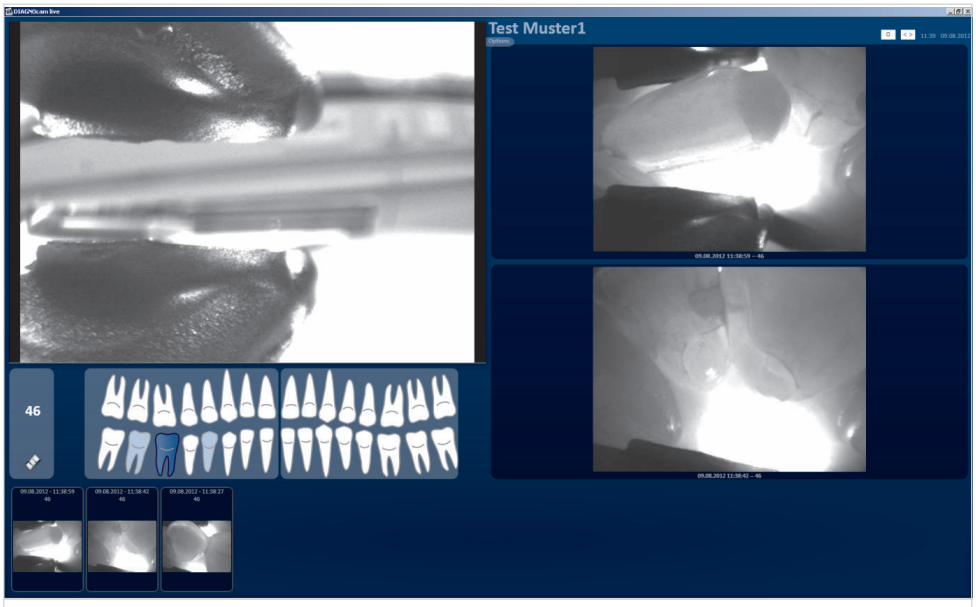
Start-up the recording mode

- Click on the "DIAGNOcam Live" field.

Step 5:

- Select tooth.

- Attach tip.



Tooth scheme

Presentation	Meaning
White tooth	No images stored.
Light-blue tooth	Images are stored for this tooth
Dark-blue tooth	Currently selected tooth, stored images are shown in the line below.

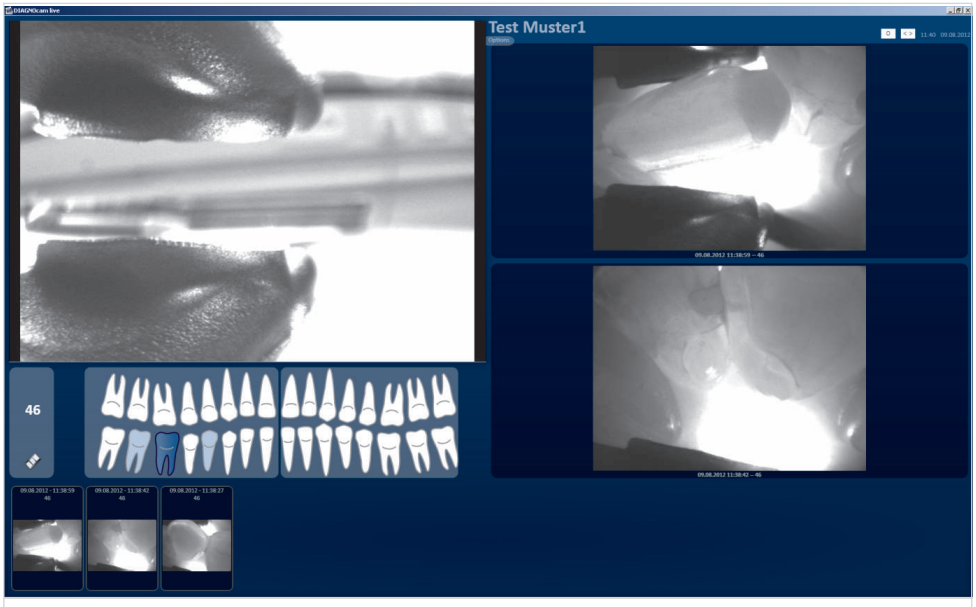
Note

The tooth number of the selected tooth in the tooth scheme (e.g. 47) is shown to the left of the tooth scheme. If a tooth selected, only the images of the selected tooth are displayed.
If no tooth is selected, an exclamation mark is shown instead of the tooth number. All images recorded or images that are not assigned to a tooth are displayed.
White exclamation marks: All recorded images are displayed.
Light-blue exclamation marks: Images that are not assigned to a tooth are displayed.

Step 6:

- Trigger the exposure.
- Position the **DIAGNOcam** accordingly on the tooth.

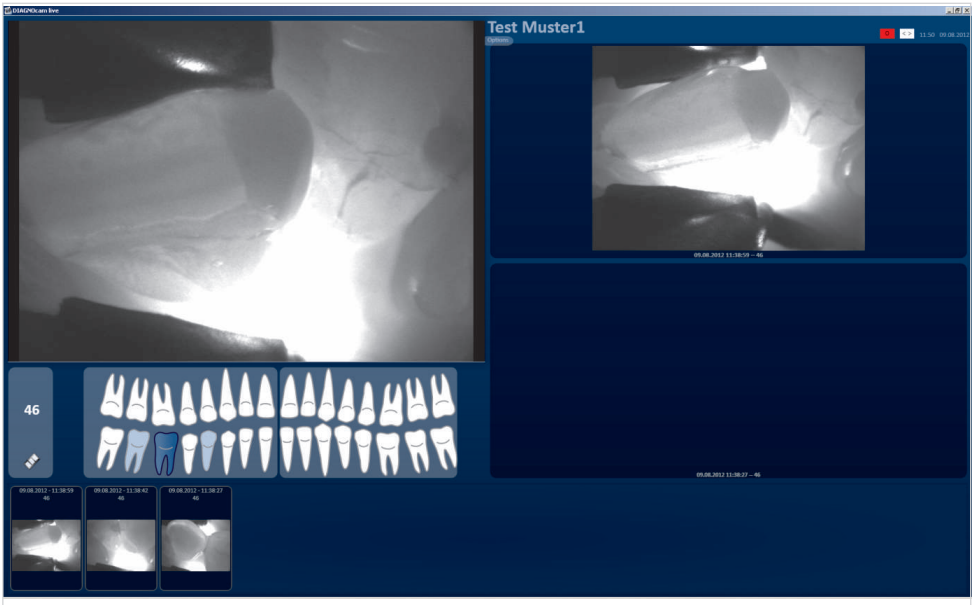
- Trigger the exposure by clicking on image 1 or actuating the ring switch ①.



- Image on top left: Current live image
- Image on right top and right in the middle: Most recently saved images

▸ In order to display an earlier image from the lower row in image 3, click on the corresponding image in the lower row with the mouse to select it (blue framed).

Icon	Definition
	▪ Ring switch is red: Disabled ▪ Ring switch is white: enabled
	▪ Tooth selection <> red: disabled ▪ Tooth selection <> white: enabled
	No tooth selected
	Enable/disable video camera

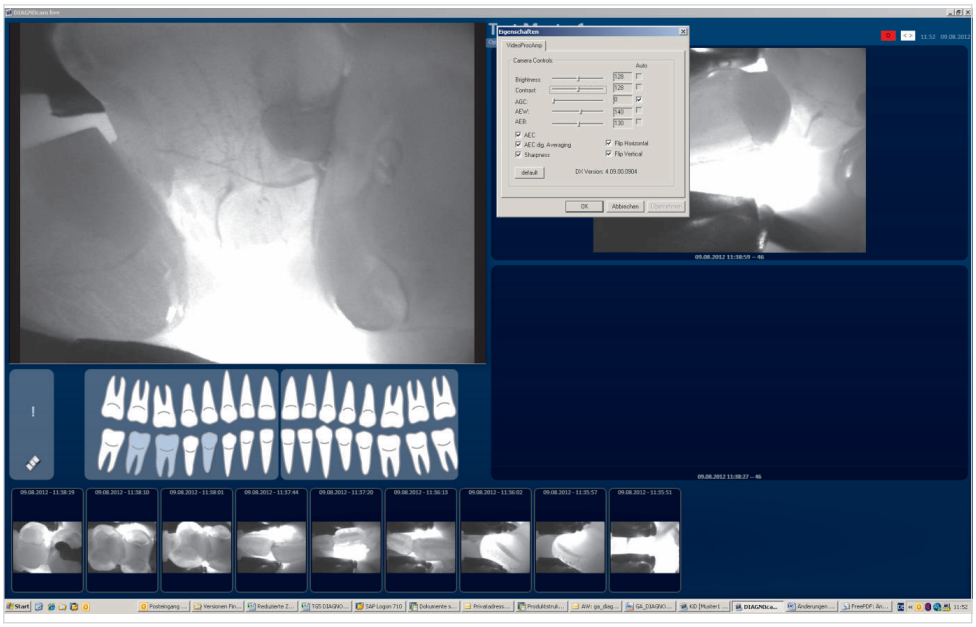


Setting brightness/contrast

▸ Select the "Options" field

We recommend using the default setting. If the teeth are displayed too brightly, it may be advantageous to change the AEW values accordingly.

- Use "Default" to reset to factory settings

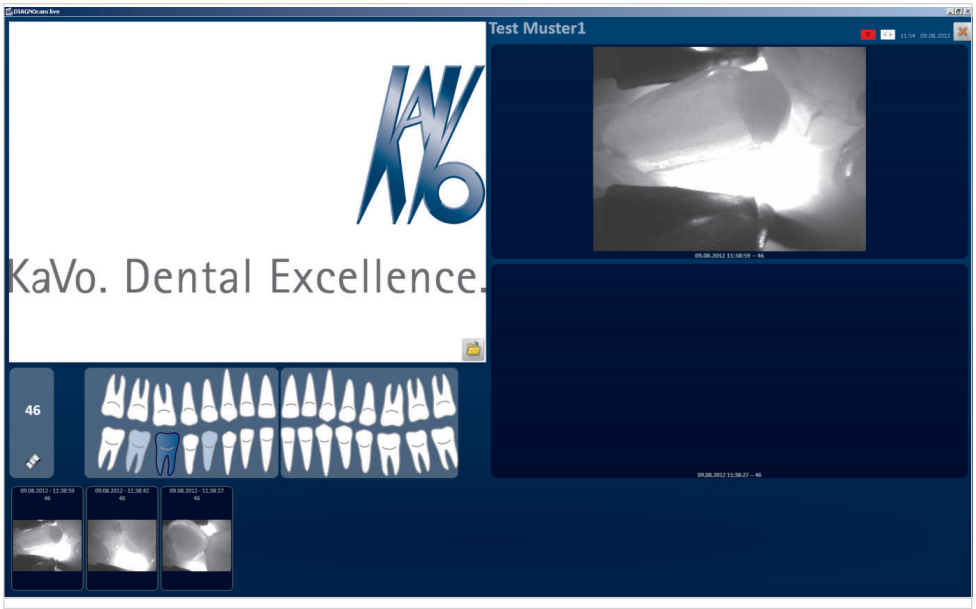


DIAGNOcam Review Mode

Images can viewed and compared in review mode.

Start review mode from recording mode (DIAGNOcam video)

- Pull-off the tip.



- Click on the "Folder" symbol.

- Attach a tip to return to view mode.

- Click on the "Ruler" symbol to measure a length in the image.

- Click on the "Ruler" symbol again to mark the length measurement in red. The "Remove" button can be used to delete the length measurement marked in red.

- Click on the "inverse" symbol to show an inverted display of the image.

- Click on "False colour" to display the image in false colours.

- Click on the "Tool bar" symbol to open or close the "Tool bar".

- Click on the "Original image" symbol to cancel any changes made.

- Click on the "Cancel" symbol to cancel the last change made.

- Click on the "Printer" symbol to print the image.

- Click on the "Delete" symbol to delete the image.

- Click on the "Export image" symbol to export the image.

Display recorded images of a tooth

- Select tooth 48 in the tooth scheme in the left bottom of the window by clicking on it with the mouse.

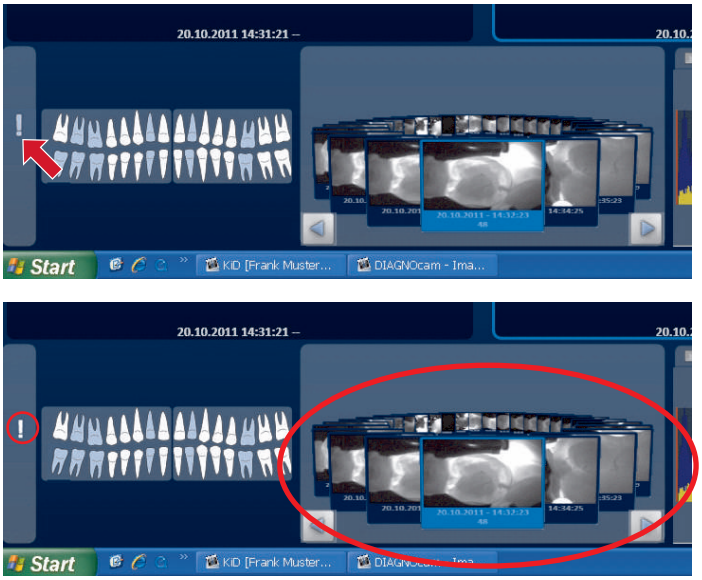
  The selected tooth (48) is shown dark blue.
  The tooth number of the selected tooth (48) is shown to the left of the tooth scheme.
  The images assigned to the tooth are shown in the carousel in the middle and bottom of the window.

Display unassigned images

- In order to display all images that are not assigned to a tooth double-click on the field showing the number "48".

  A light-blue exclamation mark is shown to the left of the tooth scheme.
  The images that are not assigned to a tooth are shown in the carousel in the middle and bottom of the window.

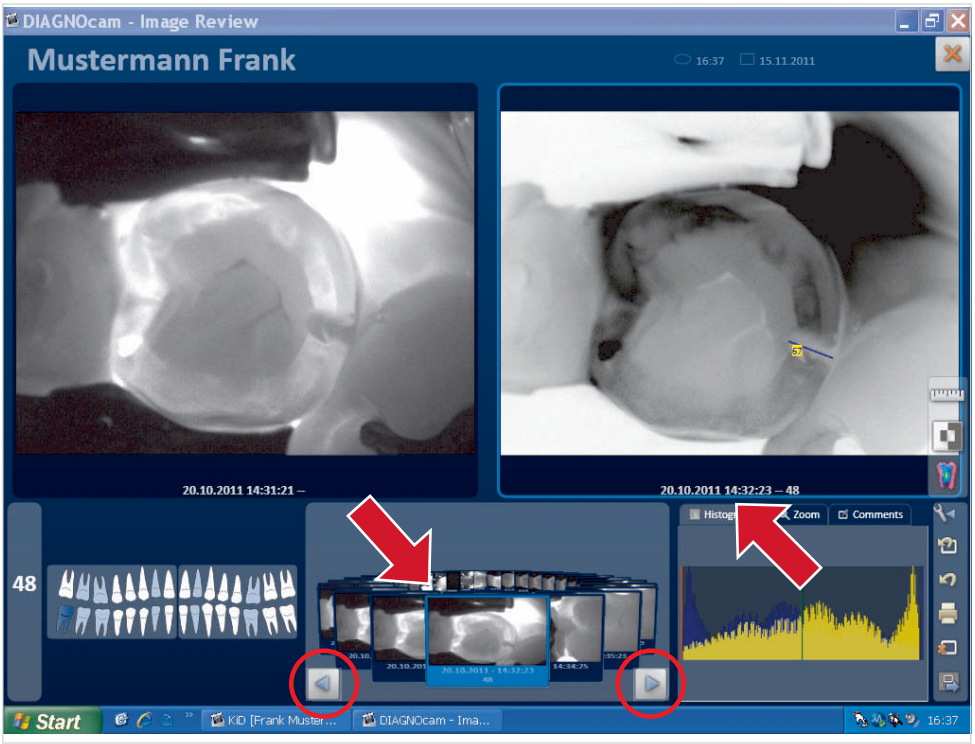
Display all images



- Click on exclamation mark to display all images (assigned and unassigned images).

  A white exclamation mark is shown to the left of the tooth scheme.
  The images recorded (assigned and unassigned) are shown in the carousel in the middle and bottom of the window.

Scrolling through images



- Click on the right top window region to display the active (front) image in the carousel in the upper window region.

  The selected window region on top is shown with a dark-blue frame.

- Use the navigation arrows to scroll forward or backward through the images in the carousel.

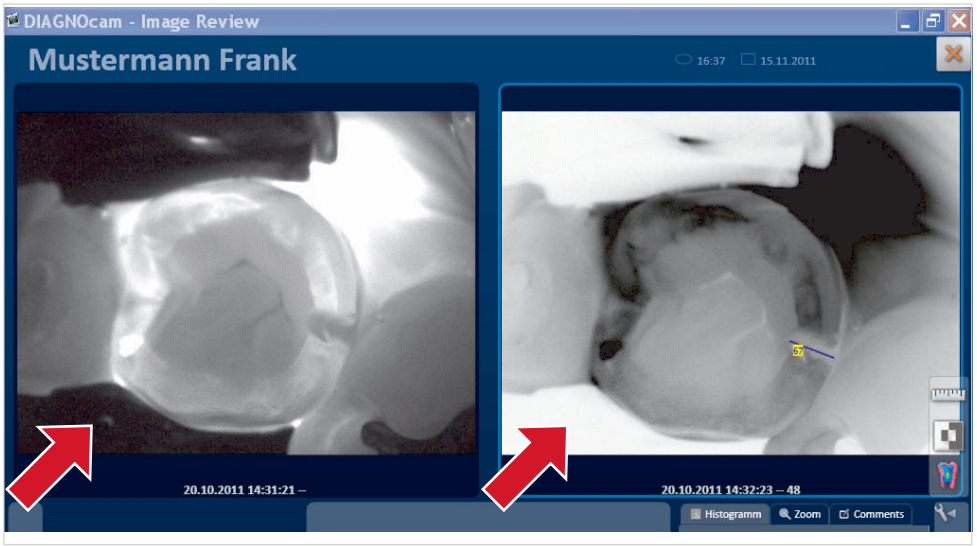
Fixing images

- In order to fix an image in the selected window region, click on another window region.

  The selected window region on top is shown with a dark-blue frame.

Comparing images

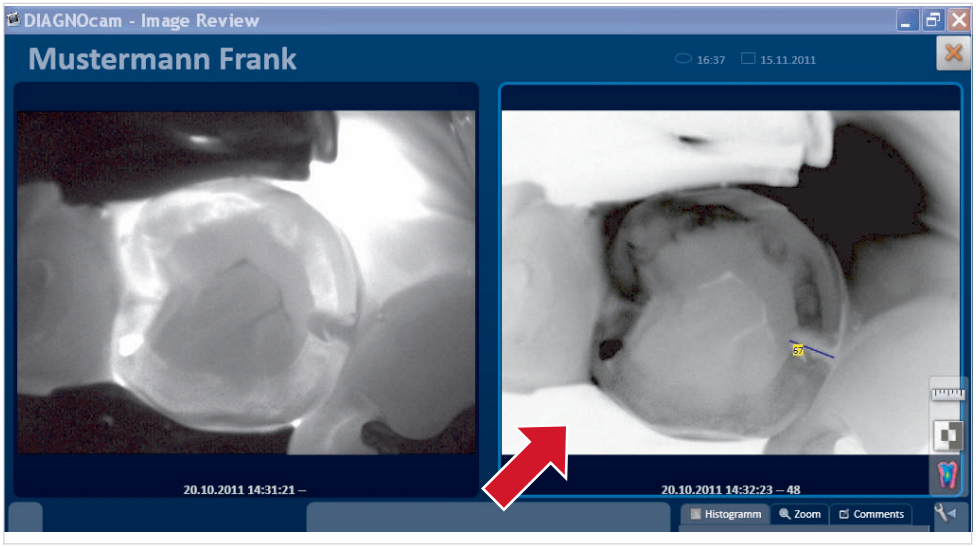
Images can be "fixed" in a window region on the top to allow them to be compared. You can then scroll through the images in another window region.



- Click on the window region, e.g. on the top right.

  The "active" images in the carousel are displayed sequentially in the selected window region.
  The image stays "fixed" in the non-selected window region.

Enlarging/dividing an image



- Double-click on either one of the two window regions.

  The two window regions on top are combined into a large one.
  The image is shown at magnified scale.

- Double-click on the large window region to divide the window region into two windows.

  The image is displayed reduced in size in the top left or right window region.
  The previously displayed image is displayed in the respective other window region.

6 Reconditioning methods according to EN ISO 17664

The listed instructions for cleaning and sterilising were validated as being suitable by the medical device manufacturer for preparing a medical device. This usually requires validation and routine monitoring of the procedure. Moreover, any deviation by the rehabilitating entity from the instructions provided should be carefully analysed for impact on efficacy and possible consequences.

The following components must be reconditioned:

- Surface of the device
- Tips

⚠ CAUTION

Damage due to penetrating liquids.
Malfunctions from penetrated liquids.

- ▶ Do not allow any liquids to enter the device!

6.1 Preparations for cleaning

Note
The software must always be closed, before unplugging the **DIAGNOcam**.

- ▶ Remove tip.

6.2 Cleaning

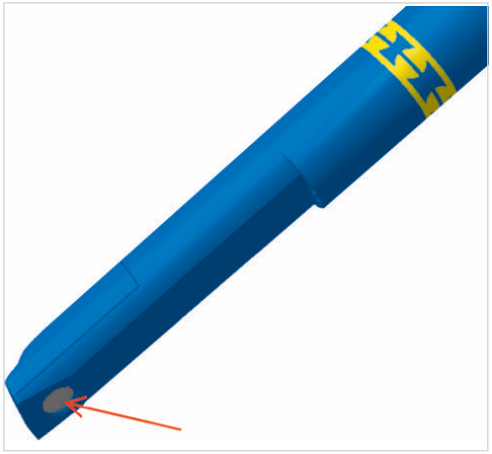
Note
Do not use solvents or aggressive chemicals!

- ▶ Remove major soiling directly after soiling with a single-use paper towel.

6.3 Manual cleaning

- ▶ Clean all outer surfaces of the DIAGNOcam with a soft cloth and one of the specified disinfectants.
- ▶ Clean the tips under running water (tap water quality, temperature: 30°C ± 5°C, flow rate: 2 l/min) for 30 seconds using a medium-hard toothbrush.
- ▶ If the window is soiled, clean it with isopropanol 70% and a Q-tip.

- Clean gently, since excessive force may damage the window.



6.4 Machine cleaning

Not applicable.

6.5 Disinfection

6.5.1 Manual disinfection

⚠ CAUTION

Product damage due to improper disinfection.
Malfunctions.

- Use disinfectant in accordance with the manufacturer's instructions!
- Perform wipe disinfection only!
- Do not immerse product in liquids

⚠ CAUTION

Material damage caused by spray disinfection.

- Do not subject the DIAGNOcam to spray disinfection.

KaVo recommends the following products based on material compatibility.
The microbiological efficacy must be ensured by the disinfectant manufacturer.

- Microcide AF made by Schülke&Mayr (liquid or cloths)
- Dürr FD322
- INCIDIN liquid
- Cavicide

For range of applications, please refer to the manufacturer's Instructions for Use.

- Wipe the surface of the DIAGNOcam and of the tips with a soft cloth and approved disinfectants for disinfection.

6.5.2 Automated disinfection

Not applicable.

6.6 Sterilisation

⚠ CAUTION

Product damage due to improper sterilisation
Damage to the sterilised object

- ▸ No hot air sterilisation, no chemical cold sterilisation, do not sterilise with ethylene oxide!

⚠ CAUTION

Moisture
Non-sterility

- ▸ Ensure dryness. Autoclaves with a after-vacuum ensure dryness! In addition, drying can be accelerated through a 10 minute drying phase with the autoclave door open.

Only the tips can be sterilised.

Sterilisation should directly follow cleaning.

Bag the tips prior to sterilisation.

The KaVo products released for sterilisation have a maximum temperature resistance of 138°C.

KaVo recommends, e.g.
- STERIclave B 2200/2200P made by KaVo
- Citomat/K-Serie made by Getinge

- ▸ Sterilising the probes in an autoclave:

Procedure	Duration / Temperature
Autoclave three times with an initial vacuum for	at least 3 minutes / 134 °C -1 °C/ +4 °C

Store the tips in a bag

Note

When sterilising several handpieces in a single sterilisation cycle, do not exceed the maximal load of the steriliser.

6.7 Control and functional checks

6.7.1 General

- Check for cleanliness.

6.7.2 Checking the tips

- Hold tips against a light source (e.g. daylight source) and check the optical fibres seen in the sleeve for contamination and defects.

7 Troubleshooting

Note

If the **DIAGNOcam** is being unplugged while the software is still running, error messages may be displayed at the next start-up. Always close the software before unplugging the **DIAGNOcam**.

- If error messages are displayed at start-up, close all programs, and shut-down and reboot the PC/laptop.

- Turn off the DIAGNOcam without delay if any malfunctions occur!
- Immediately notify your KaVo contact!

8 Accessories

1.005.1300 Tip large

1.005.1360 Tip small

1.005.1380 Holder DIAGNOcam

Additional accessories:
USB extension cable 3 m **Mat. no. 1.005.1076**
CD DIAGNOcam multi-user **Mat. no. 1.009.6958**
CD DIAGNOcam single-user **Mat. no. 1.009.5110**
CD VDDS plugin software **Mat. no. 1.009.6960**

9 Data on electromagnetic compatibility according to EN 60601-1-2

9.1 Electromagnetic Transmissions

The device is designed for use in an environment as specified below. The customer or the user of the should ensure that the device is used in an environment of the specified type.

Measurements of emitted interference	Conformance	Electromagnetic environment - Guidelines
HF emissions according to CISPR 11	Group 1	The device uses HF energy for its internal functions exclusively. 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	The device 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 EN 61000-3-2	Class A	The device 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 EN 61000-3-3	Conforms	The device 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 Resistance to electromagnetic interference

The device is designed for use in an environment as specified below. The customer or the user of the should ensure that the device is used in an environment of the specified type.

Interference immunity tests	EN 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to EN 61000-4-2	± 6 kV contact discharge ± 8 kV atmospheric discharge	± 2/4/6 kV contact discharge ± 2/4/8 kV atmospheric 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	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to EN 61000-4-5	± 1 kV push-pull voltage ± 2 kV common mode voltage	± 1 kV push-pull voltage ± 2 kV common mode voltage	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage interruptions, short-term interruptions and fluctuations of the supply voltage according to EN 61000-4-11	< 5% U_T (> 95% interruption) for ½ period 40 % U_T (60% interruption) for 5 periods 70 % U_T (30% interruption) for 25 periods < 5% U_T (> 95% interruption) for 5 s (250 periods)	< 5% U_T (> 95% interruption) for ½ period 40 % U_T (60% interruption) for 5 periods 70 % U_T (30% interruption) for 25 periods < 5% U_T (> 95% interruption) for 5 s (250 periods)	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user needs the to work even if the power supply is interrupted, we recommend supplying energy to the from an uninterruptible power supply or battery.
Magnetic field at a supply frequency (50/60 Hz) according to EN 61000-4-8	3 A/m	3 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 Immunity to electromagnetic interference

The device is designed for use in an environment as specified below. The customer or the user of the should ensure that the device is used in an environment of the specified type.

Interference immunity tests	EN 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Wire-based HF interference according to EN 61000-4-6 Wireless HF interference according to EN 61000-4-3	3 V_{eff} 150 kHz to 80 MHz outside the ISM bands[a] 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 3 V/m	Handheld and mobile wireless devices should not be used at a shorter distance from the including cables than the recommended safe clearance calculated using the appropriate equation for the emission 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 maximal nominal power of the transmitter in watts (W) as specified by the transmitter manufacturer and d is the recommended safe clearance in metres (m). [b]The field strength of stationary wireless radio transmitters as measured locally[c]should be lower than the conformance level at all frequencies. [d]Interference is possible in the vicinity of devices bearing the following icon.

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.

[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 40.70 MHz.

[b]The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz are intended to reduce the probability of mobile/handheld communications facilities causing interference when they are inadvertently introduced into the patient area. For this reason, the additional factor of 10/3 is applied in the calculation of the recommended safe clearances in these ranges of frequencies.

[c]The field strength of stationary transmitters, such as, e.g. 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 theoretical considerations. A site study should be considered to determine the electromagnetic environment in terms of stationary transmitters. If the measured field strength at the site, at which the is used, exceeds the compliance levels shown above, the should be monitored to demonstrate proper function. If any uncommon performance characteristics are observed, additional measures may be required, such as, e.g., changing the orientation or using a different location for the .

[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

The is intended for use in an electromagnetic environment in which the HF interference parameters are controlled. The customer or the user of the can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the depending on the output of the communication device as indicated below.

Safe distance depending on the transmission frequency:

Rated power of the transmitter in W	150 kHz to 80 MHz $d=1.17\sqrt{P}$ m	80 MHz to 800 MHz $d=1.17\sqrt{P}$ m	800 MHz to 2.5 GHz $d=2.33\sqrt{P}$ 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 in the above table, the recommended safe distance d in meters (m) can be calculated using the equation for the respective gap, where P is 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.

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