

VistaCam iX

Proof interchangeable head

EN



Installation and Operating Instructions

CE

9000-618-178/30



 **DÜRR
DENTAL**

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Important information

1. About this document

These Installation and Operating Instructions form an integral part of the appliance. They conform to the relevant version of the equipment and the technical standards valid at the time of installation.



DÜRR Dental cannot be held liable and cannot offer guarantees for safe and smooth operation of this appliance in the case that notes and instructions contained in these Installation and Operating Instructions are not observed.

The translation of the manual has been carried out in good faith. The original German language version of the manual prevails. Dürr Dental accepts no liability in the case of incorrect translation.

1.1 Warnings and Symbols

Warnings

The warnings in this document point to possible danger of injury to personnel and material damage.

They are marked with the following warning symbols:



General warning symbol

The warnings are structured as follows:



SIGNAL WORD
Description of the type and source of danger

The possible consequences from disregarding the warning are listed here

- Observe these measures in order to avoid the danger.

The signal word indicates one of the four danger levels of the warnings:

DANGER Immediate danger of serious or fatal injury

WARNING Possible danger of serious or fatal injury

CAUTION Danger of minor injury

NOTICE Danger of extensive material damage

Further symbols

These symbols are used in the document and on the appliance:



Note, e.g. special details regarding economic use of the appliance.



Wear protective gloves.



CE mark



Take note of accompanying documents.



Dispose of properly in accordance with EU Directive (2002/96/EU - WEEE).



Only use once (disposable).



Sterilise at 134 °C

Handling instructions

Handling instructions are marked with a bullet point:

- Carry out the handling step.

1.2 Copyright notice

All circuits, processes, names, software programs and appliances quoted are protected by copyright.

Printing or copying of these Installation and Operating Instructions, even excerpts thereof, may only be carried out with the written approval of DÜRR Dental.

2. Safety

DÜRR Dental has developed and designed this unit in such a way that dangers are effectively ruled out if operated in accordance with the intended use. However, a small degree of risk is always present.

Please observe the following notes.

2.1 Correct usage

The Proof interchangeable head is a plug-on camera head for the VistaCam iX handpiece. Using the Proof interchangeable head, the VistaCam iX intraoral camera creates images with blue-violet light, which support prophylaxis and caries diagnostics.

2.2 Incorrect usage



WARNING

Danger of explosion from ignition of combustible substances

- Do not operate the appliance in rooms in which combustible mixtures are present, e.g. operating theatres.



CAUTION

The blue-violet light of the camera can dazzle

- Do not use the camera directly on the eye.

Any other use or use beyond the correct usage is considered to be improper use. Dürr Dental is not liable for any resulting damage.

2.3 General Safety Notes

- Observe the laws and regulations applicable at the place of use when operating the appliance.
- Prior to each use, check the functioning and condition of the appliance.
- Do not modify or alter the appliance.
- Observe the Installation and Operating Instructions.
- Ensure the Installation and Operating Instructions are available to the operator at all times.

2.4 Specialist personnel Handling

Persons that operate the appliance are dentists and dental personnel. As a result of

their training and know-how, they must ensure proper handling.

- Instruct every operator in the handling of the appliance.

Installation and repair

- All installation, new settings, changes, expansions and repairs must be carried out either by DÜRR Dental personnel or by a suitably qualified person approved by DÜRR Dental.

2.5 Only use original parts

- Only use the accessories and special accessories stated or approved by DÜRR Dental.
- Only use original working parts and spare parts.



Dürr MEDICAL accepts no liability for damage or injury resulting where accessories or special accessories or where non-original working parts or spare parts not specifically approved have been used.

2.6 Transport

Only the original packaging provides optimum protection of the device during transport.



Dürr Dental cannot be held responsible for any damage to the appliance resulting from transport in unsuitable packaging, even during the period of guarantee.

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

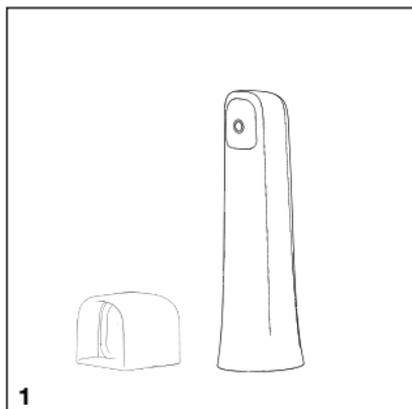
2.7 Disposal

Appliance



Dispose of the appliance properly. Within the European Union, dispose of the unit according to EU Directive 2002/96/EC (WEEE).

- If you have any questions concerning disposal of the product, please contact DÜRR Dental or your specialist dental supplier.



Product description

3. Overview

3.1 Scope of delivery

VistaCam iX Proof interchangeable head2108-130-51

Spacers (5 pieces)

Hygienic protective covers (20 pieces)

Quick start instructions

3.2 Accessories

Spacers (5 pieces)2108-132-50

Hygienic protective covers

(500 pieces)2108-010-50

3.3 Special accessories

Storage box2108-135-50

3.4 Wear and spare parts

Disposable materials

Hygienic protective covers

(500 pieces)2108-010-50

FD 350 Disinfection wipes. . CDF350C0140

Cleaning set for

VistaCam optical element2101-025-50



Information on spare parts can be found in the spare parts catalogue at www.duerr.de/etk.

4. Technical data

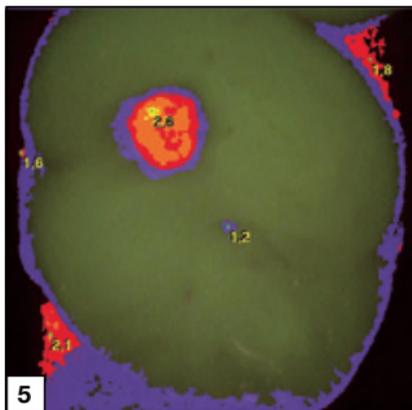
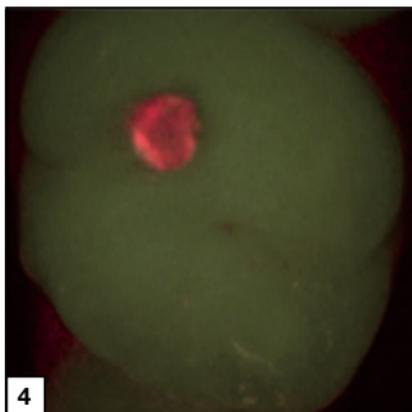
4.1 Proof interchangeable head

Illumination		4 LEDs
Wavelength of LED light	nm	405
Sharpness level	mm	12
Opening angle		68°

4.2 Ambient conditions

Ambient conditions for storage and transport

Temperature range	°C	-15 to +60
Rel. humidity	%	Max. 90
Air pressure	hPa	700 - 1060

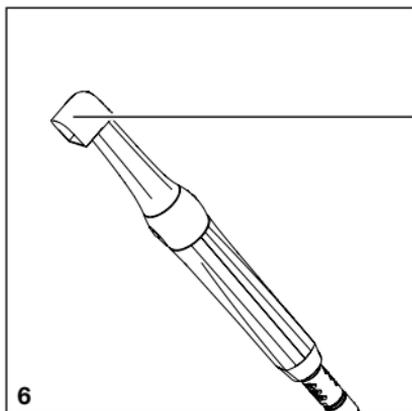


5.2 Analysis

The images are analysed in the DBSWIN or VistaEasy imaging program on the computer.

The prophylaxis view (figure 4) shows the original image. The caries view (figure 5) analyses the intrinsic biofluorescence of the substances with the caries filter. The colour scale and the numeric values provide reliable information on carious lesions:

		Healthy tooth enamel
	1.0	Early-stage caries, incipient enamel caries
	1.5	Enamel caries up to enamel-dentine junction
	2.0	Dentine junction already exceeded
	2.5	Deep dentine caries



5.3 Spacer

The spacer (5) enable optimum analysis of images. The position and the distance of the image are reproducible. In addition, the spacer screens off the image area and minimises the penetration of external light.



Installation



For information on the assembly, connection and installation of the device, see the Installation and Operating Instructions of the VistaCam iX handpiece (9000-618-176) and the Installation and Configuration Manual of the VistaCam iX (document no. 9000-618-179).



Use

6. Preparation

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

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

6.1 Preparing teeth for prophylaxis view

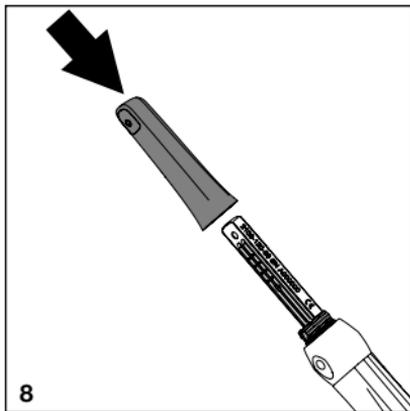
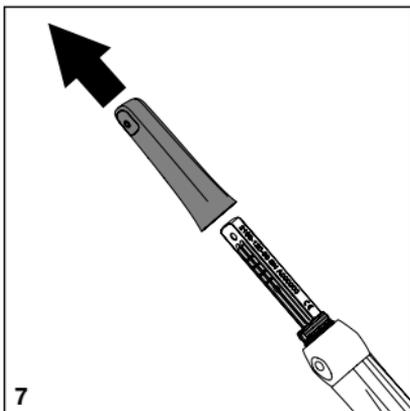
The prophylaxis view provides comprehensive evidence of the status of oral hygiene.

- Do **not** professionally clean teeth for the prophylaxis view.

6.2 Preparing teeth for caries view

Teeth must be clean and dry for the caries view.

- Carry out professional teeth cleaning.
- Remove polishing paste using the air/water spray.
- Dry the teeth.



7. Handling



CAUTION

The blue-violet light of the camera can dazzle

- Do not use the camera directly on the eye.

7.1 Changing the interchangeable head

The function of the camera depends on the interchangeable head.



Always store the interchangeable head on the handpiece or in the storage box.



CAUTION

Leakage currents possibly too high when touching open contacts

- Never come into contact with patients and open contacts on the handpiece at the same time.

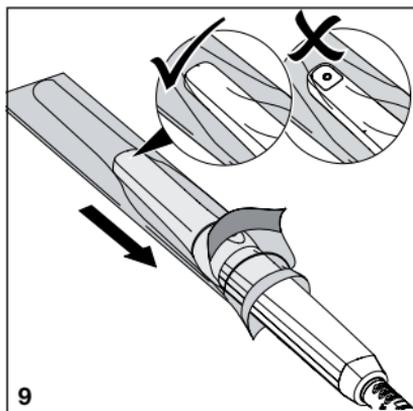
- Pulling off the interchangeable head
- Pull the interchangeable head off the handpiece upwards.

Putting on the interchangeable head

- Ensure that the handpiece and the interchangeable head are completely dry.
- Hold the interchangeable head and handpiece so that the optical element is on the side of the image sensor.
- Slide the interchangeable head onto the handpiece until it engages.

7.2 Switching on the camera

- Connect the camera to a USB port of the computer using the connection cable.
- To start the imaging program, see software manual (DBSWIN 2100-725-91, VistaEasy 9000-618-137).



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7.3 Using the hygienic protective cover



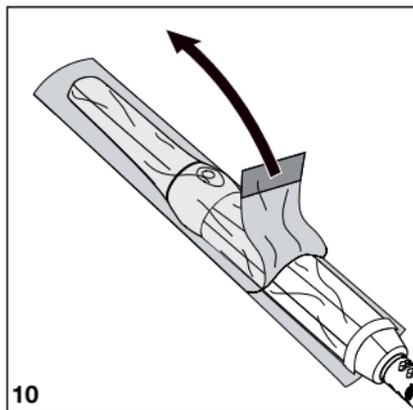
WARNING

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

- Do not use the camera without fitting a hygienic protective cover.
- Do not use the hygienic protective cover more than once (disposable item).

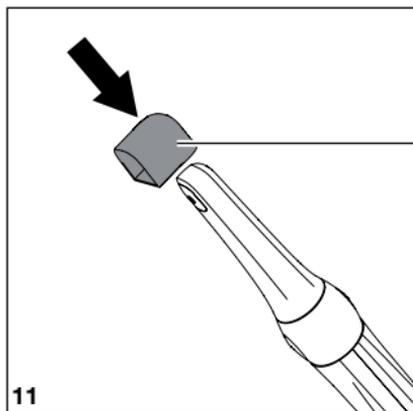


Wear protective gloves when putting on the hygienic protective cover.



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- Hold the camera so that the optical element is face down.
- Lift the white edge of the hygienic protective cover and slide the camera tip into the cover. The transparent plastic side must face upwards.
- Stretch the disposable hygienic protective cover an extra 2 - 3 mm so that the cover presses tightly against the optical element.
- Carefully press the disposable hygienic protective cover against the window of the optic itself with the fingertips. Make sure there are no air bubbles between the window of the optic itself and the disposable hygienic protective cover.
- Hold the disposable hygienic protective cover firmly at the white edge and pull off the transparent plastic side in the direction of the camera tip.
- Pull the paper underside off the camera tip in the direction of the handpiece.



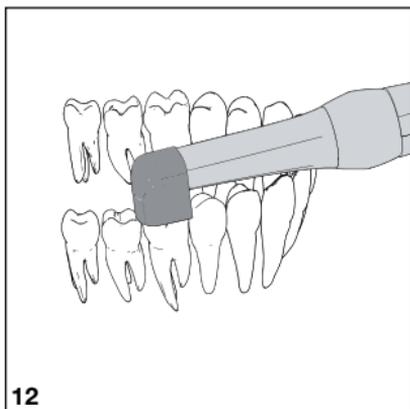
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7.4 Putting on the spacer



Sterilise the spacer in the vacuum steriliser prior to each use (see 9.3 Preparing the spacer).

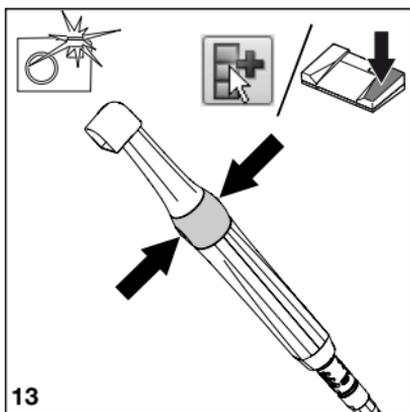
- Connect the spacer (5) onto the camera from above. Make sure that the spacer is not covered by the window of the optic itself of the Proof interchangeable head.



7.5 Recording an image

i Teeth must be professionally cleaned and dried for the caries view (see 6. Preparation).

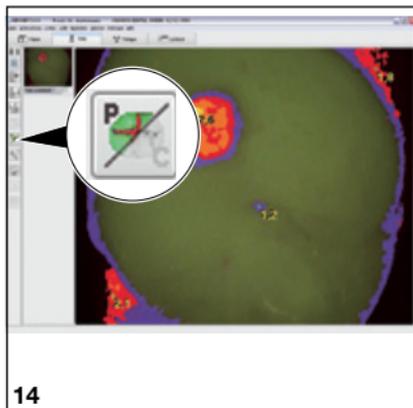
- Reduce the penetration of external light. Turn off or dim sources of external light (e.g. operating lights).
- Place the camera with spacer onto the corresponding tooth.
- Press on one point of the capture ring. Alternatively, operate the foot switch or software button.
The camera switches to "Freeze" mode. The freeze frame will be transmitted to the imaging program or monitor.
- Edit the image in the imaging program and save. (For further information, see the manual for the imaging program.)
- To return to the Live mode, press the control ring again.



7.6 'Switching off the camera

- Carefully pull off the hygienic protective cover and dispose of it.
- Clean the camera (see 9.1 Cleaning the interchangeable head).
- Place the camera in the handpiece holder.
The camera switches off automatically.

i Always stow the camera with the interchangeable head plugged on.



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8. Analysis

As soon as a still image is recorded, it is placed in the imaging program (in the image strips in DBSWIN).

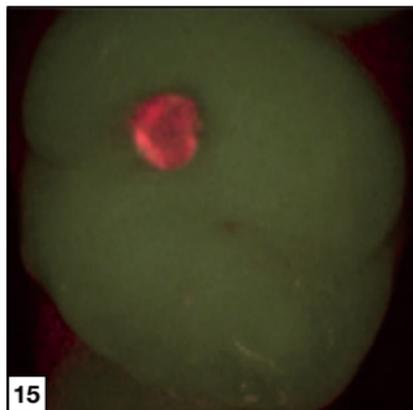
Select view:



Switch to prophylaxis view (image 15).



Switch to caries view (image 16).

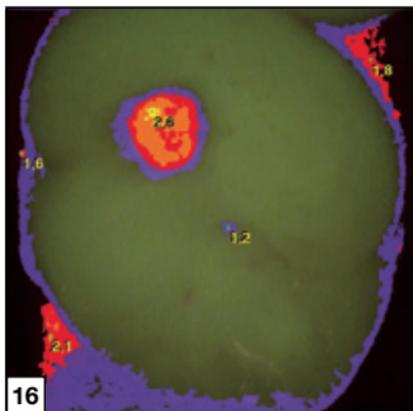


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8.1 Prophylaxis view analysis

The prophylaxis view shows the image without filter.

Red areas indicate caries-causing bacteria. The healthy tooth enamel is shown as green areas.

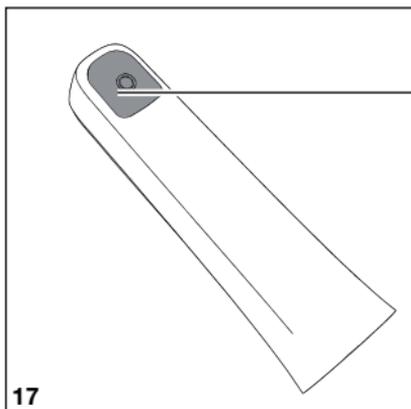


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8.2 Caries view analysis

The caries view analyses the image with the caries filter. The colour scale and the numeric values provide reliable information on carious lesions:

		Healthy tooth enamel
1.0		Early-stage caries, incipient enamel caries
1.5		Enamel caries up to enamel-dentine junction
2.0		Dentine junction already exceeded
2.5		Deep dentine caries



9. Cleaning and disinfection

6 9.1 Cleaning the interchangeable head



WARNING

Incorrect cleaning can damage the interchangeable head

- Only clean the surface of the interchangeable head.
 - Never clean the interchangeable head from inside.
 - Only use disinfection and cleaning agents specifically approved by Dürr Dental.
 - Do not use any aggressive or abrasive cleaning materials.
 - Only clean the interchangeable head using wipe disinfection.
 - Do not clean the interchangeable head by submerging or spraying in combination with disinfectant.
 - Do not steam sterilise the interchangeable head.
- Wipe the surface of the interchangeable head with a disinfection wipe (e.g. FD 350). Leave out the window of the optic itself.

9.2 Cleaning the optical element



WARNING

Damage of the optical element from incorrect cleaning

- Only use the cleaning set for the VistaCam optical element (order number 2101-025-50). Residues of disinfectants soil the optical element.
- Clean the window of the optic itself of the interchangeable head (6) with the cleaning set for VistaCam.

9.3 Preparing the spacer

The following instructions have been validated by Dürr Dental as suitable for preparing the spacer for its reuse.

Preparation procedure:

1. Cleaning and disinfecting (automatic or manual)
2. Sterilising in the vacuum steriliser

The preparer is responsible for ensuring that the preparation carried out with the equipment, materials and personnel involved achieve the desired results.

If there is any deviation from the validated preparation, the preparer is responsible for the effectiveness and possible negative consequences of the preparation.

- Carry out validation and routine monitoring of the preparation process.
- Observe the applicable national regulations for cleaning, disinfection, sterilisation and storage of the spacer

Automatic cleaning and disinfecting



Use cleaning and disinfecting equipment in accordance with the manufacturer's instructions.

- Remove heavy soiling with a disposable disinfection wipe (e.g. FD 350).
- Place the spacer in the appliance so that it is well rinsed and the water can flow away.
- Carry out the cleaning and disinfection cycle in accordance with the manufacturer's instructions.
- Check the spacer for any remaining soiling after completing the cleaning and disinfection cycle. If necessary, repeat the cycle.

Manually cleaning and disinfecting using the wet chemical process



When manually cleaning using the wet chemical process, use a VAH/DGHM listed disinfectant. Observe the manufacturer's instructions for the disinfectant.

- Remove heavy soiling with a disposable disinfection wipe (e.g. FD 350).

- Place the spacer fully into an instrument disinfection and cleaning solution (e.g. ID 212, ID 212 forte, ID 213).
- Check the spacer for any remaining dirt after completing the cleaning and disinfection cycle. If necessary, repeat the cycle.
- Rinse the spacer with water.
- Dry the spacer with hygienically clean disposable wipes or with compressed air.

Sterilising



WARNING

Damage to the spacer from incorrect sterilisation.

- Do not exceed 134 °C.
- Do not sterilise in the hot air steriliser.
- Always sterilise together with instruments in order to achieve a balanced temperature distribution.
- Avoid metal contact of the spacer with other instruments or the edge of the tray.
- Position the spacer away from the heating bars and without contact to the inner walls.
- Pack the spacer in a container or in sterile product packaging.
- Equip the sterilisation tray with filter paper.
- Place the spacer on the middle sterilisation tray.
- Sterilise the spacer.
 - Temperature: 134 °C
 - Working time: 3 min
 - Pressure: 3 bar/0.3 MPa absolute
 - Humidity: 100 %

Storage

Store the spacer so it is protected against contamination.

10. Maintenance

The industrial camera is maintenance-free.



11. Tips for Operators and Service Technicians

EN

Problem	Possible cause	Solution
Image contains a high amount of red; healthy tooth substance is not properly green	<ul style="list-style-type: none">• Penetration of external light	<ul style="list-style-type: none">• Check the position of the spacer (directly on the tooth).• Turn off or dim sources of external light (e.g. operating lights); darken the room.
Image cloudy, milky	<ul style="list-style-type: none">• Disposable hygienic protective cover not placed correctly on the window of the optic itself	<ul style="list-style-type: none">• Place the disposable hygienic protective cover correctly on the window of the optic itself.
	<ul style="list-style-type: none">• Window of the optic itself soiled.	<ul style="list-style-type: none">• Clean the window of the optic itself (see 9.2 Cleaning the optical element).
	<ul style="list-style-type: none">• Image sensor soiled.	<ul style="list-style-type: none">• Clean the image sensor (see 9.2 Cleaning the optical element).
	<ul style="list-style-type: none">• Optical element scratched	<ul style="list-style-type: none">• Replace the interchangeable head.
	<ul style="list-style-type: none">• Handpiece defective.	<ul style="list-style-type: none">• Send the handpiece for repair.
Image too dark	<ul style="list-style-type: none">• LEDs defective	<ul style="list-style-type: none">• Replace the interchangeable head.
No image	<ul style="list-style-type: none">• USB cable not connected	<ul style="list-style-type: none">• Connect the USB cable.
	<ul style="list-style-type: none">• USB cable defective	<ul style="list-style-type: none">• Replace the USB cable.
	<ul style="list-style-type: none">• Computer not switched on, software not started	<ul style="list-style-type: none">• Computer switched on and start software.
	<ul style="list-style-type: none">• Camera driver not correctly installed	<ul style="list-style-type: none">• Check the driver installation and software settings.



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