

# VistaCam iX Proxi

EN



Installation and Operating Instructions



9000-618-254/30



 DÜRR  
DENTAL

1608V003E.7



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## Important information

### 1 About this document

These installation and operating instructions form part of the unit.

 If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

#### 1.1 Warnings and symbols

##### Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:

 General warning symbol

The warnings are structured as follows:

 **SIGNAL WORD**  
**Description of the type and source of danger**

Here you will find the possible consequences of ignoring the warning

➤ Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

- **DANGER**  
Immediate danger of severe injury or death
- **WARNING**  
Possible danger of severe injury or death
- **CAUTION**  
Risk of minor injuries
- **NOTICE**  
Risk of extensive material/property damage

##### Other symbols

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

 Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.

 Comply with the specification in the accompanying documents.

 CE labelling

 Date of manufacture

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

 Do not reuse.

 Application part type B

 Steam sterilise at 134 °C

 Wear protective gloves.

#### 1.2 Copyright information

All names of circuits, processes, names, software programs and units used in this document are protected by copyright.

The Installation and Operating Instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from Dürr Dental.



## 2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

### 2.1 Intended use

The Proxi interchangeable head is an attachable head for the VistaCam iX hand-piece as of serial number B000484.

The Proxi interchangeable head enables the detection of approximal caries by virtue of the translucence of the healthy tooth enamel to light waves in the infra-red range.

### 2.2 Improper usage

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.



#### WARNING

##### Risk of explosion due to ignition of combustible materials

- › Do not operate the unit in any rooms in which inflammable mixtures may be present, e.g. in operating theatres.



#### CAUTION

##### The light of the camera is very bright and can dazzle

- › Do not use the camera directly on the eye.

### 2.3 General safety information

- › When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
- › Prior to each use, check condition of the device and make sure it is in perfect working order.
- › Do not convert or modify the units.
- › Observe the Installation and Operating Instructions.
- › Make the Installation and Operating Instructions available to the person operating the device at all times.

### 2.4 Qualified personnel

#### Operation

Operating personnel are dentists and dental personnel.

They must ensure safe and appropriate handling on the basis of their training and know-how.

- › Instruct or have every user instructed in handling the unit.

#### Installation and repairs

- › Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

### 2.5 Protection from electric shock

- › When working on the units observe all the relevant electrical safety regulations.
- › Never touch the patient and unshielded plug connections on the device at the same time.
- › Immediately replace any damaged lines and connections.

## Observe the EMC rules concerning medical devices

-  For information on electromagnetic compatibility (EMC), see the installation and operating instructions for VistaCam iX (order number 9000-618-176).

## 2.6 Only use genuine parts

- › Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
- › Only use only genuine working parts and spare parts.

-  DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.

The use of non-approved accessories, special accessories or non-genuine working parts / spare parts (e.g. mains cable) can have a negative effect in terms of electrical safety and EMC.

## 2.7 Transport

The original packaging provides optimum protection for the device during transport. If required, original packaging for the unit can be ordered from Dürr Dental.

-  Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.
- › Only transport the device in its original packaging.
  - › Keep the packing materials out of the reach of children.

## 2.8 Disposal

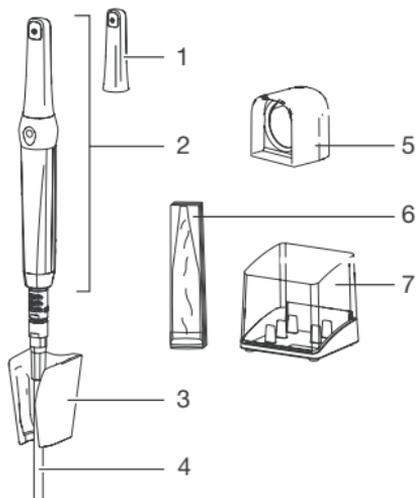
### Unit

 The unit must be properly disposed of. Within the European Union, the unit must be disposed of in accordance with EU Directive 2012/19/EU (WEEE).

- › If you have any questions about the correct disposal of parts, please contact your dental trade supplier.



## 3 Overview



- 1 Proxi interchangeable head
- 2 Handpiece with interchangeable head
- 3 Handpiece holder
- 4 USB connecting cable (to computer)
- 5 Positioning holder
- 6 Poly disposable hygienic protective cover, Proxi
- 7 Storage box (optional)

### 3.1 Scope of delivery

The following items are included in the scope of delivery:

#### Proxi interchangeable head for VistaCam iX . . . . . 2108-130-56

- Proxi interchangeable head
- Positioning holder (3 pieces)
- Poly disposable hygienic protective covers, Proxi (20 pieces)
- Installation and operating instructions
- Quick start instructions

### 3.2 Accessories

The following articles are necessary to operate the unit, depending on the actual application:

- Positioning holder (3 pieces) . . . 2108-132-52
- Poly disposable hygienic protective covers, Proxi (500 pieces) . . . . . 2108-010-60
- Poly disposable hygienic protective covers, Proxi (100 pieces) . . . . . 2108010053

### 3.3 Special accessories

The following optional items can be used with the unit:

- Storage box . . . . . 2108-135-50

### 3.4 Disposable materials

The following materials are consumed during operation of the device and must be ordered separately:

- Poly disposable hygienic protective covers, Proxi (500 pieces) . . . . . 2108-010-60
- Poly disposable hygienic protective covers, Proxi (100 pieces) . . . . . 2108010053

### Cleaning and disinfection

- FD 350 Disinfectant wipes. . . CDF350C1040
- FD 333 rapid surface disinfectant . . . . . CDF333C6150
- FD 322 rapid surface disinfectant . . . . . CDF322C6150
- FD 366 sensitive disinfectant for sensitive surfaces. . . . . CDF366C6150

### 3.5 Wear parts and spare parts

The following wear parts must be replaced at regular intervals:

- Positioning holder (3 pieces) . . . 2108-132-52

## 4 Technical data

### 4.1 Proxi interchangeable head

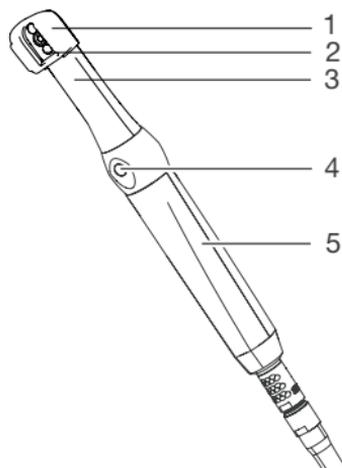
#### Proxi interchangeable head

Light source		LED
Wavelength	nm	850
Sharpness level	mm	7

#### Handpiece with Proxi interchangeable head

Length	mm	190
Weight (without cable)	g	51

## 5 Operation



- 1 Positioning holder
- 2 Optical system
- 3 Proxi interchangeable head
- 4 Capture ring
- 5 Handpiece

The VistaCam iX handpiece with the Proxi interchangeable head creates a black and white image for detecting caries in the approximal region.

The optical system is placed on the row of teeth and an image is created by actuating the capture ring. The positioning holder facilitates the placement of the optical system on the row of teeth. In addition, the positioning holder screens off the image area and minimises the penetration of external light.

Two powerful infra-red LEDs are installed in the optical system. The infra-red light illuminates the tooth and is reflected with varying intensity depending on the translucence (light transmission) of the dental structures. The reflected light is detected by the optical system and is evaluated as a black and white image by the DBSWIN imaging program (from Version 5.6) or VistaEasy (from Version 5.6).



## 5.1 Evaluation

The black and white image shows structures with varying translucency as different levels of brightness. The lower the translucency, the higher the reflection of the infra-red light and the brighter the structure. It is possible to make out the following structures:

- Healthy enamel appears very dark, high translucency
- Approximal caries appears bright, low translucency
- Dentine appears bright, low translucency
- Several restorations appear bright, no translucency



*Figure 1: Any lesions on the mesial surface can be recognised as a wide bright strip up to the enamel/dentine limit.*



*Figure 2: Enamel lesions on the mesial surface can be seen as wedge-shaped structures within the dark translucent tooth enamel. The lesions reach to the inner half of the enamel.*

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

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

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



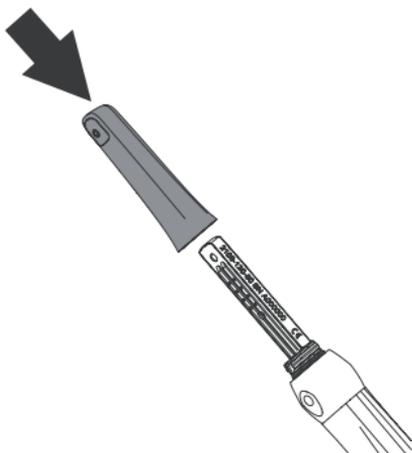
**i** For information on the assembly, connection, and installation of the device, see the assembly and operating instructions of the VistaCam iX handpiece (9000-618-176) and the installation and configuration manual of the VistaCam iX (document no. 9000-618-179).

## 6 Operation

### 6.1 Preparation of the device

#### Place 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 clicks into place.



#### Using the hygienic protective cover



#### WARNING

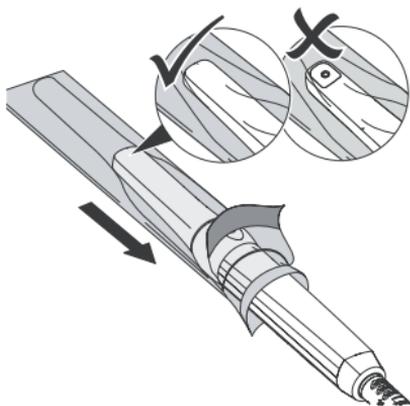
**Danger of cross contamination with failure to use or repeated use of a disposable hygienic protective cover**

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



Wear protective gloves when applying the disposable hygienic protective cover.

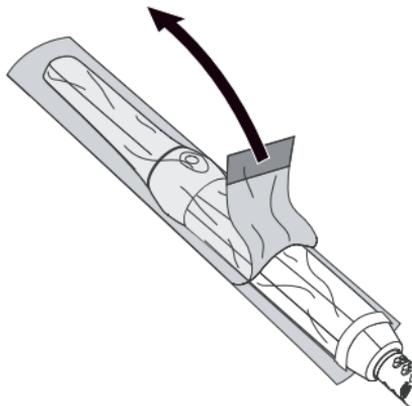
- › Hold the camera so that the optical element faces down.
- › Lift the white edge of the disposable hygienic protective cover and slide the camera head carefully into the cover. The transparent plastic side must face upwards.



- › 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 optical window using your fingers. Ensure that there

are no air bubbles between the optical window and the disposable hygienic protective cover.

- › Hold the disposable hygienic protective cover firmly on the white edge and pull off the transparent plastic side in the direction of the camera head.



- › Pull off the paper underside from the camera head in the direction of the hand-piece.

#### Placing on the positioning holder

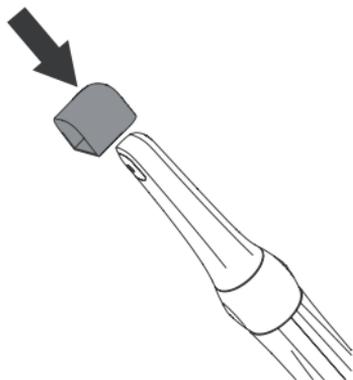


#### WARNING

**Danger of cross-contamination when used without reprocessing or following incorrect reprocessing**

- › Sterilise the light protection in the steam steriliser (see "7.3 Preparing the positioning holder") before each use.
- › Place the positioning holder onto the interchangeable head from above. Make sure the positioning holder itself does not

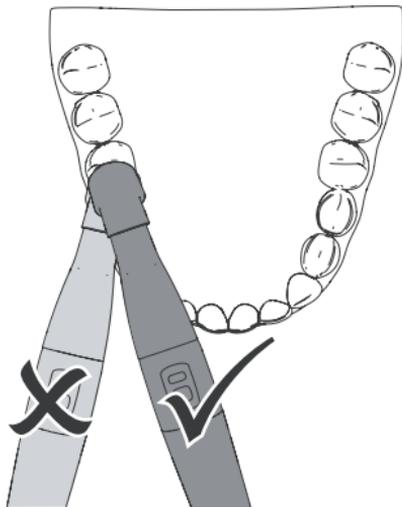
obscure the optical element of the interchangeable head.



## 6.2 Positioning the unit correctly

The camera must be positioned correctly to achieve a good picture quality.

- › Position the camera in a line with the teeth.



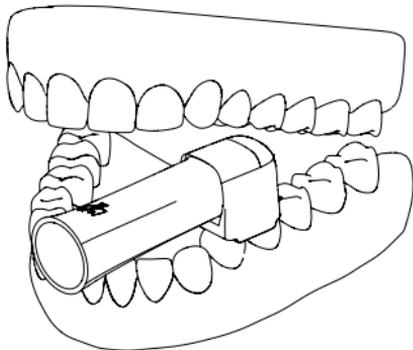
- › Place the spacer vertically on the tooth surface. The spacer must come into contact with the teeth.



- › Ensure that the relevant approximal area is located in the centre of the image section.
- › If the structure underneath the enamel is not visible, change the angle of the camera slightly.

### 6.3 Operating the unit

- › Reduce the penetration of external light. Turn off or dim sources of external light (e.g. operating lights).
- › Dry the row of teeth with compressed air.
- › Place the camera with positioning holder on the row of teeth above the approximal area. The two infrared LEDs illuminate the respective mesial and distal enamel area of the two adjacent teeth.



- › Press on one point of the capture ring. The camera switches to "Freeze" mode. The freeze frame will be displayed in the imaging program / transmitted to the monitor.
- › Edit the image using the imaging program and save. (For further information, refer to the software manual.)
- › To return to "Live" mode, press on a point on the capture ring again.

## 7 Cleaning and disinfection

### 7.1 Cleaning and disinfect the interchangeable head

Use the following cleaning and disinfectant agents as disinfectant wipes:

- FD 350 Disinfectant wipes
- FD 333 wipes disinfectant wipes
- FD 322 rapid surface disinfectant
- FD 333 rapid surface disinfectant
- FD 366 sensitive disinfectant for sensitive surfaces



#### NOTICE

**Incorrect cleaning and disinfection 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 Dürer 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 disinfectant wipe (e.g. FD 350).

#### Result:



In order to protect the interchangeable head from soiling during storage, place the interchangeable head in its storage box after cleaning.

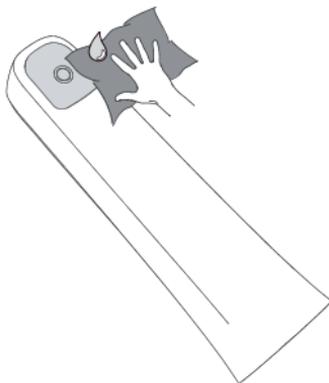
### 7.2 Cleaning the optical element



#### NOTICE

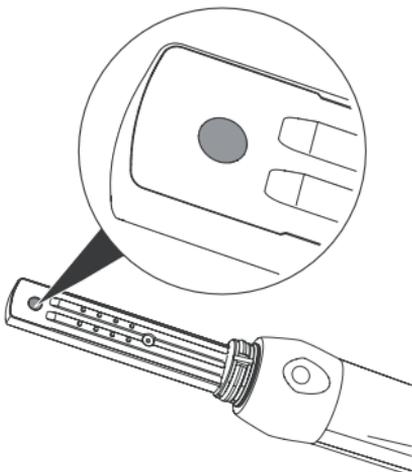
**Damage of the optical element from incorrect cleaning**

- › Only use the cleaning set for VistaCam optical element. Disinfectant residues soil the optical element.
- › Clean the window of the optical window of the interchangeable head from outside using the microfibre cloth with a drop of VistaCam optical element cleaner or alcohol.

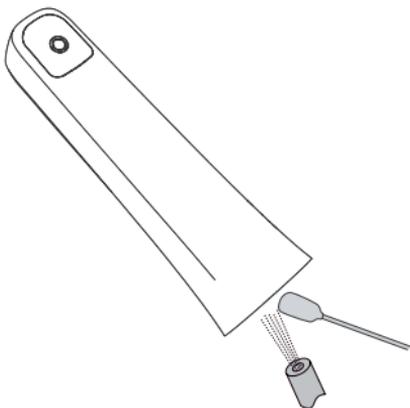




- › With the interchangeable head removed, clean the surface of the image sensor using the cleaning set for VistaCam Optik.



- › If particles can still be seen on the image, dry clean the interchangeable head from the inside with compressed air or with a foam rod (from the cleaning set).



### 7.3 Preparing the positioning holder

The following instructions have been validated by Dürr Dental in order to prepare the product for reuse.

Reprocessing procedure:

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

The person performing the reprocessing is responsible for ensuring that the reprocessing carried out with the utilised equipment, materials and personnel achieve the desired results. Given any deviation from the validated reprocessing, the person performing the reprocessing is responsible for the effectiveness and for any potential adverse consequences of the reprocessing.

- › Carry out the validation and routine monitoring of the reprocessing process.
- › Follow the applicable national regulations during cleaning, disinfection, sterilisation and storage.

#### 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 product in the unit in such a way that it is rinsed thoroughly and the water can run off.
- › Carry out the cleaning and disinfection cycle in accordance with the manufacturer's instructions.
- › After the end of the cleaning and disinfection cycle, check the product for any remaining soiling. If necessary, repeat the cycle.

## Manually clean and disinfect using the wet chemical process

-  When manually cleaning using the wet chemical process, use a VAH/ DGHM listed disinfectant. Comply with the reaction times stated in the disinfectant manufacturer information.
- › Remove heavy soiling with a disposable disinfection wipe (e.g. FD 350).
- › Immerse the product in an instrument disinfection and cleaning solution (e. g. ID 212, ID 212 forte, ID 213).
- › After the end of the cleaning and disinfection cycle, check the product for any remaining soiling. If necessary, repeat the cycle.
- › Rinse parts thoroughly with water.
- › Dry the spacer with hygienically clean disposable wipes or with compressed air.

- › Comply with all national and local guidelines and standards regarding the sterilisation of medical devices.

### Storage

- › Store the product protected against contamination.

## Steam sterilising



### WARNING

**Incorrect sterilisation reduces effectiveness and can damage the product.**

- › Only steam sterilisation is permitted.
- › Comply with the specified process parameters.
- › Do not use any other methods.

Process parameters

Temperature: 134 °C



Gauge pressure above that of environment: 2.16 bar / 0.216 MPa

Holding time: 5 min

- › Parts for sterilisation must be sterilised before each use in a small steam steriliser according to EN 13060 with a type B sterilisation cycle and final drying.
- › Comply with the manufacturer information regarding usage of the steam steriliser and the correct placement of parts for sterilisation.



## 8 Tips for operators and service technicians



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

Problem	Probable cause	Solution
<b>Image is too light in a specific region</b>	The angle of the camera to the tooth is not ideal	<ul style="list-style-type: none"> <li>› Change the holding angle of the camera to the tooth.</li> </ul>
<b>Snow effect on the image</b>	Clearance of the camera to the tooth is too high, no optimum illumination	<ul style="list-style-type: none"> <li>› Ensure that the spacer does not come into contact with the teeth.</li> </ul>
	Camera used without spacer	<ul style="list-style-type: none"> <li>› Always use a spacer for imaging using the Proxi interchangeable head.</li> </ul>
<b>Dark shadow in the dentine</b>	Hygienic protective cover or optical element soiled	<ul style="list-style-type: none"> <li>› Check the hygienic protective cover, clean or replace if necessary.</li> <li>› Check the optical element and clean if necessary (see "7.2 Cleaning the optical element").</li> </ul>
<b>Image is too light or too dark</b>	Incorrect settings in the imaging software	<ul style="list-style-type: none"> <li>› Alter the brightness of the image in the imaging software.</li> <li>› Adapt the brightness in the configuration of the imaging software to change the brightness settings.</li> </ul>
<b>Too many reflections in the image</b>	Saliva in the mouth	<ul style="list-style-type: none"> <li>› Dry the row of teeth with a cloth or compressed air.</li> <li>› Change the holding angle of the camera lightly.</li> </ul>
	Teeth with large-surface fillings and a small surface with intact enamel in the image section	<ul style="list-style-type: none"> <li>› This image does not permit exact analysis.</li> </ul>









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