

VistaCam iX Poly

EN



Installation and Operating Instructions



9000-618-201/30



 **DÜRR
DENTAL**

1411V005E.7

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Important information

1 Documentation

These Installation and Operating Instructions form an integral part of the unit. They conform to the relevant version of the equipment and the status of technology valid at the time of first operation.



Dürr Dental cannot guarantee smooth operation and safe function of the unit and will not accept any liability where the instructions and notes contained in these installation and operating instructions are not strictly observed.

This translation has been carried out in all good faith. The original German version is decisive. Dürr Dental accepts no liability for incorrect translation.

1.1 Warnings and symbols

Warnings

The warnings in this document are there to point out 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 type and source of danger

Possible consequences of ignoring the safety warning here

- Measures to be taken to avoid any possible danger.

The signal word differentiates between different levels of danger:

– **DANGER**

High risk of danger of serious injury or death

– **WARNING**

Possible risk of danger of serious injury or death

– **CAUTION**

Risk of danger of minor injuries

– **NOTICE**

Risk of serious damage

Further symbols

These symbols are used within the documentation and on the unit itself:



Notes, e.g. special instructions concerning economical use of the unit.



Observe the accompanying documentation.



CE-labeling



Date of manufacture



Dispose of product correctly and in accordance with EU directive (2002/96/EG-WEEE).



Only use once.



Part type B



Steam sterilise at 134 °C



Wear protective glasses (goggles).



Wear protective gloves



1.2 Notes on copyright

All circuits, processes, names, software and appliances quoted are protected under industrial property rights.

Any reprinting of the technical documentation, in whole or in part, is subject to prior approval of Dürr Dental being given in writing.

2 Safety

Dürr Dental has designed and constructed this appliance so that when used correctly there is no danger to people or property. Nevertheless, there are residual risks. Please follow the instructions below carefully.

2.1 Correct use

The Poly interchangeable head is a plug-on head with polymerization lamp for the Vista-Cam iX handpiece.

This polymerization lamp is designed for light-hardening dental materials (e.g. adhesives, composites and compomers), which can be hardened using rays of blue light with wavelengths of 460 ± 10 nm (photoinitiator camphor quinone).

2.2 Incorrect use

Any use of this appliance above and beyond that specifically described in these instructions will be deemed to be as not according to the intended use. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The user bears all risks.

The Poly interchangeable head is not suitable for polymerisation of dental materials which cannot be hardened using light of wavelengths 460 ± 10 nm.



WARNING

Risk of explosion due to inflammation of combustible materials

- Do not use the appliance in rooms in which combustible mixtures may be present, e.g. in operating theatres.



2.3 General safety notes

- Before using the appliance observe any and all guidelines, laws, regulations and other restrictions which may apply to the appliance.
- Before each use check the function and condition of the appliance.
- Do not convert or change the appliance in any way.
- Observe the Installation and Operating Instructions precisely.
- Keep the Installation and Operating Instructions in an accessible place so that the operator has instant access to them.

2.4 Qualified personnel

Instructions for use

Persons that operate the appliance are dentists and dental personnel.

As a result of their training and know-how, they must ensure safe and appropriate handling.

- Each operator using the appliance must be trained in its handling.

Installation and repair

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

2.5 Protection against electrical current

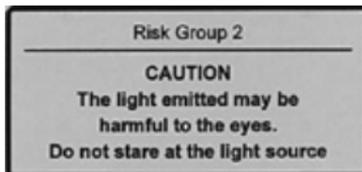
- When working on and with the appliance always observe the local electrical safety procedures.
- Never come into contact with patients and open plug-in connections on the appliance at the same time.
- Damaged supply lines and connections must be replaced immediately.

Observe guidelines for electro-magnetic compatibility for medical devices



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

2.6 Protect from energy intensive light



The polymerisation lamp is a product of Risk group 2 according to EN 62471. If the eyes are exposed to optical radiation for a prolonged period, the radiation can damage the eyes.

- Do not look into the lamp.
- Only use a polymerisation lamp with light protection.
- Wear polymerisation eye protection that absorbs UV and blue light.



2.7 Only use original parts

- Only use accessories and special accessories stipulated or approved by Dürr Dental.
- Only use original working parts and spare parts.



Dürr Dental accepts no liability for damage or injury caused by the use of accessories, special accessories or parts other than original working parts and spare parts which were not specifically approved by the manufacturer.

2.8 Transport

The original packaging offers the optimum protection for the appliance during transport.

If required, the original packaging for the unit can be ordered at Dürr Dental.



Dürr Dental cannot accept any liability for damage caused during transport by the use of unsuitable packaging, this is also valid during the warranty term.

- Only transport the appliance in its original packaging whenever possible.
- Keep the packing materials out of the reach of children.

2.9 Disposal

Appliance



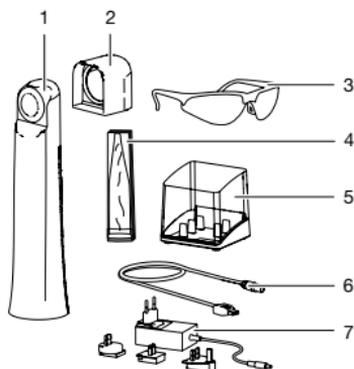
Dispose of the appliance correctly. Within the European Union dispose of the appliance according to EU directive 2002/96/EG (WEEE).

- If you have any questions concerning correct disposal, please contact Dürr Dental or your usual dental supplier.



Product description

3 Overview



- 1 Poly interchangeable head
- 2 Light protection
- 3 Polymerisation protective glasses
- 4 Poly disposable protective sheath
- 5 Storage box (optional)
- 6 USB-connecting cable
- 7 Power unit with country specific adapter

3.1 Delivery Contents

The following articles are supplied with the unit:

Poly interchangeable head for VistaCam iX2108-130-52

- Poly Interchangeable Head
- Disposable protective sheaths (3 pieces)
- USB-connecting cable with power unit
- Poly disposable protective sheaths (20 pieces)
- Polymerisation protective glasses
- Installation and Operating Instructions
- Short introduction

3.2 Accessories

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

- Disposable protective sheaths (3 pieces)2108-132-51
- Poly disposable protective sheaths (500 pieces)2108-010-60
- Polymerisation protective glasses2108-020-50

3.3 Special accessories

The following articles can be used with the unit but are optional:

- Storage box2108-135-50

3.4 Disposable materials

The following materials are used when operating the unit and must be ordered separately:

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

Cleaning and disinfecting

- FD 350 Disinfectant wipes. . CDF350C1040
- FD 333 surface disinfectant. CDF333C6150
- FD 322 surface disinfectant. CDF322C6150
- FD 366 sensitive disinfection of delicate surfaces. CDF366C6150

3.5 Working parts and spare parts

The following working parts must be replaced at regular intervals:

- Disposable protective sheaths (3 pieces)2108-132-51



4 Technical data

4.1 Poly Interchangeable Head

Polymerisation lamp

Light source		LEDs
Wavelength	nm	460
Light intensity	mW/ cm ²	1000
Diameter of the optics	mm	10

Handpiece with Poly interchangeable head

Length	mm	205
Weight (without cable)	g	55
Operating mode*	T1/T2 = 12 % 40 s/5.5 min (switch-on/off time)	

- * At an ambient temperature of max. 40 °C and while observing the switch-on/off time, the handpiece/the interchangeable head reaches a maximum surface temperature of 60 °C.

4.2 Power unit

Power supply type

Manufacturer	GlobTek Inc.
Model	GTM41076-0612-X.X

Electrical data of power unit

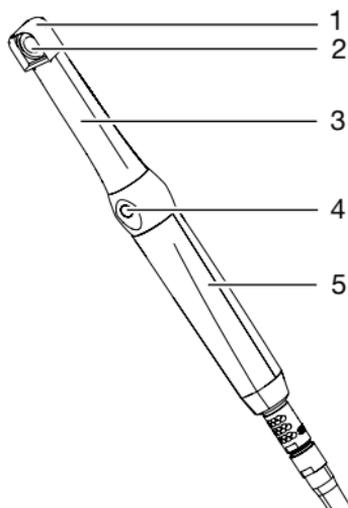
Nominal voltage	V AC	100 - 240
Electrical frequency	Hz	47 - 63
Max. nominal current	A	0.5
Output voltage	V DC	12
Max. output voltage fluctuations	%	±1
Output current	A	0.5
Rated power	W	6

Connection cable

Cable length	cm	250
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5 Function



After every 5 seconds the handpiece vibrates once and there is an audible signal. After 20 seconds the handpiece vibrates twice, there is a repeated audible signal (2x) and the appliance automatically switches off.

- 1 Light protection
- 2 Optical element with LED located directly behind
- 3 Poly interchangeable head
- 4 Pressure sensitive release
- 5 Handpiece

The VistaCam iX handpiece with the Poly interchangeable head acts as a polymerisation lamp which emits blue light in order to harden appropriate dental materials. The light protector focusses the light onto one particular area and protects the operator from any glare.

The appliance is switched on or off by pressing the manual capture. The maximum length of light emission is limited to 20 seconds.

The actual light intensity is increased in two steps after switching on. For the first 5 seconds the light intensity is 520 mW/cm², after this the light intensity increases to a constant 1000 mW/cm².



6 Installation

6.1 Safe connection of appliance

Danger can arise when connecting units with each other or to parts of the system (e.g. through discharge current).

- Only connect units when there can be no question of danger to operator or to patient.
- Only connect units when there can be no environmental impairment through such interconnection.
- When it is not clear from the unit data sheets that such connection will cause no danger, then a qualified expert should be consulted to ensure no danger (e.g. one of the product manufacturers).
- Observe the specifications of IEC 60601-1 (EN 60601-1) when connecting the appliance with other appliances, e.g. a PC system, as well as outside the vicinity of the patients.
- Only connect additional appliances (e.g. computer, monitor, printer) which at least comply with the IEC 60950-1 (EN 60950-1) standard.



A master copy of the system manufacturer's declaration according to Article 12 of Directive 93/42/EWG can be found in our download section under www.duerr.de (Document No. 9000-461-264).

6.2 Connecting up the device

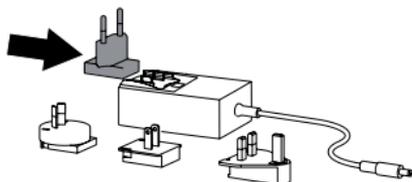
The power supplied via the USB-connecting cable of the VistaCam iX for the camera interchangeable head is not sufficient for the Poly interchangeable head. Therefore the handpiece must be connected to the USB-connecting cable with power unit supplied.



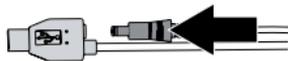
The USB-connecting cable with power unit allows all available Vista-Cam iX interchangeable heads to be operated.

To operate the Poly interchangeable head connection to the power unit is fully sufficient without added connection to a computer. The application as polymerisation lamp requires no software.

- Connect the appropriate country specific adapter to the power unit.



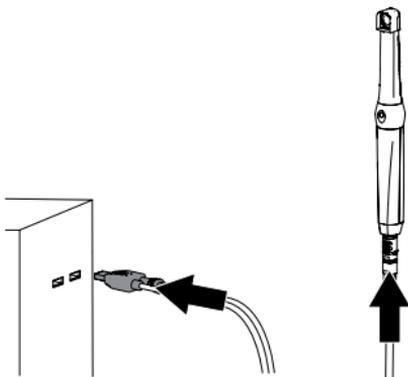
- Connect the power unit to the USB-combination connector.



- Connect the connecting cable to the camera.



- If the appliance is to be used with other interchangeable heads, connect the handpiece using the USB-combination connector to a computer.



- Plug the power unit into the mains supply socket.



7 Instructions for use



WARNING

Injury through light sensitivity

- Persons who are light-sensitive or who are taking light-sensitive medication (photo-sensitizers) should not be exposed to the light from the appliance.

7.1 Prepare the unit



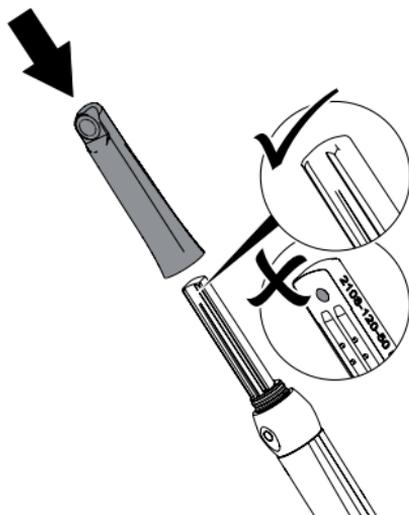
NOTICE

Dirty or damaged optical elements can lead to insufficient hardening

- Check that the optical element is clean, if necessary clean.
- If the optical element looks opaque or badly scratched, change the interchangeable head.
- Check the light intensity with appropriate test device.
- Before every use clean and disinfect the appliance (see "8 Cleaning and disinfecting").

Slide interchangeable head on

- Ensure that the handpiece and the interchangeable head are completely dry.
- Hold the interchangeable head and the handpiece such that the optical element is on the opposite side to the image sensor.
- Slide the interchangeable head onto the handpiece until it locks into place.



Use disposable protective sheaths



WARNING

There is a danger of cross contamination where disposable protective sheaths are not used or are used more than once

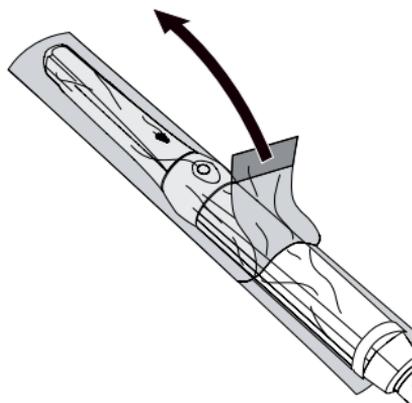
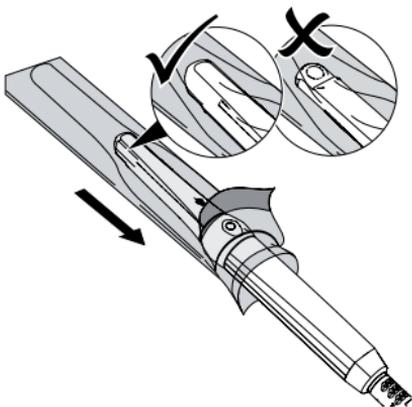
- Do not use the camera without fitting a disposable protective sheath.
- Do not use the disposable protective sheath more than once (disposable item).



When applying the disposable protective sheath wear protective gloves.



- Hold the camera such that the optical element is facing down.
- Lift the white edge to the disposable protective sheath and slide the camera head carefully into the sheath. The transparent plastic side must be facing upwards.
- Hold the disposable protective sheath firmly at the white edging and pull the transparent plastic side in the direction of the camera head.



- Stretch the protective sheath an extra 2 - 3 mm so that the sheath presses tightly against the optical element.
- Carefully press the protective sheath against the window of the optical element with the tips of the fingers. Be careful to ensure no air bubbles occur between the window of the optic itself and the protective sheath.

- Pull the paper lower side from the camera head in the direction of the handpiece.

Mount light protector

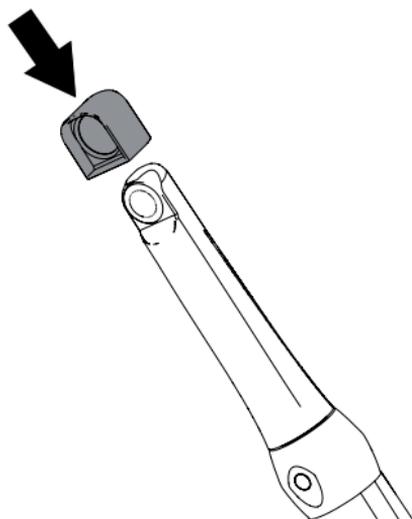


WARNING

Risk of cross contamination when used without or after wrong treatment

- Sterilise the light protector before every use in a steam steriliser (see "8.2 Prepare light protector").

- Place the light protector from above onto the interchangeable head. Carefully ensure that the light protector itself does not obscure the optical element of the interchangeable head.



7.2 Using the appliance

Risk Group 2

CAUTION

The light emitted may be harmful to the eyes.
Do not stare at the light source



CAUTION

Radiated light can damage the eyes

- Do not peer into the light source.
- Wear polymerisation eye protection that absorbs UV and blue light.



CAUTION

The blue light of the polymerisation lamp is high energy. It can dazzle and produces heat.

- Only use a polymerisation lamp with light protection.
- Do not point the polymerisation lamp at any soft tissue or unprotected skin.
- Observe the exposure times.
- Observe at least 10 seconds pause between two polymerisation cycles.



When the appliance is used as a polymerisation lamp, no software and no connection is required on a computer.

If the Poly interchangeable head is attached, the imaging software (e. g. DBSWIN) shows no image (black).

Establish exposure times

The exposure time is dependent on the dental materials being employed.

Where the distance between the polymerisation lamp and the dental material is greater then the exposure time must be extended.

- Observe the information supplied with the dental material, if necessary contact the manufacturer.

Carry out treatment

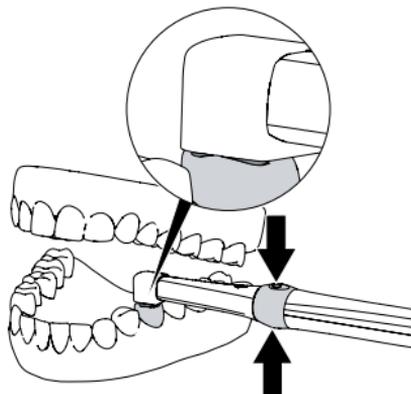


Wear polymerisation protective glasses which absorb UV and blue light.



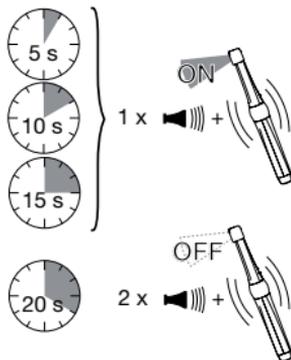
Observe any information concerning the dental materials employed.

- Hold the polymerisation lamp with light protection close to the dental material requiring hardening. Carefully ensure that the distance between these is as small as possible but that the light protector itself does not come into contact with the dental material.
- At one point press the manual capture.



The polymerisation lamp begins to light up.

It lights for max. 20 seconds. After every 5 seconds the handpiece vibrates once and there is an audible signal. After 20 seconds the handpiece vibrates twice and the appliance automatically switches off.



- Once the exposure time has been attained press the manual capture.

8 Cleaning and disinfecting

8.1 Cleaning and disinfecting of interchangeable head

Use the following cleaning and disinfectant agents as disinfectant wipes:

- ✓ FD 350 Disinfectant wipes
- ✓ FD 333 wipes Disinfectant wipes
- ✓ FD 322 Quick acting surface disinfectant
- ✓ FD 333 Quick acting surface disinfectant
- ✓ FD 366 Disinfectant for sensitive surfaces



NOTICE

The wrong 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 dirt during storage, place the interchangeable head in its storage box after cleaning.

8.2 Prepare light protector

Dürer Dental has verified the suitability of the following instructions for preparing the product for further use.

Preparation process:

1. Cleaning and disinfection (automatic or manual)
2. Sterilisation in steam steriliser

The person responsible for preparation must ensure that the process and the equipment, materials, and personnel used achieve the required results. If there is any deviation from the validated preparation process, the person responsible for the preparation is responsible for the effectiveness of the process and for any adverse consequences.

- Carry out validations and routine monitoring of the preparation process.
- Observe any national and local regulations that apply to the cleaning, disinfection, sterilisation and storage.

Automatic cleaning and disinfection



Use a cleaning and disinfection device in accordance with the manufacturer's instructions.

- Remove coarse impurities with a disposable disinfectant wipe (e.g. FD 350).
- Place the product in the device in a way that ensures that it is properly rinsed and that the water can flow away.
- Carry out the cleaning and disinfection cycle in accordance with the instructions of the manufacturer.
- Once the cleaning and disinfection cycle is complete, check the product for any residual impurities. If necessary, repeat the cycle.

Manual cleaning and disinfection by means of a wet chemical procedure



When carrying out manual cleaning by means of a wet chemical procedure, use a VAH/DGHM-listed disinfectant. Observe the instructions of the manufacturer of the disinfectant.



- Remove coarse impurities with a disposable disinfectant wipe (e.g. FD 350).
- Place the product completely immersed in an instrument disinfection and cleaning solution (e.g. ID 212, ID 212 forte, ID 213).
- Once the cleaning and disinfection cycle is complete, check the product for any residual impurities. If necessary, repeat the cycle.
- Rinse the product with water.
- Dry the product with disposable hygienic wipes or compressed air.

Steam sterilisation



WARNING

Incorrect sterilisation inhibits the effectiveness, and can damage the product

- Only use steam sterilisation.
- Observe the process parameters.
- Do not use any other process.

Process parameters

Temperature: 134 °C

Gauge pressure above ambient:

2.16 bar / 0.216 MPa

Working time: 5 min

- Sterilise the parts for sterilisation before each use in a small steam steriliser according to EN 13060 and in sterilisation cycle Type B with subsequent drying.
- Observe the manufacturer's instructions for the use of the steam steriliser and the correct placement of the parts for sterilisation.
- Observe all national and local guidelines and regulations concerning the sterilisation of medical devices.

Storage

- Store the product protected against contamination.

9 Function control

9.1 Check light intensity

The light intensity can be checked using a suitable measuring instrument (e.g. LED Demetron radiometer).

- Switch on the polymerisation lamp but without disposable sheath or light protection cover.
- Check the light intensity with appropriate test device.
- If the light intensity is too low
Clean the optical lens and the measuring instrument and retest, if necessary change the interchangeable head.



134 °C





Trouble-shooting

10 Tips for Operators and Technicians



Repairs above and beyond simple maintenance may only be carried out by a qualified technician or one of our service technicians.

Problem	Probable cause	Solution
Polymerisation lamp does not light	Interchangeable head not correctly in place	<ul style="list-style-type: none"> Remove interchangeable head and try fitting again.
	USB-connecting cable or power unit not connected	<ul style="list-style-type: none"> Check cable connections.
	Wrong USB-connecting cable (without power unit) used	<ul style="list-style-type: none"> Only use USB-connecting cable with power unit (see "3.3 Special accessories").
Dental material does not harden	Exposure times too short	<ul style="list-style-type: none"> Observe exposure times (see "Establish exposure times").
	Distance between polymerisation lamp and dental material too great	<ul style="list-style-type: none"> Hold the polymerisation lamp as close as possible, but without making contact, to the dental material.
	Optical element dirty or scratched	<ul style="list-style-type: none"> Clean optical element, change interchangeable head if necessary.
	Disposable protective sheath mounted incorrectly	<ul style="list-style-type: none"> Use disposable protective sheath correctly (see "7.1 Prepare the unit").
	Dental material employed is unsuitable	<ul style="list-style-type: none"> Only use dental material which responds to hardening by light of wavelength 460 ± 10 nm. Check the use by date and the storage conditions of the dental material.
	Light intensity too low	<ul style="list-style-type: none"> Check the light intensity with appropriate test device.
Appliance does not switch on or switches off too soon	Appliance overheating	<ul style="list-style-type: none"> Wait until the appliance has sufficiently cooled.



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