New as of: 04.2021

Dentsply Sirona

LEDlight Plus

Instructions for use

English

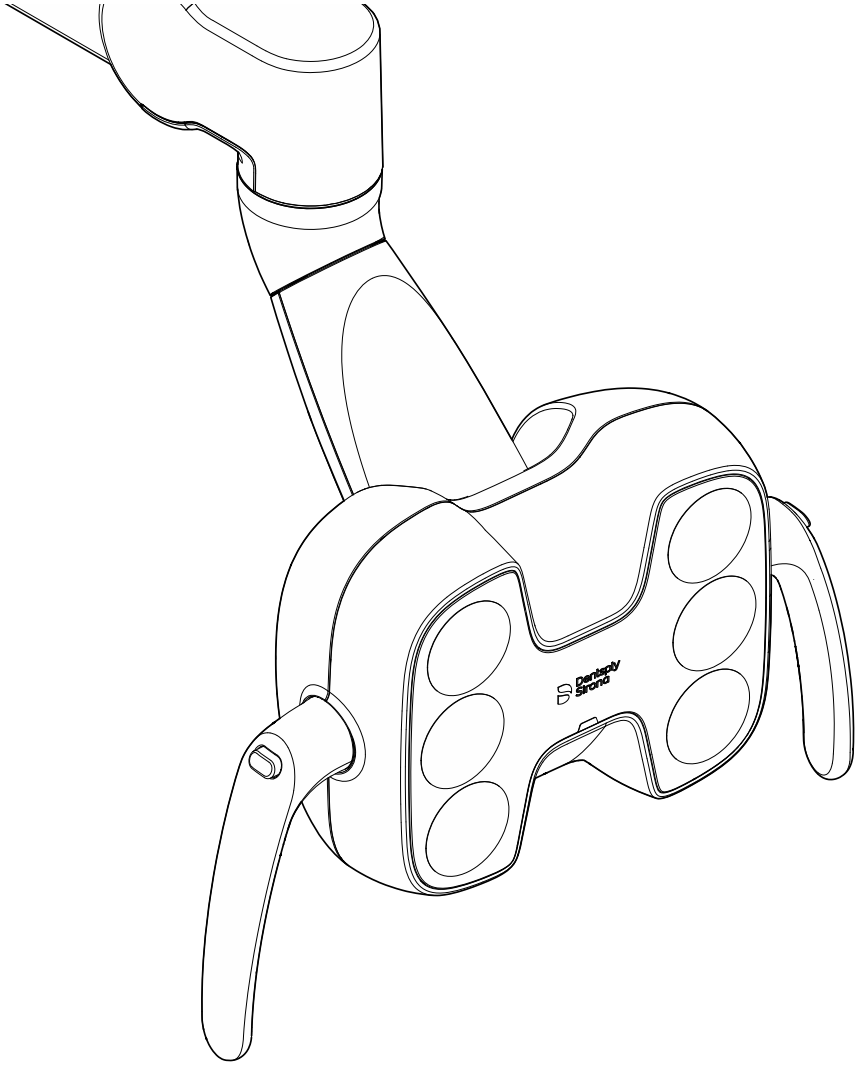


Table of contents

1 General information

1.1 Dear Customer,

We are pleased that you have equipped your practice with the LEDlight Plus operating light.

You now have a light with LED technology featuring powerful illumination, lamp longevity and low energy consumption. Its mechanical adjustability on three axes ensures optimal positioning.

Please perform maintenance and cleaning based on the corresponding instructions.

Familiarize yourself with the lamp by reading these Operating Instructions before putting it into operation.

It is important to observe all safety information to prevent personal injury and material damage.

Your LEDlight Plus Team

1.2 Contact data

Customer Service Center

In the event of technical queries, please use our online contact form at the following address:
http://srvcontact.sirona.com

Importer

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

Tel.: +49 (0) 6251/16-0
Fax: +49 (0) 6251/16-2591
E-Mail: contact@dentsplysirona.com
www.dentsplysirona.com

Authorized agent in the EU

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

EC REP

Manufacturer's address

MEDFRUTION ELECTRONICS TECHNOLOGY CO., LTD
Xinnan Industrial Area, Guanhua Road, Guanyao Town, Nanhai District, Foshan City, Guangdong Province, China

1.3 General information about this operating manual

Observe the Operating Instructions

Please familiarize yourself with the unit by reading through these Operating Instructions before putting it into operation. It is essential that you comply with the specified warning and safety information.

Keep documents safe

Always keep the Operating Instructions handy in case you or another user require(s) information at a later point in time. Save the Operating Instructions on the PC or print them out.

If you sell the unit, make sure that the Operating Instructions are included with it either as a hard copy or on an electronic storage device so that the new owner can familiarize himself with its functions and the specified warning and safety information.

Online portal for technical documents

We have set up an online portal for the Technical Documents at www.dentsplysirona.com/manuals. From here, you can download these Operating Instructions along with other documents. Please complete the online form if you would like a hard copy of a particular document. We will then be happy to send you a printed copy free of charge.

Help

If you have difficulties despite having thoroughly studied the Operating Instructions, please contact your dental depot.

1.4 Structure of the document

1.4.1 Identification of the danger levels

To prevent personal injury and material damage, please observe the warning and safety information provided in these instructions for use. Such information is highlighted as follows:

⚠ DANGER

An imminent danger that could result in serious bodily injury or death.

⚠ WARNING

A possibly dangerous situation that could result in serious bodily injury or death.

⚠ CAUTION

A possibly dangerous situation that could result in slight bodily injury.

NOTE

A possibly harmful situation which could lead to damage of the product or an object in its environment.

IMPORTANT

Application instructions and other important information.

Tip: Information for simplifying work.

1.4.2 Formats and symbols used

The formats and symbols used in this document have the following meaning:

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Requests you to do something.
See "Formats and symbols used [→ 6]"	Identifies a reference to another text passage and specifies its page number.
• List	Designates a list.
"Command / menu item"	Indicates commands / menu items or quotations.

1.5 Scope of these Operating Instructions

This document describes the operation of the LEDlight Plus operating light as a unit model in the treatment center.

The LEDlight Plus can be operated as a unit model with the Intego range treatment centers. The LEDlight Plus is attached to the lamp support tube of the treatment center. It is operated via the user interface of the treatment center and the proximity sensor.

1.6 Warranty and liability

Maintenance

Maintenance must be performed at scheduled intervals to ensure the operational and functional reliability of your product and to protect the safety and health of patients, users and other persons. For more information, please refer to the sections, "Maintenance performed by the service engineer" and "Inspection and maintenance" in the operating instructions for your treatment center.

The owner is responsible for making sure that all maintenance activities are performed.

As manufacturers of medical electrical equipment, we can assume responsibility for the safety properties of the unit only if maintenance and repairs on the unit are performed either by us or by agencies which we have expressly authorized and if components of the unit are replaced by original spare parts in case of failure.

Exclusion of liability

In the event that the system owner fails to fulfill its obligation to perform maintenance activities or ignores error messages, Sirona Dental Systems GmbH and its authorized dealers cannot assume any liability for any damage thus incurred.

1.7 Intended purpose

The operating light is designed for illumination of the treatment area and may only be used by trained dental personnel.

The operating light is not intended for operation in areas subject to explosion hazards.

Intended use also includes compliance with these operating instructions.

1.8 Indication and Contraindication

Indications

- Treatment-assistance through illumination of the treatment area for:
  - Caries
  - Periodontitis
  - Endodontics
  - Implantology
  - Tooth displacement
  - Dental care (tooth cleaning, etc.)
  - Other dentist practices

  Note: Patients suffering from the following diseases do not suffer any adverse effects from the operating light as the LEDs used do not produce any UVA or UVB rays.
  - Actinic prurigo (AP)
  - Hydroa vacciniforme
  - Lupus erythematosus (LE)
  - Xeroderma pigmentosum (XP)

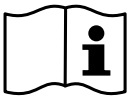
Contraindications

- Patients suffering from any of the following diseases may only be treated with the lowest possible light output. You must consult the dermatologist treating the patient concerned in each case:
  - Chronic actinic dermatitis (CAD)
  - Polymorphous / polymorphic light eruption (PLE/PMLE)
  - Cutaneous porphyrias
  - Solar urticaria
- Patients taking the following medications have an increase sensitivity to light. These patients should be treated with the lowest possible light output. You must consult the doctor treating the patient concerned in each case:
  - High doses of amiodarone
  - Photofrin
  - Foscan
  - other photodynamic therapy (PDT) drugs
- Users with existing age-related macular degeneration (AMD) or who are predisposed to AMD should always work at the lowest possible (but still adequate) brightness level.

2 Safety instructions

2.1 Information on the unit

Accompanying documents



This symbol can be found on the rating plates on the units.

Meaning: When operating the unit, observe the instructions for use.

This symbol can be found on the rating plates on the units.

Meaning: The accompanying documents are available on the manufacturer's website.

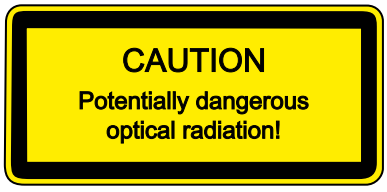
2.2 Care, cleaning, and disinfecting agents

Unsuitable care and cleaning agents or disinfectants may corrode the surface of the unit or impair its functioning.

Therefore, use only care and cleaning agents and disinfectants which have been approved by the manufacturer. For more information, see the chapter "Care, cleaning, and disinfecting agents".

2.3 Trouble-free operation

2.4 Blinding



IEC 62471: Risk group 1
Wavelength: 400 nm to 780 nm

⚠ WARNING

Due to the extreme brightness of the LED technology employed, directing the light beam into the patient's or user's eyes should be avoided! Briefly looking into the light beam is harmless.

2.5 Composite mode

⚠ CAUTION

To delay premature curing when composite materials are used, always operate the light in composite mode under these circumstances. The irradiance based on the spectral sensitivity of the camphorquinone is < 3 W/m² in accordance with ISO 9680:2014. Despite the reduction in irradiance, modern high-sensitivity composite materials in particular can cure prematurely as a result of other light sources, e.g. cap lamps, ceiling lamps, daylight, etc. The application procedure must, therefore, be checked on an individual basis.

2.6 Shade selection of dental restorative materials

IMPORTANT
The shade selection of dental restorative materials should be carried out in daylight.

2.7 Mechanical stability

⚠ CAUTION
Additional loads (such as auxiliary units) must not be mounted on the support arm system.

2.8 Modifications and extensions to the device

For reasons of product safety, this product may be operated only with original Dentsply Sirona parts or third-party parts expressly approved by Dentsply Sirona. In the event of changes which were not foreseen, Dentsply Sirona is not liable for resulting damages.

2.9 Safety checks

Please observe the chapter on "Safety-related tests" in the operator manual for your treatment center.

2.10 Electromagnetic compatibility

Medical electrical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC). It must be installed and operated in compliance with the specifications provided for the respective treatment center in the document "Installation Requirements".

Portable RF communication units, including accessories, should not be used at a low level to the unit. Non-compliance can lead to a reduction in the performance features of the unit.

To ensure safe operation from the standpoint of EMC, please observe the chapter entitled "Electromagnetic compatibility" in the document "Installation Requirements".

2.11 Dismantling/Installation

When dismantling and reinstalling the unit, proceed according to the installation instructions for new installation in order to guarantee its functioning, stability and safety.

This unit must not be used in areas subject to explosion hazards.

3 Unit description

3.1 Standards/Approvals

The LEDlight Plus operating light complies with the following standards (the list below is not exhaustive):

- IEC 60601-1 (Electrical and Mechanical Safety)
- IEC 60601-1-2 (Electromagnetic Compatibility)
- ISO 9680:2014 (Operating Light)
- IEC 62471 (Photobiological Safety of Lamps and Lamp Systems)
- ISO 17664 (Sterilization of Medical Products)

CE

LEDlight Plus bears the CE mark in accordance with the provisions of the Regulation (EU) 2017/745 of April 5, 2017 concerning medical devices.

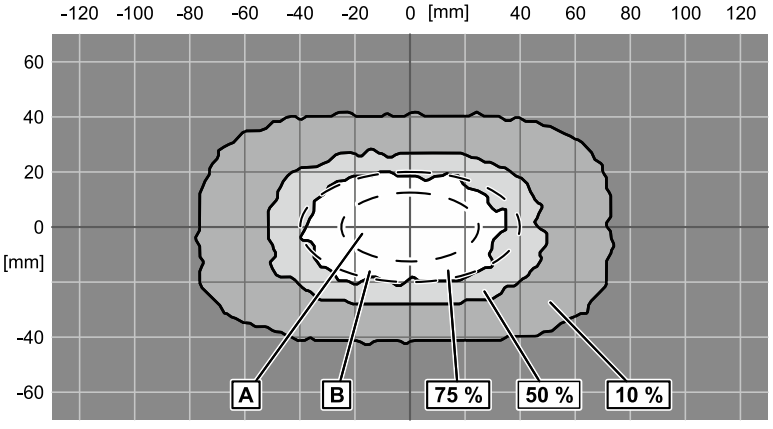
MD

This product is a medical device.

The operating light fulfills the requirements of the Directive on the Restriction of Hazardous Substances, 2011/65/EU.

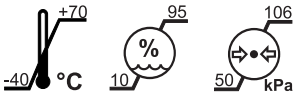
3.2 Technical data

Model designation:	LEDlight Plus
Light source:	6 light-emitting diodes (of those, 4 for normal mode and 2 for composite mode)
Illuminance:	Can be adjusted from 5000 lux to 30000 lux in accordance with ISO 9680
Lighting control:	Electronic, 5-level brightness control via the contactless sensor control, composite mode
Color temperature:	5000 K
Color rendering index (CRI)	Ra > 90
Unit model power connection:	Electrical supply via the treatment center
Overvoltage category:	2 acc. to IEC 60664-1
Power consumption of operating light:	15 W
Light field size:	Approx. 160 mm x 80 mm at distance of 700 mm, measured from the light emission area of the light
Light distribution:	The following image shows the light distribution at 30000 Lux.



Area A: min. 75% illuminance according to ISO 9680 standard
Area B: min. 50% illuminance according to ISO 9680 standard
75% / 50% / 10%: Measured illuminance with the operating light

Protection class:	The unit supplying power corresponds to protection class I
Degree of protection against ingress of water:	Ordinary equipment (IP X0 – without protection against ingress of water)
Operating mode:	Continuous operation

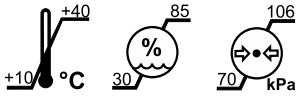


Transport and storage conditions:

Temperature: -40°C – +70°C (-40°F – +158°F)

Relative humidity: 10% – 95%

Air pressure: 50 kPa – 106 kPa



Operating conditions:

Ambient temperature: 10°C – 40°C (50°F – 104°F)

Relative humidity: 30% - 85% no condensation

Air pressure: 70 kPa – 106 kPa

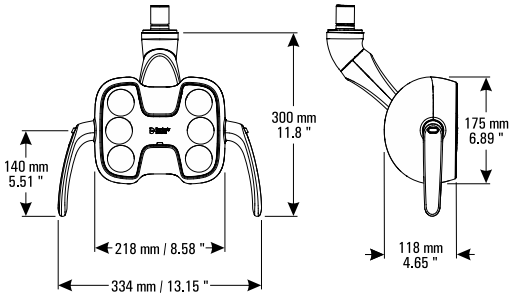
Installation location: ≤3000 m above sea level.

Pollution degree: 2 acc. to IEC 60664-1

Year of manufacture:

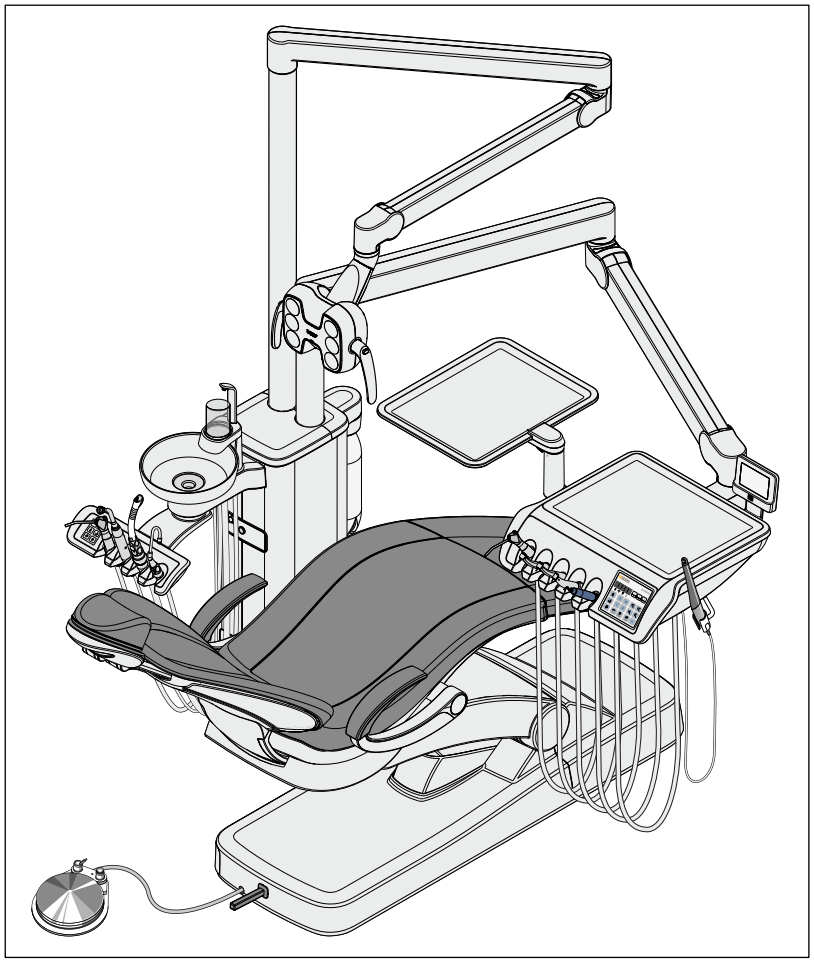
On the type plate of the operating light

Dimensions of light crown in millimeters:

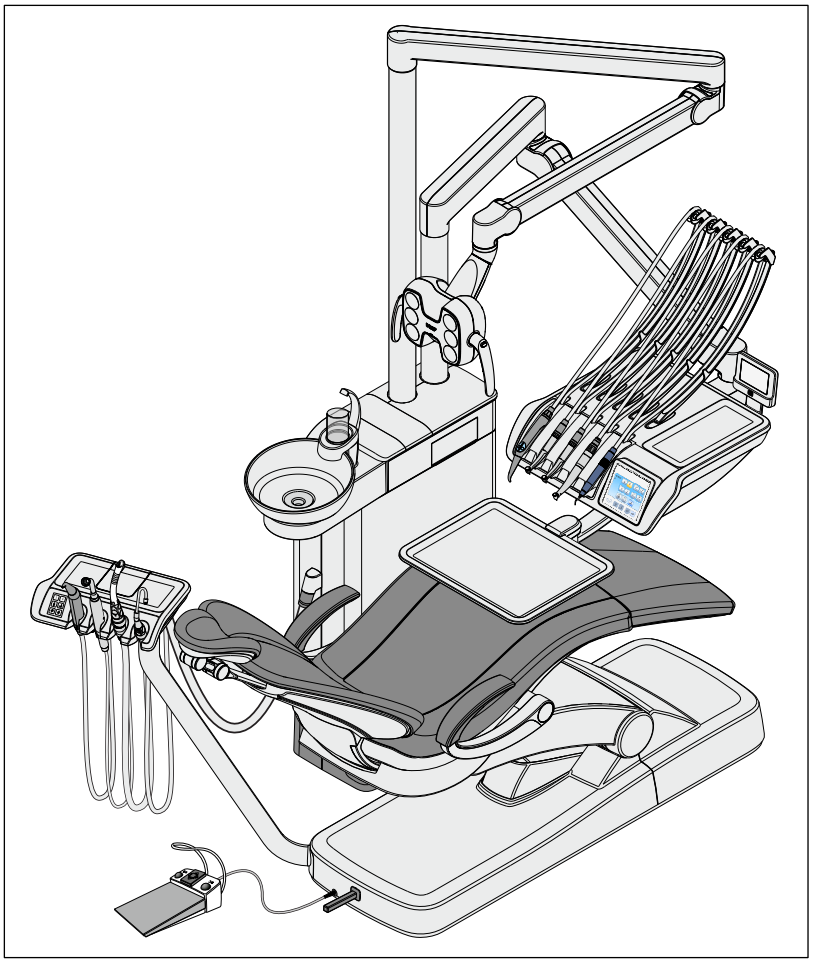


3.3 System overview

The LEDlight Plus is fastened to a height-adjustable support arm system. The LEDlight Plus can be easily adjusted with the handgrips to illuminate the treatment area. Brakes in the support arm hold the LEDlight Plus in the position to which it has been adjusted. The restricted light field illuminates the treatment area without dazzling the patient.



LEDlight Plus on Intego



LEDlight Plus on Intego Pro

4 Operation

4.1 Overview of usage options

The following usage options are available on the LEDlight Plus operating light:

As a unit model on the Intego range:

- Dentist and assistant element
- Contactless sensor

Switching states for operation via the dentist and assistant element

The following switching states can be set in sequence via the dentist and assistant element:

1. Switched on: The operating light is switched on at the preset brightness level.

   In normal mode, the 4 outer light fields of the 6 total light fields light up.
2. Composite function: The operating light switches to composite mode in order to delay the hardening of composite materials.

   In composite mode, the 2 inner light fields of the 6 total light fields light up.
3. Switched off

Switching states for operation via the contactless sensor

The following switching states can be set in sequence via the contactless sensor:

1. Switched on: The operating light is switched on at the preset brightness level.

   In normal mode, the 4 outer light fields of the 6 total light fields light up.
2. Composite function: The operating light switches to composite mode in order to delay the hardening of composite materials.

   In composite mode, the 2 inner light fields of the 6 total light fields light up.
3. Switched off

Mixed operation via the dentist and assistant element and contactless sensor

Mixed operation via the dentist/assistant element and contactless sensor can lead to irregularities in the switching sequence. We therefore recommend opting for one of the operation options.

4.2 Operation via the dentist or assistant element

Press the *Operating light* fixed key on the dentist or assistant element repeatedly to set the switching states “Switched on”, “Composite function” or “Switched off”:

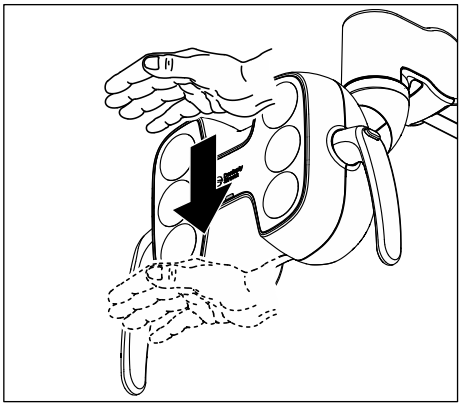
➢ Press the *Operating light* fixed key on the dentist or assistant element (several times if necessary).
  ↳ The examination light switches to "switched on", "composite function" or "switched off".

The brightness level is programmed using the contactless sensor, see below.

4.3 Operation via contactless sensor

The contactless sensor is located underneath the operating light. The switching states and brightness can be set by a manual movement. Operation via the contactless sensor optimally supports hygiene, especially in connection with sterile treatment work.

Switching the operating light to the normal mode



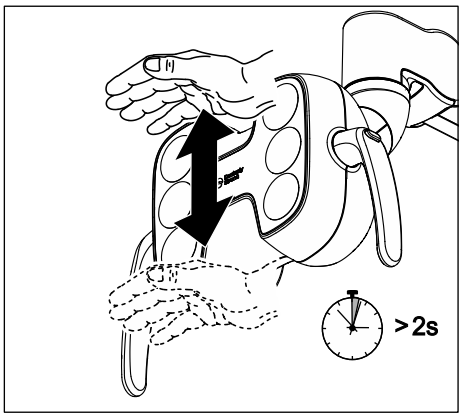
✓ The operating light is switched off.

➢ Move your hand quickly (< 1 s) underneath the contactless sensor.

↳ The operating light switches to the last brightness level to be set in **normal mode**.

Programming the brightness level in normal mode

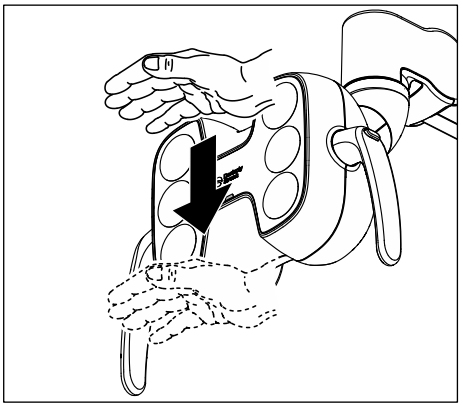
IMPORTANT
The brightness control for the operating light has 5 levels. When the maximum brightness level is reached, the operating light gets progressively darker. When the minimum brightness level is reached, the operating light gets lighter. The light flashes twice to indicate that the maximum or minimum brightness level has been reached.



✓ The operating light is switched on in the Normal mode.

1. Hold your hand underneath the contactless sensor for at least 2s.
   - If the operating light is set at a low brightness level, the brightness gradually increases.
   - If the operating light is set at a high brightness level, the brightness gradually decreases.
2. As soon as you have set the required brightness level, move your hand away from the contactless sensor.
   - The operating light flashes briefly. This indicates that you have left the programming mode.
   - The programmed brightness setting is then saved for normal mode.

Switching the operating light to the composite function



✓ The operating light is switched off.

1. Move your hand quickly (< 1 s) underneath the contactless sensor.
   - The operating light switches to normal mode.
2. Move your hand quickly (< 1 s) again underneath the contactless sensor.

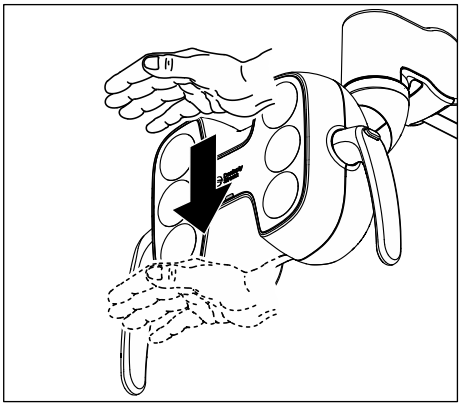
The composite function is set.

✓ The operating light is switched on in the Normal mode.

➢ Move your hand quickly (< 1 s) underneath the contactless sensor.

The composite function is set.

Switching the operating light off



✓ The operating light is switched on in the Normal mode.

1. Move your hand quickly (< 1 s) underneath the contactless sensor.
   - The operating light switches to composite mode.
2. Move your hand quickly (< 1 s) again underneath the contactless sensor.

The operating light is switched off.

✓ The operating light is operated with the **Composite function**.

➢ Move your hand quickly (< 1 s) underneath the contactless sensor.

The operating light is switched off.

4.4 Positioning the light field

The LEDlight Plus enables you to adjust the light field in a way that optimally supports viewing of areas of the mouth which are difficult to access.

Position the light field in such a way that its center is over the patient's mouth.

⚠ CAUTION

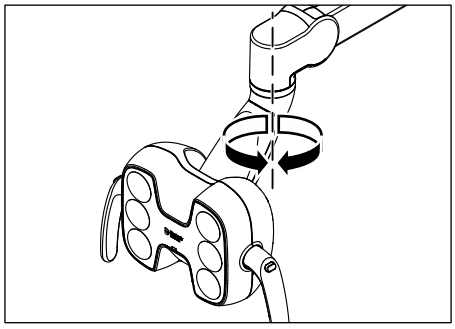
The light field must be readjusted depending on the treatment position.

The patient may be dazzled.

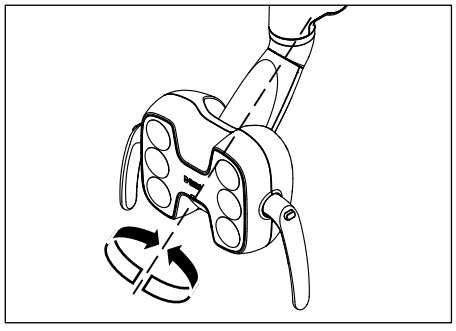
➢ Position the light in such a way that the patient is not dazzled.

IMPORTANT

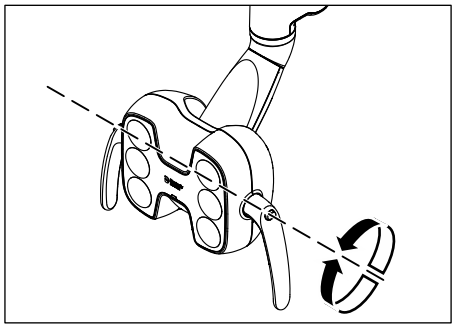
Position the operating light so that the distance between the light emission window and patient mouth is 70 cm. This guarantees optimum illumination and avoids dazzling the patient.



Rotate LEDlight Plus



Incline LEDlight Plus sideways



Tilt LEDlight Plus

5 Care and cleaning instructions for the practice team

5.1 General information

To maintain the value and safe functioning of your operating light, it is necessary to have it cared for, cleaned and disinfected by the practice team regularly. This will minimize the risk of contamination for patients and users and ensure proper functioning.

The national requirements and recommendations for hygiene and disinfection must be observed, e.g. Robert Koch Institute (RKI), American Dental Association (ADA), Centers for Disease Control and Prevention (CDC), etc.

1. Clean and disinfect the lamp components after each patient.
2. Clean/disinfect the parts of the support arm system at least 1x at the end of the practice day.

NOTE

Drugs have a chemical reaction with the surface of the unit.

Due to their high concentrations and the substances they contain, many drugs can dissolve, etch, bleach, or stain surfaces.

➢ Wipe any drug residues off the unit immediately with a moist, white cloth!

5.2 Basics

Reprocessing mainly involves the following steps:

- Preliminary cleaning
- Cleaning
- Disinfection
- Sterilization if possible

The operating light must be reprocessed immediately, or at the latest, one hour after treatment. Preliminary cleaning should be done with disposable/paper towels.

Inappropriate care and cleaning of the device can result in failure or damage. Technical personnel must be trained in the handling of medical devices.

5.3 Care, cleaning agents, and disinfectants

NOTE

Authorized care, cleaning agents, and disinfectants

Use only care, cleaning and disinfecting agents approved by the manufacturer

A continuously updated list of approved agents can be downloaded from the Internet at http://www.sirona.com/manuals. Click on the menu items *"General documents"*, *"All products"* and then open the *"Care, cleaning and disinfection agents"* document (REF 59 70 905).

5.4 General processing instructions

The general processing instructions apply to the operating light unless there are any other additional product-specific processing instructions in these operating instructions. The manufacturer's instructions related to disinfectants must be observed (temperature, concentration, exposure times, etc.).

Manual cleaning

The device can be cleaned manually using a cloth or soft brush. Unless specified otherwise, use drinking water that is warm to the touch to clean surface contamination.

Manual disinfection

The operating light can be wiped with surface disinfectants. Use a soft colorless cloth and approved disinfectant for disinfection. Other disinfection methods such as spray disinfection, immersive bath, etc. cannot be used.

Machine cleaning and disinfection

Thermal disinfection at up to 93°C in accordance with ISO 15883-1/-2 is possible with labeled components. To do so, use cleaning and disinfection device.

Manual drying

No drying is required following wiping with disinfectants since surplus disinfectant evaporates. Surplus water from the cleaning process can be removed with a soft cloth.

Sterilization

Sterilization may be conducted for components that are marked accordingly. Steam sterilizers that fulfill the requirements of EN 13060, class B (e.g., DAC Premium / DAC Professional) are approved.

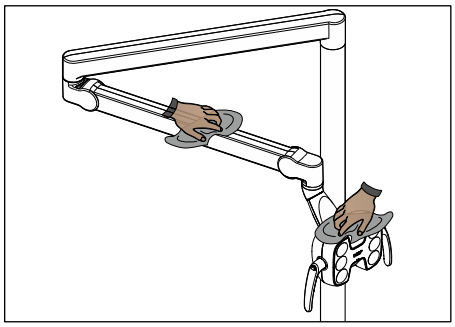
The sterilization must be completed with multiple vacuum fractionation (class B sterilizer). The process parameters can be found in the engraved characters on the relevant components and the instructions for use for these.

During the drying cycle, the sterilized parts must not exceed a temperature of 140 °C (284 °F) during the drying.

5.5 Inspection, maintenance and testing

Unless otherwise specified in this operating manual, test all components for proper functioning on a regular basis and carry out a visual inspection for damage and wear. Exchange damaged components if necessary.

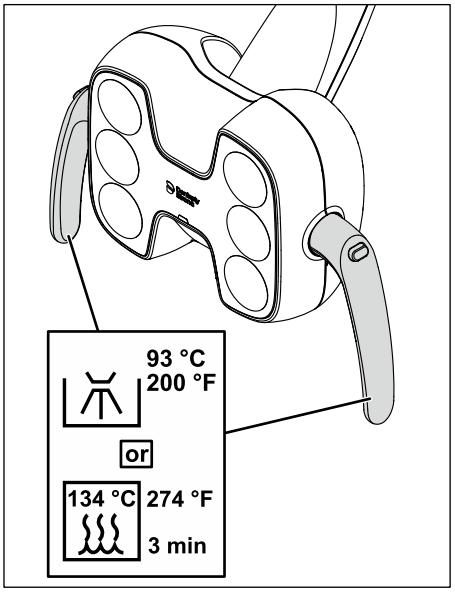
5.6 Cleaning and disinfecting lamp components



Complete a manual clean in order to remove any dirt and disinfectant residue (see "General processing instructions").

The lamp components including the light exit window can be wiped with surface disinfectants approved by the manufacturer.

5.7 Cleaning and disinfecting the handles



The handles for the LEDlight Plus can be wiped with disinfectant, thermally disinfected as well as sterilized. Spare handles can be ordered from a specialized dealer (REF 66 84 372).

⚠ CAUTION

The spare handles are not disinfected or sterilized when delivered.

Complete a thermal disinfection or sterilization before initial use.

For thermal disinfection or sterilization the handles must be removed from the operating light (see “Remove/attach handles” [→ 23].

Clean the handles with neutral standard commercial cleaning agents before processing. Wipe them with disinfectant or thermal disinfect before sterilizing. Package the handles in sterile packaging before sterilizing.

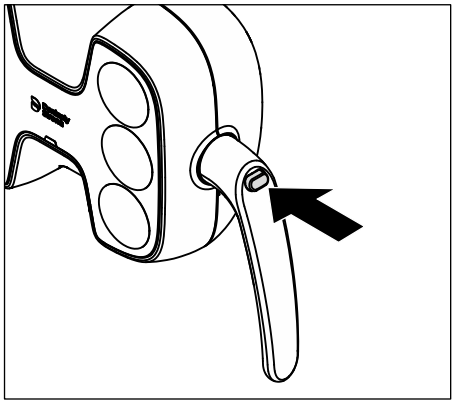
Thermal disinfection or sterilization may result in a slight discoloration of the handles over time. This does not affect their functionality.

Replace the handles after 200 sterilization cycles at the latest or 500 thermal disinfection cycles at the latest.

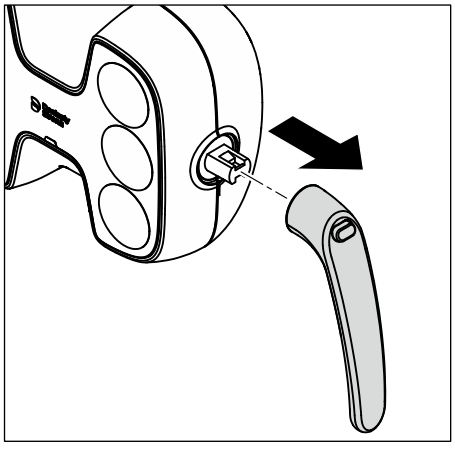
5.8 Remove/attach handles

For thermal disinfection or sterilization the handles must be removed from the operating light.

Remove handles

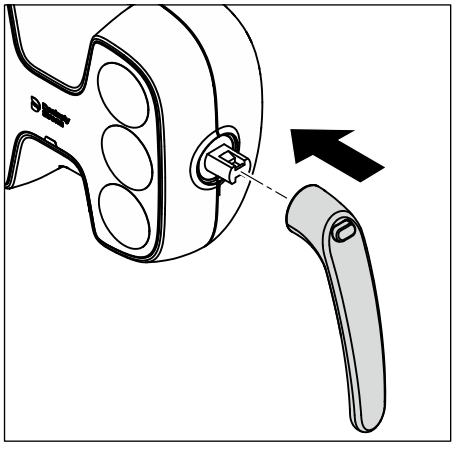


1. Cover the handle with your hand and press on the release button of the handle using your thumb.
   ↳ The handle is released.



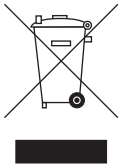
2. Remove the handle to the side.

Attach handle



1. Attach the handle from the side onto the operating light until it audibly latches.
2. Check the handle for firm seating.

6 Disposal



In accordance with Directive 2012/19/EU and national disposal regulations regarding old electrical and electronic devices, please be advised that such items must be disposed of in a special way within the European Union (EU). These regulations require the environmentally friendly recycling/disposal of old electrical and electronic devices. Such items must not be disposed of as domestic refuse. This has been expressed using the icon of the “crossed out trash can”.

Disposal procedure

We feel responsible for our products from the first idea to their disposal. For this reason, we give you an option to return our old electronic and electrical devices.

If you wish to dispose of your devices, please proceed as follows:

In Germany

To initiate return of the electrical device, please send a disposal request to enretec GmbH. You have the following options here:

- Use the ‘Returning an electrical device’ button under the ‘eom’ menu item on the enretec GmbH homepage (www.enretec.de).
- Alternatively, you can also contact enretec GmbH directly.

  enretec GmbH
  Kanalstraße 17
  16727 Velten, Germany

  Phone: +49 3304 3919-500
  E-mail: eom@enretec.de

In accordance with the national disposal regulations regarding old electrical and electronic devices (ElektroG), as the manufacturer, we assume the costs for disposing of the electrical and electronic devices in question. Disassembly, transport and packaging costs shall be borne by the owner / operator.

Prior to disassembly/disposal of the unit, it must be prepared professionally (cleaned/disinfected/sterilized).

If your unit is not permanently installed, it will be collected from the practice. If it is permanently installed, it will be picked up curbside at your address by appointment.

Other countries

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

We reserve the right to make any alterations which may be required due to technical improvements.

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