

Instructions for use **ENG**



CLED11 PPS

Examination light

SYMBOLS

The warning symbols indicate all instructions that are important for safety. Failure to comply with them can lead to injury, damage to the luminaire or the equipment. In combination with the following signal words the warning symbols means:



DANGER
Can lead to death or serious injury
WARNING
Can lead to injury



Comply with operating Instructions



CE conformity mark



Mainswitch: on



Mainswitch: off;



Appliance of protection class II



Storage humidity



Storage temperature



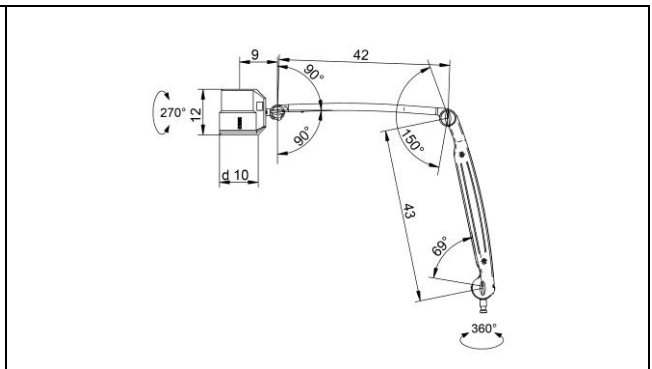
Disposal



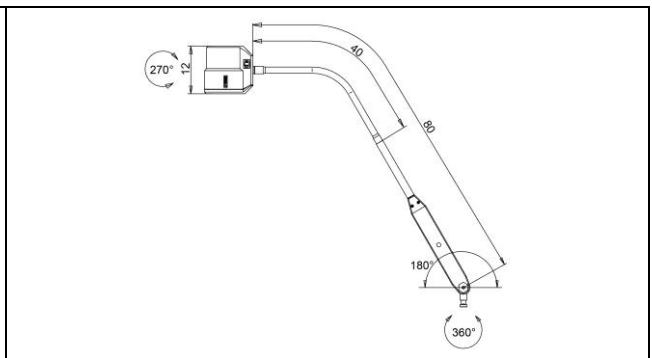
Manufacturer

VARIANTS:

CLED11FX PPS



CLED11SX PPS



CONTENTS

| | | |
|-----|---|---|
| 1 | SAFETY INSTRUCTIONS..... | 3 |
| 1.1 | Intended use | 3 |
| 1.2 | User profiles | 3 |
| 1.3 | Safety instructions | 3 |
| 1.4 | Warning levels..... | 4 |
| 2 | SCOPE OF SUPPLY | 4 |
| 2.1 | CLED11FX PPS..... | 4 |
| 2.2 | CLED11SX PPS..... | 4 |
| 3 | MOUNTING..... | 4 |
| 4 | OPERATION | 4 |
| 5 | DISINFECTION CLEANING..... | 4 |
| 6 | SAFETY INSPECTIONS | 5 |
| 7 | DEMOUNTING | 5 |
| 7.1 | Disposal | 5 |
| 8 | ACCESSORIES..... | 5 |
| 9 | ADDITIONAL INSTRUCTIONS | 5 |
| 10 | TROUBLESHOOTING | 6 |
| 11 | TECHNICAL DATA..... | 6 |
| 12 | ELECTROMAGNETIC COMPATIBILITY (EMC) | 7 |

1 SAFETY INSTRUCTIONS

1.1 Intended use

The luminaire CLED11 is an examination luminaire. Its intended use is to illuminate the body of the patient to support diagnosis or treatment. An interruption of the diagnosis or treatment caused by a light failure is always possible without a risk for the patient. The luminaire can not be used in operating rooms.

1.2 User profiles

Medical professional

A medical professional is any person who has completed medical training and is working in his or her professional field.

Cleaning professional

A cleaning professional is trained in national and job-related hygiene regulations.

Electrician

An electrician is trained in the fields of electronics and electrical engineering and is familiar with the relevant standards and regulations.



Qualified professional

A qualified professional is capable of mounting and dismounting the luminaire thanks to professional training, knowledge and experience and knowledge of the regulations.

1.3 Safety instructions

- ▶ Operation by a medical professional
- ▶ The instructions form part of the product. They must be stored and made accessible to all subsequent users.
- ▶ Any work on the luminaire (including repairs) must be carried out by qualified electricians only. Mounting must be performed by a qualified professional only.
- ▶ The luminaire must not be altered or manipulated in any way. Only approved original parts must be used. Any use other than the intended use with original parts may give rise to other technical values and life-threatening danger.
- ▶ Operation in potentially explosive areas is prohibited. The luminaire power supply is a potential ignition source.
- ▶ The luminaire must only be operated in dry, dust-free rooms.
- ▶ The luminaire must not be left switched on without supervision.
- ▶ Do not use any luminaire that is damaged. Defective cables are also potential hazards. Do not place the cable close to any heat source or on sharp edges.
- ▶ Damage to the eyes. Never look directly into the light source.
- ▶ Replace any glass that is damaged before operating the luminaire again.
- ▶ Never place additional loads on the luminaire head or the arm.
- ▶ The luminaire must not be covered by a cloth or any similar item while it is in operation.
- ▶ The ventilation openings (where they exist) must be free whenever the luminaire is in operation.
- ▶ The luminaire must not be operated near to external heat sources that exceed the maximum ambient temperature of the luminaire.
- ▶ The luminaire must not be used in environmental conditions other than those for which it is intended.
- ▶ The luminaire must only be used for the intended use described in this document.
- ▶ The manufacturer cannot be held responsible for any injury or damage that is caused as a result of any use other than the intended use or of any failure to comply with safety instructions and warnings.
- ▶ It's recommended to protect the luminaire with an additional earth leakage circuit breaker.

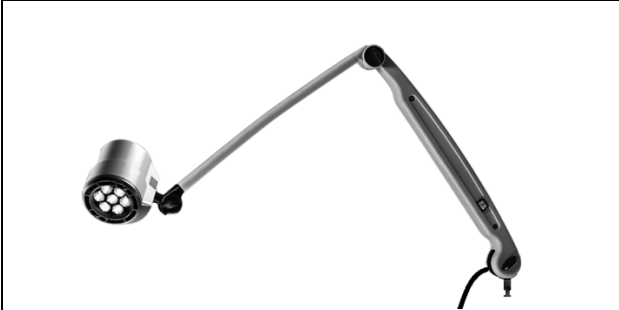
1.4 Warning levels

| |
|--|
|  DANGER |
| Indication of hazards that can lead to death or serious injury if measures are disregarded. |
|  WARNING |
| Indication of hazards that can lead to injury if measures are disregarded. |
| CAUTION |
| Indication of hazards that can lead to damage to property if measures are disregarded. |

2 SCOPE OF SUPPLY

2.1 CLED11FX PPS

The following are included in the scope of supply:



1x Luminaire
1x Power cable

2.2 CLED11SX PPS

The following are included in the scope of supply:





1x Luminaire
1x Power cable

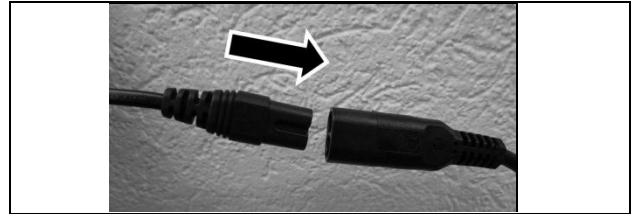
3 MOUNTING

- ▶ The luminaires are equipped with an adapter pin. The luminaire must be positioned in one of the accessories described in chapter 8.

4 OPERATION

| |
|--|
|  DANGER |
| Electric shocks are life-threatening |
| <ul style="list-style-type: none"> ▶ Do not insert any power cable that is damaged. ▶ If there is any sign of damage to the power cable, replace it immediately with a new one. ▶ The supply voltage and frequency must match the data on the type plate. |

| |
|--|
|  WARNING |
| Risk of eye damage |
| ▶ Never look directly into the beam of light |




- ▶ Insert power cable to the luminaire
- ▶ Connect the power cable with the power supply



- ▶ Switch the luminaire on/off

5 DISINFECTION CLEANING

| |
|---|
|  DANGER |
| Electric shocks are life-threatening |
| ▶ Remove the connector from the power supply and put the switch in the "OFF" position before the disinfection cleaning. |

| |
|---|
| CAUTION |
| Damage to property caused by incorrect cleaning |
| <ul style="list-style-type: none"> ▶ No cleaning agents containing alcohol, solvents, chlorine or abrasive products must be used. Those agents can cause damages in the plastic parts. ▶ The cleaning and disinfection agents must be suitable and approved for plastics like PC, PMMA, PA and ABS. ▶ Concentrated disinfectants may damage the cover. ▶ Pay attention to the specifications from the data sheet of the agent for concentration and residence time. ▶ Unsuitable cloths can cause scratches. |

| |
|---|
| NOTE |
| Dirt decreases luminosity |
| <ul style="list-style-type: none"> ▶ Clean regularly to keep the cover clean. ▶ Disinfection only by wiping is permitted. |



- ▶ Clean the PMMA cover with a suitable cleaning cloth and a suitable cleaning agent.

CAUTION

To minimize the risk of disease transmission, in addition to complying with this user manual, you must also comply with the applicable occupational health and safety regulations and the requirements of national bodies with responsibilities for hygiene and disinfection.

6 SAFETY INSPECTIONS

DANGER

Electric shocks are life-threatening

- ▶ Remove the connector from the power supply and put the switch in the "OFF" position.
- ▶ The connector cable must be checked for damage at least once per year.

NOTE

- ▶ Maintenance and repairs must only be carried out by qualified electricians.
- ▶ The corresponding user profile is described in Chapter 1, Safety instructions

7 DEMOUNTING

DANGER

Electric shocks are life-threatening

- ▶ Remove connector from the power supply and put the switch in the "OFF" position before demounting.

7.1 Disposal

Do not dispose the luminaire in household refuse. Dispose the luminaire at a disposal point in accordance with local regulations or take them to a dealer that provides an appropriate disposal service.
Cut off the cable directly on the housing.



The products listed above are more than 95% recyclable. The luminaires have been constructed to be compatible with recycling so that a high proportion of the materials used in these products can be recycled or converted into energy after the end of service life. They contain no materials that are dangerous or that need to be monitored.

8 ACCESSORIES

| Description | Item code |
|--|-------------|
| 16mm MOBILE BASE | HWSCAM14255 |
| COOLVIEW WALL BRACKET ASSEMBLY | CABW14271 |
| Rail Mount Bkt 16mm | CABKTR16 |
| 1 Meter Medirail kit. Boxed with endcaps | CABKTRAIL |
| 16mm Desk Clamp | OABKT16D |

9 ADDITIONAL INSTRUCTIONS

The luminaire itself is maintenance-free.

You can obtain additional documents about this product from the manufacturer upon request.

These luminaires do not affect any other devices.

To save energy, the luminaire should only be switched on when actually needed.

10 TROUBLESHOOTING


| Fault | Possible cause | Troubleshooting | User profiles |
|------------------------------|------------------|--|------------------------------|
| The luminaire does not light | Contact problem | Switch on again | All |
| The luminaire does not light | Lamp defective | Contact manufacturer service | By manufacturer service only |
| The luminaire does not light | No mains voltage | Check mains voltage, check all connections | Electrician |

11 TECHNICAL DATA

| Electrical: | |
|--|---|
| Nominal input voltage | see type label of the luminaire |
| Frequency range | 50/60Hz |
| Power consumption | 13W (18VA) |
| Input current | 0.09A |
| Power factor | 0.72 |
| Lighting data: | |
| Central illuminance E_c at 1.0m (3.28 feet) distance | 40'000 lx * |
| Light field diameter d_{10} at 1.0m (3.28 feet) distance | $\varnothing = 18\text{cm (7.1")}^*$ |
| Light field diameter d_{50} at 1.0m (3.28 feet) distance | $\varnothing = 9\text{cm (3.54")}^*$ |
| Colour temperature | 4400K * |
| Colour rendering index R_a | >93 |
| Colour rendering index R_9 | >90 |
| Total irradiance E_e at maximum intensity | <180 W/m ² |
| | * -10% / +20% tolerance |
| Environmental conditions for transport, storage and operation: | |
| Ambient temperature (storage and transport) | -20°C to +70°C (-4°F to +158°F) |
| Ambient temperature (operation) | +10°C to +35°C (+50°F to +95°F) |
| Relative humidity (non-condensing) | max. 75% |
| Weight: | |
| CLED11FX PPS | 1.4kg (3.09 lb) |
| CLED11SX PPS | 1.4kg (3.09 lb) |
| Operating mode: | |
| Operating mode | Continuous operation |
| Klassifizierung: | |
| CLED11FX / SX PPS | Schutzklasse II |
| Degree of protection as per IEC 529 | IP 20 |
| According to standard 93/42/EWG | Class I |
| Electrical safety test and EMC according to: | EN/IEC 60601-1 EN/IEC 60601-2-41 EN/IEC 60601-1-2 |
| GMDN-Code | 12276 |
| Service life of light source: | |
| Service life LED | 30'000h (L70/B50) |

12 ELECTROMAGNETIC COMPATIBILITY (EMC)

| Electromagnetic emission guidelines | | |
|--|---------------|--|
| The medical device is intended for operation in an electromagnetic environment such as the one specified below. The user must ensure that it is operated in such an environment. | | |
| Emissions | In accordance | Electromagnetic environment |
| High-frequency emissions (CISPR 11) | Group 1 | The medical device uses HF energy exclusively for its internal function. This means that its HF emissions are very low, and it is unlikely that adjacent electronic devices will receive interference. |
| High-frequency emissions (CISPR 11) | Class B | The medical device is intended for use in all facilities, including residential buildings and facilities that are directly connected (without a transformer) to the same low voltage network as residential buildings. |
| Emissions from harmonics (IEC 61000-3-2) | Class A | |
| Emissions from voltage fluctuations/flicker (IEC 61000-3-3) | Compliance | |

| Electromagnetic interference resistance guidelines | | | |
|---|---|---|--|
| The medical device is intended for operation in an electromagnetic environment such as the one specified below. The user must ensure that it is operated in such an environment. | | | |
| Interference resistance to | IEC 60601-1-2 testing level | Conformity level of the medical device | Electromagnetic environment |
| Electrostatic discharge (ESD) (IEC 61000-4-2) | Contact discharge: ± 6 kV Air discharge: ± 8 kV | ± 6 kV ± 8 kV | Floors made of timber, concrete or ceramics tiles are preferred. Where synthetic floor covering is used the relative humidity should be at least 30%. |
| Fast transients/ electrical disturbance variables/ bursts (IEC 61000-4-4) | Power supply cables: ± 2 kV Longer input and output cables: ± 1 kV | ± 2 kV Not applicable | The quality of the mains power supply should match that of a typical business or hospital environment. |
| Surge voltages/surges (IEC 61000-4-5) | ± 1 kV phase-to-phase voltage ± 2 kV phase-to-earth voltage | ± 2 kV ± 1 kV | The quality of the mains power supply should match that of a typical business or hospital environment. |
| Magnetic field in the power supply frequency (50/60 Hz) (IEC 61000-4-8) | 3 A/m | 3 A/m | In proximity of this medical device, do not operate devices with unusually strong network-frequency magnetic fields (transformer stations etc.) . |
| Voltage dips and short interruptions to the power voltage (IEC 61000-4-11) | Cut >95 %, 0.5 periods Cut 60 %, 5 periods Cut 30 %, 25 periods Cut >95 %, 5 seconds | Cut >95 %, 0.5 periods Cut 60 %, 5 periods Cut 30 %, 25 periods Cut >95 %, 5 seconds | The supply voltage quality should be that of a typical business or hospital environment. If the user requires continued function during any interruption of the energy supply system, we recommend that the medical device be powered by an uninterrupted power supply or a battery. |
| Radiated HF disturbance variable (IEC 61000-4-3) | 3 V/m 80 MHz - 2.5 GHz | 3 V/m | Recommended minimum distance of portable and mobile radio devices of PEIRP radiated power to the medical device, including its cables: $d = 1.17\sqrt{P}$ |
| Conducted HF disturbance values (IEC 61000-4-6) | $3 V_{\text{rms-value}}$ 150 kHz - 80 MHz: | $3 V_{\text{rms-value}}$ | Recommended minimum distance of portable and mobile radio devices of PEIRP radiated power to the medical device, including its cables: 80MHz - 800MHz: $d = 1.17\sqrt{P}$ 800MHz - 2.5GHz: $d = 2.33\sqrt{P}$ |
| d = recommended safe distance [m], P = Rated Power of the sender [W]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. | | | |
| Interference may occur in the vicinity of equipment marked with:  | | | |

| Recommended safe distances from portable and mobile HF communications equipment | | |
|---|-------------------|--------------------|
| Rated Power of the sender [W] | 150 kHz - 800 MHz | 800 MHz - 2.5 GHz |
| 0.01 | 0.12 m (0.39 ft) | 0.23 m (0.75 ft) |
| 0.1 | 0.37 m (1.21 ft) | 0.74 m (2.43 ft) |
| 1 | 1.17 m (3.84 ft) | 2.33 m (7.64 ft) |
| 10 | 3.7 m (12.14 ft) | 7.37 m (24.18 ft) |
| 50 | 8.27 m (27.13 ft) | 16.48 m (54.07 ft) |
| 100 | 11.7 m (38.39 ft) | 23.3 m (76.44 ft) |



Brandon Medical Co. Ltd.
Elmfield Road, Morley
Leeds
LS27 0EL

Telephone: +44 (0) 113 27 77393
Fax: +44 (0) 113 27 28844

<http://www.brandon-medical.com>
e-mail: enquiries@brandon-medical.com

