



Installation and Operating Instructions 23 **ENG**



D^{med}® Triango 100

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1 SAFETY INSTRUCTIONS

1.1 Intended use

The Triango lamp 100 is a treatment lamp (small surgical lamp). It is an individual lamp for use in operating rooms that is used near the patient to support diagnosis or treatment, which poses no risk to the patient in the event of any interruption caused by light failure. It is meant for continuous operation and is not intended to be combined with other medical devices.

1.2 User profiles

Health Professional

All individuals who have completed medical training and work in the professional field they trained for.

Cleaning Specialist

Trained in national and workplace connected hygiene regulations.

Qualified Electrician

Trained in the areas of electronics and electrical engineering and knows the relevant standards and regulations.

Qualified Specialist



Qualified due to his technical training, knowledge and experience and knowledge of the rules, to carry out the assembly / demounting.

1.3 Safety instructions

- ▶ Operation by Health Professional
- ▶ The instructions form part of the product and must be stored and made available to all future users.
- ▶ All work on the luminaire (incl. repairs) may only be performed by a qualified electrician. The assembly may only be performed by a qualified specialist.
- ▶ The luminaire may not be altered or manipulated. Only approved genuine parts may be used. Any use other than the one intended with the genuine parts can lead to other technical values and life-threatening hazards.
- ▶ Operation in potentially explosive areas is prohibited. The current supply of the luminaire represents a potential ignition source.
- ▶ The luminaire may only be operated in dry and dust-free rooms.
- ▶ The luminaire should not be on without supervision.
- ▶ In the case of luminaires with protection class I, the protective earth conductor (PE) must be connected to luminaires housing.
- ▶ Do not use a damaged luminaire. Defective cords and a defective ergonomic handle also represent a potential hazard. Do not place a cord near heat sources or sharp edges.
- ▶ This product may emit dangerous radiation. Damage to the eyes: never look directly into the light cone.
- ▶ Replace damaged lenses before operating the luminaire again.
- ▶ Only connect the luminaire to the supply network with a protective earth conductor (PE), to prevent an electrical shock.
- ▶ Do not place extra loads on the luminaire head and the arm system.
- ▶ The luminaire must not be covered with a cloth or similar during operation.
- ▶ The ventilation openings (if available) must always be kept free during 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 outside the specified ambient conditions.
- ▶ The luminaire may only be used for the intended use described here.
- ▶ The manufacturer cannot be held responsible for any damages resulting from use deviating from its intended use, or the failure to observe the safety instructions and warnings.
- ▶ The Triango 100 F must be secured while being transported within the clinic
- ▶ Do not use with medical devices that may react sensitively to a light spectrum within the visible range (such as pulsating light and/or light with a high illumination intensity).
- ▶ When using a number of luminaires at the same time, the total irradiance must not exceed $E_e 1000W/m^2$.
- ▶ Before connecting to the mains power supply, one must check for matching of network data with device data.

1.4 Warning levels

 DANGER
Warning of hazards that can result in death or serious injury if there is a failure to follow the instructions.
 WARNING
Warning of hazards that can result in injury if there is a failure to follow the instructions.
CAUTION
Warning of hazards that can result in material damage if there is a failure to follow the instructions.

1.5 Specific fastening instructions

Triango 100 C

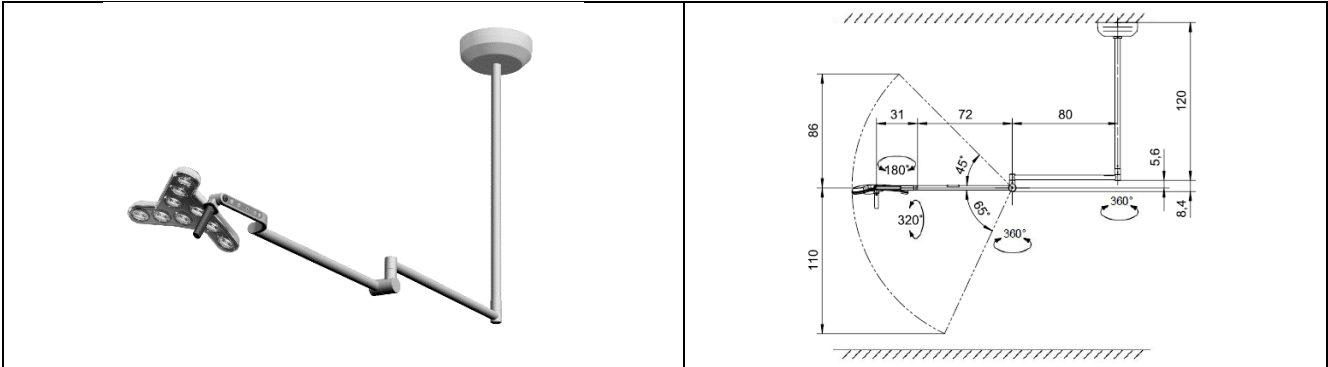
- ▶ **Fastening material is not included with delivery.**
- ▶ The ceiling mounting must only be mounted on ceilings having a concrete stability class B25 (C20/25) or higher.
- ▶ Solid ceiling reinforcement parts must not come into contact with the ceiling mounting. If there is any doubt, an authorized professional must confirm that mounting is possible on the mounting base being used.
- ▶ Borings must be made by specialists in compliance with the boring tolerances for the reinforcement anchor that have been approved by the manufacturer.
- ▶ Screws must be tightened carefully using a torque wrench that complies with the instructions of the mounting element manufacturer.

Triango 100 W

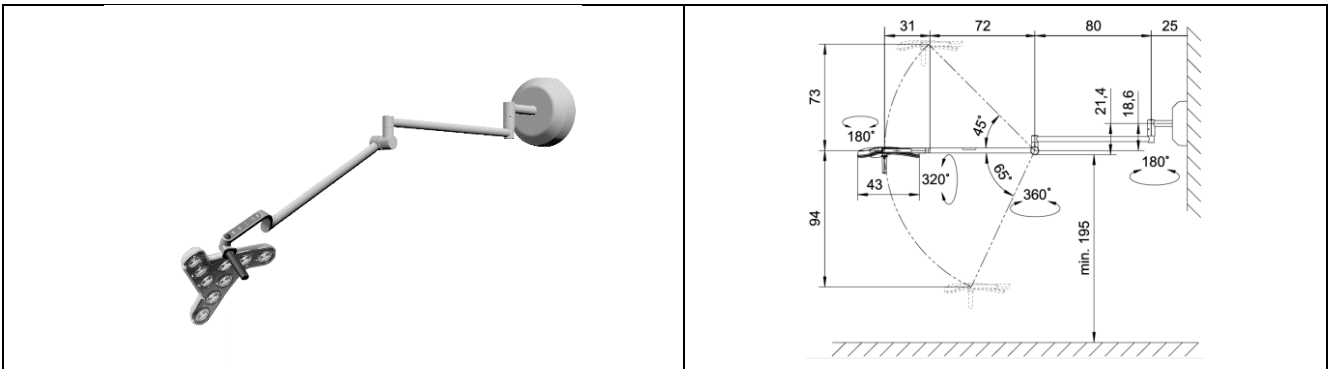
- ▶ **Fastening material is not included with delivery.**
The luminaire must only be mounted on walls that can guarantee a secure hold. Specialist staff will find details of the requirements in Chapter 5.1 (Load data).

2 VERSIONS

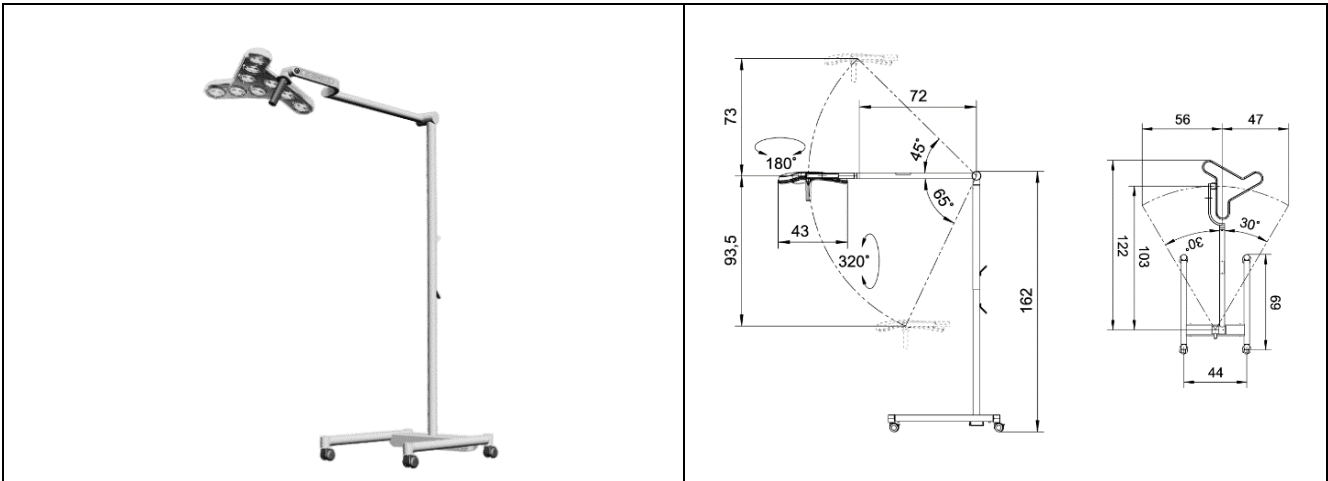
2.1 Triango 100 C



2.2 Triango 100 W



2.3 Triango 100 F

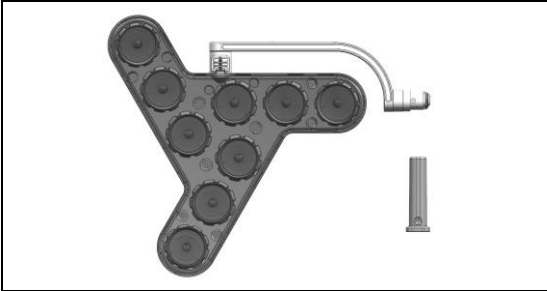


3 SCOPE OF DELIVERY

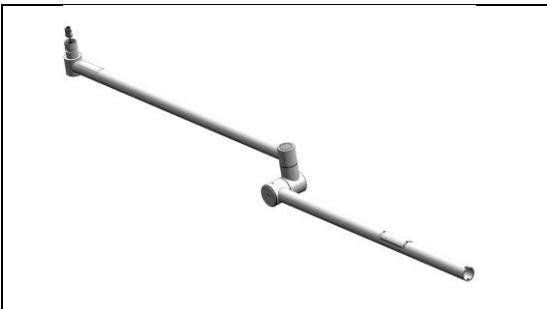
3.1 TRIANGO 100 C

included with delivery:

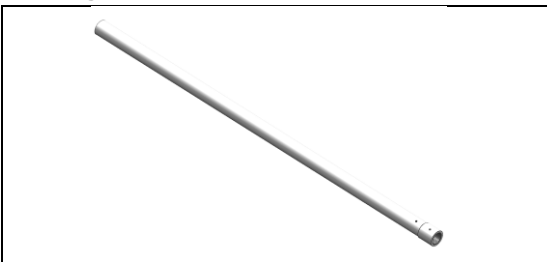
1 luminaire head with sterilizable handgrip



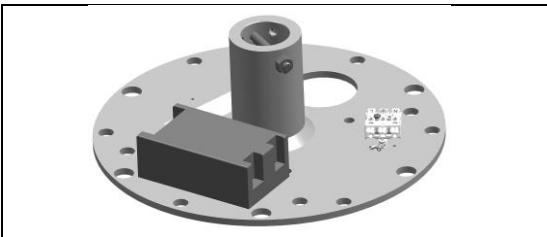
1 ceiling arm



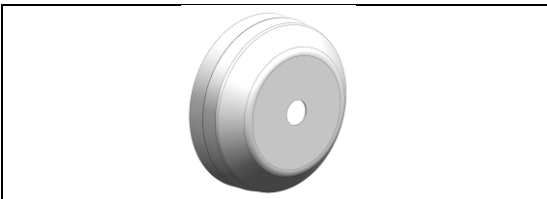
1 ceiling conduit



1 ceiling bracket



1 ceiling cover



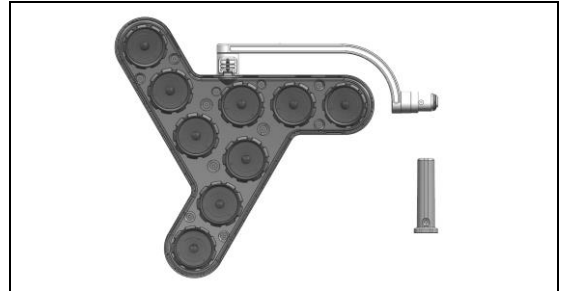
1 end ring



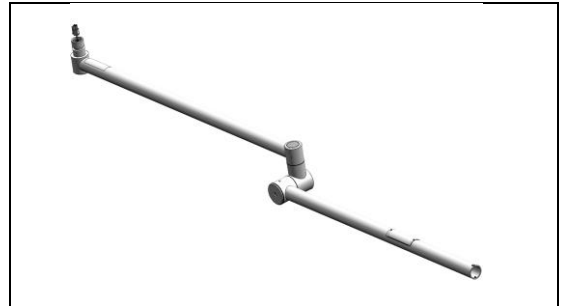
3.2 TRIANGO 100 W

included with delivery:

1 luminaire head with sterilizable handgrip



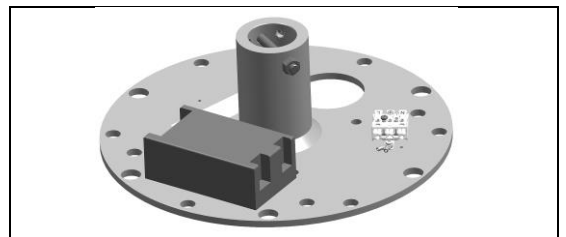
1 arm for wall-mounting



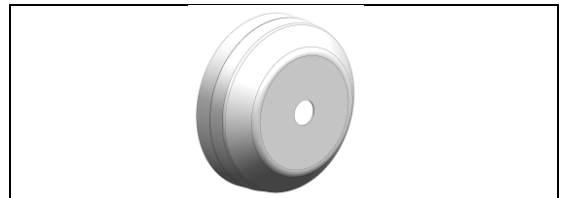
1 wall-mounted joint



1 wall bracket



1 wall cover



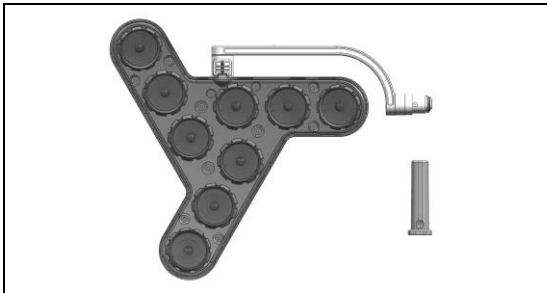
1 end ring



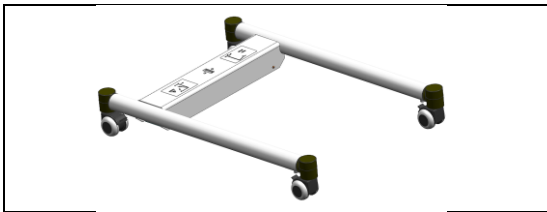
3.3 Triango 100 F

Included with delivery:

1 luminaire head with sterilizable handgrip



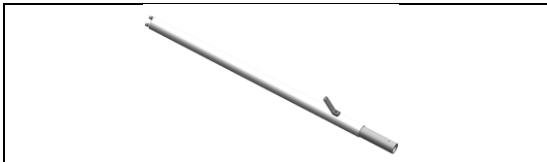
1 roller frame



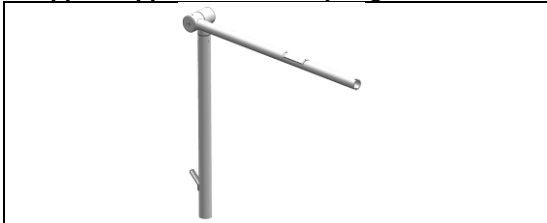
1x power cable



1x lower support tube



1x upper support tube with spring balanced arm



1x set for assembly of triango F



4 MOUNTING Triango 100 C

4.1 Workload data

Bending moment M_B	245 Nm
Vertical weight F_G	160 N

4.2 Attach ceiling bracket

⚠ DANGER

Assembly by qualified personnel

- ▶ Mounting must be done by qualified personnel only. Lack of appropriate knowledge could be life-threatening.

⚠ DANGER

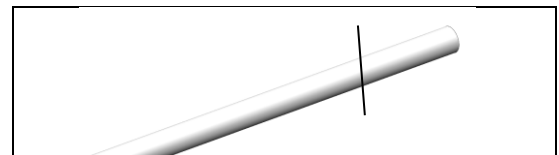
Life-threatening danger from a falling luminaire.

- ▶ The ceiling must be made of solid concrete to guarantee a secure hold.
- ▶ Use a suitable fastening.

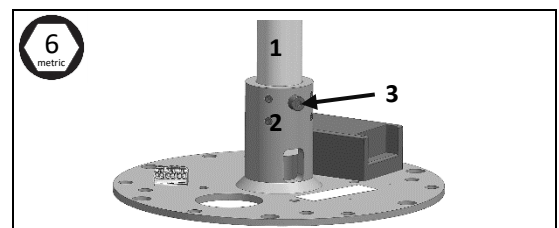
⚠ DANGER

Electric shocks are life-threatening.

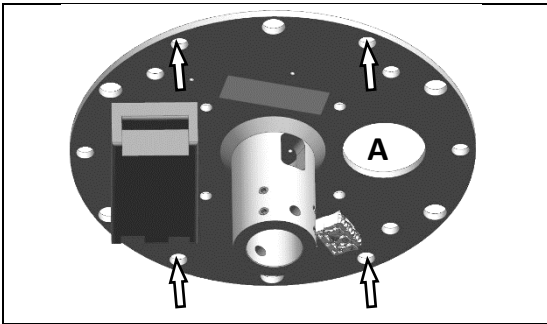
- ▶ All poles of the luminaire must be separated by an external lockable switch from the power supply network.



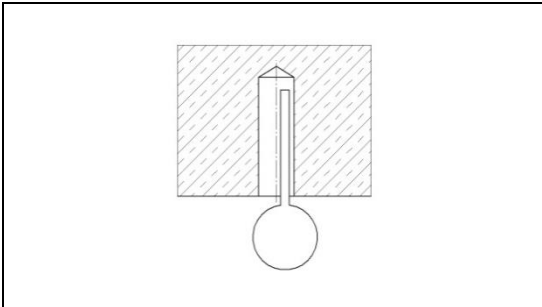
- ▶ Saw the ceiling conduit to the desired length at the top end using a metal saw and deburr.



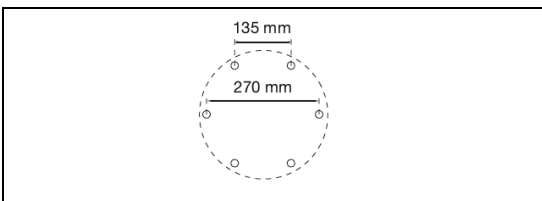
- ▶ Remove fastening screw 3 .
- ▶ Insert ceiling tube 1 into the ceiling bracket 2 and drill with $d=9\text{mm}$. Use the existing hole in the ceiling bracket. Bore the opposite hole separately.
- ▶ Note: pull through the cable after sawing and drilling from the lower side to the upper pipe side (the 3-pin plug first)



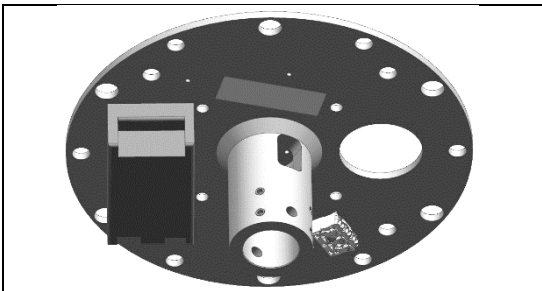
- ▶ Make 4 bore hole markings (10mm dia.); note the position of opening A for the electrical connection



- ▶ Drill holes and blow out with a bellows



- ▶ Check the distances between them



- ▶ Hold the ceiling bracket on the ceiling and hammer in the fastening anchor using a hammer
- ▶ Tighten the fastening using manufacturer instructions

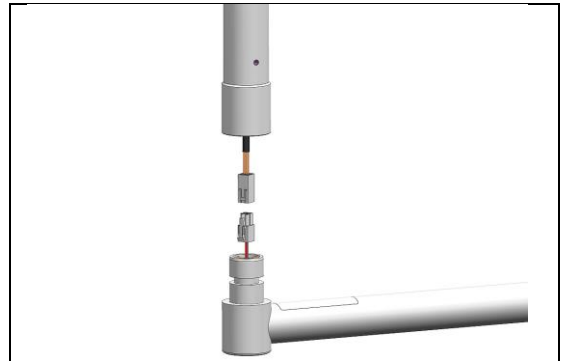
⚠ WARNING

Risk of injury from falling parts.

- ▶ The ceiling bearing must be secured to the fastening material, that must be suitable for the corresponding ceiling condition.
- ▶ Mounting must be performed by two people

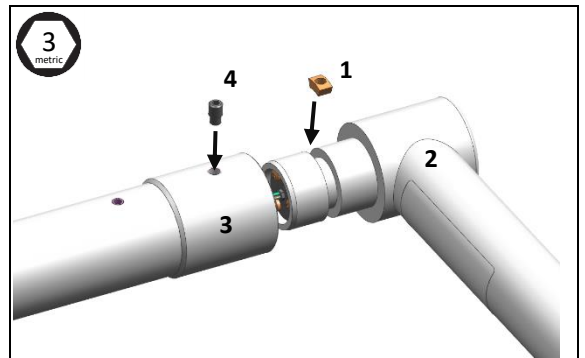
CAUTION

Use protective equipment in line with tool manufacturer's instructions.

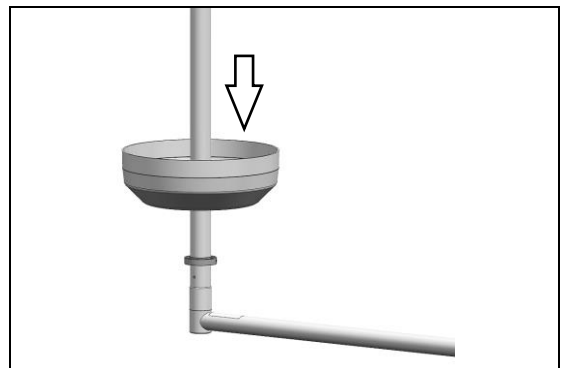


- ▶ Connect the plug from the ceiling tube with plug on the ceiling arm
- ▶ Carefully push protruding cable into the ceiling tube

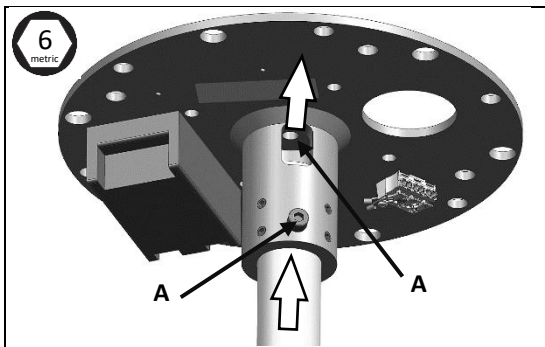
Perform this assembly step on an even surface:



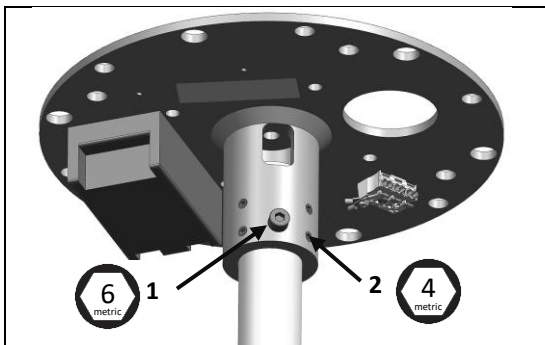
- ▶ Insert the sliding piece 1 above into the ceiling arm groove 2
- ▶ Push the ceiling tube 3 and ceiling arm 2 together
- ▶ Secure the sliding piece 1 by screwing in the threaded stud 4 (up to the stop)
- ▶ Loosen the threaded stud 4 again by a maximum of a ¼ turn and checking the rotating function.



- ▶ Place the end ring and ceiling cover on the ceiling tube.



- ▶ Pull the ceiling tube cable through the opening A of the ceiling holder
- ▶ Insert ceiling tube into the ceiling holder
- ▶ Secure the safety screw 1 and the M8 nut

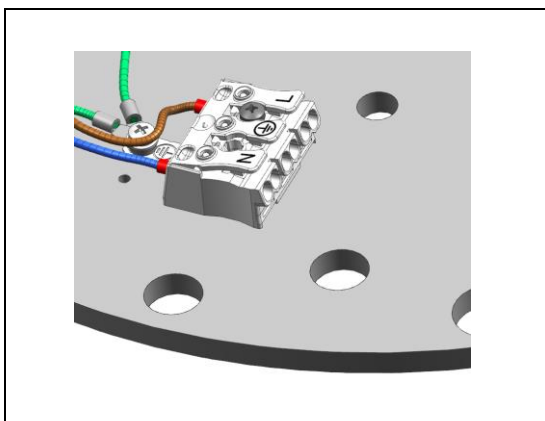


- ▶ Tighten the safety screw 1 and the M8 nut (20 Nm)
- ▶ Tighten all 4 grub screw 2 (5 Nm)

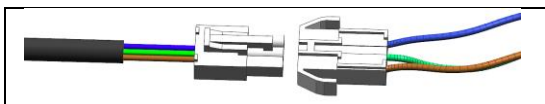
⚠ DANGER

Electric shocks are life-threatening.

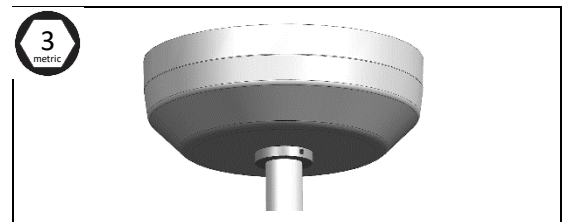
- ▶ Switch off the fuses before working on the power connection
- ▶ This device may only be connected to a mains power supply with a protective earth conductor (PE) to prevent any risk of an electric shock



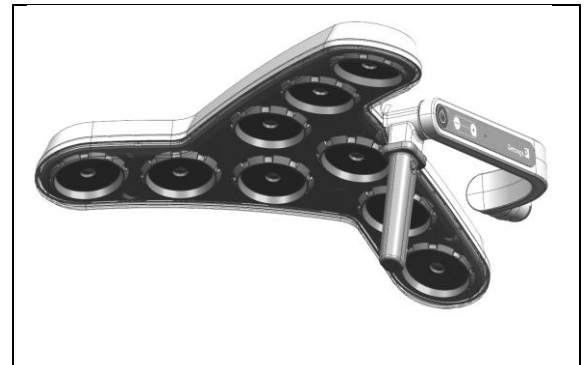
- ▶ Create the power connection



- ▶ Connect the ceiling tube plug with the power supply plug



- ▶ Push cover and retaining ring over the ceiling bearing and tighten them (0.5Nm)



- ▶ Continue with luminaire head assembly, see Chap.7

5 MOUNTING Triango 100 W

5.1 Workload data

Bending moment M_B	275 Nm
Vertical weight F_G	155 N

5.2 Attach ceiling bracket

⚠ DANGER

Assembly by qualified personnel

Mounting must be done by qualified personnel only. Lack of appropriate knowledge could be life-threatening.

⚠ DANGER

Danger to life through electric shock

- ▶ All poles of the luminaire must be separated by an external lockable switch from the power supply network.

CAUTION

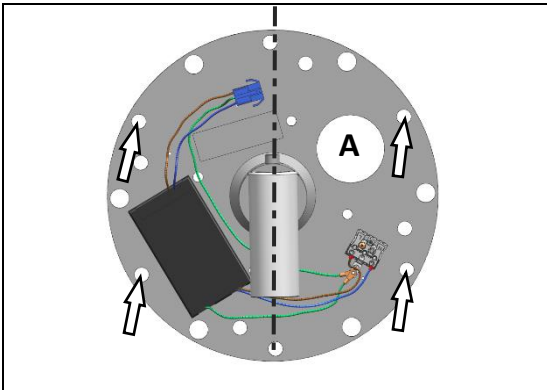
Determine the fastening means to use according to the workload data table

- ▶ Observe the dimensioning of the rod before assembly

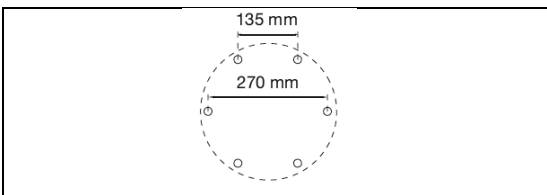
CAUTION

Observe the position of the wall bracket

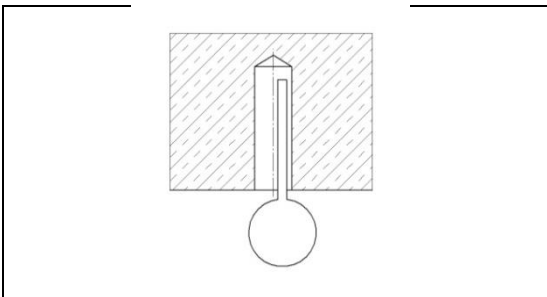
- ▶ Alignment of the wall bracket must be undertaken according to the axis in the picture
- ▶ Failure to comply with correct alignment will compromise mechanical safety
- ▶ We recommend using a counter-plate on lightweight construction walls (not included with delivery).



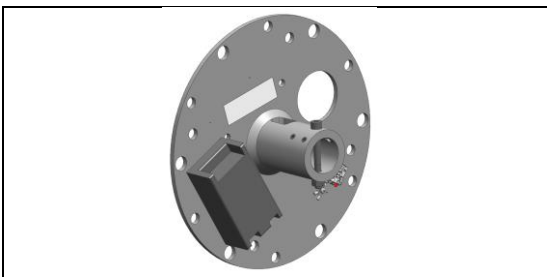
- ▶ Make 4 bore hole markings (10mm dia. min.); consider the position of opening A for the electrical connection



- ▶ Check the distances between them



- ▶ Drill holes and blow out with a bellows

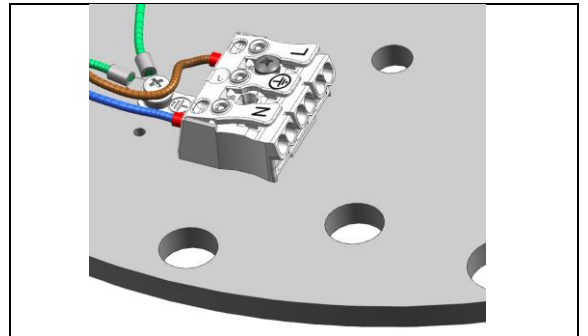


- ▶ Hold the ceiling bracket on the ceiling and hammer in the 4 fastening anchors using a hammer
- ▶ Tighten the fastening using manufacturer instructions

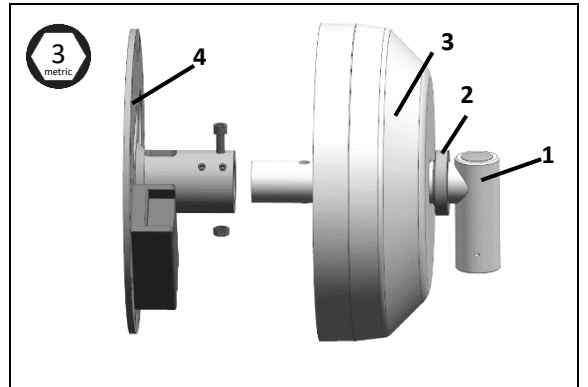
⚠ DANGER

Electric shocks are life-threatening.

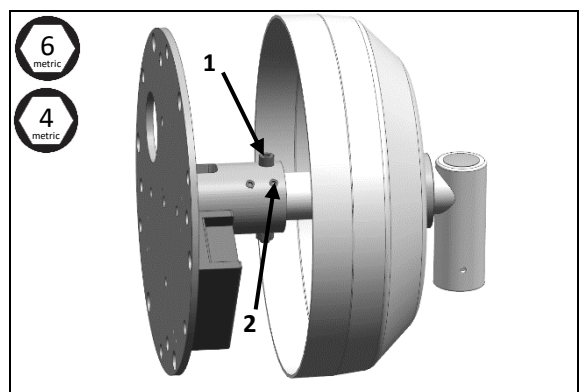
- ▶ Switch off the fuse before working on the power connection
- ▶ This device may only be connected to a mains power supply with a protective earth conductor (PE) to prevent any risk of an electric shock



- ▶ Create the power connection



- ▶ Place wall angle 1 (with end ring 2 and hood 3 in position) in the wall bracket 4 and simultaneously pull plug through the rectangular cutout



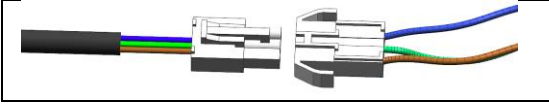
- ▶ Wall angle in vertical alignment, mount with M8 self-locking 1 bolt and nut and tighten slightly

5.3 Mounting the arm for wall-mounting assemble

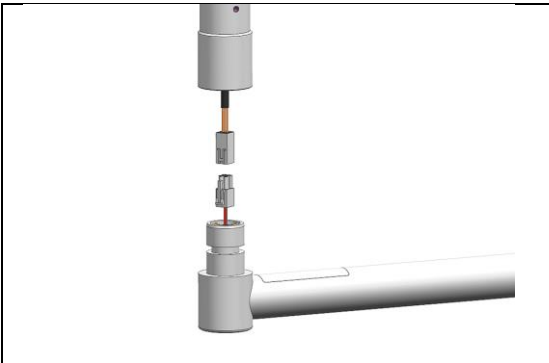
⚠ WARNING

The opening spring balanced arm is an injury hazard

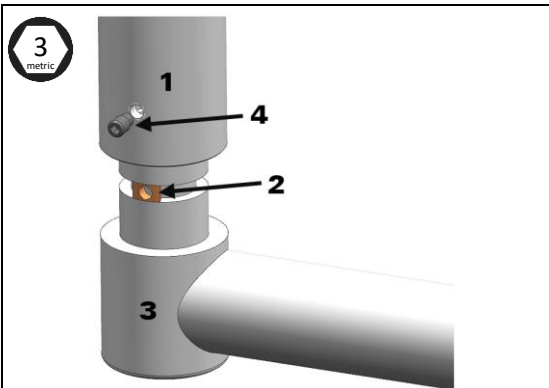
- ▶ Do not remove the transport safeguard until after the luminaire head has been mounted.



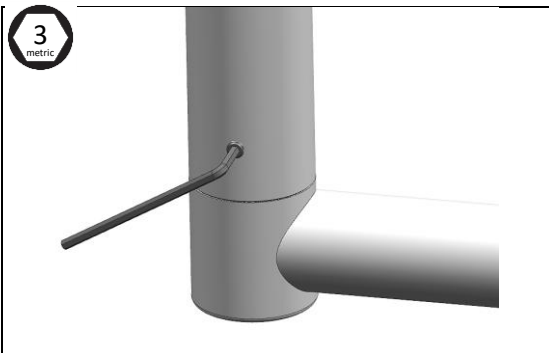
- ▶ Connect the wall-mounted joint plug to the wall bracket plug



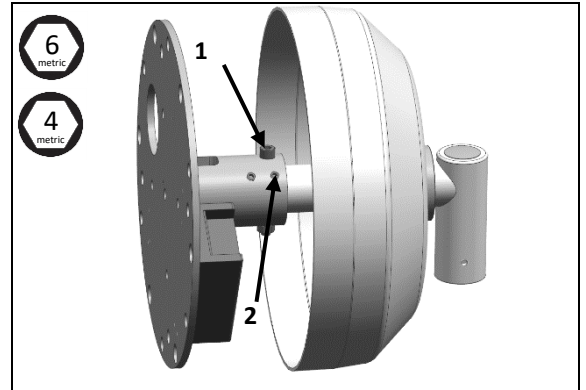
- ▶ Connect the wall arm plug to the wall-mounted joint plug



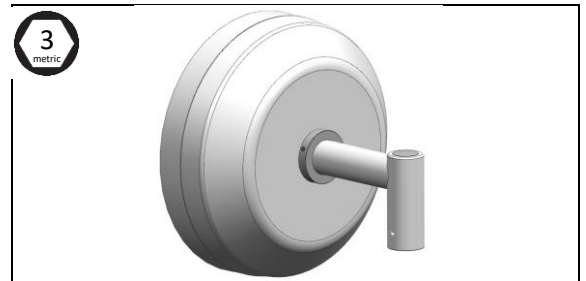
- ▶ Insert the arm for wall-mounting **3** into wall bracket **1** slightly
- ▶ Insert the sliding piece **2** into the groove
- ▶ Push up the arm **3** in such a way that the hole in the wall bracket is aligned with the hole in the sliding piece
- ▶ Screw grub screw **4** into wall bracket



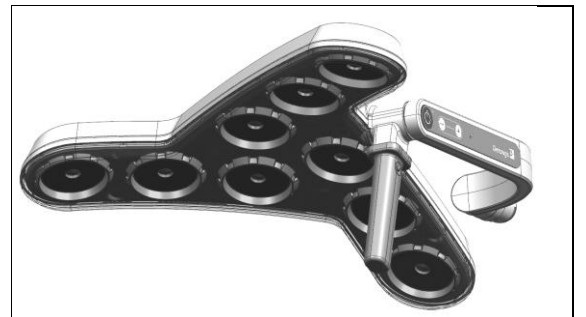
- ▶ In the case of a dead stop, screw this back by a ¼ turn and check the turning function



- ▶ Move out the arm for wall-mounting in all positions and align horizontally. Then tighten the 4 grub screws **2** (5 Nm) as well as the self-locking bolt **1** with M8 nut (20 Nm).

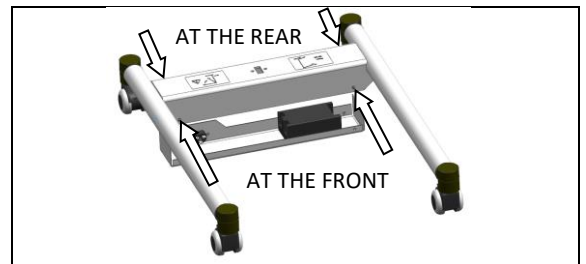


- ▶ Push cover against the wall and tighten firmly with end ring (0.5Nm)

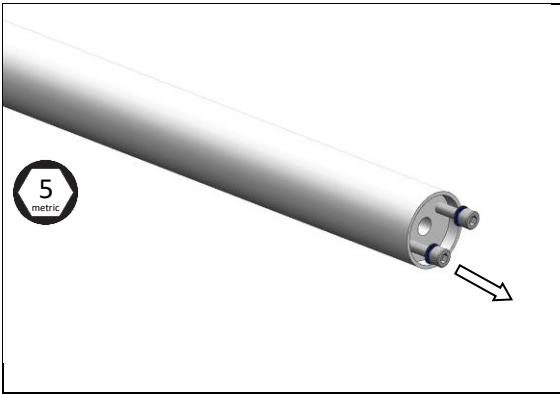


- ▶ Continue with luminaire head assembly, see Chap.7

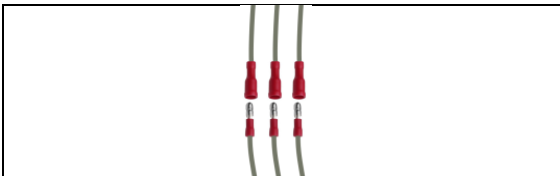
6 MOUNTING Triango 100 F



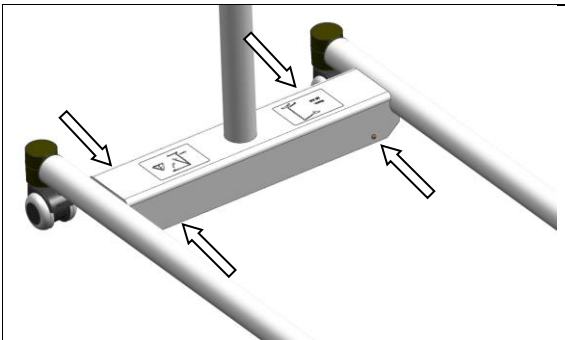
- ▶ Remove the 4 crosstip screws and remove the power supply pan



- ▶ Loosen the 2 Allen screws on the lower support tube
- ▶ Feed the support tube cable through the roll tripod
- ▶ Fasten the support tube to the roll tripod using 2 Allen screws and serrated washers (10 Nm)
- ▶ The cable holder must be aligned at the rear

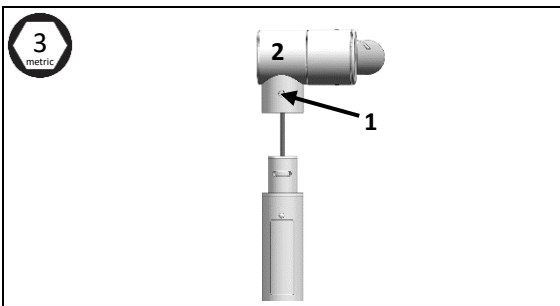


- ▶ Connect the same colored stranded wires on the lower support tube and the power supply

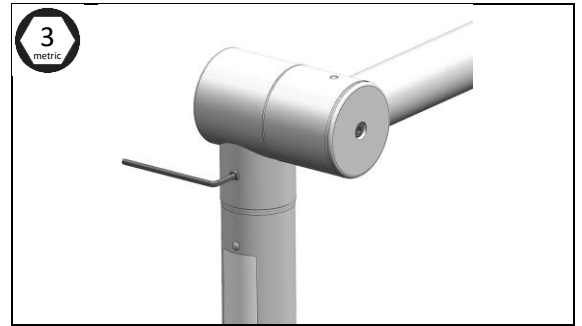


- ▶ Further tighten down the power supply pan with crosstip screws and serrated washers.

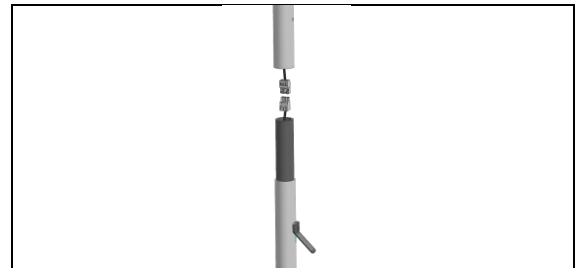
Perform this assembly step on an even surface:



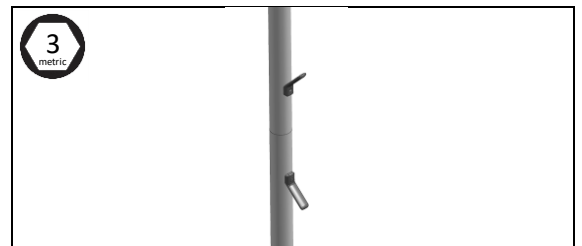
- ▶ Loosen the grub screw 1
- ▶ Place the spring balanced arm 2 on the upper support tube



- ▶ Screw in the grub screw in the alignment shown
- ▶ In the case of a grub screw dead stop, screw this back by a 1/4 turn and check the turning function



- ▶ Push together the plug on the upper and lower support tube until they click
- ▶ Place the upper support tube on the lower one

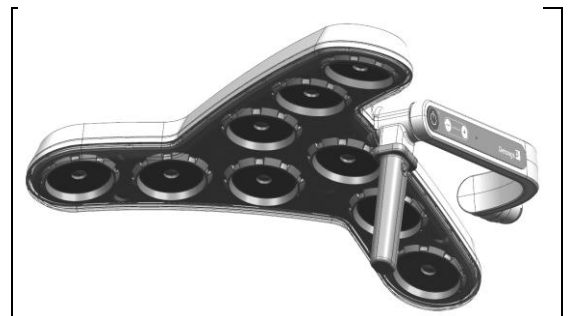


- ▶ Tighten the cable holder using a 3-type Allen screw on the upper support tube (2.4 Nm)

⚠ WARNING

Never unscrew the upper cable holder - risk of injury.

- ▶ If both cable holders are unscrewed, the connecting piece will come loose and falls down, which can lead to personal injury and damage to the cable and device.



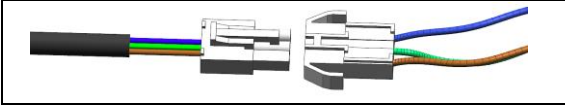
- ▶ Continue with luminaire head assembly, see Chap.7

7 LUMINAIRE HEAD ASSEMBLY

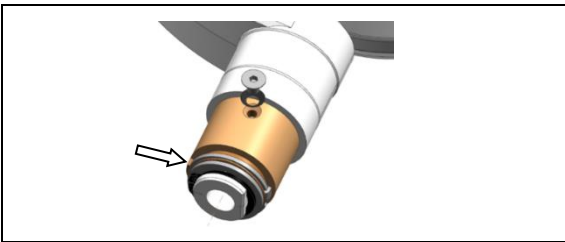
WARNING

Risk of injury from a falling luminaire head

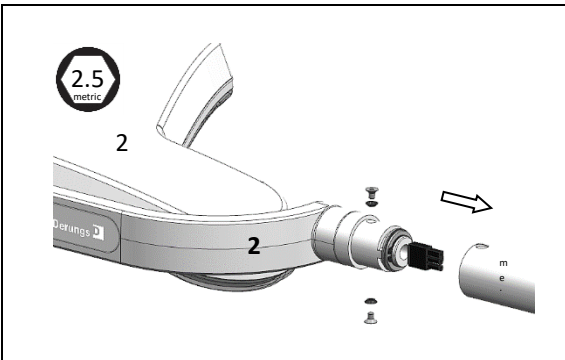
- ▶ Ensure that the luminaire head is secured in an orderly fashion.
- ▶ Damage to due to a poorly mounted luminaire head.



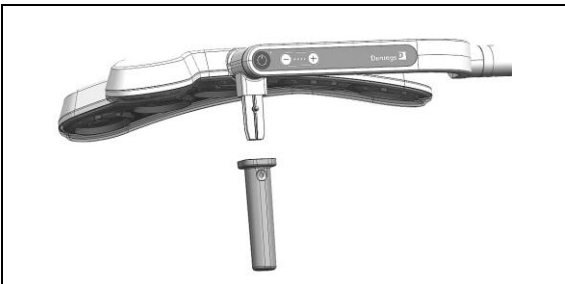
- ▶ Connect the luminaire head plug to the wall-mounted joint plug



- ▶ Before assembly one must ensure that the brass nose (see arrow) and the cardan joint bracket are on the left



- ▶ Push together the luminaire head **1** and arm **3**; in doing so the cardan joint bracket must be on the left **2** of the luminaire head
- ▶ then screw in both countersunk screws M4 (both with a toothed washer) in (1. 5Nm)
- ▶ Check the turning function



- ▶ Plug in the handle

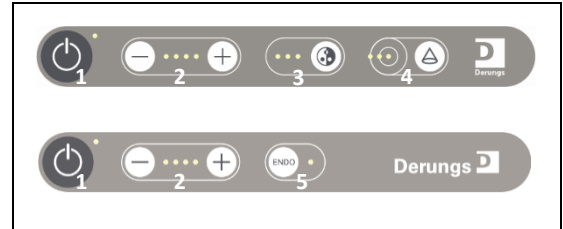
8 OPERATION

WARNING

Warning against damage to eyes

- ▶ Never look directly into the light cone.

Operating function (dependent on the model)



- ▶ Switch the luminaire on or off using the button **1**.
- ▶ The luminaire can be dimmed using the +/- buttons **2**
- ▶ The light color can be adjusted at **3**
- ▶ The focus can be adjusted at **4**
- ▶ The mode of use of the endoscope can be adjusted at **5**
- ▶ Before each use, perform a function test: all LEDs in the light cone must come on.

Triango 100 F

DANGER

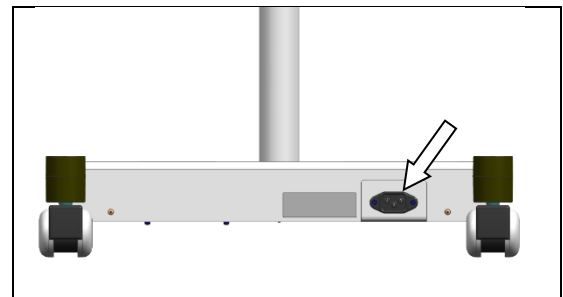
Electric shocks are life-threatening.

- ▶ Do not plug in any damaged power cables.
- ▶ If there are any signs of damage to the power cable, immediately replace it with a new one.
- ▶ Connection voltage and frequency must match data on the type plate.
- ▶ Only connect the luminaire to the supply network with a protective earth conductor (PE).

CAUTION

Triango 100 F

- ▶ Wind the power cable onto the cable holder when not in operation



- ▶ Plug in cable
- ▶ Connect cable to the network

9 CLEANING

DANGER

Danger to life through electric shock

- ▶ Before cleaning: disconnect the power connection from the network

CAUTION

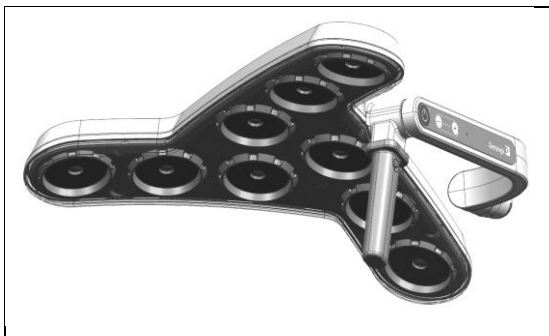
Material damage due to incorrect cleaning

- ▶ For cleaning, only use agents which do not affect functioning of the luminaire.
- ▶ For cleaning, do not use any solvent or chlorine based or abrasive detergents as they can, among other things, result in cracking of plastic parts.
- ▶ The cleaning agents used must be approved for use on plastics such as PC, PMMA, PA and ABS.
- ▶ Damage to the luminaire due to concentrated disinfectant.
- ▶ For concentration and application times, please consult the information provided with the agent used.
- ▶ Use of the wrong cloths can make scratches

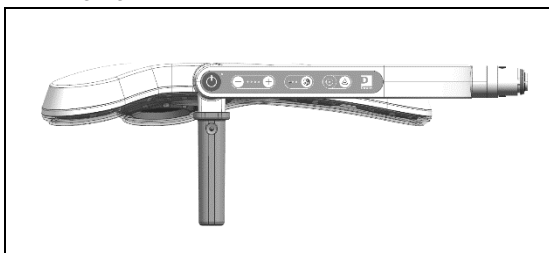
CAUTION

Dirt reduces the luminosity

- ▶ Keep cover clear through regular cleaning.
- ▶ Only wipe cleaning allowed.



- ▶ Clean the PA clear cover using a non-abrasive cleaning cloth and a suitable cleaning agent



- ▶ Wipe cleaning is only allowed in a horizontal position

Recommended cleaning agent

Use a mild soap solution or commercially available detergent as a cleaning agent. Wipe the surfaces

of the devices with a slightly moistened cloth; add a mild soap solution (detergent) if necessary. Finally wipe dry the outer surfaces using a soft, clean cloth.

CAUTION

Clean external luminaire parts using the following prescribed diluted products:

- ▶ Lysoformin®
- ▶ Dismozon®
- ▶ Hexaquant®plus
- ▶ Sagrotan® quick disinfectant cleaner

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.

9.1 Sterilization of the ergonomic handle

- ▶ Sterilization must be carried out in accordance with ISO 17665-1 (Sterilization of health care products in moist heat).

CAUTION

Damage to the hand grip

- ▶ Do not sterilize with hot air

- ▶ Package the hand grip in a sterile bag before sterilization.
- ▶ The hand grip is designed exclusively for damp sterilization with 3 times fractioned pre-vacuum and saturated steam with the following parameters:

Temperature	134°C
Overpressure	2.0 bar
Dwell time	6 min
Vacuum drying	20 min

WARNING

Warning against burns

- ▶ The ergonomic handle must be cooled to room temperature before use.

- ▶ After sterilization check the ergonomic handle for mechanical integrity; do not continue to use damaged ergonomic handles

10 SAFETY INSPECTIONS

DANGER

Electric shocks are life-threatening.

Deenergize the device/pull out the mains plug and secure against being switched on again.

CAUTION

- ▶ Maintenance and repairs can only be performed by qualified electricians.
- ▶ The corresponding user profile is in Section 2 Safety instructions.

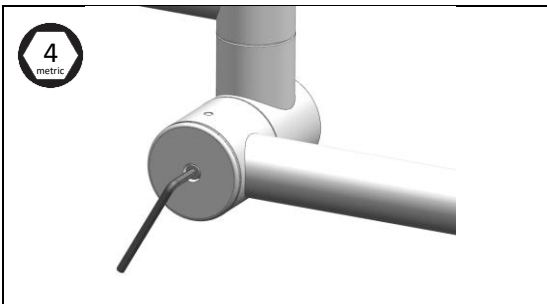
annually:

- Check the power supply cable for damage and replace if necessary
- Check the fastening screw on the underside tripod foot and tighten if necessary.
- Paint damage
- Cracks on plastic parts
- Deformation of the carrier system
- Loosening of parts

10.1 Setting the spring force

CAUTION

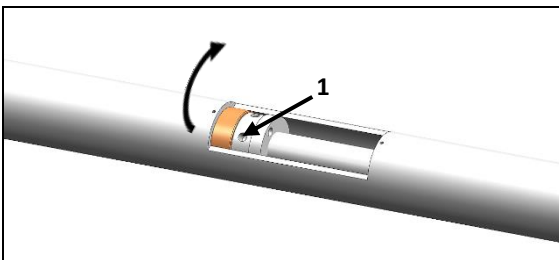
The spring force is set at the optimum setting in the factory.



- ▶ As a first measure slightly tighten the joint cover (by a ¼ turn); this to achieve greater stability of the luminaire head, if necessary

Otherwise:

- ▶ Remove the service cover of the spring balanced arm (loosen the 2 crosstip screws)



- ▶ Place a suitable tool (e.g. a 3-type Allen key) into the hole 1, turn by ¼ turn in the direction of the arrow, a repeat a number of times until the desired stability is reached

- ▶ Screw the service cover on again (attention: do not tighten too strongly)

11 DEMOUNTING

DANGER

Electric shocks are life-threatening.

- ▶ Disconnect the power connection from the network

DANGER

Risk of injury

- ▶ The spring balanced arm is under a high spring force. If the terminal device is not in the uppermost spring balanced arm position, the spring balanced arm will move rapidly upwards and lead to severe injuries. Only disassemble the terminal device when the spring balanced arm is in the uppermost position

11.1 Disposal

Do not place the luminaire in the household waste. Bring the luminaire and lamp, according to local regulations, to a disposal site or give it to a dealer with the appropriate service offering.

Cut the cable directly at the casing.



The products listed above are over 95% recyclable. In order for a high percentage of the used materials to either be physically re-used or used for energy after the end of this product's life cycle, the luminaires have been designed with recycling in mind. They do not contain hazardous or supervision-requiring substances.

12 ACCESSORIES



Ergonomic handle (order no. D10.295.000)



Handle cover (order no. D15.445.000)

13 ADDITIONAL INFORMATION

Additional documents may be requested from the manufacturer for this product.
Using this luminaire does not present a risk to other equipment.
To save energy, the luminaire should only be switched on when it is actually needed.

The expected service life of the luminaire is 10 years.

The radiation emitted by this product represents the exposure limit value for reduction of the risk of photobiological dangers on the basis of IEC 62471.

14 TROUBLESHOOTING

Fault	Possible cause	Troubleshooting	User profile
The luminaire does not light up	Contact fault	Switch on again	All
The luminaire does not light up	Lamp defective	Contact manufacturer's service dept.	Only by manufacturer's service dept.
The luminaire does not light up	No mains voltage	Check voltage, check all connections	Qualified Electrician

15 TECHNICAL DATA

Electrical Data:	
Rated input voltage	100 – 240 VAC
Frequency range	50 / 60 Hz
Power consumption	65 – 80 VA
Input current	320 – 640 mA
Power factor	0.41-0.52
Integral electronic transformer	24 VDC output
Photometric values:	
Central illuminance E_c at 1.0m distance	100'000 lx *
Light field diameter d_{10} at a distance of 1.0 m: Triango 100-1, Triango 100-3, Triango Endo 100-1 Triango Fokus 100-1, Triango Fokus 100-3	dia. = 18 cm * dia. = 18 cm / 23 cm / 28 cm*
Light field diameter d_{50} at a distance of 1.0 m:	dia. = 10.9cm *
Color temperature: Triango 100-1, Triango Fokus 100-1, Triango Endo 100-1 Triango 100-3, Triango Fokus 100-3	4300K * 3700K* / 4300K* / 4700K*
Color rendering Index R_a	95*
Color rendering Index R_9 : Triango 100-1, Triango Fokus 100-1, Triango Endo 100-1 Triango 100-3, Triango Fokus 100-3	90* 95*
Depth of illumination $L_1 + L_2$	100 + 20.5 cm
	* -10% / +20% tolerance
Ambient conditions for transport, storage and operation:	
Ambient temperature (storage and transport)	-20°C to +70°C
Ambient temperature (operation)	10°C to +35°C
rel. air humidity (non-condensing)	max. 75%

Weight:

Luminaire head	2.4 kg
Triango 100 C	15.9 kg
Triango 50 Wall	15.3 kg
Triango 100 F	20.0 kg

Operating mode:

Operating mode	Continuous operation
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Classification:


Triango 100	Protection class I
Degree of protection according to IEC 60529	IP 20
Luminaire head	IP 43 (horizontal position)
Classification according to 93/42 ECC – Annex IX (Medical Device Class)	Class I
U.S. FDA Device Class	Class I
Electrical safety testing and EMC according to:	ANSI/AAMI ES60601-1 CAN/CSA-C22.2 No 60601-1 EN/IEC 60601-1 EN/IEC 60601-2-41 EN/IEC 60601-1-2
Blue light danger according to EN/IEC 62471	RG 1 (low risk)

Life cycle of the light source:

Life cycle	50,000 h (L70/B50)
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16 ELECTROMAGNETIC COMPATIBILITY (EMC)

Guidelines - Electromagnetic disturbance emissions		
The medical device is intended for operation in an electromagnetic environment such as described below. The user must ensure that it is operated in such an environment.		
Emissions	Compliance according to	Electromagnetic environment
RF emissions (CISPR 11)	Group 1	The medical device uses RF energy only for its internal function. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be affected.
RF emissions (CISPR 11)	Class A	The health care product is designed for use in non-residential homes and those that are connected directly to a public low voltage distribution systems that also supplies the home.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations / flicker emissions (IEC 61000-3-3)	Compliant	

Guidelines - Electromagnetic immunity			
The medical device is intended for operation in an electromagnetic environment such as described below. The user must ensure that it is operated in such an environment.			
Immunity against	IEC 60601-1-2 test level	Conformance level of the medical device	Electromagnetic environment
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ± 8 kV Air discharge: ± 15 kV	± 8 kV ± 15 kV	Floors are preferably made of wood, concrete or ceramic tiles. In the case of synthetic floor covering, the relative humidity should be at least 30%.
Rapid transient electrical disturbances: Bursts (IEC 61000-4-4)	Power cables: ± 2 kV Longer input and output power cables: ± 1 kV	± 2 kV Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Impulse voltage/surges (IEC 61000-4-5)	± 1 kV voltage outer conductor - outer conductor ± 2 kV voltage outer conductor - earth	± 1 kV n/a	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Magnetic field at the supply frequency (50/60 Hz) (IEC 61000-4-8)	30 A/m	30 A/m	Devices with strong line-frequency magnetic fields (transformer stations, etc.) should not be operated in the vicinity of the medical device.
Voltage dips and interruptions in the power supply (IEC 61000-4-11)	<5% Vt (>95% dip in Vt) 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° <5% Vt (>95% dip in Vt) 1 cycle at 0° 40%Vt (60% dip in Vt) for 5 cycles 70% Vt(30% dip in Vt) for 25/30 cycles (50 Hz/60 Hz) at 0° <5% Vt (>95% dip in Vt) dropout 250/300 cycles 50 Hz, 60 Hz		The quality of the supply voltage should correspond to that of a business or hospital environment. If the user requires continued functioning during interruptions in the power supply, we recommend powering the medical device from an uninterruptible power supply or a battery.
Emitted RF disturbance (IEC 61000-4-3)	80 MHz up to 2.5 GHz: 10 V/m	10 V/m	Recommended separation distance from portable and mobile RF devices in transmission power PEIRP of the medical device including its cords: $d = 0.35\sqrt{P}$
Conducted RF interference (IEC 61000-4-6)	150 kHz up to 80 MHz: 3 V	3 V	Recommended separation distance from portable and mobile RF devices in transmission power PEIRP of the medical device including its cords: 80 MHz – 800 MHz: $d = 1.2\sqrt{P}$ 800 MHz - 2.5 GHz: $d = 2.3\sqrt{P}$
d = recommended separation distance [m], P = nominal power of transmitter [W]. The field strength of stationary radio transmitters should be for all frequencies, according to an on-site examination, less than the compliance level. Faults are possible in the area around devices which are marked with the following pictogram: 			

Recommended safety distances to portable and mobile RF communications equipment		
Power of transmitter [W]	150 kHz - 800 MHz	800 MHz - 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12 m (0.39 ft)	0.23 m (0.76 ft)
0.1	0.38 m (1.25 ft)	0.73 m (2.4 ft)
1	1.2 m (3.9 ft)	2.3 m (7.6 ft)
10	3.8 m (12.5 ft)	7.3 m (23.9 ft)
100	12m (39 ft)	23 m (76 ft)