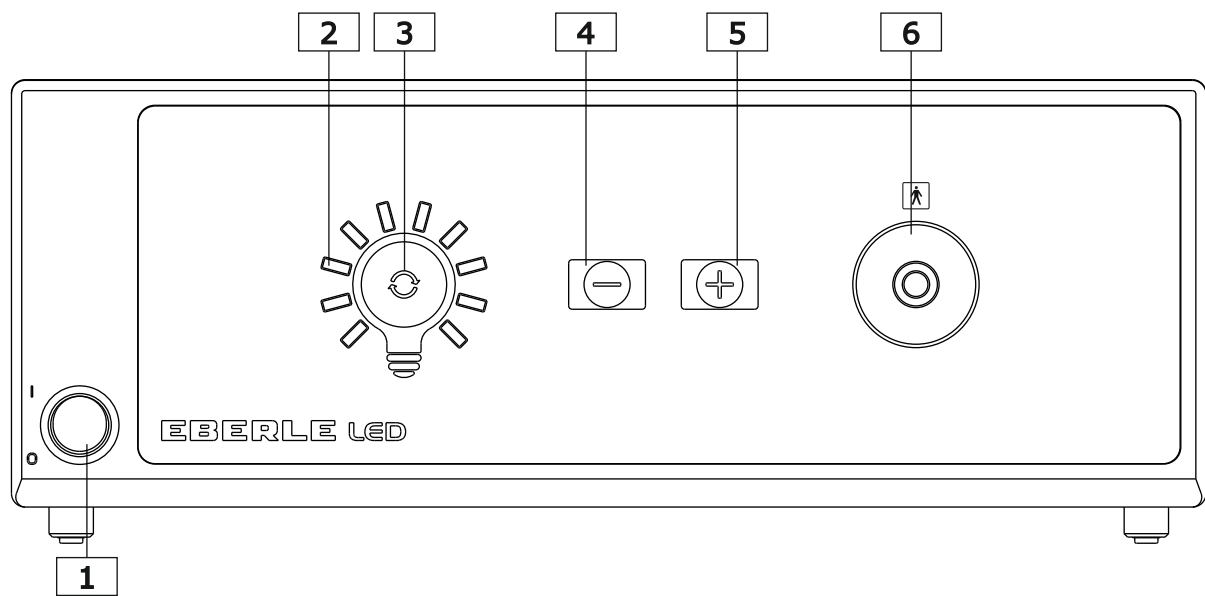
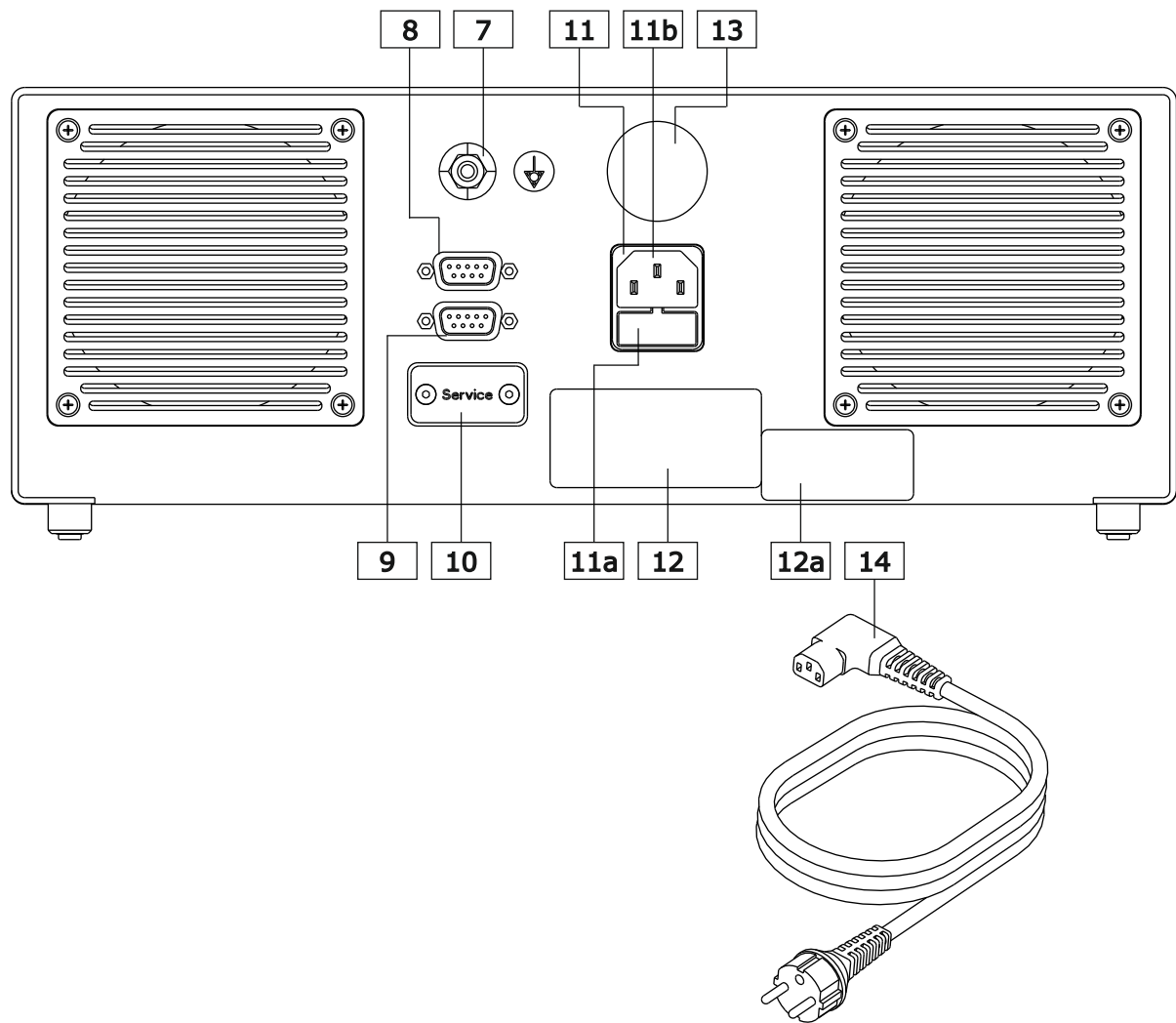






- | | |
|---|---------------------------------------|
| 1 | Power switch |
| 2 | Display illuminance (10% steps) |
| 3 | Display service life of LED exceeded |
| 4 | Key to decrease illuminance |
| 5 | Key to increase illuminance |
| 6 | Connection for light conducting cable |



7	Equipotential bonding
8	ECB (external communication)
9	ECB (external communication)
10	Service port
11	Power connector
11a	Mains fuse box with fuse holder
11b	Connector for power plug
12	Type plate
12a	Type plate
13	Certification label
14	Mains power cable

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1. General Information, Description, and Field of Application

The EBERLE light source LED was developed for use in the field of endoscopy / laparoscopy. It serves as endoscopic illumination during clinical diagnostics or surgical procedures.



The light source LED shall only be used by skilled and trained expert staff, while permanently monitoring the user's application, in the designated medical facilities!

The EBERLE light source LED is attached to a rigid and flexible endoscope or microscope using a light conducting cable. It may not be used in any other way! Operators that do not possess according training and qualification for laparoscopic surgery may not use the system.

Please read these operating instructions carefully before using the light source for the first time. They contain all necessary information to ensure correct connection and operation of the device. In addition, the required safety and cleaning instructions are mentioned and explained.

Keep these operating instructions in a safe and easily accessible place for future reference.



Applying or operating the device in non-conformance to these operating instructions can injure the patient and/or the operator and can damage the light source!

We thank you for your confidence and wish you much success with the EBERLE light source LED!

2. Scope of Delivery

After delivery of the light source, at first the packaging should be checked for external damage.

The following parts are included in the delivery of the light source LED (art. no. 913030):

- | | | |
|---|---|--------------------|
| 1 | Light source LED | article no. 913030 |
| 1 | Mains power cable 1.8m [14] | article no. 913035 |
| | Operating instructions light source LED | |

Should one or several components be damaged or found to be missing, please immediately contact an EBERLE representative or an authorized service or distribution centre.

3. Symbol definitions

	Triangular icons advise the user to important information that must be observed.
	Circular icons with a diagonal bar indicate actions that are prohibited.
	This symbol alerts the user to an information that must be observed. Failure to observe this information can result in patient or user injury and / or damage the unit.
	This symbol alerts the user that the instructions for use must be followed.
	This symbol alerts the user to follow the operating instructions.
	This symbol on the packaging, instruction manuals, and / or the device indicates that this product shall not be treated as consumer waste. The correct disposal will help to prevent health or environmental impacts.
	This symbol indicates a device with one or more applied parts of Type BF
	This symbol on the packaging indicates the upper and lower storage temperature for the device.
	This symbol on the packaging indicates the upper and lower humidity limits for the device.
	This circular symbol indicates that products with damaged packaging must not be used.
	This symbol in conjunction with a date e.g. 2007-06, shows the usability of the product until the specified date.
	This symbol identifies products that have been sterilized in the final packaging and additional the sterilization process, in the illustrated case, the sterilization with ethylene oxide.
	This circular symbol identifies products that are approved for single use only and may not be reused.

3.1 Safety Instructions and Warnings

	Applying or operating the light source not in accordance with these operating instructions can result in the patient and / or the operator being injured and in components of the light source being damaged!
	Electrical medical devices and appliances underlie special requirements, need special measures pertaining to the electrical safety and electromagnetic interferences / environment. The installation of premises and devices must correspond to the requirements of the applying standards and to the applicable national regulations (also refer to chapter 10)! The light source is only reliably grounded, if the control unit is connected to a CEE 7/4 Schuko socket. Routinely check the plug and the cable and do not use in case of damage! The light source may only be switched on, once all connecting cables have been completely connected. Prior to every application, check the light source and with regard to damages and operational capability! The light conducting cable connections and the endoscope tip can warm up during operation. Do not place these on the patient and avoid direct contact, danger of burns! The light source has a Storz adaptation – only light guide cables with this adaptation are permitted. If HF surgery is used, the “applied part” of the shaver system is to be removed from the patient. Mobile HF communication devices such as GSM telephones can also influence electrical medical devices! Do not operate these devices near electrical medical devices and keep them a distance of at least 30cm away! Applying HF surgery in the direct vicinity of the device may result in interferences! Place the light source out of the reach of the patient on a secure base. For the operation, please observe the permissible environmental conditions!
	Do not operate the light source in an area exposed to explosion hazards. When using ignitable anaesthetic gases in the close vicinity of the light source there is a risk of explosion.
	The device must be disconnected from the mains for all maintenance, cleaning and disinfection work. The outer surfaces of the light source can be cleaned and disinfected with a disinfectant or cleaning agent. Make sure that no fluid penetrates into the device! Always observe the manufacturer's specifications when applying and reconditioning applied parts and accessories!
	Do not open the device! Risk of electric shock! Arbitrary opening, repairing or modifying of the device absolves us from any liability regarding the operational safety of the system and leads to expiry of any claims whatsoever during the period of warranty!
	Using incompatible third-party components and cables may result in the patient and/or the operator being endangered or injured and may influence the service capability of the light source pertaining to electromagnetic interferences!

	Ensure sufficient aeration at the ventilation inlets and outlets at the back of the device. Insufficient ventilation leads to damage or malfunction of the device!
	Always observe the manufacturer's specifications when applying and reconditioning applied parts and accessories!
	The light source serves to illuminate the surgical area. The device does not have any significant performance features as defined by the standard aside from the clinical functions described. In case of faults, operate the light source separated from possibly disturbing sources. In the event the light source malfunctions (e.g. due to excess voltage), please have a replacement unit in store!
	Avoid using the light source in the immediate vicinity of other devices or stacked together with other devices, this may result in malfunctioning. If no other type of assembly is possible, the devices need to be monitored and proper functioning must be checked.
	The operating time of the light source should correspond to the usual application cycle.
	Avoid direct visual contact with the LED light at the light guide outlet.
	The application parts connected to the light source must correspond to type BF or CF.
	In order to avoid damage to the light exit of the cable or light entry of the endoscope due to reflections or excessive heating, only light guide cables with a cross-section matched to the light entry diameter of the endoscope may be used.

4. Connection and Start-Up of Device

All components should again be visually checked for any signs of damage before connecting and starting the device.

	A damaged packaging can lead to unsterile or damaged parts. Damaged parts and parts from damaged sterile packaging must not be used and replaced immediately!
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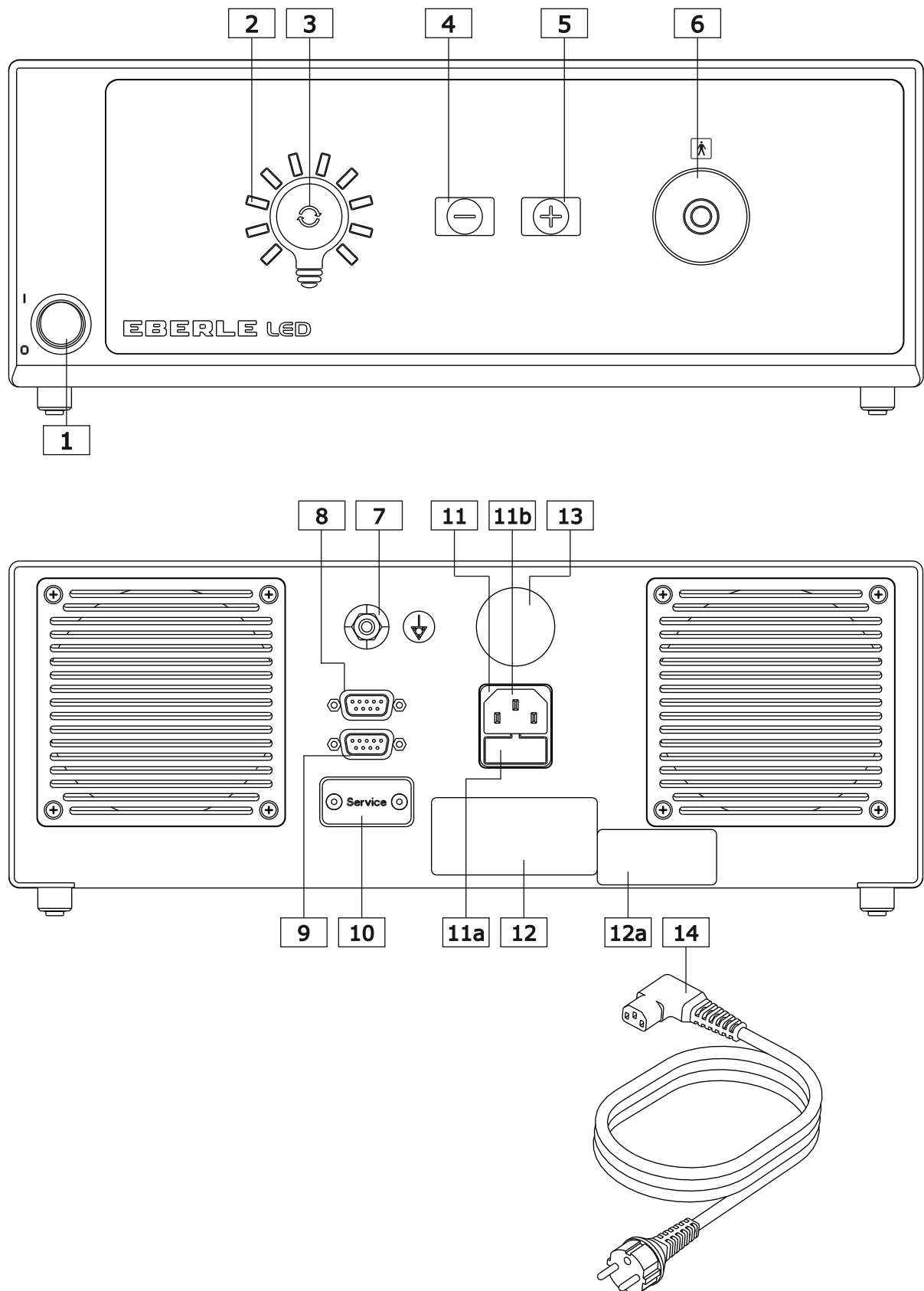
	The sequence for connecting and starting the device, shown below, must always be observed.
---	--

Please proceed as described below:

- Switch off power switch [1] at the front of the light source casing (position **0**)
- Plug the mains power cable [14] into the connector [11b] at the back of the device; now connect to the mains power supply.
- Establish equipotential bonding [7] (if required, by qualified personnel)
- Switch on power switch [1] at the front of the light source casing (position **I**) and check the operating controls for correct functioning.

The light source is now ready for operation!

5. Operation



5.1 Assignment of Keys

Power switch [1]

The device is switched on by pressing the power switch.

The power switch has two switch positions:

I	ON	switched
O	OFF	off

A green indicator lamp is lit, when the device is switched on.

Key: illuminance [4/5]

To set the illuminance press the keys  [4] and  [5] until the desired luminance is reached

5.2 Displays

Illuminance [2]

Display of the illuminance in 10% steps

Service life of LED exceeded [3]

When the theoretical service life is exceeded, the display  [3] flashes 30sec the light source has been switched on. Please contact an EBERLE representative or an authorized service and distribution centre.

5.3 Connections



Never touch the patient and the connections on the control unit at the same time!

Equipotential bonding [7]

Generally, the control unit is earthed by the 3-pin safety plug, if it is connected – as stipulated - to an earthed power cable. When this device is operated in rooms of application group 2 according to DIN VDE 0107 it is indispensable that the device is connected to the stationary equipotential bonding of the room or of the medical device cart by a corresponding cable. The device has an according plug connector for this (according to DIN 42801).

ECB [8/9]

Coded connection (Eberle Communication BUS)



The ECB port is used for the mutual control of Eberle devices. Only use EBERLE approved equipment and connecting cables for connection to the ECB.

Service Port [10]

Service and diagnostic port



The service port is for diagnostics, and may be used only by authorized personnel and for service purposes only.

Power connector [11]

The plug of the power cable is connected to this inlet connector for non-heating apparatus [11]. Only use the delivered power cable [14]. The fuses of the device are located in the fuse holder [11a]. Please only use the fuse types that are mentioned on the type plate [12]! How to exchange the fuses is explained in the service chapter of these operating instructions.

6. Device-specific Symbols

	Key to decrease the illuminance [4]
	Key to increase the illuminance [5]
	Display illuminance [2]
	Display service life of LED exceeded [3]
	Power switch on [1]
	Power switch off [1]
	Connection for equipotential bonding [7]

7. Preparation of Device and of Accessories

Prior to the first use the device must be cleaned in accordance with the procedure described under point 7.1. It cannot be sterilized.

The cleaning, disinfection, and sterilization methods apply that are listed in these or in other instructions that may possibly be included in the delivery of the device or of the accessories. This does not apply to accordingly designated, disposable articles that come in sterile packing

Insufficient cleaning, disinfection, and/or sterilization can result in the patient and/or the operator being infected. The operator is responsible for the validation of these processes.

7.1. Cleaning of the Device

The outer surfaces of the device can be cleaned and disinfected with a disinfectant or cleaning agent for spray/wipe disinfection. Here, always observe the specifications of the disinfectant manufacturer, DGHM / VAH as well as RKI with regard to concentration and reaction times.

Cleaning agents and application:

Bacillol® AF, Bode Chemie GmbH, Hamburg
Spray and wipe disinfection
Undiluted, 5 min.

	Disconnect the device from the mains supply prior to any cleaning and disinfecting procedure!
	When cleaning the device please pay attention that no liquid enters the casing!

8. Service, Maintenance, Inspection, and Disposal



Repairs or maintenance on the devices may only be carried out by the manufacturer or by service personnel authorized by the manufacturer and only using original parts.

The mains fuse can be exchanged by local qualified personnel as described below:

- Switch off power switch [1] at the front of casing (position **O**)
- Disconnect the power plug [14] and the equipotential bonding [7] from the device
- With a slotted screwdriver or any other suitable tool lift the mains fuse holder out of the mains fuse box [11a]
- Remove the defective fuses and insert new fuses in accordance with type plate [12]
- Insert mains fuse holder into mains fuse box [11a]
- Connect power plug [14] and equipotential bonding [7]
- Switch on power switch [1] (position **I**)

Regular maintenance can help to detect defects and malfunctions at an early stage and thus to possibly extend the service life of the device; however, it is not compulsory.

Independent of the country-specific safety regulations (e.g. accident prevention regulation, inspection interval regulations), we recommend a yearly function and safety inspection according to EN 62353; VDE 0751-1 by an authorized service centre. This inspection should be shown on the rear of the device by means of a sticker.

National regulations are to be observed, should it become necessary to dispose of the device. The returned device must be accompanied by a proof of disinfection.

9. Trouble Shooting

Symptom	Possible Cause	Remedy
Malfunction of device - out of operation - power switch on - power switch light is off	- power supply failed - mains fuse defective	- check power supply - exchange fuse of device

Device failures or disturbances resulting due to the presence of electromagnetic disturbances are not to be expected (also refer to chapter 3.1 / chapter 10).

10. Technical Data

Safety classification, IEC 601-1	Protective class applied part	I Typ BF
Classification MDD 93/42/EEC	Risk class	I
Electrical data	Supply voltage Mains frequency Mains fuse max. input power	100-240 V/AC 50/60 Hz 2 x T1AH250V 100 VA
Possible EM or other interferences Interference emission/immunity	IEC 60601-1-2 Group/Class IEC 60601-1-2 Classification IEC 61000-3-2 Class	I / B Environment: professional med. care institutions A
Protection system	Dust / humidity	IP20
Illuminance		max. 700 lm (with 5mm light conductor)
Colour temperature		5000-6500 K
Wave length		400-700 nm
Operating conditions	Temperature relative humidity max. height MSL min. pressure	15 to 30°C 30-75% not condensed 2000m 795hPa
Storage, transport conditions	Temperature relative humidity Shelf life	-10 to 70°C 30-75% not condensed Storage time without use max. 2 years
Mechanical data	Dimensions: L/W/H in mm Weight	300x350x125mm 6900g
Packaging (collapsible box with inlay)	dimensions: l/w/h in mm weight corrugated cardboard weight PE insert	470x470x365mm 1200g 1100g
Application cycle	1-10 uses per day for a duration of 10-45 minutes	
Accessories	See compatibility list (page 16)	

Guidelines and Manufacturer's Declaration – Electromagnetic Emissions

The Light Source LED is destined for operation in the electromagnetic environment mentioned below. The customer or the user of the Light Source LED should ensure that it is used in such an environment.

Emission measurements	Conformity	Electromagnetic environment – guidelines
HF emissions pursuant to CISPR 11	group 1	The Light Source LED uses HF energy only and exclusively for its internal function. Therefore, the HF emission is extremely low, and it is very unlikely that neighbouring electronic devices will be disturbed. The Light Source LED is suitable for use in all establishments, including domestic establishments and those directly connected to the PUBLIC MAINS SUPPLY that supplies buildings used for domestic purposes.
HF emissions pursuant to CISPR 11	class B	
Harmonic components pursuant to IEC 61000-3-2	class A	
Voltage fluctuations / flicker pursuant to IEC 61000-3-3	conforms	

Guidelines and Manufacturer's Declaration – Electromagnetic Emissions

The Light Source LED is intended for operation in environments as stated below. The customer or user of the Light Source LED shall ensure that it is operated in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
ESD IEC 61000-4-2 IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors shall be made out of wood or concrete or shall be covered with ceramic tiles. If the floor is covered with synthetic material the relative humidity must amount to at least 30 %.
Bursts IEC 61000-4-4	± 2 kV power supply lines 100kHz repetition frequency ± 1 kV input/output	± 2 kV power supply lines 100kHz repetition frequency ± 1 kV input/output	The quality of the supply voltage shall correspond to a typical environment as is found in commercial or hospital locations.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	The quality of the supply voltage shall correspond to a typical environment as is found in commercial or hospital locations.
Voltage drops, short interruption and fluctuations of the supply voltage IEC 61000-4-11	0 % UT; 0,5 Periode dip in UT; 0,5 cycle 0 % UT; 1 Periode dip in UT; 1 cycle 70 % UT; 25/30 Perioden dip in UT; 25/30 cycles 0 % UT; 250/300 Perioden dip in UT; 250/300 cycles	0 % UT; 0,5 Periode dip in UT; 0,5 cycle 0 % UT; 1 Periode dip in UT; 1 cycle 70 % UT; 25/30 Perioden dip in UT; 25/30 cycles 0 % UT; 250/300 Perioden dip in UT; 250/300 cycles	The quality of the supply voltage shall correspond to a typical environment as is found in commercial or hospital locations. If the user of the Light Source LED requires continued functioning also in the event the power supplies are interrupted, it is advisable to energize the Light Source LED with an USV or a battery.
Supply frequency magnetic fields at (50/60) Hz IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields shall correspond to a typical environment as is found in commercial or hospital locations.

Conducted RF disturbances IEC 61000-4-6 Radiated RF disturbances IEC 61000-4-3	3 V eff. * 150 kHz – 80 Mhz (*6 V eff. in ISM bands) 3 V/m 80 MHz – 2,7 GHz	3 V eff. * 150 kHz – 80 Mhz (*6 V eff. in ISM bands) 3 V/m 80 MHz – 2,7 GHz	Portable and mobile communication devices shall not be used in closer proximity to the Light Source LED or its cables than the recommended safety distance: d = 1,17√P 150 kHz – 80 Mhz d = 1,2√P 80 MHz - 800 Mhz d = 2,3√P 800 MHz - 2,7 Ghz The field strength of stationary transmitters, as determined by a field survey, shall be less than the compliance level for all frequencies. Disturbances are possible in the close proximity of devices showing the following symbol. 
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Test determinations for INTERFERENCE IMMUNITY of ENCASEMENTS against high-frequency wireless communication devices						
Test frequency Mhz	Frequency band ^a Mhz	Radio service ^a	Modulation ^b	Maximum Output W	Distance m	INTERFERENCE IMMUNITY TEST LEVEL V/m
385	380 to 390	TETRA 400	Pulse modulation ^b 18 Hz	1,8	0,3	27
450	430 to 470	GMRS 460, FRS 460	FM ^c ± 5 kHz deviation 1 kHz sinus	2	0,3	28
710	704 to 787	LTE band 13, 17	Pulse modulation ^b 217 Hz	0,2	0,3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation ^b 18 Hz	2	0,3	28
870						
930						
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	Pulse modulation ^b 217 Hz	2	0,3	28
1 845						
1 970						

Test frequency Mhz	Frequency band ^a Mhz	Radio service ^a	Modulation ^b	Maximum Output W	Distance m	INTERFERENCE IMMUNITY TEST LEVEL V/m
2 450	2 400 to 2 570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation ^b 217 Hz	2	0,3	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation ^b 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE: If necessary, the distance between the transmitting antenna and the ME DEVICE or ME SYSTEM may be reduced to 1 m in order to reach the INTERFERENCE IMMUNITY TEST LEVEL. The 1 m test distance is allowed according to IEC 61000-4-3

^a For some radio services, only the frequencies for the radio connection from the mobile communication device to the base station (uplink) were included in the table.

^b The carrier must be modulated with a square wave signal with a 50% duty cycle.

^c As an alternative to frequency modulation (FM), a pulse modulation with 50 % duty cycle with 18 Hz may be used since this, if not the actual modulation as well, would constitute the worst case.

Recommended safety distances between portable and mobile RF telecommunication devices and the Light Source LED

The Light Source LED is intended for use in an electromagnetic environment, in which RF disturbances are controlled. The user (customer) of the Light Source LED may help to prevent electromagnetic disturbances by observing the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the Light Source LED – dependent on the output power of the communication device as stated below.

Nominal power of transmitter W	Safety distance dependent on transmitter frequency m		
	150 kHz – 80 MHz $d = 1,17\sqrt{P}$	80 MHz - 800 MHz $d = 1,2\sqrt{P}$	800 MHz - 2,7 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,38	0,73
1	1,17	1,2	2,3
10	3,70	3,8	7,3
100	11,7	12	23

If the nominal power of certain transmitters is not stated in above table, the protective distance d in meters (m) can be determined using the equation given in the respective column. Here, P is the maximum nominal power of the transmitter in watt (W) according to the details given by the manufacturer of the transmitter.

Note 1: For 80 MHz and 800 MHz the higher frequency range applies.

Note 2: These guidelines may not be applicable for all cases. The propagation of electromagnetic factors is influenced by the absorption and reflection of buildings, objects, and humans.

11. Compatibility

Please only use the EBERLE components listed in below table for operation on the EBERLE light source LED!

Artikel-Nr.	Artikel
900003	Light conducting cable, ø4,8 mm, length 2500 mm
900015	Light conducting cable, ø4,8 mm, length 2300 mm
900023	Light conducting cable, ø4,8 mm, length 1800 mm
900032	Light conducting cable, ø4,8 mm, length 3000 mm
900034	Light conducting cable, ø4,8 mm, length 3500 mm
900035	Light conducting cable, ø4,8 mm, length 4000 mm
900036	Light conducting cable, ø4,8 mm, length 5000 mm
900037	Light conducting cable, ø3,5 mm, length 1800 mm
900038	Light conducting cable, ø3,5 mm, length 2300 mm
900039	Light conducting cable, ø3,5 mm, length 2500 mm
900040	Light conducting cable, ø3,5 mm, length 3000 mm
900041	Light conducting cable, ø3,5 mm, length 4000 mm
900042	Light conducting cable, ø3,5 mm, length 5000 mm
913035	Mains power cable 1,8m
913036	ECB connecting cable 1,0m
Future EBERLE products may also be compatible. Detailed information regarding this can be obtained from every EBERLE representative.	



Using non-compatible foreign accessories can endanger or injure the patient and/or the operator!

12. Warranty

The warranty period for the EBERLE light source LED shall be 12 months. Within this period, errors resulting from faulty material and/or inadequate workmanship will be remedied by the manufacturer free of charge.

Transport costs and shipping risks, however, will not be carried by the manufacturer. For further information, please refer to our General Terms and Conditions of Business.



Do not open the device! Arbitrary opening, repairing or modifying of the device absolves us from any liability regarding the operational safety of the system and leads to expiry of any claims whatsoever during the period of warranty!

13. Addresses**Development, Production
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