BF-RhodoLED®
User Manual

BF-RhodoLED®

Manufacturer and distributor: Biofrontera Pharma GmbH

CE 0535

Foreword

Thank you for choosing to use our innovative BF-RhodoLED® LED-lamp for photodynamic therapy.
The BF-RhodoLED® has been developed in accordance with the latest technical standards, and ensuring straightforward and clear usage as well as energy efficiency were important considerations in the design, in addition to ensuring a controlled and constant emission of light with the desired wavelength. The appliance provides optimal light output and flexibility for such usage, and caters in equal measure for the requirements of practitioners and patients.

Provided that the LED lamp is installed and used in accordance with the instructions in this user manual, your lamp will provide you with many years of flawless use. If you have any questions, please contact your dedicated sales representative:

Dedicated sales representative:

Name:_____

Tel.:_____

Email:_____

Or contact:

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Introduction

This user manual and the accompanying eye protectors form an integral part of the medical appliance. Prior to using the lamp, the operating instructions should be read carefully in their entirety in order to ensure proper use in accordance with the relevant instructions.

The latest version of the document is available at www.bf-rhodoled@biofrontera.com .

Please note the safety instructions, precautionary measures and warnings mentioned in the manual.

Warranty

The manufacturer, Biofrontera Pharma GmbH, provides a two year warranty for all the lamp components (except for the eye protectors), from the date of delivery of the appliance. The warranty is in line with statutory regulations for warranties, and applies to the purchase of new appliances. During the warranty period, any defective parts will be replaced, unless it can be demonstrated that the user has caused the defect or that the usage of the LED lamp has contravened the instructions contained in this user manual. In such cases, the damage will not be covered by the manufacturer's warranty.

In the case of defective parts covered by the warranty, please contact the manufacturer at the address above.

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1 Area of use of the BF-RhodoLED®

The BF-RhodoLED® LED lamp is intended solely for use in photodynamic therapy (PDT) by trained staff in medical practices and hospitals. PDT is used to treat skin diseases such as actinic keratosis, acne, basal cell carcinoma, Bowen's disease and warts. The therapy involves the affected area of skin being treated with a gel or cream containing 5-aminolevulinic acid or an ALA ester, which acts as a photo-sensitiser, before being exposed to the lamp. The lamp emits red light that does not transfer heat and which has an average wavelength of approximately 635 nm.

For the treatment of pre-cancerous skin lesions (actinic keratosis AK), it is recommended to use the lamp together with Biofrontera's medication Ameluz®. The Ameluz® Gel combines a penetration-promoting nanoemulsion with the endogenous agent 5-aminolevulinic acid, which acts as a photo-sensitiser. Ameluz® is spread in 1 mm thick layer on the affected area of skin and on 5 mm of the surrounding skin. After a 3 -hour exposure to this under a suitable cover, the area is illuminated from a distance of 5 to 8 cm using the BF-RhodoLED®. Detailed information regarding the use of Ameluz® is available in the operating instructions. The light dosage used for the illumination is 37 J/cm^2. The resulting photophysical processes result in the creation of toxic substances, in particular reactive oxygen species, which kill the changed cells in a targeted fashion.

Restricted patient groups:
Actinic keratosis does not occur in children and adolescents under the age of 18.

When using Ameluz® together with PDT, the following temporary side-effects may occur during and after the period of irradiation:
Very common - reported by at least 10% of the people treated

- Reactions around the area of administration, such as hardening, burning, itching, pain, scaling of the skin, scabbing, redness and tissue swelling caused by excess tissue

Common - reported by 1% - 10% of the people treated

- Headaches
- Reactions around the area of application such as discomfort (stinging, tingling or numbness), skin tension, abrasion, increased sensitivity to pain, blistering, feelings of warmth

Occasional - reported by 0.1% - 1% of the people treated

- Reactions around the area of application such as bleeding, discharges, discoloration, dry skin, thickening of the outer layer of skin, discomfort, ulcers, red or dark red spots on the body, unpleasant or abnormal touch sensations, swelling of the eyelids and skin rash with pustules
- Chills
- Flushing, fever
- Pain
- Anxiousness
- Exudation

When using other ALA-containing drugs together with BF-RhodoLED®, similar and perhaps other side-effects may occur. Information about side effects can be obtained from the usage instructions or directly from the manufacturer.

For questions about Ameluz® and the combination treatment together with the BF-RhodoLED® lamp, please contact Biofrontera Pharma GmbH (ameluz@biofrontera.com or bf-rhodoled@biofrontera.com).

The clinical approval trials for Ameluz® have demonstrated that the quality and power of the light source used for PDT is a critical factor in the success of the treatment. The BF-RhodoLED® lamp uses LED technology, with the light emitted being automatically restricted to the relevant wavelengths. This is the part of the spectrum that stimulates the molecule protoporphyrin IX in the skin of the patient, thereby giving rise to the desired medical effects.

The lighting programmes predefined in the BF-RhodoLED® for PDT are configured to provide a light dose of 37 J/cm^2 in a wavelength range around 635 +/-9 nm at a distance of 6 cm. The patient can be informed by audio signals about the remaining time during the light treatment. The lamp permits flexible programming of various illumination cycles and the regulation of lighting and ventilation parameters during the treatment. The treatment can thus be tailored to react to the possible pain or specific requirements of the patient.

2 Safety instructions, precautions, warnings and environmental protection notices

2.1 Safety instructions and precautions

- The LED lamp has been developed for use in photodynamic therapy and is only intended for use under medical supervision.
- The LED lamp may only be used by personnel who have been given adequate training in how to use it.
- The accompanying user manual must be read carefully prior to use of the device.
- Prior to the initiation of the treatment, the patient must be informed about the treatment by medical personnel trained for such therapy, and must be instructed not to move during the period of treatment.
- It is imperative that a distance of 5 to 8 cm from the patient must be observed during treatment, otherwise the light dosage on the skin will deviate from the desired 37 J/cm^2. In order to provide a measure of the treatment distance, the distance slider and the scale bars on both sides of the lamp head can be used. In order to ensure that the treatment distance is maintained, the patient should remain in a fixed lying or sitting position during the treatment.
- Trained staff should be present during the treatment.
- The patient and the personnel carrying out the treatment must wear the relevant eye protection during the treatment. The eye protection relates solely to the IPL (Intense Pulsed Light) range and cannot be penetrated by red light with an average wavelength of approx. 635 nm. The eye protectors are NOT suitable for use with laser treatment.
- It is hereby stated that the light source should not be looked at directly during the treatment if the eye protectors are not being worn. **Non-adherence to these precautionary measures can lead to permanent eye damage!!**
- The lamp should be set up and operated in a temperature between 0°C and+ 40°C, and in a relative humidity of 10 % to 90 %.
- Medical electronic devices require special precautionary measures to be taken with regard to the electro-magnetic compatibility (EMC); the installation and initiation of the device must therefore be carried out in accordance with the current operating instructions.
- The lamp may NOT be used outdoors.
- Neither the lamp nor its remote control unit may come into contact with water or be exposed to moisture.
- If the device is not being used or is being left unattended for a long time, the plug should be pulled out of the mains socket to ensure safety.
- Only unplug the lamp once it has been turned off.
- When using the wall-mounted or mobile models, there is a risk of tripping over the power cable or the mobile feet. When transporting the device or not using it, always wind the power cable around the star knobs.
- Neither the lamp nor the power pack should be exposed to mechanical loads or serviced or opened by the user. Assembly and servicing may only be carried out by certified professionals.
- The lamp may not be set up, stored or operated close to a source of extreme heat.

- Neither the medical lamp nor the remote control unit may be cleaned using a solvent, as this would cause surface damage.
- Ensure that the remote control unit is always returned to the fixture intended for this purpose on the storage shelf. Storing the remote control unit by hanging it can lead to damage to the spiral cord and the plug fitting.
- The control panel must be protected from external mechanical influences and sharp objects.
- Please do not place heavy objects on the shelf or use this for sitting, leaning or pushing, as this can lead to the device tipping over or the storage shelf breaking.
- Do not place a cupboard or other office furniture in front of the socket to which the lamp is connected. The power socket should be kept freely accessible.
- Depending on the positioning, the bracket arm comprises slots below the connecting portion of the bracket arm and to the right of the support tube. Ensure when setting up or adjusting the device that fingers or other objects are NOT placed in the ventilation slots (Figure 1). **Note: Risk of trapping fingers! The mobility of the bracket arm may be obstructed by objects!**
- If the wheels are locked, the device will tip over if exposed to a force of 110N at a height of 1.5 m, so the use of the device for leaning on or for support is NOT permitted.
- Keep a good hold of the device when transporting it over unstable or uneven surfaces and do NOT leave it standing on such surfaces.

Both the maintenance and the assembly of the mobile LED lamp and its components (including the opening of individual components) may only be carried out be professionals certified and trained by Biofrontera. In the event of the servicing or assembly being carried out by any other parties, Biofrontera Pharma GmbH assumes no responsibility or liability regarding the safety of the device.

The assembly of the support rail for wall mounting (see chapter 3.4) of the LED lamp is **NOT** carried out by Biofrontera. Please contact a qualified tradesman or in-house technical personnel for this task. Costs relating to the assembly are borne by the customer. The qualified tradesman or in-house technical personnel must check the condition of the wall in such cases and affix the support rail in a proper and safe way. The installation instructions and specifications regarding load capacity of the support rail are provided in the Biofrontera installation manual, in "chapter 3.4 Assembly", and are to be adhered to by the tradesman or service technician carrying out the task. Liability regarding the support rail is borne by the tradesman or service technician carrying out the task.
The mounting of the lamp head and bracket arm unit on the affixed support rail, as well as the mounting of the storage shelf and the remote control unit onto the wall mounting, are to be carried out by a member of the Biofrontera service team. Biofrontera assumes responsibility for the correct assembly of this.

Once the BF-RhodoLED® has been assembled, a brief introduction to getting started with the lamp is provided by the Biofrontera service technician.

2.2 Warnings

Before using the lamp, the user manual should be read carefully. If the photodynamic therapy is combined with Biofrontera's Ameluz® medication, further information about usage is available in the Ameluz®**product information and package insert.** Any use of the lamp or of Biofrontera's Ameluz® medication that deviates from the usage as specified in this user manual or the Ameluz® usage information is considered to constitute misuse. In such cases, Biofrontera assumes no responsibility or liability.

- **Caution: The source emits red light with a wavelength of approx. 635 nm. Do not stare directly into the light source, since eye damage and irritation may result. Risk Class II Product. Wear protective eye wear!**
- Caution: In order to avoid the risk of incurring electric shocks, the device may only be connected to a power supply with an earth conductor.
- Warning: Changes may not be made to the ME device.
- During treatment, the patient, the practitioner and all other persons present must wear the correct eye protection, which cannot be penetrated by the specific wavelengths.
- The assembly and servicing of the lamp must be carried out by professionals trained for this by Biofrontera.
- Caution: The mobile LED-lamp weighs 44 kg, and should not therefore be lifted alone.
- The USB and Internet interfaces on the right hand side of the remote control unit may not be used for importing data while the appliance is being used for treatment.
- Please note that the mobile lamp must be placed in its parking position (see figure 1) during transport, in order to avoid a risk of tipping over.
- **NEVER place the lamp on unstable or uneven surfaces.**
- If the fins on the light head (ventilation slots) are defective or if any other damage is apparent, the lamp may NOT be used for treatment. Please contact the manufacturer immediately.
- The plexiglass plate may NOT be touched during or directly after treatment, as in the event of faulty operation the max. temperature can reach approx. 73 °C.

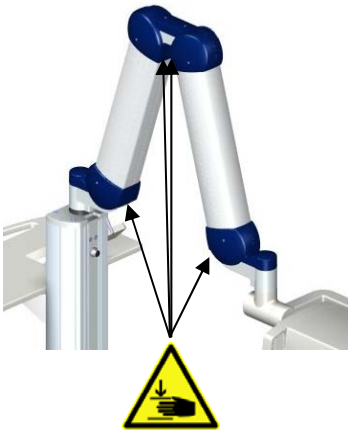


Figure 1: The bracket arm in a parked position incl. arrows indicating potential areas where fingers can get trapped

3 Description of appliance

3.1 General information

The light-field of the LED lamp consists of a total of 128 LEDs and lenses (arranged in a rectangle), which emit a uniform, bundled, visible red light with an average wavelength of approximately 635 +/- 9 nm (figure 2a). The half-band width of the lamp is 20 nm.

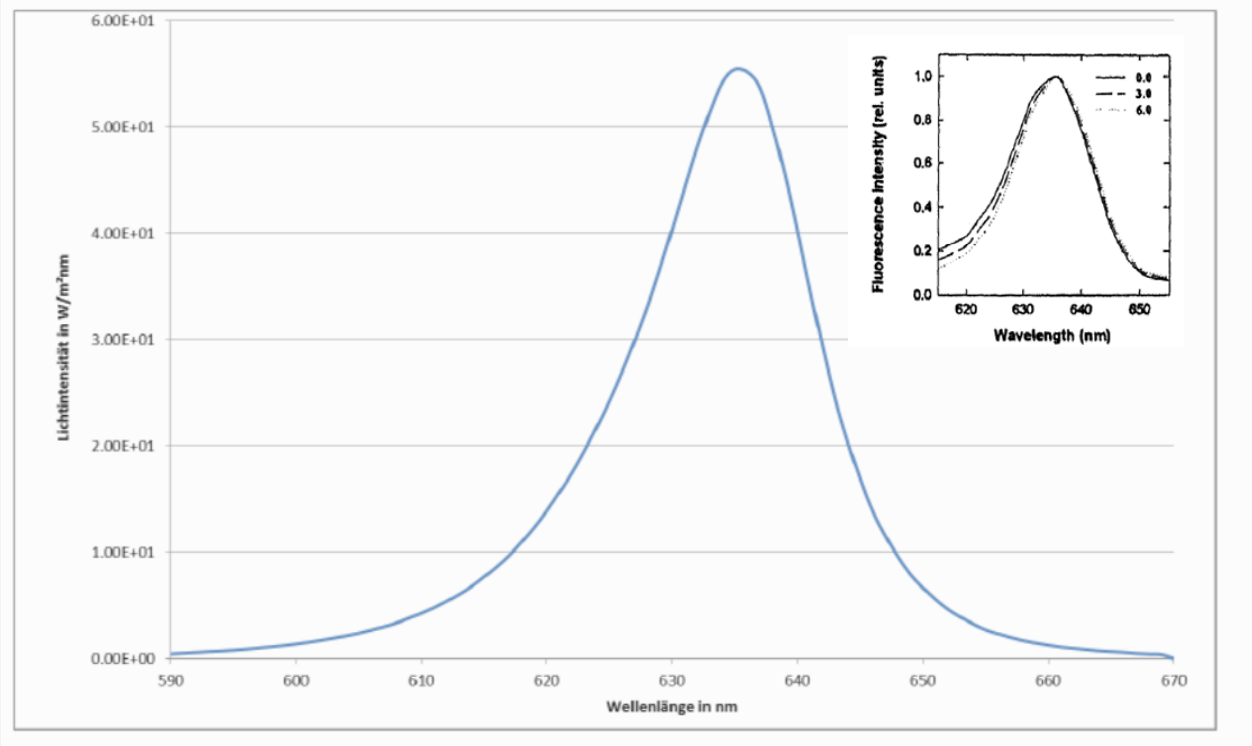


Figure 2: a) Light spectrum of the LEDs of the BF-RhodoLED; b) Absorption spectrum of PPIX in cells (from Moan et al., 1996)

In accordance with the usage guidelines for Ameluz®, a light dosage of 37 J/cm^2 in the wavelength range of approximately 630 nm is applied. The light stimulates the protoporphyrin IX contained in skin cells, with the absorption maximum being 630 nm (in chloroform) and 635 nm (in living cells; Moan et al., 1996; see inset in figure 2b).

In particular the absorption maximum in living cells is therefore catered for perfectly by the BF-RhodoLED®. The LEDs are therefore calibrated so that the skin being treated receives a light dosage of 37 J/cm^2 under the following conditions:

- Radiation time of 10 minutes at maximum power
- Treatment distance of 6 cm
- Wavelength range of 635 +/- 9 nm

In practical terms, the distance to the area of skin being treated is between 5 cm and 8 cm. The required light dosage of 37 J/cm^2 is pre-defined for the BF-RhodoLED® in the software program (see point 4.2.2 Operating concept for the BF-RhodoLED®). It is only possible to manually adjust the

lighting dosage with newly created user profiles. The illumination area of the LED lamp is 8 x 18 cm. As the intensity decreases towards the edge of this area, the effective treatment area is 6 x 16 cm.

3.2 Overall design of the lamp:

There are two models of the lamp available:

a) LED lamp with mobile frame (product no.: BF-LED-FV)
b) LED lamp for wall mounting (product no.: BF-LED-WH)

Model a) "LED lamp with mobile frame" consists of the following components (figure 3):

- Lamp head with lifting arm and bracket arm
- Storage shelf with control unit (remote control)
- Mobile frame (support rail and casters)

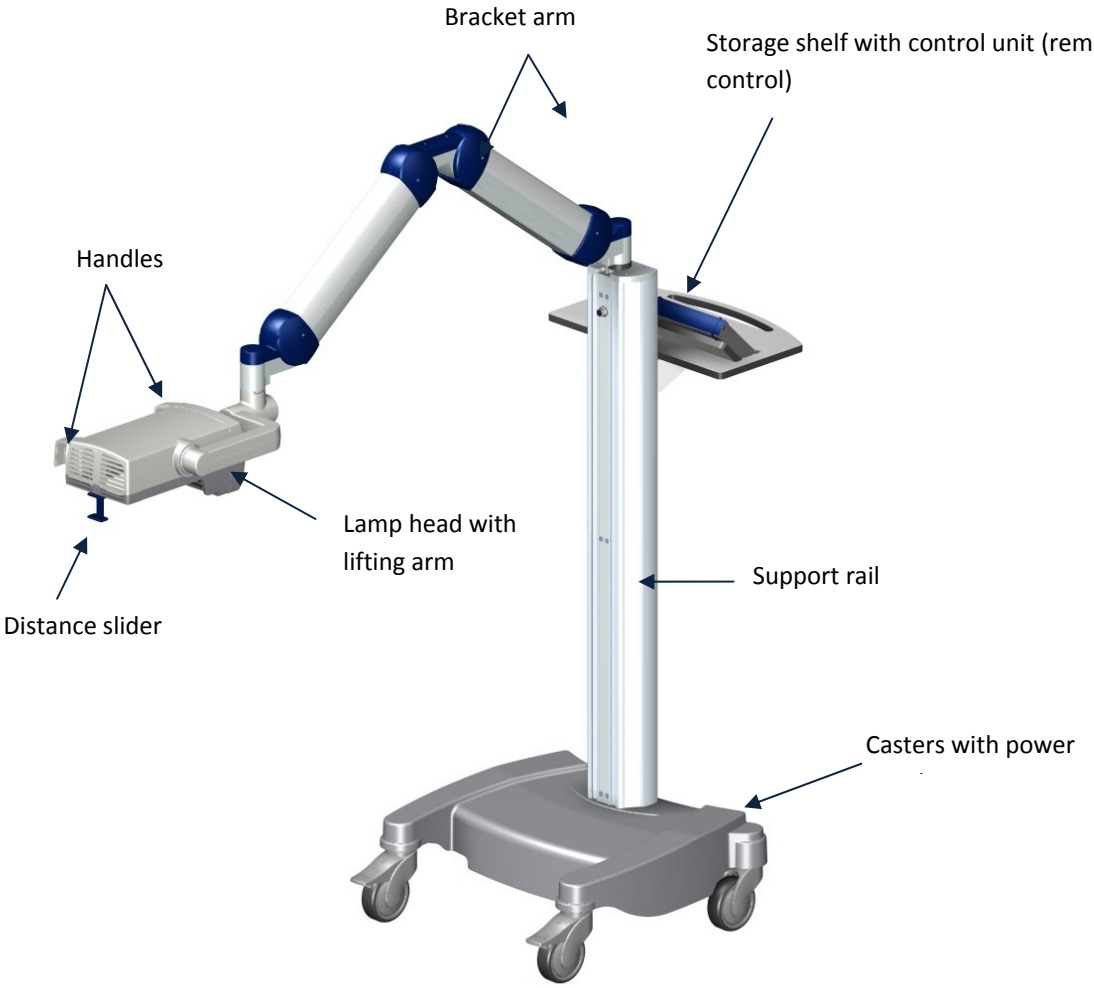


Figure 3: LED lamp with mobile frame

Model a) "LED lamp for wall mounting" consists of the following components (figure 4):

- Lamp head with lifting arm and bracket arm
- Storage shelf with control unit (remote control)

- Wall bracket

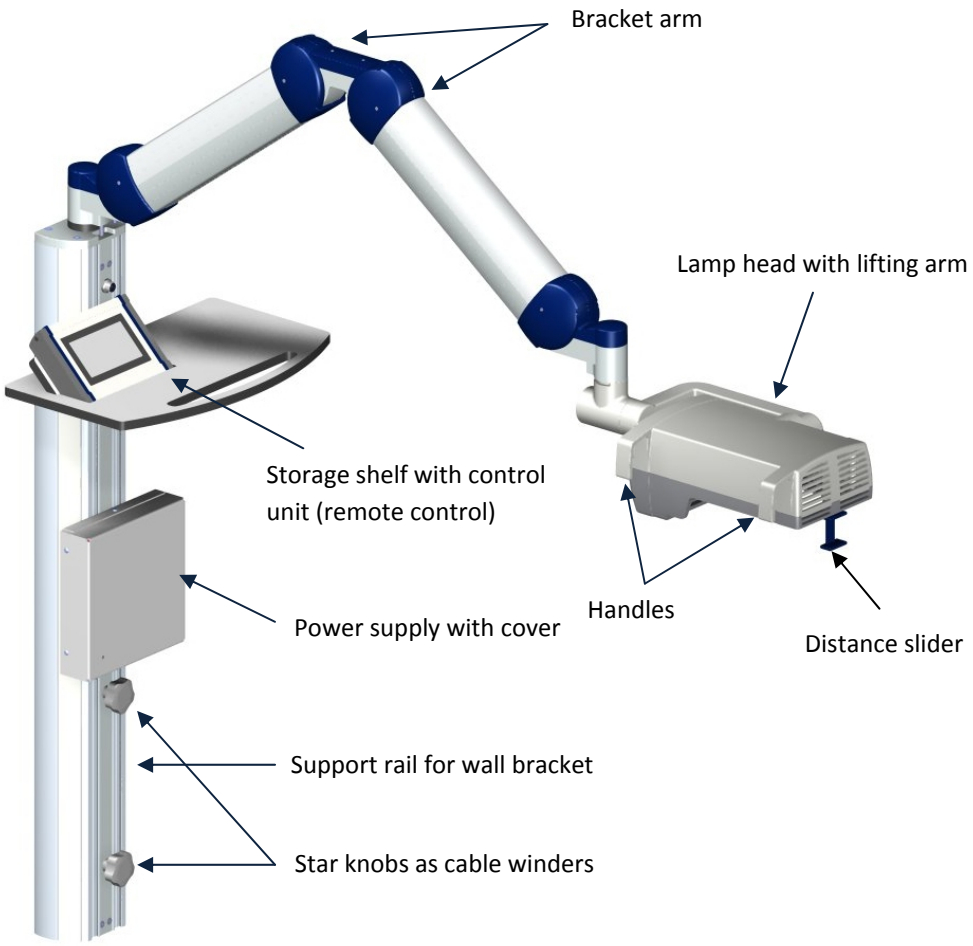


Figure 4: LED lamp for wall mounting

The structure of the lamp head, the bracket arm and the remote control are identical for both models. The swivel range to the left and to the right of the vertical rail is +/- 24 degrees for the mobile model and +/- 90 degrees for the wall-mounted LED lamp. In order to ensure that the best possible movement range is enabled for the lamp head, all degrees of freedom have been taken into account. Both models can be adjusted horizontally and vertically. The lamp head can also be tilted sideways. The high quality bracket arm and the use of gas springs allows the lamp head to be adjusted to and remain in any position.

3.3 Appliance and accessory parts

Two packets are included in each delivery. Please check that the following appliance and accessory parts have been delivered in the packets described below.

Appliance parts:

Packet	Quantity	Description
1	1 pre-assembled unit	Unit consisting of: Lamp head with lifting arm and bracket arm (with 3 cable conduits inside) with covers and 3 protruding plug sockets on the end
	1	Control unit (remote control) with spiral cord (with plug on the end) and storage
	1	User manual
	1	Declaration of conformity

In addition, one of the following appliance parts is ordered and delivered:

Packet	Quantity	Description
2 a	1 pre-assembled unit	Mobile model: Support rail with flange (with 3 cable conduits inside) and a support tube with 3 protruding plug sockets, two star knobs, casters with power supply connections (with covers) including a power cord and with pre-assembled weights under the casters
2 b	1 pre-assembled unit	Wall bracket Support rail with flange (with 3 cable conduits inside) and a support tube with 3 protruding plug sockets, with pre-assembled power supply with cover, including a power cord and two star knobs on the front of the support rail
	1	Installation instructions for mounting the wall bracket

All the required connector elements for assembly, such as screws, rotary locking bolts with nuts and caps and, if necessary, a standard wall anchor plug (for the wall-mounted model), are including in the delivery. Please make these available to the Biofrontera service technician when assembling the mobile LED lamp. Tools are not included in the delivery but are carried by the service technicians.

If the wall-mounted version of the BF-RhodoLED® is purchased, a local professional tradesman or service technician must be contacted. Once this person has set up the wall mounting, the Biofrontera service technician can assemble and mount the LED lamp.

Please provide the tradesman or service technician with the specific installation instructions for setting up the wall mounting. Prior to mounting, the specific wall conditions must be checked carefully by the tradesman or the service technician and the wall bracket must be erected correctly and safely in accordance with the assembly specifications, using suitable anchors and screws.

All other steps in the assembly, as well as a brief introduction to getting started with the LED lamp, are carried out by the Biofrontera Pharma GmbH service technican.

Accessory parts:

Packet	Quantity	Description
1	1	IPL pair of Skyline eye glasses with green filters for the user (Figure 5)
	1	White Spectra Shield eye protection caps for the patient (Figure 6)
	10 pairs	IPL disposable eye protection pads for patients (Figure 7)

Figure 5: IPL Skyline eye protection glasses
IPL Glasses S3
Order no.: 3P.111.333.BF1

Figure 6: White eye protection caps Skyline (9162)
Spectra Shield white
Order no.: 3199-7316BF

Figure 7: IPL disposable eye protection pads (50)
Order no.: MASP238-50-IPL

The above three eye protection types are used in IPL (Intense Pulsed Light) treatment and are also suited for use with PDT therapy. The protective glasses (figure 5) have a green filter with an optical density (OD) of about 1, which absorbs red light in the wavelength range from 600 to 700 nm and has a minimal effect on the perceived brightness. The user of the lamp is therefore ensured a good view as well as protection from light in this wavelength range. The frames of the eye protection are adjustable, making these eye protectors suitable for use by wearers of glasses as well. The IPL disposable eye protection pads (figure 6) absorb red light in the wave length range from 500 to 1100 nm and the eye protection caps (figure 7) absorb red light in the wavelength range from 400 to 1400 nm. The optical density of the IPL disposable eye protection pads is 6 and the eye protection caps 7. Both options are effective and comfortable to wear for patients during the light treatment, and can also be combined if desired. Please carefully read the accompanying usage information before using the various eye protectors. Additional eye protection glasses, caps and pads can be ordered from

Biofrontera Pharma GmbH using the order number listed below. These eye protectors may NOT be used during laser treatment

3.4 Assembly

The assembly of the mobile LED lamp is carried out by a trained technician from Biofrontera Pharma GmbH. No liability is assumed for damage resulting from the user carrying out the assembly.

The affixing of the wall bracket for the BF-RhodoLED® is **NOT** carried out by Biofrontera. Please contact a local professional tradesman or service technician for this task. The guidelines for safe working loads and safe installation are provided in the separate installation guide. This should be made available to the tradesman or service technician prior to the assembly taking place.

3.4.1 Assembly of the mobile LED lamp

3.4.1.1 Appliance parts required

a) The base delivered with the mobile model, which is provided as a pre-assembled unit, consists of the following components and the 3 cable conduits in the support rail (figure 8):

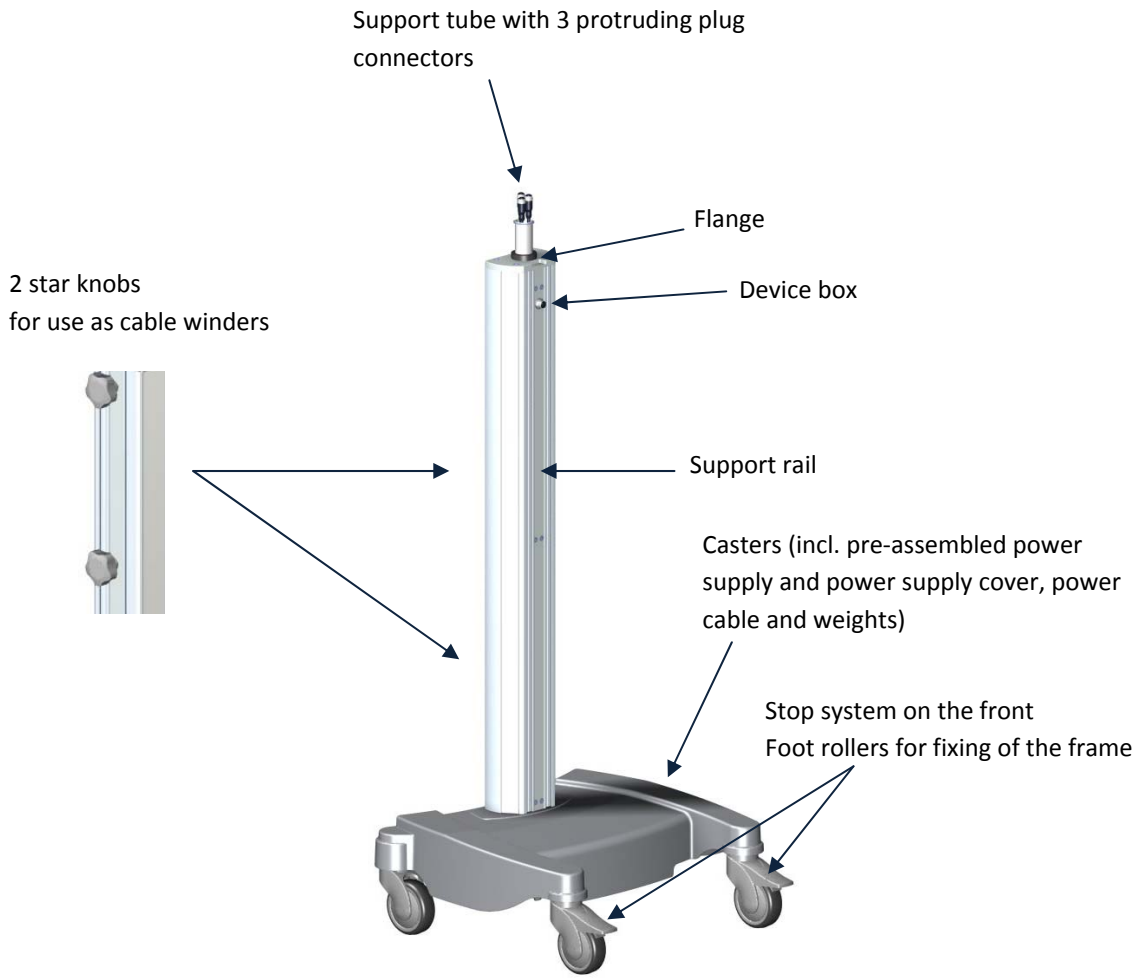


Figure 8: Pre-assembled base of the mobile model

b) The pre-assembled unit consists of the the following components, including the cable conduits in the bracket arm, electronics integrated into the lamp head and plug connectors protruding from the bracket arm (figure 9):

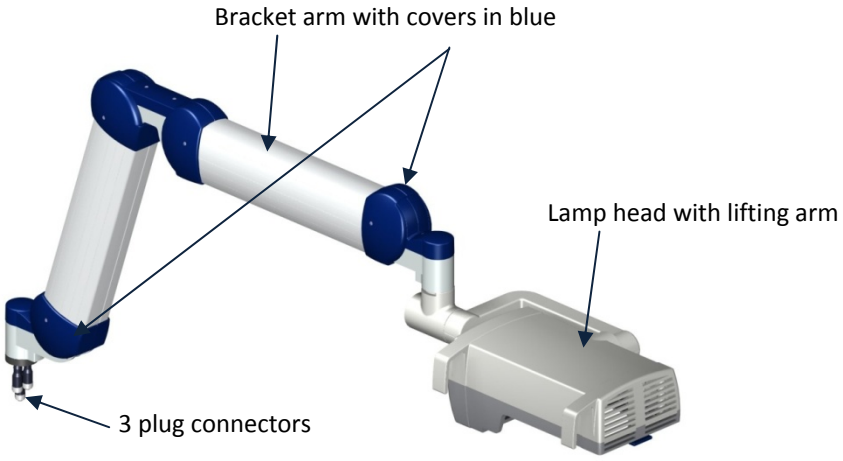


Figure 9: Pre-assembled unit with lamp head, lifting arm and bracket arm

c) The storage shelf consists of the following components (figure 10):

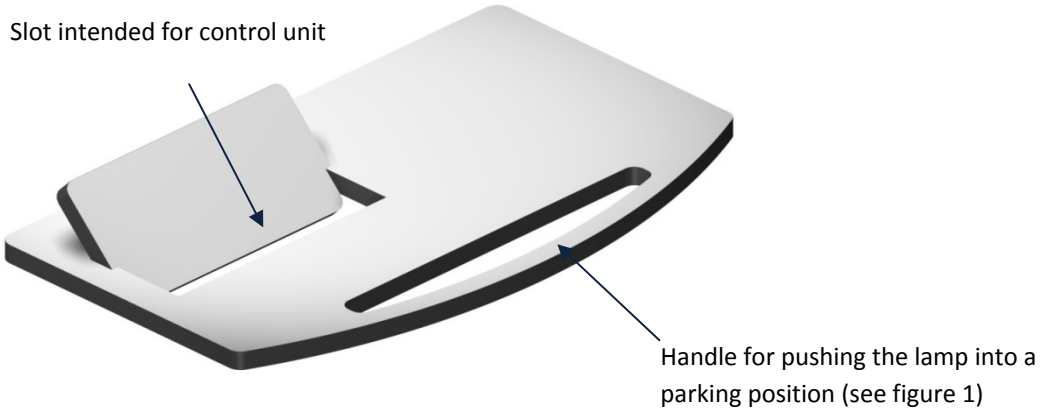


Figure 10: Storage tray for mobile LED lamp

d) Connecting elements and tools required:

- 4 rotary locking bolts (bolted to the shelf) with nuts and caps
- Allen key sizes 2.5 and 4
- Snap ring pliers
- Ring wrench size 13

3.4.1.2 Mounting the bracket arm and lamp head unit on the lamp base's support rail

a) First, the safety ring of the support tube (see figure 11) is removed with the snap ring pliers.

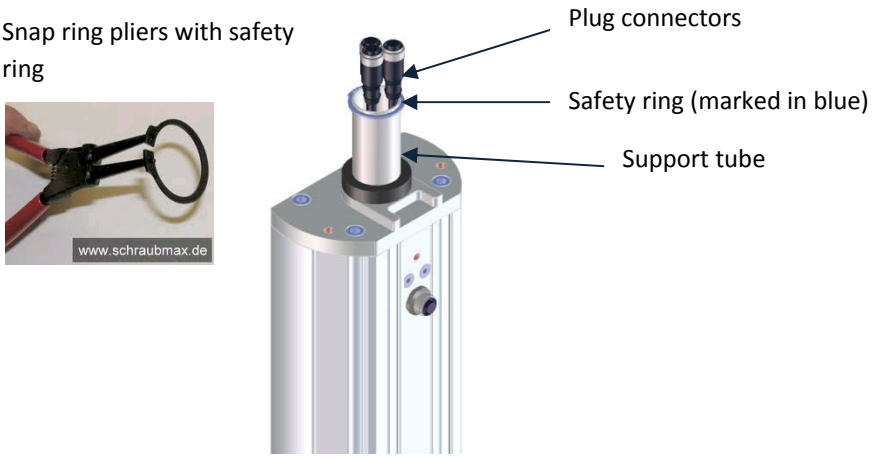


Figure 11: Support tube with 3 protruding plug connectors

b) The blue cover at the end of the bracket arm (see figure 12) is removed using the size 2.5 Allen key. Ensure that the bracket arm is in the extended position when removing the cover.

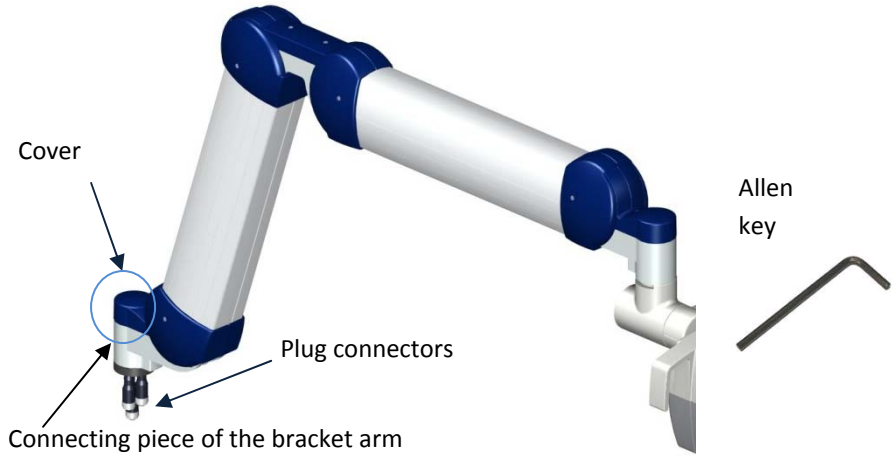


Figure 12: Bracket arm with 3 protruding plug connectors

c) In the next step, the 3 plug connector plugs protruding from the support tube of the mobile frame are passed through the connecting tube of the bracket arm and the connecting piece of the bracket arm is set on the support tube. It is recommended that there are two people available to carry out this procedure. Finally, the safety ring is fixed to the support tube again using the snap ring pliers (figure 13).

e) Now the 3 connector plugs protruding from the bracket arm are drawn a short way out of the aluminium rail and connected to the 3 connector plugs in the support tube (figures 11 and 12). Please ensure that the colours match on the respective plugs.

f) In the final step, the connected cable conduits are pushed back into the support tube and the cover is replaced while the bracket arm is extended, using the size 2.5 Allen key (figure 13).

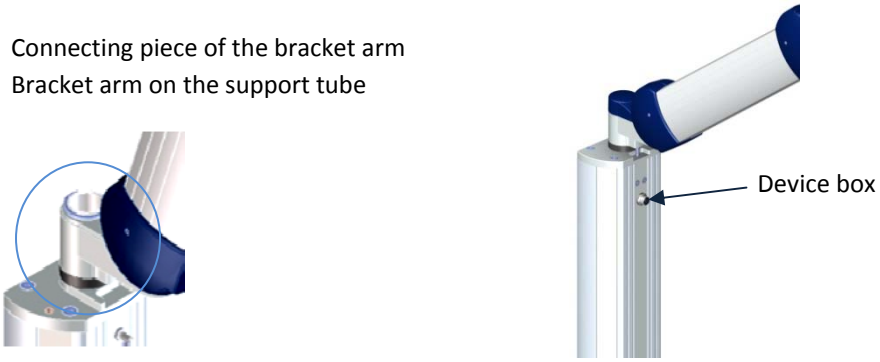


Figure 13: Mounting the bracket arm on the support tube

3.4.1.3 Connecting the storage shelf

The storage shelf can be connected at any height on the support rail (figure 14). For this, the caps are removed from the 4 rotary locking bolts and the nuts are loosened.

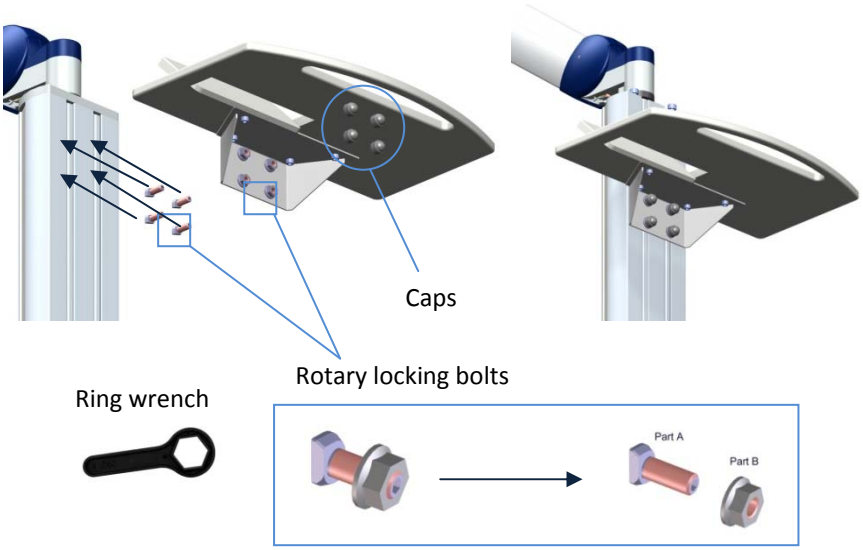


Figure 14: Mounting of the storage shelf onto the support rail of the mobile frame

The 4 rotary locking bolts are then aligned in such a way that they are parallel with the grooves of the support rail. The storage shelf is now placed in position and each rotary locking bolt is locked in place by twisting until they stop (90° clockwise) using the size 4 Allen key. Finally, the nuts are tightened using the size 13 ring wrench and the caps are replaced.

3.4.1.4 Connecting the remote control

There is a plug on the end of the remote control unit's spiral cable. This is connected to the device box located under the bracket arm (figure 13). Pay attention to the correct coding. This concludes the assembly of the LED lamp with mobile frame.
Note that the remote control unit should always be put back in the slot on the storage tray intended for this purpose when not in use (figure 15), in order to avoid the control unit being dropped and to avoid the unit or the spiral cable being damaged.

Figure 15: Remote control unit in its storage slot

3.4.2 Assembling the wall-mounted LED lamp

The following specification regarding the load capacity of the wall bearing the LED lamp must be adhered to by the tradesman or service technician when mounting the support rail for use as a wall bracket:

The wall on which the support rail is being attached as a wall bracket must be able to support a load of 50 kg. Depending on the specifics of the wall, suitable anchor bolts need to be used.

Attachment of the support rail is described in section 3.4.2.2 and in the separate installation instructions and MUST be carried out by a tradesman or service technician.

3.4.2.1 Appliance parts required

a) Wall bracket - consisting of a support rail with the following components and the integrated cable conduits (figure 16):

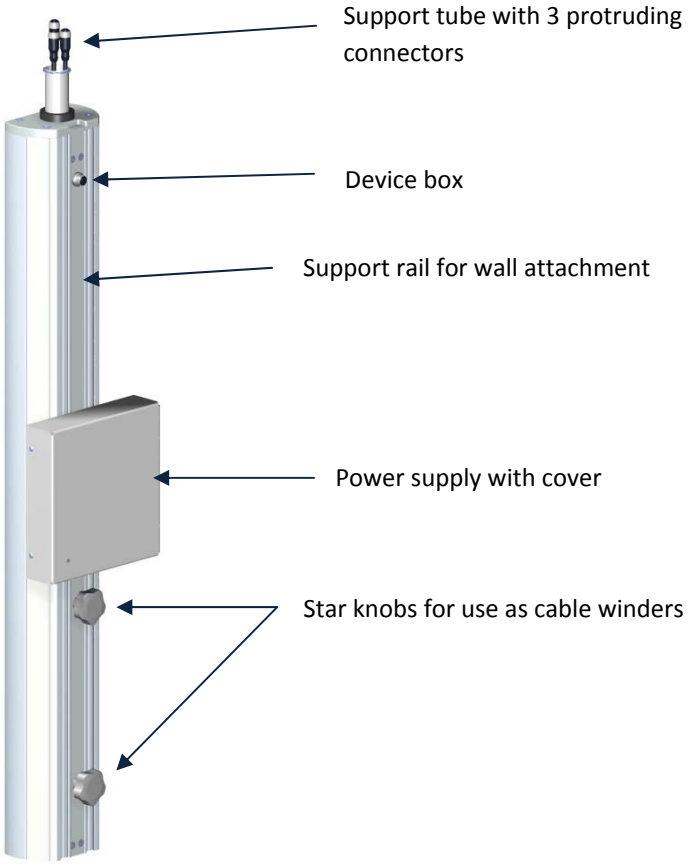


Figure 16: Support rail forming the wall bracket

b) pre-assembled unit consisting of bracket arm, lifting arm and lamp head, the same as with the mobile LED lamp in point 3.4.1.1b

c) See point 3.4.1.1c regarding the support shelf

e) Connecting elements and tools:

- 6 x 60 screws and and 10 x 50 standard plugs
- Rotary locking bolts (bolted to the shelf) with nuts and caps
- Allen key sizes 2.5 and 4
- Phillips screwdriver
- Ring wrench 13
- Snap ring pliers

3.4.2.2 Mounting the wall support rail

a) The first step in the assembly is to remove the support rail's cable covers (figure 17), in order to be able to mark the drilling positions on the wall and carry out the drilling.

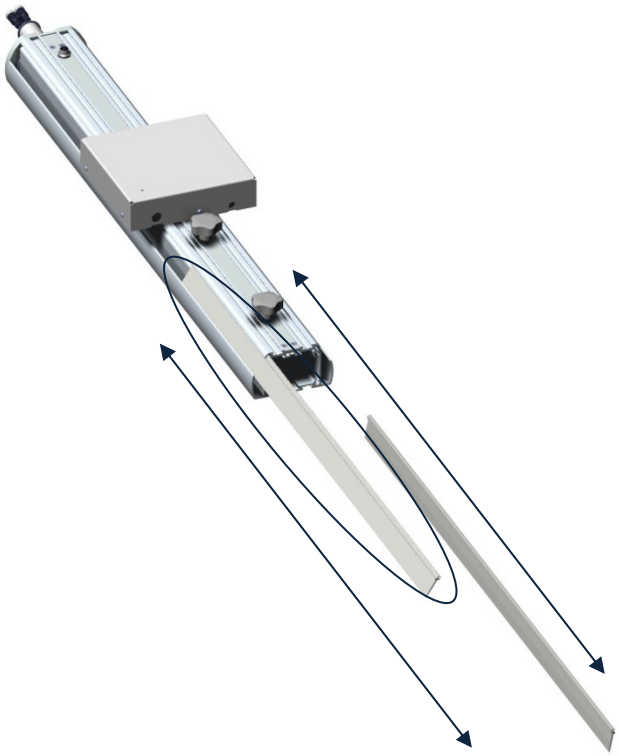


Figure 17: Removal and affixing of the cable covers

b) For attaching the support rail, there are four pairs of holes in the support rail with spacings between the holes in each pair of 105 mm. The first pair is located 125 mm below the upper end of the rail and the interval between the pairs of holes is 250 mm (figure 18). The locations for drilling can now be marked on the wall.

The holes can then be drilled in the wall. Caution: The accompanying anchor plugs (10 x 50) intended for attaching the rail are intended for 10 mm holes, but can only be used for solid walls. Special anchor plugs should be used for other walls.

c) Then screw on the support rail using the accompanying screws (6 x 60) and a Phillips screwdriver (figure 19). Ensure during this process that the cable conduits are not damaged. Then re-affix the cable covers to the support rail (figure 17).

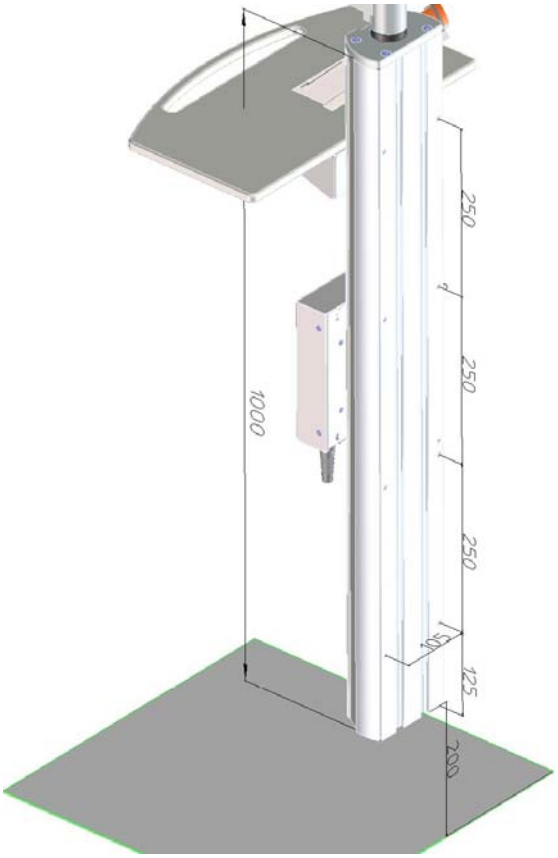


Figure 18: Position of the pairs of drill holes on the support rail rail on the wall

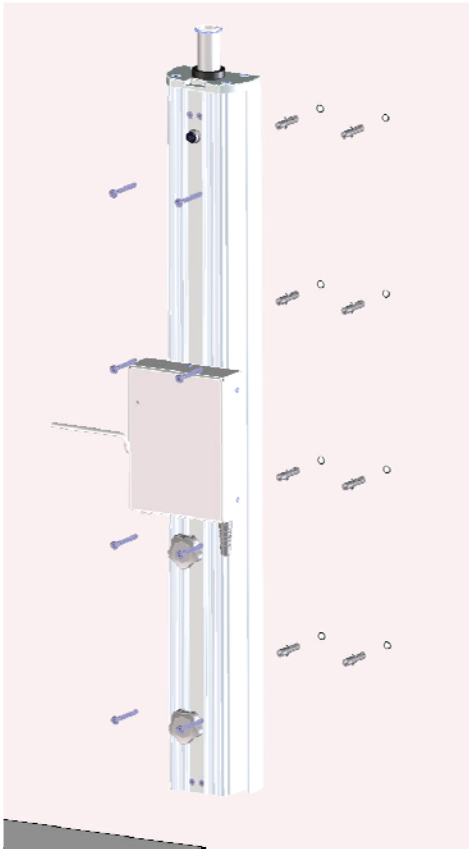


Figure 19: Attaching the support Support rail on the wall

All further steps of the assembly must be carried out by trained service technicians from Biofrontera

3.4.2.3 Mounting the bracket arm - lamp head unit on the wall bracket

See mobile model point 3.4.1.2

3.4.2.4 Mounting the storage shelf

See mobile model point 3.4.1.3.
In the wall-mounted model, the storage shelf is attached above the power supply box.

3.4.2.5 Connecting the remote control

See mobile model point 3.4.1.4

The device box is located above the storage shelf on the support rail, which is a difference compared to the mobile model (figure 16).

3.5 Getting started

The power cord can then be plugged in and the appliance can be started up in accordance with the usage instructions.

3.6 Additional information

There are two aluminium star knobs on the support rail of both the mobile and wall-mounted models, which can be used for winding the power cable. In order to avoid a risk of tripping over the cable or the cable being damaged, always wind the power cable around these knobs when the appliance is not in use or if it is being transported. The star knobs have only limited load-bearing capacity, so heavy objects should not be hung on them.
Please contact Biofrontera Pharma GmbH directly in the event of defective appliance or accessory parts. Original replacement parts must be used when replacing defective components. Accessory parts can be ordered from Biofrontera Pharma GmbH (see order numbers under points 3.3 "Appliance and accessory parts“).

4 Operating instructions

4.1 Setting up the LED lamp for the treatment

When positioning the LED lamp for treatment purposes, first position the bracket arm at the required height (depending on whether the patient is lying or sitting down). Using the handle on the lamp head, position the lamp head at a distance of 5 to 8 cm from the area of skin to be treated. There is a scale bar and a distance slider at the end of the lamp head, with the slider set at 5 cm. These two aids simplify the establishment of the correct treatment distance. Prior to starting treatment, the lamp is to be set up in accordance with the operating concept described in the following sections.

4.2 Turning on and operating the LED lamp

Note 1: Always use eye protectors! When the lamp is turned on, everyone present must wear eye protection.
Note 2: Always connect the power before starting treatment.

4.2.1 Turning on the LED lamp

Once the lamp power supply unit has been connected to the socket, press the button on the left side of the mobile remote control to start the device. Attention: This button is used to switch on and not to switch off the lamp. Switching off the lamp is described in section 4.2.2.2.2 "Home Screen".

Figure 20: Remote control

4.2.2 Operating concept for the LED lamp

4.2.2.1 Operating concept design

The lamp has a modern operating concept with a colour display and an integrated, capacitive touch screen. The use of a touch screen and customisable software buttons facilitates an intuitive and easy operation of the lamp. The power button is located on the left side under the remote control spiral cord. On the right side behind the cap there is a USB and network cable port. An external memory may be connected to the USB port. It is also possible to load updates of current software versions or new treatment programs. You can establish a direct connection to the lamp with the test software (software under development) with the help of the network connection. Should you have any questions in this regard, please contact Biofrontera Pharma GmbH directly.

4.2.2.2 LED lamp operation

4.2.2.2.1 Start screen

The Biofrontera corporate logo and software version (SW-Version: 1.2) are displayed during the LED lamp operating system start-up (figure 21). The operating system takes approx. 30 seconds to load.

Figure 21: Start screen

4.2.2.2.2 Home screen

The home screen view appears after starting the operating system. You can select this view by pressing 3 different buttons ("Treatment", "Settings" and "Service") (Figure 22). Switch off the LED lamp by pressing the button.

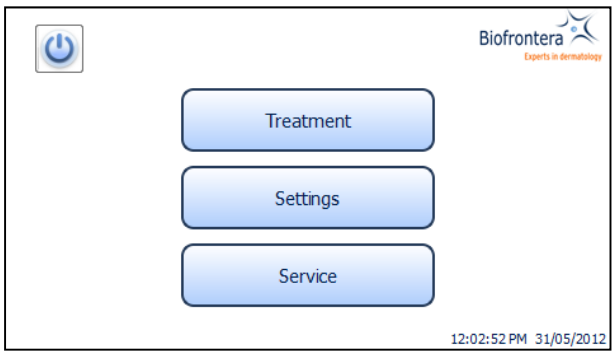


Figure 22: Home screen

4.2.2.2.3 Setting up the LED lamp

The LED lamp must first be positioned over the skin area being treated prior to each PDT therapy. Use the "Start adjustment" button to switch on a weak "Adjustment" light, which marks the irradiated affected area of the skin for the respective lamp position. This adjustment light, distance slider and graduation (scaling) on both lamp faces help to adjust the lamp correctly before starting treatment. Please press the buttons "Stop adjustment" and "Back" after adjusting the lamp to enter the treatment menu again (figures 23 and 24).

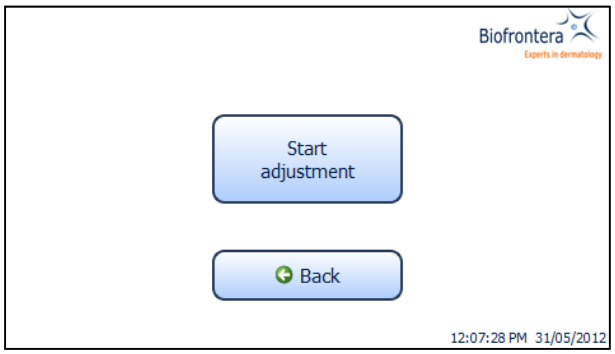


Figure 23: Start adjustment

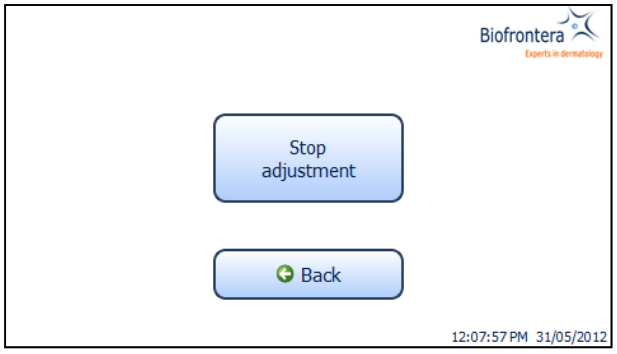


Figure 24: Stop adjustment

4.2.2.2.4 Treatment menu

Each selected profile (for profile selection see figure 25) is depicted as a diagram in the treatment menu. The x- and y-axis specify the treatment duration and beam intensity respectively. For the example shown in figure 25, the affected area is subjected to 10 minutes of permanent irradiation at 100% power.

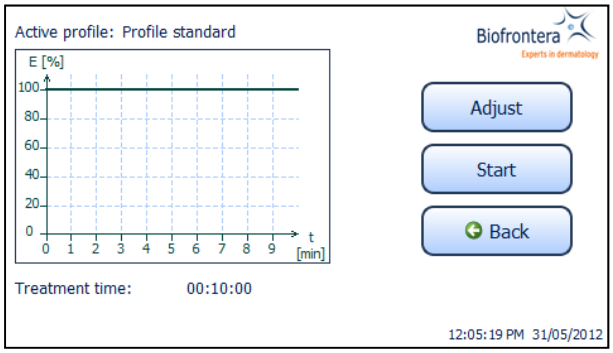


Figure 25: Treatment menu

4.2.2.2.5 Treatment in standard profile

In the treatment menu, you can press the "Start" button to begin the treatment with the configured "Profile standard" at an illumination with high, constant luminous intensity. The entire therapy takes 10 minutes in this variant. The remaining treatment duration is displayed next to the diagram.

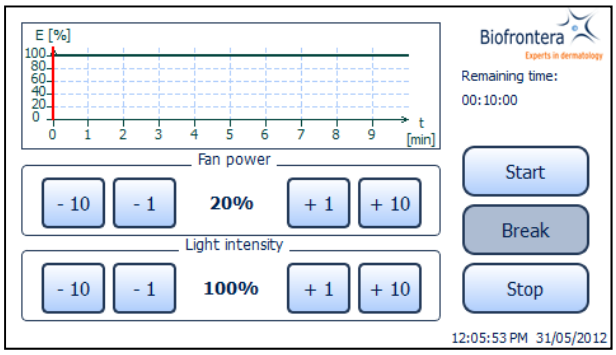


Figure 26: Profile standard

Figure 26 illustrates the "Profile standard". There are three buttons in the bottom right section of the screen. Start the treatment with the "Start" button, you can interrupt the treatment at any time via the "Break" button without setting the clock back. Press the "Start" button again to resume the treatment. End the treatment using the "Stop" button. You will automatically return to the treatment menu.

You can configure the power to the patient fan both before and during the treatment with the plus and minus buttons in increments of 1% or 10%. The patient can thus be supplied individually with exactly the right quantity of air, which can be changed during the illumination. The patient fan continues to run when the treatment is paused. Stop the ventilator by aborting the treatment.

In addition to the fan power, you can adjust the light intensity during the illumination with the plus and minus buttons in the standard menu. This cannot be changed during illumination for all other program profiles. This setting option for the standard profile allows the operating personnel to react individually to potential pain experienced by the patient during the illumination by reducing the light dose. The treatment duration is extended automatically with reduced light intensity, with the result that the same light dosage of 37 J/cm^2 is administered.

4.2.2.2.6 Treatments with other pre-set profiles

You can select other saved program profiles in addition to the "Profile standard". For this purpose, touch the diagram in the treatment menu (see figure 25) to open the selection menu for the saved profiles (figure 27). The following program profiles are preprogrammed ex works and retrievable immediately:

- Profile standard: light intensity is constant from the beginning to the end of the treatment (compare figure 26).
- Profile easy 1: The affected area is illuminated for 90 seconds with full light intensity followed by a reduction to 70 %.
- Profile easy 2: The affected area is illuminated with 30% light intensity followed by an increase to full light intensity within 3 minutes.
- Profile slow interval: constant variation with full light intensity for 2 minutes and a 1 minute pause (without light).
- Profile medium interval: constant variation with full light intensity for 30 seconds and a 15 second pause (without light).
- Profile fast interval: constant variation with full light intensity for 10 seconds and a 5 second pause (without light).

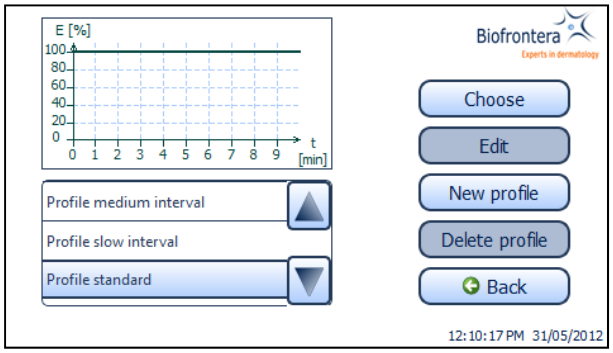


Figure 27: Profile selection menu

The same light dosage of 37 J/cm^2 is achieved with all profiles automatically.

Figure 28 shows a selected profile by way of example. The buttons "Start", "Pause" and "Stop" for the treatment are described above as per the standard profile.

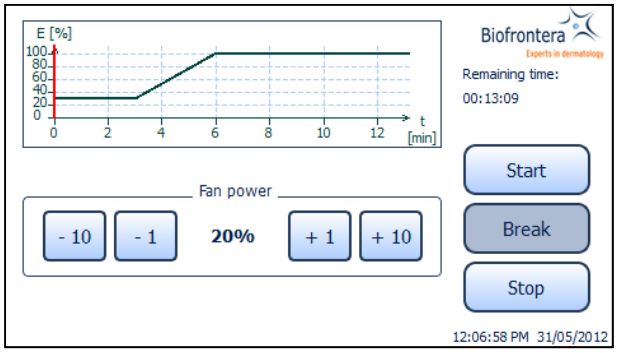


Figure 28: Profile easy 2

The profile is also shown here during the entire treatment. The remaining treatment duration is represented in the right section of the screen. You can change the fan power during the illumination as desired. Unlike the standard program, you cannot, however, deviate from the pre-configured luminous intensity during the illumination.

4.2.2.2.7 Programming new or changing existing profiles

New profiles can be programmed directly into the operating unit or imported via a USB stick. You can change or delete existing profiles flexibly.

To create new profiles into the operating unit, press the field "new profile" in the profile selection menu (see figure 27). A new menu opens allowing you to choose between programming or importing a new profile (figure 29).

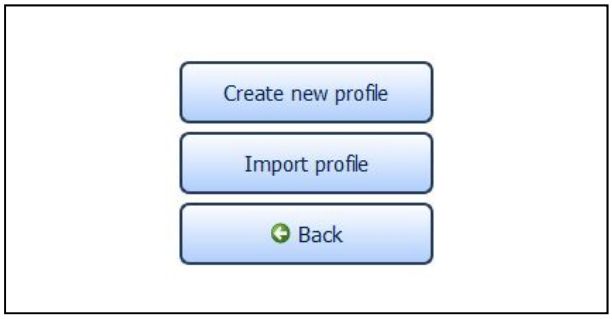


Figure 29: Create/import new profile

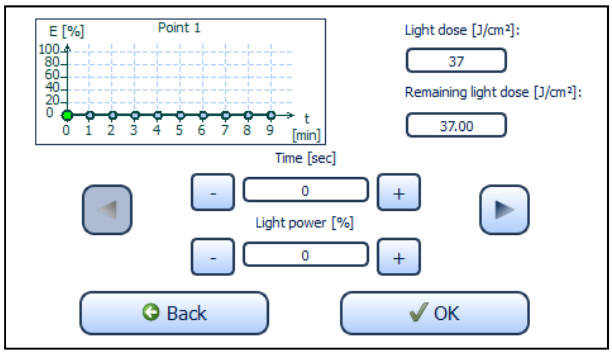


Figure 30: Menu programming new profiles

The menu to program or change profiles opens after you have selected "Create new profile". The menu comprises a diagram in which 10 variable points are represented. The point currently active is marked in green. An input field for the entire light dosage and a display field for the remaining light dose are shown to the right next to the diagram. In the lower part of the screen there are two input fields for the treatment duration and light output (light intensity, brightness), two green arrows right and left to change between points and two buttons to cancel or save ("Back" and "OK").
Apart from point 0 where only the light output can be changed, you can now adjust the duration and light output for each single point. The distance between point 0 and 1 is 1 minute. To configure, select the respective points with the arrow keys and adjust the desired light output and duration either with the plus or minus keys or via direct input by touching the input field. You can proceed in the same way with all ten points. If you configure different light outputs for two consecutive points, the light output during the period of time configured for the point at the front end changes continuously. Two points must be configured at the same time but with different light outputs in order to obtain an abrupt change in the light output. You can either enter the treatment duration for point ten manually or you can allow the software to determine the required time after entering the desired illumination dose by pressing the "Split" button. The button "Split" only appears when point ten is selected and when the light outputs for points nine and ten are not set to zero.

When you have finished editing all points, save the profile with the "OK" button. The "Back" button cancels the programming. All settings are lost when you confirm and close the warning message. Programming for profiles requiring more than ten points cannot be programmed on the operating unit and must be requested from Biofrontera.

To edit a profile, select the desired profile (see figure 27) and press the "Edit" button. A menu for programming or changing profiles will open (figure 30), the use of which has already been explained in the previous section. The selected profile is now shown and can be changed as described.

4.2.2.2.8 Importing new profiles

To import a new profile, plug in a USB stick with the saved profile into the operating unit. Select the field "Import Profile" (see figure 29) to open the corresponding menu (figure 31). Should there be no USB stick inserted when selecting this field or no profile available on the stick, a warning message will appear. If profiles are available, another menu will open where you can select the profiles for import.

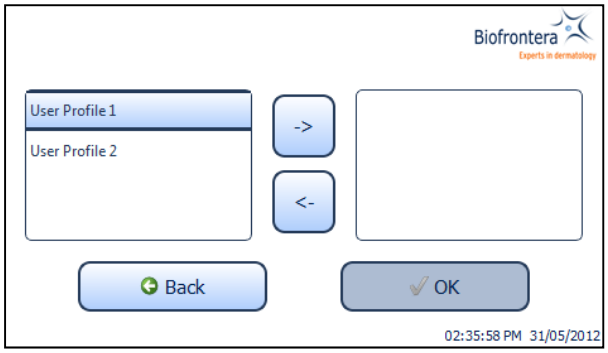


Figure 31: Import profile

The profiles are shown in list boxes: to the left the profiles on the USB stick and to the right the selected profiles. You can select a desired profile by tapping on it in the left list. Add with the middle arrow keys. Import the selected profiles by pressing the "OK" button. Return to the profile selection menu with the help of the "Back" button.

4.2.2.2.9 On-Screen keyboard

When the input of text or numbers is required, a keyboard will open (figure 32). Use the Shift key to switch between upper and lower case and the "ABC" and "123" to switch between letters and numbers or special characters. You can make corrections with the backspace key. Abort by clicking on the bottom left button. Your input is confirmed and saved with the bottom right button.

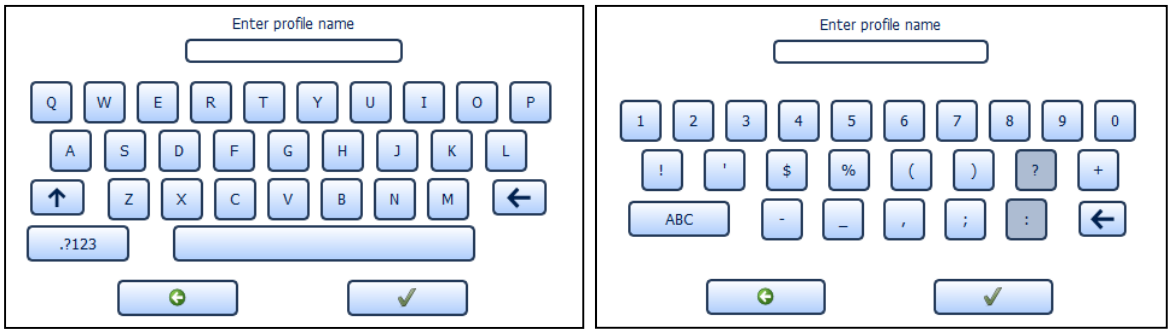


Figure 32: Keyboard

4.2.2.2.10 Settings menu

The Settings menu is invoked (figure 33) by pressing the "Settings" button in the home screen view (see figure 22).

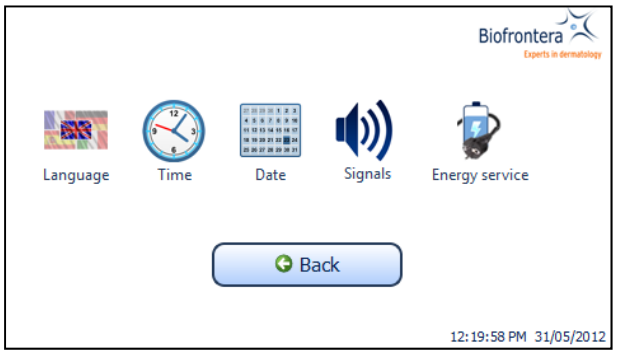


Figure 33: Settings menu

You can configure the following parameters in this menu:

- Language
- Time zone/time
- Date
- Signals
- Energy service

Switch back to the home screen menu via the "Back" button.

4.2.2.2.11 Language settings

Select this by tapping on the desired language. You can use the arrow keys to scroll through the list. You can confirm the selected language with the "OK" button (figure 34). Switch back to the settings menu without changes by pressing the "Back" button.

Figure 34: Language setting

4.2.2.2.12 Time and time zone setting

You can set the time via the plus and minus buttons and confirm via "OK" in the menu represented in figure 35. In the time zone menu on the right you can select and confirm a time zone as well. You will then automatically return back to the settings menu. The summer/winter time changeover occurs automatically with the correct basic setting.

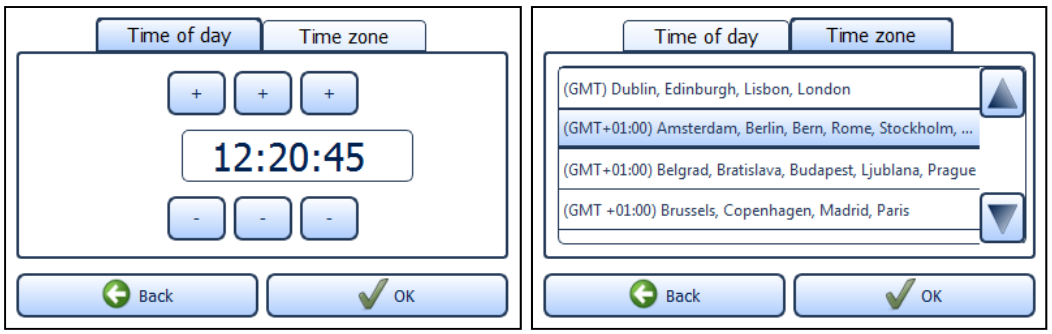


Figure 35: Time and time zone setting

4.2.2.2.13 Date setting

You can select the date by clicking on it and confirm by pressing the "OK" button. You will then automatically return to the settings menu (figure 36).

Figure 36: Date setting

4.2.2.2.14 Sound settings

Activate and deactivate the sound tones for typing, warnings and during the treatment. To do this, select the desired fields and confirm with the "OK" button (figure 37). If "Turn off sound" is activated, all signal tones are switched off.

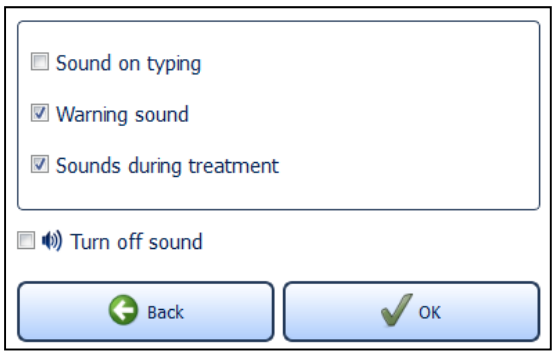


Figure 37: Sound setting

During the treatment, the sound tones serve as a point of reference for the remaining treatment duration for the patient. After 1/4 of the treatment duration a short sound tone will sound, after 1/2 of the time two sound tones, and 3/4 of the time three sound tones. Four sound tones signal the end of the treatment. Close the menu via the "Back" button and the settings menu appears.

4.2.2.2.15 Power management

Providing the Standby function is not manually deactivated via the check box "Never turn off lamp automatically" located at the bottom of the screen, the pre-set lamp will turn off after 10 minutes of non-use (figure 38). You can change this time span in the menu "Energy service" via the plus and minus buttons. The settings are confirmed with the "OK" button and rejected with the "Back" button. In both cases you will return to the settings menu.

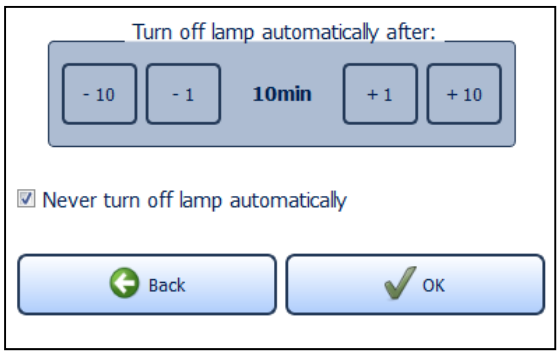


Figure 38: Energy management

If the configured time expires, a request appears for 10 seconds asking if you wish to prevent shut down. The LED lamp turns off automatically upon expiry of 10 seconds.

4.2.2.2.16 Service menu

Authorisation is required to access the service menu. This can occur either by entering a service password or plugging in a service USB stick. This service is carried out by professionals trained for this by Biofronteras only.

5 Dealing with error messages

Biofronteras medical lamp has an integrated monitoring function. In the event of a fault, an error message will appear in the message display. Possible error messages are set out in the table below.

Error message	Possible causes	Measures
Lamp overheated!	• The temperature of the surrounding environment is too high. • The ventilators or ventilator slits are blocked. • The air inlets or outlets are adversely affected.	Wait until the standard temperature has been reached. Check the ventilator and test the air inlets and outlets. Remove any visible foreign bodies which may be present. Please inform Biofronteras' qualified personnel in the case of damage to the cooling system.
Service required!	• The maximum number of operating hours has been reached → Calibrate	Contact Biofronteras Service personnel or Biofronteras directly, so that a service can be carried out.
Lamp error! Please inform yor supplier.	• Some of the LEDs have malfunctioned.	Further treatments may be carried out. You should, however, inform qualified Biofronteras personnel.
Lamp error! Treatment no longer possible.	• Too many LEDs have malfunctioned. Sufficient illumination can no longer be guaranteed.	Contact the Biofronteras service personnel immediately or Biofronteras directly.
Communication error!	• Cable breakage in the remote control spiral cord. • Poor contact between the remote control connection plug and the conduit box.	Inform Biofronteras' qualified personnel to remedy the fault.
Lamp not calibrated!	• The lamp is not calibrated. • Improper calibration.	Please inform Biofronteras' qualified personnel immediately.

If your LED lamp no longer functions correctly for some unknown reason, you should proceed as follows:

- Remove the power supply unit for half a minute from and then re-plug back into the socket (software reboot).
- Turn back on the lamp with the remote control and verify functionality.

Should the fault occur again, please contact Biofrontera Pharma GmbH immediately. The lamp may not be used until the fault has been rectified.

For all other malfunctions and difficulties with operation please contact the field service employee from Biofrontera responsible for your area immediately or contact Biofrontera Pharma GmbH directly. You will find the contact details on page 2.

6 Servicing

Servicing may only be performed by Biofrontera. Please schedule a service with Biofrontera as soon as a service message appears on your display. Your LED lamp should be service-free for the first years. Services are required after approx. 12.000 operating hours or a maximum of 2 years. After 10.000 operating hours an appropriate message appears on the operating unit. After 12.000 operating hours or 2 years following the last service at the latest the LED lamp switches off automatically. The lamp may still be turned on. Further treatments can, however, no longer be carried out until the device is serviced once again. The gas springs (pneumatic and tension springs) in the extension and scissors arm should be checked on an annual basis by qualified Biofronteras personnel and readjusted if necessary.

7 Maintenance

7.1 Maintenance of BF-RhodoLED®

The device may under no circumstances be cleaned with aggressive cleaning agents or solvents (e.g. acetone), as these promote wear and tear of the surface (paint coating), safety signs and graduation (scaling) as well as the logo. Do not clean the device with a great deal of water as the lamp has not been declared as watertight and the inboard electronics can be damaged. Please observe the cleaning policies below:

Daily: Wipe the perspex disk on the underside of the lamp head with a damp, soft cloth (e.g. microfibre or cosmetic cloth).

Weekly: Wipe the entire lamp with a soft, dry or damp cloth.

Monthly: Check lamp for possible damage.

7.2 Maintenance of the eye protection glasses

Please observe the cleaning policies for the eye protection below:

Daily: Wipe the eye protection glasses with green filter (for the operator) with a damp, soft cloth (e.g. microfibre or cosmetic cloth).

After each treatment: Wipe the white eye protection caps (for the patient) with a damp, soft cloth (e.g. microfibre or cosmetic cloth) and sterilise with a cloth soaked in alcohol.

Provided that the cleaning of the eye protection complies with these specifications and those contained in the instructions for use there is no expiry date. The eye protection must be exchanged immediately in the case of mechanical damage, as sufficient protection can no longer be guaranteed. The eye protection can be reordered from Biofrontera Pharma GmbH (order no. see page 15).

8 Disposal instructions

Environmental protection and the national waste disposal regulations applicable for these products are to be observed when disposing the lamp including accessories. The lamp only contains harmless substances and falls under the waste electrical and electronic equipment directive. The lamp and accessories can be sent back to Biofrontera Pharma GmbH free of charge or collected by the dedicated service technician. In this case, please do not hesitate to contact Biofrontera GmbH.

9 Technical data

9.1 Regulatory classification

BF-RhodoLED is a medical product of class IIa that meets the requirements of the 93/42/EEC guidelines for marketability in the European market. The medical device has been tested and verified by the notified body BSI Group Deutschland GmbH.

9.2 Electrical connectors

Power supply unit:

- Primary wide-range input 120 – 240 VAC
- Secondary safety extra-low voltage output 48 VDC
- Secondary standby voltage output 5 VDC

Mother board for voltage management and control:

- Supply voltage input 48 VDC
- Standby voltage input 5 VDC plus Standby contact
- RS485 interface
- Output supply voltage HMI board 24 VDC
- 4 x ports LED board 8-pin (2 x LED circuits, temperature (3-pin))
- 4 x connector ventilator (2-pin)

LED board:

- 2 x ports mother board 8-pin (2 x LED circuits, temperature (3-pin))

Human Machine Interface (HMI) for operation:

- Supply voltage input 24 VDC
- RS485 interface

10 Specification

Type	BF-RhodoLED® Medical product IIa; Device of protection class 1 with lamp head declared as type B applied part;
Design variants	LED-lamp with mobile version or wall mounting version
Software Version No.	1.2
Service life of the lamp	Approx. 4 years during continuous operation
Number of LEDs	128
Luminous flux	Max. 6400 (50 x 128) lm at 350 mA/ LED According to factory calibration: approx. 227 mA/LED (= 100%) Deviations: +/- 15 % (261,05/ 192,95 mA/LED at 5 cm treatment distance.
light dosage of the pre-configured program	All pre-configured programs have been adjusted in such a way that at 6 cm distance in a wavelength range of 635 +/- 9 nm with an light dosage of 37 J/cm^2 is administered.
Operating hours until next calibration	After 12.000 operating hours or a maximum of 2 years. After 10.000 operating hours a message appears that a service is pending. After 12.000 operating hours or 2 years the lamp switches off automatically.
Average wave length	Approx. 635 +/- 9 nm
Adjustable light dose	1 to 99 J/ cm^2
Illuminated area	An area of 8 x 18 cm is illuminated. The effective treatment area is 6 x 16 cm, as there is a drop in beam intensity in the peripheral areas.
Radiation intensity	Approx. 77 mW/cm^2 (= 100%) Deviations: +/- 15 % (88,55/ 65,45 mW/ cm^2 at 5 cm treatment distance
Transport and storage conditions	Temperature: -30°C to +80°C Atmospheric pressure: 500 hPa - 1060 hPa Relative humidity: 10% - 90%, non-condensing
Operating conditions	Temperature: 0°C to +40°C Atmospheric pressure: 500 hPa - 1060 hPa Operational altitude: ≤ 2000 m above NN Relative humidity: 10% - 90%, non-condensing This PDT lamp is suitable for continuous operation!
Maximum temperature of the applied part's perspex disk for specified use	Approx. 71 °C
Operating voltage	120 – 240 VAC, 50/60 Hz
Output voltage	48 VDC
Power consumption	In calibrated normal operation: approx. 140 VA In standby mode: approx. 85 VA
Over-voltage category	II
Degree of contamination	2

Material group (CTI)	IIIb
Protection class	IP20
Total lamp weight	Mobile variant approx. 44 kg; variant wall mounting approx. 17 kg

For further information, you can obtain the specification/technical manual of BF-RhodoLED® directly from Biofrontera Pharma GmbH.

11 Labelling instructions

11.1 Labelling instructions on the lamp

The product sticker is located either on the reverse side of the mobile foot in the case of the mobile version or on the power supply cover box in the case of the version with wall mounting. It contains manufacturer and product specifications (classification, serial and order number and the power supply used) as well as IP (Ingress) protection and the CE-marking with the BSI Group Deutschland GmbH mark.

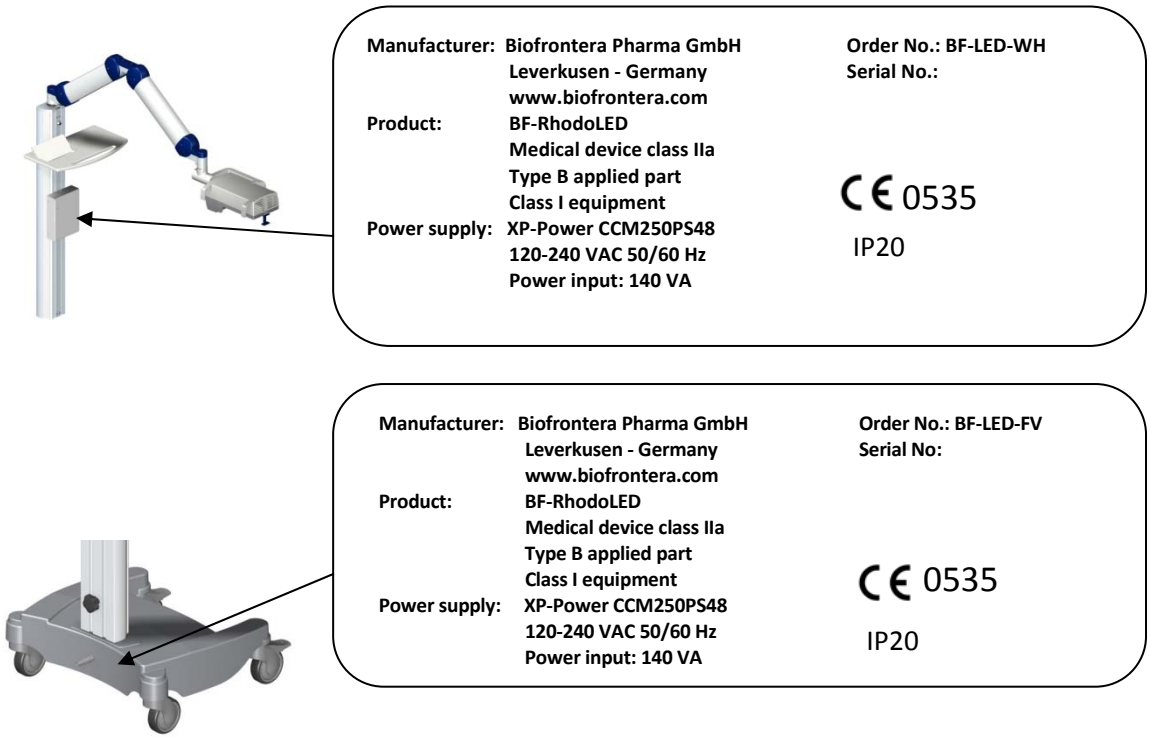


Figure 39: Product sticker

Sticker with warning instructions, special disposal instructions and further instructions are represented in the following figures 40 to 43.

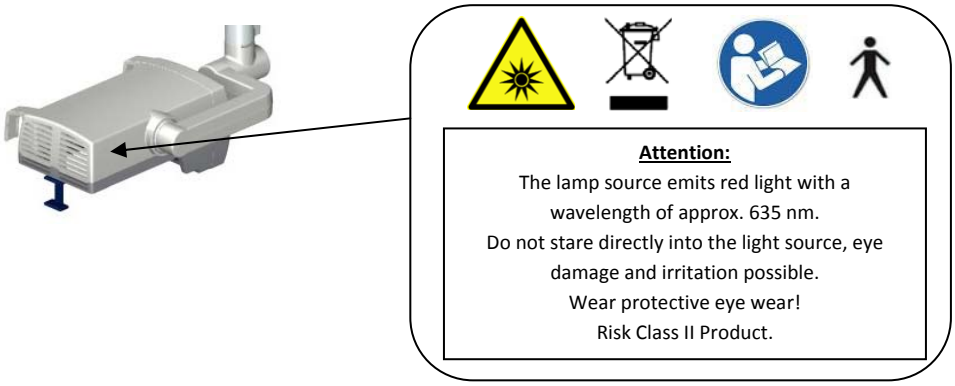
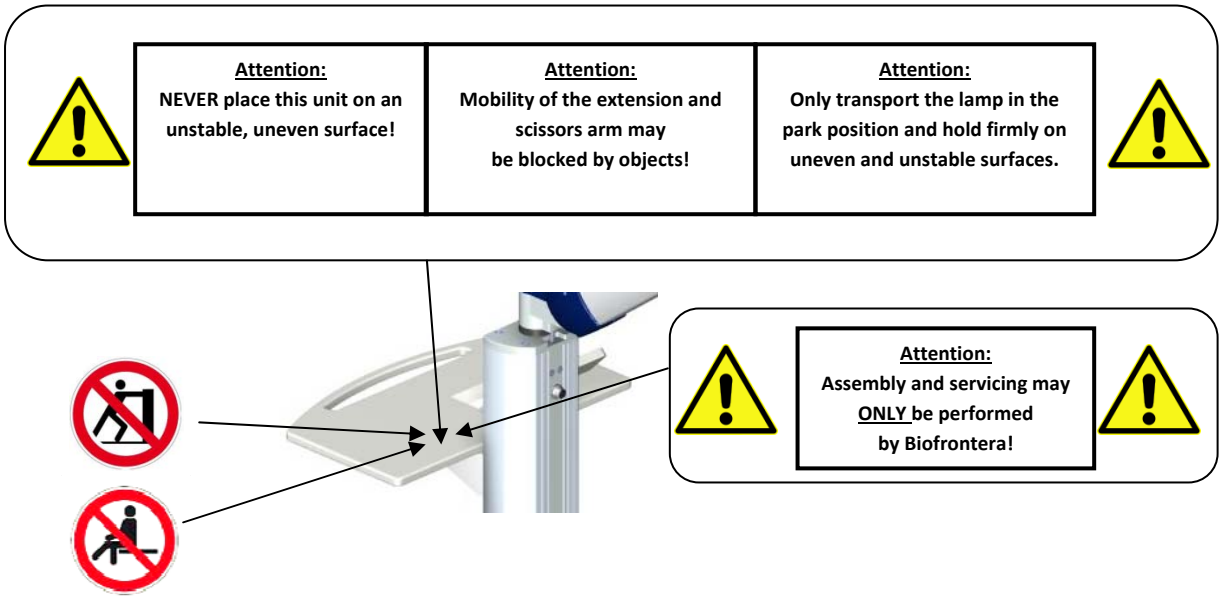


Figure 40: Warning instructions and notes on the lamp head for both design variants

a)



b)

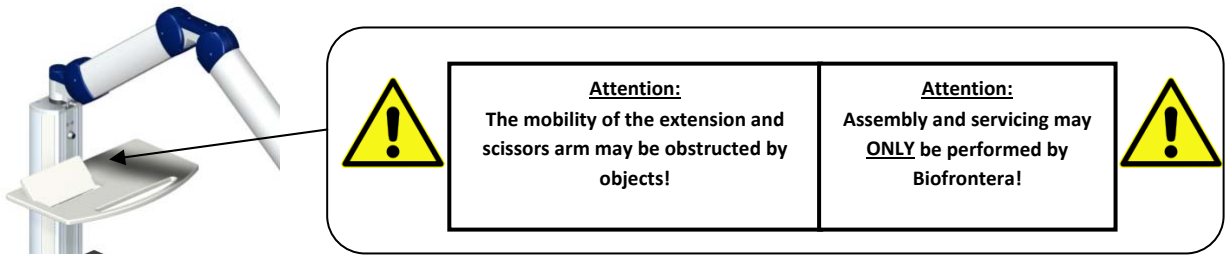


Figure 41: a) Instructions on the storage shelf of the wall mounted version
b) Instructions on the storage shelf of the wall mounted version

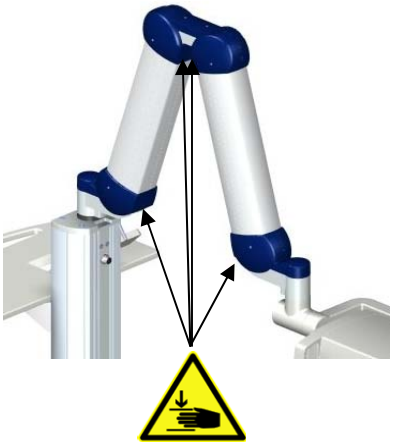


Figure 42: Instructions on the risk of finger trapping in the extension and scissors arm for both design variants

4 Instructions for existing ground connector connections (see figure 43) are located:

- Mobile version: next to the grounding screws, which are located within and next to the power supply cover box beneath the mobile foot respectively
- Wall mounted version: next to the grounding screws, which are located inside the cover box
- for both design variants: one extra on the power supply cover box

Figure 43: Instructions for ground connector connection

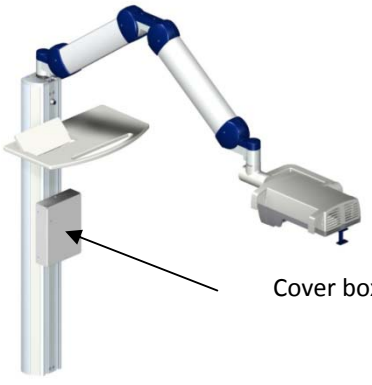


Figure 44: Wall mounted version

Figure 45: Mobile version

Instructions on the existing potential compensator conductor are located on the carrier bar (mobile version) or wall rail (wall mounting) beneath the potential compensator conductor, see figure 44.

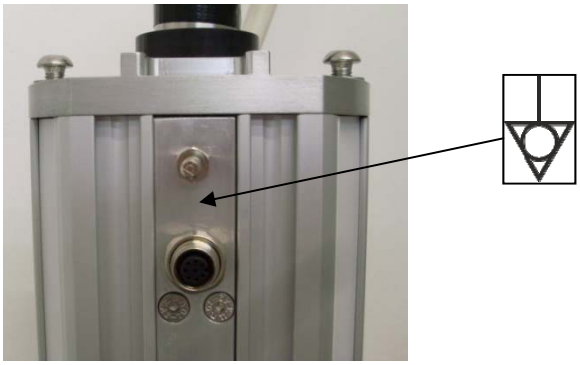


Figure 44: Potential compensator conductor

All depicted symbols are summarised in a table in section 11.2 "Explanation of symbols“

11.2 Explanation of the symbols used on the lamp

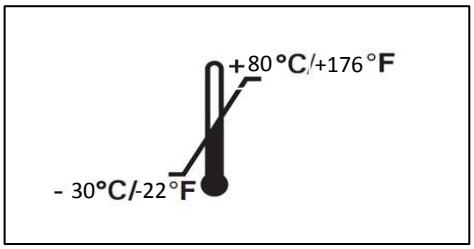
Symbol	Description
	Degree of protection against electric shock; Lamp head is declared as Type B applied part.
	Warning instruction for the light source: Attention: The source emits red light with a wavelength at approx. 635 nm. Do not stare directly into the light source, eye damage and irritation possible. Risk class II product. Wear protective eye wear!
IP20	IP (Ingress Protection): Protection class of the housing against contact, foreign bodies and water 2 = against ingress of solid foreign bodies ≥ 12,5 mm Ø and larger 0 = Not protected against water
	Technical and electric devices must not be disposed of with household waste. Please pay attention to the applicable disposal instructions found in the user manual.
	Symbol for existing ground connector connections
	Follow the instructions for use!
CE 0535	The device complies with the Council Directive 93/42/EEC regarding medical products and bears the CE-marking with the mark of the notified body. Devices with CE marks are subject to quality inspections in accordance with this Directive.

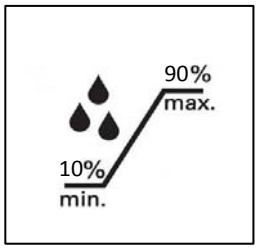
	General warning signs: • Assembly and servicing may ONLY be performed during the service by Biofrontera! • Only transport lamp in the park position! • The mobility of the extension and scissors arm may also be obstructed by objects! • When removing from its packing case, please ensure that the extension and scissors arm is in a taut position under reciprocal pressure in order to release easily. • Caution: heavy, do NOT lift alone. • NEVER place this unit on an unstable, uneven surface!
	Warning sign - risk of trapping fingers!
	Symbol for existing potential compensation conductor *Function/Application:* The purpose of a potential compensation conductor is to connect all conducting, metallic parts of a system to each other by the protective earthing in order to achieve the same electrical potential for the connected parts. Protection against contact voltage is thus guaranteed. Releasing the potential compensation conductor is forbidden. It should be firmly fitted to the support splint. Please observe the requirements for ME-systems set out in EN 60601-1 when using the potential compensation cable (chapter 16).
	Safety instruction: Please do not push. There is a risk that the device may fall over by virtue of the force applied.
	Safety instruction: Please do not sit on the equipment. There is a risk that the device may fall over through the force applied.

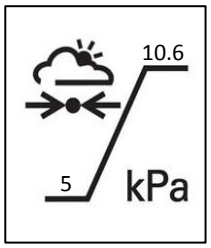
11.3 Labelling instructions on the packaging

- Package 1 and 2a+b: Attention: Protect from moisture and keep dry!

- Package 1 and 2a+b: Attention: Please transport and store at -30°C/ -22°F to +80°C/ 176°F, a relative humidity of 10% to 90% and at an atmospheric pressure of 500 hPa (5 kPa) - 1060 hPa (10,6 kPa).







- Package 1 and 2a+b: Attention: Do not throw the package, damage possible!

- Package 2a: Attention: heavy, do NOT lift alone.
- Labelling of the individual packages with package 1, package 2a and package 2b
- Package 1 and 2b: Attention: Stack to a maximum height of two packages!

- Package 2a: Attention: Do not stack!

- Package 1: Attention: The extension and scissors arm of the units consisting of lamp head, lamp holder and extension and scissors arm is packed in a taut position. When removing from its packing case, please ensure that the extension and scissors arm is in a taut position under reciprocal pressure in order to release easily.

12 Electromagnetic Compatibility (EMC)

BF-RhodoLED® satisfies the EMC requirements of the international standard IEC 60601-1-2:2007-12. The requirements are satisfied under the following conditions described below.
The device is a medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use.
Portable and mobile HF communication equipment can affect the device. Use with unapproved accessories can affect the device negatively and alter the electromagnetic compatibility.
BF-RhodoLED® may not be used directly adjacent to or between other electrical equipment.

Guidelines and Manufacturer's Declaration – Electromagnetic emissions		
BF-RhodoLED® is designed for operation in the electromagnetic environment specified below. The customer or user of the device is to ensure that it is used in such an environment.		
Measured Emission	**Compliance**	**Electromagnetic Environmental Guidelines**
HF emissions CISPR 11	Group 1	BF-RhodoLED® must send out electromagnetic energy in order to perform its intended function. Electronic devices located in the vicinity can therefore be affected.
HF emissions according to CISPR 11	Class B	BF-RhodoLED® is designed for use in all types of premises, including those that are connected directly to a public supply network which also supplies residential buildings.
Harmonic emissions according to IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker according to IEC 61000-3-3	Not applicable	

Guidelines and Manufacturer's Declaration – Electromagnetic Interference Susceptibility			
BF-RhodoLED® is designed for operation in the electromagnetic environment specified below. The customer or user of the device is to ensure that it is used in such an environment.			
Interference Susceptibility Tests	**IEC 60601 Test Voltages**	**Compliance Level**	**Electromagnetic Environmental Guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Flooring should be made from wood or concrete or be covered with ceramic tiles. If the flooring is covered by synthetic material, the relative humidity must be at least 30%.
Rapid transient electrical interference (bursts) according to IEC 61000-4-4	±2 kV for network lines ±1 kV for input and output lines	±2 kV for network lines	The quality of the supply voltage should comply with that which is typical for a business or hospital environment.
Voltage surges according to IEC 61000-4-5	±1 kV normal mode voltage - outer conductor ±2 kV	±1 kV normal mode voltage - outer conductor ±2 kV	The quality of the supply voltage should correspond to a typical business or

	common mode voltage - outer conductor - earth	common mode voltage - outer conductor - earth	hospital environment.
Voltage drops, intermittent power loss and fluctuations in supply voltage according to IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	The quality of the supply voltage should correspond to a typical business or hospital environment. If the user of the device wishes to continue operating the device despite interruptions to the power supply occurring, it is recommended that the device is powered from an interference-free power supply or fed by a battery.
Magnetic field at supply frequencies (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at network supply frequency should comply with the values which are typical for business and hospital environments.
Note: U_T is the AC network supply voltage before applying the test voltage.			

Guidelines and Manufacturer's Declaration – Electromagnetic Interference Susceptibility			
BF-RhodoLED® is designed for operation in the electromagnetic environment specified below. The customer or user of the device must ensure that it is used in such an environment.			
Interference Susceptibility Tests	**IEC 60601 Test voltages**	**Compliance Level**	**Electromagnetic Environmental Guidelines**
Conduction-induced HF interference according to IEC 61000-4-6 Radiation-induced HF interference according to IEC 61000-4-3	3 V $_{\text{Effective value}}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile radio devices are not to be used at a distance to the device including supply lines which is lower than the recommended safe clearance distance calculated for the applicable transmission frequency using the applicable formula.

			Recommended safe clearance distance: d = 1.2√P for 150 kHz to 80 MHz d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2,5 GHz Where P is the nominal output of the transmitter in watts (W) according to manufacturer's information and d is the recommended safe clearance distance in metres (m). The field strength of stationary radio transmitters should be lower than the compliance level for all frequencies as per a local site examination. b: Interference is possible in the vicinity of devices bearing the following symbol. 

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

Note 2: It is possible that these guidelines may not be applicable in all cases. The emanation of electromagnetic quantities is influenced by absorption and reflection of buildings, objects and people.

a: Theoretically, the field strength of stationary transmitters such as, for example, base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters cannot always be precisely predetermined. An study of electromagnetic phenomena of the site should be conducted in order to determine the electromagnetic environment with respect to the stationary transmitters. If the measured field strength at the location in which the device is to be used is found to exceed the compliance level stated above, should the device be monitored, it may be necessary to adopt additional measures such as, for example, changing the orientation or the position of the device.

b: Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than $[U_1]$ V/m.

Recommended safe clearance distances between portable and mobile HF-telecommunication equipment and the BF-RhodoLED®

BF-RhodoLED® is intended for use in an electromagnetic environment in which HF interference is controlled. The customer or user of this device is able to assist in preventing electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunication equipment (transmitters) and the device - depending on the maximum power output of the communications device as indicated below.

Nominal Power of the Transmitter W	**Safe Clearance Distance, depending on the Transmission Frequency m**		
	150 kHz to 80 MHz d = 1.2√P	**80 MHz to 800 MHz d = 1.2√P**	**800 MHz to 2.5 GHz d = 2.3√P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximal nominal output is not provided in the above table, the recommended safe distance d in meters (m) can be calculated using the the formula belonging to the respective column, whereby P is the maximum nominal power output of the transmitter in Watts (W) as defined by the transmitter manufacture.

Note 1: at 80 MHz the higher frequency range applies.

Note 2: It is possible that these guidelines may not be applicable in all cases. The emanation of electromagnetic quantities is influenced by absorption and reflection of buildings, objects and people.