

RhodoLED[®] XL

User Manual

Manufacturer: Biofrontera Pharma GmbH
Distributor: Biofrontera Inc.

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Biofrontera Inc. et al v. Sun Pharmaceutical et al

Sun Pharmaceutical's Exhibit 2043

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Foreword

Thank you for choosing the RhodoLED[®] XL LED lamp for your photodynamic therapy. RhodoLED[®] XL has been developed in accordance with applicable technical standards to provide high energy efficiency as well as constant light emission at the desired wavelength.

Your lamp must be installed and maintained by a qualified Biofrontera technician and used only in accordance with the instructions in this manual. You may request the latest printed version covering this model from Biofrontera at any time.

Our drug Ameluz[®] and medical device RhodoLED[®] XL have been approved in combination for photodynamic therapy; the only approved use of our lamp is in combination with Ameluz[®] gel. This user manual provides important RhodoLED[®] XL product details, precautions and warnings, and operating instructions. For Ameluz[®], please use its US prescribing information. The Ameluz[®] prescribing information includes information on how to use the gel along with contraindications, warnings and precautions and dosage and administration.

Thorough reading and use of both this user manual and the Ameluz[®] USPI is required prior to treatment.

Our combination Ameluz[®]/RhodoLED[®] XL for photodynamic therapy is only to be used by physicians or healthcare professionals.

For further questions about Ameluz[®], RhodoLED[®] XL or the combination therapy please contact your sales representative or Biofrontera (**Ameluz-US@biofrontera.com**). See contact information below or visit us at <http://www.biofrontera.us.com/>

Sales representative:

Name: _____

Tel.: _____

E-mail: _____

Biofrontera Inc.

**120 Presidential Way
Suite 330
Woburn, MA 01801
USA
Phone: (844) 426-3589**

Warranty and Disclaimers

Please see the terms and conditions of your contract for this information.

Manufacturer

Biofrontera Pharma GmbH, Hemmelrather Weg 201, 51377 Leverkusen, Germany

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1 Intended Use

RhodoLED[®] XL is a red light-emitting LED lamp, which is used exclusively in combination with Ameluz[®] gel for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.

2 RhodoLED[®] XL - General Description

RhodoLED[®] XL is comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. The device is connected to the mains via a fixed mains supply cable.

3 Warnings and Precautions



The RhodoLED[®] XL has been developed for use in photodynamic therapy in combination with Ameluz[®] gel (excitation wavelength 635 nm). Any other use or combination of use is prohibited.



During PDT side-effects such as application site erythema, pain, irritation, edema, pruritus, exfoliation, scab, induration and vesicles may occur. For further information please see Ameluz[®] USPI chapter 6.



The user manual must be read carefully prior to using the RhodoLED[®] XL.



The RhodoLED[®] XL may only be used by healthcare professionals who have received adequate training in its use.



Bright light, do not stare into the light source



Protective eye wear must be used by patient, healthcare providers and any persons present during the illumination period.

Do not stare in the LED beam. LEDs are classified in the exempt group according to IEC 62471:2006.



**CLASS 1
LASER PRODUCT**

Distance sensor of RhodoLED[®] XL is a class 1 laser product in compliance with IEC 60825-1:2014. A class 1 laser product is safe under all conditions of normal use.

Risk of trapping fingers!



Depending on positioning, fingers can be trapped between LED panels, between LED panels and the holding bracket, between the movable part and the fixed part of the lamp head holding bracket.



Neither the RhodoLED[®] XL nor the power supply unit should be exposed to excessive mechanical stress or serviced by unauthorized personnel. Assembly and servicing may only be carried out by Biofrontera qualified professionals.



In order to avoid the risk of electrical shock, the device may only be connected to a power supply with a grounded connection.



Neither the RhodoLED[®] XL nor its control unit may come into contact with water as this may lead to severe damage or electrical shock (exception: cleaning with a damp cloth).



The RhodoLED® XL should be operated and housed indoors in areas with temperatures between 59 °F and 86 °F (15 °C and 30 °C), and relative humidity of 10 % to 90 %.



Medical electronic devices require special precautionary measures with regard to the electro-magnetic compatibility (EMC); to avoid electro-magnetic disturbances, please do not place the device close to other electrical devices.



There is a risk of tripping over the power cord or the lamp base. When transporting or when device is not in use, unplug and keep the power cord rolled up.



Ensure that the control unit is always returned to parking position to avoid damage during transport.



The control unit should not be exposed to strong external pressure or sharp objects.



A person trained in operation of the RhodoLED® XL must always be present during treatment.



Before treating affected skin area with the topical medication check the proper functioning of the RhodoLED® XL. Do not use a damaged device for treatment.



RhodoLED® XL is intended for operation in non-residential facilities and such like that are connected directly to a public low-voltage supply network that also supplies residential buildings. RhodoLED® XL shall be operated in environments of professional health care facilities except in the vicinity of RF surgical equipment and outside the RF-shielded room of a magnetic resonance imaging system



The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.



Do not place the device in such a way that it is difficult to disconnect the device's power plug from the mains during operation.



The device must be protected against unauthorized use.

Maintenance and initial set up of the RhodoLED® XL must be carried out by authorized personnel. In the event of servicing or set up being carried out by any other party, Biofrontera assumes no responsibility or liability regarding the safety or use of the device.

4 RhodoLED® XL Technical Description

4.1 Light emitting diodes (LED)

RhodoLED® XL is a red-light emitting LED lamp, comprised of three main components, the lamp head, an easily adjustable spring arm, and the mobile base with castors for smooth transport. In addition, the lamp has a convenient touchscreen monitor and aids for positioning the lamp head. RhodoLED® XL has 45 LEDs per panel with a total of 5 panels (225 LEDs), which emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm.

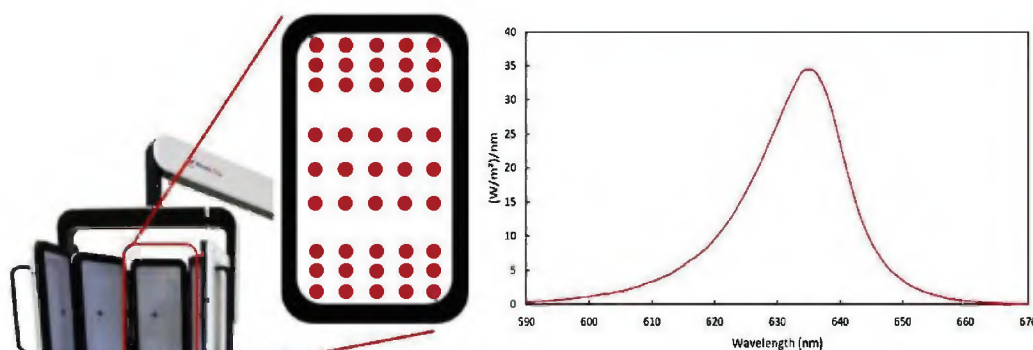


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm² under the following conditions:

- Illumination time of 13.5 minutes
- Treatment distance of 4.9 ± 0.6 inch (12.5 cm ± 1.5 cm)

The illumination area of the LED lamp is 9.06 x 11.42 inch (23 cm x 29 cm) for all panels in a curved shape.

The LEDs are distributed on each panel in a specific way (see Figure 1), such that they are more densely packed towards the upper and lower edges than in the center region of each panel. This distribution optimizes the homogeneity of illumination over the treated skin.

4.2 RhodoLED[®] XL Components

The RhodoLED[®] XL consists of the following main components (Figure 2):

- Lamp head with telescope suspension
- Spring arm
- Control unit
- Mobile base (includes support rail, castors and power supply)

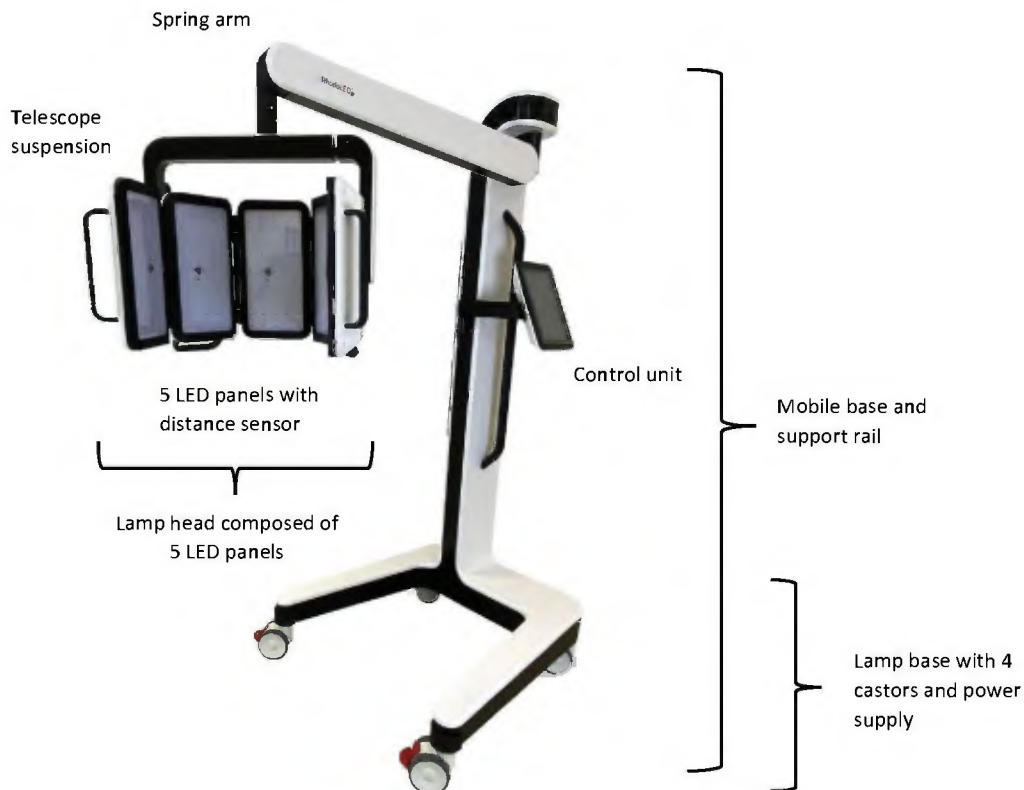


Figure 2: RhodoLED[®] XL main components

5 Operating environment of RhodoLED[®] XL

RhodoLED[®] XL shall be operated in environments of professional health care facilities. For a detailed description in electromagnetic compatibility see chapter 15. RhodoLED[®] XL is intended for operation in non-residential facilities and such like that are connected directly to a public low-voltage supply network that also supplies residential buildings.

6 Eye Protection

Protective eye wear must be used by patient, healthcare providers and any persons present during the illumination period. Do not stare into the LED beam. RhodoLED® XL LEDs are classified in the exempt group product according to IEC 62471:2006. The operator and other persons present must wear protective glasses with a visible light transmission (VLT) of approximately 10 %. The patient must wear eye protection such as disposable eye protection pads or eye caps with an optical density for visible light of 6 or higher. Both options are effective and comfortable for use during treatment.

Note: Eyewear is not part of the medical device. Please carefully read any accompanying usage information before using any eye protection.



Protective eye wear must be used by patient, healthcare providers and any persons present during the illumination period.

Do not stare in the LED beam. LEDs are classified in the exempt group according to IEC 62471:2006.

7 RhodoLED® XL PDT Summarized Step-by-Step Instruction

These instructions should be used in conjunction with detailed operating instructions below (chapter 8). The section titles and numbers listed next to the instruction refer to the detailed instructions that correspond with each step.

Note: Every user of the RhodoLED® XL must be trained in operating the device. The initial training is provided by Biofrontera during set-up of the RhodoLED® XL. Recurrent training is not mandatory but can be provided by Biofrontera employees or other authorized parties. Before treating a patient with Ameluz®, please ensure that RhodoLED® XL is in good working order.

- STEP 1) Plug in the lamp.
- STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter 8.4.3).
- STEP 3) Check the proper functioning of the RhodoLED® XL.
- STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®.
- STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6).
- STEP 6) Select active panels (see chapter 8.4.5).
- STEP 7) Position the lamp and adjust the lamp head over the skin area to be treated (distance 4.9 inch /12.5 cm) (see chapter 8.4.6).
- STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6).
- STEP 9) Start treatment by pressing **Start**, the illumination period begins (see chapter 8.4.9).
Remind the patient to remain still throughout the illumination period.
If audible indicators during treatment are activated, explain the sounds to the patient.

If the patient needs a break, press **Pause** on the screen.

To resume treatment, press **Resume** (see chapter 0).

To abort the illumination, press **Cancel** (see chapter 0).

Always stay with the patient during the illumination period.

STEP 10) At the end of the illumination period, remove patient's protective eyewear and follow further instructions in the Ameluz[®] USPI.

8 Detailed Operating Instructions

Note: Every user of the RhodoLED[®] XL must be trained in operating the device. The initial training is provided by Biofrontera during set-up of the RhodoLED[®] XL. Recurrent training is not mandatory but can be provided by Biofrontera employees. The device must be protected against unauthorized use.



Protective eye wear must be used by patient, healthcare providers and any persons present during the illumination period.

Do not stare in the LED beam. LEDs are classified in the exempt group according to IEC 62471:2006.

8.1 Transport of RhodoLED[®] XL and Spring Arm Lock Function

During transportation the RhodoLED[®] XL must be in the transport position (see Figure 3). For the transport position the spring arm is moved down as far as possible and the locking bolt at the joint between head and spring is moved to the right (Figure 3). In this position, the spring arm is locked and cannot be moved upwards. To release the spring arm lock, push the locking bolt to the left (Figure 3). The locking function is located at the bottom of the spring arm, close to the lamp head connection.

For transport, please ensure that the control unit of RhodoLED[®] XL is placed on the left side (see Figure 3).

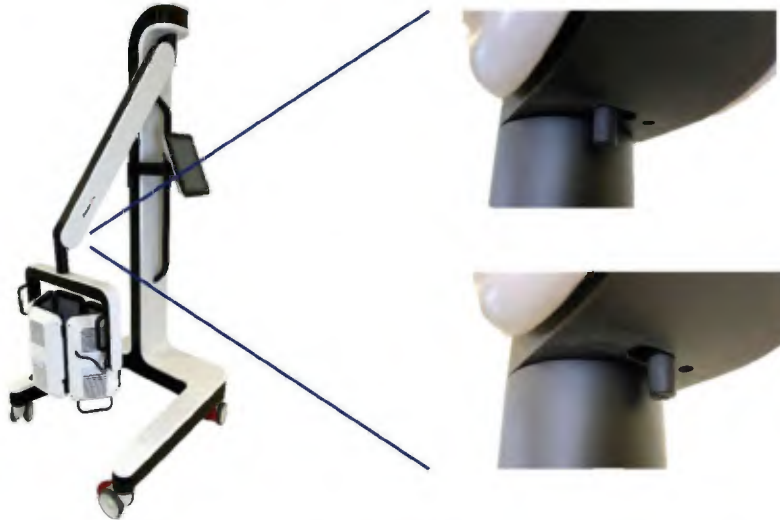


Figure 3: Transport position of RhodoLED® XL and locking function of spring arm. Locking function is located at the bottom of the spring arm, close to the lamp head connection.

8.2 Movement Areas

The swivel range of the spring arm to the left and right of the main axis is $\pm 5^\circ$. The vertical range of the spring arm is 68° . The spring arm with internal gas spring allows seamless adjustment to any height. The lamp head can be rotated by 360° (Figure 4). In addition, the panels can be tilted up to 90° at the holding bracket (Figure 4).

Note: If the spring arm is at the top, it may collide with the LED panels when they are rotated 360° .

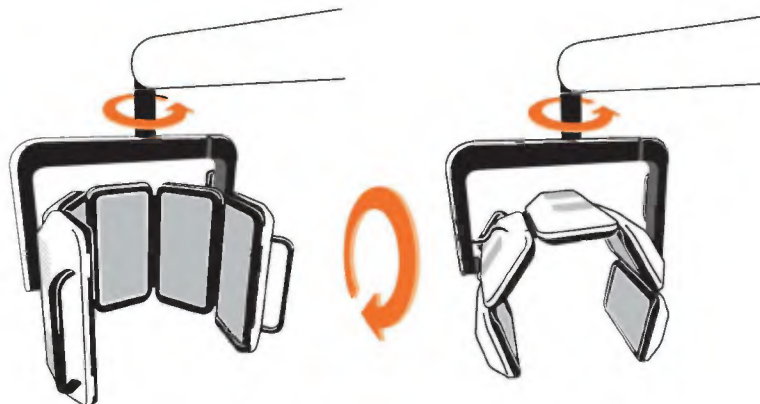


Figure 4: Rotation and tilting of the lamp head.

The orientation of the panels can be changed from a curved shape to an unfolded form by pulling the holding bracket apart (Figure 5).

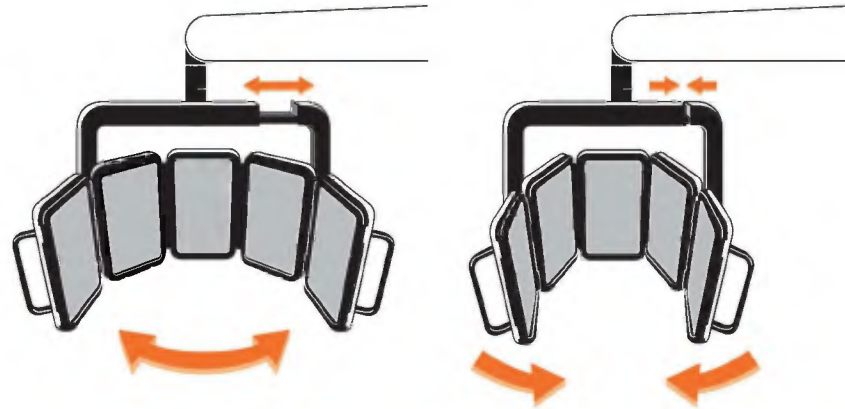


Figure 5: Movement range of the lamp head.

Note: The RhodoLED® XL LED panels should only be used in curved shape and not in a fully unfolded form. This is necessary to ensure the application of 37 J/cm^2 during the illumination.

The control unit can be turned from the left to the right side of the device (see Figure 6). The control unit must be brought completely into the selected position until it snaps into place.

Note: If the control unit is not snapped into position, there may be a collision between the spring arm and the control unit.

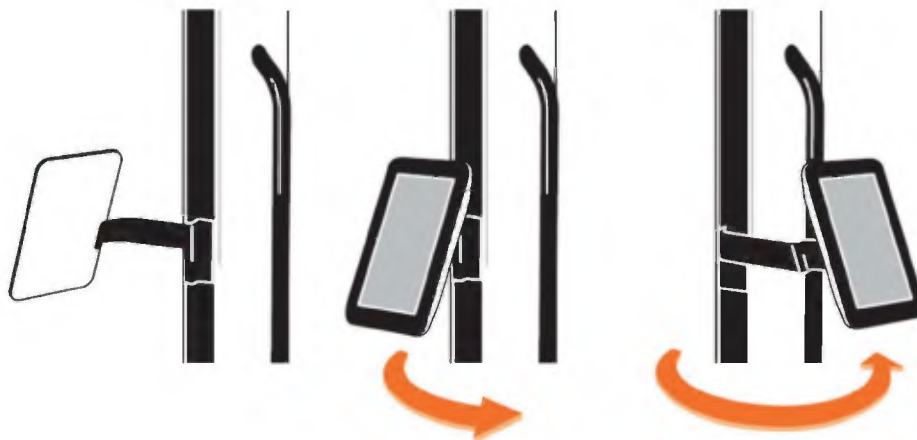


Figure 6: Control unit positions

8.3 Turning RhodoLED® XL On and Off

Note: Before turning on the lamp, the power cord must be plugged in into the power grid. RhodoLED® XL is intended for operation in non-residential facilities and such like that are connected directly to a public low-voltage supply network that also supplies residential buildings.

Note: Do not place the device in such a way that it is difficult to disconnect the device's power plug from the mains during operation.

The RhodoLED® XL is equipped with a cable winding system. To unwind the cable, pull the plug out of the opening of the lamp base. When the cable is being unwound, a clicking sound is heard. The power button is located on the right side of the control unit. With the lamp plugged in, press the power button to start the device.

To power down the device, press the power button and the device shuts down. RhodoLED® XL can also be switched off via the software. To switch the device off, press the software power button in the upper right corner. To rewind the cable, remove the plug from the wall socket and slightly pull on the cable once. Hold the cable loosely in your hand to allow rewinding. The cable winder will pull the cable in automatically until it is fully rolled up. Do not completely release the cable when winding it up to avoid damage of the device.



Figure 7: Control unit of RhodoLED[®] XL with power button

8.4 RhodoLED[®] XL Controls

8.4.1 Control Unit

The touchscreen of the control unit can be used while wearing commercially available examination gloves.

8.4.2 Splash Screen

The Biofrontera corporate logo and software version are displayed during the LED lamp operating system start-up (Figure 8). The operating system takes approximately 10 seconds to load.



Figure 8: Splash screen

8.4.3 Home Screen

The home screen appears after the operating system has loaded.

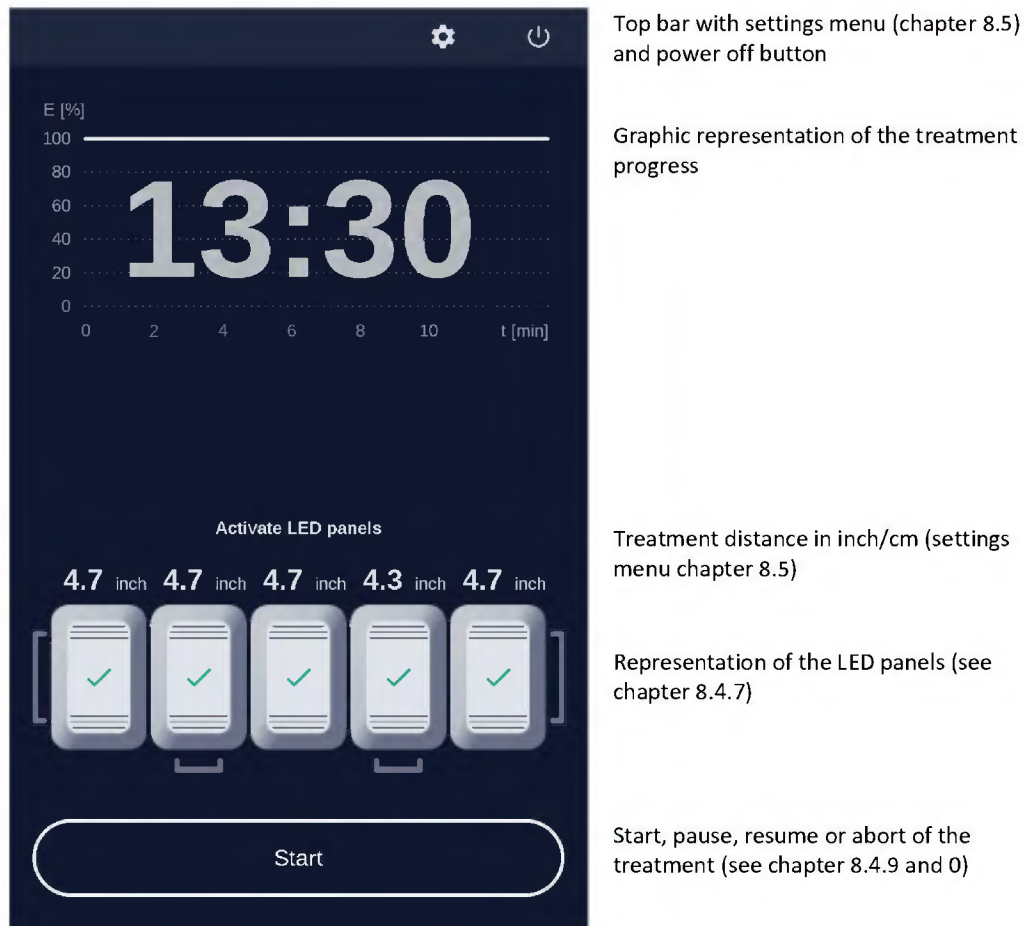


Figure 9: Home screen

8.4.4 The Treatment Profile

The RhodoLED® XL has a fixed LED light intensity which ensures the application of 37 J/cm² within the 13.5-minute treatment time.

8.4.5 Selecting Active LED Panels

The device has 5 LED panels which are also displayed by the software (Figure 10). The illustrated panels are visible from the back side and the corresponding panel of the device can be identified via the handles, starting from the left. All panels are activated by default and can be deactivated via the software. To deactivate LED panels, press on the illustrated panel. For easier orientation, the panel number can also be found at the backside of the respective panel (Figure 11).



Figure 10: Software illustration of RhodoLED® XL LED panels (all panels are activated)



Figure 11: Panel number at the backside of the panel

Deactivated panels are displayed in grey with a power symbol in their centers (Figure 12). Activated panels are highlighted and the current distance to the treatment area is displayed.



Figure 12: Coloring of a switched off panel

8.4.6 Treatment Area

The illumination area of RhodoLED® XL is 9.06 x 11.42 inch (23 cm x 29 cm) when all panels are arranged in the standard curved shape. This usually allows a full-face illumination. However, face and head sizes are subject to strong variations between patients. As a rough guidance, the midlines of the outer two panels marks the outer boundaries of the illumination area (see Figure 13 as guidance).

Note: The RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form. This is necessary to ensure the application of 37 J/cm² during the illumination.

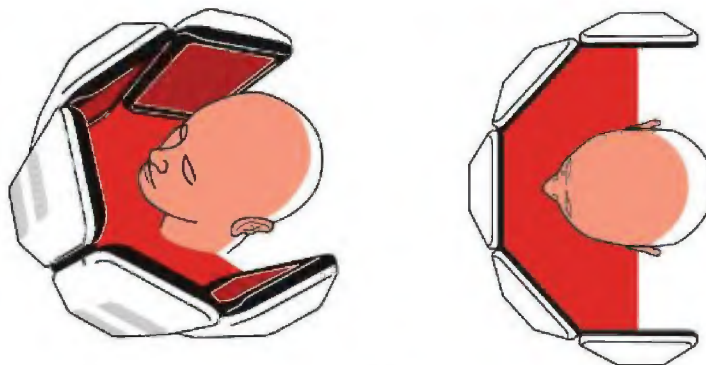


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

Note: If less than 5 panels are used for a treatment, it must be ensured that at least three adjacent panels are used. The treatment area is thereby reduced and reaches from the midline of the one outer panel to the other midline of the other outer panel.

If a treatment with less than 5 active LED panels is started, a message dialog appears which must be confirmed.

8.4.7 Adjusting the Treatment Distance

The correct treatment distance for the RhodoLED® XL is 4.9 ± 0.6 inch (12.5 ± 1.5 cm). Each LED panel is equipped with a distance sensor to allow individual adjustment of all panels. The distance sensor is automatically switched on if the panel is switched on. The current distance of each panel is shown on the control unit display above the panel illustration. The following table summarizes the visualization of the treatment distance.

Note: When starting the treatment, the LED panels that are too close or too far away from the treatment area will nevertheless also light up. To disable an LED panel during the treatment it must be switched off on the display (see Figure 12).

Table 1: Adjusting the treatment distance

Pictogram	Meaning
	Treatment distance is correct for this LED panel (4.9 ± 0.6 inch / 12.5 ± 1.5 cm), adjustment light is/turns on
	Treatment distance is too small for this LED panel. LED panel must be further away from treatment area, adjustment light is/turns off
	Treatment distance is too large for this LED panel. LED panel must be closer to the treatment area, adjustment light is/turns off
	This LED panel is switched off

8.4.8 Adjustment Light

If the correct treatment distance of 4.9 inch (12.5 cm) is set the LEDs of the panel light up at a low light intensity to allow an easy adjustment of the distance and the target treatment area.

The size of the treatment area is 9.06 x 11.42 inch (23 cm x 29 cm) for all panels in a curved shape.

Note: When starting the treatment, the LED panels that are too close or too far away from the treatment area will nevertheless also light up. To disable an LED panel during the treatment it must be switched off on the display (see Figure 12).



Figure 14: Low light intensity for correct adjustment of LED panels.

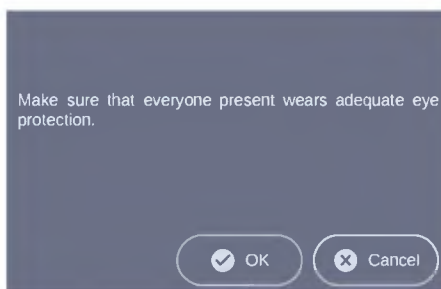
8.4.9 Starting an Illumination

To start a treatment, press the **Start** button. Before starting the treatment make sure every person present wears the correct eye protection (see chapter 6) and confirm the query for eye protection (Figure 15).



Protective eye wear must be used by patient, healthcare providers and any persons present during the illumination period.

Do not stare in the LED beam. LEDs are classified in the exempt group according to IEC 62471:2006.



Press **OK** to start the treatment

Press **Cancel** to go back to the menu

Figure 15: Note on eye protection before starting treatment.

During the illumination, the remaining treatment time is displayed in the diagram. The progress is marked green in the profile and with a green dotted vertical line (**Figure 16**).



Top bar with settings menu (chapter 8.5) and power off button

Graphic representation of the treatment progress

Current treatment distance in inch/cm (chapter 8.4.7)

Active LED panels (chapter 8.4.5)

Start, pause, resume or abort of the treatment (see also 0)

Figure 16: Treatment progress.

8.4.10 Pause, continue, or cancel a treatment



Pause the active treatment press **Pause**

To cancel the treatment press **Cancel**

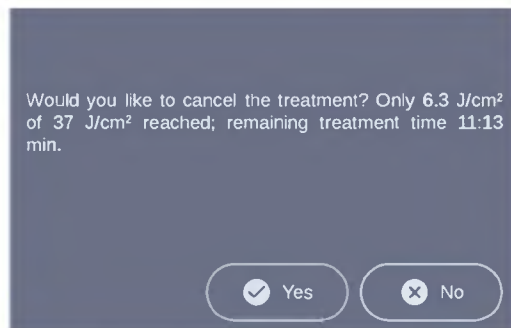


To continue the paused treatment press **Continue**

To cancel the treatment press **Cancel**

Figure 17: Pause, continue, and cancel a treatment.

To abort the current treatment, press the **Cancel** button. The applied light dose and the remaining treatment time is displayed in a query. Confirm the query to cancel the treatment (Figure 18).



Press **Yes** to cancel the treatment

Press **No** to continue the treatment

Figure 18: Cancelled treatment message shows applied light dose and remaining treatment time.

Note: If you cancel prior to the end of the total treatment time, the internal timer will reset. The remaining treatment time will not be saved.

After pressing **Cancel** and **Yes** or upon completion of the treatment the software will automatically return to the home screen.

8.4.11 Audio Signals After Treatment

After completion of the treatment a signal occurs, and the lamp will stop the illumination. Audio signals can be deactivated via the settings menu (see chapter 8.5.4).

Further audio signals occur for queries that must be confirmed and may occur in the event of an error. A description of possible errors can be found in chapter 9.

8.5 Settings Menu



To open the settings menu, select the gear symbol in the upper right corner of the screen.

The settings menu is organized in the tabs **General**, **Service** and **Info**.

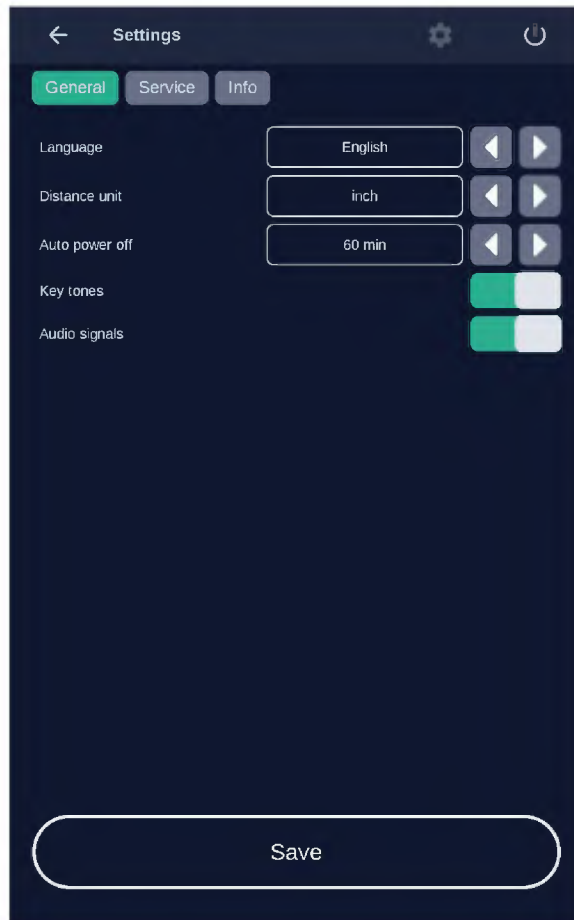


Figure 19: The settings menu is organized in the three main tabs **General**, **Service** and **Info**

8.5.1 Language

Language settings are part of the **General** settings tab. Select a language by tapping on the left and right arrows. The software provides the languages English, Spanish and German.

Confirm the selected language by pressing the **Save** button, to discard the settings leave the menu without pressing **Save**.

8.5.2 Distance Units

Unit settings are part of the **General** settings tab. The distance of the LED panels to the treatment area can be displayed in inch or in cm. Select a distance unit by tapping on the arrows.

Confirm the selected distance unit by pressing the **Save** button, to discard the settings leave the menu without pressing **Save**.

8.5.3 Auto power off

Auto power off settings are part of the **General** settings tab. The auto power off setting is used to set the time after which the lamp is automatically switched off. Values of 15, 30, 60 and 120 minutes can be selected.

Confirm your selected auto power off time by pressing **Save**, to discard the settings leave the menu without pressing **Save**.

8.5.4 Sound Settings

Sound settings are part of the **General** settings tab. Activate and deactivate the audio signals for typing and sounds during the treatment. To do this, activate or deactivate the corresponding sliding switch. A green slider means the sound is currently switched on.

Confirm your selection by pressing **Save**, to discard the settings leave the menu without pressing **Save**.

Note: Warning sounds will be emitted if an error occurs during operation of the lamp. Warning sounds cannot be turned off.

8.5.5 Info-Tab

The system status provides information about the current hardware and software status of the device. This includes information about:

- The serial numbers of the systems core components
- Automatic switch off settings
- Software version
- List of occurred errors (chapter 9)

Note: In case of a malfunction of the device, please have this information available.

8.5.6 Service Menu



Authorization is required to access the service menu. Only authorized personnel can access the service menu. See also chapter 10.

9 Error Messages

The RhodoLED® XL has an integrated monitoring function. In the event of a malfunction, an error message will appear in the message display. Possible error messages are set out in the table below. Please ensure

that you always correctly record the error code when contacting Biofrontera customer service in case of an error message.

Note: even if usage of the lamp is still possible in case of an error, please contact your local sales representative or Biofrontera if an error message persists.

Error code	Possible causes	Measures
001 System error	Error in system of the device	<ul style="list-style-type: none"> - Confirm the system error - Please contact your local sales representative or Biofrontera
002 Communication error	Communication between the control unit and the LED panels disturbed	<ul style="list-style-type: none"> - Confirm the communication error - Treatment can be continued by confirming the message dialog - Please contact your local sales representative or Biofrontera - If there is a permanent error in the communication, no further treatment is possible
003 Panel error 	Error in the control of one or more LED panel Defective LED panels are marked with a red triangle	<ul style="list-style-type: none"> - Confirm the Panel error - Treatment can be continued by confirming the message dialog - Please contact your local sales representative or Biofrontera
004 Distance sensor error	Error in control of the distance sensors	<ul style="list-style-type: none"> - Confirm the Distance sensor error - Treatment can be continued by confirming the message dialog - Please contact your local sales representative or Biofrontera
005 Update process error	The software needs updating	<ul style="list-style-type: none"> - Please contact your local sales representative or Biofrontera
006 Temperature sensor error	Defective temperature sensor or defect in temperature sensor control	<ul style="list-style-type: none"> - Confirm the Distance sensor error - Treatment can be continued by confirming the message dialog - Please contact your local sales representative or Biofrontera
007 Cooling system error	The ventilators or ventilator slots are blocked The air inlets or outlets are adversely affected	<ul style="list-style-type: none"> - Check the ventilators and test the air inlets and outlets - Remove any visible foreign objects which may be present - In case of continuing impairment of the cooling system, please contact your local sales representative or Biofrontera
The treatment is paused due to an overheated LED panel. Wait until normal temperature is reached.	The temperature is too high	<ul style="list-style-type: none"> - Wait until the standard temperature has been reached - Treatment can then be resumed

If your RhodoLED[®] XL no longer functions properly for some unknown reason, proceed as follows:

- Unplug the power supply for half a minute and then plug back into the outlet (This action prompts a software reboot).
- Turn the lamp back on using the control unit and verify functionality.

Should the problem persist, please contact your sales representative or Biofrontera. The lamp may not be used until the problem has been rectified.

For all other malfunctions and difficulties with operation please contact your sales representative or Biofrontera. You will find the contact details on page 2 of the manual.

Please have the system status (chapter 8.5.5) available if you contact your sales representative or Biofrontera.

10 Servicing and repairs

Servicing and repairs may only be performed by Biofrontera-authorized personnel. For RhodoLED[®] XL no spare parts for replacement by the user are available.

Device is not serviced while in use with patients.

If servicing or repairs are done by third parties, RhodoLED[®] XL warranty is void and Biofrontera cannot be held responsible for potential malfunctions of or damages to the device or the patients.

Attention

Setup, Service and Maintenance may only be performed by Biofrontera!

Figure 20: Servicing and maintenance may only be performed by Biofrontera

11 Maintenance and Cleaning

The device may under no circumstances be cleaned with aggressive cleaning agents or solvents (e. g. acetone or highly concentrated ethanol), as these promote wear and tear of the surface (paint coating) and labeling. Please use only a damp cloth when wiping over the labels.

Please avoid allowing any penetration of liquids into the lamp, RhodoLED[®] XL is not waterproof and the electronics inside may be damaged. Do not maintain or clean the device while in use with patients.

Always unplug the lamp prior to cleaning and please observe the following cleaning practices:

Daily: Wipe the plexiglass screen located on the bottom of the lamp head with a damp soft cloth (e. g. a microfiber cloth).

Weekly: Wipe the entire lamp. Do not use a very wet or dripping cleaning cloth. The unit is not waterproof and damage could occur. Weekly cleaning can be carried out using a damp cloth or Multi-Purpose Cleaners (Clorox Healthcare VersaSure Wipes).

Please observe the following checks:

Monthly: Check lamp for obvious visible damage such as damaged cables, worn off labeling, cracks on the lamp housing, etc.
Do not use a damaged device for treatment and please inform your supplier.

12 Disposal Instructions

Follow all local and governmental disposal laws and regulations when disposing of the RhodoLED® XL.

13 Technical Data

13.1 Electrical Connectors

Power supply unit:

- Primary wide-range input 100-120 VAC
- Secondary safety extra-low voltage output 48 VDC
- Secondary standby voltage output 5 VDC

LED controller board:

- Supply voltage input 48 VDC
- 2x CAN interface (2 pin)
- LED board FFC (12 pin)
- Distance sensor FFC (4 pin)
- 2 x connector ventilator (3 pin)

LED board:

- LED controller board FFC 12 pin (3 x LED circuits, temperature)
- Distance sensor FFC (4 pin)

Human Machine Interface (HMI) for operation:

- Supply voltage input 48 VDC (2 pin)
- Secondary standby voltage input 5 VDC (4 pin)
- CAN interface (3 pin)
- USB interface (5 pin, covered)
- Speaker (2 pin)
- Touch controller (4 pin)
- Display backlight (6 pin)
- Display data LVDS (20 pin)
- On/off switch (2 pin)
- MHI module to pillar external connector (9 pin)

13.2 Specification

Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.12.00.3739
Service interval	Biofrontera recommends performing service every 2 years
Number of LEDs	225
Typical peak wavelength	635 nm ± 5 nm
Light dose	Approx. 37 J/ cm ² at 4.9 inch (12.5 cm) distance, 13.5 min
Typical irradiance	approx. 46 mW/cm ² ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	approx. 55 mW/cm ² at 4.9 inch (12.5 cm) distance
Illuminated area	An area of 9.06 x 11.42 inch (23 cm x 29 cm) is illuminated using all panels in curved shape.
Max. deviation of the intensity over the treatment area	Approx. 20 %
Treatment distance	4.9 ± 0.6 inch (12.5 cm ± 1.5 cm) Measuring accuracy ± 0.3 cm (0.1 inch)
Transport conditions	Temperature: -4 °F to +140 °F (-20 °C to +60 °C) Atmospheric pressure: 500 hPa - 1060 hPa Relative humidity: 10 % - 90 %, non-condensing
Storage conditions	Temperature: +59 °F to +95 °F (+ 15 °C to +35 °C) Atmospheric pressure: 500 hPa - 1060 hPa Relative humidity: 10 % - 90 %, non-condensing Maximum storage time 180 days
Operating conditions	Temperature: +59 °F to +86 °F (+15 °C to + 30 °C) Atmospheric pressure: 500 hPa - 1060 hPa Operational altitude: ≤ 4800 m above NN Relative humidity: 10 % - 90 %, non-condensing. RhodoLED® XL must be operated in environments of professional healthcare facilities.
Operating voltage	100-120 VAC, 60 Hz
Output voltage	48 VDC
Power consumption	In normal operation: approx. 750 VA In standby mode: approx. 85 VA
Over-voltage category	II
Degree of contamination	2
Material group (CTI)	IIIb
Protection class	IP20
Size of the lamp	Height 5.76 ft (175.5 cm) Width: 2.51 ft (76.4 cm)

	Depth: 3.19 ft (97.1 cm)
Total lamp weight	165 lb (75 kg)

For further information please directly contact Biofrontera.

14 Labeling and Symbols

14.1 Label on the Lamp Base



Figure 21: Product label (serial number and date of manufacturing vary) with UDI code of RhodoLED[®] XL on lamp base, individual code depends on the serial number and date of manufacturing of the device.



Figure 22: No stepping on the device, no disposal in household waste, information on setup and service.



Figure 23: Instruction for ground connector connection (not visible from the outside)

14.2 Label on LED Panels

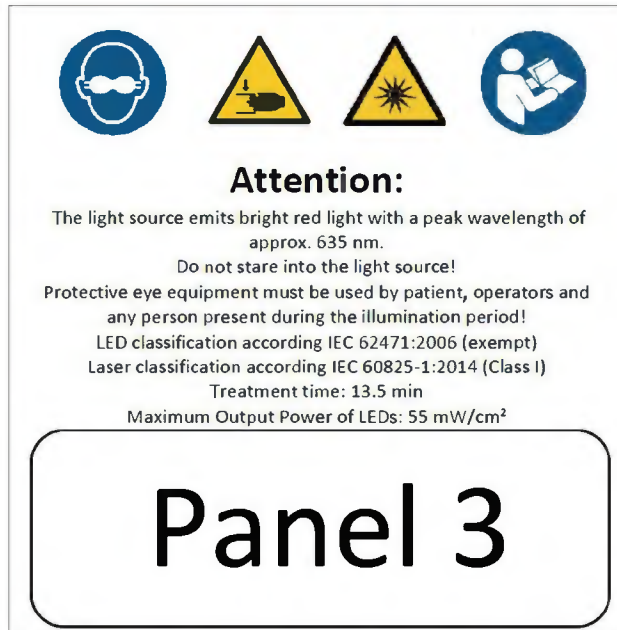


Figure 24: Instruction and notes on the LED panels



Figure 25: LED Panel numbering from Panel 1 to Panel 5

14.3 Description of Symbols

Symbol	Description
	Eye protection is required.
	Distance sensor of RhodoLED® XL is a class 1 laser product. A class 1 laser product is safe under all conditions of normal use.
IP20	IP (Ingress Protection): Protection class of the housing against contact, foreign bodies and water 2 = against ingress of solid foreign bodies $\geq 12,5$ mm $\varnothing$ 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!
	<u>General warning signs:</u> <ul style="list-style-type: none"> • Assembly and servicing may <u>ONLY</u> be performed by Biofrontera • Only transport lamp in the park position • Caution: heavy, do NOT lift alone.
	Warning sign - risk of trapping fingers!
	Bright light, do not stare into the light source
	Do not step on the device.

15 Electromagnetic compatibility

RhodoLED[®] XL complies with the EMC requirements of IEC 60601-1-2:2014 + A1:2020. Other electrical devices can influence the device.

The use of accessories, transducers and cables other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or reduced electromagnetic immunity of the equipment and may lead to incorrect operation. Assembly, service and repairs may only be performed by Biofrontera.

Guidelines and manufacturer's declaration – electromagnetic emissions		
<p>RhodoLED[®] XL is intended for operation in the electromagnetic environment detailed below. The customer or operator of the device should ensure that it is operated in this environment.</p> <p>The emission characteristics of RhodoLED[®] XL allow its use in industrial and hospital and healthcare professional environments (CISPR 11, Class A). When used in a residential environment (for which CISPR 11 normally requires Class B), this device may not provide adequate protection of radio services. The user may need to take corrective action by moving or repositioning the device.</p>		
Emission readings	Conformity	Electromagnetic environment - guidelines
HF emissions CISPR 11	Group 1	RhodoLED [®] XL only uses HF energy for its internal functionality. For this reason, its HF emission is very low and it is not likely that neighboring electronic devices would be disturbed.
HF emissions in accordance with CISPR 11	Class A	RhodoLED [®] XL is intended for operation in non-residential facilities and such like that are connected directly to a public low-voltage supply network that also supplies residential buildings.
Harmonics in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations/flickers in accordance with IEC 61000-3-3	In compliance	

Guidelines and manufacturer's declaration – electromagnetic immunity			
<p>RhodoLED[®] XL is intended for operation in the electromagnetic environment detailed below. The customer or operator of the device should ensure that it is operated in this environment.</p>			
Immunity tests	IEC 60601 test levels	Compliance level	Electromagnetic environment - guidelines

Static discharge in accordance with IEC 61000-4-2	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV and ±15 kV air discharge	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV and ±15 kV air discharge	Floors should be made of wood or concrete or finished with ceramic tiles. If the floor is finished with synthetic material, the relative air humidity must be at least 30 %.
Fast, transient electrical disturbances/bursts in accordance with IEC 61000-4-4	±2 kV for mains lines 100 kHz repetition frequency	±2 kV for mains lines	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Surges in accordance with IEC 61000-4-5	±1 kV voltage outer conductor - outer conductor ±2 kV outer conductor - earth	±1 kV voltage outer conductor - outer conductor ±2 kV outer conductor - earth	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment.
Voltage dips, brief interruptions and fluctuations in the supply voltage in accordance with IEC 61000-4-11	0 % U_T for 0.5 cycles at phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° (applicable only to me equipment connected to single-phase a.c. mains) 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	0 % U_T for 0.5 cycles at phase angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° (applicable only to me equipment connected to single-phase a.c. mains) 0 % U_T for 1 cycle 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycles	The quality of the supply voltage should correspond to that of a typical commercial or hospital environment. If the operator of the device needs functionality to be maintained despite interruptions in the energy supply, it is advisable to run the device on an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field in accordance with IEC 61000-4-8	30 A/m	30 A/m	Mains frequency magnetic fields should correspond to the values typically found in the commercial and hospital environment.
Comment: U_T is the mains AC voltage prior to application of the test level			

Guidelines and manufacturer's declaration – electromagnetic immunity			
RhodoLED [®] XL is intended for operation in the electromagnetic environment detailed below. The customer or operator of the device should ensure that it is operated in this environment.			
Immunity tests	IEC 60601 test levels	Compliance level	Electromagnetic environment - guidelines
Conducted HF disturbances in accordance with IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V ISM bands 0.15 – 80 MHz 80 % AM with 1 kHz	3 V 6 V	Portable and mobile communication devices should not be used in closer proximity of the unit or its cables than the recommended safety distance of 300 mm.
Radiated HF disturbances in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80 % AM with 1 kHz	3 V/m	Interference may occur in the vicinity of equipment marked with the following symbol. 
Comment 1: These guidelines may not be applicable in all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects, and people.			

Recommended safety distances between portable and mobile HF telecommunication devices and the RhodoLED[®] XL.

Portable RF communications equipment (radios, including their accessories such as antenna cables and external antennas) should not be used at a distance less than 30 cm (or 12 inch) from the manufacturer's specified parts and leads of the RhodoLED[®] XL. Failure to do so may result in a reduction in the performance of the device.

RhodoLED[®] XL should not be used directly alongside or between other electrical equipment.

Guidelines and manufacturer's declaration – proximity fields from RF wireless communication equipment		
RhodoLED [®] XL is intended for operation in the electromagnetic environment detailed below. The customer or operator of the device should ensure that it is operated in this environment.		
Service	Frequency range/ discrete frequencies MHz	Compliance level [V/m]
TETRA 400	385	27
GMRS 460, FRS 460	450	29
LTE Band 13, 17	710 745 780	9
GSM 800/900, TETRA 800, iDEN 820, CDMA, LTE Band 5	810 870 930	28
GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4, 25	1720 1845 1970	28
Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	2450	28
WLAN 802.11 a/n	5240 5500 5785	9