Exhibit 4: Infringement Claim Chart for U.S. Patent No. 11,697,028 (the "'028 Patent")

The following chart is based on information known to date. Sun Pharmaceutical Industries, Inc. ("Sun Pharma") reserves the right to amend and update this chart as additional information is obtained and analyzed. Sun Pharma further reserves the right to issue expert reports explaining in detail Biofrontera AG, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera Inc.'s (collectively, "Biofrontera" or "Defendants") infringement of the '028 Patent. The exemplary claim mappings below rely on images and data from the Biofrontera BF-RhodoLED® XL and Ameluz®.

As outlined in the below claim chart, Defendants directly infringe, either literally or under the doctrine of equivalents, at least claims 1, 2, 4–6, 16, 17, 19, 20, and 21 of the '028 Patent through their importation, sale, offer for sale, making, and/or use of the Accused Products. Sun Pharma contends that each element of each asserted claim is literally met unless otherwise indicated. But to the extent that any claim element is found not to be literally met with respect to the Accused Products, Sun Pharma contends that the element is met under the doctrine of equivalents because there are no substantial differences between the Accused Products, and the element and the Accused Products perform substantially the same function, in substantially the same way, to achieve substantially the same result.

Moreover, Biofrontera actively induces its customers (who are not licensed by Sun Pharma to practice the '028 Patent) ("Biofrontera Customers") to use and purchase the Accused Products, such that the Biofrontera Customers directly infringe at least claims 1, 2, 4–6, 16, 17, 19, 20, and 21 of the '028 Patent. For example, Biofrontera provides manuals to the Biofrontera Customers which instruct them to use Accused Products to practice at least claims 1, 2, 4–6, 16, 17, 19, 20, and 21 of the '028 Patent. Biofrontera further assists the Biofrontera Customers in installing, maintaining, testing, and using the Accused Products such that the Biofrontera Customers directly infringe at least claims 1, 2, 4–6, 16, 17, 19, 20, and 21 of the '028 Patent. Biofrontera also markets and advertises the Accused Products. Biofrontera has knowledge of its infringement by no later than the filing date of the *inter partes* review filed by at least Biofrontera AG. *Biofrontera AG v. DUSA Pharms., Inc.*, No. IPR2024-00874 (P.T.A.B. Apr. 30, 2024).

Further, Biofrontera contributes to others practicing at least claims 1, 2, 4–6, 16, 17, 19, 20, and 21 of the '028 Patent because Biofrontera sells and offers to sell the Accused Products for use in practicing the '028 Patent. Biofrontera knows the Accused Products are especially made or adapted to practice the asserted claims and are not staple articles of commerce suitable for substantial noninfringing use.

'028 Patent Claim 1	**Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®**
1[pre] A system for photodynamically diagnosing or treating a patient, comprising:	The BF-RhodoLED® XL is a system for photodynamically diagnosing or treating a patient. For example, the BF-RhodoLED® XL includes an "LED lamp for . . . photodynamic therapy." "Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy." "The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel. . . . Any other use or combination of use is prohibited." The BF-RhodoLED® XL "is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." The BF-RhodoLED® XL's "[i]ntended use" is for "lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp."

RhodoLED® XL

Biofrontera
Deep in dermatology

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 certified 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.

Biofrontera Inc., *User Manual for RhodoLED® XL*, at 2 (Nov. 2021) [hereinafter "BF-RhodoLED® XL User Manual"] (annotated), https://www.ameluz.com/fileadmin/AmeluzUSImages/05-pdf/Ameluz-Full-Prescribing-Information.pdf.

	RhodoLED® XL Biofrontera Deep in dermatology **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. BF-RhodoLED® XL User Manual, Sec. 3.

RhodoLED® XL

Biofrontera
Deep in dermatology

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.**

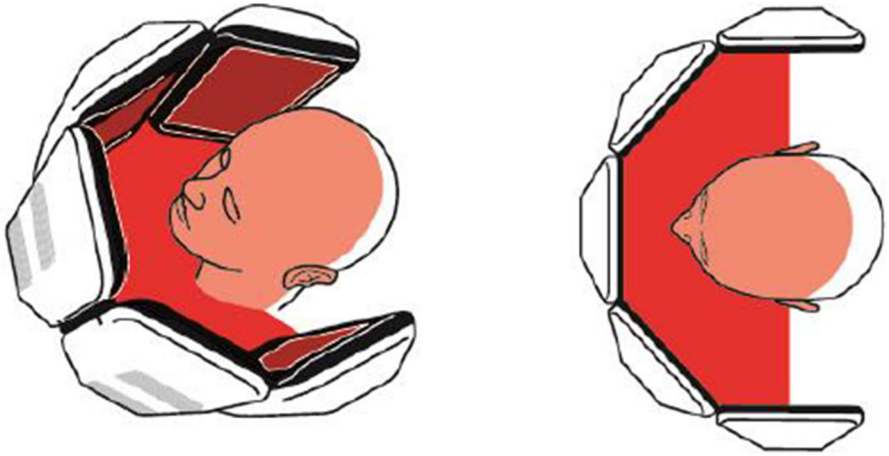


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Sec. 8.4.6, Fig. 13.

----------INDICATIONS AND USAGE----------

AMELUZ, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1).

Biofrontera Inc., *Highlights of Prescribing Information for Ameluz®*, at 1 (Dec. 2021) [hereinafter "Ameluz® Prescribing Information"] (annotated), https://www.ameluz.com/fileadmin/AmeluzUSImages/05-pdf/Ameluz-Full-Prescribing-Information.pdf.

RhodoLED® XL

Biofrontera
Deep in dermatology

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.

BF-RhodoLED® XL User Manual, Sec. 1.

1[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and	The BF-RhodoLED® XL includes an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels. For example, the BF-RhodoLED® XL includes a lamp head with five panels connected by hinged structures on inner side surfaces of adjacent panels. The BF-RhodoLED® includes a "[l]amp head" with "5 LED panels." The LED panels are connected with hinges on the inner side surfaces of adjacent panels (shown below with red annotations).

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)

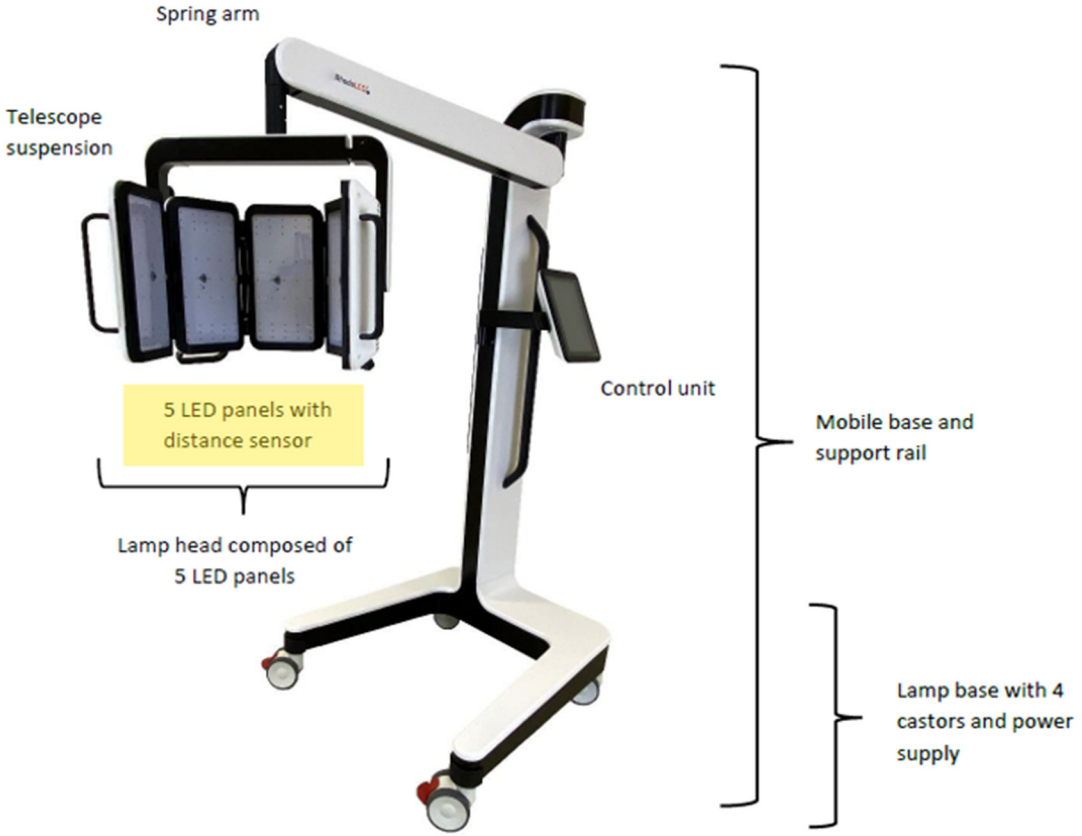


Figure 2: RhodoLED® XL main components

BF-RhodoLED® XL User Manual, Fig. 2 (annotated).

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.

BF-RhodoLED® XL User Manual, Sec. 2.

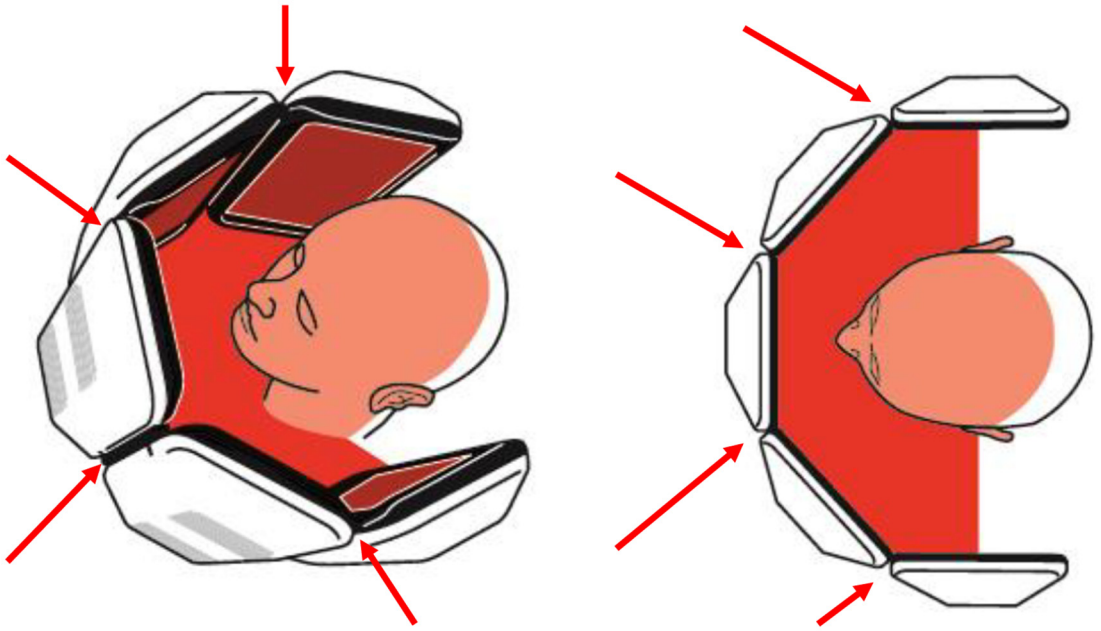
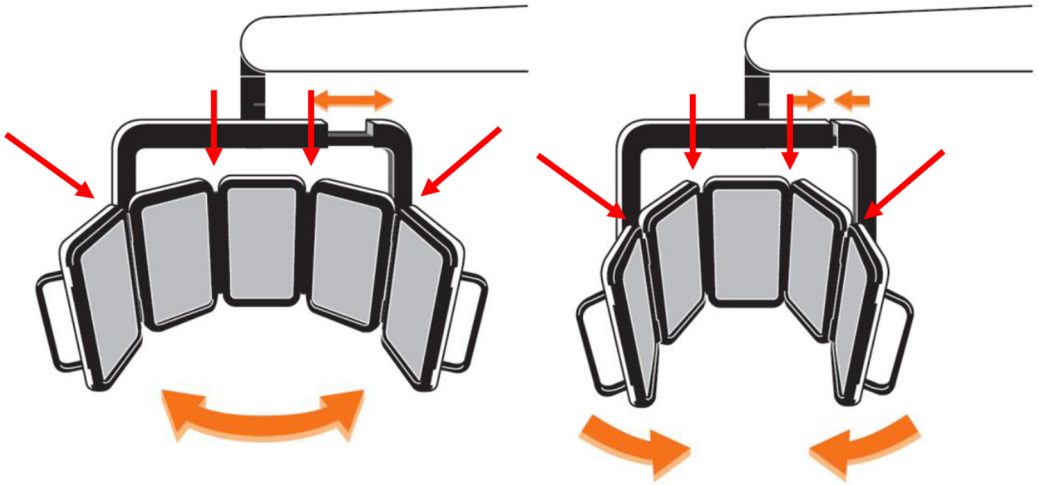


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Fig. 13 (annotated).

	 **Figure 5:** Movement range of the lamp head. BF-RhodoLED® XL User Manual, Fig. 5 (annotated).
1[b] light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,	The BF-RhodoLED® XL includes light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources. For example, the BF-RhodoLED® XL includes LEDs disposed on the surface of five panels. The BF-RhodoLED® XL has "45 LEDs per panel with a total of 5 panels (225 LEDs)." For example, the BF-RhodoLED® XL is configured to uniformly illuminate a treatment surface of the patient via the LEDs. The five LED panels are configured to "emit a uniform, visible red light." The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm." The maximum deviation of the intensity over the treatment area is approximately 20%.

<table>
<tr><td></td><td>

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.

BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).

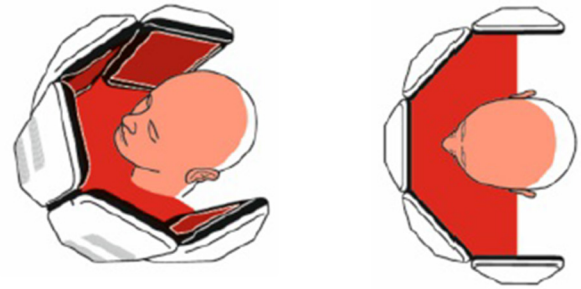
13.2 Specification

Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.08.03.2920
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, 10 min
Typical irradiance	61 mW/cm^2 ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	73.2 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 %

BF-RhodoLED® XL User Manual, Sec. 13.2 (annotated).

</td></tr>
<tr><td>1[c] one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five</td><td>The BF-RhodoLED® XL includes one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel.

For example, “[t]he BF-RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form.” The LED panel orientation “can be changed from a curved shape to an unfolded form by pulling the holding bracket apart.” In the “curved shape,” the center panel is configured to face the treatment</td></tr>
</table>

panels being configured to be angled relative to the center panel,	surface, such as the patient's head, while the remaining four panels are configured to be angled relative to the center panel. For example, "[t]he size of the treatment area is 9.06 x 11.42 inch . . . for all panels in a curved shape." **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.**  BF-RhodoLED® XL User Manual, Fig. 13.  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. BF-RhodoLED® XL User Manual, Sec. 3. 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. BF-RhodoLED® XL User Manual, Sec. 4.1.

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

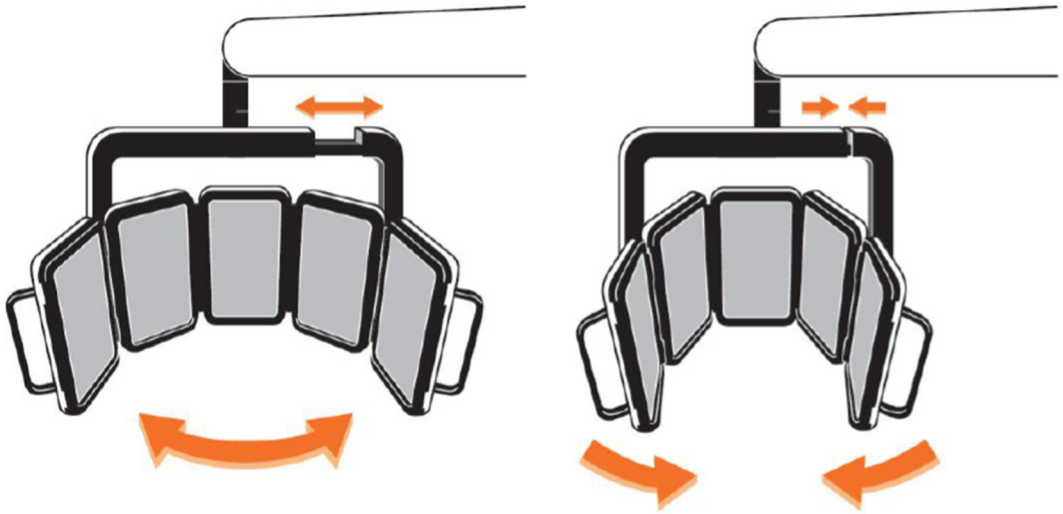


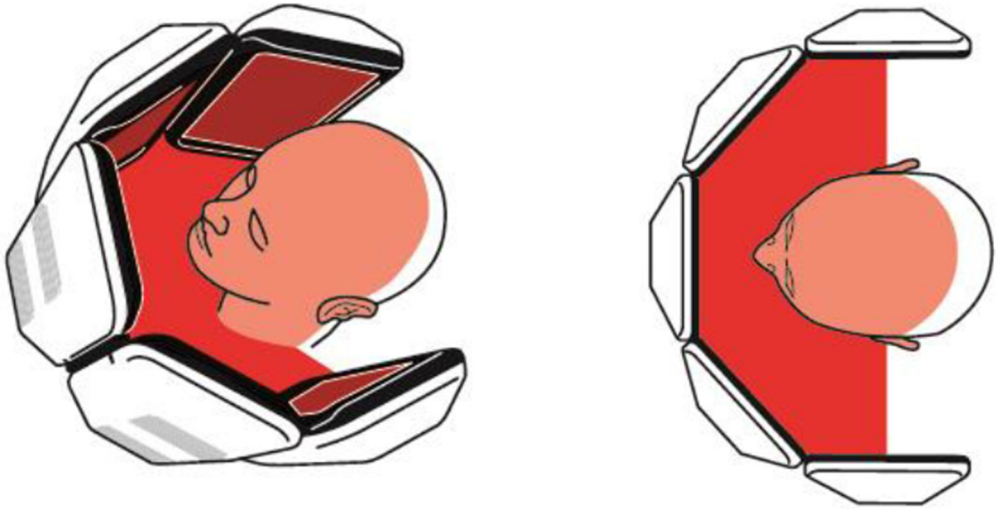
Figure 5: Movement range of the lamp head.

BF-RhodoLED® XL User Manual, Sec. 8.2, Fig. 5.

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.

BF-RhodoLED® XL User Manual, Sec. 8.4.8.

1[d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and	The BF-RhodoLED® XL includes five panels, wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface. For example, the BF-RhodoLED® XL instructs in its User Manual that the "LEDs are calibrated such that the skin being treated receives a light dose . . . under the following conditions: . . . Treatment distance of 4.9 +/- 0.59 inch." As one example, the treatment surface may be a patient's face. The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions: - Illumination time of 10 minutes - Treatment distance of 4.9 ± 0.59 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. BF-RhodoLED® XL User Manual, Sec. 4.1.

	 **Figure 13:** Treatment area of RhodoLED® XL from the side and in top view. BF-RhodoLED® XL User Manual, Fig. 13.
1[e] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not	The BF-RhodoLED® XL includes five panels, wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges. For example, each of the BF-RhodoLED® XL's five panels are rectangular, such that for each panel, there are two first edges (the sides), and two second edges (the top and bottom), where the second edges are shorter than the first two edges. The BF-RhodoLED® XL's LEDs each have "a fixed LED light intensity." The LEDs are arranged such that a higher intensity of light is emitted proximate the second edges (i.e., the shorter edges) compared to the intensity of light emitted not proximate the second edges. For example, 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."

proximate the second edges.	 BF-RhodoLED® XL User Manual, Fig. 14.

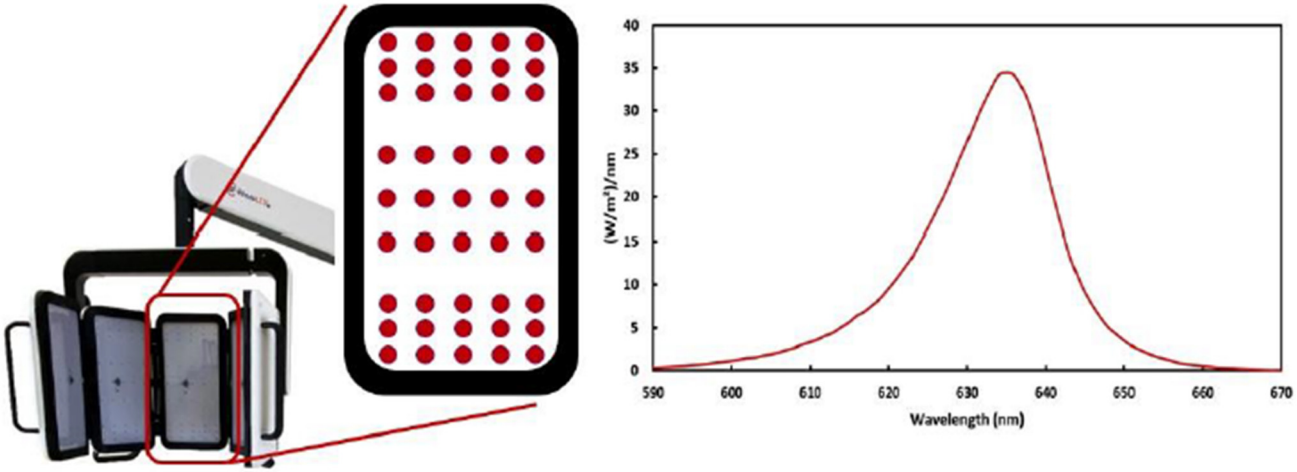


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions:

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 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.

BF-RhodoLED® XL User Manual, Sec. 4.1, Fig. 1.

	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 10-minute treatment time. BF-RhodoLED® XL User Manual, Sec. 8.4.4.
'028 Patent Claim 2	**Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®**
The system of claim 1, wherein the illuminator is configured to output red light at a dose of 30 J/cm^2 to 150 J/cm^2.	The BF-RhodoLED® XL includes the system of claim 1, wherein the illuminator is configured to output red light at a dose of 30 J/cm^2 to 150 J/cm^2. The BF-RhodoLED® XL includes the system of claim 1, as detailed above. *See* claim 1. The BF-RhodoLED® XL's illuminator is configured to output red light at a dose of 30 J/cm^2 to 150 J/cm^2. For example, the BF-RhodoLED® XL's lamp head is configured to output red light at a dose of 30 J/cm^2 to 150 J/cm^2. The BF-RhodoLED® XL is a "red light-emitting LED lamp." The LED panels emit a "uniform,

	visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm." The LED panels are configured to output red light at a dose of "37 J/cm^2 during the illumination." **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. BF-RhodoLED® XL User Manual, Sec. 1. **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. The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions: - Illumination time of 10 minutes - Treatment distance of 4.9 ± 0.59 inch (12.5 cm ± 1.5 cm) BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).
'028 Patent Claim 4	**Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®**
The system of claim 1, wherein a plurality of the light sources are	The BF-RhodoLED® XL includes the system of claim 1, wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm. The BF-RhodoLED® XL includes the system of claim 1, as detailed above. *See* claim 1.

<table>
<tr><td>configured to emit light having a wavelength in a range of 400 nm to 700 nm.</td><td>The BF-RhodoLED® XL includes five panels, wherein a plurality of the light sources are configured to emit light having a wavelength in a range of 400 nm to 700 nm. For example, the BF-RhodoLED® XL LEDs are configured to emit light with a “[t]ypical peak wavelength” of “635 nm +/ 5 nm.”

13.2 Specification
<table><tr><td>Type</td><td>RhodoLED® XL
Medical device class III; Device of protection class 1</td></tr><tr><td>Certification</td><td>UL certified E513735</td></tr><tr><td>Software Version No.</td><td>g2.08.03.2920</td></tr><tr><td>Service interval</td><td>Biofrontera recommends performing service every 2 years</td></tr><tr><td>Number of LEDs</td><td>225</td></tr><tr><td>Typical peak wavelength</td><td>635 nm ± 5 nm</td></tr><tr><td>Light dose</td><td>Approx. 37 J/ cm² at 4.9 inch (12.5 cm) distance, 10 min</td></tr><tr><td>Typical irradiance</td><td>61 mW/cm² ± 20 % at 4.9 inch (12.5 cm) distance</td></tr><tr><td>Max irradiance</td><td>73.2 mW/cm² at 4.9 inch (12.5 cm) distance</td></tr><tr><td>Illuminated area</td><td>An area of 9.06 x 11.42 inch (23 cm x 29 cm) is illuminated using all panels in curved shape.</td></tr><tr><td>Max. deviation of the intensity over the treatment area</td><td>Approx. 20 %</td></tr><tr><td>Treatment distance</td><td>4.9 ± 0.59 inch (12.5 cm ± 1.5 cm)
Measuring accuracy ± 0.3 cm (0.1 inch)</td></tr><tr><td>Transport conditions</td><td>Temperature: -4 °F to +140 °F (-20 °C to +60 °C)
Atmospheric pressure: 500 hPa - 1060 hPa
Relative humidity: 10 % - 90 %, non-condensing</td></tr></table>BF-RhodoLED® XL User Manual, Sec. 13.2 (annotated).</td></tr>
<tr><th>’028 Patent Claim 5</th><th>Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®</th></tr>
<tr><td>5[pre] A method of photodynamically diagnosing or</td><td>The BF-RhodoLED® XL can be used in conjunction with a method for photodynamically diagnosing or treating a patient.</td></tr>
</table>

treating a patient, comprising:	For example, the BF-RhodoLED® XL can be used in conjunction with a method for photodynamically diagnosing or treating a patient. The BF-RhodoLED® XL includes an "LED lamp for . . . photodynamic therapy." "Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy." "The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel. . . . Any other use or combination of use is prohibited." The BF-RhodoLED® XL "is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." The BF-RhodoLED® XL's "[i]ntended use" is for "lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp."

RhodoLED® XL

Biofrontera
Deep in dermatology

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 certified 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.

BF-RhodoLED® XL User Manual, at 2 (annotated).

	RhodoLED® XL Biofrontera Deep in dermatology **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. BF-RhodoLED® XL User Manual, Sec. 3.

RhodoLED® XL

Biofrontera
Deep in dermatology

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.**

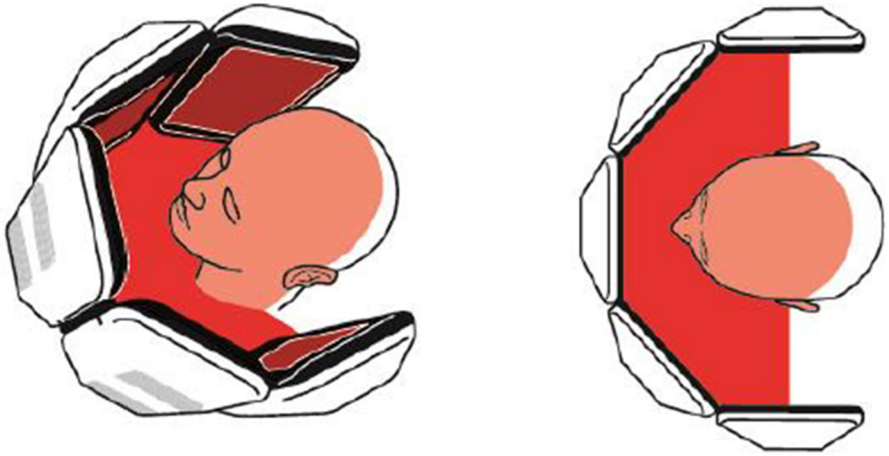


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Sec. 8.4.6, Fig. 13.

	----------INDICATIONS AND USAGE---------- AMELUZ, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1). Ameluz® Prescribing Information, at 1. RhodoLED® XL Biofrontera Deep in dermatology **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. BF-RhodoLED® XL User Manual, Sec. 1.
5[a] administering 5-aminolevulinic acid (ALA) to the patient;	The BF-RhodoLED® XL can be used in conjunction with administering 5-aminolevulinic acid (ALA) to the patient. For example, the BF-RhodoLED® XL and Ameluz® "have been approved in combination for photodynamic therapy." Ameluz® contains 5-Aminolevulinic acid (ALA). Step 4 of the use of the BF-RhodoLED® XL is "[t]reat the affected skin area: Application, incubation, and removal of the topical medication according to the

	USPI of Ameluz®." The BF-RhodoLED® XL "is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." RhodoLED® XL Biofrontera Deep in dermatology **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 certified 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.** BF-RhodoLED® XL User Manual, at 2 (annotated).

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

AMELUZ® (aminolevulinic acid hydrochloride) topical gel, 10%, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED®* lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.

IMPORTANT SAFETY INFORMATION

AMELUZ® (aminolevulinic acid hydrochloride), topical gel, 10%
Purpose: Photosensitizing agent

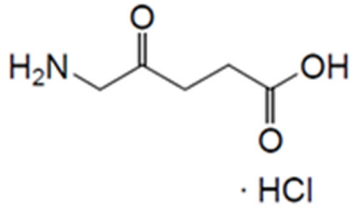
Uses: AMELUZ® gel, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED® lamp, is used for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.

Biofrontera, *Indication and Important Safety Information* (annotated), https://us.ameluz.com (last visited June 24, 2024).

11. DESCRIPTION

AMELUZ (aminolevulinic acid hydrochloride) topical gel, 10% is a non-sterile white-to-yellowish gel. The gel formulation contains a nanoemulsion.

Aminolevulinic acid, a porphyrin precursor, is a white to off-white crystalline solid. It is readily soluble in water, methanol, and dimethylformamide. Its chemical name is 5-amino-4-oxo-pentanoic acid hydrochloride, molecular weight is 167.59 and molecular formula is $C_5H_9NO_3 \cdot HCl$. The structural formula of aminolevulinic acid hydrochloride is represented below:



Ameluz® Prescribing Information, Sec. 11.

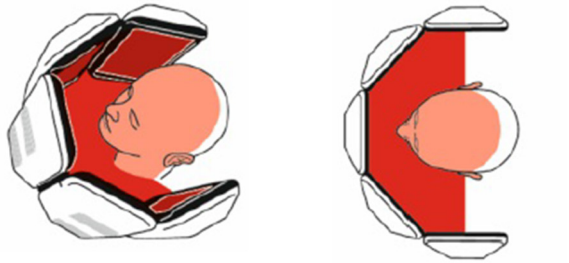
	STEP 1) Plug in the lamp. STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter8.4.3). STEP 3) Check the proper functioning of the RhodoLED® XL. STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®. 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 8.4.10). To abort the illumination, press **Cancel** (see chapter 8.4.10). Always stay with the patient during the illumination period. BF-RhodoLED® XL User Manual, Sec. 7 (annotated).

	----------INDICATIONS AND USAGE---------- AMELUZ, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1). Ameluz® Prescribing Information, at 1.
5[b] positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and	The BF-RhodoLED® XL can be used in conjunction with positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels. For example, the BF-RhodoLED® XL instructs in its User Manual that the "LEDs are calibrated such that the skin being treated receives a light dose . . . under the following conditions: . . . Treatment distance of 4.9 +/- 0.59 inch." Step 5 of the use of the BF-RhodoLED® XL is "[p]osition the patient comfortably and equip the patient with protective eyewear." Step 7 of the use of the BF-RhodoLED® XL is "[p]osition the lamp and adjust the lamp head over the skin area to be treated." The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions: - Illumination time of 10 minutes - Treatment distance of 4.9 ± 0.59 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. BF-RhodoLED® XL User Manual, Sec. 4.1.

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.**



BF-RhodoLED® XL User Manual, Fig. 13.

	STEP 1) Plug in the lamp. STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter8.4.3). 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 8.4.10). To abort the illumination, press **Cancel** (see chapter 8.4.10). Always stay with the patient during the illumination period. BF-RhodoLED® XL User Manual, Sec. 7 (annotated). For example, the BF-RhodoLED® XL's illuminator comprises five panels connected by hinged structures on inner side surfaces of adjacent panels. The BF-RhodoLED® XL has "5 LED panels" with hinges (shown below with red annotations).

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)

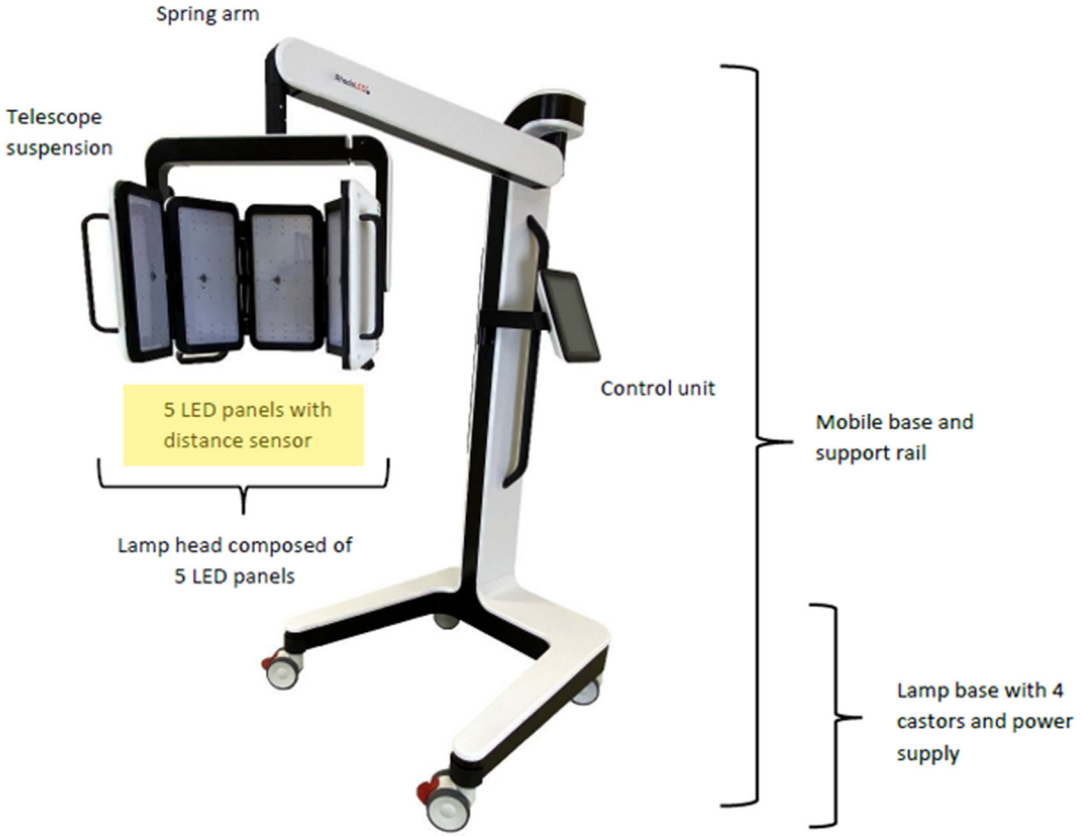
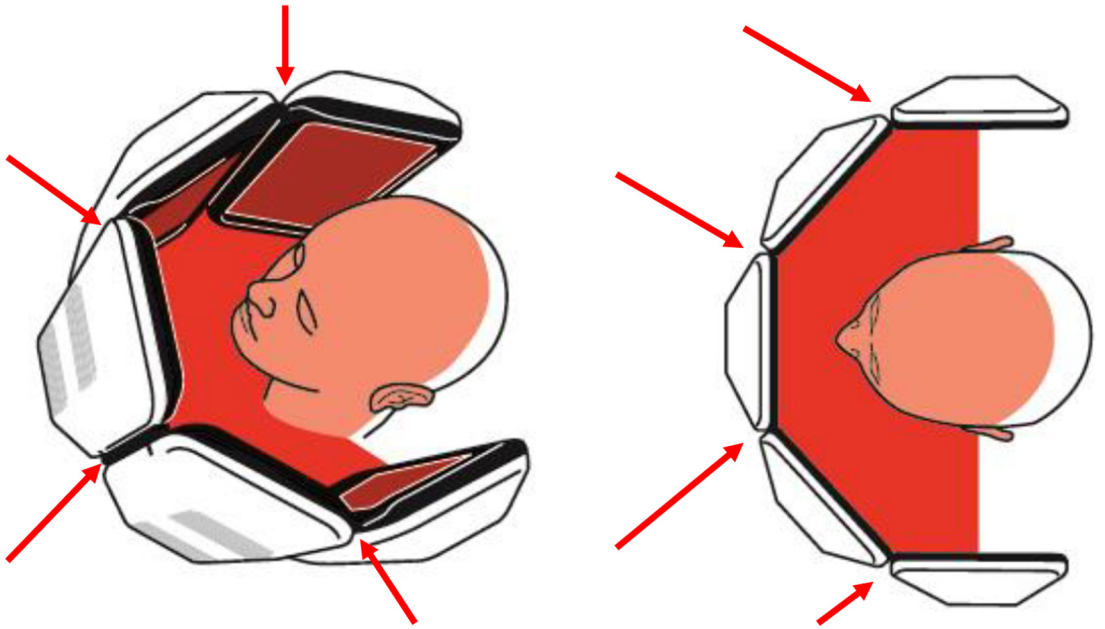
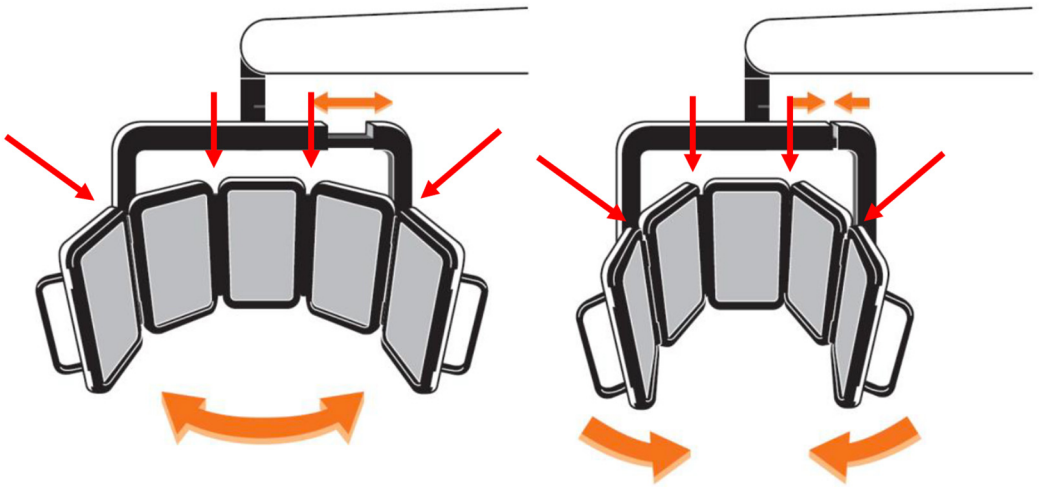


Figure 2: RhodoLED® XL main components

	BF-RhodoLED® XL User Manual, Fig. 2 (annotated).  **Figure 13:** Treatment area of RhodoLED® XL from the side and in top view. BF-RhodoLED® XL User Manual, Fig. 13 (annotated).

	 **Figure 5:** Movement range of the lamp head. BF-RhodoLED® XL User Manual, Fig. 5 (annotated).
5[c] uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface,	The BF-RhodoLED® XL can be used in conjunction with uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface. For example, the BF-RhodoLED® XL includes LEDs, which are light sources, that are disposed on the surface of the five panels. The BF-RhodoLED® XL's five panels' LEDs illuminate the patient's treatment surface, such as a patient's face. Step 7 of the use of the BF-RhodoLED® XL is "[p]osition the lamp and adjust the lamp head over the skin area to be treated." Step 9 of the use of the BF-RhodoLED® XL is "[s]tart treatment by pressing **Start**, the illumination period begins."

	STEP 1) Plug in the lamp. STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter8.4.3). 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 8.4.10). To abort the illumination, press **Cancel** (see chapter 8.4.10). Always stay with the patient during the illumination period. BF-RhodoLED® XL User Manual, Sec. 7 (annotated). For example, the BF-RhodoLED® XL is configured to uniformly illuminate a treatment surface of the patient via the LEDs. The five LED panels are configured to "emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm." The maximum deviation of the intensity over the treatment area is approximately 20%.

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.

BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).

13.2 Specification

Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.08.03.2920
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, 10 min
Typical irradiance	61 mW/cm^2 ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	73.2 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 %

BF-RhodoLED® XL User Manual, Sec. 13.2 (annotated).

For example, BF-RhodoLED® XL's five panels are positioned to allow treatment within approximately four inches of the treatment surface. The BF-RhodoLED® XL's "LEDs are calibrated such that the skin being treated receives a light dose . . . under the following conditions: . . . Treatment distance of 4.9 +/- 0.59 inch." One example of a treatment surface is a patient's face.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions:

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 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.

BF-RhodoLED® XL User Manual, Sec. 4.1.

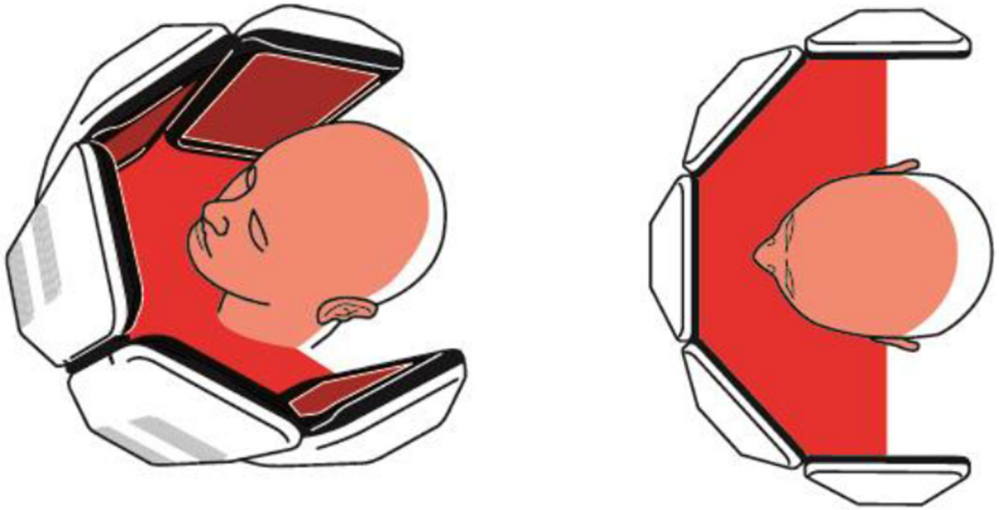


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Fig. 13.

5[d] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.	The BF-RhodoLED® XL includes five panels, wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges. For example, each of the BF-RhodoLED® XL's five panels are rectangular, such that for each panel, there are two first edges (the sides), and two second edges (the top and bottom), where the second edges are shorter than the first two edges. The BF-RhodoLED® XL's LEDs each have "a fixed LED light intensity." The LEDs are arranged such that a higher intensity of light is emitted proximate the second edges (i.e., the shorter edges) compared to the intensity of light emitted not proximate the second edges. For example, 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."  BF-RhodoLED® XL User Manual, Fig. 14.

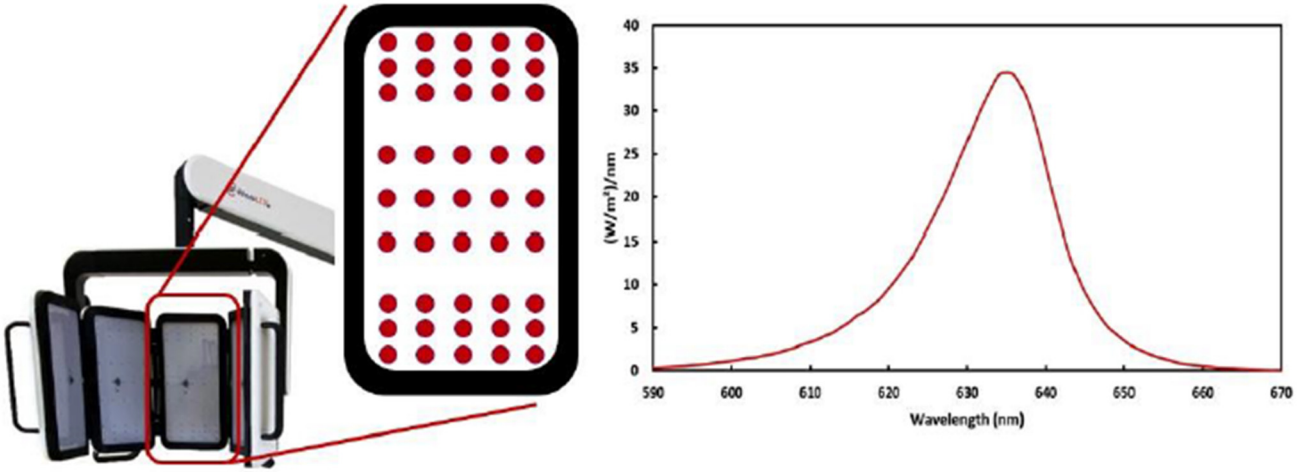


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions:

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 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.

BF-RhodoLED® XL User Manual, Sec. 4.1, Fig. 1.

	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 10-minute treatment time. BF-RhodoLED® XL User Manual, Sec. 8.4.4.

'028 Patent Claim 6	**Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®**
The method of claim 5, wherein the illuminating comprises outputting red light during at least part of the time when the treatment surface is illuminated.	The BF-RhodoLED® XL can be used in conjunction with the method of claim 5, wherein the illuminating comprises outputting red light during at least part of the time when the treatment surface is illuminated. The BF-RhodoLED® XL includes the method of claim 5, as detailed above. *See* claim 5. The BF-RhodoLED® XL can be used wherein the illuminating includes outputting red light during at least part of the time when the treatment surface is illuminated. The BF-RhodoLED® XL is a "red light-emitting LED lamp." The BF-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." **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. BF-RhodoLED® XL User Manual, Sec. 1. **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. BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).
'028 Patent Claim 16	**Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®**

16[pre] A system for photodynamically diagnosing or treating a patient, comprising:	The BF-RhodoLED® XL is a system for photodynamically diagnosing or treating a patient. For example, the BF-RhodoLED® XL includes an "LED lamp for . . . photodynamic therapy." "Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy." "The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel. . . . Any other use or combination of use is prohibited." The BF-RhodoLED® XL "is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." The BF-RhodoLED® XL's "[i]ntended use" is for "lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp."

RhodoLED® XL

Biofrontera
Deep in dermatology

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 certified 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.

BF-RhodoLED® XL User Manual, at 2 (annotated).

	RhodoLED® XL Biofrontera Deep in dermatology **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. BF-RhodoLED® XL User Manual, Sec. 3.

RhodoLED® XL

Biofrontera
Deep in dermatology

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.**

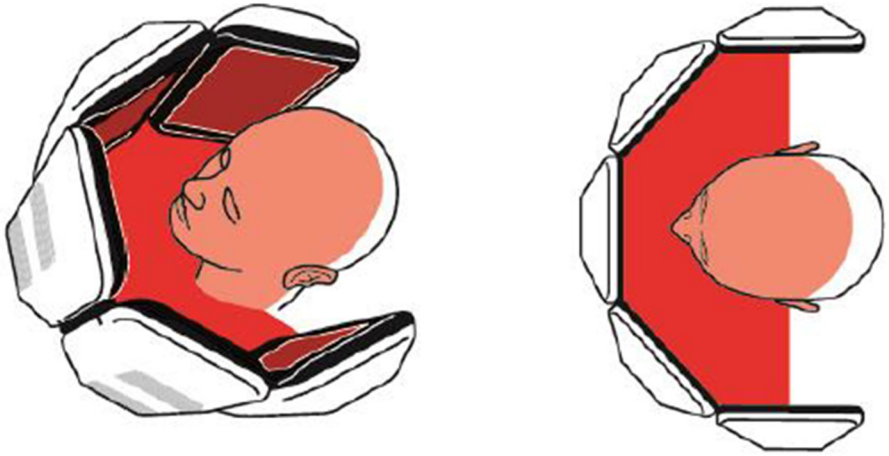


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Sec. 8.4.6, Fig. 13.

	----------INDICATIONS AND USAGE---------- AMELUZ, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1). Ameluz® Prescribing Information, at 1. RhodoLED® XL Biofrontera Deep in dermatology **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. BF-RhodoLED® XL User Manual, Sec. 1.
16[a] a mobile base supported by at least four wheels;	The BF-RhodoLED® XL includes a mobile base supported by at least four wheels. For example, the BF-RhodoLED® XL has a "[m]obile base" connected to a "lamp base" with four wheels.

RhodoLED® XL

Biofrontera
Deep in dermatology

- Control unit
- Mobile base (includes support rail, castors and power supply)

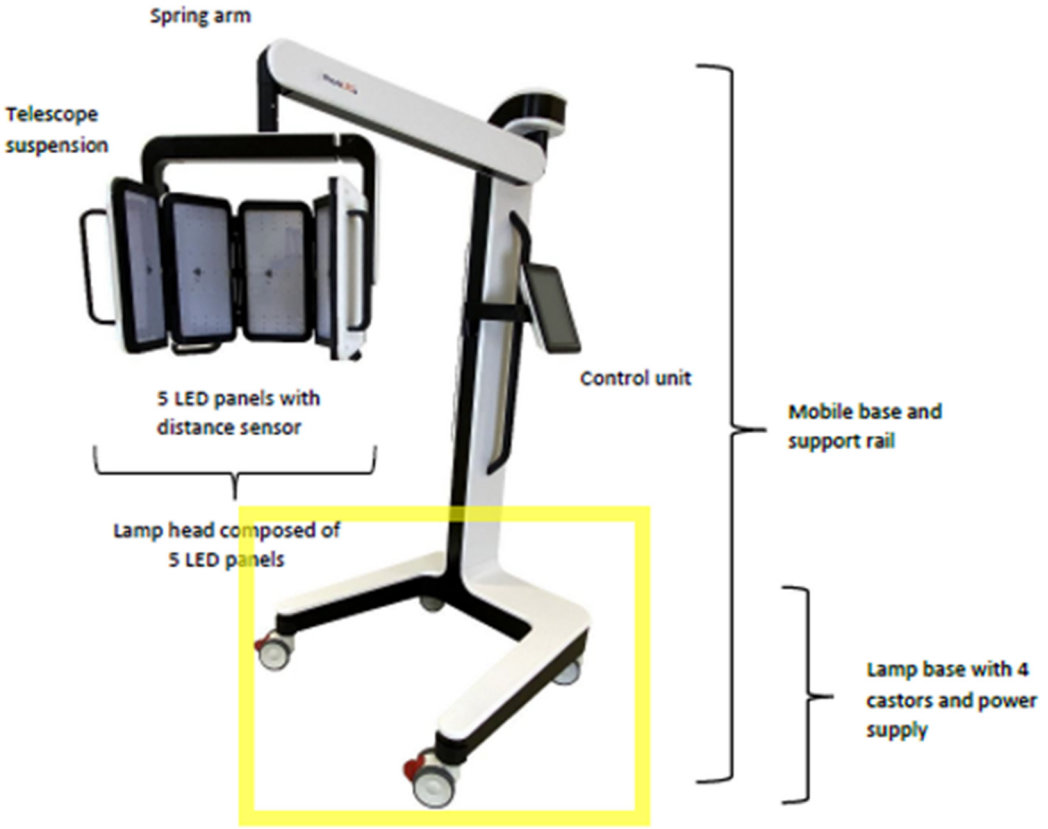


Figure 2: RhodoLED® XL main components

BF-RhodoLED® XL User Manual, Sec. 4.2 (annotated), Fig. 2 (annotated).

16[b] a pillar perpendicular to the base;	The BF-RhodoLED® XL includes a pillar perpendicular to the base. For example, the BF-RhodoLED® XL has a pillar connected to the mobile base, and the pillar is perpendicular to the base. The BF-RhodoLED® XL includes a pillar (vertical portion of the "[m]obile base") connected the the bottom portion of the "[m]obile base." The vertical portion of the "[m]obile base" is perpendicular to the bottom portion of the "[m]obile base."

RhodoLED® XL

Biofrontera
Deep in dermatology

- Control unit
- Mobile base (includes support rail, castors and power supply)

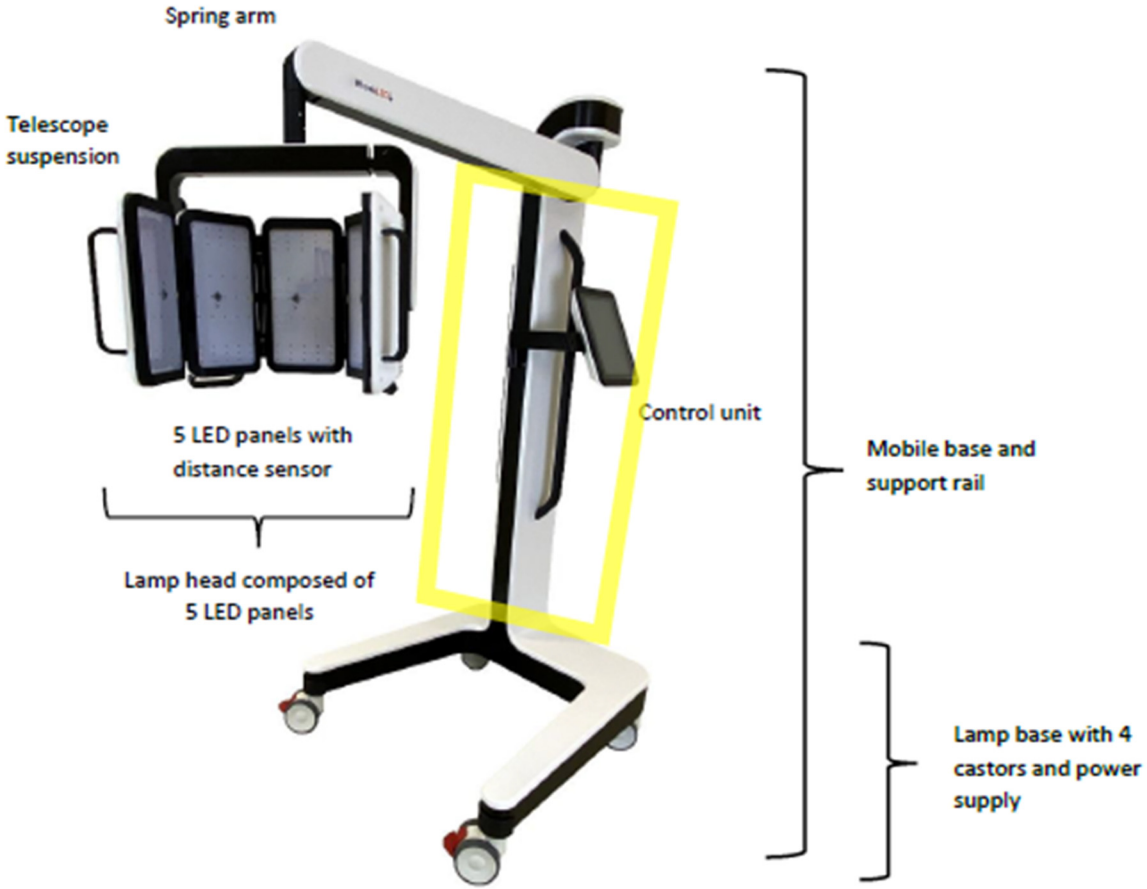


Figure 2: RhodoLED® XL main components

	BF-RhodoLED® XL User Manual, Fig. 2 (annotated).
16[c] a controller disposed to be supported by the pillar;	The BF-RhodoLED® XL includes a controller disposed to be supported by the pillar. For example, the BF-RhodoLED® XL has a control unit disposed to be supported by the pillar.

RhodoLED® XL

Biofrontera
Deep in dermatology

- Control unit
- Mobile base (includes support rail, castors and power supply)

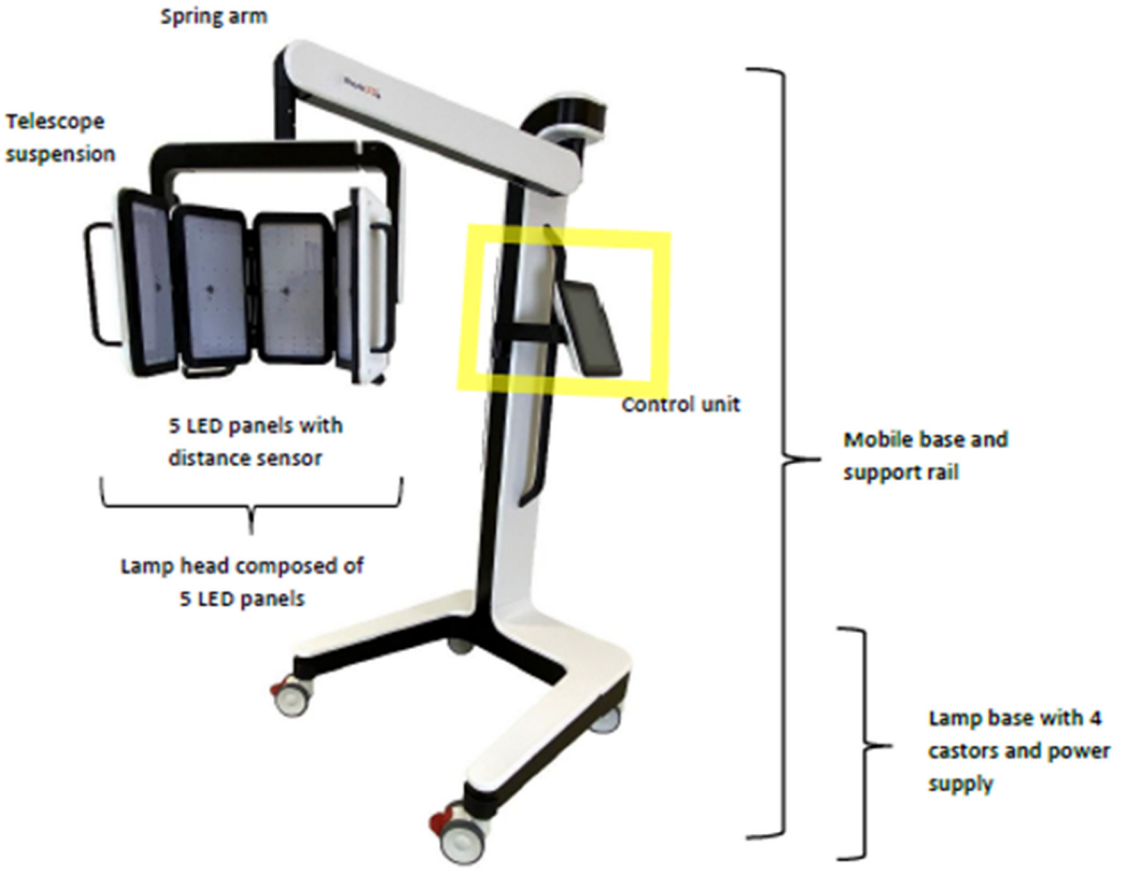
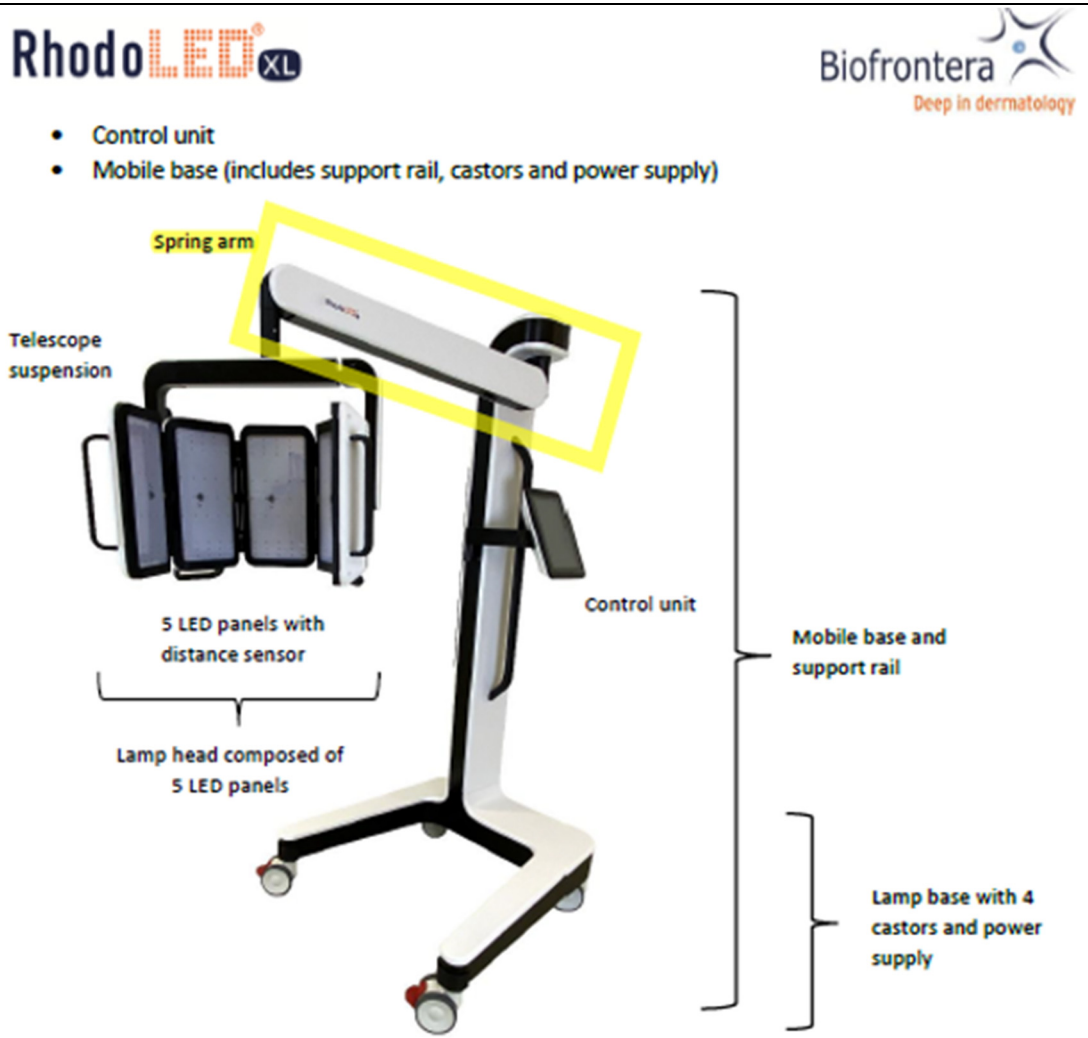


Figure 2: RhodoLED® XL main components

	BF-RhodoLED® XL User Manual, Fig. 2 (annotated).
16[d] an arm mounted to a top portion of the pillar; and	The BF-RhodoLED® XL has an arm mounted to a top portion of the pillar. For example, BF-RhodoLED® XL has a spring arm connected to the top portion of the pillar.



BF-RhodoLED® XL User Manual, Fig. 2 (annotated).

16[e] an illuminator connected at an end of the arm,	The BF-RhodoLED® XL includes an illuminator connected at an end of the arm. For example, BF-RhodoLED® XL lamp head is connected at an end of the spring arm. The BF-RhodoLED® XL includes "main components," including a "[l]amp head" with "5 LED panels." The "[l]amp head" is connected to the end of the "[s]pring arm." **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. BF-RhodoLED® XL User Manual, Sec. 2.

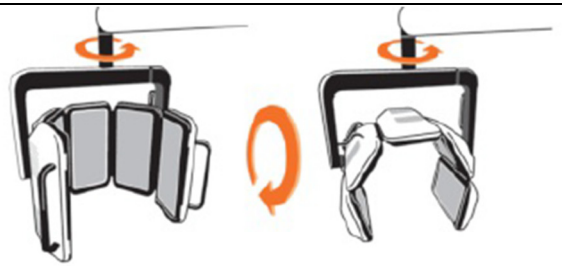


Figure 4: Rotation and tilting of the lamp head.

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

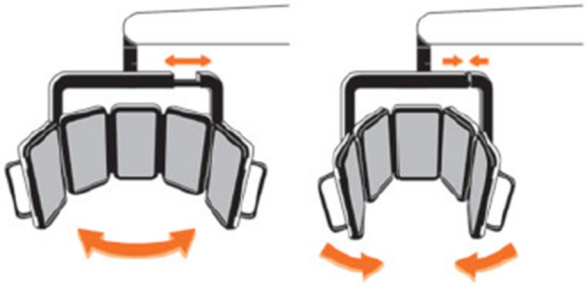


Figure 5: Movement range of the lamp head.

BF-RhodoLED® XL User Manual, Figs. 4–5.

RhodoLED® XL

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- Control unit
- Mobile base (includes support rail, castors and power supply)

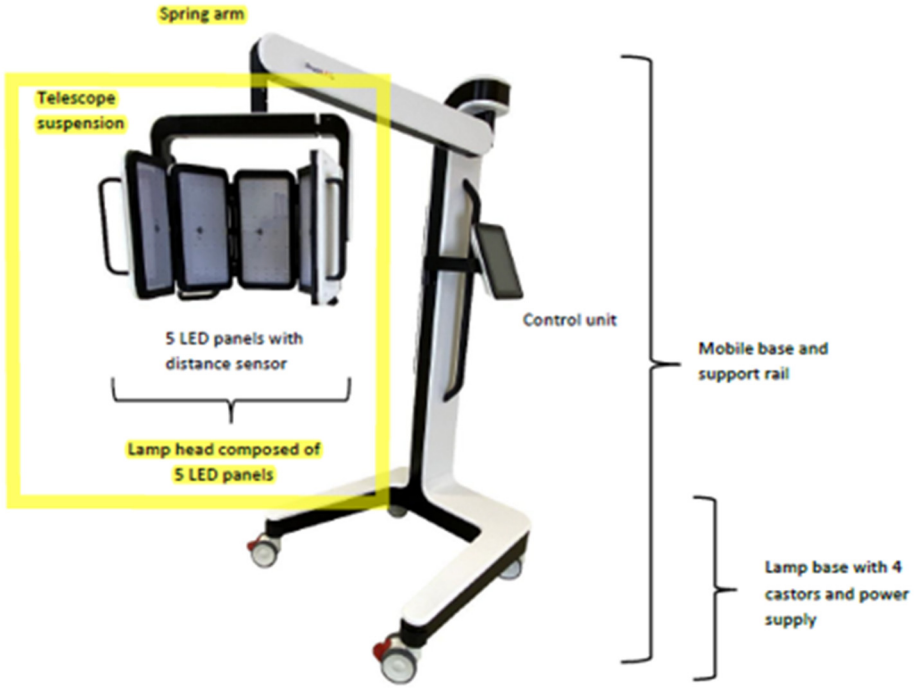
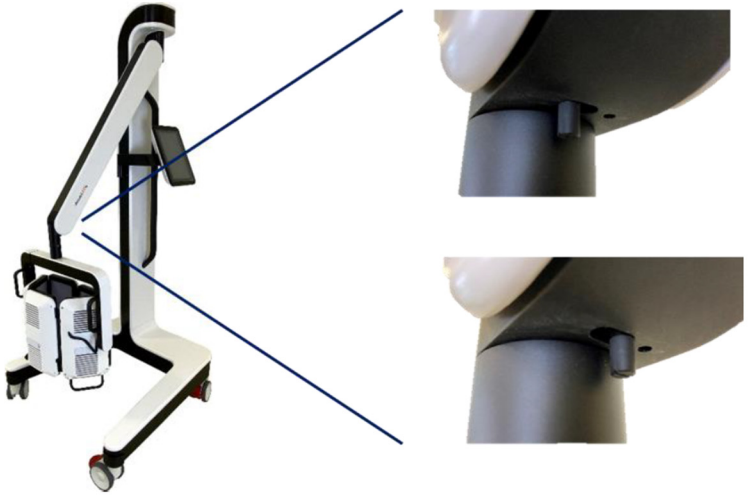


Figure 2: RhodoLED® XL main components

BF-RhodoLED® XL User Manual, Fig. 2 (annotated)

16[f] the arm being hinged to allow adjustment of a position of the illuminator relative to the base,	The BF-RhodoLED® XL includes five panels, wherein the arm is hinged to allow adjustment of a position of the illuminator relative to the base. For example, the BF-RhodoLED® XL' includes "an easily adjustable spring arm" which is hinged to allow for the adjustment of a position of the lamp head relative to the mobile base. "The swivel range of the spring arm to the left and right of the main axis is +/- 5°. The vertical range of the spring arm is 68°. The spring arm with internal gas spring allows seamless adjustment to any height."  BF-RhodoLED® XL User Manual, Fig. 3.

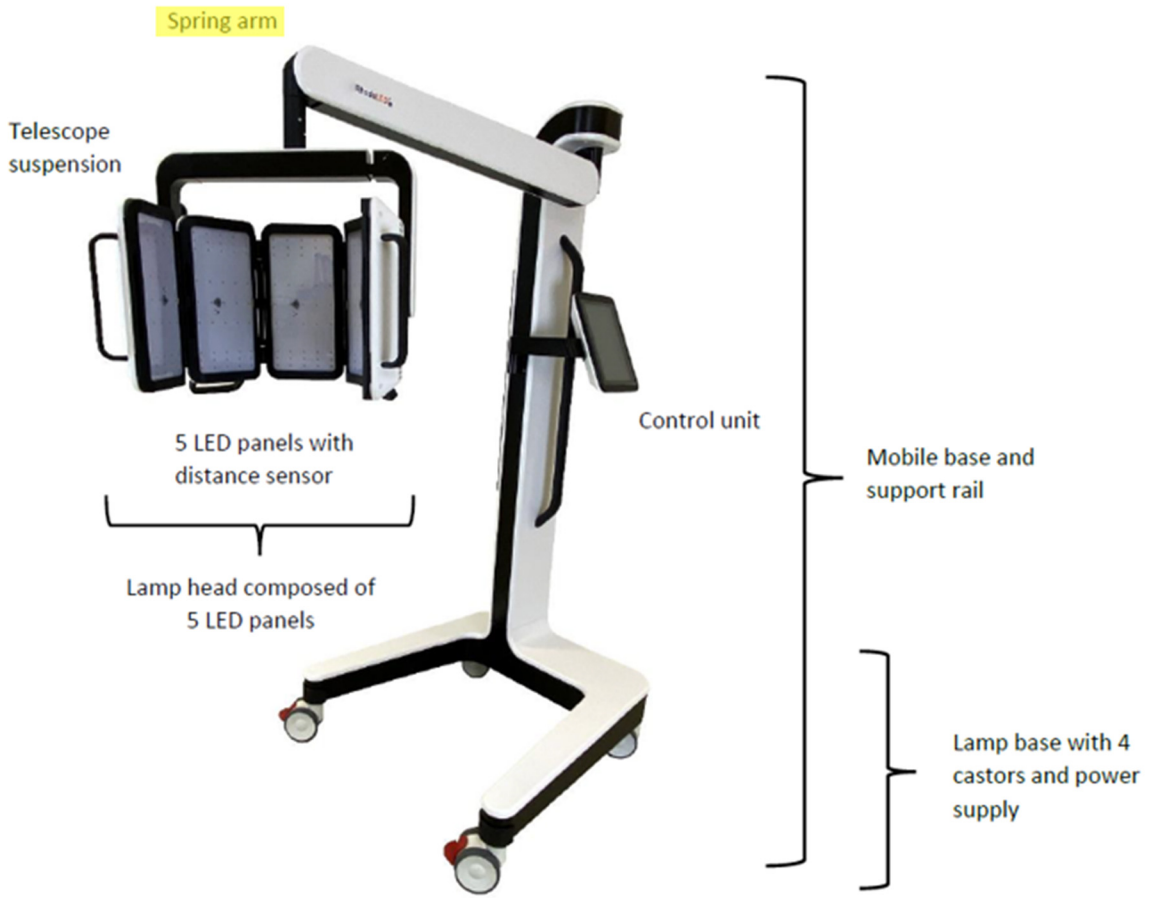


Figure 2: RhodoLED® XL main components

BF-RhodoLED® XL User Manual, Fig. 2 (annotated).

	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. BF-RhodoLED® XL User Manual, Sec. 2. **8.2 Movement Areas** The swivel range of the spring arm to the left and right of the main axis is +/- 5°. 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). BF-RhodoLED® XL User Manual, Sec. 8.2.
16[g] the illuminator comprising: five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually	The BF-RhodoLED® XL includes an illuminator, including five panels connected by hinged structures to allow continuous illumination across the five panels, wherein the five panels are individually configurable to control illumination from each of the five panels. For example, the BF-RhodoLED® XL includes a lamp, including five panels connected by hinged structures to allow continuous illumination across the five panels. The lamp includes "5 LED panels" with hinges (shown below with red annotations). The BF-RhodoLED® XL is designed to "emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm." The maximum deviation of the intensity over the treatment area is approximately 20%. The RhodoLED® XL emits the light to the

configurable to control illumination from each of the five panels,	treatment area through its LEDs, including by connecting the five panels by hinged structures to allow for continuous illumination across the five panels. **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. BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).

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)

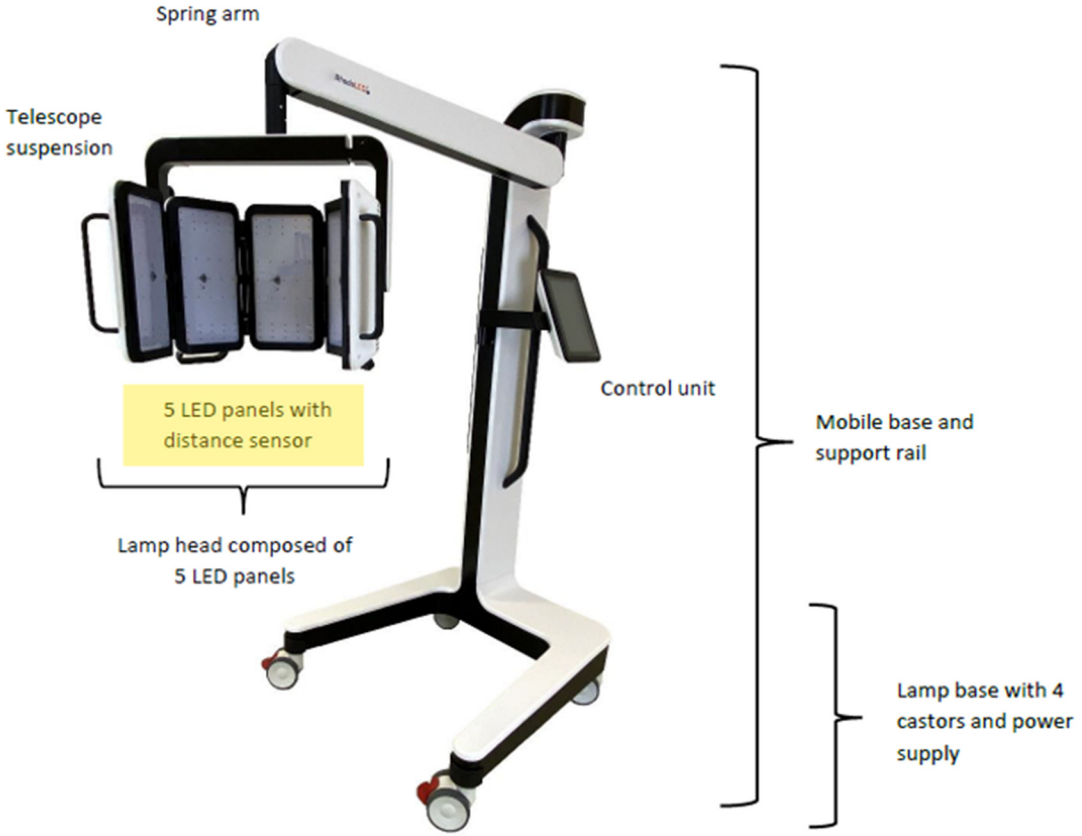
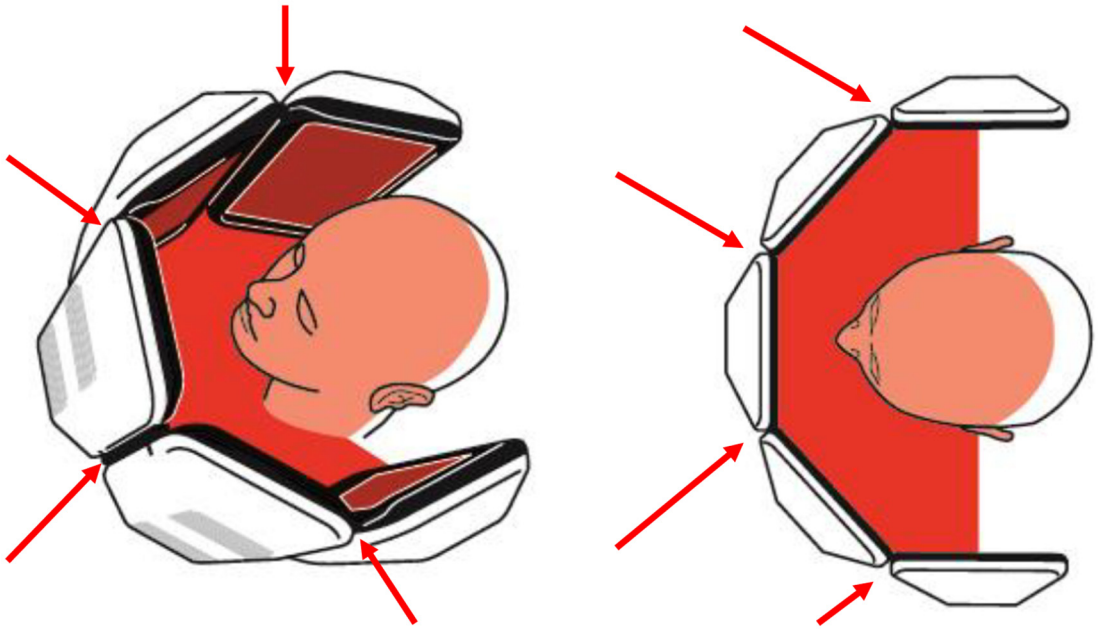


Figure 2: RhodoLED® XL main components

	BF-RhodoLED® XL User Manual, Fig. 2 (annotated).  **Figure 13:** Treatment area of RhodoLED® XL from the side and in top view. BF-RhodoLED® XL User Manual, Fig. 13 (annotated).

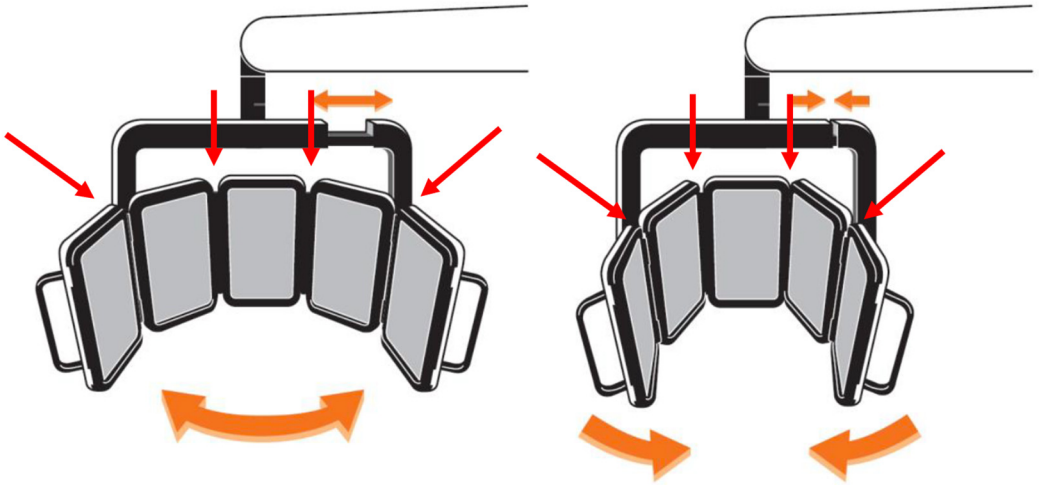


Figure 5: Movement range of the lamp head.

BF-RhodoLED® XL User Manual, Fig. 5 (annotated).

For example, the maximum deviation of the intensity over the treatment area is approximately 20%.

13.2 Specification

Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.08.03.2920
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, 10 min
Typical irradiance	61 mW/cm^2 ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	73.2 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 %

BF-RhodoLED® XL User Manual, Sec. 13.2 (annotated).

For example, the BF-RhodoLED® XL includes five panels, wherein the five panels are individually configurable to control illumination from each of the five panels. The LED panels are individually configurable to control illumination. "All panels are activated by default and can be deactivated via the software. To deactivate LED panels, press on the illustrated panel."

	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) BF-RhodoLED® XL User Manual, Sec. 8.4.5 (annotated), Fig. 10.
16[h] light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the	The BF-RhodoLED® XL includes light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges. For example, the BF-RhodoLED® XL includes LEDs disposed on surfaces of the five panels. The BF-RhodoLED® XL's five panels include "45 LEDs per panel with a total of 5 panels (225 LEDs)." For example, the BF-RhodoLED® XL includes an illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources. The BF-RhodoLED® XL is configured to uniformly illuminate a treatment surface of the patient (such as a patient's face) via the LEDs.

<table>
<tr>
<td>treatment surface is illuminated, each of the five panels having two first edges and two second edges shorter than the two first edges, the light sources arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges, and</td>
<td>For example, the BF-RhodoLED® XL includes LEDs that are configured to output light uniformly during at least part of a time when the treatment surface is illuminated. The five LED panels are configured to “emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm.” The maximum deviation of the intensity over the treatment area is approximately 20%.

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.

BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).

13.2 Specification
<table><tr><td>Type</td><td>RhodoLED® XL
Medical device class III; Device of protection class 1</td></tr><tr><td>Certification</td><td>UL certified E513735</td></tr><tr><td>Software Version No.</td><td>g2.08.03.2920</td></tr><tr><td>Service interval</td><td>Biofrontera recommends performing service every 2 years</td></tr><tr><td>Number of LEDs</td><td>225</td></tr><tr><td>Typical peak wavelength</td><td>635 nm ± 5 nm</td></tr><tr><td>Light dose</td><td>Approx. 37 J/ cm² at 4.9 inch (12.5 cm) distance, 10 min</td></tr><tr><td>Typical irradiance</td><td>61 mW/cm² ± 20 % at 4.9 inch (12.5 cm) distance</td></tr><tr><td>Max irradiance</td><td>73.2 mW/cm² at 4.9 inch (12.5 cm) distance</td></tr><tr><td>Illuminated area</td><td>An area of 9.06 x 11.42 inch (23 cm x 29 cm) is illuminated using all panels in curved shape.</td></tr><tr><td>Max. deviation of the intensity over the treatment area</td><td>Approx. 20 %</td></tr></table>BF-RhodoLED® XL User Manual, Sec. 13.2 (annotated).

For example, the BF-RhodoLED® XL includes five panels, wherein each of the five panels having two first edges and two second edges shorter than the two first edges. For example, each of the BF-RhodoLED® XL’s</td>
</tr>
</table>

	five panels are rectangular, such that for each panel, there are two first edges (the sides), and two second edges (the top and bottom), where the second edges are shorter than the first two edges. The BF-RhodoLED® XL's LEDs each have "a fixed LED light intensity." The LEDs are arranged such that a higher intensity of light is emitted proximate the second edges (i.e., the shorter edges) compared to the intensity of light emitted not proximate the second edges. For example, 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."  BF-RhodoLED® XL User Manual, Fig. 14.

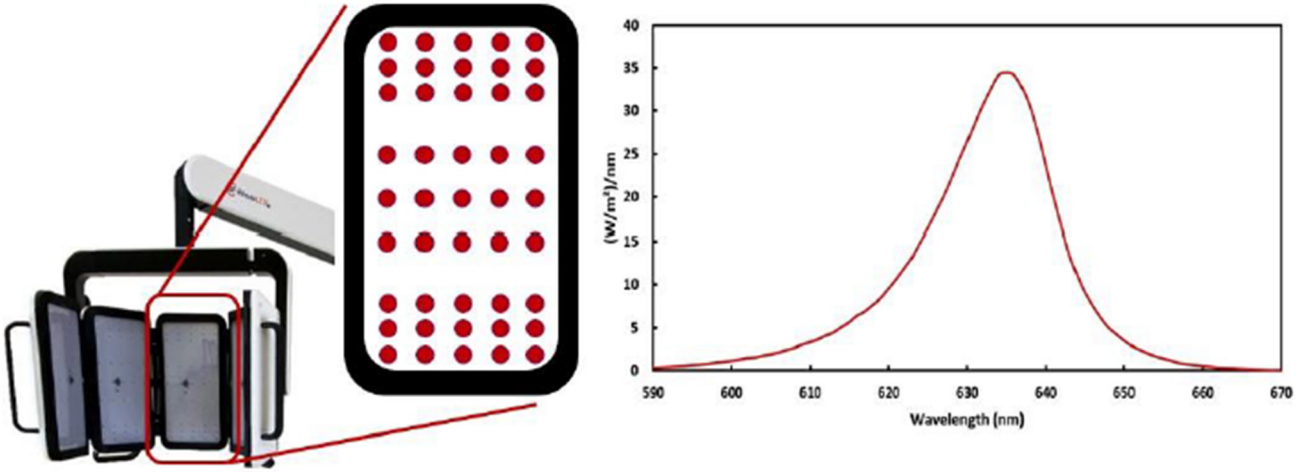


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

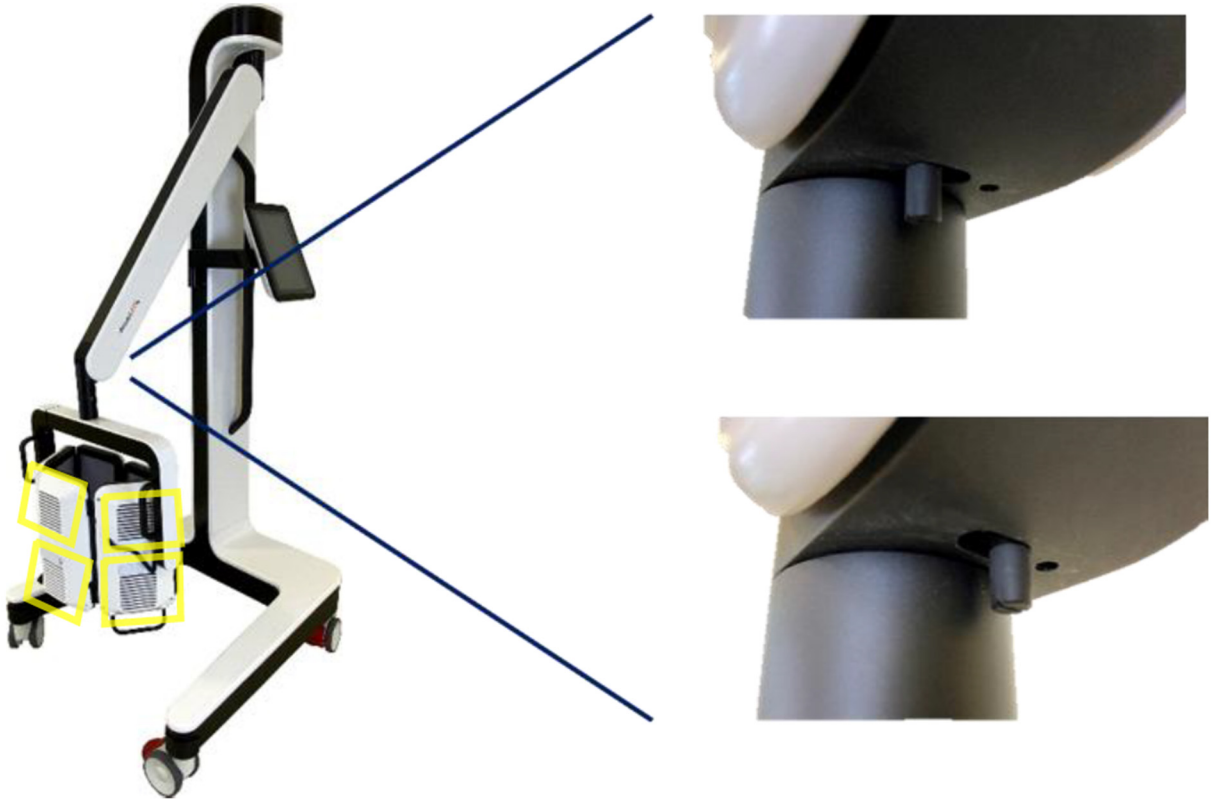
The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions:

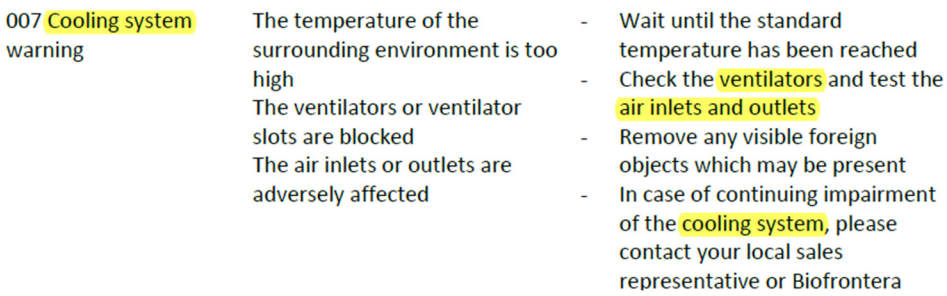
- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 inch (12.5 cm ± 1.5 cm)

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.

BF-RhodoLED® XL User Manual, Sec. 4.1, Fig. 1.

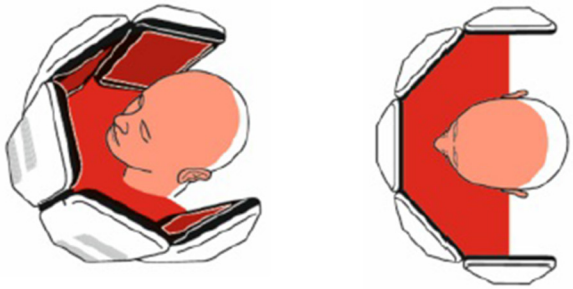
	8.4.4 **The Treatment Profile** The RhodoLED® XL has a fixed LED light intensity which ensures the application of 37 J/cm² within the 10-minute treatment time. BF-RhodoLED® XL User Manual, Sec. 8.4.4.
16[i] one or more fans mounted to at least one of the five panels.	The BF-RhodoLED® XL includes one or more fans mounted to at least one of the five panels. For example, the BF-RhodoLED® XL includes one or more fans mounted to at least one of the five panels. Each panel includes fans. The RohodoLED XL includes a "cooling system" with "ventilators," "air inlets," and "outlets." 

	BF-RhodoLED® XL User Manual, Fig. 3 (annotations in yellow added).  BF-RhodoLED® XL User Manual, Sec. 9 (annotated).
'028 Patent Claim 17	**Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®**
The system of claim 16, wherein one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels are configured to be angled relative to the center panel.	The BF-RhodoLED® XL includes the system of claim 16, wherein one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels are configured to be angled relative to the center panel. The BF-RhodoLED® XL includes the system of claim 16, as detailed above. *See* claim 16. The BF-RhodoLED® XL includes five panels, wherein one of the five panels is positioned as a center panel configured to face the treatment surface, and two or more of the five panels are configured to be angled relative to the center panel. For example, "[t]he BF-RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form." The LED panel orientation "can be changed from a curved shape to an unfolded form by pulling the holding bracket apart." In the "curved shape," the center panel is configured to face the treatment surface, such as the patient's head, while the remaining four panels are configured to be angled relative to the center panel. For example, "[t]he size of the treatment area is 9.06 x 11.42 inch . . . for all panels in a curved shape."

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.**



BF-RhodoLED® XL User Manual, Fig. 13.

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.

BF-RhodoLED® XL User Manual, Sec. 3.

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.

BF-RhodoLED® XL User Manual, Sec. 4.1.

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

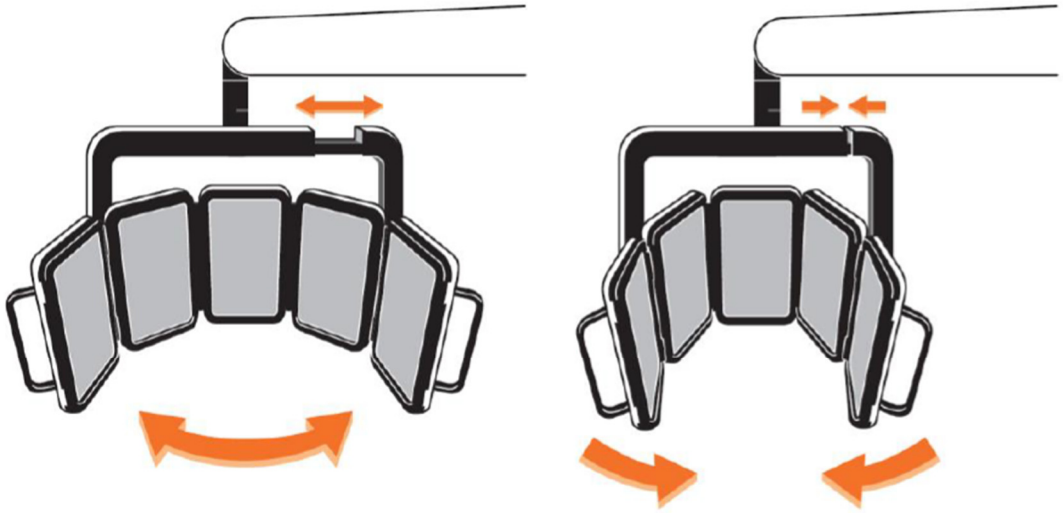


Figure 5: Movement range of the lamp head.

BF-RhodoLED® XL User Manual, Sec. 8.2, Fig. 5.

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.

BF-RhodoLED® XL User Manual, Sec. 8.4.8.

’028 Patent Claim 19	Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®
19. The system of claim 16, wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated.	The BF-RhodoLED® XL includes the system of claim 16, wherein one of the five panels is positioned as a center panel configured to face the treatment surface, wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated. The BF-RhodoLED® XL includes the system of claim 16, as detailed above. *See* claim 16. The BF-RhodoLED® XL includes light sources, wherein the light sources are configured to output red light during at least part of the time when the treatment surface is illuminated. The BF-RhodoLED® XL is a “red light-emitting LED lamp.” The BF-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.” **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. BF-RhodoLED® XL User Manual, Sec. 1. **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. BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).

'028 Patent Claim 20	**Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®**
20[pre] A system for photodynamically diagnosing or treating a patient, comprising:	The BF-RhodoLED® XL is a system for photodynamically diagnosing or treating a patient. For example, the BF-RhodoLED® XL is a system for photodynamically diagnosing or treating a patient. The BF-RhodoLED® XL includes an "LED lamp for . . . photodynamic therapy." "Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy." "The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel. . . . Any other use or combination of use is prohibited." The BF-RhodoLED® XL "is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." The BF-RhodoLED® XL's "[i]ntended use" is for "lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp."

RhodoLED® XL

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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 certified 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.

BF-RhodoLED® XL User Manual, at 2 (annotated).

	RhodoLED® XL Biofrontera Deep in dermatology **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. BF-RhodoLED® XL User Manual, Sec. 3.

RhodoLED® XL

Biofrontera
Deep in dermatology

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.**

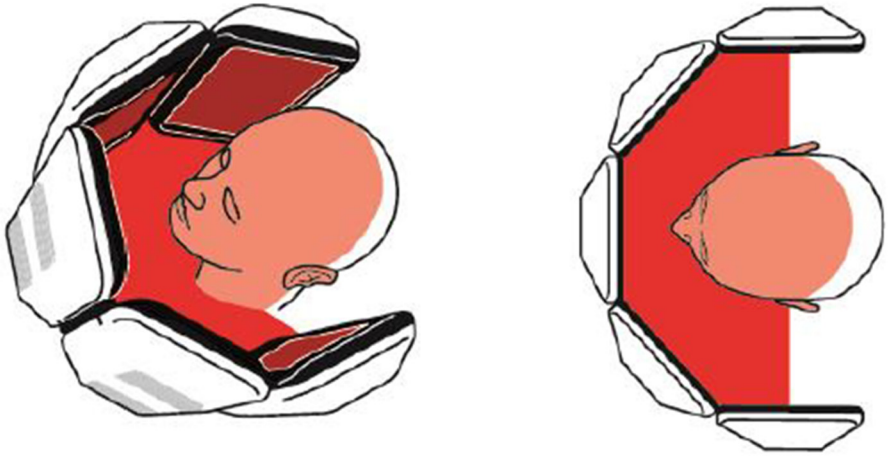


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

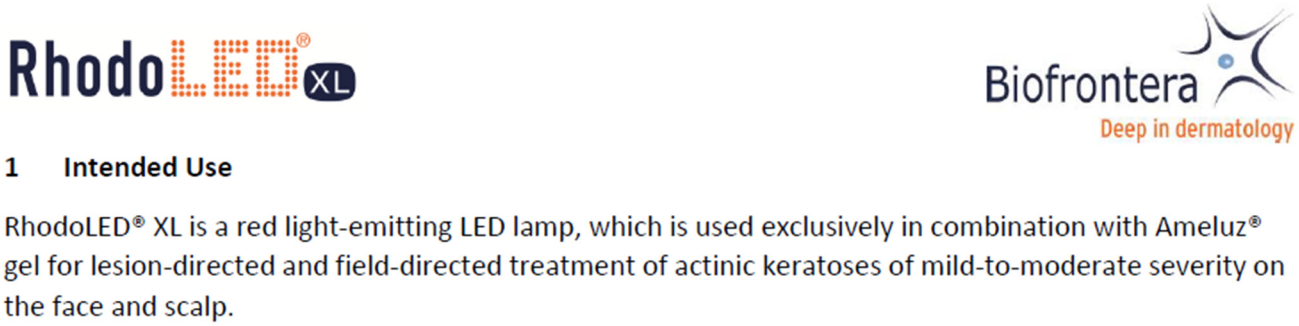
BF-RhodoLED® XL User Manual, Sec. 8.4.6, Fig. 13.

<table>
<tr><td></td><td>

----------INDICATIONS AND USAGE----------

AMELUZ, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1).

Ameluz® Prescribing Information, at 1.


RhodoLED® XL

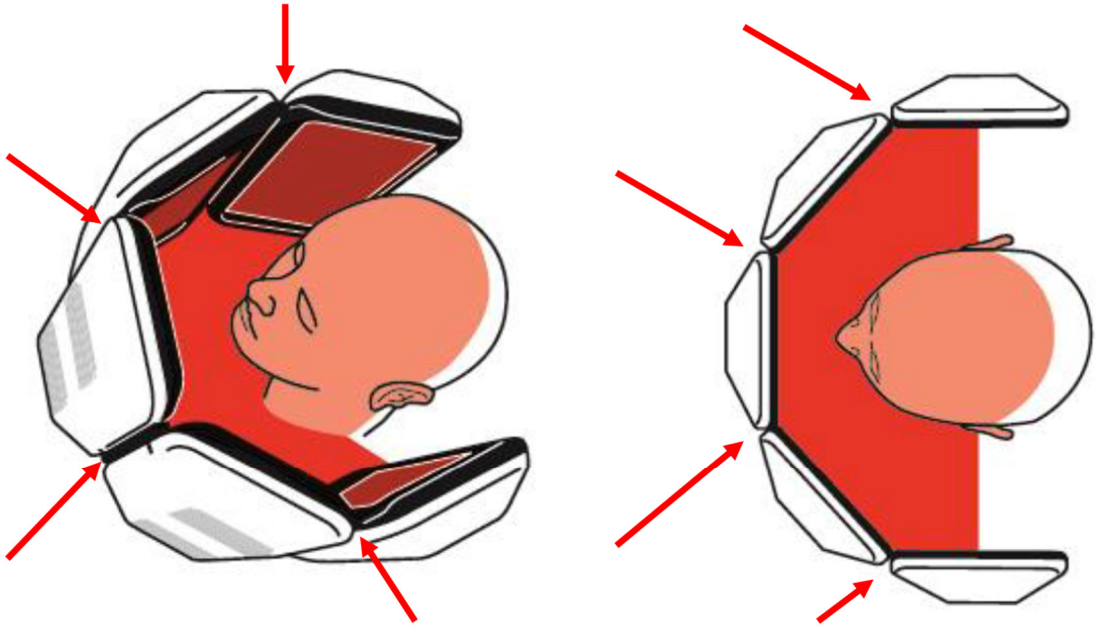
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1 Intended Use

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.

BF-RhodoLED® XL User Manual, Sec. 1.
</td></tr>
<tr><td>20[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the</td><td>The BF-RhodoLED® XL includes an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels, wherein the illuminator is configured to output light at a variable irradiance density during treatment.

For example, the BF-RhodoLED® XL has an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels. The BF-RhodoLED® XL includes “main components,”</td></tr>
</table>

illuminator is configured to output light at a variable irradiance density during treatment; and	including a "[l]amp head" with "5 LED panels." The LED panels are connected with hinges on the inner side surfaces of adjacent panels (shown below with red annotations).  **Figure 13:** Treatment area of RhodoLED® XL from the side and in top view. BF-RhodoLED® XL User Manual, Fig. 13 (annotated).

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)

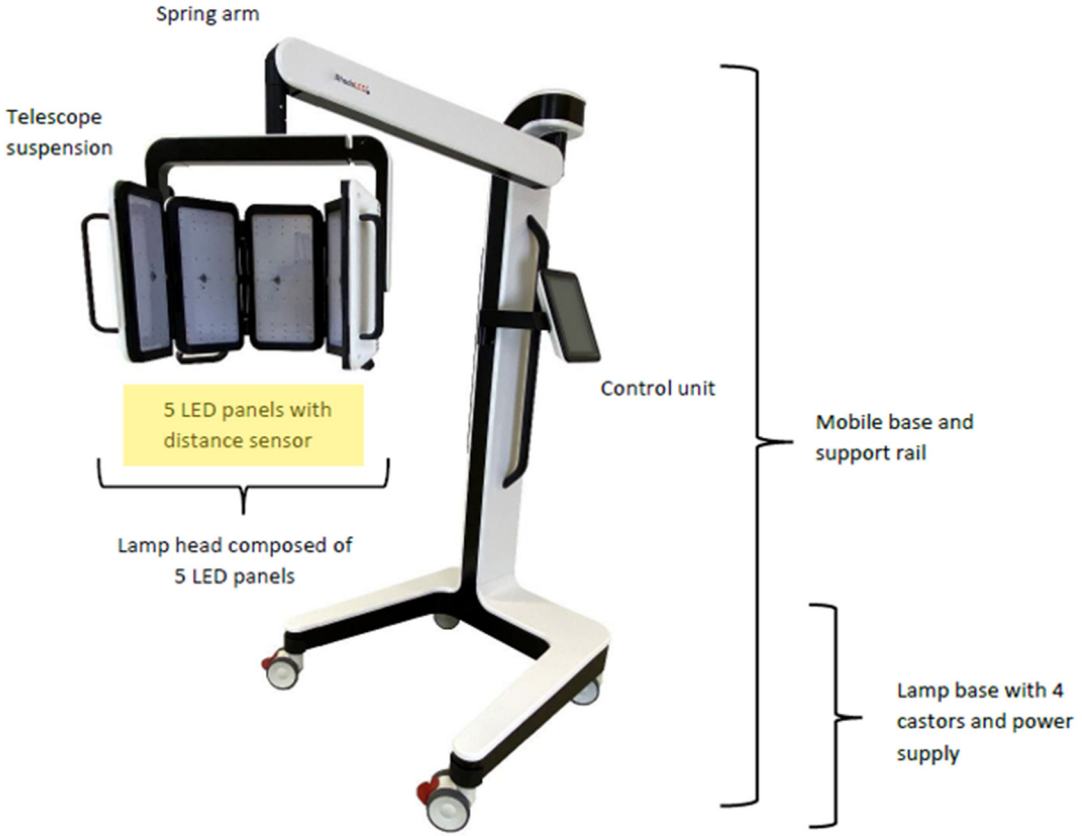


Figure 2: RhodoLED® XL main components

	BF-RhodoLED® XL User Manual, Fig. 2 (annotated). For example, the BF-RhodoLED® XL includes an illuminator, wherein the illuminator is configured to output light at a variable irradiance density during treatment. The BF-RhodoLED® XL's irradiance varies between "61 mW/cm^2 +/- 20%" (i.e., between 49 mW/cm^2 and 73 mW/cm^2). "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." **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. BF-RhodoLED® XL User Manual, Sec. 2.

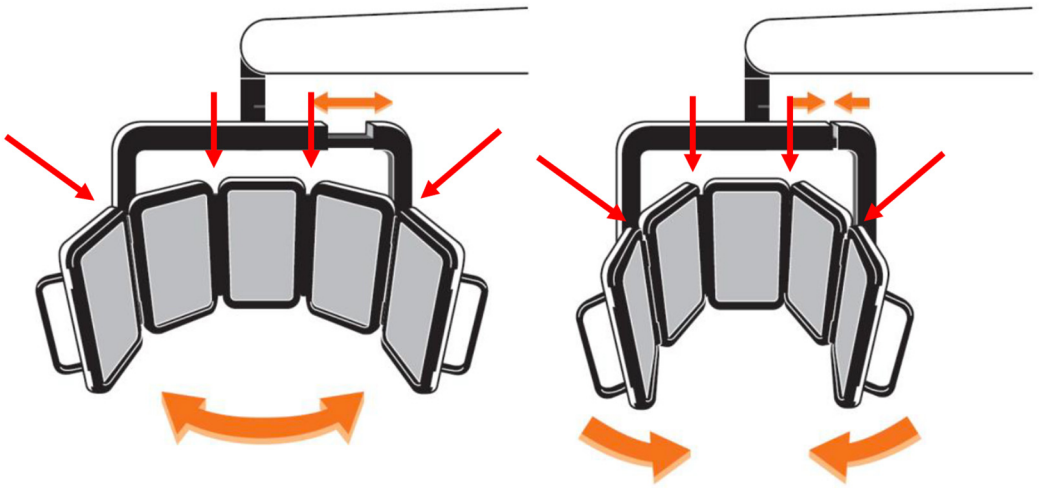


Figure 5: Movement range of the lamp head.

BF-RhodoLED® XL User Manual, Fig. 5 (annotated).

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 10-minute treatment time.

BF-RhodoLED® XL User Manual, Sec. 8.4.4.

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)

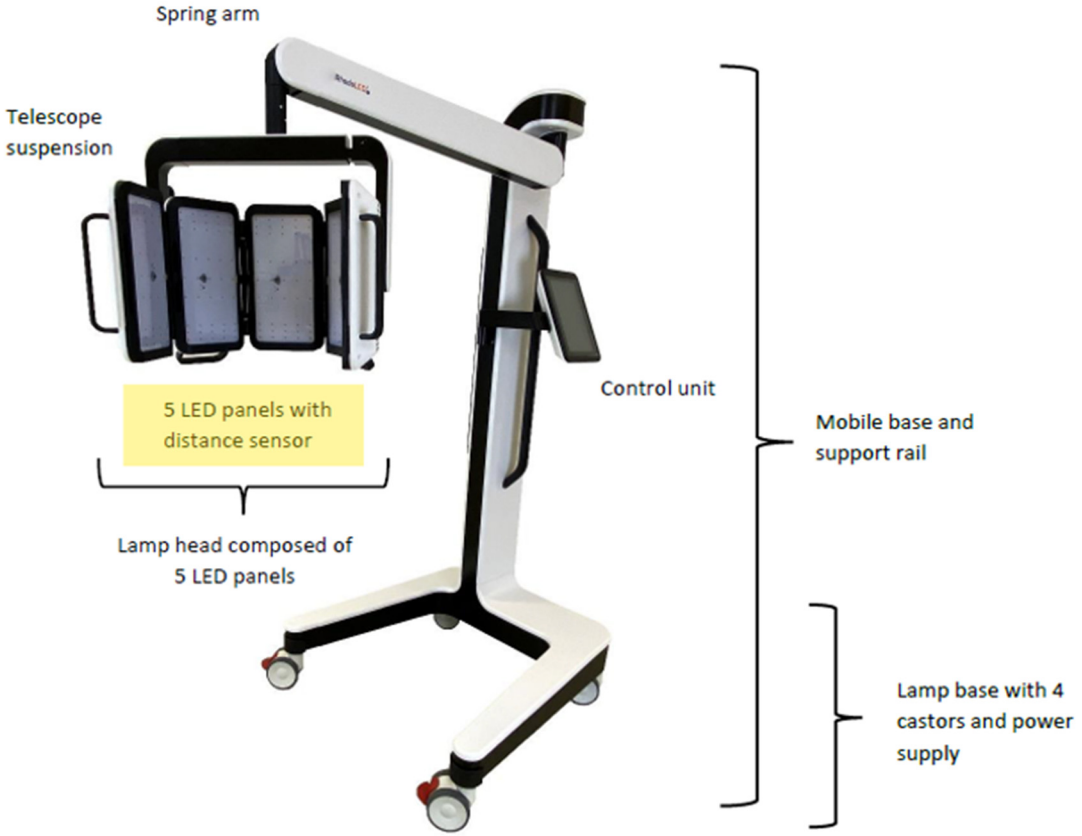


Figure 2: RhodoLED® XL main components

BF-RhodoLED® XL User Manual, Fig. 2 (annotated).

13.2 Specification

Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.08.03.2920
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, 10 min
Typical irradiance	61 mW/cm^2 ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	73.2 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 ± 0.59 inch (12.5 cm ± 1.5 cm) Measuring accuracy ± 0.3 cm (0.1 inch)

BF-RhodoLED® XL User Manual, Sec. 13.2 (annotated).

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.

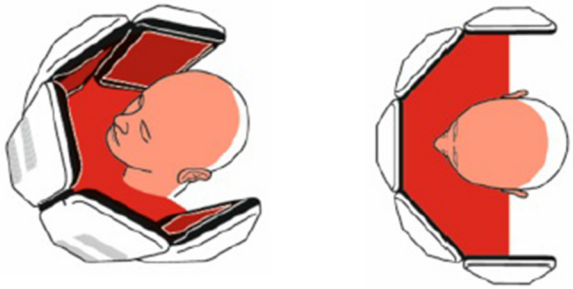
BF-RhodoLED® XL User Manual, Sec. 8.48.

	 **Figure 14:** Low light intensity for correct adjustment of LED panels. BF-RhodoLED® XL User Manual, Fig. 14.
20[b] one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel,	The BF-RhodoLED® XL includes one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel. For example, "[t]he BF-RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form." The LED panel orientation "can be changed from a curved shape to an unfolded form by pulling the holding bracket apart." In the "curved shape," the center panel is configured to face the treatment surface, such as the patient's head, while the remaining four panels are configured to be angled relative to the center panel. For example, "[t]he size of the treatment area is 9.06 x 11.42 inch . . . for all panels in a curved shape."

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.**



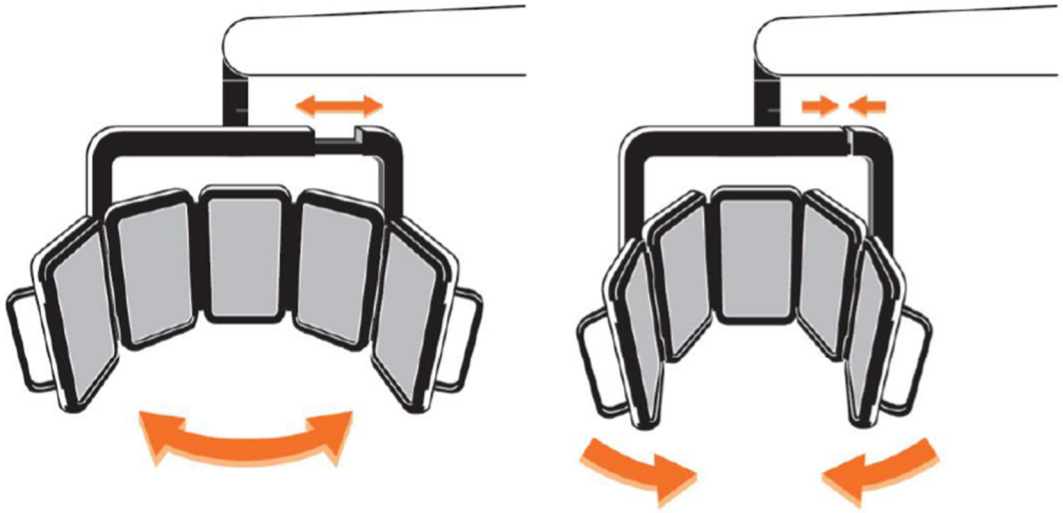
BF-RhodoLED® XL User Manual, Fig. 13.

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.

BF-RhodoLED® XL User Manual, Sec. 3.

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.

BF-RhodoLED® XL User Manual, Sec. 4.1.

	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. BF-RhodoLED® XL User Manual, Sec. 8.2, Fig. 5. 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. BF-RhodoLED® XL User Manual, Sec. 8.4.8.
20[c] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and	The BF-RhodoLED® XL includes five panels, wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface. For example, the BF-RhodoLED® XL instructs in its User Manual that the "LEDs are calibrated such that the skin being treated receives a light dose . . . under the following conditions: . . . Treatment distance of 4.9 +/- 0.59 inch." As one example, the treatment surface may be a patient's face.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions:

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 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.

BF-RhodoLED® XL User Manual, Sec. 4.1.

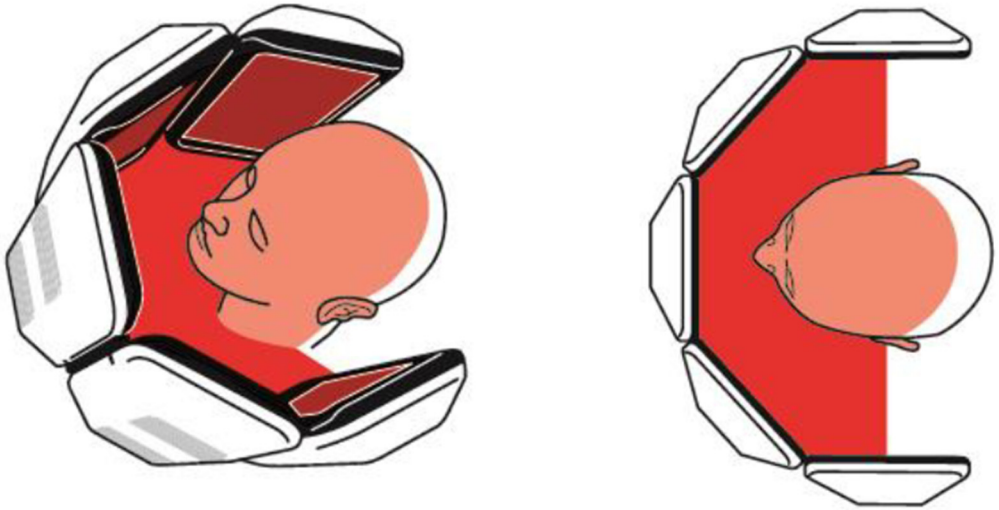


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Fig. 13.

20[d] wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.	The BF-RhodoLED® XL includes five panels, wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges. For example, each of the BF-RhodoLED® XL's five panels are rectangular, such that for each panel, there are two first edges (the sides), and two second edges (the top and bottom), where the second edges are shorter than the first two edges. The BF-RhodoLED® XL's LEDs each have "a fixed LED light intensity." The LEDs are arranged such that a higher intensity of light is emitted proximate the second edges (i.e., the shorter edges) compared to the intensity of light emitted not proximate the second edges. For example, 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."  BF-RhodoLED® XL User Manual, Fig. 14.

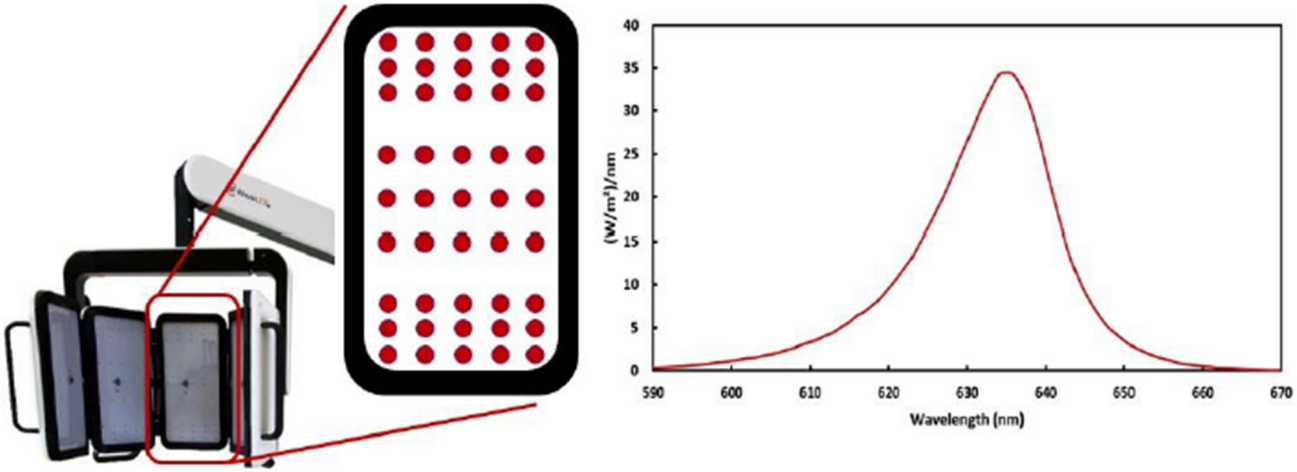


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions:

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 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.

BF-RhodoLED® XL User Manual, Sec. 4.1, Fig. 1.

	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 10-minute treatment time. BF-RhodoLED® XL User Manual, Sec. 8.4.4.
'028 Patent Claim 21	**Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®**
21[pre] A system for photodynamically diagnosing or treating a patient, comprising:	The BF-RhodoLED® XL is a system for photodynamically diagnosing or treating a patient. For example, the BF-RhodoLED® XL is a system for photodynamically diagnosing or treating a patient. The BF-RhodoLED® XL includes an "LED lamp for . . . photodynamic therapy." "Ameluz® and medical device RhodoLED® XL have been approved in combination for photodynamic therapy." "The RhodoLED® XL has been developed for use in photodynamic therapy in combination with Ameluz® gel. . . . Any other use or combination of use is prohibited." The BF-RhodoLED® XL "is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp." The BF-RhodoLED® XL's "[i]ntended use" is for "lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp."

RhodoLED® XL

Biofrontera
Deep in dermatology

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 certified 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.

BF-RhodoLED® XL User Manual, at 2 (annotated).

	RhodoLED® XL Biofrontera Deep in dermatology **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. BF-RhodoLED® XL User Manual, Sec. 3.

RhodoLED® XL

Biofrontera
Deep in dermatology

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.***

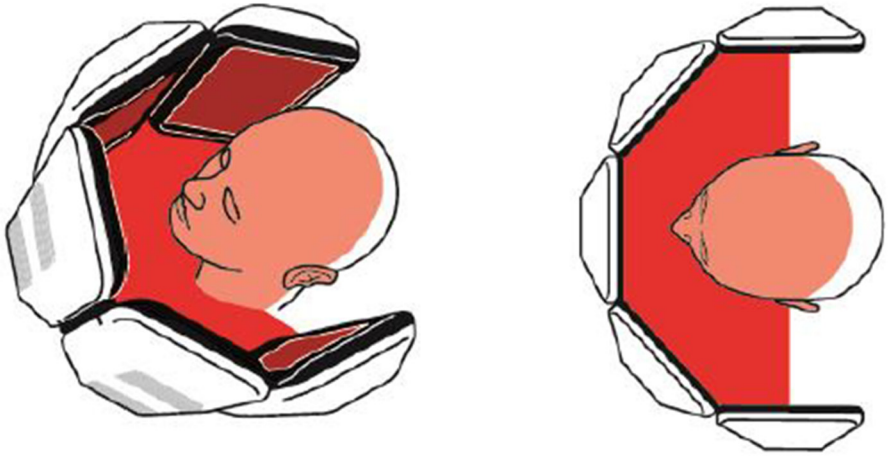


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

	BF-RhodoLED® XL User Manual, Sec. 8.4.6, Fig. 13. **----------INDICATIONS AND USAGE----------** AMELUZ, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED or RhodoLED XL lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1). Ameluz® Prescribing Information, at 1. RhodoLED® XL Biofrontera Deep in dermatology **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. BF-RhodoLED® XL User Manual, Sec. 1.
21[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces	The BF-RhodoLED® XL includes an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels. For example, the BF-RhodoLED® XL includes a lamp head with “5 LED panels” with hinges (shown below with red annotations).

of adjacent panels; and	

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)

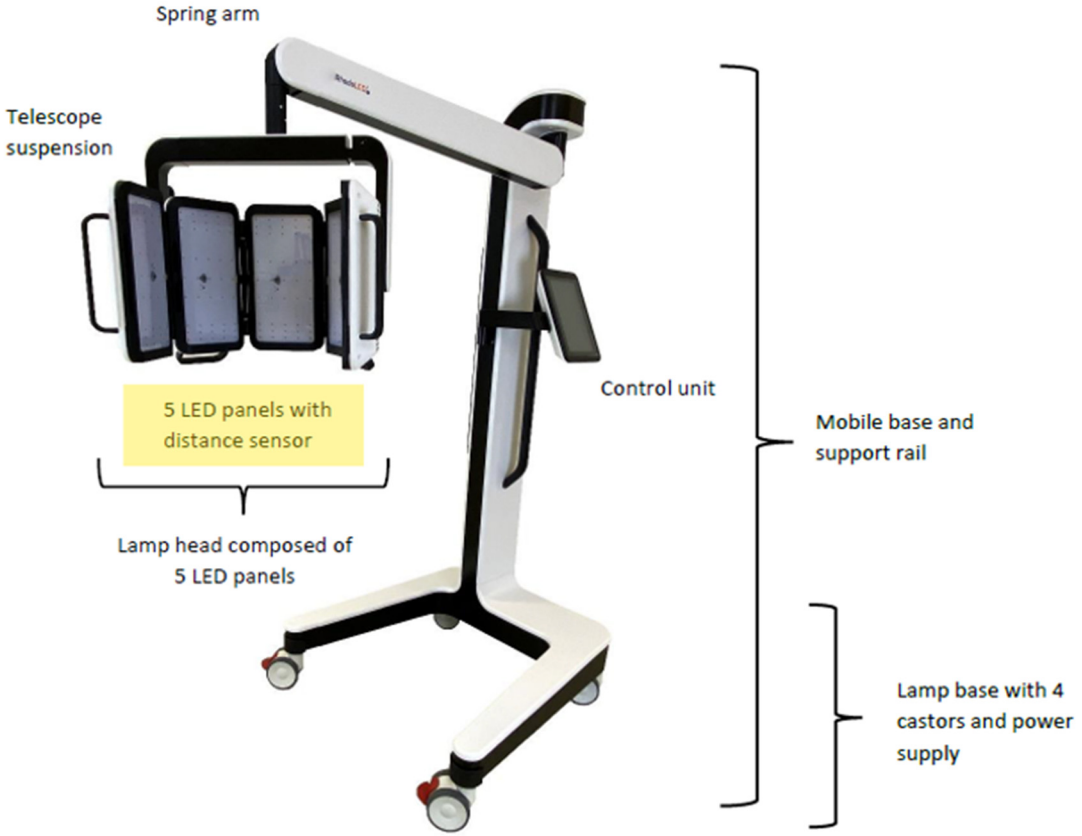
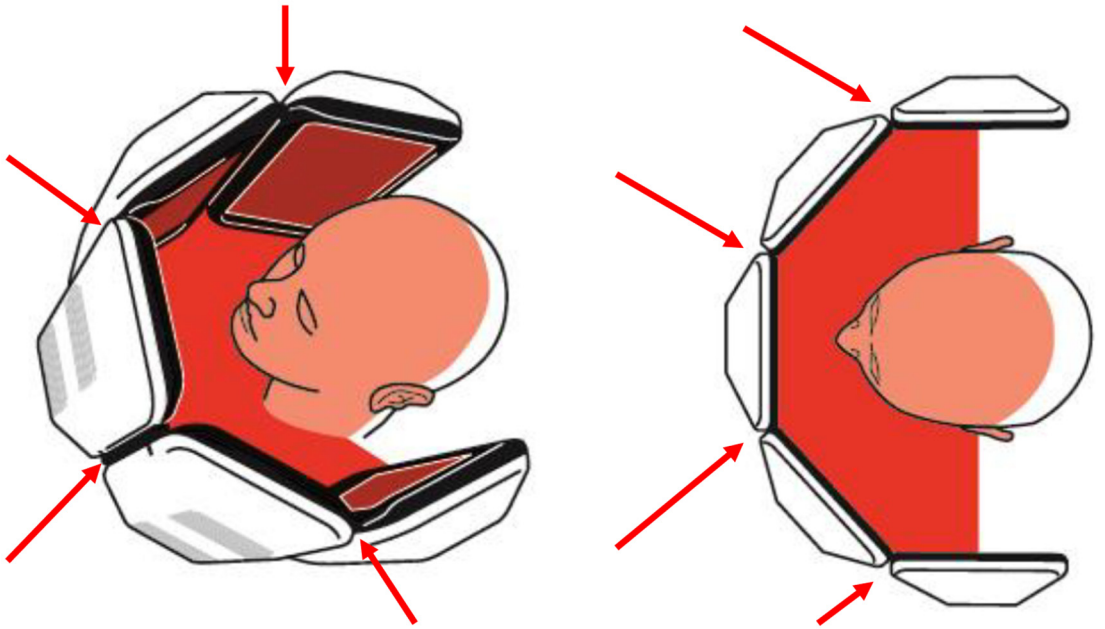
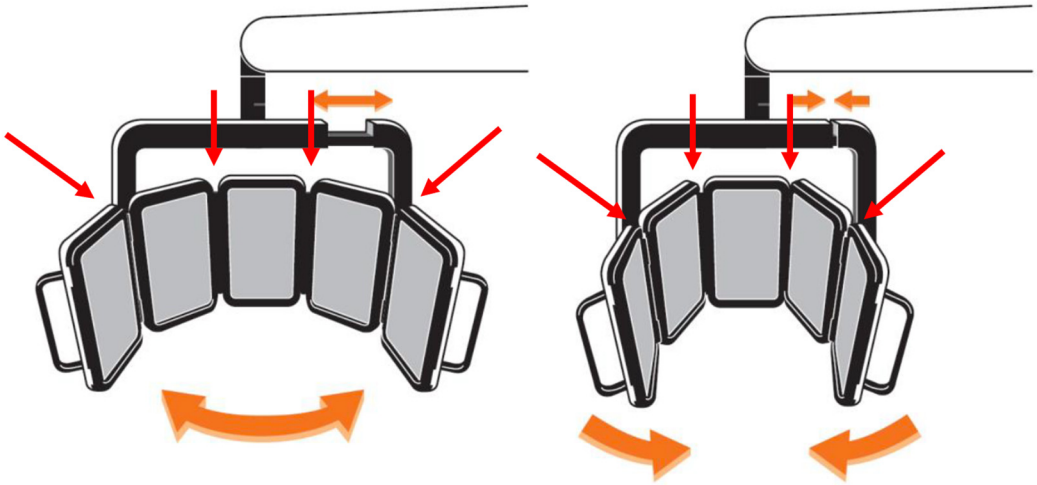


Figure 2: RhodoLED® XL main components

	BF-RhodoLED® XL User Manual, Fig. 2 (annotated).  **Figure 13:** Treatment area of RhodoLED® XL from the side and in top view. BF-RhodoLED® XL User Manual, Fig. 13 (annotated).

	 **Figure 5:** Movement range of the lamp head. BF-RhodoLED® XL User Manual, Fig. 5 (annotated).
21[b] light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,	The BF-RhodoLED® XL includes light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources. For example, the BF-RhodoLED® XL has LEDs disposed on surfaces of the five panels. The BF-RhodoLED® XL has "45 LEDs per panel with a total of 5 panels (225 LEDs)." For example, the BF-RhodoLED® XL is configured to uniformly illuminate a treatment surface of the patient via the LEDs. The five LED panels are configured to "emit a uniform, visible red light. The typical peak wavelength is approximately 635 nm with a half-band width of 16 nm." The maximum deviation of the intensity over the treatment area is approximately 20%.

<table>
<tr><td></td><td>

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.

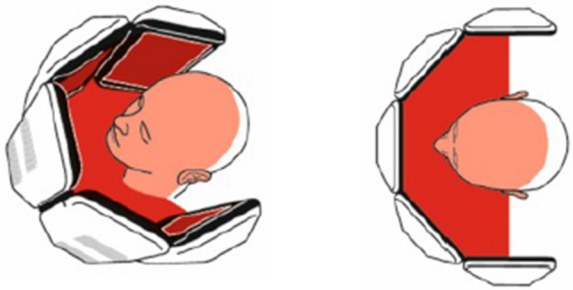
BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).

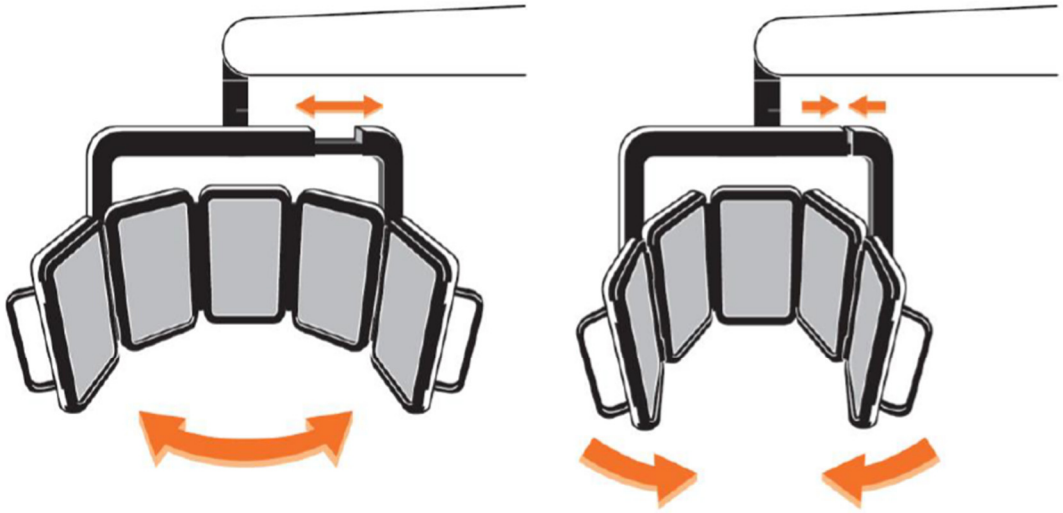
13.2 Specification

Type	RhodoLED® XL Medical device class III; Device of protection class 1
Certification	UL certified E513735
Software Version No.	g2.08.03.2920
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, 10 min
Typical irradiance	61 mW/cm^2 ± 20 % at 4.9 inch (12.5 cm) distance
Max irradiance	73.2 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 %

BF-RhodoLED® XL User Manual, Sec. 13.2 (annotated).
</td></tr>
<tr><td>21[c] one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five</td><td>The BF-RhodoLED® XL includes five panels, wherein one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the BF-RhodoLED® XL's five panels are configured to be angled relative to the center panel.

For example, "[t]he BF-RhodoLED® XL LED panels should only be used in curved shape and not in fully unfolded form." The LED panel orientation "can be changed from a curved shape to an unfolded form by pulling the holding bracket apart." In the "curved shape," the center panel is configured to face the treatment surface, such as the patient's head, while the remaining four panels are configured to be angled relative to the</td></tr>
</table>

panels being configured to be angled relative to the center panel,	center panel. For example, "[t]he size of the treatment area is 9.06 x 11.42 inch . . . for all panels in a curved shape." **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.**  BF-RhodoLED® XL User Manual, Fig. 13.  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. BF-RhodoLED® XL User Manual, Sec. 3. 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. BF-RhodoLED® XL User Manual, Sec. 4.1.

	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. BF-RhodoLED® XL User Manual, Sec. 8.2, Fig. 5. 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. BF-RhodoLED® XL User Manual, Sec. 8.4.8.
21[d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,	The BF-RhodoLED® XL includes five panels, wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface. For example, the BF-RhodoLED® XL instructs in its User Manual that the "LEDs are calibrated such that the skin being treated receives a light dose . . . under the following conditions: . . . Treatment distance of 4.9 +/- 0.59 inch." As one example, the treatment surface may be a patient's face.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions:

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 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.

BF-RhodoLED® XL User Manual, Sec. 4.1.

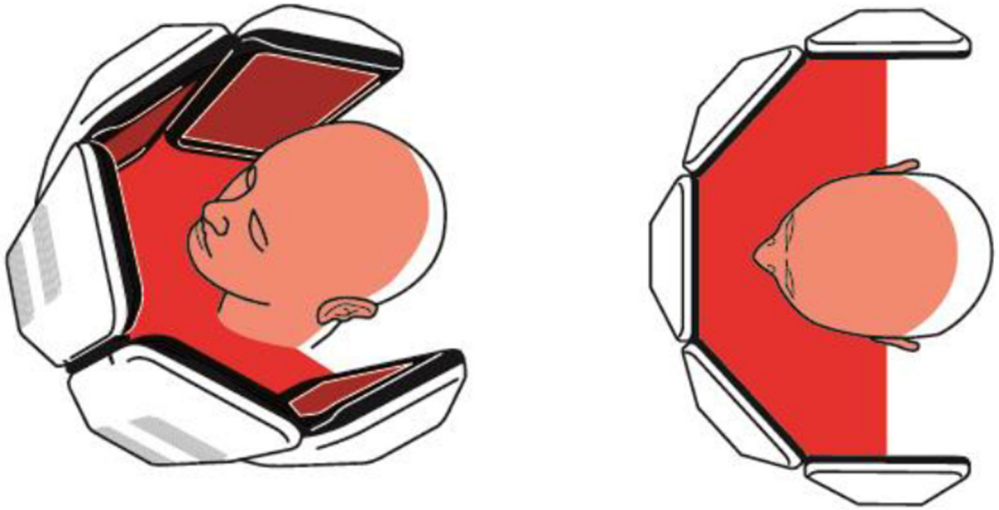


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Fig. 13.

<table>
<tr>
<td>21[e] wherein the five panels are individually configurable to control illumination from each of the five panels, and</td>
<td>The BF-RhodoLED® XL includes five panels, wherein the five panels are individually configurable to control illumination from each of the five panels.

For example, the BF-RhodoLED® XL includes five panels, wherein the five panels are individually configurable to control illumination from each of the five panels. The LED panels are individually configurable to control illumination. “All panels are activated by default and can be deactivated via the software. To deactivate LED panels, press on the illustrated panel.”

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)

BF-RhodoLED® XL User Manual, Sec. 8.4.5 (annotated), Fig. 10.</td>
</tr>
<tr>
<td>21[f] wherein each of the five panels has two first edges and two second edges shorter than the two first edges,</td>
<td>The BF-RhodoLED® XL includes five panels, wherein each of the five panels has two first edges and two second edges shorter than the two first edges, and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.</td>
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</table>

and the light sources are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light emitted not proximate the second edges.	For example, each of the BF-RhodoLED® XL's five panels are rectangular, such that for each panel, there are two first edges (the sides), and two second edges (the top and bottom), where the second edges are shorter than the first two edges. The BF-RhodoLED® XL's LEDs each have "a fixed LED light intensity." The LEDs are arranged such that a higher intensity of light is emitted proximate the second edges (i.e., the shorter edges) compared to the intensity of light emitted not proximate the second edges. For example, 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."  BF-RhodoLED® XL User Manual, Fig. 14.

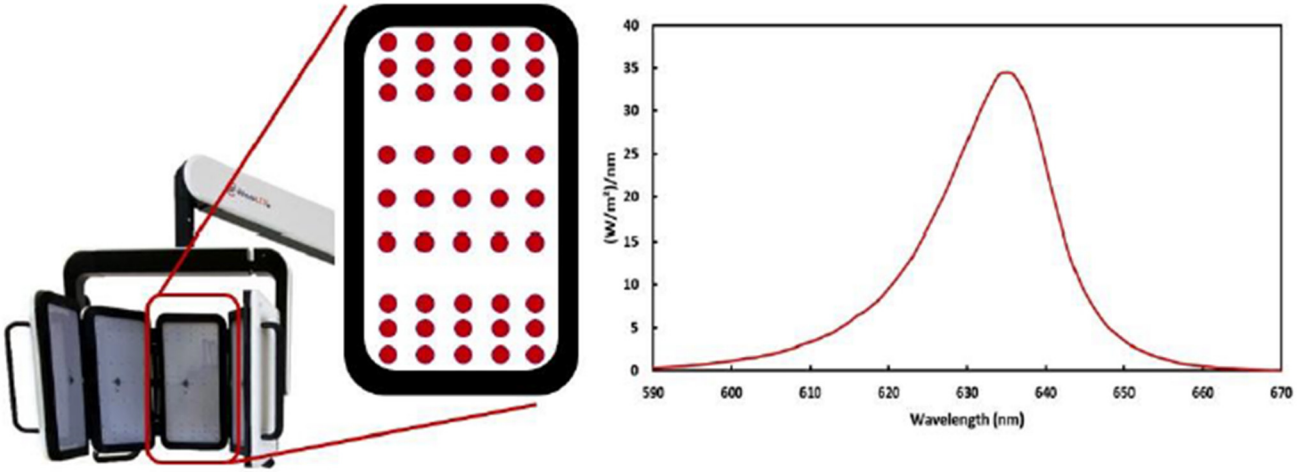


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm^2 under the following conditions:

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 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.

BF-RhodoLED® XL User Manual, Sec. 4.1, Fig. 1.

	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 10-minute treatment time. BF-RhodoLED® XL User Manual, Sec. 8.4.4.