

EXHIBIT 3

Exhibit 3: Infringement Claim Chart for U.S. Patent No. 11,445,512 (the “’512 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 ’512 Patent. The exemplary claim mappings below rely on images and data from 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 1-3, 5, 8, and 20 of the ’512 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 element and 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 ’512 Patent) (“Biofrontera Customers”) to use and purchase the Accused Products, such that the Biofrontera Customers directly infringe at least claims 1-3, 5, 8, and 20 of the ’512 Patent. For example, Biofrontera provides manuals to the Biofrontera Customers which instruct them to use the Accused Products, to practice at least claims 1-3, 5, 8, and 20 of the ’512 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 1-3, 5, 8, and 20 of the ’512 Patent. Biofrontera also markets and advertises the Accused Products used in combination with the same. Defendants have knowledge of their infringement of the ’512 Patent at least through the filing of this litigation.

Further, Biofrontera contributes to others practicing at least claims 1-3, 5, 8, and 20 of the ’512 Patent because Biofrontera sells and offers to sell the Accused Products for use in practicing the ’512 Patent. Biofrontera knows that 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.

'512 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.”



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>.



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



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.

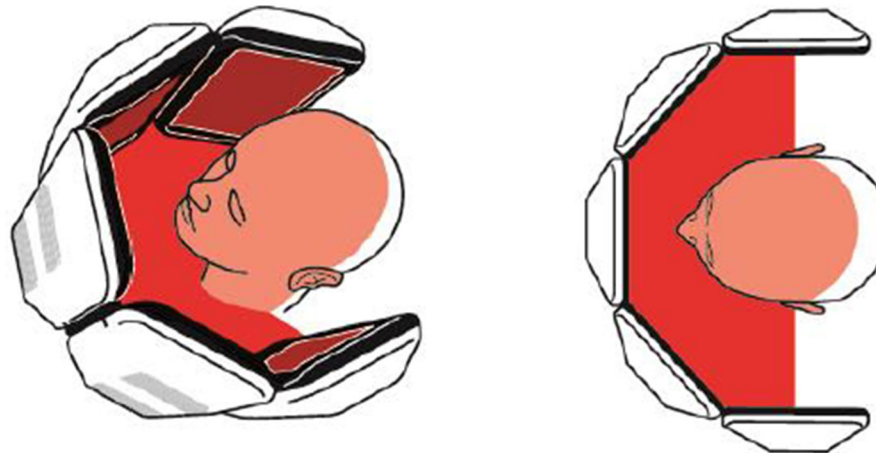


Figure 13: Treatment area of RhodoLED[®] XL from the side and in top view.

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



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 at least five panels connected by nested hinges on inner side surfaces of adjacent panels,	The BF-RhodoLED® XL includes an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels. For example, the BF-RhodoLED® XL includes a lamp head with five panels connected by nested hinges on inner side surfaces of adjacent panels. The BF-RhodoLED® XL 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)

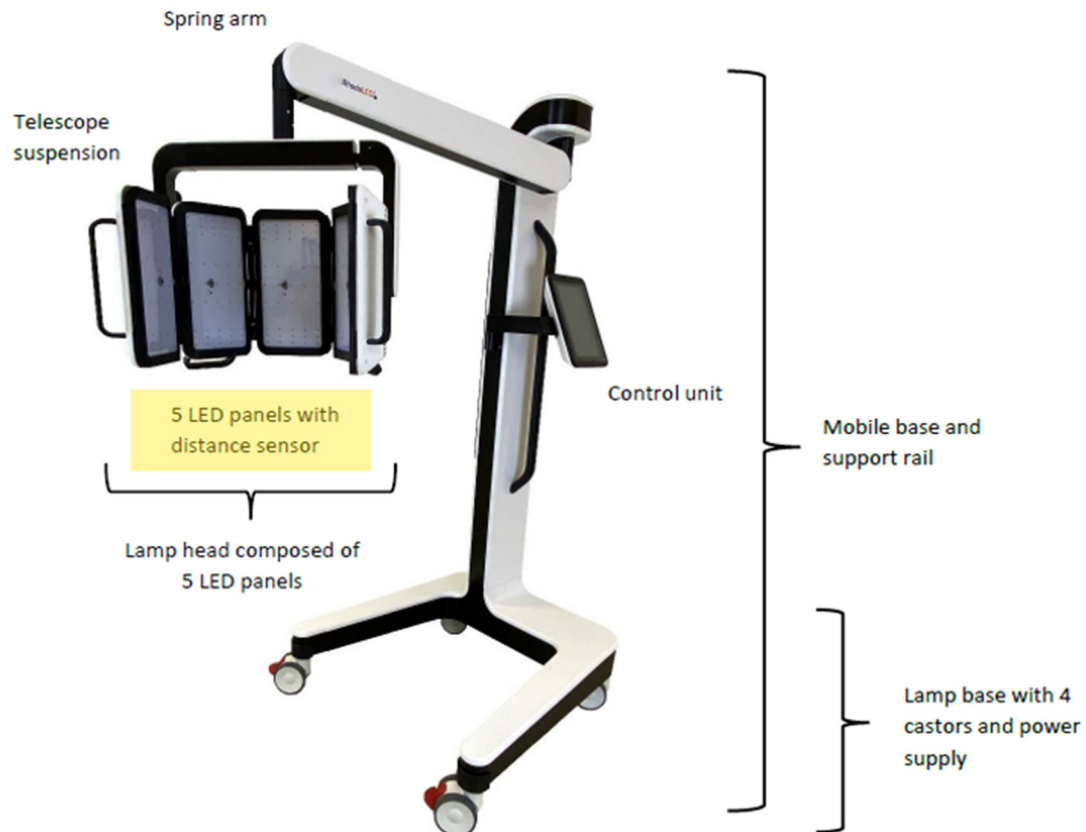


Figure 2: RhodoLED® XL main components

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.

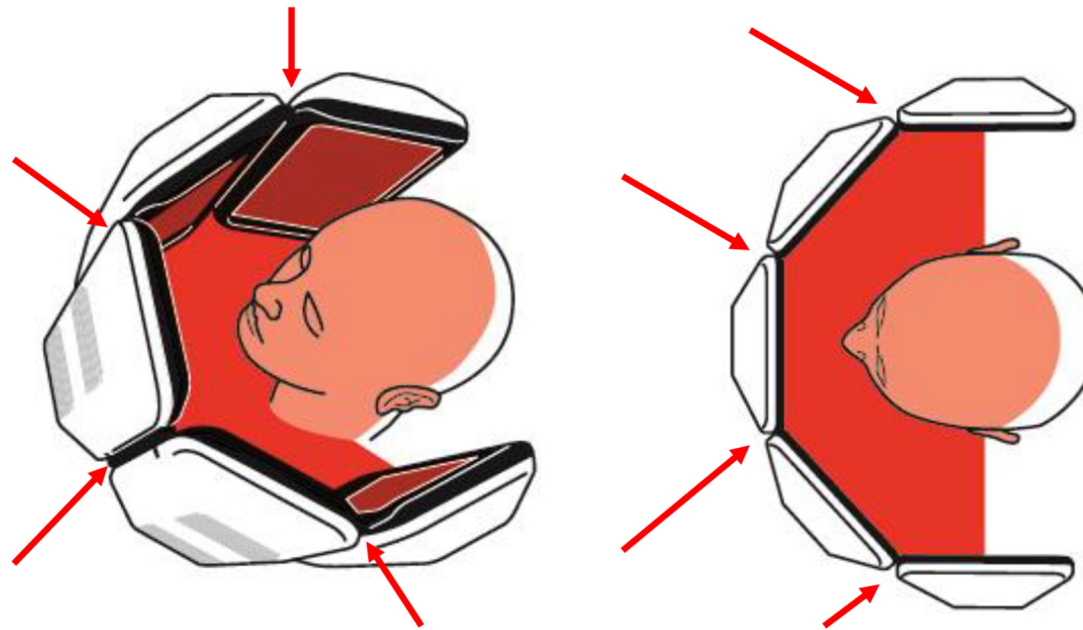


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

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

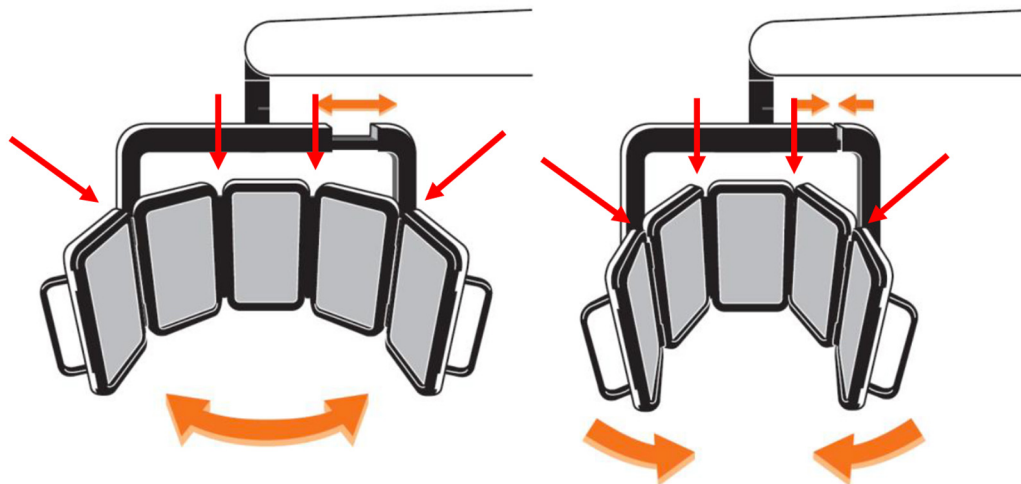


Figure 5: Movement range of the lamp head.

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

1[b] light sources disposed on surfaces of the at least 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 at least 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’s lamp head is configured 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 $\pm$ 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 $\pm$ 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).

1[c] one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at

The BF-RhodoLED® XL includes five panels, wherein at one of the at least five panels being positioned as a center panel configured to face the treatment surface, and two or more of the at least 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

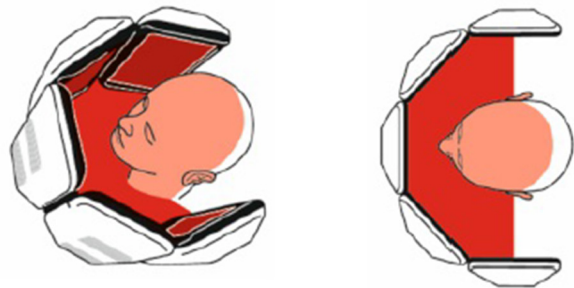
least five panels being configured to be angled relative to the center panel,

head, while the remaining four panels are configured to be angled relative to the center panel. For example, “the 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).

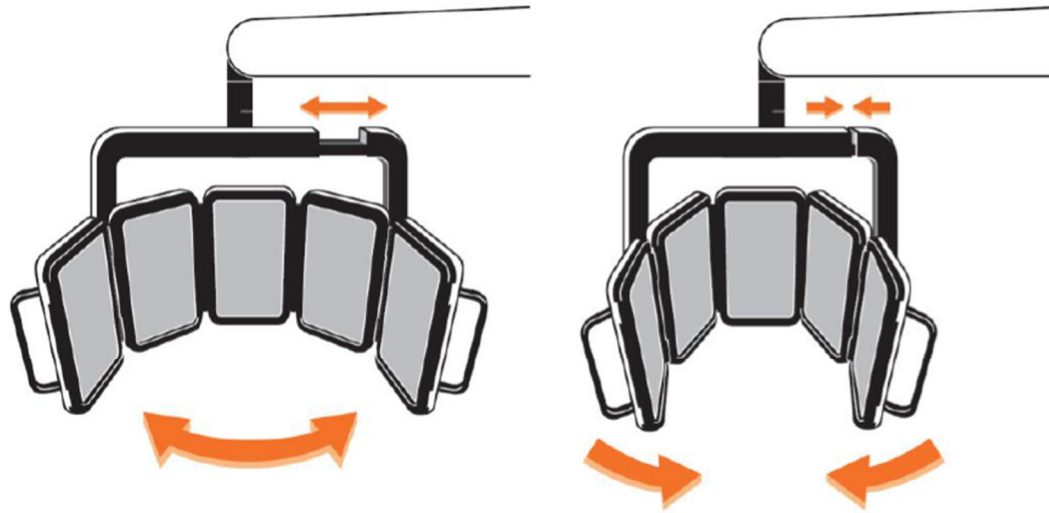


Figure 5: Movement range of the lamp head.

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.

BF-

1[d] wherein each of the at least 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 at least 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.

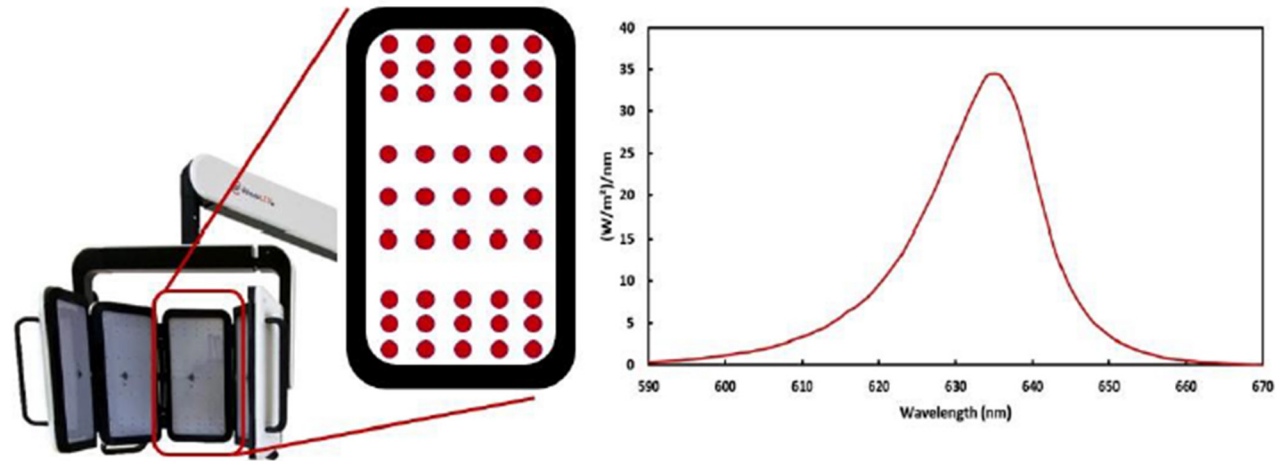


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

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

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 inch ($12.5 \text{ cm} \pm 1.5 \text{ cm}$)

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.
'512 Patent Claim 2	Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®
The system of claim 1, wherein the illuminator is configured to uniformly illuminate the treatment surface when the treatment surface is at a distance of two to four inches from the illuminator.	The BF-RhodoLED® XL includes the system of claim 1, wherein the illuminator is configured to uniformly illuminate the treatment surface when the treatment surface is at a distance of two to four inches from the illuminator. The BF-RhodoLED® XL includes the system of claim 1, as detailed above. <i>See</i> claim 1. The BF-RhodoLED® XL includes an illuminator, wherein the illuminator is configured to uniformly illuminate the treatment surface when the treatment surface is at a distance of two to four inches from the illuminator. 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%.

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/cm² 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.

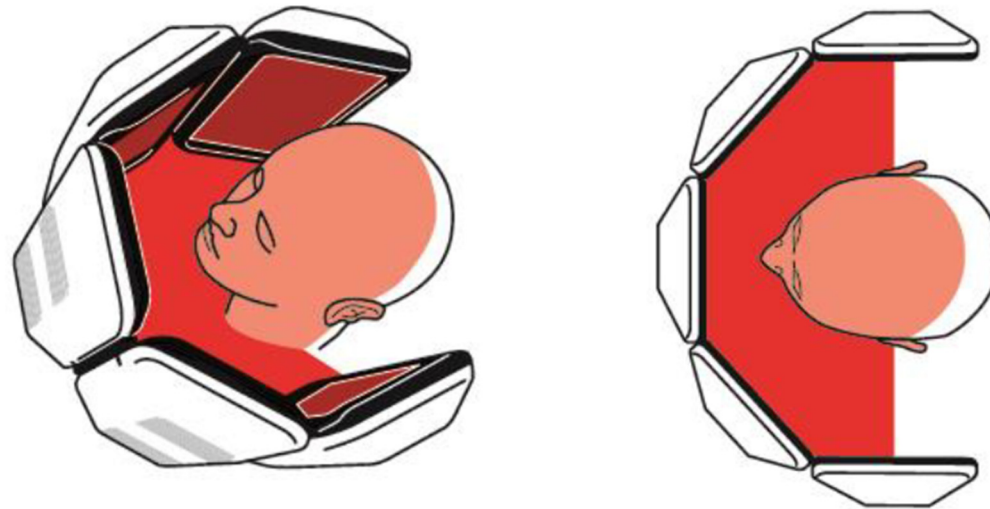


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Fig. 13.

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 $\pm$ 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 $\pm$ 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).

'512 Patent Claim 3

Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®

The system of claim 1, wherein the illuminator is configured to

The BF-RhodoLED® XL includes the system of claim 1, wherein the illuminator is configured to output red light at a dose of about 30 J/cm² to about 150 J/cm².

The BF-RhodoLED® XL includes the system of claim 1, as detailed above. *See* claim 1.

output red light at a dose of about 30 J/cm² to about 150 J/cm².	The BF-RhodoLED® XL includes an illuminator, wherein the illuminator is configured to output red light at a dose of 30 J/cm² to 150 J/cm². For example, the BF-RhodoLED® XL's lamp head is configured to output red light at a dose of 30 J/cm² to 150 J/cm². 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/cm² 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. BF-RhodoLED® XL User Manual, Sec. 4.1 (annotated).
---	---

	The RhodoLED® XL LEDs are calibrated such that the skin being treated receives a light dose of approximately 37 J/cm² under the following conditions: - Illumination time of 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).
'512 Patent Claim 5	Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®
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, 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. <i>See</i> claim 1. The BF-RhodoLED® XL includes light sources, 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's LEDs are configured to emit light with a "[t]ypical peak wavelength" of "635 nm +/- 5 nm."

	13.2 Specification <table border="1"> <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).	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)	Transport conditions	Temperature: -4 °F to +140 °F (-20 °C to +60 °C) Atmospheric pressure: 500 hPa - 1060 hPa Relative humidity: 10 % - 90 %, non-condensing
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)																										
Transport conditions	Temperature: -4 °F to +140 °F (-20 °C to +60 °C) Atmospheric pressure: 500 hPa - 1060 hPa Relative humidity: 10 % - 90 %, non-condensing																										
'512 Patent Claim 8	Biofrontera BF-RhodoLED® XL, Individually or in Combination with Ameluz®																										
8[pre] A method of photodynamically diagnosing or treating a patient, comprising:	The BF-RhodoLED® XL can be used in conjunction with a method for photodynamically diagnosing or treating a patient. For example, the BF-RhodoLED® XL can be used in conjunction with a method for photodynamically 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.”



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).



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



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.

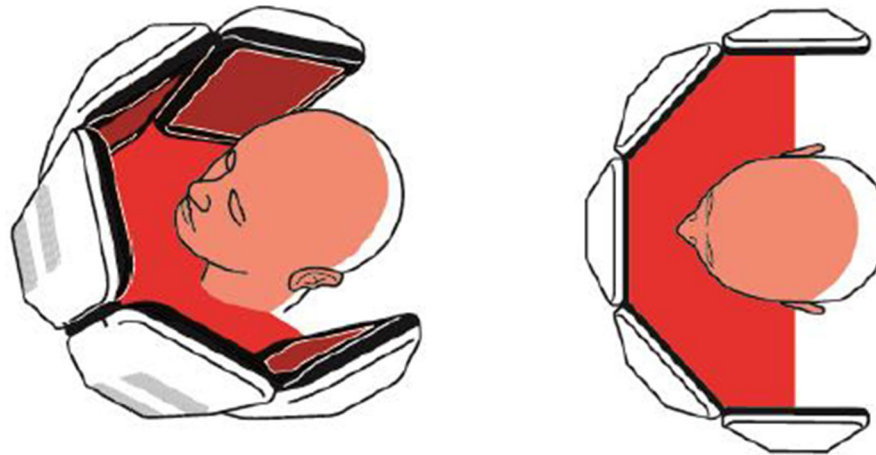


Figure 13: Treatment area of RhodoLED[®] XL from the side and in top view.

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.  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.
8[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.”



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

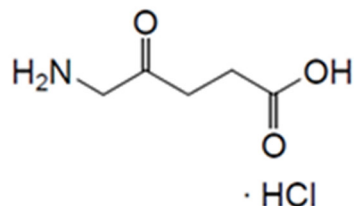
Uses: AMELUZ® gel, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED® lamp, is used for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.

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-oxopentanoic 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.

- | | |
|--|---|
| | <p>STEP 1) Plug in the lamp.</p> <p>STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter 8.4.3).</p> <p>STEP 3) Check the proper functioning of the RhodoLED® XL.</p> <p>STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®.</p> <p>STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6).</p> <p>STEP 6) Select active panels (see chapter 8.4.5).</p> <p>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).</p> <p>STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6).</p> <p>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.</p> |
|--|---|

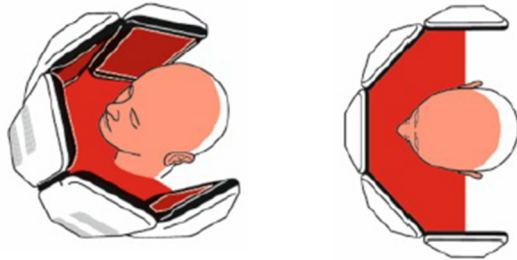
BF-RhodoLED® XL User Manual, Sec. 7 (annotated).

	-----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.
8[b] positioning an illuminator proximate to the patient, the illuminator comprising at least five panels connected by nested hinges 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 at least five panels connected by nested hinges 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/cm² 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 chapter 8.4.3).
- STEP 3) Check the proper functioning of the RhodoLED® XL.
- STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®.
- STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6).
- STEP 6) Select active panels (see chapter 8.4.5).
- STEP 7) Position the lamp and adjust the lamp head over the skin area to be treated (distance 4.9 inch /12.5 cm) (see chapter 8.4.6).
- STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6).
- STEP 9) Start treatment by pressing **Start**, the illumination period begins (see chapter 8.4.9).
Remind the patient to remain still throughout the illumination period.
If audible indicators during treatment are activated, explain the sounds to the patient.
If the patient needs a break, press **Pause** on the screen.
To resume treatment, press **Resume** (see chapter 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 lamp head comprises five panels connected by nested structures on inner side surfaces of adjacent panels. The BF-RhodoLED® XL's lamp head has "5 LED panels" with nested 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)

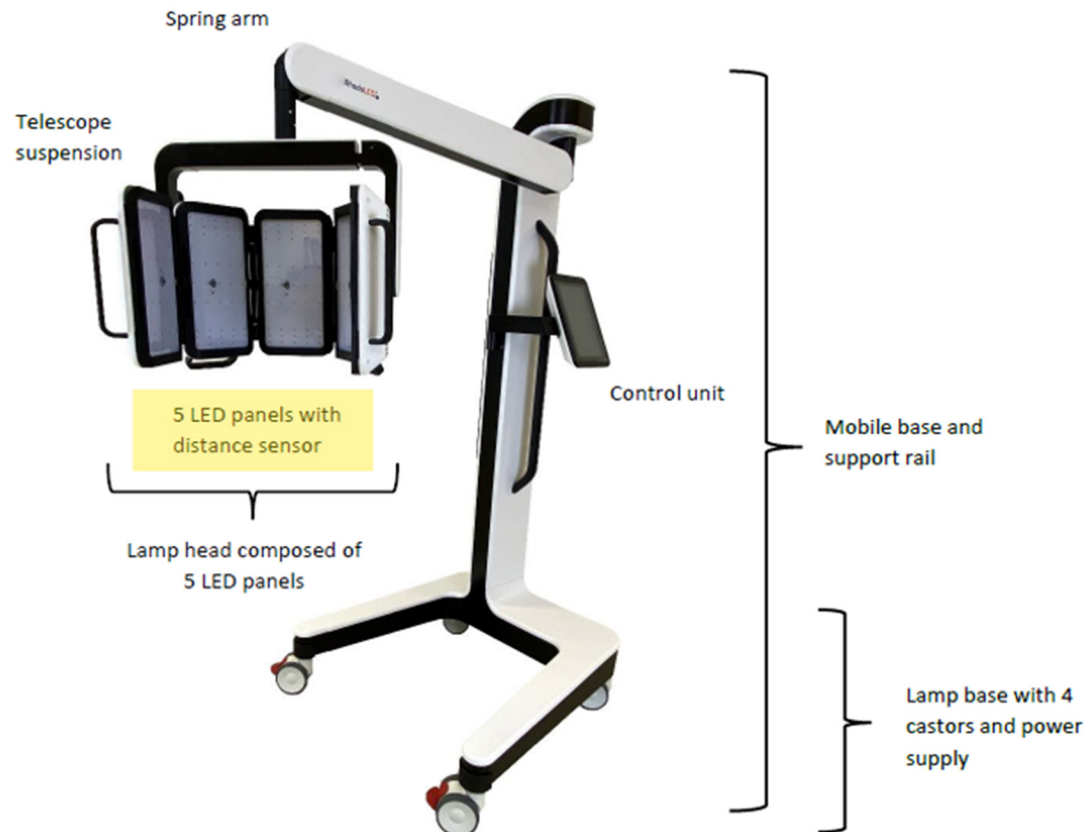


Figure 2: RhodoLED® XL main components

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

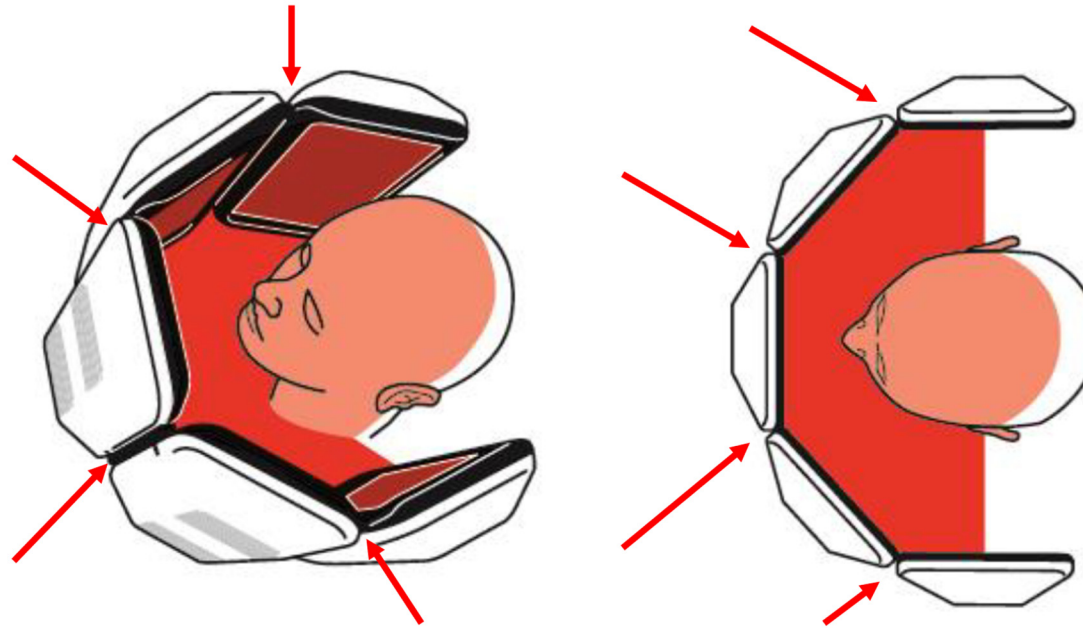


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

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

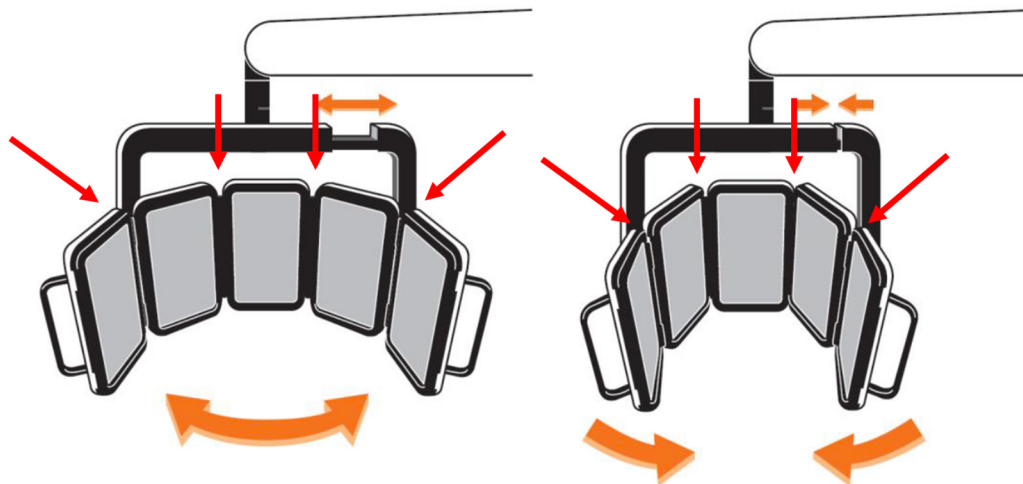


Figure 5: Movement range of the lamp head.

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

8[c] uniformly illuminating a treatment surface of the patient with light sources disposed on the at least five panels of the illuminator,

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.

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 LEDs illuminate the patient's treatment surface, such as the patient's face. 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%. 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.”

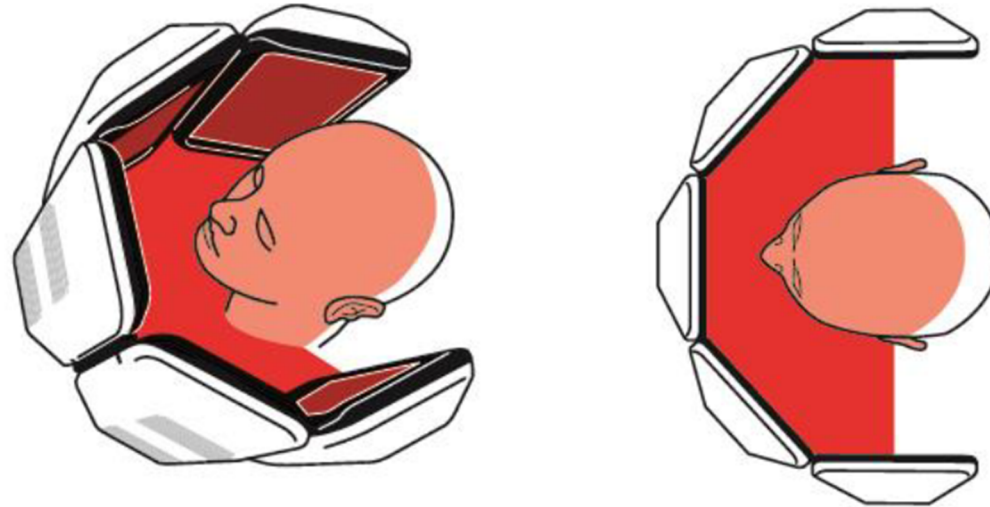


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

BF-RhodoLED® XL User Manual, Fig. 13.

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 $\pm$ 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 $\pm$ 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).

	STEP 1) Plug in the lamp. STEP 2) Turn on the lamp and wait for the home screen to appear (see chapter 8.4.3). STEP 3) Check the proper functioning of the RhodoLED® XL. STEP 4) Treat the affected skin area: Application, incubation, and removal of the topical medication according to the USPI of Ameluz®. STEP 5) Position the patient comfortably and equip the patient with protective eyewear (see chapter 6). STEP 6) Select active panels (see chapter 8.4.5). STEP 7) Position the lamp and adjust the lamp head over the skin area to be treated (distance 4.9 inch /12.5 cm) (see chapter 8.4.6). STEP 8) Put on protective eyewear and make sure anyone remaining in the treatment room also wears protective eyewear (see chapter 6). STEP 9) Start treatment by pressing Start, the illumination period begins (see chapter 8.4.9). Remind the patient to remain still throughout the illumination period. If audible indicators during treatment are activated, explain the sounds to the patient. If the patient needs a break, press Pause on the screen. To resume treatment, press Resume (see chapter 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).
8[d] wherein each of the at least five panels has two first edges and two second edges shorter than the two first edges, and the light	The BF-RhodoLED® XL includes five panels, wherein each of the at least 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, the BF-RhodoLED® XL has five panels and each of the five panels has two first edges and two second edges shorter than the two first edges. Each panel has two first edges (the sides) and two second edges (the top and bottom) that are shorter length than the first two edges.

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's LEDs are arranged such that a higher intensity of light is emitted proximate the second edges compared to the intensity of light. The BF-RhodoLED® XL "has a fixed LED light intensity," and its "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.

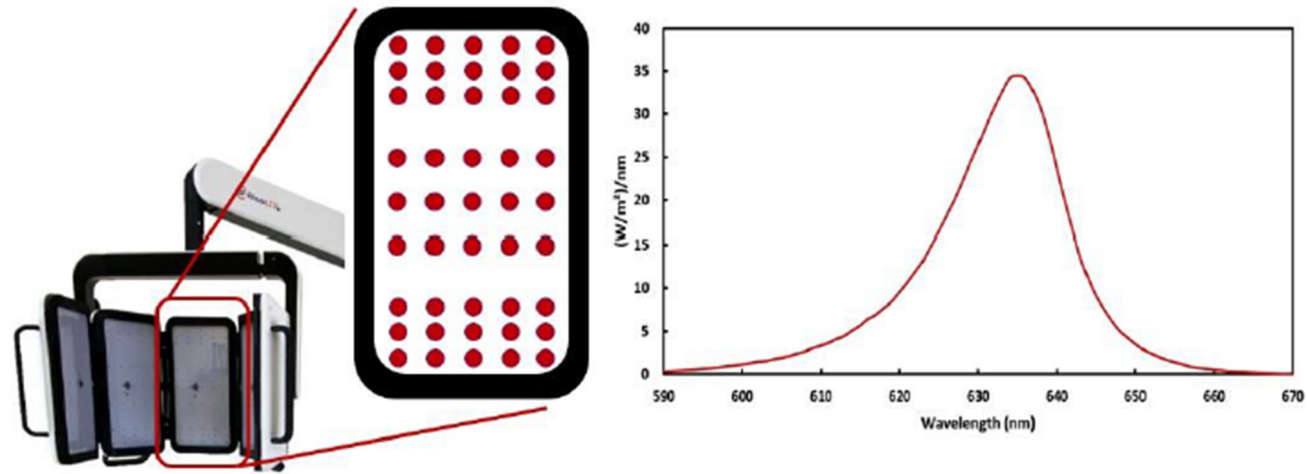


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

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

- Illumination time of 10 minutes
- Treatment distance of 4.9 ± 0.59 inch (12.5 cm $\pm$ 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.
'512 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 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.”



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).



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



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.

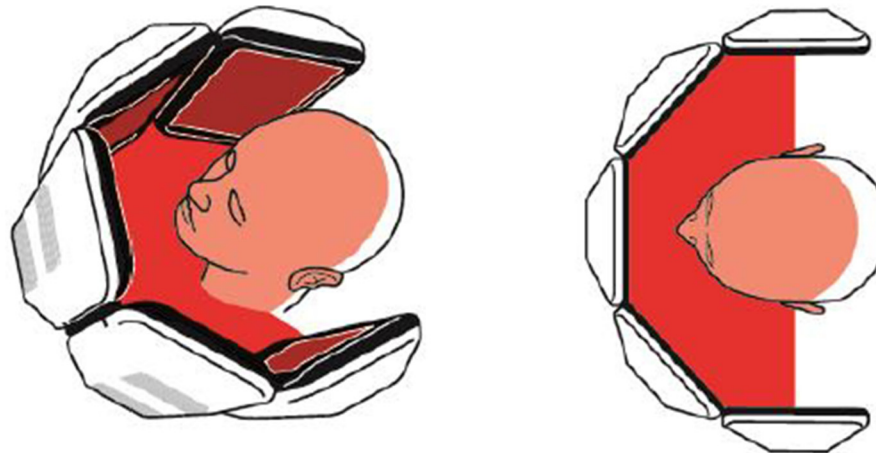


Figure 13: Treatment area of RhodoLED[®] XL from the side and in top view.

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.  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.
20[a] an illuminator comprising five panels connected by nested hinges on inner side surfaces of	The BF-RhodoLED® XL includes an illuminator comprising five panels connected by nested hinges on inner side surfaces of adjacent panels, the nested hinges being configured so as to allow continuous illumination across the at least five panels. For example, the BF-RhodoLED® XL has a lamp head comprising five panels connected by nested hinges on inner side surfaces of adjacent panels. The BF-RhodoLED® XL includes “main components,” including a “[l]amp head”

adjacent panels, the nested hinges being configured so as to allow continuous illumination across the at least five panels,	with “5 LED panels.” The LED panels are connected with nested hinges on the inner side surfaces of adjacent panels (shown below with red annotations). 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 nested 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 treatment area through its LEDs, including by connecting the five panels by nested hinges to allow for continuous illumination across the five panels.
---	---

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)

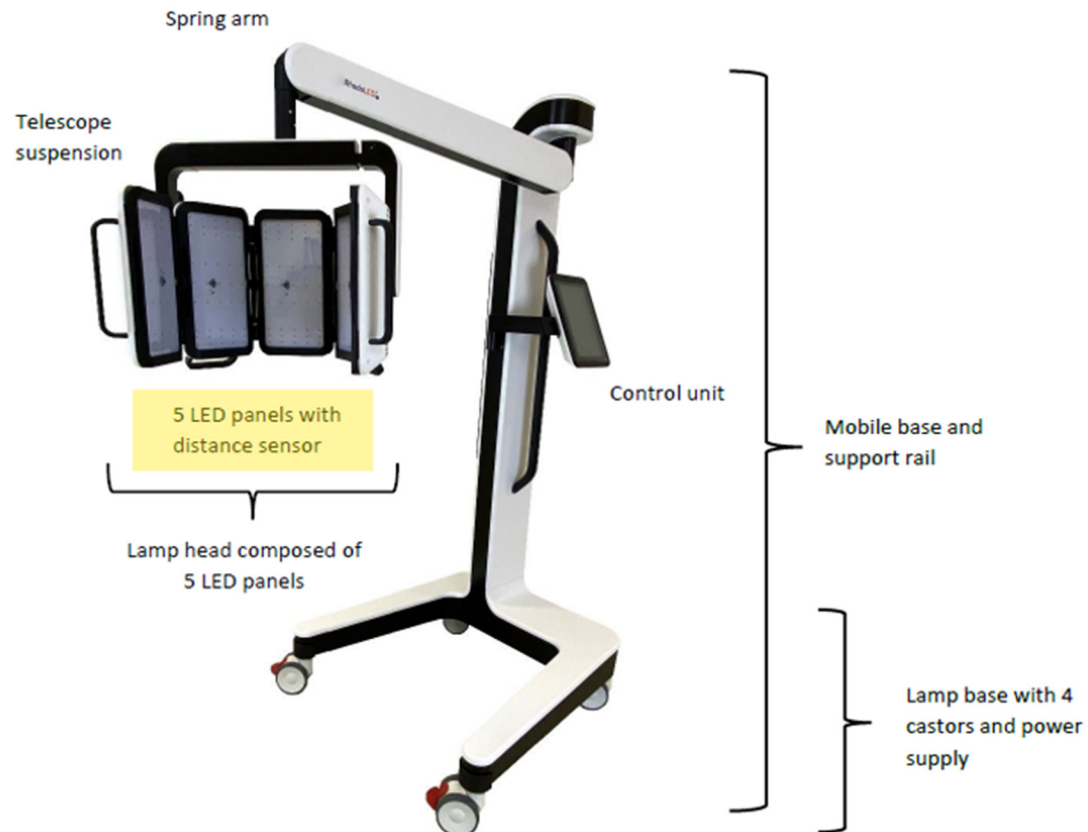


Figure 2: RhodoLED® XL main components

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.

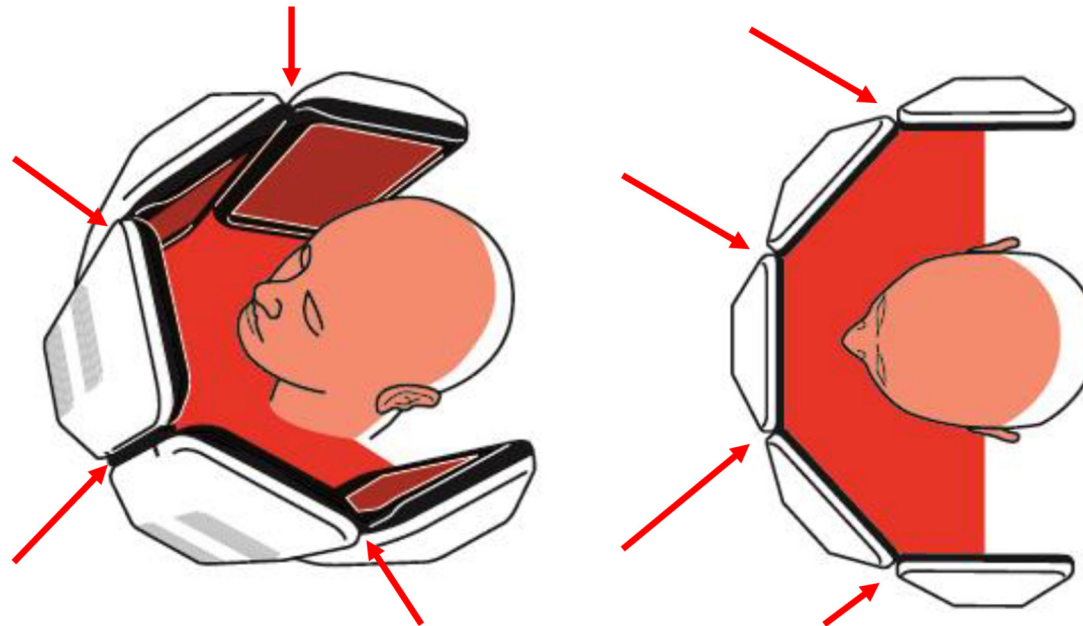


Figure 13: Treatment area of RhodoLED® XL from the side and in top view.

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

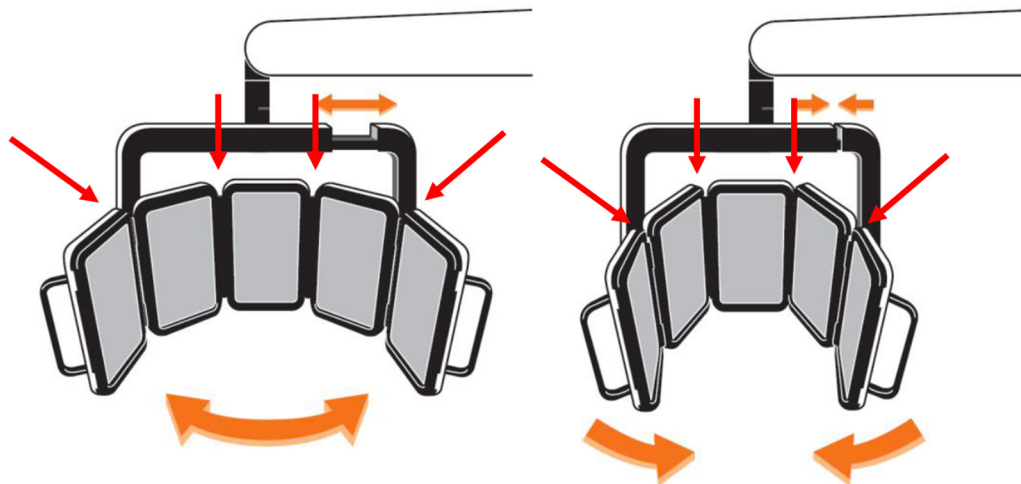


Figure 5: Movement range of the lamp head.

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

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.

20[b] light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a

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).”

treatment surface of the patient via the light sources,

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.

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

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).

20[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 panels being configured to be angled relative to the center panel,

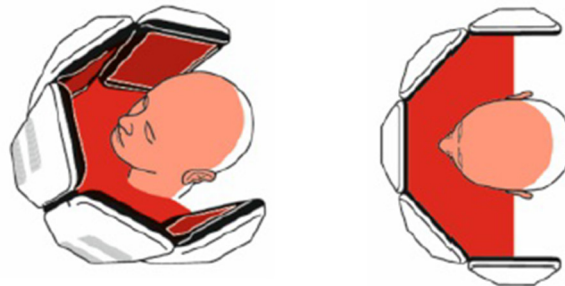
The BF-RhodoLED® XL includes five panels, wherein one of the five panels being positioned as a center panel configured to face the treatment surface, and two or more of the five panels being configured to be angled relative to the center panel.

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).

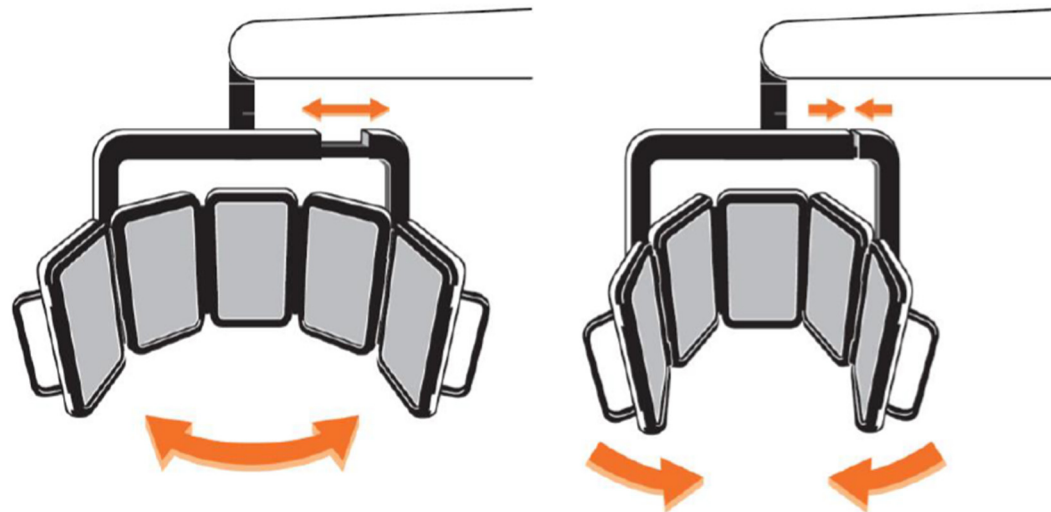


Figure 5: Movement range of the lamp head.

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

BF-

	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[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 has two first edges and two second edges shorter than the two first 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.

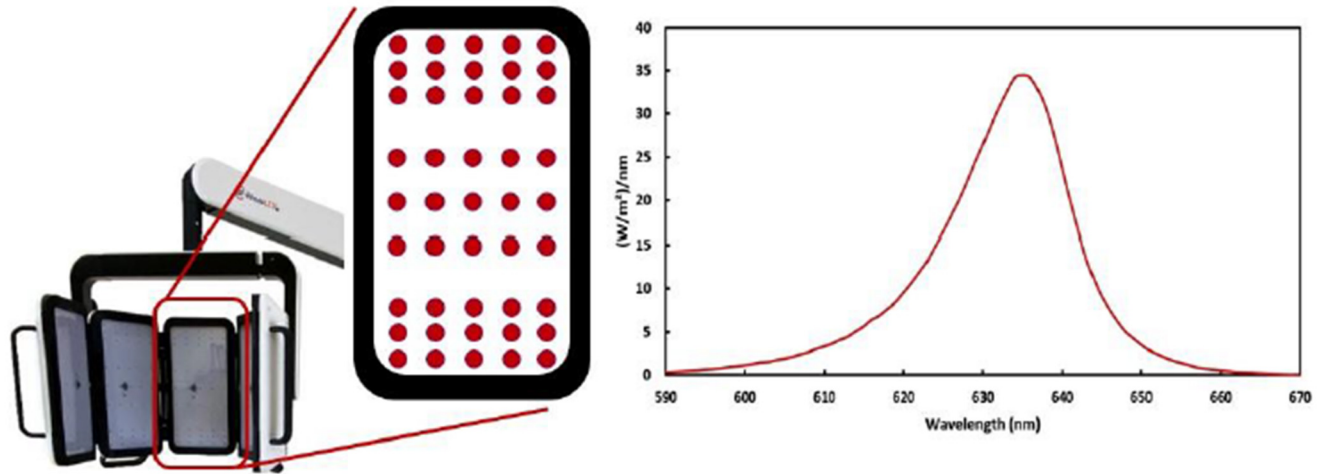


Figure 1: LED panels with LED distribution and emission spectrum of RhodoLED® XL LEDs.

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 ($12.5 \text{ cm} \pm 1.5 \text{ cm}$)

The illumination area of the LED lamp is 9.06×11.42 inch ($23 \text{ cm} \times 29 \text{ cm}$) 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.