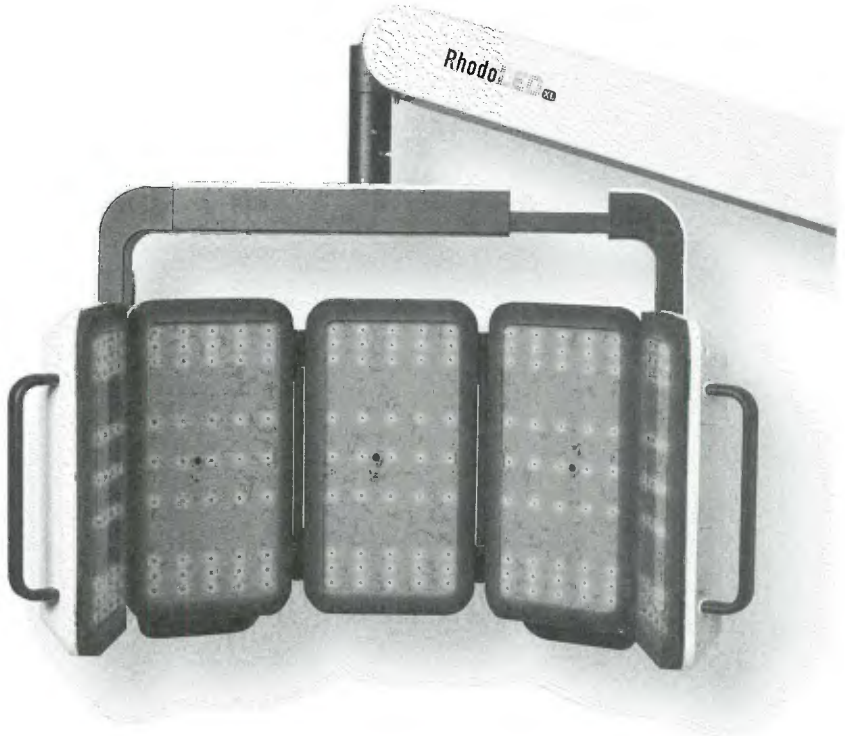
Talk to your Biofrontera PDT Consultant about integrating the RhodoLED® XL into your practice



INDICATION

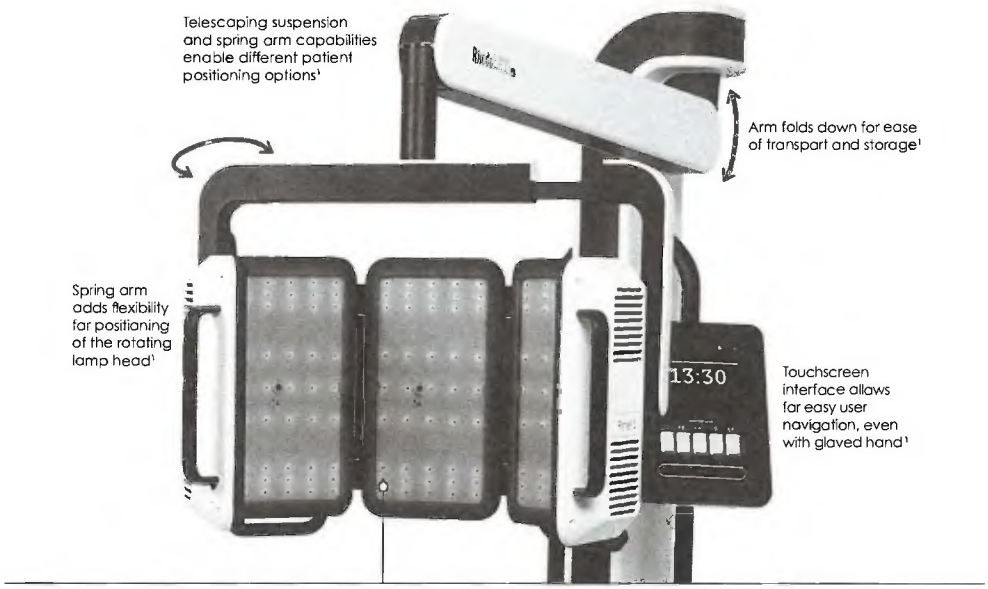
AMELUZ®, in combination with photodynamic therapy (PDT) using BF-RhodoLED® or RhodoLED® XL lamp, a narrowband, red light illumination source, is indicated for lesion-directed and field-directed treatment of actinic keratoses (AKs) of mild-to-moderate severity on the face and scalp.

Please see Important Safety Information inside and accompanying PI.

AMELUZ®
[aminolevulinic acid HCl] topical gel, 10%
& RhodoLED® XL

EXHIBIT
4
12/19/24 bm
PENGAD 800-631-6989

Non-confidential



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IMPORTANT SAFETY INFORMATION

BF-RhodoLED® and RhodoLED® XL

The BF-RhodoLED® or RhodoLED® XL must only be used in combination with AMELUZ® (aminolevulinic acid hydrochloride) topical gel, 10%.

The BF-RhodoLED® and RhodoLED® XL may only be used by trained healthcare professionals.

To avoid eye irritation, glare, or injury, protective eye equipment must be used by any person present during the illumination with BF-RhodoLED® or RhodoLED® XL. RhodoLED® XL emits bright light, do not stare into the light source. LEDs are classified in the exempt group according to IEC 62471:2006.

Neither the BF-RhodoLED®, RhodoLED® XL nor their power supply units should be exposed to excessive mechanical stress or serviced by unauthorized personnel. Assembly and servicing may only be carried out by Biofrontera authorized personnel.

Risk of trapping fingers!

Beware of tipping the BF-RhodoLED®! Do not place the lamp on uneven or unstable surfaces. Do not place heavy objects on the storage shelf or use for sitting, leaning or pushing.

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

BF-RhodoLED® or RhodoLED® XL may not come into contact with water as this may lead to severe damage or electrical shock (exception: cleaning with a damp cloth).

AMELUZ®

AMELUZ®, in conjunction with lesion preparation, is only to be administered by a health care provider. Photodynamic therapy with AMELUZ® involves preparation of lesions, application of the product, occlusion and illumination with BF-RhodoLED® or RhodoLED® XL. Lesions that have not completely resolved shall be retreated 3 months after the initial treatment.

AMELUZ® shall not be used by persons who have known hypersensitivity to porphyrins, or other AMELUZ® ingredients (including soybean phosphatidylcholine). AMELUZ® should also not be used for patients who have porphyria or photodermatoses.

Hypersensitivity reactions and transient amnestic episodes have been reported with the use of AMELUZ®.

Patients should protect treated lesions from sunlight for 48 hours following treatment.

Special care should be taken to avoid bleeding during lesion preparation in patients with inherited or acquired coagulation disorders.

Direct contact of AMELUZ® with the eyes and the mucous membranes should be avoided.

During PDT, the most common side effects which may occur are application site erythema, pain/burning, irritation, edema, pruritus, exfoliation, scab, induration and vesicles.

Concomitant use of the following photosensitizing medications may increase the phototoxic reactions after PDT: St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones, and tetracyclines.

Please read the US Full Prescribing Information for AMELUZ® and/or US User Manual of BF-RhodoLED® and/or RhodoLED® XL lamp available together at https://www.ameluz.com/PI.

You are encouraged to report side effects of AMELUZ®. Please contact Biofrontera Inc. at 1-844-829-7434 or FDA at 1-800-332-1088 or www.fda.gov/medwatch.

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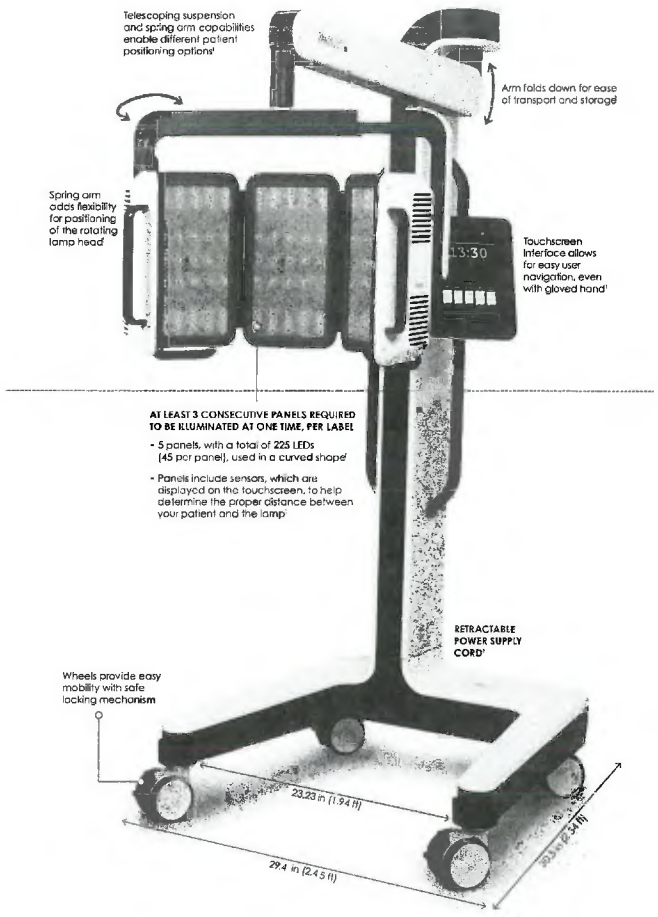

Type	RhodoLED® XL Medical device class III Device of protection class 1[1]
Number of LEDs	225
Typical peak wavelength	635 nm ± 5 nm
Light dose	Approx. 37 J/cm² at 4.9 inch distance, 13:30 min
Illuminated area	An area of 9.06 x 11.42 inch is illuminated using all five panels in curved shape
Treatment distance	4.9 ± 0.6 inch Measuring accuracy ± 0.1 inch
Operating voltage	100-120 VAC, 60 Hz
Output voltage	48 VDC
Size of the lamp	**Height:** 5.76 ft **Width:** 2.51 ft **Depth:** 3.19 ft
Total lamp weight	165 lb
Typical irradiance	Approx. 46 mW/cm² ± 20 % at 4.9 inch distance
Max irradiance	Approx. 55 mW/cm² at 4.9 inch distance
Certification	UL certified

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The RhodoLED® XL should be the lamp of choice for PDT, as it will be a great improvement for patients, in my opinion. The RhodoLED® XL multi-panel lamp head fits nicely over a patient's face or scalp for the short treatment, while providing better coverage. Overall, it will offer a better experience for both the patient and the healthcare provider.

Ted Lain, MD, MBA

STAY UP TO DATE ON RhodoLED® XL

Please see Important Safety Information inside and accompanying PI.

Reference: 1. RhodoLED XL User Manual, 2024.

Biofrontera

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