

EXHIBIT 10C

Exhibit 10C: Technical Domestic Industry Claim Chart for U.S. Patent No. 11,697,028 (“’028 Patent”) – Sun Pharmaceutical Industries, Inc.’s BLU-U® Blue Light Photodynamic Therapy Illuminator – Model 4170E (“BLU-U® 4170E”) device, individually and in combination with Levulan® Prescription Medicine

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 its practice of the ’028 Patent. The exemplary claim mappings below rely on images and data from the BLU-U® 4170E, individually and in combination with Levulan® prescription medicine.

As outlined in the below claim chart, the domestic article BLU-U® 4170E device individually and/or in combination with Levulan® prescription medicine practices at least exemplary claims 1, 3, 4, 5, 7, 9, 16–18, and 21 of the ’028 Patent.

’028 Patent Claim 1	BLU-U® 4170E
1[pre] A system for photodynamically diagnosing or treating a patient, comprising:	The BLU-U® 4170E is a system for photodynamically diagnosing or treating a patient. For example, the BLU-U® 4170E is a Blue Light Photodynamic Therapy Illuminator that is intended to provide phototherapeutic light to a body.



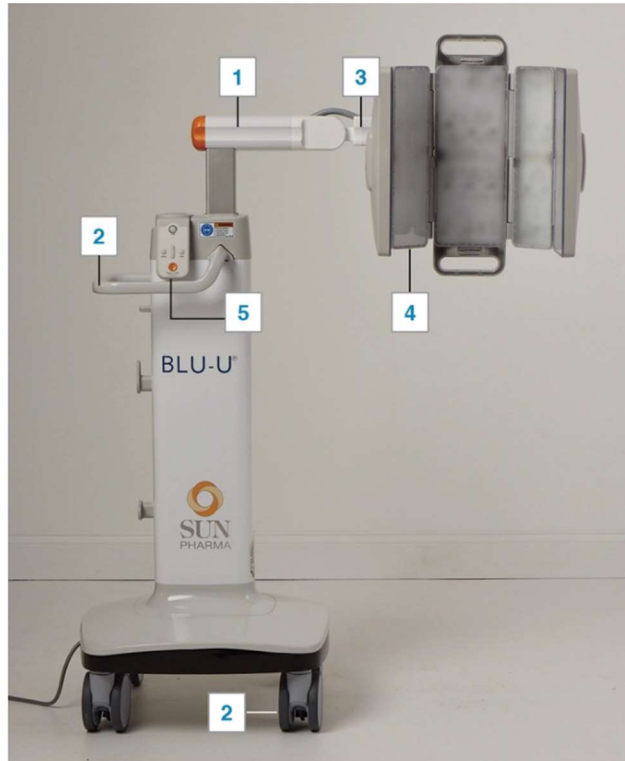
		A large black rectangular redaction box covering the image content.	
	Ex. 43C. For example, it is designed to provide a uniform distribution of blue light to areas of a patient's face, scalp or upper extremities. It is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris. The BLU-U® 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.		



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	Ex. 48C.		



		A large, solid black rectangular block covering the majority of the table's content area, indicating redacted information.	
	Ex. 44C.		

Product Diagram:

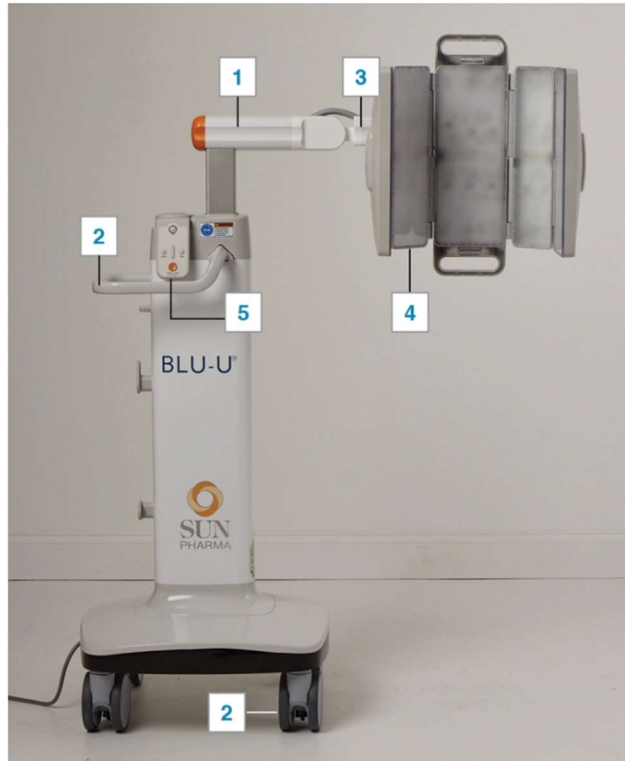
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

	OPERATING MANUAL BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E Indications for Use: The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities. The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The BLU-U® 4170E is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris. Ex. 28 at 4.
1[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels; and	The BLU-U® 4170E includes an illuminator that comprises five panels connected by hinged structures on inner side surfaces of adjacent panels. For example, the BLU-U® 4170E is a Photodynamic Therapy Illuminator intended to provide phototherapeutic light to the body. It includes a Five Panel LED Treatment array.

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.



		A large solid black rectangular area used for redaction, covering the majority of the table's content.	
	Ex. 43C.		

OPERATING MANUAL**BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E****Indications for Use:**

The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.

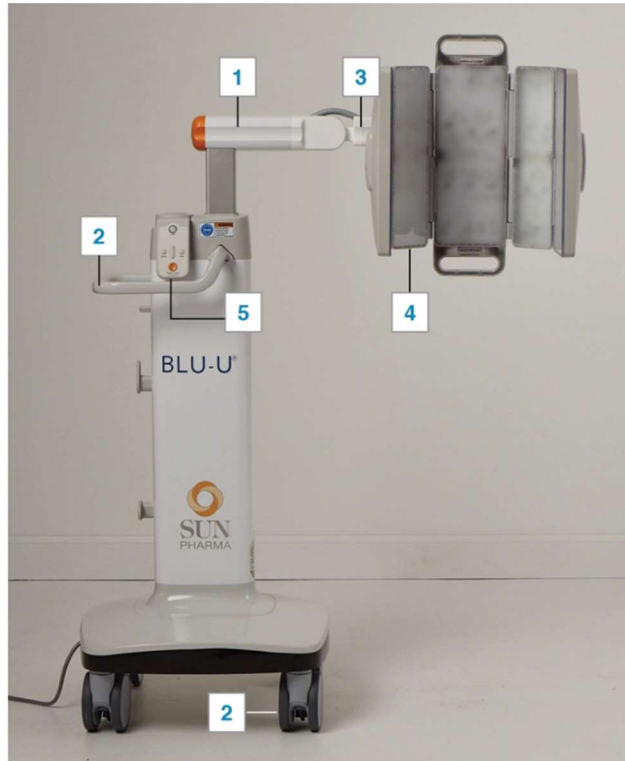
The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The **BLU-U®** 4170E is generally indicated to treat dermatological indications. The **BLU-U®** 4170E is specifically indicated to treat moderate inflammatory acne vulgaris.

Ex. 28 at 4.

The BLU-U® 4170E includes a “Five Panel LED treatment array” with five “head panels” that are connected by hinges. The hinges are hinged structures on inner side surfaces of adjacent panels.



		A large solid black rectangular area used for redaction, covering the majority of the table's content.	
	Ex. 43C.		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

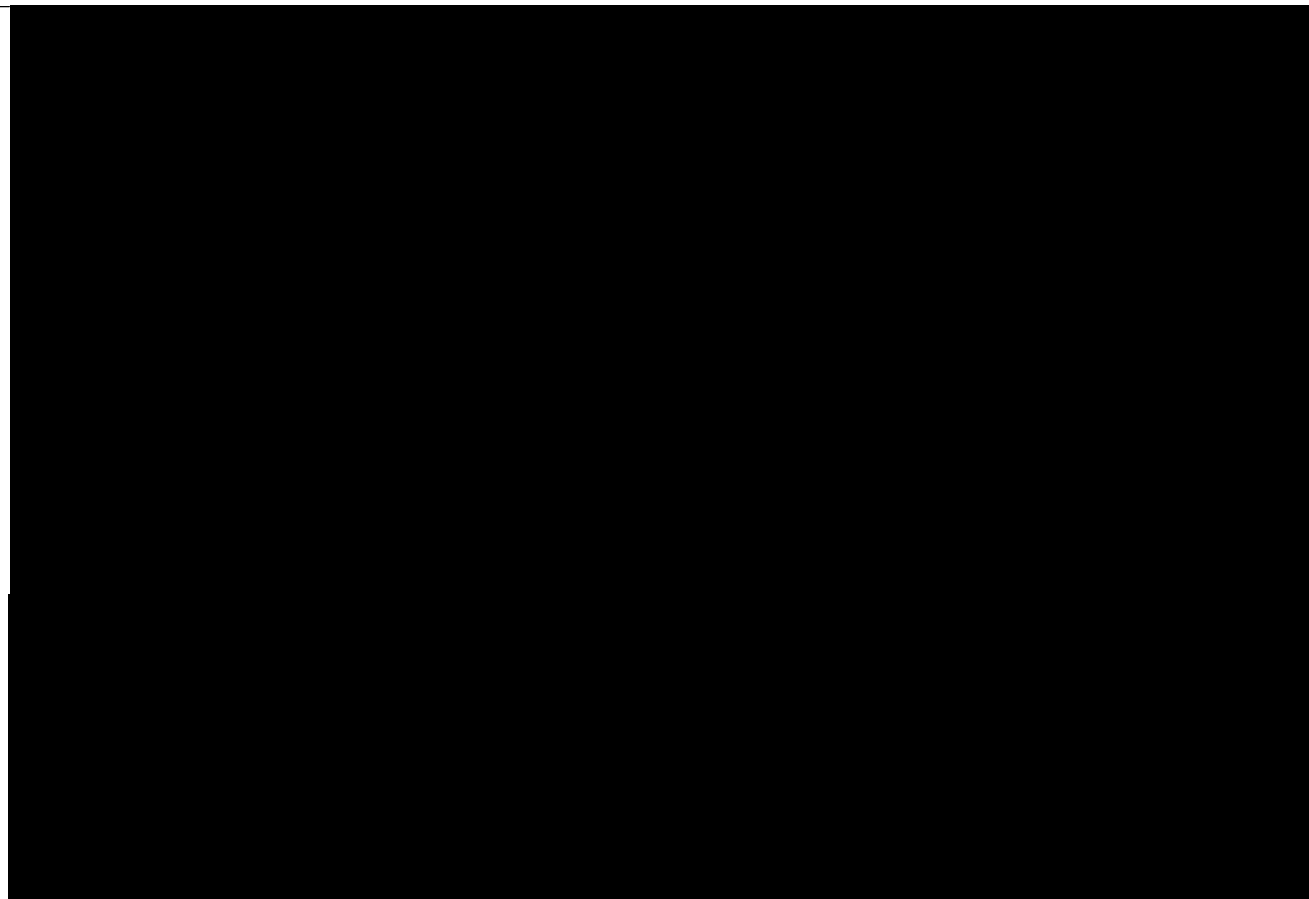
The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

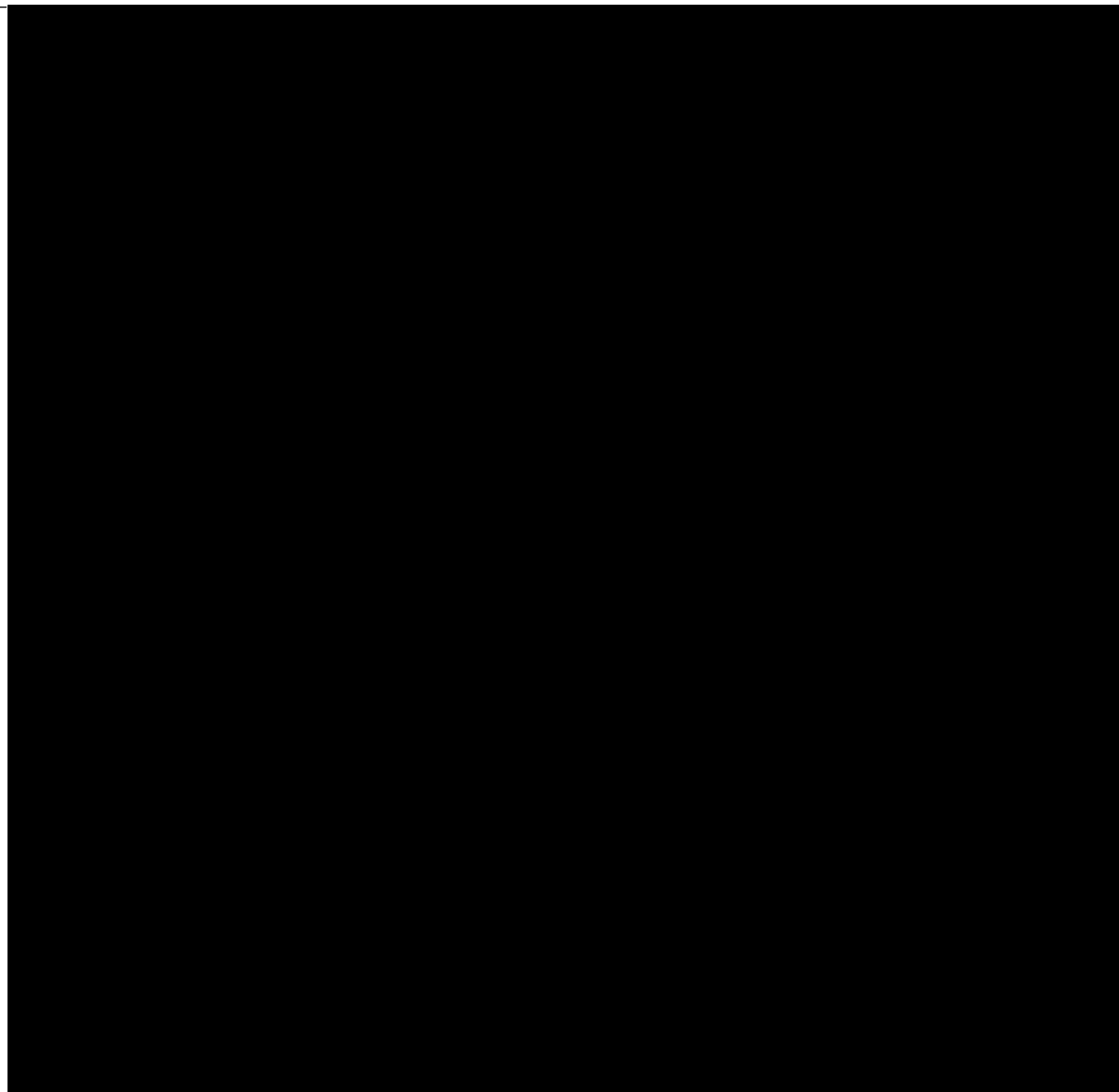
Head Panel Rotation Adjustment:

The Head panels are attached to each other via rotating hinge assemblies that contain torque inserts that maintain position without the need for an additional lock. This allows the Head to be configured flat or fully “U” shaped depending on the requirements for treatment. Each hinge assembly contains alignment markers (Orange bars) that align when the Head is placed into the “U” configuration required for PDT therapy. The rotation of the Head is constrained by hard stops built into the hinge assemblies which prohibit over-rotation in either direction. See the images below.

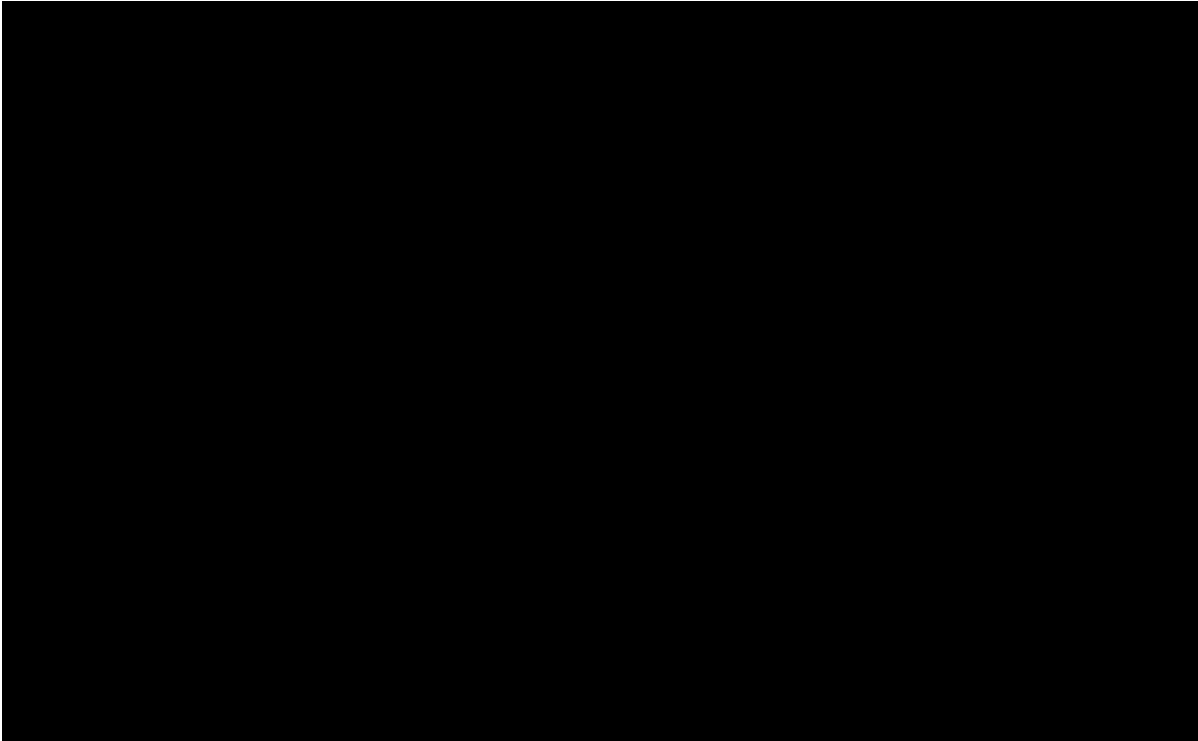
Ex. 28 at 16.

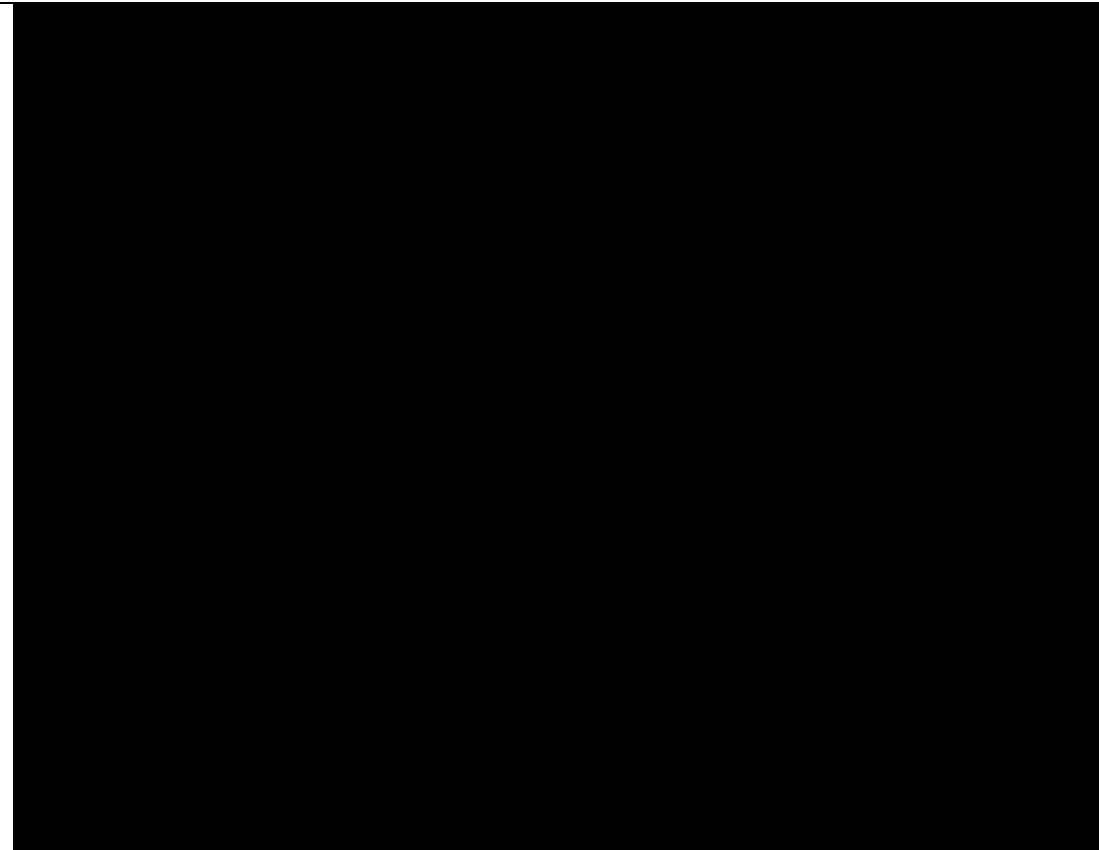


Ex. 49C (red annotations added).



Ex. 50C (red annotations added).

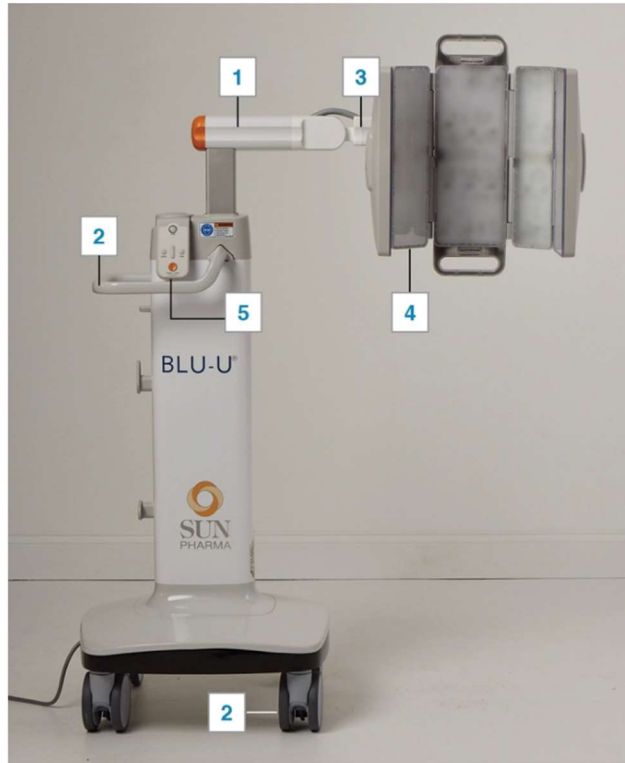
1[b] light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,	The BLU-U® 4170E includes light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources. For example, the BLU-U® 4170E includes LEDs, which are light sources, that are disposed on surfaces of the five panels.  Ex. 49C.
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Ex. 43C.



	A large rectangular area of the table is completely redacted with a solid black fill.	
	Ex. 51C.	

Product Diagram:

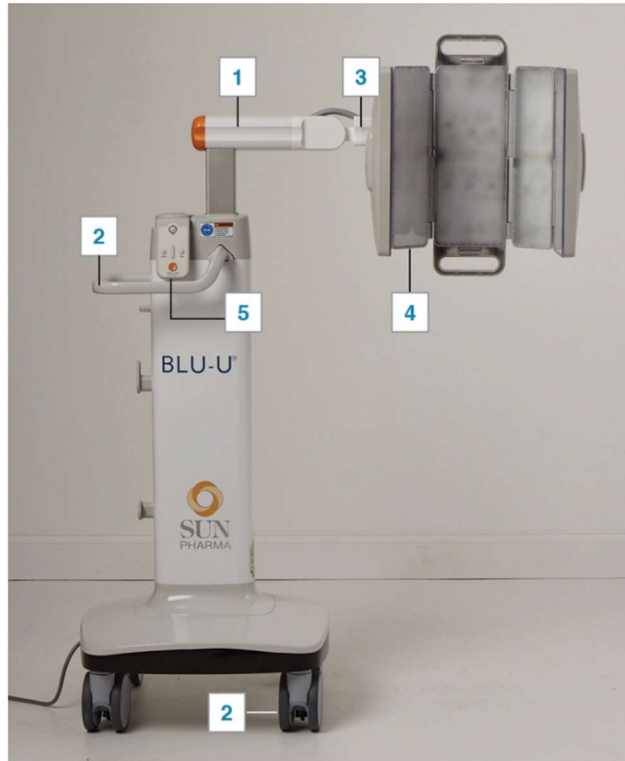
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

The BLU-U® 4170E includes an illuminator, a Five Panel LED Treatment array, that is configured to uniformly illuminate a treatment surface of the patient via the LEDs.

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

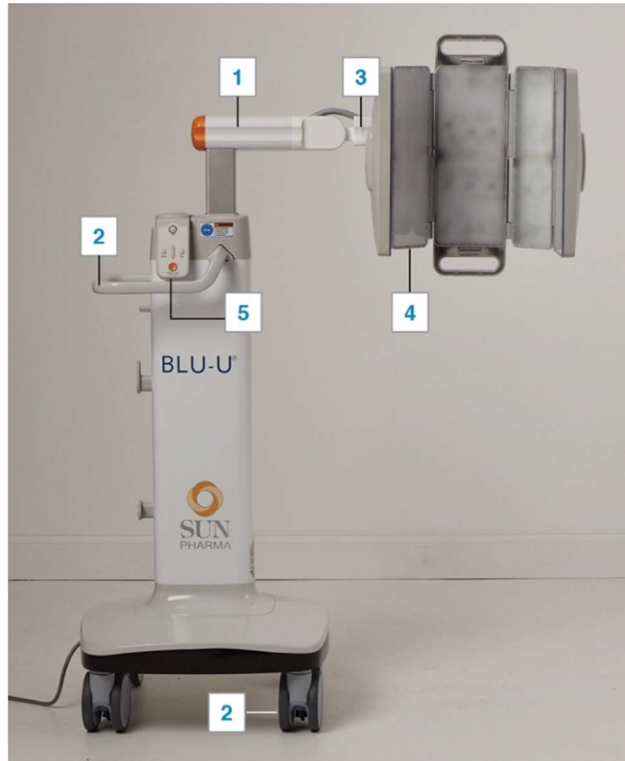
Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.



		A large black rectangular redaction box covering the majority of the upper half of the table's content area.	
	Ex. 44C. For example, the BLU-U® 4170E is “designed to provide a uniform distribution of blue light to areas of the patient’s face, scalp or upper extremities.”		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

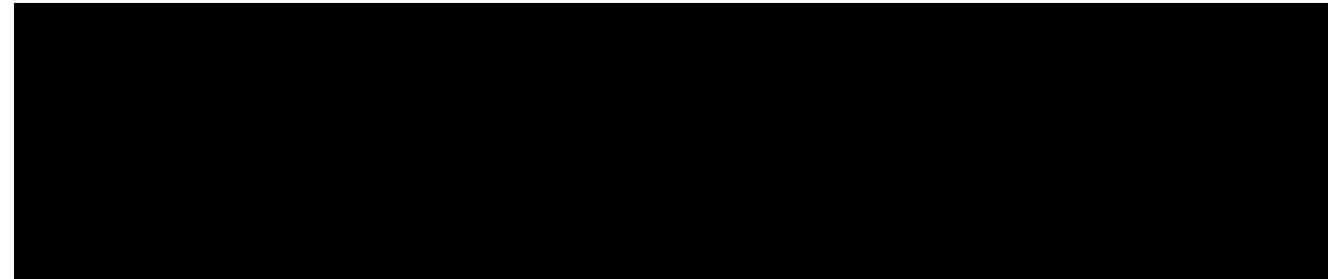
Ex. 28 at 7.

For example, the measured output of the BLU-U® 4170E over the active emitting area has an allowable range of [REDACTED] of the measured maximum.

See generally Ex. 52C.



Ex. 52C at 1.



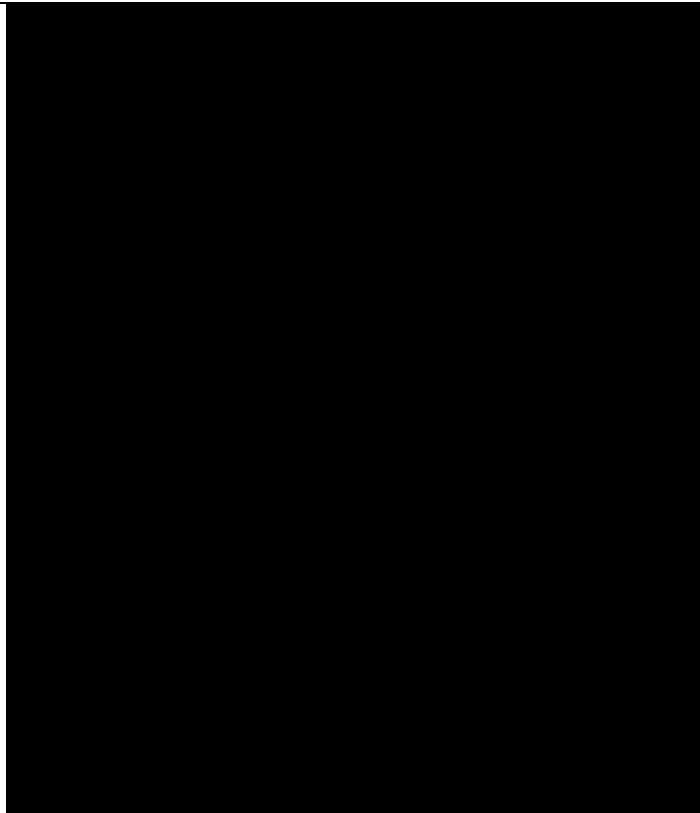
Ex. 52C at 6.

See generally Ex. 53C.

		
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 panels being configured to be	The BLU-U® 4170E 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, the BLU-U® 4170E may be configured in a “U” shape configuration for PDT therapy. In the “U” configuration, the center panel is configured to face the treatment surface, while the remaining four panels are configured to be angled relative to the center panel.	



angled relative to
the center panel,



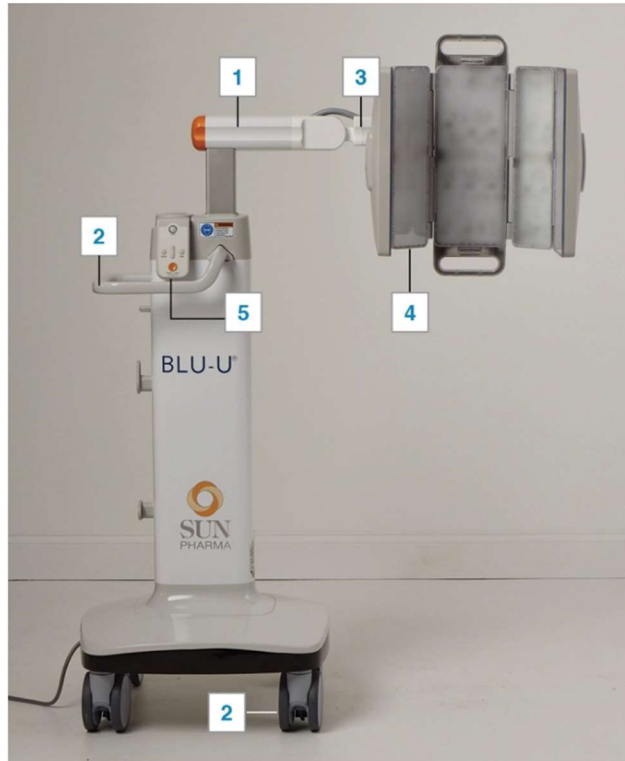
Ex. 48C.



	Ex. 44C.		



	Ex. 54C.		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.



	The BLU-U® 4170E includes a Head assembly that can be tilted and/or rotated to allow for the optimum position for treatment.
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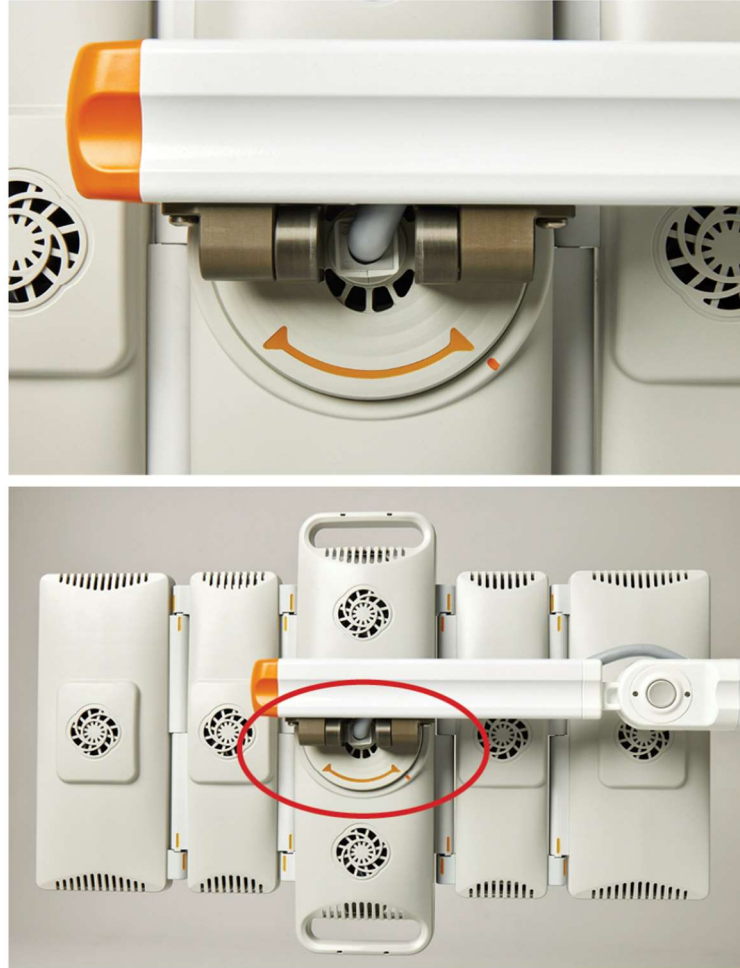
Head Tilt Adjustment:

The Head assembly can be tilted +/- 90 degrees from the stowed position (center panel facing the floor). This allows for the Head to be placed in the optimum position for treatment. The tilt mechanism utilizes torque inserts which eliminate the need for an additional lock. The torque inserts are capable of holding the Head at any position through the allowed 180 degree range of motion. See the images below.



Head Rotation Adjustment:

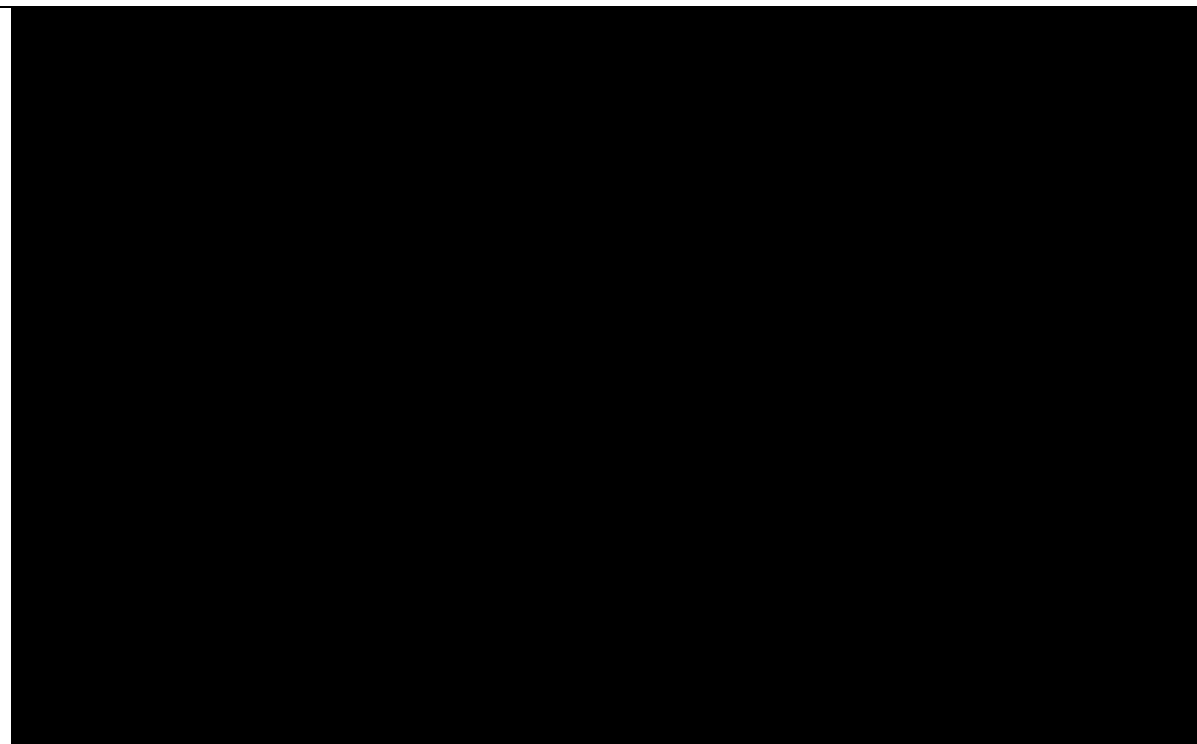
The Head assembly can be rotated +/- 90 degrees from the stowed position (center panel long axis aligned with the Arm center axis). This allows the Head to be placed in the optimum position for treatment. The rotation mechanism has two detent positions at the ends of the travel to lock the head into position for treatment. There are two position indicators located on the back of the center panel housing that align with indicator marks engraved into the back plate when the Head is at the limit of travel. See the images below.



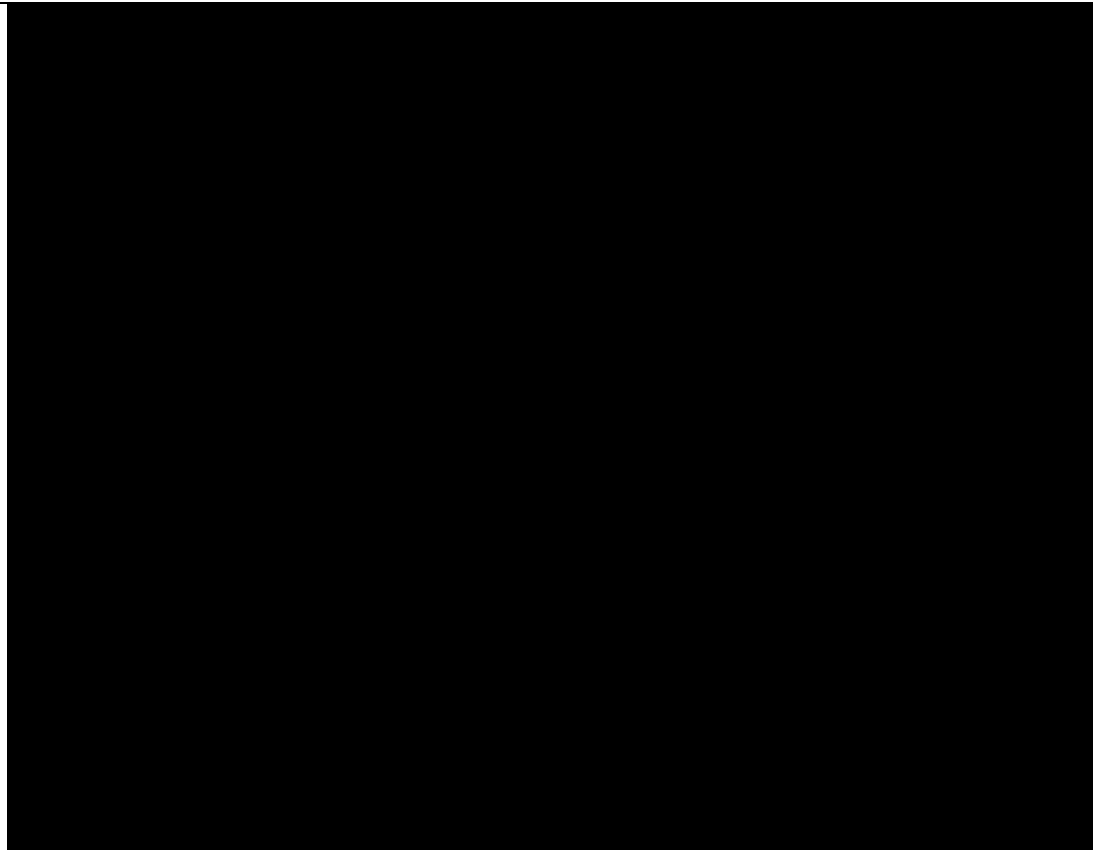
Ex. 28 at 14-15.

1[d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface, and	The BLU-U® 4170E includes five panels wherein the panels are positioned to allow treatment within approximately four inches of the treatment surface. For example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the face, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels. 2. Position the BLU-U® around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface: - a.) The patient's nose should be no closer than 2" from the surface and - b.) The patient's forehead and cheeks should be no further than 4" from the surface and - c.) The sides of the patient's face and the patient's ears should be no closer than 2" from the BLU-U® surface Ex. 28 at 18. As another example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the scalp, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels. 2. Position the BLU-U® around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface: - a.) The patient's scalp should be no closer than 2" from the surface and - b.) The patient's scalp should be no further than 4" from the surface and - c.) The sides of the patient's face and the patient's ears should be no closer than 2" from the BLU-U® surface Ex. 28 at 19.
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	As another example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the upper extremities, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels. 2. Position the BLU-U® around the patient's upper extremities so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface: a. The patient's upper extremities should be no closer than 2" from the surface and d.) The patient's upper extremities should be no further than 4" from the surface Ex. 28 at 20.
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 proximate the second edges.	The BLU-U® 4170E includes 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. Each of the five LED panels of the BLU-U® 4170E are rectangular, such that for each panel, there are two first edges and two second edges, where the second edges are shorter than the two first edges.

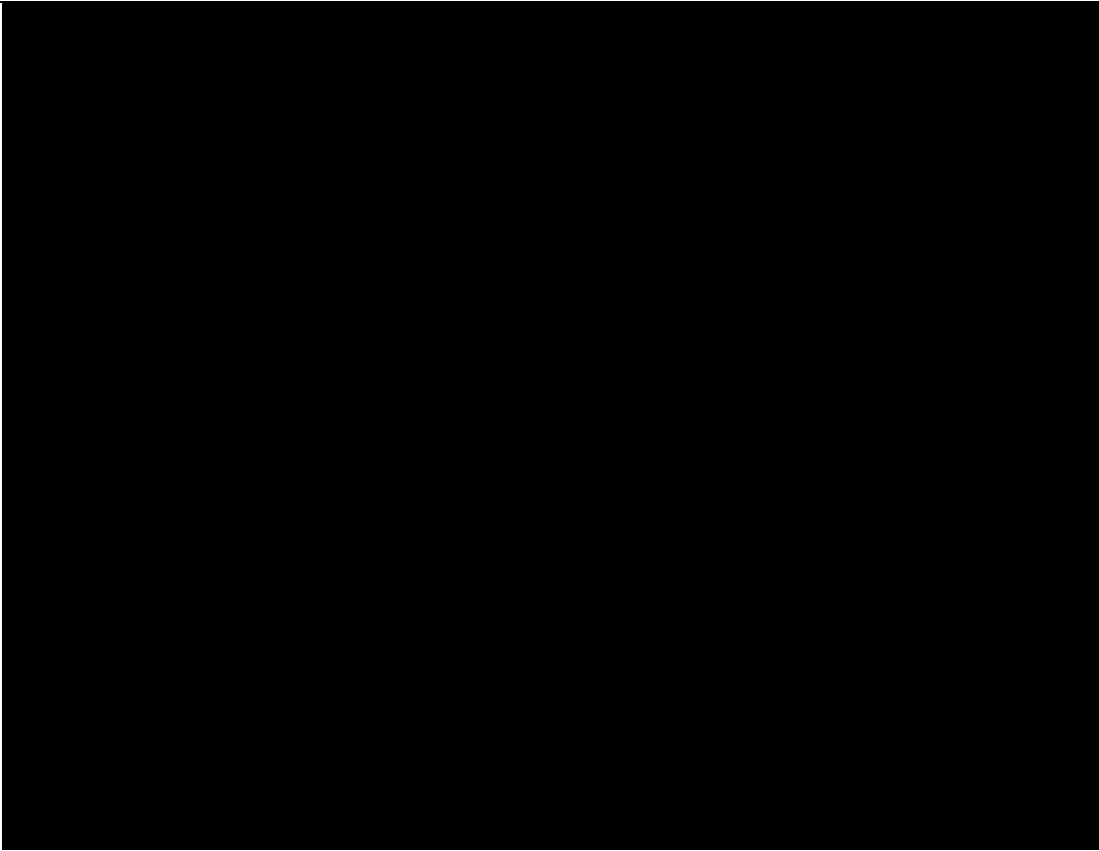


Ex. 49C.



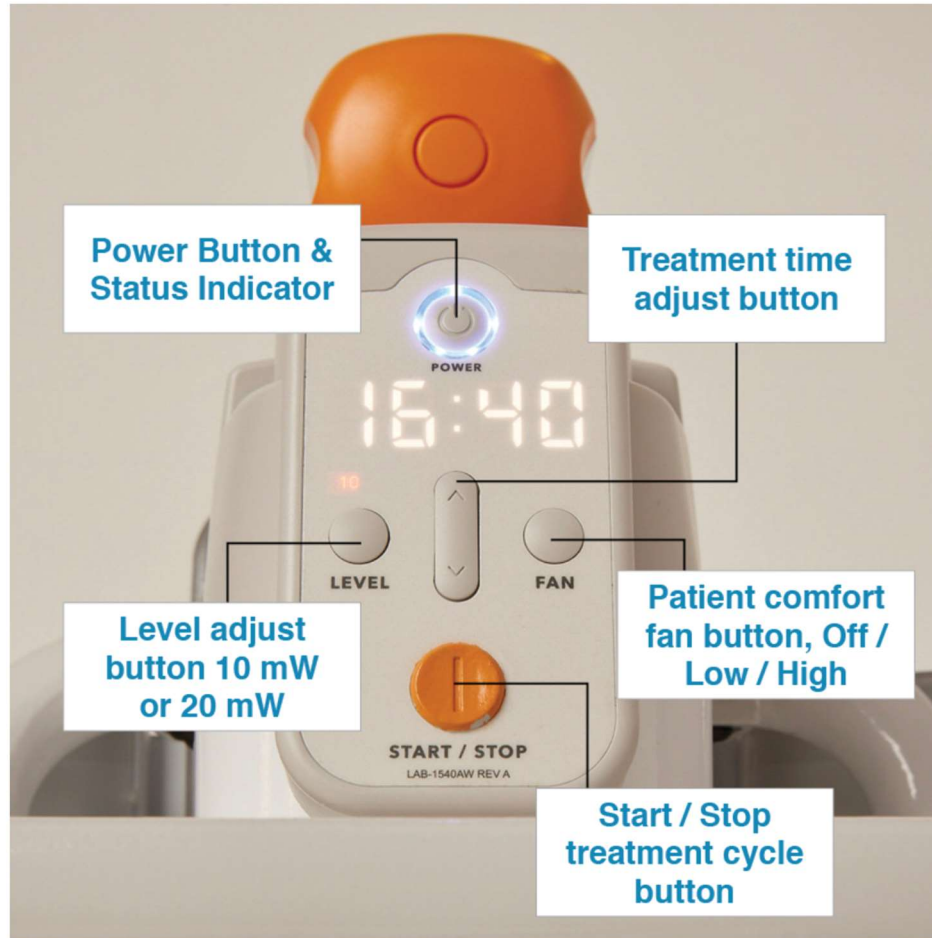
Ex. 43C.

The BLU-U® 4170E's 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.

	 Ex. 43C.
'028 Patent Claim 3	<u>BLU-U® 4170E</u>
The system of claim 1, wherein the illuminator is configured to output light at an	The BLU-U® 4170E includes the system of claim 1, wherein the illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/cm². The BLU-U® 4170E includes the system of claim 1, as detailed above. <i>See</i> claim 1.

irradiance density of 10 mW/cm² to 30 mW/cm².

The BLU-U® 4170E's illuminator is configured to output light at an irradiance density of 10 mW/cm² to 30 mW/cm². For example, the BLU-U® 4170E is configured to output power from the LED treatment array at either 10 mW/cm² or 20 mW/cm². The maximum power output is 22 mW/cm².



Ex. 28 at 8.

OPERATING MANUAL**BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E*****Power Button & Status Indicator:***

The system **Power Button** is used to load the pre-programed treatment cycle. The system will automatically load the 10 mW power level at initial power up and will reset to 10mW power level after the completion of any treatment cycle, and will display time as 16:40. The 20mW power level setting can be selected by pressing the Level button, this will change the time displayed to 8:20. The Power button is also used as a system status indicator, blue ring indicates normal operation, amber ring indicates a fault condition.

- Pressing the Power button while the treatment cycle is “Paused” will cancel the treatment cycle and clear the time display.
- Pressing the Power button with the Main Power Switch activated (on) will toggle to load and or clear a treatment cycle for the system.

Level Button:

The **Level Button** is used to toggle between 2 power settings, 10mW & 20mW. The power level can be selected after pressing the power button to load one of the pre-programmed cycles. The timer will automatically set the correct time for the power level chosen.

- The power level selected will be displayed above the level button as 10 or 20.

Ex. 28 at 10.

Power Output	10 mW/cm ² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm ² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm ² , continuous Output Wavelength: 417 nm + 5 nm Output Uniformity: 30%
Light Dose	Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm ² at 10mW/cm ² or 8 minutes, 20 seconds to deliver 10 J/cm ² at 20 mW/cm ²

Ex. 28 at 6.

'028 Patent Claim 4	<u>BLU-U® 4170E</u>				
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 BLU-U® 4170E 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 BLU-U® 4170E includes the system of claim 1, as detailed above. <i>See</i> claim 1. The BLU-U® 4170E is configured such that a plurality of the LEDs emit light within the range of 400 nm to 700 nm. For example, the BLU-U® 4170E is configured to output a wavelength of 417 nm + 5 nm. <table border="1" data-bbox="470 558 1558 914"> <tr> <td data-bbox="470 558 911 805">Power Output</td><td data-bbox="911 558 1558 805"> 10 mW/cm² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm², continuous Output Wavelength: 417 nm + 5 nm Output Uniformity; 30% </td></tr> <tr> <td data-bbox="470 805 911 914">Light Dose</td><td data-bbox="911 805 1558 914"> Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm² at 10mW/cm² or 8 minutes, 20 seconds to deliver 10 J/cm² at 20 mW/cm² </td></tr> </table> Ex. 28 at 6.	Power Output	10 mW/cm² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm², continuous Output Wavelength: 417 nm + 5 nm Output Uniformity; 30%	Light Dose	Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm² at 10mW/cm² or 8 minutes, 20 seconds to deliver 10 J/cm² at 20 mW/cm²
Power Output	10 mW/cm² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm², continuous Output Wavelength: 417 nm + 5 nm Output Uniformity; 30%				
Light Dose	Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm² at 10mW/cm² or 8 minutes, 20 seconds to deliver 10 J/cm² at 20 mW/cm²				
'028 Patent Claim 5	<u>BLU-U® 4170E</u>				
5[pre] A method of photodynamically diagnosing or treating a patient, comprising:	The BLU-U® 4170E in conjunction with Levulan® can be used in a method of photodynamically diagnosing or treating a patient. For example, the BLU-U® 4170E is a Blue Light Photodynamic Therapy Illuminator that is intended to provide phototherapeutic light to a body.				



		A large black rectangular redaction box covering the entire image area of the table cell.	

Ex. 43C.

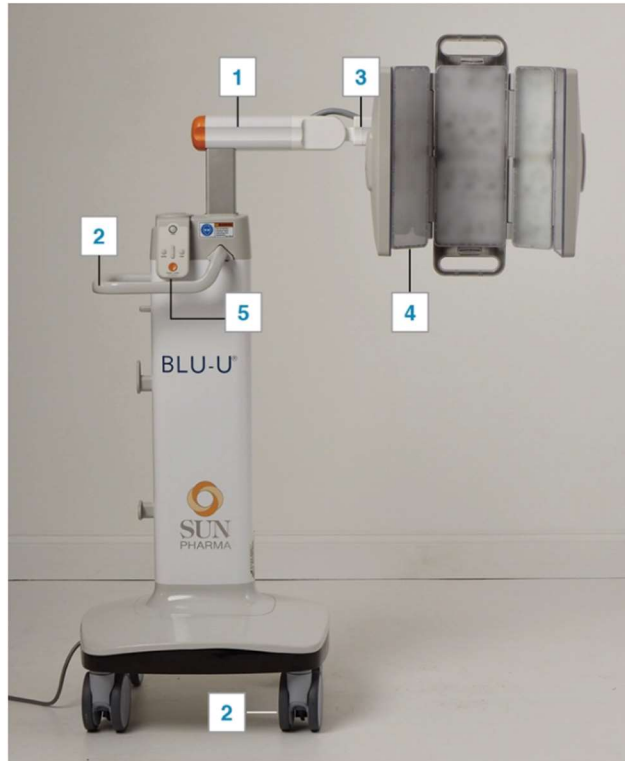
For example, it is designed to provide a uniform distribution of blue light to areas of a patient's face, scalp or upper extremities. It is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris.



		A large, solid black rectangular block covering the majority of the table's content area, indicating redacted information.	
	Ex. 48C.		



		A large solid black rectangular area used for redaction, covering the majority of the table's content.	
	Ex. 44C.		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

	OPERATING MANUAL BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E Indications for Use: The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities. The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The BLU-U® 4170E is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris. Ex. 28 at 4.
5[a] administering 5-aminolevulinic acid (ALA) to the patient;	The BLU-U® 4170E in conjunction with Levulan® can be used in administering 5-aminolevulinic acid (ALA) to the patient. For example, the BLU-U® 4170E can be used in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities. OPERATING MANUAL BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E Indications for Use: The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities. The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The BLU-U® 4170E is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris. Ex. 28 at 4.

Levulan® Kerastick® contains 5-aminolevulinic acid.

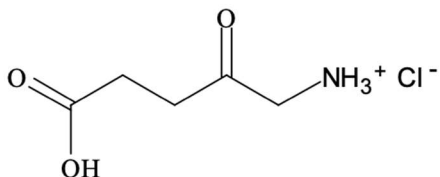
**LEVULAN®KERASTICK™ (aminolevulinic acid HCl) for Topical Solution, 20%
For Topical Use Only
Not for Ophthalmic Use**

DESCRIPTION

LEVULAN® KERASTICK™ (aminolevulinic acid HCl) for Topical Solution, 20%, contains the hydrochloride salt of 5-aminolevulinic acid (ALA), an endogenous 5-carbon aminoketone.

Aminolevulinic acid HCl (ALA HCl) is a white to off-white, odorless crystalline solid that is very soluble in water, slightly soluble in methanol and ethanol, and practically insoluble in chloroform, hexane and mineral oil.

The chemical name for ALA HCl is 5-amino-4-oxopentanoic acid hydrochloride (MW = 167.59). The structural formula is represented below:



Ex. 43C, Levulan Kerastick FDA Label at 1.

Levulan® Kerastick® is approved by the FDA “using the BLU-U Blue Light Photodynamic Therapy Illuminator” for the treatment of “non-hyperkeratotic actinic keratoses of the face or scalp.”

	INDICATIONS AND USAGE The LEVULAN KERASTICK for Topical Solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of non-hyperkeratotic actinic keratoses of the face or scalp. Ex. 43C, Levulan Kerastick FDA Label at 6.
positioning an illuminator proximate to the patient, the illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels	The BLU-U® 4170E 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 BLU-U® 4170E includes an illuminator, as it is a Photodynamic Therapy Illuminator intended to provide phototherapeutic light to the body and includes a “Five Panel LED treatment array.”



		A large solid black rectangular area used for redaction, covering the majority of the table's content.	
	Ex. 43C.		

OPERATING MANUAL**BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E****Indications for Use:**

The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.

The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The **BLU-U®** 4170E is generally indicated to treat dermatological indications. The **BLU-U®** 4170E is specifically indicated to treat moderate inflammatory acne vulgaris.

Ex. 28 at 4.

The BLU-U® 4170E can be used by positioning the BLU-U® 4170E proximate to the patient. For example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the face, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels.

2. Position the **BLU-U®** around the patient's head so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:
 - a.) The patient's nose should be **no closer** than 2" from the surface
and
 - b.) The patient's forehead and cheeks should be **no further** than 4" from the surface
and
 - c.) The sides of the patient's face and the patient's ears should be **no closer** than 2" from the **BLU-U®** surface

Ex. 28 at 18.

As another example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the scalp, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels.

2. Position the **BLU-U®** around the patient's head so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:

- a.) The patient's scalp should be **no closer** than 2" from the surface
and
- b.) The patient's scalp should be **no further** than 4" from the surface
and
- c.) The sides of the patient's face and the patient's ears should be **no closer** than 2" from the **BLU-U®** surface

Ex. 28 at 19.

As another example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the upper extremities, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels.

2. Position the **BLU-U®** around the patient's upper extremities so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:

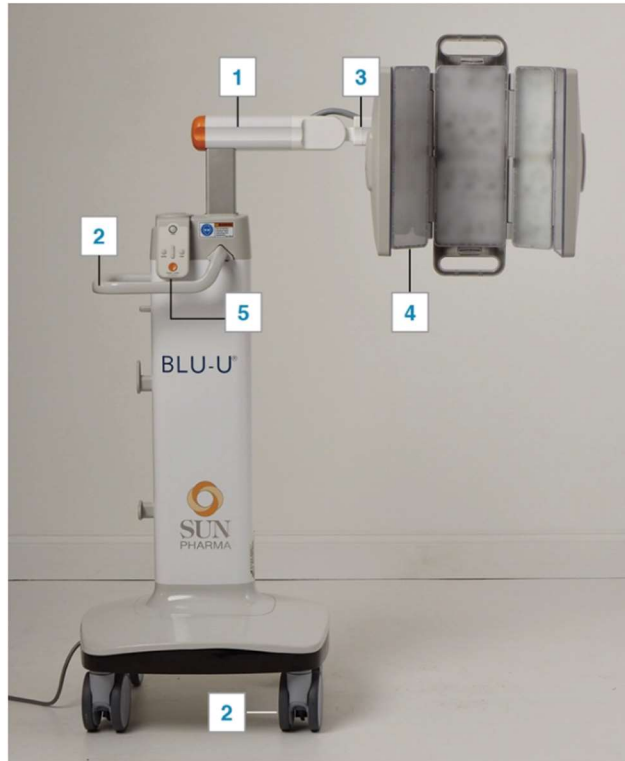
- a. The patient's upper extremities should be **no closer** than 2" from the surface
and
- d.) The patient's upper extremities should be **no further** than 4" from the surface

Ex. 28 at 20.

The BLU-U® 4170E includes a "Five Panel LED treatment array" with five "head panels" that are connected by hinges. The hinges are hinged structures on inner side surfaces of adjacent panels.



		A large, solid black rectangular block used for redaction, covering the majority of the table's content area.	
	Ex. 43C.		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

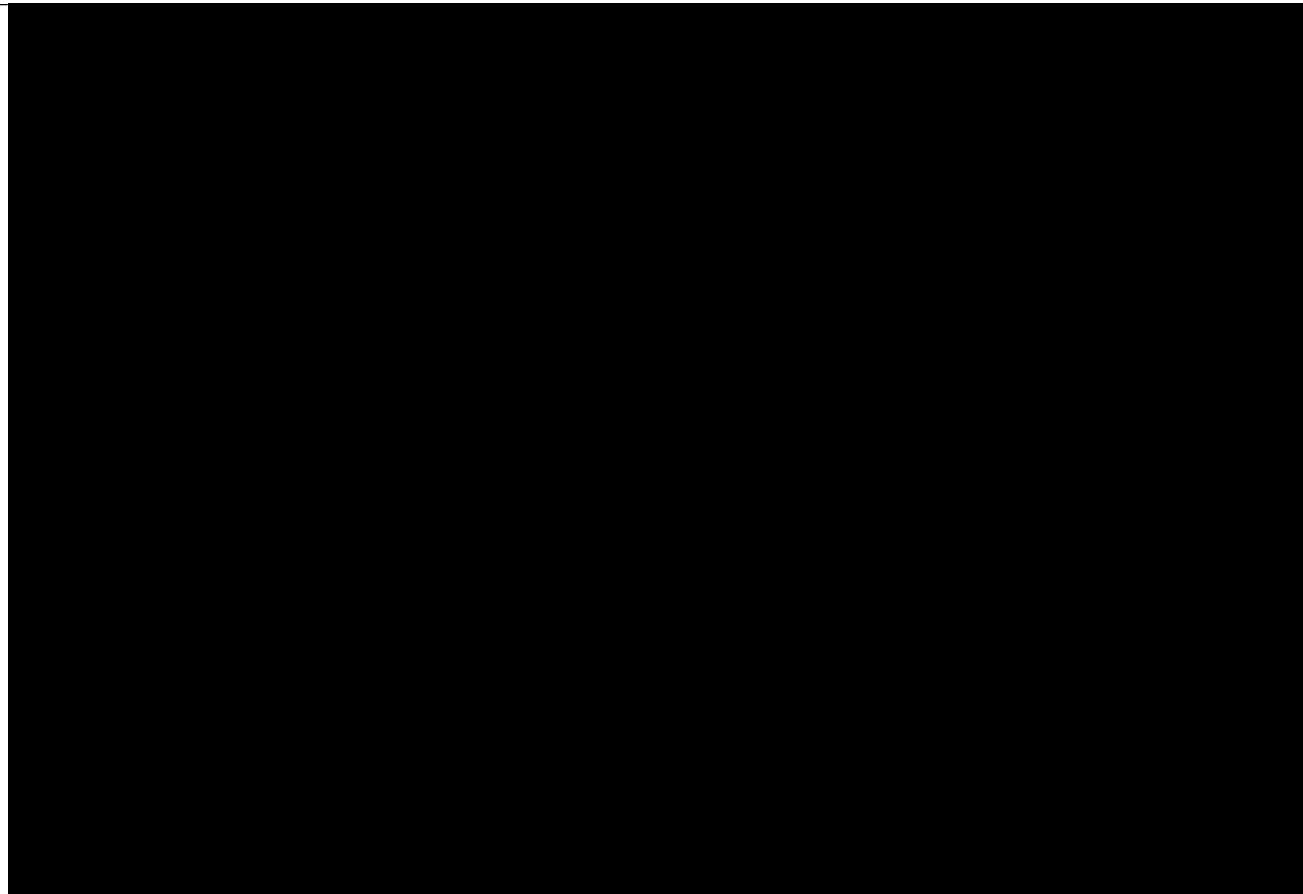
The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

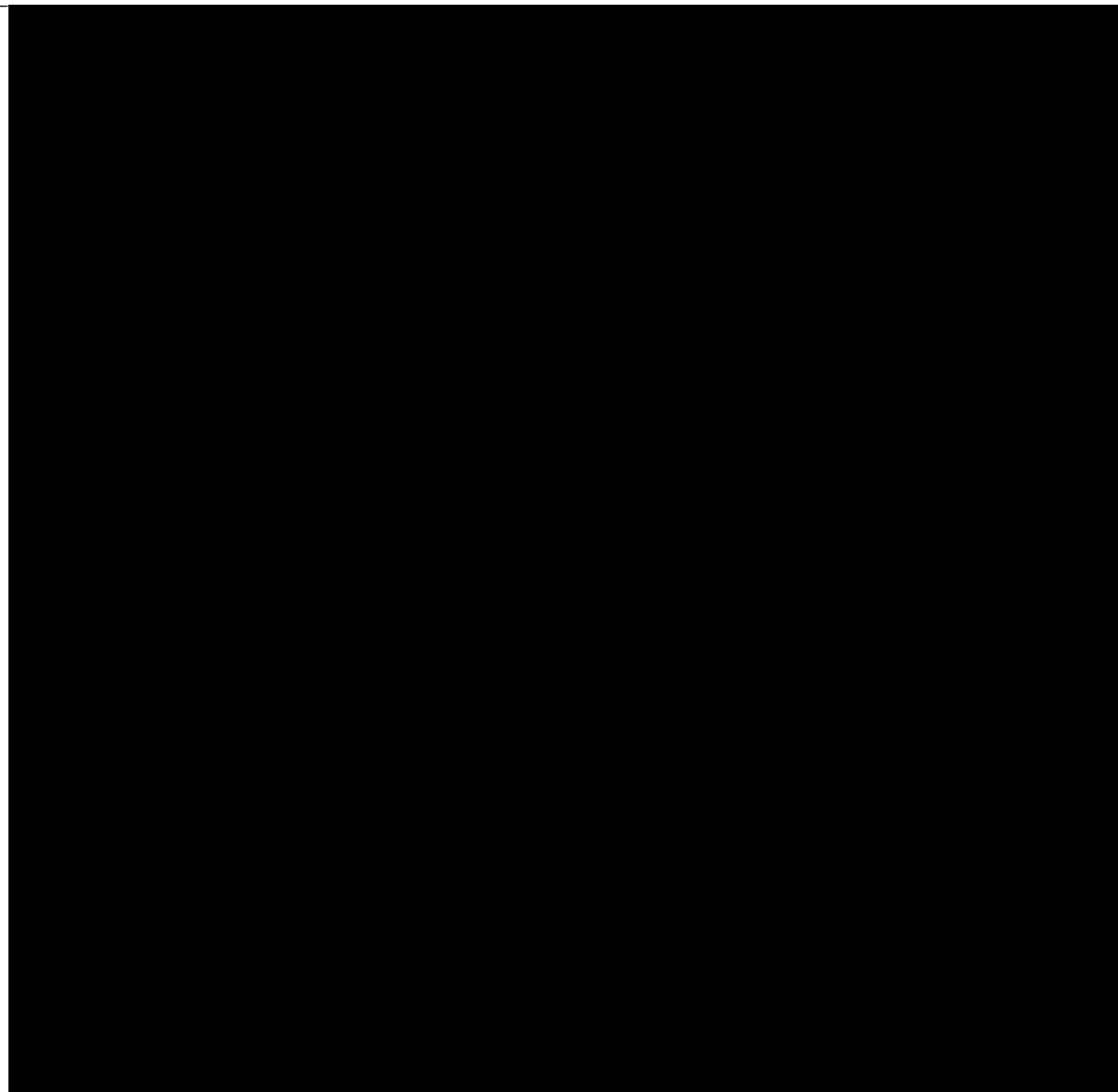
Head Panel Rotation Adjustment:

The Head panels are attached to each other via rotating hinge assemblies that contain torque inserts that maintain position without the need for an additional lock. This allows the Head to be configured flat or fully “U” shaped depending on the requirements for treatment. Each hinge assembly contains alignment markers (Orange bars) that align when the Head is placed into the “U” configuration required for PDT therapy. The rotation of the Head is constrained by hard stops built into the hinge assemblies which prohibit over-rotation in either direction. See the images below.

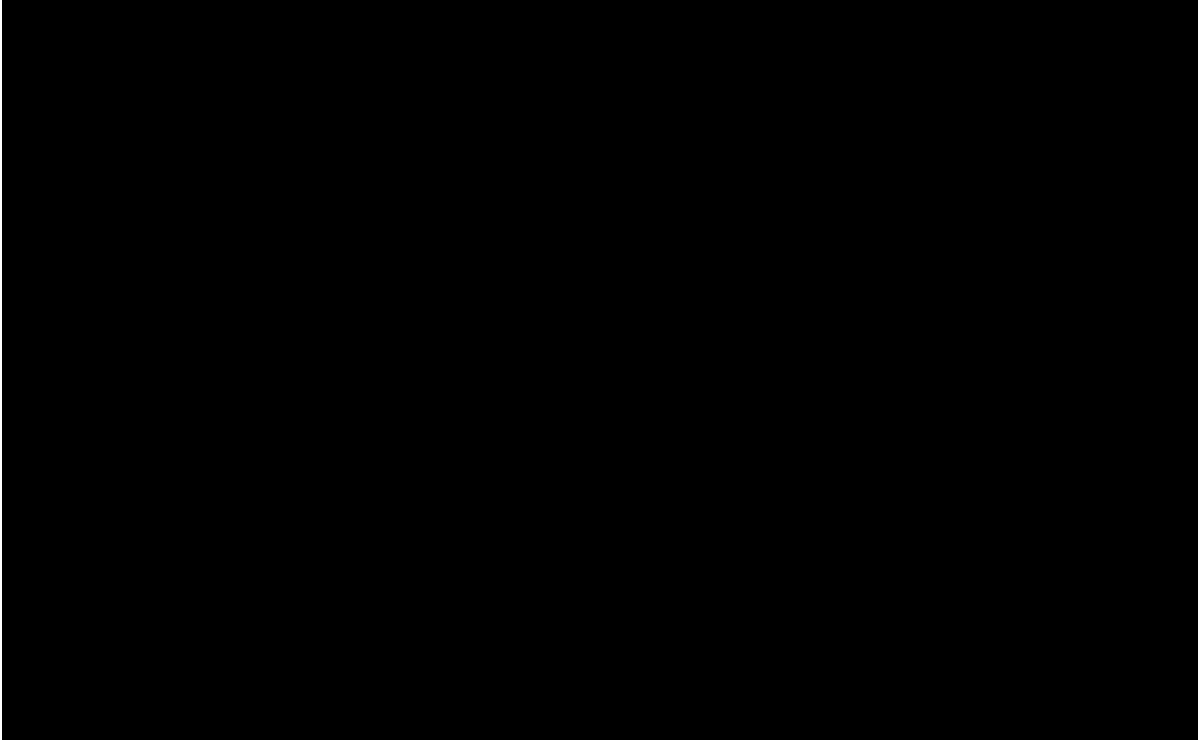
Ex. 28 at 16.

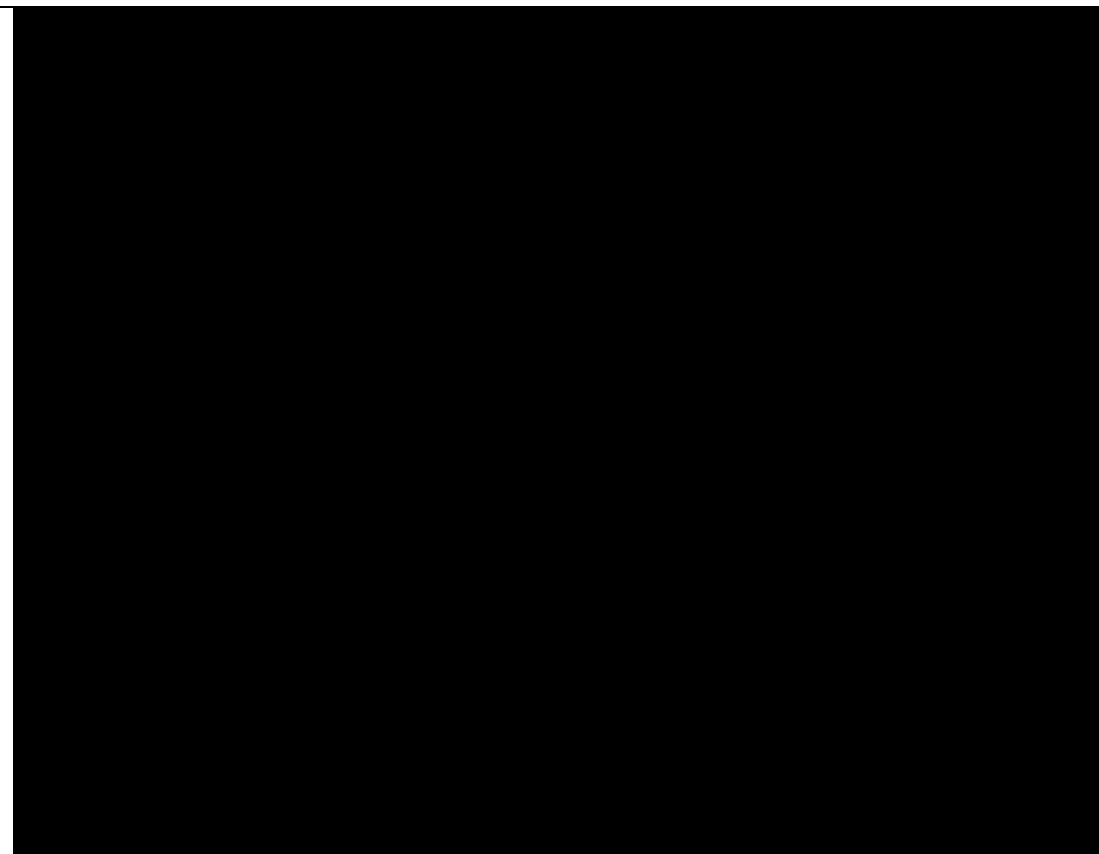


Ex. 49C (red annotations added).

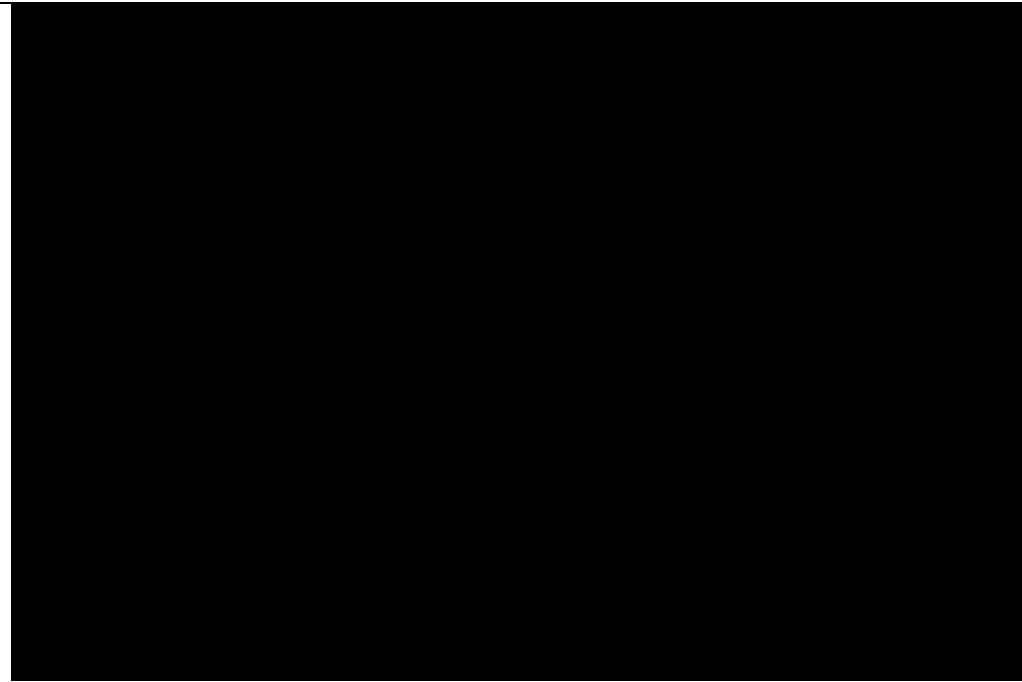


Ex. 50C (red annotations added).

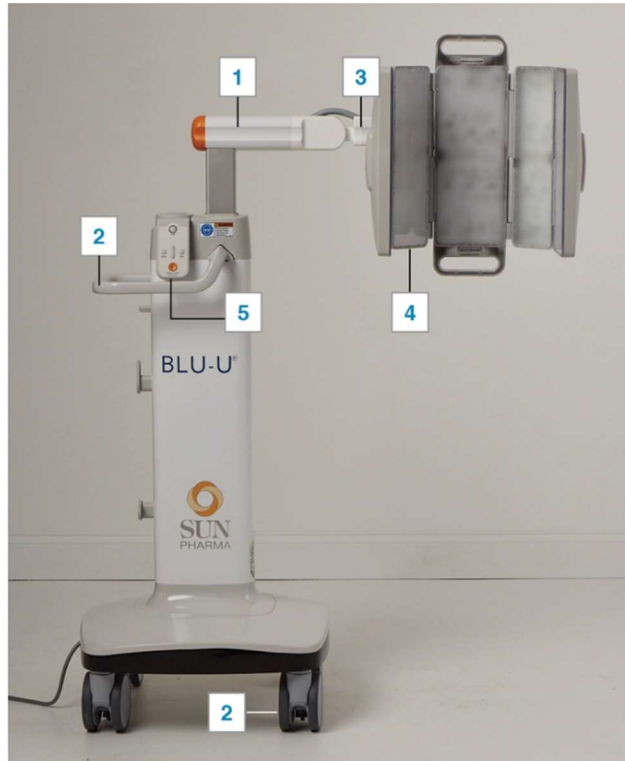
5[d] and uniformly illuminating a treatment surface of the patient with light sources disposed on the five panels of the illuminator, the five panels being positioned to allow treatment within approximately four inches of the treatment surface	The BLU-U® 4170E can be used in conjunction with uniformly 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 BLU-U® 4170E includes LEDs, which are light sources, that are disposed on surfaces of the five panels.  Ex. 49C.
--	---



Ex. 43C.



Ex. 51C.

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

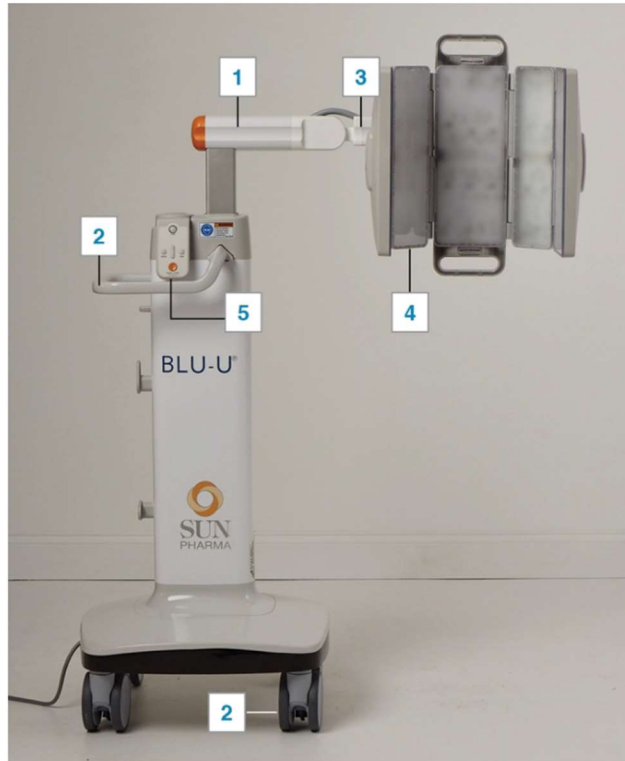
The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

The BLU-U® 4170E is an illuminator that is configured to uniformly illuminate a treatment surface of the patient via the LEDs.



		A large black rectangular redaction box covering the majority of the upper half of the table's content area.	
	Ex. 44C. For example, the BLU-U® 4170E is “designed to provide a uniform distribution of blue light to areas of the patient’s face, scalp or upper extremities.”		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

[REDACTED]

For example, the measured output of the BLU-U® 4170E over the active emitting area has an allowable range of [REDACTED] of the measured maximum.

See generally Ex. 52C.

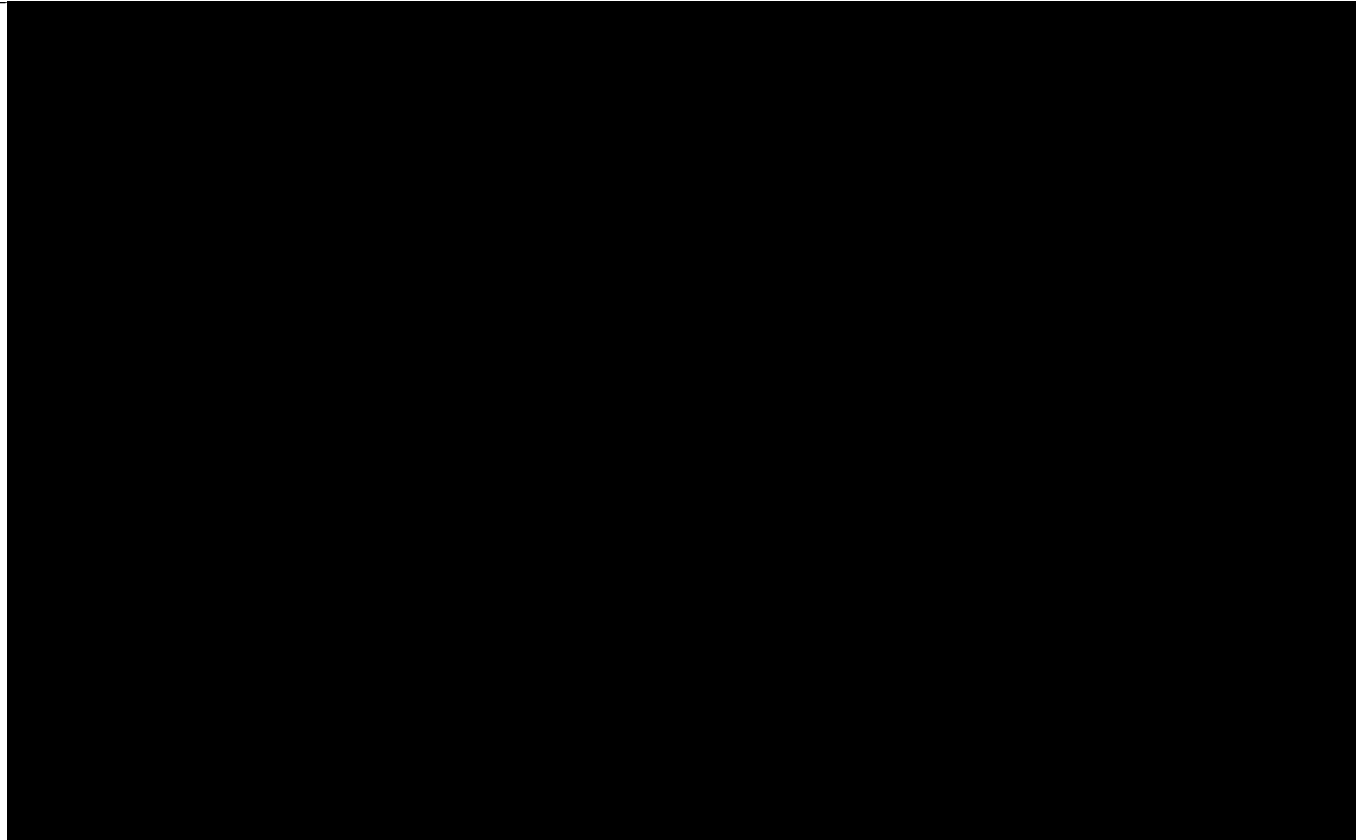
[REDACTED]

Ex. 52C at 1.

[REDACTED]

Ex. 52C at 6.

See generally Ex. 53C.



The BLU-U® 4170E can be used in conjunction with the five panels being positioned to allow treatment within approximately four inches of the treatment surface. For example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the face, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels.

2. Position the **BLU-U®** around the patient's head so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:
 - a.) The patient's nose should be **no closer** than 2" from the surface
and
 - b.) The patient's forehead and cheeks should be **no further** than 4" from the surface
and
 - c.) The sides of the patient's face and the patient's ears should be **no closer** than 2" from the **BLU-U®** surface

Ex. 28 at 18.

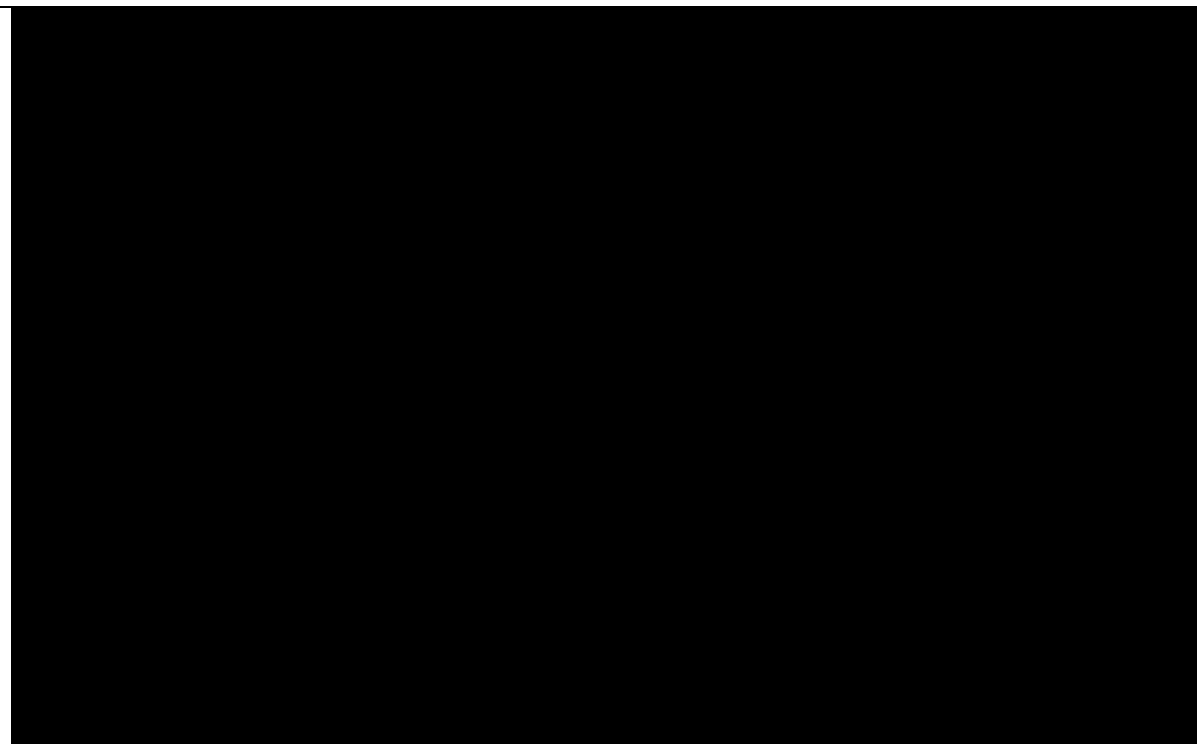
As another example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the scalp, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels.

2. Position the **BLU-U®** around the patient's head so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:
 - a.) The patient's scalp should be **no closer** than 2" from the surface
and
 - b.) The patient's scalp should be **no further** than 4" from the surface
and
 - c.) The sides of the patient's face and the patient's ears should be **no closer** than 2" from the **BLU-U®** surface

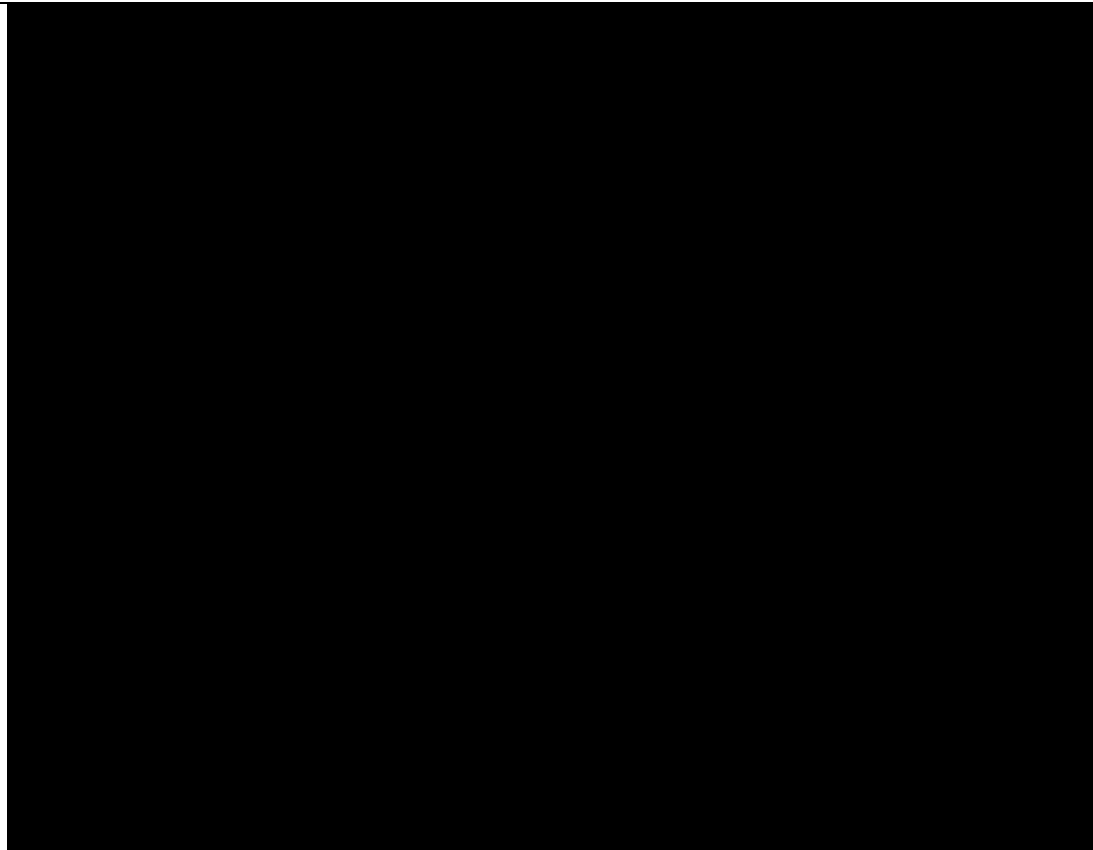
Ex. 28 at 19.

As another example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the upper extremities, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels.

	2. Position the BLU-U® around the patient's upper extremities so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface: a. The patient's upper extremities should be <i>no closer</i> than 2" from the surface and d.) The patient's upper extremities should be <i>no further</i> than 4" from the surface Ex. 28 at 20.
5[f] 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 BLU-U® 4170E includes 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. Each of the five LED panels of the BLU-U® 4170E are rectangular, such that for each panel, there are two first edges and two second edges, where the second edges are shorter than the two first edges.

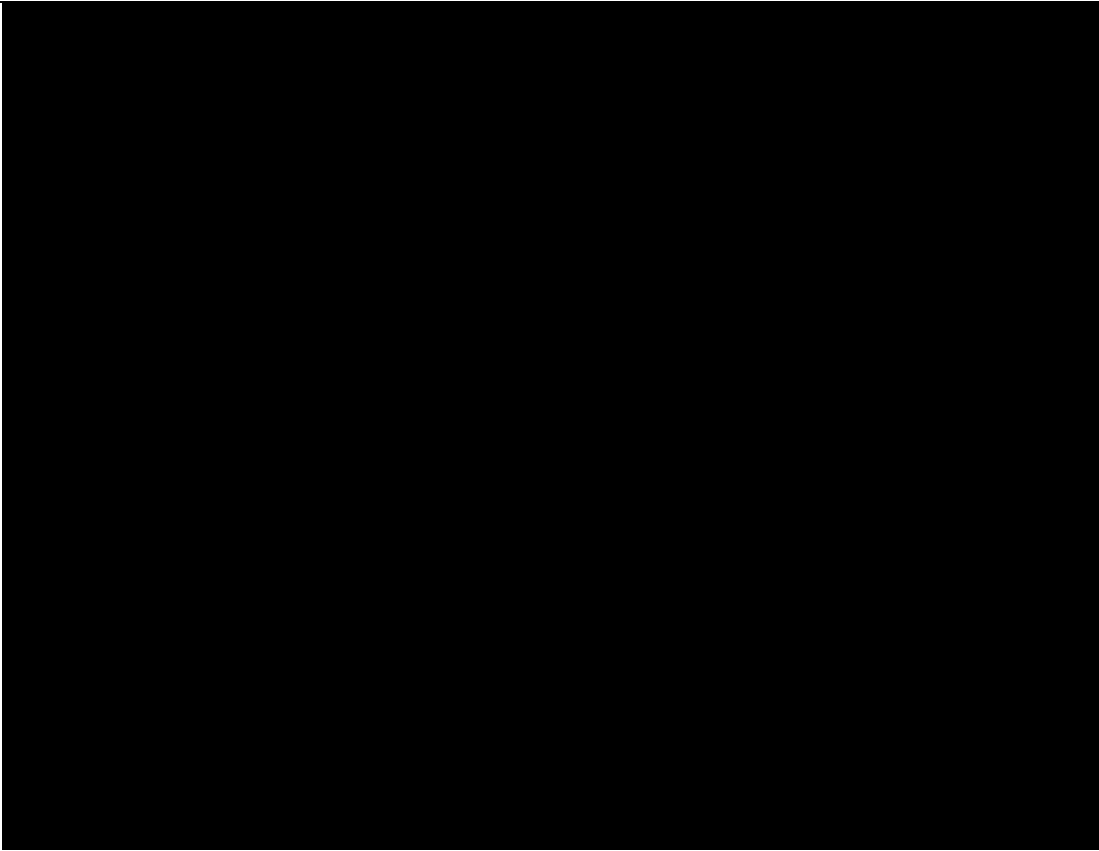


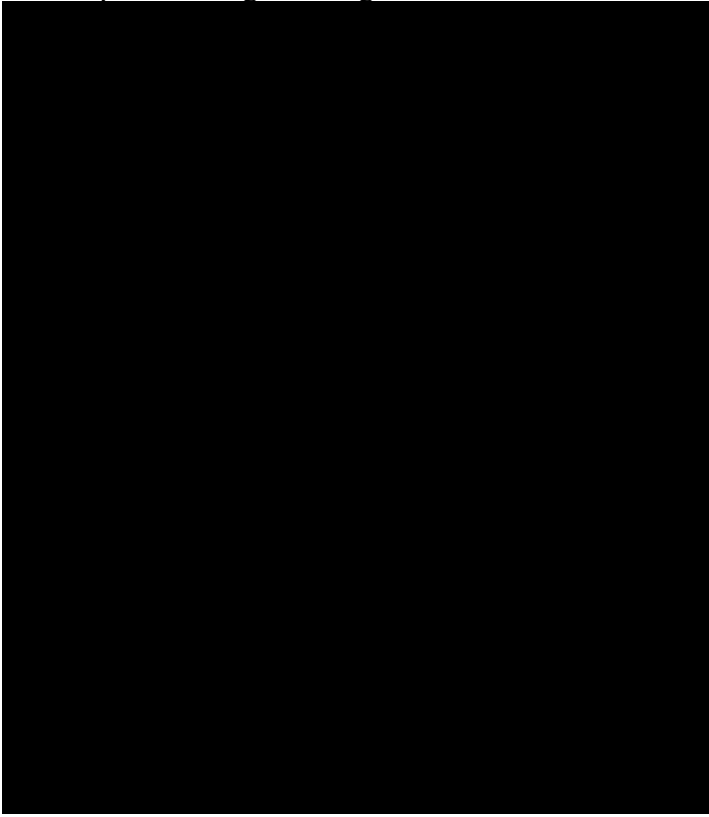
Ex. 49C.



Ex. 43C.

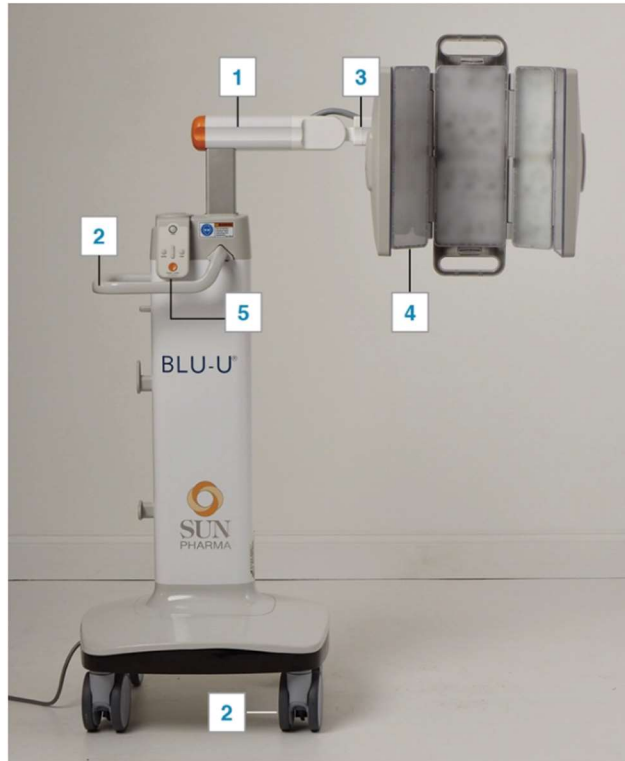
The BLU-U® 4170E's LEDs are arranged such that a higher intensity of light is emitted proximate the second edges (*i.e.*, the shorter edges) compared to the intensity of light emitted not proximate the second edges.

	
	Ex. 43C.
'028 Patent Claim 7	<u>BLU-U® 4170E</u>
The method of claim 5, wherein the illuminating comprises outputting blue light during at	The BLU-U® 4170E in conjunction with Levulan® can be used with the method of claim 5, wherein the illuminating comprises outputting blue light during at least part of the time when the treatment surface is illuminated. The BLU-U® 4170E includes the method of claim 5, as detailed above. <i>See</i> claim 5.

least part of the time when the treatment surface is illuminated.	The BLU-U® 4170E can be used wherein the illuminating comprises outputting blue light during at least part of the time when the treatment surface is illuminated. For example, the BLU-U® 4170E outputs blue light during the time when the treatment surface is illuminated.  Ex. 48C.
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		A large, solid black rectangular block covering the majority of the table's content area, indicating redacted information.	
	Ex. 44C.		

Product Diagram:

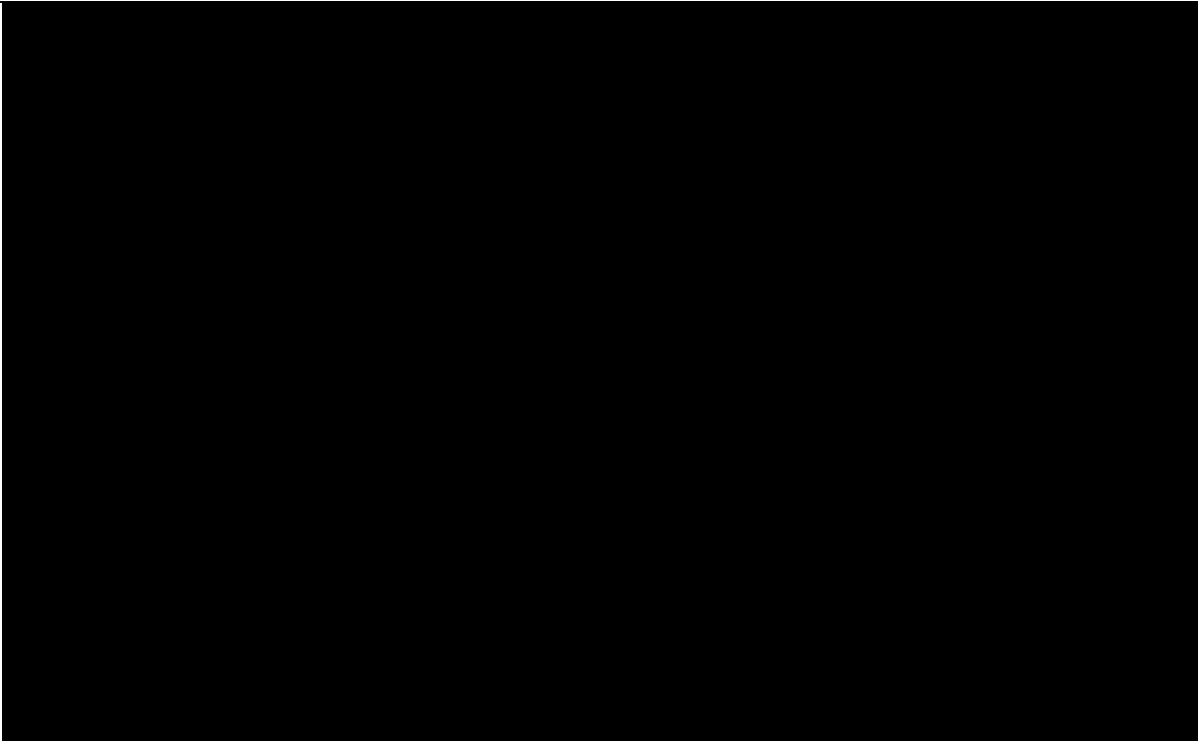
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

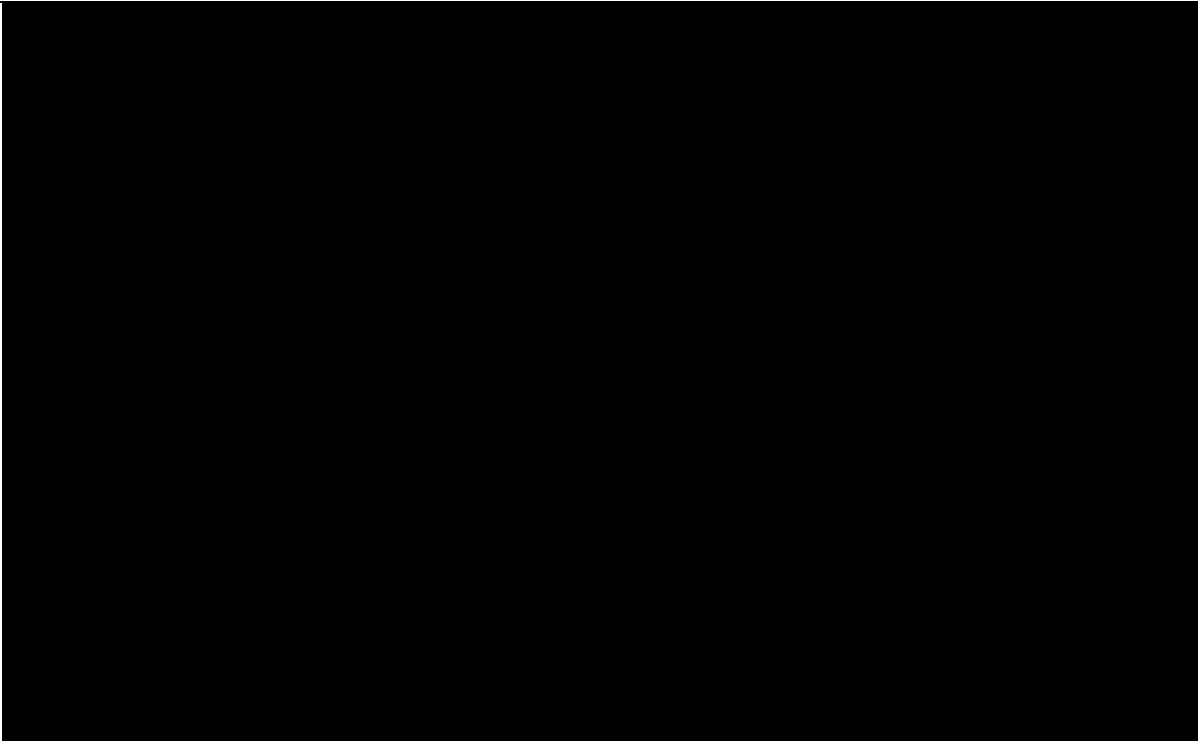
Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

The BLU-U® 4170E is configured to output blue light, including at a wavelength of 417 nm + 5 nm.

least three first panels; and	 Ex. 49C.
the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side	The BLU-U® 4170E includes the at least three first panels and the at least two second panels are connected in an alternating manner such that each of the at least two second panels has a first lateral side connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels. For example, the BLU-U® 4170E's three first panels (the first, third, and fifth panels) and the two second panels (the second and fourth panels) are connected in an alternating manner, such that the second panel has a lateral side connected to first panel and a lateral side connected to the third panel, and the fourth panel has a lateral side connected to the third panel and a lateral side connected to the fifth panel.

connected to a respective one of the at least three first panels and a second lateral side connected to another respective one of the at least three first panels.	 Ex. 49C.
'028 Patent Claim 16	<u>BLU-U® 4170E</u>
16[pre] A system for photodynamically diagnosing or treating a patient, comprising:	The BLU-U® 4170E is a system for photodynamically diagnosing or treating a patient. For example, the BLU-U® 4170E is a Blue Light Photodynamic Therapy Illuminator that is intended to provide phototherapeutic light to a body.



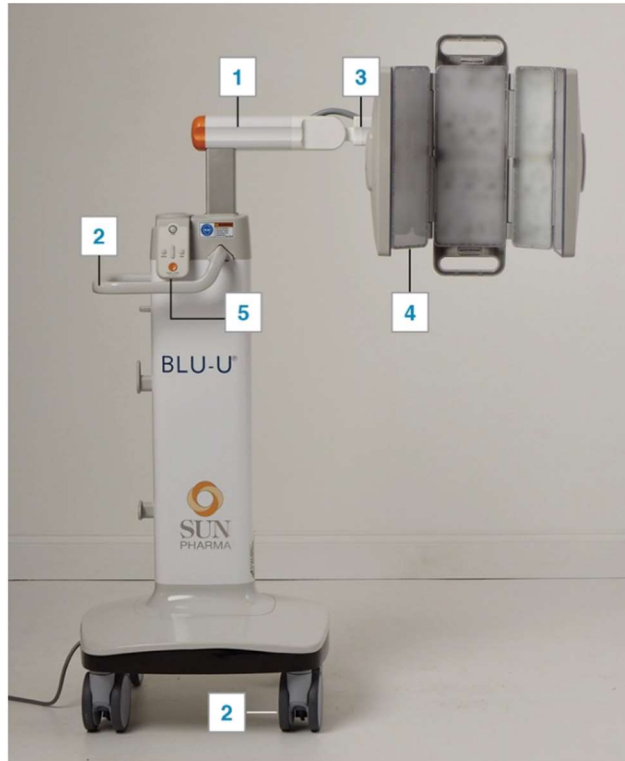
		A large solid black rectangular area used for redaction of an image.	
	Ex. 43C. For example, it is designed to provide a uniform distribution of blue light to areas of a patient's face, scalp or upper extremities. It is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris. The BLU-U® 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.		



	Ex. 48C.		



		A large, solid black rectangular block covering the majority of the table's content area, indicating redacted information.	
	Ex. 44C.		

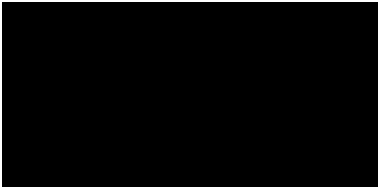
Product Diagram:

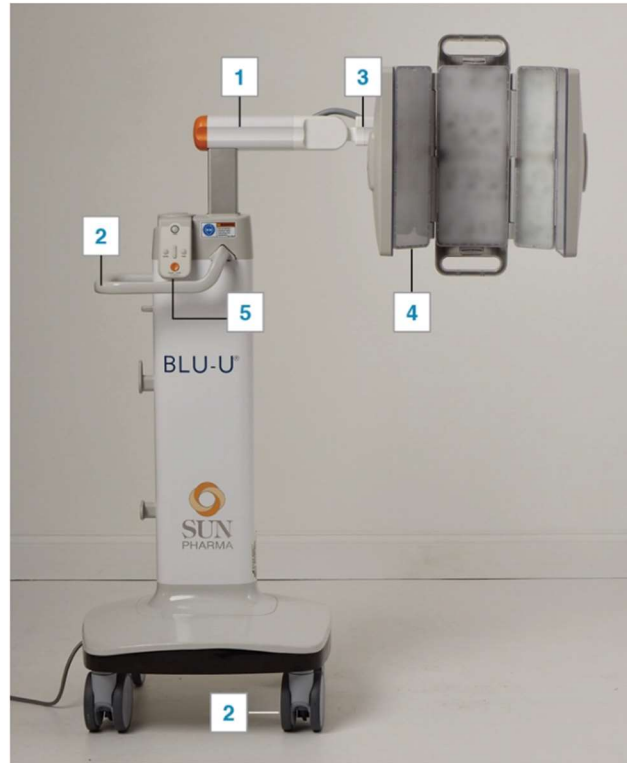
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

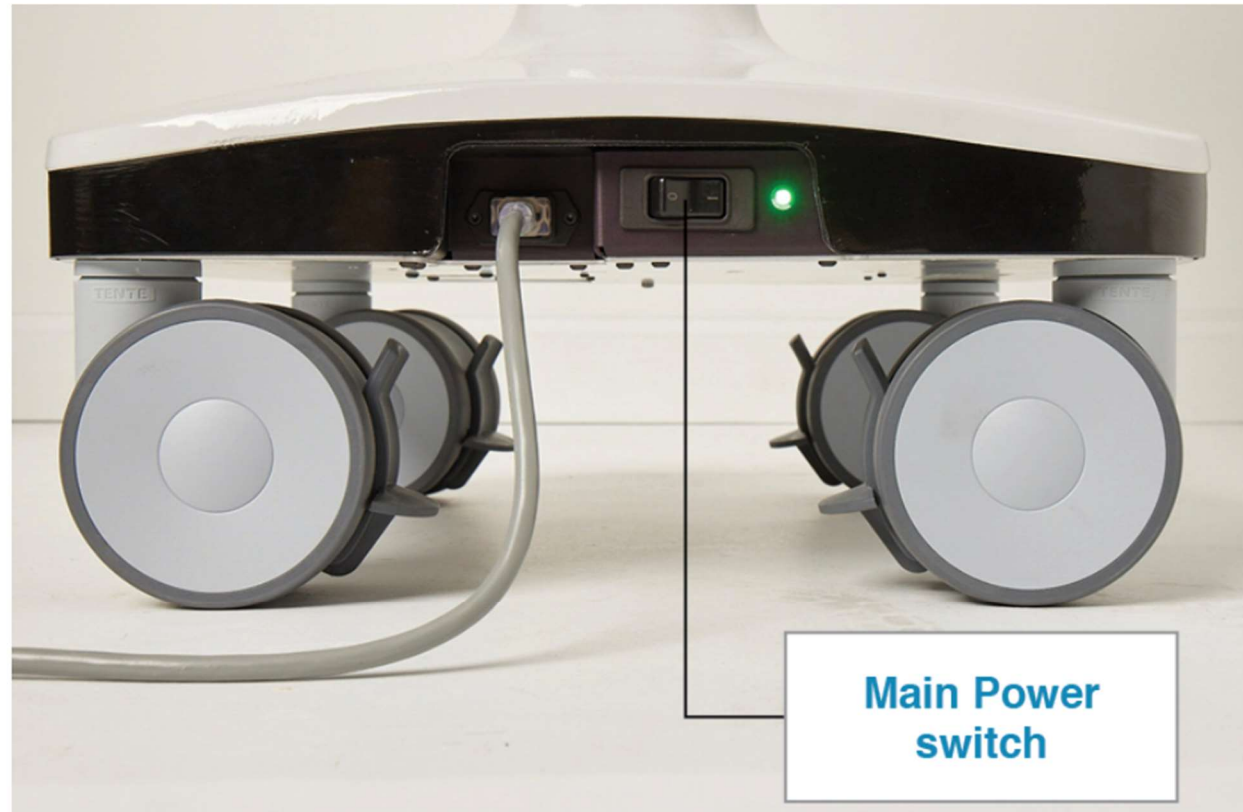
Ex. 28 at 7.

	OPERATING MANUAL BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E Indications for Use: The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities. The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The BLU-U® 4170E is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris. Ex. 28 at 4.
16[a] a mobile base supported by at least four wheels;	The BLU-U® 4170E includes a mobile base supported by at least four wheels. For example, the BLU-U® 4170E includes a mobile base supported by four wheels  Ex. 43C.

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Ex. 28 at 7.

OPERATING MANUAL**BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E**

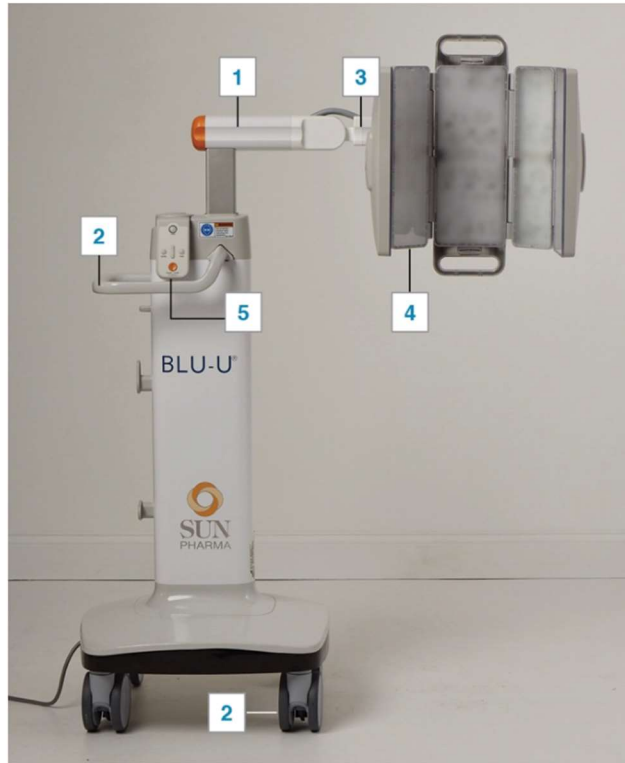
Ex. 28 at 9.

16[b] a pillar
perpendicular to
the base;

The BLU-U® 4170E includes a pillar perpendicular to the base.



	A large solid black rectangular block used for redaction, covering the majority of the table's content area. Ex. 43C.
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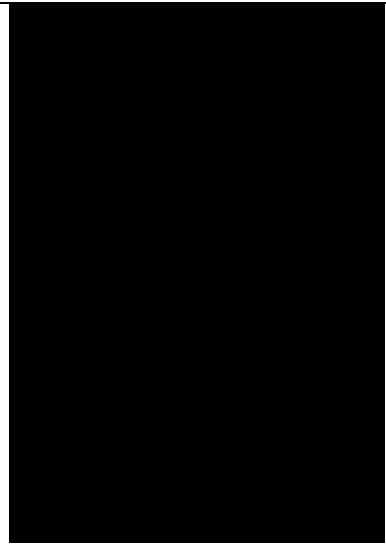
Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

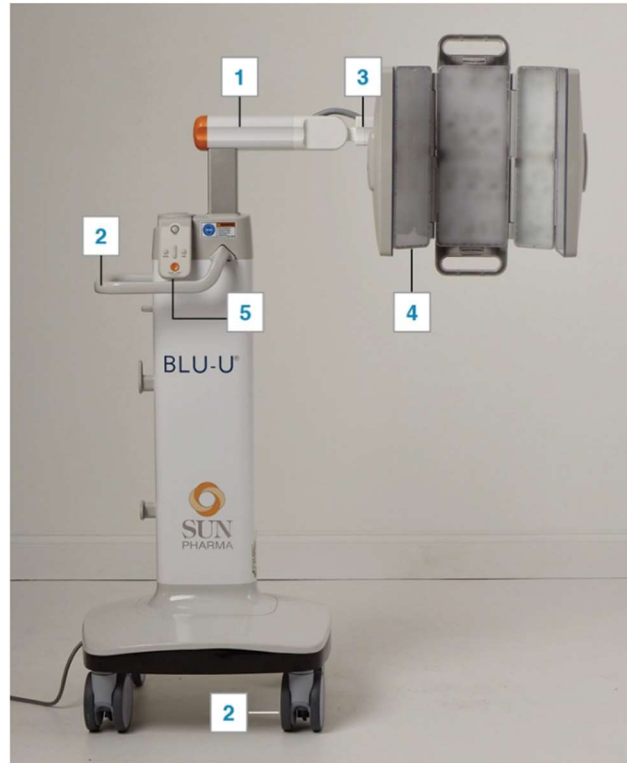
Ex. 28 at 7.

16[c] a controller disposed to be supported by the pillar;

The BLU-U® 4170E includes a controller disposed to be supported by the pillar. For example, the BLU-U® 4170E includes a Control Panel and User Interface that is disposed to be supported by the pillar.



Ex. 43C.

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

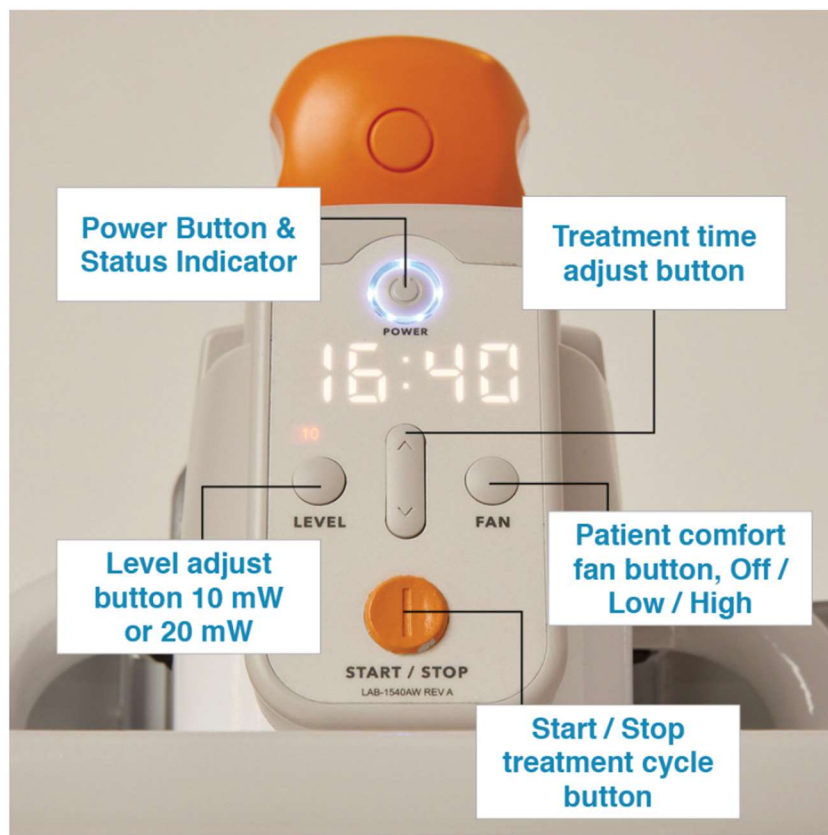
Ex. 28 at 7.

OPERATING MANUAL**BLU-U®** Blue Light Photodynamic Therapy Illuminator, Model 4170E**Controls:**

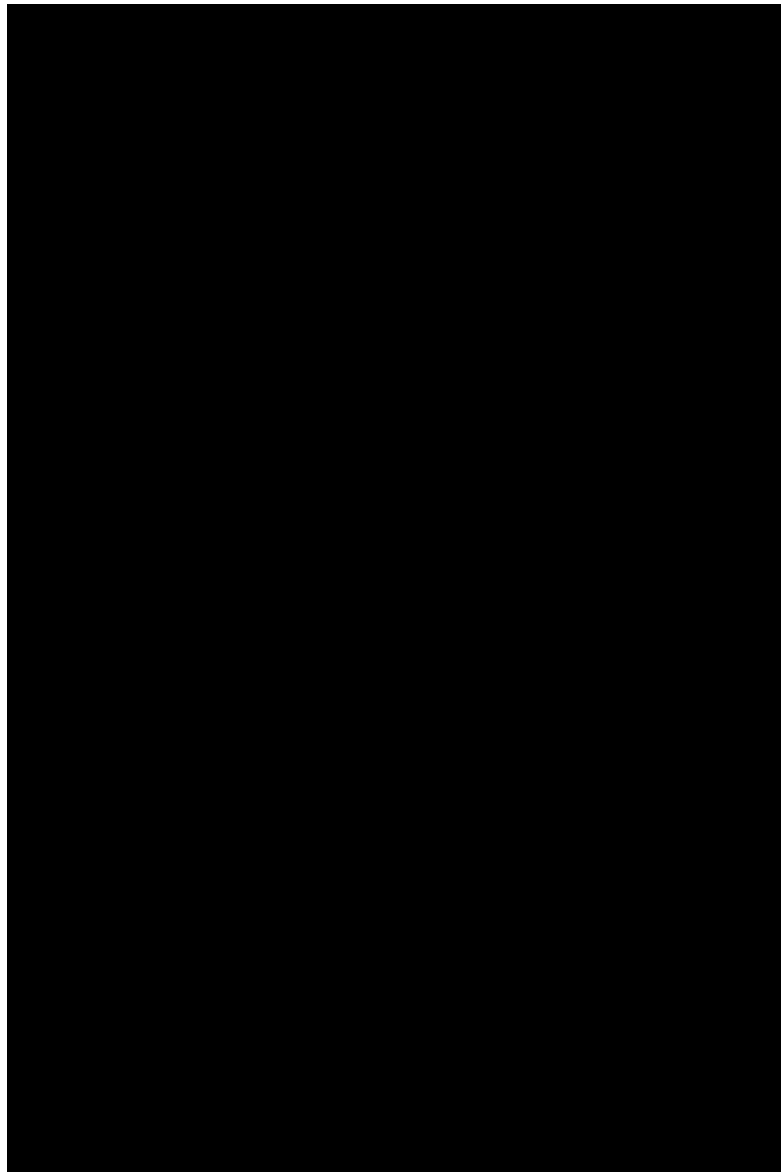
Controls for the **BLU-U®** are located on the User Interface. See the image below.



Caution – Use of controls or adjustments or performance of procedures other than those specified herein could result in improper operation of the system.



Ex. 28 at 8.



Ex. 55C.



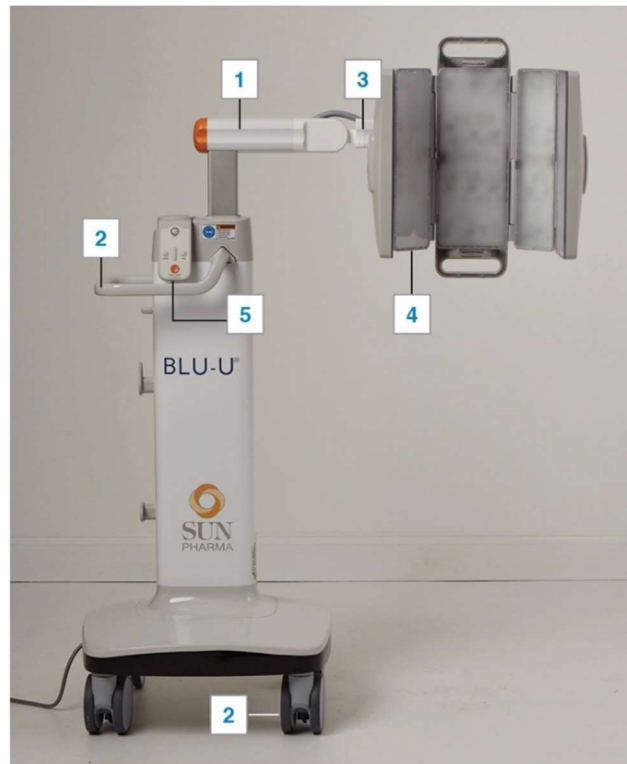
	A large solid black rectangular area covering the majority of the table's content, indicating redacted information.	
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Ex. 45.

16[d] an arm mounted to a top portion of the pillar; and

The BLU-U® 4170E includes an arm mounted to a top portion of the pillar. For example, the BLU-U® 4170E includes a pivoting arm.

Product Diagram:



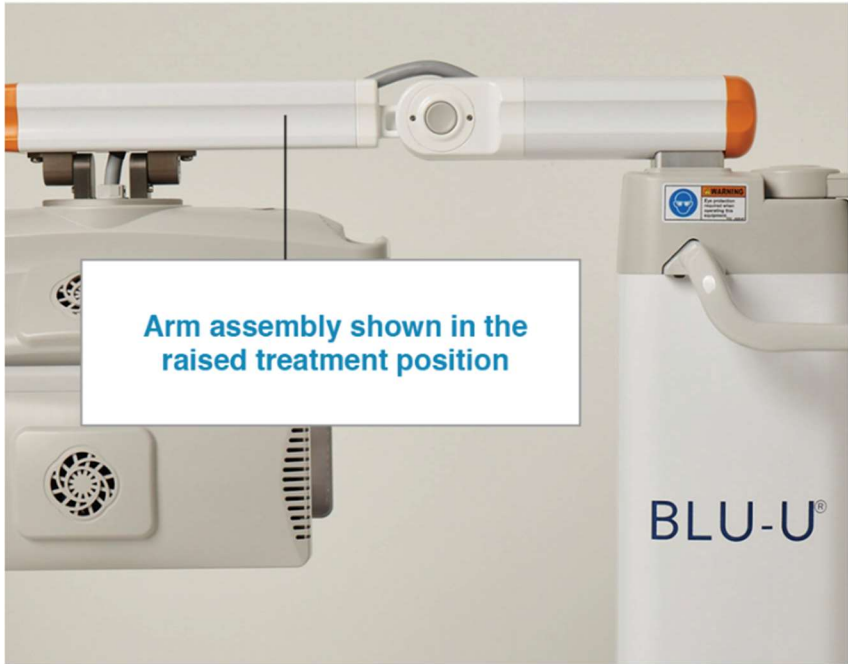
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Ex. 28 at 7.

Horizontal Arm Adjustment:

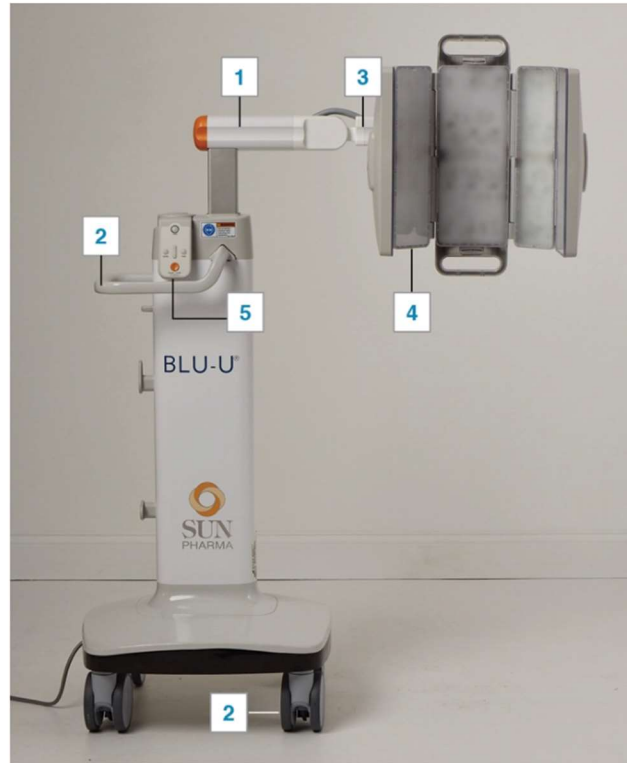
The horizontal Arm assembly can be folded to stow the Arm & Head for storage and transit or extended to put the system into the treatment position. The lock for the horizontal arm is located approximately at the midpoint on the Arm assembly as shown in the image below (grey button). To unlock the Arm, put slight pressure on the arm towards the post assembly while pressing the release button, then lift the Arm. While lifting the arm, release the release button and the Arm will automatically lock in place once raised into the use position. To lower the Arm, pull the arm up slightly while pressing the release button, then lower the Arm to the stowed position, the Arm will automatically lock in place once in the fully stowed position.



	 Arm assembly shown in the raised treatment position BLU-U® Ex. 28 at 13.
16[e] an illuminator connected at an end of the arm,	The BLU-U® 4170E includes an illuminator connected at an end of the arm. For example, the BLU-U® 4170E includes an “Five Panel LED treatment array.” That array is connected to the end of the pivoting arm.

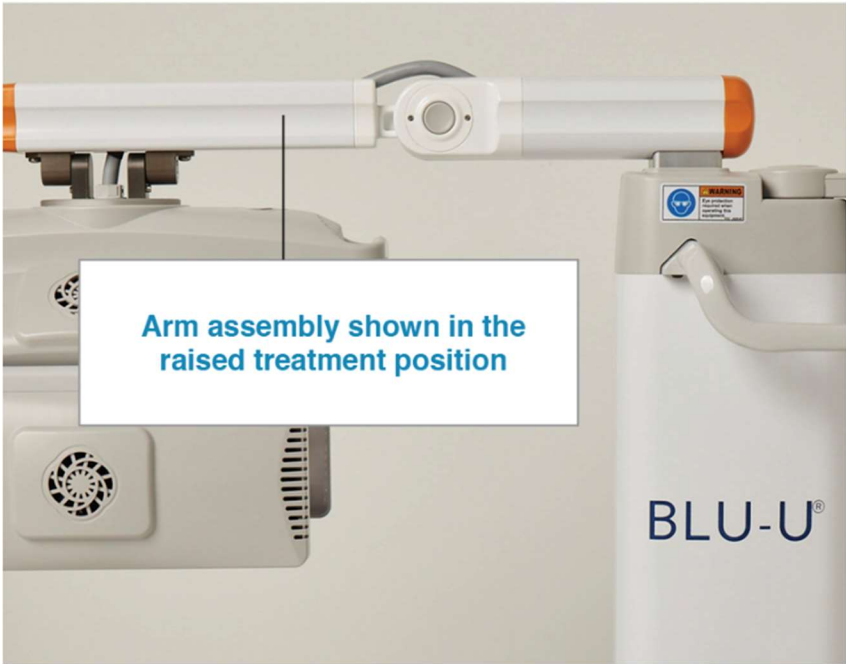


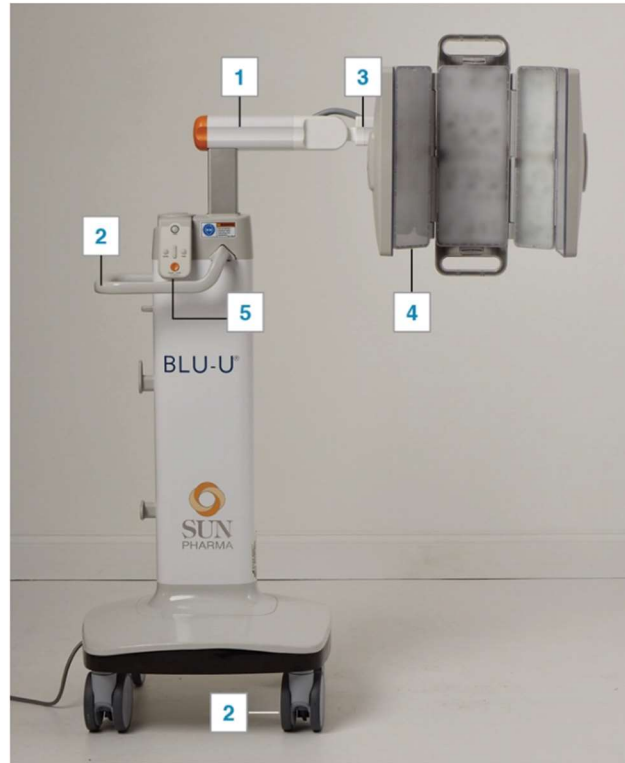
		A large, solid black rectangular block used for redaction, covering the majority of the table's content area.	
	Ex. 43C.		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Ex. 28 at 7.

	 Ex. 28 at 13.
16[f] the arm being hinged to allow adjustment of a position of the illuminator relative to the base,	The BLU-U® 4170E includes the arm being hinged to allow adjustment of a position of the illuminator relative to the base. For example, the pivoting arm is hinged to allow adjustment of the position of the Five Panel LED treatment array relative to the base.

Product Diagram:

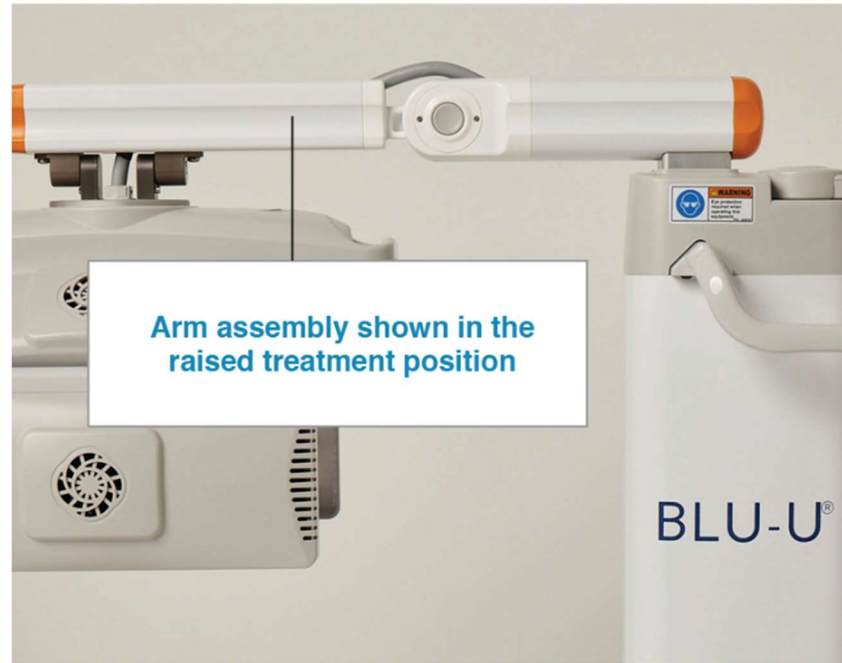
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Ex. 28 at 7.

Horizontal Arm Adjustment:

The horizontal Arm assembly can be folded to stow the Arm & Head for storage and transit or extended to put the system into the treatment position. The lock for the horizontal arm is located approximately at the midpoint on the Arm assembly as shown in the image below (grey button). To unlock the Arm, put slight pressure on the arm towards the post assembly while pressing the release button, then lift the Arm. While lifting the arm, release the release button and the Arm will automatically lock in place once raised into the use position. To lower the Arm, pull the arm up slightly while pressing the release button, then lower the Arm to the stowed position, the Arm will automatically lock in place once in the fully stowed position.



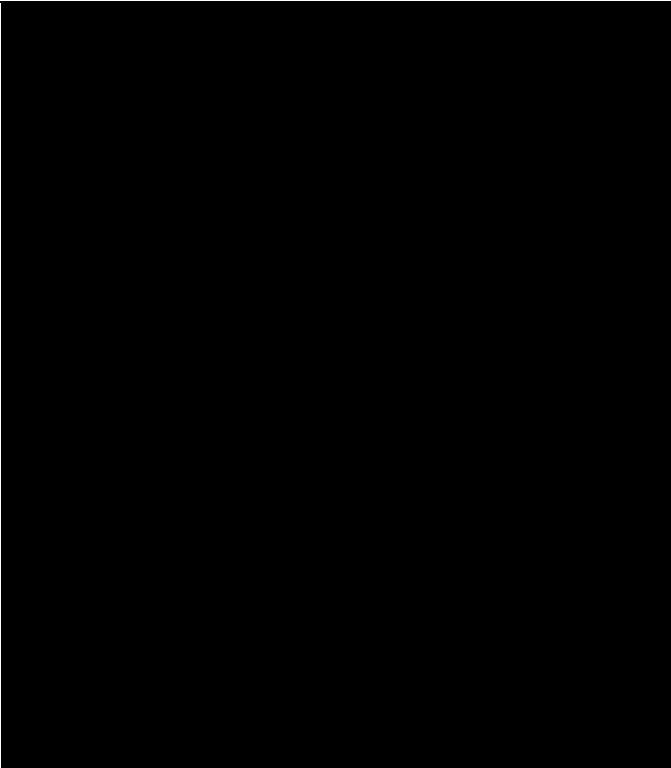


Ex. 28 at 13.

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 BLU-U® 4170E includes an illuminator that comprises 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 BLU-U® 4170E includes a Five Panel LED Treatment array with five “head panels” that are connected by hinged structures. The BLU-U® 4170E is designed to provide a “uniform distribution of blue light” to the treatment area through the Five Panel LED Treatment array, including by connecting the five panels by hinged structures to allow for continuous illumination across the five panels. Each of the five panels are individually configurable to control illumination from each of the five panels of the LED treatment array.

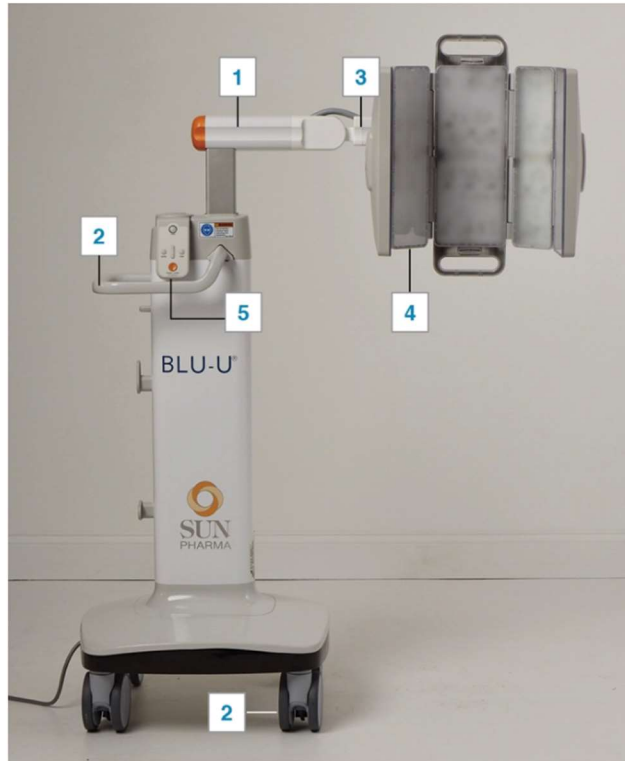
configurable to control illumination from each of the five panels,	 Ex. 43C.
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		A large, solid black rectangular block covering the majority of the table's content area, indicating redacted information.	
	Ex. 48C.		



	Ex. 44C.	A large, solid black rectangular block covering the majority of the table's content area, indicating that the information has been redacted.	
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Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

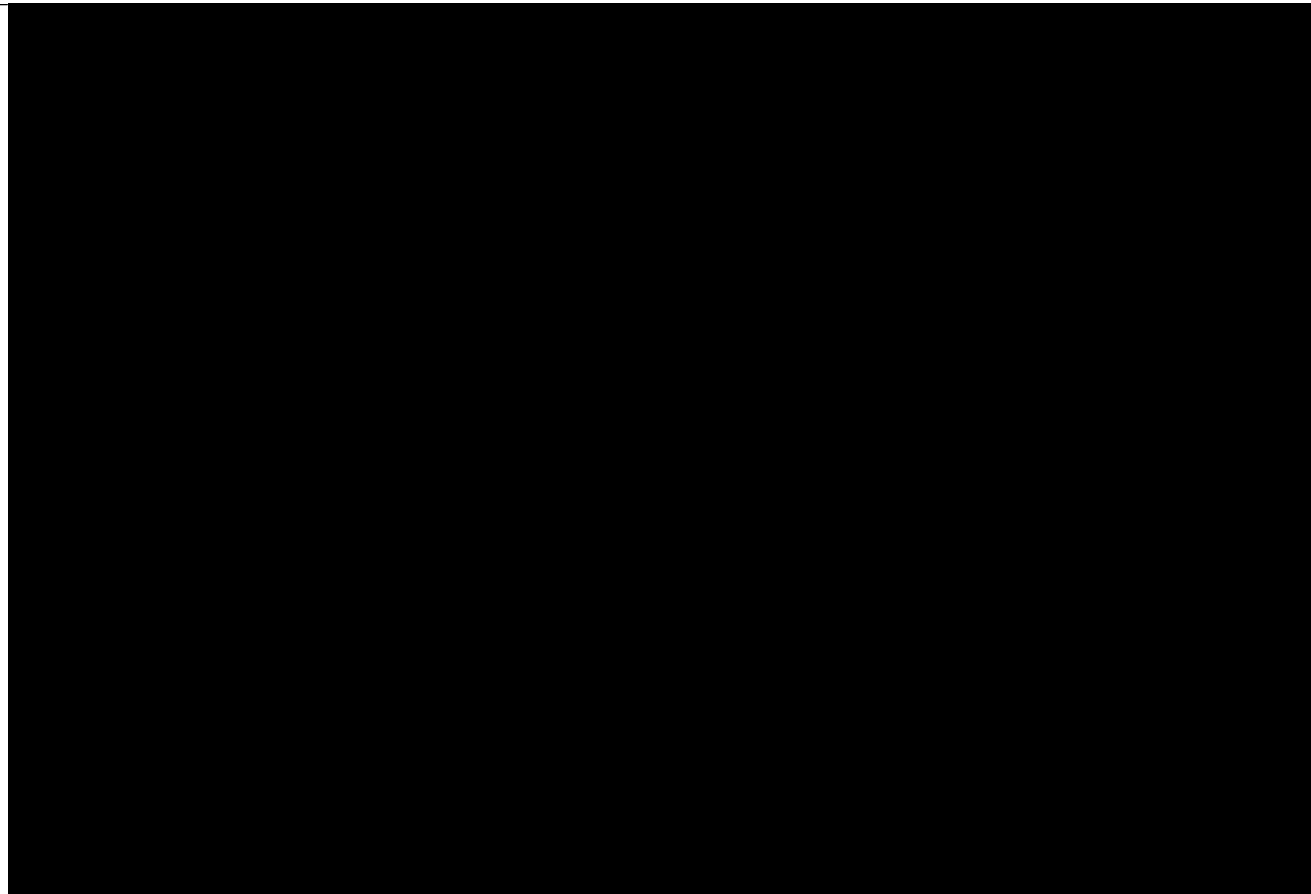
The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

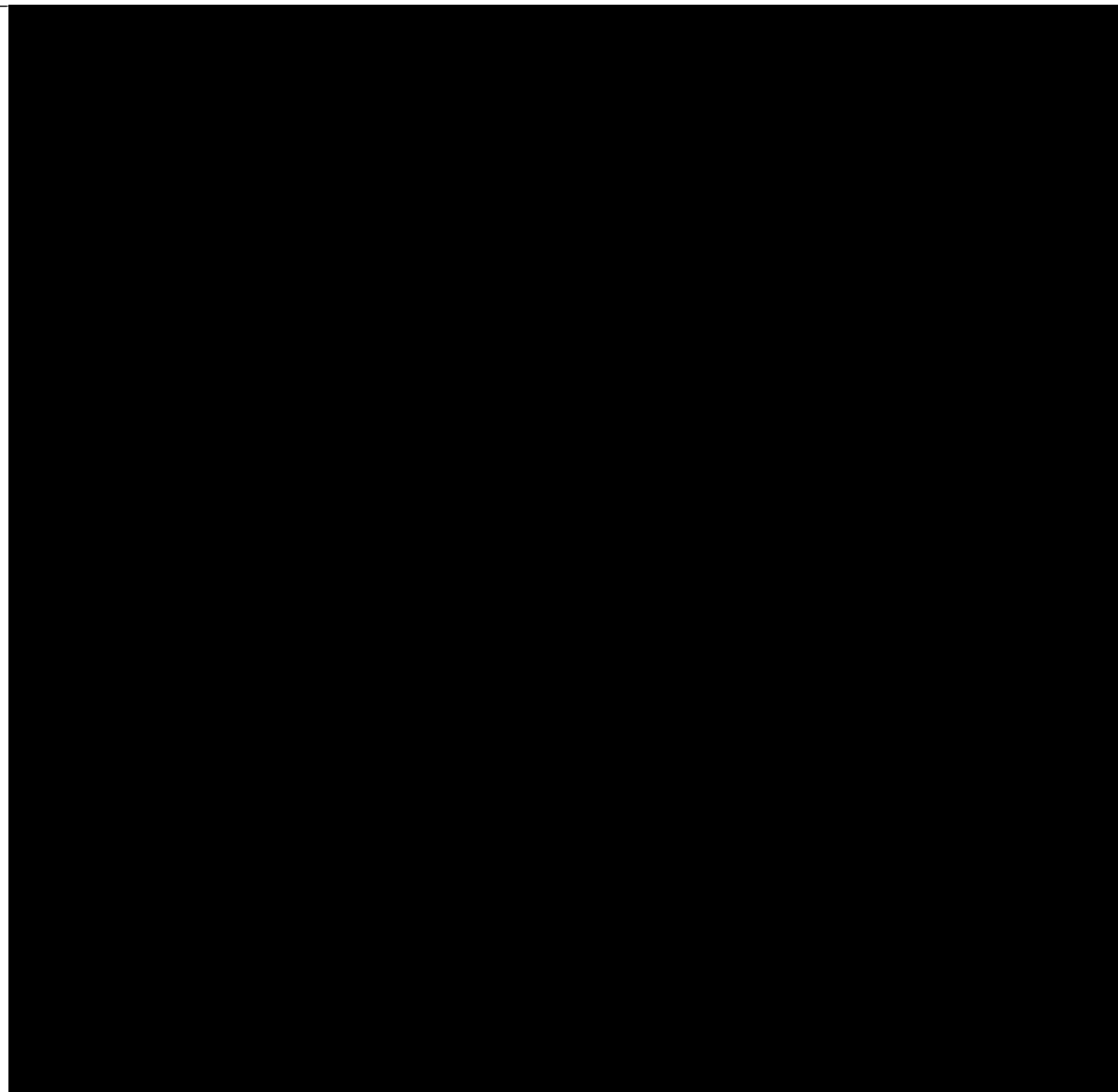
Head Panel Rotation Adjustment:

The Head panels are attached to each other via rotating hinge assemblies that contain torque inserts that maintain position without the need for an additional lock. This allows the Head to be configured flat or fully “U” shaped depending on the requirements for treatment. Each hinge assembly contains alignment markers (Orange bars) that align when the Head is placed into the “U” configuration required for PDT therapy. The rotation of the Head is constrained by hard stops built into the hinge assemblies which prohibit over-rotation in either direction. See the images below.

Ex. 28 at 16.



Ex. 49C (red annotations added).



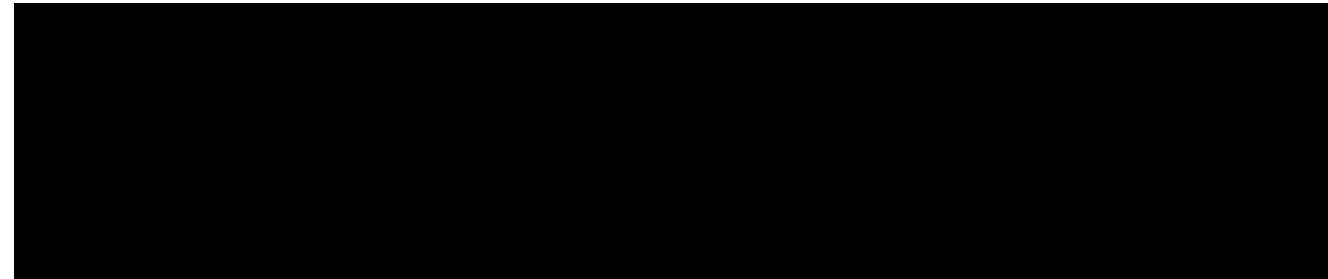
Ex. 50C (red annotations added).

For example, the measured output of the BLU-U® 4170E over the active emitting area has an allowable range of [REDACTED] of the measured maximum.

See generally Ex. 52C.

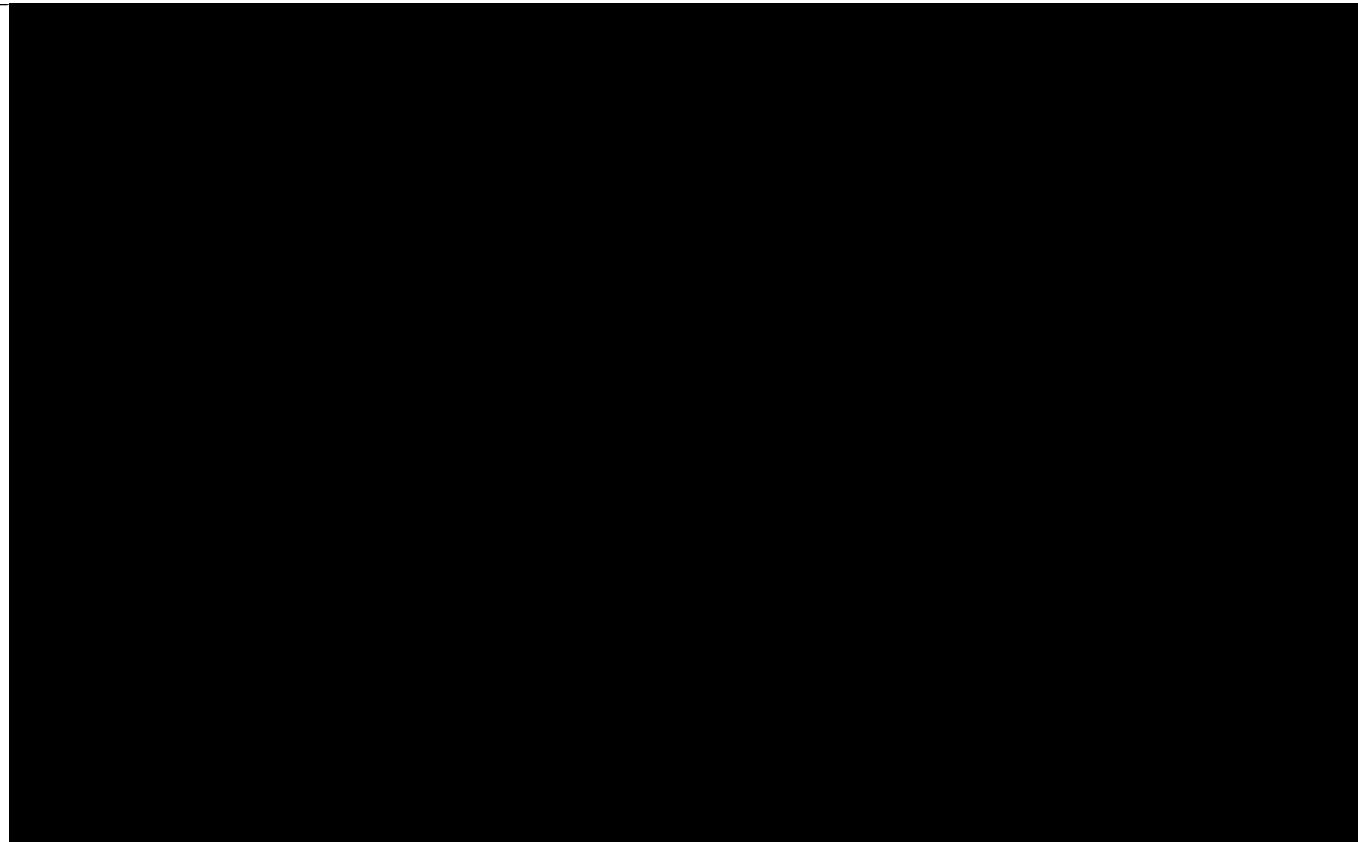


Ex. 52C at 1.

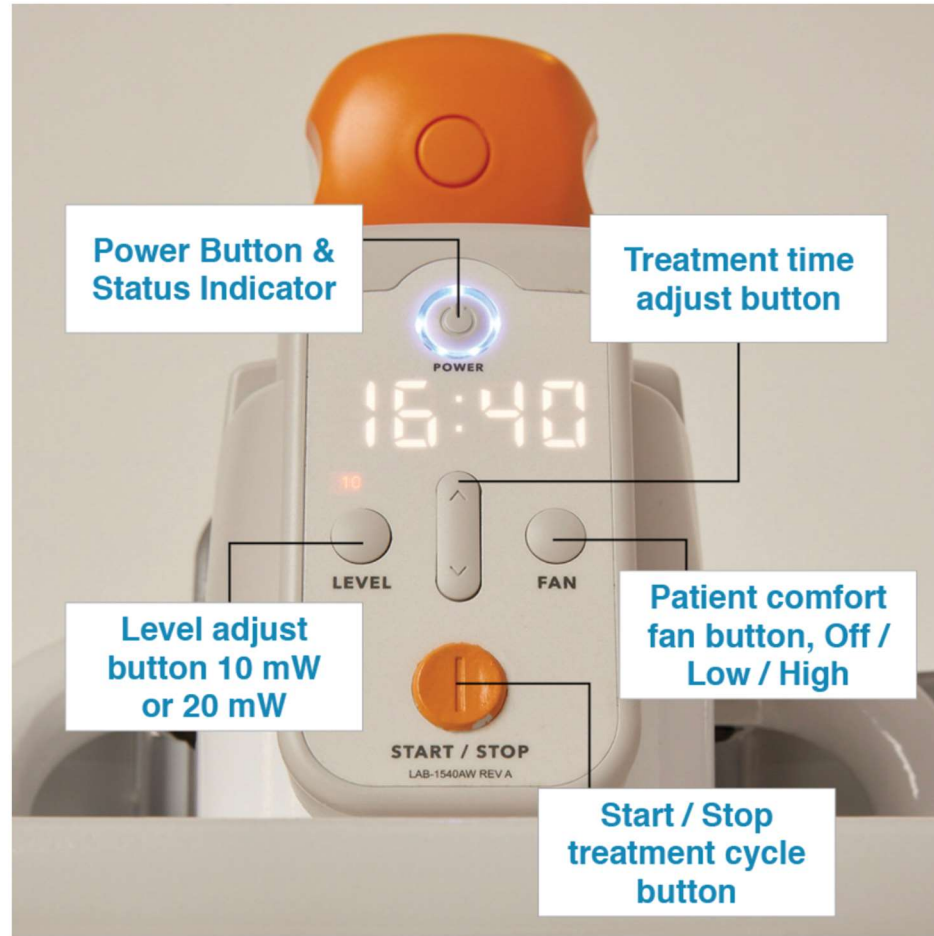


Ex. 52C at 6.

See generally Ex. 53C.



Each of the five panels are individually configurable to control illumination from each of the five panels of the LED treatment array. For example, the BLU-U® 4170E is configured to output power from the LED treatment array at either 10 mW/cm² or 20 mW/cm². Moreover, “each LED is individually controllable.” Ex. 56C.



Ex. 28 at 8.

OPERATING MANUAL**BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E*****Power Button & Status Indicator:***

The system **Power Button** is used to load the pre-programed treatment cycle. The system will automatically load the 10 mW power level at initial power up and will reset to 10mW power level after the completion of any treatment cycle, and will display time as 16:40. The 20mW power level setting can be selected by pressing the Level button, this will change the time displayed to 8:20. The Power button is also used as a system status indicator, blue ring indicates normal operation, amber ring indicates a fault condition.

- Pressing the Power button while the treatment cycle is “Paused” will cancel the treatment cycle and clear the time display.
- Pressing the Power button with the Main Power Switch activated (on) will toggle to load and or clear a treatment cycle for the system.

Level Button:

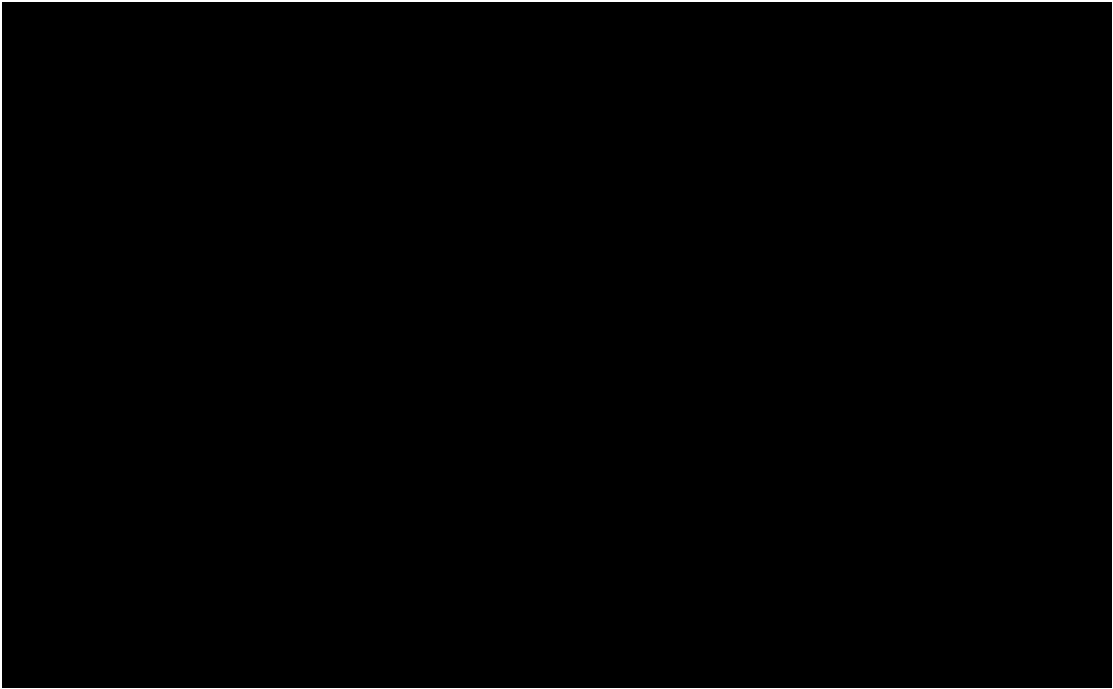
The **Level Button** is used to toggle between 2 power settings, 10mW & 20mW. The power level can be selected after pressing the power button to load one of the pre-programmed cycles. The timer will automatically set the correct time for the power level chosen.

- The power level selected will be displayed above the level button as 10 or 20.

Ex. 28 at 10.

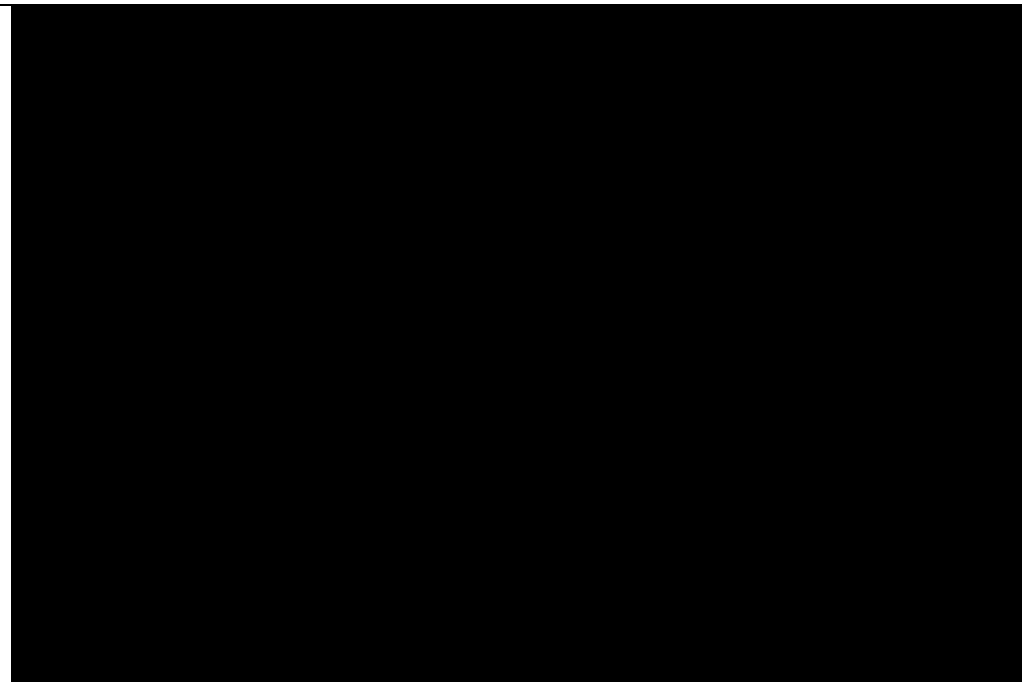
Power Output	10 mW/cm ² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm ² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm ² , continuous Output Wavelength: 417 nm + 5 nm Output Uniformity: 30%
Light Dose	Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm ² at 10mW/cm ² or 8 minutes, 20 seconds to deliver 10 J/cm ² at 20 mW/cm ²

Ex. 28 at 6.

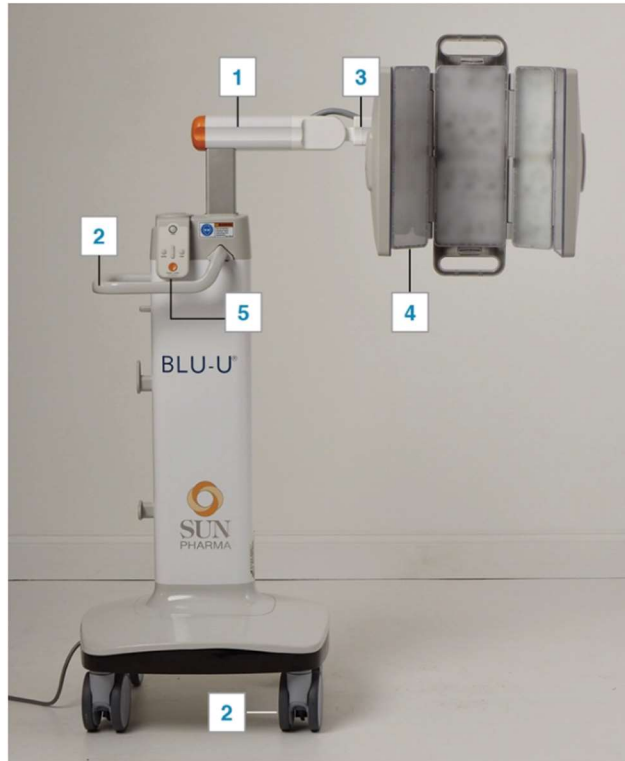
16[h] light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources, the light sources being configured to output light uniformly during at least part of a time when the treatment surface is illuminated, 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	The BLU-U® 4170E 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. The BLU-U® 4170E 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. For example, the BLU-U® 4170E includes LEDs, which are light sources, that are disposed on surfaces of the five panels.  Ex. 49C.
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compared to the
intensity of light
emitted not
proximate the
second edges,
and

Ex. 43C.



Ex. 51C.

Product Diagram:

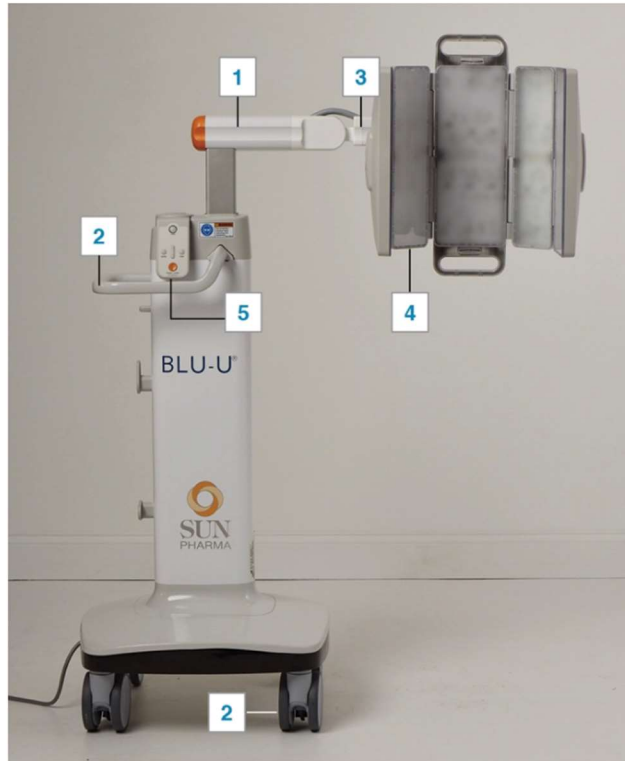
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

The BLU-U® 4170E includes an illuminator, a Five Panel LED Treatment array, that is configured to output light uniformly during at least part of the time when the treatment surface of the patient is illuminated via the LEDs.

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

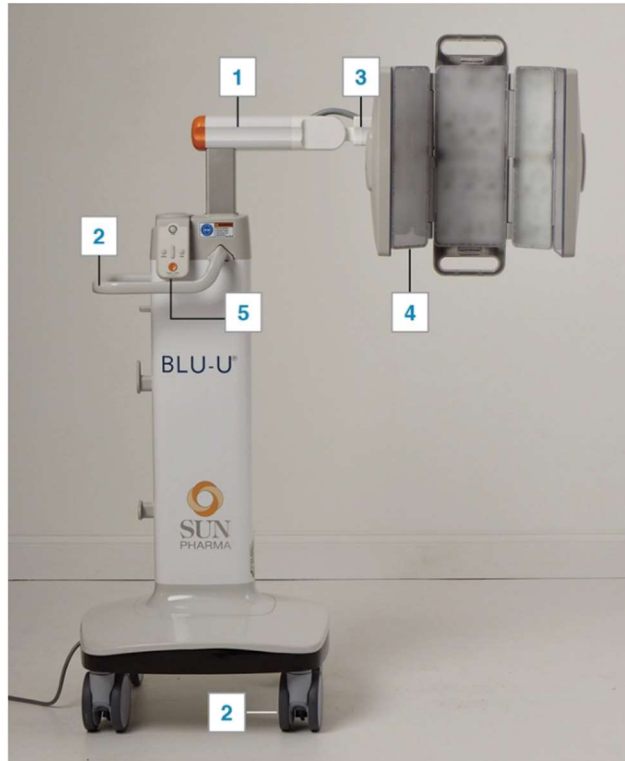
Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.



		A large black rectangular redaction box covering the majority of the upper half of the table's content area.	
	Ex. 44C. For example, the BLU-U® 4170E is “designed to provide a uniform distribution of blue light to areas of the patient’s face, scalp or upper extremities.”		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

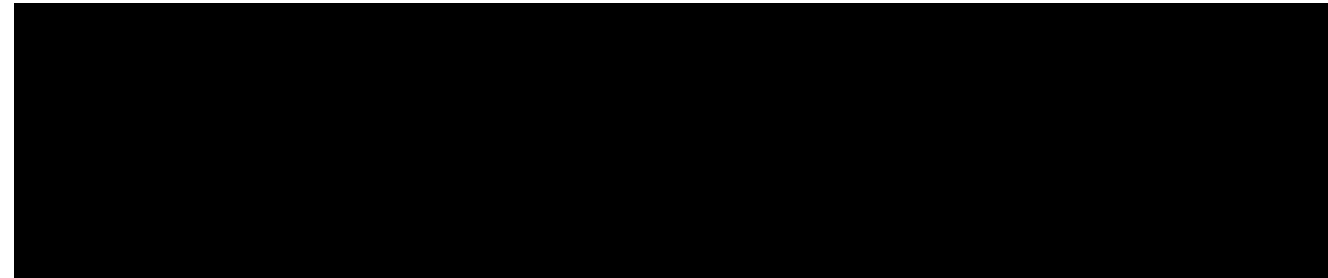
Ex. 28 at 7.

For example, the measured output of the BLU-U® 4170E over the active emitting area has an allowable range of [REDACTED] of the measured maximum.

See generally Ex. 52C.

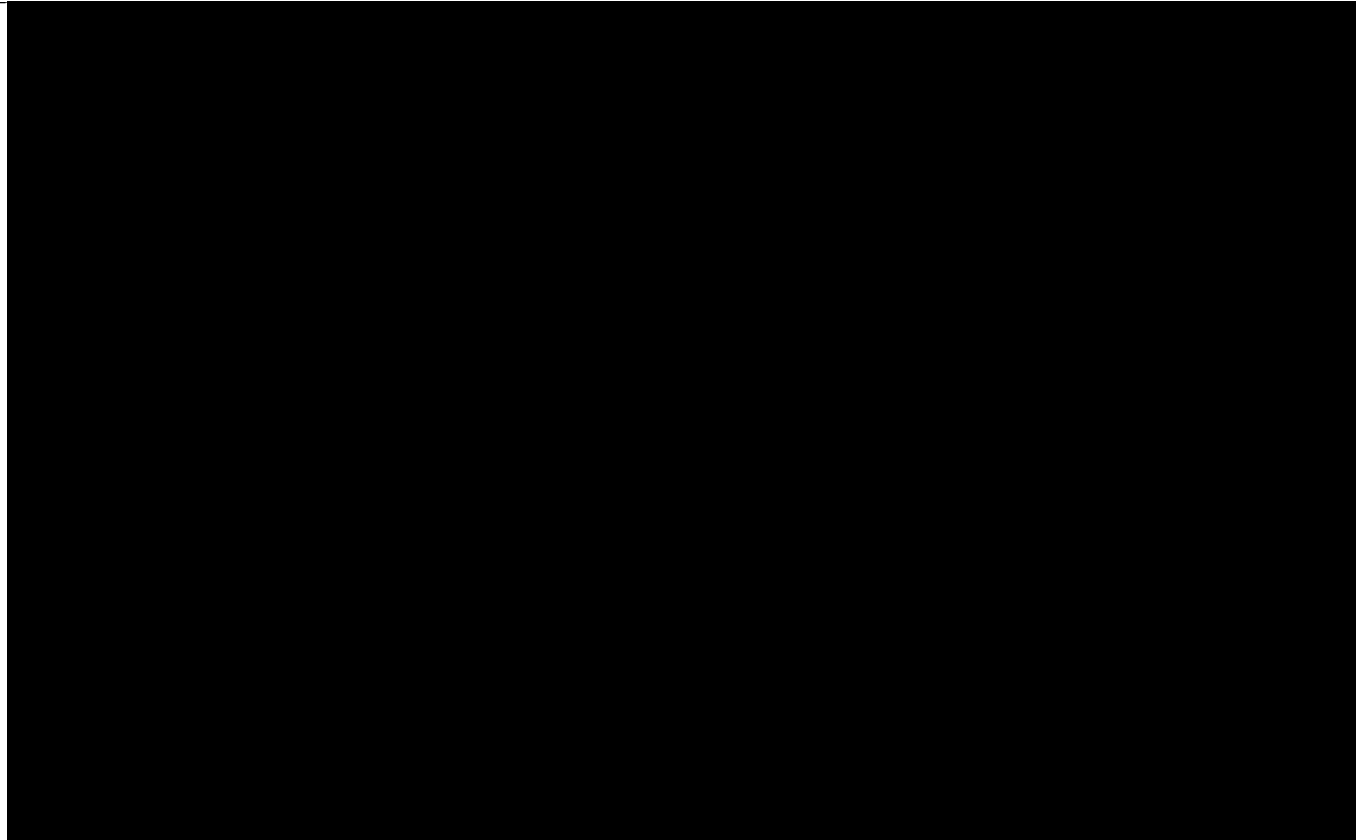


Ex. 52C at 1.

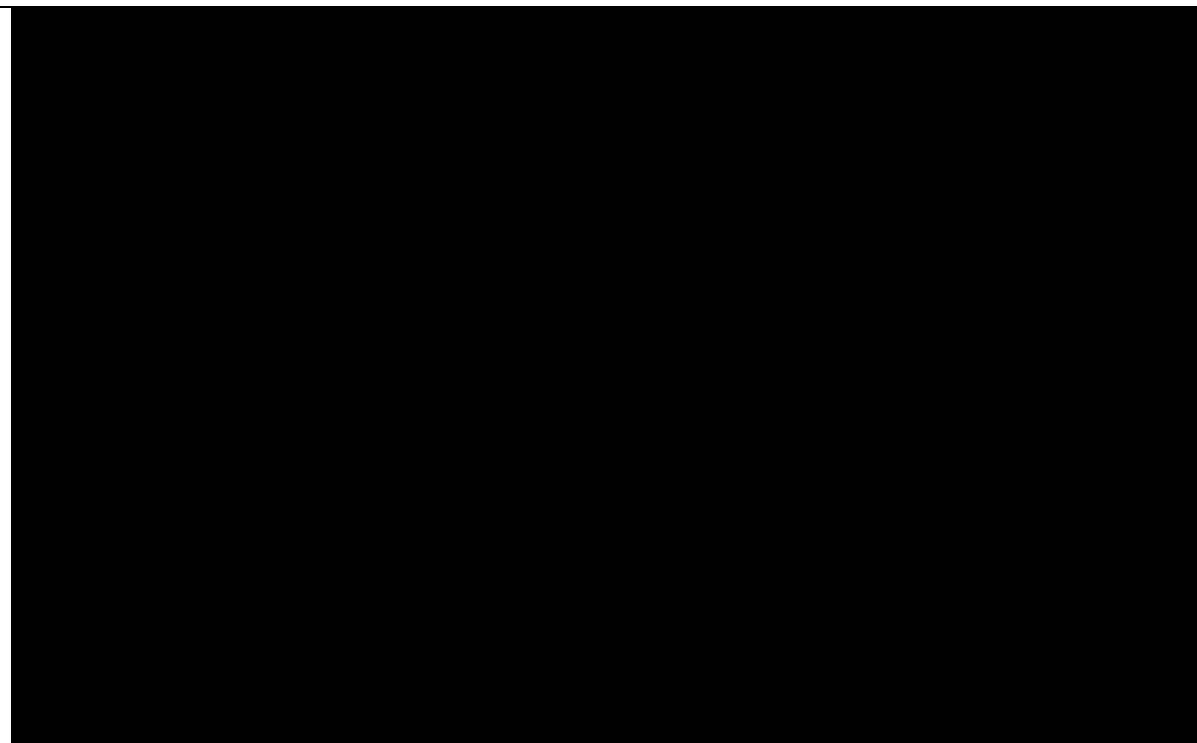


Ex. 52C at 6.

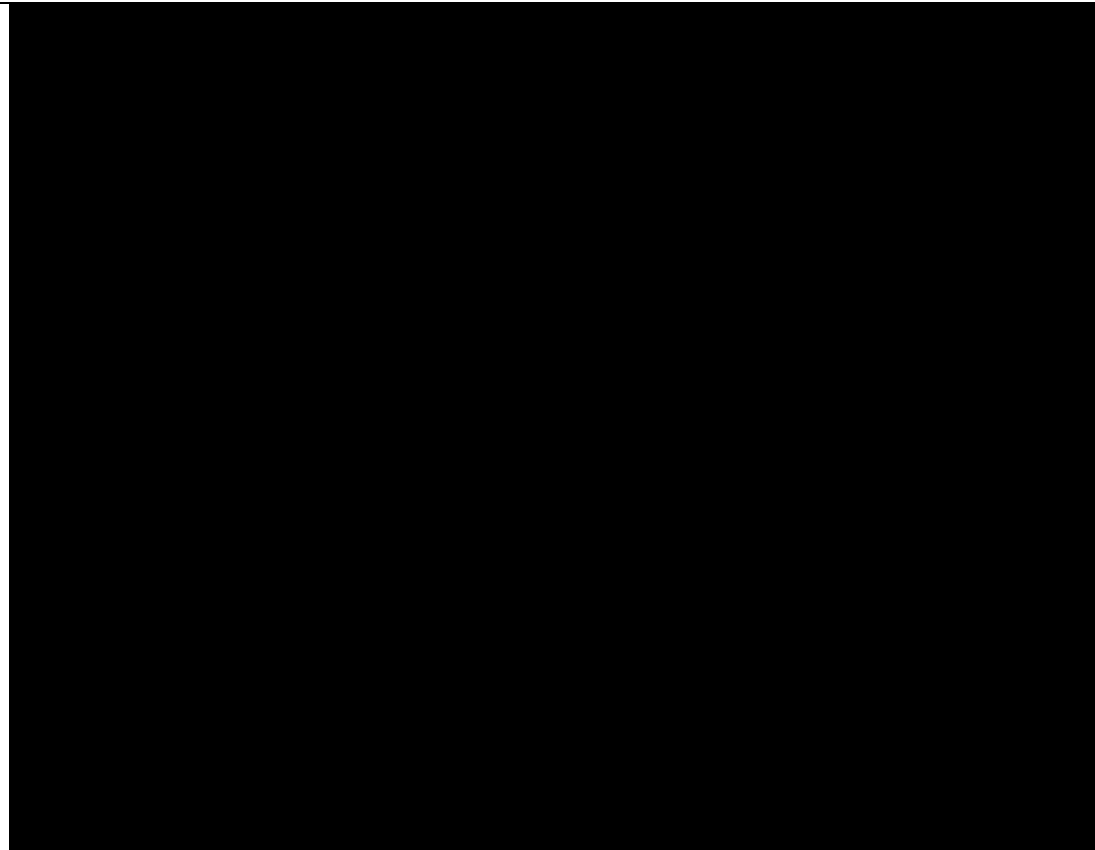
See generally Ex. 53C.



Each of the five LED panels of the BLU-U® 4170E are rectangular, such that for each panel, there are two first edges and two second edges, where the second edges are shorter than the two first edges.

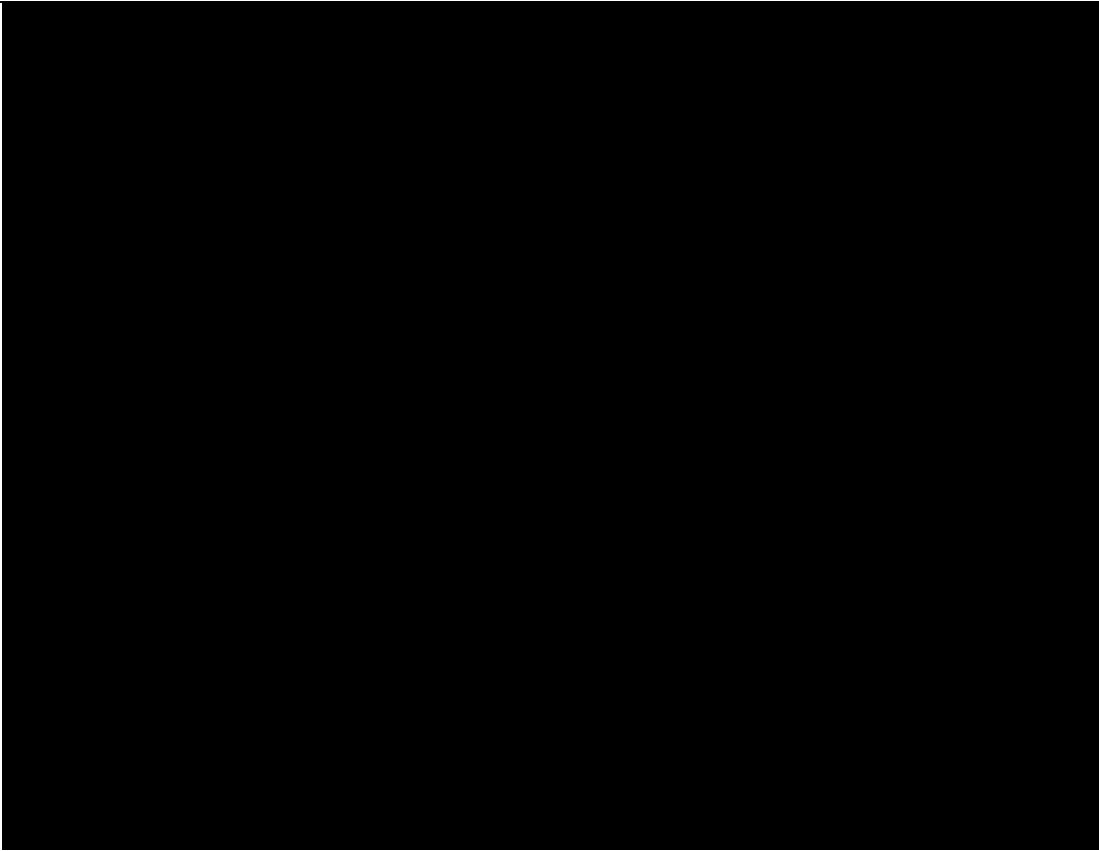


Ex. 49C.

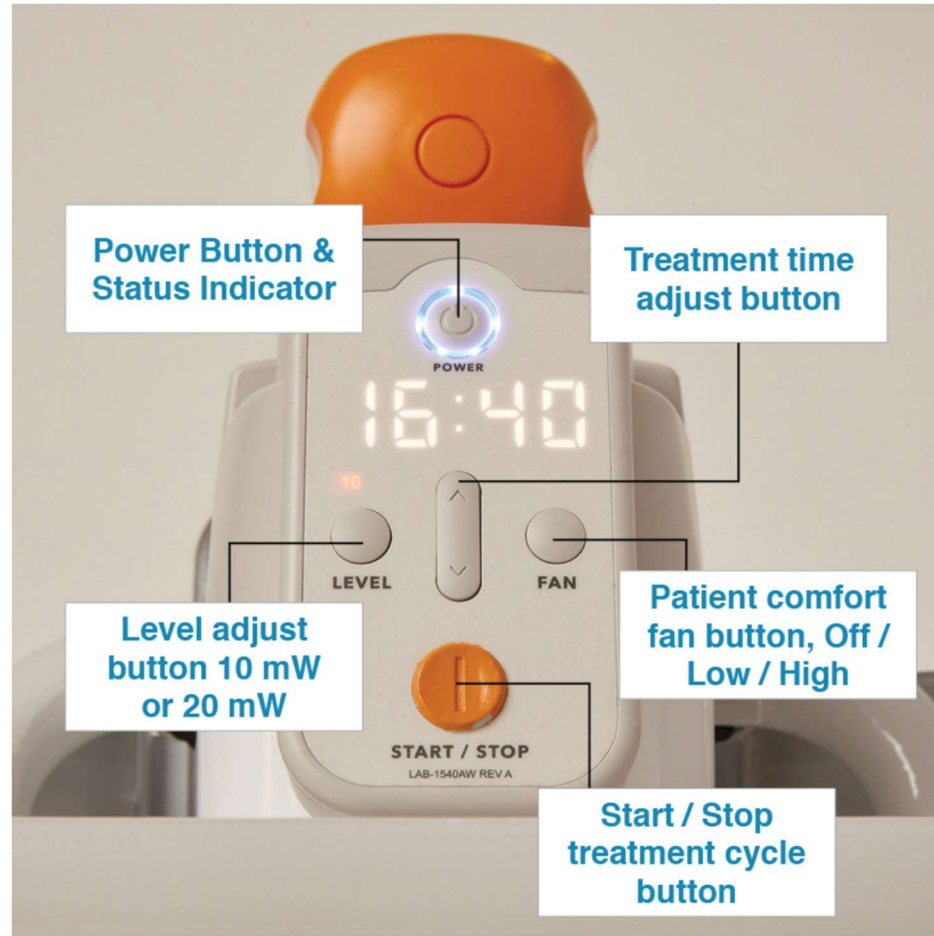


Ex. 43C.

The BLU-U® 4170E's 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.

	 Ex. 43C.
16[i] one or more fans mounted to at least one of the five panels.	The BLU-U® 4170E includes one or more fans mounted to at least one of the five panels. For example, the center panel includes two patient comfort fans that allows the center panel to direct cooling airflow to the patient during the treatment.

	Description: The BLU-U® is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment. Ex. 28 at 7.
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Ex. 28 at 8.

	<i>Patient Comfort Fan Button:</i> The Fan Button is used to control the two Patient comfort fans. The button toggles the fans through three settings, Off / Low / Hi. • Patient Comfort Fan button becomes active upon pressing the Power button to load a treatment cycle, the button can be used to cycle through the three settings, Off / Low / Hi. • The Patient cooling fans will automatically shut off when the cycle timer reaches zero during a treatment Ex. 28 at 10.
'028 Patent Claim 17	<u>BLU-U® 4170E</u>
17. 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 BLU-U® 4170E 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 BLU-U® 4170E includes the system of claim 16, as detailed above. <i>See</i> claim 16. The BLU-U® 4170E includes a center panel that is configured to face the treatment surface and two or more panels are configured to be angled relative to the center panel. For example, the BLU-U® 4170E may be configured in a “U” shape configuration for PDT therapy. In the “U” configuration, the center panel is configured to face the treatment surface, while the remaining four panels are configured to be angled relative to the center panel.



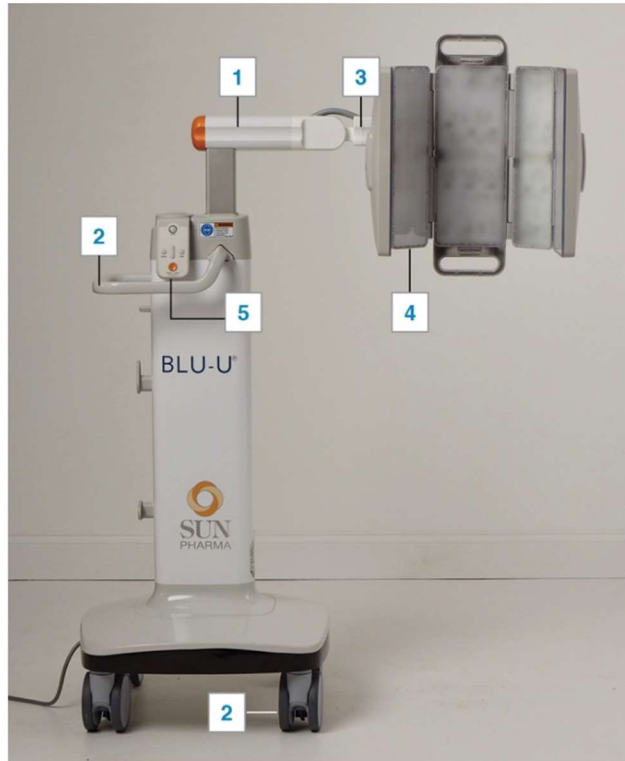
		A large, solid black rectangular block covering the majority of the table's content area, indicating redacted information.	
	Ex. 48C.		



	Ex. 44C.		



	Ex. 54C.		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

The BLU-U® 4170E includes alignment markers (Orange bars) that align when the Head is placed into the “U” configuration required for PDT therapy.

Head Panel Rotation Adjustment:

The Head panels are attached to each other via rotating hinge assemblies that contain torque inserts that maintain position without the need for an additional lock. This allows the Head to be configured flat or fully “U” shaped depending on the requirements for treatment. Each hinge assembly contains alignment markers (Orange bars) that align when the Head is placed into the “U” configuration required for PDT therapy. The rotation of the Head is constrained by hard stops built into the hinge assemblies which prohibit over-rotation in either direction. See the images below.

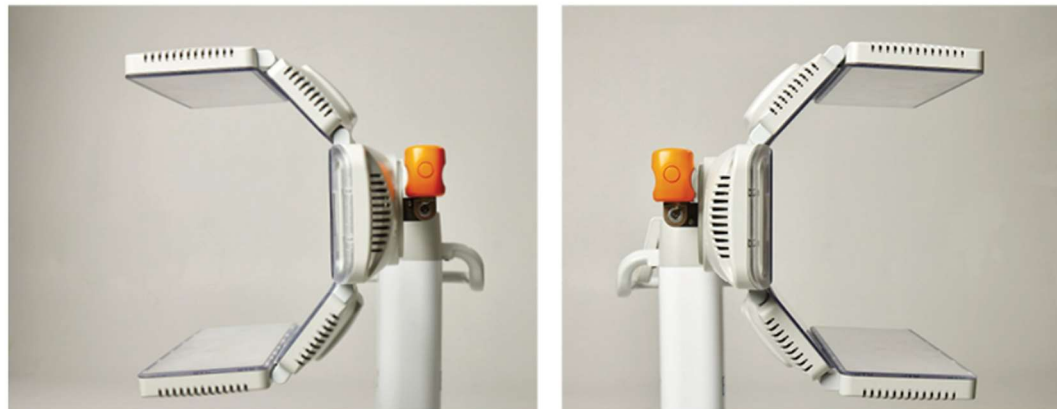


Ex. 28 at 16.

The BLU-U® 4170E includes a Head assembly that can be tilted and/or rotated to allow for the optimum position for treatment.

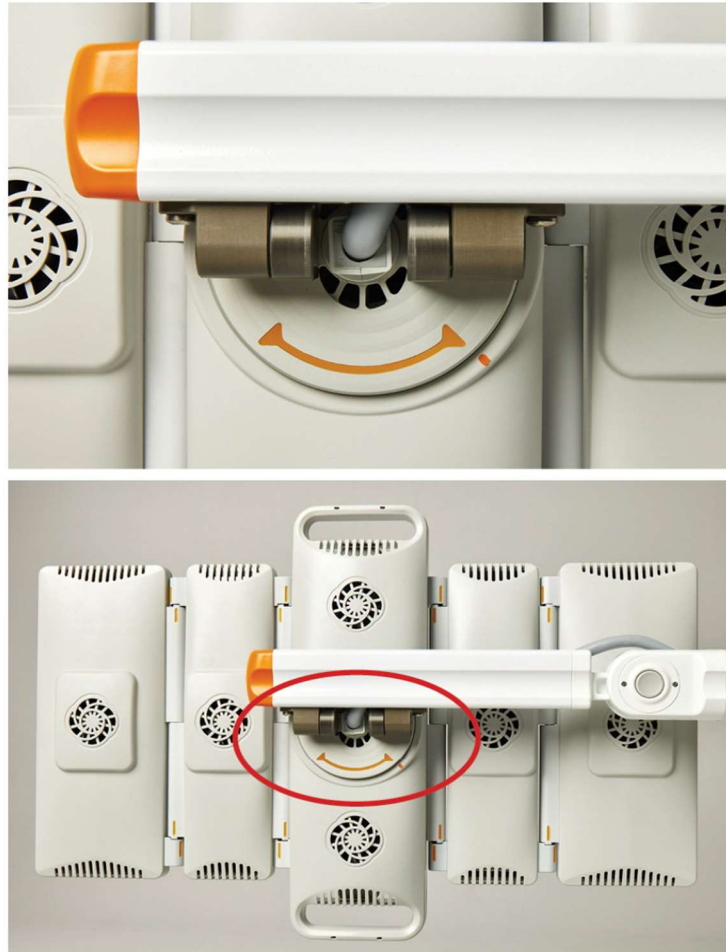
Head Tilt Adjustment:

The Head assembly can be tilted +/- 90 degrees from the stowed position (center panel facing the floor). This allows for the Head to be placed in the optimum position for treatment. The tilt mechanism utilizes torque inserts which eliminate the need for an additional lock. The torque inserts are capable of holding the Head at any position through the allowed 180 degree range of motion. See the images below.

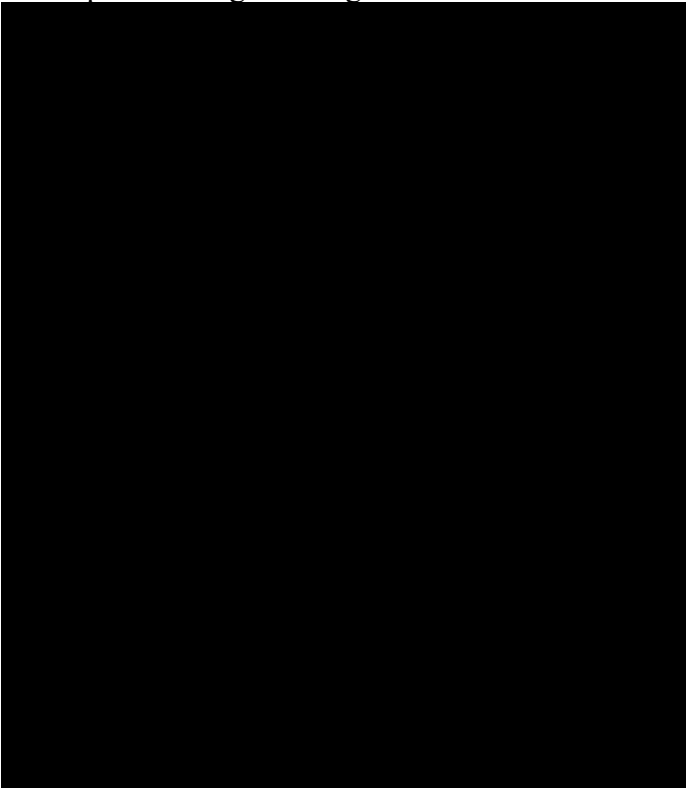


Head Rotation Adjustment:

The Head assembly can be rotated +/- 90 degrees from the stowed position (center panel long axis aligned with the Arm center axis). This allows the Head to be placed in the optimum position for treatment. The rotation mechanism has two detent positions at the ends of the travel to lock the head into position for treatment. There are two position indicators located on the back of the center panel housing that align with indicator marks engraved into the back plate when the Head is at the limit of travel. See the images below.

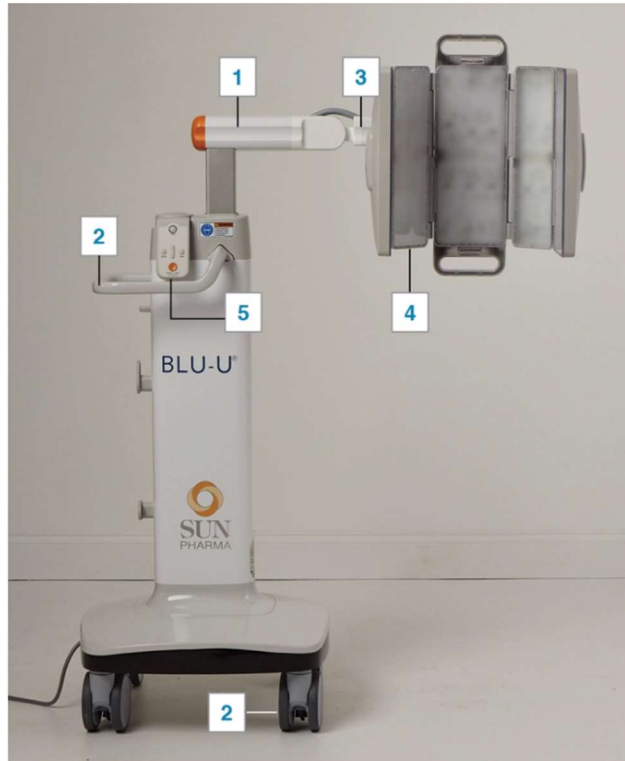


Ex. 28 at 14-15.

'028 Patent Claim 18	<u>BLU-U® 4170E</u>
18. The system of claim 16, wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated.	The BLU-U® 4170E includes the system of claim 16, wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated. The BLU-U® 4170E includes the system of claim 16, as detailed above. <i>See</i> claim 16. The BLU-U® 4170E includes wherein the light sources are configured to output blue light during at least part of the time when the treatment surface is illuminated. For example, the BLU-U® 4170E outputs blue light during the time when the treatment surface is illuminated.  Ex. 48C.



	A large, solid black rectangular block used for redaction, covering the majority of the table's content area. Ex. 44C.
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Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

The BLU-U® 4170E is configured to output blue light, including at a wavelength of 417 nm + 5 nm.

	<table><tr><td>Power Output</td><td>10 mW/cm² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm², continuous Output Wavelength: 417 nm + 5 nm Output Uniformity; 30%</td></tr><tr><td>Light Dose</td><td>Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm² at 10mW/cm² or 8 minutes, 20 seconds to deliver 10 J/cm² at 20 mW/cm²</td></tr></table>	Power Output	10 mW/cm ² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm ² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm ² , continuous Output Wavelength: 417 nm + 5 nm Output Uniformity; 30%	Light Dose	Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm ² at 10mW/cm ² or 8 minutes, 20 seconds to deliver 10 J/cm ² at 20 mW/cm ²
Power Output	10 mW/cm ² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm ² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm ² , continuous Output Wavelength: 417 nm + 5 nm Output Uniformity; 30%				
Light Dose	Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm ² at 10mW/cm ² or 8 minutes, 20 seconds to deliver 10 J/cm ² at 20 mW/cm ²				
	Ex. 28 at 6.				
'028 Patent Claim 21	<u>BLU-U® 4170E</u>				
21[pre] A system for photodynamically diagnosing or treating a patient, comprising:	The BLU-U® 4170E is a system for photodynamically diagnosing or treating a patient. For example, the BLU-U® 4170E is a Blue Light Photodynamic Therapy Illuminator that is intended to provide phototherapeutic light to a body.				



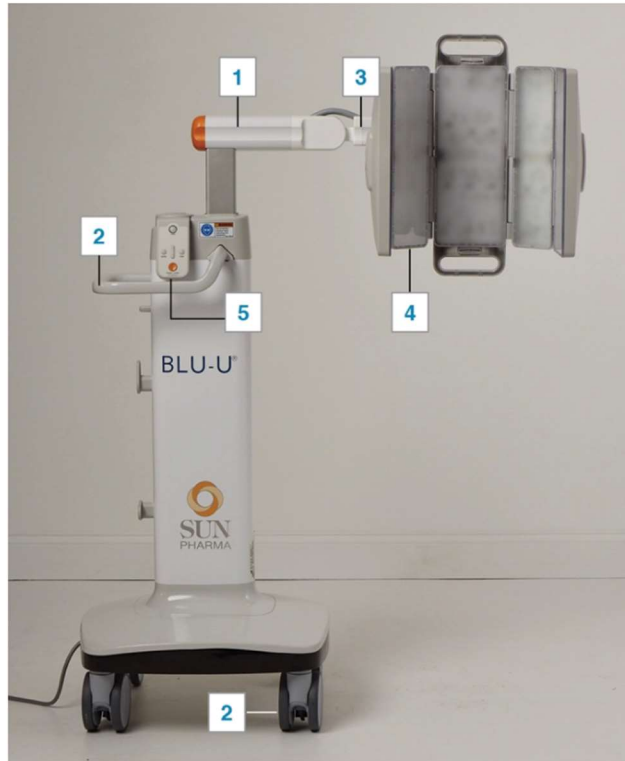
		A large black rectangular area used for redaction of an image.	
	Ex. 43C. For example, it is designed to provide a uniform distribution of blue light to areas of a patient's face, scalp or upper extremities. It is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris. The BLU-U® 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.		



		A large, solid black rectangular block covering the majority of the table's content area, indicating redacted information.	
	Ex. 48C.		



		A large, solid black rectangular block covering the majority of the table's content area, indicating redacted information.	
	Ex. 44C.		

Product Diagram:

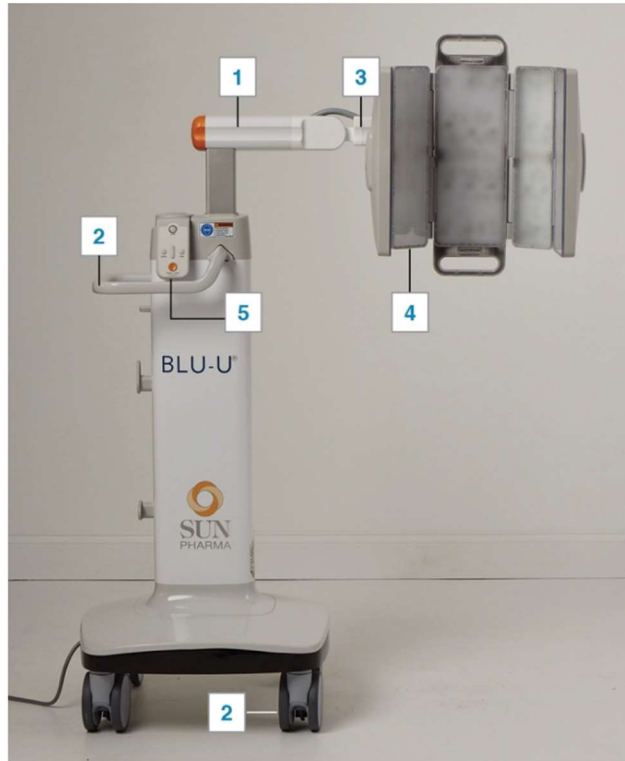
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

	OPERATING MANUAL BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E Indications for Use: The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities. The BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The BLU-U® 4170E is generally indicated to treat dermatological indications. The BLU-U® 4170E is specifically indicated to treat moderate inflammatory acne vulgaris. Ex. 28 at 4.
21[a] an illuminator comprising five panels connected by hinged structures on inner side surfaces of adjacent panels;	The BLU-U® 4170E includes an illuminator that comprises five panels connected by hinged structures on inner side surfaces of adjacent panels. For example, the BLU-U® 4170E is a Photodynamic Therapy Illuminator intended to provide phototherapeutic light to the body. It includes a Five Panel LED Treatment array.

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.



		A large solid black rectangular area used for redaction, covering the majority of the table's content.	
	Ex. 43C.		

OPERATING MANUAL**BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E****Indications for Use:**

The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170E, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.

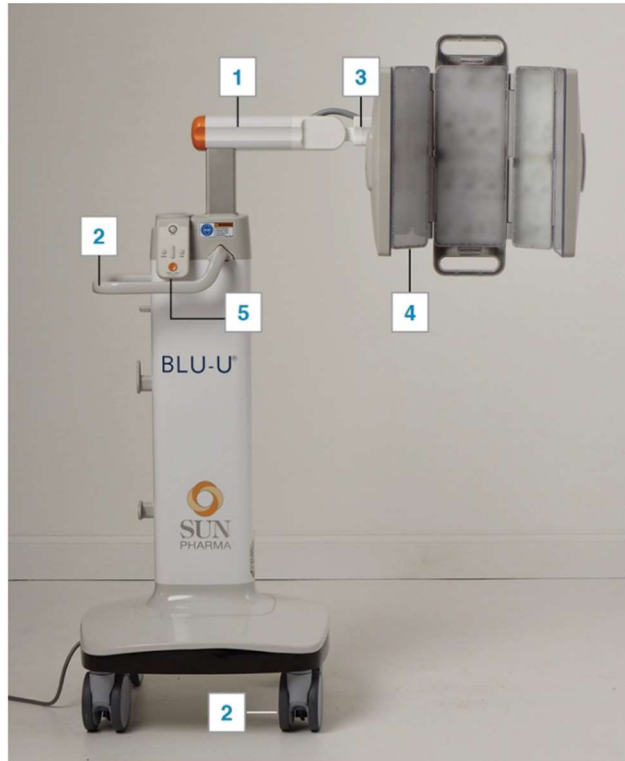
The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170E is intended to provide phototherapeutic light to the body. The **BLU-U®** 4170E is generally indicated to treat dermatological indications. The **BLU-U®** 4170E is specifically indicated to treat moderate inflammatory acne vulgaris.

Ex. 28 at 4.

The BLU-U® 4170E includes a “Five Panel LED treatment array” with five “head panels” that are connected by hinges. The hinges are hinged structures on inner side surfaces of adjacent panels.



		A large solid black rectangular area used for redaction, covering the majority of the table's content.	
	Ex. 43C.		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

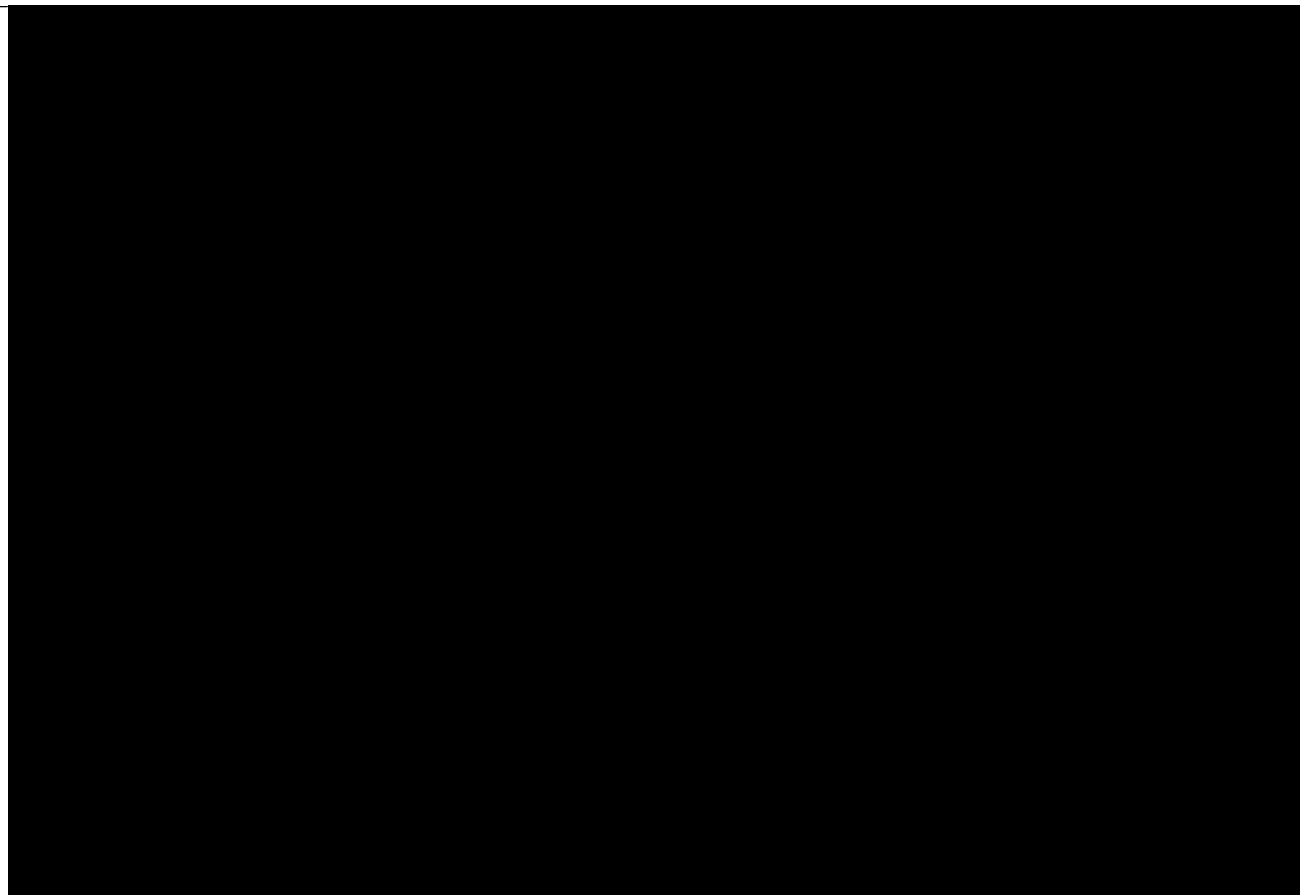
Ex. 28 at 7.

Head Panel Rotation Adjustment:

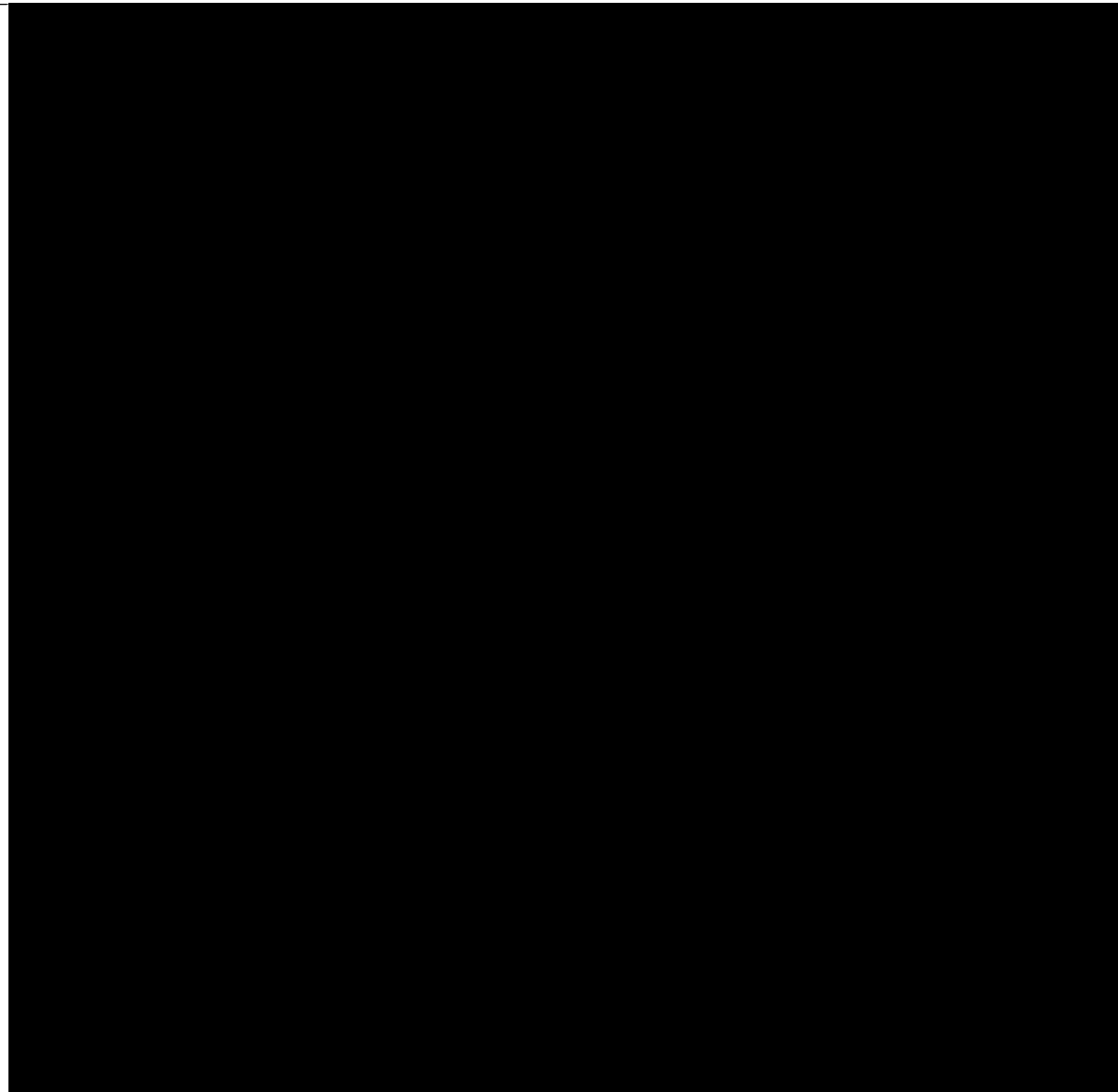
The Head panels are attached to each other via rotating hinge assemblies that contain torque inserts that maintain position without the need for an additional lock. This allows the Head to be configured flat or fully “U” shaped depending on the requirements for treatment. Each hinge assembly contains alignment markers (Orange bars) that align when the Head is placed into the “U” configuration required for PDT therapy. The rotation of the Head is constrained by hard stops built into the hinge assemblies which prohibit over-rotation in either direction. See the images below.



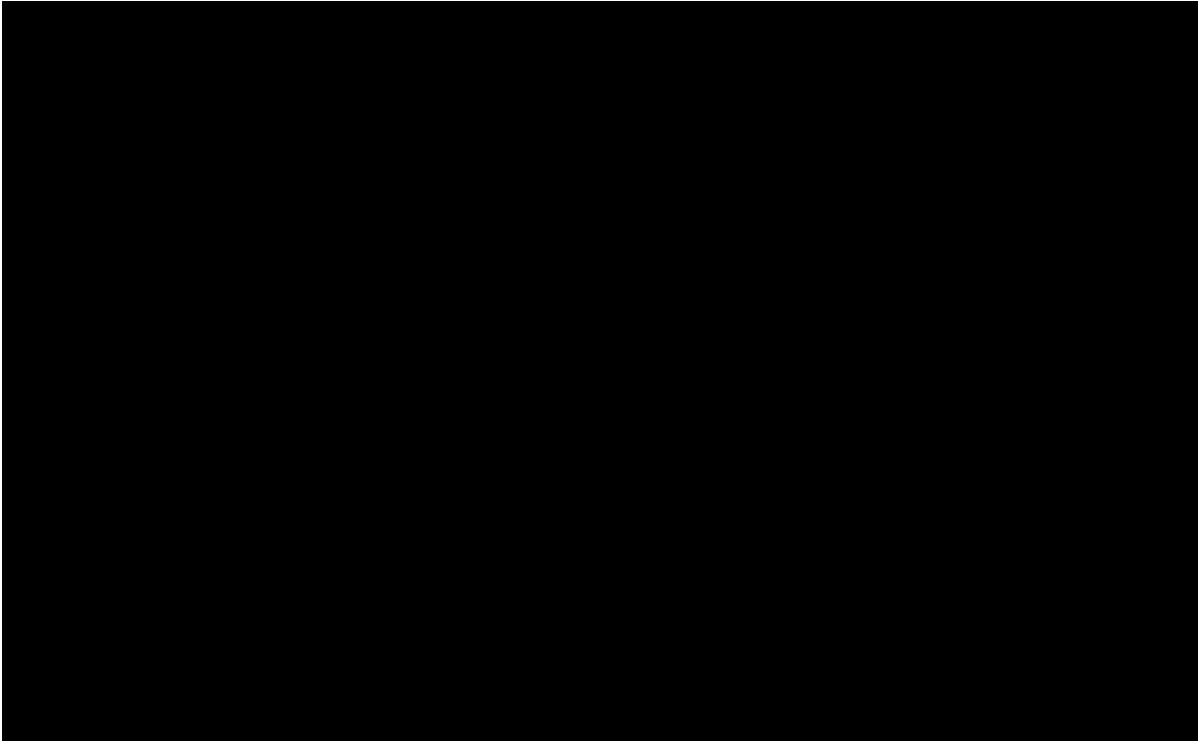
Ex. 28 at 16.

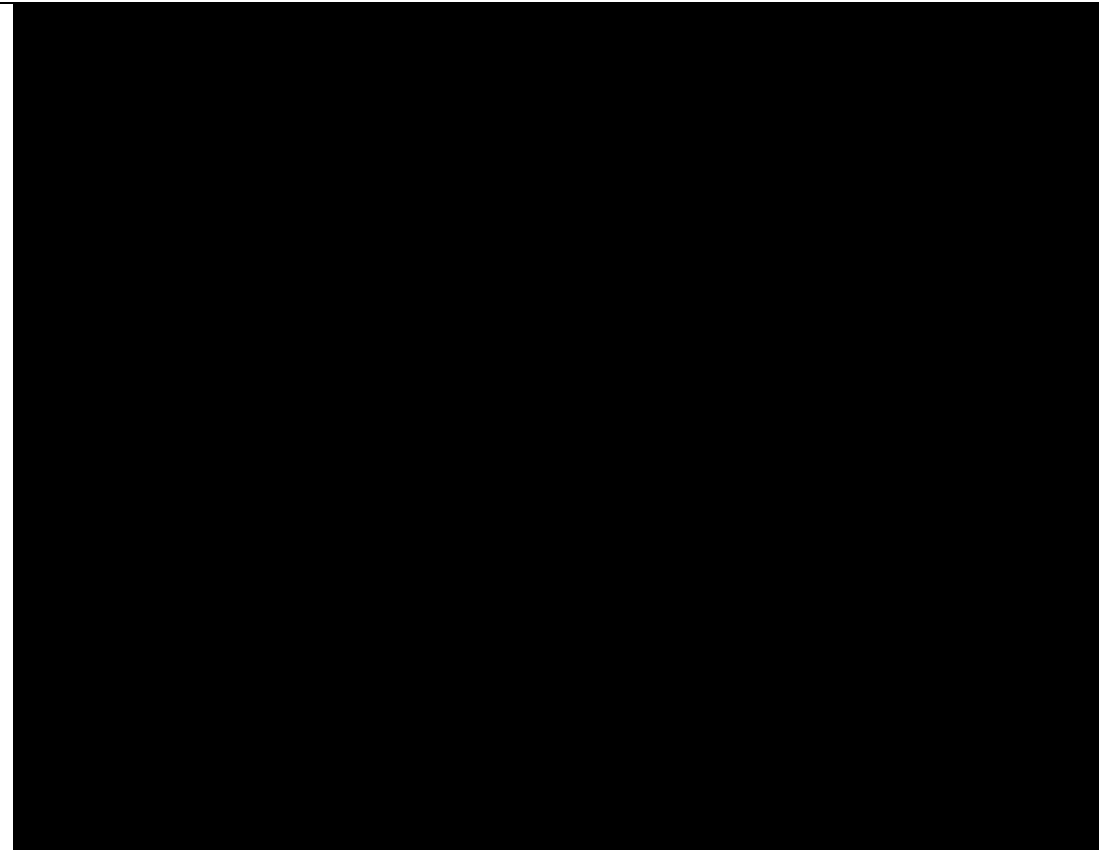


Ex. 49C (red annotations added).

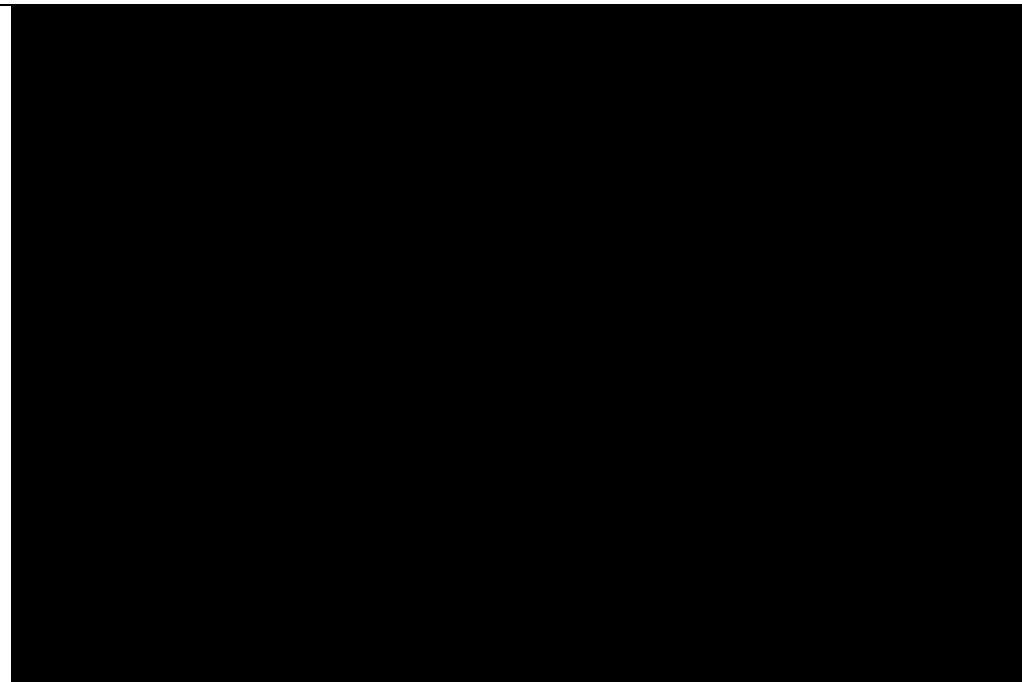


Ex. 50C (red annotations added).

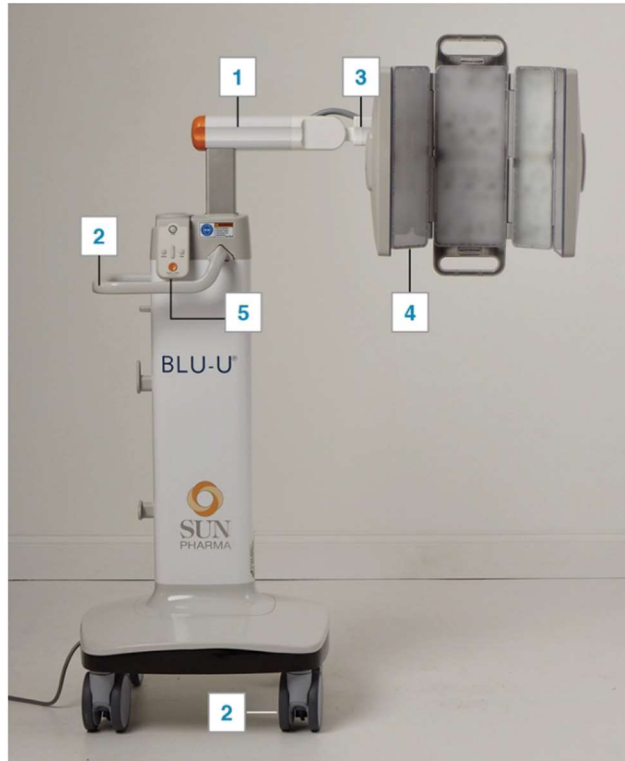
21[b] and light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,	The BLU-U® 4170E includes light sources disposed on surfaces of the five panels, the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources. For example, the BLU-U® 4170E includes LEDs, which are light sources, that are disposed on surfaces of the five panels.  Ex. 49C.
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Ex. 43C.



Ex. 51C.

Product Diagram:

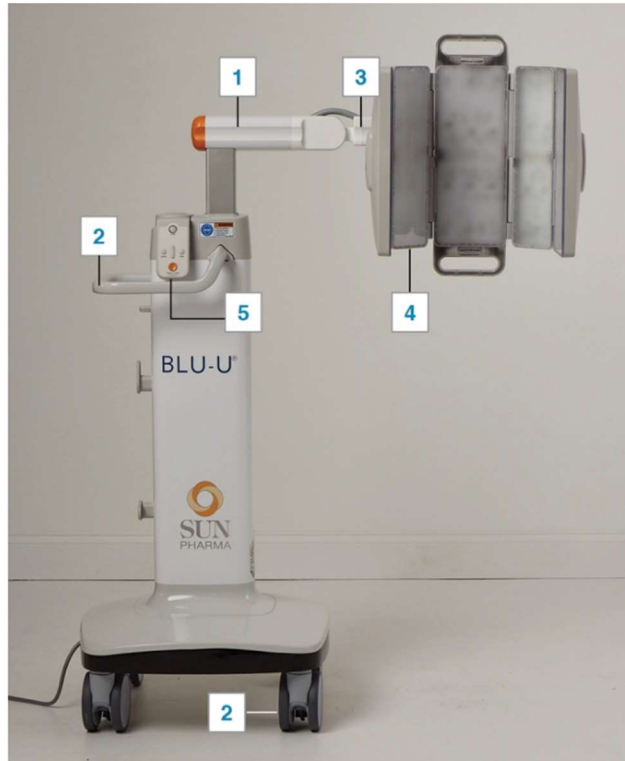
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

The BLU-U® 4170E includes an illuminator, a Five Panel LED Treatment array, that is configured to uniformly illuminate a treatment surface of the patient via the LEDs.

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

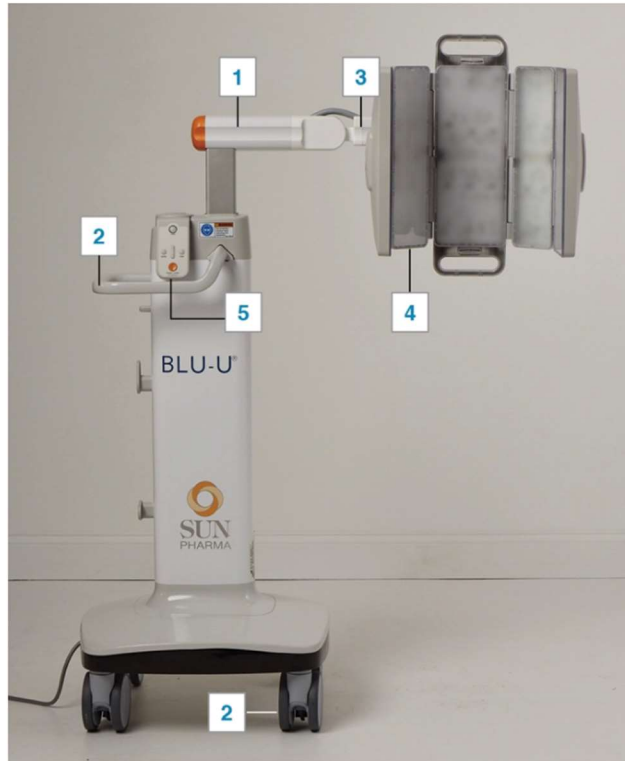
Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.



		A large black rectangular redaction box covering the majority of the upper half of the table's content area.	
	Ex. 44C. For example, the BLU-U® 4170E is “designed to provide a uniform distribution of blue light to areas of the patient’s face, scalp or upper extremities.”		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

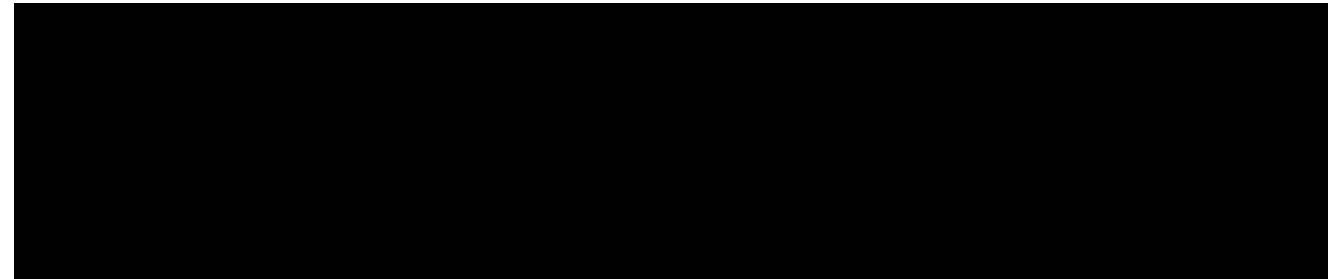
Ex. 28 at 7.

For example, the measured output of the BLU-U® 4170E over the active emitting area has an allowable range of [REDACTED] of the measured maximum.

See generally Ex. 52C.

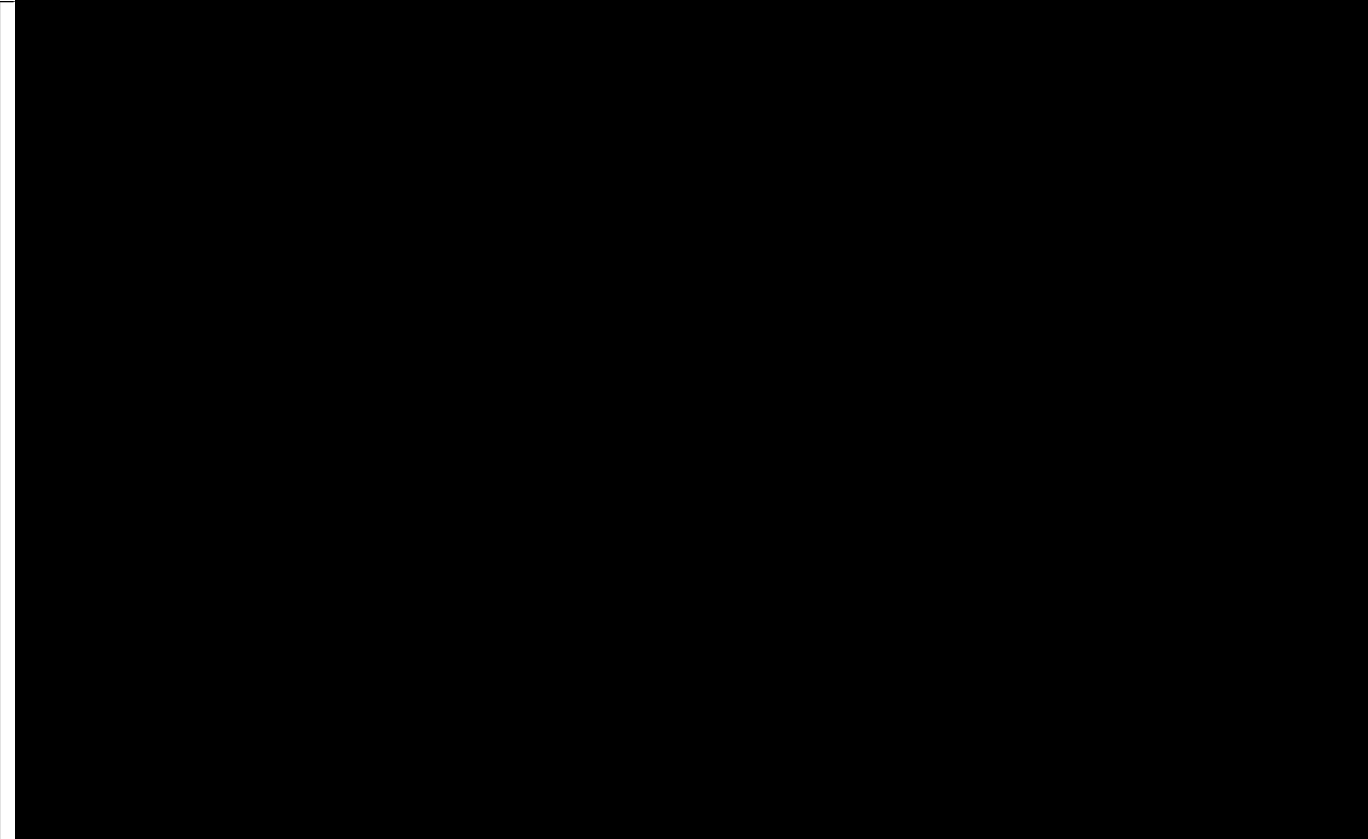


Ex. 52C at 1.



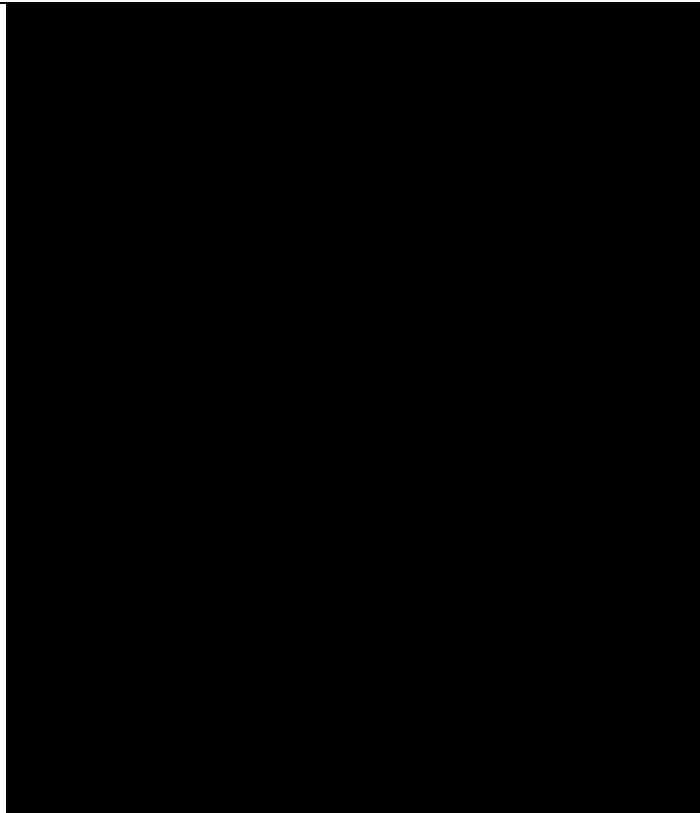
Ex. 52C at 6.

See generally Ex. 53C.

		
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 panels being configured to be	The BLU-U® 4170E 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, the BLU-U® 4170E may be configured in a “U” shape configuration for PDT therapy. In the “U” configuration, the center panel is configured to face the treatment surface, while the remaining four panels are configured to be angled relative to the center panel.	



angled relative to
the center panel,



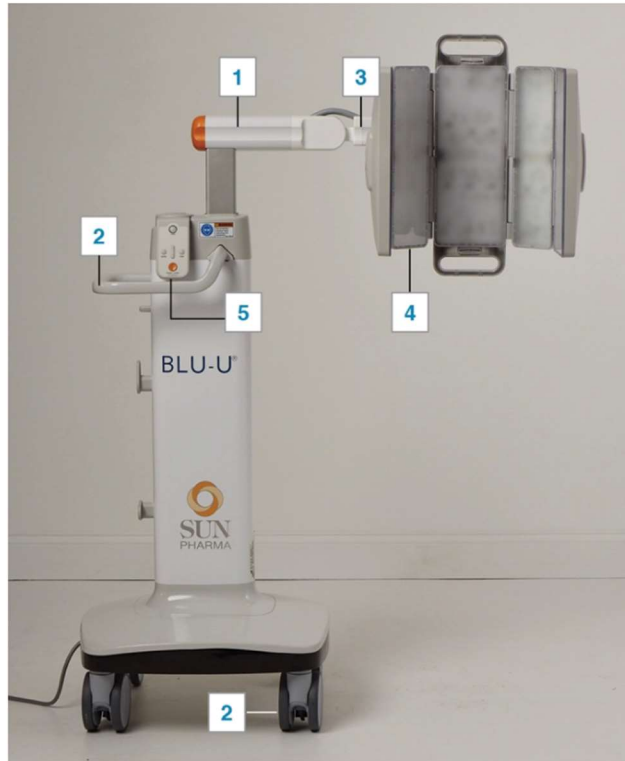
Ex. 48C.



	Ex. 44C.		



	Ex. 54C.		

Product Diagram:

- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

Ex. 28 at 7.

The BLU-U® 4170E includes alignment markers (Orange bars) that align when the Head is placed into the “U” configuration required for PDT therapy.

Head Panel Rotation Adjustment:

The Head panels are attached to each other via rotating hinge assemblies that contain torque inserts that maintain position without the need for an additional lock. This allows the Head to be configured flat or fully “U” shaped depending on the requirements for treatment. Each hinge assembly contains alignment markers (Orange bars) that align when the Head is placed into the “U” configuration required for PDT therapy. The rotation of the Head is constrained by hard stops built into the hinge assemblies which prohibit over-rotation in either direction. See the images below.

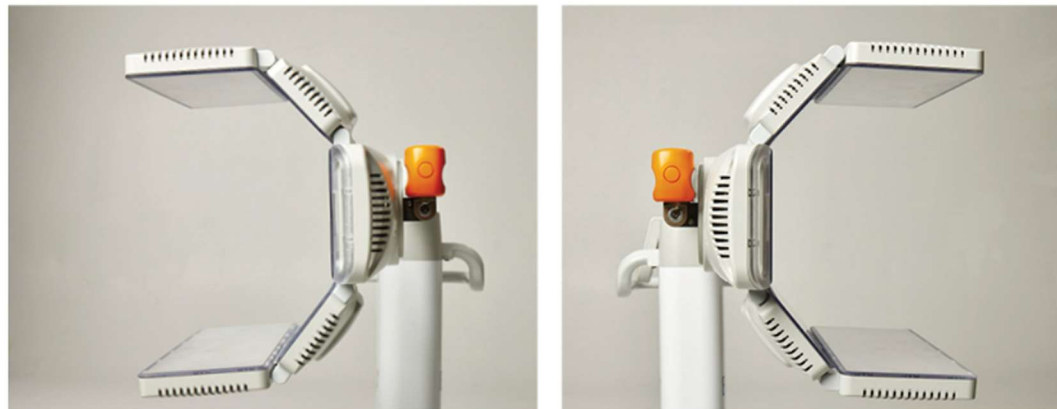


Ex. 28 at 16.

The BLU-U® 4170E includes a Head assembly that can be tilted and/or rotated to allow for the optimum position for treatment.

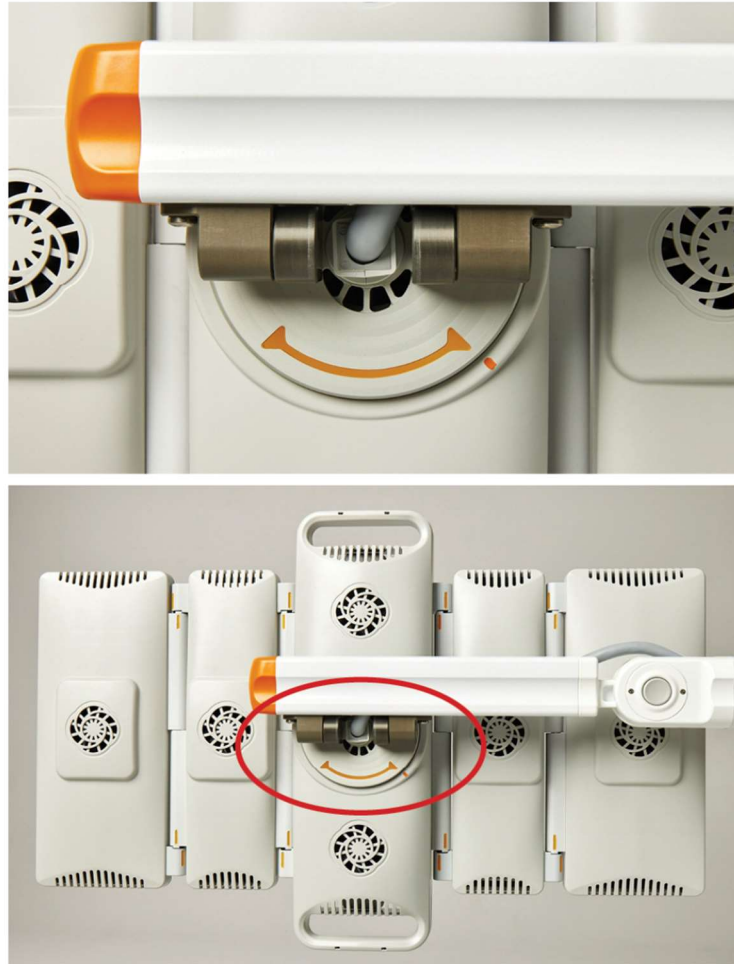
Head Tilt Adjustment:

The Head assembly can be tilted +/- 90 degrees from the stowed position (center panel facing the floor). This allows for the Head to be placed in the optimum position for treatment. The tilt mechanism utilizes torque inserts which eliminate the need for an additional lock. The torque inserts are capable of holding the Head at any position through the allowed 180 degree range of motion. See the images below.



Head Rotation Adjustment:

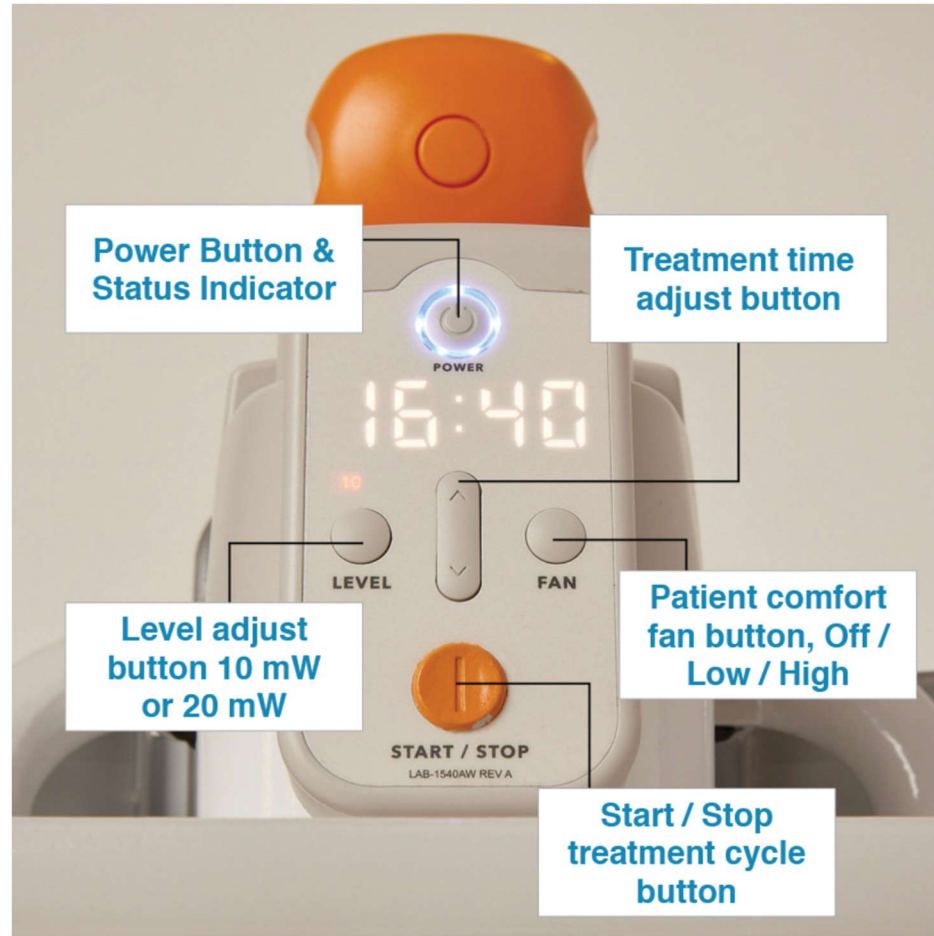
The Head assembly can be rotated +/- 90 degrees from the stowed position (center panel long axis aligned with the Arm center axis). This allows the Head to be placed in the optimum position for treatment. The rotation mechanism has two detent positions at the ends of the travel to lock the head into position for treatment. There are two position indicators located on the back of the center panel housing that align with indicator marks engraved into the back plate when the Head is at the limit of travel. See the images below.



Ex. 28 at 14-15.

21[d] wherein the five panels are positioned to allow treatment within approximately four inches of the treatment surface,	The BLU-U® 4170E includes five panels wherein the panels are positioned to allow treatment within approximately four inches of the treatment surface. For example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the face, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels. 2. Position the BLU-U® around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface: - a.) The patient's nose should be no closer than 2" from the surface and - b.) The patient's forehead and cheeks should be no further than 4" from the surface and - c.) The sides of the patient's face and the patient's ears should be no closer than 2" from the BLU-U® surface Ex. 28 at 18. As another example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the scalp, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels. 2. Position the BLU-U® around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface: - a.) The patient's scalp should be no closer than 2" from the surface and - b.) The patient's scalp should be no further than 4" from the surface and - c.) The sides of the patient's face and the patient's ears should be no closer than 2" from the BLU-U® surface Ex. 28 at 19.
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	As another example, the BLU-U® 4170E instructs in its User Manual that when treating lesions on the upper extremities, the five panels should be positioned around a patient's head such that the treatment surface lies between two and four inches from the panels. 2. Position the BLU-U® around the patient's upper extremities so the entire surface area to be treated lies between 2" and 4" from the BLU-U® surface: a. The patient's upper extremities should be no closer than 2" from the surface and d.) The patient's upper extremities should be no further than 4" from the surface Ex. 28 at 20.
21[e] wherein the five panels are individually configurable to control illumination from each of the five panels, and	The BLU-U® 4170E includes five panels wherein the panels are individually configurable to control illumination from each of the five panels. For example, the BLU-U® 4170E includes a Five Panel LED Treatment array, where each of the five panels are individually configurable to control illumination from each of the five panels of the LED treatment array. For example, the BLU-U® 4170E is configured to output power from the LED treatment array at either 10 mW/cm² or 20 mW/cm². Moreover, "each LED is individually controllable." Ex. 56C.



Ex. 28 at 8.

OPERATING MANUAL**BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170E*****Power Button & Status Indicator:***

The system **Power Button** is used to load the pre-programed treatment cycle. The system will automatically load the 10 mW power level at initial power up and will reset to 10mW power level after the completion of any treatment cycle, and will display time as 16:40. The 20mW power level setting can be selected by pressing the Level button, this will change the time displayed to 8:20. The Power button is also used as a system status indicator, blue ring indicates normal operation, amber ring indicates a fault condition.

- Pressing the Power button while the treatment cycle is “Paused” will cancel the treatment cycle and clear the time display.
- Pressing the Power button with the Main Power Switch activated (on) will toggle to load and or clear a treatment cycle for the system.

Level Button:

The **Level Button** is used to toggle between 2 power settings, 10mW & 20mW. The power level can be selected after pressing the power button to load one of the pre-programmed cycles. The timer will automatically set the correct time for the power level chosen.

- The power level selected will be displayed above the level button as 10 or 20.

Ex. 28 at 10.

Power Output	10 mW/cm ² ± 10% – Use with Levulan Kerastick 10 or 20 mW/cm ² ±10% – Light alone treatment of acne Maximum Output: 22 mW/cm ² , continuous Output Wavelength: 417 nm + 5 nm Output Uniformity: 30%
Light Dose	Timer defaults to 16 minutes, 40 seconds to deliver 10 J/cm ² at 10mW/cm ² or 8 minutes, 20 seconds to deliver 10 J/cm ² at 20 mW/cm ²

Ex. 28 at 6.



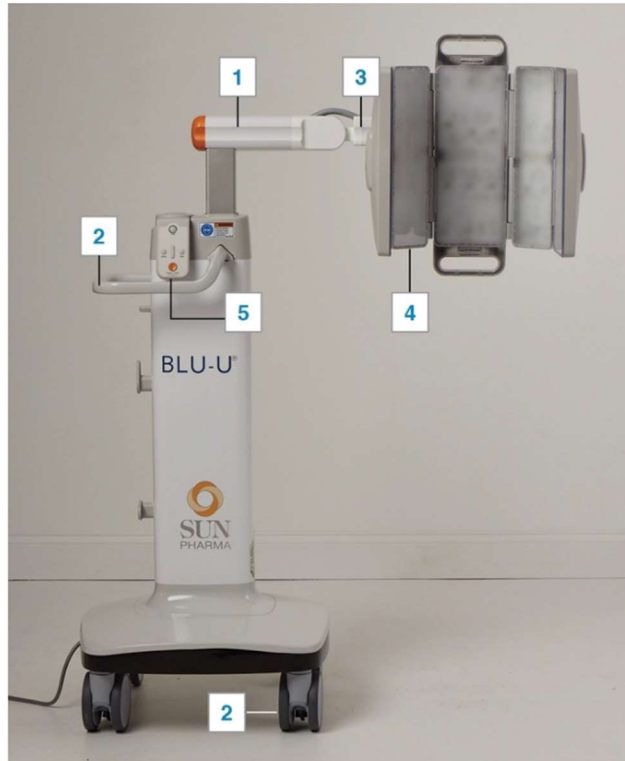
	A large solid black rectangular area used for redaction, covering the majority of the table's content.
Ex. 43C.	



	Ex. 48C.		



	Ex. 44C.		

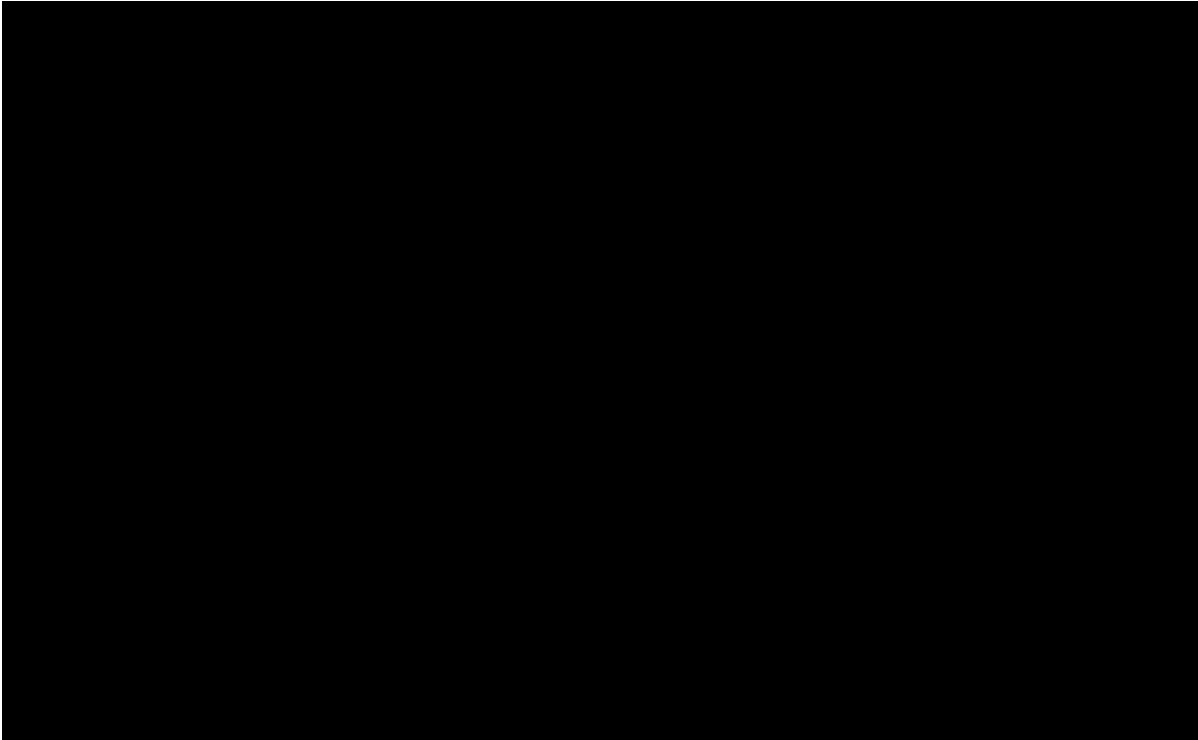
Product Diagram:

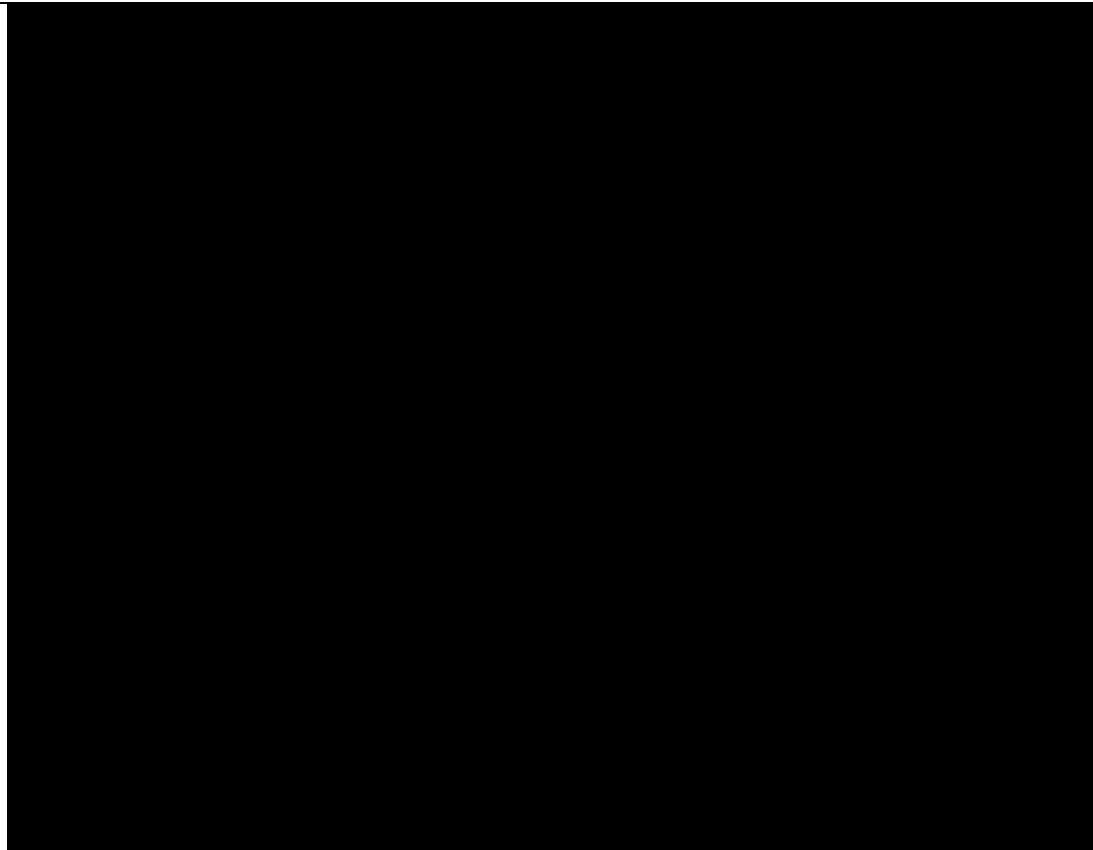
- ① Adjustable height positioning of the unit for treatment flexibility.
- ② Large locking casters and post handle for easier mobility.
- ③ A pivoting arm for compact storage and easy movement within the treatment facility.
- ④ Five Panel LED treatment array.
- ⑤ Control Panel / User Interface.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 5 individual LED panels connected by hinges. The panels are covered by a protective shield, the center panel directs cooling airflow to the patient to improve comfort during the treatment.

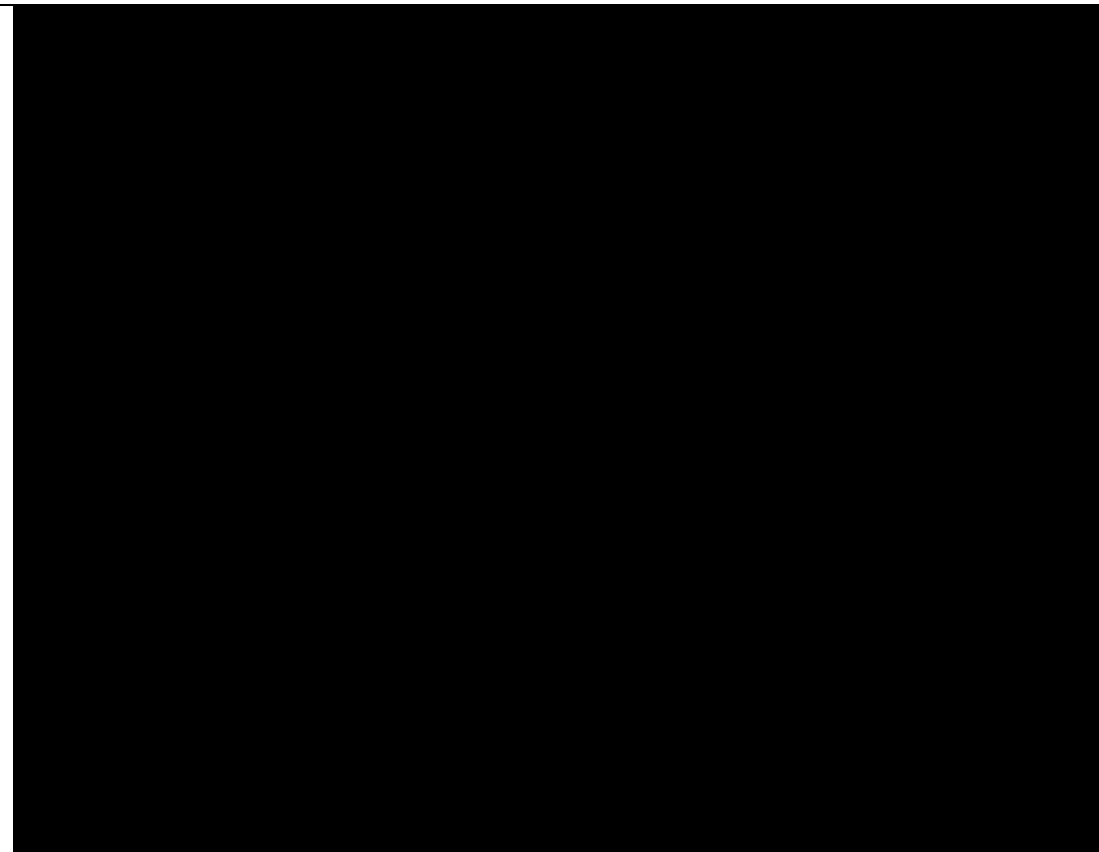
Ex. 28 at 7.

21[f] 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 BLU-U® 4170E includes 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. Each of the five LED panels of the BLU-U® 4170E are rectangular, such that for each panel, there are two first edges and two second edges, where the second edges are shorter than the two first edges.  Ex. 49C.
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Ex. 43C.

The BLU-U® 4170E's 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.



Ex. 43C.