



**BLU-U™**  
Blue Light Photodynamic  
Therapy Illuminator

---

**MODEL 4170**

---

**Customer Service**

All service, repair, or calibration of this equipment shall be referred to:

Berlex Laboratories  
Phone: 1-888-BERLEX4

## TABLE OF CONTENTS

Indications for Use .....	3
Cautions and Warnings .....	3
Product Specifications .....	4
Description .....	5
Controls .....	5
Main Power Switch .....	5
Key Switch .....	5
Timer .....	6
Indicator Lights .....	7
System Status Indicator Error Conditions .....	7
Instructions for Use .....	8
Initial Set-Up .....	9
Set-Up .....	9
Procedure for Treating Lesions on the Face .....	9
Following Patient Treatment .....	10
Procedure for Treating Lesions to the Scalp .....	10
Troubleshooting .....	11
Customer Service .....	Outside Back Cover
Warranty Coverage and Disclaimers .....	Outside Back Cover

## OPERATING MANUAL

### BLU-U™ Blue Light Photodynamic Therapy Illuminator Model 4170

#### INDICATIONS FOR USE

DUSA Pharmaceuticals' **BLU-U™** blue light photodynamic therapy illuminator Model 4170, in combination with the Levulan® Kerastick™ (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of non-hyperkeratotic actinic keratoses of the face or scalp.

*Le dispositif d'éclairage **BLU-U™** à lumière bleue de DUSA Pharmaceuticals, destiné à un usage thérapeutique photodynamique et utilisé avec Levulan® Kerastick™ pour Solution Topique, est indiqué pour le traitement des kératoses actiniques non hyperkératotiques du visage ou du cuir chevelu.*

#### CAUTIONS AND WARNINGS

##### CAUTION!

Federal law restricts this device to sale to or use by or on the order of a physician.

##### AVERTISSEMENT!

*Conformément à la législation des Etats Unis, seul un médecin peut acheter, utiliser ou donner l'ordre d'utiliser ce dispositif.*

##### WARNING!

The BLU-U™ blue light photodynamic therapy illuminator, in combination with the Levulan® Kerastick™ for Topical Solution, is indicated for the treatment of non-hyperkeratotic actinic keratoses of the face or scalp. Do not use this device with other photosensitizing drugs. Refer to the Levulan Kerastick for Topical Solution package insert for additional information. The patient and all medical personnel should wear protective eyewear at all times during operation of the BLU-U. Use only eyewear which blocks light with wavelengths of at least 500 nm and shorter with an Optical Density (O.D.) of two or greater.

##### ATTENTION!

*Le dispositif d'éclairage **BLU-U™** à lumière bleue, destiné à un usage thérapeutique photodynamique et utilisé avec Levulan® Kerastick™ pour Solution Topique, est indiqué pour le traitement des kératoses actiniques non hyperkératotiques du visage ou du cuir chevelu. En aucun cas, il ne doit être utilisé avec d'autres médicaments photosensibil-*

BLU-U™ Blue Light Photodynamic Therapy Illuminator

isants. Reportez-vous à la notice de Levulan Kerastick pour Solution Topique pour toutes informations complémentaires.

Le patient ainsi que l'ensemble du personnel médical doivent porter des lunettes de protection pendant toute la durée de fonctionnement du dispositif BLU-U. N'utilisez que des lunettes qui arrêtent les rayons lumineux ayant une longueur d'onde d'au moins 500 nm et une densité optique de deux ou plus.

## PRODUCT SPECIFICATIONS

The BLU-U is an electrical Class I, Type B device designed for indoor use only. It has been tested to the following standards: UL2606.1 and CAN/CSA C22.2 No.601.1:1994. General specifications are listed below.

<b>Power cord</b>	3-conductor hospital grade electrical cord
<b>Power requirements</b>	120 VAC 2.5 Amp 60 Hz
<b>Footprint (light unit + stand)</b>	39.25" W 26.5" D 50" min; 63" max H
<b>Overall dimensions of the light unit</b>	20.75" W 18.75" D 15.25" H
<b>Weight (light unit + stand)</b>	160 lbs.
<b>Operating Temperature Range</b>	20 – 30° C (68 – 86° F)

## 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 or scalp for the use stated above. It is comprised of 7 horizontally mounted U-shaped fluorescent tubes within a plastic chassis. The tubes are covered by a polycarbonate shield, which directs cooling airflow within the unit and significantly minimizes the risk of glass-patient contact in the event of tube breakage.

The **BLU-U** is mounted on a floor-stand, which permits rapid positioning for AK lesions located on the face or scalp, as well as adjustment for patient height. The control panel is also affixed to the floor stand.

The **BLU-U** has a built-in power output monitoring and diagnostic system, which illuminates a neon light to inform the user of the system's status.

The **BLU-U** has a system timer used to set the light dose delivered to the patient.

## CONTROLS

Controls for the **BLU-U** are located on the floor stand.

### **Main Power Switch**

The Main Power Switch is a two position rocker switch, labeled "1" and "0" located next to the electrical cord.

1 = ON

0 = OFF

Push the Main Power Switch to "1" to turn on power to the system.

Push the Main Power Switch to "0" to disconnect all electrical components within the **BLU-U** from the AC line.

### **Key Switch**

The Key Switch is the "ON/OFF" switch for the **BLU-U** and requires a special key to operate.

Remove the key and store it securely whenever the unit is not in use, to prevent unauthorized use of the **BLU-U**.

Turn the Key Switch to "1" to turn on power to the **BLU-U** control electronics. This activates the Timer so that the prescribed exposure time can be entered. When activated, the timer will remem-

BLU-U™ Blue Light Photodynamic Therapy Illuminator

ber and display the last treatment time setting.

**Note**

**When the Key Switch is turned off, it should not be turned back on again for at least five (5) seconds to ensure that the control electronics have properly powered down and reset.**

**Timer**

The system Timer is used to control the operation of the fluorescent tubes. Use the Timer to:

- Set the exposure time,
  - Initiate light exposure,
- and after the set exposure time has elapsed,
- Automatically turn off the tubes.

The following buttons control operation of the Timer:

**Button**

**Function / Operation**

**Time Select**

The Time Select buttons are used to set the exposure time. Depress the UP ARROW button to increase time. Depress the DOWN ARROW button to decrease time.

When first depressed, these buttons change the displayed reading slowly; if they remained depressed, the display changes quickly. Depressing and releasing these buttons quickly makes small adjustments to the displayed time.

**Start/Stop**

**The Start/Stop button toggles between the running and stopped states of the Timer and Tubes.**

After the exposure time has been set, depress this button once to turn on the tubes and initiate the Timer countdown sequence.

Depress it a second time to turn off the tubes and stop the Timer.

**Note**  
**If the light treatment is interrupted, see the Levulan Kerastick package insert for further details before proceeding.**

**Indicator Lights**

Indicator lights for the **BLU-U** are located on the control panel on the floor stand.

**Indicator**

**Function / Operation**

System Status Indicator

The red neon light, located to the right of the **Timer**, indicates system status. At the beginning of each light treatment, the **System Status Indicator** flashes three (3) times to indicate that the system control electronics and the neon light are functioning normally, and that the **BLU-U** is ready for use.

If **System Status Indicator** light fails to flash three (3) times immediately after the initiation of timed light treatment, the **BLU-U** *should not be used* until the problem has been identified or a qualified service technician has serviced the unit. (See the **Troubleshooting Table**)

If a patient has been dosed with the Levulan Kerastick, see the Levulan Kerastick package insert for further instructions on early termination or cancellation of light treatment.  
 If the **System Status Indicator** lights at any other time, refer to Table 1 below:

**SYSTEM STATUS INDICATOR ERROR CONDITIONS**

Table 1

**Condition**

**Action**

**RAPID FLASHING**

Continuous rapid flashing of the **System Status Indicator** immediately after initiation of the timed light treatment indicates a problem with the electronic control system.

Discontinue the treatment.  
 Turn the **Key Switch** and the **Main Power Switch** to the "0" (off) position, and call DUSA's customer service department.  
*If the patient has been dosed with the Levulan Kerastick, see the Levulan Kerastick package insert for further instructions on early termination or cancellation of light treatment.*

If this happens, the **BLU-U** will not be operational and will not light.

BLU-U™ Blue Light Photodynamic Therapy Illuminator

### Slow Flashing

Continuous slow flashing of the **System Status Indicator** (3 flashes every 4 seconds) after initiation of the timed light treatment indicates that either:

- The **BLU-U** output power is too high, or
- A problem exists with the **BLU-U**'s electronic control system.

Discontinue the treatment.

Turn the **Key Switch** and the **Main Power Switch** to the "0" (off) position, and call DUSA's customer service department.

*If the patient has been dosed with the Levulan Kerastick, see the Levulan Kerastick package insert for further instructions on early termination or cancellation of light treatment.*

### Steady On

The **System Status Indicator** lights steadily during the treatment (for at least 10 seconds at a time). This indicator code, which may occur after initiation of the timed light treatment, indicates that:

- The **BLU-U** output power is too low, or
- The end of tube lifetime has been reached.

- Complete the treatments of any patients who have already been dosed with the Levulan Kerastick, and

- Call DUSA's customer service department.

### Exposure Time Indicator

This four-digit red LED located on the Timer unit displays the remaining exposure time in minutes and seconds. Prior to pushing the Start button to begin light exposure, the display indicates the amount of exposure time set.

When you press the Start button, the *Exposure Time Indicator* display counts down the amount of exposure time remaining. The tubes turn off automatically when the display reaches "00:00".

## INSTRUCTIONS FOR USE

**Note - If patient light treatment is interrupted, terminated prematurely, or cannot be administered, see the Levulan Kerastick package insert for important further instructions.**

### ***Initial Set-Up***

1. Plug the female end of the supplied electrical cord into the mating jack on the floor stand base and plug the other end into a standard 120 VAC outlet.
2. Press the **Main Power Switch** to the "I" (on) position.

### ***Set-Up***

1. Using the key, turn the **Key Switch** to the "I" (on) position. Verify that the red **Timer** display is active.
2. Position the safety goggles on the patient prior to treatment. Place the safety goggles over the patient's eyes and insure the goggles are secure against the patient's face. Verify that the goggles do not cover or shadow any area intended for treatment.
3. Place the patient in an upright, sitting position. **The procedure for positioning the BLU-U depends on the location of the lesions to be treated and is found in the following 2 sections.** The patient's head may be supported during treatment. Ensure that the method of head support does not cover or shadow any area intended for treatment.

### ***Procedure for Treating Lesions on the Face***

1. Loosen the knobs on either side of the light unit and rotate it to the vertical position (the "U" shaped bulbs stacked vertically). Retighten the knobs to lock the light unit in place.
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

#### **Note:**

**The patient's hair should not cover or shadow the area to be treated. However, the patient's hair may be closer than 2" to the surface of the BLU-U without any deleterious effects.**

3. Set the **Timer** to the prescribed treatment time of 16 minutes 40 seconds by depressing the *Time Select* buttons. Continue to depress these buttons until the correct time is displayed.
  4. Insure that all personnel are wearing safety goggles and then depress the **Start/Stop** switch on the **BLU-U Timer**. The **System Status Indicator** will flash three (3) times and go off. If it does not flash three times, try the remedies in the Troubleshooting Table. If the System Status Indicator still does not flash three times, do not use the BLU-U even if the Timer works and the tubes light; system output may be incorrect under these circumstances. [See the Levulan Kerastick package insert for further instructions on cancellation of light treatment.]
  5. Verify that all seven tubes are lit. If one or more does not light, discontinue the light treatment and call **for service**. See the Levulan Kerastick package insert for further details on early termination or cancellation of light treatment.
  6. Periodically check the **System Status Indicator**. If the **System Status Indicator** lights during treatment, see "Indicator Lights" in the Controls section.
  7. Take care that the patient does not move during the time the **BLU-U** is on as this may result in under exposure of the lesion(s).
- At the end of the treatment period, the **Timer** will automatically turn off the **BLU-U**.

### ***Following Patient Treatment***

1. Remove the patient from the **BLU-U** and remove the patient's goggles.
2. Turn the **Key Switch** on the **BLU-U** to the "0" position
3. Remove the key from the **BLU-U** and store it in a secure location where unauthorized personnel cannot use it.

### ***Procedure for Treating Lesions to the Scalp***

Loosen the knobs on either side of the light unit and rotate it to the horizontal position (the 'U' shaped bulbs stacked horizontally). Retighten the knobs to lock the light unit in place. 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

**Note:**

**The patient's hair should not cover or shadow the area to be treated. However, the patient's hair may be closer than 2" to the surface of the BLU-U without any deleterious effects.**

3. Set the Timer to the prescribed treatment time of 16 minutes 40 seconds by depressing the Time Select buttons. Continue to depress these buttons until the correct time is displayed.
4. Insure that all personnel are wearing safety goggles and then depress the Start/Stop switch on the BLU-U Timer. The System Status Indicator will flash three (3) times and goes off. If it does not flash three times, try the remedies in the *Troubleshooting Table*. If the System Status Indicator still does not flash three times, do not use the BLU-U even if the Timer works and the tubes light; system output may be incorrect under these circumstances. [See the Levulan Kerastick package insert for further instructions on cancellation of light treatment.]
5. Verify that all seven tubes are lit. If one or more does not light, discontinue the light treatment and call DUSA's customer service department. See the Levulan Kerastick package insert for further details on early termination or cancellation of light treatment.
6. Periodically check the System Status Indicator. If the System Status Indicator lights during treatment, see "Indicator Lights" in the Controls section.
7. Take care that the patient does not move during the time the BLU-U is on as this may result in under exposure of the lesion(s).

At the end of the treatment period, the Timer will automatically turn off the BLU-U.

*Following patient treatment*

1. Remove the patient from the BLU-U and remove the patient's goggles.
2. Turn the Key Switch on the BLU-U to the "0" position.
3. Remove the key from the BLU-U and store it in a secure location where unauthorized personnel cannot use it.

***Troubleshooting***

The following chart has been included to assist in determining a solution for a problem or error. In all cases where the BLU-U is inoperable or patient light treatment is interrupted, refer to the Levulan Kerastick package insert for further instructions on early termination or cancellation of light treatment.

Symptom	Possible Cause	What To Do
No power / Fans not running / No Timer display upon turning Key Switch to the "I" (on) position.	BLU-U is not plugged in.	Verify that the BLU-U is plugged into a standard 120 VAC wall outlet.
	No power is present at the wall outlet	Verify that power is present at the outlet.
	Main Power Switch is not set to "I" (on).	Verify that the Main Power Switch is in the "I" (on) position.
	Key Switch is not fully turned to "I" (on).	Verify that the Key Switch is in the "I" (on) position by rotating it clockwise 1/4 turn until a "click" is felt. If the fans now run, but the Timer still does not light or lights intermittently, there is an internal electrical fault. In this case use of the BLU-U will not be possible. Call for service.
One or more fuses in the Fused Power Entry Module have blown.	Check the fuses in the Fused Power Entry Module, located next to the socket for the electrical cord on the base of the floor stand <ul style="list-style-type: none"> <li>• Turn the Key Switch and Main Power Switch to the "0" (off) position</li> <li>• Unplug the unit</li> <li>• With a small screwdriver, slide out the fuse holder</li> <li>• Check the status of the two fuses. If either or both fuses are blown (as indicated by a break in the thin wire connecting the two metal ends of the fuse), replace with 5A 125 VAC fuses (0.5 x 20 mm fast acting, Bussman # GMA-5A)</li> <li>• Replace the fuse holder</li> <li>• Plug the unit into a standard 120 VAC wall outlet</li> </ul>	

**Symptom****Possible Cause****What To Do**

		<ul style="list-style-type: none"><li>• Turn the Main Power Switch and Key Switch to the "1" (on) position.</li></ul> If normal operation does not resume or the fuse continues to blow, there is an internal electrical fault. In this case use of the BLU-U will not be possible. Call for service
	Internal electrical fault.	Use of the BLU-U will not be possible. Call for service.
<b>System Status Indicator does not flash three (3) times when the Start/Stop button on the Timer is pressed</b>	Neon light or control circuitry is not functioning properly.	Discontinue use of the BLU-U. Call for service.
<b>System Status Indicator rapidly flashing</b> -Tubes not lit	Control circuitry is not functioning properly.	Use of the BLU-U will not be possible. Call for service.
<b>System Status Indicator slowly flashing</b> -Tubes lit	Power output is above specified range.  Control circuitry is not functioning properly.	Discontinue use of the BLU-U. Call for service  Discontinue use of the BLU-U. Call for service.
<b>System Status Indicator on steady range</b>	Power below specified	Complete treatment of patients already dosed with the Levulan Kerastick.

Symptom	Possible Cause	What To Do
or intermittently -Tubes lit		Call for service.
Tubes not all lit	Tube(s) cracked or broken. Control circuitry is not functioning properly.	Discontinue use of the <b>BLU-U</b> . Call for service. Discontinue use of the <b>BLU-U</b> . Call for service.
F001 Error Code Displayed on Timer	Timer error	With the Key Switch turned to "I" (on), press the Start/Stop button to clear the Timer display.
F101 Error Code Displayed on Timer	Timer error	Call customer service to receive further instructions.
F002 Error Code Displayed on Timer	Timer error	With the Key Switch turned to "I" (on), press the Start/Stop button to clear the Timer display.
F202 Error Code Displayed on Timer	Timer error	Call customer service to receive further instructions.
F303 Error Code Displayed on Timer	Timer error	Call customer service to receive further instructions.

Customer Service

All service, repair, or calibration of this equipment shall be referred to:  
Berlex Laboratories  
Phone:1-888-BERLEX4

Warranty Coverage and Disclaimers:

See the Terms and Conditions of your contract for specific information.

Manufactured for:

**DUSA Pharmaceuticals, Inc.**

25 Upton Drive

Wilmington, MA 01887

MAN-00000150 Rev. A Printed in USA