

OPERATING MANUAL

BLU-U[®] Blue Light Photodynamic Therapy Illuminator
Model 4170

DUSA[®]

Operating Manual



BLU-U[®] Blue Light Photodynamic Therapy
Illuminator Model 4170

Operating Manual

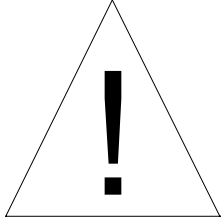
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Symbols and Definitions:



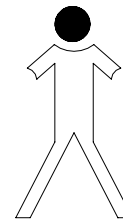
Reference User Manual



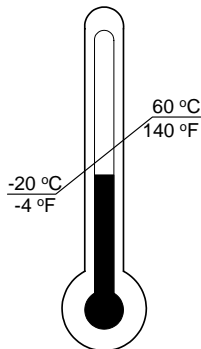
Warning/ Caution



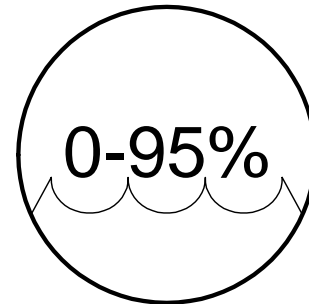
Indicates the Electrical Specification and Location of the Required Fuses



This Equipment Conforms to the IEC Publication 878-02-02 Type B Classification



Indicates the Upper and Lower Temperatures Allowed for Storage and Transport



Indicates the % Humidity Allowed for Storage and Transport



Indicates Need to Wear Eye Protection

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Indications for Use:

DUSA Pharmaceuticals, Inc.[®] **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 minimally to moderately thick actinic keratoses (AK) of the face or scalp.

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

Cautions and Warnings:

<p style="text-align: center;">WARNING:</p> <p>The BLU-U[®] Blue Light Photodynamic Therapy Illuminator, in combination with the Levulan[®] Kerastick[®] for Topical Solution, 20% is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp. Do not use this device with other photosensitizing drugs. Refer to the Levulan[®] Kerastick[®] for Topical Solution, 20% Package Physician Insert for additional information.</p> <p>When using the BLU-U[®] for acne, do not use this device with photosensitizing drugs.</p>
<p style="text-align: center;">WARNING:</p> <p>All personnel should read and understand the instructions in this manual before the system is used. Failure to do so may result in improper operation of the system.</p>
<p style="text-align: center;">WARNING:</p> <p>Use only eyewear which blocks light with wavelengths of at least 500nm and shorter with an Optical Density (OD) of two or greater.</p>
<p style="text-align: center;">WARNING:</p> <p>To avoid risk of electrical shock, connect the power cord to a properly wired grounding receptacle only.</p>
<p style="text-align: center;">WARNING:</p> <p>Never attempt to service the device when it is connected to a power source. Hazardous voltages inside the device may cause severe electrical shock. Disconnect the power cord before servicing.</p>
<p style="text-align: center;">WARNING:</p> <p>Do not allow fluids to enter the device. Damage to the device may result.</p>
<p style="text-align: center;">CAUTION:</p> <p>The device should not be serviced or opened except by qualified service technicians. Tampering by unqualified persons may cause damage to the unit or personal injury.</p>
<p style="text-align: center;">CAUTION:</p> <p>Federal law restricts this device to sales by or on the order of a physician or licensed medical practitioner.</p>

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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, CAN/CSA C22.2 No.601.1:1994, EN60601-1, and EN 60601-1-2. General specifications are listed below.

Power cord	3-conductor hospital grade electrical cord
Power requirements	120/220 - 240 VAC; 60/50 Hz; 2.5/1.5 A
Footprint (light unit + stand)	Width: 90.8 cm (35.75 inches) Depth: 67.31 cm (26.5 inches) Height Minimum: 129.5 cm (51 inches) Height Maximum: 163.2 cm (64.25 inches)
Overall dimensions of the light unit	Width: 52.71 cm (20.75 inches) Depth: 47.63 cm (18.75 inches) Height: 38.74 cm (15.25 inches)
Weight (light unit + stand)	72.6 kg (180 lbs.)
Operating Temperature Range	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 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.

The **BLU-U[®]** is rated for short-time operation.

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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 “**I**” and “**0**,” located next to the electrical cord.

I	=	ON
0	=	OFF

Push the **Main Power Switch** to “**I**” 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 “**I**” 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 remember 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 thirty (30) 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.

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The following buttons control operation of the Timer:

BUTTON	FUNCTION / OPERATION
<p>Time Select</p> <p>   </p>	<p>The Time Select buttons are used to set the exposure time.</p> <p>Depress the  (up arrow) button to increase time. Depress the  (down arrow) button to decrease time.</p> <p>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.</p>
<p>Start/Stop</p>	<p>The Start/Stop button toggles between the <i>running</i> and <i>stopped</i> states of the Timer and Tubes.</p> <p>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.</p>

Note:

If the light treatment for actinic keratoses of the face or scalp is interrupted, see the Levulan® Kerastick® for Topical Solution, 20% package physician insert for further details before proceeding.

If the light treatment for acne is interrupted, reset and continue treatment.

Indicator Lights:

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

INDICATOR	FUNCTION / OPERATION
<p>System Status Indicator</p>	<p>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.</p>

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® for Topical Solution, 20%, for the treatment of actinic keratoses of the face or scalp, see the Levulan® Kerastick® for Topical Solution, 20% Package Physician 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** on the following page.

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System Status Indicator Error Conditions:

Table 1

CONDITION	ACTION
<p>Rapid Flashing</p> <p>Continuous rapid flashing of the System Status Indicator immediately after initiation of the timed light treatment indicates a problem with the electronic control system.</p> <p>If this happens, the BLU-U® will not be operational and will not light.</p>	<p>Discontinue the treatment.</p> <p>Turn the Key Switch and the Main Power Switch to the “0” (off) position, and call for service.</p> <p><i>If the patient has been dosed with the Levulan® Kerastick® for Topical Solution, 20%, see the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further instructions on early termination or cancellation of light treatment.</i></p>
<p>Slow Flashing</p> <p>Continuous slow flashing of the System Status Indicator (3 flashes every 4 seconds) after initiation of the timed light treatment indicates that either:</p> <ul style="list-style-type: none"> • The BLU-U® output power is too high, or • A problem exists with the BLU-U® electronic control system. 	<p>Discontinue the treatment.</p> <p>Turn the Key Switch and the Main Power Switch to the “0” (off) position, and call for service.</p> <p><i>If the patient has been dosed with the Levulan® Kerastick® for Topical Solution, 20%, see the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further instructions on early termination or cancellation of light treatment.</i></p>
<p>Steady On</p> <p>The System Status Indicator lights steadily during the treatment (for at least 10 seconds at a time)</p> <p>This indicator code, which may occur after initiation of the timed light treatment, indicates that:</p> <ul style="list-style-type: none"> • The BLU-U® output power is too low, or • The end of tube lifetime has been reached. 	<ul style="list-style-type: none"> • Complete the treatments of any patients who have already been dosed with the Levulan® Kerastick®, and • Call for service.
<p>Exposure Time Indicator</p>	<p>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.</p> <p>When you press the Start button, the <i>Exposure Time Indicator</i> display counts down the amount of exposure time remaining. The tubes turn off automatically when the display reaches “00:00”.</p>

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Instructions for Use with the Levulan[®] Kerastick[®] for the treatment of Actinic Keratoses:

Note - If a patient's light treatment is interrupted, terminated prematurely, or cannot be administered, see the Levulan[®] Kerastick[®] for Topical Solution, 20% Package Physician Insert for important further instructions.

Initial Set-Up:

1. Inspect the unit power fuse holder to ensure the correct line voltage has been selected.
2. 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 120/220 - 240 VAC outlet.
3. 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 eye protection on the patient prior to treatment. Place the eye protection over the patient's eyes and insure the eye protection is secure against the patient's face. Verify that the eye protection does 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.

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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 appropriate eye protection 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 (Table 2)**. 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[®] for Topical Solution, 20% Package Physician 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[®] for Topical Solution, 20% Package Physician 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 “System Status Indicator Error Conditions” (Table 1) 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).
8. 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 eye protection.
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.

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Procedure for Treating Lesions on the Scalp:

1. 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.
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

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 appropriate eye protection 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** (Table 2). 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[®] for Topical Solution, 20% Package Physician 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 customer service. See the Levulan[®] Kerastick[®] for Topical Solution, 20% Package Physician 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 “System Status Indicator Error Conditions” (Table 1) 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).
8. 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 eye protection.
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.

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Instructions for Use for the Light Only treatment of Acne:

Initial Set-Up:

1. Inspect the unit power fuse holder to ensure the correct line voltage has been selected.
2. 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 120/220 - 240 VAC outlet.
3. 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 eye protection on the patient prior to treatment. Place the eye protection over the patient's eyes and insure the eye protection is secure against the patient's face. Verify that the eye protection does not cover or shadow any area intended for treatment.
3. Place the patient in an upright, sitting position. 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 Acne:

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. For treatment of the face, 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** for the desired treatment time by depressing the *Time Select* buttons. Continue to depress these buttons until the correct time is displayed. The recommended exposure time is 16 minutes and 40 seconds per treatment (10 joules/cm²). Light treatments should be performed two to three times per week until the desired clinical results have been achieved with a maximum recommended total cumulative light exposure of 320 joules/cm². Insure that all personnel are wearing appropriate eye protection and then depress the *Start/Stop* switch on the **BLU-U[®]**

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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 (Table 2)**. 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.*

4. Verify that all seven tubes are lit. If one or more does not light, discontinue the light treatment and **call for service**.
5. Periodically check the **System Status Indicator**. If the **System Status Indicator** lights during treatment, see “System Status Indicator Error Conditions” (Table 1) in the Controls section.
6. Take care to minimize patient movement during the time the **BLU-U[®]** is in use.
7. 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 eye protection.
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.

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Troubleshooting/Service and Repair:

CAUTION:

Components of the system should not be opened, except by a Qualified Service Person. Tampering by Unqualified Persons can harm the person and/or damage the unit.

Trouble Shooting Table

The following chart has been included to assist in determining a solution for a problem or error.

Table 2

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 proper line voltage has been selected on the fuse holder. Verify that the BLU-U[®] is plugged into a standard 120/220 - 240 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.

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Symptom	Possible Cause	What To Do
	One or more fuses in the Fused Power Entry Module have blown.	<p>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.</p> <ul style="list-style-type: none"> • Turn the Key Switch and Main Power Switch to the "0" (off) position • Unplug the unit • With a small screwdriver, slide out the fuse holder • Check the status of the two fuses by using the fuse key. 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 two (2) 10A fuses provided in the Fuse Kit Assembly (D1015). • Reinsert the fuse holder • Plug the unit into a standard 120/220 - 240 VAC wall outlet • Turn the Main Power Switch and Key Switch to the "I" (on) position. <p>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.</p>
	Internal electrical fault.	Use of the BLU-U[®] will not be possible. Call for service.
System Status Indicator does not flash three (3) times when the Start/Stop button on the Timer is pressed	Neon light or control circuitry is not functioning properly.	Discontinue use of the BLU-U[®] . Call for service.
System Status Indicator rapidly flashing <i>Tubes not lit</i>	Control circuitry is not functioning properly.	Use of the BLU-U[®] will not be possible. Call for service.
System Status Indicator slowly flashing <i>Tubes lit</i>	Power output is above specified range.	Discontinue use of the BLU-U[®] . Call for service.
	Control circuitry is not functioning properly.	Discontinue use of the BLU-U[®] . Call for service.

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Symptom	Possible Cause	What To Do
System Status Indicator on steady or intermittently <i>Tubes lit</i>	Power below specified range.	Complete treatment of patients. Call for service.
Tubes not all lit	Tube(s) cracked or broken.	Discontinue use of the BLU-U[®] . Call for service.
	Control circuitry is not functioning properly.	Discontinue use of the BLU-U[®] . Call for service.
F001 Error Code Displayed on Timer	Timer error	With the Key Switch turned to "I" (on), press the <i>Start/Stop</i> 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 <i>Start/Stop</i> 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.
<i>Err</i> Error Code Displayed On Timer	Timer error	Call customer service to receive further instructions.

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Transport and Storage:

1. The **BLU-U**[®] can be safely stored in a cool dry area. Care should be taken to avoid rough handling or jarring of the unit.
 2. **Storage Conditions:**
 - -20°C to 60°C (-4°F to 140°F)
 - 0 to 95% RH, Non-Condensing
 - 500hPa to 1600hPa
-

Cleaning/Disinfecting:

WARNING:

Turn the power off and disconnect the power cord before cleaning the machine. Failure to do so may result in severe electrical shock or death.

CAUTION:

Never immerse machine in liquids. Do not use abrasive materials to clean the machine. Do not allow water to enter this device. Do not clean the inside of this device. Doing so will cause damage to this machine.

1. The exterior surface of the **BLU-U**[®] may be wiped down with a mild disinfectant or isopropyl alcohol. Dry with a clean dry cloth.
2. The outside surface of the plastic shield may be wiped down with a mild disinfectant or isopropyl alcohol. Dry with a clean dry cloth.
3. If goggles are used for eye protection, their surface may be wiped down with a mild disinfectant or isopropyl alcohol after each use. Dry with a clean dry cloth.

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Customer Service:

For service, repair, or calibration of this equipment call:

DUSA Pharmaceuticals, Inc.[®]

Phone: 1-877-533-3872

or

978-657-7500

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, U.S.A.
www.dusapharma.com