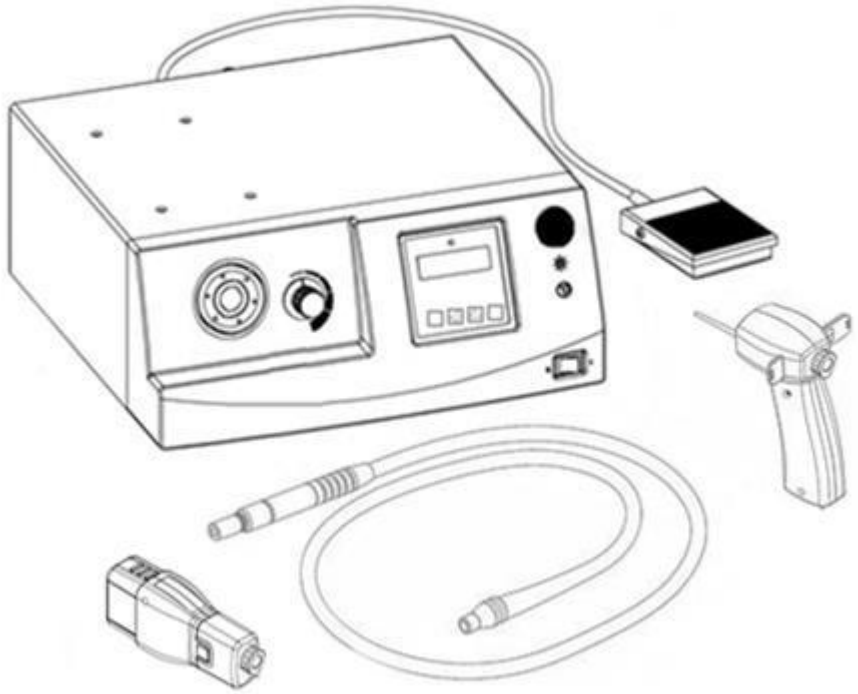
Daavlin
Let's Be Clear



Lumera

Phototherapy System

Operation Manual

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Table of Contents

1. GENERAL INFORMATION

Indications for Use

The Lumera Phototherapy System is indicated for use to treat diagnosed skin disorders such, as but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The population may range from pediatric to geriatric.

The Lumera Phototherapy System is intended for use on all skin types (I -VI).

Caution: Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by law to use or order the use of the device.

Lumera Phototherapy System Overview

The Lumera Phototherapy System is an Ultraviolet light source and energy delivery system with emission within the UVB wave range (290-320nm). It is used for the phototherapy of skin disease. The system consists of the Light Source, two delivery attachments, (a Spot Handpiece for use on skin not covered by hair and a Fiberoptic Brush for use on the scalp) and a Light Guide that connects the attachments to the light source.

The operation of the device is simple. The Timer and an Output Level knob control energy delivery and offer flexibility of adjustment for various treatments. Activation of the timer can also be controlled remotely with a Foot Switch. The flexible Light Guide allows easy access to different areas of the skin. The attachments have been designed to direct the light energy to the areas that need treatment without exposing adjacent healthy skin.

The Spot Handpiece provides localized treatment of skin lesions when the affected skin is not covered with hair. Its output patterns allow UVB delivery to specific target areas. The “Flag” output pattern is for treatment in the shape of small “tiles” that can be placed next to each other. Double exposure in the border areas is minimal and in case it happens, will not produce awkward, straight tan lines. Other patterns are suitable for different lesion shapes. The design is lightweight and compact, making handling easy and comfortable.

The Fiberoptic Brush has been designed to deliver UVB energy to the scalp. The difference between phototherapy on other areas of the skin and the scalp is that (in most cases) the scalp is covered with hair which absorbs light and acts as a barrier to phototherapy provided by conventional methods. The Fiberoptic Brush allows delivery of ultraviolet directly onto the scalp, bypassing the hair barrier, with the ultraviolet conducted through optical fibers arranged in the pattern of a hairbrush. The emitting rounded tips of the fiberoptic “bristles” deliver the ultraviolet by dispersing it directly onto affected skin.

Important Safeguards and Warnings

Warning: Connect device to an electrically grounded power outlet that matches the voltage and frequency for the machine ONLY. Use ONLY a medical grade, three (3)-wire extension cord if needed.

Warning: Do not use this device for other than its intended purposes.

Warning: Do not operate device in the presence of flammable gases including flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Warning: To prevent electric shock, do not use this device near water or other liquids. If device comes into contact with water or other liquids, disconnect the unit from its power outlet immediately. Make sure that device is completely dry before re-connecting it to the power outlet.

Warning: Do not operate this device with a damaged cord or plug.

Warning: If the device malfunctions, cease operation immediately.

Warning: To prevent electric shock, disconnect the device from power outlet prior to cleaning or servicing the unit.

Warning: To eliminate risk of fire, when replacing the fuse, replace ONLY with a fuse of the same type and rating.

Warning: **DANGER - ULTRAVIOLET RADIATION.** As with natural sunlight, overexposure can cause eye and skin injury, and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer. **ALWAYS WEAR PROTECTIVE EYEWEAR: FAILURE TO DO SO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.** Medications or cosmetics may increase skin sensitivity to Ultraviolet radiation. Inform physician before using this device if you are using medications or have a history of skin problems or sensitivity to light.

Warning: **Do not look directly into the emitting end of Light Guide or Spot Handpiece while operating it.**

Warning: Do not remove protective goggles and gloves during the treatment or service of the unit.

Warning: Do not alter this device in any way. Modifications to this device can cause injury to patients, therefore no modifications are allowed.

Warning: If psoralens (photosensitizing drugs) are being used as part of your treatment ("PUVA"), your eyes should be protected from exposure to ultraviolet (sunlight) for 24 hours after taking the drug. Ultraviolet blocking glasses are provided with all devices.

Warning: Erythema can result in as little as 15 seconds of exposure, or approximately 200 millijoules of dose to UVB light. Prior to using the device, contact your prescribing physician for specific treatment instructions and dosing information.

Warning: This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class A and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) is/are connected
- Consult the manufacturer or field service technician for help

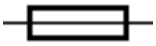
Caution: Forced air-cooling is necessary for proper operation of the lamp and power supply. To avoid system overheat do not block ventilation fans. Provide a minimum of three inches (8 centimeters) clearance around the device.

Caution: Do not operate the device unless both cooling fans are working.

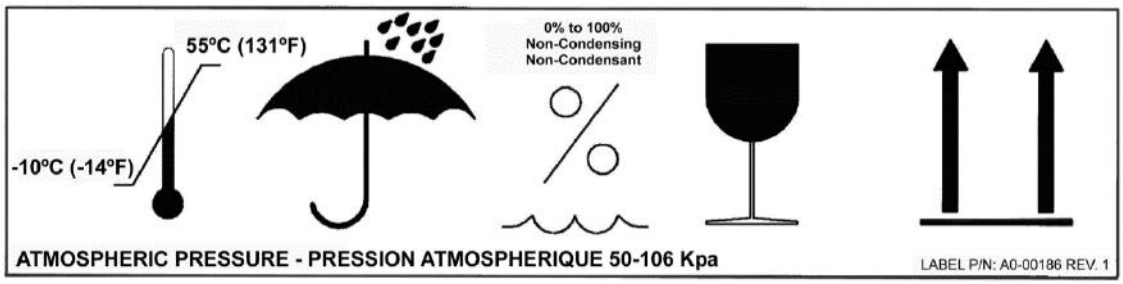
Caution: Do not touch the Lamp Module immediately after operation. Allow it to cool for at least ten (10) minutes.

Caution: Do not touch ends of the Liquid Light Guide. Contamination of the tips will reduce ultraviolet output.

Table of the symbols and their meaning

	**DANGER - HIGH VOLTAGE**
	**WARNING - CONSULT ACCOMPANYING DOCUMENTS**
	**POWER OFF**
	POWER ON
	**LAMP READY**
	**LIGHT GUIDE CHECK SYMBOL**
	**CAUTION - MAY BE HOT**
	**WARNING - UV LIGHT HAZARD**
	**TYPE B DEVICE**
	**FOOTSWITCH**
	**FUSE**

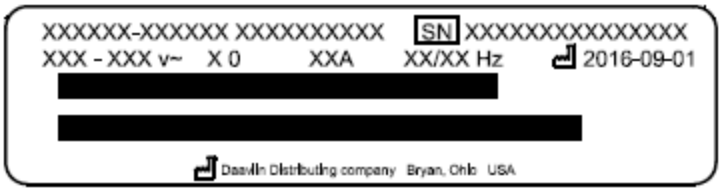
Shipping Label:



Label Explanation:

(i) Ambient temperature range for transportation -10°C to +55°C
(ii) Allowable relative humidity range of 10% to 85%, non-condensing
(iii) Allowable atmospheric pressure range of 500 hPa to 1060 hPa
(iv) Fragile
(v) Keep package in upright position.

Serial Number Label:



SpotLite Handpiece label:

Daavlin Distributing Company
SpotLite™
P/N: 101CTSPOTLIGHT
S/N: XXXXX
LABEL P/N: 090CTSERIALNMBR, REV 0

Light Guide Label:

.

CE Label (CE Devices Only)

EU Rep Label (CE Devices Only)

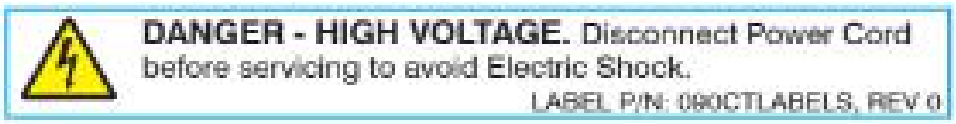
CE Packaging Label (CE Devices Only)

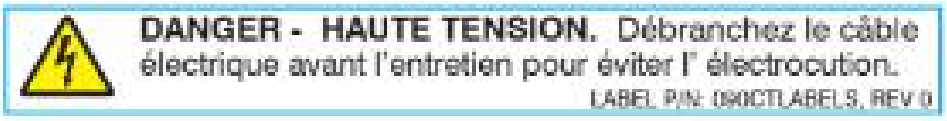
Risk Group 2 Label (CE Devices Only)

The following is an example of the information required for the risk label placed on all CE devices. The X's in this example will be filled in with the correct lamp type, UV spectrum, primary emission range, and the min and max output.

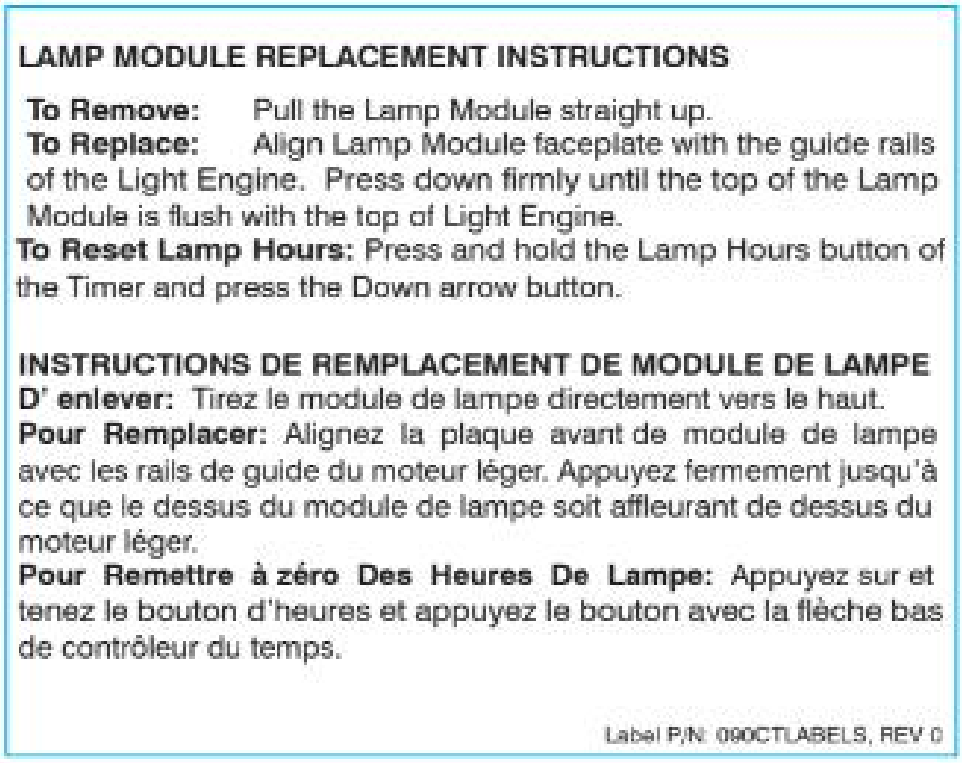
The following labels are 1 sheet all labelled as 090CTLABELS.

Danger Labels:





Lamp Replacement Instructions Label:



Caution Label:

CAUTION - To avoid system overheat do not block cooling fans.

CAUTION - Federal Law restricts this device to sale by or on the order of a physician.

WARNING - UV Light Hazard. Avoid looking directly at light.

ATTENTION - consult accompanying documents.

DANGER - ULTRAVIOLET RADIATION. As with natural sunlight, overexposure can cause eye and skin injury, and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer.

ALWAYS WEAR PROTECTIVE EYEWEAR: FAILURE TO DO SO MAY RESULT IN SEVERE BURNS AND/OR LONG-TERM INJURY TO THE EYES.

Medications or cosmetics may increase skin sensitivity to Ultraviolet radiation. Inform physician before using this device if you are using medications or have a history of skin problems or sensitivity to light.

LABEL P/N: 090CTLABELS, REV 0

ATTENTION - pour éviter la surchauffe de système ne bloquez pas les ventilateurs.

ATTENTION - la loi fédérale limite ce dispositif à la vente par ou sur l'ordre d'un médecin.

AVERTISSEMENT - Risque de lumière UV. Évitez de regarder directement la lumière.

ATTENTION - consultez les documents d'accompagnement.

DANGER - RAYONNEMENT ULTRAVIOLET. Comme avec la lumière du soleil normale, la surexposition peut causer des dommages d'oeil et de peau, et des réactions allergiques. L'exposition répétée peut causer le vieillissement prématuré de la peau et/ou du cancer de peau.

TOUJOURS UTILISEZ DES LUNETTES PROTECTEURS : LE MANQUE DE FAIRE AINSI PEUT AVOIR COMME CONSÉQUENCE DES BRÛLURES GRAVES OU DES DOMMAGES CHRONIQUES AUX YEUX.

Les médicaments ou les produits de beauté peuvent augmenter la sensibilité de peau au rayonnement ultraviolet. Informez le médecin avant d'utiliser ce dispositif si vous utilisez des médicaments ou vous avez un histoirique des problèmes ou de sensiblilté de peau à la lumière.

LABEL P/N: 090CTLABELS, REV 0

2. SYSTEM DESCRIPTION AND FUNCTIONAL CHARACTERISTICS

Lumera Phototherapy System

The Lumera Phototherapy System consists of the **UVB Light Source (1)**, **Foot Switch (2)**, **Light Guide (3)**, and the delivery attachments **Spot Handpiece (4)** and **Fiberoptic Brush (5)**. The Power Cord and UV-blocking Goggles are not shown in Figure 2.1. They are however included with the Lumera System package.

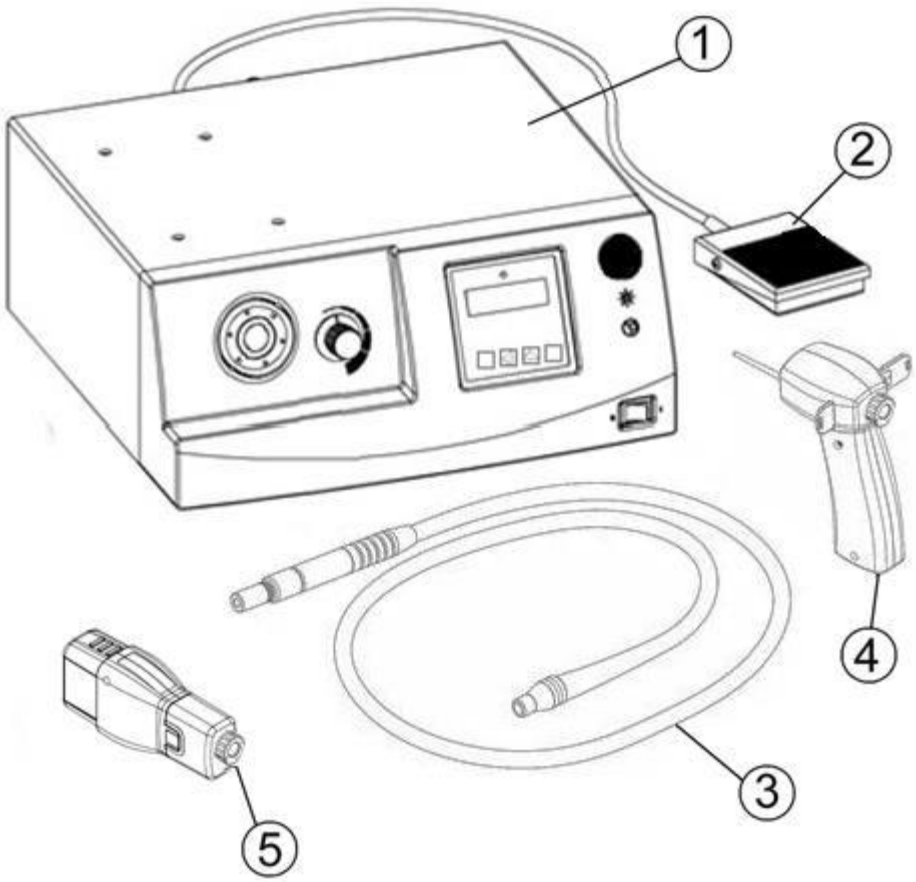


Figure 2.1. Lumera Phototherapy System

UVB Light Source

The device emits therapeutic UVB energy (290-320nm) which is generated by a metal halide, UVB enhanced lamp in the Light Source and transmitted through a flexible Light Guide to the delivery attachments. The Spot Handpiece is used to treat affected areas on the skin not covered with hair and the Fiberoptic Brush is used for scalp treatment. A Timer and an Output Level Knob control the energy dose delivered. The UVB Light Source has a Foot Switch that can initiate, pause, and resume treatment after the treatment time has been set on the timer.

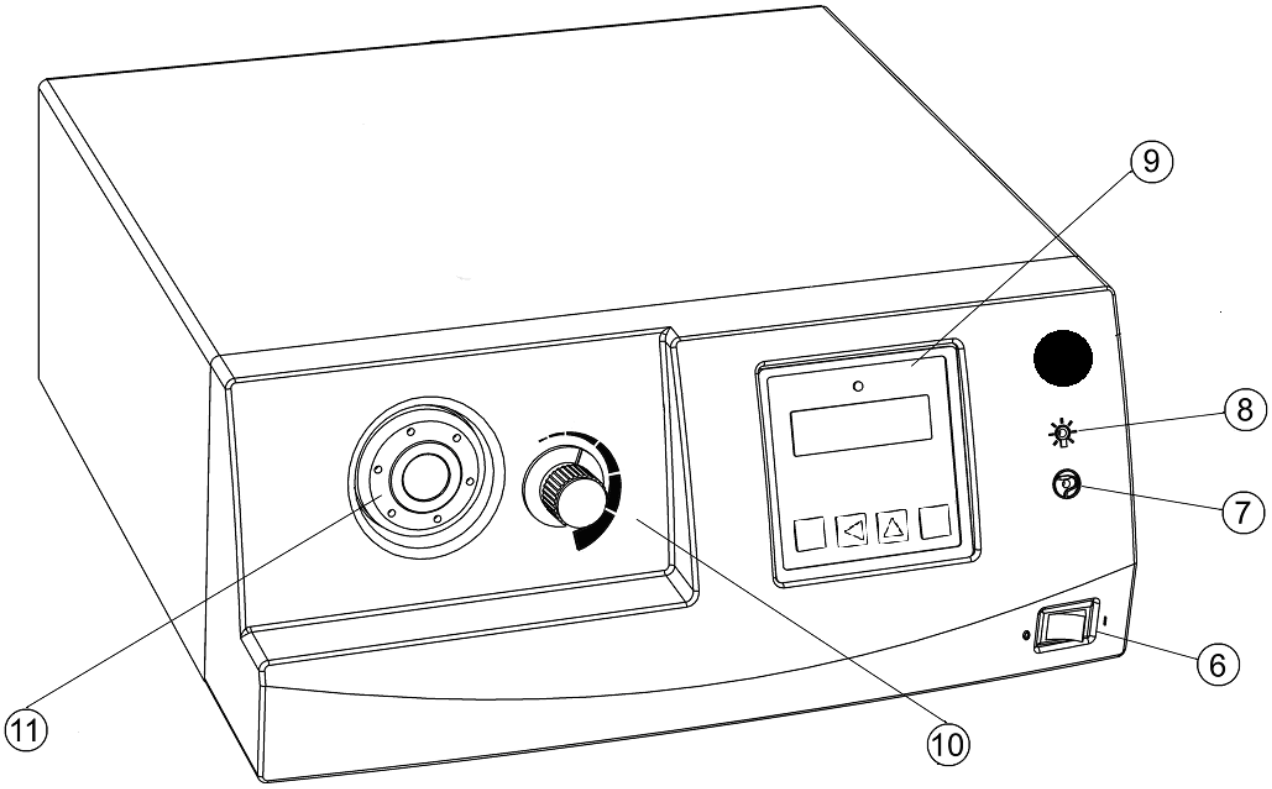


Figure 2.2. Front of the Light Source

The Power Switch (6) has ON (I) and OFF (O) positions and controls electrical energy powering the Light Source.

The Light Guide Not Inserted Indicator (7), when lighted, denotes that the Light Guide is not inserted into the **Light Guide Port (11)** or that the Light Guide is not inserted properly. The Light Guide Port has a sensor that detects the presence and proper insertion of the Light Guide. Do not insert anything but the Light Guide into the port.

The Lamp Ready Indicator (8), when lighted, indicates that the lamp is warmed up and the UVB Light Source is ready for calibration and/or treatment. It takes approximately three to four minutes for the lamp to warm up after the unit is turned on.

The Timer (9) controls the time interval of activation. It also keeps track of lamp operating hours.

The Output Level Knob (10) adjusts the intensity level of the light output. Turning the knob clockwise increases the light output and turning the knob counterclockwise decreases the light output.

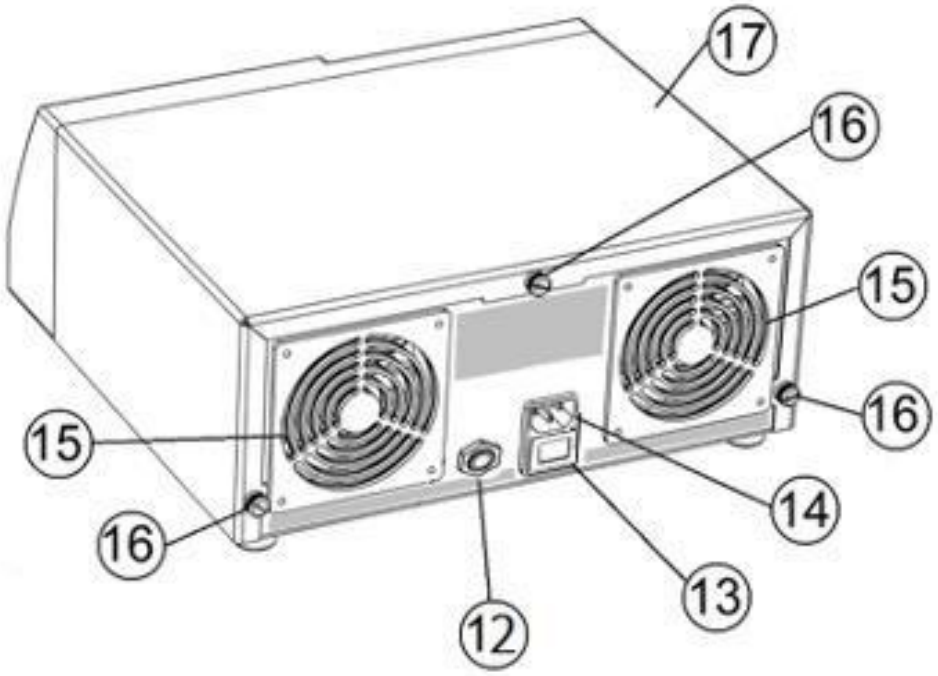


Figure 2.3. Back of the Light Source

The Foot Switch Socket (12) accepts only the Foot Switch connector.

The Fuse Holder (13) contains the electrical fuses.

The Power Cord Socket (14) accepts a common IEC 320 type Power Cord for power connection to the electrical outlet.

The Cooling Fans (15) provide air circulation for cooling of the Light Source.

Three Thumb Screws (16) secure the **Chassis Cover (17)**.

The Foot Switch (2), when inserted, remotely controls the activation of the light beam. When pressing and releasing the Foot Switch, the light beam is activated only when the switch is released. After the treatment time has been set on the timer, you can initiate, pause, and resume treatment time by pressing down on the Foot Switch.

The Spot Handpiece (SP-3) with Light Guide provides localized treatment of skin lesions when the affected skin is not covered with hair. Its output profiles allow light delivery on the target areas.
The "Flag" output pattern is for treatment in the shape of small "tiles" that can be placed next to each other. Double exposure in the border areas is minimal and in case it happens, will not produce awkward straight tan lines. Other patterns are suitable for different lesion shapes. Its lightweight and compact design makes handling easy and comfortable. With the "Flag" pattern, the Spot Handpiece produces a 17X17 mm light output profile. The Spot Handpiece has **Pattern Inserts (18)** to control the spot shape and size. These inserts are placed in the handpiece through a slot on its side. A **Distance Gauge** attaches to the Spot Handpiece for accurate targeting and precise dose delivery. The Light Guide plugs into the Light Guide Port Locator on the front of the Light Source. The locking ring is used to lock in the Light Guide to the Spot Handpiece assembly.

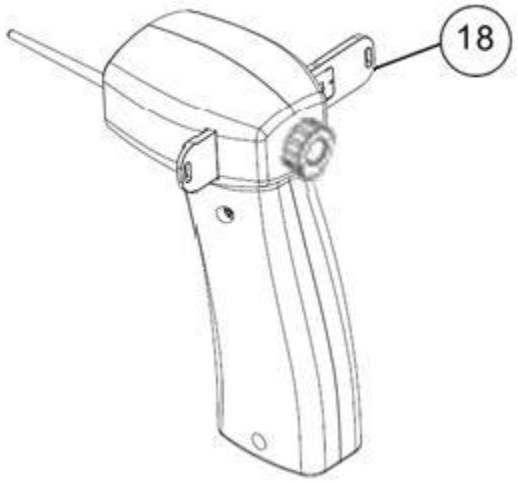


Figure 2.4. Spot Handpiece

The Light Guide (LG-5)

The Light Guide transmits energy from the UVB Source to the delivery attachments. The Light Guide **Proximal End (19)** plugs into the Light Guide Port located on the front of the Light Source. The Light **Guide Distal End (20)** connects to the Light Guide Port of the fiberoptic brush or the spot handpiece. Ensure the lock ring on your attachment is unlocked by spinning it counterclockwise, then insert the Light Guide Distal End into the port of the attachment and twist the lock ring clockwise to lock the Light Guide into the attachment.

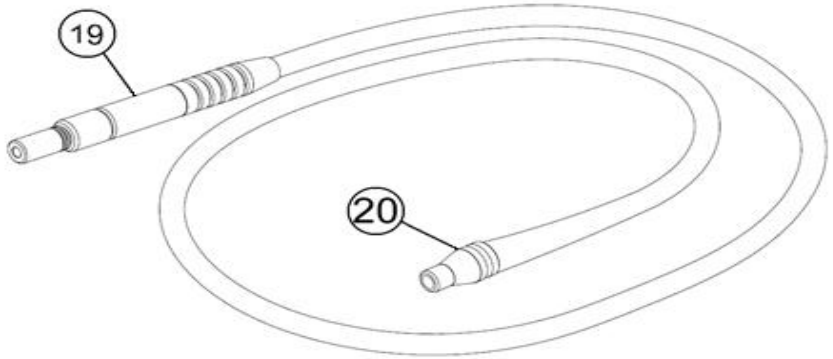


Figure 2.5. The Light Guide

Fiberoptic Brush (FB-10)

The Fiberoptic Brush (FB-10) has been designed to deliver UVB energy to the hair covered scalp bypassing the hair barrier. The UV is conducted to the scalp through the hair by optical fibers arranged in the pattern of a hairbrush. The optical fiber array produces a 20X50 mm light emitting profile. The Fiberoptic Bristles guide the UV between the hair and the Fiberoptic Tips spread it over and around the contact point, delivering it directly onto affected skin. The locking ring **(21)** is used to lock in the Light Guide to the brush assembly.

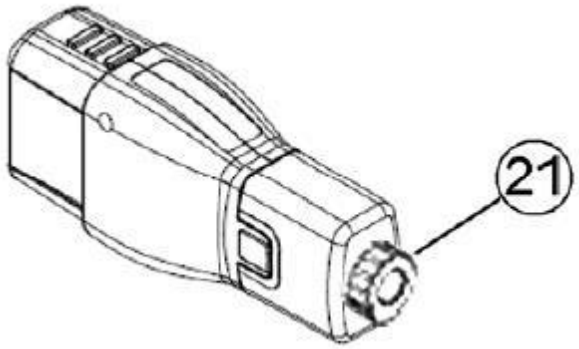


Figure 2.6. Fiberoptic Brush

When storing the brush, it is recommended that the Protective/Rinse Cap is placed on the Fiberoptic Brush during storage.

Protective Gear

UV-blocking Goggles (two pair) are included with each Lumera Phototherapy System for eye protection. Ultraviolet radiation is harmful to the eyes and eye protection is necessary during treatment. Additional goggles can be ordered from Daavlin by contacting the sales or customer service department. Every person present in the treatment room must wear UV-blocking Goggles while the Light Source is activated, whether for calibration, radiometric testing, or treatment.

The protective eyewear provided meets the ANSI Z87.1-2003 standard and blocks 99.9% of UV in wavelengths 180-380 nm and has wrap-around side shields. If other eyewear is used, it must meet the same standard.

Skin protection

Although Daavlin does not supply our customers with gloves or protective clothing, it is essential to protect skin from unnecessary UVB exposure during calibration, radiometric testing or treatment.

The patient and physician or technician must wear ***clothing*** that absorbs UV, has long sleeves and covers the whole body (except the areas to be treated). Medium to thick woven cotton material is sufficient for protection.

To minimize cumulative exposure, the person performing the calibration, radiometric testing or treatment must wear ***UV absorbing gloves, sunscreen lotion*** and/or ***industrial type UV protection*** covering the face and neck at all times while the Light Source is activated.

For scalp treatment, the patient shall use ***sunscreen lotion with SPF 30 or higher*** rating and must cover areas adjacent to the exposed skin, such as the face, neck, and ears.

Unpacking

- Prior to unpacking the Lumera Phototherapy System, inspect the package for visual damage during shipment. If the package is noticeably damaged, notify the shipping company and Daavlin customer service immediately.
- Remove wrapping material from all the components.
- Inspect all parts for visible damage. If any parts are missing or have noticeable damage, please notify Daavlin customer service.
- Save, if possible, packaging material in case you have to ship the device.

Installation

- Unscrew the Thumb Screws located on upper middle and bottom corners on the back of the Chassis Cover.
- Place the device on a flat surface.
- Slide the cover towards the back of the unit until the Arrow on the inside shield is completely exposed which is approximately one and a half inches (1 ½) or four (4) centimeters and lift it straight up.
- Make sure that the Lamp Module top is flush with the top of the Light Engine Guide Rail.

Warning: Do not touch Reflector, Arc Lamp, or Electrode inside the Lamp Module. Contamination of the lamp with oils from fingerprints may result in premature lamp failure.

- If the Lamp Module has been removed from the Light Engine, refer to the Lamp Replacement section of this manual for detailed instructions on proper insertion of the Lamp Module.
- To replace the chassis cover, align front edge of cover to the arrow on the power supply shield, lower it down then slide it towards the front of the unit until it is flush with the front edge. Tighten thumb screws.
- Place the Light Source in its designated place. Ensure that there is a minimum of three (3) inches or eight (8) centimeters clearance around the device for air circulation. Do not place the device in an enclosed cabinet.
- Plug the Power Cord into the Power Cord Socket on the back of the Light Source.
- Before connecting the device to main power, ensure that the wall outlet is properly grounded. If the wall outlet does not match the plug type on the Power Cord provided, contact Customer Service for assistance.

- Plug the Power Cord into the wall outlet.

Before Initial Power On

- Confirm that installation has been completed according to the instructions in Section 3.
- Make sure that recommended protective wear is available for immediate use.
- If during power on sequence there is any indication that the system may have a potential problem, refer to troubleshooting instructions or contact customer service.

4. SYSTEM OPERATION

Power on Sequence

- Ensure that everybody in the room is wearing recommended eye and skin protection.
- Turn the Power Switch on the front of the device to ON (I) position.
- Wait for approximately 4 minutes until the Lamp Ready Indicator is illuminated, indicating that the lamp has warmed up and the Light Source is ready for operation with the Lumasure meter.
- After using the Lumasure Meter and the Output Level Knob to set your desired output, the Light Source is ready for treatment.

Safety Features

The device has two important safety features. If the Light Guide is not inserted, the Light Source will not open the shutter to allow UVB to be emitted. If the Light Guide is pulled out while the Light Source is activated, the shutter closes to prevent UVB from being emitted.

If the system malfunctions and the shutter remains open after the timer cycle has ended, a continuous audible sound will alert the operator about the malfunction. If this happens, the unit must be turned off and service arrangements must be made.

PARTIAL UVB TIME CHART ↓

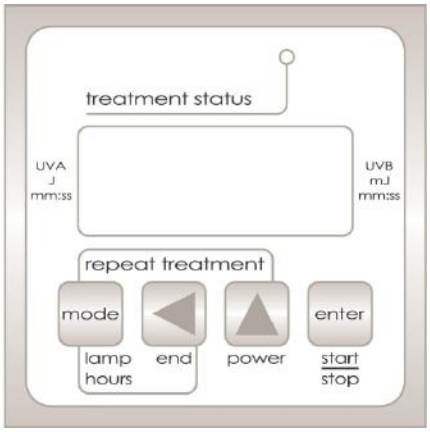
mW/cm2 mJoules	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	7.0
240	01:36	01:20	01:09	01:00	00:53	00:48	00:44	00:40	00:34
280	01.52	01:33	01:20	01:10*	01:02	00:56	00:51	00:47	00:40
320	02.08	01:47	01:31	01:20	01:11	01:04	00:58	00:53	00:46

The UVA Time Chart (not shown here) is configured the same as the UVB Time Chart. The doses are listed in Joules and the energy output levels and times are different than the UVB output levels. Each chart is clearly marked.

Timer Operation

To administer a treatment, you must enter your desired treatment time. Based on the example above the treatment time will be 1:10.

1. Press any key to awaken the unit. The word “C0dE” will appear.
2. Enter in your key code. Unless it has been changed, the factory preset key code is 0007.
3. Once the key code has been entered, the display should read 00:00. Press END if the timer says HOLD.
4. Press the ▲ key until the first digit of your desired time is displayed. If the treatment time is one minute and ten seconds (01:10), the first digit will be a “1”.
5. Press the ◄ key to move the “1” one space to the left. The display should read 00:10.
6. Press the ▲ key until the next desired number is displayed (“1” in this case). The display should read 00:11.
7. Press the ◄ key to move the “1” one space to the left. The display will now read 01:10.
8. When the desired time is displayed (in this case 01:10) press the ENTER key to lock in your treatment time.



Put on your goggles and position yourself per the instructions.

9. Begin the treatment by pressing ENTER or by pressing the footswitch.
10. To repeat the same treatment for another exposure, press the ENTER key or press the footswitch.

Note: The Digital Timer will beep three times to signal the end of a treatment. It will also flash the treatment time on the display.

Special Functions of the Digital Timer

- To pause an active treatment press either the footswitch, END key or ENTER key.
- When a treatment is paused the screen will read “HOLD”. To resume a paused treatment, press the ENTER key or the footswitch.
- To end or cancel an active treatment press the END key two times.
- If you make a mistake while entering a time, repeatedly press the ◄ key until all zeros are displayed.
- To check the age (in hours) of your lamps press the MODE and ◄ keys together at the same time. The lamps must be off to do this.

Special Notes

- The maximum time that can be entered is 59 minutes and 0 seconds
- It is **not** possible to enter 60 seconds. You must enter 1:00 minute instead.

- A short beep is sounded for every valid key entered. A long beep is sounded when an invalid key is entered.

- If power goes off during a treatment, the system will remember how much of the treatment has elapsed. When power is restored, your device will be on “HOLD”. To continue the treatment, press START. To cancel the treatment press END.

- The small orange light above the display will be lit when a treatment is in process. It will blink when the treatment is paused.

Power off Sequence

- Turn off the UVB Light Source by pressing the Power Switch to the OFF (O) position.

- Frequent lamp ignition will degrade the lamp prematurely. If the light source is to be used within two (2) hours, do not turn it off. Harmless visible light will continue to emit when the light source is left on.

- Disconnect the brush from the Light Guide by pressing on two rectangular tabs on the connecting end of the attachment and pull apart.

- Disconnect the Light Guide from the Light Guide Port by holding Proximal End and gently pulling out.

- Place the appropriate Dust Caps on the ends of the attachment and Light Guide and store.

Output Level Adjustment

The Output Level Knob adjusts the intensity of the light output. The knob rotates an internal attenuator of the device and varies the output intensity of the light beam.

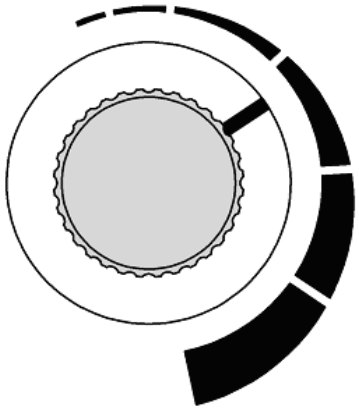


Figure 4.3. Output Level Knob

- To adjust the output level, turn the knob clockwise to increase and counter-clockwise to decrease. Turn the knob by first pressing it lightly to engage. This design feature prevents output changes by accidental touching.

Instruction for Use of the LumaSure 308 Meter

The LumaSure meter is used to measure the irradiance in the UVB spectral range. Operation is simple and safe.

Power Supply

The LumaSure meter is supplied with a 9V battery, which provides power for an operating time of about 100 hours. In order to change the battery, the compartment at the rear of the device must be opened by undoing the crosshead screws. The design of the connections prevents reverse connection. Before closing the battery compartment, make sure all wires are fully inside the compartment. **If the device is left unused for relatively long periods, the battery should be removed from the device.**

On/Off Function

The on switch, located at the top of the meter, is used to turn the device on. When the switch is moved to the on position, four dashes will be displayed as the meter warms up before a value of P00.0 is shown indicating that the meter is ready for use. To switch the device off, move the switch into the off position.

Operating Procedure

1. Ensure that everyone within 10 feet of the device has suitable eye and skin protection.
2. Turn on the LumaSure UVB Meter by moving the switch to the “ON” position. The instrument will do a self-test for a few seconds before displaying a power reading.
3. Turn on the device and wait for the green LED “Lamp Ready” light to illuminate (approximately 4 minutes).
4. For Lumera Spot Handpiece:
    a. Connect the Spot Handpiece to the Light Guide and the Light Guide to the Light Source.

   b. Remove any pattern inserts from the handpiece during calibration. If the output beam does not entirely fill the detector area, a false reading will be indicated. The irradiance meter (mW/cm^2) will not change by changing the pattern inserts.
   c. Place the Spot Handpiece over the detector of the meter, with the active area of the detector directly under the exit aperture of the Spot Handpiece, so the calibration point is sitting in the point indent on the detector. Align the pilot beam to the detector making sure it overfills it.
5. For Lumera Fiberoptic Brush:
   a. Connect the Fiberoptic Brush to the Light Guide and the Light Guide to the Light Source.
   b. Place the Fiberoptic Brush over the receptacle of the meter, with the active area of the detector directly under the central fibers of the Fiberoptic Brush, within the provided indentation across the meter.
6. Set the timer on the Lumera to approximately 50 seconds. .
7. Press ENTER on the timer or engage the Foot Switch to begin UV output.
8. Adjust the output level knob to the desired output reading in mW/cm^2
9. Wait a few seconds until the meter reading stabilizes and record the reading shown on the meter.
10. Press ENTER on the timer or engage the Foot Switch again to deactivate the shutter and interrupt the UV output.
11. Reset the Timer.
12. After a reading has been taken turn the meter off by moving the switch into the “off” position.

Other Notes

The meter is designed for application at surrounding temperatures of between +5 and +40 C, and should be protected from direct sunlight and moisture. Ordinary non-aggressive plastic cleaners are recommended for cleaning. Take particular care to see that moisture does not enter the housing when cleaning the display window.

Detector Head Operating Instructions

The Lumera detector head is used as part of the LumaSure meter to measure UVB irradiance. The detector head consists of one detector for the UV-B wavelength range.

The detector head is connected through a short cable and a connector to the meter. In order to measure the irradiance, the detector head is orientated with the sensor element to the light source. Please see manual for the unit that is being calibrated for specific calibration output measurement instructions.

Warning: The appropriate protection and safety procedures must always be observed when working with UV radiation sources.

When operating the detector head, the permitted operating temperature from +5 to +40 C must be ensured. The lead must not be kinked.

The diffusing screen (small round indentation) of the detector should not be touched with bare fingers. It can be cleaned with acetone, using a cotton-wool bud or a clean cloth. Ordinary, non-aggressive cleaning materials that leave no deposits are recommended for cleaning the housing.

This meter is recommended to be calibrated annually. Calibration of the detector head is carried out by the Calibration Laboratory for Optical Radiation Quantities of Daavlin and confirmed with a factory certificate. The meter is shipped with a calibration label that says when the meter was last calibrated and when the next calibration is due. Contact the Daavlin service department to obtain a quote and an RA # to send your meter back when calibration is due.

5. PHOTOTHERAPY FUNDAMENTALS

Principles of Ultraviolet Phototherapy

Ultraviolet UVB Phototherapy involves exposing the skin to energy of a particular spectrum of the ultraviolet band called UVB. This area is defined as wavelengths of 290 to 320 nanometers. Exposure to this part of the spectrum has been proven beneficial for the control of skin conditions listed in the indications for use. For details on phototherapy and how it benefits these skin conditions, the user should consult medical literature and experts in the field.

Regarding the rules for determining the dosimetry for UVB phototherapy, the following principles apply:

- The skin needs a certain amount of energy (Millijoules/cm^2) for the condition to subside.
- UVB exposure at each treatment is limited by the susceptibility of skin to erythema and the patient's ability to tolerate exposure in the involved areas.
- As a general rule, the light exposure per treatment should not exceed the Minimum Erythema Dose (MED), which is the lowest exposure to ultraviolet required to produce erythema, or slight redness of the skin. On certain parts of the body or, if the involved area is small, the patient can tolerate a dose higher than the MED.
- Treatment can resume when the skin reaction to ultraviolet has subsided, usually 48 hours after exposure.
- With each treatment, exposure to ultraviolet radiation produces skin melanogenesis (tanning of the skin). Tanning increases skin tolerance to ultraviolet permitting an increase in exposure in subsequent treatments.
- Treatment is repeated until the condition falls into remission.
- To keep the disease in permanent remission a maintenance treatment at regular time intervals is recommended.

Phototherapy Contraindications and Precautions

As with natural sunlight, overexposure to UVB can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer.

Some patients have a history of skin problems or sensitivity to light. Certain medications and cosmetics contain substances that may increase skin sensitivity to ultraviolet radiation.

The physician responsible for phototherapy must screen and evaluate all patients prior to UVB phototherapy treatments and monitor them for complications during and after the treatments.

The following patient types should NOT be treated with this device unless the physician responsible considers phototherapy necessary and safe.

- Individuals with light sensitive disease, including, but not limited to, Porphyria or Lupus Erythematosus.
- Individuals with a current or past history of Melanoma.
- Individuals with Invasive Squamous Cell Carcinoma or past history of Invasive Squamous Cell Carcinoma.
- Individuals with aphakia, because of the significantly increased risk of retinal damage due to the absence of lenses.
- Females who are or suspect that they may be pregnant.
- Patients exhibiting Multiple Basal Cell Carcinoma or having a history of Basal Cell Carcinoma should be carefully observed during and after treatment.
- Patients having a history of X-ray therapy or Grenz-ray therapy should be carefully observed for signs of Carcinoma.
- Patients having a history of Arsenic Therapy should be carefully observed for signs of Carcinoma.
- Special care should be taken in treating patients who are receiving parallel therapy with known photosensitizing agents such as, but not limited to: ACE inhibitors, Non-steroidal Anti-inflammatories, Amiodarone, Phenothiazines, Ciprofloxacin, Protriptyline, Nalidixic Acid, Sulfonamides, Tetracyclines, Nifedipine, Thiazides, Coal Tar or Plant-derived Psoralens, Griseofulvin, Halogenated Salicylanilides (bacteriostatic soaps), certain organic staining dyes (Methylene Blue, Toluidine Blue, Rose Bengal, and Methyl Orange) and some dietary supplements believed to act as photosensitizing agents.

6. TREATMENT PROCEDURE

Minimum Erythema Dose and Skin Types

The Minimum Erythemal Dose (MED) is an important first stop in determining an appropriate treatment program. The MED varies from individual to individual. There are six skin types, each with a different tolerance to UV.

Type	Skin Color	Skin Reaction to Ultraviolet Light
I	Very Fair	Always burns easily and severely; tans little or not at all
II	Fair	Usually burns easily and severely; tans minimally and lightly
III	Medium	Burns moderately gains average tan
IV	Olive	Burns minimally, tans easily and above average
V	Moderately Pigmented (Brown)	Rarely burns, tans easily and substantially
VI	Dark Brown to Black	Tans profusely and never burns

Table 1 – Classification of sun-reactive skin types used in clinical practice

The typical UVB MED for unexposed skin, as derived from medical literature, is given in the following table. The values in Table 2 are averages for individuals with the same skin type and for a typically unexposed area, such as the buttocks. Other areas of the skin may have a higher or lower MED. If the area of the skin to be treated is routinely exposed to light, even slight tanning will alter the MED.

Type	Typical UVB MED of unexposed skin
I	45 mJ/cm^2
II	75 mJ/cm^2
III	90 mJ/cm^2
IV	120 mJ/cm^2
V	150 mJ/cm^2
VI	240 mJ/cm^2

Table 2 – Typical UVB MED of unexposed skin

There is variation between individuals with the same skin color. In order to accurately control the dose and ensure patient safety and comfort, the MED must be determined for each patient before beginning phototherapy.

Determination of Minimum Erythemal Dose (MED)

In determining the MED, it is important to consider the area that is going to be treated. If the scalp is to be treated, the MED must be determined by exposing uninvolved skin sites such as the buttocks. If other areas of the body are to be treated, an area with similar skin thickness and sun exposure should be used for MED determination.

Determine the estimated MED based on skin type (see Tables 1 & 2 of section 6). This will result in a more accurate dose determination in the following procedure.

To determine the MED, perform the following steps:

- Select and mark with a marker five areas of 3 cm^2 each. Number the areas consecutively with the numbers 1 to 5.

- Use the Spot Treatment Handpiece to deliver a range of exposure doses from approximately half of what is recommended for the skin type of the patient to twice the recommended MED. Space the doses equally. Make a note on the patient chart.

- Examine the test MED spots 2 days later. Evaluate the erythema level at each test spot and determine the MED for the patient. The MED is defined as the lowest dose that resulted in clearly defined erythema over the entire area. To determine the actual value, multiply the delivered dose by the percentage corresponding to the lowest area of marked erythema. Record the MED on the patient chart.

Phototherapy Dosimetry and Treatment Regimen

The sequence of treatments is called the "Treatment Regimen". The Treatment Regimen is defined by the initial dose and each subsequent dose until treatment is complete or discontinued. The guidelines presented here are generally accepted by phototherapists. The initial dose can be a single MED, a fraction of the MED or a multiple of the MED, at the discretion of the treating physician.

Some simple rules for dose determination for subsequent treatments are presented in Table 3 below. The typical frequency of treatments is once every 2-3 days (once a week for maintenance treatments). The final determination of treatment parameters is the responsibility of the treating physician. The guidelines presented below should be considered recommendations and used **for reference only.** The treating physician will determine the frequency of the treatments when treatment is complete or when treatment should be discontinued. The same applies to maintenance treatments.

Previous Treatment Effect (1-3 days post-treat)	Dose Increase/Decrease Rule
No sun-burning reaction	Increase exposure dose by 20%.
Mild sunburn reaction	Maintain dose at the level of previous treatment.
Moderate sunburn	Skip treatment until reaction subsides, and then resume with a 20% reduction from the last dose.
Severe sunburn	Discontinue treatment until reaction subsides. Determine MED again and resume with revised regimen.

Table 3. – Energy Increase/Decrease Rule

Recommendation for treatment conclusion:

- When clearing is obtained, treat 3 times at the last dose and then switch to maintenance mode.
- Maintenance mode is once per week treatment at the final dose level.

Treatment shall be discontinued, at the discretion of the treating physician, if no improvement is observed after 6-8 treatments.

Exposure Time Calculation for Spot Treatment

The exposure time for spot treatment can be calculated as follows:

(a) Determine the MED needed for the patient (mJ/cm^2). Please refer to section 6 for procedures.

(b) Obtain the Spot Handpiece irradiance (in mW/cm^2) using the UVB meter. Adjust the irradiance output to the desired level by rotating the Output Level Knob on the Light Source clockwise to increase and counterclockwise to decrease the output.

TIP:
Set the Output Level to one of the values shown on the time chart provided.

(c) Find the power output in the horizontal column.

(d) Find the desired dose in the vertical rows.

(e) The time to deliver the desired dose is that value shown where the power column and the dose row intersects.

NOTE: This is the time required to deliver the desired dose to a single exposed area. It may take a number of exposures to cover a given plaque or lesion.

Spot Treatment

Caution: Verify safe conditions. Confirm that everybody in the room has suitable eye protection and confirm that both the operator and patient are wearing appropriate skin protection.

- Turn on the device. Connect the Spot Handpiece to the Light Guide and the Light Guide to the Light Source. Calibrate the Handpiece and record the maximum output for reference.

- The dose is to be defined by the treating physician. Refer to patient chart and treatment protocol to identify the dose. Follow the instructions in this manual to calculate output level adjustment and treatment time. Proceed to light source set-up.

- Set the output level and exposure time according to the specified treatment parameters.

- Place sterile thermometer sheath or attach the (sterilized) Distance Gauge and an appropriate Pattern Insert for the area to be treated. Position the Spot Handpiece over the affected area.

- After treatment time is set, press ENTER on the timer or engage the Foot Switch to initiate exposure. Keep Handpiece still over the skin until exposure time has elapsed.

- Proceed to the next area (if necessary) until the area to be treated is completed.

Note: To keep track of the treated areas you can use an ink pad to stamp the perimeter of each treated spot. The area is treated when covered completely with irradiated spots.

- Press ENTER on the timer or engage the Foot Switch to deactivate the shutter if treatment needs to be interrupted or aborted. Press ENTER or engage the Foot Switch to resume if needed. Hold the switch for two (2) seconds to reset the timer.

- When the exposure time has elapsed, the shutter will close and there will be an audible indicator that exposure time is completed. After the light source has been shut off, you will continue to see harmless visible light. Only when timer is set with the treatment time and the ENTER button or the Foot Switch is pressed, will there be UV output.

- When finished, disconnect flexible Light Guide from Spot Handpiece. Clean Handpiece if needed. Dispose properly of all other single use items. Store flexible Light Guide and Spot Handpiece.

- If the light source is to be used again within 2 hours, do not turn it off. Frequent lamp ignitions will degrade the lamp prematurely.

Exposure Time Calculation for Scalp Treatment with the Fiberoptic Brush

The exposure time for the affected scalp area can be determined as follows:

(a) Determine the MED needed for the patient. Please refer to previous section of section 6 for testing procedure.

(b) Determine the total area of the scalp (in cm^2), **or portion thereof**, to be treated at a time.

TIP:
The typical area of the scalp is 500 cm^2. Divide the scalp into five sections (1, 2, 3, 4 and 5. See Figure 6.1). The time chart that is provided for scalp treatment assures a 100 cm^2 treatment area or 1/5 of the average scalp. The times shown on the chart represent the amount of time it will take to deliver a given dose to 100 cm^2 of scalp.

(c) Determine Dose. (Defined by treating physician.)

(d) Determine the Fiberoptic Brush irradiance (in mW/cm^2) using a UVB meter. Adjust the irradiance output to one of the levels shown on time chart provided by rotating the Output Level Knob on the Light Source clockwise to increase and counterclockwise to decrease the output.

(e) The power output is on the top row. Find the power output of your unit.

(f) The doses are in the left column.

(g) The time to deliver the desired dose is that value shown where the power output column and the dose row intersect.

TIP:
If the time that is determined does not allow enough time to evenly distribute the dose over the entire area, reduce brush irradiance to increase the treatment time.

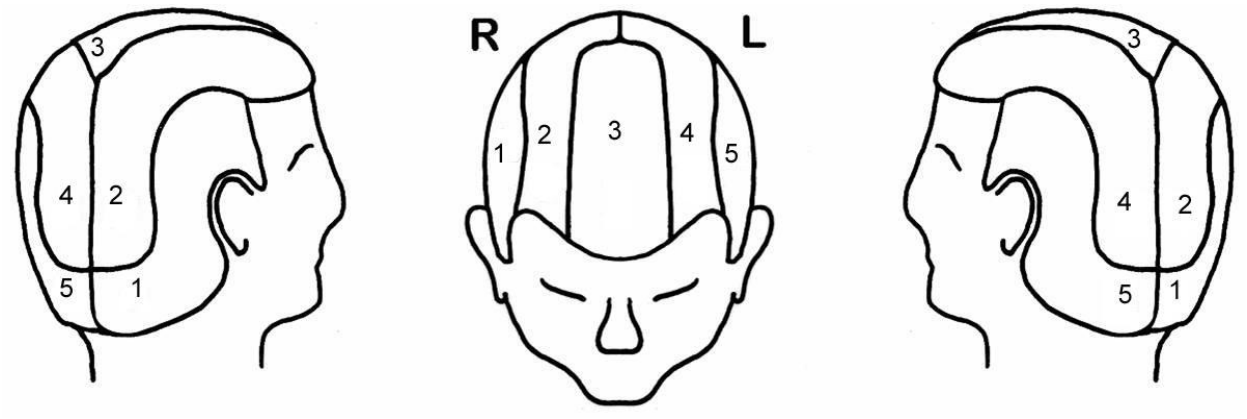


Figure 6.1 Scalp Sections

Scalp treatment

Caution:	Verify safe conditions. Confirm that everybody in the room has suitable eye protection and confirm that both the operator and patient are wearing appropriate skin protection.

- Turn on the device. Connect the Fiberoptic Brush to the Light Guide and the Light Guide to the Light Source. Calibrate the Fiberoptic Brush and record the output.
- If this is the first time that the Fiberoptic Brush is being used, mark the patient's name and other identifying information on the brush and its container.

Note:	The Brush is a personal item. To eliminate the risk of transmission of diseases, each patient must have his or her own brush.

- The dose is to be defined by the treating physician. Refer to patient chart and treatment protocol to identify the dose. Make adjustment for the time that the brush is not in contact with the scalp during treatment. Follow the instructions in this manual to calculate output level adjustment and treatment time. Proceed to light source set-up.
- Set the output level and exposure time according to the specified treatment parameters.
- Divide the scalp area into five equal strips and treat one strip at a time. Use a marker pen if necessary to mark the borders of each strip. If there is little scalp involvement with few affected areas, treat only the affected areas, one at a time (make exposure time calculations accordingly). If the affected area is widespread, treat the whole scalp.
- Position the Fiberoptic Brush over the affected area. Press ENTER on the timer or engage the Foot Switch to initiate exposure.
- Deliver UVB light on the scalp with a slow, gentle, steady combing action at a rate of approximately ¾ inch per second (1-2 cm/second).

- Expose adjacent strips until all sites on the scalp have been exposed.

- Avoid overexposure of the area close to the border of the strips. Keep the Brush moving at all times when it is touching the scalp. If you have to stop the movement, even momentarily, lift the brush away from the scalp of the patient.

- Press ENTER on the timer or engage the Foot Switch to deactivate the shutter if treatment needs to be interrupted or aborted. Press ENTER or engage the Foot Switch to resume if needed. Hold the switch for two (2) seconds to reset the timer.

When the exposure time has elapsed, the shutter will close and there will be an audible indicator that exposure time is completed. After shutter has closed, you will continue to see harmless visible light.

TIP: The application of mineral oil to the patient's psoriatic scalp will enhance the penetration of therapeutic UV and improve therapeutic response. The lubricating effect of the mineral oil will also prolong the life of the brush.

- When finished, disconnect flexible Light Guide from Fiberoptic Brush. Clean Brush and store it in its container. Dispose properly of all other single use items. Store flexible Light Guide and Fiberoptic Brush.

- If the light source is to be used again within 2 hours, do not turn it off. Frequent lamp ignitions will degrade the lamp prematurely.

7. CLEANING AND MAINTENANCE

UVB Light Source:

- Ensure the main Power Switch is turned off and the Power Cord is unplugged before cleaning the unit.

- Periodically wipe the exterior surfaces with a soft cloth moistened with 70% isopropyl alcohol solution to remove surface contamination.

Caution: Do not allow any liquid to get into the Light Guide Port.

- Allow exterior surfaces of the device to dry before use. Never apply any liquid directly to the surface of the device.

- Do not expose the device to autoclaving or any cleaning or sterilization process involving excessive heat or moisture, as this could lead to damage and void the warranty.

- No cleaning of any interior components of the device is required.

Light Guide:

Warning:	Light Guide can be damaged or suffer impaired light transmission if not handled properly.
Warning:	Damage from UV energy will occur if a Fiberoptic Bundle or a Liquid Light Guide other than the one provided is used.

- Avoid bending or kinking the Light Guide radically. The bend radius during use or storage should not be less than five (5) inches (thirteen (13) centimeters). Avoid squeezing or puncturing the jacket of Light Guide.
- Be extremely careful not to scratch, mar, or accidentally apply light activated material to the Light Guide end tips.
- To clean the Light Guide, use a soft cloth, moist with mild detergent and water solution. Wipe with dry cloth until dried thoroughly.
- Clean Light Guide weekly. If you notice an abrupt drop in output within a short period or time (2-3 hours of unit operation), call customer service.
- To clean the quartz end tips of the Light Guide use 70% Isopropyl Alcohol and cotton tip applicators.
- To disinfect, soak the Light Guide in disinfectant solution. Follow solution manufacturer's instructions carefully. Do not allow Light Guide to remain in any solution, including sterile water, for more than thirty (30) minutes.
- ** DO NOT gas or steam sterilize the Light Guide. Store loosely coiled.

Spot Handpiece

- Wipe with alcohol. Use brush or cotton swab soaked in alcohol to remove skin particles and debris from the exit aperture.
- To disinfect use soft cloth, moist with disinfectant solution. Do not dip the Spot Handpiece in disinfectant because it will be damaged. Follow solution manufacturer's instructions carefully. Wipe with dry cloth until dried thoroughly.
- Wipe exterior surfaces, if needed, with a cloth moistened with deionized water. Wipe with dry cloth and remove disinfectant thoroughly before use.
- Sterilize the distance gauge by using an autoclave or other procedures established by the institution.

Fiberoptic Brush

- Fill the Wash Cup that is provided with the brush with rubbing alcohol to about 1/3 full. Insert the brush in the cup until the holding detents click. Holding together the brush and cup by hand, shake a few times. Remove Brush from Cup and dispose of alcohol properly. Allow to drip dry or for faster drying, blow clean air.

- For removal of any remaining scale from the Fiberoptic Bristles use a small brush or cotton swab soaked in alcohol. Remove skin particles and debris from the fibers by gently pushing it towards the tips. Rinse with rubbing alcohol or deionized water following the wash procedure.

- To disinfect, soak the fiber tips in disinfectant solution using the Wash Cup. Ensure that only the fiber tips are in the solution. Do not dip the entire Fiberoptic Brush because it will be damaged. Follow solution manufacturer's instructions carefully. Do not allow Fiberoptic Brush to remain in any solution, including sterile water, for more than thirty (30) minutes.

- **After disinfection, rinse the fiber tips, if needed, with deionized water. Allow to drip dry.**

- Wipe exterior surfaces, if needed, with cloth moistened with deionized water. Wipe with dry cloth and remove disinfectant thoroughly before use.

- Blow clean, oil free compressed air if available in the direction of the fibers to accelerate drying. Ensure that brush is dry before use.

UVB meter

- Wipe receptacle with alcohol. Clean the rest of the meter with soft, lint free, dry cloth. Moisten with alcohol if needed.

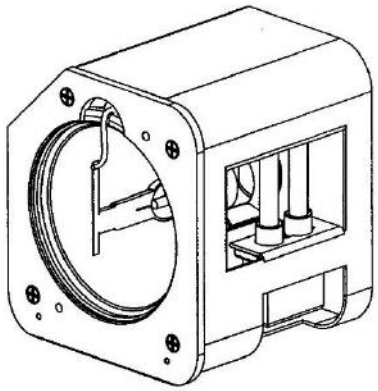
UV-block Goggles

- Wipe with alcohol. Use brush or cotton swab soaked in alcohol to remove skin particles and debris from surfaces. Each patient should have his or her own personal set of goggles.

8. LAMP MODULE REPLACEMENT

Lamp Module Replacement

Warning:	To prevent electric shock, disconnect the device from power outlet prior to any part replacement.
Warning:	DO NOT TRY TO REPLACE LAMP MODULE WITHOUT ALLOWING THE LIGHT SOURCE TO COOL DOWN FIRST. The lamp operates at very high temperatures. Failing to allow time for the unit to cool down for at least ten (10) minutes before replacing the Lamp Module may cause severe burns.



- Remove the Power Cord from the unit.
- Unscrew the Thumb Screws located on the back of the Chassis Cover.
- Slide the Chassis Cover towards the back until the Arrow on the inside shield is completely exposed (approximately one and the half (1 ½) inch) (four (4) centimeters) and lift the cover up. (see figure 8.1)

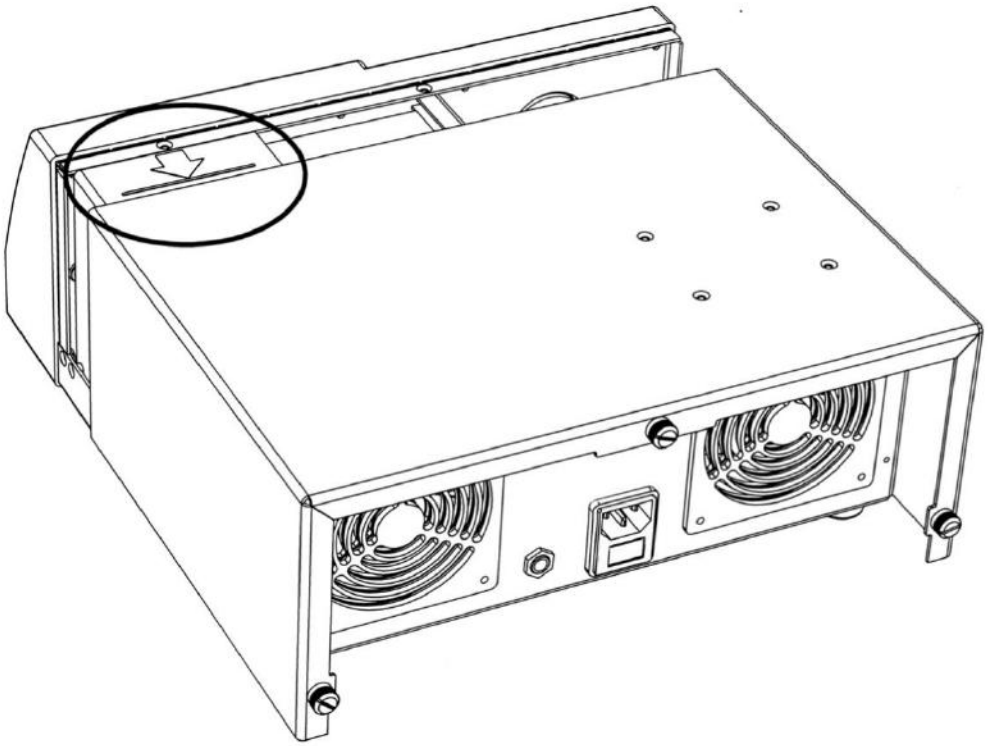


Figure 8.1

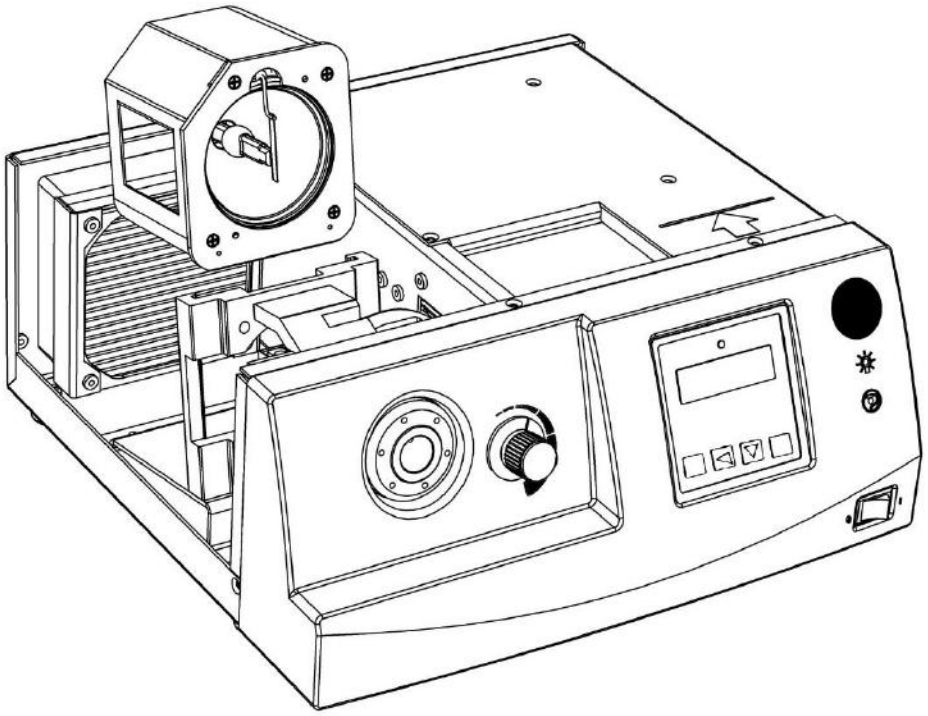


Figure 8.2

Remove used Lamp Module from the unit by sliding it up from the Light Engine. (Lamp Module might encounter a little resistance.) See Figure 8.2

> ***Warning:*** Do not touch lamp in the Lamp Module. Oils from fingerprint on the lamp may result in premature lamp failure.

Make sure that the side marked “THIS SIDE UP” is facing upwards and the connector on the Lamp Module is on the same side as the connector on the Light Engine.

Place the new Lamp Module into Light Engine and gently push it down until the Lamp Module is flush with the top of the light module guide rail.

Align Chassis Cover with the Line on the power supply shield and lower it down. Slide Chassis Cover towards the front of the unit until it is flush with the front end and tighten Thumb Screws.

Plug the Power Cord back into the Light Source Power Cord Socket.

Plug the unit back to the main power.

Metal Halide Lamp Hazards

Warning: The lamp in the Lamp Module contains a very small amount of mercury. Mercury compounds are hazardous materials. Inhalation of vaporized mercury can be harmful to the lungs, kidneys, and nervous system. Mercury that penetrates the skin or is ingested can also be harmful. If mercury is inhaled, penetrates the skin, or is ingested accidentally, seek emergency medical treatment immediately.

In extremely rare occasions the bulb may burst and release mercury. If this happens, the following precautions should be observed to minimize the risk of exposure to mercury. The total mercury contained in the lamp is less than 40 mg (less than a 2 mm diameter sphere, about 1/25 or the mercury found in a typical household thermometer). Most of this amount will remain within the unit.

Always wear gloves and safety glasses when handling or replacing a UVB Light Source assembly after such an event.

Leave the area immediately after event to avoid inhalation of the mercury vapor.
Thoroughly ventilate the area for at least 30 minutes, before returning to the area.

After the bulb housing has cooled down, any mercury residue should be picked up with a special adsorptive agent, which is available from lab equipment dealers.

Carefully remove gloves after handling a broken bulb. Wash hands thoroughly with soap and water. Follow all applicable federal and local health, safety, and environmental regulations.

Do not replace Lamp Module, turn on or try to operate the system until all mercury contamination has been cleaned up and removed and unit integrity has been checked by authorized service personnel.

Label with red marker as hazardous waste (or put in marked bag) and dispose all lamp fragments, Lamp Module, gloves, and cleaning material.

The probability of a bulb bursting is further minimized when the following guidelines are followed:

Do not touch the bulb with bare hands.

If the mercury capsule or reflector of the bulb is touched accidentally, then clean the fingerprints off with denatured alcohol and wipe dry with a soft, clean, lint-free cloth. Do not use cleaning rags or materials that can leave a residue.

Do not use a bulb that shows any scratches, cracks, or other damage.

Always place the Lamp Module on a flat surface or table to prevent it from falling and the mercury capsule being ruptured.

For further information please visit the following website regarding the handling of mercury:
http://www.epa.gov/mercury/spills/index.htm

9. BASIC TROUBLESHOOTING

Troubleshooting Guide

Warning: **DANGER – HIGH VOLTAGE -** To avoid Electric Shock Disconnect Power Supply Cord before servicing the unit

Caution: Do not touch Lamp Module immediately after operation. Allow it to cool for ten (10) minutes.

Fault	Action
Unit Does Not Turn On	Check that Power Cord is properly connected Check that Power Switch on the front panel is ON Check power availability at the selected power outlet Check the fuse. Replace if necessary Contact Daavlin Customer Service
Lamp Fails to Ignite (Power is on, fans are running, and front panel illuminated)	Check that Lamp Module is installed properly Check that the Chassis Cover is installed correctly Replace Lamp Module Contact Daavlin Customer Service
Lamp flickers or output varies within one treatment	Replace Lamp Module Contact Daavlin Customer Service
Low UV Output	Verify that the Light guide is pushed completely into the Light Guide socket. Verify that both ends of the Light guide are clean. (See cleaning instructions for Light guides) Replace Lamp Module (See Lamp Module replacement instructions) Contact Daavlin Customer Service
Shutter does not Open	Verify that the Light guide is properly inserted into the Light Guide socket. Contact Daavlin Customer Service
Timer Not Running	Shut down the system, wait 10 minutes and restart. Contact Daavlin Customer Service
UVB Light Source turns off after a few minutes of operation	Obstructed air intake; overheating causes thermal safety switch to trip. Make sure that the unit has sufficient clearance around it (3 to 4 inches). Allow unit to cool (5 -10 minutes). Contact Daavlin Customer Service
Unit Blows Fuses repeatedly	Contact Daavlin Customer Service
Fans Do Not Work	Contact Daavlin Customer Service
The system buzzer makes a continuous sound. Light output activated after the timer cycle has elapsed.	System malfunctions and the shutter remains open after the timer cycle has ended. Turn off the unit immediately. Contact Daavlin Customer Service

Fuse Replacement

The external Fuse Holder is located below the Power Cord Socket on the rear panel of the Light Source.

Remove Power Cord from Power Cord Socket on back of device.

Open the Fuse Holder Cover using a small, flat blade screwdriver.

Use the same screwdriver as a lever to remove the fuses from the Fuse Holder. Identify blown fuse and pull it out from the Fuse Holder.

Replace blown fuse(s) with a fuse of the same size and rating.

Place fuse holder back into the Power Entry Module and shut the cover.

If the fuse blows again within a short time, contact Daavlin Customer Service to request Return Material Authorization number and return the unit for repair.

10. TECHNICAL SPECIFICATIONS

System Classifications

FDA	Class II Medical Device
CDRH	Ultraviolet Lamp for Dermatological Disorders
MDD	Class II A Medical Device
UL 60601-1	Class I Electrical Protection, Class B Applied Part
Mode of Operation	Continuous

UVB Light Source

Lamp Operating Power:	200 Watts nominal
Therapeutic Spectrum:	290-320 nm
Input Voltage:	100-240 VAC
Frequency:	50/60 Hz
Input Current:	4 A @ 120 Volts (2 A @ 220 Volts)
Utility Connection:	Single-phase Grounded Outlet
Fuses 100-125 Volt Operation:	6.25 Amp, 250 Volt, Slow Blow, .25” X 1.25” - 2 ea.
Fuses 215-240 Volt Operation:	3.15 Amp, 250 Volt, Slow Blow, .25” X 1.25” - 2 ea.
Lamp:	Metal Halide UV Enhanced Lamp
Lamp life:	Approximately 500 hours

Audible Alarm:A continuous buzzer noise indicates system malfunction.

Operating Environment

Operating temperature:	10°C to 40°C
Relative Humidity:	30-70%
Liquids Ingress Rating	IP20 (no protection against the effects of vertically falling drops of liquid)

The light source is not suitable for use in the presence of a flammable anesthetic (or mixture of such anesthetic with air, pure oxygen, or nitrous oxide).

Timer

Timing Mode:	Interval - Countdown.
Programmable Timing Range:	00:01 – 59:00 (minutes: seconds).
Timing Accuracy:	±0.3% of setting.
Running Hours Memory:	Time kept in non-volatile memory.
Front Panel Indicator:	An LED indicates the Timer state.
Front Panel Switches:	Two (2) for setting the time. One (1) for displaying the lamp hours.
Audible Alarm:	A buzzer indicates beginning, completion and interruption of timing cycle.

Footswitch

Type:	SPDT Momentary
Length:	8 feet (2.4 meters)
Connector:	Phono Plug Type, Stereo, .25” Shaft
Liquids Ingress Rating	IPX8, (protection against the effects of vertically falling drops of liquid

Shipping and Storage (Lumera System and Attachments)

Ambient temperature range	-10°C to +55°C
Allowable relative humidity range	0% to 100%, non-condensing
Allowable atmospheric pressure range	500 hPa to 1060 hPa
Handling:	Fragile
Carton Position	Keep package in upright position

Fiberoptic Brush

Total number of fibers:	35
Active Area:	0.8 X 2 inches (2 X 5 centimeters)
Overall dimensions:	3.1” X 1.2” X 4.9” (8 X 4 X 12.5 cm)
Weight:	4.5 oz (128 gm)

Spot Handpiece

Active Area:	adjustable up to 3 cm^2
Overall dimensions:	1.8” X 1.2” X 5.1” (4.5 X 3 X 13 cm)
Weight:	4 oz (115 gm)

Light Guide

Active diameter:	5 mm active diameter
Length:	6 feet (1.8 meters)
Outer Diameter	1 cm (0.4")
Weight:	12. oz (340 gm)
Minimum Bend Radius:	5 cm (2")
Core Type:	Proprietary Liquid

11. GLOSSARY

Attenuator	A mechanism to adjust the light output of the Light Source
Erythema	Redness of the skin caused by exposure to light
Fluence	Unit of energy density on a surface, milli Joules per centimeter square
Irradiance	Unit of power density on a surface, milli Watts per centimeter square
Joules	Unit of energy
MED	Minimum Erythemal Dose
Melanogenesis	The skin reaction that produces melanin and tans the skin
Milli Joule	Unit of energy (1000th of a joule)
Nanometer	Unit or length. One billionth of a meter
Optical Fiber	A flexible fiber that allows light to travel along its length
Remission	Interruption in the intensity of a disease
Shutter	A metal slat that prevents harmful UVB from being exposed
Spectrum	A range of wavelengths of light
Ultraviolet B	Ultraviolet Light between 290 and 320 nanometers
Watt	Unit of Power (Energy per time)

12. SERVICE AND WARRANTY

Daavlin stands behind the quality products it manufactures.

All Daavlin phototherapy equipment (excluding the lamp, which is warranted for 60 days) is warranted to be free from defects in workmanship and material for a period of two (2) years from the date of installation, at the original consumer's premises, under normal use and service. Daavlin will replace or repair any parts that shall appear to have been defective in material and/or workmanship. Daavlin shall bear all costs related to parts, labor, and shipping for the term of the warranty. Daavlin may require smaller units to be sent back to the factory for repair. Lamp output/control system calibration is not covered by warranty. **Read Operating Instructions & General Information and Installation and Service Manual for complete warranty information.**

During the coverage period, Daavlin will arrange for a qualified service technician to repair or replace the systems or components mentioned as covered in accordance with the terms and conditions of this contract. This contract covers only products at the original consumer's premises under normal use and service. The warranty will be null and void if non-qualified technicians perform any repair or maintenance unless prior written authorization is obtained from Daavlin. This includes the use of Daavlin recommended components, test equipment, and procedures.

Daavlin is not responsible or liable for **any** work (in warranty or out of warranty) performed by non-qualified technicians unless written authorization prior to the repair is granted. This includes the use of Daavlin recommended components, test equipment and procedures.

It will be at Daavlin's discretion whether subcontractors or Daavlin technicians perform any required service work.

This warranty does not apply to any unit which has been used, repaired or altered outside the factory in any way so as to affect the design, or which has been subject to misuse negligence or accident, or operated in any way other than in accordance with our operating instructions. The warranty does not extend to repairs made necessary by the use of parts or accessories not recommended by the manufacturer. This warranty does not cover damage in transit.

Daavlin warrants its lamps for sixty (60) days against defects in material and workmanship and to operate at the time of initial installation in an electrical circuit having the correct characteristics for proper lamp operation. No warranty is made as to useful lamp life or as to reduction in ultraviolet output due to any causes.

Daavlin may require the return of merchandise claimed to be defective for its examination and shall be the sole judge as to whether material is in fact defective under the terms of this warranty. Daavlin reserves the right to bill for travel time, expenses and service cost for requested "warranty" service trips which result in work not covered by the warranty. This may include, but is not limited to, a tripped circuit breaker, an unplugged machine or a blown fuse.

The foregoing shall be the buyer's exclusive remedy. In no case will Daavlin be liable for consequential damages even if Daavlin has been advised of the possibility of such damages. The foregoing warranties are in lieu of all other warranties expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

How We Handle Warranty and Service

Service work is divided into two levels of urgency: Major Service Needs and Minor Service Needs.

Major Service: Within three (3) working days, Daavlin will exercise all due effort to make any necessary repairs to a machine that is inoperable, unless otherwise arranged.

Minor Service: Within seven (7) working days, Daavlin will exercise all due effort to make any necessary repairs to a machine that has a minor malfunction, unless otherwise arranged. Such minor repairs include but are not limited to malfunctioning ballasts or lamp holders, inoperative beeper, inoperative lamp position (other than burned out lamps).
The following types of work are examples of "maintenance" and do not fall within the scope of the warranty: Required periodic calibration (lamp output control), replacement of lamps, cleaning and leveling the equipment. Any work performed by Daavlin technicians or subcontractors which falls outside the warranty will be billed at the prevailing service rate at the time of service.

Responsibilities of the Buyer

Upon delivery from a common carrier, the buyer must open and examine contents of the shipment. Any damage must be reported to the shipping carrier and to Daavlin within 24 hours of receipt of merchandise.
The buyer must cooperate in conducting minor diagnostic work when a problem is being reported. This may entail running one or more short operational routines and answering diagnostic questions. Failure to answer diagnostic questions may result in being charged for on-site service calls.

Always call the Daavlin Service Department if you think a problem exists before any service work is performed.

Contact Information

US & All Countries	1-800-322-8546	USA & Canada
Excluding those in	1-419-636-6304	Overseas
Europe	1-419-636-1739	Fax
	service@daavlin.com	E-Mail
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Bryan, Ohio 43506 USA

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13. READER'S COMMENTS FOR USER MANUAL

Dear Valued Customer:

In order to improve the quality and utility of our manuals and inserts, our company needs the active cooperation and participation of its users. Your comments, as a user, will be greatly appreciated and reviewed for information in the next revision of this document.

Please comment on the completeness, accuracy, organization, usability, and readability of this manual on the insert below, and return to Daavlin.

Thank you.

Please cut out along the dotted lines and mail to the following address:
Daavlin
P.O. Box 626
Bryan, Ohio 43506

Have you found errors in this document? ☐ Yes ☐ No

If Yes, specify by page. _____

Is the manual easy to read? ☐ Yes ☐ No

If No, specify by page. _____

Is the manual easy to understand? ☐ Yes ☐ No

How can this document be improved? _____

Rev Number and Date of Manual (found at the bottom of each page) _____

Other Comments: _____

MNL-00015 [1]: Lumera Operation Manual

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All Signature (Date and Time) shown in this report are in GMT.

Type	MNL	**Status**	CURRENT	
Effective Date	30-Nov-2022	**Periodic Review Date**	30-Nov-2023	
Owner	MHAIR	**Organization Unit Name**	DAV	Daavlin
Description	This manual serves as an instruction on how to operate the Lumera phototherapy device.			

Revision Notes (7)

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