ML24000

OPERATION AND SERVICE MANUAL

Daavlin
Let's Be Clear

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1.0 Introduction

Thank you for purchasing a Daavlin Phototherapy Unit. The use of light for the treatment of photoresponsive skin disorders has been our passion since 1981. From the beginning we have been devoted to providing our customers with the highest quality products coupled with industry leading customer service.

At Daavlin, we are always keeping track of new developments and are doing our best to implement the latest findings in our products. We appreciate receiving feedback from the medical community and patients, so we can further improve our products. If you have any comments or suggestions, please contact our Customer Service department and your input will be channeled to the appropriate person.

The purpose of this manual is to instruct users on the proper methods of operation and general maintenance. In addition to this, the manual also addresses important information regarding device specifications, warnings, treatment protocols and warranty information. Please take a moment to read the entire operation manual before operating your Daavlin phototherapy unit.

Here at Daavlin we are proud of our tradition of development and innovation in the field of phototherapy, and we are honored that you have chosen us for your phototherapy needs. Let's be clear. Our commitment to you starts…Now!

Sincerely,

The Daavlin Distributing Company

205 West Bement Street
P.O. Box 626
Bryan, OH 43506-0626

Phone: (800) 322-8546, (419) 636-6306
Fax: (419) 636-1739
Email: info@daavlin.com
Website: www.Daavlin.com

2.0 Indications for Use

The ML24000 UVA-1 Phototherapy Unit is a full body medical ultraviolet device, which is intended for the treatment of atopic dermatitis (eczema) on all skin types (I-VI).

WARNING: Do not use these devices for anything other than their intended purposes.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or any other practitioner licensed by the law of the state in which he/she practices.

3.0 Intended Use

The ML24000 UVA-1 Phototherapy Unit is a medical ultraviolet light source, which is intended for use by or under the direction of a physician for therapeutic treatment for individuals who require ultraviolet or visible radiation for diagnose skin disorders.

4.0 Classifications

FDA:	Class II Device
93/42/EEC:	Class IIa Device
IEC 60601-1:	Class I Device
Pollution Degree:	Class II
Mode of Operation:	Non-continuous
IEC/EN 62471:2006 UV Risk Group:	Risk Group 2 (Moderate-Risk)

WARNING: This device is designed for intermittent operation only and not for continuous use. The device should not be cycled continuously. For treatments greater than 20 minutes in duration the device should be either turned off or left idling for a minimum of 50% of the administered treatment time, e.g. a treatment lasting 40 minutes in duration should be followed by a cool down period of 20 minutes.

5.0 Operating Specifications

Ambient Temperature:	15°C to 30°C (59°F to 86°F)
Relative Humidity:	10% to 95%, Non-condensing
Liquid Ingress Rating:	IPX0 (This device does not have protection against ingress of water.)
Ocular Hazard Distance:	3 Meters (9.84 Feet)
Altitude:	≤ 2000m

WARNING: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

6.0 Transport and Storage Specifications

Ambient Temperature:	-40°C to 70°C (-40°F to 158°F)
Relative Humidity:	10% to 95%, Non-condensing
Atmospheric Pressure:	50 kPa to 106 kPa
Altitude:	≤ 2000m

7.0 EMC Precautions

The devices contained in this manual have been tested and found to comply with the EMC limits of the international standard IEC 60601-1-2. These limits are designed to provide reasonable protection against interference in a typical medical installation. The system can radiate radio frequency energy if not installed in accordance with the instructions and may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If the system does cause interference with other devices, which can be determined by turning the system off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Re-orient or relocate the receiving device
- Increase the separation between the equipment
- Connect the System into an outlet on a circuit different from that to which the other device(s) is connected

Consult the manufacturer or field service technician for help.

7.1 Environmental Specifications

The device should be used in an electromagnetic environment as described below.

Table 1 Electromagnetic Emissions

Emissions Test	Conformity	EMC Environment Guide
RF Emission Following CISPR 11 (EN 55011)	Group 1	Test unit only radiates RF energy for internal use in powering lamps, and it seems unlikely that nearby medical devices would be affected.
RF Emission Following CISPR 11 (EN 55011)	Class B	The device is suitable for healthcare environment operation in hospitals and clinics
Limits for Harmonic Current Emissions Following IEC 61000-3-2	Class A	The device is suitable for healthcare environment operation in hospitals and clinics
Limitation of Voltage Changes, Voltage Fluctuations, and Flicker Following IEC 61000-3-3	Compliant	The device is suitable for healthcare environment operation in hospitals and clinic

Table 2 Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Actual Level
Electrostatic discharge immunity test following IEC 61000-4-2	+/- 8kV (conductive surfaces, coupling planes) +/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)	+/- 8kV (conductive surfaces, coupling planes) +/- 2kV, +/- 4kV, +/- 8kV, and +/- 15kV (non-conductive surfaces)
Radiated, radio-frequency, electromagnetic field immunity test following IEC 61000-4-3	80 MHz to 2.7GHz @ 10.0 V/m	80 MHz to 2.7GHz @ 10.0 V/m
Electrical fast transient/burst immunity test following IEC 61000-4-4	+/- 2kV	+/- 2kV
Surge immunity test following IEC 61000-4-5	+/- 0.5 kV, +/- 1.0 kV, +/- 2kV	+/- 0.5 kV, +/- 1.0 kV, +/- 2kV
Conducted Immunity test following IEC 61000-4-6	0.15 MHz to 80 MHz @ 3.0 Vrms 6.765 MHz to 6.795 MHz @6.0 Vrms 13.553 MHz to 13.567 MHz @ 6.0 Vrms 26.057 MHz to 27.283 MHz @ 6.0 Vrms 40.66 MHz to 40.70 MHz @ 6.0 Vrms	0.15 MHz to 80 MHz @ 3.0 Vrms 6.765 MHz to 6.795 MHz @6.0 Vrms 13.553 MHz to 13.567 MHz @ 6.0 Vrms 26.057 MHz to 27.283 MHz @ 6.0 Vrms 40.66 MHz to 40.70 MHz @ 6.0 Vrms
Power frequency magnetic field immunity test following IEC 61000-4-8	50 Hz, 30 A/m	50 Hz, 30 A/m
Voltage dips and interruptions immunity test following IEC 61000-4-11	30% Reduction for 500 mS at 0 degrees, 100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270,315 degrees, 100% Interruption at 5000 mS at 0 degrees	30% Reduction for 500 mS at 0 degrees, 100% Interruption for 10 mS at 0, 45, 90, 135, 180, 225, 270,315 degrees, 100% Interruption at 5000 mS at 0 degrees

Table 3 Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHZ to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. [a] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

a. Field strength from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m

8.0 Electrical Specifications

The device is manufactured in the following electrical configurations. Always refer to the identification label of the device to determine which electrical configuration the device is manufactured to.

- Mains input = 230V, 3~, 60Hz, 100A Operating = 230V, 3~, phase to phase
- Mains input = 400V, 3N~, 50Hz, 100A Operating = 230V~, single-phase (phase to neutral)

9.0 Site Selection

A site should be chosen within reach of the specified electrical connection (refer to the Facility Requirements Guide) and where the unit can be left in place without obstructing traffic flow. It is important that the unit be properly grounded. The site should not be in any area where water or moisture might collect and should be protected from access by children and other unintended users.

WARNING: To avoid the risk of electric shock this equipment must only be connected to a supply mains with a protective earth.

CAUTION: This device is a Class A Medical Device suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

10.0 UVA-1 Output Spectrum

The treatment light is generated by 24 1000 Watt High Intensity Discharge Metal Halide Lamps. The light emitted is in the UVA band with a primary emission range of 350-400 nanometers. The output spectrum of the system is shown in Figure 1.4. Some of the light outside the 350-400nm peak emission range is typical for these types of systems and does not affect safety or efficiency.

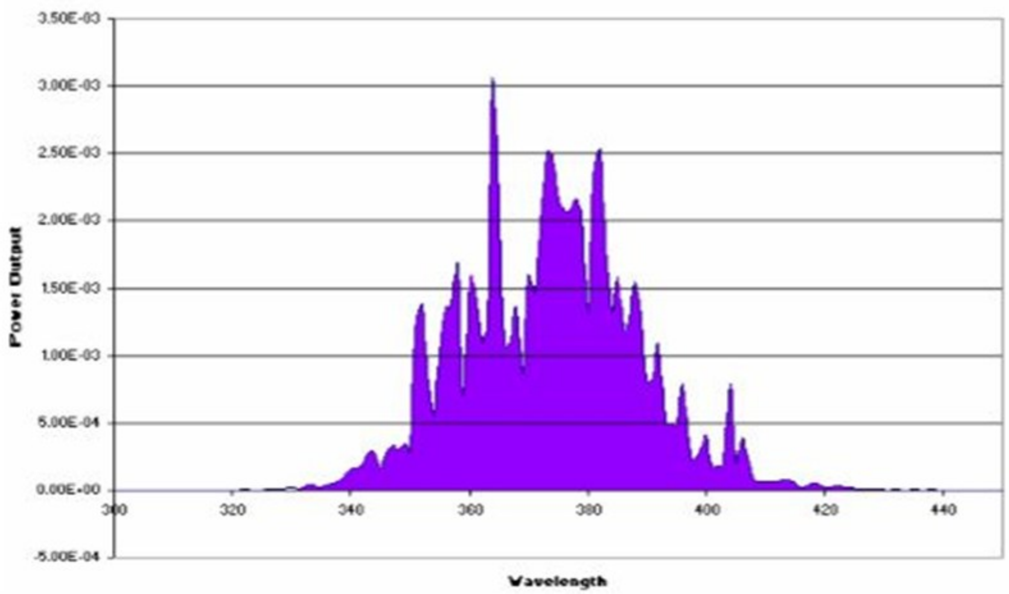


Figure 1

10.1 Irradiance Specifications

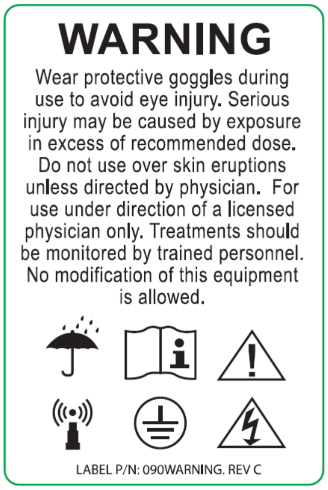
The power output of your unit is dependent on the style and quantity of lamps contained within the device. The power output of your unit is fixed and cannot be altered by the user. The power output value of your device, as measured at the factory, is shown on the *Power Output Certificate* included with your device literature. The table below represents the possible output range of your unit.

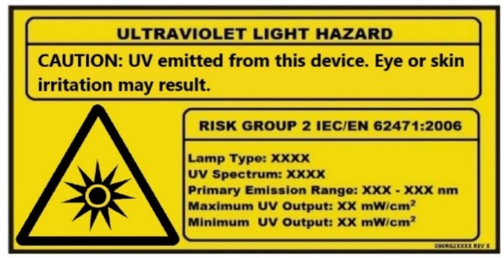
Lamp Style:	High Intensity Discharge
Minimum Output:	9" Away: 60 mW/cm^2 (+/- 10%)
Maximum Output:	9" Away: 100 mW/cm^2 (+/- 10%)

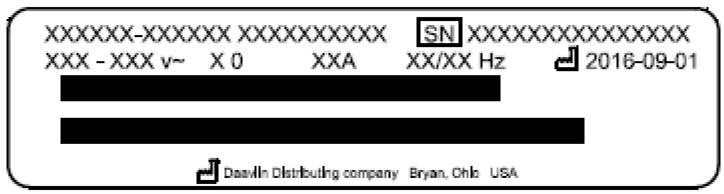
Note: Irradiance measurements taken with Gigahertz-Optik P-9710-1 Optometer.

10.2 Labels and Symbols

A warning label is affixed to your device in a prominent and easily readable position. Please read the label carefully as it contains important safety information for you. According to IEC/EN 62471:2006, sources of optical radiation are classified into risk groups subject to their potential photobiological hazard. This device falls under Risk Group 2 (Moderate-Risk) and does not pose a severe hazard due to the natural aversion response to bright light or thermal discomfort. A Risk Group 2 warning label, which also includes the primary emission range and potential output range, is affixed to your device in a prominent and easily readable position. In addition to the warning labels mentioned above, an identification label indicates the serial number and date of manufacture that is specific to your device.

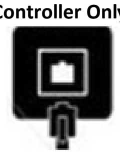






The ML24000 features a Data Connection port located on the Device. This port is only to be used as a data only connection to the ML24000 Flex Controller Box. This data port is identified by the following label.

To ML24000
Controller Only



The ML24000 Flex Controller Box comes affixed with two additional labels containing important information regarding the Flex Controller Box model number, system rating, and DC input jack rating. This information is identified by the following labels.

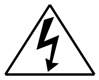
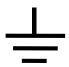
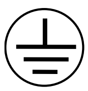
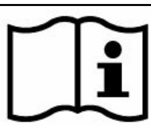
Volts: 230~ *Phase:* One *Amps:* 1.5 *Hertz:* 50

Model: 101MLRTB220

Daavlin Distributing Company Bryan, Ohio USA

Voltage: 12 VDC *Current:* 1.5A

The following is a chart detailing all symbols located on the cabinet and their definitions:

	DANGEROUS VOLTAGE
	ATTENTION, CONSULT ACCOMPANYING DOCUMENTS
	NON-IONIZING RADIATION
	EARTH (ground)
	PROTECTIVE EARTH (ground)
	ALTERNATING CURRENT
3N~	THREE-PHASE ALTERNATING CURRENT WITH NEUTRAL CONDUCTOR
	OPERATING INSTRUCTIONS
	REFER TO INSTRUCTION MANUAL/BOOKLET
To ML24000 Controller Only 	DATA ONLY ETHERNET PORT
L1, L2, L3	PHASE CONDUCTORS

11.0 Training Requirements

Phototherapy services require staff that have appropriate training, knowledge, and clinical skills in order to ensure effective outcomes and quality care for patients. Staff must be assessed as being competent and safe in order to provide phototherapy treatments that maximize benefit and minimize adverse effects. Recommended training requirements include:

- Staff should be either a physician, nurse, or any other practitioner licensed by the law of the state or country in which he/she practices
- Training and experience in dermatology is important to provide holistic patient care. This knowledge includes:
    - Anatomy and the Physiology of the skin
    - Recognition and understanding of skin diseases
    - Skin assessment
    - Understanding of photoresponsive diseases
- Theoretical knowledge of phototherapy and its use
- A period of supervised practice for approximately 3 months with a competent practitioner
- Managers should ensure that staff members have, or are provided with, the appropriate level of training and education needed prior to administering phototherapy services.

12.0 Warnings & Cautions

12.1 Electrical Shock Hazards

- Warning: A qualified, licensed electrician must wire the service for this device in accordance with all national and local codes and the electrical instructions provided in the accompanying Service & Installation Instructions manual. Unauthorized personnel should not open the panels. The Daavlin Service Department should be consulted before any service is performed.
- Warning: Prior to each use, always verify that the device is in correct working order and operating condition and plugs, sockets, lamps, and electrical cables and connections are not worn or damaged.
- Warning: Upon detection or discovery of faulty, worn, or damaged component(s), factory authorized service personnel must replace the component(s) in accordance with the accompanying Service & Installation Instructions manual and test the device for proper functionality prior to placing the device in use again.
- Warning: Before opening the device casing to perform maintenance or service, read, understand, and follow all warnings, cautions, and instructions in this and the accompanying Service & Installation Instructions manual, both of which are provided with the device.
- Warning: Before opening the device casing to perform maintenance or service, disconnect the device from the power source.
- Warning: The device must never be directly exposed to liquids of any kind. If the device is inadvertently exposed to liquid, it must be tested for safe function before being placed in operation again.

- Warning: No modification of this equipment is permitted. Unauthorized modification will void the warranty and may result in hazardous or improper device operation.

12.2 Ultraviolet Light Exposure & Bodily Injury Hazards

- Warning: All treatments must be administered under the direction of a licensed physician only.
- Warning: To protect the eyes during operation, the operator, patient and anyone in view of the device must wear UV blocking glasses or tightly fitting goggles designed to block 100% of all UVA and UVB light from the eye area when worn. Failure to do so may result in severe burns or long-term injury to the eyes. **Always use Daavlin-approved eyewear purchased through Daavlin.**
- Warning: Serious injury may be caused by exposure in excess of recommended dose.
- Warning: Do not use over skin eruptions without express consent from the attending physician.
- Warning: Do not treat when the patient present has noticeable burns.
- Warning: If a patient experiences burning, never treat the patient until the noticeable effects of burning subside, and always reduce the subsequent treatment time.
- Caution: Trained personnel must monitor all treatments.
- Caution: To protect unaffected skin during operation, the operator, patient and anyone in view of the device must generously apply UV blocking skin protection to all exposed skin that the attending physician does not intend to treat with ultraviolet light.
- Caution: Center patients between the lamps during treatment to avoid over exposure to isolated areas of the body.

12.3 Equipment & Property Damage Hazards

- Warning: A qualified, licensed electrician must wire the service for this device in accordance with all national and local codes and the electrical instructions provided in the accompanying Service & Installation Instructions manual.   Unauthorized personnel should not open the panels. The Daavlin Service Department should be consulted before any service is performed.
- Caution: Orient the power cord to protect it from being pulled or otherwise damaged.
- Caution: The device must never be directly exposed to flowing or splashing liquid or water.
- Caution: The device should be placed a minimum of 1 inch (2.5 cm) away from surrounding walls, devices, and furniture to ensure proper cooling airflow.
- Caution: The room that the device is placed in should be vented to allow free air displacement to ensure the device and surroundings remain cool.
- Caution: Only original components and accessories should be used with the device to avoid damage.
- Caution: The device contains glass lamps. Avoid excessive force to the device to prevent lamp damage.
- Caution: The device control system display is susceptible to damage from excessive force. Avoid excessive force to the control system to prevent damage.
- Caution: If the device malfunctions, cease operation immediately. If the device is placed close to other equipment, it is possible that the cause is interference by external noise sources and fields, in which case you should follow the remedies found under EMC Precautions. If the device continues to malfunction cease operation and contact the Daavlin Service Department.

- Caution: This device is a Class A Medical Device suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
- Caution: This device is designed for intermittent operation only and not for continuous use. The device should not be cycled continuously. For treatments greater than 20 minutes in duration the device should be either turned off or left idling for a minimum of 50% of the administered treatment time, e.g. a treatment lasting 40 minutes in duration should be followed by a cool down period of 20 minutes.

13.0 Unlocking the Device

To prevent unauthorized use, the device will "self-lock" when left idle for twenty (20) minutes. To unlock your unit follow the instructions below.

1. Press any key to awaken your unit.
2. Your device will display the word "CODE".
3. The factory preset key code is "0007". Press the ▲ key seven times. Your unit will now display "0007".
4. Press the "ENTER" key to unlock your unit.

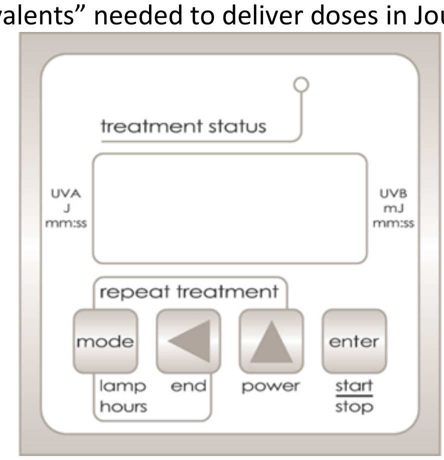
14.0 Changing or Disabling the Key Code

If you would like to disable or personalize your factory default key code, please contact the Daavlin service department at 1-800-322-8546 for step by step instructions.

15.0 Flex Timer Instructions

15.1 Determining a Treatment Time

When using time as a dose, there are two treatment methods that can be used. The simplest is to start at a prescribed time and then increase treatment times by a specific time increment or by a percentage. Another method is to use the factory power output levels (shown on the *Power Output Certificate*) to determine estimated "time equivalents" needed to deliver doses in Joules (UVA-1).



To determine a "time equivalent", consult the laminated Time Chart that is provided and find the power output on the top row (horizontal axis). The numbers in the left most column (vertical axis) represent a range of potential treatment doses. Find the dose then trace that row to the right until it intersects with the column corresponding to the factory power output of the device. The time equivalent is shown where the two lines intersect. For example, if the factory power output is 8.0 mW/cm^2 and the dose to be delivered is 2 Joules, then the appropriate treatment time will be 04:10. A partial time chart illustrating this is shown on the following page.

Note: For your convenience, and as an alternative to the UV time chart, the latest version of our free iPhone and Android application "Phototherapy Math" is available for download at the iTunes app store and Android market. It quickly calculates treatment times, backup safety times, and makes the calculation of dose and time increases simple. If using a PC, visit www.phototherapymath.com for a web-based calculator and additional information.

15.2 Partial UVA, UVA-1 Time Chart

	mW/cm2 / Joules	5	6	7	8	9	10	12	14
	1.0	03:20	02:47	02:23	02:05	01:51	01:40	01:23	01:11
→	2.0	06:40	05:33	04:46	04:10**	03:42	03:20	02:47	02:23
	3.0	10:00	08:20	07:09	06:15	05:33	05:00	04:10	03:34

15.3 Setting Up a Treatment Time

To administer a treatment, you must enter your desired treatment time. Based on the example above the treatment time will be 4:10.

1. Press any key to awaken the unit. The word "CODE" will appear.
2. Enter in your key code. Unless you have changed it, the factory preset key code is 0007.
3. Once the key code has been entered, the display should read 00:00.
4. Press the ▲ key until the first digit of your desired time is displayed. If the treatment time is one minute and ten seconds (04:10), the first digit will be a "4".
5. Press the ◄ key to move the "4" one space to the left. The display should read 00:40.
6. Press the ▲ key until the next desired number is displayed ("1" in this case). The display should read 00:41.
7. Press the ◄ key to move the "4" one space to the left. The display will now read 04:10.
8. When the desired time is displayed (in this case 04:10) 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.

To repeat the same dose for another exposure, press the END key to clear the display. Then press the MODE and POWER keys at the same time and release. This will automatically bring up the last treatment administered. Press ENTER to start the treatment.

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.

15.4 Special Functions of the Digital Timer

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

15.5 Special Notes

- The maximum time that can be entered is 59 minutes and 59 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.

15.6 Flex Timer Range and Accuracy

Time Range:	1 Second - 59 Minutes 59 Seconds (00:01 - 59:59)
Timer Accuracy:	+/- 5%
Sensor Accuracy:	+/- 10%

Timer and sensor accuracies are compliant with IEC 60601-2-75.

16.0 Treatment Protocols

16.1 MED Testing

The more accurate but more complicated method of determining a patient's initial dose is through MED testing. Because this is a cumbersome process, many doctors do not wish to determine a patient's initial dose in this manner. However, before we discuss the procedure in greater detail, let us first define the terms.

MED stands for Minimum Erythemal Dose and is defined as the minimal dose of UV that will cause marked erythema on a patient's skin. As an example, a skin type IV will have an MED somewhere within the range of 200-600 millijoules of narrow band UVB. See Protocols for all skin types and ranges.

MED testing results in a more accurate starting point. Because of the subjective nature of a patient's response to the skin-typing quiz, the empirical method is more subject to error. In many cases, testing will show that a patient may be more tolerant to ultraviolet than would have been suggested by simple skin typing.

It is important to start phototherapy patients at as high a dose as possible. Underdosing a patient causes excessive tanning that means that the patient must undergo more and more aggressive treatment just to overcome the natural UV screening effect of tanned skin. This results in an excessively high cumulative dose to clear the patient's disease.

When setting up a UVA-1 patient, the key element in determining exactly how much UVA-1 radiation the patient will receive is the MED. The first UVA-1 treatment is always a percentage of the MED that has been entered. Thereafter, each succeeding treatment is some percentage of the preceding dose. Each and every dose is mathematically related to the MED value, whether this value was determined by MED testing or by skin typing.

The following section provides instructions on exactly how MED testing is carried out in the doctor's office.

16.2 MED Testing Procedure

The first stage in performing MED testing is to determine the patient's skin type. The patient's skin type is then used to determine the dosages that will be used to perform MED testing. Many physicians use a simple table of questions to determine a patient's tolerance to light. The table is reproduced below:

Skin Type	History
Skin Type I	Always burns, never tans
Skin Type II	Always burns, sometimes tans
Skin Type III	Sometimes burns, always tans
Skin Type IV	Always tans, never burns
Skin Type V	Brown skinned (Chinese, Mexican American)
Skin Type VI	Black

Once you have determined the patient's skin type you can proceed to the testing stage.

16.3 Daavlin Dose Patch (sold separately)

The Daavlin Dose Patch is a disposable adhesive MED/MPD test panel. There are six exposure windows measuring 2cm x 2cm. The panel is applied directly to the patient's skin like a bandage. The Dose Patch is hypoallergenic and can be used for all skin types.

16.4 General Instructions for MED Testing

Daavlin Dose Patch

Dose Patch can be used on any part of body. Non-exposed areas of arms, buttocks and back are common test sites. Protect the patient's eyes and cover areas not being tested with UV blocking clothing or sunscreen. The person doing the testing should also take protective measures against incidental exposure.

Remove the two adhesive end pieces on the back of the patch. Apply the patch in the desired location. Make sure it is stretched tightly across the skin. Use two or more patches if more than six exposure levels are required.

Determine the doses you will test for (recommended doses below). Open exposure window #1. Begin the test by exposing the entire patch area to ultraviolet light source. As each dose level is reached, open exposure windows in consecutive order. The last window opened equals the lowest dose; the first window opened equals the highest dose.

The patient will need to return in 48 hours to have the test results read for UVA-1. The resulting MED will now be the initial MED for setting up the patient for the first treatment.

16.5 RECOMMENDED PROTOCOL FOR UVA-1

Irradiation 5 x week for 3 weeks (altogether 15 exposures) Determination of the UVA 1 MED prior to treatment Start with 1 MED if MED < 70 J/cm2. Increase of the dose by 20 % every time if there is not an erythematous reaction and by good tolerability until a maximal dose of 70 J/cm2.

NOTE: REFERENCE THE APPLICABLE TIME CHARTS SUPPLIED WITH YOUR ML24000 FOR DOSING TIMES

17.0 Care of Your Phototherapy Unit

17.1 Recommended Maintenance Schedule

Action	Frequency
Dusting of the unit and lamps	Once a month
Fully clean all internal reflectors, lamps, and protective acrylic	Annually
Power Output Measurement (Timer Only)	Every 100 hours of use and when lamps are replaced (Meters can be rented or purchased through Daavlin)
Replace lamps	UVA – Every 500-800 hours of use.

17.2 Cleaning/Disinfection

17.2.1 General Cleaning

For general use, use a clean non-abrasive cloth, not paper towels, and a mild cleaning solution such as Dawn Liquid Dishwashing Soap to gently wipe down the exterior of the device.

17.2.2 Low-Level Disinfection

To reduce micro-organisms on the patient-contacting surfaces, disinfect these surfaces between uses of the device, including when the same patient has the device for use. For disinfection while the same patient uses the device, we have tested several cleaners that do not degrade the Acrylic and can be seen in Table 4 Daavlin Tested Cleaners.

Cleaner/Solution	Contact Time
Monk brand Wipes	Follow the contact time instructions provided with the Monk brand Wipes
70% Isopropyl Alcohol	3 min

Table 4 Daavlin Tested Cleaners

1. Thoroughly wipe down the surfaces and allow contact time listed in Table 4 Daavlin Tested Cleaners.
2. Allow to air dry and inspect for visible contaminants.
3. If contaminants remain repeat until no visible containments remain repeat steps 0 and 2.

17.2.3 High-Level Disinfection

Follow a high-level disinfection protocol between the use of the device on different patients. Use a high-level disinfectant, such as Steris Corporation's Resert XL-HLD, and follow the manufactures guidelines. See also "FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices" available at: https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and

17.3 Cleaning of the Filter

A trained technician should clean the internal filters and cavities of the machine annually. Do not attempt to clean these filters without proper training, as certain solutions may damage the filters. **Only Daavlin authorized personnel should perform this function.**

Allow the filters to cool down.

Use a vacuum to remove dust from black filters on both sides of each lamp column.

Depending on the frequency of use and the location of the unit, the filters may collect dirt. This will impair UV intensity.

17.4 Relamping

Only Daavlin authorized personnel may carry out lamp replacement

The UV output of the lamps typically degrades to unacceptable levels after 500-800 hours of use. Only use the replacement lamps specified in this manual when relamping. Although other lamps may fit and light, they may also produce excess amounts of UVB which could be harmful to the patient. Always return lamp filters to their original position after relamping. Follow all federal and local regulations when relamping and disposing of discarded lamps.

Note: Always measure lamp intensity before and after lamp replacement. It is important to notify everyone concerned that the lamps have been replaced as patient exposure times may need adjusting.

17.5 Removing and Fitting Lamps

1. Measure lamp intensity of current lamp before replacement.
2. Switch the lamp off; allow the lamps to cool down.
3. Turn unit off at the breaker.
4. Remove the air filter brackets and acrylic from each column.
5. Put on latex gloves when handling filters and lamps.
6. Remove the three clear filters from each column and place them in a safe location.
7. Remove the six colored filters from each column and place them in a safe location.
8. Grasp the end of the lamp and pull from lamp socket.
9. Insert the new lamps into the lamp sockets.
10. Replace the filters in reverse order that they were removed.
11. Replace the air filter brackets and acrylic for each column.
12. Reconnect the unit at the breaker.
13. Switch on the unit and measure UV intensity in order to be able to redefine the necessary exposure times.

Notify all those involved with the unit's operation of the lamp replacement as patient exposure times may need adjusting.

17.6 Resetting Your Lamp Hours

Whenever the lamps are changed in your device, it is important to reset the lamp age to zero.

To Reset lamp hours to zero when installing new lamps, take the following steps:	
Press MODE, then ◄ and ENTER all at the same time	**Then…**
Press ▲	**Then…**
Press ENTER	**Then…**
Press MODE and ◄ at the same time	**Then…**
Press END	

17.7 Troubleshooting

Problem	What To Do
Deposits in the glass cylinder of the lamp	It is quite normal for deposits to collect in the glass cylinder of the lamp after the lamps have been switched off. These deposits are the result of the metal halide precipitating inside the lamp when it cools down. They will disappear completely once the lamp is switched on and warms up again.
The lamp does not ignite.	When troubleshooting the problem, please note in certain, rare cases, it may take up to 2 minutes for a lamp to ignite (such a lamp will ignite normally once it has been ignited several times). *Make sure that the main switch is on. *Make sure the unit is properly plugged in. (Check all plug connections.) *Check all fuses in the unit and the building. *If the lamp is defective, change the lamp. *If the ignition unit is defective, contact the Daavlin Service Department. *If it is impossible to ignite the lamp or if the lamp produces only a weak, bluish light, switch the device off immediately to prevent damage to the ignition units. Contact Daavlin Service Department.
Filters have slipped or are defective	Never operate the unit if the filters have slipped or are defective. Switch the device off. Contact Daavlin Service Department.

17.8 Spare Parts and Accessories

Description	Daavlin Part No.
Metal Halide High Pressure Lamp, 1000 W	101MLLAMP
Colored Filter (260mm x 230mm)	100MLFLTRGLSRD
Clear Filter (639mm x 292mm)	100MLFLTRGLSCLR
UVA-1 Irradiance Meter	925GOX97
Dose Patch (box of 100)	101MTDP100
Cleaning Wipes	908WPDISMNK
UV Safety Glasses – Fit Over Green	905GR
UV Safety Goggles with Elastic Band – Red	101RDG

18.0 Clinical Benefit

UV phototherapy normally consists of two distinct phases: Clearing and Maintenance. The clearing phase increases exposure to the light to the levels required to clear the skin, but over a long enough period to minimize discomfort to the patient. The maintenance phase is employed to extend the benefits of the clearing phase treatment, while limiting total exposure. During the maintenance phase, treatments are normally continued at the last level reached during the clearing phase.

Typically, treatments are very brief and occur about three times a week. Results vary, but psoriasis symptoms commonly begin to improve in as little as 6 -8 treatments; vitiligo usually begins to re-pigment within about 8 weeks. Phototherapy is safe for most patients, including those who are pregnant, elderly or immuno-compromised.

19.0 Cybersecurity

All controllers require a key code/password to activate the treatment entry mode, thereby reducing device access only to qualified physicians and trained users. The Flex controller has no connection to the outside world.

20.0 Warranty

20.1 Limited Warranty Policy

This Limited Warranty is provided to the original purchaser (the “Purchaser”) of the Daavlin device (the “Equipment”). Daavlin warrants Equipment to conform with the Equipment specifications and be free from defects in material and workmanship during the device Warranty Period. No warranty is made as to useful lamp life or as to reduction in ultraviolet output due to any cause. DAAVLIN MAKES NO OTHER WARRANTIES OF ANY KIND WHATSOEVER TO PURCHASER OR ANY THIRD PARTIES WITH RESPECT TO THE EQUIPMENT AND HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Product	Warranty Period
New Equipment	1 Year
Remanufactured Equipment	90 Days
Lamps	90 Days

20.2 Warranty Coverage

This Limited Warranty applies only to Equipment or components found to be defective due to materials and workmanship. This Limited Warranty does not apply when Equipment is purchased for the purposes of renting commercially to customers for home use. This Warranty does not apply to any Equipment which has been used, repaired or altered outside the factory in any way so as to affect the design, or operated in any way other than in accordance with our operating instructions. The Limited Warranty does not apply to Equipment failure or damage caused by shipping or customer abuse, misuse, or accident, incorrect customer installation, improper electrical service, lack of proper maintenance, and Acts of God. This Limited Warranty does not extend to repairs made necessary by use of parts or accessories not recommended by the manufacturer. Daavlin shall not be responsible for any indirect, incidental, special, punitive, or consequential damages of Purchaser. Daavlin does not provide end support for Microsoft Windows software installed on PCs that are part of a Daavlin phototherapy system. A PURCHASER'S SOLE REMEDY UNDER THIS LIMITED WARRANTY IS REPAIR OR REPELACMENT OF THE EQUIPMENT.

20.3 Customer Responsibility

In the event that warranty service is requested, the Purchaser must reasonably cooperate with Daavlin to verify the warranty claim of the Purchaser, including conducting minor diagnostic work. Failure to participate in diagnostic work may result in being charged for on-site service calls. The Purchaser must allow Daavlin, at Daavlin's option, to inspect the Equipment or component parts on request.

20.4 Warranty Service

During the warranty period, Daavlin will, at Daavlin's option, repair or replace any Equipment or components that appear to have been defective in material or workmanship, with new or remanufactured materials. 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 Limited Warranty. In such situations, Daavlin will cover freight expenses in the continental USA to ship products covered under warranty both to and from Daavlin's servicing center if the product fails during the first three months. If the product fails after three months during the warranty period, the customer is responsible for in-bound freight charges while Daavlin pays freight charges back to the Purchaser. All Equipment ships ground unless the Purchaser covers costs for expedited shipping. Daavlin is not responsible for any delays occurring during transport of the Equipment.

During the term of the Limited Warranty, Daavlin will, at Daavlin's option, arrange for a qualified service technician to repair or replace any defective systems or components as covered in accordance with the terms and conditions of this Limited Warranty. It will be at Daavlin's sole discretion whether subcontractors or Daavlin employed technicians will perform the required warranty service work. However, this Limited Warranty will be declared null and void if non-qualified technicians perform any repair or maintenance on the Equipment unless prior written authorization has been obtained from Daavlin. Even with Daavlin's authorization, Daavlin shall not be responsible or liable for any such work (in or out of warranty). Daavlin reserves the right to bill for labor, expenses, and services for requested "warranty" service trips which result in work not covered by this Limited Warranty. This may include, but is not limited to, a tripped circuit breaker, an unplugged machine, or a blown fuse.

20.5 Disposal

Please contact Daavlin at 1-800-322-8546 for disposal instructions for the unit and/or cabinet and all accessories.

20.6 Other Services

Extended warranties are available and may be purchased from Daavlin's aftermarket sales department.

In the event that this Limited Warranty conflicts with other warranties included in Daavlin's Equipment manual, the terms and conditions of this Limited Warranty shall prevail.

20.7 Contact Information

USA & Canada:	1-800-322-8546
Overseas:	1-419-636-6304
Fax:	1-419-636-1739
E-Mail:	service@daavlin.com
Website:	www.daavlin.com
	Daavlin 205 W. Bement Street PO Box 626 Bryan, Ohio 43506 USA

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