ML24000 with Smart Touch™ control system
Operation Manual

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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,

Daavlin Distributing Company

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

Phone: (800) 322-8546, (419) 636-6304
Fax: (419) 636-1739
Email: info@daavlin.com
Website: www.Daavlin.com

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2.0 Indications for Use

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

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.

ML24000 with Smart Touch™ control system manual is an integral part of the ML24000 device. Anyone operating the device must read and understand this manual in its entirety before operating the device, including all warnings, cautions, and instructions. Instructions vital to the safety of persons operating the device, receiving treatment from the device and property, including but not limited to the device, are contained in this manual. If these instructions are not understood and followed, damage and serious injury, including death, may occur.

This manual conforms to all regulatory standards applicable to the device at the time of manufacture of the device and the original printing of the manual. All rights are reserved for the device design and all associated materials, including software and mechanical applications and methods, trade names and logos used. The device and manual are subject to change without notification. No part of this manual may be reproduced or used for any purpose other than operating the device unless express written consent is obtained from Daavlin.

The ML24000 PC, full body phototherapy device, is a medical ultraviolet cabinet, which is intended for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I – VI).

3.0 Intended Purpose/Use

The ML24000 PC UVA-1 Phototherapy Unit is a full-body medical ultraviolet device, 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 diagnosed 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)

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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)
Ambient Luminance:	250 – 500 lux

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

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- 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

The ML24000 should be used in an electromagnetic environment as listed 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 ML24000 device is suitable for healthcare environment operation in hospitals and clinics
Mains Harmonics Following IEC 61000-3-2	Class A	The ML24000 device is suitable for healthcare environment operation in hospitals and clinics
Mains Voltage Dips and Flicker Following IEC 61000-3-3	Compliant	The ML24000 device is suitable for healthcare environment operation in hospitals and clinic

Table 2 Electromagnetic Immunity

Emissions Test	IEC 60601 Test Level	Actual Level
ESD Following IEC 61000-4-2	+/-2kv, 4kv, 6kv, and 8kv (conductive surfaces) +/-2kv, 4kv, 8kv, and 15kv (non-conductive surfaces)	+/-2kv, 4kv, 6kv, and 8kv (conductive surfaces) +/-2kv, 4kv, 8kv, and 15kv (non-conductive surfaces)
Bursts following IEC 61000-4-4	+/- 2kv	+/- 2kv
Surges following IEC 61000-4-5	+/- 2kv	+/- 2kv
Voltage drops, etc. following IEC 61000-4-11	5% for 10ms, 40% for 100ms, 30% for 500ms, 0% for 5000ms	5% for 10ms, 40% for 100ms, 30% for 500ms, 0% for 5000ms
H-Field following IEC 61000-4-8	3 A/m	3A/m

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8.0 Accuracy

The measuring device will maintain a 5% level of timer accuracy and a 10% level of sensor accuracy if the device is calibrated every one hundred (100) hours as recommended. The Smart Touch™ control system will display a reminder message when calibration is due. Please contact Daavlin for Calibration Instructions. Timer and sensor accuracies are compliant with IEC 60601-2-75.

9.0 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 = 230VAC, 3Φ, 60Hz, 100A; Operating = 230VAC, 3Φ, Line-to-Line
- Mains Input = 400VAC, 3Φ with Neutral (Wye), 50Hz, 100A; Operating = 230VAC single phase, Line-to-Neutral

10.0 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.

Figure 1 Warning Label

In addition to the warning label mentioned above, an identification label indicates the serial number and date of manufacture that is specific to your device.

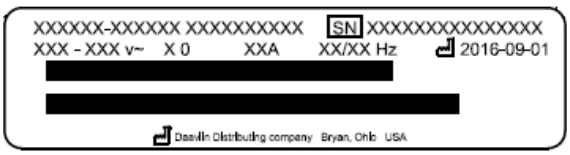

Figure 2 Identification Label

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ML2400 PC models feature one Ethernet port located on the back of the Device. This Ethernet port is only to be used as a data only connection to the Smart Touch™ control system PC. This Ethernet port is identified by the following label.

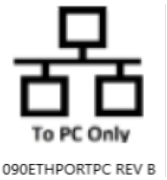

Figure 3 Data Only Ethernet Port Label

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 Xs in this example will be filled in with the correct lamp type, UV spectrum, primary emission range, and the min and max output.

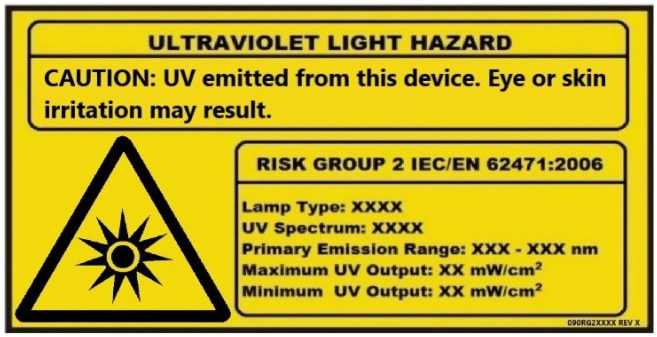

Figure 4 Risk Group 2 Label

CE Packaging Label (CE Devices Only)

Figure 5 CE Packaging Label

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

Symbol	Definition
	DANGEROUS VOLTAGE
	NON-IONIZING RADIATION

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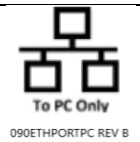
Symbol	Definition
⏚	EARTH (ground)
⏚	PROTECTIVE EARTH (ground)
Φ	PHASE
	OPERATING INSTRUCTIONS
L1, L2, L3	PHASE CONDUCTORS
	DATA ONLY ETHERNET PORT
	KEEP DRY
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	DANGER HIGH VOLTAGE
	CE MARK LABEL

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Symbol	Definition
EC REP EMERGO EUROPE Westervoortsedijk 60 6827 AT Arnhem The Netherlands 090REPEU REV D	EU REP LABEL (CE ONLY DEVICE) LABEL
For supply connections, use wiring materials suitable for at least 105 °C 090SUPPLYCONN REV B	WIRING MATERIALS LABEL (CE DEVICES ONLY)
MD 090MD Rev A	MEDICAL DEVICE LABEL

11.0 Delivery and Inspection

When you first receive the device, please inspect the shipping crate or box.

Any signs of shipping damage must be noted on the delivery receipt that you will be asked to sign by the delivery driver. Be sure to open the crate and verify that there is no damage to your unit before the driver leaves. If it is not possible for you to inspect your unit before the driver leaves, we recommend you write “Concealed damage possible. Further inspection required” on the delivery receipt. If damage is discovered after unpacking the unit, save all packing materials and call Daavlin at 1 800 322 8546 for inspection and repair.

Note: The delivering carrier must be notified of any shipping damage within twenty-four (24) hours to protect your right to an insurance claim.

Note: As part of the claims process the delivering carrier may require that a damage inspection be conducted. The delivering carrier may request to conduct the inspection at the delivery site, provided that a mutually agreed upon date and time can be established, or they may elect to collect the package for inspection at their facilities.

12.0 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. The device should be positioned in such a way that the power inlet or circuit breakers on the device are easily accessible. 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.

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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.

13.0 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.

14.0 Important Safeguards and Warnings

14.1 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.

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- 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.

14.2 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.
- Caution – Use of controls or adjustments or performance of procedures other than those specified herein result in HAZARDOUS radiation exposure

14.3 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,

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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.

15.0 Smart Touch™ control system Accessories

15.1 Printer (Domestic Units Only)

A printer is provided and should be connected to the Daavlin ML 24000 PC. The printer is used to obtain hard copy records of individual treatment data and treatment history data. Always read, understand, and follow all instructions provided with the printer before putting it in to operation.

15.2 USB Mass Storage Device

A Removable USB drive is provided with the device. It can be used to transfer and backup patient data and to install software revisions and upgrades. If this item is lost or needs to be replaced for any reason, you will be responsible for the cost to replace this item. This item is required for specific maintenance functions.

15.3 Glasses and Goggles

Two pairs of tightly fitting UV blocking goggles for patient use and two pairs of UV blocking glasses for operator use are provided with the machine. Clean the goggles and glasses between uses using a 70% isopropyl alcohol, or a solution of 1 part bleach 3 parts water solution. Soak the goggles and glasses in the solution for 5 minutes, then rinse thoroughly with water. Dry the goggles and glasses before re-using.

Caution: Patients must wear tightly fitting UV blocking goggles at all times during treatment to avoid serious eye injury. Device operators must wear UV blocking glasses at all times when in the area of the device while it is in operation to avoid serious eye injury. The goggles and glasses may come into contact with breached dermis during use, therefore an individual pair of goggles is recommended for each patient and an individual pair of glasses is recommended for each operator.

16.0 Theory of Operation

16.1.1 Control System

Primarily, the unit is operated through input provided at the Smart Touch™ control system, consisting of a standalone PC and Daavlin Smart Touch™ operator interface software.

16.1.2 System Logon

Input to the control system is limited to established users. To enter input into the control system, the established user must “logon” to the system. By default, each device is installed with one established user, which is assigned with the user ID, “Admin”. Upon setup, each user ID, including the “Admin”

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user ID, is assigned the case sensitive password “daavlin”. Before an assigned device operator can control the system, including the “Admin”, he/she must log on using an established user ID and default password. Upon initial login, each user must change the system assigned default password.

16.1.3 User Profiles

To manage control of system users, the Smart Touch™ software has three (3) pre-programmed user profiles: Admin, Supervisor, and Operator. Each user profile has different levels of authority. When subsequent users are established in the system, a user profile is assigned. Assigning and changing the user profile should be considered carefully, as it controls user input to patient treatments.

Example: A relatively new phototherapist might only be granted authority to treat patients within the standard treatment protocols. The authority to add patients or significantly alter their treatment programs could be restricted.

Example: A highly experienced phototherapist might be granted the authority to add patients, select their skin type, edit their protocols, edit or develop global protocols with only the authority to set up new users being withheld.

16.1.3.1 Admin

The Admin profile is assigned only to the “Admin” user ID and is intended for use by the primary control system administrator and has the highest level of authority, giving the assigned user unrestricted use of the system. Furthermore, log on under this profile allows the user to establish and edit subsequent user IDs for additional users.

16.1.3.2 Supervisor

This user ID can be assigned to multiple users. By default, users assigned with this profile have level-one and level-two functionality. Functionality can be increased or decreased simply by selecting or deselecting the functionality options.

16.1.3.3 Operator

This user ID can be assigned to multiple users. By default, users assigned with this profile have level-one functionality. Functionality can be increased or decreased simply by selecting or deselecting the functionality options.

16.1.4 Treating Patients

Authorized users enter and save patient data including name, skin type, treatment type (UVA-1) treatment frequency, etc. into the system database. Based on this information, the system automatically chooses and assigns a pre-programmed treatment protocol. Each time a treatment is initiated for a patient, the system will choose the appropriate treatment from the protocol. At this point, the user may adjust and or accept the treatment dose, based on the authority of his/her user profile. Upon acceptance of the dose, the treatment is administered by starting the machine from the Smart Touch™ control panel.

16.1.5 Treatment Protocols

The system is pre-programmed with default treatment protocols, which are intended to be used as treatment guidelines. The attending physician is the determining authority on all treatment doses. The treatment protocols can be edited “globally” or by individual patient. When a protocol is edited globally, all patient’s setup subsequent to the change will follow the new protocol. Patients’ setup with that protocol prior to the change will follow the previous protocol. When a protocol is edited for an individual patient, subsequent treatments for that patient only will be affected by the changes.

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16.1.6 History

When a treatment is administered, the system records relevant information in a history file. History saved includes Patient Name, Date, Time, Treatment Delivered, Treatment Duration, and User. The history record can be viewed or printed by authorized users at any time. History records are printed for individual treatments immediately following a treatment or for a patient's entire history from the history menu.

17.0 Initial Use

17.1 Software Startup

Once the device has been properly installed select the Smart Touch™ icon, from the Windows® Desktop, by double clicking or double tapping (touch screens only) it. The system will display the Splash screen (See Figure 6 Splash Screen) while the software is in the startup processes, which are Connecting and Loading. The process in progress will be displayed in the top left corner of the screen (See Figure 6 Splash Screen). Upon setup, the Splash screen will disappear, and the User Logon screen will appear (See Figure 7 User Logon Screen), indicating the Smart Touch™ software and the Daavlin ML24000 phototherapy cabinet is ready for operation.

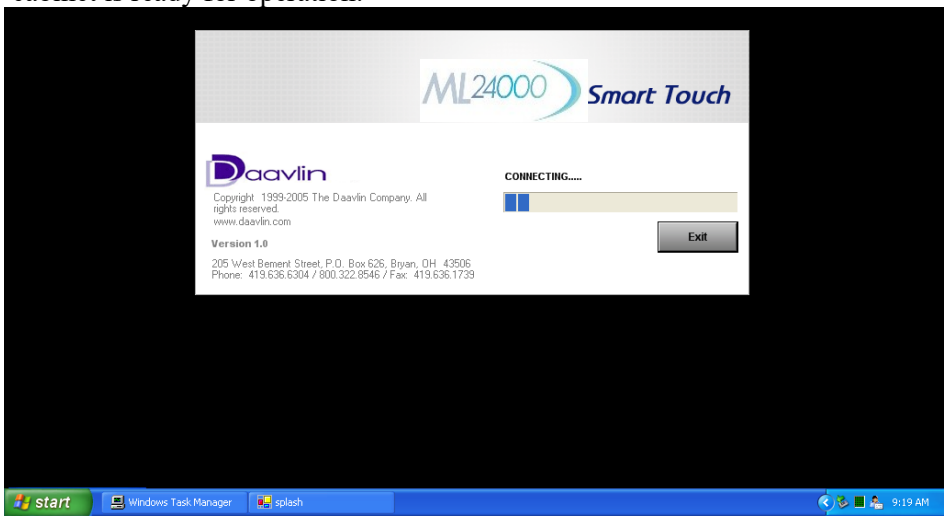

Figure 6 Splash Screen

18.0 Administrator Selection

Prior to the initial use of the device, the primary device administrator, usually the attending physician, charge nurse, or head phototherapist, must be appointed and their user profile established in the Smart Touch™ control system. This appointment should be considered carefully, as the system administrator will have full system operation capabilities including data manipulation, protocol editing, user setup, and system calibration.

18.1 Administrator Setup

1. At the User Logon screen (See Figure 7 User Logon Screen), select the *Admin* user in the **Select Username** field by tapping it once. The *Admin* user name will appear in the **User Name** field and the cursor will appear in the **Password** field.

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2. Type the default password in the **Password** field using the keyboard at the bottom of the display, and then tap the **Logon button** once. The default password is "daavlin", and it must be entered in all lowercase letters.

Figure 7 User Logon Screen

Note: The system will now require the administrator to select and setup a new logon password. It is important to remember the new password, as the system will only allow subsequent logon using the new password. Passwords should be kept secret, as the system will record the username in system activity history. The **Password** is limited to 1 – 10 characters of any combination.

3. The Change Password screen will be displayed (See Figure 8 Change Password Screen). The **Old Password** field will be populated automatically by the default password, and the cursor will be in the **New Password** field.
4. Type the new password in the **New Password** field, and then tap the **Tab** button once. The cursor will move to the **Confirm Password** field.
5. Retype the new password, and then tap **Save** once. The Main Menu screen will be displayed (See Figure 9 Main Menu Screen), and the system administrator setup is complete.

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Figure 8 Change Password Screen

Figure 9 Main Menu Screen

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19.0 New User Setup

Only authorized users can perform this function.

Warning: Entering improper or erroneous data in the New User Setup process could result in serious patient injury. The data entered when setting up a patient will determine which preprogrammed protocol is selected for the patient treatments, and therefore directly impacts the patient's treatment dose. Only highly skilled and trained personnel should perform this process.

1. Logon to the Smart Touch™ control system and tap the **User Setup** button once from the Main Menu (See Figure 9 Main Menu Screen). The **Select a Username** screen will be displayed.
2. Tap the **Add New User** button once. The User Setup screen will be displayed (See Figure 10 User Setup Screen) and the cursor will appear in the **User Name** field.
3. In the **User Name** field, type the user's common name or nickname, and tap the **Tab** key once. (This is the name that will appear in the Username List). The cursor will move to the **Last Name** field.
4. In the **Last Name** field, type the user's last name / family name, and tap the **Tab** key once. The cursor will move to the **First Name** field.
5. In the **First Name** field, type the user's first name / given name and tap the down arrow button once in the **User Status** drop down window.

   Note: The **User Name**, **Last Name**, and **First Name** are limited to 1 - 10 characters of any combination.

6. Select the type of user, "Operator" or "Supervisor", from the **User Status** drop down window by tapping once on the chosen type. The default system capabilities will automatically be selected based on the chosen user type. A selected system capability is denoted by the appearance of a check mark in the white selection box next to the capability description.
7. If desired, select or deselect system capabilities to be granted to the user by tapping once on the white box next to the capability. To select or deselect an entire level, tap once on the white selection box next to the level heading.
8. Save the user's profile by tapping once on the **Save Changes** button. The message "Saving User Data" will appear during the save process, and then the message "User Data Saved" will appear momentarily. The user is now saved, and the system is ready for the next operation.
9. Subsequent users can be added by repeating steps 2 – 8 of this instruction.
10. To exit to the Main Menu screen, tap once on the **Exit** button. Instructions for performing the other User Setup functions are located in the Edit User Data section of this manual.

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Figure 10 User Setup Screen

20.0 User Logon

Warning: It is important that all user's logout when immediate system activity will not be performed by the user, when the system is left unattended, or when other individuals could have unsupervised access to the system. Logout will prevent unauthorized users from performing system functions that are potentially hazardous to patients and property.

To ensure accurate records, always verify that the date and time shown at the top left corner of the display and the user name located at the top right corner of the display are accurate before proceeding.

20.1 Initial Logon

Upon initial logon of a new user, the Smart Touch™ software will require the user to change the default password.

1. At the logon screen (See Figure 7 User Logon Screen), select the assigned user name in the **Select Username** box by tapping it once. The selected user name will appear in the **User Name** field and the cursor will appear in the **Password** field.

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2. Type the default password in the **Password** field using the keyboard at the bottom of the display, and then tap the **Logon** button once. The default password is "daavlin", and it must be entered in all lowercase letters.

Note: The system will now require the user to select and setup a new logon password. It is important to remember the new password, as the system will only allow subsequent logon using the new password. Passwords should be kept secret, as the system will record the user name in system activity history. The **Password** is limited to 1 – 10 characters of any combination.

3. The Change Password screen will be displayed (See Figure 8 Change Password Screen) with the **Old Password** field automatically populated by the default password, and the cursor will be in the **New Password** field. Type the new password in the **New Password** field, and then tap the **Tab** button once. The cursor will move to the **Confirm Password** field.
4. Retype the new password, and then tap **Save** once. The Main Menu screen will be displayed (See Figure 9 Main Menu Screen) the user password will be changed, and logon is complete.

Note: Although all default buttons will appear on the Main Menu screen, only those operations that the user is authorized to use will be functional. Functioning buttons are shown in black, while non-functioning buttons are shown in gray.

20.2 Subsequent Logon

Only authorized users can perform this function.

1. At the User Logon screen (See Figure 7 User Logon Screen), select the assigned user name in the **Select Username** box by tapping it once. The selected user name will appear in the **User Name** field and the cursor will appear in the Password field.
2. Type the chosen user password in the **Password** field using the keyboard at the bottom of the display, and then tap the **Logon** button once. The Main Menu screen will appear (See Figure 9 Main Menu Screen), indicating that the user logon is complete.

Note: Although all default buttons will appear on the Main Menu screen, only those operations that the user is authorized to use will be functional. Functioning buttons are shown in black, while non-functioning buttons are shown in gray.

21.0 New Patient Setup

Only authorized users can perform this function. To successfully complete new patient setup, data is required in the following fields, areas, and boxes: **Patient PIN**, **Last Name**, **First Name**, **Birthdate (mm/dd/yyyy)**, **Language Preferences**, **Skin Type**, **Treatment Type**, and **Schedule**.

1. Logon to the Smart Touch™ control system and access the Main Menu screen.
2. Select the **Add New Patient** button, by tapping it once. The Patient Setup screen will be displayed (See Figure 11 Patient Setup Screen), and the cursor will appear in the **Patient PIN** field.
3. Enter the desired patient personal identification number (PIN) in the **Patient PIN** field using the keyboard at the bottom of the display and press the **Tab** key once to move to the **Last Name** field.
4. Type the user's last name / family name and tap the **Tab** key. The cursor will move to the **First Name** field.

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5. Type the user's first name / given name and tap the **Tab** key. The cursor will move to the **M.I.** field.

   Note: Entry of the **Patient PIN**, **Last Name**, and **First Name** is limited to any combination of 1 - 10 alphanumeric characters.

6. If desired, type the first initial of the patient's middle name. The cursor will automatically move to the **mm** field of the **Birthdate**.
7. Type the two-digit numeric equivalent of the month in which the patient was born. The cursor will automatically move to the **dd** field.
8. Type the two-digit numeric equivalent of the day in which the patient was born. The cursor will automatically move to the **yyyy** field.
9. Type the four-digit numeric equivalent of the year in which the patient was born. The cursor will automatically move to the **PASI** field.

   Note: The birth date must be entered in the following format mm/dd/yyyy, for example, enter 05/14/1971 for a patient whose birthday is the 14th day of May 1971.

10. If desired, type the patient's PASI score, or tap the **Tab** key once.
11. If desired select an established diagnosis code from the diagnosis drop down box.

    Note: Diagnosis code selected may limit treatment options depending on custom setup.

12. If desired select an established billing code from the billing drop down box.
13. Tap once on the down arrow button in the **Languages Preferences** drop down box. A list of all available language options for patient-directing voice announcements is displayed.
14. Tap once on the language preferred by the patient. If the patient prefers not to hear voice announcements, select the "No Voice" option. The selected language will be displayed in the drop-down box and the drop down list will be minimized.
15. Select the patient's preference for voice announcements, "Male" or "Female", by tapping once on the applicable circle in the **Language Preferences** box.

Warning: The patient-directing voice announcements of this device are safety features used to inform the patient of the treatment status, protective procedures, and system failures. While selecting the "No Voice" option will prevent the patient from hearing these important safety messages, graphic messages will continue to be displayed on the external control system to keep the operator informed of the system status.

16. Select the patient's skin type by tapping once on the circle next to the appropriate skin type in the **Skin Type** box.
17. Select the type of treatment intended for the patient by tapping once on the applicable circle in the **Treatment Type** box.
18. Select the treatment frequency schedule by tapping once on the circle next to the desired schedule in the **Schedule** box.

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Warning: Entering improper or erroneous data in the Patient Setup process could result in serious patient injury. The data entered when setting up a patient will determine which preprogrammed protocol is selected for the patient treatments and therefore directly impacts the patient's treatment dose. Only highly skilled and trained personnel should perform this function under the guidance of the attending physician.

19. Save the patient's profile by tapping once on the **Save** button. The message "Saving Patient's Data" will appear during the save process and then the message "Patient's Data Saved" will appear momentarily. The patient data are now saved, and the system is ready for the next operation.
20. Subsequent patients can be added by repeating steps 2 – 19 of this instruction.
21. To exit to the Main Menu, tap once on the **Exit** button. Instructions for editing patient's profiles are located in the Edit Patient Data section of this manual.

Figure 11 Patient Setup Screen

22.0 Selecting a Patient

Only authorized users can perform this function. Searches are performed to select patients for treatment or to view and edit patient data.

1. From the Main Menu press the **Edit Patient** button for editing or viewing patient data or press the **Treat Patient** button to administer a patient treatment and then follow one of the three search methods listed below.

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Figure 12 Select a Patient Screen

22.1.1 Search Options

The three available patient search methods are:

- **By PIN**: In the **Select Patient by PIN…** field, enter the patient's PIN and press **Go**. The Treatment Setup screen or Patient Setup screen, as applicable, will appear. To perform a search using this method, the complete and exact patient PIN must be used.
- **By Name**: Select any of the **Search by Name…** fields (**Last Name**, **First Name** and **M. I.**) then type one or more letters of the associated name and press **Search**. A list of patient names from the database in alphabetical order beginning with the first letter typed will be displayed. To select the desired patient, tap once on the patient's name.
- **Browse the Entire Database**: Press the **Search** button with all fields blank. A list of all the names in the database will appear in alphabetical order. Tap the down arrow or drag the slide downward until you find the patient's name. Touch the name to select it.

At any time during this process, press the **Cancel** button to exit to the Main Menu.

23.0 Treating a Patient

Only authorized users can perform this function.

1. Log on and access the Main Menu.
2. Select the patient to treat following the **Selecting a Patient** instructions in this manual.
3. The Treatment Setup screen will appear (See Figure 13 Treatment Setup Screen). This screen displays the Previous, Current (proposed), and Next treatment information, based on the assigned protocol. If the secondary treatment option was chosen when the patient was set up, a proposed secondary treatment will also be displayed.

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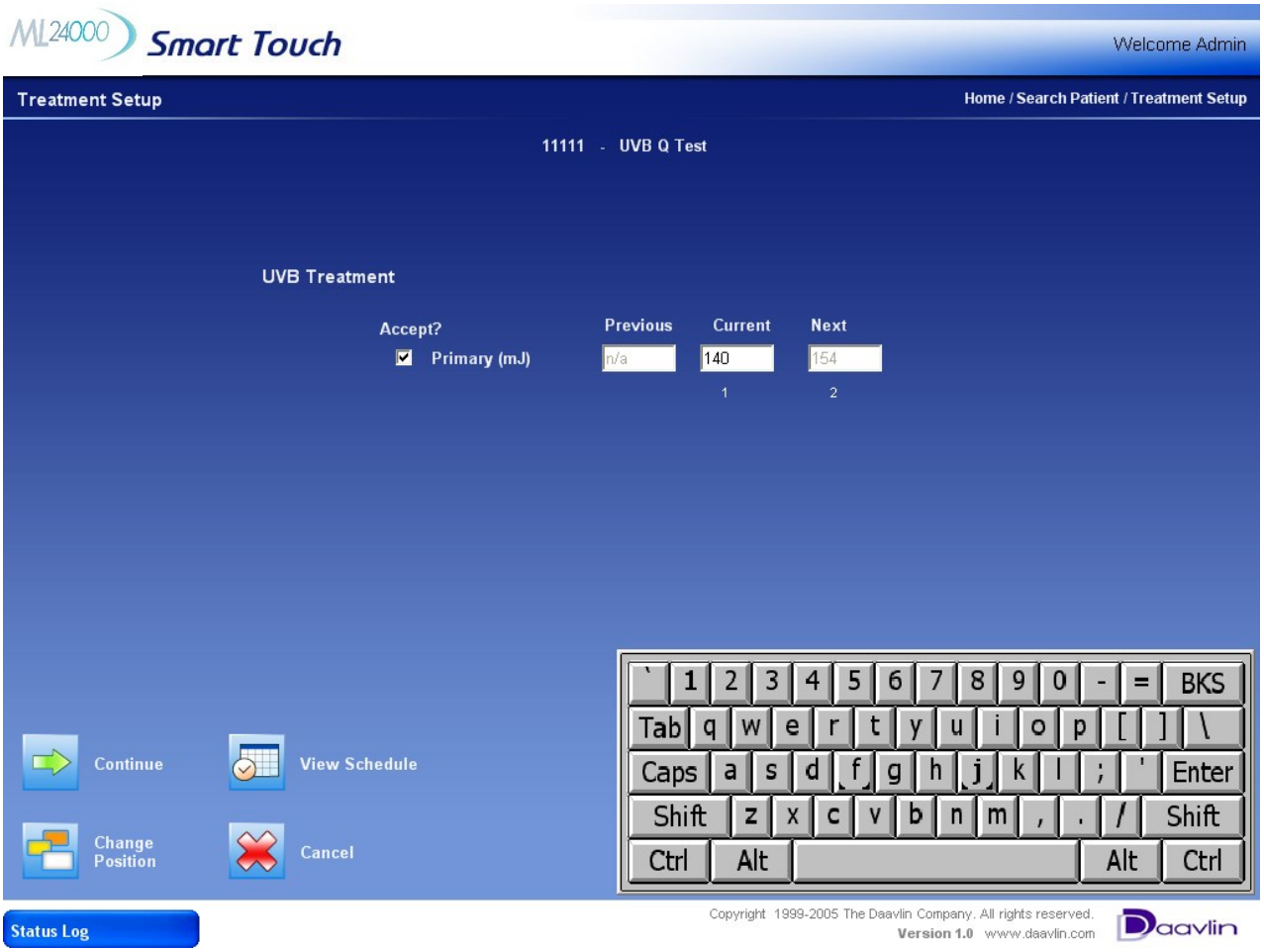

Figure 13 Treatment Setup Screen

4. If no variation from the recommended current dose is desired, check the **Accept?** box for both the primary and secondary treatment (if giving a secondary treatment). If no secondary treatment is necessary, do not check the secondary **Accept?** box. See the Changing the Treatment As-You-Go section of this manual for instructions on changing the recommended dose before treating.

<u>Warning</u>: To prevent serious patient injury, always verify the dose displayed in the Current field before accepting the dose and continuing with the treatment process.
To avoid serious injury by administering the wrong treatment to the patient, always verify that the patient's name and PIN shown at the top left corner of the display match the patient receiving treatment before administering the treatment.

5. Press the **Continue** button. The Treatment in Process screen will appear (See Figure 14 Treatment in Process Screen).

<u>Note:</u> If the **Accept?** Box is left blank and the **Continue** button is pressed, no treatment will be given. A window will appear reminding you to select a treatment. You must select (check) one box to continue.

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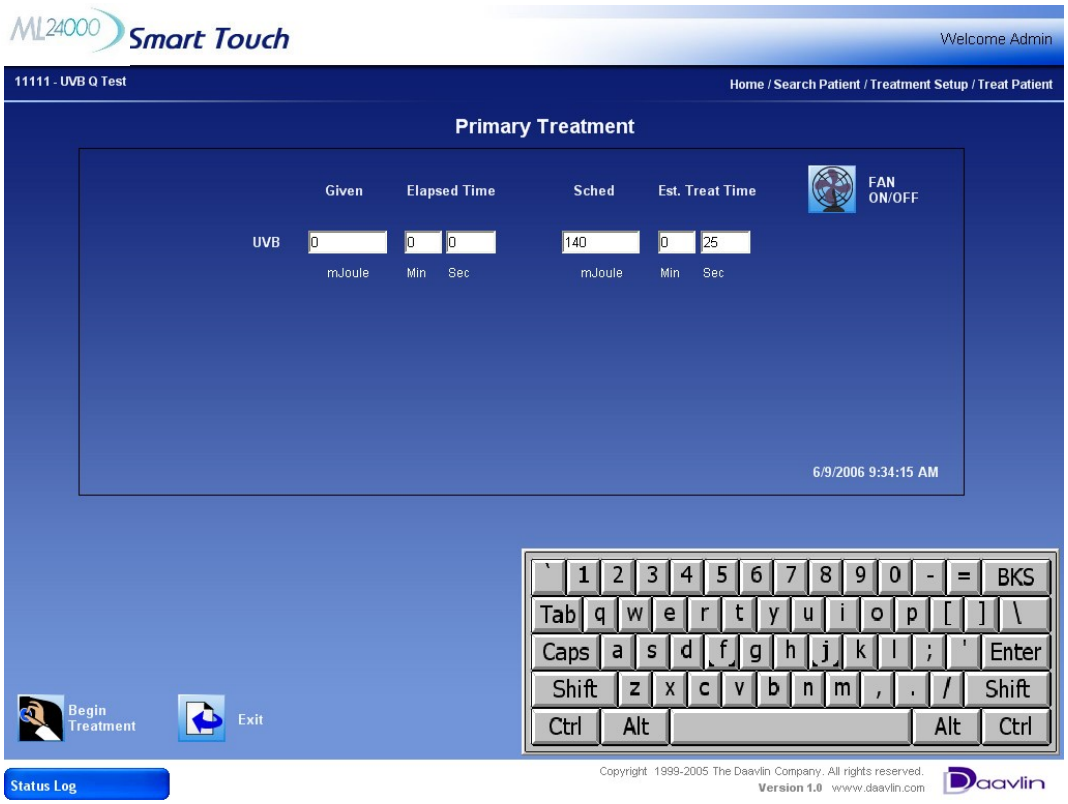

Figure 14 Treatment in Process Screen

6. Press **Begin Treatment** or press the yellow Lamp button on the inside button box to start the treatment process. After a ten second delay, the lamps will turn on and the treatment will begin. To cancel the treatment without proceeding, press **Exit**.
7. During treatment, the scheduled dose (**Sched**) and the estimated treatment duration (**Est. Treat Time**) are shown on the right side of the display and the accumulated dose (**Given**), and elapsed treatment time (**Elapsed time)** are shown on the left side of the display. When the treatment is complete, the lamps will turn off and the Treatment Complete screen will appear (See Figure 15 Treatment Complete Screen).
8. If a printed treatment summary is desired, press the **Print Treatment Summary** button to obtain a hard copy record of the treatment. The printed record includes: Patient name, PIN, Prescription, the delivered treatment time and dose, the scheduled treatment dose, the date and time of treatment and the User's name.
9. Press the **Exit** button to return to the Main Menu screen

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Figure 15 Treatment Complete Screen

23.1 End of Protocol Treatments

Upon entry of all treatments the operator will be prompted with a message asking them if they would like to add a treatment to the protocol. The operator must select "Yes" before selecting any other field to add a subsequent treatment or "No" to exit the treatment screen. The system will no longer suggest a dose but will leave the CURRENT DOSE field blank. The operator must determine and enter each treatment dose from that time forward, with limitations. See the Warning Rules and Authorities section of this manual for those limitations.

23.1.1 History

The Smart Touch™ software maintains a complete treatment history of each patient.

1. To access a patient's historical records, press **Edit Patient** from the Main Menu.
2. Press the **View/Edit Schedule** button, on the Edit Patient Screen.
3. Then press the **View History** button to move to the Patient History screen.
4. Use the >>> or <<< (scroll) keys to view the entire history.
5. Press the **PRINT** button to print a hard copy of the Patient's entire treatment history.

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24.0 Changing the Treatment As-You-Go

Warning: Entering improper or erroneous data when changing the treatment dose as-you-go could result in serious patient injury. Be sure to understand How Protocols Work before changing a patient's treatment dose. Only highly skilled and trained personnel should perform this process.

24.1 Changing the Proposed Dose

Only authorized Users can perform these functions. The Users must be logged in and in the Treatment Setup screen.

1. From the Treatment Setup screen (See Figure 13 Treatment Setup Screen), make desired changes to the dose in the **Current** field.

   Note: When entering the new dose, be sure to use decimal points as appropriate. For example, a dose of one and a half joules should be entered as 1.5 J.

2. Put a check in *User Data*
3. in the box under the check box labeled **Accept?** to indicate that the dose is acceptable for the treatment.
4. Press the **Continue** button. The Treatment in Process screen will appear.

25.0 Note: The treatment in process screen will appear if the newly proposed dose does not exceed built-in limitations or the operator has the authority to make the proposed change. Otherwise, a warning will be displayed on the screen. See the 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

26.0 Cybersecurity

Daavlin's Smart Touch controller exists on an isolated network. USB ports are active. The ethernet port is active. Most Smart Touch controlled devices utilize a UV4001 board. There is no connection, wired or wireless, to any external network and/or the World Wide Web. The ethernet port is an active network port on the Linux system. The SD card is active. A physical jumper can

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be configured to boot from the SD slot. The SD slot is not available external to the device. There is no driver for the USB slot, rendering it inactive. One Smart Touch controlled device utilizes a UV3001 board. There are no ethernet ports affixed to the board, however, a Perle adapter is connected to a D-SUB connector to provide an ethernet port. This ethernet port is an active network port on the Linux system. There are no SD ports or USB ports

Warranty and Contact Information section of this manual for system limitations on how they may be overridden.

26.1 Changing Position

To move a patient's treatment forward or backward in the protocol, follow these instructions.

1. While at the Treatment Setup Screen (See Figure 13 Treatment Setup Screen), press **Change Positions**. The Change Protocol screen will appear.
2. Use the >>> or <<< (scroll) keys to view the entire protocol.
3. Find the position in the protocol (past or future) that fits the patient's needs and select it.
4. A message, which requires confirmation, will be displayed verifying the new position. Press **Yes** to proceed or **No** to cancel.
5. If accepted, the new position will become the current dose.

27.0 <u>Note:</u> If the position is moved higher in the protocol and it exceeds the standard safety limit increase from the previous dose, a warning stating that the "dose entered is high" is displayed. Press Yes to proceed or No to cancel. If the user has the authority to accept this change and override the warning, the system will proceed. If not, the Authorization Screen will appear. Please see the 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

28.0 Cybersecurity

Daavlin's Smart Touch controller exists on an isolated network. USB ports are active. The ethernet port is active. Most Smart Touch controlled devices utilize a UV4001 board. There is no connection, wired or wireless, to any external network and/or the World Wide Web. The ethernet

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port is an active network port on the Linux system. The SD card is active. A physical jumper can be configured to boot from the SD slot. The SD slot is not available external to the device. There is no driver for the USB slot, rendering it inactive. One Smart Touch controlled device utilizes a UV3001 board. There are no ethernet ports affixed to the board, however, a Perle adapter is connected to a D-SUB connector to provide an ethernet port. This ethernet port is an active network port on the Linux system. There are no SD ports or USB ports

Warranty and Contact Information section in this manual.

29.0 Warning Rules and Authorities

The Smart Touch™ control system has been designed to provide flexibility in providing treatments while ensuring safety and protection from poor judgment. When an operator whose authority is limited to treating within established limits enters a dose that is beyond those limits, the system responds in two ways:

A warning is displayed, denoted by a gray message window when a dose is entered that is slightly beyond limit. To proceed, press **Yes,** or to return to the previous screen, press **No**.

If the operator selects **Yes**, and the dose selected is beyond the protocol limits, an Authorization PIN is requested. A red message window will appear and a list of authorized users will be provided. To proceed, one of the listed users will have to enter their **User Name** and **Password** then press **Continue** to accept the changes. If the changes are not acceptable then press the **Cancel** button to return to the previous screen.

Figure 16 Authorization Screen

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29.1 **Rules for Warning Messages**

The authorization rules applicable throughout the system are described below:

29.1.1 When Treating or Editing a Patient's Protocol

A warning will be displayed when:

- The operator changes a dose to a value that is between 1 and 2 steps beyond the current dose

OR

- The operator changes a dose to a value that is greater than the largest difference between consecutive treatments for that treatment schedule.

- If the time since the last treatment is greater than the **Maximum Time between Treatments (Authorization is Not Required)** but less than the **Maximum Time between Treatments (Authorization is Required)**.

OR

- If the time since the last treatment is less than 18 hours. (See Treatment Variables).

An Authorization PIN will be required when:

- The difference between the current dose and the previous dose is two times greater than the largest difference between consecutive treatments for that schedule.
- If the time since the last treatment is greater than Maximum Time between Treatments (Authorization is Required). (See Treatment Variables).

30.0 Edit Patient Data

Only authorized users can edit patient data.

1. Logon to the Smart Touch™ control system.
2. From the Main Menu, select the **Edit Patient** button by tapping it once. The Select a Patient screen will appear (See Figure 12 Select a Patient Screen).
3. Follow the instructions in the Selecting a Patient section of this manual. Once the patient has been selected, return to these instructions and continue with the desired edit function listed below.

30.1 Notes

To add, edit, or view patient specific notes for the selected patient, tap the **Patient Notes** button once. Add, edit, or view notes as desired in the Patient Notes screen (See Figure 17 Patient Notes Screen). Close the Patient Notes screen and save additions or changes to the notes by tapping the **Ok** button once or close the Patient Notes screen without saving additions or changes to the notes by tapping the **Cancel** button once.

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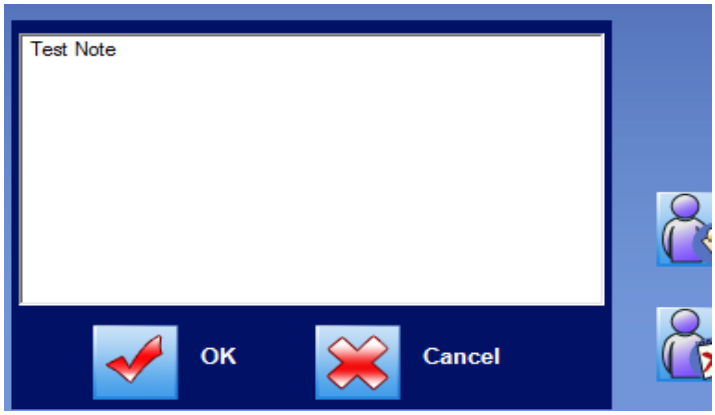

Figure 17 Patient Notes Screen

30.2 Delete

To delete the data for the selected patient, tap the **Delete Patient** button once. A window will appear as a reminder that this action cannot be undone. To proceed with permanently deleting the patient and all records associated with the patient, tap the **Yes** button once. To exit back to the patient edit screen without deleting the patient and all associated records, tap either the **No** button once or the **Cancel** button once.

30.2.1 Personal Data

To edit **Last Name**, **First Name**, **M. I.**, or **Birthdate**, follow these instructions:

1. Tap twice on the appropriate field to highlight and replace all data in the field. The data highlighted in blue will be replaced with new data as it is typed.
2. When all editing is complete, tap the **Save** button once to save the data.
3. Tap once on the **Exit** button to return to the Main Menu.

To edit **Language Preferences**, follow these instructions:

1. Tap the down arrow button once in the **Languages Preferences** drop down box. A list of all available language options for patient-directing voice announcements is displayed.
2. Tap once on the language preferred by the patient. If the patient prefers not to hear voice announcements, select the "No Voice" option. The selected language will be displayed in the drop-down box and the list will be minimized.
3. Edit the patient's preference for voice announcements, "Male" or "Female", by tapping once on the applicable circle in the **Language Preferences** box.

Warning: The patient-directing voice announcements of this device are safety features used to inform the patient of the treatment status, protective procedures, and system failures. While selecting the "No Voice" option will prevent the patient from hearing these important safety messages, graphic messages will continue to be displayed on the external control system to keep the operator informed of the system status.

30.2.2 Treatment Data

To edit a patient's protocol or a global protocol, follow the instructions in the *Edit Protocols* section of this manual. The Skin type and Treatment type cannot be changed for a particular patient once a treatment has been administered for that patient.

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31.0 Protocols

31.1 As Required Protocols

The As Required Protocol is an open protocol, which is not self-adjusting. This protocol allows the User (if they have the authority) to manually enter in a dose as needed. This protocol will always suggest the previous dose as the current dose each time the patient is treated. If treatment adjustment is required, then the User can make the adjustments as-you-go or prior to the treatment in the View/Edit Patient's Schedule screen.

Note: Reference the applicable time charts supplied with your ML24000 for dosing times.

31.2 End of Protocol – Maintenance Treatments

When a patient's protocol has reached its end (becoming maintenance therapy), the User must establish the dose for each subsequent treatment. This operates the same as if the patient was on an **As Required Protocol.**

31.2.1 After a protocol has ended

1. Each time the patient is selected for a treatment a gray message box appears asking "Do you wish to add another treatment", select **Yes** to proceed or select **No** to cancel the treatment.
2. If you wish to add additional treatments before a treatment is selected, see 26.3 Edit Protocols**.**

31.3 Edit Protocols

31.3.1 Global Protocols

Only authorized users can edit global protocols. Editing global protocols will only affect patients that are set up in the system and assigned the edited protocol after it has been edited. Editing global protocols will not affect patient treatment schedules that are already set up in the system at the time the protocol is edited.

1. Logon to the Smart Touch™ control system.
2. From the Main Menu, tap the **Edit Global Protocols** button once. The Global Protocol Setup selection screen will appear (See Figure 18 Global Protocol Setup Selection Screen).
3. Determine which protocol shall be edited and select the applicable protocol attribute by tapping the associated circle in the **Skin Type**, **Treatment Type**, and **Schedule** boxes once.

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Figure 18 Global Protocol Setup Selection Screen

4. To proceed to the Global Protocol Setup edit screen (See Figure 19 Global Protocol Setup Edit Screen), tap the **OK** button once, or to cancel and exit to the Main Menu screen, tap the **Cancel** button once.

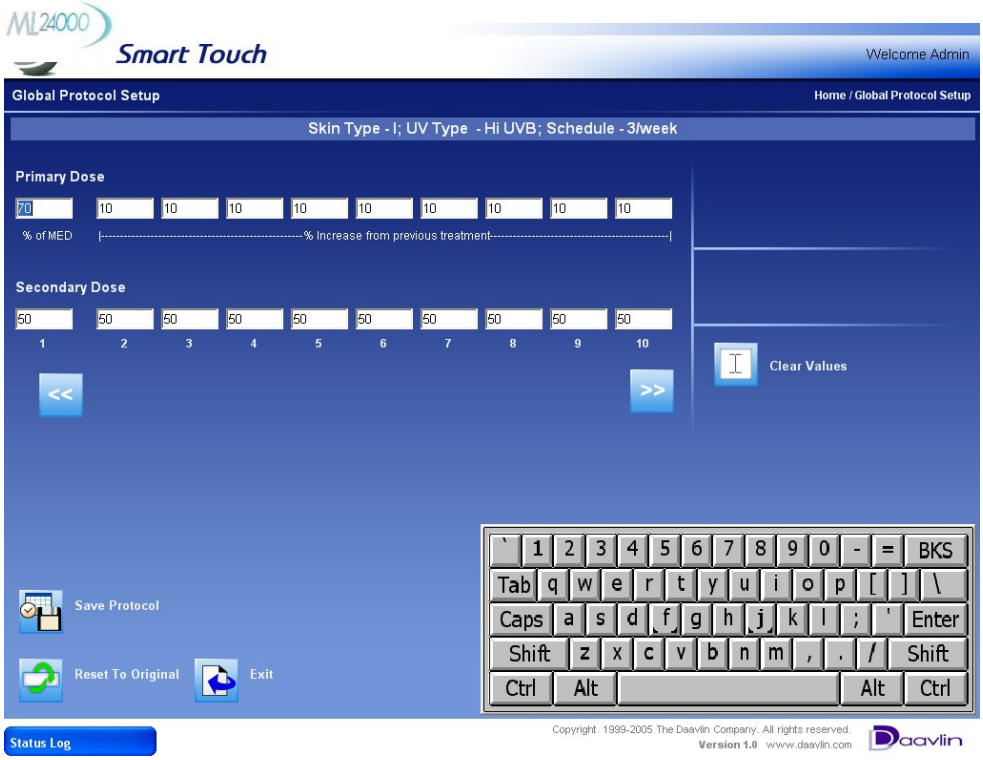

Figure 19 Global Protocol Setup Edit Screen

<u>Warning</u>: Changing protocols can be dangerous and can result in treatments that will seriously injure patients. Be sure to understand *How Protocols Work* before making any changes to protocols. Always review the entire protocol after changes have been made and before it is implemented for use. Only highly skilled and trained personnel should perform this process.

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5. Tap the appropriate field twice to highlight and replace all data in the field. The data highlighted in blue will be replaced with new data as it is typed.
6. Using the keyboard type the new data.
7. To scroll forward and backward in the protocol schedule, tap the <<< or >>> buttons.
8. To undo all editing without saving changes and remain in the edit mode, tap the **Reset to Original** button once. This will reset the protocol to the current global protocol.
9. When all editing is complete and reviewed, tap the **Save Protocol** button once to save the data.
10. To exit to the Main Menu screen, tap the **Exit** button once.

31.3.2 Patient Specific Protocols

Only authorized users can edit patient specific protocols. Editing patient specific protocols will only affect the schedule of the patient for which the change is made. Editing patient specific protocols will not affect treatment schedules of other patients.

1. Logon to the Smart Touch™ control system.
2. From the Main Menu, select the **Edit Patient** button by tapping it once. The Select a Patient screen for the selected patient will appear (See Figure 12 Select a Patient Screen).
3. Follow the instructions in 22.0 Selecting a Patient. Once the patient has been selected, return to these instructions, and continue with Step 4 (below).
4. Tap once on the View/Edit Schedule button once. While the data is obtained, the "Retrieving Schedule" message will be displayed. When the schedule is located, the message will disappear, and the applicable Patient Protocol Setup edit screen will be displayed (See Figure 20 Patient Protocol Setup Edit Screen (UVB)).

Figure 20 Patient Protocol Setup Edit Screen (UVB)

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Warning: Changing protocols can be dangerous and can result in treatments that will seriously injure patients. Be sure to understand *How Protocols Work* before making any changes to protocols. Always review the entire protocol after changes have been made and before it is implemented for use. Only highly skilled and trained personnel should perform this process.

5. Tap twice on the appropriate field to highlight and replace all data in the field. The data highlighted in blue will be replaced with new data as it is typed.
6. Using the keyboard type the new data.
7. To scroll forward and backward in the protocol schedule, tap the <<< or >>> buttons.
8. To undo all editing without saving changes and remain in the edit mode, tap once on the **Reset to Protocol** button. This will reset the protocol to the current global protocol.
9. When all editing is complete and reviewed, tap once on the **Save Protocol** button to save the data.
10. To exit to the Main Menu screen, tap once on the **Exit** button. The Patient Setup screen (See Figure 11 Patient Setup Screen) will appear. Tap once on the **Exit** button.

32.0 System Settings

Only authorized users can view and edit the System Settings.

1. Logon to the Smart Touch™ control system.
2. From the Main Menu, select the **System Settings** button by tapping on it once. The System Settings screen will appear which includes **Treatment Variables, Control Panel** and **Lamp Information** buttons.
3. Select the desired button by tapping it once.
4. View or edit the settings by following the applicable instructions in this section of the manual.

32.1 Control Panel

The **Control Panel** button is a direct link to the Windows® operating system Control Panel. Various settings capabilities exist within the operating system Control Panel.

Caution: Never edit settings in the Windows® operating system Control Panel that are not described in this manual without first consulting Daavlin. Changing these settings may cause system failure.

32.1.1 Treatment Variables

The settings contained in the Treatment Variables screen (See Figure 21 Treatment Variables Screen) are described below.

- **Minimum time between treatments** – sets the number of hours that must elapse between treatments before subsequent treatments can be delivered without displaying a warning message.
- **Maximum time between treatments** – (Authorization not required) – sets the maximum number of hours that can elapse between treatments before a warning message is displayed.

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- **Maximum time between treatments** – (Authorization IS required) – sets the maximum number of hours that can elapse between treatments before a warning message is displayed that requires authorization (See Warning Rules and Authorities section in this manual).
- **Idle time before logging out** – sets the maximum number of minutes that can elapse without any lamp or treatment activity, or screen taps before automatic system logout and suspend occurs.
- **Days between calibration** – sets the number of calendar days that can elapse between calibrations before the system displays a message indicating that the calibration is due (See the accompanying Service & Installation Manual for Calibration information).
- **Lamp hours between calibrations** – sets the number of lamp hours that can accumulate between calibrations before since the last calibration before the system displays a message indicating that the calibration is due.

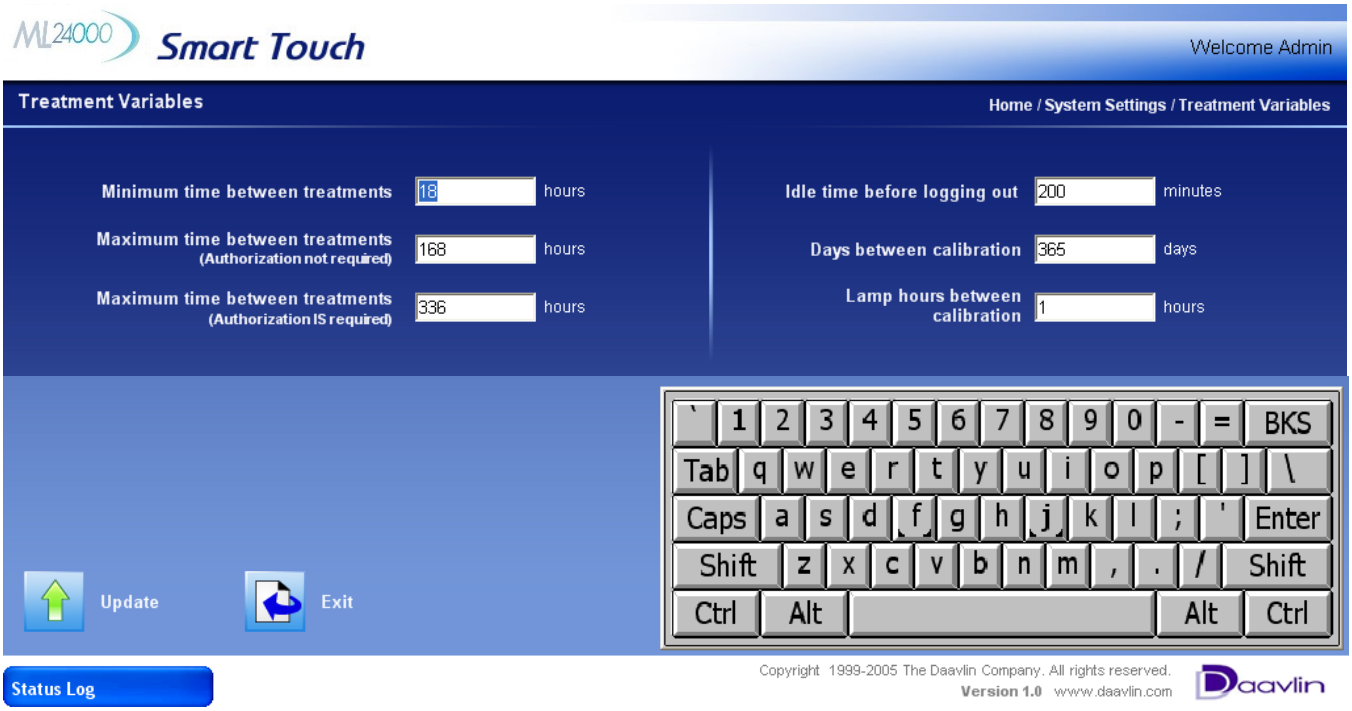

Figure 21 Treatment Variables Screen

32.1.2 Lamp Information

The settings contained in the Lamp Information screen are described below.

- **Hours since last re-lamp –** displays the number of hours that the current lamps have been in operation. The field for the corresponding lamp type is reset to zero when the **Re-lamp UVA-1 button** is pressed.
- **Last re-lamp date –** displays the date that the **Re-lamp UVA-1** button was last pressed.
- **Hours since last calibration –** displays the number of hours that the current lamps have been in operation since the machine was last calibrated. This field is automatically reset upon completion of each calibration process.
- **Last calibration date –** displays the date that the system was last calibrated. This field is automatically updated upon completion of each calibration process.
- **Total Lamp Hours –** displays the total number of hours that the device has operated. This field cannot be reset.
- **Last power output** – displays the last power output taken from the internal sensors before the lamps shut off.

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33.0 Edit User Data

Warning: Entering improper or erroneous data in the New User Setup process could result in serious patient injury. The data entered when setting up a patient will determine which preprogrammed protocol is selected for the patient treatments, and therefore directly impacts the patient's treatment dose. Only highly skilled and trained personnel should perform this process.

Only authorized users can edit patient data.

1. Logon to the Smart Touch™ control system.
2. From the Main Menu, select the **User Setup** button by tapping it once. The Select a Username screen will appear which includes a list of all established system users. (See Figure 22 Select a Username Screen).
3. Select the user profile to be edited by tapping the Username once. The User Setup screen will appear (See Figure 10 User Setup Screen).

Figure 22 Select a Username Screen

4. From the User Setup screen, edit the user's profile as desired.
5. To save changes, tap the **Save Changes** button once. The "Saving user data" message will appear while the data is being saved and then the "User data saved" message will appear momentarily.
6. Tap the **Exit** button once to exit to the Main Menu.

34.0 Generating Reports

1. Logon to the Smart Touch™ software.
2. From the Main Menu, tap the **Reports** button once. The Reports Menu will appear.

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34.1 Generating an Individual Report

1. From the Reports Menu, tap the **Individual Report** button once. The Individual Report screen will appear.
2. On this screen select either the **Treatment History** or **Last Treatment** check box. **Treatment History** Report will show information for all past treatments. **Last Treatment** Report will provide information on only the most recent treatment.
3. In the **Patient ID** box, enter the individuals PIN number.
4. Tap the **Generate Report** button once to create the individual report.

34.2 Generating a Daily Summary Report

1. From the Reports Menu, tap the **Daily Summary Report** button once. The Daily Summary Report screen will appear.
2. On this screen select either the **ForToday** or **ForTheDate** checkbox. **ForToday** Reports will show information for all the current day's treatments. **ForTheDate** Reports will provide information for all treatments given on the date selected on the drop-down calendar to the right of this checkbox.
3. Tap the **Generate Report** button once to create the desired Daily Summary Report.

34.3 Using the Report Wizard

1. From the Reports Menu, tap the **Report Wizard** button once. The Report Wizard screen will appear.
2. On this screen decide on the categories to sort by and then select the corresponding ascending or descending checkbox. For example, selecting the **Ascending** checkbox for **Number of Treatments** will result in all patients being listed with the patient having the fewest number of treatments first and the patient having the greatest number of treatments last.
3. If desired the database can be sorted using up to four different categories. A minimum of one category must be selected in order to generate the report.
4. Tap the **Generate Report** button once to create the desired custom report.

34.4 Generating a Device Data Report

1. From the Reports Menu, tap the **Device Data Report** button once. The Device Data Report will be generated and displayed.

34.5 Generating a Safety Limits History Report

1. From the Reports Menu, tap the **Safety Limits History Report** button once. The Safety Limits History Report screen will appear.
2. On this screen select the **Start Date** and **End Date** using the drop-down calendars.
3. Select the **UVA-1 Lamps** radio button.
4. Tap the **Generate Report** button once to create the Safety Limits History Report.

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35.0 Backup/Restoration of Database

35.1 Backup the Database to Removable USB Drive (Recommended Daily)

1. Exit the Smart Touch™ software so that you have the Windows Desktop (Start Menu) on the screen.
2. Insert the Removable USB drive into one of the USB ports

   Note: On PC models these ports are on the front of the desktop PC.

3. Click on 'Start' (bottom left) to bring up the Start Menu.
4. Drag the mouse to 'Programs' and when the next window appears click on 'Backup Restore' to initiate the Backup/Restore Utility
5. Verify that the Backup Database button (Top) is selected and then click "Start' (bottom)
6. Once finished message above green status bar will read 'Database Backup Complete'

   Note: In the event an Error message appears reading "Cannot open backup device…" a file named 'BackUp' must be created on the removable USB device, and then repeat above steps after exiting the Backup/Restore Utility.

7. Click the Exit button to close the Backup/Restore Utility.
8. Remove the USB drive from the USB port.

35.2 Restoring the Database from the Removable USB Drive

In the event your patient database is corrupted or lost, the Backup/Restore Utility can be used to restore the database using the backup file 'STUV.bak' located on the Removable USB Drive. Completing this restoration will result in the database being returned to the way it was at the time of the most recent Backup described in the 'Backup the Database to Removable USB drive' section of this manual.

1. Insert the Removable USB drive into one of the USB ports

   Note: On PC models these ports are on the front of the desktop PC.

2. Exit the Smart Touch™ software so that you have the Windows Desktop (Start Menu) on the screen.
3. Click on 'Start' (bottom left) to bring up the Start Menu.
4. Move the mouse to 'Programs' and when the next window appears click on 'Backup Restore' to initiate the Backup/Restore Utility
5. Verify that the Restore Database button (Top) is selected and then click "Start' (bottom)
6. Once finished, the message above green status bar will read 'Database restoration complete'

   Note: In the event an Error message appears reading "Cannot open backup device…" then the database has not been previously backed up to the Removable USB Device. See note at end of this section.

7. Click the Exit button to close the Backup/Restore Utility.
8. Remove the USB drive from the USB port.

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Note: If a backup to the removable USB device has not been recently performed, or if such backup has never been performed, please contact the Daavlin Service department at 1-800-322-8546. Database restoration may still be possible from backup files automatically stored on the computer.

36.0 Care of Your Phototherapy Unit

36.1 Maintenance

WARNING: BUILDING/SERVICE CIRCUIT BREAKER AS WELL AS MACHINE CIRCUIT BREAKER SHOULD BE DISCONNECTED BEFORE ATTEMPTING ANY REPAIRS - HEED WARNING LABELS. ONLY TRAINED EMPLOYEES SHOULD PERFORM MAINTENANCE.

Table 3 Electromagnetic Emissions

Action	Frequency
Dusting of the unit	Once a month
Fully clean all internal reflectors, lamps, and protective acrylic	Annually
Unit calibration	Every 100 hours of use and when lamps are replaced (Meters can be rented or purchased through Daavlin)
Replace lamps	UVA-1 Every 500-800 hours of use.

36.2 Cleaning

36.2.1 Between Treatments

All customer contact surfaces and accessories should be cleaned between treatments / uses of the machine. To keep the device clean between each apply 70% isopropyl alcohol or 1 part bleach 3 parts water solution to a non-abrasive cloth and wipe the patient contact surfaces free of any dust, dirt, and debris. Patient contact surfaces typically include the internal and external handles and platform, but may include other areas of the device. Clean glasses and goggles according to the instructions in the accessories section of this manual.

36.2.2 Exterior & Dusting

We suggest using “Monk” Brand Wipes for exterior cleaning as they disinfect and will not harm any ultraviolet or light transmitting surfaces. These wipes are available for purchase through Daavlin. When dusting the unit, we recommend using a feather duster or a similar non-abrasive cleaning device.

36.2.3 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.

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

36.3 Lamp Replacement

36.3.1 Relamping

Note: Only Daavlin authorized personnel may carry out lamp replacement

Lamps may need to be replaced due to burnout or because their energy output has decreased to the point that you may no longer be receiving an effective treatment. 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.

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 in safe location.
7. Remove the six colored filters from each column and place in 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.

37.0 Voltage Specification

Three phase, 50/60 Hz, 225-235 VAC Line-to-line, 80-amp three phase breaker.

38.0 Lamp Specification

Item Number	101MLLAMP
Specification	1000 Watt
Type	Metal Halide

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39.0 Eyewear Specification

Item Number 913GR Green Goggles
Item Number 905GR Fit Over Green UV Safety Glasses

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40.0 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.

41.0 Spare Parts and Accessories

Description	Daavlin Part Number
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
Green Goggles	913GR

42.0 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.

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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

43.0 Cybersecurity

Daavlin's Smart Touch controller exists on an isolated network. USB ports are active. The ethernet port is active. Most Smart Touch controlled devices utilize a UV4001 board. There is no connection, wired or wireless, to any external network and/or the World Wide Web. The ethernet port is an active network port on the Linux system. The SD card is active. A physical jumper can be configured to boot from the SD slot. The SD slot is not available external to the device. There is no driver for the USB slot, rendering it inactive. One Smart Touch controlled device utilizes a UV3001 board. There are no ethernet ports affixed to the board, however, a Perle adapter is connected to a D-SUB connector to provide an ethernet port. This ethernet port is an active network port on the Linux system. There are no SD ports or USB ports

44.0 Warranty and Contact Information

44.1 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

44.2 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

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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.

44.3 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.

44.4 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.

44.5 Disposal

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

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44.6 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.

44.7 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

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