Phothera™

Operation Manual

Phothera 4000XL 4800MAX

Modes of Operation:

Smart Touch | Dosimetry | ClearLink

Your health is our purpose, and your care is our promise.

Phothera

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1.0 Introduction

Thank you for purchasing a Phothera 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 Phothera, 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 Phothera phototherapy unit.

Here at Phothera 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 Phothera Staff

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 they practice.

2.0 General Information

2.1 Manual Use

This Operating Instructions & General Information manual is an integral part of the Phothera 4000XL/4800MAX 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, can be caused.

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. 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 expressed written consent is obtained from Phothera.

This manual will detail instructions for all potential control scenarios for the Phothera 4000XL/4800MAX.

- For instructions regarding SmartTouch™ control, reference section *8.0 SmartTouch™ Control System.*
  Note: Any instructions relevant to SmartTouch™ Multiple Machine control will be listed where applicable.
- For instructions regarding how to switch between PC (SmartTouch™) and Timer (ClearLink™) control modes, reference section *8.20 Switching from PC to Backup Time Controller.*
- For instructions regarding ClearLink™ control, reference section *9.0 ClearLink™ Timer Operation (CL Models Only).*

2.2 Indications for Use

The Phothera 4000XL/4800MAX, 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).

The Phothera 4000XL/4800MAX Phototherapy Device is not a Class III or implantable device. The Summary of Safety and Clinical Performance is not required.

2.3 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

2.4 Classifications

FDA:	Class II Device
EU 2017/745:	Class IIa Device
IEC 60601-1:	Class I Device
Pollution Degree:	Class II
Mode of Operation:	Continuous
IEC/EN 62471:2006 UV Risk Group:	Risk Group 2 (Moderate-Risk)

2.5 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 of use as recommended. The SmartTouch™ and ClearLink™ control systems will display a reminder message when calibration is due. Please contact Phothera for calibration.

2.6 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.

The Phothera 4000XL/4800MAX should be operated in a cool and clean environment. For the comfort of the patient during treatment, all Phothera 4000XL/4800MAX case models are equipped with two ventilation fans on top of the unit. To dissipate heat an exhaust fan directly over the cabinet is recommended. To be effective, the exhaust fan must have an adequate supply of fresh air and a place to expel the exhausted air, such as out of doors or into a very large area. To ensure a continuous supply of fresh air to the room, a louver-style door is recommended, or grates can be installed in the existing door.

2.7 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

2.8 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

3.0 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. All Phothera 4000XL/4800MAX units have the same electrical configuration no matter the lamp type or how many lamps are in the unit. Depending on the country the Phothera 4000XL/4800MAX can be a single phase, split phase, or three phase unit.

- 400VAC, 10A 3ϕ/200-240VAC, 1/2ϕ 20A 50/60Hz.

Phothera 4000XL/4800MAX case models are supplied with 8-foot (2.5 meters) cable, which must be permanently wired into a wall junction box. The Phothera 4000XL/4800MAX is a fixed unit because it needs to be permanently wired to a junction box. The electrical junction box must be installed in accordance with the National Electric Code, and local codes. The junction box should be on a standard, non-Residual Current Device (RCD) or ground fault circuit interrupter (GFCI) breaker.

Instructions on wiring the Phothera 4000XL/4800MAX to the junction box can be found in the service manual.

3.1 Site Selection

A site should be chosen within reach of the specified electrical connection (refer to the Electrical Requirements section of your specific device) and where the unit can be left in place without obstructing traffic flow. The device should be positioned in such a way 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.

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

CAUTION: This device is a Class IIa 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.

4.0 Lamp Types

The device is available with lamps that emit UVA (peak 350 nm) or Narrow Band UVB / TL-01 (peak 311 nm) and can be equipped with 40 or 48 lamps of either type or a combination of 20 or 24 lamps of each type. The device can be controlled by either a ClearLink controller, a Smart Touch PC, or in conjunction with multiple other devices as a part of Phothera's MultiMachine™ process. Always refer to the identification label of the device to determine which lamp type the machine is equipped with. The table below contains examples of model numbers and descriptions to identify the lamp type(s) contained in a device.

Model Number	Description of Device
Phothera 4800MAX NBUVB	Phothera 4800MAX with 48 Narrow Band UVB / TL-01 lamps (peak 311 nm)
Phothera 4800MAX Combo	Phothera 4800MAX with 24 Narrow Band UVB / TL-01 lamps (peak 311 nm) and 24 UVA lamps (peak 350 nm)
Phothera 4800MAX UVA	Phothera 4800MAX with 48 UVA lamps (peak 350 nm)
Phothera 4000XL NBUVB	Phothera 4000XL with 40 Narrow Band UVB / TL-01 lamps (peak 311 nm)
Phothera 4000XL Combo	Phothera 4000XL with 20 Narrow Band UVB / TL-01 lamps (peak 311 nm) and 20 UVA lamps (peak 350 nm)
Phothera 4000XL UVA	Phothera 4000XL with 40 UVA lamps (peak 350 nm)

Your device can be equipped with a variety of different lamps, each having a different effect on the skin. It is important to check that the proper lamps are installed in the device. Consult the Lamp Specification Guide below and if there is any question as to whether or not your device is equipped with the lamps that you have ordered, contact Phothera immediately. The code numbers shown are generally located at the base of the lamp.

Applicable Units	UVA	Narrowband UVB
Phothera 4000XL/4800MAX	F72T12-BL-HO-RDC F79T12UVA120W	-TL-01/100W-FS72 -FS72T12/NBUVB/HO/RDC/100W TL120W/01

The Phothera 4000XL/4800MAX should be used in an electromagnetic environment as listed below in Table 1 and Table 2.

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 Phothera 4000XL/4800MAX device is suitable for healthcare environment operation in hospitals and clinics
Limits for Harmonic Current Emissions Following IEC 61000-3-2	Class A	The Phothera 4000XL/4800MAX 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 Phothera 4000XL/4800MAX 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

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
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			

Table 4 Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure 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:

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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			
b. 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			

5.0 Labels and Symbols

5.1 Domestic and International Units

Warning labels are affixed to your device in a prominent and easily readable position. Please read the labels carefully as they contain important safety information for patients. See Figure 1.

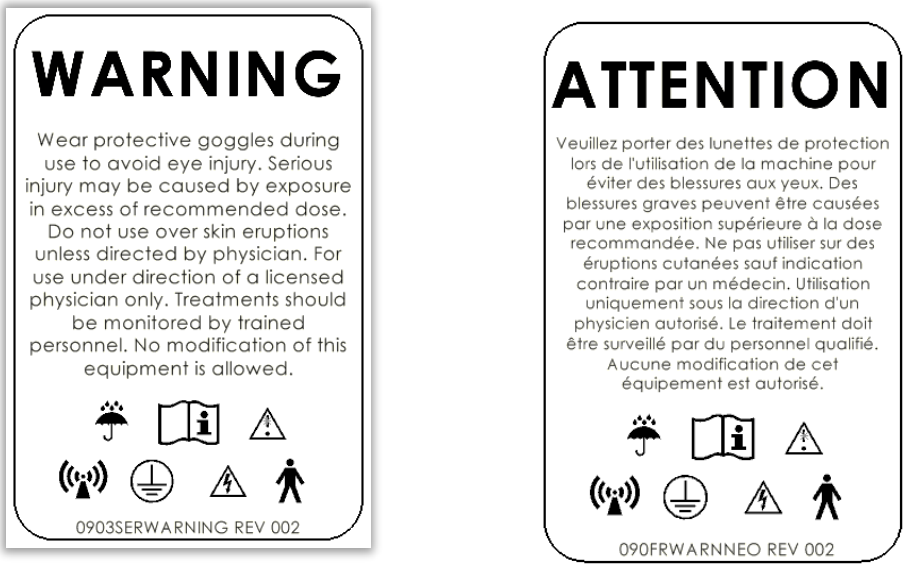


Figure 1 Warning Labels

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. See Figure 2.

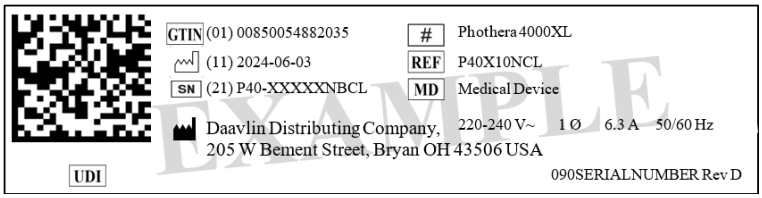


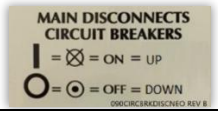
Figure 2 Serial Number Label

Phothera 4000XL/4800MAX models feature one Ethernet port located on the side of the Device. This Ethernet port is only to be used as a data only connection to the SmartTouch™ Control PC. This Ethernet port is identified by the following label shown in Figure 3.

Figure 3 PC Only Label

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

	TYPE B EQUIPMENT
	DANGEROUS VOLTAGE
	ATTENTION, CONSULT ACCOMPANYING DOCUMENTS
	NON-IONIZING RADIATION
	FAN
	LIGHTS
	PROTECTIVE EARTH (ground)
	OPERATING INSTRUCTIONS
	DATA ONLY ETHERNET PORT
	KEEP DRY
	MEDICAL DEVICE
	WIRES ARE LIVE/ENERGIZED.
	RELAY CONTROLS UVB LAMPS
	RELAY CONTROLS UVA LAMPS
	SAFETY RELAY
	UVA TERMINAL BLOCK
	UVB TERMINAL BLOCK
	UVA/UVB COMBO TERM BLOCK

	LINE ONE, LINE TWO OR NEUTRAL WIRES ON INCOMING TERMINAL BLOCK.
	MAIN CIRCUIT BREAKER SWITCH
	DANGER HIGH VOLTAGE
	DANGER HIGH VOLTAGE FRENCH
	NBUVB LAMP
	UVA LAMP
	CE/SGS SAFETY MARK LABEL
	KEYCODE SAFETY LABEL
	KEY SWITCH LABEL
	EU REP LABEL (CE ONLY DEVICE) LABEL
	MEDICAL DEVICE LABEL

5.2 UV Risk Group

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.

Figure 4

Figure 5

6.0 Training Requirements

Phototherapy services require staff that has 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.

7.0 Warnings & Cautions

7.1 Electrical Shock Hazards

- **Caution**: Do not operate this device with a damaged cord or plug.
- **Caution**: If appliance coupler or mains plug is used as the mains disconnect, do not position the ME equipment so that it is difficult to operate the disconnection device.
- **Caution**: To avoid the risk of electric shock, this equipment must only be connected to a supply main with a protective earth.
- **Caution**: To prevent electric shock, remove power to the device prior to cleaning and servicing.
- **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**: Before opening the device casing to perform maintenance or service, disconnect the device from the power source. To disconnect the power from the device, turn the circuit breaker to the off position.
- **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 *Service & Installation Instructions* manual and test the device for proper functionality prior to placing the device in use again.
- **Warning**: The device must never be directly exposed to flowing or splashing 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**: Before opening the device casing to perform maintenance or service, read, understand, and follow all warnings, cautions, and instructions in this and the *Service & Installation Instructions* manual, both of which are provided with the device.

7.2 Ultraviolet Light Exposure & Bodily Injury Hazards

- **Warning**: To protect the eyes during operation, the operator and anyone in view of the device must wear the provided UV blocking glasses or goggles designed to block 100% of all UVA and UVB light from the eye area when worn. **Always use Phothera approved eyewear purchased through Phothera.**
- **Warning:** Do not remove protective eyewear, or any other protective equipment, during treatment.
- **Warning**: If psoralens (photosensitizing drugs) are being used as part of a treatment ("PUVA"), the eyes should be protected from exposure to ultraviolet (sunlight) for 24 hours after taking the drug. Ultraviolet blocking glasses are provided with all Phothera phototherapy devices.
- **Warning**: Do not use over skin eruptions without express consent from the attending physician.
- **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**: 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.
- **Warning**: Erythema can result in as little as 15 seconds of exposure, or approximately 200 millijoules of dose to UVB light. If using this phototherapy unit at home, contact your prescribing physician for specific treatment instructions and dosing information.
- **Caution**: Center patients between the lamps during treatment to avoid over exposure to isolated areas of the body.
- **Warning**: All people and pets should leave the treatment area to avoid exposure to ultraviolet light.
- **Warning**: Ask your doctor about protecting areas of your body that have not been exposed to sunlight.
- **Warning**: Do not use this device for anything other than its intended purpose.
- **Warning**: This device is only to be used by authorized users.
- **DANGER – ULTRAVIOLET RADIATION.** As with natural sunlight, overexposure can cause eye and skin injury, and allergic reactions. Repeated exposure may cause premature aging of the skin and/or skin cancer. **ALWAYS WEAR PROTECTIVE EYEWEAR: FAILURE TO DO SO MAY RESULT IN SEVERE ERYTHEMA OR LONG-TERM INJURY TO THE EYES.** Medications or cosmetics may increase skin sensitivity to ultraviolet radiation. Inform your physician before using this device if you are using medications or have a history of skin problems or sensitivity to light.
- **Warning**: All treatments must be administered under the direction of a licensed physician only.

7.3 Equipment & Property Damage Hazards

- **Warning**: **NO MODIFICATION OF THIS EQUIPMENT IS PERMITTED.** Unauthorized modification will void the warranty and may result in hazardous or improper device operation.
- **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 Phothera Service Department.
- **Caution**: If necessary, operation of equipment may be terminated by disconnecting unit from AC mains. This can be accomplished by unplugging device or, if hard wired, turning off quick disconnect.
- **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**: 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**: 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 device should be a minimum of 12 inches (30 cm) away from RF generating equipment
- **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 *Service & Installation Instructions* manual. Unauthorized personnel should not open the panels. The Phothera Service Department should be consulted before any service is performed.
- **Warning**: The UV4001 board will beep when there is a system error or when SmartTouch™ is disconnected from the unit.

8.0 SmartTouch™ Control System

Primarily, the unit is operated through input provided at the SmartTouch™ control system, consisting of a touch screen enabled or standalone PC and SmartTouch™ operator interface software. If using a Phothera standalone SmartTouch™ PC, there are two primary SmartTouch™ applications to be used:

- **STUV**: Use this software if the SmartTouch™ PC only has one phototherapy device connected to it. This software will control a single instance of SmartTouch™.
- **STMM**: Use this software if the SmartTouch™ PC has multiple phototherapy devices connected to it. This software will control multiple instances of SmartTouch™ from a sole control hub (the SmartTouch™ PC).

The following instructions will apply to both versions of the software, with differentiating instructions for SmartTouch™ Multiple Machine being denoted as such.

8.1 Accessories

8.1.1 USB Mass Storage Device

A Removable USB drive is provided with the SmartTouch™ PC. 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 of replacing this item. This item is required for specific maintenance functions.

8.1.2 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.

8.2 Theory of Operation

8.2.1 Dosimetry

The Phothera 4000XL/4800MAX is equipped with integrating dosimetry, which means that sensor(s) built into the device monitor and measure lamp energy output during treatment. This information is sent to the main control system, where it is accumulated and recorded. When the amount of energy programmed (Joules or millijoules) by the operator has been delivered, the control system automatically turns off the lamps and indicates that the treatment is complete.

> **Note:** The measuring device will maintain a 5% level of time accuracy and a 10% level of sensor accuracy if the device is calibrated every one hundred (100) hours of use as recommended. The SmartTouch™ control system will display a reminder message when calibration is due. Please contact Phothera for calibration.

8.2.2 Control Systems

The Phothera 4000XL/4800MAX may be equipped with two different control systems, SmartTouch™ PC or a SmartTouch™ PC/Timer combination. These control systems and their operation are outlined below. **Special note**: If your Phothera 4000XL/4800MAX is the PC/Timer combination model you may use either control system. However, if you use the external timer controller, the patient treatment records will not be stored in the SmartTouch™ database. A key switch located on the right side of the unit is used to switch between the PC and ClearLink controller. The PC that is provided with the Phothera 4000XL/4800MAX is not a medical device and is not intended to have patient contact.

8.2.3 SmartTouch™ PC Control System

Primarily, the unit is operated through input provided at the SmartTouch™ control system, consisting of a touch screen enabled or standalone PC and Daavlin SmartTouch™ operator interface software. In addition, secondary operation of limited functions of the machine (lamps on/off, fan on/off,) can be controlled at a “button box” located inside the machine.

8.2.4 System Login

Input to the control system is limited to established users. To enter input into the control system, the established user must "login" 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" user ID, is assigned the case sensitive password "daavlin". Before an assigned device operator can control the system, including the "Admin", he/she must login using an established user ID and default password. Upon initial login, each user must change the system assigned default password.

8.2.5 User Profiles

To manage control of system users, the SmartTouch™ 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.

8.2.6 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, logon under this profile allows the user to establish and edit subsequent user ID's for additional users.

8.2.7 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.

8.2.8 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.

8.2.9 Treating Patients

Authorized users enter and save patient data including name, skin type, treatment type (UVA, UVB, or a Combination), 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 Soft Touch™ control panel or the "button box" inside the machine.

With patients who are affected moderately on the majority of the body and severely in local areas, for example the knees and elbows, secondary treatments, subsequent to the primary treatment, may be desired in the severely affected areas to ensure proper clearing. When administering secondary treatments, the patient is typically instructed to shield areas of the body that are not affected or are only moderately affected, leaving only the severely affected areas exposed during the secondary treatment. The SmartTouch™ control system allows for secondary treatments to be selected and administered if desired.

8.2.10 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 patients 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. See the *Understanding How Protocols Work* section of this manual for complete details on the preprogrammed protocols contained in this device.

8.2.11 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 can be printed for individual treatments immediately following a treatment or for a patient's entire history from the history menu.

8.3 Initial Use

Before doing the initial startup, ensure the device has been properly installed by a Phothera technician or by following the instructions in the *Service and Installation* manual.

8.3.1 Unit Startup

Power up the unit by plugging in the power cord and turning on the circuit breaker located on the right side access panel. The green LED on the access panel will become active once the power is turned on, indicating there is power to the internal controller. The internal controller will begin to go through a boot cycle that is approximately 45 seconds long. The unit's lamp cooling fans will turn on for this allotted time period. After the 45 seconds the internal controller will have completed its boot cycle, the lamp cooling fans will shut off, and the amber LED on the access panel become active indicating the unit is ready to operate.

8.3.2 Software Startup

From the Windows® Desktop, select the SmartTouch™ icon (**STUV**) or the SmartTouch™ Multiple Machine icon (**STMM**) by double clicking or double tapping (touch screens only) it. The system will display the language selection screen (See **Figure 6 – Language Selection Screen**). Select the appropriate language flag. After selecting a language, the user login screen will come up (See **Figure 7 – User Login Screen**).

Figure 6 – Language Selection Screen

8.4 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 SmartTouch™ 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.

8.4.1 Administrator Setup

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

1. 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.

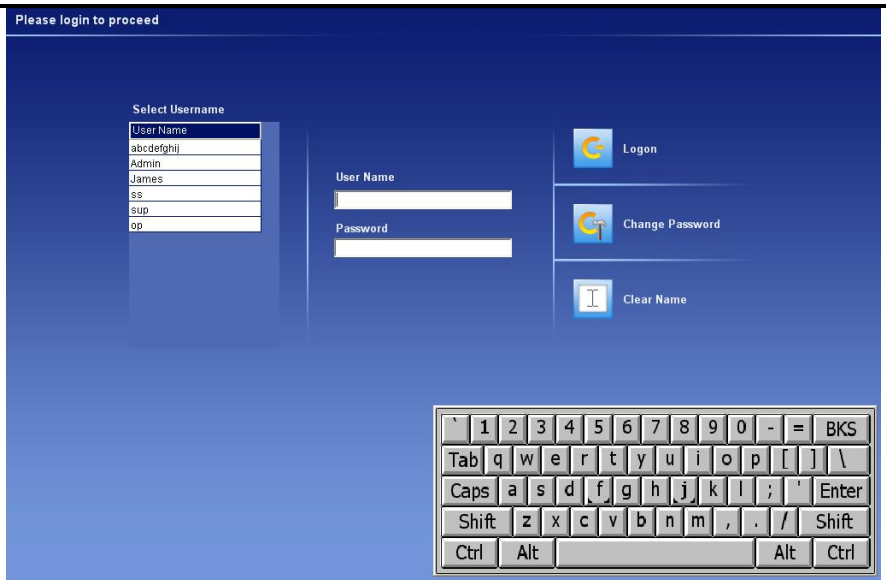


Figure 7 – User Login Screen

***Note**: The system will now require the administrator to select and setup a new login password. It is important to remember the new password, as the system will only allow subsequent login 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.*

2. 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.

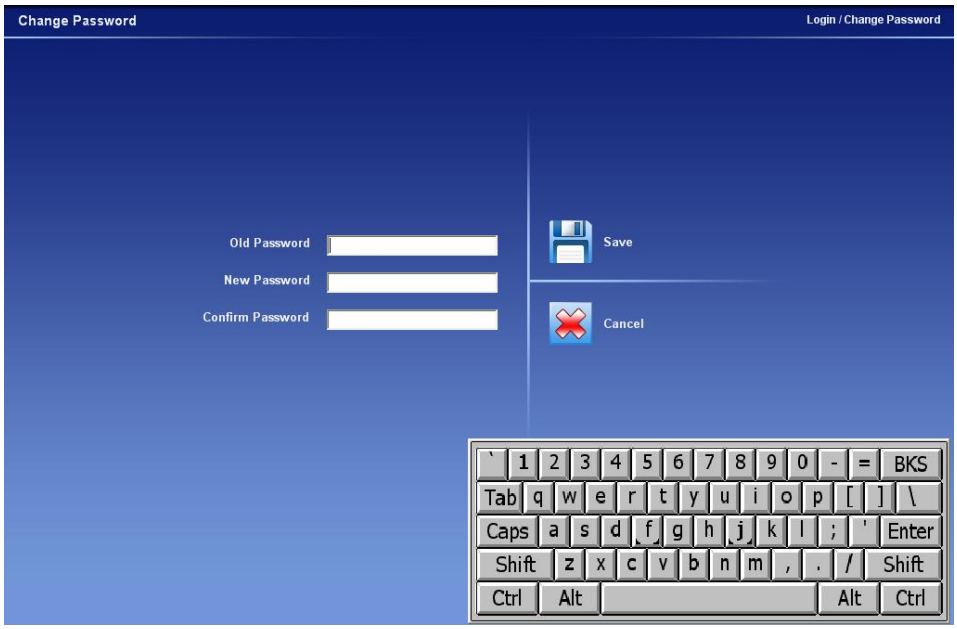


Figure 8 – Change Password Screen

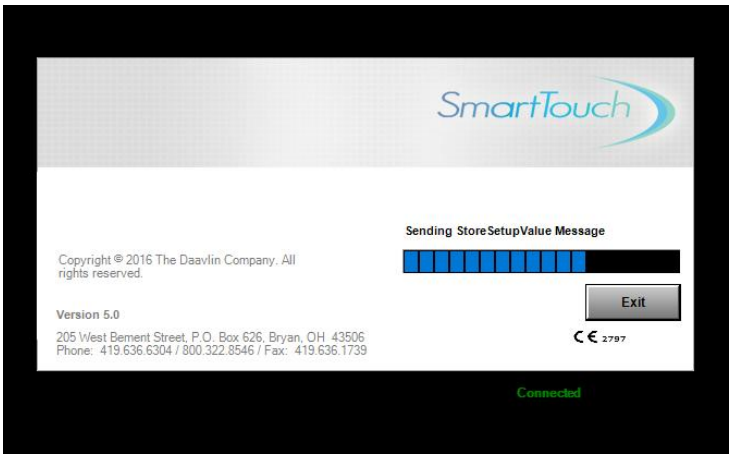


Figure 9 – Loading Screen

3. 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 10 – Main Menu Screen**), and the system administrator setup is complete
5. After saving the password, the system will display the loading screen (See **Figure 9 – Loading Screen**) while the software is booting up and connecting with the unit for the first time. The process in progress will be displayed in the top left corner of the screen (See **Figure 9 – Loading Screen**). Below the progress bar, the status of the unit connection will be displayed with a green "connected" (See **Figure 9 – Loading Screen**) or a red "disconnected" message. Make sure your unit is turned on and fully booted up for the "connected" message to occur.
6. When the loading is completed, and the unit is properly linked with SmartTouch™, the Main Menu screen will be displayed (See **Figure 10 – Main Menu Screen for STUV**).

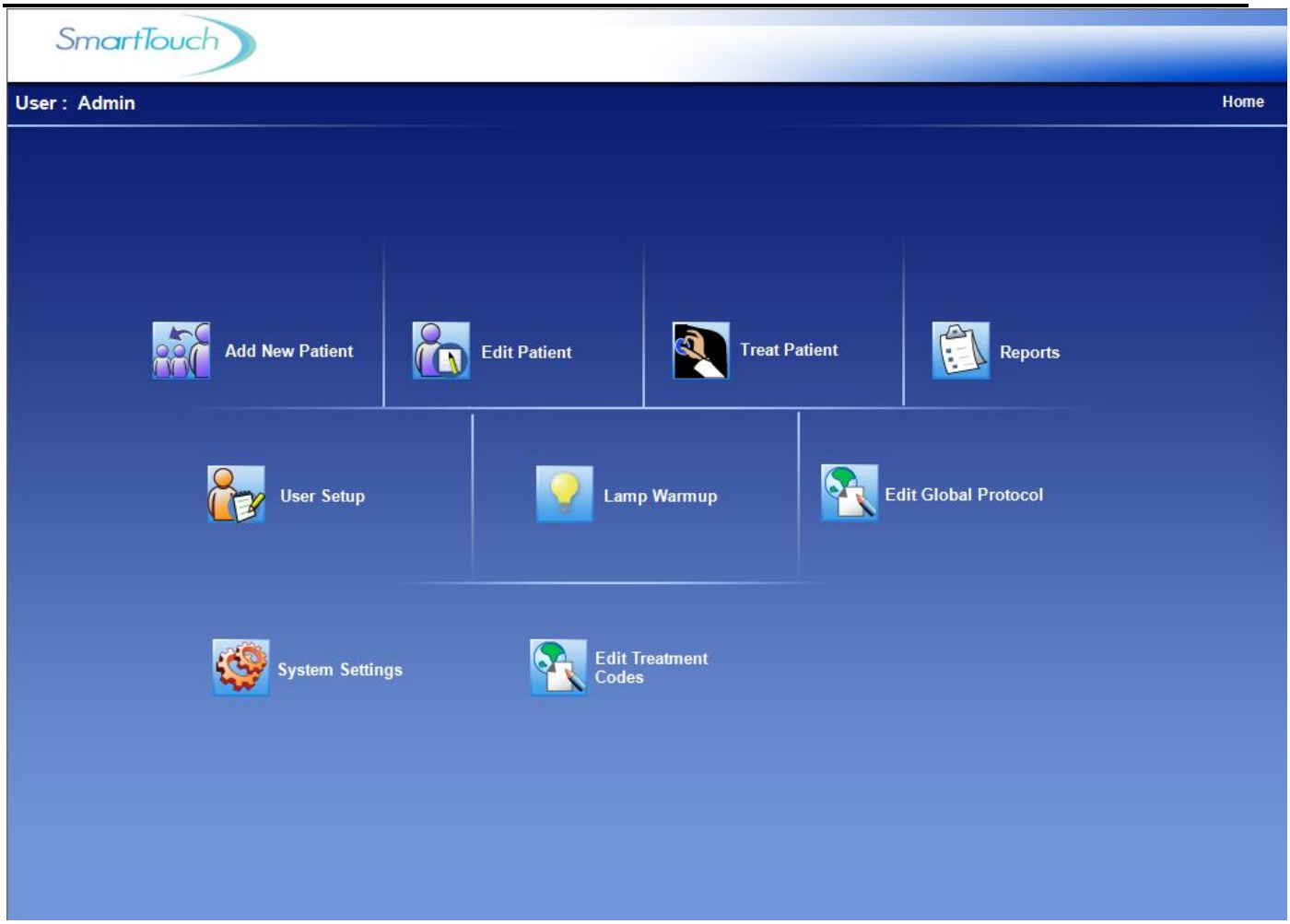


Figure 10 – Main Menu Screen for STUV

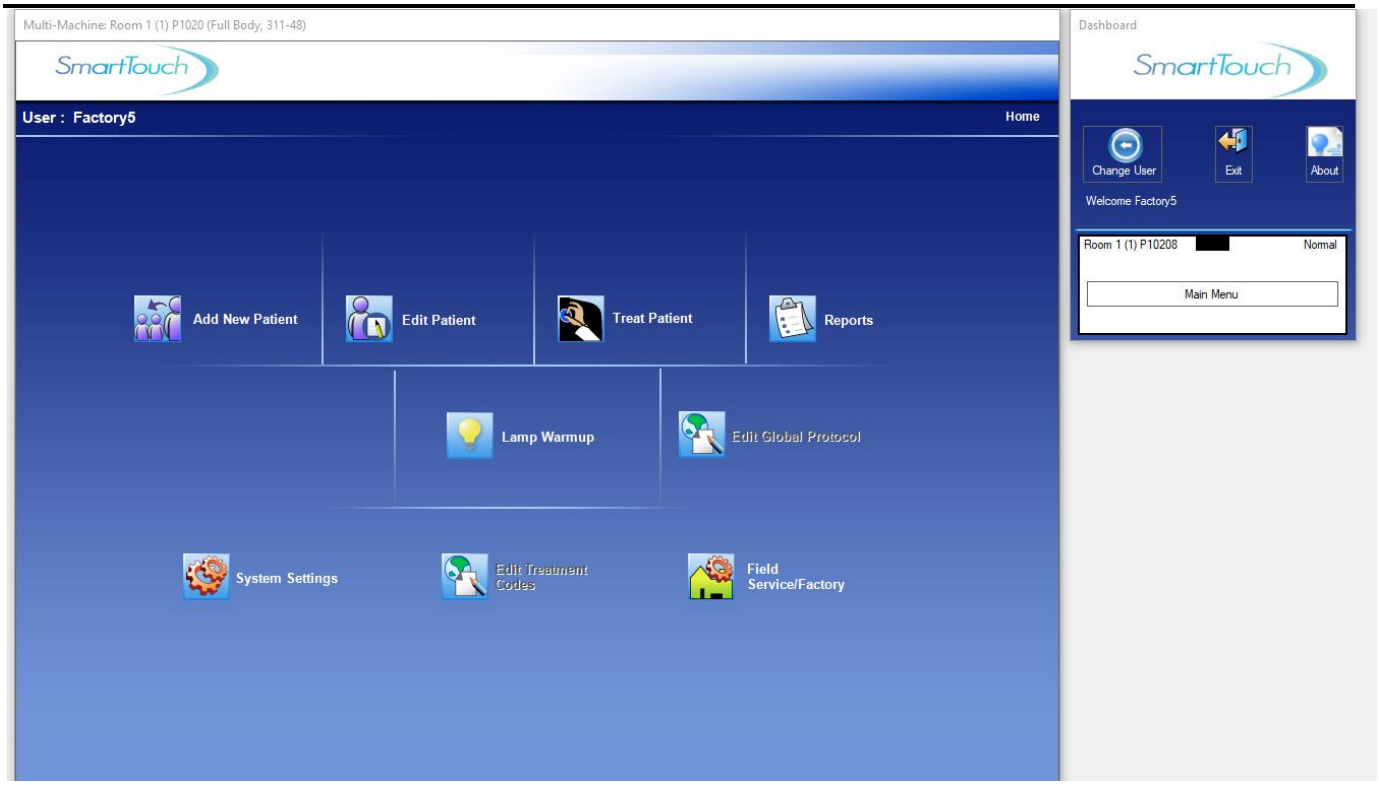


Figure 11 - Main Menu Screen for STMM

8.5 Dashboard Device Selection (Multiple-Machine ONLY)

If using STMM with multiple machines connected to the PC, docked on the right-hand side of the screen you will see the SmartTouch™ Multiple Machine Dashboard window. This window will allow you to select which device is active in the Main Window. The 'active' device will be indicated by a black box in the top center of the device's dashboard status window. The serial number for the 'active' device will also be indicated in the top left corner of the Main SmartTouch™ window. Each 'instance' of SmartTouch™ will get its own box in the dashboard.

The Dashboard Window will be used for the following:

1. Actively monitor the status of each device connected to SmartTouch™ Multiple Machine software.
2. Select device to be controlled/monitored in the Main SmartTouch™ Window.
3. Change User
4. Exit SmartTouch™ Multiple Machine application.

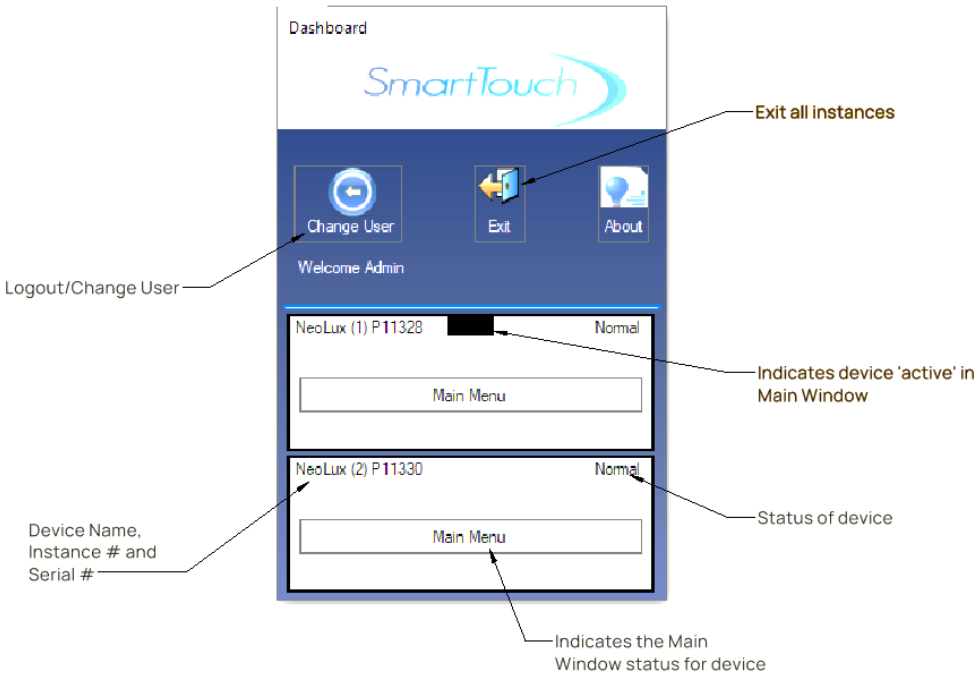


Figure 12 - STMM Dashboard Window

8.6 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. Login to the SmartTouch™ control system and tap the **User Setup** button once from the Main Menu (See **Figure 10 – 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 13 – 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* section of this manual.

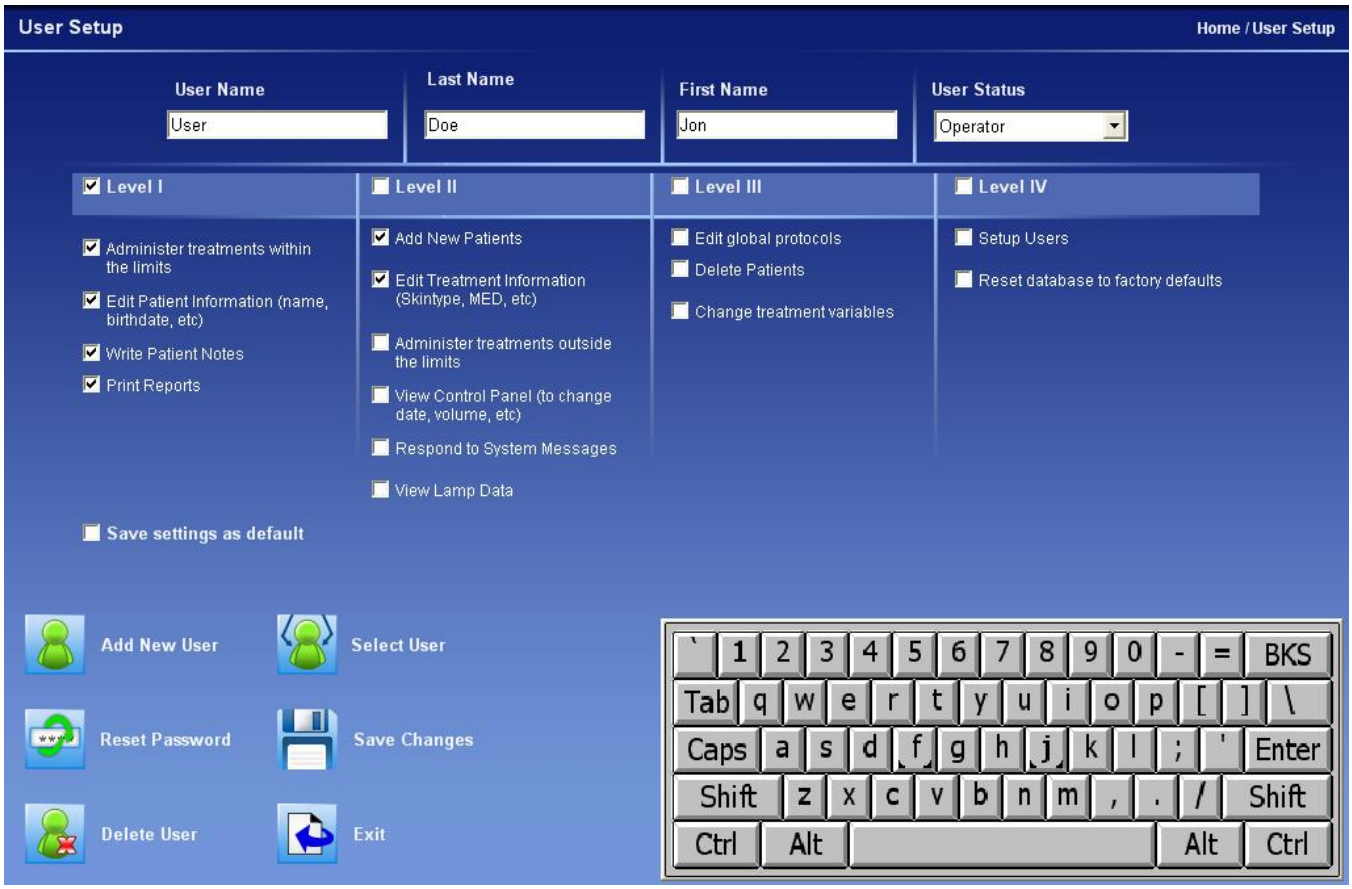


Figure 13 – User Setup Screen

8.7 User Login

Warning: It is important that all users log out 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. Log out 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.

8.7.1 Initial Login

Upon initial login of a new user, the SmartTouch™ software will require the user to change the default password. login

1. At the login screen (See **Figure 7 – User Login 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 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 login password. It is important to remember the new password, as the system will only allow subsequent login 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 – Loading Screen**), the user password will be changed, and login 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.*

8.7.2 Subsequent Login

Only authorized users can perform this function.

1. At the User Login screen (See **Figure 7 – User Login 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 10 – Main Menu Screen**), indicating that the user login 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.*

8.8 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**, **Schedule**, and **Patient's MED** (if applicable).

1. Login to the SmartTouch™ 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 14 – Patient Setup Screen**), and the cursor will appear in the **Patient PIN** field.

Figure 14 – Patient Setup Screen

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.
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 (Psoriasis Area Severity Index), 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. If the treatment type includes UVB, the **Patient's MED** field will appear. Tap once in the **Patient's MED** field to move the cursor to this position, and enter the patient's MED. If the patient's MED is unknown and an MED test shall not be performed, tap once on the **Suggested MED Range** button. The MED range for the skin type selected will be displayed. After determining the MED to be used, tap **ok** once to close the **Suggested MED Range** window. Type the MED to be used in the **Patient's MED** field.
19. If secondary treatments are desired, select the type of secondary treatment by tapping once on the square next to the appropriate secondary treatment type (UVA or UVB) in the **Secondary treatment** area located above the **Skin Type** and **Treatment Type** boxes.
20. Select the treatment frequency schedule by tapping once on the circle next to the desired schedule in the **Schedule** box.

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.

***Note**: Choose the **Treatment Type**, **Patient's MED** (if applicable), and **Skin Type** carefully. This data determines the treatment protocol selected and cannot be edited once a treatment has been administered.*

21. 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.
22. Subsequent patients can be added by repeating steps 2-21.
23. 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.

8.8.1.1 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.

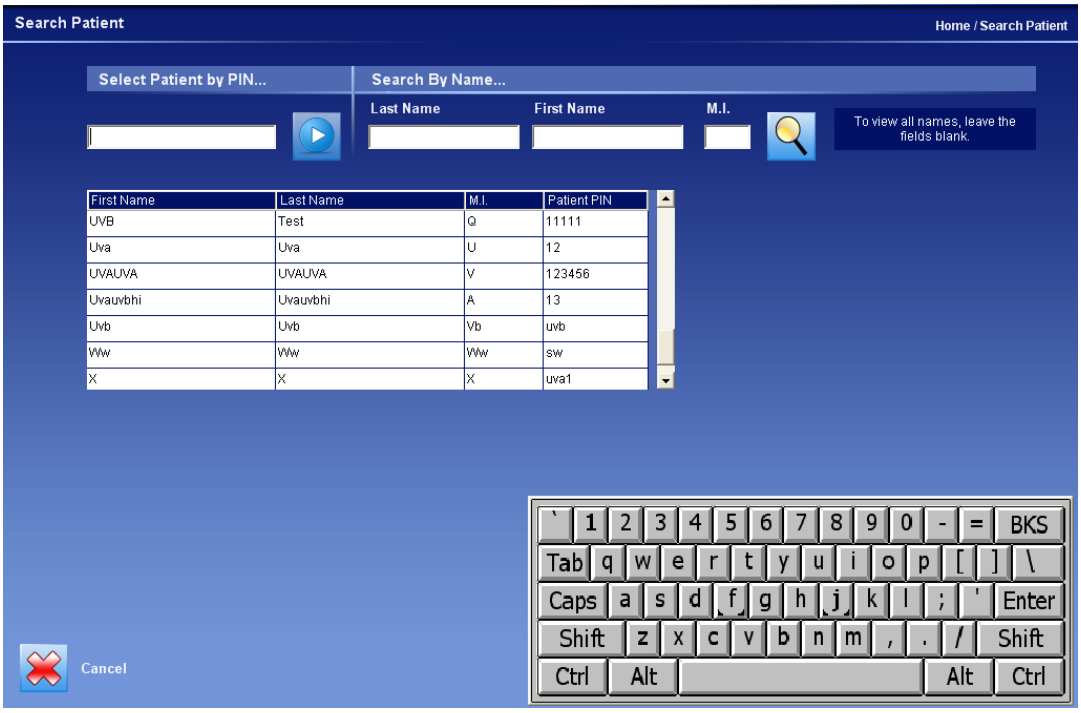


Figure 15 – Select a Patient Screen

8.8.2 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 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.

8.8.3 Treating a Patient

Only authorized users can perform this function.

1. Login 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 16 – 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.

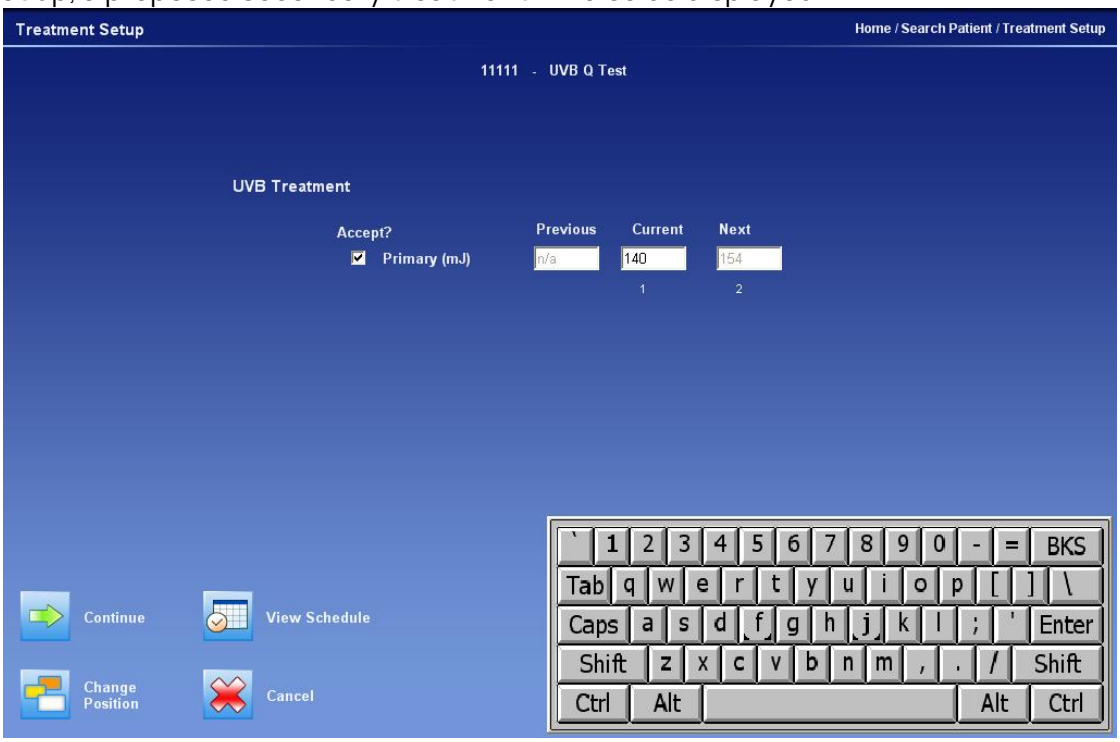


Figure 16 – Treatment Setup Screen

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.

Warning: 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 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 17 – Treatment in Process Screen**).

Note: *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.*

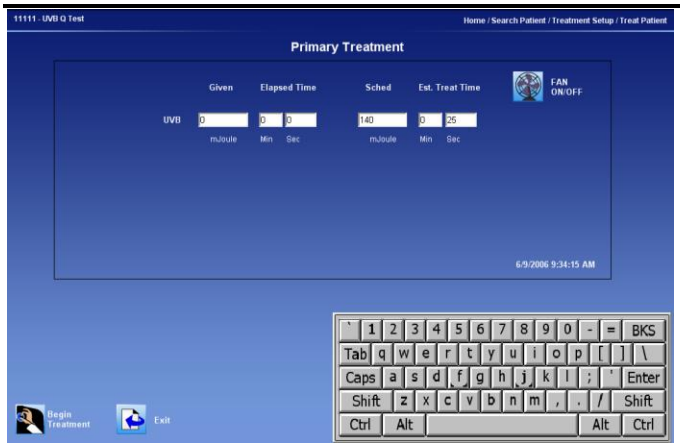


Figure 17 – Treatment in Process Screen

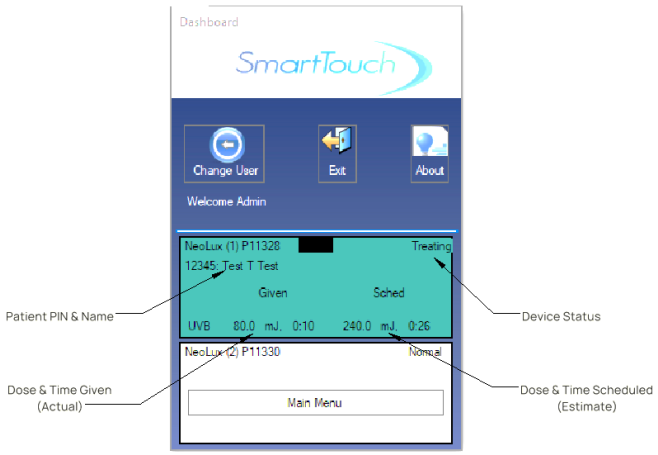


Figure 18 – Treatment In Process on STMM Dashboard

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)** is 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 19 – Treatment Complete Screen**).

Note: *If the door is not fully closed when beginning or during a treatment, the lamps will not turn on. The message, "**The door is open. Please close the door to continue treatment**", will be displayed and announced (if a language is selected). Once the door is closed, and the **Resume** button is pressed on the external display or the yellow button is pressed on the internal button box, the treatment will begin after a ten second delay.*

Note: *The treatment time estimate may not be accurate at the beginning of the treatment. If, for example, the previous treatment was short, the lamps may not have fully warmed up. Since the current time estimate is based on the previous treatment's lamp output, this would make the system estimate a large amount of time for the current treatment. If it seems excessive, pay attention, but do not stop the treatment. If the treatment time estimate does not seem reasonable after one minute, stop the treatment.*

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. ***Note**: Printer not included.
9. Press the **Exit** button to return to the Main Menu screen

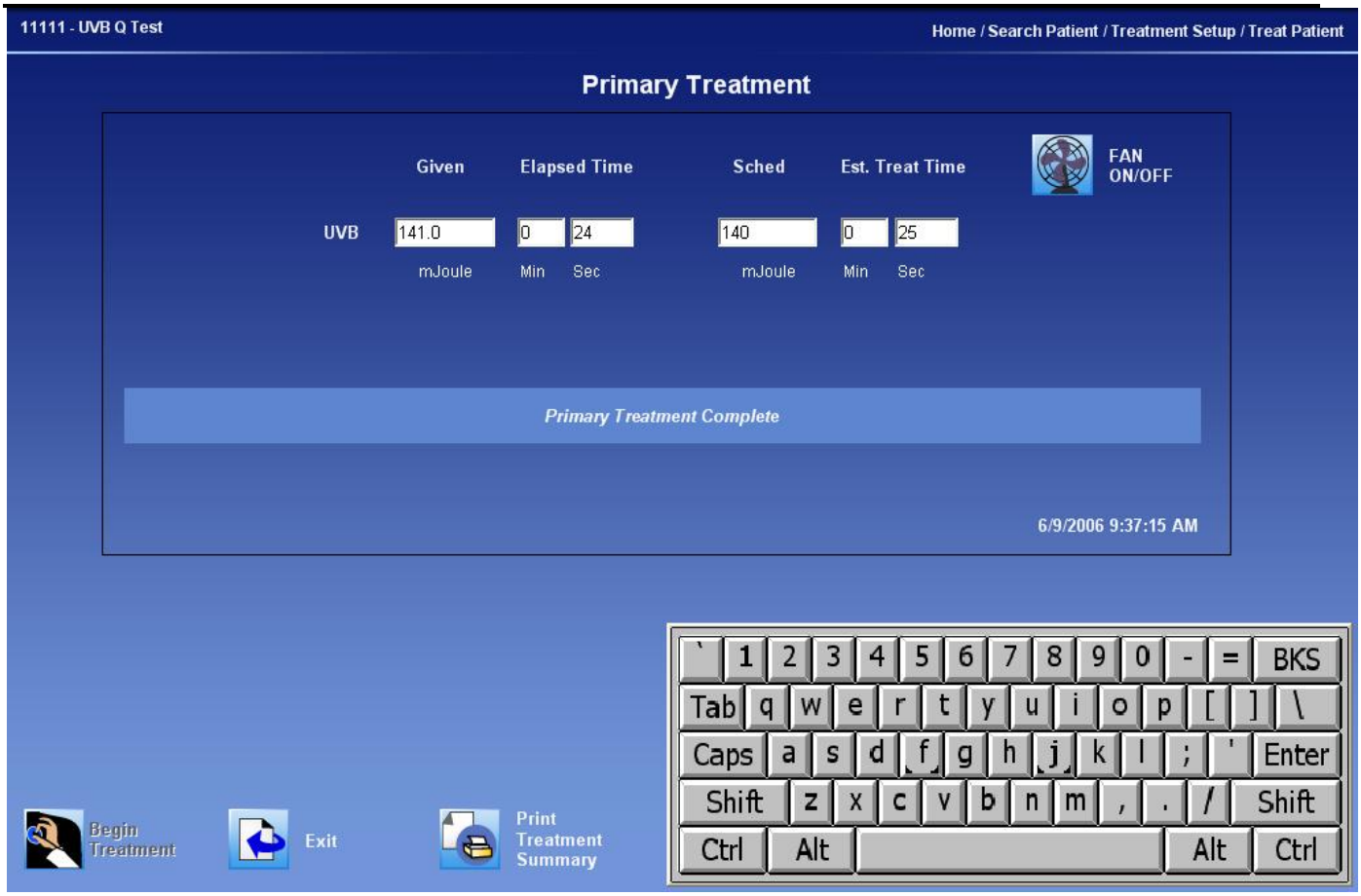


Figure 19 – Treatment Complete Screen

8.8.4 Pausing the Treatment

Press the **Pause** button on the Treatment in Process screen.

OR

Press the yellow Lamp button on the internal Button Box.

OR

Open the door.

8.8.5 Resuming the Treatment

Press the **Resume** button on the Treatment in Process screen.

OR

Press the yellow Lamp button on the internal Button Box.

OR

Close the door and press the **Resume** button on the Treatment in Process screen.

8.8.6 End of Protocol Treatments

All UVA protocols have 25 standard treatment steps and all UVB protocols have 29. Upon entry of all treatments subsequent to the 25th (UVA) and 29th (UVB) treatment 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.

8.8.7 History

The SmartTouch™ 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.

8.9 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 read and understand the How Protocols Work section of this manual before changing a patient's treatment dose. Only highly skilled and trained personnel should perform this process.

8.9.1 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 16 – 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 the box under the check box labeled **Accept?** to indicate that the dose is acceptable for the treatment.
3. Press the **Continue** button. The Treatment in Process screen will appear.

***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 Warning Rules and Authorities section of this manual for system limitations on how they may be overridden).*

8.9.2 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 16 – 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 by clicking on 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.

***Note**: 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 Warning Rules and Authorities section in this manual.*

8.10 Warning Rules and Authorities

The SmartTouch™ 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. (see **Figure 20 – Authorization Screen**)

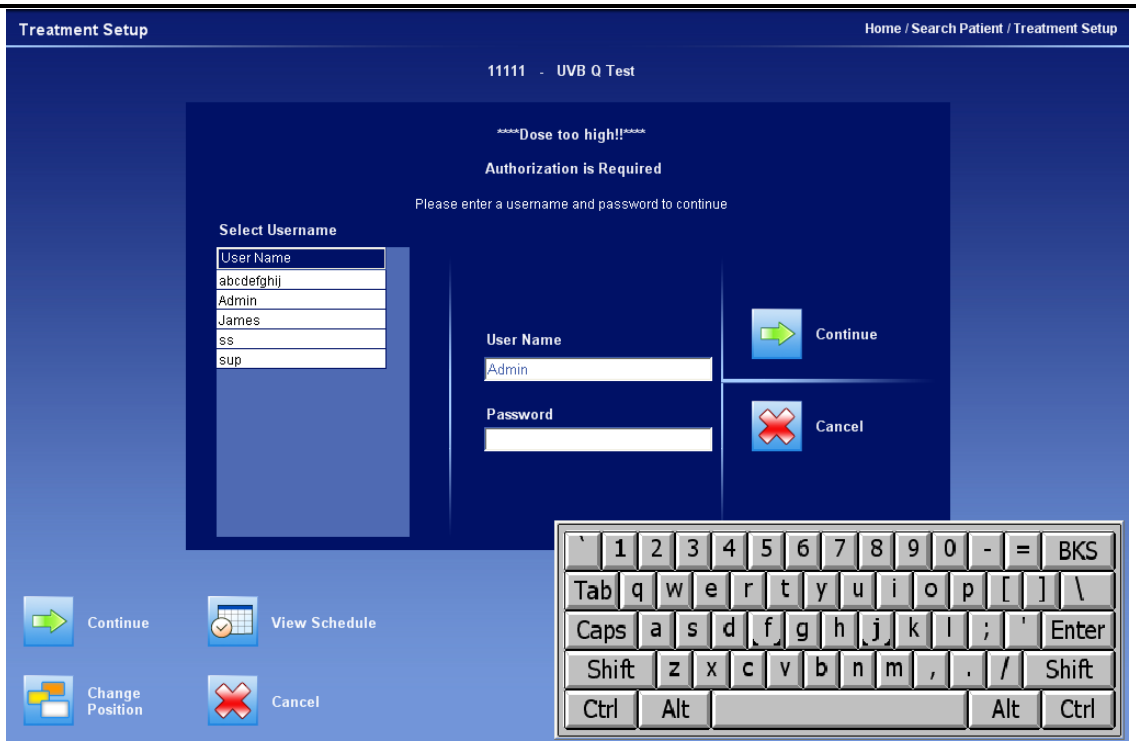


Figure 20 – Authorization Screen

8.11 Rules for Warning Messages

The authorization rules applicable throughout the system are described below:

8.11.1 When Setting up a Patient

- If an operator enters an MED that is below the suggested range, an FYI warning is displayed.

OR

- If an operator enters, an MED above the highest value in the range an authorized user's PIN must be entered to have the value accepted.

8.11.2 When Treating or Editing a Patient's Protocol

A warning will be displayed when:

UVA

- 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.

UVB

- 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 represents a percentage change from the previous dose that is greater than the largest percentage increase for that schedule.

Both UVA and UVB

- 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 in the System Settings* section of this manual).

An Authorization PIN will be required when:

UVA

- The difference between the current dose and the previous dose is two times greater than the largest difference between consecutive treatments for that schedule.

UVB

- The operator changes the dose to a value greater than 2 steps beyond the current dose.

OR

- The percentage change between the current dose and the previous dose is greater than the largest percentage increase for that schedule.

Both UVA and UVB

- If the time since the last treatment is greater than Maximum Time between Treatments (Authorization is Required). (See Treatment Variables in the System Settings section of this manual).

8.12 Edit Patient Data

Only authorized users can edit patient data.

1. Login to the SmartTouch™ 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 15 – 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.

8.12.1 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 21 – 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.

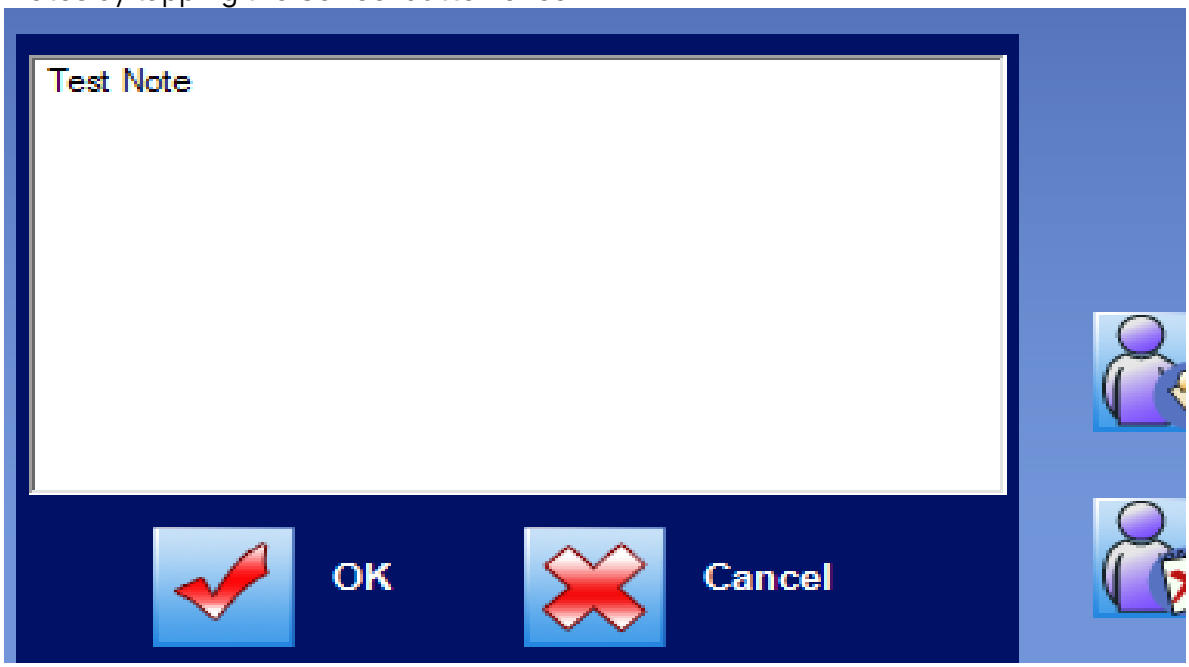


Figure 21 – Patient Notes Screen

8.12.2 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.

8.12.3 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. Using the keyboard at the bottom of the display, type the new data.
3. When all editing is complete, tap the **Save** button once to save the data.
4. 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.

8.12.4 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, Treatment type, and MED cannot be changed for a particular patient once a treatment has been administered for that patient.

8.12.5 Understanding How Protocols Work

8.12.6 UVA Protocols

8.12.6.1 Primary Treatments

UVA protocols use absolute numbers and differ from narrow band UVB protocols in that a change at any given position does not automatically affect the succeeding treatments in the protocol.

8.12.6.2 Secondary Treatments

Secondary UVA doses also use absolute numbers that have a direct relation to the primary dose, which is usually half, but this depends on the patient's Skin Type and the Treatment Schedule.

See the tables in the UVA Protocol Values section of this manual.

8.12.7 Narrow Band UVB Protocols

8.12.7.1 Primary Treatments

The key to understanding narrow band UVB protocols is to remember that they are percentage based, rather than a progression of absolute numbers as in the case of UVA protocols.

- The first treatment of a narrow band UVB dose is always a **percentage of the MED** that was entered when the patient was set up. Therefore, if the patient's MED was entered as 100 millijoules and the chosen protocol calls for a first dose equal to 70% of the MED, that treatment will be 70 millijoules.
- Each subsequent dose will be a **percentage increase over the previous dose.** Therefore, if the protocol calls for the second dose to be a 10% increase over the previous or first dose, in the example above, the second dose would be 77 millijoules, or 1.1 times 70 millijoules.

Therefore, when editing a global narrow band UVB protocol, the percentage by which that particular treatment will increase over the previous treatment is changed, or in the case of treatment number one, the percentage of the MED that will be delivered. It is important to keep in mind that each treatment has an effect on all succeeding treatments. Therefore, if a patient's dose is changed, subsequent doses will automatically update to reflect the percentage increase of the new dose.

See the tables in the Narrow Band UVB Protocol Values section of this manual.

8.12.7.2 Secondary Treatments

Secondary narrow band UVB doses are set at 50% of the primary dose by default. This is standard throughout the narrow band UVB protocol. Therefore, if the primary dose is scheduled for 250 millijoules then the secondary dose is 125 millijoules.

8.12.8 HI and LOW Narrow Band UVB Protocols

Both high and low narrow band UVB protocols operate under the same principles. The difference is the aggressiveness of the protocols. See the following table:

Skin	% of MED for the 1st Treatment	
Type	**HI- NB UVB**	**Low- NB UVB**
1	70	30
2	70	30
3	70	30
4	70	30
5	70	30
6	70	30

High narrow band UVB protocols start out more aggressively but have smaller percent increases while Low narrow band UVB protocols start at a lower percentage of the MED but increase more aggressively. The High narrow band UVB protocol is overall the most aggressive protocol. See the Narrow Band UVB Protocol Values section of this manual.

8.12.8.1 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.

8.12.8.2 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.**

1. **UVA** protocols are **25** treatments long.
2. **Narrow Band UVB** protocols are **29** treatments long.

8.12.8.3 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 the section on **Edit Protocols**.

8.13 UVA Protocol Values

8.13.1 UVA Clearing Phase Protocols (Skin Types I - III)

Number of Treatments = 25

UVA, Skin Type I, 11011

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	0.5	0.5	1.0	1.0	1.5	1.5	2.0	2.0	2.5	2.5	3.0	3.0	3.5	3.5	4.0	4.0	4.5	4.5	5.0	5.0	5.0	5.0	5.0	5.0	5.0
SECONDARY DOSE (JOULES)	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0

UVA, Skin Type I, 3/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	1.5	1.5	1.5	2.0	2.0	2.0	2.5	2.5	2.5	3.0	3.0	3.0	3.5	3.5	3.5	4.0	4.0	4.0	4.5	4.5	4.5	5.0	5.0	5.0	5.0
SECONDARY DOSE (JOULES)	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0

UVA, Skin Type I, 2/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	1.5	1.5	1.5	2.0	2.0	2.0	2.5	2.5	2.5	3.0	3.0	3.0	3.5	3.5	3.5	4.0	4.0	4.0	4.5	4.5	4.5	5.0	5.0	5.0	5.0
SECONDARY DOSE (JOULES)	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0

UVA, Skin Type II, 11011

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	1.5	1.5	2.0	2.0	2.5	2.5	3.0	3.0	3.5	3.5	4.0	4.0	4.5	4.5	5.0	5.0	5.5	5.5	6.0	6.0	6.5	6.5	7.0	7.0	7.5
SECONDARY DOSE (JOULES)	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0

UVA, Skin Type II, 3/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0
SECONDARY DOSE (JOULES)	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0

UVA, Skin Type II, 2/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0
SECONDARY DOSE (JOULES)	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0

UVA, Skin Type III, 11011

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10.0	10.5	11.0	11.5	12.0	12.0	12.0	12.0	12.0	12.0
SECONDARY DOSE (JOULES)	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10.0	10.5	11.0	11.5	12.0	12.0	12.0	12.0	12.0

UVA, Skin Type III, 3/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10.0	10.5	11.0	11.5	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0
SECONDARY DOSE (JOULES)	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0	9.5	10.0	10.5	11.0	11.5	12.0	12.0	12.0	12.0	12.0

UVA, Skin Type III, 2/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	3.5	5.0	6.5	8.0	9.5	11.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0
SECONDARY DOSE (JOULES)	2.0	3.0	4.0	5.0	5.5	6.0	6.50	7.0	7.5	8.0	8.5	9.0	9.5	10.0	10.5	11.0	11.5	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0

8.13.2 UVA Clearing Phase Protocols (Skin Types IV - VI)

Number of Treatments = 25

UVA, Skin Type IV, 11011

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	3.5	3.5	4.5	4.5	5.5	5.5	6.5	6.5	7.5	7.5	8.5	8.5	9.5	9.5	10.5	10.5	11.5	11.5	12.5	12.5	13.5	13.5	14.0	14.0	14.0
SECONDARY DOSE (JOULES)	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0

UVA, Skin Type IV, 3/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	4.5	5.5	6.5	7.5	8.5	9.5	10.5	11.5	12.5	13.5	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0
SECONDARY DOSE (JOULES)	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0

UVA, Skin Type IV, 2/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	4.5	5.5	6.5	7.5	8.5	9.5	10.5	11.5	12.5	13.5	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0
SECONDARY DOSE (JOULES)	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0

UVA, Skin Type V, 11011

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	4.5	4.5	5.5	5.5	6.5	6.5	7.5	7.5	8.5	8.5	9.5	9.5	10.5	10.5	11.5	11.5	12.5	12.5	13.5	13.5	14.5	14.5	15.5	15.5	16.0
SECONDARY DOSE (JOULES)	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0

UVA, Skin Type V, 3/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	6.5	7.5	8.5	9.5	10.5	11.5	12.5	13.5	14.5	15.5	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0
SECONDARY DOSE (JOULES)	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0

UVA, Skin Type V, 2/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	5.5	6.5	7.5	8.5	9.5	10.5	11.5	12.5	13.5	14.5	15.5	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0	16.0
SECONDARY DOSE (JOULES)	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0

UVA, Skin Type VI, 11011

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	5.5	5.5	7.0	7.0	8.5	8.5	10.0	10.0	11.5	11.5	13.0	13.0	14.5	14.5	16.0	16.0	17.5	17.5	19.0	19.0	20.0	20.0	20.0	20.0	20.0
SECONDARY DOSE (JOULES)	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0	17.0	18.0	19.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0

UVA, Skin Type VI, 3/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	6.5	7.5	8.5	9.5	10.5	11.5	12.5	13.5	14.5	15.5	16.5	17.5	18.5	19.5	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
SECONDARY DOSE (JOULES)	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0	17.0	18.0	19.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0

UVA, Skin Type VI, 2/week

TREATMENT #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
PRIMARY DOSE (JOULES)	6.5	8.0	9.5	11.0	12.5	14.0	15.5	17.0	18.5	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
SECONDARY DOSE (JOULES)	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0	17.0	18.0	19.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0

8.13.3 UVA Maintenance Phase Protocols: 1/week, 3/month, 2/month, 1/month

Maximum Number of Treatments = 4

ALL SKIN TYPES: Dose should be held steady at last clearance phase dose.

8.14 Narrow Band UVB Protocol Values

8.14.1 LO Dose Narrow Band UVB Clearing Phase Protocols: 11011, 3/week, 2/week

Maximum Number of Treatments = 29

ALL SKIN TYPES, ALL SCHEDULES

TREATMENT #	% of MED	% INCREASE OVER PREVIOUS DOSE																											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
PRIMARY DOSE (MILLIJOULES)	30	20	19	18	17	16	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0	0	0	0	0	0	0	0
	% OF PRIMARY DOSE																												
SECONDARY DOSE (MILLIJOULES)	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50

8.14.2 LO Dose Narrow Band UVB Maintenance Phase Protocols: 1/WEEK

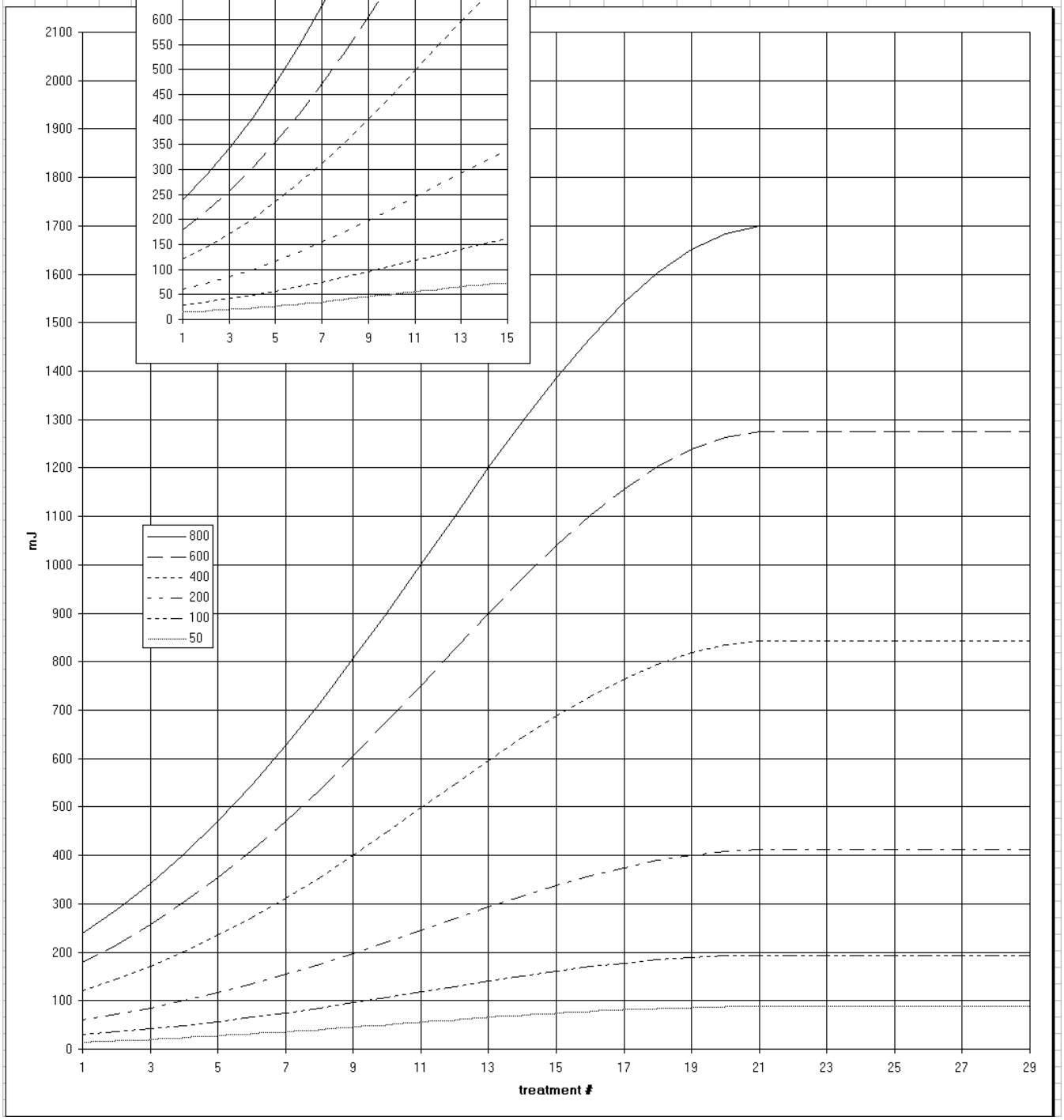
Maximum Number of Treatments = 4

ALL SKIN TYPES: Dose should be held steady at last clearance phase dose

The following charts provide a graphic example of the LO Dose Narrow Band UVB clearing phase protocols. Doses corresponding to several MED values from each protocol are calculated and plotted.

LO Dose Narrowband UVB, All Skin Types, Schedule 11011, 3/week, 2/week

MED	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
800	240	288	342	403	471	546	627	714	806	902	1001	1101	1200	1296	1386	1469	1542	1603	1651	1684	1700	1700	1700	1700	1700	1700	1700	1700	1700
600	180	216	257	303	354	410	471	536	605	677	751	826	900	972	1040	1102	1157	1203	1239	1263	1275	1275	1275	1275	1275	1275	1275	1275	1275
400	120	144	171	201	235	272	312	355	401	449	498	547	596	643	688	729	765	795	818	834	842	842	842	842	842	842	842	842	842
200	60	72	85	100	117	135	155	176	198	221	245	269	293	316	338	358	375	390	401	409	413	413	413	413	413	413	413	413	413
100	30	36	42	49	57	66	75	85	96	107	118	129	140	151	161	170	178	185	190	193	194	194	194	194	194	194	194	194	194
50	15	18	21	24	28	32	36	41	46	51	56	61	66	71	75	79	82	85	87	88	88	88	88	88	88	88	88	88	88



HI Dose Narrow Band UVB Clearing Phase Protocols: 11011, 3/week, 2/week
Maximum Number of Treatments = 29

SKIN TYPES I & II, ALL SCHEDULES

TREATMENT #	% of MED	% INCREASE OVER PREVIOUS DOSE																											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
PRIMARY DOSE (MILLIJOULES)	70	10	10	10	10	10	10	10	10	10	10	10	10	10	9	8	7	6	5	4	3	2	1	0	0	0	0	0	0
	% OF PRIMARY DOSE																												
SECONDARY DOSE (MILLIJOULES)	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50

SKIN TYPES III & IV, ALL SCHEDULES

TREATMENT #	% of MED	% INCREASE OVER PREVIOUS DOSE																											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
PRIMARY DOSE (MILLIJOULES)	70	15	15	15	15	15	15	15	15	15	15	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0	0	0
	% OF PRIMARY DOSE																												
SECONDARY DOSE (MILLIJOULES)	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50

SKIN TYPES V & VI, ALL SCHEDULES

TREATMENT #	% of MED	% INCREASE OVER PREVIOUS DOSE																											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
PRIMARY DOSE (MILLIJOULES)	70	15	15	15	15	15	15	15	15	15	15	15	15	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	0
	% OF PRIMARY DOSE																												
SECONDARY DOSE (MILLIJOULES)	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50

8.14.3 HI Dose Narrow Band UVB Maintenance Phase Protocols: 1/WEEK

Maximum Number of Treatments = 4

8.14.4 ALL SKIN TYPES: Dose should be held steady at last clearance phase dose

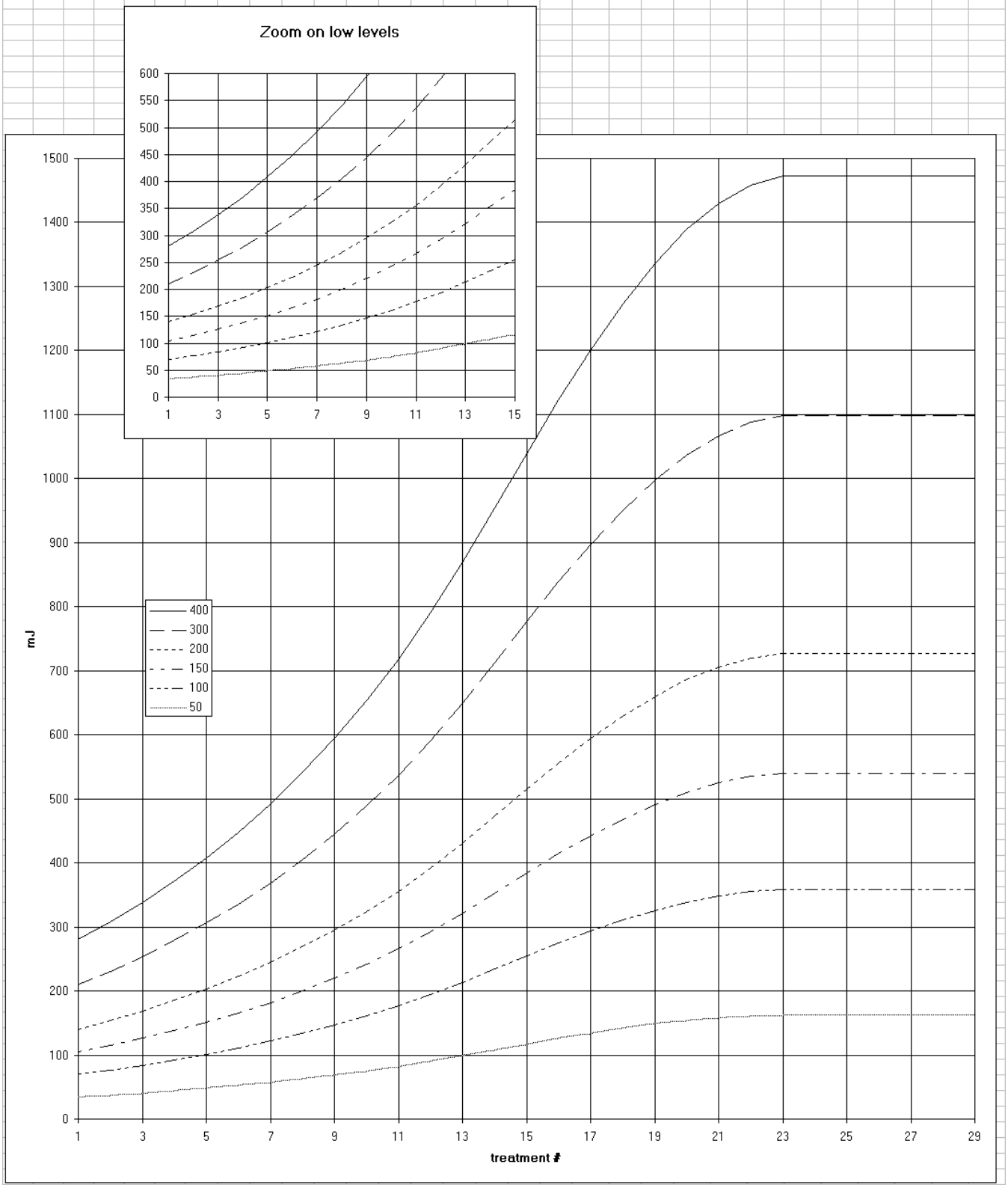
MED Ranges

Skin Type	Narrowband MED Range (mJ/cm²)
I	50-300
II	100-400
III	150-500
IV	200-600
V	250-700
VI	300-800

The following charts provide a graphic example of the HI Dose Narrow Band UVB clearing phase protocols. Doses corresponding to several MED values from each protocol are calculated and plotted.

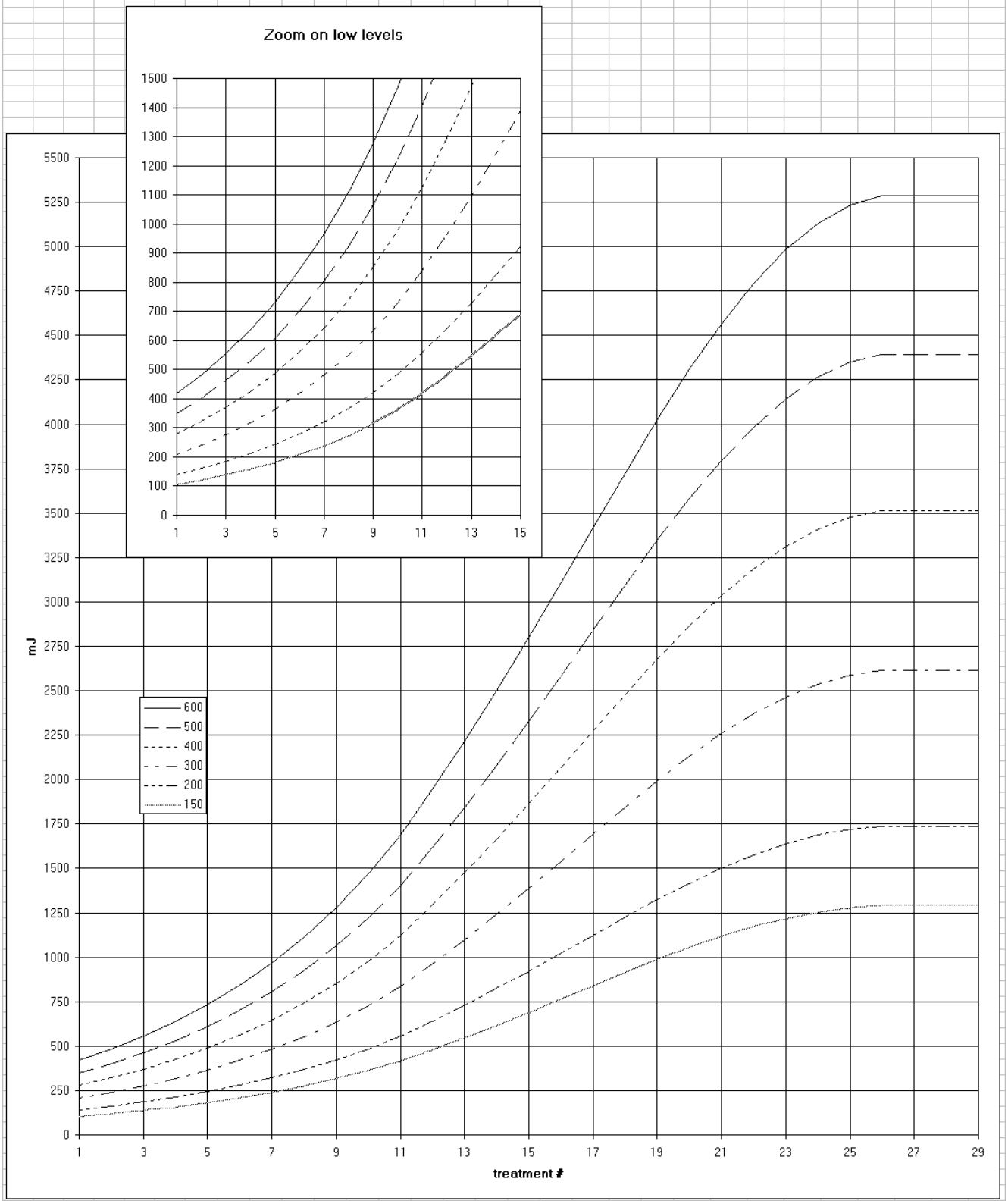
HI Dose Narrowband UVB, Skin Types I - II, Schedule 11011, 3/week, 2/week

MED	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
400	280	308	338	371	408	448	492	541	595	654	719	790	869	955	1040	1123	1201	1273	1336	1389	1430	1458	1472	1472	1472	1472	1472	1472	1472
300	210	231	254	279	306	336	369	405	445	489	537	590	649	713	777	839	897	950	997	1036	1067	1088	1098	1098	1098	1098	1098	1098	1098
200	140	154	169	185	203	223	245	269	295	324	356	391	430	473	515	556	594	629	660	686	706	720	727	727	727	727	727	727	727
150	105	115	126	138	151	166	182	200	220	242	266	292	321	353	384	414	442	468	491	510	525	535	540	540	540	540	540	540	540
100	70	77	84	92	101	111	122	134	147	161	177	194	213	234	255	275	294	311	326	339	349	355	358	358	358	358	358	358	358
50	35	38	41	45	49	53	58	63	69	75	82	90	99	108	117	126	134	142	149	154	158	161	162	162	162	162	162	162	162



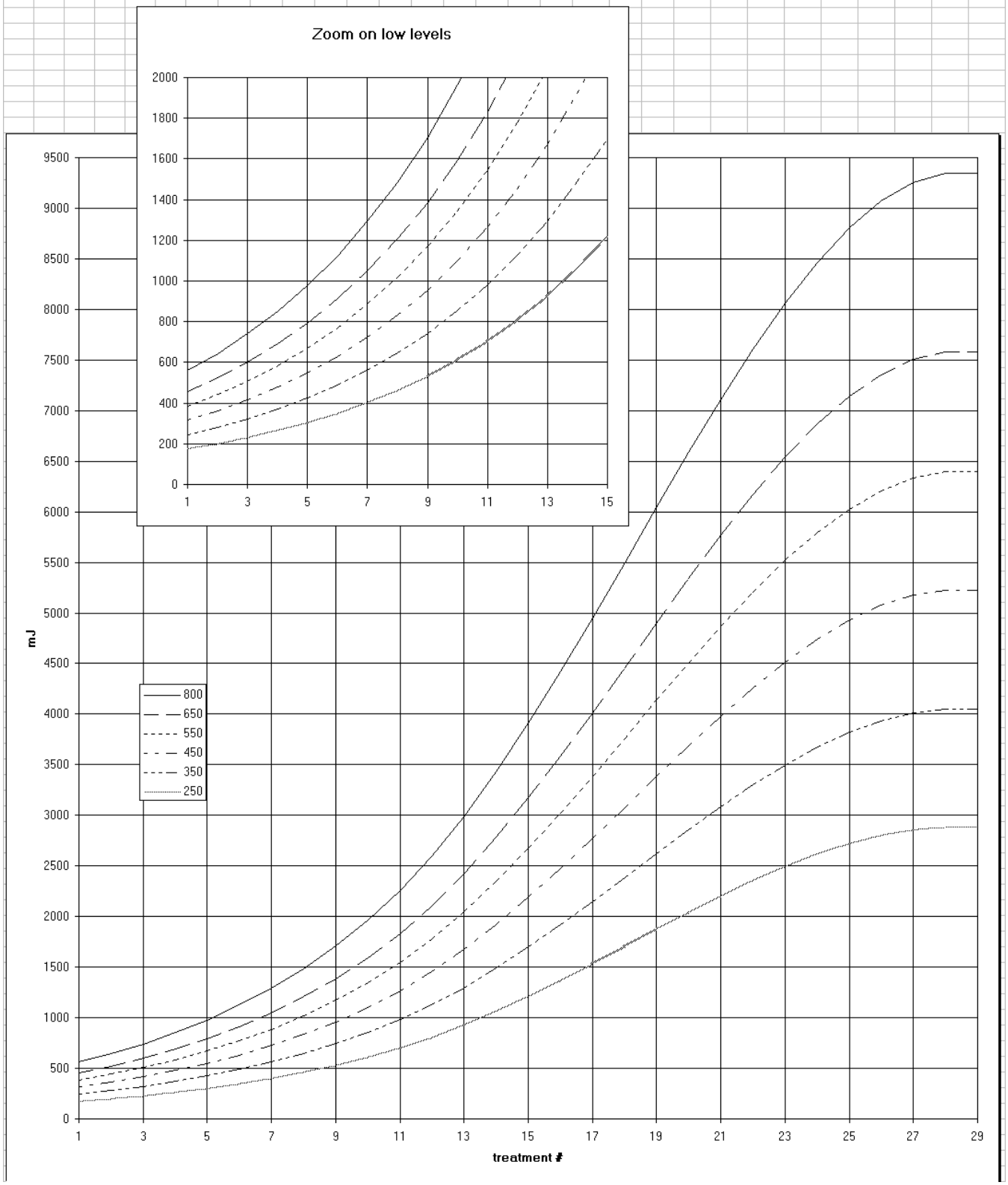
HI Dose Narrowband UVB, Skin Types III-IV, Schedule 11011, 3/week, 2/week

MED	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
600	420	483	555	638	733	842	968	1113	1279	1470	1690	1943	2215	2502	2802	3110	3421	3728	4026	4307	4565	4793	4984	5133	5235	5287	5287	5287	5287
500	350	402	462	531	610	701	806	926	1064	1223	1406	1616	1842	2081	2330	2586	2844	3099	3346	3580	3794	3983	4142	4266	4351	4394	4394	4394	4394
400	280	322	370	425	488	561	645	741	852	979	1125	1293	1474	1665	1864	2069	2275	2479	2677	2864	3035	3186	3313	3412	3480	3514	3514	3514	3514
300	210	241	277	318	365	419	481	553	635	730	839	964	1098	1240	1388	1540	1694	1846	1993	2132	2259	2371	2465	2538	2588	2613	2613	2613	2613
200	140	161	185	212	243	279	320	368	423	486	558	641	730	824	922	1023	1125	1226	1324	1416	1500	1575	1638	1687	1720	1737	1737	1737	1737
150	105	120	138	158	181	208	239	274	315	362	416	478	544	614	687	762	838	913	986	1055	1118	1173	1219	1255	1280	1292	1292	1292	1292



HI Dose Narrowband UVB, Skin Types V - VI, Schedule 11011, 3/week, 2/week

MED	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
800	560	644	740	851	978	1124	1292	1485	1707	1963	2257	2595	2984	3431	3911	4419	4949	5493	6042	6585	7111	7608	8064	8467	8805	9069	9250	9342	9342
650	455	523	601	691	794	913	1049	1206	1386	1593	1831	2105	2420	2783	3172	3584	4014	4455	4900	5341	5768	6171	6541	6868	7142	7356	7503	7578	7578
550	385	442	508	584	671	771	886	1018	1170	1345	1546	1777	2043	2349	2677	3025	3388	3760	4136	4508	4868	5208	5520	5796	6027	6207	6331	6394	6394
450	315	362	416	478	549	631	725	833	957	1100	1265	1454	1672	1922	2191	2475	2772	3076	3383	3687	3981	4259	4514	4739	4928	5075	5176	5227	5227
350	245	281	323	371	426	489	562	646	742	853	980	1127	1296	1490	1698	1918	2148	2384	2622	2857	3085	3300	3498	3672	3818	3932	4010	4050	4050
250	175	201	231	265	304	349	401	461	530	609	700	805	925	1063	1211	1368	1532	1700	1870	2038	2201	2355	2496	2620	2724	2805	2861	2889	2889



8.14.5 VIT Dose Narrow Band UVB Clearing Phase Protocols: 2/week

Maximum Number of Treatments = 29

ALL SKIN TYPES, ALL SCHEDULES

TREATMENT #	% of MED	% INCREASE OVER PREVIOUS DOSE																											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
PRIMARY DOSE (MILLIJOULES)	100	25	20	17	14	13	11	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	% OF PRIMARY DOSE																												
SECONDARY DOSE (MILLIJOULES)	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50	50

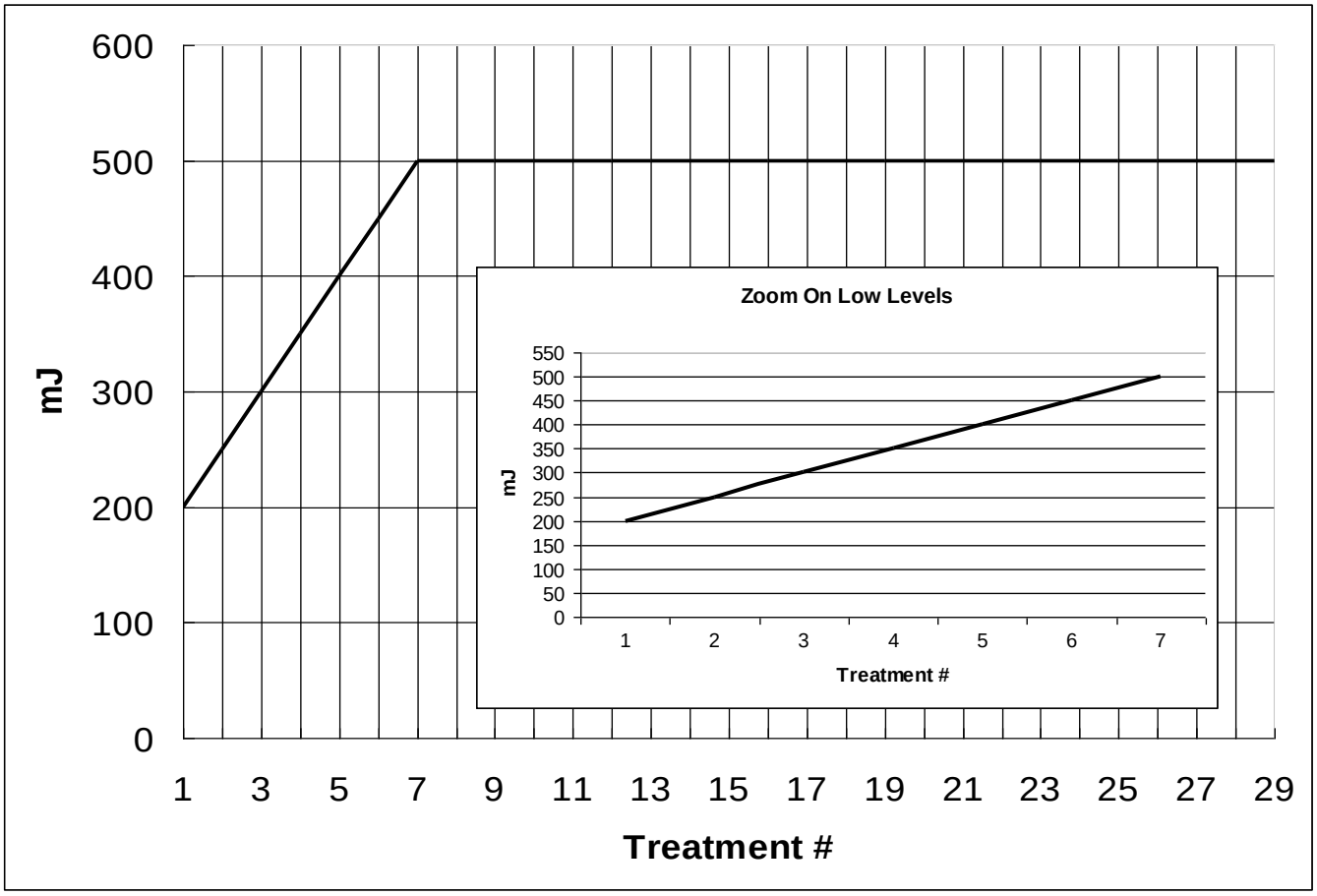
MED for all skin types of Vitiligo patients is 200 mJ/cm^2.

Percentages were rounded to the nearest whole number.

Default Vitiligo treatment is set up for 2/week opposed to 11011 and 3/week based on analyst of scientific literature.

VIT Narrowband UVB, All Skin Types, Schedule 2/week

MED	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
200	200	250	300	350	400	450	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500



8.15 Edit Protocols

8.15.1 Global Protocols

Only authorized users can edit global protocols. Editing global protocols will only affect patients that are setup 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 setup in the system at the time the protocol is edited.

1. Login to the SmartTouch™ control system.
2. From the Main Menu, tap the **Edit Global Protocols** button once. The Global Protocol Setup selection screen will appear (See).
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.

Figure 22 – Global Protocol Setup Selection Screen

4. To proceed to the Global Protocol Setup edit screen (See **Figure 23 – 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.

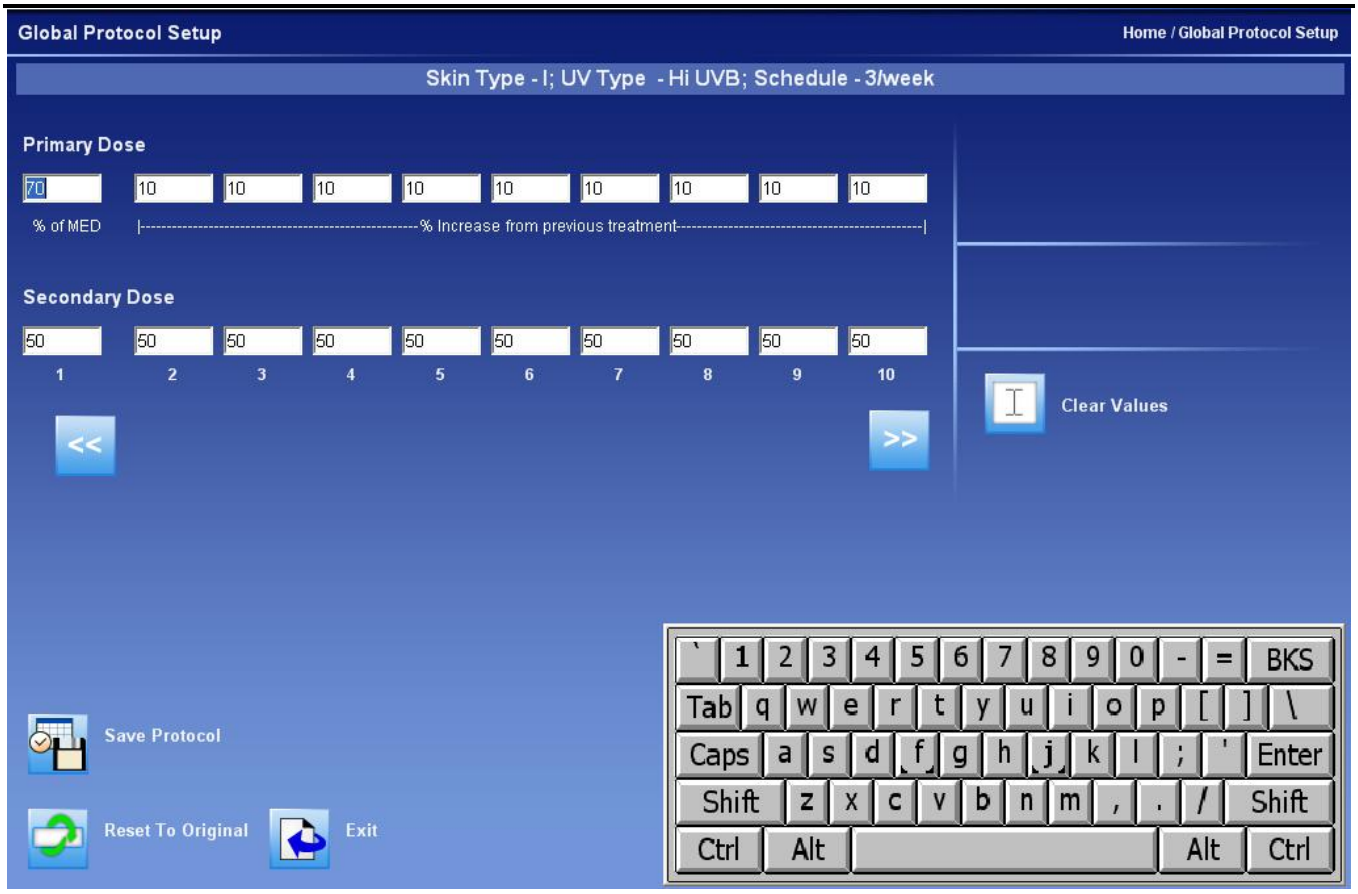


Figure 23 – Global Protocol Setup Edit Screen

Warning: Changing protocols can be dangerous and can result in treatments that will seriously injure patients. Be sure to read the *Understanding How Protocols Work* section of this manual 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 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 at the bottom of the display, 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.

8.15.2 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. Login to the SmartTouch™ 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 15 – 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 step 4 of these instructions.
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 23 – Global Protocol Setup Edit Screen** & **Figure 24 – Patient Protocol Setup Edit Screen (UVB)**).

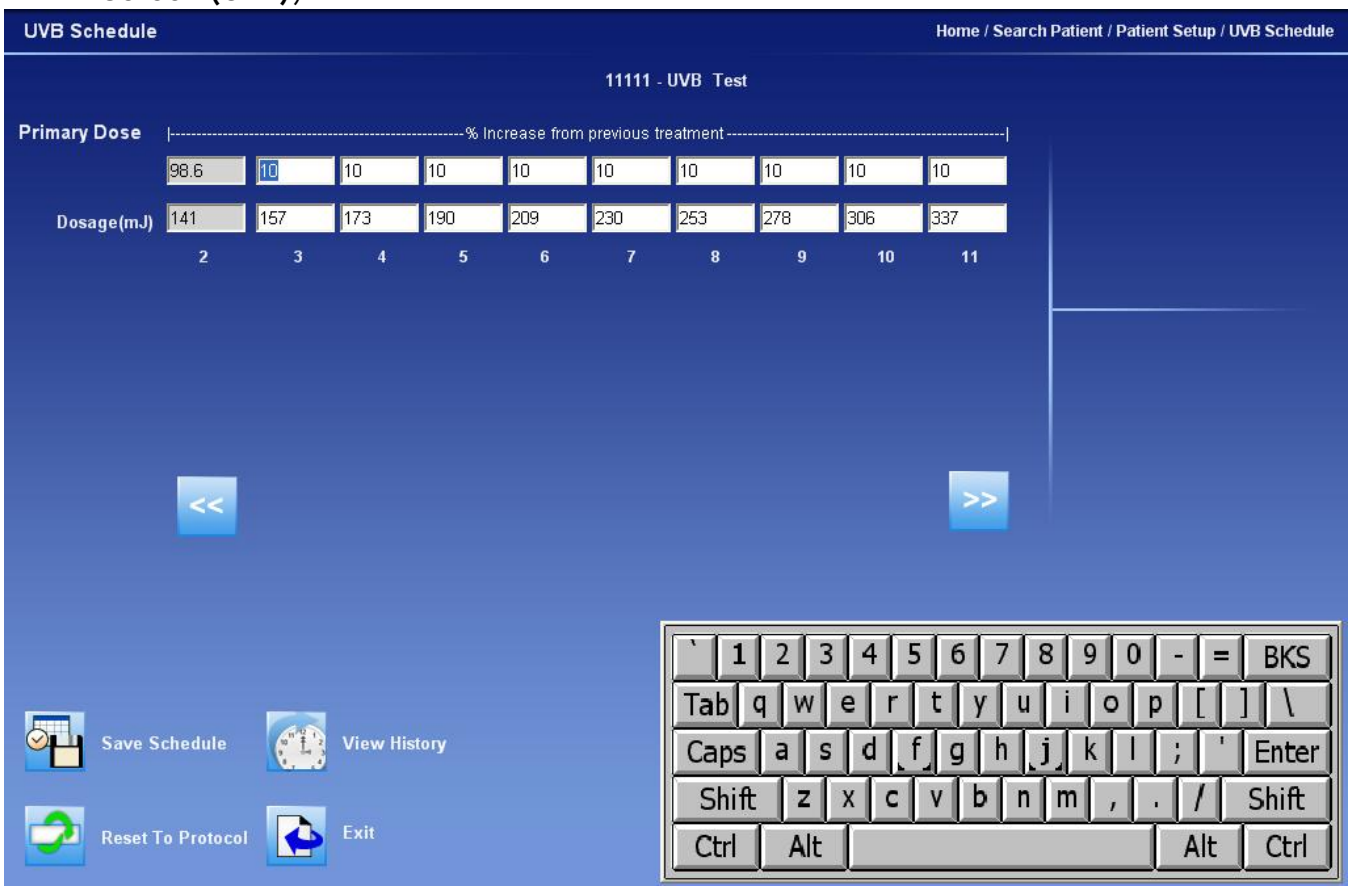


Figure 24 – Patient Protocol Setup Edit Screen (UVB)

Warning: Changing protocols can be dangerous and can result in treatments that will seriously injure patients. Be sure to read the *Understanding How Protocols Work* section of this manual 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 at the bottom of the display, 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 14 – Patient Setup Screen**) will appear. Tap once on the **Exit** button.

8.16 System Settings

Only authorized users can view and edit the System Settings.

1. Login to the SmartTouch™ 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.

8.16.1 Treatment Variables

The settings contained in the Treatment Variables screen (See **Figure 25 – 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.
- **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 Service & Manual for Calibration information).
- **Lamp hours between calibrations** – sets the number of lamp hours that can accumulate between calibrations since the last calibration before the system displays a message indicating that the calibration is due. (See the Service & Manual for Calibration information).

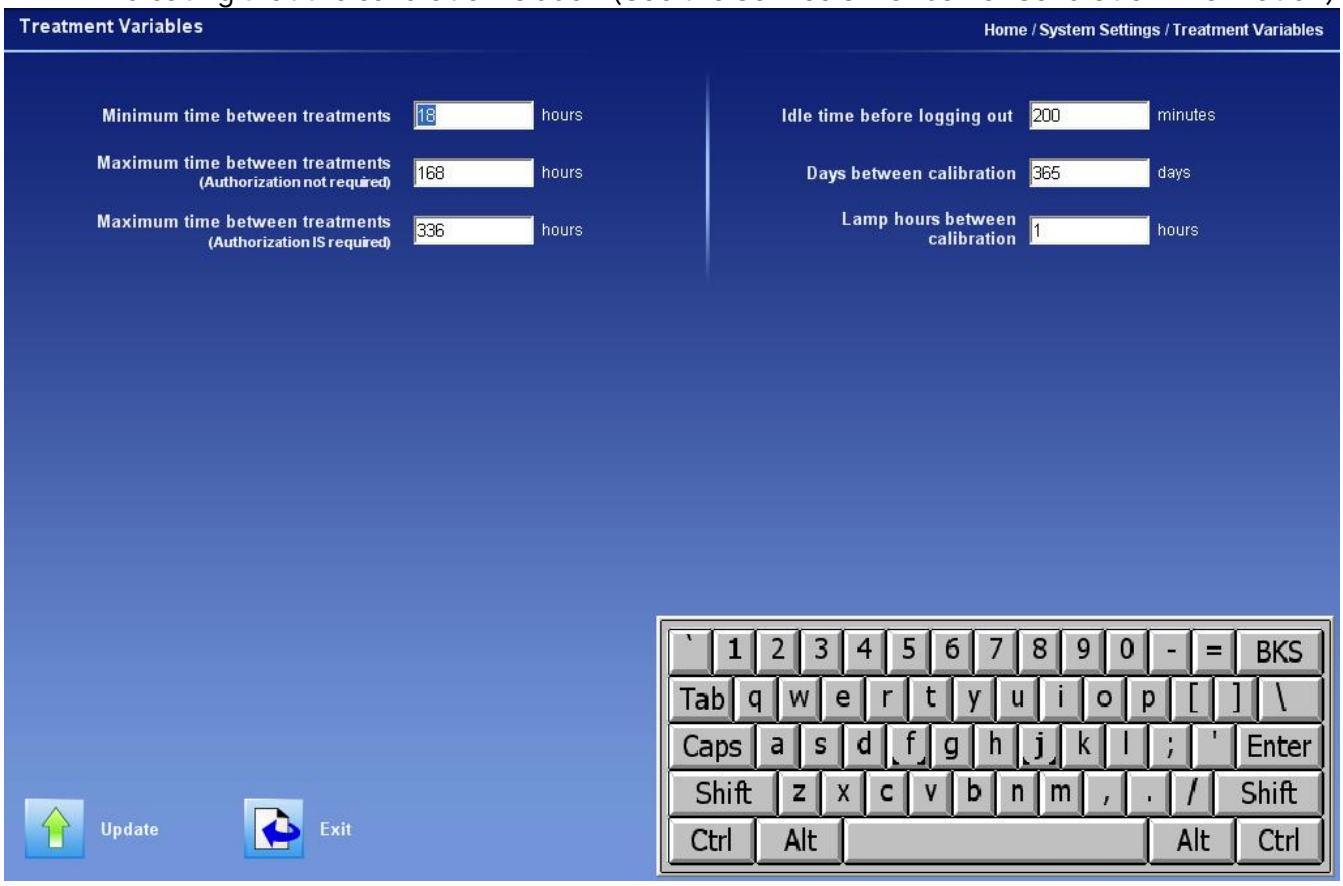


Figure 25 – Treatment Variables Screen

8.16.2 Lamp Information

The settings contained in the Lamp Information screen (See **Figure 26 – 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** or **Re-lamp UVB** button is pressed. (See the Service manual for lamp replacement [re-lamp] information).
- **Last re-lamp date –** displays the date that the **Re-lamp UVA** or **Re-lamp UVB** 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.

Figure 26 – Lamp Information Screen

8.17 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.

5. Login to the SmartTouch™ control system.
6. 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 27 – Select a Username Screen**).
7. Select the user profile to be edited by tapping the Username once. The User Setup screen will appear (See **Figure 13 – User Setup Screen**).

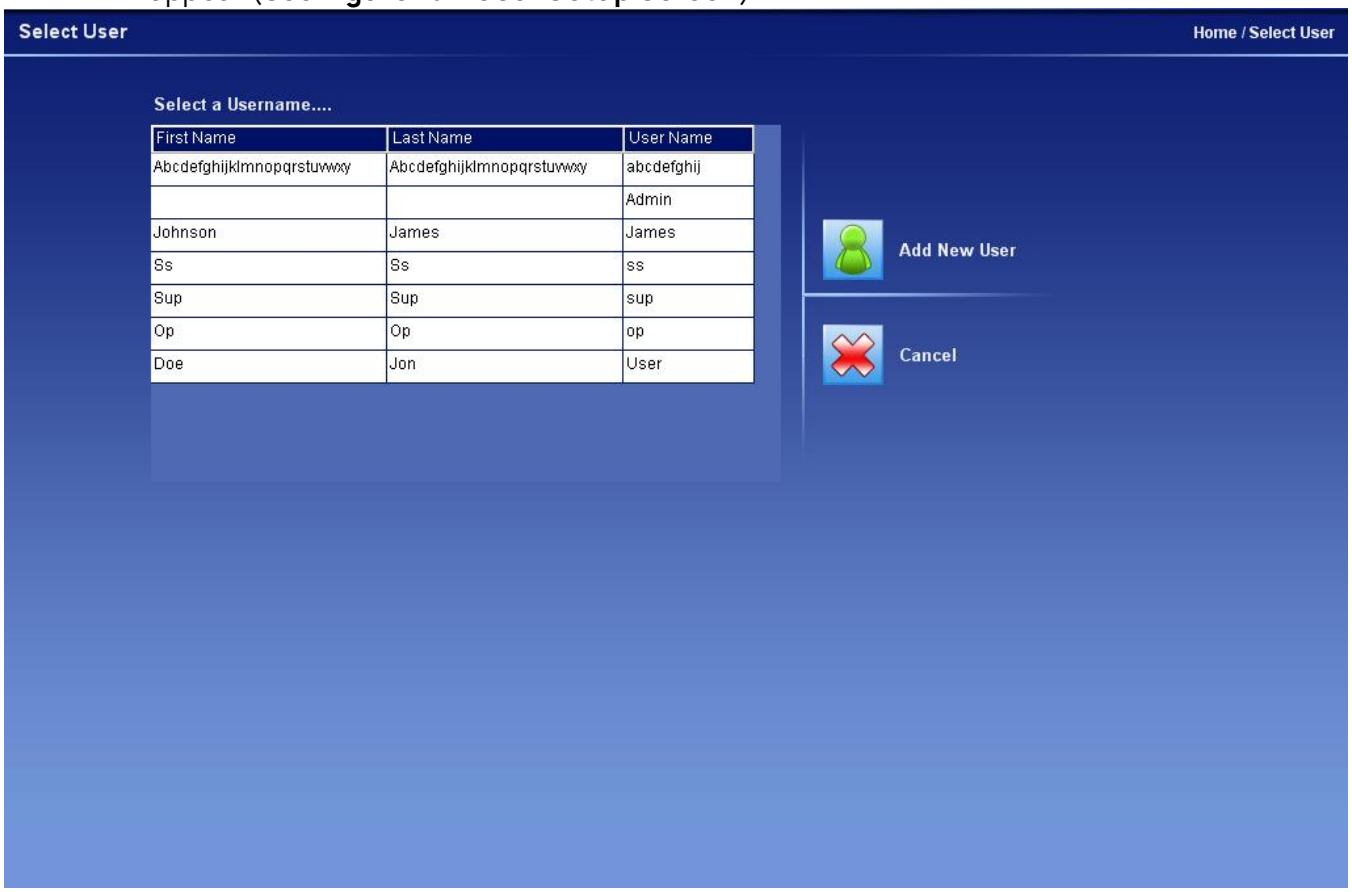


Figure 27 – Select a Username Screen

8. From the User Setup screen, edit the user's profile as desired.
9. 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.

10. Tap the **Exit** button once to exit to the Main Menu.

8.18 Generating Reports

1. Login to the SmartTouch™ Software.
2. From the Main Menu, tap the Reports button once. The Reports Menu will appear.

8.18.1 Generating an Individual Report

3. From the Reports Menu, tap the **Individual Report** button once. The Individual Report screen will appear.
4. 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.
5. In the **Patient ID** box, enter the individuals PIN number.
6. Tap the **Generate Report** button once to create the individual report.

8.18.2 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.

8.18.3 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.

8.18.4 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.

8.18.5 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 **UVB Lamps** or **UVA lamps** radio button.
4. Tap the **Generate Report** button once to create the Safety Limits History Report.

8.19 Backup/Restoration of Database

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

1. Exit the SmartTouch™ 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 which are located 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 a message above the green status bar will read 'Database Backup Complete'.

   ** 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.

8.19.2 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 which are located on the front of the PC

2. Exit the SmartTouch™ 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, a message above the green status bar will read 'Database restoration complete'
   ** 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.

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 Phothera Service department at 1-216-831-0600. Database restoration may still be possible from backup files automatically stored on the computer.

8.20 Switching from PC to Backup Time Controller

SmartTouch™ PC is the preferred operation platform for a Phothera 4000XL/4800MAX unit. In case of malfunction, some Phothera 4000XL/4800MAX units may be equipped with a backup Timer(s). To operate the unit with the backup timer, first power down the unit by turning off the circuit breaker on the right-side access panel. Locate the key switch on the right side of the unit in either the casing or the frame near the circuit breaker. Turn the key from the PC icon to the Timer icon. Power the unit back on.

8.21 Timer Boot Up

Once the Phothera 4000XL/4800MAX unit is powered on in Timer mode, the Timer will immediately begin to go through a boot cycle. After a few seconds, the timer will begin to go through a boot up countdown of approximately 45 seconds. After the countdown, the timer will be ready for use.

8.22 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 milliJoules (UVB) or Joules (UVA or visible light).

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 4.0 mW/cm^2 and the dose to be delivered is 280 mJ, then the appropriate treatment time will be 01:10. A partial time chart illustrating this is shown below.

Note: For your convenience, and as an alternative to the UVB 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.

Partial UVB Time Chart

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

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

9.0 ClearLink™ Timer Operation (CL Models Only)

9.1 Cybersecurity

Phothera's ClearLink controller is a stand-alone controller. There is no connection, wired or wireless, to any external network and/or the World Wide Web. The controller looks for encrypted .rx files only. All other files are ignored and cannot run. If an .rx file is not present, an encrypted .hst file is written to the USB drive. A J-Link adapter is required to transfer any executable files. The J-Link port is not accessible external to the device

9.2 Common ClearLink™ Functions

The system beeps to signal the end of the treatment and displays the delivered dose with the elapsed time.

If power goes off during a treatment, the system will track how much of the treatment has elapsed and will allow the treatment to resume when power is restored.

9.3 Downloading Treatment History

Your doctor may require that you provide a treatment history file so he or she can monitor your progress. To download history files, insert a USB drive into the USB port. The controller will prompt you to press the "Export Data" button. Then, press the Enter key. When the download is complete, remove the USB drive and take it to your doctor.

9.4 Post-Treatment

After a treatment, you may protect any areas that feel sunburned with sunscreen for the next several treatments or until they appear normal. (Make a note in your notebook.) You should see your physician at the intervals he or she requests when actively using the unit. Always take the notebook with you when you see your physician.

9.5 Unlocking the Device

To prevent unauthorized use, the device will self-lock when left idle for twenty (20) minutes.

1. Tap the blank screen. The Phothera logo will appear.
2. Tap the logo. The Lock Screen will appear (unless disabled).

Figure 28 Logo Screen

3. Using the keypad, enter the number 7 (unlocking code).
    a. PIN will read as "0007".
4. Press the Enter key to unlock.

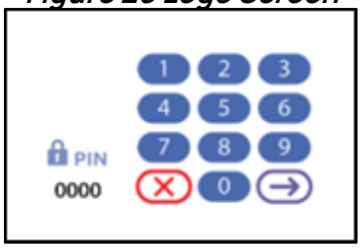


Figure 29 Lock Screen

9.5.1 Changing or Disabling the Unlock Code

The unlocking code is a safety feature that prevents someone from accidentally turning on or tampering with the device. It works just like a key. To remove the feature or to change it to a number that is easier to remember, contact Phothera's service department at 1-216-831-0600 for step-by-step instructions.

9.6 Dosimetry Mode

9.6.1 Features of the ClearLink™ Dosimetry Home-Control System

The ClearLink™ Dosimetry Home-Control System uses a built-in sensor as part of a function called integrating dosimetry to monitor the amount of light energy being produced by the device. The

system then automatically adjusts the length of each treatment to account for variations in light output caused by changes in room temperature and aging of the lamps.

9.6.2 Running a Treatment

After unlocking the device, the Treatment Screen will appear:

1) Press the Treat Patient button, then

2) Touch the ▲/▼ arrows to set the desired dose in MilliJoules (UVB) or Joules if you have a UVA device.

Note: *UVB treatments are commonly dosed in MilliJoules. This can be changed to Joules upon request by calling the Phothera service department.*

3) Press the Enter → arrow to enter the Treatment Confirmation screen.

   Confirm the Dose and Estimated Treatment Time. If changes are needed to the dose, press the Return ← arrow and return to step 2.

Put on your goggles

4) If the Dose and Estimated Treatment Time are correct, press the Enter → key to begin the treatment. 3 second countdown will begin.

5) After a 3 second delay, the lamps will turn on and the screen will track your progress. The lamps will shut off when the treatment is over.

6) To pause an active treatment, press the Pause ⏸ button. To resume, press the Play ▷ button. To end or cancel an active treatment, first pause the treatment, then press the Cancel ✕ button.

9.7 Timed Mode

Note: Before entering a treatment time into your device, please read section 8.22 (Determining a Treatment Time).

9.7.1 Running a Treatment

After unlocking the device, the Treatment Screen will appear:

1) Press the “Treat Patient” button, then

2) Touch the ▲/▼ arrows to enter the desired treatment time. ***Note:*** *It is* ***not*** *possible to enter a time of 60 seconds. You must enter 1 minute instead.*

3) Press the Enter → arrow to enter the Treatment Confirmation screen.

4) Confirm the Time. If a change is needed, press the Return ← arrow and return to step 2).

Put on your goggles

5) If the Time is correct, press the Enter → key to begin the treatment. A 3 second countdown will begin.

6) After a 3 second delay, the lamps will turn on and the screen will track your progress. The lamps will shut off when the treatment is over.
7) To pause a treatment, press the Pause ⏸ button. To resume, press the Play ▷ button. To end or cancel a treatment, first pause the treatment, then press the Cancel ✕ button.

10.0 Timer Range and Accuracy

Backup Time Range:	1 Second - 59 Minutes 59 Seconds (00:01 - 59:59)
Dose Range:	UVA: 0.1 Joules - 999.9 Joules UVB: 1 Millijoule - 9999 Millijoules
Timer Accuracy:	+/- 5%
Sensor Accuracy:	+/- 10%
Calibration:	1 year or every 100 hours of use, or upon changing lamps

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

11.0 Controlling the Fans

Both the patient and the operator can control the cooling fans:

- Operator: by pressing the **Fan On/Off** button on the display in SmartTouch™ (N/A for operator for ClearLink controlled devices)
- Patient: by pressing the blue fan button on the internal Button Box. (See **Figure 30 - Button Box**)

Figure 30 - Button Box

12.0 Care of Your Phothera 4000XL/4800MAX Phototherapy Device

12.1 Recommended Maintenance Schedule

Action	Frequency
Dusting of the unit and lamps	Once a month
Fully clean all internal reflectors, lamps, and acrylic shields.	Annually
Unit calibration and clean all the fan filters.	Every 100 hours of use or once a year (whichever occurs first) and when lamps are replaced. (Meters can be rented or purchased through Phothera)
Replace lamps	*UVB – Approximately Every 300 hours of use. *UVA –Approx Every 500 hours of use.

"* Lamp life will vary significantly depending on average treatment time and other environmental conditions."

12.2 Cleaning/Disinfection

12.2.1 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.

12.2.2 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 3 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 3 Tested Cleaners

1. Thoroughly wipe down the surfaces and allow contact time listed in Table 3 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.

12.2.3 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

12.2.4 Cleaning Between Treatments

All customer contact surfaces and accessories should be cleaned between treatments / uses of the machine. To keep the device clean between each treatment 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. See the *Service Manual* for complete cleaning and maintenance instructions.

13.0 Lamp Replacement

The Phothera 4000XL/4800MAX is like all other florescent UV phototherapy devices, it will decrease in output over the life of a set of lamps. Typically, at the point of lamp failure the power will have decreased approximately 30% for initial value. As doses will have been increased to compensate for this, when the lamps are replaced, treatment times will need to be decreased proportionally on timer-controlled devices. On dosimetry devices, automatic compensation for lamp output changes is incorporated, however, Phothera procedures for calibration and potential dose adjustments must be followed.

Please contact Phothera for additional information. Note that timely lamps replacement by Phothera, or its authorized agent will avoid this situation.

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.

DO NOT REPLACE LAMPS INDIVIDUALLY. ALL LAMPS SHOULD BE REPLACED AT THE SAME TIME TO AVOID UNEVEN TREATMENTS OR BURNS. PLEASE CONTACT THE PHOTHERA SERVICE DEPARTMENT PRIOR TO REPLACING YOUR LAMPS TO OBTAIN IMPORTANT INFORMATION ON HOW THE OUTPUT OF YOUR UNIT WILL BE AFFECTED BY THE CHANGE.

Because of differences between brands, replace lamps with the same brand as originally installed.

1. Flip the circuit breaker on the device to the OFF position. Remove the four to six screws from around the top and bottom edge of the acrylic that is in front of the lamp(s) you want to remove. Use a 1/8" allen wrench to remove the screws from the acrylic.
2. Pull the acrylic out of the bottom and top lamp plate and set it aside.

3. Grasp the lamp to be removed with both hands and press up until it clears the bottom socket, then remove the lamp. Reverse the process to install lamps and acrylic.

Note: Please see the Lamp Inspection section, for the correct specifications of replacement lamps and the Maintenance section for instructions on how to reset the lamp age monitor.

14.0 Lamp Cooling Fan Filter Replacement

1. There are four fan filters that need to be cleaned at least after every 100 hours of use. The filters are located at the bottom of the unit on the right door, left door, back right of the main cabinet, and the back left side of the main cabinet. NOTE: Time between cleaning the filters may vary. Cleaning the filters may need to be done more often depending on the surrounding environment.
2. Pull the square filter holder down/out to unsnap the four clips holding the filter holder on.
3. Remove the filter from the holder, shake off the dirt and rinse with water. Place filter back in the filter holder. Let filter dry completely before placing back on the unit. NOTE: Filters will need to be replaced if damage occurs to them.
4. Reinstall the filter holder to the unit by pressing it back into place.

15.0 Warranty and Contact Information

15.1 Limited Warranty Policy

This Limited Warranty is provided to the original purchaser (the "Purchaser") of the Phothera device (the "Equipment"). Phothera 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. PHOTHERA 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

15.2 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. Phothera shall not be responsible for any indirect, incidental, special, punitive, or consequential damages of Purchaser. Phothera does not provide end support for Microsoft Windows software installed on PCs that are part of a Phothera phototherapy system. PURCHASER'S SOLE REMEDY UNDER THIS LIMITED WARRANTY IS REPAIR OR REPELACMENT OF THE EQUIPMENT.

15.3 Customer Responsibility

In the event that warranty service is requested, the Purchaser must reasonably cooperate with Phothera 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 Phothera, at Phothera's option, to inspect the Equipment or component parts on request.

15.4 Warranty Service

During the warranty period, Phothera will, at Phothera's option, repair or replace any Equipment or components that appear to have been defective in material or workmanship, with new or remanufactured materials. Phothera 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, Phothera will cover freight expenses in the continental USA to ship products covered under warranty both to and from Phothera'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 Phothera pays freight charges back to the Purchaser. All Equipment ships ground unless the Purchaser covers costs for expedited shipping. Phothera is not responsible for any delays occurring during transport of the Equipment.

During the term of the Limited Warranty, Phothera will, at Phothera'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 Phothera's sole discretion whether subcontractors or Phothera 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 Phothera. Even with Phothera's authorization, Phothera shall not be responsible or liable for any such work (in or out of warranty). Phothera 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.

15.5 Disposal

Please contact Phothera at 1-216-831-0600 for disposal instructions for the unit and/or cabinet and all accessories.

15.6 Other Services

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

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

15.7 Contact Information

Phone **1-216-831-0600**
***Press 1 for Daavlin**
Fax **1-419-636-1739**
E-Mail **service@phothera.com**
Website: **www.phothera.com**

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