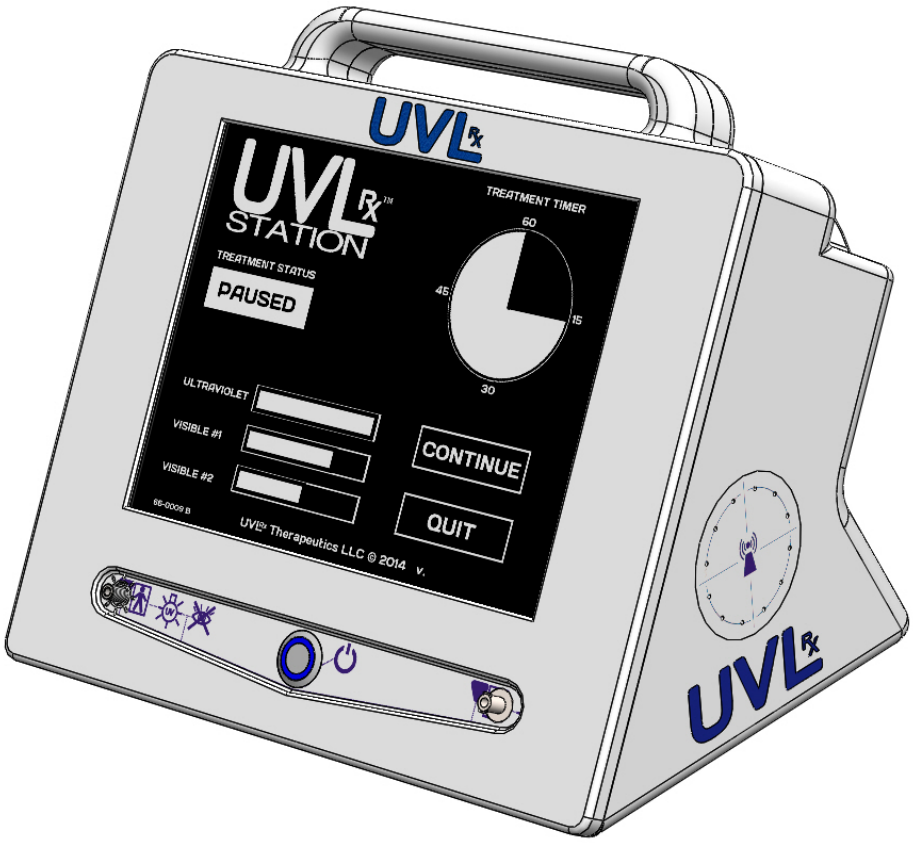
UVLRx™ STATION

Intravenous Light Therapy



UVLrx Station™ Model UVL1500 User Manual

Model UVL1500:	Manufactured in the U.S.A., for Export Only.
Caution:	Federal law restricts this device to sale by or on the order of a physician or properly licensed healthcare provider.
Manufacturer:	UVLrx Therapeutics Inc. 640 Brooker Creek Blvd., Suite 455, Oldsmar, FL 34677

UVLRX STATION

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1. INTRODUCTION

The UVLrx Station™, Model UVL1500, is designed to emit a combination of UVA + RED light for 30 minutes, followed by an automatic transition to a combination of RED + GREEN light for 30 minutes. Total treatment time lasts 60 minutes. The three key wavelengths are:

- UVA: 365 nm – reduction of pathogens
- RED: 630 nm – immune system modulation, inflammation reduction, and ATP synthesis up-regulation
- GREEN: 530 nm –improve blood oxygen transport and favorable hemodynamics

Each wavelength strategically targets key biochemical pathways within the body, which, when combined, generate an observable reduction in patient pain.

The UVLrx Station™ is designed to give authorized users a unique ability to harness and deliver the therapeutic power of light. Authorized users will not be required to make any adjustments to the device's output parameters. UVLrx Station™ is designed to work only with UVLrx Therapeutics' Patient Cable and Dry Light Adapter™ (DLA), through secure radio frequency identification technology (RFID). The optical emission from UVLrx Station™ is delivered through the Patient Cable, through the DLA, and into an existing 20ga x 1" catheter, illuminating the passing blood supply in the vein. No part of the DLA extends beyond the catheter lumen or into the body.

1.1. INDICATION FOR USE

The UVL1500 and accessories are intended for Intravenous Light Therapy for immune system modulation, reduction of inflammation, reduction of pathogens in the blood stream, improved adenosine triphosphate (ATP) synthesis, reduction of pain, improved circulation and blood oxygen transport, and improved wound healing.

1.2. CONTRAINDICATIONS

- Patients less than 18 years old
- Pregnancy and breastfeeding
- Diagnosed with or have been treated for clotting disorders (e.g. thrombophlebitis, factor V Leiden)
- Known blood clot located proximal to the proposed catheter site
- Axillary lymph node dissection with lymph edema along extremity of proposed catheter site
- Active cellulitis along proposed catheter site
- Proposed catheter site distal to AV fistula
- Subject is hypersensitive or allergic to tape or Tegaderm® or any components in contained in such adhesive products

1.3. ACKNOWLEDGEMENTS AND ACCREDITATIONS

The UVLrx Station™ is designed to be in accordance with:

- Manufactured Under:
  - FDA Good Manufacturing Practices
  - ISO 13485 Medical Device Quality
- IEC 62471 Light Emitting Diode Safety
- IEC 60601-1-2 EMC
- IEC 60601-1-1 Safety

2. WARNINGS AND CAUTIONS

Review this User Manual completely, prior to use. Warnings and Cautions refer to conditions which either may possibly cause injury to the patient or user, or may possibly cause equipment damage or malfunction, respectively.

2.1. RESTRICTIONS ON USE

U.S. Federal Law restricts this device to be sold by a physician or by the order of a physician.

This light-based device is intended only for physicians trained in the use of these this device.

2.2. WARNINGS

- Do not use equipment if, upon receipt, package is opened, damaged, or shows any signs of tampering.
- Do not use equipment in the presence of flammable anesthetics, gases, disinfecting agents, cleaning solutions, or any material susceptible to ignition due to electrical sparking.
- To avoid the risk of electric shock, this equipment must be connected to a supply mains with protective earth. The voltage and frequency characteristics must be compatible with those listed on the unit or in this manual. Do not use plug adapters or extension cords; such devices may defeat the safety ground and could result in injury.
- Do not use sterile equipment beyond the expiration date listed on the label. Sterility of the UVL1520 cannot be assured beyond the expiration date. UVLrx Station and Patient Cable supplied non-sterile. Do not attempt to sterilize UVLrx Station or Patient Cable.
- Do not excessively bend, kink or crush the Patient Cable. Always inspect the Patient Cable for signs of excessive wear or damage. If wear or damage is found, discontinue use and replace immediately. Failure to do so may compromise output wavelength calibrated irradiance.
- Patient Cables are provided non-sterile. Clean only as provided in this user manual. Do not attempt to sterilize the Patient Cable.
- Do not excessively bend or kink the power cord. Always inspect cords for signs of excessive wear or damage. If wear or damage is found, discontinue use and replace immediately. Using a damaged power cord could possibly cause injury.
- Do not store liquids on or near to the device, or in such an orientation as might possibly lead to a spill onto or into the device.
- Do not immerse any part of the UVLrx Station™ in fluids for any reason. Immersion may render the device inoperable.
- This system may cause radio interference or may disrupt the operation of nearby equipment. Avoid stacking equipment. It may be necessary to take mitigation measures, such as or re-orienting or relocating the UVL1500 or shielding the location. See section 14.1 and 15 for additional information regarding radio interference and EMC data.

- The Patient Cable, and by extension the Dry Light Adaptor, is the applied part. Avoid contact with other non "BF" rated powered instruments while in contact with the patient, as this may create a current leakage path to earth.
- Do not connect known damaged equipment or equipment that is corroded or wet. Failure to comply may cause injury or result in damage to equipment.
- All Dry Light Adaptors are single-use only. Do Not Re-sterilize. The ability to effectively clean and re-sterilize this single use device has not been established and subsequent re-use may adversely affect the performance, safety and/or sterility of the device. After use, dispose of properly.
- Do not look directly into the emission port, patient cable, or DLA aperture(s) while operating.
- If using in conjunction with concomitant (drug) therapy, consult with the drug manufacturer's safety information regarding photosensitization effects.
- Do not position the UVLrx Station™ in an orientation that makes disconnecting the medical grade power cord from the device difficult.
- The means to isolate all poles of UVLrx Station™ from supply mains is removal of the detachable power cord from the appliance inlet. See section 14.3 of this manual for power cord requirements.
- The UVL1500 should be protected against unauthorized use.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

2.3. CAUTIONS

- Handle all equipment carefully. If any equipment is dropped or damaged in any way, return it immediately for service.
- Do not use this equipment if you suspect it of functioning improperly or other than described herein.
- Use only associated UVLrx Therapeutics™ approved equipment and accessories. They have been tested and certified to specific medical standards. Using unapproved accessories may result in improper operation, may negatively affect EMC performance and may result in non-compliance to medical standards. Observe section 15.3 for EMC information.
- The warranty becomes void and the manufacturer is not liable for direct or resulting damage if:
  1. The device or the accessories are improperly used, prepared or maintained;
  2. The instructions in the manual are not adhered to;
  3. Non-authorized persons perform repairs, adjustments or alterations to the device or accessories.
- There are no user-serviceable parts inside, except for the fuses. No modification of this equipment is allowed. Removing the cover may introduce an electrical shock hazard by

exposing you to dangerously high voltages or other risks or disrupt the integrity of the delivery of light.

- Do not attempt to service the device yourself (other than fuses). Always contact your UVLrx Therapeutics™ authorized distributor for service.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.
- Service intervals, as listed in section 11 “Service”, are required to keep the equipment operating at optimum performance.
- Provide adequate ventilation for UVLrx Station™ by placing the device such that the sides and back are no closer than 2” from an opposing surface (e.g. wall) to optimize cooling performance.
- Do not scratch the optical faces of the Patient Cable. Damage may result.
- Do not use any instrumentation, especially sharp objects, to make selections on the touchscreen display. Damage may result.
- Replace the dust cap on the Calibration Port between uses to ensure consistent optical calibrations.
- Do not ship the device except as packaged in the custom shipping case provided with the UVLrx Station™. Using unapproved packaging may result in improper operation, or damage to the equipment.
- Ensure training is provided to you only by UVLrx Therapeutics authorized representative(s). The UVLrx Station™ should only be used by healthcare providers who have received training in its use.
- The UVLrx Station™ integrates with standard 20-ga x 1” catheters. UVLrx Therapeutics does not endorse or train on techniques concerning PIV catheterization and normal saline drip. Please ensure proper technique is implemented and PIV integrity will be maintained before incorporating the UVLrx Station™.
- Consult patient medical history for sensitivity to ultraviolet light.
- The UVLrx Station™ should be utilized in a clearly marked treatment area.
- Turn the UVLrx Station™ off before leaving unattended.
- Use of controls or adjustments or performance of procedures other than those specified herein may be hazardous.
- Clean all the equipment and associated accessories according to the instructions or use.
- Clean both ends of Patient Cable, specifically the optical faces, with an isopropyl alcohol wipe (minimum 70% IPA), prior to first use.
- Clean Patient Cable with an isopropyl alcohol wipe (minimum 70% IPA), between uses, however leave Patient Cable end connected to UVLrx Station™ emission port unless changing Patient Cables.
- IV pole mounting requires use of included Pole Clamp, allowing up to 1” diameter IV poles.

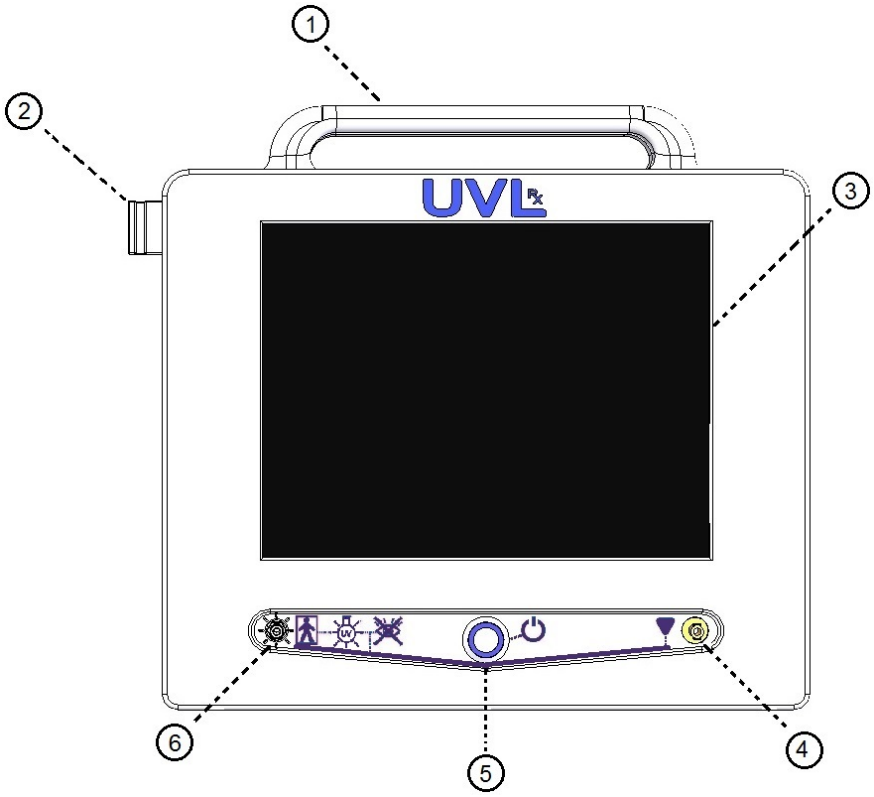
3. SYSTEM COMPONENTS

.

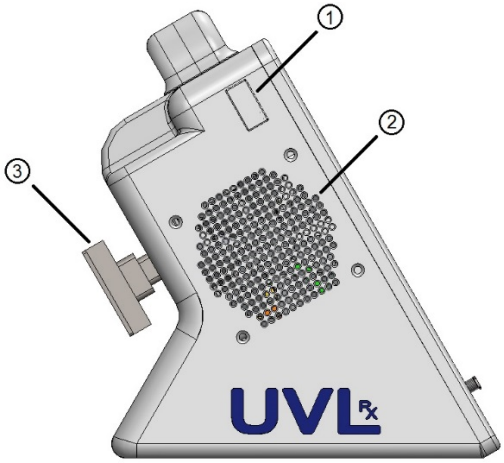
The Model UVL1500 UVLrx Station™ is supplied with:

(1) Model UVL1500 User Manual
(2) Two (2) Patient Cables
(3) Power Cord
(4) IV Pole Clamp
(5) Custom Hard-Sided Shipping Case

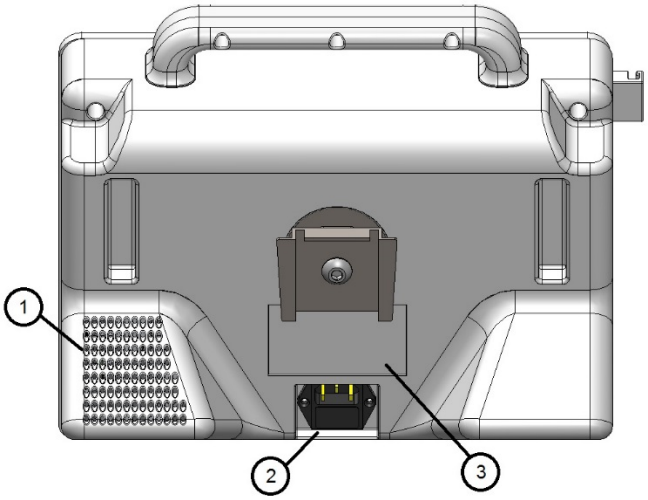
3.1. UVLRX STATION™ DESCRIPTION



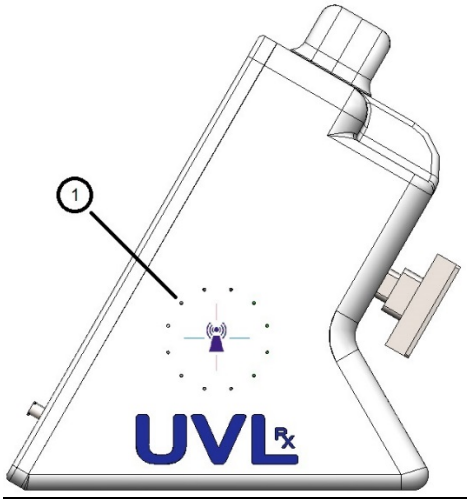
1. Handle	Allow user to move the device
2. Patient Cable Holder	Holds fiber optic cable when not in use
3. Touch Screen Display	Provides graphical user interface – Display "ON" indicates device is ON.
4. Calibration Port	The distal end of the Patient Cable (with the DLA adapter and Slip Lock Ring) connects to this port for calibration prior to each treatment. Ensure Integrated dust-cap in place between calibrations.
5. Blue Ring-Lit Stand-By Switch	Provides user with means to place device into and out of stand-by mode. One press turns the device ON. Press and hold the button for two seconds to return to stand-by mode. Marked with stand-by symbol.
6. Emission Port	Optical energy emitted from this port. Patient Cable normally connected to this port. Type BF Applied Part.



1. Patient Cable Holder	Holster the Patient Cable when not in use
2. Input Fan Vent	Vent displaces cool air internally to maintain internal temperatures. Leave at least 2” between this side and an opposing surface (e.g. wall)
3. IV Pole Mounting Bracket	Bracket designed for connection to UVLrx Therapeutics™ supplied Pole Clamp

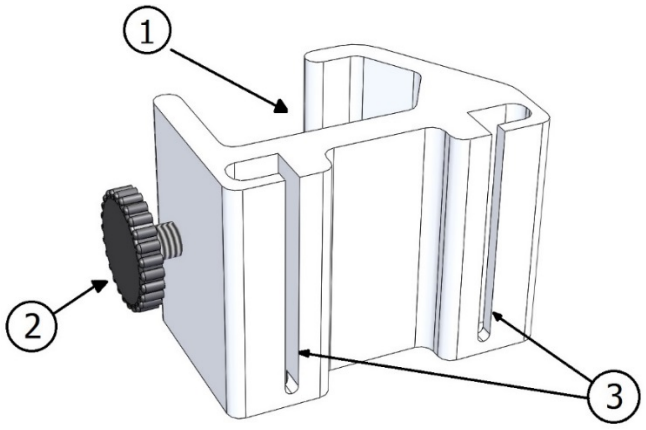


1. Exhaust Fan Vent	Vents air from within device. Leave at least 2” between this side and an opposing surface (e.g. wall)
2. Power Entry Module	Connect to AC mains with IEC compatible power cord.
3. Device Label	Supplies device specific information.



1. RFID Ring Lit Indicator	A ring of LEDs, surrounding an antenna symbol, flash when the user is prompted to scan either the Patient Cable or Dry Light Adapter RFID security tag.

Pole Clamp:

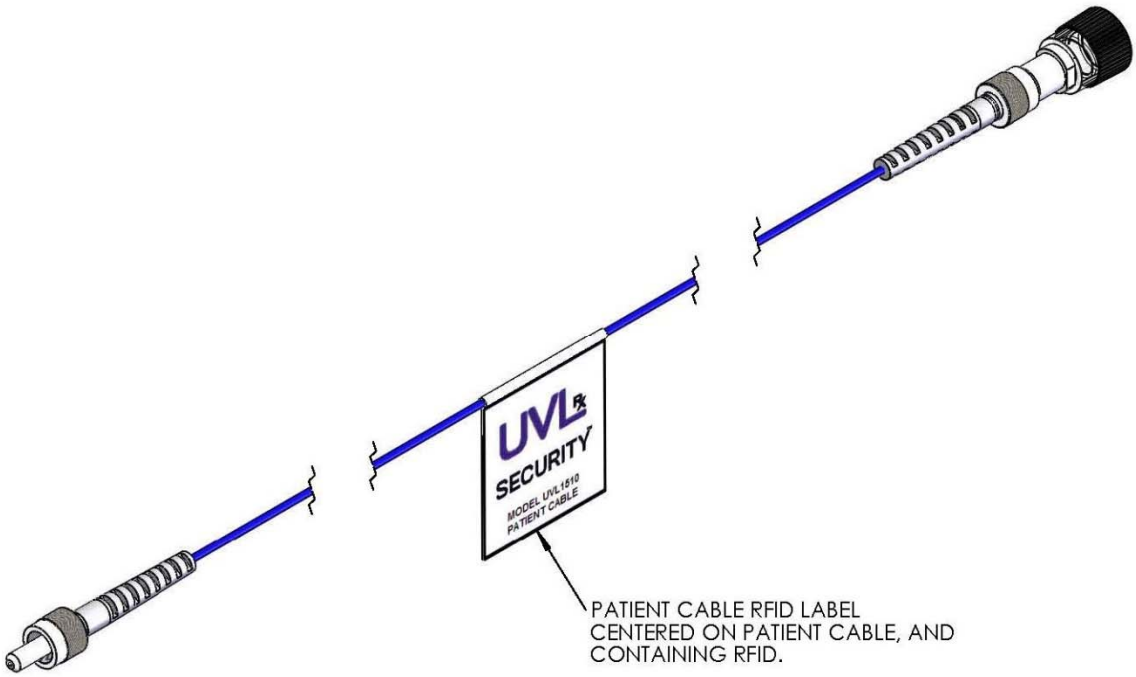


1. IV Pole slot	Attach pole clamp to IV Pole here
2. IV Pole Tensioner	Tighten the IV Pole Tensioner to ensure Pole Clamp is fastened securely to IV Pole
3. IV Pole Mounting Bracket Slots	Bracket designed to slide down into slots

3.1.1. UVLrx Station™ – Cleaning Instruction

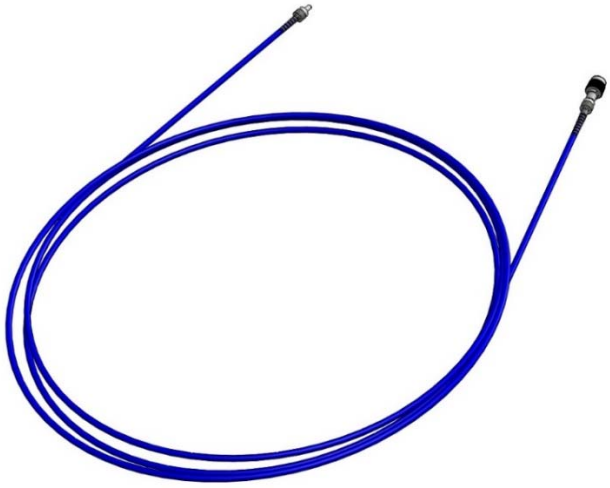
The UVLrx Station™ surfaces may be cleaned with an isopropyl alcohol wipe (minimum 70% IPA), or lightly dampened cloth with a mild detergent. Do not allow fluids into the fan vent holes, or into the Power Entry Module. Ensure the UVLrx Station™ is unplugged prior to cleaning.

3.2. PATIENT CABLE DESCRIPTION

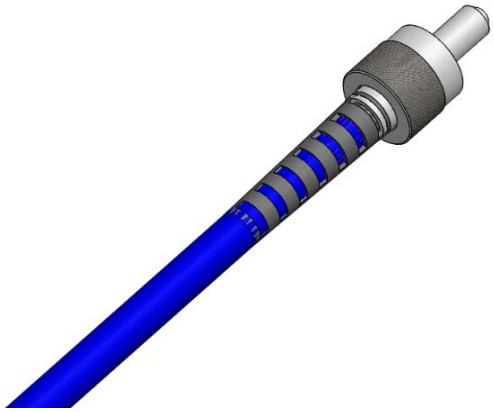
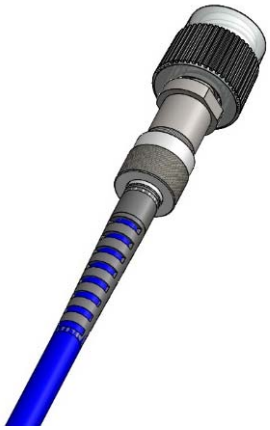


The UVLrx Station™ is supplied with two (2) Patient Cables. Each Patient Cable is five feet long, and is designed for 6-months of use. Dispose of Patient Cable after 6-months per section 8 of this manual. Patient Cables are designed for extended, reusable use and are provided non-sterile. The Patient Cable is identified by the Patient Cable RFID Label, centered on the patient cable, which also contains an RFID identification device (see Section 7 of the User Manual for description of UVLrx Security™ usage).

Each Patient Cable arrives coiled within a clear, sealed bag (see image at right).



Each Patient Cable is designed for extended, reusable use, and can be cleaned with an isopropyl alcohol wipe (minimum 70% IPA). The Patient Cable contains two ends which each serve a specific purpose:

	
Emission Port Side: Connect to emission port on UVLrx Station™	Calibration Port / DLA Side: Connect to either Calibration Port on UVLrx Station™ or to Dry Light Adapter™ (DLA)

- Note: Disposal of the UVL1510 Patient Cable is required after six months of use. See Section 8.5

3.2.1. Patient Cable – Cleaning Instruction

Upon initial use, the Emission Port Side will contain a black silicone rubber sleeve. Wearing clean, non-latex gloves, remove this sleeve and gently wipe down the metal stem and optical face there with an isopropyl alcohol wipe (minimum 70% IPA). This will ensure no oil or debris remains on the optical face. Once cleaned, carefully insert this end into the Emission Port on the UVLrx Station™. Screw the terminal down firmly. This end should not be removed during routine use, except to replace the Patient Cable. Two Patient Cables are supplied with the UVLrx Station™ for a projected 12 months of use. The Patient Cable is an accessory which can be purchased from UVLrx Therapeutics Inc. Only UVLrx Therapeutics supplied Patient Cables may be used with the UVLrx Station™. UVLrx Station™ calibrates prior to each treatment, and calibration accuracy and consistency are dependent upon use of UVLrx Therapeutics supplied Patient Cables.

Cleaning of the Calibration Port / DLA side of the Patient Cable may be accomplished as follows:

(1) Remove the stainless steel tapered adapter from the end of the Patient Cable.

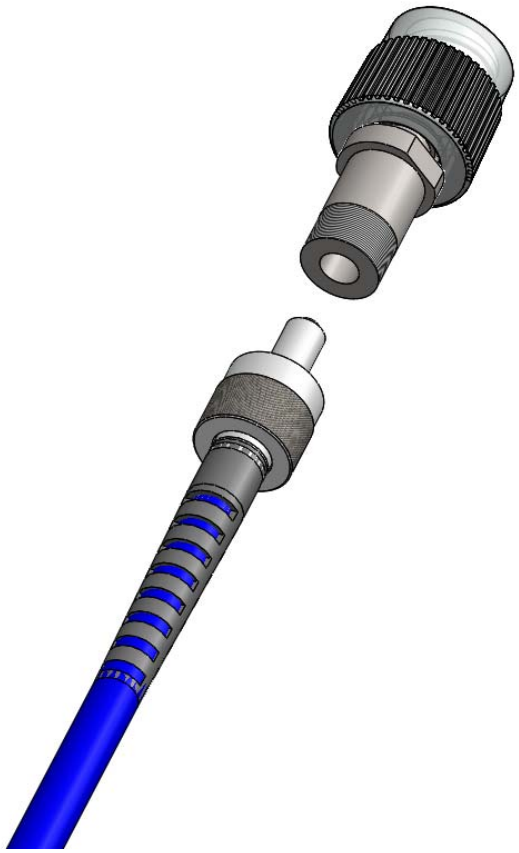
(2) Gently wipe down the metal stem and optical face of the fiber optic cable with an isopropyl alcohol wipe (minimum 70% IPA).

(3) Gently wipe down the faces of the tapered adapter and slip lock ring.

Note: The tapered adapter and this end of the Patient Cable may be submerged in either isopropyl alcohol or hydrogen peroxide as necessary.

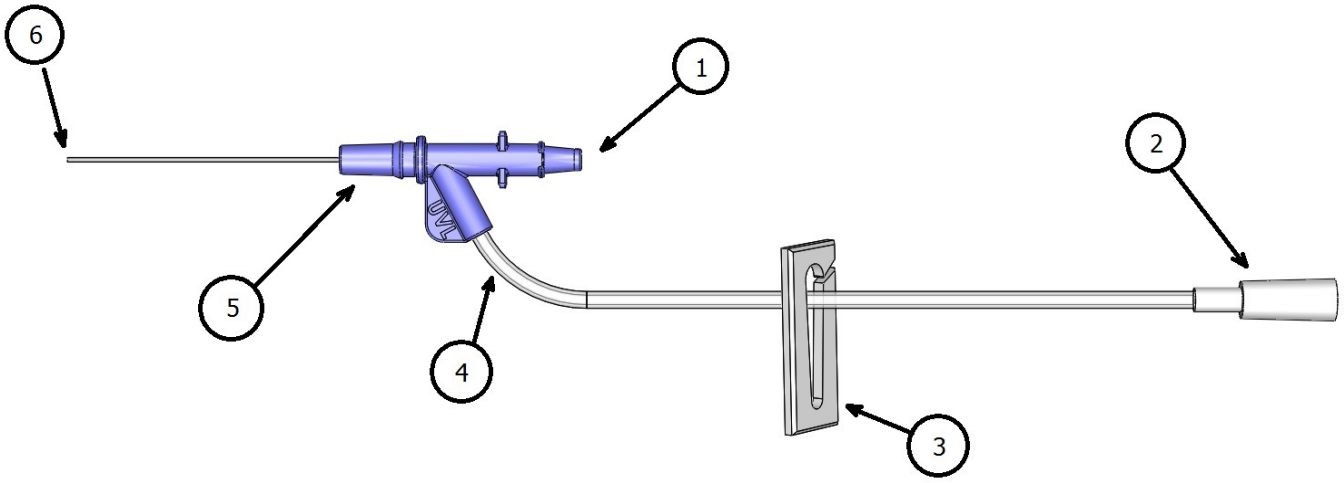
(4) Allow all surfaces to air dry.

(5) Reassemble the tapered adapter onto the Patient Cable and screw down tightly.



3.3. DRY LIGHT ADAPTER™ (DLA)

The Dry Light Adapter™ (DLA) is a single patient, single use disposable component. The DLA is supplied sterile in a Tyvek® pouch. Use of the Patient Cable and DLA, as supplied by UVLrx Therapeutics™, is essential to achieving the specified optical performance of the UVLrx Station™.



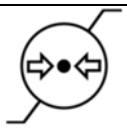
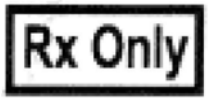
1. Patient Cable Optical Interface	This end slides into the tapered adapter of the Patient Cable, and is secured there with a ¼ turn of the Patient Cable's slip lock ring.
2. Luer Connection to Saline Drip	Connection for standard saline drip.
3. Slide Clamp	The Slide Clamp prevents ingress of fluids after the DLA is primed with saline.
4. Saline Entry Port	Saline from the saline drip enters the body of the DLA here, flows into DLA, and out alongside of the optical guide and into the patient.
5. Tapered Nozzle	Provides secure, leak-free press fit connection to standard 20ga x 1" catheter.
6. Optical Guide	This component delivers optical energy received from the Patient Cable down into the existing catheter. The Optical Guide is contained within a hypodermic stainless steel guide, and does not extend beyond the catheter lumen, nor into the patient's body.

3.3.1. Dry Light Adapter™ – Cleaning Instruction

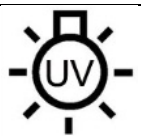
The Dry Light Adapter™ (DLA) is supplied sterile in a Tyvek® pouch. Remove the DLA from its packaging only after application of sterile gloves, to ensure no oils or fluids are transmitted to either of the optical faces of the DLA.

4. LABELS & SYMBOLS

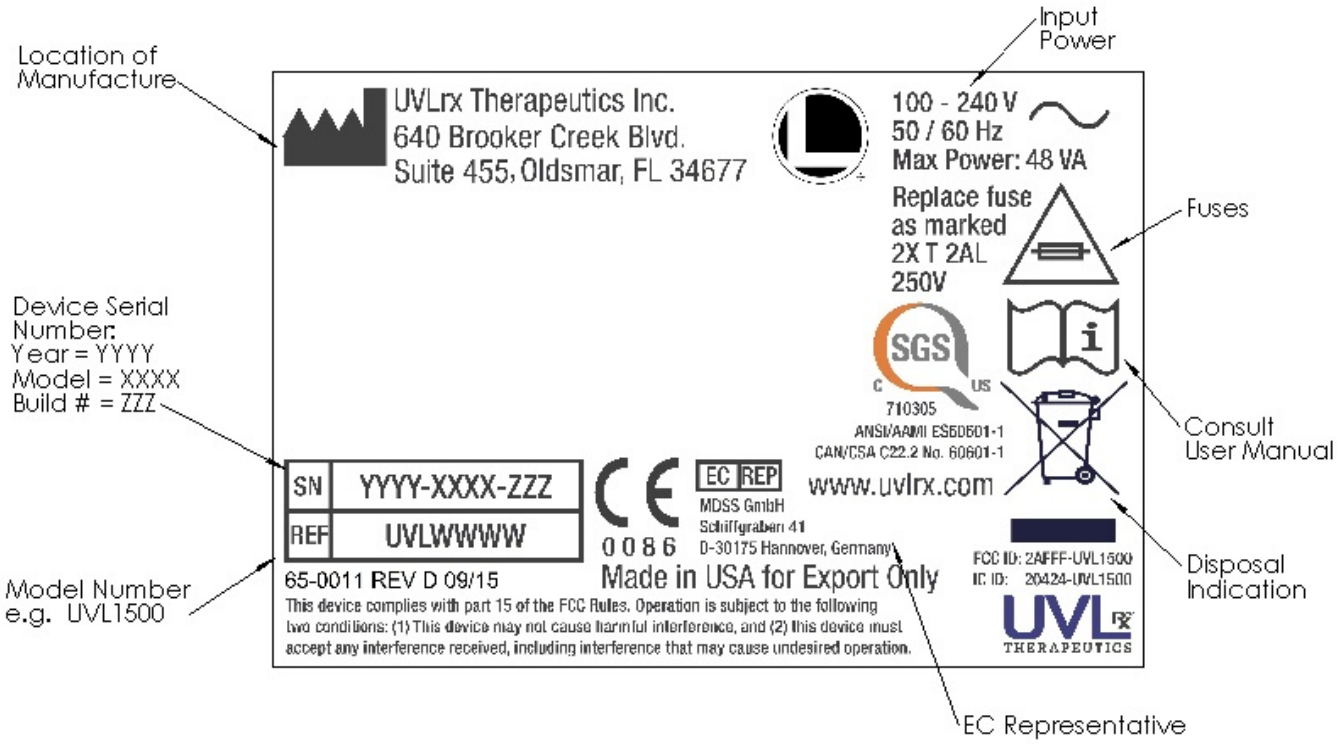
4.1. SYMBOLS

Caution		Type BF Applied Part	
Rated Supply Voltage 100-240V, 50/60 Hz		Location of Manufacture	
Fuse		Sterile Using Irradiation	
Consult Instructions for Use		Model Number	
Disposal Indication / WEEE Symbol		Serial Number	
Temperature Limitation		EC Representative	
Humidity Limitation		CE Mark Symbol	
Atmospheric Pressure Limitation		Electrical Safety and IEC Testing Symbols	
Keep Away from Rain		Sold Only to Healthcare Providers	
Non-Sterile		Do Not Use if Package is Damaged	

(symbols continued)

UV Emission Source		Stand-By Switch	
Vision Warning		Calibration	
Do Not Reuse		Do Not Resterilize	
Fragile, Handle with Care		Use By	
Non-Ionizing Radiation (RFID)		Protective Earth Ground	
L Mark Symbol			

4.2. DEVICE LABEL



The system requires two (2) fuses, each rated at 2AL and 250V with time lag “T”.

4.3. FRONT BEZEL LABEL

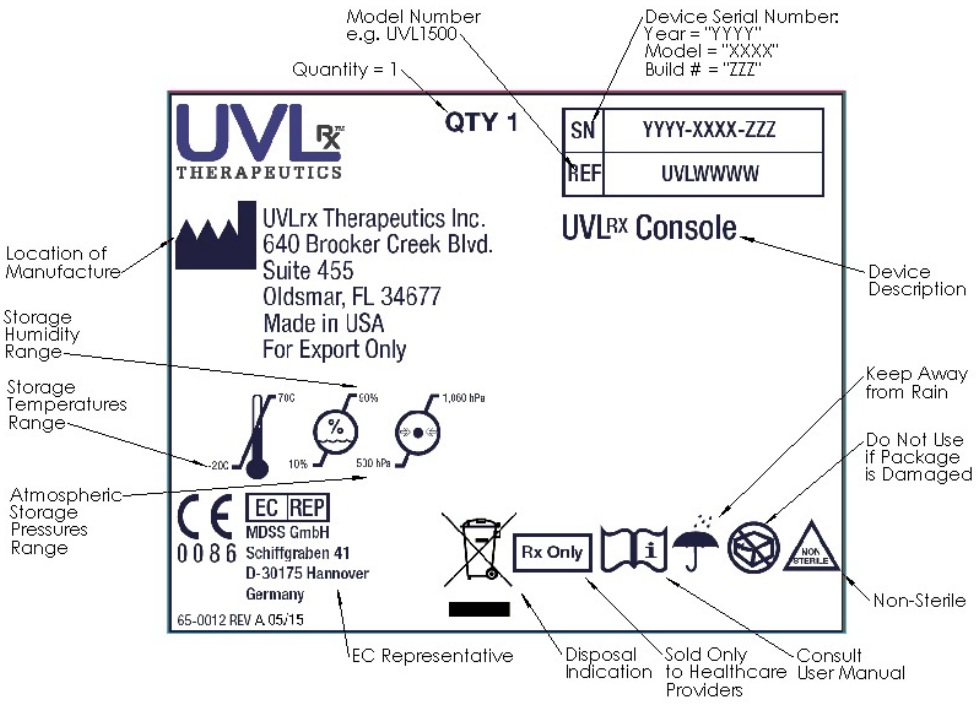
The UVLrx Station™ emits UVA light from the Emission Port. The user is cautioned not to look directly into the Emission Port when the UVLrx Station™ is emitting light (either during a calibration or during treatment). The Patient Cable should always be connected to the Emission Port when the UVLrx Station™ is used according to the User Manual. The emission port is a Type BF Applied Part.

4.4. UVLRX SECURITY™

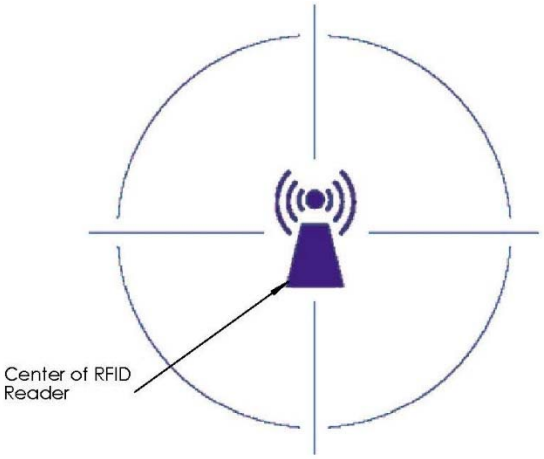
The UVLrx Station™, Model UVL1500, utilizes secure radio frequency identification (RFID) technology to ensure only UVLrx Therapeutics™ certified Patient Cables and Dry Light Adapters™ are used for treatment. The optical emission output irradiance is dependent on the specific design of the Patient Cables and Dry Light Adapters™. The UVLrx Security™ label is applied to the Dry Light Adapter Tyvek® pouch (see above left). The Patient Cable contains a UVLrx Security™ tag located mid-cable (see above right). When prompted, the user is required to place this tag within the illuminated ring on the side of the UVLrx Station™ to be scanned.

4.5. SHIPPING CASE LABEL



The UVLrx Station™ (and accessories including Model UVL1500 User Manual, Two (2) Patient Cables, Power Cord, and IV Pole Clamp) is shipped within a custom hard-sided shipping case. The healthcare provider is required to store the hard-sided shipping case for future transportation of the UVLrx Station™, to ensure the device is properly secured and cushioned. The shipping case label is affixed to the center of the lid of the shipping case.

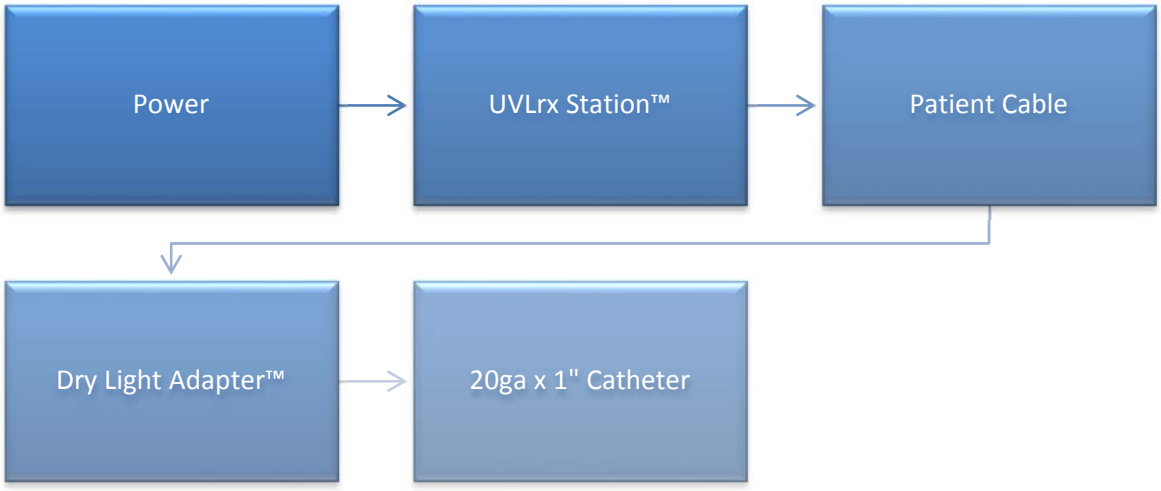
4.6. RFID TARGET LABEL



Affixed over the region on the side of the UVLrx Station where the RFID is used for accessory recognition.

5. UNPACKING & INSTALLATION

The diagram shows the connection between the power supply cable, UVLrx Station™, Patient Cable, Dry Light Adapter™, and existing 20ga x 1" catheter.



5.1. UNPACK THE UVLRX STATION™

The UVLrx Station™ is shipped from the manufacturer in a custom hard-sided shipping case. Open the shipping case and inspect to ensure the following are contained within:

(1) UVLrx Station™
(2) Model UVL1500 User Manual
(3) Two (2) Patient Cables
(4) Power Cord
(5) IV Pole Clamp

Remove the user manual, patient cables, power cord, and pole clamp. Set the shipping case aside and retain it for future transportation or service. If any component is missing, please contact customer service.

Place the UVLrx Station™ on a stabile surface or utilize the IV Pole mounting method.

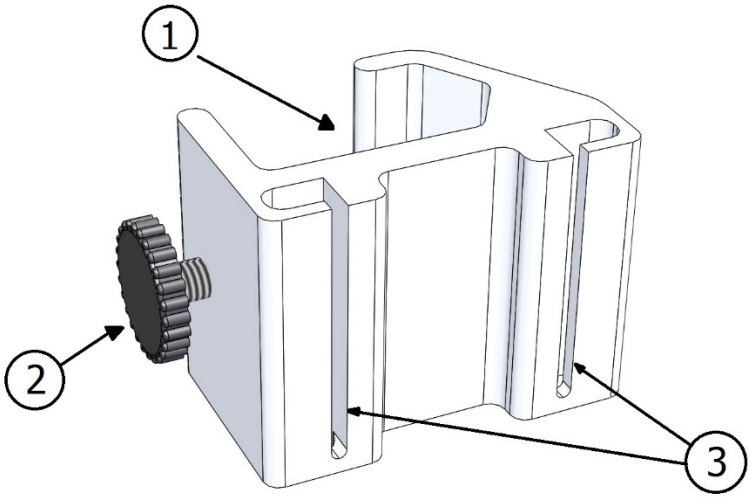
5.1. SURFACE MOUNT OR IV POLE MOUNTING?

The UVLrx Station™ is designed to be placed on a stabile surface or mounted to an IV Pole (up to 1" diameter). Prior to setting up the UVLrx Station™, decide on an initial placement configuration.

5.1.1. IV Pole Mounting Configuration

The UVLrx Station™ can be mounted to an existing IV Pole in three steps:

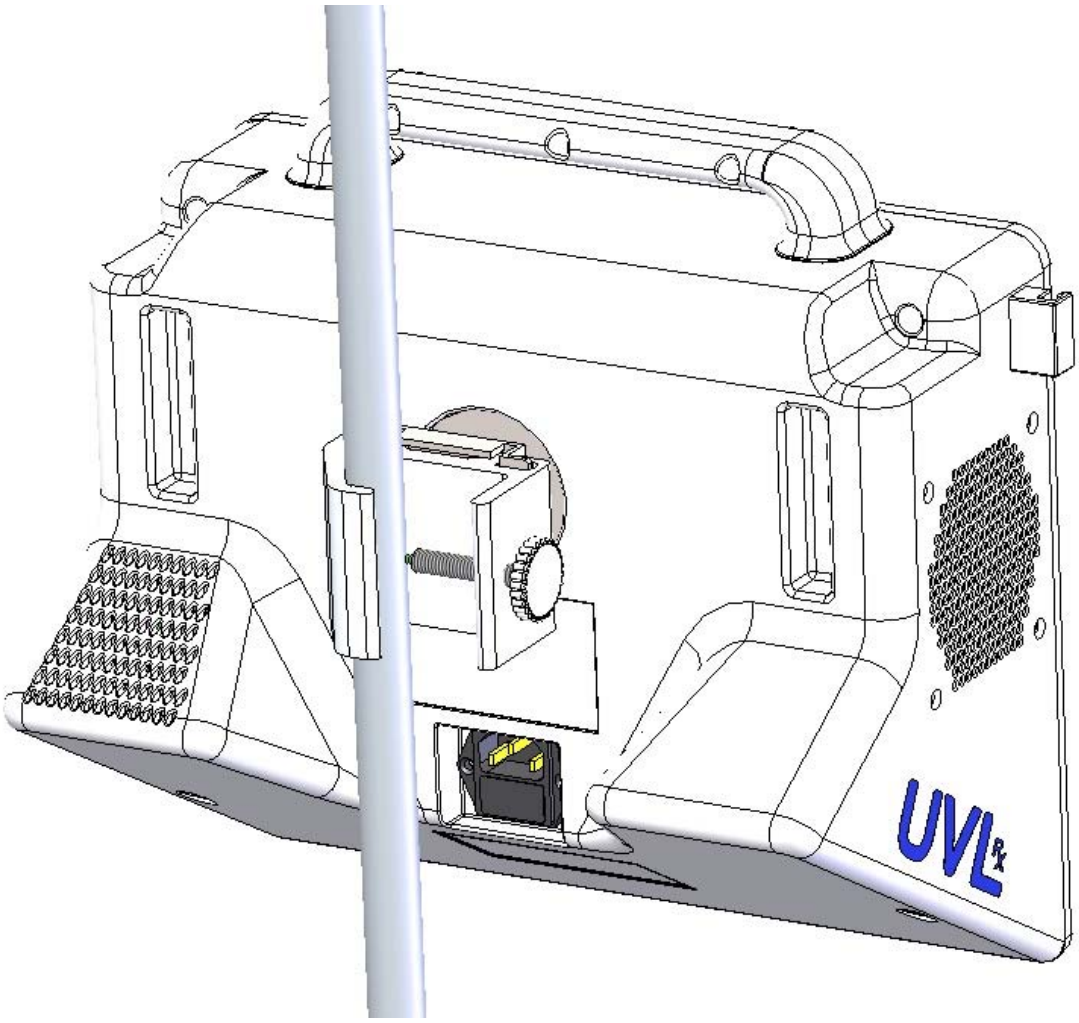
(1) Identify the Pole Clamp supplied with the UVLrx Station™



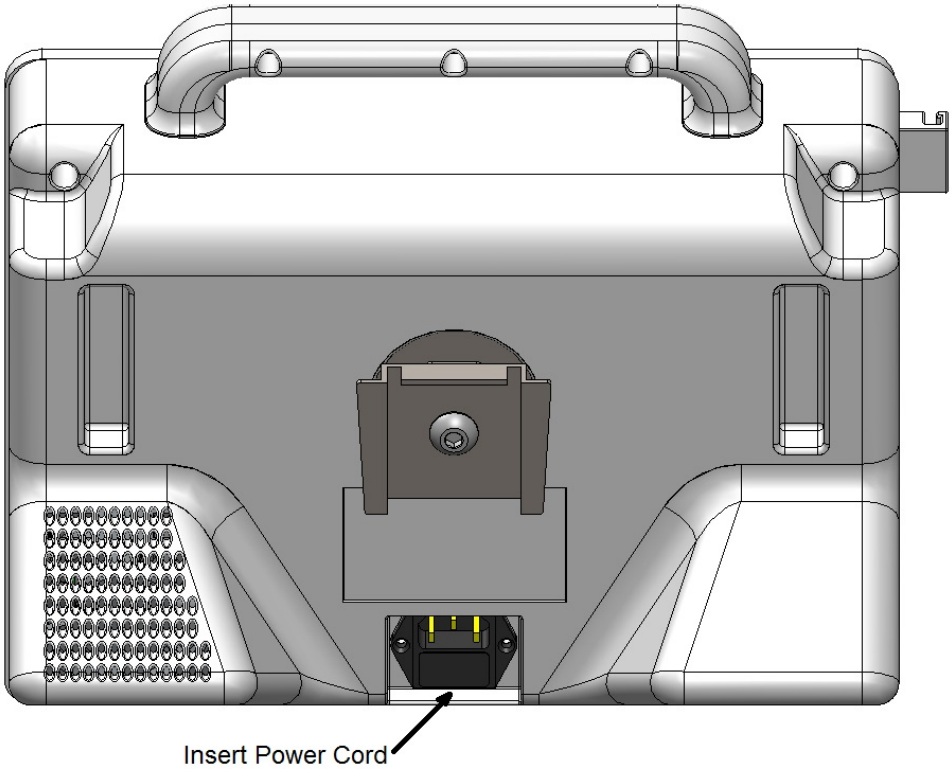
1. IV Pole slot	Attach pole clamp to IV Pole here
2. IV Pole Tensioner	Tighten the IV Pole Tensioner to ensure Pole Clamp is fastened securely to IV Pole
3. IV Pole Mounting Bracket Slots	Bracket designed to slide down into slots

(2) Connect the Pole Clamp to an existing IV Pole

(3) Slide the UVLrx Station's IV Pole Mounting Bracket into the slots of the Pole Clamp, seating it fully.



5.2. CONNECT POWER TO THE UVLRX STATION™



Connect the IEC C13 end of the power cord to the appliance inlet as indicated in the image above. Connect the other end of the power cord to AC mains with protective earth grounding.

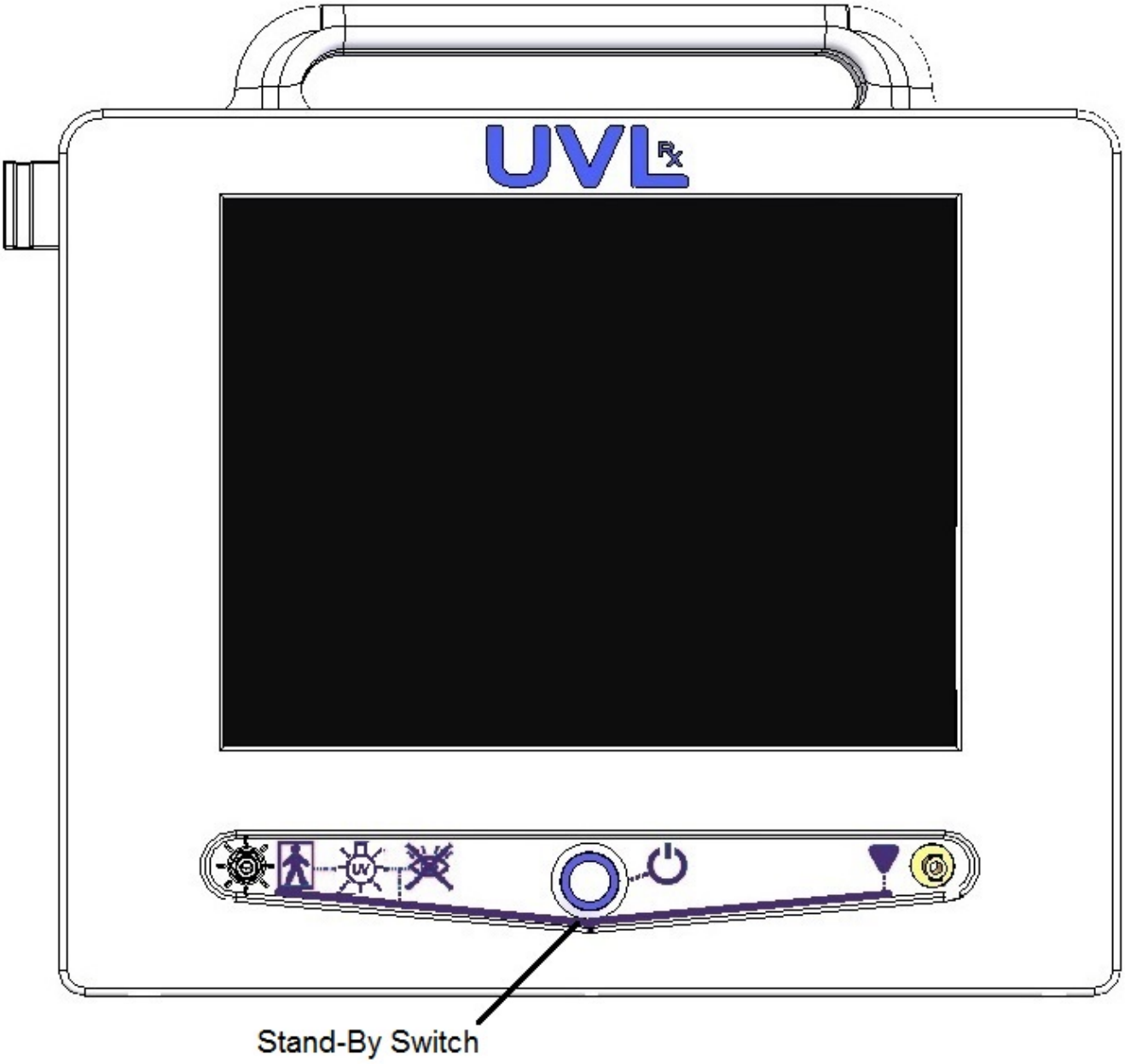
After several seconds, the blue ring-lit Stand-By Switch will begin to illuminate, “breathing” blue light. This indicates that the UVLrx Station™ is in standby-mode.

For international use, a power cord appropriate to the region must be medical grade, 18awg wire, 3 conductor, and have an IEC C13 style receptacle. The power cord supplied by UVLrx Therapeutics™ contains a NEMA 5-15P type plug.

The UVLrx Station™ is designed to accept 100-240V, 50/60 Hz.

5.3. POWER ON THE UVLRX STATION™

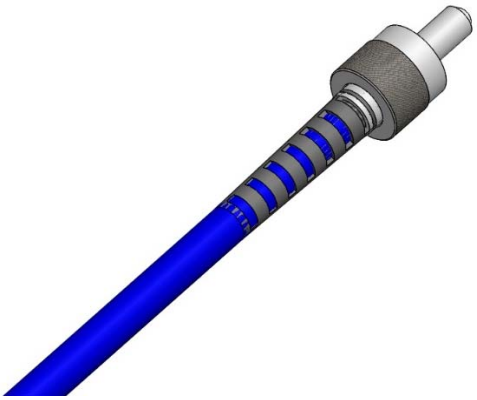
Press the STAND-BY SWITCH once. Ensure that the touchscreen display powers ON, showing the home screen. A slight fan noise will be heard. Upon exiting stand-by mode, the device will sound a single “beep”.

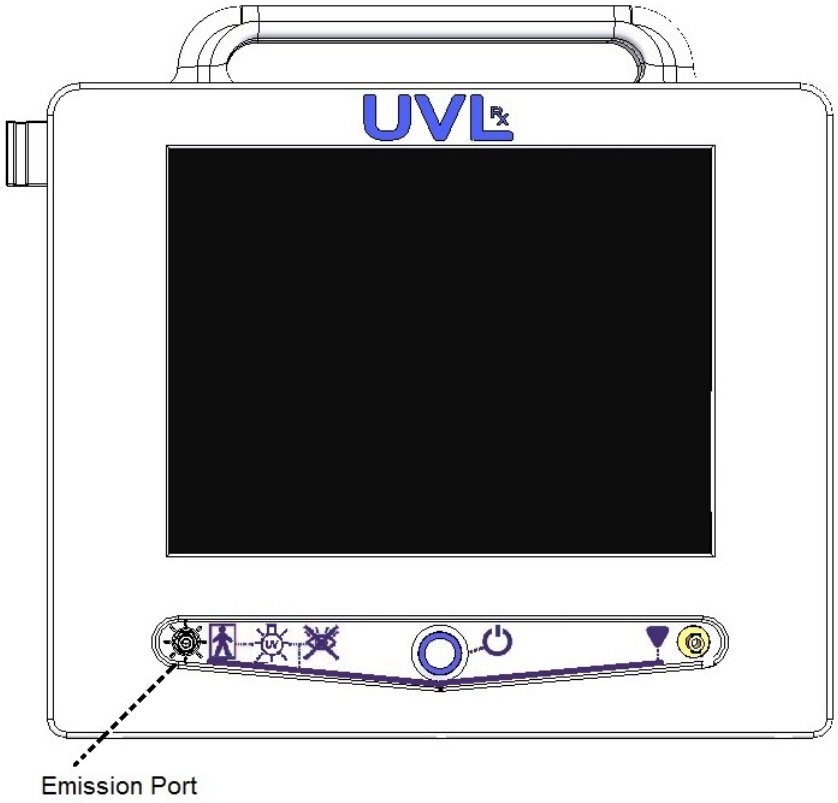


5.4. Connect the Patient Cable

Before connecting the Patient Cable to the UVLrx Station™, please follow the cleaning instructions provided in section 3.2.1. The ends of the Patient Cable are highly polished, and this procedure will ensure optimum optical performance.

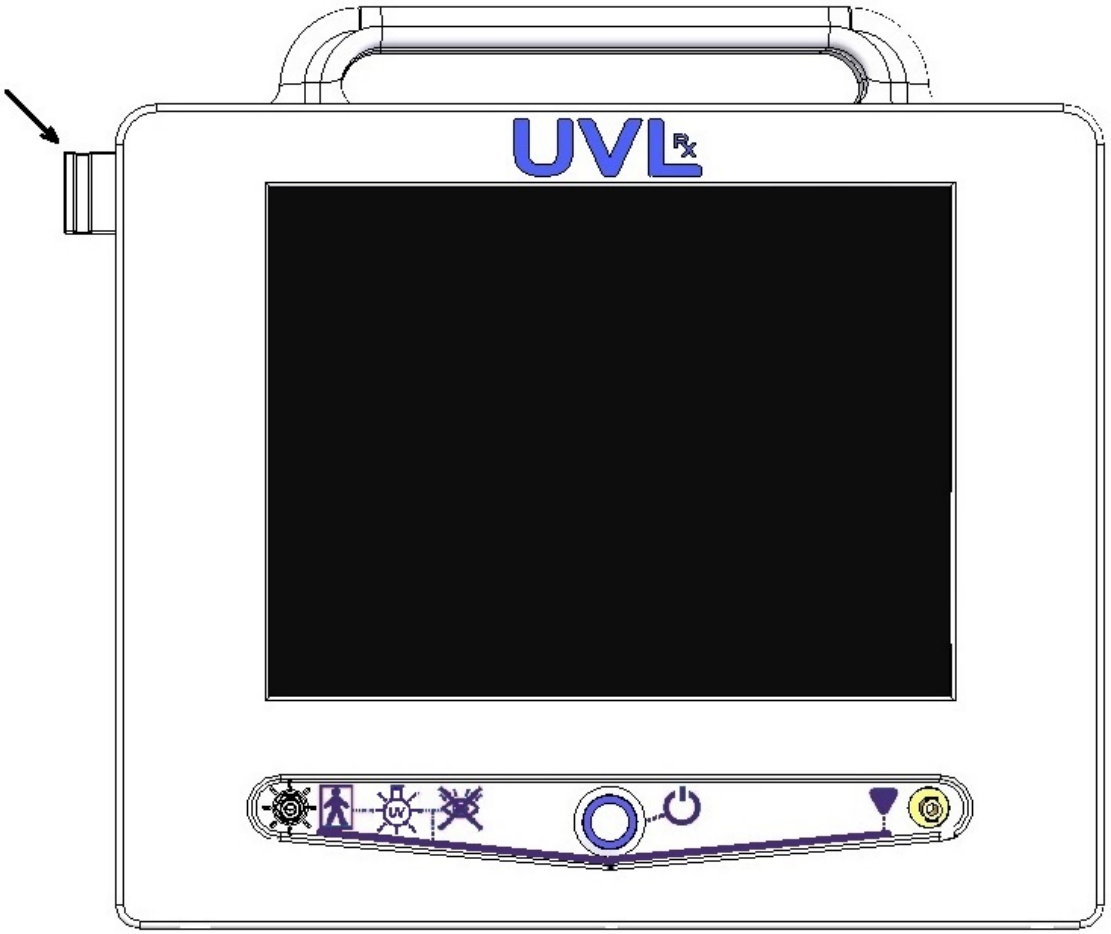
Connect the end of the Patient Cable shown at right to the Emission Port of the UVLrx Station™ shown below:





5.5. HOLSTER THE PATIENT CABLE

Secure the opposite end of the Patient Cable in the Cable Mount, indicated below:

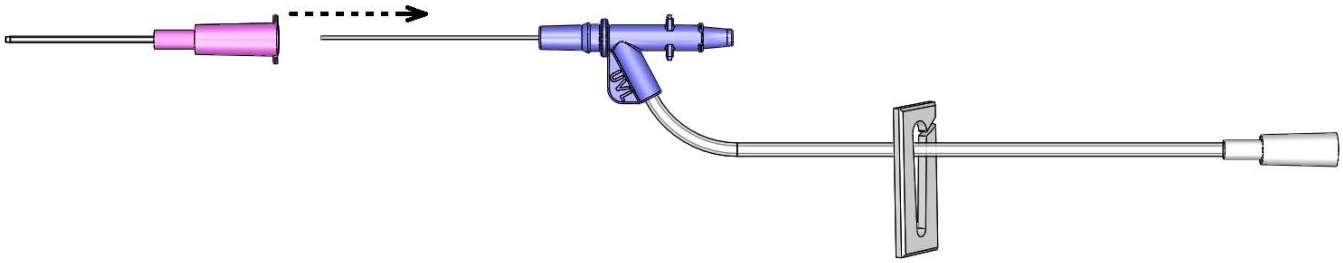


6. CONNECTION OF DRY LIGHT ADAPTER™

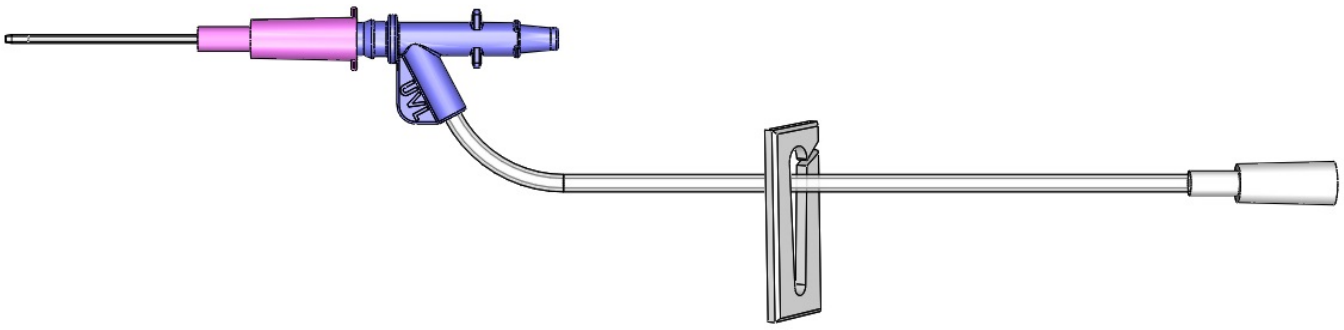
The Dry Light Adapter™ (DLA) is a single patient, single use disposable component, sold separately from the UVLrx Station™. Clinical treatment requires the use of an existing applied standard 20ga x 1" catheter. By design, the 20ga x 1" catheter is the optimal catheter inner diameter and length to ensure optimal optical performance. Use of smaller gauge catheters will not allow saline to flow normally. Use of longer catheter (lumen) length will not ensure optimal optical performance. Only DLA's and Patient Cables supplied by UVLrx Therapeutics Inc. will guarantee the UVLrx Station™ delivers the specified optical irradiance values, and correspondingly the desired optical dosages.

6.1. CONNECTION OF DRY LIGHT ADAPTER™ TO CATHETER

See section 3.3 for the figure describing the various components of the DLA. The tapered nozzle is design for a "press-fit" into standard catheters. The press-fit provides a secure, leak-free connection to the catheter. The end of the optical guide, when used with a 20ga x 1" catheter, will not exceed the length of the catheter lumen. The end of the optical guide is flat, and is not a needle. See below for press-fit connection:



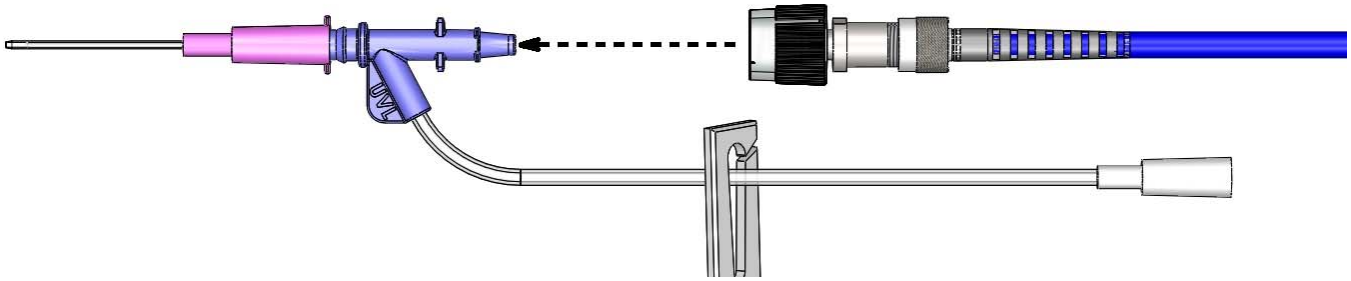
Properly seated catheter on DLA tapered nozzle: (it is good practice to wipe both optical ends of the DLA prior to connection to catheter and Patient Cable)



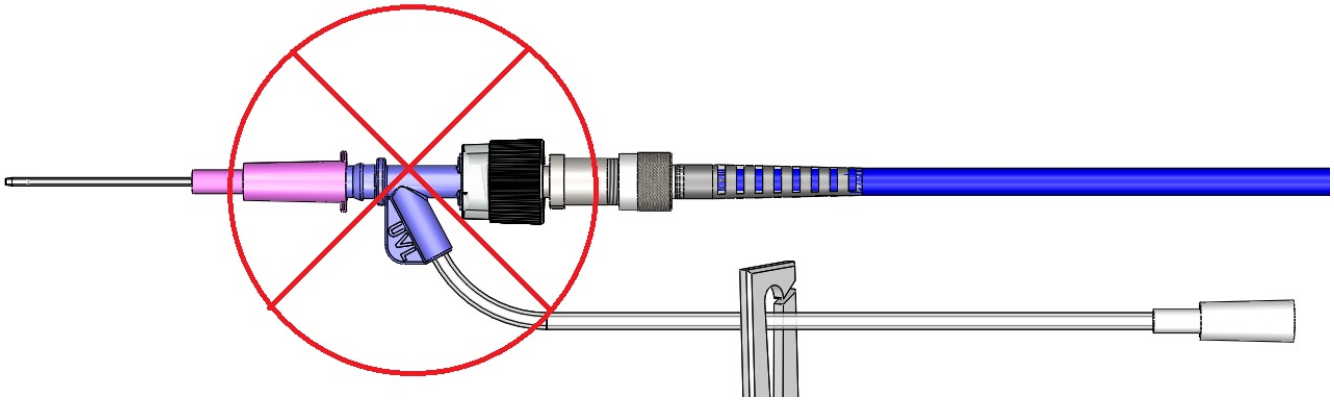
6.2. Connection of Dry Light Adapter™ to Patient Cable

See section 3.3 for the figure describing the various components of the DLA. The Patient Cable Optical Interface end of the DLA is designed to be inserted into the tapered adapter end of the Patient Cable. The tapered adapter end of the Patient Cable also contains a slip lock ring which threads over the wings of the DLA, providing a secure fit. The design of the DLA does not allow fluids to flow back through the Patient Cable Optical Interface.

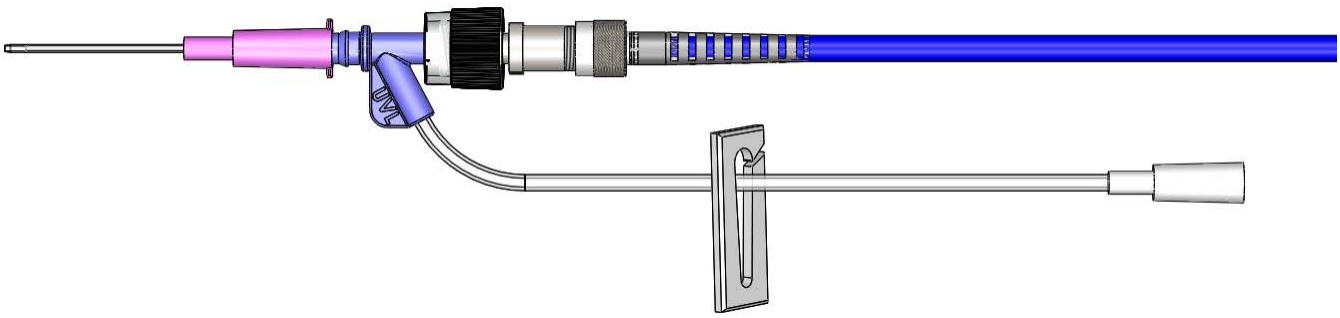
Carefully insert the Patient Cable Optical Interface end of the DLA into the tapered adapter end of the Patient Cable. Following insertion, twist the slip lock ring at least ¼ turn to ensure the DLA is fully seated. Verify the slip lock ring will no longer spin onto DLA when fully seated.



Incorrect Placement: Slip Lock Ring <u>not fully engaged</u> with DLA:



Correct Placement: Slip Long Ring <u>fully engaged</u>:



7. OPERATING INSTRUCTIONS AND USER INTERFACE

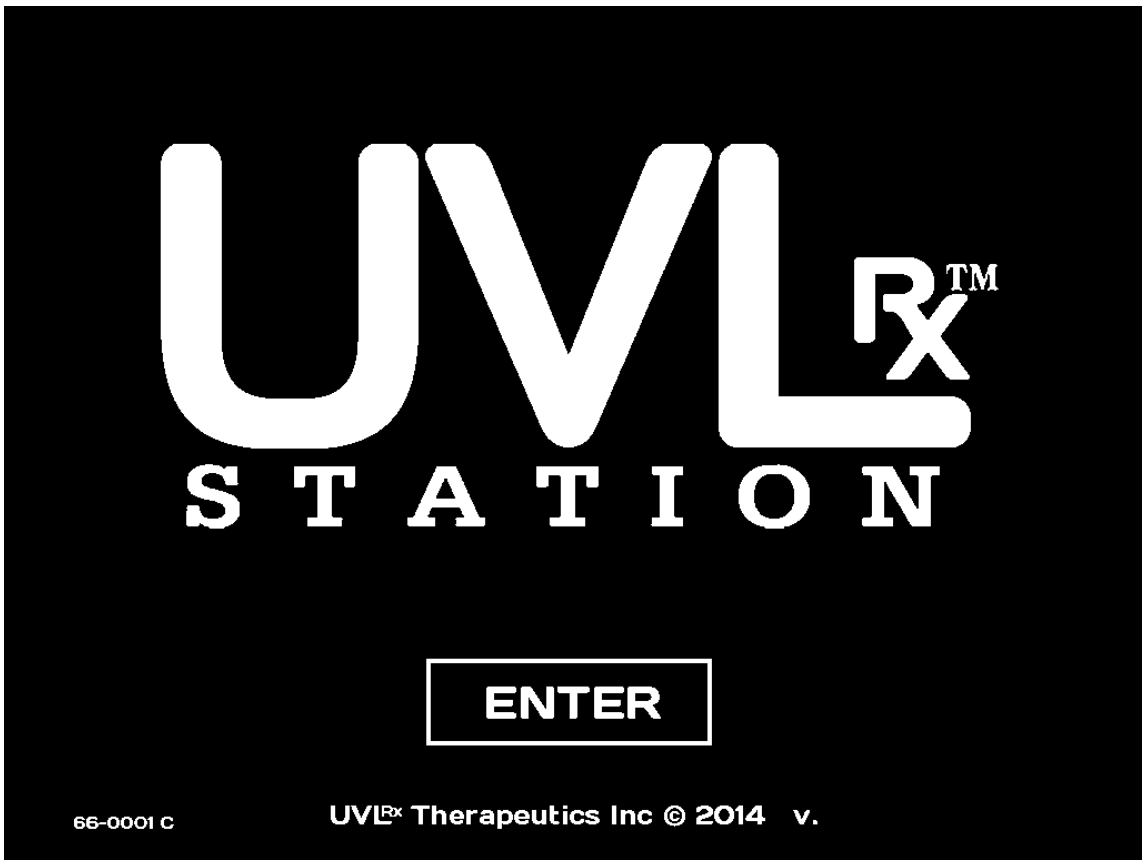
Once the UVLrx Station™ has been installed, the Patient Cable connected to the Emission Port and holstered in the Cable Mount, and the device turned ON, the device may be operated as follows. Powering

7.1. BEGINNING A TREATMENT: CALIBRATION

The UVLrx Station™ incorporates a simple touchscreen user interface to guide treatment setup.

7.1.1. Home Screen

The home screen, shown below, contains one touchscreen button, ENTER. Pressing ENTER will guide you to the next step of the device calibration. The device calibrates all wavelengths for target irradiance output prior to every patient treatment.

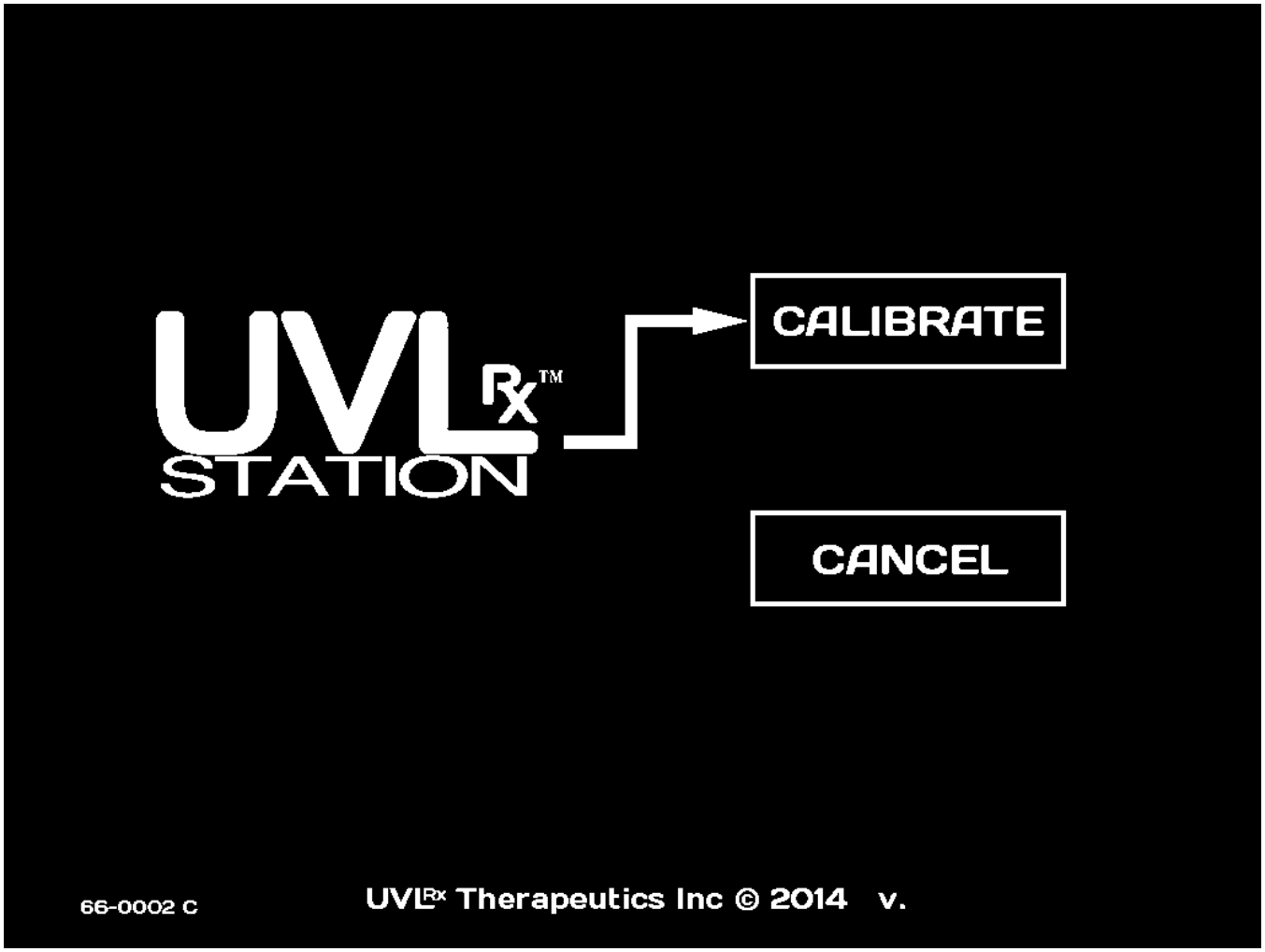


At the bottom left of all screens is a screen revision, in this case “66-0001 C”. At the bottom right of all screens is the software revision. These are useful when the healthcare provider has a service problem. The service technician, during a service call, will ask the healthcare provider which screen revision they are looking at.

Note: All screen transitions are accompanied by a single audible “beep”.

7.1.2. Main Screen

The Main Screen offers two options, CALIBRATE and CANCEL. The CANCEL function will, from any screen, return the user to the Home Screen. To proceed with calibration, press CALIBRATE.

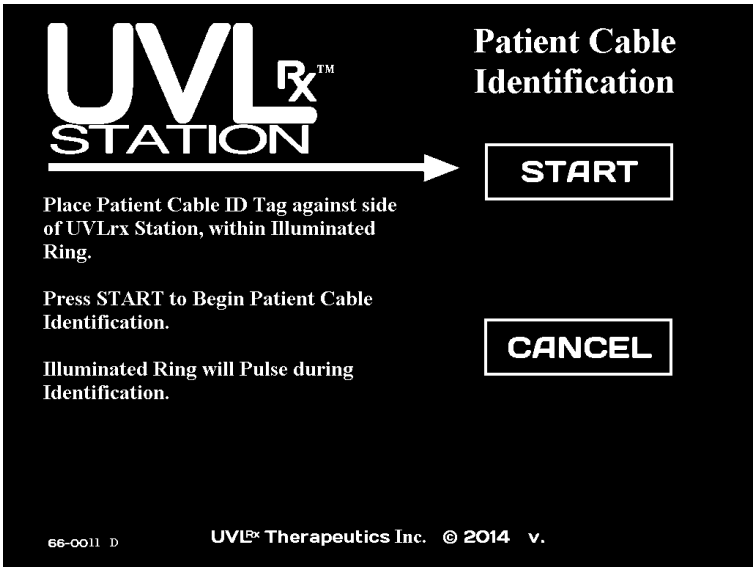


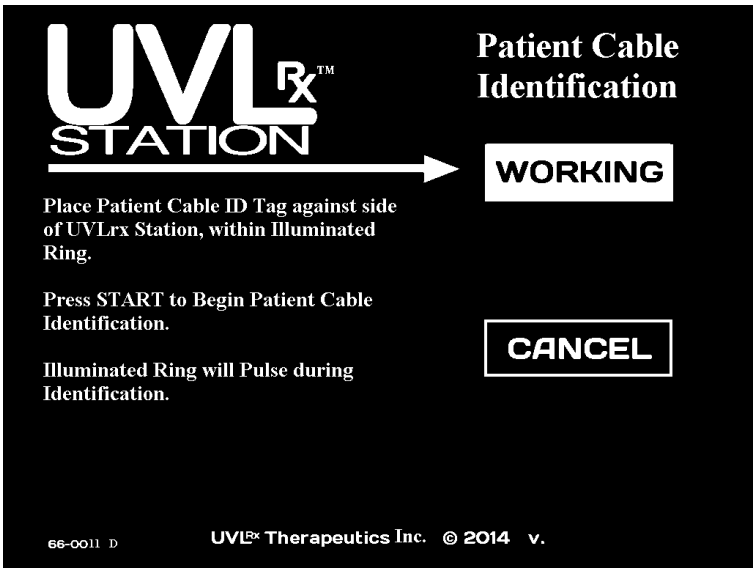
7.1.3. Patient Cable – UVLrx Security™ Scanning Screen

The Patient Cable's UVLrx Security™ tag is located approximately 2.5 feet from the Emission Port end of the Patient Cable. Upon pressing CALIBRATE from the Main Screen, the UVLrx Station™ will display the Patient Cable – Scanning Screen. Upon pressing START, a ring of twelve lights will illuminate one side of the UVLrx Station™, flashing once per second. The START button will invert and change to "WORKING". The user must place the UVLrx Security™ tag against the side of the UVLrx Station™, within the flashing ring of LEDs. Once the UVLrx Station™ recognizes the UVLrx Security™ tag, an audible beep will be heard and the LEDs will flash rapidly for three seconds. The screen will automatically transition to the Dry Light Adapter™ - Scanning Screen.

The user may press CANCEL at any time to return to the Home Screen.

If the user fails to place the UVLrx Security™ tag against the side of the UVLrx Station™, within the flashing ring of LEDs, inside of twenty seconds, the inverted "WORKING" indicator will change back to the START button, and the ring of LEDs will turn off. The user may press START to reattempt to scan the Patient Cable UVLrx Security™ tag, or press CANCEL to return to the Home Screen.



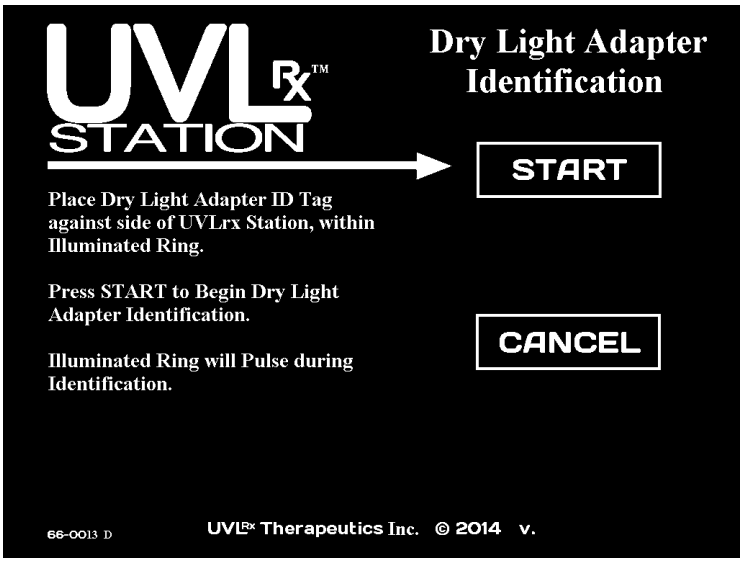


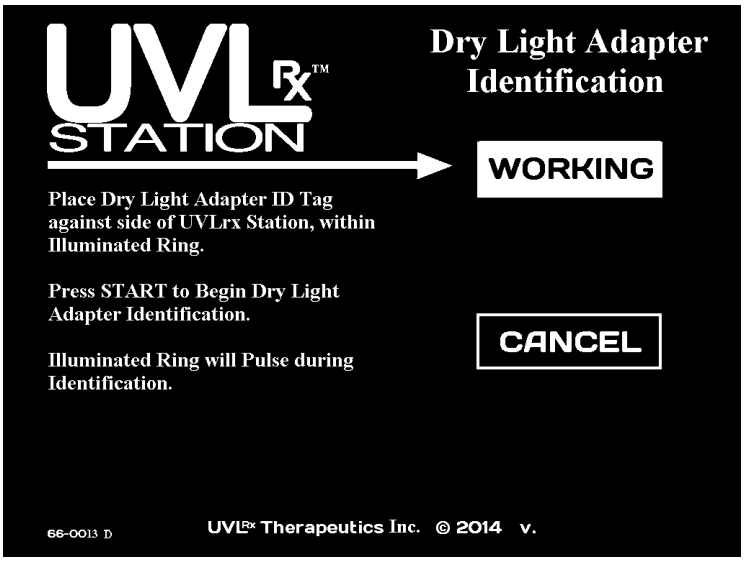
7.1.4. Dry Light Adapter – UVLrx Security™ Scanning Screen

The Dry Light Adapter's UVLrx Security™ tag is located on the front of the Tyvek® pouch of the Dry Light Adapter. After successful scan of the Patient Cable UVLrx Security™ tag, the UVLrx Station™ will display the Dry Light Adapter – Scanning Screen. Upon pressing START, a ring of twelve lights will illuminate one side of the UVLrx Station™, flashing once per second. The START button will invert and change to "WORKING". The user must place the UVLrx Security™ tag against the side of the UVLrx Station™, within the flashing ring of LEDs. Once the UVLrx Station™ recognizes the UVLrx Security™ tag, an audible beep will be heard and the LEDs will flash rapidly for three seconds. The screen will automatically transition to the Pre-Calibration Screen.

The user may press CANCEL at any time to return to the Home Screen.

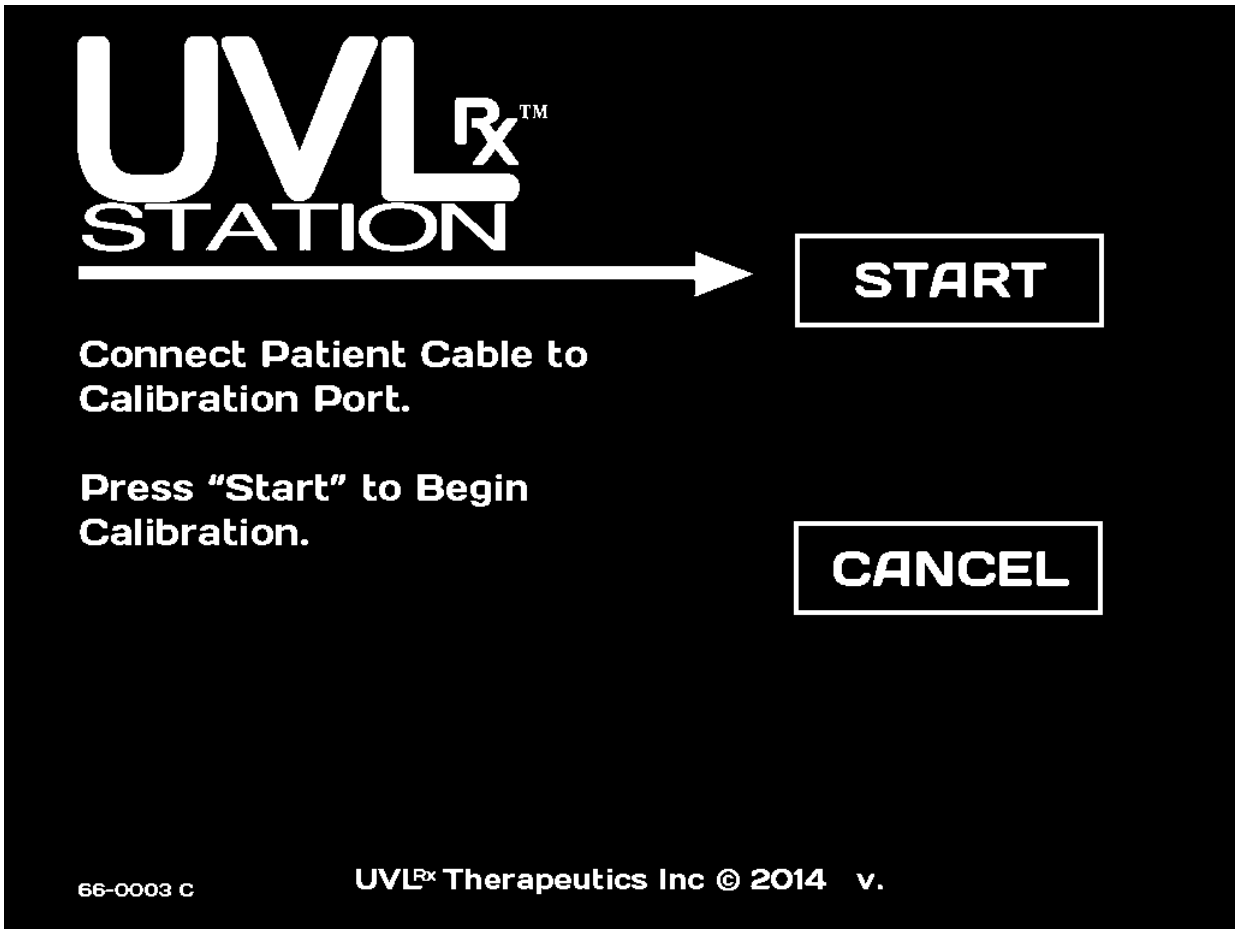
If the user fails to place the UVLrx Security™ tag against the side of the UVLrx Station™, within the flashing ring of LEDs, inside of twenty seconds, the inverted "WORKING" indicator will change back to the START button, and the ring of LEDs will turn off. The user may press START to reattempt to scan the Dry Light Adapter UVLrx Security™ tag, or press CANCEL to return to the Home Screen.

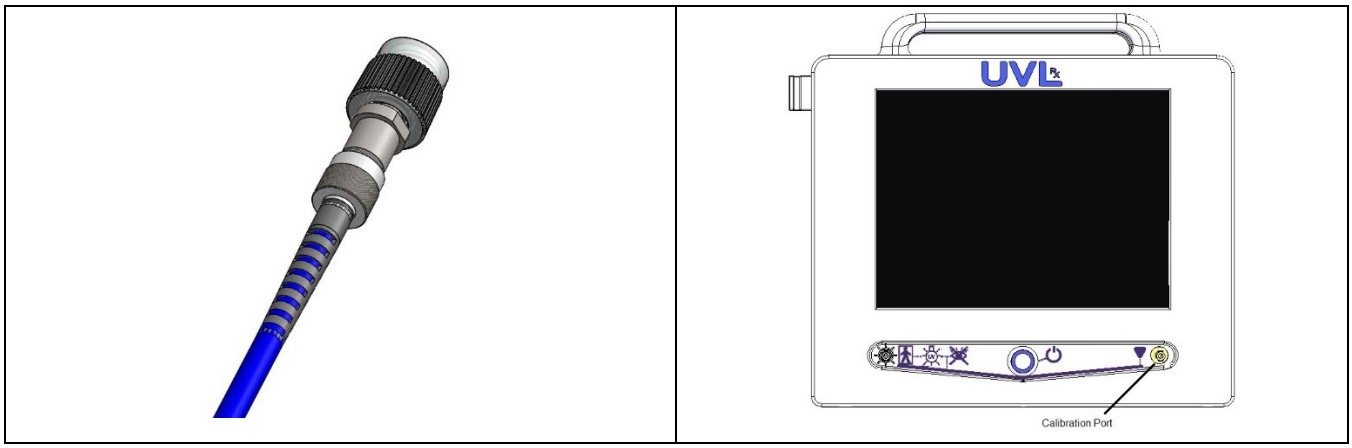




7.1.5. Pre-Calibration Screen

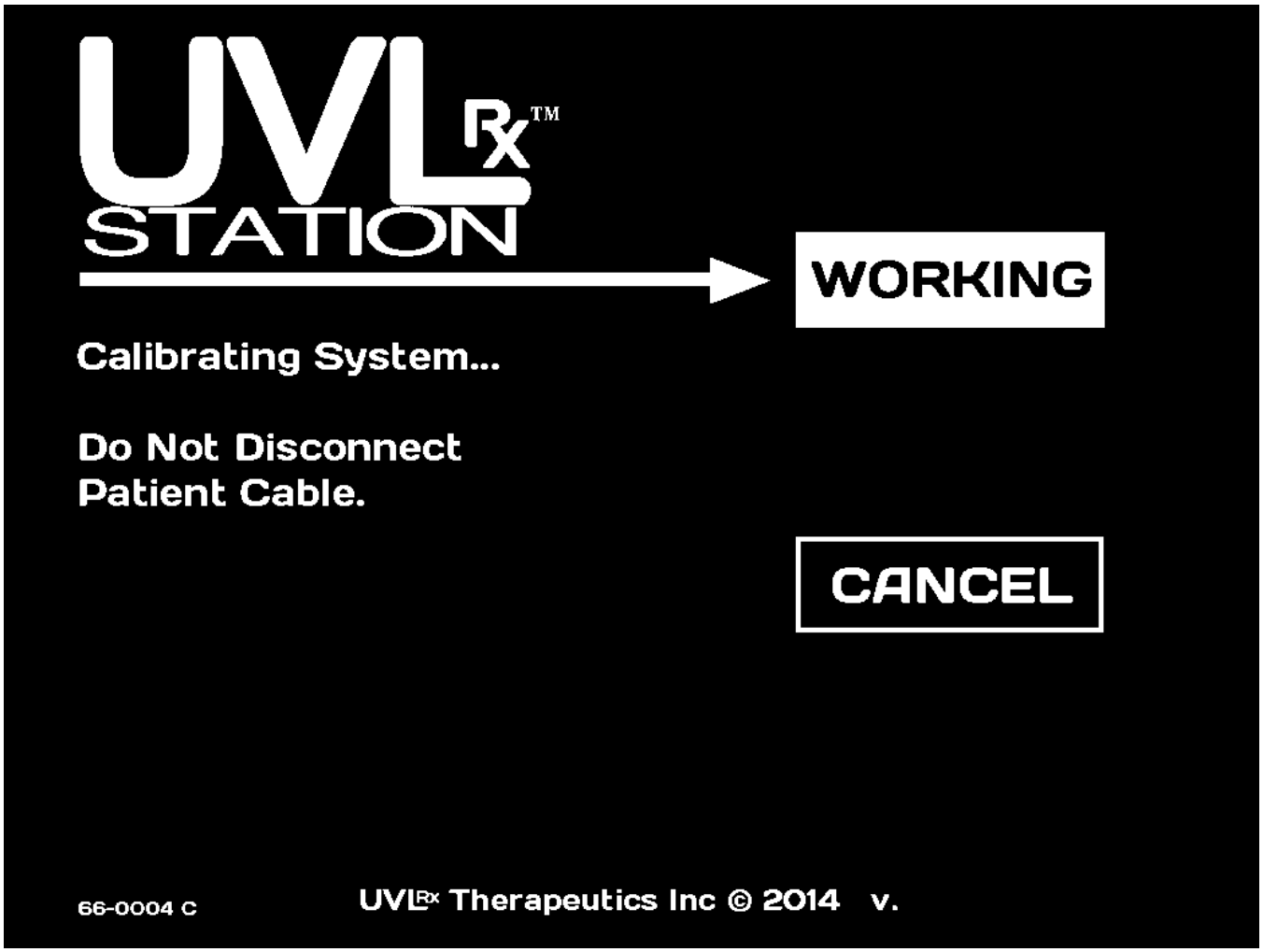
The Pre-Calibration Screen requires the user to connect the Patient Cable to the Calibration Port. Remove the dust cap from the Calibration Port. Firmly secure the Patient Cable with the tapered adapter to the Calibration Port, and twist the Slip Lock Ring of the Patient Cable until firmly seated. Press START to initiate calibration.





7.1.6. Calibration Screen

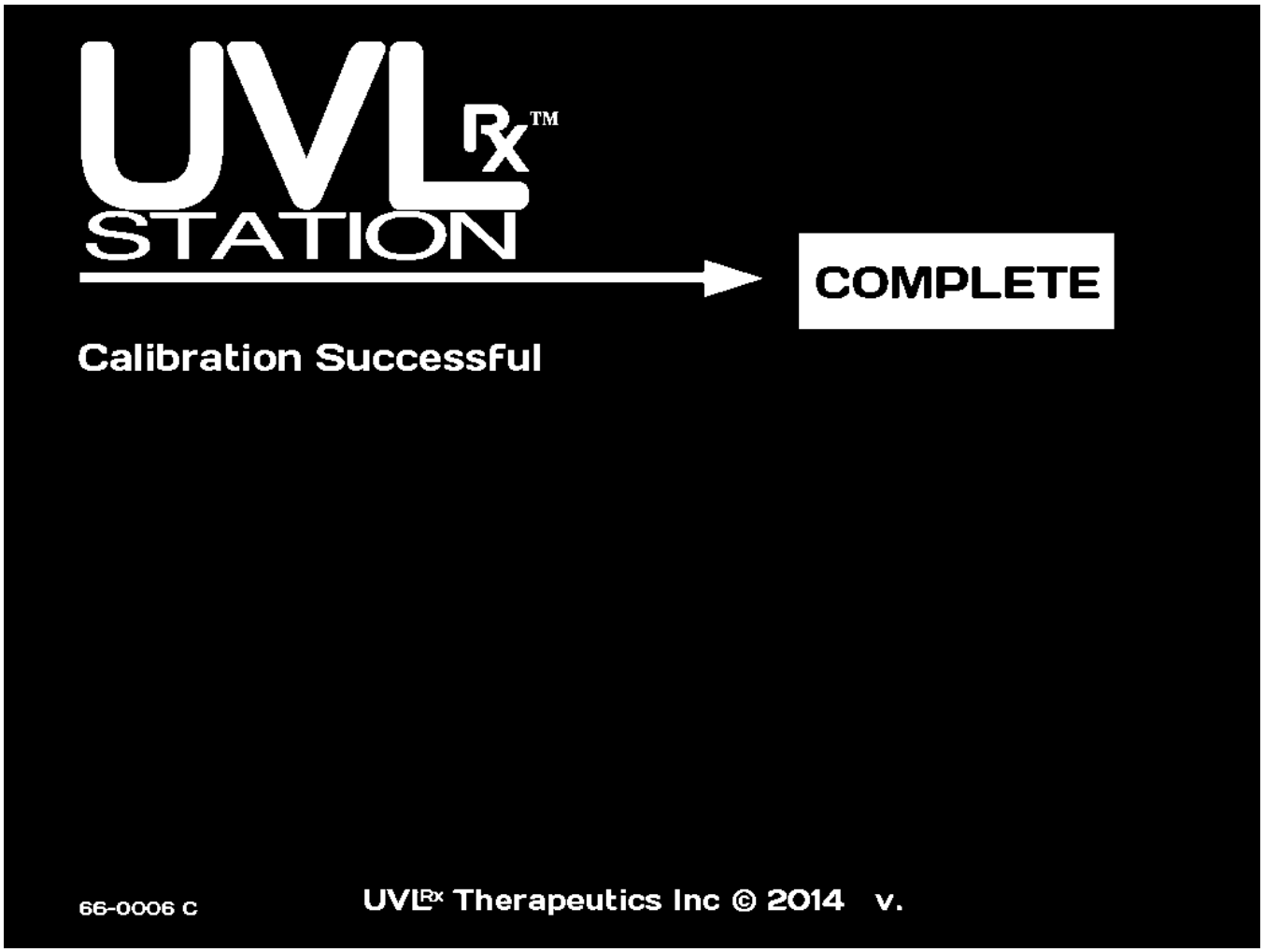
Progression to the Calibration Screen indicates the UVLrx Station™ is in process with calibration of each wavelength of the UVLrx Station. For performance specifications, see Section 14, Technical Specifications.



Note: Calibration may last several seconds. Successful calibration will automatically transition the screen to the Calibration Successful screen, followed by the Pre-Treatment Screen. If for any reason one or more of the wavelengths was not calibrated successfully, the screen will automatically transition to the Calibration Retry Screen. The Calibration Retry Screen will be described in Section 9, Troubleshooting.

7.1.7. Calibration Successful Screen

Progression to the Calibration Successful screen indicates the UVLrx Station™ successfully calibrated each wavelength of the UVLrx Station.



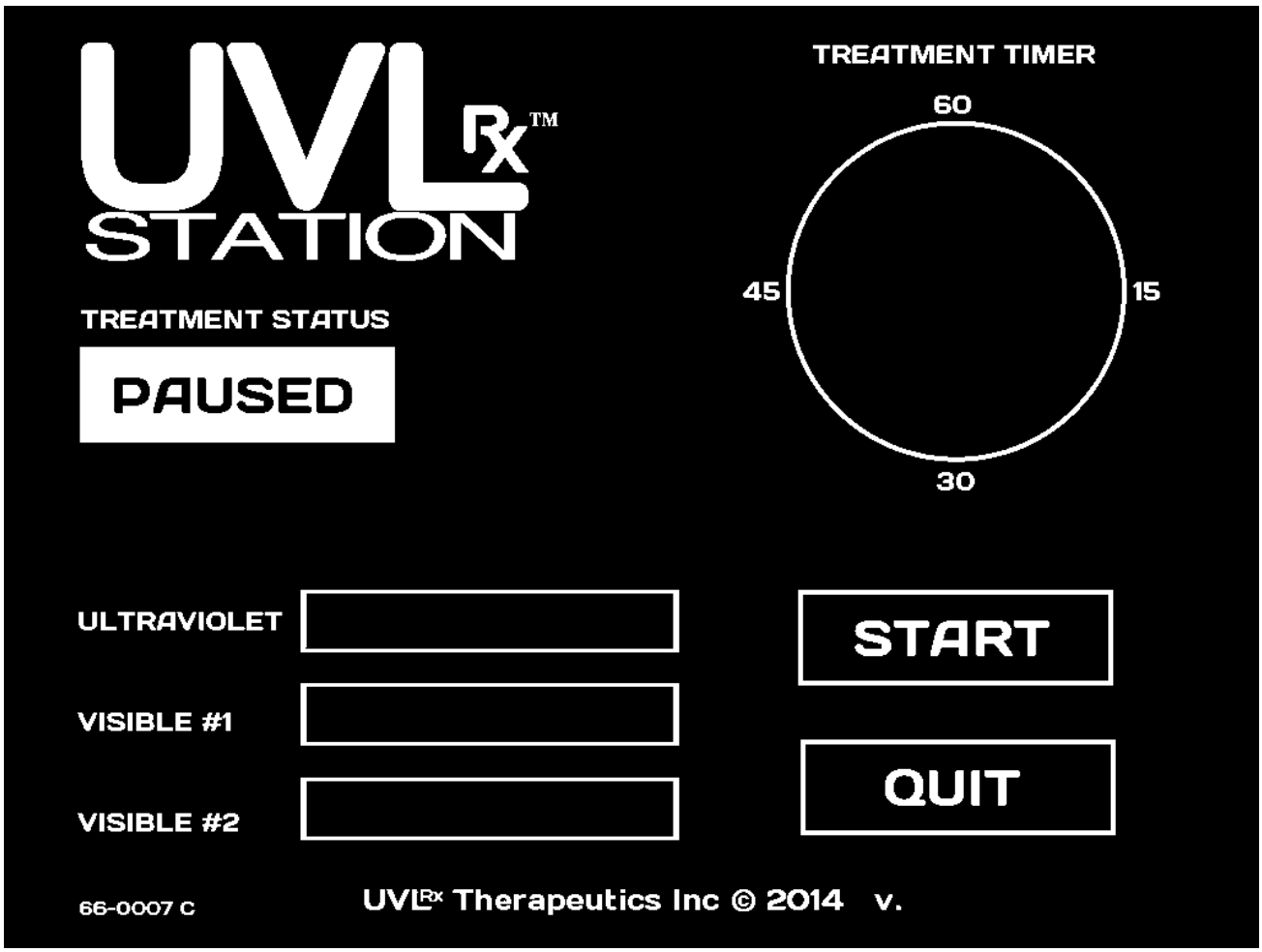
This screen will automatically transition to the Pre-Treatment Screen after several seconds.

7.2. STARTING TREATMENT

7.2.1. Pre-Treatment Screen

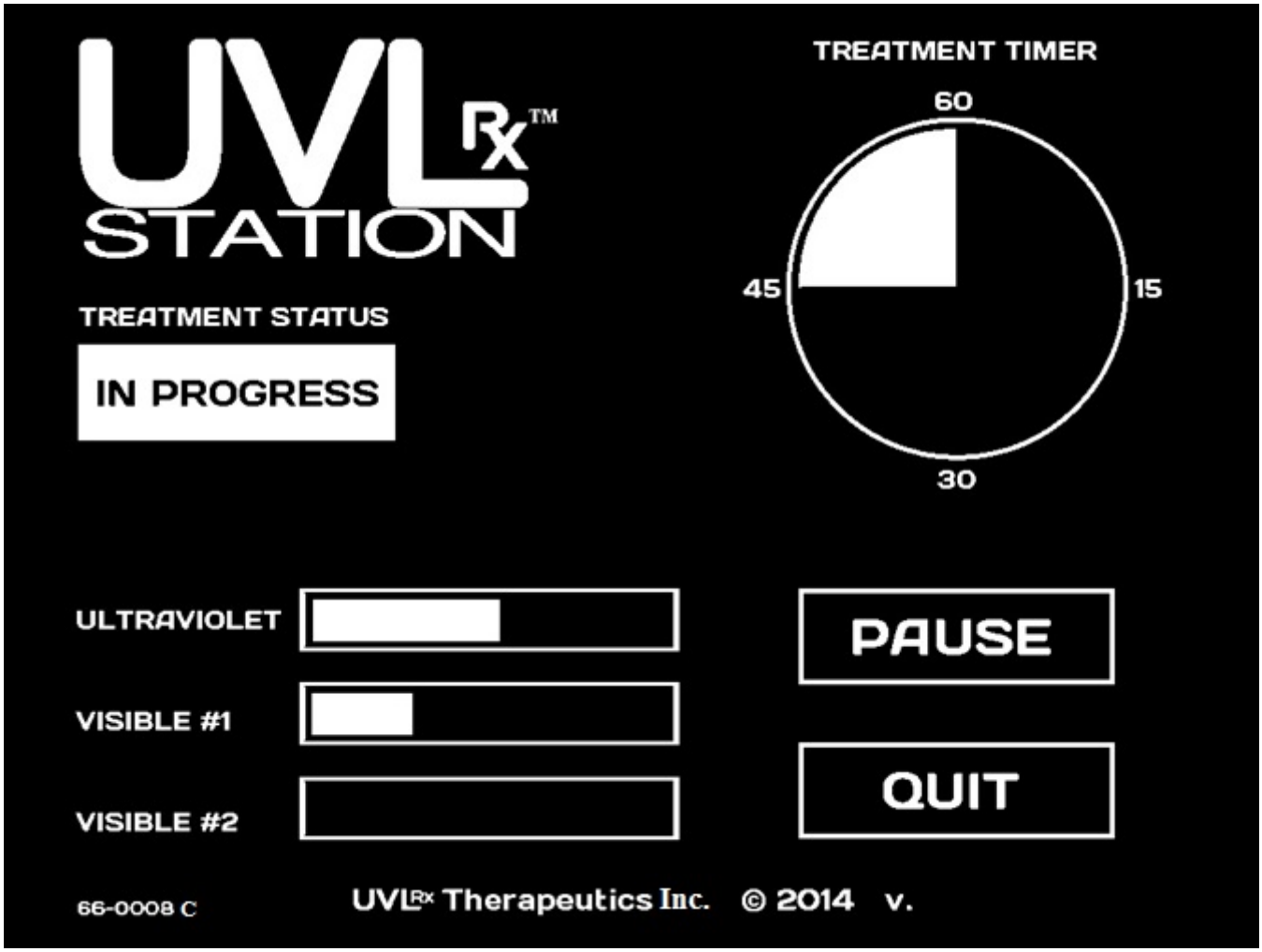
The Pre-Treatment Screen allows the user to initiate treatment. Pressing START initiates treatment. Prior to initiating treatment, ensure the Patient Cable is properly seated onto the Emission Port of the UVLrx Station™, the DLA is firmly seated into the 20ga x 1" catheter, and the DLA is firmly seated into the Patient Cable.

The Pre-Treatment Screen is shown below. Pressing QUIT will end treatment and return the user to the Home Screen. A countdown Treatment Timer is shown, which fills in white, counter clockwise as treatment progresses, from 60 minutes around to zero minutes. Three status bars are shown which fill in from left to right as treatment progresses. "ULTRAVIOLET" fills in over the first 30 minutes. "Visible #1" indicates the RED wavelength, and fills in over 60 minutes. "Visible #2" indicates the GREEN wavelength, and fills in over the second 30 minutes of treatment. The "Treatment Status" block indicates treatment is paused.



7.2.2. In-Treatment Screen

The In-Treatment Screen is displayed after the user presses START, initiating treatment. The screen below shows the treatment after the first 15 minutes of treatment has progressed. At any time, the user may press PAUSE to pause the treatment, or QUIT to end treatment and return to the Home Screen. Note the "Treatment Status" block indicates "In Progress".

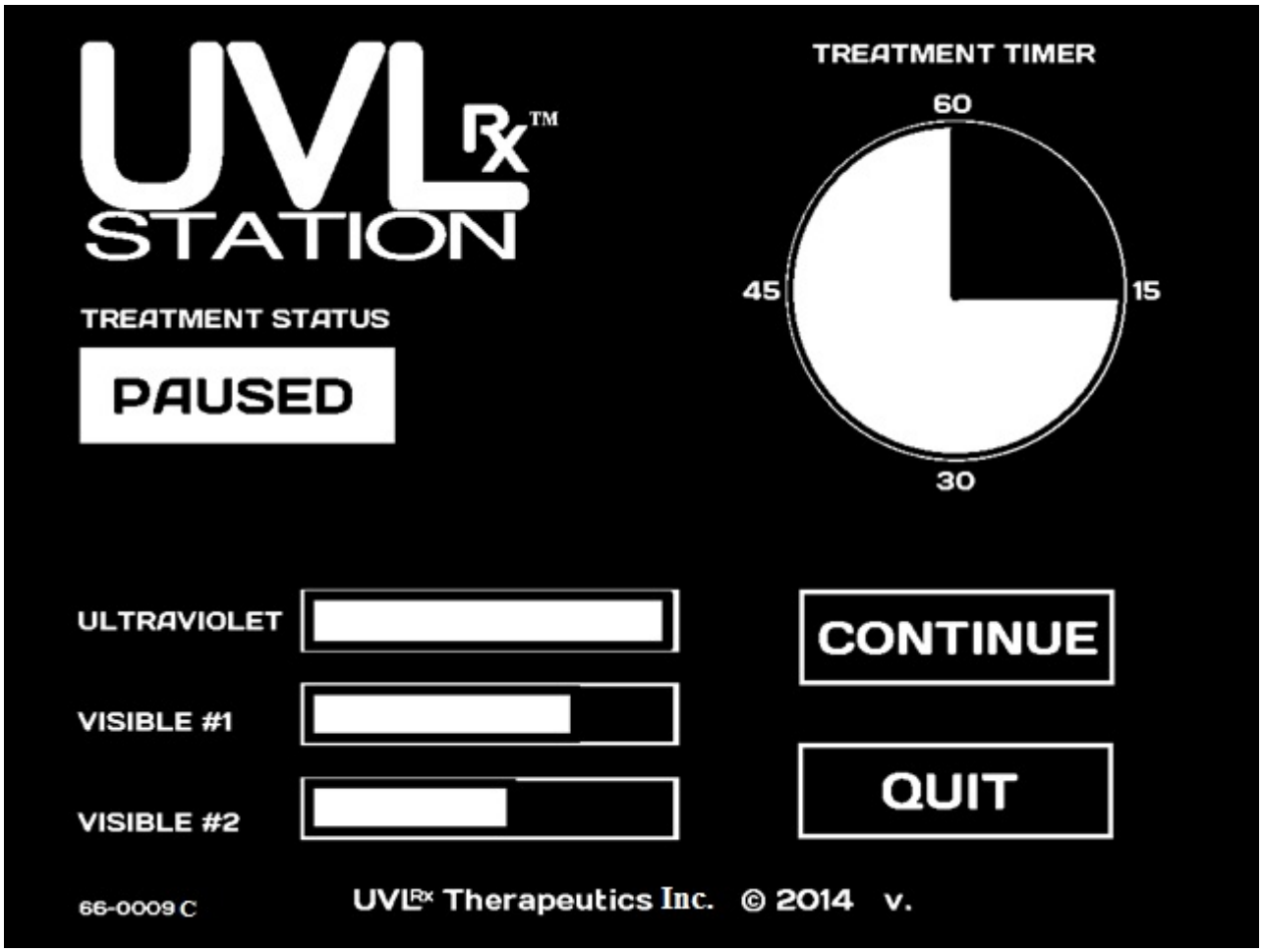


7.2.3. Treatment Paused Screen

The Treatment Paused screen is displayed after the user presses PAUSE. The screen below shows the treatment after the first 45 minutes of treatment has progressed. At any time, the user may press QUIT to end treatment and return to the Home Screen.

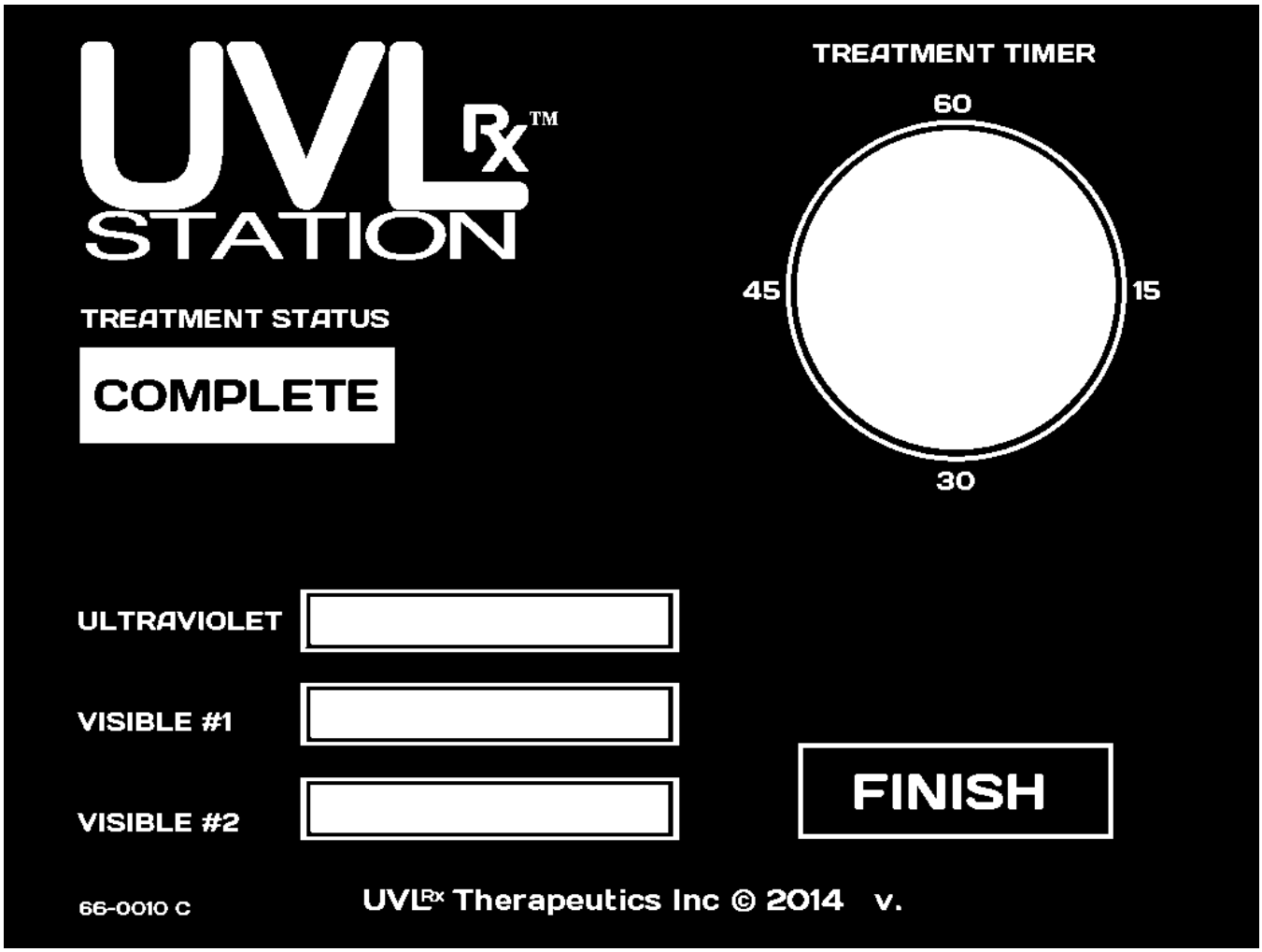
The user may press CONTINUE at any time to continue with the treatment. The PAUSE / CONTINUE cycle may be repeated as necessary to accommodate the healthcare provider and patient. When treatment is paused, the "Treatment Status" indicates "Paused".

Note: at 30 minutes, the device will emit and audible "double beep".



7.2.4. Treatment Complete Screen

The Treatment Complete screen is displayed after the treatment ends. When the treatment completes, the device will emit a “triple beep”. The user must press FINISH to return to the Home Screen.



8. MAINTENANCE

8.1. UVLRX STATION™

The fuses are the only user-serviceable component. See section 11 “Service” for regular service requirements. Do not attempt to sterilize the UVLrx Station.

8.2. PATIENT CABLE

Regular maintenance is not required for the Model UVL1510, aside from those described in Section 3.2.1. Do not attempt to sterilize the Patient Cable. There are no user-serviceable components for the Patient Cable.

8.3. DRY LIGHT ADAPTER™

Regular maintenance is not required for the Model UVL1520. There are no user serviceable components for the Dry Light Adapter.

8.4. FUSES

The Model UVL1500 requires two (2) fuses, each rated at 2AL and 250V with time lag “T”. If the fuses require changing, disconnect AC mains power from the device, and use a flat head screw driver to pop-open the fuse tray from the Power Entry Module at the back of the device. Replace the fuses, and replace the fuse tray. Ensure the tray is completely seated. Reconnect AC mains and press the Stand-By Switch. If the device does not turn on, disconnect power and verify the fuse tray is properly seated. The fuses are the only user-serviceable components.

8.5. DISPOSAL / ENVIRONMENTAL DIRECTIVES

When considering disposal of the UVLrx Station™ and accessories (e.g. UVL1510 and UVL1520), the user must dispose of in accordance with local laws and ordinances governing such disposal. UVLrx Station™ contains the following materials / components which may be considered important for disposal, including:

- Printed Circuit Boards, Plastics, Aluminum / Copper / Steel

Contact UVLrx Therapeutics Inc. before disposing of UVLrx Station™ devices. Disposal of UVL1520 should follow healthcare provider’s sharps disposal procedures.

For customers in European countries: The WEEE symbol on the product or its packaging indicates that this product must not be disposed of with other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of Waste Electrical and Electronic Equipment. The separate collection and recycling of your waste equipment at the time of disposal will help conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your medical equipment at the end of its useful life for recycling, please contact UVLrx Therapeutics.

9. TROUBLESHOOTING

9.1. CALIBRATION INCOMPLETE

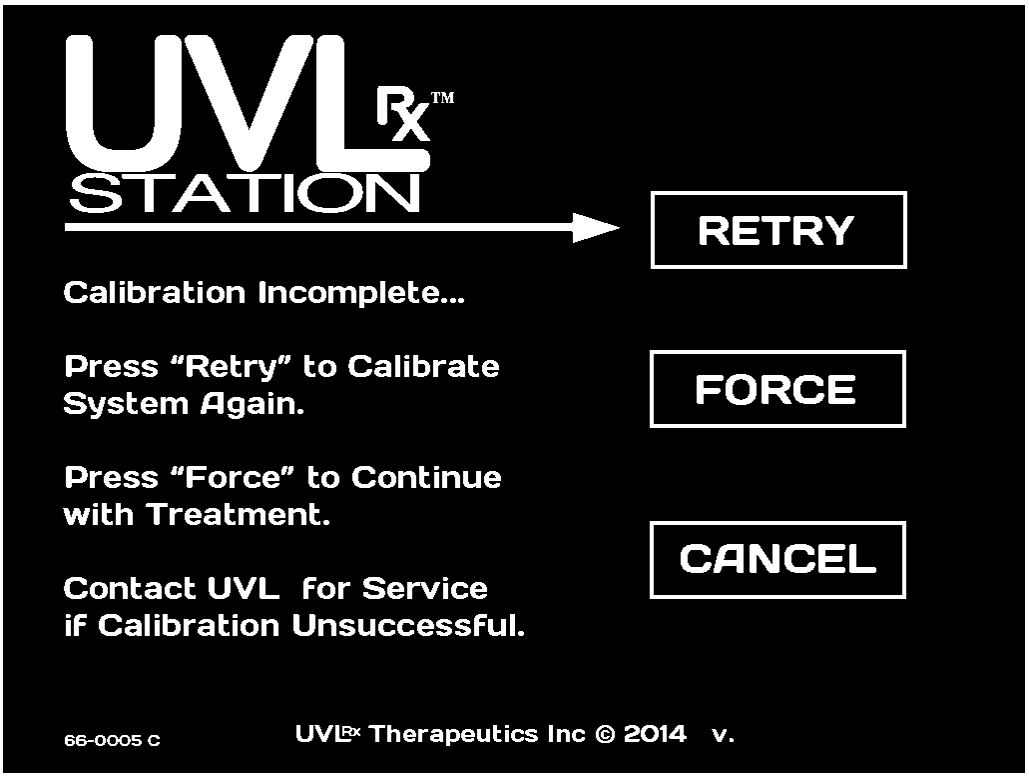
If calibration is unsuccessful, the user will be routed to the Calibration Retry Screen. There will be three numbers displayed at the bottom of the screen. Based on the three numbers, do the following:

(a) Error Code: 9 9 9

a. This code indicates the Patient Cable was either not connected to the Emission Port, the Patient Cable was not connected to the Calibration Port, or both. Verify the Patient Cable is properly connected at both ends to the UVLrx Station™ and press RETRY. The device will attempt to calibrate again. If calibration is still unsuccessful and the user is returned to the Calibration Retry Screen, try inspecting and cleaning both ends of the Patient Cable and press RETRY. If this is unsuccessful, replace the Patient Cable and press RETRY. If this is unsuccessful, contact your authorized UVLrx Therapeutics™ service center.

(b) Error Code: contains the number "3"

a. This code indicates that one or more of the wavelengths is not calibrating properly. If calibration is still unsuccessful and the user is returned to the Calibration Retry Screen, try inspecting and cleaning both ends of the Patient Cable and press RETRY. If this is unsuccessful, replace the Patient Cable and press RETRY. If this is unsuccessful, contact your authorized UVLrx Therapeutics™ service center.



9.2. UVLRX SECURITY™ SCANNING NON-RESPONSIVE

In the event that the user suspects the UVLrx Security™ scanning function is disrupted, the following steps should be attempted prior to contacting UVLrx Therapeutics™ customer service:

(a) Attempt scanning either a different Patient Cable or Dry Light Adapter™.
(b) Press the Stand-By Switch to turn the device off. Power the device back on, and attempt to scan the UVLrx Security™ tag(s) again.
(c) Power the system down, unplug the power cord, wait for three to five seconds, and reconnect the power cord. Start the system again, and attempt to scan the tag(s) again.

9.3. TOUCHSCREEN NON-RESPONSIVE

In some instances, the UVLrx Station™ is performing internal operations and the touchscreen may become unresponsive for a short period of time. If this occurs, wait a few seconds, and attempt pressing the button again.

9.4. LOSS OF POWER

In the event that the UVLrx Station™ loses power at any point in its operation, it is designed to not restart. The user must turn the device ON as usual, and go through the steps for treatment setup again. The device contains no internal memory or record of treatments, no patient data, and no user settings.

9.5. MISCELLANEOUS ERRORS

For errors not specifically called out in Section 9, Trouble Shooting, power the device OFF. Disconnect AC mains power. Wait at least 30 seconds. Plug AC mains back into the device, power the device on, and determine if the problem persists.

For all service questions, please contact your UVLrx Therapeutics™ authorized service provider.

10. PROTECTIVE EYEWEAR

The UVLrx Station™ does not require the use of protective eyewear.

11. SERVICE

The calibration procedure performed before each treatment provides a means of detection for immediate servicing requirements. General inspection and servicing is performed in the case where a device is returned for service.

Regular and proper maintenance of your equipment is the best way to protect your investment. It is essential that you have your equipment serviced once every 12-months, the “recertification”, in order to retain its optimum performance and reliability, which will reward you with safer, less problematic product performance over time.

Service at UVLrx Therapeutics authorized service centers once every 12-months is mandatory to keep your product warranties in effect. Any services and/or repairs done by any unauthorized repair facility may result in reduced performance of the equipment or equipment failure. (Refer to section 12 “Warranty”).

12. LIMITED WARRANTY

UVLrx Therapeutics™ provides warranty information in your sales agreement documentation. A 1-year limited warranty is provided standard with new Model UVL1500 purchases. UVLrx Therapeutics™ provides optional extended warranty periods, as described in QF-72-01-6 Limited Extended Warranty. The limited extended warranty requires a recertification, or annual service, be performed at the start of the extended warranty period.

13. POINT OF CONTACT

For warranty or service concerns, please contact:

UVLrx Therapeutics Inc.
Attn. Warranty Service
640 Brooker Creek Blvd.
Suite 455
Oldsmar, FL 34677
U.S.A.
Tel. 877-869-7553

For questions regarding proper operation of the device or accessories, questions regarding extended warranty or sales, and for reordering Dry Light Adapters™, Patient Cables, or replacement components, please contact:

UVLrx Therapeutics Inc.
Attn. Customer Service
200 East Carrillo Street
Suite 101
Santa Barbara, CA 93101
U.S.A.
Tel. 877-869-7553

14. TECHNICAL SPECIFICATIONS

14.1. MODEL UVL1500 SYSTEM SPECIFICATIONS

AC Input Supply	100-240V, 50/60 Hz, with protective earthing
Max Input Power (peak)	48 W
Nominal Input Power	14.5 W
Dimensions (inches)	9.5” tall x 12” wide x 8.5” deep (setting on flat surface)
Weight (lbs.)	10 lbs. max.
Fuses	two 250V, 2A, “T” lag
Type BF Applied Part	Emission Port
Risk Group Classification per 62471	Exempt
Electrical Safety Class	Class I
Water Ingression Rating	IPX0
RFID Radio Frequency and Effective Radiated Power	RFID Radio Frequency: 13.56 MHz Action Time: Momentary, 20 seconds max, during RFID Tag identification Effective Radiated Power: 75uV/m @ 3 meters

* Additional Statements Regarding Radio Frequency Emissions for UVL1500 UVLrx Station:

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme avec Industrie Canada RSS exemptes de licence standard(s). Son fonctionnement est soumis aux deux conditions suivantes: (1) ce dispositif ne doit pas causer d'interférences, et (2) cet appareil doit accepter toute interférence, y compris celles pouvant causer un mauvais fonctionnement de l'appareil.

14.2. MODEL UVL1500 PERFORMANCE SPECIFICATIONS

UVA Peak Wavelength (λ)	365 nm ± 10nm
UVA Output Irradiance*	1000 uW/ cm^2 ± 20%
UVA Dosage** (30-minutes)	1800 mJ/cm^2 ± 20%
RED Peak Wavelength (λ)	630 nm ± 10nm
RED Output Irradiance*	270 uW/ cm^2 ± 20%
RED Dosage** (60-minutes)	972 mJ/cm^2 ± 20%

GREEN Peak Wavelength (λ)	530 nm ± 20nm
GREEN Output Irradiance*	225 uW/ cm^2 ± 20%
GREEN Dosage** (30-minutes)	405 mJ/cm^2 ± 20%
Pulse Frequency	Continuous
Light Source(s)	Monochromatic Light Emitting Diode (LED)
Power Supply	100-240V, 50/60 Hz, 12VDC, 65W max IEC 60601 input-to-output isolation, Class B EMC, BF application approval, dual fusing, 4.5kVAC isolation input-to-output 1.9k VAC input-to-ground and output-to-ground
Treatment Duration	60 minutes

* Measured as follows: Model UVL1500 calibration protocol followed, then Model UVL1510 Patient Cable connected to Model UVL1520 Dry Light Adapter™ (DLA) which in turn is connected to 20ga x 1" catheter. DLA with catheter placed into fixture aligning tip of catheter lumen at aperture of integration cube which is connected to calibrated spectrometer. Irradiance is measured as output in final configuration.

* * Calculated as: [irradiance (uW/cm^2) x duration (minutes) x 60 seconds] ÷ 1000 = mJ/cm^2

14.3. Power Cord Requirements

For EU use, a power cord appropriate to the region must be an 8-foot medical grade, 18awg wire, 3 conductor, and have an IEC C13 style receptacle. The power cord supplied by UVLrx Therapeutics™ contains a NEMA 5-15P type plug.

14.4. Accessory Technical Specifications: Model UVL1510 Patient Cable

Dimensions (meters)	1.525 long
Weight (grams)	12 max

14.5. Accessory Technical Specifications: Model UVL1520 Dry Light Adapter

Dimensions (centimeters)	17.2 long (max) x 2.54 wide
Weight (grams)	3 max

14.6. List of Accessories

The list of applicable accessories for the UVL1500 include the power cord (see section 14.3), the Model UVL1510 Patient Cable (see section 14.4), the Model UVL1520 Dry Light Adapter (see section 14.5), and standard 20 gauge x 1" catheter.

15. PRODUCT ENVIRONMENTAL REQUIREMENTS

15.1. MODEL UVL1500 & ACCESSORIES ENVIRONMENTAL TECHNICAL SPECIFICATIONS: STORAGE

The following ranges apply for the Model UVL1500, UVL1510, and UVL1520 while packed for transport or storage in the custom shipping case originally provided with the UVLrx Station™:

Ambient Temperature (Celsius)	-20 to +70
Relative Humidity (%) (non-condensing)	10% to 90%
Atmospheric Pressure (hPa)	500 to 1060

The above values also apply to the Model UVL1510 (packed individually in shipping box for replacement patient cables) and the Model UVL1520 (sold separately in shipping box).

15.2. MODEL UVL1500 & ACCESSORIES ENVIRONMENTAL TECHNICAL SPECIFICATIONS: OPERATION

The following ranges apply while operating the UVLrx Station™ in normal use.

Ambient Temperature (Celsius)	+10 to +35
Relative Humidity (%) (non-condensing)	30% to 75%
Atmospheric Pressure (hPa)	700 to 1060

15.3. MODEL UVL1500 ELECTROMAGNETIC REQUIREMENTS

Table 1

Guidance and manufacturer's declaration –electromagnetic emissions		
The UVL1500 is intended for use in the electromagnetic environment specified below. The customer or the user of the UVL1500 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The UVL1500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The UVL1500 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration –electromagnetic immunity			
The UVL1500 is intended for use in the electromagnetic environment specified below. The customer or the user of the UVL1500 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable - optical I/O only	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode (line to line) ±2 kV common mode (lines to earth)	±1 kV differential mode (line to line) ±2 kV common mode (lines to earth)	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	3 A / m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the UVL1500 requires continued operation during power mains interruptions, it is recommended that the UVL1500 be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 4

Guidance and manufacturer's declaration –electromagnetic immunity			
The UVL1500 is intended for use in the electromagnetic environment specified below. The customer or the user of the UVL1500 should assure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the UVL1500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	**Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 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, [a]should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 			
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths 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 UVL1500 is used exceeds the applicable RF compliance level above, the UVL1500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UVL1500. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.			

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the UVL1500

The UVL1500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the UVL1500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UVL1500 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.79	3.79	7.27
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

UVLrx Therapeutics Inc.
640 Brooker Creek Blvd.
Suite 455
Oldsmar, FL 34677

CE 0086
EC REP
MDSS GmbH
Schiffgraben 41
D-30175 Hannover, Germany