



Veralase Clinical Laser User Instructions

www.veralase.com
Model Number: 301



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1. General Information

Devices are sold and supported by Veralase for medical research and development in many fields of study. Veralase lasers are designed for preclinical and clinical treatments for skin ailments and other medical research under appropriate institution review board (IRB) supervision.

Please carefully read the following important safety precautions prior to unpacking and operating this equipment. In addition, please refer to the complete User's Manual for additional important notes and cautionary statements regarding the use and operation of the system.

Do not attempt to operate the system without reading all the information provided with each of the components.

NOTE: The laser should only be operated by personnel authorized to use Class IV laser devices. This manual is only intended as additional training for these professionals.

2. Symbols and Definition



WARNING

Situation has the potential to cause bodily harm or death.



ELECTRICAL SHOCK

Hazard arising from dangerous voltage. Any mishandling could result in irreparable damage to the equipment, and personal injury or death.



LASER RADIATION WARNING



READ USER INSTRUCTION

Please read **all** instructions that were provided prior to operation of the system.

If there are any questions, please contact Veralase LLC or the authorized representative through whom the system was purchased.

3. System Specifications

| | Symbol | Typical (1) | Units |
|-------------------------|------------------|---------------|--------|
| Optical | | | |
| Output Power (CW) | P_o | < 2 (@1270nm) | Watts |
| Wavelength (1) | λ_c | 1270nm-1275nm | nm |
| Spectral Width | $\Delta\lambda$ | 10 | nm 3dB |
| Wavelength Temp. Coeff. | λ_{coef} | 0.7 | nm/C |
| Standard Optical Output | | 6x6 | mm |

(1) Other models are available for different wavelength, contact veralase for more information

| | | | |
|--------------------------|--|------------------|-----|
| Electrical / Data | | | |
| Power Adapter Input | | 100 - 240 | VAC |
| | | 50-60 | Hz |
| Power Adapter Output | | 5 | VDC |
| | | 1200 | mA |
| Handheld Laser Input | | micro USB type C | |

| | | | |
|--------------------------------------|--|-------------|----|
| Program Parameters | | | |
| Current Level - Up to 5 settings (2) | | 0, 0.2 to 7 | A |
| Burst Pulse Width (2) | | 0 to 32000 | ms |
| Burst Pulse Frequency (2) | | 0 to 500 | Hz |
| Number of Pulses per Burst | | 0 to 32000 | |
| Auto-Delay Between Burst Cycles | | 0 to 32000 | ms |

(2) Programmable setpoints for each setting

4. Laser Specifications

| | Min | Max | Units |
|-------------------------|--------------|-----|--------|
| General | | | |
| Dimensions | 71 x 44 x 23 | | mm |
| | 3 x 1.7 x 1 | | inches |
| Operating Temperature | 0 | 40 | C |
| Storage Temperature | -10 | 60 | C |
| Current draw while idle | | <10 | mA |
| Current draw while off | | <2 | mA |
| Power on wait time | | 1.5 | sec |

| CW Operation | Min | Max | Units |
|----------------------|-----|-------|--------|
| Laser Current | | | |
| Range | 0 | 7,000 | mA |
| Resolution | 50 | | mA |
| Accuracy | 50 | | +/- mA |
| Noise/Ripple | | 175 | mA |
| Compliance Voltage | 1 | 3.3 | V |

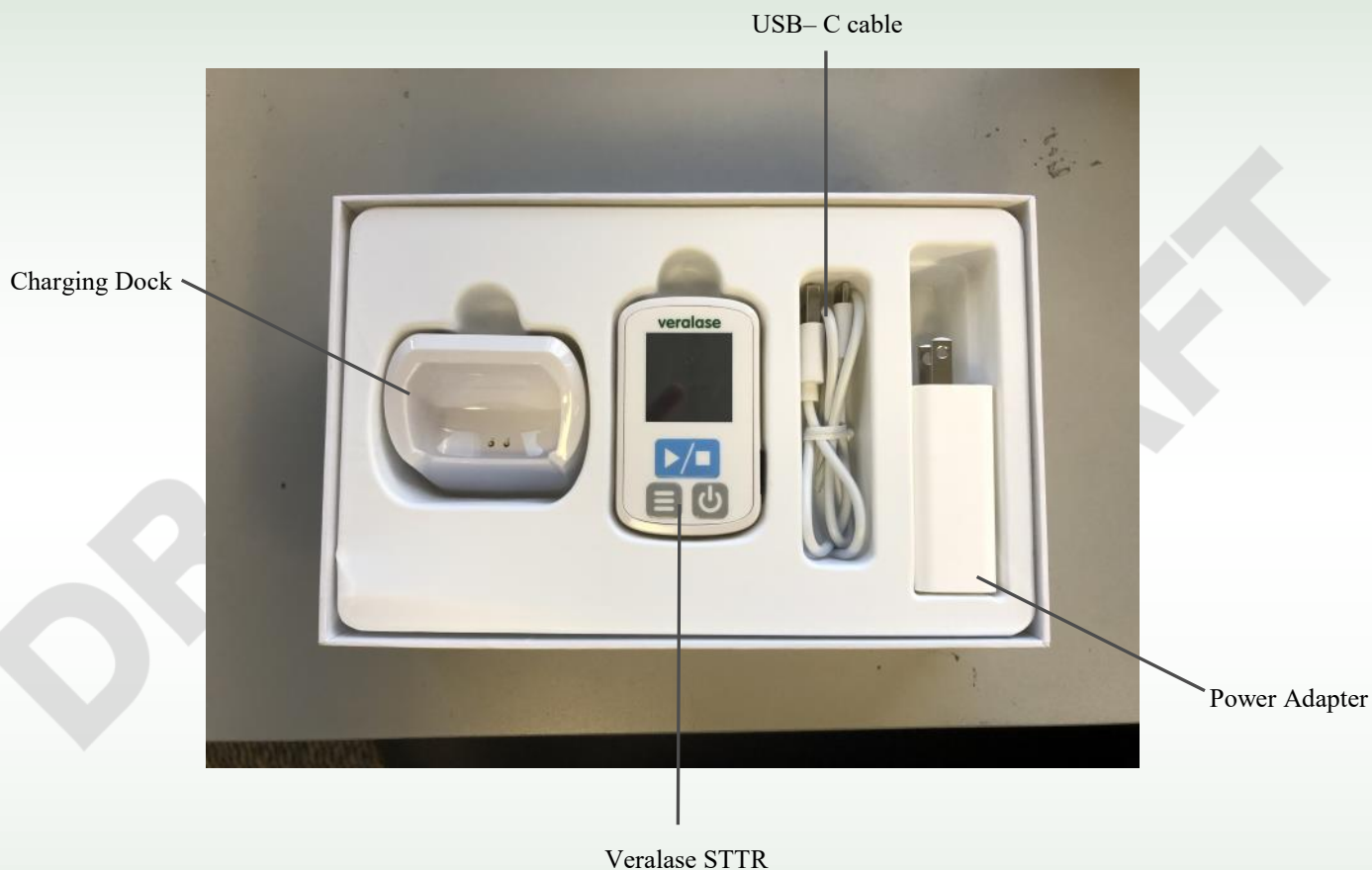
Programming

| | | | |
|---|--|-------------|----|
| Stock Program Modes / Parameters | | | |
| Current Level | | 0 to 7 | A |
| Burst Pulse Width | | 0 to 32000 | ms |
| Burst Pulse Frequency | | 0 to 500 | Hz |
| Number of Pulses per Burst | | 0 to 32000 | |
| Auto-Delay Between Burst Cycles | | 0 to 32000 | ms |
| Number of Cycles per Trigger | | 1 to 160000 | |

5. System Setup

Unpacking

Remove all items from the box and verify each item is accounted for. The system is carefully packaged to minimize the possibility of damage during shipment. Inspect the shipping box for external signs of damage or mishandling. Inspect the contents for damage. The contents of the box include:



If any item is missing or damaged, immediately contact Veralase LLC or the authorized representative from whom the system was purchased.

It is suggested to save the packaging material and box, in case the equipment needs to be stored or relocated at a future date.

6. Safety Features



Class IV Laser Device.

Only for use by authorized personnel.

Lasers can produce serious injury to the eyes if not handled with care.

Interlock

Interlock should be attached to the door of the room of operation, and laser will immediately stop operation if interlock is detached.

Password

Laser is associated with default password set at the factory. The default password is **1234**. The customer is strongly advised to change the password before starting using the device

See Section 8 for instruction on change the Password



Safety glasses

Authorized personnel **MUST** wear laser safety glass before using the laser.

Laser safety glasses can be found at www.thorlabs.com or

www.newport.com

Capacitive sensor

Capacitive sensor has ON or OFF modes. Researcher can choose turn on or turn off based on their experiment requirements. When capacitive is ON, the laser can only fire when sensor detects tissue in full contact with the outer ring of the laser aperture.

7. Device Modes and Design

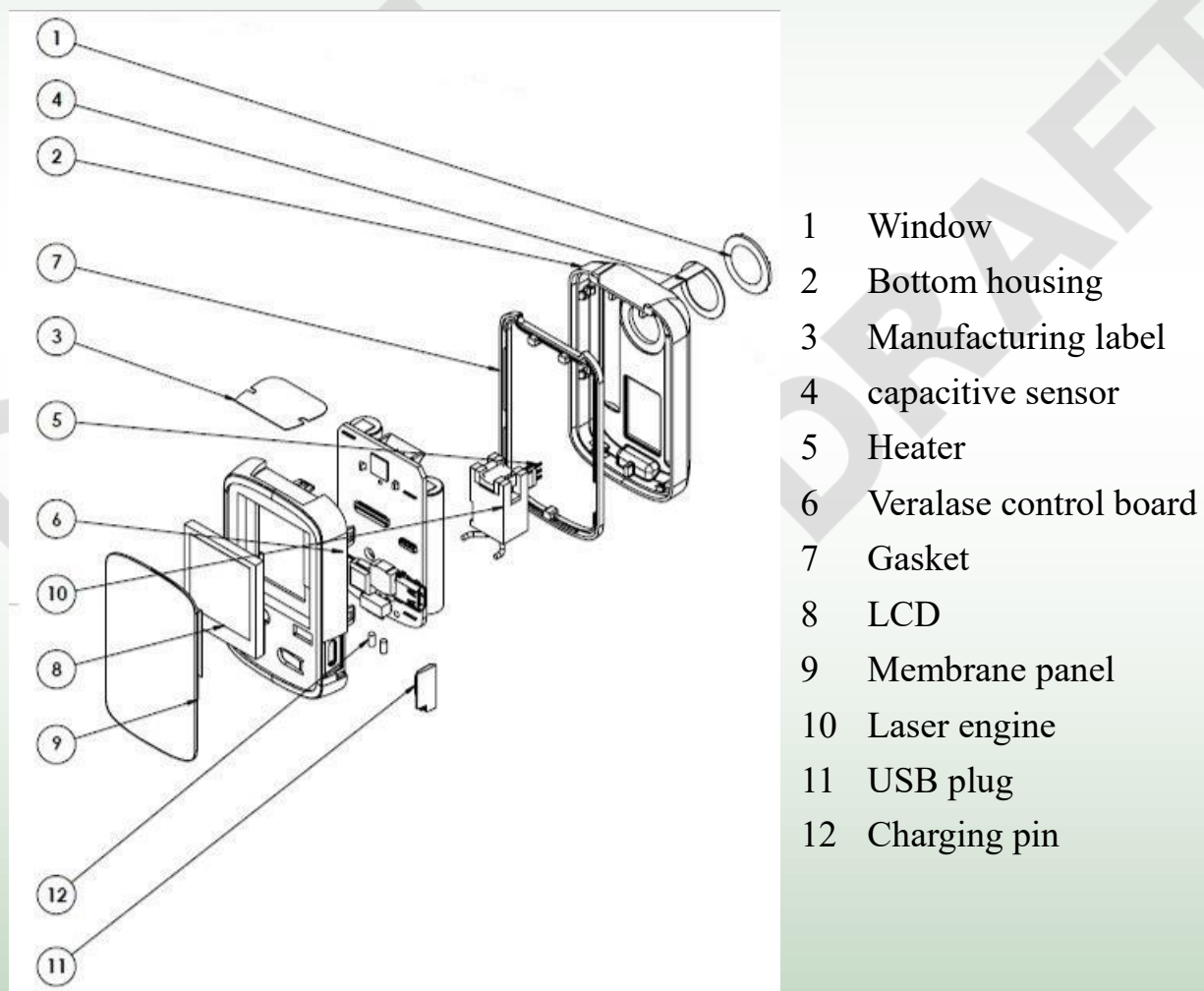
7.1 Laser Modes

The Veralase laser is designed for both R&D use and medical use. See Section 8 for programming and use in R&D and Section 9 for medical use mode.

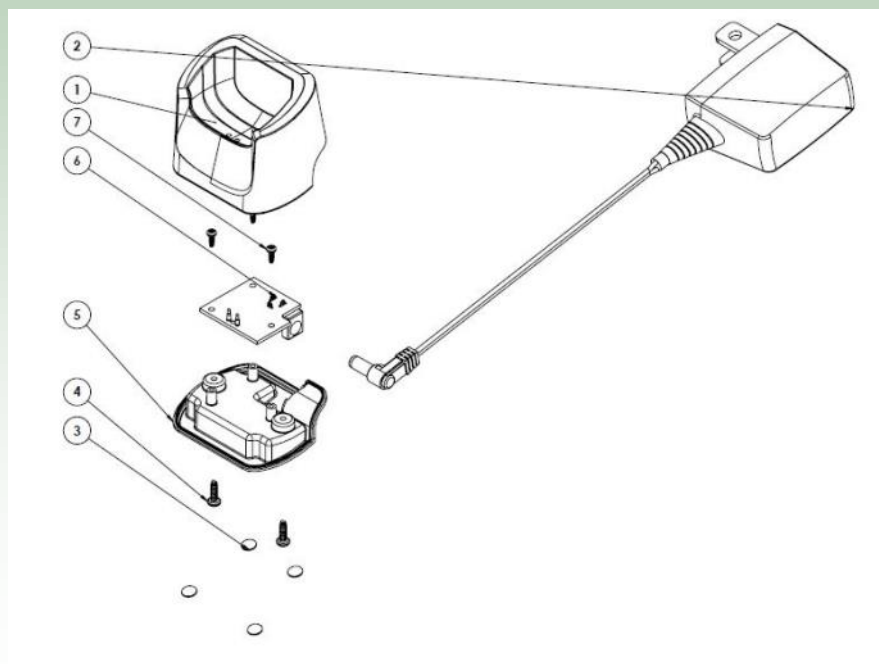
7.2 Laser Design

a. Laser components.

Note, Veralase device is NOT designed to be disassembled and serviced. Never open laser device.

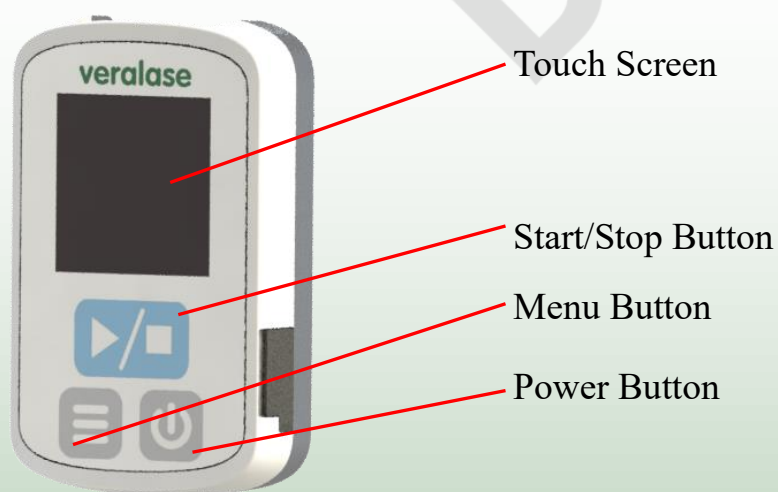


b. Docking station charger components



- 1 Dock top
- 2 Charger
- 3 Dock bumper
- 4 Dock fixture screw
- 5 Dock bottom
- 6 Dock Control board
- 7 Dock internal screw

c. Buttons and touch screen



8. How to Use for R&D

8.1 Turn on/ Turn off the device

- Press the Power Button to turn on the device
- Press and hold the Power Button for 2 seconds to turn off the device

8.2 Warning screen

- After device is powered on, the screen will display a warning, click any button to go to proceed.

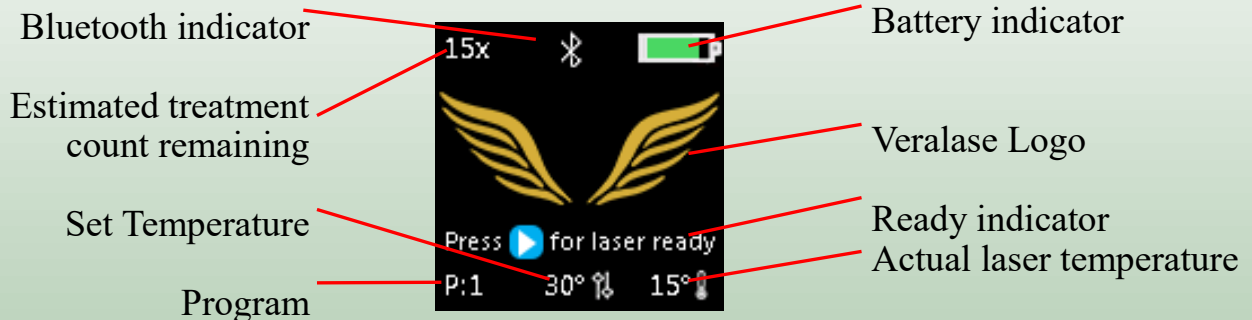
Invisible laser radiation. Avoid eye or skin exposure to direct or scattered radiation.
Class IV Laser
Product 1270nm, 2W

8.3 Passcode screen

- Enter the passcode by touch screen, the default passcode is 1234. Change the passcode by selecting the Menu Button, then pressing the Change Password icon with your finger and follow the directions.
- Successfully inputting the password will open the main screen



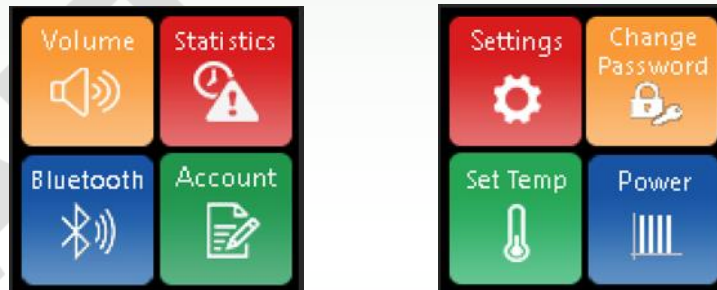
8.4 Main screen



- Estimated treatment count remaining provides user estimate of how many treatment cycles are left based on current battery.
- Bluetooth indicator shows when Bluetooth is enabled on the device
- Program shows which program is currently active. The program options are 1, 2, 3, 4, 5 and M for Manual. User can adjust the program by clicking the Power Button repeatedly to cycle through the program options.
- Target temperature displays the set temperature for the device.
- Actual temperature indicates the current laser diode temperate.

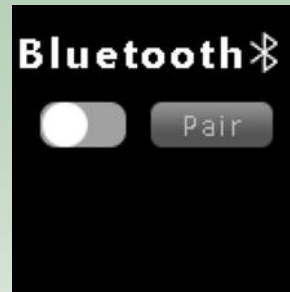
8.5 Menu screen

Press Menu Button to go to menu screen. Press again to go to second menu page, then press again to exit back to Main screen. The menu icons on the screen are touch sensitive. Simply press the menu item with your finger to

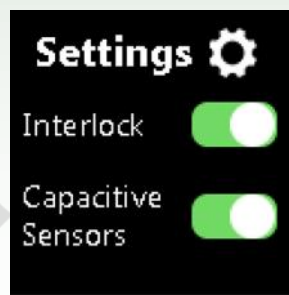


select. To exit a given menu, simply press the Menu or Start/Stop Button.

- Volume icon is for sound volume setting. Touching volume icon on the screen activates the sound page, the plus and minus buttons are used to adjust the volume.
- User can check Statistics information by touching Statistics icon. Statistics shows the usage statistics of the device.
- Bluetooth icon is used to pair or unpair a phone or tablet to device by Bluetooth.
 - To Pair: turn on blue Bluetooth pair button on the screen. This will put the device into pairing mode. Open the Veralase app on your mobile phone. The app will requests a pair code. Input the pair code 654321, then device will pair to app. Pairing will happen automatically in the future.

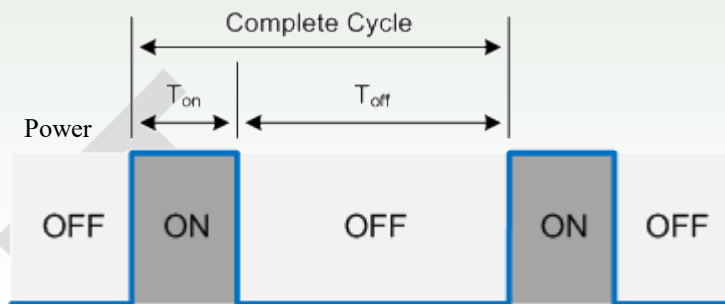


- d. Account identifies the user's account information for that device.
- e. Settings allows user to turn on or off the features. Touch the slide bar to activate or de-activate the feature.

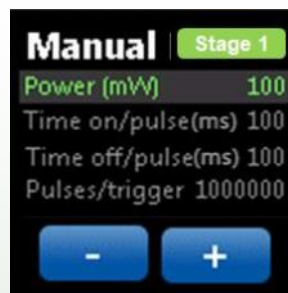


- f. Change passcode is used to set device passcode. To avoid unauthorized change the passcode.
- g. Set temp icon is used to adjust the operation laser temperature. Laser wavelength changes with laser temperature so it is important to maintain this parameter. Press plus and minus buttons to increase and decrease the set temperature.

- h. Program allows user to view and edit 5 database setting programs and 1 manual setting program. User can tap their finger on any parameter and use the plus and minus buttons to adjust the values for each program parameter. Each program has five stages where laser power profile varies from stage 1 ,2, 3, 4 to 5 with four parameters:
- Power (mW): Peak power setting
 - Time on/pulse (ms): time on in each cycle
 - Time off/pulse (ms): time off in each cycle
 - Pulses/trigger: number of cycles to repeat

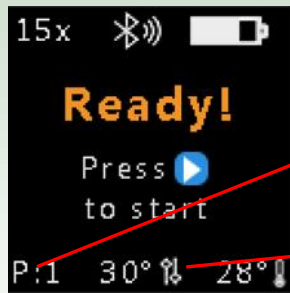


When programming is complete, press the Start/Stop Button to confirm the changes and exit the laser setting.



8.6 Start to treat

To start the treatment, user needs to mount the laser device properly then put the laser into ready mode. Full aperture contact is required if capacitive sensor is ON. Press the Start/Stop Button to set the laser into ready mode, then press Start/Stop Button again to start the laser program treatment. Note the device may first adjust temperature of the laser then automatically run the laser program.



Cycle the program by pressing Power Button

Change the temperature by menu



Under laser

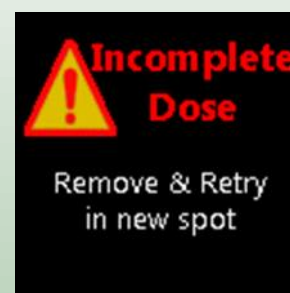
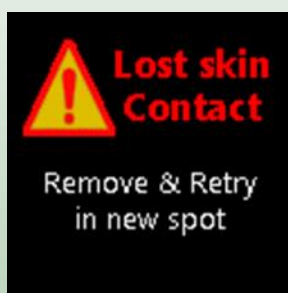
treatment screen, the countdown time indicator and treatment sound are used to tell the user how many seconds remains to finish the treatment.



60s remaining

a. Safety modes

User can only use the device with full contact if capacitive sensors is ON. Failure to fully contact the sensor before treatment or during treatment will cause the laser to stop immediately. The Start/Stop Button can be used to manually stop the laser during treatment. If treatment is interrupted, the laser will stop and display a status screen that will require the user to remove the device and restart the treatment process from the beginning.



If the capacitive sensor is OFF, then user may keep a certain distance between the laser aperture and the treatment tissue; if this is the case, it is important to understand that the laser spot size increased with distance. Care will need to be taken to ensure the spot size and power density is appropriate for the research of interest and that all safety protocols are followed .

b. Heater ON or OFF

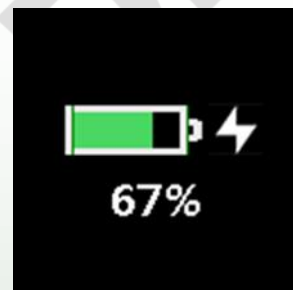
User can turn on / off the heater by changing the parameter in the database and syncing the device. The Warming screen will be skipped if heater function is OFF.



8.7 Lower battery and

charging

The device will show low battery indicator to remind user if charging is needed. Please use the laser power supply with USB-C cable provide with device or use docking station charger. Use of other chargers may damage device.



9. How to Use for Medical Applications

9.1 Turn on/ Turn off the device

- Press the Power Button to turn on the device
- Press and hold the Power Button for 2 seconds to turn off the device

9.2 Main screen



- Estimated treatment count remaining provides user with an estimate of how many treatment cycles are left based on current battery.
- Bluetooth indicator shows when Bluetooth is enabled on device
- Program shows which program is currently active. The program options are 1, 2, 3, 4, 5 and M for Manual. User can adjust the program by clicking the Power Button repeatedly to cycle through the program options.

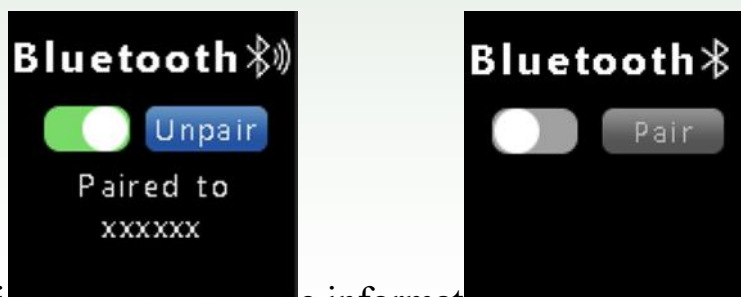
9.3 Menu screen



Press Menu Button to go to menu screen. Press again to exit.

- Volume icon is for sound volume setting. Touching volume icon on the screen activates the sound page, the plus and minus buttons are used to adjust the volume.

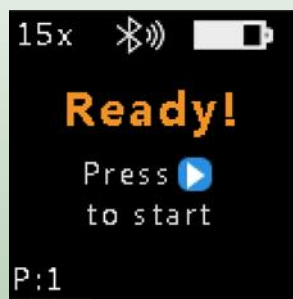
- b. User can check Statistics information by touching Statistics icon
- c. Bluetooth icon is used to pair or unpair a phone or tablet to device on Bluetooth.
 - To pair: turn on Bluetooth function by clicking left slide icon, then press the blue pair button. This will put the device into pairing mode. Open the Veralase app in your mobile phone. The app will requests a pair code. Input the pair code 654321, then device pairs to app. Pairing will happen automatically in the future.



- d. Account icon identifies the device information.

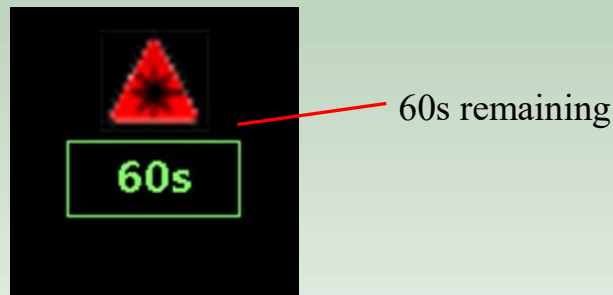
9.4 Start to Treatment

To start the treatment, user needs to mount the laser device properly then put the laser into ready mode. Press the Start/Stop Button to set the laser into to ready mode. The device aperture must be fully in contact with the skin for the system to work. Place the device in full contact with the tissue for treatment, then press Start/Stop Button again to start the laser program treatment. Note the device may first adjust temperature of the laser then automatically run the laser program.



Cycle the program
by pressing Power
Button

Under laser treatment screen, the countdown time indicator and treatment sound are used to tell the user how many seconds remained to finish the treatment.



User can only use the device with full laser aperture contact against the tissue. Failure to touch laser aperture to tissue surface before treatment or during treatment will cause the laser to stop immediately. The Start/Stop Button can be used to manually stop the laser during treatment. If treatment is interrupted, the laser will stop and display a status screen then require the user to remove the device and restart the treatment process from the beginning.



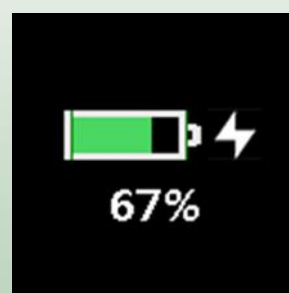
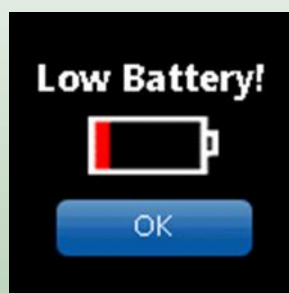
9.5 Lower

The device

battery

and charging

will show lower battery indicator to reminder user if charging is needed. Please use the laser power supply with USB-C cable provide with device or use docking station charger. Use of other chargers may damage device.



9.6 Human application as vaccine adjuvant (confidential)

- a. Turn on the device and verify battery level is adequate and the estimated remaining treatment count on the top left of the screen is displayed



- b. Mount and secure the laser onto the vaccine mounting frame (sold separately). Hook the bottom into the frame first, then snap in the top portion as shown below.



- c. Peel off the double side back of laser mounting frame, and stick the frame with laser device on the arm or suitable area of the body. Start the laser treatment cycle by pressing the Start Button.

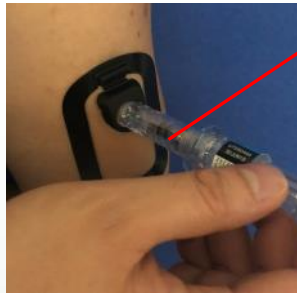


- d. When the treatment is successfully completed as shown on the LCD display, release the device by lifting the top of the vaccine guide frame, and removing the device from the frame. The guide ring on the vaccine frame will flip back onto skin to show where the vaccine shot should be administered.



Vaccine frame guide ring

- b. Use the recommended safety syringe to inject the vaccine as shown below. Remove the frame after vaccine is administered. Dispose of the frame and syringe in the appropriate disposal containers.



Safety syringe

10.Warning Indications



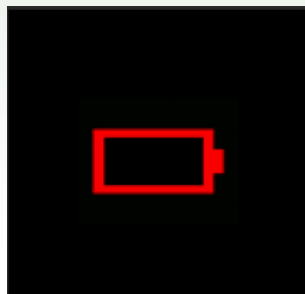
Description:
Low battery

User Action:
Charge the device



Description:
No Pulse

User Action:
Contact Veralase to order
replenishment



Description:
Battery critically low

User Action:
Charge the device



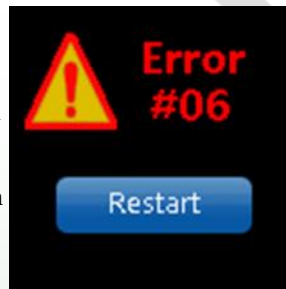
Description:
Device expires

User Action:
Contact Veralase to order
replenishment



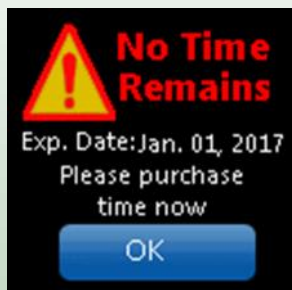
Description:
Laser is too hot

User Action:
Wait for laser to cool down
(Medical)
Wait for cooling down or
adjust the temp tolerance in
database (R&D)



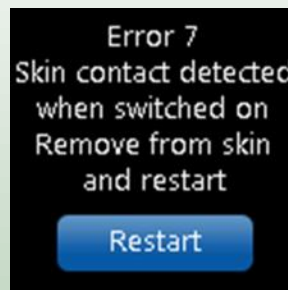
Description:
Laser junction temperature is
way out of range .
Refer to full error table on next
page

User Action:
Press the restart .
Contact Veralase if problem
continues



Description:
No time remaining

User Action:
Contact Veralase to order
replenishment



Description:
Capacitive sensor detects
object before device ON

User Action:
Remove the device from
object and press the
Restart .Contact Veralase if
problem continues

Error Table

| Error # | Error Condition | User Action | Screen message |
|---------|--|---|--|
| 1 | Battery below low_battery_voltage_mv | Charge the laser device | Error: Low Battery |
| 2 | Laser junction temperature is out of range | Wait for temperature reset. Call Veralase if problem continues | Error: Hot Error: Cold |
| 3 | No pulses/time remaining | Call Veralase to replenish the usage | Error: No pulses Error: No time |
| 4 | internal data corruption, laser table | Call Veralase | Error # 4 |
| 5 | internal data corruption, sound table | Call veralase | Error # 5 |
| 6 | Laser junction temperature is way out of range (no calibration or malfunction) | Restart. Call Veralase if problem continues | Error # 6 |
| 7 | capacitive sensors failed/way out of range/show contact on powering on | Remove the device from skin, then restart. | Error # 7 |
| 8 | battery below battery_stop_mv | Charge the laser device | Error: Critical Battery Icon |
| 9 | shorted power transistor/laser driver (discuss with Peter) | Call Veralase | Error # 9 |
| 10 | program data download not correct | Call Veralase | Error # 10 |
| 11 | Any button stuck | Restart. Call Veralase if problem continues | Error # 11 |
| 12 | internal data corruption, setup | Call Veralase | Error # 12 |
| 14 | Timer malfunction) | Call Veralase | Error # 14 |

11.Maintenance



Inspection and cleaning of the laser window is recommended after each use. Wipe down device with anti-bacterial swab such as an alcohol swab and be sure device is fully clean and dry before next use. Never open the laser housing.



If laser or the window appears damaged, do not use the device and contact your laser service provider for repair or replacement

veralase

www.veralase.com