GEMINI NOVA™

810 + 980 DIODE LASER

USER MANUAL

ULTRADENT PRODUCTS, INC.

powered by aws


Rx Only
FEDERAL LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A DENTIST
OR PHYSICIAN OR OTHER LICENSED MEDICAL
PRACTITIONER
APERTURE
DANGER: CLASS 4 LASER RADIATION WHEN WAND OPEN AND INTERLOCKS DEFEATED
VISIBLE AND INVISIBLE LASER RADIATION. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION.
DANGER
MAX POWER LASER RADIATION
INVISIBLE OUTPUT: 2.0 W AVERAGE / UP TO 10 W PEAK @ 810 nm OR 980 nm
INVISIBLE OUTPUT: 2.0 W AVERAGE / UP TO 20 W PEAK @ 810 nm + 980 nm
VISIBLE OUTPUT: 1 mW @ 650 nm (cw)
DC Power 15 V / 3.6 A

WARNINGS & CAUTIONS

Failure to comply with precautions and warnings described in this User Manual may lead to exposure to dangerous optical radiation sources. Please comply with all safety instructions and warnings.

CAUTION: Read these instructions carefully prior to using your Gemini Nova 810 + 980 soft tissue diode laser system.

CAUTION: Ensure all users are properly trained prior to use. Consult your distributor for training recommendations. Mandatory training on the Gemini Nova 810 + 980 soft tissue diode laser system is done via this manual.

CAUTION: Do not modify this equipment without authorization of the manufacturer.

CAUTION: Laser fume and/or plume may contain viable tissue particles.

CAUTION: Do not use in the presence of combustible or combustion supporting gases.

CAUTION: Always test activate the device outside the mouth before using on a patient.

CAUTION: This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate the interference.

CAUTION: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in pages 52–56 of this manual.

CAUTION: Periodically inspect laser eyewear for pitting and cracking.

CAUTION: In the event abnormal performance is observed, discontinue use and contact our equipment support team at 801.553.4574 or equipment.repair@ultradent.com for technical support and live troubleshooting with a technician.

WARNING: Visible and Invisible Laser Radiation – Class IV Laser Product. Avoid eye or skin exposure to direct or scattered radiation.

WARNING: Laser safety eye protection MUST BE WORN by the operator, patient, assistant, and anyone present when the laser is activated. Eye protection must conform to Specification DIN EN207 Annex II of the Directive 89/686/EEC with wavelength protection of 810 nm–980 nm, and ±20 nm of OD+5.

WARNING: Never direct or point the beam at a person's eyes.

WARNING: Do not look directly into the beam or at specular reflections.

WARNING: Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. If aimed directly at these surfaces, the laser beam will reflect and create a potential hazard.

WARNING: Never operate a laser without a fiber or PBM tip attached.

WARNING: Laser aperture at the end of the Wand.

WARNING: Laser aperture warning label affixed to the system Wand.

WARNINGS & CAUTIONS

WARNING: Always place the device into standby mode when leaving the Gemini Nova system unattended for a few minutes or between patients.

WARNING: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

WARNING: Do not open unit housing at any time. Danger from optical radiation may exist.

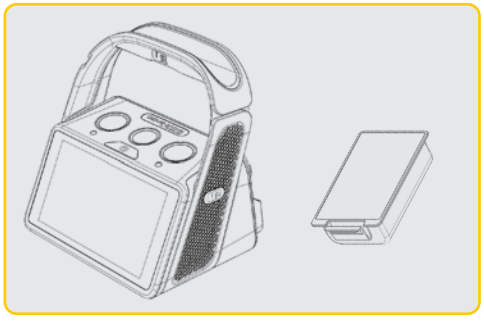
WARNING: The use of accessories, other than those specified, except those supplied or sold by Ultradent Products, Inc., as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the Gemini Nova system. Refer to pages 52–56 for additional information.

MAGNETIC ATTRACTION HAZARD: This product contains permanent magnets, including those in the **Wand Battery Pack.** Magnetic fields can attract ferrous (iron-containing) metal objects – such as screws, tools, keys, bolts, and clips – from a distance, causing them to snap forcefully toward the product without warning. Fingers, hands, or other body parts caught between an attracted metal object and this product may suffer serious pinching or potential injuries. When the Wand Battery Pack is disconnected from the Wand, take extra care as it may independently attract nearby small metal parts. Always store the Wand Battery Pack in the Base and keep it away from metal objects and components when not in use.

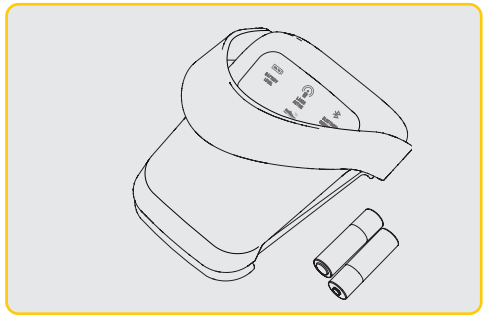
Safety is paramount when using any energy-based surgical instrument and your office should implement a safety program for the Gemini Nova 810 + 980 soft tissue diode laser system (Gemini Nova system). If your office does not already have a safety officer, one should be appointed to be responsible for understanding proper use, safe operation, and maintenance of the Gemini Nova system. Their duties should include training office personnel in all aspects of system safety and management of the Gemini Nova laser and all accessories.

WHAT IS IN THE BOX

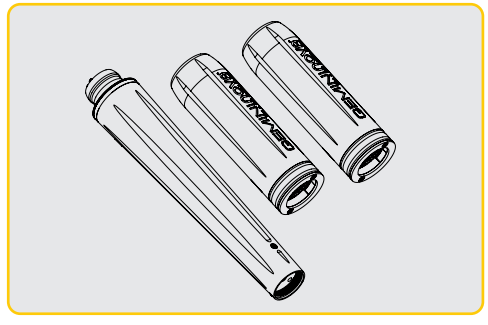
The Gemini Nova system includes the following:



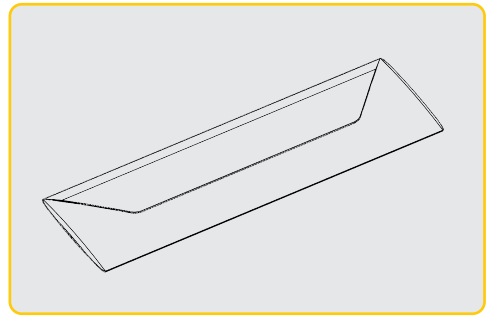
Base and Base Battery Pack



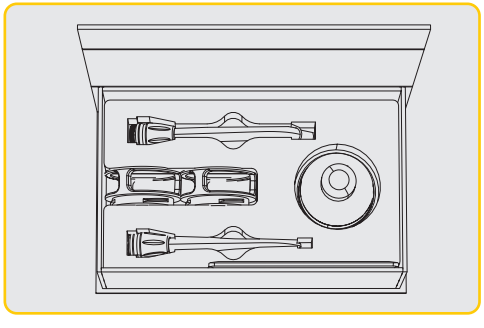
Foot Pedal with AA Batteries (2)



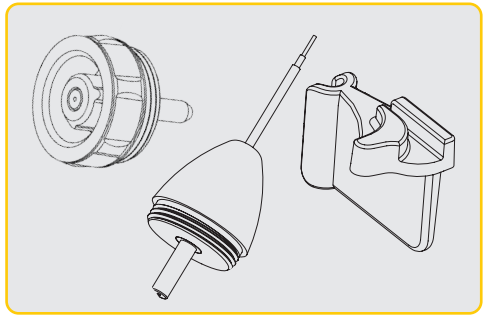
Wand and Wand Batteries (2)



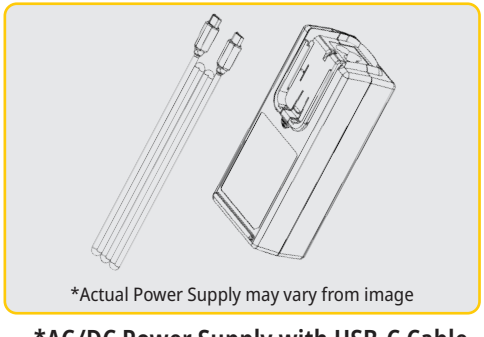
Barrier Sleeve Starter Pack



3 mm, 7 mm, and 25 mm PBM Adapters, 25 mm PBM Spacers (2)

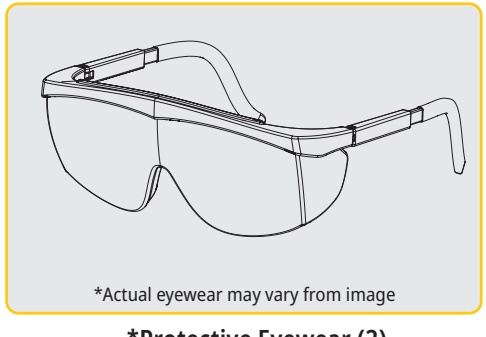


PBM Light Adapters (5), Pre-Initiated Disposable Tips (10), Bending Tool (1)



*Actual Power Supply may vary from image

***AC/DC Power Supply with USB-C Cable**



*Actual eyewear may vary from image

***Protective Eyewear (2)**

NOTE: The laser ships with the Lithium-ion battery already installed.

NOTE: Use proper care when transporting the unit.

ALSO INCLUDED: Laser Warning Sign, Laser Training Card Information, and Quick Start Guide.
Please note that warranty information is included in the back of the User Manual.

WARNING: No modification of this equipment is allowed.

UNPACKING INSTRUCTIONS

A manufacturer or dealer representative can provide assistance when you are ready to remove the laser from its shipping container. Please do not attempt to unpack the Gemini Nova laser or install the system without reading this manual first. If you are unsure about any aspect of the assembly, call your customer service representative or dealer for assistance.

SHIPPING CONTAINER INFORMATION

The shipping container you received with your Gemini Nova system was specifically designed to safely transport the device.
In the unlikely event that you need to return the laser for service or repair, please retain the original shipping container.

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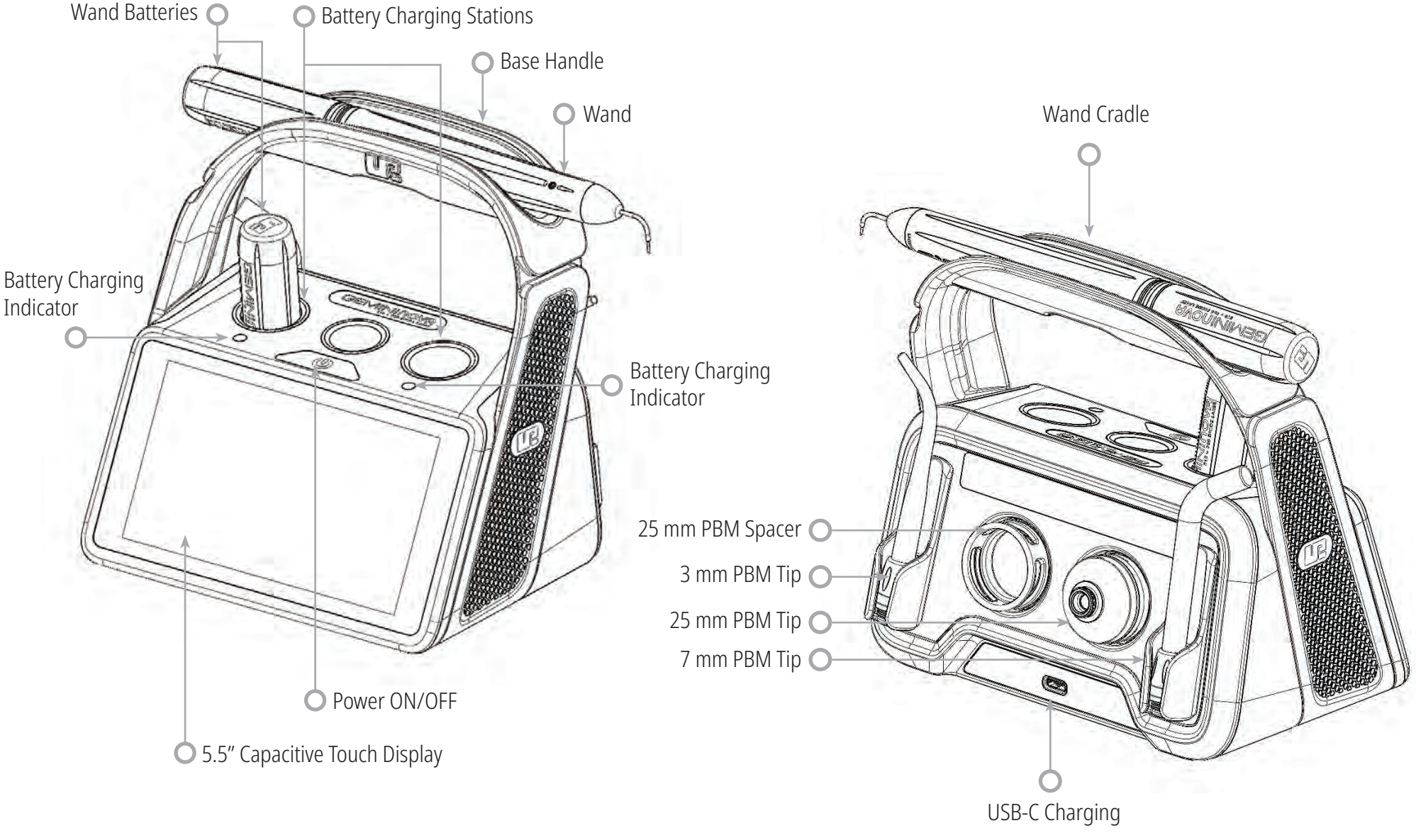
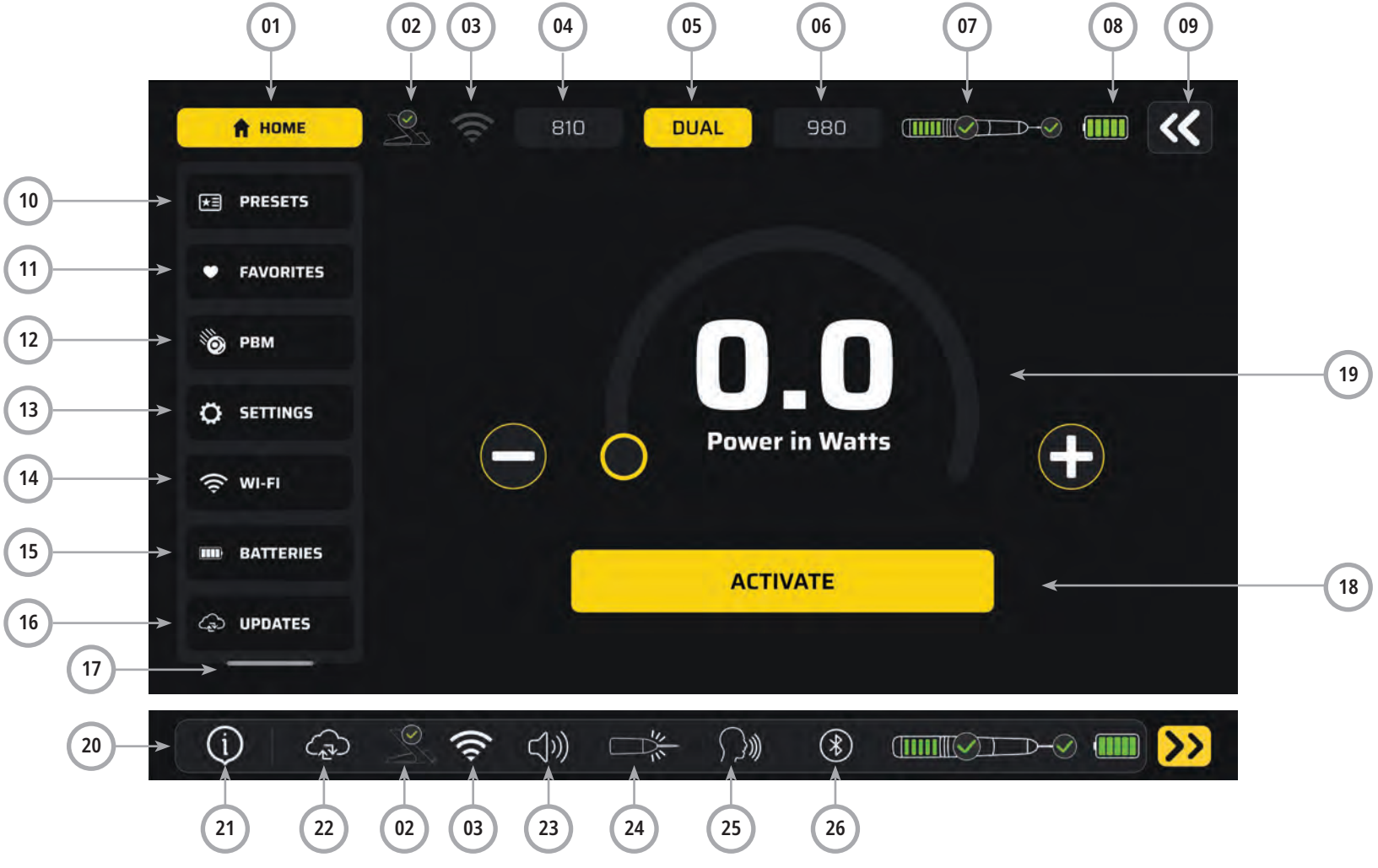


OVERVIEW - DISPLAY



01 - HOME MENU
02 - FOOT PEDAL STATUS
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06 - 980 WAVELENGTH
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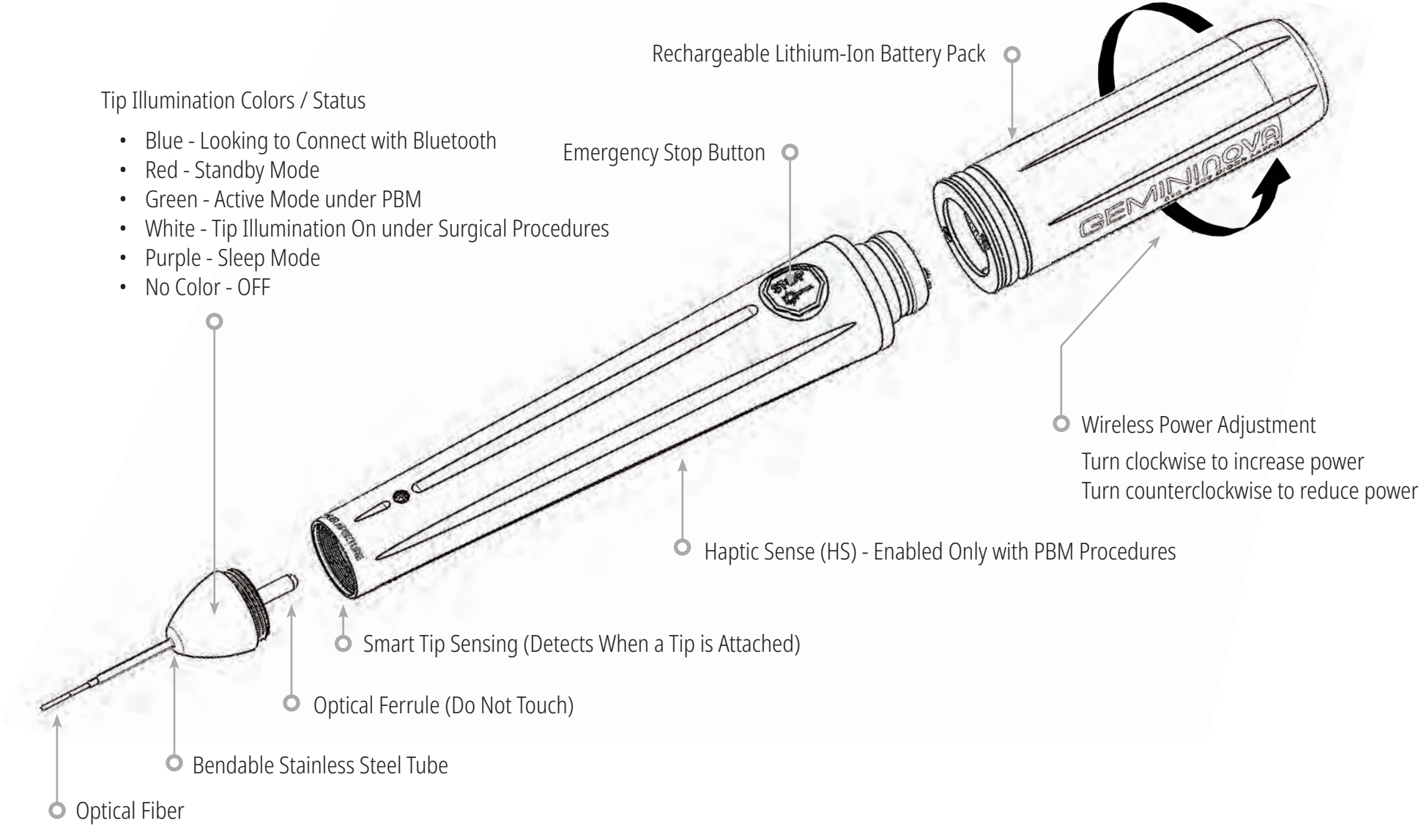
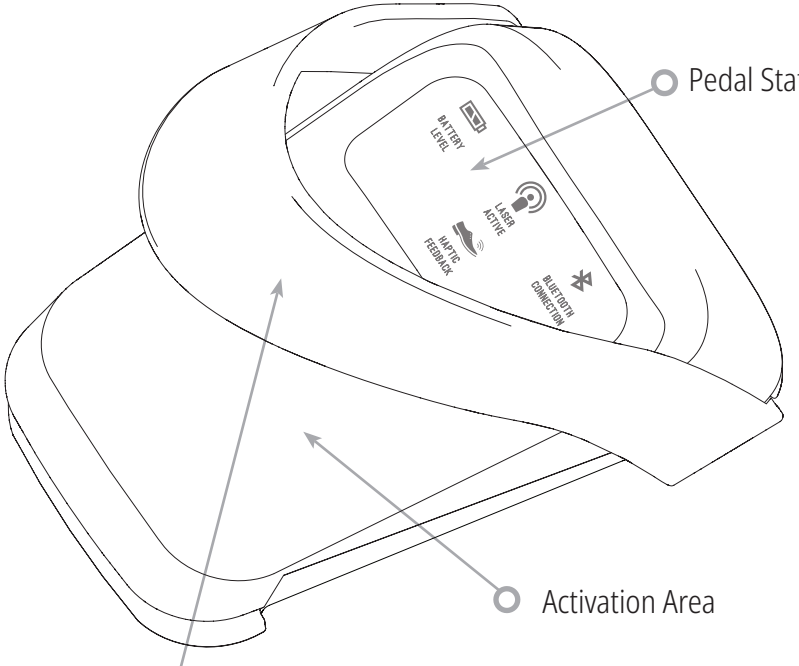
OVERVIEW - WAND

The Gemini Nova system offers a cordless Wand that is detached from the laser base for maximum portability. The Wand will require cleaning and sterilization after each patient treatment. Disposable Fiber Tips are intended for single-use only and must be disposed of after each patient use.

Refer to pages 38–42 for cleaning and sterilization procedures.



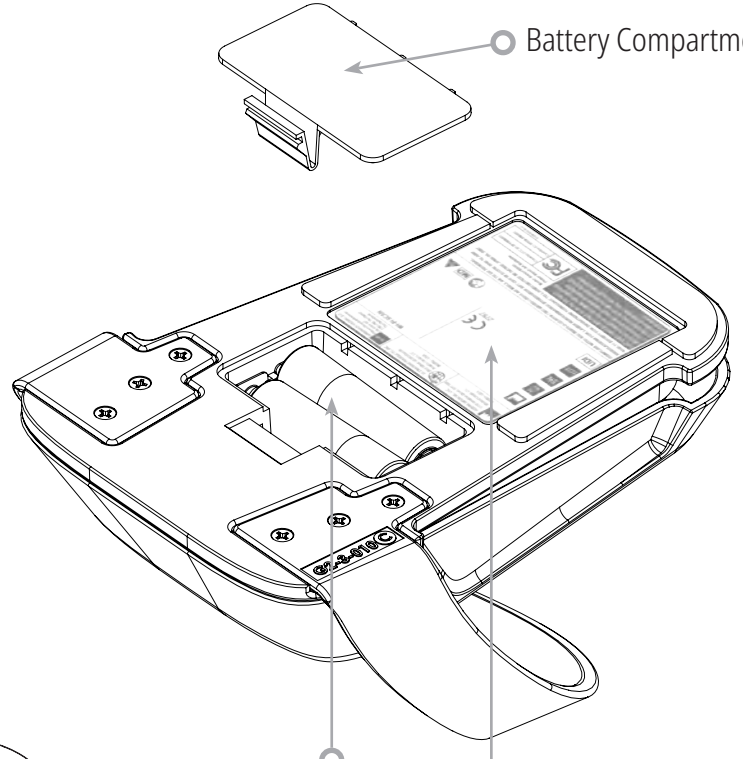
OVERVIEW - FOOT PEDAL



Pedal Status Indicators

Activation Area

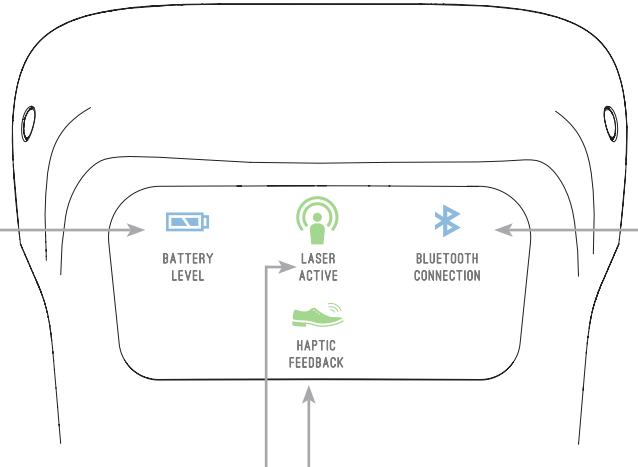
Overstep/Shroud Protection



Battery Compartment Lid

AA Batteries (x2)

Label/Anti-Skid Areas



Battery Indicator

- 50 to 100%
- 25 to 49%
- 0 to 24%

Foot Pedal will not connect if battery indication shows red

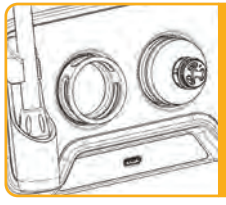
Bluetooth

Icon turns blue when connected

Haptic Sense (HS) indicator

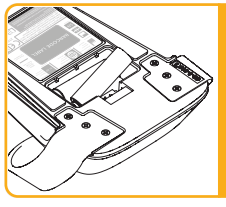
Laser Active turns green when pedal is pressed.

OVERVIEW - QUICK START



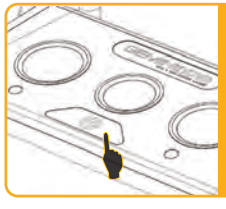
1. Plug In Power Supply

For initial setup, insert the Base Battery Pack and charge the battery for 2 hours using the AC/DC power supply. Plug the power supply into an AC outlet, then connect the USB-C cable to the power supply and the port on the back of the Gemini Nova Base.



2. Insert AA Batteries into Foot Pedal

Install the (2) provided AA batteries into the wireless Foot Pedal. When replacing the AA batteries, we recommend an ALKALINE type battery.



3. Turn Laser Unit and Foot Pedal ON

Press the ON/OFF button on the Base to turn on the device. Tap the Foot Pedal to turn it on.

4. Connect Device to Wi-Fi

Follow the on-screen instructions to download the Gemini Laser app and connect your device to Wi-Fi. (Detailed connection steps are available on page 35.)

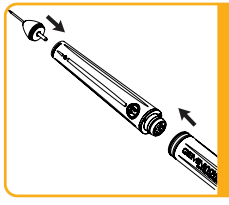
5. Enter Electronic Key Passcode

Enter the electronic key passcode on the display using the UP and DOWN arrow keys. The sequence is UP, DOWN, UP, DOWN. Checkmarks will appear as the code is entered correctly.

6. Select Your Desired Wavelength

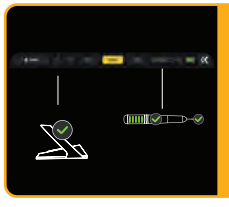
Select the desired laser wavelength on the display screen:

810 nm, Dual, or 980 nm Wavelength.



7. Attach Wand Battery and Tip

Attach a charged Wand Battery and the appropriate tip for the procedure you would like to perform.



8. Ensure Foot Pedal, Wand, and Base Are Connected

Verify that all connections in the top menu are active by confirming green check marks on the Foot Pedal, Wand Battery, and Tip icons. This indicates the system components are connected and ready for use.

9. Select Your Desired Power Setting

Select your desired power setting manually or by selecting a preset procedure within the menu.

10. Activate the Laser

Tap the ACTIVATE button.

11. Firing the Laser

To fire the laser, press the Foot Pedal. To stop firing the laser, release the Foot Pedal.

PRODUCT INFORMATION & USER MANUAL

On the home page, select the shortcut menu (1), then tap the information icon (2) on the left to access product information about your Gemini Nova laser.

Scan the QR code below or visit ultradent.com/resources/product-instructions and select “Gemini Nova Laser” to download the latest version of the User Manual.

ACCESS SHORTCUT MENU 1

2 INFORMATION ICON

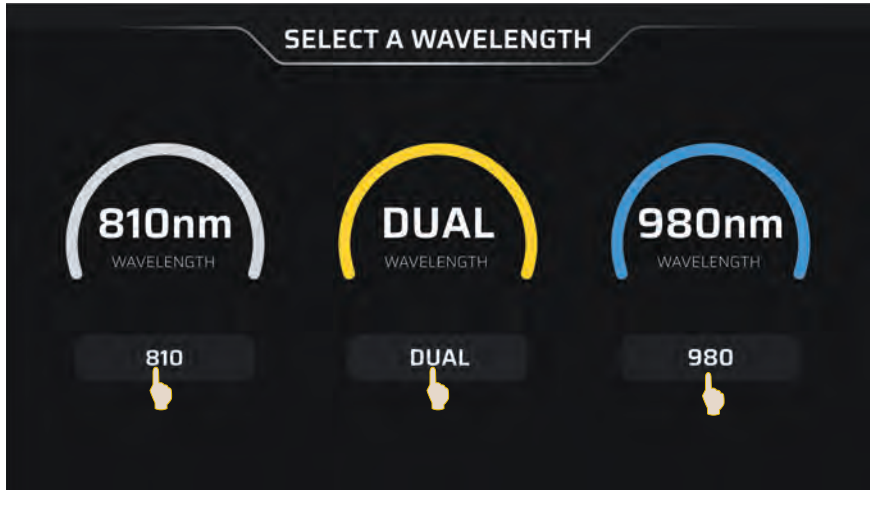
01 - ELECTRONIC KEY PASSCODE

The Gemini Nova system is equipped with an electronic key passcode. When you turn the laser unit on, the passcode screen will show in the middle of the display. Enter the correct passcode sequence using the UP and DOWN arrows:

UP, DOWN, UP, DOWN

02 - SELECTING A WAVELENGTH

When the system is powered on and the passcode entered, you'll be prompted to select one of three wavelength modes: 810 nm, 980 nm, or Dual. The selected wavelength button illuminates in its corresponding color-coded theme, with the user interface updating to match the chosen wavelength: gray for 810 nm, yellow for dual wavelength, and blue for 980 nm. A wavelength mode must be selected to proceed but can be changed anytime.



By selecting the desired wavelength, voice confirmation (if enabled) will sound as follows:

- "810 STANDBY"
- "980 STANDBY"
- "DUAL WAVELENGTH STANDBY"

03 - MANUAL POWER ADJUSTMENT

The Gemini Nova system delivers up to 2.0 Watts of average power. Adjust power by rotating the Wand Battery, sliding or tapping the SCROLL BAR arch, or pressing the PLUS/MINUS buttons on the display. Each adjustment changes the power by 0.1 Watts, with faster adjustments by holding the controls. Activate the laser by tapping the ACTIVATE button, and then press the Foot Pedal to initiate.

CLINICAL TIP

Optimal results are achieved by regulating the power and the speed that the operator moves the Fiber Optic Tip. Tissue charring is an undesirable aftereffect of too much power or of the Fiber Tip moving too slowly. Always use the least amount of power that is required to complete the procedure. The ideal tissue response will show little or no discoloration after treatment and will result in less collateral damage and faster healing.

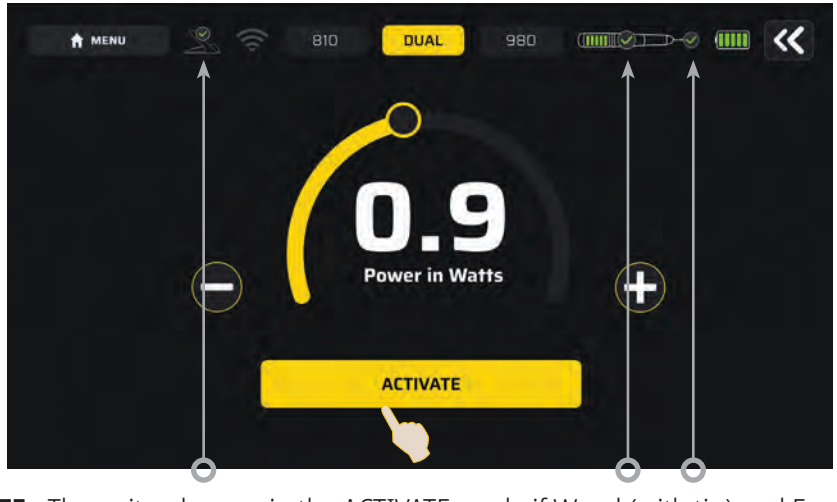
Avoid penetrating or damaging the periosteum, and do not attempt to use the laser on alveolar bone.

Because the laser energy is attracted to melanin and hemoglobin, power must be reduced when treating patients with darker pigmented soft tissue.

04 - LASER STANDBY AND ACTIVATE MODES

The ACTIVATE/STANDBY selection serves a dual purpose. The button activates (ACTIVATE) or deactivates (STANDBY) the laser. The system powers up in STANDBY mode and requires wavelength selection before activation. The system will provide audio confirmation of wavelength selected (unless muted). Each time the ACTIVATE/STANDBY button is touched, the system toggles between ACTIVATE and STANDBY modes with audio confirmation of power selection. A Wand Battery Pack and tip must be attached to the Wand to enable activation. The red aiming beam and tip illumination appear only in ACTIVATE mode.

Touching any control other than the SCROLL BAR or PLUS/MINUS buttons returns the system to STANDBY. In ACTIVATE mode, pressing the Foot Pedal fires the laser with an audible beep. A 0.25-second delay prevents accidental activation.



NOTE: The unit only goes in the ACTIVATE mode if Wand (with tip) and Foot Pedal are connected to the Base.

"810 STANDBY"
"980 STANDBY"
"DUAL WAVELENGTH STANDBY"

"0.9 WATTS ACTIVE"
"0.9 WATTS STANDBY"

05 - PRESET AND CUSTOM PROCEDURE SETTINGS

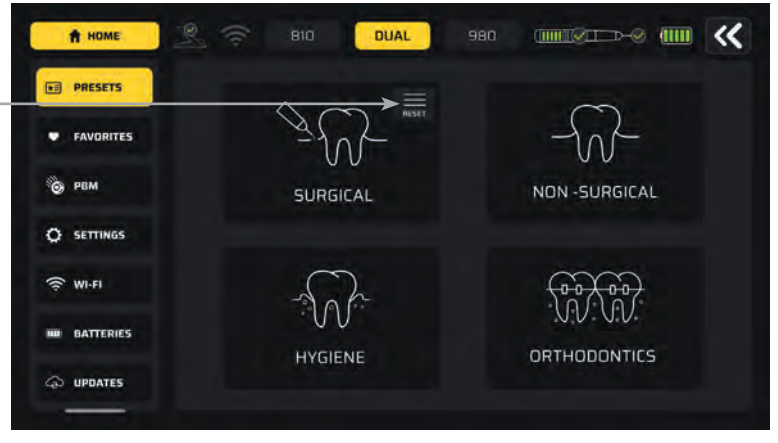
The Gemini Nova system is preprogrammed with procedure presets in various categories. Within each category are the most commonly used procedures with suggested power settings. Always use the minimum amount of power necessary to perform a particular procedure. Manual power adjustment may be necessary depending on patient and procedural needs. Tap PRESETS to view all procedure categories on the display. Select the appropriate category for your procedure.

Use the scroll bar on the left to browse the available presets. Press, hold, and drag the three horizontal gray lines on the right of the screen to adjust the order of presets based on frequency of use.

The left and right navigation arrows enable users to toggle between various menus, including preset categories and settings. The presence of multiple menus is indicated by a pagination icon.

NOTE: Preset procedure settings are only a general recommendation from the manufacturer. They are not meant to replace the need for proper training or clinical judgment of the operator.

To revert back to the original preset procedure order, tap the RESET button within the appropriate category on the preset home page.



When a procedure is selected, its corresponding power setting will appear on the power indicator. To exit, tap the back button to return to the preset procedure page. Alternatively, tap PRESETS to return to the procedure categories or use the menu to navigate to other sections.

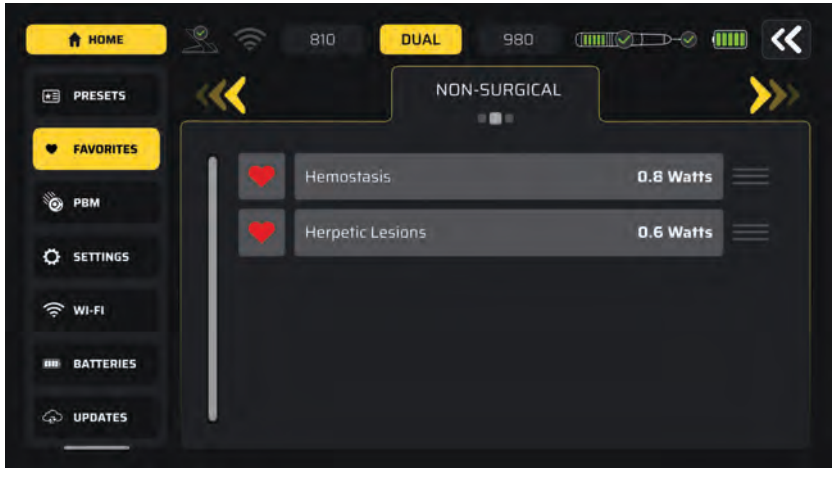
The Gemini Nova system allows customization of preset procedure power settings.

To change and save a custom preset power, tap the edit icon next to the procedure you want to modify. Use the SCROLL bar or PLUS/MINUS icons to adjust the power, and then tap SAVE. If you would like to restore power to factory settings, tap RESET, and power will revert back to factory settings.

Updated power settings will appear in the preset procedures list with a three-line icon below the power value. This icon indicates that the procedure has been customized by the user.

06 - FAVORITE PROCEDURES

Add frequently used presets to the FAVORITES menu by tapping the heart icon. A red heart indicates a saved favorite. Favorites appear in both the preset list and the FAVORITES menu and can be added or removed at any time. If no favorites are selected in a category, a message reading "No Favorites Selected For This Category Yet" will display. Favorites are wavelength-specific and only appear under the wavelength in which they were saved (i.e., 810 nm, Dual, 980 nm).

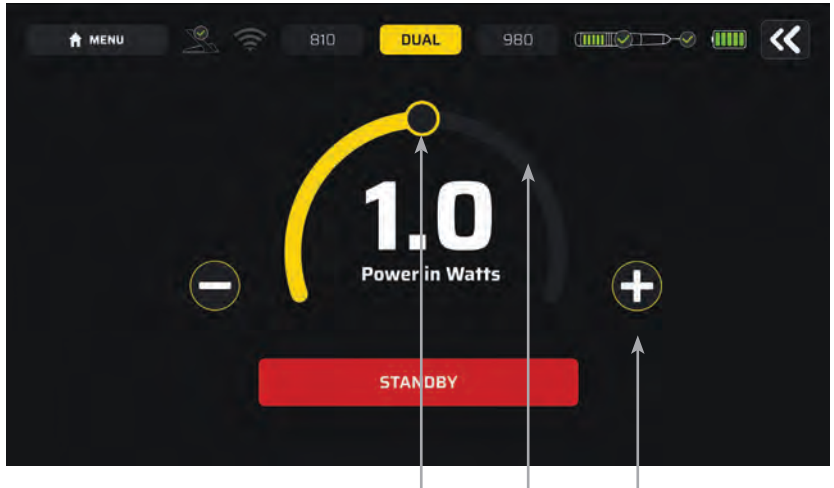


07 - MANUAL PROCEDURES

To perform manual procedures, start on the home page and select a wavelength. The Power in Watts screen appears. Adjust power up to 2.0 W by rotating the Wand Battery, sliding or tapping along the SCROLL BAR, or tapping the PLUS/MINUS buttons. Each adjustment changes the power by 0.1 Watts, with faster adjustments by holding the controls.

Attach a Battery Pack and tip to the Wand. Tap ACTIVATE to enable the laser, and then press the Foot Pedal to fire. The red aiming beam and tip illumination appear only in ACTIVATE mode.

When in ACTIVATE mode, touching any control other than the SCROLL BAR or PLUS/MINUS buttons returns the system to STANDBY. A beep sounds when the laser fires, and a 0.25-second delay prevents accidental activation. Release the Foot Pedal to stop firing the laser. Tap STANDBY to deactivate the laser.

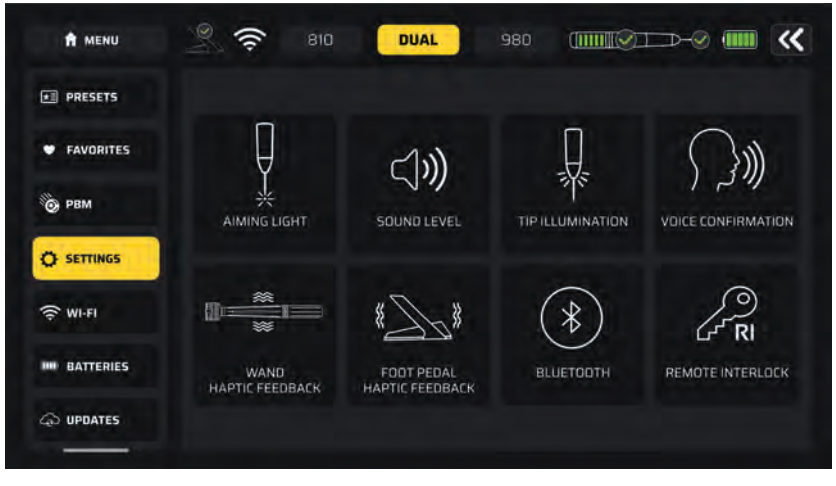


SETTINGS AND CUSTOMIZATION

The settings menu offers options for customizing your device setup.

Select SETTINGS from the home menu tab to display the main configuration menu. Navigate between individual settings screens using the left and right arrows located at the top of each menu. Alternatively, select SETTINGS from the main menu to view all options by their respective icons.

NOTE: Adjustments are saved automatically, and the system will restore the last-used configuration upon startup. To exit, tap HOME or use the navigation menu to access other sections.



08 - AIMING LIGHT

To change the aiming light intensity, select “Aiming Light” in the settings menu. Use the slide bar to change the levels between LOW, MEDIUM, HIGH, and OFF.

NOTE: A brief preview of each setting displays when the Wand Battery is connected and the Wand is powered on. The Wand does not need to be on to adjust settings.

09 - SOUND LEVEL

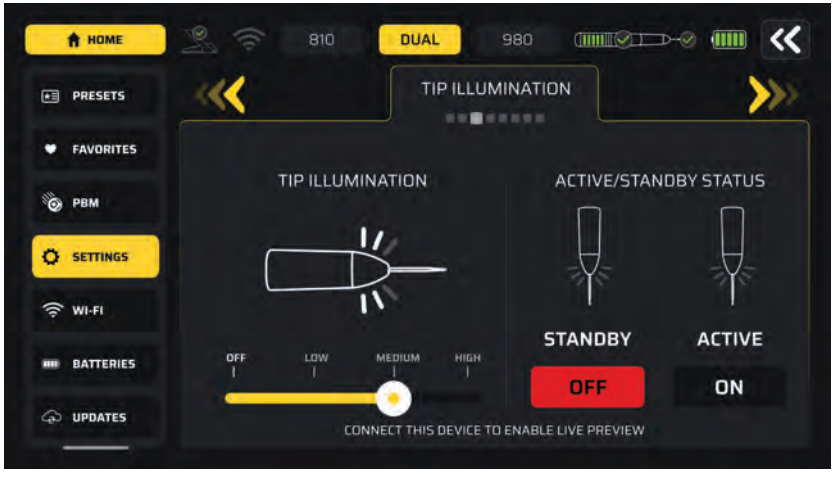
To change the volume, select “Sound Level” in the settings menu. Use the slide bar to change the levels between LOW, MEDIUM, HIGH, and OFF for the Wand and the Base.

NOTE: A brief preview of each volume level is audible on the Base during adjustment and on the Wand when the Wand Battery is connected and the Wand is powered on. The Wand does not need to be on to adjust settings, only to hear the preview.

10 - TIP ILLUMINATION

In the SETTINGS menu, select "Tip Illumination" and use the slide bar to adjust the intensity to LOW, MEDIUM, HIGH, or OFF. By default, Active/Standby Status is enabled.

The ACTIVE/STANDBY LED Status is a convenience feature that enables users to quickly identify the state of the Wand. When enabled, this feature provides a visual indication of the following Wand statuses:

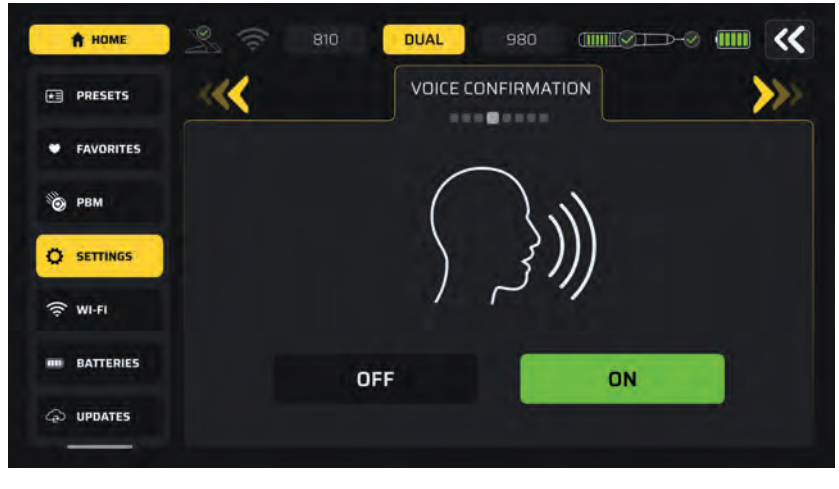


- Blue: The Wand is searching for a Bluetooth connection. This state is typically brief, as the Wand pairs with the system rapidly.
- Red: The Wand is in Standby Mode and connected to the Base.
- Green: The LED illuminates briefly when activating Surgical Mode and remains solid green throughout PBM procedures.
- Purple: This color indicates that the Wand is in Sleep Mode.
- No Color: If the Wand LED is unlit, the ACTIVE/STANDBY status feature is either disabled or the device has powered OFF automatically to conserve battery.

NOTE: A brief preview of the Wand aiming light intensity is displayed when the Wand Battery is connected and the Wand is powered on. The Wand does not need to be powered on to adjust settings, only to view the preview.

11 - VOICE CONFIRMATION

To enable or disable voice confirmation, select "Voice Confirmation" in the SETTINGS menu and toggle on or off using the ON/OFF buttons.



12 - HAPTIC FEEDBACK

The Gemini Nova system provides haptic (tactile) feedback through the Foot Pedal and Wand. When enabled, vibration is delivered during laser operation to provide confirmation of activation.

- Foot Pedal: Haptic feedback is available for all procedures when the Haptic Feedback Pedal setting is enabled.
- Wand: Haptic feedback is available during PBM procedures when the Haptic Feedback Wand setting is enabled. During surgical and non-surgical procedures, haptic feedback is not provided during laser activation; however, haptic feedback remains available while adjusting power by twisting the Wand Battery.

To adjust the intensity (LOW, MEDIUM, HIGH, or OFF), select Haptic Feedback Pedal or Haptic Feedback Wand, and then use the slider to set the desired level.

Note: A preview of the selected haptic intensity is provided as settings are adjusted. Preview is available on the Foot Pedal when connected, and on the Wand when the Wand Battery is connected and the Wand is powered on.

13 - BLUETOOTH CONNECTION - WAND, BASE, AND FOOT PEDAL

The Gemini Nova laser automatically connects to the Wand and the Foot Pedal via Bluetooth.

In the SETTINGS menu, select “Bluetooth” to check the connection status and signal strength of the Wand and Foot Pedal to the Base Unit.

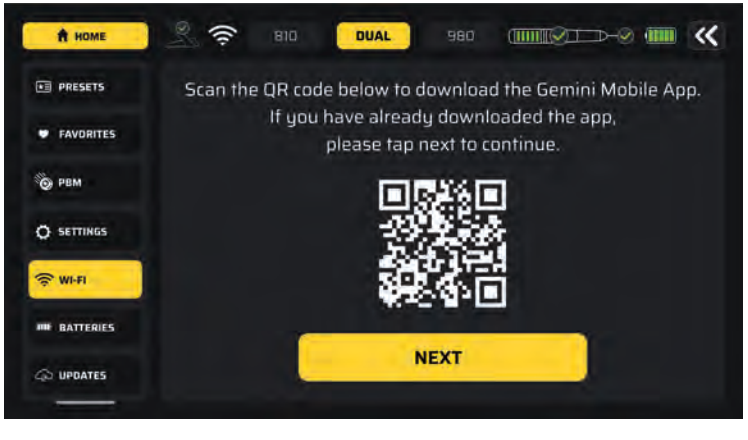
If the Wand or Foot Pedal is misplaced while powered ON, open the Bluetooth menu and select the ‘Play’ icon associated with the missing item. The missing device will emit a sound, vibrate, and flash its LED lights to assist in recovery. To stop the alert, rotate the Wand Battery or tap the Foot Pedal. Additionally, selecting the Play icon on the Base will also stop the sound.

14 - REMOTE INTERLOCK (Switch Not Included)

The Gemini Nova system includes a wireless remote interlock feature for creating a dedicated laser treatment room. This feature uses Bluetooth technology to communicate with the laser device and consists of two components: a sensing unit with a Bluetooth chip and a hall-effect sensor mounted on the wall, and a magnetic field unit (housed magnet) attached to the door. When the door opens, the sensing unit detects the change in the magnetic field and wirelessly signals the Gemini Nova device to deactivate laser emissions. Note that the user will not be able to activate and use the laser if the door is open to the treatment room. This feature is only available by purchasing the Remote Interlock Kit which is not included with your Gemini Nova system. For further assistance, please contact the manufacturer.

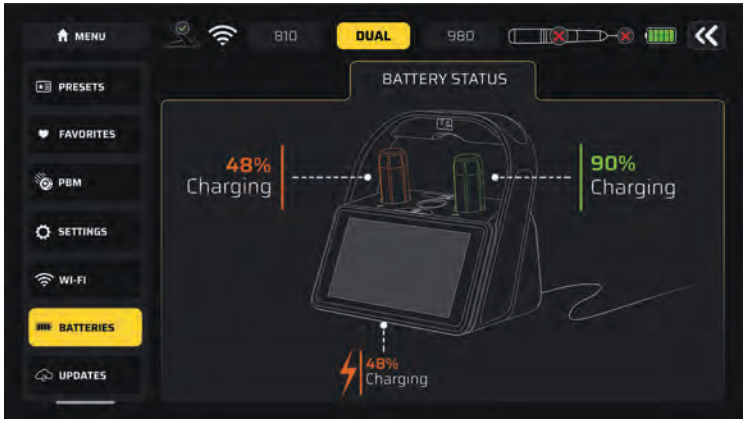
15 - WI-FI SET UP

Select the Wi-Fi tab in the menu and follow the on-screen instructions to download the mobile app and connect your device to Wi-Fi. (Detailed connection steps are available on page 35.)



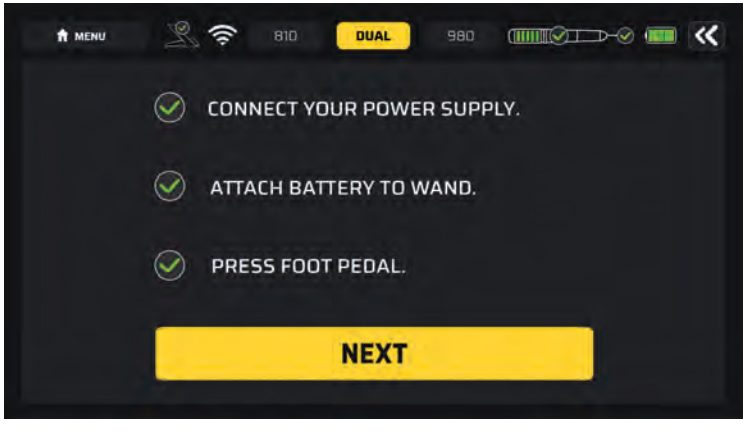
16 - BATTERY STATUS

Tap the BATTERIES tab in the menu to check the charge levels of the Base Battery Pack and both Wand Battery Packs, as well as the connection status of the Wand Batteries. Battery level icons for the Base Battery Pack and connected Wand Battery Pack are also displayed in the top-right corner of the screen. When a Wand Battery is inserted or external power is connected, the battery status screen appears for 5 seconds before returning to the previous display.
Note: See pages 31–33 for additional battery information.

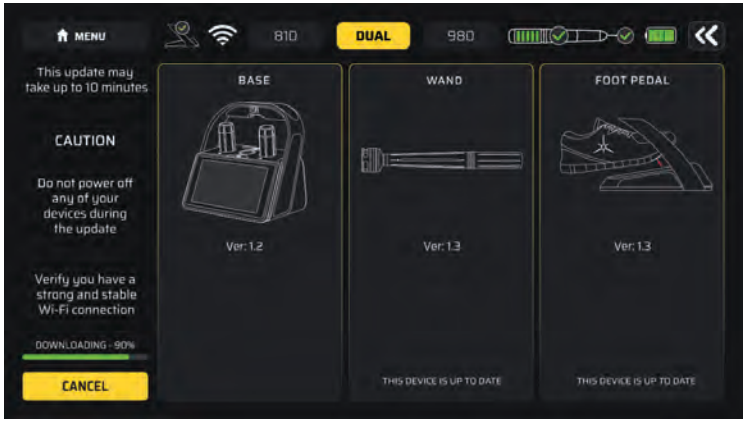


17 - SOFTWARE UPDATE

Software updates will be available periodically and can be accessed from the UPDATES menu tab. Updates may apply to any or all three devices: the Base, Wand, or Foot Pedal.

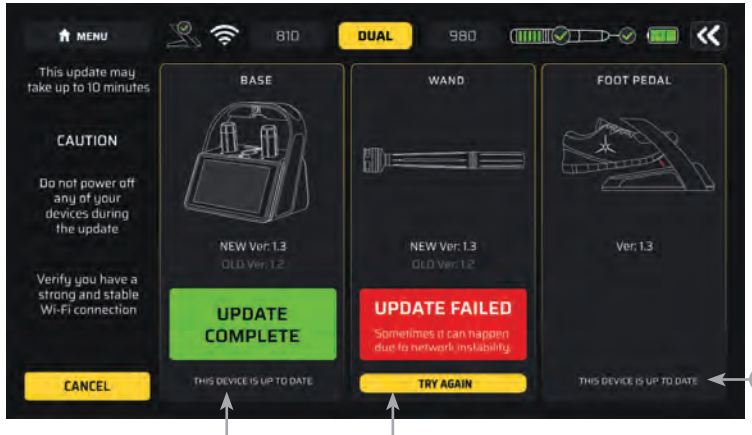


When an update is available, you will be prompted to connect the Base to a power supply and ensure the Wand and Foot Pedal are powered on. A green checkmark confirms each connected device; a red X indicates it is not yet connected. Once all devices are confirmed, tap NEXT to proceed.



The update will begin automatically and cycle through all devices requiring an update. Do not turn off any devices during this process. The update may take up to 10 minutes.

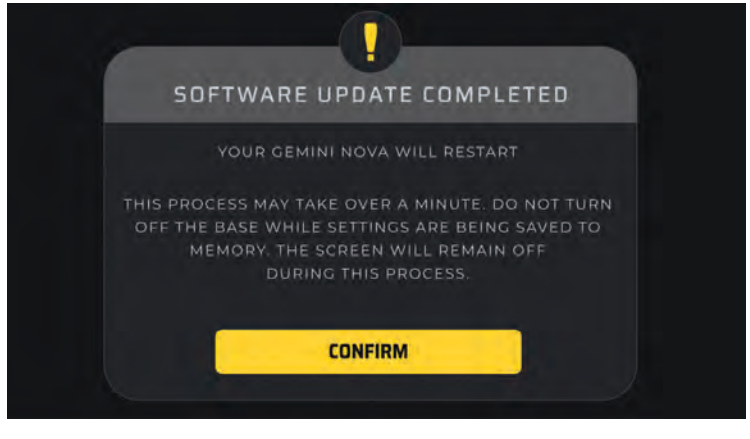
After the update, tap CONFIRM to restart the Gemini Nova system. The screen may stay off for over one minute. Do not turn off the Base while it restarts and saves settings.



"This Device Is Up to Date" indicates that the device has the latest software and no updates are required.

"Update Complete" confirms that the update was successfully installed.

"Update Failed" indicates that the update was not successful. Select TRY AGAIN, as the update will likely install on the next attempt. This may occur if the internet connection is unstable.



Once restarted, power cycle the Foot Pedal and Wand by removing and reinstalling their batteries (two AA batteries and the Wand Battery, respectively).

18 - PHOTOBIOMODULATION (PBM) WARNINGS AND CAUTIONS

CAUTION: Do not connect or disconnect a PBM Adapter while the Gemini Nova system is turned on. Only connect or disconnect a PBM Adapter when the Gemini Nova system is inactive or in standby mode.

CAUTION: Do not use any harsh chemicals or abrasives to clean the glass optics within a PBM Adapter. Doing so may damage the glass.

CAUTION: Do not autoclave the 25 mm PBM Adapters, 25 mm PBM Spacers, or PBM Light Adapters. Doing so will damage the components.

CAUTION: The 25 mm PBM Spacers and Light Adapters are single-use only to avoid possible cross contamination. They must be disposed of after use in a biohazard medical waste SHARPS container.

CAUTION: Wavelength-appropriate eye protection must be worn at all times while using, and in proximity of, a PBM Adapter while it is in use.

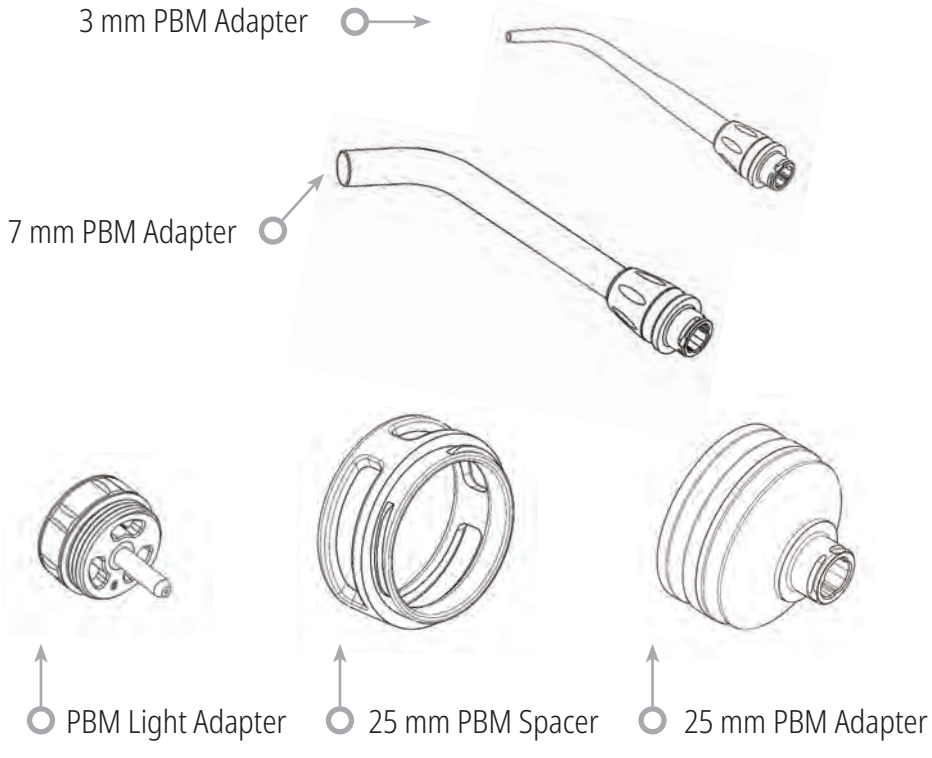
WARNING: The PBM Adapters must only be used with a Gemini Nova system. Do not attempt to use a PBM Adapter with any other laser system or light source.

WARNING: Never look directly into a PBM Adapter while the laser is active, even with safety eyewear on.

WARNING: Do not use the 3 mm, 7 mm, or 25 mm PBM Adapters without the PBM Light Adapter attached.

WARNING: Do not use the 25 mm PBM Adapter without a 25 mm PBM Spacer attached.

PBM COMPONENTS



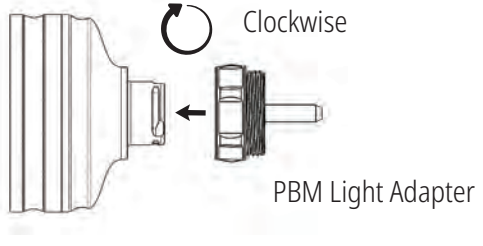
3 mm and 7 mm PBM Adapters can be used intraorally

PBM ADAPTER ASSEMBLY

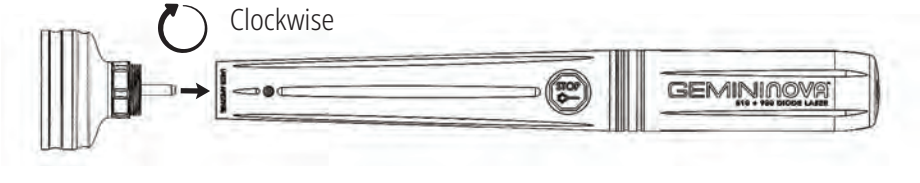
Note: The 25 mm PBM Adapter is shown for assembly steps 1–3. The PBM Light Adapter attachment and the threading procedure for securing the PBM Adapters to the Wand are the same for all PBM Adapter sizes.

Prior to use, all protective coverings must be removed from the PBM Adapter and Light Adapter. In addition, PBM Adapters must be cleaned, disinfected, and/or sterilized before attaching to Light Adapter or Wand. See pages 38–42 for cleaning, disinfection, and sterilization instructions.

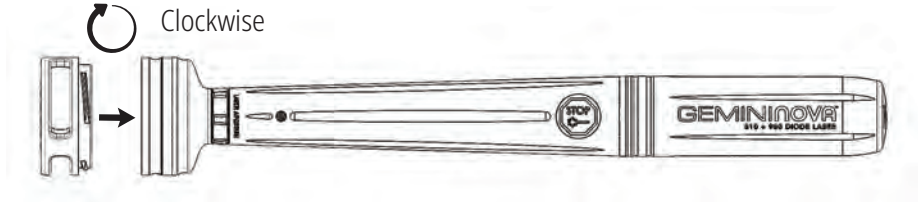
1. Insert the Light Adapter into the PBM Adapter and turn it a quarter turn clockwise to secure it in place.



2. Turn clockwise to securely screw the PBM Adapter with the attached Light Adapter onto the end of the Wand.



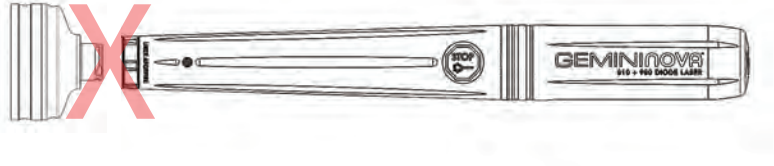
3. If using the 25 mm PBM Adapter, a 25 mm PBM Spacer must be attached to the end of the Adapter for proper light focusing to the targeted tissue. Turn clockwise to screw the spacer onto the end of the 25 mm PBM Adapter.



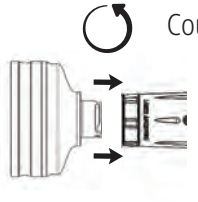
To remove from the Wand, unscrew the PBM Adapter counterclockwise. This will remove the Light Adapter and the PBM Adapter, together (see note below). Pull the Light Adapter apart from the PBM Adapter to separate them, and discard the Light Adapter and 25 mm PBM Spacer (if using the 25 mm PBM Tip).

Replace the protective coverings when the PBM Adapters are not in use.

Note: Remove the PBM Adapter and PBM Light Adapter together. Do not remove the PBM Adapter alone, as the PBM Light Adapter can be difficult to remove from the Wand by hand.

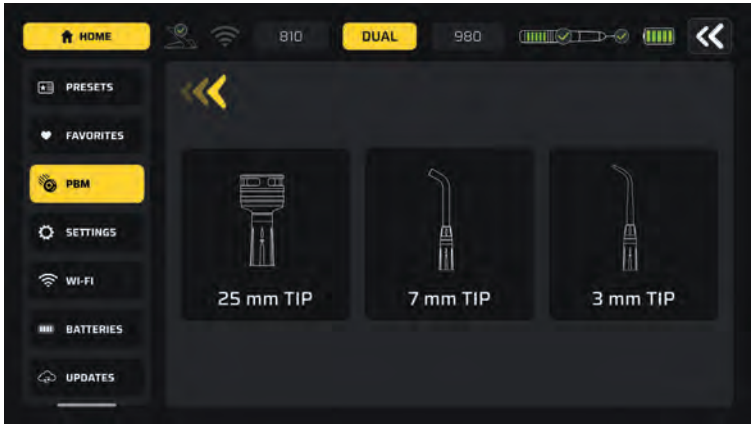


If the PBM Light Adapter is stuck to the Wand: Reattach the PBM Adapter to the PBM Light Adapter and use it as leverage to remove both the PBM Adapter and the PBM Light Adapter from the Wand simultaneously.



PBM PROCEDURES:

Tap the MENU button and select PBM from the list to set up a PBM procedure.



Select the desired tip size and the calculation method for the procedure dose (Energy in Joules or Dose in J/cm^2). Adjust the procedure time by rotating the Wand Battery, sliding or tapping the slide bar, or pressing the PLUS/MINUS buttons on the display. The dose amount and corresponding procedure time per spot will display and update as adjustments are made. Click NEXT to proceed.

Position the PBM Adapter at the procedure site, tap the ACTIVATE button, and press the Foot Pedal to begin.

Tip Selection | Timer Adjustment | Energy Selection

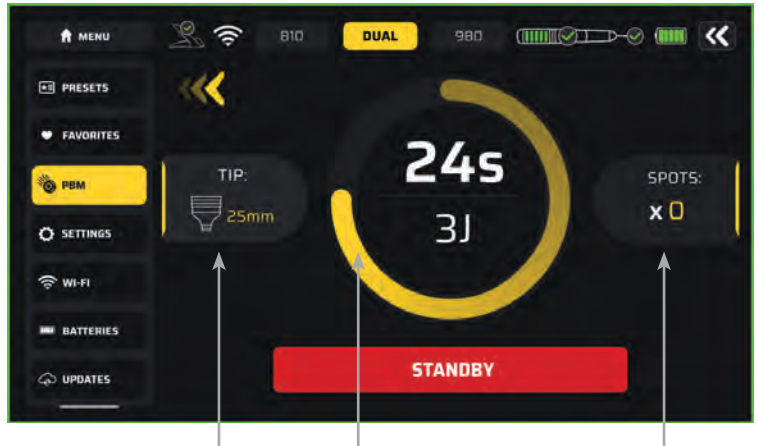
Note that there is a time limit for each tip size when using PBM procedures.

3 mm Tip: Max 50 seconds

7 mm Tip: Max 50 seconds

25 mm Tip: Max 30 seconds

Timer cannot be adjusted after unit is in ACTIVATE mode.



Tip Selected | Timer | Total Spots Treated

PBM USE RECOMMENDATIONS

Affected muscles and/or joints have to be exposed to an adequate level of laser energy over a period of time to provide effective results. Some cases may need multiple or repeated procedures before improvement occurs. Repeat as necessary and monitor the patient's progress.

Diode laser wavelengths, particularly 810 nm, are absorbed by melanin and can cause increased tissue heating in patients with darker skin. Adjust power and procedure time accordingly.

In the Gemini Nova system, PBM manual settings are available for pain management. Use professional judgment to select laser settings, monitor the patient, and adjust power or procedure time as needed for safety and comfort.

To begin procedure, hold the PBM Adapter in contact with the target area in a fixed position for the duration of the session. For larger areas, move the PBM Adapter to a new location and begin a new procedure only after the previous cycle is complete.

PBM ADVERSE EVENTS AND CONTRAINDICATIONS

If patient discomfort or reddening of the skin in the procedure area occurs at any time during procedure, you can do the following:

- Defocus the laser energy by moving the adapter a few centimeters back from the skin
- Decrease the procedure time
- Stop procedure

If blistering of the skin occurs or the patient feels a burning sensation, immediately stop procedure and rinse the area with cool water or place a cold pack on the affected area for at least 5 minutes. Afterwards, apply a burn ointment or spray. DO NOT USE ICE.

- Do not use over articles of clothing
- Do not use on or apply to open wounds
- Do not apply ointment, creams, lotions, or heating lotion patches at, or in close proximity to, the procedure area
- Do not apply therapies prior to procedure that could change body temperature, such as ultrasound, ice/heat pack, electrical stimulation, or heating patches

PBM ADVERSE EVENTS AND CONTRAINDICATIONS (CONTINUED)

- Avoid procedure sites with tattoos
- Different implant materials will respond differently to laser energy and heat; be aware of any implants and their location; avoid direct exposure to laser energy or heat at the site of the implant
- Excessive fatty tissue is known to transmit heat without much attenuation, therefore increase distance or decrease procedure time
- Muscle tissue closer to the skin surface may experience a higher absorption of heat; carefully monitor skin temperature and reduce procedure time as necessary
- Patients with swelling and/or inflammation may be sensitive to heat; reduce procedure time as necessary to ensure comfort during procedure
- Patients with tender or sensitive skin may be hypersensitive to heat; reduce procedure time as necessary to ensure comfort during procedure
- Scar tissue has been associated with poor circulation and reduced cooling through heat transport by blood; reduce procedure time as necessary to avoid overheating
- Do not use or apply directly over the site of any known primary malignant carcinoma or secondary metastasis except for palliative care with informed consent and oncologist permission
- Do not use on pregnant women as the effects of photobiomodulation therapy on the fetus are unknown

PBM ADAPTER MAINTENANCE

When using PBM adapters (3 mm, 7 mm, or 25 mm), specific components are required for proper use. A PBM Light Adapter must first be secured to the end of the PBM Adapter before attaching the PBM Adapter to the Wand. For the 25 mm PBM Adapter, a 25 mm PBM Spacer must also be attached to its end. Both disposable PBM Light Adapters and 25 mm PBM Spacers are supplied non-sterile and should be cleaned with isopropyl alcohol wipes before use. **Note:** Keep the protective caps in place while wiping the PBM Light Adapters. These components are intended for single-use only and should never be autoclaved or reused to prevent damage or cross contamination.

The 25 mm PBM Adapter is also provided non-sterile by the manufacturer and can be wiped as needed using isopropyl alcohol wipes. Do not submerge the 25 mm PBM Adapter in any type of cleaning solution. DO NOT AUTOCLAVE the 25 mm PBM Adapter.

Use the included cleaning cloth to gently wipe the glass optics of the 25 mm PBM Adapter as needed. Do not use any harsh chemicals or abrasives to clean the glass optics within the 25 mm PBM Adapter. Doing so may damage the glass.

The 3 mm and 7 mm PBM Adapters can be cleaned and sterilized per the instructions on pages 40–42.

PBM ADAPTER SPECIFICATION

	3 mm PBM Adapter	7 mm PBM Adapter	25 mm PBM Adapter
Dimensions	95 x 29 x 14.9 mm	95 x 29 x 14.9 mm	25 x 32 x 32 mm
Weight	17 grams	20 grams	22 grams
Spot Size	0.07 cm^2	0.38 cm^2	4.91 cm^2
Power	0.3 Watt Average	0.3 Watt Average	1.0 Watt Average
Power Density	4286 mW/cm^2	780 mW/cm^2	204 mW/cm^2

19 - DISPOSABLE TIP OPERATION

The Disposable Fiber Tip is relatively flexible but may break if bent at an angle that is too sharp. Use the provided bending tool* to bend the Tip to the desired angle. Do not bend the Tip beyond what the bending tool permits.

Protein debris from gingival tissue accumulates on the Disposable Fiber Tip during surgery, and the heat that develops will deteriorate the optical efficiency. Fibers can fracture if a blackened area greater than 3–4 mm develops.

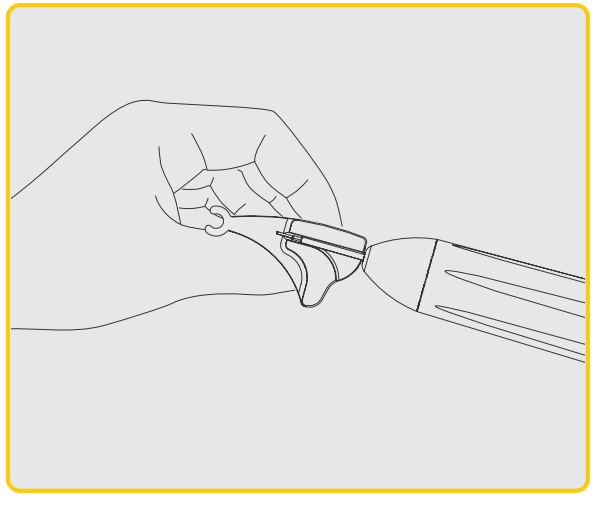
Replace the disposable, single-use Fiber Optic Tip as necessary and for each new patient. The tips are provided in a sealed package. They are designed for single-use only and must be discarded after use.

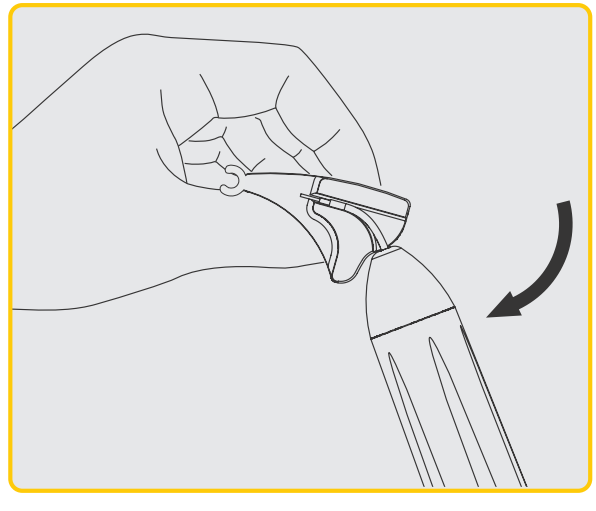
LASER BEAM INTEGRITY

The Aiming Light uses the same delivery path as the working beam and therefore serves as an effective indicator of delivery system integrity.

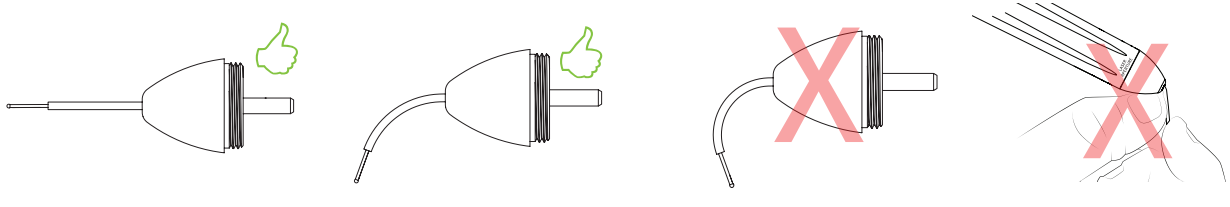
With the Laser System powered on (but not activated via the Foot Pedal), project the red Aiming Light perpendicular to a flat surface. Verify that the projected "spot" is round and evenly illuminated.

If the spot is absent at the laser aperture, appears dim, or is misshapen, this may indicate damage or misalignment within the Laser System.





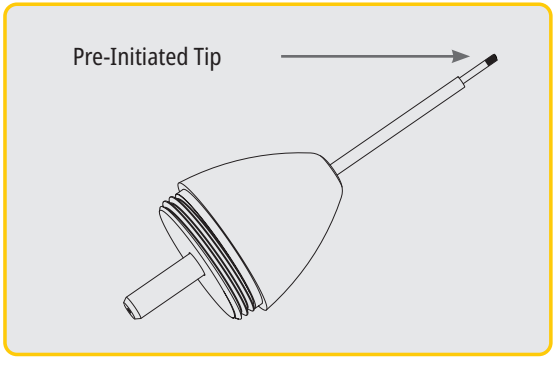
*Only use the bending tool with CLEAN tips prior to use. If the bending tool contacts a tip that has been used on a patient it must be disposed of in an infectious waste container (SHARPS).



DO NOT OVERBEND TIP / DO NOT BEND WITH FINGER

DISPOSABLE TIPS

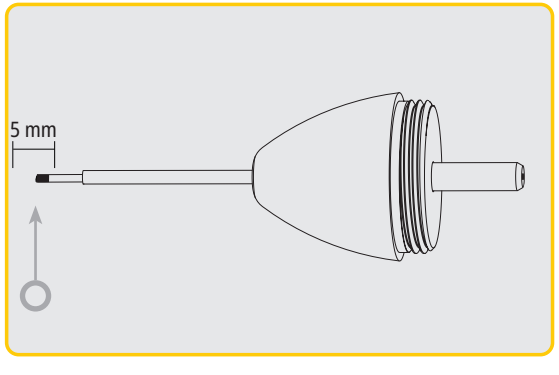
The Gemini Nova system's single-use 5 mm Fiber Tips come pre-initiated, containing black pigment at the tip to focus laser energy. Initiated Tips are required for soft-tissue removal or cutting procedures.



Before a procedure, to clean the tip without removing initiation, activate the laser at 1.0 Watt for 1–2 seconds, then wipe with isopropyl alcohol.

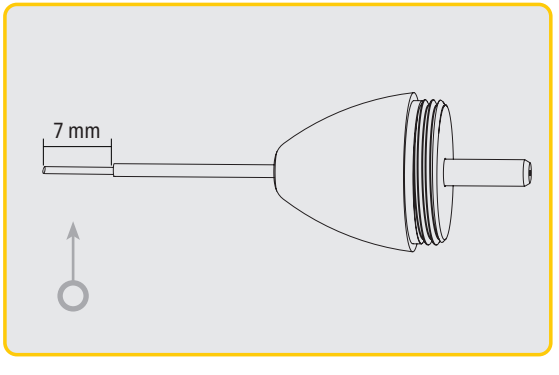
If initiation is lost or a tip is uninitiated, fire the laser at low power while rubbing the tip on articulating film to deposit pigment and initiate it.

Procedures that do not remove tissue (e.g., decontamination, aphthous ulcers) should use a 7 mm Uninitiated Tip. To remove initiation from a 5 mm Tip, wipe the pigment off with gauze and isopropyl alcohol before firing the laser.



5 mm Tips (Pre-Initiated)

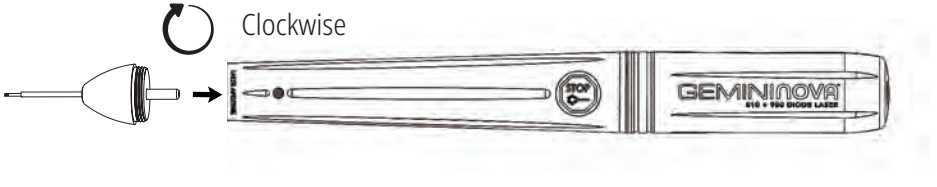
A 5 mm Tip is recommended for surgical procedures like incision/excision, implant recovery, tooth exposure, operculectomy, gingivoplasty, gingivectomy, frenectomy, and troughing.



7 mm Tips (Uninitiated)

A 7 mm Tip is recommended for procedures such as decontamination and aphthous ulcer.

Insert the Disposable Fiber Tip into the Wand and turn clockwise to secure the tip in place.

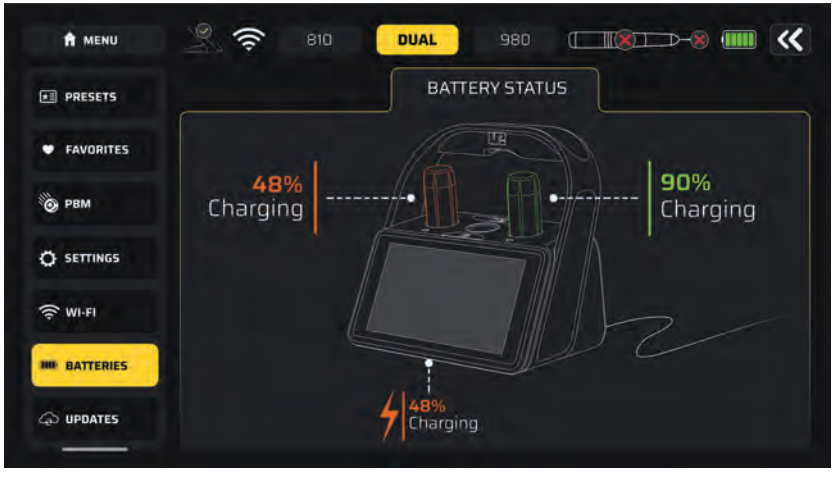


20 - BASE BATTERY AND WAND BATTERIES

The Gemini Nova laser is powered by rechargeable Lithium-ion Base and Wand Batteries. The Base Battery, located at the bottom of the Base Unit, powers the system and charges the two provided Wand Batteries. When not connected to a power supply, the Base Battery can charge each Wand Battery up to two times. Wand Batteries charge only when the Base is powered on; however, the Base itself does not need to be actively charging to charge the Wand Batteries if the Base Battery has sufficient charge.

Connect the provided AC/DC power supply with USB-C cable to the rear of the Base and charging will start immediately. When connected to the provided power supply, the system continues to operate while maintaining the charge of the Base and Wand Batteries. It is recommended to fully charge the system prior to initial use after unpacking. Refer to the Base power supply information on page 32 for additional details.

To view the charge levels and status for each battery, select the BATTERIES tab in the home menu.



A colored LED Battery Charging Indicator is located next to each Wand Battery charging port on the Base and displays the following Wand Battery charge levels:

LED Off: 100%

Green: 21%–99%

Red: 20% or less

Battery Charging Indicator

Individual charge statuses appear in the right corner of the top menu bar.

Wand Battery Charge Level	Wand Battery Usage Time (assuming 1.2 W in dual wavelength mode)
	19–24 minutes
	13–18 minutes
	7–12 minutes
	2–6 minutes
	0 minutes Wand will go into STANDBY and will not fire.

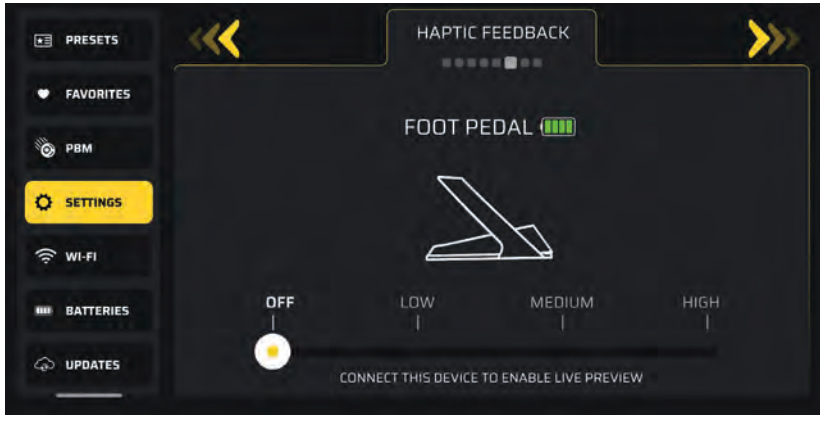
Base Battery Charge Level	Base Battery Usage Time (assuming one Wand Battery charging)
	5 hours
	4 hours
	3 hours
	2 hours
	Expect Base Battery to last 1 hour without Wand Battery charging.

TYPICAL CHARGING TIMES

- Base Battery: Base Batteries take approximately 2 hours to reach a full charge from a depleted state using the provided AC/DC power supply with USB-C cable.
- Wand Batteries: Two Wand Batteries seated in the Base reach a full charge in approximately 1.5 hours under typical conditions.

TYPICAL OPERATING DURATION

- Base Battery (unplugged): A fully charged Base Battery provides over 4 hours of continuous operation under typical conditions, including intermittent laser activation and charging seated Wand Batteries.
- Wand Battery: A fully charged Wand Battery can support approximately 10 average procedures (1.2 W in dual wavelength mode for 2 minutes), equivalent to 20–24 minutes of active laser firing. Duration may vary depending on power settings and usage patterns.



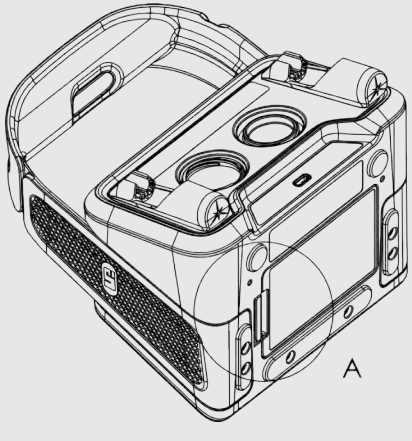
Note: The Foot Pedal battery level can be found in the SETTINGS menu under Foot Pedal haptic feedback.

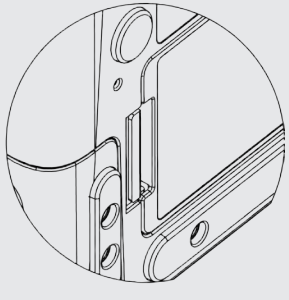

50 to 100%


25 to 49%


0 to 24%

The Base Battery is equipped with a Battery Management System (BMS) that continuously monitors performance. Each cell is managed and charged independently to help maintain optimal battery health. If replacement is required, the Battery can be removed by pressing the battery tab and sliding the Battery out of the Base.





PUSH TAB TO RELEASE

To preserve battery life, the Wand automatically exits ACTIVATE mode after 5 minutes of inactivity and enters STANDBY. After an additional 10 minutes of inactivity, the Wand transitions to SLEEP mode. If the Wand remains in SLEEP mode for 10 additional minutes, it will automatically power off. To power the Wand back on, remove and reattach the Wand Battery.

The Lithium-ion battery has a typical lifespan of 2 years, at which time it is advised that the battery be replaced.

CAUTION: For optimal battery longevity, avoid leaving the unit plugged into the power supply for over 48 hours. It's recommended to allow the battery to fully drain to the low (1 bar) level before initiating a recharge. When storing the unit for extended periods, it's advisable to keep the battery level at medium (2 bars) to enhance battery life.

ONLY USE THE POWER SUPPLY PROVIDED WITH THE GEMINI NOVA SYSTEM. USE OF ANY OTHER POWER SUPPLY MAY RESULT IN DAMAGE TO YOUR DEVICE.

21 - POWER SUPPLY

Use only the provided AC/DC power supply for charging the system battery and as an alternate laser power source. During initial setup use the AC/DC power supply for 2 hours to fully charge the battery.

Plug the power supply into an AC outlet, then connect the USB-C cable from the power supply to the corresponding port on the back of the Base. Only use the power supply provided with the system.

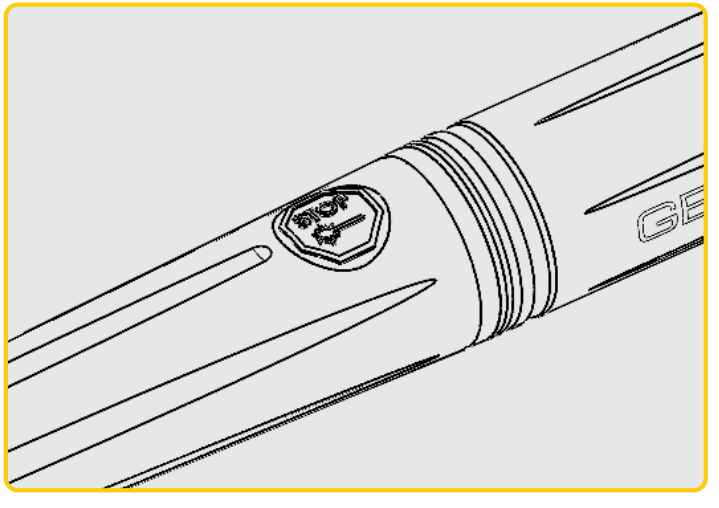
WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with Protective Earth.

22 - OPERATING MODE

The Gemini Nova system will only deliver energy in pulsed "temporal emission mode" and is optimized to provide the operator ideal control of target tissue temperatures and efficiency of energy delivered. The pulse width is fixed and not user adjustable. The operator will only need to adjust the laser wavelength and average power.

23 - EMERGENCY STOP

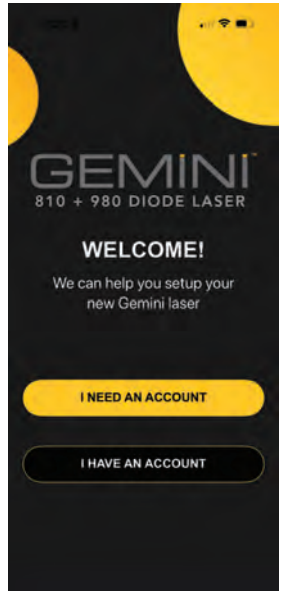
The Gemini Nova system can be immediately deactivated in any mode, at any time, and in any power setting by pressing the red STOP button located on the Wand.

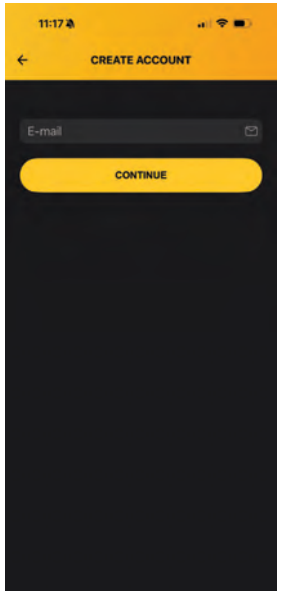


24 - ENABLING WI-FI CONNECTIVITY VIA MOBILE APP

The Gemini Nova system connects to your local Wi-Fi network, providing internet access directly to the unit. This connection enables important features such as performance updates, technical support, procedure tracking, and more.

The Gemini Laser app is available for both iOS and Android devices. Scan the QR code and you will be able to download the appropriate app for your mobile device.

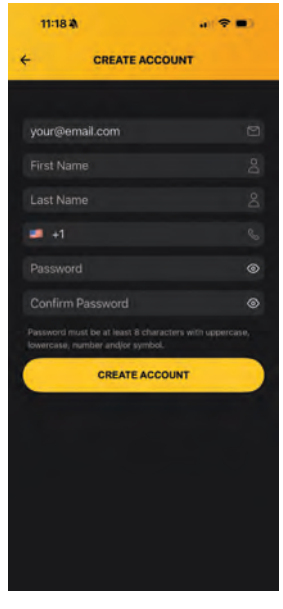




Please note that the Gemini Laser app enables seamless connectivity with any Gemini device on your local network. It's simple and intuitive to use.

After downloading the app from the App Store, follow the on-screen instructions to complete a quick registration. If you are already a Gemini EVO customer, there's no need to register again; you can sign in with your existing login credentials.

If you encounter connectivity issues due to a secure firewall or antivirus software, please contact your network administrator for assistance.



To complete your registration, simply follow the sequence of on-screen prompts. As part of the process, you'll be asked whether you are in private practice or part of a DSO group. Please answer accurately, as this helps us communicate with your practice appropriately.

WI-FI CONNECTIVITY AND MOBILE APP

Additional menus, such as training videos and downloads, can be accessed here.

Add a new Gemini Laser to the app.

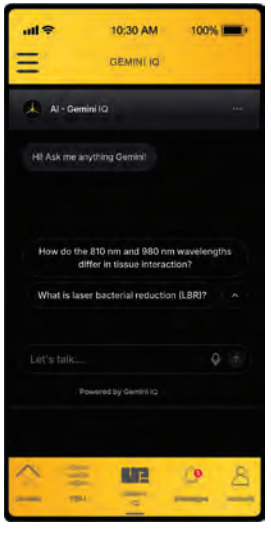
Accessing the Dashboard is simple. You can track all your procedures within the app by selecting the Dashboard icon associated with your Gemini Laser.

The home icon brings you to the main home screen where you can monitor your devices.

Access your account preferences here.

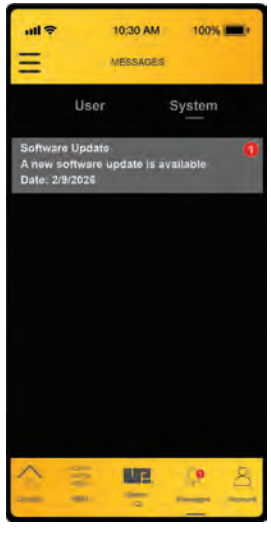
The Systems page gives you complete visibility into your devices, allowing you to monitor battery health, connectivity, serial numbers, and Bluetooth status, among several other features.

The app features a PBM calculator that allows you to calculate any dose by selecting your preferred tip and sliding the timer bar to set your desired procedure duration in seconds. The app will automatically display the dose in real time. You can switch between tips without resetting the time, and the calculation will update instantly.



Gemini IQ is an incredible new feature powered by a custom language model dedicated to the entire Gemini product line. You can ask any question about Gemini products and receive instant assistance with usability and functionality. Simply type your question, and the app will respond.

NOTE: Gemini IQ does not replace clinical judgment, is not a cleared diagnostic or treatment planning tool, and should not be relied upon as a substitute for professional training.



The Messages page keeps you informed with login activity, software update notifications, and any relevant information related to your Gemini Nova device. This feature is especially helpful for alerting you when a new software update is available or when an important system message requires your attention.

25 - MOBILE APP DASHBOARD

Once connected to Wi-Fi, the Gemini Nova laser shares data with the dashboard on your mobile app, allowing you to monitor various laser parameters and proce-dures. To access the dashboard, select the Dashboard icon associated with the Gemini laser you are connected to.

Some of the data you can view on your Gemini Laser App Dashboard includes:

Preset vs. Manual Procedures

Most Used Manual Power Settings

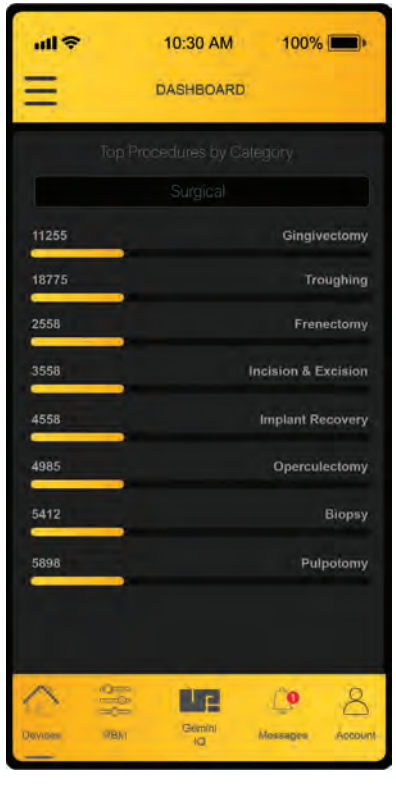
Total Procedures

Lifetime Laser Usage

Wavelength Usage

Top 10 Preset Procedures

Top Procedures by Category



Similar user interface for Android users. Layout is subject to change based on future updates on all platforms.

26 - WEB DASHBOARD

In addition to the Mobile App Dashboard you can access even more data through the Web Dashboard by visiting the following link:

dashboard.geminilaser.com/authentication/login

Using the same login credentials you created in the mobile app, you'll be able to view all of your Gemini data in one place.

The dashboard offers a range of tools to help you manage your Gemini Nova device, including:

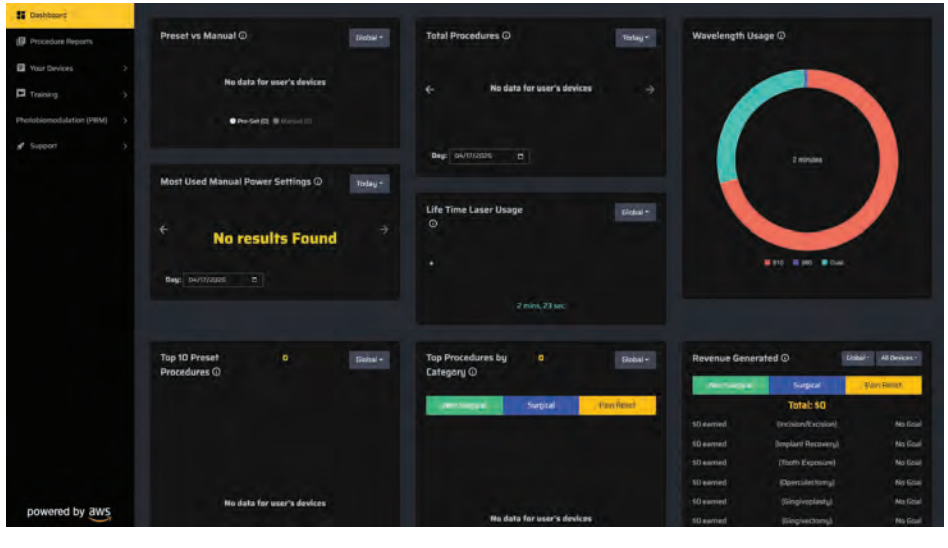
A comprehensive overview of all activity on your Gemini Nova laser

Vitals to monitor the overall health of your device

Customizable preset settings and procedure fees for ROI tracking

Access to download the latest User Manual

Calibration details and access to download the calibration certificate for your device



GUIDELINES

The Gemini Nova laser is not supplied in sterile condition, nor must it be sterilized before use except for the 3 mm and 7 mm PBM Adapters. The following cleaning and disinfection procedures are recommended before the initial use and after each subsequent use:

1. The Disposable Fiber Tips are supplied non-sterile by the manufacturer and should be wiped with isopropyl alcohol wipes by the operator prior to use. The tips are to be discarded in an infectious waste container (SHARPS) after each use. There is no reuse or reprocessing procedure indicated for the Disposable Fiber Tips. An FDA-cleared barrier sleeve designed specifically for the Gemini Nova Wand with Disposable Fiber Tip, 3 mm PBM Adapter, or 7 mm PBM Adapter must be applied to the Wand after attaching the selected tip and before use (510k 211026). See Figure 1. Discard the sleeve after each use and follow the proper disinfection guidelines.

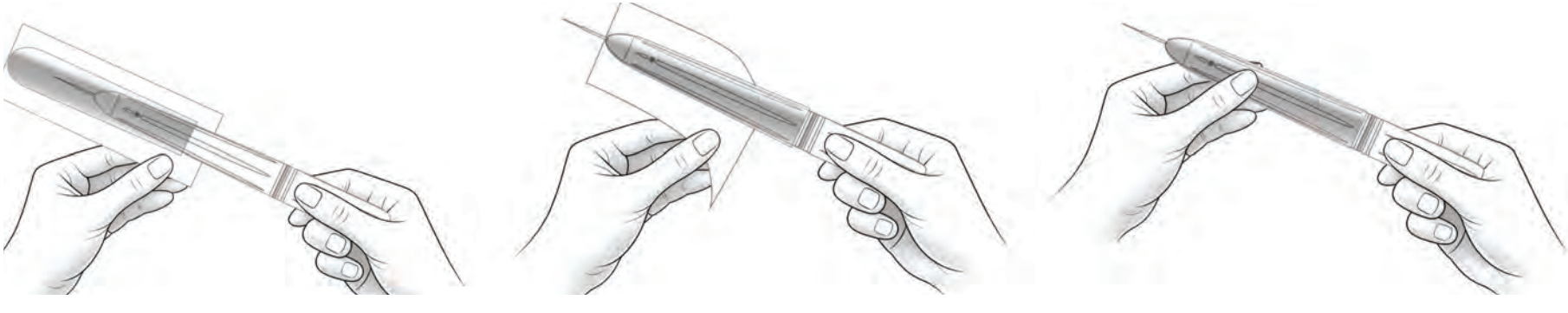
2. The 25 mm PBM Adapter is provided non-sterile and must be wiped down with isopropyl alcohol wipes by the operator prior to and after each use. **Note:** Do not submerge 25 mm PBM Adapter lens in liquid.

3. The 25 mm PBM Spacers (only to be used with the 25 mm PBM Adapter) are supplied non-sterile and should be wiped with isopropyl alcohol wipes by the operator prior to use. The 25 mm PBM Spacers are to be discarded in an infectious waste container (SHARPS) after each use. There is no reuse or reprocessing procedure indicated for the 25 mm PBM Spacers.

4. The disposable PBM Light Adapters are supplied non-sterile and should be wiped with isopropyl alcohol wipes by the operator prior to use. **Note:** Keep the protective caps in place while wiping the PBM Light Adapters. The PBM Light Adapters are to be discarded in an infectious waste container (SHARPS) after each use. There is no reuse or reprocessing procedure indicated for the disposable PBM Light Adapters.

5. The 3 mm and 7 mm PBM Adapters are also provided non-sterile by the manufacturer and should be cleaned and sterilized prior to initial use and after each use following the instructions on page 40.

Figure 1



CLEANING, DISINFECTION, AND STERILIZATION

The Gemini Nova Wand cannot be steam sterilized, therefore a cleaning and disinfection process will be needed. The cleaning process is intended to remove blood, protein, and other potential contaminants from the surfaces and crevices of reusable accessories. This process may also reduce the quantity of particles, microorganisms, and pathogens present. Cleaning must be performed within a maximum of 1 hour after the procedure and always after disinfection. The disinfection process is intended to destroy pathogens and other microorganisms by physical or chemical means.

WAND CLEANING AND DISINFECTION

(DO NOT AUTOCLAVE OR SPRAY THE WAND DIRECTLY)

1. After use, carefully remove the Disposable Fiber Tip or PBM Adapter from the Wand. Dispose of the Fiber Tip, 25 mm PBM Spacer, and/or PBM Light Adapter in an infectious waste container (SHARPS).

2. Clean the Wand by using one CaviWipes®* towelette, or equivalent product, for 30 seconds to completely pre-clean exposed areas of all gross debris.

3. Use a new towelette to thoroughly wet all pre-cleaned areas for disinfection, keeping all areas wet for 2 minutes at room temperature (68° F/20° C). Repeated use of towelettes may be required to ensure that the surfaces remain visibly wet.

4. Visually inspect the Wand to ensure there is no visible debris remaining. If necessary, continue wiping with CaviWipes towelette, or an equivalent product, until all visible debris is removed.

5. Wipe all exposed areas of the Wand with isopropyl alcohol wipes to remove any residue left by the CaviWipes towelette.

WARNING: THE GEMINI NOVA LASER AND ITS COMPONENTS CANNOT BE CLEANED WITH AN AUTOMATED CLEANING PROCESS.

NOTE: REPLACE THE RED PROTECTIVE CAP ON THE WAND WHEN NOT IN USE.

*Not a registered trademark of Ultradent Products, Inc.

25 mm PBM ADAPTER

The 25 mm PBM Adapter is supplied non-sterile and may be wiped with isopropyl alcohol wipes. DO NOT AUTOCLAVE or submerge the 25 mm PBM Adapter in any type of cleaning solution.

When using the 25 mm PBM Adapter, attach a 25 mm PBM Spacer. Spacers are non-sterile, should be wiped with isopropyl alcohol before use, and are single-use only. Do not autoclave or reuse.

Before attaching the 25 mm PBM Adapter to the Wand, secure a PBM Light Adapter to the end of the PBM Adapter. Light Adapters are also non-sterile, must be wiped with isopropyl alcohol before use, and discarded after each procedure along with the 25 mm PBM Spacer. **Note:** Keep the protective caps in place while wiping the PBM Light Adapters. These components are intended for single-use only and should never be autoclaved or reused to prevent damage or cross contamination.

Use the included cleaning cloth to gently wipe the glass optics of the 25 mm PBM Adapter as needed. Do not use any harsh chemicals or abrasives to clean the glass optics within the 25 mm PBM Adapter. Doing so may damage the glass.

STEAM STERILIZATION

3 mm AND 7 mm INTRAORAL PBM ADAPTERS

The steam sterilization process is intended to destroy infectious microorganisms and pathogens. Always perform the sterilization procedure immediately after cleaning and prior to use, and only use FDA-cleared (USA) or CE-marked (Europe) sterilization accessories such as sterilization pouches and autoclave trays. An FDA-cleared barrier sleeve designed specifically for the Gemini Nova Wand with 3 mm PBM Adapter or 7 mm PBM Adapter must be applied to the Wand after attaching the 3 mm and 7 mm PBM Adapters and before use (510k 211026). Discard the sleeve after each use and follow proper disinfection instructions. Before attaching the 3 mm or 7 mm PBM Adapter to the Wand, secure a PBM Light Adapter to the end of the PBM Adapter.

The disposable PBM Light Adapters are supplied non-sterile by the manufacturer and should be wiped with isopropyl alcohol wipes by the operator prior to use. **Note:** Keep the protective caps in place while wiping the PBM Light Adapters. Discard the PBM Light Adapter after each use. It is not designed for autoclaving or reuse.

1. Place the 3 mm and/or 7 mm PBM Adapters in a separate single-wrap, self-seal autoclave pouch.

2. Place on an autoclave tray with paper side down; do not stack other instruments on top of the pouch.

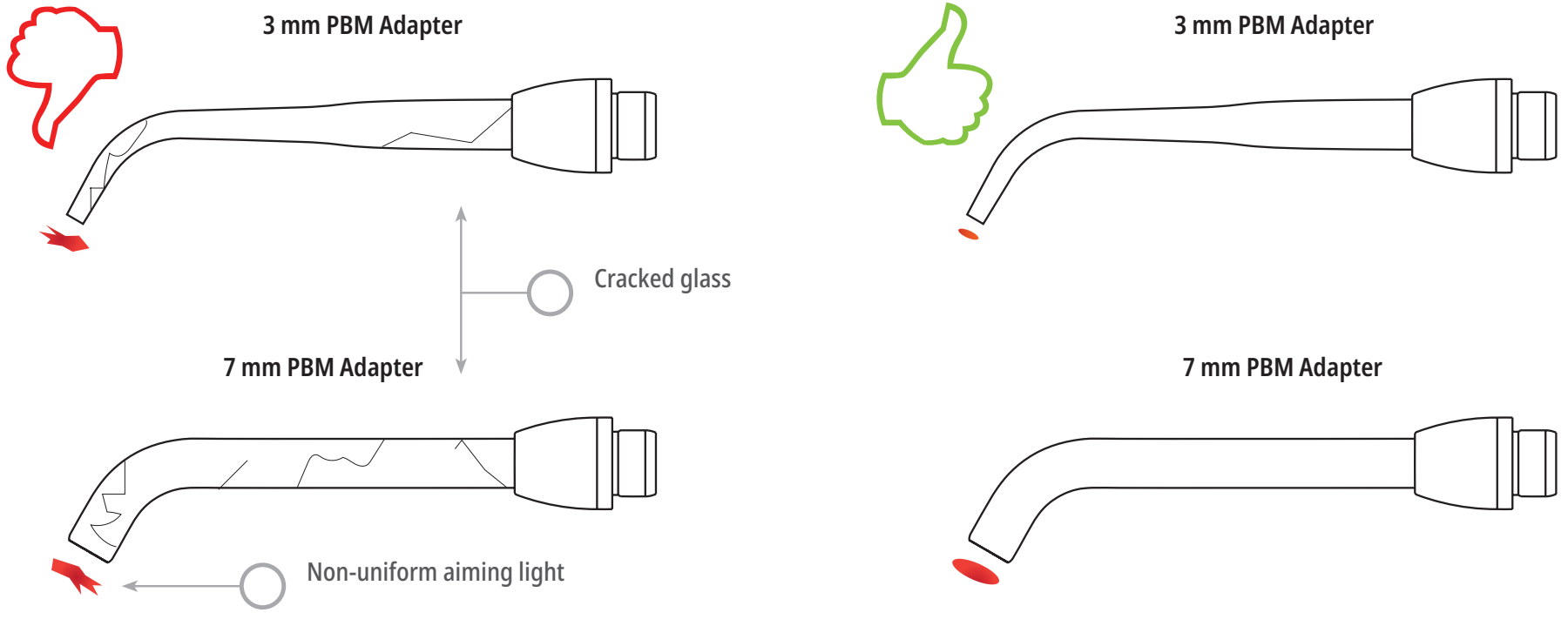
3. Place the tray inside the autoclave chamber and set the cycle to 135° C (275° F) for a minimum of 10 minutes with a dry time of 30 minutes. This suggested sterilization cycle of 135° C (275° F) for a minimum of 10 minutes with a dry time of 30 minutes is considered by the United States Food and Drug Administration to be a standard sterilization cycle. We recommend sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the U.S. FDA for the selected sterilization cycle specifications.

   It is recommended to use a sterilizer and any accessories that are capable of reaching 135° C (275° F) and capable of reaching a 10-minute cycle with a 30 minute dry time such as the Getinge Sterilizer 533LC (FDA 510k #K070657) along with an FDA-cleared sterilization pouch such as Chex-all 3x8" (FDA 510k #K162258).

4. Once the cycle is completed, remove the tray and let the sterilized item cool and dry. The 3 mm and/or 7 mm PBM Adapters must remain in the sterilization pouch until used in order to maintain sterility.

5. Visually inspect the 3 mm and/or 7 mm PBM Adapter to ensure the product is not degraded. The criteria for degradation are listed on page 41.

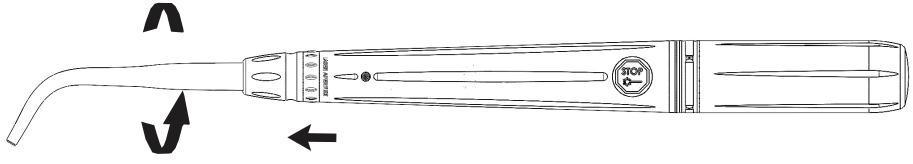
A visual and mechanical inspection of the PBM Adapters after each sterilization should be conducted to ensure adapters have not degraded and lost performance. Unacceptable deterioration includes cracked glass, delamination of anodized material, a non-uniform circular spot when checking the aiming light on a flat surface, and not being able to securely attach the PBM Adapter onto a Light Adapter. In the event the adapters have cracked glass or a non-circular aiming light spot, please contact the manufacturer for review.



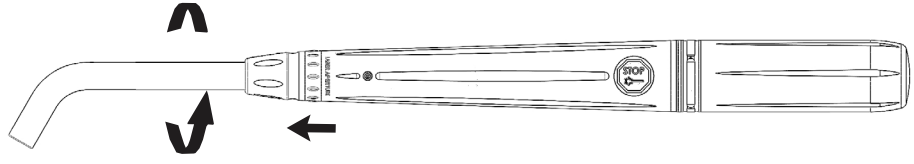
DO NOT USE ABRASIVE MATERIALS TO CLEAN THE WAND OR PBM ADAPTERS.

Remove/reassemble the 3 mm/7 mm PBM Adapter following the instructions below.

Turn the PBM Light Adapter and the 3 mm PBM Adapter counterclockwise to remove them, together, from the Wand.

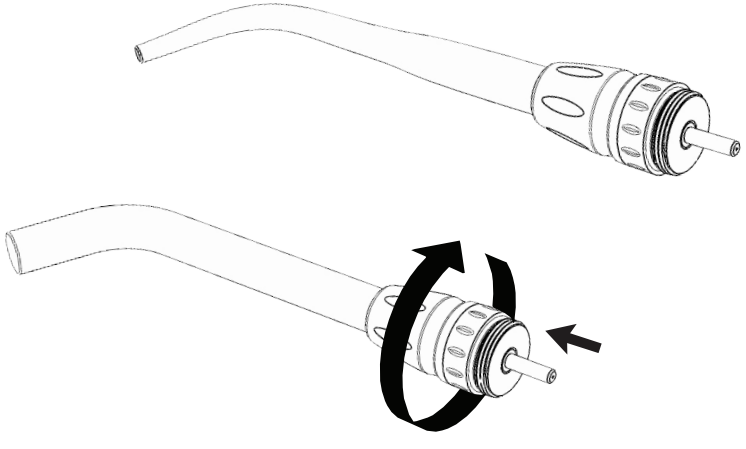


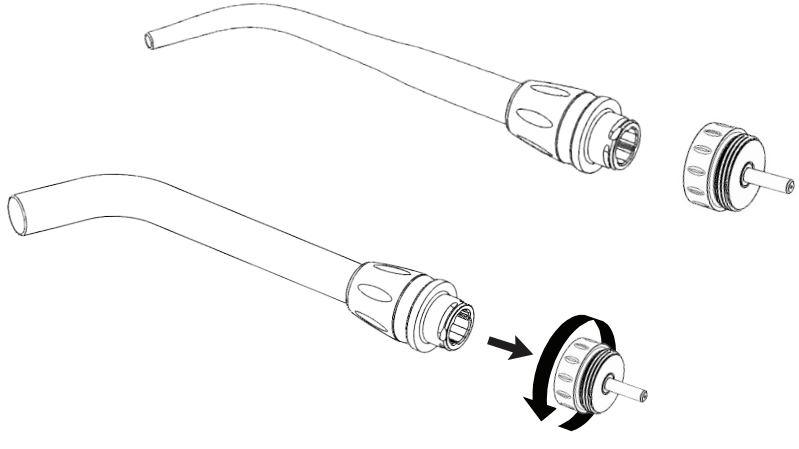
Turn the PBM Light Adapter and the 7 mm PBM Adapter counterclockwise to remove them, together, from the Wand.



Follow these steps to apply or remove the PBM Light Adapter to/from the PBM Adapter:

The PBM Light Adapter must be attached to the end of the 3 mm or 7 mm PBM Adapter before securing it to the Wand. Application and removal use the same clockwise and counterclockwise motions.





NOTE: The Gemini Nova Base is not routinely contaminated by procedures. The display should be covered with a protective clear adhesive barrier film and replaced after each patient. If the exterior of the Gemini Nova Base should become contaminated, it should be wiped down with CaviWipes, or equivalent product, then re-covered with a new protective plastic cover. We recommend wringing out any cleaning wipes before use to avoid dripping liquid on the Base.

DO NOT SPRAY ANY DISINFECTANT DIRECTLY ON THE BASE OR THE WAND BECAUSE IT WILL DAMAGE THE COMPONENTS.

DO NOT USE ABRASIVE MATERIALS TO CLEAN THE WAND OR THE DISPLAY.

GUIDELINES

The following procedure guidelines are provided as a guide only and have been developed based on information provided by experienced laser users and educators. Always review the patient's history to evaluate possible contraindication for use of local anesthesia or other complications.

All clinical procedures performed with the Gemini Nova system must be subjected to the same clinical judgment and care as traditional techniques and instruments. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment.

INDICATIONS FOR USE

The Gemini Nova system is intended for the incision, excision, vaporization, ablation, and coagulation of oral soft tissues including marginal and interdental gingival and epithelial lining of free gingiva and the following specific indications:

- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival troughing for crown impressions
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic, and aphthous ulcers of the oral mucosa
- Treatment of aphthous ulcers
- Vestibuloplasty
- Tissue retraction for impression
- Lesion (tumor) removal

Laser Periodontal Procedures

- Laser soft tissue curettage
- Laser removal of diseased, infected, inflamed, and necrosed soft tissue within the periodontal pocket
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
- Sulcular debridement (removal of diseased, infected, inflamed, and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility)
- Reduction of bacterial level (decontamination) and inflammation

Pain Therapy

- Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, muscle spasm, minor sprains and strains, and minor muscular back pain, the temporary increase in local blood circulation; and the temporary relaxation of muscle

All procedures listed in this manual are safe if performed by a licensed, trained professional. The potential side effects to the patient can include swelling, inflammation, redness of the skin, scarring, tissue pigment changes, and infection after treatment. All of these conditions can be reduced by cautiously following the appropriate aftercare or post-operative care instructions.

GUIDELINES

In addition to receiving proper training in the use of soft tissue dental lasers, users should be familiar and experienced with these procedures using electrosurgical devices or traditional instruments before performing them on patients with the Gemini Nova system. Inexperienced users should seek appropriate training guidance before attempting clinical treatments with the laser system.

In order to ensure the safe use of the Gemini Nova system in your facility, please check to make sure that the proposed location is compatible with the specifications listed below.

POWER REQUIREMENTS

External AC/DC Power Supply - Use only the provided Gemini Nova system power supply. DO NOT use any other power supply.

Input Power: 100-240 V, 50-60 Hz, 1.5 A

Output Power: 5 V, 5.8 V, 9 V, 12 V, 15 V, 15.1 V, 20 V, 60 W

HEATING AND VENTILATION

Operating environmental conditions to be within 10°–40°C (50°–104°F), and 95% relative humidity or less. Transportation and storage environmental conditions to be within 0°–40°C (32°–104°F), and relative humidity of 95% or less. Atmospheric pressure to be within 70 kPa–106 kPa in operating, transportation, and storage conditions.

COMBUSTIBLE CHEMICALS AND GASES

All gases that are combustible or support combustion and are used in the operatory area where the Gemini Nova system is being operated must be turned off during the procedure. Cleaning supplies or other flammable chemical compounds should be stored in an area away from the surgical site in order to avoid possible combustion. Do not use in the presence of supplemental therapeutic oxygen supplies for patients with respiratory or related diseases.

PLUME EVACUATION

Plume evacuation should be addressed when vaporizing tissues. A high volume vacuum system should be used, and 0.1 micron or less high filtration masks that are suitable for virus and bacterial control should be worn by clinicians.

CAUTION: LASER FUME AND/OR PLUME MAY CONTAIN VIABLE TISSUE PARTICULATES

DISPOSAL

Please adhere to local guidelines for the environmentally responsible disposal of your laser unit, especially when it comes to electronic components and batteries. Alternatively, you have the option to ship, at your expense, the laser unit to the manufacturer for proper disposal.

OPERATORY ACCESS DURING LASER USE

Access to the treatment area should be restricted while the lasers are in use. A sign indicating “LASER IN USE” should be placed in a designated area adjacent to the treatment area entry location.

GUIDELINES

Safe use of the Gemini Nova system is the responsibility of the entire dental team including the doctor, any system operators, and the dental office safety officer. In order to properly assess the favorable conditions of treatment, below is a pre-treatment checklist to help ensure treatment to your patient is safe:

- Ask the patient about allergy to local or topical anesthetics
- Make sure the laser warning sign is posted in the operating area
- Make sure the patient and operator(s) are all wearing laser protective eyewear specific to the Gemini Nova system
- Have the patient fill out an informed consent form for laser treatment
- If performing a non-surgical procedure, use an Uninitiated Fiber Tip
- If performing a surgical procedure, use an Initiated Fiber Tip

Adjust the laser power settings as needed to fit the clinical circumstances of the case. The preset procedure settings built into the Gemini Nova system are simply a manufacturer's recommendation. Optimal power level may vary case by case.

MARKETING REQUIREMENTS REGARDING MEDICAL DEVICE SAFETY (USA)

The United States Food and Drug Administration (FDA) has control over the sale and use of all medical devices including the Gemini Nova system. Manufacturers of products subject to performance standards under the Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control are required to certify compliance with the regulations and furnish various reports to the Center for Devices and Radiological Health (CDRH).

For manufacturers of medical lasers (such as the Gemini Nova system), additional review by the FDA of the safety and effectiveness of the device is required.

Companies who intend to market a medical laser or equivalent device must receive authorization from the FDA before the device is permitted into commercial distribution. The premarket notification (510k) process used for the Gemini Nova system is applicable for devices that are documented to be substantially equivalent to existing legally marketed Class II devices.

STATUTORY LICENSURE FOR DENTAL LASER USE

Usually, states or provinces do not have a specific licensure requirement for use of surgical laser devices by dentists. Many states do, however, require hygienists who will be using lasers to attend licensure training that includes both a lecture and hands-on experience.

The license applicants are then required to pass a proficiency test for certification prior to using lasers. These courses are usually taught by members of the Academy of Laser Dentistry who possess instructor credentials. Such training would be appropriate for use of the Gemini Nova system.

OSHA PROVISIONS

Worker safety is the responsibility of the employer and is regulated by Occupational Safety and Health Administration (OSHA), a division of the U.S. Department of Labor. OSHA recognizes ANSI standard Z136.1 as a source for analyzing safety with respect to medical lasers.

For more information see OSHA Technical Manual (TED1- 0.15A) Section III, Chapter 6, 1999. A safety program is recommended for the safety of your patients and office staff in connection with the use of the laser. It is also recommended to check and comply with applicable state and provincial safety and health organization requirements.

CONTRAINDICATIONS

Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease, lung disease, bleeding disorders, immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from the patient's physician is advisable when doubt exists regarding treatment.

The Gemini Nova system is not indicated for hard tissue procedures. The laser is attracted to melanin, hemoglobin, and to some extent, water. Avoid prolonged exposure of the energy when working in and around the cervical areas of the tooth. Due to the thin layer of enamel in this area, energy may be absorbed by the hemoglobin in the pulp and pulpal hyperemia may occur. Extended exposure to such energy could cause patient discomfort and even lead to possible pulpal necrosis.

EYE AND SKIN PROTECTION

While the Gemini Nova system is in use, doctors, system operators, auxiliary staff, patients, and anyone in the operatory must wear the appropriate safety eyewear that has been designed for use with the 800-plus nm wavelengths associated with lasers. Eye protection must conform to Specification DIN EN207 Annex II of the Directive 89/686/EEC with optical density of OD+5 for the wavelength range of 800 nm–1000 nm.

Nominal Ocular Hazard Distance (NOHD) is the distance from the source of laser emission to the point where it no longer exceeds its Maximum Permissible Exposure (MPE), the highest level of laser radiation to which a person may be exposed without hazardous effects or adverse biological changes in the eyes or skin. The Nominal Hazard Zone (NHZ) is the space within which the level of direct, reflected, or scattered radiation during normal operation exceeds the appropriate MPEs. The outer limit of the NHZ is equal to the NOHD. The NOHD for persons NOT wearing recommended safety glasses is shown in Table 1 below.

Table 1: NOHD (INCHES/CM)

RADIATION SOURCE	MPE µj/cm^2	DIVERGENCE ANGLE	WITHOUT EYE PROTECTION
Fiber Optic Tip	1.4	12° (+/- 1°)	87.2 in./ 221.6 cm
3 mm PBM Adapter	1.4	39° (+/- 1°)	27 in./ 69 cm
7 mm PBM Adapter	1.4	12° (+/- 1°)	88 in./ 223.5 cm
25 mm PBM Adapter	1.5	4.5° (+/- 1°)	244 in./ 620 cm

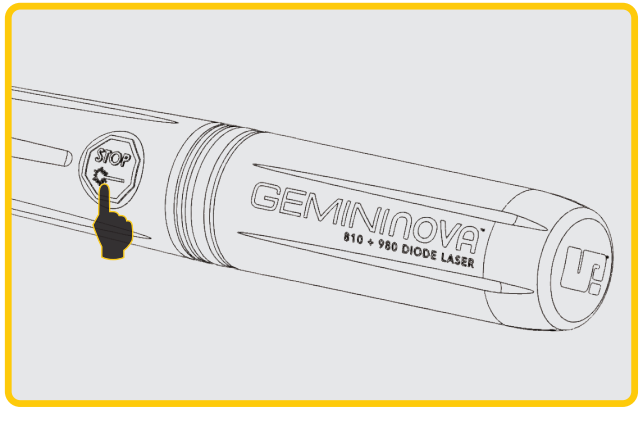
NEVER POINT THE LASER TIP DIRECTLY AT THE EYES OF ANYONE WHILE EMITTING ENERGY.

EMERGENCY SHUTDOWN OPTIONS:

The Gemini Nova system has been designed with several methods to terminate emission of laser energy in emergency situations.

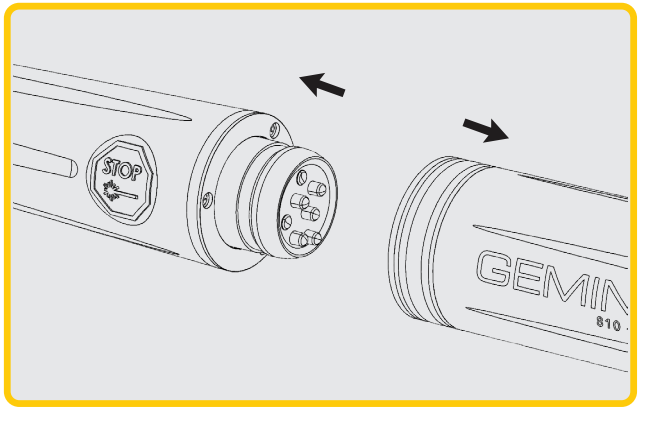
These methods include a power button (ON/OFF) located on the Base and an emergency (STOP) button located on the Wand.

Perform any of these actions to terminate laser emissions in the event of a real or perceived emergency:



Press the emergency "STOP" button on the Wand.

Press the "ON/OFF" button on the Base.



Separate Wand Battery from the Wand.

Gemini Nova System

Dimensions of Laser Unit	6.4″ (L) x 5.2″ (W) x 6.5″ (H) - 16.3 cm (L) x 13.3 cm (W) x 16.5 cm (H)
Dimensions of Foot Pedal:	6.5″ (L) x 4.5″ (W) x 4.1″ (H) - 16.5 cm (L) x 11.5 cm (W) x 10.5 cm (H)
Weight Laser Unit:	2.26 lb. - 1.03 kg Foot Pedal: 0.63 lb. - 0.28 kg
Laser classification:	Class IV laser device
Beam delivery system:	Diode laser coupled to optical tip(s)
Wavelength:	810 nm ± 10 nm 980 nm ± 20 nm Dual Wavelength ± 20 nm (50% @ 810 nm / 50% @ 980 nm)
Maximum average power:	810 nm @ 2.0 Watts ± 20% Peak: Up to 10 W 980 nm @ 2.0 Watts ± 20% Peak: Up to 10 W Dual Wavelength @ 2.0 Watts ± 20% Peak: Up to 20 W
Aiming beam wavelength:	650 ± 10 nm
Aiming beam power:	1 mW max
Beam divergence:	254 mrad
Power range:	0.1 Watt to 2.0 Watts Average
Pulse frequency:	83-3333 Hz

Pulse width:	0.06 ms
Duty cycle:	0.5%–20.0%
Voice confirmation:	YES
Power requirements:	Input: 100-240 VAC @ 50 to 60 Hz - 1.5 A Output: 5 V, 5.8 V, 9 V, 12 V, 15 V, 15.1 V, 20 V, 60 W
Battery:	Base Battery: 7.2 V Rechargeable Lithium-ion Wand Battery: 3.7 V Rechargeable Lithium-ion
Wireless frequency:	Bluetooth at 2.4 GHz Wi-Fi: 2.4 GHz / WPA2, WPA-Enterprise
Maximum Operating Altitude:	5,000 meters or 16,404 feet
The Gemini Nova system complies with the following: **IEC 60825-1 / EN/IEC 60601-1 IEC 60601-1-2 IEC 60601-2-22** **21 CFR 1040.10 and 1040.11** **FCC part 15 (47 CFR)**	

CALIBRATION

Recalibration is recommended every 12 months in order to assure accuracy of optical output power is within +/- 20%. The Gemini Nova system may be returned to the manufacturer for recalibration, which you can arrange by contacting your distributor. Certain government or corporate entities may require calibration certificates which can also be provided by the manufacturer. A factory calibration record and certificate should be downloaded from your Gemini Nova system Dashboard.

ADVERSE EFFECTS

If used properly, there are no known adverse effects of using the Gemini Nova system. Please thoroughly read and understand all Warnings, Precautions, and Contraindications in this manual prior to use. In the event the laser malfunctions due to exposure to certain environment conditions, magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, accelerations, and any potential thermal ignition sources, discontinue use and follow the instructions in the service and troubleshooting section of this manual. Additional measures may be necessary such as reorienting or relocating the device.

No separate equipment is recommended to be used to assess the favorable conditions which are acceptable for treatment or to assess the unfavorable conditions which would render a treatment unacceptable or hazardous.

Maximum LASER OUTPUT of laser radiation with the magnitudes of cumulative measurement uncertainty and any expected increase in the measured quantities after manufacture is stated as the standard uncertainty of measurement.

WIRELESS INTERFERENCE

FCC regulation statement:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Any changes or modifications made to this device that are not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC RF Exposure statement:

This device has been tested for SAR and complies with FCC radiation exposure limits set forth for an uncontrolled environment at 0 mm separation distance. End users must follow the specific operating instructions for satisfying RF exposure compliance.

ISED Regulation Statement:

This device has been tested for SAR and complies with ISED radiation exposure limits set forth for an uncontrolled environment at 0 mm separation distance. End users must follow the specific operating instructions for satisfying RF exposure compliance.

ALL OTHER CONDITIONS

In the event that the Gemini Nova system fails to operate correctly, and your distributor representative is unable to help, the system will need to be returned to the manufacturer for repair. There are no user-repairable parts available for the device. It is recommended that the system be returned in its original shipping box. If not available, one can be requested at the time you discuss your service incident with your distributor representative.

OVERVIEW AND RECOMMENDATIONS

The Gemini Nova system has been developed using a secure product development lifecycle that incorporates threat modeling, cybersecurity risk assessment, secure software design, verification of security controls, and independent penetration testing. These activities are intended to ensure the confidentiality, integrity, and availability of the system throughout its operational life.

The Gemini Nova system includes multiple integrated cybersecurity safeguards across the Base Unit, wireless peripherals (Wand and Foot Pedal), mobile application, and supporting cloud services. These safeguards include:

- Secure communication protocols (TLS 1.2 or higher)
- Authenticated and signed firmware updates
- Encryption of data in transit and at rest
- Device-unique credentials and X.509 certificates
- Access control and role-based authorization
- Integrity checking of software and configuration files
- Mutual authentication between system components
- Continuous monitoring for software and configuration integrity

These controls help prevent unauthorized access, reduce the risk of software tampering or manipulation, and maintain safe and effective operation of the device in its intended clinical environment.

Software Updates and Patch Management

The Gemini Nova system supports secure delivery of manufacturer-authorized software and firmware updates, including cybersecurity patches.

All updates are digitally signed by Azena Medical, cryptographically verified for authenticity and integrity prior to installation, and delivered over encrypted communication channels.

When an update becomes available:

- Users are notified through the device dashboard or associated software interface
- Security patches are released as needed based on identified vulnerabilities and risk assessment

Users are encouraged to apply software updates as soon as practical to maintain device cybersecurity, safety, and performance. If an update fails integrity verification, the system automatically prevents installation and retains the previous verified software version.

Software Bill of Materials (SBOM)

Azena Medical maintains a Software Bill of Materials (SBOM) for the Gemini Nova system, including third-party and open-source software components used across the device, mobile application, and cloud services.

The SBOM supports ongoing cybersecurity risk monitoring, vulnerability tracking, and lifecycle management and is maintained in a machine-readable format. SBOM information is made available to users upon request or through manufacturer-provided channels.

Vulnerability Handling and Reporting

Azena Medical maintains a Coordinated Vulnerability Disclosure (CVD) process to receive, assess, and address reported cybersecurity vulnerabilities.

Individuals who identify cybersecurity concerns or potential vulnerabilities may report them using the technical support contact information provided with the device labeling or on the Azena Medical website.

If a vulnerability is confirmed:

- A cybersecurity risk assessment is conducted
- Mitigations and patches are developed as needed
- Users are notified of required actions, patches, or recommended compensating controls
- All software updates undergo validation before release
- Security-relevant events and corrective actions are documented in accordance with regulatory requirements

User Responsibilities

To support secure operation of the Gemini Nova system, users and system administrators **should:**

- Install software updates and patches promptly when notified
- Connect the device only to secure networks with appropriate access control and firewall protections
- Maintain physical security of the device and restrict access to authorized personnel
- Follow organizational policies for password management and credential protection
- Implement recommended cybersecurity practices for local IT environments, including network segmentation and monitoring

Failure to follow these recommendations may increase cybersecurity risk and could impact device safety or performance.

Secure Configuration, Monitoring, and Recovery

The Gemini Nova system is shipped in a secure configuration appropriate for its intended clinical use. Unused communication interfaces are disabled by default, and critical safety functions are protected by authentication, encryption, and integrity checks.

The system continuously monitors for anomalous conditions such as authentication failures, software integrity violations, and unexpected communication behavior. When such events are detected, the system logs the event and may restrict operation or enter a safe state. Critical functions, including laser activation, are automatically disabled if required security conditions are not met.

The system supports secure recovery mechanisms, including rollback to a previously verified software version and restoration of authenticated configuration data by authorized service personnel.

Logging and Forensic Support

The Gemini Nova system maintains security-relevant audit logs to support servicing, troubleshooting, and cybersecurity investigations. Logged events may include software updates, authentication events, configuration changes, and detected integrity violations. Logs are stored securely, protected from unauthorized modification, and retained for a defined period consistent with regulatory requirements.

End of Support and Decommissioning

Azena Medical will communicate end-of-support timelines for the Gemini Nova system when applicable. After the end of support, the manufacturer may no longer be able to provide cybersecurity updates, and cybersecurity risks may increase over time.

When decommissioning the device, sensitive data and credentials should be securely removed using manufacturer-approved procedures, and devices should be disposed of or returned in accordance with applicable regulations and institutional policies.

Additional Information

A Manufacturer's Disclosure Statement for Medical Device Security **(MDS2)** containing detailed cybersecurity and network integration information is available upon request for the Gemini Nova system.

Electromagnetic Compatibility

Notice: The Gemini Nova system complies with all requirements for electromagnetic compatibility according to IEC 60601-1-2: 2014.

CAUTION: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

Portable and mobile Radio Frequency (RF) communications equipment can affect medical electrical equipment.

WARNING: The use of accessories, other than those specified, except those supplied or sold by Ultradent Products, Inc., as replacement parts for internal or external components, may result in increased EMISSIONS or decreased IMMUNITY of the Gemini Nova system.

Accessories: Medical grade power supply - Maximum length 6 ft. (1.8 meters)

Foot Pedal and Wand: Wireless Bluetooth at 2.4 GHz

Description: The Foot Pedal and Wand use Bluetooth BLE 4.2 technology, which operates at a frequency of 2402 to 2480 MHz with TX power of +0 dBm and RX sensitivity of -94.8 dBm and uses GFSK modulation. The Foot Pedal and Wand are preconfigured by the manufacturer to only sync with the Gemini Nova system that has a matching unique identifier and BLE keys. This prevents interference with other RF wireless technologies that may be present.

As a safety measure, any termination of the Bluetooth link between the Foot Pedal or Wand and the Nova system during use will result in the immediate termination of any laser emission. Reference the Service and Troubleshooting section of this manual should you encounter any connectivity issues between the Nova system and the Foot Pedal or Wand.

This device has passed wireless coexistence testing with common devices found in dental practices at a minimum separation distance of 30 cm.

Definitions

Emission (electromagnetic): When electromagnetic energy is emitted by a source.

Interference Immunity: The ability of a device or system to work without errors even if there is electromagnetic interference.

Immunity Level: The maximum level of a certain electromagnetic interference that affects a particular device or system, where the device or system remains operative with a certain level of performance.

Electromagnetic Emission

The Gemini Nova system is intended for operation in the electromagnetic environment specified below. The customer or user of the Gemini Nova system should make sure that it is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions according to CISPR 11	GROUP 1	The Gemini Nova system 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 according to CISPR 11	CLASS A	The Gemini Nova system 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 according to IEC 61000-3-2	CLASS A	
Voltage fluctuations flicker emissions according to IEC 61000-3-3	COMPLIES	

Interference Immunity

The Gemini Nova laser is intended for operation in the electromagnetic environment specified below. The customer or user of the Gemini Nova laser should make sure that it is used in such an environment.

INTERFERENCE IMMUNITY TEST	IEC 60601-1-2 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Electrostatic discharge (ESD) according to IEC 61000-4-2	+/- 2, +/-4, +/- 6, +/-8 kV contact discharge +/- 2, +/-4, +/-8, +/-15 kV air discharge	+/- 2, +/-4, +/- 6, +/-8 kV contact discharge +/- 2, +/-4, +/-8, +/-15 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 50%.
Electrical fast transient/burst according to IEC 61000-4-4	100 kHz repetition +/- 2 kV for power supply lines 100 kHz repetition +/- 2 kV for power input/ output lines	100 kHz repetition +/- 2 kV for power supply lines Not applicable	The quality of the line power supply should be that of a typical commercial or hospital environment.
Surge voltages according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode voltage	± 1 kV differential mode ± 2 kV common mode voltage	The quality of the line power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and variations of the power supply according to IEC 61000-4-11	Voltage (VAC) 100, 240 over 0% residual with ½ cycles on a phase angle of 0 ° / 90 ° / 180° / 270 ° Voltage (VAC) 100, 240 over 0% residual with 1 cycle on a phase angle of 0 ° / 90 ° / 180° / 270 ° Voltage (VAC) 100, 240 over 70% residual with 25 cycles on a phase angle of 0 ° / 90 ° / 180° / 270 ° Voltage (VAC) 100, 240 over 0% residual with 250 cycles on a phase angle of 0 ° / 90 ° / 180° / 270 °	Voltage (VAC) 100, 240 over 0% residual with ½ cycles on a phase angle of 0 ° / 90 ° / 180° / 270 ° Voltage (VAC) 100, 240 over 0% residual with 1 cycle on a phase angle of 0 ° / 90 ° / 180° / 270 ° Voltage (VAC) 100, 240 over 70% residual with 25 cycles on a phase angle of 0 ° / 90 ° / 180° / 270 ° Voltage (VAC) 100, 240 over 0% residual with 250 cycles on a phase angle of 0 ° / 90 ° / 180° / 270 °	The quality of the line power supply should be that of a typical commercial or hospital environment. If the user of the Gemini Nova laser requires it to continue functioning following interruptions of the power supply, it is recommended to have the Gemini Nova laser powered by an uninterruptible power supply or a battery.
Magnetic field of power frequencies (50/60 Hz) according to 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.

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 radio equipment must not be used within the recommended working clearance from the Gemini Nova laser and its cables, which is calculated based on the equation suitable for the relevant transmission frequency. Recommended separation distance d= [1.2] √P d= [1.2] √P at 80 MHz to 800 MHz d= [2.3] √P at 800 MHz to 2.5 GHz Where P is the nominal transmitter output in Watts (W) specified by the transmitter manufacturer and d is the recommended working clearance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1] should be less than the compliance level[2] in each frequency range. Interference is possible in the vicinity of equipment bearing the following graphic symbol. 

NOTES

The higher frequency range applies at 80 MHz and 800 MHz.

[1] 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. An investigation of the location is recommended to determine the electromagnetic environment resulting from stationary HF transmitters. If the measured field strength in the location in which the Gemini Nova laser is used exceeds the applicable RF compliance level above, the Gemini Nova laser should be observed to verify normal operation. If unusual performance characteristics are observed, it may be necessary to take additional measures such as reorientation or repositioning of the Gemini Nova laser.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

WORKING CLEARANCES

The Gemini Nova laser is intended for operation in an electromagnetic environment where radiated HF interference is checked. The customer or the user of the Gemini Nova laser can help prevent electromagnetic interference by duly observing the minimum distances between portable and/or mobile RF communication devices (transmitters) and the Gemini Nova laser. These values may vary according to the output power of the relevant communication device as specified below.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER [W]	WORKING CLEARANCE ACCORDING TO TRANSMISSION FREQUENCY [M]		
	150 KHZ TO 80 MHZ	80 MHZ TO 800 MHZ	800 MHZ TO 2.5 GHZ
	d= [1.2] √P	d= [1.2] √P	d= [2.3] √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance in meters (m) can be determined using the equation in the corresponding column, where P is the maximum nominal output of the transmitter in Watts (W) specified by the transmitter manufacturer.

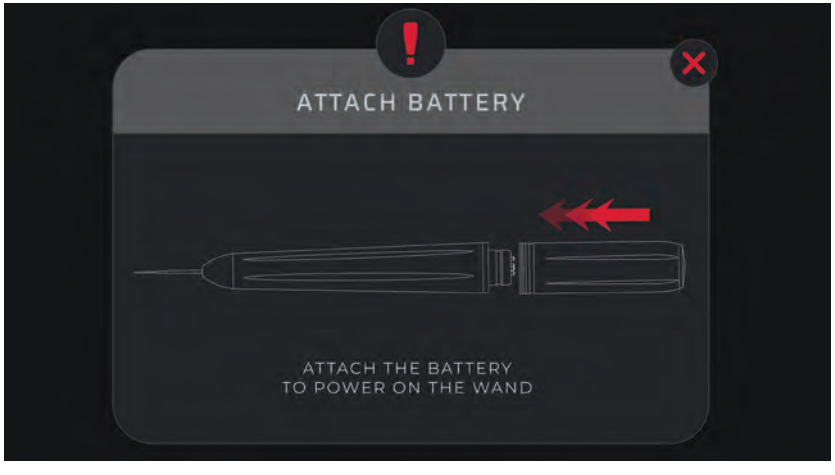
Remark 1: The higher frequency range applies at 80 MHz and 800 MHz.

Remark 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is influenced by their absorption and reflection by buildings, objects, and persons.

The Gemini Nova system has been designed to provide advisory messages when an error has occurred.

WAND BATTERY NOT ATTACHED

If the Wand Battery is not properly connected to the Wand, this message will appear, prompting the battery to be attached to the Wand.

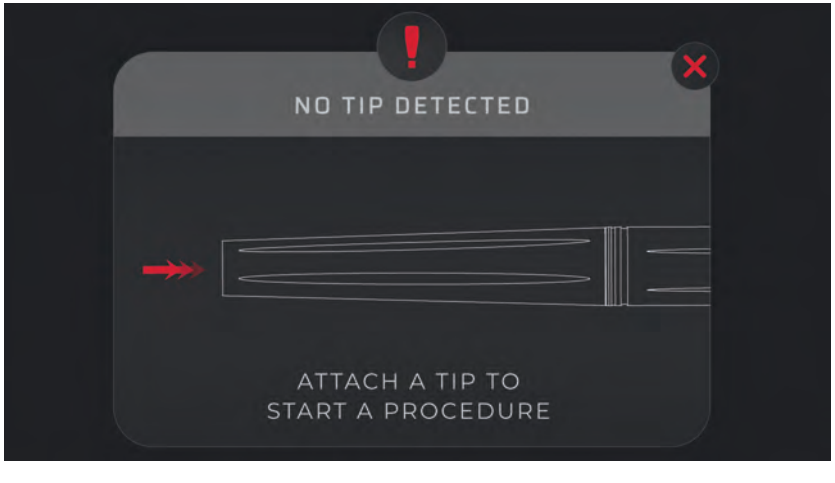


STEP ON FOOT PEDAL

The Foot Pedal may fall asleep after a period of inactivity. When this prompt appears, simply step on the pedal to wake it.

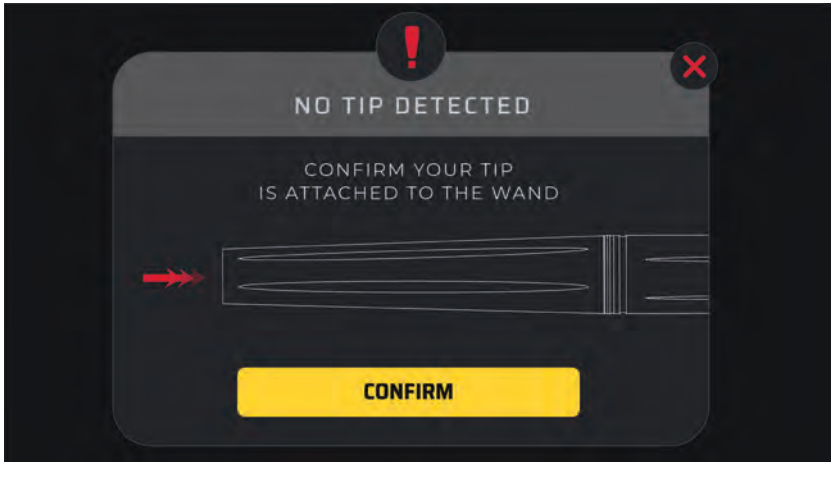
NO TIP DETECTED

If the laser is active and the tip is removed, the unit will return to standby mode. You will be prompted to attach a tip before continuing. The laser cannot be fired without a tip attached.



NO TIP DETECTED

If the laser does not detect a tip on the Wand, you will be prompted to attach a tip and confirm before starting the procedure. The laser cannot be fired without a tip attached.



WAND ASLEEP

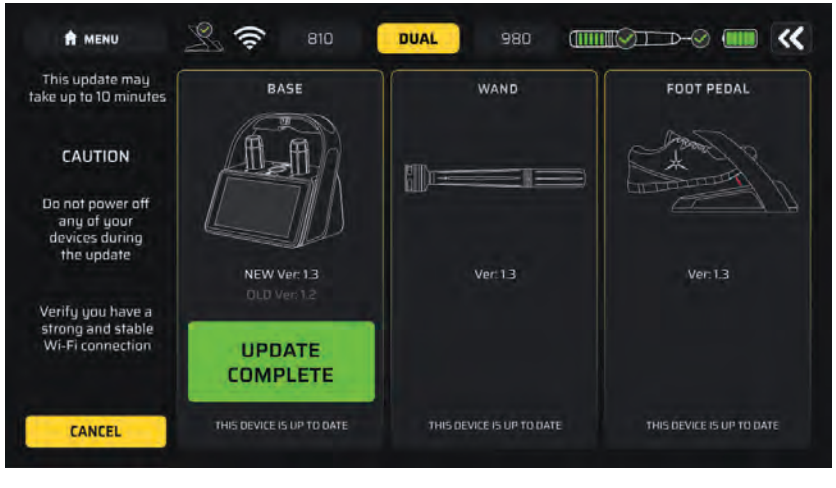
After 15 minutes of inactivity, the Wand will fall asleep. Shake the Wand to wake it up.

WI-FI CONNECTION FAILED

If the Wi-Fi setup fails, this alert prompts users with troubleshooting solutions.

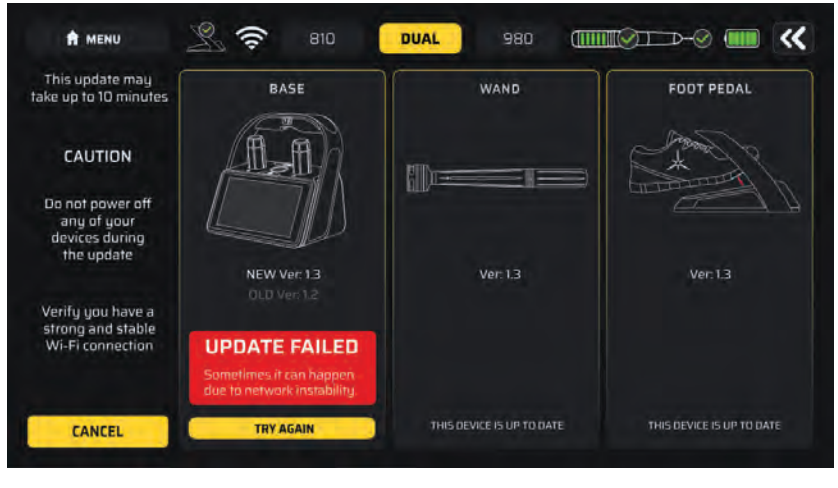
SOFTWARE UPDATE SUCCESSFUL

This notification appears after an update has been successfully installed.



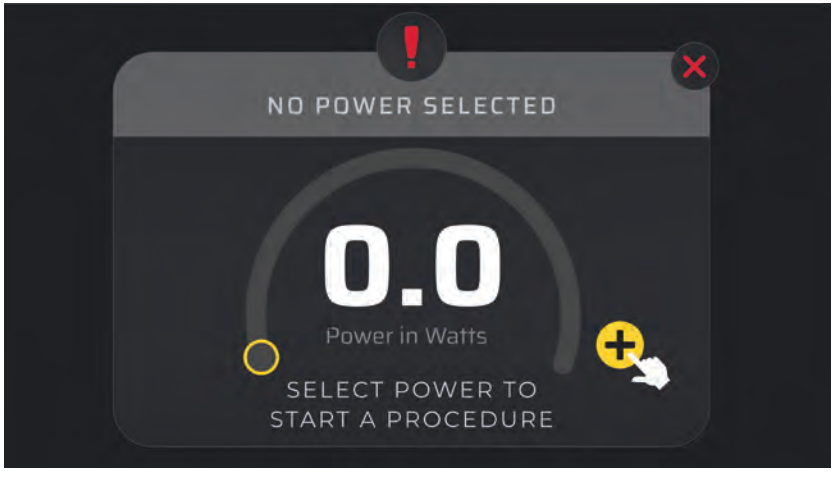
SOFTWARE UPDATE FAILED

This alert appears if an update has failed. Tap TRY AGAIN to install the update.



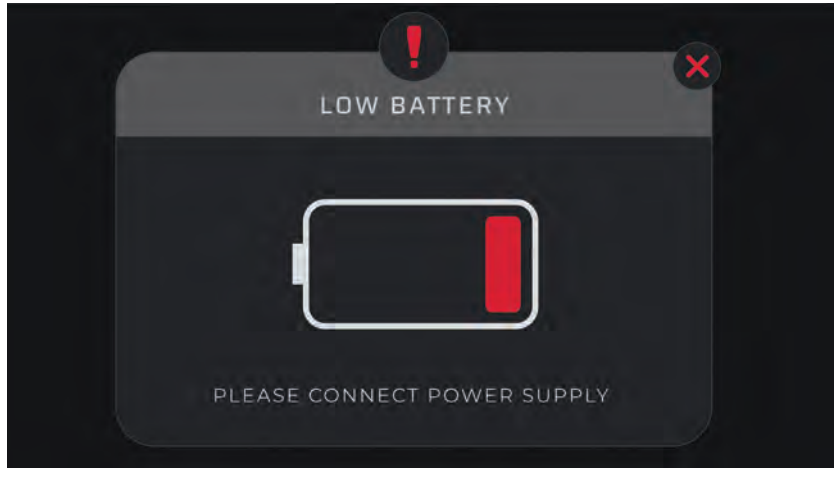
NO POWER SELECTED

When preparing to perform a procedure, this alert will appear if a power level has not been selected.



BASE BATTERY LOW

When the Base Battery is too low, you will be prompted to connect your Base to a power supply before continuing with a procedure.



WAND BATTERY LOW

When the Wand Battery is too low, you will be prompted to change the Wand Battery before continuing with a procedure.

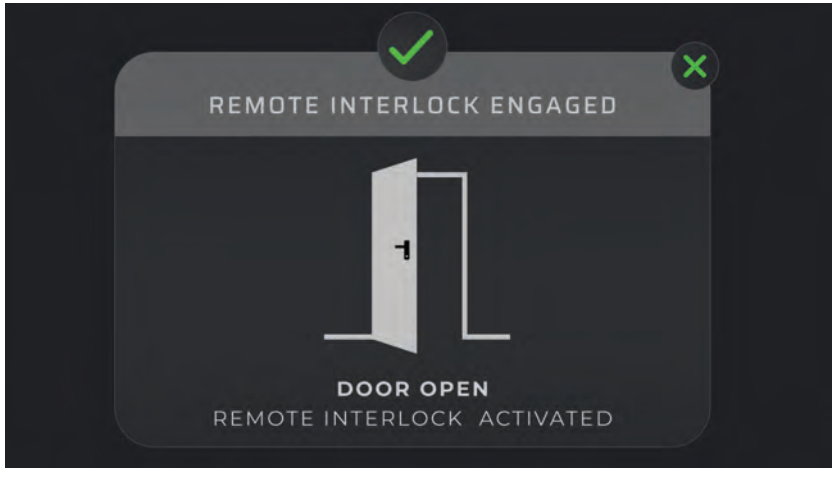
FOOT PEDAL LOW BATTERY

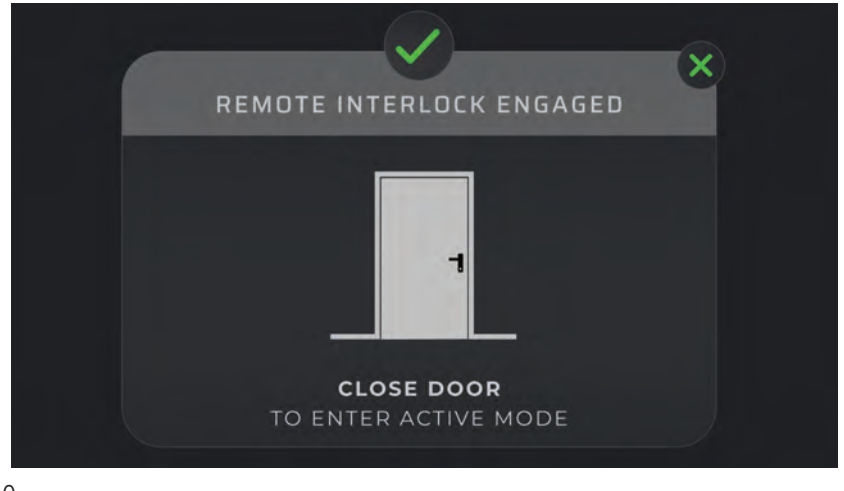
When the Foot Pedal battery is too low, you will be prompted to replace with new AA batteries before continuing with a procedure.

REMOTE INTERLOCK ENGAGED

This message appears when the remote interlock is active in two situations:

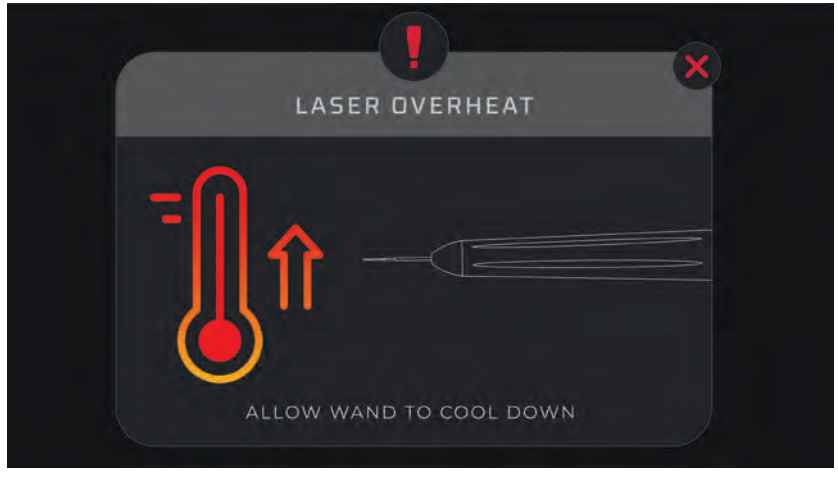
- Laser in use: If the door is opened while the laser is active, this warning will appear, and the laser will automatically switch to standby mode
- Before activation: If the door is already open, this warning will appear, and the laser cannot be activated until the door is closed



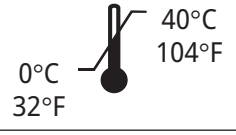
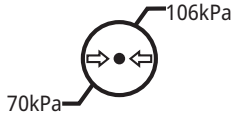
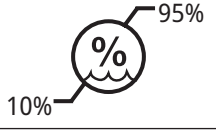
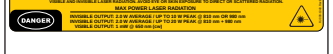


LASER OVERHEAT

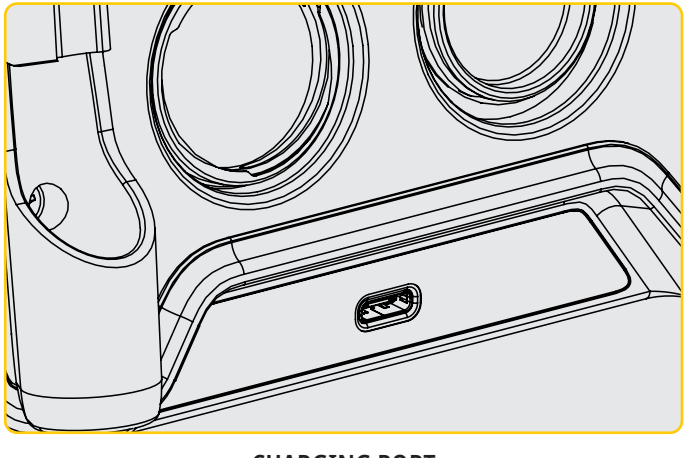
After long periods of use, the Wand may overheat. If this message appears, allow the Wand to cool down before continuing use.



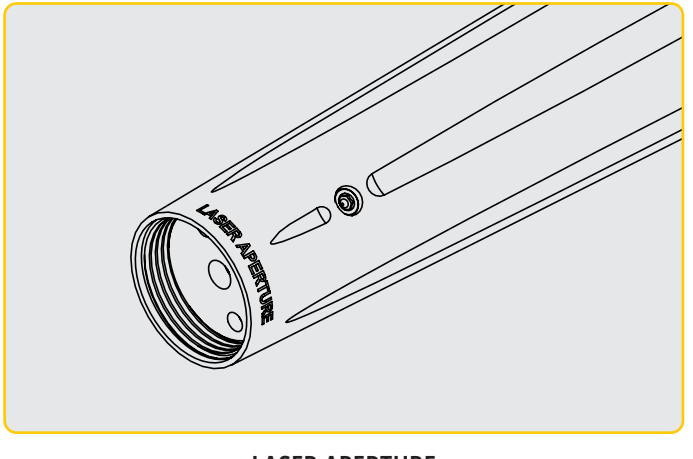
LABELING

SYMBOLS	DESCRIPTION	SYMBOLS	DESCRIPTION
	**MANUFACTURER** INDICATES WHICH COMPANY MANUFACTURES		**SHIP VERTICAL, WITH ARROWS POINTED UPWARD**
	**DATE OF MANUFACTURE** INDICATES THE DATE AND YEAR OF MANUFACTURE		**FRAGILE - HANDLE WITH CARE**
	**CATALOG PART NUMBER** INDICATES THE MANUFACTURER PART NUMBER		**DO NOT USE IF PACKAGE IS DAMAGED**
	**SERIAL NUMBER** INDICATES SERIAL NUMBER FOR THE PRODUCT PART		**RECOMMENDED STORAGE TEMPERATURE**
	**NON-IONIZING RADIATION**		**ATMOSPHERIC PRESSURE LIMITATION**
	**LASER APERTURE** INDICATES WHERE LASER ENERGY COMES OUT		**RELATIVE HUMIDITY RANGE**
	**WARNING** INDICATES POSSIBLE EXPOSURE TO BOTH RED AND INFRARED LASER RADIATION		**KEEP AWAY FROM HEAT/SUNLIGHT**
	**PRESCRIPTION STATEMENT** FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTIST OR PHYSICIAN OR OTHER LICENSED MEDICAL PRACTITIONER		**KEEP DRY**

SYMBOLS	DESCRIPTION
	**TYPE B APPLIED PART** THE APPLIED PART IS NOT CONDUCTIVE TO THE PATIENT
	**MUST REFER TO USER MANUAL**
	**LASER STOP** EMERGENCY SWITCH TO STOP LASER OUTPUT POWER



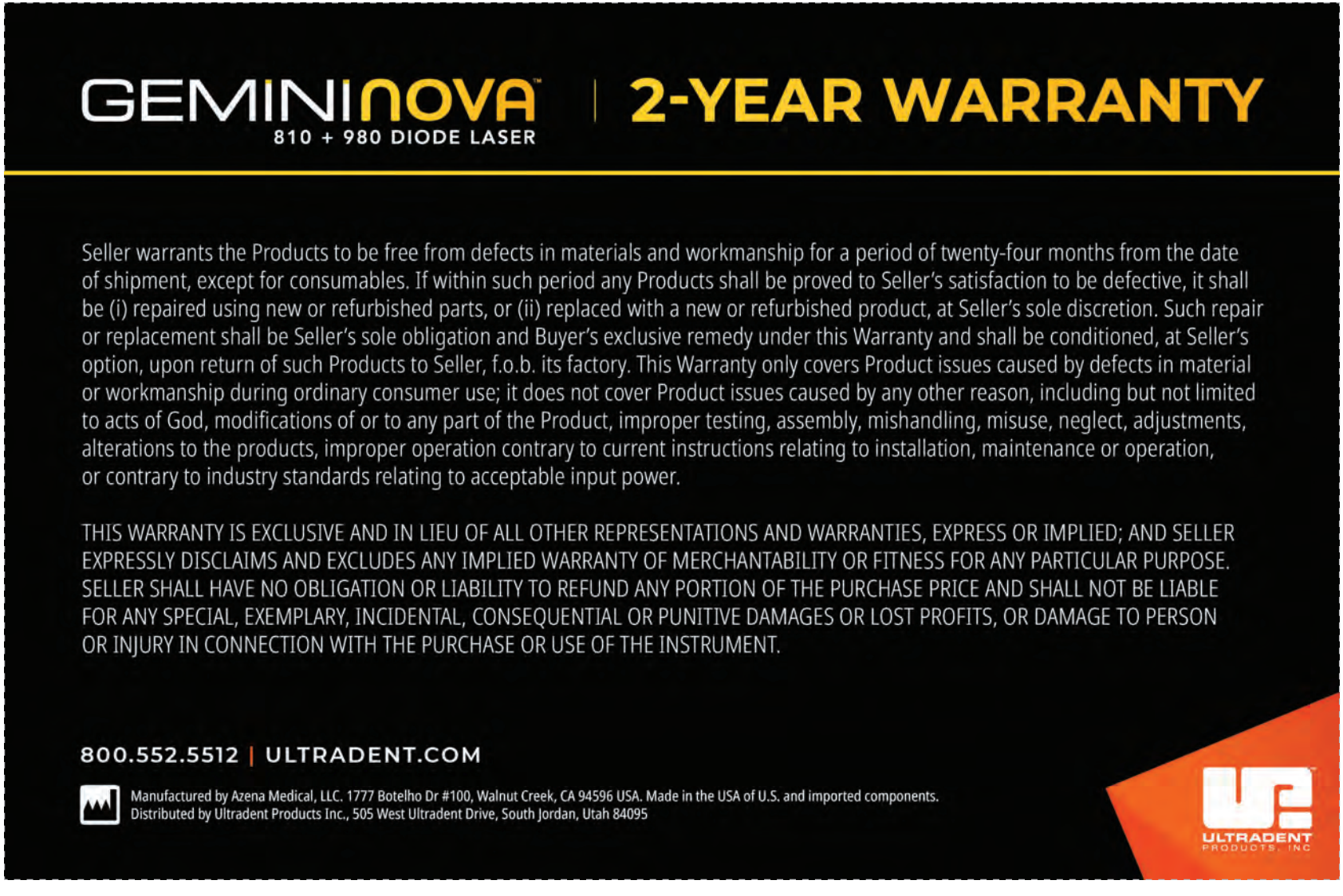
CHARGING PORT



LASER APERTURE

WARRANTY

Your Gemini Nova system comes with a 2-year factory warranty. Your warranty certificates can be downloaded by accessing your **dashboard** page at dashboard.geminilaser.com or under the warranty icon in the iOS and Android apps.



FAVORABLE CONDITIONS CHECKLIST

- Proper eye protection is fitted to clinician and patient, and lenses are clean
- Medical history of the patient is reviewed, and contraindications ruled out
  Refer to the User Manual for the complete list of contraindications
- Verify battery charge is sufficient for procedure
- Treatment room has proper laser safety signage displayed
- Correct procedure tip selected: **Initiated Fiber Tip** for surgical or incision procedures, **Uninitiated Tip** for non-surgical decontamination or hygiene use, or **PBM Adapters** for pain management procedures
- Disposable Fiber Tip attached securely and inspected
- 25 mm PBM Spacer for 25 mm PBM Adapter is being used
- Light Adapter is attached to a PBM Adapter when a PBM Adapter is being used
- Single-use tips, PBM Light Adapters, and 25 mm PBM Spacers are cleaned with alcohol per the User Manual and discarded after use
- Patient's treatment site is clean
- Proper barrier sleeve is being used

NOTES

NOTES

NOTES

GEMINI NOVA™

810 + 980 DIODE LASER

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Manufactured by Azena Medical, LLC. 1777 Botelho Drive, Suite 100, Walnut Creek, CA 94596 USA. Made in the USA of U.S. and imported components.
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