ALAN
Dental Equipment

Dental Diode Laser Wireless Pen

810nm ±15nm

1 Introduction

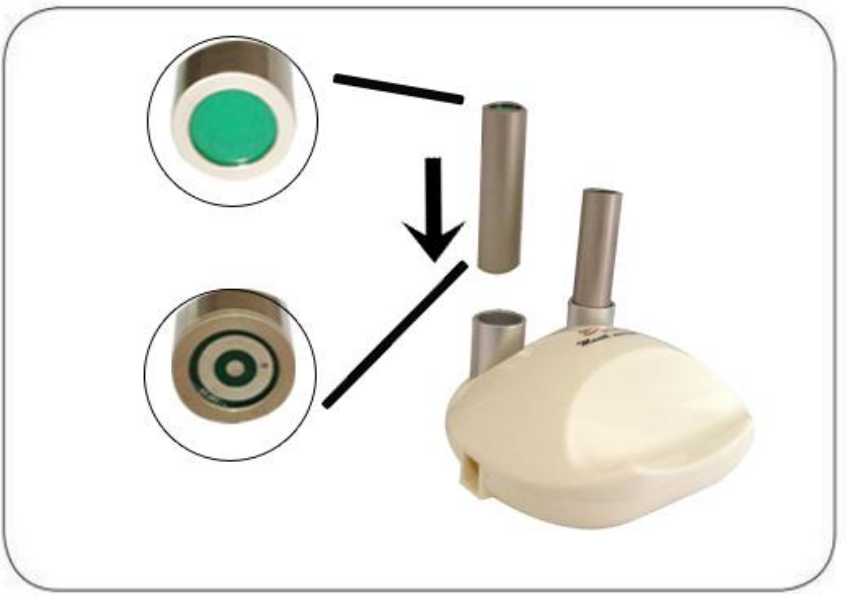
1.1 DESCRIPTION

The k*Laser dental soft tissue laser is surgical device designed for a wide variety of dental soft tissue procedures. The k*Laser uses a solid state laser diode as a source of invisible infrared radiation. The energy is delivered to the treatment site via the fiber Tip, a single -use fiber optic tip assembly. Several types of fiber Tips are available for use with the K*Laser to perform different procedures.

The K*Laser system consists of two elements:

The K*Laser Handpiece, that contains the laser diode, the replaceable fiber optic fiber Tip, removable cover with integrated finger grip, a main body with control electronics, integrated selector switch, organic LED(OLED)display, and rechargeable battery. The K*Laser Handpiece delivers laser energy, under user control , to the treatment site.

The K*Laser Charging Station is used for charging and storing the K*Laser and replacement batteries. The K*Laser and discharged batteries are placed in receptacles in the charging station where they are automatically recharged. Up to two batteries with or without main bodies attached may be charged at one time. The Charging Station contains two charging indicator lights located on the top panel of the charger. There is one indicator for each of the battery receptacles at the top of the unit. A green light indicates that the Battery is charging. The charging station is powered by a low voltage power supply that connects at the left of the unit.



1.2 INDICATIONS FOR USE

Dental Soft Tissue Indications: Incision,excision,vaporization,ablation and coagulation of oral soft tissues including marginal and inter-dental gingival and epithelial lining of free gingiva and the following specific indication:

.Excisional and incisional biopsies
.Exposure of unerupted teeth
.Fibroma removal
.Frenectomy
.Frenotomy
.Gingival troughing for crown impressions
.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
.Soft tissue crown lengthening
.Treatment of canker sores,herpetic and aphthous ulcers of the oral mucosa
.Tissue retraction for impression
.Vestibuloplasty

Laser periodontal procedures,including:
.Laser soft tissue curettage
.Laser removal of diseased,infected, inflamed and necrosed soft tissue within the periodontal pocket
.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, probing depth,attachment loss and tooth mobility).

1.3CONTRAINDICATIONS

All clinical procedures performed with the K*Laser must be subjected to the same clinical judgment and care as with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. 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, and immune system deficiency, or any medical conditions or medications that my contraindicate use of certain light/laser type sources associated with this device. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

2 Precautions and Warnings

2.1 CLINICAL

CLINICAL USE: Use your clinical judgment to determine all aspects of treatment including, but not limited to, the laser treatment protocol, technique, power settings, pulse duration and pulse interval settings, mode of operation as well as the tip type and other procedural requirements. Always start treatment at the lowest power settings for that specific indication and increase as required. Closely observe and monitor clinical effects and use your judgment to determine clinical parameters and approach for the treatment. Make appropriate power and settings and adjustments to compensate for varying tissue compositions, density and thickness.

Cutting with the K*laser is a thermal process and any transfer or accumulation of heat into adjacent structures may results in a burn and tissue damage. Always start treatment at the lowest power for the specific indication and increase as required. Be aware of the underlying and adjacent structures such as nerves and blood vessels when cutting with this device. Do not direct laser energy towards hard tissues such as tooth or bone or any metallic dental material restorations. Do not direct energy towards metallic restorations, cements or other dental materials. Exercise extreme caution when using this laser inside the pocket, 3rd molar sockets, channels and other openings where visibility is limited.

Anesthesia:

When treating soft tissue, anesthesia may not be necessary: patients should be closely monitored for signs of pain or discomfort at all times. If such signs are present, adjust settings, apply anesthesia, or cease treatment if required.

TIP BREAKAGE: Use a bite block to prevent accidental biting and breakage of the tip: use high-speed suction to prevent patient inadvertently swallowing a broken tip and choking.

K*laser WINDOW: Check and clean the protective window of the fiber optics shaft with a cotton swab moistened with isopropyl alcohol.

CAUTION: Failure to check and clean the window will lead to reduced optical power efficiency and permanent damage to the system.

2.2 LASER SAFETY

DANGER: Do not look directly into the beam or at specular reflections. Never direct or point the beam at anyone's eyes.

WARNING: Do not use this device if you suspect it is function improperly or other than described herein.

CAUTION: All persons present in the operatory must wear protective laser eyewear for the laser wavelength of 980nm.

CAUTION: Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. Laser beam reflections from these surfaces create a potential hazard.

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

2.3 ELECTRICAL SAFETY

CAUTION: Use only the power supplies and power cords/plug sets furnished with the laser device. The use of any other power supplies or cords may create hazardous conditions and may damage the device.

CAUTION: Plug the power supply into a grounded receptacle only. Connection to an ungrounded receptacle may create hazardous conditions.

2.4 FIRE SAFETY

DANGER: Do not operate this device in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen (O2) should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfection should be allowed to evaporate before laser is used. Attention should also be draw to the danger of ignition of endogenous gases.

2.5 CLEANING AND STERILIZATION

WARING: The single use Tips are supplied non-sterilize and must be sterilized before use. The cover is another component that requires sterilization.

2.6 PERSONAL PROTECTIVE EQUIPMENT

PROTECTIVE EYEWEAR REQUIED: Doctor, patient , assistant and all others inside the operatory must wear appropriate laser eyewear protection for the laser wavelength of 940 nm. Periodically inspect laser eyewear for pitting and cracking.

LASER PLUME: Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue. Use high speed suction and clinical masks for protection at all times during the laser procedure.

3 Installation

3.1 UNPACKING

Carefully unpack the shipping container and inspect the contents. If any parts are damaged or missing, contact us please.

Inside the shipping container you will find the following items:

Description	QTY
Charging Station	**1**
Power Supply	**1**
Main Body	**1**
Cover	**1**
Tip	**20**
Cover Grips	**1**
Tip Initiation Blocks	**2**
Rechargeable Battery	**2**
Laser Safety Glasses	**2**
Cleaning Kit	**2**
User Manual	**1**

3.2 CLEANING AND STERILIZATION BEFORE USE ON PATIENTS

The laser and accessories are provided non-sterile. Cleaning and sterilization of accessories and components that come in contact with open tissue is required prior to use on patients.

3.3 BATTERY CHARGING

You must charge the batteries before using the device.

Plug in the charging station power supply to an AC power receptacle and

connect it to the charging station. Place the charging station on a surface where it will not be disturbed or come in contact with liquids or contaminants.

Place the batteries' Contact PCB faces down, in any one of the battery charging receptacles at the top of the charging station. Laser batters have contacts on both ends and allow placement into the receptacle in contact PCB face down. The batteries will connect automatically to the charging contacts when inserted, and the charging indicator will be on to indicate that the charging has started. If the indicator LED is off, the battery is already charged an is ready for use. Attaching the main body to the battery is optional, but not required to charge a battery.

The battery charging indicator on the top of the charger will display the charge condition of each of the batteries placed in the charger. If no battery is installed, the charging indicator will be off.
Allow the batteries to charge for a minimum of two hours before first use. If the battery has been charging for more than two hours and the indicator has not turned off, the battery might be damaged any may need to be replaced. When the battery charging indicator turns off, the battery is fully charged and you may prepare the device for use.
NOTE: Charge spare batteries for a minimum of 2 hours before use.

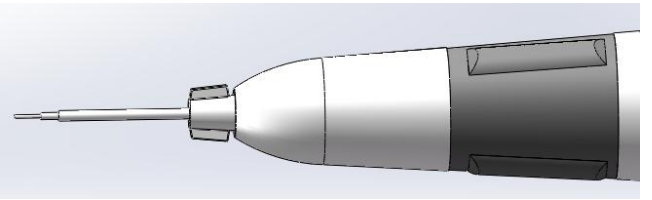
3.4 BATTERY INSTALLATION

Slide a fully charged battery assembly into the socket at the end of the main body of the K*laser, a magnet inside the main body will grip and hold the battery in place. (Battery assemblies have contacts on one end, contact PCB face the body). To remove a battery, gently pull the battery from the socket until the magnet releases the battery assembly.

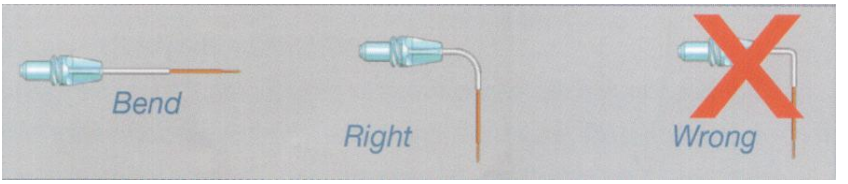
3.5ATTACHING TIP

To install a fiber TIP, slide a sterile cover onto the main body. Make sure cover is properly oriented and first snug against the button on the main body.

Insert a sterile tip into the open end of the cover. Tighten the tip by turning clockwise completely. Once installed, verify the tip appears to extend straight from the cover. If it appears angled, remove and re-install the tip until it appears straight.



Once properly installed, you may bend the metal cannula against the finger according to the procedure requirements.



CAUTION: Do not bend the tip at a sharp angel – the tip may break.

4 OPERATING INSTRUCTIONS

4.1 PERSONAL PROTECTIVE EQUIPMENT

PROTECTIVE EYEWEAR REQUIRED: Doctor, patient, assistant and all others inside the operatory must wear appropriate laser eyewear protection for the laser wavelength of 980 nm. Periodically inspect laser eyewear for pitting and cracking.

LASER PLUME: Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue. Use high speed suction and clinical masks for protection at all times during the laser procedure.

4.2 PREPARATION FOR USE

Before using, assure that the following conditions have been met.

.The laser charging station power supply is plugged into working AC power receptacle, and at least on battery is connected to the charging station and charged for at least 2 hours.

.The laser cover has been sterilized using the sterilization the sterilization instruction.

.The laser has been assembled, including the cover and fully charged battery assembly.

.A tip appropriate for the planned procedure has been installed in the laser cover.

4.3 STARTING THE LASER

Turn on the laser by installing the battery.

NOTE: To avoid the ERROR message. Do not hold the handpiece over the rubber finger grip area at any time in STANBY mode. If an error message occurs, simply remove your fingers from the rubber grip and wait until error message is cleared.

Safety operation of laser electronic devices requires prevention of the unauthorized use of the devices. An electronic key is implemented in the laser for purpose, when " PLEASE ENTER KEY" appears, there is progression bar shown for 3 seconds. Triple check the selector switch (press in three times, quickly) to advance to the next screen. (procedure menu). If key is not entered , system will rest with welcome screen shown. To get back to the "PLEASE ENTER KEY " screen , press the selector switch once.

4.4 INITIAL SELECTION OF A PROCEDURE

The select procedure screen will appear once the key is properly entered.
Once can scroll through twelve preset procedures. To select preset procedures.
To select a preset procedure, slide up or down through the selected desired procedure.
When you have selected a procedure by pressing the selector switch , the tip initiation screen will appear with the preset values for the operation : 1.4 W continuous or CW mode.
After two seconds the system will enter the Ready mode and the laser will be ready for firing by pressing on the rubber grip to initiate the tip. After completing the initiation of the tip, press down the selector switch to start use with the preset.

4.5 SYSTEM MODES

STANDBY MODE: For all operation leading up to the firing of the laser, the system has remained in STANDBY MODE (as noted by the amber LED in the display) In STANDBY MODE , the user has the ability to select new procedure, modify settings for the procedure, and make any other changes necessary , In this mode, the laser is disabled from accidental firing.

READY MODE: When a procedure is selected or when you have made any needed adjustment and are ready to perform a procedure, place the system into READY mode, by pressing down the selector switch. When the laser is ready mode, the led light will be green. Only in this mode is the red aiming beam activated and the laser can be fired, when in ready mode , you may adjust the power only . In order to save modified settings to the pre-set procedure press in and hold selector switch for 1.5 seconds, screen saved will indicate that modifications are saved to the current procedure name. You may ensure that all safety procedure, press in and hold the selector switch for 1.5 seconds, screen saved will indicate that modifications are saved to current procedure name. You must ensure that all safety precautions have been followed prior to entering ready mode.

4.6 FIRING THE LASER

EMERGENCY STOP: To immediately stop laser emission, pull the battery from the K*laser main body.

NOTE: Most procedures require tip initiation before using the K*laser. For those procedures that require tip initiation, you must complete the tip initiation steps before using the K*laser in a procedure on a patient. If tip initiation is not required, or if it has been already initiated, press the selector to bypass this operation.

1. Assure that laser has an tip installed that is appropriate for the planned procedure.
2. Assure that all personnel in the room we wearing laser protective eyewear.
3. After the user enters ready mode , the led on the laser will turn green, the red aiming beam shall also turn on at this time. The laser is now ready to fire.
4. Prior to firing, verify that the tip is installed correctly into the laser cover by shining the red aiming beam onto a bright surface such as a white table top. Ensure that the aiming beam image appears as in the example below:

When the tip is straight , the aiming beam will look like a circle, outlining the area where main laser power is applied.

When tip is bent, the aiming beam will look more like a spot, and the main laser power (invisible infrared radiation), will be applied in the middle area of the spot..

5. Using the aiming beam to position the tip over the target treatment area. Place the laser tip on the treatment area and press the finger switch (or gently squeeze the finger frip) on the laser. Actuation will occur when finger grip is pressed over the any one of the six ridges anywhere along the whole length.
6. The laser will immediately emit a beep tone, then after a 0.3 second delay, the laser will fire. Laser firing is indicated by a blinking green led light and pulsing beep sound.
7. Release the finger switch to stop laser emission.

4.7 TIP INITIATION INSTRUCTIONS

VERIFYING THE FIBER OPTIC TIP

Prior to initiating the fiber optic tip, verify that the tips is installed correctly into the K*laser cover (see previous section).

The Tip Initiation Aid screen appears as you enter Ready Model [1.4W/CW].You will need to have the Tip Initiation Block handy to perform this step.

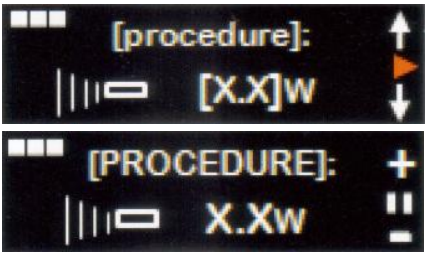
Touch the fiber optic tip to the surface of the tip initiation block, without firing, Fire the laser by gently squeezing the finger grip, allowing the tip to sink into the block. Pull the tip out when the metal cannula touches the block, still firing until just before the tip is out of the block. Fire the laser into the air once. You will see a white flash or a glowing tips. A glowing tip indicates that the tips is ready for use. During a procedure, there is a chance the fiber optic tip can lose its initiation. Re[eat the tip initiation. Repeat the tip initiation procedure if necessary.

NOTE: You must also autoclave the tips initiation block for every procedure to prevent cross contamination.

When you have finished the tip initiation, you are ready to begin your procedure on the patient. Press the Selector Switch to move to the Main Screen while keeping the system in Ready Mode.

4.8 MAIN SCREEN

The Main screen shows the current settings of the K*laser.



The top left corner of the screen displays the battery power level.

The top center of the screen displays the name of the currently selected procedure.

The Pulse Mode icon (lower left)indicates the currently selected pulse mode.

The Power icon (lower center)indicates the currently laser power setting (average output power)

While in ready mode, you may adjust the power level at any time during the procedure by toggling up(+)or down(-)the Selector Switch; however the pulse mode may not be changed in READY mode. You must return to STANDBY to change the pulse mode.

When your procedure is complete, press the Selector Switch on the K*laser to enter STANDBY mode. The LED on the K*laser will become amber. The system is now in STANDBY mode. You can modify and save new setting for the procedure by changing power values and pressing and holding the Selector Switch for approximately 1.5 seconds during READY mode.

NOTE: Pressing the finger switch for 60 seconds while firing will cause the laser to stop firing.

To continue firing, release the finger switch, and then press again.

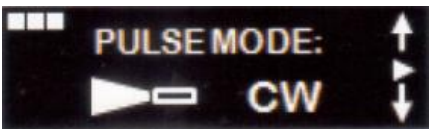
4.9 SELECTING A DIFFERENT PROCEDURE

While in the Main Screen, in Standby Mode, highlight the Procedure Name using the “UP” motion of the Selector Switch, and select by pressing in. Procedure screen will be displayed.

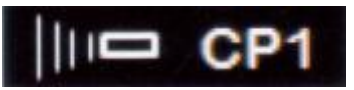
Scroll up or down to select new procedure, or select your own Custom setting. After new procedure is selected, system will go to Tip Initiation and Main screen in the Ready mode. If you need to continue modification of the preset, switch to Standby mode.

4.10 SELECTING A PULSE MODE

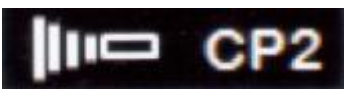
While in the Main Screen, in Standby mode, highlight and select the pulse mode icon to access the Pulse Mode menu, where one of three available pulse modes can be chosen by using the Selector Switch.



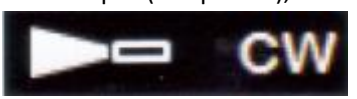
For a pulse that is 0.1ms on, followed by 0.2 ms off, select CP1.



For a pulse mode that is 1.0 ms on followed by 1.0 ms off, select CP2.



For continuous wave output (not pulsed), select CW.



Return to the main screen by selecting one of the available pulse modes.

4.11 ADJUSTING LASER POWER

If you wish to change the power setting, highlight and select the power icon in the Main Screen in Standby mode to display the Power Setting screen. The figure below does not show a power setting, but rather has “[X.X]W” to indicate the numeric format of the average power setting.

The Power Setting Screen displays the current laser output power setting in both Peak and Average Power values and allows you to adjust the power up or down.

Using the Selector Switch, scroll up to the “+”sign to increase the power; scroll down to the “-”sign to decrease the power. The power setting increases or decreases by one increment each time the Selector Switch is scrolled. When the power setting has reached its upper or lower limit, the value will remain at the limit.

Return to the main screen by pressing the Selector Switch in. You can also access the Settings Menu from this screen .For further details of the Settings Menu refer to the Maintenance section of this manual.

5 Clinical

5.1 PRESETS

K*laser has 10 pre-programmed setting and 3 custom settings for your selection. The three additional custom settings are blank for you to store preferred settings for daily use

	Preset Name	Tip Initiation	Peak Power	Average Power	Pulse Length	Pulse Interval
1	Gingivectomy	Yes	3.00W	1.00W	CP1(0.10ms）	0.20ms
2	Troughing	Yes	2.00W	1.00W	CP2(1.00ms）	1.00ms
3	Excision	Yes	1.80W	0.90W	CP2(1.00ms）	1.00ms
4	Frenectomy	Yes	2.00W	1.00W	CP2(1.00ms）	1.00ms
5	Implant Recovery	Yes	2.40W	1.20W	CP2(1.00ms）	1.00ms
6	Crown Lengthening	Yes	1.80W	0.90W	CP2(1.00ms）	1.00ms
7	Perio Pockets	Yes	1.60W	0.80W	CP2(1.00ms）	1.00ms
8	Exposure of Unerupted Teeth	Yes	1.80W	0.90W	CP2(1.00ms）	1.00ms
9	Aphthous Ulcers	No	0.70W	0.70W	CW	
10	Hemostasis	No	0.50W	0.50W	CW	
11	Endo(*）		0.10W	0.10W	CW	
12	Custom1(*)		0.10W	0.10W	CW	
13	Custom2(*)		0.10W	0.10W	CW	

（*）Minimum defaults provided for user setting of Endodontic Procedures such as Pulpotomy and Pulpotomy as an adjunct to root canal therapy.

The first 8 procedures listed are performed in contact mode. Aphthous Ulcer and Hemostasis require a defocused mode of application.

300 μm fiber optic Tips are recommended for removing less fibrous tissue types.400 μm fiber optic Tips are recommended for removing fibrous tissue and inside the pocket.

All of the procedures listed require tip initiation except for Hemostasis and Aphthous Ulcer.

For information on how to initiate the fiber optic Tips. please refer to Tip Initiation Instructions provided in Section 4.

6 Cleaning and Sterilization

6.1 CLEANING AND DISINFECTION

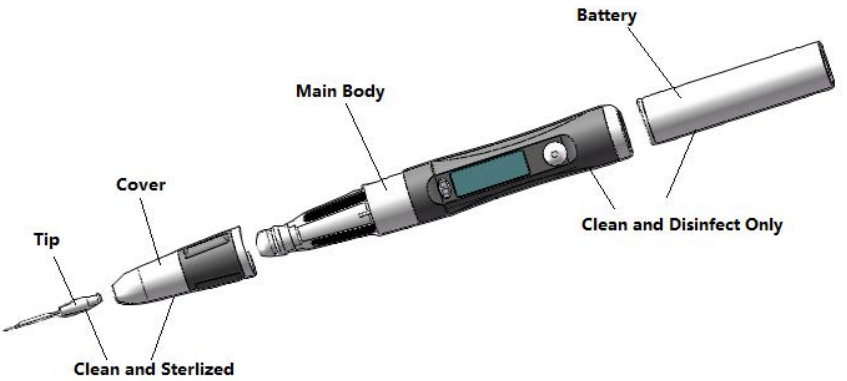
The k*laser must be cleaned prior to use on every patient. The K*laser is designed to be partially disassembled to permit application of disinfectant solution to surfaces that are exposed to contamination.

CAUTION: During use, the internal components of the K*laser under the cover can be hot to the touch. Allow the K*laser to cool for a few minutes before removing the cove for cleaning and sterilization.

To cleaning the K*laser main body and battery, perform the following steps in the indicated order:

1. Place the K*laser in STANDBY mode.
2. Wear protective gloves and eyewear when handling the contaminated main body and battery.
3. Remove the used from the cover(if present) and dispose it.
4. Remove the battery from the main body and set it aside.
5. Pull the K*laser cover forward and slide it off the body of the main body.
6. Wipe the main body cover, and the battery with cotton, gauze soaked in chemical disinfectant.
7. For additional disinfection, leave the components wrapped in the disinfection soaked gauze for 10 minutes.
8. Remove the soaked gauze and wipe the components dry with dry gauze.

To sterilize the cover, follow the instructions provided in the next section titled Sterilization.



6.2 STERILIZATION*

Before use, the Tip, cover and tip initiation Block are design to be sterilization an autoclave. To sterilize the Tip , cover, and tip initiation block perform the following steps in the indicated order:

1. Individually place the Tip, cover, and tip initiation block inside separate single wrap self-seal autoclave pouches.
2. Remove autoclave tray and place pouches on the tray.
3. Place the ray in the autoclave chamber and sterilize using the following: The recommended autoclave cycle for tip , cover, and tip initiation block is as follows:
   Temperature: 250℉(121℃)｜Pressure: 15psi(1 bar) ｜ Time cycle: 20 minutes
4. When the autoclave cycle is complete, remove the tray and let the fiber tip , cover, tip initiation block cool and dry. There are no specific requirements for the drying time. Drying of the cover and tip is suggested for better handling only.
5. The fiber tip, cover, tip initiation block are now ready for use.

When the cover has been sterilized, slide the cover the main body and push it toward the window gently until it “clicks” into place. Install the tip into the cover, connect the battery, and the K*laser is ready for use.

Although KSD medical, Inc, has validated the parameters for the recommended autoclave sterilization procedure, it is the responsibility of the user to properly validate his or her autoclave sterilization.
(*) Sterilization validation has been conducted for steam sterilization method at the recommended parameters of T=121℃, P=15psi, and t=20min. The sterilization assurance level for which testing was conducted was not less than 10^{-6} killed organisms in one half cycle.

6.3 DISPOSAL

TIP

Tips are designed to be used one time only. Tip must be sterilized prior to use. Proper tip disposal in a biohazard medical waste sharps container is required. Do not reprocess tip.

BATTERIES

Lithium ion batteries contain toxic materials and should not be disposed of in landfills or incinerators. Dispose of depleted batteries as directed by your local solid waste handling regulations. If you have questions or need advice about sage disposal of used batteries, ~~~~~~~

DEVICE AND PARTS

The K*laser is a medical device subject to regulations governing its disposal.

7 Maintenance

7.1 REGULAR MAINTENANCE

Do not use bleach or abrasive cleansers on any surfaces of the main body. Return the K*laser to charging station for recharging between procedures or when the low-battery indicator is illuminated.

Periodically check the laser aperture for contamination. If the aperture ontaminated, wipe with a cotton swab moistened with isopropyl alcohol until clean. The cover must be removed from the main body to be able to access the laser aperture for cleaning.

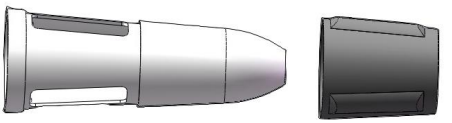
WARINING: Failure to clean the aperture when contaminated, will lead to reduced optical power efficiency and permanent damage to system.

WARINING: To prevent aperture contamination, please keep the tip plug or protective cover attached to handpiece when not in use.

7.2 K*laser COVER GRIP REPLACEMENT

Although the cover is designed to survive repeated autoclave sterilization cycles. It's rubber grip may become worn or damaged through repeated use. The grip has been designed to be replaceable by the user if it becomes worn or damaged. System is shipped with two additional grips for this purpose.

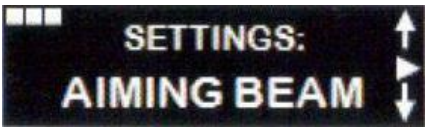
To replace the rubber grip, remove the K*over from the main body . slide the old grip off of the small end of the cover and slide a new rubber grip onto the same end with the large end of the grip first.



7.3 SYSTEM CONFIGURATION

The settings menu screen allows you to adjust the settings of the user interface.

The settings menu is entered by pressing and holding down the selector switch for approximately 1.5 seconds when in the main screen while in standby mode.



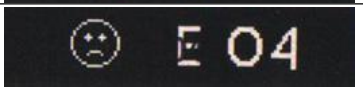
8 Troubleshooting and Repairs

8.1 TROUBLESHOOTING

The following tables list warning and error messages, which indicate conditions that can usually be remedied by the user. If the recommended corrective action does not solve the problem and the message persists, restart the K*laser by removing the battery, waiting 5 seconds, and re-installing the battery.

8.2WARNING AND ERROR MESSAGES

The Warning and Error screens display codes and recommended corrective actions.If a Warning or Error message is displayed, perform the indicated corrective action.

Error/Warning Code	Error/Warning Description	Action
	**E01** Temperature Sensor open(check at start up)	Call Service
	E02 Temperature Sensor short(check at start up)	Call Service
	E03Laser system overheated	Wait to cool off
	E04Laser current is outside of allowed range	Call Service
	E05Finger switch actuated in standby mode	Release Finger Switch
	E06 Up/down/select switch stuck	Call Service
	E07 Check Sum Error (memory integrity)	Call Service
	W01 Warning temperature	Wait to cool off
	W02 Warning low battery level	Battery replacement may be necessary

8.3 REPAIRS

There are no user-serviceable parts in the K*laser. Do not open any device or attempt to make repairs. Doing so may expose the user to unsafe voltages, high temperatures, or laser energy and may void the product's limited warranty.

9 Calibration

9.1 LASER CALIBRATION

KSD recommends that a laser calibration be performed every 12 months to ensure that the laser output power corresponds to displayed power. Annual calibration can be performed at KSD Service Center.

10 Specifications

Classifications	
FDA Device Classification	79 GEX Class II Medical Device
CDRH Laser Classification	Class IV(4) Laser
Electrical Safety Classification	CISPR 11 Class 1 (Type B Applied Part)
Dimensions	
Charging Station(WxDxH)	4.72''x3.54''x1.89''/12cmx9cmx4.8cm
K*laser Handpiece, with surgical tip and battery attach(LxDia)	7.6''x0.74''/19.2cmx1.9cm
Power Supply(WxDxH）	4.0''x3.2''x1.3''/10cmx8cmx3.2cm
Weight	
K*laser Complete System	1.21lbs.(0.56kg)
K*laser Charging Station	0.60lbs.(0.27kg)
K*laser with Battery attached	0.31lbs.(0.14kg)
K*laser Charging Station Power Supply and cord /plug set	0.22lbs.(0.10kg)
Electrical	
Voltage(to power supply)	100-230VAC
Amperage(max)	0.8A
Frequency	50-60Hz
Battery	Lithium Ion 3.7V 650mAh
Recharge Time(fully discharged)	2 hours
Safety	Discharge over current sensor and resettable circuit breaker

(continued)

Laser	
Medium	**AlGanlnAs**
Wavelength	**980nm±15nm**
Output power	**0-3.0W MaxCW/0-5.0W Peak Power(Pulse model)**
Power accuracy	**±20%**
Pulse Duration8	**Continuous 丨 0.1ms 丨 1ms**
Pulse Interval	**---------- 丨 0.2ms 丨 1ms**
Aiming Beam	**Laser diode,max2mW(from 200 μ m tip), 650±10nm,Class 3B**
N.O.H.D	**2.61m**
Environmental	
Temperature-operating	**68° -77° F(20° -25° C)**
Temperature-storage	**59° -90° F(15° -35° C)**
Humidity-operating	**15-95% non-condensing**
Humidity-storage	**10-70% non-condensing**
Altitude-operating	**max.10,000ft(3048m)**
Altitude-storage	**Max.12,000ft(3658m)**

11 Limited Warranty

(a)Seller warrants the goods and parts which are of its manufactured and shipped hereunder to be free defects in material and workmanship for thirty-six (36) months from shipment(don't include batteries).

(b)This warranty is the only warranty made by seller with respect to the goods delivered hereunder and no representative or person is authorized to assume on Seller's behalf, any obligations or liabilities beyond this warranty in connection with the sale of Seller's goods. This warranty is made to the original purchase only at the original location and is non-transferable, and may only be modified or amended by a written instrument signed by a duly authorized office of the seller. Major sub-systems manufactured by other firms, but integrated into Seller's system are covered by the original manufactured's warranty. Goods or parts which are replaced or repaired under this warranty are warranted for 90 days after replacement/repair.

(c)All accessories used with K*laser lasers must be manufactured by or certified in writing by K*laser. Use of non-authorized accessories will void the warranty, all service contracts and all liability to K*laser.

(d)Seller's sole and exclusive liability and the Buyer's sole and EXCLUSIVE REMEDY under this warranty shall be, at Seller's election, the repair or replacement of goods, only if Seller is promptly notified by buyer upon discovery of the defects and the Seller's examination of such goods discloses to Seller's satisfaction that such defects actually exist and the goods have not been(i)repaired, worked on, or altered to affect the stability, reliability, or proper operation of such goods;(ii)subject to misuse, negligence or accident, or (iii) connected, installed, used or adjusted otherwise than in accordance with the instructions furnished by Seller.

Replacement parts may be new or equivalent to new. Seller, at its sole discretion, may repair or replace any component or hardware product that manifests a defect in materials or workmanship during the Limited Warranty Period.

(e)All goods which Buyer considers defective shall be returned to Seller's office, transportation costs prepaid and borne by Buyer (unless otherwise agreed to in writing).The risk of loss of goods shipped or delivered to Seller's plan to repair or replacement will be borne by Buyer.

(f)If it is found that Seller's Product has been returned without cause and is still serviceable, Buyer will be notified and the product returned at Buyer's expense ;in addition, a charge for testing and examination may, in Seller's sole discretion, be made on Products so returned.

Please keep the product ID.

Warranty service can only be effected with product ID number.

After Sales Service Card

Buying Commodity:	
Model No.:	
Product ID:	
Buying Date:	
ADD:	
Zip Code:	
TEL:	
Email:	
Ask for Service:	

Email and add aftersales for register users.

Please fill the above chart for register or asking for help.