Cyber TM

Thulium Laser System

Value analysis*

AND PRODUCT
INFORMATION
PACKET

COOK® MEDICAL

PRECISE CUTTING WITHOUT AFFECTING SURROUNDING TISSUE
HIGHLY CUSTOMIZABLE TO PATIENT NEEDS AND SURGEON PREFERENCES

* Prepared in the context for value analysis committees in a hospital setting

Disclaimer: The information provided herein reflects Cook's analysis of the procedure(s) and/or device(s), based upon the instructions for use (IFU), from sources that may include, but are not limited to, published journal articles, data on file with the manufacturer, physician and consultant input, the CPT coding system, and Medicare payment systems. This analysis is provided for general information purposes only, and Cook does not warrant or assume any liability or legal responsibility for this information. The entity assessing the product is solely responsible for determining the accurate cost of treatment at its site and the codes assigned to the services and items in the medical record. Each entity should use its own economic data to fully assess the assumptions and analysis stated herein.

Contents

Product overview

The thulium YAG laser was introduced for treatment of benign prostatic hyperplasia (BPH) in 2005 but it is still a relatively new technology in the United States.[1-6] The first published reports discussing use of this laser in the US began in 2010 with two studies evaluating safety and efficacy.[2,6]

The Cyber TM Thulium Laser System is designed to provide value.

Hospitals	Thulium laser procedures may have shorter hospitalization times[3-5,7] with fewer short-term complications and lower complication rates[8,9] compared to monopolar and bipolar transurethral resection of the prostate (TURP), which may reduce costs associated with retreatments and rehospitalization.
Healthcare providers	Thulium YAG laser procedures show improved hemostasis, thus reducing the irrigation volume required,[3, 5] and allowing for better visualization[5] compared to monopolar and bipolar transurethral resection of the prostate (TURP) and open prostatectomy (OP), and potentially reducing the risk of needing blood transfusion.[3, 4] These procedures may be performed with continued anticoagulation regimen in most cases.[1,2,6,9] Thulium laser procedures may reduce the need for postoperative pain medications[10] and can potentially be performed in patients who are overweight,[11] have prostates ranging from 30–130 g,[1, 6, 9] or have co-morbidities (i.e., myocardial infarction, diabetes mellitus).[2] The utilization of reusable laser fibers may also result in cost savings.[1,5,7,9]
Patients	Thulium YAG laser procedures may have shorter hospitalization times and catheterization times[3-5,7] compared to monopolar and bipolar transurethral resection of the prostate (TURP) and open prostatectomy, potentially allowing for improved patient comfort following the operation and a reduced need for pain medications,[10] and thulium laser procedures preserve sexual function in over 50% of patients.[12,13]
Payers	Shorter catheterization time, shorter hospital stays, decreased risk of bleeding, and lower complication rates may also help reduce the cost of these laser procedures compared to monopolar and bipolar transurethral resection of the prostate (TURP) and open prostatectomy.[1,3-5,7,9]

The key considerations for your value analysis include:

1. **The product**

   Procedures for BPH utilizing the thulium laser may be performed in medically complex[1] patients, with continued anticoagulation regimen, and with prostates ranging from 30–130 g. In addition, hospital stay, catheterization time, blood loss, and complication rates may be improved for thulium procedures compared to monopolar or bipolar TURP or open prostatectomy.[1,3-5,7,9]

   Additional product features include the following:

   - The thulium laser operates at a 2010 nm wavelength (close to the peak absorption wavelength of water at 1940 nm), which means it provides excellent tissue vaporization and hemostasis with a higher tissue ablation rate and lower tissue penetration depth when used at 70 W compared to the 80 W greenlight kalium titanyl phosphate (KTP) laser that operates at a wavelength of 532 nm (close to the peak absorption wavelength of blood), allowing for briefer operative time with more precise tissue incision compared to the 80 W greenlight KTP laser.[14]
   - The thulium laser can be used with reusable bare-ended and side-firing fibers, allowing it to be used in more varied applications including tissue vaporization, vaporesection, enucleation, incision of the bladder neck, and treatment of urethral stenosis.[14]

2. **The financial impact**

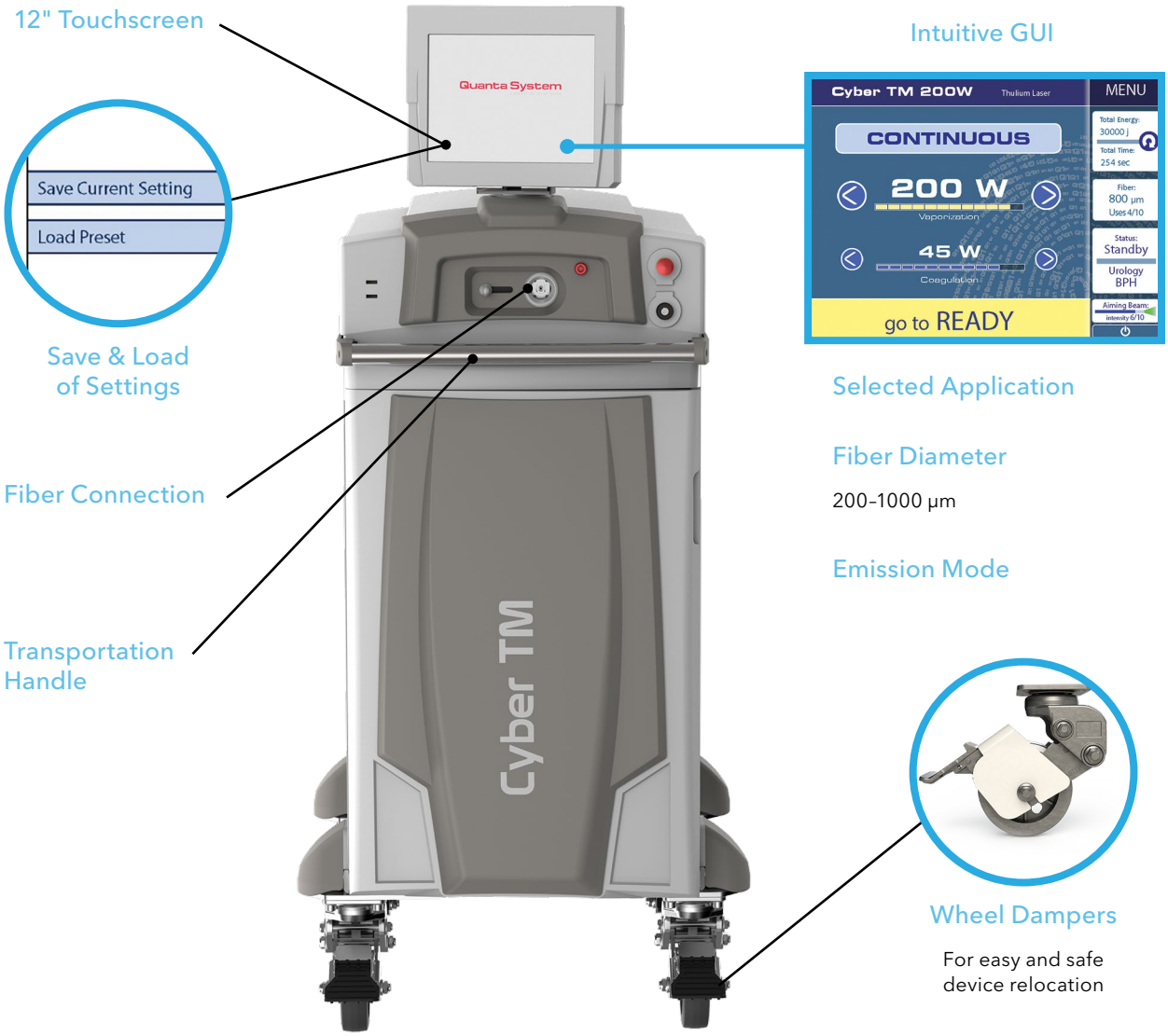
   Shorter catheterization time, shorter hospitalization time, lower complication rates, reduced need for pain medications, and the utilization of reusable laser fibers can potentially reduce costs for the patient, the payer, and the hospital.[1,3-5,7,9]

Product information

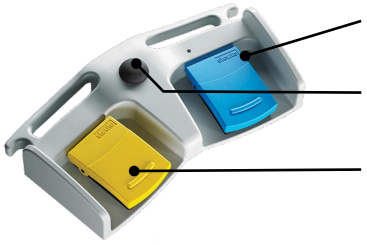
Product design

The Cyber TM laser system is a diode-pumped, solid state Tm:YAG laser. The laser system delivers invisible 2010 nm laser radiation. A range of fibers are available for different applications: a side-firing fiber with 600 µm core diameter and bare optical fibers ranging from 200 to 1000 µm core diameter. Each fiber has a microchip that manages the recognition and the expiration of the fibers themselves. The laser system also consists of an air-cooled internal mechanism, ensuring safe operating temperatures with no external water connections. Laser energy emission and system status selection is activated through a touchscreen feature located in the laser console.

The Cyber TM Thulium laser system includes a 12-inch touchscreen and wheel dampers and a transportation handle for easy and safe device relocation and transportation. The system comes with save and load settings, selected applications, and a fiber connection for fiber diameters of 200–1000 µm; and the emission mode can be continuous or pulsed. The double footswitch also enables an immediate switch from cutting to coagulation mode, without bothersome interruptions for settings readjustment.



DOUBLE FOOTSWITCH



The double footswitch enables immediate switch from cutting to coagulation mode, without bothersome interruptions for settings readjustments.

Product intended use

The Cyber TM Thulium Laser System is intended for endourological applications for treating lower urinary tract symptoms, such as benign prostatic hyperplasia (BPH). Additional uses are highlighted in the user manual.

Value analysis

Overview

Using **cost, quality,** and **clinical outcomes** to make evidence-based decisions

Healthcare professionals understand the importance of a high-quality product that makes economic sense. In the ever-changing healthcare landscape, healthcare providers must not only focus on the best clinical option for their patients, but also the most cost-effective option. They can no longer focus solely on the individual procedure but must also be mindful of the total care of that patient, including follow-up, return to work, and overall quality of life.

This value analysis for the Cyber TM Thulium Laser System focuses on the variables that can be controlled, laser choice, allowing healthcare providers to make evidence-based decisions regarding how to treat their patients.

Hospitals

Thulium laser procedures may have shorter hospitalization times[3-5, 7] with fewer short-term complications and lower complication rates[8,9] compared to monopolar and bipolar transurethral resection of the prostate (TURP), which may reduce costs associated with retreatments and rehospitalization.

Healthcare providers:

Thulium YAG laser procedures show improved hemostasis, thus reducing the irrigation volume required,[3,5] and allowing for better visualization[5] compared to monopolar and bipolar transurethral resection of the prostate (TURP) and open prostatectomy, and potentially reducing the risk of needing blood transfusion.[3,4] These procedures they may be performed with continued anticoagulation regimen in most cases.[1,2,6,9] Thulium laser procedures may reduce the need for postoperative pain medications[10] and can potentially be performed in patients who are overweight,[11] have prostates ranging from 30–130 g,[1,6,9] or have co-morbidities (i.e., myocardial infarction, diabetes mellitus).[2] The utilization of reusable laser fibers may also result in cost savings.[1,5,7,9]

Patients

Thulium YAG laser procedures may have shorter hospitalization times and catheterization times[3-5,7] compared to monopolar and bipolar transurethral resection of the prostate (TURP) and open prostatectomy, potentially allowing for improved patient comfort following the operation and a reduced need for pain medications,[10] and thulium laser procedures preserve sexual function in over 50% of patients.[12,13]

Payers

Shorter catheterization time, shorter hospital stays, decreased risk of bleeding, and lower complication rates may also help reduce the cost of these laser procedures compared to monopolar and bipolar transurethral resection of the prostate (TURP) and open prostatectomy.[1, 3-5, 7, 9]

Thulium laser and related procedures may pose additional risks for patients. For the list of potential adverse events associated with thulium laser procedures, please refer to the Instructions for Use (IFU).

Economic value analysis

In the treatment of benign prostatic hyperplasia (BPH), the duration of hospitalization, the speed of patient recovery, and effective hemostasis are all significant factors in determining a product's economic value. For example, a transurethral resection of the prostate (TURP) procedure might cost less compared to laser acquisition costs are factored in, but a TURP procedure requires a longer hospitalization and longer recovery time and involves more potential complications, when compared to thulium YAG laser procedures.[3,5,8,9] Thus, the overall cost of care must be considered as part of the value analysis.

Higher reintervention rates for TURP procedures may have negative consequences, including increasing the overall cost to treat patients.

- The weighted average cost of a **hospital outpatient** BPH laser procedure without complications has been estimated at **$4,465.55**.[a]
- The weighted average cost of a **hospital outpatient** TURP procedure without complications has been estimated at **$4,404.81.**[b]
- Prostate removal procedures (laser and/or TURP) are reimbursed in the hospital outpatient setting on average at **$4,505.89**[a] by Medicare. Thus, the average reimbursement rate is less than the average weighted cost of the laser procedure and only slightly more than TURP.

Assume a hospital performs 150 benign prostatic hyperplasia (BPH) procedures per year.

	Cyber TM Thulium Laser System	TURP
Estimated weighted average per procedure cost	$4,176.72[c]	$4,404.81[d]
Estimated laser fiber cost per fiber	$303.00	$0.00
Estimated average annual cost	$671,957.62	$660,721.50
Estimated recurrence rates	1–1.5%	5-15%
Estimated cost if 1.5% of thulium procedures fail and 10% of TURP procedure fail	$10,079.36	$66,072.15
Estimated average annual cost, plus reinterventions	$682,036.99	$726,793.65
Estimated acquisition cost for thulium laser system and TURP generator	$180,000.00	$50,000.00
Estimated average total cost – year 1	$862,036.99	$776,793.65

Return on investment (150 cases per year)	Cyber TM Thulium Laser System	TURP	Savings
Year 1	$862,036.99	$776,793.65	($93,783.31)
Year 2	$682,036.99	$726,793.65	
Year 3	$682,036.99	$726,793.65	
Year 4	$682,036.99	$726,793.65	
Year 5	$682,036.99	$726,793.65	
Total cost	**$3,590,184.94**	**$3,683,968.25**	
Year 6	$682,036.99	$726,793.65	($317,566.61)
Year 7	$682,036.99	$726,793.65	
Year 8	$682,036.99	$726,793.65	
Year 9	$682,036.99	$726,793.65	
Year 10	$682,036.99	$726,793.65	
Total Cost	**$7,000,369.89**	**$7,317,936.50**	

Under these assumptions, a savings is potentially already recognized by year 3. By year 5, a savings of approximately $94,000 could be recognized, and by year 10, a savings of approximately $318,000 could be recognized.

NOTE: Eliminating days a patient must stay in the hospital may free up rooms and staff to focus on other, more severe treatment areas and/or patients.

For more information on this economic value analysis and to further understand the use of the of thulium laser system and fibers, please contact your local Cook representative.

a. The average Medicare reimbursement rate was calculated using CPT codes 52601, 52630, 52647, 52648, and 52649.

b. The procedure cost is the average geometric mean cost of CPT codes 52601 and 52630 for TURP and CPT codes 52647, 52648, and 52649 for thulium laser; from the CY2020 Hospital Outpatient Prospective Payment System (OPPS) Final Rule (Medicare program: changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. Centers for Medicare & Medicaid Services Web site: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientpps/cms-1753-fc. Accessed November 22, 2021.

c. The estimated total hospitalization cost was calculated using the Medicare 2020 NFRM APC Offset File, using APC 5375. Centers for Medicare & Medicaid Services Web site: https://www.cms.gov/license/ama?file=/files/zip/2022-nfrm-opps-apc-offset-file.zip. Final amount was calculated by subtracting $288.83 from the total procedure cost for thulium, since fibers and device costs were added in. Thus leaving, $4,176.72 as the final procedure cost prior to thulium device costs being added back in.

d. The estimated total hospitalization cost was calculated using the Medicare 2020 NFRM APC Offset File, using APC 5375. Centers for Medicare & Medicaid Services Web site: https://www.cms.gov/license/ama?file=/files/zip/2022-nfrm-opps-apc-offset-file.zip. Final amount encompasses the device related portion which includes electrodes.

Preclinical data analysis

A study was performed on ex vivo porcine kidneys to compare continuous wave (CW) thulium laser tissue ablation at varied power outputs (30–70 W) to an 80 W kalium titanyl phosphate (KTP) greenlight laser and to simulated transurethral resection of the prostate (TURP). Conditions to simulate an in vivo setting (e.g., bleeding) were implemented in the study design.[14] Outcomes of interest included tissue ablation rate (change in the weight of tissue after 10 minutes of ablation), bleeding rate (change in swab weight after 60 seconds on bleeding surface), and coagulation depth as measured from histology. The thulium laser showed increased tissue ablation rate at increased power outputs, with a significantly greater ablation rate than the greenlight laser. Both lasers showed significantly lower bleeding rates compared to TURP. Thulium YAG laser had a similar depth of coagulation as TURP and significantly smaller zone of coagulation compared to greenlight.[14]

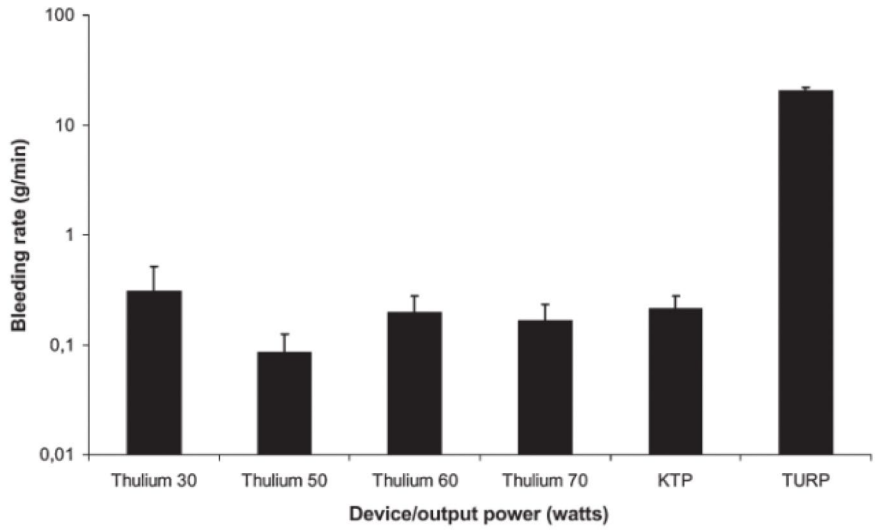


Figure 1*. "Bleeding rates of the CW thulium laser at various power output levels, compared to the 80 W KTP laser and TURP on a logarithmic scale. The thulium laser bleeding rate was reduced approximately 100-fold as compared to TURP ($P < 0.05$)."[14]

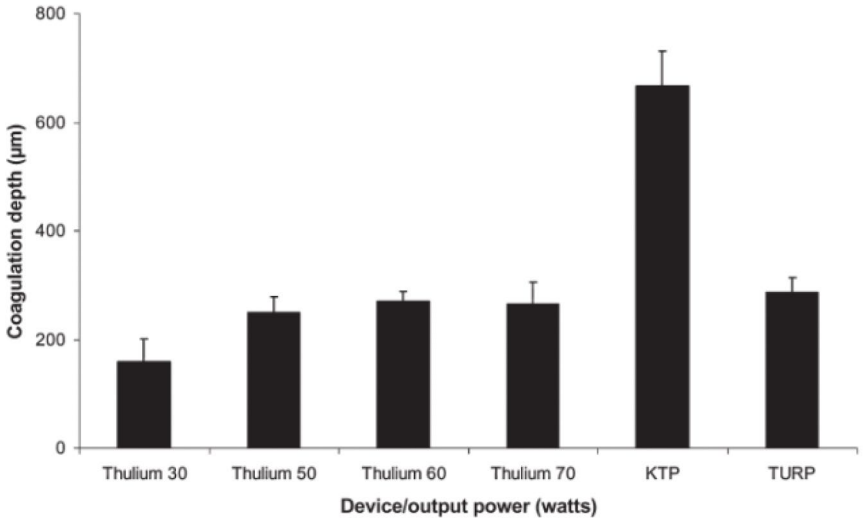


Figure 2*. "Comparison of coagulation zone depth achieved with the CW thulium laser at three different output power levels, the 80 W KTP laser, and TURP. The KTP laser displays a significantly deeper coagulation zone than TURP or the thulium laser ($P < 0.05$)."[14]

In this study, tissue ablation rate, bleeding rate, and coagulation depth were tested ex vivo for comparison between the thulium laser at varied power outputs, the KTP greenlight laser, and a benchtop simulation of TURP. With increasing power output, the tissue ablation rate improved for the thulium laser and the thulium laser was able to perform at a greater tissue ablation rate than the greenlight laser. The thulium laser showed a significant reduction in bleeding rate compared to TURP, supporting the conclusion that the thulium laser provides improved hemostasis compared to TURP. The thulium laser also was able to significantly reduce the bleeding rate but did not create an increased coagulation depth that is seen with the greenlight laser, demonstrating that there is less thermal tissue damage from the thulium laser with similar effectiveness in coagulation compared to the greenlight laser.[14]

*Figures reproduced with permission from the Journal of Endourology, 2008

Summary

BPH can be complicated, but laser choice does not have to be. The data referenced throughout this document can help healthcare providers make evidence-based decisions. By using this information, providers can determine whether the Cyber TM Thulium Laser System is an appropriate choice for their patients.

Hospitals

Thulium laser procedures may have shorter hospitalization times[3-5, 7] with fewer short-term complications and lower complication rates[8,9] compared to monopolar and bipolar transurethral resection of the prostate (TURP), which may reduce costs associated with retreatments and rehospitalization.

Healthcare providers

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The key considerations for your value analysis include:

The product

Procedures for BPH utilizing the thulium laser may be performed in medically complex[1] patients, with continued anticoagulation regimen, and with prostates ranging from 30–130 g. In addition, hospital stay, catheterization time, blood loss, and complication rates may be improved for thulium procedures compared to monopolar or bipolar TURP or open prostatectomy.[1,3-5,7,9]

Additional product features include the following:

- The thulium laser operates at a 2010 nm wavelength (close to the peak absorption wavelength of water at 1940 nm), which means it provides excellent tissue vaporization and hemostasis with a higher tissue

ablation rate and lower tissue penetration depth when used at 70 W compared to the 80 W greenlight kalium titanyl phosphate (KTP) laser that operates at a wavelength of 532 nm (close to the peak absorption wavelength of blood), allowing for briefer operative time with more precise tissue incision compared to the 80 W greenlight KTP laser.

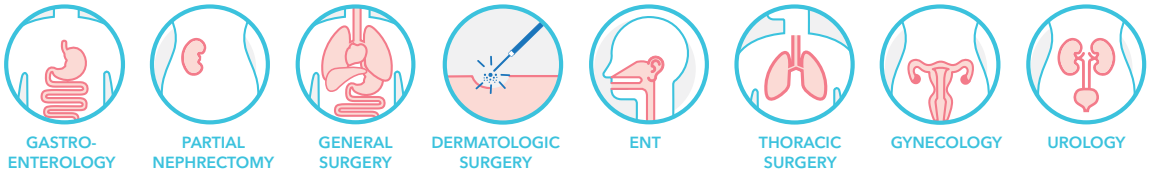
- The thulium laser can be used with reusable bare-ended and side-firing fibers, allowing it to be used in more varied applications including tissue vaporization, vaporesection, enucleation, incision of the bladder neck, and treatment of urethral stenosis.[14]

The financial impact

Shorter catheterization time, shorter hospitalization time, lower complication rates, reduced need for pain medications, and the utilization of reusable laser fibers can potentially reduce costs for the patient, the payer, and the hospital.[1,3-5,7,9]

Specialties impacted

Urology is the main intended use outlined in this document, but there are other specialties impacted. For a full list of these specialties please refer to the IFU.



Impact on patients

Because the thulium YAG laser procedures may have shorter hospitalization times and catheterization time,[3-5, 7] the patient may experience reduced discomfort following the operation and a reduced need for pain medications[10] compared to monopolar and bipolar transurethral resection of the prostate (TURP) and open prostatectomy, and thulium laser procedures preserve sexual function in over 50% of patients.[12, 13]

Additional references of interest: 8, 10, and 15–27.

Material management information

Order numbers and sizing

Order Number	Reference Part Number	Fiber Diameter µm	Usage
Cyber TM 200 Thulium Laser System			
G57981	CYBER-TM-200	N/A	N/A
Quanta Standard Surgical Laser Fibers			
G57961	OAF002011	200	Single Use
G57966	OAF702711	272	Single Use
G57968	OAF703611	365	Single Use
G57970	OAF005511	550	Single Use
G57972	OAF008011	800	Single Use
G57974	OAF009911	1000	Single Use
G57962	OAF002013	200	Reusable
G57967	OAF702713	272	Reusable
G57969	OAF703613	365	Reusable
G57971	OAF005513	550	Reusable
G57973	OAF008013	800	Reusable
G57975	OAF009913	1000	Reusable
Quanta Ball-Tip Surgical Laser Fiber			
G57965	OAF302711	272	Single Use
Quanta Side Fiber			
G58340	OAF506011	600	Single Use

If you like these Cook products, you may also be interested in these other offerings from Cook Medical: cookmedical.com/urology/quanta-overview/laser-overview/.

Product specifications

The Cyber TM Thulium Laser System is intended for endourological applications for treating lower urinary tract symptoms, such as benign prostatic hyperplasia (BPH). Additional uses are highlighted on the thulium product page.

System safety features

Cyber TM Thulium Laser System incorporates the following safety features:

- The laser will stop firing when the pressure is removed from the footswitch.
- An automatic circuit breaker shuts the system off in the event of an electrical overload.
- The laser provides an operating room door interlock connection, which much be set up by the hospital personnel.
- The key can only be removed when the key switch is in the OFF position.
- An on-board microprocessor continuously monitors the status of the system and displays messages on the video screen along with appropriate operator prompts.
- Laser energy cannot be emitted from the system unless a fiberoptic has been connected.
- Laser will go into ready mode when the READY button is touched.
- A continuous audible tone is heard when the surgical beam is activated (i.e., foot pedal is pressed).
- A small delay occurs before laser energy is emitted after the laser is placed in READY status.
- An emergency laser stop switch is available to disable the system immediately, in the case of an emergency situation.

Coding and reimbursement

For the most up-to-date information, please visit cookmedical.com/support/reimbursement/ and click the Urology tab under "Coding and Reimbursement Guides", then click Urology Laser Procedures 2022

FDA 510(k) clearance letter (or approval letter)

accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K131081

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 3, 2013

Quanta System Spa
% Mr. Maurizio Bianchi
Via IV Novembre N° 116
21058 Solbiate Olona (VA)
Italy

Re: K131081
Trade/Device Name: Cyber Tm Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general surgery and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 12, 2013
Received: June 13, 2013

Dear Mr. Bianchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family

Indications for Use:

The Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including:
Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

Urology:
Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Uretheral Tumors and Ureteral Tumors.
- Ablation of Benign Prostatic Hypertrophy (BHP).
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostrate
- Laser Enucleation of the Prostate
- Laser Ablation of the Prostate
- Condylomas
- Lesions of external genitalia

Note: The Cyber Tm 180 and Cyber Tm 200 are only approved for the treatment of BPH when used at power levels greater than 150W.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Neil R Ogden
2013.06.27 15:35:22 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131081

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6-2

Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family
Indications for Use: continued

Gastroenterology:
Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitas
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131081

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6-3

Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family

Indications for Use: continued

Gynecology:
Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis):

- Intra-uterine treatment of submucous fibroids
- benign endometrial polyps, and uterine septum by incision, excision, ablation and or vessel coagulation
- Soft tissue excision procedures such as excisional conization of the cervix

ENT:
Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

Dermatology and Plastic Surgery:
Incision, excision, resection, ablation, vaporization, coagulation and hemostasisof soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

- Basal Cell Carcinomas
- Lesion of skin and subcutaneous tissue
- Skin tags
- Plantar warts

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131081

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Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family

Indications for Use: continued

General Surgery
Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesion
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial Nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of Decubitus Ulcer
- Hemorrhoids
- Debridement of Statis Ulcer

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)
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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131081

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Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family

Indications for Use: continued

Thoracic and Pulmonary
Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

- Laryngeal lesions
- Airway obstructions including carcinoma
- Polyps and granuloma
- Palliation of obstructing carcinoma of the tracheobroncial tree

Arthroscopy
Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue):

- Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including
- Percutaneous Laser Disc Decompression/Discectomy
- Foraminoplasty
- Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery.

Prescription Use __X___ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131081

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Instructions for use (IFU)

Note: The information provided in the Instructions for Use (IFU) reflects Quanta System's analysis of the procedure(s) and/or device(s). The information and graphics were provided by Quanta System directly and are presented without change by Cook Medical.

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

This section describes the instructions for use of the device CYBER TM . They include:

- *Startup procedure*
- *Operating instruction*
- *Description of possible Alarm messages*
- *Shut down procedure and protection from unauthorized use*

5.1 Startup procedure

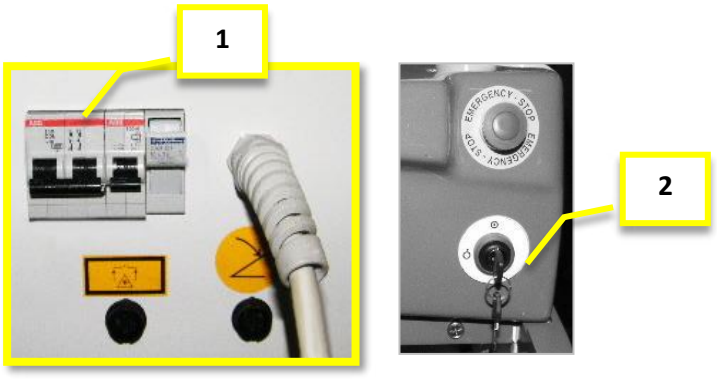
Before proceeding with the startup procedure of the device, verify the correct connection of the following parts:

- Power supply cable
- Interlock connector
- Key switch
- Footswitch
- Optical fiber

Also, make sure the emergency red button is not pushed.

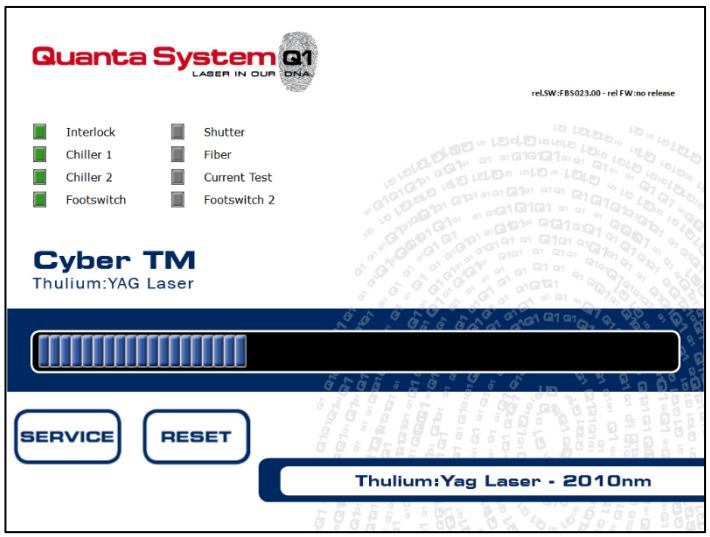
<u>To turn the device on:</u>

- Switch the circuit breaker on **(1)**
- Insert the key switch **(2)** and turn right, towards the ⊙ symbol. If the laser fails to start, check the emergency push button is not pressed. If the emergency push button is depressed twist to the right to release and turn the key to start the laser



5.1.1 *The Touchscreen PC panel – Startup*

The laser starts up and checks safety and auto-calibration.
Bye the touch panel it is possible to see and follow the check controls.



As the laser completes each check, information is displayed in the screen.

You don't have to press any button to exit to this screen.
When the system completes the warmup the Fast Selection Screen will appears (see cap. 5.2.1).

- *Press RESET only if you need to restart the system.*
- *Press Service to enter directly in to the Service Control Panel (see cap 5.4.5)*

If the system enters in Alarm during the startup operations, please call the Service Responsible of maintenance.

5.2 Main Controls

5.2.1 *Fast Selection Screen*

Once the start up is complete the Fast Selection Screen will appear:

Select the desired function by the arrows and then click over the Icon.

The Icons to access to the operative Main Screen are:

- Laser in air
- Laser in water
- Urology - BPH

Selecting one of this icons the system will show the Main Menu with suggested laser output parameters. These pre-sets are intended as suggested settings, the surgeon have to consider to change the settings in order to have the desired effect over the target tissue.

The following icons open the connected area or shut down the laser system:

Press “SERVICE” to enter in the Service Panel (cap. 5.4.5)

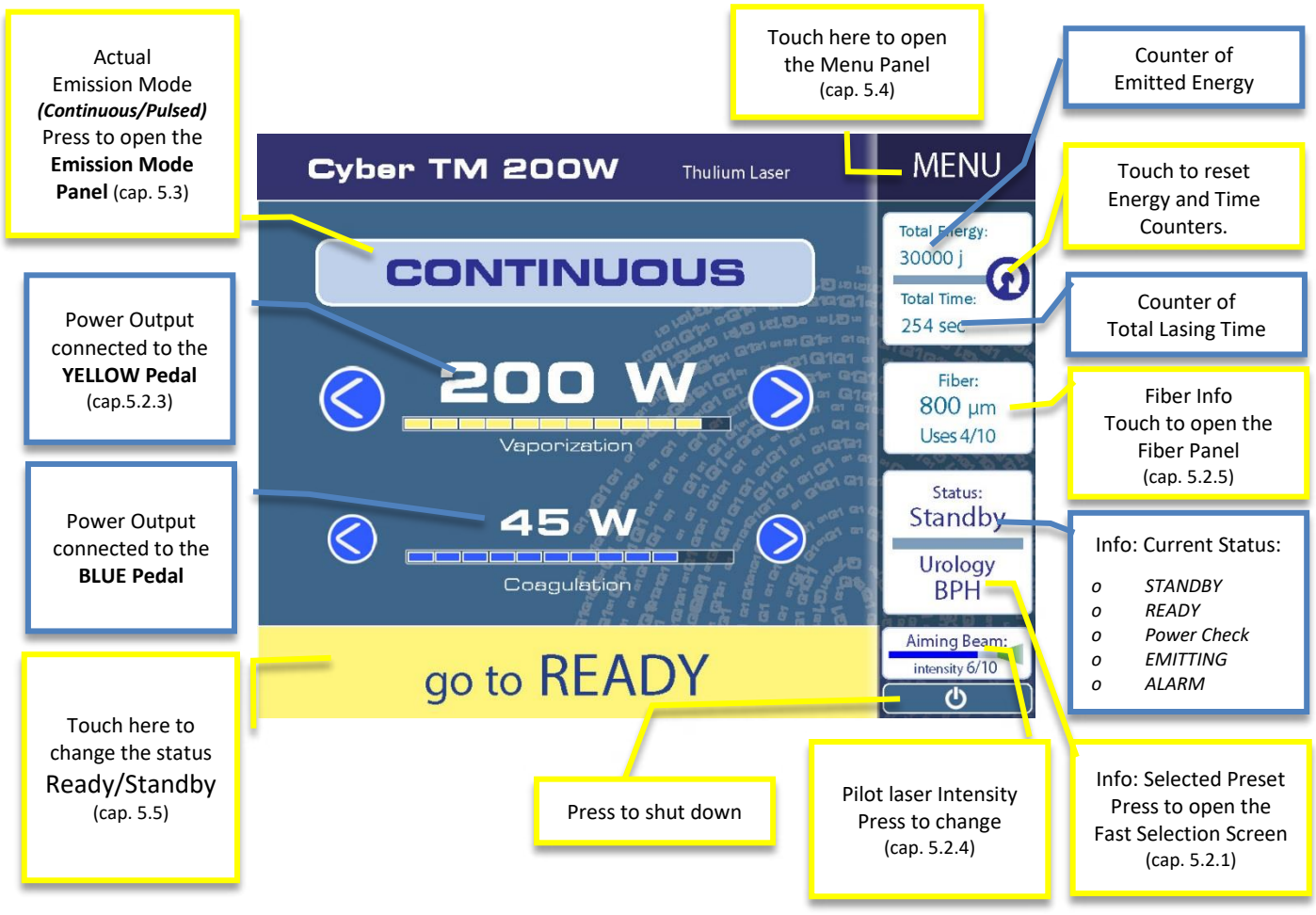
Press “Shut Down” to turn off the System

5.2.2 *Main Screen*

The Main Screen of the CYBER TM will appears with different pre-set of the output emission of the single footswitches (blue and yellow), depending to the selected icon in to the previous screen (see cap. 5.2).

The Main screen contains the controls and displays the technical element for operating and monitoring the laser. It is essential that operators understand and use these controls properly.

Main Screen:



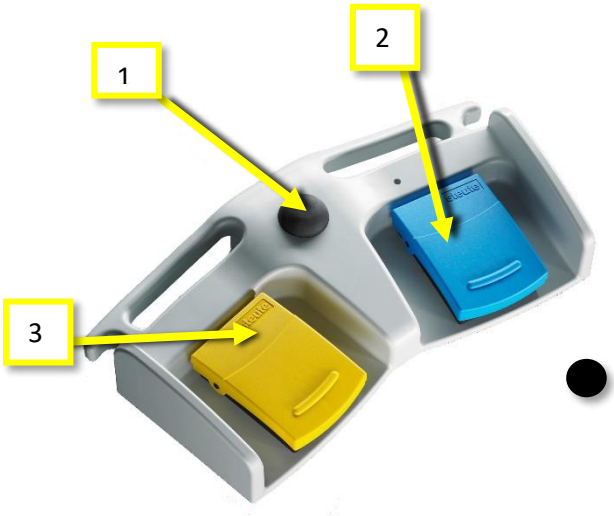
Display Areas

Active Button

5.2.3 *Power Output Controls*

Touch  to increase the energy output related to the blue/yellow pedal .

Touch  to decrease the energy output related to the blue/yellow pedal .



1. Ready/Standby Element
2. Coagulation Pedal
3. Main Emission Pedal

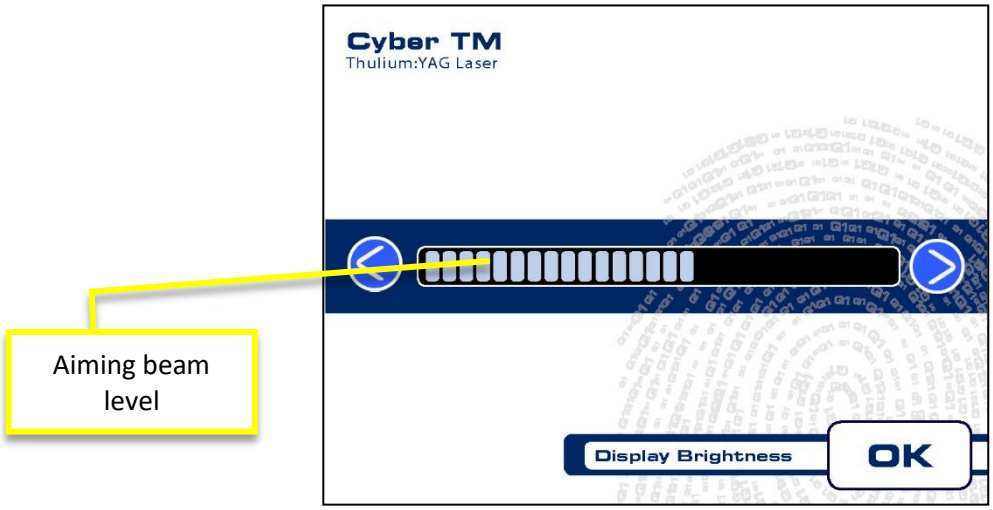
Press this button or touch the dedicate button on the main screen to change the status from **Standby** to **Ready** and vice versa.

The Yellow Pedal is dedicate to the main action over the Target Area *(Cutting / Ablation / Vaporization)*
It is possible to set the output in Continuous Emission or in Pulsed Emission (Cap. 5.3)

The Blue Pedal is dedicated to the Coagulation Effect.
The emission mode, using this footswitch, is forced Continuous.

5.2.4 *Pilot laser*

Press the Pilot Laser Button on the Main Screen (see Cap 5.2.2) to open the Pilot Laser Panel.



Touch  to increase the aiming beam intensity.

Touch  to decrease the aiming beam intensity.

Once reached the desired aiming beam intensity, press OK to confirm and return to the main screen.

Pressing the Pilot Laser Button on the Main Screen when the laser system is in Standby status, the laser pilot (Green or Red) will be activated, maintaining the CYBER TM in standby mode.

This function give you the possibility to check in a safe condition the connected fibers evaluating the shape of the laser beam immediately out of the fiber tip.

5.2.5 *Fiber INFO*

It is possible to open the Fiber Info Panel touching the Fiber Display in the Main Screen (Cap 5.2.2). The Fiber Info Panel will appears automatically when you insert a Quanta System fiber and connect the Code Plug to the dedicated frontal connector (Cap 5.5.1).

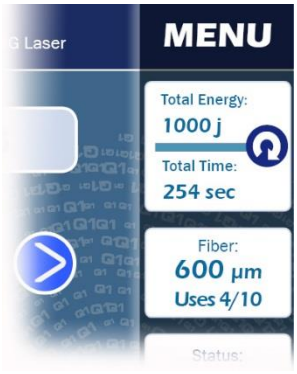
The following information of the connected fiber are stored in the internal microcip of Code Plug:

- Code of the fiber
- Fiber Type
- Uses
- First use time (data)
- Last use time (data)
- Total Energy emitted (J)

Press ESC to come back to the main Screen

If a non-unauthorized fiber is connected, the CYBER TM system will not recognize the fiber and will be denied to change the laser status to Ready.
If an expired Optical Fiber (single-use / reusable) is connected to the laser system, an error message will appear.

5.2.6 *Reset Counter Energy and Lasing Time*



During the emission the values of Joules emitted and Lasing Time will be increased.

To reset the time/energy counters press

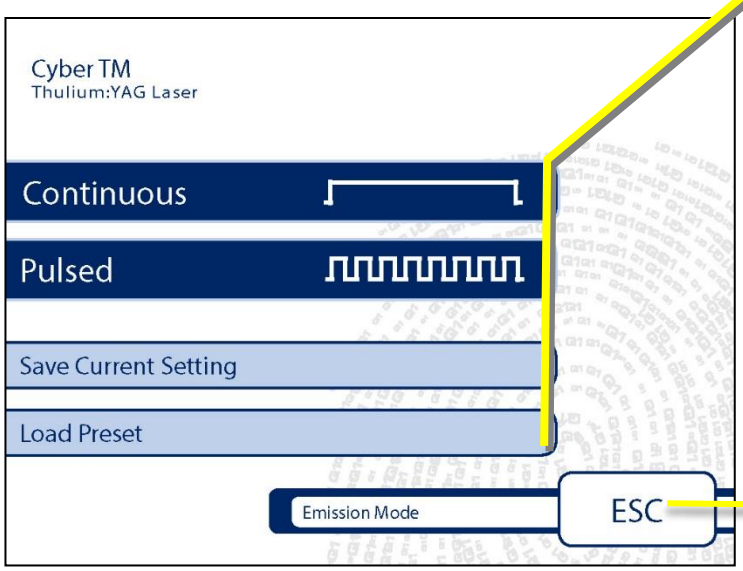
5.3 Emission Control Panel

Press Emission Box (see 5.2.1) to change the treatment mode.

This button has influence only over the output power related to Yellow pedal pressure.

Press Emission Box to open the Emission Screen Selection

The **Emission Control Panel** shows up:



Select the desired Emission of laser beam:

- **Continuous**
- **Pulsed**

Or

- Save Current Setting
- Load Preset

Press ESC to exit without changes

It is possible to select Continuous Emission, Pulsed Emission, Load a Preset or Save the Current Setting emission with a dedicated name**.**

Pressing:

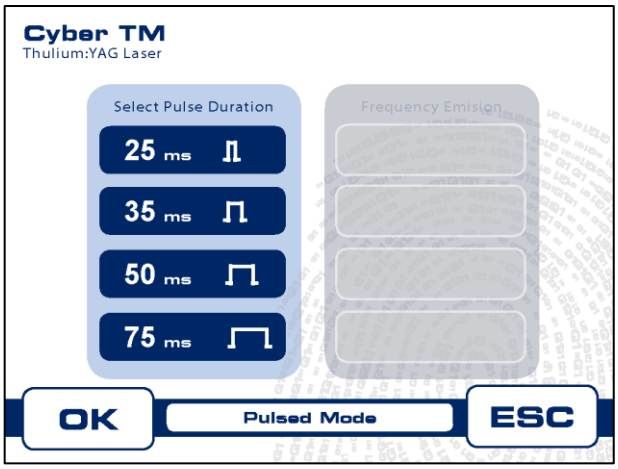
Continuous	- to sets a continuous emission and exit to the main screen
Pulsed	- to enter in the Pulsed Screen Selection
Save Current Setting	- to enter in the Save Setting Screen
Load Preset	- to enter in the Load Preset Screen

5.3.1 *Continuous Emission*

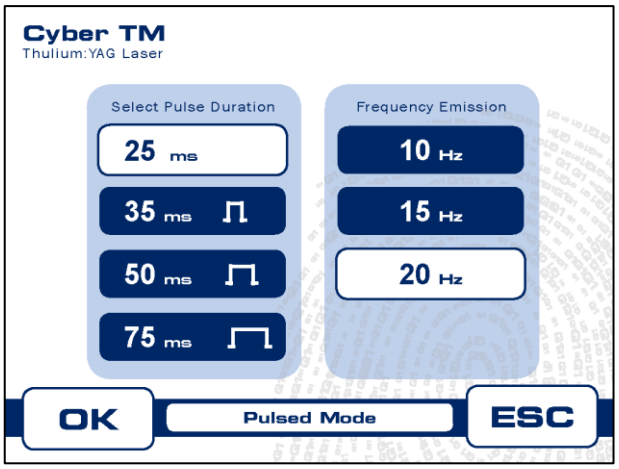
Press “Continuous” in to the Emission Control Panel (see cap. 5.3), in order to set the laser beam with a continuous emission.

5.3.2 *Pulsed Emission*

Press “Pulsed” in to the Emission Control Panel (see cap. 5.3), in order to set the laser beam with a Pulsed emission by the Pulse Panel Control:



Selecting the desidered pulse duration the possible frequency emission will appers.



Select the desired frequency available and press OK to set the Laser Emission with the selected output specifications and come back to the Main Screen.

Possible Pulsed Options:

Pulse Duration	Pulse Frequency Emission		
25 ms	20 Hz	15 Hz	10 Hz
35 ms	20 Hz	15 Hz	10 Hz
50 ms	-	15 Hz	10 Hz
75 ms	-	-	10 Hz

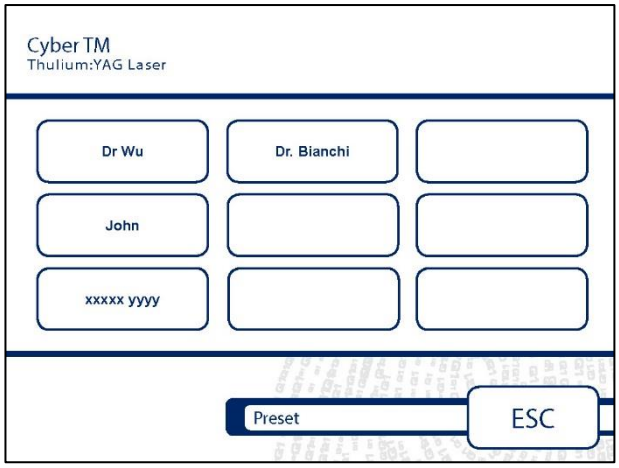
5.3.3 *Save Current Setting*

Press “Save Current Setting” in to the Emission Control Panel (see cap. 5.3), in order to open the Save Panel Control and save the current settings under a dedicated name.

The system will save:

- The emission settings (Pulse/Continuous) and power output related to the Yellow Pedal
- The power output related to the Blue Pedal

The Blue pedal has ever the continuous mode as permanent emission setting.



Select a free box to save with a new name or select an existent box to overwrite the current setting.

Selecting an existent box it is possible to conserve or change the saved name.

Press ESC to exit to the Save Panel.

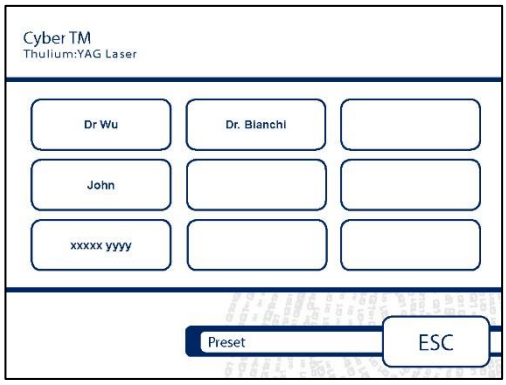
5.3.4 *Load Preset*

Press “Load Preset” in to the Emission Control Panel (see cap. 5.3), in order to load a preset saved under a dedicated name.

The system will active:

- The emission settings (Pulse/Continuous) and power output related to the Yellow Pedal
- The power output related to the Blue Pedal

The Blue pedal has ever the continuous mode as permanent emission setting.



Select an existent box in order to load the connected settings.

Press ESC to exit without changes.

5.4 MENU

Press “Menu” in to the Emission Control Panel (see cap. 5.3), in order to enter in the Main Menu Control Panel:

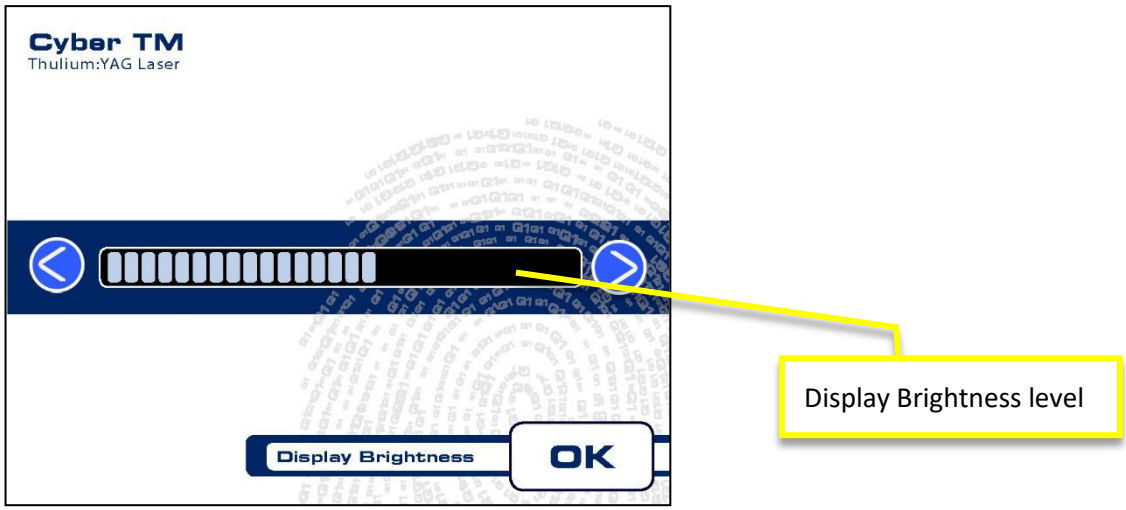
The available functions are:

- Display – Setting of brightness
- Audio – Setting of Sounds
- Language – Setting of Language
- Device Info – shows Device information
- Service – password needed

Press ESC to exit to the Main Screen.

5.4.1 *Display Panel*

Press “Display” in to the Main Menu Control Panel (cap. 5.4), in order to enter in the Display Control Panel:



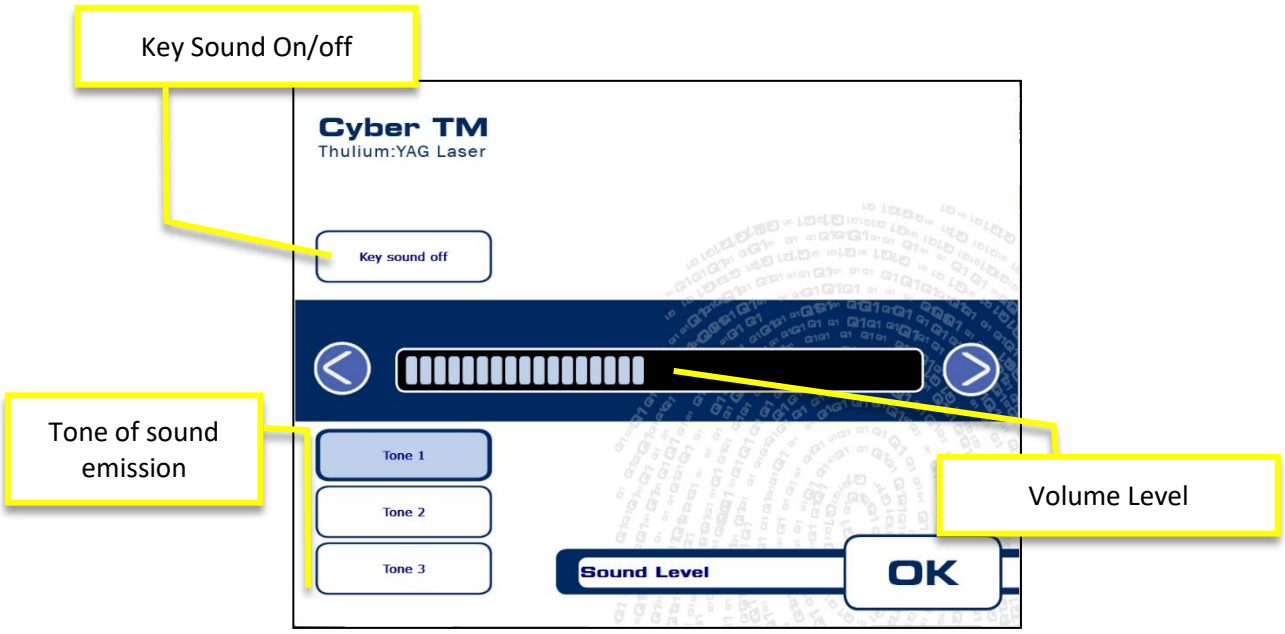
Touch  to increase the Brightness.

Touch  to decrease the Brightness.

When the Display Brightness corresponds to your desire, press OK to confirm and return to the Main Screen.

5.4.2 *Audio Panel*

Press “Audio” in to the Main Menu Control Panel (cap. 5.4), in order to enter in the Audio Control Panel:



Touch  to increase the Volume.

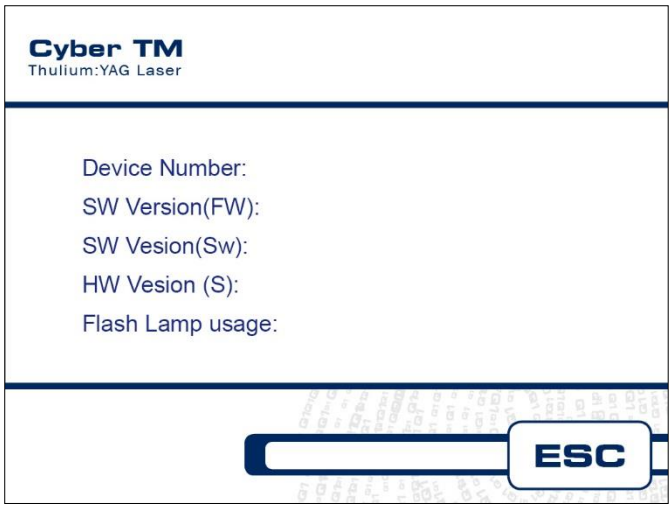
Touch  to decrease the Volume.

Select Buttons Tone 1-2-3 to change the tone output of sound connected to the emission status of yellow and blue pedal.

When the Sound Settings correspond to your desire, press OK to confirm and return to the Main Screen.

5.4.3 *Device Info*

Press “Device Info” in to the Main Menu Control Panel (cap. 5.4), in order to enter in the Display Control Panel:



The Device Info Panel shows the following parameters:

- Device Number
- Software Version (Fw)
- Software Version (Sn)
- Hardware Version (S)
- Flash Lamp Usage

Press “Esc” to exit to the Main Screen

5.4.4 *Language*

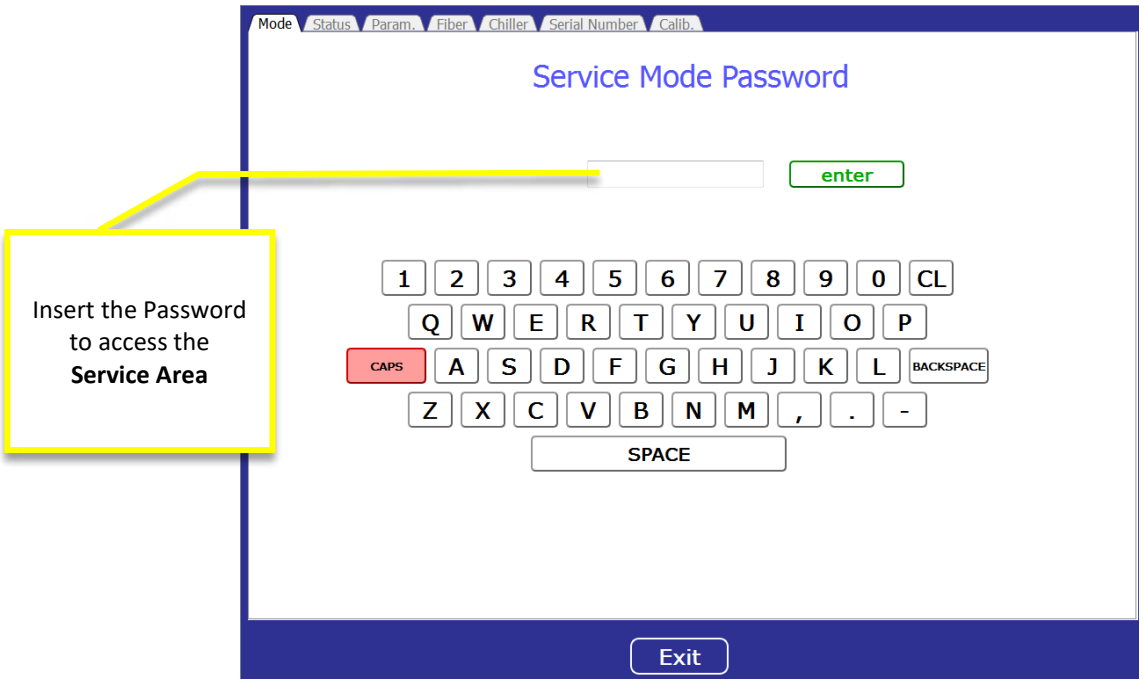
Press “Language” in to the Main Menu Control Panel (cap. 5.4), in order to enter in the Language Control Panel:

Select the desired language.

Press OK to confirm the selection and exit from the Language Control Panel.

5.4.5 *Service Panel*

Press “Service” in to the Main Menu Control Panel (cap. 5.4), in order to enter in the Service Password Insert Panel:

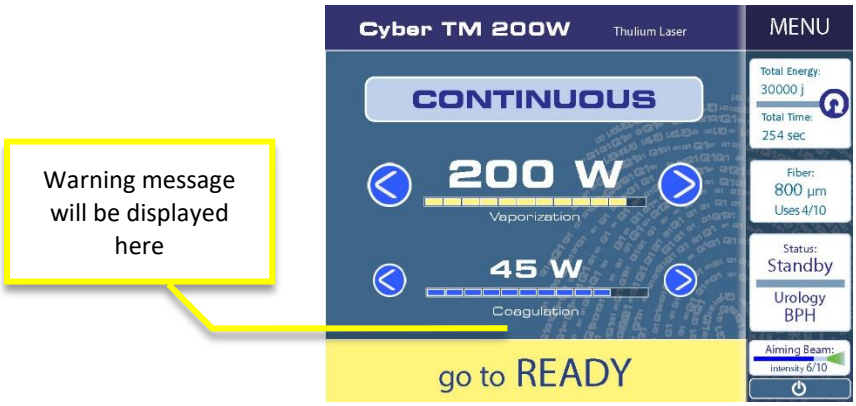


The SERVICE Area is accessible only using the correct password.

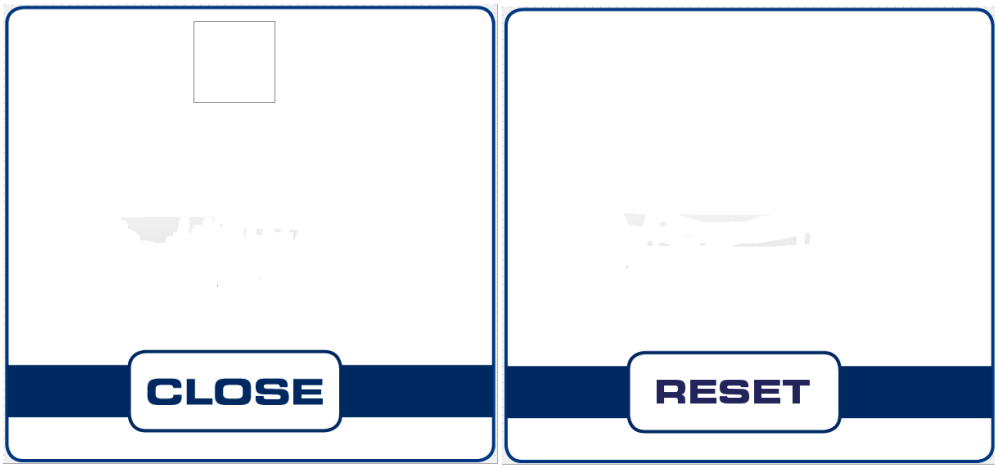
Press ESC to exit from the Service Panel.

5.4.6 *Alarms*

During operation, different alarms may be displayed. Example of possible Alarm windows are shown below:



A pop-up window will open in case of an alarm.



Possible error messages are listed in the Table below, with possible causes and actions. Blocking errors need manual restart of the system (a “reset” button is provided in the error pop-up window).

Error Message	Type	Possible Cause	Actions
Shutter	Pop-up / Blocking	Application shutter is not in the required position. The shutter could be mechanically blocked or the notor could be faulty.	• Call service
Fiber	Pop-up / Blocking	The fiber presence sensor is faulty.	• Call Service
Footswitch	Pop-up / Blocking	The footswitch was disconnected for more than 1 minute or it is faulty	• Replace the footswitch • Call service
Current check	Pop-up / Blocking	The diode current driver or the control chain is faulty.	• Call service
Chiller 1	Pop-up / Blocking	Chiller 1 (top) does not work correctly	• Check that there is enough water • Check that the temperature in the room is not exceeding the specification or that the exhaust air is recirculated (too close to a wall or to a corner) • Call service in case the issue is not one of the above.

Chiller 2	Pop-up / Blocking	Chiller 2 (bottom) does not work correctly	• Check that there is enough water • Check that the temperature in the room is not exceeding the specification or that the exhaust air is
			recirculated (too close to a wall or to a corner) • Call service in case the issue is not one of the above.
Action not allowed in emission phase.	Pop-up	The user tried to change a parameter that can't be modified in emission state	• release the footswitch before modifying the parameter
Wait	Pop-up	The user tried to change a parameter when the system is in "WAIT" state.	• Wait until the state turns to "READY" or to "STANDBY"
All Sessions Expired Replace the Fiber	Pop-up	The optical fibre connected expired all the sessions when the user tried to go in "READY" state	• Change the fibre with a new one
No fiber	Pop-up	No fibre was connected when the user tried to go in "READY" state	• Connect an optical fibre to the laser
Fiber not Identified	Pop-up	The fibre was not correctly identified when the user tried to go in "READY" state	• Connect a valid codeplug to the laser
Footswitch Disabled	Pop-up	The user pressed the "READY/STANDBY" button on the footswitch out of the main control interface (for example in the setting menu)	• Go to the main user interface before using the "READY/STANDVY" button
Error in changing mode.	Pop-up	Internal error	• Restart the system, if the issue is not solved, call service
Timeout communication	Pop-up	Communication error	• Restart the system, if the issue is not solved, call service
Voltage Out Range	Warning	The wall plug do not supply the correct voltage (nominal voltage +/- 10%)	• Connect the system to a wall-plug that can supply the correct voltage.

Warn. footswitch	Warning	The foot-switch pre-alarm is active. The pedal is disconnected or faulty. The user tried to go in the "READY" state with the footswitch pressed	• Release the footswitch before pressing the "go to READY" button • Check the footswitch connection
Warn footswitch2	Warning	The blue foot-switch pre-alarm is active. The blue pedal is disconnected or faulty. The user tried to go in the "READY" state with the blue footswitch pressed	• Release the footswitch before pressing the "go to READY" button • Check the footswitch connection
Power LOW	Warning	The internal powermeter measured a power less than 50% of the set value	• The user may decide to operate the system. • Call service
Power -40	Warning	The internal powermeter measured a power 40% lower than the set value	• The user may decide to operate the system. • Call service
Power -30	Warning	The internal powermeter measured a power 30% lower than the set value	• The user may decide to operate the system. • Call service
Power -20	Warning	The internal powermeter measured a power 20% lower than the set value	• The user may decide to operate the system. • Call service
Power HIGH	Warning	The internal powermeter measured a power more than 50% higher than the set value	• The user may decide to operate the system. • Call service
Power +30	Warning	The internal powermeter measured a power 30 higher than the set value	• The user may decide to operate the system. • Call service
Power +20	Warning	The internal powermeter measured a power 20 higher than the set value	• The user may decide to operate the system. • Call service
Curr.Out Range	Warning	The diode current is out of the range required to provide the set energy	• Call service
Interlock Active	Warning	The door interlock is not correctly connected	• Connect the door interlock plug • Check the connection with the door sensor

5.5 Activation of Laser Emission

Once chosen the power and emission settings that are suitable for the surgery being undertaken and the settings have been agreed by the surgeon, the laser operator can start the laser emission as follows:

5.5.1 *Insert the Optical Fiber*

The optical fiber is used to deliver laser energy to the patient. It is connected to the device through a special optical connector accessible from the frontal panel. The connector has a microswitch that disable laser emission if the fiber is missing or not installed properly.

- Open the optical connector moving the toggle on the right side.
- Connect the Optical Fiber in the optical fiber port, rotating the connector clockwise.
- Connect the Code Plug in to the dedicated connector.

The device accepts fiber with SMA905 connector and with Code Plug Recognizer System (only with Quanta System internal code). True the code plug the system recognize the diameter and type (single use / reusable) of the connected optical fiber. If the fiber is not connected or recognized to the device, an error message will appear when you try to change the status in Ready mode.

When the fiber is recognized the Fiber Info Panel will appears (cap 5.2.5)

The following information of the connected fiber are stored in the internal microcip of Code Plug:

- Code of the fiber
- Fiber Type
- Uses
- First use time (data)
- Last use time (data)
- Total Energy emitted (J)

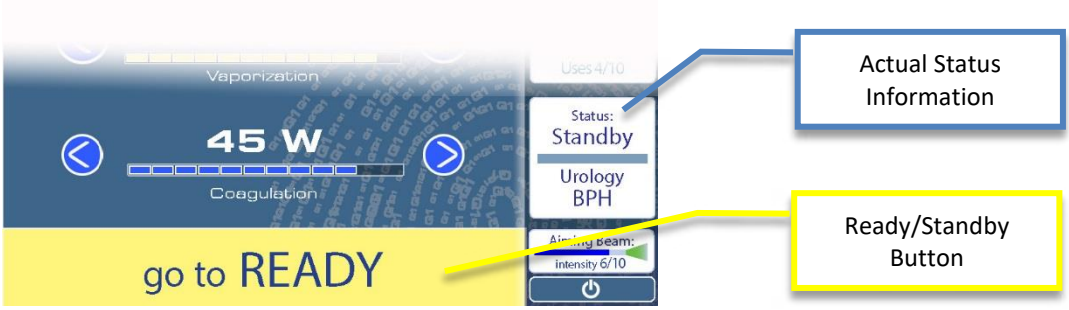
Press ESC to come back to the main Screen

If a non-unauthorized fiber is connected, the CYBER TM system will not recognize the fiber and will be denied to change the laser status to Ready.

If an expired Optical Fiber (single-use / reusable) is connected to the laser system, an error message will appear.

5.5.2 *Ready / Standby*

Touch the READY/STANDBY Button (cap5.2.1) to change the status of the laser System.



The display in the right area of the main screen identify the System STATUS.

Once the System is switched on, the status is automatically in STANDBY mode.
In STANDBY mode, the laser is not firing and the system cannot emit any energy.
To enter in READY mode press the READY button on display, or the footswitch.

In the READY mode, the laser is ready to fire and emit energy once the footswitch is pressed.

Ready Mode

When you change the system status for the first time from Standby to Ready, a “Warning Safety Screen” will appear:

WARNING!
All the personnel present in the laser working area must wear all the protective items.

Touch the display to exit from the "Warning Safety Panel".

If the fiber is not well connected or an invalid fiber is inserted, touching the "Ready/Standby" buttons an Error Message will appear.

When the system enters in READY Mode, the display shows the Ready state and the Ready/Standby button will change:

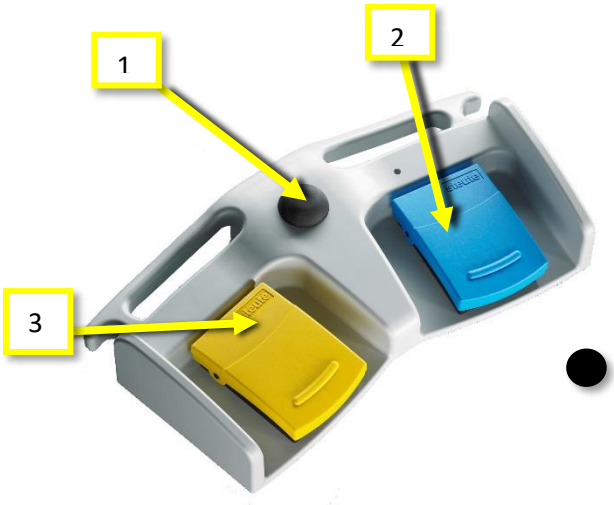
The internal photodiode starts monitoring the laser output energy.

Warning: *It is now possible to start laser emission by pressing the footswitch.*

Warning: *Before starting the laser emission, you have to be sure that the laser beam is oriented to the treatment area and the power output respect your desired setting.*

5.5.3 *Emission Mode*

In "Ready" mode, by pressing the footswitch, the Laser System start to emit the laser beam through the connected optical fiber.
The emitted power output values, connected to the Blue and Yellow Pedal, are shown on the Main Screen display (see picture below).

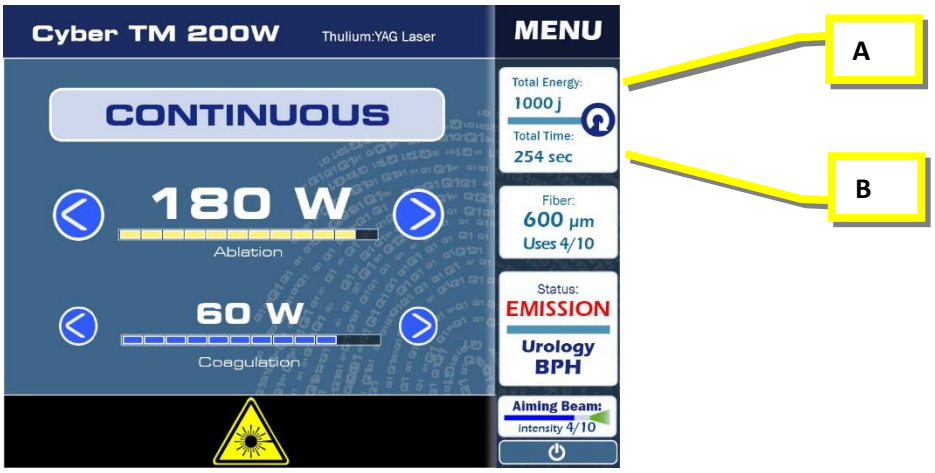


1. Ready/Standby Element
2. Coagulation Pedal
3. Main Emission Pedal

Press this button or touch the dedicate button on the main screen to change the status from **Standby** to **Ready** and vice versa.

The Yellow Pedal is dedicate to the main action over the Target Area *(Cutting / Ablation / Vaporization)*
It is possible to set the output in Continuous Emission or in Pulsed Emission (Cap. 5.3)

The Blue Pedal is dedicated to the Coagulation Effect.
The emission mode, using this footswitch, is forced Continuous.



During the emission the values of Joules (A) emitted and Lasing Time (B) will be increased.
To reset the time/energy counters see cap 5.2.6.

During LASER EMISSION, the Ready/Standby button will be inactive, displaying the following image with the laser warning emission symbol, the display shows the EMISSION state:

During the treatment, if the output energy fluctuates or differs more than +/- 20% from the selected initial value, then Energy Warning (Energy HIGH or LOW) is displayed accordingly. In case of Energy Warning the system does not stop, allowing in any case continuation of the treatment.

At the end of the treatment, release the footswitch and enter in the standby mode by pressing the Ready/Standby area on the display or the dedicated pedal of the double footswitch.
For starting a new ready session, press Ready/Standby area on the display or the dedicated pedal of the footswitch.

<u>Annotation:</u> If the footswitch is kept released for a long time during the READY mode, the system will automatically enter the STANDBY mode.

5.5.4 *Led Signals*

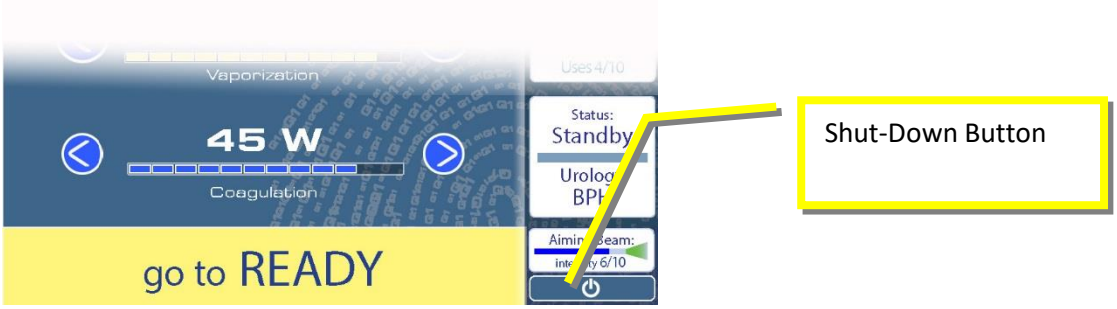
When the laser is in STANDBY the green led is blinking, while in READY Mode the green led lights continuously.

When the footswitch is pressed and the laser is in READY Mode, in addition to the green light on, the yellow led blinks and the laser emits an audible noise.

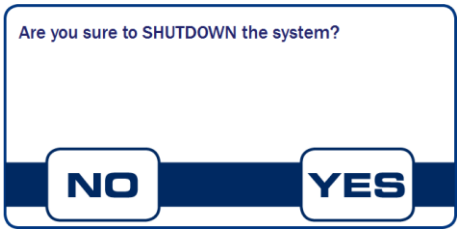
- **STANDBY mode: green blinking**
- **READY mode: green fix**
- **EMISSION mode: yellow fix + green fix**

5.6 Shut-down procedure

To shut the laser device down, press the STANDBY button and press the Shout-Down button.



The window below will appear:



Press YES to confirm or No to come back to the Main Screen.

Wait the shut-down procedure and then turn the key switch in the counter clockwise direction to the symbol ○.

Warning: *Remove the key-switch to avoid any use by unauthorized personnel.*

Solutions portfolio

Clinical

Vista® Education and Training programs

Vista® Education and Training programs set a high standard for product education via peer-to-peer interaction. The Vista® training programs use Cook-selected qualified faculty, Cook-specific content training, and peer-to-peer interaction in every session. The programs are designed to focus on product education.

Visit https://vista.cookmedical.com for more information or speak to your local Cook Sales representative for upcoming events in your area.

Reimbursement

Cook's policy is to offer information that is complete, accurate, straightforward, and consistent with the statutes and regulations of the federal government and well-accepted coding guidelines as established by the Centers for Medicare and Medicaid Services (CMS), the American Medical Association (AMA), the American Hospital Association (AHA), and other relevant professional societies.

Cook's reimbursement assistance team can provide Medicare reimbursement rates, assessment of Medicare and commercial insurance coverage policies, and coverage appeals support.

Purchasing

Digital catalog

Cook can provide a URL to an image for each product in the Cook Medical catalog. These URLs are delivered to a customer in a spreadsheet that can be uploaded to display the images in customer's purchasing platform (ERP) or clinical information system. Product images allow end users to view and validate the items.

E-commerce

Cook can help you order electronically. E-commerce is an automated, paper-free method of transacting purchase orders, acknowledgements, invoices, and dispatch and receiving notifications. Cook offers value-added-network (VAN), direct EDI, XML, and web-based methods of ecommerce transactions and ordering.

GS1 standards

GS1 is an international, not-for-profit association that creates and implements standards to bring efficiency and visibility to supply chains across multiple industries. The GS1 standards for healthcare focus on improving patient safety and supply-chain efficiency. They do this by providing unique product identification (GTINs), clean data (GDSN), and location information (GLNs) numbers.

All our products are GS1 compliant. Having GS1-compliant products gives systems improved visibility in the supply chain.

Customer Support & Distribution

Distribution support

At Cook Medical, we partner with health systems to identify the distribution model that best fits their needs. We're glad to engage in a discussion regarding the desire to ship Cook Medical items through a third-party distributor or a customer's self-distribution center.

Shipping

Standard shipping is included for most fiber orders, although Cook may require a minimum order quantity or dollar amount. Expedited shipping may be available and subject to an additional cost which will be prepaid by Cook and invoiced to the customer. Cook's shipping policy is subject to change and may be updated from time to time. Please refer to cookmedical.com/support/ordering-returns for current order requirements and further information about shipping options.

Item master cleanup

Cook Medical can perform an item master cleanup for its customers. This includes, but is not limited to, helping customers correct pricing discrepancies, discover unit of measure discrepancies, locate unavailable or invalid part numbers, provide GTINs, and offer contract information. This will ensure that the ordering process between the customer and Cook Medical is seamless.

Product use and SKU reduction

Cook Medical can provide cross-referencing to all customers who request it. This includes cross-referencing between a competitor and Cook and between Cook's stock and nonstock items.

Consolidated packaging

Cook's consolidated packaging program combines separate product orders in clear, heat-sealed plastic bags that will ensure that the integrity of each purchase order (PO) is maintained. A packing slip with scannable barcode is included in each heat-sealed pack. Our process includes placing individually bagged POs into as few boxes as possible by using a mutually agreed-upon order cutoff time. Fewer boxes received means a more streamlined receiving process, reduced shipping and freight costs, and reduced cardboard recycling waste and expense.

Sustainability

At Cook, we strive to perform in an environmentally responsible manner by incorporating the best management practices, fostering the sustainable use of natural resources, promoting pollution prevention, reducing waste generation, and recycling and reusing materials where possible within our operations. Cook has a corporate sustainability team responsible for finding new ways to reduce waste for our customers and for us. Currently, our sustainability strategy is focused mainly on improving the environmental performance of our facilities, packaging, and recycling.

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