Litho Holmium YAG Laser System

Highly customizable to patient's needs and surgeon preference

Value analysis*

AND PRODUCT INFORMATION PACKET

COOK® MEDICAL

* Prepared for value analysis committees in a hospital setting.

Contents

Product overview

Ultrasonic lithotripsy was initially introduced for percutaneous renal surgery in the late 1970s and was the first minimally invasive treatment for kidney stones.[1] Since then, there has been a revolution in holmium surgery to meet the increasing demand for efficacy and versatility. By the 1990s, the holmium:YAG laser had become "the dominant tool for laser lithotripsy."[1] Holmium lasers offer a multiapplication platform able to perform lithotripsy, HoLEP, and laser soft tissue malformations. The Litho 60, Litho 100, and Litho 150 contain new technology—Virtual Basket—that improves stone fragmentation efficiency,[2,3] with the goal to increase the effectiveness of treating BPH (benign prostatic hyperplasia).

The Litho family of lasers is designed to provide value.

Laser lithotripsy	
Hospitals	Holmium lithotripsy procedures have been shown to decrease ureteral stone retropulsion[5] and procedure time,[2,3,5] which may reduce costs associated with operating room time and retreatments.
Healthcare providers	The Litho Virtual Basket feature allows fine lithotripsy and minimal stone movement[2] without the need for expensive additional fibers,[6] which may reduce costs as compared to other holmium laser competitors.[7]
Patients	Holmium lithotripsy procedures may have shorter hospitalization[8] compared to pneumatic lithotripsy, and Virtual Basket technology reduces holmium lithotripsy procedure times[5] with few complications,[9] potentially allowing for improved patient comfort following the operation.
Payers	Holmium lithotripsy procedures may offer potential cost savings from multiuse laser fibers, shorter procedure time,[5] and shorter hospitalization time[8] as well as from having few severe complications.[9,10]

VB-HoLEP (HoLEP with Virtual Basket)	
Hospitals	VB-HoLEP procedures are more efficient[11] with faster prostate enucleation and hemostasis,[12] potentially reducing the costs associated with operating room time.[11,12]
Healthcare providers	VB-HoLEP procedures are more efficient[11] with less bleeding,[13] improved hemostasis,[12] and faster hemostasis.[12]
Patients	VB-HoLEP procedures may provide less bleeding,[13] reduced hospital stays with the chance of same-day discharge,[11,12] and low complication rates.[15]
Payers	Potential cost savings may be the result of shorter operating time,[11,12] shorter hospitalization time,[13] no need for additional fibers,[6] faster hemostasis,[12] and low risk of severe complications. [12,13,15]

*NOTE: References may be found on page 36 of this packet.

The key considerations for your value analysis include:

1. **The product:**
    - Procedures for laser lithotripsy and enucleation of the prostate utilizing the holmium YAG laser (which is indicated for prostates) may be performed on almost any patient group,[17] multiple stones, stones of all known composition,[14] and patients on blood thinner medications.[17] In addition, hospital stay, procedure time,[11,13] and complication rates are low[15] for holmium procedures with Virtual Basket technology.[11]

2. **Key product features:**

Vapor Tunnel	Consisting of a single specific long pulse, this emission mode allows limited retropulsion and fine stone ablation. The Vapor Tunnel is designed to use the minimum peak power in accordance with selected output settings.
Virtual Basket	The double pulse modulation used with the Litho Virtual Basket emission mode allows limited stone movements and fine lithotripsy. With the Virtual Basket, a first pulse is used to generate the vapor bubble, and a second pulse, emitted from the same fiber, propagates through the bubble to irradiate the target.
Advantages of Vapor Tunnel and Virtual Basket	These features have no extra costs for additional special fibers. They allow users to limit stone movement, ease treatment with a more stable target, and limit time-consuming fiber repositioning.

The Litho lasers can be operated with a large range of fibers, depending on the application, flexibility, and settings required. All fibers are available both as disposable and reusable (except ball-tip and side firing fibers).[6]

3. **The financial impact:**
    - Low complication rates,[15] shorter procedure times,[11,12] and reusable laser fibers can potentially reduce costs for the patient, the payer, and the hospital.[14,16]

*NOTE: References may be found on page 36 of this packet.

Product design

The Litho 60, Litho 100, and Litho 150 holmium laser systems each consist of a flash pumped CTH:YAG laser source, an internal chiller as cooling system, an optical fiber launch system, and power and control electronics. Its emission wavelength, 2100 nm, lies in the infrared portion of the EM spectrum. The maximum output power of the device is 60, 105, or 152 W depending on the model. For the release of laser radiation to the patient, the Litho 60, Litho 100, and Litho 150 devices use a quartz optical fiber with a diameter up to 1000 µm to be used for the surgical applications. The laser can operate in a pulsed mode with maximum frequency of 60, 80, or 100 Hz, depending on the model. In this case, the release is by pulses that are repeated over time with an adjustable frequency. Each holmium YAG laser model brings outstanding innovation by offering the exclusive Vapor Tunnel, Virtual Basket, and MasterPULSE technologies for advanced retropulsion control.

No.	Component description
1	Key switch
2	Touchscreen display (control panel)
3	Optical fiber connector
4	RFID Antenna
5	External protection shutter
6	Hand Presence Sensor
7	Red emergency push button
8	LED indicator
9	Footswitch connector
10	Braking twin wheels

Braking twin wheels

The Litho 60/100/150 laser devices are equipped with four braking twin wheels with dual lock. With one brake pedal, it is possible to operate these different functions:

Brake pedal

Directional lock

Neutral

Total lock

The Litho laser system has a 12 inch touchscreen, wheel dampers, and a transportation handle for easy and safe device relocation and transportation. The control system comes with a main switch, a red emergency push button, and an LED indicator located on the front panel. The double footswitch also enables immediate switch from cutting to coagulation mode, without bothersome interruptions for settings readjustment.

Product intended use

The Quanta holmium YAG laser system is intended for urological applications such as laser lithotripsy (urinary stone management), prostate health management, and treating urinary soft tissue malformations. Additional uses are outlined in the Litho 60, Litho 100, and Litho 150 brochures found on the Litho 60, Litho 100, and Litho 150 laser product pages.

Value analysis

Overview

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

Healthcare professionals understand the importance of a high-quality product and one that makes economic sense as well. In this 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, the patient's return to work, and the patient's overall quality of life.

The value analysis for the Litho 60, Litho 100, and Litho 150 laser system focuses on the variable that can be controlled—laser choice—thus allowing healthcare providers to make evidence-based decisions to treat their patients.

Laser lithotripsy	
Hospitals	Holmium lithotripsy procedures have been shown to decrease ureteral stone retropulsion[5] and procedure time,[2,3,5] which may reduce costs associated with operating room time and retreatments.
Healthcare providers	The Litho Virtual Basket feature allows fine lithotripsy and minimal stone movement[2] without the need for expensive additional fibers,[6] which may reduce costs as compared to other holmium laser competitors.[7]
Patients	Holmium lithotripsy procedures may require shorter hospitalization[8] compared to pneumatic lithotripsy, and Virtual Basket technology reduces holmium lithotripsy procedure times,[5] potentially allowing for improved patient comfort following the operation.
Payers	Holmium lithotripsy procedures may offer potential cost savings from multiuse laser fibers, shorter procedure time,[5] shorter hospitalization time,[8] and few severe complications.[10]

VB-HoLEP (with Virtual Basket)	
Hospitals	VB-HoLEP procedures are more efficient,[11] with faster prostate enucleation and hemostasis,[12] potentially reducing the costs associated with operating room time.[11,12]
Healthcare providers	VB-HoLEP procedures are more efficient[11] with less bleeding,[13] improved hemostasis, and faster hemostasis.[12]
Patients	VB-HoLEP procedures may cause less bleeding,[13] with the chance of same-day discharge,[11,12] and result in lower complication rates.[15]
Payers	Potential cost savings may be realized by shorter operating time,[11,12] no need for additional fibers,[6] faster hemostasis,[12] and low risk of severe complications. [12,13,15]

Holmium laser and related procedures may put the patient at additional risk. For the list of potential adverse events associated with holmium laser procedures, please refer to the Litho 60, Litho 100, and Litho 150 product brochures.

*NOTE: References may be found on page 36 of this packet.

Economic value analysis

In the treatment of benign prostatic hyperplasia (BPH) and kidney stones, duration of hospitalization, lower complication rates, and effective hemostasis are all significant factors in determining a product's economic value. Boston Scientific's Lumenis MOSES® laser system has the same medical benefits as Quanta's Litho 150 laser system[5,13] because both use pulse modulation technology (Virtual Basket/Moses).[11] However, the Litho 150 laser system offers multiple cost benefits: reusable laser fibers, no additional fee to add Virtual Basket technology, and lower acquisition costs.

Assume your hospital performs 150 procedures per year

	Quanta Litho 150 System	Lumenis Pulse 120H System
Estimated laser fiber cost	$272 per procedure	$400 per procedure
Estimated annual fiber cost	$40,800	$60,000
Estimated acquisition cost for holmium YAG and Moses laser systems	$185,000	$200,000
Estimated cost for addition of Moses/Virtual Basket technology	$0	$25,000
Estimated average total cost – year 1	**$225,800.00**	**$285,000.00**

Return on investment (150 cases per year)	Quanta System	Lumenis System	Savings
Year 1	$225,800.00	$285,000.00	**($136,000)**
Year 2	$40,800.00[a]	$60,000.00[a]	
Year 3	$40,800.00	$60,000.00	
Year 4	$40,800.00	$60,000.00	
Year 5	$48,000.00	$60,000.00	
Total Cost	**$389,000.00**	**$525,000.00**	
Year 6	$40,800.00	$60,000.00	**($232,000)**
Year 7	$40,800.00	$60,000.00	
Year 8	$40,800.00	$60,000.00	
Year 9	$40,800.00	$60,000.00	
Year 10	$40,800.00	$60,000.00	
Total Cost	**$593,000.00**	**$825,000.00**	
NOTE: By year 1, a potential savings of $59,200.00 is recognized. By year 5, a potential savings of approximately $136,000.00 could be seen, and by year 10, a potential savings of approximately $232,000.00 could be seen.			

a. The cost per year was calculated by subtracting the acquisition cost and the Moses/Virtual Basket technology cost, as it is not relevant after the first year.

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

Nonclinical data analysis

A study was performed to compare holmium laser enucleation of the prostate (HoLEP) and holmium laser enucleation of the prostate with the Virtual Basket technology (VB-HoLEP) to treat benign prostatic hyperplasia (BPH). Both groups were treated with settings of 1.8 joules at 45 Hz by Cyber Ho 100 laser platform (Quanta System, Samarate, Lombardia, Italy) and 550 µm reusable fibers.[13] The randomized study evaluated patients preoperative and postoperative on catheterization time, operative time, blood loss, irrigation volume and hospital stay. The study found that there wasn't a significant difference in preoperative parameters between patients in both groups. Postoperatively, the VB-HoLEP resulted in a lower hemoglobin loss (blood loss) and a more rapid operating time. Overall HoLEP and VB-HoLEP had the same catheterization time, irrigation volume, and hospital stay.[13]

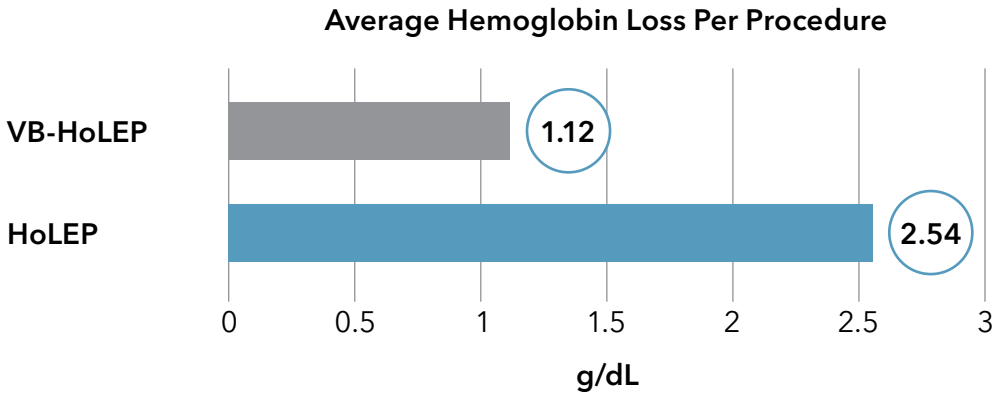

Figure 1 shows the average hemoglobin loss per BPH procedure. The VB-HoLEP procedure resulted in less hemoglobin loss with a 1.12 g/dL vs the HoLEP procedure with only a loss of 2.54 g/dL.[13]

*NOTE: References may be found on page 36 of this packet.

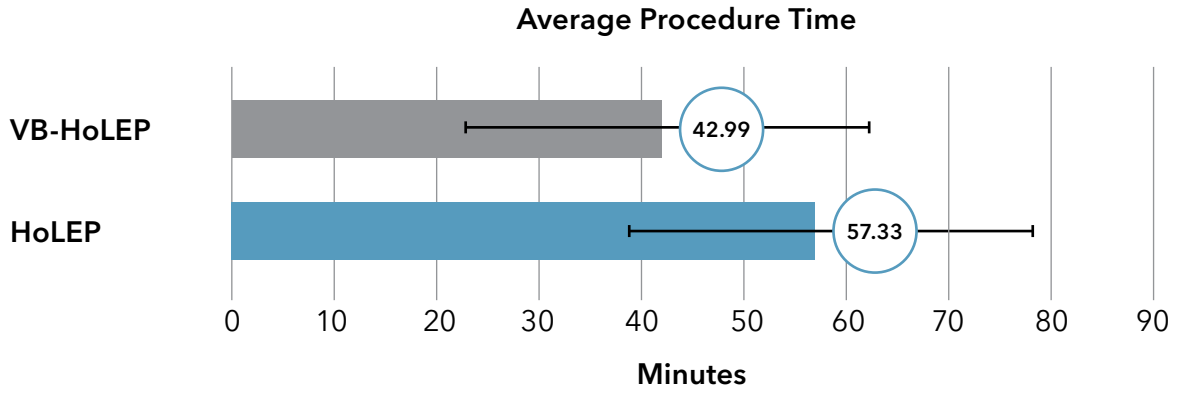

Figure 2 shows the average operative times for the treatment of BPH. The VB-HoLEP procedure resulted in a more rapid operating time with 42.99 ± 18.51 minutes. Whereas the HoLEP procedure had an average operating time of 57.33 ± 29.71 minutes.[13]

In this study, VB-HoLEP had a faster procedure time and resulted in lower blood loss during procedure. However, the procedures did not differ in catheterization time, hospital stay, and irrigation volume. It was reported that the Virtual Basket technology demonstrated significantly less retropulsion and lower fragmentation time. Although HoLEP and VB-HoLEP are both efficient procedures, based on this study one can conclude that VB-HoLEP may be the superior method.[13]

*NOTE: References may be found on page 36 of this packet.

Summary

BPH and kidney stones 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 if the holmium YAG laser system is an ideal choice for their patients.

The Litho family laser system is designed to provide value.

Laser lithotripsy	
Hospitals	Holmium lithotripsy procedures have been shown to decrease ureteral stone retropulsion[5] and procedure time,[2,3,5] which may reduce costs associated with operating room time and retreatments.
Healthcare providers	The Litho Virtual Basket feature allows fine lithotripsy and minimal stone movement[2] without the need for expensive additional fibers,[6] which may reduce costs as compared to other holmium laser competitors.[7]
Patients	Holmium lithotripsy procedures may require shorter hospitalization[8] compared to pneumatic lithotripsy, and Virtual Basket technology reduces holmium lithotripsy procedure times,[5] potentially allowing for improved patient comfort following the operation.
Payers	Holmium lithotripsy procedures may offer potential cost savings from multiuse laser fibers, shorter procedure time,[5] and shorter hospitalization time[8] as well as from having few severe complications.[9,10]

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Hospitals	VB-HoLEP procedures are more efficient[11] with faster prostate enucleation and hemostasis,[12] potentially reducing the cost of operating room time.[11,12]
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Payers	Potential cost savings may be the result of shorter operating time,[11,12] no need for additional fibers,[6] faster hemostasis,[12] and low risk of severe complications. [12,13,15]

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The key considerations for your value analysis include:

1. **The product:**

   Procedures for laser lithotripsy and enucleation of the prostate utilizing the holmium YAG laser (which is indicated for prostates) may be performed on almost any patient group,[17] multiple stones, stones of all known composition,[14] and patients on blood thinner medications.[17] In addition, hospital stay, procedure time,[11,13] and complication rates are low[15] for holmium procedures with Virtual Basket technology.[11]

Key product features

Vapor Tunnel	Consisting of a single specific long pulse, this emission mode allows limited retropulsion and fine stone ablation. The Vapor Tunnel is designed to use the minimum peak power in accordance with selected output settings
Virtual Basket	The double pulse modulation used with the Virtual Basket emission mode allows limited stone movements and fine lithotripsy. With the Virtual Basket, a first pulse is used to generate the vapor bubble, and a second pulse, emitted from the same fiber, propagates through the bubble to irradiate the target
Advantages of Vapor Tunnel and Virtual Basket	These features have no extra costs for additional special fibers. They allow users to limit stone movement, ease treatment with a more stable target, and limit time-consuming fiber repositioning.

The Litho lasers can be operated with a large range of fibers, depending on the application, flexibility, and settings required. All fibers are available both as disposable and reusable (except ball-tip and side firing fibers).[6]

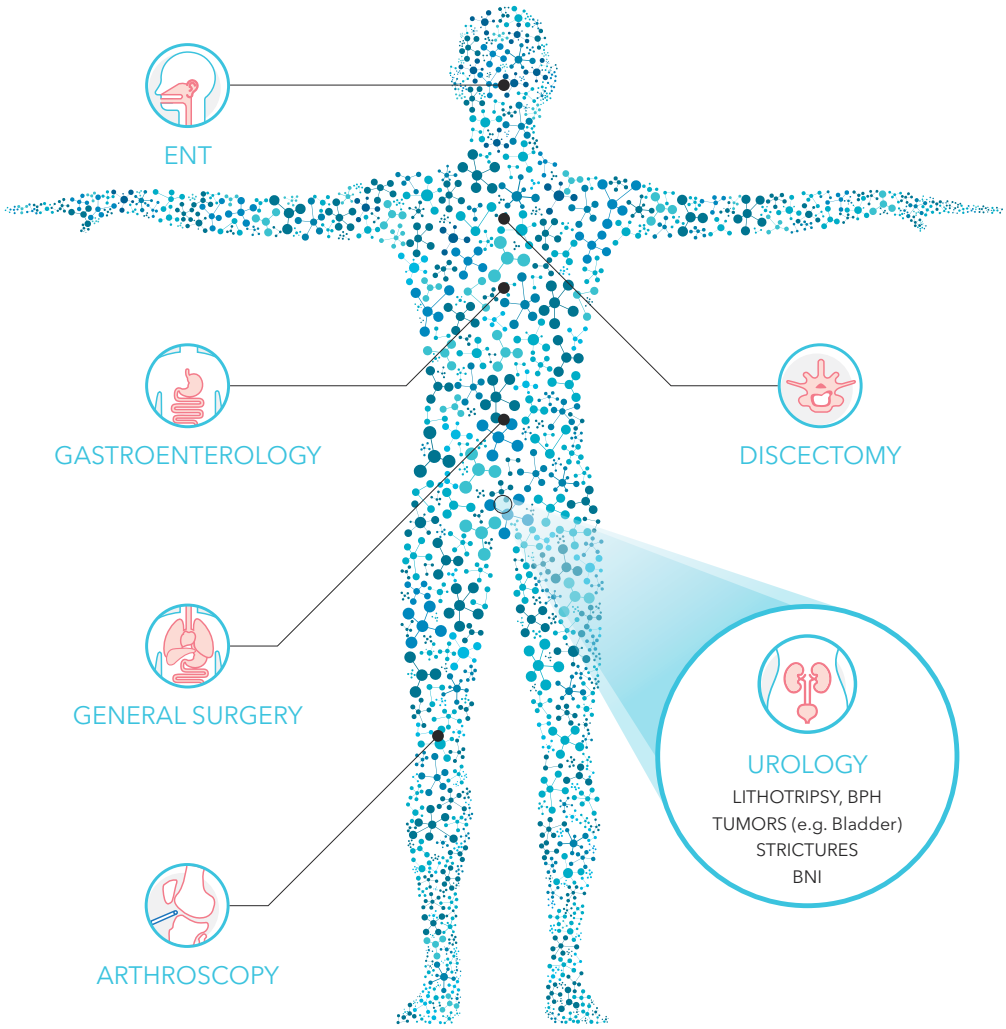
2. **The financial impact**

   - Low complication rates,[15] shorter procedure times,[11,12] and reusable laser fibers can potentially reduce costs for the patient, the payer, and the hospital.[14,16]

*NOTE: References may be found on page 36 of this packet.

Specialties impacted

- Urology is the main intended use of the product, but there are other specialties impacted. For a full list of these specialties, please see the Litho family product brochures.



Impact on patients

- Because the holmium YAG laser procedures may have a shorter hospitalization times[13,12] and low complication rates,[15] the patient may have improved comfort after the operation.

*NOTE: References may be found on page 36 of this packet.

Material management information

Order numbers and sizing

Order Number	Reference Part Number	Average Power (W)	Frequency Rate (Hz)	Energy per Pulse (J)
Litho family products				
G58931	LITHO-150	Up to 152	Up to 100	Up to 5
G57980	LITHO-100	Up to 105	Up to 80	Up to 5
G57979	LITHO-60	Up to 60	Up to 60	Up to 5

Order Number	Reference Part Number	µm	Use
Standard fibers: This probe features a bare (flat) tip, providing frontal laser emission. It can be coupled with lasers intended for general use in lithotripsy, benign prostatic hyperplasia (BPH), and soft tissue surgery.[6]			
G57961	OAF002011	Optical Fiber 200 µm	Single Use
G57962	OAF002013	Optical Fiber 200 µm	10x Reusable
G57966	OAF702711	Optical Fiber 272 µm	Single Use
G57967	OAF702713	Optical Fiber 272 µm	10x Reusable
G57968	OAF703611	Optical Fiber 365 µm	Single Use
G57969	OAF703613	Optical Fiber 365 µm	10x Reusable
G57970	OAF005511	Optical Fiber 550 µm	Single Use
G57971	OAF005513	Optical Fiber 550 µm	10x Reusable
G57972	OAF008011	Optical Fiber 800 µm	Single Use
G57973	OAF008013	Optical Fiber 800 µm	10x Reusable
G57974	OAF009911	Optical Fiber 1000 µm	Single Use
G57975	OAF009913	Optical Fiber 1000 µm	10x Reusable

*NOTE: References may be found on page 36 of this packet.

Order Number	Reference Part Number	µm	Use
Ball-tip fibers: This probe consists of a specially designed ball-tip fiber for safe and smooth insertion inside of already bent flexible scopes, preventing damage to the scope's internal channel while it moves through that channel.[6]			
G57965	OAF302711	Optical Fiber 272 µm Ball-Tip	Single Use

Order Number	Reference Part Number	µm	Use
Side firing fibers: This probe can be coupled with lasers intended for soft tissue ablation. Lateral emission allows for smooth and intuitive tissue ablation, including laser ablation of the prostate.[6]			
G58340	OAF506011	Side Firing Fiber 600 µm Standard	Single Use

See other Cook product offerings you may be interested in: cookmedical.com/urology/quanta-homepage.

Product specifications

The Quanta holmium YAG laser system is intended for urological applications such as laser lithotripsy (urinary stone management), prostate health management, and urinary soft tissue malformations. Additional uses are outlined in the Litho laser product brochure located on the Litho laser product page.

System safety features

The Litho 60, Litho 100, and Litho 150 laser systems incorporate 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 device is provided with an operating room door interlock connection, which must 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.
- Energy cannot be emitted from the laser system unless a fiber has been connected.
- The laser will go into ready when the READY button is touched.
- A continuous audible tone is heard when the surgical beam is activated (i.e., when the foot pedal is pressed).
- An emergency laser stop switch is available to disable the system immediately, in the case of an emergency.

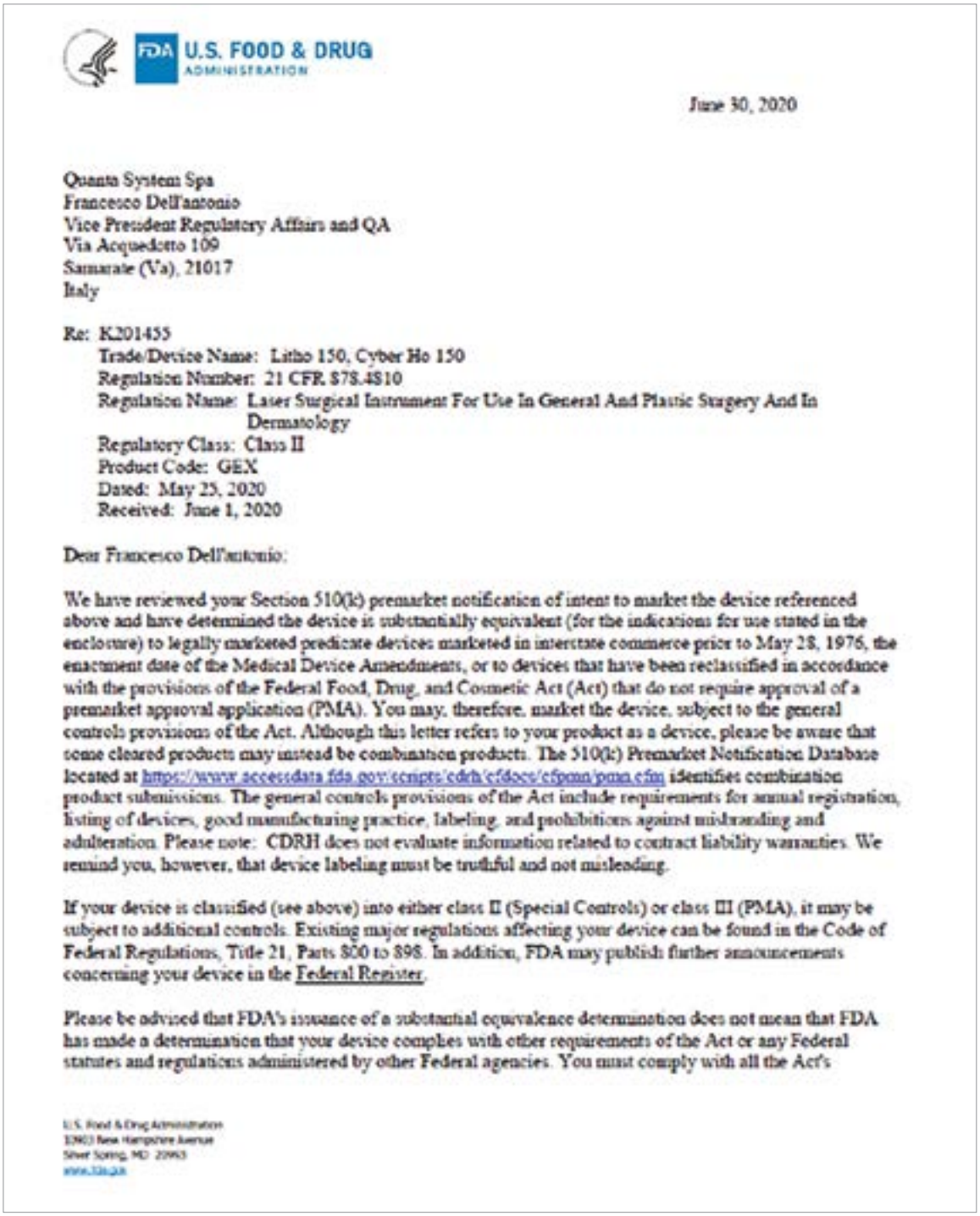
Coding and reimbursement

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."

*NOTE: References may be found on page 36 of this packet.

FDA 510(k) clearance letter

(The Litho 150 clearance letter is available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K201455.) For information regarding the FDA clearance letter(s) for the Litho 60/100 please contact your local Cook representative.



U.S. FOOD & DRUG ADMINISTRATION

June 30, 2020

Quanta System Spa
Francesco Dell'antonio
Vice President Regulatory Affairs and QA
Via Acquedotto 109
Samarate (Va), 21017
Italy

Re: K201455
Trade/Device Name: Litho 150, Cyber Ho 150
Regulation Number: 21 CFR §78.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 25, 2020
Received: June 1, 2020

Dear Francesco Dell'antonio:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

*NOTE: References may be found on page 36 of this packet.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2020.06.30 11:43:41 -04'00'

Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

*NOTE: References may be found on page 36 of this packet.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K201455

Device Name
Multicavity Holmium laser

Indications for Use (Describe)

The Multicavity Holmium laser system and its fiber optic delivery system are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue in use in medical specialties including: Urology, Urinary Lithotripsy, Gastroenterology, Arthroscopy, Discectomy, Gynaecology, ENT and General Surgery.

Urology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) including:
- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors,
- Ablation of Benign Prostatic Hypertrophy (BPH),
- Transurethral incision of the prostate (TUIP)
- Holmium Laser Resection of the Prostate (HoLRP)
- Holmium Laser Enucleation of the Prostate (HoLEP)
- Holmium laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of external genitalia

Lithotripsy and Percutaneous Urinary Lithotripsy

- Endoscopic fragmentation of urethral, ureteral, bladder and renal calculi including cystine, calcium oxalate, monohydrate and calcium oxalate
- dehydrate stones.
- Endoscopic fragmentation of kidney calculi
- Treatment of distal impacted fragments of steinstrasse when guide wire cannot be passed.

Gastroenterology

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

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers

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*NOTE: References may be found on page 36 of this packet.

- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Haemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Rendu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Arthroscopy

Arthroscopy/Orthopaedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue) in small and large joints of the body, excluding the spine but including:

- Ligament and tendon Release
- Contouring and sculpting of articular surfaces
- Capsulectomy in the Knee
- Chondroplasty in the Knee
- Debridement of inflamed synovial tissue
- Chondromalacia Ablation
- Chondromalacia and tears
- Plica Removal
- Meniscectomy
- Loose Body Debridement
- Lateral retinacular release

Ablation of soft, cartilaginous and bony tissue in Minimal Invasive Spinal Surgery including
- Percutaneous Laser Disc Decompression/Discectomy of the L4-5 and L5-S1 lumbar discs, including Foraminoplasty
  Percutaneous Cervical Disc Decompression/Discectomy
  Percutaneous Thoracic Disc Decompression/Discectomy

Gynaecology

Open and laparoscopic gynaecological surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis) of soft tissue

ENT

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and haemostasis of soft tissue and cartilage) including:
- Endonasal tumor Surgery
- Partial turbinectomy
- Polypectomy

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*NOTE: References may be found on page 36 of this packet.

- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery

General Surgery

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

- Appendectomy
- Skin incision
- Excision of external and internal lesions
- Complete of partial resection of internal organs, tumors and lesions
- Biopsy

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*NOTE: References may be found on page 36 of this packet.

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.

Additionally, below is the abridged IFU for the Litho 150 system which contains important information also used for the Litho 60/100 products.

QUANTA HOLMIUM LASER SYSTEM

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 Quanta Holmium. 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

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

To turn the device ON:

- Set the main switch to the I configuration on the rear panel. At the start-up, the horizontal LED bar on the upper front panel turns blue.
- Turn the key switch in the ⊙ configuration (clockwise) to turn on the system. If the laser fails to start, check that the emergency push button is not pressed. If the emergency push button is pressed, twist it to allow its release and turn the key to start the laser.

The **Loading screen** and then the **Home screen** (once the system has checked for the proper functioning and status of device elements) appear:

5.2 Operating instructions

5.2.1 Home Screen (fast selection screen)

Once the start-up is successfully completed, select on the Home Screen the desired application, or load a previously saved profile, by touching on one of the five large blue icons:

*NOTE: References may be found on page 36 of this packet.

The available choices are:

- **LITHOTRIPSY:** to enter the Pedal Settings Screen and select the Emission Mode with the pre- loaded parameters for Lithotripsy procedure (see Section 5.2.1.2);
- **BPH:** to enter the Pedal Settings Screen and select the Emission Mode with the pre-loaded parameters for BPH procedure (see Section 5.2.1.2);
- **SOFT TISSUES:** to enter the Pedal Settings Screen and select the Emission Mode with the pre-loaded parameters for Soft Tissues procedure (see Section 5.2.1.2);
- **MANUAL SETTINGS:** to directly enter the Main Screen (see Section 5.2.2) and skip the guided selection of output settings reported in Section 5.2.1.2
- **LOAD PRESETS:** to load a previously saved set of treatment parameters (Sections 5.2.1.4 and 5.3.1);

5.2.1.1 Language and Shutdown buttons

The Language and Shutdown buttons are also displayed in the Home screen:

Language: touch here to enter the Language managing panel (Section 5.3.5)

Shutdown: touch here to turn the system OFF

5.2.1.2 Pedal Settings Screen

When selecting LITHOTRIPSY, BPH, or SOFT TISSUES, the Pedal Settings Screen appears with a list of possible Emission Modes for the specific application. Possible emission modes are summarized in the list below and can be selected for both Footswitch 1 and Footswitch 2, independently.

Lithotripsy*

- Dusting High Frequency
- Dusting Vapor Tunnel
- Popcorning
- Fragmentation

BPH*

- HoLEP (Shockwave Enucleation)
- Delicate Areas
- HoLAP (Ablation/Vaporization)
- Coagulation

Soft Tissues*

- Precise Cut
- Fast Cutting
- Ablation
- Coagulation

**Possible emission modes on the Pedal Settings Screens.*

On the Pedal Settings Screen, select the treatment emission mode combined with Footswitch 1 and with Footswitch 2 (see also Section 3.2.6):

Emission modes for Footswitch 1 (LEFT PEDAL)

Emission modes for Footswitch 2 (RIGHT PEDAL)

Press OK to confirm the choice and enter the **Main Screen** (Section 5.2.2), or ← to return to the **Home Screen** (Section 5.2.1).

*NOTE: References may be found on page 36 of this packet.

5.2.1.3 Manual Settings

The User is directly redirected to the Main Screen (see Section 5.2.2), skipping the guided selection of output settings reported in Section 5.2.1.2.

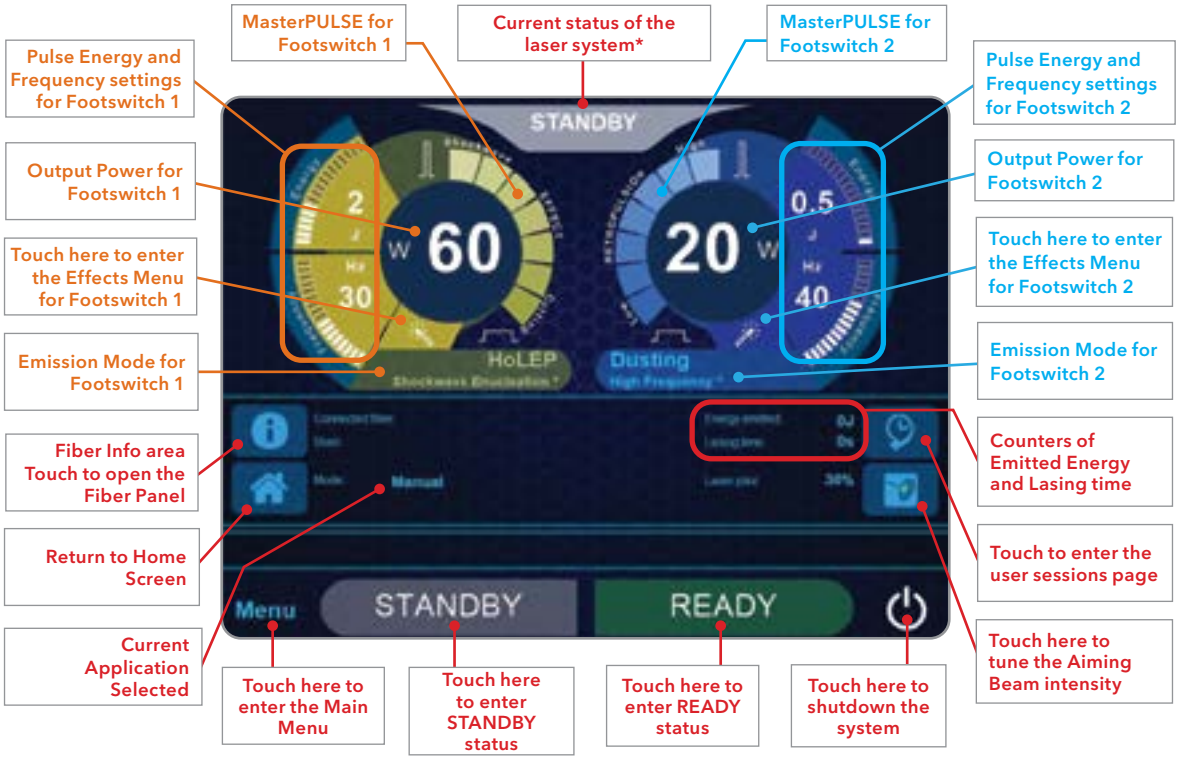
5.2.1.4 Load Presets

The User can load a previously saved set of treatment parameters.

NOTE! With respect to the procedure detailed in Section 5.3.1, the user cannot overwrite or save a new preset.

5.2.2 Main Screen

This section details the Main Display Screen. Refer to the figure below.



*NOTE: References may be found on page 36 of this packet.

Possible System status are:

- STANDBY (see Section 5.4.2)
- READY (see Section 5.4.3)
- LASING (see Section 5.4.4)
- ERROR (see Section 5.5)
- OFF (during the shutting down procedure)

Settings regarding pulse energy, frequency and the MasterPULSE are set automatically depending on the application selected in the Application screen.

Warning: Emission parameters of the presets are intended as suggested settings only. The surgeon has to consider changing the settings in order to have the desired effect over the target tissue based on his visual feedback and best clinical advice.

5.2.2.1 Emission Mode

Press the Emission Mode area to enter the Pedal Setting Screen (see also Section 5.2.1.2) and changed separately the treatment mode combined with Footswitch 1 and with Footswitch 2:

*NOTE: References may be found on page 36 of this packet.

The following screen shows up allowing to select the desired treatment mode exclusively for the selected pedal:

- First select the desired application ("*Mode*" - *left column*);
- Then select the treatment of preference ("*Setting*" - *right column*, updated depending on the selection in the left column)

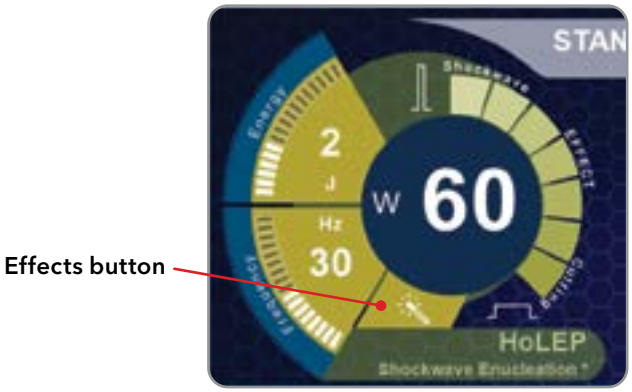
Press OK to confirm the selection, or ← to exit without changes.

5.2.2.2 Effects Menu

In the picture below, the case of **Footswitch 1** is shown; the same holds for **Footswitch 2**.

By pressing the Effects button, shown in the picture, the emission mode effect can be selected:

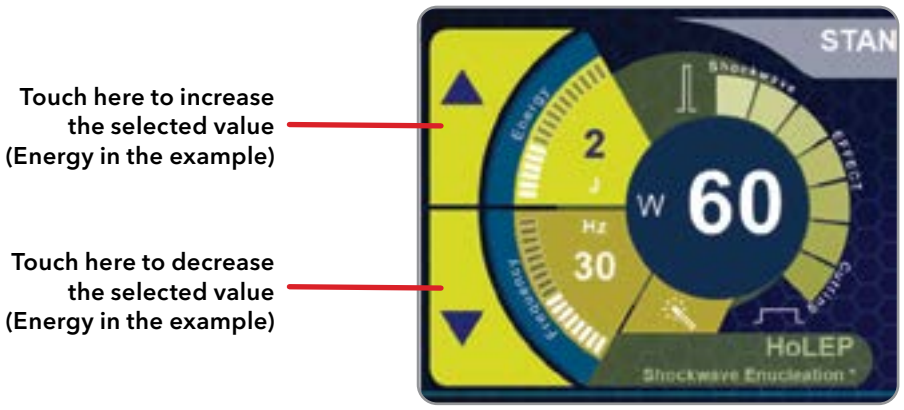
- **Standard:** conventional pulse emission mode;
- **Virtual Basket:** based on the principle that when a cavitation bubble collapses, there is a "suction effect" that prevents or inverts retropulsion of the target stone (acting as a virtual stone basket). With Virtual Basket mode, the first part of the pulse generates the cavitation bubble and, at its maximum expansion, the second part of the laser beam is emitted.



*NOTE: References may be found on page 36 of this packet.

5.2.2.3 Energy and Frequency settings

In the picture below, the case of **Footswitch 1** is shown; the same holds for **Footswitch 2**. Energy (J) and Frequency (Hz) adjustment does not require acceptance by pressing any confirmation button. In case of wrong adjustment, simply tune again the parameters according to the desired settings.



Energy

The treatment energy can be tuned by tapping on the "Energy" area. Lateral ▲/▼ buttons appear and the energy value gets highlighted with a different color.

The operator can increase/decrease this parameter by pressing ▲/▼ buttons, or by using the cursors.

When the user tries to increase the output energy over the maximum value available (with respect to the set frequency) the laser device will not allow additional energy increment, keeping both parameters unaffected.

Frequency

The pulse repetition rate can be tuned by tapping on the "Frequency" area. Lateral ▲/▼ buttons appear and the frequency value gets highlighted with a different color.

The operator can increase/decrease this parameter by pressing ▲/▼ buttons, or by using the cursors.

If the energy setting is too high for the selected frequency, the laser will automatically decrease the pulse energy value (output frequency is permitted to increase). The emitted sound, when firing, changes according to the selected frequency.

*NOTE: References may be found on page 36 of this packet.

Note: If the selected settings of the Energy and/or Frequency are not exactly the ones of the preset emission mode, but still in the acceptance range of the preset, an asterisk appears close to the mode name (e.g. "Delicate Areas *" in the figure). Further changes of the settings parameters modify the mode name into "Expert - Touch to modify".

5.2.2.4 MasterPULSE

The MasterPULSE element consists of a 7-steps bar wrapping around the output power button. The user can tune pulse duration (pulse width) by selecting different steps on the MasterPULSE bar (*shortest pulse* on top, *longest pulse* at the bottom).

Note: In COAGULATION mode, MasterPULSE bar is disabled.

*NOTE: References may be found on page 36 of this packet.

5.2.2.5 Fiber INFO

When a Quanta System RFID Fiber is connected and the RFID system is active, the system automatically recognizes the type of the fiber and number of the previous uses (see also Section 5.5.1), further showing the Fiber Info Panel on the display.

The Fiber Info Panel appears also by pressing on the Fiber Info area. Here you can find the following information:

- Fiber Code
- Fiber LOT
- Fiber Type
- Diameter
- Number of Uses
- Time of First and Last use
- Total emitted Joules (energy)

Figure 5.1: Fiber identified - POPUP.

Press  to return to the main screen.

If an unauthorized fiber is connected to the RFID system, the fiber will not be recognized and an error message will appear (see the example in Figure 5.2). If an expired optical fiber (disposable/ reusable) is connected to the laser system, an error message will appear.

Press  to return to the main Screen.

Figure 5.2: Fiber not identified/not selected - POPUP.

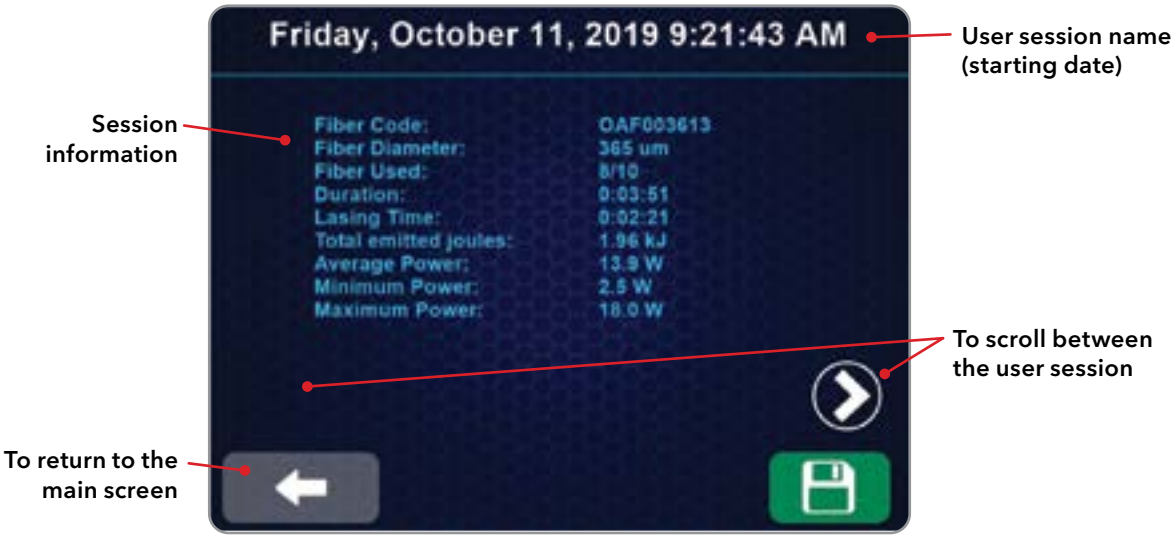
By touching the Fiber Info area with no fiber inserted, the User can approach the RFID connector to the laser port with the fiber still contained in its sterilization packaging. When doing so, the User can identify the fiber without opening the fiber sterile envelope. Follow the description detailed on the screen in order to perform this procedure.

*NOTE: References may be found on page 36 of this packet.

5.2.2.6 User sessions and counters

The emitted energy (Joules) and Lasing time (s) counters are shown in the main screen and increase during radiation emission. All the information regarding the user session can be reached through the button shown in the picture.

The following page will appear:



By scrolling through the pages, using the arrows, the latest 30 sessions are displayed. The information shown are:

- **Fiber code:** reference number of the fiber used
- **Fiber diameter**
- **Fiber used:** number of uses of the fiber related to the total number of uses permitted (in case of reusable fibers)
- **Duration:** duration of the user session
- **Lasing time:** emission time counter of the session
- **Total emitted joules:** energy counter
- **Average power**
- **Minimum power**
- **Maximum power**

*NOTE: References may be found on page 36 of this packet.

The first session starts with a new fiber and with the first emission.

A session ends in the following ways:

- The device shutdown
- The detachment of the fiber
- Through the button "save" at the bottom of the user sessions page.

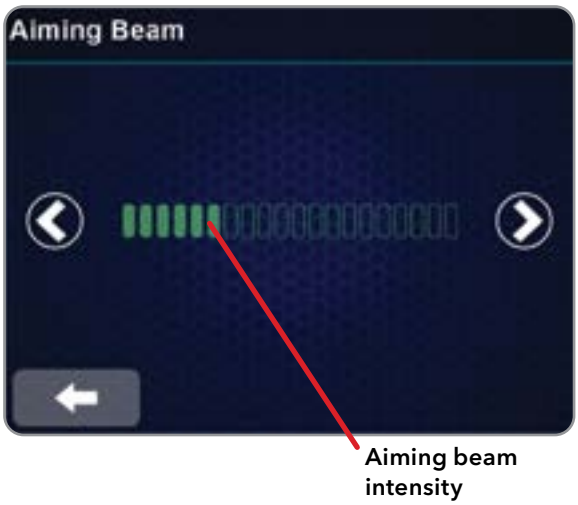
Once the session has been closed, the emitted energy and the lasing time counters will be reset.

5.2.2.7 Pilot laser (Aiming beam)

The aiming beam is adjustable by software, by tapping on the related icon in the main interface (see figure on the right). The label next to it displays the current level of the pilot laser intensity.

Touch the </> buttons on the Aiming Beam settings screen (below) to decrease/increase the aiming beam intensity. Once the desired aiming beam intensity has been reached, press  to confirm and return to the main screen.

Note: Pressing the Pilot Laser Button on the Main Screen when the laser system is in Standby status, the green pilot laser will be activated, maintaining the laser system in Standby mode. This function gives the possibility to check connected fibers in a safe condition, evaluating the shape of the laser beam immediately out of the fiber tip.



*NOTE: References may be found on page 36 of this packet.

5.5 Alarm and warning description

Different alarms may be displayed on the control panel. Every time an alarm occurs, a yellow message appears at the bottom of the screen specifying the alarm type (see example below):

When an alarm occurs, the System behaviour is different depending on the issue level of severity.

ERROR Status: In the "ERROR" status power electronics are cut off through a suitable switch and the device starts running in a safe mode or gets restarted. Chiller pump is Off. This Error occurs every time the Control finds the System in a status that is not-coherent with the command sent by the Microprocessor. This may occur also during the Start-Up procedure.

STANDBY Status: Some alarm/warnings force the system in "STANDBY" status, preventing to enter in Ready mode till the cause of the alarm has been solved.

*NOTE: References may be found on page 36 of this packet.

A complete list of all the possible alarm types is provided below.

Error message	Issue related (see chapter 8 - Troubleshooting)	System behavior
Connecting... Cannot open Serial Port ComX	Serial port communication fault	Message on screen
Capacitor voltage error	Capacitor voltage error	Force STANDBY status
Charger overload	Charger overload	Message on screen
High temperature discharger (#)	High temperature discharger	ERROR status
Energy Low (L#)	Energy Low - Lamp	Message on screen
Energy High (L#)	Energy High - Lamp	Message on screen
Energy very Low (L#)	Low Energy warning (<20%) - Lamp	Message on screen
Energy very High (L#)	High Energy warning (>20%) - Lamp	Message on screen
Lamp not ignited (#)	Lamp not ignited	ERROR status
Simmer Check ERROR (#)	Simmer # error	ERROR status
Low water flow (#)	Low water flow	ERROR status
Flow-switch ERROR (#)	Flow-switch error	ERROR status
Chiller ERROR	Chiller error (level, temperature)	If STANDBY > message on screen, force STANDBY status; If READY / EMISSION > ERROR
Galvo System ERROR	Galvanometer motor error	If STANDBY > message on screen, force STANDBY status; If READY / EMISSION > ERROR
Shutter not Closed ERROR	Shutter not closed	ERROR status
Shutter not Open ERROR	Shutter not open	ERROR status
Remote interlock open	The remote interlock contacts are open	Force STANDBY status
Pedal unconnected	Pedal not connected	Force STANDBY status
Pedal pressed in STANDBY	Pedal pressed in STANDBY	Message on screen
Blast sheild not present	Blast sheild wrong installation	Force STANDBY status
Fiber not connected	Fiber not present/connected	Force STANDBY status
Fiber not identified	Fiber not identified by RFID	Force STANDBY status
Not identified and not selected	RFID warning	Force STANDBY status
Fiber code not valid	RFID warning	Force STANDBY status
Fiber expired	RFID warning	Force STANDBY status
Critical Errors and Warnings appearing during start-up procedure		
Critical Error: FW_RAM	FW error	Message on screen - Fail safe status
Critical Error: FW_CRC32		
Critical Error: FW_FSCM		
Critical Error: FW Communication		
Critical Warning: FW watch dog	FW error	Message on screen - Fail safe status

*NOTE: References may be found on page 36 of this packet.

5.6 Shutdown procedure and protection against unauthorized use

Once device operation is accomplished and the laser is in Standby mode, one can proceed with its shutdown procedure as follows:

- Disconnect the optical fiber from the device and cover the laser device output connector with its dedicated protection shutter
- Touch the Shutdown button on the screen to initiate the Shutdown procedure
- A popup window will ask the user to confirm the shutdown of the device; press YES to confirm, or to return to the main screen:

- After this, the User has to wait 10-15 seconds during which the Chiller reaches a "standby" condition. After that, the User can safely switch the system off:
    - Turn the key switch to the configuration and remove the key to prevent unauthorized uses
    - Turn off the main switch on the rear panel and unplug the power cable
    - Disconnect the remote interlock
    - Disconnect the footswitch
    - Keep the device and its accessories in a dry and safe place

In order to avoid improper use of the device, keys shall be removed when the device is not being used.

*NOTE: References may be found on page 36 of this packet.

Solutions portfolio

Clinical

Vista® training and education programs

Cook Medical's 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

We have the ability to 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

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 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 clean-up

Cook Medical can perform an item master clean-up for its customers. This includes, but is not limited to, helping customers correct pricing discrepancies, discovering unit of measure discrepancies, locating unavailable or invalid part numbers, providing GTINs, and offering 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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