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Minimize migration, maximize performance.

H-30™

HOLMIUM LASER SYSTEM

With the H-30™ Holmium Laser System and Holmium Laser Fibers with SmartSync™ Technology you can safely and effectively treat stones and soft tissue malformations within the urinary tract.

COOK® MEDICAL

H-30™

HOLMIUM LASER SYSTEM

The H-30 Holmium Laser System features a variable pulse width to minimize stone migration and maximize tissue coagulation. Choose between three configurations. The 230 V system produces 30 W power. The H-30 also delivers a full 30 W when configured at 115 V and 20 amps. (Other lasers only provide 15 W when configured for 20 amps.) A 115 V and 15 amp setup is also available.

With the advantages of a full 30 W and a variable pulse width, the H-30 allows you to treat urethral strictures and perform bladder neck incision. It can be used for the ablation and resection of bladder, urethral and ureteral tumors. The laser system is also ideal for treating any type of calculi, regardless of color or composition, in the kidneys, ureters or bladder.

System Features

- A variable pulse width minimizes stone migration and maximizes tissue coagulation.
- The 30 W treatment power allows you to treat stones and soft tissue malformations.
- A green aiming beam provides better contrast and visualization of the surgical site.
- User-friendly touch screen controls allow you to change the power parameters during procedures.

Specifications

Laser type	Pulsed Holmium: YAG
Laser wavelength	2100 nm
Maximum average power	30 Watts
Pulse duration	Short and long
Pulse energy	0.5 to 3.5 Joule
Repetition rate	5 to 20 Hz
Visible aiming beam	Diode laser, green, 32 nm (adjustable < 3 mW maximum)
Electrical requirements	115/230 V~ 15/20 A single-phase
Physical dimensions	20 in (50 cm) wide 23 in (59 cm) deep 51 in (129 cm) high
Weight	176 lbs. (80 kg)
Safety compliance	UL/CSA 2601 EN 60601-1 EN 60825-1 EN 60601-1-2

Holmium Laser Fibers

Holmium Laser Fibers with SmartSync Technology are compatible with most SMA-905 holmium lasers, but they provide an advanced level of functionality when they are used with the H-30. The SmartSync microchip communicates with the H-30 to identify the size of the attached fiber, limit the laser energy to the fiber's maximum allowable power output, and record all information related to the case (i.e., power settings, number of pulses and any suspected laser system or laser fiber malfunction).

Single-Use Fibers

Single-use fibers have red connectors and are offered in the following core diameters (micron): 150, 200, 273, 365, 550 and 940.

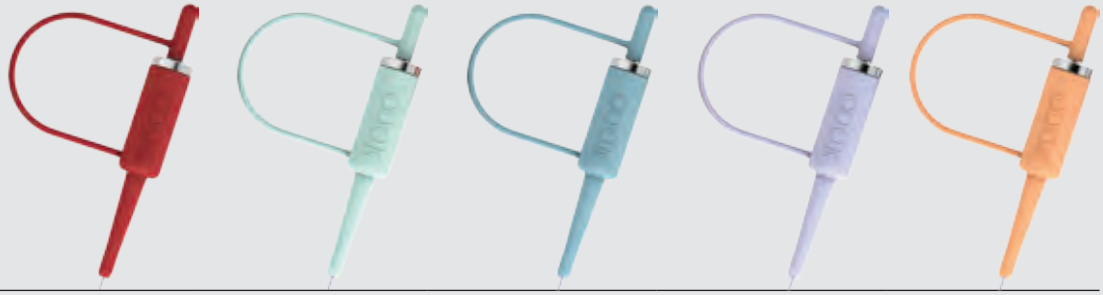
Multi-Use Fibers

Multi-use fibers have color-coded connectors that allow you to easily identify the fiber size. These fibers are offered in the following core diameters: 273 (green), 365 (blue), 550 (violet) and 940 (orange) µm.

The number of uses for each multi-use fiber will depend upon the careful handling and reprocessing of the fiber.

Features

- Color-coded connectors help you determine the appropriate usage and size of a fiber.
- The integrated protective material in the hub absorbs errant blasts and protects the optical deck on the laser system from damage. This protective material makes the blast shield a redundant measure.
- A SmartSync microchip communicates with the H-30 to identify and record important information.



Use	Single-Use	Multi-Use	Multi-Use	Multi-Use	Multi-Use
Core diameter microns	150, 200, 273, 365, 550, 940	273	365	550	940

H-30™

HOLMIUM LASER SYSTEM

Order Number	Reference Part Number	Fiber Diameter µm	Comments
H-30 Holmium Laser			
G23663	**HL-30A**	-	115 V, 15 amp
G23071	**HL-30B**	-	115 V, 20 amp
G23664	**HL-30C**	-	230 V
Holmium Laser Radiation Warning Sign			
G50016	**HLA-2000**	-	-
Holmium Laser Safety Glasses			
G50015	**HLA-2010**	-	-
Holmium Laser Safety Goggles			
G50014	**HLA-2020**	-	-
Stripping Tool			
G50011	**HLA-2120**	273	-
G50010	**HLA-2130**	365	-
G50009	**HLA-2150**	550	-
G50012	**HLA-2110**	940	-
Fiber Steam Sterilization Tray			
G50008	**HLA-2200**	-	-
Fiber Cleaving Tool			
G50013	**HLA-2100**	-	-
Fiber Inspection Microscope			
G49750	**HLA-2300**	-	-

Additional extended warranty, service agreements and training programs are available for the H-30.

Fibers for Use with H-30 and Non-SMA-905 Connector Laser Systems

Order Number	Reference Part Number	Fiber Diameter µm	Connector Color
Single-Use Holmium Laser Fiber			
G23731	HLF-S150-H30	150	red
G23733	HLF-S200-H30	200	red
G23553	HLF-S273-H30	273	red
G23552	HLF-S365-H30	365	red
G23734	HLF-S550-H30	550	red
G23735	HLF-S940-H30	940	red
Multi-Use Holmium Laser Fiber*			
G23668	HLF-M273-H30	273	green
G23667	HLF-M365-H30	365	blue
G23666	HLF-M550-H30	550	violet
G23665	HLF-M940-H30	940	orange

**The connector color identifies the fiber diameter.*

Contact your local Cook representative or Customer Service for details.

Fibers for Use with H-30 and SMA-905 Connector Laser Systems

Order Number	Reference Part Number	Fiber Diameter µm	Connector Color
Single-Use Holmium Laser Fiber			
G25292	HLF-S150-HSMA	150	red
G25293	HLF-S200-HSMA	200	red
G25294	HLF-S273-HSMA	273	red
G25295	HLF-S365-HSMA	365	red
G25296	HLF-S550-HSMA	550	red
G25297	HLF-S940-HSMA	940	red
Multi-Use Holmium Laser Fiber*			
G25298	HLF-M273-HSMA	273	green
G25299	HLF-M365-HSMA	365	blue
G25300	HLF-M550-HSMA	550	violet
G25301	HLF-M940-HSMA	940	orange

**The connector color identifies the fiber diameter.*

Contact your local Cook representative or Customer Service for details.

Functional Specification for Holmium Laser

Introduction

Required is a holmium laser for fragmenting stones of varying sizes and hardness in all areas of the urinary tract. The secondary role will be for excision or coagulation of soft tissue/tumour with minimal damage to surrounding tissue.

Mandatory Functional Requirements

30 watts adjustable power setting	Yes
• adjustable pulse energy of 0.3-3.5 Joules	Yes - 30W laser
• varying pulse duration and repetition rate	Adjustable 0.5 - 3.5J
• ureteroscopes.	Yes - LONG and SHORT pulse duration options. Repetition rate of 5-20Hz
• The device must have an adjustable aiming beam	Yes - Fully compatible with all urology cystoscopes, nephroscopes, semi-rigid ureteroscopes and flexible ureterorenoscopes.
Control panel for adjusting all parameters	Yes
• The device have alarms/warning in case of malfunctioning of machine to protect user	Yes - please see 'H-30 Quick User Guide' for diagram of touchscreen. Very intuitive and user-friendly
• Ten sets of laser safety goggles/glasses adequate to provide protection from the main beam and the aiming beam must be supplied.	glasses specifications: OD5+ @ 2100nm, D,I,R 1400-2200 L4
• Four sets of laser safety signs stating the class and type of laser which can be hung from a hook, will be supplied.	Yes
1. State the power supply requirements of the laser.	230 V~ ± 10%; 50/60 Hz; 10 A
2. State the power consumption requirements of the laser.	230 V~ ± 10%; 50/60 Hz; 10 A
3. Provide a list of compatible urology scopes.	All urological scopes are compatible - all brands/sizes of cystoscopes, semi-rigid ureteroscopes, nephroscopes and flexible ureterorenoscopes
4. State any limitations on the duration or type of lithotripsy procedures which can be performed with this laser.	No limitiations - all Urological lithotripsy can be carried out with this machine including: bladder stones, ureteroscopies, flexible ureterorenoscopies and PCNL
5. the operating temperature of the device	10-25 degrees Celsius
6. Please provide details of the beam delivery including:	
- Wavelength	2100nm=532nm
- output accuracy	See pg11 of Service Manual for technical info
- width, divergence distance and subtense angle	See pg11 of Service Manual for technical info
- output calibration, if any	Internal energy meter, detects laser energy prior to entry into laser fibre and warns if energy out of accepted range (+/-20%)
- output power incremental steps	Energy options: 0.5, 0.6, 0.7, 0.8, 1.0, 1.2, 1.5, 2.0, 2.5, 3.0, 3.5J. Frequency options: 5, 8, 10, 12, 15, 20Hz. Note, not all energies/frequencies available for all fibre sizes.
7. information on the fibres:	
- available range of reusable fibres including details on “smart” or “intelligent fibres”	Sizes: 273, 365, 550 and 940µ reuseable fibres are available. All 3m in length with 7mm clear tip when new and blue buffer. All our fibres are 'Smartsync' fibres that communicate between the laser and the fibre. This ensures only the correct fibres are used with the machine, ensures the power levels remain in line with fibre size and assists with troubleshooting and technical feedback. All the case data is stored on a microchip in the fibre connector, this greatly speeds up the troubleshooting process and allows us to quickly ascertain all the settings/time/pulses/error messages/operating conditions during a case where a technical issue may have occured.
- recommended number of uses	Max 20 uses

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- does the manufacturer support the use of generic fibres	No - Laser will not accept generic fibres
	Sizes: 150, 200, 273, 365, 550 and 940µ single-use fibres are available. 150µ is the smallest fibre available on the market and we have the largest range of singe-use fibre sizes on the market. All 3m in length with 7mm clear tip and blue buffer. All our fibres are 'Smartsync' fibres that communicate between the laser and the fibre. This ensures only the correct fibres are used with the machine, ensures the power levels remain in line with fibre size and assists with troubleshooting and technical feedback. All the case data is stored on a microchip in the fibre connector, this greatly speeds up the troubleshooting process and allows us to quickly ascertain all the settings/time/pulses/error messages/operating conditions during a case where a technical issue may have occured
- Does the manufacturer support the use of generic or third-party single-use fibres – if so, give examples	No - Laser will not accept generic fibres
- In all cases state compatible with flexible ureteroscopes	Compatible with all brands/sizes of flexible ureteroscopes
8. the pulse mode including	
- method	Pulsed laser
- output energy range	0.5, 0.6, 0.7, 0.8, 1.0, 1.2, 1.5, 2.0, 2.5, 3.0, 3.5J
- range of repetition frequency available and incremental steps	5, 8, 10, 12, 15, 20Hz
- pulse duration range and incremental steps	SHORT or LONG mode. Varies between 300 - 1200µs depending on settings used
- pulse interval and incremental steps	N/A - can change energy, rate and pulse duration
9. Please provide details of the aiming beam including:	
- output power	Diode laser, green 532nm, adjustable < 3mW max.
- beam width	2mm
- details of focusing	Coaxial with working beam through focusing lens
- beam accuracy	Coaxial with working beam as it is launched into the fibre
- alignment with therapeutic beam	Coaxial
10. the operating wavelength	Laser 2100nm, aiming beam 532nm
	Fan powered air cooling system and an enclosed water cooling system. Water cooling system has deionising cartridges and a water filter in the system. Water and DI cartridge exchanged every PM. Laser is designed to work for long periods with maximum cooling of the laser rod for increased efficiency
12. State the warming up time – from power on to clinically usable	<20 seconds
14. State the power supply requirements	230 V~ ± 10%; 50/60 Hz; 10 A
15. State if there are any novel features designed to improve the safety of the device and/or protect the scopes to be used with the laser.	Our main novel safety feature and USP is that our laser fibres have a newly designed novel connector that absorbs any errant laser energy rather than transferring it along the protective layers of the fibre. Other fibres may transfer errant energy along the protective coatings of the fibre which results in a weak point where the fibre is deflected ultimately leading to a broken fibre at that point and the high possibility for scope damage if the break isn't spotted quickly enough. Our fibre conenctor reduces weaknesses at deflection that are associated with other laser fibres thus reducing the incidents of broken laser fibres and scope damage.
16. the laser class	Class IV
17. the nominal ocular hazard distance in continuous and pulsed mode	Laser only has a pulsed mode. NOHD is less than 0.5m when fired through a fibre during normal use - up to 14.7m during some service operations. Full info in Chapter 2 of Service Manual

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19. The details of all safety features which are included in the design of the machine	Safety features include: visible and audible emmisions indicator to warn when the laser is being fired; fibre detection system with Smartsync fibres to ensure the correct fibres are used with the machine and to ensure power levels cannot be increased to unsafe levels with small sizes of fibre; emergency stop fitted to the front of the machine in case of emergency; case logging on the Smartsync fibre giving the opportunity to provide full case data for each procedure; visible aiming beam to ensure laser energy being delivered to the correct precise location; fibres packaged with a drape sticker to hold the fibre in place during procedures, reduces the need for scrub nurses to physically hold the fibre and in turn could help avoid clincial incidents due to fibres being broken; our status bar on the control screen quickly highlights any errors to the users and will put the machine back in standby mode for any error critical to safe operation; finally our fibres connector is designed to absorb any errant energy as outlined in Q15 above. This can reduce scope damage associated with broken fibres from weak points at full deflection.
20. The details of	
- all user controls including foot pedals	Intuitive touch screen to change settings and go between Standby and Ready states. Gives information on total energy for the case, can see fibre information (single/reusable, number of uses, lot no.), see date of last PM, when next PM is due, number of cases carried out by the machine, temperature of the coolant and diagnostic info. Foot switch is used by the clinician to fire the laser once it is in Ready state.
- steps required before the laser is fired	Laser plugged in to normal 3 pin plug socket, laser mains switch switched on,laser turned on via key, fibre and footpedal attached to the machine. Settings selected. Ready mode entered.
- status indicators	Status bar highlighting whether laser is on Standby or Ready mode, when it is lasing and displays any error messages. There is a visible and audible emissions indicator to warn when the laser is being fired.
21. the dimensions of the unit	50cm wide, 59cm deep, 129cm high. Has a very small footprint to take up minimal space in theatres. Significantly smaller footprint than most 'desktop' lasers
22. the method of cooling	Fan powered air cooling system and an enclosed water cooling system. Water cooling system has deionising cartridges and a water filter in the system. Water and DI cartridge exchanged every PM. Laser is designed to work for long periods with maximum cooling of the laser rod for increased efficiency
23. the weight of the unit	104kg
26. Do any checks need to be carried out after the equipment has been moved?	Not if moved on internal corridors - we don't recommend transporting between buildings/cross site once installation has been completed
27. The first placed on the market in the EU.	2013
28. Confirm that the laser is CE marked	Yes
33. Origin of manufacture	USA
34. First date of system manufacture	Summer 2012
35. Expected last date of system manufacture	Ongoing, new unit, will be manufactured for the foreseeable future
36. Details of primary reference site	
37. Details of delivery time (weeks)	4-5 weeks
41. Estimated technical lifetime of the equipment	10 years
42. Typical response time in the event of equipment failure	24 hours
43. Warranty period and any exclusions applying to this period	2 years - negligence/mistreatment are excluded. PM servicing needs to be paid for during warranty period as outlined in 'After Sales' document

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Service Clientèle

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NOM DU PRODUIT : H-30 Holmium Laser System - H-30™ système laser holmium, **DESTINATION :** Cette section présente l'utilisation du système laser holmium H-30 dans les applications cliniques. Les informations sont fournies par spécialité et incluent des recommandations opératoires ainsi que des indications et contre-indications spécifiques. Les informations fournies dans cette section ne sont pas exhaustives et ne sont pas destinées à remplacer la formation ou l'expérience du médecin. Seuls les médecins et le personnel dûment formés et connaissant bien les consignes et précautions de sécurité incluses dans ce manuel doivent utiliser le H-30. Une révision de la formation suivie auparavant est vivement suggérée et recommandée., **CLASSE DU DISPOSITIF MEDICAL :** <IIb, **ORGANISME NOTIFIE :** LRQA 0088, **FABRICANT :** Cook Urological, **MODE D'EMPLOI :** Veuillez lire attentivement les instructions figurant sur la notice ou l'étiquetage du dispositif médical, **REMBOURSEMENT :** Pris en charge par l'assurance maladie., **DATE DE PUBLICATION :** 2012 Décembre, **NUMÉRO DE RÉFÉRENCE INTERNE :** URO-BFRM-H30BR-FR-201212

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