Lumenis Pulse[™] 100H Holmium Laser System Technical Specifications

Average Power: 100 Watts Laser Source: Holmium:YAG Wavelength: 2.1 μm Energy per Pulse: 0.2-3.5 Joules Repetition Rate: 5-53 Hertz

Note: Using any third-party laser fibers not listed as compatible with Lumenis Pulse[™] Laser Systems and VersaPulse[™] PowerSuite[™] Laser Systems may void the customer's warranty.

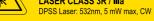
*Bench test results may not necessarily be indicative of clinical performance.

Risk information

The use of the Lumenis Pulse 100H in urology is contraindicated for patients who are unable to receive endoscopic treatments or are intolerant to prolonged anesthesia, as well as for resection or excision of large, vascularized organs. Holmium lasers are intended solely for use by physicians trained in the use of the Ho:YAG (2.1 μ m) wavelength. Incorrect treatment settings can cause serious tissue damage. The laser should be used only on tissues that are fully observable. See the system user manual for a complete list of contraindications and risks.



LASER CLASS 4 / IV Holmium: YAG: 2.1µm, 3.5J max, 600 µs pulse max LASER CLASS 3R / IIIa



DANGER - VISIBLE AND INVISIBLE LASER RADIATION AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION CLASS 4 LASER PRODUCT per IEC 60825-1: 2007/2014 CLASS IV LASER PRODUCT per 21 CFR 1040.10 and 1040.11 except for comformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 as described in the Laser Notice No. 56, dated May 8, 2019 LB-20001720 C

References:

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- 9. Kronenberg P, Traxer O. Update on lasers in urology 2014: current assessment on holmium: yttrium-aluminum-garnet (Ho:YAG) laser lithotripter settings and laser fibers. World J Urol. 2015 Apr;33(4):463.
- 10. Ventimiglia E, Doizi S, Kovalenko A, et al. Effect of temporal pulse shape on urinary stone phantom retropulsion rate and ablation efficiency using holmium: YAG and super-pulse thulium fibre lasers. BJU Int. 2020 Jul; 126(1):159-67.

Boston Scientific acquired the global surgical business of Lumenis Ltd.

Lumenis Pulse™ 100H is the registered product name. Lumenis Pulse™ 100H Holmium Laser System is manufactured and sold by Boston Scientific. Lumenis is a registered trademark of Lumenis Be.

Rx only.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France. All images are the property of Boston Scientific. All trademarks are the property of their respective owners.



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Advancing science for life[™]



Lumenis Pulse[™] 100H Holmium Laser System

Versatile, powerful, reliable



Versatile and powerful high efficiency for HoLEP and stone treatment

100W of power for effective HoLEP procedures



Over 15 years of clinical evidence have made HoLEP the right choice for Urologists and patients worldwide.^{1,2}



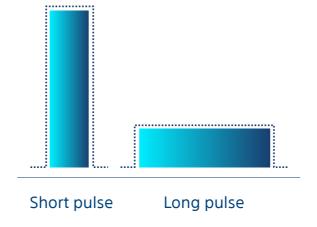
HoLEP is recommended by the AUA for BPH.³ Among its advantages is a low reoperation rate, and wide patient applicability.^{2,4} Compared with alternative treatment options (e.g., TURP and Open Prostetectomy) for BPH, HoLEP has a significant advantage in efficacy and safety.^{1,2,5,6}

Stone dusting

Stone dusting lithotripsy is effective at pulverizing stones of various sizes and types.⁷ Dusting with high power lasers allows you to pulverize the stone and may reduce the need for retrieval devices or ureteral access sheaths.⁸ The low energy per pulse applied in dusting may minimize retropulsion.^{*,9}

Embedded retropulsion capabilities

The system allows physicians to quickly switch to a long-pulse mode which is designed to address retropulsion.^{*, 10}



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A comprehensive solution

The combination of different laser parameters allows for a wide range of medical specialties, including Urology, Arthroscopy, General Surgery, ENT, Gynecology, Gastroenterology and more.

Reliable

100,000 Lumenis Pulse[™] 100H Laser Systems patients to date and growing.^{**} Case Saver mode informs the surgeon during the procedure in the event of system malfunction.



Ease of use

The graphical user interface with a touch screen allows for the tracking of accumulated energy during the procedure and double settings are controlled by the systems' dual pedals.



Customizable dual pedals

Allows for easy switching between two sets of laser settings during procedure in addition to a foot-operated ready/standby mode.

Enhanced visibility

Green aiming beam designed for endoscopic visibility.



Validated with range of delivery devices

SlimLine[™] family of fibers: Designed for durability, flexibility and versatility in urological procedures.

SlimLine[™] 200 D/F/L, Single-Use Fiber, with ball tip: Designed for flexible ureteroscopy procedures.