

«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

<Reference: 97518004-FA>
SRN: IL-MF-000016033

30 March 2026

Urgent Field Safety Notice - Product Advisory **CO₂ Laser Systems and VersaPulse PowerSuite (VPPS) Dual Wavelength (DW)** **Systems Service Activities**

Dear «Users_Name»,

Boston Scientific has identified that Service Manuals for the VersaPulse (VPPS) Dual Wavelength (DW) and CO₂ Laser Systems include incorrect or incomplete laser safety eyewear protection information, resulting in the potential for ocular harm.

This Product Advisory applies only to personnel performing installation and service activities on the VPPS DW Systems and CO₂ Laser Systems. See Table 1 for affected system UPNs, revised eyewear specifications, and associated Service Manuals. No other devices are impacted, and no product is being removed. See Appendix 1 for the revised servicing instructions that will be included in the upcoming service manual update for VPPS DW Systems. There are no changes to the servicing instructions for CO₂ Systems.

Clinical Impact

The laser systems' performance and intended clinical use are not impacted. However, service/installation personnel may operate the laser system with optical covers open or removed during installation and service activities, which may result in direct laser exposure. If service/installation personnel use inadequate laser safety eyewear protection, the most serious potential harm is ocular injury. No injuries have been reported related to this issue and based on medical safety assessment, the likelihood of such harm occurring is considered remote.

Device Description

The VPPS Dual Wavelength system is intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in different medical specialties such as (but not limited to) Urology, Gynecology, Gastroenterology, and general surgery.

The AcuPulse and UltraPulse Family of CO₂ Lasers Systems and accessories are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue.

Instructions:

1- For VPPS DW Systems: Immediately begin following the revised service manual steps included in Appendix 1.

2- Ensure all eyewear used during installation/service meets the revised values in Table 1.

a- Specifically, the laser protection level (DI LB), optical density (OD), Nominal Ocular Hazard Distance (NOHD) applicable to the system and service mode.

3- Forward this notice to any installation/service personnel within your organization.

4- Continue to follow all existing safety warnings, precautions, and training requirements when performing service activities.

5- Please complete the attached Acknowledgement Form even if you do not have any affected product.

6- When completed, please return the Acknowledgement Form to your Boston Scientific office for the attention of «Customer_Service_Fax_Number» on or before 17 April 2026.

Please note that this is an informational notice to you. **No** product is being recalled.

Your national Competent Authority has been informed of this communication. Any adverse events or quality concerns associated with use of these devices should be reported to Boston Scientific and Regulatory Authorities if appropriate.

Safety is our highest priority. We are providing this notice to ensure you have the necessary information to support safe use of these systems during servicing. If you need additional assistance or have questions about this notice, please contact your local Boston Scientific representative.

Yours sincerely,



Brandon Erickson
Vice President, Global Quality
Boston Scientific

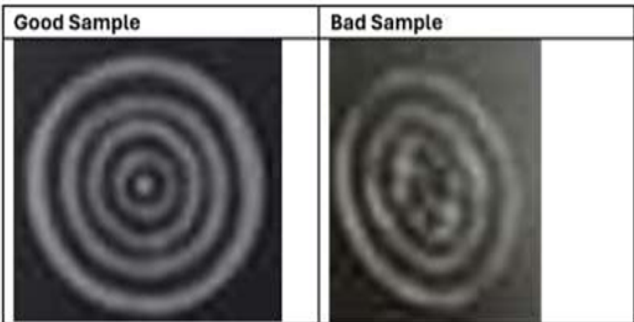
Attachment: - Acknowledgement Form

Table 1 Laser Safety Eyewear Revised Specifications and Service Manual Information

Laser protection level (D LB/DI LB), Optical Density (OD), Nominal Ocular Hazard Distance (NOHD)

Console	Console UPNs	Console GTINs	Service Manual Part #	Current Values in SMs			Revised Values			Safety Eyewear Part #
				DI LB	OD	NOHD	DI LB	OD	NOHD	
VPPS DW – 2100nm wavelength	RG0638-807-01 0638-800-00 0638-800-00CN	07290109145877 07290109140582 07290109146157	0636-499-00	Not listed	Not listed	Not listed	DI LB 5	4	55m	SP001-97186937-001
VPPS DW – 1064nm wavelength	0638-800-01 0638-801-01 0638-807-01	07290109146164 07290109146249 07290109146225		Not listed	Not listed	Not listed	D LB 6	5+	133m	
AcuPulse Waveguide	GA-0000140 GA-0000140CN RG-0000140	07290109140315 07290109146010 07290109146003	PB0000301	D LB 4, I LB 3	4	333m	DI LB 4	4	150m	
AcuPulse DUO	GA-0001110CN GA-0001111CN GA-0001113CN GA-1000000 GA-1000000CN RG-1000000	07290109146539 07290109146546 07290109146553 07290109140292 07290109146034 07290109146027	PB0000300	D LB 4, I LB 3	4	333m	DI LB 4	4	150m	
UltraPulse DUO	GA-2000000 RG-2000000	07290109140322 07290109146133	SM-0000400	D LB 4, I LB 3	4	175m	DI LB 4	3	119m	AX-2008056

Appendix 1 Revised Servicing Instructions for VPPS

Summary of Change: VPPS Service Manual Update (0636-499-00)	Service Manual Update: Section 3 Calibration, Adjustment and Alignment: 3.0.1 Overview	Additional Info														
	TOOLS & EQUIPMENT REQUIRED: Target Alignment Tool SP0638-497-51	Add Target Alignment Tool as required equipment														
	3.2.2.3 Resonator Alignment: Steps 4(h)-4(m) h. Remove the Cross-Hair Target tool and insert the Target Alignment tool (P/N SP0638-497-51) for adjusting the OC. i. Place a chemical Burn Paper (3207-0091) for testing the laser footprint and make a burn spot on the paper. If the mark is not solid and symmetrical, adjust the OC adjustment screws to achieve a nice, round pattern per the example below: Good Sample Bad Sample  j. Repeat steps e-i until the spot size is centered in the Target Alignment tool and a clear, round, symmetric spot is achieved on the burn paper. k. After aligning the resonator, tighten the screws and check that the spot is still centered in the Target Alignment tool, and a clear, round, symmetric spot is achieved on the burn paper. l. Once the burn mark is centered within the crosshairs and the spot size is centered in the Target Alignment tool, remove the tool and position the power meter head behind the aperture so that the YAG energy passing through the hole is directed onto the power meter sensor. Activate the laser and measure the output power in accordance with the table below. Adjust the lamp energy/current as needed to reach the specified minimum power (for Nd:YAG, begin at 10 A). <table><tr><td>YAG</td><td>Lamp voltage</td><td>Lamp Max energy/current</td><td>Frequency</td><td>Required minimum power</td></tr><tr><td>HO:YAG</td><td>800v</td><td>75J</td><td>12.5 Hz</td><td>34W</td></tr><tr><td>Nd:YAG</td><td>800v</td><td>60A</td><td>60 Hz</td><td>70W</td></tr></table> m. Reinstall the first Relay Mirror and perform the Fiber Alignment Procedure in Topic 3.1.4.	YAG	Lamp voltage	Lamp Max energy/current	Frequency	Required minimum power	HO:YAG	800v	75J	12.5 Hz	34W	Nd:YAG	800v	60A	60 Hz	70W
YAG	Lamp voltage	Lamp Max energy/current	Frequency	Required minimum power												
HO:YAG	800v	75J	12.5 Hz	34W												
Nd:YAG	800v	60A	60 Hz	70W												



Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_To» - «Hospital_Name» - «City» - «Country_name»

Acknowledgement Form – Product Advisory

**CO2 Laser Systems and VersaPulse PowerSuite (VPPS) Dual Wavelength (DW)
Systems Service Activities**

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By signing this form, I confirm that

**I have read and understood
the Boston Scientific Field Safety Notice**

dated 30 March 2026 for the

**CO2 Laser Systems and VersaPulse PowerSuite (VPPS) Dual Wavelength (DW)
Systems Service Activities**

NAME* _____ **Title** _____

Telephone _____ **Email** _____

Customer' SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy