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Philips Image Guided Therapy Corporation

URGENT Field Safety Notice

Philips Laser System (LAS-100) Error 500

JUN-2022

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Dear Valued Philips Laser System Customer,

Philips IGTD identified an issue with the LAS-100 Philips Laser System that may pose a risk for patients or users. This URGENT Field Safety Notice letter is intended to inform you about:

1. What the problem is and under what circumstances it can occur

Philips has identified an intermittent mechanical fault with the LAS-100 Philips Laser Systems manufactured prior to 18-MAY-2022. For affected units, on occasion, the system may detect an inoperable hardware component during power up. When this issue occurs, the user will be visually alerted on the system display as "Error 500 – System Failure" (see Figure 1). The user will not be able to proceed until the error is cleared. In this event, a delay in treatment may occur since the device is not able to fully initialize to a ready state. This fault was identified after seven (7) complaints of Error 500 were received. To date, Philips has not received reports of patient or user harm due to this issue.

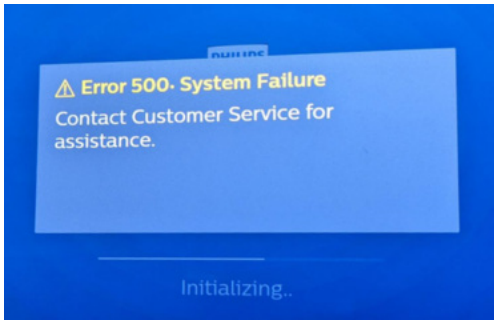

Figure 1: Example of an Error 500 visual alert

The LAS-100 Philips Laser System (see Figure 2) is used in minimally invasive interventional procedures within the cardiovascular system, and for the removal of pacemaker and defibrillator cardiac leads.

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Figure 2: LAS-100 Philips Laser System

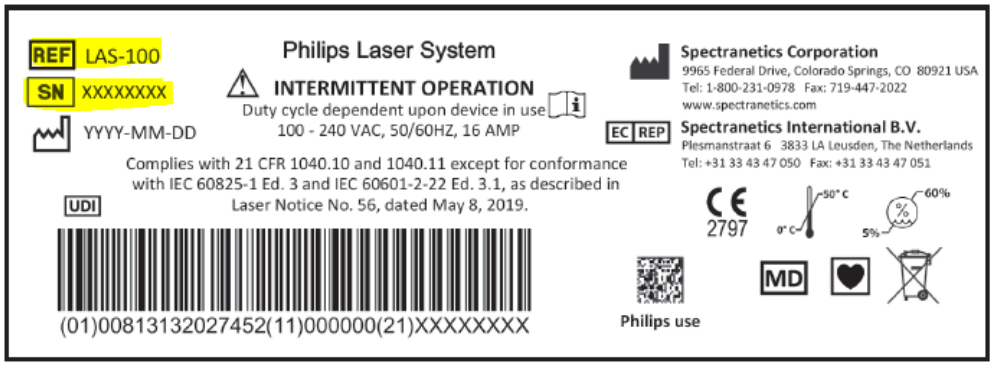
As an alternative treatment, the CVX-300 Excimer Laser System, which is clinically equivalent to the LAS-100 Philips Laser System, can be used, if available, for peripheral and coronary atherectomy and lead extraction as per the Instructions for Use of the laser catheters.

2. Hazard/harm associated with the issue

If this issue is present, it only occurs during the system boot-up process and prior to clinical use. If this issue is not present, the user may continue to use the device as usual.

3. Affected products and how to identify them

Only the Philips Laser Systems (PLS), model number LAS-100 with the serial number range of 100000 to 100104 are affected. The model and serial number of the PLS are printed on the primary label on the back of the device as shown below.



4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

Philips internal testing confirms that 1-3 reboots of the system will temporarily resolve the issue. Philips also recommends the continued use of the Philips Laser System, and to follow the Operator's Manual, as there is no expected harm to the user or patient.

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Philips recommends notifying all Philips Laser System users within your facility of this communication and retain a copy of this letter for reference. To acknowledge receipt of this notification, please complete, sign, and return the Customer Reply Form, included with this letter, within 30 days upon receipt of this notice to the following **Email:** IGTD_INTL_FieldSafety@philips.com

If you are a distributor or have forwarded affected device(s) to another end user, it is imperative that all end-users with affected devices receive this URGENT Field Safety Notice. Therefore, send a copy of this notification to any customer to whom you have distributed the affected product. If you need any further information or support concerning this issue, please contact your local Philips representative or Philips IGTD Customer Service:

Philips Laser System (PLS) Customer Service:
Tel. +31 334347050
Email: igtdcustomerservice-int-spnc@philips.com
Hours of Operation: Monday- Friday 8:00AM - 5:00PM CET

Region	Phone number	Region	Phone number
APAC	+3222750171	France	+33157324031
Austria	+431501375037	Germany	+494028991234
Belgium	+3222566604	IIG (excl.Italy)	+31202046555
CEE (excl. Poland)	+31202046550	Italy	+390245281151
Denmark	+4543310566	META	+31202046527
Finland	+358922943008	Norway	+4722971709

5. Actions planned by Philips IGTD to correct the problem
Philips will notify all affected customers and arrange for a Field Service Engineer (FSE) to replace the shutter assembly with an improved shutter assembly free of charge beginning June 2022,. The updated assembly improves the Philips Laser System's performance and integrity.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Megan Olen
Head of Quality, Philips IGTD
Phone: +1 (719) 447 - 2592
Megan.Olen@philips.com

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: LAS-100 Error 500, 2022-IGT-IGTD-002

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:
We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that handle LAS-100 Philips Laser Systems.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please complete and return this Response Form to your local Philips representative or the following addresses:
Email: IGTD_INTL_FieldSafety@philips.com
Postal:
Philips Image Guided Therapy
ATTN: Emily Vandaele (2022C02)
Plesmanstraat 6, 3833
Leusden, Netherlands

It is important that your organization acknowledges receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this corrective action.