Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 216 **dated** 28/11/2022 **Regarding NCMDR FSCA of Philips Laser System (LAS-100) from (mfr: Spectranetics Corporation).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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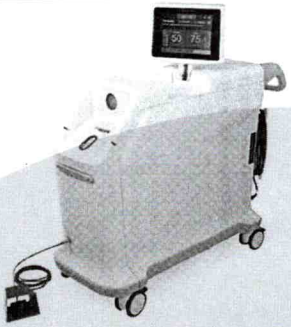
Circular No. 216 / 2022

4 -05-1444 H

28 -11-2022

Field Safety Corrective Action of Philips Laser System (LAS-100) from Spectranetics Corporation

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17313
Product	Philips Laser System (LAS-100).
Description	Pulsed excimer laser.
Manufacturer	Spectranetics Corporation.
The affected products	Philips Laser Systems (PLS), model number LAS-100, with software version number 0.5.0.3.
Reason	Intermittent software issue. the system may detect an error that will visually alert the user on the system display as "Error 106 – System Failure" or "Error 108 – System Failure".
Action	1. Philips recommends the continued use of the Philips Laser System, and to follow the Operator's Manual. As a temporary mitigation, until software becomes available tentatively in Q2 2023. 2. Please refer to the attached FSN for more information. 3. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

PHILIPS

URGENT Field Safety Notice

Philips Image Guided Therapy Corporation

Philips Laser System (LAS-100) with software version number 0.5.0.3
Error 106 and Error 108

October 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 this letter for your records.

Dear Valued Philips Laser System Customer,

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

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

Philips has identified an intermittent software issue with the LAS-100 Philips Laser Systems. For affected units, having software version 0.5.0.3, the system may detect an error that will visually alert the user on the system display as "Error 106 – System Failure" or "Error 108 – System Failure" as described below:

- Error 106 is triggered when the actual ratio of energy between the Prism Energy Sensor (PES) and Vessel Energy Sensor (VES) differs from the expected (calculated) ratio (this is also known as sensor mismatch error), and in all complaints, Error 106 is triggering under conditions where it should not trigger (false positive).

- Error 108 is triggered when the PLS detects that 10 or more of the last 100 pulses were invalid (missing), and in all complaints, Error 108 is triggering under conditions where it should not trigger (false positive).

These issues may be triggered during installation and/or clinical use resulting in the error. The system then enters a non-recoverable safe state, and the user will not be able to proceed until the error is cleared.

These issues were identified after a trend in complaints was confirmed (42 complaints in total from 01 April 2021 to 19 September 2022 for Error 106 and 25 complaints in total from 01 April 2021 to 19 September 2022 for Error 108). To date, Philips has not received reports of patient or user harm due to this issue.

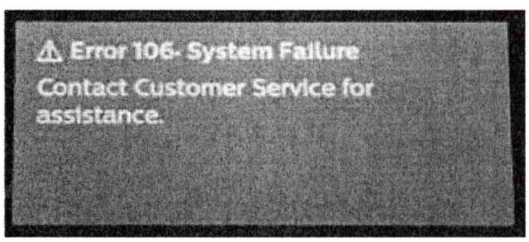

Figure 1: Example of an Error 106 visual alert

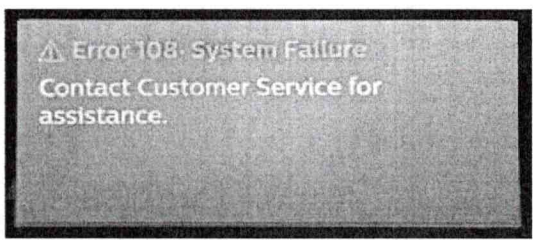

Figure 2: Example of an Error 108 visual alert

PHILIPS

The LAS-100 Philips Laser System (see Figure 3) is used in minimally invasive interventional procedures within the cardiovascular system, and for the removal of pacemaker and defibrillator cardiac leads.

Figure 3: 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 may occur during installation or during clinical use. If this issue is not present, the user may continue to use the device in accordance with its Operator's Manual. An electronic copy of the manual can also be found at www.Philips.com/IFU

To date, Philips has not received reports of patient or user harm due to this issue. If Error 106 or Error 108 occurs during clinical use, it may result in delay in initiation of treatment and/or treatment beyond initial scope and/or unable to treat patient as the most likely short-term consequences. No long-term health consequences are expected as a result of Error 106 or Error 108.

3. Affected products and how to identify them

Only the Philips Laser Systems (PLS), model number LAS-100, with software version number 0.5.0.3 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. The version of the software can be found under Settings (gear icon).

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

Philips recommends the continued use of the Philips Laser System, and to follow the Operator's Manual. As a temporary mitigation, until software becomes available tentatively in Q2 2023, the user can perform steps when visually alerted on the system display as follows:

Error 106

Philips internal testing confirms that the following steps may temporarily resolve the issue, if encountered:

1. System restart
2. Recalibration of the catheter in use or calibration of a new catheter

PHILIPS

Error 108

Philips internal testing confirms that the following steps will resolve the issue, if encountered:

1. System restart
2. Recalibration of the catheter in use or calibration of a new catheter
3. Once the system is in the Ready State, pause 2 seconds before pressing the footswitch

Philips also recommends notifying all Philips Laser System users within your facility of this communication and retaining 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 need any further information or support concerning this issue, please contact your local Philips representative or Philips Image Guided Therapy Devices Customer Service:

Philips Laser System (PLS) Customer Service:
Global: Tel. +31 334347050
Email: igtdcustomerservice-int-spnc@philips.com
Hours of Operation: Monday- Friday 8:30AM - 6:00PM CET

Region	Phone number
APAC	+3222750171
Austria	+431501375037
Belgium	+3222566604
CEE (excl. Poland)	+31202046550
Denmark	+4543310566

Region	Phone number
France	+33157324031
Germany	+494028991234
IIG (excl. Italy)	+31202046555
Italy	+390245281151
META	+31202046527

5. Actions planned by Philips Image Guided Therapy Corporation to correct the problem

A software update will resolve Error 106 and Error 108. Philips expects the updated software to become available tentatively in Q2 2023. Philips will then contact all affected customers and arrange for a Field Service Engineer (FSE) to update the system software during preventive maintenance or service visits. Upon the customer visit, where software will be installed to resolve Error 106 and Error 108, the FSE will also install an isolator used to provide added protection and help reduce vibration of the sensors, for Error 106, at no charge to the customer.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Emily Vandaele
Quality Manager,
Philips Image Guided Therapy International