

SAFETY BULLETIN

Reference Number: **SB-23-02**

Date: **9 March 2023**

Ellex Integre Pro™ LIO Output Issue

Dear Customer,

Ellex-Lumibird Medical is committed to product quality, safety and reliability. On this basis, we would like to inform you of a potential issue that was recently identified in a number of Integre Pro/Scan laser devices.

Description of the issue:

When using a Laser-Indirect-Ophthalmoscope (LIO) as the delivery device, a scattered laser beam inside the Laser Cavity may exit through the Slit Lamp output port (SDS) and get emitted from the Objective Lens when the laser is fired.

Root Cause:

Incorrect assembly of a sub-module in the laser cavity system.

Potentially affected devices:

We have identified a number of devices manufactured between Dec, 2022 and Feb, 2023 that could potentially be affected by this issue.

Please refer to **Appendix A** "Distribution List" for details of the potentially affected units and serial numbers.

Customer Actions:

If you are in receipt of any of the potentially affected devices, an authorised Ellex service representative will soon be in contact with you to check the device and perform any necessary corrections.

Please do not use the device until such time.

Additionally, kindly complete and sign Appendix B "Customer Acknowledgement Form" and return it to eservice@ellex.com upon receiving this bulletin.

Factory Preventative actions:

Ellex-Lumibird Medical has implemented a number of containment and preventative actions in the Integre production line to ensure this issue won't occur in future units.

If you have any questions, please contact your local Ellex-Lumibird representative or email us on eservice@ellex.com.

We apologise for the inconvenience this issue may cause and would like to thank you for your understanding and support.

Yours sincerely,



Said Himzawi
Service Manager
Ellex – Lumibird Medical Group

Attachments:

Appendix A – Distribution List

Appendix B – Customer Acknowledgment Form