

December 14, 2022

Field Safety Notice

Leica Biosystems Melbourne Pty Ltd Single Registration Number (SRN): AU-MF-000016740

Dear valued customer,

This is to notify you that Leica Biosystems has been made aware of two compliance issues for the ThermoBrite Elite instrument:

- An automatically resetting thermal cut-out switch,
- Potential crush/pinch hazard.

Description of the problem

Thermal cut-out

It has been identified that the thermal cut-out switch, which is an automatically resetting thermal cut-out switch, does not meet the requirements of Section 14.3 of the IEC/UL 61010-1 standard. To fully comply with the standard the current thermal cut-out switch must be replaced.

Crush/pinch hazard

A potential crush/pinch hazard has been identified if a user places their hands between the drip tray and support bracket of the ThermoBrite Elite instrument while the instrument is operational. This does not meet the requirements of Section 7.3 of the IEC/UL 61010-1 standard. To fully comply with the standard, inner protective covers need to be installed on the instrument.

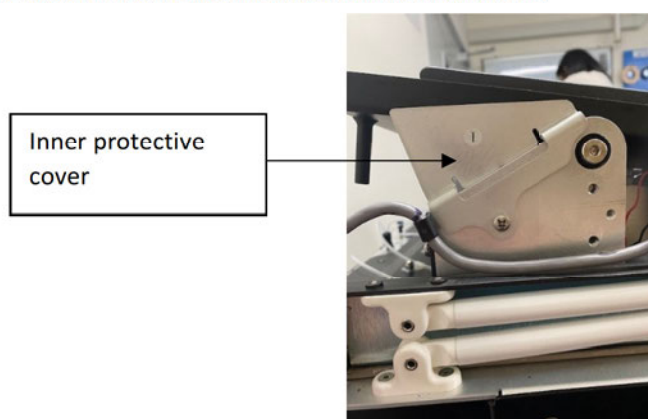


Figure 1: Inner protective covers to be installed on ThermoBrite Elite instrument

Manufacturer assessment of these compliance issues has shown that the functionality of the ThermoBrite Elite instrument is not impacted, and continued use of the device is safe.

Actions Required

Please confirm receipt of this letter as soon as possible by:

1. Signing and dating the attached Acknowledgement Form.
2. Scan and email the signed form to Leica Biosystems LBSMEL_RA@LEICABIOSYSTEMS.COM.

Kindly pass this notice to all those within your organization who need to be aware of this issue.

No further action on your part is required.

Actions taken by Leica Biosystems

A local Leica Biosystems Representative will contact you to schedule a time to:

- Replace the thermal cut-out switch in the ThermoBrite Elite instrument and;
- Add inner protective covers.

This will ensure that the ThermoBrite Elite instrument is fully compliant to the IEC/UL 61010-1 standard.

No cost will be incurred for this work.

Your cooperation in this matter is appreciated and Leica Biosystems sincerely apologises for any inconvenience this may have caused.

Kind regards,

DocuSigned by:



Signing Reason: I approve this document
Signing Time: Dec-14-2022 | 12:52:54 AEDT

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Staff Regulatory Affairs Specialist | **Leica Biosystems**

495 Blackburn Road, Mount Waverley
VIC 3149, Australia
LeicaBiosystems.com

Reference : 202209-01

ACKNOWLEDGEMENT FORM

ThermoBrite Elite UL Compliance

Instrument Serial Number(s) : _____

I hereby acknowledge receipt of the Leica Biosystems Field Safety Notice.

Contact Person (please print)

Signature

Date

Facility Name (please print)

Please email the completed form to LBSMEL.RA@LEICABIOSYSTEMS.COM within 5 days of receipt.