

Field Action Notice for the Leica CM1950, Cryostat Device.

Attention: Lab Manager, Users

Dear Sir/Madam,

Leica Biosystems is issuing this Field Action Notice (FAN) to inform you about a Field Action involving the cryostat, Leica CM1950. You are receiving this notification as our records indicate that you have received one or more of the devices concerned.

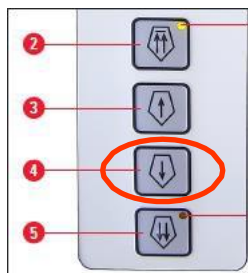
Affected devices:

Leica CM1950: All devices with serial number: 12825 - 12831, 12833, 12835 - 12845,
12848 - 12852, 12854 - 12870, 12872, 12876, 12878 - 12879,
12884 - 12885

Description of the problem:

As part of our post market surveillance, we have identified software issues related to the most recent firmware update on the cryostat Leica CM1950.

1: When turning the handwheel and shortly pressing the specimen head forwards button (IFU Fig 32-4, chapter 7.1.2) at a distinct handwheel position, it could occur that the fine drive keeps moving forward until the handwheels stops. Thus, the sample could approach faster than expected towards the microtome blade and may lead to damage of the sample.



2: Due to a loss of communication between 2 PCBA components it may happen that chamber cooling is not working properly. This communication loss is displayed as E04 (Error 4) on the clock display. Depending on the status of the cooling system it may happen that cooling chamber, and especially freezing shelf, is heating up within several minutes. This could lead to thawing of stored samples and thus potentially damage the tissue stored on the freezing shelf.

Advice on Immediate Actions To Be Taken:

At the time you receive this notification, you should perform the following actions immediately:

1.: Do not press the specimen head forwards button while turning the handwheel

2.: Closely monitor chamber temperature display and do not leave frozen samples unsupervised on the freezing shelf. As noted in the IFU do not store any samples for longer time in the cryochamber and remove all samples when workflow is finished. In case you observe error E04, please switch off the device, wait for 10 seconds and turn the device on again. Check whether the cryostat is working as expected and you may resume sectioning. At your earliest convenience, call your service partner and schedule a visit which will be prioritised.

We recommend using a backup instrument, if available. If you decide to you use the affected cryostat, please follow the actions described above. Our Service organisation will contact you in the coming weeks to organize the upgrade of your instrument(s).

Please maintain awareness of this Field Action Notice and keep this record with the instrument file.

Your prompt understanding and assistance is appreciated and necessary to prevent possible loss of patient tissue. Please note that all efforts are being enacted at Leica Biosystems to correct this issue as soon as possible.



Transmission of this Field Action Notice:

Kindly please pass this Field Action Notice to the user(s) of this product(s) and to all those within your organization who need to be aware of this issue.

Please confirm receipt of this letter within 5 days or as soon as possible by completing the attached FIELD ACTION NOTICE RETURN RESPONSE FORM.

Leica Biosystems is committed to quality and customer safety, and we appreciate your attention to this Field Action Notice.

If you have any questions about this Field Action Notice, please contact your local Leica Biosystems representative or contact the below reference person.

Contact reference person:

Should you have any questions, please contact

Jensen, Heather

Leica Biosystems

LBSNUS.Field-Action@leicabiosystems.com

Please sign the enclosed Field Action Notice Return Response Form to confirm that you have received and understood this Field Action Notice.

We sincerely apologize for any inconvenience caused by this event.

Best regards,



FIELD ACTION NOTICE RETURN RESPONSE FORM
2025/Rev.1

January

Leica CM1950

Please record the serial number of your device(s):

Please check box.

I have read and understand the instructions provided in this Field Action Notice

Yes No

Name: _____

Title: _____

Phone: _____

Firm Name: _____

Address: _____

City/State: _____

Signature: _____

Please complete and return the Field Action Notice Return Response Form within 5 days after receipt to company email address.

Contact:

Andreas Helmstetter

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Email: LBSNUS.Field-Action@leicabiosystems.com

