Advancing Cancer Diagnostics
Improving Lives

April, 2024/Rev.1

Field Action Notice for the HistoCore Pegasus and HistoCore Pegasus Plus

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 HistoCore Pegasus and HistoCore Pegasus Plus. You are receiving this notification as our records indicate that you have received one or more of the devices concerned.

Affected devices:

HistoCore Pegasus:	All devices with serial number: G0061 - G0154, G0156 - G0530, G0532 - G0779, G0781, G0782
HistoCore Pegasus Plus:	All devices with serial number: P0061 - P0080, P0082 - P0116, P0119 - P0156, P0158- P0164, P0166 - P0201, P0203 - P0232, P0234

Description of the problem:

As part of our post market surveillance, we have identified an issue related to poorly processed or damaged biopsy tissue specimens on the HistoCore PEGASUS and HistoCore PEGASUS Plus systems. The problem is associated with reagent levels exceeding the maximum fill level marks on reagent bottles or in the paraffin tanks.

The overfilling of reagents by users, excess reagent carried from the basket during initial loading, or excessive reagent in the biopsy pads/wraps can lead to reagent levels surpassing the maximum fill level mark. As a result, excess reagent may flow into other bottles through the air manifold during a processing protocol, causing cross-contamination.

Advice on Immediate Actions To Be Taken:

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

-Check reagent status in reagent bottles and paraffin status in paraffin bath. In case of any signs of contamination (such as muddiness, turbidity, or liquid separation) are observed, you should stop using the instrument for tissue processing and call for service.

-When no cross contamination was observed, continue with the following actions:

-In order to ensure defined condition, please check reagent/paraffin level. If they are over the maximum level mark, you should pour out the excess reagent/paraffin, and empty the condensation bottle.

-To secure further processing, reagent and wax bath levels shall be always checked in terms of not exceeding maximum fill level. As long as maximum fill level is between the minimum and maximum level, your instrument is fine, and you can continue processing.

-Please always kindly follow the recommendations below.

1) Before running the protocol, inspect the reagent level in reagent bottles and paraffin level in paraffin baths. Make sure that all processing reagents and paraffin level is between the Min and Max. and regularly empty the condensation bottle (weekly). (Refer to IFU 2.2.3 Operating the instrument; 9.3 Cleaning and maintenance schedule)
2) The reagent bottle and paraffin bath should be filled between the Min and Max line as indicated in the Instructions for Use. (Reagent level: Refer to IFU 4.4 Basic instrument/hardware 4.4.1 Retorts)
3) Formalin should be dripped out from the basket before adding it into the retort to avoid large carryover volume of formalin into the reagent bottle.
4) Please check if the current carrier material has large volume of carryover. If yes, please change to an appropriate carrier material.
5) Please do not clean the Mold or metal lid in the retort during the cleaning protocol.

As a further countermeasure, a Leica Service Engineer will arrange a visit at your facility to replace the current air manifold on your HistoCore Pegasus and HistoCore Pegasus Plus.

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 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

Robert Gropp
Leica Biosystems Nussloch GmbH
Heidelberger Str. 17-19
69226 Nussloch - Germany
Tel.: 0049/ (0)6224 143 345
robert.gropp@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 are sincerely sorry for any inconvenience caused by this issue.

Best regards,

Robert Gropp
Director, RAQA
Leica Biosystems Nussloch GmbH
(The undersign confirms that the FAN is being made with the knowledge of the relevant Health Authorities)

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Leica BIOSYSTEMS

FIELD ACTION NOTICE RETURN RESPONSE FORM

April, 2024/Rev.1

HistoCore Pegasus and HistoCore Pegasus Plus

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
Heidelberger Straße 17-19 | 69226 Nussloch (Germany)
T: +49 6224 143 413
Email: LBSNUS.Field-Action@leicabiosystems.com