November 13, 2023

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-G0701
HistoCore Pegasus Plus:	All devices with serial number: P0061-P0211

Description of the problem:
As part of our post market surveillance, we have been made aware of an issue regarding poorly processed and/or damaged biopsy tissue specimens on the HistoCore PEGASUS / HistoCore PEGASUS Plus resulting from incorrect assignment of the carryover value set for created or edited protocols. If the setup of carryover is lower than the actual carryover, it may potentially cause tissue damage (mainly under-processed tissue).

Advice on Immediate Actions To Be Taken:
As an immediate action, please ensure you are selecting the correct setting of the carryover value for any created or edited protocols, following the instructions in the Instruction for Use (IFU), chapter 6, "Protocol Setup", section 6.1.5, "Carryover setting":

> “When a reagent drains out of a retort, a certain amount of the reagent remains in the retort and mixes with the next reagent in the protocol. The carryover setting is an estimate of the amount of a reagent that is carried over from one protocol step to the next. The reagent management system takes the carryover setting into consideration when determining reagent concentrations.

The residual reagent carried over can come from:
• Reagent retained on retort walls and baskets
• Reagent on and infiltrated into tissue
• Reagent on and infiltrated into small-tissue carriers (e.g. biopsy pads, biopsy cassettes, wraps, etc.).”

“Because biopsy pads can have up to 10 times the carryover of standard cassettes, it is important to set a truly representative carryover value in your protocols (as it is to accurately enter the number of cassettes in each run). If you set too high a carryover value, the system calculates an excessive degradation of reagents, which will require you to replace them sooner than necessary. With too low a setting, the system will consider that reagents are purer than they are. Thus, you will use reagents beyond their optimal effectiveness, resulting in poor processing quality.”

Also, please note section 6.1.4, "Protocol validation" which states,

“Supervisors creating or editing protocols (or copying pre-defined protocols) can validate them in the software. This serves as a sign that the protocols have passed the laboratory’s validation tests and can be used for regular clinical processing. Supervisors can also make valid protocols invalid.”

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
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 are sincerely sorry for any inconvenience caused by this issue.

Best regards,

Jensen, Heather
Director, Post Market Surveillance
Quality and Regulatory Affairs

Jernelid, Maria
VP Global Quality Assurance & Regulatory Compliance
Quality and Regulatory Affairs

FIELD ACTION NOTICE RETURN RESPONSE FORM

HistoCore Pegasus and HistoCore Pegasus Plus

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

_____

_____

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