

June 2022

Field Action Notice for the ASP6025, Leica ASP300 S, Leica ASP200 S, HistoCore PEARL, HistoCore Spectra ST

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 ASP6025, Leica ASP300 S, Leica ASP200 S, HistoCore PEARL and HistoCore Spectra ST. You get this notification as our records indicate that you have received one or more of the instruments concerned and that you have used the Remote Service functionality in the past.

Affected devices:

- ASP6025: All devices with serial number: 163, 168, 202, 214, 219, 242, 245, 248, 260, 261, 302, 386, 444, 454, 462, 464, 488, 490, 492, 603, 609, 628, 686, 709, 712, 732, 779, 803, 875, 878, 937, 947, 959, 979, 997, 1023, 2043, 2049, 2123
- Leica ASP300 S: All devices with serial number: 585, 2021, 2052, 2090, 2849, 3168, 3203, 3208, 3216, 3336, 3447, 3485, 3561, 3671, 3672, 3791, 4003, 4059, 4060, 4067, 4180, 4182, 4184, 4264, 5205, 5337, 5668, 5727, 6110, 6349, 6391, 6419, 6580, 6670, 6671, 6748, 8107
- Leica ASP200 S: Device with serial number: 230
- HistoCore Pearl: Device with serial number: 191
- HistoCore Spectra ST: Device with serial number: 362

Description of the problem:

As part of our post market surveillance, we have identified 7 IT vulnerabilities affecting the PTC (Parametric Technology Corporation) Axeda agent (RemoteCare), which we are collectively calling Access:7. Exploiting these vulnerabilities, attackers with network access to a target device could remotely execute a cyber-attack, access its file system, or alter system configurations.

In worst case scenario the hacker would get full remote control of the device and could potentially damage/destroy the samples by shutting down the device or manipulation of parameters like temperatures.

As part of this Field Action, we are going to avoid this scenario on the affected devices.

Advice on immediate actions to be taken:

As an immediate action, we ask you to remove the devices from the network by unplugging the network cable and to cover the network port with an enclosed label as shown below to prevent someone from reconnecting the device to the network.

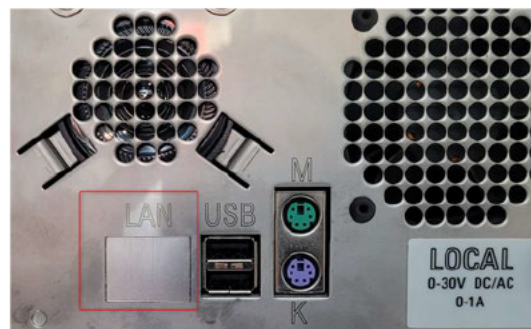
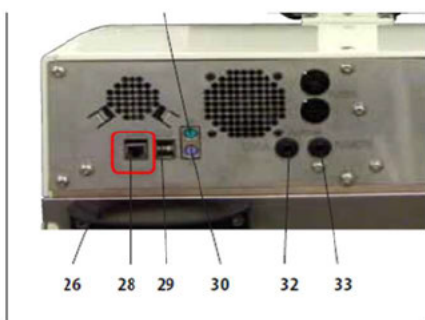
Label



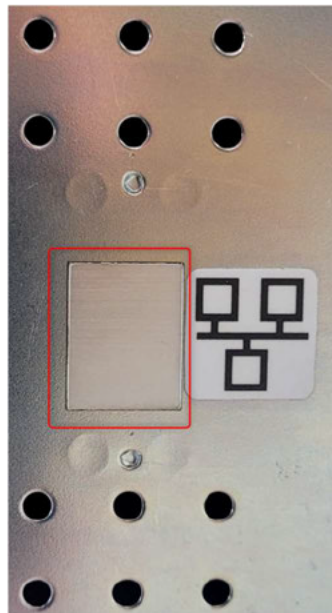
Application of the enclosed label:

First clean the surface with alcohol based cleaner around the area where the adhesive label shall be placed (grease free). Then remove the provided enclosed label from the foil and place it on the surface as shown in the pictures below.

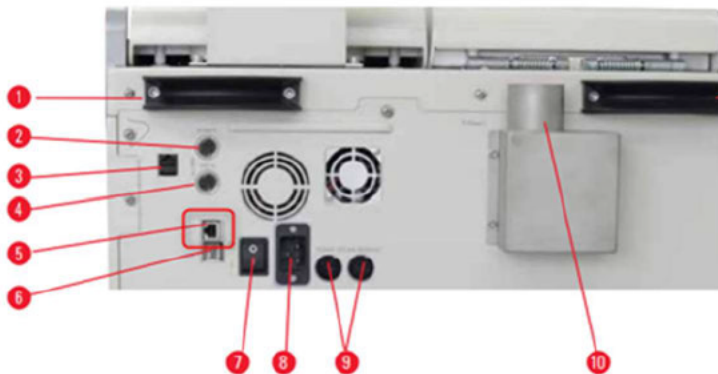
ASP6025



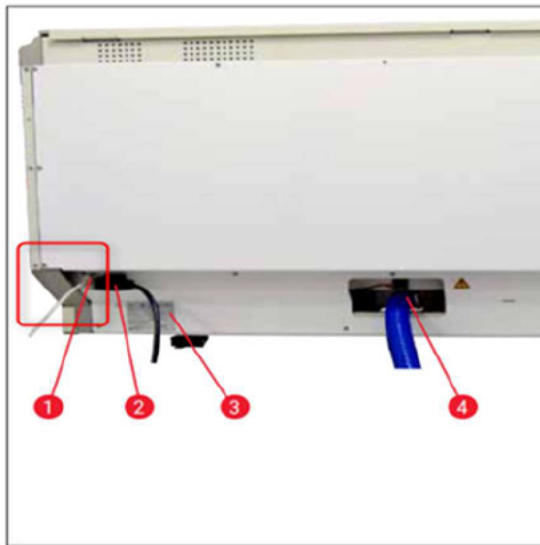
Leica ASP300 S, Leica ASP200 S



HistoCore PEARL



HistoCore Spectra ST



Transmission of this Field Action Notice:

This Field Action Notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the affected devices have been transferred.

Please maintain awareness of this Field Action Notice and resulting action to ensure effectiveness of the corrective action.

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

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

RA/QA Manager

Leica Biosystems Nussloch GmbH

FIELD ACTION NOTICE RETURN RESPONSE FORM

ASP6025, Leica ASP300 S, Leica ASP200 S, HistoCore PEARL, HistoCore Spectra ST

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

Please acknowledge by checking all the boxes below.

- I have read and understood the Field Action Notice.
- I have removed the device from the network by unplugging the network cable
- I have placed the provided label on the rear side of the instrument as mentioned in the "Advice on immediate action to be taken"

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 your local Leica contact person:

Contact: Address and fax number / email must be entered by the Regional SU Managers themselves