

Urgent Field Action Notice for the Cryostat Devices

Attention: Lab Manager, Cryostat Users

March/2019

Dear Sir/Madam,

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

Affected devices:

- Leica CM1950: All devices with serial number: 8092; 8091; 8089 to 8087; 8081; 8078; 8077; 8073; 8071 to 8067; 8064 to 8062; 8058 to 8053; 8051 to 8049; 8047; 8043; 8040; 8038 to 8033; 8031 to 8025; 8023 to 8004; 8002 to 7940; 7938 to 7892; 7890 to 7469; 7466; and all devices with serial number lower than 7466
- Leica CM1860/UV: All devices with serial number: 4201; 4200; 4196; 4193; 4192; 4188; 4186 to 4184; 4180; 4179; 4173 to 4170; 4168; 4166 to 4160; 4158; 4157; 4154 to 4152; 4149; 4147; 4145 to 4135; 4133 to 4092; 4090; and all devices with serial number lower than 4090
- Leica CM1520: All devices with serial number: 1450; 1448; 1446 to 1444; 1442; 1439; 1437; and all devices with serial number lower than 1437
- Leica CM3050 S: All devices with serial number: 7398; 7396 to 7394; 7392; 7398 to 7387; 7385 to 7381; 7379; and all devices with serial number lower than 7379
- Leica CM1850UV: 2822; and all devices with serial number lower than 2822
- Leica CM1850: 7265; and all devices with serial number lower than 7265
- Leica CM1510 S: 6600; and all devices with serial number lower than 6600
- Leica CM1100: 1418; and all devices with serial number lower than 1418

Description of the problem:

As part of our post market surveillance, we recognized that some customers are using flammable freezing sprays within the cryostat chamber. All flammable freezing sprays can potentially ignite and therefore can cause serious injuries. The risk should be indicated on the labelling of these sprays. The current cryostat labelling, however, does not include any specific warning about usage of flammable freezing sprays. As part of this Field Action we are going to improve the labelling on the affected devices.

Advice on immediate actions to be taken:

As an immediate action, we ask you to improve the labelling with the attached adhesive label as shown below

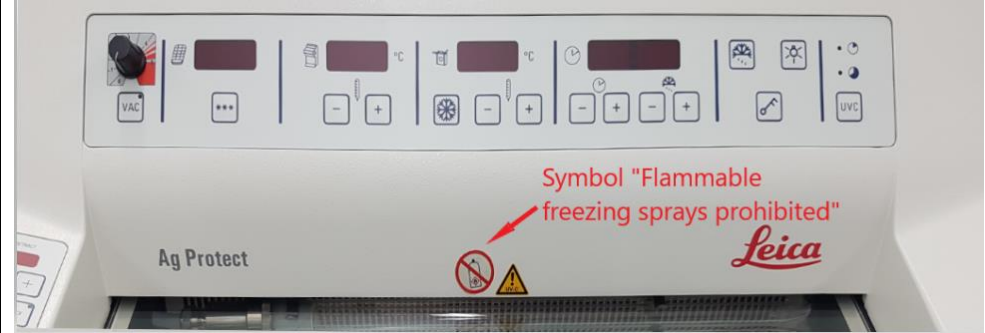
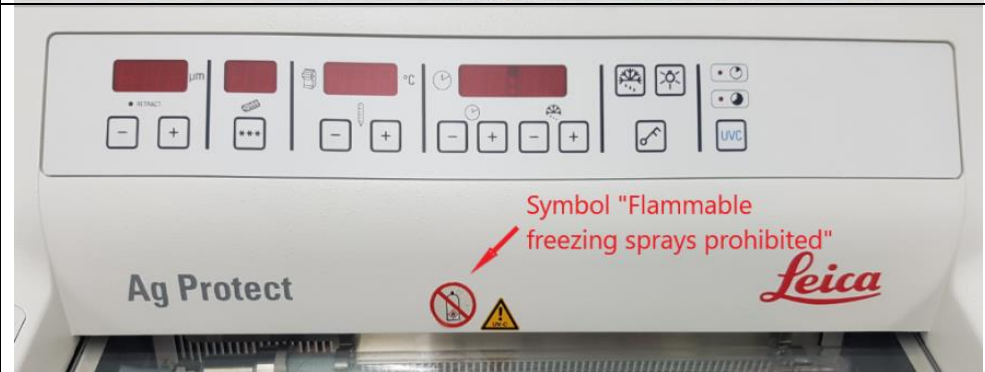

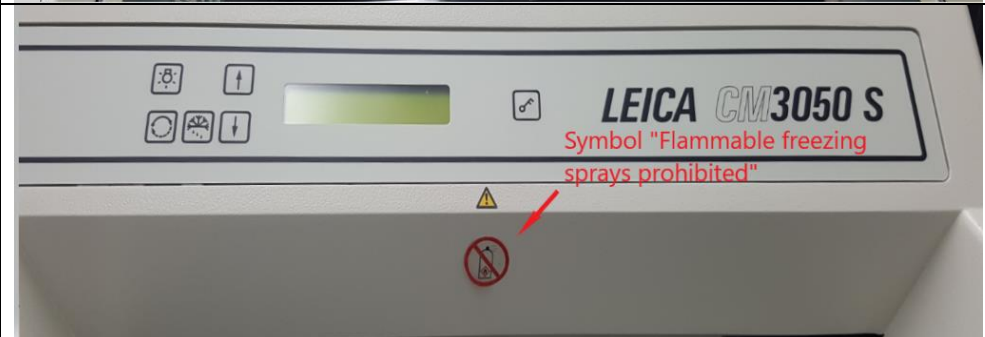



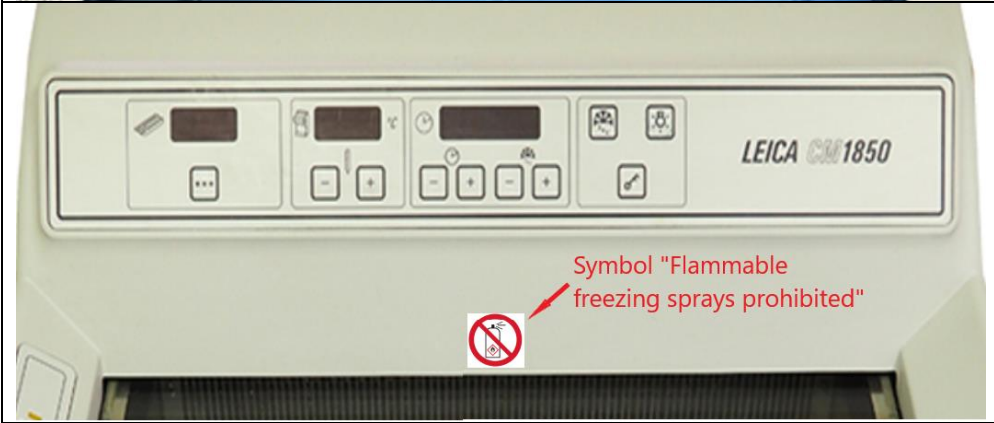

on the devices, as well as adding a supplemental sheet to the current Instruction for Use (IFU).

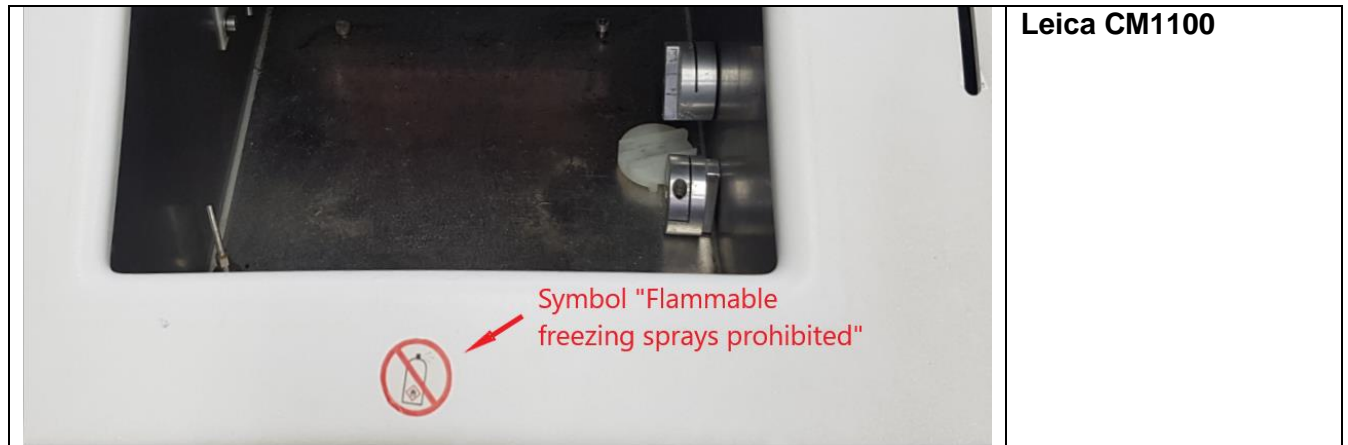
1. Application of the adhesive label:

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

Positioning Symbol „Flammable freezing sprays prohibited“	Device
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 <p>Symbol "Flammable freezing sprays prohibited"</p>	Leica CM1950
 <p>Symbol "Flammable freezing sprays prohibited"</p>	Leica CM1860UV
 <p>Symbol "Flammable freezing sprays prohibited"</p>	Leica CM1520/ Leica CM 1860
 <p>Symbol "Flammable freezing sprays prohibited"</p>	Leica CM3050 S

 <p>Symbol "Flammable Ag Protect freezing sprays prohibited"</p>	Leica CM1850 UV
 <p>Symbol "Flammable freezing sprays prohibited"</p>	Leica CM1850
 <p>Symbol "Flammable freezing sprays prohibited"</p>	Leica CM1510 S



2. Add the safety amendment to the Instruction for Use (IFU):

Add the safety amendment, as attached to this Field Action Notice, to the Cryostat Instruction for Use.

Your prompt assistance to place the provided adhesive label nearby the cryostat chamber of the instrument and to add the safety amendment in the IFU is appreciated and necessary to prevent a possible serious adverse event.

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.

Contact reference person:

Should you have any questions, please contact

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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

(The undersign confirms that the FAN is being made with the knowledge of the relevant Health Authorities)

FIELD ACTION NOTICE RETURN RESPONSE FORM

Leica CM1860/ CM1860UV/ CM1520/ CM3050 S/ CM1950/ CM1850/ CM1850UV and CM1510 S

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

Please acknowledge by checking the boxes below.

- I have read and understood the Field Action Notice.
- I have placed the provided label near the cryostat chamber as mentioned in the “Advice on immediate action to be taken”
- I have added the safety amendment provided to the IFU as mentioned in the “Advice on immediate action to be taken”

Name: _____

Title: _____

Phone: _____

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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 Sales Managers themselves