Urgent Field Action Notice for Instrument ASP6025

Attention: Lab Manager, ASP6025 Users

Dear Sir/Madam,

June/2017

Leica Biosystems is issuing this urgent Field Action Notice (FAN) to inform you about a Field Action (FA) that we are initiating to address an issue we have experienced with our ASP6025 Tissue Processor. You have received this notification as our records indicate that you have received one or more of the instruments concerned.

Affected devices:
ASP6025 Tissue Processor
Serial Numbers: 163, 169, 200-821, 823-895, 897-899, 901-1123 (all odd - serial numbers)

Description of the problem:
The affected devices mentioned above have incorrect labelling with regard to the specified voltage for the Alarm Connectors on the rear side of the instrument (please refer to the pictures below).

Alarm Connectors labelling

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The current incorrect labels specify 125Va.c. as maximum voltage. It has been identified, that if somebody connects such 125Va.c. to the 6.3mm stereo jack, there would be hazardous voltage accessible on the plug which could lead in the worst case to a serious electrical incident.
In addition, the current specification in the Instruction for Use (IFU) has an incorrect labelling with regard to the specified voltage for the Alarm Connectors (please refer to the pictures below).

Instruction for Use page 20:

Local/remote alarm relay:

30 V DC, max. 1 A
120 V AC, max. 0.25 A
2 terminals for 6.3 mm stereo jack.
Each with isolated switching contact
(operable both as normally-open and
normally-closed circuit)

Instruction for Use page 60:

The maximum values of the alarm system connected to the instrument must not exceed the following:
For 30 V DC, max. 1 A
For 120 V AC, max. 0.25 A

Local alarm: socket (**32**)
Remote alarm: socket (**33**)
Each alarm is connected to the plug (**66**) as follows (Fig. 63):

Shared terminal:	2nd neck (**69**)
Opening contact (inner terminal):	1st neck (**67**)
Closing contact (outer terminal):	Tip (**68**)

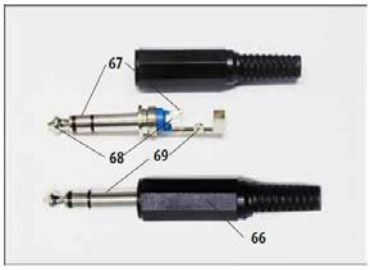


Fig. 63

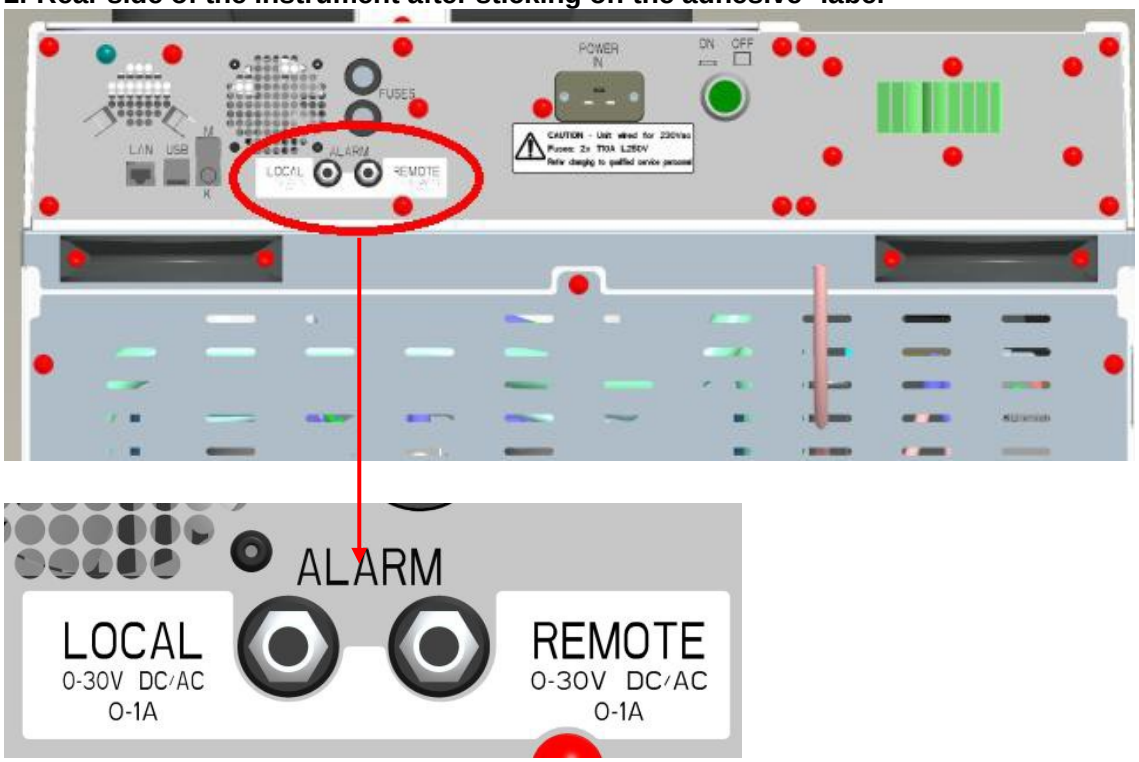
The translated IFU's on the CD (part# 14049580200) and the "online help" of the Instruments have also an incorrect labelling with regard to the specified voltage of the Alarm Connectors.

Advice on immediate actions to be taken:
As an immediate action, we ask that you to first clean the surface around the Alarm Connectors (grease free). Then remove the provided adhesive label (1) from the foil and place it at the Alarm Connectors as shown in the pictures below. The engraved specification must not be readable anymore!

Leica Biosystems Nussloch GmbH · Heidelberger Straße 17-19, 69226 Nussloch · Registergericht Mannheim HRB 333205
Geschäftsführer: Dr. Matthias Weber · Gert Schaumburg · Horst Maiwald · www.LeicaBiosystems.com

1. Adhesive label:

2. Rear side of the instrument after sticking on the adhesive label



As outlined on the new label, the maximum voltage that can be applied to the Alarm Connector is 30V DC/AC. In case you do not use the External Alarms no further immediate action is necessary. For ASP 6025 Tissue Processors where the external Alarm is used, please ensure that the maximum voltage is not exceeded by the connected external device.

Your prompt assistance to place the provided adhesive label on the rear side of the instrument and to ensure that the maximum Voltage at the Alarm Connectors(if used) does not exceed the limits is appreciated and necessary to prevent a possible serious electrical incident.

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In a second step, you will receive within the next few weeks a package containing:

- Detailed description about further corrective actions where we need your assistance
- Attachment to correct your printed Instruction for Use (English and German language)
- USB stick with:
  a. Software update for the instrument to correct the "online help"
  b. PDF files to replace Instruction for Use in all other languages
- Second Return Form to confirm completion of all corrective actions

Please note that we will only send out the package related to the second step, after we have received your Field Action Notice Return Response Form as attached.

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 organization 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

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.

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Leica Biosystems Nussloch GmbH · Heidelberger Straße 17-19, 69226 Nussloch · Registergericht Mannheim HRB 333205
Geschäftsführer: Dr. Matthias Weber · Gert Schaumburg · Horst Maiwald · www.LeicaBiosystems.com

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)

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FIELD ACTION NOTICE RETURN RESPONSE FORM

ASP6025, Tissue Processor

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

_____

_____

Please check both boxes.

- ☐ I have read and understood the Field Action Notice.
- ☐ I have placed the provided label on the 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:

Address and fax number / email must be entered by the Regional Sales Managers themselves

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