

Urgent Medical Device Field Action

AUGUST-28-2026 | FSCA 2026-001 - OT 1557893 Customer letter | Rev 00

Subject: Issue with FLUOSOFT LX version 1.6.2

Products affected:

Our records indicate that the below listed products were delivered to your location. Please verify if you have any of the listed products and complete the information below.

Item number	Fluooptics/Getinge Reference	Order	Serial number	UDI
FSLX	FLUOSOFT LX		Version 1.6.2	+B475FSLXCL0/\$+162Q

Description of the issue

Under certain conditions, we have identified that an issue might prevent the device from performing as intended. A functional anomaly has been identified in the FLUOSOFT LX software (version 1.6.2), specifically within the injection module, on the High Sensitivity page.

The issue affects the auto-exposure functionality (automatic adjustment of the camera sensitivity). According to specifications, the grayscale level detection used for automatic exposure should be calculated exclusively within the defined Region of Interest (ROI) circle. However, due to this anomaly, grayscale detection may instead be performed over the entire image.

As a result, external signals located outside the ROI (e.g., surgical instruments or surrounding fluorescent tissues) may influence the automatic sensitivity adjustment. This can lead to suboptimal exposure settings in the region of interest.

We are not aware of instances where a patient was injured due to one of the described issues.

Potential hazards

This issue may result in an inappropriate adjustment of camera sensitivity during procedures performed in automatic injection mode.

In particular:

- The signal within the region of interest may be under-exposed.
- Visualization of anatomical structures may be degraded.

This may impact:

- Parathyroid perfusion assessment, potentially affecting interpretation of tissue vascularization.
- Angiography procedures, including visualization of vessels prior to dissection.

At this stage, no injuries or adverse patient events related to this issue have been reported.

Precautions

Until the corrective action is implemented, users are advised to apply the following precautions:

- Be aware that the automatic exposure function in High Sensitivity mode may be influenced by signals outside the ROI.
- Avoid positioning highly fluorescent objects (e.g., surgical instruments or strongly emitting tissues) outside but close to the ROI during acquisition.

- Carefully review image quality and exposure level during use, especially when performing perfusion assessment or angiography.
- If image quality is not satisfactory, adjust sensitivity manually or re-acquire the image under optimized conditions.

Corrective action

A Software update that correct this issue has been developed.

Getinge will initiate an immediate field action of all affected device units. You will be contacted by your Getinge sales or service representative to plan for the update of your device.

Please complete & return the attached acknowledgement form and maintain awareness on this notice and related actions until your FLUOSOFT LX has been updated to ensure effectiveness of the corrective action.

Distribution

This Getinge Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action. In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. The competent authority has been informed about this communication and issue.

We apologize for any inconvenience this may cause and we will do our outmost to carry through this action as swiftly as possible.

Attachments

FSCA-26-001 – OT 1557893_Customer Response Form

Should you have questions or require additional information, please let us know.

Sincerely,

Electronically signed by: Olivier
PACAUD
Research - approve this document
Date: Aug 28, 2023 13:03:37 GMT+2

Electronically signed by: Marion
BOUDET
Research - approve this document
Date: Aug 28, 2023 09:31:11 GMT+2

Olivier PACAUD
General Manager
FLUOPTICS SAS
44 rue des berges, 38000 Grenoble
France

Marion BOUDET
Quality and Regulatory Affairs Manager
FLUOPTICS SAS
44 rue des berges, 38000 Grenoble
France

Contact details of local representative for your market

Contact Name
Contact e-mail
Contact phone
Contact office address

Reply Form

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Products affected:

Our records indicate that the below listed products were delivered to your location. Please verify if you have any of the listed products and complete the information below.

Item number	Fluoptics/Getinge Order Reference	Software version	Serial number
FSLX	FLUOSOFT LX	Version 1.6.2	

Record the total number of affected products currently located at your facility here please →

Confirmation:

Please check the boxes below as appropriate. Make sure to tick the first box. Should you not understand the communication please reach us for guidance. Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

- ☐ We have read the Field Safety Notice and we understand the communication and the required actions.
- ☐ The devices are in our use and located at the address this communication was sent to.
- ☐ The new software version 1.6.3 have been installed and after verification the device is working correctly with this new version.
- ☐ The devices are in our use but in a location different from where this communication was sent to, namely: *
- ☐ We have sold / moved our devices to another facility. *

* New device location (if applicable)

Serial numbers at this new location: _____		
New Facility Name	Contact name / title	e-Mail address
New Address (no PO box)	City, State, ZIP/Postal code	Phone number (Fax number)

For device distributors only:

- ☐ We have checked our stock and quarantined inventory. We have reviewed the list of devices to identify any affected customers.
- ☐ The new software version 1.6.3 have been installed and after verification the device is working correctly with this new version.

Please return your completed form to: **[INSERT SSU or 3rd party distributor CONTACT]**

Getinge market organization	Contact name / title	e-Mail address
Address	City, ZIP/Postal code	Phone number

Signature

Facility Representative Information

Signature: _____

Date: _____

Name: _____