

Urgent FIELD SAFETY NOTICE (FSN)

Sender Hamamatsu Photonics Deutschland GmbH
Arzbergerstr. 10
82211 Herrsching a. A.
Germany

Addressee all users, operators und sales organizations

Dear Hamamatsu Photonics customer,

As Hamamatsu Photonics' authorized representative we perform in collaboration with the manufacturer a field safety corrective action (FSCA). Exclusively concerned by this action is the **NanoZoomer S360**. This safety information contains important information.

The national competent authority was informed together with this FIELD SAFETY NOTICE.

Keep this safety information until the related FSCA is completed.

In case your **NanoZoomer S360** is already transferred to third party users, please forward this FSN accordingly and - if possible - inform us about the new user.

If you have any questions regarding this safety information please get in touch with your local Hamamatsu subsidiary, your distributor, your usual NanoZoomer support engineer or our safety officers for medical devices in Herrsching. Safety officers are available by email or phone:

bschuster@hamamatsu.de (phone: +49 / (0)8152 375 265) or
mfels@hamamatsu.de (phone: +49 / (0)8152 375 260).

With best regards,
Hamamatsu Photonics Deutschland GmbH

HAMAMATSU PHOTONICS DEUTSCHLAND GMBH

Address:
Arzbergerstr. 10
82211 Herrsching – Deutschland
Phone: +49 (0) 8152 375 0
Fax: +49 (0) 8152 2658
Web: www.hamamatsu.de

Bank Details:
The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Swift-BIC-Code: BOTK DE DX XXX | IBAN: DE07 3001 0700 0000 2208 74
Deutsche Bank
Swift-BIC-Code: DEUT DE MM XXX | IBAN: DE54 7007 0010 0175 1304 00

Commercial Registration:
München HRB 79474
WEEE-Reg.-No. DE 834 183 19
VAT-No. DE 128 228 814
Managing Director: Dr. Peter Eggl



Urgent Field Safety Notice

NanoZoomer S360 software NZAcquire combined with 2D Datamatrix option
FSCA-identifier (e.g. date)
Field Safety Corrective Action

Date: DD.MM.YYYY

Attention: all users, operators and sales organisations

Details on affected devices:

Product Name:	NanoZoomer S360
Product Number:	C13220-01
Affected Software Name:	NZAcquire in combination with Datamatrix Option
Affected Software Numbers:	C14297-21 & U14593
Affected SN (C13220-01):	000010, 000012, 000017, 000018, 000019, 000023, 000025, 000028, 000037

Description of the problem:

Under certain conditions barcode information of one slide can be overwritten with barcode information of other slides. This could happen only if a Datamatrix barcode is used. The issue could occur only if a Slide Image is clicked with specific timing (period) regarding to the scanning of another slide. In such case the slide which is currently scanned would retrieve and embed barcode information from the other slide. Only affected by this issue is following combination of software: U14297-21 NZAcquire (v1.0.x - v1.1.2) with option U14593 Datamatrix for NZAcquire (v1.0.0).

This means Whole Slide Images could contain wrong barcode information. Only affected by this issue are 2D barcodes. The issue can not appear if only 1D barcodes are used.

Advise on action to be taken by the user:

Users shall not view another slide image during the scanning process to prevent the occurrence of barcode interchange.

NanoZoomer support will contact you to update NZAcquire and Datamatrix option.

Please dispose software installer CDs of the affected version to prevent any inadvertently re-installation of the software.

Depending on the use case Hamamatsu recommends the operator to check image files created with the affected software. Hamamatsu offers help regarding the validation of existing data created with the affected software. If you like to get help, please inform Hamamatsu, your local dealer or usual contact regarding NanoZoomer.

Transmission of this Field Safety Notice : (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

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Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

Hamamatsu Photonics Deutschland GmbH
Benjamin Schuster
Arzbergerstr. 10
82211 Herrsching
Germany

Phone: +49 / 8152 / 375 265
E-Mail: pms-med@hamamatsu.eu

Hamamatsu confirms that this notice has been notified the appropriate Regulatory Agency

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Please fill out necessarily and return by fax (or email to bschuster@hamamatsu.de),
in order to enable Hamamatsu Photonics proving the receipt of the above Field Safety Notice (FSN).

FAX-Reply
to +49(0)8152-375-222

Hamamatsu Photonics Deutschland GmbH
c/o. Mr Benjamin Schuster. / Mr. Michael Fels

Customer name:

Customer address

Postcode/City:

Phone/Fax:

FSN income date:

Please fill out this form and send to the above presented fax number. You confirm hereby the receipt and notice of the FSN (NIRO-200NX DPA AMP Unit).

date

signature of relevant person

stamp

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