Rev 2: February 2020

FSN Ref: Manufacturer's ref number

FSCA Ref: 230355130070

Date: 2023.04.17

Field Safety Notice
NanoZoomer

For Attention of*:Health institutions, users, distributors

Contact details of local representative (name, e-mail, telephone, address etc.)*
Please add contact details of external partner (if applicable)
Please add contact details of responsible Hamamatsu subsidiary
UKRP: Hamamatsu Photonics UK Limited, 2 Howard Court,10 Tewin Road, Welwyn Garden City, Hertfordshire, AL7 1BW, UK **Telephone: (44)1707-294888** **Fax: (44)1707-325777** **E-mail: pms-med@hamamatsu.co.uk**
EC-REP: Hamamatsu Photonics Deutschland GmbH, Arzbergerstr. 10, 82291 Herrsching am Ammersee, Germany **Telephone +49 (0) 8152 375 140** **Fax: +49 (0) 8152 375 222** **E-Mail: pms-med@hamamatsu.eu**

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Field Safety Notice (FSN)

NanoZoomer

Digital slide may be assigned an incorrect barcode as meta data.

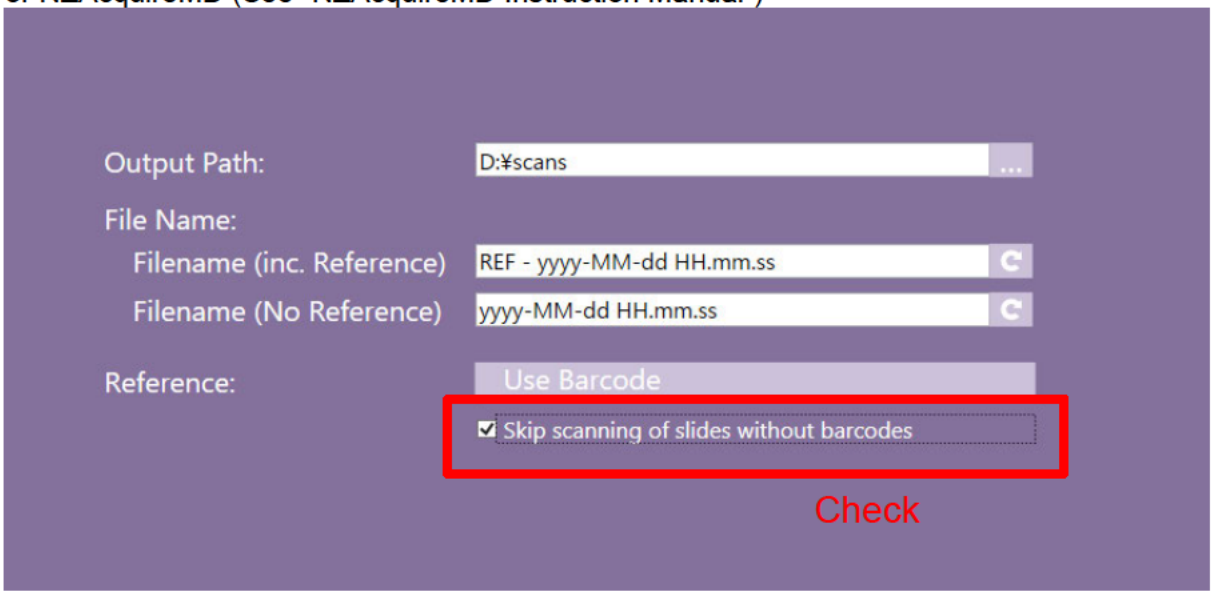
1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Microscope slide digital imaging scanner IVD (GMDN code 62575). A mains electricity (AC-powered) device designed to be used in a histopathology laboratory to scan clinical specimens on microscope slides, at a microscopic level, to produce images in a digital format. Also known as a whole slide scanner or digital pathology slide scanner, it is a bench-top unit with slide tray slots, high-resolution cameras, a user interface, and integrated software.
1.	2. Commercial name(s)*
	• NanoZoomer S60 • NanoZoomer S360 • NanoZoomer S360MD Slide scanner system • NanoZoomer S60v2MD Slide scanner system • NanoZoomer S20MD Slide scanner system
1.	3. Unique Device Identifier(s) (UDI-DI)
	• NanoZoomer S60: Not assigned • NanoZoomer S360: Not assigned • NanoZoomer S360MD Slide scanner system: 04582389010697 • NanoZoomer S60v2MD Slide scanner system: 04582389010789 • NanoZoomer S20MD Slide scanner system: 04582389010741
1.	4. Primary clinical purpose of device(s)*
	NanoZoomer is an automated digital slide creation, viewing and management system intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of pathology slides.
1.	5. Device Model/Catalogue/part number(s)*
	• NanoZoomer S60: C13210-01 • NanoZoomer S360: C13220-01 • NanoZoomer S360MD Slide scanner system: C13220-21MDEU • NanoZoomer S60v2MD Slide scanner system: C16600-21MDEU • NanoZoomer S20MD Slide scanner system: C16300-21MDEU
1.	6. Software version
	NZAcquire versions 2.0.2 to 3.0.8, or NZAcquireMD version 1.0.1 to 1.1.1
1.	7. Affected serial or lot number range
	The affected NanoZoomer types/models and their serial numbers are listed in the appendix.
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Under certain conditions it can happen that a digital slide is assigned an incorrect barcode as meta data. This can lead to a situation where tissue is assigned to a wrong patient. Details can be found in 2.6 “Background on issue”.

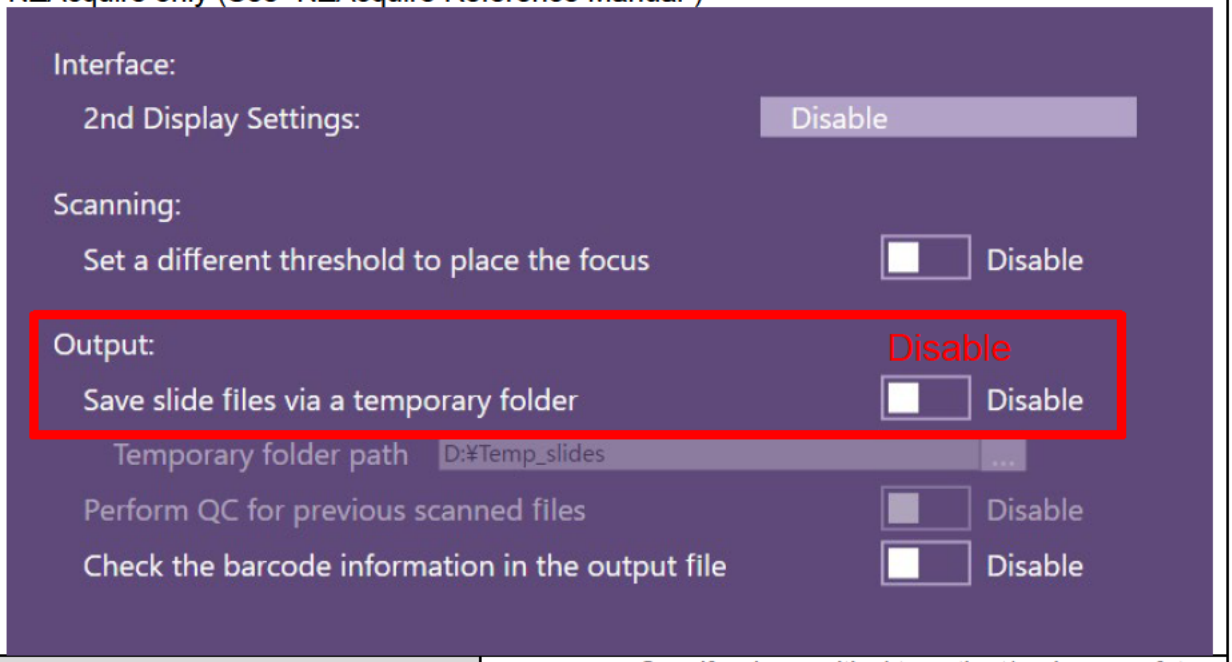
2.	2. Hazard giving rise to the FSCA*
	Under certain conditions a scanned slide can retain the barcode information of the previous slide.
2.	3. Probability of problem arising
	N/A
2.	4. Predicted risk to patient/users
	Diagnosis could be delayed or a misdiagnosis could be made.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The error may occur on a scanned slide when: (a) there is no barcode present on the slide or the barcode of the slide cannot be read and (b) the previous scanned slide is still in the transfer process from a temporary folder on the scanner PC to the user specified destination. Notes: (1) one or multiple scanned slides remain in the temporary folder as long as either (a) the optional Quality Check has not yet been confirmed by the user, or (b) the slide(s) could not yet be transferred to the specified destination e.g. due to network limitations. (2) The error cannot occur if the software (NZAcquire or NZAcquireMD) is configured so that (a) slides without barcode or with unreadable barcode are not scanned or (b) slides are not allowed to be saved temporarily (3) The error will never occur under the IVDD version of the scanning software (NDP.Scan).
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☐ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other ☐ None To avoid this problem, disable saving files in the temporary folder feature or enable the feature that skips scanning slides if no barcode is read (or present on the slide). The two software settings are attached as a screenshot. Details can also be found in the instructions for use. Please dispose software installer CDs of the affected version to prevent any inadvertently re-installation of the software.

NZAcquire (See "NZAcquire Reference Manual")
or NZAcquireMD (See "NZAcquireMD Instruction Manual")



NZAcquire only (See "NZAcquire Reference Manual")



3.	2. By when should the action be completed?	Specify where critical to patient/end user safety.

3. Particular considerations for: IVD

Is follow-up of patients or review of patients' previous results recommended?
No

The issue occurs under certain conditions and has a low probability of occurrence.

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer*** ☐ Product Removal ☒ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None NanoZoomer support will contact users to update NZAcquire or NZAcquireMD.	
3.	6. By when should the action be completed?	N/A
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Hamamatsu Photonics K.K.
	b. Address	812, Joko-cho, Higashi-ku, Hamamatsu City, 431-3196 Japan
	c. Website address	www.hamamatsu.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	List of NanoZoomer type numbers and device serial numbers.
4.	10. Name/Signature	[redacted] PRRC of Manufacturer
		[redacted]

	Transmission of this Field Safety Notice
	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.