

Date: 2023.05.23

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

Field Safety Notice (FSN)

NanoZoomer

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

1. Information on Affected Devices*	
1.	<p>1. Device Type(s)*</p> <p>Microscope slide digital imaging scanner IVD (GMDN code 62575).</p> <p>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.</p>
1.	<p>2. Commercial name(s)*</p> <ul style="list-style-type: none"> • NanoZoomer S60 • NanoZoomer S360 • NanoZoomer S360MD Slide scanner system • NanoZoomer S60v2MD Slide scanner system • NanoZoomer S20MD Slide scanner system
1.	<p>3. Unique Device Identifier(s) (UDI-DI)</p> <ul style="list-style-type: none"> • 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.	<p>4. Primary clinical purpose of device(s)*</p> <p>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.</p>
1.	<p>5. Device Model/Catalogue/part number(s)*</p> <ul style="list-style-type: none"> • 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.	<p>6. Software version</p> <p>NZAcquire versions 2.0.2 to 3.0.8, or NZAcquireMD version 1.0.1 to 1.1.1</p>
1.	<p>7. Affected serial or lot number range</p> <p>The affected NanoZoomer types/models and their serial numbers are listed in the appendix.</p>
1.	<p>8. Associated devices</p> <p>N/A</p>

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>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”.</p>

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 <u>and</u> (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 <u>cannot</u> 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.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification / inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment / reinforcement of Instructions For Use (IFU) <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p>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.</p> <p>Please dispose software installer CDs of the affected version to prevent any inadvertently re-installation of the software.</p>

NZAcquire (See “NZAcquire Reference Manual”) or NZAcquireMD (See “NZAcquireMD Instruction Manual”)

Output Path: D:\scans

File Name:

Filename (inc. Reference) REF - yyyy-MM-dd HH.mm.ss

Filename (No Reference) yyyy-MM-dd HH.mm.ss

Reference: Use Barcode

Skip scanning of slides without barcodes

Check

NZAcquire only (See “NZAcquire Reference Manual”)

Interface:

2nd Display Settings: Disable

Scanning:

Set a different threshold to place the focus Disable

Output: Disable

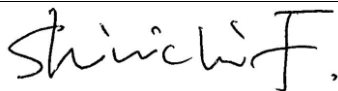
Save slide files via a temporary folder Disable

Temporary folder path D:\Temp_slides

Perform QC for previous scanned files Disable

Check the barcode information in the output file Disable

3.	2. By when should the action be completed?	Specify where critical to patient/end user safety.
3.	3. Particular considerations for:	<p>IVD</p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> <p>The issue occurs under certain conditions and has a low probability of occurrence.</p>

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	Shinichi Fujisaka PRRC of Manufacturer
		

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

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

List of Serial Numbers

Status: 14.04.2023

C13220-01							
Serial Numbers:							
000003	000074	000130	000210	000278	000347	000406	000508
000007	000075	000132	000211	000283	000348	000407	000518
000008	000076	000133	000217	000285	000349	000409	000519
000009	000077	000134	000218	000286	000350	000410	000521
000010	000078	000135	000223	000287	000354	000413	000522
000011	000079	000137	000224	000288	000356	000416	000525
000012	000080	000138	000225	000291	000357	000417	000526
000013	000081	000140	000226	000293	000358	000419	000527
000015	000082	000142	000227	000294	000360	000420	000528
000017	000083	000143	000228	000295	000365	000422	
000018	000085	000145	000229	000296	000366	000427	
000019	000086	000147	000230	000298	000367	000430	
000023	000087	000148	000233	000299	000369	000433	
000025	000088	000149	000234	000300	000370	000434	
000028	000089	000150	000235	000301	000371	000435	
000033	000090	000153	000236	000302	000378	000436	
000034	000091	000156	000238	000303	000380	000437	
000036	000092	000160	000239	000304	000381	000440	
000037	000093	000161	000240	000305	000382	000442	
000038	000096	000163	000241	000306	000383	000444	
000042	000099	000164	000242	000307	000384	000445	
000043	000100	000165	000246	000308	000385	000446	
000044	000101	000166	000251	000309	000386	000447	
000047	000102	000167	000252	000319	000387	000448	
000048	000103	000173	000256	000320	000388	000449	
000052	000105	000175	000258	000321	000389	000457	
000053	000106	000181	000259	000322	000390	000460	
000054	000107	000183	000260	000323	000391	000461	
000056	000115	000194	000262	000326	000392	000465	
000057	000116	000204	000264	000328	000396	000466	
000060	000118	000205	000267	000331	000397	000478	
000061	000120	000206	000273	000332	000398	000484	
000063	000123	000207	000275	000333	000401	000485	
000064	000124	000208	000276	000334	000402	000490	
000065	000128	000209	000277	000338	000403	000505	

C13210-01							
Serial Numbers:							
000015	000198	000253	000279	000300	000324	000336	000394
000023	000217	000254	000280	000301	000326	000338	000395
000029	000222	000260	000283	000305	000327	000339	000398
000041	000232	000262	000284	000308	000328	000340	000400
000059	000233	000264	000285	000309	000330	000342	000401
000073	000234	000266	000286	000310	000331	000346	000405
000076	000239	000267	000288	000312	000332	000350	
000109	000243	000269	000294	000315	000333	000353	
000166	000244	000271	000296	000316	000334	000390	
000197	000246	000273	000298	000323	000335	000393	

C13220-21MDEU							
Serial Numbers:							
100006	100010	100014	100018	100023	100027	100041	100045
100007	100011	100015	100019	100024	100028	100042	
100008	100012	100016	100020	100025	100030	100043	
100009	100013	100017	100021	100026	100035	100044	

C16300-21-MDEU							
Serial Numbers:							
100001	100004	100007	100021	100025	100029	100032	
100002	100005	100008	100022	100026	100030	100034	
100003	100006	100009	100024	100028	100031	100035	

C16600-21MDEU							
Serial Numbers:							
000481	100002	100004	100006				
100001	100003	100005	100007				

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	230355130070
FSN Date*	2023.05.23
Product/ Device name*	1. NanoZoomer S60 2. NanoZoomer S360 3. NanoZoomer S360MD Slide scanner system 4. NanoZoomer S60v2MD Slide scanner system 5. NanoZoomer S20MD Slide scanner system
Product Code(s)	1. NanoZoomer S60: C13210-01 2. NanoZoomer S360: C13220-01 3. NanoZoomer S360MD Slide scanner system: C13220-21MDEU 4. NanoZoomer S60v2MD Slide scanner system: C16600-21MDEU 5. NanoZoomer S20MD Slide scanner system: C16300-21MDEU
Batch/Serial Number (s)	

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/>	I performed all actions requested by the FSN.	Customer to complete or enter N/A
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
<input type="checkbox"/>	Other Action (Define):	
<input type="checkbox"/>	I do not have any affected devices.	Customer to complete or enter N/A
<input type="checkbox"/>	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	Within one week of receipt of this FSN

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.