Rev 1: September 2018

FSN Ref: FSN-SCANIPMEDICAL-001

FSCA Ref: FSCA-SCANIPMEDICAL-001

Date 21 June 2021

Urgent Field Safety Notice
Simpleware ScanIP Medical

For the attention of: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative:*
[redacted], Simpleware Product Group, Synopsys (Northern Europe), Bradninch Hall, Castle Street, Exeter, Devon, EX4 3PL; +4401392 42[redacted]; simpleware-qms@synopsys.com

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Urgent Field Safety Notice (FSN)
Simpleware ScanIP Medical
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Simpleware ScanIP Medical is a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment option. Not supplied sterile.
1.	2. Commercial name(s)
	Simpleware ScanIP Medical; Simpleware ScanIP
1.	3. Unique Device Identifier(s) (UDI-DI)
	Simpleware ScanIP 7.0: Created before UDI-DI system. Simpleware ScanIP 2016.09: 00863520000307 Simpleware ScanIP M-2017.06: 00863520000314 Simpleware ScanIP N-2018.03: 00863520000321 Simpleware ScanIP Medical; Simpleware ScanIP O-2018.12: 00863520000338 Simpleware ScanIP Medical; Simpleware ScanIP P-2019.09: 00863520000345 Simpleware ScanIP Medical; Simpleware ScanIP Q-2020.03: 00863520000369 Simpleware ScanIP Medical; Simpleware ScanIP Q-2020.06: 00863520000352 Simpleware ScanIP Medical; Simpleware ScanIP R-2020.09: 00863520000376 Simpleware ScanIP Medical; Simpleware ScanIP R-2021.03: 00863520000383
1.	4. Primary clinical purpose of device(s)*
	Simpleware ScanIP Medical software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment option.
1.	5. Device Model/Catalogue/part number(s)*
	N/A
1.	6. Software version
	7.0; 2016.09; M-2017.06; N-2018.03; O-2018.12; P-2019.09; Q-2020.03; Q-2020.06, R-2020.09; R-2021.03
1.	7. Affected serial or lot number range
	N/A
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	A bug in Simpleware ScanIP Medical was discovered. Under rare circumstances, the anatomical orientation tags/labels (APLRSI) may be displayed incorrectly, for example they may have medical orientations in the slice view (for example L/R) which are incorrect. Although the bug has been fixed for the new product release (S-2021.06a/S-2021.06), it is still present for users with versions 7.0 through R-2021.03.
	2. Hazard giving rise to the FSCA*

2.	If not mitigated, the greatest hazard to the end-user and patient is that anatomical orientation tags/labels may be displayed incorrectly, leading to operator misunderstanding and errors during resampling or re-alignment of image data. If not detected, the greatest risk would be catastrophic (death or serious injury) if making diagnostic decisions based on this data.
2.	3. Probability of problem arising
	Based on risk analysis, the probability of the problem arising is very low/remote, as it requires using the scripting API (rather than the GUI) and call the Align tool functionality
2.	4. Predicted risk to patient/users
	Based on risk analysis, before and after mitigation, the potential severity of the bug is still high, even though the probability is low. As mitigation actions cannot remove the bug altogether, the correction is to upgrade Simpleware ScanIP Medical to the latest version where the bug has been removed, and the potential risk therefore eliminated.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The manufacturer became aware of the bug through a customer bug report, and identified the potential impact on June 2nd, 2021. This bug has existed since at least version 7.0 and has never been detected or reported before. From version 7.0, the bug affected both GUI and scripting operations. From O-2018.12, to reproduce the issue, the user must be using the scripting API (rather than the GUI) and call the Align tool functionality. So, such a process would normally be very rare, and the nature of script writing is that users tend to test these operations thoroughly to define reproducible and automated protocols. For these reasons it would be extremely rare for the bug to not be detected by end users before such scripts reach production stage.
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 The user should stop using Simpleware ScanIP Medical R-2021.03 and earlier versions and immediately upgrade to the latest version (S-2021.06a/S-2021.06) of the software on SolvNetPlus. The user should also uninstall and/or delete previous installers. If this is not immediately possible, the user should always remove all DICOM tags before: • Using the “Register datasets” tool through the GUI or scripting. • Or applying any image rotation transforms (e.g. align or flip) through the GUI or scripting.

	This action can be completed by using the “DICOM tags” tool in the “General” section of the “Home” tab.	
3.	2. By when should the action be completed?	Immediately.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients’ previous results recommended? No Device is software-only and not an implantable device, diagnostic image device or IVD.	
3.	4. Is Customer Reply Required? *	Yes – please see attached form.
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None The bug has been fixed for the S-2021.06a/S-2021.06 release. Simpleware ScanIP Medical users who are using older releases (versions 7.0 to R-2021.03) are required to stop using their version, uninstall it, and upgrade to the new release.	
3	6. By when should the action be completed?	Immediately – the bug has been fixed for version S-2021.06a/S-2021.06 and the next action is for affected users to upgrade to the new release.
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?	
	N/A	

	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? *	Not planned yet
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	Synopsys (Northern Europe) Ltd.
	b. Address	Bradninch Hall, Castle Street, Exeter, Devon, EX4 3PL
	c. Website address	https://www.synopsys.com/simpleware.html
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Process initiated on June 17th, 2021.	
4.	9. List of attachments/appendices:	Reply form attached with email
4.	10. Name/Signature	[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.