FSN Ref: IF-RND-FSN-260325 FSCA Ref: IF-RND-FSCA-260325

Date: 25-03-2026

Urgent Field Safety Notice
INFINITT PACS 7.0 (7.0.0.8 BN01021)

For Attention of : All the users of INFINITT PACS 7.0(SW Ver : 7.0.0.8 BN01021), PACS administrators

Contact details of local representative (name, e-mail, telephone, address etc.)*
● Contact: INFINITT Europe GmbH ● Name: Kevin Lim ● E-mail: Kevin.Lim@infinitteu.com ● Address: Gaugrafenstraße 34, 60489 Frankfurt am Main Germany

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Urgent Field Safety Notice (FSN)
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1. Information on Affected Devices	
1.	1. Device Type(s)*
	Software medical device – Picture Archiving and Communication System (PACS), INFINITT PACS 7.0 is a software-only medical device (SaMD) that provides storage, retrieval, distribution, and display of medical images. It operates on standard IT hardware and is not supplied sterile.
1.	2. Commercial name(s)
	INFINITT PACS 7.0
1.	3. Unique Device Identifier(s) (UDI-DI)
	08809278790130
1.	4. Primary clinical purpose of device(s)*
	INFINITT PACS 7.0 is a combination of PACS and 3D system. PACS allows radiologists to make a diagnosis by using reliable digital images gained from modality such as Computed Tomography (CT), Magnetic Resonance Imaging (MRI). Volumetric image also provides intuitive visualization which makes both doctors and patients more understand the image. PACS and 3D imaging system are widely implemented in medical centers, hospitals, clinics, and imaging centers around the world. INFINITT PACS system includes a client software which archives, stores, and transfers the DICOM image and a server software which views DICOM images stored in the storage.
1.	5. Device Model/Catalogue/part number(s)*
	N/A
1.	6. Software version
	INFINITT PACS 7.0.0.8 BN01021
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*
	1) It has been confirmed that during the site-specific IHP-G7 synchronization process, missing DICOM header values are not properly retrieved due to incomplete MPR mode logic. 2) It was confirmed that the TIC graph displays time as integer seconds by truncating DICOM Content Time (0008,0033) millisecond values, which is consistent with the current product design specification. This behavior does not modify or corrupt the original time information stored within the DICOM data itself. 3) It was confirmed that during IHP-G7 synchronization, T2 pixel intensity is incorrectly calculated because the DICOM Rescale Slope value is not stored in the database, leading to displayed values approximately ten times higher than actual. 4) It was confirmed that a logic conflict between the Viewer's Auto Close function and the session restoration mechanism leads to a caching synchronization failure. When re-opening a study after exceeding the cache limit, the system may incorrectly render a cached image of the most recently accessed patient. However, UI headers correctly correspond to the selected patient, and a built-in safety warning is triggered. 5) It has been confirmed that when retrieving high-capacity images such as Tomosynthesis in a slow network environment, annotations for a new slice are rendered before the image due to download delays caused by scrolling operations. This is presumed to be a transient synchronization delay issue. 6) It was confirmed that a specific sequence involving

	screen layout changes and viewport maximization leads to the temporary display of a different study date for the same patient. This behavior occurs when switching between studies with varying series counts while restoring layouts, yet the on-screen patient and study information remain accurate.
2.	2. Hazard giving rise to the FSCA*
	The software defects identified in INFINITT PACS 7.0 encompass various display-related malfunctions, including incorrect pixel intensity and windowing values in MPR mode, a systematic overestimation of T2 cardiac MRI pixel values by a factor of approximately ten, truncation of sub-second acquisition times in TIC graphs and 4D sequences, temporary display of different patient images under specific navigation conditions (accompanied by an on-screen warning), transient misalignment between annotations and image slices in low-bandwidth environments, and the inadvertent loading of incorrect prior study dates for the same patient. The primary hazard associated with these malfunctions is the potential for incorrect image display or inaccurate quantitative measurements which—had the system been in clinical use—could have compromised the accuracy of radiological interpretation and diagnostic decision-making, posing a potential risk to both users and, indirectly, patients. Crucially, the system was not in clinical use at the time these incidents were identified; no patients were examined or diagnosed using the affected software, and zero (0) cases of patient harm have occurred, consistent with IMDRF Annex F code F27 (Problem Identified During Non-Clinical Procedure) and Annex E code E2403 (No Clinical Signs, Symptoms or Conditions). Once the required software updates and user installation are completed, residual risk is assessed to be negligible, and the diagnostic reliability of the device is fully guaranteed.

	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

INFINITT Healthcare recommends the following precautionary measures until the mandatory software update has been installed and confirmed. If the system is used in conjunction with an IHP Server, users should not rely on MPR mode for quantitative pixel value analysis or windowing-based interpretation; if anomalous values are observed, cross-reference using 2D images of the same anatomical location. Numeric quantitative measurements on MR images, particularly cardiac MRI T2 sequences, should not be used for diagnostic purposes, as displayed pixel intensity values may not reflect actual values. Time-Intensity Curve (TIC) graphs and 4D sequence phase timing should not be used for sub-second precision analysis; where required, verify ContentTime values directly from the DICOM header. Prior to commencing any interpretation, users must verify that the patient name and study information displayed on screen correspond to the intended patient, and must confirm that the correct prior study date has been loaded before performing longitudinal comparisons. When navigating volume images such as breast tomosynthesis, users must ensure that image loading is fully complete before reading annotation positions.

Required actions

1) Please complete the customer reply form.
2) Contact your local representative to obtain information as to the software upgrade schedule.
3) Please share this notice with any health professional within your organization that needs to be aware.

3.	2. By when should the action be completed?	If you receive this notification, please check the device and stop using it. 2026-05-01
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No The device was not used in the actual field.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	2026-05-01
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 Not appended to this FSN	

	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:	
	Not planned yet	
4	6. Anticipated timescale for follow-up FSN	Not planned yet
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**INFINITT Healthcare Co., Ltd.**
	b. Address	**12F Daerung Post Tower III, 27 Digital-ro 34-gil, Guro-gu, Seoul, 08378, South Korea**
	c. Website address	**www.infinitt.co.kr**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	**Customer list, Customer Reply Form**
4.	10. Name/Signature	**Name: Sang Wook Cho** **Title : PRRC**
		Signature 

	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.