Synaptive

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FSN & FSCA Ref: CAP-00324 – ClearCanvas RIS/PACS

Date: XX-March-2020

Urgent Field Safety Notice
ClearCanvas RIS/PACS

For Attention of: Biomedical Department

[Clinic Name]
[Street Address]
[City, State/Province, ZIP/Postal Code]
[Country]

Contact details of manufacturer

Synaptive Medical Inc.
555 Richmond St. W.
Suite 800
Toronto, ON
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Phone: [International Contact Number]

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Urgent Field Safety Notice (FSN)
ClearCanvas RIS/PACS

RE: ClearCanvas RIS/PACS software defect found in the device that is encountered when it is used with non-DICOM compliant JPEG 2000 compressed images.

1. **Information on Affected Devices**
1. Device Type(s)
ClearCanvas RIS/PACS is a Picture Archiving and Communication Software System (PACS) for the management and review of medical image data, and other digital images.
2. Commercial name(s)
ClearCanvas RIS/PACS which may also be known as ClearCanvas Workstation Clinical Edition, ClearCanvas Workstation Personal Edition, ClearCanvas ShareStation, ClearCanvas ShareAgent, ClearCanvas RIS/PACS Team Edition, or ClearCanvas RIS/PACS Cleome Edition
3. Primary clinical purpose of device(s)
The ClearCanvas RIS/PACS is an image management system whose intended use is to provide scalable Digital Imaging and Communications in Medicine (DICOM) compliant PACS solutions for hospitals and related institutions and sites, which will archive, distribute, retrieve and display images and data from all hospital modalities (such as CR, CT, DR, MR, and other devices) and information systems.
4. Device Model/Catalogue/part number(s)
SYN-0524
5. Software version
Affects versions 3.0 and higher of the software device
6. Affected serial or lot number range
All license keys for version 3.0 and higher

2. Reason for Field Safety Corrective Action (FSCA)

1. Description of the product problem

This recall has been initiated due to a software defect found in the device that is encountered when it is used with non-DICOM compliant JPEG 2000 compressed images. The software improperly uses the DICOM bit depth (i.e. the Bits Stored tag) to decompress the compressed pixel data stream for display, instead of the bit depth that is encoded in the compressed pixel data stream itself. In non-DICOM compliant images where the DICOM and compressed pixel data stream bit depths do not match, the software outputs an image with some loss of precision in the decompressed pixel data.

When images compressed using JPEG 2000 with the characteristics described above are displayed using the affected device, the images will initially appear too dark (or too light), or in many cases completely black (or white). There is a potential for reduced ability to see subtle contrast differences between adjacent pixels in the image. If the user attempts to adjust the Window and Level to bring the anatomy into view, the user should notice that it is more sensitive than usual and find it more difficult to obtain an image of acceptable quality or an image that displays subtle contrast differences.

2. Hazard giving rise to the FSCA

While the likelihood of potential serious health consequences is remote, the use of the defective software associated with this recall could result in misdiagnosis, potentially causing significant indirect harm necessitating temporary, but serious medical intervention. To date, there have been no known patient or user injuries related to this issue.

3. Probability of problem arising

The probability of this incident occurring is 0.0015%.

4. Predicted risk to users

The individual risk of harm to the user is negligible.

5. Background on Issue

Synaptive received two complaints of images appearing dark and grainy on initial display in a non-medical device with underlying image display functionality similar to ClearCanvas RIS/PACS. The customer complaints prompted an investigation which uncovered a software defect.

3. **Type of Action to mitigate the risk**			
	1. Action To Be Taken by the User ☒ Other Actions to be taken by the Customer/User 1. a) If ClearCanvas RIS/PACS is NOT used for viewing images on removeable media such as CDs, and this issue is encountered, configure the PACS or DICOM device that is sending images to ClearCanvas RIS/PACS to send uncompressed images, or images compressed with a compression algorithm other than JPEG 2000. b) If ClearCanvas RIS/PACS IS used for viewing images on removeable media such as CDs OR if it is not possible to change the sending device to send uncompressed images, contact Synaptive's Product Support Recall Line at +1 647 243 3111 to request assistance to correct the device. Note that if the software is subsequently re-installed, the device will need to be corrected again. Contact Synaptive to repeat the correction. 2. Acknowledge receipt of this notification using the enclosed form		
	2. By when should the action be completed?	Within 10 business days	
	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)		Yes, Within 10 business days
	4. Action Being Taken by the Manufacturer ☒ Other The above is a workaround. You are not required to discontinue using the device nor return the device to Synaptive Medical.		
	5. Is the FSN required to be communicated to the patient /lay user?		No

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4. **General Information**	
1. FSN Type	New
2. Further advice or information already expected in follow-up FSN?	No
3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4. List of attachments/appendices:	1) Customer response form
5. Name/Signature	Name: Maham Ansari Title: Director, Regulatory Affairs 

Transmission of this Field Safety Notice
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. 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 and the national Competent Authority if appropriate, as this provides important feedback.