PHILIPS

Field Safety Notice

URGENT - Field Safety Notice

Medical Device Recall

Philips JETStream WorkSpace software version 2 and later
DO NOT USE TRANSFER COEFFICIENT PROCESSING PARAMETER IN THYROID ANALYSIS APPLICATION

Dear Customer,

A problem has been detected in the Philips JETStream WorkSpace (also known as JetStream Workstation), that, if it were to re-occur, could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Holly Wight-Lee
Sr. Mgr. Post Market Correction and Removals

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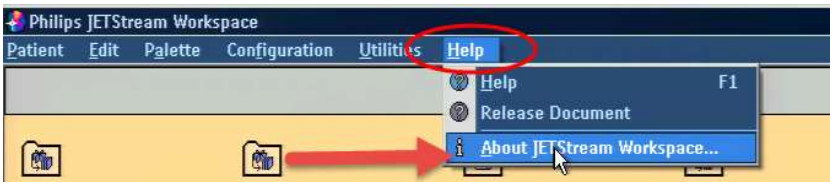
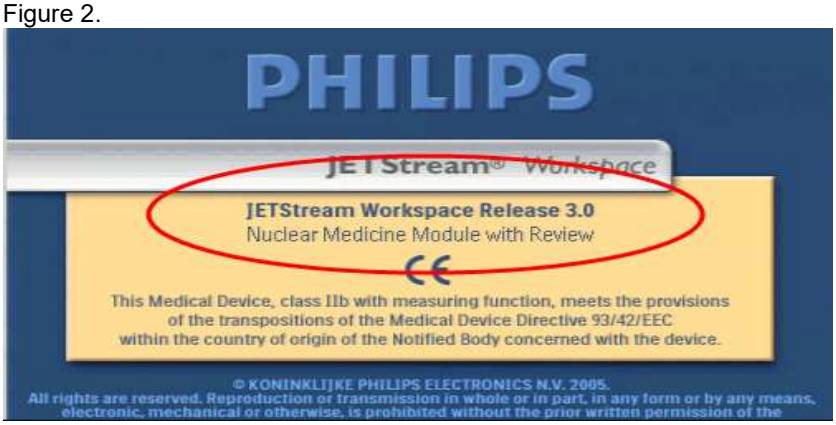
AFFECTED PRODUCTS	882310 JETStream WorkSpace 882311 JETStream WorkSpace upgrade 882313 JETStream WorkSpace SW ONLY
PROBLEM DESCRIPTION	As a result of a customer reported problem, Philips has identified an issue that occurs when using the JETStream WorkSpace Thyroid Analysis Application to calculate thyroid uptake values using the Transfer Coefficient (TCO) processing parameter identified in the Instructions for Use. In certain cases, when using the Transfer Coefficient parameter, thyroid uptake values may be calculated as lower than the actual uptake.
HAZARD INVOLVED	This issue has the potential to result in image misdiagnosis and incorrect treatment of a patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	This issue applies to versions 2.0 or higher of JETStream Workspace. To determine what version of JETStream Workspace you have, select **Help->About JETStream Workspace** as shown in the Figure 1.  (Figure 1) The **About JETStream Workspace** window appears as shown in the Figure 2.  (Figure 2)

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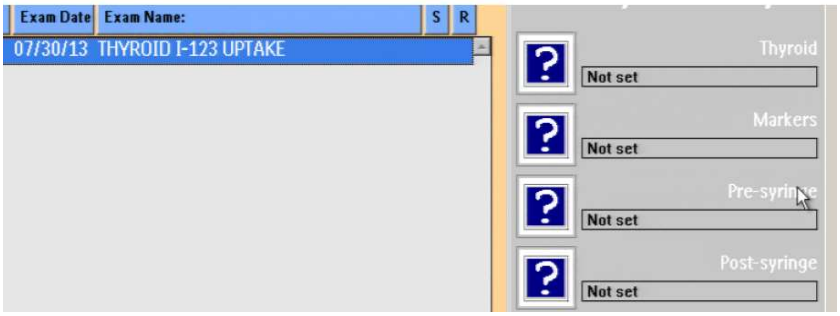
ACTION TO BE TAKEN BY CUSTOMER / USER	When calculating thyroid uptake, **do not use the Transfer Coefficient processing parameter**. The following steps can be used to determine thyroid uptake values in place of using the TCO parameter. 1) Acquire a background image and an image of the dose prior to dosing the patient using the same acquisition parameters as you would to image the patient thyroid. Perform the following steps after the aforementioned images have been acquired. 2) Load the dose image into the “Pre-syringe” bucket. 3) Load the background image into the “Post-syringe” bucket. 4) Load the patient thyroid image into the “Thyroid” bucket. Refer to Figure 3 for the 3 buckets used. The “Markers” bucket is optional and has no impact on thyroid uptake calculations.  (Figure 3) 5) When prompted for a Defaults file, either choose a default with a Transfer Coefficient of 1.0 or click Cancel. 6) During the *Optional Mask* step, you must draw an ROI (Region Of Interest) around the dose (similar to the example image shown in Figure 4). The goal for this ROI is to make sure the entire capsule or syringe is masked and only the *majority* of the scatter is excluded. It may help the user to increase the intensity of the image so everything is visualized. The size of the mask should be determined by the site to give optimal results. 7) Proceed to the Results Page.

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	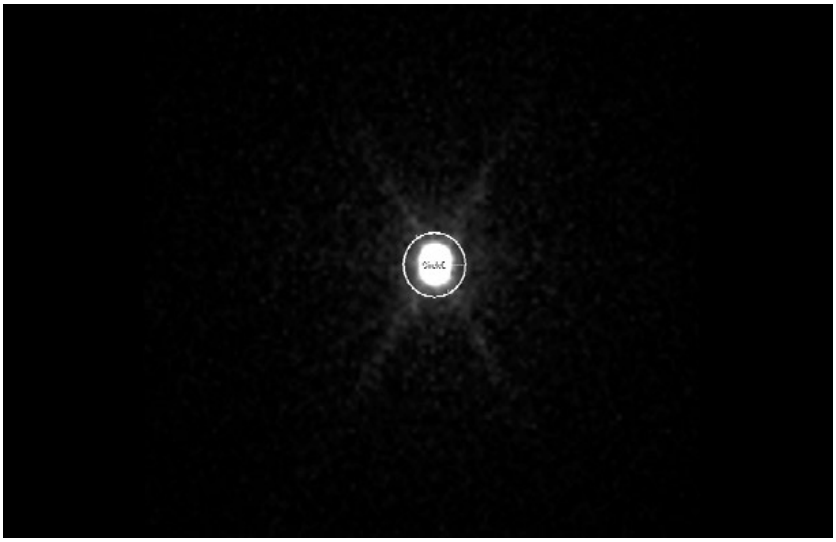 (Figure 4)
ACTIONS PLANNED BY PHILIPS	Customers were notified that in 2014 this product would no longer be supported by Philips; therefore, continued use is at the discretion of the customer. Philips will not be deploying a software patch for this issue as the product is no longer supported by the manufacturer. Philips Healthcare is notifying all affected users of the JETStream Workspace Thyroid Analysis application recommending that customers calculate thyroid uptake utilizing the method provided in this document and not using the Transfer Coefficient parameter.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741

Customer Information Letter
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Customer Reply for FSN CLE18-028
Please email completed form to safetynoticeuki@philips.com.

Contact Name	
Telephone Number	
Email Address	
Facility Name	
Street Address City, Post Code	

CUSTOMER ACKNOWLEDGEMENT:

I acknowledge that I have received this Customer Information Letter.

I understand this Customer Information Letter and my device(s) is affected by this issue.

CUSTOMER NAME (please print) TITLE

CUSTOMER SIGNATURE DATE

Please email the completed reply form to safetynoticeuki@philips.com.

If you experience difficulty carrying out the instructions contained in this document, contact your local Philips representative.