Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.....02..... dated 10/01/21 Regarding NCMDR Field Safety Corrective Action of JET Stream WorkSpace from (Philips Healthcare).

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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Circular No. 02 / 2021

27-05-1442 H

10-01-2021

Field Safety Corrective Action of JET Stream WorkSpace from Philips Healthcare.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15457
Product	JET Stream WorkSpace.
Description	Capital Equipment.
Manufacturer	Philips Healthcare.
The affected products	Software version 2 and later Affected Products: 882310 JETStream WorkSpace 882311 JETStream WorkSpace upgrade 882313 JETStream WorkSpace SW ONLY.
Reason	When using the Transfer Coefficient parameter, thyroid uptake values may be calculated as lower than the actual uptake.
Action	1. When calculating thyroid uptake, do not use the Transfer Coefficient processing parameter. The mentioned steps in the attachment can be used to determine thyroid uptake values in place of using the TCO parameter. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

PHILIPS

Advanced Molecular Imaging FSN CLE18-028 Revision: 01 19-Nov-2020

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:

This notice has been reported to the appropriate Regulatory Agency.

Sincerely,

Holly Wright Lee

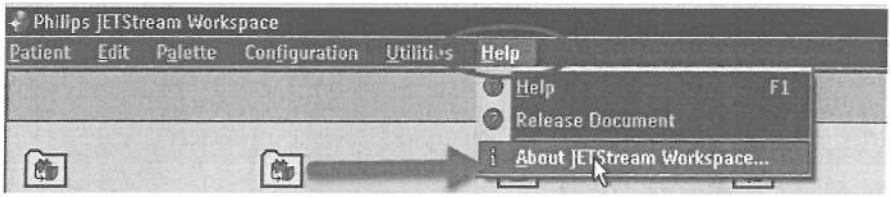
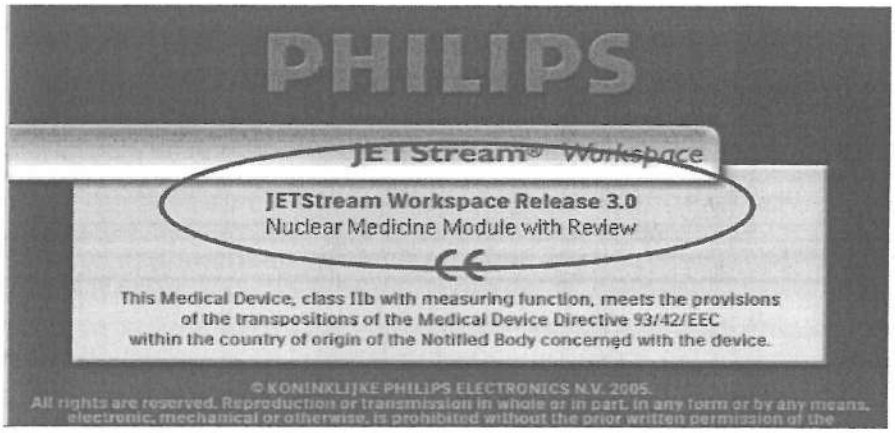
Holly Wright-Lee
Sr. Mgr. Post Market Corrections and Removals

PHILIPS

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

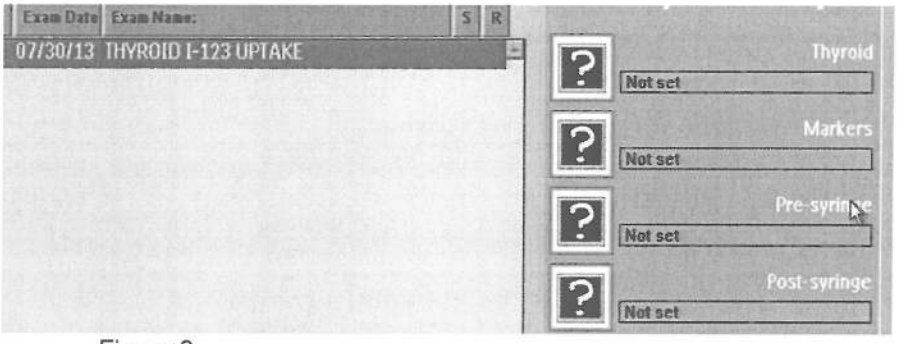
AFFECTED PRODUCTS	882310 JETStream WorkSpace 882311 JETStream WorkSpace upgrade 882313 JETStream WorkSpace SW ONLY
PROBLEM DESCRIPTION	As a result of a customer reported problem, Philips has identified an issue that occurs when using the JETStream WorkSpace Thyroid Analysis Application to calculate thyroid 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. 

PHILIPS

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

	Figure 2
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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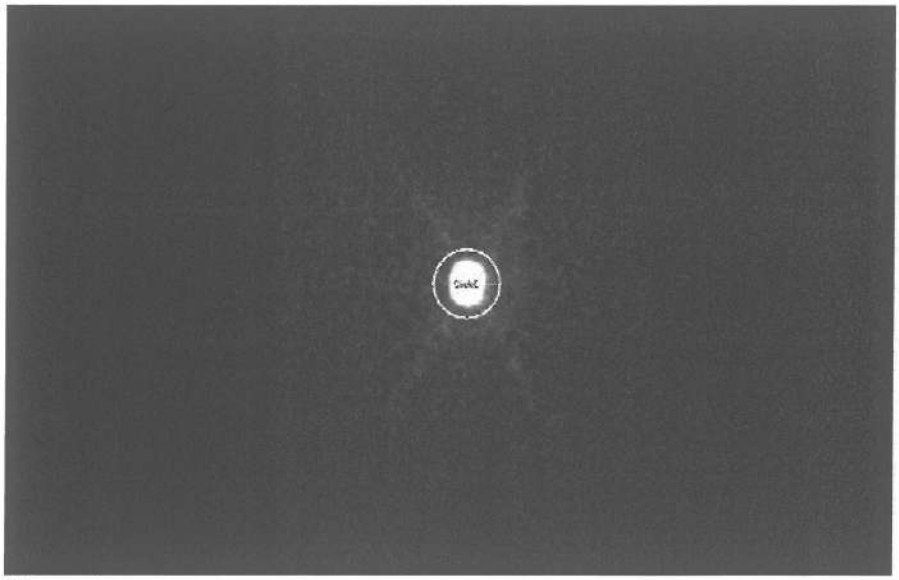
URGENT - Field Safety Notice

Medical Device Recall

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

	 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:

Please email completed form to: ***CTNM.QARA@Philips.com***

By signing this form, you acknowledge having received, read, and understood the content of this letter and have taken appropriate actions.

Name (please print)	Title
Signature	Date

Contact information:

Phone	Email