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URGENT Field Safety Notice

IntelliSpace Cardiovascular 7.0
Delayed diagnosis due to software issue preventing study data from being archived, copied, or exported

10-Jan-2025

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.

Please retain this notice for your records.

Dear Customer,

Philips has become aware of a potential safety issue with IntelliSpace Cardiovascular (ISCV) 7.0 where study data is not able to be archived, copied, or exported.

This Urgent Field Safety Notice supersedes "Important Product Notice 2023-EI-EDI-003" dated March 12, 2024, that was distributed regarding this issue.

This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

Philips has identified the following issue with IntelliSpace Cardiovascular (ISCV) software version 7.0: When the field "Reason for Study" in the application is populated (via HL7 or manually) into ISCV with more than 64 characters, the study data cannot be archived, exported, or copied from ISCV via DICOM or to a CD, but the images are available on the ISCV database and are accessible to every authorized user within the application.

2. Hazard/harm associated with the issue

The issue results in an inability to archive, copy, or export study data where the "Reason for Study' exceeds 64 characters. The lack of data management may result in a delay to diagnosis.

3. Affected products and how to identify them

Identification of impacted product:
Impacted products can be identified by the product name, reference number, and lot number (represents the software version) which are located on the About Screen as shown in Figure 1.

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Product Name	Reference Number	Lot Number (Software Version)
Intellispace Cardiovascular	830089	7.0.0.0

Figure 1. Example of the About Screen

Intended Use:
Philips IntelliSpace Cardiovascular software product is an integrated multimodality image and information system designed to perform the necessary functions required for import, export, storage, archival, review, analysis, quantification, reporting and database management of digital medical images. IntelliSpace Cardiovascular is only to be used as a supporting device during open heart surgery and cardiac interventional procedures.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

A. You may continue to use your system in accordance with its intended use.

B. If study data cannot be archived, exported, or copied from ISCV via DICOM or to a CD, update the "Reason for Study" field using less than 64 characters.

C. Circulate this notice to all users of the system so that they are aware of the issue.

D. Please retain this notice with your system until Philips has implemented the software correction.

E. Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt of this notice.

5. Actions planned by Philips Patient Care Informatics (SRN# NL-MF-000001489) to correct the problem.

A Philips representative will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site and install a software solution to resolve the issue (reference FCO83000217).

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Please be assured that maintaining the highest level of safety and quality is our greatest priority. 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 Agencies.

Sincerely,

Electronically signed by: Rohini Gadre
Reason: I am the author of this document
Date: Jan 10, 2025 14:46 GMT+1

Rohini Gadre
Head of Quality
Philips Patient Care Informatics

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URGENT Field Safety Notice Response Form

Reference: IntelliSpace Cardiovascular 7.0; study date cannot be archived, copied, or exported, 2023-EI-EDI-003 (FCO83000217)

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- You may continue to use your system in accordance with its intended use.
- If study data cannot be archived, exported, or copied from ISCV via DICOM or to a CD, update the "Reason for Study" field using less than 64 characters.
- Circulate this notice to all users of the system so that they are aware of the issue.
- Please retain this notice with your system until Philips has implemented the software correction.

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this notice has been properly distributed to all users that handle IntelliSpace Cardiovascular 7.0.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return this completed response form to your local Philips representative: *<Local Market to input contact information>.*