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Updated URGENT Field Safety Notice

IntelliSpace Cardiovascular

Report content may be inaccurate when using Finding Codes to add information

05-SEP-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 letter for your records.

Dear Customer,

The URGENT Field Safety Notice has been updated to:

- Clarify that the issue occurs in both the Echo Module and Vascular Ultrasound Module
- Clarify the impacted software versions
- Update Section 4 to include guidance for continued use prior to software solution implementation
- Update Philips planned actions to implement the software solution on all systems

Philips has become aware of a potential safety issue affecting IntelliSpace Cardiovascular (ISCV) 6.1, 6.2, 7.0, 7.1, and 8.0 where report content may be inaccurate due to missing or incomplete information. 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 a software issue affecting IntelliSpace Cardiovascular (ISCV) software versions 6.1, 6.2, 7.0, 7.1, and 8.0. When using the Echo Module or Vascular Ultrasound Module of ISCV, the issue may result in missing or incomplete information when Finding Codes are used to add information under the following circumstances:

a) When the same Finding Code is added into multiple Finding Groups in the same report file, all of the expected Finding Codes do not appear in the report, or
b) If the Finding Code is sent to the conclusion section of the report by double clicking the Finding Code, the expected Finding Code does not appear in the conclusion of the report.

The issue was identified during internal testing; there have been no customer complaints or reported adverse events associated with this issue.

2. Hazard/harm associated with the issue

Missing or incomplete information in the report may result in a delay in diagnosis or misdiagnosis, it may also result in patients not getting the right treatment in a timely manner.

3. Affected products and how to identify them

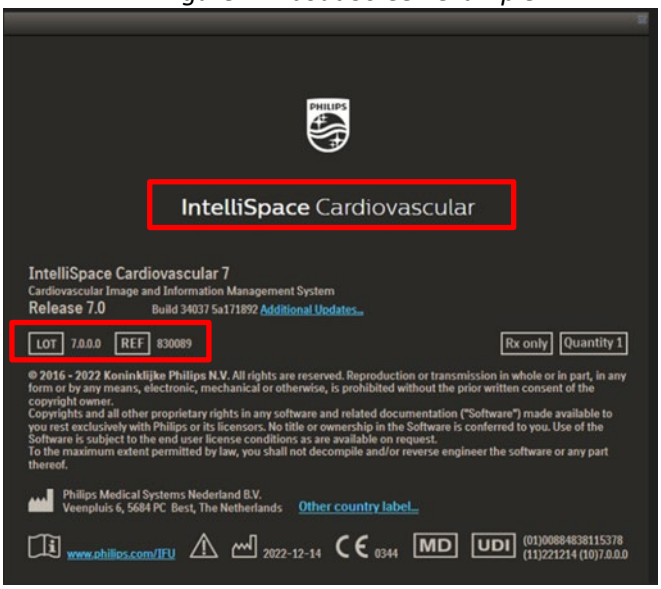
Identification of impacted product:
IntelliSpace Cardiovascular is a cardiovascular image and information management solution and may be used across the cardiology departments in your enterprise and connected to your Electronic Medical Records (EMR), picture archiving, or advanced visualization applications.

Impacted products are listed in Table 1 and 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.

Table 1. About Screen example

Product Name	Reference Number	Lot Number (Software Version)
IntelliSpace Cardiovascular	830089	6.1, 6.2
IntelliSpace Cardiovascular	830089	7.0, 7.1
IntelliSpace Cardiovascular	830089	8.0

Figure 1. About Screen example



Intended Use:
Philips IntelliSpace Cardiovascular (ISCV) 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 cardiovascular images, waveforms and data related to cardiology.

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

- If you need to use a finding code more than once for a particular report profile:
  - Replace the duplicated finding code temporarily by using the manual text entry function while completing the report.
  - To replace the duplicated finding code in the database, use the clinical application tool to create a new finding code based on the original and replace it in the findings group.
- You may continue to use your system(s) in accordance with the intended use and by following the recommendation above.
- Circulate this notice to all users of this device so that they are aware of the potential issue.
- Please retain this letter with your system(s) until a solution is installed on your system; ensure the letter is in a place likely to be seen/viewed.
- Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt of this letter via email to: **FCO.Nordic@philips.com**

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5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule time for a Field Service Engineer (FSE) to install a software upgrade to resolve the issue (reference 2025-EI-PCI-001).

If you need any further information or support concerning this issue, please contact your local Philips representative.

Telephone	80 30 30 35
Email	philips.service@philips.com

This notice has been reported to the appropriate Regulatory Agencies

Sincerely,

Peter Jangenfeldt
Head of Services & Solutions Delivery, Nordic

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Updated URGENT Field Safety Notice Response Form

Reference: IntelliSpace Cardiovascular - Report content may be inaccurate when using Finding Codes to add information (2025-EI-PCI-001 Rev B)

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 Urgent Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Follow the instructions provided in Section 4 of the Urgent Field Safety Notice.

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

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: **FCO.Nordic@philips.com**