PHILIPS

URGENT Field Safety Notice

IntelliSpace Cardiovascular 6.x, 7.x, and 8.x

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

04-APR-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,

Philips has become aware of a potential safety issue affecting IntelliSpace Cardiovascular (ISCV) 6.x, 7.x, and 8.x 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.x, 7.x, and 8.x. When using the Echo 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 section, 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.

Please refer to Attachment A for a detailed description of the two workflows associated with the issue.

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:
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.x
IntelliSpace Cardiovascular	830089	7.x
IntelliSpace Cardiovascular	830089	8.x

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

- Verify that text added into the report conclusion matches the data in the *work area interpret sheet* (Refer to Attachment A Screenshot 2)
- 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 review the workflows described in Attachment A and identify whether either workflow is currently in use, or planned to be used, at your facility. Please note your response in the attached customer response form.

- If these are not planned to be used at this time, please contact Philips Informatics Customer Support and ensure that this correction is implemented before beginning to use these workflows.

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: *<Local Market to input contact information>*

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

Once all customer responses have been received, a Philips representative will contact customers who use or may use the affected workflows to schedule a time to install the software solution on your system(s) to resolve the issue (reference FCO-TBD).

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market/Business>*

This notice has been reported to the appropriate Regulatory Agencies

Philips regrets any inconvenience caused by this problem.

Sincerely,

Rohini Gadre
Head of Quality
Philips Patient Care Informatics

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URGENT Field Safety Notice Response Form

Reference: IntelliSpace Cardiovascular 6.x, 7.x, and 8.x; report content may be inaccurate when using Finding Codes to add information, 2025-EI-PCI-001 (FCO-TBD)

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 Medical Device Correction letter.
- 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 review the workflows described in Attachment A and complete the Workflow Questionnaire below:

Workflow Questionnaire

1.	Do you currently use the Thin (web-based) client?	☒YES ☐NO
2.	Are the workflows in Attachment A currently used or planned to be used by your facility until you upgrade to latest version ISCV (Version 8.1 onwards)?	☒YES ☐NO

Note: If you are not utilizing the workflows described in Attachment A, the correction is not applicable to you.

- If these workflows are not planned to be used at this time, please contact Philips Informatics Customer Support and ensure that this correction is implemented before beginning to use these workflows.

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 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: <Local Market to input contact information>.

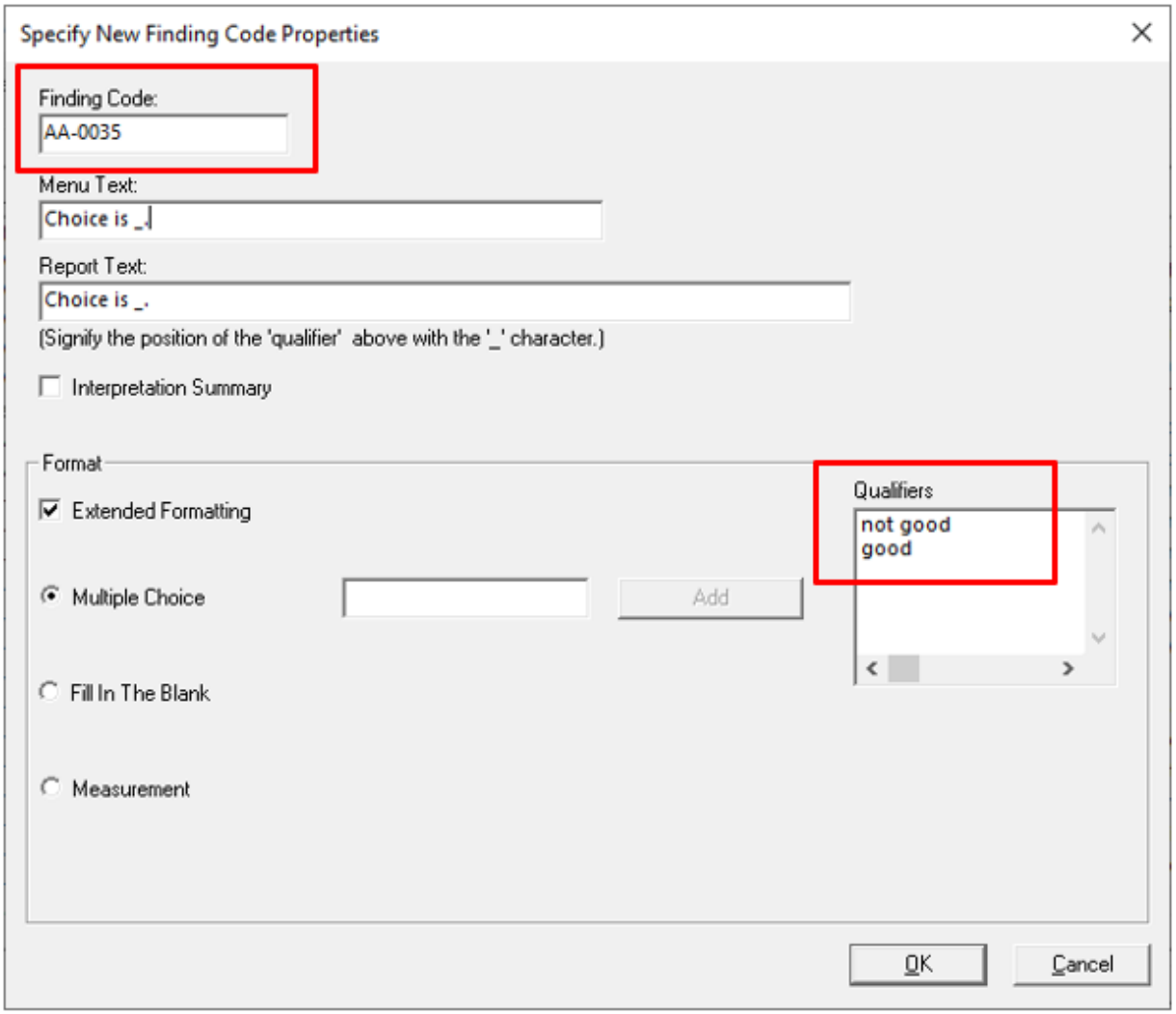
Attachment A

Description of Affected Workflows

In the Echo Module of ISCV:
a. When the same “Finding Code” is added into multiple “Finding Groups” in the same ‘Section’ not all the Finding codes are shown in the report.
b. **Also,** if the Finding Code is sent to the “Conclusions” of the report by double clicking the Finding Code, that expected Finding Code does not appear in the conclusion of the report.

This issue impacts only thin clients (web-based version). In the Thick client this functionality works fine.

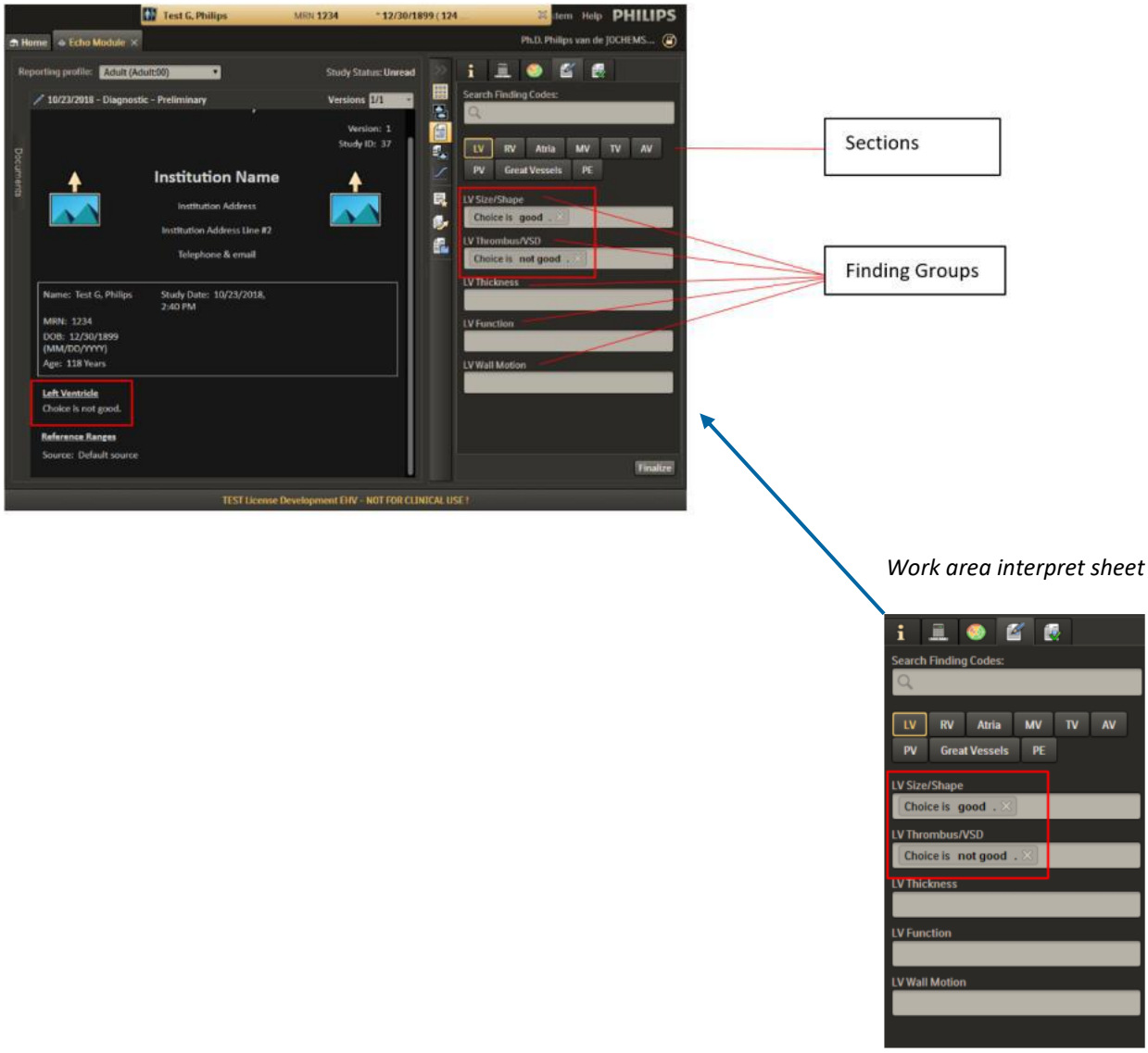
Screenshot 1: Definition of the finding codes with Multiple choice modifier:



Create a finding code (Choice is_) and Choices/Qualifiers (good/not good) with a multiple-choice modifier as shown in screenshot 1.

Screenshot 2, In the Echo Module add the same finding code (Choice is_) to the study (in work area interpret sheet), with different Qualifiers (good/not good) i.e. First add ‘choice is good’ to LV Size /Shape and then add ‘choice is not good’ to LV thrombus/VSD. Notice in the report (on the left-hand side) only the last added finding code_Qualifer i.e. ‘Choice is not good’ is added instead of displaying both the finding code_Qualifer (‘Choice is good’ and ‘Choice is not good’) from the finding groups. The issue is that the last entered finding code_Qualifier overwrites the previously entered finding code_Qualifier in the report. This is observed in all the sections (LV, RV, etc.).

Screenshot 2



Screenshot 3: Double clicking a finding code_Qualifer, will insert the finding code_Qualifer into the 'Conclusions' section of the work area report sheet (on the left-hand side as shown in the Screenshot). A plus sign (+) is prefixed to the finding code_Qualifer in the finding group to indicate that the finding code_Qualifer has been successfully added into the 'Conclusion.' However, in this example while the finding code_Qualifer has a prefixed plus sign, but it does not appear in the 'Conclusions' section, this is because in this case, the last entered finding code_Qualifier (choice is not good) overwrites the previously entered finding code_Qualifier (Choice is good) in the report. This is observed in all the sections (LV, RV, etc.) however not in between sections (The finding code_Qualifer entered in LV section added to the conclusion will not be overwritten by the finding code_Qualifer that is entered in RV section even if it is entered last in the RV section).

Screenshot 3