

Philips Ultrasound

FSN79500509-519

2019 APR 26

URGENT – Field Safety Notice

Philips EPIQ & Affiniti Ultrasound Systems Patient Data Software Issue

Dear Customer,

A problem has been detected in the Philips EPIQ & Affiniti Ultrasound Systems, that, if it were to re-occur, could pose a risk for patients. 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 to prevent risks for patients, and
- 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.

Please retain a copy with the equipment Instructions for Use.

Philips recently discovered a software issue associated with the Edit functionality on the Patient Data Entry (PDE) screen. This issue could result in one patient's images getting unexpectedly moved into another patient's folder.

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

Philips reported this notice to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Ron Nolte
Senior Director, Quality and Regulatory
Philips Ultrasound

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AFFECTED PRODUCTS	<p>All EPIQ and Affiniti Ultrasound Systems with software version 4.0 (worldwide), or 1.9 & 2.1 (China only). Including models EPIQ 5G, EPIC 5C, EPIQ 5W, EPIQ 7G, EPIC 7C, EPIQ 7W, EPIQ CVx, Affiniti 30, Affiniti 50, and Affiniti 70.</p> <p>Products running any other software versions prior to 4.0 (worldwide) or 1.9 & 2.1 (China only) are not affected.</p>
PROBLEM DESCRIPTION	<p>When the user uses the Edit functionality on the Patient Data Entry (PDE) screen, there is the potential that one patient’s images could get unexpectedly moved into another patient’s folder.</p> <p>This issue will only occur if the user executes the following steps:</p> <p><u>Modality Worklist (MWL):</u></p> <ol style="list-style-type: none"> 1. User selects Patient A from the MWL screen, acquires images, and ends exam. 2. Patient B is ready to be scanned, user mistakenly selects Patient A again from the MWL screen, and prepares to initiate exam. 3. Before capturing any images for patient B, user realizes the mistake and returns to the MWL screen. The modality worklist is grayed-out. 4. User clicks Edit to re-enable the modality worklist. 5. User selects Patient B from the worklist, acquires images, and ends exam. <p>This results in one folder (study) for Patient B containing both Patient A and Patient B’s exams. The user may not realize the error looking at the study or images. It looks as if both exams belong to Patient B.</p> <p>If the user manually exports this study containing two different patient series data to a PACS, the PACS will receive a single study instance unique identifier (UID) with image series data from two different patients (patient name and id are different in each series).</p> <p>The result is essentially the same for “Send at end of Exam”, or “Send as you Scan”, but the effect is delayed until you start sending the second exam. In both cases, the DICOM objects from the first exam will be valid, but the DICOM objects from the second exam will be invalid as they are the same study instance UID as the first exam but for a different patient name and id.</p> <p><u>Manual Patient Entry:</u></p> <ol style="list-style-type: none"> 1. User enters information into the PDE screen for Patient A, acquires images, and ends exam.

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	<ol style="list-style-type: none"> 2. Patient B is ready to be scanned, but user mistakenly reenters the same information for Patient A again into the PDE screen, and prepares to initiate exam. 3. The following fields have to be the same to reproduce the issue: patient name (last, first, MI), patient ID, patient gender, patient DOB. 4. Before capturing any images, user realizes the mistake and returns to the PDE screen. The PDE screen fields are grayed-out. 5. User clicks “Edit” to re-enable the PDE screen fields. 6. User enters information into PDE screen for Patient B, acquires images, and ends exam. 7. User navigates to the Patient Directory screen. <p>This results in two folders/studies labeled as “Patient B.” One study is really Patient A’s, but the user may not realize the error by looking at the study or images. It looks as if both studies belong to Patient B.</p> <p>If the user exports these two studies manually, it will appear to the PACS as two valid DICOM Studies with two valid image series for the same patient (the second patient name and id). The PACS should not notice any problem from a DICOM tag perspective.</p> <p>If the user exports as “Send at End of Exam” or “Send as you Scan”, both studies will arrive at the PACs normally, and should appear to be correct - two studies on two different patients with valid image series data for each. However, the studies on the PACS will not match the studies on the system; there will appear to be two studies on the second patient, as is stated in the issue. Again, the PACS should not notice any problem from a DICOM tag perspective.</p>
<p>HAZARD INVOLVED</p>	<p>If a user is unaware that a patient’s images were saved to another patient’s folder, there is a potential for the following hazards:</p> <ul style="list-style-type: none"> • Misdiagnosis of clinically significant condition • Wrong treatment / delay of treatment • Incorrect therapy being ordered • Unnecessary therapy/ treatment • Loss of patient data/ acquired images
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>All EPIQ and Affiniti Ultrasound Systems with software version 4.0 (worldwide), or 1.9 & 2.1 (China only). Including models EPIQ 5G, EPIC 5C, EPIQ 5W, EPIQ 7G, EPIC 7C, EPIQ 7W, EPIQ CVx, Affiniti 30, Affiniti 50, and Affiniti 70.</p> <p>Products running any other software versions prior to 4.0 (worldwide) or 1.9 & 2.1 (China only) are not affected.</p> <p>How to determine the software version of your Ultrasound system:</p> <ul style="list-style-type: none"> • Power up the system and allow it to finish the boot sequence • Press “Support” on the right side of the control panel

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	<ul style="list-style-type: none"> • Under “System Management” click “System Information” • The software version is listed in the Software Information Section
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>If the user mistakenly selects or manually enters a prior patient from the PDE screen, the user can avoid this software issue by using the Clear functionality instead of the Edit functionality.</p> <p>The software will work correctly when executing the following steps:</p> <p><u>Modality Worklist:</u></p> <ul style="list-style-type: none"> • If the user mistakenly selects the incorrect patient from the worklist, click the Clear (instead of Edit) button to cancel the action. • The user can select the correct patient from the worklist. <p><u>Manual Patient Entry:</u></p> <ul style="list-style-type: none"> • If the user mistakenly enters a previous patient’s information into the PDE screen, click the Clear (instead of Edit) button to cancel the action. • The user can enter the correct patient information. <p>Please complete the included reply form on the last page and return to Philips as soon as possible via email to fco.nordic@philips.com.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips will resolve the issue by providing a software update, at no cost, to correct the issue in the software version that is currently installed on your system.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative</p> <p>Telephone 80 30 30 35</p> <p>Email philips.service@philips.com</p>

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Customer Reply Form

Please complete and email to fco.nordic@philips.com

Contact Name	
Telephone Number	
Email Address	
Facility Name	
Street Address City, State, Zip	

CUSTOMER ACKNOWLEDGEMENT:

I acknowledge that I have reviewed and understand this Urgent - Medical Device Correction Letter.

- My device is not affected, because it is running a software version other than 4.0 (worldwide), or 1.9 & 2.1 (China only)
- My device is affected because it is running software version 4.0 (worldwide), or 1.9 & 2.1 (China only). I understand what actions do I need to take until my system software is updated.

CUSTOMER NAME (please print)

TITLE

CUSTOMER SIGNATURE

DATE

If you experience difficulty carrying out the instructions contained in this communication, please contact your local Philips representative at

Telephone 80 30 30 35

Email philips.service@philips.com