Heidelberg Engineering GmbH · Max-Jarecki-Str. 8 · 69115 Heidelberg · Germany

2019-07-03

Dr. Frank Müller

Urgent Field Safety Notice for HEYEX 2 Users

Affected devices:
-    ANTERION with HEYEX 2 image management
All software versions are affected.

Identification: TFID-3439

Dear Customer,

This is an important notice of an error in the default configuration of Heidelberg Engineering devices with HEYEX 2 software, which could lead to the incorrect display of patient master data. This error presents when data and images are unintentionally sent to an automatically created worklist partner. Identifying this automatically created worklist partner and avoiding this operation will ensure that this error does not occur and that the affected device can still be used safely. This configuration error can be corrected with a software update that can simply be installed remotely.

Is my device affected?
Acquisition stations for SPECTRALIS, HRT, HEP and ANTERION with HEYEX 2 are affected. That includes viewing stations where an Image Capture Module is installed. True stand-alone acquisition stations that do not use a separate server and that do not have a viewing station configured are not vulnerable.

When does the error occur?
The error occurs when examination data are transferred to the contact via drag-and-drop functionality or by query/retrieve to the automatically created worklist partner. Then these patient data are erroneously displayed in the context of another patient, e.g. in the master data menu, on the diagnostic viewer and the reports. It is important to note that it is a display error and that the image data are still assigned to the correct patient in the database.

How do I recognize the specific worklist partner?

The automatically created worklist partner can be recognized by a name pattern and can be found in the "contacts" section in the navigator action bar (see Figure 1 and Figure 2).
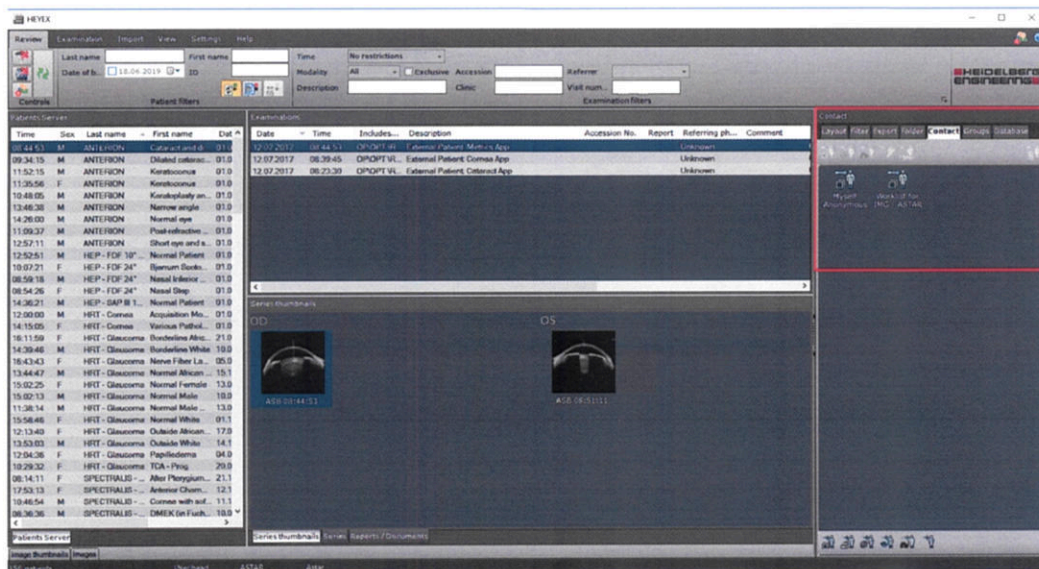

Figure 1: The automatically created worklist partner is located in the action bar of the navigator under "Contact".

The name is determined by the installed software modules and the name of the computer:

"Worklist for <name of the module> – <name of the computer>" e.g. "Worklist for HRA - Computer1".

Depending on the type of workstation, the <name of the module> can be HRA, ANTERION, IMG, HRT or HEP. The <name of the computer> is the local computer host name.
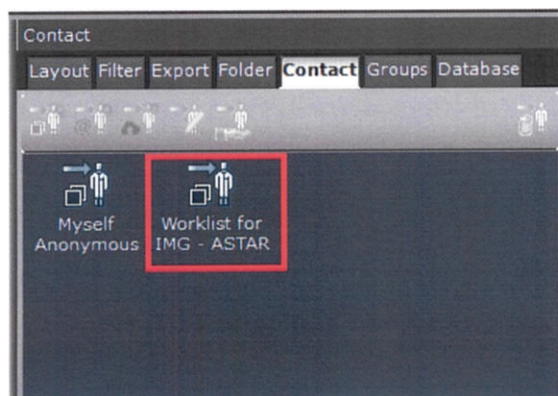

Figure 2: Example for affected worklist partner. The name is "Worklist for <name of the module> - <name of the computer" and depends on the system: Depending on the type of workstation, the <name of the module> can be HRA, ANTERION, IMG, HRT or HEP; the <name of the computer> is the local computer host name. Do not drag and drop patient data (including series and examinations) onto this type of contact.

What do I need to take into account when using my device?

- Do not drag-and-drop patient data onto the automatically created worklist partner as described above.
- Do not execute a query or retrieve data using the automatically created worklist partner.
- Always check whether displayed patient master data match the selected patient. In the event that displayed patient master data do not belong to the selected patient, do not create any new reports or screen shots of data for the affected patient. In this case, check already exported reports of this patient and correct the data manually or discard them if necessary.

A service technician will contact you within the next days to correct the configuration. This configuration correction will be performed remotely via a simple update. At the same time, the technician will also confirm the integrity of your database, ensuring that it is free of inconsistencies.

What should I do now?

Please distribute this notice to all involved persons in your organization or other organizations who should be aware of it.

The national competent authority has received a copy of this field safety notice.

Please provide contact details by completing the confirmation form and returning it to:

> Heidelberg Engineering GmbH
> Attn. Dr. Frank Müller
> Max-Jarecki-Straße 8
> 69115 Heidelberg
> Germany
>
> FSCA@HeidelbergEngineering.com

Please keep this field safety notice, at least until the field safety corrective action has been completed.

We apologize for any inconvenience caused as a result of this issue. Please do not hesitate to contact us at FSCA@HeidelbergEngineering.com if you have any further concerns. We thank you in advance for your cooperation.

Kind regards,

Dr. Frank Müller
Head of Product Safety
Heidelberg Engineering GmbH

Confirmation form

Please fill out the form and return it to:

Heidelberg Engineering GmbH
Attn. Dr. Frank Müller
Max-Jarecki-Straße 8

69115 Heidelberg
GERMANY

Mail: FSCA@HeidelbergEngineering.com
Fax: +49 6221 6463 62

Device:	All acquisition stations for ANTERION with HEYEX 2 (all software versions)
Software Version:	All
Identification:	TFID-3439
Date:	2019-07-03
Type of action:	Recommended action

Our documents show that you have received an affected device. Please provide contact details below so that a service technician can make an appointment for a remote session at your earliest convenience.

Contact Name:

Phone   :
Fax   :
E-mail   :

Organization :

Department   :

Address   :

☐ I have received and taken note of the field safety notice concerning HEYEX 2.

☐ I have informed all concerned persons within and outside my organization about the recommended actions.

City, Date   Name, Signature

For Heidelberg Engineering GmbH only
Received

Signature