

## **Urgent Field Safety Notice**

### **2016-01/01**

#### **Software-Update for EyeSuite i.8.2.1.0 in Connection with DICOM**

Koeniz, 30.11.2016

**Sender:**

Haag-Streit AG  
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Vigilance Manager  
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Schweiz

**To:**

Ophthalmologists  
Eye Care Hospital Staff  
Opticians  
Product Distributors for Haag-Streit AG

**Affected Product:**

Software EyeSuite Version i.8.2.1.0 in Connection with DICOM

Item number:       **7220374 EyeSuite DICOM Option**  
                          **7220379 DICOM License**

**Description of the problem and established root causes:**

Due to a software programming error in the current version of EyeSuite i.8.2.1.0, patient data can be stored under the wrong patient on the DICOM Server.

Data mix up on the DICOM storage system only occurs, if the system is used in an unusual way, following a non-standard workflow, e.g. if the examiner returns unplanned to a patient on the worklist who is already completed and changes are made to the records. After the data has been saved, they will be stored on the DICOM Server under the last planned patient edited in the worklist.

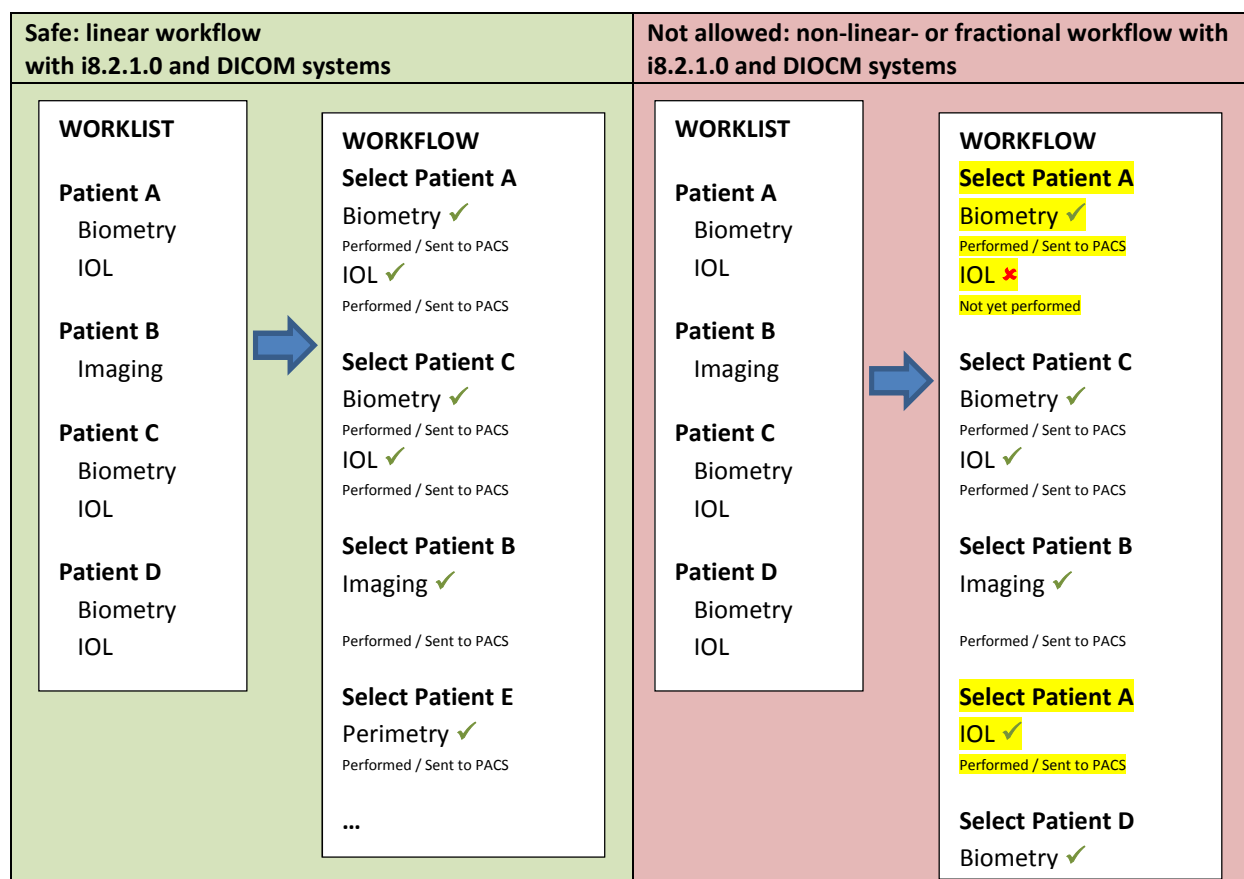
The data on the EyeSuite database is not affected by this mix up and always displays the correct information

### Measures to be taken by the user

- If you are using EyeSuite version i.8.2.1.0 in Connection with DICOM, please follow the instructions below:

Steps to avoid data mix up on DICOM Systems with i8.2.1.0:

- Only create data for actual Worklist entries.
- The order, how you select workflow entries does not matter.
- **Don't** add / change data to Patient files that you already completed the worklist entry.
- If you need to add / change data on a Patient, create a new worklist entry for the specific task.



- If you have not updated to the current version EyeSuite i.8.2.1.0, your system is not affected by this error. Do not update to version i.8.2.1.0. Older versions are not affected by this error.

### Further measures

Haag-Streit currently is working on a new software version solving the issue and this will become available in the next weeks.

Once a corrected version of EyeSuite is available, your dealer will contact you for an update.

### **Transmission of this Field Safety Notice**

According to our documentation, you or your institute has purchased one or more DICOM licenses.

Please make all users of the product mentioned above and other relevant personnel aware of this **Field Safety Notice**.

Please complete the attached letter of acknowledgement and send it as soon as possible to the address below. Please retain this information until the completion of the above described procedures.

The Swiss Competent Authority Swissmedic has received a copy of this **Field Safety Notice**.

If you have any questions and for return the acknowledgement letter please contact:

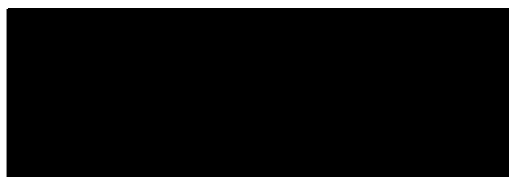
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We apologize for any inconvenience this **Field Safety Corrective Action** is causing you.

HAAG-STREIT AG



Vigilance Manager



Safety Representative for Products

## Acknowledgement Letter

I hereby confirm to have received the **Urgent Field Safety Notice „Software-Update for EyeSuite i.8.2.1.0 in Connection with DICOM”**.

Name und Address  
of the Institute: \_\_\_\_\_

Name of the employee: \_\_\_\_\_

Number of DICOM-Licenses: \_\_\_\_\_

- ☐ We have already updated to EyeSuite i.8.2.1.0 and have read and understood the instructions
- ☐ We have not yet updated to EyeSuite i.8.2.1.0 and will not do this either

Date: \_\_\_\_\_

Signature of employee: \_\_\_\_\_

Please send the completed form by E-Mail to:

[vigilance@haag-streit.com](mailto:vigilance@haag-streit.com)

or by Fax to:

+41 31 978 02 82