Urgent Field Safety Notice

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226,
USA

GE Healthcare Ref: FMI 12167

2011-07-06

To: Image Diagnost International GmbH Customers
Hospital Administrators / Risk Managers
Radiology Department Managers

RE: **Image Diagnost (IDI) MammoWorkstation: Mismatch of patient images and reports**

Image Diagnost International GmbH, a GE Healthcare company, has become aware of a potential data mismatch on certain IDI MammoWorkstation with a licensed IDI Reporting module. This issue may impact patient safety. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

When a patient (Patient A) is opened on the IDI MammoWorkstation, the Report Input Mask on the control monitor may display the correct patient data of Patient A, while the Virtual Viewbox on the review monitors displays images of another patient (Patient B).
If a report is created, the report will be archived to Patient B on the IDI MammoWorkstation. No report will be created for Patient A. However, if the report is printed (in PDF format), the PDF document will contain incorrect patient annotation of Patient A.
If the report is exported to an external screening system, the report of Patient B will be assigned to the wrong patient (Patient A).

NOTE: Please refer to the Appendix for further details.

Safety Instructions

Visually verify that the patient data displayed on the Report Input Mask on the control monitor is the same as the one indicated on the images displayed in the Virtual Viewbox on the review monitors. If there is a patient data mismatch, close the patient and then re-open the patient.

Affected Product Details

IDI MammoWorkstation versions v.4.5.0, v.4.5.2, v.4.5.3 and v.4.6.0, with IDI Reporting module installed are affected.

NOTE: To check if your workstation is affected, please refer to the Appendix for further details.

Product Correction

GE Healthcare will provide a software update at no cost. A GE Healthcare or Image Diagnost service representative will contact you to arrange for this modification.
After the software update is installed, a warning message will be displayed if the patient opened in the Report Input Mask is not the same as the one opened in the Virtual Viewbox of the IDI MammoWorkstation. This update will not affect the performance or any other functionality of your current equipment.

Contact Information

If you have any questions regarding this Field Safety Notice or the identification of affected items please contact your local Sales/Service representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately.

Sincerely,

[redacted]

Vice President QARA
GE Healthcare Systems

[redacted]

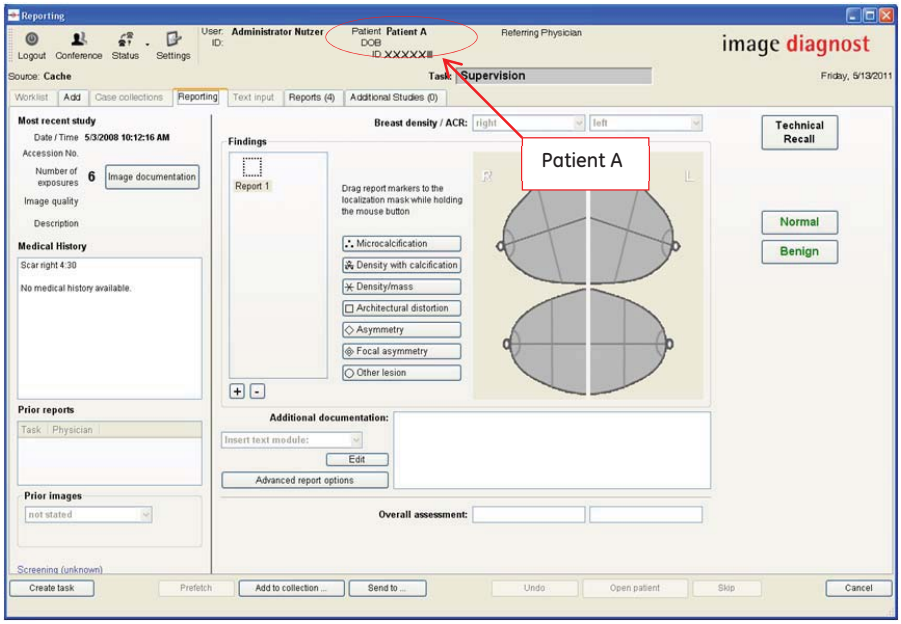
[redacted]

Chief Medical Officer
GE Healthcare

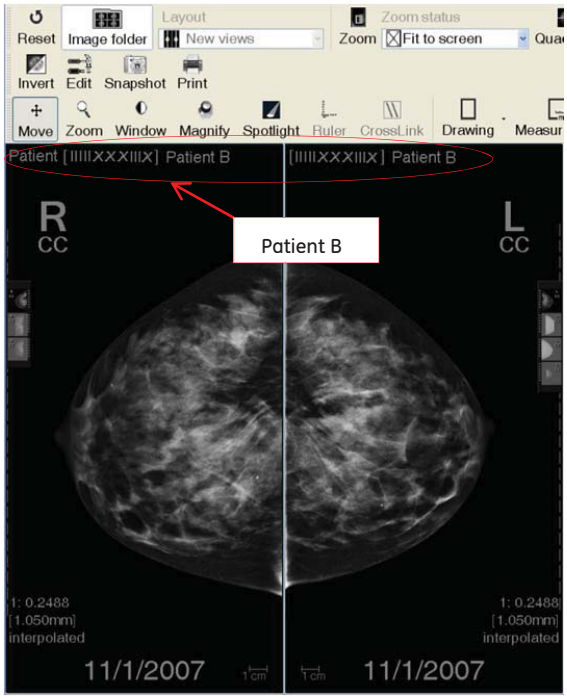
Safety Issue

When **Patient A** is opened on the IDI MammoWorkstation, the Report Input Mask on the control monitor may display patient data associated to **Patient A** while the Virtual Viewbox on the review monitors displays images of **Patient B**.

Report Input Mask on the control monitors:



Virtual Viewbox on the review monitors:

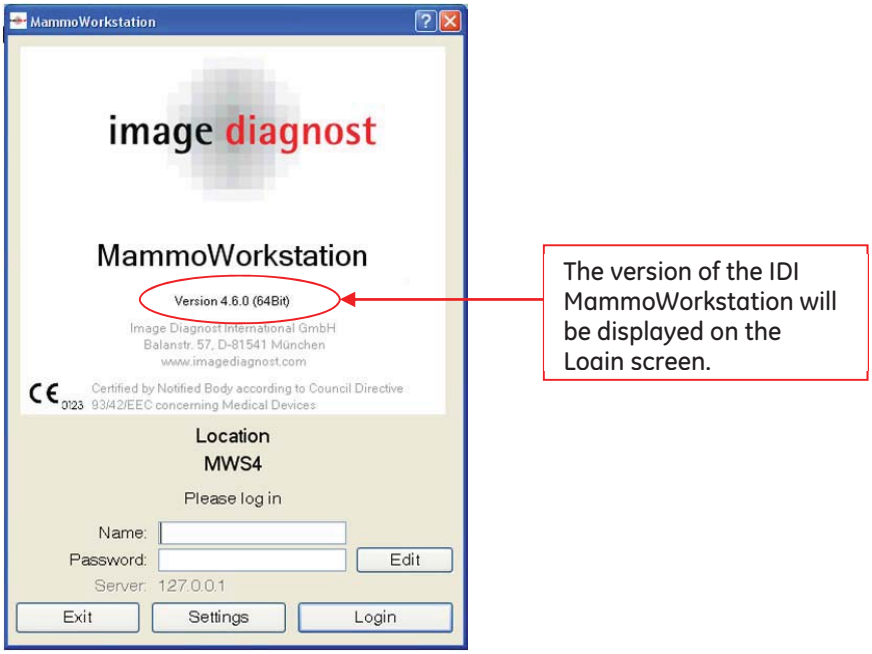


The report, which is created based on the information of the images of **Patient B,** will be correctly saved under **Patient B** within the IDI MammoWorkstation.
The created report contains the Accession Number and the Study Instance UID of the Worklist task of the actually opened **Patient A**.
If the report is printed (in PDF format), the wrong Accession Number will be present on the top of the PDF document.
If the report is exported to an external screening system, which validates patients based on the Accession Number or on the Study Instance UID of the Worklist tasks associated to this patient, the report will be assigned to the wrong patient.

Affected Product Details

IDI MammoWorkstations, which meet all three of the following criteria, are affected:

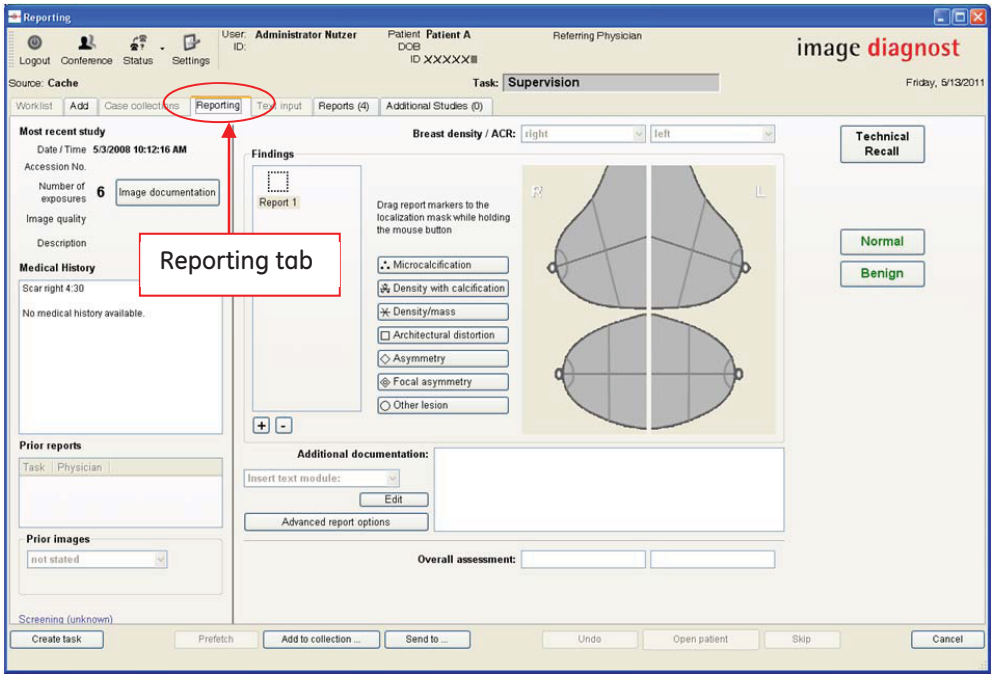
- Affected IDI MammoWorkstation versions are: v.4.5.0, v.4.5.2, v.4.5.3, or v.4.6.0. To check the version of the IDI MammoWorkstation, start the IDI MammoWorkstation:



- The Reporting module must be licensed:
  If the Reporting module is licensed, the Reporting tab in the Patient Manager must be available and the Reporting view will be displayed when opening a patient:

  Note:

  If the Reporting module is not licensed, the Additional Studies view will be displayed when opening a patient.



- An external screening system has been configured.