

medavis GmbH · Bannwaldallee 60 · 76185 Karlsruhe,
Germany

Company
Contact Person
Department
Street
12345 Town
LAND

Karlsruhe, 05.08.16

**Urgent Safety Information
Procedure Instruction regarding DICOM Importer Pro**

Dear Mr. Dr. John Doe,

Recipient:

Users of the Dicom Importer Pro

Identification of the Medical Devices Involved

DICOM Importer Pro in the version 3.1.1.1.

Description of the Problem including the Ascertained Reason:

DICOM Importer Pro enables the user applying a DICOM worklist to determine which patient data (name, ID) from the studies to be imported are to be replaced with data of the selected worklist entry.

Therefore the CD with the studies is first read-in and then the DICOM worklist is called to link the pictures with the patient data and to send it updated to the DICOM target archive.

This order of the program operating complies to the usual processing of the user interface from above to below.

If the procedure described above is executed in reversed order (first the call the DICOM worklist and then read-in of the CD) it leads to a transferring from the studies with the original patient data to the target archive and a not correct link with the patients from the DICOM worklist for call-up.

As a consequence there is a risk that for a accessed patient the studies/images of another patient are displayed automatically. Usually this is obvious to the user through the display of the original patient data in PACS.

What measures are to be taken by the Recipient?

The manual of the application is immediately completed with the exact procedure instruction. A new version of the application, in which the execution of the workflow in reversed order is not possible anymore, is provided soon and the users are informed separately.

Abide exactly by this order when importing and linking studies/images, if you want to take over patient and examination data from a modality worklist:

- ✓ You have already loaded the data to be imported and selected the respective images/series.

1. Open the tab **Modality Worklist**.






PID	Name	Gs.	Geb.	Untersuchung	Beschreibung	Zeit	Mod
1039	Bischof^Karl	M	1940.12.07	MR Schädel	MR Schädel	2007.05.16 00:00	MR
10003	Gaertner^Gabi	M	1963.01.13	MR Handgeli li	MR Handgeli li	2007.05.16 00:00	MR
1035	Mueller^Rita	F	1936.07.17	MR Abdomen	MR Abdomen	2007.05.17 00:00	MR
1028	Röntgen^Conrad	M	1903.06.19	MR Abdomen	MR Abdomen	2007.05.17 00:00	MR
1027	Blume^Eva	F	1947.08.04	MR Herz	MR Herz	2007.05.18 00:00	MR
1033	Meier^Max	M	1933.12.18	MR Knie links	MR Knie links	2007.05.18 00:00	MR
10013	Peterson^Sam	F	1996.05.04	MR head	MR head	2007.06.12 00:00	MR
10014	McCann^Jackie	F	1977.07.08	MR left wrist	MR left wrist	2007.06.12 00:00	MR
10015	Wacht^Oliver	M	1947.09.05	MR carpal crina	MR carpal crina	2007.06.12 00:00	MR

2. Call the worklist from the worklist server via the button .

3. Mark the wished entry in the worklist.

4. Set which data you want to overtake from the worklist via the respective button.

- : The import data are NOT linked with worklist entries. The selected data are imported in the way they are provided by the source (CD, DVD, directory).
- : The patient data from the selected worklist entry are linked with the studies/images to be imported.
- : The patient and study data from the selected worklist entry are linked with the studies/images to be imported.

5. Start the import process via the button .

Passing on of the information described here:

Please ensure in your organisation, that all users of the products mentioned above and other persons to be informed are to be informed of this **urgent safety information**. If you have handed over the products to any third party, please forward a copy of this information or inform the contact person mentioned down.

Please save the information at least as long as the measure has ended.

The German Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact:

medavis GmbH
Partner Support
Bannwaldallee 60
76185 Karlsruhe
Germany
Tel. +49 72192910-900
Tel. +49 72192910-111
E-Mail: support@medavis.de
Business hours: Mo.-Fr. until 9.00 am to 17.00 pm

Sincerely yours,

medavis GmbH

First name, Name