Urgent Field Safety Notice

VEPRO

March 20th, 2019

Internal Ref. Nr.: FSCA 2019-001

VEPRO AG ▪ Germany ▪ Max-Planck-Strasse 1-3 ▪ 64319 Pfungstadt

To
Hospital Management
Head of Radiology
PACS-Administration
Head of IT Department
Safety Manager for Medical Products

Subject: Important software update for the product EMR Manager

In certain situations, current data sent by imaging modalities in the image archive cannot be accessed and displayed. Thus, these image data are missing in the archive for diagnosis.

Dear Customers,

With this safety information we would like to draw your attention to a possible problem with the product EMR Manager.

Affected software versions

This issue affects the following versions of the EMR Manager product:

- Version 8.2 including Service Packs SP1 – SP10   (Revision 20542 – Revision 24659)
- Version 9.0 including Service Packs SP1 – SP4   (Revision 24589 – Revision 27009)

For software version 8.x, the lifecycle is over and support was discontinued by May 2018.

Description of the problem

The product component VEPRO Job Manager is responsible for the distribution of data from and to imaging modalities. The management of the upcoming tasks is done via queues for the respective devices. Normally, these queues are processed concurrently simultaneously.

However, a problem in the described software versions may, in rare cases, cause other queues to become blocked when a queue for a target device is overloaded and multiple jobs for a target device remain in a wait state for an extended period of time.

Due to blocking of the other queues, current data from imaging modalities can arrive with a great delay in the medical archive.

This can lead to a delayed treatment of a patient because the image information relevant for the diagnosis cannot be retrieved in the image archive in a timely manner.

Measures to mitigate potential risks

VEPRO is working on a software update which fixes the problem. This update is expected to be available no later than 31/03/2019. Our support team will contact you to arrange the software update procedure. Customers who work with the current version 9.0 get this update for free.

Customers who use previous software versions must first upgrade to the current software version 9.0. To do this, please contact your local sales representative.

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![VEPRO logo]

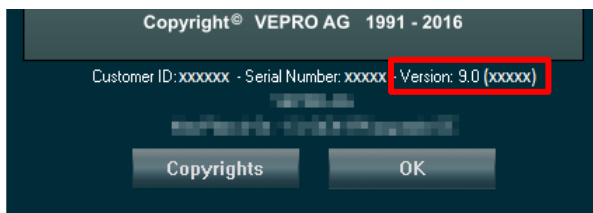March 20th, 2019   Internal Ref. Nr.: FSCA 2019-001

If you notice the lack of up-to-date diagnostic material relevant to the diagnosis before the software update is available, please carry out the following steps:

1. Resubmit the missing information from the imaging modality to the VEPRO PACS archive

2. Contact the VEPRO Support Team using the contact address below. The support team will assist you so that you can quickly access the missing data again.

3. Perform the diagnosis directly on the imaging modality.

Identification of the affected products

To determine if your product is affected by the problem described here, please start the EMR Manager Viewer.

Click on the symbol [?] in the title bar. Here you select the entry "Info about VEPRO". The product version and revision (in brackets) are displayed as shown marked in red below.

Passing on the information described here:

Please make sure in your organization that all users of the products named above and other persons to be informed are aware of this urgent fiels safety notice. If you have given the products to third parties, please forward a copy of this information or inform the contact person listed below.

Please retain this information at least until the action has been completed.

The german national competent authority „Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)" has received a copy of this "Urgent Safety Information".

Contact Person

If you have further questions regarding the problem described and the measures recommended, please contact:

VEPRO Support
Phone: +49 (0)6157 800 688
Fax: +49 (0)6157 600 686
E-Mail: support@vepro.com

With best regards,