

Address

Würzburg, 30.01.2014

## Safety notice

Product: **aycan OsiriX**  
Effective versions:  $\leq$  Version 2.08.002  
aycan Reference: ID69728  
Recipients: User

To whom it may concern,

aycan would like to inform you of potential risk related to use of **aycan OsiriX** under the conditions described below.

## Overview

Medical imaging modalities generate data according to the DICOM-Standard. The DICOM file contains image data, and also information in regards to the image geometry, which among others describes image resolution ('pixel spacing') etc. Typically an image in a DICOM file has the same resolution in all areas of the image.

Certain medical imaging modalities available generate DICOM images, which under specific circumstances could contain different resolutions in different areas of the image.

## Specific problem description

DICOM Images generated for example by Philips Ultrasound equipment type '**Philips HD11 XE**' can have different resolutions within the same image. **aycan OsiriX** may calculate incorrect measurement lengths, areas, and volumes from the ROI (Region of Interest) function if the DICOM image resolution is not consistent across the entire image. While this has been identified in certain Philips ultrasound equipment, the same issue can also occur in different modality types from other manufacturers.

## Resolution

aycan will within a short period of time provide a software update which will check DICOM images for different resolutions within a single image and display a warning message when this is identified in an image. The software update will be available at <http://www.osirix-pro.de/2-8-4>

Please contact aycan or aycan reseller if you experience a problem downloading the software update.



W.C. Röntgen

**Till the software update is available, please be aware of the following advice**

1. Please find out from the manufacturer of your medical imaging modality, if the device generates DICOM files with different resolutions within the same image.
2. In case of such a behavior of that particular imaging modality, please use the ROI (Region of Interest) function only directly at the modality (e.g. determination of length).

**Communication and Notification**

Please share this letter with all users of the **aycan OsiriX** system and impacted modalities.

If you have sold or transferred **aycan OsiriX** software to any third party organizations, please forward a copy of this letter to impacted third parties, and notify the aycan point of contact listed below.

Please keep this letter on file for your records until the **aycan OsiriX** software has been updated and this risk has been removed from you system.

Appropriate regulating authorities in the United States and in the European Union (Germany) have been notified and received a copy of this letter.

**Contact person for Europe/Africa/Asia/Australia**

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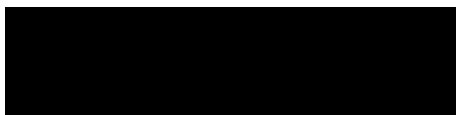
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Thank you for your attention.  
With kind regards



Matthias Bröner

Safety and Compliance Officer  
aycan Digitalsysteme GmbH



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