URGENT - Field Safety Notice
Advanced Vessel Analysis (AVA) on the Extended Brilliance Workspace (EBW) – German Version Only

The *Latin* terms associated with Left and Right Renal Vessel annotations in the German localized version for the user interface are reversed.

Dear Customer,

A potential problem has been detected in German localized version of the Philips AVA application on the following products:

- EBW v4.0.2 and v 4.0.3;
- GEMINI TF, TOF 16 & 64 with v3.5 and v3.5.1 software,
- GEMINI TF Big Bore v3.6,
- EBW NM v1.0 and v1.1 (Includes BrightView XCT and BrightView sold as accessory with systems.),
- PET Apps Suite v2.0 w/EBW v4.0.2.

This Field Safety Notice is intended to inform you about:

1. what the problem is and under what circumstances it can occur
2. the action that should be taken by the customer /user in order to prevent risks for patients
3. the action planned by Philips to correct the problem.

If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agency.

Thank you for your attention to this matter.
Sincerely,

[redacted]
Senior Director, Quality and Regulatory CT/NM

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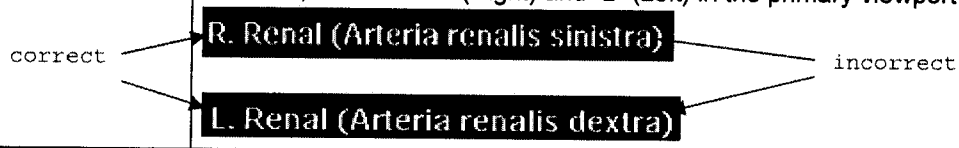
AFFECTED PRODUCTS	The German localized version of AVA on: 1. EBW software v 4.0.2 and v 4.0.3 2. GEMINI TF, TOF 16 & 64 with v 3.5 and v 3.5.1 software 3. GEMINI TF Big Bore v 3.6 4. EBW NM v 1.0 and v 1.1 (Includes BrightView XCT and BrightView-sold as accessory with systems.) 5. PET Apps Suite 2.0 w/EBW 4.0.2 6. If you have used the Advanced Vessel Analysis temporary license to enable the AVA application on your EBW 4.0.2/4.0.3 any patient studies performed within the 60 day trial are subject to this safety notice.
PROBLEM DESCRIPTION	The right and left *Latin* annotations for the Renal Vessel labels are reversed; however, the main "R" (Right) and "L" (Left) in the primary viewport is correct. 
HAZARD INVOLVED	There is a potential that the physician could misread the right and left renal vessels causing a potential misdiagnosis.
HOW TO IDENTIFY AFFECTED PRODUCTS	The version of the EBW can be found by clicking on 'Help' button at the upper right corner of the screen.
ACTION TO BE TAKEN BY CUSTOMER / USER	Check the medical records of patients that have had a renal vessel procedure conducted since November 2008 to ensure that there was not a misinterpretation in the "R" (Right) and "L" (Left) vessels.
ACTIONS PLANNED BY PHILIPS	Philips Healthcare will implement a field corrective action (FCO 72800470 and 88200364) to provide a software update to all affected users.
FURTHER INFORMATION AND SUPPORT	CT and PET Customers should contact their local Customer Care Service Center.