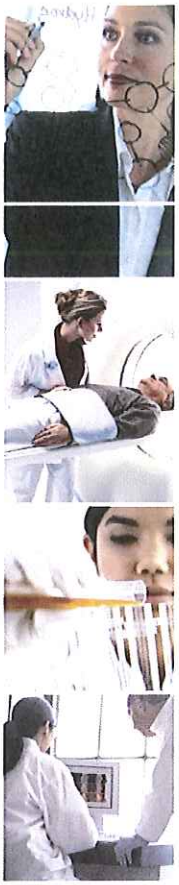
SIEMENS



Molecular Imaging

Safety Customer Advisory Notice

CAN 004-2016

To: Director of the Radiology Department
Director of the Nuclear Medicine / PET Imaging Department
Risk Management Officer
Users of Siemens Biograph mCT and mCT Flow systems

Re: Utilizing a third party or liquid PET QC phantom without performing the recommended Cross Calibration procedure may result in a variation of the PET quantification (SUVs) within the attenuation corrected PET images.

Dear Valued Siemens Customer,

It has been brought to our attention that utilizing a phantom other than the Siemens solid Germanium-68 phantom may impact the Calibration Factor values generated during the PET Quality Control procedure.

Depending on the type of uniform phantom utilized to perform the PET Quality Control, the PET Calibration Factor may be biased due to the system using a specific mu-value of 0.1 cm^{-1} which is based on the Siemens solid Germanium-68 phantom. The system will use this default mu-value, regardless of the actual mu-value of the phantom utilized for PET Quality Control; this may cause a variation in the quantification of the attenuation corrected PET images.

In order to correct for the variation in mu-values, we recommend that you perform the scanner cross calibration procedure. In addition to cross calibrating the PET scanner to the dose calibrator, this procedure will also account for the different mu-value of a liquid or third-party solid Germanium-68 Quality phantom to ensure more accurate quantification in the PET attenuation corrected images. For complete instructions on the Cross Calibration procedure, please see your Siemens Biograph Operator's Manual.

Please ensure that this customer advisory notice is placed in your Biograph Operator's Manual and disseminated to all operators of the Biograph mCT systems. If this equipment is no longer in your possession, we kindly ask that you forward this letter to the new owner of the equipment, and please inform Siemens about the change in ownership.

Adverse events or quality problems experienced with the use of this product should be reported to Siemens through the contact information provided below and may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

If you have any questions regarding this advisory notice, please contact your local Siemens representative at the contact numbers provided below.

- America: 1-800-888-7436
- Europe, Middle East, and Africa: +49 9131 940 4000
- Asia and Australia: +86 (21) 3811 2121

Sincerely,

Matt Shah
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Molecular Imaging
CAN004-2016

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