


THE CLINICAL TRIALS NETWORK PROGRAM

PET/CT Scanner Validation

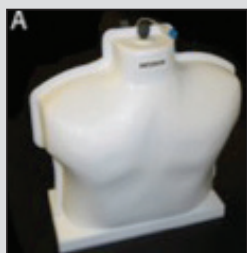
Thank you for your interest in the CTN Scanner Validation Program. A successful validation ensures that your study patients as well as your clinical patients are being scanned on a quantitatively and qualitatively accurate PET/CT.

Overview

The CTN's Scanner Validation Program was established to ensure the quantitative accuracy of PET/CT scanners used in multicenter trials. The phantom was designed as a clinical simulator to evaluate the detection of lesions in an anthropomorphic model. Since inception, the program has collected nearly 500 phantom data sets from nearly 200 imaging sites sampling the spectrum of commercially available PET/CT systems¹. This data set has allowed the CTN to develop acceptance criteria to determine quantitative acceptance of PET imaging acquired in multicenter studies. Below are the main goals of the program:

-  To provide **relevant and meaningful** assurances to trial sponsors that PET/CT scanners in their trials will perform quantitatively and qualitatively above predetermined standards, rationally set, based upon seven years of data collection and analysis.
-  To provide **constructive** feedback to imaging sites regarding their scanner's performance characteristics based upon our historical collected data.
-  To globally **raise the bar** for quantitative PET/CT imaging in clinical trials and clinical practice.

Scanner Validation Process



Scanner validation requires the use of the unique CTN phantom; i.e., a "clinical simulator" that mimics lesions in the human torso and provides both qualitative and quantitative information in conditions similar to actual clinical imaging settings.

To be validated, staff at imaging centers must successfully complete the steps in the process illustrated below for each PET/CT scanner being tested.

Site /Sponsor requests scanner validation

Site completes and returns PET/CT Equipment form provided by CTN

CTN Initiates phantom shipment

Site returns CTN phantom

Validated; Site receives report and Certificate

CTN reviews phantom images and worksheet

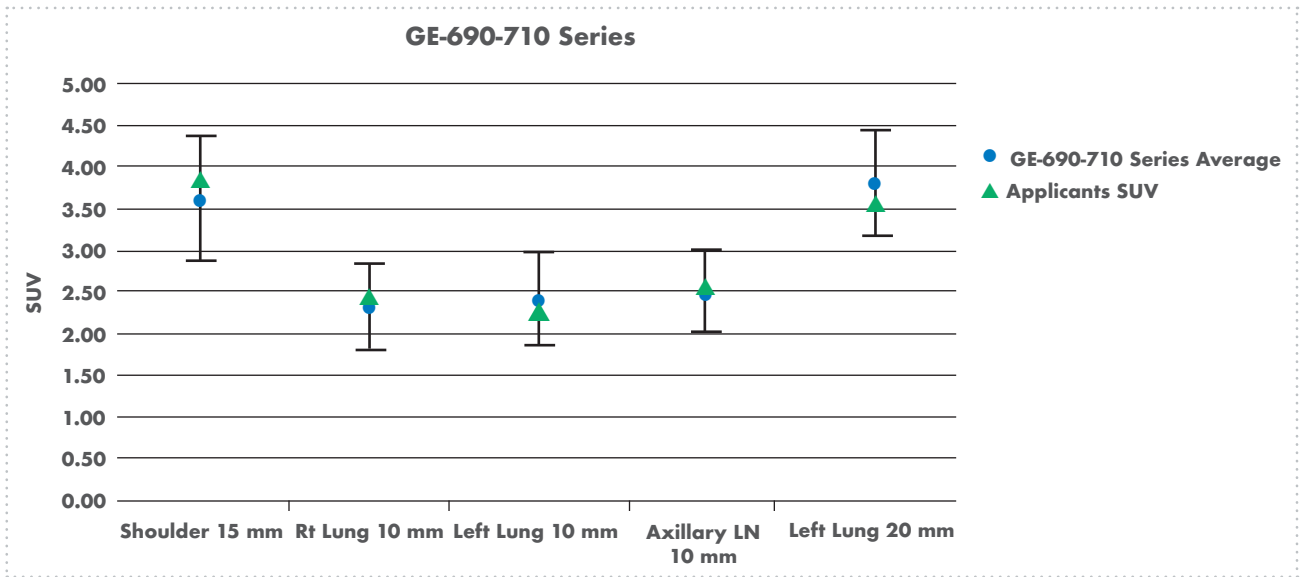
Site performs phantom scan; uploads/sends images and worksheet

¹John J. Sunderland and Paul E. Christian; Quantitative PET/CT Scanner Performance Characterization Based Upon the Society of Nuclear Medicine and Molecular Imaging Clinical Trials Network Oncology Clinical Simulator Phantom; J Nucl Med 2015 56:145-152

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Review Analysis

Two reviewers will perform the image review, including at least one PhD-level physicist specifically trained in scanner validation. If images meet all required parameters, the validation is considered successful. A scanner performance report is prepared and sent to the site along with a Certificate of Validation. This scanner performance report includes an evaluation of the scanner’s lesion detection ability, technical and quantitative assessment. You will also receive a comparative analysis (pictured below) of your scanner to scanners of the same model, along with suggestions, if needed, to improve the quality and/or accuracy of the images.



*The comparative analysis plot above indicates how a site’s scanner performed quantitatively in this current validation exercise and how it compares – lesion by lesion – to other scanners in the same model group.

Scanner Validation Fees

Categories	Fees
Initial Validation	\$2,000 up to 2 scanners \$500 each additional scanner
CTN Phantom Shipping	Shipping fees vary by location
Re-validation	\$1,000 up to 2 scanners

Note: If failed more than once, site will be charged for \$500 per scanner for an additional attempt. If a previously-validated scanner was validated more than 18 months ago, you will be billed as an Initial Validation.

Contact

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