

Method and Phantom Design for the Evaluation of Material Quantification Accuracy of Contrast-Enhanced Spectral Computed Tomography (CT) Systems User Manual

Part 1: Protocol for Phantom Preparation Used in Evaluating Quantitative Measurements with Contrast-Enhanced Spectral Computed Tomography (CT)

Introduction:

This document outlines the procedure for constructing tissue-mimicking phantoms from Lucite (PMMA) material.

Lucite (PMMA) is utilized due to its radiological properties, which closely match those of soft human tissues, particularly under the spectral imaging conditions. Its x-ray attenuation profile is akin to soft tissue, making it an excellent surrogate for evaluating the iodine quantification in a clinically realistic setting.

These phantoms are intended for the evaluation of quantitative measurements in spectral contrast-enhanced CT systems.

Equipment/Supplies:

- 1- Lucite (PMMA) slabs
- 2- Water
- 3- Iodinated contrast agents like Iohexol (Omnipaque) or Iopamidol (Isovue) solutions, with known concentration typically available in high concentrations from laboratory supply retailers.



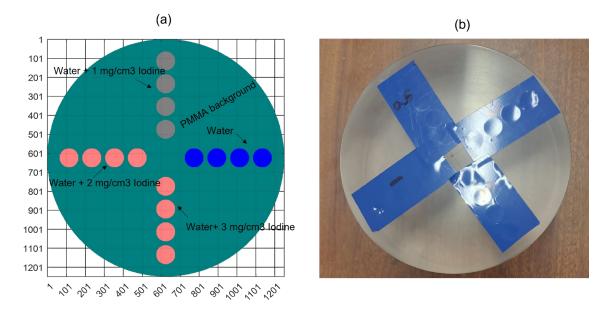


Figure 1: An illustrative example of the proposed phantom design is shown. Figure (a) presents a diagram a cylindrical breast phantom, composed of a PMMA background and containing iodine targets created with a water solution at concentrations of 0, 1, 2, and 3 mg/cm³. Figure (b) displays a photograph of the actual physical phantom used in the experiments.

Phantom Preparation Protocol:

- Begin by cutting the PMMA slabs into a cylindrical shape, the diameter of which should correspond to the application requirements. Ensure the height of the cylinder surpasses the scanner's field of view in the Longitudinal (z) direction for a realistic simulation of the scatter effect.
- 2. Drill cylindrical holes into the PMMA cylinder, starting near the center and extending toward the periphery (Example: see Figure 1). Ensure to include at least two locations per concentration, with one near the center and another at the periphery. In Figure 1, the example phantom design has four locations per concentration.
- 3. Prepare iodine/water mixtures by following a standardized dilution protocol to obtain three distinct iodine concentrations. These concentrations should cover at least the lower clinical range, which varies depending on the application.
- 4. Pour each of the three different concentration solutions into the holes created in the cylindrical phantom. Ensure each concentration is placed in at least two separate locations within the phantom.



5. Carefully seal the holes to prevent any leaks that might damage the X-ray machine. The sealing method may vary but it should ensure absolute tightness.

Imaging Protocol:

- 1. Carry out scans and obtain the iodine material decomposition images under a variety of irradiation conditions, image reconstruction parameters, changing tube voltage, tube current, filtration, and dose levels settings. The scans should also accommodate different phantom sizes, collectively encompassing the entire clinical range.
- 2. For each set of irradiation conditions and phantom size, multiple realizations should be conducted to allow uncertainty estimation (at least three).

References:

[1] Assessing Spectral Efficiency in Quantitative Contrast-Enhanced Breast CT Using a GaAs Photon-Counting Detector: A Simulation Approach. Bahaa Ghammraoui, MU Ghani, JL Manus, SJ Glick - Physics in Medicine and Biology

[2] Assessing Spectral Efficiency in Quantitative Contrast-Enhanced Breast CT Using a CdTe Photon-Counting Detector: An Experimental study – Proceeding – CERN meeting workshop, Geneva, May 2024

Part II: Evaluation Method and Quantitative Metrics

Introduction:

This document outlines a method for assessing quantitative measurements in contrastenhanced spectral computed tomography (CT) systems, utilizing the phantom design detailed in the "Part I: Protocol for Phantom Preparation Used in Evaluating Quantitative Measurements with Contrast-Enhanced Spectral Computed Tomography (CT)."

Figure of merits:

The performance of the quantitative methods for each iodine concentration under investigation can be assessed in using the following metrics:



1- Root-mean-square error (RMSE) between the estimated and known iodine concentrations C_i and C_i^{true} respectively. The RMSE is calculated using:

$$RMSE = \sqrt{\frac{\sum_{i=1}^{N} (C_i - C_i^{true})^2}{N}}$$

In this equation, N represents the total number of inserted iodine discs, which is equivalent to the number of realizations multiplied by the number of locations of the disks with the same known concentration.

2- Precision of the iodine estimation, as indicated by the standard deviation (σ_c^r) of the estimated iodine concentration across various realizations. This is calculated using the equation:

$$\sigma_c^r = \sqrt{\frac{\sum_{i=1}^N (C_i - C_i^{mr})^2}{N}}$$

In this case, C_i^{mr} denotes the mean values of the estimated iodine concentration across different realizations. The "precision of the iodine estimation" refers to the method's ability to estimate iodine concentration values consistently and accurately. The population standard deviation provides a measure of the precision of the estimated iodine concentration across different realizations, thus facilitating the evaluation of the method's overall precision.

3- Precision of the iodine estimation, as indicated by the standard deviation of the estimated iodine concentration values at different insertion locations (σ_c^l). This is calculated using the formula:

$$\sigma_{c}^{l} = \sqrt{\frac{\sum_{i=1}^{N_{l}} (C_{i} - C_{i}^{ml})^{2}}{N_{l}}}$$

Here, C_i^{ml} represents the mean values of the estimated iodine concentration across the different locations of the disks with the same known concentration, and N_l represents the number of disks studied with that concentration. The standard deviation between insertion locations provides a measure of the precision of the estimated values at different locations, thus assisting in evaluating the effects of beam hardening, scatter effect and cupping artifacts on the estimated values of iodine concentration.

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov



The specified metrics should be reported for each of the following:

- Varying phantom concentrations and sizes.
- Different operating voltages (kVp) of the x-ray source.
- Various levels of tube current (mAs).
- Reconstruction parameters.

To cover the entire clinical range of the device in examination.

References:

[1] Assessing Spectral Efficiency in Quantitative Contrast-Enhanced Breast CT Using a GaAs Photon-Counting Detector: A Simulation Approach. Bahaa Ghammraoui, MU Ghani, JL Manus, SJ Glick - Biomedical Physics & Engineering Express (BPEX)

[2] Assessing Spectral Efficiency in Quantitative Contrast-Enhanced Breast CT Using a CdTe Photon-Counting Detector: An Experimental study – Proceeding – CERN meeting workshop, Geneva, May 2024