LIDC

SUBCOMMITTEE (#1) CT INCLUSION CRITERIA

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REPORT ON CT SCANNING INCLUSION CRITERIA, SCANNER CHARACTERISTICS AND QA

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Section 1 – CT Scanning inclusion criteria

The following inclusion criteria have been developed through discussions with both the CT protocol committee and the full steering committee. The inclusion criteria *are* meant to be a flexible description of the CT imaging protocols that the LIDC had decided to include in the database.

These ARE NOT recommendations of CT protocols for CT screening or follow-up for lung cancer. Please note that the LIDC DOES NOT endorse lung cancer screening, but its member institutions are involved in several research studies that are investigating the utility and efficacy of screening for lung cancer. The LIDC is using the results of these various lung cancer screening studies as part of its database.

It is recognized that it is not possible to develop one protocol that is identical across all CT scanners utilized by LIDC members because of :

(a) differences in CT scanners from different manufacturers

(b) differences in how each site performs lung cancer screening, diagnostic scans and follow-up imaging for lung cancer (noting that the LIDC is not paying for these scans and therefore may not be able to dictate the exact protocol)

(c) and that the technology is still rapidly evolving.

The LIDC recommends the following guiding principles for inclusion criteria:

1. That the thinnest slice thickness possible on a given CT scanner be used that will result in a diagnostic scan through the entire chest in a single breathhold
2. That these recommended protocols will have to be periodically revised in response to changes in member institutions' CT scanners and changes in CT technology as it continues to evolve.
3. Quality Control of the CT scanners is not specifically addressed in these inclusion criteria. Sites will be encouraged to apply for the ACR CT accreditation program as it commences.

Section 1.1 –Screening Exams of Asymptomatic Patients – CT Scanning inclusion criteria

Given these principles, the *currently recommended inclusion criteria for* CT scanning protocols used for screening exams are summarized in the table below:

Scanner Type	Multidetector Spiral CT
Scan kVp	120 to 140
Scan mA/Rotation time or mAs [1,2]	Scanner, Slice thickness, Scan time and Patient Dependent GE Scanners: Range: 40 -80 mAs .8 sec scanner: 50 to 100 mA .5 sec scanner: 80 to 160 mA Siemens Scanner Range: 20 to 40 mAs Philips Scanners Range: 20 to 40 mAs
Detector Collimation (mm)	4 x 2.5 mm (or thinner)
Reconstructed Slice Thickness (mm)	2.5 mm (or thinner)
Image Reconstruction Interval (mm)	At least continguous, overlapping preferred Ex. For 2.5 mm slice thickness, internal <= 2.5 mm
Table Speed (mm/s) / Pitch	Tablespeed necessary to cover chest in 1 breath of <30 s; Tablespeed > 15 mm/s Table Speed is scanner and slice thickness depenedent. Ex. HS mode for GE LightSpeed using 4 x 2.5 mm uses pitch 1.5, 15 mm/rotation, 18.75mm/s
Reconstruction filter (kernel)	Manufacturer specific, multiple recons preferred GE: Bone, Lung, Standard – All 3 recons when possible[3]. Philips MX8000 – B and C filters Toshiba Aquiliion – FC 51, FC 10 – both when possible Siemens VolZoom – B30, B50f – both when possible
Position; Breath Hold	Supine; At maximum inspiration (TLC).

Table 1. Screening CT Inclusion Criteria Guidelines

[1] The goal for GE scanners should be to keep mAs between 32 and 64. As faster scanners are used, the mA should increase to keep the mAs constant. Thus, if a site was using 40 mA at 0.8 s rotation time (32 mAs) and that scanner is upgraded to 0.4 s scanner, then the mA should increase to 80 mA.

Constant mAs	Rotation time	mA	Rotation time	mA	Rotation Time	mA
32	0.8	40	0.5	60	0.4	80
40	0.8	50	0.5	80	0.4	100
64	0.8	80	0.5	120	0.4	160

[2] Siemens and Philips scanners specify mAs – which is really an "effective" mAs = mA * time/pitch. The DICOM header should fill the mA and exposure fields correctly.

[3] LIDC sites will use one of the three filters for their clinical scan; sites are requested to reconstruct images using the other two filters for inclusion in the LIDC database as well, whenever possible.

Section 1.2 –Diagnostic Exams of Patients w/Identified Nodule – CT Scanning inclusion criteria

For patients in whom a nodule has been detected, different types of diagnostic exams may be performed to determine if the nodule(s) detected are benign or malignant. Two types of studies are to be included in the LIDC database:

1. Low Dose Followup imaging for nodules
   a. These scans will use the same criteria as the Low Dose screening exams as described in Table 1.
2. Limited Diagnostic Scans through Nodule
   a. These scans will use higher radiation dose levels, use thin slices and are limited in coverage. These are described in Table 2.

Therefore, the *currently recommended inclusion criteria for* CT scanning protocols used for diagnostic exams are summarized in the table below:

Scanner Type	Spiral CT – Single Detector or MultiDetector
Scan kVp	120 to 140
Scan mA/Rotation time or mAs	Necessary for Diagnostic Image Quality; no spec value
Reconstructed Slice Thickness (mm)	3 mm (or thinner)
Image Reconstruction Interval (mm)	At least continguous, overlapping preferred Ex. For 2.5 mm slice thickness, internal <= 2.5 mm
Table Speed (mm/s) / Pitch	Necessary for Diagnostic Exam, no specified value
Reconstruction filter (kernel)	Manufacturer specific, multiple recons preferred GE: Bone , Standard. – both when possible Philips/Marconi – B, C filter- both when possible Toshiba Aquiliion – FC 51, FC 10 – both when possible Siemens VolZoom – B30, B50f – both when possible Others TBD
Position; Breath Hold	Supine; At maximum inspiration (TLC).

Table 2 – Limited Diagnostic CT Inclusion Criteria Guidelines

Section 1.3 –Retrospective/Diagnostic Exams of Diagnosed Cancer Patients – CT Scanning inclusion criteria

Given the above principles, the *currently recommended inclusion criteria for* CT scanning protocols used for diagnostic exams of diagnosed cancer patients are summarized in the table below:

Scanner Type	Spiral CT – Multidetector or Single Detector Scanners
Scan kVp	120 to 140
Scan mA/Rotation time or mAs [1,2]	Necessary for Diagnostic Image Quality; no spec. value
Reconstructed Slice Thickness (mm)	5 mm (or thinner)
Image Reconstruction Interval (mm)	At least continguous, overlapping preferred Ex. For 2.5 mm slice thickness, internal <= 2.5 mm
Table Speed (mm/s) / Pitch	Necessary for Diagnostic Exam, no specified value
Reconstruction filter (kernel)	Manufacturer specific, multiple recons preferred GE: Bone , Standard. – both when possible Philips MX8000 – B and C filter, both when possible Toshiba Aquiliion– FC 51, FC 10 – both when possible Siemens VolZoom – B30, B50f – both when possible
Position; Breath Hold	Supine; At maximum inspiration (TLC).

Table 3 – Diagnostic Scans for Diagnosed Cancer Patients CT Inclusion Criteria Guidelines

Section 2 – Acceptable Image Quality

As part of the *recommended inclusion criteria for* CT scanning protocols, the steering committee and CT scanning subcommittee agreed that there should some criteria applied to exclude cases based on unacceptable image quality. To date, these criteria have not been established.

Image quality centers around the following problems with images that may influence the ability to detect or characterize the imaged nodules:

1. Excessive image noise
    a. Due to too low of a technique for a given sized patient or for a given slice thickness (e.g. using same mAs for 1 mm as for 2.5 mm thickness)
    b. Due to incorrect choice of kVp, mA, scan time, mAs, slice thickness or recon filter
2. Excessive patient motion
    a. Due to patient breathing during scan
    b. Due to patient moving on table
3. Streak or Ring artifacts
    a. Due to poorly calibrated scanner (Ring)
    b. Due to scanner malfunction (Streak or ring)
    c. Due to patient/metallic implants (Streak)
4. Other Problems at the discretion of the reviewing radiologists

Discussion has centered around the inclusion of "clinically acceptable" images in the LIDC database. This has not been defined, but has *de facto* been described as any case in which the image quality was acceptable enough so that a study was not repeated.

Steering committee dis cussions also centered on whether or not cases with suboptimal image quality should be included to:

- stress CAD systems or
- allow CAD systems to be tested on these cases and provide a useful assist to cases that would be difficult for human observers.

Activities have been undertaken in which several of the LIDC radiologists reviewed cases from an existing database of images. The DICOM headers of these cases were reviewed as well to determine if there were some systematic trend towards excessive noise from a given scanner/technique combination. While there were some cases with high amounts of noise and some with patient motion, no guidelines have been established for excluding cases from the LIDC based on poor image quality.

Section 3 – CT Scanner Characteristics

The purpose of this section is to describe the physical characteristics of CT scanners that will be collected for the LIDC database. This data is collected on a one-time basis and is meant to provide a representative description of the physical performance of each scanner. This is necessarily limited to scanners on which prospective cases were collected for the LIDC; the LIDC will not have any means to collect data on scanners from which retrospective cases were collected.

The following physical characteristics of each scanner will be measured. When appropriate, these parameters will be measured using the same imaging protocol that is used for either the screening or diagnostic CT scans that will be included in the LIDC image database:

1) **Water Calibration** – Determines how closely a scanner is calibrated to water (which should be close to 0 HU under all scanning conditions; measured using an ROI at center of a water phantom)
2) **Noise** – Performed under specific set of scanning and image reconstruction parameters (for LIDC, we would perform this test under clinical operating conditions rather than manufacturer's suggested conditions). This determines the amount of random variation occurring under specified conditions. Measured with water phantom (usually at same time as Test 1 – water calibration).
3) **Uniformity** – Determines how much variation exists within a reconstructed image of homogeneous medium (typically water or water-equivalent phantom). Again, measured at same time as Test 1 - just with measurements at 12:00, 3:00, 6:00 and 9:00 positions.
4) **Contrast Scale** – Measures the differences between various standard materials. Can be limited to one measurement of the difference between water and plexiglas or expanded to several materials (plexi, polyethylene, teflon or a bone-equivalent material) such as the ACR phantom will use. This is a basic characteristic of scanner, selected beam energy and filtration scheme.
5) **Slice thickness** – Describes an essential component of z-axis resolution and is a basic characteristic of scanner operation. Simple measures record only the number of 0.5mm or 1.0 mm bars visible in an image (see below). More complete is a slice sensitivity profile (SSP) which can be measured in several different ways –including either a bead or disk method; from the derived SSP curves, the full width at half maximum (FWHM) is a common descriptor for the nominal slice thickness. We would measure these only for slice thickness values used in patient images.
6) **In plane spatial resolution** – A basic characteristic of scanner operation. Simple measures record only the size of visible objects (such as bars or small squares or circles). More complete descriptions include the Modulation Transfer Function (MTF –see Appendix 1) which can be obtained using a plexiglas bar pattern phantom and some simple calculations. This in heavily influenced by reconstruction algorithm (i.e. GE's standard, bone, lung and similar for other scanners). An example is shown below.
7) **Low Contrast Resolution** – Measures the ability to resolve objects of different size under low contrast conditions (differences between object and background is typically 3-6 HU). There are some low contrast phantoms which are imaged and scored visually (what size object can be observed visually) and some proposed statistical techniques (based on image noise and contrast scale).

8) **Radiation Dose Estimates** – Measures the radiation dose to a standard phantom under a set of specified scanning conditions (kVp, mA, time, slice thickness, pitch). This would be measured using conventional CTDI techniques (pencil ionization chamber, electrometer, 32 cm plexglas phantom) as well as in air (no phantom – values measured in air are often used as inputs for software packages that calculate estimates of effective dose)/ Would be performed with the techniques used in the clinical imaging protocol

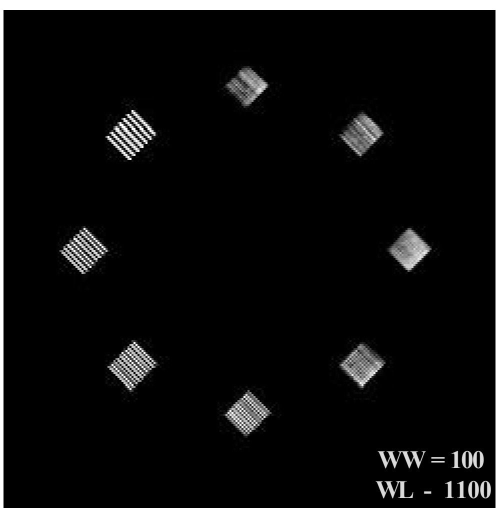
The Data collected above would be described in two ways:

1. Image Data (see Examples below)
2. Quantitative measures

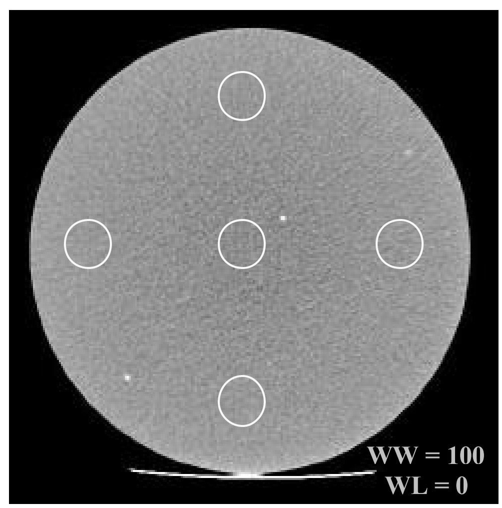
Tables would be constructed to contain both original data and any derived values

Original values: Mean value at center, Mean value at 12:00, Mean value at 3:00, Std Dev at center, mean value of plexiglas, mean value of ACR phantom materials, Slice thickness from .5mm bars, FWHM from SSP curves, Size of spatial objects resolved (subjective), measurements for Droege-Morin version of MTF, low contrast resolution (subjective), $CTDI_{100}$, center, $CTDI_{100}$, periphery

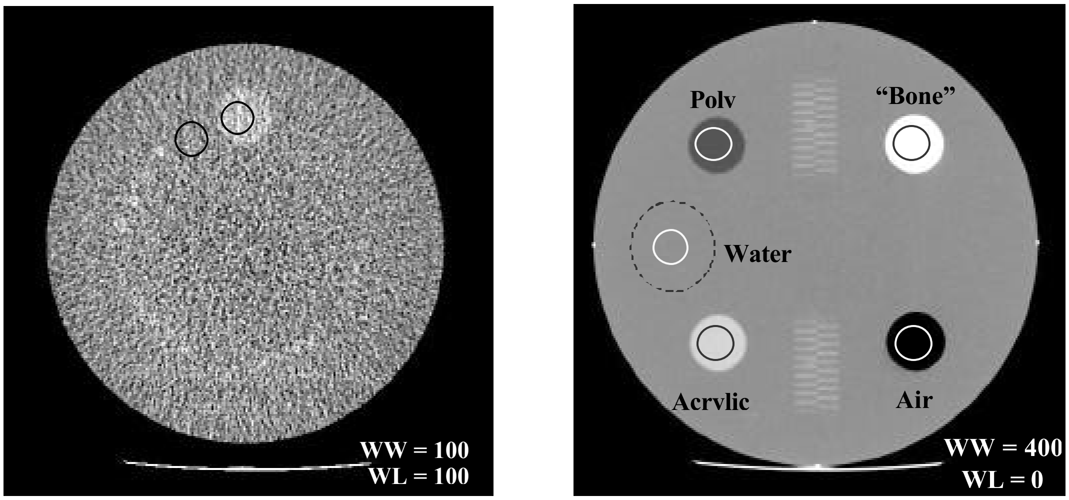
Derived values: Max Difference for Uniformity, contrast scale (Plexi-water), Bone-water, MTF curve values at 6 spatial frequencies, CTDIw



(a)



(b)



(c) (d)

Figure 1 - Representative Images from ACR phantom: (a) Image of Aluminum bar patterns from ACR phantom used to measure in-plane spatial resolution; (b) image of Uniformity module with ROIs placed to measure water calibration (center), noise (from center) and uniformity from ROIs placed at 12,3, 6 and 9 o’clock, (c) Image of low contrast module at relatively high dose technique; ROI shown is placed to measure HU difference between cylinders and background; (d) Image of slice thickness ramps (center of image) and cylinders with ROIs placed to measure mean values of different materials and contrast scale.

Section 4 – CT Scanner QA

Each of the member sites of the LIDC have been encouraged to apply for accreditation by the American College of Radiology (ACR). The ACR CT accreditation program requires each site to: (a) attest to the fact that they meet ACR standards for acceptance testing, annual physics testing and an ongoing QA program (as described In "ACR Standard For Diagnostic Medical Physics Performance Monitoring Of Computed Tomography Equipment") , (B) To Perform A Series Of Physics measurements on the ACR CT phantom, and (c) to perform a series of radiation dose measurements using CTDI phantoms. However, this is often under the direction of each site's clinical operation and not the research component of each member institution.

The LIDC members have agreed to at least perform and submit bimonthly water phantom measurements to serve as one indicator of ongoing QA at each scanner being used prospectively for data collection – especially for those scanners used for low dose lung cancer screening studies.

From these measurements, the LIDC will record:

i) Water calibration

ii) Noise

iii) Uniformity

The water phantom procedure and data collection are described in Appendix 2

Appendix 1 – Procedure to measure In-Plane Spatial Resolution using Droege-Morin approach to obtain MTF

This approach to obtaining MTF measurement is easily obtained, can be measured at any scanner, does not require immediate DICOM access to images and provides a reasonable approximation to the intended function.

This approach requires a phantom with several values of line pairs such as available with the GE QA phantom. This phantom has values of 3.125, 3.85, 5, 6.25, 8.33 and 10 lp/cm. To obtain the estimate of the MTF function requires the following steps:

1) Scan the phantom at a thick enough slice with low noise. Choose the reconstruction algorithm to be analyzed.
2) From reconstructed images, first measure mean value of Plexiglas (μ_p) and the mean value (μ_w) and standard deviation (σ_w) of water, using the scanner's region of interest (ROI) tools.
3) Next, place regions of interest (ROI) on each bar pattern. Measure the standard deviation of each ROI (σ_{bar}).
4) Finally, use the following equation to measure MTF for each spatial frequency:

$$MTF(u) = 1.11 \sqrt{(\sigma^2_{bar} - \sigma^2_w)} / ((\mu_p - \mu_w)/2)$$

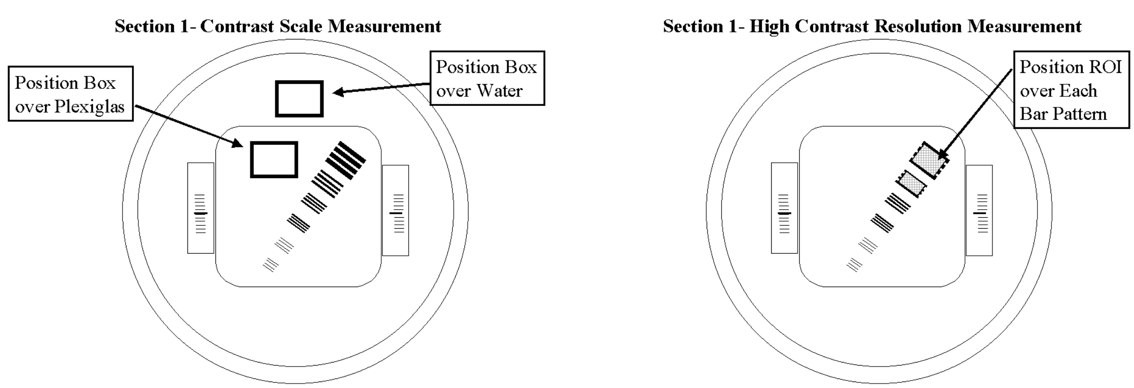


Figure A1.1. Diagram of phantom and measurement. Each bar pattern is a different spatial frequency.

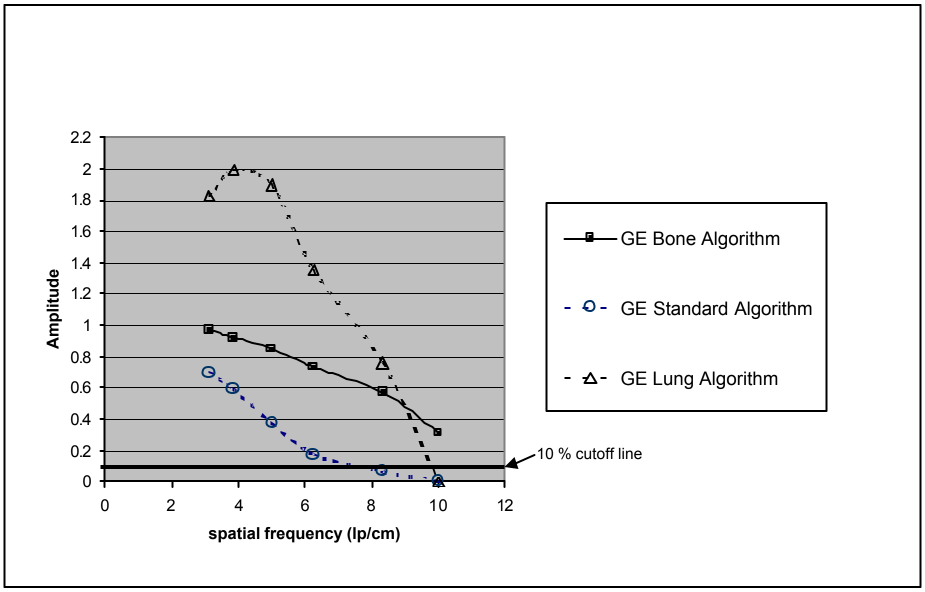


Figure A1.2 This figure demonstrates one easily obtained measurement of the Modulation Transfer Function (MTF) curve. The x-axis is the spatial frequency measured in line pairs per cm (lp/cm). The larger values of spatial frequency (e.g high frequencies) represent the rapid changes typical of smaller objects. The y-axis represents the modulation (ratio of output amplitude to input amplitude) that occurs at each frequency. A value of 1.0 means no loss of information, while values close to 0.0 represent a near total loss of information. Values greater than 1.0 mean that the spatial frequency is amplified or overenhanced (larger differences are displayed than actually occurred in the image). Note that GE standard has lower modulation values than bone and lung, but it also has much lower noise performance (not shown here). As higher frequencies are amplified or enhanced, so is image noise. MTF, along with image noise, are important scanner characteristics.

APPENDIX 2 - Bi-Monthly Water Phantom Tests Performed by Technologist

Bi-monthly water phantom tests will be performed on all CT scanners used by the LIDC members to test for water attenuation, field uniformity, and noise. Field uniformity refers to CT number (HU) variations in a uniform field and is assessed by comparing the attenuation in a region of interest (ROI) at the center of the uniform field versus along the edges.

Water phantom tests will ensure that the CT equipment is operating optimally at the acquisition parameters described by the protocol, and that degradations in performance can be rapidly determined and processes established for their correction.

The images and measurements obtained from water phantom testing will be submitted for inclusion into the CT Scanner Physics aspect of the LIDC database

A2.1 Description of the Phantom.

A water phantom will be used. These phantoms are usually supplied by the CT manufacturer at the time of scanner installation for purposes of routine quality assurance testing (See Figure X.2 below)

A2.2 Positioning the Phantom

Place the phantom into the scanner. If a phantom holder is available, then placing the phantom on this holder should provide the correct orientation of the phantom for testing. If a phantom holder is NOT available, then carefully place the phantom on the table top. Avoid placing the phantom directly above any metal in the table or metallic connectors as this will affect results. You can secure the phantom to the table with flexible tape (which will not affect image quality), although avoid any tape of high attenuation, as this too may affect the results.

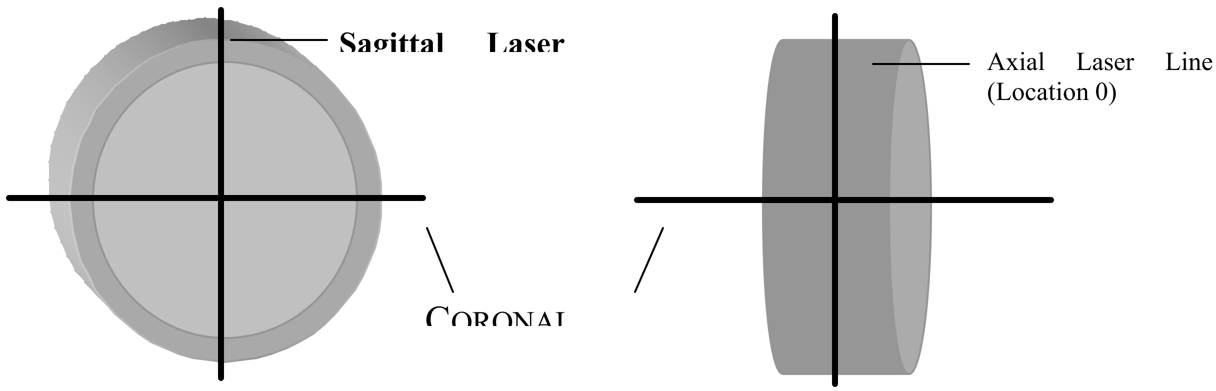
Align the phantom so that is located in the center of the gantry in the axial, coronal and sagittal planes. Do this by first positioning the phantom so that the CT *external alignment laser or lights* are accurately positioned over the center portion of the phantom containing water only. If there is no external alignment laser, use the internal laser/lights for positioning. Make sure to avoid adjacent materials (or phantom modules if using multi-purpose modular phantoms) as volume averaging effects may affect test results. Use the laser alignment lights to align the phantom accurately in the coronal, sagittal and axial planes:

- Align the axial light to the center of the phantom containing water only.
- Align the coronal light to up/down center of the phantom (If there are horizontal lines on either side of the phantom; then align to these)
- Align the sagittal light to the left and right center of the phantom (If there is a vertical line on the face of the phantom, then use this).

When the alignment is correct,

(a) If you are using external alignment lasers, then set the external landmark at this point;

(b) If you are using internal alignment lasers, then set the internal landmark at this point.



Front View of Phantom **Side View of Phantom (Z-axis)**

Figure A2.1 Front and side views of water phantom. Note that axial laser line is located directly over the center of the water phantom.

A2.3 Scanning the Phantom for Water Calibration and Noise

Prescribe a short helical scan that goes through the center of axial location 0. Use the same technical factors prescribed for screening CT exams for the ACRIN/NLST on this scanner platform. Use a display field of view (reconstructed image diameter) as close to but not smaller than the diameter of the water-equivalent phantom. The scan series should extend the entire width of the phantom (z-axis).

A2.4 Measurement of Water calibration, Uniformity and Noise

Of the reconstructed images, select one image representing the center of the phantom for measurements.

a) View this phantom image with a WW = 100 and a WL = 0. Place one ROI of approximately 400 mm^2 in the center of the image, one at the 12 o'clock position (2 cm from the edge), and one at the 3 o'clock position (2 cm from the edge) (see Figure X.3 below).
b) Record the mean value and standard deviation for each ROI in the Phantom Data Sheet
c) On the data sheet, calculate and record the Uniformity Value: Uniformity Value = Center mean CT # - Edge mean CT # for the two edge ROIs.
d) With these ROIs on the image, perform a SCREEN SAVE function to save the image with the ROIs and their mean and standard deviation values in the image.
e) With all graphics turned off, view the image carefully with the room lighting reduced. Examine the image for artifacts such as rings or streaks and record the presence and appearance of any artifacts on the data sheet. If artifacts are present, a service engineer may need to be contacted to investigate the artifact.

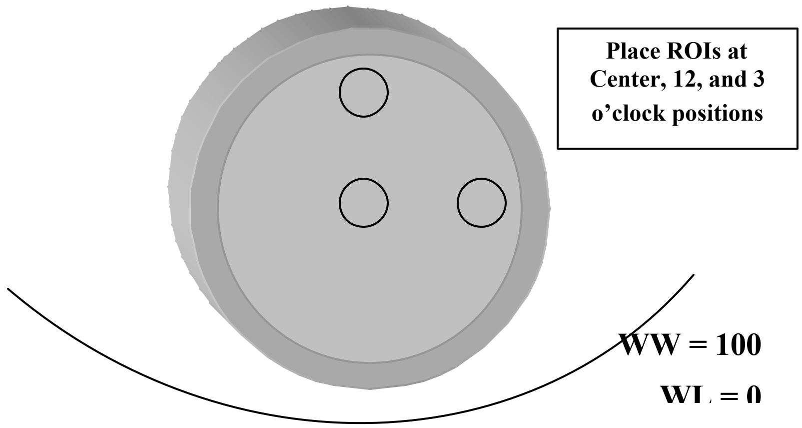


Figure A2.2 – Measurement of Noise and Uniformity on Section 3.

A2.5 Data Transfer of the Phantom Images

Push the water phantom images and the screen save images with the ROIs and numerical values to the LIDC data transfer workstation. Transfer the image data (original water images as well as screen save) to the LIDC water phantom archive.