QIBA 2017 CT Small Lung Nodule Profile: Overview and Status Update

Biomarker Committee Co-Chairs: James Mulshine, MD; Sam Armato, PhD, David Gierada, MD

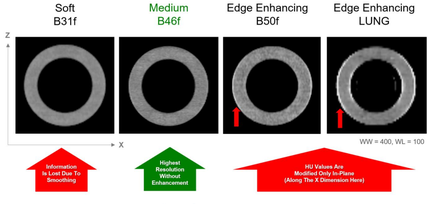
Quantitative Imaging Biomarkers Alliance RSNA

Fundamental CT Image Quality Properties

Introduction

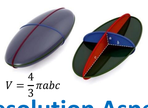
Precise volume measurement of lung nodules down to 6mm requires careful control of fundamental CT image properties throughout a CT scanner's field of view. For this high image contrast measurement task, the following properties must be confirmed at three positions from iso-center for a CT scanner and image acquisition protocol:

1. Edge Enhancement

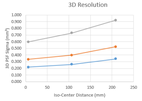


2. 3D PSF Resolution

The volume of the 3D PSF is the main indicator of volumetric measurement precision for small solid lung nodules and it changes throughout the CT scanner FOV.



$V = \frac{4}{3}\pi abc$



3. Resolution Aspect Ratio

A CT acquisition system with a spherical 3D PSF = M has better volumetric measurement performance than a 3D PSF with the same volume as M but with a higher Z/X aspect ratio.

4. HU Bias

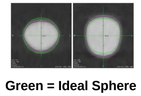
Large biases in HU values for air and water can influence volumetric measurement performance particularly when 3D resolution is poor.

5. Noise

High levels of image noise can also influence volumetric performance, particularly when 3D resolution is poor.

6. 3D Spatial Warping

Some systems can introduce high levels of 3D spatial warping. This must be avoided to obtain high quality 3D volume measurements.



Green = Ideal Sphere
Purple = Warped Boundary

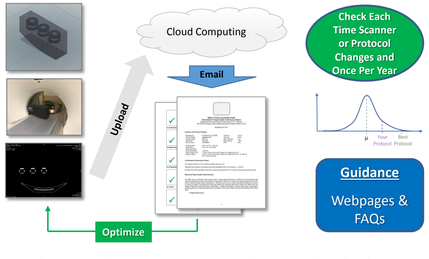
The First CT Image Quality Crowd-Sourcing Study

Aim: To quantitatively determine the most effective lung cancer screening CT scanners and protocols using an ultra-low cost, crowd-sourced approach.

Slice Thickness	Sites	Soft Recon	Medium Recon	Edge En. Recon
<= 0.625	4 (15%)	0	3	1
0.8, 1.0, 1.25	13 (48%)	7	2	4
>= 1.5	10 (37%)	6	3	1

- **2 month data collection period**
- **27 international sites participated working in collaboration with the Prevent Cancer Foundation and the Lung Cancer Alliance**
- **54 CT scanners were evaluated**
- **63% followed general screening slice thickness guidelines**
- **19% followed main QIBA SLN Profile guidelines**
- **Obtained fundamental CT image quality properties at 3 distances from scanner iso-center**
- **Found numerous opportunities to improve protocols and volumetric performance**

Proposed New Low-Cost Phantom & Automated Analysis



Fundamental CT Image Properties Are Checked at Three Distances From Iso-Center (0, 100, & 200mm)

- Kernel Edge Enhancement:
  Air to Delrin Enhancement <= 5%
- 3D Resolution:
  3D PSF Ellipsoid Volume <= 1.5mm^3
- 3D Resolution Aspect:
  PSF Sigma Z/X <= 2.0
- Linearity Bias:
  Air and Acrylic Bias < 35 HU
- Image Noise:
  Acrylic Noise <= 50 HU SD
- 3D Spatial Warping:
  Delrin Cylinder RMSE <= 0.3

~ 90 Phantoms To Be Distributed Globally By January

Alternative Phantoms Can Be Proposed

Small Lung Nodule Volume Assessment and Monitoring in Low Dose CT Screening

Final Profile Review In Progress

Profile Claims

This profile proposes evidence-based consensus standards and processes for measurement of volume and size change in solid lung nodules. Accuracy in measuring nodule size in the low-dose lung screening environment is critical to reducing the rate of false positives and the impact of such findings on work-up cost and patient management.

Overview: The profile addresses accuracy/precision of CT volumetry for solid lung nodules 6-10 mm

Profile Claim 1: For a measured **nodule volume** of Y, and a CV as specified in the table below, the true nodule volume is:

$$Y \pm (1.96 \times Y \times CV), \text{ with 95\% confidence.}$$

Profile Claim 2: A measured **change in nodule volume** of X% indicates that a true change in nodule volume has occurred if:

$$X > (2.77 \times CV1 \times 100), \text{ with 95\% confidence.}$$

To quantify the amount of change, if Y1 and Y2 are the volume measurements at the two time points, and CV1 and CV2 are the corresponding values from the table below, then the 95% confidence interval for the true change is:

$$(Y_2\text{-}Y_1) \pm 1.96 \times \sqrt{([Y_1 \times CV1]^2 + [Y_2 \times CV2]^2)}.$$

Nodule Diameter (mm)	Nodule Volume (mm^3)	Coefficient of Variation (CV)	True Volume 95% CI Limits (mm^3)
6 mm	113	0.29	± 64
7 mm	154	0.23	± 69
8 mm	268	0.19	± 100
9 mm	382	0.16	± 120
10 mm	524	0.14	± 144
11 mm	697	0.12	± 164
12 mm	905	0.11	± 195

All Interested:
Join QIBA, Meet Virtually, Create Consensus Profiles

We acknowledge the contributions of committee participants and RSNA Staff: Joseph Koudelik, Julie Lisiecki, Fiona Miller

Various QIBA projects and activities have been funded in whole or in part with Federal funds from the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Service, under Contracts Nos. HHSN268201000050C, HHSN268201300071C, and HHSN268201500021C.

Proposed Clinical Site Conformance Procedures

Overview

The rate of false positive screening work-ups with low-dose CT screening for lung cancer is significantly reduced if suspicious pulmonary nodules are not evaluated unless they are > 6 mm in diameter. Using volumetric criteria to determine the growth rate of suspicious pulmonary nodules results in even greater efficiency of screening work-up rate. For this reason, precise size characterization of lung nodules is of fundamental importance for high quality lung cancer screening.

Clinical Conformance Steps

1. **CT Scanner and Lung Nodule Analysis Software**
   a) Verify CT scanner model is QIBA approved.
   b) Verify ACR CT accreditation is being followed.
   c) Verify lung nodule analysis software is QIBA approved. (QIBA vendor approvals are pending)
2. **Lung Screening Protocol**
   a) Establish and save a CT Lung Screening Protocol.
   b) CT scan a QIBA lung nodule phantom with the saved Protocol.
   c) Upload phantom DICOM data and obtain a passing Protocol report.
   d) Perform Step 2 Once Per Year and if **Protocol** or CT Scanner changes.
3. **Lung Nodule, Protocol, & Segmentation**
   a) Visually verify that nodule is solid, not attached to structures, has a diameter 6 - 10mm, and that the saved Protocol was used on the same scanner at all time points to be volume measured.
   b) Visually verify artifacts (e.g. motion, streaking) absent and image noise is not excessive.
   c) Visually verify measurement of nodule is free of segmentation issues.
4. **Obtain Volumetric Nodule Measurement Guidance**
   a) Use online QIBA calculator to obtain the latest measurement guidance.

~5 Min CT Phantom Scan Time

Proposed Vendor Conformance Procedures

CT Scanner Vendor

For each CT scanner vendor recommended model and acquisition protocol, a 2^4 full factorial Design Of Experiments (DOE) for the fundamental CT image properties at 3 distances from iso-center will be defined and performed with variation on mAs, field of view, pitch, and iterative recon setting.

Example Recommended Protocol:

mAs	40
kVp	100
Rotation Time (s)	0.50
Filed of View (cm)	35.0
Pitch	1.50
Slice Thickness(mm)	1.00
Slice Spacing (mm)	0.75
Reconstruction Kernel	I40-4
Table Height	Centered

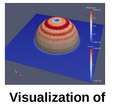
Example Design Of Experiments (DOE):

Exp. #	mAs	FOV	Pitch	Iter.	Notes
A	40	35.0	1.50	I40-4	Repetition 1
01	30	30.0	1.25	I40-3	[-, -. -, -]
02	30	30.0	1.25	I40-5	[-. -, -, +]
03	30	30.0	1.75	I40-3	[-. -, +, -]
04	30	30.0	1.75	I40-5	[-, -, +, +]
05	30	40.0	1.25	I40-3	[-, +, -, -]
06	30	40.0	1.25	I40-5	[-, +, -, +]
07	30	40.0	1.75	I40-3	[-, +, +, -]
08	30	40.0	1.75	I40-5	[-, +, +, +]
B	40	35.0	1.50	I40-4	Repetition 2
09	50	30.0	1.25	I40-3	[+, -. -, -]
10	50	30.0	1.25	I40-5	[+. -, -, +]
11	50	30.0	1.75	I40-3	[+. -, +, -]
12	50	30.0	1.75	I40-5	[+, -, +, +]
13	50	40.0	1.25	I40-3	[+, +, -, -]
14	50	40.0	1.25	I40-5	[+, +, -, +]
15	50	40.0	1.75	I40-3	[+, +, +, -]
16	50	40.0	1.75	I40-5	[+, +, +, +]
C	40	35.0	1.50	I40-4	Repetition 3

Analysis Software Vendor

- Scans of well characterized synthetic and clinical zero change datasets will be provided
- Analysis of measurements will verify that the measurement software has:
  - Near zero volume measurement bias
  - A volume measurement CV that does not exceed the SLN Profile's CV table

Smallest Lesion Shape Supported By The Profile



Visualization of Volumetric Error