QIBA 2018 CT Small Lung Nodule Profile: Overview and Status Update

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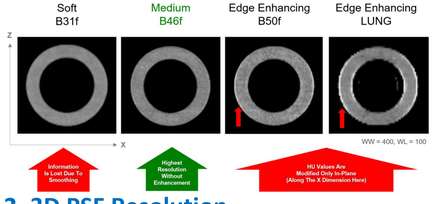
Quantitative Imaging Biomarkers Alliance RSNA

Fundamental CT Image Quality Properties

Introduction

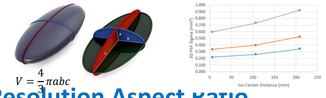
Precise volume measurement of lung nodules down to 6mm requires careful control of fundamental CT image properties throughout a CT scanner's field of view. For this high image contrast measurement task, the following properties must be confirmed at three positions from iso-center for a CT scanner and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

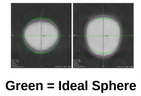
Large biases in HU values for air and water can influence volumetric measurement performance particularly when 3D resolution is poor.

5. Noise

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

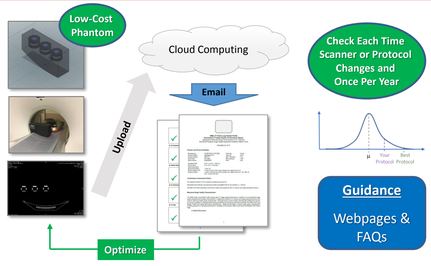
6. 3D Spatial Warping

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

CT Image Quality Conformance



Fundamental CT Image Properties Are Checked at Three Distances From Iso-Center (0, 100, & 160mm)

- 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

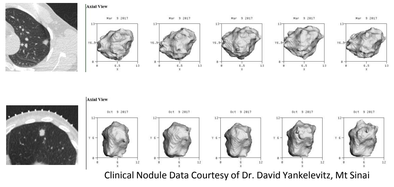
65 Phantoms Have Been Globally Distributed

Alternative Phantoms Can Be Proposed

CT Lung Nodule Analysis Software Conformance

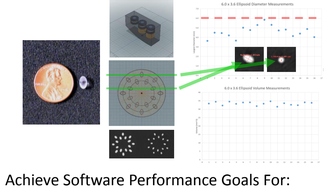
Submit Volume Measurements For:

1. Clinical Zero-Change Nodules (n=45 cases)



Clinical Nodule Data Courtesy of Dr. David Yankelevitz, Mt Sinai

2. Synthetic Acrylic Ellipsoids (n=80 ellipsoids)



Axial Diameter
Mean: 4.60 mm
SD: 0.61 mm
CV: 13%

Volume
Mean: 33.33 mm
SD: 0.98 mm
CV: 3%

Achieve Software Performance Goals For:

- Bias (<= 5%)
- Coefficient of Variation
- Measurement Linearity & Slope

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)	Minimum Detectable Difference (from Claim 2a)
6 mm	113	0.29	± 64	80.3%
7 mm	154	0.23	± 69	63.7%
8 mm	268	0.19	± 100	52.6%
9 mm	382	0.16	± 120	44.3%
10 mm	524	0.14	± 144	38.8%
11 mm	697	0.12	± 164	33.2%
12 mm	905	0.11	± 195	30.5%

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

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Clinical Site Conformance Procedure

14 Steps To Conformance

QIBA Conformance Certification Mark

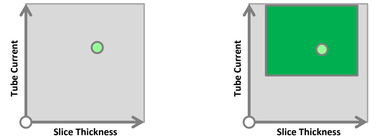
Step	Description	Actor	Conforms
	Preparing For Lung Nodule Measurement		
1.0	**CT Scanner and Lung Nodule Analysis Software Verification** For each analysis software application to be used for lung cancer screening nodule measurement:		
1.1	Verify that the CT scanner manufacturer and model name is on this QIBA verified list available in the Conformance Section of the QIBA Small Lung Nodule Profile Wiki page.	Radiologist	☐ Yes ☐ No
1.2	Verify that the software name, including version number, is on this QIBA verified list available in the Conformance Section of the QIBA Small Lung Nodule Profile Wiki page.	Radiologist	☐ Yes ☐ No
2.0	**CT QA and Lung Screening Protocol Verification** For each CT scanner to be used for lung cancer screening nodule measurement:		
2.1	Verify that the CT scanner is FDA approved and consistently following ACR CT accreditation and manufacturer installation and maintenance requirements.	Medical Physicist	☐ Yes ☐ No
2.2	Establish a CT lung cancer screening protocol and save it on the CT scanner. Sites may use their existing lung screening protocol or pick a protocol from a continuously updated list provided by QIBA in the Conformance Section of the QIBA Small Lung Nodule Profile Wiki page.	Radiologist and Technologist	☐ Yes ☐ No
2.3	CT scan a QIBA CT reference object with the saved CT lung screening protocol.	Technologist	☐ Yes ☐ No
2.4	Submit the CT reference object scan to the site listed in the Conformance Section of the QIBA Small Lung Nodule Profile Wiki page and obtain a passing automated image quality report. If the site does not receive a passing CT image quality report, repeat steps 2.1 to 2.4 until a passing report is obtained.	Radiologist or Technologist or Medical Physicist	☐ Yes ☐ No
3.0	**CT Nodule Analysis Software Verification** For each CT nodule analysis software system to be used for lung cancer screening nodule measurement:		
3.1	Verify that the CT nodule analysis software is FDA approved.	Radiologist or Image Analyst	☐ Yes ☐ No
3.2	Download the clinical site conformance verification data zip file and nodule measurement spreadsheet from the Conformance Section of the QIBA Small Lung Nodule Profile Wiki page (which contains five pairs of nodule scans). Perform nodule volume measurements and for all of the nodules listed. Email the nodule volume measurement spreadsheet to the email listed in the Conformance Section of the QIBA Small Lung Nodule Profile Wiki page and obtain a passing nodule volume measurement software report.	Radiologist or Image Analyst	☐ Yes ☐ No
	Performing Lung Nodule Measurement		
4.0	**CT Data Acquisition, Lung Nodule, and Segmentation Verification** For each CT lung cancer screening and solid lung nodule follow-up CT scan:		
4.1	If performing the measurement of volume change, verify that the same CT scanner and image acquisition protocol was used at both time points.	Radiologist	☐ Yes ☐ No
4.2	Verify that the patient did not receive IV contrast as part of the CT study.	Radiologist	☐ Yes ☐ No
4.3	Visually verify that the nodule to be measured is solid, has a largest diameter between 6mm and 10mm, has <= 1/3 of its surface area attached to structures with similar attenuation, and that the saved and verified CT lung nodule acquisition protocol was used at all nodule scanning time points.	Radiologist	☐ Yes ☐ No
4.4	Visually verify that significant artifacts (e.g. motion, streaking) are not present and that image noise is not excessive at the location of the solid nodule to be measured.	Radiologist	☐ Yes ☐ No
4.5	Visually verify that the measurement of the solid nodule is free of segmentation errors.	Radiologist	☐ Yes ☐ No
5.0	**Obtain Volumetric Nodule Measurement Guidance** For each series of CT lung nodule measurements consisting of one or more time points:		
5.1	Use a QIBA small lung nodule Profile on-line calculator listed in the Conformance Section of the QIBA Small Lung Nodule Profile Wiki page for guidance on levels of volumetric measurement error for each lung nodule measurement and change measurement.	Radiologist	☐ Yes ☐ No

Scanner & Software Vendor Conformance Procedures

CT Scanner Vendor

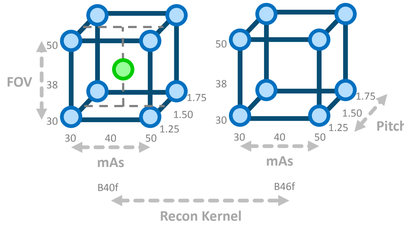
Problem: Clinical sites start with a vendor provided CT imaging protocol and then in practice adjust to radiologist preferences and individual patients.

Solution: Have CT vendors verify that image quality performance remains acceptable over a range of commonly varying acquisition parameters. Parameters include FOV, mAs, kVp, slice thickness, reconstruction kernel, and pitch



Single Operating Point **Wider Operating Envelope**

Design of Experiments



The Extent of this DOE Defines a Safe "Operating Envelope" that a Clinical Site Can Use When Acquiring CT Images For Small Lung Nodule Volume Measurements

Nodule Analysis Software Vendor

- CT scans of well characterized synthetic (80) and clinical zero-change (45) nodules will be provided
- Analysis of volume measurements will verify that the nodule measurement software has the required:
  - Volume measurement bias
  - Volume measurement CV
  - Volume measurement linearity and slope