QIBA Profile Conformance

Self - Attestation Document

QIBA Profile title	CT Tumor Volume Change for Advanced Disease (CTV-AD)
QIBA Profile version	June 22, 2018
Company/Institution doing self-attestation	
Company/Institution responsible person	
Date Self-Attestation was submitted to QIBA	
Date Self-Attestation was reviewed by QIBA	
Date Conformance was registered by QIBA	

Some checklist items reference a required Assessment Procedure which may be found in the Profile Document.

Some checklist items have clarifications, rationale, or guidance in the corresponding Discussion section in the Profile Document.

To obtain a copy of the Profile Document, visit http://qibawiki.rsna.org/index.php/Profiles

If a QIBA Conformance Statement is already available for an actor (e.g. your acquisition device), a site may choose to provide a copy of that statement rather than confirming each of the requirements in that Actors checklist yourself.

Vendors publishing a QIBA Conformance Statement shall provide a set of "Model-specific Parameters" (as shown in Annex A) describing how their product was configured to achieve conformance. Vendors shall also provide access or describe the characteristics of the test set used for conformance testing.

QIBA Conformance Statements

QIBA Conformance Statements are documents prepared and published by vendors or sites to describe the intended conformance of their products, staff or institution to one or more QIBA Profiles.

Conformance requirements are defined in the QIBA Profile document for each Actor in the Profile. For some requirements, the Profile document also defines assessment procedures.

This conformance statement contains all relevant checklists for all relevant actors for site or product conformance. Supporting material is available on the QIBA wiki conformance section for the respective profile. Checklists in this conformance statement document need to be filled out.

Users can use Conformance Statements to determine whether their staff and products can be expected to deliver the biomarker performance described in the Profile Claim. Achieving the performance claim depends on all Actors described in the Profile being present at the site and conforming to the requirements.

A QIBA Conformance Statement is not intended to promote or advertise aspects of a product or site not directly related to its implementation of QIBA capabilities.

IMPORTANT NOTE: Vendors and sites are solely responsible for the accuracy and validity of their QIBA Conformance Statements. QIBA and its sponsoring organizations have not evaluated or approved any QIBA Conformance Statement or any related product, site or staff, and QIBA and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any QIBA Conformance Statement.

QIBA Conformance Statement for a Product

QIBA Conformance Statement			
Vendor	**Product Name**	**Version**	**Date**
Any Medical Systems Co.	AlphaScanner	V2.3, V2.4, V3.0	2019-03-12
This product conforms to all specifications required for the QIBA Profiles and Actors listed below:			

Profiles Implemented	Actors Implemented	Notes
CT Tumor Volume Change for Advanced Disease (CTV-AD) (2018)	Acquisition Device	See A.1
	Reconstruction Software	See A.2

Links to Additional Information	
Submitter's QIBA information:	www.anymedicalsystemsco.com/qiba
General information on QIBA:	qibawiki.rsna.org

Annex A: Conformance Notes

A.1 CT Volume Change (2018) – Acquisition Device

Model-specific Instructions and Parameters

The following parameter values were used when demonstrating conformance and are provided for reference. Other values may also achieve conformance.

Acquisition Activity Parameters

kVp	120
Number of Data Channels (N)	64
Width of Each Data Channel (T, in mm)	
Gantry Rotation Time in seconds	
mA	
Pitch	
Scan FoV	

SCANNER AND RECONSTRUCTION SOFTWARE CHECKLIST

Scanner(s) Checked - Make/Model/Version :

Parameter	Conforms (Y/N)	Requirement
Product Validation (section 3.2)		
Acquisition Protocol		Shall be capable of making validated protocols (designed and validated by the manufacturer and/or by the site) available to the technologist at scan time.
		Shall prepare a protocol conformant with section 3.5.2 "Protocol Design Specification".
		Shall validate that the protocol achieves an f50 value that is between 0.3 mm^{-1} and 0.5 mm^{-1} for both air and soft tissue edges. See 4.1. Assessment Procedure: In-plane Spatial Resolution
		Shall validate that the protocol achieves a standard deviation < 60HU. See 4.2. Assessment Procedure: Voxel Noise
Reconstruction Protocol		Shall be capable of performing reconstructions and producing images with parameters set as specified in 3.5.2 "Protocol Design Specification".

IMAGE ANALYSIS TOOL CHECKLIST

Image Analysis Tool(s) Checked - Make/Model/Version :

Parameter	Conforms (Y/N)	Requirement
Product Validation (section 3.2)		
Multiple Tumors		Shall allow multiple tumors to be measured.
Multiple Tumors		Shall either correlate each measured tumor across time points or support the radiologist to unambiguously correlate them.
Reading Paradigm		Shall be able to present the reader with both timepoints side-by-side for comparison when processing the second timepoint.
Reading Paradigm		Shall be able to re-process the first time point (e.g. if it was processed by a different Image Analysis Tool or Radiologist).
Tumor Volume Computation		Shall be validated to compute volume within 5% of the true volume. See 4.3 Assessment Procedure: Tumor Volume Computation.
Tumor Volume Repeatability		Shall be validated to achieve tumor volume repeatability with: • an overall repeatability coefficient of less than 0.16 • a small subgroup repeatability coefficient of less than 0.21 • a large subgroup repeatability coefficient of less than 0.21 See 4.4. Assessment Procedure: Tumor Volume Repeatability.
Tumor Volume Bias & Linearity		Shall be validated to achieve: • an overall tumor volume %bias of less than the Allowable Overall %Bias • a tumor volume %bias for each shape subgroup (spherical, ovoid, lobulated) of less than the Allowable Shape Subgroup %Bias • slope ($\hat{\beta}_1$) between 0.98 and 1.02 • quadratic-term ($\hat{\beta}_2$) between -0.05 and 0.05 The Allowable Overall %Bias and the Allowable Shape Subgroup %Bias are taken from Table 3.2.2-1 based on the overall repeatability coefficient achieved by the Image Analysis Tool using the assessment procedure in section 4.4. See 4.5 Assessment Procedure: Tumor Volume Bias & Linearity.
Confidence Interval of Result		Is encouraged to calculate and make available to the operator the 95% confidence interval for tumor volume change based on the equation: $(Y_2 - Y_1) \pm 1.96 \times \sqrt{(Y_1 \times wCV_1)^2 + (Y_2 \times wCV_2)^2}$ Where Y_1 and Y_2 is the volume measured at timepoint 1 and 2,

Parameter	Conforms (Y/N)	Requirement
		wCV_1 and wCV_2 is the within-nodule coefficient of variation for Y_1 and Y_2 as taken from the following table, D_1 and D_2 is the longest in-plane diameter of the volume at timepoint 1 and 2:

D_1, D_2	10-34mm	35-49mm	50-100mm
wCV_1, wCV_2	0.141	0.103	0.085

Table 3.2.2-1:
Allowable Tumor Volume %Bias based on Overall Repeatability Coefficient

Overall Repeatability Coefficient $\widehat{RC}$	Allowable Overall %Bias (RMSE Target: 7.1%)	Allowable Shape Subgroup %Bias (RMSE Target: 7.8%)
0.05	6.60%	7.32%
0.06	6.37%	7.11%
0.07	6.09%	6.86%
0.08	5.75%	6.56%
0.09	5.35%	6.20%
0.10	4.88%	5.79%
0.11	4.30%	5.31%
0.12	3.59%	4.75%
0.13	2.63%	4.06%
0.14	0.84%	3.17%
0.15	0.00%	1.84%
0.155	0.00%	0.00%
0.16	n/a (failed repeatability)	n/a (failed repeatability)

F.3 Format of a QIBA Conformance Statement for a Site

Each Conformance Statement shall follow the format shown in the following table.

The submitter may add a cover page and information required by their documentation policies.

QIBA Conformance Statement		
Site Name	**Responsible Person**	**Date**
Mercy General Hospital – Oncology Dept.	Dr. Marcus Welby	2019-03-12
This site conforms to all specifications required for the QIBA Profiles and Actors listed below:		
Profiles Implemented	**Actors Implemented**	**Notes**
CT Volume Change (2018)	Technologist	See A.1
	Radiologist	See A.2
	Physicist	See A.3
	Site	See A.4
Links to Additional Information		
Submitter's QIBA information: www.anymedicalsystemsco.com/qiba		
General information on QIBA: qibawiki.rsna.org		

Annex A: Conformance Notes

<The following text is example text. Revise as to reflect how your site achieved conformance.>

A.1 CT Volume Change (2018) – Technologist

Technologists assigned to use this scanner (Site maintains up-to-date lists of conformant technologists) received training that included details of this Profile. Periodic spot checks confirm they continue to follow the profile details.

A.2 CT Volume Change (2018) – Radiologist

Chest radiologists on staff ((Site maintains up-to-date lists of conformant radiologists) have

- Reviewed the quality assurance guidelines described in section 3.4 of the profile
- Completed the performance assessment described in section 4.4 of the profile and met or exceeded the target in section 3.5 of the profile

A.3 CT Volume Change (2018) – Physicist

The Physicist requirements are completed and logged by a contract physicist on a semi-annual basis.

A.4 CT Volume Change (2018) - Site

Conformance was confirmed for the following list of rooms/devices:

- Acme CT Scanner, Model: Exelsior, Version: 3.5

SITE CHECKLIST

Site Checked:

Parameter	Conforms (Y/N)	Requirement
Site Conformance (section 3.1)		
Scanners		Shall confirm all participating scanners conform to this Profile.
Reconstruction Software		Shall confirm all participating reconstruction software conforms to this Profile.
Image Analysis Tools		Shall confirm all participating image analysis tools conform to this Profile.
Radiologists		Shall confirm all participating radiologists conform to this Profile.
Physicists		Shall confirm all participating physicists conform to this Profile.
Technologists		Shall confirm all participating technologists conform to this Profile.

PHYSICIST CHECKLIST

Note: The role of the Physicist actor may be played by an in-house medical physicist, a physics consultant or other staff (such as vendor service or specialists) qualified to perform the validations described.

Physicist(s) Checked:

Parameter	Conforms (Y/N)	Requirement
Periodic QA (section 3.4)		
QC		Shall perform relevant quality control procedures as recommended by the manufacturer.
QC		Shall record the date/time of QC procedures for auditing.
Protocol Design (section 3.5)		
In-plane Spatial Resolution		Shall validate that the protocol achieves an f50 value between 0.3 mm^{-1} and 0.5 mm^{-1} for both air and soft tissue edges. See 4.1. Assessment Procedure: In-plane Spatial Resolution
Voxel Noise		Shall validate that the protocol achieves a standard deviation < 60HU. See 4.2. Assessment Procedure: Voxel Noise

RADIOLOGIST CHECKLIST

Note: The Radiologist is responsible for the protocol parameters, although they may choose to use a protocol provided by the vendor of the scanner. The Radiologist is also responsible for ensuring that the protocol has been validated, although the Physicist actor is responsible for performing the validation. Protocol design should be done collaboratively between the physicist and the radiologist with the ultimate responsibility to the radiologist. Some parameters are system dependent and may require special attention from a physicist.

Radiologist(s) Checked:

Parameter	Conforms (Y/N)	Specification	
Staff Qualification (section 3.3)			
Tumor Volume Computation Repeatability		Shall, if operator interaction is required by the Image Analysis Tool to perform measurements, be validated to achieve tumor volume change repeatability with: • an overall repeatability coefficient of less than 0.16 • a small subgroup repeatability coefficient of less than 0.21 • a large subgroup repeatability coefficient of less than 0.21 See 4.4. Assessment Procedure: Tumor Volume Change Repeatability.	
Protocol Design (section 3.5)			
Acquisition Protocol		Shall prepare a protocol to meet the specifications in this table.	
Acquisition Protocol		Shall ensure technologists have been trained on the requirements of this Profile.	
Total Collimation Width		Shall set to Greater than or equal to 16mm.	Total Collimation Width (0018,9307)
IEC Pitch		Shall set to Less than 1.5.	Spiral Pitch Factor (0018,9311)
Nominal Tomographic Section Thickness (T)		Shall set to Less than or equal to 1.5mm.	Single Collimation Width (0018,9306)
Scan Duration for Thorax		Shall achieve a table speed of at least 4cm per second, if table motion is necessary to cover the required anatomy.	Table Speed (0018,9309)
Reconstruction Protocol		Shall prepare a protocol to meet the specifications in this table.	

Parameter	Conforms (Y/N)	Specification	
Reconstruction Protocol		Shall ensure technologists have been trained on the requirements of this Profile.	
Reconstructed Image Thickness		Shall set to between 0.5mm and 2.5mm (inclusive).	Slice Thickness (0018,0050)
Reconstructed Image Interval		Shall set to less than or equal to the Reconstructed Image Thickness (i.e. no gap, may have overlap).	Spacing Between Slices (0018,0088)
Subject Handling (section 3.6)			
Contrast Protocol		Shall prescribe a contrast protocol (which may be No Contrast) that achieves enhancement consistent with baseline.	
Use of intravenous contrast		Shall determine whether the selected contrast protocol, if any, will achieve sufficient tumor conspicuity.	
Use of oral contrast		Shall determine whether the selected contrast protocol, if any, will achieve sufficient tumor conspicuity.	
Image QA (section 3.9)			
Patient Motion Artifacts		Shall confirm the images containing the tumor are free from artifact due to patient motion.	
Dense Object Artifacts		Shall confirm the images containing the tumor are free from artifact due to dense objects, materials or anatomic positioning.	
Clinical Conditions		Shall confirm that there are no clinical conditions affecting the measurability of the tumor.	
Tumor Size		Shall confirm (now or during measurement) that tumor longest in-plane diameter is between 10 mm and 100 mm. (For a spherical tumor this would roughly correspond to a volume between 0.5 cm^3 and 524 cm^3.)	
Tumor Margin Conspicuity		Shall confirm the tumor margins are sufficiently conspicuous and unattached to other structures of equal density to distinguish the volume of the tumor.	
Contrast Enhancement		Shall confirm that the phase of enhancement, if any, and degree of enhancement are consistent with baseline.	
Patient Positioning Consistency		Shall confirm that any tumor deformation due to patient positioning is consistent with baseline (e.g. tumors may deform differently if the patient is supine in one scan and prone in another).	
Breath Hold Consistency		Shall confirm that the breath hold state and degree of inspiration is consistent with baseline.	
Scan Plane Consistency		Shall confirm that the anatomical slice orientation (due to gantry tilt or patient head/neck repositioning) is consistent with baseline.	

Parameter	Conforms (Y/N)	Specification
Reconstructed Image Thickness		Shall confirm that the reconstructed image thickness is between 0.5mm and 2.5mm, and consistent with baseline (e.g. within 0.5mm).
Field of View		Shall confirm that the image field of view (FOV) resulting from acquisition and reconstruction settings appears consistent with baseline.
Tumor Measurability		Shall disqualify any tumor they feel might reasonably degrade the consistency and accuracy of the measurement. Conversely, if artifacts or attachments are present but the radiologist is confident and prepared to edit the contour to eliminate the impact, then the tumor need not be judged non-conformant to the Profile.
Image Analysis (section 3.10)		
Reading Paradigm		Shall re-process the first time point if it was processed by a different Image Analysis Tool or Radiologist.
Result Verification		Shall review & approve margin contours produced by the tool.

TECHNOLOGIST CHECKLIST

Technologist(s) Checked:

Parameter	Conforms (Y/N)	Specification
Subject Handling (section 3.6)		
Use of intravenous contrast		Shall use the prescribed intravenous contrast parameters.
Use of oral contrast		Shall use the prescribed oral contrast parameters.
Artifact Sources		Shall remove or position potential sources of artifacts (specifically including breast shields, metal-containing clothing, EKG leads and other metal equipment) such that they will not degrade the reconstructed CT volumes.
Table Height & Centering		Shall adjust the table height for the mid-axillary plane to pass through the isocenter.
Table Height & Centering		Shall position the patient such that the “sagittal laser line” lies along the sternum (e.g. from the suprasternal notch to the xiphoid process).
Breath hold		Shall instruct the subject in proper breath-hold and start image acquisition shortly after full inspiration, taking into account the lag time between full inspiration and diaphragmatic relaxation.
Image Data Acquisition (section 3.7)		
Acquisition Protocol		Shall select a protocol that has been previously prepared and validated for this purpose (See 3.5.2 "Protocol Design Specification").
Localizer		Shall confirm on the localizer (scout) image the absence of artifact sources that could affect the planned volume acquisitions or alter the attenuation of lung nodules.
Scan Duration for Thorax		Shall achieve a Table Speed (0018,9309) of at least 4cm per second, if table motion is necessary to cover the required anatomy.
Image Data Reconstruction (section 3.8)		
Reconstruction Protocol		Shall select a protocol that has been previously prepared and validated for this purpose (See section 3.5.2 "Protocol Design Specification").
Reconstructed Image Thickness		Shall set to between 0.5mm and 2.5mm (inclusive) if not set in the protocol.
Reconstructed Image Interval		Shall set to less than or equal to the Reconstructed Image Thickness (i.e. no gap, may have overlap) and consistent with baseline.
Reconstruction Field of View		Shall ensure the Reconstruction Field of View (0018,9317) spans at least the full extent of the thoracic and abdominal cavity, but not substantially greater than that.