Panel Members

- Brian Garra, MD, QIBA Ultrasound Washington VAMC/FDA
- Alexander Guimaraes, MD, PhD, QIBA MR Oregon Health & Science University
- Michael McNitt-Gray, PhD, QIBA CT UCLA
- David Mozley, MD, QIBA SPECT Endocyte, Inc.
- Anne Smith, PhD, QIBA PET Siemens Medical Solutions, USA
QIBA Conformance Statement

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Product Name</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Medical Systems Co.</td>
<td>AlphaScanner</td>
<td>V2.3, V2.4, V3.0</td>
<td>2017-03-12</td>
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</tbody>
</table>

This product conforms to all specifications required for the QIBA Profiles and Actors listed below:

<table>
<thead>
<tr>
<th>Profiles Implemented</th>
<th>Actors Implemented</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT Volume Change (2014)</td>
<td>Acquisition Device</td>
<td>See A.1</td>
</tr>
<tr>
<td></td>
<td>Reconstruction Software</td>
<td>See A.2</td>
</tr>
<tr>
<td>CT Volume Change (2017)</td>
<td>Acquisition Device</td>
<td>See A.3</td>
</tr>
</tbody>
</table>

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 (2014) – 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.
QIBA Conformance Statement

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Responsible Person</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercy General Hospital – Oncology Dept.</td>
<td>Dr. Marcus Welby.</td>
<td>2012-03-12</td>
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</table>

This site conforms to all specifications required for the QIBA Profiles and Actors listed below:

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<thead>
<tr>
<th>Profiles Implemented</th>
<th>Actors Implemented</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT Volume Change (2014)</td>
<td>Technologist</td>
<td>See A.1</td>
</tr>
<tr>
<td></td>
<td>Radiologist</td>
<td>See A.2</td>
</tr>
<tr>
<td></td>
<td>Site</td>
<td>See A.3</td>
</tr>
</tbody>
</table>

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Annex A: Conformance Notes

A.1 CT Volume Change (2014) – Technologist

All technologists assigned to use this scanner received training that included details of this Profile. Periodic spot checks confirm they continue to follow the profile details.

A.2 CT Volume Change (2014) – Radiologist

All chest radiologists on staff 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
Assessment Scope

- Claim
  - Test Full Chain
  - Test Partial Chain
  - Test Individual Activities

- Result
  - Activity #1
  - Activity #2
  - Activity #3
  - Activity #4
  - Activity #5

Result
## Assessment Patterns

<table>
<thead>
<tr>
<th></th>
<th>Self-Claim</th>
<th>Community</th>
<th>Formal Cert.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unit of Conformity</strong></td>
<td>Profile/Actor</td>
<td>Profile/Actor</td>
<td>Profile/Actor (Site?)</td>
</tr>
<tr>
<td><strong>Test Plan</strong></td>
<td>Standard Methods</td>
<td>Common Tools</td>
<td>Managed method &amp; tools</td>
</tr>
<tr>
<td><strong>Testing</strong></td>
<td>Vendor Testing</td>
<td>Test Events</td>
<td>Accredited Test Labs</td>
</tr>
<tr>
<td><strong>Certification</strong></td>
<td>Vendor Claim</td>
<td>Corroborated Claim</td>
<td>Accredited Certification Bodies</td>
</tr>
<tr>
<td><strong>Surveillance</strong></td>
<td>User reports non-conformity</td>
<td>Community Tracking</td>
<td>Formal Auditing</td>
</tr>
<tr>
<td><strong>Penalties</strong></td>
<td></td>
<td></td>
<td>Formal Penalties</td>
</tr>
<tr>
<td><strong>Remediation</strong></td>
<td>Next Release</td>
<td>Vendor Patch</td>
<td>Tracked Resolution</td>
</tr>
</tbody>
</table>

Also consider Periodic Assessment Vs Audit/Just-in-Time/Continuous Assessment
Scope Limbo: How low do we go?

Select Profile Candidate
Coordinate Groundwork
Perform Groundwork
Draft Profile Text
Publish Profile
Tech/Clinically Confirm Profile
Develop phantoms
Develop test plans
Develop test tools
Conduct Connectathons
Issue Product Certificates
Accredit Sites
Conduct Surveillance
Impose Penalties

...
Questions

• Who cares that a site/person/device is conformant with a QIBA Profile?

• What task(s) or decision(s) will conformance affect

• How will it affect those tasks?
  – Remove cost? Increase confidence? Allow usage of the biomarker? Change clinical decisions?

• What should a conformance statement state to support those tasks?

• Who should claim conformance?
  – Vendors? Radiologists? Sites?

• Who should test conformance?
  – Sites? Vendors? Regulators?

• How much testing and certification cost is acceptable/appropriate

• How can such costs be minimized while still delivering the value