Ultrasound QA/QC Workshop
Shear Wave Elastography and
Pulse-Echo Quantitative Ultrasound Evaluation

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Member of the AAPM Ultrasound and Imaging Metrology and Standards Subcommittees

2021 Annual meeting of the American Association of Physicists in Medicine

July 28th, 2021, 10:30-11:30 ET
Quantitative Imaging Biomarker

Structural or functional characteristic from tissue measured objectively and derived from an in vivo image as an indicator of a normal biological or pathogenic process or the response to a therapeutic intervention

**Technical Performance**

(Bias, linearity, precision)

**Clinical Performance**

Correlation with the biological/pathogenic process or therapeutic response

“Need to define common standards and a cross-disciplinary, systems-based approach to assess performance”

MISSION: Improve the value and practicality of QIBs by reducing variability across devices, patients, and time

The QIBA process

QIBA Profiles: Documents designed by biomarkers committees providing guidelines to standardize biomarker quantification that meet performance claims of bias, linearity, and precision.
QIBA Ultrasound Biomarker Committees

- Shear wave speed (Stage 1)
- Contrast-enhanced ultrasound (Stage 0)
- Volume blood flow (Stage 0)
- Pulse-echo quantitative ultrasound (PEQUUS) (Stage 0)
Shear wave elastography

- Ultrasound based technique used to quantify non-invasively the elasticity (i.e., stiffness) of tissue
- Shear (transverse) waves are induced remotely by acoustic radiation force fields created by long, intense ultrasound (compressional) pulses
- The shear wave speed (SWS) is used as a surrogate of tissue elasticity

\[ SWS = \sqrt{\frac{G}{\rho}} \]

- \( G \) = Shear modulus (kPa)
- \( \rho \) = mass density (kg/m\(^3\))

Assuming an isotropic, homogeneous, purely elastic solid
QIBA SWS Profile

**STATUS: STAGE 1 - PUBLIC COMMENT**

**Goal:** Standardization of SWS quantification as a biomarker for liver fibrosis

**Activities for profile implementation**
1. Staff Qualification
2. Product validation
3. Pre-delivery
4. **Installation**
5. **Periodic QA**
6. Protocol Design
7. Subject selection
8. Subject handling
9. SWS acquisition
10. Imaging QA

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**QIBA SWS Biomarker Committee, Profile: Ultrasound Measurement of Shear Wave Speed for Estimation of Liver Fibrosis, Version 3-15-21**

**Execution and conformance checklists**

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## Installation (Acceptance testing)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Actor</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware damage</td>
<td>Manufacturer / clinical staff</td>
<td>No physical damage</td>
</tr>
<tr>
<td>Software verification</td>
<td>QA Manager</td>
<td>Shall confirm the software version equals the version specified in the QIBA Conformance Statement or one listed in Appendix D of profile</td>
</tr>
<tr>
<td>SWS measurement bias</td>
<td>QA Manager</td>
<td>Shall confirm that SWS measurement bias is within ±5%</td>
</tr>
</tbody>
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QIBA SWS Biomarker Committee, Profile: Ultrasound Measurement of Shear Wave Speed for Estimation of Liver Fibrosis, Version 3-15-21
# Periodic QA

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Actor</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>US Imaging QA</td>
<td>QA Manager</td>
<td>Shall perform standard ultrasound system QA on the ultrasound scanner as specified by AIUM guidelines*</td>
</tr>
<tr>
<td>SWS Measurement bias and System QA testing using SWS phantom</td>
<td>QA Manager</td>
<td>Shall confirm that bias of measurements of SWS on a QIBA elastic phantom using standard instrument settings and acquisition procedures annually, and after any software change, is within ±5% of the expected values in phantoms</td>
</tr>
<tr>
<td>US Imaging and SWS phantom characterization and stability testing</td>
<td>QA Manager</td>
<td>Test for changes in acoustic and elastic properties of phantom, return to manufacturer for reconditioning (or replace) if a weight change of &gt;0.5% has occurred</td>
</tr>
</tbody>
</table>

*AIUM Quality Assurance Manual for Gray Scale Ultrasound Scanners,*

QIBA SWS Biomarker Committee, Profile: Ultrasound Measurement of Shear Wave Speed for Estimation of Liver Fibrosis, Version 3-15-21
Homogeneous phantoms calibrated following protocol for Verasonics research scanner

The QA manager should arrange for independent verification of phantom characteristics (tolerances provided in the profile)

Phantoms should be re-weighted every six months; if change larger than 0.5% is observed, phantom should be retested

SWS measurements must be done at the temperature recommended by phantom manufacturer

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Ultrasound Imaging Phantom</th>
<th>Shear wave speed phantoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attenuation (dB/cm/MHz)</td>
<td>0.5±0.1</td>
<td></td>
</tr>
<tr>
<td>Backscatter @ 3MHz (cm⁻¹ sr⁻¹)</td>
<td>10⁻⁴ – 10⁻³</td>
<td></td>
</tr>
<tr>
<td>Speed of sound (m/s)</td>
<td>1540±30</td>
<td>1520-1540</td>
</tr>
<tr>
<td>Shape</td>
<td>Cylindrical or rectangular</td>
<td>Cylindrical</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>15±3</td>
<td>20</td>
</tr>
<tr>
<td>Diameter (cm)</td>
<td>12.5±3</td>
<td>12.5</td>
</tr>
<tr>
<td>Stiffness</td>
<td>N/A</td>
<td>Normal Liver (0.9-1.2m/s) and F3 fibrotic liver</td>
</tr>
</tbody>
</table>
QIBA Ultrasound Biomarker Committees

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- Volume blood flow (Stage 0)
- Pulse-echo quantitative ultrasound (PEQUS) (Stage 0)

Quantitative Ultrasound
AIUM/QIBA PEQUS Biomarker Committee

• **Mission:** Reach consensus on how to measure and report pulse-echo quantitative ultrasound (PEQUS) features among manufacturers and under equivalent conditions in the context of assessing liver steatosis.

• Motivated by the interest and/or introduction of commercial implementation of PEQUS biomarkers for liver steatosis (fat infiltration) including:
  - ✔ Attenuation (fractional loss of ultrasound intensity per unit length)
  - ✔ Sound speed (propagation speed of ultrasound waves)
  - ✔ Backscatter (fraction of ultrasound intensity scattered back to the transducer)

• **Status:** *Stage 0 (Est. March 2020, working towards profile)*
AIUM/QIBA PEQUS Timeline

**SPECIFIC AIM 1**
First draft of profile based on evidence from literature

**SPECIFIC AIM 2**
Phantom characteristics for multisite study

**SPECIFIC AIM 3**
Multisite study to refine claims of bias, variance, inter- and intra-observer variability, and confounders

**SPECIFIC AIM 4**
Discussion of version 1 of profile

June 2020 – August 2021
August 2021 – August 2022
August – November 2022
Take home messages

1) Quantitative imaging biomarkers are quantitative features extracted from medical images that are surrogates of structural/functional characteristics of tissue

2) The RSNA QIBA, in collaboration with other organizations such as the AIUM, works towards standardizing their implementation and validation

3) The QIBA Shear Wave Speed biomarker committee has released its profile for public comment, which includes specific QA tasks for acceptance and periodic testing

4) The AIUM/QIBA Pulse-Echo Quantitative Ultrasound (PEQUS) Biomarker Committee is working on the profile to standardize the quantification of acoustic attenuation, sound speed, and backscatter as biomarkers for liver steatosis
Acknowledgments

The PEQUS biomarker committee is supported by

Co-chairs of AIUM/QIBA PEQUS Biomarker Committee

Anthony Samir, MD
Massachusetts General Hospital

Michael Wang, PhD
General Electric

Members of AIUM/QIBA PEQUS Attenuation, Sound Speed, Backscatter and Phantom Working groups
Thank you for your attention

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