Title: QIBA SWS Measurement System Procedure

Revision Data

Rev	Change Description	Printed Name
01	Initial version	Andy Milkowski
02	Reduced number of depths, added TI, MI, etc to data table and clarified transducer repositioning procedure.	Andy Milkowski

List of Tables

1 Introduction

1.1 Purpose

This document describes a RSNA QIBA procedure for assessing the variation and bias of Shear Wave Speed measurements across manufacturers on lossless phantoms.

1.2 Scope

This document procedure is applicable to ultrasound shear wave speed measurements data recording and analysis. This procedure is platform-independent.

The intended audience of this document is the team members responsible for capturing and analyzing shear wave speed data for QIBA.

1.3 Definitions, Acronyms, and Abbreviations

Acronym or Abbreviation	Definition
DICOM	Digital Imaging and Communications in Medicine
FOV	Field-of-view
ROI	Region-of-interest
SWS	Shear Wave Speed

2 Verification Environment

The following items are required for performing the Verification:

- Appraiser receives training on the use and operation of the ultrasound system and shear wave speed measurement. This training shall at least include the use of transducer and gel application, measurement and operation on elasticity phantoms, and operating the shear wave speed measurement.
- Confirm Ultrasound system running latest software build and with a license to run SWS.
    - Prepare any additional configuration or scripts necessary to collect data
- Identify transducers and prepare data collection sheets for each
- Identify custom QIBA elasticity phantoms and associated calibration information.

3 Verification Procedure

3.1 Verification Preparation

The following section outlines the procedure for preparing the accuracy validation:

1. Initiate data collection by filling out the appropriate section of the Report Form.
2. Initialize the system, such as starting with a ‘new patient’ using phantom ID as patient ID and using experiment conducting site as institution/user ID, and initiating SWS feature.

3.2 Verification Execution

1. Appraiser holds the transducer on the face of the phantom with the appropriate gel and initiates a measurement as necessary on a system.
2. Appraiser 1 initiates a shear wave speed measurement at the first depth, i.e. 2cm. Record measurements by saving image or writing result.
3. Initiate any other data collection if required by the manufacture (such as RF data dumps).
4. Without moving (do not lift the transducer), shear wave speed measurements are repeated 4 additional times, for a total of 5 shear wave speed measurements at a given depth.
5. Appraiser lifts and repositions transducer. Appraiser moves to next depth (i.e. 5cm) and measures 5 shear wave speed collections and (optionally) associated data.
6. Appraiser 1 repeats for remaining depth (8cm). This completes “Trial#1” section of the data collection.
7. Appraiser 2 takes turn to repeat 2 to 6.
8. Appraiser 3 takes turn to repeat 2 to 6.
9. Appraiser 1, 2 and 3 repeat the procedure again for “Trial#2” and “Trial#3” sequentially.
10. Optionally, all above steps are repeated for another transducer.

4 Verification Report Form

Page 1 of 3

Ultrasound Platform S/N	Software Build	Transducer
Appraiser #1 Name	Signature	Date

Phantom Name	Phantom ID	TI : MI : Isspa: Ispta:

Trial#1

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

Trial#2

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

Trial#3

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

Verification Report Form

Ultrasound Platform S/N	Software Build	Transducer
Appraiser #2 Name	Signature	Date
Phantom Name	Phantom ID	TI : MI : Isspa: Ispta:

Trial#1

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

Trial#2

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

Trial#3

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

Verification Report Form

Ultrasound Platform S/N	Software Build	Transducer
Appraiser #3 Name	Signature	Date
Phantom Name	Phantom ID	TI : MI : Isspa: Ispta:

Trial#1

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

Trial#2

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

Trial#3

	Measurements				
Depth	1	2	3	4	5
2cm					
5cm					
8cm					

5 Analysis

5.1 Conversions

Shear wave speed will be used for analysis. For systems that report elasticity measurement (Young's modulus value) by the following equation [1], the

$$c = \sqrt{\frac{Y}{2\rho(1+v)}}, \quad (1)$$

Where c (m/s) is shear velocity, Y (kPa) is Young's modulus, ρ is density (g/cm2), and v is Poisson ratio. Assuming density as 1.0 and is 0.5, a simplified relationship is

$$c \approx \sqrt{\frac{Y}{3}}, \quad (2)$$

5.2 Numerical Analysis

The different ultrasound systems, transducers, appraisers, depths can be analyzed through an Analysis of Variance (ANOVA). The Analysis of Variance will decompose the variation into depth, appraisers, ultrasound systems, locations (optionally) and interactions between the above. Sample is shown below. Actual analysis will depend on the data collected.

Source	DF	SS	MS	F	
Systems	2	xx	xx	xx	Siemens, SSI, Echosens (others can be added)
Appraiser	2	xx	xx	xx	Appraiser 1,2 and 3
Depth	2	xx	xx	xx	2, 5 and 8cm
Appraiser x Depth	4	xx	xx	xx	
System x Appraiser	4	xx	xx	xx	
System x Depth	4	xx	xx	xx	
Equipment	116	xx	xx	xx	
Total	134	xx			

5.3 Acceptance Criteria

F statistic should be analyzed at the α=0.05 level. Any of the factors that exceed this level are statically different than the others. Further analysis will determine if the issue will be investigated and improved, or whether final criteria be established from this criteria.

Appendix A: Information on CIRS customized phantom (#####0

2428 Alameda Avenue, Suite 316, Norfolk, Virginia, 23513 USA
800-617-1177 * 757-855-2765

www.cirsinc.com

DATA SHEET (here is an example of the data sheet, will be replaced by the final QIBA recommendataion phantom)

Product:

S/N:

Quantity: Three (3)

	5 kPa	10 kPa	20 kPa	40 kPa
Serial Number	E959-1	E959-2	E959-3	E959-4
Phantom Wt	1879 g	1876 g	1878 g	1879 g
Gel Batch #	RDG350	RDG351	RDG366	RDG367
Speed of Sound (m/s)	1538	1539	1537	1540
Attenuation (dB/cm/mHz)	0.47	0.50	0.49	0.54
Contrast (dB wrt CIRS ref)	-1	0	-1	-2

Elasticity (kPa)	5.9	12.4	23.9	42.6

The elasticity measurement is an average of measurements (4) taken on a sample from each batch. The modulus of elasticity is calculated by measuring the deformation of the gel when a sphere of known size is placed on the sample. Our method of measuring elasticity is robust but not sophisticated. So, we are assuming an accuracy of +/- 10% in the range of 5 to 70 kPa.

References:

[1]. William F. Hosford. Mechanical Behavior of Materials. Cambridge University Press, 2005.