

QIBA Profile:

Ultrasound Measurement of Shear Wave Speed for Estimation of Liver Fibrosis

Stage: A. Initial Draft

|  |  |  |
| --- | --- | --- |
| **Notation in this Template** | | |
| **Template Element** | **Appears as** | **Instructions** |
| Boilerplate text | Plain black text | Don't change.  Should appear in all profiles. |
| Example text | Plain grey text | Provides an example of content and wording appropriate to that location.  Rewrite it to your needs and change the text color back to Automatic (which will make it black). |
| Placeholder | <text in angle brackets> | Replace text and <> with your text.  Use Find/Replace for ones that appear frequently. |
| Guidance | Comment with "GUIDANCE" at the top. | Delete it when you've followed it and don't need it anymore. |

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# Change Log:

This table is a best-effort of the authors to summarize significant changes to the Profile.

|  |  |  |
| --- | --- | --- |
| **Date** | **Sections Affected** | **Summary of Change** |
| 2015.12.30 | All | New Profile transfer (Manish Dhyani, Brian Garra) |
| 01/2016 -03/2016 | All | Several iterations (Manish Dhyani, Brian Garra) |
| 04/07/2016 | All | Shared with committee for comments |
| 4/7-10/2016 | All | Word edits, consistent highlighting rules, a New Proposed Assessment Compliance Procedure added in Section 4 |

# Open Issues:

The following issues are provided here to capture associated discussion, to focus the attention of reviewers on topics needing feedback, and to track them so they are ultimately resolved. In particular, comments on these issues are highly encouraged during the Public Comment stage.

|  |
| --- |
| **Q1. Does BMI affect assessment of liver fibrosis using SWS elastography?**  A. It may decrease the precision of the assessment because of reduced shear wave elastography quality. Eg. Some patients with larger BMI’s may not be able to be measured to QIBA standards based on this issue.  [**Note:** We may have to have a separate claim for larger patients where SWS measurements have less precision or these patients automatically get disregarded if they cannot meet the criteria for accurate estimation.] |
| **Q2. What is the maximum liver depth and subcutaneous tissue for making measurements?**   1. Discussion [Subcutaneous Tissue + distance from capsule = 5-7cm??]? |
| **Q3. What is the effect of inflammation on SWS and what is it’s magnitude?**  A. Inflammation stiffens the liver but the magnitude is not known precisely.  References: [End of Document] |
| **Q4. Number of measurements?**  **[Definitely 10 - ?Less than 10]**  A. The total number of measurements that are needed to make an SWS estimate per patient.  [Vendor Specific instructions for number of measurements versus the total number of measurements recommended].  B. Criteria for inclusion or exclusion for a given measurement?  B1. Standardize?  C. Repeatability versus reliability? [Decreasing variance may result in increase bias] |
| **Q4. What sort of Phantom should be used for periodic QA and compliance (Section 3.3 of Profile)**   1. **Viscoelastic versus elastic phantom?**   Viscoelastic phantom to distinguish differences between different systems.  For a single machine, elastic phantoms will be affordable and practical.   1. **Complex versus simple?**   Simple since the liver is relatively simple unlike the breast.   1. **Multiple manufacturers versus single?**   **Phantom Specifications:**  Attenuation: 0.5 dB/cm/Mhz  Back Scatter: Integrated back scatter [values??]  Speed of Sound: 1520-1540 m/sec  Stiffness: Example - 2 part phantom  Normal Liver Equivalent & Fibrotic F3 Liver equivalent  Temporal Stability: <5% change in the above parameters over 6 months.  **QIBA testing to verify specifications (paid for by vendor?)**  Refer to QIBA development committee as a possible source of revenue.  **QIBA testing to verify stability?**  Refer to QIBA development committee as a possible source of revenue.  **QIBA testing facility?**  Refer to QIBA development committee as a possible source of revenue.  Discuss phantom for acoustic focus and acoustic output   1. **Frequency of periodic QA?**   As specified by ACR/AIUM guidelines – annually/anytime the software changes? |
| **Q5. Pass Fail Tolerances for Phantom Tests** |
| Q6. How does each MFR identify and display outliers in their images. Should QIBA specify a standard handling? [Section 3.7] |
| Q7. ROI location in most homogenous region of SWS color map?  [Should this be a closed issue – if agreed upon or is there a way to decrease variability amongst users].  Q. ROI Size - If user selected – how big? (size of homogenous region versus variance) |
| Q. DICOM conformance – Are new header fields needed? |
| Q. Number of values averaged for each pixel in the color image.  **[Image reconstruction section of Profile]** |
| Q. Color Maps – Should these be QIBA specified?  Color scale and number of colors in the map. |
| **Q. Give stiffness in m/sec or kPa?** |

# Closed Issues:

The following issues have been considered closed by the biomarker committee. They are provided here to forestall discussion of issues that have already been raised and resolved, and to provide a record of the rationale behind the resolution.

|  |
| --- |
| **Q. At what point in the respiratory cycle should acquisition occur?**  A. Suspended tidal respiration (references needed) |
| **Q. Should the patient fast prior to acquisition?**  A. At least 3 hours prior to acquisition (references needed) |
| **Q. Does Steatosis affect assessment of liver fibrosis using elastography**  A. No. [References: End of Document] |
| **Q. How to best acquire from patients where intercostal approach is not feasible (narrow intercostal spacing, COPD)?**   1. If intercostal approach is unavailable, we recommend excluding the patient. [Consider MRE]. |

# 1. Executive Summary

The goal of a QIBA Profile is to help achieve a useful level of performance for a given biomarker.

The **Claim** (Section 2) describes the biomarker performance.  
The **Activities** (Section 3) contribute to generating the biomarker. Requirements are placed on the **Actors** that participate in those activities as necessary to achieve the Claim.   
**Assessment Procedures** (Section 4) for evaluating specific requirements are defined as needed.

This QIBA Profile ***Ultrasound Measurement of Shear Wave Speed for Estimation of Liver Fibrosis*** addresses estimation of liver fibrosis which is often used to determine when and how to treat patients with diffuse liver disease, and also monitor progression or response to treatment. It places requirements on Acquisition Devices, Technologists, Radiologists, Reconstruction Software and Image Analysis Tools involved in Subject Handling, Image Data Acquisition, Image Data Reconstruction, Image QA and Image Analysis.

The requirements are focused on achieving sufficient accuracy and avoiding unnecessary variability of the estimation of liver fibrosis.

The clinical performance target is to achieve SWS measurements with a bias of mean value relative to MRE of ± 5% and an overall coefficient of variation of 5% (SD/mean).

This document is intended to help clinicians basing decisions on this biomarker, imaging staff generating this biomarker, vendor staff developing related products, purchasers of such products and investigators designing trials with imaging endpoints.

Note that this document only states requirements to achieve the claim, not “requirements on standard of care.” Conformance to this Profile is secondary to properly caring for the patient.

QIBA Profiles addressing other imaging biomarkers using CT, MRI, PET and Ultrasound can be found at qibawiki.rsna.org.

# 2. Clinical Context and Claims

Clinical Context

Elastography as a biomarker for the identification of moderate fibrosis grade defined as ≥ F2 fibrosis in the METAVIR system of staging liver fibrosis. This might be used to monitor progression of fibrosis during anti-fibrosis therapy or to monitor regression of fibrosis.

Elastography as a biomarker for the evaluation of cirrhosis defined as F4 stage of fibrosis of the METAVIR system of staging liver fibrosis.

**Conformance to this Profile by all relevant staff and equipment supports the following claim(s):**

Compliance with the activities of this Profile by relevant staff and equipment supports the following

claim(s):

**CLAIM 1**

**Measured (biomarker):** The biomarker is shear wave speed (SWS) in the liver of a patient computed by creation of a shear wave [FibroScan measurements were not included in phase 2 so it has been excluded for now] by an acoustic radiation force push. Measurements using the non-imaging FibroScan device are not covered by this profile. A table for comparing FibroScan values with SWS values obtained in this profile will be listed at the end of this section when validated comparisons become available. The biomarker is used for a single measurement and also for monitoring shear wave speed changes over time.

**Clinical Application:** SWS is measured in the liver of patients with suspected diffuse liver disease, with or without fatty infiltration of the liver and with suspected fibrosis or cirrhosis.

**Bias:** When measured in the right lobe of the liver in the manner specified in the profile and with equipment compliant with the specifications of the profile, the measured SWS will be within ± 5% of the true SWS. This is based on numerous measurements of phantoms with physical properties very similar to human liver.

**Precision:** When measured in the right lobe of the liver in the manner specified in the profile with profile compliant equipment:

The measured shear wave speed is Y m/sec the 95% CI is Y ± (1.96 X “Y” X 0.05). [as measured with a coefficient of variation of 5%].

* **Reliable measurements are made at a single location of the liver at the depth and approach specified and relationship to vessels as specified in the profile.**
* **Specify range of liver stiffness/Shear wave speeds over which the profile applies.**
* **Patients are included as defined in the profile below.**

The same values hold for longitudinal studies when the same or different operators measure liver under the standard profile protocol.

Tests have shown that active inflammation in the liver affect SWS measurements. So when a patient has severe chronic active hepatitis, SWS may OVERESTIMATE the degree of fibrosis (increased bias).

While the claim was developed by extensive review of the literature, it is currently a consensus claim that has not yet been fully substantiated by studies that strictly conform to the specifications given here. The expectation is that during the Technical Confirmation and Clinical Confirmation phases, data on the actual field performance will be collected and changes made to the claim or the details accordingly. At that point, this caveat may be removed or re-stated.

Claim 2: For a measured change in shear wave speed of X (Y2-Y1), a 95% confidence interval for the change is (Y2-Y1) ± 1.96 X [(Y1 X 0.05)2 + (Y2 x 0.05)2]1/2

[Check that the CV is constant over the range of phase 2 phantom measurements]

**This claim holds when:**

* **Reliable measurements are made at each time-point in exactly the same location of the liver documented by relationship of ROI compared to hepatic vessels at the depth and approach specified in the profile.**
* **Measurements at each time point are acquired using manufacturer specified protocol.**
* **Specify range of liver stiffness/Shear wave speeds over which this profile applies?**
* **Patients are included as defined in the profile below.**

Claim 3: For a measured shear wave speed of X the 95% confidence interval for the true speed is *X* ± 5%. [supported by measured bias relative to frequency corrected MRE]

**Discussion**

**Clinical interpretation**

1. Currently the only consensus standard for interpretation in the United States is that formulated by the Society of Radiologists in Ultrasound in October 2014. According to that standard, measurements are used to classify a patient into one of the three categories below:
   1. Table of Liver Fibrosis Categories and Corresponding Representative Shear Wave Speed Values.

|  |  |  |  |
| --- | --- | --- | --- |
| Ultrasound System | No Fibrosis or Minimal Fibrosis (METAVIR F0-F1) | Moderate Fibrosis (METAVIR F2 and F3) | Severe Fibrosis/Cirrhosis (METAVIR F3 – F4) |
| System A | SWS < 1.37 m/s (<5.7kPa) | 1.37 < SWS < 2.2 m/s (> 5.7 kPa, < 15 kPa) | SWS > 2.2 m/s (> 15 kPa) |
| System B |  |  |  |
| System C |  |  |  |

For cutoff values for specific ultrasound systems, please refer to the Manufacturer Specific Protocols in Appendix D.

* 1. With respect to the magnitude of true change:   
     The magnitude of the true change is defined by the measured change and the error bars (+-83%). If you measure the volume to be Y1 m/sec at baseline and Y2 m/sec at follow-up, then the measured change is an Xm/sec increase in speed. The 95% confidence interval for the true change is a (Y2-Y1) ± 1.96 X [(Y1 X 0.05)2 + (Y2 x 0.05)2]1/2 increase in speed. Clinical interpretation with respect to progression or response:  
     Currently a significant change is defined as progression from one fibrosis category to another as shown in the Table above.

While Claim 1 has been informed by an extensive review of the literature and expert consensus and phantom studies that have not yet been fully substantiated by studies that strictly conform to the specifications given here. The expectation is that during field test, data on the actual field performance will be collected and any appropriate changes made to the claim or the details of the Profile. At that point, this caveat may be removed or re-stated.

# 3. Profile Activities

The Profile is documented in terms of “Actors” performing “Activities”. Equipment, software, staff or sites may claim conformance to this Profile as one or more of the “Actors” in the following table.

Conformant Actors shall support the listed Activities by conforming to all requirements in the referenced Section.

Table 1: Actors and Required Activities

|  |  |  |
| --- | --- | --- |
| **Actor** | **Activity** | **Section** |
| Ultrasound Scanner  (Acquisition Device) | Pre-delivery | 3.1. |
| Subject Handling | 3.5. |
| Image Data Acquisition | 3.6. |
| Technologist | Subject Handling | 3.5. |
| Image Data Acquisition | 3.6. |
| Image Data Reconstruction | 3.7. |
| Radiologist | Subject Handling | 3.5. |
| Image QA | 3.8. |
| Image Analysis | 3.10. |
| Reconstruction Software | Image Data Reconstruction | 3.7. |
| Image Analysis Tool | Image Analysis | 3.10. |

The requirements in this Profile do not codify a Standard of Care; they only provide guidance intended to achieve the stated Claim. Failing to conform to a “shall” in this Profile is a protocol deviation. Although deviations invalidate the Profile Claim, such deviations may be reasonable and unavoidable and the radiologist or supervising physician is expected to do so when required by the best interest of the patient or research subject. How study sponsors and others decide to handle deviations for their own purposes is entirely up to them.

The sequencing of the Activities specified in this Profile are shown in Figure 1:

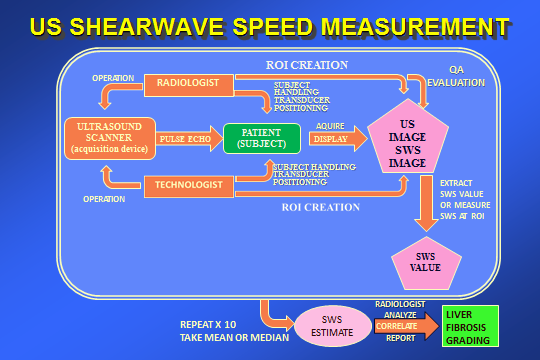


Figure 1: Ultrasound Measurement of Shear Wave Speed for Estimation of Liver Fibrosis - Activity Sequence

## 3.1. Pre-delivery

This activity describes calibrations, phantom imaging, performance assessments or validations prior to delivery of equipment to a site (e.g. performed at the factory) that are necessary to reliably meet the Profile Claim.

### 3.1.1 Discussion

### 3.1.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Acoustic Output (SWS Mode) | MFR output testing | Below FDA acoustic output limits.  MFR specification and certification. |
| Phantom Testing | MFR QA | QIBA pre-specified phantom testing. 95%CI or CV [XX to YY%].  Bias: +-5% of nominal. xx |
| Software verification | MFR | Software version equals version specified in QIBA profile (Manufacturer specific section – Appendix D). |
| Hardware and transducer Manufacturer specified parameters | MFR | Shall ensure the equipment intended for use is listed in Appendix D as a compliant combination of System, Software Revision and Transducer. |
|  |  |  |

## 3.2. Installation

This activity describes calibrations, phantom imaging, performance assessments or validations following installation of equipment at the site that are necessary to reliably meet the Profile Claim.

### 3.2.1 Discussion

### 3.2.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Hardware Damage | MFR Engineer | No physical damage. |
| Clinical Staff | No physical damage. |
| Software verification | MFR/Site Operations Manager | Software version equals version specified in QIBA profile (Manufacturer specific section – Appendix D.). |
| Phantom testing | MFR Engineer/ Site Operations Manager/ Site QA Manager | Measure SWS on a viscoelastic phantom using standard instrument settings and acquisition procedures. Compare with baseline values provided by manufacturer (refer to section 3.1, 3.2 and appendix).  Tolerances: TBD |
|  |  |  |
|  |  |  |

## 3.3. Periodic QA

This section describes calibrations, phantom imaging, and performance assessments conducted periodically at the site, that are necessary to reliably meet the Profile Claim.

### 3.3.1 Discussion

Imaging QA: See the following guidelines (links provided).

AIUM QA guidelines:

<http://www.aium.org/loginRequired/store/productDetail.aspx?cId%3d102%26page%3d2%26pId%3dRQA&cId=102&page=2&pId=RQA>

AACR QA guideline [Link]

Phantom for SWS Testing:

[See question Open issue 4]

### 3.3.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Imaging QA | Operator/QA Manager | Standard Ultrasound system QA as specified by AIUM/ACR QA guidelines. |
| Phantom SWS Test | Operator/QA Manager | Shall periodically measure SWS on a viscoelastic phantom using standard instrument settings and acquisition procedures. Compare with baseline values provided by manufacturer (refer to section 3.1, 3.2 and appendix).  Tolerances: TBD |
| Acquisition Device | Shall be capable of performing SWS measurements at reproducible instrument settings. |
| Qualification | Operator/QA Manager | Department approved personnel with experience in making the SWS measurement on both phantoms and patients. |
|  |  |  |

## 3.4. Subject Selection

This activity describes criteria and procedures related to the selection of appropriate imaging subjects that are necessary to reliably meet the Profile Claim.

### 3.4.1 Discussion

Patients who need clinical assessment of liver.

**Liver Depth:** Maximum Liver Depth: Open issue Q2

High subcutaneous fat over the intercostal rib space may cause significant aberration to the elastography push pulse and prevent good reliable and repeatable measurement [Claim 2/3]

**Intercostal Space:** Measurement and minimum width:

Some patients may have narrow intercostal approach which could prevent a good acoustic window, making visualization of the liver difficult through an intercostal approach.

Patients with COPD may case shifting of the liver to a lower position preventing good visualization through the intercostal approach.

**Prior Surgery:** If subjects have had a surgical resection of the right lobe of the liver or sections of right lobe of the liver, that prevent an intercostal approach measurement, then the patient should be considered for exclusion.

**Informed Consent:** Obtain informed consent as needed per institutional policy. HIPAA authorization shall be obtained for research or other purposes as outlined in institutional policies.

### 3.4.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Clinical concern | Patient | Concern for Liver Disease |
| Liver Depth | Patient | BMI/thickness of subcutaneous fat that allows a reliable SWS assessment. |
| Intercostal space | Patient | Sufficiently wide intercostal space for probe placement. |
| Breathing | Patient | Ability to hold breath for acquisition. |
| Prior Surgery | Patient | Presence of right lobe of the liver visible through intercostal space.  Absence of shadowing because of surgical/other scars. |
| Informed Consent | Technologist or Radiologist | Informed consent obtained. |
|  |  |  |

## 3.5. Subject Handling

Subject handling for quantitative shear wave ultrasound focuses on proper preparation of the patient for the acquisition of high reliability data. As Shear Wave Elastography is very new, an information/instruction sheet supplied to the patient prior to the acquisition may be very helpful. The sheet can describe the technology, explain why it is useful, and give instructions to the patient on how to fast prior to the procedure. An example patient information sheet is given in appendix XXX.

Instruction on how the patient should suspend respiration should be given immediately prior to the data acquisition procedure. Practice runs should be performed allowing the patient to practice how to suspend respiration. This will provide the patient or subject with useful information on what the ultrasound probe feels like and how long they will be asked to hold their breath.

Suspended tidal respiration is recommended to avoid changes in pressure on the liver that might affect liver stiffness. In addition, this form of suspended respiration may result in less movement of the liver during acquisition in patients not able to fully suspend respiration since the diaphragm may move less than after a deep inspiration.

### 3.4.1 Discussion

### 3.4.2 Specification

| **Parameter** | **Actor** | **Specification** |
| --- | --- | --- |
| Fasting State[[1]](#endnote-1) | Technologist/  Sonographer | Shall instruct the patient to avoid food or beverage for a minimum of 4 hours prior to the procedure. May hand out a patient information sheet describing how to accomplish the fasting and how it is important for obtaining good SWS results.  Shall query the patient prior to acquisition on whether they actually fasted or not. Offer to acquire the data on a later date or later in the day if the patient is not in a fasting state. |
| Radiologist | Shall query the patient prior to acquisition on whether they actually fasted or not. Offer to acquire the data on a later date or later in the day if the patient is not in a fasting state. |
| Respiration[[2]](#endnote-2) | Technologist/Sonographer  Or Radiologist | Shall perform several practice acquisitions with patient in suspended tidal respiration so that the patient may practice the technique and get used to the sensation of the ultrasound transducer while in suspended tidal respiration, and the duration of the required breath hold.  Shall ensure that patient is in suspended tidal respiration during acquisition and that no other liver movement is observed during acquisition |
| Informed Consent | Technologist or Radiologist | Obtain informed consent as needed per institutional policy. HIPAA authorization shall be obtained for research or other purposes as outlined in institutional policies. |
| Acquisition Information | Technologist or Radiologist | Shall provide general information on shear wave elastography and specific information on how the acquisition will be conducted including number of acquisitions, transducer application between ribs, amount of pressure applied, need for breath hold etc. |

## 3.6. Image Data Acquisition

This section describes details of the data acquisition process that are necessary to reliably meet the Profile Claim. It includes calibrations, performance assessments or validations during acquisition that are necessary to reliably meet the Profile Claim.

### 3.6.1 Discussion

*Image Acquisition:*

Patient positioning for SWS acquisition varies somewhat between institutions. Supine or oblique left decubitus positions are similar enough so as not to induce variation in liver stiffness. (ref)

Intercostal positioning of the transducer has been shown to reduce variability in measurements. However, there are situations where intercostal acquisition is not feasible. For example, smaller patients may not have wide enough intercostal spaces to allow positioning of the transducer intercostally without partial blockage of transducer elements resulting either in obvious shadowing or loss of transmit power on the shear wave push pulse. Either will likely results in poor quality shear wave speed estimates. Another problem arises when the subject as COPD and the hyper-expanded lung pushes the liver below the costal margin. In these cases, consider excluding the subject and using MRE and/or liver biopsy for evaluation.

Please refer to manufacturers’ instructions on acquisition techniques, procedures and machine specific pitfalls for additional information. The appendices contain this material for a number of major manufacturers (appendix D).

***Image Data Acquisition***

The parameters in image acquisition also apply to Elastography data acquisition. There are some additional parameters specific to elastography as noted below.

Region of interest (ROI) positioning is critical. A depth greater than 2cm deep to the liver capsule will avoid the slightly stiffer liver tissue beneath the capsule. A depth <5cm will help to ensure that the shear wave amplitude is sufficient for reliable estimates of shear wave speed. Positioning away from discrete structures is important as the algorithms used to estimate SWS assume homogeneous isotropic tissue, not heterogeneous tissue containing specific structures or lesions. An image should be acquired to document the ROI location relative to vessels so as to allow acquisition at the same location for additional measurements either at the same time or on follow-up examinations.

Positioning the ROI away from the centerline of the image may introduce variation in SWS estimates as may changing the ROI size. The effects of changing ROI size have not yet been systematically examined.

As for imaging, please refer to manufacturer specific instructions and specifications for guidance on additional steps to take during acquisition (see appendix D).

Positioning the ROI at a constant depth as close as practicable is important because SWS estimates are known to decline as a function of depth with many current SWS software implementations. Acquiring at a near constant depth will help to minimize variation induced by variations in acquisition depth.

### 3.6.2 Specification

| **Parameter** | **Actor** | **Requirement** | **DICOM Tag** |
| --- | --- | --- | --- |
| Patient Position | Technologist or Radiologist | Shall ensure that the patient is positioned supine or in an oblique left lateral decubitus position (for example 45o left lateral, not full left lateral decubitus) |  |
| <another actor> | Shall <specific requirement on a different actor relating to the same parameter>. |  |
| Transducer Position | Technologist or Radiologist | Shall position the transducer at an intercostal space wide enough to accommodate the transducer and at the correct level to image/acquire from the upper right liver lobe.  Shall position the transducer face long axis parallel to the intercostal space and check for correct positioning by inspection of the image for shadowing at the image edges.  Shall position the transducer perpendicular to the skin surface |  |
| Ultrasound image | Technologist or Radiologist | Shall ensure that the liver image is of high quality without areas of shadowing or artifacts |  |

| **Parameter** | **Actor** | **Specification** |
| --- | --- | --- |
| Region of Interest (ROI) Placement | Technologist or Radiologist | Shall position the ROI at least 2cm deep to the liver capsule and less than 5cm from the transducer face.  Shall position the ROI away from discrete structures such as liver margin, nodules, portal triads or hepatic veins for acquisition of SWS estimates  Shall position the ROI near the center of the image in the lateral direction and away from the right or left image margins.  A standard ROI size should be chosen and all acquisitions performed using this size (if the size is adjustable).  Should try to place the ROI at a constant depth for all acquisitions, but specifically for follow up acquisitions from the same patient or subject. |
| Liver Movement | Technologist or Radiologist | Shall acquire only when there is no visible liver motion. |

## 3.7. Image Data Reconstruction

[Processing for Display for example the color lookup table in SWE Imaging? Should this be Fixed versus Variable across manufacturers?**]**

This activity describes criteria and procedures related to producing images from the acquired data that are necessary to reliably meet the Profile Claim.

### 3.7.1 Discussion

### 3.7.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Number of values averaged for each pixel in the color image. | MFR | To be discussed. |
|  |  |
| Color Maps | MFR | QIBA specified? |

## 3.8. Image QA

This activity describes criteria and evaluations of the images that are necessary to reliably meet the Profile Claim.

As SWS estimates may be highly variable with current implementations, care must be taken to avoid introducing additional variation. Assessment of the quality of each acquisition should be made and values obtained during suboptimal acquisitions should be deleted and not included in mean or median estimates. Examples of suboptimal acquisitions that may be detected include: liver movement during acquisition, inadvertent shift of ROI to a deeper or shallower depth, patient talking during acquisition, transducer slippage during acquisition and placement of the ROI near to a vessel or other discrete structure.

### 3.8.1 Discussion

### 3.8.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Outlier identification and handling | MFR image processing software | How does each MFR identify and display outliers in their images. Should QIBA specify a standard handling [**open issue**]?  Identification and display meets MFR specifications as specified in manufacturer specific section (Appendix D) |
| Suboptimal SWS Acquisition handling | Technologist or Radiologist | Shall exclude any SWS estimate deemed to have been acquired suboptimally either by inspection of the saved images or by observations made during the acquisition. |
| User training on image display | MFR manual and application specialist | Training on user identification and interpretation of outliers. |
|  |  |  |

## 3.9. Image Distribution

This activity describes criteria and procedures related to distributing images that are necessary to reliably meet the Profile Claim.

### 3.9.1 Discussion

### 3.9.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| DICOM conformance | MFR | DICOM header modifications/adaptations /usage. |
| DICOM committee | DICOM header modifications/adaptations /usage. |
| PACS Manufacturer | PACS – workstation correctly handles new DICOM header fields. |
|  |  |  |

## 3.10. Image Analysis

This activity describes criteria and procedures related to producing quantitative measurements from the images that are necessary to reliably meet the Profile Claim.

### 3.10.1 Discussion

### 3.10.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| ROI location selection | Technologist/  Radiologist/ | Reference Section 3.6.1  ROI location in most homogenous region of SWS color map [open issue]. |
| ROI size selection | Technologist/  Radiologist/MFR | MFR specifications if fixed (Appendix D).  If user selected – how big? (size of homogenous region versus bigger to decrease variance) |
|  |  |  |
|  |  |  |

# 4. Assessment Procedures

To conform to this Profile, participating staff and equipment (“Actors”) shall support each activity assigned to them in Table 1.

To support an activity, the actor shall conform to the requirements (indicated by “shall language”) listed in the specifications table of the activity subsection in Section 3.

Although most of the requirements described in Section 3 can be assessed for conformance by direct observation, some of the performance-oriented requirements cannot, in which case the requirement will reference an assessment procedure in a subsection here in Section 4.

Formal claims of conformance by the organization responsible for an Actor shall be in the form of a published QIBA Conformance Statement. Vendors publishing a QIBA Conformance Statement shall provide a set of “Model-specific Parameters” (as shown in Appendix D) 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.

Proposed general assessment procedure (4-9-16 –to be reviewed by the process committee prior to full implementation):

Rationale: A checklist-based approach is used for assessment for conformance for three major reasons:

1. Checklists are easily followed during implementation of any protocol and will be easier to use than the basic profile because they are organized primarily by chronological task order rather than by task type and “actor” as in the profile.

2. Checklists of tasks may be used both for implementation of a profile AND for assessment of conformance of the profile in a clear, easy to understand manner.

3. Checklists are used extensively to evaluate imaging practices for conformance to practice and imaging guidelines for accreditation purposes (for example AIUM and ACR accreditation programs) and thus can be readily adapted for the QIBA profile conformance program. This sort of conformance monitoring is well understood by imaging centers since most have applied for or are already accredited.

The assessment procedure below is based on two-level checklists laid out in chronological order which works best for actual acquisition of quantitative image data. Some activities (such as periodic QA monitoring) do not fall clearly into the acquisition chronological order and so are separate checklists with tasks in approximate chronological order. More complex tasks may require “sub-checklists” which are listed as separate checklists to improve the readability of the main checklist and a hyperlinked to the main checklist and reference in the main checklist for those using paper (vs. electronic) checklists.

While not required, the assessment checklists are also useful for actual use in site activities such as data acquisition to help ensure conformance to the profile.

The checklists are found in Appendix E and the sub-checklists are found in Appendix F. Specific procedures for evaluation of some checklist items are found in sections 4.1 – 4.yyy below or in the manufacturer specific instructions listed in Appendix D., and are referenced in the appropriate place on the checklist.

Conformance to the profile will be monitored by evaluation of checklists from a random sampling of acquisitions along with review of corresponding specific assessment documentation as outlined in the subsections below. Each line item in the main checklist is assigned a potential point score on a 200 point scale depending on how critical the line item is to the data quality needed to meet the profile claims.

For a given line item the site achieves the maximum number of points if fully compliant including full compliance in any related sub-checklists. A partially compliant score is assigned (less than the maximum potential score) according the assessment rules defined in the procedures covered in sections 4.1-4.yyy below or according to the assessment of the assessor performing conformance monitoring.

A passing score for site conformance is 85% of the maximum possible points listed on the conformance checklist.

## 4.1. Assessment Procedure:

## [To be defined]

## 4.2. Assessment Procedure: <Parameter Y>

## [To be defined]

## 4.3. Assessment Procedure:

## [To be defined]

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# Appendices

## Appendix A: Acknowledgements and Attributions

## Appendix B: Background Information

## Appendix C: Conventions and Definitions

## Appendix D: Model-specific Instructions and Parameters

## Appendix E: Primary Checklists for Profile Execution and Conformance

## Appendix F: Secondary Checklists for Profile Execution and Conformance

1. [↑](#endnote-ref-1)
2. [↑](#endnote-ref-2)