SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____ SCANNER QUAL/QA OPERATOR QUAL PHANTOM QUAL/QA OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Device Installation

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2= MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.1.2.0	**Pre-delivery**					
3.1.2.1	Acoustic Output Check (SWS Mode)	Manufacturer acoustic output levels meets FDA recommendation	MFR	1		
3.1.2.2	Acoustic Transmit Focusing Check	Manufacturer specifies and certifies	MFR	1		
3.1.2.3	Instrument Testing Using SWS Phantom	SWS estimates are acquired from a QIBA calibrated phantom. Results compared with Manufacturer specifications	MFR	1		US Imaging Phantom Specifications: Attenuation: 0.5 dB/cm/MHz Back Scatter: Approximately 10-4 – 10-3 cm-1Str-1 at 3 MHz or sufficient to create mean speckle brightness comparable to a human liver-mimicking phantom (± 3 dB). Speed of Sound: 1520-1540 m/sec. Stiffness: Normal Liver Equivalent & Fibrotic F3 Liver equivalent. ± 5% of the specified values. QIBA phantoms are checked and calibrated at a calibration center (Mayo)
3.8.2.1	SWS Imaging Performance	Identification and display meet manufacturer specifications listed in Appendix D	MFR	1		
3.1.2.4	**Hardware Specification Check**	All Scanner, Transducer and Other Specified Devices Are Present and Operating correctly	Operator	3		Required Scanner components are found in the scanner specific instructions appendix D.
3.1.2.4	Software verification	S/W version equals version specified in QIBA profile (Appendix D)	MFR	1		

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____ SCANNER QUAL/QA OPERATOR QUAL PHANTOM QUAL/QA OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Device Installation

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2= MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.2.2.0	**Installation**					
3.2.2.1	Hardware Damage Check	No physical damage to medical device	MFR Engineer / Clinical Staff			
3.2.2.2	Software verification	S/W version equals version specified in QIBA profile (Appendix D)	MFR / Site Operations Manager			
3.2.2.3	Baseline Ultrasound SWS System Testing	Measure SWS on a QIBA elastic phantom using standard instrument settings and acquisition procedures. Compare with baseline values provided by calibration center (refer to section 3.1, 3.2 and appendix)	MFR Engineer/ Site Operations Manager/ Site QA Manager			currently the center for calibration of SWS phantoms is Mayo Clinic

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____ SCANNER QUAL/QA OPERATOR QUAL PHANTOM QUAL/QA OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Device Installation

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2= MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.3.2.0	**Site Quality Assurance**					
3.3.2.1	US Imaging QA Check	U/S system QA checks and conform to quality criteria using AIUM / ACR QA guidelines	Operator / QA manager			On arrival then annually unless potential problem found during operations
3.3.2.2	US SWS system QA using SWS Phantom	Measured SWS on an QIBA elastic phantom using standard instrument settings and acquisition procedures match baseline values obtained at installation (section 3.2.2.3)	Operator / QA manager			Annual testing and testing after any software/hardware change.
3.3.2.3	Ultrasound system QA phantom tests Intersystem Agreement	Measured SWS on a QIBA visco-elastic phantom using standard instrument settings and acquisition procedures. Compare with baseline values obtained from other machines	Operator / QA manager		NA	Values should meet crosssectional profile claims. Annual testing and testing after any software/hardware change. FOR FUTURE USE
3.3.2.4	Operator Training	SWS operator is department approved/trained	Operator Site manager QA manager			training on initial operator selection
3.3.2.5	Operator Qualification	SWS Operator meets performance requirements on phantoms & subjects phantom test CV ≤ yy and/or case review IQR ≤ 0.30	Operator Site manager QA manager			after initial training and practice and during periodic case review
3.3.2.6	Phantom Stability Testing	Phantom stability performed by weighing and comparing wt with initial value. If wt changes by > 0.5% sent to calibration center for recalibration	Operator / QA manager			Begin stability testing every 6 months. If no changes are noted after six months can change interval to every 12 months. Recalibrate as necessary. Use phantom stability QA form to record results

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____Subject:_____ SUBJECT SELECTION SUBJECT HANDLING SWS ACQUISTION OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Patient & Acquisition

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.4.2.0	**Subject Selection**					
3.4.2.1	Clinical Indication	Liver Disease That May Lead to Increased Stiffness and Increased Shear Wave Speed (for example liver fibrosis)	Patient			
3.4.2.2	Body Wall	Total body wall thickness < 4cm at intercostal location	Patient Operator			allows SWS measurement to be made at a maximum depth of 6.5 cm from the skin surface and at least 2 cm below the liver capsule.
3.4.2.3	Intercostal Space	Intercostal spacing adequate for transducer	Patient Operator			Evaluate intercostal space by manual palpation
3.4.2.4	Breathing	Patient can hold breath in suspended tidal for acquistion;	Patient Operator			Refer to appendix D for manufacturers acquisition time
3.4.2.5	Prior Surgery Right Liver Lobe	Right lobe of liver present , no scarring or shadowing from surgery	Patient Operator			Confirm subject has right lobe of liver if history of previous hepatic surgery
3.4.2.6	Informed Consent	Informed consent obtained	Technologist or Radiologist			IC and HIPAA forms per institutional policy

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____Subject:_____ SUBJECT SELECTION SUBJECT HANDLING SWS ACQUISTION OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Patient & Acquisition

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.5.2.0	**Subject Handling**					
3.5.2.1	Fasting Instructions	Fasting instructions provided	Technologist or Radiologist			Instruct patient on how to accomplish fasting as well as exceptions (e.g. oral medications, insulin)
3.5.2.2	Oral/Written Orientation	Supplied patient with general information sheet and general SWS information discussed	Technologist or Radiologist			example Appendix G; Instruction sheet emphasizes importance of following instructions to obtain good SWS results
3.5.2.3	Fasting State	On query Patient has successfully fasted 4 hours;	Technologist or Radiologist			Offer to acquire data on a later date or later in the day if patient is not in a fasting state
3.5.2.4	Informed Consent Confirmation	Informed consent confirmed	Technologist or Radiologist			IC and HIPAA forms per institutional policy
3.5.2.5	Breath Hold Instruction	Patient has been instructed on suspending respiration	Technologist or Radiologist			Patient to understand duration of required breath hold and ultrasound sensation
3.5.2.6	Breath Hold Practice	Patient has successfully praacticed suspended tidal respiration	Technologist or Radiologist			Perform several practice acquisitions with patient in suspended tidal respiration
3.5.2.7	Respiratory Motion	No liver movement observed during acquistion practice	Technologist or Radiologist			

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____Subject:_____ SUBJECT SELECTION SUBJECT HANDLING SWS ACQUISITION OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Patient & Acquisition

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.6.2.0	**Image Data Acquistion**					
3.6.2.1	Patient Position	Patient positioned in supine or 30 degree oblique LLD	Technologist or Radiologist			**Not** full left lat decubitus which has been shown to produce a small but statistically significant increase in SWS
3.6.2.2	Transducer Position	Transducer positioned at intercostal space	Technologist or Radiologist			Space must be wide enough to accommodate transducer & image upper Rt lobe (segments 5 or 8)
3.6.2.3	Transducer Orientation	Transducer long axis is parallel to intercostal space and also parallel to liver capsule.	Technologist or Radiologist			Palpate rib space and position transducer face parallel to the long axis of the intercostal space. Orientation to liver capsule is to have ultrasound beam as perpendicular to liver capsule as possible.
3.6.2.5	Transducer Contact	Transducer in contact with skin surface	Technologist or Radiologist			
3.6.2.6	Ultrasound Image Confirmation	Confirms absence of focal structures near image center, no acoustic shadowing from the ribs to suggest improper transducer position/orientation.	Technologist or Radiologist			
3.6.2.7	Measurement Region of Interest (ROI) Depth	ROI positioned 2 cm deep to liver; <6.5 cm from transducer face	Technologist or Radiologist			If a follow up study use the same depth as previous study
3.6.2.8	Measurement Region of Interest (ROI) Position	ROI positioned near center of image, away from right/left margins and away from discrete structures	Technologist or Radiologist			discrete structures refer to structures such as: such as liver margin, nodules, portal triads or hepatic veins
3.6.2.9	Region of Interest (ROI) Size	ROI box diameter is 10mm or 10 x 10 mm	Technologist or Radiologist			See appendix D. Refer to MFR specifications. If a choice is given choose an ROI equal to or larger than 10mm
3.6.2.10	Repeat Region of Interest (ROI) Placement	ROI placed at constant depth for all acquisitions, and follow up acquisitions	Technologist or Radiologist			
3.6.2.11	Number of Measurements	Minimum 10 acquistions for a qualifying measurement	Technologist or Radiologist			MFR may specify more than 10 images. Please refer to vendor specific instructions (Appendix D)
3.6.2.12	Liver Movement-Observation	Acquistion repeated if breathing or motion observed	Technologist or Radiologist			

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____Subject:_____ SUBJECT SELECTION SUBJECT HANDLING SWS ACQUISTION OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Patient & Acquisition

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.6.2.13	Liver Movement-Images	Acquisition repeated if Pre acquistion liver image is not identical to post acquistion	Technologist or Radiologist			Save images for documentation. If liver movement appears on pre and post image comparison then movement during acquisition MAY have occurred depending on the SWS scanner used. If feasible re-acquire.

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____ Subject _____ Image Recon Image QA Analysis/Dist OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Processing & Analysis

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.7.2.0	**Image Data Reconstruction**					
3.7.2.1	Number of values averaged per color pixel	MFR should specify number of values averaged per color pixel	MFR			
3.7.2.2	Identification of Outliers	User understands how each manufacturer identifies outlier - Appendix D	Operator, Radiologist, MFR			
3.7.2.3	Color Maps	Color elastogram map identifies Red = Hard; Blue = Soft	MFR			
3.7.2.4	Black and White Maps	B&W elastogram map identifies Black = Hard; White = Soft	MFR			
3.7.2.5	Color Scale	Continuous sRBG scale (24-36 bit)	MFR			

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____ Subject _____ Image Recon Image QA Analysis/Dist OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Processing & Analysis

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.8.2.0	**Per Case SWS Image Related QA**					
3.8.2.2	Suboptimal SWS Acquistion handling	SWS estimates excluded if associated are suboptimal due to motion or other factors	Technologst Radiologist			
3.8.2.3	User training on image display	User has been trained on identification and interpretation of outliers and on placement of ROI on SWS Image	MFR, Manual, Applications Specialist			

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____ Subject _____ Image Recon Image QA Analysis/Dist OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Processing & Analysis

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.9.2.0	**DICOM Support**					
3.9.2.1	DICOM Header	DICOM header usage meets committee specifications	MFR			
3.9.2.2	DICOM SWS	The SWS DICOM header definitions for SWS Created	DICOM committee			
3.9.2.3	DICOM Workstation	PACS workstation correctly handles new SWS DICOM header fields	PACS manufacturer			

SITE NAME: _____ DATE: _____ OPERATOR NAME/CODE:_____

CHKLIST ENTRY FOR (CIRCLE):

SWS SYSTEM: _____ Subject _____ Image Recon Image QA Analysis/Dist OTHER>>>

QIBA SHEAR WAVE SPEED PROFILE EXECUTION CHECKLIST V5.0 Processing & Analysis

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator	COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS
3.10.2.0	**Image Analysis**					
3.10.2.1	ROI location selection	ROI located in most homogeneous region of SWS color map (Appendix D) *Reference Section 3.6.1*	Technologist Radiologist			
3.10.2.2	ROI size selection	Manufacturer ROI size meets size specifications in Appendix D	Technologist Radiologist			
3.10.2.3	Image/Data Transfer	Successful Image and Data Transfer ot PACS or Other Storage	Technologist Radiologist			

ITEM#	TASK/PARAMETER	CRITERION	RESPONSIBILITY/ACTOR	COMPLETED BY [1= MFR; 2 = MFR Engineer; 3 = Site Op Manager; 4 = Site QA Manager; 5 = Operator

COMPLETED? [YES, NO, NA]	NOTES/EXPLANATIONS