QIBA Profile Conformance

Self - Attestation

QIBA profile title	Diffusion – Weighted Magnetic Resonance Imaging (DWI)
QIBA profile version	December 20, 2019
Company/Institution doing self-attestation	
Company/Institution responsible person	
Date Self-Attestation was submitted to QIBA	
Date Self-Attestation was reviewed by QIBA	
Date Conformance was registered by QIBA	

Document

Some checklist items reference a required Assessment Procedure which may be found in the Profile Document.

Some checklist items have clarifications, rationale, or guidance in the corresponding Discussion section in the Profile Document.

To obtain a copy of the Profile Document, visit http://qibawiki.rsna.org/index.php/Profiles

If a QIBA Conformance Statement is already available for an actor (e.g. your acquisition device), a site may choose to provide a copy of that statement rather than confirming each of the requirements in that Actors checklist yourself.

Vendors publishing a QIBA Conformance Statement shall provide a set of "Model-specific Parameters" (as shown in Annex A) 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.

QIBA Conformance Statements

QIBA Conformance Statements are documents prepared and published by vendors or sites to describe the intended conformance of their products, staff or institution to one or more QIBA Profiles.

Conformance requirements are defined in the QIBA Profile document for each Actor in the Profile. For some requirements, the Profile document also defines assessment procedures.

This conformance statement contains all relevant checklists for all relevant actors for site or product conformance. Supporting material is available on the QIBA wiki conformance section for the respective profile. Checklists in this conformance statement document need to be filled out.

Users can use Conformance Statements to determine whether their staff and products can be expected to deliver the biomarker performance described in the Profile Claim. Achieving the performance claim depends on all Actors described in the Profile being present at the site and conforming to the requirements.

A QIBA Conformance Statement is not intended to promote or advertise aspects of a product or site not directly related to its implementation of QIBA capabilities.

IMPORTANT NOTE: Vendors and sites are solely responsible for the accuracy and validity of their QIBA Conformance Statements. QIBA and its sponsoring organizations have not evaluated or approved any QIBA Conformance Statement or any related product, site or staff, and QIBA and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any QIBA Conformance Statement.

QIBA Conformance Statement for a Product

QIBA Conformance Statement			
Vendor	**Product Name**	**Version**	**Date**
This product conforms to all specifications required for the QIBA Profiles and Actors listed below:			
Profiles Implemented	**Actors Implemented**	**Notes**	
Diffusion – weighted MRI 12-20-2019	Image Analysis Tools	See A.2	
Links to Additional Information			
Link to QIDW section storing phantom test data (specify data sets used for conformance testing)			
https://bit.ly/2QXLo3e			
General information on QIBA: qibawiki.rsna.org			

Annex A: Conformance Notes

A.2 DWI/ADC System QC Image Analysis Software

(*for generation of performance report for MRI acquisition device assessment per 3.2.2 specifications in Diffusion – weighted MRI 12-20-2019 profile*)

Parameter	Conformance (select "Yes" if *any* requirement is met; "No" if *none* are met)	Requirement
Software Deployment		
Web-based SW	□ *Yes* □ *No* □ *N/A*	Web-based QC SW executables, updates and version numbers shall be maintained by SW vendor Optional comment _____
Web-based data	□ *Yes* □ *No* □ *N/A*	Site QC DICOM data and derived reports shall be maintained by QC SW vendor and remain accessible to site user for specified periods from DICOM upload date: DICOM data maintained for _____ months, and QC reports maintained for _____ months following upload of DICOM data. Optional comment _____
Site-based SW installation	□ *Yes* □ *No* □ *N/A*	QC SW executables and updates shall be operational when installed on a site-owned server meeting the following system requirements: _____ _____ Optional comment _____
Site Data		
DWI / ADC QC phantom	□ *Yes* □ *No* □ *N/A*	QC SW shall be able to process data of the following phantom(s): QIBA DWI phantom at 0ºC as described in https://qibawiki.rsna.org/images/a/a5/QIBA_DWI_Profile_Conformance_Testing_Supplement_1_20210401a.pdf Alternative phantom(s)_____ Optional comment _____
DWI / ADC QC scan protocol	□ *Yes* □ *No* □ *N/A*	QC SW shall be able to process above phantom(s) data acquired using following scan protocol(s): QIBA conformance testing as described in https://qibawiki.rsna.org/images/a/a5/QIBA_DWI_Profile_Conformance_Testing_Supplement_1_20210401a.pdf

Parameter	Conformance (select "Yes" if *any* requirement is met; "No" if *none* are met)	Requirement
		Alternative protocol(s) _____ Optional comment _____
DWI / ADC QC DICOM data requirements	□ *Yes* □ *No* □ *N/A*	QC SW shall be able to process above phantom(s) data acquired using above scan protocol(s) adhering to the following requirements (check all that apply): □ DICOM data from GE MRI scanners □ DICOM data from Siemens MRI scanners □ DICOM data from Philips MRI scanners □ DICOM data from Hitachi MRI scanners □ DICOM data from Toshiba MRI scanners □ DICOM data from United Imaging MRI scanners □ Data in classic *DICOM format* □ Data in enhanced DICOM format □ Full exam including non-DWI series along with directional and trace DWI □ Exam including both directional and trace DWI □ Exam including only trace DWI □ Exam including only scanner-generated ADC maps Optional comment _____
Site QC SW User		
Site user duties	□ *Yes* □ *No* □ *N/A*	For proper QC SW operation, the site user shall perform the following operations (check all that apply): □ Prepare and scan phantom according to specified protocol (e.g. https://qibawiki.rsna.org/images/a/a5/QIBA_DWI_Profile_Conformance_Testing_Supplement_1_20210401a.pdf) □ Upload (for web-based QC SW) or navigate to (for site-based QC SW) phantom DICOM data meeting above requirements □ Select DWI/ADC series for QC analysis □ Manually define ROIs/VOIs on phantom target tubes for QC analysis □ Initiate QC analysis of ROI/VOI targets □ Generate QC analysis report(s) □ Identify which metrics are within/outside of QIBA target performance levels

Parameter	Conformance (select "Yes" if *any* requirement is met; "No" if *none* are met)	Requirement
		□ Identify which scan acquisition parameters are within/outside of specified scan protocol ranges □ Initiate archival, email, or printing of QC analysis report(s) Optional comment _____

QC Analysis SW		
DICOM metadata	□ *Yes* □ *No* □ *N/A*	QC analysis SW shall utilize the following DICOM metadata for calculations and protocol conformance testing (check all that apply): □ b-value □ Diffusion-encode directionality and trace DWI □ Proper pixel intensity scaling of DWI □ Proper pixel intensity scaling and units of ADC map □ Magnetic field strength □ Repetition time TR □ Echo time TE □ Image FOVs □ Acquisition matrices (phase and frequency) □ Image matrices □ Slice thickness □ Slice center-to-center spacing □ Quantity of slices □ In-plane phase-encode direction (row or column) □ In-plane parallel imaging acceleration factor □ Number of signal averages at each b-value □ Institution name □ Scanner manufacturer □ Scanner model □ Scanner serial number □ Scanner software version Optional comment _____
		QC analysis SW shall perform the following operations (check all that apply): □ ADC maps are automatically generated on a pixel-by-pixel basis by mono-exponential fit of DWI pixel

QC SW functions	□ *Yes* □ *No* □ *N/A*	intensity vs b-value □ Allow definition of circular ROIs 10-20mm diameter including at least 80pixels on each sample tube □ Location of each ROI is manually defined by the SW user □ Location of each ROI is automatically defined by the SW □ ROIs for each sample tube are automatically combined across slices to create a single VOI for each tube from which quantitative technical performance metrics (see below) are derived □ Statistics are derived on a pixel-by-pixel basis over sequential multi-pass DWI series, then summarized for each ROI/VOI according to methods defined in https://qibawiki.rsna.org/images/a/a5/QIBA_DWI_Profile_Conformance_Testing_Supplement_1_20210401a.pdf □ Location of ROIs/VOIs are rendered and numerically identified in color (in outline or pixel masks) superimposed on grayscale ADW or ADC maps for user inspection □ ADC maps generated by SW shall provide values within random error of that calculated by the scanner or by QIBA-provided QC SW Optional comment _____
Technical performance metrics	□ *Yes* □ *No* □ *N/A*	Using statistical methods described in https://qibawiki.rsna.org/images/a/a5/QIBA_DWI_Profile_Conformance_Testing_Supplement_1_20210401a.pdf, the QC analysis SW shall assess MRI scanner technical performance for the following metrics (check all that apply): □ ADC bias at magnet isocenter □ Within-exam ADC repeatability at isocenter (RC and wCV) □ ADC linearity over range of known diffusion coefficient values (from 0.13 to 1.1) x10^{-3} mm^2/s or provide list of known values for the given phantom □ ADC b-value dependence □ ADC random error estimated from intra-exam sequential 4-pass DWI scans □ SNR of DWI from intra-exam sequential 4-pass DWI at b=0 □ Graphical plot and/or table of SNR of DWI estimated from intra-exam sequential 4-pass DWI at

		all acquired b-values □ An indication of which scanner's performance metrics pass/fail thresholds established in QIBA DWI profile □ Generated metric shall be within random error of that calculated by QIBA-provided QC SW Optional comment _____
QC Report output	□ *Yes* □ *No* □ *N/A*	The QC analysis SW shall provide exportable/printable output of the MRI scanner technical performance for the following information (check all that apply): □ Site name and scanner demographics including system serial number □ Phantom scan date and DWI series numbers analyzed □ Scan protocol compliance check-list for DICOM metadata □ ADC bias at magnet isocenter □ Within-exam ADC repeatability at isocenter (RC and wCV) □ ADC linearity over range of known diffusion coefficient values (from 0.13 to 1.1) $x10^{-3}$ mm^2/s (provide list of known diffusion values for a given phantom) □ ADC *b*-value dependence □ ADC random error estimated from intra-exam sequential 4-pass DWI scans □ SNR of DWI from intra-exam sequential 4-pass DWI at b=0 □ Graphical plot and/or table of SNR of DWI estimated from intra-exam sequential 4-pass DWI at all acquired b-values □ An indication of which scanner's performance metrics pass/fail thresholds established in QIBA DWI profile □ Location of ROIs/VOIs rendered and numerically identified in color (in outline or pixel masks) superimposed on grayscale ADW or ADC maps Optional comment _____