

# Quantitative Imaging Biomarkers Alliance<sup>®</sup>



## QIBA Profile Conformance

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### Self - Attestation

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#### Document

QIBA profile title	Diffusion – weighted magnetic resonance imaging
QIBA profile version	February 05, 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	

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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.

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# 1 QIBA Conformance Statement for a Product

QIBA Conformance Statement			
Vendor	Product Name	Version	Date
Any Medical Systems Co.	AlphaScanner	V2.3, V2.4, V3.0	2017-03-12
This product conforms to all specifications required for the QIBA Profiles and Actors listed below:			
Profiles Implemented	Actors Implemented	Notes	
Diffusion – weighted MRI 02052019	Acquisition Device	See A.1	
	Image Analysis Tools	See A.2	
Links to Additional Information			
Submitter's QIBA information: <a href="http://www.anymedicalsystemsco.com/qiba">www.anymedicalsystemsco.com/qiba</a>			
General information on QIBA: <a href="http://qibawiki.rsna.org">qibawiki.rsna.org</a>			

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## **Annex A: Conformance Notes**

### **A.1 ADC change (2019) – Acquisition Device**

#### **Model-specific Instructions and Parameters**

The following parameter values were used when demonstrating conformance and are provided for reference. Other values may also achieve conformance.

Shall we include the tables for acquisition parameters for the respective organ?

## Acquisition Device Checklist

Parameter	Conforms (Y/N)	Requirement
<b>Site Qualification (Section 3.2)</b>		
Acquisition Protocols	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall be capable of storing protocols and performing scans with all the parameters set as specified in Section 3.6 "Protocol Design Specification" and Appendix D
DWI Tags	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall preserve tags related to DWI, including private tags, which may be vendor-specific. Some key tags are specified in Appendix D.
Short-term (intra-exam) ADC repeatability at/near isocenter	<input type="checkbox"/> Yes <input type="checkbox"/> No	$RC \leq 1.5 \times 10^{-5} \text{ mm}^2/\text{s}$ and $wCV \leq 0.5\%$ for ice-water phantom or other quantitative DWI phantom
Long-term (multi-day) ADC repeatability at/near isocenter	<input type="checkbox"/> Yes <input type="checkbox"/> No	$RC \leq 6.5 \times 10^{-5} \text{ mm}^2/\text{s}$ and $wCV \leq 2.2\%$ for ice-water phantom or other quantitative DWI phantom
DWI $b=0$ SNR	<input type="checkbox"/> Yes <input type="checkbox"/> No	$SNR (b=0) \geq 50 \pm 5$ for ice-water phantom or other quantitative DWI phantom.
ADC $b$ -value dependence	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 2\%$ for ice-water phantom or other quantitative DWI phantom over $b$ -value pairs 0-500; 0-900; and 0-2000 $\text{s}/\text{mm}^2$
Maximum  bias  with offset from isocenter: within 4 cm in any direction	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 4\%$ for uniform DWI phantom
R/L offset $< 10$ cm (with A/P and S/I $< 4$ cm)	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 10\%$ for uniform DWI phantom
A/P offset $< 10$ cm (with R/L and S/I $< 4$ cm)	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 10\%$ for uniform DWI phantom
S/I offset $< 5$ cm (with R/L and A/P $< 4$ cm)	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 10\%$ for uniform DWI phantom
<b>Pre-delivery (Section 3.3)</b>		

<b>Parameter</b>	<b>Conforms (Y/N)</b>	<b>Requirement</b>
Performance metrics	<input type="checkbox"/> Yes <input type="checkbox"/> No	Scanner shall meet established vendor performance metrics for given model
DWI sequence	<input type="checkbox"/> Yes <input type="checkbox"/> No	Scanner shall be capable to acquire single-shot DWI
DICOM conformance	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall be capable of performing reconstructions and producing images with all the parameters set as specified in 3.4.2 "Protocol Design Specification".
<b>Periodic QA (Section 3.5)</b>		
Periodic DWI QA	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall perform system qualification and periodic QA that includes assessment of ADC bias, random error, linearity, DWI SNR, DWI image artefacts, <i>b</i> -value dependence and spatial uniformity (3.2)
<b>Protocol Design (Section 3.6)</b>		
Scan Protocol Parameters	<input type="checkbox"/> Yes <input type="checkbox"/> No	Device scan protocol parameters shall be within organ-specific ranges listed in the protocol specification tables (3.6.2)
<b>Image Data Acquisition (Section 3.9)</b>		
Scan Procedure	<input type="checkbox"/> Yes <input type="checkbox"/> No	Study of each patient shall be performed on the site pre-qualified scanner using approved receiver coil and pre-built profile-conformant scan protocol (3.6).

## Scanner Operator Checklist

Parameter	Conforms (Y/N)	Requirement
<b>Site Qualification (section 3.2)</b>		
Acquisition Protocols	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall prepare scan protocols conformant with section 3.6.2 "Protocol Design Specification" and phantom qualification (Appendix D) and ensure that DWI acquisition parameters ( $b$ -value, diffusion direction) shall be preserved in DICOM and shall be within ranges allowed by study protocol (both for phantom and subject scans).
Acquisition Device Performance	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall perform assessment procedures (Section 4) for site qualification and longitudinal QA for the acquisition devices participating in trial to document acceptable performance for phantom ADC metrics as specified in table 3.2.2
Reconstruction SW Performance	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm that reconstruction SW is capable of performing reconstructions and producing images with all the parameters set as specified in section 3.6.2 "Protocol Design Specification" and meet DWI DICOM header and image registration requirements specified in 3.10.2, including storage of $b$ -values, DWI directionality, image scaling and units tags, as specified in DICOM conformance statement for the given scanner SW version, as well as the model-specific Reconstruction Software parameters utilized to achieve conformance.
<b>Periodic QA (section 3.5)</b>		
Periodic DWI QA	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall perform system qualification and periodic QA that includes assessment of ADC bias, random error, linearity, DWI SNR, DWI image artefacts, $b$ -value dependence and spatial uniformity (3.2.2)
<b>Protocol Design (section 3.6)</b>		
Protocol	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall check that implemented scan protocol parameters comply with the organ-specific scan protocol requirements as detailed in the profile specifications in Table 3.6.2.
<b>Image Data Acquisition (section 3.9)</b>		
Patient Positioning	<input type="checkbox"/> Yes <input type="checkbox"/> No	Predefined positioning procedure and receiver coil (e.g. always head-first or always feet-first, torso phased-array) shall be used for all study subjects. Subject-specific landmark shall be centered on the target organ, which shall be located as close as is feasible to magnet isocenter.

Parameter	Conforms (Y/N)	Requirement
Scan Parameters	<input type="checkbox"/> Yes <input type="checkbox"/> No	Subject-specific adjustments within allowed parameter ranges (Table 3.6.2) shall be made to suit body habitus. Parameter adjustments for a given subject shall be constant for serial scans.†
Acquisition Device	<input type="checkbox"/> Yes <input type="checkbox"/> No	The same scanner shall be used for baseline measurement and a subsequent longitudinal measurement for detecting change in ADC.
<b>Image Data Reconstruction (section 3.10)</b>		
Trace DWI and ADC map generation across subjects and time	<input type="checkbox"/> Yes <input type="checkbox"/> No	Procedural steps for image reconstruction, archiving of original, uncorrected images (if generated), and ADC map generation shall be held constant for all subjects and time points including: image interpolation; image registration prior to combination into trace DWI and across <i>b</i> -values; selection of <i>b</i> -values and fit algorithm to estimate ADC. ADC shall be calculated using the mono-exponential model of DWI signal decay with increasing <i>b</i> -value, starting with protocol-specific low <i>b</i> -value to compensate for perfusion effects.
<i>b</i> -value record	<input type="checkbox"/> Yes <input type="checkbox"/> No	Scanner operator shall verify that the reconstruction SW records <i>b</i> -values, or if not shall manually record the <i>b</i> -values, that are used to generate the ADC map.
<b>Image QA (section 3.11)</b>		
ADC quality	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm DWI and ADC maps conform to adequate quality specifically considering points listed above (3.11.1) and shall exclude artefact-rich images and ROI from repeatability analysis.
<b>Image Distribution (section 3.12)</b>		
Trace DWI	<input type="checkbox"/> Yes <input type="checkbox"/> No	All trace DWI at each acquired <i>b</i> -value shall be stored in local PACS and distributed to image analysis workstation(s)
ADC maps	<input type="checkbox"/> Yes <input type="checkbox"/> No	ADC maps generated on the MRI scanner shall be stored in local PACS and distributed to image analysis workstation(s) with preserved DICOM scale tags. ADC map scale/units and <i>b</i> -values used for generation shall be recorded.
Image DICOM	<input type="checkbox"/> Yes <input type="checkbox"/> No	DICOM tags essential for downstream review and diffusion analysis shall be maintained including, pixel intensity scaling*, <i>b</i> -value, and DWI directionality vs trace, and ADC scale and units. Trace DWI DICOM at each acquired <i>b</i> -value shall be archived in the local PACS.

\*Chenevert, T.L., et al., *Errors in Quantitative Image Analysis due to Platform-Dependent Image Scaling*. *Transl Oncol*, 2014. **7**(1): p. 65-71.



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## Reconstruction Software Checklist

<b><i>Image Data Reconstruction (Section 3.10)</i></b>		
Trace DWI	<input type="checkbox"/> Yes <input type="checkbox"/> No	Trace DWI shall be auto-generated on the scanner and retained for all $b > 0$ . For equal $b$ -value on 3 orthogonal directions, trace DWI is the geometric average of the 3-orthogonal directional DWI.
DICOM DWI	<input type="checkbox"/> Yes <input type="checkbox"/> No	Exported DWI DICOM shall provide acquired $b$ -values and directionality.
Spatial Registration	<input type="checkbox"/> Yes <input type="checkbox"/> No	Spatial misalignment between directional DWI and across $b$ -values due to eddy currents or patient motion shall be corrected by image registration prior to generation of trace DWI and ADC maps.

## A.2 ADC change (2019) – Image Analysis Software

### Image Analyst Checklist

Parameter	Conforms (Y/N)	Requirement
<b>Staff Qualification (section 3.1)</b>		
Qualification	<input type="checkbox"/> Yes <input type="checkbox"/> No	May be a radiologist, technologist, physicist, or other scientist that shall undergo documented training by a qualified radiologist in terms of anatomical location and image contrast(s) used to select measurement target; and by qualified physicist in understanding key DWI acquisition principles of diffusion weighting and directionality and diffusion test procedures, procedures to confirm that diffusion-related DICOM metadata content is maintained along the network chain from Scanner to PACS and analysis workstation and in use of the Image Analysis Tool, including ADC map generation from DWI (if not generated on the scanner), and ADC map reduction to statistics with ROI/VOI location(s)
<b>Site Qualification (section 3.2)</b>		
Image Analysis Tool Performance	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall test Image Analysis Tool to ensure acceptable performance according to 3.13.2 specifications for study image visualization, DICOM and analysis meta-data interpretation and storage, ROI segmentation, and generation of ADC maps and repeatability statistics for qualification phantom (below)
Phantom ADC ROI	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm that phantom ADC ROI is 1-2 cm diameter (>80 pixels without interpolation) for all Acquisition Device specifications in Table 3.2.2
Phantom ADC metrics	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall evaluate and record phantom ADC metrics (bias, linearity and precision) according to Table 3.2.2 specifications for Acquisition Device qualification and periodic QA using QIBA-provided or qualified site Image Analysis Tool
<b>Image QA (section 3.11)</b>		
ADC quality	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm DWI and ADC maps conform to adequate quality specifically considering points listed above (3.11.1) and shall exclude artefact-rich images and ROI from repeatability analysis.
<b>Image Distribution (section 3.12)</b>		

Parameter	Conforms (Y/N)	Requirement
Trace DWI	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall ensure that all trace DWI at each acquired <i>b</i> -value shall be stored in local PACS and distributed to image analysis workstation(s)
ADC maps	<input type="checkbox"/> Yes <input type="checkbox"/> No	ADC maps generated on the MRI scanner shall be stored in local PACS and distributed to image analysis workstation(s) with preserved DICOM scale tags. ADC map scale/units and <i>b</i> -values used for generation shall be recorded.
Image DICOM	<input type="checkbox"/> Yes <input type="checkbox"/> No	DICOM tags essential for downstream review and diffusion analysis shall be maintained including, pixel intensity scaling [113], <i>b</i> -value, and DWI directionality vs trace, and ADC scale and units. Trace DWI DICOM at each acquired <i>b</i> -value shall be archived in the local PACS.
<b>Image Analysis (section 3.13)</b>		
ROI Determination	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall segment the ROI on ADC maps consistently across time points using the same software / analysis package guided by a fixed set of image contrasts and avoiding artefacts

## Image Analysis Tool Checklist

**ACCEPTABLE:** Actors that shall meet this specification to conform to this profile.

**TARGET:** Meeting this specification is achievable with reasonable effort and adequate equipment and is expected to provide better results than meeting the ACCEPTABLE specification.

**IDEAL:** Meeting this specification may require extra effort or non-standard hardware or software, but is expected to provide better results than meeting the TARGET.

Parameter	Conforms (Y/N)	Requirement
<b>Image Analysis (section 3.13)</b>		
ROI geometry	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p><i>Acceptable: Screen-shot(s) documenting ROI placement on ADC maps shall be retained in the subject database for future reference</i></p> <p><i>Target: ROI as a binary pixel mask in image coordinates shall be retained in the subject database for future reference</i></p> <p><i>Ideal: ROI shall be saved as a DICOM segment object</i></p>
Image Display	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Acceptable / Target: Software shall allow operator-defined ROI analysis of DWI/ADC aided by inspection of ancillary MR contrasts</p> <p>Ideal: Above plus multi view-port display where DWI/ADC and ancillary MR contrasts from the same scan date are displayed side-by-side and geometrically linked per DICOM (e.g., cursor; cross-hair; ROI; automatically replicated in all view-ports); images from different scan date(s) can be displayed side-by-side, though not necessarily geometrically linked; and ROIs/VOIs may include multiple noncontiguous areas on one slice and/or over multiple slices</p>
Analysis Procedure	<input type="checkbox"/> Yes <input type="checkbox"/> No	Analysis steps, derived metrics and analysis software package shall be held constant for all subjects and serial time points
ADC statistics	<input type="checkbox"/> Yes	Acceptable/Target: Shall allow display and retention of ROI statistics in patient DICOM database (PACS). Statistics shall include: ADC mean, standard deviation, and ROI/VOI area/volume

Parameter	Conforms (Y/N)	Requirement
	<input type="checkbox"/> <i>No</i>	Ideal: ADC pixel histogram, additional statistics for ADC maximum, minimum, explicit inclusion vs exclusion of “NaNs” or zero-valued pixels shall be retained with the statistics
ADC scaling	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	ADC maps scale and units shall be recorded. The difference(s) in mean ADC within replicate ROIs defined on the scanner and analysis workstation(s) shall be less than the ROI standard deviation of the ADC.
ADC map storage	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Acceptable/Target: offline generated ADC maps shall be stored in ITK-compatible format (e.g., NIFTI or MHD) with meta-data traceable to original DWI DICOM (and geometry)  Ideal: parametric map DICOM)
Fit algorithm type	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	The specific choice of the fit algorithm shall be recorded, held constant within a study and reported with any dissemination of study findings.
Fit algorithm bias	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	For offline ADC map generation, the mean ADC shall agree with scanner-generated, or DRO ground truth, ADC values to within one ROI standard deviation.
<i>b</i> -value and direction	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Software shall extract <i>b</i> -values and diffusion axis direction from DICOM header

## 2 QIBA Conformance Statement for a Site

QIBA Conformance Statement		
Site Name	Responsible Person	Date
Mercy General Hospital – Oncology Dept.	Dr. Marcus Welby	2015-03-12
This site conforms to all specifications required for the QIBA Profiles and Actors listed below:		
Profiles Implemented	Actors Implemented	Notes
ADC change (2019)	Scanner operator	See A.1
	Image Analyst	See A.2
	Site	See A.3
Links to Additional Information		
Submitter's QIBA information: <a href="http://www.anymedicalsystemsco.com/qiba">www.anymedicalsystemsco.com/qiba</a>		
General information on QIBA: <a href="http://qibawiki.rsna.org">qibawiki.rsna.org</a>		

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## **Annex A: Conformance Notes**

### **A.1 ADC change (2019) – Scanner operator**

All scanner operators assigned to use this scanner received training that included details of this Profile. Periodic spot checks confirm they continue to follow the profile details.

### **A.2 ADC change (2019) – Image analyst**

All image analysts have

- Reviewed the quality assurance guidelines described in section 3.4 of the profile
- Completed the performance assessment described in section 4.4 of the profile and met or exceeded the target in section 3.5 of the profile

### **A.3 ADC change (2019)– Site**

List of rooms/device instances that are included in this claim.

Or do we add a section to the Table above where the devices are listed, e.g. in the Instrumentation/Devices section.

## Site Checklist

Parameter	Conforms (Y/N)	Requirement
<b>Site Qualification (Section 3.2)</b>		
<i>Qualification activities</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall perform qualification activities for Acquisition Device, Scanner Operator, and Image Analyst to meet equipment, reconstruction SW, image analysis tool and phantom ADC performance metrics as specified in Table 3.2.2 and by trial-specific protocol 3.6.2
<b>Periodic QA (Section 3.5)</b>		
Periodic DWI QA	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall perform periodic QA for Acquisition Device that includes assessment of ADC bias, random error, linearity, DWI SNR, DWI image artefacts, <i>b</i> -value dependence (linearity) and spatial uniformity (3.2.2)
<i>Equipment</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Same, pre-qualified equipment and SW shall be used over the length of trial, and all preventive maintenance shall be documented over the course of the trial. Re-qualification shall be performed in case of major SW or hardware upgrade.



## Acquisition Device Checklist

Parameter	Conforms (Y/N)	Requirement
<b>Site Qualification (Section 3.2)</b>		
Acquisition Protocols	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall be capable of storing protocols and performing scans with all the parameters set as specified in Section 3.6 "Protocol Design Specification" and Appendix D
DWI Tags	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall preserve tags related to DWI, including private tags, which may be vendor-specific. Some key tags are specified in Appendix D.
Short-term (intra-exam) ADC repeatability at/near isocenter	<input type="checkbox"/> Yes <input type="checkbox"/> No	$RC \leq 1.5 \times 10^{-5} \text{ mm}^2/\text{s}$ and $wCV \leq 0.5\%$ for ice-water phantom or other quantitative DWI phantom
Long-term (multi-day) ADC repeatability at/near isocenter	<input type="checkbox"/> Yes <input type="checkbox"/> No	$RC \leq 6.5 \times 10^{-5} \text{ mm}^2/\text{s}$ and $wCV \leq 2.2\%$ for ice-water phantom or other quantitative DWI phantom
DWI $b=0$ SNR	<input type="checkbox"/> Yes <input type="checkbox"/> No	$SNR (b=0) \geq 50 \pm 5$ for ice-water phantom or other quantitative DWI phantom.
ADC $b$ -value dependence	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 2\%$ for ice-water phantom or other quantitative DWI phantom over $b$ -value pairs 0-500; 0-900; and 0-2000 $\text{s}/\text{mm}^2$
Maximum  bias  with offset from isocenter: within 4 cm in any direction	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 4\%$ for uniform DWI phantom
R/L offset $< 10$ cm (with A/P and S/I $< 4$ cm)	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 10\%$ for uniform DWI phantom
A/P offset $< 10$ cm (with R/L and S/I $< 4$ cm)	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 10\%$ for uniform DWI phantom
S/I offset $< 5$ cm (with R/L and A/P $< 4$ cm)	<input type="checkbox"/> Yes <input type="checkbox"/> No	$< 10\%$ for uniform DWI phantom
<b>Pre-delivery (Section 3.3)</b>		

<b>Parameter</b>	<b>Conforms (Y/N)</b>	<b>Requirement</b>
Performance metrics	<input type="checkbox"/> Yes <input type="checkbox"/> No	Scanner shall meet established vendor performance metrics for given model
DWI sequence	<input type="checkbox"/> Yes <input type="checkbox"/> No	Scanner shall be capable to acquire single-shot DWI
DICOM conformance	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall be capable of performing reconstructions and producing images with all the parameters set as specified in 3.4.2 "Protocol Design Specification".
<b>Periodic QA (Section 3.5)</b>		
Periodic DWI QA	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall perform system qualification and periodic QA that includes assessment of ADC bias, random error, linearity, DWI SNR, DWI image artefacts, <i>b</i> -value dependence and spatial uniformity (3.2)
<b>Protocol Design (Section 3.6)</b>		
Scan Protocol Parameters	<input type="checkbox"/> Yes <input type="checkbox"/> No	Device scan protocol parameters shall be within organ-specific ranges listed in the protocol specification tables (3.6.2)
<b>Image Data Acquisition (Section 3.9)</b>		
Scan Procedure	<input type="checkbox"/> Yes <input type="checkbox"/> No	Study of each patient shall be performed on the site pre-qualified scanner using approved receiver coil and pre-built profile-conformant scan protocol (3.6).

## Scanner Operator Checklist

Parameter	Conforms (Y/N)	Requirement
<b>Site Qualification (section 3.2)</b>		
Acquisition Protocols	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall prepare scan protocols conformant with section 3.6.2 "Protocol Design Specification" and phantom qualification (Appendix D) and ensure that DWI acquisition parameters ( $b$ -value, diffusion direction) shall be preserved in DICOM and shall be within ranges allowed by study protocol (both for phantom and subject scans).
Acquisition Device Performance	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall perform assessment procedures (Section 4) for site qualification and longitudinal QA for the acquisition devices participating in trial to document acceptable performance for phantom ADC metrics as specified in table 3.2.2
Reconstruction SW Performance	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm that reconstruction SW is capable of performing reconstructions and producing images with all the parameters set as specified in section 3.6.2 "Protocol Design Specification" and meet DWI DICOM header and image registration requirements specified in 3.10.2, including storage of $b$ -values, DWI directionality, image scaling and units tags, as specified in DICOM conformance statement for the given scanner SW version, as well as the model-specific Reconstruction Software parameters utilized to achieve conformance.
<b>Periodic QA (section 3.5)</b>		
Periodic DWI QA	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall perform system qualification and periodic QA that includes assessment of ADC bias, random error, linearity, DWI SNR, DWI image artefacts, $b$ -value dependence and spatial uniformity (3.2.2)
<b>Protocol Design (section 3.6)</b>		
Protocol	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall check that implemented scan protocol parameters comply with the organ-specific scan protocol requirements as detailed in the profile specifications in Table 3.6.2.
<b>Image Data Acquisition (section 3.9)</b>		
Patient Positioning	<input type="checkbox"/> Yes <input type="checkbox"/> No	Predefined positioning procedure and receiver coil (e.g. always head-first or always feet-first, torso phased-array) shall be used for all study subjects. Subject-specific landmark shall be centered on the target organ, which shall be located as close as is feasible to magnet isocenter.

Parameter	Conforms (Y/N)	Requirement
Scan Parameters	<input type="checkbox"/> Yes <input type="checkbox"/> No	Subject-specific adjustments within allowed parameter ranges (Table 3.6.2) shall be made to suit body habitus. Parameter adjustments for a given subject shall be constant for serial scans.†
Acquisition Device	<input type="checkbox"/> Yes <input type="checkbox"/> No	The same scanner shall be used for baseline measurement and a subsequent longitudinal measurement for detecting change in ADC.
<b>Image Data Reconstruction (section 3.10)</b>		
Trace DWI and ADC map generation across subjects and time	<input type="checkbox"/> Yes <input type="checkbox"/> No	Procedural steps for image reconstruction, archiving of original, uncorrected images (if generated), and ADC map generation shall be held constant for all subjects and time points including: image interpolation; image registration prior to combination into trace DWI and across <i>b</i> -values; selection of <i>b</i> -values and fit algorithm to estimate ADC. ADC shall be calculated using the mono-exponential model of DWI signal decay with increasing <i>b</i> -value, starting with protocol-specific low <i>b</i> -value to compensate for perfusion effects.
<i>b</i> -value record	<input type="checkbox"/> Yes <input type="checkbox"/> No	Scanner operator shall verify that the reconstruction SW records <i>b</i> -values, or if not shall manually record the <i>b</i> -values, that are used to generate the ADC map.
<b>Image QA (section 3.11)</b>		
ADC quality	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm DWI and ADC maps conform to adequate quality specifically considering points listed above (3.11.1) and shall exclude artefact-rich images and ROI from repeatability analysis.
<b>Image Distribution (section 3.12)</b>		
Trace DWI	<input type="checkbox"/> Yes <input type="checkbox"/> No	All trace DWI at each acquired <i>b</i> -value shall be stored in local PACS and distributed to image analysis workstation(s)
ADC maps	<input type="checkbox"/> Yes <input type="checkbox"/> No	ADC maps generated on the MRI scanner shall be stored in local PACS and distributed to image analysis workstation(s) with preserved DICOM scale tags. ADC map scale/units and <i>b</i> -values used for generation shall be recorded.
Image DICOM	<input type="checkbox"/> Yes <input type="checkbox"/> No	DICOM tags essential for downstream review and diffusion analysis shall be maintained including, pixel intensity scaling*, <i>b</i> -value, and DWI directionality vs trace, and ADC scale and units. Trace DWI DICOM at each acquired <i>b</i> -value shall be archived in the local PACS.

\*Chenevert, T.L., et al., *Errors in Quantitative Image Analysis due to Platform-Dependent Image Scaling*. Transl Oncol, 2014. 7(1): p. 65-71.

## Image Analyst Checklist

Parameter	Conforms (Y/N)	Requirement
<b>Staff Qualification (section 3.1)</b>		
Qualification	<input type="checkbox"/> Yes <input type="checkbox"/> No	May be a radiologist, technologist, physicist, or other scientist that shall undergo documented training by a qualified radiologist in terms of anatomical location and image contrast(s) used to select measurement target; and by qualified physicist in understanding key DWI acquisition principles of diffusion weighting and directionality and diffusion test procedures, procedures to confirm that diffusion-related DICOM metadata content is maintained along the network chain from Scanner to PACS and analysis workstation and in use of the Image Analysis Tool, including ADC map generation from DWI (if not generated on the scanner), and ADC map reduction to statistics with ROI/VOI location(s)
<b>Site Qualification (section 3.2)</b>		
Image Analysis Tool Performance	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall test Image Analysis Tool to ensure acceptable performance according to 3.13.2 specifications for study image visualization, DICOM and analysis meta-data interpretation and storage, ROI segmentation, and generation of ADC maps and repeatability statistics for qualification phantom (below)
Phantom ADC ROI	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm that phantom ADC ROI is 1-2 cm diameter (>80 pixels without interpolation) for all Acquisition Device specifications in Table 3.2.2
Phantom ADC metrics	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall evaluate and record phantom ADC metrics (bias, linearity and precision) according to Table 3.2.2 specifications for Acquisition Device qualification and periodic QA using QIBA-provided or qualified site Image Analysis Tool
<b>Image QA (section 3.11)</b>		
ADC quality	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall confirm DWI and ADC maps conform to adequate quality specifically considering points listed above (3.11.1) and shall exclude artefact-rich images and ROI from repeatability analysis.
<b>Image Distribution (section 3.12)</b>		
Trace DWI	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall ensure that all trace DWI at each acquired $b$ -value shall be stored in local PACS and distributed to image analysis workstation(s)

Parameter	Conforms (Y/N)	Requirement
ADC maps	<input type="checkbox"/> Yes <input type="checkbox"/> No	ADC maps generated on the MRI scanner shall be stored in local PACS and distributed to image analysis workstation(s) with preserved DICOM scale tags. ADC map scale/units and <i>b</i> -values used for generation shall be recorded.
Image DICOM	<input type="checkbox"/> Yes <input type="checkbox"/> No	DICOM tags essential for downstream review and diffusion analysis shall be maintained including, pixel intensity scaling [113], <i>b</i> -value, and DWI directionality vs trace, and ADC scale and units. Trace DWI DICOM at each acquired <i>b</i> -value shall be archived in the local PACS.
<b>Image Analysis (section 3.13)</b>		
ROI Determination	<input type="checkbox"/> Yes <input type="checkbox"/> No	Shall segment the ROI on ADC maps consistently across time points using the same software / analysis package guided by a fixed set of image contrasts and avoiding artefacts

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## Reconstruction Software

<b><i>Image Data Reconstruction (Section 3.10)</i></b>		
Trace DWI	<input type="checkbox"/> Yes <input type="checkbox"/> No	Trace DWI shall be auto-generated on the scanner and retained for all $b > 0$ . For equal $b$ -value on 3 orthogonal directions, trace DWI is the geometric average of the 3-orthogonal directional DWI.
DICOM DWI	<input type="checkbox"/> Yes <input type="checkbox"/> No	Exported DWI DICOM shall provide acquired $b$ -values and directionality.
Spatial Registration	<input type="checkbox"/> Yes <input type="checkbox"/> No	Spatial misalignment between directional DWI and across $b$ -values due to eddy currents or patient motion shall be corrected by image registration prior to generation of trace DWI and ADC maps.

## Image Analysis Tool Checklist

**ACCEPTABLE:** Actors that shall meet this specification to conform to this profile.

**TARGET:** Meeting this specification is achievable with reasonable effort and adequate equipment and is expected to provide better results than meeting the ACCEPTABLE specification.

**IDEAL:** Meeting this specification may require extra effort or non-standard hardware or software, but is expected to provide better results than meeting the TARGET.

Parameter	Conforms (Y/N)	Requirement
<b>Image Analysis (section 3.13)</b>		
ROI geometry	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p><i>Acceptable: Screen-shot(s) documenting ROI placement on ADC maps shall be retained in the subject database for future reference</i></p> <p><i>Target: ROI as a binary pixel mask in image coordinates shall be retained in the subject database for future reference</i></p> <p><i>Ideal: ROI shall be saved as a DICOM segment object</i></p>
Image Display	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Acceptable / Target: Software shall allow operator-defined ROI analysis of DWI/ADC aided by inspection of ancillary MR contrasts</p> <p>Ideal: Above plus multi view-port display where DWI/ADC and ancillary MR contrasts from the same scan date are displayed side-by-side and geometrically linked per DICOM (e.g., cursor; cross-hair; ROI; automatically replicated in all view-ports); images from different scan date(s) can be displayed side-by-side, though not necessarily geometrically linked; and ROIs/VOIs may include multiple noncontiguous areas on one slice and/or over multiple slices</p>
Analysis Procedure	<input type="checkbox"/> Yes <input type="checkbox"/> No	Analysis steps, derived metrics and analysis software package shall be held constant for all subjects and serial time points
ADC statistics	<input type="checkbox"/> Yes	Acceptable/Target: Shall allow display and retention of ROI statistics in patient DICOM database (PACS). Statistics shall include: ADC mean, standard deviation, and ROI/VOI area/volume



Parameter	Conforms (Y/N)	Requirement
	<input type="checkbox"/> <i>No</i>	Ideal: ADC pixel histogram, additional statistics for ADC maximum, minimum, explicit inclusion vs exclusion of “NaNs” or zero-valued pixels shall be retained with the statistics
ADC scaling	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	ADC maps scale and units shall be recorded. The difference(s) in mean ADC within replicate ROIs defined on the scanner and analysis workstation(s) shall be less than the ROI standard deviation of the ADC.
ADC map storage	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Acceptable/Target: offline generated ADC maps shall be stored in ITK-compatible format (e.g., NIFTI or MHD) with meta-data traceable to original DWI DICOM (and geometry)  Ideal: parametric map DICOM)
Fit algorithm type	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	The specific choice of the fit algorithm shall be recorded, held constant within a study and reported with any dissemination of study findings.
Fit algorithm bias	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	For offline ADC map generation, the mean ADC shall agree with scanner-generated, or DRO ground truth, ADC values to within one ROI standard deviation.
<i>b</i> -value and direction	<input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Software shall extract <i>b</i> -values and diffusion axis direction from DICOM header