



QIBA profile conformance testing

DWI MR

Supplement 1

Version 20210401

MRI System DWI Profile Conformance Assessment

Using the QIBA DWI Phantom

Version 20210331

I. INTRODUCTION

Conformance to the QIBA DWI Profile requires objective assessment of an MRI scanner in performing quantitative DWI measurements. The QIBA DWI phantom provides an array of samples having known diffusion coefficients for quantitative comparison to ADC values generated by the MR system. The following procedure outlines DWI phantom preparation, data acquisition, ADC map generation, data analysis and target performance levels to achieve conformance with the DWI Profile. These procedures may be used by MRI system vendors for conformance testing their platforms, as well by imaging centers evaluating individual MR scanners.

II. PHANTOM PREPARATION

Note: Once at thermal equilibrium with ice water, the QIBA DWI phantom is usable for only 1-2 hours. Coordinate phantom preparation to be within 1-2 prior to DWI scan session.

Since diffusion is sensitive to temperature, absolute quantitation of systematic bias requires temperature control. Once at thermal equilibrium, an ice water bath serves to maintain phantom temperature at 0°C thereby establishing known diffusivities.

Required Materials (Figure 1):

1. QIBA DWI Phantom is commercially available at <https://www.qalibre-md.com/diffusion-phantom/> and contains 13 vials of polyvinylpyrrolidone (PVP) at various concentrations. An Allen wrench is provided to remove 6 plastic bolts on each polar cap and a coin-like disk to loosen plastic fill-port plug in center of each polar cap.
2. At least 2 containers to serve as ice-buckets.
3. Five to 6 liters of ice cubes, ice chips or crushed ice. A '10pound bag of ice' from a convenience store would suffice.
4. Sink basin and source of tap water (or de-ionized water) for phantom filling.
5. Insulated bag (provided with phantom) to hold phantom prior to scanning.
6. Digital thermometer (provided with phantom).

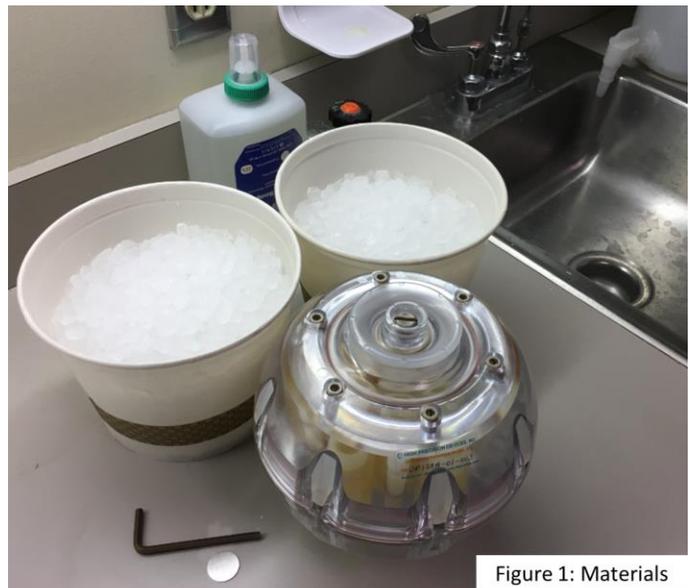


Figure 1: Materials

Initial Cooling:

1. It is preferred the phantom be pre-cooled prior to final fill with ice water slurry, otherwise the phantom may not reach 0°C and/or its usable ice hold-time is shortened. Pre-cooling can be achieved by either of:
 - a. Store phantom for over 5 hours in a standard refrigerator (typically 37°F or at 3°C), but *not in a freezer!* Remove phantom from refrigerator and immediately move onto “Final Cooling” step.
 - b. Fill an ice bucket with ice and approximately equal volume of cold water. Confirm 6 plastic Allen bolts are gently and evenly tightened on one polar cap and remove 6 plastic Allen bolts and polar cap on the other side of phantom. Place phantom in the sink basin and fill with the ice water slurry. Roll the phantom back and forth slightly so water (and some ice) fills both sides of the phantom. Allow the filled phantom to sit for approximately 15minutes. Empty phantom of ice water slurry and immediately move onto “Final Cooling” step.
 - c. If size of ice bucket container is large enough to submerge the phantom, fill the container with ice, then add cold water. Remove both polar caps and submerge the phantom in the ice water slurry. Roll the phantom back and forth to fill both sides with ice water. Allow the phantom to sit submerged for 15minutes. Empty phantom of ice water slurry and immediately move onto “Final Cooling” step.

Final Cooling:

1. Fill the first ice bucket with ice, then fill to top with cold water and set aside.
2. Immediately after initial cooling step, remove *both* polar caps of the phantom (6 Allen bolts each). Confirm large O-rings under each polar cap are properly seated in grooves.
3. In one side of the phantom, pack in ice cubes/chips to the brim (Figure 2a). Shake the phantom to distribute ice in available spaces and, if possible, pack in more ice. Confirm the large O-ring is properly seated in groove and install polar cap on the ice-packed side. Gently tighten 6 Allen bolts evenly and confirm the fill-port plug is tight – but do not over tighten!
4. In the other side of the phantom, pack in ice cubes/chips to the brim (Figure 2a). Shake the phantom to distribute ice in available spaces and, if possible, pack in more ice. *Do not install the polar cap yet.*
5. Pour ice water from the first ice bucket into the open polar cap. Roll phantom back and forth so water fills both sides of the phantom. Add more ice water to fill to the brim (Figure 2b).
6. Inspect capped side of the phantom to confirm water has not leaking out. If water is leaking, gently and evenly tighten Allen bolts only enough to stop the leak – do not over tighten.
7. Confirm the large O-ring is properly seated in groove and install the top polar cap aligning holes. Gently tighten bolts evenly – do not over tighten! Roll phantom over to confirm water is not leaky out of either polar cap. If water is leaking, gently and evenly tighten Allen bolts to stop the leak – do not over tighten.
8. Shake and roll phantom to get air bubbles to one polar end. Use metal disk (or coin) to remove plastic fill-port and add ice water through plug hole to displace air bubbles. Replace the plug and gently tighten.
9. Wipe off water from surface of the phantom and do final

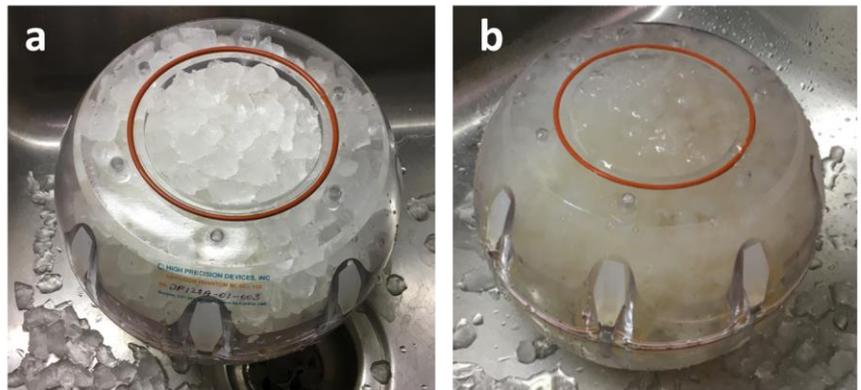


Figure 2: (a) Pack ice in both halves of pre-cooled phantom, then (b) fill with ice water.

inspection for leaks.

10. Place phantom in insulated bag (or refrigerator) and ***allow to sit for an additional hour*** to reach thermal equilibrium at 0°C prior to MRI scan.

III. PHANTOM IMAGING

The ice water-filled DWI phantom may develop surface condensation. To prevent condensate from reaching scanner components, wrap phantom in plastic, absorbent material (e.g. hospital 'blue pads') or set on towels. For visual clarity, the phantom is illustrated without absorbent wraps in Figure 3.

Positioning:

1. Start a "New Examination" and enter subject as "Head-First, Supine".
2. Indicate "QIBA DWI Profile Conformance Testing" in Exam Description or comment field.
3. Place phantom on/within blue pads or towels (not shown) to keep condensate off MRI components. Use pads to secure the phantom in the center of the head coil.
4. Have polar caps aligned along foot-head axis (Figure 3a) with serial number sticker on foot-end, posterior side (Figure 3b). Landmark on the center of the phantom (Figure 3c).

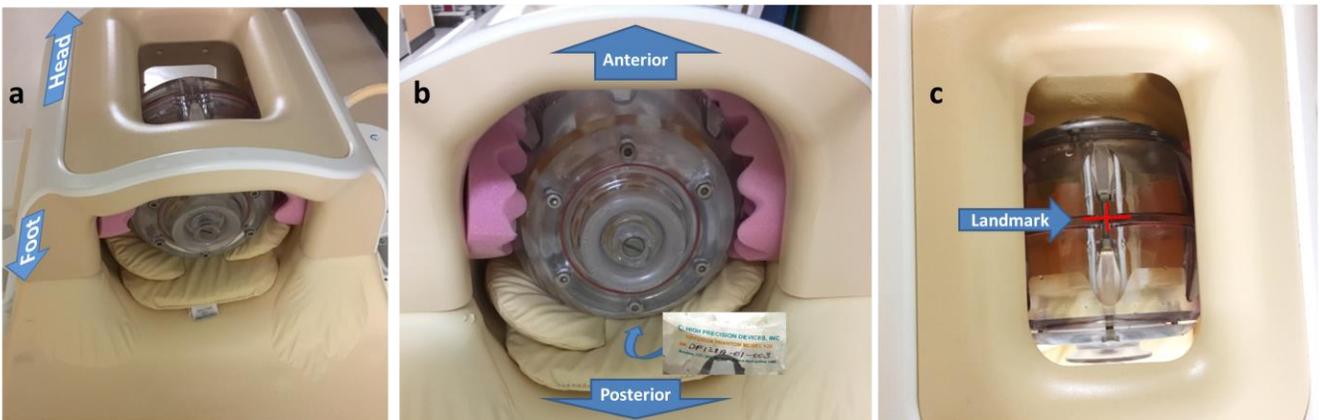


Figure 3: (a) Position the DWI phantom on pads in the head coil such that polar caps are aligned along the foot/head axis, and (b) the serial number sticker is on the foot-end facing down (i.e. posterior). (c) Landmark on the center of the phantom as shown.

Scanning:

1. Survey - Acquire survey series that includes axial, sagittal and coronal sections through the middle of the phantom. Site-preference is acceptable and specific acquisition parameters are not crucial for survey.
2. T2WT - Acquire a T2-weighted axial multi-slice series taken from site's routine brain protocol. Acquire approximately 35 axial slices to span the full extent of the phantom, other acquisition parameters are not crucial.

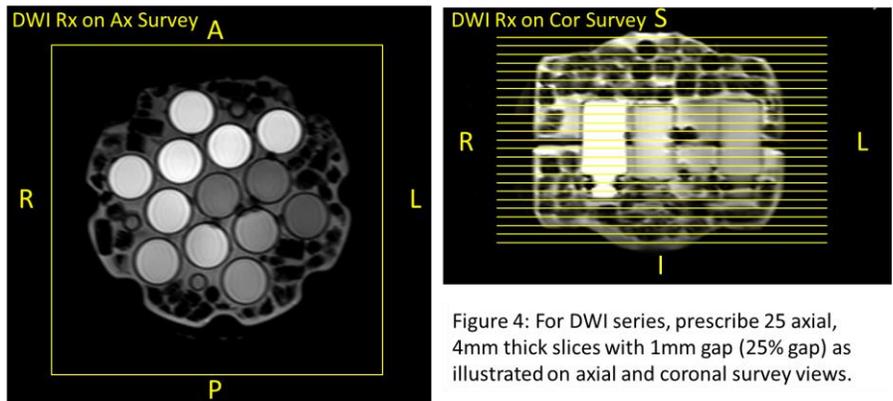


Figure 4: For DWI series, prescribe 25 axial, 4mm thick slices with 1mm gap (25% gap) as illustrated on axial and coronal survey views.

QIBA Profile Conformance Testing – DWI MR

3. DWI PASS1 – Include “PASS1” in the series description. Using parameters in Table 1, graphically prescribe 25 axial DWI slices as shown in Figure 4.
4. Acquire “DWI PASS1” using specific acquisition parameters given in Table 1. Use the shim routine expected to yield best magnetic field uniformity over full extent of the DWI phantom. Allow the system to perform a “full prescan calibration” (i.e. allow system to optimize hardware, shim, center frequency, transmit power, and receiver-gain or signal-scale settings).
5. DWI PASS2 – “Copy-Paste” PASS1 series and insert “PASS2” in series description. **Do not** change acquisition conditions or calibration, that is avoid full prescan re-calibration. Acquire “DWI PASS2”.
6. DWI PASS3 – “Copy-Paste” PASS2 series and insert “PASS3” in series description. **Do not** change acquisition conditions or calibration, that is avoid full prescan re-calibration. Acquire “DWI PASS3”.
7. DWI PASS4 – “Copy-Paste” PASS2 series and insert “PASS4” in series description. **Do not** change acquisition conditions or calibration, that is avoid full prescan re-calibration. Acquire “DWI PASS4”.
8. Generate ADC Maps – Using software available on the MRI system, generate ADC maps from DWI PASS1, 2, 3, 4. Use all b-values and a mono-exponential model (the standard) for ADC map creation.
9. DICOM – Archive the exam in local PACS/media as usual. In addition, export the exam in “Classic DICOM” format retaining all DICOM tags. That is, avoid processing the exam through a “de-identification” routine that may remove some DICOM tags.

Table 1: DWI Acquisition Parameters

Parameter	Value
Field Strength	1.5T or 3T
Receiver Coil	Head coil \geq 8 elements
Sequence	DWI EPI, Single Spin-Echo or Mono-Polar
Slice Orientation	Axial
FOV	220mm x 220mm
Acq Voxel Size	1.72 x 1.72 x 4mm
Acq Matrix (frequency x phase)	128 x 128 \pm 2
Recon Voxel Size	(0.86 x 0.86 x 4mm) to (1.72 x 1.72 x 4mm)
Recon Matrix	(128 x 128) to (256 x 256)
Parallel imaging Acceleration	Yes, factor = 2
Phase Encode Direction	Anterior - Posterior
Frequency Encode Direction	Right - Left
Foldover-suppr. / Oversampling	Off or default
Number of Slices	25
Stacks or Packages	1
Slice thickness	4mm
Slice gap	1mm or 25% of slice thickness
B0 Shim	Best quality volume shim routine
B1 Shim	Off or default
Scan Mode	Multislice
Technique	Spin Echo
Fast Imaging Mode	Echo Planar Imaging
Shot Mode / Number of shots	Single-shot
Echoes	1
Partial Echo	Off
TE	Shortest
Flip Angle	90deg
TR	8000ms
Halfscan (partial-Fourier) factor	\geq 0.75
Water-fat shift	Minimum
Fat suppression	Off or default, but do not perform "STIR"
Diffusion Encoding Directions	Three orthogonal
b-values	0 [§] , 500, 1000, 1500, 2000 s/mm ²
Average High b-values	Off
Gradient Mode	Maximum
NSA (number of averages)	2
Preparation phases	Full prep PASS1; Auto prep or manual prep with no adjustments PASS2, 3, 4
Geometry Correction	Default
Bandwidth in Freq-dir	Maximum
Scan Duration (min:sec)	\leq 3:40 per pass or \leq 15:00 total for 4 passes

[§] If b=0 cannot be acquired, keep lowest b-value \leq 50 s/mm²

IV. IMAGE ANALYSIS & PERFORMANCE METRICS

A suite of Matlab routines were developed to convert the QIBA DWI exam data from Classic DICOM into uniform data structures and identify PVP sample tubes for extraction of region and volume of interest (ROI and VOI) statistics. The manner DWI DICOM are sorted varies across vendors, local configuration and software version, therefore the processing routines were designed to first catalog the full exam so each “trace” DWI series can be identified. In the event trace DWI at all b-values are not combined in one series (per PASS), or trace DWI are mixed with individual directional DWI, additional pre-processing steps are required. Details in use of these analysis tools are outlined in section V of this document.

Sites may elect to perform their own analysis using another image analysis platform. Procedures to follow and benchmark levels for conformant performance are provided below.

1. Qualitative Inspection – Analysis shall be performed on trace DWI (geometric mean of three orthogonal directional DWI) at each b-value and each “PASS”. Identify the 4 trace DWI series and confirm each series contains trace DWI at each of 5 b-values. Inspect trace DWI for evidence of eddy currents. Single-shot EPI DWI tend to be spatially distorted due to magnetic field inhomogeneity (particularly near air bubbles), though eddy currents create incremental unique distortion for each diffusion encoding direction. These manifest as spatial blur in trace DWI formed by the geometric mean of miss-aligned directional DWI. Spatial blur in trace DWI that increases with b-value and/or distance from magnet iso-center are further evidence of eddy currents. Eddy currents are sometimes easier to detect as bright/dark edge artifacts on ADC maps. Inspect trace DWI/ADC for evidence of eddy currents, any other major discrete artifact, as well as significant spatial shift in the A/P direction (i.e. phase-encode direction) across PASSES 1-4 due to system drift. The DWI DICOM header should be inspected to ensure reasonable conformance to the scan protocol parameters in Table 1.
2. Quantitative Analysis – Create ADC maps from trace DWI b-value pairs denoted by subscripts, $ADC_{0,500}$; $ADC_{0,1000}$; $ADC_{0,1500}$ and $ADC_{0,2000}$ via the standard mono-exponential model for individual image pixels,

$$ADC_{b1,b2} = \frac{1}{(b2-b1)} \ln \left(\frac{DWI_{b1}}{DWI_{b2}} \right). \quad \text{Eq1}$$

The objective is to define one set of 10 to 15mm diameter circular ROIs centered in each measurement tube and apply these ROIs to all DWI and ADC over all 4 passes. In addition, if the analysis software allows combination of ROIs for a given tube over ≈ 5 central slices thereby creating a VOI, this is preferred for improved statistics. The ADC mean (μ) is defined as the spatial (i.e. over ROI or VOI) average of the temporal (i.e. over 4 passes) average map calculated on a pixel-by-pixel basis. The ADC standard deviation (σ) is defined as the spatial average of the temporal standard deviation map calculated on a pixel-by-pixel basis. Note, this standard deviation is distinct from calculating the spatial average of ADC within the ROI (or VOI) for each of 4 passes, then calculating the within-exam sample standard deviation (σ_w) of the 4 average ADCs. These are used to calculate the following performance metrics.

- a. **Bias** in ADC measurement is estimated using the mean ADC, μ , from ROIs (or VOIs) for each tube by,

$$ADC \text{ bias} = \mu - DC_{true}; \text{ or } \% \text{ bias} = 100\% \frac{(\mu - DC_{true})}{DC_{true}}, \quad \text{Eq2}$$

where the (nominal) DC_{true} values for concentrations of PVP are provided in Table 2. Percent bias estimated by the central measurement tube (0% PVP) shall be $\leq 4\%$ to meet conformance.

b. **Repeatability** of phantom ADC measurement is assessed by using average of repeated ROI ADC means at isocenter and the within-exam sample standard deviation (σ_w) to estimate RC and wCV as a metric of system technical performance:

$$RC = 2.77 \cdot \sigma_w; \quad wCV = 100\% \frac{\sigma_w}{\mu} \quad \text{Eq3}$$

Short-term (intra-exam) repeatability is assessed using multi-pass ADC, while long-term repeated scanning of the phantom over multiple days/weeks/months more closely resembles serial scanning of patients in longitudinal studies. The allowed short-term and long-term ADC repeatability for the central measurement tube are RC $<1.5 \times 10^{-5} \text{mm}^2/\text{s} = 0.015 \mu\text{m}^2/\text{ms}$ (wCV $<0.5\%$) and $<6.5 \times 10^{-5} \text{mm}^2/\text{s} = 0.065 \mu\text{m}^2/\text{ms}$ ($<2.2\%$), respectively.

c. **Linearity** with respect to calibrated phantom ADC values (DC_{true}) is tested by linear regression fit for mean VOI ADC values of tubes with corresponding PVP concentrations:

$$\mu = \beta_0 + \beta_1 DC_{true} \quad \text{Eq4}$$

For conformance, R-squared (R^2) of the linear model fit should be >0.90 and the 95% CI for the slope should be within the interval 0.95 to 1.05.

d. **b-value dependence** should not be apparent since PVP exhibits mono-exponential signal decay with b-value. That is, there should be no significant b-value dependence in measured ADC so one expects $ADC_{0,500} \approx ADC_{0,1000} \approx ADC_{0,1500} \approx ADC_{0,2000}$ for any given PVP concentration. System non-linearity in b-value encoding and/or DWI signal biased by the noise floor can lead to an apparent b-value dependence in ADC. The assessor should calculate b-value dependence as:

$$ADC \text{ bvalue dependence} = 100\% \left\| \frac{(ADC_{bmin,b2} - ADC_{bmin,b1})}{ADC_{bmin,b1}} \right\| \quad \text{Eq5}$$

Maximum difference between any of $ADC_{0,500}$, $ADC_{0,1000}$, $ADC_{0,1500}$, $ADC_{0,2000}$ to their average shall be $\leq 2\%$ for the central measurement tube to meet conformance.

e. **Random measurement error** (precision) are estimated from the 4-pass ADC by,

$$Random \ Error = 100\% \frac{\sigma}{\mu}, \quad \text{Eq6}$$

and shall be $\leq 2\%$ for the central measurement tube to meet conformance.

f. **SNR** of DWI is estimated by analysis of the 4 temporally-contiguous DWI scans (“passes”). The average of 4 DWI passes on a pixel-by-pixel basis, defines the “Signal Image” (for each b-value). The standard deviation over the 4 passes on a pixel-by-pixel basis, define the “Noise Image” (for each b-value). Using the previously-defined ROIs (VOIs), measure the spatial mean on Signal Image and Noise Image. The SNR is estimated as,

$$SNR = \frac{Spatial \ mean \ of \ ROI \ on \ Signal \ Image}{Spatial \ mean \ of \ ROI \ on \ Noise \ Image} \quad \text{Eq7}$$

The b=0 SNR shall be ≥ 45 for the ice-water central measurement tube to meet conformance.

Table 2: Nominal Diffusion Coefficient of PVP Solutions Equilibrated to 0°C

PVP Concentration	Diffusion Coefficient
0%	$1.1 \times 10^{-3} \text{mm}^2/\text{s}$ (true value)
10%	$0.83 \times 10^{-3} \text{mm}^2/\text{s}$ (nominal value)
20%	$0.60 \times 10^{-3} \text{mm}^2/\text{s}$ (nominal value)
30%	$0.40 \times 10^{-3} \text{mm}^2/\text{s}$ (nominal value)
40%	$0.24 \times 10^{-3} \text{mm}^2/\text{s}$ (nominal value)
50%	$0.13 \times 10^{-3} \text{mm}^2/\text{s}$ (nominal value)

QIBA PVP PHANTOM QC TOOLS

A suite of Matlab routines (available from <https://bit.ly/2QXLo3e> in “QIBA PVP Phantom QC Tools” folder) were developed to convert the QIBA DWI exam data from classic DICOM into uniform data structures for generation of QC statistics. Available Matlab-based routines compiled as “p-libraries” are: *qiba_build_combo.p*; *run_PVP_qc_combo.p* and *qiba_proc_combo.p*. To call these p-libraries from the Matlab (R2019+) workspace, copy the three p-routines into the user’s Matlab search path.

1. *qiba_build_combo.p* functionality is to:
 - a. read classic DICOM for the full acquired exam (all series) detailed in Section III
 - b. Create “scaninfo.txt” catalog listing site/system demographics and key content for each series.
 - c. Detect candidate trace DWI series for PASS1,2,3,4 and prompt user to confirm their selection.
 - d. Reorder variable platform-specific DWI into uniform Matlab data structures and store within a script-created “*DataStructsBin” directory.
 - e. Calculate ADC_{b_1,b_2} for all b -value pairs (Eq1) and ADC by mono-exponential fit of all b -values, as well as Signal and Noise Images (Eq7). Results are stored as Matlab data structures in the “*DataStructsBin” directory.
 - f. Prompt user to select “masterDNA_QIBA_DWI_Conformance_v1.mat”, to compare to acquisition parameters from DICOM to those defined in Table 1. Protocol deviations for few key parameters are flagged and stored in “CompliChckReport*.txt”.
2. *run_PVP_qc_combo.p* functionality (best to run within “*DataStructsBin” directory) is to:
 - a. Select the “*_SIGNALnNOISE.mat” file created in step 1.
 - b. Display numbered mosaic of all DWI slices, and prompt user to input number of first and last slice for analysis where PVP tubes are seen with relatively low artifact.
 - c. Automatically define VOIs on tubes and save ROI information in “...ROIpvp.mat”, and a one-page QC Report “*_QC_Summary_1.pdf” listing system performance values (see Figure 5) for comparison to device checklist in QIBA DWI profile. Additional performance content is stored in “*_SIGNALnNOISE_DWI_SNR_1.pdf”.
3. *qiba_proc_combo.p* is optional, though may be used to convert output from *run_PVP_qc_combo* into csv files based on pre-generated “...ROIpvp.mat” or for manually defined new ROI (VOI) set. For more details, refer to *qiba_mproc* functionality provided in “QIBA_DWI_Profile_Conformance_Testing_Supplement_2” on QIBA Wiki.

Alternatively, two C++-compiled 64-bit Windows binaries executables (*qiba_mbuild.exe* and *qiba_mproc.exe*) are available for “QIBAphan” SW to use without Matlab and may be downloaded from <https://bit.ly/2QXLo3e> in “QIBA_DWI_Phan_AnalysisSW” folder. Details on use of the Windows binaries are provided in “QIBA_DWI_Profile_Conformance_Testing_Supplement_2” available on the QIBA Wiki. NOTE that “QIBAphan” users would have to further process output multi-pass CSV files with ROI statistics to generate performance metrics in Eqs(2-5) and QC report in their preferred environment (e.g., Excel)

Institution: UNIVERSITY of MICHIGAN Main
 SysID / NickName: Ph30T42001 / Ph30T42001
 Manufacturer: Philips Medical Systems
 Field Strength: 3.0T
 Serial #: 42001; SW ver: 5.4.1f5.4.1.1

Acq DateExSer: d2019081313e600370249s1101
 SetPass Analyzed: Set1-Pass1-Pass2-Pass3-Pass4
 ROI File: Ph30T42001-Set1-Pass1-Pass2-Pass3-Pass4-SIGNALnNOISE
 TR(ms) = 8000; TE(ms) = 100.686; NAV = 2
 FOV(mm) = 220 220
 Slice Thk(mm) = 4; No. Slices = 25
 Bandwidth (Hz/Px) = 1561
 AcqFreq Mx = 128; AcqPhase Mx = 130
 Phase Enc Dir: COL
 Parallel Imaging: YES; PI Factor = 2
 Receiver Coil: MULTI COIL
 b-values = 0 500 1000 1500 2000

***** Central Tube Allb-Fit Results: *****

ADC Bias = 0.97 %
 ADC TemporalRandomError = 0.63 %
 ADC SpatialNonUniformity = 0.95 %
 ADC b-value Dependence = 2.11 %
 ADC wSigma = 0.00083 um2/ms
 ADC wCV = 0.07 %
 ADC RC = 0.00229 um2/ms
 Low-b DWI SNRest via MultiPass = 201; via bkgnd = 1212
 High-b DWI SNRest via MultiPass = 64; via bkgnd = 192

QC Script: run-PVP-qc-20210331; Date: 31-Mar-2021

ROI Locs slices 11 to 16

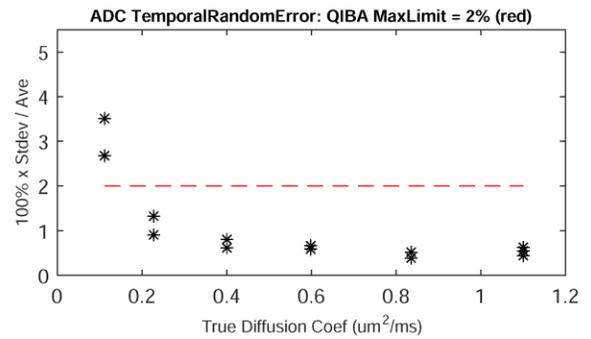
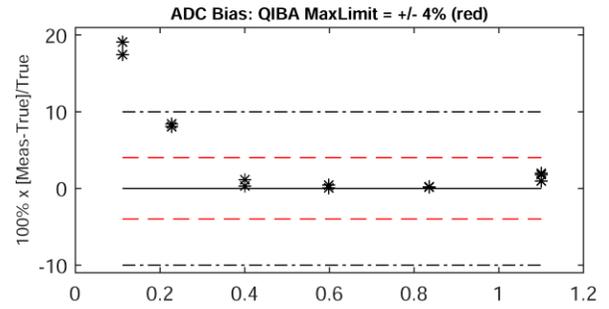
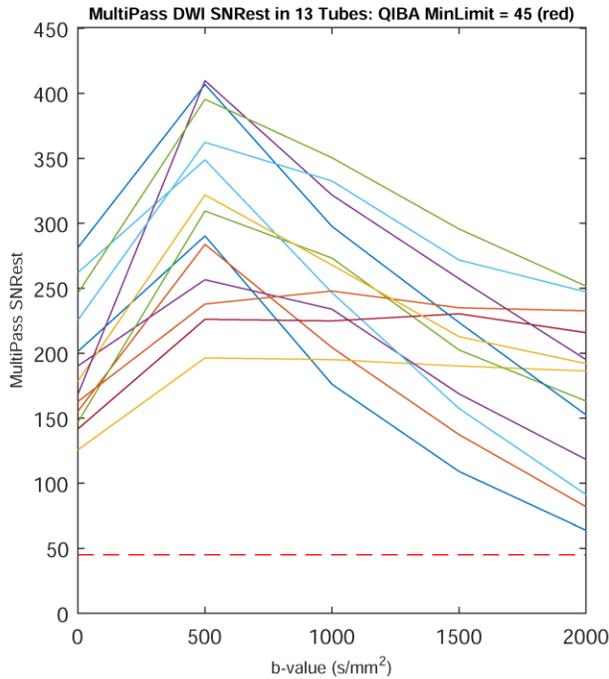
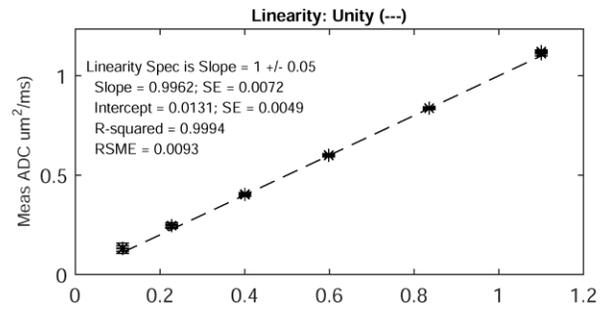
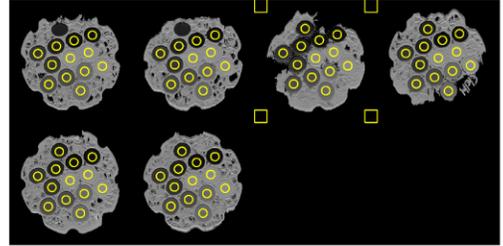


Figure 5: Sample QC Report