| Checklist items (See Comment Resolutions tab for feedback comments) | | Site A (Liverpool NSW) | | *Site B (Brazil)* | | Site C (Cornell) | | Site D (Invicro) | | Comments (from checklists and freeform feedback) | Committee Discussion | Resolution | Status | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Conform | Comments | Conform | Comments | Conform | Comments | Conform | Comments | | | | 0 | **TBD** To be discussed |
| | | | | | | | | | | | | | 0 | OK No action requested |
| | | | | | | | | | | | | | 0 | Discuss Need to decide resolution |
| | | | | | | | | | | | | | 3 | TODO Resolution decided |
| **Site Checklist** | | | conformance testing checklist: no feedback | | | | provide google-fomrs that auto-fill generates the report; relist actors and their checklist instructions and how pull-down to fill in; explain simlarities across actors; allow multiple scanner for site report | | conformance testing checklist: create conformance data template; and provide SW tha would auto-generate | | We are in the process of creating forms using Google Docs. | Use Google Docs to facilitate report generation and recording. | Done | Profile update completed |
| **Qualification activities** | **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** | **Y** | | ***Y*** | ***FW*** | **Y** | **FW** | **Y** | **checked for brain: clarify purpose of Spec Table for "profile claim" vs clinical trial specific protocol** | | **This is an interesting point, but goes beyond the scope of the DWI Profile. The BC will bring this to the attention of the Process Committee.** | | | |
| **Periodic DWI QA** | **Shall perform periodic QA for Acquisition Device that includes assessment of ADC bias, random error, linearity, DWI SNR, DWI image artefacts, *b*-value dependence (linearity) and spatial uniformity (3.2.2)** | **Y** | | ***Y*** | ***FN*** | **Y** | **FW** | **Y** | | | **Maybe ask for the opinion afterwards not during the first pass.**<br><br>**This spec appears under multiple actors, and should be consolidated.** | Shall perform **annual** periodic QA **(and after major software or hardware changes)** for Acquisition Device that includes assessment of ADC bias, random error, linearity, DWI SNR, DWI image artefacts, *b*-value dependence (linearity) and spatial uniformity (3.2.2) | **Done** | |
| Equipment | 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. | Y | | *Y* | *FW* | Y | FW | Y | | | | Add: 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) | Done | |
| **Device Checklist** | | | profile phantom scan protocol (old) | | *profile phantom scan protocol (old): having ambient temeprature pahntom protocol would be deisred* | | long-tube ice-phantom: suggested vendor responsibility for QC conformance testing | | clarify T-measurements optional with ice-water | | **Discrepancies in the profile vs the conformance testing.**<br>Should indiciate no sagittal and coronal scans; only axial scans for QA.<br>Also *b*-value changes: specify 0, 500, 1000, 1500, 2000 s/mm². Also used by current conformance testing service. only 3m40s per b-value, ~15min total, which is very small compared to phantom prep. **Must change in Appendix D** (vendor-specific phantom protocols)<br>Indicate TE minimum (but not greater than 125 ms, per vendor requirements in Appendix D);<br>No indication for full k-space? No less than 75% partial coverage of k-space<br>TR should be 8–10 s.<br><br>Should vendors be responsible for device checklists? Should this be part of the QA script when there is an upgrade in h/w or s/w? Vendor represenative can serve as the actor responsible for these specifications.<br><br>Ice-water phantom can be difficult to use. Temperature-measurement requirement may be excessive, unless there is a strong indication of bias. | Indicate optional measurement of phantom temperature unless there is significant bias in a measurement.<br><br>Axial orientation of phantom.<br><br>b-values: 0, 500, 1000, 1500, 2000 s/mm²<br><br>TE: minimum, but not greater than 125 ms<br><br>No less than 75% coverage of k-space<br><br>TR: 8–10 s<br><br>Vendors can serve as actor responsible for device checklist<br><br>***Match what's in conformance protocol" in progress for Siemens and Canon** | ToDo | |
| Acquisition Protocols | 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 | Y | multiple organs | *Y* | *R: brain* | Y | R: prostate | Y | checked for brain | Site C focused on prostate | These are acceptable, require no changes. However, some what obvious, and likely covered by scanner operator specs regarding imaging protocol implementation (Spec 30)<br><br>This is also somewhat redundant with Scanner Operator spec with same title. Propose removing | Remove | Done | |

| Checklist items (See Comment Resolutions tab for feedback comments) | | Site A (Liverpool NSW) | | *Site B (Brazil)* | | Site C (Cornell) | | Site D (Invicro) | | Comments (from checklists and freeform feedback) | Committee Discussion | Resolution | Status | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| DWI Tags | Shall preserve tags related to DWI, including private tags, which may be vendor-specific. Some key tags are specified in Appendix D. | Y | | *Y* | *R* | Y | R | Y | | | Will preserve because can be violated in practice by clinical sites | | | |
| **Short-term (intra-exam) ADC repeatability at/near isocenter** | **Short-term RC < 1.5x10$^{-5}$ mm$^2$/s and wCV < 0.5% for ice-water phantom or other quantitative DWI phantom** | **Y** | | ***Y/N*** | ***FW (research) FN(clinical): not feasible in clinical setting, not clear how often should be done*** | **Y** | **FN** | **Y** | | | **Necessary for assessment of SNR and downstream effects.** | **Leave spec alone, but add text in appendix:<br><br>E.1: "..., which are necessary for assessment o hte impact of SNR."** | **Done** | |
| Long-term (multi-day) ADC repeatability at/near isocenter | Long-term RC < 6.5x10$^{-5}$ mm$^2$/s and wCV < 2.2% for ice-water phantom or other quantitative DWI phantom | Y | | *Y* | *FW (research) FN(clinical): not clear time interval and phantom positioning* | Y | FW | Y | **clarify consistent phantom positioning on different dates** | | This should be part of routine QA, i.e., on annual basis.<br><br>Indicate phantom orientation: water vials should be on patient left. With axial orientation of QIBA phantom, this would have label oriented towards posterior direction.<br><br>May benefit from THIS SIDE DOWN printed on phantom label, or other fiducial on phantom shell. | **Leave spec alone, but add text in appendix. Contact phantom manufacturers and indicate desire for stronger external fiducials to ensure consistent positioning<br><br>E.1: "For long-term reproducibility, it is key to consistently position the phantom in the same orientation."<br><br>4.1: "...with consistent positioning and orientation"** | todo | need to contact phantom manufacturers |
| DWI *b*=0 SNR | SNR (*b*=0) > 50±5 for ice-water phantom or other quantitative DWI phantom. | Y | | *Y/N* | *FW (research) FN (clinical)* | Y | FW | Y | | | Can't estimate SNR without QA measurement; QA measurement protocol will yield SNR. | No change. | | |
| ADC *b*-value dependence | ADC *b*-value dependence < 2% for ice-water phantom or other quantitative DWI phantom over *b*-value pairs 0-500; 0-900; and 0-2000 s/mm$^2$ | Y | | *Y* | *FW (research) FN(clinical)* | Y | FW | Y | | | Must edit spec to reflect new b-values.<br><br>Shows up for image analyst as well | ADC *b*-value dependence < 2% for ice-water phantom or other quantitative DWI phantom over *b*-value pairs 0–500; 0–1000; 0–1500; and 0–2000 s/mm$^2$ | Done | eliminate double specs across actors |
| Maximum \|bias\| with offset from isocenter: | Maximum \|bias\| with offset from isocenter:<br>within 4 cm in any direction < 4% for uniform DWI phantom | | | *Y* | *FW (research) FN (clinical)* | Y | FW | Y | | | Assumes routine QA (i.e., annual or at hw/sw change) and consistent phantom positioning per previous comments/discussion | Retitled:Maximum \|bias\| with offset from isocenter: within 4 cm in any directionof isocenter | | |
| **Offcenter study: device checklist options** | | | | | | | | | | | | | | |
| **R/L offset 4-10 cm (with A/P and S/I < 4 cm)** | **< 10% for uniform DWI phantom** | | | ***N*** | ***follow-up with TC task*** | **Y** | **FN** | **Y** | **clarify optional and offset bias measurement range, between 8 to 12 cm ..." (for example)** | | **Take these requirements and turn them into optional specifications in use cases with significant off-isocenter measurements.<br><br>See edits to consensus Profile dated April 2021 from UMich.<br><br>Could phrase:<br>Additional requirements for studies involving off-center ADC measurement (adjusted for orientation):<br><br>"The maximum ADC bias in a cylindrical volume with a 4 cm radius and a 20 cm length, centered around isocenter, shall be less than 10%."<br><br>Ultimately, TF feels that this is a difficult set of specs to define for the purpose of the Profile, and does not meet the Impact and Effort criteria.** | **Remove as a specification. Add text in appendices to indicate importance of evaluating off-isocenter bias per needs of a study involving off-center ADC measurements.<br><br>End of E.1:<br>"For studies involving off-center ADC measurement (adjusted for orientation), the maximum ADC bias in a cylindrical volume with a 4 cm radius and a 20 cm length, centered around a point between 8–12 off-isocenter, shall be less than 10%."** | **Done** | |
| **A/P offset 4-10 cm (with R/L and S/I < 4 cm)** | **< 10% for uniform DWI phantom** | | | ***N*** | ***follow-up with TC task*** | **Y** | **FN** | **Y** | **clarify optional: different phantom and coil, dependent on clinical trial protocol** | | | **see above** | **done** | |
| **S/I offset 4-10 cm (with R/L and A/P < 4 cm)** | **< 10% for uniform DWI phantom** | | | ***N*** | ***follow-up with TC task*** | **Y** | **FN** | **Y** | **clarify optional: create study/organ specific confromace protocols and test procedures** | | | **see above** | **done** | |
| **Pre-delivery, QA, protocol, image: device checklist options** | | | | | | | | | | | | | | |
| Performance metrics | Scanner shall meet established vendor performance metrics for given model | Y | | *Y* | R | Y | R | Y | | | Seems obvoius, doesn't meet Violation Criteria. | Remove | Done | |
| DWI sequence | Scanner shall be capable to acquire single-shot DWI | Y | | *Y* | R | Y | R | Y | | | Unlikely to be violated | Remove | Done | |
| DICOM conformance | Shall be capable of performing reconstructions and producing images with all the parameters set as specified in 3.4.2 "Protocol Design Specification". | Y | | *Y* | R | Y | R | Y | | | Keep, ensures conformance to imaging protocol specs; Change reference from "3.4.2" to "3.6.2" | Change reference from "3.4.2" to "3.6.2"<br><br>Merge with Scan Protocol Parameters below. | Done | |

| Checklist items (See Comment Resolutions tab for feedback comments) | | Site A (Liverpool NSW) | | *Site B (Brazil)* | | Site C (Cornell) | | Site D (Invicro) | | Comments (from checklists and freeform feedback) | Committee Discussion | Resolution | Status | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Periodic DWI QA** | **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)** | **Y** | | ***Y*** | **FW (research) FN(clinic** | **Y** | **FW** | **Y** | | | **Majority finds this feasiable; BC finds it useful.**<br><br>**Annual QA and QA post-upgrade should be reasonable**<br><br>**Redundant, should consolidate** | **No change (besides indicating annual QA)** | **Done** | **consolidate spec (now appears only in site)** |
| Scan Protocol Parameters | Device scan protocol parameters shall be within organ-specific ranges listed in the protocol specification tables (3.6.2) | | | *Y* | R | Y | R | Y | | | Is this redundant with DICOM conformance? Perhaps merge with 25? | Incorporate "DICOM Conformance" above into this spec | Done | Will need to remove 3.3 pre-delivery spec, adjust spec/ref in 3.6. |
| Scan Procedure | 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). | Y | | *Y* | R | Y | FW | Y | | | Keep: Profile should be implemented only on scanners that are prequalified.<br><br>But repetitive with other actors: if so, **move to Site (see spec 9)** | Combined with spec 9 | Done | |
| **Scanner Operator Checklist Specs** | | | | | | | experienced research tech: academic site | | | | Might be more difficult for a clinical site: need more real-world testing. | No change. May get feedback from clinical confirmation testing, or use in clinical trial. | | |
| Acquisition Protocols | 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). | Y | | *Y* | R | Y | FW | Y | | | In Device checklist, where is this most relevant? | Keep here, as it's more comprehensive. | Done | |
| **Acquisition Device Performance** | **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** | **Y** | | ***Y*** | **FW (research) FN(clinic** | **Y** | **FW** | **Y** | | | **Needs real-world clinical vetting, beyond scope of technical confirmation process.** | **No change.** | | |
| Reconstruction SW Performance | 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. | Y | | *Y* | R | Y | R | Y | | | May be redundant, keep or excise via Violation?<br><br>Merge with previous reconstruction spec, keep only for one actor.<br><br>Should any of this be reiterated in Recon SW specs? | Merge with lines 25 and 27, "DICOM Conformance", as part of Device Checklist | Done | |
| **Periodic DWI QA** | **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)** | **Y** | | ***Y*** | **FW (research) FN(clinic** | **Y** | **FW** | **Y** | | | **QA needed to assess scanner performance, as above.**<br><br>**Redundant, keep under device checklist** | **Remove this instance, already present in Line 26 above** | **Done** | |
| Protocol | 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. | Y | | *Y* | R | Y | R | Y | | | | Merge with line 30, Acquisition Protocols, this is redundant<br><br>Simply deleted. Text largely exists already in 30. | Done | |

| Checklist items (See Comment Resolutions tab for feedback comments) | | Site A (Liverpool NSW) | | *Site B (Brazil)* | | Site C (Cornell) | | Site D (Invicro) | | Comments (from checklists and freeform feedback) | Committee Discussion | Resolution | Status | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Patient Positioning | 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. | Y | | Y | R | Y | R | Y | | | | Remove, unlikely to be violated | Done | |
| Scan Parameters | 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.† | Y | | Y | R | Y | R | Y | | | Remove, unlikely to be violated, OR could merge this and line 35 into single spec<br><br>More to ensure consistency across timepoints. If not keeping in checklist, should show up in appendices.<br><br>Proposal: Use the same settings for the same patient over different timepoints. List this as a common footnote for 3.6.2 tables (parameter specfiications). For Line 35 (patient positioning), make sure there is an associated parameter row in the spec table. | Will merge 34–36 with 30, "Protocol" as part of Scanner Operator checklist.<br><br>30 reads:<br><br>"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). Shall check for protocol conformance, consistent patient positioning (orientation, target lesion location relative to isocenter), and that all subject-specific adjustments (i.e., to suit body habitus) are consistent across serial scans." | Done | |
| **Acquisition Device** | **The same scanner shall be used for baseline measurement and a subsequent longitudinal measurement for detecting change in ADC.** | **Y** | | **Y** | **FW (research) FN(clinic** | **Y** | **FW** | **Y** | | | **This is a requirement based on the literature used to inform our claims: we don't have good data on the reproducibility of ADC on a single patient across multiple scanners.** | **No change.** | | |
| Trace DWI and ADC map generation across subjects and time | 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 *b*-values; selection of b-values and fit algorithm to estimate ADC. ADC shall be calculated using the mono-exponential model of DWI signal decay with increasing *b*-value, starting with protocol-specific low *b*-value to compensate for perfusion effects. | Y | | Y | R | Y | R | Y | | | Remove, unlikely to be violated<br><br>There can be default options that are reset post s/w upgrades. Important to keep analysis of parameters consistent across TPs.<br><br>Perhaps shorten this but keep the spirit of this entry.<br><br>**"Number and magnitude of *b*-values shall be consistent across TPs for patients. ADC maps shall be generated in a consistent manner across TPs, including post-processing, fit model, and image registration."** | Use quoted bold material | Done | |
| *b*-value record | Scanner operator shall verify that the reconstruction SW records *b*-values, or if not shall manually record the *b*-values, that are used to generate the ADC map. | Y | | Y | R | Y | R | Y | | | Keep? This one is important, need clinical input<br><br>About metadata. If generating ADC maps offline, will need these. | Keep | Done | |
| ADC quality | 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. | Y | | Y | R | Y | FW | Y | | | Seems obvious, remove. | Remove, unlikely to be violated | Done | |
| Trace DWI | All trace DWI at each acquired b-value shall be stored in local PACS and distributed to image analysis workstation(s) | Y | | Y | R | Y | R | Y | | | Was regarding offline generation of ADC maps, which would require trace DWI vs directional DWIs. Perhaps make mention of this in the Appendix? In principle, this is already done.<br><br>Make comment in Appendix, remove spec. Assuming this is usually archived. | Remove | Todo | need to add comment in appendix of streamlined profile |
| ADC maps | 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 *b*-values used for generation shall be recorded. | Y | | Y | R | Y | R | Y | | | Beyond our control. Common sense is that scale is needed. Need a note (in Appendix?) that it is recomended to record that the scale is correct, e.g., via phantom scanning.<br><br>**Potentially a problem when viewing in PACS**. Should be mitigated by following Assessment Procedures. This seems potentially impactful, so recommend putting this into main body vs. appendix. Might consider footnote at bottom of appropriate checklist re: Assessment Procedure completion. | Convert into a note in main text?<br><br>**Shorten and Keep (02May2022)** | Done | shortened language to:<br>"ADC maps shall be preserved with DICOM scale tags. ADC map scale/unitws and b-values used for generation shall be recorded" |

| Checklist items (See Comment Resolutions tab for feedback comments) | | Site A (Liverpool NSW) | | *Site B (Brazil)* | | Site C (Cornell) | | Site D (Invicro) | | Comments (from checklists and freeform feedback) | Committee Discussion | Resolution | Status | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Image DICOM | DICOM tags essential for downstream review and diffusion analysis shall be maintained including, pixel intensity scaling [113], *b*-value, and DWI directionality vs. trace, and ADC scale and units. Trace DWI DICOM at each acquired *b*-value shall be archived in the local PACS. | Y | | *Y* | R | Y | FW | Y | | | Users don't have control over this. Perhaps move to acq. device checklist | Move to acq device | Done | |
| **Image Analyst Checklist Specs** | | | | | same params repetative in multiple actor checklists | | NA: QIBA BC used QIBAphan | | | | TODO: identify any potential remaining duplicate specs<br><br>Site C used ice-water phantom, raw data analyzed using QIBAPhan by UMich | | | |
| Qualification | 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) | Y | | *Y* | R | | | Y | | | Y and R, but might be important to keep<br><br>***Make more concise** | shortened text | Done | |
| Image Analysis Tool Performance | 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) | Y | | *Y* | R | | | Y | | | Keep?<br><br>Seems reasonable, but maybe a bit unspecific. Possible to narrow? | Keep | Done | |
| Phantom ADC ROI | 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 | Y | | *Y* | R | | | Y | | | I don't think is necessarily routine, so should be kept to specify ROI diameter | Keep | Done | |
| **Phantom ADC metrics** | **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** | **Y** | | ***N*** | ***N*, but follow-up with TC TF** | | | **Y** | | | **Site B says this is feasible but did not perform.**<br><br>**Analysis is now facilitated by availability of 3rd-party services.** | **added bit about qiba-certified services** | **done** | |
| ADC quality | 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. | Y | | *Y* | R | | | Y | | | can likely remove | revmoved | Done | |
| Trace DWI | Shall ensure that all trace DWI at each acquired *b*-value shall be stored in local PACS and distributed to image analysis workstation(s) | Y | | *Y* | R | | | Y | | | already covered, remove. See line 43, "Image DICOM" under Scanner Operator checklist | Remove | done | |

| Checklist items (See Comment Resolutions tab for feedback comments) | | Site A (Liverpool NSW) | | *Site B (Brazil)* | | Site C (Cornell) | | Site D (Invicro) | | Comments (from checklists and freeform feedback) | Committee Discussion | Resolution | Status | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ADC maps | 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 *b*-values used for generation shall be recorded. | Y | | Y | R | | | Y | | | already covered, remove. See line 43, "Image DICOM" under Scanner Operator checklist | Remove | done | |
| Image DICOM | DICOM tags essential for downstream review and diffusion analysis shall be maintained including, pixel intensity scaling [113], *b*-value, and DWI directionality vs. trace, and ADC scale and units. Trace DWI DICOM at each acquired *b*-value shall be archived in the local PACS. | Y | | Y | R | | | Y | | | redundant with line 43, remove | Remove | done | |
| ROI determination | 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 | Y | | Y | R | | | Y | | | Unlikely to be violated? Can be.<br><br>Merge with Line 38, regarding consistency of imaging across pts and TPs, also include analysis (i.e., ROI determination) | Did not merge with 38, b/c this is strict an analysis specification, and not related to image acquisition by the scanner operator | Done | |
| **Reconstruction SW Specs** | | | | | | | | | | | | | | |
| Trace DWI | 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. | Y | | Y | R | Y | R | Y | | | Unlikely to be violated<br><br>Not always a given, can use different reconstruction s/w, so keep | Keep | Done | |
| DICOM DWI | Exported DWI DICOM shall provide acquired *b*-values and directionality. | Y | | Y | R | Y | R | Y | | | Already covered in line 43 | Remove | Done | |
| **Spatial Registration** | **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.** | **N** | | **Y** | **R** | **N** | **FW** | **Y** | | | **Unclear how often this is done. If we take this spec out, what changes? And may not be done in our claim literature.** | **Remove this specification. Make mention in Section/Appendix on image quality and artifacts.**<br><br>**Already in 3.11.1 under eddy current bullet, so no change to text ,just remove spec** | **Done** | |
| **Image Analysis Tool Specs** | | | | | NA: site tool not tested | | Not tested: QIBAphan used | | QIBAphan used: clarify performance evaluation for site tool vs QIBAphan and DRO | | Should indicate this is optional for when sites use their own tools: need to evaluate using DRO and compare to scanner output. | Clarify intent for this set of specifications.<br><br>Some specific to phantom, but many general to pts. | | |
| ROI geometry | Acceptable: Screen-shot(s) documenting ROI placement on ADC maps shall be retained in the subject database for future reference; Target: ROI as a binary pixel mask in image coordinates shall be retained in the subject database for future reference; Ideal: ROI shall be saved as a DICOM segment object | Y | | NA | | NA | | Y | | | NA: did not perform these tests, no change needed | keep | | |
| Image Display | Acceptable / Target: Software shall allow operator-defined ROI analysis of DWI/ADC aided by inspection of ancillary MR contrasts; 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 | NA | | NA | | NA | | Y | | | Keep this requirement? May need more feedback from larger number of sites; most sites used QIBA- or vendor-supplied tools<br><br>If site uses their own off-line tool, this is a relevant spec; otherwise N/A. I.e., generating their own ADC maps vs. using vendor-supplied maps.<br><br>Concerns about co-registration discussed.<br><br>Move to Appendix? Move to Assessment Procedures? | Final decision: keep, but removing "images from different scant date(s) can be displayed side-by-side, though not necessarily geometrically linked; and" | | |
| Analysis Procedure | Analysis steps, derived metrics and analysis software package shall be held constant for all subjects and serial time points | Y | | NA | | NA | | Y | | | Worth keeping this? Covers many bases. Or is this so obvious that it is standard GCP? | Keep, stresses the importance of consistency | done | |

| Checklist items (See Comment Resolutions tab for feedback comments) | | Site A (Liverpool NSW) | | *Site B (Brazil)* | | Site C (Cornell) | | Site D (Invicro) | | Comments (from checklists and freeform feedback) | Committee Discussion | Resolution | Status | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ADC statistics | 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; 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 | Y | | NA | | NA | | Y | | | Need input on how widespread these stats are across vendors/analysis tools | keeping for homebuilt analysis routines, adjusted language to exlcude NaNs, and record inclusion or exclusion of zero-valued pixels | Done | |
| ADC scaling | 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. | Y | | NA | | NA | | Y | | | Isn't this already covered with line 43? How frequently is this not clear? aren't units and exponents recorded in DICOM header? May not be provided in header, but in series description? 0028:1055, Window Center and Width Explanation is standard? | Remove, already captured by Image DICOM spec in Acq. Device. We want dicom tags to be used in lieu of series descriptors, which may be anonymized. | Done | |
| ADC map storage | 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) | Y | | NA | | NA | | Y | | | Is this really required to meet the claim? | Remove, make comment in main body in 3.13.1 "i.e., in an ITK-compatible format (such as NIFT or MHD) or as a parametric map DICOM." | Done | |
| Fit algorithm type | The specific choice of the fit algorithm shall be recorded, held constant within a study and reported with any dissemination of study findings. | Y | | NA | | NA | | Y | | | Is this really required to meet the claim? Is it violated? Aren't most fits two-point? Won't all fits be monoexponential fits to presumed Gaussian behavior? | Keep, with add'l text regarding linear-log fit vs non-linear-standard SI fit | Done | |
| Fit algorithm bias | 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. | Y | | NA | | NA | | Y | | | Keep this | | | |
| *b*-value and direction | Software shall extract *b*-values and diffusion axis direction from DICOM header | Y | | NA | | NA | | Y | | | Violated in practice? | | | |
| **QC analysis SW options** | | | qCal & site tools used | | QIBAphan used by BC | | QIBAphan used by BC | | Site used QIBAphan | | | | | |
| Phantom ADC QC metrics | Software with independent QA option shall evaluate and report phantom scan protocol compliance and ADC metrics including bias, random error, linearity, DWI SNR, *b*-value dependence and spatial uniformity according to Table 3.2.2 to enable performance assessment for Acquisition Device qualification (3.2) and periodic QA (3.5) | Y | | | | | | Y | Design and auto-generate appropriate QC report format or use qCal | | | | | |