
# QIBA Profile Conformance

# Self - Attestation Document

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| QIBA Profile title | FDG-PET/CT as an imaging biomarker measuring response to cancer therapy |
| QIBA Profile version | November 18, 2016 |
| 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 | |

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

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

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

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

Vendors publishing a QIBA Conformance Statement shall provide a set of "Model-specific Parameters" (as shown in Annex A) describing how their product was configured to achieve conformance. Vendors shall also provide access or describe the characteristics of the test set used for conformance testing.

## QIBA Conformance Statements

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

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

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

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

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

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

# QIBA Conformance Statement for a Product

| QIBA Conformance Statement | | | |
|---|---|---|---|
| **Vendor** | **Product Name** | **Version** | **Date** |
| 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 |
|---|---|---|
| CT Tumor Volume Change for Advanced Disease (CTV-AD) (2018) | Acquisition Device | See A.1 |
| | Reconstruction Software | See A.2 |

| Links to Additional Information | |
|---|---|
| Submitter's QIBA information: | www.anymedicalsystemsco.com/qiba |
| General information on QIBA: | qibawiki.rsna.org |

# Annex A: Conformance Notes

## A.1 FDG-PET/CT – Acquisition Device

**Model-specific Instructions and Parameters see QIBA profile**

## QIBA FDG PET/CT Scanner Checklist

The following questionnaire/checklist may be used to ascertain a PET scanner's qualification for quantitative imaging according to the QIBA FDG PET/CT Profile.

| | **Parameter** | **Specification** | Pass? |
|---|---|---|---|
| 1. | Calibration factors | All necessary calibration factors needed to output PET images in units of Bq/ml shall be automatically applied during the image reconstruction process. | |
| 2. | PET Scanner calibration | Shall be able to be calibrated according to the following specifications: Using a uniform cylinder containing F-18 in water solution (ideally using the same solution used for dose calibrator cross-calibration) Slice-to-slice variability shall be no more than ± 5% (not including end slices, as per ACR PET Core Lab). | |
| 3. | Weight | Shall be able to record patient weight in lb or kg as supplied from the modality worklist or operator entry into scanner interface. Shall be stored in Patient Weight field (0010,1030) in the DICOM image header, as per DICOM standard. | |
| 4. | Height | Shall be able to record patient height in feet/inches or cm/m as supplied from the modality worklist or operator entry into scanner interface. Shall be stored in Patient Size field (0010,1020) in the DICOM image header, as per DICOM standard. | |
| 5. | Administered Radionuclide | Shall be able to enter the radionuclide type (i.e. F-18) by operator entry into the scanner interface and through predefined protocol. Shall be recorded in Radionuclide Code Sequence (0054,0300) in the DICOM image header [e.g. (C-111A1, SRT, "$^{18}$Fluorine")]. | |
| 6. | Administered Radiotracer | Shall be able to record the radiotracer (i.e. FDG), as supplied by operator entry into the scanner interface. Shall be recorded in Radionuclide Code Sequence field (0054,0300) in the DICOM image header, e.g. (C-B1031, SRT, "Fluorodeoxyglucose F$^{18}$"). | |
| 7. | Administered Radiotracer radioactivity | Shall be able to enter the administered radioactivity, in both MBq and mCi, as supplied by operator entry into the scanner interface. Shall be recorded in Radionuclide Total Dose field (0018,1074) in the DICOM image header in Bq. | |
| 8. | Administered Radiotracer Time | Shall be able to record the time of the start of activity injection as supplied by operator entry into the scanner interface. Shall be recorded in Radiopharmaceutical Start Date Time field (0018,1078) (preferred) or Radiopharmaceutical Start Time field (0018,1072). | |
| 9. | Decay Correction Methodology | Encoded voxel values with Rescale Slope field (0028,1053) applied shall be decay-corrected by the scanner software (not the operator) to a single reference time (regardless of bed position), which is the start time of the first acquisition, which shall be encoded in the Series Time field (0008,0031) for original images.<br>Corrected Image field (0028,0051) shall include the value "DECY" and Decay Correction field (0054,1102) shall be "START", which means that the images are decay-corrected to the earliest Acquisition Time (0008, 0032). | |

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| 10. | Scanning Workflow | Shall be able to support Profile Protocol (Section 3) PET and CT order(s) of acquisition.<br>Shall be able to pre-define and save (by imaging site) a Profile acquisition Protocol for patient acquisition. | |
| 11. | CT Acquisition Parameters | Shall record all key acquisition parameters (technique) in the CT image header, using standard DICOM fields. | |
| 12. | PET-CT Alignment | Shall be able to align PET and CT images within ±2 mm in any direction. | |
| 13. | Activity Concentration in the Reconstructed Images | Shall be able to store and record (rescaled) image data in units of Bq/ml and use a value of BQML for Units field (0054,1001). | |
| 14. | Tracer Uptake Time | Shall be derivable from the difference between the Radiopharmaceutical Date Time field (0018,1078) (preferred) or Radiopharmaceutical Start Time field (0018,1072) and the Series Time field (0008,0031) or earliest Acquisition Time field (0008,0032) in the series (i.e., the start of acquisition at the first bed position), which should be reported as Series Time field (0008,0031). | |
| 15. | PET Voxel size | See Section 4.3 (PET Voxel size) under the Reconstruction Software specification requirements. | |
| 16. | CT Voxel size | Shall be no greater than the reconstructed PET voxel size.<br>Voxels shall be square in transaxial dimensions, although are not required to be isotropic in the Z (head-foot) axis.<br>Not required to be the same as the reconstructed PET voxel size. | |
| 17. | Subject Positioning | Shall be able to record the subject position in the Patient Orientation Code Sequence field (0054,0410) (whether prone or supine) and Patient Gantry Relationship Code field Sequence (0054,0414) (whether head or feet first). | |
| 18. | DICOM Conformance | All image data and scan parameters shall be transferable using appropriate DICOM fields according to the DICOM conformance statement for the PET/CT scanner. | |
| 19. | DICOM Data transfer and storage format | PET images shall be encoded in the DICOM PET or Enhanced PET Image Storage SOP Class, using activity-concentration units (Bq/ml) with additional parameters stored in public DICOM fields to enable calculation of SUVs.<br>PET images shall be transferred and stored without any form of lossy compression. | |
| 20. | Metadata | Shall be able to accurately propagate the information collected at the prior stages and extend it with those items noted in the Reconstruction section. | |
| 21. | Data Corrections | PET emission data must be able to be corrected for geometrical response and detector efficiency, system dead-time, random coincidences, scatter and attenuation. | |
| 22. | Reconstruction Methodology | Shall be able to provide images without resolution recovery. | |

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| 23. | Reconstruction Methodology / Output | Shall be able to perform reconstructions with and without attenuation correction. | |
| 24. | Data Reconstruction 2D/3D Compatibility | Shall be able to perform reconstruction of data acquired in 3D mode using fully 3D image reconstruction algorithms.<br>Shall be able to perform reconstruction of data acquired in 2D mode using 2D image reconstruction algorithms. | |
| 25. | Quantitative calibration | Shall apply appropriate quantitative calibration factors such that all images have units of activity concentration, e.g. kBq/mL. | |
| 26. | Multi-bed data | Shall combine data from multiple over-lapping bed positions (including appropriate decay corrections) so as to produce a single three-dimensional image volume. | |
| 27. | Voxel size | Shall allow the user to define the image voxel size by adjusting the matrix dimensions and/or diameter of the reconstruction field-of-view.<br>Shall be able to reconstruct PET voxels with a size 4 mm or less in all three dimensions (as recorded in Voxel Spacing field (0028,0030) and computed from the reconstruction interval between Image Position (Patient) (0020,0032) values of successive slices).<br>Voxels shall be square in transaxial dimensions, although voxels are not required to be isotropic in the z (head-foot) axis. | |
| 28. | Reconstruction parameters | Shall allow the user to control image noise and spatial resolution by adjusting reconstruction parameters, e.g. number of iterations, post-reconstruction filters. | |
| 29. | Reconstruction protocols | Shall allow a set of reconstruction parameters to be saved and automatically applied (without manual intervention) to future studies as needed. | |

## F.3 Format of a QIBA Conformance Statement for a Site

Each Conformance Statement shall follow the format shown in the following table.

The submitter may add a cover page and information required by their documentation policies.

| 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** |
| FDG-PET/CT (2016) | Technologist | |
| | Physicist | |
| | Physician | |
| | Site | |
| **Links to Additional Information** | | |
| Submitter's QIBA information: www.anymedicalsystemsco.com/qiba | | |
| General information on QIBA: qibawiki.rsna.org | | |

# Annex A: Conformance Notes

QIBA FDG PET/CT Imaging Site

The following checklist may be used to ascertain a PET imaging site's qualification for quantitative imaging according to the QIBA FDG PET/CT profile. Answers may be provided either as "current practice" or as "feasible", depending on the context, but it should be made clear both which was expected and how the site answered.

| # | ***Site and Personnel Qualifications*** | ***Status*** |
|---|---|---|
| 1. | The site is accredited (ACR, IAC, TJC, etc.) or has Qualified status for clinical trials (ECOG-ACRIN, SNMMI-CTN, EARL, CROs, etc.) | __ yes<br>__no |
| 2. | The site has the support of technologists, physicists, and physicians experienced in the use of FDG-PET/CT, and meeting the qualifications described below. | __ yes<br>__no |
| 3. | Technologists: PET studies are performed by technologists whose certification is equivalent to the recommendations published by the representatives from the Society of Nuclear Medicine Technologists Section (SNMTS) or the American Society of Radiologic Technologists (ASRT) and should also meet all local, regional, and national regulatory requirements for the administration of ionizing radiation to patients. | __ yes<br>__no |
| 4. | Physicists: The medical physicist is certified in Medical Nuclear Physics or Radiological Physics by the American Board of Radiology (ABR); in Nuclear Medicine Physics by the American Board of Science in Nuclear Medicine (ABSNM); in Nuclear Medicine Physics by the Canadian College of Physicists in Medicine; or equivalent certification in other countries; or have 3 years of PET experience. Regardless of certification, the physicist should have specific experience in PET and its quantitative use. | __ yes<br>__no |
| 5. | Physicians overseeing and interpreting PET/CT scans are qualified by the ABR (Diagnostic and/or Nuclear Radiology) or American Board of Nuclear Medicine (ABNM) or equivalent within the United States or an equivalent entity appropriate for the geographic location in which the imaging study(ies) will be performed and/or interpreted. | __ yes<br>__no |
| | ***Imaging Procedures*** | |
| 6. | Patient height and weight are entered into scanner during PET/CT acquisition. | __ yes<br>__no |
| 7. | Blood glucose is measured for each patient within 2 hours preceding FDG administration. Measured value and measurement time are documented. | __ yes<br>__no |
| 8. | If and when glucose threshold is exceeded, the reason shall be documented. | __ yes<br>__no |
| 9. | For each patient, the pre-injection FDG activity is measured and injected and residual activity is measured. Initial and residual measurement times and injection time are entered into the console. | __ yes<br>__no |

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| 10. | FDG is administered through a 24-gauge or larger indwelling catheter placed anatomically remote to any sites of suspected pathology, preferably in an antecubital vein. Intravenous ports should not be used, unless no other venous access is available. In the case of manual administration, a three-way valve system should be attached to the intravenous cannula so as to allow at least a 10 cc normal (0.9% NaCl) saline flush following FDG injection. For automated injection devices alternate flushing mechanisms are allowed. | __ yes<br>__no |
| 11. | For follow-up scans, patients are imaged with the same workflow (i.e. patient handling, imaging acquisition, image processing, and image analysis) as for baseline scans. | __ yes<br>__no |
| 12. | The FDG uptake time (from injection to scan) is 60 minutes, with an acceptable range of 55-75 minutes. When repeating a scan on the same subject, uptake time for the 2nd scan is within 10 minutes of that for the first scan. | __ yes<br>__no |
| 13. | If the patient is observed to take a deep breath during the CT scan it is documented and a repeat CT study is considered. | __ yes<br>__no |
| 14. | When a patient is rescanned, the same scan direction is used. | __ yes<br>__no |
| 15. | Reconstructed PET images, with and without attenuation correction, and CT images are archived at the imaging site. | __ yes<br>__no |
| | ***QA/QC*** | |
| 16. | The site performs all PET/CT scanner QA/QC procedures recommended by the manufacturer and at the recommended frequency (e.g., daily, weekly, quarterly) and assures that the output values are acceptable. | __ yes<br>__no |
| 17. | Daily QA procedures are performed prior to any subject scan. | __ yes<br>__no |
| 18. | A water or water-equivalent phantom is scanned and evaluated daily and acceptable output is ensured. | __ yes<br>__no |
| 19. | Dose calibrator constancy is evaluated daily on the F-18 setting. Day-to-day differences no greater than 2.5% are allowed. Cs-137, Co-57, or simulated F-18 may be used. | __ yes<br>__no |
| 20. | The dose calibrator accuracy is evaluated monthly with measured values differing no more than 2.5% from the actual source value. Cs-137, Co-57, or simulated F-18 may be used. | __ yes<br>__no |
| 21. | Dose calibrator linearity is assessed at least annually over a range of 37-1110 MBq, with deviation of no more than 2.5% over the entire range. | __ yes<br>__no |
| 22. | Scales for patient weight measurement are evaluated annually or after any repair by qualified personnel, with error no more than 2.5% from expected values using a NIST-traceable or equivalent standard. | __ yes<br>__no |
| 23. | The glucose measuring device is measured and tested according to a CLIA-approved, CLIA-cleared, or equivalent (if outside the United State) procedure. | __ yes<br>__no |

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| 24. | The PET/CT scanner computer and all clocks in the imaging facility used to record activity/injection measurements are synchronized to standard time reference within +/-1 minute.<br>Synchronization of all clocks used in the conduct of the FDG-PET/CT study is checked weekly and after power outages or civil changes for Daylight Savings (North America) or Summer Time (Europe). | __ yes<br>__no |
| 25. | Quantitative Calibration Accuracy: PET scanner quantitative accuracy relative to the dose calibrator is verified quarterly and after scanner upgrades, maintenance or repairs, new setups and modifications to the dose calibrator via a uniform phantom scan of activity measured in the dose calibrator, achieving a large central ROI mean SUV value of 1.0 (acceptable range 0.9-1.1). | __ yes<br>__no |
| 26. | Axial Uniformity: Using a uniform cylinder phantom or equivalent shall obtain a slice-to-slice variability of less than 10% for the slices within the central 80% of the axial FOV. | __ yes<br>__no |
| 27. | PET Resolution: Cold rods (as in the Jaszczak or ACR PET phantoms) of diameter 9.5 mm or smaller must be visible. A hot cylinder (as in the ACR PET phantom) of 12 mm or smaller must be visible OR the 13 mm sphere of the NEMA image quality phantom must be visible. | __ yes<br>__no |
| 28. | PET noise: In a uniform phantom of 0.1 to 0.2 µCi/ml F-18 concentration the coefficient of variation of voxel values within a rectangular or circular region of at least 3 cm (side or diameter) must be no greater than 15% for all slices within the central 80% of the axial FOV. | __ yes<br>__no |
| | ***Specific Personnel Responsibilities*** | |
| 29. | A technologist or physicist assesses uniformity (within-plane and across slices) and compares with previous results. Quarterly and following software upgrades. | __ yes<br>__no |
| 30. | A technologist or physicist shall perform the Quantitative Calibration Accuracy test. Quarterly and following software upgrades or changes to the dose calibrator | __ yes<br>__no |
| 31. | A physicist shall perform and document performance of a quantitative assessment (using a phantom with differing size defined targets such as the ACR or NEMA IQ phantoms processed with routine image reconstruction protocols) for lesion resolution. Annually. | __ yes<br>__no |
| 32. | A physicist Shall perform a quantitative assessment of image noise in phantom images to be of consistent and acceptable quality. Annually. | __ yes<br>__no |