

Pre-activation checklist for FLYRCADO™ (flurpiridaz F 18) injection

Author:

James Case, PhD, MASNC

Managing Partner

Cardiovascular Imaging Technologies

1. Hardware requirements

☐ PET Scanner Hardware

- Scanner design (Mandatory)
 - Full (360 degree) coverage
 - Complete coverage of heart in single bed position
 - Frame or list acquisition modes
 - PET system capable of ECG gating (8 gate minimum) and static acquisition
- Scanner (Recommended)
 - List mode acquisition
 - Dynamic, ECG gated and static re-binning modes
- Scanner (Optional)
 - 3D/Time-of-Flight (TOF) (< 400 ps)
 - “Digital” detector system
 - Field of view sufficient to view heart and spleen in single bed position

☐ Attenuation Correction (CT or Line Source) Hardware

- Scanner design (Mandatory)
 - Capability of performing low dose CTAC or line source AC acquisition
- Scanner (Recommended)
 - Capable of covering the heart in a single breath hold (approximately < 10 seconds)
 - ECG gating for Ca scoring in patients with no known CAD
 - CT dose reduction scanning modes
- Scanner (Optional)
 - Diagnostic CT capabilities: ≥ 16 slices for Ca scoring or ≥ 64 CTAC

1. Hardware requirements *(continued)*

☐ Exercise Stress Testing Equipment

- Treadmill or Bicycle Ergometer
- 12-Lead ECG Monitoring System
- Blood Pressure Monitoring System w/ Pulse Oximetry

☐ Pharmaceutical Stress Testing Equipment (Required)

- Infusion Pumps (dipyridamole or adenosine)
- Pharmacologic Stress Agents
- 12-Lead ECG Monitoring System
- Blood Pressure Monitoring System

2. Software requirements

☐ PET Acquisition and Reconstruction Software

- Integrated imaging protocols (Mandatory)
 - Pre-define rest, pharm stress and exercise protocols
 - Pre-defined and integrated CT or line source acquisitions
- PET Image Reconstruction Software (Mandatory)
 - Iterative Reconstruction (emission data)
 - Misregistration correction
 - Gated (8 gates minimum) and Static mode reconstruction
 - Post filtering (Gaussian or Butterworth)
 - Attenuation correction
 - Scatter and randoms correction
- PET Image Reconstruction Software (Recommended)
 - Iterative reconstruction (CT)
 - Software for compensating for implanted metal devices
 - Post filtering (Gaussian and Butterworth)
 - Dynamic reconstruction
 - Listmode reframing into static, ECG gated and dynamic data
 - Worklist integration
 - Native Dicom Storage
 - Ability to use an alternate CT for reconstruction (e.g. stress CT for rest attenuation correction or vice versa)

- PET Image Reconstruction Software (Optional)
 - 16 ECG gates
 - Time-of-flight
 - Respiratory gating
 - Point spread modeling

☐ PET Image Review and Reporting Software

- Image Display (Mandatory)
 - Reorientation in American College of Cardiology, Cardiac Oblique angles
 - Multi slice display covering the entire heart volume in short axis, vertical long axis and horizontal long axis views
 - Display of ECG gated dataset as cine over gated frames
 - Color look-up tables including linear color tables (for example: thermal and gray) and feature enhancing color tables (for example: cool or isocontour)
 - Quality assessment environment for displaying registration of CT (or AC map) overlay with emission data

2. Software requirements *(continued)*

PET Image Review and Reporting Software *(continued)*

- Image Display (Recommended)
 - F18 Flyrcado normal databases
 - Visual assessment of trans axial CT slices for the presence/absence of coronary calcium
 - Coronary blood flow assessment suite
 - Assessment of image quality metrics
- Image Display (Optional)
 - Assessment of wall motion and thickening
 - Assessment of likelihood of disease
 - Phase analysis
 - Assessment of coronary calcium
- Integration & Compliance (Recommended)
 - Diagnostic quality display monitors
 - PACS (Picture Archiving and Communication System) Compatibility
 - DICOM & HL7 Compliance
 - Secure Remote Access & Cloud Integration (256-bit encryption or better) (For multi-site collaboration)
 - Report Standardization (Align with ASNC/ SNMMI guidelines)

3. Facility & Departmental Design

Radiation & Shielding Considerations

Establish shielding, laboratory layouts that achieve:

- ALARA shielding calculations recommend a target dose < 5 mSv/year for staff, or regulatory limit (10 CFR 20) of 50 mSv/year or 20 µSv in any 1 hour in radiation-controlled areas
- Public, uncontrolled areas, the limits are 1 mSv/year or 20 µSv in any 1 hour (10 CFR 20)
- New or existing shielding modifications for PET or PET/CT. Shield is necessary to meet 10 CFR 21. Factors to consider
 - Number of patients per day
 - Un-occupied space adjacent to scanning room.
 - Dosing and uptake in shielded areas or adjacent to unoccupied areas
 - Segregated waiting areas for radiation safety for patients post rest imaging
 - Separate bathroom areas
- Hot Lab
 - Dose calibrator for F18
 - 511 keV rated Tungsten syringe shields
 - Space for onsite decay of F18 tracers
- Radionuclide infusion system (optional)
- Adequate distance between exercise stress monitoring staff and patient
- Shielding of exercise team when distance is insufficient for 10 CFR 20 compliance or ALARA recommendations

4. Administrative & Regulatory Requirements

- ☐ **Regulatory & Licensing** (Consult RSO or Radiation Physicist)
 - Contracting & Vendor Agreements Completed
 - Radioactive Material License Secured
 - Accreditation & Certification Requirements Met
 - Formulary Considerations Reviewed

- ☐ **Staffing & Clinical Oversight**
 - Interpretation Physicians must have experience reading nuclear cardiology images: Nuclear Medicine Physicians, Radiologists, Cardiologists. Recommend sub-specialty certification such as CBNC, ABNM, ABR or equivalent
 - Direct Stress Supervision: Physician or APP (direct supervision defined by MC based on place of service)
 - Additional Staffing Needs: ACLS and BLS certified EKG monitoring personnel (i.e., Nurses, Paramedics, EKG Techs) Nuclear Medicine Technologists. CT Radiology Technologist if required

5. Protocols

- ☐ **Pre-Scan Preparation Checklist**
 - Patient fasting requirements
 - Medication adjustments (Caffeine, beta-blockers, etc)
 - Hydration recommendations
 - Pregnancy test for female patients of childbearing years

- ☐ **Supplies for Flyrcado Injection and Scanning**
 - 18-25-gauge IV set-up
 - 3-way stop cock with short tubing
 - 30 ml Saline Flush (ie. 3 x 10 ml)
 - Radiolucent ECG leads

- ☐ **Clinical Protocols & Standard Operating: Stress Testing**
 - Scheduling & Workflow Optimization
 - Testing ordering instructions
 - Patient Informed Consent Process
 - Stress Testing (Pharmacologic/Exercise) Protocols
 - Emergency & Safety Procedures

- ☐ **Clinical Protocols & Standard Operating: Imaging**
 - PET Myocardial Perfusion Imaging (MPI) Protocols (Recommended): All systems
 - Rest/Stress Same, day pharmacological stress
 - Rest/Stress Same, two-day pharmacological stress
 - Blood flow options for pharmaceutical stress
 - Exercise stress test
 - PET Myocardial Perfusion Imaging (MPI) Protocols (Recommended): PET/CT
 - Known CAD (e.g. without CACS)
 - No Known CAD (e.g. with CACS, optional)

- ☐ **Post-Scan Considerations**
 - Post acquisition radiation exposure guidance
 - Patient discharge instructions

- ☐ **Emergency Preparedness**
 - Adverse reaction protocol for contrast or stressor (Management of allergic reactions to stress agents or contrast)
 - Radiation spill and containment procedures (Quick-reference guide for spills)
 - Radiation spills clean up kit for F18 tracers
 - Crash Cart accessibility and Defibrillator Checks (Ensure readiness for cardiac events)

6. Data Management & Compliance

☐ Cybersecurity & Data Privacy

- HITECH compliance and security review such as MDS2
- Limited remote system access. Patched and up-to-date operating systems and network hardware
- Encryption & Secure Access for Patient Imaging Data (HIPAA compliance). Consider limiting USB access
- Use of strong passwords, application auditing
- Regularly monitor for changes in cyber-threat best practices

☐ Quality Control & Accreditation Audits

- Quality Control & Accreditation Audits
- Routine audits to ensure imaging protocols meet accreditation standards (IAC, ACR)
- Regular quality reviews
- Integrate Flyrcado into quality improvement programs

7. Training & Continuing Education

☐ Technologists

- Isotope handling
- Imaging Protocol
- Common Image artifacts: prevention and correction
- Display
- Record keeping

☐ Physicians

- Flyrcado imaging properties
- Common artifacts and quality assessment
- Image interpretation: static, gated and dynamic (blood flow)
- Reporting

☐ PET MPI Performance Benchmarks

- Total patients scanned per time period
- False positive rates (comparison with angiography)
- Image artifacts
- Imaging and processing times

☐ Continuous Process Improvement (CPI) Plan

- Regular case reviews and protocol optimizations based on performance data
- Staff review of other performance metrics

Mandatory: Implementation of minimum performance standards for performing Flyrcado MPI acquisition for achievement of optimal image quality and interpretation

