

# MEDRAD Intego™ PET Infusion System

## Technical Note: Radiation Safety



### Overview

The MEDRAD Intego™ PET Infusion System is designed to replace the manual process of FDG dose preparation and, in doing so, reduce the radiation dose received by the pharmacist or technologist preparing the doses.

The Intego System reduces radiation exposure through the following design elements:

- Use of multi-dose vials of FDG, replacing unit-dose syringes or vials and the corresponding need to handle each patient dose.
- Use of a specially-designed tungsten vial shield in which the FDG vial is delivered from the radiopharmacy. Use of this vial shield, along with the tungsten-shielded vial piercing device, minimizes the time of unshielded exposure required in handling doses.
- An integrated dose calibrator, eliminating the need for the user to handle and assay the FDG doses before and after administration.
- A lead shielded mobile cart which contains the FDG and provides radiation shielding to levels below the 10 CFR 20.1301 "Dose limits for individual members of the public" requirement of 0.002 rem (0.02 mSv) in any one hour in all operating conditions.
- Use of an automated saline flush after administration of the FDG to minimize residual radiation in the administration tubing.

### Design Goal for Operator Exposure

The design specification for the Intego System was to reduce radiation exposure associated with the preparation and handling of the FDG by at least 20% compared to current practices. To determine the radiation exposure associated with current practices, MEDRAD reviewed published literature to estimate the amount of radiation dose received from FDG preparation and handling per patient operation. As a result of this review<sup>1</sup>, MEDRAD established the following benchmarks to assess the radiation shielding effectiveness of the Intego System:

<b>Finger Dose Baseline:</b>	75 $\mu\text{Sv}/\text{patient operation}$
<b>Finger Dose Specification:</b>	60 $\mu\text{Sv}/\text{patient operation}$ (20% reduction)
<b>Body Dose Baseline:</b>	3.75 $\mu\text{Sv}/\text{patient operation}$
<b>Body Dose Specification:</b>	3.00 $\mu\text{Sv}/\text{patient operation}$ (20% reduction)

Note that these baselines, and therefore the specifications, are based on the syringe-based practice common in the United States. Syringe-based practices generally have a lower exposure from FDG preparation and handling than vial-based practices commonly followed in Europe. MEDRAD chose the syringe-based method as a more conservative baseline which, therefore, set a more stringent criterion for the Intego System design.

### Test Methodology

MEDRAD designed and completed a test protocol<sup>2</sup> to demonstrate that the Intego System would meet the radiation exposure reduction design specifications. The intent of the protocol was to simulate a clinical environment as closely as possible to compare actual radiation exposure to the baseline levels described above.

Ten registered Nuclear Medicine Technologists (NMTs) experienced in the handling and administration of FDG participated in the test. Each received a minimal amount of training in the use of the Intego System prior to the test to ensure testing was completed with novice, rather than expert users. This helped provide for a more conservative test protocol as novice users are more likely to spend more time with the system and, therefore, be exposed to the FDG for a longer period of time than expert users.

During the testing, infusions were made into unshielded empty vials to simulate the portion of exposure typically received by the NMT from the patient. Data was collected to quantify operator exposure during specific portions of the process:

- Installing the multi-dose vial of approximately 700 mCi (25.9 GBq) of FDG into the Intego System,
- Performing ten (10) complete patient infusions of 15 mCi (555 MBq) each, including attachment and removal of the Patient Administration Set (PAS), with a 30-minute delay between each procedure, and
- Removing the multi-dose vial of FDG and Source Administration Set (SAS) immediately after completion of the ten patient infusions.

## Residual Radioactivity in the Patient Administration Set

To help ensure a precise patient dose and to minimize radiation exposure, the Intego System automatically flushes the Source Administration Set (SAS) and Patient Administration Set (PAS) with saline after each FDG infusion. It is *not* necessary to assay the PAS after each FDG infusion because the residual radioactivity is insignificant relative to the prescribed dose.

To quantify the residual radioactivity, MEDRAD conducted measurements of residual radioactivity in the PAS at several prescribed dose levels using an average FDG vial concentration of approximately 20.8 mCi/ml (770 MBq/ml). The following table summarizes the results of this testing.

Delivered Dose (mCi)	PAS Residual (mCi)
25	0.011
20	0.007
15	0.003

At the maximum delivered dose of 25 mCi (925 MBq) and an average FDG vial concentration, the PAS residual was approximately 11  $\mu$ Ci (0.4 MBq). At a more typical clinical dose of 15 mCi (555 MBq), the PAS residual was approximately 3  $\mu$ Ci (0.1 MBq).

Each NMT wore a combination of body and ring dosimetry badges, provided and reported by Landauer, Inc., during the testing per the following chart:

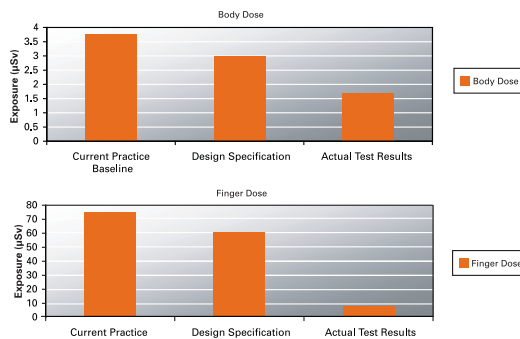
Description	Test Badge	Test Ring
Multi-dose Vial Installation	Test-Badge 1 Test-Badge 2	Test Ring 1 (dominant hand) Test Ring 2 (non-dominant hand) Test Ring 3 (dominant hand)
Ten, 15mCi Infusions	Test-Badge 1 Test-Badge 3	Test Ring 1 (dominant hand) Test Ring 2 (non-dominant hand) Test Ring 4 (dominant hand)
Multi-dose Vial and SAS Removal	Test-Badge 1 Test-Badge 4	Test Ring 1 (dominant hand) Test Ring 2 (non-dominant hand) Test Ring 5 (dominant hand)

The total exposure per procedure was calculated by adding the exposure during each portion of the process and then normalizing this exposure across ten patient infusions.

### Results

The total exposure per procedure was found to be 1.7  $\mu$ Sv body dose and 7.6  $\mu$ Sv finger dose. The following table and chart compares these results to the baseline and design specification per procedure exposure levels.

	Baseline	Design Specification (% reduction)	Actual Test Results (% reduction)
Body Dose	3.75 $\mu$ Sv	3.0 $\mu$ Sv (20%)	1.7 $\mu$ Sv (55%)
Finger Dose	75.0 $\mu$ Sv	60.0 $\mu$ Sv (20%)	7.6 $\mu$ Sv (90%)



Based on the testing described above, MEDRAD met its minimum design specification of 20% reduction in body

and finger dose compared to the baseline syringe-based method. Actual test results demonstrated a 90% reduction in finger dose and a 55% reduction in body dose.

The literature review also provided an estimate that the percentage of body dose received from FDG preparation and handling in the syringe-based method is 45% of total dose (the remainder comes from patient care). In the vial-based method, the percentage of total dose from FDG preparation and handling is 64%. Based on these estimates and using the design specification and actual test results obtained from the testing described herein, the potential total body dose reduction may be as follows:

	At Design Specification of 20% Dose Reduction	At Actual Test Result of 55% Dose Reduction
Expected Body Dose Reduction (vs. Syringe-based method)	9%	25%
Expected Body Dose Reduction (vs. Vial-based method)	13%	35%

<sup>1</sup> MEDRAD Document DF-100627 Rev. 01  
<sup>2</sup> MEDRAD Document TPR-000200 Rev. B

MEDRAD reserves the right to modify the specifications and features described herein, or discontinue manufacture of the product described at any time without prior notice or obligation. Please contact your authorized MEDRAD representative for the most current information.

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