



OHIO DEPARTMENT OF HEALTH

246 North High Street
Columbus, Ohio 43215

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Ted Strickland/Governor

Alvin D. Jackson, M.D./Director of Health

January 2, 2008

Traci Kime, Licensing Assistant
Materials Safety and Inspection Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safeguards
US Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Kime,

Attached is a sealed source and device registration amendment recently issued by the Ohio Department of Health, Bureau of Radiation Protection.

Please have the product registration listed below and attached, added to NRC sealed source and device registry and added to the sealed source and device web site.

SSD number	Action Taken	Issue Date
OH-0104-D-104-S	Amendment	Dec 19, 2007

If you have any questions or need clarification, I may be contacted at 614-644-2727.

Sincerely,

Chuck McCracken, Supervisor
Decommissioning, Waste and Safeguards
Bureau of Radiation Protection

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

AMENDED IN ITS ENTIRETY

NO: OH-0104-D-104-S

Date: Dec 19, 2007

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DEVICE TYPE: Source holder, for Mosaic PET Animal Imaging System

MODEL: 4535-674-39691, 4535-679-56361

MANUFACTURER/DISTRIBUTOR:

Philips Medical Systems
595 Miner Road
Highland Heights, OH 44143

SEALED SOURCE MODEL DESIGNATION:

Isotope Product Laboratories
Model HEG-137 with product code HEG-0096

ISOTOPE:

Cesium-137

MAXIMUM ACTIVITY:

370 MBq (10 mCi) nominal ($\pm 15\%$)

LEAK TEST FREQUENCY:

6 months

PRINCIPLE USE:

(T) Other - Non-human use PET scanner

CUSTOM DEVICE:

_____ Yes X No

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DEVICE TYPE: Source holder, for Mosaic PET Animal Imaging System

DESCRIPTION:

System Overview

The MOSAIC system is a miniaturized Positron Emission Tomography (PET) scanner used to scan small laboratory research animals. It is designed to be mobile so that it can be relocated as needed. Due to the small size, a transmission attenuation correction source holder assembly (subject of this registration) must be manually inserted and removed when used.

The source holder is inserted through an access port at the 9 o'clock position on the face of the scanner entrance using a T-handle. The T-handle is 150 mm (6") long and has a quick release mechanism that attaches to a hole in the source holder, and is used to position the source holder assembly into a retaining mechanism attached to the ring drive mechanism of the detector assembly. The source holder has two raised guide surfaces that fit into channel slots on the Source Loader Assembly. The source holder, and its position within the Source Loader Assembly, is held in position with two pin detent mechanisms. (See Attachment 1)

General Construction

The source holder assembly is a block with raised guide surfaces on the top and bottom, has an opening on the back for the T-handle to attach, and a hole for the inserting a source in the front. A retaining plate is screwed over the opening where the source is inserted. A spring holds the source snugly in position so that it does not move. (See Attachments 2 and 3)

Size/dimensions

The collimator block assembly (Attachment 3) is composed of a couple parts. The source holder block is approximately 41.6 mm (1.636") high by 28.6 mm (1.125") wide by 54.6 mm (2.15") deep. The retaining plate is about 28.7 mm (1.13") high by 12.7 mm (0.5") wide.

On/off indicators and mechanism

The collimator block does not have an on/off mechanism. Once the source is loaded, there is a constant beam of radiation coming from the collimator block. The block is inserted and removed manually from the MOSAIC scanner to produce the requisite radiation beam for the imaging software to calculate attenuation correction factors.

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DEVICE TYPE: Source holder, for Mosaic PET Animal Imaging System

DESCRIPTION: continued

The on/off indicator is located on the control panel on the top left side of the scanner assembly housing. The radiation flag indicator flips to indicate the radiation symbol when the source holder is detected, and implies there is a radiation field present.

The Collimator Block Assembly is detected by using an optical eye switch that is "trained" to recognize the color of the assembly.

The MOSAIC system is a computer operated spectral acquisition and control system. The operator controls are designed to provide remote control of the system operation, and a manual override is provide on the top left side on the front of the system housing.

Materials of construction

The main source holder block is made from tungsten. The collimator guide tracks are made of stainless steel. The remaining components of the source loader assembly and collimator block assembly, excluding spring and screws, are made of aluminum with a clear Iridite finish for corrosion protection.

Method of securing source in device

The source capsule is shipped to the customer separately from source holder assembly. Using the manufacture's instructions, the user assembles the source holder assembly prior to initial use. The manufacturer initially tests the MOSAIC system and radiation profiles using the source and source assembly prior to shipping to the customer. After testing the system, the manufacturer then disassembles the Collimator Block Assembly and ships the items separately to the customer.

The Collimator Block Assembly fits into Source Loader Assembly that is attached to the Ring Drive Assembly using guide pins and is held in position with spring loaded detent pins.

Safety features

The source capsule is secured in position in the source housing block by a retaining plate that is screwed over the opening where the source capsule is located.

The Collimator Block Assembly is inserted into the Source Loader Assembly using a T-handle mechanism minimize the hand dose while mounting and removing the source holder.

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DEVICE TYPE: Source holder, for Mosaic PET Animal Imaging System

DESCRIPTION: continued

Due to the close fit between to scanner housing cover and the Source Loader Assembly, if the collimator block were to disengage from the detent pins, it could not fall out of the Source Loader Assembly. If the Collimator Block Assembly was not properly inserted and mounted in position, the MOSAIC system would be unable to acquire the spectral information required.

Source description

The source is a registered sealed source manufactured by Isotope Product Laboratories model number HEG-137 but marketed under a catalog number of HEG-0096 and uses an A3105 capsule. The source is doubly encapsulated in stainless steel. The dimensions are 6 mm (0.236") in diameter by 8 mm (0.315") long.

Source storage

The Collimator Block Assembly is removed when it is not in use and stored in a user provided shielded container. The manufacturer can sell the user a shielded container to store the source holder.

Transportation

The sealed source special form certification is submitted, and maintained, by IPL. Copies of the special form certificates for the source may be obtained through IPL.

The source should be transported in a type A package.

Registration change history

November 2004 - design change to source holder block and assembly
December 2007 - change model number due to detector change (not part of registration), discontinue model 4535-679-56361, change model number to 4535-674-39691

LABELING:

The devices are labeled in accordance with Ohio Administrative Code (OAC) Chapters 3701:1-38 [10 CFR Part 20 equivalent] and 3701:1-46 [10 CFR 31 & 32 equivalent]. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of the manufacturer, and the words "CAUTION - RADIOACTIVE MATERIAL".

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LABELING: continued

A Lexan "Caution Radioactive Material" label with trefoil is attached to the lower side metal cover of the MOASIAC units, adjacent to the breaker panel. It is visible to the operator. The label is 51 mm (2") high by 102 mm (4") wide and is attached with adhesive.

A Lexan "Caution Radioactive Material" label with trefoil is attached to the collimator block. The label is 20 mm (0.8") high by 30 mm (1.2") wide and is attached with adhesive.

A 38 mm (1.2") diameter round trefoil label is installed in the operator control panel that rotates to indicate "on/off" for the presence of the collimator block assembly.

A Lexan "Rayonnement - Danger - Radiation" label is installed on the lower side metal cover adjacent to the breaker panel. The label is 22 mm (7/8") high by 31 mm (1.2") wide and is attached with adhesive.

A Lexan label is installed on the collimator block stating the company name, isotope used, radionuclide activity, and date of assay. The label is 20 mm (0.8") high by 31 mm (1.2") wide and is attached with adhesive.

DIAGRAM:

Attachment 1 - MOSAIC Source Handling Assembly Overview
Attachment 2 - Source Loader Assembly
Attachment 3 - Collimator Block Assembly

CONDITIONS OF NORMAL USE:

The devices are expected to be subjected to environments typically found in a clinical/office environment. Since the device is portable, it may experience vibration, shock, and falls typical during normal transportation and handling.

The expected useful life of the source/device is 10 years. After that time, the source may continue to be used after inspection.

PROTOTYPE TESTING:

The manufacturer has demonstrated by calculation that the device is expected to remain intact and contain the source after being dropped to the floor.

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EXTERNAL RADIATION LEVELS:

The following dose rates were reported by the manufacturer for the MOSAIC system containing a 10 mCi Cs-137 source. The dose rates are the maximum measurements from the front plane of the scanner opening.

EXTERNAL RADIATION LEVELS: continued

Maximum Radiation Level	
Distance cm (inches)	From Front Plane of Opening mSv/hr (mRem/hr)
5 (2)	2 (200)
30 (12)	0.30 (30)
100 (39)	0.03 (3)

The dose rates were taken with no material present in the measuring area. The manufacturer indicates this represents the highest radiation levels of any possible configuration. The radiation levels present may be significantly higher in the presence of a radioactive animal "patient" due to the diagnostic radionuclides in the patient.

QUALITY ASSURANCE AND CONTROL:

The manufacturer maintains a quality assurance and control program, which meets the FDA requirements for Good Manufacturing Practices under 21 CFR Part 820.

Manufacture and distribution of all devices is conducted under a QA/QC program that covers the design, manufacturing and servicing of MOSAIC. Prior to distribution, in accordance with the manufacturer's QA/QC Program, the following and other additional checks will be made of each device:

- All designs conform to information submitted in support of individual applications to include materials, dimensions within stated tolerances, manufacturing methods, and assembly methods.
- All units are leak tested to less than 185 Bq (5 nCi).
- All units are tested for proper operation of all safety features.
- All units are verified that radiation levels do not exceed the maximum limits stated in each device application.
- All units have the correct labeling on the device and inclusion of appropriate user manuals.

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DEVICE TYPE: Source holder, for Mosaic PET Animal Imaging System

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

License requirements - The device shall be distributed to persons specifically licensed by Ohio, an Agreement State or the NRC.

Leak testing - These devices must be leak tested by a specific licensed person at intervals not to exceed 6 months, using techniques capable of detecting 185 Bq (5 nCi, 0.005 uCi) of removable contamination.

Transfer and disposal - The device containing the sealed source may be transferred only to a specifically licensed person as specified in OAC Chapter 3701:1-46 (10 CFR 31 & 32 equivalent), or disposed at a specifically licensed disposal facility.

Administrative procedures must be established to (1) ensure that the source is properly shielded and secured when not installed in the MOSAIC system, and (2) minimize hand doses from radiation exposure while handling the device.

REVIEWER NOTE: The collimator block does not come with a shield to block the beam of radiation during assembly or handling.

Source Environmental Conditions - The source shall not be subjected to conditions that exceed the ANSI N43.6 classification of 77C66535. The source classification indicates that the source met the following test requirements without leaking.

Temperature-6	-40°C (-40°F) for 20 minutes, +800°C (1,472°F) for one hour, thermal shock to 20°C (68°F).
External Pressure-6	25 kN/m ² (3.6 lb _f /in ²) absolute to 170 MN/m ² (24,656 lb _f /in ²) absolute
Impact-5	dropped 5 kg (11 lb) from 1 meter (3.28 ft)
Vibration-3	30 minute test time 25 to 50 Hz at 5g peak amp; 50 to 90 Hz at 0.635 mm peak to peak amplitude and 90 to 500 Hz at 10g
Puncture-5	drop 300 grams (10.6 oz) from 1 meter (3.28 ft) onto source

This registration sheet and the information contained within the references shall not be changed without the written consent of the Department.

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SAFETY ANALYSIS SUMMARY:

Based on review of the Model 4535-674-39691 and 4535-679-56361, and the information and test data cited below, we conclude that the device is acceptable for licensing purposes.

Furthermore, we conclude that the device would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the Model 4535-674-39691 and 4535-679-56361 are hereby incorporated by reference and are made a part of this registry document:

Application dated October 31, 2003 with enclosures; and

Letters dated December 16, 2003, and February 20, 2004 with enclosures.

Amendment request dated November 10, 2004 with enclosures.

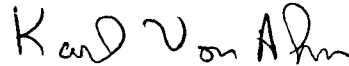
Amendment request dated November 16, 2007 with enclosures.

ISSUING AGENCY:

Ohio Department of Health
Bureau of Radiation Protection

Date: 12-19-07

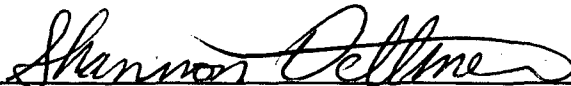
Reviewer:



Karl Von Ahn, RRPT

Date: 12-19-07

Concurrence:



Shannon Dettmer

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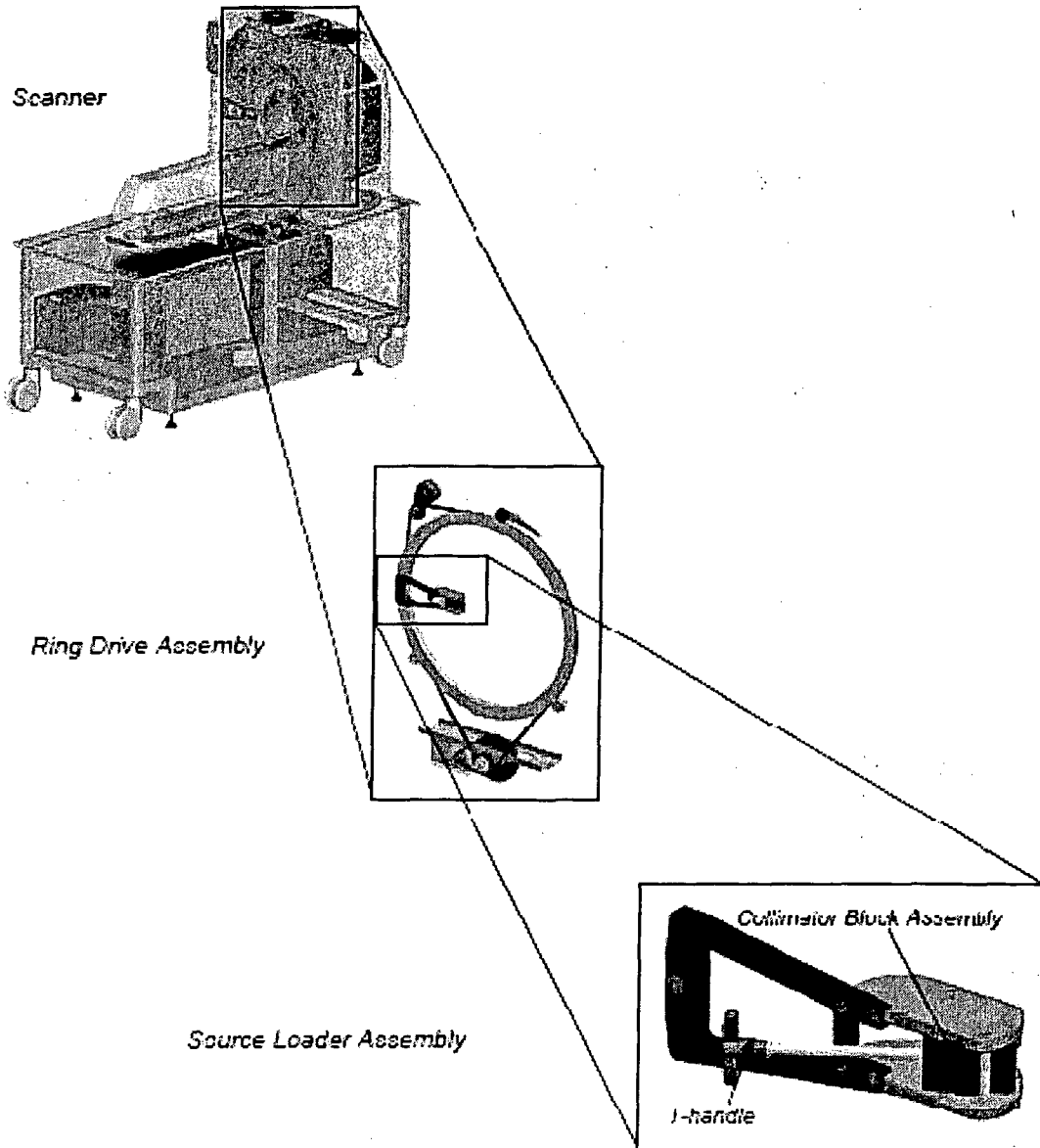
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MOSAIC Source Handling Assembly Overview



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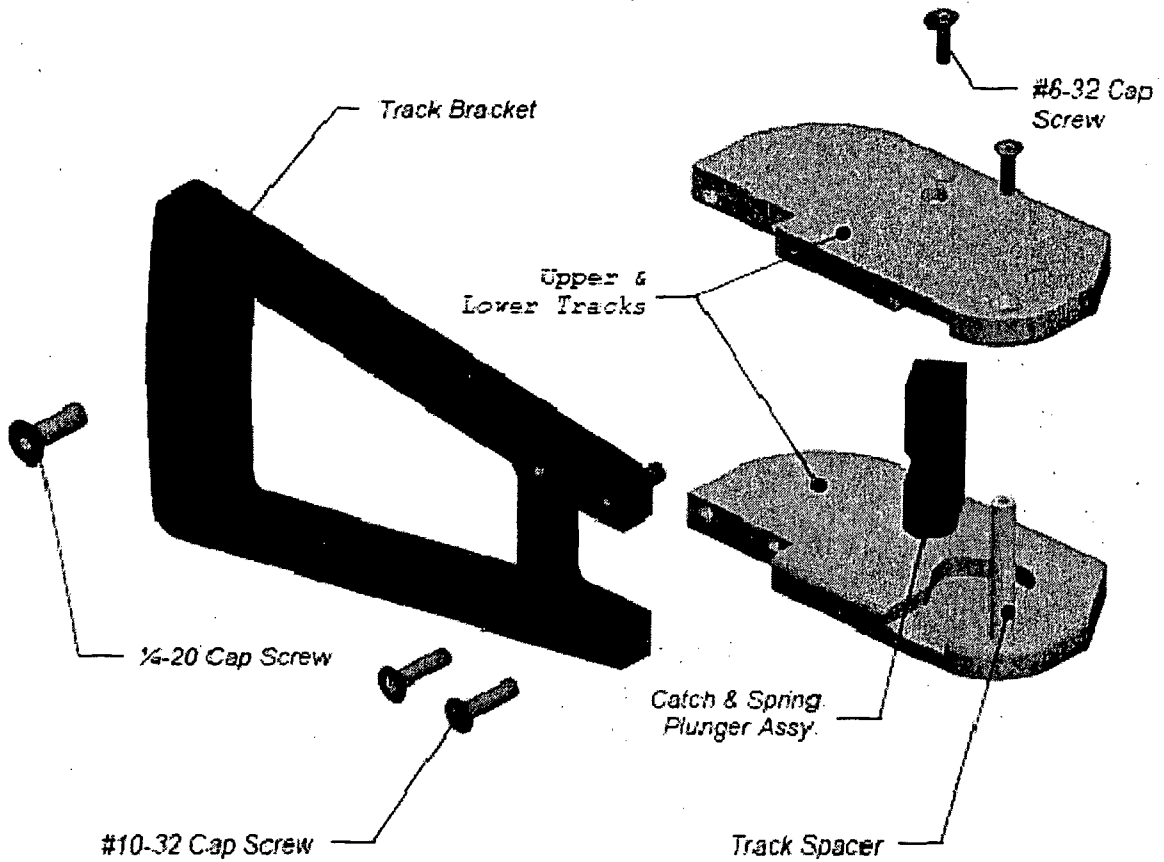
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Source Loader Assembly



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Collimator Block Assembly

