PURER I 123

SPECTamine®

Iofetamine HCl I 123 Injection

Extended expiration–
Expiration time is increased to 12 hours after time of calibration.

Better patient dosimetry– Improved radionuclidic purity reduces patient radiation exposure.

Please see adjacent page for brief summary of prescribing information.

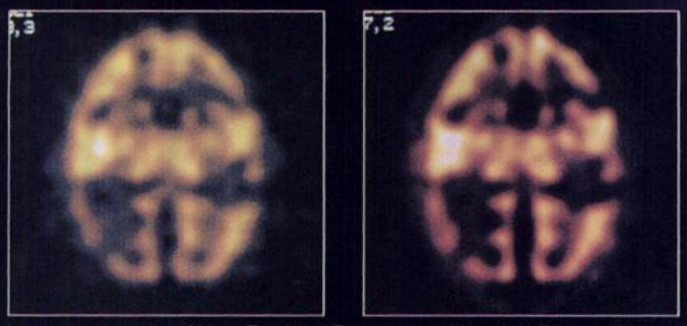
Superior image quality—

Reduced interference from radionuclidic impurities enhances image quality over an extended shelf-life.

Phantom studies comparing SPECTamine® (Iofetamine HCl I 123 Injection) labeled with

Te 124 (p,2n) iodine

I 127 (p,5n) iodine



Images courtesy of New England Deaconess Hospital, Boston, Mass. Images acquired with SME 810 dedicated head unit, Strichman Medical Equipment, Inc., Medfield, Mass.

For additional information on the use of SPECTamine,® contact your local Medi-Physics Territory Manager, MPI Professional Service Center or call 1-800-451-7732.

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140 East Ridgewood Avenue
Paramus, NJ 07652

SPECTamine®
Iofetamine HCl I 123 Injection

For complete product information, consult package insert, a brief summary of which follows:

DIAGNOSTIC – FOR INTRAVENOUS USE

DESCRIPTION: SPECTAMINE® Iofetamine HCl I 123 Injection, is supplied as a sterile, apyrogenic, aqueous, isotonic sodium chloride solution for intravenous administration. Each milliliter of the solution contains 37 megabecquerels (1 millicurie) of iofetamine HCl I 123 at calibration time, 0.15 milligram iofetamine HCl, 0.017 millimole sodium phosphate, and 8.0 milligrams sodium chloride for isotonicity. The pH is adjusted to 4.5-6.0 with sodium hydroxide or hydrochloric acid. SPECTAMINE contains no bacteriostatic preservative and is packaged in single dose vials. The radionuclidic composition at calibration time is not less than 98.0 percent I 123, not more than 1.9 percent I 125, and not more than 0.1 percent all others (I 126 and Te 121). The radionuclidic composition at the 12-hour expiration time is not less than 96.3 percent I 123, not more than 3.5 percent I 125, and not more than 0.2 percent all others.

INDICATIONS AND USAGE: SPECTAMINE (Iofetamine HCl I 123 Injection) is recommended for use as a lipid-soluble brain-imaging agent. It has been shown to be useful in the evaluation of nonlacunar stroke especially when used within 96 hours of onset of focal neurological deficit. The rates of agreement between abnormal images and the neurological examination suggestive of ischemic cerebrovascular insufficiency appear to increase with the severity of symptoms. Its usefulness for the measurement of cerebral blood flow has not been established.

CONTRAINDICATIONS: None known.

WARNINGS: SPECTAMINE (Iofetamine HCl I 123 Injection) should not be administered to individuals with known hypersensitivity to sympathomimetic amines or to those individuals taking monoamine oxidase inhibitors.

PRECAUTIONS:

General

Some primate (Macaca fascicularis) studies have shown marked eye uptake of iofetamine HCl I 123. Localization has not been studied in the isolated human eye although in vivo images suggest the concentration of iofetamine HCl I 123 is below the limit of detection. Individual human variations in pharmacokinetics of this drug and the long-term effect on the eye have not been elucidated.

The contents of the vial are radioactive. Adequate shielding of the preparation must be maintained at all times.

Do not use after the expiration time and date (12 hours after calibration time) stated on the label.

Potassium Iodide Oral Solution should be administered before the examination to minimize thyroid uptake of iodine 123.

The prescribed iofetamine HCl I 123 dose should be administered as soon as practical from the time of receipt of the product (i.e., as close to calibration time or before, if possible), in order to minimize the fraction of radiation exposure due to relative increase of radionuclidic contaminants with time.

To minimize radiation dose to the bladder, the patient should be encouraged to drink fluids and void frequently.

SPECTAMINE, as well as other radioactive drugs, must be handled with care. Appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Drug Interactions

There has been a single report of elevated diastolic hypertension (about 30 mm Hg) occurring 18 hours after administration of SPECTAMINE in a patient maintained on therapeutic doses of valproic acid.

Concurrent use of monoamine oxidase (MAO) inhibitors and compounds containing the amphetamine structure has been known to result in hypertensive crisis. Caution, therefore, should be exercised when administering SPECTAMINE (Iofetamine HCl I 123 Injection) to individuals taking medications known to potentiate the effects of sympathomimetic amines. It is recommended that SPECTAMINE not be administered during or within 14 days following administration of MAO inhibitors.

Sympathomimetic amines may affect the biodistribution of SPECTAMINE and, thus, may influence the image quality and diagnostic utility of the image.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility in male or female animals. The Ames test was negative for mutagenic effects.

Pregnancy Category C

Animal reproduction studies have not been conducted with SPECTAMINE. It is also not known whether SPECTAMINE can cause fetal harm when administered to a man or a pregnant woman or can affect reproduction capacity. SPECTAMINE should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability, should be performed during the first few (approximately ten) days following the onset of menses.

Nursing Mothers

Since Iodine I 123 is excreted in human milk, formula feeding should be substituted for breast feeding if the agent must be administered to the mother during lactation.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: In a clinical study in 93 patients with sudden onset of focal neurological deficit, e.g., cerebral infarction, 7 patients died within 2 to 55 days after administration. The deaths were considered to be a result of the disease state. Although there was no concurrent control group, statistics from historical controls support this evaluation.

There is evidence suggesting that the administration of 1 to 2 milligrams of iofetamine HCl, the carrier in SPECTAMINE, may increase systolic blood pressure by about 10 mm Hg. In a patient with a history of hypertension, there has been a single report of sudden onset of hypertension and dizziness with transient chest tightness which occurred 5-10 minutes after administration of SPECTAMINE. One case of transient unilateral hearing loss also was reported several hours after the use of SPECTAMINE in a patient with a coincidental upper respiratory infection.

As with all organic-iodine-containing compounds, the possibility of allergic reactions must be considered.

HOW SUPPLIED: SPECTAMINE is supplied in nominal 3.5 ml vials as a sterile, apyrogenic, aqueous, isotonic sodium chloride solution for intravenous injection. Each milliliter contains 37 megabecquerels (1 mCi) of iofetamine HCl I 123 at calibration time.

It is available in individual vials containing 111 megabecquerels (3 mCi) of iofetamine HCl I 123 at calibration time in a volume of 3 ml.

Single use vials are packaged in individual lead shields with plastic outer container.

THIS PRODUCT INFORMATION ISSUED AUGUST 1988

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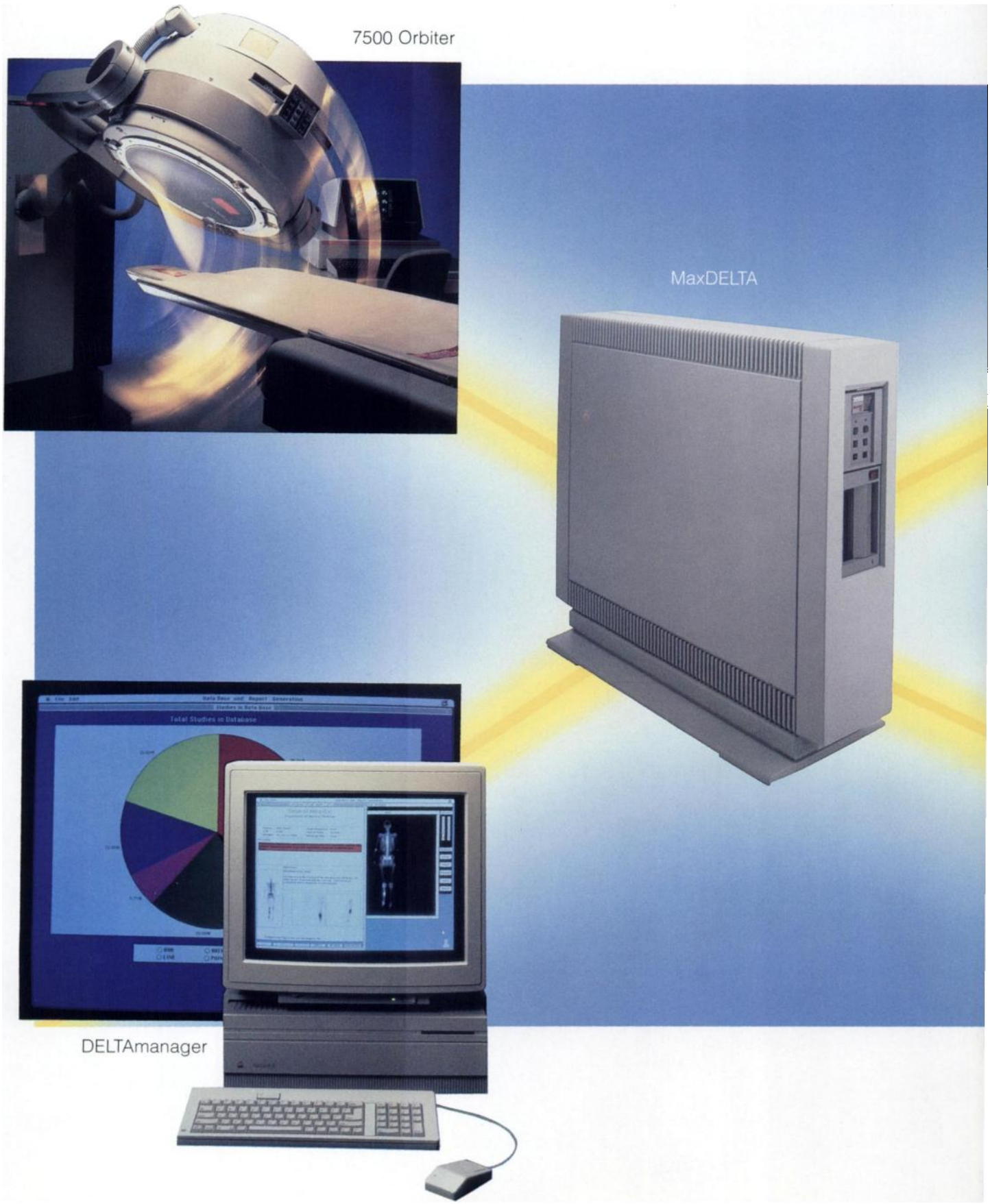

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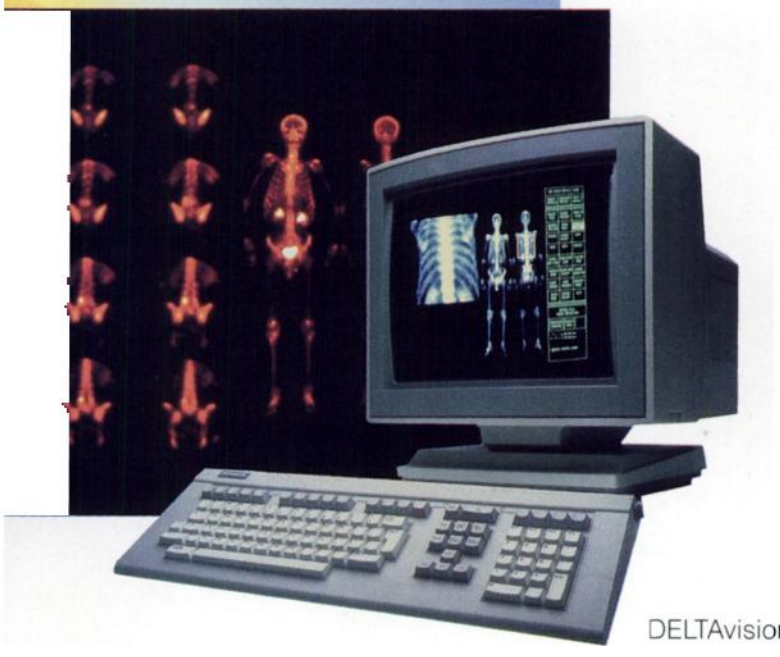

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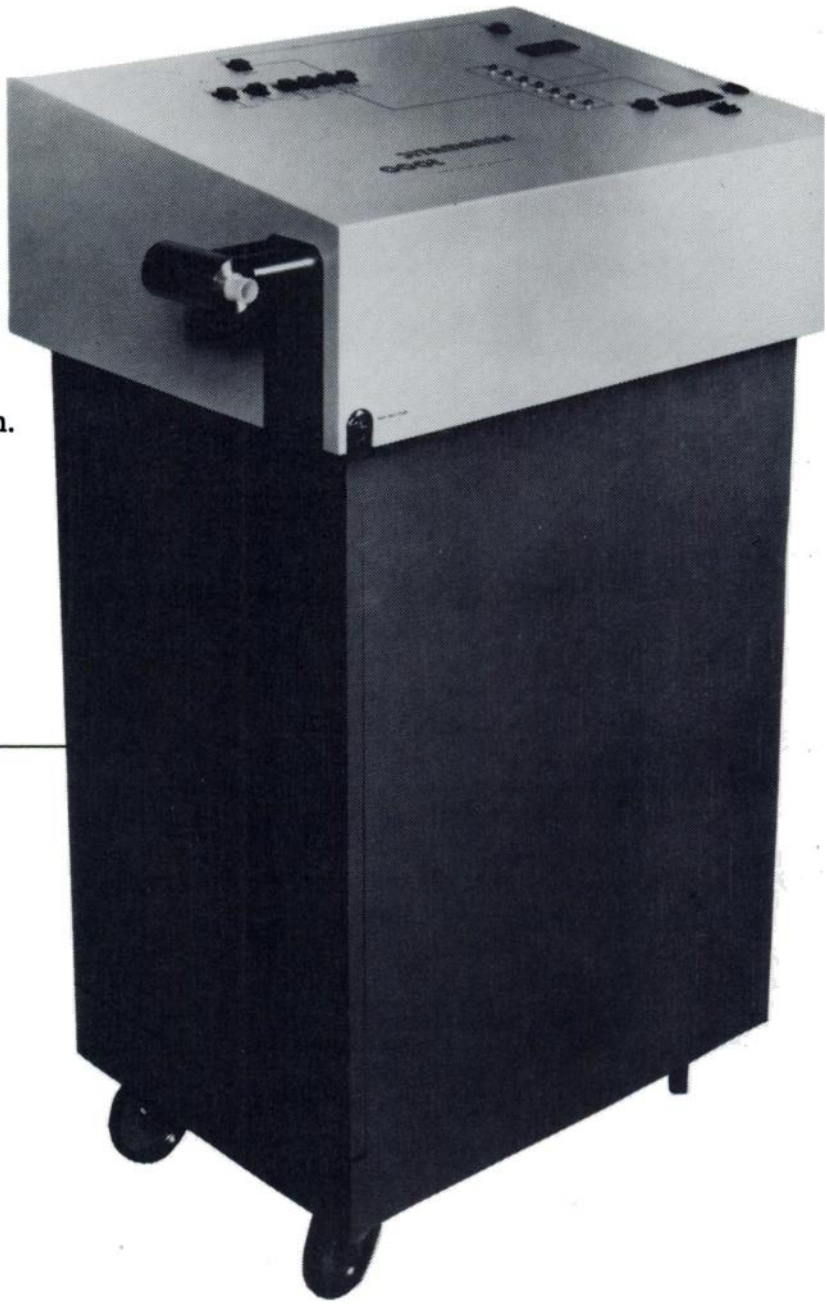

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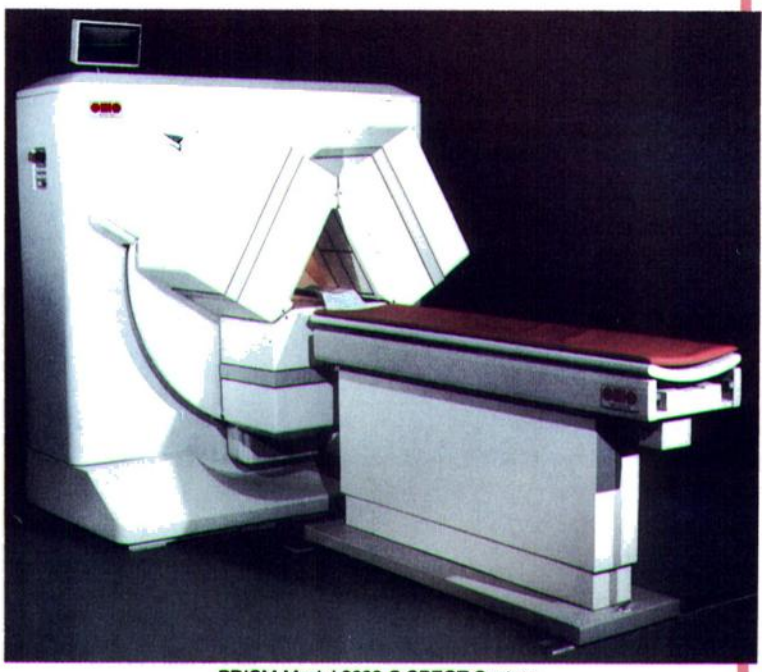

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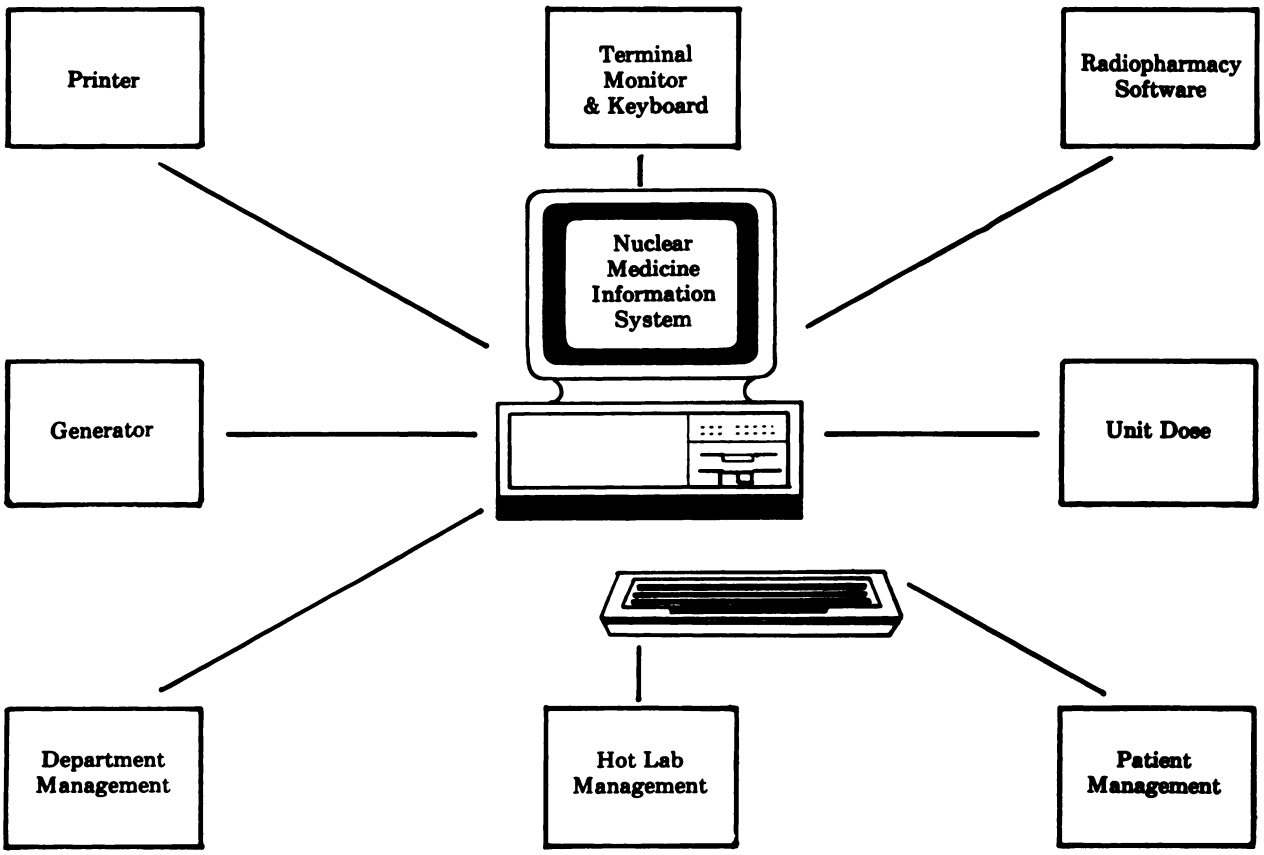

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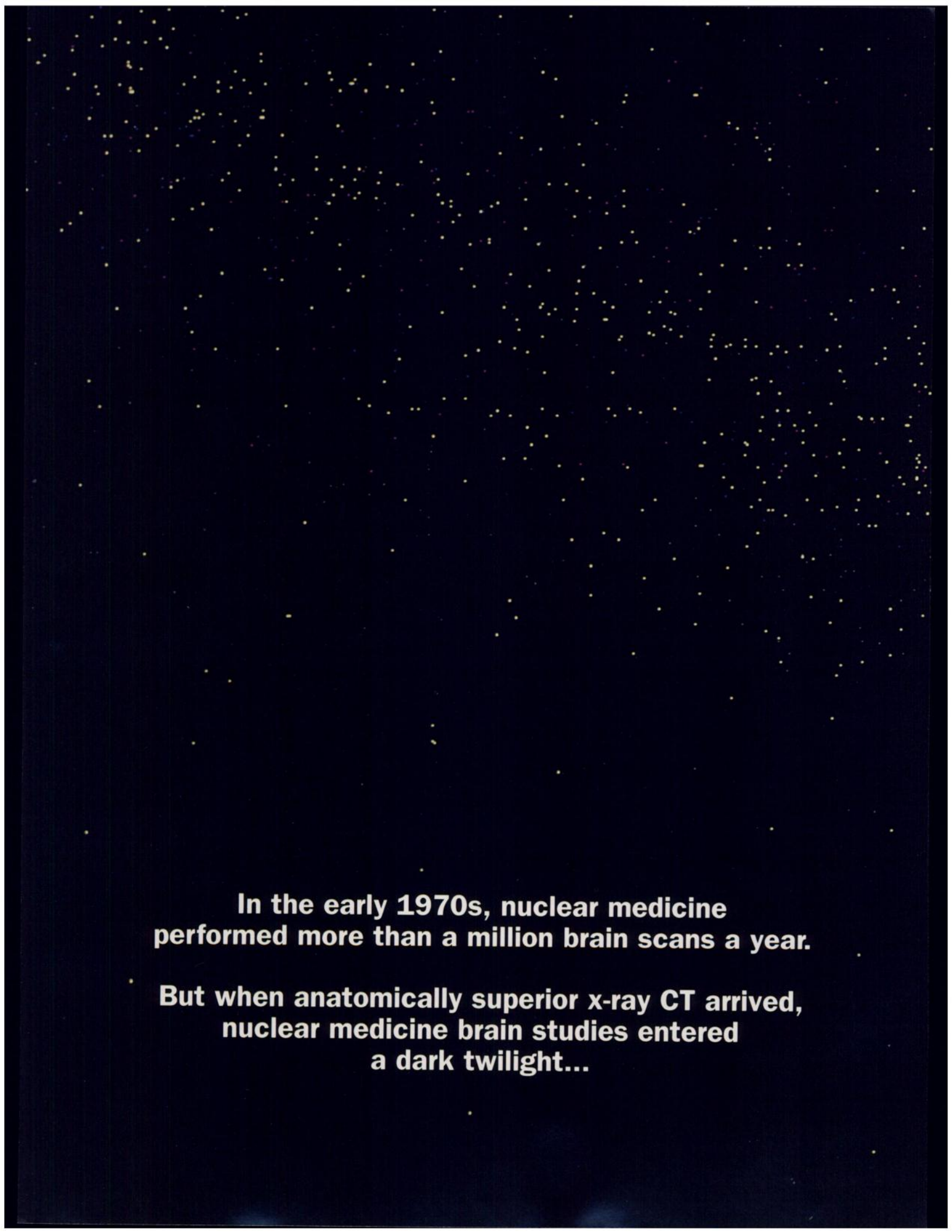
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Please see following page for full prescribing information.

Code N.159Z

Ceretec™

kit for the preparation of

Technetium Tc99m Exametazime Injection

Diagnostic radiopharmaceutical —
For intravenous single use only

DESCRIPTION

The Amersham Ceretec™ kit is supplied as packs of 5 single dose vial units for use in the preparation of a technetium Tc99m exametazime intravenous injection as a diagnostic radiopharmaceutical for use as an adjunct in the detection of altered regional cerebral perfusion. Each single dose vial unit contains a pre-dispensed sterile, non-pyrogenic, lyophilized mixture of 0.5 mg exametazime [(RR,SS)-4,8-diaza-3,6,6,9-tetramethylundecane-2,10-dione bisoxime], 7.6 µg stannous chloride dihydrate (minimum stannous tin 0.6 µg; maximum total stannous and stannic tin 4.0 µg per vial) and 4.5 mg sodium chloride, sealed under nitrogen atmosphere with a rubber closure. The product contains no antimicrobial preservative.

Caution: Federal (U.S.A.) Law prohibits dispensing without a prescription.

Prior to publication of the USAN, exametazime was formerly known as hexamethylpropylene amine oxime (HM-PAO). The name HM-PAO appears in many publications.

When sterile pyrogen-free sodium pertechnetate Tc99m in isotonic saline is added to the vial, a Tc99m complex of exametazime is formed.

Administration is by intravenous injection for diagnostic use.

Physical Characteristics

Technetium Tc99m decays by isomeric transition with a physical half-life of 6.03 hours.(1) Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal radiation emission data — technetium Tc99m

Radiation	Mean %/ disintegration	Mean energy (keV)
Gamma 2	87.87	140.5

1) Dillman, L.T. and Von der Lage, F.C. Radionuclide decay schemes and nuclear parameters for use in radiation-dose estimation. MIRD Pamphlet No. 10, p62, 1975.

External radiation

The specific gamma ray constant for technetium Tc99m is 206 microCoulomb kg^{-1}/37 MBq-h, (0.8 R/millicurie-h) at 1 cm. The first half-value thickness of lead (Pb) for technetium Tc99m is 0.2 mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of a 2.7 mm thickness of Pb will decrease the external radiation exposure by a factor of 1,000.

Table 2. Radiation attenuation by lead shielding

Shield thickness (Pb) mm	Coefficient of attenuation
0.2	0.5
0.95	10^{-1}
1.8	10^{-2}
2.7	10^{-3}
3.6	10^{-4}
4.5	10^{-5}

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals relative to the time of calibration are shown in Table 3.

Table 3. Physical decay chart — Tc99m half life 6.03 hours

Hours	Fraction remaining	Hours	Fraction remaining
0*	1.000	7	0.447
1	0.891	8	0.399
2	0.795	9	0.355
3	0.708	10	0.317
4	0.631	11	0.282
5	0.563	12	0.252
6	0.502	24	0.063

*Calibration time (time of preparation)

CLINICAL PHARMACOLOGY

When technetium Tc99m pertechnetate is added to exametazime in the presence of stannous reductant, a lipophilic technetium Tc99m complex is formed. This lipophilic complex is the active moiety. It converts with time to a secondary complex which is less lipophilic. When the secondary complex is isolated from the lipophilic species, it has been shown to be unable to cross the blood-brain-barrier. **A consequence of the conversion of lipophilic to secondary complex is that the useful life of the reconstituted agent is restricted to 30 minutes.**

Studies in normal volunteers have shown that the technetium Tc99m complex of the RR,SS(d,l) diastereoisomer of exametazime is rapidly cleared from the blood after intravenous injection. Uptake in the brain reaches a maximum of 3.5-7.0% of the injected dose within one minute of injection. Up to 15% of the activity is eliminated from the brain by 2 minutes post injection, after which little activity is lost for the following 24 hours except by physical decay of technetium Tc99m. The activity not associated with the brain is widely distributed throughout the body particularly in muscle and soft tissue. About 30% of the injected dose is found in the gastrointestinal tract immediately after injection and about 50% of this is excreted through the intestinal tract over 48 hours. About 40% of the injected dose is excreted through the kidneys and urine over the 48 hours after injection resulting in a reduction in general muscle and soft tissue background.

INDICATIONS AND USAGE

Technetium Tc99m exametazime scintigraphy may be useful as an adjunct in the detection of altered regional cerebral perfusion in stroke.

CONTRAINDICATIONS

None known.

PRECAUTIONS

The contents of the Ceretec vial are not radioactive. However, after the sodium pertechnetate Tc99m is added, adequate shielding of the final preparation must be maintained.

The contents of the Ceretec™ vial are intended only for use in preparation of technetium Tc99m exametazime injection and are NOT to be administered directly to the patient.

A thorough knowledge of the normal distribution of intravenously administered technetium Tc99m exametazime injection is essential in order to interpret pathologic studies accurately.

The technetium Tc99m labeling reaction involved in preparing technetium Tc99m exametazime injection depends on maintaining tin in the divalent (reduced) state. Any oxidant present in the sodium pertechnetate Tc99m employed may adversely affect the quality of the preparation. Sodium pertechnetate Tc99m containing oxidants should not be used for the preparation of the labeled product. **To meet the last requirement, a generator must be eluted within 24 hours prior to obtaining any eluate for reconstitution with the Ceretec kit.**

Sodium Chloride Injection, USP must be used as the diluent. Do not use bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc99m injection because it will increase the oxidation products and adversely affect the biological distribution of Ceretec.

GENERAL

The contents of the Ceretec vial are sterile and pyrogen free. The vial contains no bacteriostatic preservative. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiopharmaceutical.

Technetium Tc99m exametazime injection, like other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to the patient consistent with proper patient management.

Radiopharmaceuticals should be used only by or under the control of physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

To minimize radiation dose to the bladder, the patient should be encouraged to void when the examination is completed and as often thereafter as possible. Adequate hydration should be encouraged to permit frequent voiding.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long term animal studies have been performed to evaluate carcinogenic potential or whether technetium Tc99m exametazime affects fertility in males or females. Studies in rats did not demonstrate mutagenic potential following intraperitoneal administration at doses of 70, 140 and 280 mg/kg.

Pregnancy Category C

Since adequate reproduction studies with technetium Tc99m exametazime have not been performed in animals to determine whether this drug affects fertility in males and females, has teratogenic potential, or has other adverse effects on the fetus, this radiopharmaceutical preparation should not be administered to pregnant or nursing women unless it is considered that the benefits to be gained outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those which are elective in nature, in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc99m is excreted in human milk during lactation. It is not known whether exametazime is excreted in human milk. Therefore, formula feedings should be substituted for breast feeding.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Rash with generalized erythema, facial edema, and fever has been reported. A transient increase in blood pressure was seen in 8% of patients.

DOSAGE AND ADMINISTRATION

The user should wear waterproof gloves and use shielding at all times when handling the vial and syringes.

The recommended dose range for i.v. administration, after reconstitution with sodium pertechnetate Tc99m, to be used in the average adult (70 kg) is 370-740 MBq (10-20 mCi).

Do not use the final radiopharmaceutical preparation more than 30 minutes after time of reconstitution. Discard any unused material.

Dynamic imaging may be performed between 0 to 10 minutes following injection. Static imaging may be performed from 15 minutes up to 6 hours after injection.

Although gross abnormalities of regional cerebral perfusion may be visualized by planar imaging, it is strongly recommended that SPECT imaging is carried out to maximize the value of the study.

RADIATION DOSIMETRY

Based on human data, the absorbed radiation dose to an average human adult (70 kg) from an intravenous injection of this product are estimated below. The values are listed as µGy/MBq [rads/mCi] with urination every 2 hours. Bladder wall dose is 19 µGy/MBq [0.07 rads/mCi] with 4 hour urination and 89 µGy/MBq [0.33 rads/mCi] with no urination.

Table 4. Estimated Absorbed Radiation Dose*

Target organ	Absorbed radiation dose Tc99m exametazime injection			
	µGy/MBq	rads/mCi	µGy/740/MBq	rads/20mCi
Lachrymal glands	69.4	0.258	51.36	5.16
Gallbladder wall	51.0	0.19	37.74	3.80
Kidney	35.0	0.13	25.90	2.60
Thyroid	27.0	0.10	19.98	2.00
Upper large intestine wall	21.0	0.079	15.54	1.58
Liver	15.0	0.054	11.10	1.08
Small intestine wall	12.0	0.044	8.88	0.88
Lower large intestine wall	15.0	0.054	11.10	1.08
Urinary bladder wall	13.0	0.047	9.62	0.94
Brain	6.9	0.026	5.11	0.52
Ovaries	6.3	0.023	4.66	0.46
Testes	1.8	0.007	1.33	0.14
Whole body	3.6	0.013	2.66	0.26
Red Marrow	3.4	0.013	2.52	0.26
Bone Surfaces	4.8	0.018	3.55	0.36
Eyes	6.9	0.026	5.11	0.52

*Data supplied by Oak Ridge Associated Universities, Radiopharmaceutical Internal Dose Information Center.

ANIMAL TOXICOLOGY SUMMARY

Acute toxicity studies have been performed on intravenously administered Ceretec in male and female rats and rabbits. No adverse reactions or mortality were observed at a dose equivalent to the single injection of 1200 times the maximum human equivalent dose. Fourteen day repeat-dose studies in rats and rabbits at a cumulative dose of up to 14,000 times the maximum human equivalent dose did not reveal adverse reactions, abnormalities, or mortality. At termination, thorough histopathology, hematology and blood chemistry revealed no abnormalities.

HOW SUPPLIED

The kit comprises five individual vials of sterile, non-pyrogenic, freeze-dried mixture of exametazime stannous chloride dihydrate and sodium chloride, five radiation labels, five sterile alcohol swabs, five radiochemical purity worksheets, and one package insert. The vial and contents are sealed under a nitrogen atmosphere with a rubber stopper.

PROCEDURE

For the Preparation of Technetium Tc99m Exametazime Injection

Use aseptic technique throughout.

1) Place one of the vials in a suitable shielding container and swab the rubber septum with the sterile swab provided.
2) Using a 10 ml syringe, inject into the shielded vial 5 ml of sterile eluate from a technetium Tc99m generator (see notes 1-4). Before withdrawing the syringe from the vial withdraw 5 ml of gas from the space above the solution to normalize the pressure in the vial. Shake the shielded vial for 10 seconds to ensure complete dissolution of the powder.
3) Assay the total activity and calculate the volume to be injected. The patient dose should be measured in a suitable radioactivity calibration system immediately prior to administration.
4) Complete the label provided and attach to the vial shield. The technetium Tc99m exametazime injection is ready for quality control.
5) Maintain adequate shielding of the radioactive preparation.
6) **Do not use the preparation more than 30 minutes after time of formulation. Discard any unused material.**
7) Visually inspect the reconstituted material at a safe distance behind leaded glass, and do not use if there is evidence of foreign matter.

Cautionary Notes

1) 0.37-1.11 GBq (10-30 mCi) technetium Tc99m may be added to the vial.
2) Before reconstitution the generator eluate may be adjusted to the correct radioactive concentration (0.37-1.11 GBq [10-30 mCi] in 5 ml) by dilution with preservative-free non-bacteriostatic saline for injection.
3) Generator eluate more than 2 hours old should not be used. **For the highest radiochemical purity reconstitute with freshly eluted technetium Tc99m generator eluate.**
4) **Use only eluate from a technetium Tc99m generator which was previously eluted within 24 hours.**
5) The pH of the prepared injection is in the range 9.0-9.8.

Storage

Store the kit at 2-25 °C.

Store the formulated drug at room temperature (15-25 °C) using appropriate radiation shielding.

The Illinois Department of Nuclear Safety has approved this reagent kit for distribution to persons licensed to use by-product material identified in § 35.200 of 10 CFR Part 35 and to persons who hold an equivalent license issued by an Agreement State.

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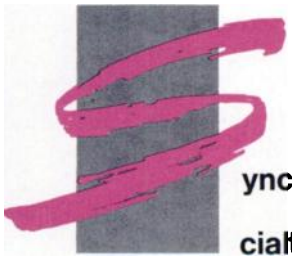

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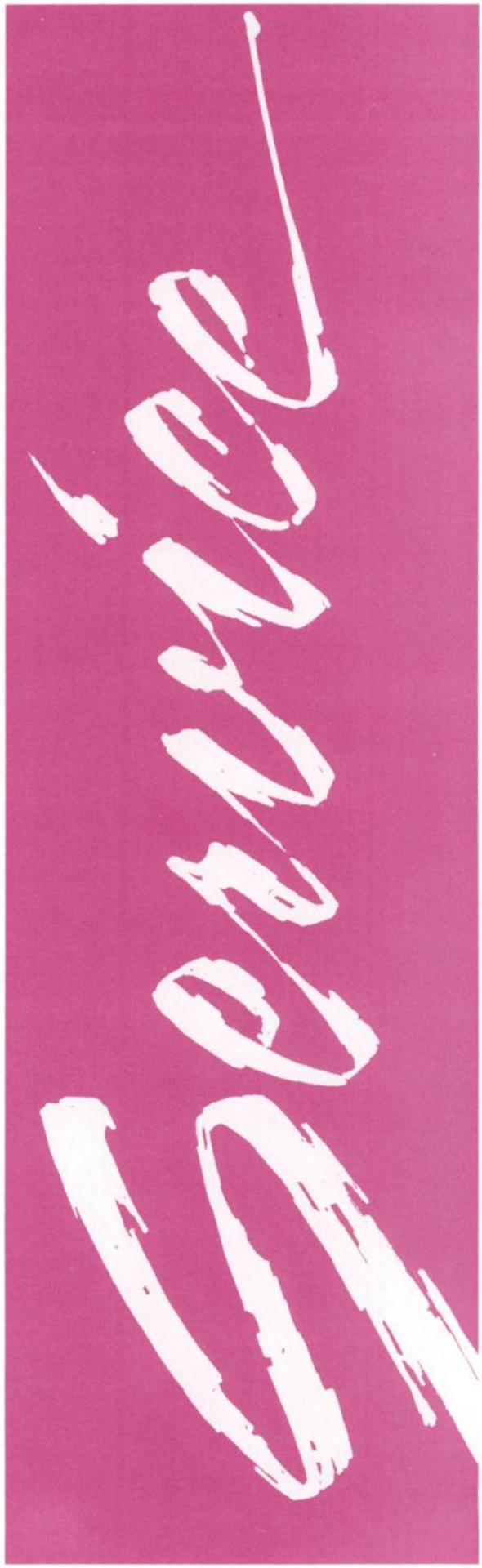

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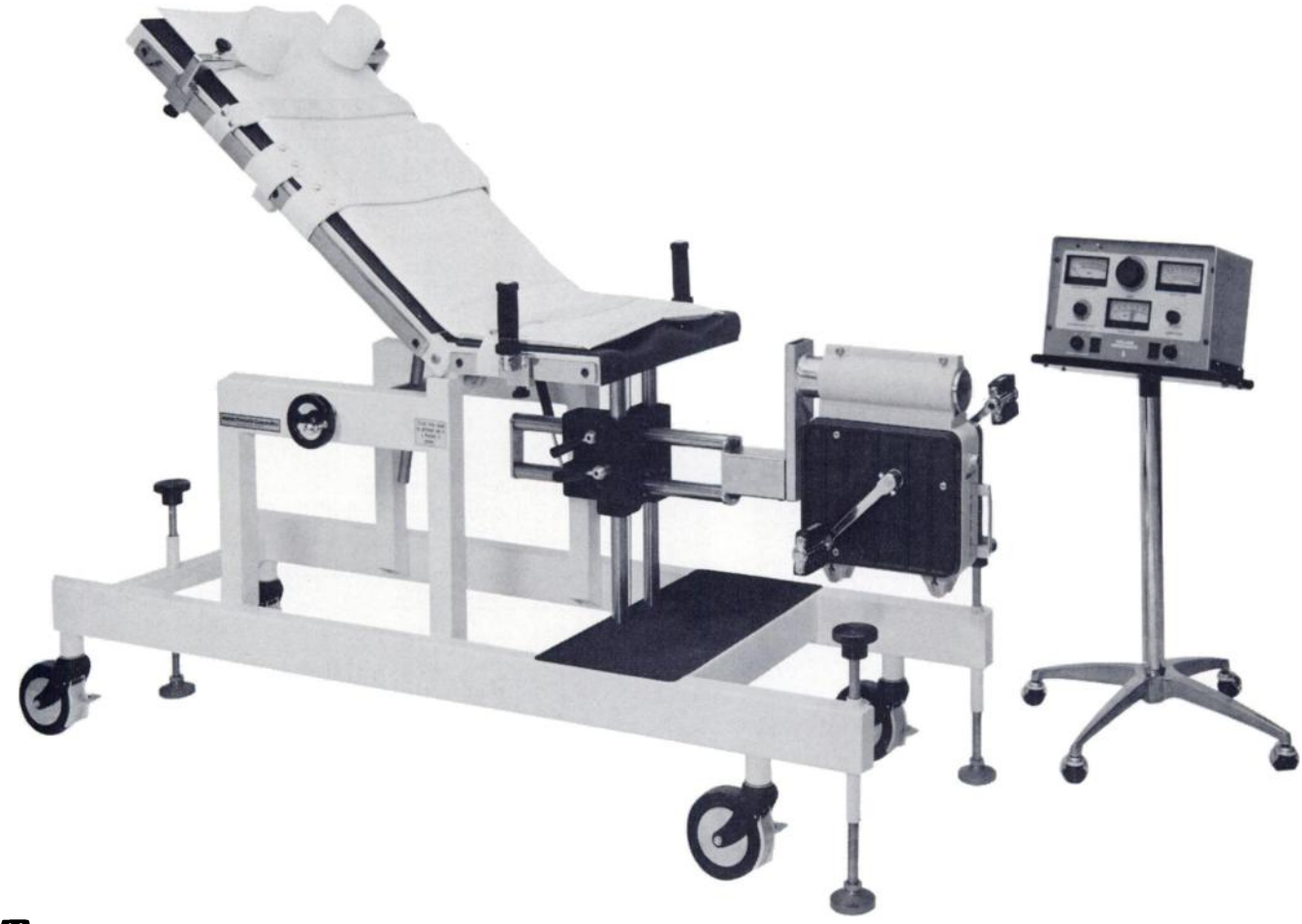

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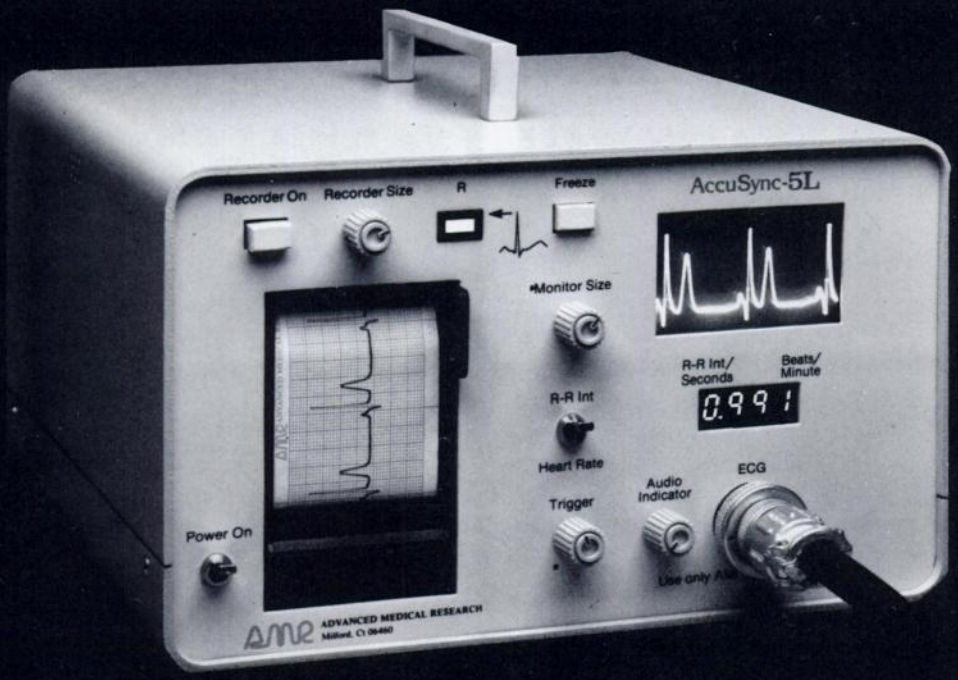

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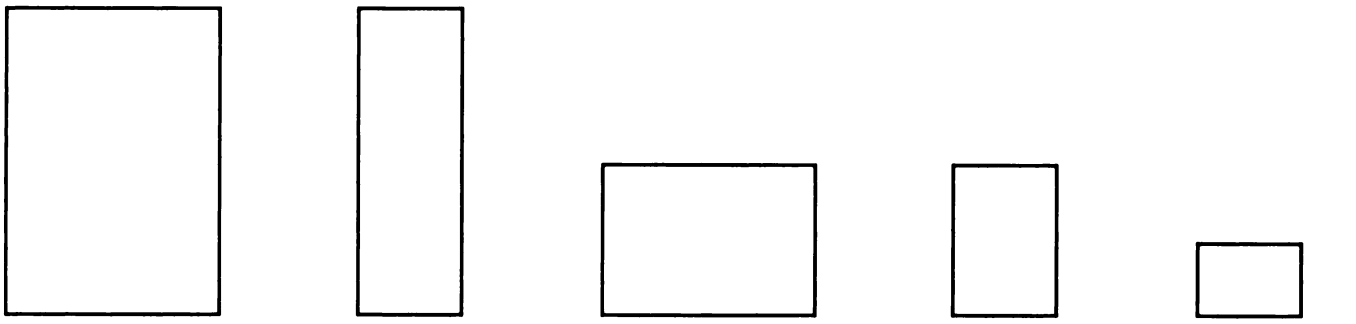

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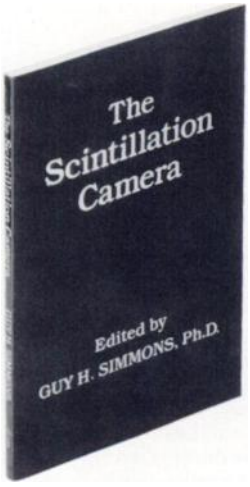

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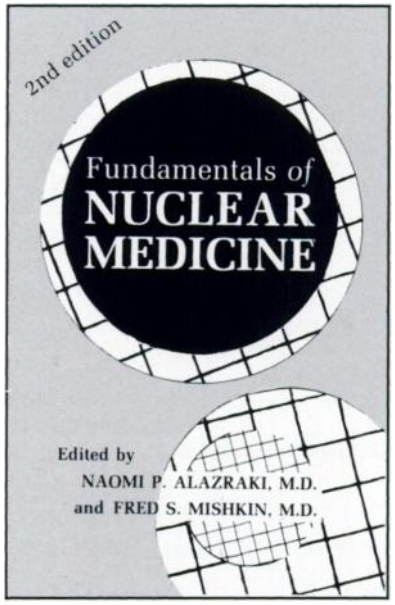

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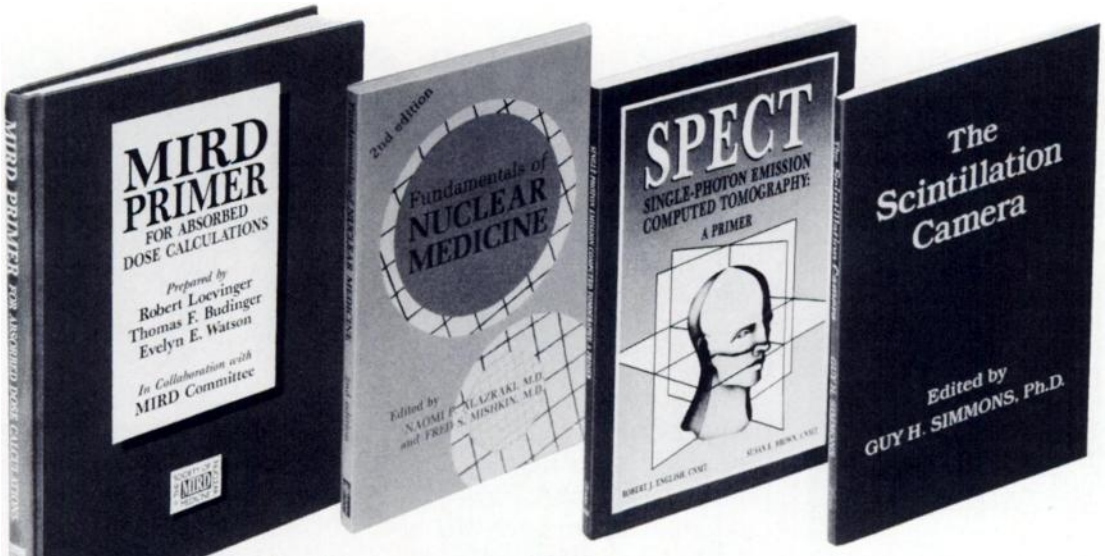

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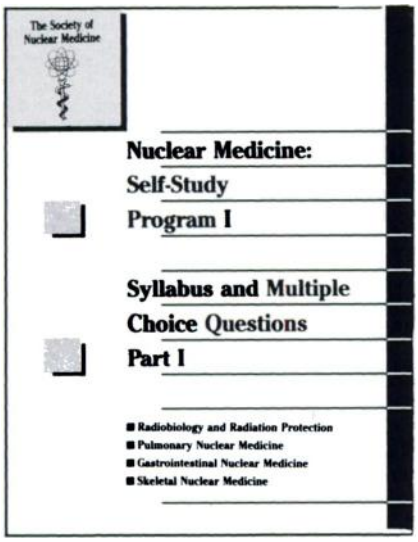

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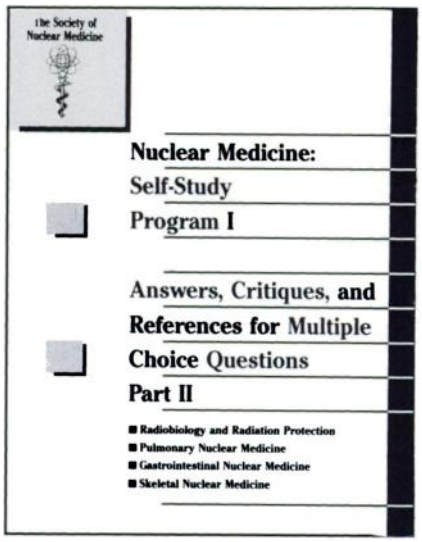

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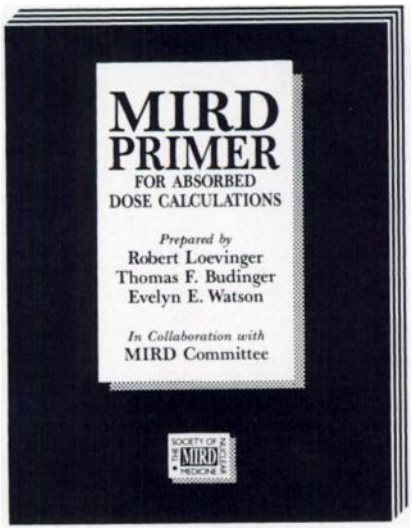

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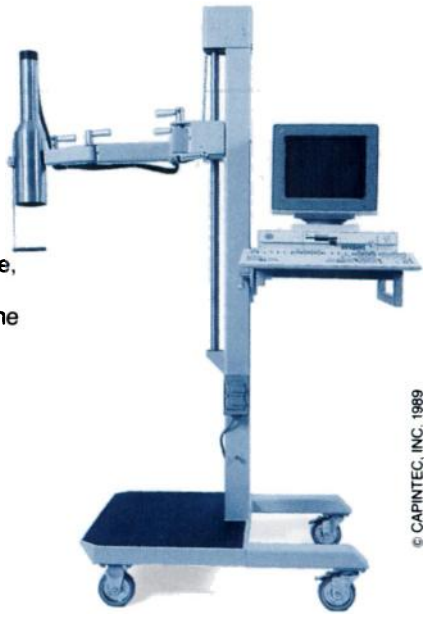

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Policy—*The Journal of Nuclear Medicine* accepts classified advertisements from medical institutions, groups, suppliers, and qualified specialists in nuclear medicine. Acceptance is limited to Positions Open, Positions Wanted, Equipment Available, and Seminars. We reserve the right to decline, withdraw, or modify advertisements that are not relevant to our readership.

Rates for Classified Listings—$15.00 per line or fraction of line (approx. 50 characters per line, including spaces). Please allow 28 characters for the first line which will appear in capital letters. Special rates for *SNM members* on Positions Wanted: $10.00 per line. *Note: Box numbers are available for the cost of the 2 lines required.*

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Publisher-set charges: page $100; half page $75; quarter page $40; eighth page $25.

Terms—Payment must accompany order. Make checks payable, in U.S. dollars on U.S. banks only, to: The Society of Nuclear Medicine.

Deadline—first of the month preceding the publication date (January 1 for February issue). Please submit classifed listings typed double spaced. No telephone orders are accepted.

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Positions Available

Cardiologist

NUCLEAR CARDIOLOGIST. Florida Heart Group, a large single specialty group practice, has a unique opportunity for a Board eligible or Board certified invasive or non-invasive cardiologist with a nuclear cardiology subspecialty. We are an aggressive, well-managed practice located in one of the most desirable and fastest growing communities in the United States. Our physicians are strongly affiliated with the sixth largest cardiovascular center in the country, Florida Hospital Orlando. Florida Heart Group offers unlimited potential for a dedicated, highly motivated physician in a progressive medical and business atmosphere. The position is office-based and requires candidates to be proficient in the subspecialty areas of nuclear first pass and SPECT Thallium Imaging. Send your CV to: Gregg W. Nelson, CEO, Florida Heart Group, P.A. 615 E. Princeton St., Suite 300, Orlando, FL 32803. (407)894-4474. EOE.

Physician

We are seeking an experienced Board-eligible or certified nuclear medicine PHYSICIAN to join our Clinical and Research Radiology Faculty at the University of Washington, to assume major responsibility for directing patient care services at Harborview Medical Center, an affiliate institution. There are complete state-of-the-art clinical facilities plus an imaging research center which includes nuclear, angiographic, MRI and PET imaging suites. Major research in nuclear medicine includes radiolabeled antibodies, osteoporosis, positron studies of cancer, heart and lung and extensive work in radiochemistry and computer sciences. There are six full-time students in nuclear medicine plus research fellows and active medical student teaching. Will consider Assistant or Associate Professor level. Salaries are highly competitive. The University of Washington is an equal opportunity employer. Please contact: Charles H. Chesnut III, MD, Professor, Radiology and Medicine, Director, Osteoporosis Research Center, Division of Nuclear Medicine, University of Washington, Dept. of Radiology, Seattle, WA 98195. EOE.

Training Programs

Department of Nuclear Medicine at SUNY/Buffalo offers the following TRAINING PROGRAMS: 1) Two-year nuclear medicine residency program; 2) Fellowships in nuclear oncology/monoclonal antibody research and cardiollgy; 3) One-year nuclear medicine programs for qualified radiologists; and 4) Five-year track programs combining nuclear medicine with radiology or internal medicine leading to board eligibility in both specialties. The programs offer a comprehensive exposure to all aspects of nuclear medicine and allied imaging fields and research. For further information and applications for July 1, 1989, contact: Joseph A. Prezio, MD, SUNY/Buffalo Nuclear Medicine, 20 Diefendorf Annex, 3435 Main St., Buffalo, NY 14214. AA/EOE.

Residency

NUCLEAR MEDICINE RESIDENCY. July 1989. Comprehensive imaging/RIA/therapy program in three hospitals (private, country, VA) with 2800 total beds. Mobile imaging for 216 ICU beds. Large pediatric population. Strong cardiovascular emphasis. Training includes SPECT, NMR, PET with optional rotation in CT/ultrasound. Contact: Warren H. Moore, MD, Department of Radiology, Baylor College of Medicine, One Baylor Plaza, Houston, TX 77030. Baylor College of Medicine is an equal opportunity A/A employer.

Radiologist

RADIOLOGIST. 10-man private group seeks BC/BE diagnostic radiologist with special competency or Board certification in nuclear medicine. Practice covers two hospitals and outpatient office with a total of 120,000 exams/yr. Beautiful midwestern university town. Excellent salary/fringes with early partnership arrangement. Send CV or call: Joe McColley, MD, 909 E. University St., Bloomington, IN 47401.(812)336-9446. EOE.

Technologist

NUCLEAR MEDICINE TECHNOLOGIST. The University of Utah Medical Center is accepting applications for a registered or registry-eligible imaging technologist. Our division provides a full range of imaging, cardiac, and research procedures with multiple cameras and computers. Competitive salary and benefits. Salt Lake City is a pleasant city located near mountains, ski resorts, and other recreational areas. Contact: Paul E. Christian, Nuclear Medicine, University of Utah Medical Center, Salt Lake City, UT 84132; (801)581-2716. EOE.

Nationwide: Considering a change? Let our 10 years of placement experience help you locate the best opportunity. Supervisory and staff positions available for NUCLEAR MEDICINE TECHNOLOGISTS throughout the US. Attractive salaries, interview, and relocation assistance included. Fee paid by employer. Ask about our new Short Term Travel Assignments. Call or send resume to: Department DRB. StarMed Staffing Corporation, 2701 Rocky Point Dr., Suite 100, Tampa, FL 33607. 1-(800)Star-Med. EOE.

NUCLEAR MEDICINE TECHNOLOGIST. University of Illinois Hospital, Registered or registry eligible. Salary commensurate with experience, excellent benefits. Tuition waiver. EOE. Resume to Jeff Rellis, Supervisor, Nuclear Medicine, M/C 931, 1740 Taylor St., Chicago, IL 60612, (312)996-3965.

NUCLEAR MEDICINE TECHNOLOGIST. Immediate opening for registered technologist with experience in cardiology, SPECT imaging, Elscint instrumentation, and processing preferred. Salary commensurate with experience and education. Send CV to: Dr. James B. Kho, PO Box 1468, Terre Haute, IN 47808. EOE.

Maui Sun Maui Surf Maui Sail. Private medical group in hospital setting has an immediate opening for a Staff NUCLEAR MEDICINE TECHNOLOGIST. This full-time, day position for a CNMT or recent grad of an accredited program offers competitive salary and benefits. Serious inquiries only. Send resume to: Maui Radiology Consultants, PO Box 1229, Wailuku, HI 96783. Attn: Nick Gladdis. (808)242-2954. EOE.

Australian Nuclear Science & Technology Organization
Lucas Heights, near Sidney, NSW, Australia

DIRECTOR
BIOMEDICINE AND HEALTH
Position No. BH1

- Salary $75,315 plus allowance ($2371), a car, Commonwealth superannuation and relocation expenses where appropriate.
- An opportunity to lead and expand the national radiopharmaceutical R&D program.
- Possible opportunity for part-time consultancy work at university teaching hospitals.

ANSTO is a Commonwealth Statutory Authority with a commercially oriented mission to apply nuclear science and technology in industry, medicine, agriculture and the community generally. The commercial arm for radiopharmaceutical production is Australian Radioisotopes, which supplies the majority of products used in nuclear medicine in Australia. The recently formed Biomedicine and Health program is an independent research unit whose output would be exploited by Australian Radioisotopes. Close liaison has to be maintained between the two groups.

The Biomedicine and Health program includes research and development work on an extensive range of diagnostic and therapeutic radiopharmaceuticals for Australian nuclear medicine. A comprehensive range of reactor produced radionuclides is already supplied by Australian Radioisotopes, and in 1991 the national medical cyclotron (to be located at Royal Prince Alfred Hospital, Syndey) will be operational. A full range of cyclotron radiopharmaceuticals will be developed.

In addition to radiopharmaceutical development the Biomedicine and Health program includes work on biomedical application of neutrons and on radiation biology, with an emphasis on radiotherapy.

A biomedical scientist is required, as Director of the Biomedicine and Health program, to manage all aspects of the research program of a large multi-disciplinary group of predominantly biomedically and chemically oriented scientists.

Appointment may be either on a term or permanent basis depending on individual circumstances.

Knowledge, qualification and skills

Post-graduate qualifications in a biomedical field, with extensive high quality research and administrative experience in a nuclear medicine related area are required. Medical qualifications would be desirable but not essential. The ideal candidate would have a proven record in medical research, leadership ability of a high order with well developed communication and liaison skills.

The contact officer for further information is Dr. P.M. Kelly, Telephone (02)543 3315.

Application forms and selection criteria may be obtained by telephoning (02)543 3064 or writing to the Recruitment Officer, Australian Nuclear Science and Technology Organization, Private Mail Bag 1, Menai 2234, quoting the above position number.

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Nuclear Medicine Technologist

838-bed Presbyterian Hospital of Dallas is one of the Southwest's leading tertiary care, teaching complexes. Not only do opportunities for career challenge and learning abound, but also such unique rewards as:

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Our Nuclear Medicine Department, which performs approximately 5,000 imaging and nonimaging procedures annually is seeking a well trained, highly skilled and motivated technologist immediately for a full-time position.

To maintain your skills, your responsibilities include performing a dynamic range of diagnostic and therapeutic procedures, radiopharmacy, instrumentation quality, and engaging in in-service education and continuing education. To support you, instrumentation includes five gamma cameras integrated to ADAC and ELSCINT computers, an ELSCINT SPECT SYSTEM and P/Cs' to fully automate certain tasks.

Qualifications: Degreed or non-degreed registered or registry eligible. Licensed in a state or eligible for licensure in the State of Texas. Salary: Commensurate with experience.

For more information, please submit the coupon below to: ***Kathy Gardner, Recruiting Office, PRESBYTERIAN HOSPITAL OF DALLAS, 8200 Walnut Hill Lane, Dallas, TX 75231 (214) 696-7458 (collect).***

JNM-2/89

I'd like additional information on career opportunities in Nuclear Medicine at Presbyterian Hospital:

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Date of Graduation _____

Brief history of related work experience _____

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An Equal Opportunity Employer

Chief Technologist Nuclear Medicine

Burlington, VT

The Medical Center Hospital of Vermont is seeking a dynamic individual to manage the day-to-day operations of the Nuclear Medicine Division of Radiology. As a member of our progressive management team, there are opportunities to improve operations, select equipment, participate in teaching and introduce and market new imaging techniques.

Qualified candidates must be ARRT/NMBCT certified with at least 5 years experience in nuclear medicine. Supervisory experience is strongly preferred with demonstrated effective technical, managerial, and leadership skills.

MCHV is a 500-bed tertiary care facility affiliated with the University of Vermont College of Medicine and the School of Radiologic Technology. Our Nuclear Medicine Division serves as the primary clinical affiliate for the nuclear medicine program at UVM. The division is housed in a new state-of-the-art facility. Our geographic location on Lake Champlain and in the heart of the Green Mountains, offers many recreational, cultural and educational opportunities. Please respond with resume to or contact: **Jean Ransom, Human Resources Department, Burgess Building, Medical Center Hospital of Vermont, Burlington, VT 05401, 1(800)722-9922.**

MCHV

Medical Center Hospital of Vermont

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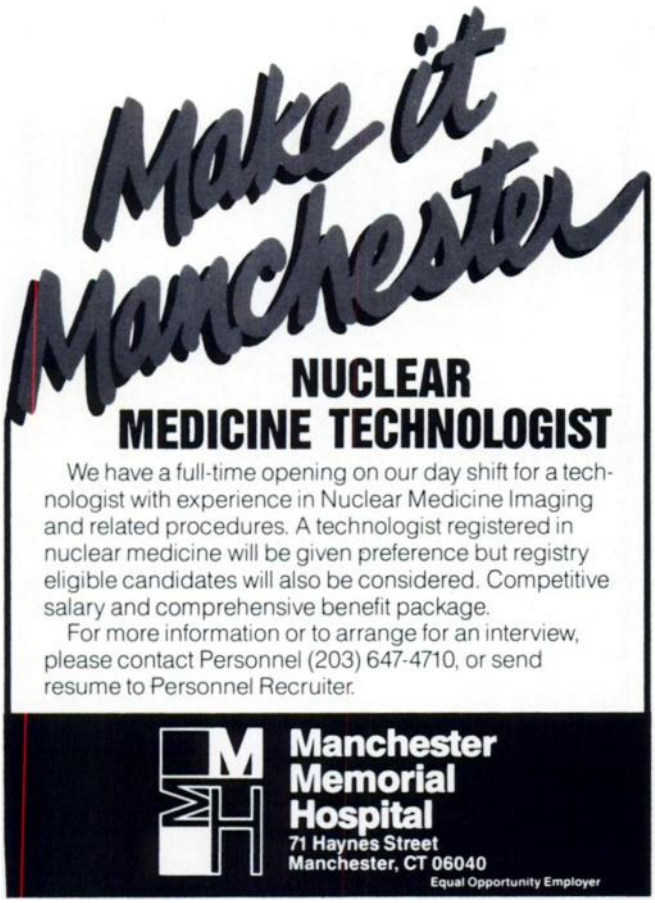

Cyclotron Operator/ Chemistry Associate

The Center for Metabolic Imaging at Creighton University has two immediate openings for Cyclotron Operator/Chemistry Associate to operate and maintain CTI-112 cyclotron, carry out routine production of positron emitting radiopharmaceuticals (such as ^{18}FDG, $^{13}NH_3$) for clinical studies, and to develop new radiopharmaceuticals for metabolic studies. The candidates should have BS/MS degree in either electronic engineering or mechanical engineering with some chemistry background. Experience with handling of radioactive materials is necessary. Interested candidates should send resume and transcript to:

Dr. Chyng-Yann Shiue
Director, Center for Metabolic Imaging
Department of Radiology
Creighton University
601 N. 30th St.
Omaha, NE 68131

An equal opportunity employer.

Postdoctoral Position: Organic/Medicinal Chemist.

The Center for Metabolic Imaging at Creighton University has an opening for organic/medicinal chemist interested in biomedical research with positron emission tomography (PET). Broad synthetic background required to develop compounds labeled with positron emitters 11_C, 13_N, and 18_F for in vivo metabolic studies. Experience with handling of radioactive materials is desirable but not essential. Interested candidates should send resume and names of three references to:

Dr. Chyng-Yann Shiue
Director, Center for Metabolic Imaging
Department of Radiology
Creighton University
601 N. 30th St.
Omaha, NE 68131

An equal opportunity employer.

PET Operator/ Medical Physicist

The Center for Metabolic Imaging at Creighton University has two immediate openings for PET Operator/Medical physicist to operate and maintain CTI-931 ECAT scanner. The candidate should have MS/BS degree in electronic engineering, computer science, or medical physics. Experience with VAX or SUN station system is desirable. Interested candidates should send resume and transcript to:

Dr. Chyng-Yann Shiue
Director, Center for Metabolic Imaging
Department of Radiology
Creighton University
601 N. 30th St.
Omaha, NE 68131

An equal opportunity employer.

Administrative Chief Nuclear Medicine Technologist

The Nuclear Medicine department of a progressive acute medical center has an exciting and challenging career opportunity for an experienced individual to assume an administrative position.

Equipment includes two state-of-the-art SPECT cameras, one portable camera, and three computers. Certification by the ARRT and NMTCB is required. Bachelor's Degree preferred.

Competitive salary with excellent benefit package provided.

Please send resume to:

Department of Human Resources
Inter-Community Medical Center
303 N. Third Avenue
Covina, CA 91723.

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Brigham and Women's Hospital is a 720-bed Harvard affiliated teaching hospital located in Boston, MA, an area rich in culture, education, and recreational opportunities. We currently have the following opportunity available:

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This position is responsible for the daily administration of the Nuclear Medicine Division which performed 6,500 exams last year, with a staff of 7 technologists and support help. The department has 7 rooms of which there are 3 SPECT systems and nuclear cardiology. 3-5 years' progressive experience as a Nuclear Medicine technologist with at least 2 years in a supervisory capacity in a teaching hospital environment. CNMT or A.R.R.T. (N) required, Bachelor's degree preferred.

We offer a competitive salary and excellent benefit package including a subsidized health club membership, with the opportunity to join an expanding, world renowned health care institution. **Interested and qualified applicants should send resumes to Leslie Griffin Scavo.**

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Nuclear Medicine Technologist

Indiana University, a teaching, acute care, and research center, located on the growing joint campus of Indiana and Purdue Universities, is accepting applications for the position of Staff Nuclear Medicine Technologist. Two positions are currently available. One at University Hospital and one at Riley Children's Hospital. Both Hospitals offer a full range of diagnostic and research services, including cardiology, SPECT, dual-photon absorptiometry and RIA. Qualified candidates must have a BS degree and certification in nuclear medicine. Salary commensurate with experience. Excellent benefits. Interested candidates should send a resume to: **Phyllis Gootee, IUPUI Personnel Dept., Union Building, 620 Union Dr., Indianapolis, IN 46223. An equal opportunity, affirmative action employer, educator and contractor. M/F.**

Director, Nuclear Medicine Stanford University Medical Center

The Department of Diagnostic Radiology and Nuclear Medicine at Stanford Medical School is searching for a director of the nuclear medicine program. The director will also have an academic appointment as Associate Professor or Professor. Prerequisites include certification by the American Board of Nuclear Medicine, research training and productivity, board clinical expertise, evidence of teaching ability, administrative experience, and leadership characteristics. Stanford University is committed to increasing representation of women and members of minority groups on its faculty and particularly encourages applications from such candidates.

The Nuclear Medicine Unit is moving its clinical facilities to new quarters in a recently constructed wing of Stanford University Hospital and is updating its equipment to state-of-the-art. The Unit includes a radioimmunoassay facility and research laboratories.

The program at the affiliated Palo Alto Veterans Administration Medical Center is also occupying new quarters and has outstanding equipment, including a PET scanner. Among the research facilities available in the Department are MRI/MRS and image processing instrumentation and wet labs for radiopharmaceutical development. Opportunities for collaborative research with an outstanding Department of Electrical Engineering are available.

The candidate will be expected to coordinate the scholarly, teaching and clinical activities of these units into a cohesive academic program. All interested candidates should send a letter of inquiry, including a curriculum vitae, to **Nuclear Medicine Search Committee Chairman, Dept. of Diagnostic Radiology/Nuclear Medicine, Stanford University School of Medicine, S-078, Stanford, California 94305.**

An Equal Opportunity Employer

Minneapolis VA Medical Center

The jointly-sponsored Veterans Administration/University of Minnesota PET program is now recruiting for September, 1989. Applications are invited from experienced, research-oriented organic chemists with demonstrated expertise in PET radiochemistry. The successful applicant will join a team of established PET investigators working in a state-of-the-art research environment at the Veterans Administration Medical Center. This position is ideally suited for a talented, academically-minded scientist who wishes to earn a competitive salary and enjoy excellent benefits.

For confidential consideration, send CV and bibliography to: DA Rottenberg, MD, Medical Director, VAMC/UMHC PET Program,

c/o Robert A. Petzel, MD
Chief of Staff
Veterans Administration Medical Center
One Veterans Drive
Minneapolis, MN 55417

AN EQUAL OPPORTUNITY EMPLOYER

Nuclear Medicine Technologist

As facilities of the North Broward Hospital District, South Florida's most stable and successful multi-hospital system, Broward General Medical Center (744-beds) and North Broward Medical Center (419-beds) are dedicated to service that reflects health care curriculum. As we continue to upgrade and expand we have immediate positions available for NUCLEAR MEDICINE TECHNOLOGISTS.

You must be a graduate of an approved Nuclear Medicine Technology program, have a Florida State license, and be ARRT-N and/or CNMT Registered. (Both are preferred)

Broward General Medical Center and North Broward Medical Center offer excellent salaries and benefits including low-cost temporary housing. Please call (305)355-5357 collect or send resume in confidence to:

Human Resources, Broward General Medical Center
1800 S. Andrews Ave., Fort Lauderdale, FL 33310.

EOE M/F/H/V Facilitico of the North Broward Hospital District

Nuclear Medicine Technologist

The University of Alabama Hospital, UAB, is seeking registered or registry eligible Nuclear Medicine Technologists for its nuclear medicine division of radiology. University Hospital, located in Birmingham, is an 800-bed medical center and teaching institution offering opportunity for maximum professional development as well as competitive salary and excellent benefits program. Interested candidates may contact: **Scott Brown at (205)934-6321, or forward resume to: Personnel Administration, University of Alabama Hospital, 619 South 19th St., Birmingham, AL 35233. AA/EOE.**

The Brain, the Self, and Nuclear Medicine

Bonn, West Germany, April 7–8, 1989

TOPICS:

Overview and Introduction

The relationship between brain function and neurophysiology
The self and philosophy
Models of the brain, models of the self
Interactionism between the brain and the self

Basic Sciences

Neurophysiology
Models for metabolism
Models for receptor studies
Instrumentation–present and future
Radiopharmacology–present and future

The Brain: Resting and Cognitive States

The development of brain function
PET findings in normal mental activity
SPECT findings in normal mental activity
SPECT during WADA test, sleep and dream

Dementia

Neurology and neuropsychology
PET findings
Differential diagnosis (SPECT)

Psychiatric Diseases

Applications of brain imaging in psychiatric diseases
Brain imaging and neuropsychology
PET applications
rCBF with xenon-133 in schizophrenia
IMP and schizophrenia

For further information contact:

Michael D. Devous, PhD, Nuclear Medicine Center, UT Southwestern Medical Center, 5323 Harry Hines Boulevard, Dallas, TX 75235-9061, (214)688-3315

Hans J. Biersack, MD, Professor and Chairman, Department of Nuclear Medicine, University of Bonn, Sigmund-Freud-Straße 25, D-5300 Bonn 1, West Germany, 2 28/280 2180

EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE CONGRESS 1989

AUGUST 28 – SEPTEMBER 1
STRASBOURG, FRANCE

SCIENTIFIC PROGRAM

Plenary sessions, with lectures given by invited speakers, will feature the following main topics: Oncology, Emission Tomography, Cardiology, Pediatrics, Neurology.

Scientific Papers, Works-in-Progress, Technicians' Program, Scientific and Commercial Exhibition, and Pre- and Post-Congress Meetings are also included.

Topics related to nuclear medicine will be considered for inclusion in the scientific program as follows:

Clinical science applications:
Cardiology and Circulation, Bone/Joint Diseases, Pulmonary Diseases, Neurology, Nephrology, Hematology, Endocrinology, Pediatrics, Gastroenterology, Oncology, Immunology, Infectious Diseases

Physical science—basic research:
Computers and Data Analysis, NMR: Imaging and In Vivo Spectroscopy, Dosimetry, Radiobiology, Instrumentation

Laboratory science and in vitro applications:
Radioassay, Tumor Markers, Cell Labeling, Genetic Engineering

Radiopharmaceutical:
General, Halogens, Positrons, Proteins/Antibodies, Technetium

Call for Abstracts:
The deadline for the receipt of abstracts is:

March 15, 1989

SCIENTIFIC SECRETARIAT:
Institut de Physique Biologique
4, rue Kirschleger
Faculte de Medecine
F-67085 STRASBOURG
Tel.: 88-35-42-22
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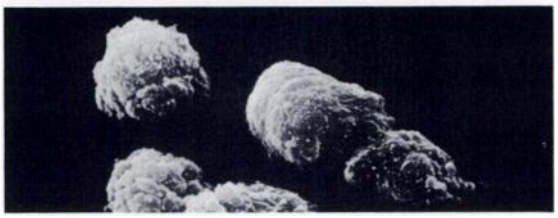
FAX: 88-37-14-97

EXHIBITION:
A comprehensive exhibition of equipment and radiopharmaceutical manufacturers will be on display.

For further information:
Exhibition Manager:
Michèle Siegrist
Palais de la Musique et des Congrès
Avenue Schutzenberger
67082 STRASBOURG CEDEX
Tel.: 88-35-03-00

PRESIDENT OF THE CONGRESS:
Prof. Jacques Chambron

CLINICAL APPLICATIONS OF MONOCLONAL ANTIBODIES IN CANCER DETECTION AND THERAPY.



ONE-DAY SEMINAR, MARCH 11, 1989, AT THE J.W. MARRIOTT HOTEL IN LOS ANGELES, CALIFORNIA.

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The Society of Nuclear Medicine

SNM 36th Annual Meeting

Tuesday, June 13–
Friday, June 16, 1989

St. Louis, MO
Cervantes Convention Center

Call for Abstracts for Works-in-Progress

The 1989 Scientific Program Committee solicits the submission of abstracts from members and nonmembers of The Society of Nuclear Medicine for the 36th Annual Meeting in St. Louis. Works-in-Progress accepted for the program will be published in a separate on-site show directory that will be distributed to all those who attend the meeting. Original contributions on a variety of topics related to nuclear medicine will be considered, including:

- INSTRUMENTATION
- COMPUTERS AND DATA ANALYSIS
- RADIOASSAY
- RADIOPHARMACEUTICAL CHEMISTRY
- DOSIMETRY/RADIOBIOLOGY
- NUCLEAR MAGNETIC RESONANCE
- CLINICAL SCIENCE APPLICATIONS
  - Bone/Joint
  - Cardiovascular
  - Endocrine
  - Gastroenterology
  - Infectious Disease and Immunology
  - Neurology
  - Oncology/Hematology
  - Pediatrics
  - Pulmonary
  - Renal/Hypertension

Authors seeking publication for the full text of their papers are strongly encouraged to submit their work to the *JNM* for immediate review.

A complete educational program for technologist will be offered and technologists are encouraged to submit abstracts of their work for consideration.

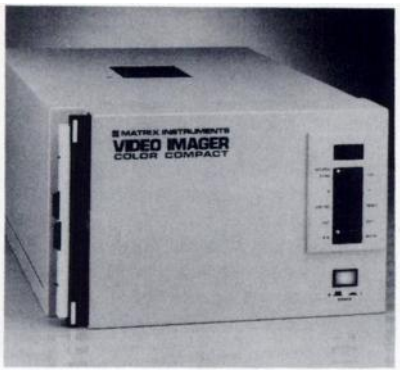
The official abstract form for Works-in-Progress may be obtained from the September 1988 issue of the *JNM* or by calling or writing:

The Society of Nuclear Medicine
Att: Abstracts
136 Madison Avenue, New York, NY 10016-6760
Tel: (212)889-0717
FAX: (212)545-0221

Deadline for Works-in-Progress is Thursday, April 7, 1989

Each description of the products below was condensed from information supplied by the manufacturer. The reviews are published as a service to the professionals working in the field of nuclear medicine and their inclusion herein does not in any way imply an endorsement by the Editorial Board of The Journal of Nuclear Medicine *or by The Society of Nuclear Medicine.*

New Video Imager



Matrix Instruments, Inc., has announced the introduction of its Color Compact Video Imager—the first compact film recorder capable of recording multiple color images on a single sheet of 8-inch or 10-inch film. Only 9.5" high by 15.5" wide by 28.5" deep, the color compact can be ordered in versions that will generate four or six images, in color or black and white, on standard or instant print sheet film or transparencies. At the heart of this recorder is the Matrix RBG filter wheel assembly, with which color components are sequentially displayed on a high resolution monochrome CRT, resulting in a superior quality color composite of the superimposed red, green, and blue exposures. This capability makes this imager ideal for color flow doppler ultrasound, nuclear medicine, and other color applications. To maximize reliability, the Color Compact Video Imager uses microprocessor electronics that have been proven in many other Matrix recorders. Built-in software ensures simple initial calibration and set-up for consistent, optimal performance. In addition, memories store up to four sets of image parameters for recall at any time. **Matrix Instruments, Inc., 1 Ramland Rd., Orangeburg, NY 10962. Attn: Susan Hubener. (914) 365-0190.**

Circle Reader Service No. 101

Basic Gamma Counter

Packard Instrument Company has introduced its Cobra™ One single detector gamma-counting system. With advanced technology based on multichannel analysis and built-in computer control, this basic low-cost CPM system provides cost-effective upgrading capabilities through hardware and software modules. The system is easily configured to meet today's laboratory applications, and its modularity and expandability make it suited for future applications without investing in new equipment. The Cobra One system offers a choice of either a two-inch or three-inch NaI(Tl) detector. Three counting regions, a 15 to 2000 keV energy range, and low background allow precise counting of both high and low energy radionuclides. The unit can provide unattended sample processing due to its 1000-tube capacity sample changer and 60 user programs. Volume independence is achieved through the use of protocol-adjustable elevator positions, which align the sample in the optimum location for counting, regardless of sample volume. A powerful built-in IBM-compatible computer features a 20Mb hard drive and a 3.5-inch floppy disc drive to accept and run a variety of software products and operate all system functions. **Packard Instrument Company, 2200 Warrenville Rd., Downers Grove, IL 60515. Attn: Jim Vondran. (312) 969-6000.**

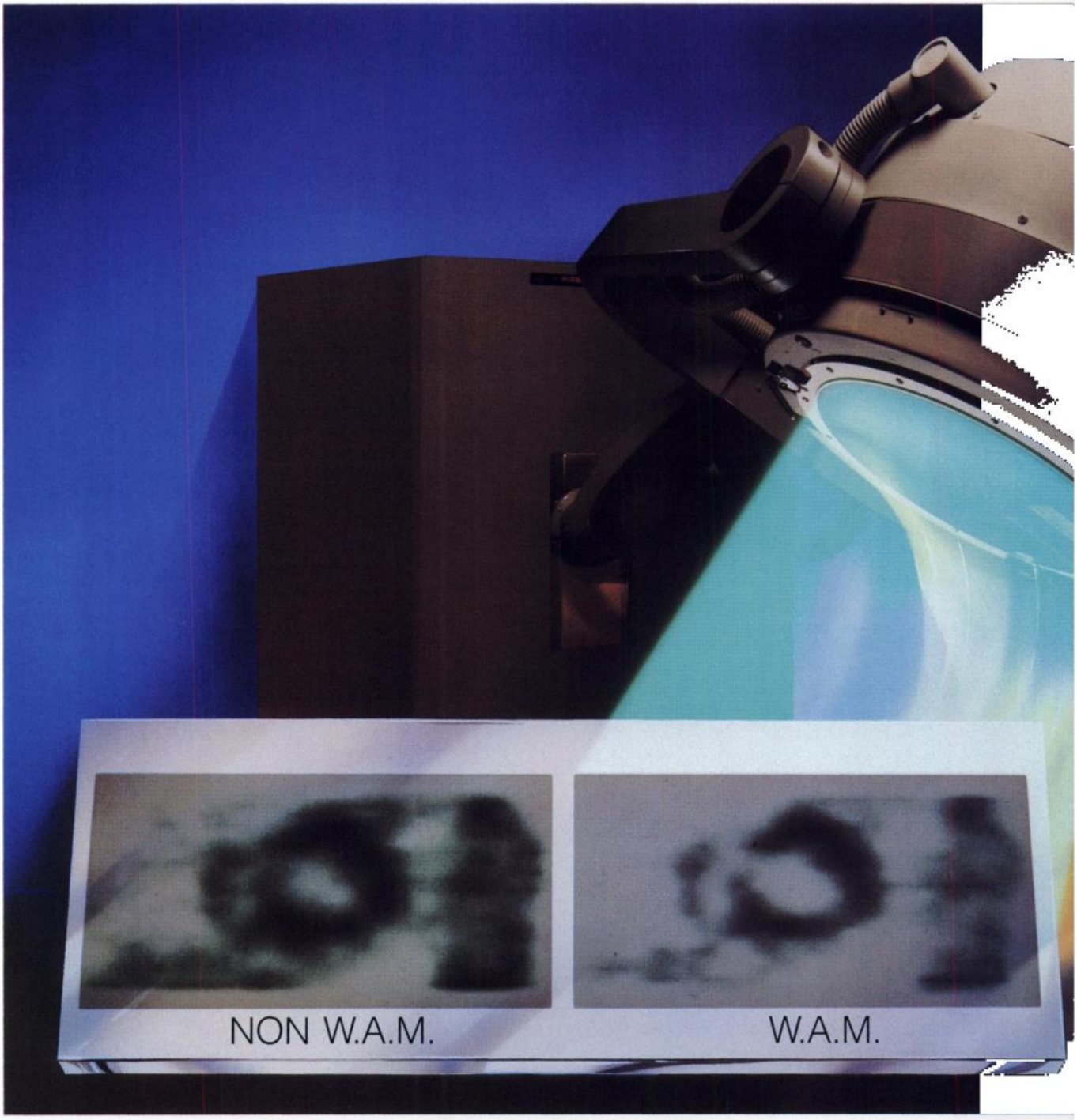
Circle Reader Service No. 102

MZ-Display Software

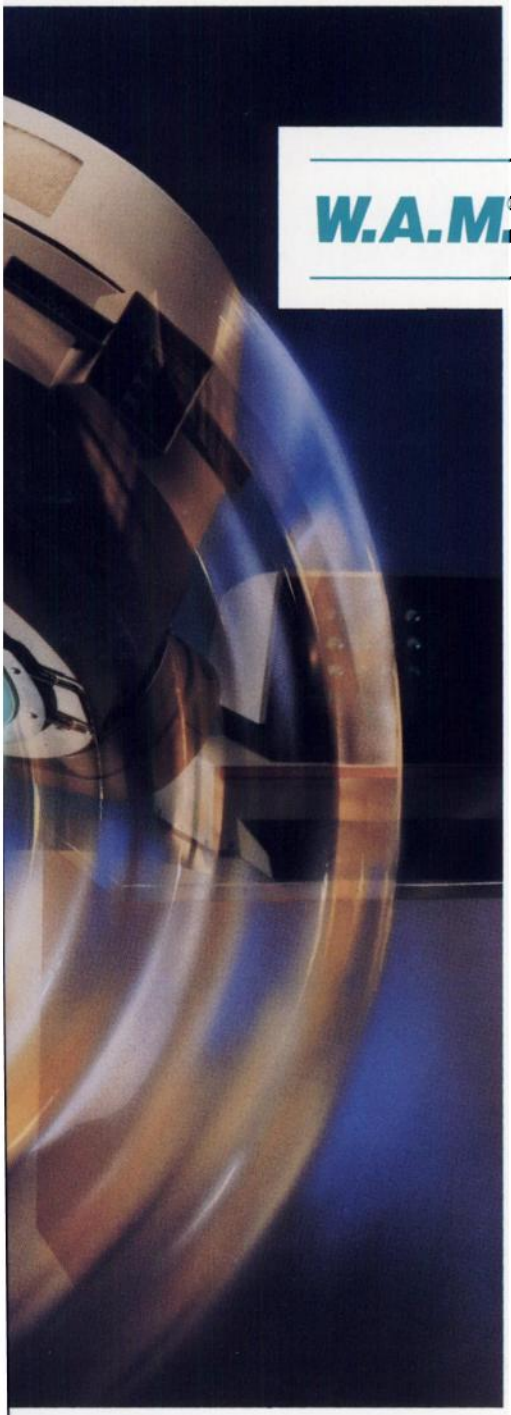
ADAC Laboratories has announced that its newest nuclear medicine dynamic software release will incorporate a new multizone display program named MZ-Display. This new program allows the user greater flexibility in the presentation and formatting of multiple image sets from the same patient or from several different patients. The program is designed for use with the ADAC DPS 33000 and DPS 3300 Micro computer systems. MZ-Display makes extensive use of the mouse for menu selections and produces multiple display zones that contain graphics as well as images. The program automatically sets up the number of zones to be displayed depending on the number of image sets (called screen groups) that are selected, or the number of zones can be selected from the menu. For SPECT thallium users, both stress and redistribution images in four, six, eight, or 16 zones can be displayed. The program will separate the two image sets into groups that can be operated together or separately. The groups can be realigned and displayed in either forward or reverse cine and can be normalized, scaled, or enhanced to provide optimum screens. This new program, which requires the use of the ADAC array processor for its operations, allows ADAC users to control the display of data as never before. **ADAC Laboratories, 540 Adler Dr., Milpitas, CA 95035. Attn: Bruce Quill. (408) 945-2990.**

Circle Reader Service No. 103

SIEMENS



Unretouched Thallium 201 SPECT Reconstruction Images. Clinical Impression: W.A.M. Invaluable for Thallium SPECT Imaging.



A to Z... our technical edge gets sharper! From Anger, to DIGITRAC™ to ZLC™ we've never stopped improving the Gamma Camera!

And now...

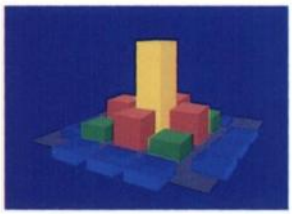
W.A.M.® The Cutting Edge in SPECT!

Up Front Technology!

The Weighted Acquisition Module is NOT a software package. It is an exclusive accessory for all Siemens Rotational cameras that interfaces directly to the DIGITRAC detector system.

Where the WHOLE Image Counts!

W.A.M. improves upon less efficient, conventional pre-selected energy windowing. The proprietary W.A.M., "realtime spatial filtering signal processor," uses *each* event weighted value, from *every* detected photon, to produce a *complete* image.



For Improved Image Contrast! By obviating scatter corruption, W.A.M. increases diagnostic confidence with superior image contrast and acquisition throughput by providing 2 simultaneous data sets.

W.A.M. When your image counts!

DELTAVISION, DELTASTORE, MicroDELTA, MaxDELTA, BASICAM, LEM+, ORBITER, BODYSCAN, the PET system and W.A.M.

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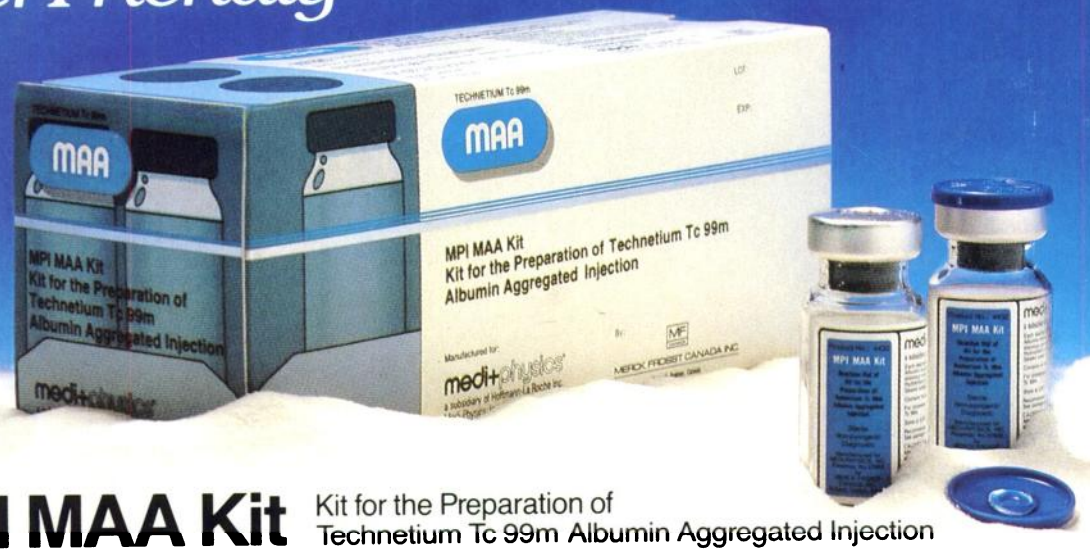
2000 Nuclear Drive Des Plaines, IL 60018 312-635-3259

Siemens ... technology with integrity.

Circle Reader Service No. 126

"User Friendly"*



MPI MAA Kit

Kit for the Preparation of
Technetium Tc 99m Albumin Aggregated Injection

* May be used in adults and children as an adjunct in the evaluation of pulmonary perfusion
* Lyophilized product offers excellent stability
* No refrigeration required during shipping
* Up to 100 mCi per reaction vial
* Color-coded packaging and labeling for easy identification
* Color-coded flip-top seal for convenient one-handed opening

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Paramus, NJ 07652

For complete prescribing information consult package insert, a brief summary of which follows:

DIAGNOSTIC – FOR INTRAVENOUS USE

DESCRIPTION: The kit consists of 10 multidose reaction vials which contain the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce Technetium Tc 99m Albumin Aggregated Injection for diagnostic use by intravenous injection.

Each 10 mL reaction vial contains 2.5 mg of Albumin Aggregated, 5.0 mg of Albumin Human, 0.06 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.11 mg) and 1.2 mg of sodium chloride; the contents are in a lyophilized form under an atmosphere of nitrogen. Sodium hydroxide or hydrochloric acid has been used for pH adjustment. No bacteriostatic preservative is present.

The Albumin Human was non-reactive when tested for hepatitis B surface antigen (HB_sAg) by radioimmunoassay. The aggregated particles are formed by denaturation of Albumin Human in a heating and aggregation process. Each vial contains 4 to 8 million particles. By light microscopy, more than 90% of the particles are between 10 and 70 micrometers, while the typical average size is 20 to 40 micrometers; none is greater than 150 micrometers.

Technetium Tc 99m Albumin Aggregated Injection for intravenous use is in its final dosage form when sterile isotonic sodium pertechnetate solution is added to each vial. No less than 90% of the pertechnetate Tc 99m added to a reaction vial is bound to aggregate at preparation time and remains bound throughout the 6 hour lifetime of the preparation.

INDICATIONS AND USAGE: Technetium Tc 99m Albumin Aggregated Injection is a lung imaging agent which may be used as an adjunct in the evaluation of pulmonary perfusion in adults and children.

CONTRAINDICATIONS: Technetium Tc 99m Albumin Aggregated Injection should not be administered to patients with severe pulmonary hypertension.

The use of Technetium Tc 99m Albumin Aggregated Injection is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

WARNINGS: Although adverse reactions specifically attributable to Technetium Tc 99m Albumin Aggregated have not been noted, the literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.

PRECAUTIONS:

General

The contents of the kit before preparation are not radioactive. However, after the sodium pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained.

In patients with right to left heart shunts, additional risk may exist due to the rapid entry of Albumin Aggregated into the systemic circulation. The safety of this agent in such patients has not been established.

Hypersensitivity reactions are possible whenever protein-containing materials such as pertechnetate labeled Albumin Aggregated are used in man. Epinephrine, antihistamines, and corticosteroids should be available for immediate use.

The intravenous administration of any particulate materials such as Albumin Aggregated imposes a temporary small mechanical impediment to blood flow. While this effect is probably physiologically insignificant in most patients, the administration of Albumin Aggregated is possibly hazardous in acute cor pulmonale and other states of severely impaired pulmonary blood flow.

The components of the kit are sterile and non-pyrogenic. It is essential to follow directions carefully and to adhere to strict aseptic procedures during preparation.

Contents of the vials are intended only for use in the preparation of Technetium Tc 99m Albumin Aggregated Injection and are *NOT* to be administered directly to the patient.

The Technetium Tc 99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium pertechnetate Tc 99m containing oxidants should not be employed.

The preparation contains no bacteriostatic preservative. Technetium Tc 99m Albumin Aggregated Injection should be stored at 2-8°C and discarded 6 hours after reconstitution.

Technetium Tc 99m Albumin Aggregated Injection is physically unstable and consequently the particles settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactive particles.

If blood is drawn into the syringe, unnecessary delay prior to injection may result in clot formation *in situ*.

Do not use if clumping of the contents is observed.

Technetium Tc 99m Albumin Aggregated, as well as other radioactive drugs must be handled with care. Once sodium pertechnetate Tc 99m is added to the vial, appropriate safety measures must be used to minimize radiation exposure to clinical personnel. Care must also be taken to minimize the radiation exposure to patients in a manner consistent with proper patient management.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Albumin Aggregated Injection affects fertility in males or females.

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc 99m Albumin Aggregated Injection. It is also not known whether Technetium Tc 99m Albumin Aggregated Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc 99m Albumin Aggregated Injection should be given to a pregnant woman only if clearly needed.

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

The lowest possible number of particles should be used in right-to-left shunting, in neonates, and in severe pulmonary disease.

ADVERSE REACTIONS: The literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported (see Warnings).

HOW SUPPLIED:

MPI MAA Kit
Kit for the Preparation of Technetium Tc 99m Albumin Aggregated Injection
Product No. 4432.

Each kit contains 10 reaction vials, each vial containing in lyophilized form, sterile and non-pyrogenic:

Albumin Aggregated	2.5 mg
Albumin Human	5.0 mg
Stannous Chloride (minimum)	0.06 mg
(Maximum stannous and stannic chloride	0.11 mg)
Sodium chloride	1.2 mg

HCl or NaOH has been used for pH adjustment. The vials are sealed under an atmosphere of nitrogen.

Twenty labels with radiation warning symbols and a package insert are supplied in each carton.

Circle Reader Service No. 30