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.

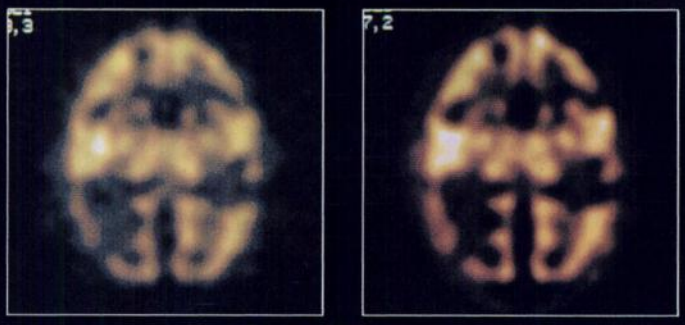
Superior image quality—

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

Medi-Physics, Inc.
140 East Ridgewood Avenue, Paramus, NJ 07652

Circle Reader Service No. 1

NRC REQUIREMENT:

"A licensee shall survey for removable contamination, once each week, all areas where radiopharmaceuticals are routinely prepared for use, administered or stored."

NUCLEAR REGULATORY COMMISSION
Publication 10CFR35, "Medical Use of By-Product Material," Paragraph 35.70, "Surveys for Contamination and Ambient Radiation Exposure Rate."

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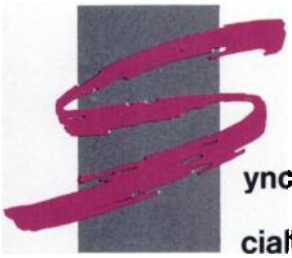

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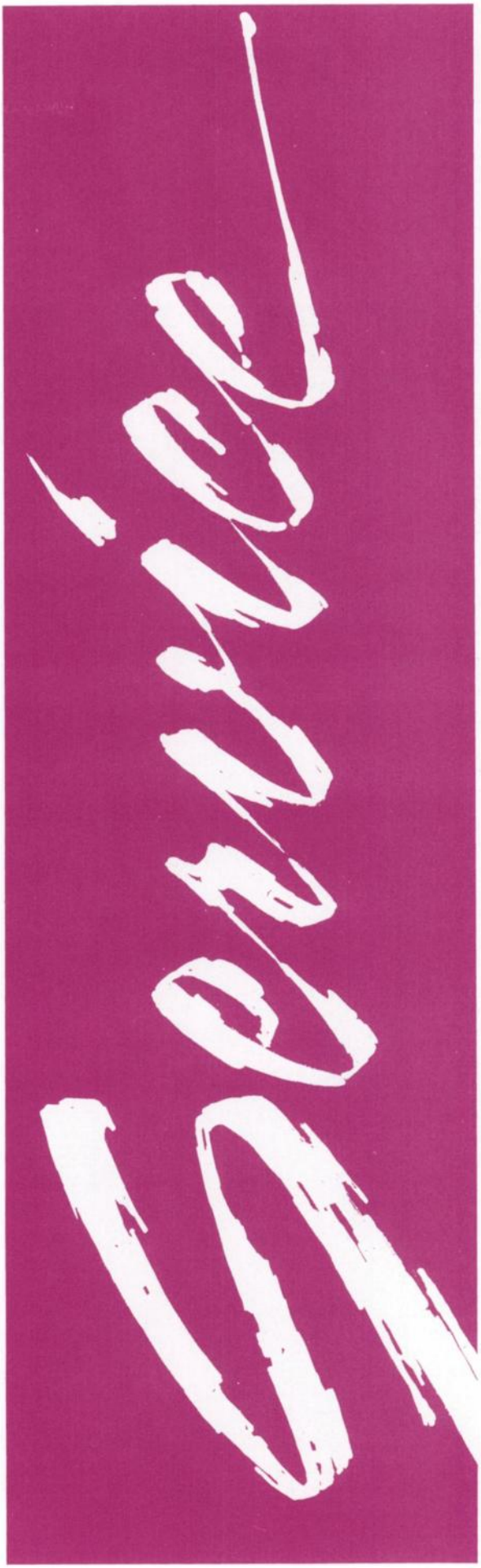

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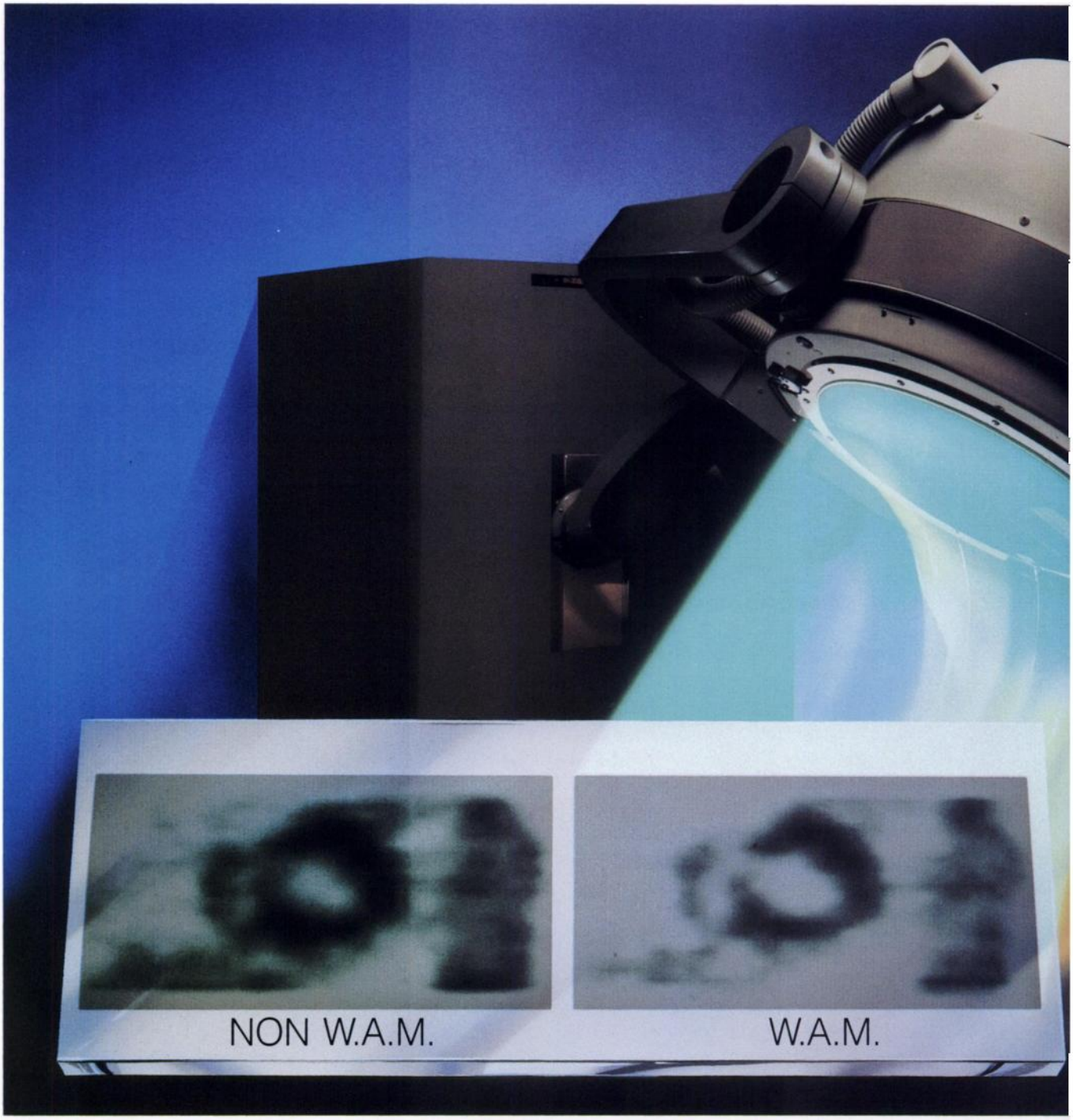
Circle Reader Service No. 10

SIEMENS



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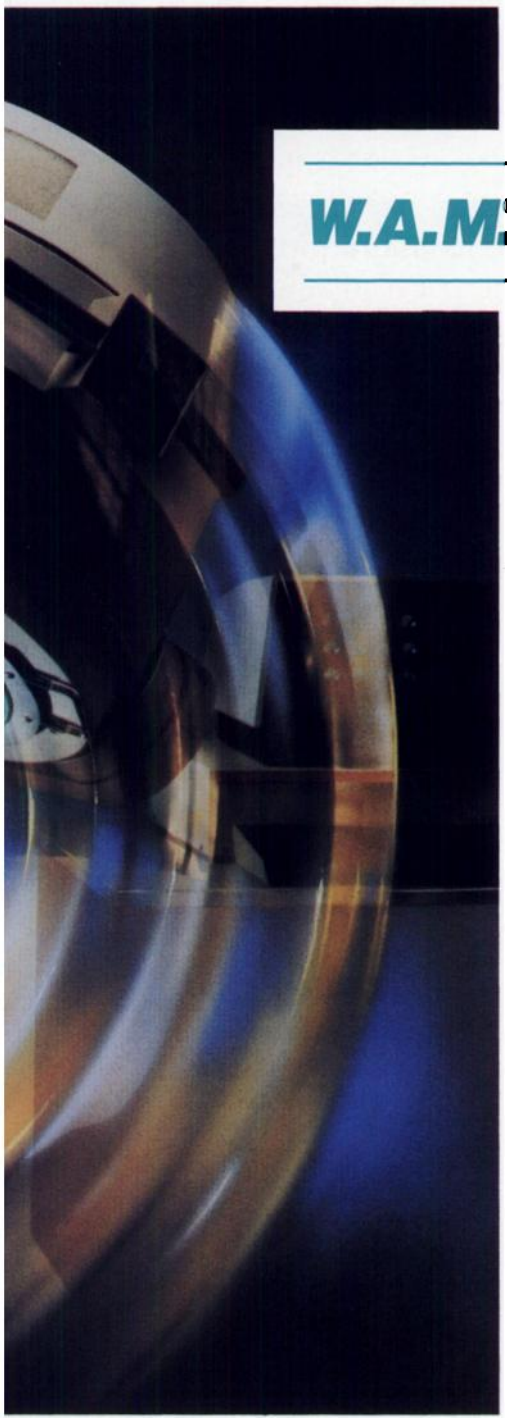

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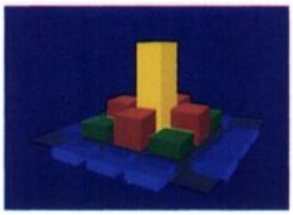

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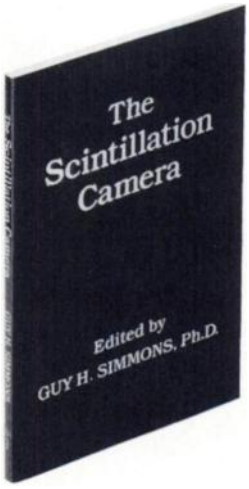
Circle Reader Service No. 126

The Scintillation Camera



***The Scintillation Camera*, edited by Guy H. Simmons, PhD. 140pp. Paperbound. $30 for members, $35 for non-members.**

Although the scintillation camera, invented by Hal Anger in 1958, has been called the most significant instrumentation event in the history of nuclear medicine, no one publication had been written that explains all its major features. The Instrumentation Council of The Society of Nuclear Medicine has filled that void with *The Scintillation Camera.*

The Scintillation Camera, edited by Guy H. Simmons, PhD, shows you how to select an instrument, evaluate its performance, and monitor its operation in a clinical setting. *The Scintillation Camera* is also an excellent aid for teaching the principles of the camera to those unfamiliar with its capabilities.

Abbreviated Table of Contents

1. The Detector Assembly
2. Collimator Design, Properties, and Characteristics
3. On-Line Corrections for Factors that Affect Uniformity and Linearity
4. Display Devices
5. Quality Assurance Procedures
6. Specification and Purchase of Anger-Type Scintillation Cameras
7. Acceptance Testing and Performance Evaluation
8. Index

The Scintillation Camera will be a valuable addition to every nuclear medicine library, both as a reference tool, and as a convenient resource to answer those questions that you face each day. Order your copy today.

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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

EXHIBITION

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

Registration and fees:

Non-Members of European Association of Nuclear Medicine: By June 15 the registration fee for non-members will be 1425 FF, VAT included. After June 15 the registration fee for non-members will be 1780 FF, VAT included.

Members of European Association of Nuclear Medicine: If EANM member fees are registrated by April 1: no Congress fee. If EANM member fees are registrated after April 1: full Congress fee must be paid minus 120 DM (membership fee), i.e.:

—925 FF, VAT included, by June 15, 1989
—1280 FF, VAT included, after June 15, 1989

Social Program

A comprehensive social program has been planned, including the Opening Ceremony with a concert and welcome cocktail (free of charge), a concert in the Cathedral of Strasbourg, a folkloric evening in the Alsatian vineyard (Riquewhir), a dinner dance in the Pourtales Castle near Strasbourg, and the Farewell Party in the Orangerie Gardens.

Accompanying persons' program: Numerous and attractive excursions and activities are planned.

PRESIDENT OF THE CONGRESS: Prof. Jacques Chambron

SCIENTIFIC SECRETARIAT:
Institut de Physique Biologique
Faculté de Médecine
4, rue Kirschleger
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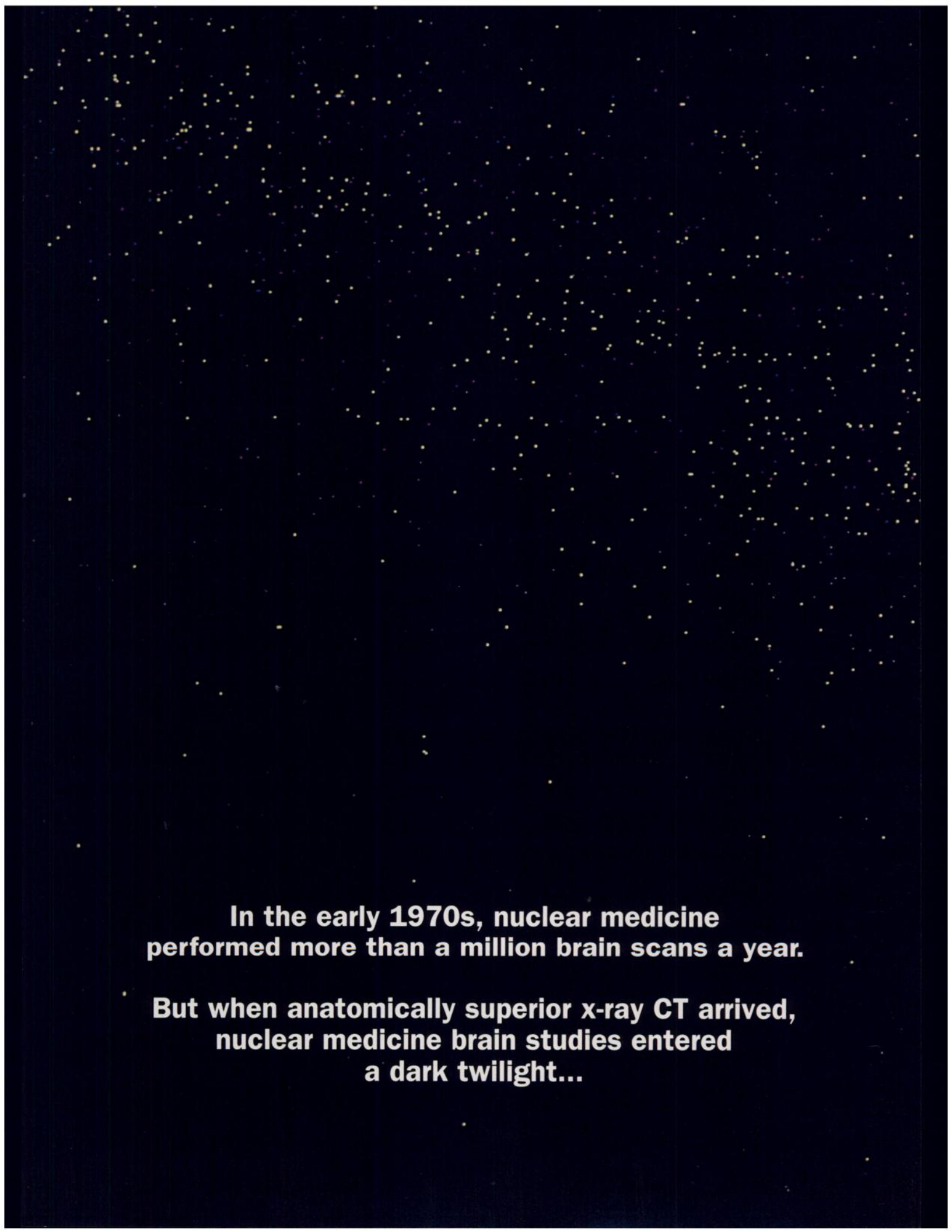
In the early 1970s, nuclear medicine performed more than a million brain scans a year.
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Please see following page for full prescribing information.

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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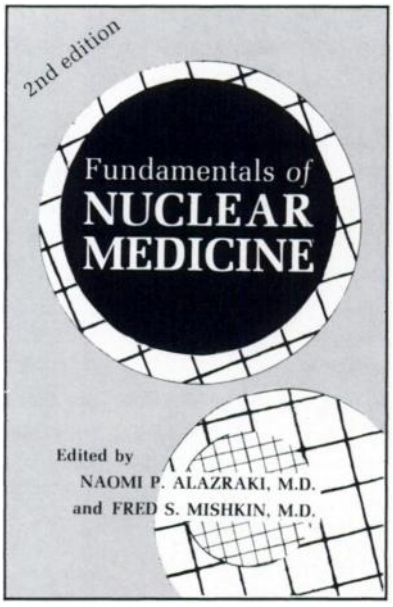

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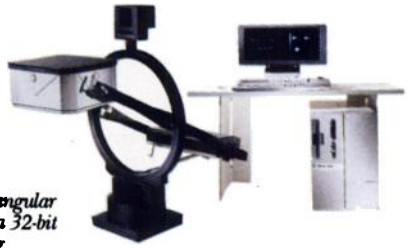

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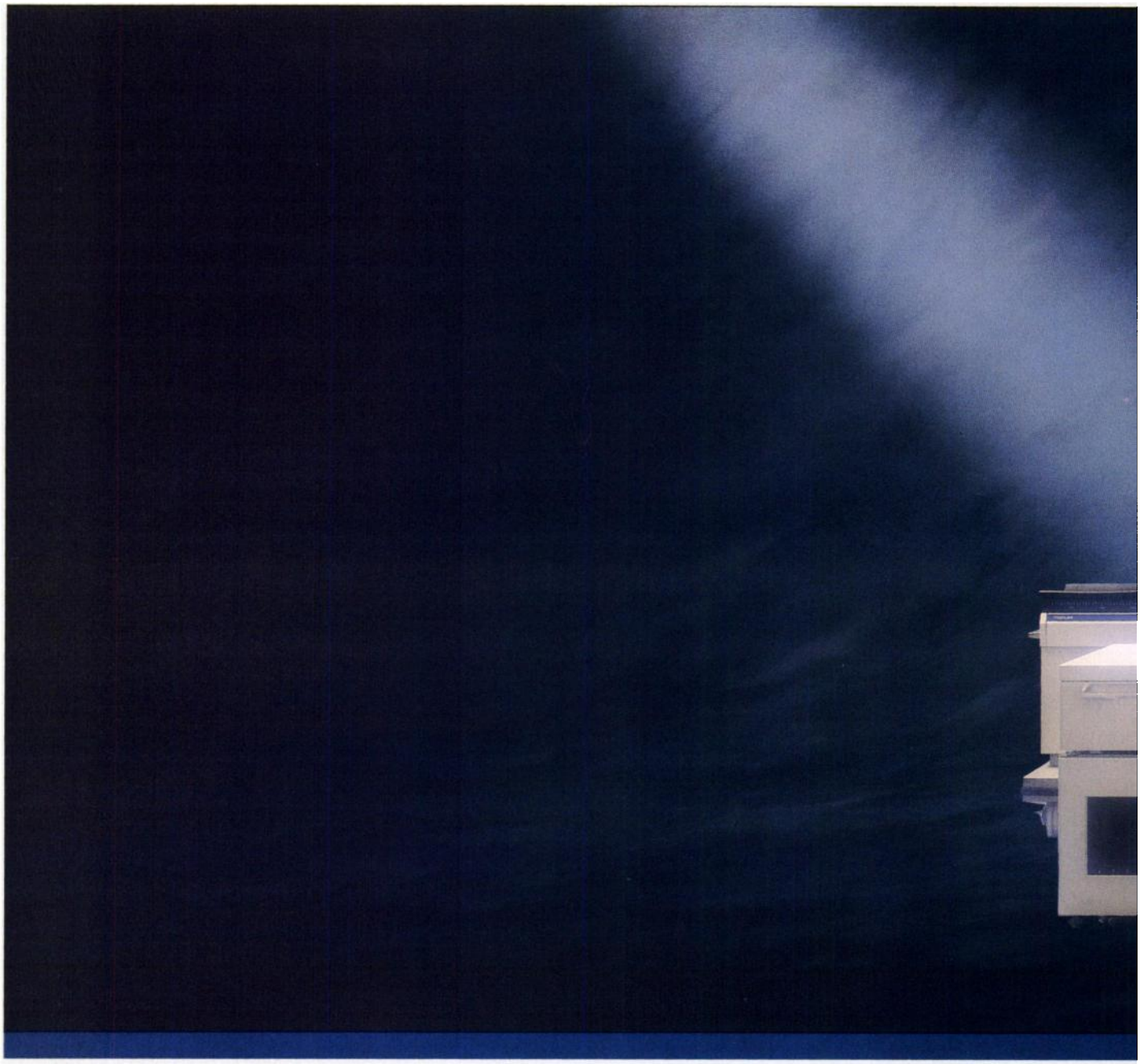

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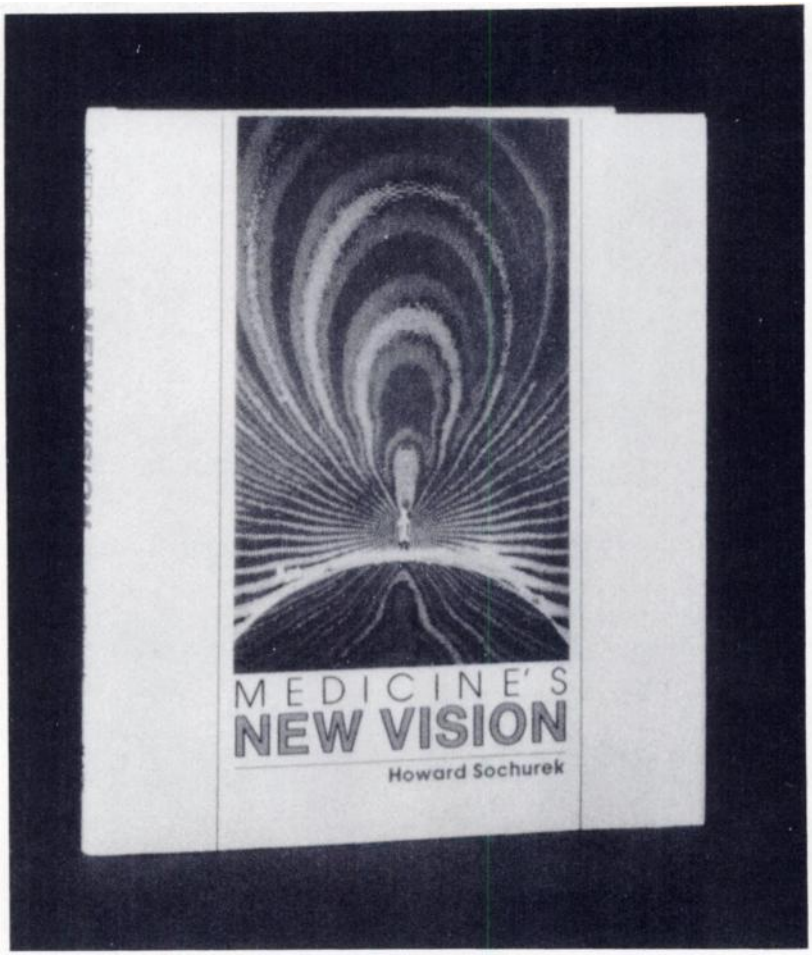

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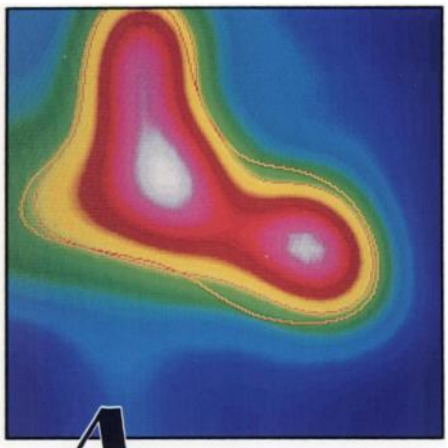

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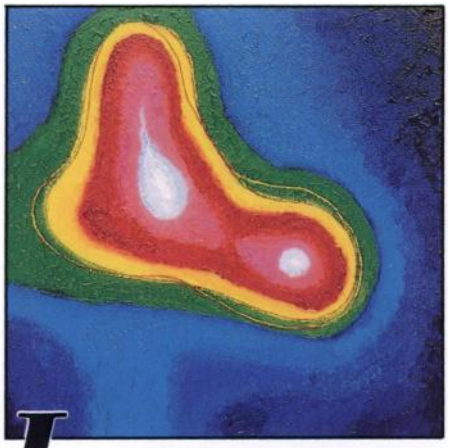

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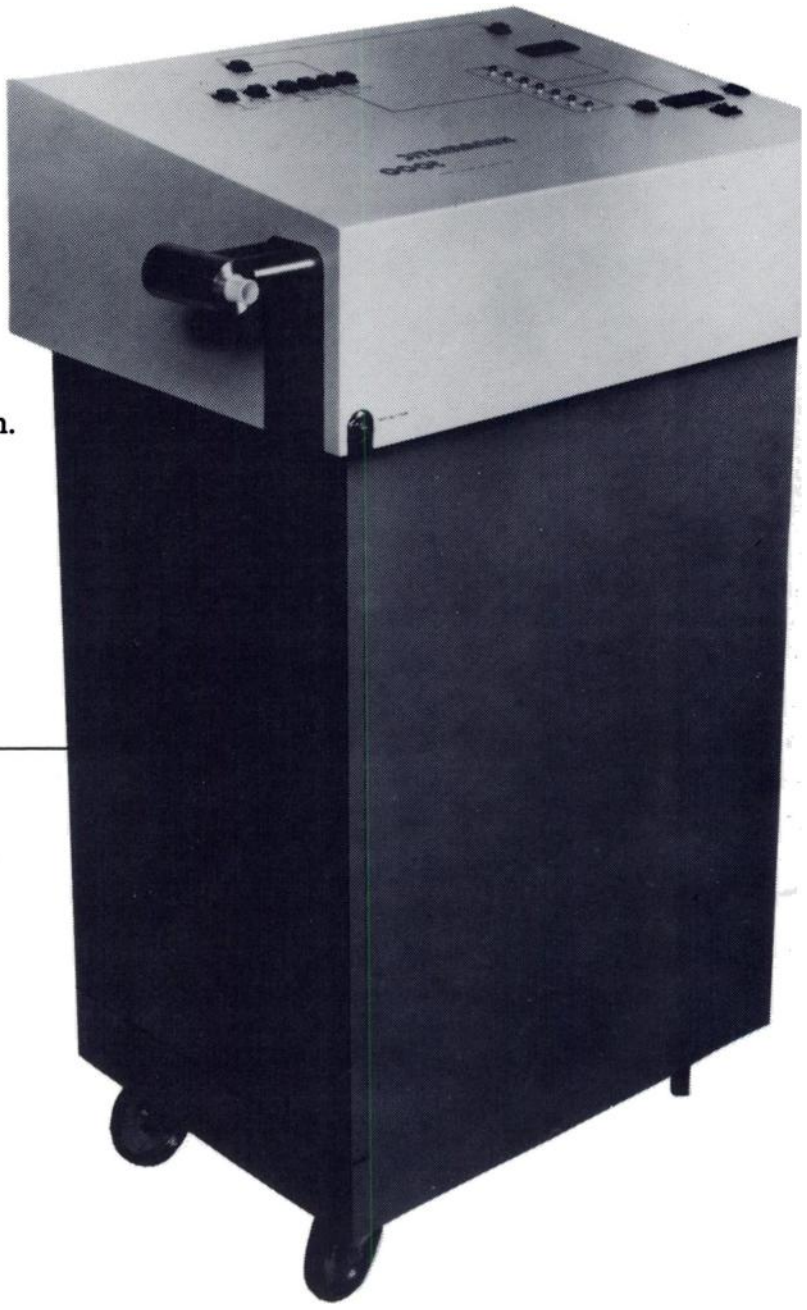

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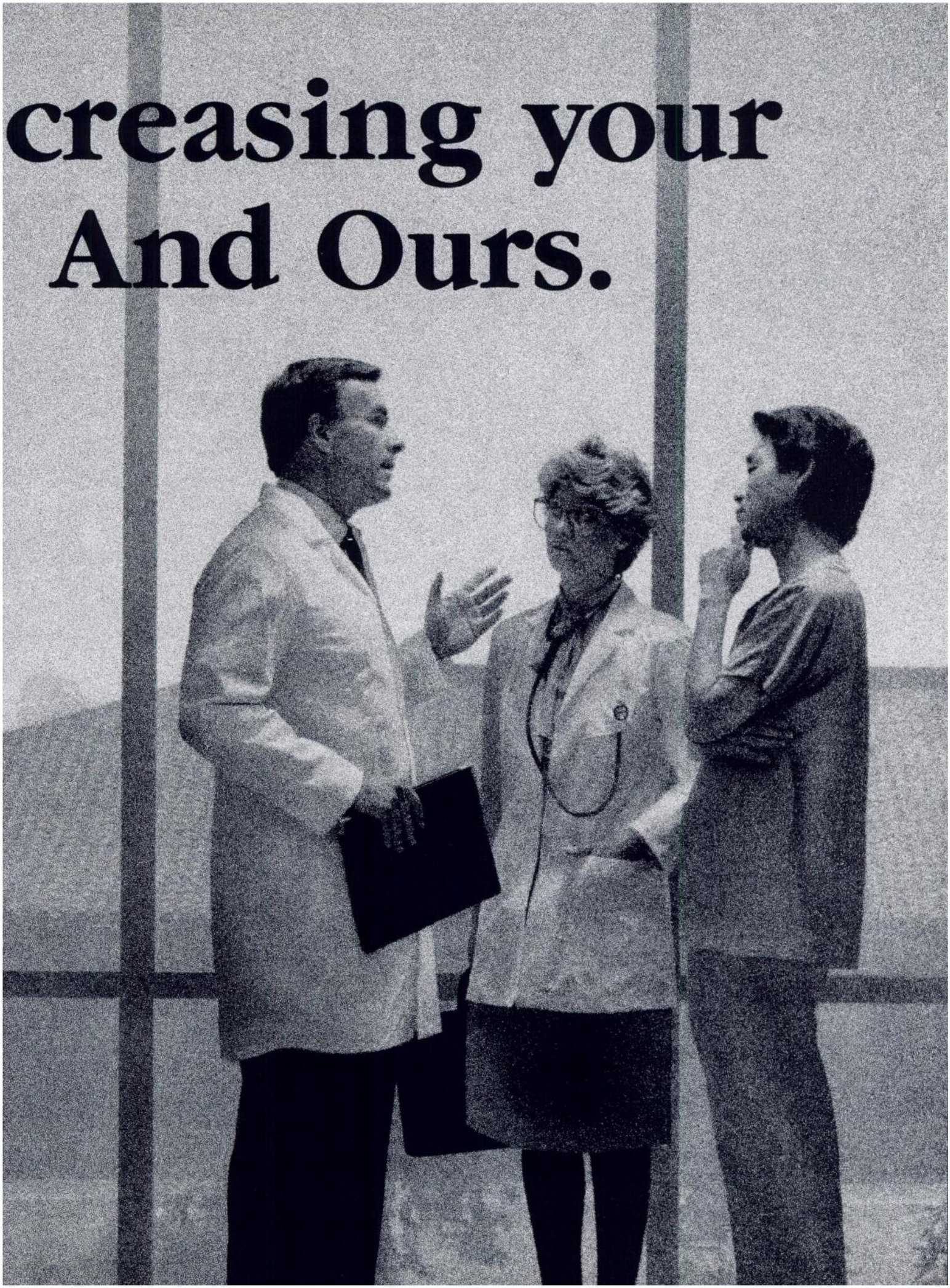
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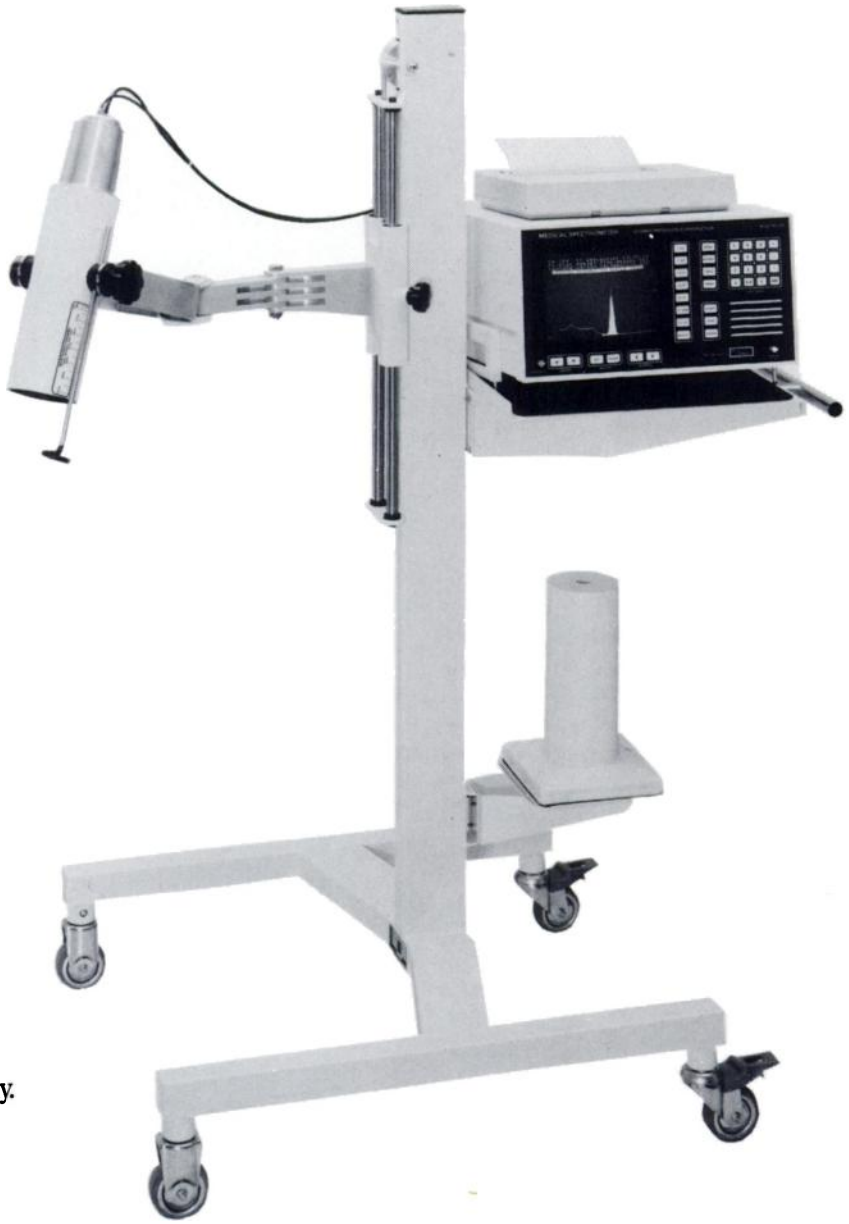

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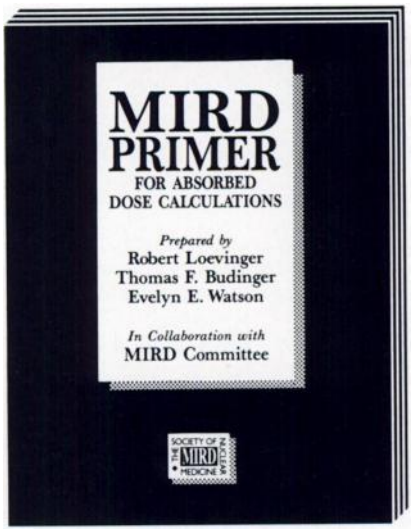

MIRD PRIMER

For Absorbed Dose Calculations

Prepared by

Robert Loevinger
Thomas F. Budinger
Evelyn E. Watson

In Collaboration with the MIRD Committee

The MIRD Primer for Absorbed Dose Calculations was prepared by the MIRD Committee to provide a fresh explanation of the MIRD schema with examples designed to illustrate applications.

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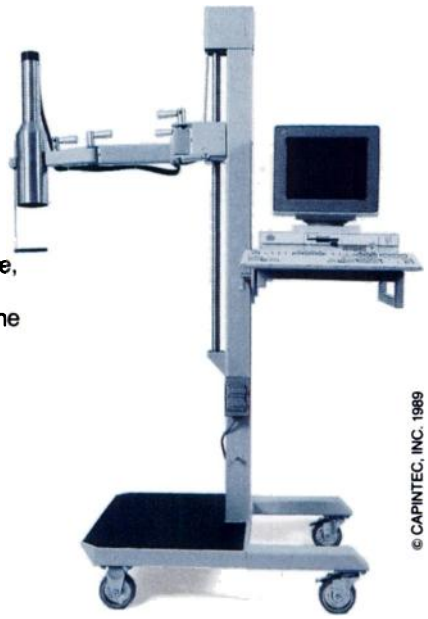

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Positions Available

Residency

NUCLEAR MEDICINE RESIDENCY–July 1989. San Francisco General Hospital Medical Center, University of California, SF, Program B, 2-yr ACGME approved program satisfying American Board of Nuclear Medicine training requirements both in basic science and performance/interpretation of imaging and non-imaging *in vivo* procedures, radioimmunoassay, and radionuclide therapy. Emphasis on SPECT, nuclear cardiology, use of computers. Prerequisite: 2 yr ACGME approved residency in internal medicine, pathology, pediatrics, or radiology. Send CV to: Myron Pollycove, MD, Chief, Nuclear Medicine Dept., San Francisco General Hospital Medical Center, San Francisco, CA 94110. Equal Opportunity/Affirmative Action Employer.

RESIDENCY in nuclear medicine, University of Missouri, Columbia. Two year residency in nuclear medicine starting July 1, 1989. Residency is integrated program between University and affiliated Harry S. Truman Memorial Veterans Hospital. Strong emphasis on neurological SPECT imaging and nuclear cardiology. Clinical experience includes large radioimmunoassay laboratory, pediatric patients, with opportunities in CT, ultrasound, and MR correlations. Residents are strongly encouraged to participate in ongoing clinical and basic research. Program approved by American Board of Nuclear Medicine. Candidates should have 2 yr prior training in an ACGME approved residency. For further information and application forms, contact: Richard A. Holmes, MD, Chief of Nuclear Medicine and Program Director, University of Missouri at Columbia, N219 Medical Sciences, Columbia, MI 65212. EOE.

Radiologist

Arizona, progressive 15-man group seeking Board certified RADIOLOGIST with board or special competency in nuclear medicine. Also will participate in general radiology. Three hospital practice with SPECT, general imaging, and computer facilities performing cardiology, transplant, nephrology, and neuroimaging. Approximately 9000 std/yr. Expanding practice in the Phoenix area. PET facility by 1992. Send inquiries to: Richard J. Petersen, MD, 450 W. 5th Place, Mesa, AZ 85201 (602)835-3775. EOE.

Technologist

NUCLEAR MEDICINE TECHNOLOGIST. Eisenhower Medical Center, located near Palm Springs, seeks a full-time Nuclear Med Tech for presently vacant position. Must be Registered Nuclear Medicine Technologist (or registry eligible). Recent experience in an acute care hospital is preferred. We offer a generous benefit package inclusive of medical, dental, life, LTD, and vision care insurance. Starting salary is commensurate with experience. Interested individuals, please call Human Resources to request an employment application. Eisenhower Medical Center, 39000 Bob Hope Drive, Rancho Mirage, California 92270. (619)773-1356. EOE/MFH.

NUCLEAR MEDICINE TECHNOLOGIST. Unique, challenging opportunity for a Tech. to join a fast growing, newly constructed, well equipped department offering state-of-the-art equipment including SPECT camera/computer systems. Department located in an active, 203-bed acute care hospital in Northern California approx. 100 miles north of Sacramento. Unlimited recreational possibilities are present. Candidate must be ARRT or NMTCB registered. A competitive salary, excellent benefit package, relocation funds and bonus recruitment program are available. Send resume or contact: Carole Mickelson, Radiology Manager, Enloe Memorial Hospital, 5th Ave. & The Esplanade, Chico, CA 95926. Call collect (916)891-7300 ext. 7378. EOE.

NUCLEAR MEDICINE TECHNOLOGIST. Position available for a registered or registry eligible technologist. We are a 750-bed hospital with an expanding Nuclear Cardiology Laboratory. SPECT thallium experience preferred. We offer an excellent salary and benefit package. Send resume to: Methodist Hospital, Dept. of Cardiac Diagnostics, Box 1201, Lubbock, TX 79408. EOE.

NUCLEAR MEDICINE TECHNOLOGISTS. Pitt County Memorial Hospital, a 550-bed regional medical center affiliated with East Carolina University School of Medicine, is currently recruiting nuclear medicine technologists. Qualified candidates must possess an associate's degree in nuclear medicine with ARRT or NMTCB certification. PCMH offers excellent salary and benefits. For immediate consideration, call or send resume to: Employment Office, Pitt County Memorial Hospital, PO Box 6028, Greenville, NC 27834. 1(800) 346-4307 or (919) 551-4556. EOE/AA.

NUCLEAR MEDICINE TECHNOLOGIST. St. John's Regional Health Center, an 886-bed acute care facility, has a full-time staff opening. The applicant must be registered or registry-eligible. A bachelor's degree is preferred. Experience in SPECT, data processing, and cardiovascular nuclear medicine is preferred. On-call rotation is required. We offer a salary range of $23,200–30,200, an excellent benefit package, and a sign-on bonus of $1500. Send resume to, or call collect: Jerri Flikkema, (417)885-2946, St. John's Regional Health Center, 1235 E. Cherokee, Springfield, MO, 65804-2263. Equal opportunity employer.

NUCLEAR MEDICINE TECHNOLOGIST, part-time or full-time in a private nuclear cardiology facility performing perfusion imaging and ventriculography only. Siemens-ADAC systems. Opportunity to acquire echocardiography training. Pleasant working environment, excellent remuneration, and fringe benefits. Recent graduate or experienced technologist. Please send resume and description of interests and goals to: Nuclear Cardiology Laboratory, 7777 Forest Lane, Suite C-804, Dallas, TX 75230. EOE.

NUCLEAR MEDICINE TECHNOLOGIST. Position available for a registered or registry eligible technologist in a 365-bed acute care community hospital in scenic eastern Tennessee. Chattanooga is about 90 min from Atlanta, Birmingham, Knoxville, and Nashville, and has a population of ~ 450,000 people who enjoy excellent weather, low taxes and cost-of-living. The Nuclear Medicine Department has three GE 400T cameras, a mobile Technicare camera and two MDS A³ computers. A full-time Harvard trained nuclear physician is the medical director of the department. Heavy cardiac load, including SPECT. Send resume to: The Human Resources Department, Memorial Hospital, 2500 Citico Avenue, Chattanooga, TN 37404. Or call (615)629-8576.

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.

Applications Specialist

APPLICATIONS SPECIALIST. In this highly visible marketing position you will be responsibile for training customers on the use of computer systems software, demonstrate equipment at trade shows, and provide customer support with post-training follow-up calls. This position requires a minimum of 3 yr staff level experience as a nuclear medicine technologist. The successful candidate will have a strong clinical background in cardiac work as well as general clinical work such as renals, lungs, brains, and bone imaging. Experience working on ADAC Systems is a plus. Applicants should have ARRT and CNMTB registration. AA and/or BS degree a plus. Excellent verbal and written communication skills required. Ability/willingness to travel is also required. Send resume to: ADAC Laboratories, 540 Alder Drive, Milpitas, CA 95035. ADAC Laboratories is an Affirmative Action/Equal Opportunity Employer.

Clinical Development Specialist

CLINICAL DEVELOPMENT SPECIALIST. In this challenging position you will specify, test, and validate clinical software for nuclear medicine applications. You will also write software documentation, provide in-house technical support for customers, and applications specialists and assist software engineers in the testing and de-bugging of clinical software. This position requires a minimum of 3 yr staff level experience as a nuclear medicine technologist. The successful candidate will have a strong clinical background in cardiac work as well as general clinical work such as renals, lungs, brains, and bone imaging. Experience working on ADAC Systems is a plus. Applicants should have ARRT and CNMTB registration. AA and/or BS degree a plus. Excellent verbal and written communication skills required. Send resume to: ADAC Laboratories, 540 Alder Drive, Milpitas, CA 95035. Or call Debbie Cavanaugh at (408)945-2990. ADAC Laboratories is an Affirmative Action/Equal Opportunity Employer.

Positions Wanted

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We offer a challenging and exciting career opportunity within one of the most innovative and progressive radiology departments in the country. We offer an excellent salary and a comprehensive benefits package, including relocation assistance and much more. Qualified applicants should send resume or contact: **Larry Brooks, Employment Services, Baptist Memorial Hospital, Medical Center, 910 Madison Avenue, Memphis, TN 38146.**

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MASI, a mobile healthcare services provider located in Fort Worth, Texas, is seeking an experienced **Nuclear Medicine Technologist.** If you are tired of the routine job and wish to expand your career and if you can work independently and enjoy a challenge, you may be the candidate we are looking for.

We currently have a position available in East Texas. This area offers very pleasant living with numerous outdoor activities and is also within one hour of a major metropolitan area.

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MASI

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Equal Opportunity Employer

NUCLEAR MEDICINE

TECHNOLOGIST

St. Peter's Hospital, the largest Catholic acute-care hospital in Northeastern New York State, is a 447 bed teaching hospital offering a wide range of primary, secondary and tertiary medical services. Located in Albany, our upstate area is rich in recreational and educational opportunities.

St. Peter's offers competitive salary and benefits as well as relocation assistance. If you are Registered or Registry eligible seeking full or part-time work which provides career growth and development opportunities, please submit resume or contact Mrs. Dale Walsh, Employment Specialist, at (518) 454-1293 for additional information.

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M. Donald Blaufox, MD, PhD
Chairman, Department of Nuclear Medicine
Albert Einstein College of Medicine
1300 Morris Park Avenue
Bronx, NY 10461.

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The candidate is to lead the new section of radiopharmacy. He/she must have advanced academic degrees (equivalent to promotion and habilitation) or comparable highly qualified experiences in the field of radiopharmacy. He/she must have the license to produce radiopharmaceuticals for nuclear medical application (Section 15 AMG-Arzneimittelgesetz i.e. regulation of the food and drug administration of Federal Republic of Germany). The candidate is to cooperate with the pharmaceutical institute of the University of Tübingen. The university initiated to set up a PET and cyclotron unit.
The University of Tübingen favors to increase the ratio of women in research and teaching and encourages qualified female scientists for application.
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RESIDENT, NUCLEAR MEDICINE

The University of Wisconsin nuclear medicine residency program in Madison, Wisconsin, has an opening for a first year resident in nuclear medicine starting July 1, 1989. The two-year program at the University of Wisconsin Hospital and Clinics and the Middleton Veterans Hospital is accredited by the ACGME and satisfies the requirements of the American Board of Nuclear Medicine. The clinical department serves over 900 beds at the two hospitals, currently performs over 6,000 examinations yearly and is expanding. Nuclear medicine is a section of a clinically and academically strong radiology department and includes a very active and innovatove nuclear cardiology division. In June 1989 the nuclear medicine department will move into a new wing of the University Hospital and will contain all new equipment including a state-of-the-art three-headed SPECT system, as well as other SPECT and planar gamma camera imaging systems. Furthermore, a state-of-the-art PET scanner is present. Residents are encouraged to participate in ongoing projects or develop new projects. Madison is a beautiful city with four lakes and plenty of outdoor recreation, and has frequently been listed as one of the top ten cities to live in multiple national surveys. The University Hospital has an excellent location, and is within one mile of the University of Wisconsin college campus and the state capital. Interested applicants should contact: Scott B. Perlman, MD, MS, Nuclear Medicine Service, University of Wisconsin Hospital, 600 Highland Avenue, Madison, WI 53792. (608)262-7014. An Equal Opportunity/Affirmative Action Employer.

NUCLEAR MEDICINE TECHNOLOGIST

Bishop Clarkson Memorial Hospital, Nebraska's First Hospital, is currently accepting applications for a Staff Nuclear Medicine Technologist. Clarkson Hospital is a 550 bed hospital located in Omaha, Neb., and services a wide region of the three state area with the finest in health care. Our large and spacious department is equipped with current state-of-the-art computers, 4-LFOV cameras (3-SPECT), 2-mobile cameras, a BMA unit and a thyroid probe which allows a wide variety of imaging to be accomplished. Emphasis on cardiology and oncology with a strong referral base leads to a stimulating work atmosphere. Unit dose radiopharmaceutical delivery is only five blocks away. This progressive community, hospital and Nuclear Medicine Department has a board certified Nuclear Medicine physician, 6 Staff Technologists, 2 secretaries and immediate plans for further expansion to provide and maintain the high quality of services associated with Clarkson. Situated in the Midwest, Omaha offers a wide variety of pleasing opportunities for recreation and is in close proximity to other areas of recreational facilities. Clarkson is located in central Omaha, is easily accessible and offers a competitive salary with a flexible benefits program. Quality living at a reasonable price defines the living atmosphere of Eastern Nebraska/Western Iowa. Applicants must be registered or registry eligible by the NMTCB or ARRT. Please contact Ann Siewert, Employment Coordinator, Bishop Clarkson Memorial Hospital, 44th and Dewey Ave., Omaha, NE 68105 or call (402) 559-2024.

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JNMT

Classified advertisements for the June issue (Annual Meeting issue) of *Journal of Nuclear Medicine Technology* must be received by March 27th. This issue will be mailed April 14th.

NUCLEAR MEDICINE TECHNOLOGISTS

The State of California is now implementing the nuclear medicine technology regulations. State certification will be required to practice nuclear medicine technology in California beginning in 1990. If you are interested in becoming certified in California please contact:

Radiologic Health Branch
Certification Unit-NMT
Attention: David Wheeler
1232 Q Street
Sacramento, CA 95814

NUCLEAR MEDICINE TECHNOLOGIST

Our 297-bed teaching hospital, located in Chicago's historic Hyde Park district, is seeking a Staff Technologist to perform RIA, quality control and scanning procedures.

You must be a graduate from an approved school of Nuclear Medicine or possess equivalent qualifications. Certification in Nuclear Medicine Technology or eligibility is mandatory.

We offer a competitive salary and comprehensive benefits. Send resume, apply in person or call: **Employment Manager, (312) 947-4595, Human Resources, Chicago Osteopathic Medical Center, 5200 S. Ellis, Chicago, IL 60615.** Equal Opportunity Employer M/F.

CHICAGO OSTEOPATHIC MEDICAL CENTER

Nuclear Medicine Physician

The Division of Nuclear Medicine at The Children's Hospital is seeking a full-time staff nuclear medicine physician. Candidate should be Board certified or Board eligible in nuclear medicine or nuclear radiology. Position is available on or before May 1, 1989. Experience in pediatric nuclear medicine not required. The Children's Hospital is affiliated with Harvard Medical School and its medical staff hold appointments at the medical school. Academic rank and salary will depend on candidate's background, experience, and qualifications. The Children's Hospital has a distinguished history and a worldwide reputation for excellent clinical care, teaching, and research in pediatrics. It has 340 inpatient beds and a large outpatient service.

The Division is equipped with two Siemens Orbiter systems (SPECT), one Siemens LFOV system, and two Siemens LEM systems. There are five dedicated computer systems linked in a network served by a VAX 750 system. Images and diagnostic reports are in an integrated data base. Excellent opportunities in clinical investigation and teaching. The Division supports a well equipped research laboratory including facilities for radiopharmaceutical research and imaging. Applicants should forward their curriculum vitae to: ST Treves, MD, Director, Division of Nuclear Medicine, The Children's Hospital, 300 Longwood Ave., Boston, MA 02115. EOE.

NUCLEAR MEDICINE TECHNOLOGIST

Northern Virginia Doctors Hospital a progressive 267-bed facility located in Northern Virginia has an immediate opening for a Nuclear Medical Technologist. Procedures include routine, SPECT, and Iofetamine examinations. New camera and computer expected soon to enhance department capabilities. Salary commensurate with experience and excellent benefits package. Applications or inquiries should be directed to:

Human Resources
Northern Virginia Doctors Hospital
601 S. Carlin Springs Road
Arlington, VA 22204-1096
(703)578-2045
EOE

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NUCLEAR MEDICINE TECHNOLOGIST POSITION AVAILABLE

Large expanding university hospital has full-time nuclear medicine technologist staff position available. Candidate must be A.R.R.T. registered or C.N.M.T. certified or exam eligible. Experience in all phases of nuclear medicine, including computers & SPECT imaging, are especially helpful.

For further information, please contact:

Veronica Valentine, C.N.M.T.
Chief Administrative Technologist
Division of Nuclear Medicine
Hahnemann University Hospital
Broad & Vine Streets—M.S. #309
Philadelphia, PA 19102
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PARTICIPATE

NUCLEAR MEDICINE WEEK

July 30–August 5, 1989

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 Technologist Program
Call for Works-in-Progress

The 1989 Scientific and Teaching Sessions Committee solicits the submission of abstracts from members and nonmembers of The Society of Nuclear Medicine for the 36th Annual Meeting in St. Louis. Abstracts accepted for the program will be published in the June issue of the *Journal of Nuclear Medicine Technology.* Works-in-progress will be published in the September issue of the *Journal of Nuclear Medicine Technology.* Original contributions on a variety of topics related to nuclear medicine will be considered, including:

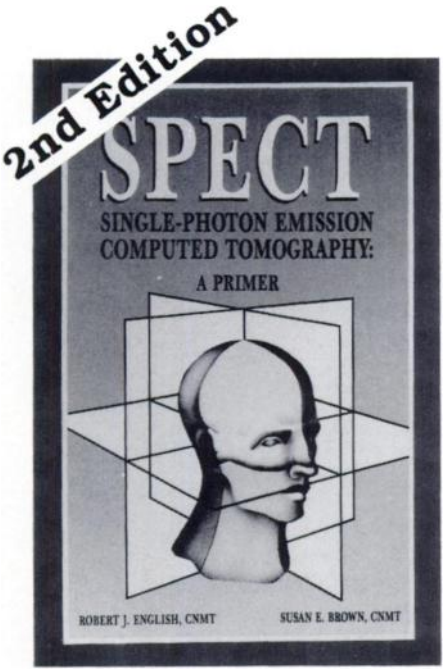
- INSTRUMENTATION
- COMPUTERS AND DATA ANALYSIS
- RADIOASSAY
- RADIOPHARMACEUTICAL CHEMISTRY
- DOSIMETRY/RADIOBIOLOGY
- NUCLEAR MAGNETIC RESONANCE
- CLINICAL SCIENCE APPLICATIONS
  - Bone/Joint
  - Cardiovascular
  - Endocrine
  - Gastroenterology
  - Infectious Disease and Immunology
  - Neurology
  - 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 *JNMT* for immediate review.

The official abstract form for Scientific Papers and 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 receipt of abstracts is Thursday, January 12, 1989.
Deadline for receipt of works-in-progress is Friday, April 7, 1989.
At the 1989 Annual Meeting, cash awards will be given to the three best papers. First prize is $200, second prize $150, and third prize $100.



A PRIMER
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Robert J. English, CNMT
and Susan E. Brown, CNMT

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The second edition of the widely successful Primer continues to answer the nuclear medicine technologist's fundamental questions about SPECT, as both a textbook and as an extension of any manufacturer's operating manual. Designed as a study guide for SPECT technology and SPECT applications, the Primer has been revised to include useful and informative protocols for various SPECT studies. These protocols have been developed to provide both the novice and the more experienced technologist with step-by-step examples of SPECT procedures. After reading the second edition, you too will be able to successfully create and use your own SPECT protocols.

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Publication Date: June 1989

For ordering information contact:
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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.*

Electronic Pipette

MLA has introduced a microprocessor-controlled electronic pipette which allows an operator to easily perform a series of different pipetting steps automatically. More than an automatic pipette, Metron Electronic Pipette can be programmed to aspirate, to dispense, to titrate, and/or dilute any volume from 10 μl to 1000 μl in a preselected order of steps. To do this, simply enter the information into an easy-to-use control box. These steps are memorized and stored even when power has been turned off. Variability in test results can be minimized and precision improved by having an electronically controlled device do the pipetting. Metron maximizes liquid handling productivity by performing complete test procedures by simply pressing one button. Metron is available with a choice of nozzles: 50 μl, 200 μl, and 1000 μl, to satisfy most of today's pipetting needs. **Medical Laboratories Automation, Inc., 270 Marble Ave., Pleasantville, NY 10570-2982. Attn. Edward Kozel. (914)747-3020.**

Circle Reader Service No. 101

Flood Source Cases

Du Pont has introduced storage cases for two of its flood sources that increase safety and convenience in the nuclear medicine department. Flood sources are used to calibrate gamma cameras and other instrumentation. Storage cases for the 18-in and 24-in flood sources have more shielding, which results in lower radiation readings on case surfaces to reduce exposure to users. In addition the larger case has

support legs and castors. The castors permit the case to be rolled, rather than carried, to the area of use, and the support legs allow the case to stand upright, permitting the source to be removed without having to lift the case onto a horizontal surface. **Du Pont Company, External Affairs Dept., Wilmington, DE 19898. Attn. Michelle Gauthier. (508)671-8007.**

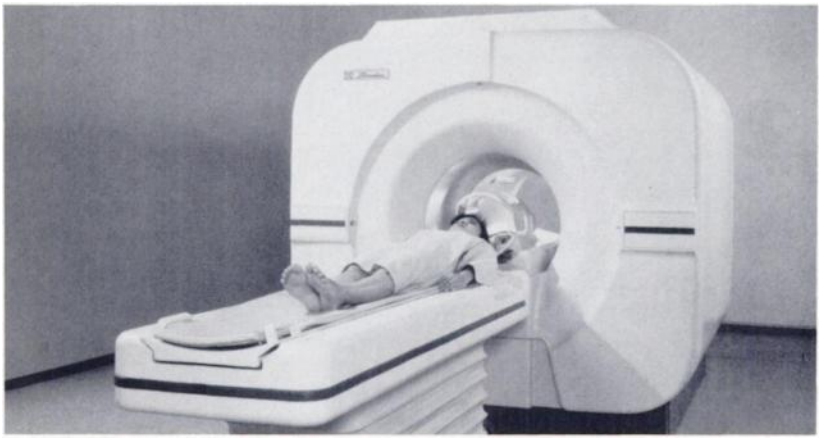
Circle Reader Service No. 102

MRI or CT Information with PET Data

Scanditronix, Inc., has introduced the first computer software program which combines the anatomical information from magnetic resonance imaging or computed tomography with positron emission tomography data. This program is a major advance for physicians and researchers using PET. It adds more reliability to the analysis of PET studies. The program stores data for anatomical regions of interest, which the user combines with MRI or CT data for each patient. The combination produces anatomical templates which can be overlayed on each PET slice to indicate precise anatomy. The user can make global adjustments to scale, orientation, and position in order to obtain an initial match. Individual regions of interest may then be moved, deleted, or redrawn as needed. **Scanditronix, Inc., 106 Western Ave., Essex, MA 01929. Attn. Steven Kendall. (508)768-6994.**

Circle Reader Service No. 103

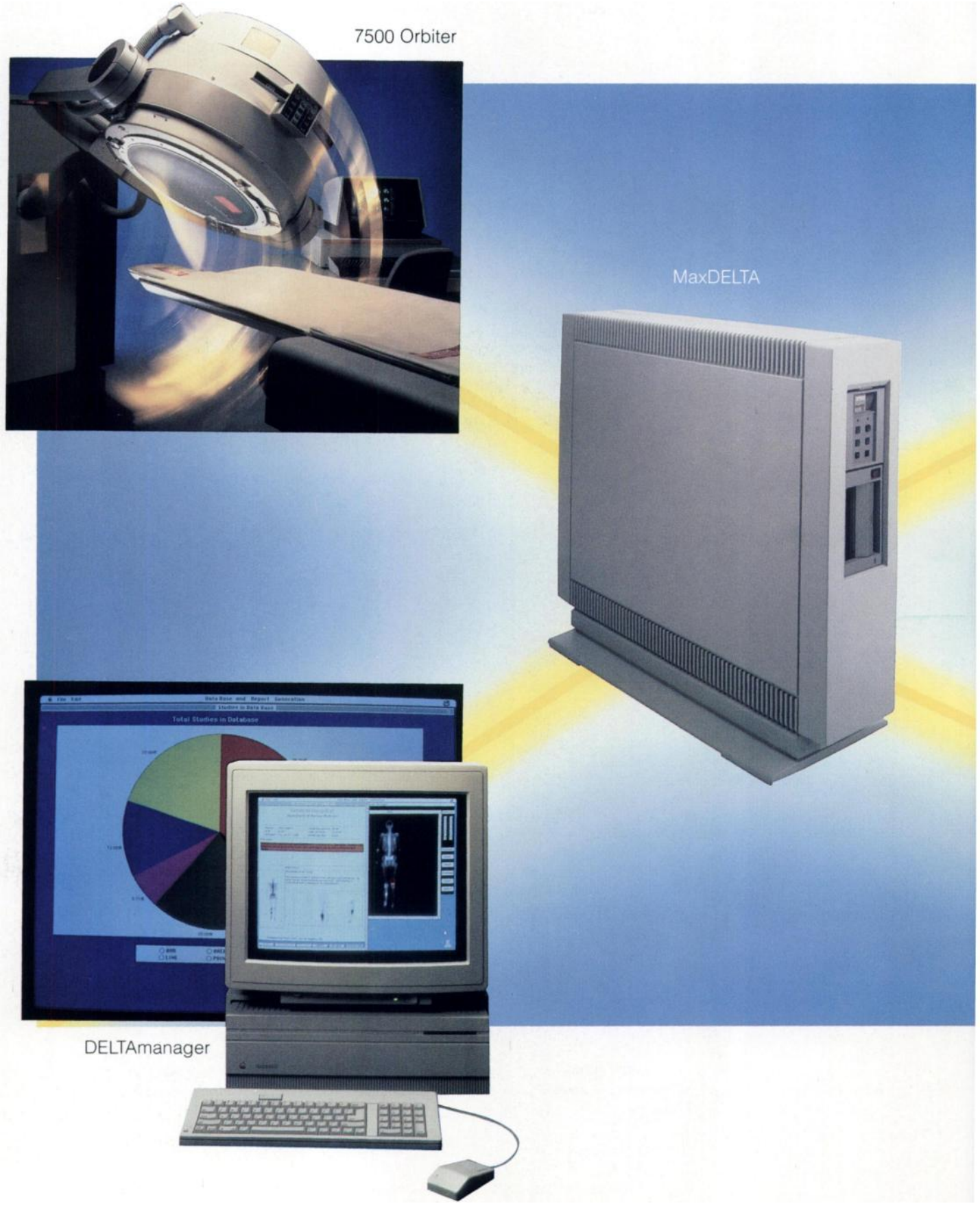
New MRI System

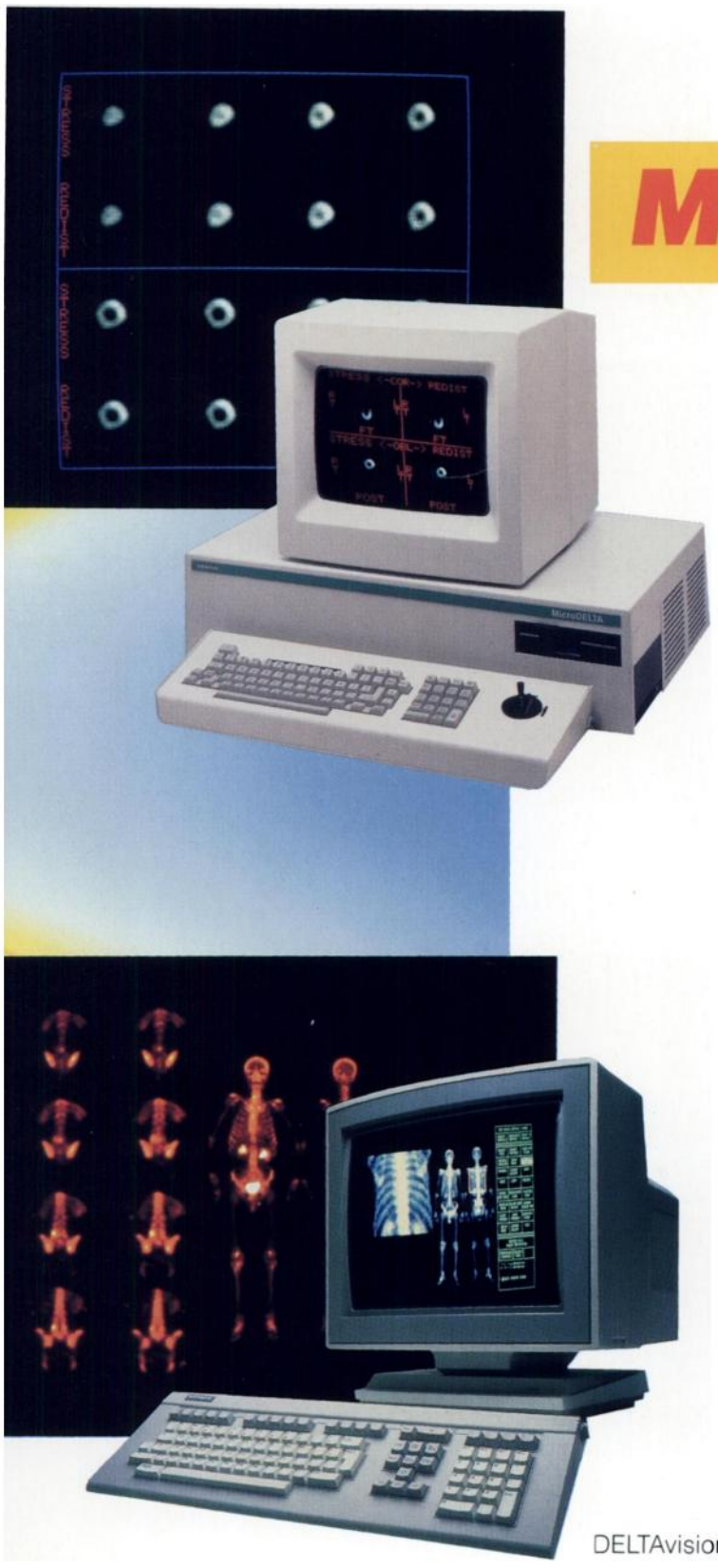


Shimadzu Medical Systems has introduced a new magnetic resonance imaging system. The SMT-50A is a superconducting 0.5 Telsa unit. Focal points include the stability and homogeneity of the 0.5 magnet. A superconducting shim coil, along with the main coil, provides 0.1 parts per million (ppm)/hour stability and assures ideal homogeneity of the 10 ppm/35 diameter spherical volume (DVS). Use of the system is beneficial in diagnosing many tumors and vascular conditions such as aneurysms. MRI also provides excellent visualization of the posterior fossa, which can be difficult to see under other diagnostic methods without contrast agents. The SMT-50A also features a 1024 × 1024 matrix display for enhanced image quality, plus some of the most sophisticated software available for MR imaging, as well as a 2.4 giga-byte optical disk that permits increased patient image archive capacity. Up to 19,000 images can be stored per disk, compared to just 100 on the standard floppy disk format. The system is available in both stationary and mobile models. **Shimadzu Medical Systems, 100 W. Walnut St., Gardana, CA 90248-3130. Attn. Andrea Menke. (714)755-0400.**

Circle Reader Service No. 104

SIEMENS





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Circle Reader Service No. 4

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MPI MAA Kit

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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