The Journal of Nuclear Medicine

JNM

Volume 32, Number 6 • June 1991

1192 Car	bon-14-Ure	Breath Test	in Gastritis a	and Ulcer Disease
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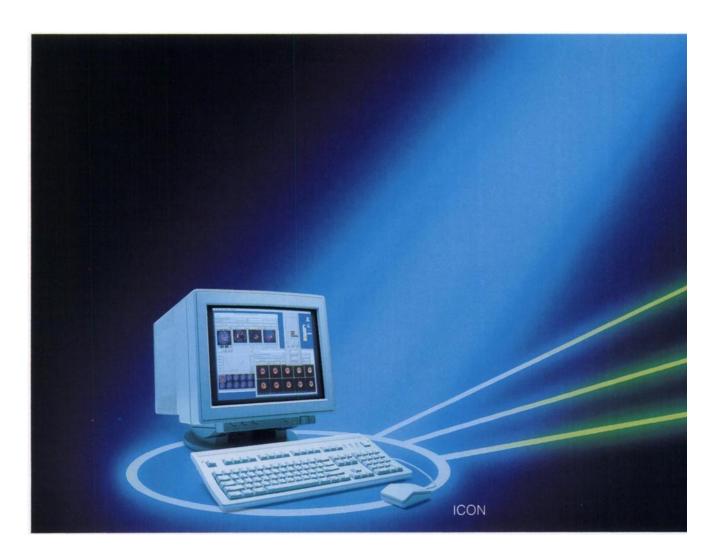
- 1206 Abnormal Brain Perfusion in Cocaine-Dependent Polydrug Users
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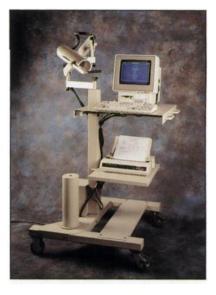
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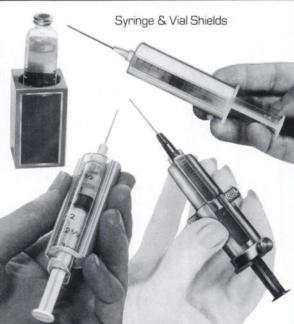




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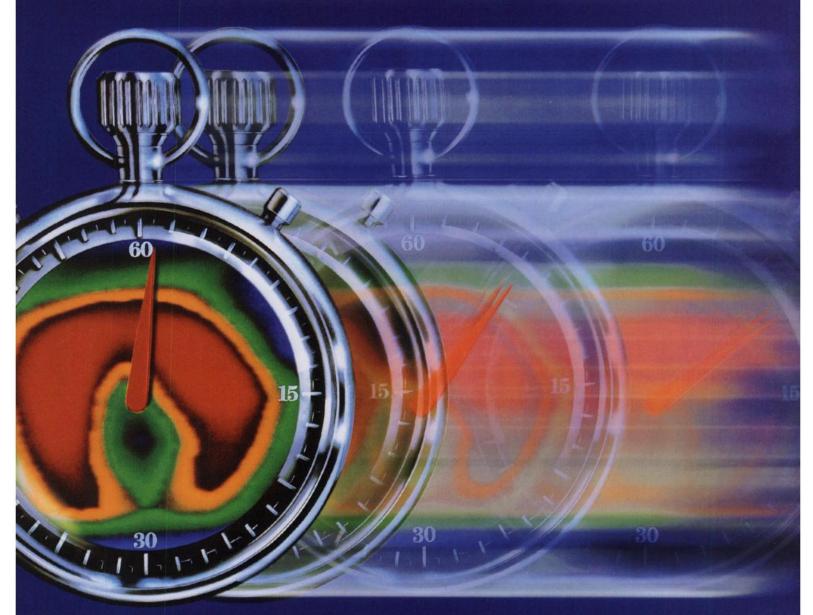
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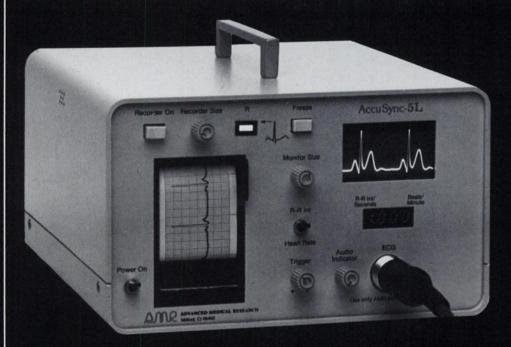


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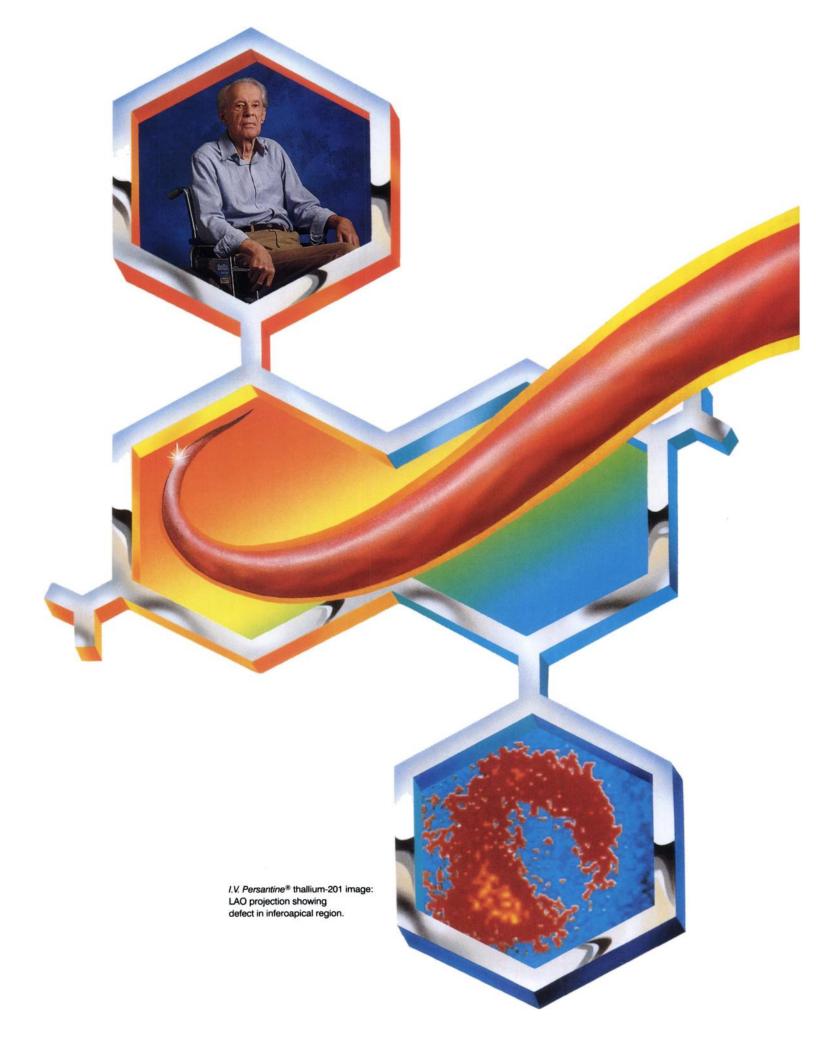


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- Iskandrian AS, Heo J, Askenase A, et al: Am Heart J 1988; 115:432-443.
 Leppo JA: J Nucl Med 1989; 30:281-287.
- Ranhosky A, Kempthorne-Rawson J, et al: Circulation 1990; 81:1205-1209.
- 4. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT.

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Radiopharmaceuticals

THALLOUS CHLORIDE TI 201 DIAGNOSTIC FOR INTRAVENOUS USE

DESCRIPTION: Thallous Chloride TI 201 is supplied in isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. The aqueous solution at the time of calibration contains 37MBo/ml (1mC/ml) Thallous Chloride TI 201. The pH is adjusted with hydrochlor acid and/or sodium hydroxide solution. It is made isotonic with 9mg/ml sodium chloride and is preserved with 9mg/ml benzyl alcohol. Thallium TI 201 is cyclotron produced with no carrier added and contains no less than 98% Thallium TI 201 as a percentage of total activity with contaminants less than 0.3% Thallium TI 200, 1.2% Thallium TI 200 and 0.2% Lead Pb 203 expressed as a percentage of TI 201 activity at calibration. It is recommended that Thallous Chloride TI 201 be administered close to calibration time to minimize the effect of higher levels of radionuclide contaminant.

MONCATIONS AND USAGE: Thallous Chloride TI 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction. It may also have prognostic value regarding survival, when used in the clinically stable patient following the onset of symptoms of an acute myocardial infarction, to assess the site and size of the perfusion defect.

Thallous Chloride TI 201 may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of sichemic heart disease (atheroscierotic coronary artery disease), it is usually not possible to differentiate recent from old myocardial infarction, or to differentiate exactly between recent myocardial infarction and ischemia.

Thallous Chloride TI 201 is indicated also for the localization of sites of parathyroid hyperactivity in patients with elevated serum calcium and parathyroid homone levels. It may also be useful in preparative screening to localize extrathyroidal and mediastinal sites of parathyroid hyperactivity and for post-surgical reexamination. Thallous Chloride TI 201 has not been adequately demonstrated to be effective for the localization of normal parathyroid glands.

CONTRAMDICATIONS: None known

WARRINGS: In studying patients in whom myocardial infarction or ischemia is known or suspected, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Everices etress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

PRECAUTIONS: Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of Thallous Chloride TI 201 scans. Attention is directed to the fact that thallium is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that the thallium may likewise be affected.

GENERAL: Do not use after the expiration time and date (5 days maximum after calibration time) stated

On not use if contents are turbid.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration

auministration.

Thallous Chloride TI 201, as all radioactive materials, must be handled with care and used with appropriate safety measures to minimize external radiation exposure to clinical personnel. Care sho also be taken to minimize radiation exposure to patients in a manner consistent with proper patient

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential, or whether Thallous Chloride Ti 201 affects fertility in males or females. 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.

onset or menses.

Prepagancy Category C: Adequate reproductive studies have not been conducted in animals with Thallous Chloride TI 201. It is also not known whether Thallous Chloride TI 201 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Thallous Chloride TI 201 should not be given to a pregnant woman except when benefits clearly outweigh the potential risks.

Nersing Nethers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, nursing should not be undertaken when a patient is administered radioactive material.

material.

Padiatric Use: Safety and effectiveness in children below the age of 18 have not been established.

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.

ADVERSE REACTIONS: A single adverse reaction to the administration of Thallous Chloride TI 201 has been reported consisting of hypotension accompanied by pruritus and a diffuse rash which responded to antihistamines and steroids within one hour.

HOW SUPPLIED: Thallous Chloride TI 201 for intravenous administration is supplied as a sterile, nonpyrogenic solution containing at calibration time 37MBq/ml (1mCi/ml) of Thallous Chloride TI 201, 9mg/ml sodium chloride, and 9mg/ml of berzyl alcohol. The PH is adjusted with hydrochloric acid and/or sodium hydroxide solution. Visia are available in the following quantities of radioactivity: 81.4, 122.1, 162.8, 244.2, 325.6 and 366.3MBq (2.2, 3.3, 4.4, 6.6, 8.8 and 9.9mCi) of Thallous Chloride

Store at room temperature (15-30°C)



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IV PERSANTINE (dipyridamole USP) Prescribing Informa

For Intravenous Injection

INDICATIONS AND USAGE IV Persantine® (dipyridamole USP) is indicated as an alternative to exercise in thallium myocardial perfusion imaging for the evaluation of coronary artery disease in patients who cannot exercise adequately.

CONTRAINDICATIONS Hypersensitivity to dipyridamole.

WARNINGS Serious adverse reactions associated with the administration of intravenous Persantine® (dipyridamole USP) have included fatal and non-fatal myocardial infarction, ventricular fibrillation, symptomatic ventricular tachycardia, transient cerebral ischemia, and bronchospasm. In a study of 3911 patients given intravenous Persantine as an adjunct to thallium myocardial perfusion imaging, two types of serious adverse events were reported: 1) four cases of myocardial infarction (0.1%), two fatal (0.05%); and two non-fatal (0.05%); and severse events was small (0.05%) of 3911, the potential clinical information to be gained through use of intravenous Persantine thallium imaging (se Indications and Usage noting the rate of false positive and false negative results) must be weighed against the risk to the patient. Patients with a history of unstable angina may be at a greater risk for severe myocardial ischemia. Patients with a history of asthma may be at a greater risk for bronchospasm during IV Persantine use.

against the risk to the platein. Patients with a history of asthma may be at a greater risk for bronchospasm during IV Persantine use. When thallium myocardial perfusion imaging is performed with intravenous Persantine, parenteral aminophylline should be readily available for relieving adverse events such as bronchospasm or chest pain. Vital signs should be monitored during, and for 10-15 minutes following, the intravenous infusion of Persantine and an electrocardiographic tracing should be obtained using at least one chest lead. Should severe chest pain or bronchospasm occur, parenteral aminophylline may be administered by slow intravenous injection (50-100 mg over 30-60 seconds) in doses ranging from 50 to 250 mg. In the case of severe hypotension, the patient should be placed in a supine position with the head tilted down if necessary, before administration of parenteral aminophylline. If 250 mg of aminophylline does not relieve chest pain symptoms within a few minutes, sublingual nitroglycerin may be administred. If chest pain continues despite use of aminophylline and nitroglycerin, the possibility of myocardial infrarction should be considered. If the clinical condition of a patient with an adverse event permits a one minute delay in the administration of parenteral aminophylline, thallium-201 may be injected and allowed to circulate for one minute before the injection of aminophylline. This will allow initial thallium perfusion imaging to be performed before reversal of the pharmacologic effects of Persantine on the coronary circulation.

PRECAUTIONS See WARNINGS.

Drug Interactions Oral maintenance theophylline may abolish the coronary vasodilatation induced by intravenous Persantine® (dipyridamole USP) administration. This could lead to a false negative thallium

intravenous Persantine® (dipyridamole USP) administration. This could lead to a false negative thallium imaging result.

Carcinogenesis, Mutagenesis, Impairment of Fertility In studies in which dipyridamole was administered in the feed at doses of up to 75 mg/kg/day (9.4 times* the maximum recommended daily human oral dose) in mice (up to 128 weeks in males and up to 142 weeks in females) and rats (up to 111 weeks in males and person the maximum recommended daily human oral dose) and females) there was no evidence of drug related carcinogenesis. Mutagenicity tests of dipyridamole with bacterial and mammalian cell systems were negative. There was no evidence of impaired fertility when dipyridamole was administered to male and female rats at oral doses up to 500 mg/kg/day (63 times* the maximum recommended daily human oral dose). A significant reduction in number of corpora lutea with consequent reduction in implantations and live fetuses was, however, observed at 1250 mg/kg/day.

Pregeancy Category B Reproduction studies performed in mice and rats at daily oral doses of up to 125 mg/kg (15.6 times* the maximum recommended daily human oral dose) and in rabbits at daily oral doses of up to 20 mg/kg (2,5 times* the maximum recommended daily human oral dose) have revealed no evidence of impaired embryonic development due to dipyridamole. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human responses, this drug should be used during pregnancy only if clearly needed.

**Calculation based on assumed body weight of 50 kg.

**Nersing Nothers Dipyridamole is excreted in human milk.

**Pediatric Use Safety and effectiveness in children have not been established.

**PUNERSE REACTIONS Aberes reaction information concerning intraveous Persantings (disvridamole).

ADVERSE REACTIONS Adverse reaction information concerning intravenous Persantine® (dipyridamole USP) is derived from a study of 3911 patients in which intravenous Persantine was used as an adjunct to thallium myocardial perfusion imaging and from spontaneous reports of adverse reactions and the Serious adverse events (fatal and one fatal).

published literature. Serious actives events (fatal and non-fatal myocardial infarction, severe ventricular arrhythmias, and serious actives events (fatal and non-fatal myocardial infarction, severe ventricular arrhythmias, and serious CNS abnormalities) are described above (see WARNINGS). In the study of 3911 patients, the most frequent adverse reactions were: chest pain/angina pectoris (19.7%), ebadache (12.2%), and dizziness (11.8%). Adverse reactions occurring in greater than 1% of the patients in the study are chest pain/angina pectoris (19.7%), headache (12.2%), dizziness (11.8%), electrocardiographic abnormalities/setrasystoles (5.2%), hypotension (4.6%), nausea (4.6%), flushing (3.4%), electrocardiographic abnormalities/tactycardia (3.2%), dyspnea (2.6%), pain unspecified (2.6%), blood pressure lability (1.6%), hypertension (1.5%), paresthesia (1.3%), fatigue (1.2%).

(1.2%). Less common adverse reactions occurring in 1% or less of the patients within the study included: Cardiovascular System: Electrocardiographic abnormalities unspecified (0.8%), arrhythmia unspecified (0.6%), palpitation (0.3%), ventricular tachycardia (0.2% see WARNINGS), bradycardia (0.2%), myocardial infarction (0.1% see WARNINGS), AV block (0.1%), syncope (0.1%), orthostatic hypotension (0.1%), atrial fibrillation (0.1%), supraventricular tachycardia (0.1%), ventricular arrhythmia unspecified (0.03%) see WARNINGS), heart block unspecified (0.03%), cardiomyopathy (0.03%), edema (0.03%).

edma (0.03%). Central and Peripheral Nervous System: Hypothesia (0.5%), hypertonia (0.3%), nervousness/anxiety (0.2%), tremor (0.1%), abnormal coordination (0.03%), somnolence (0.03%), dysphonia (0.03%), migraine (0.03%), vertigo (0.03%), estigo (0.03%), somnolence (0.03%), dysphonia (0.03%), migraine (0.03%), vertigo (0.03%), estigo (0.03%), appetite increased (0.03%), vertigo (0.03%), bronchospasm (0.2% see WARNINGS), hyperventilation (0.1%), chinitis (0.1%), coughing (0.03%), pleural pain (0.03%), the estigo (0.03%), disphoresis (0.4%), asthenia (0.3%), malaise (0.3%), injection site reaction unspecified (0.4%), diaphoresis (0.4%), asthenia (0.3%), malaise (0.3%), arthragia (0.3%), injection site pain (0.1%), rigor (0.1%), earache (0.1%), finnitus (0.1%), vision abnormalities unspecified (0.1%), dysgeusia (0.1%), thirst (0.03%), depersonalization (0.03%), renal pain (0.03%), perineal pain (0.03%), breast pain (0.03%), intermittent claudication (0.03%), leg cramping (0.03%). Perineal pain (0.03%), breast pain (0.03%), intermittent claudication (0.03%), leg cramping (0.03%).



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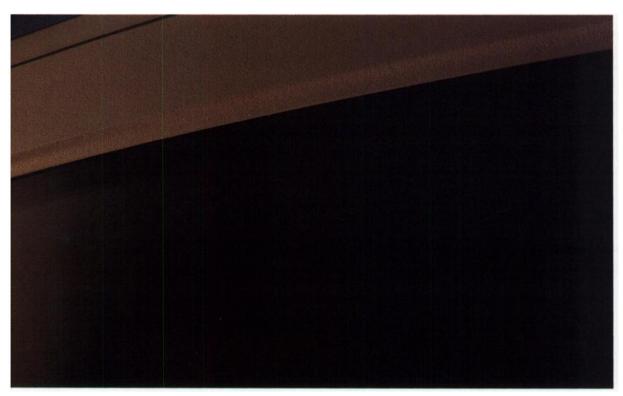
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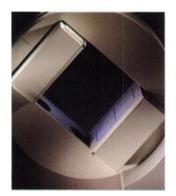
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(See Pages 48A-49A)

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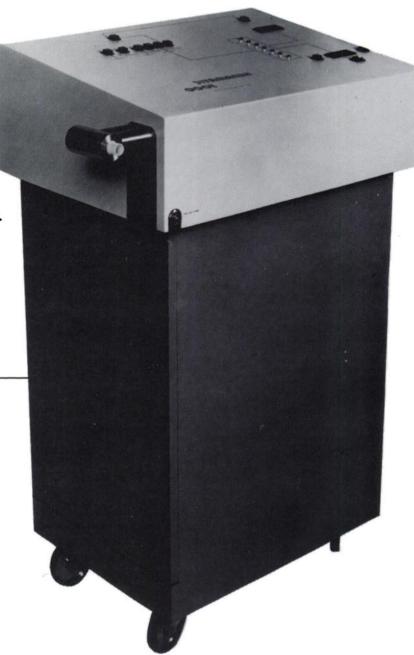
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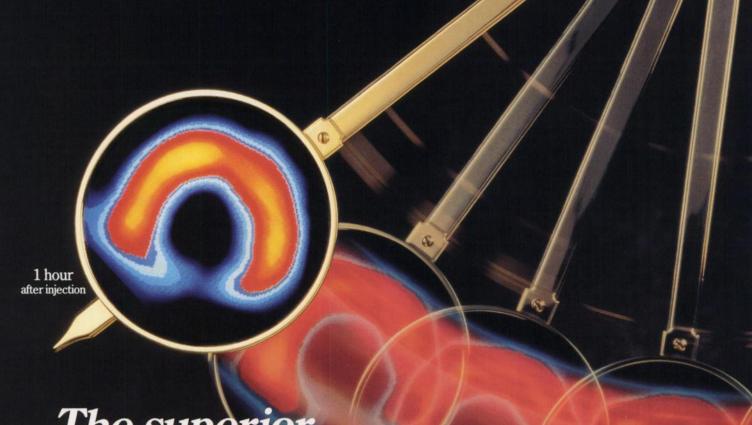
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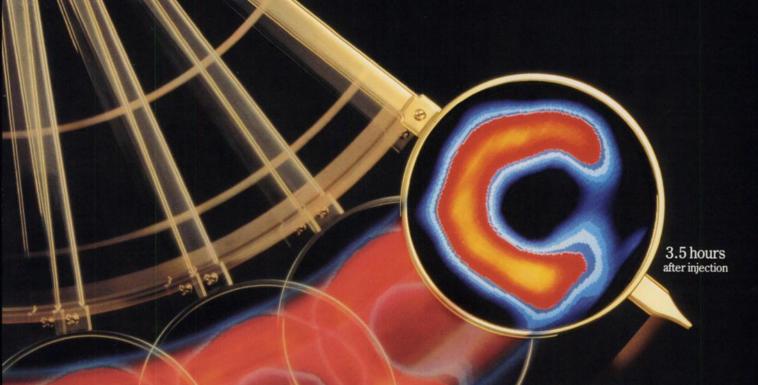


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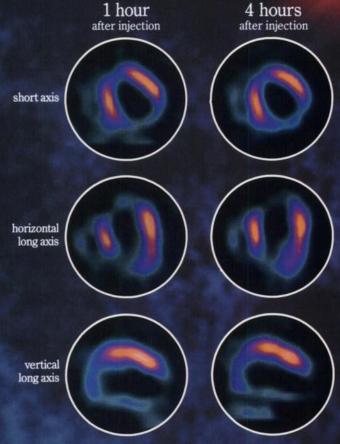
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CARDIOLITE scans (SPECT) from a 62-year-old male with three prior myocardial infarctions (LFOV camera equipped with a high-resolution collimator. 64 x 64 matrix, 180° arc RAO to LPO. 64 projections, 25 s/projection)

Please see last page of advertisement for brief summary of prescribing information.

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High degree of accuracy in detection of myocardial abnormalities

In blinded studies, **CARDIOLITE** imaging was 83% to 96% sensitive and 79% to 100% specific in detecting myocardial infarction, when compared with final diagnoses1

Reassuring safety profile

No known contraindications Few adverse reactions

Of 2780 patients in worldwide trials, approximately 8% experienced a transient metallic taste following injection. A few cases of transient headache, mild nausea, flushing, and non-itching rash have also been reported. In worldwide commercial experience, one patient showed signs and symptoms consistent with seizure 8 to 10 min after injection. No other adverse reactions specifically attributable to the use of CARDIOLITE have been reported.1

Reference

1. Data on file, Du Pont File H-23531.



Radiopharmaceutical

FOR DIAGNOSTIC USE

DESCRIPTION: Each 5 mL vial contains a sterile, non-pyrogenic, lyophilized mix-

Tetrakis (2-methoxy isobutyl isonitrile) Copper (I) tetrafluoroborate - 1.0 mg

Sodium Citrate Dihydrate - 2.6 mg

L-Cysteine Hydrochloride Monohydrate - 1.0 mg

Mannitol - 20 mg

Stannous Chloride, Dihydrate, minimum (SnCl₂•2H₂O) - 0.025 mg

Stannous Chloride, Dihydrate, (SnCl₂•2H₂O) - 0.075 mg Tin Chloride (Stannous and Stannic) Dihydrate, maximum (as SnCl₂•2H₂O) -

Prior to lyophilization the pH is 5.3 to 5.9. The contents of the vial are lyophilized and stored under nitrogen

This drug is administered by intravenous injection for diagnostic use after reconstitution with sterile, non-pyrogenic, oxidant-free Sodium Pertechnetate Tc99m Injection. The pH of the reconstituted product is 5.5 (5.0-6.0). No bacteriostatic preservative is

The precise structure of the technetium complex is Tc99m[MIBI]₆ where MIBI is 2-methoxy isobutyl isonitrile.

INDICATIONS AND USAGE: CARDIOLITE®, Kit for the preparation of Technetium Tc99m Sestamibi, is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium, and in the localization of the abnormality, in patients with suspected myocardial infarction. It is also useful in the evaluation of myocardial function using the first-pass technique.

ONTRAINDICATIONS: None known

WARNINGS: In studying patients in whom cardiac disease is known or suspected, take care to assure continuous monitoring and treatment in accordance with safe, accepted clinical procedure.

PRECAUTIONS:

GENERAL

The contents of the vial are intended only for use in the preparation of Technetium Tc99m Sestamibi and are not to be administered directly to the patient without first undergoing the preparative procedure (as outlined in the full prescribing information).

Radioactive drugs must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patients consistent with proper patient

Contents of the kit before preparation are not radioactive. However, after the Sodium Pertechnetate Tc99m Injection is added, adequate shielding of the final preparation must be maintained.

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.

Technetium Tc99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, Sodium Pertechnetate Tc99m Injection containing oxidants should not be used.

Technetium Tc99m Sestamibi should not be used more than six hours after preparation.

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

In comparison with most other diagnostic technetium-labeled radiopharmaceuticals, the radiation dose to the ovaries (1.5 rads/30 mCi) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOS-AGE AND ADMINISTRATION section.)

The active intermediate, Cu(MIBI)₄BF₄, was evaluated for genotoxic potential in a battery of five tests. No genotoxic activity was observed in the Ames, CHO/HPRT and sister chromatid exchange tests (all in vitro). At cytotoxic concentrations (≥ 20 µg/mL), an increase in cells with chromosome aberrations was observed in the in vitro human lymphocyte assay. Cu(MIBI) BF did not show genotoxic effects in the in vivo mouse micronucleus test at a dose which caused systemic and bone marrow toxicity (9 mg/kg, >600 \times maximal human dose).

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc99m Sestamibi. It is also not known whether Technetium Tc99m Sestamibi can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc99m Sestamibi 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 Tc99m Pertechnetate is excreted in human milk during lactation. It is not known whether Technetium Tc99m Sestamibi is excreted in human milk. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS: During clinical trials, approximately 8% of patients experienced a transient metallic or bitter taste immediately after the injection of Technetium Tc99m Sestamibi. A few cases of transient headache, flushing and non-itching rash have also been attributed to administration of the agent. One patient demonstrated signs and symptoms consistent with seizure, 8 to 10 minutes after administration of the drug. No other adverse reactions specifically attributable to the use of Technetium Tc99m Sestamibi have been reported.

DOSAGE AND ADMINISTRATION: The suggested dose range for I.V. administration to be employed in the average patient (70 kg) is:

370 to 1110 MBq (10 to 30 mCi)

The dose administered should be the lowest required to provide an adequate study consistent with ALARA principles (See also PRECAUTIONS).

When used in the diagnosis of myocardial infarction, imaging should be completed within four hours after administration (see also CLINICAL PHARMACOLOGY section in full prescribing information).

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Radiochemical purity should be checked prior to patient administration.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

Store at room temperature (15 to 30°) before and after reconstitution

RADIATION DOSIMETRY: Table 4 shows the radiation doses to organs and tissues of an average patient (70 kg) per 1110 MBq (30 mCi) of Technetium Tc99m Sestamibi injected intravenously.

Table 4. Radiation Absorbed Doses from Tc99m Sestamibi

Estimated Radiation Absorbed Dose

	REST				
	2.0 h	our void	4.8 hour void		
Organ	rads/ 30 mCi	mGy/ 1110 MBq	rads/ 30 mCi	mGy/ 1110 MBq	
Breasts	0.2	2.0	0.2	1.9	
Galibladder Wall	2.0	20.0	2.0	20.0	
Small Intestine	3.0	30.0	3.0	30.0	
Upper Large					
Intestine Wall	5.4	55.5	5.4	55.5	
Lower Large					
Intestine Wall	3.9	40.0	4.2	41.1	
Stomach Wall	0.6	6.1	0.6	5.8	
Heart Wall	0.5	5.1	0.5	4.9	
Kidneys	2.0	20.0	2.0	20.0	
Liver	0.6	5.8	0.6	5.7	
Lungs	0.3	2.8	0.3	2.7	
Bone Surfaces	0.7	6.8	0.7	6.4	
Thyroid	0.7	7.0	0.7	6.8	
Ovaries	1.5	15.5	1.6	15.5	
Testes	0.3	3.4	0.4	3.9	
Red Marrow	0.5	5.1	0.5	5.0	
Urinary Bladder					
Wall	2.0	20.0	4.2	41.1	
Total Body	0.5	4.8	0.5	4.8	

Stabin, M., July, 1990, Oak Ridge Associated Universities, P.O. Box 117, Oak Ridge, TN 37831, (615) 576-3449.

HOW SUPPLIED: Du Pont's CARDIOLITE®, Kit for the preparation of Technetium Tc99m Sestamibi is supplied as a 5 mL vial in kits of two (2), five (5) and thirty (30) vials, sterile and non-pyrogenic.

Prior to lyophilization the pH is between 5.3 and 5.9. The contents of the vials are lyophilized and stored under nitrogen. Store at room temperature (15 to 30°C) be ore and after reconstitution. Technetium Tc99m Sestamibi contains no preservatives. Included in each two (2) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each five (5) vial kit is one (1) package insert, five (5) vial shield labels and five (5) radiation warning labels. Included in each thirty (30) vial kit is one (1) package insert, thirty (30) vial shield labels and thirty (30) radiation warning labels.

The US Nuclear Regulatory Commission has approved this reagent kit for distribution to persons licensed to use byproduct material identified in 35.100 and 35.200 of 10 CFR Part 35, to persons who hold an equivalent license issued by an Agreement State, and, outside the United States, to persons authorized by the appropriate authority.

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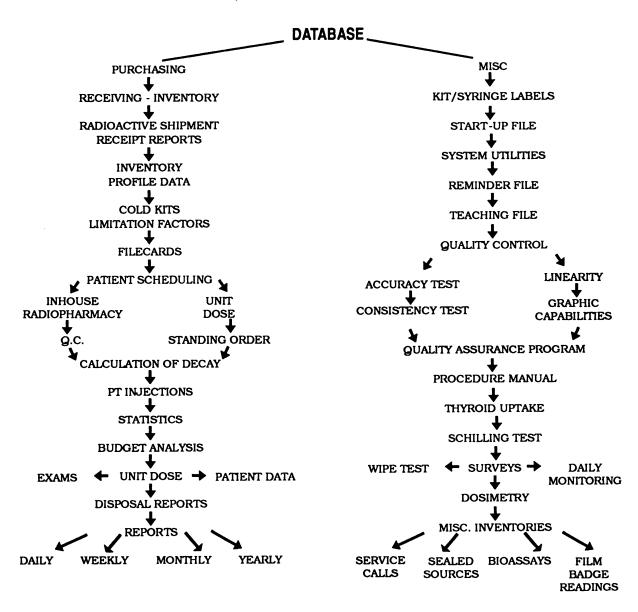
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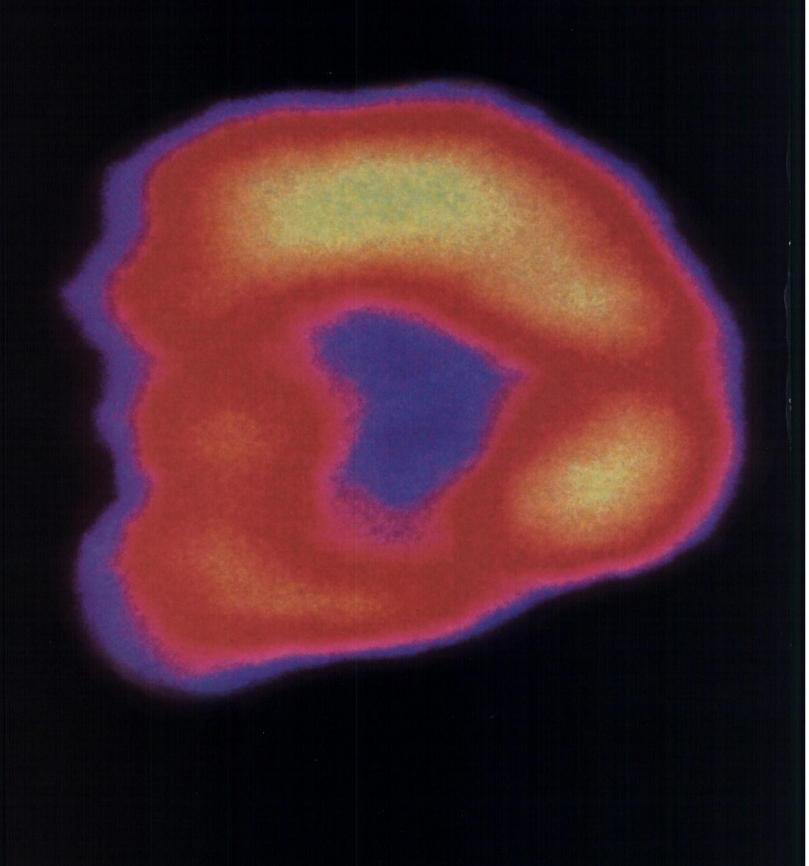


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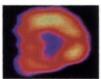
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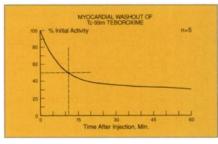




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CardioTec

(Kit for the Preparation of Technetium Tc 99m Teboroxime)

Please see the brief summary of prescribing information for CardioTec on the adjacent page.



Cardiotec*

Kit for the Preparation of Technetium Tc 99m Teboroxime

FOR DIAGNOSTIC USE

DESCRIPTION

Each 5 mL reaction vial contains a sterile, nonpyrogenic, lyophilized formulation of 2.0 mg cyclohexanedione dioxime, 2.0 mg methyl boronic acid, 2.0 mg pentetic acid, 9.0 mg citric acid, anhydrous; 100 mg sodium chloride, 50 mg gamma cyclodextrin and 0.058 mg (maximum) total tin expressed as stannous chloride (SnCL₂), 0.020 mg (minimum) stannous chloride (SnCl2). The pH is adjusted with sodium hydroxide and/or hydrochloric acid prior to lyophilization. The contents of the vial are lyophilized and sealed under nitrogen at the time of manufacture. No bacteriostatic preservative is present.

When sterile, pyrogen-free sodium pertechnetate Tc 99m injection is added to the vial, and the solution is heated at 100°C for 15 minutes, the diagnostic agent Technetium Tc 99m Teboroxime is formed for administration by intravenous injection. The pH of the reconstituted product is 3.7 (range 3.3 to 4.1).

INDICATIONS AND USAGE

Technetium Tc 99m Teboroxime is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected coronary artery disease using rest and stress techniques.

CONTRAINDICATIONS None known.

WARNINGS

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate monitoring, resuscitation and support apparatus.

PRECAUTIONS

General

Contents of the reaction vial are intended only for use in the preparation of Technetium Tc 99m Teboroxime and are not to be administered directly to the patient.

Contents of the kit before preparation are not radioactive. However, after the addition of sodium pertechnetate Tc

99m injection, adequate shielding of the final preparation must be maintained.

The components of the kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during the addition of the pertechnetate solution and the withdrawal of doses for patient administration.

The technetium Tc 99m labeling reactions involved in preparing the agent depend on maintaining the stannous ion in the reduced state. Any oxidant present in the sodium pertechnetate Tc-99m supply may thus adversely affect the quality of the radiopharmaceutical. Hence, sodium pertechnetate Tc-99m containing oxidants should not be employed.

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.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers.

Tc-99m Teboroxime should be formulated no more than 6 hours prior to clinical use.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.8 rads/50 mCi) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE and ADMINISTRATION section.)

No long-term animal studies have been performed to evaluate carcinogenic potential or to determine the effects of Cardiotec on fertility in males or females.

Three different mutagenicity assays (a reversion test with bacteria, a chromosomal aberration assay and an *in vivo* mouse micronucleus assay) conducted with cold (decayed) technetium la-

beled Cardiotec gave negative results. Cardiotec was weakly positive for inducing forward mutations at the TK locus in L5178Y mouse lymphoma cells in the absence of metabolic activation (but only at high concentrations that were toxic to the cells and reduced growth to 33% or less relative to vehicle controls). Cardiotec was negative in this assay in the presence of metabolic activation.

Pregnancy Category C

Animal reproduction studies have not been conducted with Technetium Tc 99m Teboroxime. It is also not known whether Technetium Tc 99m Teboroxime can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Teboroxime should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those 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 Tc 99m is excreted in human milk during lactation. Therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS

Uncommon adverse reactions reported in clinical trials include metallic taste in mouth, burning at injection site, facial swelling, numbness of hand and arm, hypotension and nausea after administration of Technetium Tc 99m Tehoroxime.

HOW SUPPLIED

Cardiotec* (Kit for the Preparation of Technetium Tc 99m Teboroxime) is supplied in kits of 5, 10, and 25 reaction vials. (J4-282A)



Reference
1. Data on file, Squibb Diagnostics.

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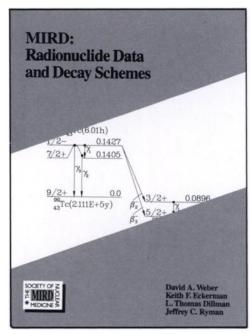
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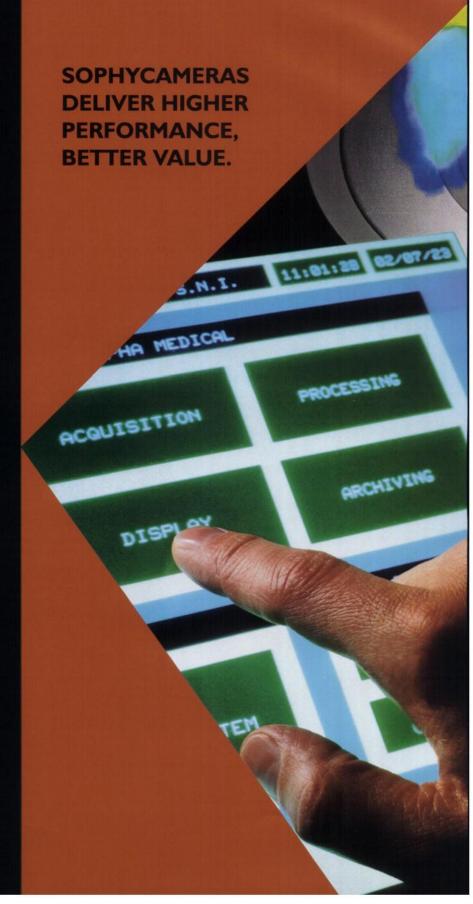
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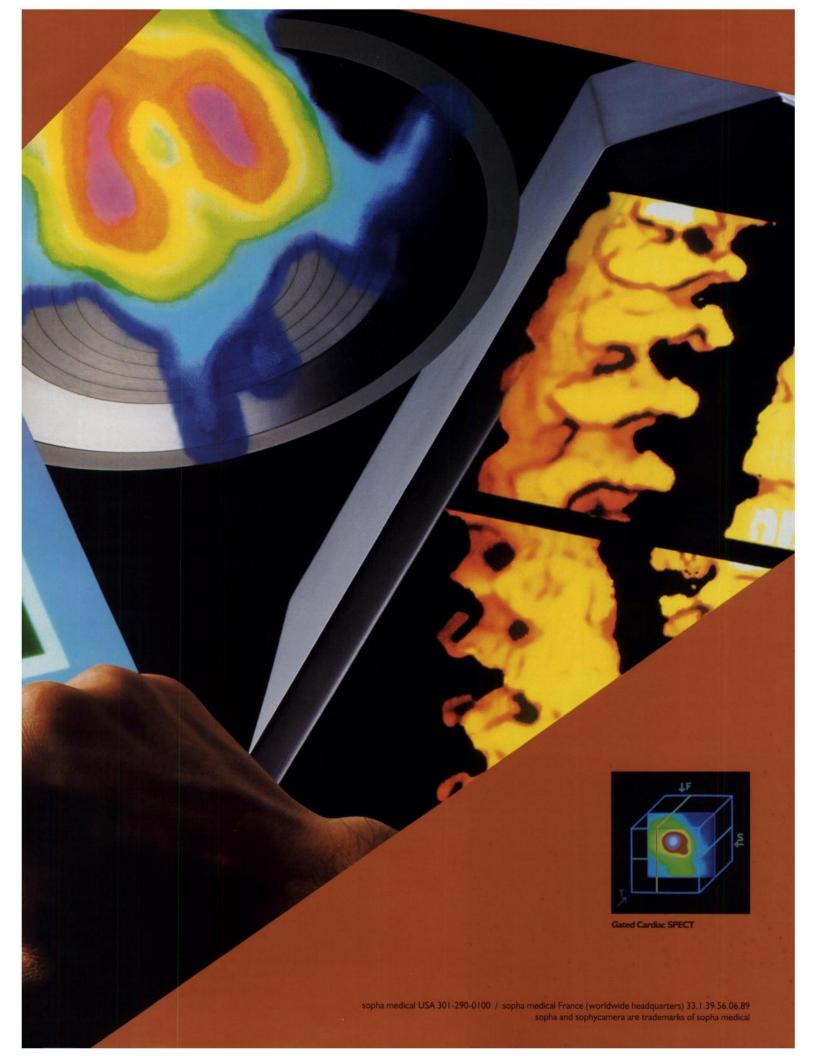
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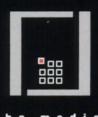
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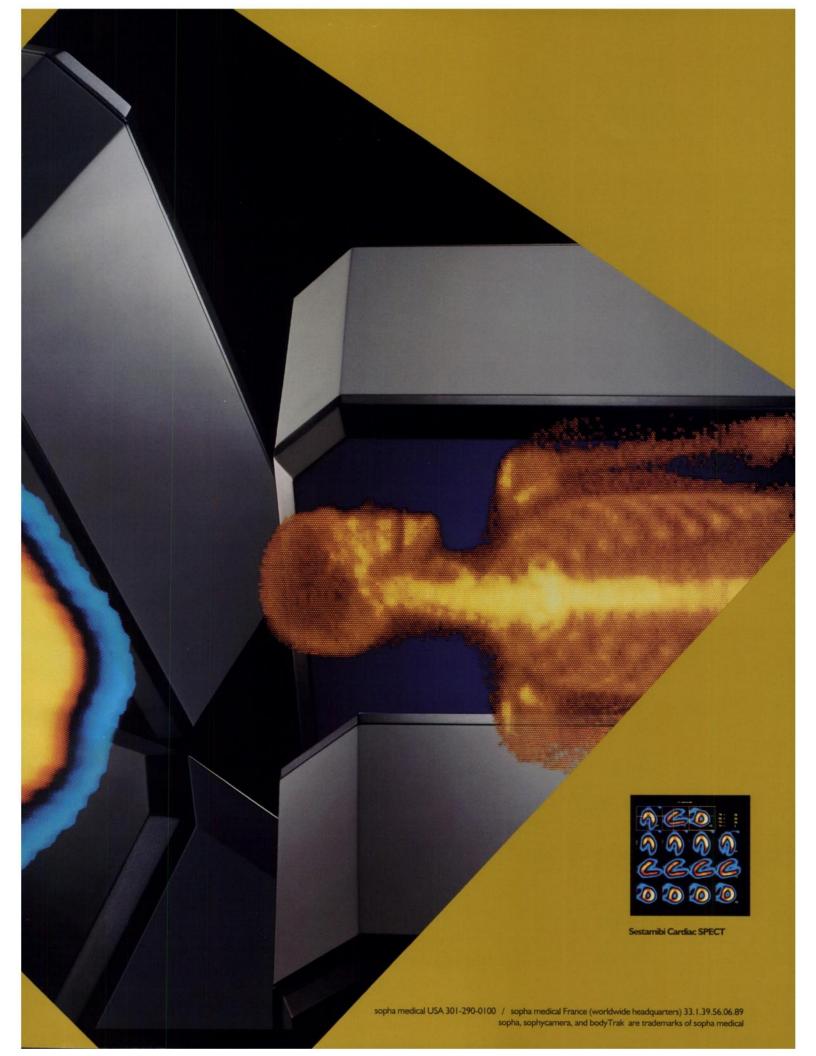
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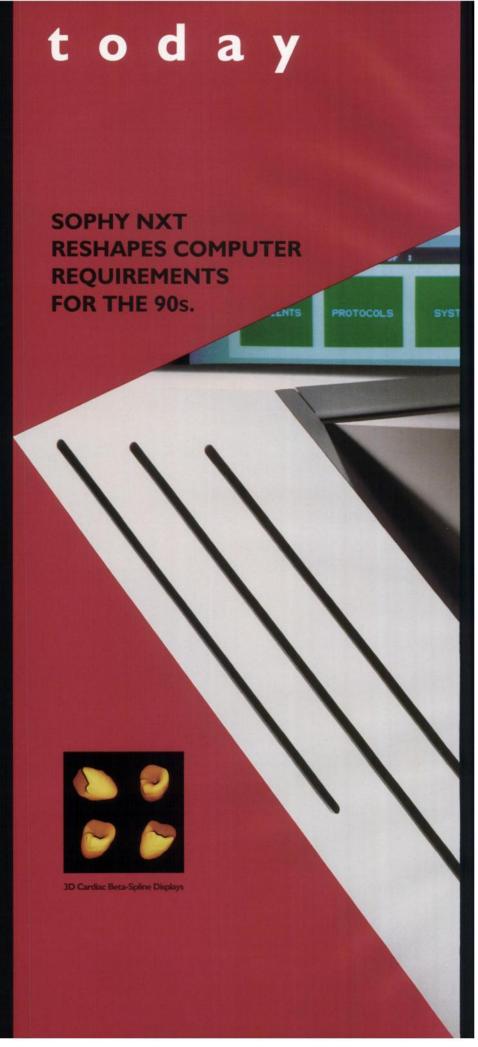
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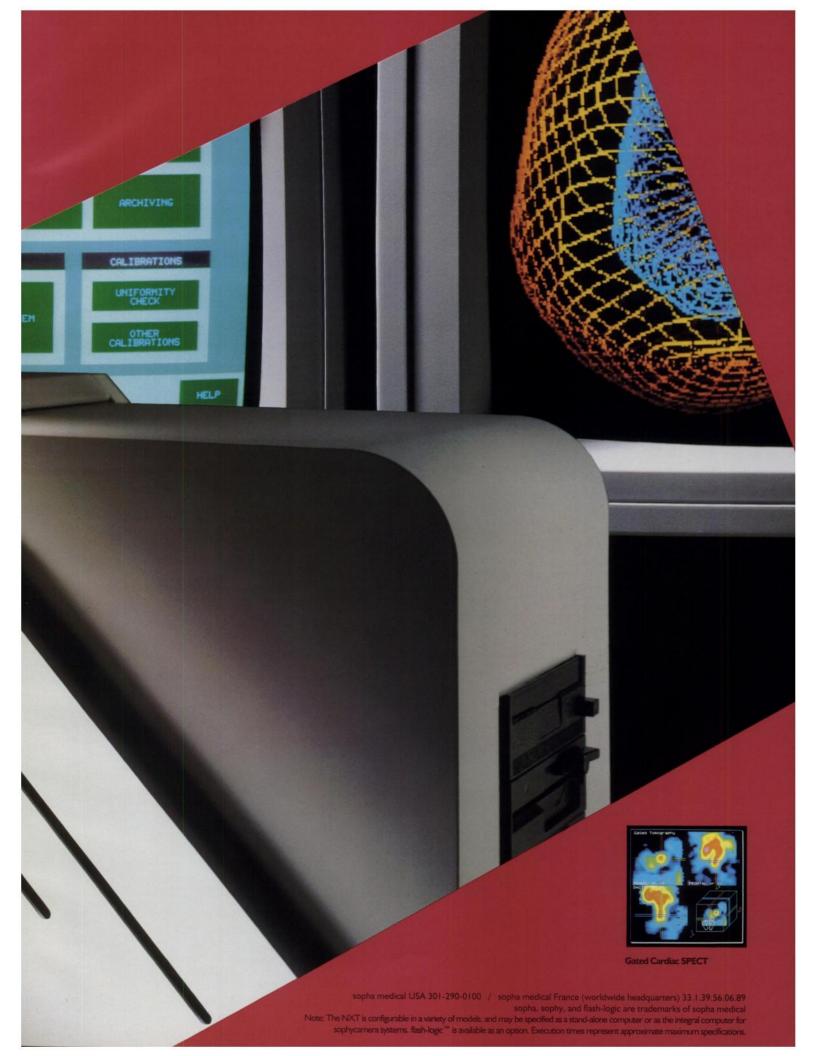
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Physician

RADIOLOGIST-strong in ultrasound, vascular imaging, and angiography needed for South Jersey hospital practice. BC or in process. \$175-\$200K + base salary plus excellent benefit package. Send CV in confidence to Box 603, The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016.

RADIOLOGIST-nuclear/general-needed for South Jersey hospital practice. BC or in process. \$175-\$200K+ base salary plus excellent benefit package. Also need qualified locum tenens for immediate coverage. Send CV in confidence to Box 602, The Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016.

NUCLEAR MEDICINE PHYSICIAN. The University of California, Davis School of Medicine has a full-time faculty position available in the Nuclear Medicine Division of the Department of Radiology. Appointment will be at the Assistant/Associate/Full Professor level (In-Residence or in the Professor of Clinical Radiology Series). Candidates must be Board certified in Nuclear Medicine or Radiology with a special competence in Nuclear Medicine, eligible for licensure in California, and have an academic background in Nuclear Medicine. Since this position will be open until filled, please forward curriculum vitae, a letter outlining background and in-terests in teaching/research and the names of five references as promptly as possible. Applications will not be accepted after December 31, 1991. Reply to: William E. Brant, MD, Chairman, Search Committee for Nuclear Medicine Physician, Department of Radiology, 2516 Stockton Boulevard, Ticon II Building, Sacramento, California 95817. The University of California is an Equal Opportunity/Affirmative Action Employer and en-courages applications from members of minority groups

NUCLEAR MEDICINE PHYSICIAN. The Mt. Sinai Medical Center in NY is seeking applicants for a junior faculty position. Candidates with experience preferred. The department has a full clinical, research and educational program and is developing a PET imaging center. Send CV to: Stanley J. Goldsmith, MD, Dept. of Physics/ Nuclear medicine, Box 1141, Mt. Sinai Medical Center, One Gustave L. Levy Place, New York, NY 10029.

NUCLEAR MEDICINE PHYSICIAN at the Assistant Professor level in academically oriented program. Board (ABNM) certified or eligible. Experience in all aspects of nuclear medicine with interest in research. Send CV to: John R. Hansell, MD, Chief, Department of Nuclear Medicine, VA Medical Center, 39th & Woodland, Philadelphia, PA 19104. Equal Opportunity/Affirmative Action Employer. Qualified female and minority candidates are encouraged to apply.

DIRECTOR OF NUCLEAR MEDICINE. The Brigham and Women's Hospital is seeking a Director of Nuclear Medicine. The Division of Nuclear Medicine has a strong research program in SPECT and radiopharmaceutical development. The successful candidate must qualify for a faculty appointment as Associate Professor at Harvard Medical School and be board certified in Nuclear Medicine. Please send curriculum vitae to: B. Leonard Holman, MD, Chairman, Department of Radiology, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115. Brigham and Women's Hospital/Harvard Medical School is an affirmative action/equal opportunity educator and employer.

DIRECTOR, DIVISION OF NUCLEAR MEDI-DIRECTOR, DIVISION OF NUCLEAR MEDI-CINE. The Department of Radiology, University of Brit-ish Columbia is seeking a Director of Nuclear Medicine. Salary commensurate with experience and qualifications. Proposed start date July 1, 1991. The deadline for closing this competition is May 31, 1991. Please send curriculum vitae and bibliography and names of three references to: Brain C. Lentle, MD, Professor and Head, Department of Radiology, Vancouver General Hospital, Heather Pavil-ion, Room 63, Floor A, Vancouver, BC, V5Z 1M9. In ac-cordance with the Canadian immigration requirements. cordance with the Canadian immigration requirements, this advertisement is directed to Canadian citizens and permanent residents of Canada. The University of British Columbia is committed to the federal government's em-ployment equity programme and encourages applications from all qualified individuals.

NUCLEAR MEDICINE PHYSICIAN. We are seeking an ABNM board eligible or recently board certified nuclear medicine physician to join the Nuclear Medicine Department at St. Luke's Medical Center in Milwaukee, WI. St. Luke's Medical Center is the largest private hospital in Wisconsin, is well known as a cardiac center, and has recently begun a 5-year expansion program that will see the hospital grow from its current 600 beds to well over 1,000 beds. The department is very active in nuclear cardiology, SPECT imaging, and general nuclear medicine excluding RIA. The department currently has 8 gamma cameras, a large Siemens computer system, and fun-ding to purchase both a triple head camera and a dual rectangular head camera later this year. The department has an approved 4-year nuclear medicine residency which will shortly be affiliated with the University of Wisconsin. The position includes a combination of clinical, teaching, and research responsibilities. The salary and benefits of this position are excellent. For more information, please contact David L. Yuille, MD, at (414)649-6418, or send your curriculum vitae to Nuclear Medicine, St. Luke's Medical Center, 2900 W. Oklahoma Ave., Milwaukee, WI 53215.

Northern California-The Permanente Medical Group, Inc., a growing multispecialty group practice, is seeking a BC/BE NUCLEAR MEDICINE PHYSICIAN to join a staff of two physicians and one physicist at our Oakland medical center. Strong clinical background required with emphasis in cardiovascular and thyroid diseases. Full complement of SPECT equipment. University affiliations are available and clinical research is encouraged. We of-fer competitive salaries and an excellent benefits package. Respond with CV to: Dan Navarro, MD, Department of Nuclear Medicine, Kaiser Permanente Medical Center, 280 W. MacArthur Blvd., Oakland, CA 94611. EOE.

Radiologist

RADIOLOGIST/nuclear medicine-25-person radiology group in central New Jersey seeks a board certified radiologist with additional nuclear medicine boards or radiologist with additional nuclear medicine boards of ABR special competency to share responsibilities in nuclear medicine and some general radiology. Cardiac, nuclear and SPECT experience required. Practice includes two 450-bed hospitals, 3 offices, radiology residency, and medical student teaching. Send CV to Richard Feinstein, MD, c/o Kathy McGrath, Radiology Group of New Brunswick, 230 Old Bridge Turnpike, South River, NJ 08829.

Technologist

Outstanding career opportunity for full-time certified NUCLEAR MEDICINE TECHNOLOGIST to work at a new high-profile imaging center in California. Applicant must be licensed or certification eligible in California in all scopes. SDI is a private imaging center in Fairfield located 40 minutes N.E. of San Francisco, 3 hours S.W. of Lake Tahoe and 20 minutes east of the Napa Valley wine country. Salary and benefits are competitive, the atwine country. Salary and benefits are competitive, the almosphere is cordial, and the housing is still affordable. Please send resume to: Solano Diagnostics Imaging Center, Attention: Jill Branham, 1101 B. Gale Wilson Blvd., Suite 100, Fairfield, CA 94533 (707) 421-2373.

CHIEF TECHNOLOGIST. Nuclear Medicine Department. Salary: \$37,800-\$56,700. The UCSF, Dept. of ment. Salary: \$37,800-\$56,700. The UCSF, Dept. of Nuclear Medicine at SFGH, is seeking an individual to admin., develop and maintain program in Q.A., Radiation Safety and Equip. Maintenance in both In Vivo and In Vitro procedures. Must have excel. interpersonal and comm. skills, 3 yrs. recent super. exper. + computer & software Mgt., B.S. in biological/physical science and current CA. Nuc. Med. certificate. Send resumé to: JO: CMIE89122, UCSF Personnel, 1350-7th Avenue, SF, CA 94143, FOF. 94143. EOE.

Positions Wanted

ABNM-certified physician, 49, seeks relocation, Ex-ABNM-certined physician, 49, seeks relocation. Extensive academic and private practice experience in all aspects of Nuclear Medicine including cardiac imaging, tumor imaging, SPECT techniques, and R.I.A. Reply to: Box 601. The Society of Nuclear Medicine, 136 Madison Ave., New York, NY 10016.

Equipment

For sale: Technicare 420/550, ADAC's vertical CDS, system I, system III, DPS 2800. We offer the highest prices for all types of nuclear medicine cameras & computers. Call Franklin at Imaging Solutions (415) 924-9155.

NUCLEAR MEDICINE

Mercy Healthcare Sacramento currently has several opportunities for professionals interested in joining our Nuclear Medicine departments at Mercy General Hospital and Mercy San Juan Hospital. Ideally located in beautiful Sacramento, these progressive and fast-paced environments offer the chance to work with stateof-the-art equipment and an outstanding team of professionals.

Mercy General Hospital

Senior Nuclear Medicine Technologist

In this full-time day position, we have an exceptional opportunity for a Senior Nuclear Medicine Tech who has 3 years of nuclear medicine experience. You must have a CA state certification, the ability to develop protocol, integrate software, problem-solve and perform imaging and wet lab procedures. NMTCB, ARRT-NM, ASCP-NM certification preferred.

For consideration, please send resume to: Mercy General Hospital, Human Resources, 4001 J Street, Sacramento, CA 95819.

Mercy San Juan Hospital

Nuclear Medicine Manager

In this position, you will be responsible for the daily operation and play an integral role in the planning and growth of this multicamera department. You must have a current CA state licensure and/or be eligible in all categories of Nuclear Medicine Technology and previous supervisory experience. NMTCB, ARRT-NM and ASCP-NM preferred. Relocation assistance will be offered on an individual basis.

Lead Technologist

As Lead Technologist, you will enjoy working in this multi-camera department with responsibilities that include planning, organizing and controlling the daily patient workload. You must have a CA license and/or eligible and SPECT experience. NMTCB and ARRT-NM preferred.

For consideration, please send resume to: Mercy San Juan Hospital, Human Resources, 6501 Coyle Avenue, Carmichael, CA 95608.

Mercy offers an excellent salary and benefits package including a strong commitment to transfer and promotion opportunities locally and through our Catholic Healthcare West affiliation. Please respond to the hospital corresponding with the position of interest or call us at (800) 688-3834. We are proud to be an equal opportunity employer.

Mercy Healthcare Sacramento



MANAGER—PET CLINICAL APPLICATIONS SOFTWARE

We're CTI... the leading worldwide supplier of products and services for the positron emission tomography market with a corporate mission to expand the clinical use of PET. Our strong partnership with Siemens and collaboration with leading PET research centers around the world have further enhanced our position as the leader in PET.

We're seeking a special individual to provide technical leadership for the development of applications software designed to meet the needs of our clinical users. Responsibilities will involve the definition and prototyping of clinical applications software; management of software development at research collaborator sites; and active participation in PET research programs at the nearby University of Tennessee Medical Center.

Ideal candidates will have an advanced degree in Engineering, Science, or Computer Science and at least eight years experience developing medical image processing software, preferably in PET or nuclear medicine. Excellent leadership, interpersonal, and communications skills are required. A strong customer orientation—focused on the needs of clinical users—is also very important.

CTI is headquartered in Knoxville, Tennessee—an area with extensive educational, cultural, and recreational opportunities; a low cost-of-living; and high-quality, affordable housing. We offer career opportunities we consider very special: a technically-challenging product, the chance to contribute significantly to the success of a growing business, and a unique working environment. We also offer a competitive compensation, benefits, and relocation package. Please send a current resume to: Jack Kreyling, Recruiting Specialist, CTI, 810 Innovation Drive, Box 22999, Knoxville, TN 37933. An Equal Opportunity Employer.



We're looking for special people who are looking for a special company... perhaps we're looking for each other.

Nuclear Medicine Technologists

The University of Texas M.D. Anderson Cancer Center, one of the world's leading comprehensive cancer institutions, is seeking registered or registry eligible candidates in Nuclear Medicine to work in our fully computerized and highly automated Division of Diagnostic Imaging.

M.D. Anderson, located within the renowned Texas Medical Center in Houston, offers reimbursement for interviewing expenses, interest free loans, competitive salaries, an excellent benefit package, and relocation assistance. Houston offers diverse cultural, dining, sports, and entertainment activities and Texas residents do not pay state income tax.

We recognize your contribution as a prestigious professional and encourage you to call Victor Stonebrook at (713) 792-8005 collect or send your resume to: M.D. Anderson Cancer Center, 1515 Holcombe Blvd., HMB 205, Houston, Texas 77030.



Equal opportunity/affirmative action employer. Smoke-free environment.

NUCLEAR MEDICINE TECHNOLOGIST

Washoe Medical Center, northern Nevada's largest medical facility, is seeking a full-time Technologist to join our Nuclear Medicine Department. This individual must have A.R.R.T., A.S.C.P. or N.M.T.C.B. registration or certification in Nuclear Medicine Technology, with a working knowledge of same, including nuclear cardiology and computer applications. C.P.R. certification also is required. Membership in The Society of Nuclear Medicine is preferred.

On-campus fitness and child care centers and much more. And beautiful Lake Tahoe and other dazzling vacation resorts are just minutes away! Please send your resumé with salary history to:

M. Andrea Webster Human Resources Supervisor



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Nuclear Medicine Technologist

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As we celebrate 100 years of providing care and concern to the Yakima Valley in South Central Washington we invite you to join our family. We are seeking a registered/certified technologist or a professional with 3 years of nuclear medicine experience.

We offer a competitive salary package and a cafeteria style approach to your benefits, including healthcare and childcare reimbursement. You can make your own choices at St. Elizabeth. For more information call Jerri Daily, Employment Coordinator, St. Elizabeth Medical Center, 110 South 9th Avenue, Yakima, WA 98902, (509) 575-5096. EOE.

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Nuclear Medical Technologists (CNMT)

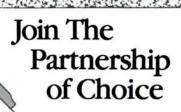
OUR LADY OF THE LAKE Regional Medical Center, located in Baton Rouge, LA, Louisiana's largest and finest acute-care facility, is currently seeking Nuclear Medical Technologists who are CNMT registered or registry eligible. We offer assistance with interviewing and moving expenses, an excellent salary structure, and a comprehensive benefit package.

We are located one hour's drive from historic New Orleans and three hours' drive from the sandy beaches of Florida.

Interested candidates call or send confidential resume to:

> Dawn Abbott Human Resources Dept. Our Lady of the Lake Regional Medical Center 5000 Hennessy Blvd.

> > Baton Rouge, LA 70809 (504)765-8803



Southern California Permanente Medical Group, the nation's largest and most respected multi-specialty group practice, is seeking

RADIOLOGISTS

Nuclear Medicine BC in Radiology BC/BE in Nuclear Medicine. Prior experience in thyroid clinic helpful.

We provide you the freedom, technology and resources to focus on quality patient care, the collaborative support of knowledgeable colleagues and the opportunity to make a significant contribution to your field.

Our compensation and benefits package includes: Guaranteed practice and income
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Send your curriculum vitae to: Irwin P. Goldstein, M.D., Associate Medical Director, SCPMG, Dept. 066, Walnut Center, Pasadena, CA 91188-8013.

Or call 1-800-541-7946.



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Hoag Hospital, a 417-bed non-profit hospital nestled on the scenic Southern California coast between Los Angeles and San Diego has an outstanding career opportunity in its nuclear medicine department.

Candidate will perform all aspects of Nuclear Medicine Technology, including SPECT imaging and computer processing of acquired data. Requires a working knowledge of radiopharmacy and NMTCB certification. The department features:

- GEMINI SPECT camera interfaced to STAR II computer
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 TOSHIBA dual-load and whole-body camera

Technologists rotate on all cameras and computers. And Hoag offers you

an opportunity to advance through a unique three-step career ladder.

Send resumé to Teresa LeBasu, Recruiter, Human Resources Department, 301 Newport Blvd., Bax Y, Newport Beach, CA 92658-8912, or call Jan Hanchett, Technical Manager, (714) 760-5636.

Nuclear Medicine Technologist Hiring Bonus \$1,000

Our progressive 200 Bed regional referral medical center, located in south central Nebraska, has an excellent full-time position available for a Registered or Registry Eligible Nuclear Medicine Technologist. We offer excellent benefits, salary, relocation assistance, paid interviewing, travel expenses and a sign on Bonus. To learn more about our job opportunity, call us at 1-800-658-4250!

Human Resources Good Samaritan Hospital 31st & Central Avenue Kearney, Nebraska 68847



Nuclear Medicine Technologist

The Department of Nuclear Medicine at The United Hospital is currently seeking a full-time certified Nuclear Medicine Technologist.

The United Hospital is a 350-bed tertiary care facility located in Grand Forks, North Dakota and is affiliated with the University of North Dakota Medical School.

The Nuclear Medicine Department performs more than 3,000 exams per year and is expected to rise further as renovations and expansions are completed. The department is equipped with state-of-the-art Siemens SPECT/Computer systems as well as planar cameras.

Qualified candidate will have a current valid NMTCB certification or registry eligible as well as proficiency in the performance of imaging and pharmaceutical preparation procedures. One to three years experience preferred.

We offer a competitive salary and excellent benefit package. For more information or to apply contact Margo Svoboda, Employment Coordinator, or Steve Metcalf, Nuclear Medicine Supervisor at:

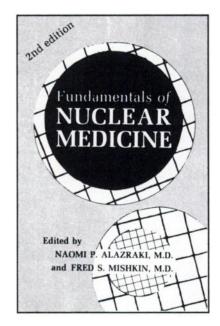
> The United Hospital 1200 So. Columbia Road Grand Forks, ND 58201 1-800-437-5375 or (701)780-5119

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Fundamentals of Nuclear Medicine

2nd Edition

Edited by Naomi P. Alazraki, MD and Fred S. Mishkin, MD



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SPECIAL STUDENT OFFER: Bulk quantities of Fundamentals of Nuclear Medicine, 2nd Edition, are available for instructors to introduce medical and technologist students to nuclear medicine. Accredited instructors may purchase a minimum of 10 copies at \$4.00 each (includes shipping).

The Society of Nuclear Medicine 136 Madison_Avenue, Dept. 588J New York City, NY 10016-6760

SPECT BRAIN IMAGING CLINICAL FELLOWSHIP

Department of Radiology Section of Nuclear Medicine



BENEFIT:

This program is designed for nuclear medicine physicians, radiologists, technologists and referring physicians. It is intended to educate participants about the clinical utility of SPECT brain imaging with agents such as SPECTamine® and Ceretec®. Objectives include:

- Development of interpretation skills for brain images.
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- Knowledge of image acquisition and reconstruction.
- Appreciation of factors that influence image quality.
- Knowledge of quality control techniques for SPECT.

SPONSORSHIP:

This program is sponsored by the Medical College of Wisconsin.

TUITION:

The tuition fee of \$650 includes the course syllabus, handouts, breaks, breakfasts, lunches, and other amenities involved in making this a pleasant learning experience. Maximum enrollments have been established. Cancellations prior to the course will be refunded, less a \$30 administrative fee.

CREDIT

The Medical College of Wisconsin is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Accordingly, the Medical College of Wisconsin designates this continuing medical education activity as meeting the criteria for 13.00 hours in Category I toward the Physician's Recognition Award of the American Medical Association.

Nuclear Medicine Technologists who attend the SPECT Brain Imaging Clinical Fellowship are eligible for 1.0 VOICE credit.

☐ August 26–27, 1991	☐ October 21–22, 1991
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A check in the amount of \$650 sh	ould accompany this registration form lical College of Wisconsin. Telephone
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CardioGen-82° Rubidium Rb 82 Generator

INDICATIONS AND USAGE

Rubidium chloride Rb 82 injection is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction.

Cardiogen-82 (Rubidium Rb 82 Generator) must be used with an infusion system specifically labeled for use with the generator and capable of accurate measurement and delivery of doses of rubidium chloride Rb 82 injection not to exceed a single dose of 2220 MBq (80 mCi) and a cumulative dose of 4440 MBq (120 mCi) at a rate of 50 mL/min with a maximum volume per infusion of 100 mL and a cumulative volume not to exceed 200 mL. These performance characteristics reflect the conditions of use under which the drug development clinical trials were conducted.

which the drug development clinical trials were conducted.

Adequate data from clinical trials to determine precise localization of myocardial infarction or identification of stress-induced ischemia have not been collected.

Positron emission tomographic (PET) instrumentation is recommended for use with rubidium chloride Rb 82 injection.

CONTRAINDICATIONS

None known

WARNINGS

Caution should be used during infusion as patients with congestive heart failure may experience a transitory increase in circulatory volume load. These patients should be observed for several hours following the Rb-82 procedure to detect delayed hemodynamic disturbances.

PRECAUTIONS

General

Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of rubidium chloride Rb 82 scans. Attention is directed to the fact that rubidium is physiologically similar to potassium, and since the transport of potassium is affected by these factors, the possibility exists that rubidium may likewise be affected.

Rubidium chloride Rb 82 injection must be administered only with an appropriate infusion system capable of meeting the performance characteristics previously described. (See INDICATIONS AND USAGE). The drug should be used only by those practitioners with a thorough understanding of the use and performance of the infusion system.

standing of the use and performance of the infusion system.

Repeat doses of rubidium chloride Rb 82 injection may lead to an accumulation of the longer lived radioactive contaminants strontium Sr 82 and strontium Sr 85.

Since eluate obtained from the generator is intended for intravenous administration, aseptic techniques must be strictly observed in all handling. Only additive free Sodium Chloride Injection USP should be used to elute the generator. Do not administer eluate from the generator if there is any evidence of foreign matter.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to insure minimum radiation exposure to occupational workers.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or to determine whether rubidium Rb 82 may affect fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with rubidium Rb 82. It is also not known whether rubidium Rb 82 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Rubidium Rb 82 should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

Ideally, examinations using radiopharmaceuticals, especially those examinations 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

It is not known whether rubidium Rb 82 is excreted in human milk. Due to the short half-life of rubidium Rb 82 (75 sec) it is unlikely that the drug would be excreted in human milk during lactation. However, because many drugs are excreted in human milk, caution should be exercised when rubidium Rb 82 is administered to nursing women.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

No adverse reactions specifically attributable to rubidium Rb 82 have been reported during controlled clinical trials.

HOW SUPPLIED

Cardiogen-82 (Rubidium Rb 82 Generator) is supplied in the form of strontium Sr 82 adsorbed on a hydrous stannic oxide column with an activity of 90-150 millicuries Sr-82 at calibration time. The generator is encased in a lead shield surrounded by a labeled plastic container. Complete assay data for each generator are provided on the container label. Cardiogen-82 (Rubidium Rb 82 Generator) is intended for use only with an appropriate, properly calibrated infusion system labeled for use with the generator.

(J4-263)

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lesued: March 1991

Circle Reader Service No. 77



PET perfusion studies without a cyclotron

CardioGen-82° (Rubidium Rb 82 Generator) is the only generator-based myocardial perfusion agent indicated for PET imaging.

Now in 45 to 60 minutes you can have PET images to help you distinguish normal from abnormal myocardium. All without the expense of a cyclotron!

The short 75-second half-life lowers the radiation burden to the patient. When incorporated into the Rubidium Infusion System, serial imaging of myocardial blood flow changes can be performed as often as every ten minutes.



Rubidium-82 Infusion System

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Remove the PET collar from your department. Get the PET images you need in 45 to 60 minutes, without a costly cyclotron.

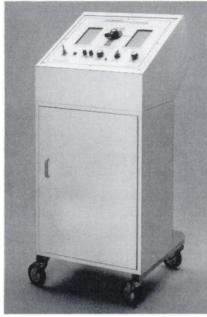
CardioGen·82





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.

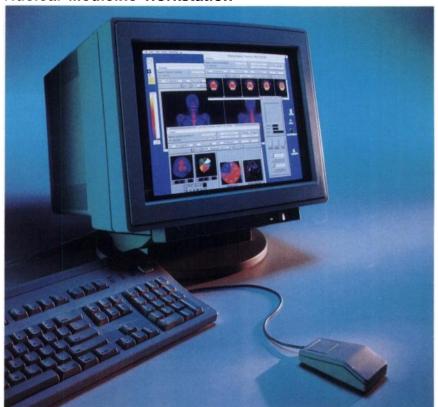
Pulmonex Xenon System



Atomic Products introduces the Pulmonex Xenon System, a complete integrated system with a delivery unit and built-in gas trap. Simple operation of a single handle on the front panel permits full-system control of xenon gas flow from initial application to the final washout of the xenon into the gas trap. With all the controls located on the front panel, the user can control the system, observe the patient, and monitor the gamma camera from one position. There are three easy functions to use when performing a ventilation study on the Pulomonex: Start, Single Breath and Equilibrium Imaging, and Washout. One technologist can perform an entire study by moving a single handle. It's safe and simple. All internal systems are completely shielded for patient and operator safety. A bacteriostatic filter is used at the mouthpiece to prevent system contamination. Atomic Products Corporation, P.O. Box 702, Shirley, NY 11967. (516) 924-9000.

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Nuclear Medicine Workstation



Siemens Medical Systems, Inc. has designed a nuclear medicine workstation, ICON, that features a direct-manipulation user interface, distributed processing, and universal networking to existing configurations. The direct-manipulation user interface effectively meets the need of the user by saving time through simplicity of operation and high processing speed. The system provides direct access to all tasks, eliminating repetitive user interactions and increasing processing speed, while the software incorporates pull-down menus and graphics for all functions. Dedicated processors provide true distributed processing and task independence without compromising speed and clinical throughput. Software protocols may be customized to ensure consistency in application, intuitive interaction, and accuracy. Comprehensive software, standard with all ICON computers, offers a spectrum of acquisition, processing, and display capabilities, including an easy to learn software interface. ICON systems support many network configurations including a high speed bi-directional data transfer between MicroDELTA™/MaxDELTA™ computers and DELTAmanager for virtually unrestricted data access, a high speed Ethernet interface, and local area networking. ICON's universal networking cabability extends and enhances the value of existing computer systems. Scott Moore, Nuclear Medical Division, Siemens Medical Systems, Inc., 2501 Barrington Road, Hoffman Estates, IL 60195. (708) 304-7252.

Circle Reader Service No. 102

Radioisotope Calibrator

Capintec, Inc. announces the availability of the CRC® -712 series, radioisotope dose calibration systems designed specifically for PET applications. Features include manual and automatic range selection for fast activity reading, up to five remote chamber configurations, Curie/Becquerel readout, RS-232 interface, auxiliary display units, and data logging printer capabilities. When the CII ionization chamber is used in a laboratory

hot cell, it is advantageous to mount the chamber under an opening in the floor of the hot cell so that the chamber doesn't take up work space in the hot cell. A mounting flange is available for the ionization chamber, which matches the mounting holes that are provided in the laboratory cell. Capintec Instruments, Inc., 6 Arrow Road, Ramsey, NJ 07446. (201) 825-9500.

Circle Reader Service No. 103

Mab Solid Phase RIA



Becton Dickinson has released a new T4 monoclonal antibody (Mab) solid phase radioimmunoassay test. Solid phase antibody coated tubes are used so no centrifugation or shaking is necessary. No reagent reconstitution is required because the reagents are sup-

plied in liquid form. Handling is reduced because the procedure only requires two pipetting steps for sample and tracer and one incubation. Incubation is done at room temperature. Sample requirements are flexible. Assay requires only $25~\mu L$ of sample and can be run on serum, EDTA, plasma, or heparinized plasma. The assay covers the range of 0 to $20~\mu g/dL$ with a sensitivity of $0.38~\mu g/dL$. Comparison studies with other commercially available T4 radioimmunoassay procedures indicate good correlation between methods. Irene Forssen, Becton Dickinson Diagnostic Instrument Systems, 7 Loveton Circle, Sparks, MD 21152. (301) 785-6204.

Circle Reader Service No. 104

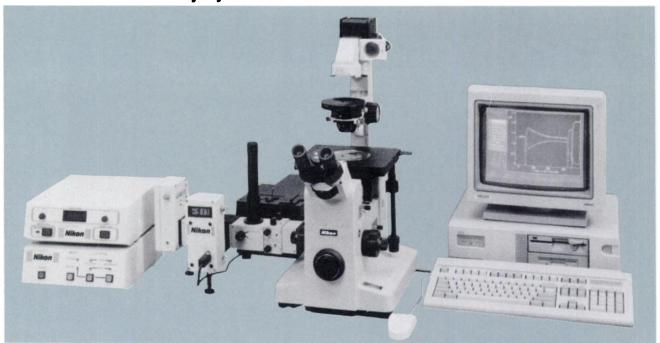
CAMAC ADC

EG&G Ortec introduces the Model ADI14 CAMAC 16K ADC, a 14-bit analog-to-digital (ADC) converter with a fast FERabus readout and CAMAC. The converter has the digital

resolution and synchronization needed for high-multiplicity coincidence experiments with germanium detectors. Its 16,000 channels and 5 μ s conversion time allow handling of high count rates over a wide range of energies. With 5 μ s conversion zerosuppression, the FERabus readout skips ADCs without data in 3 ns, and reads out active ADCs at a rate of 100 ns per word. Individual gates, pile-up rejection inputs, and a master gate input offer unprecedented control for coincidence experiments. The converter's live-time clock takes the guesswork out of coincidence dead-time corrections. CAMAC controls include zero and overflow suppression, FERabus or CAMAC readout, individual gates, master gate, singles or coincidence modes, individual lower-level discriminators, upper-level discriminator, and dc-offset. Sanford Wagner, EG&G Ortec, 100 Midland Road, Oak Ridge, TN 37831. (615) 482-4411.

Circle Reader Service No. 105

Fluorescence Photometry System



Nikon Inc.'s Instrument Group has developed a comprehensive photometry system for measuring and analyzing low-level intracellular ions in living cells. The Photoscan™ system provides digital photometers for measuring photon counts per millisecond and versatile software for single- or dual-channel data acquisition and data analysis. Neuroscientists, cell biologists, and others working with fluorescence microscopy can integrate Photoscan with their fluorescence microscopes regardless of brand. Photoscan can connect the system to IBM-compatible personal computers for complete data acquisition, analysis, and publication-quality hard

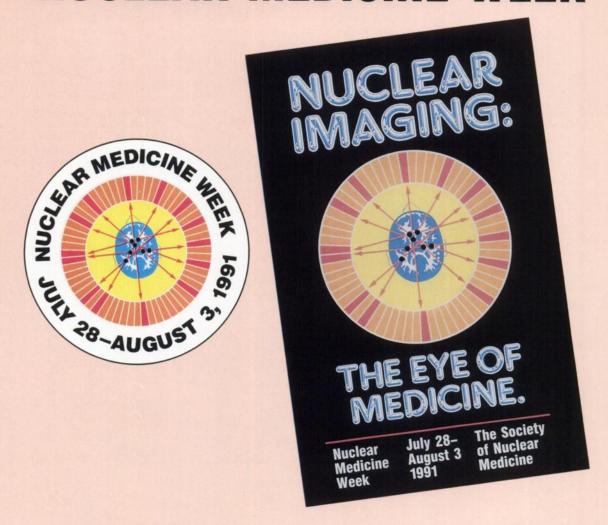
copy. Three versions of the photometry system are available. Photoscan 1 is designed for studying single-emission fluorochromes such as FLUO-3 or the dual-emission probes such as INDO-1 for calcium analysis. It is a single-emission or a simultaneous dual-emission photon counting photometer system complete with data acquisition and analysis capabilities. Photoscan 2 is ideal for studying dual excitation ratio fluorescence probes such as the popular calcium fluorochrome FURA-2. It performs real-time ratio fluorescence measurements for both single- and dual-wavelength excitation probes with either single- or dual-emission capability. It is a

complete system with digital PMTs, optical chopper-based dual wavelength fiber optic illumination system, and easy-to-use data acquisition and analysis software. Photoscan 3 is similar to Photoscan 2 but uses a 10-hole filter wheel for multi-wavelength excitation, which allows simultaneous multiple fluorochrome studies. Photoscan was developed by Photon Technology International Inc. of South Brunswick, New Jersey and is being marketed in the United States by Nikon. Instrument Group, Nikon Inc., 1300 Walt Whitman Drive, Melville, NY 11747. (516) 547-8500.

Circle Reader Service No. 106

New Products 47A

CELEBRATE NUCLEAR MEDICINE WEEK



This year Nuclear Medicine Week will be observed from July 28-August 3. Nuclear Medicine Week, sponsored by The Society of Nuclear Medicine and Technologist Section, was developed to educate the general public and health care professionals of the diagnostic and treatment capabilities of nuclear medicine.

Nuclear Medicine Week is the only time during the year that the entire nuclear medicine community unites to present its message. It is an excellent opportunity to reach out to those who could benefit from nuclear medicine; it is also a most opportune time to promote your facility to referring physicians and potential patients.

A new poster, button and sticker have been designed to help you promote this worldwide event in your community. In addition, a set of guidelines with suggestions to increase participation is available from the Society. We encourage all those involved in nuclear medicine to join with us to increase the awareness and improve the perception of nuclear medicine.

To purchase posters, buttons and stickers for your institution, and to receive a guidelines packet, visit the Nuclear Medicine Week booth located in the registration area of the Convention Center.

CELEBRATE NUCLEAR MEDICINE WEEK

July 28 - August 3, 1991

The following materials are available for promoting Nuclear Medicine Week in your area.

One poster, sticker, and a button, all in full color, have been designed for this year.

osters —	I would like posters × \$		\$	
uttons —			<u> </u>	
uttons —			\$	
	I would like to order buttons		>	
tickers —	\$.25 each (same design as the button)			
	I would like to receive stickers. (Minimum order is 10 stickers)		\$	
		Total	\$	
	☐ I would like to order a <u>free</u> set of Guidelin Nuclear Medicine Week.	nes for p	romoting	
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	Nuclear Medicine Week. must be enclosed with your order. Payments must be m U.S. banks. No foreign funds will be accepted. Make The Society of Nuclear Medic	nade in U. e checks p cine	S. dollars d ayable to	
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Please return this form to:

Nuclear Medicine Week
The Society of Nuclear Medicine
136 Madison Avenue,
New York, NY 10016-6760

Cardiotec*

Kit for the Preparation of Technetium Tc 99m Teboroxime

FOR DIAGNOSTIC USE

DESCRIPTION

Each 5 mL reaction vial contains a sterile, nonpyrogenic, lyophilized formulation of 2.0 mg cyclohexanedione dioxime, 2.0 mg methyl boronic acid, 2.0 mg pentetic acid, 9.0 mg citric acid, anhydrous; 100 mg sodium chloride, 50 mg gamma cyclodextrin and 0.058 mg (maximum) total tin expressed as stannous chloride (SnCL2), 0.020 mg (minimum) stannous chloride (SnCl₂). The pH is adjusted with sodium hydroxide and/or hydrochloric acid prior to lyophilization. The contents of the vial are lyophilized and sealed under nitrogen at the time of manufacture. No bacteriostatic preservative is present.

When sterile, pyrogen-free sodium pertechnetate Tc 99m injection is added to the vial, and the solution is heated at 100°C for 15 minutes, the diagnostic agent Technetium Tc 99m Teboroxime is formed for administration by intravenous injection. The pH of the reconstituted product is 3.7 (range 3.3 to 4.1).

INDICATIONS AND USAGE

Technetium Tc 99m Teboroxime is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected coronary artery disease using rest and stress techniques.

CONTRAINDICATIONS

None known.

WARNINGS

Stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate monitoring, resuscitation and support apparatus.

PRECAUTIONS

General

Contents of the reaction vial are intended only for use in the preparation of Technetium Tc 99m Teboroxime and are not to be administered directly to the patient.

Contents of the kit before preparation are not radioactive. However, after the addition of sodium pertechnetate Tc

99m injection, adequate shielding of the final preparation must be maintained.

The components of the kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during the addition of the pertechnetate solution and the withdrawal of doses for patient administration.

The technetium Tc 99m labeling reactions involved in preparing the agent depend on maintaining the stannous ion in the reduced state. Any oxidant present in the sodium pertechnetate Tc-99m supply may thus adversely affect the quality of the radiopharmaceutical. Hence, sodium pertechnetate Tc-99m containing oxidants should not be employed.

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.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper patient management and to ensure minimum radiation exposure to occupational workers.

Tc-99m Teboroxime should be formulated no more than 6 hours prior to clinical use.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In comparison with most other diagnostic technetium labeled radiopharmaceuticals, the radiation dose to the ovaries (1.8 rads/50 mCi) is high. Minimal exposure (ALARA) is necessary in women of childbearing capability. (See Dosimetry subsection in DOSAGE and ADMINISTRATION section.)

No long-term animal studies have been performed to evaluate carcinogenic potential or to determine the effects of Cardiotec on fertility in males or females. Three different mutagenicity assays (a reversion test with bacteria, a chromo-

reversion test with bacteria, a chromosomal aberration assay and an *in vivo* mouse micronucleus assay) conducted with cold (decayed) technetium la-

beled Cardiotec gave negative results. Cardiotec was weakly positive for inducing forward mutations at the TK locus in L5178Y mouse lymphoma cells in the absence of metabolic activation (but only at high concentrations that were toxic to the cells and reduced growth to 33% or less relative to vehicle controls). Cardiotec was negative in this assay in the presence of metabolic activation.

Pregnancy Category C

Animal reproduction studies have not been conducted with Technetium Tc 99m Teboroxime. It is also not known whether Technetium Tc 99m Teboroxime can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m Teboroxime should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability, should be performed during the first few (approximately 10)

Nursing Mothers

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

days following the onset of menses.

Pediatric Use

Safety and effectiveness in children below the age of 18 have not been established.

ADVERSE REACTIONS

Uncommon adverse reactions reported in clinical trials include metallic taste in mouth, burning at injection site, facial swelling, numbness of hand and arm, hypotension and nausea after administration of Technetium Tc 99m Teboroxime.

HOW SUPPLIED

Cardiotec* (Kit for the Preparation of Technetium Tc 99m Teboroxime) is supplied in kits of 5, 10, and 25 reaction vials. (J4-282A)



Reference
1. Data on file, Squibb Diagnostics.

