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Please see complete Package Insert before prescribing; a Brief Summary is included on the following page.


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CintiChem®
TECHNETIUM 99m

Technetium Tc 99m Normal Serum Albumin (Human) Reagent Kit HSA
DIAGNOSTIC-FOR INTRAVENOUS USE

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Indications and usage

Technetium Tc 99m Human Serum Albumin is used as an agent for imaging the heart blood pool and to assist in the detection of pericardial effusion and ventricular aneurysm.

contraindications

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

warnings

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

This radiopharmaceutical preparation should not be administered to children or to patients who are pregnant or to nursing mothers unless the expected benefits to be gained outweigh the potential hazards.

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

precautions

The components of the kit are sterile and pyrogen-free. It is essential that the user follows the directions carefully and adheres to strict aseptic procedures during preparation of the radiodiagnostic.

Technetium Tc 99m Human Serum Albumin must not be used after three hours from the time of formulation.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Human Serum Albumin should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established.

Technetium Tc 99m Human Serum Albumin, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients, consistent with proper patient management.

The labeling reactions involved in preparing the agent depend on maintaining the tin in the reduced state. Any oxidant present in the Sodium Pertechnetate Tc 99m supply may thus adversely affect the quality of the prepared agent. Hence, Sodium Pertechnetate Tc 99m containing oxidants, or other additives, should not be employed without first demonstrating that it is without adverse effect on the properties of the resulting agent.

adverse reactions

Hypersensitivity reactions are possible whenever protein-containing materials such as Technetium Tc 99m labeled human serum albumin are used in man. Epinephrine, antihistamines and corticosteroid agents should be available for use.

how supplied

unit dose kit

The kit consists of 10 unit dose reaction vials each containing a lyophilized mixture of 7 mg human serum albumin and 0.08 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment.

multidose kit

The kit consists of 5 multidose reaction vials each containing a lyophilized mixture of 21 mg human serum albumin and 0.23 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment.

FOR FULL PREPARATION AND PRESCRIBING INFORMATION, SEE PACKAGE INSERTS.

Notes: [1]Refer to package insert for full preparation and prescribing information. [2]Data on file at Union Carbide Corporation, Tuxedo, New York

UNION CARBIDE FROM ATOM TO IMAGE

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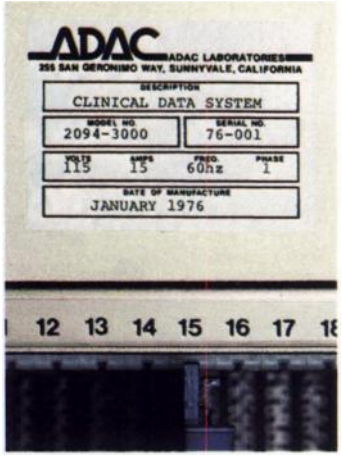
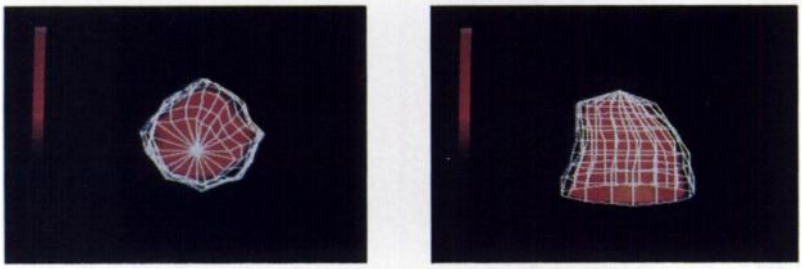
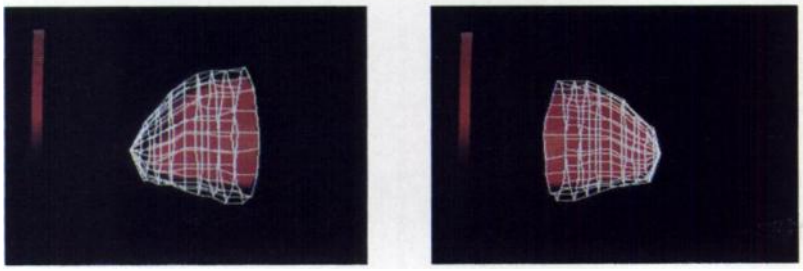




LAO Inferior



LPO RAO

Shade Program:
A three dimensional representation of the left ventricle is constructed for each segment using the 8 areas of interest of each plane in each segment. The even spacing of the planes is known since it was specified to perform the reconstruction; therefore, the areas of interest, x and y dimensions, can be connected to create the depth, z dimension. The operator can specify the projection for the constructed three dimensional image or "birdcage." Rotation can be done on the heart's x, y and z axis. Clinically, it is very valuable to rotate to the RAO, LPO, Superior Aspect, and Inferior Aspect. For example, the RAO projection allows the viewing of the long axis of the left ventricle without the right ventricle superimposed, since the edge detection did not include the right ventricle.

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Medronate produces high-target-to-background scans that readily demonstrate altered osteogenesis.[1]

- 90–94% blood clearance by two hours after administration
- Lowest soft-tissue uptake of all of the phosphonate bone agents in current use.[2]

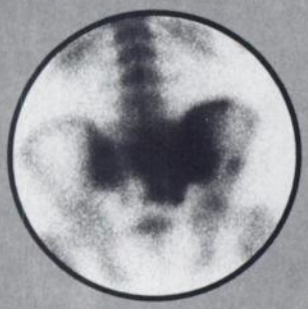
Convenience

- When necessary, imaging may begin an hour after injection (optimal imaging time is 1 to 4 hours).
- AN-MDP is stored and used at room temperature (15–30°C).

Economy

- You get 6 vials of reagent with each AN-MDP kit, instead of the usual 5.

Posterior pelvis



Posterior right side

A 54-year-old male with metastatic CA of the prostate was administered 15 mCi technetium Tc 99m-labeled AN-MDP. The images were recorded at 500K counts. Courtesy of Century City Hospital, Los Angeles.

For complete prescribing information, consult the package insert, a summary of which follows.

AN-MDP™ Technetium Tc 99m Medronate Kit

Indications and usage. Technetium Tc 99m Medronate may be used as a bone imaging agent to delineate areas of altered osteogenesis.

Contraindications. None known.

Warnings. This class of compounds is known to complex cations such as calcium. Particular caution should be used with patients who have or who may be predisposed to hypocalcemia (i.e., alkalosis)

Precautions. Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Medronate and are *NOT* to be administered directly to the patient. Technetium Tc 99m Medronate, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to patients consistent with proper patient management.

To minimize radiation dose to the bladder, patients should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as possible for the next 4–6 hours.

Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use. Optimal imaging results are obtained 1–4 hours after administration.

Carcinogenesis, mutagenesis, impairment of fertility: No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Medronate affects fertility in males or females.

Pregnancy category C: Animal reproductive studies have not been conducted with Technetium Tc 99m Medronate. It is also not known whether Technetium Tc 99m Medronate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc 99m 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.

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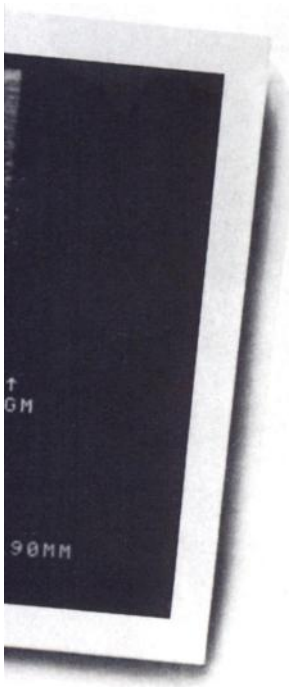

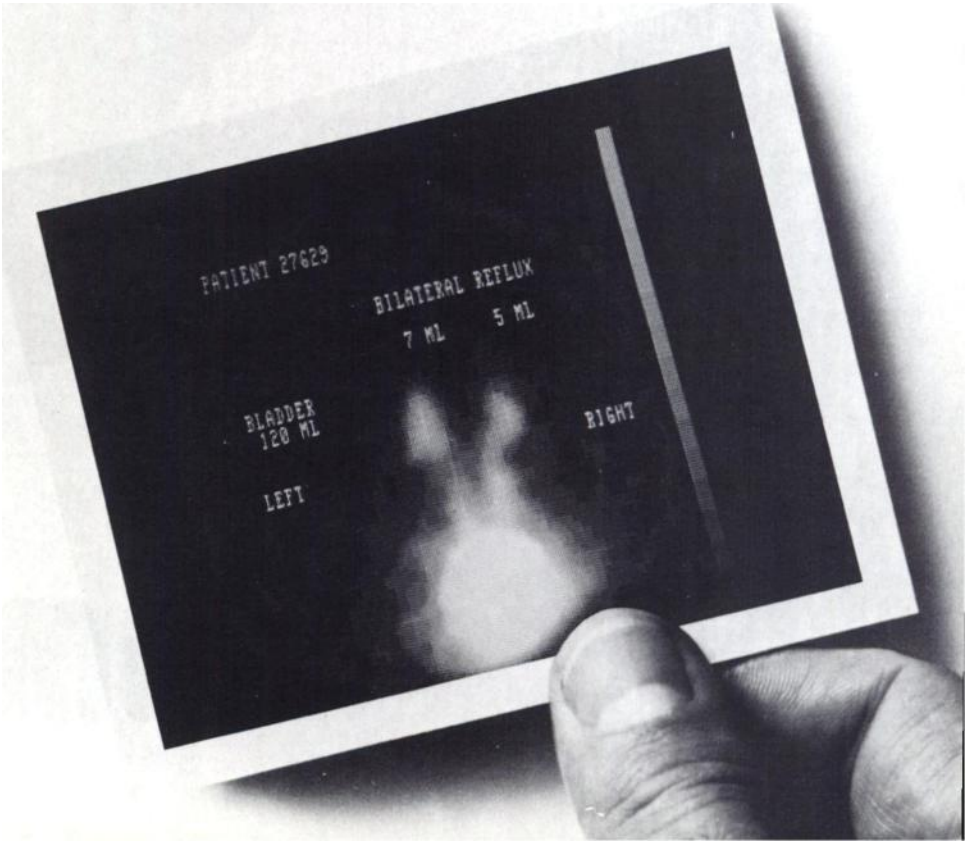

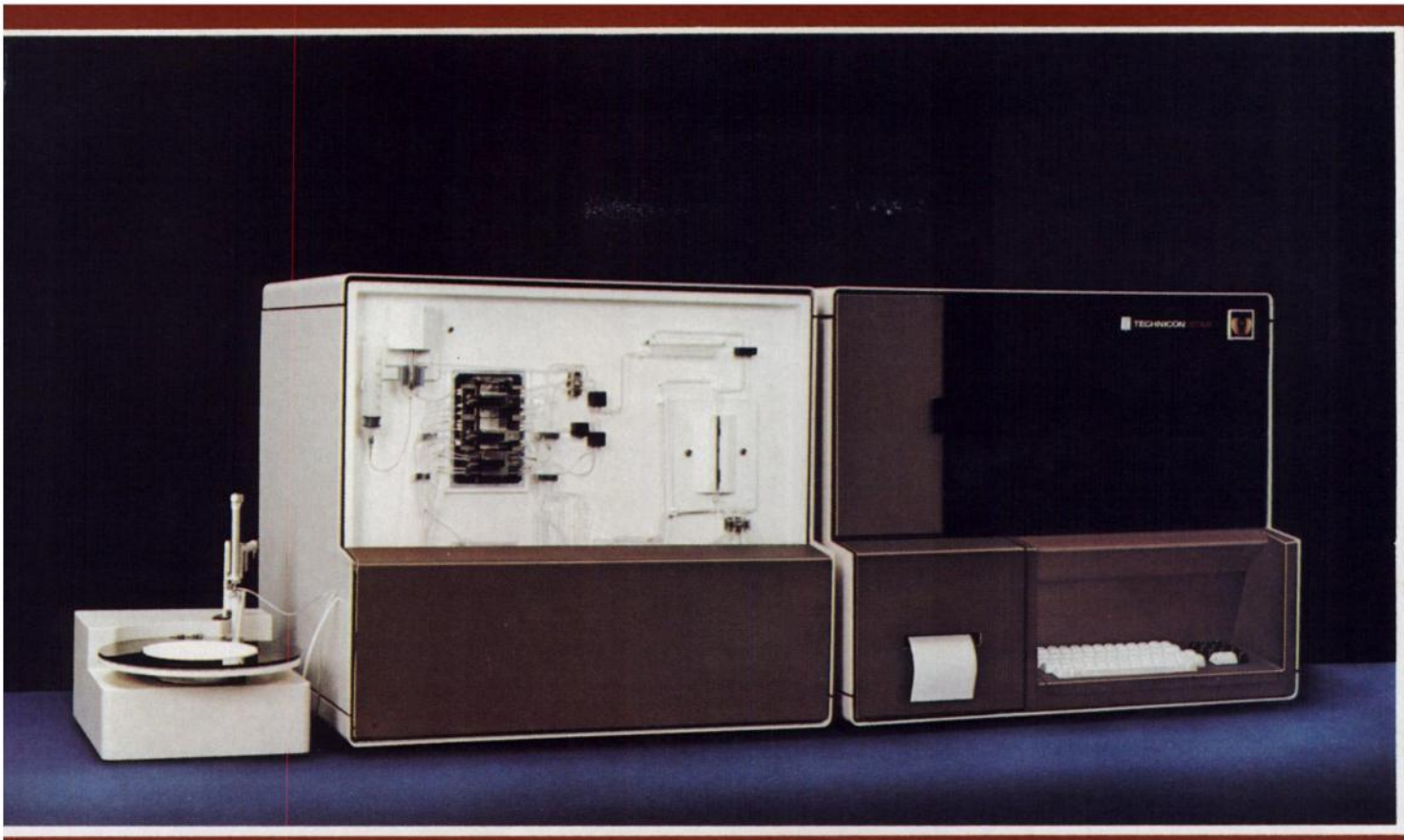

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*IEEE Transactions on Nuclear Science, Volume NS-25 No. 1, February 1978.

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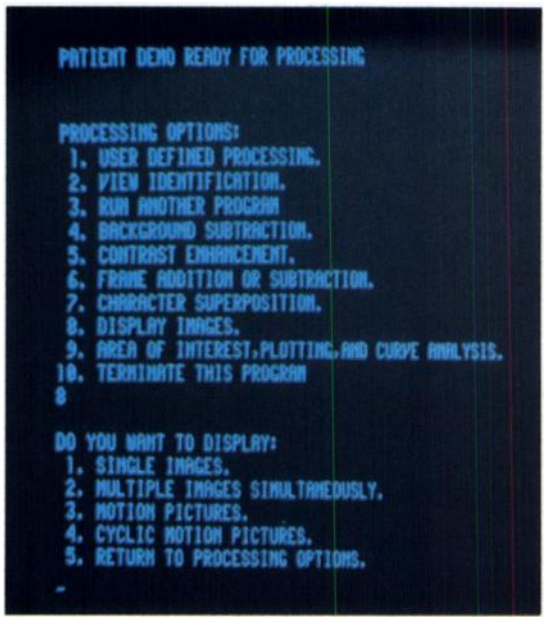

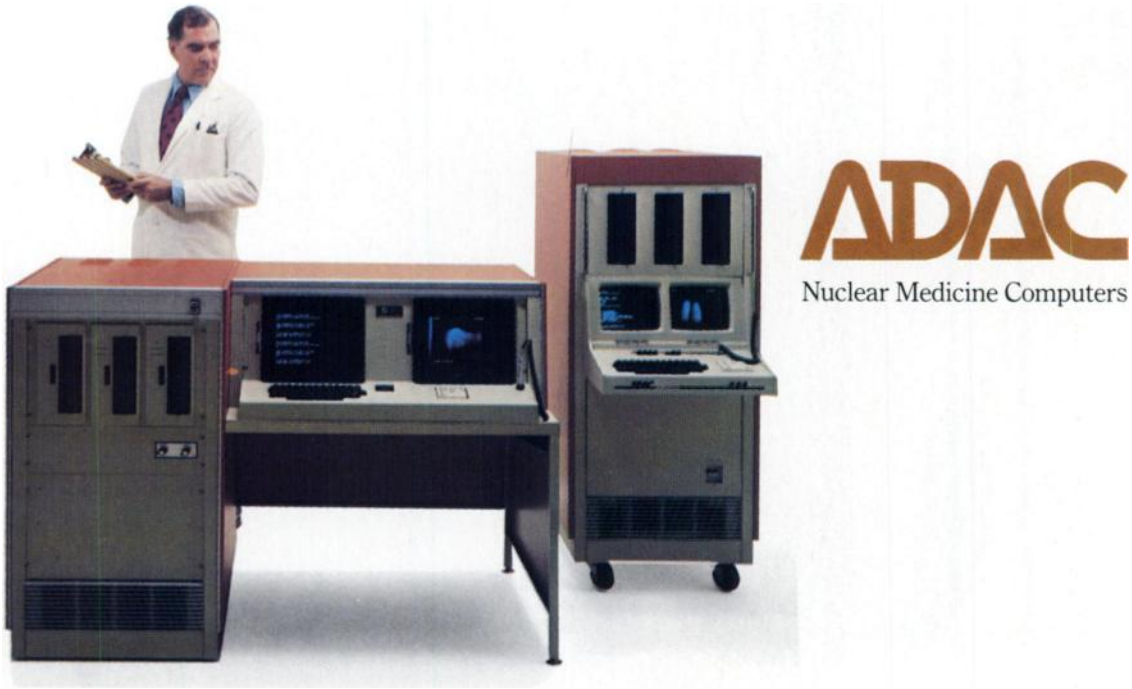

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(Thallous Chloride Tl 201 Injection)

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The IMAGE MAKERS

Thallium-201 (Thallous Chloride Tl 201 Injection)— the agent of choice for analysis of myocardial ischemia.[1]

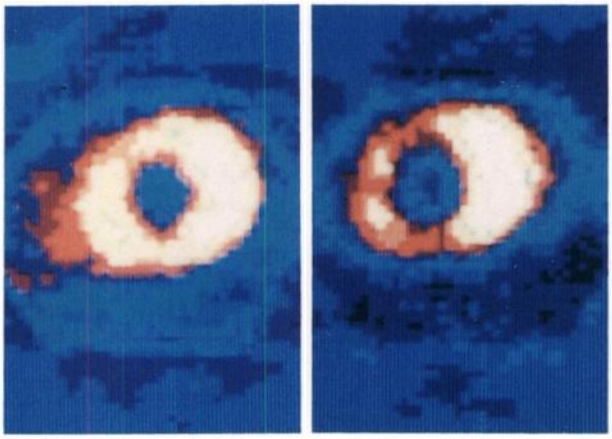


Image showing thallium-201 perfusion at rest.

Image showing decreased thallium-201 perfusion in the ischemic heart after exercise.

The two images above show thallium-201 perfusion in a 44 year old male at rest and after exercise. As can be noted, the stress thallium-201 image reveals a perfusion defect in the apex which is fairly well perfused in the at rest scan. In addition, diffuse decreased perfusion can be noted in the anterior lateral myocardium and it persists in both scans (probably from previous myocardial infarction).

Although coronary arteriography is currently the most useful tool in evaluating the extent of coronary artery disease[2] and for identifying individual stenotic arteries,[3] the information gained does not necessarily reflect regional myocardial perfusion.

The goal of thallium-201 imaging.

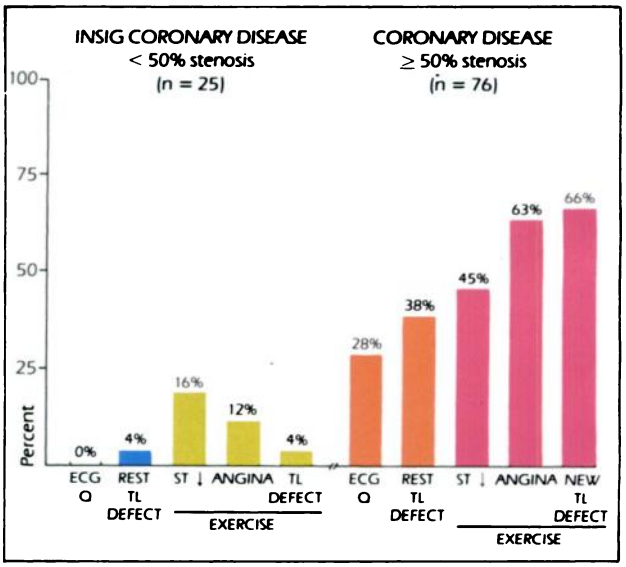
The goal is to identify areas of the myocardium that are normally perfused under resting conditions, but to which perfusion is not augmented to meet increased demands during exercise.[2]

Results of thallium-201 perfusion studies.

A growing number of clinical studies attest to the utility of thallium-201 imaging as a technique that improves the diagnostic accuracy of stress ECG:[4]

- In a study of 101 patients with suspected coronary heart disease, thallium-201 imaging was found to be useful for the detection of exercise-induced myocardial ischemia. Detection of coronary artery disease was most sensitive when thallium-201 imaging was combined with stress electrocardiography.[3] (See bar chart, below.)
- Combination of the results of rest and exercise thallium-201 imaging and electrocardiography permitted identification of 94% of the patients with coronary artery disease in a second study.[5]
- Again, in a 55-patient study, the combination of thallium-201 imaging after exercise and the ECG during maximum exercise had a sensitivity of 98%. The exercise thallium-201 image was 100% specific for coronary artery disease.[6]

Coronary artery disease: Sensitivity of ECG and Thallium-201 imaging, alone and together.[3]



Thallium-201 (Thallous Chloride Tl 201 Injection) imaging to confirm acute myocardial infarction

● Serial images may be useful in differentiating ischemic from infarcted myocardium in the post-infarction period.[7]

● Thallium-201 myocardial perfusion imaging in the subject at rest is a sensitive indicator of previous myocardial infarction.[5]

● Dual radionuclide imaging with thallium-201 and technetium Tc99m stannous pyrophosphate has been found to be a highly sensitive means of detecting infarcts. For example, in one study of 80 patients, combined imaging was 100% sensitive;[8] however, both were falsely negative in 12 of 80 patients that had either small infarcts or left ventricular hypertrophy. Thallium-201 correctly localized the acute transmural infarct site in all 51 patients with a positive image.

Analysis of ischemic heart disease, Detection of myocardial infarction, Dynamic assessment of cardiac function, Coronary angiography... All with imaging agents from Mallinckrodt—The Image Makers

Ask your Mallinckrodt/Nuclear representative about our complete line of cardiac imaging agents. In every case, Mallinckrodt brings its experience and reputation to bear on your requirements for imaging agents that are:

● effective diagnostic aids
● convenient and easy to use
● delivered as you need them, when you need them.

See brief summary of full prescribing information on following page.

1. Hamilton, GW; Narahara, KA; Yee, H; et al: Myocardial Imaging with Thallium-201: Effect of Cardiac Drugs on Myocardial Images and Absolute Tissue Distribution. J. Nucl. Med. 19:10-16, 1978.
2. Spies, SM: Radioisotope Techniques in Clinical Cardiology. J.A.M.A. 239:1651-1653 (April 21) 1978.
3. Ritchie, JL; Trobaugh, GB; Hamilton, GW; et al: Myocardial Imaging with Thallium-201 at Rest and During Exercise: Comparison with Coronary Arteriography and Resting and Stress Electrocardiography. Circulation 56:66-71 (July) 1977.
4. Klein, GJ, and Kostuk, WJ: Diagnostic Accuracy of Non-Invasive Stress Myocardial Perfusion Imaging. Clinical Cardiology, Abstracts of the 49th Scientific Sessions, II-207.
5. Sternberg, L; Wald, RW; Feiglin, DH; et al: Myocardial Perfusion Imaging with Thallium-201: Correlation with Coronary Arteriography and Electrocardiography. CMA Journal 118:283-287 (February 4) 1978.
6. Carrillo, AP; Marks, DS; Pickard, SD; et al: Correlation of Exercise ^{201}Thallium Myocardial Scan with Coronary Arteriograms and the Maximal Exercise Test. Chest 73:321-326 (March) 1978.
7. Smitherman, TC; Osborn, RC, Jr.; and Narahara, KA: Serial Myocardial Scintigraphy After a Single Dose of Thallium-201 in Men After Acute Myocardial Infarction. Am. J. Cardiol. 42:177-183 (August) 1978.
8. Berger, HJ; Gottschalk, A; and Zaret, BL: Dual Radionuclide Study of Acute Myocardial Infarction: Comparison of Thallium-201 and Technetium-99m Stannous Pyrophosphate Imaging in Man. An. Intern. Med. 88:145-154, 1978.

THALLIUM 201

(Thallous Chloride Tl 201 Injection)

THALLOUS CHLORIDE Tl 201 INJECTION

Diagnostic—For Intravenous Use

Brief Summary—for full prescribing information consult package insert.

DESCRIPTION

Thallous Chloride Tl 201 is supplied in isotonic solution as a sterile, nonpyrogenic diagnostic radiopharmaceutical for intravenous administration. Each ml contains 1 mCi Thallium Chloride Tl 201 at calibration time made isotonic with 9 mg sodium chloride and preserved with 0.9% (v/v) benzyl alcohol. The pH is adjusted to between 4.5-7.0 with hydrochloric acid and/or sodium hydroxide. Thallium Tl 201 is cyclotron produced. It is essentially carrier-free and contains no more than 1.0% Thallium Tl 200 and no more than 1.0% Thallium Tl 202.

CLINICAL PHARMACOLOGY

Carrier-free **Thallous Chloride Tl 201** has been found to accumulate in viable myocardium in a manner analogous to potassium. Experiments employing labeled microspheres in human volunteers have shown that the myocardial distribution of **Thallous Chloride Tl 201** correlates well with regional perfusion.

In clinical studies, thallium images show areas of infarction as "cold" or nonlabeled regions which are confirmed by electrocardiographic and enzyme changes. Regions of transient myocardial ischemia corresponding to areas perfused by coronary arteries with partial stenoses have been visualized as cold spots when thallium was administered in conjunction with an exercise stress test.

After intravenous administration, **Thallous Chloride Tl 201** clears rapidly from the blood with maximal concentration by normal myocardium occurring at about ten minutes.

Five minutes after intravenous administration only 5-8 percent of injected activity remained in the blood. A biexponential disappearance curve was obtained, with 91.5 percent of the blood radioactivity disappearing with a $T_{1/2}$ of about 5 minutes. The remainder had a $T_{1/2}$ of about 40 hours.

Approximately 4 to 8 percent of the injected dose was excreted in the urine in the first 24 hours. The whole body disappearance half-time was 9.8 ± 2.5 days. Kidney concentration was found to be about 3 percent of the injected activity and the testicular content was 0.15 percent. Net thyroid activity was determined to be only 0.2 percent of the injected dose, and the activity disappeared in 24 hours. From anterior and posterior whole-body scans, it was determined that about 45 percent of the injected dose was in the large intestines and contiguous structures (liver, kidneys, abdominal musculature)[1].

[1]Atkins, H. L., et al. Thallium-201 for Medical Use. Part 3: Human Distribution and Physical Imaging Properties. *Journal of Nuclear Medicine*, 18(2):133-140, Feb. 1977.

INDICATIONS AND USAGE

Thallous Chloride Tl 201 may be useful in myocardial perfusion imaging and for the diagnosis and localization of myocardial infarction.

It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic 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.

CONTRAINDICATIONS

None known

WARNINGS

When studying patients suspected or known to have myocardial infarction or ischemia, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

PREGNANCY CATEGORY C

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. **Thallous Chloride Tl 201** should not be used in pregnant women except when benefits clearly outweigh the potential risks.

PRECAUTIONS

Ideally, examinations using radiopharmaceutical drug products—especially those elective in nature—of women of childbearing capability should be performed during the first ten days following the onset of menses.

NURSING MOTHERS

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

Safety and effectiveness in children have not been established.

CARCINOGENESIS

No long-term animal studies have been performed to evaluate carcinogenic potential.

Data are not available concerning the effect on the quality of Thallium Tl 201 scans of marked alterations in blood glucose, insulin or pH (such as is found in diabetes mellitus). 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.

As in the use of any radioactive material, care should be taken to minimize radiation exposure to the patient consistent with proper 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 radionuclides and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radionuclides.

This drug should not be used six (6) days after the calibration date.

ADVERSE REACTIONS

Adverse reactions related to use of this agent have not been reported to date.

HOW SUPPLIED

Thallous Chloride Tl 201 is supplied in a sterile, nonpyrogenic solution for intravenous administration. Each ml contains 1 mCi Thallium Tl 201 at calibration time, 9 mg sodium chloride and 0.9 percent (v/v) benzyl alcohol. The pH is adjusted to between 4.5-7.0 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 2.0, 4.0 and 8.0 millicuries of Thallium Tl 201.

The contents of the vial are radioactive. Adequate shielding and handling precautions must be maintained.

TechneScan® PYP™ Kit (Stannous Pyrophosphate) for preparation of Technetium Tc-99m Stannous Pyrophosphate.

BRIEF SUMMARY

CLINICAL PHARMACOLOGY

When injected intravenously, **TechneScan PYP Tc-99m** has a specific affinity for areas of altered osteogenesis. It is also concentrated in the injured myocardium, primarily in areas of irreversibly damaged myocardial cells.

One to two hours after intravenous injection of **TechneScan PYP Tc-99m**, an estimated 40 to 50 percent of the injected dose has been taken up by the skeleton and approximately 0.01 to 0.02 percent per gram of acutely infarcted myocardium. Within a period of one hour, 10 to 11 percent remains in the vascular system, declining to approximately 2 to 3 percent twenty-four hours post injection. The average urinary excretion was observed to be about 40 percent of the administered dose after 24 hours.

TechneScan PYP also has an affinity for red blood cells. When administered 30 minutes prior to the intravenous administration of sodium pertechnetate Tc-99m approximately 76 percent of the injected activity remains in the blood pool providing excellent images of the cardiac chambers.

INDICATIONS AND USAGE

TechneScan PYP Tc 99m is a skeletal imaging agent used to demonstrate areas of altered osteogenesis, and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction.

As an adjunct in the diagnosis of confirmed myocardial infarction (ECG and serum enzymes positive), the incidence of false negative images has been found to be 6 percent. False negative images can also occur if made too early in the evolutionary phase of the infarct or too late in the resolution phase. In a limited study involving 22 patients in whom the ECG was positive and serum enzymes questionable or negative, but in whom the final diagnosis of acute myocardial infarction was made, the incidence of false negative images was 23 percent. The incidence of false positive images has been found to be 7 to 9 percent. False positive images have also been reported following coronary by-pass graft surgery, in unstable angina pectoris, old myocardial infarcts and in cardiac contusions.

TechneScan PYP is a blood pool imaging agent which may be used for gated cardiac blood pool imaging. When administered intravenously 30 minutes prior to the intravenous administration of sodium pertechnetate Tc-99m approximately 76 percent of the injected activity remains in the blood pool.

CONTRAINDICATIONS

None.

WARNINGS

This radiopharmaceutical should not be administered to patients who are pregnant or lactating unless the information to be gained outweighs the potential hazards.

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.

Warning: Preliminary reports indicate impairment of brain scans using pertechnetate Tc-99m which have been preceded by bone scan. The impairment may result in false positives or false negatives. It is recommended, where feasible, that brain scans precede bone imaging procedures.

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

The **TechneScan PYP Kit** must be maintained at refrigerator temperature until use.

The contents of the **TechneScan PYP** reaction vial are intended for use in the preparation of Technetium Tc-99m Stannous Pyrophosphate. **TechneScan PYP** may also be reconstituted with sterile, pyrogen-free normal saline containing no preservatives and injected intravenously prior to the administration of sodium pertechnetate Tc-99m.

Sodium pertechnetate Tc-99m solutions containing an oxidizing agent are not suitable for use with the **TechneScan PYP Kit**.

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

TechneScan PYP Tc-99m should not be used more than six hours after preparation.

PRECAUTIONS

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

Bone Imaging

Both prior to and following **TechneScan PYP Tc-99m** administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the **TechneScan PYP Tc-99m** injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.

Cardiac Imaging

Patient's cardiac condition should be stable before beginning the cardiac imaging procedure.

If not contraindicated by the cardiac status, patients should be encouraged to ingest fluids and to void frequently in order to reduce unnecessary radiation exposure.

Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing the three recommended projections.

Blood Pool Imaging

TechneScan PYP should be injected by direct venipuncture. Heparinized catheter systems should be avoided.

ADVERSE REACTIONS

None.

HOW SUPPLIED

Catalog Number—*094* **TechneScan PYP Kit**

Kit Contains:

5—Stannous Pyrophosphate Reaction Vials (lyophilized) for the preparation of Technetium Tc-99m Stannous Pyrophosphate.

Reaction Vial Contains:
12.0 mg sodium pyrophosphate and 3.4 mg stannous chloride (lyophilized). Hydrochloric acid is added for pH adjustment prior to lyophilization.

5—Radioassay Information String Tags.

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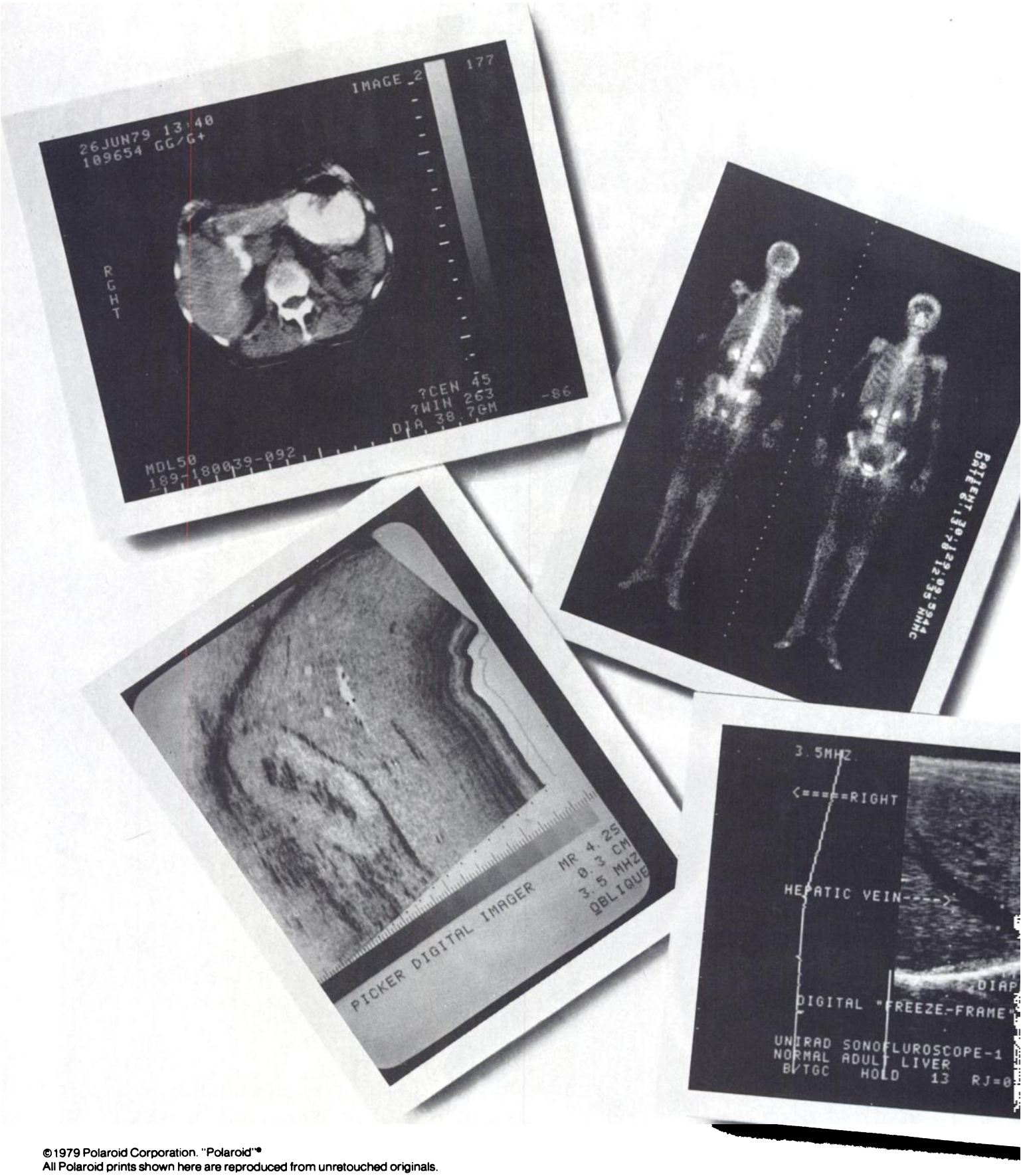

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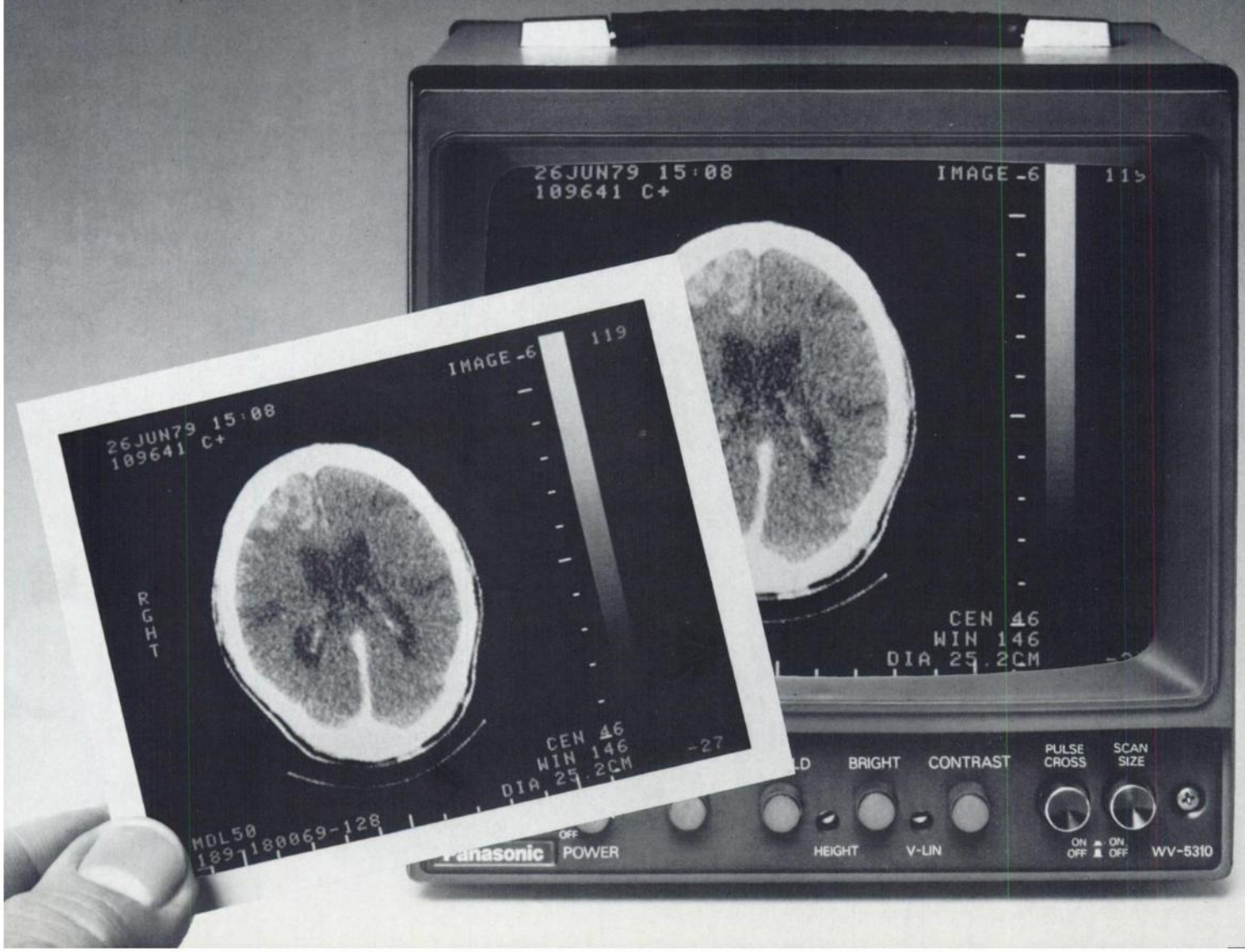

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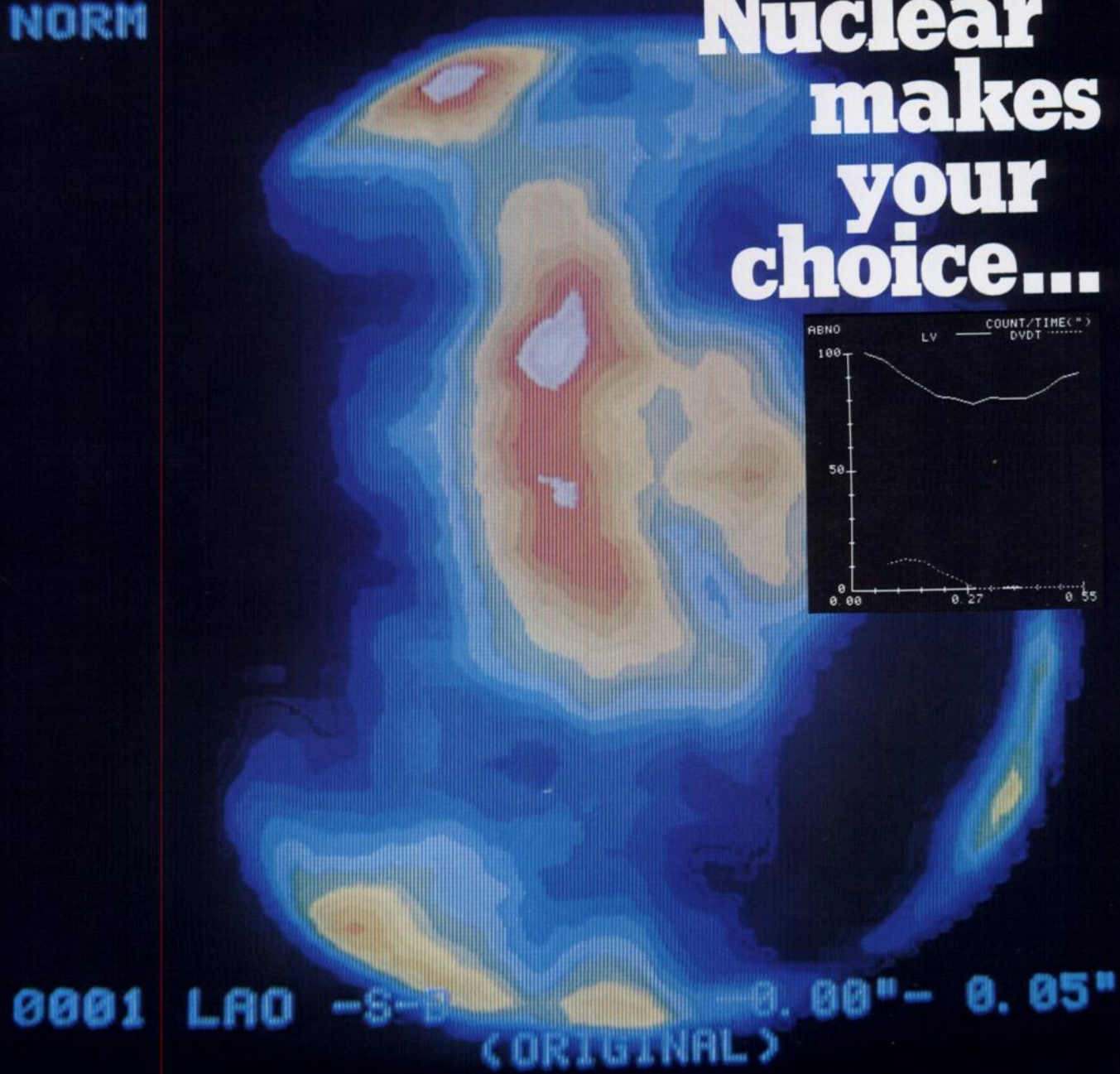

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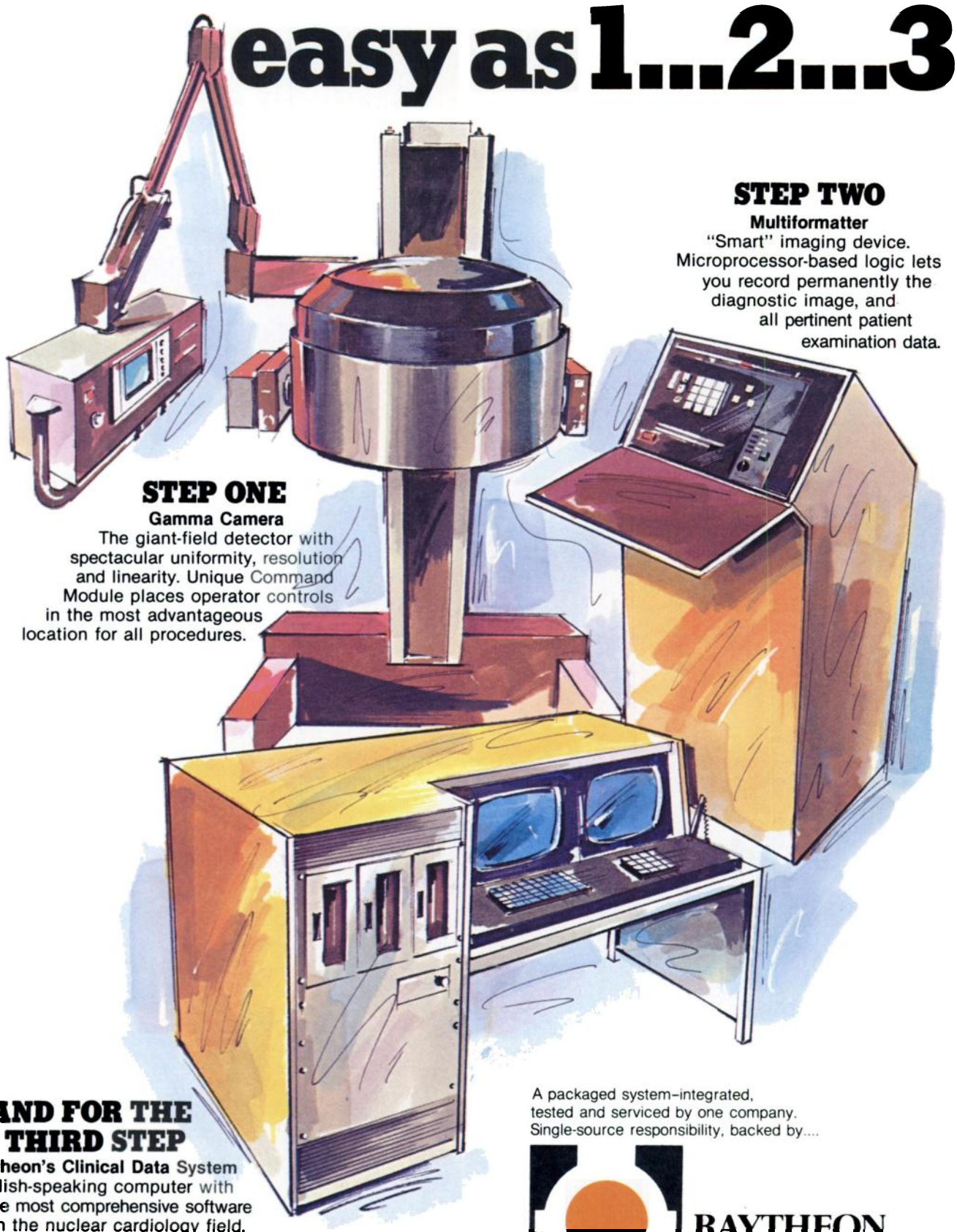

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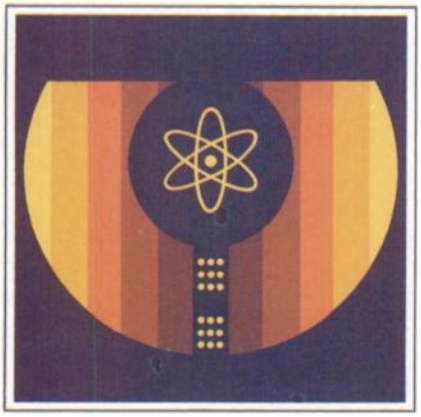

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1. Davis MA, and Jones AG: **Sem Nucl Med 6**:19, 1976
2. Subramanian G, McAfee JG, Blair RJ, Kallfelz FA, and Thomas FD: **J Nucl Med 16**:744, 1975

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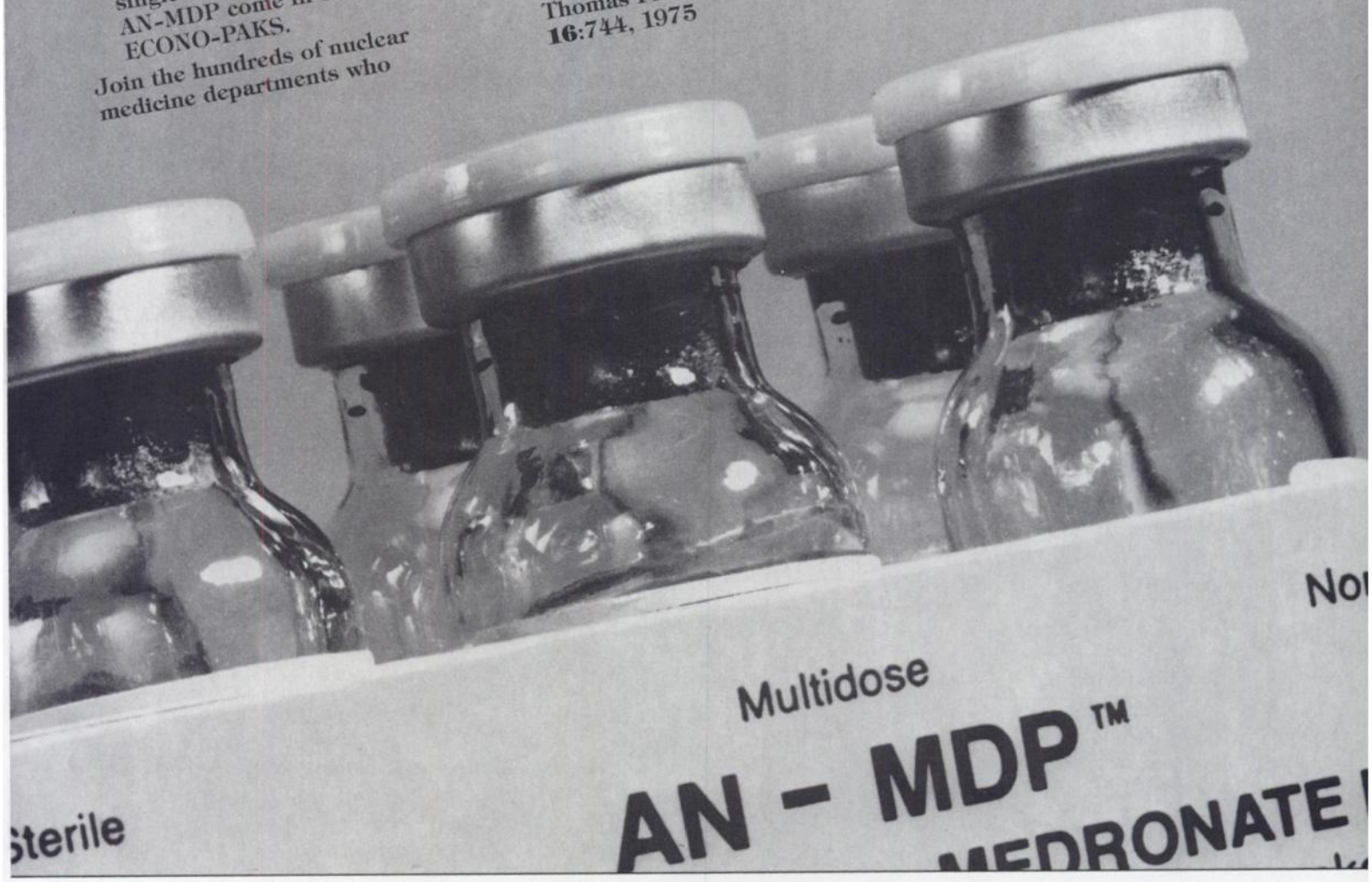

Pediatric use: Safety and effectiveness in children have not been established.

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. No adverse reactions specifically attributable to the use of Technetium Tc 99m Medronate have been reported.

Dosage and administration. The suggested dose range for i.v. administration, after reconstitution with oxidant-free sodium pertechnetate Tc 99m Injection, to be employed in the average patient (70 kg) is:

Bone imaging: 10–20 mCi Technetium Tc 99m Medronate

Scanning is optimal at about 1–4 hours post-injection. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

How supplied. AN-MDP™ is supplied both in the single-dose and multidose form. Both are available in sets of 6 or 30 sterile and nonpyrogenic vials. Each nitrogen-flushed vial contains, in lyophilized form:

	Single dose	Multidose
Medronic acid	5.0 mg	10.0 mg
Stannous chloride (minimum)	0.25 mg	0.51 mg
Maximum total stannous and stannic chloride	0.51 mg	1.01 mg

The pH is adjusted to 5.0–5.5 with HCl and NaOH prior to lyophilization. Included in each 6-vial kit is one package insert and 12 radiation labels. In each 30-vial kit is one package insert and 60 radiation labels. Refrigeration is not necessary.

Description	Catalog Number
Single dose 6-vial kit	K-401-S
Single dose 30-vial ECONO-PAK	K-402-S
Multidose 6-vial kit	K-401
Multidose 30-vial ECONO-PAK	K-402


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See following page for brief summary of package insert

C797134

Postop sepsis?

Where does gallium-67 imaging fit into your fever workup?

PLEASE SEE LAST PAGE FOR FULL PRESCRIBING INFORMATION.

Gallium-67 imaging:

Why you should consider ordering a gallium scan when you suspect postop abscess:

Routinely available

Gallium scans are routinely available in virtually all nuclear medicine departments.

Diagnostic results early

Most abscesses avidly take up gallium 6-24 hours postinjection, although delayed (48-72 hour) images may be useful to distinguish pathologic from physiologic fecal concentration.

Superior to CT, ultrasound

CT and ultrasound generally do not localize inflammation that does not produce a mass (eg, peritonitis, pyelonephritis). In addition, small abdominal masses missed by CT have been seen on gallium studies.[1,2,3]

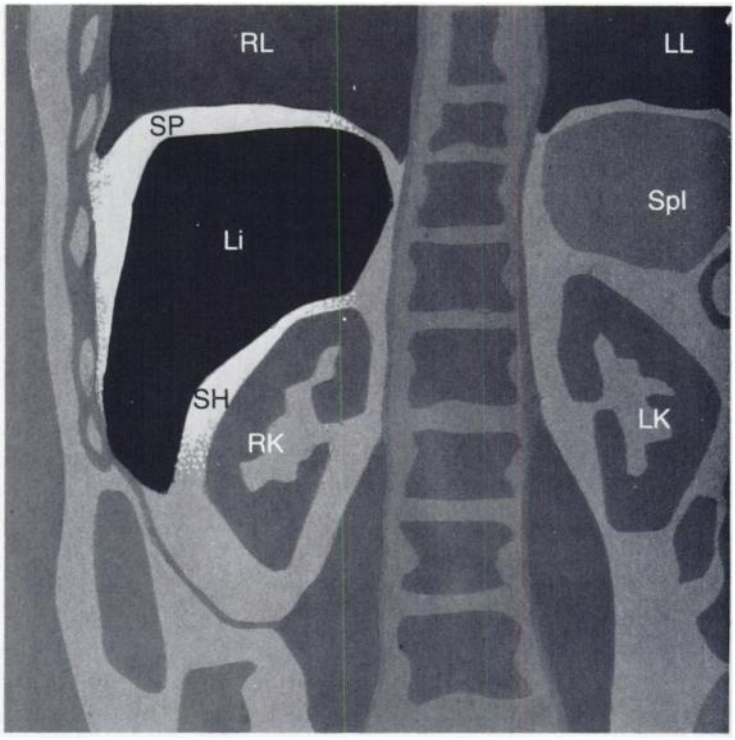
No interference from respiration, clips, staples

Respiratory motion of critically ill patients can render CT studies uninterpretable . . . as can metallic surgical clips, staples, and sutures.

No special preparation

Although bowel prep may be necessary for delayed studies, no cathartics need be administered for early images; NPO patients need no special preparations.

What a gallium scan can



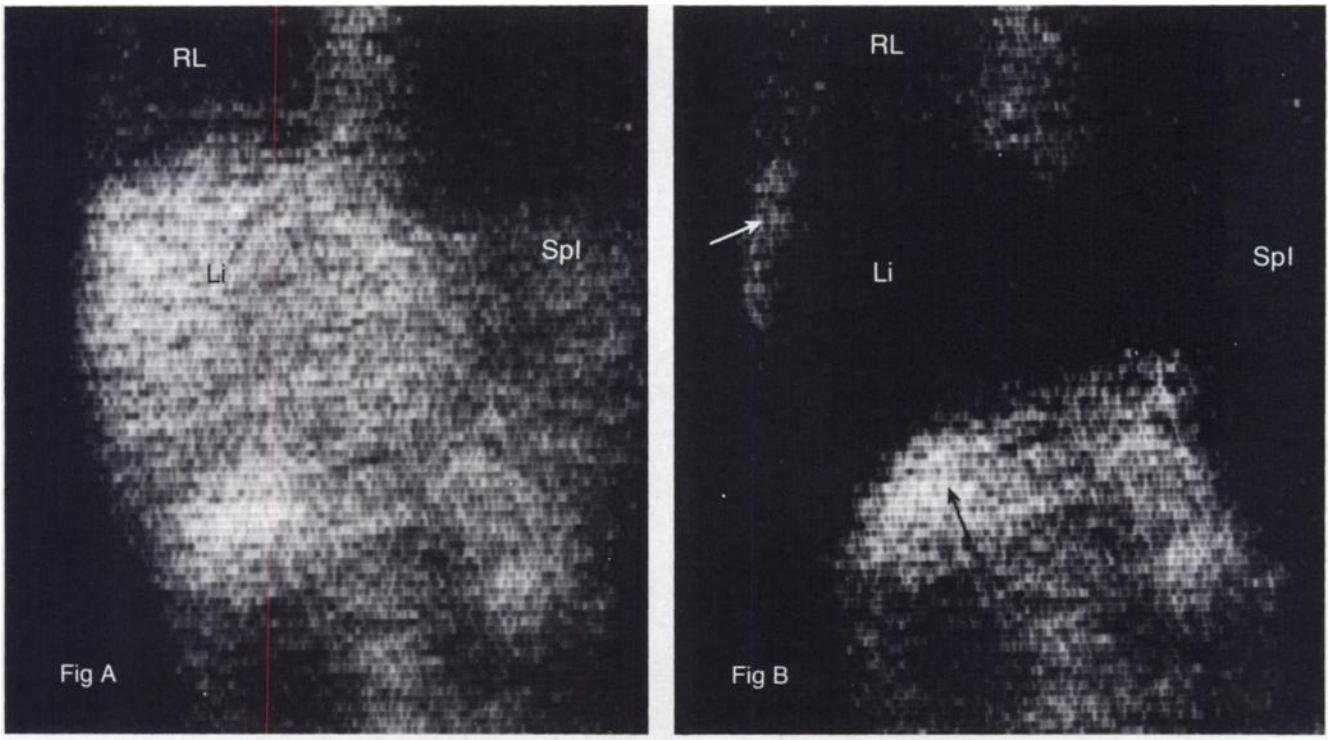
Idealized coronal section demonstrating the normal anatomic relationships between the right lung, liver, and right kidney, with highlighting of right subphrenic and subhepatic spaces. (Li = liver, LK = left kidney, LL = left lung, RK = right kidney, RL = right lung, SH = subhepatic space, Spl = spleen, SP = subphrenic space.)

A slide teaching program and home study monograph, *Diagnosing Postop Infection,* is available upon request from NEN. Write Teaching Program Administrator, New England Nuclear, 549 Albany St., Boston, MA 02118, or call **(800) 225-1572, ext. 2234 TOLL FREE.**

If the gallium study is normal, no further

Detects and localizes focal inflammation Superior to CT, ultrasound

show you in subphrenic and subhepatic abscesses:



CASE REPORT: *James R, 35 y M* The patient was a 35-year-old male who developed leukocytosis and spiking fevers eight days following surgical resection for regional enteritis. Chest X-ray demonstrated a small right pleural effusion. Abdominal echography was inconclusive due to excessive bowel gas. An anterior gallium scan (Fig A) showed normal isotope uptake in the liver, and suspicious areas of increased uptake in right subphrenic and right subhepatic spaces, suggesting focal infection. The same anterior view, but with computer subtraction of normal liver-spleen uptake (Fig B), clearly reveals persistent gallium accumulation in small right subphrenic and larger right subhepatic abscesses (arrows). These findings were confirmed at laparotomy. Anatomic detail in the gallium studies can be appreciated by comparison to the coronal anatomic section drawing.

Gallium Citrate Ga67

NEN New England Nuclear®

radiographic evaluation may be required.[4]

See following page for full prescribing information.

Gallium Citrate Ga67

FOR DIAGNOSTIC USE

DESCRIPTION: Gallium Citrate Ga 67 is supplied in isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. Each milliliter of the isotonic solution contains 2mCi of Gallium Ga 67 on the calibration date, as a complex formed from 9ng gallium chloride Ga 67, 2mg of sodium citrate, 6.8mg sodium chloride, and 0.9% benzyl alcohol w/v as preservative. The pH is adjusted to between 4.5-7.5 with hydrochloric acid and/or sodium hydroxide solution. Gallium Ga 67, with a half-life of 78 hours, is cyclotron produced by the proton irradiation of enriched zinc oxide, is essentially carrier-free and contains negligible concentrations of other radioactive isotopes.

PHYSICAL CHARACTERISTICS

Gallium Ga 67 decays to stable Zinc Zn 67 by electron capture with a physical half-life of 78 hours.

TABLE 1. Principle Radiation Emission Data

Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-2	38.3	93.3
Gamma-3	20.9	184.6
Gamma-5	16.8	300.2
Gamma-6	4.7	393.5

TABLE 2. Gallium Ga 67 Decay Chart Half-Life 78 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining	Hours	Fraction Remaining
-48	1.53	30	0.77	90	0.45
-36	1.38	36	0.73	96	0.43
-24	1.24	42	0.69	108	0.38
-12	1.11	48	0.65	120	0.35
- 6	1.05	54	0.62	132	0.31
0*	1.00	60	0.59	144	0.28
6	0.95	66	0.56	156	0.25
12	0.90	72	0.53	168	0.23
18	0.85	78	0.50		
24	0.81	84	0.47	*Calibration Time	

EXTERNAL RADIATION

The specific gamma ray constant for Gallium Ga 67 is 1.6R/mCi-hr. at 1cm. The first half value thickness of lead is 0.66mm. 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 3. For example, the use of 4.1mm of Pb will decrease the external radiation exposure by a factor of 10.

TABLE 3. Radiation Attenuation by Lead Shielding

mm of Pb	Radiation Attenuation Factor	mm of Pb	Radiation Attenuation Factor
4.1	10^{-1}	25	10^{-3}
12	10^{-2}	48	10^{-4}

CLINICAL PHARMACOLOGY: Carrier-free Gallium Citrate Ga 67 has been found to concentrate in certain viable primary and metastatic tumors. The mechanism of concentration is unknown, but investigational studies have shown that Gallium Ga 67 accumulates in lysosomes and is bound to a soluble intracellular protein.

It has been reported in the scientific literature that following intravenous injection, the highest tissue concentration of Gallium Ga 67—other than tumors—is in the renal cortex. After the first day, the maximum concentration shifts to bone and lymph nodes, and after the first week, to liver and spleen. Gallium is excreted relatively slowly from the body. The average whole body retention is 65% after 7 days, with 26% having been excreted in the urine and 9% in the stools.

INDICATIONS AND USAGES: Gallium Citrate Ga-67 may be useful in demonstrating the presence and extent of the following malignancies: Hodgkins disease, lymphomas and bronchogenic carcinoma. Positive Ga-67 uptake in the absence of prior symptoms warrants follow-up as an indication of a potential disease state.

Gallium Citrate Ga 67 may be useful as an aid in detecting some acute inflammatory lesions.

CONTRAINDICATIONS: None known.

WARNINGS: Gallium Citrate Ga 67 should not be administered to children or to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards. Ideally, examinations using radiopharmaceutical drug products, especially those elective in nature of a woman of childbearing capability should be performed during the first few (approximately ten) days following the onset of menses.

PRECAUTIONS: A thorough knowledge of the normal distribution of intravenously administered Gallium Citrate Ga 67 is essential in order to accurately interpret pathologic studies.

The findings of an abnormal gallium concentration usually implies the existence of underlying pathology, but further diagnostic studies should be done to distinguish benign from malignant lesions. Gallium Citrate Ga 67 is intended for use as an adjunct in the diagnosis of certain neoplasms. Certain pathologic conditions may yield up to 40% false negative gallium studies. Therefore a negative study cannot be definitively interpreted as ruling out the presence of disease.

Lymphocytic lymphoma frequently does not accumulate Gallium Ga 67 sufficiently for unequivocal imaging; and the use of gallium with this histologic type of lymphoma is not recommended at this time.

Gallium Citrate Ga 67, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients consistent with proper patient management.

No long term animal studies have been performed to evaluate carcinogenic potential.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Gallium Citrate Ga 67 should be used in pregnant women only when clearly needed.

Gallium Citrate Ga 67 has been found to accumulate in breast milk and should not be used in nursing mothers.

Safety and effectiveness in children have not been established.

Gallium Ga 67 localization cannot differentiate between tumor and acute inflammation; and other diagnostic studies must be added to define the underlying pathology.

The expiration date of the drug is seven days after the date of calibration.

ADVERSE REACTIONS: Severe itching, erythema and rash were observed in one patient of 300 studied.

DOSAGE AND ADMINISTRATION: The recommended adult (70kg) dose of Gallium Citrate Ga 67 is 2-5mCi. Gallium Citrate Ga 67 is intended for intravenous administration only.

Approximately 10% of the administered dose is excreted in the feces during the first week after injection. Daily laxatives and/or enemas are recommended from the day of injection until the final images are obtained in order to cleanse the bowel of radioactive material and minimize the possibility of false positive studies.

Studies indicate the optimal tumor to background concentration of ratios are often obtained about 48 hours post-injection. However, considerable biological variability may occur in individuals, and acceptable images may be obtained as early as 6 hours and as late as 120 hours after injection.

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

Radiopharmaceuticals should be used by persons who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agencies authorized to license the use of radionuclides.

RADIATION DOSIMETRY

The dosimetry values listed in Table 4 for Gallium Citrate Ga 67 are those of the MIRD Committee:*

TABLE 4. Dosimetry of Gallium Citrate Ga 67 for Maximal Dose of 5mCi

	Rads/5mCi		Rads/5mCi
Whole Body	1.30	Testes	1.20
Skeleton	2.20	Gastrointestinal Tract	
Liver	2.30	Stomach	1.10
Bone Marrow	2.90	Small Intestine	1.80
Spleen	2.65	Upper Large Intestine	2.80
Kidney	2.05	Lower Large Intestine	4.50
Ovaries	1.40		

*MIRD Dose Estimate Report No. 2, J. Nucl. Med. 14: 755-6. (1973).

HOW SUPPLIED: Gallium Citrate Ga 67 is supplied sterile and non-pyrogenic for intravenous use. Each ml contains 2mCi of Gallium Ga 67 on the calibration date, as a complex formed from 9ng gallium chloride Ga 67, 2mg of sodium citrate, 6.8mg sodium chloride, and 0.9% benzyl alcohol w/v as preservative. The pH is adjusted to between 4.5-7.5 with hydrochloric acid and/or sodium hydroxide solution.

Vials are available from 3mCi to 18mCi in increments of 3mCi on calibration date.

The contents of the vial are radioactive and adequate shielding and handling precautions must be maintained.

Catalog Number NRP-121 511300 December 1979

References

1. Haaga JR, Alfidi RJ, Havrilla TR, et al: CT detection and aspiration of abdominal abscesses. *AJR* 128:465-474, 1977.
2. Shimshak RS, Korobin M, Hoffer PB, et al: Complementary role of Ga^{67} imaging and CT in evaluation of suspected abdominal infection. *J Nucl Med* 19:262-269, 1978.
3. Levitt RG, Biello DR, Sagel SS, et al: Computed tomography and ^{67}Ga citrate radionuclide imaging for evaluating suspected abdominal abscess. *AJR* 132:529-534, 1979.
4. Biello DR, Levitt RG, Melson GL: The roles of Gallium-67 scintigraphy, ultrasonography and computed tomography in the detection of abdominal abscesses. *Sem Nucl Med* 9:58-67, 1979.

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NE-0109

ISOTRON

INVENTORY CONTROL COMPUTER

This small desk top microprocessor computer provides complete inventory control and NRC record keeping functions for the nuclear medicine department.

It is user programmable — you program it to fit your requirements even down to the half-life of the radionuclide so the Isotron never becomes obsolete in the rapidly changing field of nuclear medicine.

The Isotron can keep track of up to 20 different radiopharmaceuticals simultaneously by both radionuclide and chemical form! Updates the quantity of radioactivity every minute to reflect radioactivity decay.

The Isotron performs patient dose/volume calculations.

The Isotron subtracts the administered dose from the decayed activity and provides a running total of remaining activity.

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An optional hard copy data printer is available with the Isotron, known as the Isocord, which provides three copies of all pertinent data for your record keeping.

The Isotron may be used with any manufacturers dosecalibrator.

The Cost? Very reasonable. When combined with the Isocord and our Assayer 1 Dosecalibrator the total price is less than competitive systems with 50% of the capabilities.

RADX gave you the first calculating dosecalibrator, the first printing dosecalibrator, and now the first desk top inventory control computer, the ISOTRON.

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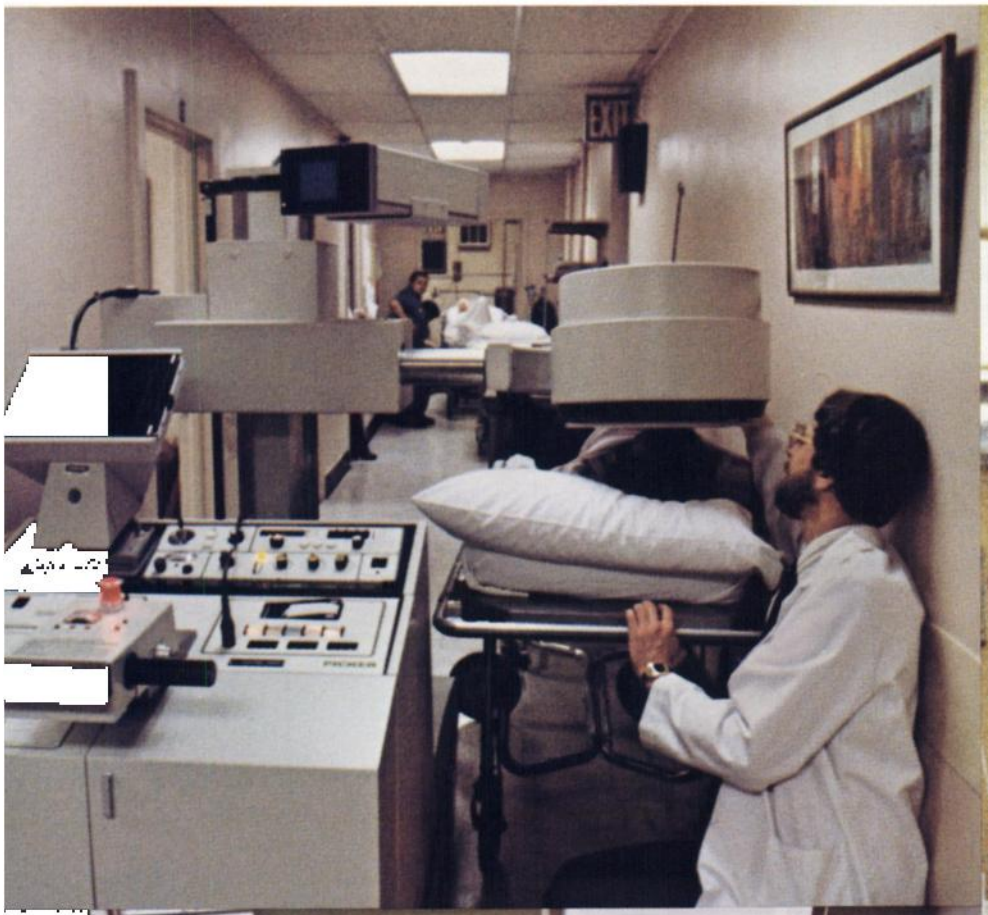
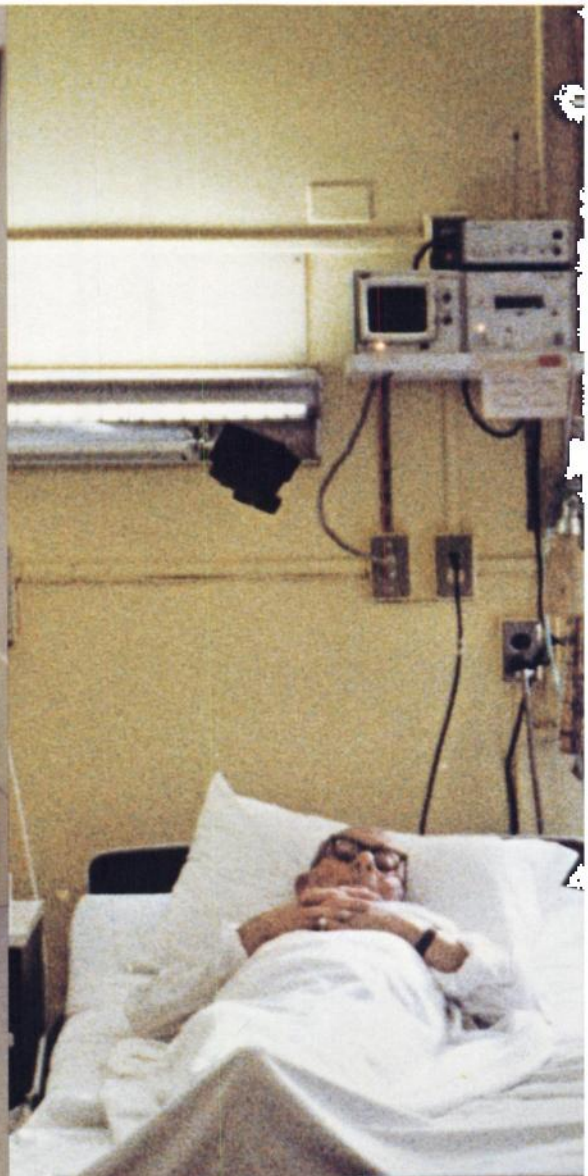
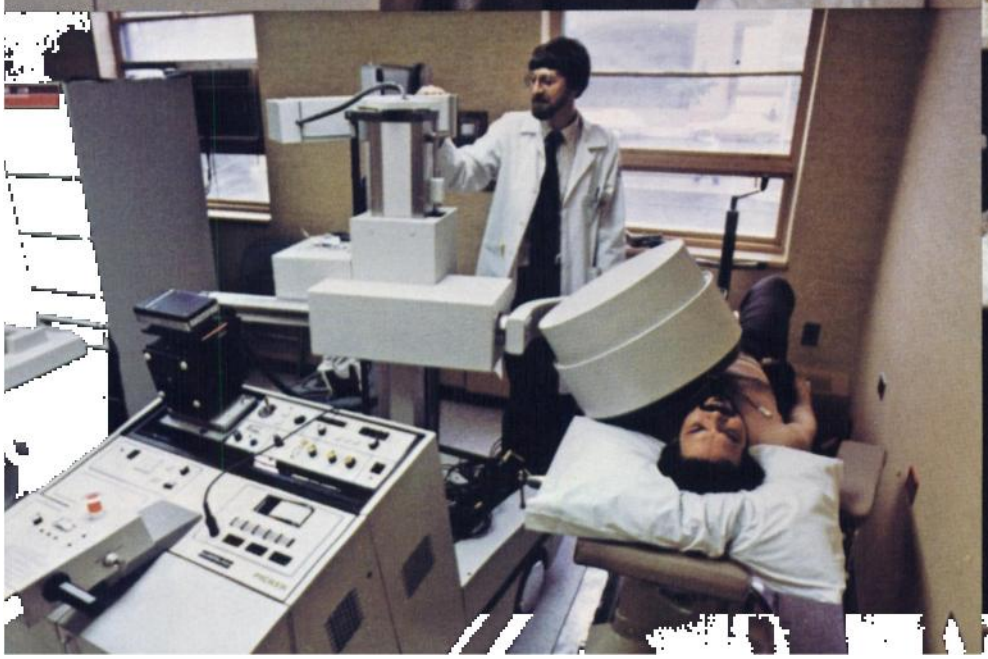
YOUR NUCLEAR MEDICINE DEPARTMENT'S NUCLEAR MEDICINE DEPARTMENT.







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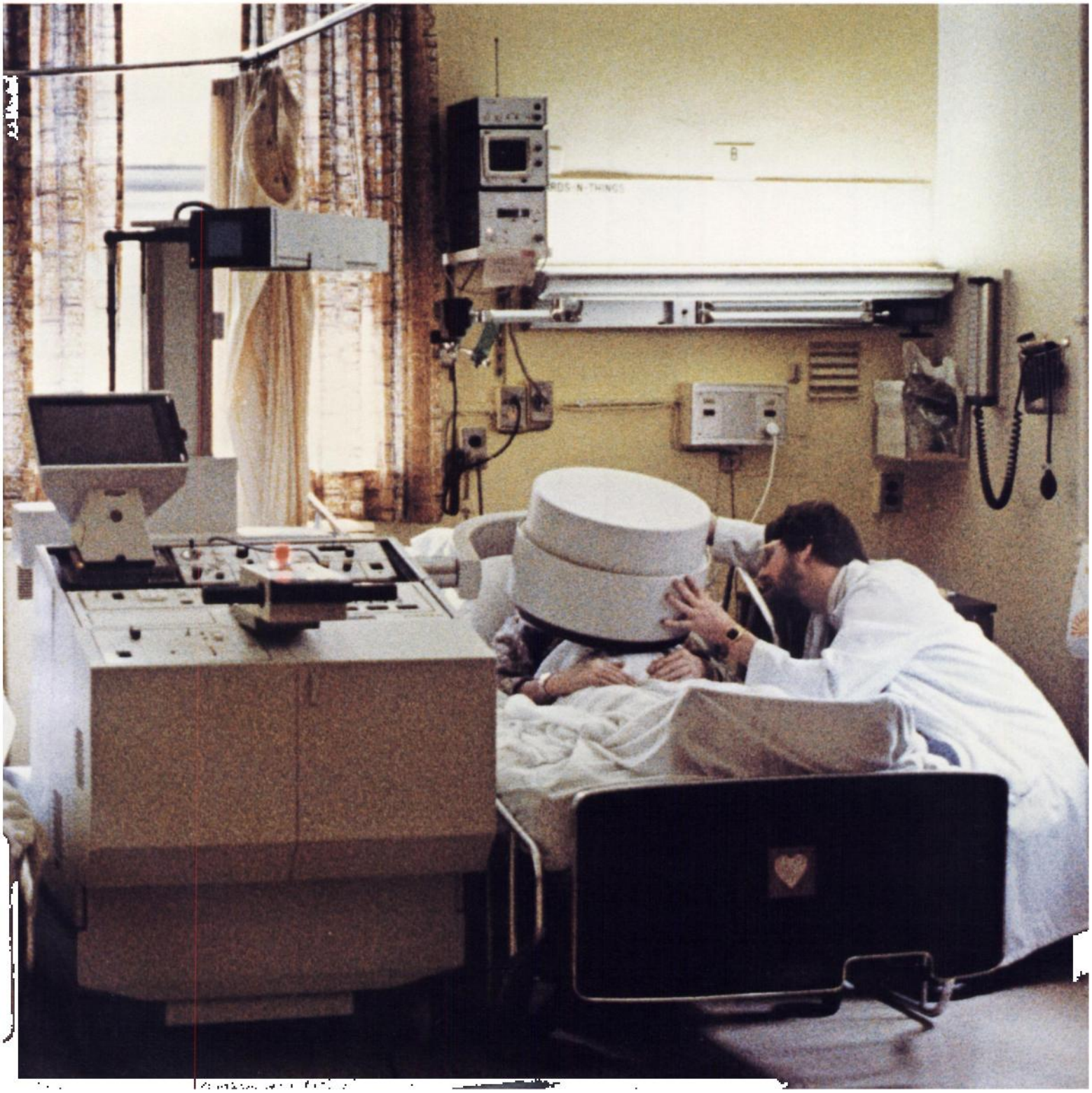


MODEL 256D
WELL COUNTING SYSTEM

GAMMA SPECTROMETER for NUCLEAR MEDICINE

Do you check your incoming radionuclides for purity and possible contamination? Better yet, do you have permanent proof of your quality assurance?

With over 20 years of experience in nuclear instrumentation, The Nucleus offers two complete gamma spectrometry systems designed for radionuclide analysis — and at a price suitable for tight budgets!

MULTICHANNEL ANALYZER

A multichannel analyzer is ideally suited for gamma scintillation spectrometry utilizing a NaI well-type detector. Out standard Model 256D (256 channels of memory) offers all the features required to analyze and compare a known gamma spectra with any unknown sample. And, the data add/subtract feature lets you "strip" known spectra from a mixture of radionuclides. For more sophisticated solid state detectors, we recommend the Model 1024D with 1024 channels of memory. Standard features on the 1024D include an integral 8-decade region of interest sum counter, multichannel scaling, and teletype output. Both models offer a direct reading LED display of channel number and total counts per channel with an illuminated marker cursor.

SCOPE DISPLAY

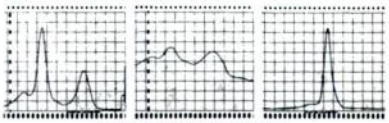
The built-in 5-inch CRT provides a bright, clear display of the accumulated data. On the Model 256D, the memory may be split into halves, 128/128 channels each. This permits direct comparison of spectra. For example, store a known I-125 spectrum in the first half, and then examine the second half spectrum of an incoming shipment. The Model 1024D features a 1024 channel memory which may be split into halves and quarters; each may be overlapped for direct comparison. Naturally, both vertical and horizontal expands are standard on every Nucleus MCA.

WELL DETECTOR

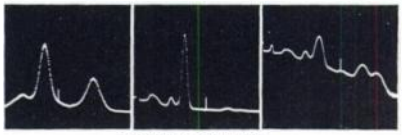
Numerous NaI scintillation probes are available for nearly every gamma spectrum analysis requirement. If you already have such a detector, most likely it will be compatible with either of these multichannel analyzers. Pictured is our Model WP-2000 well-type NaI scintillation probe with a 1.75" by 2" well crystal, on a 2" photomultiplier tube. Well size is .7" (17 mm) diameter by 1.5" (3.8 mm) deep. Resolution is 9% or better, full-width-half-maximum for Cs-137 (0.662 meV). The crystal is surrounded by .75 inches of lead.

HARD COPY RECORDER

For permanent records, a hard copy recorder documents the accumulated spectra. Any chart recorder is compatible, and several inexpensive models are available. Of course, a scope camera by Polaroid makes quick work of documentation. Linear and log readouts are standard features of these MCAs. Reproduced below are actual copies or photographs of some gamma spectra.



HARD COPY RECORD



SCOPE DISPLAYS

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Picture what a Nucleus Gamma Spectrometer can do in your lab. We have mentioned just a few uses - you can probably suggest many more. Some of our customers are presently using this system for monitoring lab waste, reading wipe/smear tests, and uptake applications. Complete systems are available now! But, if you have some equipment and want to talk with our engineers about compatibility or discuss your particular requirements, just write or call, today. Let us send you free brochures describing these and other fine nuclear instruments for quality assurance, health physics and teaching laboratories.

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OSTEOLITE bone imaging in orthopedics

The superior technique:

"The bone scan may be the only technique capable of locating sites of suspected or unsuspected (bone) trauma."[1]

1. *Sem Nucl Med* **6**:107, 1976

The superior agent:

OSTEOLITE™

Technetium Tc 99m Medronate Sodium Kit (MDP)

NEN New England Nuclear®

In bone trauma...when the X-ray is inconclusive.

Most rapid blood clearance[2]

- At 90 minutes postinjection, blood clearance of MDP pharmacologically identical to OSTEOLITE was approximately equal to that of tested pyrophosphate agents at 6 hours postinjection.
- At 3 hours, MDP blood levels were considerably less than those of tested EHDP and pyrophosphate.

Result: low-background studies, whether you must scan early to meet patient-flow demands, or at 3 hours for more optimal image detail.

Lowest soft tissue activity[2,3]

The "difference in soft tissue activity (highest with polyphosphate and lowest with MDP) is discernible in clinical images."[2] A University of Minnesota study found that only 4% of 175 MDP images showed moderate to marked soft tissue activity, compared to 17% of EHDP images.[3]

Result: highest assurance of visualizing all skeletal structures.

Highest target-to-background differential[4]

OSTEOLITE's rapid blood clearance and lower soft tissue uptake usually enable current gamma cameras to resolve peripheral skeletal structures and phalanges.

Result: confidence of detecting resolution-challenging alterations in osteogenesis...even roentgenographically "invisible" fractures and small metastases.

Convenient storage and preparation

Available in 5-vial or 30-vial "Convenience Packs," OSTEOLITE can be stored and used at room temperature (15–30 C).

REFERENCES:

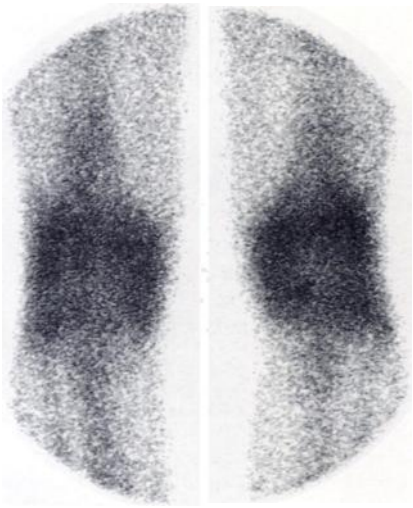
1. Marty R et al: Bone trauma and related benign disease: Assessment by bone scanning. *Sem Nucl Med* 6:107, 1976
2. Subramanian G et al: Technetium-99m-methylene diphosphonate—a superior agent for skeletal imaging: Comparison with other technetium complexes. *J Nucl Med* 16:744, 1975
3. Forstrom L et al: Data on file at New England Nuclear, Medical Diagnostics Division, North Billerica, MA
4. Davis MA, Jones AG: Comparison of ^{99m}Tc-labeled phosphate and phosphonate agents for skeletal imaging. *Sem Nucl Med* 6:19, 1976

OSTEOLITE™

Technetium Tc 99m Medronate Sodium Kit (MDP)

RL, right knee

LL, right knee



Post

Ant

A 23-year-old graduate student actively engaged in amateur soccer complained of pain in both knees. X-rays of both knees suggested the possibility of a stress fracture only at the right proximal tibia. OSTEOLITE images of the right knee displayed focal uptake in the proximal tibia, consistent with the diagnosis of a stress fracture. A routine anterior view of both knees disclosed a roentgenographically occult stress fracture of the left proximal tibia as well.

Images produced with 19.6 mCi technetium-99m labeled OSTEOLITE; recorded at 500 K counts, Searle LFOV™ camera with Micro Dot™ Imager.

Please see following page for full prescribing information.

New England Nuclear®

OSTEOLITE™

Technetium Tc 99m Medronate Sodium Kit (Formerly Known as MDP)

October 1977

DESCRIPTION: New England Nuclear's OSTEOLITE™ Technetium Tc 99m Medronate Sodium Kit (formerly known as MDP), is supplied sterile and non-pyrogenic in lyophilized kit form suitable for reconstitution with sodium pertechnetate Tc 99m to form a diagnostic skeletal imaging agent for intravenous administration. Each vial contains 10mg medronate disodium and 0.85mg stannous chloride dihydrate; pH is adjusted to between 7.0–7.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial are lyophilized and stored under nitrogen.

PHYSICAL CHARACTERISTICS

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. (SOURCE: Martin, M. J. Nuclear Data Project, Oak Ridge National Laboratory, March, 1976.) Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data—Technetium Tc 99m

Radiation	Mean %/ Disintegration	Mean Energy (keV)
Gamma-2	88.96	140.5

To facilitate correction for physical decay of Technetium Tc 99m, the fractions of initial activity that remain at selected intervals after the time of calibration are shown in Table 2.

Table 2. Physical Decay Chart: Technetium Tc 99m Half-Life 6.02 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	8	.398
1	.891	9	.355
2	.794	10	.316
3	.708	11	.282
4	.631	12	.251
5	.562	18	.126
6	.501	24	.063
7	.447		

*Calibration Time

EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 0.8R/mCi-hr. at 1cm. The half value layer is 0.2mm of Pb. To facilitate control of radiation exposure from millicurie amounts of Technetium Tc 99m, the use of a 6.35mm thick standard radiation elution lead shield will attenuate the radiation emitted by a factor greater than 10^{-6}.

Table 3. 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}
5.4	10^{-6}
6.3	10^{-7}

CLINICAL PHARMACOLOGY: Upon intravenous injection, Technetium Tc 99m OSTEOLITE exhibits a specific affinity for areas of altered osteogenesis. In humans, blood levels fall to 4-10% of the injected dose by two hours post-injection and to 3-5% by three hours. During the first 24 hours following its administration in patients with normal renal function, 50-75% of the radioactivity is excreted into the urine and less than 2% of the injected dose remains in the vascular system.

Uptake of the Technetium Tc 99m in bone appears to be related to osteogenic activity and to skeletal blood perfusion. The deposition in the skeleton is bilaterally symmetrical, with increased accumulation in the axial structure as compared to the appendicular skeleton. There is increased activity in the distal aspect of long bones as compared to the diaphyses. In pediatric patients, in whom the epiphyseal centers are still open, there is more marked accumulation of the radiopharmaceutical in the distal aspects of long bones than is seen in adults in whom the epiphyseal centers are closed. Localized areas of abnormal accumulation of the radiopharmaceutical may be seen in primary skeletal malignancies, metastatic malignancies to bone, acute or chronic osteomyelitis, arthritides, recent fractures, areas of ectopic calcification, Paget's disease, regional migratory osteoporosis, areas of aseptic necrosis and, in general, any pathological situation involving bone in which there is increased osteogenic activity or localized increased osseous blood perfusion. Since increased osteogenic activity and localized increased osseous blood perfusion are not usually present in chronic bone diseases, bone imaging agents, in general, are not effective in detecting such diseases. Localized areas of decreased accumulation of the radiopharmaceutical may be noted in areas of bone which have received localized fields of external radiation or to which blood flow has been interrupted. OSTEOLITE has also been noted to accumulate in areas of acute myocardial infarction from one to fourteen days after the pathologic event.

INDICATIONS AND USAGE: Technetium Tc 99m OSTEOLITE may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS: None known.

WARNINGS: The contents of the OSTEOLITE vial are intended only for use in the preparation of Technetium Tc 99m medronate sodium and are NOT to be directly administered to the patient.

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

PRECAUTIONS: A thorough knowledge of the normal distribution of intravenously administered Technetium Tc 99m medronate sodium is essential in order to accurately interpret pathologic studies.

Technetium Tc 99m medronate sodium, as well as any radioactive agent, must be handled with care. Once sodium pertechnetate Tc 99m is added to the kit, appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

The Technetium Tc 99m labeling reaction involved in preparing Technetium Tc 99m medronate sodium depends on the maintenance of tin in the divalent state. Any oxidant present in the sodium pertechnetate Tc 99m employed may adversely affect the quality of the prepared agent. Thus, sodium pertechnetate Tc 99m containing oxidants should not be used without first demonstrating that it is without adverse effect on the properties of the resulting agent.

The use of bacteriostatic sodium chloride as a diluent for sodium pertechnetate Tc 99m may adversely affect the biologic distribution of the prepared agent, and its use is not recommended.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m medronate sodium should be used in pregnant women only when clearly needed..

It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken when a patient is administered radioactive material.

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: None reported.

DOSAGE AND ADMINISTRATION: The recommended dose for the average 70kg adult patient is 15mCi with a range of 10-20mCi. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Optimal imaging results are obtained within one to four hours after administration.

OSTEOLITE should be used within six hours after aseptic reconstitution with sodium pertechnetate Tc 99m. For optimum results this time should be minimized.

The vial contains no bacteriostat.

Radiopharmaceuticals should be used by persons who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate governmental agencies authorized to license the use of radionuclides.

RADIATION DOSIMETRY

The estimated absorbed radiation dose to an average patient (70kg) from an intravenous injection of a maximum dose of 20 millicuries of Technetium Tc 99m OSTEOLITE is shown in Table 4.

Table 4. Absorbed Radiation Dose

Organ		Technetium Tc 99m Medronate Sodium (rads/20mCi)
Total Body		0.13
Bone Total		0.70
Red Marrow		0.56
Kidneys		0.62
Liver		0.16
Bladder Wall	2 hr void	2.60
	4.8 hr void	6.20
Ovaries	2 hr void	0.24
	4.8 hr void	0.34
Testes	2 hr void	0.16
	4.8 hr void	0.22

Method of calculation: A Schema for Absorbed-Dose Calculations For Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, p. 7, 1968.

HOW SUPPLIED: NEN's OSTEOLITE™ Technetium Tc 99m Medronate Sodium Kit is supplied as a set of five or thirty vials, sterile and non-pyrogenic. Each nitrogen-flushed vial contains in lyophilized form:

Medronate Disodium—10mg
Stannous Chloride Dihydrate—0.85mg

The pH is adjusted to between 7.0–7.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial were lyophilized under nitrogen. Store at room temperature (15°-30° C). Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.

INSTRUCTIONS FOR PREPARATION OF TECHNETIUM Tc 99m OSTEOLITE: Aseptically inject 2 to 8ml of sodium pertechnetate Tc 99m (pertechnetate in isotonic saline without a bacteriostat) into the supplied vial of OSTEOLITE enclosed by a radiation shield. Swirl for at least ten seconds to dissolve completely. Label appropriately. Suitable labels have been supplied with each OSTEOLITE Kit. Use within six hours after reconstitution. For optimum results, this time should be minimized.

Using proper shielding, the vial containing the reconstituted solution should be visually inspected to insure that it is clear and free of particulate matter.

The contents of the kit vials are not radioactive; however, **after reconstitution with sodium pertechnetate Tc 99m the contents are radioactive and adequate shielding and handling precautions must be maintained.**

Do not use if there is a vacuum in the immediate drug container or if air is injected into the container when the dose is withdrawn.

Catalog Number NRP-420 (5 vial kit)
Catalog Number NRP-420C (30 vial kit)

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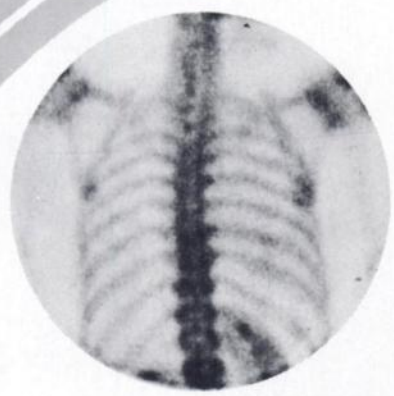

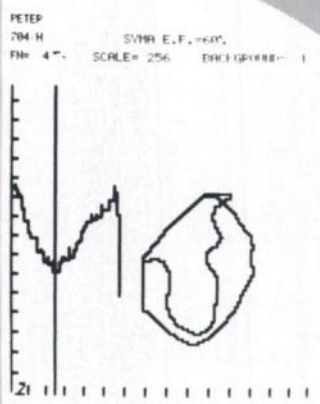

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The DYMAX-MBLF has an effective detection area 250% larger than any mobile camera now available. It also has an on-board computerized clinical processor. . And all at a surprisingly low price!

The DYMAX-MBLF can be used for all routine work in your nuclear medicine lab and to perform patient bedside procedures requiring a large field of view in the ICCU or emergency room, such as:

- Lung studies in suspected pulmonary emboli cases
- Myocardial perfusion emission tomography studies
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Check these outstanding peformance highlights:

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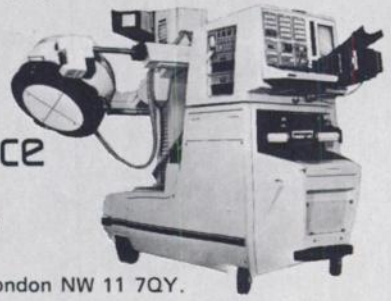
- Linearity: ± 1% of FOV diameter
- Maximum imaging count rate: 120Kc/s with 20% window



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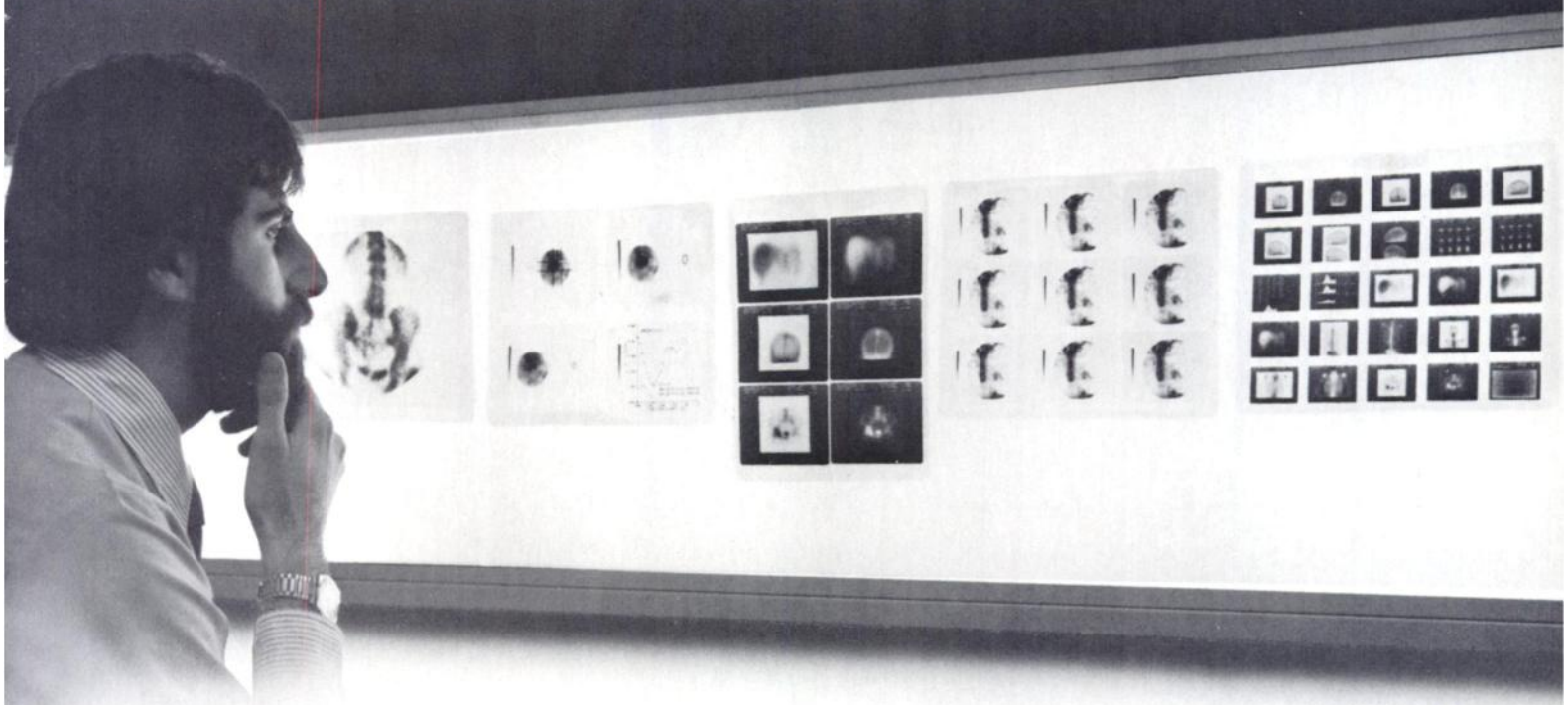
and that's next.



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- Needs boiling only once for 5 minutes.
- Buffer is injected into the reaction vial immediately after removal from the boiling water bath. No waiting is required.
- Dose vial can be cooled at room temperature, or, for rapid preparation, can be rapidly cooled in a cold environment for sooner use.
- **CINTICHEM® TECHNETIUM 99m TSC** can provide a versatile solution for your imaging needs when **specifically requested** on your prescription if prepared doses are obtained from a radiopharmacy.
- Compared to competitive "convenience packaging", a **CintiChem®** Standing Order allows you to optimize your kit purchases and delivery schedule to meet your individual dosage needs; reduces your shelf space requirements; and continuously assures you of product with the longest expiration date available.

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indications and usage

Technetium Tc 99m Sulfur Colloid Injection is used as an agent for imaging areas of functioning reticuloendothelial cells in the liver, spleen, and bone marrow.

contraindications

None known.

warnings

The contents of the two syringes, one syringe containing the sodium thiosulfate solution and the second syringe containing the appropriate buffer solution, are intended ***only*** for use in the preparation of the Technetium Tc 99m Sulfur Colloid Injection and ***are not to be directly administered to the patient.***

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

This radiopharmaceutical preparation should not be administered to children or to patients who are pregnant or during lactation unless the expected benefits to be gained outweigh the potential hazards.

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.

precautions

The components of the kit are sterile and pyrogen-free. It is essential that the user follows the directions carefully and adheres to strict aseptic procedures during preparation of the colloid.

The stability of the colloidal preparation may be decreased in the presence of polyvalent cations, thus resulting in the agglomeration of the individual colloidal particles. These larger particles are likely to be trapped by the pulmonary capillary bed following intravenous injection.

It is recommended that Sodium Pertechnetate Tc 99m solutions containing more than 10 micrograms/ml of aluminum ion not be used for formulation of the Technetium Tc 99m Sulfur Colloid Injection. The Sodium Pertechnetate Tc 99m solution must also be free of any traces of oxidizing agents such as peroxides and hypochlorites.

Technetium Tc 99m Sulfur Colloid Injection is physically unstable and as such the particles will settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactivity.

It is also recommended that because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m Sulfur Colloid Injection not be used after **six** hours from the time of formulation.

The preparation contains no bacteriostatic preservative.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Sulfur Colloid Injection should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established.

Technetium Tc 99m Sulfur Colloid Injection, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients, consistent with proper patient management.

adverse reactions

Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulfur colloid preparations.

One death and several cases of lung and soft tissue uptake other than RES have been reported in the association with the use of Technetium Tc 99m Sulfur Colloid Injection.

how supplied

The TECHNETIUM 99m SULFUR COLLOID KIT is supplied as a sterile pyrogen-free kit consisting of: five reaction vials, each containing 0.5 ml 1.0 N hydrochloric acid in water; five sterile syringes (labeled "A"), each containing 1.9 mg sodium thiosulfate anhydrous in 1.1 ml aqueous solution; five sterile syringes (labeled "B"), each containing 5.3 mg gelatin in 2.1 ml aqueous buffer solution containing 177 mg sodium acetate anhydrous

storage

Store finished drug at room temperature.

FOR FULL PREPARATION AND PRESCRIBING INFORMATION, SEE PACKAGE INSERT.

CintiChem®

TECHNETIUM 99m **TSC** Kit For The Preparation Of Technetium Tc 99m Sulfur Colloid Injection

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Our ^{125}I Doxorubicin (Adriamycin) Radioimmunoassay Kit features a rapid, simple procedure with 100 picogram sensitivity in serum, plasma or urine. Six precalibrated standards as well as a control serum are supplied. The stable ^{125}I tracer and one hour incubation time makes this kit a unique tool in cancer management.

1. Bonadonna, G. et al: Phase I and preliminary Phase II evaluation of adriamycin (NSC 123127), Cancer Res. *30*, 2572, 1970
2. Middleman, E. et al: Clinical trials with adriamycin. Cancer, *28*, 844, 1971
3. Wang, J. et al: Therapeutic effect and toxicity of adriamycin in patients with neoplastic diseases. Cancer, *28*, 837, 1971

*Tradename Adria Labs.

Methotrexate [^{125}I] Radioimmunoassay Kit

High dose Methotrexate therapy in combination with leucovorin "rescue" treatment creates a vital need for close monitoring of circulating Methotrexate plasma levels. Methotrexate overdose has been shown to be associated with severe myelosuppression, renal damage[1 2] and hepatotoxicity.[3]

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1. S.W. Pitman et al: Clinical Trial of High-Dose Methotrexate (NSC-740). With Citrovorum Factor (NSC-3590)-Toxicologic and Therapeutic Observations. Cancer Chemotherapy Reports Part 3 Vol. 6, No. 1, July 1975.
2. Stoller, Ronald G. et al: Use of Plasma Pharmacokinetics to Predict and Prevent Methotrexate Toxicity. N.E. Jr. of Med. Vol. 297 No. 12:630-634, Sept. 22, 1977.
3. Jaffe N. and Traggis D. Toxicity of high-dose methotrexate (NSC- 740) and citrovorum factor (NSC-3590) rescue in osteogenic sarcoma. Cancer Chemother. Rep. Part 3, Vol.6(1):31-36, 1975.

For further information call or write:

Diagnostic Biochemistry Inc.

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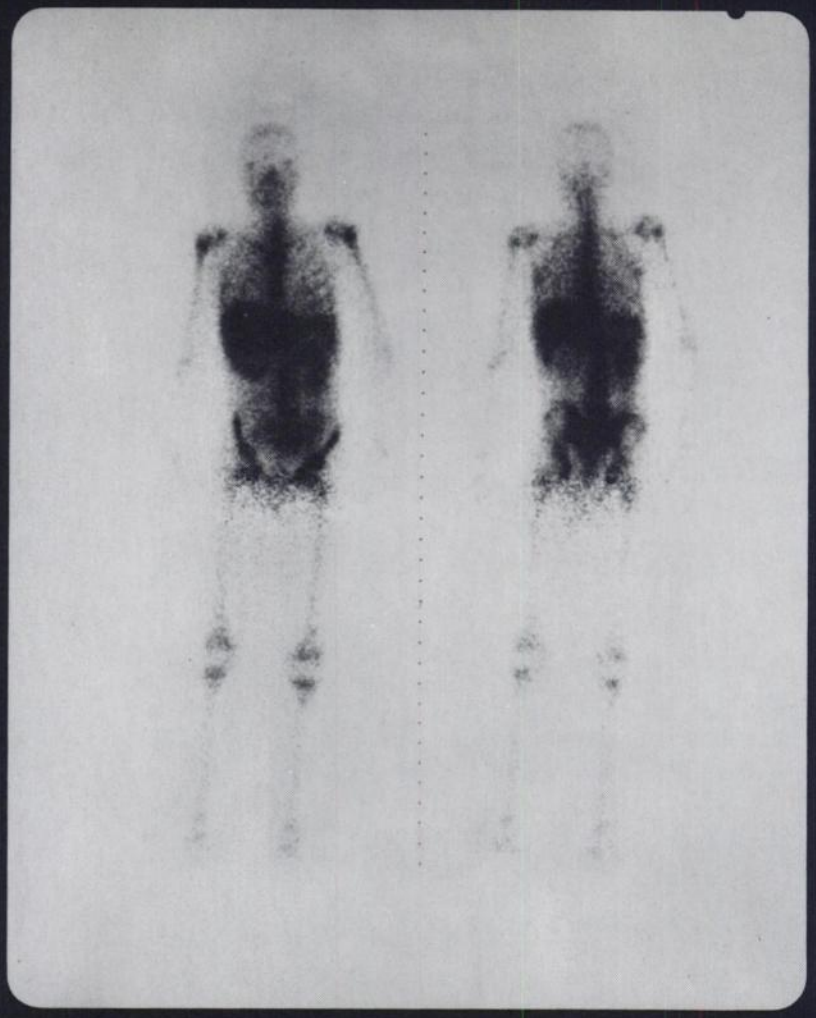

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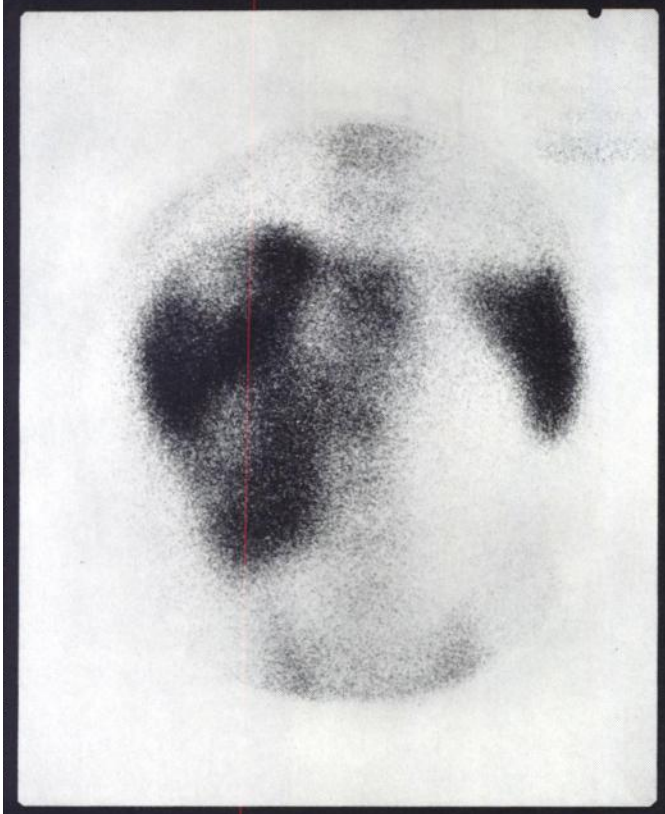

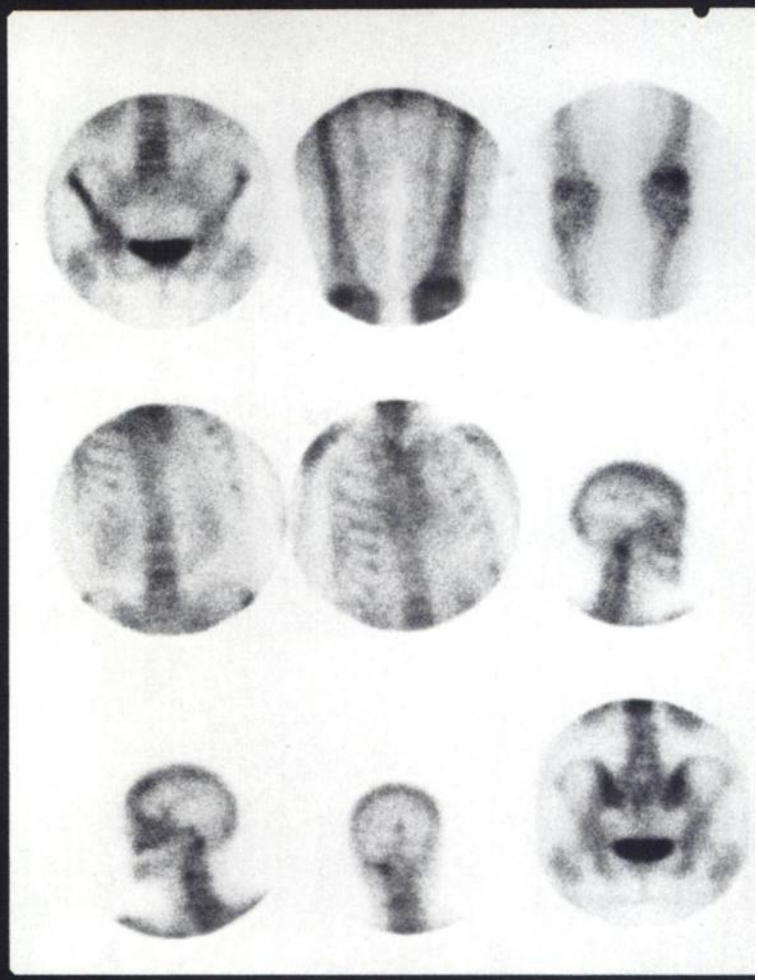

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[1] The Code of Federal Regulations† clearly limits the permissible ^{133}Xe exposure to 1 MPC for 40 hours per week for 13 weeks. The data is continuously updated and displayed by the "XenAlert."

†10 CFR, Part 20, Sec. 20.103 and Appendix B, Table 1.

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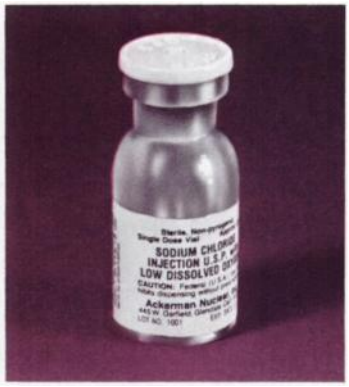

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SODIUM CHLORIDE INJECTION U.S.P. with LOW DISSOLVED OXYGEN is a sterile isotonic solution of sodium chloride in water for injection. It contains no antimicrobial agent. It contains 0.9% sodium chloride and is packaged in single dose vials. The osmolarity is 300 mOsm/1, the dissolved oxygen content is less than 5 ppm.

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WARNING:
Excessive amounts of sodium chloride by any route may cause hypopotassemia and acidosis. Excessive amounts by the parental route may precipitate congestive heart failure and acute pulmonary edema, especially in patients with cardiovasular disease, and in patients receiving corticosteroids or corticotropin drugs that may give rise to sodium retention. No antimicrobial agent has been added.

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Unused amounts should be discarded immediately following withdrawal of any portion of the contents.

HOW SUPPLIED:

Catalog No.	Product	Packaging
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1/78

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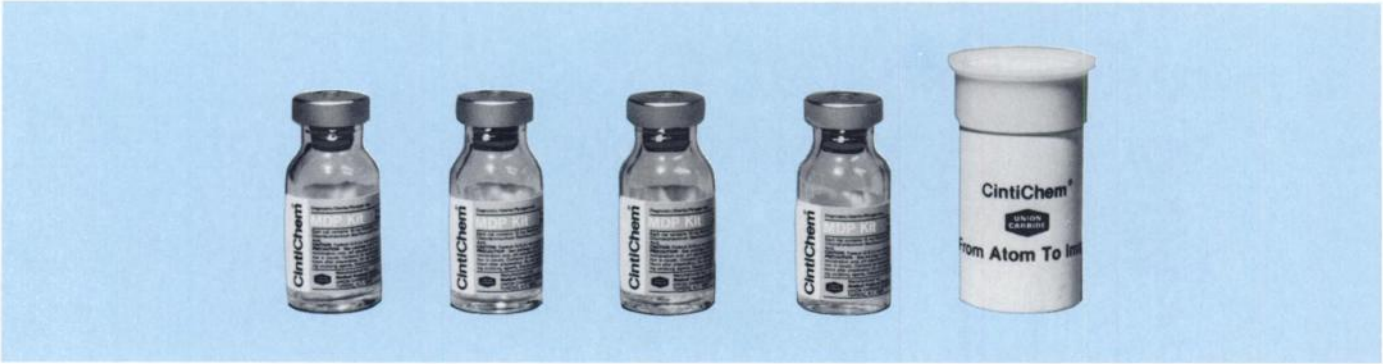

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CintiChem® MDP KIT

Technetium Tc 99m Medronate Kit

BRIEF SUMMARY OF PRESCRIBING INFORMATION

indications and usage

Technetium Tc 99m Medronate may be used as a bone imaging agent to delineate areas of altered osteogenesis.

contraindications

None known.

warnings

This class of compound is known to complex cations such as calcium. Particular caution should be used with patients who have, or who may be predisposed to, hypocalcemia (i.e., alkalosis).

This radiopharmaceutical drug product should not be administered to children, to pregnant women, or to nursing mothers, unless the expected benefit to be gained outweighs the potential risk.

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.

precautions

general

Technetium Tc 99m Medronate as well as other 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 management.

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 for the next 4-6 hours.

This preparation contains no bacteriostatic preservative.

Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use.

pregnancy category C

Adequate reproductive studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Medronate should be used in pregnant women only when clearly needed.

nursing mothers

It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken while a patient is on the drug since many drugs are excreted in human milk.

pediatric use

Safety and effectiveness in children have not been established .

adverse reactions

No adverse reactions specifically attributable to the use of Technetium Tc 99m Medronate have been reported.

how supplied

Union Carbide's Technetium Tc 99m Medronate Kit is supplied as a sterile, pyrogen-free kit containing 5 vials.

Each 10 ml vial contains 10 mg medronic acid, 0.17 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.29 mg), and 2 mg ascorbic acid. The pH has been adjusted to 4-8 with either HCl or NaOH prior to lyophilization. Following lyophilization, the vials are sealed under a nitrogen atmosphere.

Product #17500502 Multidose vial shield with cap and retainer ring available separately.

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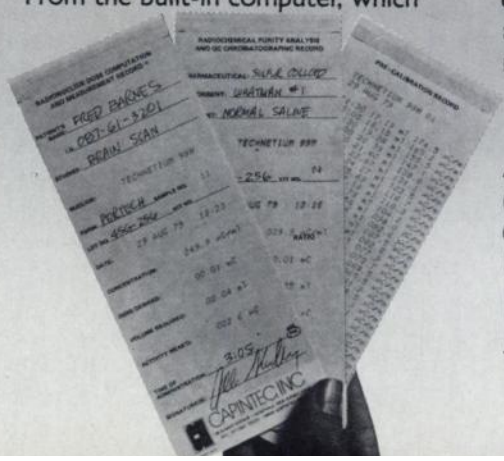

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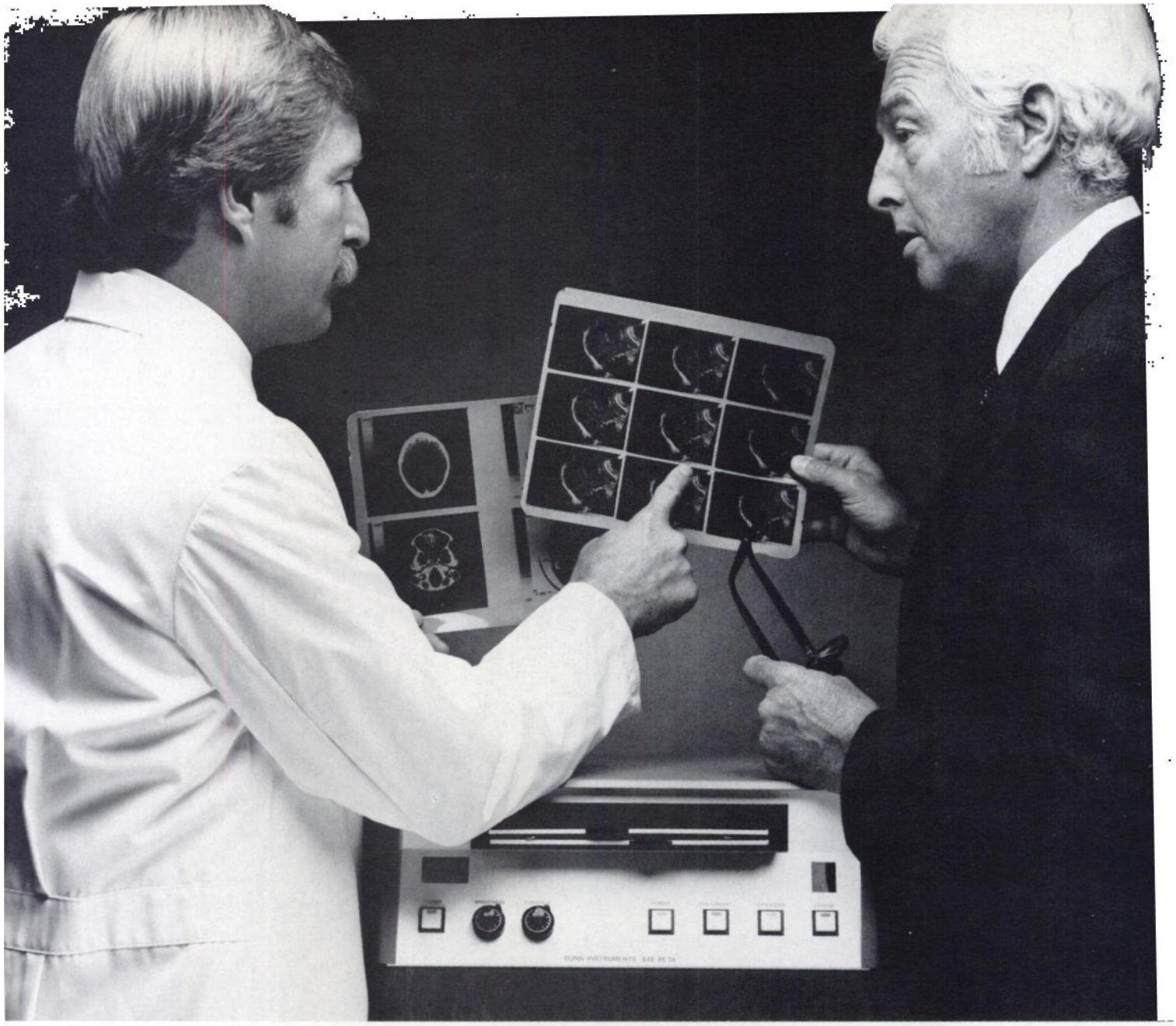

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Applications for a one year training program in Nuclear Medicine Technology are being accepted by the Geisinger Medical Center. Classes will begin September 4, 1979. Standard qualifications are preferred but other qualifications will be considered on an individual basis. Inquiries should be sent to:

David R. Brill, M.D.
Section of Nuclear Medicine
Geisinger Medical Center
Danville, Pennsylvania 17821

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This section in the *Journal of Nuclear Medicine* contains "Positions Open", "Positions Wanted", and "For Sale" listing. Nondisplay "Positions Wanted" ads by members of the Society are billed at 60¢ per word for each insertion with no minimum rate. Nondisplay "Positions Wanted" ads by nonmembers and all nondisplay "Positions Open" and "For Sale" ads by members and nonmembers are charged at 85¢ per word. Display advertisements are accepted at $125 for ⅛ page, $185 for ¼ page, $295 for ½ page, and $510 for a full page. Closing date for each issue is the 1st of the month preceding publication. Agency commissions and cash discounts are allowed on display ads only. Box numbers are available for those who wish them.

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This meeting is jointly organized by the Cross Cancer Institute in Alberta, Veterans Administration Hospital, Seattle, Washington, the Faculty of Pharmacy and the Division of Continuing Medical Education, University of Alberta, Edmonton, Alberta.

The Faculty will consist of Dr. R.L. Hayes, Dr. P. Hoffer, Dr. G.S. Johnston, Dr. R. Sephton, Dr. M. Welch and Dr. J. Rasey.

Abstracts are invited and abstract forms and further details may be obtained from:

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The Radiochemical Centre Amersham

For further information please write or phone
The Radiochemical Centre Limited, Amersham, England. Telephone: 024-04-4444
In the Americas: Amersham Corporation, Illinois 60005. Telephone: 312-593-6300
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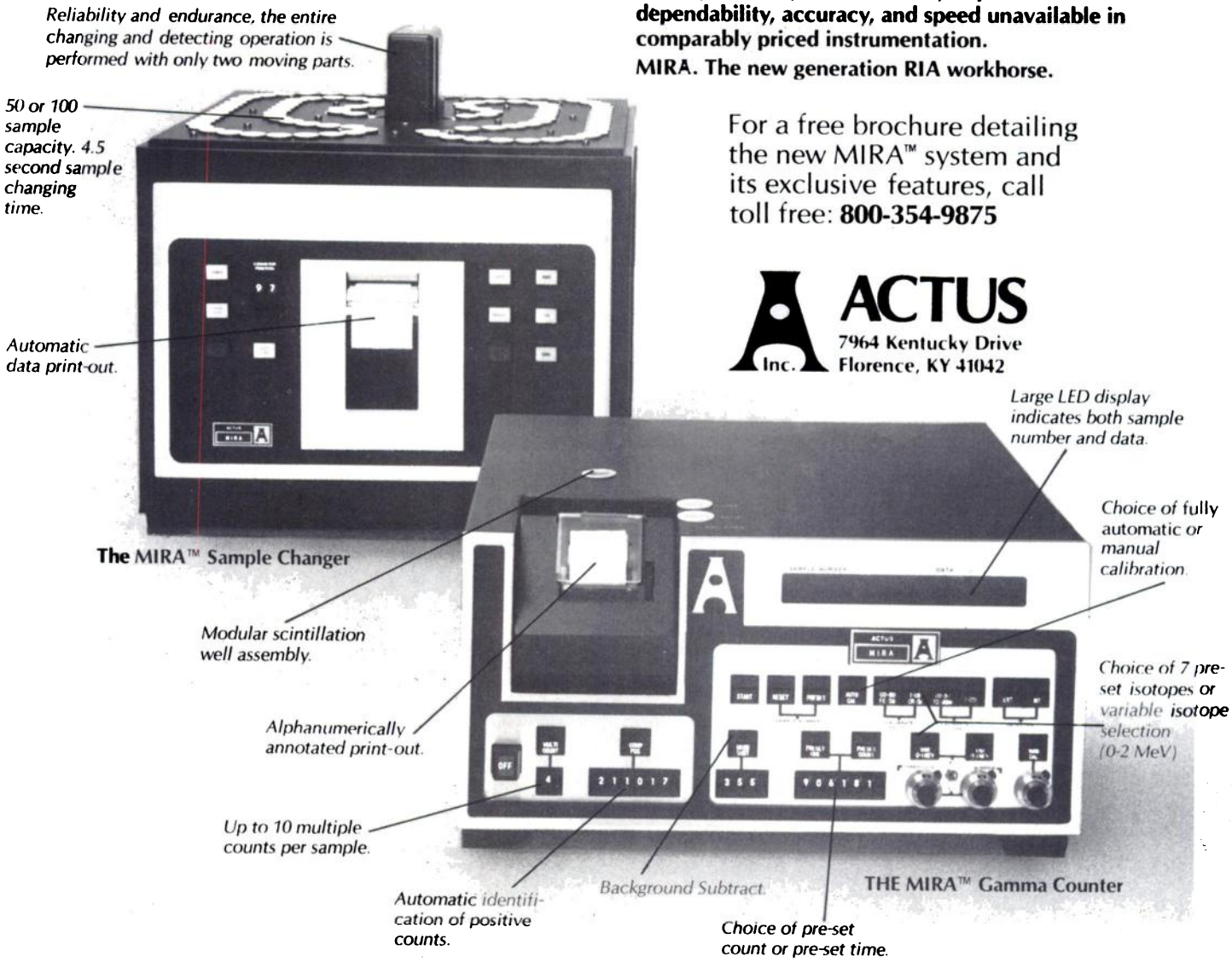

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Ultra-TechneKow® FM (Technetium Tc 99m) Generator

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Ultra-TechneKow® FM

(Technetium Tc-99m Generator)

For the Production of Sodium Pertechnetate Tc 99m

DESCRIPTION

The **Ultra-TechneKow** FM Generator is prepared with fission-produced molybdenum-99. This generator provides a closed system for the production of sterile metastable technetium-99m, which is produced by the decay of molybdenum-99. Sterile, pyrogen-free isotonic solutions of Sodium Pertechnetate Tc 99m can be obtained conveniently by periodic aseptic elution of the generators. These solutions should be crystal clear.

The generator consists of a sealed glass chamber containing specially processed alumina. This treated alumina has a high absorption capacity for molybdenum-99 and a low affinity for technetium-99m. As a result, elution of the generator yields a solution of technetium-99m containing negligible amounts of molybdenum-99.

ACTIONS

The pertechnetate ion distributes in the body similarly to the iodide ion but is not organified when trapped in the thyroid gland. Pertechnetate tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. It also concentrates in thyroid gland, salivary glands, stomach and choroid plexus. After intravascular administration it remains in the circulatory system for sufficient time to permit blood pool, organ perfusions, and major vessel studies. It gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

INDICATIONS

Sodium pertechnetate Tc-99m is used for brain imaging, thyroid imaging, salivary gland imaging, placenta localization and blood pool imaging.

CONTRAINDICATIONS

None.

WARNINGS

This radiopharmaceutical should not be administered to patients who are pregnant or during lactation unless the information to be gained outweighs the potential hazards.

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.

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

PRECAUTIONS

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

At the time of administration the solution should be crystal clear.

ADVERSE REACTIONS

None.

DOSAGE AND ADMINISTRATION

Sodium pertechnetate Tc-99m is usually administered by intravascular injection but can be given orally. The dosage employed varies with each diagnostic procedure.

The suggested dose range employed for various diagnostic indications in the average patient (70 kg) is:

brain imaging:	10 to 20 mCi
thyroid gland imaging:	1 to 10 mCi
salivary gland imaging:	1 to 5 mCi
placenta localization:	1 to 3 mCi
blood pool imaging:	10 to 20 mCi

NOTE: Up to 1 gram of reagent grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of sodium pertechnetate Tc-99m injection for brain imaging, placenta localization and blood pool imaging.

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

HOW SUPPLIED

The **Ultra-TechneKow FM** (Technetium Tc 99m) Generators contain the following amount of molybdenum-99 at the time of calibration stated on the label.

Catalog Number	
100	0.25 curies
101	0.50 curies
106	0.75 curies
102	1.0 curies
103	1.5 curies
104	2.0 curies
105	2.5 curies
107	3.0 curies

Each generator is supplied with the following components for the elution of the generator.

- 6—Sterile, graduated, evacuated collecting vials
- 6—Sterile Luer-Lock needles with plastic covers
- 6—Pressure-sensitive "Caution—Radioactive Material" collecting vial labels
- 6—Pressure-sensitive radioassay data labels for lead dispensing shield

EVACUATED COLLECTING VIALS. Collecting vials are available on request in 5, 10, 20 and 30 milliliter sizes.

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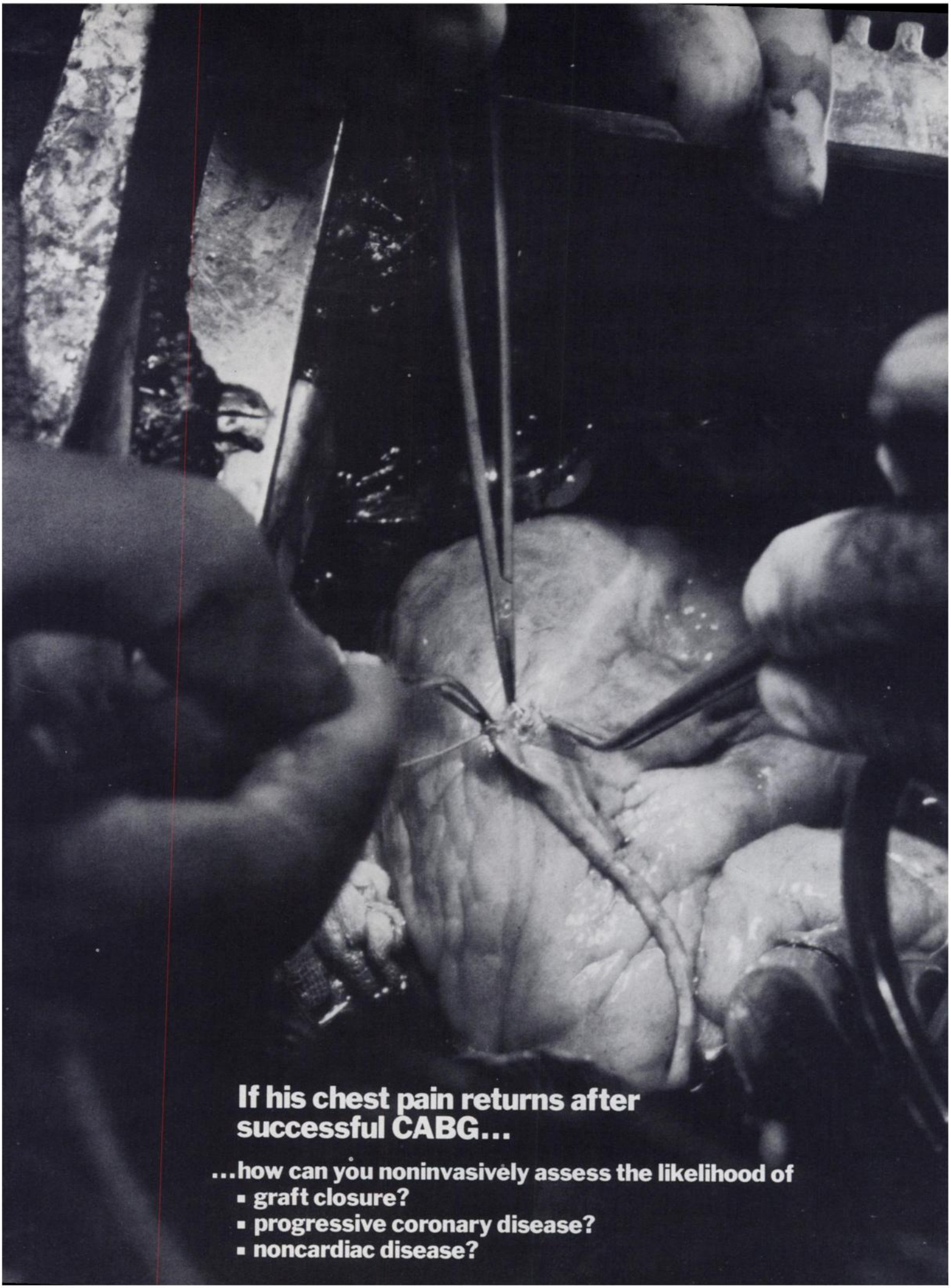
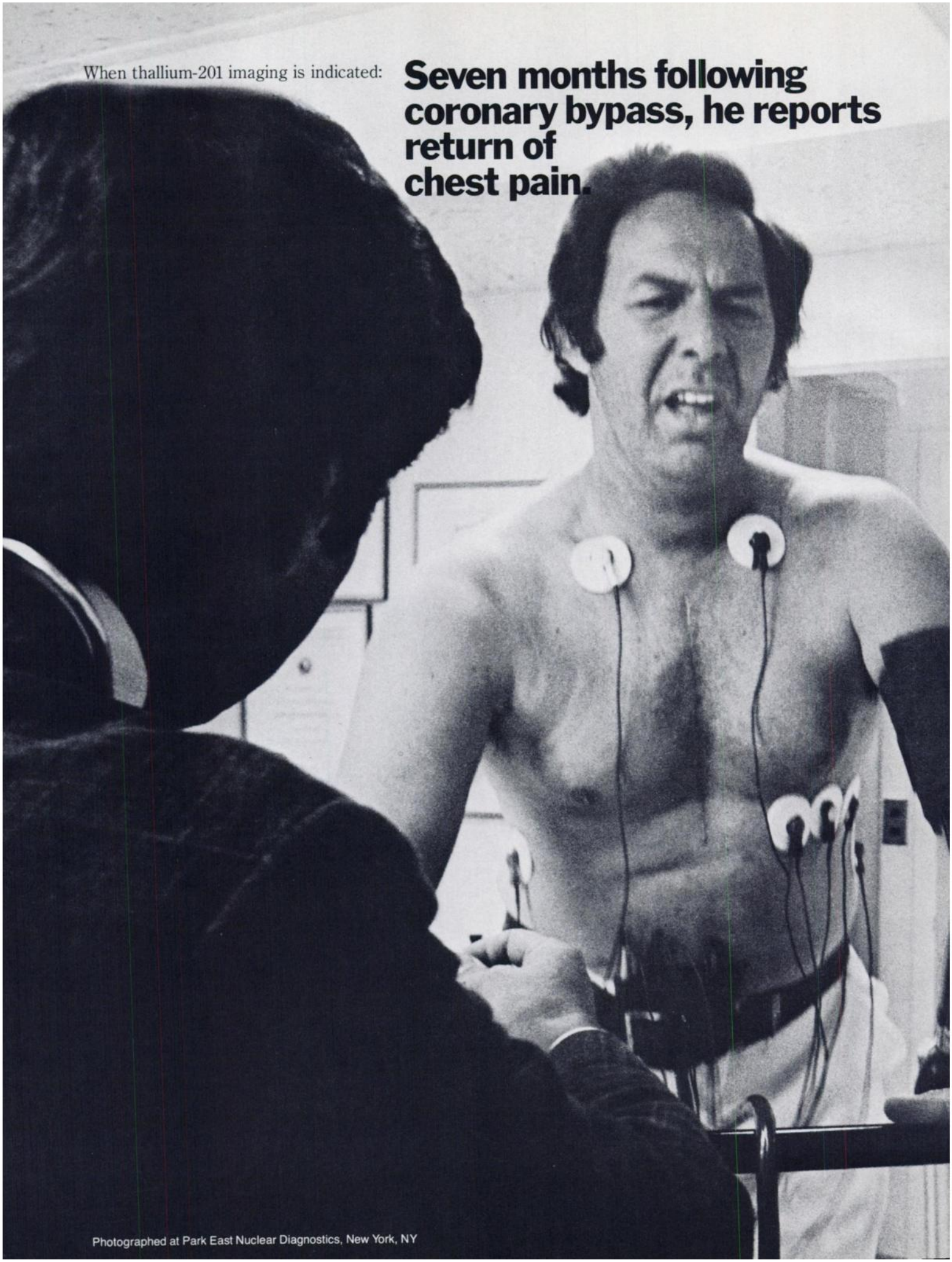
RADIOPHARMACEUTICALS


If his chest pain returns after successful CABG...
...how can you noninvasively assess the likelihood of
▪ graft closure?
▪ progressive coronary disease?
▪ noncardiac disease?

When thallium-201 imaging is indicated:

Seven months following coronary bypass, he reports return of chest pain.



Photographed at Park East Nuclear Diagnostics, New York, NY

As the population of successful coronary bypass patients continues to grow, physicians will encounter an increasing number who report a return of chest pain after varying postoperative periods.

Complaints of chest pain in post-bypass patients deserve thorough, progressive workup... usually including exercise electrocardiography. Without exercise ECG evidence of myocardial ischemia, the clinician must decide on symptoms alone whether or not to suggest repeat coronary angiography. In such a setting, myocardial perfusion imaging with thallium-201 may rule out—or confirm—the possibility of electrically silent graft occlusion or extension of disease.

Localizes in perfused myocardium

Thallium-201 is a radioactive isotope that, following intravenous injection, distributes within myocardial cells in proportion to regional perfusion. Nuclear medicine imaging performed following injection will display relative regional perfusion and myocardial cell viability.

When used in conjunction with stress electrocardiography, thallium-201 has proven successful in demonstrating regional ischemia that may escape detection by ECG. A region that appears "cold" following exercise and injection, but "fills in" on repeat imaging a few hours later, suggests stress ischemia secondary to fixed stenosis that restricts perfusion during exercise. A region that remains persistently "cold" generally indicates irreversible myocardial scarring.

Reveals graft patency/occlusion

Many institutions routinely perform preoperative and postoperative stress thallium studies to obtain functional evidence of graft-mediated reperfusion of formerly ischemic regions. This sequence of studies can serve as a valuable baseline in the event that the patient returns with a complaint of chest pain:

- If a repeat thallium study discloses ischemia in the regions formerly perfused by the grafts, occlusion may be suspected.
- If the repeat study suggests new areas of ischemia, progression of atherosclerotic disease may have occurred.
- If the repeat study is essentially unchanged from the postoperative findings, nonischemic etiology should be explored.

Useful with/without baseline

Even if baseline stress-thallium studies are not available, this procedure can still provide valuable diagnostic guidance—particularly if it is negative, or displays clear evidence of ischemia in the grafted regions.

Information, teaching program available

New England Nuclear offers an extensive range of journal reprints on the use of thallium-201 imaging, and provides teaching rounds material and reference monographs at no charge, as a service to the profession. For more information on thallium-201, use the coupon below, or call **800-225-1572, ext 2234** toll free.

Thallous Chloride Tl 201

See following page for full prescribing information.

Teaching Program Administrator

NE-0312

New England Nuclear
Medical Diagnostics Division

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Please send me:
- ☐ Journal reprints on the clinical use of thallium-201 imaging
- ☐ Home-study monograph on thallium-201 imaging
- ☐ Scheduling information on thallium-201 teaching slide program

Name .....

Title/Specialty .....

Institution .....

Address .....

City ..... State ..... Zip .....

Thallous Chloride Tl 201

November 1977

FOR DIAGNOSTIC USE

DESCRIPTION: Thallous Chloride Tl 201 is supplied in isotonic solution as a sterile, non-pyrogenic diagnostic radiopharmaceutical for intravenous administration. The aqueous solution at calibration time contains 1mCi/ml Thallous Chloride Tl 201, adjusted to pH 4.5-6.5 by the addition of hydrochloric acid and/or sodium hydroxide solution. It is made isotonic with 0.9% sodium chloride and is preserved with 0.9% benzyl alcohol. Thallium Tl 201 has a half-life of 73.1 hours and is cyclotron-produced. It is essentially carrier-free, and contains less than 0.25% lead Pb 203 and less than 1.9% Thallium Tl 202.

PHYSICAL CHARACTERISTICS

Thallium Tl 201 decays by electron capture to Mercury Hg 201 with a physical half-life of 73.1 hours.[1] Photons that are useful for detection and imaging are listed in Table 1. The lower energy X-rays obtained from the Mercury Hg 201 daughter of Tl 201 are recommended for myocardial imaging, because the mean %/disintegration at 68-80.3 keV is much greater than the combination of gamma-4 and gamma-6 mean %/disintegration.

Table 1. Principal Radiation Emission Data

Radiation	Mean %/Disintegration	Mean Energy (keV)
Gamma-4	2.65	135.3
Gamma-6	10.0	167.4
Mercury X-rays	94.5	68-80.3

[1] Martin, M.J., Nuclear Data Project, ORNL, January 1977

EXTERNAL RADIATION

The specific gamma ray constant for Thallium Tl 201 is 0.47R/mCi-hr. at 1 cm. The first half-value layer is 0.23mm of lead. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from the interposition of various thicknesses of lead (Pb) is shown in Table 2. For example, the use of 4.4mm of lead will decrease the external radiation exposure by a factor of about 10,000.

Table 2. Radiation Attenuation By Lead Shielding

mm of Lead (Pb)	Coefficient of Attenuation
0.23	0.5
0.83	10^{-1}
1.9	10^{-2}
3.1	10^{-3}
4.4	10^{-4}
5.7	10^{-5}

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals before and after calibration are shown in Table 3.

Table 3. Thallium Tl 201 Decay Chart: Half-Life 73.1 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining	Hours	Fraction Remaining
-72	1.98	18	0.84	72	0.51
-60	1.77	24	0.80	78	0.48
-48	1.58	30	0.75	84	0.45
-36	1.41	36	0.71	90	0.43
-12	1.12	42	0.67	96	0.40
-6	1.06	48	0.63	108	0.36
0*	1.00	54	0.60	120	0.32
6	0.95	60	0.57	132	0.29
12	0.89	66	0.54	144	0.26

*Calibration Time

CLINICAL PHARMACOLOGY: Carrier-free Thallous Chloride Tl 201 has been found to accumulate in viable myocardium in a manner analogous to potassium. Experiments employing labeled microspheres in human volunteers have shown that the myocardial distribution of Thallous Chloride Tl 201 correlates well with regional perfusion.

In clinical studies, thallium images have been found to visualize areas of infarction confirmed by electrocardiographic and enzyme changes. Regions of transient myocardial ischemia corresponding to areas perfused by coronary arteries with partial stenoses have been visualized when thallium was administered in conjunction with an exercise stress test. It is usually not possible to differentiate recent from old myocardial infarction, and no exact differentiation can be made between recent myocardial infarction and ischemia.

After intravenous administration, Thallous Chloride Tl 201 clears rapidly from the blood with maximal concentration by normal myocardium occurring at about ten minutes.

INDICATIONS AND USAGE: Thallous Chloride Tl 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction.

It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

CONTRAINDICATIONS: None known.

WARNINGS: 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. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

Ideally, examinations using radiopharmaceutical drug products—especially those elective in nature—of women of childbearing capability should be performed during the first ten days following the onset of menses.

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 thallium Tl 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.

Thallous Chloride Tl 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 should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

No long-term animal studies have been performed to evaluate carcinogenic potential.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Thallous Chloride Tl 201 should be used in pregnant women only when clearly needed.

It is not known whether this drug is excreted in human milk. As a general rule nursing should not be undertaken when a patient is administered radioactive material.

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Adverse reactions related to use of this agent have not been reported to date.

DOSAGE AND ADMINISTRATION: The recommended adult (70kg) dose of Thallous Chloride Tl 201 is 1-1.5mCi. Thallous Chloride Tl 201 is intended for intravenous administration only.

For patients undergoing resting thallium studies, imaging is optimally begun within 10-20 minutes after injection. Several investigators have reported improved myocardial-to-background ratios when patients are injected in the fasting state, in an upright posture, or after briefly ambulating.

Best results with thallium imaging performed in conjunction with exercise stress testing appear to be obtained if the thallium is administered when the patient reaches maximum stress and when the stress is continued for 30 seconds to one minute after injection. Imaging should begin within ten minutes post-injection since target-to-background ratio is optimum by that time. Several investigators have reported significant decreases in the target-to-background ratios of lesions attributable to transient ischemia by two hours after the completion of stress testing.

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

Radiopharmaceuticals should be used by persons with specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agencies authorized to license the use of radionuclides.

RADIATION DOSIMETRY

The estimated absorbed radiation dose[2] to an average patient (70kg) from an intravenous injection of a maximum dose of 1.5 millicuries of Tl 201 is shown in Table 4.

Table 4. Radiation Dose Estimates of Thallous Chloride Tl 201: Absorbed Dose/1.5mCi Thallium Tl 201 Administered

	Rads/1.5mCi
Heart	0.51
Small Intestines	0.97
Kidneys	2.2
Liver	0.93
Red Marrow	0.51
Ovaries	0.85
Testes	0.81
Thyroid	1.12
Total Body	0.36

[2] Values listed include a maximum correction of 13% to the radiation doses from Tl 201 due to the radiocontaminants Pb 203 and Tl 202.

HOW SUPPLIED: Thallous Chloride Tl 201 for intravenous administration is supplied as a sterile, non-pyrogenic solution containing at calibration time, 1mCi/ml of Thallous Tl 201, 9mg/ml sodium chloride, and 9mg/ml of benzyl alcohol. The pH is adjusted to between 4.5-6.5 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 1.5, 3.0, 4.5, 6.0, and 9.0 millicuries of Thallous Tl 201.

The contents of the vial are radioactive. Adequate shielding and handling precautions must be maintained.

Catalog Number NRP-427

New England Nuclear
Medical Diagnostics Division
601 Treble Cove Rd., North Billerica, MA 01862

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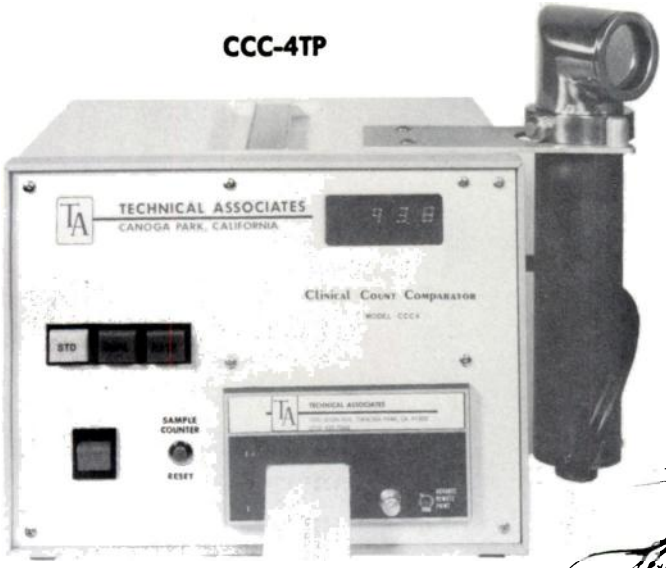

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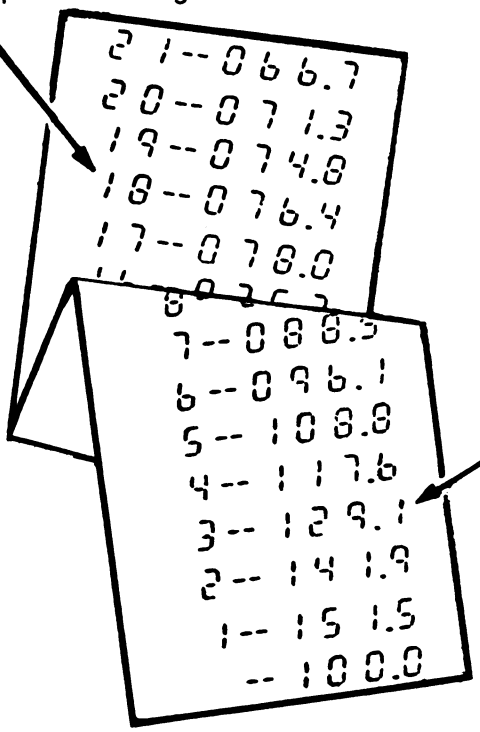

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- Operator **error protection**
- Versatile — settable for other isotopes

TECHNICAL ASSOCIATES

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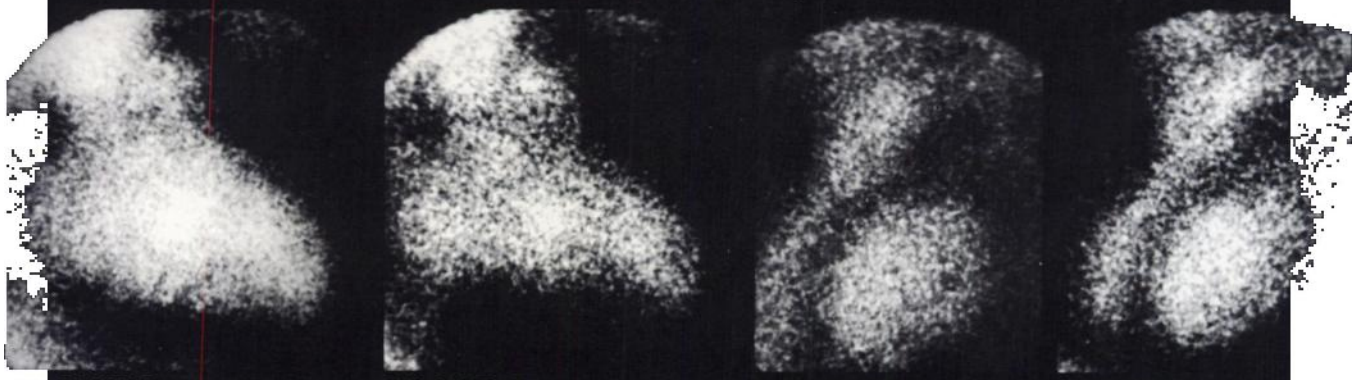
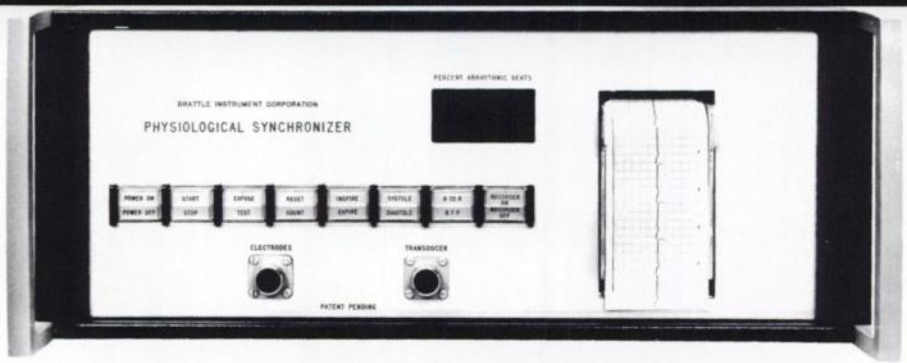
Help your cardiologist study heart kinetics non-invasively with Brattle-gated scintiphotos.



RAO, DIASTOLE — RAO, SYSTOLE — LAO, DIASTOLE — LAO, SYSTOLE

The RAO view shows akinesis of the lower antero-lateral wall and apex; and contraction of the inferior wall and high up the antero-lateral wall. The LAO view shows good contraction posteriorly and akinesis of the septal aspect of the chamber. Patient was injected IV with 20mCi of ^{99m}Tc-labelled Human Serum Albumin. The agent was prepared using the New England Nuclear Electrolysis Kit for labelling HSA. Write or call for a portfolio of Brattle-gated lung, liver and heart studies.



No knobs, no meters, no errors
The spartan panel above tells the second-best part of our story. If you want to photograph peak systole, press the SYSTOLE button. If, say, you want systole only at full expiration, press the EXPIRATION button as well. If only breathing is relevant, don't press the heart button.

The Brattle is connected to the patient and to your gamma (or x-ray or ultrasonic) camera. Whenever the patient is in the selected phase, both the scope and the scaler on your gamma camera are gated ON, and film is exposed. Otherwise, they are OFF.

Brattles lock onto patients—and stay locked on
It doesn't matter if the patient's heart rate and breathing depth change while he's under the collimator because we stay right with him. Brattles contain an ECG to track heart, a plethysmograph to track respiration, and a tiny computer to deduce systole and diastole times from the heart signal. And because it's all built in, your operator need not be a physiologist.

We don't cover our tracks—we print them
The panel lights flash whenever the patient reaches the selected phases; and pushing the RECORDER-ON button gets you an ECG tracing marked with breathing and camera-on times. You can verify function before, during and after exposure.

A single pair of axillary electrodes captures both heart and breath
It's easy. And we supply disposable, pre-filled electrodes.

Some Brattles have been in clinical use for over three years—in community and major hospitals
More than half of our instruments are in community hospitals and the list is growing rapidly. Upon request, we'll supply names of happy users in your area.

What's the next step? Get in touch
Ask your NEN man about Brattles and HSA Kits. He can show you a portfolio of clinical pictures and arrange to have one of our people give you a demo. Or write or call us direct. We'll send you brochures on this and other models, and will give you your own set of clinical pictures and a bibliography on gated scintigraphy. If you wish, we'll even make you a Brattle owner. (This is the best part of our story.)

Brattle Instrument Corporation

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