



Xenon

Xenon Xe 133

**How you like it
When you like it**

How you like it

MPI Xenon Xe 133 is now available in four product configurations—from unit dose to bulk:

- Ventilation Study System (V.S.S.)
- 10 mCi vials
- 20 mCi vials
- 1.3-1.7 Ci ampules (crushable and breaksealed)

When you like it

MPI Xenon Xe 133 delivery and calibration schedule—utmost convenience and optimal product use:

Product	1st Rec.	Calibrated 12:00 Noon
V.S.S.	Monday	Thursday
10 & 20 mCi vials	Monday	Thursday
	Thursday	Monday
1.3-1.7 Ci Ampules	Monday	Prior Friday

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

Xenon Xe 133-V.S.S. For the study of pulmonary ventilation.

Xenon Xe 133 Gas Ampule & MPI Xenon Xe 133 Gas Vial.

For the study of pulmonary ventilation and assessment of cerebral blood flow.

DESCRIPTION: The Xenon Xe 133-Ventilation Study System consists of a sealed frangible capsule containing 10 millicuries \pm 20% of Xenon Xe 133 gas at calibration time and date with less than 1% carrier xenon in air. Xenon Xe 133 Gas vials is supplied as a carrier-free gas in concentrations of 10 to 50 mCi per milliliter of gas for inhalation. Xenon Xe 133 Gas Ampule is supplied as a carrier-free gas in 4 ml crushable or break-sealed glass ampule in concentrations of 0.43 to 0.33 Curie/ml. Xenon Xe 133 is produced by fission of Uranium-235. It is chemically and physiologically related to elemental xenon, a non-radioactive monoatomic gas which is physiologically inert except for anesthetic properties as high doses.

CONTRAINDICATIONS: None known.

WARNINGS: Xenon Xe 133 should not be administered to children or to patients who are pregnant, or to nursing mothers unless the benefits to be gained outweigh the potential hazards. Ideally, examinations using radio-pharmaceuticals, 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. 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.

There are no well-controlled studies in pregnant women which allow any conclusions as to the safety of Xenon Xe 133 for the fetus, Xenon Xe 133 should be used in pregnant women only when clearly needed.

Concentrated Xenon Xe 133 gas supplied in ampule must be diluted to the activity range appropriate to the route of administration.

PRECAUTIONS: Xenon Xe 133 gas 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.

Exhaled Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers for such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic.

ADVERSE REACTIONS: Adverse reactions specifically attributable to Xenon Xe 133 have not been reported.

HOW SUPPLIED: Each Ventilation Study System (V.S.S.) contains Xenon Xe 133 in a sealed frangible capsule containing 10 millicuries \pm 20% at calibration time and date stated on the label. Each Xenon Xe 133 Gas ampule is supplied in 4 ml crushable or break-sealed ampules containing 1.7 to 1.3 Curies. Each Xenon Xe 133 Gas vial contains 10 or 20 mCi of gas.

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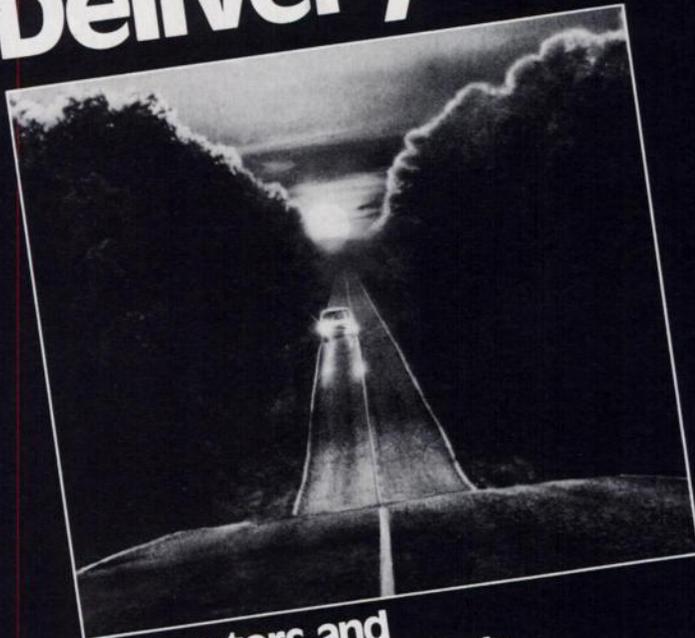
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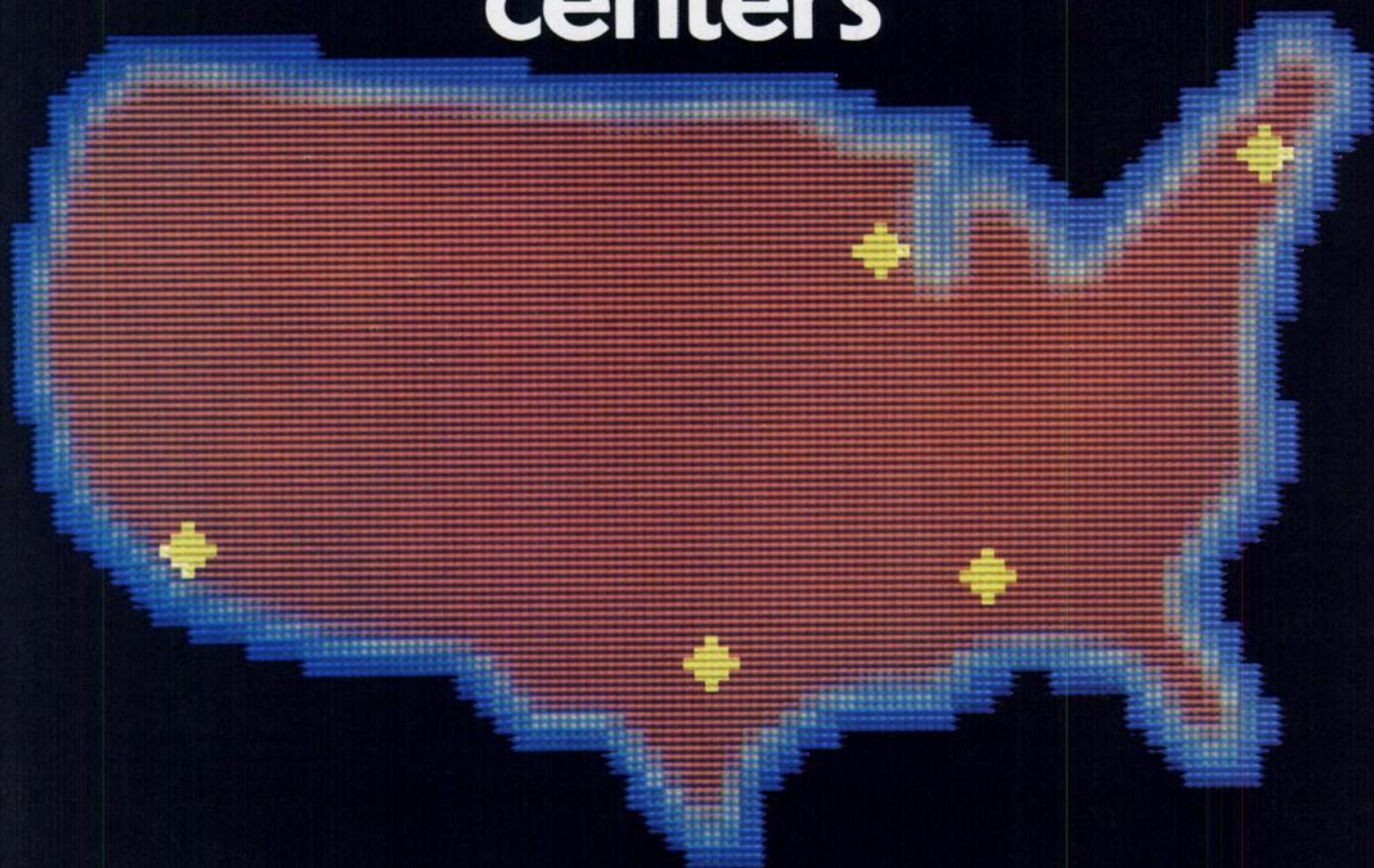
to Nuclear Medicine

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*In a recent independent survey of 400 nuclear medicine departments. Data on file at Mallinckrodt.

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From: DIFFERENCES BETWEEN Tc-99m-MDP STABILIZED AND UNSTABILIZED. K.T. Study, K.A. Reed, and D.L. Laven. University of New Mexico, Albuquerque, NM; reprinted with author's permission from J.N.M.T., Vol. 8, No. 2, p. 127. Study based on biodistribution in Swiss-Webster mice.



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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 fer-

tility 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.



FROM ATOM TO IMAGE

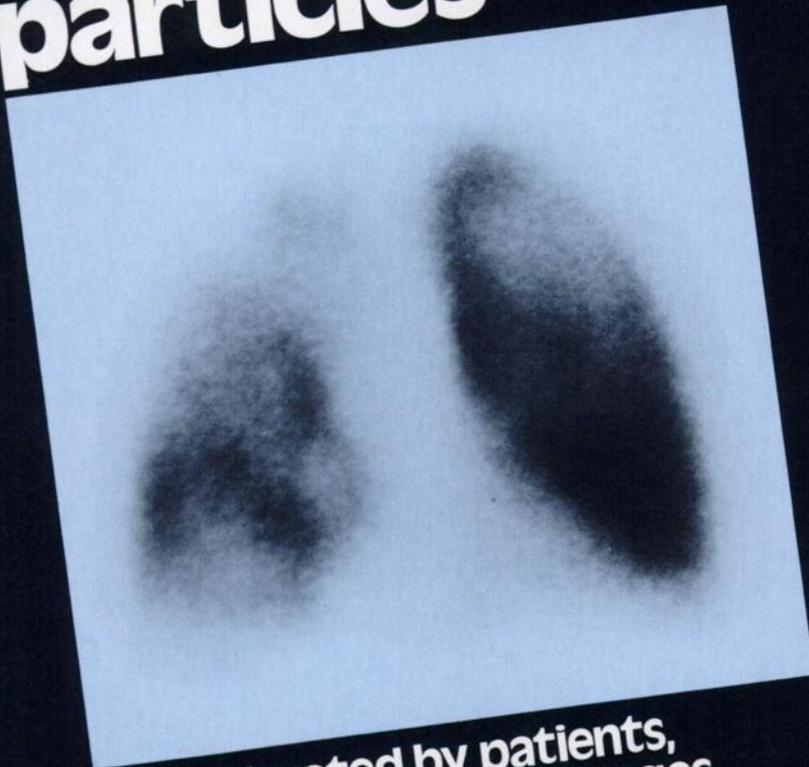
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TechneScan® MAA
Technetium Tc 99m Albumin Aggregated Kit

**The right size
particles**



**Well tolerated by patients,
it provides excellent images**

Mallinckrodt's MAA typically has a particle size of 10 to 40 microns. This controlled particle size range, plus the fact that there is no tendency to agglomerate, gives you excellent lung perfusion images. TechneScan® MAA is well-tolerated and excretion is virtually complete in 24 to 48 hours, with no evidence of antigenicity to date. This convenient one step procedure can be prepared in 20 minutes.

For more information about the TechneScan MAA Kit, call your Mallinckrodt representative.

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For technical assistance, it is **800-325-8181**
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See brief summary on following page.

**THE
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to Nuclear Medicine

MALLINCKRODT, INC., Post Office Box 5840, St. Louis, MO 63134

Mallinckrodt®
Diagnostics

TechneScan® MAA

TechneScan Tc 99m Albumin Aggregated Kit
(Lyophilized, Multi-Dose Kit)

Diagnostic — For Intravenous Use

DESCRIPTION

The **TechneScan® MAA** 10-milliliter vial contains a sterile, pyrogen-free lyophilized mixture of 2.0 milligrams of aggregated albumin human, 0.5 milligrams albumin human, 120 micrograms of stannous chloride (dihydrate), 80 milligrams of lactose, 24 milligrams of succinic acid and 1.4 milligrams of sodium acetate. Hydrochloric acid or sodium hydroxide is added for pH adjustment. **TechneScan MAA** is prepared from albumin that was nonreactive when tested for hepatitis B antigen (HBsAg) by radioimmunoassay. Each vial contains approximately $8 \times 4 \times 10^6$ aggregated albumin particles. The particle size distribution of the aggregated albumin is such that not less than 90 percent are 10 to 90 microns in size. Typically, approximately 90 percent are within the 10 to 40 micron range. There are no aggregated albumin particles greater than 150 microns in size. Reconstitution of **TechneScan MAA** with sterile, non-pyrogenic sodium pertechnetate Tc-99m provides an aqueous suspension of technetium Tc-99m albumin aggregated injection, with a labeling efficiency of 90 percent or greater.

Physical Characteristics

TechneScan Tc-99m decays by isomeric transition with a physical half-life of 6.02 hours¹. Photons that are useful for detection and imaging are listed in Table 1.

¹Martin, M.J., Nuclear Decay Data for Selected Radionuclides, ORNL Report #5114, p. 24, March, 1976.

Table 1. Principal Radiation Emission Data

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

External Radiation

The specific gamma ray constant for technetium Tc-99m is 0.8 R/mCi-hr at 1 cm. The first half value thickness of lead (Pb) for technetium Tc-99m is 0.2 mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 2.7 mm of Pb will decrease the external radiation exposure by a factor of about 1000.

Table 2. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) mm	Coefficient of Attenuation
0.2	0.5
0.95	10 ⁻¹
1.8	10 ⁻²
2.7	10 ⁻³
3.6	10 ⁻⁴
4.5	10 ⁻⁵

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

Table 3. Physical Decay Chart; Technetium Tc-99m Half-Life 6.02 Hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	8	0.398
1	0.891	9	0.355
2	0.794	10	0.316
3	0.708	11	0.282
4	0.631	12	0.251
5	0.562	18	0.126
6	0.501	24	0.063
7	0.447		

*Calibration Time

CLINICAL PHARMACOLOGY

Within 1-5 minutes of intravenous injection, over 90 percent of the technetium Tc-99m aggregated albumin particles are trapped in the arterioles and capillaries of the lung.

Organ selectivity is a direct result of particle size. Below 1-10 microns, the albumin aggregates are taken up by the reticuloendothelial system. Above 10-15 microns, the aggregates become lodged in the lung capillaries by a purely mechanical process. Distribution of aggregated albumin in the lungs is a function of regional pulmonary blood flow.

In animal tissue distribution studies, measurements of retained activity showed a lung to liver ratio of about 70:1 within the first thirty minutes. Elimination of the technetium Tc-99m albumin aggregated from the lungs occurs with a biological half-life of about 6.2 hours. Cumulative urinary excretion studies show an average of about 75% elimination of the injected Tc-99m dose 24 hours post-administration.

Elimination of the technetium Tc-99m albumin aggregates from the normal and abnormal human lungs occurs with a biological half-life of 10.8 hours. The effective half-life was estimated to be 3.8 hours for the lung.

Toxicology data are available on request.

INDICATIONS AND USAGE

TechneScan MAA Tc 99m is indicated only for scintigraphic imaging of the lungs as an adjunct to other diagnostic procedures whenever information about pulmonary circulation is desired.

CONTRAINDICATIONS

TechneScan MAA Tc 99m should not be administered to patients with severe pulmonary hypertension.

The use of **TechneScan MAA Tc 99m** is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

WARNINGS

The possibility of allergic reactions should be considered in patients who receive multiple doses of **TechneScan MAA Tc 99m**.

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

This radiopharmaceutical preparation should not be administered to persons under the age of 18, to pregnant women or to nursing mothers unless the expected benefits to be gained outweigh the potential risks.

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

In cases of right-to-left cardiac shunt, additional risk may exist due to the rapid entry of aggregated albumin particles into the systemic circulation.

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

The labeling reactions involved in preparing **TechneScan MAA Tc 99m** depend upon maintaining tin in the reduced state. Any oxidants present in the sodium pertechnetate Tc-99m may thus adversely affect the quality of the preparation. Hence, sodium pertechnetate Tc-99m containing oxidizing agents are not suitable for preparation of **TechneScan MAA Tc 99m**.

The contents of the **TechneScan MAA** vial are sterile and pyrogen-free. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiopharmaceutical.

TechneScan MAA Tc 99m is a suspension and as such the particles will settle with time. Failure to mix the vial contents adequately before use may result in a non-homogeneous suspension with a resulting non-uniform distribution of radioactivity in the lung.

It is also recommended that, because of the increasing probability of agglomeration with aging, a batch of technetium Tc-99m albumin aggregated injection will not be used after eight hours from the time of reconstitution. Refrigerate at 2° to 8°C after reconstitution. If blood is withdrawn into the syringe, unnecessary delay prior to injection may result in clot formation in situ.

The contents of the vial are under a nitrogen atmosphere and should be protected from air. On reconstitution with pertechnetate Tc-99m, the contents of the vial should be mixed by gentle swirling to avoid changes in particle size. Do not use if clumping or foaming of the contents is observed.

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 albumin aggregated 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.

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.

ADVERSE REACTIONS

The literature contains reports of deaths occurring after the administration of aggregated albumin to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparation of technetium Tc-99m albumin aggregated injection have been reported.

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

DOSAGE AND ADMINISTRATION

The recommended intravenous dose range for the average patient (70 kg) is 1 to 4 millicuries. The volume of the dose may vary from 0.4 to 1.0 ml.

The recommended number of aggregated albumin particles to be administered per dose is 200,000-1,200,000 with the suggested number being approximately 600,000.

NOTE: When large millicurie size generators are used, the eluate (yield of technetium Tc-99m) may be higher than 20 millicuries per milliliter. Before use, such eluates should be diluted with sterile, pyrogen-free saline to ensure that at least 5.0 milliliter of sodium pertechnetate Tc-99m solution is added to each reaction vial.

While the number of particles available per millicurie dose of **TechneScan MAA Tc 99m** will vary corresponding to the physical decay of technetium Tc-99m which has occurred, the particles available in any specific dose may be estimated from the following table.

PARTICLES/DOSE x 10²⁶
(X = 8 x 10⁶ PARTICLES/VIAL)

mCi Tc-99m added to vial	1 mCi	2 mCi	3 mCi	4 mCi
20	0.40	0.80	1.20	1.60
30	0.27	0.54	0.81	1.08
40	0.20	0.40	0.60	0.80
50	0.16	0.32	0.48	0.64
60	0.13	0.26	0.39	0.52

*The particles per millicurie dose will increase in relation to the physical decay of Tc-99m such that at six hours (one half-life) after preparation, the values in the table will increase by a factor of two.

In cases of right-to-left cardiac shunt the number of aggregated albumin particles administered per dose should be reduced to the minimum feasible.

The patient dose should be measured by a suitable radioactivity calibration system for total radioactivity immediately prior to administration. It is also recommended that the radiochemical purity be checked prior to administration. Resuspend particles by repeated inversion of the syringe immediately prior to injection. **TechneScan MAA Tc 99m** is injected intravenously, without aspirating, over a 20- to 30-second interval with the patient in the supine position. If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to clot formation in the syringe. Do not back flush the syringe. For optimal results, lung imaging should begin as soon as possible. It is recommended the **TechneScan MAA Tc 99m** not be injected through intravenous tubing because of the occasional observation of "hot spots" in the lung.

Radiation Dosimetry

The estimated absorbed radiation doses² from an intravenous injection of 4 millicuries of **TechneScan MAA Tc 99m** are shown in Table 4.

²Method of Calculation: A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, p. 7 (1968)

Table 4. Absorbed Radiation Dose

Tissue	rads/4 mCi
Lungs	1.044
Liver	0.116
Spleen	0.072
Kidneys	0.252
Thyroid	0.032
Bladder	0.544
Ovaries	0.036
Testes	0.028
Total Body	0.048

HOW SUPPLIED TechneScan MAA Kit

Catalog Number Technetium Tc 99m Albumin Aggregated Kit
093 (Lyophilized)

Kit Contains:

5 — Reaction Vials for the preparation of Technetium Tc-99m Albumin Aggregated Injection
Reaction Vial Contains (in lyophilized form):

2.0 mg Aggregated Albumin Human
0.5 mg Albumin Human
120 µg Stannous Chloride (Dihydrate)
80 mg Lactose
24 mg Succinic Acid
1.4 mg Sodium Acetate
Hydrochloric Acid or Sodium Hydroxide is added for pH adjustment. Each Vial contains $8 \times 4 \times 10^6$ aggregated albumin particles. **TechneScan® MAA** contains no preservatives; after reconstitution, the shielded vial should be stored at 2° to 8°C.

Included in each package is one (1) package insert and 5 radio-assay information string tags.

DIRECTIONS

Procedural Precautions
SOLUTIONS OF SODIUM PERTECHNETATE Tc-99m WHICH CONTAIN OXIDIZING AGENTS (i.e., sodium hypochlorite or hydrogen peroxide) SHOULD NOT BE USED.

Solutions obtained from the following technetium Tc-99m generators were tested and found to be acceptable for use with **TechneScan MAA: Mallinckrodt's Ultra-TechneKow® FM Generators, New England Nuclear's Technetium-99m Generator and Squibb's Minitec® Generator.** Other sources of technetium Tc-99m can be used if the user has demonstrated that they are compatible with **TechneScan MAA**.

All transfer and vial stopper entries must be done using aseptic techniques.

PROCEDURE

NOTE: The radioactive material should be shielded at all times during preparation.

1. A reaction vial is removed from the refrigerator and approximately 5 minutes are allowed for the contents to come to room temperature.
2. Affix "Caution — Radioactive Material" label string tag to reaction vial.
3. Place reaction vial in a lead shield fitted with a lid and having a wall thickness of at least 1/2 inch. Do not remove reaction vial from shield except to inspect contents prior to administration. Use adequate shielding to perform the inspection.
4. Sodium pertechnetate Tc-99m solution (5-10 ml) is added to the **TechneScan MAA**. In choosing the amount of technetium Tc-99m radioactivity to be used in the preparation of **TechneScan MAA Tc 99m**, the labeling efficiency, number of patients, administered radioactive dose, and radioactive decay must be taken into account. The recommended maximum amount of technetium Tc-99m to be added to the **TechneScan MAA** is 60 millicuries.
5. The reaction vial is gently agitated for a few seconds and allowed to stand for 15 minutes at room temperature.
6. Calculate the radioactivity concentration of the **TechneScan MAA Tc 99m** and fill in the appropriate information on the string tag.
7. Prior to withdrawing a dose, the contents of the reaction vial should be gently agitated sufficiently to effect homogeneous suspension of the aggregated albumin. Store shielded reaction vial at 2° to 8°C when not in use and discard after 8 hours from the time of reconstitution.

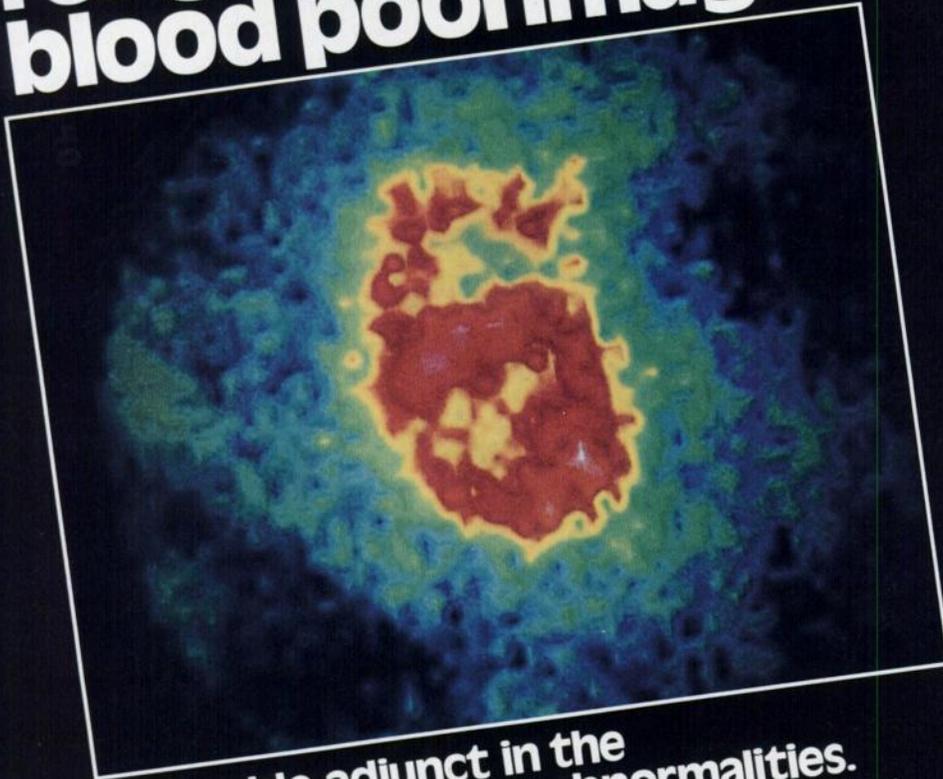
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Mallinckrodt, Inc.
St. Louis, MO 63134

TechneScan® PYP®
Technetium Tc 99m Pyrophosphate Kit

**The only one approved
for gated cardiac
blood pool imaging**



**A valuable adjunct in the
diagnosis of cardiac abnormalities.**

With this "exclusive indication," TechneScan PYP gives you the additional diagnostic capability of dynamic studies of left ventricular function and wall motion and identification of ventricular aneurysm. This is in addition to the indication of TechneScan PYP as an adjunct in the diagnosis of acute myocardial infarction.

For more information about TechneScan PYP—and all the other organ-imaging kits available from Mallinckrodt—just call your Mallinckrodt representative.

For orders call:

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For technical assistance, it is **800-325-8181**

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See brief summary on following page.

**THE
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COMMITMENT**

to Nuclear Medicine

MALLINCKRODT, INC., Post Office Box 5840, St. Louis, MO 63134



Technescan® PYP®

Technetium Tc 99m Pyrophosphate Kit

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 by 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**
Technetium Tc 99m Pyrophosphate Kit.

Kit Contains:

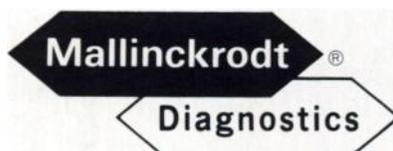
5—Stannous Pyrophosphate Reaction Vials (lyophilized) for the preparation of Technetium Tc-99m Stannous Pyrophosphate.

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.

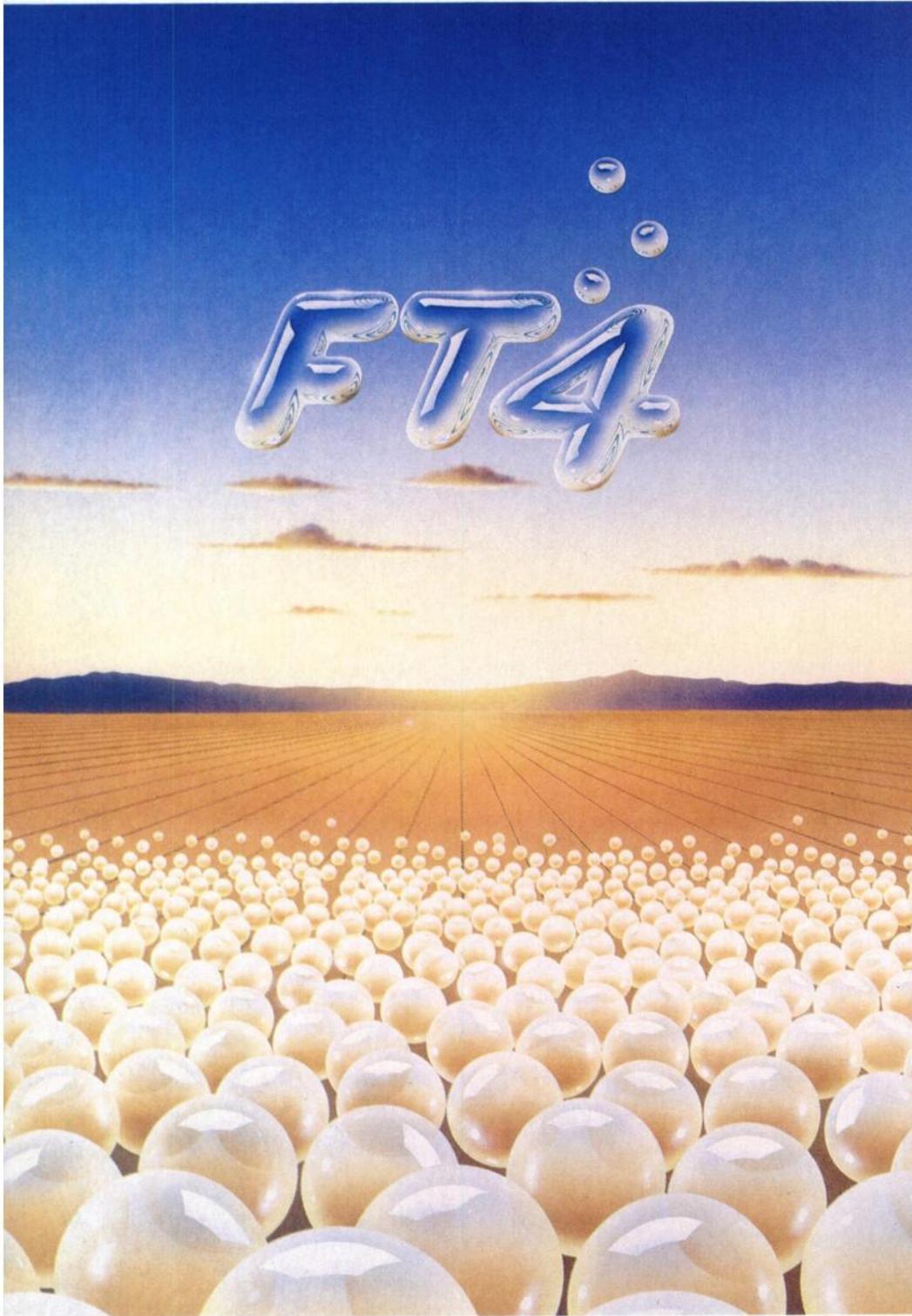
5—Radioassay Information String Tags.

For complete prescribing information, see package insert.



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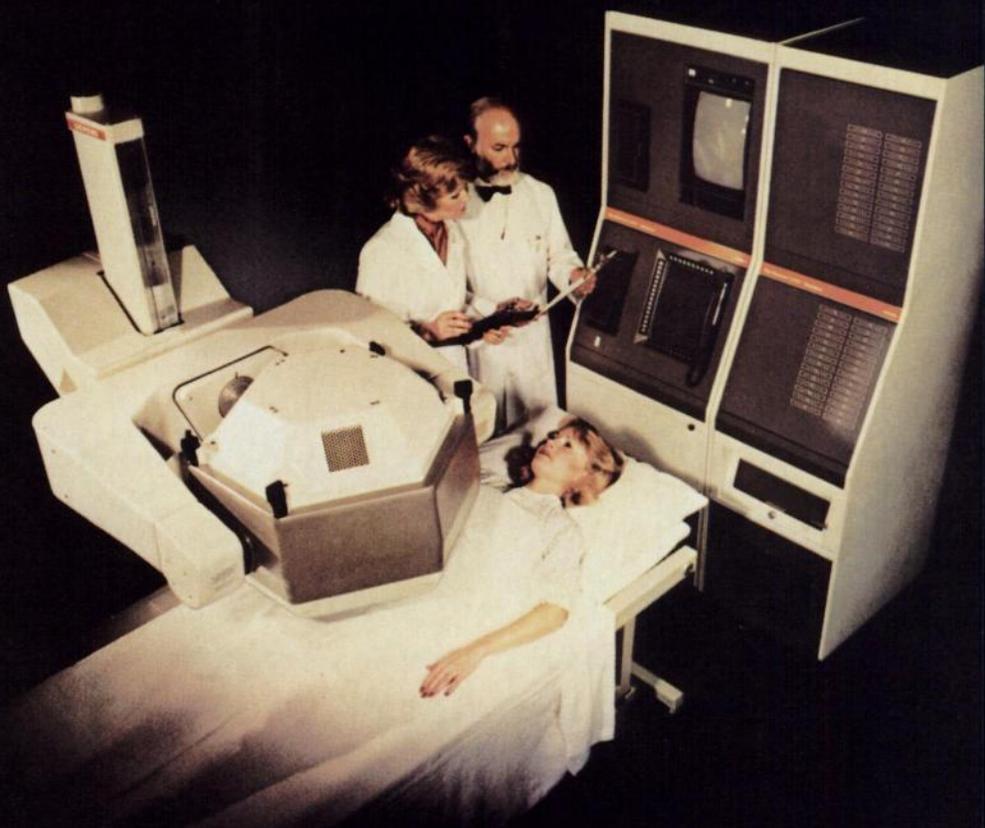
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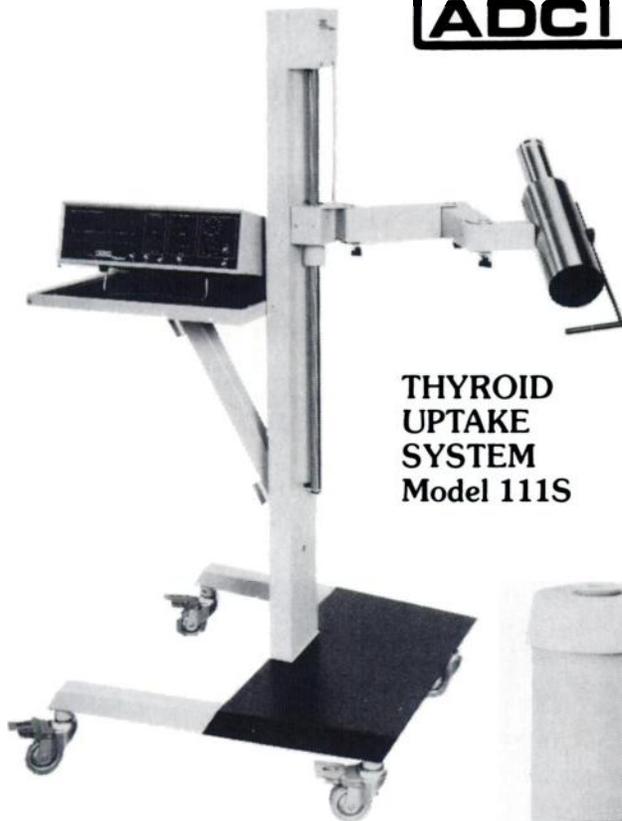


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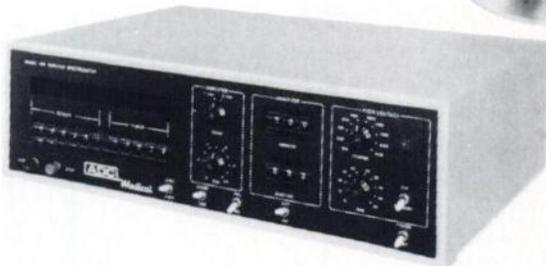
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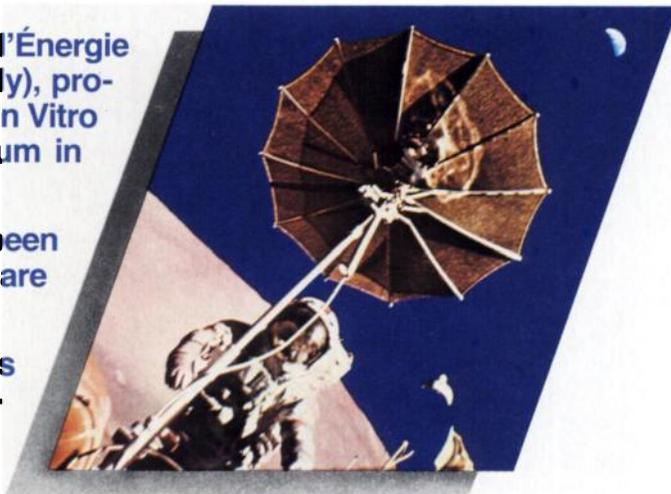
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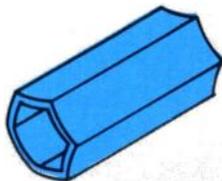
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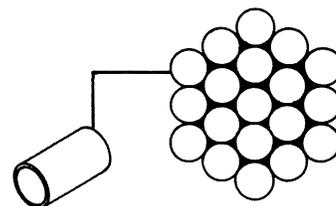
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NU TECH introduces HEX ARRAY

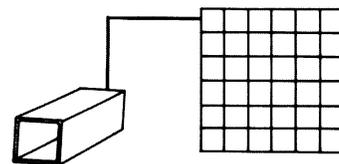
A series of collimators designed to *optimize* the clinical performance of today's generation of High Resolution Gamma Cameras and *improve* performance of older systems.



Round Holes lose efficiency/speed due to the large interstitial areas of lead that occur between individual circular openings.

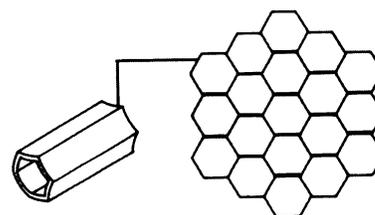


Square Holes overcome this speed disadvantage, but distort image linearity and resolution due to differential bore sizes.



Hex Holes minimize the dimensional differences between the "Flats" and "Corners" of the bore. Linearity and resolution distortions are minimized.

In addition the efficiency losses associated with the "dead lead" area in round hole designs are completely eliminated.



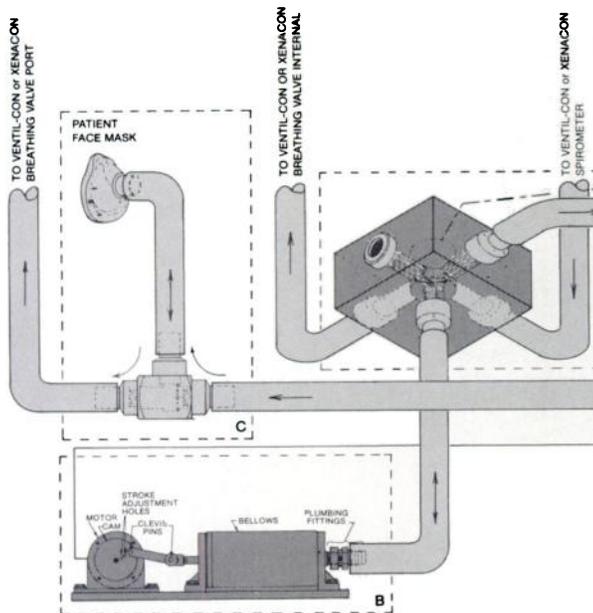
CONCLUSION: Clinical and Engineering Studies have conclusively demonstrated that the use of the HEX ARRAY technology has resulted in a line of collimators offering superior SENSITIVITY, RESOLUTION, AND LINEARITY.

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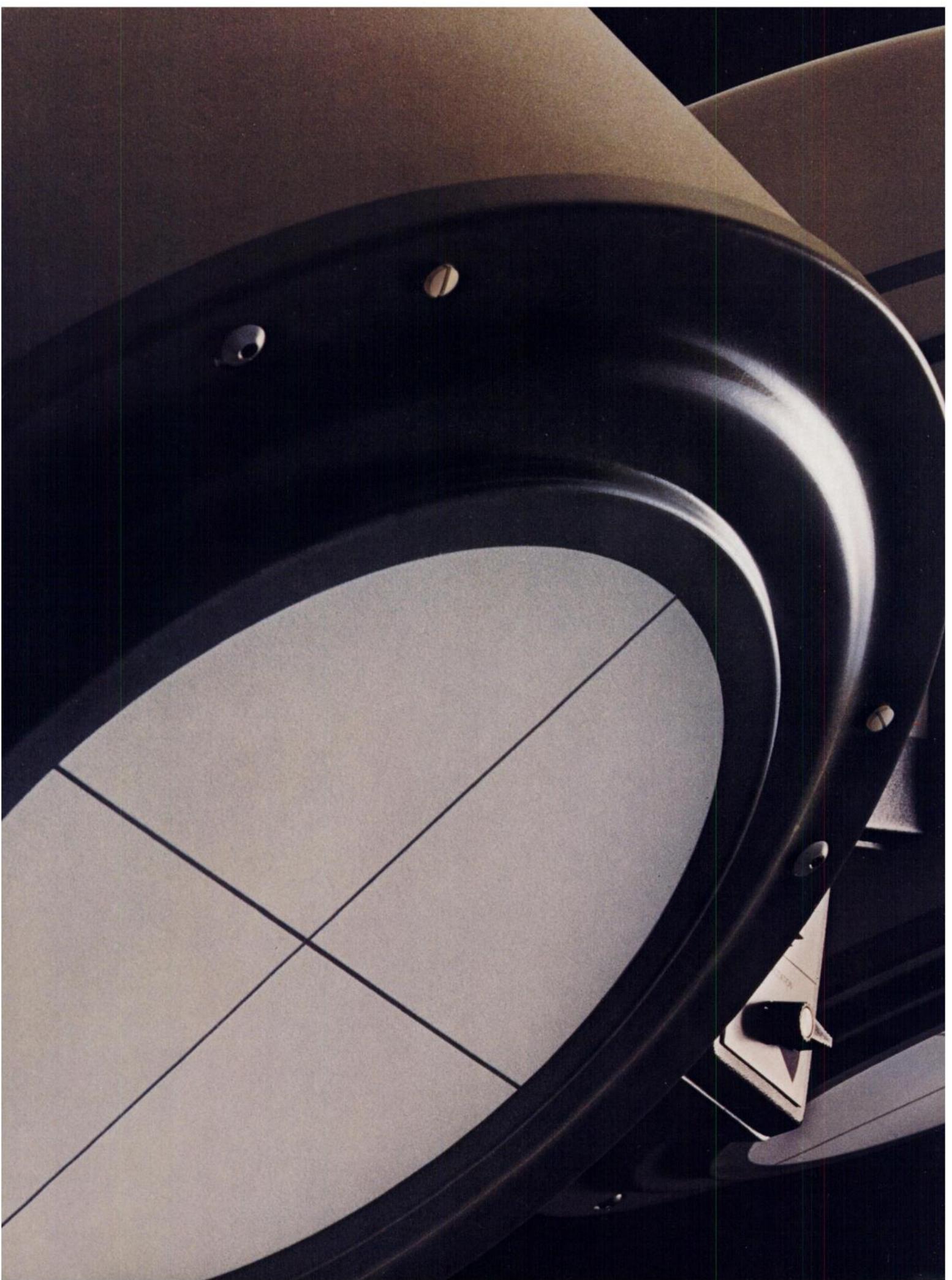
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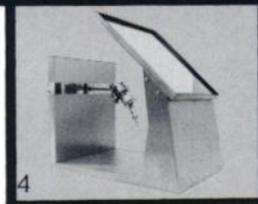
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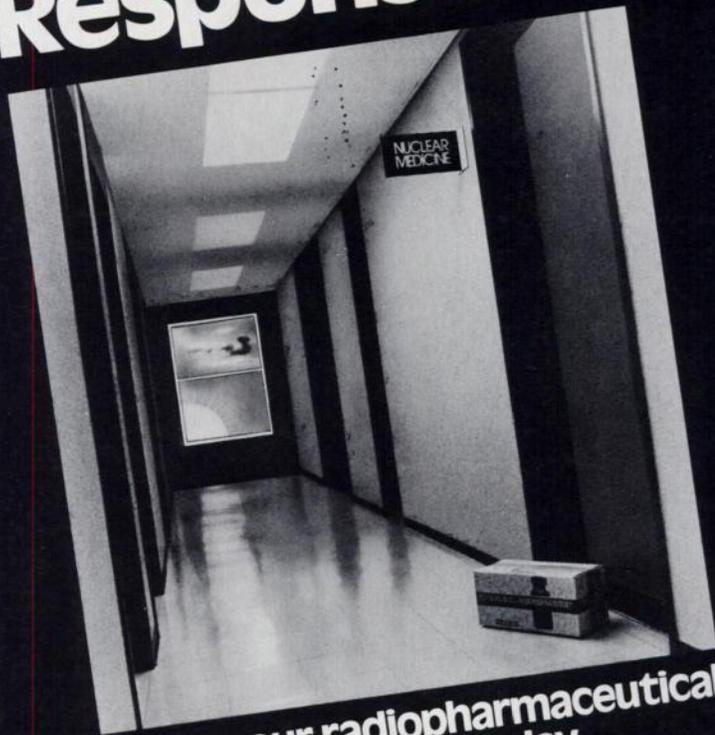


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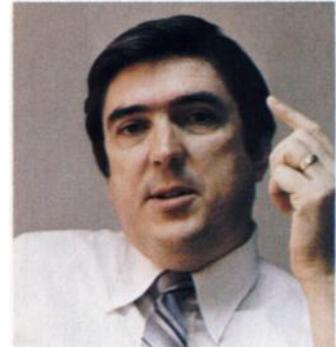
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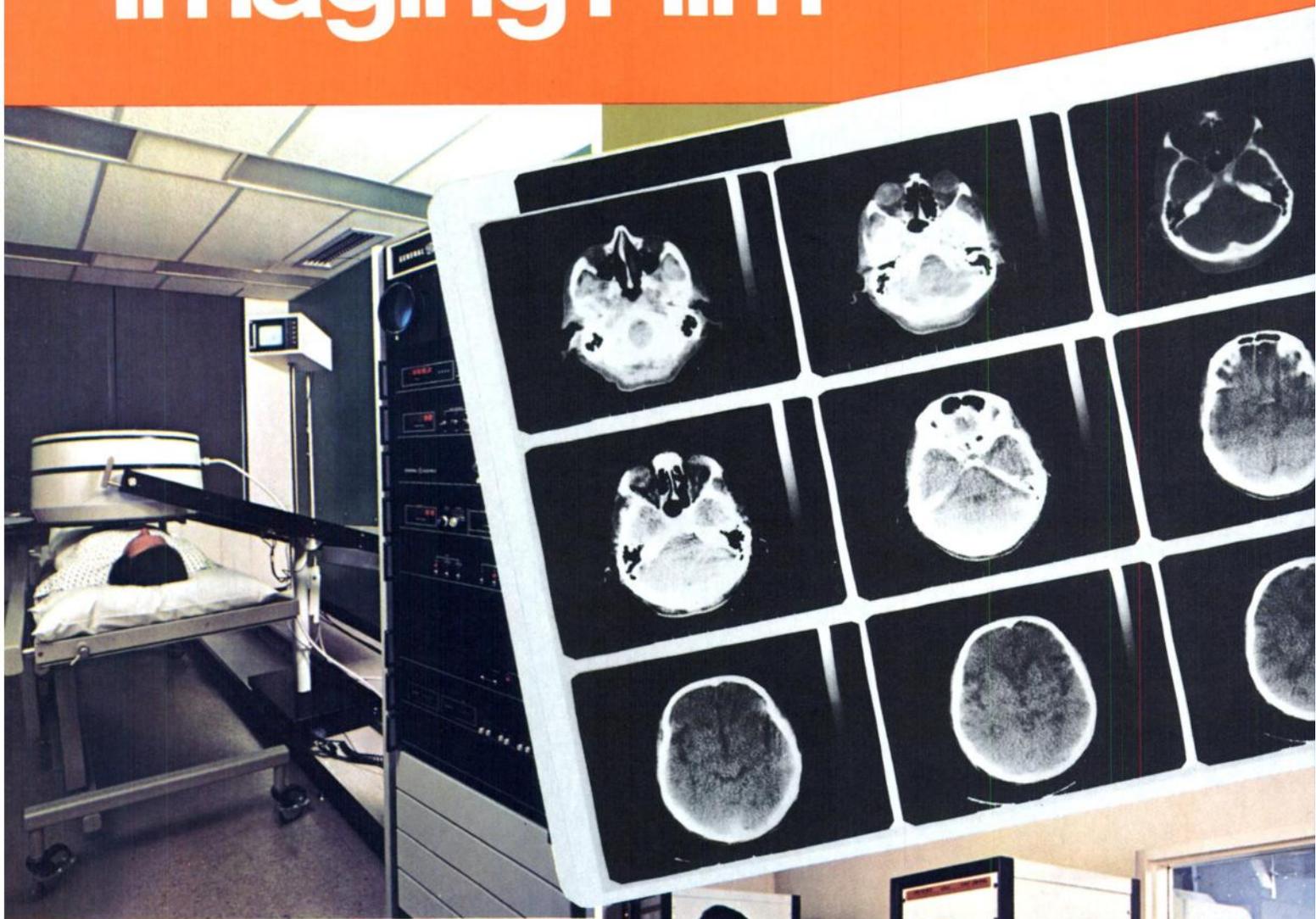


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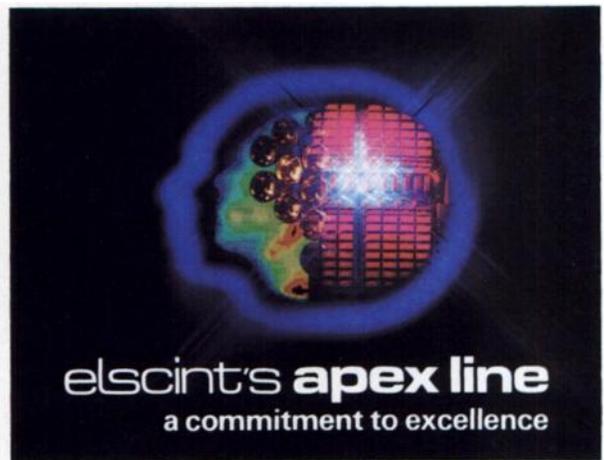
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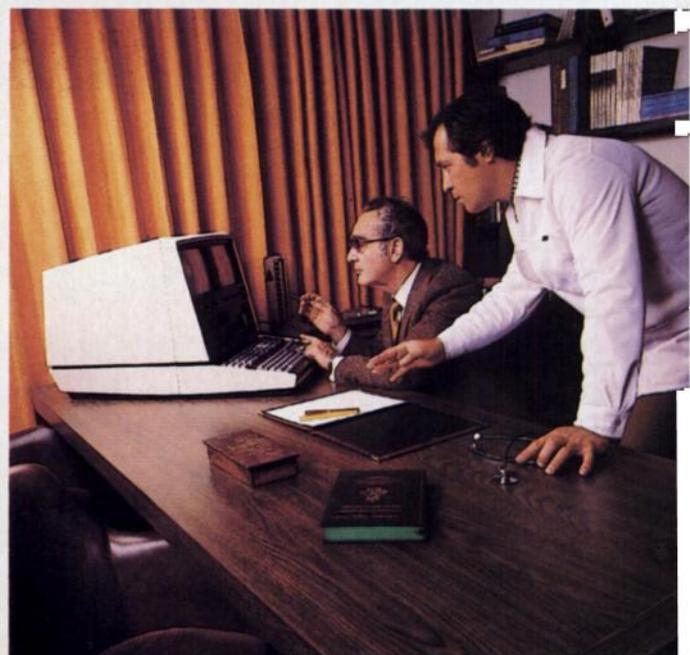
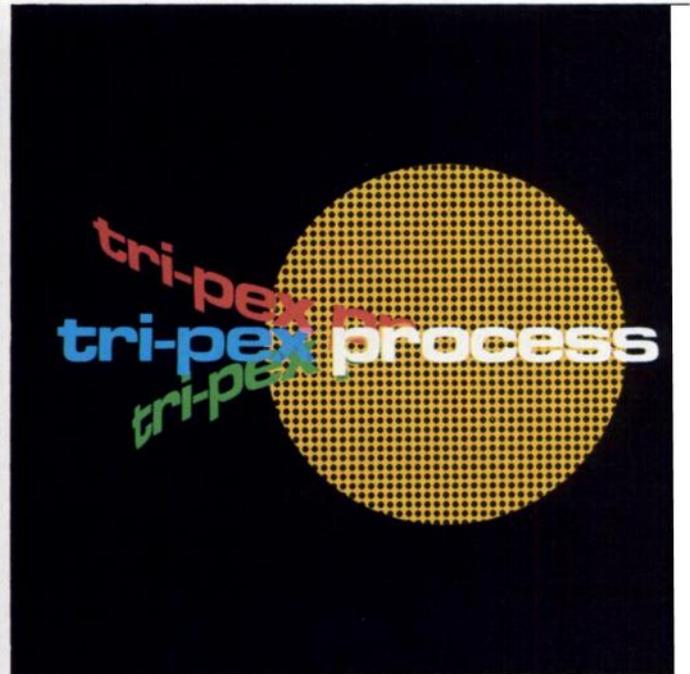
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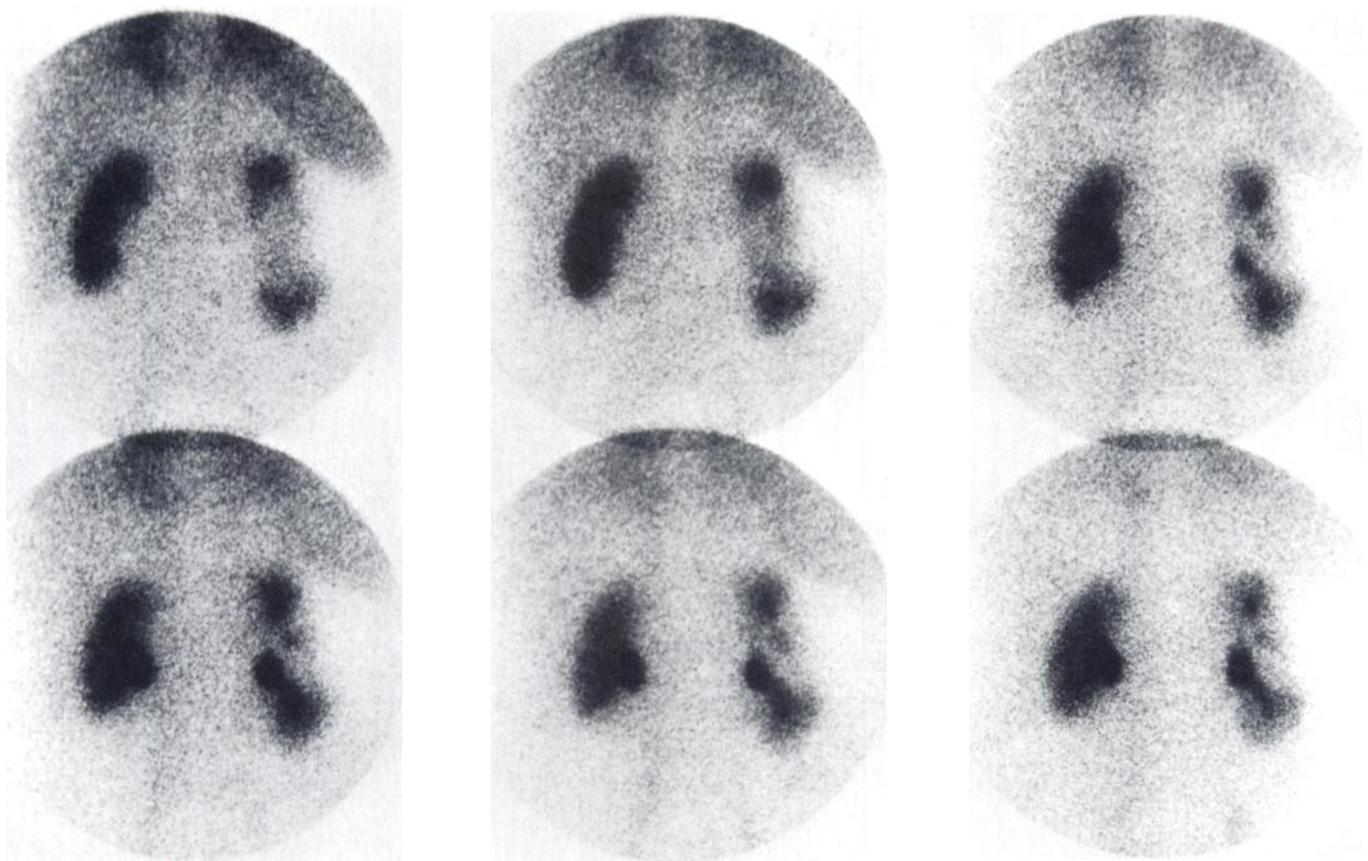
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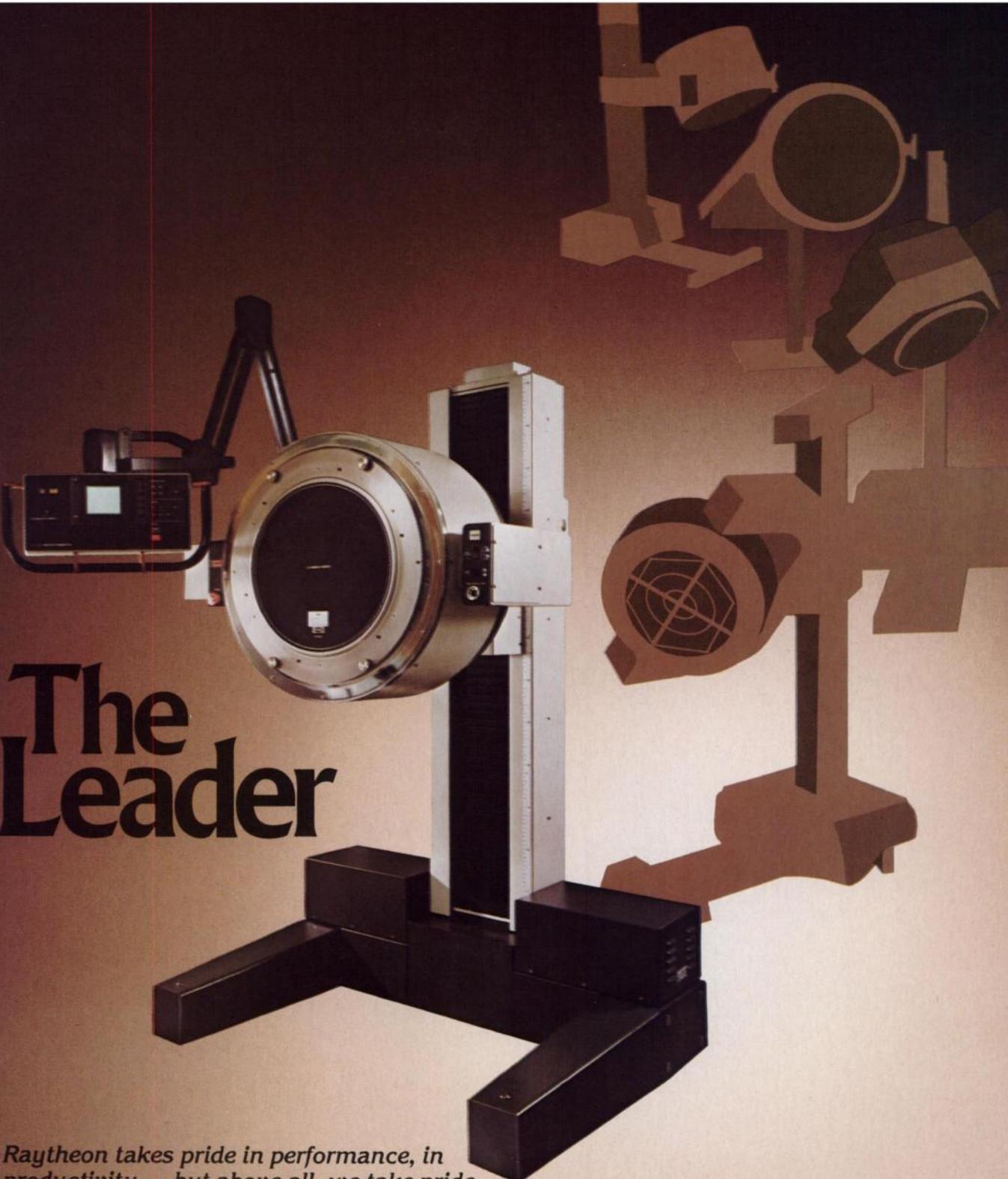
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See brief summary on following page.

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Mallinckrodt[®]
Diagnostics

TechneScan[®] MDP—Technetium Tc 99m Medronate Sodium Kit

DIAGNOSTIC

DESCRIPTION

The kit consists of reaction vials which contain the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce technetium Tc-99m medronate for diagnostic use by intravenous injection.

Each 10 ml reaction vial contains 10 mg medronic acid complexed with 0.8 mg (min.) stannous chloride (0.64 mg maximum tin) in lyophilized form under an atmosphere of nitrogen. Sodium hydroxide or hydrochloric acid have been used for pH adjustments. The addition of sodium pertechnetate Tc-99m sterile solution produces a rapid labeling which is essentially quantitative and which remains stable *in vitro* throughout the useful life of the preparation. No bacteriostatic preservative is present.

The precise structure of the reaction vial complex or of its technetium labeled form is not known at this time.

PHYSICAL CHARACTERISTICS

Technetium Tc-99m decays by isomeric transition with a physical half-life of 6.02 hours.¹ The principal photon that is useful for detection and imaging studies is listed in Table I.

TABLE I PRINCIPAL RADIATION EMISSION DATA

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

External Radiation

The specific gamma ray constant for Tc-99m is 0.8 R/mCi-hr at 1 cm. The first half value layer is 0.2 mm of Pb. To facilitate control of the radiation exposure from millicurie amounts of this radionuclide, the use of a 2.7 mm thickness of Pb will attenuate the radiation emitted by a factor of about 1,000.

TABLE II RADIATION ATTENUATION BY LEAD SHIELDING

Shield Thickness (Pb) mm	Coefficient of Attenuation
0.2	0.5
0.95	10 ⁻¹
1.8	10 ⁻²
2.7	10 ⁻³
3.6	10 ⁻⁴
4.5	10 ⁻⁵

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

¹Martin, M.J., Ed., *Nuclear Decay Data for Selected Radionuclides*, ORNL Report #5114, p. 24, March, 1976.

TABLE III PHYSICAL DECAY CHART: Tc 99m, half-life 6.02 hours

Hours	Fraction Remaining	Hours	Fraction Remaining
-5	1.778	5	0.562
-4	1.585	6	0.501
-3	1.413	7	0.447
-2	1.259	8	0.398
-1	1.122	9	0.355
0*	1.000	10	0.316
1	0.891	11	0.282
2	0.794	12	0.251
3	0.708	18	0.126
4	0.631	24	0.063

*Calibration time

CLINICAL PHARMACOLOGY

When injected intravenously technetium Tc-99m medronate is rapidly cleared from the blood and accumulates in the skeleton and urine. The skeletal uptake is bilaterally symmetrical being greater in the axial skeleton than in the long bones. Areas of abnormal osteogenesis show altered uptake making it possible to visualize a variety of osseous lesions.

Studies in humans show that, following intravenous injection, about 10% of the injected dose remains in the bloodstream at the end of one hour. This value continues to drop rapidly being down to about 5% at 2 hours. The resultant disappearance curve appears to be tri-exponential, the two fast components accounting for all but a few percent of the injected activity.

Conversely, there is a rapid deposition in bone and rapid urinary excretion. The rapid blood clearance provides bone to soft-tissue ratios which favor early imaging.

INDICATIONS AND USAGE

Technetium Tc-99m medronate is a skeletal imaging agent used to demonstrate areas of altered osteogenesis as seen for example in metastatic bone disease, Paget's disease, arthritic disease and osteomyelitis.

CONTRAINDICATIONS

None known at present.

WARNINGS

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

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

PRECAUTIONS

General

The finding of an abnormal concentration of radioactivity implies the existence of underlying pathology, but further study is required to distinguish benign from malignant lesions.

Technetium Tc-99m medronate 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.

To minimize the radiation dose to the bladder, the patient should be encouraged to void before the examination and as often thereafter as possible for the next 4-6 hours.

The preparation contains no bacteriostatic preservative. Therefore, after labeling with technetium Tc-99m the solution should be stored at 2-8°C and discarded after 6 hours.

The image quality may be adversely affected by obesity, old age and impaired renal function.

Carcinogenesis

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

Pregnancy

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. There have been no studies in pregnant women. 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

At present adverse reactions have not been reported that are specifically attributable to the use of technetium Tc-99m medronate.

DOSAGE AND ADMINISTRATION

The recommended adult dose is 10 to 20 mCi (200 µCi/kg) by slow intravenous injection over a period of 30 seconds. Optimum scanning time is 1 to 4 hours post-injection.

The patient should be encouraged to drink fluids before and after the examination and to void immediately before imaging is started. This is to minimize the contribution of the bladder content to the image.

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

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.

Radiation Dosimetry

The estimated absorbed radiation doses² to an average patient (70 kg) from an intravenous injection of a maximum dose of 20 mCi of technetium Tc-99m medronate are shown in Table IV.

²Method of calculation: A Schema for Absorbed-Dose Calculations For Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, p. 7, 1968.

TABLE IV RADIATION DOSES

Tissue	Absorbed Radiation Dose (rads/20 mCi)
Total Body	0.13
Bone Total	0.70
Red Marrow	0.56
Kidneys	0.80
Liver	0.06
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

HOW SUPPLIED

TechneScan MDP-Technetium Tc 99m Medronate Sodium Kit.

Product No. 088

Each kit consists of 5 reaction vials, each vial containing, in lyophilized form, sterile and non-pyrogenic

Medronic Acid	10 mg
Stannous Chloride (min.)	0.8 mg
(Maximum tin)	0.64 mg

The pH is adjusted to 6.5 to 7.5 with HCl or NaOH prior to lyophilization. The vials are sealed under an atmosphere of nitrogen.

Labels with radiation warning symbols and directions are supplied with each kit.

DIRECTIONS

NOTE: Use aseptic procedures throughout and take precautions to minimize radiation exposure.

To prepare technetium Tc 99m medronate.

1. Remove the central metal disc from a reaction vial and swab the closure with either an alcohol swab or a suitable bacteriostatic agent.
2. Place the vial in a suitable radiation shield. Obtain from a generator 2-10 ml of sterile, pyrogen-free sodium pertechnetate Tc-99m. The recommended maximum amount of technetium Tc-99m to be added to a reaction vial is 200 mCi. Sodium pertechnetate Tc-99m solutions containing an oxidizing agent are not suitable for use.
3. Add the sodium pertechnetate Tc-99m solution to the reaction vial aseptically.
4. Agitate the shielded vial until the contents are completely dissolved. The solution must be clear and free of particulate matter before proceeding.
5. Assay the product in a suitable calibrator, complete the radioassay information tie-on tag with radiation warning symbol and attach it to the vial.
6. Withdrawals for administration must be made aseptically using a sterile syringe and needle.
7. The finished preparation should be refrigerated at 2-8°C when not in use and discarded after 6 hours. This reagent kit is approved by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to Sections 35.14 and 35.100, Group III, of 10 CFR Part 35, or under equivalent licenses of Agreement States.

Manufactured for: MALLINCKRODT, INC., St. Louis, Missouri 63134, U.S.A.
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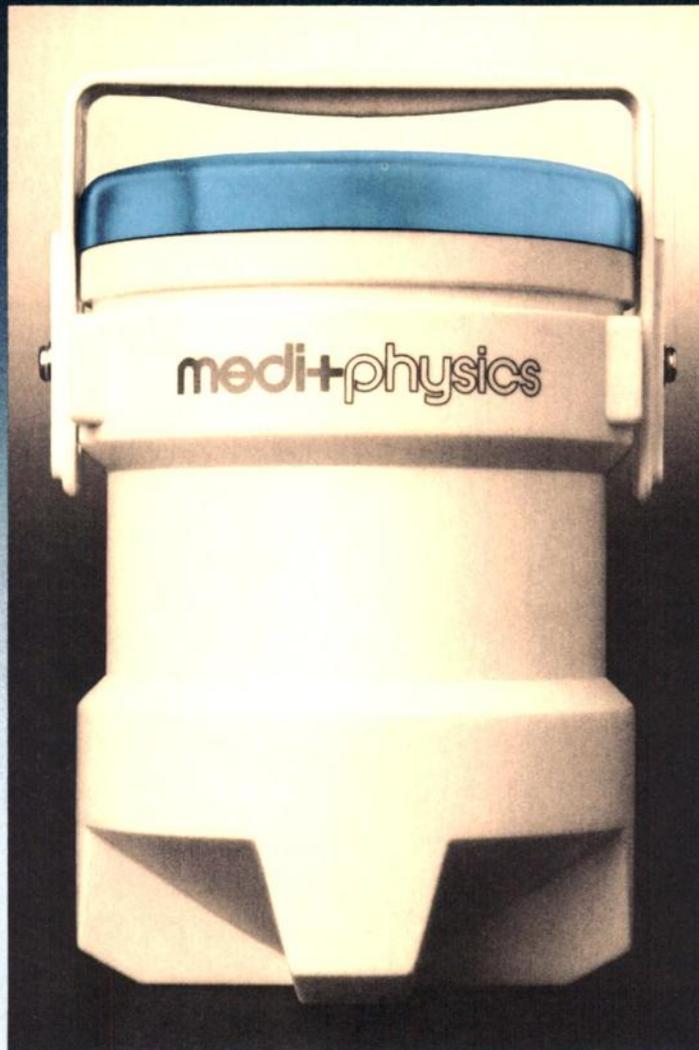


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- Studies can be conducted on comatose, uncooperative, or mechanically vented patients.
- Distribution of radioactive gas is mainly to the lungs.
- Elaborate delivery system is not required.
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- Easy to license when compared to Xenon Xe 133 gas.

MPI Krypton Kr 81m Gas Generator
Krypton Kr 81m

The Pulmonary Profile

THE CONCEPT

The pulmonary profile is a series of matched perfusion and ventilation studies done consecutively on a patient using the MPI Krypton Kr 81m Gas Generator and Technetium Tc 99m Albumin Aggregated. Following administration of the two products you are able to switch the energy window on the gamma camera and scan the patient in the same position for each of the isotopes before you move the patient to the next view. Thus, a complete series of matching views may be accumulated for any number of patient positions.

THE PURPOSE

To increase the diagnostic sensitivity and specificity of lung imaging procedures by providing an easy means of obtaining matched perfusion-ventilation images in one patient visit.

THE RESULT

A new patient study which combines ventilation and perfusion imaging procedures into one study called the *Pulmonary Profile Study*.

For information regarding the MPI Krypton Kr 81m Gas Generator Krypton Kr 81m please call Medi-Physics at (415) 658-2184, Outside California (800) 227-0492 or Inside California at (800) 772-2477.

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

MPI KRYPTON Kr 81m GAS GENERATOR KRYPTON Kr 81m

DESCRIPTION: The Krypton Kr 81m Gas Generator consists of Rubidium Rb 81 fixed to a solid support from which the Krypton Kr 81m is eluted by passage of humidified oxygen or air through the generator. Other rubidium radio-isotopes which do not decay to radioactive Krypton Kr 81m in their decay are present in the generator (Rubidium Rb 82m, for example, is present at a concentration of 30-40%).

INDICATIONS AND USAGE: The Krypton Kr 81m Gas Generator is indicated for use in the study of pulmonary ventilation.

CONTRAINDICATIONS: None known.

WARNINGS: None known.

PRECAUTIONS:

General

The Krypton Kr 81m Gas Generator as well as other radioactive drugs, must be handled with care to minimize radiation exposure to clinical personnel. Also care should be taken to minimize radiation exposure to the patient consistent with proper patient management.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or whether Krypton Kr 81m gas affects fertility in males or females.

Pregnancy-Category C

Animal reproduction studies have not been conducted with Krypton Kr 81m gas. It is also not known whether Krypton Kr 81m gas can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity. Krypton Kr 81m gas should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Krypton Kr 81m gas is administered to a nursing woman.

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

Pediatric Use

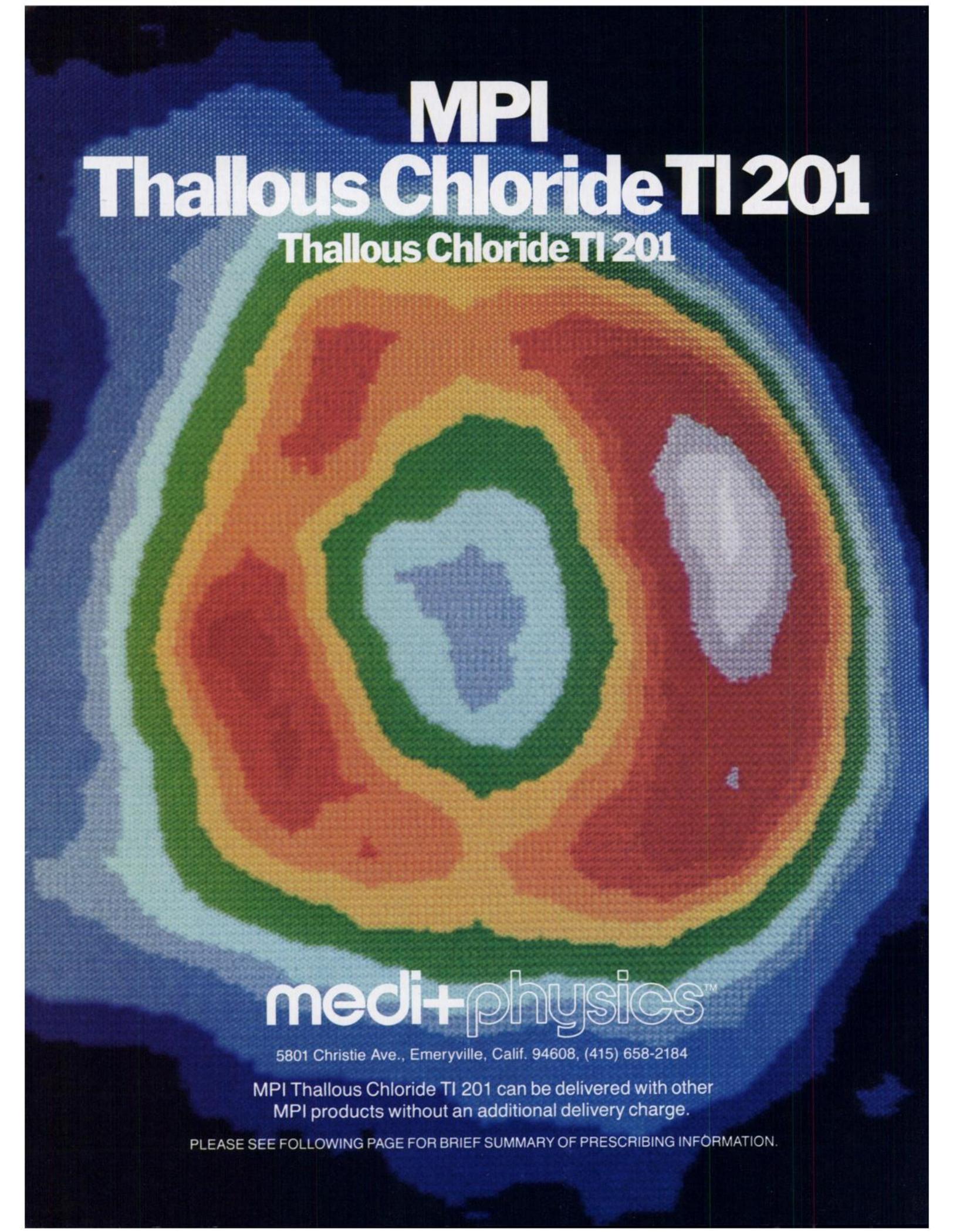
Safety and effectiveness in children have not been established.

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: None known.

DOSAGE AND ADMINISTRATION: The recommended dose range for Krypton Kr 81m is 1-10 millicuries and should be administered by continuous inhalation for a sufficient time to provide desired diagnostic information. The multiplication product of the radioactivity and the time of continuous inhalation of Krypton Kr 81m generally should not exceed 100 millicurie-minutes.

HOW SUPPLIED: The Krypton 81m Gas Generator is supplied in the form of Rubidium Rb 81, bound to a solid support, with an activity of 2-10 millicuries at calibration time. The generator is enclosed in a lead shielded filter assembly surrounded by a capped plastic canister to which a handle is affixed. The generator should be stored at room temperature. The generator expires 12 hours after date and time of calibration.



MPI

Thallous Chloride TI 201

Thallous Chloride TI 201

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5801 Christie Ave., Emeryville, Calif. 94608, (415) 658-2184

MPI Thallous Chloride TI 201 can be delivered with other MPI products without an additional delivery charge.

PLEASE SEE FOLLOWING PAGE FOR BRIEF SUMMARY OF PRESCRIBING INFORMATION.

MPI Thallous Chloride Tl 201 Injection

Thallous Chloride Tl 201
Diagnostic—For Intravenous Use
For Imaging Myocardial Perfusion

DESCRIPTION MPI Thallous Chloride Tl 201. 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.

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 MPI Thallous Chloride Tl 201. Thallous Chloride Tl 201 is available in 2.0 mCi vials.



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Thallium imaging in acute myocardial infarction

Lewis C. Becker, MD

Associate Professor of Medicine

Director, Nuclear Cardiology

The Johns Hopkins Medical Institutions
Baltimore, Maryland



One of the most significant findings to come from our clinical research over the past several years has been the observation that thallium-201 imaging, performed early after onset of symptoms, can reliably distinguish high-risk and low-risk groups of hemodynamically stable patients with acute myocardial infarction. The value of such a prognostic indicator in the management of acute MI is evident. Patients determined to be at low risk could be ambulated earlier and perhaps discharged sooner than in current practice; in the future, such patients might be placed early in a progressive-care-type unit rather than be maintained in the more expensive coronary care unit.

Patients at higher risk might be found to require more intensive monitoring for even longer periods than today. And following discharge, these patients could justifiably be subjected to much closer and long-lasting followup. Most important, reliable identification of patients at high risk would permit earlier initiation of aggressive treatment directed at limiting the extent of infarction.

Predicting mortality

Our recently reported study¹ covered 42 consecutive patients determined by conventional means (history, ECG, serum creatine kinase) to have suffered an acute MI. These were Killip class I or II patients—the largest group of MI patients, and

those normally considered to be at relatively low risk. All 42 patients were admitted within 12 hours of onset of chest pain, and underwent thallium imaging within 15 hours of onset.

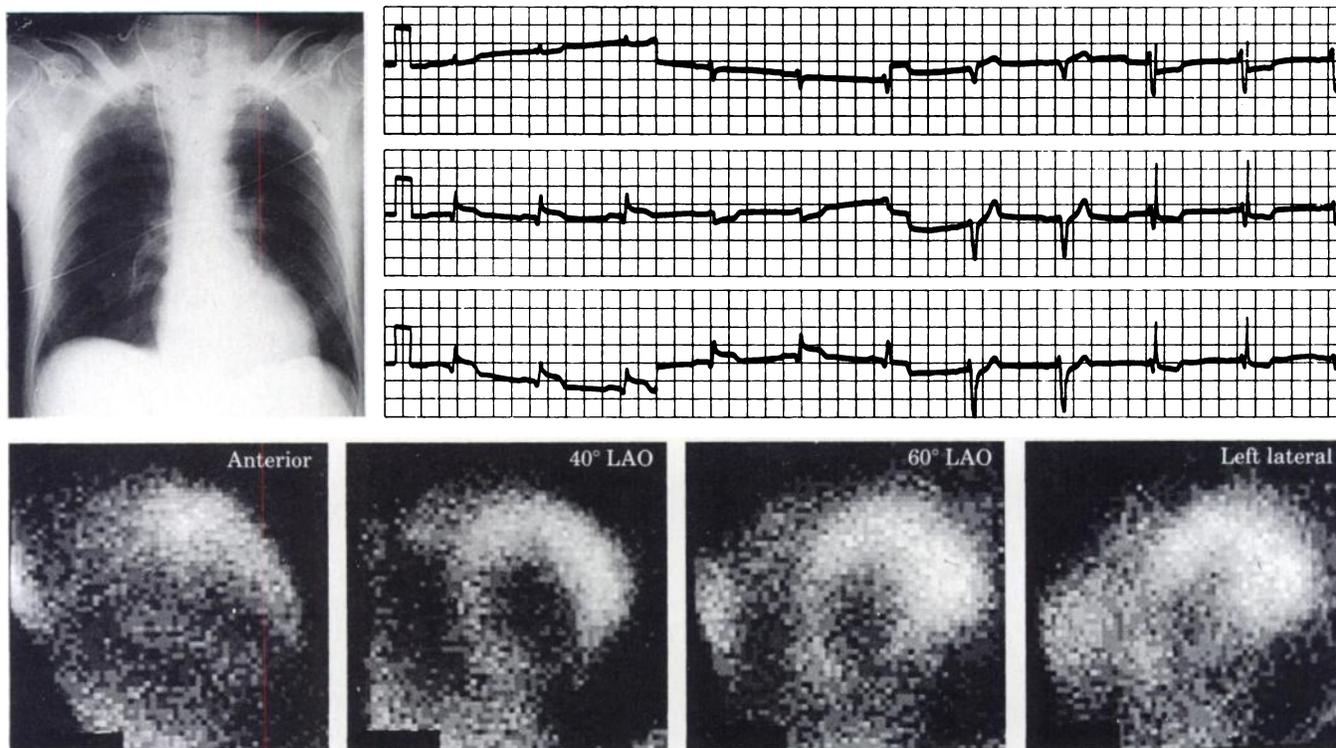
The thallium images—in the anterior, 40° LAO, and 60° LAO views—were interpreted both subjectively and by a computer-assisted quantitative technique.² For each interpretive approach, scores for all views were summed to give a total “defect score”—the lower the score, the smaller the area of thallium defect, with a total defect score of 7 corresponding to reduction in thallium uptake involving approximately 40% of the left ventricle in at least two views. The total defect scores were then correlated with the patients’ subsequent clinical course and with other clinical indices believed to have prognostic value—previous history of MI, anterior location of MI, alveolar infiltrates on admission, peak CK greater than 1,000 IU/liter, age, and sex.

Of the 42 patients, 35 survived the initial hospitalization. These survivors were followed for 6 to 20 months after discharge.

What were our results? Nonsurvivors had significantly larger thallium defects than survivors. The mean score for nonsurvivors was 14.3 vs 2.3 for survivors. In the 13 patients with a score greater than 7—ie, 40% or more involvement—the inhospital mortality was 46%; at 6 months it was 62%; and at last followup (mean 9 months) it was 92%. In the group of patients with a total defect score less than 7, the inhospital mortality was 3%; at 6 months and at last followup, it was, respectively, 7% and 7%.

These data conclusively showed that the thallium study performed within hours of admission could identify apparently stable MI patients at high-risk for mortality. In addition, when we compared the predictiveness of the thallium score with the other clinical indices—history, MI location, enzymes, etc—singly *and* in combination, the thallium study was significantly better.

We were, of course, very excited by our results. But, because this was a retrospective study, we felt it important to validate the findings prospectively. Over a 6-month period, we studied more than 90 consecutive patients admitted to the CCU with documented or strongly suspected MI. We applied the same scoring system and same dividing line (score 7)—and confirmed our ability to use thallium imaging to distinguish between high-risk and low-risk groups. The mortality rates of the two groups were almost identical to those established in the earlier retrospective study.



Admission studies in a 66-year-old male with known previous acute MI. The patient was hemodynamically stable. Chest X-ray showed slightly increased heart size, no pulmonary congestion. ECG showed ST elevation in II, III, and aV_F, indicative of acute inferior MI, as well as changes suggestive of old anterior wall damage. Thallium imaging disclosed markedly diminished uptake involving the inferior wall, apex, distal anterior wall, and septum. The total defect score was 40.7. The patient's condition gradually deteriorated, despite aggressive vasopressor administration. He died on the sixth postadmission day.

Irreversible damage and reversible ischemia

We believe the thallium study accurately predicts prognosis in MI patients because the size of the defect reflects the total hypoperfused mass of the left ventricular myocardium—both infarcted and ischemic areas. We know from observations of other investigators that the thallium defect tends to diminish with time after an acute MI. Thus the image recorded immediately after admission will show a larger defect than those recorded on serial followup over subsequent days. Our own pathologic studies have demonstrated that large thallium defects seen on post-MI images may be associated with small areas of infarction on postmortem examination.

Together, these findings strongly support the concept that areas of reduced or absent thallium on the initial post-MI images represent both ischemia and infarction, and that the "filling-in" seen on followup imaging represents resolution of ischemia due to resolution of coronary artery spasm or enlargement of coronary collaterals. Thus, the post-MI study identifies myocardium irreversibly damaged by the acute event, myocardium damaged

by previous infarction, and surrounding areas of severe ischemia that are at risk for necrosis either immediately or at some future time.

Clinical implications

In our patients, the highest percentage of in-hospital deaths was due to sudden pump failure—possibly due to the large total volume of compromised myocardium. Postdischarge deaths were generally related to a new ischemic event. In both of these high-risk groups, the thallium study might have helped in patient management decisions. For those patients who died while in the hospital, more aggressive support might have been indicated; those whose deaths occurred posthospitalization might have been identified as candidates for coronary artery bypass.

References

1. Silverman KJ, Becker LC, Bulkley BH, *et al*: Value of early thallium-201 scintigraphy for predicting mortality in patients with acute myocardial infarction. *Circulation* 61, 996–1003, 1980.
2. Burow RD, Pond M, Schafer AW, Becker L: "Circumferential profiles." A new method for computer analysis of thallium-201 myocardial perfusion images. *J Nucl Med* 20, 771–777, 1979.

Please see following page for brief summary of prescribing information.

Thallous Chloride TI 201

INDICATIONS AND USAGE: Thallous Chloride TI 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 TI 201 scans. Attention is directed to the fact that thallium is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that the thallium may likewise be affected.

Thallous Chloride TI 201, as all radioactive materials, must be handled with care and used with appropriate safety measures to minimize external radiation exposure to clinical personnel. Care 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 TI 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.

The expiration date for Thallous Chloride TI 201 is six days postcalibration.

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 TI 201 is 1-1.5mCi. Thallous Chloride TI 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.

HOW SUPPLIED: Thallous Chloride TI 201 for intravenous administration is supplied as a sterile, non-pyrogenic solution containing at calibration time, 1mCi/ml of Thallous TI 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 TI 201.

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

Catalog Number NRP-427

May 1980

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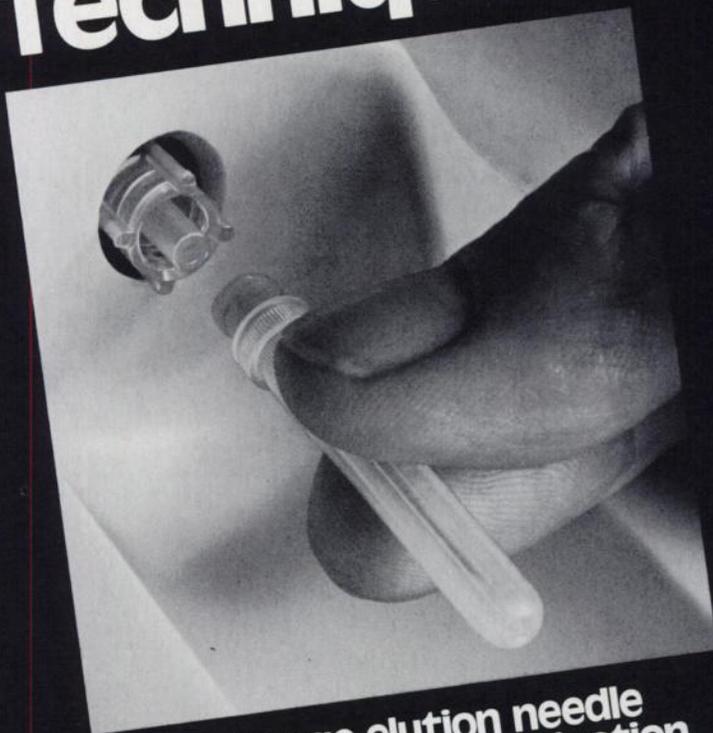
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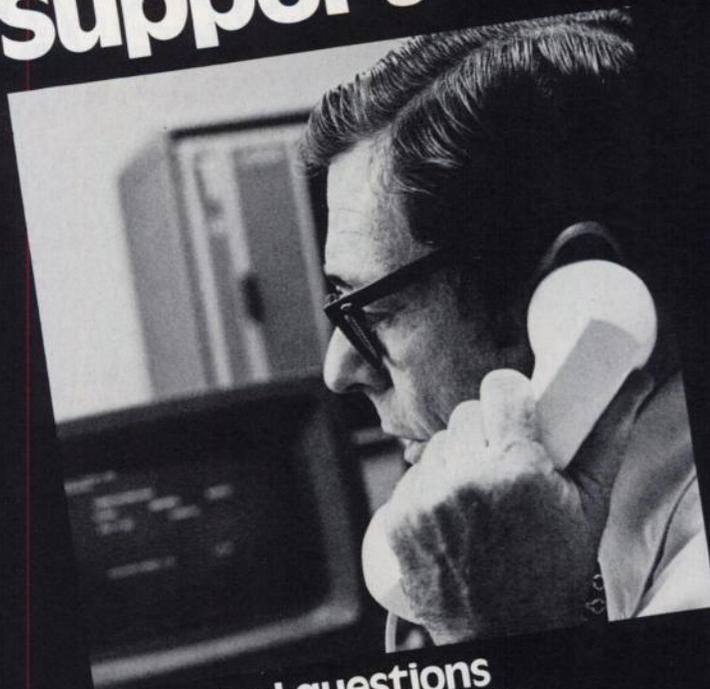
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- 30° angle standard. Other angles available.
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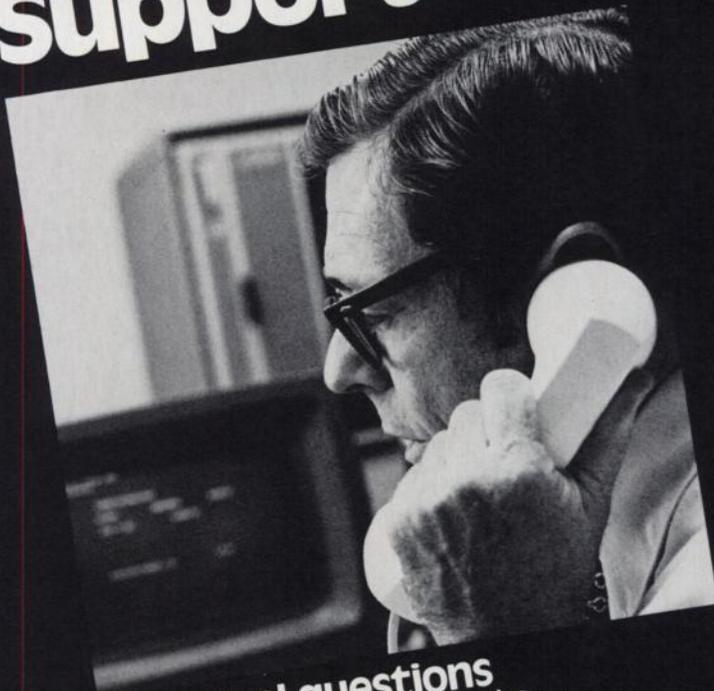
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- Computer is gated only on the R-Wave. High amplitude T-waves are ignored.
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FEATURES

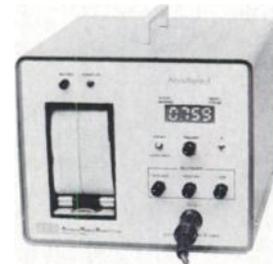
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R-Trigger pulse output, ECG output, Heart Rate/R-R int., Strip Chart Recorder, Digital CRT Monitor and Isolation Amplifier for patient safety.



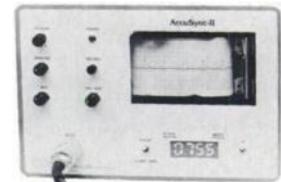
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AccuSync-III

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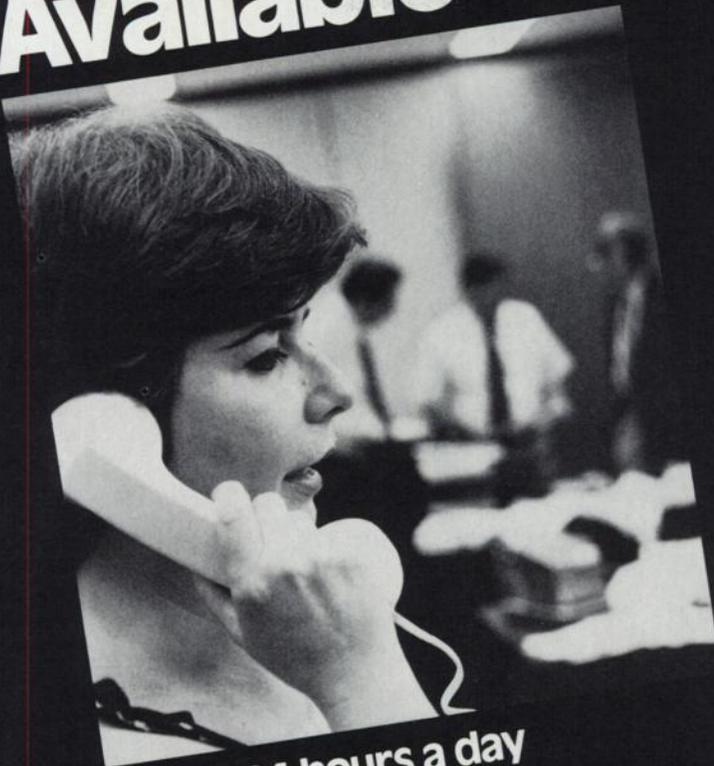
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- 30° angle standard. Other angles available.
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Tomographic Software. Along with the 30° collimator, Septa provides tomographic software which allows

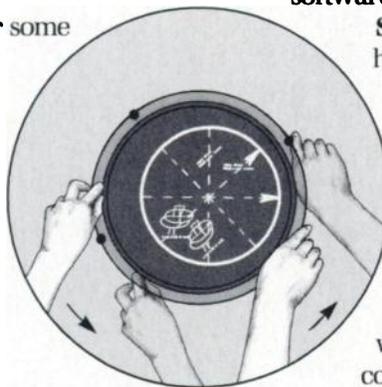
up to 12 reconstruction levels for use with Digital Equipment Corporation's Gamma-11 computer.

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Standard Imaging. The Septa 30° slant-hole design is also best for standard imaging with advantages proven in five years of clinical use.

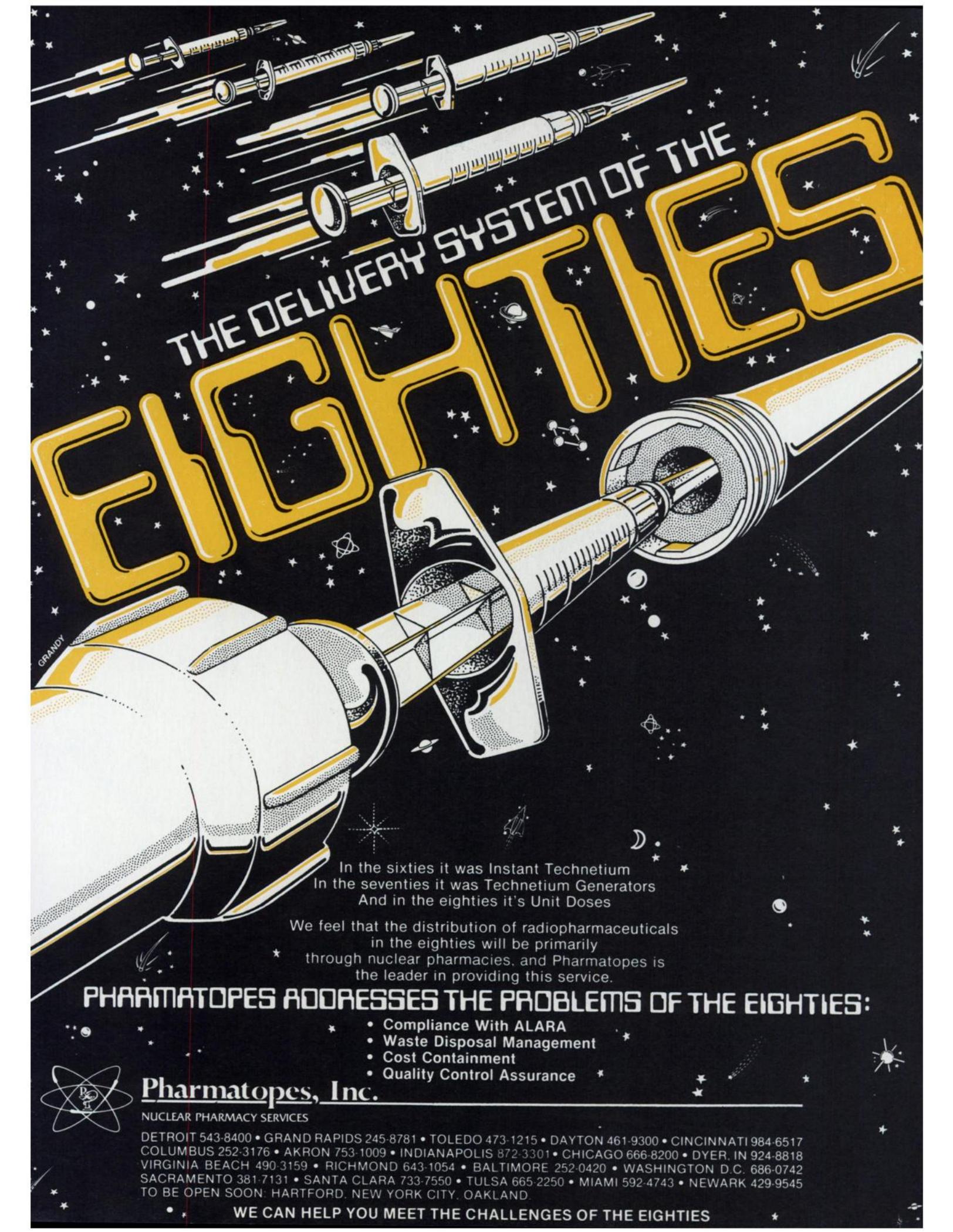
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No matter how you slice it, Septa collimators are your best buy for tomography or any other imaging. Call or write us for complete specifications and collimator prices for your camera.



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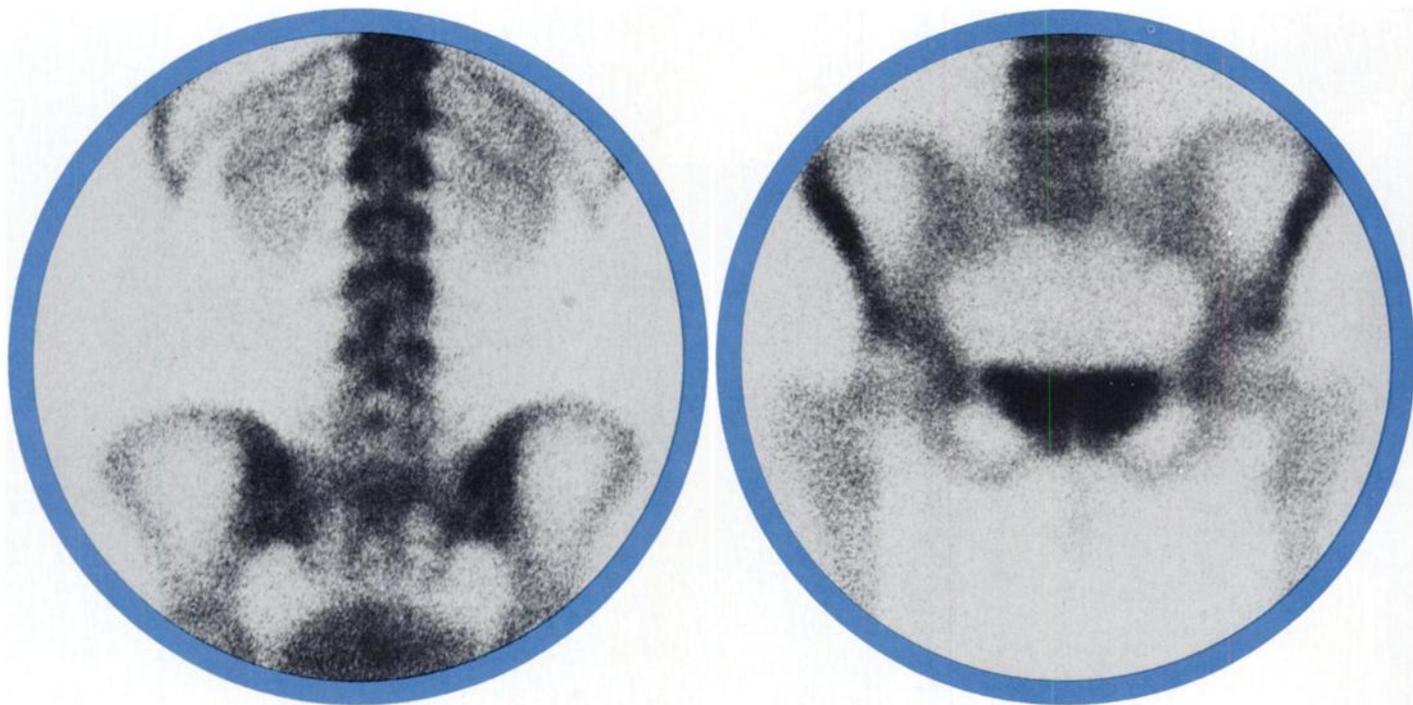
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Osteoscan-HDP represents a significant technological advance in bone scanning agents. Its unique new active ingredient, hydroxymethylene diphosphonate (HDP), provides higher bone uptake than MDP-based agents for clear, definitive scans and excellent lesion detection.



Bone uptake superior to MDP

HDP shows unusually high adsorption to bone. In a clinical comparison, Osteoscan-HDP averaged 21% higher bone uptake than the MDP-based agent.¹

Rapid blood clearance

No bone agent clears the blood faster. Only 6% of Osteoscan-HDP remains in the blood two hours after injection.² Osteoscan-HDP's rapid blood clearance contributes to the overall quality of the image and permits flexibility in scheduling patient scans from 1 to 4 hours post-injection.

Scan data:

The two scans above are of a 52-year-old female patient with lower back pain. Scan: normal. Instrument: GE MaxiCamera™ 61; information density: 600 counts/cm²; dose 20 mCi; dose to image time: 3.5 hr.

References:

1. Fogelman, I. et al: Presented at the 1980 Annual Meeting, SNM, Southeastern Chapter.
2. Silberstein, E.B.: *Radiology* 136: 747-751, 1980.
3. Littlefield, J.L., and Rudd, T.C.: *Clin. Nucl. Med.* 5:S28, 1980 (abstr.).

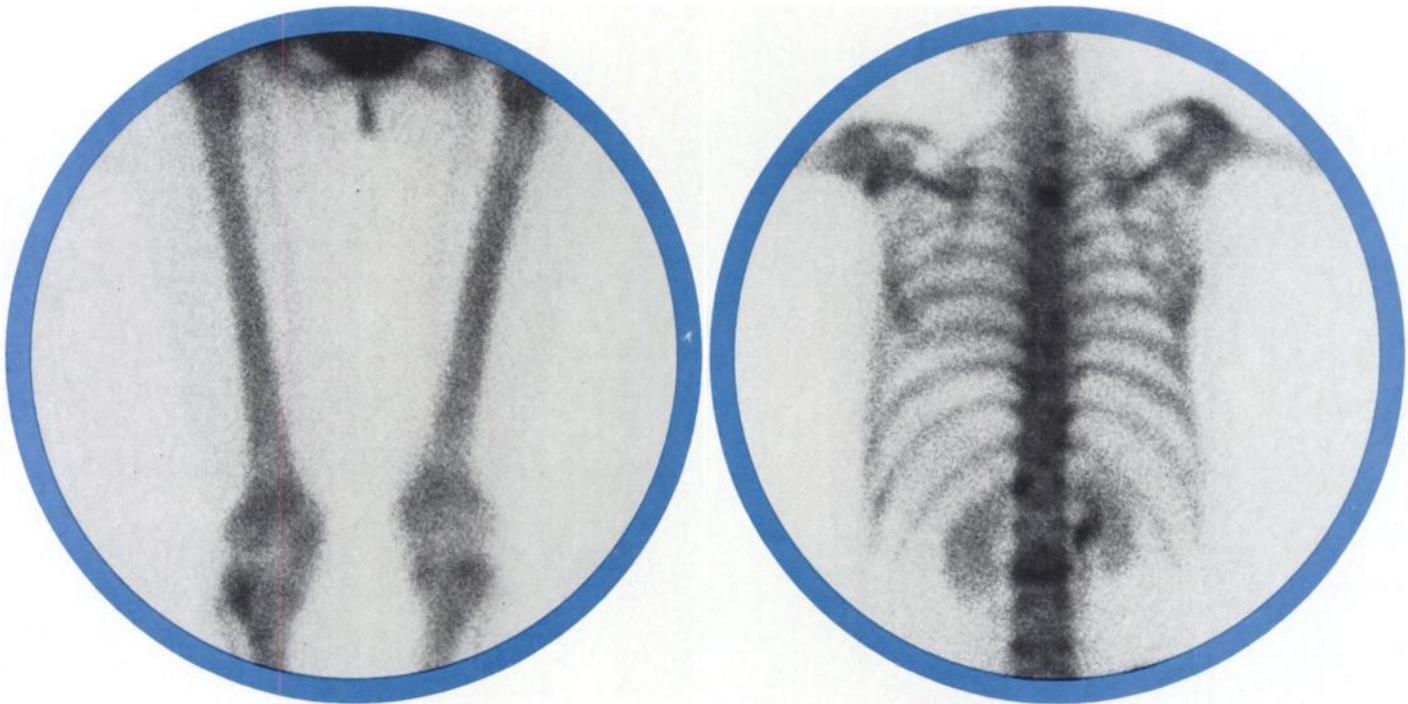
New

offering higher bone uptake

PROCTER & GAMBLE

OSTEOSCAN-HDP

Technetium Tc99m Oxidronate Kit



Unexcelled image quality³

Osteoscan-HDP's high bone uptake and rapid blood clearance permit clear visualization of skeletal detail even in difficult-to-scan elderly patients.

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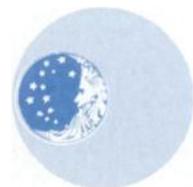
To order Osteoscan-HDP, or for further information, call or write Procter & Gamble, Professional Services, P.O. Box 85507, Cincinnati, Ohio 45201, (513) 977-5547.

High lesion sensitivity

HDP offers a high tumor-to-normal bone ratio. This results in high resolution scans capable of demonstrating subtle skeletal metastases and fractures with no sacrifice in overall image quality.

Scan data:

The two scans above are of a 59-year-old female patient with breast cancer.
Scan: abnormal deposits of radionuclide present in dorsal and lumbosacral spine.
Instrument: GE MaxiCamera™ 535;
counts: 2000K; dose 20.1 mCi;
dose to image time: 3 hr.



Please see the following page for a brief summary of prescribing information.

New

PROCTER & GAMBLE

OSTEOSCAN-HDP

Tchnetium Tc99m Oxidronate Kit

INDICATIONS AND USAGE

OSTEOSCAN-HDP (Technetium Tc99m Oxidronate Kit) is a diagnostic skeletal imaging agent used to demonstrate areas of altered osteogenesis.

CLINICAL PHARMACOLOGY

During the 24 hours following injection, Technetium Tc99m-labeled **OSTEOSCAN-HDP** is rapidly cleared from blood and other non-osseous tissues and accumulates in the skeleton and urine. In humans, blood levels are about 10% of the injected dose at one hour post-injection and continue to fall to about 6%, 4% and 3% at 2, 3 and 4 hours respectively. When measured at 24 hours following its administration, skeletal retention is approximately 50% of the injected dose. **OSTEOSCAN-HDP** exhibits its greatest affinity for areas of altered osteogenesis and actively metabolizing bone.

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

General

Contents of the vial are intended only for use in the preparation of Technetium Tc99m Oxidronate and are **NOT** to be administered directly to the patient. Technetium Tc99m Oxidronate should be formulated within **eight (8) hours** prior to clinical use. Optimal imaging results are obtained one to four hours after administration.

Technetium Tc99m Oxidronate as well as other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patients consistent with proper patient management. Radiopharmaceuticals should be used only by physicians who are qualified by specific training 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.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc99m Oxidronate affects fertility in males and females.

Pregnancy — Category C

Animal reproduction studies have not been conducted with Technetium Tc99m Oxidronate. It is also not known whether Technetium Tc99m Oxidronate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc99m Oxidronate should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc99m is excreted in human milk during lactation, therefore formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Although adverse reactions have not been reported that are specifically attributable to the use of Technetium Tc99m Oxidronate, allergic dermatological manifestations (erythema) have been infrequently reported with similar agents.

DOSEAGE AND ADMINISTRATION

General Instructions

The recommended adult dose of Technetium Tc99m-labeled **OSTEOSCAN-HDP** is 15 mCi with a range of 10 to 20 mCi. The activity of each dose should be measured by a suitable radiation calibration system just prior to administration. The dose should be given intravenously by slow injection. For optimal results imaging should be done 1-4 hours post-injection.

HOW SUPPLIED

OSTEOSCAN-HDP is supplied as a lyophilized powder packaged in vials. Each vial contains 2.0 mg oxidronate sodium and 0.16 mg stannous chloride as active ingredients, and 0.56 mg gentisic acid as a stabilizer. Kits containing 5 or 30 vials are available. The NDC number for this product is NDC 37000-403-01. The drug can be stored at room temperature both prior to and following reconstitution with ADDITIVE-FREE sodium pertechnetate Tc99m.

For additional product information, call (513) 977-5547 or write: Procter & Gamble, Professional Services, P.O. Box 171, Cincinnati, OH 45201.



TECHNETIUM 99m

GENERATOR

TECHNETIUM Tc 99m

GENERATOR

FOR THE PRODUCTION OF SODIUM PERTECHNETATE Tc 99m

description

The Union Carbide **TECHNETIUM Tc 99m GENERATOR** provides a means of obtaining a sterile, pyrogen-free solution of Sodium Pertechnetate Tc 99m in isotonic saline from elution of the generator containing Molybdenum Mo 99. Hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment. Over the life of the generator, an elution will contain a yield of 80% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 on the generator column.

clinical pharmacology

Following intravenous administration, the pertechnetate ion distributes in the body similarly to the iodide ion, but it is not organified when trapped in the thyroid gland. Sodium Pertechnetate Tc 99m tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. It also concentrates in the thyroid gland, stomach and choroid plexus.

After intravascular administration, it remains in the circulatory system for sufficient time to permit blood pool, organ perfusion, and major vessel studies. It gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

Indications and usage

Sodium Pertechnetate Tc 99m is used IN ADULTS as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; salivary gland imaging; placenta localization; and blood pool imaging including radionuclide angiography.

Sodium Pertechnetate Tc 99m is used IN CHILDREN as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; and blood pool imaging including radionuclide angiography.

contraindications

None known.

warnings

Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults and, in general, the younger the child the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

This radiopharmaceutical preparation should not be administered 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 a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

precautions

Sodium Pertechnetate Tc 99m, 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.

Pregnancy Category C, animal reproductive studies have not been conducted with Sodium Pertechnetate Tc 99m. It is also not known whether Sodium Pertechnetate Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Pertechnetate Tc 99m should be given to a pregnant woman only if 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.

The generator should not be used after 16 days from the date and time of calibration.

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

adverse reactions

No adverse reactions have been reported with the use of this radiopharmaceutical.

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 intravenous dose range employed for various diagnostic indications are as follows:

IN AVERAGE ADULT (70kg) PATIENTS:

Brain Imaging	10 to 20 millicuries
Thyroid Gland Imaging	1 to 10 millicuries
Salivary Gland Imaging	1 to 5 millicuries
Placenta Localization	1 to 3 millicuries
Blood Pool Imaging	10 to 30 millicuries

IN PEDIATRIC PATIENTS:

brain imaging: 140-280 microcuries/kg body weight. A minimum dose of 3-5 millicuries should be employed if cerebral radionuclide angiography is performed as part of the brain imaging procedure.

thyroid gland imaging: 60-80 microcuries/kg body weight.

blood pool imaging: 140-280 microcuries/kg body weight.

A minimum dose of 3-5 millicuries should be employed if radionuclide angiography is performed as part of the blood pool imaging procedure.

NOTE: Up to 1 gram of pharmaceutical grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of Sodium Pertechnetate Tc 99m for brain imaging. When Sodium Pertechnetate Tc 99m is used in children for brain or blood pool imaging, administration of potassium perchlorate is especially important to minimize the absorbed radiation dose to the thyroid gland.

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

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.

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

how supplied

Sodium Pertechnetate Tc 99m is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in sizes from 830 millicuries up to 16,600 millicuries (in approximately 830 millicurie increments) of Molybdenum Mo 99 as of noon of the day of calibration. The **TECHNETIUM Tc 99m GENERATOR** consists of:

1) sterile generator, 2) Sodium Chloride Injection source, 3) 10 cc sterile evacuated vials, 4) sterile needles, 5) elution vial shield* 6) finished drug labels. Elution vials in 5 cc and 20 cc sizes are available upon request.

*initial order only.

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- CINTICHEM[®] TECHNETIUM 99m GENERATORS come in 40 activity and day of calibration combinations, which can satisfy the range of activity needs for any size lab.
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 - Simple one-step elution. No charging of the column is necessary. Column does not have to be dried after each elution.
 - A new sterile needle is utilized for each elution, reducing the chances of a septic or pyrogenic situation occurring in routine clinical usage. This method offers an advantage compared to competitive dry column systems where the needle assembly is used for the life of the product.
 - Evacuated elution vials are available in 5 cc, 10 cc, and 20 cc volumes, allowing you to optimize the elution concentration to meet your needs.
 - Optimum shielding design minimizes radiation to personnel and to work areas, maximizes protection with minimum weight.
 - Rigid Quality Control testing, which includes an elution check on each Generator, assures that your UNION CARBIDE CINTICHEM[®] TECHNETIUM 99m GENERATOR meets our high internal specifications. Our experience obtained in over 19 years of involvement in Nuclear Medicine assures you of the highest quality product possible.
 - CINTICHEM[®] CUSTOMER SERVICE is readily accessible on our toll free telephone numbers. Personnel in this department have in-depth backgrounds covering the research, development, technical, and clinical application aspects of Nuclear Medicine.
- CINTICHEM[®] TRAFFIC, with over 19 years of experience in shipping radioactive materials, provides you with optimum delivery service and support.



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TO ASSURE
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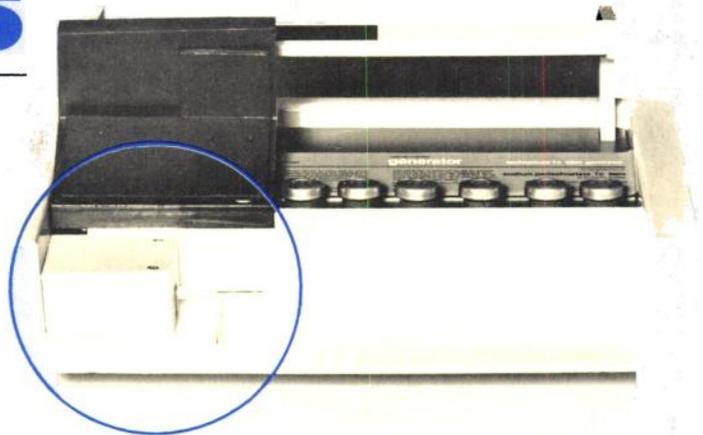
**TO MAXIMIZE
RADIATION
PROTECTION**

**AND FOR
EASY ELUTION**

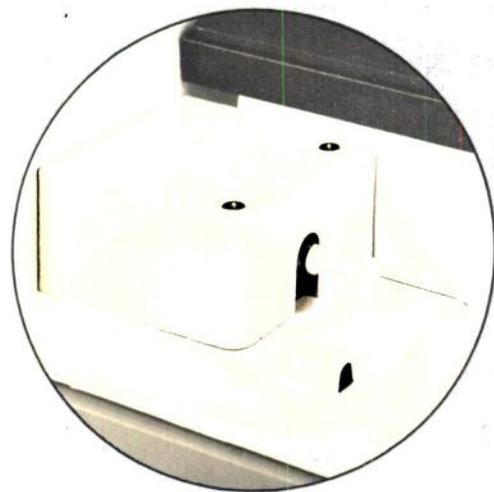
- The UNION CARBIDE CINTICHEM[®] "wet system" Technetium 99m Generator possesses a terminal fluid line 0.22 micron filter.
- Of the two nationally available "wet system"* Technetium Tc 99m Generators, currently only CINTICHEM[®] Technetium 99m GENERATORS possess both an auto-claved column *and* a terminal fluid line 0.22 micron filter to assure a sterile eluate.

*A "wet system" Technetium Tc 99m Generator consists of a shielded column containing Molybdenum Mo 99 and an internal self-contained saline supply.

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OPPOSITE PRECEDING PAGE.



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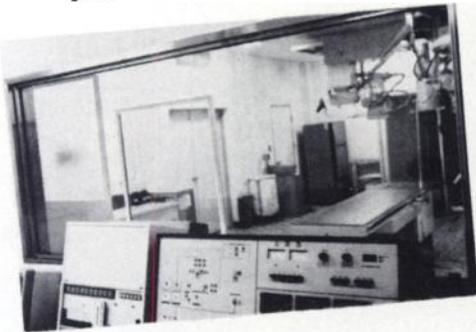
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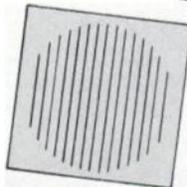
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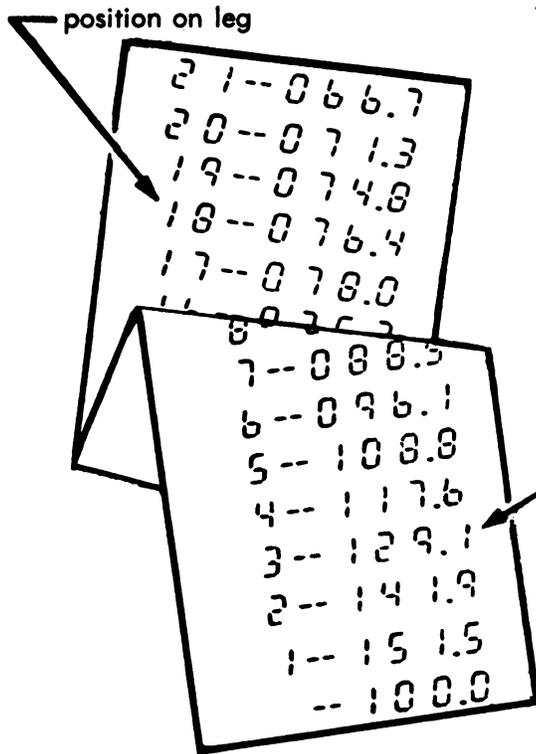
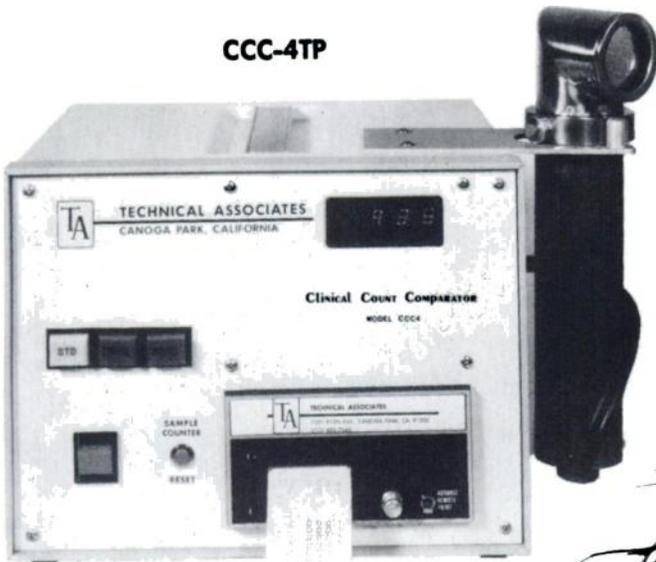
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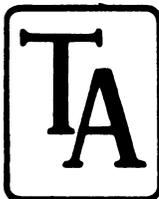
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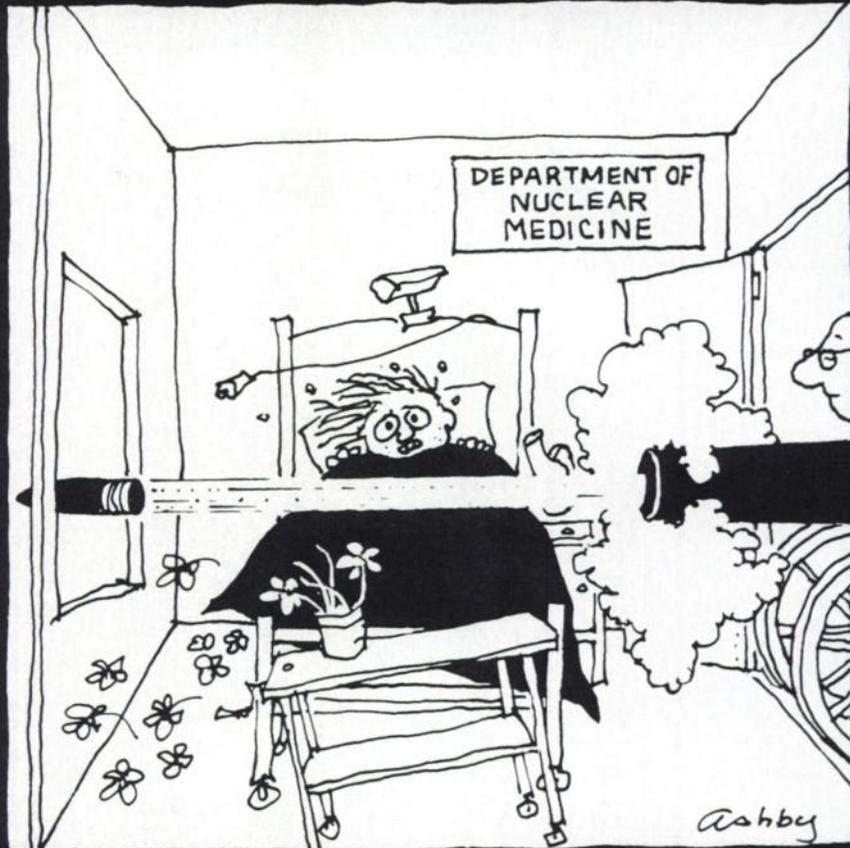
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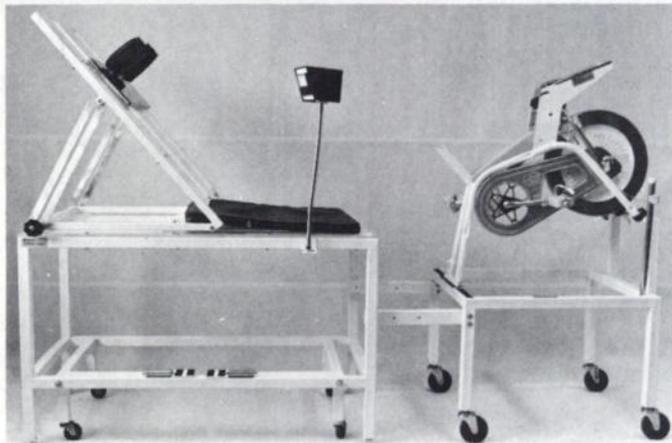
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This course will include a concentrated presentation of the physics of diagnostic and nuclear radiology and radiation biology. While the course is not designed for those taking the board examination in radiation therapy, much of the material presented will be relevant to that subject. Moreover, if sufficient numbers of students express the wish to have a review of some aspects of the physics or radiation biology of radiation therapy, separate sessions may be arranged to accommodate those persons only.

Part of two afternoons, designated as discussion sessions, will be left open. The course faculty will be available during these periods to discuss any questions, problems or areas of difficulty presented by students.

PROGRAM TOPICS:

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X-Ray Tube

Interaction and Attenuation
of X-Rays

Exposure and Dose

X-Ray Quality

X-Ray Generators

Nuclear Medicine Physics I

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JNM 4/81

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MAY 1-2, 1981

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**For further information, contact: Ms. Terrie Hernandez
Manager of Professional Education**

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Warren R. Janowitz, M.D., Program Chairman, Mount Sinai Medical Center, Div. of Nuc. Med., 4300 Alton Rd., Miami Beach, Florida 33140, (305) 674-2424.

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INDEX TO ADVERTISERS

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ADC	14A
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AMR CORPORATION	44A
BRATTLE INSTRUMENTS	IBC
CAPINTEC, INC.	53A
CARDIAC MEDICAL SYSTEMS	74A
CLINICAL ASSAYS	59A
EASTMAN KODAK	28A, 29A
EDC/MEDICAL IMAGING	46A
ELSCINT, LTD.	26A, 27A
INTERNATIONAL CIS	15A
ISO-TEX	42A
JOHNSTON LABORATORIES	55A
MALLINCKRODT, INC.	3A, 8A, 9A, 10A, 11A, 21A 32A, 33A, 41A, 43A, 45A, 63A
MEDI-PHYSICS, INC.	IFC, 1A, 34A, 35A, 36A, 37A
NEW ENGLAND NUCLEAR	4A, 38A, 39A, 40A
NUCLEAR ASSOCIATES	57A
NUCLEAR PACIFIC	20A
NUCLEAR PHARMACY	30A
NU-TECH	16A
O'NEILL ENTERPRISES	64A, 65A
PHARMATOPES, INC.	47A
PICKER CORPORATION	18A, 19A
PROCTOR & GAMBLE CO.	48A, 49A, 50A
RADIOCHEMICAL CENTRE	12A
RADX CORPORATION	17A, 58A
RAYTHEON COMPANY	31A
RESEARCH SYSTEMS, INC.	72A
SIEMENS GAMMASONICS	13A
SNM PLACEMENT	66A, 67A, 68A, 69A, 70A, 71A
SYNCOR INTERNATIONAL	60A, 61A, 73A, 74A
TECHNICAL ASSOCIATES	62A
UNION CARBIDE CORPORATION	6A, 50A, 51A, 52A, BC

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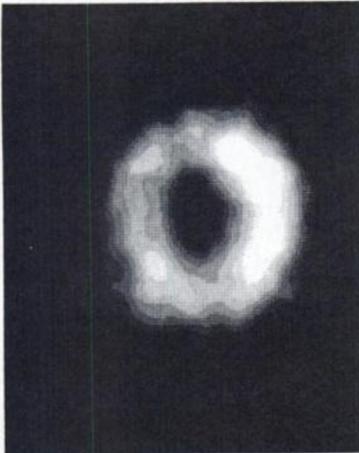
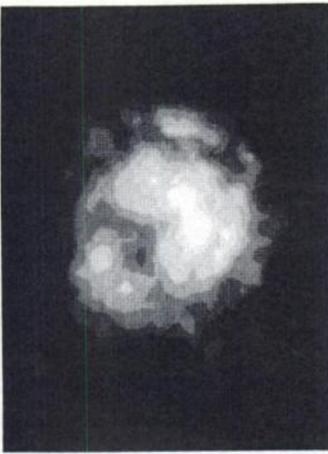
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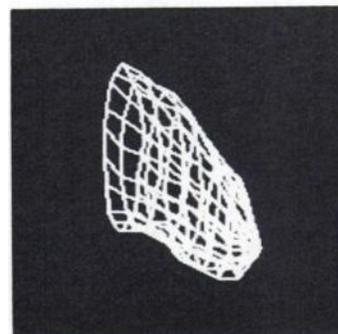
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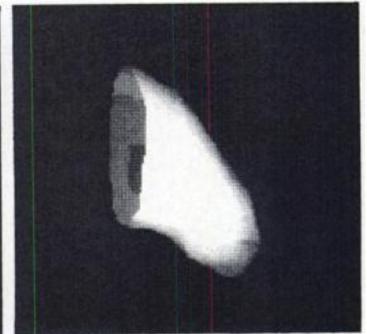
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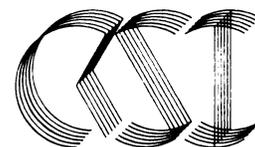


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¹Vogel RA, Kirsh DL, Lefree MT, Rainwater JO, Steele PP: Thallium-201 myocardial perfusion scintigraphy: Results of standard and multi-pinhole tomographic techniques. *The American Journal of Cardiology* 43:787-793, 1979

²Francisco D, Raymundo G, Van Kirk O, Erhardt J, Marcus M: Tomographic thallium-201 perfusion scintigrams following maximal coronary vasodilation with dipyridamole: *Circulation* 60 (suppl. 11) 11-174, 1979.

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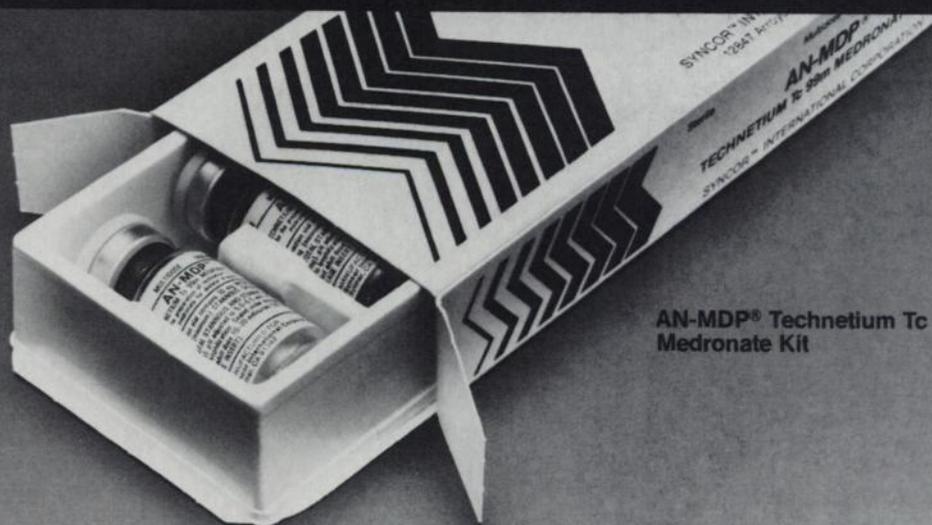


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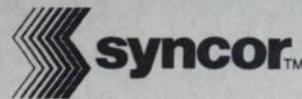
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1. Subramanian G, McAfee JG, Blair RJ, Kallfelz FA, and Thomas FD: *J Nucl Med* 16:744, 1975
2. Davis MA and Jones AG: *Sem Nucl Med* 6:19, 1976

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Please refer to the brief prescribing information on the following page.



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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 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 the patients consistent with proper patient management.

To minimize radiation dose to the bladder, the 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 and females.

Pregnancy Category C: Animal reproductive studies have not been conducted on 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 reproductive capacity. Technetium Tc 99m Medronate 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.

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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 millicuries Technetium Tc 99m Medronate. Scanning is optimal at 1–4 hours post-injection. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

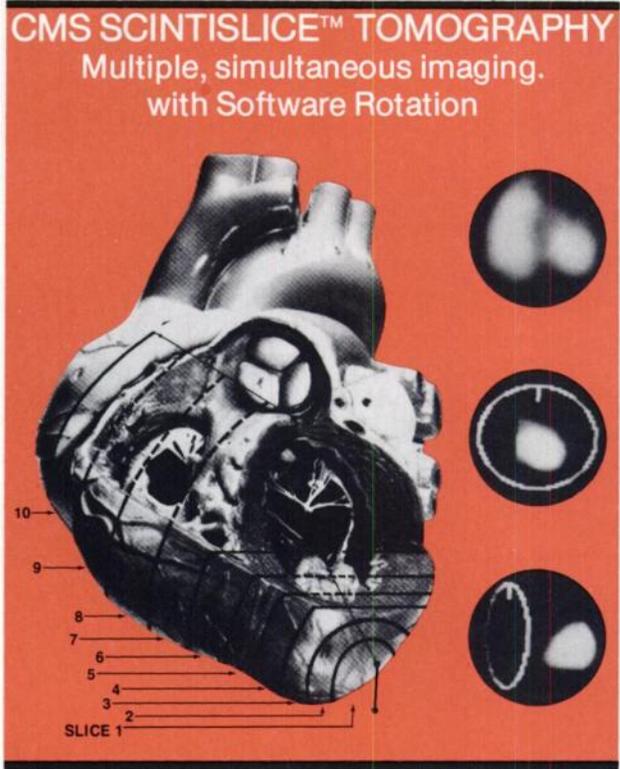
HOW SUPPLIED. The AN-MDP® Technetium Tc 99m Medronate Kit is supplied either as a set of 5 or 30 sterile and pyrogen-free vials. Each nitrogen-flushed vial contains in lyophilized form: medronic acid 10 mg, stannous chloride (minimum) 0.51 mg, maximum total stannous and stannic chloride 1.01 mg. The pH is adjusted with HCl or NaOH solutions prior to lyophilization. Included in each 5-vial kit is one package insert and 10 radiation labels. Included in each 30-vial pack is one package insert and 60 radiation labels. Refrigeration is not necessary. Technetium Tc 99m Medronate Kits contain no preservative. Vials are sealed under nitrogen; air or oxygen is harmful to the contents of the vials and the vials should not be vented.

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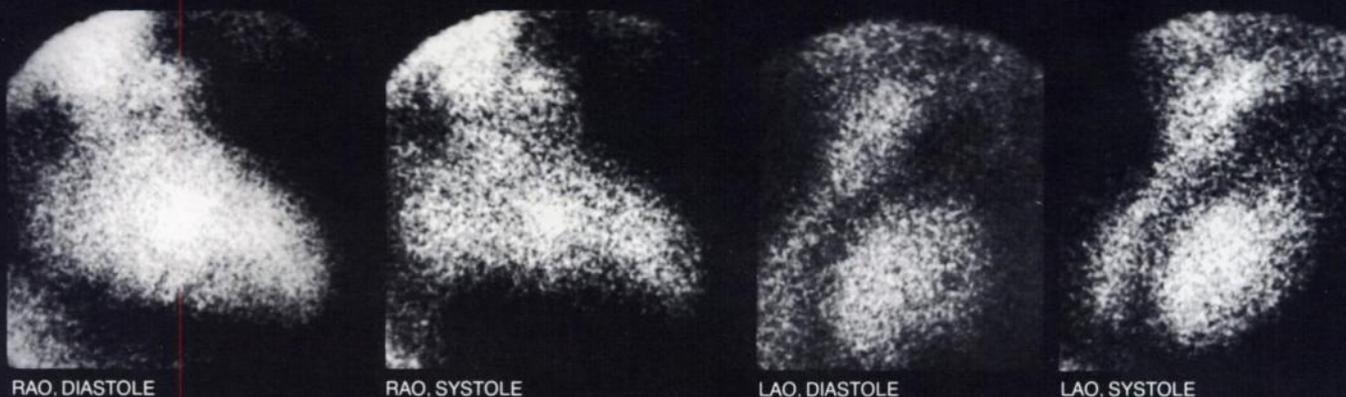
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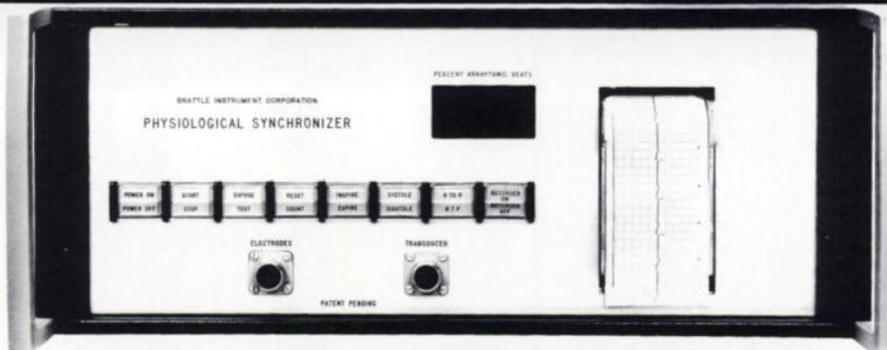
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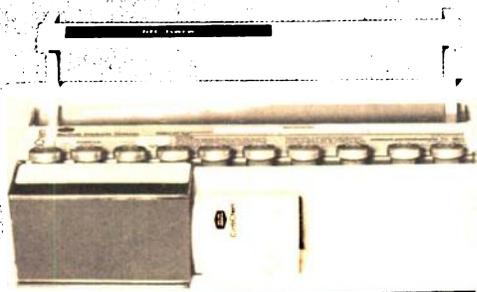
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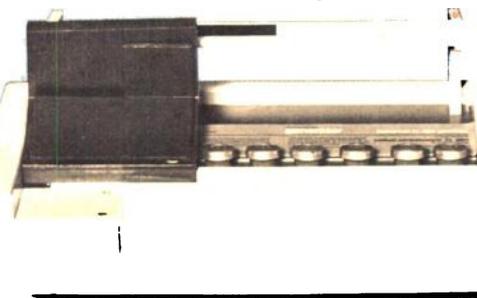
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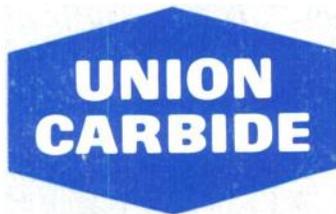


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