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	NRC (1) 4.50 mCi NCRP (2) 5.78 mCi		
67 Ga	0.94 mCi	10 mR/HR	100
	NRC (1) 3.5 mCi NCRP (2) 4.7 mCi		
131 I	0.25 mCi	10 mR/HR	50
	NRC (1) 1.0 mCi NCRP (2) 1.2 mCi		

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Isotope	Activity in Vial	Exposure at Surface of Vial Shield	Attenuation Factor
99 mTc	14 Ci	10 mR/HR	1 Million
	NRC (1) 56 Ci NCRP (2) 72 Ci		
67 Ga	2.8 mCi	10 mR/HR	300
	NRC (1) 11.0 mCi NCRP (2) 14.2 mCi		
131 I	0.49 mCi	10 mR/HR	100
	NRC (1) 1.9 mCi NCRP (2) 2.5 mCi		

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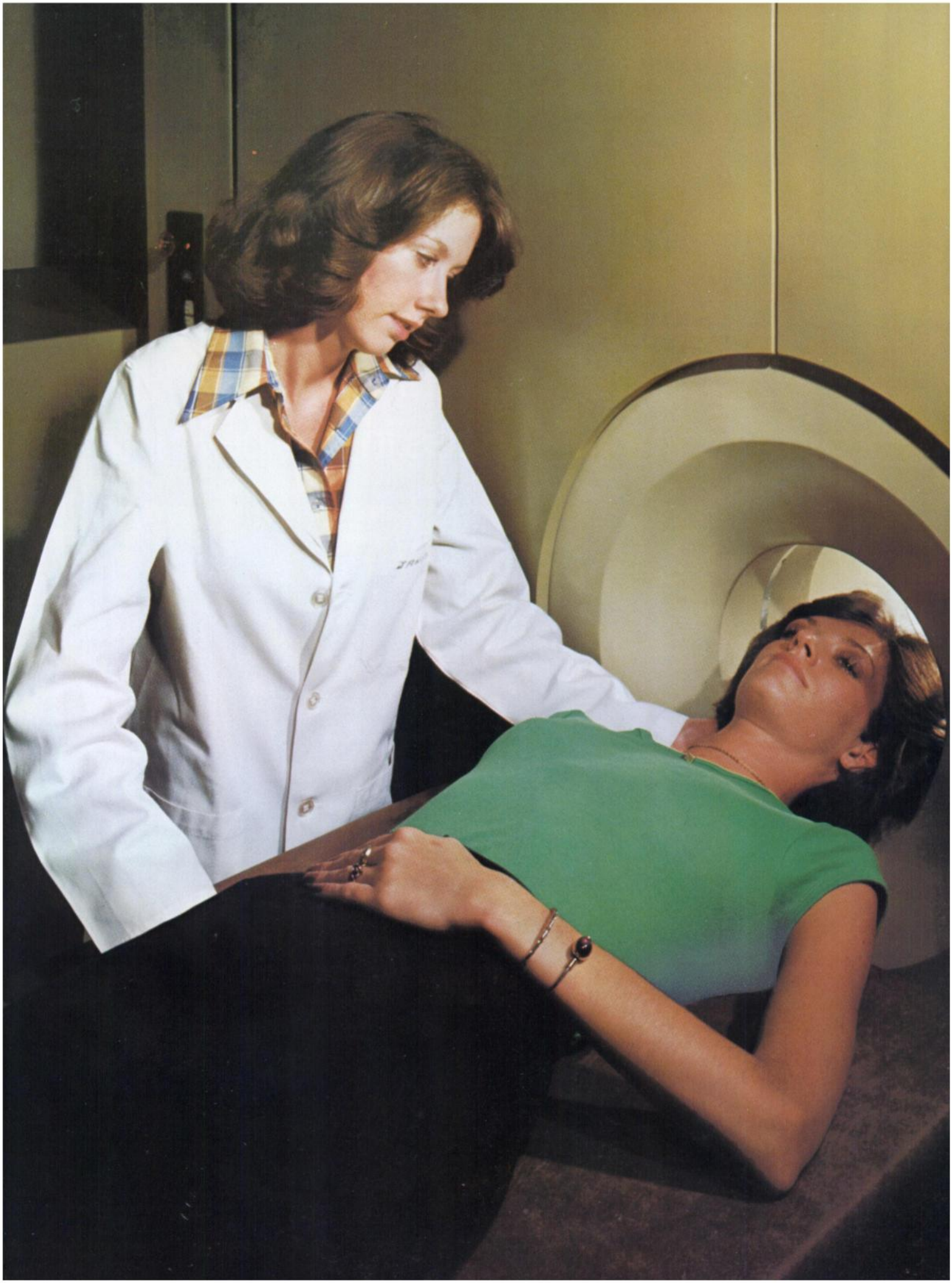

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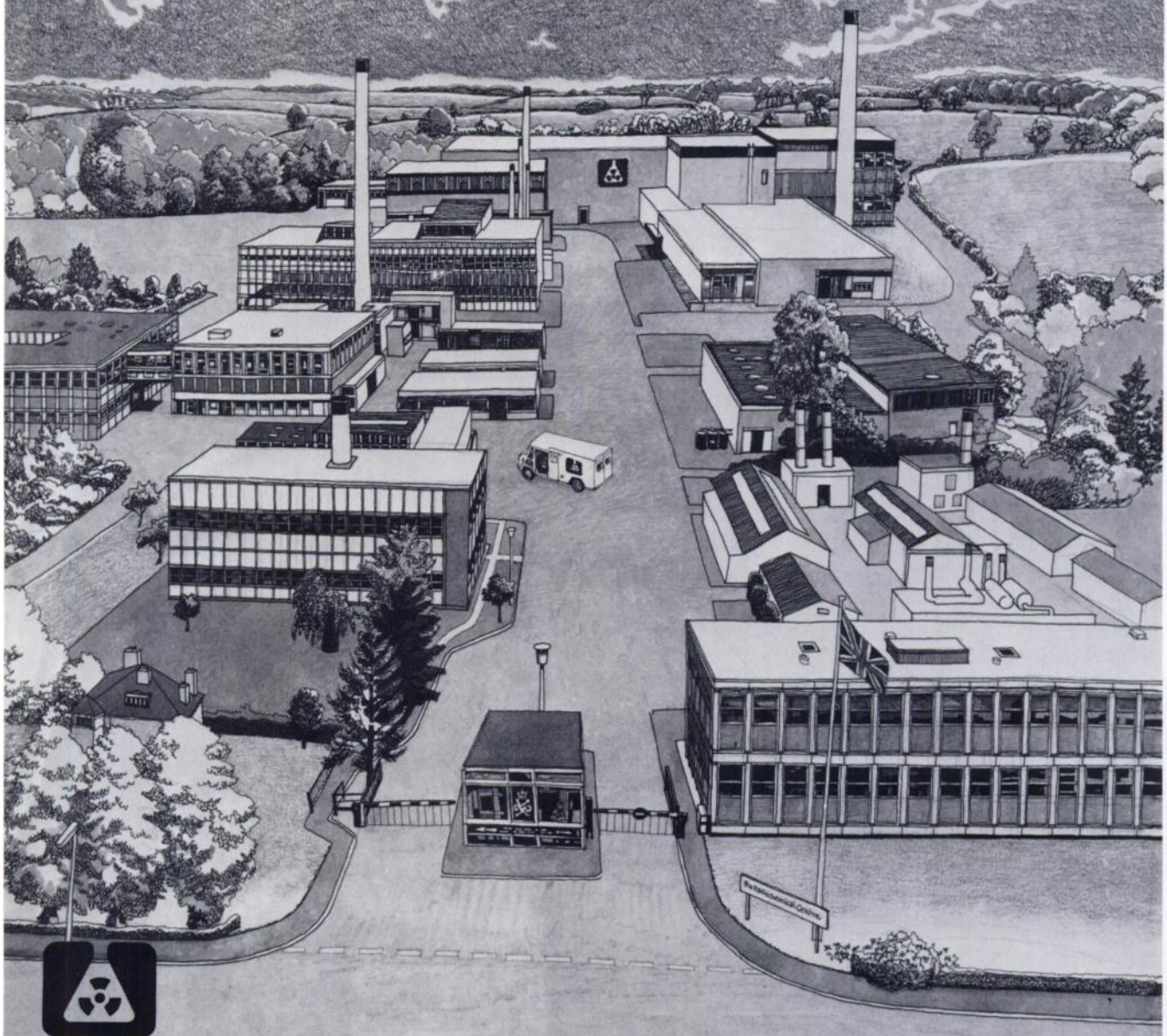

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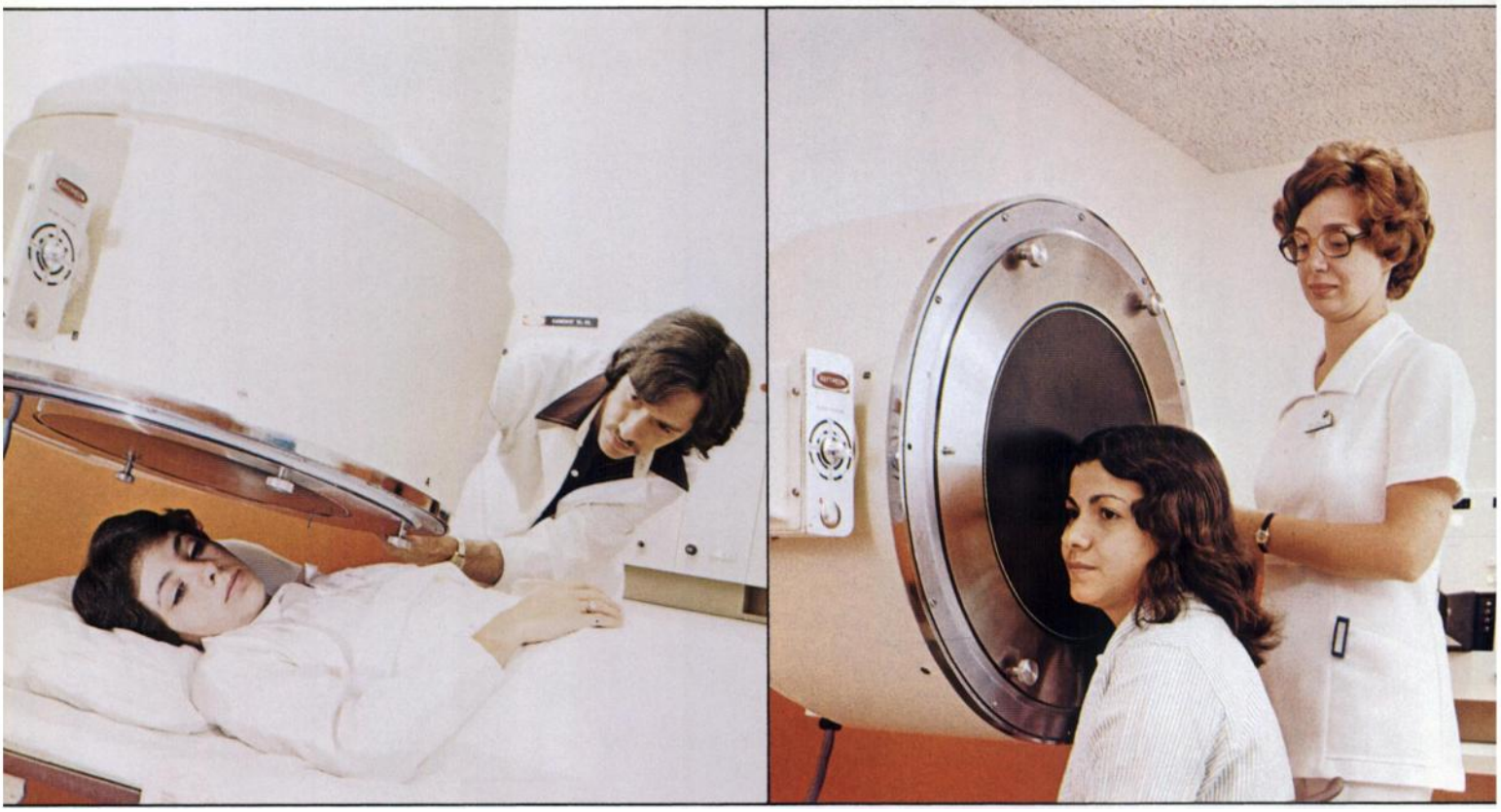

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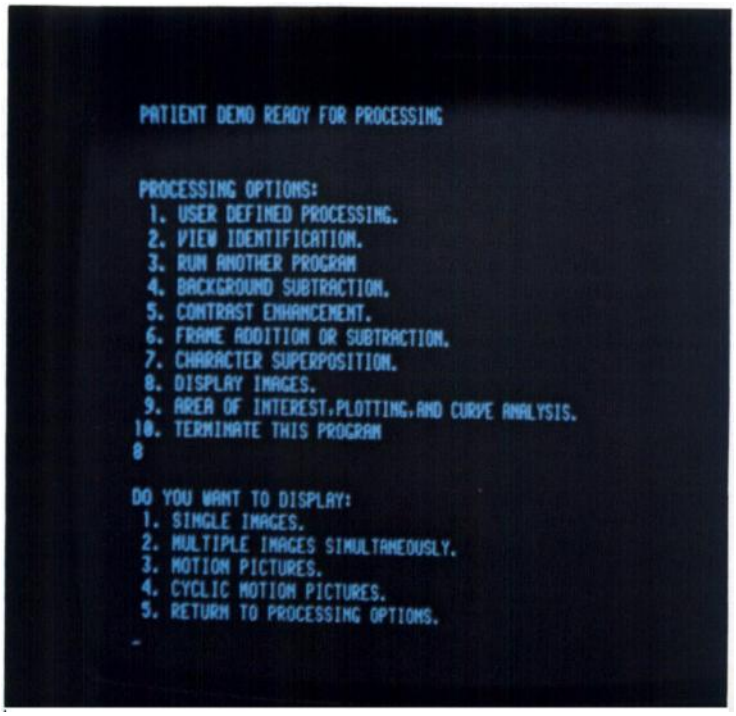

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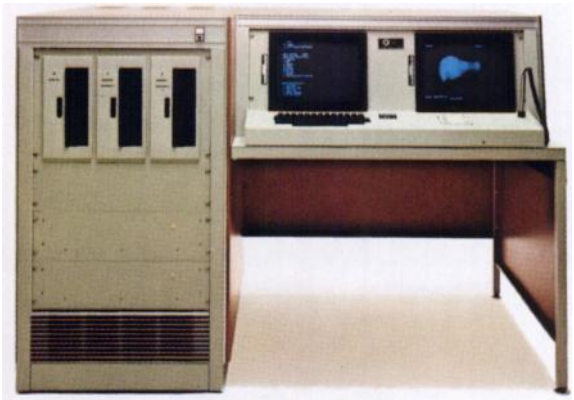

ADAC

Clinical Data Systems.

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THE QUALITIES YOU LIKED IN OUR FROZEN PRODUCT ARE ALL HERE IN ITS LYOPHILIZED SUCCESSOR.

Mallinckrodt research has now developed a formula that combines the quality features of our frozen **TechneScan MAA** product with the convenience of lyophilization. Our goal was to match—as closely as possible—particle-size range and consistency specifications that had been established with the frozen process. In our search we were determined not to compromise current product performance or specifications of our frozen product for the sake of convenience.

The introduction of Mallinckrodt's **TechneScan MAA**—Lyophilized—represents the successful conclusion of our search for a specially designed freeze dry process.

No need to freeze. Simply refrigerate for these same quality features.

Safety . . .

TechneScan MAA is very well tolerated. Effective lung excretion half-life is approximately 3.8 hours—virtually complete biological excretion occurs in about 24 to 48 hours. Although the possibility exists, there is, to date, no evidence of antibody formation.

Increased Shelf Life . . .

The expiration date of each **TechneScan MAA** lyophilized kit is now one year after date of manufacture. This extended shelf life permits the convenience of larger inventories plus the cost savings of buying in quantity.

Reliable Consistency . . .

Reconstitution does not affect either particle quality or size distribution. The particle size does not change after the addition of pertechnetate solution. There is no tendency for the particles to hydrate and increase in size after labeling. WE ENCOURAGE MICROSCOPIC EVALUATION AND COMPARISON!

Controlled Particle-Size Range . . .

Specifications require that not less than 90% of the particles be 10 to 90 microns in size, with not more than 10% below 10 microns, and none greater than 150 microns. Our investigations indicate that, typically, 90% of the **TechneScan MAA** particles are in the 10-40 microns range. This controlled particle size range, plus the fact that there is no tendency to agglomerate, results in good images of lung perfusion.

High Tagging Efficiency . . .

The tagging efficiency experienced with the **TechneScan MAA** kit is remarkably consistent, always at or near 100% conversion of pertechnetate to labeled MAA, with no loss of the label for up to 24 hours.

Easy Preparation . . .

Preparation of **TechneScan MAA** Tc 99m is easy.
(1) Allow five minutes to reach room temperature.
(2) Add Tc-99m.
(3) Agitate gently.
(4) Wait fifteen minutes for high tagging efficiency.

That's all!

Economy . . .

The **TechneScan MAA** Kit doesn't need expensive accessory equipment. Up to 15 adult patients can be scintigraphed from the preparation of a single vial of **TechneScan MAA**. This helps reduce the procedure cost per patient.

For those who were acquainted with the frozen product, we give our assurance of continued satisfaction; for those who were unable to use frozen **TechneScan MAA** because of storage considerations, we invite your evaluation of our lyophilized formula. For further information contact your Mallinckrodt representative.

LYOPHILIZED TechneScan® MAA (AGGREGATED ALBUMIN (HUMAN)) LUNG SCAN KIT

Mallinckrodt® NUCLEAR

RADIOPHARMACEUTICALS

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Consult package insert for complete prescribing information, a summary of which follows the next page.


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TechneScan® MAA LYOPHILIZED (AGGREGATED ALBUMIN (HUMAN))

Multi-Dose Kit for the Preparation of Technetated (Tc 99m) Aggregated Albumin (Human)

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), 120 micrograms of stannous chloride dihydrate, 80 milligrams of lactose, 24 milligrams of succinic acid and 1.4 milligrams of sodium acetate. **TechneScan MAA** is prepared from albumin that was nonreactive when tested for hepatitis B antigen (HB_SAg) by radioimmunoassay. Each vial contains approximately $8 \pm 2 \times 10^6$ 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 aggregated albumin, with a labeling efficiency of 90 percent or greater.

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, examination 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 is 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-homogenous 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 aggregated albumin 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 aggregated albumin should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

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 preparations of Tc 99m-labeled aggregated albumin have been reported.

Hypersensitivity reactions are possible whenever protein-containing materials such as Tc 99m labeled aggregated albumin 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.

HOW SUPPLIED

Catalog Number	
093	**TechneScan MAA** Kit (Lyophilized)

Kit Contains:

5—Aggregated Albumin (Human) Reaction Vials (1 ml each)—for the preparation of Technetated (Tc-99m) Aggregated Albumin (Human)

Reaction Vial Contains (in lyophilized form):

- 2.0 mg Aggregated Albumin (Human) ($8 \pm 2 \times 10^6$ particles)
- 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 $8 \pm 2 \times 10^6$ 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, 5 radiation labels and 5 radioassay information string tags.

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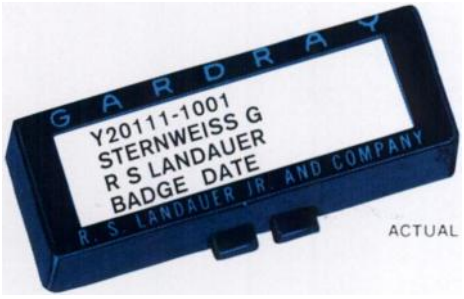

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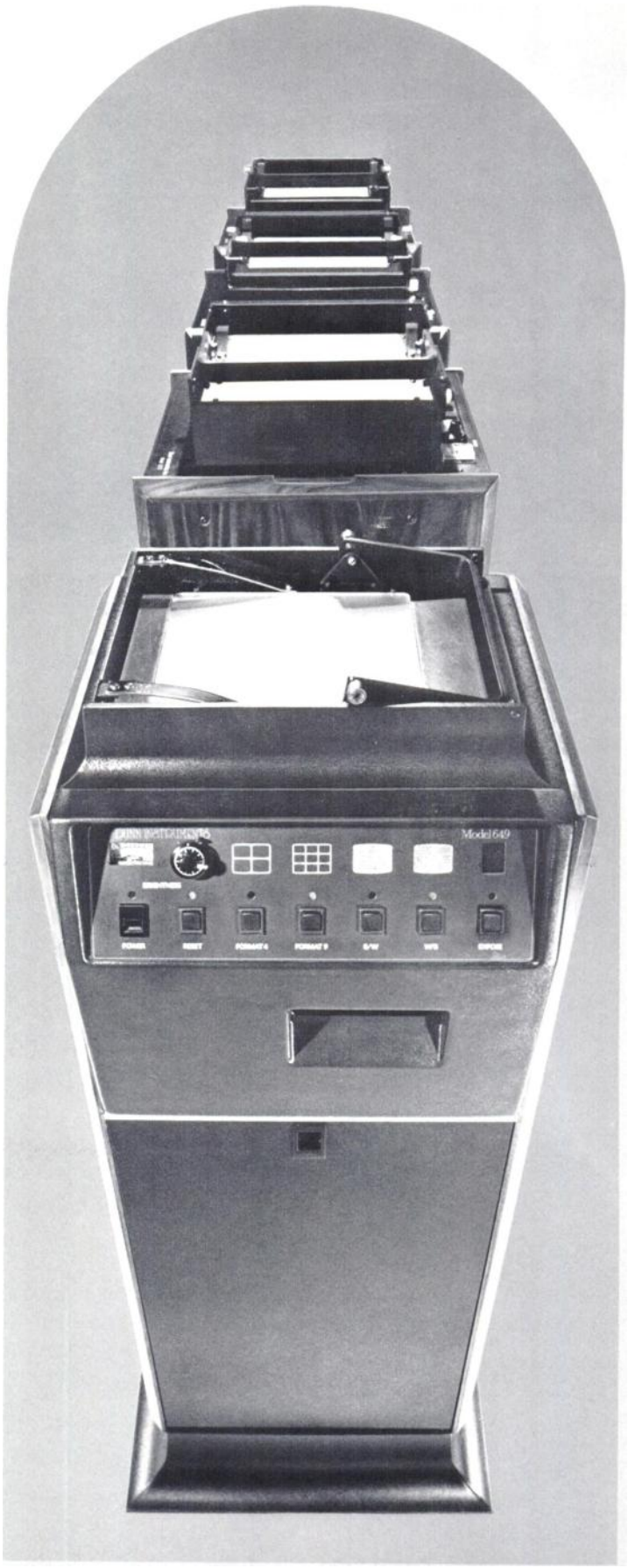


Dunn Instruments

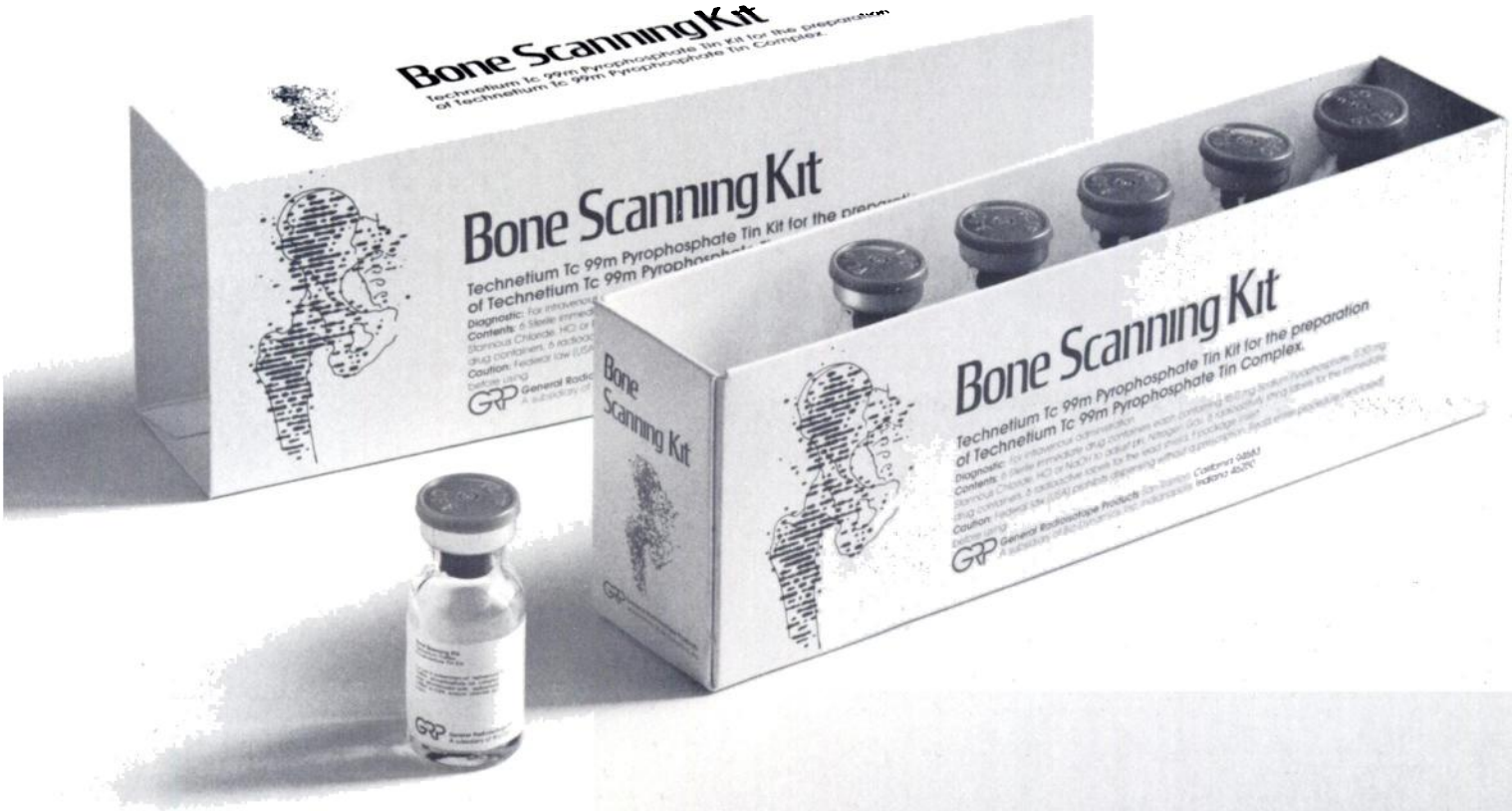
52 Colin P. Kelly Jr. St., San Francisco, CA 94107 (415) 957-1600

U.S. Patent No. 4,027,315

Bone Scanning Kit

Technetium Tc 99m
Pyrophosphate Tin Kit

- **Three [3] Hour Formulation Time**
- **Six [6] Month Shelf Life**
- **Six [6] Vials Per Kit**
- **Room Temperature Storage**
- **Freeze Dried**
- **Nitrogen Covered Inert Atmosphere**



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General Radioisotope Products
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Indianapolis, Indiana 46250

August 1977

Bone Scanning Kit

Technetium Tc 99m Pyrophosphate Tin Kit For Diagnostic Use

Description
Each reaction vial contains 15.0 mg Sodium Pyrophosphate and 0.30 mg Stannous Chloride; the product does not contain a preservative. The pH of the product is adjusted with Sodium Hydroxide or Hydrochloric Acid prior to lyophilization. At the time of manufacture, the air in the vial is replaced with a Nitrogen Gas atmosphere. When sterile, Pyrogen-free Sodium Pertechnetate Tc 99m is added to the vial, a Technetium Tc 99m Pyrophosphate Tin Complex is formed.

The precise structure of the Technetium Tc 99m Pyrophosphate Tin Complex is unknown at this time.

Administration is by intravenous injection for diagnostic use. The product as supplied is sterile and Pyrogen-free.

Physical Characteristics

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.03 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	87.9	140.5

[1]Dillman, L.T., and Von der Lage, F.C. Radionuclide Decay Schemes and Nuclear Parameters for Use in Radiation-Dose Estimation, MIRD pamphlet No. 10, p. 62, 1975.

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 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.

Table III. Physical Decay Chart: Tc 99m, half-life 6.03 hours

Hours	Fraction Remaining	Hours	Fraction Remaining
		5	0.563
		6	0.502
		7	0.447
		8	0.399
		9	0.355
0*	1.000	10	0.317
1	0.891	11	0.282
2	0.795	12	0.252
3	0.708	18	0.126
4	0.631	24	0.063

*Calibration Time

Clinical Pharmacology
Following intravenous administration of Technetium Tc 99m Pyrophosphate Tin solution, skeletal uptake occurs as a function of blood flow to bone and bone efficiency in extracting the complex. Bone mineral crystals are generally considered to be hydroxyapatite, and the complex appears to have an affinity for the hydroxyapatite crystals in bone.

Clearance of the radioactivity from the blood is quite rapid with skeletal uptake and urinary excretion being the principal mechanisms of clearance. At two hours following intravenous injection, approximately 55 percent of the injected dose was localized in bone; at four hours approximately 10 percent of the dose remains in the vascular system, decreasing to about 7 percent at 24 hours. The average urinary excretion was observed to be about 38 percent of the administered dose after eight hours, increasing to an average of about 44 percent at 24 hours. A minimum amount of uptake has been observed in soft-tissue organs, most notably the kidneys.

Indications and Usage
Technetium Tc 99m Pyrophosphate Tin Complex may be used as a bone imaging agent to delineate areas of altered osteogenesis.

Contraindications
None known.

Warnings
Technetium Tc 99m Pyrophosphate Tin should not be administered 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, of a woman of child-bearing capability should be performed during the first few (approximately 10) days following the onset of menses.

It is reported that false-positive or false-negative brain scans may result when brain scans using Sodium Pertechnetate Tc 99m are performed after a bone scan has been done using an agent containing Stannous Ions, e.g., a Pyrophosphate bone agent. This is thought to be due to the interaction of Tc 99m with Stannous Ions inside red blood cells. Therefore, in those cases where both brain and bone scans are indicated, the brain scan should be performed first, if feasible. Alternatively, another brain imaging agent, such as Tc 99m DTPA, may be employed.

The contents of the reaction vial are intended only for use in the preparation of Technetium Tc 99m Pyrophosphate Tin solution and are not to be directly administered to the patient.

Any Sodium Pertechnetate Tc 99m solution which contains an oxidizing agent is not suitable for use with the Technetium Tc 99m Pyrophosphate Tin Kit.

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

Precautions
Technetium Tc 99m Pyrophosphate Tin solution, 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 patient consistent with proper patient management.

Both prior to and following administration of Technetium Tc 99m Pyrophosphate Tin solution, the patient should be encouraged to drink fluids and to void as often as possible thereafter to minimize radiation exposure to the bladder and background interference during imaging.

Technetium Tc 99m Pyrophosphate Tin solution must be used within 3 hours of reconstitution.

Adequate reproductive studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Pyrophosphate Tin 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 the drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established.

Adverse Reactions
No adverse reactions specifically attributable to the use of Technetium Tc 99m Pyrophosphate Tin have been reported.

Dosage and Administration
The suggested dose range for intravenous administration to be employed in the average patient (70 kg) is 10 to 15 millicuries Technetium Tc 99m labeled Pyrophosphate Tin.

Technetium Tc 99m Pyrophosphate Tin solution is injected intravenously over a 10- to 20-second period. Imaging may be started at one hour after administration; however, for optimal results, bone imaging should be performed two to four hours following administration.

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.

Technetium Tc 99m Pyrophosphate Tin is prepared by adding 1 ml of Sodium Pertechnetate Tc 99m solution to the vial and shaking gently. Shielding should be utilized when preparing the Tc 99m Pyrophosphate Tin.

Radiation Dosimetry

The effective half-life was assumed to be equal to the physical half-life for all calculated values. The estimated absorbed radiation doses to an average patient (70 kg) from an intravenous injection of a maximum dose of 15 millicuries of Tc 99m Pyrophosphate Tin are shown in Table IV.

Table IV. Absorbed Radiation Dose

Tissue		Tc 99m Pyrophosphate Tin [rads/15 millicuries]
Skeleton*		0.52
Bone Marrow		0.54
Kidneys		0.42
Liver		0.16
Total Body†		0.14
Bladder	3 hour void	0.67
	6 hour void	1.05
Testes	3 hour void	0.06
	6 hour void	0.10
Ovaries	3 hour void	0.06
	6 hour void	0.10

*Dose at point of highest uptake may be a factor of 10 higher.

†If patient voids frequently after radiopharmaceutical is administered, this dose will be reduced slightly.

Method of Calculation: A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides, MIRD Pamphlet No. 1, J. Nucl. Med. Suppl 1:7, 1968.

How Supplied

A. 6 sterile immediate drug containers each containing: (Lyophilized).
   —15.0 mg Sodium Pyrophosphate
   —0.30 mg Stannous Chloride
   —HCl or NaOH to adjust pH
   —Nitrogen Gas
B. 6 radioactivity string labels for the immediate drug container.
C. 6 radioactivity labels for the lead shield.
D. 1 package insert.
E. 1 instruction card.

Storage

Store the Technetium Tc 99m Pyrophosphate Tin solution between 2° and 8°C. Use the radioactive complex within 3 hours after reconstitution.

Preparation

Do not use if there is a vacuum in the immediate drug container or if air is injected into the container when the dose is withdrawn. Formulate within three hours prior to clinical use.

1. Fix the string radioactivity label to the neck of the immediate drug container.
2. Remove the flip-cap from the container and place the container in the lead shield.
3. Use a germicide to swab the septum of the sterile reaction container.
4. Aseptically inject into the immediate drug container 1 ml of sterile, non-pyrogenic 0.9% Sodium Chloride solution containing radioactive Sodium Pertechnetate Tc 99m and withdraw an equal volume of Nitrogen Gas. Do not allow air to enter the container. Do not use the Technetium Tc 99m solution if it contains foreign matter.
5. Dissolve and mix well by gently shaking the container in the shield for 30 seconds to one minute.
6. Measure and record the Tc 99m radioactivity and calibration data on the string radioactivity label and on the shield radioactivity label. Enter the time of expiration in the space provided and fix the label to the shield.
7. Maintain adequate shielding of the Technetium Tc 99m Pyrophosphate at all times.

This reagent kit is approved by the California Department of Health for distribution to persons licensed pursuant to Sections 35.14 and 35.100, Group III of 10 CFR 35, or under equivalent licenses of Agreement States.

General Radioisotope Products
3120 Crow Canyon Road San Ramon, California 94583
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Meletron

The dosecalibrator that calibrates itself (almost)

Radx has now programmed its new Meletron to read its own calibration factors. The Meletron programmable microprocessor allows you to check each of the Isotope Selector Keys for proper multiplication factors.

Radx employs direct mathematical manipulation for the various radionuclides (other dosecalibrators vary the resistance to alter the signal from the ionization chamber to the digital meter) and these factors can now be recalled from memory and displayed on the digital readout. Since each radionuclide has a finite and discrete mathematical factor, the ability to recall and display this factor (as triggered by the Isotope Selector Key) will remove any doubt concerning this aspect of dosecalibration.

Area radiation can also be monitored by the new Meletron. With the key out, "Background – Error" will flash when the radiation level exceeds approximately 2.0 mr/hr (with an unshielded unit).

Area monitoring is standard on Meletron; an extra cost option on other dosecalibrators.

Hard copy data of your radionuclide calibrations is another RADX first. The Melecord prints; time, date, volume, calibration, patient dose, radionuclide — plus it calculates and then prints the volume to administer. Easy compliance with NRC requirements is also assured by Melefile, the RADX record keeping system which provides data cards, tab cards and a compact file to keep them in.

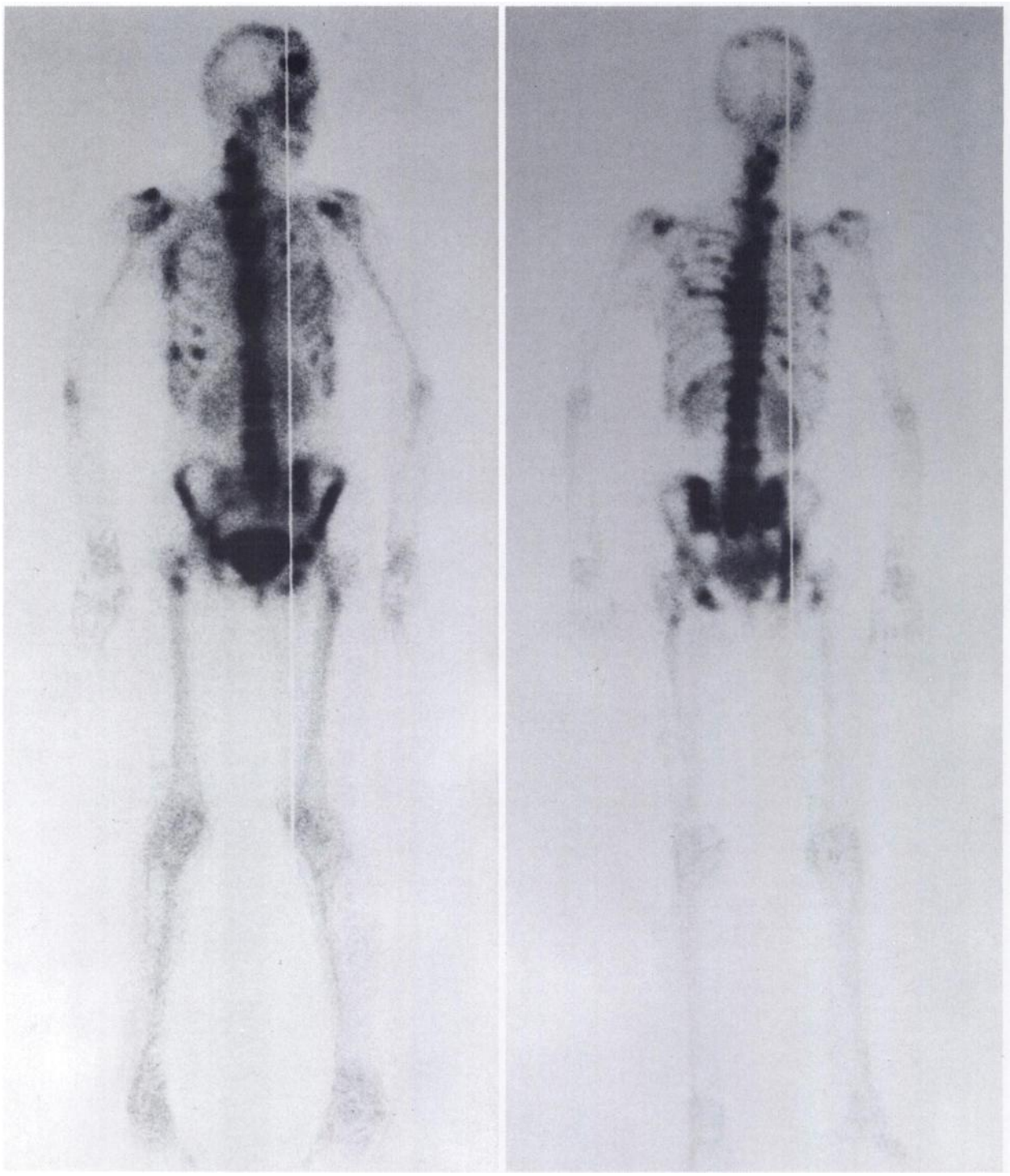
Obsolescence is eliminated. The Meletron employs the latest in microprocessor technology. The highly reliable microprocessor is readily programmable to perform a wide variety of functions. Further program modifications may be added to your unit in the field, as they are developed.

For a permanent solution to your dosecalibration and record-keeping problems, call RADX — the innovators in nuclear medicine. RADX, P. O. Box 19164, Houston, Texas 77024, 713/468-9628.

RADX

Melétron & Melécord . . . your key to accurate dosecalibration and error-free records.

Dependable bone



Anterior
R. L.

Posterior
L. R.

lesion detection

PROCTER & GAMBLE

OSTEOSCAN®

(5.9 MG DISODIUM ETIDRONATE, 0.16 MG STANNOUS CHLORIDE)

SKELETAL IMAGING AGENT

Excellent in vitro stability

Greater than 98% labeling efficiency 8 hours after preparation. Osteoscan contains sodium ascorbate, an antioxidant that inhibits action of radiolysis by-products and oxidants capable of causing complex breakdown and resultant soft tissue visualization.

Compatible with all types of technetium

Delivers consistently high-quality scans, using either instant or generator technetium.

Plus these other Osteoscan benefits

- very low tin level to minimize potential for liver visualization and for interference with subsequent brain scans
- rapid blood clearance
- high target-to-nontarget ratio
- diphosphonate's P-C-P bond for excellent in vivo stability

For further information about Osteoscan, please contact: Arnold Austin, Technical Manager, Professional Services Division, Procter & Gamble (513) 977-8547.

In Europe, contact: Philips-Duphar B.V., Cyclotron and Isotope Laboratories, Petten, Holland.

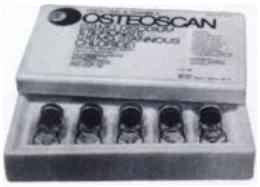
See following page for a brief summary of package insert.

PROCTER & GAMBLE

OSTEOSCAN®

(5.9MG DISODIUM ETIDRONATE, 0.16MG STANNOUS CHLORIDE)

SKELETAL IMAGING AGENT



Brief summary of Package Insert. Before using, please consult the full Package Insert included in each kit.

DESCRIPTION

Each vial of OSTEOSCAN contains 5.9 mg disodium etidronate and 0.16 mg stannous chloride as active ingredients. Upon addition of ADDITIVE-FREE ^{99m}Tc-pertechnetate, these ingredients combine with ^{99m}Tc to form a stable soluble complex.

ACTIONS (CLINICAL PHARMACOLOGY)

When injected intravenously, ^{99m}Tc-labeled OSTEOSCAN has a specific affinity for areas of altered osteogenesis. Areas of bone which are undergoing neoplastic invasion often have an unusually high turnover rate which may be imaged with ^{99m}Tc-labeled OSTEOSCAN.

Three hours after intravenous injection of 1 ml ^{99m}Tc-labeled OSTEOSCAN, an estimated 40-50% of the injected dose has been taken up by the skeleton. At this time approximately 50% has been excreted in the urine and 6% remains in the blood. A small amount is retained by the soft tissue. The level of ^{99m}Tc-labeled OSTEOSCAN excreted in the feces is below the level detectable by routine laboratory techniques.

INDICATIONS

OSTEOSCAN is a skeletal imaging agent used to demonstrate areas of altered osteogenesis.

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.

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 ^{99m}Tc-generator should be tested routinely for molybdenum breakthrough and aluminum. If either is detected, the eluate should not be used.

PRECAUTIONS

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

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.

ADVERSE REACTIONS

None.

DOSAGE AND ADMINISTRATION

The recommended adult dose of ^{99m}Tc-labeled OSTEOSCAN is 1 ml with a total activity range of 10-15 mCi. ^{99m}Tc-labeled OSTEOSCAN should be given intravenously by slow injection over a period of 30 seconds within eight (8) hours after its preparation. Optimum scanning time is 3-4 hours postinjection.

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

TECHNETIUM-99M DTPA(TIN)

Brief summary of package insert. Before using, please consult the full package insert included in every kit.

DESCRIPTION

The kit contains 10 vials, each vial containing 5 mg sterile, pyrogen-free Sodium salt of Diethylenetriamine-pentaacetic Acid (DTPA) and 0.25 mg Stannous Chloride.

Administration is by intravenous injection for diagnostic use. The product as supplied is sterile and pyrogen-free.

When sterile, pyrogen-free Sodium Pertechnetate Tc 99m is added to the vial, a chelate, Technetium Tc 99m DTPA is formed.

HOW SUPPLIED

Diagnostic Isotopes' Technetium Tc 99m DTPA Kit (Chelate) is supplied as a sterile, pyrogen-free kit containing 10 vials. Each vial contains 5 mg of Sodium salt of DTPA and 0.25 mg of $SnCl_2$. The pH is adjusted with HCl or NaOH prior to lyophilization. Following lyophilization the vials are sealed under a nitrogen atmosphere.

CLINICAL PHARMACOLOGY

Following its intravenous administration, Technetium Tc 99m DTPA rapidly distributes itself throughout the extracellular fluid space from where it is (promptly) cleared from the body by glomerular filtration. There should be little or no binding of the chelate by the renal parenchyma. A variable percentage of the Technetium Tc 99m DTPA binds to serum proteins; this ranges from 3.7% following the single injection to approximately 10% if the material is continuously infused. Although the chelate gives useful information on the glomerular filtration rate, the variable percent which is protein bound leads to a measured glomerular filtration rate which is lower than the glomerular filtration rate as determined by inulin clearances.

Technetium Tc 99m DTPA tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. The chelate does not accumulate in the choroid plexus.

Since Technetium Tc 99m DTPA is excreted by glomerular filtration, the images of the kidneys obtained in the first few minutes after injection represent the vascular pool within the kidney. Subsequent images of the kidneys represent radioactivity which is in the urine of both the collecting system and the renal pelvis.

INDICATIONS AND USAGE

Technetium Tc 99m DTPA may be used to perform kidney imaging, brain imaging, to assess renal perfusion, and to estimate glomerular filtration rate.

CONTRAINDICATIONS

None known.

WARNINGS

Technetium Tc 99m DTPA 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, of a woman of child-bearing capability should be performed during the first few (approximately 10) days following the onset of menses.

PRECAUTIONS

Technetium Tc 99m DTPA 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 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.

Pregnancy Category C: Adequate reproductive studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m DTPA 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 DTPA have been reported.

DOSAGE AND ADMINISTRATION

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

Kidney imaging and glomerular filtration rate estimation: 3 to 5 mCi.

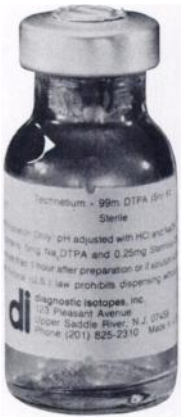
Brain imaging or renal perfusion: 10 to 20 mCi.

diagnostic isotopes incorporated
225 Belleville Avenue, Bloomfield, N.J. 07003

By the time some people can say:

"DIETHYLENETRIAMINEPENTA-ACETIC ACID AND STANNOUS CHLORIDE IN A LYOPHILIZED STATE UNDER NITROGEN"

You've got it mixed and ready to use!



Unless you're in the business, this tongue-twister may tie you up for some time. However, it only takes one minute of mixing time to prepare Diagnostic Isotopes' one-step Technetium-99m DTPA agent for injection.

DTPA becomes Technetium-99m DTPA (Tin) after adding sodium pertechnetate Tc-99m. Technetium-99m DTPA may be used to perform kidney imaging, brain imaging, to assess renal perfusion and to estimate glomerular filtration rate.

Each DTPA kit contains 10 vials. The product is sterile, pyrogen-free, has a labeling efficiency of over 95% and a shelf life of one year . . . all good reasons for ordering now.

See opposite page for a brief summary of the package insert.

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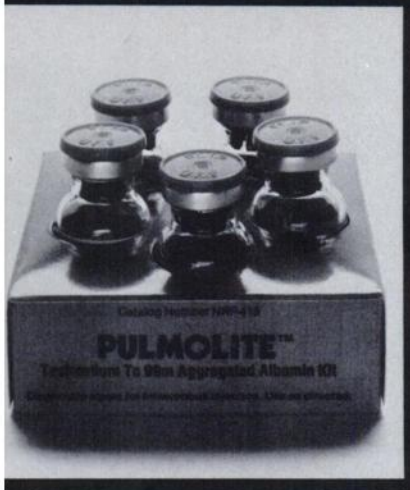
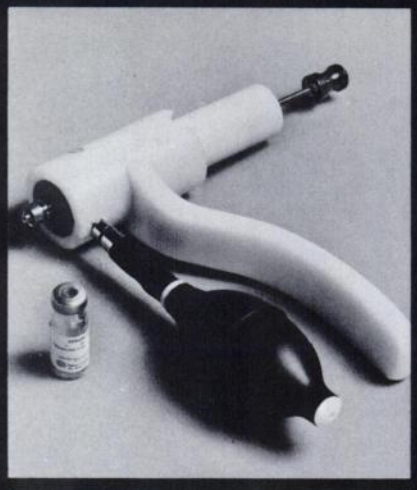
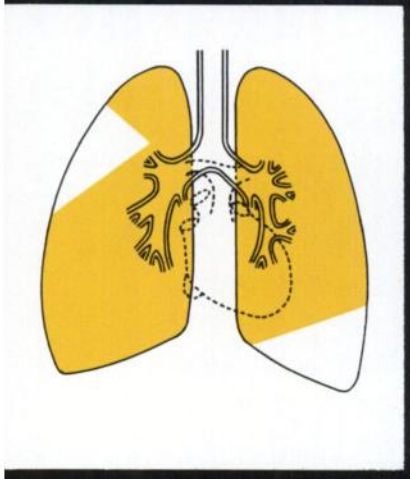
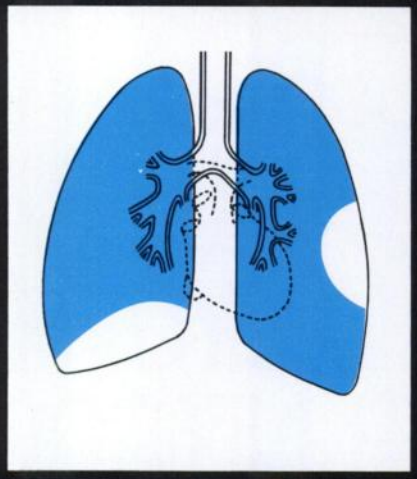
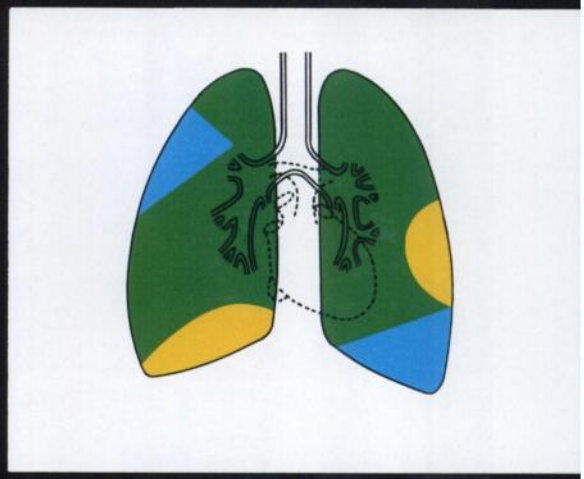
Kits Available: *DTPA, Polyphosphate, Diphosphonate.*
Prepared Radiopharmaceuticals Available: *Selenium-75, Xenon-133 (solution or gas)*











Perfusion + Ventilation: The two together are diagnostically better.

The ventilation-perfusion ratio $\left(\frac{\dot{V}}{\dot{Q}}\right)$ is the crucial factor determining the regional oxygen partial pressure. This can be evaluated by assessing the gas exchange occurring in any part of the lung. The single most *sensitive* non-invasive test for diagnosing Pulmonary Embolus is the perfusion lung image.[1] However, pulmonary diseases, such as chronic obstructive lung disease, infectious diseases, and neoplasms are all characterized by altered arterial blood flow. Therefore the most reliable way to increase the *specificity* of perfusion lung imaging is to add a Xenon 133 ventilation study.[2]

[1]Urokinase Pulmonary Embolism Trial. A National Cooperative Study. Circulation (Suppl 11) 47:11-61. 1973 (April)

[2]Wagner, Henry N. Jr., Strauss, H. William. *Radioactive Tracers In The Differential Diagnosis of Pulmonary Embolism*. Progress in Cardiovascular Diseases, Vol. XVII, No. 4 (January/February), 1975.

PULMOLITE™—Technetium Tc 99m Aggregated Albumin Kit Diagnostic—For Intravenous Use

Indications and Usage: Technetium Tc 99m aggregated albumin is indicated as a lung imaging agent to be used as an adjunct in the evaluation of pulmonary perfusion.

Contraindications: Technetium Tc 99m aggregated albumin should not be administered to patients with severe pulmonary hypertension.

The use of Tc 99m aggregated albumin 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.

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 children or to pregnant or lactating women unless the expected benefits to be gained outweigh the potential risks.

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

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.

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

The contents of the vial are sterile and non-pyrogenic. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiodiagnostic.

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

It is also recommended that, because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m aggregated albumin 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. 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 aggregated albumin should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

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 the occupational worker.

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 preparations of Tc 99m-labeled aggregated albumin have been reported.

Hypersensitivity reactions are possible whenever protein-containing materials such as Tc 99m-labeled aggregated albumin 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 (70kg) is 1 to 4 millicuries. The volume of the dose may vary from 0.2 to 1.3ml.

The recommended number of aggregated albumin particles to be administered per dose is 200,000-700,000 with the suggested number being approximately 350,000.

For ease and accuracy in dispensing the prepared agent, it is recommended that prior to reconstitution, concentrated sodium pertechnetate Tc 99m be further diluted to a volume of 8ml with fresh, preservative-free sodium chloride injection (U.S.P.).

How Supplied: PULMOLITE™ Technetium Tc 99m Aggregated Albumin Kit is supplied in kits of five (5) or thirty (30) vials, sterile and non-pyrogenic, each vial containing in lyophilized form:

Aggregated albumin (human) - 1.0mg
Normal human serum albumin - 10mg
Sodium chloride - 10mg
Stannous chloride dihydrate, maximum - 0.07mg

Each vial contains 3.6-6.5 x 10^6 aggregated albumin particles.

PULMOLITE contains no preservative; after reconstitution the shielded vial should be stored at 2° to 8°C.

Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.

Cat. No. NRP-415

Xenon Xe 133 Gas (CALIDOSE™) Dispensing System.

Indications: Inhalation of Xenon Xe 133 gas has proved valuable for the evaluation of pulmonary function and for imaging the lungs. It may also be applied to assessment of cerebral flow.

Contraindications: To date, no known contraindications to the use of Xenon Xe 133 gas have been reported.

Warnings: This radiopharmaceutical should not be administered to pregnant or lactating women unless the 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 the menses.

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

Precautions: As in the use of any other radioactive material care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers. Expired Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate governmental agency regulations. Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic. 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.

Adverse Reactions: To date, no adverse reactions based on the use of Xenon Xe 133 gas have been reported.

Dosage and Administration: Xenon Xe 133 gas is administered by inhalation from closed respirator systems or spirometers. The suggested activity range employed for inhalation by the average adult patient (70 kg) is:

Pulmonary function including imaging:
in 3 liters of air.
Cerebral blood flow: 10-30 mCi in 3 liters of air.

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

How Supplied: The Xenon Xe 133 gas is supplied as part of the Calidose™ system, consisting of 2 ml unit dose vials and the Calidose dispenser* for shielded dispensing.

Normally vials containing either 10 or 20 mCi/vial, packed up to 5 vials per shield tube, are supplied. Vial sets containing up to 100 mCi/vial are available.

*Patent Pending

Cat. No. NRP-186

NEN New England Nuclear
Radiopharmaceutical Division
Atomlight Place, North Billerica, Mass. 01862
Telephone 617-667-9531
Los Angeles: 213-321-3311

Canada: NEN Canada Ltd., 2453 46th Avenue, Lachine, Que. H7T 3C9.
Telephone: 514-636-4971, Telex: 05-821808
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Now there's an Aldosterone you can count on.

Literally, if you have a gamma counter. And most labs do. But until now, you had to use liquid scintillation methods for Aldosterone. Or you just didn't count at all.

So, if you're set up for gamma counting, our new ^{125}I Aldosterone RIA Kit adds up to just what you've been waiting for. Easy to use—no chromotography, simple extraction. Low cross reactivity. Greater precision—3% within run, 8% between run. And it comes with all the advantages, experience, and dependability of all our RIA Kits.

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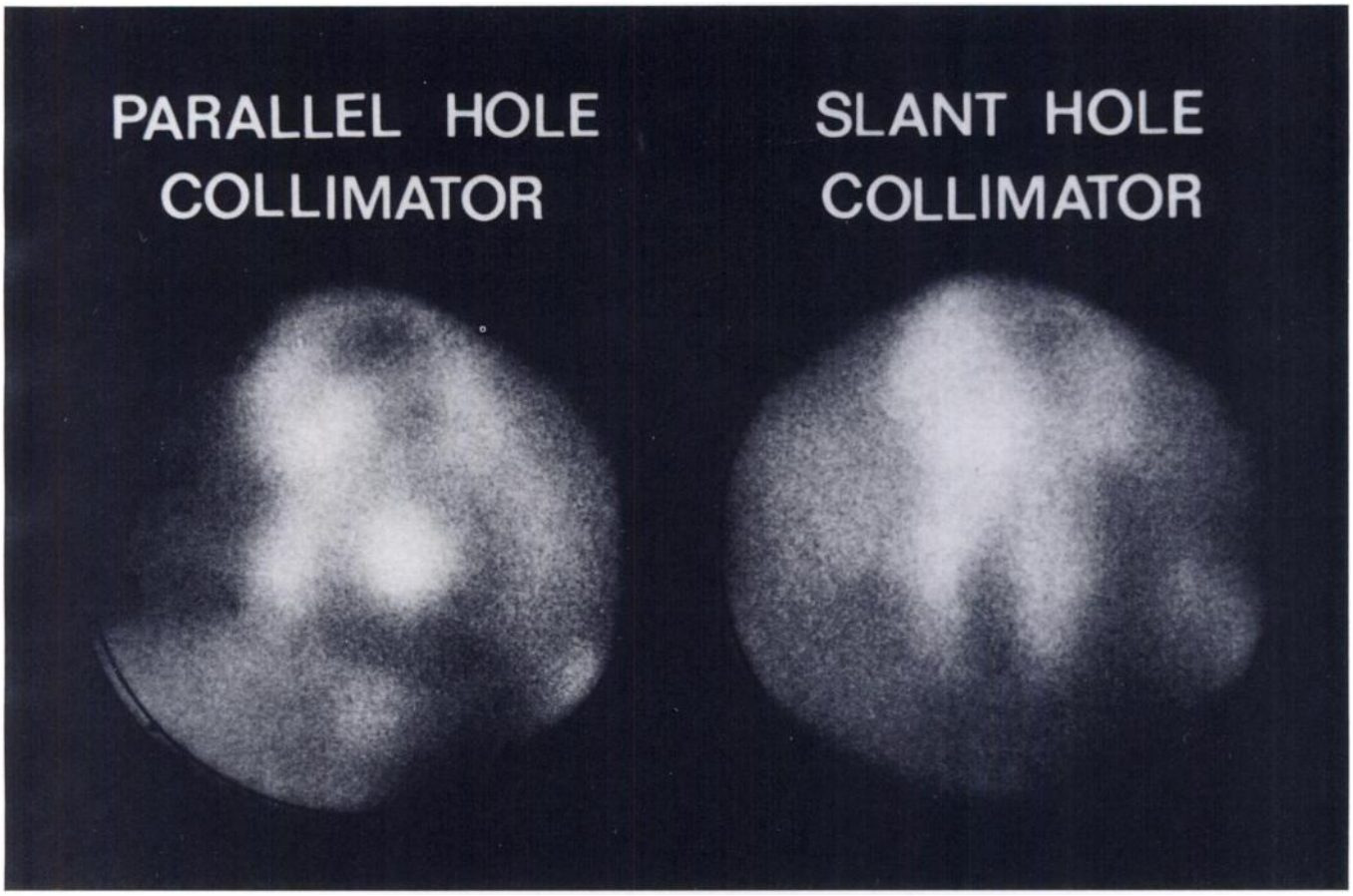

Ungated image of cardiac blood pool in patient with aortic stenosis and left ventricular hypertrophy. Both straight-bore, parallel-hole collimator and straight-bore, 30° slant-hole collimator were positioned in LAO projection. In both images camera head was positioned flat against chest. Due to slope of chest this provided about a 15° caudal angulation.

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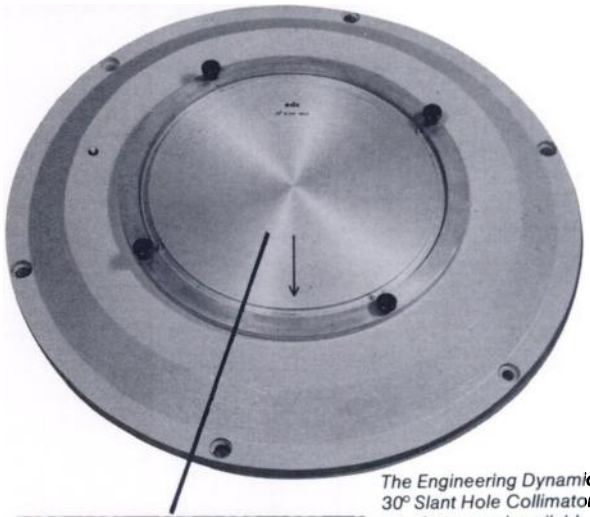

The Engineering Dynamics 30° Slant Hole Collimator—now in use and available for delivery. Other angles are available for special diagnostic procedures.

Cross-section view shows parallel square holes of collimator aligned at a 30° angle to crystal face for closer patient positioning, improved cardiac imaging.

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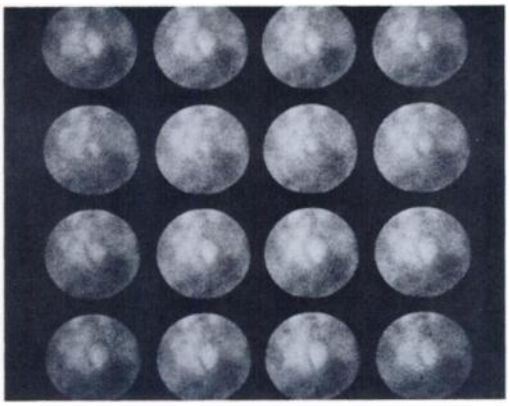

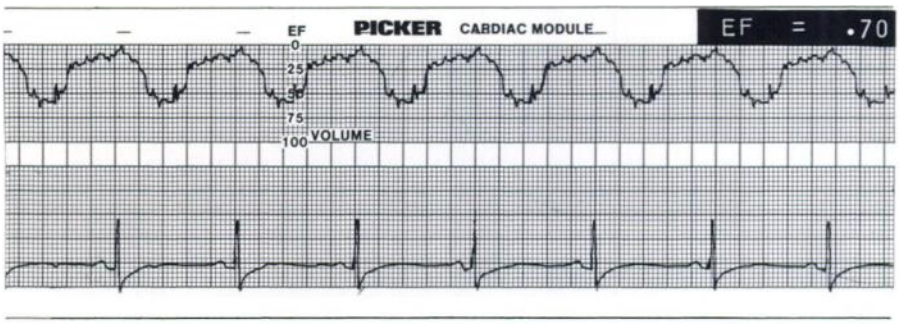

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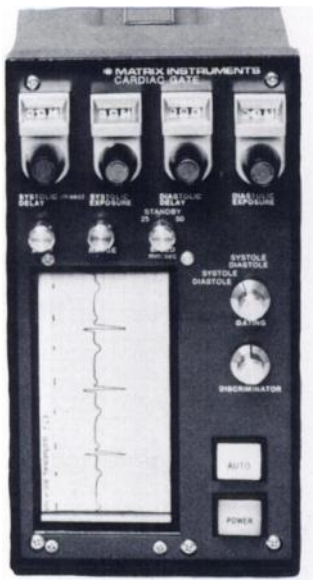


Cardiac Gate is designed to synchronize the cardiac image exposure with predetermined phases of the cardiac cycle.

The Cardiac Gate has two modes of operation: manual and automatic. In the manual mode, delay and exposure time parameters are set manually, using the R wave of the electrocardiogram as a reference. In the automatic mode, microprocessor circuitry automatically tracks the cardiac cycle and computes the position of end-systole and end-diastole. In the automatic mode, end-systole and end-diastole exposures are made without any calibration settings.

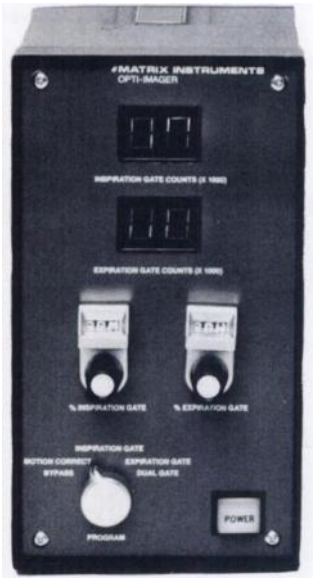
The dual gating operation mode allows recording of both end-systole and end-diastole simultaneously in a split screen two image format.

The cardiac cycle can even be divided into nine equal time segments and the image corresponding to each displayed simultaneously in a nine image format.

The Cardiac Gate includes a complete electrocardiograph module. The built in heated stylus strip chart recorder records both the ECG trace and the gating intervals.

The Cardiac Gate provides both ECG and gating outputs for computer interface.

Opti Imager



Opti-Imager is designed to provide an organ image with effects due to respiratory motion minimized. Opti-Imager has two distinct modes of operation: continuous motion correction and respiratory gating. In the continuous motion correction mode, the motion of the organ is tracked and corrected electronically without the need to attach any sensors to the patient. The distribution of counts within the organ image is monitored and corrections are applied to continuously shift the image before it is displayed to compensate for organ motion. Correction is made for motion in both the X and Y direction. Thus, the gamma camera is not gated and all the counts provided by the detector are recorded. The time required to attain a statistically satisfactory image is the same for both a motion corrected and an uncorrected image. In the gating mode, inspiration plateau and expiration plateau images are recorded. The dual gating operation mode allows recording of both inspiration and expiration plateau images simultaneously in a split screen two frame format. Dual scalers record the number of counts in each image.

The Cardiac Gate and Opti-Imager can be synchronized to yield a combination of both cardiac and respiratory gating. Mail coupon to receive detailed information and sample clinical studies.

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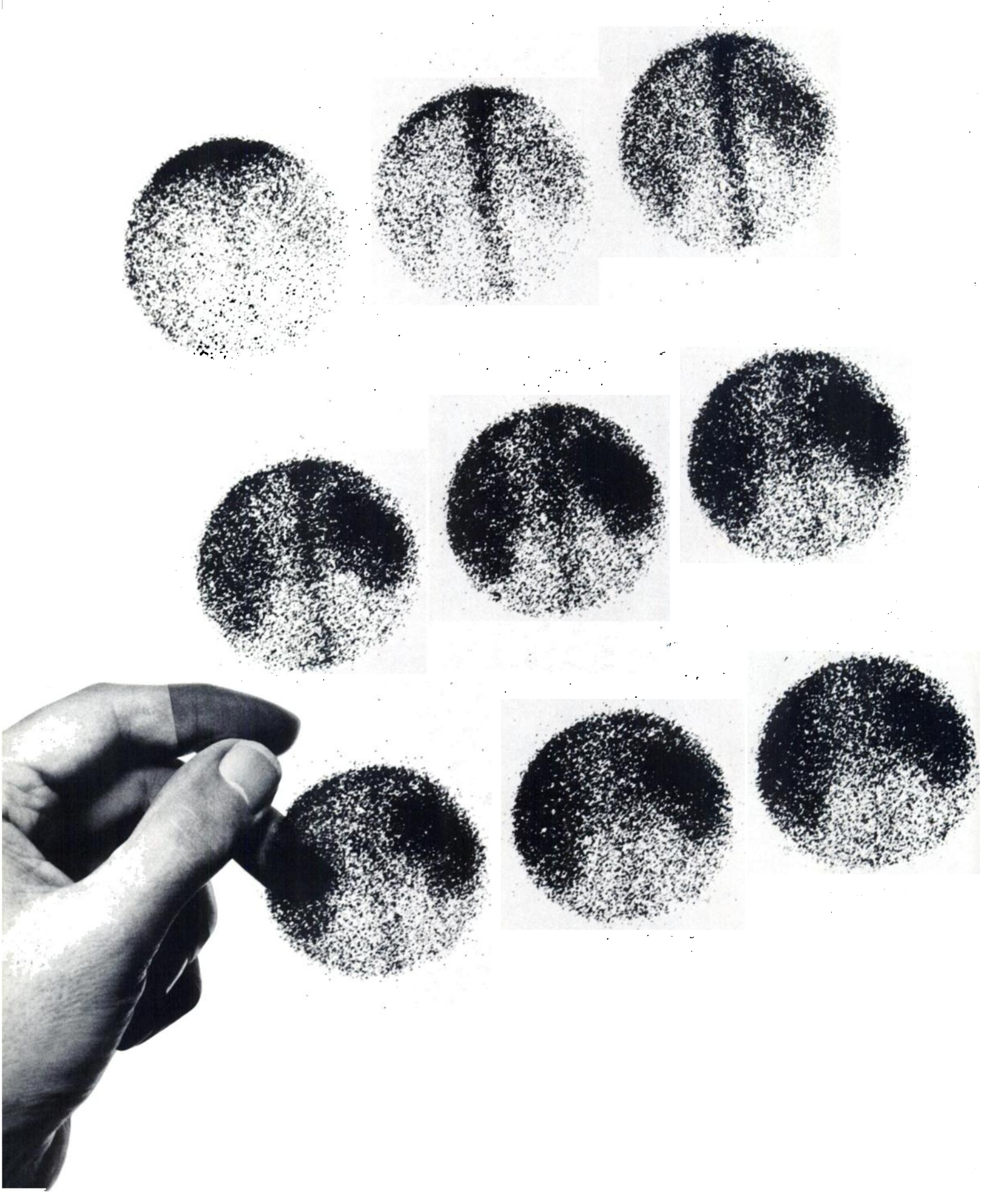

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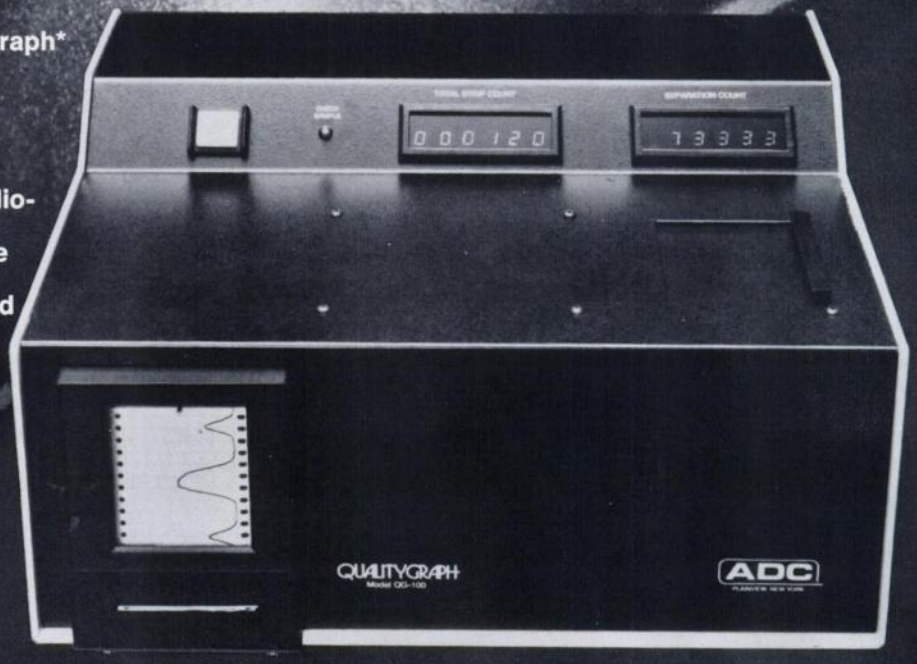

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RADIONUCLIDE DOSE COMPUTATION
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PATIENT'S NAME: James Court

I.D. 087-40-4035

STUDIES: Brain Scan

NUCLIDE: TECHNETIUM 99M

FORM: Pertech. SAMPLE NO. 09

LOT NO. 45G-256 KIT NO. 12NK-141

DATE: 21 AUG 77 14:57

CONCENTRATION: 12.34 mCi/ml

DOSE DESIRED: 20.00 mCi

VOLUME REQUIRED: 01.62 ml

ACTIVITY MEAS'D: 20.31 mCi

TIME OF ADMINISTRATION: 3:05 AM (PM)

SIGNATURE(S): Anne Wynters

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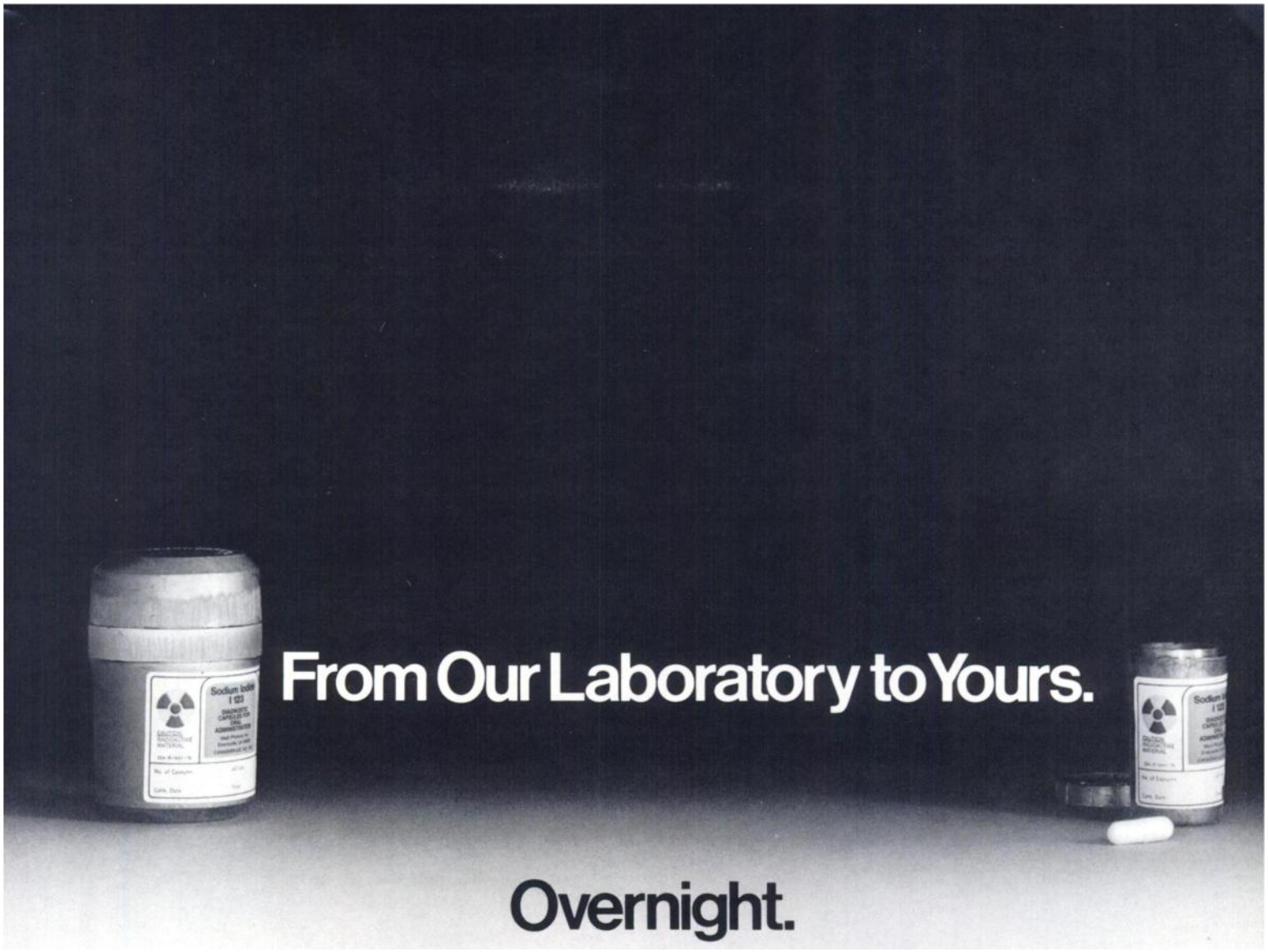

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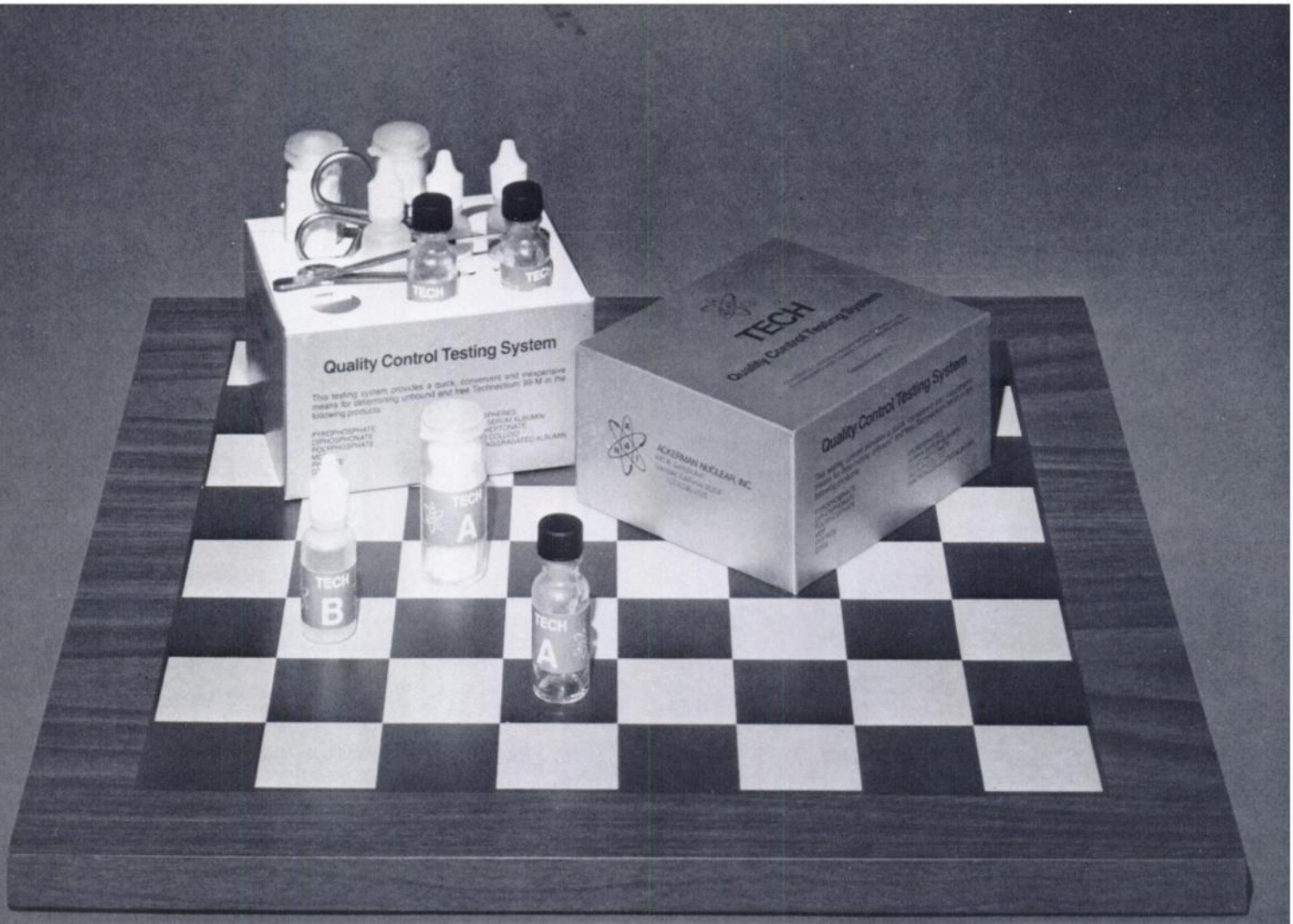

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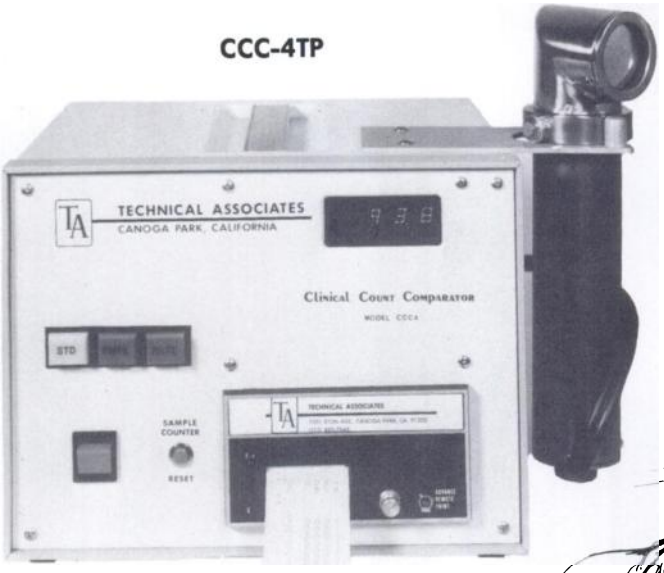

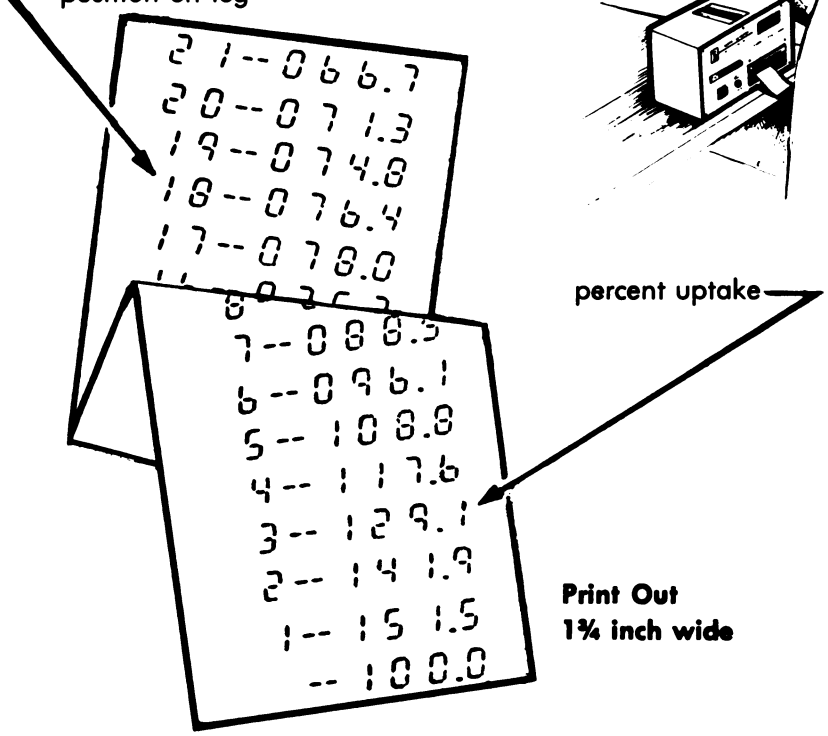

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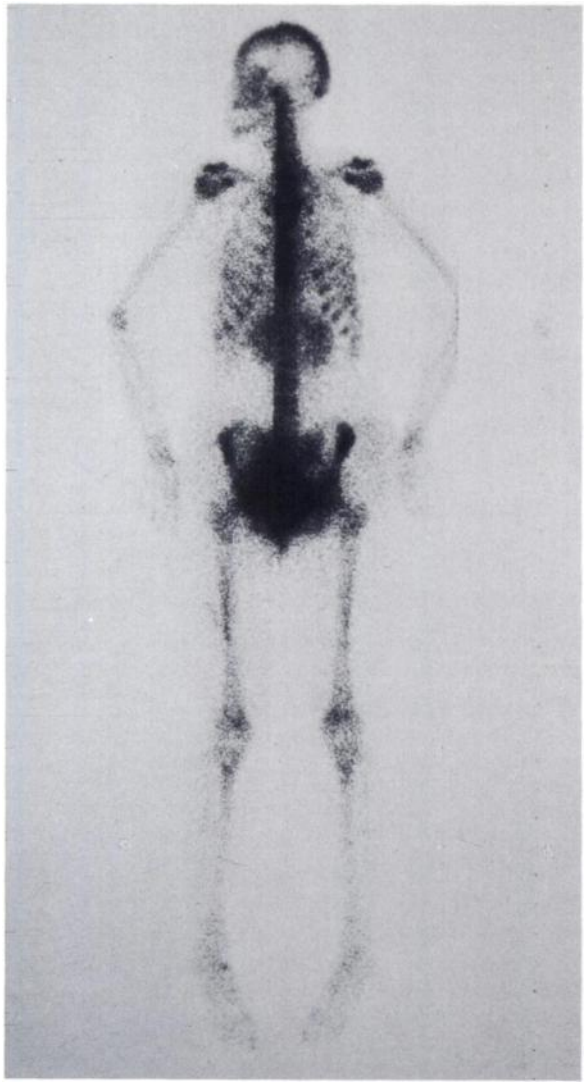

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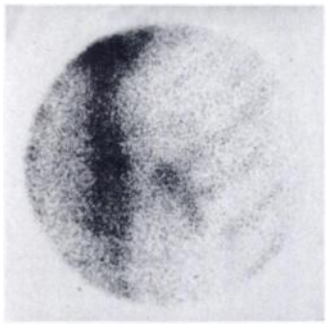
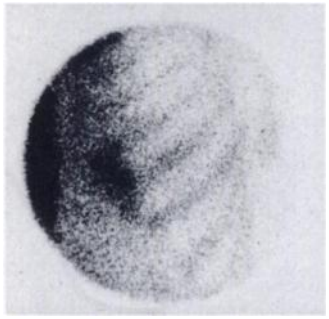
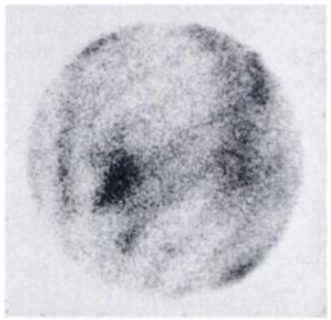


Anterior wall infarction, anterior view



Left anterior oblique



Left lateral

For brief summary of prescribing information, please see next page.

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CLINICAL PHARMACOLOGY

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

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.

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 Tc 99m pertechnetate 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 only for use in the preparation of Technetium Tc 99m Stannous Pyrophosphate and are not to be directly administered to the patient.

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 injest 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.

ADVERSE REACTIONS

None.

DOSAGE AND ADMINISTRATION

The recommended adult dose of **TechneScan PYP** is:

1. Skeletal Imaging — 5 to 15 millicuries (1 to 14 milligrams stannous pyrophosphate).
2. Cardiac Imaging — 10 to 15 millicuries (4 to 7 milligrams of stannous pyrophosphate).

TechneScan PYP Tc 99m is injected intravenously over a 10- to 20-second period. For optimal results, bone imaging should be done 1 to 6 hours following administration. Cardiac imaging should be done 60 to 90 minutes following administration. The acute myocardial infarct can be visualized from 24 hours to 9 days following onset of symptoms, with maximum localization at 48 to 72 hours. Cardiac imaging should be done with a gamma scintillation camera. It is recommended that images be made of the anterior, left anterior oblique and left lateral projections.

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

HOW SUPPLIED

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

Kit Contains:

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

Reaction Vial Contains:

15.4 mg Sterile Stannous Pyrophosphate (Lyophilized). Hydrochloric acid is added for pH adjustment prior to lyophilization.

5—Pressure-sensitive "Caution—Radioactive Material" labels.

5—Radioassay Information String Tags.

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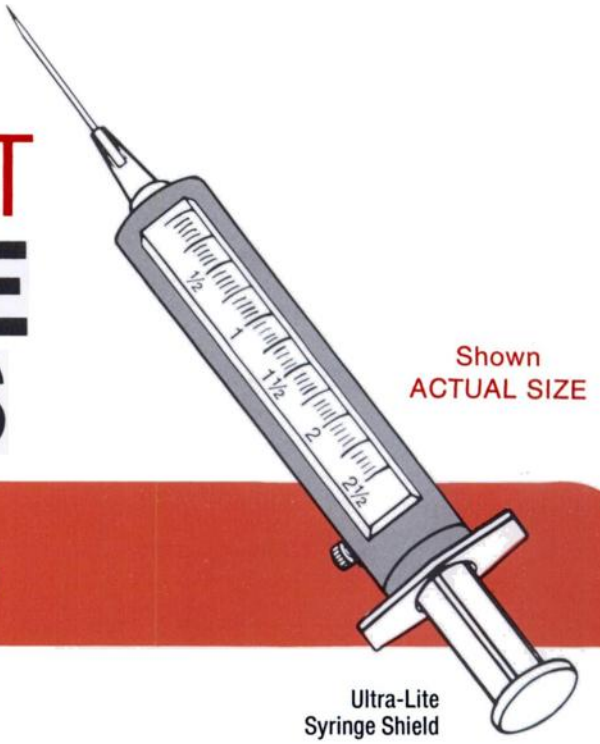

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	56-293	5 to 6 cc	1.7 oz.	95.00
^{99m}Tc THIN-WALL	56-272	2½ to 3 cc	3.2 oz.	$45.00
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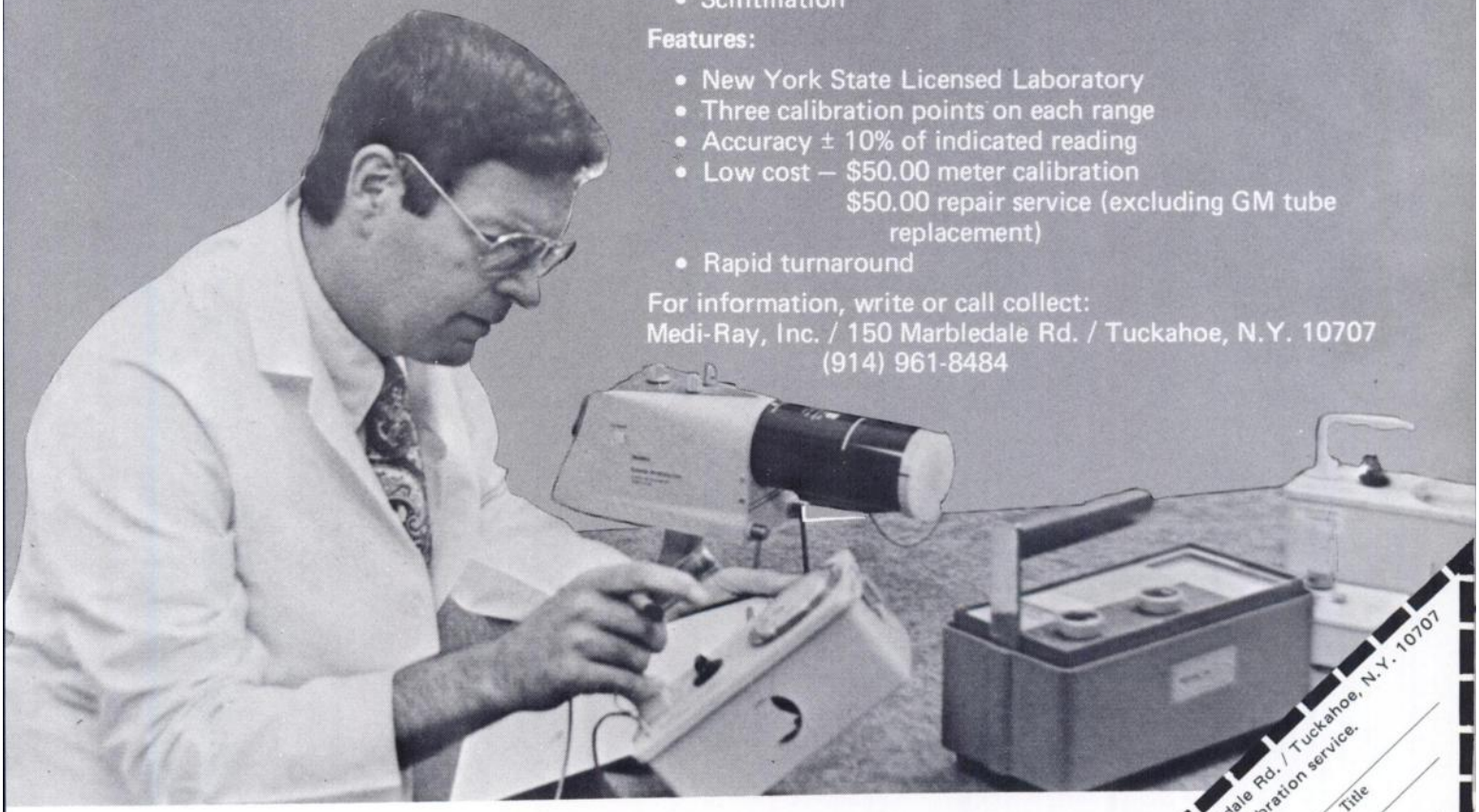

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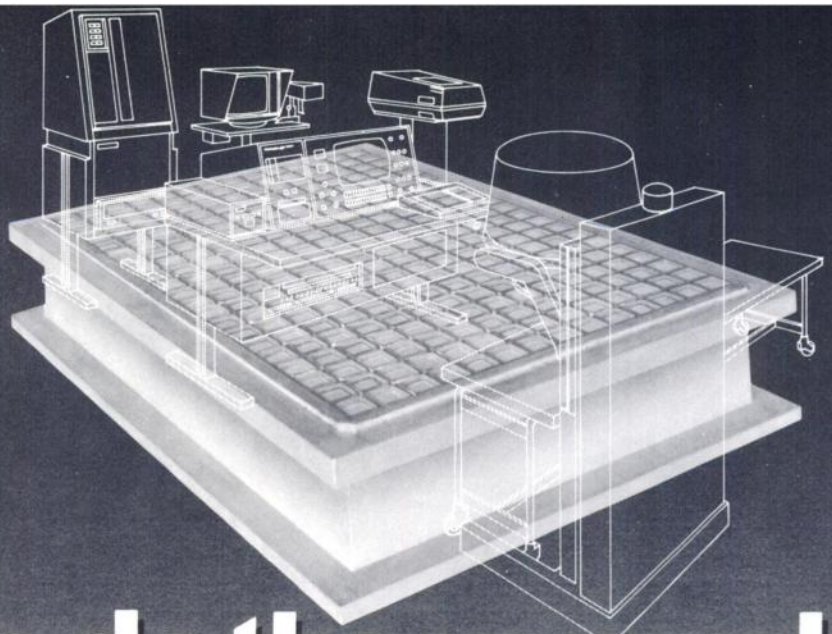

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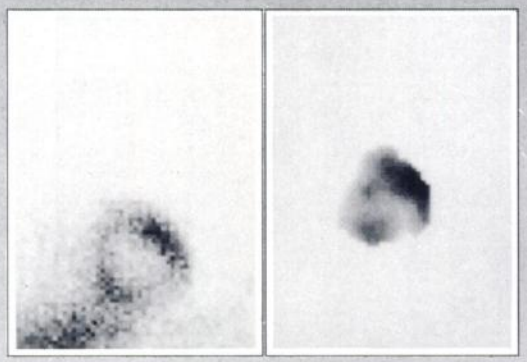
With our help the users of System Seventy-Seven are advancing the frontiers of nuclear cardiography and redefining the role that nuclear medicine can play in the noninvasive diagnostic assessment of hemodynamic function, performance of the myocardium, and coronary perfusion.



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VA HOSPITAL, ALEXANDRIA, LA, AN Equal Employment Opportunity Employer, has an immediate staff vacancy for a Nuclear Medicine Technician, starting salary $9,303 or $11,523 dependent upon qualifications and experience, periodic salary increases and generous fringe benefit package. Interested Candidates contact Personnel Service (05), VA Hospital, Alexandria, Louisiana 71301. Area code 318, 442-0251, Ext. 355.

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COMPUTER SPECIALIST—VA HOSpital—University of Colorado Medical Center. A research position is available in the Nuclear Medicine Service of the Denver VA Hospital. The primary responsibility is to function as the computer and mathematics expert of the nuclear medicine research team. Additional training and experience in electrical engineering and/or physics is desirable. Faculty appointment in the University of Colorado Medical School is available. Applications from all interested persons are welcome. Inquiries, including curriculum vitae and reference list, should be sent to: William C. Klingensmith III, M.D., Chief, Nucelar Medicine Service; Veterans Administration Hospital, 1055 Clermont Street, Denver, Colorado 80220. The Veterans Administration is an Equal Opportunity Employer.

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POSITIONS WANTED

CHIEF NUCLEAR MEDICINE TECHnologist. B.S. physics, ARRT registered. Eleven years varied clinical experience, including in-vivo and in-vitro applications, technologist and student teaching, and more recently, large department management. Willing to relocate. Reply to Box 1200 Society of Nuclear Medicine, 475 Park Ave. So., New York, N.Y. 10016.

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NUCLEAR MEDICINE SCIENTIST. ABR certified in Nuclear Medicine Physics. Ph.D. in Nuclear Chemistry. Five years experience in University Nuclear Medicine setting. Numerous publications. Desires to relocate to large metropolitan area. Reply to Box 1204, Society of Nuclear Medicine, 475 Park Avenue South, New York, N.Y. 10016.

POSITION WANTED. WRITTEN Radiology Board Certified, Eligible Oral Radiology Board Dec. 1977 and Nuclear Medicine Board July, 1978. Presently Chief Resident in the Nuclear Medicine Dept. in a University Hospital. Willing to do Radiology and Nuclear Medicine. Available Feb. 1978. Please reply, P.O. Box 1205, Society of Nuclear Medicine, 475 Park Avenue South, New York, N.Y. 10016.

NUCLEAR MEDICINE PHYSICIAN Certified in Nuclear Medicine by ABNM and in Diagnostic Radiology, University Trained, seeks a full time position starting July 1978. Please reply P.O. Box 1206 Society of Nuclear Medicine, 475 Park Avenue South, New York, N.Y. 10016.

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JNM CLASSIFIED PLACEMENT SERVICE SECTION

This section in the Journal of Nuclear Medicine contains "Positions Open", "Positions Wanted", and "For Sale" listings. Nondisplay "Positions Wanted" ads by members of the Society are billed at 50¢ per word for each insertion with no minimum rate. Nondisplay "Positions Wanted" ads by nonmembers and all nondisplay "Positions Open" and "For Sale" ads by members and nonmembers are charged at 75¢ per word. Display advertisements are accepted at $100 for ⅛ page, $145 for ¼ page, $245 for ½ page, and $425 for a full page. Closing date for each issue is the 1st of the month preceding publication. Agency commissions and cash discounts are allowed on display ads only. Box numbers are available for those who with them.

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Contact: Robert L. Pinck, M.D., Director, Dept. of Radiology, The Long Island College Hospital, 340 Henry St., Brooklyn, N.Y. 11201.

Aggregated Albumin (Human) Kit

DESCRIPTION - The kit contains 6 sterile vials containing 9-11 mg. of pyrogen-free aggregated albumin (human), 0.67 - 0.83 mg. stannous chloride, and 18 mg. sodium chloride. When sterile, pyrogen-free sodium pertechnetate Tc99m is added to the vial, technetium-labelled macroaggregated human serum albumin (Technetium MAA Tc 99m Technetium Macroaggregates) is formed. The particles of aggregated albumin in the kit are formed by the denaturation of Normal Serum Albumin (Human) USP through heat and pH adjustment. Sodium hydroxide of hydrochloric acid may be present in variable amounts. At least 95% of the macroaggregated particles are between 10 and 100 microns in size, the great bulk, (as seen on a microscope slide) being an average of 10 to 70 microns. None are larger than 150 microns. Vial counts indicate that each vial contains 6.8 ± 0.8 million particles per mg. The labelling efficiency is essentially quantitative and the bound Tc-MAA remains stable *in vitro* throughout the useful period after preparation.

Application has been filed with the U. S. Nuclear Regulatory Commission for distribution of this reagent kit to persons licensed pursuant to §35.14 and §35.100, Group III of CFR Part 35, or under equivalent licenses of agreement states; and is still pending.

ACTIONS - Following intravenous injection, Technetium MAA Tc 99m is rapidly transported by the blood stream to the lungs. The aggregates do not enter the tissues of the lungs, but remain in the pulmonary vasculature. When pulmonary blood flow is normal, the material is carried throughout the entire lung field; when pulmonary blood flow is diminished or obstructed by a disease process, the particles are correspondingly prevented in part of in whole from passage through the affected portion of the pulmonary vasculature.

Technetium Macroaggregates remain in the lungs for variable amounts of time depending on particle size. The particles disappear from the lungs in exponential fashion with the larger-sized aggregates having the longer half-life, particles ranging from 10 to 90 microns in diameter usually have a half-life of 2 to 8 hours. Apparently, the aggregates are temporarily trapped by the narrow pulmonary capillaries where the particles are broken down until they are small enough to pass. In rats 4.3% of the Tc 99m remains in the lungs after 24 hours.

Although the particles of macroaggregates remain for a time in the pulmonary capillaries, they do not appear to interfere even temporarily with pulmonary blood flow or ventilation in the dosage required for lung scanning. This is evidenced by the fact that these doses do not produce any respiratory distress nor any tachycardia, even in patients severely ill with pulmonary and/or cardiac disorders.

Once the albumin particles leave the lungs, they are carried to the liver, where they are removed from the blood stream primarily by the Kupffer cells. There, the particles are phagocytized and rapidly metabolized.

INDICATIONS - Scintillation scanning of the lungs with Technetium Macroaggregates is indicated as an adjunct to other diagnostic procedures whenever information about pulmonary vasculature is desired. The most useful clinical applications of lung scanning have been outlined by one investigator: 1) The diagnosis of pulmonary embolism; 2) differentiation of focal conditions such as bullae or cysts from diffuse pulmonary disorders; 3) determination of the degree of pulmonary vascular obliteration in parenchymal disease; and 4) evaluation of the patient's ability to withstand pulmonary surgery.

Perhaps the most frequently useful indication for the lung scan has been the early detection of pulmonary emboli. The lung scan is uniquely able to demonstrate the existence of an embolism before radiological signs become apparent. Although an area of increased radiolucency on the chest film may suggest an embolism, X-ray findings do not usually become apparent until the embolism has produced signs of ischemia or infarction. Once an embolism has been diagnosed, information obtained from the scan is of value in determining the desirability of surgical embolectomy, while subsequent scans provide information on the effectiveness of surgical or anticoagulant therapy.

Lung scanning is similarly helpful in the diagnosis of various types of malignancies affecting the lungs. Again, scanning is of value in locating the affected areas, in determining the need for and probable effectiveness of surgery or of radiation therapy, and in following up the benefits of treatment.

Useful information is also provided by the scan in the diagnosis or evaluation of other pulmonary problems, such as pneumonia, atelectasis pleural effusion, pulmonary tuberculosis, parenchymal disease, emphysema and chronic asthmatic bronchitis.

CONTRAINDICATIONS - The presence of right to left shunts which would allow Technetium MAA Tc 99m injected in a systemic vein to reach a systemic artery is contraindication to the use of this material. Particulate material such as Technetium MAA Tc99m should not be administered to patients with evidence of severe restriction to pulmonary blood flow such as may be present in pulmonary hypertension.

WARNINGS - Technetium MAA Tc99m should not be administered to patients who are pregnant, or during lactation unless the 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.

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

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

To insure the integrity of this product use needles in gauge sizes 18 to 21.

ADVERSE REACTIONS - No adverse reactions have been observed with this product. However Vincent et al (3) have recorded the only immediate and fatal reaction following infusion of Tc 99m macroaggregates (technetium labelled macroaggregates). This was in a seven-year-old child who had severe pulmonary vascular disease. The exact size of the particles used was not disclosed, and in the summary of the publication "it is suggested that this type of reaction will continue to be rare and that it will probably be somewhat predictable on the basis of clinical and laboratory evidence of severe pulmonary hypertension. Such a patient might be scanned safely by strict control of macroaggregates dose, size range and mean particle size."

The literature has recorded two adverse reactions to lung scanning with I-131 labelled macroaggregates. Wagner et al (4) observed that urticaria developed in a young girl several hours after lung-scanning procedure with Iodine-131 macroaggregates where Lugol's solution was administered to block the thyroid gland. The subject had a history of angio-edema. The reaction may have been caused by either material. Dworkin et al (5, 6) reported "I-131-labelled macroaggregated albumin highly suspect as the causative agent" in the death of a woman who was scanned for the possibility of demonstrating pulmonary embolism. With a 2½-year history of adenocarcinoma of the breast she had severe and rapidly progressive edema. Prior to scanning, the nasal administration of oxygen was interrupted. "Within 1 or 2 minutes after injection of 300 uCi of I-131 labelled macroaggregates albumin (11 mg. of albumin or 0.219 mg. per kilogram of body weight) she complained of faintness and became cyanotic, diaphoretic, and agitated with distended neck veins. The initial pulse rate of 50 rose to 140 with a fall in blood pressure to 100/30. Oxygen therapy relieved the profound dyspnea and cyanosis. An electrocardiogram 40 minutes later was compatible with acute cor pulmonale. Within several hours she had returned to her pre-scan status, but on the next day the temperature rose, dyspnea increased and she died 26 hours after the lung scan. We have continued lung scanning but limit the albumin to 0.020 mg. per kilogram, reject lots with more than 15 percent of particles over 40 microns and require two minutes for injection."

More recently, Williams (7) has reported a severe reaction immediately after injection of macroaggregated albumin (MAA) particles followed by death six hours later (while the patient was undergoing right-heart catheterization). Like those previously reported, it occurred in a patient with severe chronic pulmonary hypertension due to disease of the pulmonary vascular bed. The patient died in right heart failure. Post-mortem examination revealed "severe atheroma and thickening of all the pulmonary arteries but no macroscopic evidence of emboli. The right heart was hypertrouphied and dilated".

Transient neurological complications following intra-arterial injection of I-131 labelled macroaggregates have been reported (3).

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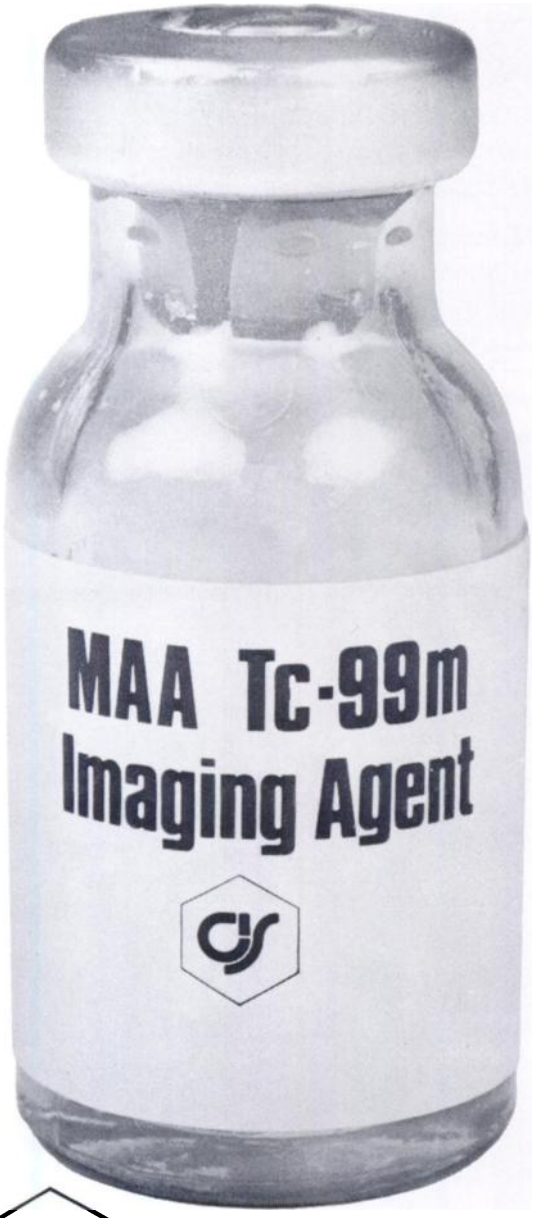

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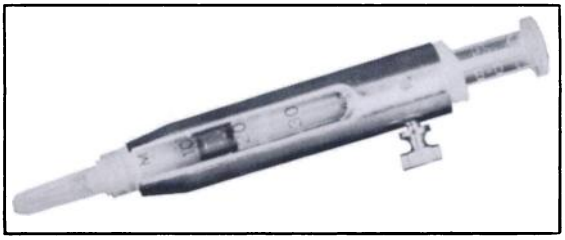

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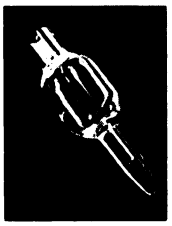

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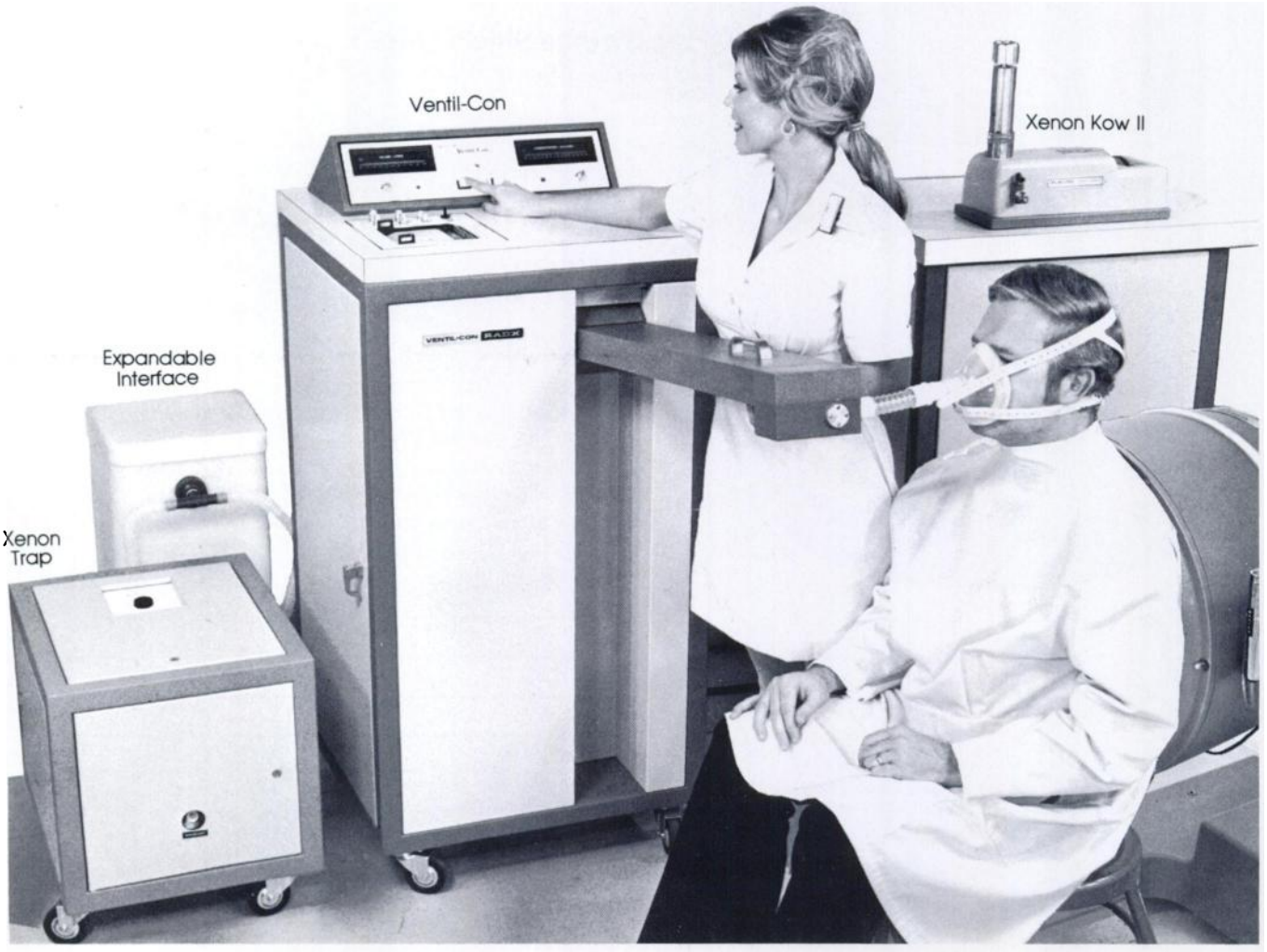

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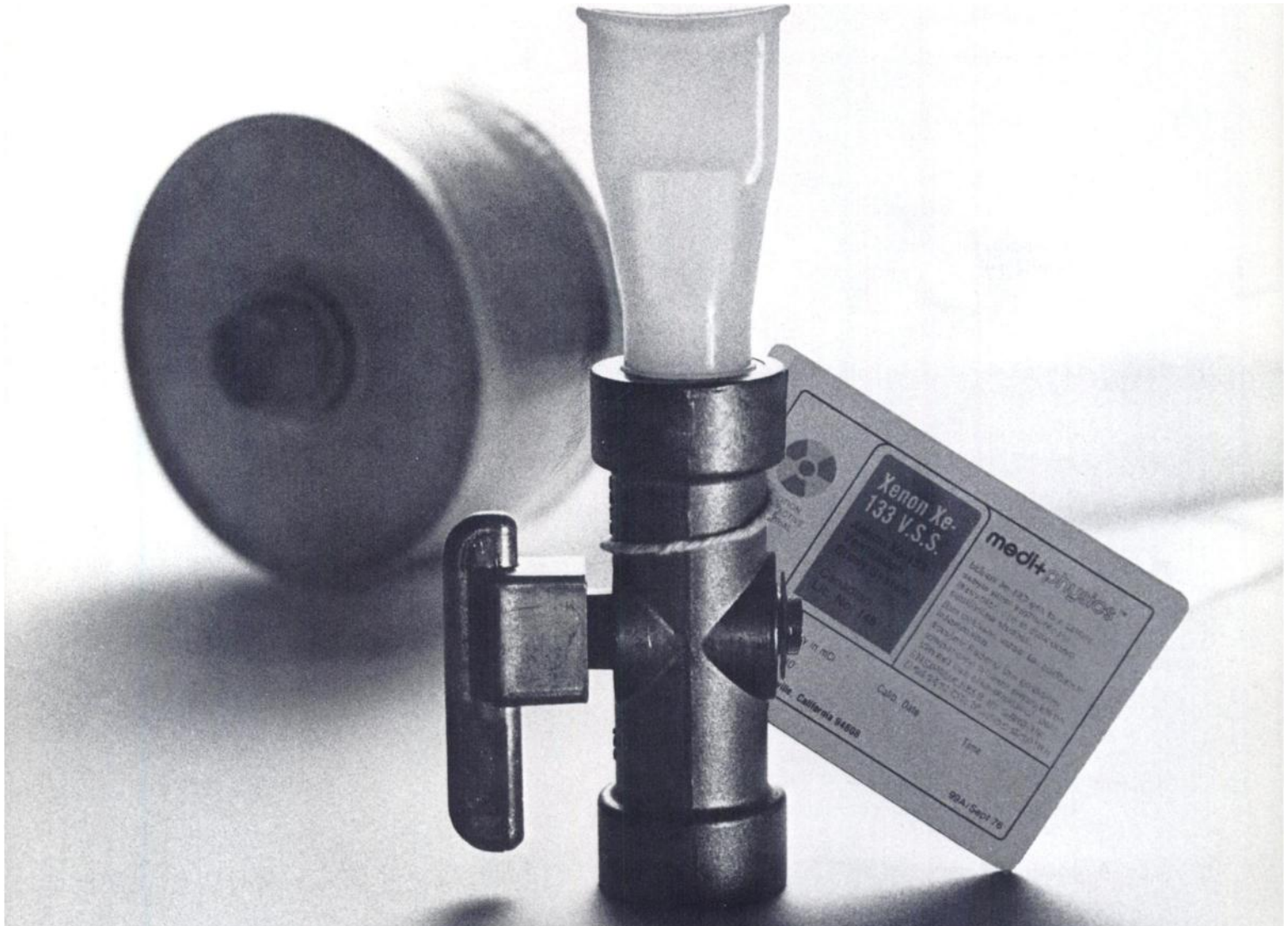

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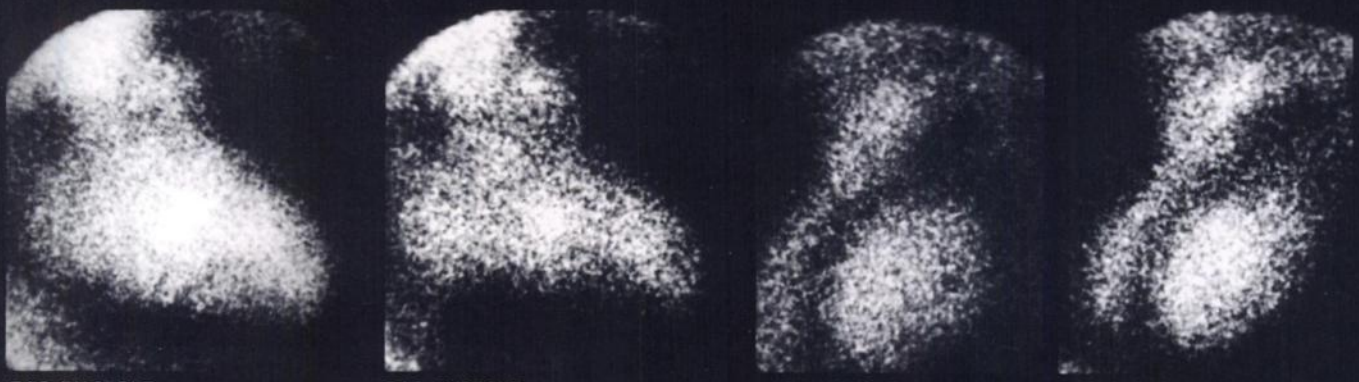

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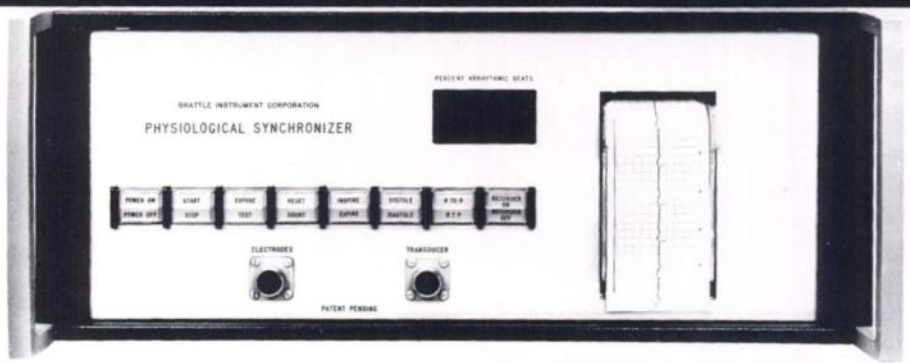

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