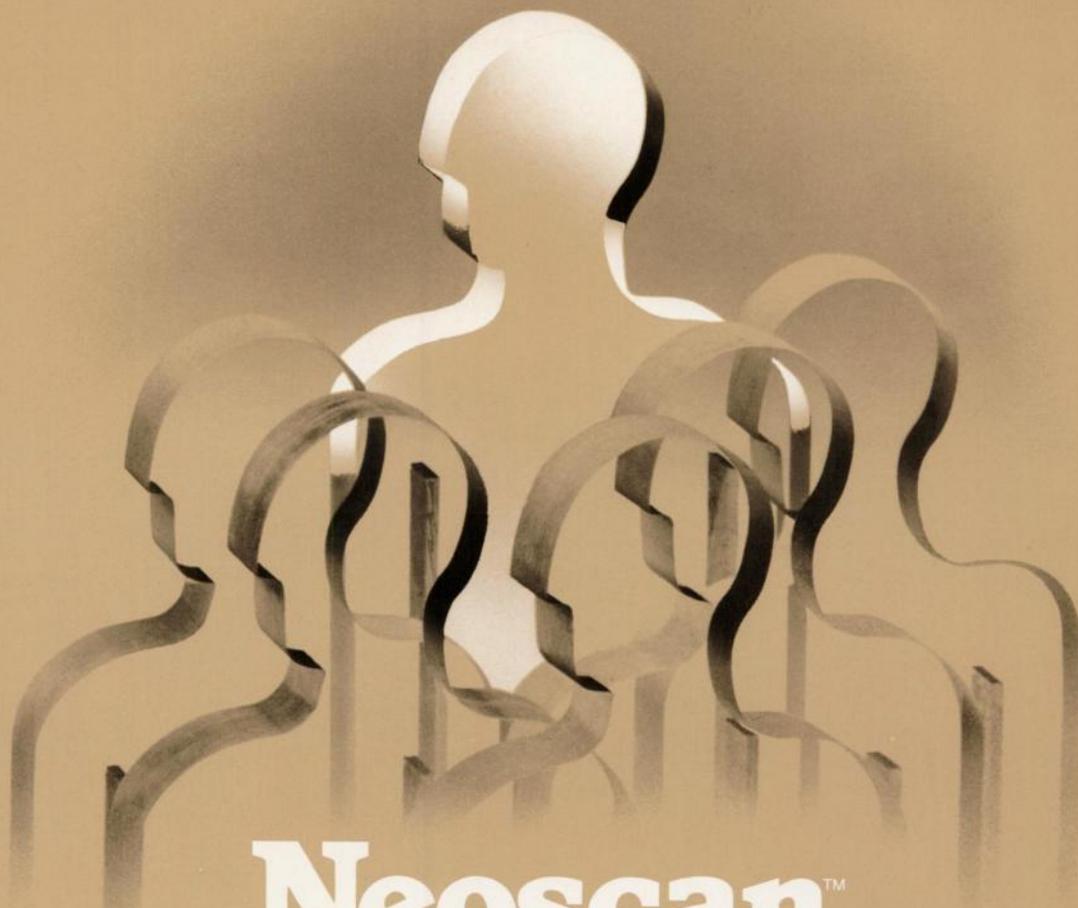


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**Neoscan™**  
**gallium citrate Ga 67**

from **medi+physics™**

**NEOSCAN MEANS** gallium citrate Ga 67 from Medi-Physics, Inc. Neoscan can aid in demonstrating the presence and extent of Hodgkin's disease, lymphoma and bronchogenic carcinoma. Positive uptake in the absence of prior symptoms warrants follow-up as an indication of a potential disease state.

**NEOSCAN MEANS** a gallium citrate Ga 67 that is produced by MPI on both the East and West Coasts and is available from 6 locations across the country for easy access when you need it. Neoscan is calibrated twice weekly in two convenient sizes: 3.0mCi and 13.2mCi.

**NEOSCAN MEANS** a gallium citrate Ga 67 that MPI will send to you with no additional delivery charge along with your supply of Sodium Iodide I 123, Technetium Prepared Products or Xenon 133-V.S.S. (xenon Xe 133).

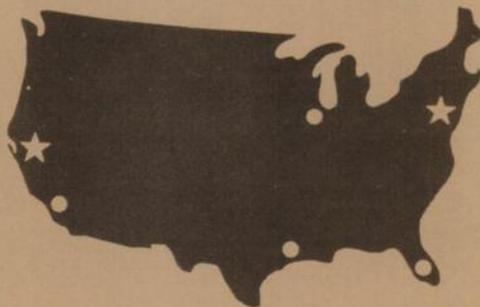
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## Neoscan™ gallium citrate Ga 67

For complete product information, consult the package insert, a summary of which follows:

**DESCRIPTION:** Neoscan for diagnostic use is supplied as a sterile, apyrogenic aqueous solution for intravenous injection. Each milliliter of the solution contains 2 millicuries of gallium Ga 67 at calibration time, no-carrier-added, 2.5% sodium citrate, and 1% benzyl alcohol as a preservative. The pH is between 4.5-7.5. Gallium Ga 67, with a half-life of 78.1 hours, is cyclotron produced by the proton irradiation of zinc Zn 68-enriched zinc oxide. The radionuclidic composition, at calibration time, is not less than 98.9% of the total activity from gallium 67 with less than 1% of the total radioactivity due to gallium 66 and with zinc 65 and other radiocontaminants contributing less than 0.1% of the total activity.

**INDICATIONS AND USAGE:** Neoscan may be useful to demonstrate the presence and extent of Hodgkin's disease, lymphomas, and bronchogenic carcinoma. Positive gallium Ga 67 uptake in the absence of prior symptoms warrants follow-up as an indication of a potential disease state.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** This radiopharmaceutical should not be administered to children or to patients who are pregnant or to nursing mothers unless the information to be gained outweighs the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of child-bearing capability should be performed during the first few (approximately 10) days following the onset of menses.

**PRECAUTIONS:** A thorough knowledge of the normal distribution of intravenously administered gallium citrate Ga 67 is essential in order to accurately interpret pathologic studies. The finding of an abnormal gallium concentration usually implies the existence of underlying pathology, but further diagnostic studies should be done to distinguish benign from malignant lesions. Neoscan is intended for use as an adjunct in the diagnosis of certain neoplasms. Negative results do not preclude the presence of disease.

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

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

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

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

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS:** No adverse reactions have been reported with the use of Neoscan at this time.

**DOSAGE AND ADMINISTRATION:** The recommended adult (70 kg) dose is 2-5 millicuries. Neoscan is intended for intravenous administration only. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

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

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

Radiopharmaceuticals should be used only by persons 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.

**HOW SUPPLIED:** Neoscan is supplied as a no-carrier-added sterile apyrogenic aqueous solution for intravenous use. Each milliliter contains 2 mCi  $\pm$  10% gallium Ga 67 at the time of calibration with 2.5% sodium citrate. Benzyl alcohol 1% is present as a preservative. The pH is between 4.5-7.5.

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

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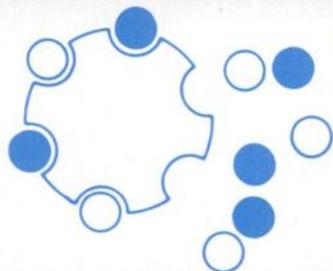
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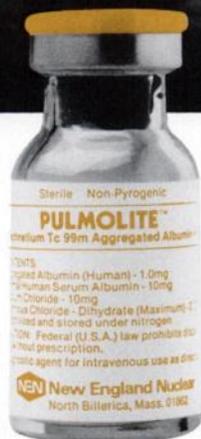
Technetium Tc 99m Aggregated Albumin Kit

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stores at room temperature

Rapidly prepared  
inject sodium pertechnetate  
Tc 99m into vial, shake for  
30 seconds—and it's ready for  
administration

Complete  
no additional reagents or  
equipment

Economical  
5 vial package and 30 vial  
Convenience Pak



**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 radio-diagnostic.

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 13ml.

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.).

**New 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  $3.6-6.5 \times 10^6$  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



**New England Nuclear**  
Medical Diagnostics Division

# Dicopac<sup>®</sup>

Oral Cyanocobalamin Co 58, Oral Cyanocobalamin Co 57 Bound to Human Gastric Juice, Cyanocobalamin I.M. Injection

#### INDICATIONS

Dicopac Kit consisting of cyanocobalamin Co 58 and cyanocobalamin Co 57 combined with human intrinsic factor is used to assess vitamin B<sub>12</sub> absorption in the diagnosis of malabsorption due to the lack of intrinsic factor, e.g. Addisonian (pernicious) anemia, and as a diagnostic adjunct in other defects of intestinal absorption.

CONTRAINDICATIONS - None.

#### WARNINGS

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

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

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

#### PRECAUTIONS

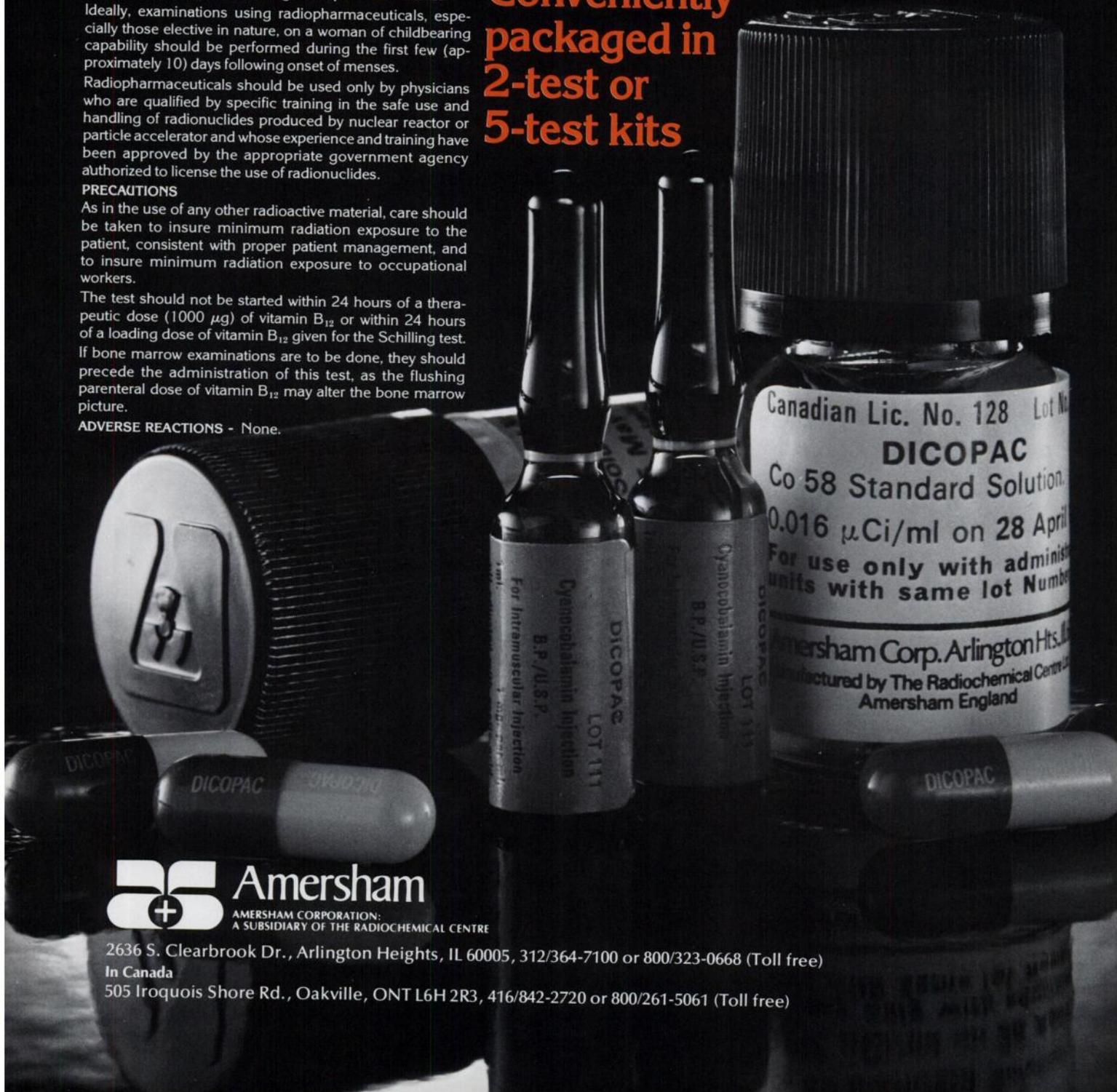
As in the use of any other radioactive material, care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers.

The test should not be started within 24 hours of a therapeutic dose (1000 µg) of vitamin B<sub>12</sub> or within 24 hours of a loading dose of vitamin B<sub>12</sub> given for the Schilling test. If bone marrow examinations are to be done, they should precede the administration of this test, as the flushing parenteral dose of vitamin B<sub>12</sub> may alter the bone marrow picture.

ADVERSE REACTIONS - None.

**One day  
test for  
Vitamin B<sub>12</sub> malabsorption**

**Conveniently  
packaged in  
2-test or  
5-test kits**



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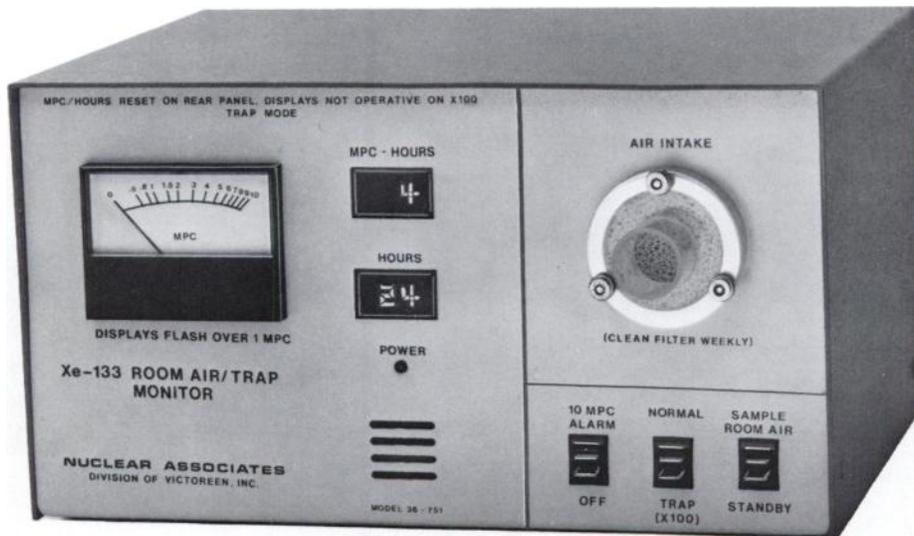
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\*The Maximum Permissible Concentration of <sup>133</sup>Xe in a restricted area is  $1 \times 10^{-5}$   $\mu$ Ci/ml for a time period of 40 hours in any 7 consecutive days.

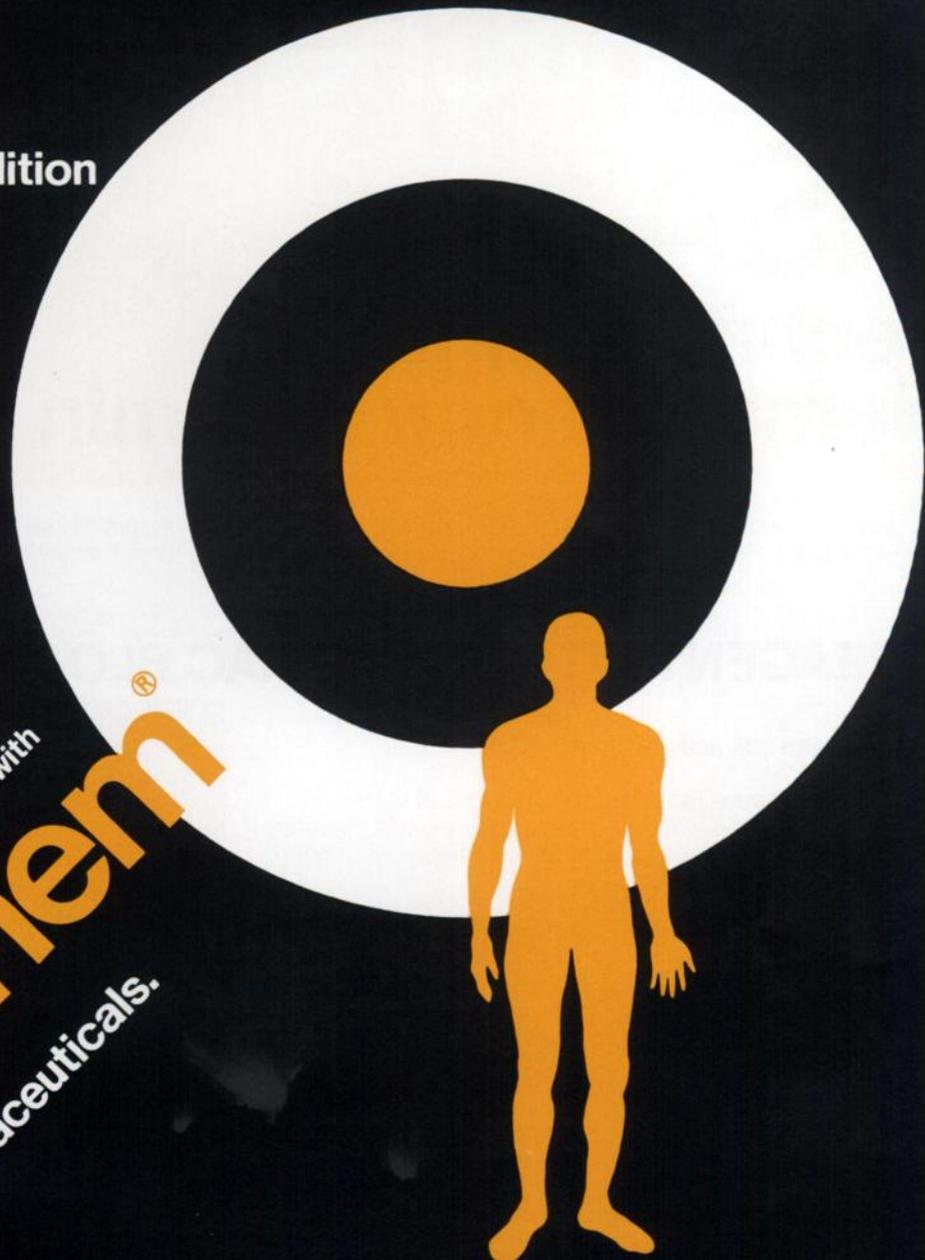
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# CintiChem<sup>®</sup>

Technetium 99m

# HSA

Unit  
Dose

## Technetium Tc 99m Human Serum Albumin Reagent Kit

Ten sterile unitdose reaction vials each containing 7 mg human serum albumin and 0.08 mg stannous tartrate, lyophilized. Hydrochloric acid was added prior to lyophilization for pH adjustment.

### REAGENT KIT FOR CARDIAC BLOOD POOL IMAGING

**Maximum vial activity 30 mCi/1 ml**

**Easy to prepare** (see directions): Just add sterile preservative-free water, Technetium 99m pertechnetate, then shake. Requires no electrolytic equipment or time-consuming procedures.

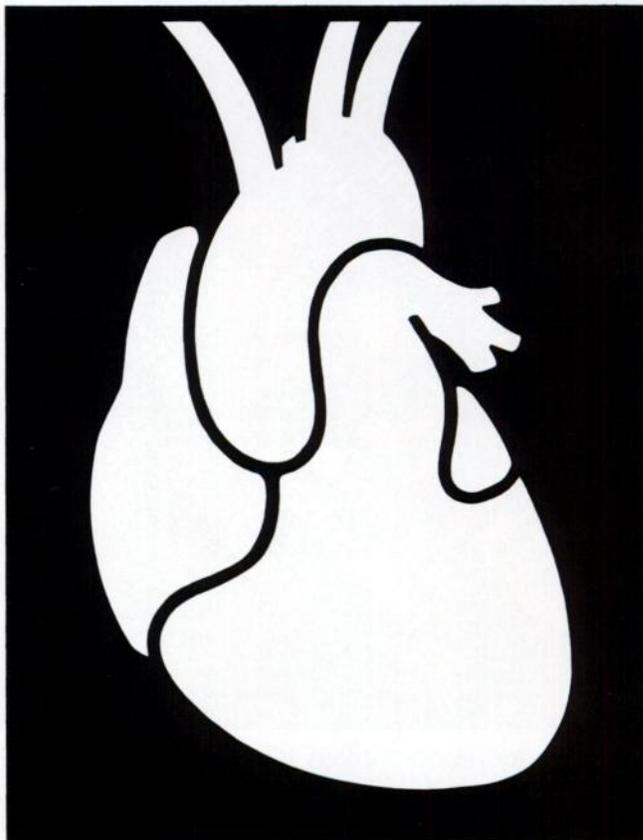
**High blood concentrations:** Approximately 60% remains in the circulation after 2 hours, approximately 45% after 4 hours (in normal patients).

**Consistently high binding efficiency:** Technetium binding range of 90-99% immediately after tagging.

**Stable formulation:** Uses stannous tartrate, which is more stable to air oxidation than stannous chloride.

**Free from extraneous constituents:** Following aseptic preparation, final product contains HSA, water, stannous tartrate, and sodium chloride.

This kit is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission pursuant to Sec. 35.14 and Sec. 35.100 Group III of 10 CFR Part 35 or under equivalent license of Agreement States.



**For ordering, customer service, and technical information on HSA (Product Number UC-HA-81) call toll-free: (800) 431-1146. In New York State call: (914) 351-2131.**

**Union Carbide Corporation**  
**Medical Products Division**  
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(OPPOSITE PAGE: PRODUCT INFORMATION)

# CintiChem®

TECHNETIUM 99m

## HSA Unit Dose Kit TECHNETIUM Tc 99m

### HUMAN SERUM ALBUMIN UNIT DOSE REAGENT KIT DIAGNOSTIC— FOR INTRAVENOUS USE

#### description

The kit consists of 10 unit dose reaction vials each containing a lyophilized mixture of 7 mg human serum albumin and 0.08 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment. All components are sterile and pyrogen-free. When a solution of sterile and pyrogen-free Sodium Pertechnetate Tc 99m in isotonic saline is mixed with these components, following the instructions provided with the kit, Technetium Tc 99m Human Serum Albumin is formed, with a labeling efficiency of 90% or greater. The product so derived has a pH of 2.5-3 and is intended for intravenous injection. The precise structure of Technetium Tc 99m Human Serum Albumin is not known at this time. The Normal Human Serum Albumin in this preparation was nonreactive when tested for hepatitis B surface antigen (HBsAg) by radioimmunoassay.

#### physical characteristics

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.03 hours<sup>(1)</sup>. Photons that are useful for detection and imaging studies are listed in Table I.

table I. principal radiation emission data

radiation	mean % / disintegration	mean energy (keV)
Gamma-2	87.9	140.5

<sup>(1)</sup>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 Technetium Tc 99m is 0.8 R/millicurie-hour 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 II. For example, the use of 2.7 mm of Pb will decrease the external radiation exposure 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 <sup>-1</sup>
1.8	10 <sup>-2</sup>
2.7	10 <sup>-3</sup>
3.6	10 <sup>-4</sup>
4.5	10 <sup>-5</sup>

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

table III. physical decay chart:  
Tc 99m, half-life 6.03 hours

hours	fraction remaining	hours	fraction remaining
0*	1.000	7	.447
1	.891	8	.399
2	.795	9	.355
3	.708	10	.317
4	.631	11	.282
5	.563	12	.252
6	.502		

\*Calibration Time. (Time of Preparation)

#### clinical pharmacology

Normal Human Serum Albumin, being a normal component of blood, leaves the vascular space at a rate slow enough to permit imaging procedures utilizing radioactive tags. Technetium Tc 99m Human Serum Albumin does not rapidly leak from the vascular space, nor is there significant accumulation in organs other than those of excretion, the kidney and bladder. Therefore, the vascular system may be imaged with a mini-

mum of background and organ interference. In humans, a two-component blood clearance rate is observed, the T 1/2 slow component ranging from 10 to 16 hours. Twenty-four hour urine clearance averaged 39%.

#### indications and usage

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

#### contraindications

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

#### warnings

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

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

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

#### precautions

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

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

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

Safety and effectiveness in children have not been established.

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

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

#### adverse reactions

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

#### dosage and administration

The suggested intravenous dose used in the average patient (70 kg) is 3-5 millicuries of Technetium Tc 99m Human Serum Albumin.

Each 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 doses<sup>(2)</sup> to an average patient (70 kg) from an intravenous injection of a maximum dose of 5 millicuries of Technetium Tc 99m Human Serum Albumin are shown in Table IV.

table IV. estimated absorbed dose

tissue	absorbed radiation dose (rads/5 mCi)
Brain	0.047
Marrow	0.076
Kidneys	0.083
Bladder	0.166
Ovaries	0.082
Testes	0.079
Total Body	0.073

<sup>(2)</sup>Method of Calculation: A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides. Supplement No. 1, MIRD Pamphlet No. 1, J. Nucl. Med., p. 7, 1968.

#### how supplied

##### kit contents

10 STERILE UNIT DOSE REACTION VIALS (5 cc, gold aluminum overseal), each containing 7 mg human serum albumin and 0.08 mg stannous tartrate, lyophilized. Hydrochloric acid was added prior to lyophilization for pH adjustment.

20 PRESSURE-SENSITIVE LABELS for final Technetium Tc 99m Human Serum Albumin preparation.

1 PACKAGE INSERT.

##### storage

Store kit contents in refrigerator (2-8°C). Do not freeze.

##### disposal

The residual materials may be discarded in ordinary trash provided the vials and syringes read background with an appropriate low range survey meter. It is suggested that all identifying labels be destroyed before discarding.

##### directions

The following directions must be carefully followed for optimum preparation of the Technetium Tc 99m Human Serum Albumin.

1. Aseptically swab rubber septum of sterile vial containing the sterile, lyophilized human serum albumin.
2. Aseptically inject 0.5 ml of Sterile Water for Injection; withdraw an equal volume of air.
3. Mix contents by swirling.
4. Place vial in appropriate lead shield.\*
- \*Use Unit Dose vial shield, Catalog No. 17500501.
5. Aseptically swab rubber septum of shielded vial.
6. Aseptically inject 1.3 ml of Sodium Pertechnetate Tc 99m having a maximum activity of 30 millicurie/ml into the vial; withdraw equal volume of air.
7. Mix contents of vial by gentle shaking for 10 seconds.
8. Affix pressure-sensitive label to shielded vial.
9. Allow to stand for 20 minutes after mixing to allow maximum tagging.
10. The TECHNETIUM 99m HSA is ready for use.
11. Mix contents of vial (step 7) prior to withdrawing patient dose.
12. Mix contents of syringe by repeated inversion immediately prior to injection.
13. Maintain adequate shielding of the radioactive preparation.
14. Do not use the preparation after 3 hours from the time of formulation.

The radioactivity concentration of the final Technetium Tc 99m Human Serum Albumin preparation may be calculated by using the following formula:

$C = A/V$  where C equals radioactivity concentration of the preparation (millicuries/ml).

$A =$  Tc 99m activity added to the reaction mixture vessel (millicuries).

$V =$  Total volume in the final mixture (ml).

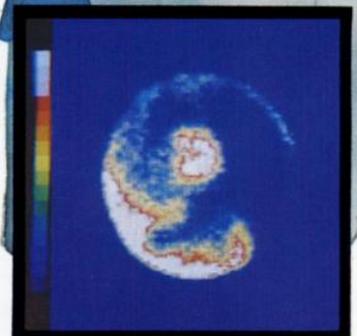
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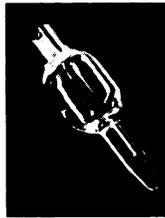
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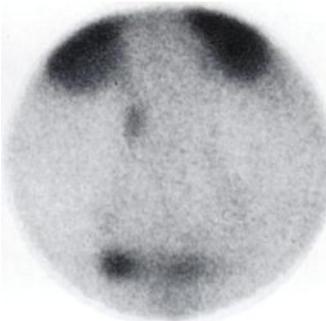
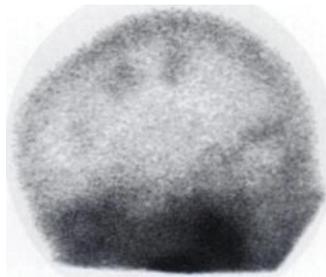
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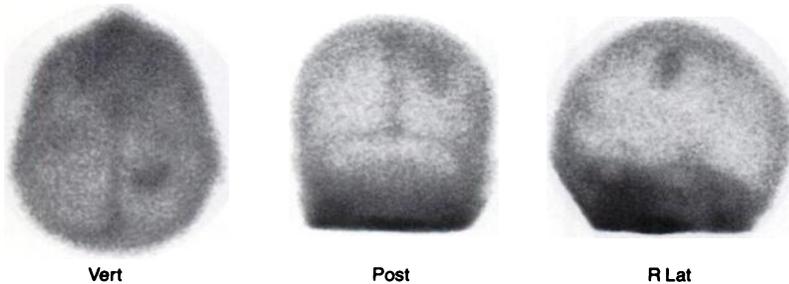


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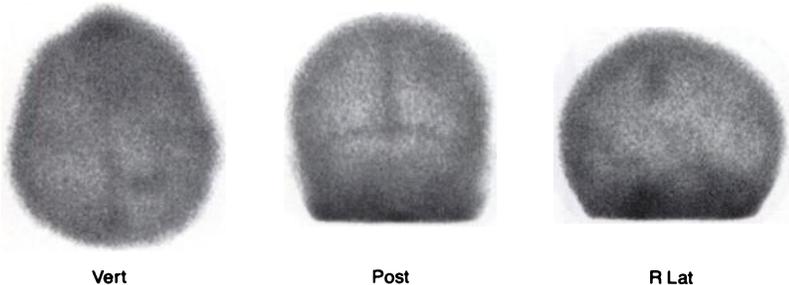
Technetium Tc 99m Glucoceptate Sodium Kit

# for brain imaging:

**Considered superior  
to technetium  
pertechnetate or DTPA<sup>1,2,3</sup>**



Glucoceptate (2 hrs)



Pertechnetate (3 hrs)

## **Higher target to background ratios**

"The results of the computer background study for <sup>99m</sup>Tc GH versus <sup>99m</sup>TcO<sub>4</sub> show an average calvaria/brain ratio of 2.1 and 1.6 for <sup>99m</sup>Tc GH and <sup>99m</sup>TcO<sub>4</sub>, respectively, at 90 min. after injection." Rollo et al<sup>2</sup>

## **May detect lesions not seen with other agents**

"...<sup>99m</sup>Tc glucoheptonate concentrates in all lesions which accumulate <sup>99m</sup>TcO<sub>4</sub> or <sup>99m</sup>Tc DTPA, and in certain cases, appears to localize lesions which do not concentrate other agents." Rollo et al<sup>2</sup>

When compared to pertechnetate ... "Glucoheptonate offers a significant improvement in lesion detection (for both infarcts and tumors)." Waxman et al<sup>3</sup>

## **Optimal imaging at 90 minutes postinjection, without KClO<sub>4</sub>**

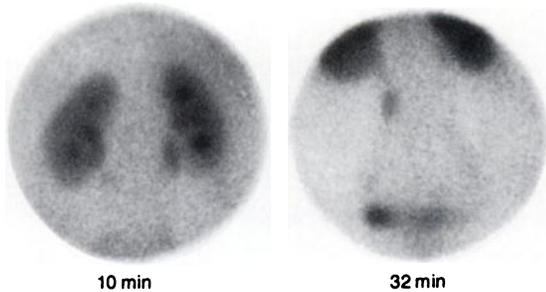
"<sup>99m</sup>Tc glucoheptonate combines the absence of oral activity with the convenience of obtaining highly diagnostically accurate images at 90 minutes." Rollo et al<sup>2</sup>

## **Excellent pharmacokinetics for busy nuclear medicine department**

"Kinetic studies have shown that while some of the activity is rapidly cleared through the urine, the remainder is retained in the renal cortex. In humans, about 25% of the injected dose is excreted in the urine during the first hour post-injection. Within the same interval, blood activity rapidly clears to less than 2% of the injected dose."<sup>4</sup>

# for dynamic and static renal imaging:

## Single radionuclide study detects masses; assesses renal size, shape, position



## A multifunctional agent

... whose appearance in the renal parenchyma and collecting system reflects cortical blood flow, tubular function and collecting system patency.

## Less limited by poor renal function than IVP

"Several patients with BUNs of 90 mg/dl or greater have been imaged, and information concerning renal size, contour and relative function obtained." Leonard et al<sup>5</sup>

## Safe method to assess renal function and morphology in patients allergic to iodinated contrast agents<sup>5</sup>

## Diagnostic results comparable to that of IVP for detection of mass lesions

"Glucoheptonate renal studies were performed on 275 patients, 55 of whom had angiography and/or surgery as well as IVP. All studies were interpreted prospectively by a board certified staff physician utilizing pertinent clinical information. In this study, the glucoheptonate images provided greater accuracy in the detection of renal mass lesions than the IVP (85% versus 67% respectively). This improved accuracy resulted from the greater sensitivity and specificity of the glucoheptonate images." Leonard et al<sup>6</sup>

1. Léveillé J et al: Technetium-99m glucoheptonate in brain-tumor detection: An important advance in radiotracer techniques. *J Nucl Med* 18 (10):957-961, 1977.
2. Rollo FD et al: Comparative evaluation of <sup>99m</sup>Tc GH, <sup>99m</sup>Tc Q<sub>4</sub>, and <sup>99m</sup>Tc DTPA as brain imaging agents. *Radiology* 123:379-383, 1977.
3. Waxman AD et al: Technetium 99m glucoheptonate as a brain scanning agent: A critical comparison with pertechnetate. *J Nucl Med* 17 (5):345-8, 1975.
4. Glucoscan (Technetium Tc 99m Glucopeptate Sodium Kit), Full Prescribing Information, New England Nuclear, May 1978.
5. Leonard JC et al: Glucoheptonate renal imaging. Given at Radiological Society of North America, Annual Meeting, Nov 29, 1977.
6. Leonard JC et al: Glucoheptonate renal imaging and the IVP: A surgical and angiographic correlative study. Given at Society of Nuclear Medicine, Southwest Chapter, April 27, 1978.

 **New England Nuclear**

See following page for full prescribing information.

# GLUCOSCAN

## Technetium Tc 99m Gluceptate Sodium Kit

May 1978

FOR DIAGNOSTIC USE

**DESCRIPTION:** New England Nuclear's GLUCOSCAN™ Technetium Tc 99m Gluceptate Sodium Kit is supplied sterile and non-pyrogenic in lyophilized kit form suitable for reconstitution with sodium pertechnetate Tc 99m to form a diagnostic imaging agent for intravenous administration. Each vial contains 200mg gluceptate sodium, 0.07mg maximum tin and 0.06mg (min.) stannous chloride. Prior to lyophilization, hydrochloric acid and/or sodium hydroxide solution may be added to adjust the pH.

### PHYSICAL CHARACTERISTICS

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

**Table 1. Principal Radiation Emission Data**

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

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

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

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	5	.562
1	.891	6	.501
2	.794	7	.447
3	.708	8	.398
4	.631		

\*Calibration Time

### EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 0.8R/mCi-hr at 1 cm. The first half-value thickness of lead (Pb) is 0.2mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of lead is shown in Table 3. For example, the use of a 6.3mm thickness of lead will attenuate the radiation by a factor greater than 10<sup>-6</sup>.

**Table 3. Radiation Attenuation by Lead Shielding**

Shield Thickness Lead (Pb) mm	Coefficient of Attenuation
0.2	0.5
0.95	10 <sup>-1</sup>
1.8	10 <sup>-2</sup>
2.7	10 <sup>-3</sup>
3.6	10 <sup>-4</sup>
4.5	10 <sup>-5</sup>
5.4	10 <sup>-6</sup>
6.3	10 <sup>-7</sup>

**CLINICAL PHARMACOLOGY:** Technetium Tc 99m Gluceptate Sodium has been shown by comparative renograms to concentrate in the kidney by both glomerular filtration and tubular secretion. Kinetic studies have shown that while some of the activity is rapidly cleared through the urine, the remainder is retained in the renal cortex. In humans, about 25% of the injected dose is excreted in the urine during the first hour post-injection. Within the same interval, blood activity rapidly clears to less than 2% of the injected dose.

Technetium Tc 99m Gluceptate Sodium has also been shown to localize in areas of intracranial pathology characterized by a disturbance in the blood brain barrier. The mechanism is probably non-specific since neoplasms,

cerebrovascular accidents and extracerebral hematomas have all shown pronounced radionuclide uptake. Used in conjunction with dynamic flow studies, Technetium Tc 99m Gluceptate Sodium may detect vascular stenoses and arteriovenous malformations. There is no concentration of the agent by the salivary glands or the choroid plexus.

**INDICATIONS AND USAGE:** Technetium Tc 99m Gluceptate Sodium is used for brain imaging.

Technetium Tc 99m Gluceptate Sodium is indicated for renal perfusion imaging as an adjunct in the diagnosis, localization and evaluation of kidney disease. It may provide useful information about renal size, shape, and position and may delineate lesions affecting renal blood flow.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** The contents of the GLUCOSCAN vial are intended only for use in the preparation of Technetium Tc 99m Gluceptate Sodium and are NOT to be directly administered to the patient.

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

Dehydration and/or patient positioning may result in failure to visualize urinary excretory structures in the presence of normal function. Adequate patient fluid intake and repositioning may reduce the incidence of such false positive studies.

**PRECAUTIONS:** Technetium Tc 99m Gluceptate Sodium, as well as any radioactive agent, must be handled with care. Once sodium pertechnetate Tc 99m is added to the kit, appropriate safety measures should be used to minimize external radiation exposure to clinical personnel.

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

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

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

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. Technetium Tc 99m Gluceptate Sodium should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS:** Although infrequent, erythema has been reported in association with the use of Technetium Tc 99m Gluceptate Sodium.

**DOSAGE AND ADMINISTRATION:** The recommended dose for the average (70kg) adult patient is 10-20 millicuries for both renal and brain imaging. Technetium Tc 99m Gluceptate Sodium is intended for intravenous administration only.

Technetium Tc 99m Gluceptate Sodium should be used within eight hours after aseptic reconstitution with sodium

pertechnetate Tc 99m. For optimal results, this time should be minimized. The reaction vial contains no bacteriostat.

Optimal results for both renal and brain imaging are obtained one hour after administration. Studies have shown that although optimal target-to-background ratios for brain lesions are obtained at two hours post-injection, there is no improvement in diagnostic efficacy after one hour.

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 governmental agencies authorized to license the use of radionuclides.

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

### RADIATION DOSIMETRY

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

**Table 4. Radiation Absorbed Doses**

Tissue	Absorbed Dose Rads/20 millicuries
Kidneys	3.40
Liver	0.20
Bladder Wall	5.60
Ovaries	0.32
Testes	0.20
Whole Body	0.15

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

Gluceptate Sodium—200mg  
Maximum Tin—0.07mg  
Stannous Chloride (min.)—0.06mg

Prior to lyophilization the pH is adjusted with hydrochloric acid and/or sodium hydroxide solution. Store at room temperature (15°-30°C). Included in each five vial kit is one package insert and six radiation labels. Included in each thirty vial kit is one package insert and thirty-six radiation labels.

**INSTRUCTIONS FOR PREPARATION OF TECHNETIUM Tc 99m GLUCEPTATE SODIUM KIT:** Aseptically inject 3 to 7ml of sodium pertechnetate Tc 99m into the supplied vial of GLUCOSCAN after placing vial in a radiation shield. Swirl for several seconds to dissolve completely. Label shield appropriately. Use within eight hours of reconstitution.

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

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

This reagent kit is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission pursuant to Section 35.14 and 35.100 Group III of 10 CFR or under equivalent licenses of Agreement States.

**Catalog Number NRP-180 (5 vial kit)  
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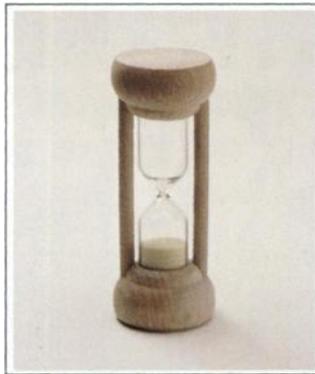


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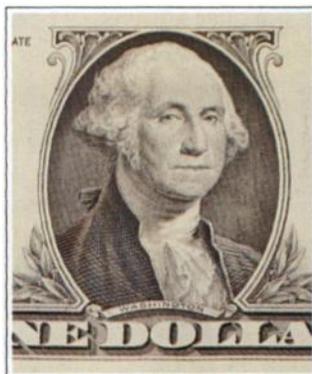
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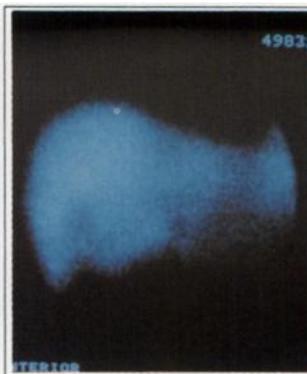
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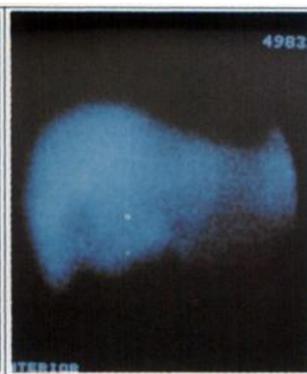
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**THE QUALITIES YOU LIKED IN OUR FROZEN PRODUCT  
ARE ALL HERE IN ITS LYOPHILIZED SUCCESSOR.**

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!

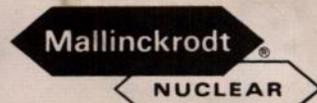
#### **Economy . . .**

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<sup>®</sup>MAA** (AGGREGATED ALBUMIN (HUMAN)) **LUNG SCAN KIT**



**RADIOPHARMACEUTICALS**

Mallinckrodt, Inc.  
P.O. Box 5840  
St. Louis, MO 63134

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

Mallinckrodt  
NUCLEAR

Mallinckrodt  
NUCLEAR

**TechneScan<sup>®</sup> MAA KIT**

AGGREGATED  
ALBUMIN (HUMAN) KIT  
(Lyophilized)  
Catalog No. 093  
Store at 2°C - 8°C

# The ice is out at Mallinckrodt.

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

## 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 (HBsAg) 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  $\mu$ g 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.



Mallinckrodt, Inc.  
P.O. Box 5840  
St. Louis, MO 63134



# Digital's new Gamma-11 Family. Affordable. Portable. And powerful.

Digital's Gamma-11 nuclear medicine data analysis system has already proven itself in more than 400 installations.

Now we've made it even better.

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So if you're considering a high-speed gamma data acquisition system — or if you're an existing Gamma-11 user interested in increased performance, new application software, or portable data acquisition — write for complete information today. Medical Data Products Group, Digital Equipment Corporation, MR2-4/M16, Marlborough,

Massachusetts 01752. European headquarters: 12, av. des Morgines, 1213 Petit-Lancy/Geneva. In Canada: Digital Equipment of Canada, Ltd.

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Computers in Hospitals

Medical Data Products Group, Digital Equipment Corporation,  
MR2-4/M16, Marlborough, MA 01752.

Please send information on Gamma-11  
 Please send information on MDA-11  
 Please have a Digital Medical Systems Specialist contact me

Name \_\_\_\_\_ Title \_\_\_\_\_  
 Hospital \_\_\_\_\_  
 Address \_\_\_\_\_  
 City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
 Telephone \_\_\_\_\_ Extension \_\_\_\_\_

PRICES APPLY IN U.S. ONLY.

JNM98



# The UNION CARBIDE Radionuclide Body Function Imager: **A Powerful New Way to Look Into Life.**

The CLEON 711 Radionuclide Body Function Imager utilizes accepted levels of conventional radiopharmaceuticals to produce computer-reconstructed, transaxial images of radioisotope concentrations in body sections. The system has been designed to provide clinical diagnostic information for early detection of organ function abnormalities and pathological changes, before anatomical changes are present.

The system can operate in a single or dual isotope mode. In the dual isotope mode there is independent data acquisition, reconstruction, and display for each isotope. There is also capability, using software options, to do array manipulations with the images from each isotope. Parameters are set for each slice – including slice thickness, scan time, radionuclide, and photon energy.

Both the Polaroid camera and sheet film can be exposed simultaneously, or the Polaroid camera can be inhibited. Up to four images can be recorded on each sheet film format.

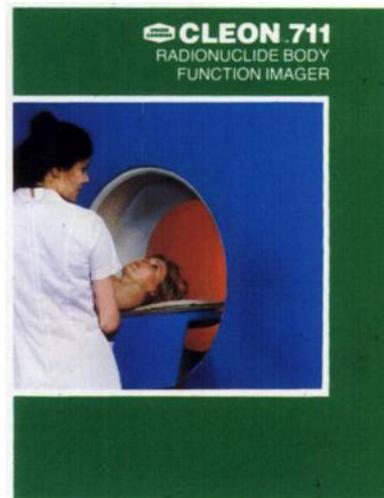
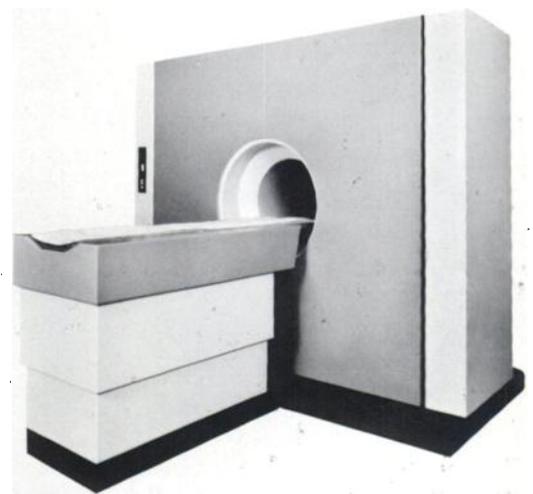
Each slice is automatically recorded on diskette at the end of each scan and can be played back at the operator's console. Once a slice is reconstructed, it can be



further manipulated using various degrees of background subtraction, upper and lower cutoff, and contrast enhancement, and recorded on film. Meanwhile, the system continues to gather data from subsequent slices. Image data stored on diskette can be played back and further manipulated at the requesting physician's convenience.

## **Ask Union Carbide for the Facts**

Imaging Systems products from Union Carbide are designed to enhance



diagnosis and research, produce a return on investment, and create better health care at lower patient cost.

If you feel you should know more about this powerful new diagnostic tool, send today for descriptive literature. Or call for a personal presentation.

**Touching your life  
through medicine . . .**



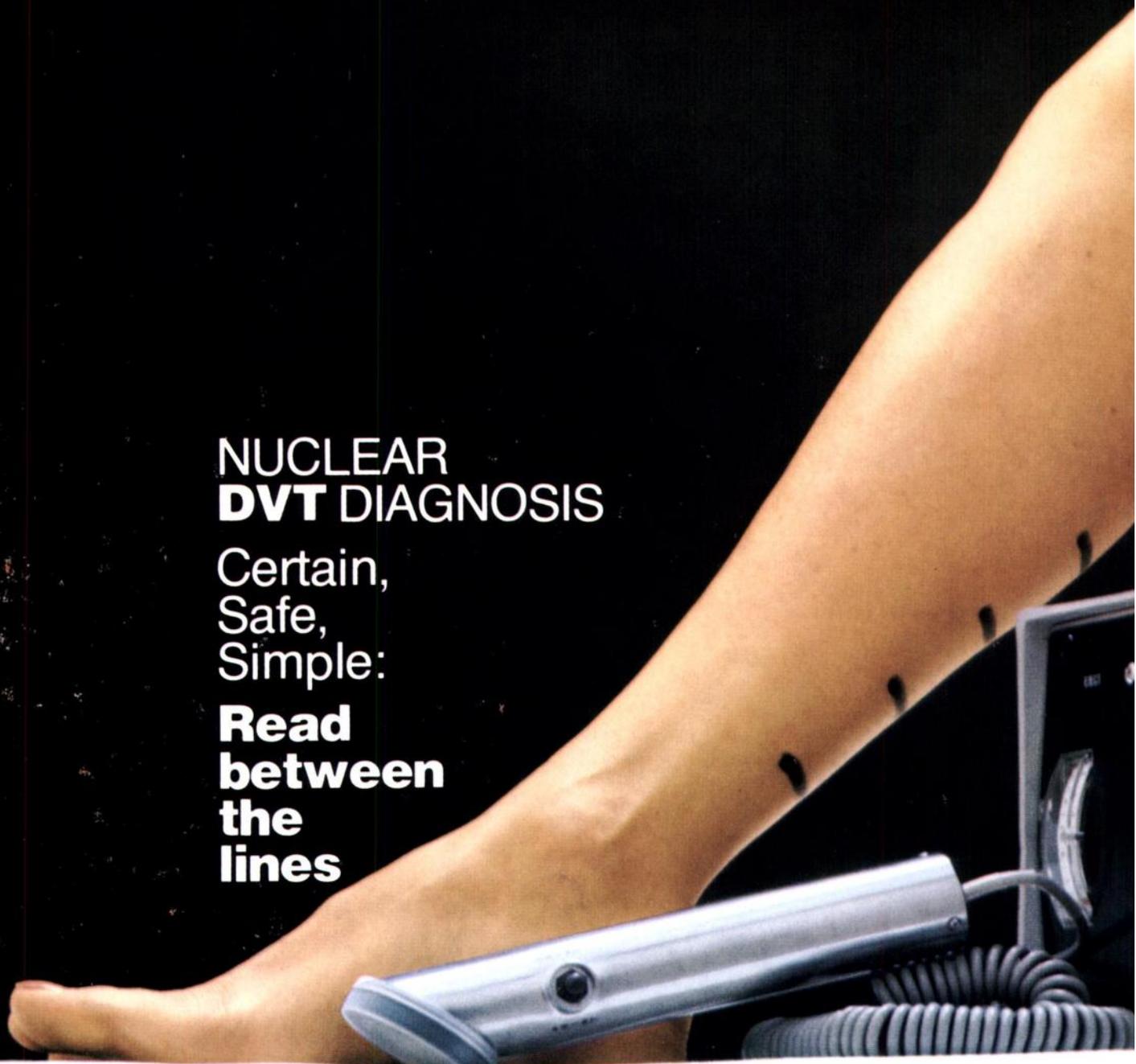
**Imaging Systems, Inc.**

333 Providence Highway  
Norwood, Massachusetts 02062  
(617) 769-5400 TELEX 924-494

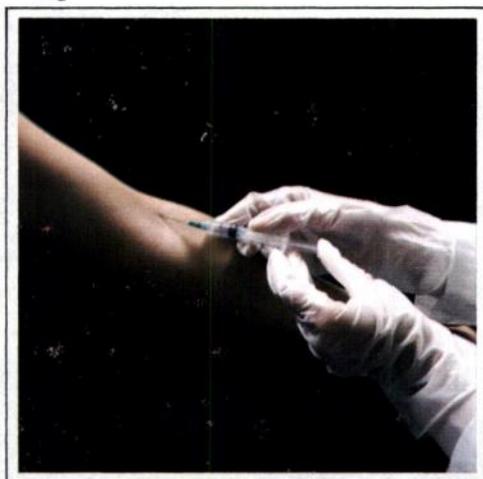
# NUCLEAR DVT DIAGNOSIS

Certain,  
Safe,  
Simple:

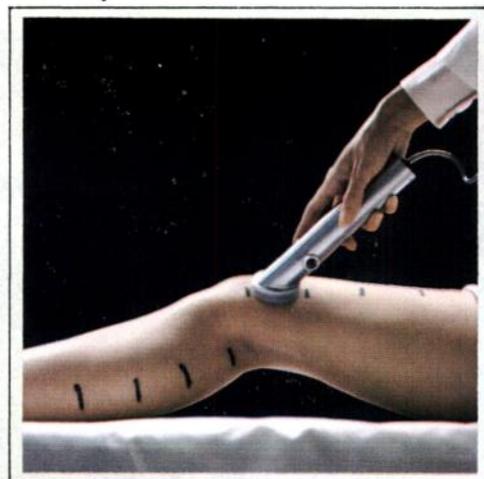
**Read  
between  
the  
lines**



Inject



Inspect



The

# IBRIN<sup>®</sup>

Radionuclide-Labeled  
(<sup>125</sup>I) Fibrinogen (Human)  
**IBRINATOR<sup>™</sup>**  
Portable Radioisotope Monitor

## System

**CERTAIN** The diagnostic accuracy of IBRIN for the detection of deep-vein thrombosis (DVT) has been confirmed in over 100 studies which show a 92% correlation with venography. IBRIN actively participates in thrombus physiology; its consistent clottability insures bioactivity and allows accurate detection of both forming and established thrombi.

**SAFE** DVT monitoring with the IBRIN System can be performed on medical, surgical and orthopedic patients. There is no need to move the patient to a special procedure area. The IBRIN System of DVT detection reduces the need to subject the patient to radiopaque venography.

**SIMPLE** IBRIN has a long *in-vivo* half-life, permitting monitoring for up to seven days without additional injections. Serial monitoring allows constant updating of the patient's status. IBRIN emits low energy radiation enabling the use of a lightweight isotope monitor such as the IBRINATOR for rapid testing of a large number of patients. Monitoring can begin within three hours after injection and results can be confirmed within twenty-four hours.

**INJECT** IBRIN, a Radionuclide-Labeled (<sup>125</sup>I) Fibrinogen (Human), is supplied freeze-dried for convenient storage and extended stability. It is reconstituted immediately prior to injection. The patient is intravenously injected with 100 $\mu$ Ci of IBRIN prior to testing.

**INSPECT** Initial monitoring can be performed three hours after the IBRIN injection. The IBRINATOR is specifically designed and built for detecting DVT. Sophisticated electronic design assures reliable accumulation of statistically valid data and eliminates most operator error. The IBRINATOR has a continuous stage design that requires all the correct data in the correct order before giving results. A digital data display and built-in printout insure ease and accuracy of data collection. Push button controls on the detector probe are provided for quick, accurate testing. The probe design includes an angled detector head to facilitate positioning for maximum operator convenience and patient comfort. The IBRINATOR is powered by rechargeable Ni-Cd batteries. A source is provided for calibration convenience and the complete unit weighs less than eight pounds.

**DETECT** The IBRIN System includes a patient data sheet which provides a convenient display of printout tape and graphical representation of data for the physician's interpretation and diagnosis.

*We will be glad to help you explain the benefits of the IBRIN System to your surgical staff. Write or phone Amersham for complete details.*

*See following page for brief summary of package insert.*

## Detect



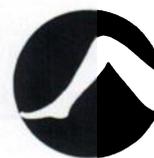
## Amersham

AMERSHAM CORPORATION:  
A SUBSIDIARY OF THE RADIOCHEMICAL CENTRE

2636 S. Clearbrook Dr., Arlington Heights, IL 60005  
312/593-6300 or 800/323-0668 (Toll free)

In Canada

505 Iroquois Shore Rd., Oakville, ONT L6H 2R3  
416/842-2720 or 800/261-5061 (Toll free)





The

# IBRIN System

**IBRIN**<sup>®</sup>  
Radionuclide-Labeled  
(<sup>125</sup>I) Fibrinogen (Human)  
**IBRINATOR**<sup>™</sup>  
Portable Radioisotope Monitor

#### INDICATIONS

IBRIN is indicated for use in prospective studies for the early detection and subsequent monitoring of developing deep-vein thrombosis and in diagnostic studies for the detection of established thrombosis in the legs.

- A. The IBRIN [Radionuclide-Labeled (<sup>125</sup>I) Fibrinogen (Human)] test is indicated in patients with signs and/or symptoms suggestive of deep-vein thrombosis with or without associated pulmonary embolism or in patients with pulmonary embolism, with or without evidence of peripheral deep-vein thrombosis. In patients with established, old or "inactive" thrombi, the test will be positive only if radionuclide-labeled fibrin deposition occurs in a sufficient quantity to allow detection. Its use is not contraindicated in patients on anticoagulants.
- B. The IBRIN [Radionuclide-Labeled (<sup>125</sup>I) Fibrinogen (Human)] test is indicated for the detection of thrombus formation in patients undergoing major orthopedic or other surgical procedures, myocardial infarction, pulmonary disease, malignant disease and other medical conditions known to predispose to thromboembolism.

#### CONTRAINDICATIONS

There are no known contraindications to the use of IBRIN. However, it should be noted that the iodides given to block the uptake of <sup>125</sup>I by the thyroid gland are contraindicated in patients with a known sensitivity to the iodides.

#### WARNINGS

This radiopharmaceutical should not be administered to patients under 18 years of age, to patients who are pregnant, or to patients who are lactating, unless the information to be gained outweighs the potential risk.

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. Nursing mothers should substitute formula feeding after the administration of Fibrinogen <sup>125</sup>I.

Extraordinary precautions have been taken in the preparation of IBRIN [Radionuclide-Labeled (<sup>125</sup>I) Fibrinogen (Human)] to eliminate the possible transmission of hepatitis. Nevertheless, the remote risk of hepatitis associated with the administration of Radionuclide-Labeled (<sup>125</sup>I) Fibrinogen (Human) cannot be entirely eliminated. The finding of viral hepatitis in any patient up to six months after the administration of IBRIN should be reported to Amersham for further evaluation, since there are numerous possible sources of hepatitis infection.

#### PRECAUTIONS

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.

This drug contains radioactive materials which must be handled only by qualified personnel in conformity with Nuclear Regulatory Commission, agreement state, or other appropriate government regulations. Care must be taken to avoid excessive exposure to its radiation. Shielding or equivalent radiation protective measures must be used.

This product is prepared from units of human plasma which have been tested using RIA methods and found non-reactive for Hepatitis B surface antigen. Approved detection methods are not sensitive enough to detect all infectious units of blood or all possible cases of hepatitis. However, IBRIN has been prepared from single donor plasma and has been injected into recipients without incidence of fibrinogen related Hepatitis B as evidenced by periodic physical examination and laboratory testing (liver profile, CBC, and Hepatitis B surface antigen and antibody by radioimmunoassay) of the recipients.

There are a number of clinical circumstances requiring consideration in the interpretation of the test results. (See complete Package Insert.)

Fibrinogen <sup>125</sup>I scanning should preferably be performed prior to venography if both procedures are contemplated, since venography may cause increases in count rate making interpretation of post-venography monitoring data difficult.

Adequate reproduction studies on animals have not been performed to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Radionuclide-Labeled (<sup>125</sup>I) Fibrinogen (Human) should be used in pregnant women only when clearly needed.

#### ADVERSE REACTIONS

There has been no reported incidence of allergic or anaphylactic reactions following the intravenous administration of IBRIN.



## Amersham

AMERSHAM CORPORATION:  
A SUBSIDIARY OF THE RADIOCHEMICAL CENTRE

2636 S. Clearbrook Dr., Arlington Heights, IL 60005  
312/593-6300 or 800/323-0668 (Toll free)

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# CMS COLLIMATORS EXPAND THE DIMENSIONS OF NUCLEAR IMAGING

## UNIVERSAL COLLIMATOR

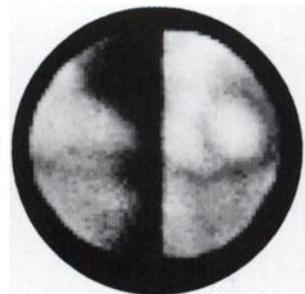
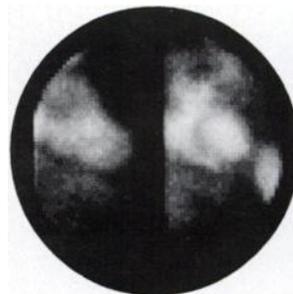
High resolution for static studies, medium sensitivity for flow studies, with one CMS Universal Collimator.

## CMS BILATERAL COLLIMATOR

Multiple, simultaneous imaging.

LARGE FIELD

SMALL FIELD



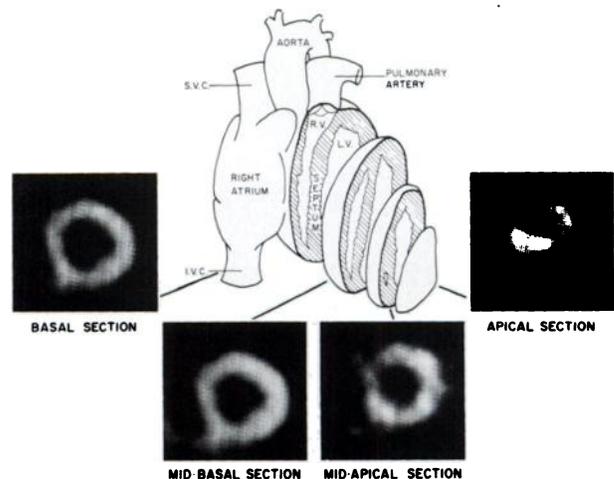
END DIASTOLE

END DIASTOLE

Study courtesy of S.M. Spies, M.D. and  
J.L. Quinn III, M.D., Northwestern Memorial Hospital.

## CMS SCINTISLICE™ TOMOGRAPHY

Multiple, simultaneous imaging.



Study courtesy of R.A. Vogel, M.D., Denver V.A. Hospital.

# CMS WRITE FOR LITERATURE

Cardiac Medical Systems Corporation  
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Today clinical diagnosis has attained high quality standards.

We feel, however, that goals are made to be overcome. That's why our RIA kits provide you with not only a series of data, but also the necessary accompaniments: accuracy, sensitivity, precision, practicality.

For example, our kit for adrenal function monitoring. Every pathological condition linked to cortisol changes requires a rapid and precise detection.

CIS offers you a kit endowed with added advantages over conventional methods.

**CORTCK 125:** kit for direct radioimmunoassay of plasmatic and urinary cortisol, with iodinated tracer, in coated tube.



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Tel. (0161) 48155 - TELEX 20064 SORINSAL

CIS RADIOPHARMACEUTICALS Inc.  
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BEDFORD MASS. 01730 - USA

SUBSIDIARIES



# WE'LL GIVE YOU TIME TO MAKE SURE YOU LOVE US.

## A SPECIAL PERFORMANCE EVALUATION PERIOD FOR THE LABORATORY CONSIDERING AUTOMATED RIA.

There's no reason to be wedded to a radioimmunoassay system that doesn't give you everything you want. We're so sure you'll love CENTRIA that we want you to evaluate it in your laboratory, under your working conditions, with your workload and personnel. At the end of the evaluation period, if you're dissatisfied, we'll take it back.\*

**The highs.** CENTRIA gives you outstandingly high throughput and efficiency. It's a snap to run as many as 72 tubes an hour with about ten minutes of hands-on time. Total automation in the three independent, integrated CENTRIA modules (pipettor, incubator/separator, counter/computer) makes it possible. And the automation also gives you outstanding reproducibility. From tube to tube. From run to run. Even from day to day.

**The lows.** If you've shopped around, you already know that our reagent cost of about 70¢ per tube is almost the lowest you can get. So low, in fact, that CENTRIA is economical to run even for less than a full batch.

**The extras.** CENTRIA diagnostic kits now cover two thirds of current RIA assay types, with more under development. Training is included. Technical and field engineering support are available. When you're using CENTRIA, we won't love you and leave you.

**Make a date.** Learn more about CENTRIA. We can show you a short film or arrange a visit to an on-line installation. And let us explain the details of our performance evaluation plan. You owe it to yourself to know as much as possible about the RIA system you're going to live with.



# Centria®

You may be more ready for automated RIA than you think.

Union Carbide Corporation, Clinical Diagnostics  
401 Theodore Fremd Avenue, Rye, New York 10580  
Telephone: (914) 967-7800

### GIVE ME A RING.

Have a Centria Representative call me to arrange  
 an appointment.  a demonstration.

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Tele. \_\_\_\_\_

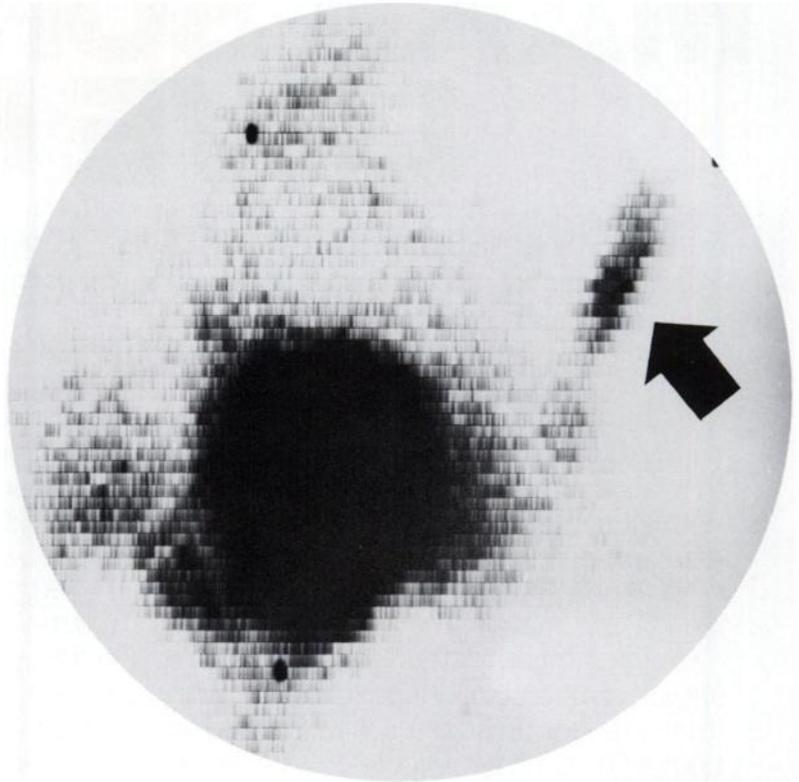
NM9

\*Customer will be obligated for freight and removal charges. Reagents not included.  
CENTRIA is a registered trademark of Union Carbide Corporation.

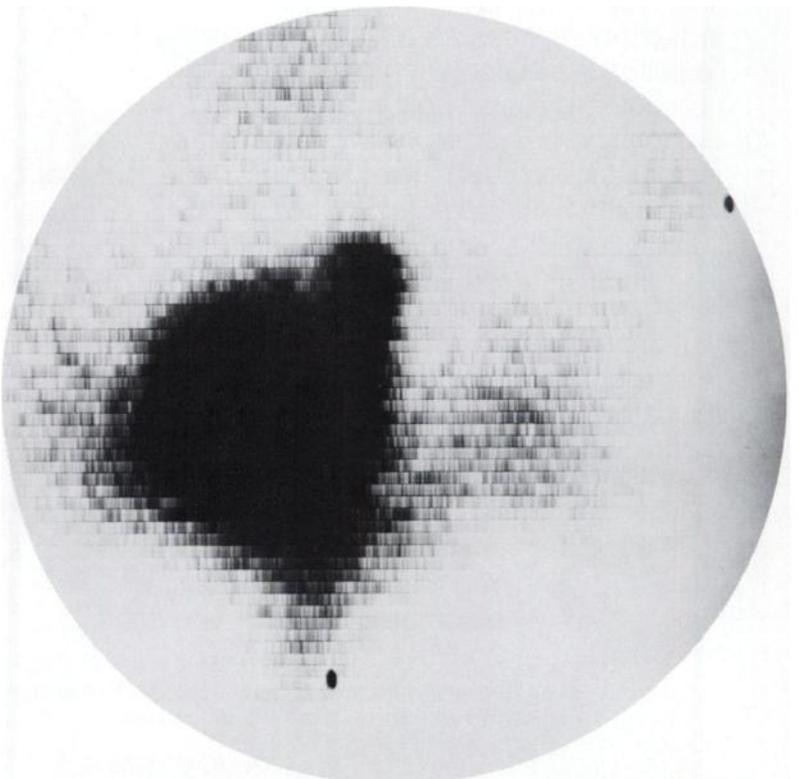
# Recent research shows...

**NOW AVAILABLE FOR  
ROUTINE USE AS AN ADJUNCT  
IN THE DIAGNOSIS OF ACUTE  
MYOCARDIAL INFARCTION.**

Solitary lesion  
seen with  
**OSTEOSCAN**<sup>®1</sup>  
Technetium Tc99m etidronate sodium kit



Same patient  
scanned with  
Tc 99m  
pyrophosphate<sup>1</sup>



In whole body scans from which these skeletal views were taken, a solitary ileal metastasis was seen with Osteoscan, but not with the pyrophosphate imaging agent.

# superiority to pyrophosphates for bone lesion detection



PROCTER & GAMBLE

# OSTEOSCAN<sup>®</sup>

## Technetium Tc99m etidronate sodium kit

Clinical evidence produced by two groups of investigators<sup>1,2</sup> demonstrates that Osteoscan outperforms pyrophosphates in detecting bone lesions.

"In ten of the 30 scans (33%) one or more metastases not detected on the Tc-PPi [pyrophosphate] image were noted by at least two of the three readers with Tc-HEDP [Osteoscan]."<sup>1</sup>

"...in three of 30 patients the Tc-PPi [pyrophosphate] scan was falsely read as normal by at least two of three readers, whereas metastatic disease was found in these patients with Tc-HEDP [Osteoscan]."<sup>1</sup>

The superior lesion detection demonstrated by Osteoscan may be explained by the higher tumor to normal bone ratios obtained.<sup>2</sup> In fact, it was concluded that Osteoscan "... is at present the agent of choice for routine clinical practice..."<sup>2</sup>

With Osteoscan, you can also expect excellent in vitro stability (greater than 98% tag 8 hours after preparation) ... a very low tin level (.16 mg stannous chloride per vial) to minimize the potential for liver visualization or interference with subsequent brain scans ... rapid blood clearance ... plus excellent in vivo stability due to Osteoscan's P-C-P bond.

For additional information, call or write Procter & Gamble, Professional Services, P. O. Box 85507, Cincinnati, Ohio 45201, (513) 977-5547.

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

#### References:

1. Silberstein, E. B. et al.: Clinical comparison of technetium-99m diphosphonate and pyrophosphate in bone scintigraphy: Concise communication, J. Nucl. Med. 19:161, 1978.
2. Fogelman, I. et al.: A clinical comparison of <sup>99m</sup>Tc-hydroxyethylidene diphosphonate (H.E.D.P.) and <sup>99m</sup>Tc-pyrophosphate in the detection of bone metastases, Clin. Nucl. Med. 2:364, 1977.

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 etidronate disodium, 0.16 mg stannous chloride and 0.56 mg sodium ascorbate as active ingredients. Upon addition of ADDITIVE-FREE sodium pertechnetate Tc99m the etidronate disodium and stannous chloride combine with Tc99m to form a stable soluble complex.

**Clinical pharmacology:** When injected intravenously, Tc99m-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 Tc99m-labeled OSTEOSCAN.

Three hours after intravenous injection of Tc99m-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 Tc99m-labeled OSTEOSCAN excreted in the feces is below the level detectable by routine laboratory techniques.

Tc99m-labeled OSTEOSCAN is also taken up in areas of necrosis and severely injured myocardial cells. Approximately 1.5 hours following intravenous injection 0.01-0.02 percent of the administered dose per gram of tissue is taken up by an acutely infarcted myocardium.

**Indications:** OSTEOSCAN 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. When used as an adjunct in the diagnosis of myocardial infarction the incidence of false negatives has been found to be approximately 14% and false positives about 16%. False negatives may result from failure to observe temporal requirements for good myocardial imaging; false positives may be related to coronary heart disease, left ventricular aneurysms, trauma, repeated cardioversion following coronary by-pass surgery or old myocardial infarcts.

**Contraindications:** None known.

**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.

The technetium used to tag the product should be routinely tested for molybdenum and aluminum; if an unacceptable level of either is found, the technetium should not be used.

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

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

#### Bone Imaging:

Both prior to and following Tc99m-labeled OSTEOSCAN administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the Tc99m-labeled OSTEOSCAN injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.

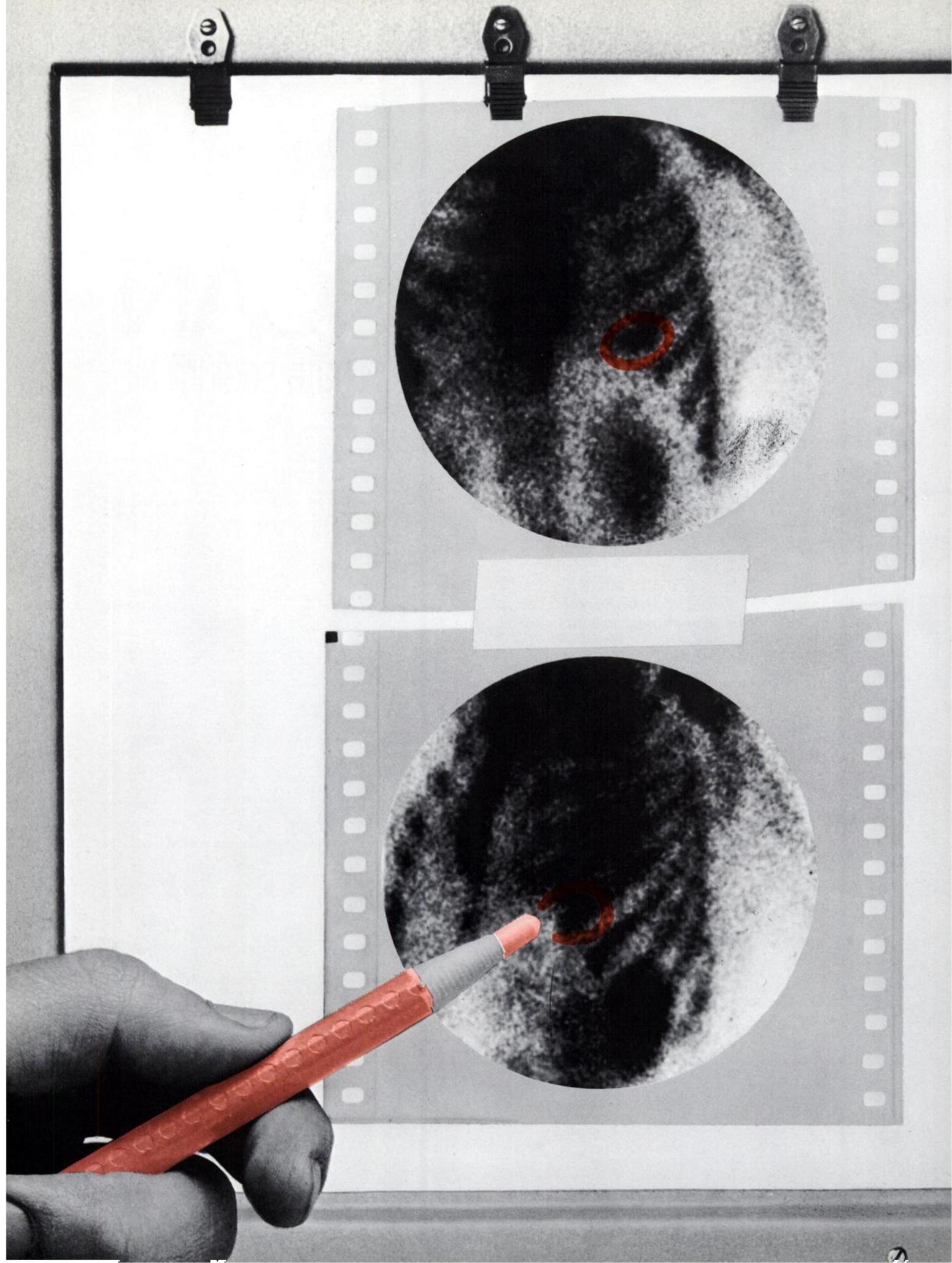
#### Cardiac Imaging:

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.

**Adverse reactions:** None known.

**Dosage and administration:** The recommended adult dose of Tc99m-labeled OSTEOSCAN is 10-15 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 bone imaging should be done 2-4 hours post injection and cardiac imaging 1-1 1/2 hours post injection. The acute myocardial infarct can be visualized from 1-9 days following onset of symptoms with maximum uptake at 2-3 days. It is recommended that three projections of the heart be made (anterior, left anterior oblique and left lateral).



**Helps detect, localize,  
and delineate  
acute myocardial  
infarction**

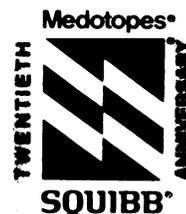
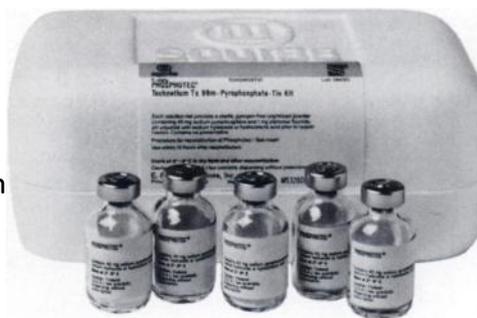
# **Phosphotec®** **Technetium Tc 99m- Pyrophosphate-Tin Kit**

In detection of acute myocardial infarction, "the agent of choice [of the several  $^{99m}\text{Tc}$  complexes] at the present time is  $^{99m}\text{Tc}$ -pyrophosphate."\* Imaging is particularly useful in detecting recent infarcts when imaging is performed within 24 hours to six days after onset of suggestive symptoms. An effective adjunct in clinical situations such as equivocal ECG's, postoperative cardiac status, and when standard diagnostic aids are difficult to interpret.

Easy preparation. Two steps:

- (1) Add sterile sodium pertechnetate  $^{99m}\text{Tc}$ . (Maintain shielding at all times.)
- (2) Shake gently, assay dose, and inject IV over 10 to 20 seconds. Cardiac imaging can be performed 45-60 minutes postinjection.

Also indicated for fast, dependable skeletal imaging.



\*Holman BL: Imaging the heart in patients with infarction. Cardiovascular Med 1:161-165, Oct, 1976

See next page for brief summary.

# Phosphotec<sup>®</sup>

## Technetium Tc 99m-Pyrophosphate-Tin Kit

**DESCRIPTION:** Phosphotec provides all the nonradioactive components required to prepare a sterile, pyrogen-free technetium Tc 99m-pyrophosphate-tin complex. Each reaction vial contains 40 mg sodium pyrophosphate (equivalent to 23.9 mg anhydrous sodium pyrophosphate) and 1 mg stannous fluoride; the product does not contain a preservative. When sterile, pyrogen-free Sodium Pertechnetate Tc 99m is added to the reaction vial, a technetium Tc 99m-pyrophosphate-tin complex is formed.

**INDICATIONS AND USAGE:** Technetium Tc 99m-Pyrophosphate-Tin complex may be used as a bone imaging agent to delineate areas of altered osteogenesis. It is also a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** This product 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 childbearing capability should be performed during the first few (approx. 10) days following the onset of menses.

It has been 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 brain scans are indicated along with imaging of bone or myocardial imaging, the brain scan should be performed first, if feasible. Alternatively, another brain imaging agent, such as Tc 99m DTPA, may be employed. False-positive and false-negative myocardial scans may occur; therefore, the diagnosis of acute myocardial infarction depends on the overall assessment of laboratory and clinical findings.

The contents of the Phosphotec 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 99mTc solution which contains an oxidizing agent is not suitable for use with Technetium Tc 99m-Pyrophosphate-Tin Kit. The contents of the kit are not radioactive. However, after sodium pertechnetate 99mTc is added, adequate shielding of the final preparation must be maintained. Technetium Tc 99m-Pyrophosphate-Tin Solution must be used within 12 hours of reconstitution.

**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 patients 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 if not contraindicated by the patient's cardiac status. The patient's cardiac condition should be stable before beginning the cardiac imaging procedure. Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing three projections (e.g., anterior, lateral, and left anterior oblique).

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. This drug 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.

For full prescribing information, see package insert.

**HOW SUPPLIED:** In a kit containing five reaction vials (5 ml size).



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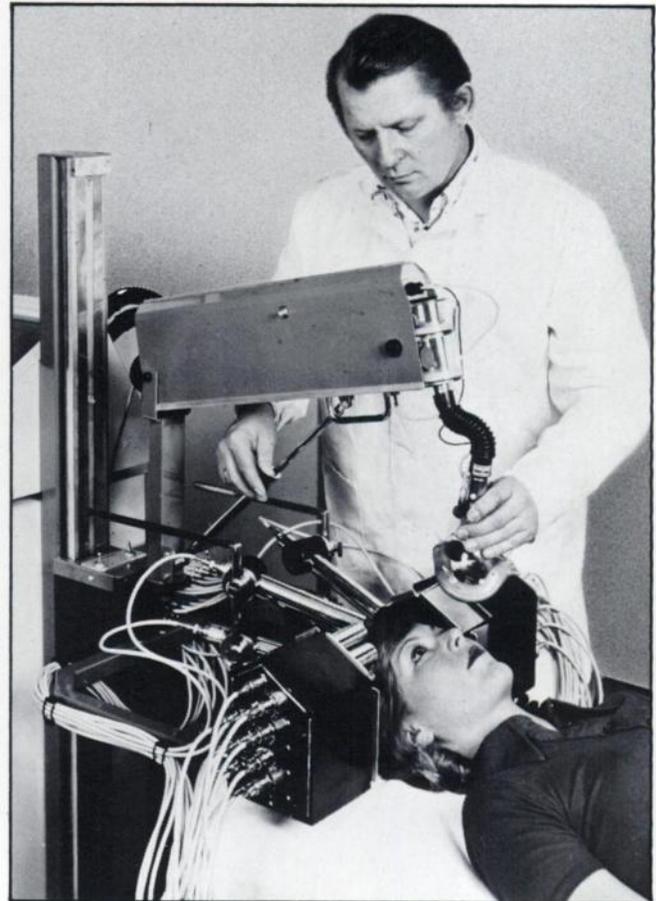
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ING DOCTOR: JANNIE BJOERKANDER			
7,0 MM HG	HGB:14,0 GR%	BP:1	
F1 ( % )	ISI ( % )	W1 ( % )	
ML/100GM/MIN		PER CE	
86 (111)	51 (108)	40 (1	
79 (102)	49 (104)	40 (1	
92 (120)	52 (109)	38 (1	
T 82 (107)	50 (106)	41 (1	
T 76 (100)	45 ( 94)	34 (1	

an unaffected hemisphere to serve as reference for an affected one. Is widely used for research volunteers and on a broad patient spectrum for frequent measurements over prolonged periods.

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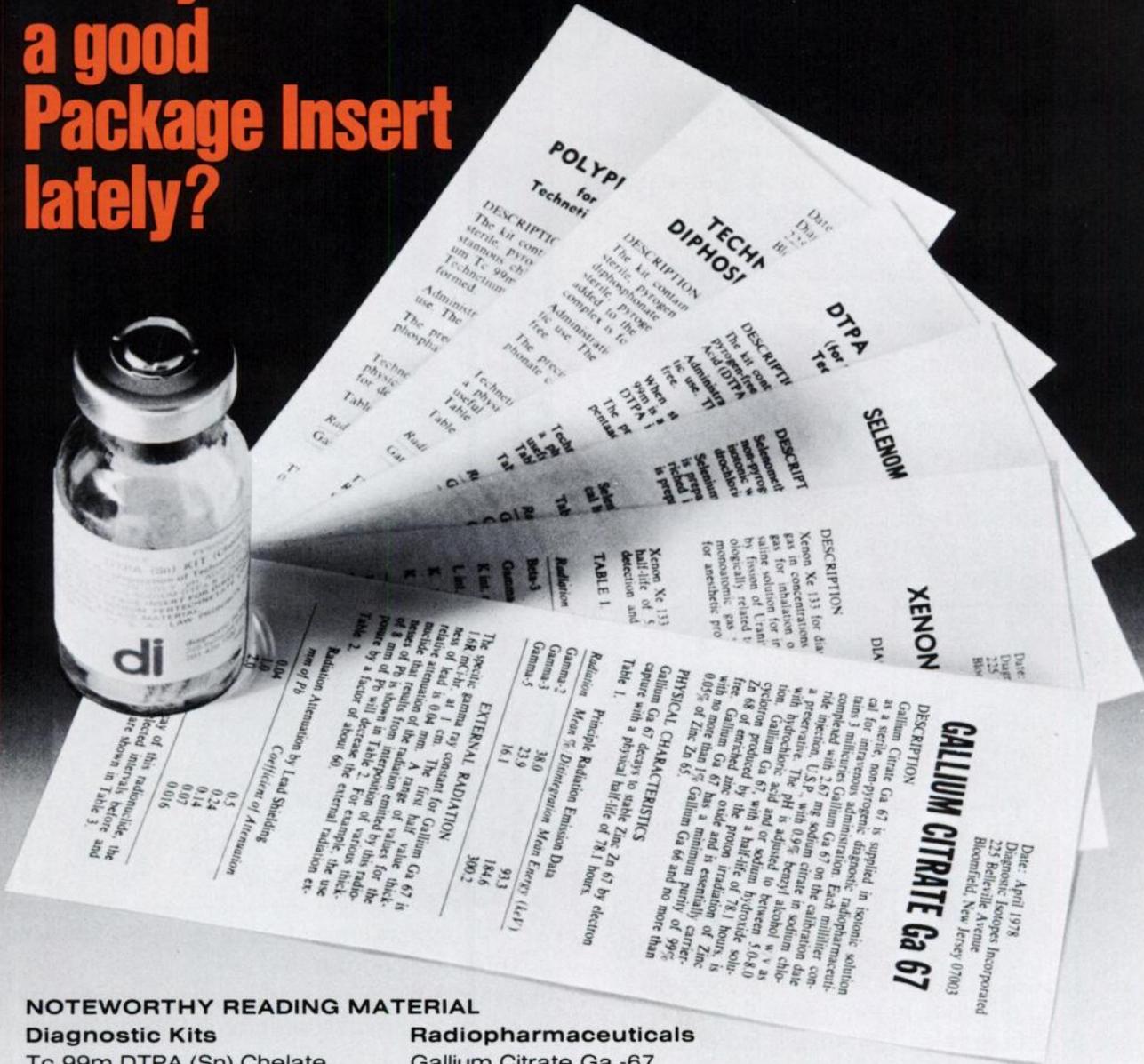
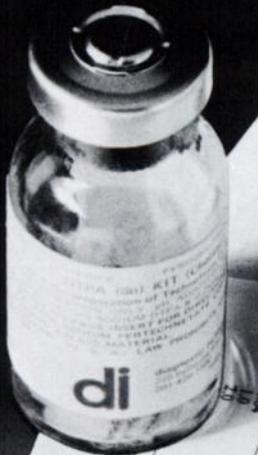
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## NOTEWORTHY READING MATERIAL

### Diagnostic Kits

- Tc 99m DTPA (Sn) Chelate
- Tc 99m Polyphosphate - Tin
- Tc 99m Diphosphonate - Tin

### Radiopharmaceuticals

- Gallium Citrate Ga -67
- Selenomethionine Se -75
- Xenon - 133 Gas
- Xenon - 133 Saline

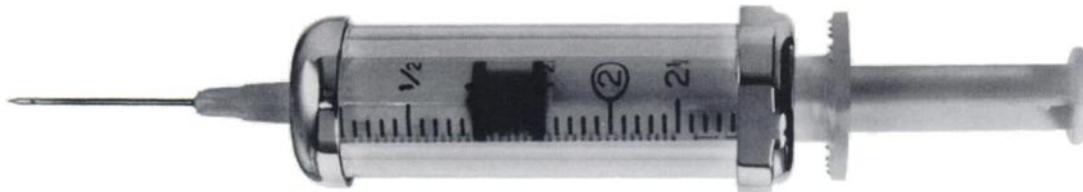
**Accessories:** "Auto Mate" Xenon Gas Hand Held Dispenser.  
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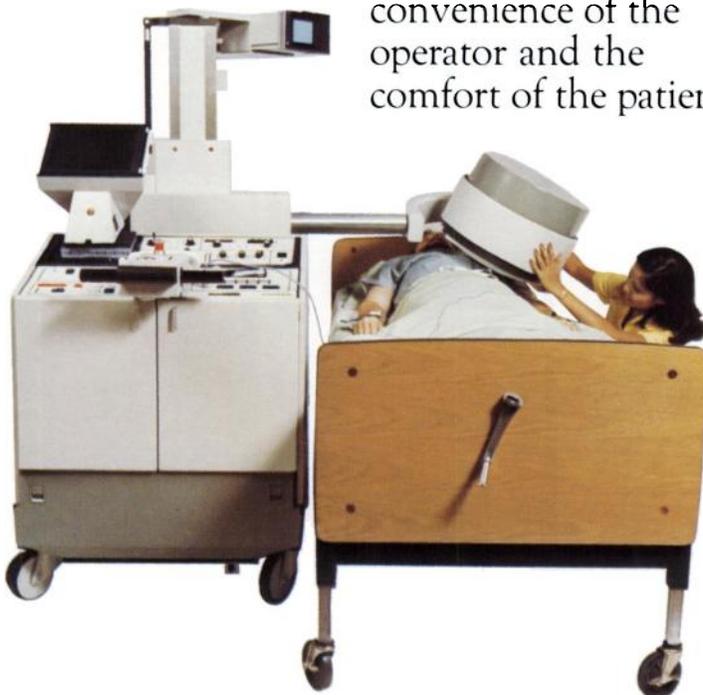
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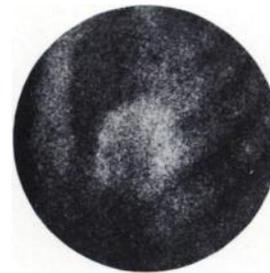
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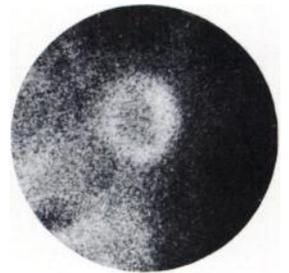
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Collimator — Ultrafine*



*Thallium 201 Study —  
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LAO View  
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Pyrophosphate  
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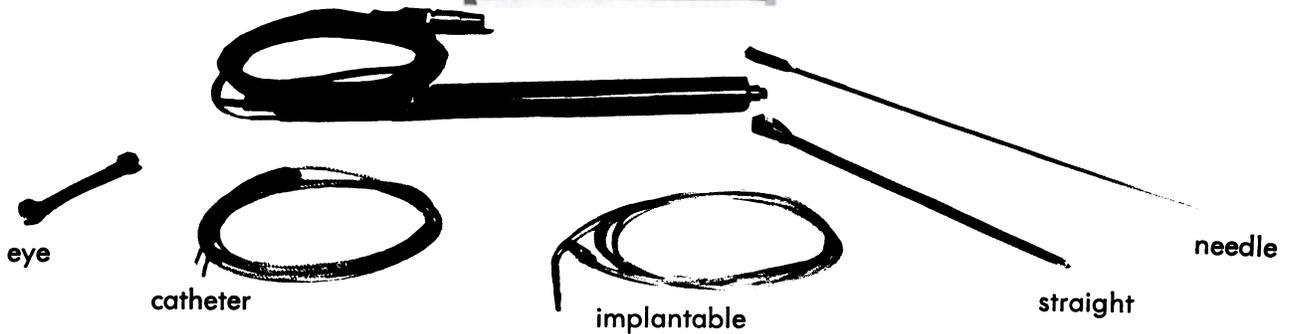
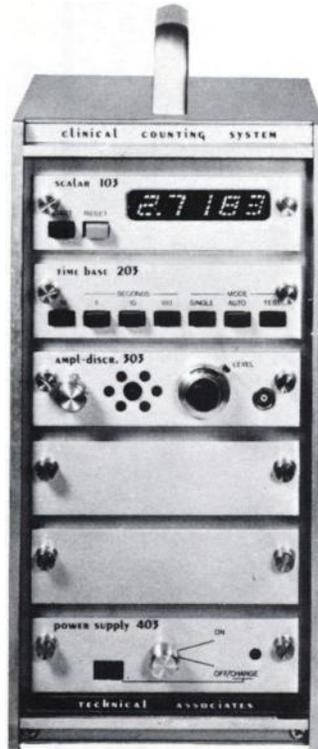
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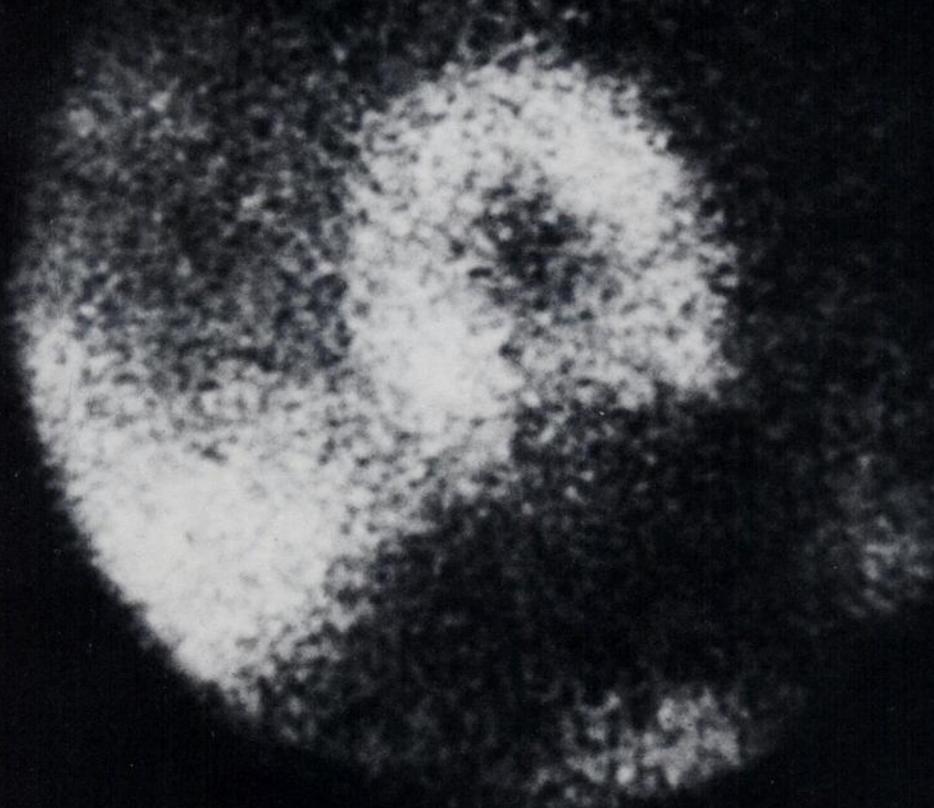
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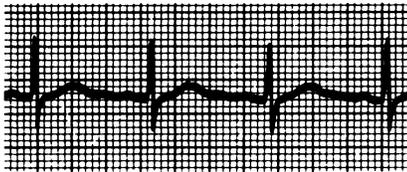


# **Thallous Chloride TI 201**

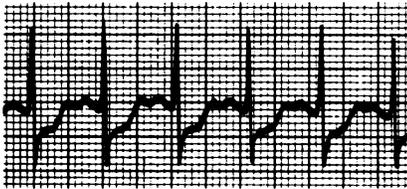
**NEN** New England Nuclear

# To help rule out, confirm or evaluate

## Coronary artery disease



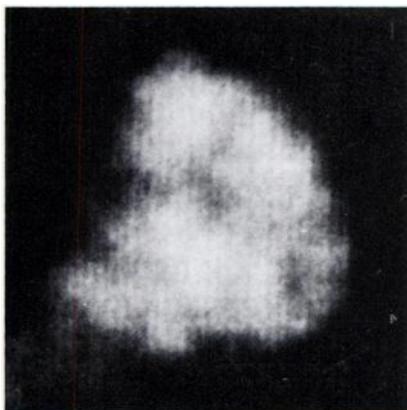
Rest



Exercise



Initial anterior view



Delayed anterior view

### Positive stress ECG without angina

**History**  
A.C., 50-year-old accountant, asymptomatic, required to undergo exercise ECG as part of "executive physical."

**ECG findings**  
Normal at rest, 2.5-3 mm ST-segment depression on exercise; denied accompanying angina.

**Thallium-201 imaging**  
Large apical defect on immediate post-exercise anterior view; defect filled in on delayed images.

**Working diagnosis**  
Coronary artery disease, confirmed on preoperative angiography.

## Acute myocardial infarction

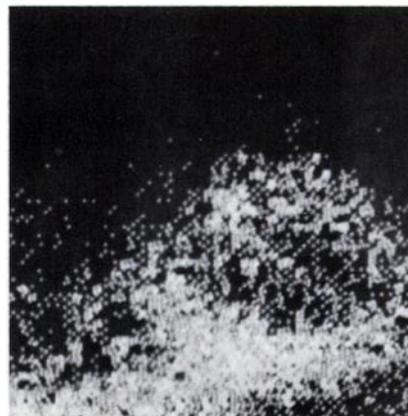
### Early diagnosis

**History**  
J.B., 54-year-old construction worker, admitted to CCU following episode of severe chest pain, diaphoresis, dizziness. Patient fell to ground upon onset of symptoms, severely bruising left thigh, chest wall. No history of angina pectoris or prior MI; ECG documented left bundle branch block.

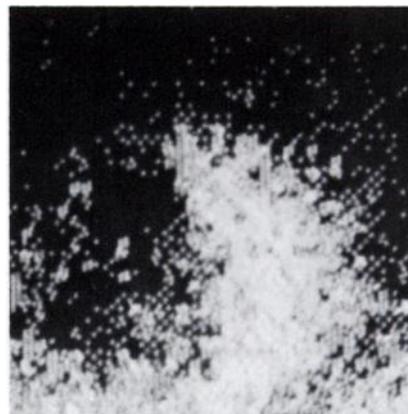
**Serum enzymes, ECG**  
Elevated shortly following admission; isoenzyme analysis unavailable to differentiate elevation secondary to trauma from possible elevation secondary to acute MI; ECG nondiagnostic because of LBBB.

**Thallium-201 imaging**  
Images made upon admission displayed anterior wall defect (anterior view), large septal defect (LAO view).

**Working diagnosis**  
Extensive antero-septal MI.

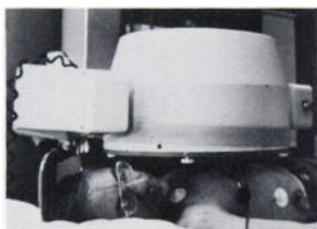


Anterior



LAO

# To start using thallium-201 in your department, you'll need



**A recent model 37 photomultiplier tube camera** with all-purpose collimator, capable of resolving 1 cm line separations on an Au 195 line phantom

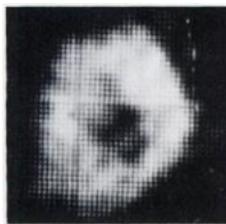


**Treadmill or bicycle ergometer and ECG recorder,** to perform maximal stress testing in accordance with good clinical practice



5 min

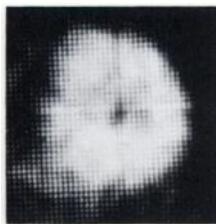
**Ability to begin imaging promptly** (within 3–5 minutes) following thallous chloride Tl 201 injection and termination of stress



15 min



45 min



120 min

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**Clinical training in scan interpretation** at an institution experienced in thallium-201 imaging\*



**Electronic image acquisition and processing,** to help resolve ambiguous studies



**Mobile imaging/acquisition instrumentation,** to facilitate acute MI thallium-201 studies when patients cannot be transported to the nuclear medicine department



**Continuing medical education on thallium-201,** for your staff and for your referring physicians\*

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## Thallous Chloride Tl 201

**NEN** New England Nuclear

See following page for full prescribing information.

# Thallous Chloride TI 201

November 1977

## FOR DIAGNOSTIC USE

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

### PHYSICAL CHARACTERISTICS

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

Table 1. Principal Radiation Emission Data

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

<sup>1</sup>Martin, M.J., Nuclear Data Project, ORNL, January 1977

### EXTERNAL RADIATION

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

Table 2. Radiation Attenuation By Lead Shielding

mm of Lead (Pb)	Coefficient of Attenuation
0.23	0.5
0.83	10 <sup>-1</sup>
1.9	10 <sup>-2</sup>
3.1	10 <sup>-3</sup>
4.4	10 <sup>-4</sup>
5.7	10 <sup>-5</sup>

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

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

Hours	Fraction Remaining	Hours	Fraction Remaining	Hours	Fraction Remaining
-72	1.98	18	0.84	72	0.51
-60	1.77	24	0.80	78	0.48
-48	1.58	30	0.75	84	0.45
-36	1.41	36	0.71	90	0.43
-24	1.28	42	0.67	96	0.40
-12	1.06	48	0.63	108	0.36
0*	1.00	54	0.60	120	0.32
6	0.95	60	0.57	132	0.29
12	0.89	66	0.54	144	0.26

\*Calibration Time

**CLINICAL PHARMACOLOGY:** Carrier-free Thallous Chloride TI 201 has been found to accumulate in viable myocardium in a manner analogous to potassium. Experiments employing labeled microspheres in human volunteers have

shown that the myocardial distribution of Thallous Chloride TI 201 correlates well with regional perfusion.

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

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

**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.

**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.

### RADIATION DOSIMETRY

The estimated absorbed radiation dose<sup>2</sup> to an average patient (70kg) from an intravenous injection of a maximum dose of 1.5 millicuries of TI 201 is shown in Table 4.

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

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

<sup>2</sup>Values listed include a maximum correction of 13% to the radiation doses from TI 201 due to the radiocontaminants Pb 203 and TI 202.

**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

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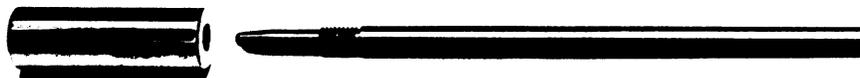
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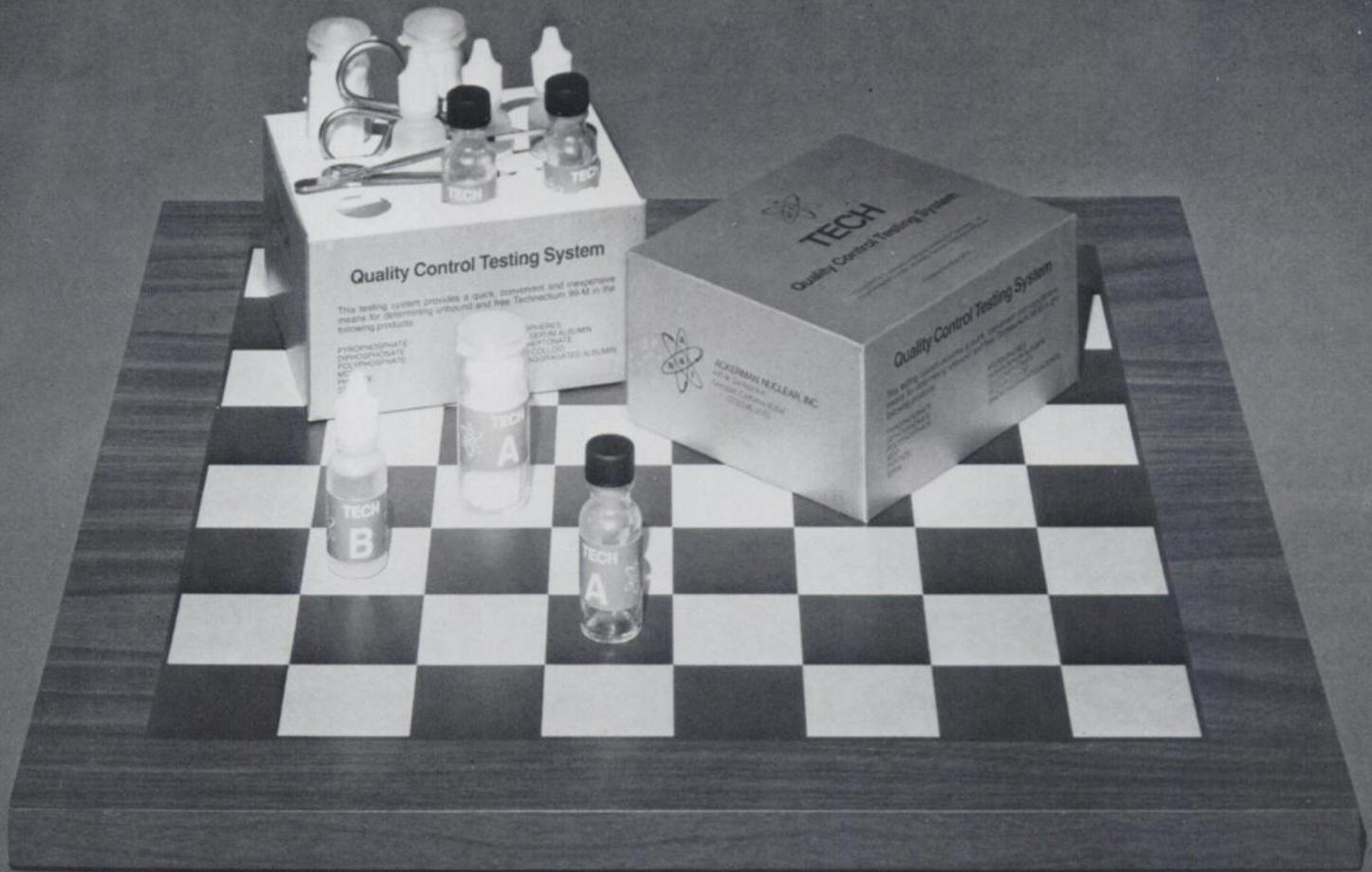
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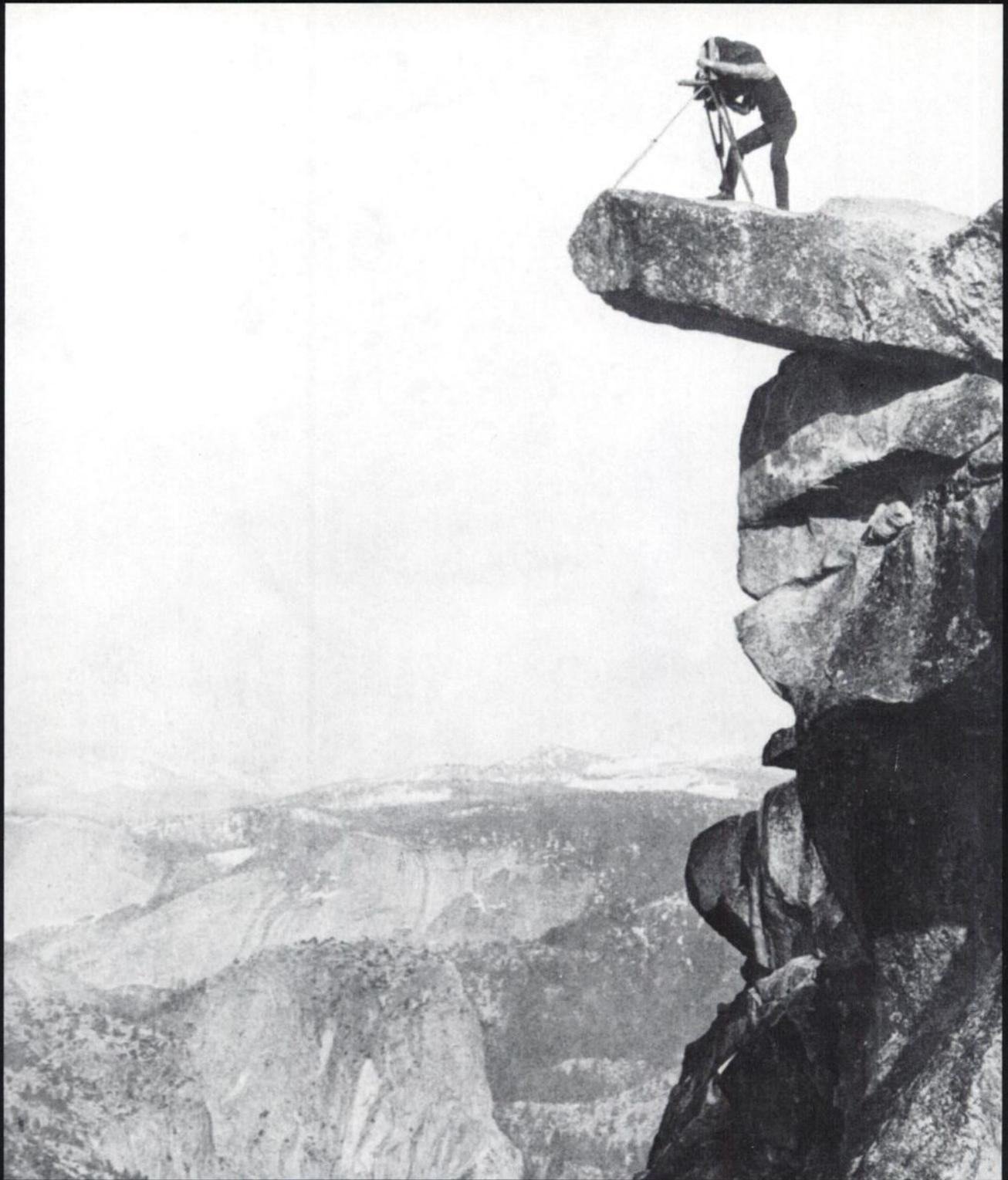
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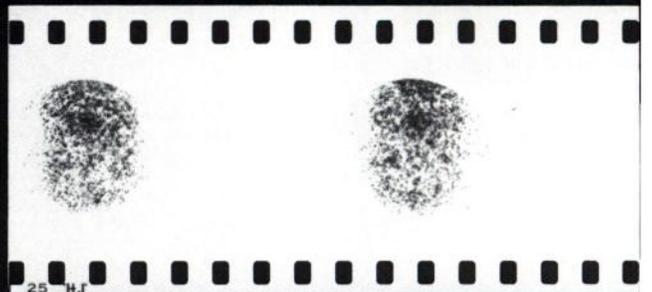
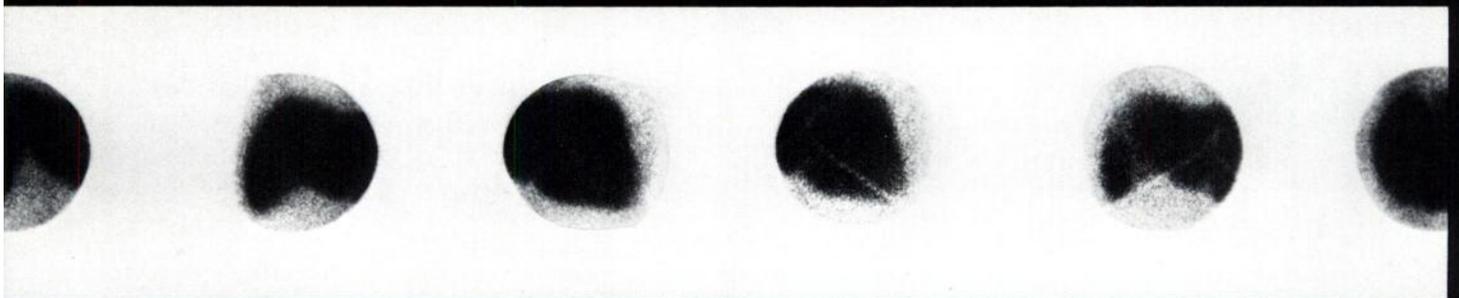
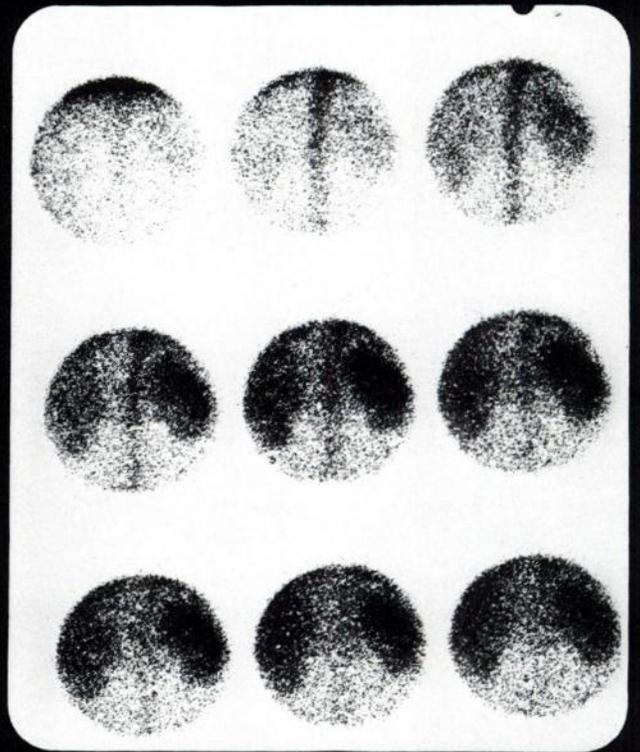
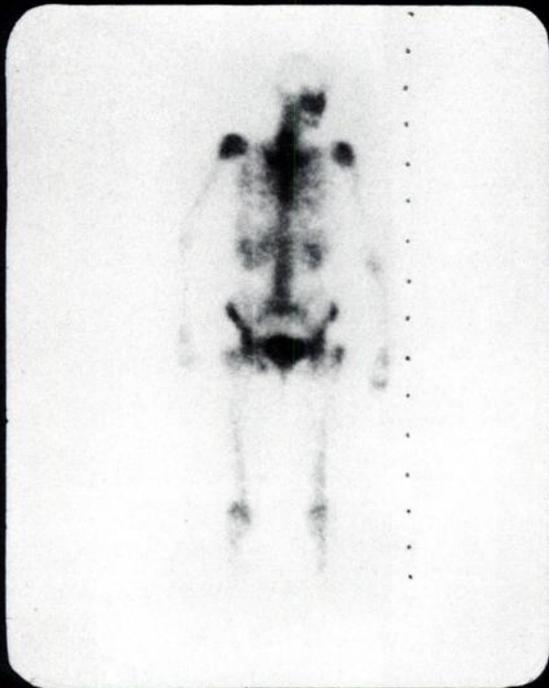
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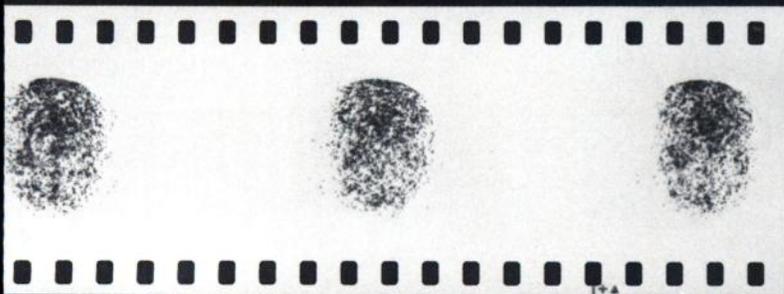
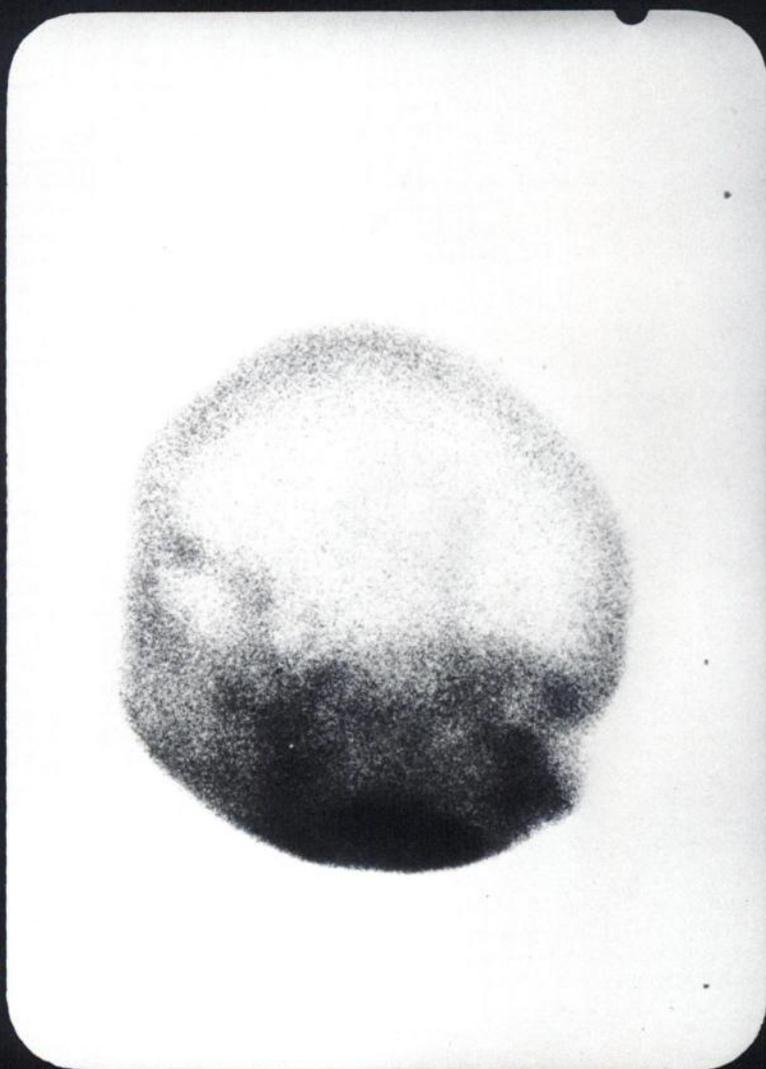


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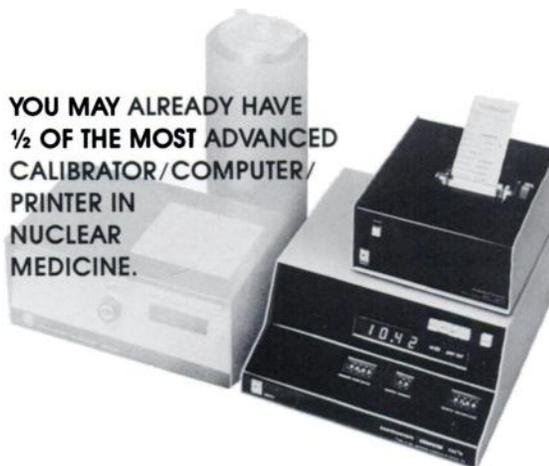
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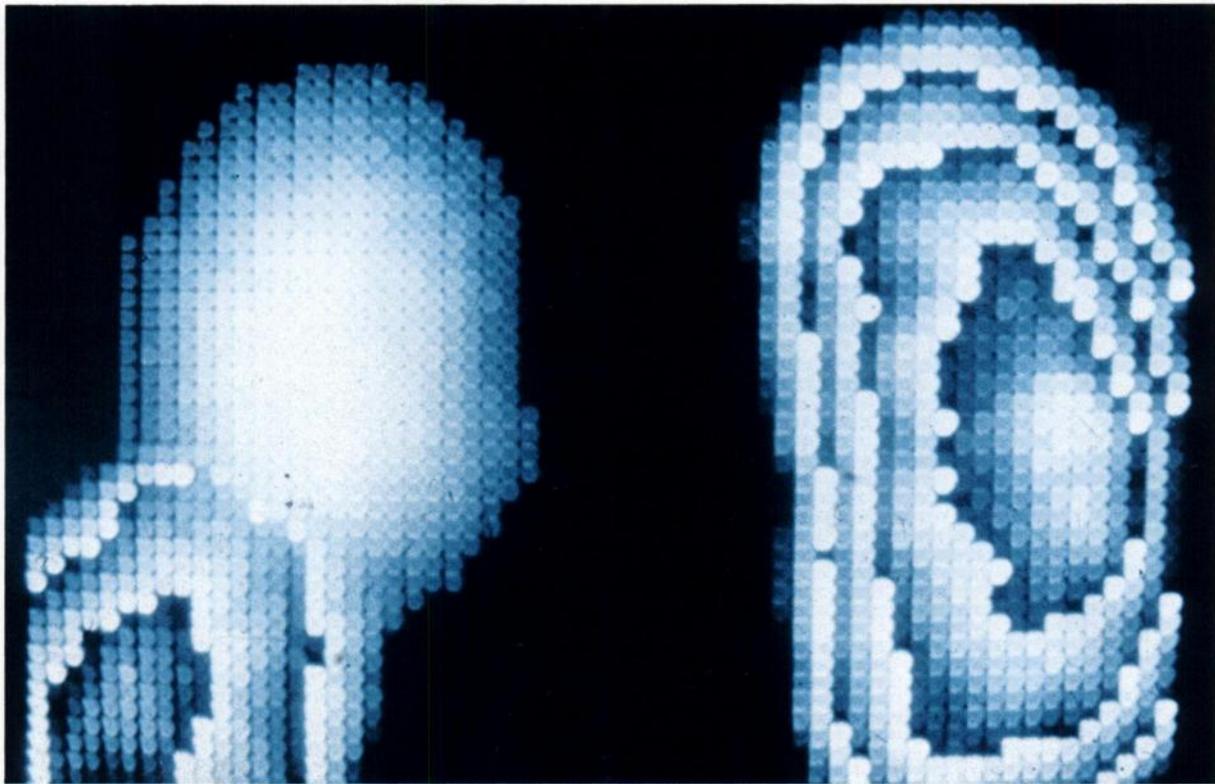
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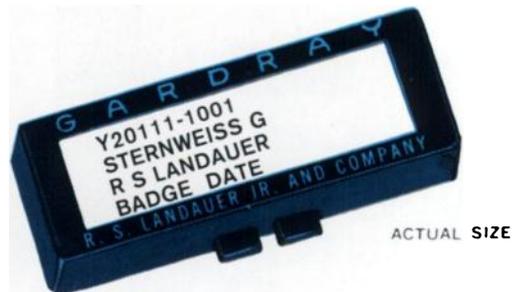
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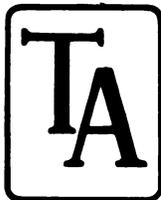
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2	0--	071.3
1	9--	074.8
1	8--	076.4
1	7--	078.0
1	6--	079.7

percent uptake

7	--	088.9
6	--	096.1
5	--	108.8
4	--	117.6
3	--	129.1
2	--	141.9
1	--	151.5
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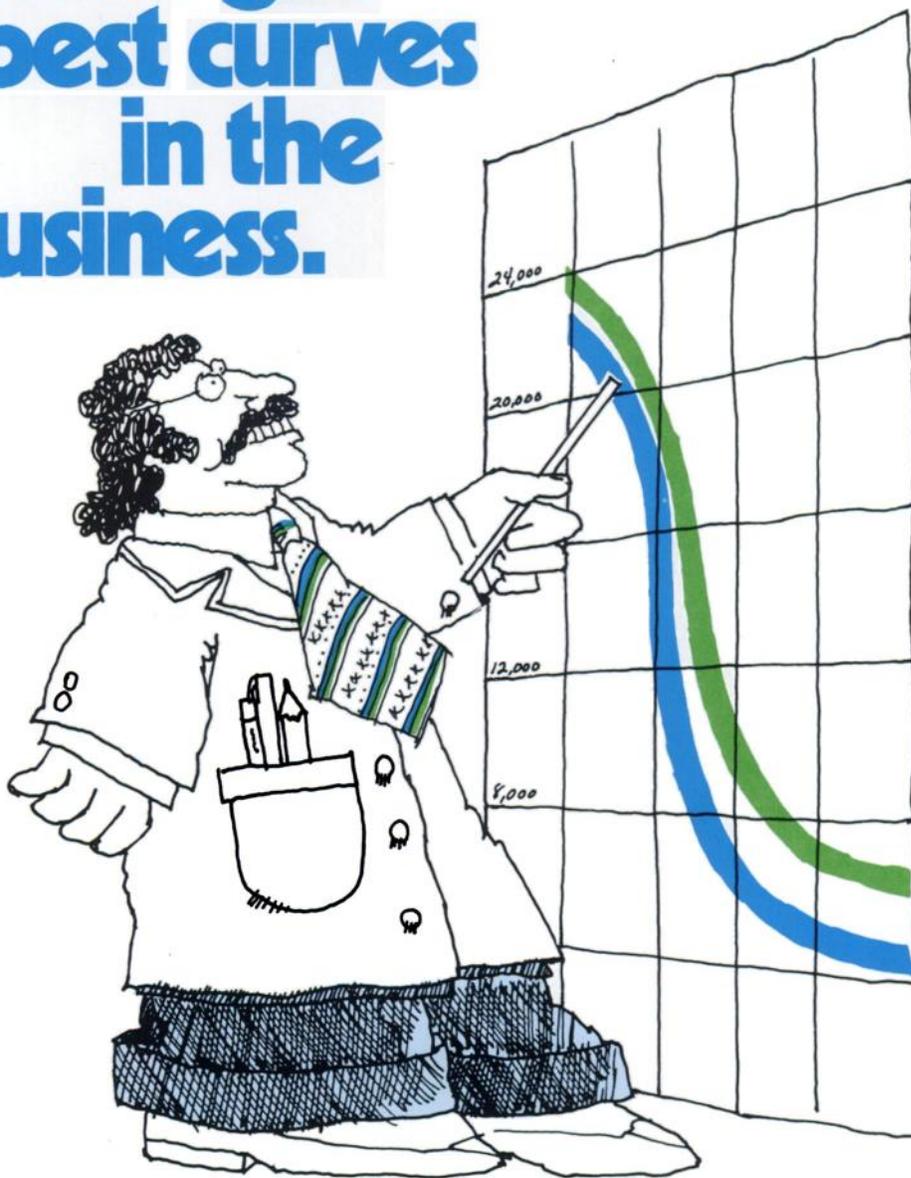
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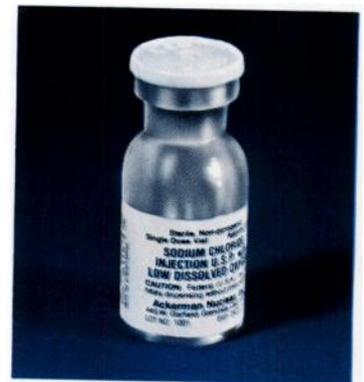


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# Gallium Citrate Ga67

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# Gallium-67 imaging: assessment of therapy

## Bronchogenic Ca

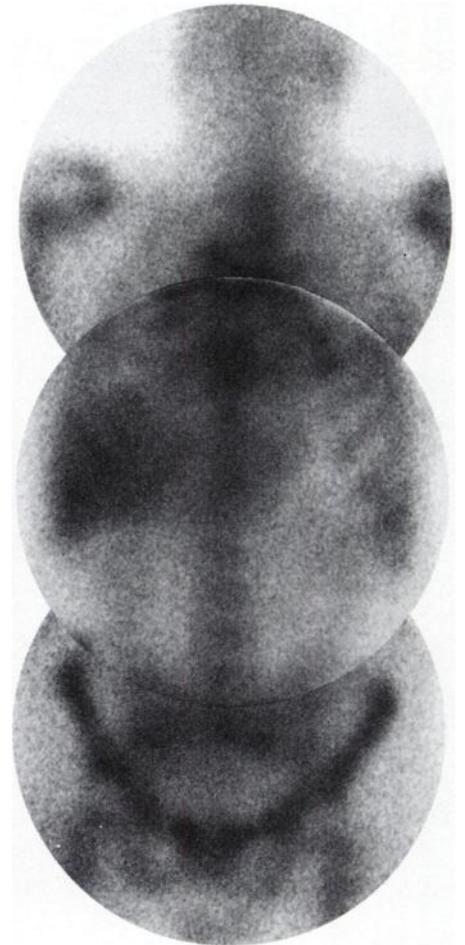
72-year-old male with neck mass; biopsy revealed anaplastic carcinoma from an uncertain primary site. Chest X-ray considered to demonstrate only mediastinal widening and neck mass. Pulmonary tomography, barium studies of bowel and IVP all negative.

*Gallium-67 scan displayed neck tumor and abnormally intense uptake in mediastinum and left lung, confirmed by cytologic studies as primary lesion.*

*Gallium-67 study helped suggest site of primary lesion, aided in disease staging and planning of radiation therapy to limited field.*



## Hodgkin's disease

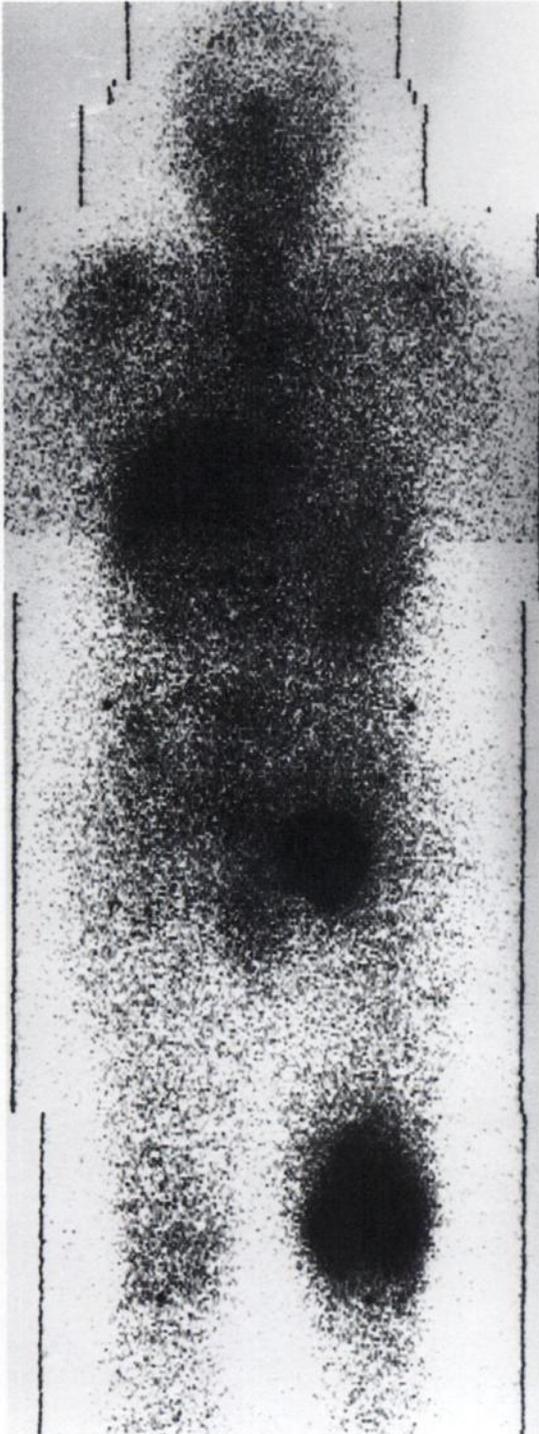


21-year-old male with low-grade FUO of six weeks duration, profuse diaphoresis and general malaise. The only finding upon physical examination was shotty adenopathy of left axilla. Chest X-ray normal.

*Gallium-67 spot images disclosed hilar and carinal uptake, confirmed upon mediastinoscopy as stage 2B Hodgkin's disease.*

# for diagnosis, staging,

## Lymphoma



46-year-old male with known history of lymphoma complained of swelling in groin; lymphangiography demonstrated large foamy nodes, some with partial replacement and some with total replacement.

*Gallium-67 whole-body scan clearly imaged inguinal adenopathy and, in addition, revealed occult abnormality of left distal femur. Subsequent bone films and biopsy confirmed skeletal involvement.*

In hundreds of institutions across the nation, gallium-67 imaging is a valuable adjunct in the diagnosis, staging and assessment of therapy directed against bronchogenic carcinoma, Hodgkin's disease and certain lymphomas.

Gallium-67 imaging can help

- detect primary and metastatic disease, particularly when employed with such traditional nuclear medicine studies as bone, brain and liver scanning
- stage disease, eg, in planning or supplementing laparotomy and lymphangiography; it is particularly valuable for staging disease in patients for whom invasive procedures are contraindicated
- assess efficacy of surgery, radiation therapy or chemotherapy in patients with demonstrated pretherapy gallium-67 uptake

New England Nuclear supplies, upon request, a special nuclear medicine department reference manual on the use of Gallium Citrate Ga 67. It also provides without charge a complete teaching rounds program on the clinical utilization of gallium-67 imaging. The program, which consists of 35mm slides, lecture outlines, home-study monographs and self-examinations, is approved for two hours of elective continuing education credit.



For additional information on gallium-67 imaging, or to schedule the teaching rounds program for your institution, write to the Teaching Program Administrator, New England Nuclear, 549 Albany Street, Boston, Mass. 02118.

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# Gallium Citrate Ga67

## FOR DIAGNOSTIC USE

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

## PHYSICAL CHARACTERISTICS

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

**TABLE 1. Principal Radiation Emission Data**

Radiation	Mean % per Disintegration	Mean Energy (keV)
Gamma-2	37.6	93.3
Gamma-3	20.5	184.6
Gamma-5	16.0	300.2
Gamma-6	4.4	393.5

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

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

\*Calibration Time.

## EXTERNAL RADIATION

The specific gamma ray constant for Gallium Ga 67 is 1.6R/mCi-hr. at 1cm. The first half value thickness of lead is 0.04mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 3. For example, the use of 8mm of Pb will decrease the external radiation exposure by a factor of 61.

**TABLE 3. Radiation Attenuation by Lead Shielding**

Radiation	Radiation
mm of Pb	Attenuation Factor
1	4.2
2	7.0
3	11
4	15

**CLINICAL PHARMACOLOGY:** Carrier-free Gallium Citrate Ga 67 has been found to concentrate in certain viable primary and metastatic tumors. The mechanism of concentration is unknown, but investigational studies have

shown that Gallium Ga 67 accumulates in lysosomes and is bound to a soluble intracellular protein.

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

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

**CONTRAINDICATIONS:** None known.

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

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

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

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

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

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

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

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

Safety and effectiveness in children have not been established.

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

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

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

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

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

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

## RADIATION DOSIMETRY

The dosimetry values listed in Table 4 for Gallium Citrate Ga 67 are those of the MIRDO Committee.\*

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

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

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

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

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

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

Catalog Number NRP-121

October 1977

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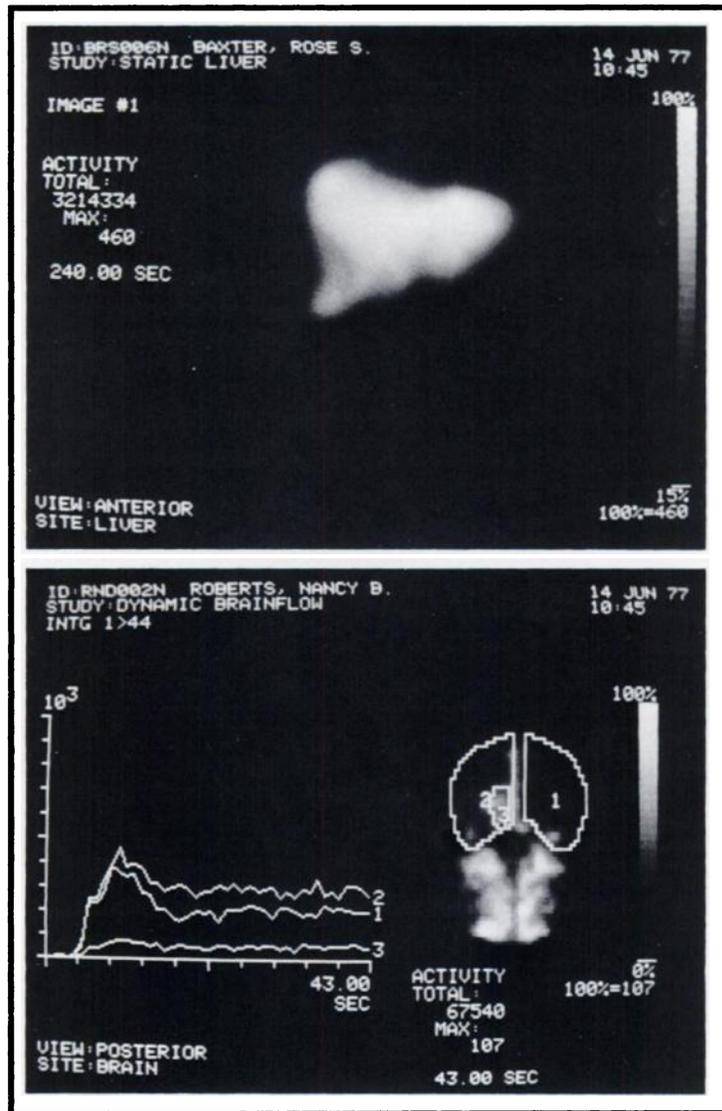
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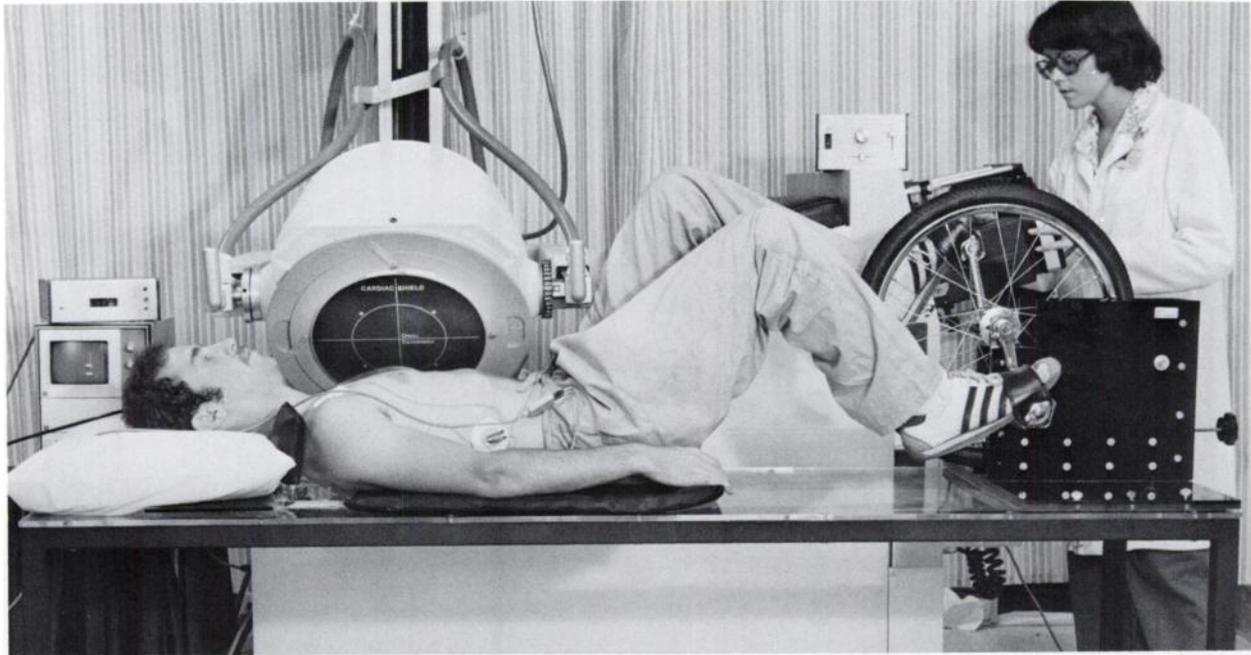
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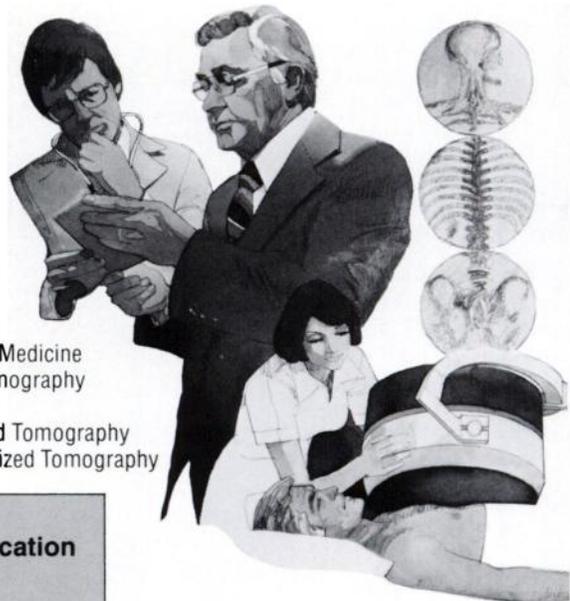
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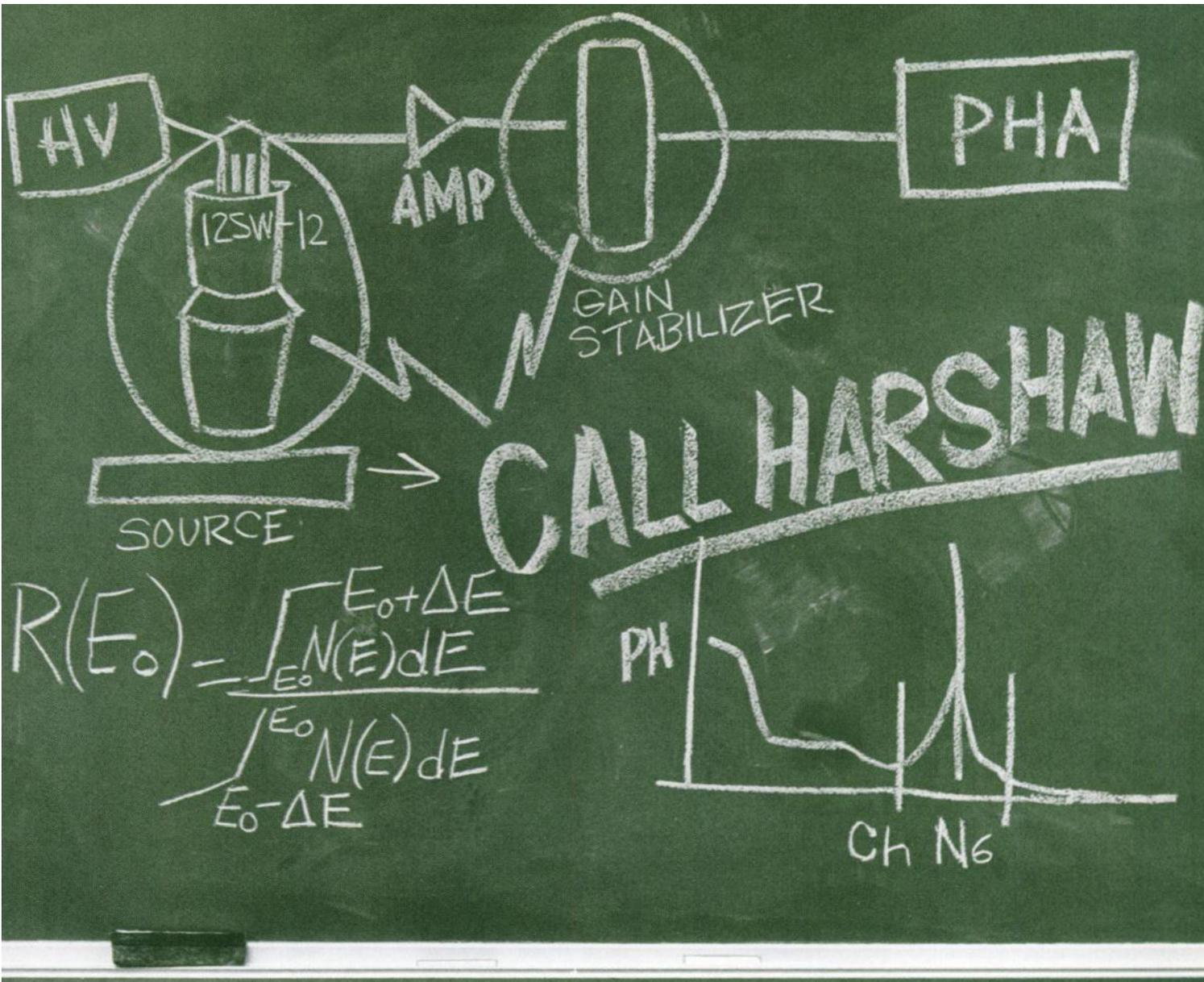
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**NUCLEAR MEDICINE RESIDENT.** Two year Residency Program in Nuclear Medicine at The New York Hospital-Cornell Medical Center. Position available July 1, 1979. Contact Jerome G. Jacobstein, M.D., Division of Nuclear Medicine, The New York Hospital-Cornell Medical Center, 525 East 68th Street, New York, New York 10021.

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**NUCLEAR PHYSICIAN—ABNM CERTIFIED,** with strong academic credentials and substantial clinical experience, seeks new position. Reply: Box 901, Society of Nuclear Medicine, 475 Park Ave. So., New York, N.Y. 10016.

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## **CRC Handbook of Nuclear Medicine**

From the expanding CRC Handbook Series in Clinical Laboratory Science, Section A, material presented in this volume is largely tabular data of properties of radiopharmaceuticals and detectors as well as clinical information of use in the field. Includes necessary text for smooth transition between tables. By Richard P. Spencer, Ph.D., and David Seligson, Sc.D., M.D., 632 pp., 7½ x 10½, 1977, \$61.75, outside U.S. \$71.50, catalog 7071VG.

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The most complete new review on the subject in nearly a decade, *Thyroid Cancer* includes general background of the thyroid gland, embryology physiology, pathology, management, patient care and the latest information on hospital radiation safety. By Larry D. Greenfield, M.D., c. 300 pp., 7 x 10, 1978, \$64.95, outside U.S. \$74.95, catalog 5205VG.

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"... an excellent monograph ... " *Medical Book News* "

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An account of how recent advances in nuclear medicine have improved diagnosis and assessment of diseases affecting the spleen. Appearance and function of both normal and diseased spleens are considered against the background of the scan.

Splenic functions and malfunctions and the problems of hypersplenism are featured. By Richard P. Spencer, M.D., Ph.D., and Howard A. Pearson, M.D., 224 pp., 7 x 10, 1975, \$43.95, outside U.S. \$49.95, catalog 5110VG.

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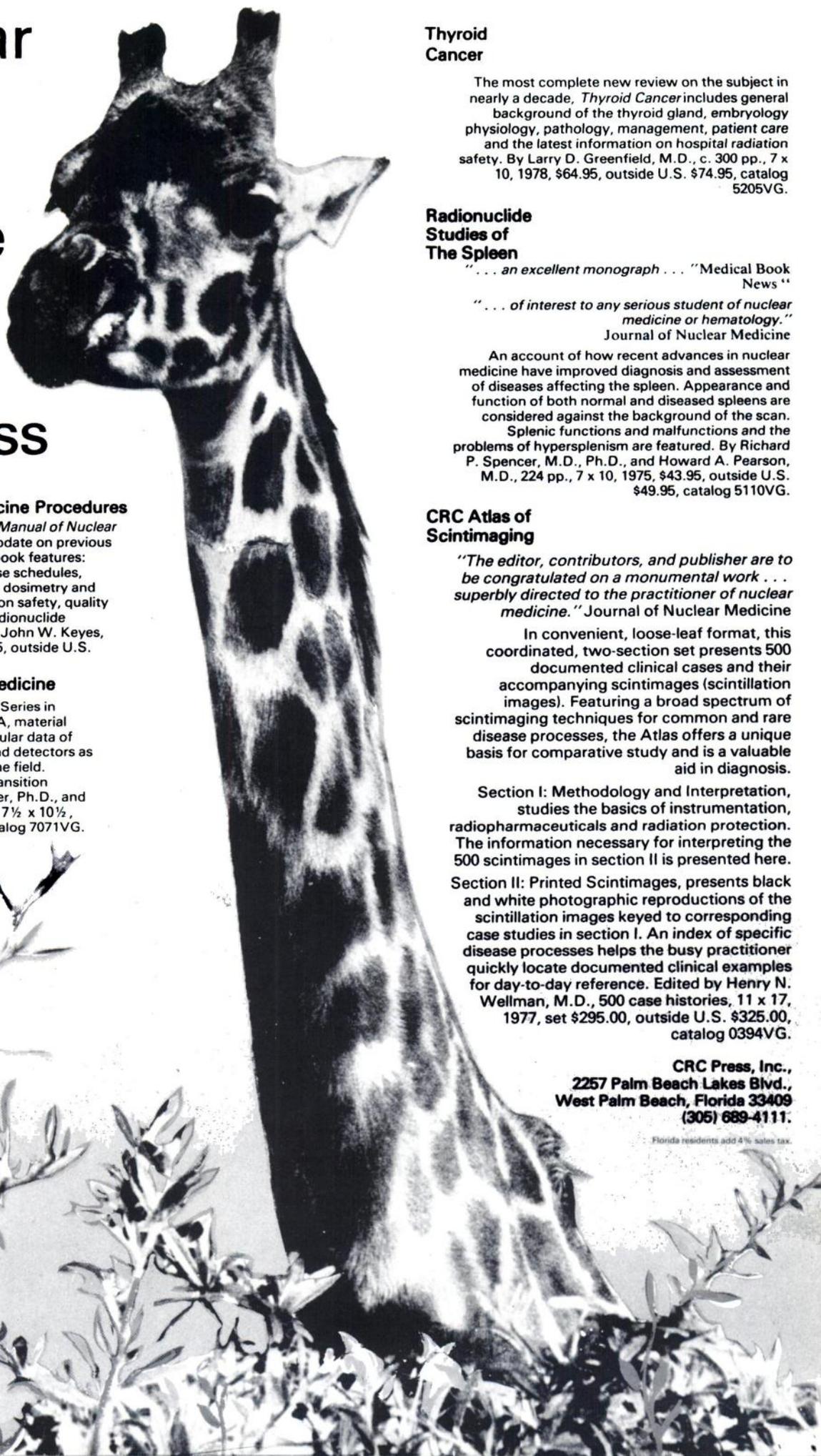
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**CONTRAINDICATIONS:** At present, there are no known contraindications to the use of Selenomethionine Se 75 Injection.

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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 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.

**PRECAUTIONS:** In the use of any radioactive material, care should be taken to insure minimum radiation exposure to the patient and occupational workers consistent with proper patient management.

Fasting prior to administration may enhance the hepatic uptake of the agent which may result in degradation of pancreatic image quality.

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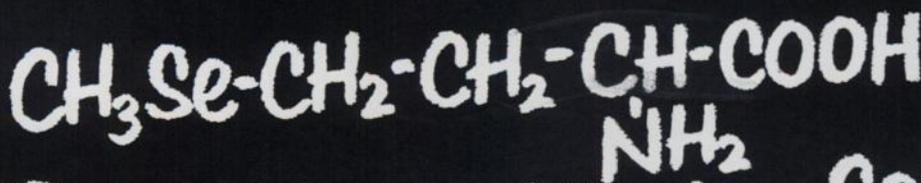
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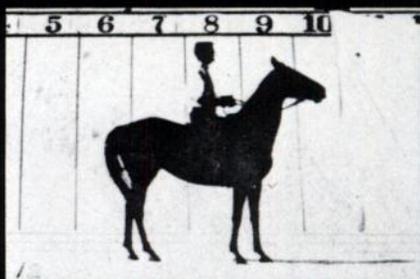
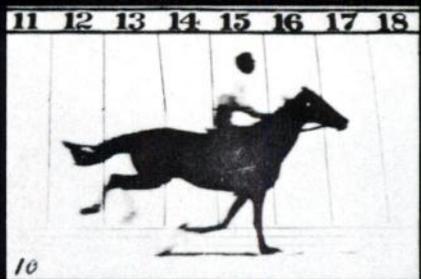
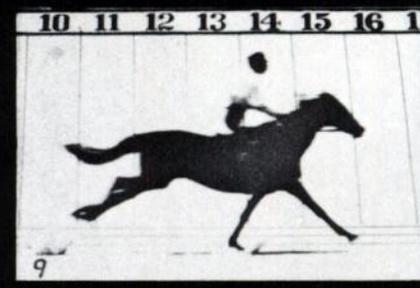
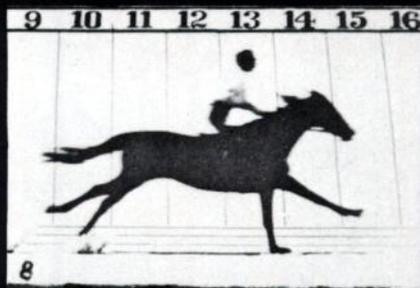
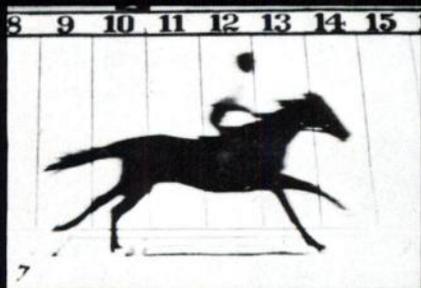
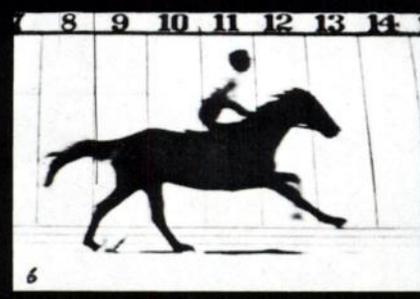
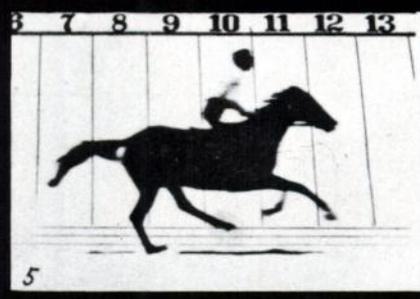
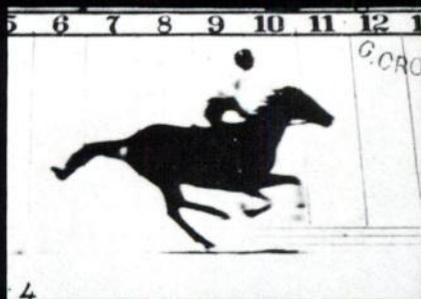
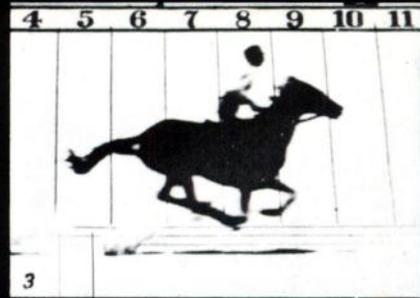
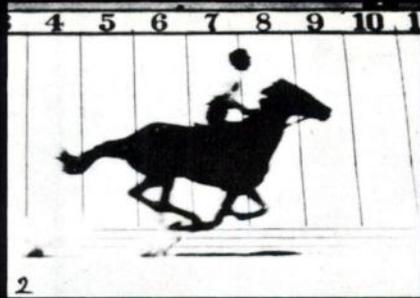
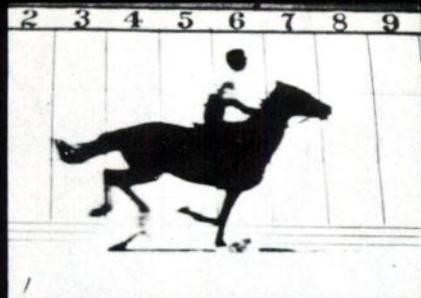
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See opposite page for brief summary.



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Eadweard Muybridge: *Galloping Horse*, 1878.  
International Museum of Photography, Rochester, NY

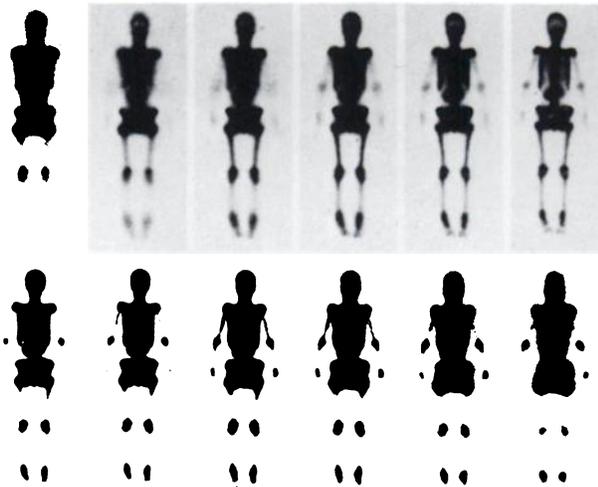
One hundred years ago our concept of how a horse ran was limited to what we thought we saw—the two front legs touching the ground in unison to propel the horse forward, followed by the two hind legs hitting the ground as the front legs recovered. But in 1878, Eadweard Muybridge altered our awareness of reality with 12 great pictures of a galloping horse—stopping the action with a very fast shutter speed. He not only successfully demonstrated that for an instant (panels 2 & 3) all four legs actually lose touch with the ground altogether, but also that horses only place one leg down at a time. Thus, he extended our vision and enabled men to see things that are not normally visible to the human eye.

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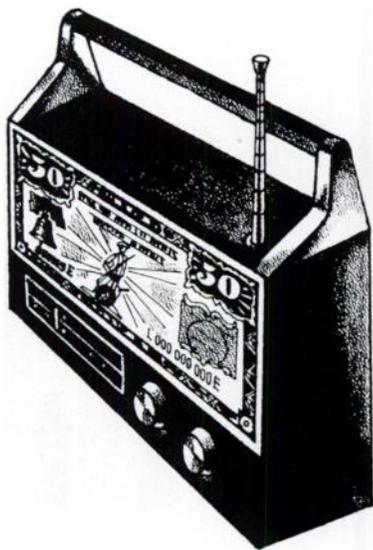
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### Technetium Tc99m Sulfur Colloid Kit-Diagnostic For Intravenous Use

Description: Each kit contains a reaction vial made with sterile, pyrogen-free, freeze-dried materials consisting of 7.0 mg sodium thiosulfate (anhydrous), 2.3 mg cesate diacid and 38.8 mg sodium bisphosphate (anhydrous) and 1.1 mg sodium hydroxide. When sterile pyrogen-free Sodium Pertechnetate Tc99m is combined with these components according to the enclosed procedure, Tc99m labeled sulfur colloid is formed. The product so derived is intended for intravenous injection. The precise structure of Technetium Tc99m Sulfur Colloid is not known at this time.

Physical Characteristics: Technetium Tc99m decays by isomeric transition with a physical half-life of 6.03 hours (1). Photons that are useful for detection and imaging studies are listed in Table I.

Radiation	Mean $\gamma$ Disintegration Gamma-2	Mean Energy (keV)
	9.7	140.5

(1) Evaluated Nuclear Structure Data File (ENSDF), Atomic Industrial Forum Steering Committee on Standards, May 1977.

External Radiation: The specific gamma ray constant for Technetium Tc99m is 0.8 R/mCi-hr at 1 cm. The first half value thickness of lead (Pb) for Technetium Tc99m is 0.2 mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interpretation of various photoabsorption data (Pb) is shown in Table II. For example, the use of 2.7 mm of Pb will decrease the external radiation exposure by a factor of 1.000.

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.

Hours	Fraction Remaining	Hours	Fraction Remaining
0	1.000	7	44.7
1	891	8	399
2	795	9	355
3	708	10	317
4	631	11	282
5	563	12	252
6	502		

#### Calibration Time

Clinical Pharmacology: Following intravenous administration, Technetium Tc99m Sulfur Colloid is rapidly cleared by the reticuloendothelial system from the blood with a nominal clearance half-life of approximately 2 1/2 minutes. Uptake of the radioactive colloid by organs of the reticuloendothelial system is dependent upon both their relative blood flow rates and the functional capacity of the phagocytic cells. In the average patient 80 to 90% of the injected colloidal particles are phagocytized by the Kupfer cells of the liver, 5 to 10% by the spleen and the balance by the bone marrow.

Indications and Usage: Technetium Tc99m Sulfur Colloid is used as an agent for imaging areas of functioning reticuloendothelial cells in the liver, spleen, and bone marrow.

Contraindications: None known.

Warnings: The contents of the two unit-dose syringes, one syringe containing the appropriate acidic solution and one syringe containing the appropriate buffer solution, are intended only for use in the preparation of the Tc99m sulfur colloid injection and are not to be directly administered to the patient.

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

Radionuclides 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.

Pregnant or nursing women should not be administered to the patients who are pregnant or nursing unless the benefits to be gained outweigh the potential hazards. Ideally, examination using radionuclides, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Precautions: The components of the kit are sterile and non-pyrogenic. It is essential that the user follow the directions carefully and adhere to the strict aseptic procedures during the preparation of the colloid.

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

It is recommended that sodium pertechnetate Tc99m solutions containing more than 10 micrograms/ml of aluminum not be used for formation of the Technetium Tc99m Sulfur Colloid Injection. The sodium pertechnetate Tc99m solution must also be free of any traces of oxidizing agents such as peroxides and hypochlorites.

Technetium Tc99m Sulfur Colloid is physically unstable and as such the particles will settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactivity.

It is also recommended that because of the increasing probability of agglomeration with aging, a batch of Technetium Tc99m Sulfur Colloid not be used after six hours from the time of formulation.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc99m Sulfur Colloid should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

Technetium Tc99m Sulfur Colloid, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients consistent with proper patient management.

Adverse Reaction: Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulfur colloid preparation. One death and several cases of lung and soft tissue uptake other than RES have been reported in association with the use of technetium Tc99m sulfur colloid.

Dosage and Administration: The suggested intravenous dose range used in the average patient (70 kg) is 1 to 8 millicuries of Technetium Tc99m Sulfur Colloid Injection.

When orally administered, the Technetium Tc99m Sulfur Colloid is not absorbed from the G.I. tract.

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

Radionuclides 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.

Radiation Dosimetry: The estimated absorbed radiation doses (1) to an average patient (70 kg) or to patients with diffuse parenchymal liver disease from an intravenous injection of a maximum dose of eight millicuries of Technetium Tc99m Sulfur Colloid Injection are shown in Table IV. For comparison, the estimated radiation doses from a maximum dose of 300 microcuries of colloidal Au-198 used as a liver imaging agent are also included.

Tissue	Absorbed Radiation Doses (Rads)			
	Normal Liver (mCi Tc99m)	(300 $\mu$ Ci Au-198)	early intermediate	intermediate advanced
Liver	2.7	12.0	1.7	7.2
Spleen	1.7	3.6	1.0	3.4
Bone Marrow	0.22	0.81	0.36	1.4
Testes	0.0088	0.011	0.017	0.063
Ovaries	0.045	0.045	0.045	0.096
Whole body	0.15	0.42	0.15	0.42

(2) Modified from: Summary of Current Radiation Dose Estimates to Humans with Various Liver Conditions from Au-198 Colloidal Gold. MIRD Dose Estimate Report No. 4. J. Nucl. Med., 16, No. 2, 173-4 (1975).

Preparation: The following directions must be carefully followed for optimum preparation of Technetium Tc99m Sulfur Colloid Injection. Gloves should be worn during the entire preparation. Proper radiation safety precautions should be maintained at all times.

- Remove central disc of aluminum crimp cap from sterile freeze-dried reaction vial.
- Place the reaction vial into a lead wall shield refer to the physical characteristics section of the insert to determine appropriate shielding. 1.8 to 1.4 of lead shielding is adequate for all levels of activity normally used with this kit and swab rubber stopper with an antiseptic.
- Using a shielded syringe, aseptically inject 1.3 milliliters containing the necessary Technetium Tc99m activity of sterile sodium pertechnetate Tc99m solution into the reaction vial. Do not use sodium pertechnetate Tc99m solution if it contains foreign matter or more than 10 micrograms of aluminum (sodium pertechnetate Tc99m solutions containing more than a total of 10 micrograms of aluminum may produce a flocculent precipitate since such a precipitate may localize in the lung). Preparations containing precipitates should not be used. Avoid using sodium pertechnetate Tc99m solution that contains preservatives, peroxide or other oxidizing agents. Dilutions of high concentration technetium Tc99m peroxide or other oxidizing agents. Dilutions of high concentration technetium Tc99m peroxide should be done with sterile pyrogen-free saline for injection that contains no preservative.
- Place a lead cover on the vial shield and dissolve the reagent by gently swirling.
- Attach a sterile needle to an "A" syringe and inject its entire contents into the reaction vial and swirl again.
- Transfer the reaction vial from vial shield and place in a vigorous boiling water bath. Water bath should be shielded with 1.8 to 1.4 lead deep enough to cover the entire vial. Bath contents of the vial keep the vial in the water bath for at least three minutes (may be kept up to 10 minutes).
- Remove the reaction vial from the water bath and place into lead shield and allow to cool for three minutes. Swab the rubber stopper with an antiseptic.
- Attach a sterile needle to the "B" syringe and aseptically inject the entire contents into the reaction vial.
- Insert necessary information on accompanying radioactive self-adhesive shield label and on the tag of the reaction vial.
- Allow to cool to room temperature before use. Maintain adequate shielding of the radioactive colloid preparation at all times.
- Use within 6 hours after preparation.
- Radioactive vials should be stored with security provisions to prevent its removal by unauthorized persons.

How Supplied: Each 6 pack contains 6 complete kits, plus instructions. Each kit is separately packaged and contains one reaction vial, two syringes, two needles, and preparation labels.

Storage: Store kit contents at room temperature, 18 to 25 C.

Disposal: The residual materials may be discarded in ordinary trash provided the vial and syringes meet background radiation levels. The ampoules, meter, and syringes meet background radiation levels. The ampoules, meter, and syringes meet background radiation levels. The ampoules, meter, and syringes meet background radiation levels.

Application has been filed with the U.S. Nuclear Regulatory Commission for a statement of the radiopharmaceutical to persons in receipt pursuant to Section 35.142 of Subchapter G, Chapter 10 of CFR Part 35, under export licenses of agreement states, and is pending.

# NEW

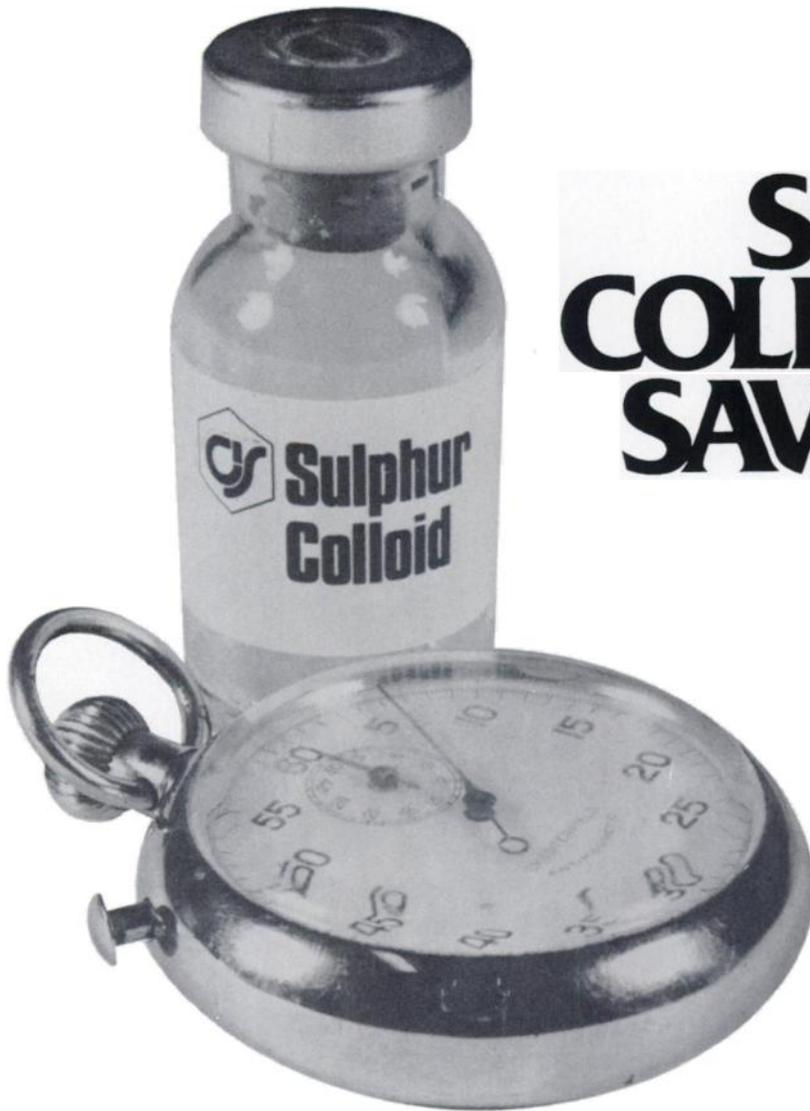
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Easily detects Xenon-133 levels as low as 20% of the maximum 40-hour airborne concentration ( $10\mu\text{Ci}/\text{m}^3$ ) specified by the U.S. Nuclear Regulatory Commission (10CFR 20.103).

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# Are you breathing Radioactive Xenon?

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# Inside information

by transverse emission tomography  
in brain and body

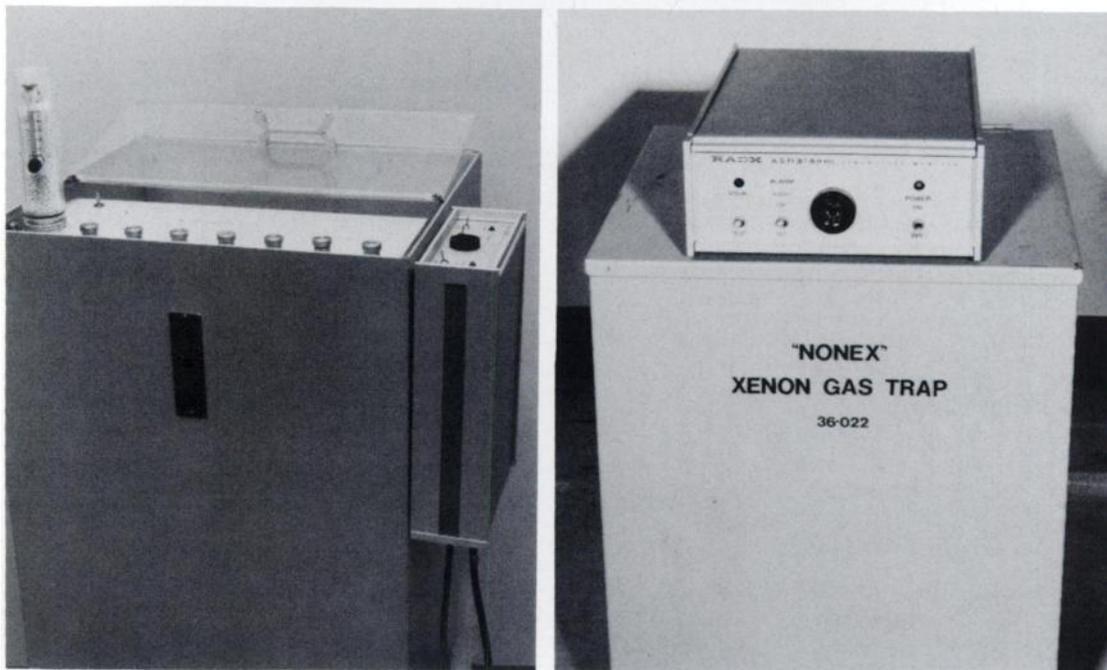
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## The New Xenalarm will monitor it

All activated charcoal packs will eventually fail. The name xenon trap is actually a misnomer, xenon delay system is much more descriptive. When it will fail depends on many variables.<sup>(1)</sup> When it fails, you need to know.

That is what the Xenalarm was designed to do. It will give you an audio/visual alarm when the concen-

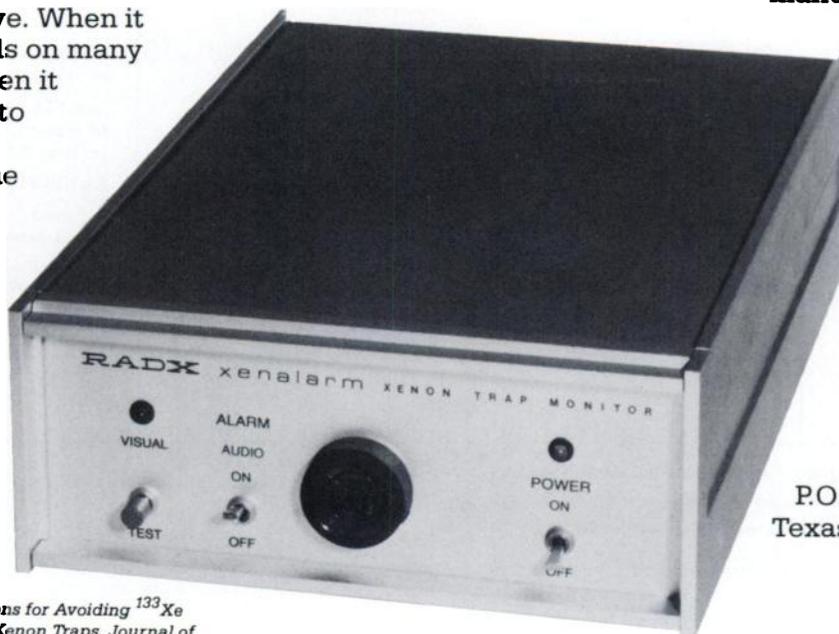
tration of Xenon-133 in the exhaust port exceeds  $1 \times 10^{-2}$  uCi/ml. It can be added to any manufacturer's xenon trap.

IT SHOULD BE ADDED TO ALL MANUFACTURERS' XENON TRAPS (Except the Radx Model 120 Xenon Trap, which has the alarm already built-in.)

For a demonstration, please call or write

**RADX**

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<sup>(1)</sup> Timpe, G.M. Precautions for Avoiding <sup>133</sup>Xe Release From Charcoal Xenon Traps. Journal of Nuclear Medicine Technology Volume 4, Number 4, Pages 208-209.

# FINALLY ...

## A chair for your Gamma Camera!

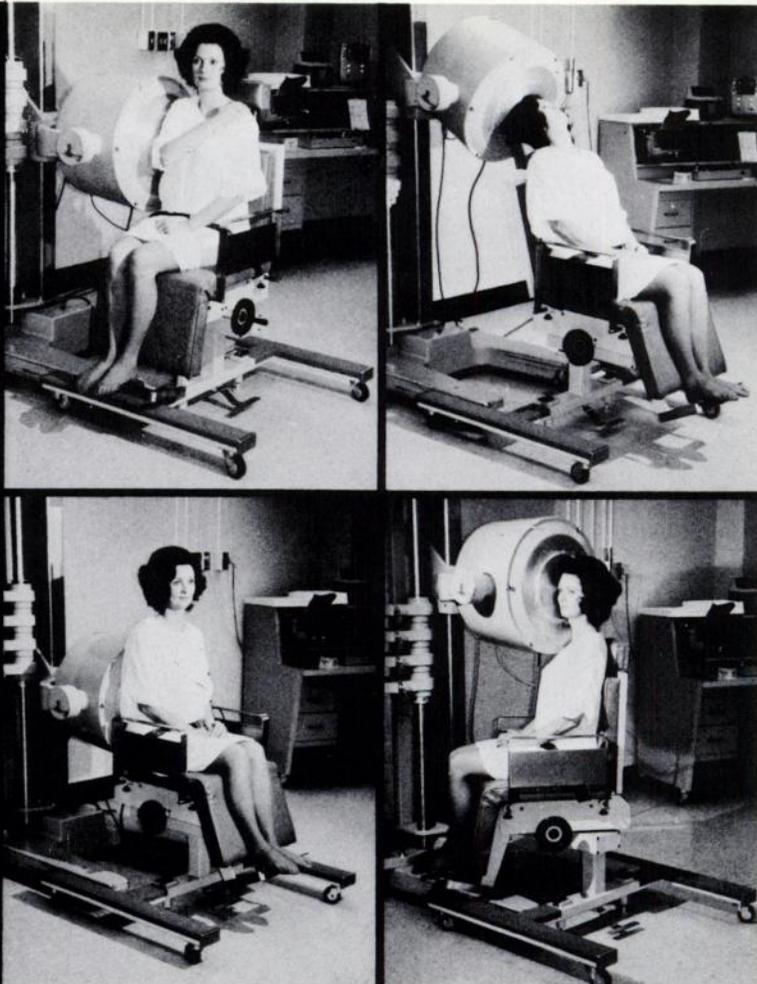
Now rapid, convenient positioning can be done on ambulatory patients for brain, lung or liver scans.

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### PRELIMINARY PROGRAM

#### SECOND INTERNATIONAL SYMPOSIUM ON RADIOPHARMACEUTICALS

Sponsored by the Radiopharmaceutical Science Council of the Society of Nuclear Medicine  
to be held March 19-23, 1979 at the Olympic Hotel.  
Seattle, Washington

#### Monday - March 19

##### KEYNOTE SPEAKER:

Gov. Dixie Lee Ray

##### PANEL ON REGULATORY AFFAIRS:

Leaders from Gov't., Industry & Users

##### RADIONUCLIDE PRODUCTION

P. Silvester (U. K.)

##### QUALITY CONTROL:

K. Kristiansen (Denmark)

#### Tuesday - March 20

##### FUNCTIONAL IMAGING:

H. Atkins  
(Brookhaven Nat'l Lab.)

##### INORGANIC RADIOPHARMACEUTICALS

E. Deutsch  
(Univ. of Cincinnati)

##### ORGANIC RADIOPHARMACEUTICALS

A. Wolf  
(Brookhaven Nat'l Lab.)

##### IMMUNOLOGY

R. Elkins (U. K.)

##### ONCOLOGY/HEMATOLOGY:

J. Adelstein  
(Peter Bent Brigham Hospital)  
G. Ege  
(Canada)

#### Wednesday - March 21

##### RES/BILIARY:

M. Loberg  
(Univ. of Maryland)

##### RENAL:

S. Winchell  
(Medi+Physics)

##### CENTRAL NERVOUS SYSTEM:

M. J. Welch  
Mallinckrodt Inst. of Rad.

SALMON BARBEQUE

#### Thursday - March 22

##### PANCREAS, PROSTATE AND ADRENALS:

M. Blau (SUNY, Buffalo)

##### THYROID:

H. Nishiyama (FDA)

##### SKELETAL:

M. Francis  
(Procter & Gamble Co.)

##### CARDIOPULMONARY

J. Pohost  
(Mass. Gen. Hosp.)

G. Hamilton  
(Univ. of Wash.)

**NOTE:** Registration will be open beginning at 3:30 pm on Sunday.  
Scientific & Commercial Exhibits will be open Monday thru Thursday.  
Scientific Tours will be available on Friday.

Abstract forms, registration, programs and hotel information available from:  
Conference Department, Society of Nuclear Medicine, 475 Park Avenue South, New York, New York 10016.

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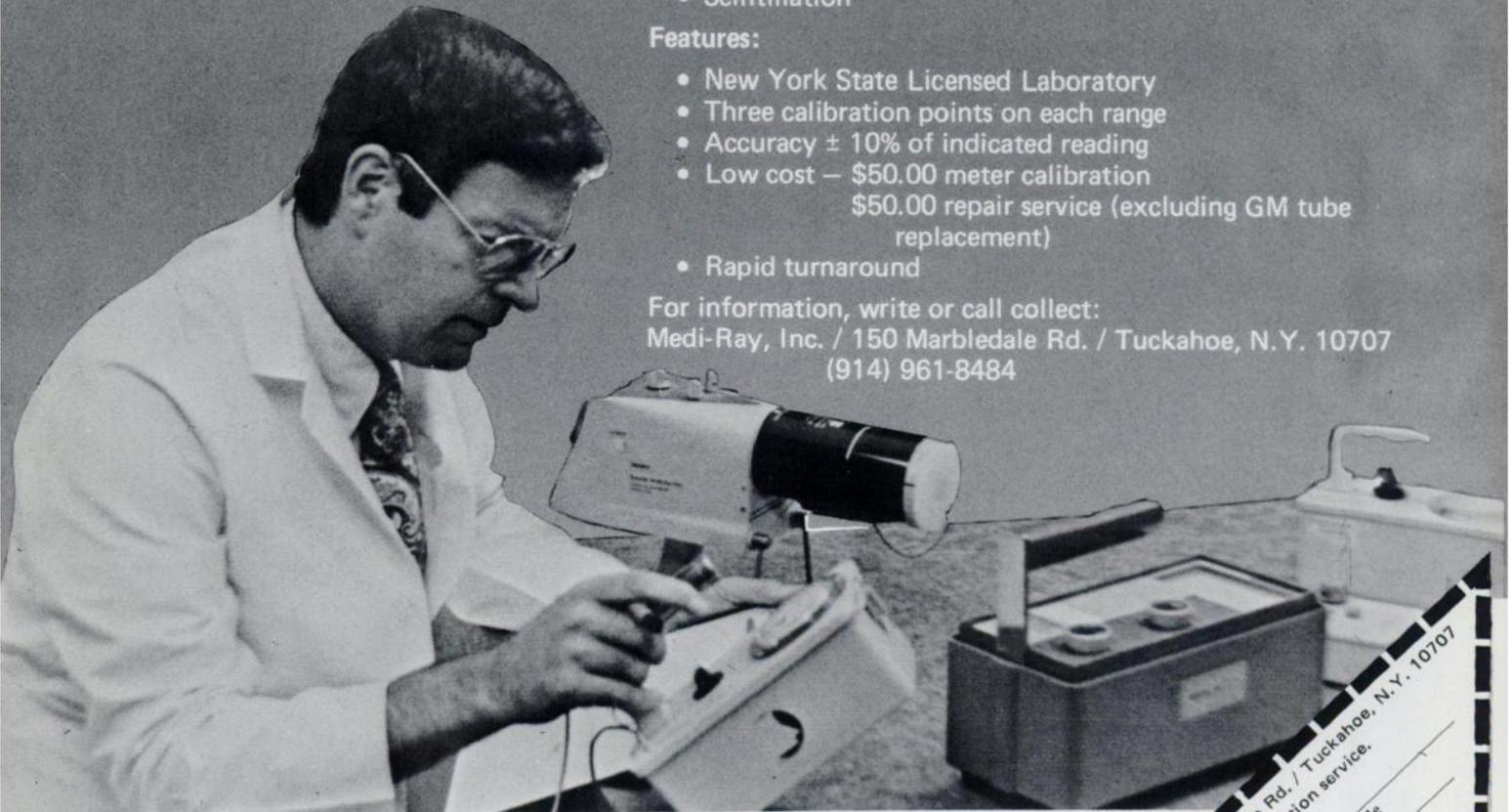
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State	_____
City	_____
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Phone	_____
Title	_____
Dept.	_____

# Talk is cheap.

## Here's how to give your community a better business environment.

As a businessperson, you know it's more effective to anticipate a problem than to react to one. What you may not know is that child abuse, child neglect and poor parenting patterns lead to juvenile and adult crime, legal system overloads, lost productivity and increased taxation. Local services to prevent child abuse are understaffed and overworked. Some of the actions you can take to eliminate these problems are listed below. Commit yourself and your company to one or more. Help stop the hurt.

### It shouldn't hurt to be a child. We want to stop the hurt.

- |   |   |
|---|---|
| <input type="checkbox"/> We are enclosing a tax-deductible donation in the name of our company.   | <input type="checkbox"/> I don't spend enough time with my children. Tonight I am going home early to find out who my children are.   |
| <input type="checkbox"/> We want to help. Please call our company and tell us what you're doing to stop the hurt of child abuse in our community.   | <input type="checkbox"/> We want to start helping right now. Enclosed is a check for \$_____. Please give our company _____ memberships in the National Committee for Prevention of Child Abuse, at \$10 each. Attached is a list of names and addresses. |
| <input type="checkbox"/> We want to make our employees more aware. We will carry an article about child abuse in our company publication. We will carry your public service announcements in our company publication. | Name _____  |
| <input type="checkbox"/> We want our employees to know more about the problem. Please send us _____ copies of the pamphlet "Prevent Child Abuse" at 10¢ a copy for 100 copies or more.                                | Title _____   |
| <input type="checkbox"/> We will provide active support to local organizations which can help prevent child abuse. For openers, we will find out the names of these organizations.                                    | Company _____   |
| <input type="checkbox"/> We will plan a day for employees' children to visit our place of work to learn what we do and why.   | Address _____   |
| <input type="checkbox"/> We will volunteer our employees' time and talent to community child abuse prevention programs.   | City _____ State _____ Zip _____  |
|   | Telephone ( _____ ) _____   |

 **prevent child abuse.**  
write: Box 2866, Chi., IL 60690  
National Committee for Prevention of Child Abuse

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& The Advertising Council

# THIS BOOK TELLS A LOT ABOUT US ...WITHOUT ONCE MENTIONING OUR NAME OR OUR PRODUCTS

The name of this volume is *Certificate of Need: An Expanding Regulatory Concept*. Not once in its 944 pages does the name Pfizer appear.

Yet, despite this, we are proud to offer this book to several hundred people in the health care field, with our compliments, as part of an important, new Pfizer program called the Certificate of Need Assistance Program.

## **A Total C.O.N. Assistance Program**

Pfizer's C.O.N. Assistance Program is designed to aid you in the increasingly regulated climate in which medicine now operates. As one of the health care industry's leaders for 129 years, Pfizer feels a responsibility not only to provide quality products but also to join the medical community in its current search for effective ways to comply with these regulations. Typical of these requirements is the Certificate of Need, or C.O.N., which is required in most cases where federal funding is involved in paying for major equipment or plant expansion.

## **Toll-free C.O.N. Assistance Service**

Applying for the C.O.N. can be a complicated process—sometimes confusing,

always time-consuming. The Pfizer C.O.N. Assistance Program can help. The two main components of this program are the book, *Certificate of Need: An Expanding Regulatory Concept*, and the toll-free C.O.N. Telephone Service to answer questions about the cost effectiveness of diagnostic equipment, as well as how this information relates to C.O.N. requirements.

To use our C.O.N. Telephone Service just phone 800-221-4688, from 9 a.m.-5 p.m. Monday through Friday. (In New York State, please call 212-573-2030, collect.)

## **Complimentary Books to Administrators and Radiologists**

Many hospital administrators have already received copies of the book. We have also offered it to chief radiologists throughout the country and to certain other medical and administrative personnel who are involved in the purchase of diagnostic equipment.

(Incidentally, if you have not personally received *Certificate of Need: An Expanding Regulatory Concept*, and you take part in major purchasing as a hospital executive or radiologist, you are welcome to a complimentary copy. To receive it, just send us your request on your official letterhead.)

The book, as its title suggests, is a comprehensive, state-by-state compilation of current C.O.N. requirements. We feel that it makes a substantial contribution to understanding this very complex subject. And it is a subject in which we feel a special responsibility, since CT Scanners usually require this document.

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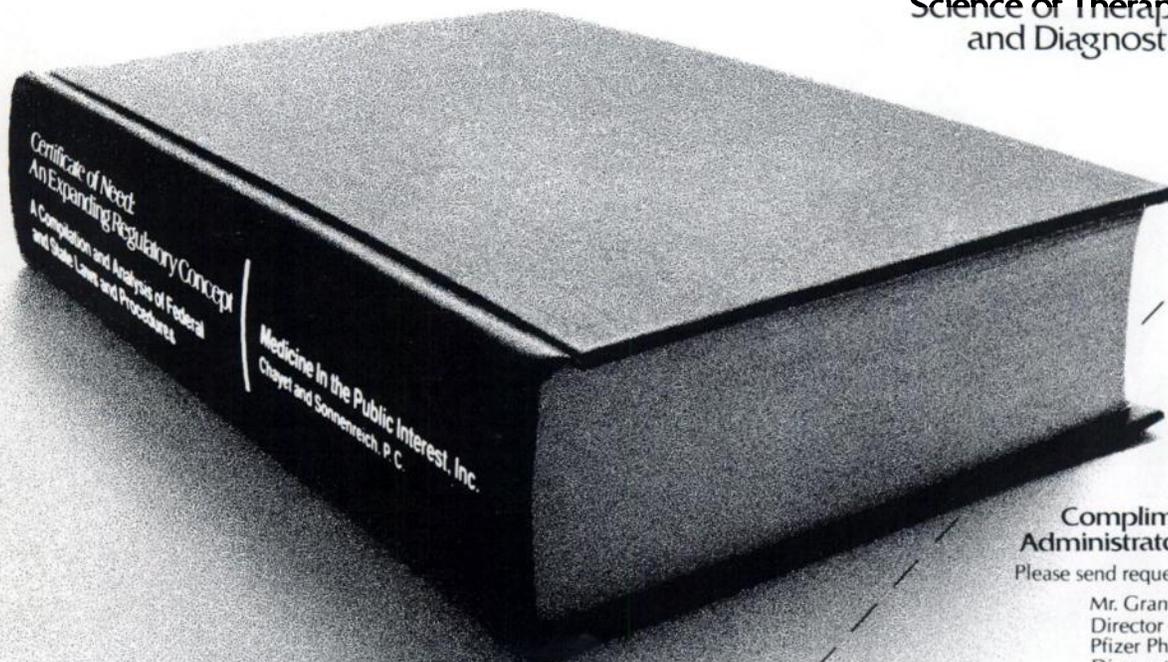
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Cool rapidly in ice water or refrigerator while observing proper radiation safety measures. Refer to package insert for full preparation instructions.

# New! TSC preparation now takes less time.

The CINTICHEM® TSC reagent kit for imaging of functioning reticuloendothelial cells in the liver, spleen and bone marrow requires less of your time to prepare than any other sulfur colloid kit available.

- Needs boiling only once for 5 minutes. Other kits can demand 2 boilings plus cooling period.
- Buffer is injected into the reaction vial immediately after removal from the boiling water bath.
- Dose vial is then rapidly cooled in an ice-water bath or similar cold environment.

## Take advantage of our other CINTICHEM products for nuclear medicine:

- Technetium 99m HEDSPA (Etidronate Disodium<sup>1</sup> Tin Kit for use in preparation of Technetium Tc 99m Etidronate Tin Complex)
  - Technetium 99m DTPA (DTPA Tin Kit for use in preparation of Technetium Tc 99m DTPA Tin Chelate)
  - Technetium 99m MAA (Technetium Tc 99m Aggregated Albumin)
  - Technetium 99m HSA (Technetium Tc 99m Human Serum Albumin)
- All of the above are available in multidose and unit dose kits.
- Technetium Tc 99m Generator for the production of Sodium Pertechnetate Tc 99m, available in 500, 1000, 1500, or 2000 millicuries.

For ordering or additional information  
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### Indications and usage

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

### Contraindications

None known.

### Warnings

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

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

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

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

### Precautions

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

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

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

Technetium Tc 99m Sulfur Colloid Injection is physically unstable and as such the particles will settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactivity. It is also recommended that because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m Sulfur Colloid Injection not be used after six hours from the time of formulation.

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Sulfur Colloid Injection should be used in pregnant women only when clearly needed. It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established.

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

### Adverse reactions

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

### Dosage and administration

The suggested intravenous dose range used in the average patient (70 kg) is 1 to 8 millicuries of Technetium Tc 99m Sulfur Colloid Injection.

When orally administered, the Technetium Tc 99m Sulfur Colloid Injection is not absorbed from the G.I. tract.

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 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.

### How supplied

- kit contents
- 5 STERILE REACTION VIALS, each containing 0.5 ml 1.0 N hydrochloric acid in water.
  - 5 STERILE SYRINGES, (labeled "A"), each containing 1.7 mg anhydrous sodium thiosulfate in 1 ml aqueous solution.
  - 5 STERILE SYRINGES, (labeled "B"), each containing 12 mg povidone in 2 ml aqueous buffer solution containing 43 mg of dibasic sodium phosphate anhydrous, 2.6 mg of monobasic sodium phosphate monohydrate, and 16 mg of sodium hydroxide.
  - 5 RADIOACTIVE SYMBOL LABELS
  - 10 PRESSURE-SENSITIVE LABELS for final Technetium Tc 99m Sulfur Colloid Injection preparation.
  - 1 PACKAGE INSERT.

Store kit contents at room temperature (18-25° C) preparation

The following directions must be carefully followed for optimum preparation of the Technetium Tc 99m Sulfur Colloid Injection.

1. Affix radioactive symbol label to reaction vial.
2. Aseptically inject 0.1-5.0 ml of sterile Sodium Pertechnetate Tc 99m, up to 75 millicuries which must contain less than 10 micrograms of aluminum, into the reaction vial. Relieve the excess pressure in the vial by withdrawing an equal volume of air. Mix the solution.
3. Assemble the thiosulfate syringe (labeled "A") and inject the total contents into the reaction vial with gentle agitation. Relieve the excess pressure by withdrawing an equal volume of air and remove the needle.
4. Immediately immerse the reaction vial in a vigorously boiling water bath, deep enough to cover the entire liquid contents of the vial. Keep the vial in the water bath for 5 minutes plus or minus 30 seconds.
5. During heating step, assemble buffer syringe cartridge (labeled "B").
6. Remove vial from water bath, place in lead shield, and vent using 20 gauge, disposable needle.
7. Immediately inject contents of syringe B into reaction vial.
8. Remove vent and shake gently for a few seconds.
9. Rapidly cool to room temperature (note: rapid cooling in an ice bath is preferable) before use and then affix the descriptive label to the dose vial shield. Maintain adequate shielding of the radioactive colloid preparation. Do not use the preparation after six hours from the time of formulation.



<sup>1</sup>USAN designation for 1-hydroxy-ethylidene-1,1-disodium phosphonate HEDSPA.

**UNION CARBIDE** CintiChem®

Technetium 99m

**TSC** Sulfur Colloid Kit for Use in Preparation of Technetium Tc 99m Sulfur Colloid Injection

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**STEP 1**  
Pipette  
standards  
patient sample or  
control



**STEP 2**  
Add  
<sup>125</sup>I Methotrexate  
derivative



**STEP 3**  
Add  
Methotrexate  
antiserum



INCUBATE ALL TUBES  
FOR 45 MINUTES

**STEP 4**  
Add  
precipitant



**STEP 5**  
Spin,  
decant and  
count precipitate



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- <sup>125</sup>I Folate
- <sup>57</sup>Co Vitamin B<sub>12</sub>
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- <sup>125</sup>I TSH-RIA
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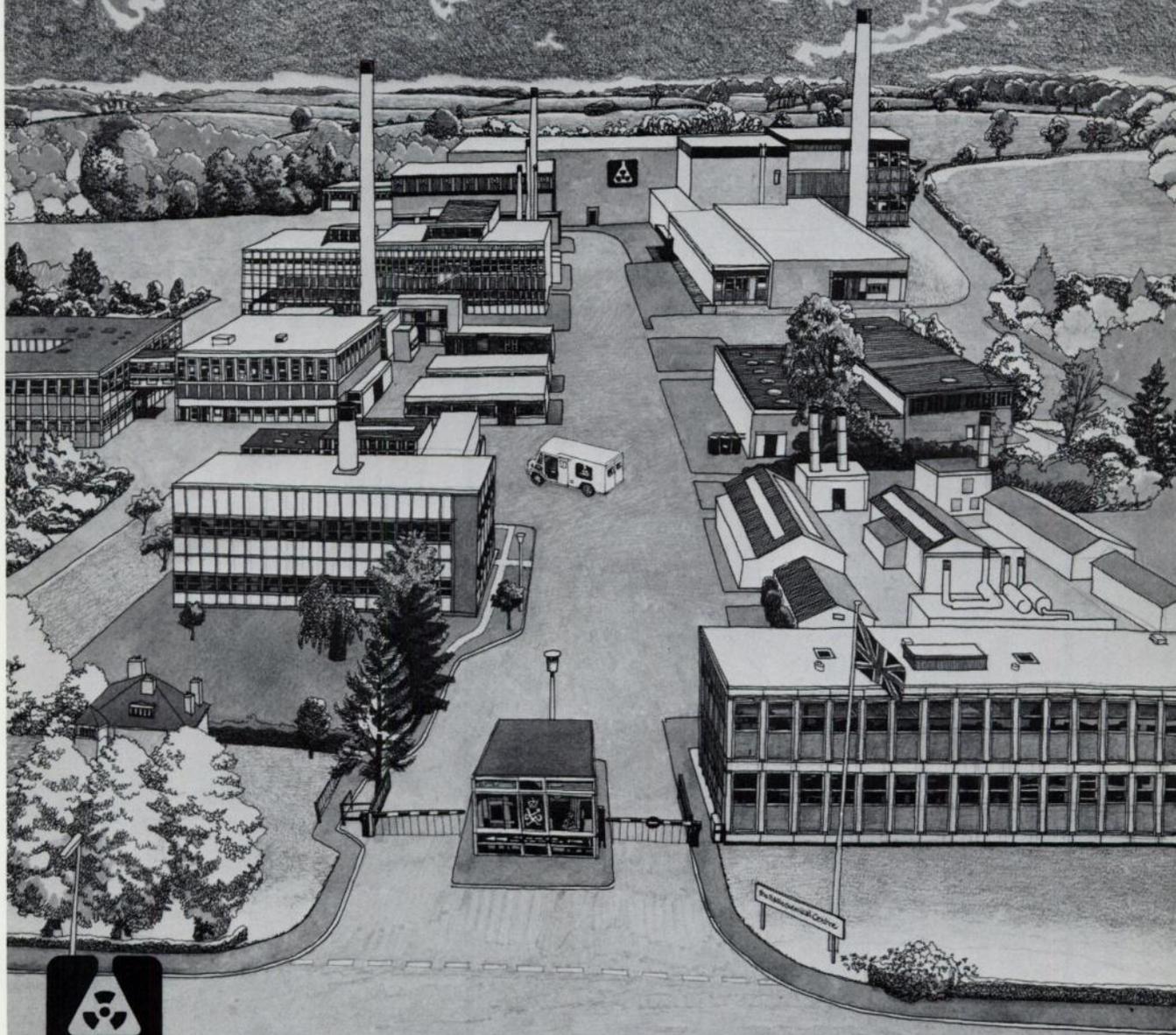
By setting ourselves a high standard of Production and Quality Control we can assure you of the reliability of our products. Their performance is validated by extensive clinical trial

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man's perception of reality  
is expanded.**

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