When nuclear medicine discusses gallium imaging, one name will keep coming up...

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).

With deliveries to meet your needs.

Contact the facility nearest you to arrange a standing order:

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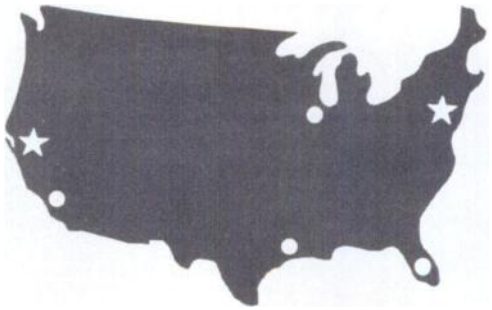

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Toll Free (Outside N.J.) (800) 631-5367
Miami (305) 557-0400

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 ± 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.

When you think of gallium imaging, think of Neoscan™ from

Your Scintigraphy Kit

Your kit starts with any of our three simple one-step preparations which combined with our new Sterile Technetium-99m Generator offers a complete package for liver, lung, bone and brain scintigraphy. Later we will be adding more kits to our range.

All our kits are tested extensively in clinical trials which include the use of other technetium-99m generators as well as our own. All are terminally sterilized and every batch is animal tested.

Agent for Bone Scintigraphy

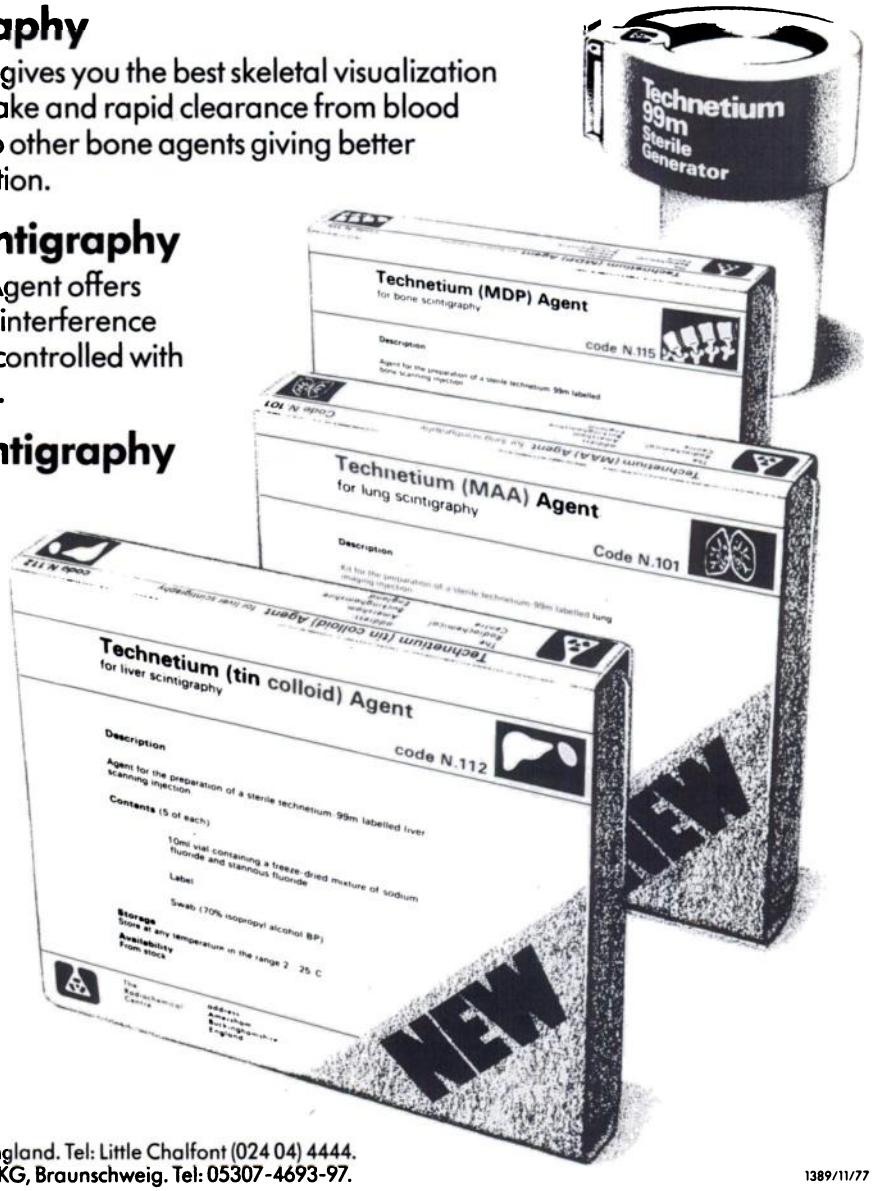
Our Technetium (MDP) Agent gives you the best skeletal visualization available today. The high bone uptake and rapid clearance from blood and soft tissue makes this superior to other bone agents giving better definition and improved discrimination.

New Agent for Lung Scintigraphy

Our new Technetium (MAA) Agent offers detailed lung visualization, with no interference from the liver. Particle size is strictly controlled with the majority in the range of 10–80μ.

New Agent for Liver Scintigraphy

The latest addition to our range is the unique Technetium (tin colloid) Agent. Its preparation is much simpler than sulphur colloid agents and requires no heating stage. It will visualize liver and spleen and unlike agents based on phytate, the colloid is formed in the vial, allowing quality control checks prior to injection.



The Radiochemical Centre Amersham

The Radiochemical Centre Limited, Amersham, England. Tel: Little Chalfont (024 04) 4444.
In W. Germany: Amersham Buchler GmbH & Co, KG, Braunschweig. Tel: 05307-4693-97.

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PULMOLITE™

Technetium Tc 99m Aggregated Albumin Kit

Convenient
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 radiodiagnostic.

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

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

The contents of the vial are under a nitrogen atmosphere and should be protected from air. Do not use if clumping or foaming of the contents is observed.

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

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

Safety and effectiveness in children have not been established.

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

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

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

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

Dosage and Administration: The recommended intravenous dose range for the average patient (70kg) is 1 to 4 millicuries. The volume of the dose may vary from 0.2 to 1.3ml.

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

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

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

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

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

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

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

Cat. No. NRP-415

NEN

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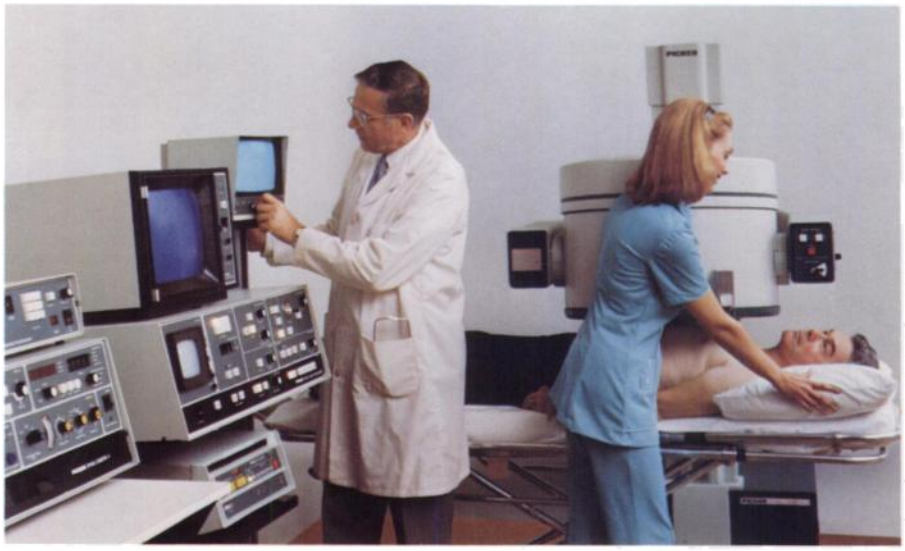
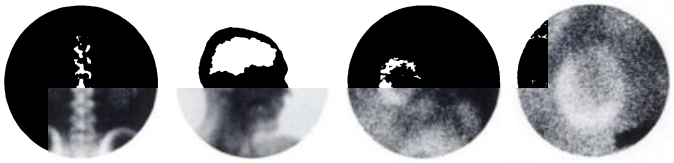
A complete nuclear image

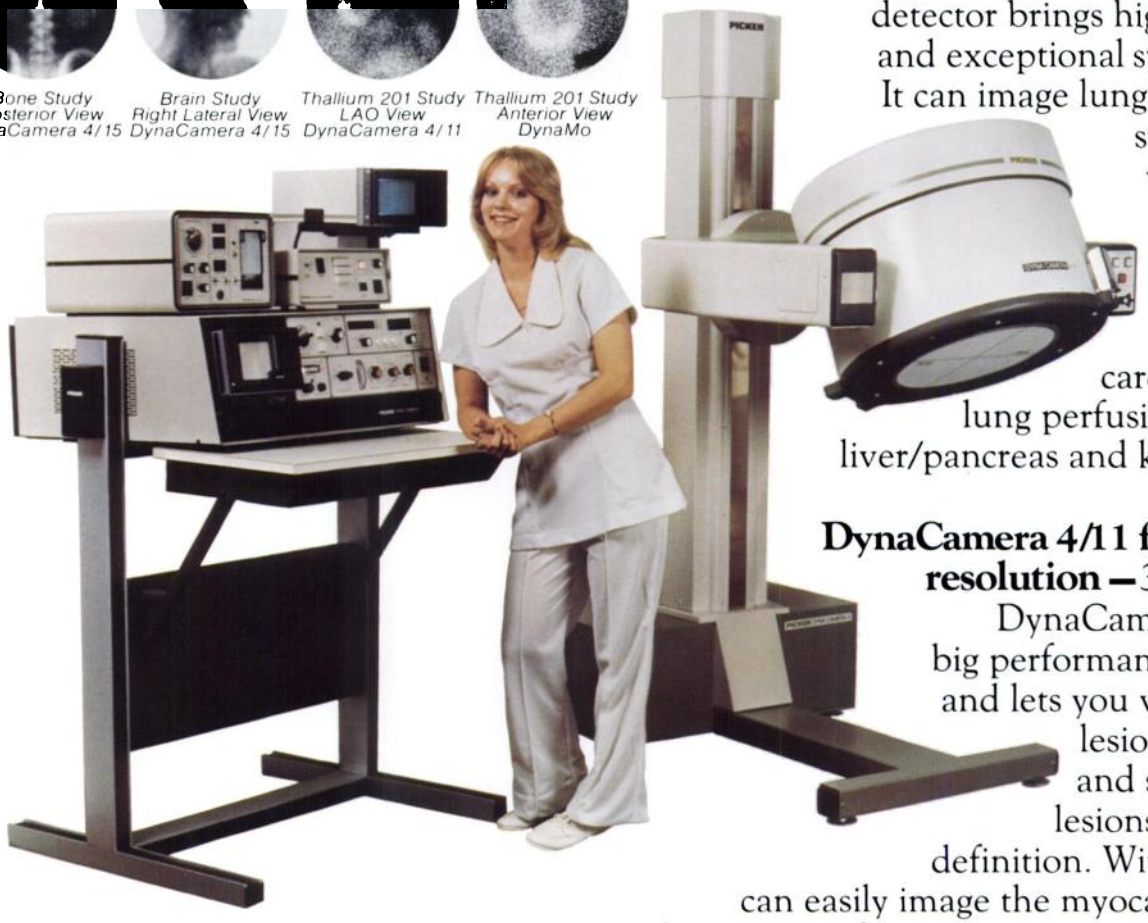


As the uses for nuclear medicine continue to expand, the responsibilities of the nuclear physician and the radiologist will increase just as rapidly. Their services are requested in more and more disciplines. Picker gamma-camera systems have been designed to allow the physician to select and refine the views he needs. Picker Dyna®Camera accessories help our cameras to see more. As our systems have grown more sophisticated in their ability to deliver results, they've also become simpler to use and maintain.

DynaCamera 4/15 takes the large view. Within the DynaCamera 4 series, Picker's 4/15 becomes the nucleus of a nuclear medicine department. Its 15"(380 mm) detector brings high uniformity and exceptional system resolution. It can image lung and liver/spleen studies in one view—without a diverging collimator. It's ideal for cerebral and cardiac flow studies, lung perfusion studies, bone, liver/pancreas and kidney studies.



Bone Study Posterior View DynaCamera 4/15 *Brain Study Right Lateral View DynaCamera 4/15* *Thallium 201 Study LAO View DynaCamera 4/11* *Thallium 201 Study Anterior View DynaMo*



DynaCamera 4/11 for unparalleled resolution—3.6 mm FWHM. DynaCamera 4/11 delivers big performance in small areas, and lets you visualize small lesions, often hidden, and shows larger lesions with clearer definition. With the 4/11, you can easily image the myocardium to locate and measure infarcts, get precise region placement in left ventricular ejection fraction studies, and obtain cardiac-output measurements.

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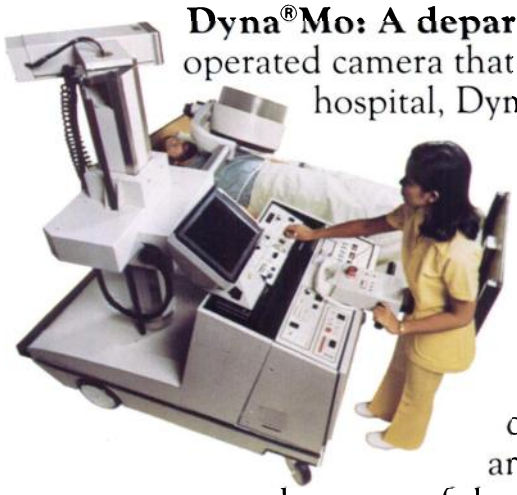
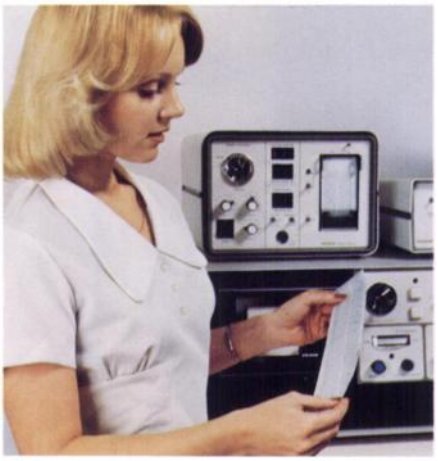
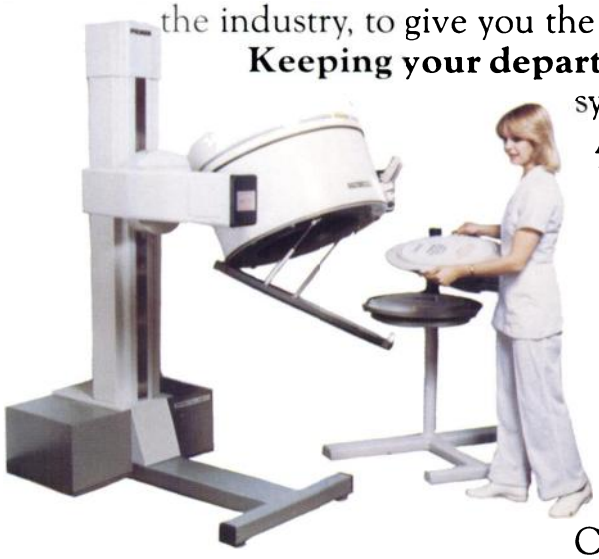


Dyna®Mo: A department on wheels. As a high-resolution, mobile, battery-operated camera that extends the role of nuclear medicine to every part of the hospital, DynaMo is a great system to have around. Its high-resolution detector – 3.6 mm FWHM – makes it the equal of our finest small field of view cameras and its quick-change collimators, five-motion detector and integral tape recorder make it a virtual department in itself.

DynaCamera accessories expand the role of your department in important new directions. Your selection of the right DynaCamera 4 gives you the range of capabilities your nuclear medicine department needs – and your selection of the right DynaCamera 4 accessories takes even greater advantage of these capabilities. For example, our Cardiac Module used in conjunction with DynaMo or any DynaCamera 4 system, allows you to compute left-ventricular ejection fraction without the expensive services of a nuclear computer. Our Clinical Image Processor significantly improves upon your present methods of viewing, analyzing, photographing and recording



images. The Picker Image Programmer makes it possible to record multiple images on a single piece of film. Our Compact Recording Camera, used with PIP, formats and photographs up to 90 images on a single film. And, we offer the widest selection of collimators in the industry, to give you the best speed, resolution, sensitivity and convenience.



Keeping your department ahead of the future. A modular DynaCamera 4 system is an investment in the future of nuclear medicine. As new technologies emerge from the laboratory, Picker gamma-camera systems will keep pace . . . and set it. Our investment in the future of nuclear medicine is rooted in 20 years of industry leadership through the concept of adding capabilities, not complications.

For full details, contact Picker Corporation, 12 Clintonville Road, Northford, CT 06472 (203-484-2711); or Picker International, 595 Miner Road, Cleveland, OH 44143.

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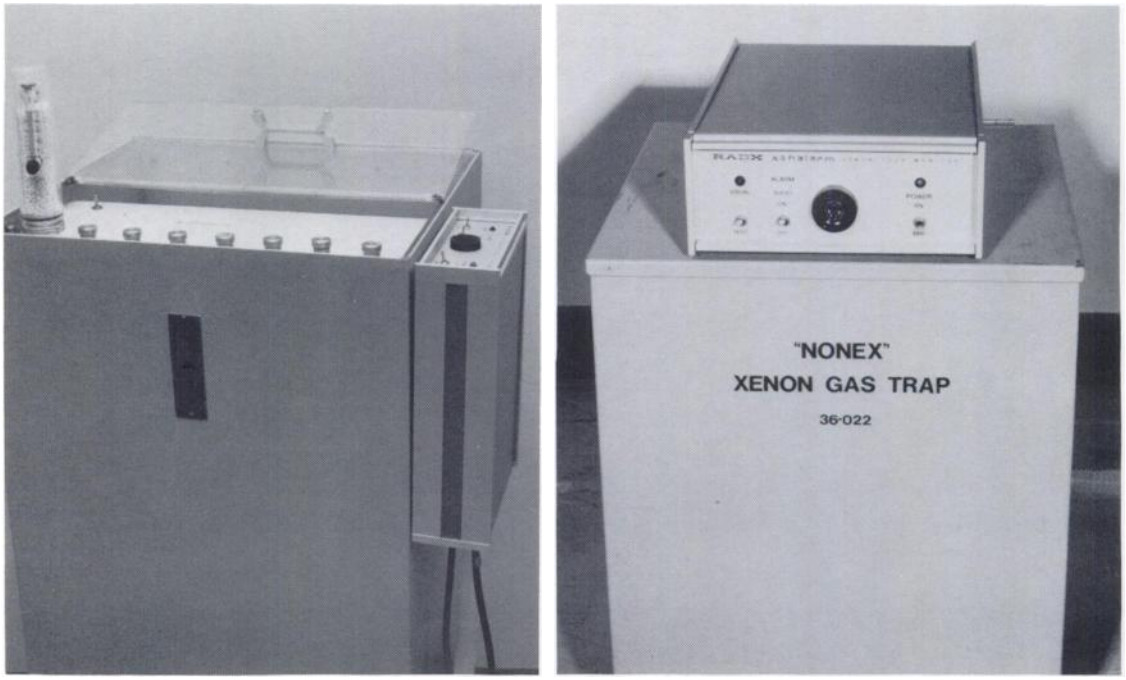
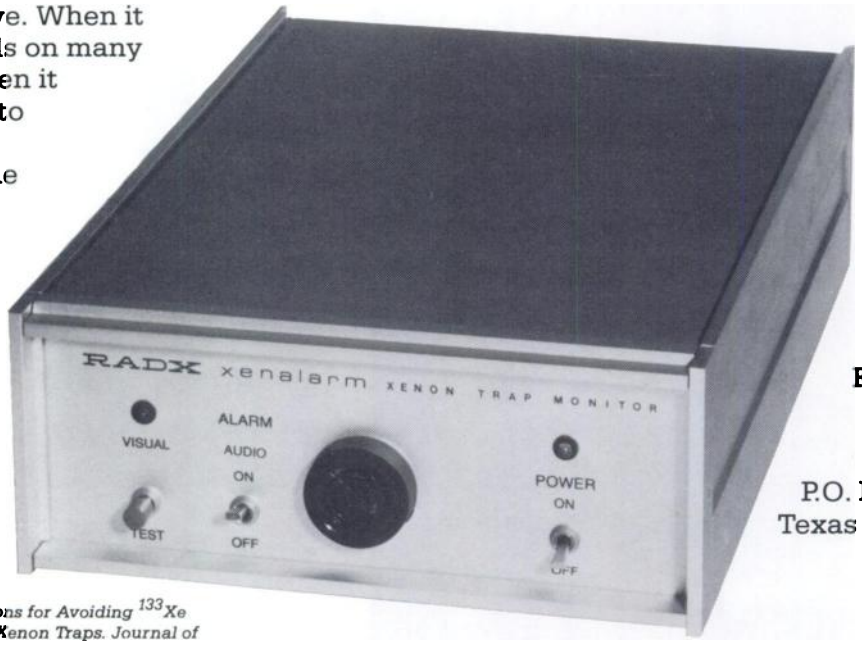


The New Xenalarm will monitor it

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.[1] 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 concentration of Xenon-133 in the exhaust port exceeds 1×10^{-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

P.O. Box 19164 • Houston, Texas 77024 • 713-468-9628

[1] *Timpe, G.M. Precautions for Avoiding ^{133}Xe Release From Charcoal Xenon Traps. Journal of Nuclear Medicine Technology Volume 4, Number 4, Pages 208-209.*

After one million* doses, TechneColl® keeps boiling along.

A time-tested formula. An outstanding performance record.
Have your Mallinckrodt Representative demonstrate the difference!

TechneColl® Sulfur Colloid Kit

for the preparation of Technetium Tc99m Sulfur Colloid

*Based on an estimated average of two patients dosed per vial.

See next page for brief summary.

Mallinckrodt NUCLEAR

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

TechneColl®

Kit for the Preparation of Technetium Tc-99m Sulfur Colloid

DESCRIPTION

The kit contains all of the non-radioactive reagents required to prepare a sterile, non-pyrogenic preparation of Technetium Tc 99m Sulfur Colloid suitable for direct intravenous injection. When sterile, pyrogen-free Sodium Pertechnetate Tc 99m is added to the reaction vial, Technetium Tc 99m Sulfur Colloid is formed with the non-radioactive reagents.

ACTIONS

Following intravenous administration, Technetium Tc 99m Sulfur Colloid is rapidly cleared by the reticuloendothelial system from the blood with a nominal clearance half-time of approximately 2½ 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 normal patient 80 to 90% of the injected colloidal particles are phagocytized by the Kupffer cells of the liver, 5 to 10% by the spleen and the balance by the bone marrow.

INDICATIONS

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

CONTRAINDICATIONS

None.

WARNINGS

The contents of the double-compartment dose syringes are intended **only** for use in the preparation of Technetium Tc 99m Sulfur Colloid 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.

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.

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

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

PRECAUTIONS

The components of the kit are sterile and nonpyrogenic. It is essential that the user follow the directions carefully and adhere 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 pertechnetate solutions containing more than 10 micrograms/ml of aluminum ion not be used for formation of the Technetium Tc 99m Sulfur Colloid.

Technetium Tc 99m 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 Tc 99m Sulfur Colloid not be used after six hours from the time of formulation.

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

ADVERSE REACTIONS

Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulfur colloid preparation. Although rare, pyrogen reactions have been reported following the administration of the drug stabilized with gelatin. Arm pain following injection has been reported.

DIRECTIONS FOR PREPARATION

Note: Read complete directions thoroughly before starting preparation procedure.

PROCEDURAL PRECAUTIONS

1. All transfer and vial stopper entries must be done using aseptic technique.
2. The **TechneColl** Kit should be stored at room temperature (approximately 25°C).
3. All **TechneColl** Kit reagents must be at room temperature before use. At lower temperatures, there may be evidence of undissolved gelatin in the double-compartment syringes. The syringes should be allowed to stand at room temperature (approximately 25°C) until the gelatin returns to solution. **Do not warm the syringes in water bath or incubator.**
4. The water bath used for heating the contents of the Reaction Vial must be at a continuous **rolling** boil during the two heating steps of the preparation procedure. The Reaction Vial should be in direct contact with the rolling boil water of the bath, and the level of the bath must be at least even with the level of the contents of the Reaction Vial.
5. If the Reaction Vial is incubated in a lead safe, the temperature of the safe should be allowed to reach the temperature of the water bath before incubating the Reaction Vial.
6. **As a result of heating the contents of the closed Reaction Vial, internal pressure will be created causing some resistance when injecting the contents of Syringe II into the Reaction Vial. The resistance may be minimized either by employing a syringe to evacuate approximately 20 ml of air from the Reaction Vial before the addition of the generator eluate (Step 3) or by venting the Reaction Vial with a sterile needle prior to injecting the contents of Syringe II into the Reaction Vial (Step 7). If venting is used, remove vent needle before returning Reaction Vial to water bath.**
7. When attaching the disposable needles to the double-compartment syringes, care must be taken to insure that the needles are firmly attached to the syringes.

PROCEDURE: for preparing Technetium Tc 99m Sulfur Colloid

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

1. Prepare a **rolling** boil water bath.
2. Fill in the necessary information on the "Caution: Radioactive Material" label and place directly over the yellow area provided on the Reaction Vial label. Attach the string tag to the neck of the Reaction Vial. **Place the Reaction Vial in a lead Dispensing Shield fitted with a lid and with a minimum wall thickness of ⅛ inch.**
3. After swabbing the rubber stopper of the Reaction Vial with an appropriate antiseptic, aseptically inject a calculated volume of technetium-99m generator eluate or prepackaged sodium pertechnetate Tc-99m into the Reaction Vial. The volume of pertechnetate solution used must be between 0.1 and 5.0 ml. (Withdraw a 5 ml or greater volume of air to relieve pressure.)
4. Aseptically assemble Syringe I* and aseptically inject the contents into the Reaction Vial.
5. Invert the Reaction Vial several times to obtain complete mixing.

*Place the disposable needle on the syringe by pressing on firmly with a slight twisting motion.

6. Immediately transfer the Reaction Vial to a lead (minimum wall thickness of ⅛ inch) Boiling Shield which has been equilibrated to the temperature of the **rolling** boil water bath. This may be accomplished by placing the shield in the rolling boil bath a few minutes prior to transferring the Reaction Vial. The level of the water bath must be even with or above the contents of the Reaction Vial. Allow the Reaction Vial to incubate for 8 minutes.
7. Aseptically assemble Syringe II.* Immediately after the incubation period (Step 6) remove the Reaction Vial from the Boiling Shield and place in the Dispensing Shield. Swab the vial stopper with an appropriate antiseptic and aseptically inject the contents of the Syringe II into the Reaction Vial.
8. **Immediately** return the Reaction Vial to the Boiling Shield and incubate for 2 minutes.
9. Remove the Reaction Vial from the Boiling Shield and place in the Dispensing Shield. Allow the contents of the Reaction Vial to cool for approximately 15 minutes to reach body temperature. The final Technetium Tc 99m Sulfur Colloid preparation should be clear to slightly hazy in appearance, but there should be no flocculent present. If a precipitate is visible, the preparation should not be used.
10. Calculate the radioactivity concentration of the Technetium Tc 99m Sulfur Colloid and fill in the appropriate information on the string tag. **Do not use this material after 6 hours from time of preparation.**

Calculation of Radioactivity Concentration

$$\text{mCi/ml of colloid} = \frac{\text{mCi of Tc99m added}}{\text{ml of Tc99m added} + 5\ \text{ml}^{**}}$$

**The total delivered non-radioactive reagent volume employed in the preparation is 5 ml.

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.

When orally administered, the Technetium Tc 99m 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.

HOW SUPPLIED

Catalog Number	TechneColl Kit
090	Package contains—5 Preparation Units for the preparation of Technetium Tc 99m Sulfur Colloid.

Each Preparation Unit Contains:

1—Reaction Vial. Contents 2.0 ml; each ml contains 50 mg phosphoric acid.

1—Syringe I (2-compartment disposable syringe)—Compartment A, 1.1 ml. Each ml contains 12 mg gelatin and 9 mg sodium chloride. Compartment B, 0.55 ml. Each ml contains 12 mg sodium thiosulfate.

1—Syringe II (2-compartment disposable syringe)—Compartment A, 0.6 ml. Each ml contains 36 mg gelatin and 9 mg sodium chloride. Compartment B, 1.0 ml. Each ml contains 544 mg sodium acetate and 4 mg disodium edetate.

2—Disposable needles.

1—Pressure-sensitive "Caution—Radioactive Material" label.

1—Radioassay information string tag.

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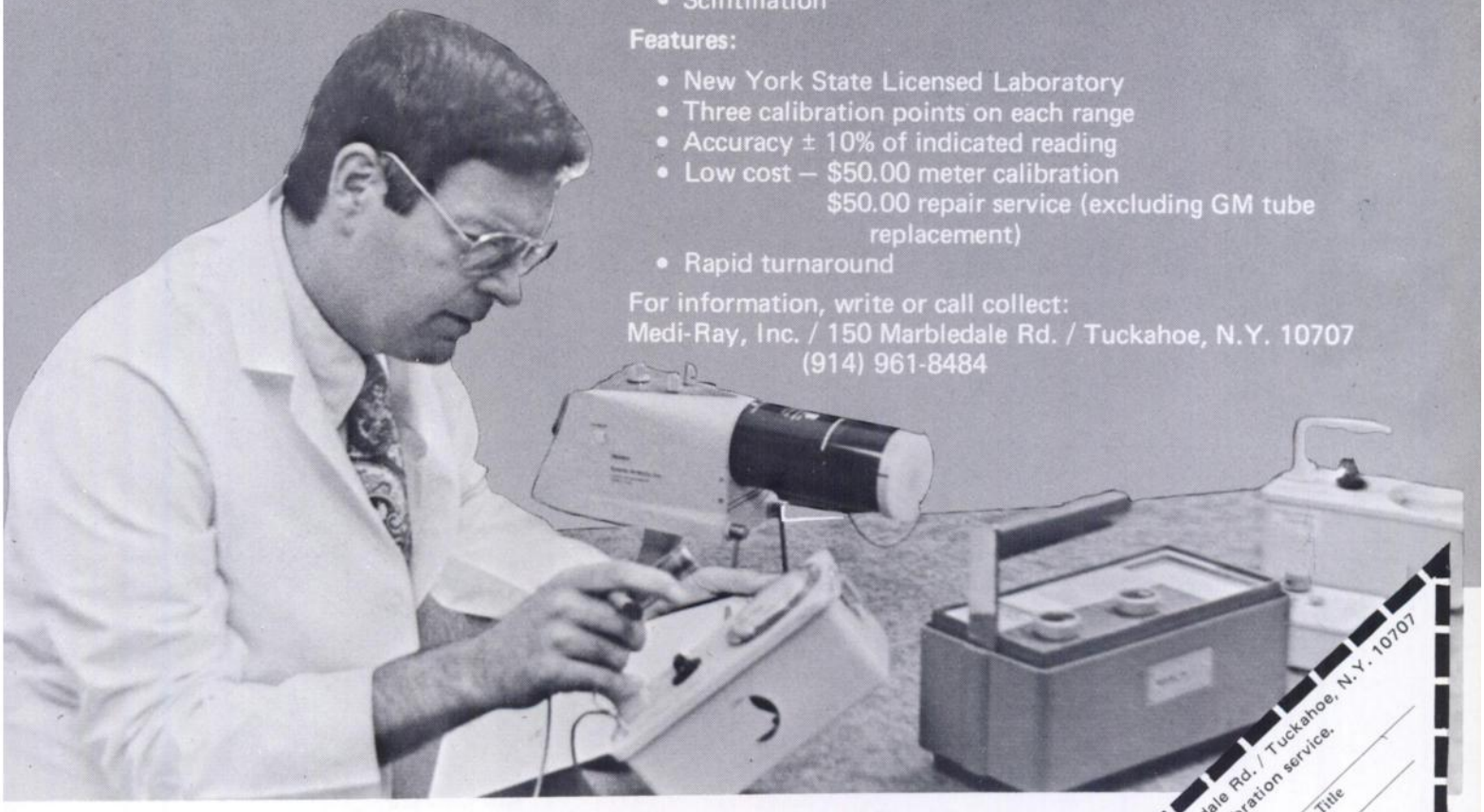

Medi-Ray, Inc.

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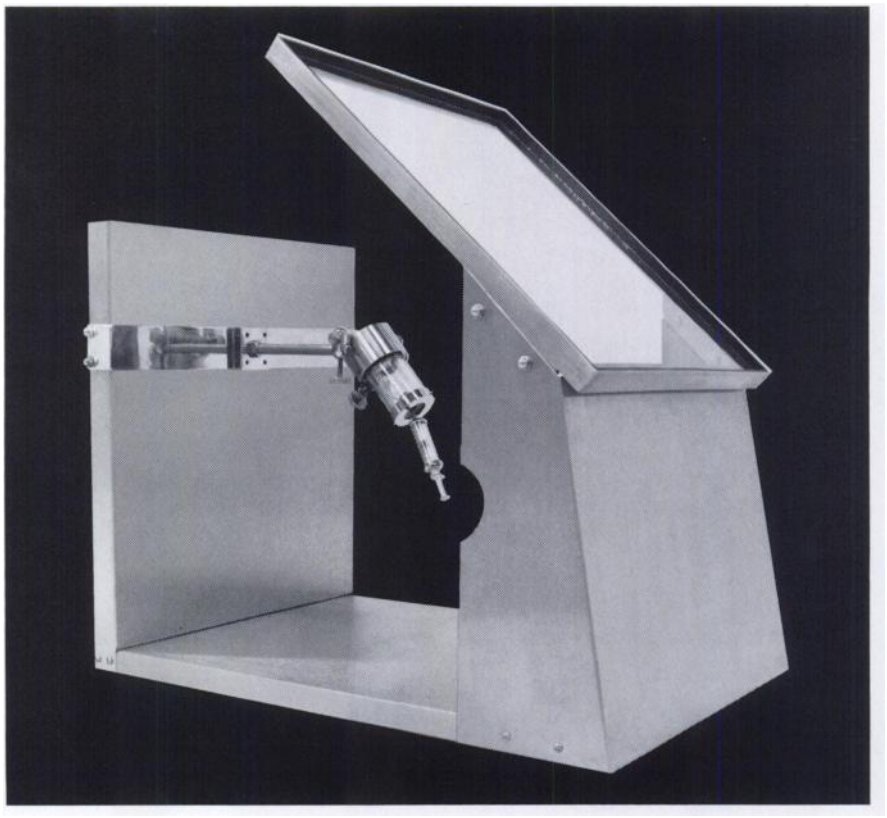
Please send information on calibration service.

Name _____ Title _____
Hospital _____ Dept. _____
Address _____ City _____
State _____ Zip _____
Phone _____



Now there's a Radiation Dose Shield that offers *more* than just protection.

Safety, versatility *and* convenience. Nuclear Pacific's new Radiation Dose Shield provides all three through an expandable, modular design that allows you to select exactly the features your working environment most requires.

The basic stand consists of a 16"x 18" cantilevered frame holding ¼" (4.8 density) lead glass, vertical stainless steel-clad forward wall and a horizontal work surface. The forward wall contains ⅜" lead lining.

The basic unit can be ordered with thicker and higher density glass (the frame accommodates thicknesses up to 1") and/or with a vial-shield-holding back wall. (As shown.)

Basic unit size is 17" wide by 25" deep and is 25" high. Net weight: 129 lbs.

Radiation Dose Shield Model 30
Basic Unit $498.00

includes:
- Front Stainless Steel with ⅜" Lead
- Side Stainless Steel with ⅜" Lead
- Bottom Stainless Steel only
- Frame with 4.8 density ¼" Lead Glass

Select the basic stand or any of these options:

Options: Add prices below to base unit, Model 30 price

Model 31-A	Back-Stainless Steel Panel	$ 68.00
Model 31-B	Back-⅜" Lead Sheet	$ 64.00
Model 31-C	Bottom ⅜" Lead Sheet	$ 86.00
*Model 31-D	Utility Bar	$ 90.00
Model 31-75	Lo Energy Vial Shield Holder	$125.00
Model 31-77	Hi Energy Vial Shield Holder	$125.00
Model 31-79	Ultra Hi Energy Vial Shield Holder	$125.00
Model 31-481	½" 4.8 Density Lead Glass	$ 63.00
Model 31-622	½" 6.2 Density Lead Glass	$100.00
Model 31-623	¾" 6.2 Density Lead Glass	$175.00
Model 31-624	1" 6.2 Density Lead Glass	$275.00

*Only one required for 1 to 4 Vial Shield Holders.

To order, contact Nuclear Pacific, Inc., (206) 763-2170.

Nuclear Pacific, Inc.

6701 Sixth Ave. S. Seattle, WA 98108

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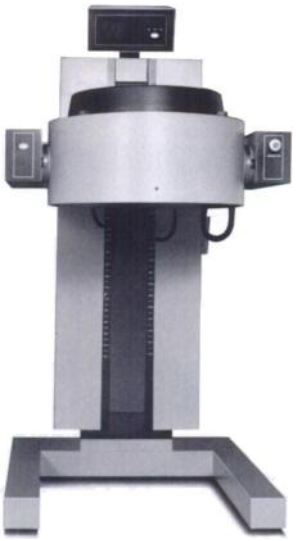
A SUBSIDIARY OF THE RADIOCHEMICAL CENTRE

The UNION CARBIDE Large Field Gamma Camera: **The Critical Difference in Diagnostic Power.**

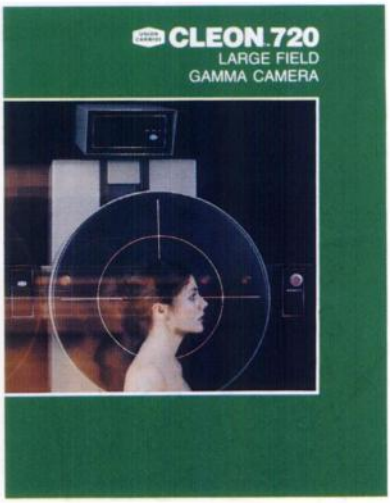


The CLEON 720 Large Field Gamma Camera is a high resolution imaging system designed for exacting, contemporary clinical nuclear medicine.

It can be installed as a stand-alone camera or connected to the CLEON 110 Image Processor as an integrated imaging and data processing system.

The unique hand control lets the technologist remain with the patient at all times while setting up the complete imaging study. Bolus injection procedures can be easily accomplished with one technologist.

The optional CLEON 110 Image Processor provides a powerful microcomputer system complete with specialized Nuclear Medicine software to permit a full range of functional analyses including automatic calculation of cardiac ejection fractions, cerebral perfusion determiniation, renal function analysis, pulmonary function analysis, and simultaneous end-systole and end-diastole data acquisition. The Image Processor is easy to use and requires no computer codes or terminology to operate.



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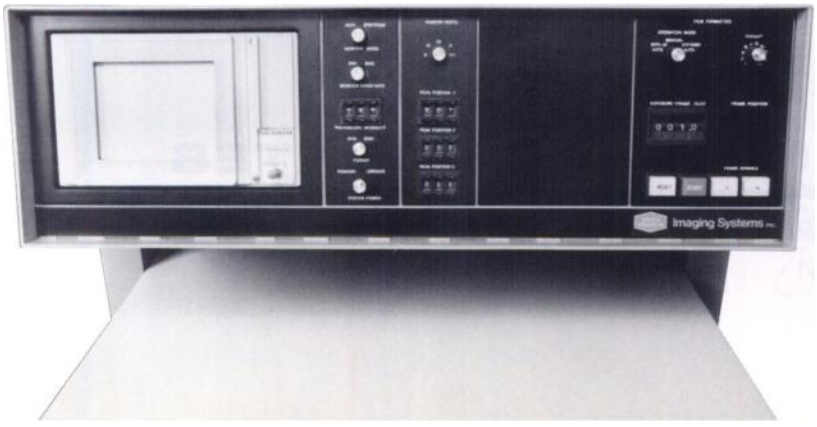

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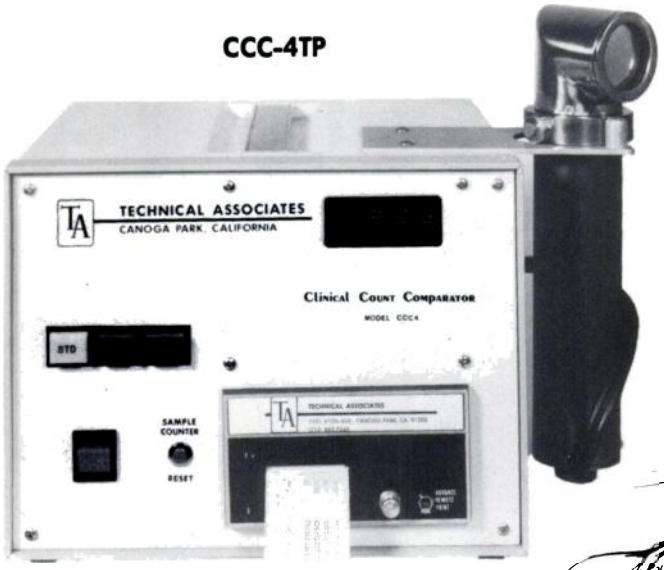
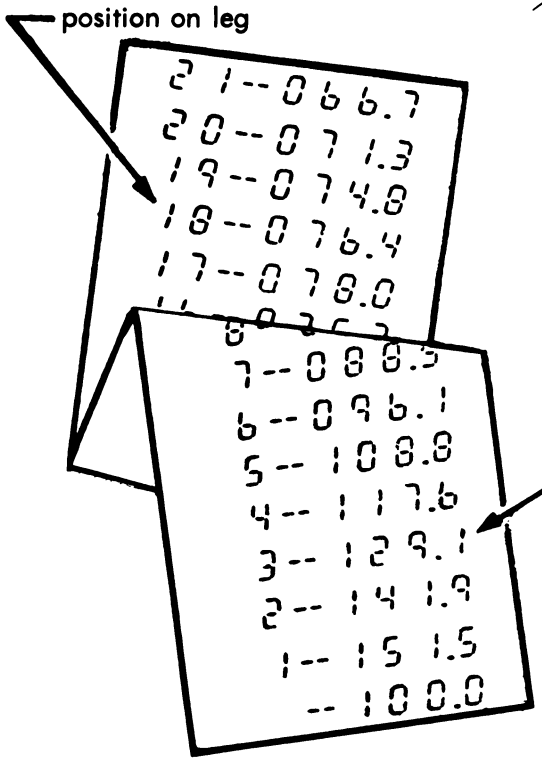
thrombosis

detection of DVT using I-125 fibrinogen

CCC-4TP





percent uptake

Print Out
1¾ inch wide

- Direct **digital percent** readout
- Printout **saves time**
- Bedside operation
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TECHNICAL ASSOCIATES

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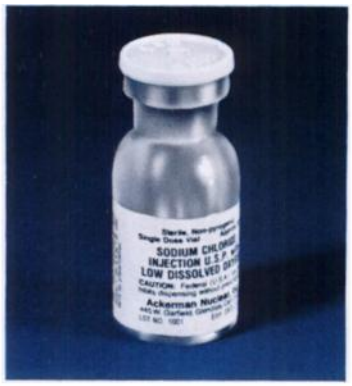
THE OBVIOUS SOLUTION

Low* Dissolved Oxygen
Non-preservative normal saline U.S.P.

Designed with Nuclear Medicine in mind, Low Dissolved Oxygen, non-preservative, normal saline for routine use is now available from Ackerman Nuclear, Inc.



- ELUTION:
  Use for eluting Technetium-99m generators.
- DILUTION:
  Use for diluting high specific concentrations of Technetium-99m.

SODIUM CHLORIDE INJECTION U.S.P.
with LOW DISSOLVED OXYGEN
pH 4.5 to 7.0

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

INDICATIONS:
SODIUM CHLORIDE INJECTION U.S.P. with LOW DISSOLVED OXYGEN is indicated for eluting, preparing and/or diluting pharmaceuticals that specify oxidants may cause adverse effects on the final product. SODIUM CHLORIDE INJECTION U.S.P. with LOW DISSOLVED OXYGEN is also used as a fluid and electrolyte replenisher or as an irrigating solution.

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

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

HOW SUPPLIED:

Catalog No.	Product	Packaging
S-25	SODIUM CHLORIDE INJECTION U.S.P. with LOW DISSOLVED OXYGEN	25/10 ml vials

Each 10 ml single dose vial contains approximately 6 ml. Each ml contains 9 mg sodium chloride providing 0.154 mEq each of sodium and chloride ions. Total osmolarity 300 mOsm/1; pH between 4.5 and 7.0. Dissolved oxygen content less than 5 ppm. Contains no preservatives.

ACKERMAN NUCLEAR, INC.
445 W. Garfield Avenue
Glendale, Calif. 91204

1/78

Decrease the amount of oxygen you add daily and reduce the effect of one more variable from your radiopharmacy. Use Low Dissolved Oxygen saline when preparing kits containing any stannous tin products.

*less than 5 ppm

For additional information call or write to:

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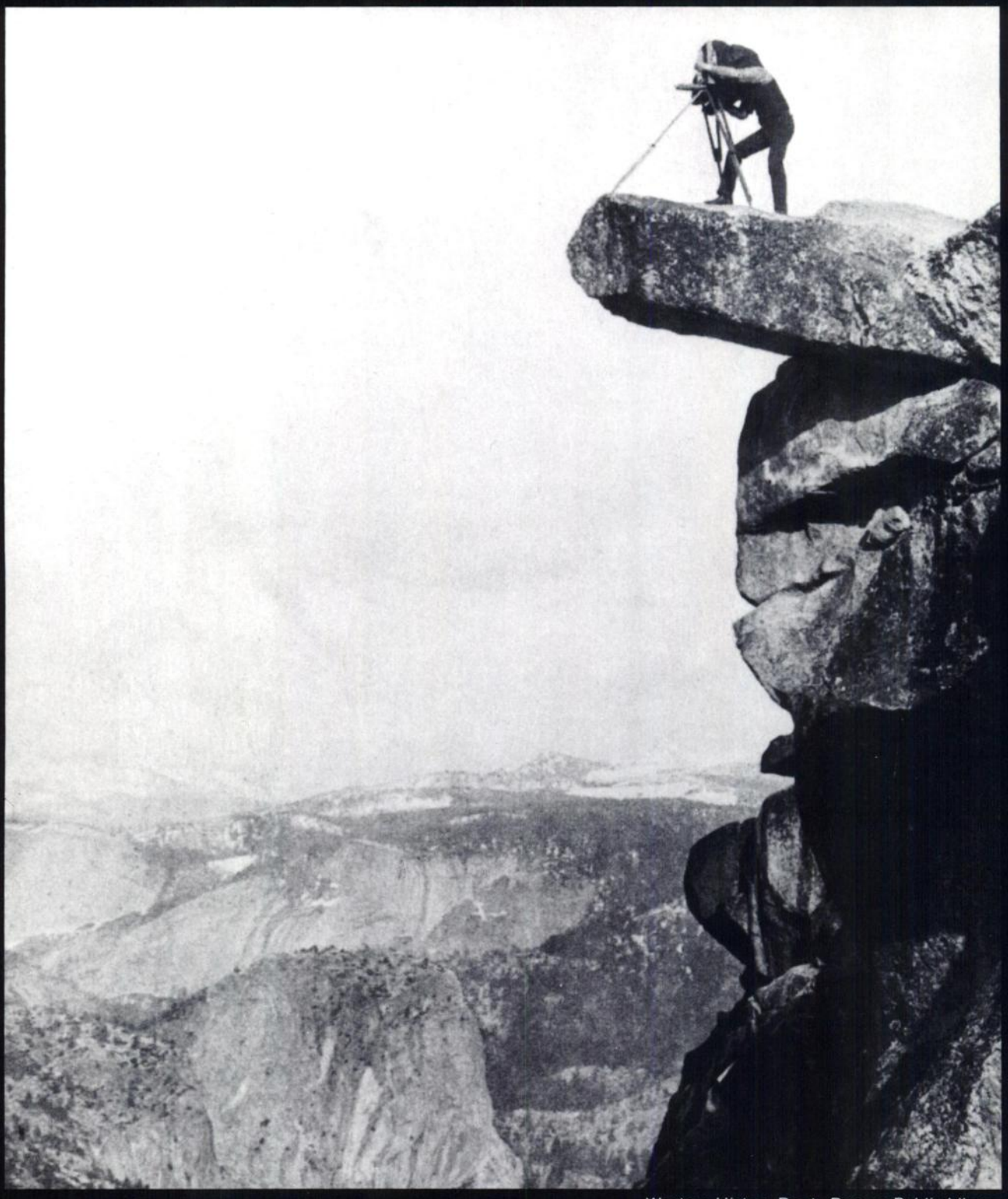
Pharmaceuticals for Nuclear Medicine
445 W. Garfield Ave.
Glendale, CA 91204, USA
(213) 240-8555



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When the subject can't be moved, it helps to have a camera that can.

With the introduction of lighter photographic cameras that enabled man to seek new perspectives from which to take pictures, new horizons in realism were made possible. Searle Radiographics similarly influences technology in the field of nuclear medicine with its extensive line of systems that extend the clinical utility of nuclear cardiology throughout the hospital.

The Pho/Gamma® L.E.M. Low-energy Mobile Scintillation Camera. With the ability to be easily maneuvered anywhere in the hospital for a wide range of cardiac studies without compromising patient comfort and safety.

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The Gamma/Cor™ RCG Cardiac Probe. A unique direct method for rapid, repeatable assessment of left ventricular performance in a noninvasive, safe manner right at the patient's bedside.

Searle nuclear cardiology systems move where they're needed to make GREAT IMAGES.

The Scintiview™ Image Control Station. An easily operated and economical system, complementing the L.E.M., other Searle Pho/Gamma cameras, and Scintistore by recording, storing, and manipulating nuclear images without additional computers, codes, and programming.

Versatility and great images. They're the reasons why this is the most efficient nuclear cardiology line available. Find out how our product technology can serve your needs in nuclear cardiology by contacting Searle Radiographics.

SEARLE

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Division of Searle Diagnostics Inc.
2000 Nuclear Drive
Des Plaines, Illinois 60018

The ice is out at Mallinckrodt.

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

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

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

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

Safety . . .

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

Increased Shelf Life . . .

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

Reliable Consistency . . .

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

Controlled Particle-Size Range . . .

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

High Tagging Efficiency . . .

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

Easy Preparation . . .

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

That's all!

Economy . . .

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

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

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

Mallinckrodt® NUCLEAR

RADIOPHARMACEUTICALS

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® 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 (HB_SAg) by radioimmunoassay. Each vial contains approximately $8 \pm 2 \times 10^6$ aggregated albumin particles. The particle size distribution of the aggregated albumin is such that not less than 90 percent are 10 to 90 microns in size. Typically, approximately 90 percent are within the 10 to 40 micron range. There are no aggregated albumin particles greater than 150 microns in size. Reconstitution of **TechneScan MAA** with sterile, non-pyrogenic sodium pertechnetate Tc-99m provides an aqueous suspension of technetium Tc-99m aggregated albumin, with a labeling efficiency of 90 percent or greater.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

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

WARNINGS

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

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

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

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

PRECAUTIONS

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

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

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

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

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

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

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

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

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

Safety and effectiveness in children have not been established.

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

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

ADVERSE REACTIONS

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

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

DOSAGE AND ADMINISTRATION

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

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

HOW SUPPLIED

Catalog Number

093 — **TechneScan MAA** Kit (Lyophilized)

Kit Contains:

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

Reaction Vial Contains (in lyophilized form):

- 2.0 mg Aggregated Albumin (Human) ($8 \pm 2 \times 10^6$ particles)
- 120 μg Stannous Chloride Dihydrate
- 80 mg Lactose
- 24 mg Succinic Acid
- 1.4 mg Sodium Acetate
- Hydrochloric Acid or Sodium Hydroxide is added for pH adjustment.

Each vial contains $8 \pm 2 \times 10^6$ aggregated albumin particles.

TechneScan MAA contains no preservatives; after reconstitution, the shielded vial should be stored at 2° to 8°C.

Included in each package is one (1) package insert, 5 radiation labels and 5 radioassay information string tags.

Mallinckrodt NUCLEAR
RADIOPHARMACEUTICALS

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

When Toshiba gave nuclear medicine the world's first jumbo gammacamera in 1973, the medical community was very impressed. But we were dedicated to giving you more, so we introduced the world's first jumbo gammacamera with high resolution, fine diagnostic detail over a large area. That was important, but we knew it still wasn't enough.

Now, we are introducing the latest in the state-of-the-art, the GCA-402. The world's first Super High Resolution, Large Field Gammacamera combining stability and exceptional workload capability in one instrument. Frankly, we're pleased.

Toshiba's system approach allows for no compromise where clinical diagnostic values are concerned. The GCA-402 is a prime example. High resolution is the basis for obtaining useful diagnostic images. The intrinsic resolution and linearity of the GCA-402, combined with its range of ten collimators provides unsurpassed images of exceptional diagnostic value. The GCA-402 incorporates 61 photo-multiplier tubes to electronically smooth the image and eliminate the high-energy collimator hole patterns unavoidable in conventional systems. Its 35cm field of view combined with 17 preselected isotope ranges allows unobstructed views of large organs, or groups of organs, as well as whole body scanning.

Toshiba's patented* delay line system and modern IC-technology provide long term stability, trouble free performance, and ease of operation.

Of course, the GCA-402 has a wide range of accessories including special collimators, whole body scanning bed, video tape and film recorders, plus, the GCA-402 may be interfaced to any computer.

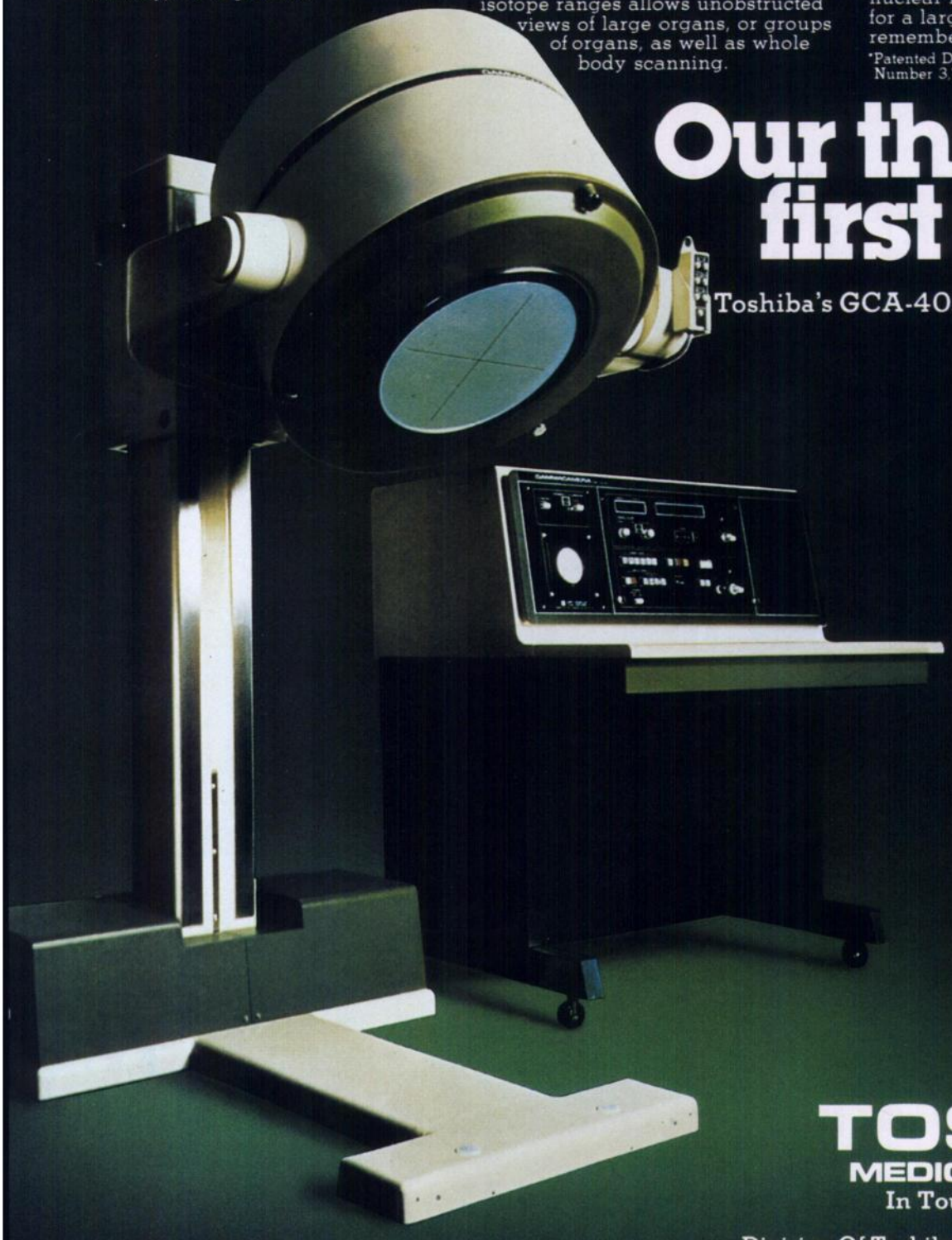
This combination of human engineering, fail-proof auto exposure and easy collimator changeover provides the highest efficiency while minimizing patient discomforture.

When you're ready to fill your nuclear medicine department's need for a large field gammacamera, remember Toshiba. We're the first.

*Patented Delay Line, U.S. Patent Number 3,717,763

Our third is first again

Toshiba's GCA-402 Jumbo Gammacamera



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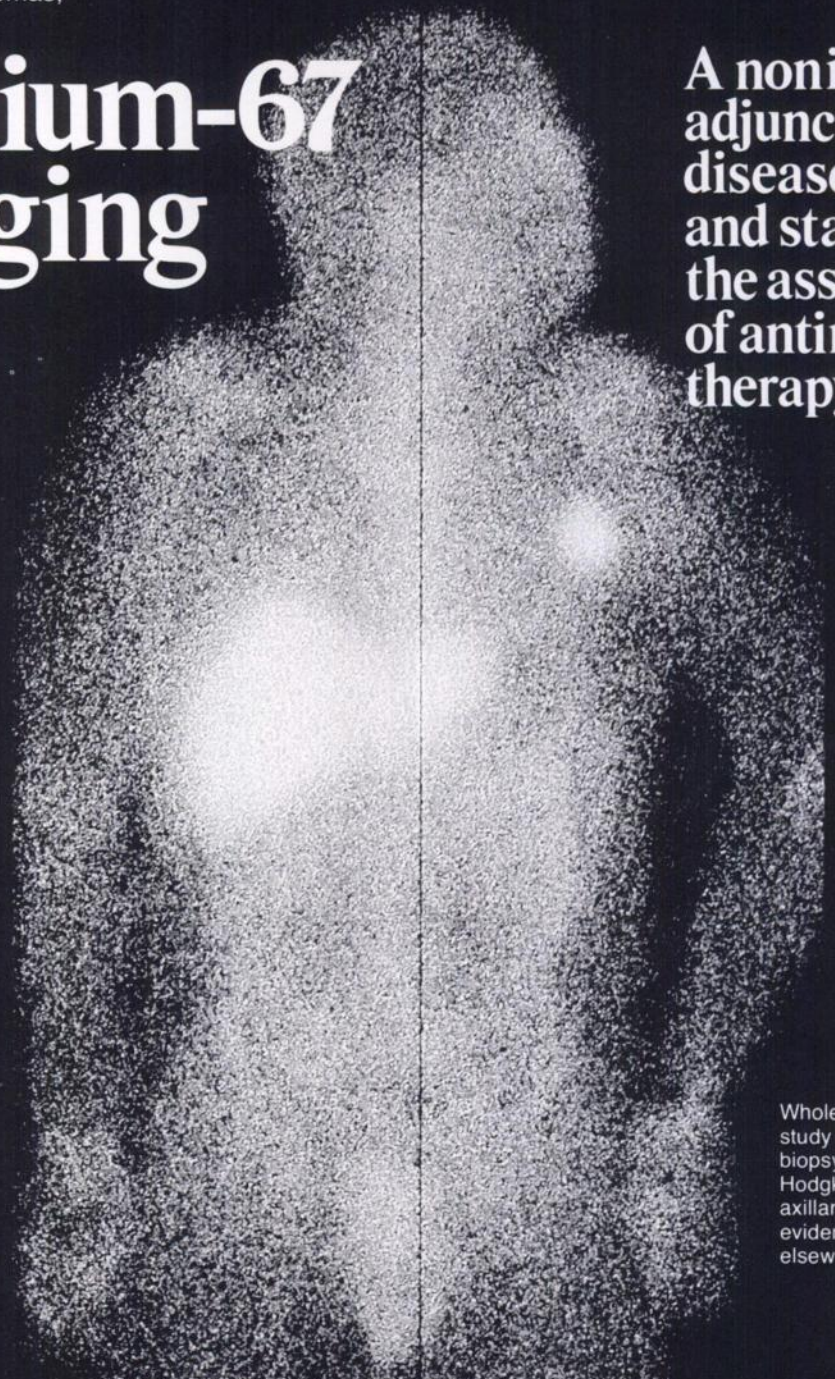
In suspected or known bronchogenic carcinoma, Hodgkin's disease and certain lymphomas, consider

Gallium-67 imaging

A noninvasive adjunct to disease diagnosis and staging, and the assessment of antineoplastic therapy



Whole-body gallium-67 study of patient with biopsy-confirmed Hodgkin's disease in axillary nodes; no evidence of disease elsewhere.

Gallium Citrate Ga 67

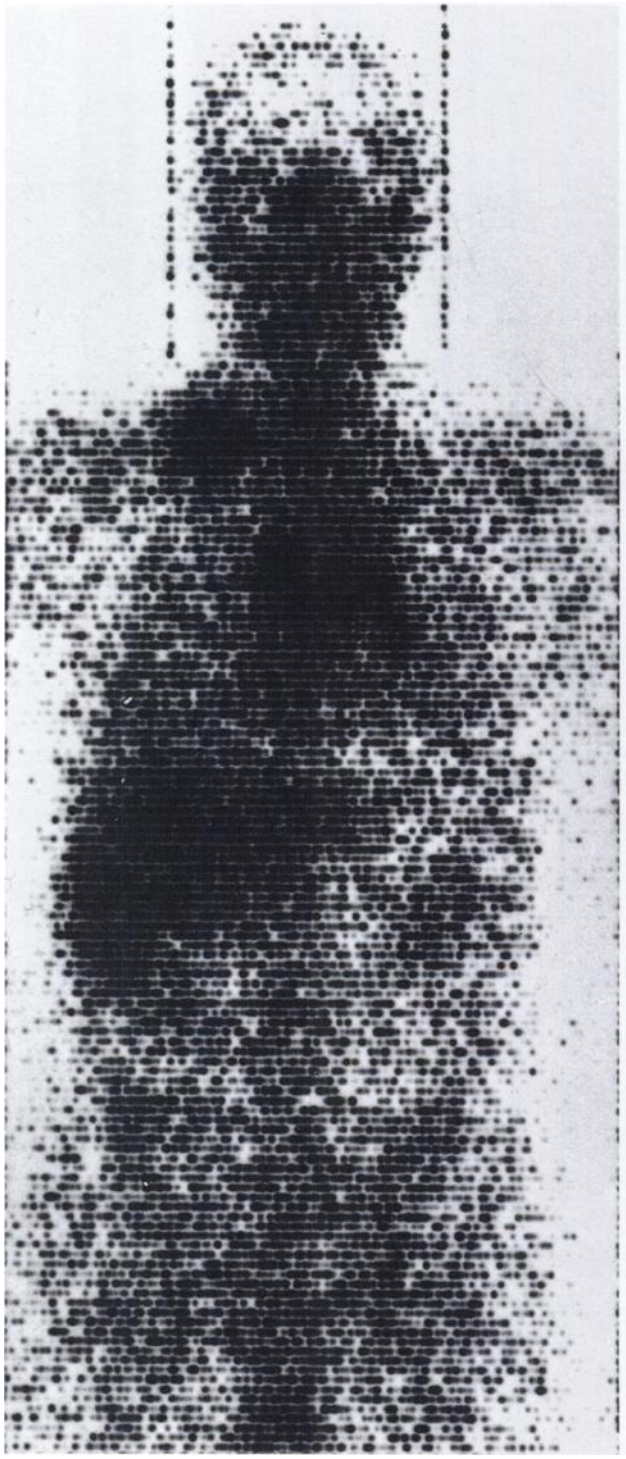
NEN New England Nuclear

Gallium-67 imaging: assessment of therapy

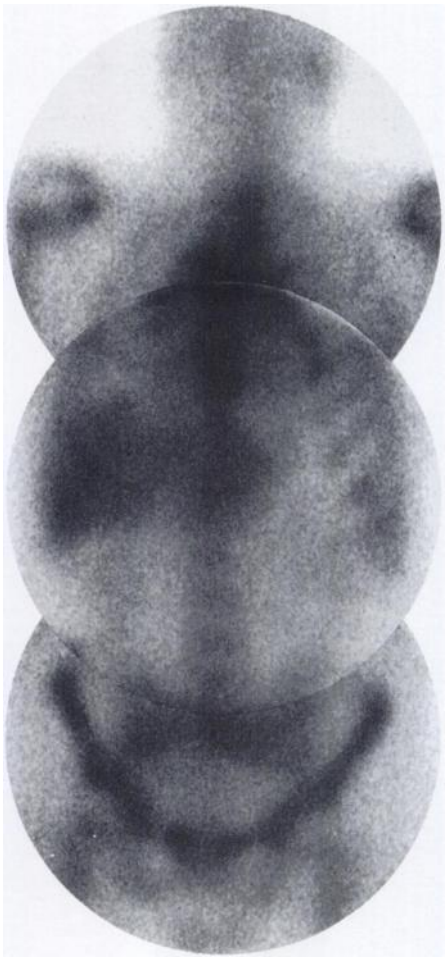
Bronchogenic Ca

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

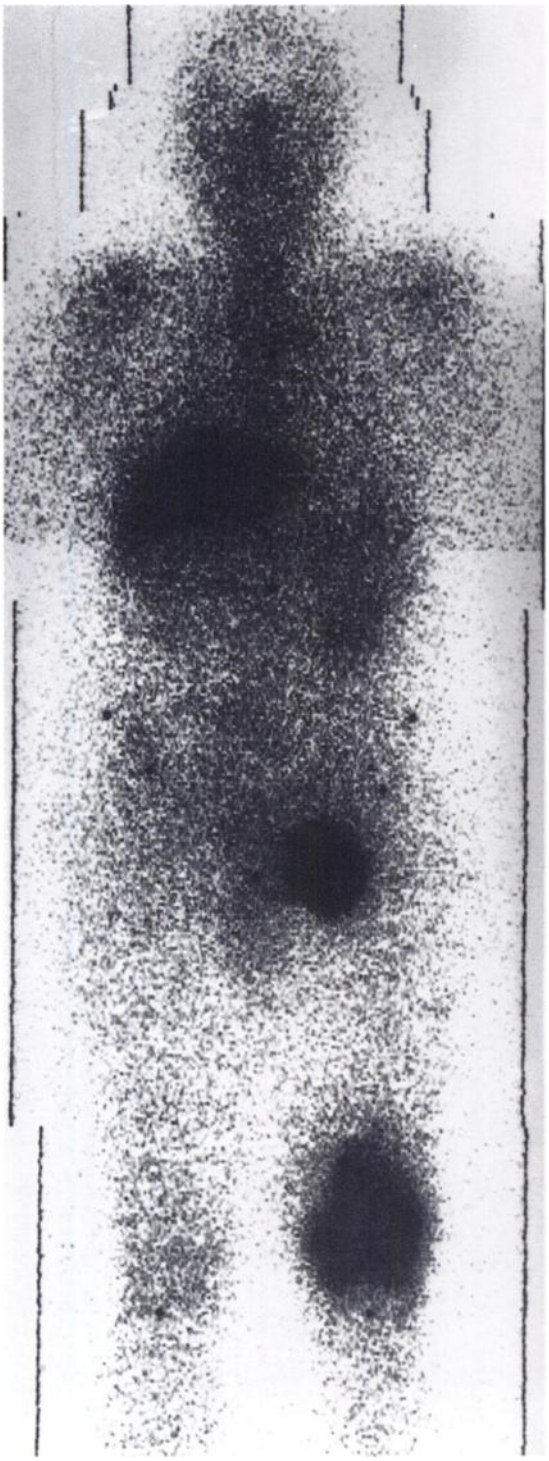


21-year-old male with low-grade FUO of six weeks duration, profuse diaphoresis and general malaise. The only finding upon physical examination was shotty adenopathy of left axilla. Chest X-ray normal.

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.

Gallium Citrate Ga67

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Please see following page for full prescribing information.

Gallium Citrate Ga67

FOR DIAGNOSTIC USE

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

PHYSICAL CHARACTERISTICS

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

TABLE 1. 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

mm of Pb	Radiation Attenuation Factor	mm of Pb	Radiation Attenuation Factor
1	4.2	5	22
2	7.0	6	31
3	11	7	44
4	15	8	61

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 MIRD Committee.*

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

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

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

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

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

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

Catalog Number NRP-121

October 1977

New England Nuclear
Medical Diagnostics Division
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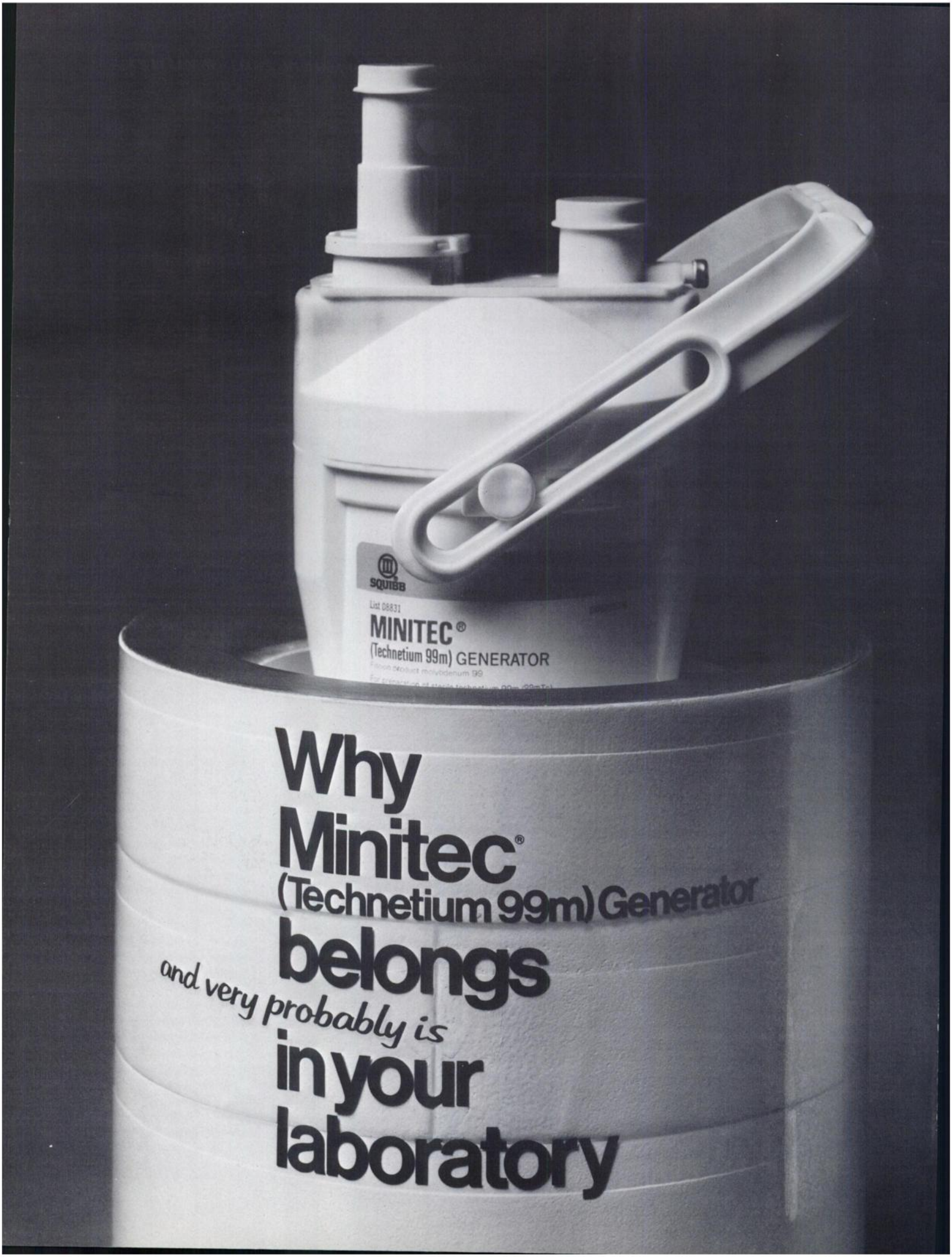
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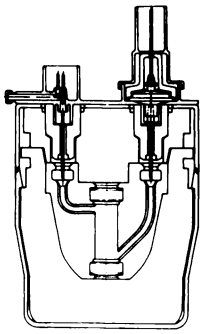

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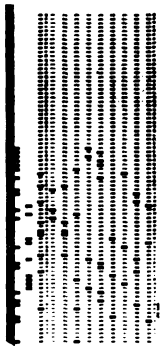

Computer Assistance

Customtec®, a free, exclusive Squibb computer service, custom-tailors generator size and delivery schedule to meet a lab's daily ^{99m}Tc requirements. Programs planned by Customtec reduce waste, increase efficiency and promote radiation safety by providing technetium when it is needed—in amounts that are needed. Ask your Squibb Representative for a free program.

Customer Service

Squibb Technical Associates have had extensive training in nuclear medicine, radiopharmaceuticals, RIA and instrumentation. When you need technical information or have an unusual problem, a call to your local TA brings the quick, personal attention of an experienced specialist. Assistance is also available at Squibb headquarters. Telephone 609-921-4100 or write Medotopes Technical Customer Service, P.O. Box 4000, Princeton, N.J. 08540.

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Products designed to complement each other are more likely to produce a better end product. When sodium pertechnetate eluate obtained from Minitec (Technetium 99m) Generator is utilized in Squibb imaging kits, the results are purity, quality, and compatibility.

See next page for brief summary.

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GENERATOR

DESCRIPTION: Minitec (Technetium 99m) Generator provides a means of obtaining a sterile, nonpyrogenic supply of technetium 99m (^{99m}Tc) as sodium pertechnetate ^{99m}Tc.
INDICATIONS AND USAGE: Sodium pertechnetate ^{99m}Tc is indicated for brain imaging, thyroid imaging, salivary gland imaging, blood pool imaging, and placenta localization.
CONTRAINDICATIONS: None known.
WARNINGS: Radiopharmaceuticals should not be administered to patients who are pregnant or to nursing mothers unless the expected benefit to be gained outweighs the potential hazards.

Since ^{99m}Tc is excreted in human milk during lactation, formula-feedings should be substituted for breast-feedings.

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.
IMPORTANT: Since material obtained from the generator may be intended for intravenous administration, aseptic technique must be strictly observed in all handling. Only the eluent provided should be used to elute the generator. Do not administer material eluted from the generator if there is any evidence of foreign matter.
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. At the time of administration the solution should be crystal clear.
ADVERSE REACTIONS: No adverse reactions specifically attributable to the use of ^{99m}Tc have been reported.

For complete prescribing information, consult package insert.
HOW SUPPLIED: Minitec (Technetium 99m) Generator is available in potencies of 220, 440, 880, 1330, 1770, or 2220 millicuries ^{99}Mo at calibration time. Complete assay data for each generator is provided on the label; directions for determining the activity of material eluted from the generator are provided in the package insert. Supplied with the generator are vials of sterile, nonpyrogenic eluent and suitable equipment for eluting, collecting, and assaying the Technetium 99m.

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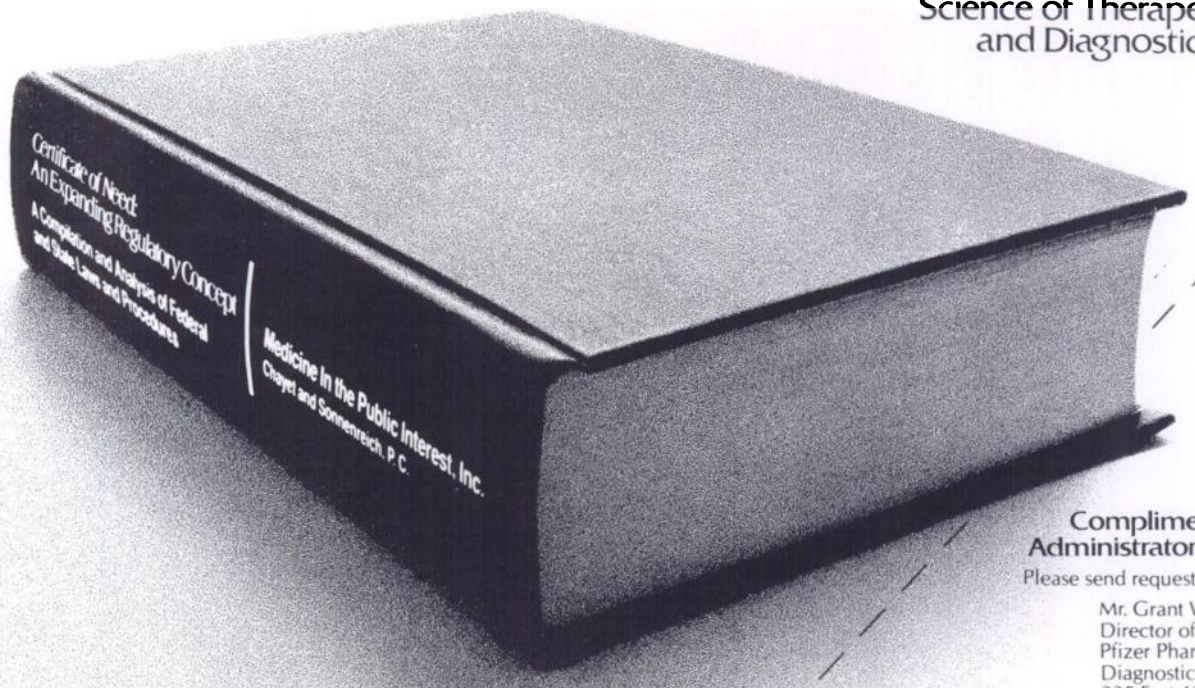

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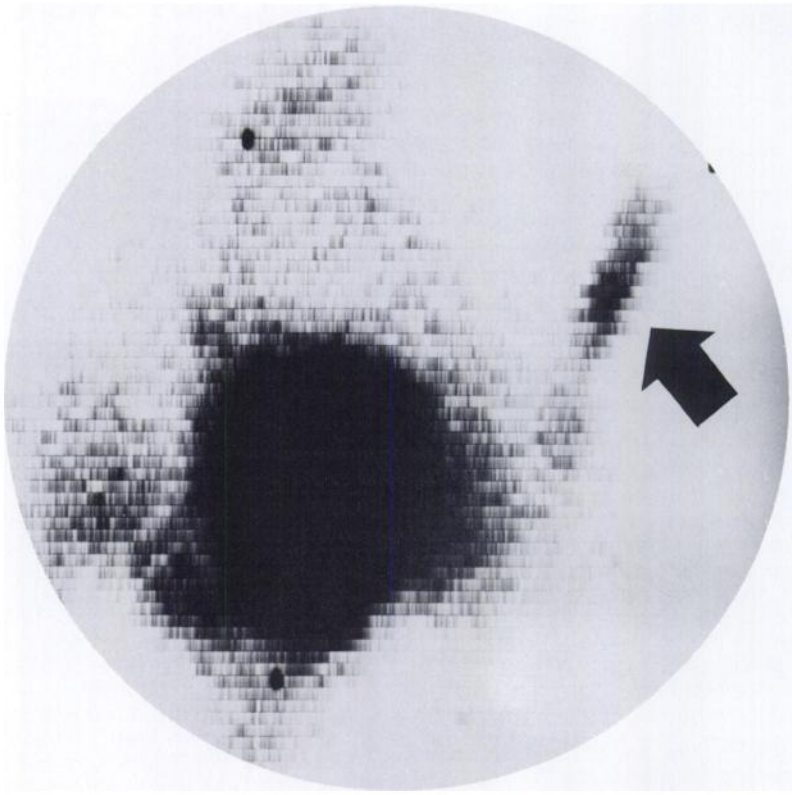

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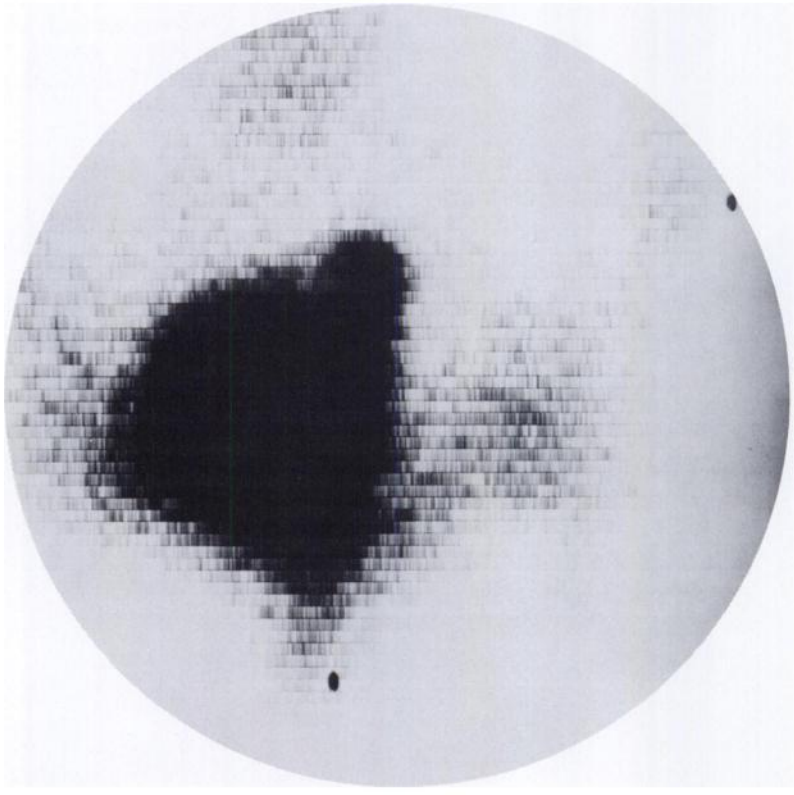

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In Europe, contact: Philips-Duphar B.V., Cyclotron and Isotope Laboratories, Petten, Holland.

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 ^{99m}Tc-hydroxyethylidene diphosphonate (H.E.D.P.) and ^{99m}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.

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

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: 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.

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

Adverse reactions: None 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. Optimum scanning time is 2-4 hours post injection.

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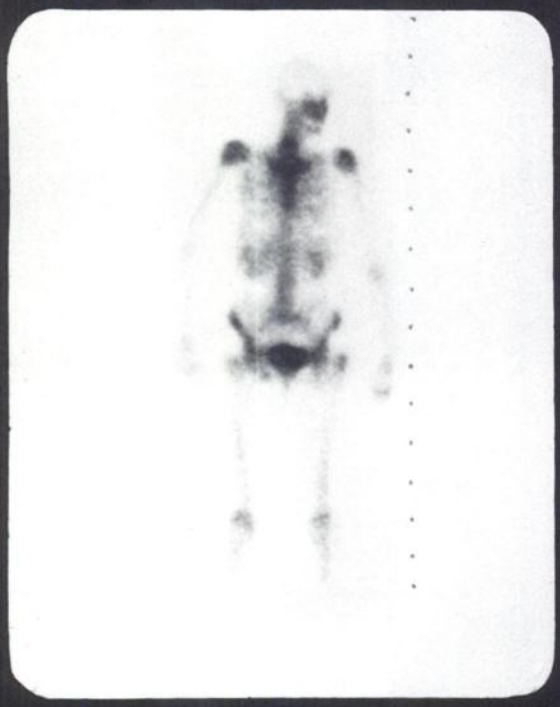

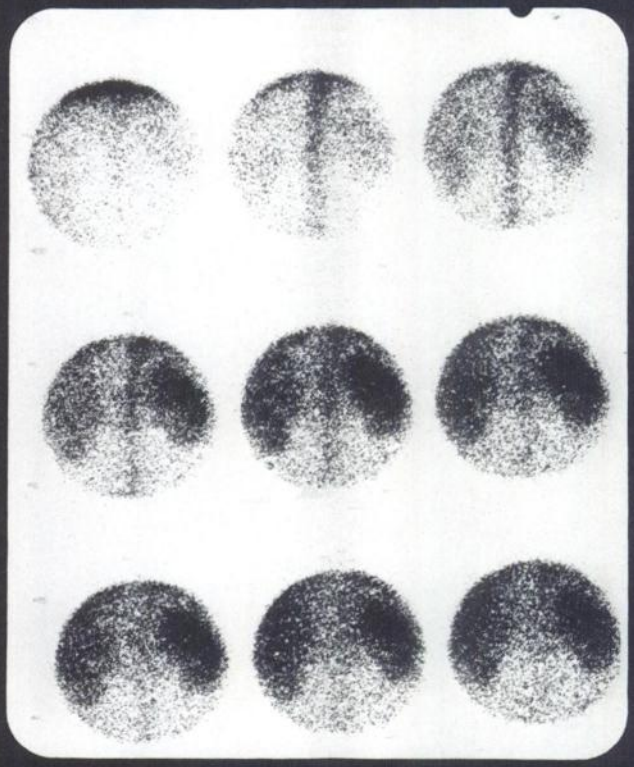

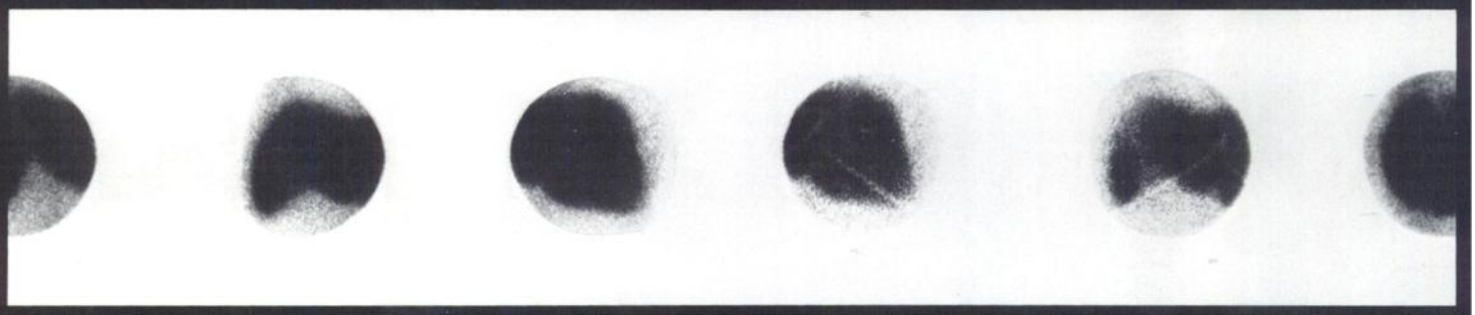

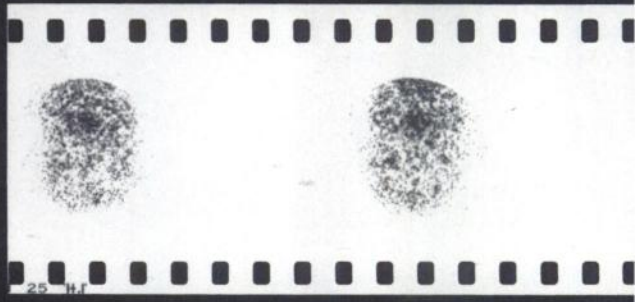

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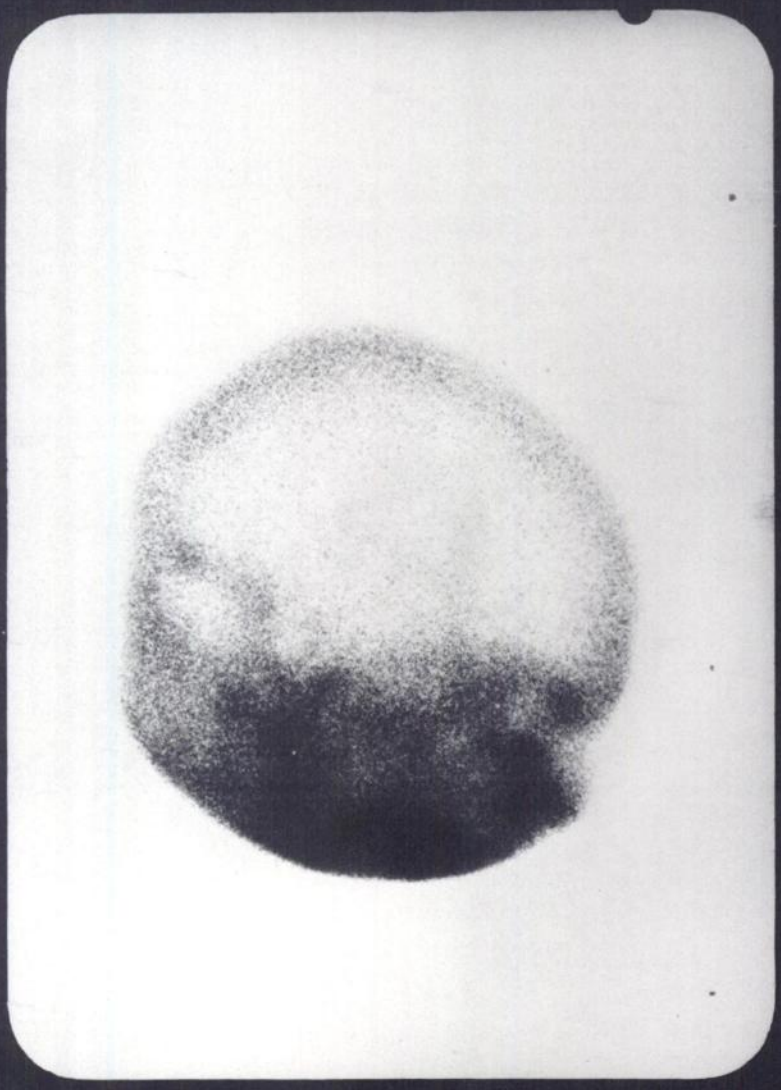

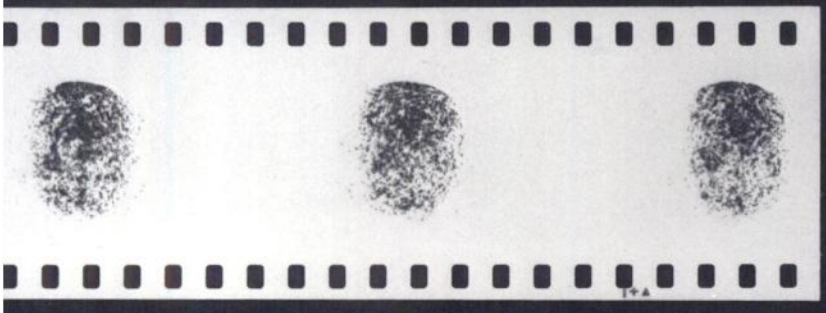

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Searle's Pho/Gamma® L.E.M./Scintistore™ combination extends nuclear medicine to the patient's environment to make GREAT IMAGES.

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And Diagnostic Products Corporation's NEONATAL TSH will give him tomorrow to grow . . . safe from a lifetime of mental retardation.

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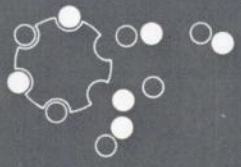

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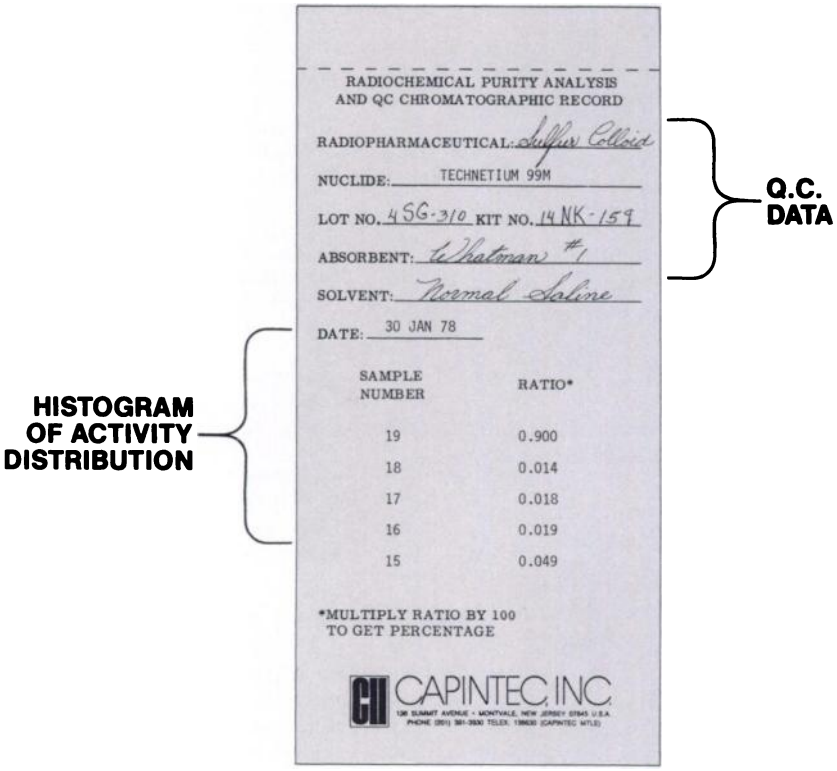

RADIOCHEMICAL PURITY ANALYSIS
AND QC CHROMATOGRAPHIC RECORD

RADIOPHARMACEUTICAL: Sulfur Colloid
NUCLIDE: TECHNETIUM 99M
LOT NO. 4SG-310 KIT NO. 14NK-159
ABSORBENT: Whatman #1
SOLVENT: Normal Saline
DATE: 30 JAN 78

SAMPLE NUMBER	RATIO*
19	0.900
18	0.014
17	0.018
16	0.019
15	0.049

*MULTIPLY RATIO BY 100
TO GET PERCENTAGE

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Q.C. DATA

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The new Capintec CRC-U® computer/printer provides a quick and easy method of computing and recording the target to non-target ratio of imaging compounds as demonstrated by radiochromotographic separation of the imaging compound.

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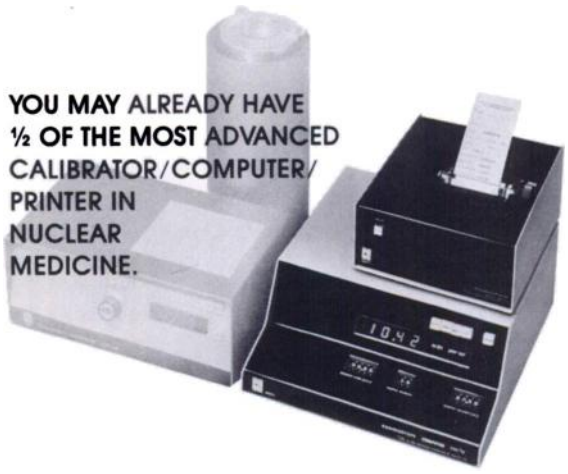

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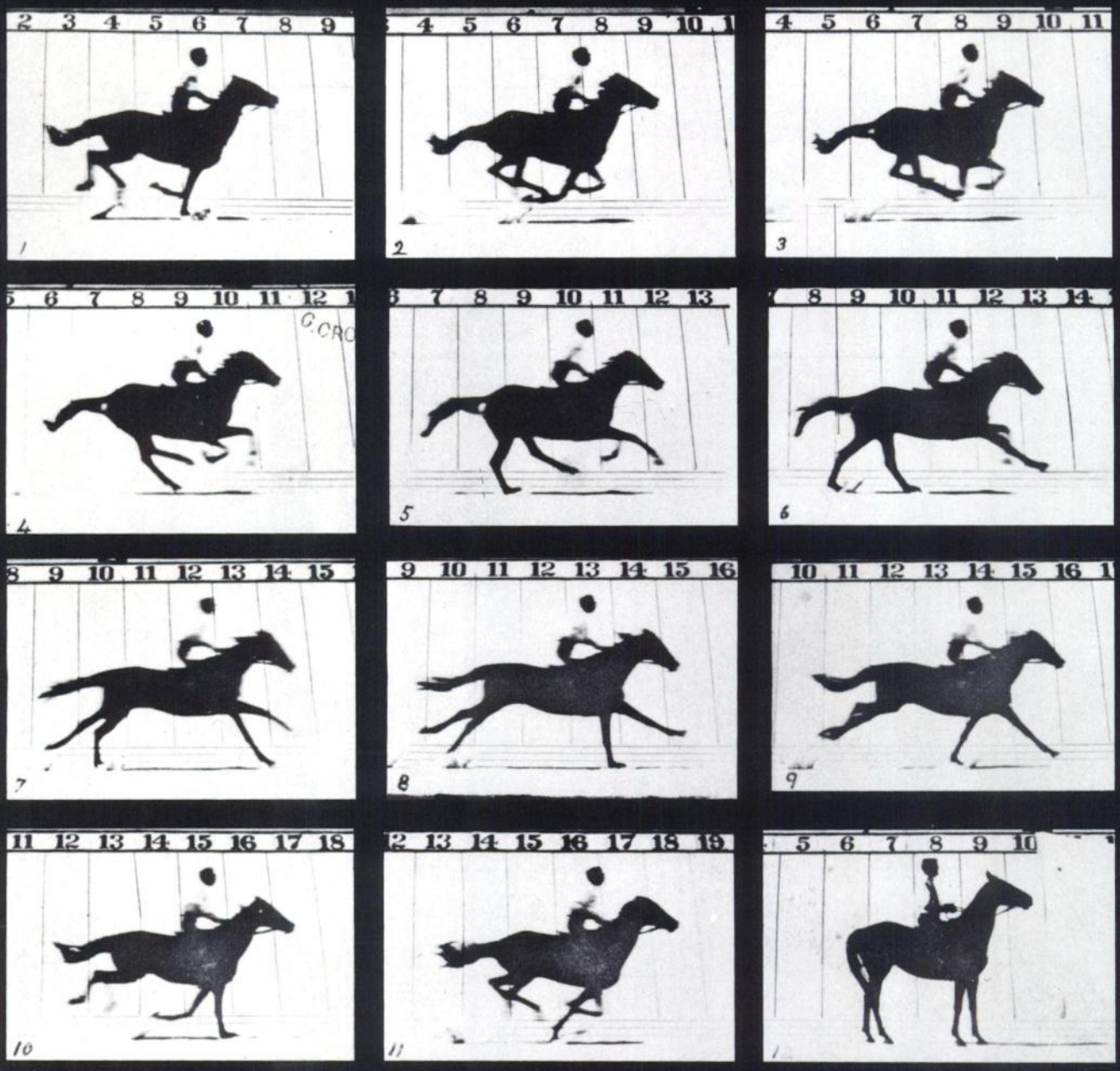


Eadweard Muybridge: *Galloping Horse*, 1878.
International Museum of Photography, Rochester, NY

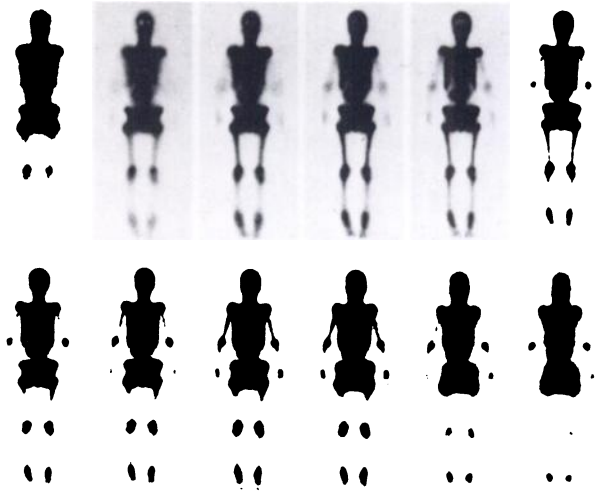
One hundred years ago our concept of how a horse ran was limited to what we thought we saw—the two front legs touching the ground in unison to propel the horse forward, followed by the two hind legs hitting the ground as the front legs recovered. But in 1878, Eadweard Muybridge altered our awareness 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.

It took more than one picture to see that horses fly.

Today, the concept of extending vision by utilizing more than one picture has been introduced into nuclear medicine by Searle's PHO/CON Emission Tomographic Scanner. PHO/CON simultaneously provides 12 tomographic images for in-depth representation of the patient in 12 separate coronal planes; thus providing improved capability for locating lesions, as well as enhancing the interpretation of images in many difficult cases by generating additional information on depth, size, shape, and probable nature. PHO/CON also minimizes the need for multiple-view imaging due to its ability to differentiate between confusing overlying activity and that of the target area of interest, and has often provided valuable clinical information in certain planes that was not evident in the one or two images offered by other nuclear cameras. And, because of a flexibility of format sizes, PHO/CON not only permits a wide variety of studies to be performed—from brain and soft tissue to whole body—but it is rapidly demonstrating its superiority for studies using Gallium-67.

PHO/CON® Emission Tomographic Scanner defines lesions better with 12 GREAT IMAGES.

For additional information on how the 12 great images of the PHO/CON Emission Tomographic Scanner can help you see things other nuclear systems may not, contact Searle Radiographics, a member of the Searle Imaging group.



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With the introduction of the MaxiCamera™ II System to nuclear imaging, GE ushered in new concepts and standards of performance, results, operator convenience, flexible capability with modular electronics, and much more.

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DataCamera provides exceptional bedside imaging and data analysis for both nuclear physicians and cardiologists.

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NUCLEAR PHARMACIST: APPLIcants should have some radiopharmaceutical education and pharmacy degree. We will provide clinical training if necessary. Salary commensurate with experience. Submit resume to: Pharmatopes, Inc., 25721 Coolidge Hwy., Oak Park, Mich. 48237, Attention: Personnel.

NUCLEAR MEDICINE TECHNOLOgist, C.S.R.T.(N.M.), for private imaging facility in Western Canada. Reply to: Mrs. Shirley Almond, Mission Profession Centre, 106, 2303 - 4th Street, S.W., Calgary, Alberta, T2S 2S7 Canada.

STANFORD UNIVERSITY—FULLTIME position in Nuclear Medicine at Assistant Professor level at affiliated teaching Veterans Adm. Hospital (Palo Alto). Desired qualifications: Proven excellence in teaching and in all aspects of clinical Nuclear Medicine, plus research experience. Excellent opportunity for advancement. Stanford is an equal opportunity employer and welcomes nominations of women and minority group members and applications from them. Interested persons please send complete curriculum vitae including names and addresses of references to: Joseph P. Kriss, M.D., Nuclear Medicine—Rm. C022, Stanford University Medical Center, Stanford, CA 94305.

PHYSICIAN, NUCLEAR MEDICINE, opening in 450 bed teaching hospital to head division of Nuclear Medicine, 83,000 diagnostic examinations with full range of diagnostic equipment. Opportunity to plan new equipment acquisition. Desire individual with two year background in Nuclear Medicine—Board Eligible or Board Certified in Nuclear Medicine with interest in full range of Radionuclide imaging procedures particularly cardiac studies. Must have background in Radiology, preferably Board Certification. Equal Opportunity Employer. Contact: Peter K. Spiegel, M.D., Chairman, Section of Diagnostic Radiology, Mary Hitchcock Memorial Hospital, 2 Maynard Street, Hanover, New Hampshire 03755. 603-643-4000, Ext. 2011.

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CONFIDENTIAL SERVICE NATIONwide. We are a search firm dealing nationwide in the Health Care Industry. All fees paid by employer. Forward resume with salary requirements and location preferences to BMI, Health Care Division, P.O. Box 6457, Columbia, S.C. 29260, (803) 787-8710.

NUCLEAR MEDICINE RESIDENCY. 830 bed VA general hospital offers AMA approved two year program. Two positions available July 1979. Located in San Fernando Valley 15 minutes from affiliated hospitals (UCLA and Wadsworth VA). Program covers isotope and ultrasound imaging, in vivo and in vitro procedures, including RIA. Prerequisite: one-two years post graduate training in medicine, radiology, or pathology. Minimum stipend: $20,000. Contact: Marvin B. Cohen, M.D., Chief, Nuclear Medicine Service. Nondiscrimination in employment. VA Hospital, 16111 Plummer St., Sepulveda, CA 91343.

ASSISTANT DIRECTOR FOR DEPARTment of Nuclear Medicine. Challenging, full-time position for certified Nuclear Medicine Physician preferrably with experience in nuclear cardiology. A comprehensive imaging program is supported by a medical physicist, highly skilled technologists, cameras and computers, all in a 247 bed university affiliated, community hospital. Successful candidate will also receive faculty appointment to the Brown University Program in Medicine. Salary and academic rank dependent upon background and experience. Submit resume to: The Miriam Hospital, Personnel Department, 164 Summit Ave., Providence, R.I. 02906. An Equal Opportunity Employer.

NUCLEAR MEDICINE TECHNOLOgist. Applications are invited from Registered Nuclear Medicine Technologists for the position of Technologist I in the Nuclear Medicine Department of the Ottawa Civic Hospital and the Ontario Cancer Foundation. Apply to: Mrs. A. Fox, Personnel Administration, Ottawa Civic Hospital, 1053 Carling Avenue, Ottawa, Ontario, K1Y 4E9.

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NUCLEAR MEDICINE TECHNOLOgist. Junior nuclear medicine technologist openings are available in the Department of Nuclear Medicine of a 247 bed community hospital. Responsibilities will be limited primarily to imaging and computer analyses. Candiate should have a bachelor's degree, be certified or eligible for certification in nuclear medicine and preferably have hands on experience with computers. Senior technologists and a medical physicist are available to provide supervision. Salary and fringe benefits are highly competitive. Submit resume to: The Miriam Hospital, Personnel Department, 164 Summit Ave., Providence, R.I. An Equal Opportunity Employer.

RECENTLY REORGANIZED LABORAtory in a 700-bed community hospital invites applications for positions in radioimmunoasasy and in nuclear medicine imaging. Qualified applicants should be registered as technologists or eligible. Computer experience is desirable. Salary commensurate with experience and comprehensive benefit package. Send resume and letter of application to: Adrienne M. Frier, Employment Supervisor, University Hospital, 1350 Walton Way, Augusta, Georgia 30902—(404) 724-5436. EOE.

RADIOLOGIST, BOARD CERTIFIED in Nuclear Medicine, to join large multispecialty pre-paid medical group. Opportunity to expand department and plan department for new hospital in 1982. Salary negotiable. Liberal fringe benefits. Contact: Hawaii Permanente Medical Group, Inc., 1697 Ala Moana Boulevard, Honolulu, Hawaii 96815. An Equal Opportunity Employer.

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CHIEF NUCLEAR MEDICINE TECHnologist, ARRT registered, 10 years experience. Capabilities include in vivo and in vitro applications. Expert with most equipment and procedures. Interested in supervising, organizing and planning established or new facilities. Reply to Box 800, Society of Nuclear Medicine, 475 Park Ave. South, New York, N.Y. 10016.

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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.

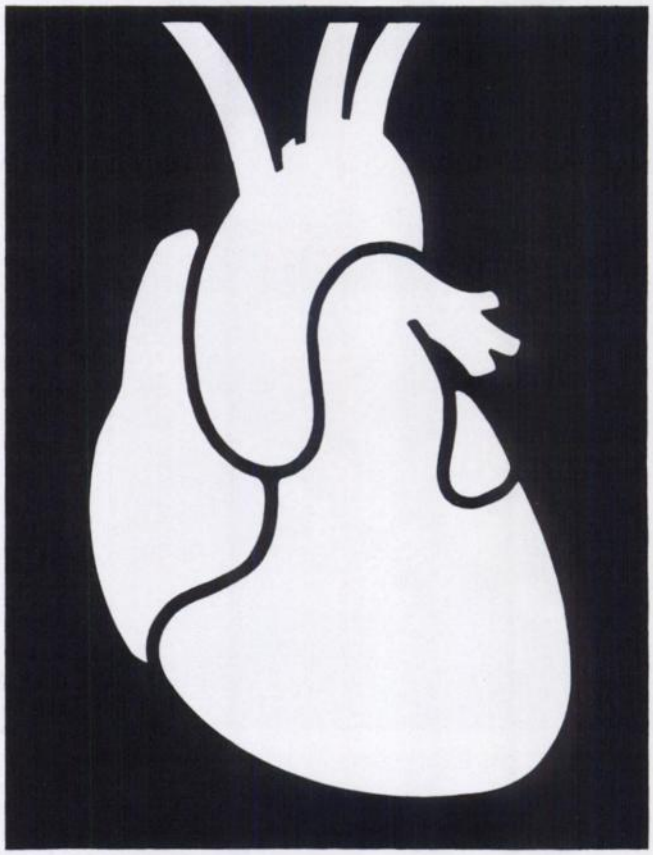
High blood concentrations: Approximately 60% remains in the circulation after 2 hours, approximately 45% after 4 hours (in normal patients).

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.



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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 (HB_sAg) by radioimmunoassay.

physical characteristics

Technetium Tc 99m 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.

table I. principal radiation emission data

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

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

external radiation

The specific gamma ray constant for 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^{-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 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 minimum 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 childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

precautions

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

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

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

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

Safety and effectiveness in children have not been established.

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

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

adverse reactions

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

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[2] 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	0.063
Bladder	0.166
Ovaries	0.082
Testes	0.079
Total Body	0.073

[2]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).

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.

Medical Products Division
Nuclear Products

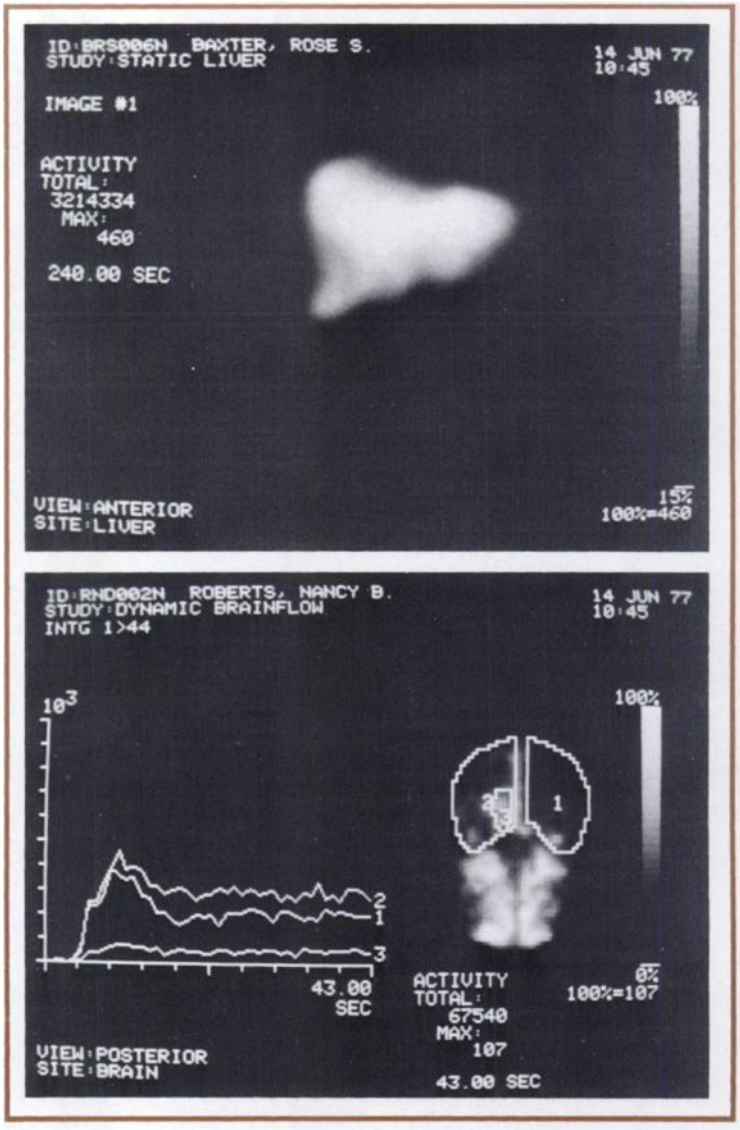
Your image depends on our quality

NMS, the **Artronix Nuclear Medicine System**, is a computer system for the acquisition and analysis of gamma camera image data. **NMS** operates on the Artronix MODULEX multi-task computer system.

NMS consists of a large number of integrated programs which are designed to permit smooth and efficient operation. Various configurations provide for simultaneous acquisition of camera data in either list or frame mode, comprehensive data analysis with interactive graphic capabilities, and programming in both FORTRAN and MUMPS. In addition to many built-in analysis and display features, the system supports customized data acquisition and analysis.

Command Program Sequences provide users with the ability to design studies for complete organ function imaging by merely specifying a string of different imaging commands. This customized study,created in minutes, can be filed away as an organ function protocol available for unlimited usage.

A complete software package operating in conjunction with the **Model 2721/2722 Nuclear Medicine Interface Subsystem** with its cache memory and compendium of gated data acquisition modes provides today's most comprehensive



Nuclear Cardiology acquisition and analysis subsystem.

Bolus Studies can be acquired in combinations of up to 100 frames/second for up to 1,000 total frames. This is the simplest and yet most useful and comprehensive of the analysis procedures.

Tracer Activity Curves provide the basis for the measurement of a broad spectrum of cardiac performance parameters, including left-to-right shunts, cardiac output, stroke volume, pulmonary transit time and both left and right ventricular ejection fractions.

Blood Pool Studies can be acquired directly in frame mode into the cache memory in the NMS interface with the averaged cardiac cycle ranging from 8 to 128 data frames of sizes 128x128 to **32x32** respectively.

Left ventricular ejection fraction, peak fractional ejection rate, peak circumferential fiber shortening, and peak flow time measures are computed and displayed along with the ED and ES images and LV activity curves.

For more information about the **Artronix Nuclear Medicine System**, call or write Artronix, Inc., or visit **Booth 206-208** at the 25th Annual Meeting of the Society of Nuclear Medicine, Anaheim, June 27-30, 1978.

Nuclear Medicine System

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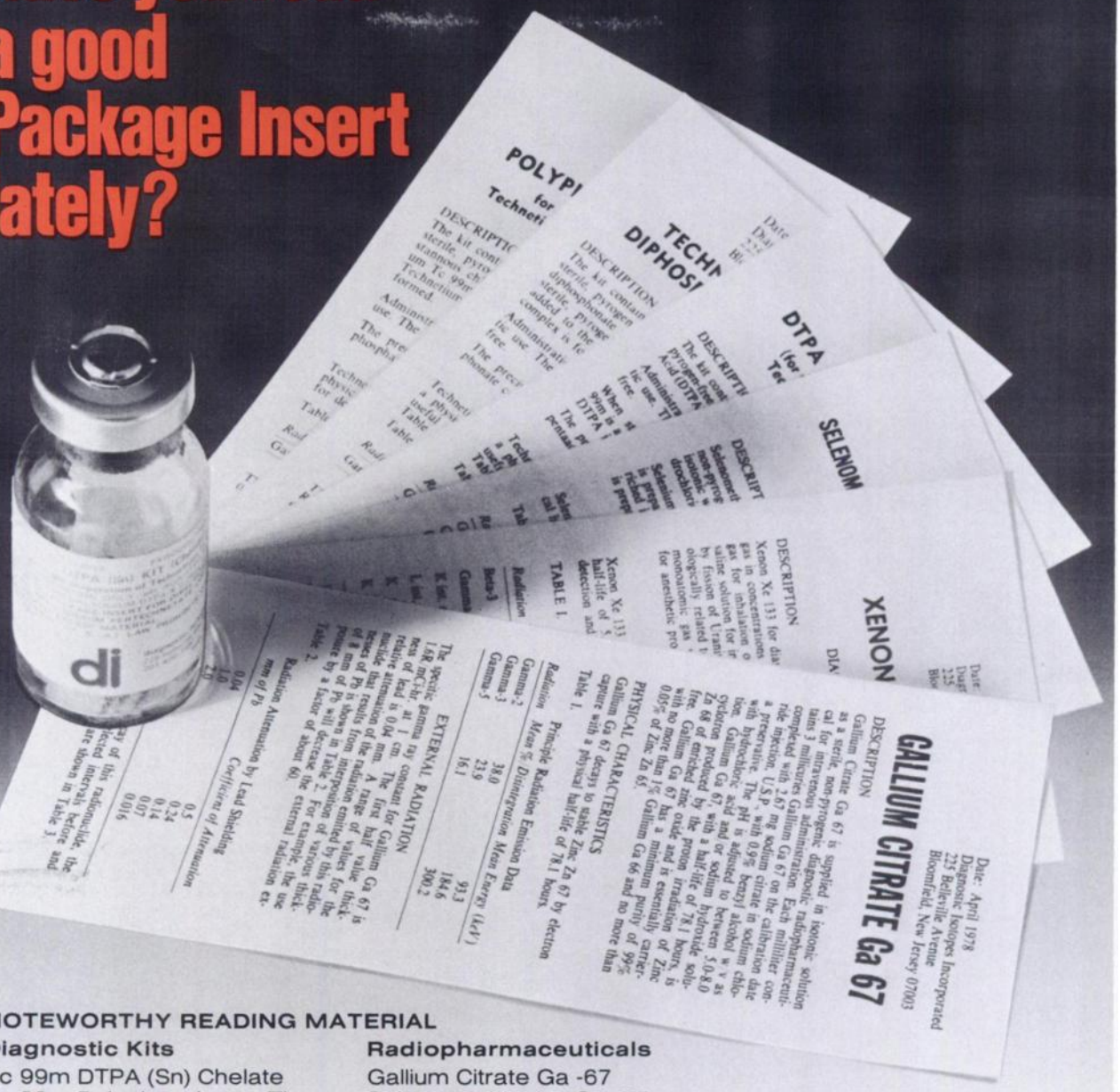

NOTEWORTHY READING MATERIAL

Diagnostic Kits	Radiopharmaceuticals
Tc 99m DTPA (Sn) Chelate	Gallium Citrate Ga -67
Tc 99m Polyphosphate - Tin	Selenomethionine Se -75
Tc 99m Diphosphonate - Tin	Xenon - 133 Gas
	Xenon - 133 Saline

Accessories: "Auto Mate" Xenon Gas Hand Held Dispenser.
Tungsten Syringe Shield.

Our package inserts say a lot about our products and we think you'll find them interesting reading. They won't tell you much about our company though, so we're offering some interesting reading on Diagnostic Isotopes, too. Let us send you a complete package. It's yours for the asking.

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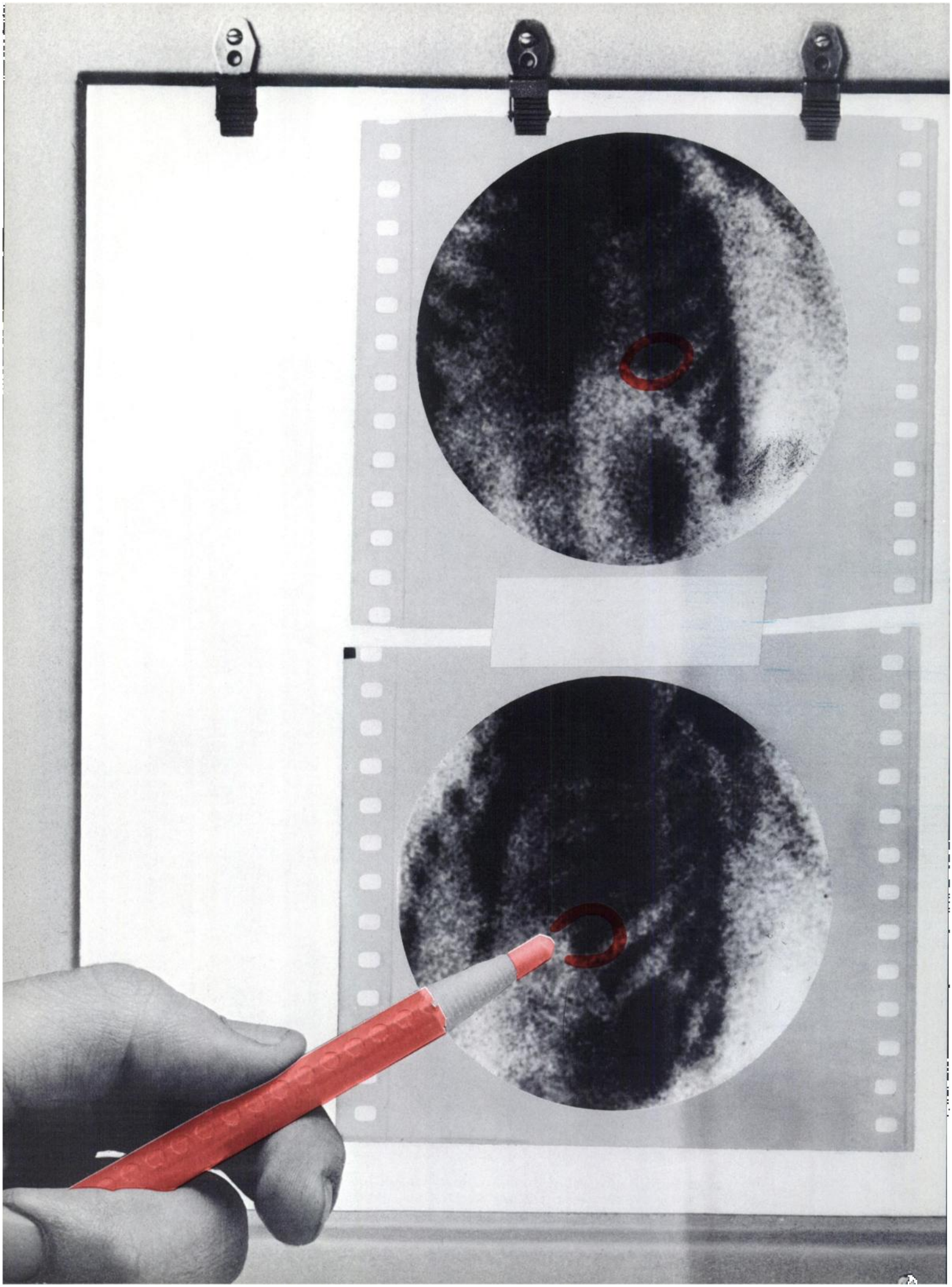


Helps detect, localize, and delineate acute myocardial infarction

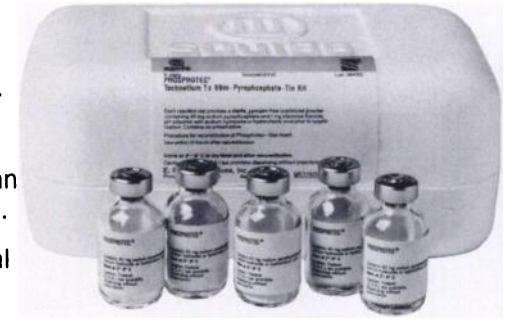
Phosphotec®

Technetium Tc 99m-Pyrophosphate-Tin Kit

In detection of acute myocardial infarction, "the agent of choice [of the several ^{99m}Tc complexes] at the present time is ^{99m}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}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.



Medotopes® TWENTIETH ANNIVERSARY SQUIBB®

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

See next page for brief summary.

New from

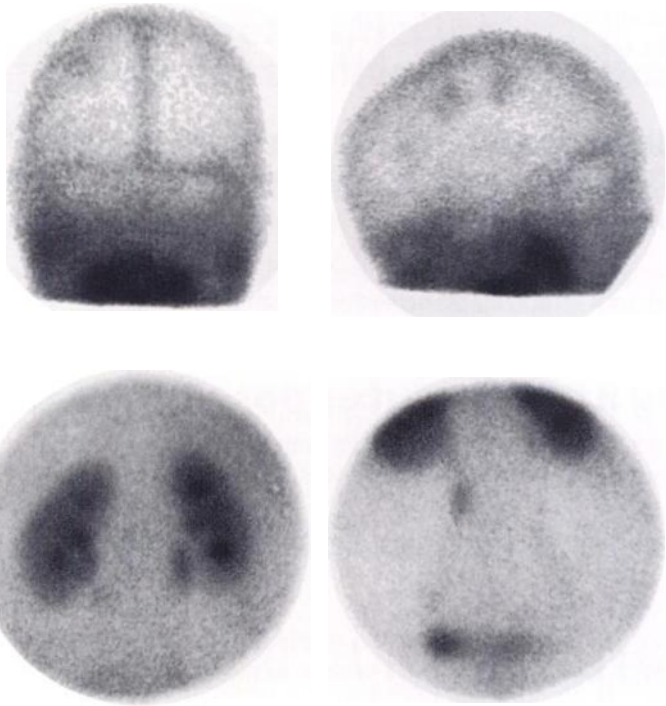
New England Nuclear

NEN

GLUCOSCAN™

Technetium Tc 99m Gluceptate Sodium Kit (Glucoheptonate)

For efficiency in brain and renal imaging



GLUCOSCAN

May 1978

Technetium Tc 99m Gluceptate Sodium Kit

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^{-6}.

Table 3. Radiation Attenuation by Lead Shielding

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

CLINICAL PHARMACOLOGY: 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)
Catalog Number NRP-180C (30 vial kit)

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

CALL TOLL-FREE: 800-225-1572 Telex: 94-0996 (In Massachusetts and International: 617-482-9595)

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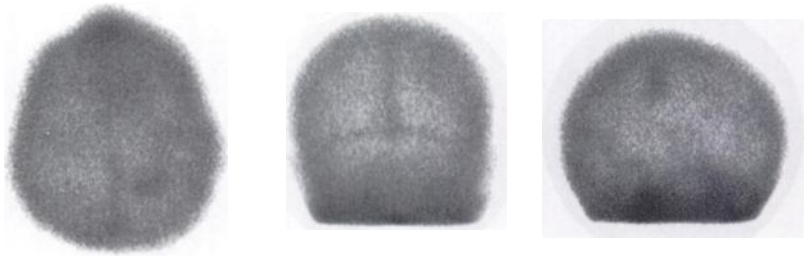
GLUCOSCAN™
Technetium Tc 99m Gluceptate Sodium Kit

for brain imaging:

Considered superior to technetium pertechnetate or DTPA[1,2,3]

Vert Post R Lat

Gluceptate (2 hrs)



Vert Post R Lat

Pertechnetate (3 hrs)

Higher target to background ratios

"The results of the computer background study for ^{99m}Tc GH *versus* $^{99m}TcO_4$ show an average calvaria/brain ratio of 2.1 and 1.6 for ^{99m}Tc GH and $^{99m}TcO_4$, respectively, at 90 min. after injection." Rollo et al[2]

May detect lesions not seen with other agents

"...^{99m}Tc glucoheptonate concentrates in all lesions which accumulate $^{99m}TcO_4$ or ^{99m}Tc DTPA, and in certain cases, appears to localize lesions which do not concentrate other agents." Rollo et al[2]

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

Optimal imaging at 90 minutes postinjection, without $KClO_4$

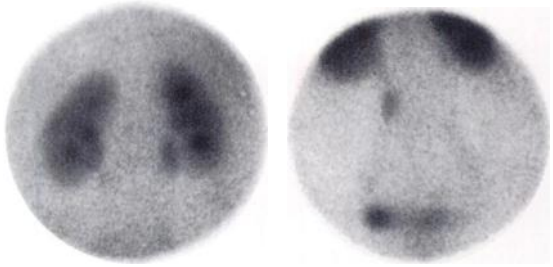
"^{99m}Tc glucoheptonate combines the absence of oral activity with the convenience of obtaining highly diagnostically accurate images at 90 minutes." Rollo et al[2]

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."[4]

for dynamic and static renal imaging:

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



10 min 32 min

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[5]

Safe method to assess renal function and morphology in patients allergic to iodinated contrast agents[5]

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[6]

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 ^{99m}TC GH; $^{99m}TcO_4$; and ^{99m}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 Gluceptate 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.

NEN New England Nuclear

See following page for full prescribing information.

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 2.0 mg sodium thiosulfate (anhydrous), 2.3 mg edetate disodium and 18.1 mg gelatin, an A syringe containing 1.5 ml of sterile, pyrogen-free 0.148 N hydrochloric acid solution and a B syringe containing 1.5 ml of sterile, pyrogen-free aqueous solution of 38.8 mg sodium biphosphate (anhydrous) and 11.1 mg sodium hydroxide. When sterile pyrogen-free Sodium Pertechnetate Tc99m is combined with these components according to the enclosed procedure, Tc99m labelled 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.

TABLE I. Principal Radiation Emission Data

Radiation	Mean % / Disintegration	Mean Energy (keV)
Gamma-2	90.7	140.5

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

External Radiation: The specific gamma ray constant for Technetium Tc 99m is 0.8 R/mCi-hr at 1 cm. The first half value thickness of lead (Pb) for Technetium Tc 99m is 0.2 mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of lead (Pb) is shown in Table II. For example, the use of 2.7mm 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	10-1
1.8	10-2
2.7	10-3
3.6	10-4
4.5	10-5

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

TABLE III. Physical Decay Chart: Tc99m, 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

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 2½ 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 Kupffer 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.

Contraindication: 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 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.

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.

This radiopharmaceutical preparation should not be administered to the patients who are pregnant or during lactation unless the benefits to be gained outweigh the potential hazards. Ideally, examination 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 non-pyrogenic. It is essential that the user follow the directions carefully and adheres to the 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 Tc99M solutions containing more than 10 micrograms/ml of aluminum ion not be used for formation of the Technetium TC99m 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 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 Tc 99m 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.

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.

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.

TABLE IV. Radiation Doses (2)

Tissue	Absorbed Radiation Doses (Rads) (8mCi Tc99m) Normal Liver		(300 uCi Au-198) Diffuse Parenchymal Disease early intermediate			intermediate advanced
	Tc99m	Au-198	Tc99m	Au-198	Tc99m	Au-198
Liver	2.7	12.0	1.7	7.2	1.3	5.7
Spleen	1.7	3.6	2.2	11.0	3.4	17.0
Bone Marrow	0.22	0.81	0.36	1.4	0.63	2.7
Testes	0.0088	0.011	0.017	0.033	0.026	0.057
Ovaries	0.045	0.042	0.065	0.081	0.096	0.14
Whole-body	0.15	0.42	0.15	0.42	0.14	0.42

(2) Modified from: Summary of Current Radiation Dose Estimates to Humans with Various Liver Conditions from Tc99m Sulfur Colloid, MIRD Dose Estimate Report No. 3 J. Nucl. Med. 16 No. 1, 108A-B (1975); and 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 99m Sulfur Colloid Injection. Gloves should be worn during the entire preparation. Proper radiation safety precautions should be maintained at all times.

1. Remove central disc of aluminum crimp cap from sterile freeze-dried reaction vial.
2. Place the reaction vial into a lead vial 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.
3. Using a shielded syringe, aseptically inject 1-3 milliliters containing the necessary Technetium Tc99m activity of sterile sodium pertechnetate Tc-99m solution into the reaction vial. Do not use sodium pertechnetate Tc 99m solution if it contains foreign matter or more than 10 micrograms of aluminum (sodium pertechnetate Tc 99m 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 Tc 99m should be done with sterile pyrogen-free saline for injection that contains no preservative.
4. Place a lead shield over the vial shield and dissolve the reagent by gently swirling.
5. Attach a sterile needle to an "A" syringe and inject its entire contents into the reaction vial and swirl again.
6. Transfer the reaction vial from vial shield and place in a vigorously boiling water bath (water bath should be shielded with 1/8" to 1/4" lead) deep enough to cover the entire liquid contents of the vial. Keep the vial in the water bath for at least three minutes (may be kept up to 10 minutes).
7. 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.
8. Attach a sterile needle to the "B" syringe and antiseptically inject the entire contents into the reaction vial.
9. Insert necessary information on accompanying radioactive self-adhesive shield label and on the tag of the reaction vial.
10. Allow to cool to room temperature before use. Maintain adequate shielding of the radioactive colloid preparation at all times.
11. Use within 6 hours after preparation.
12. 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 (15-25° C).

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.

Application has been filed with the U.S. Nuclear Regulatory Commission for distribution of this radiopharmaceutical to persons licensed pursuant to Section 35.14 and Section 35.100, Group III, of 10 CFR Part 35, or under equivalent licenses of agreement states, and is still pending.

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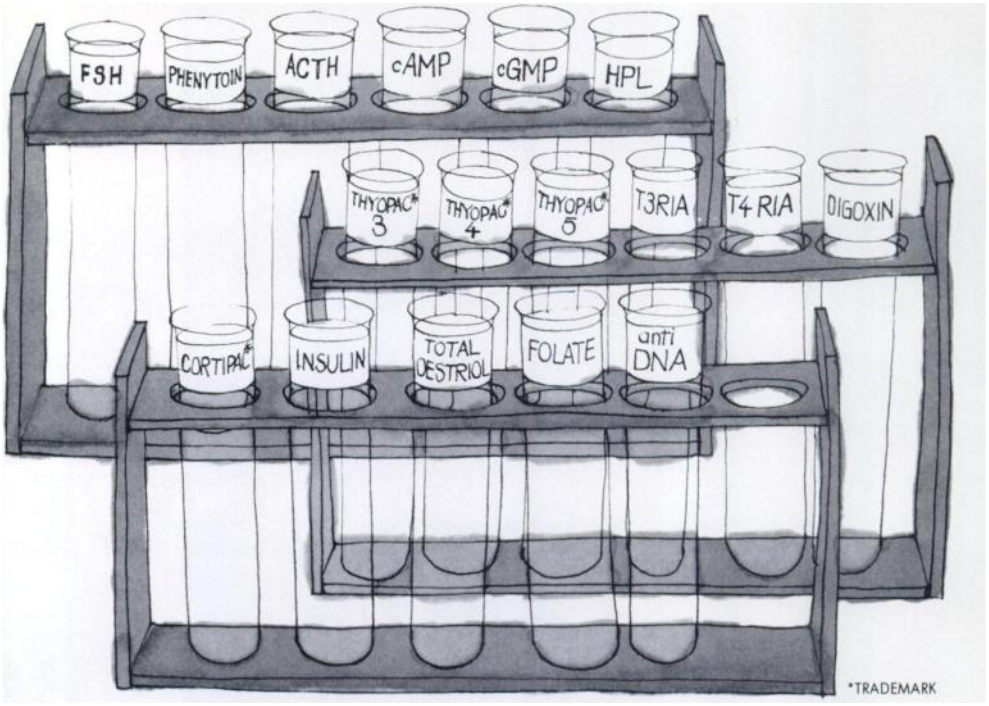

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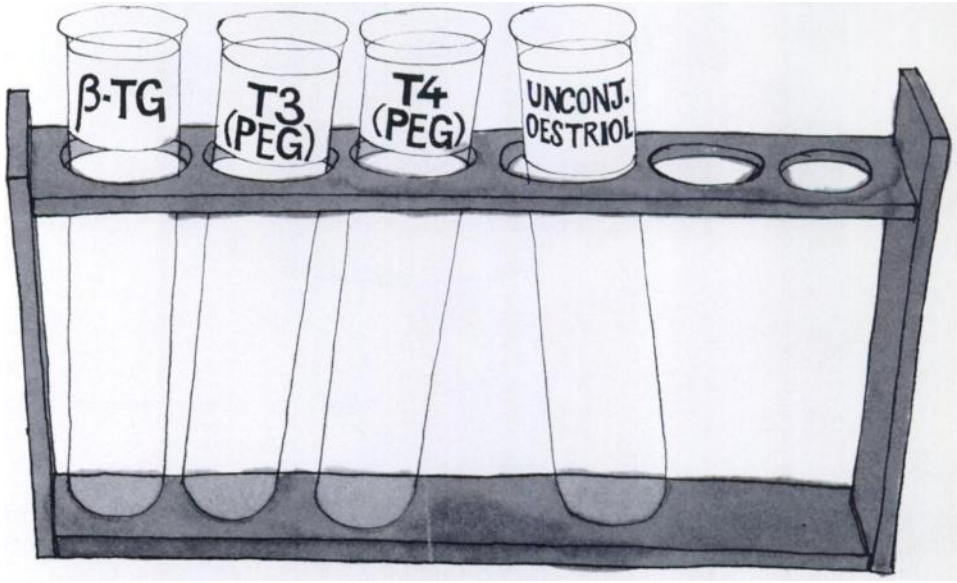

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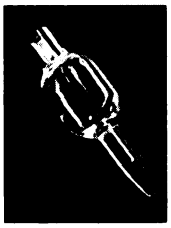

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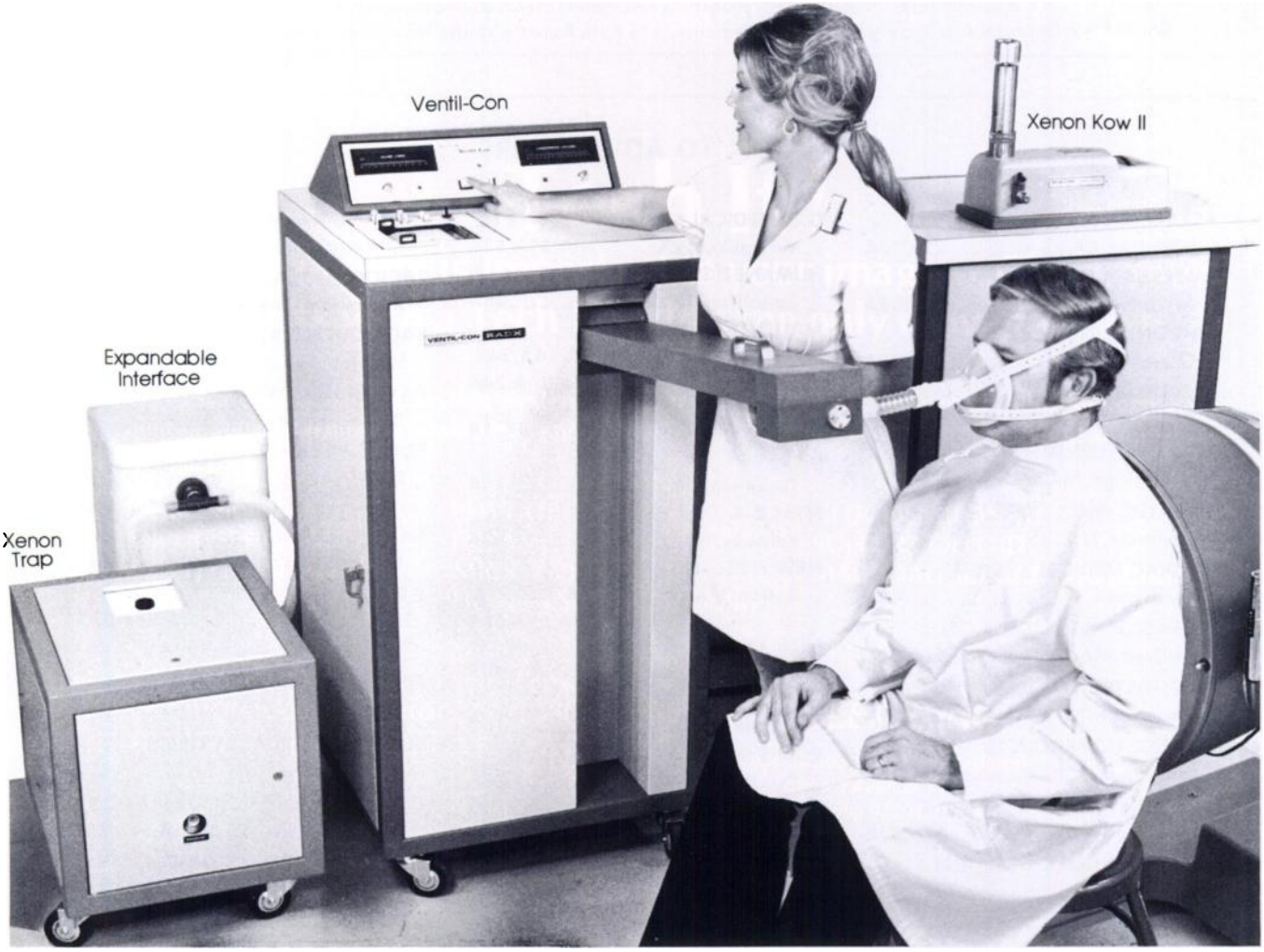

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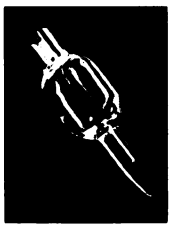

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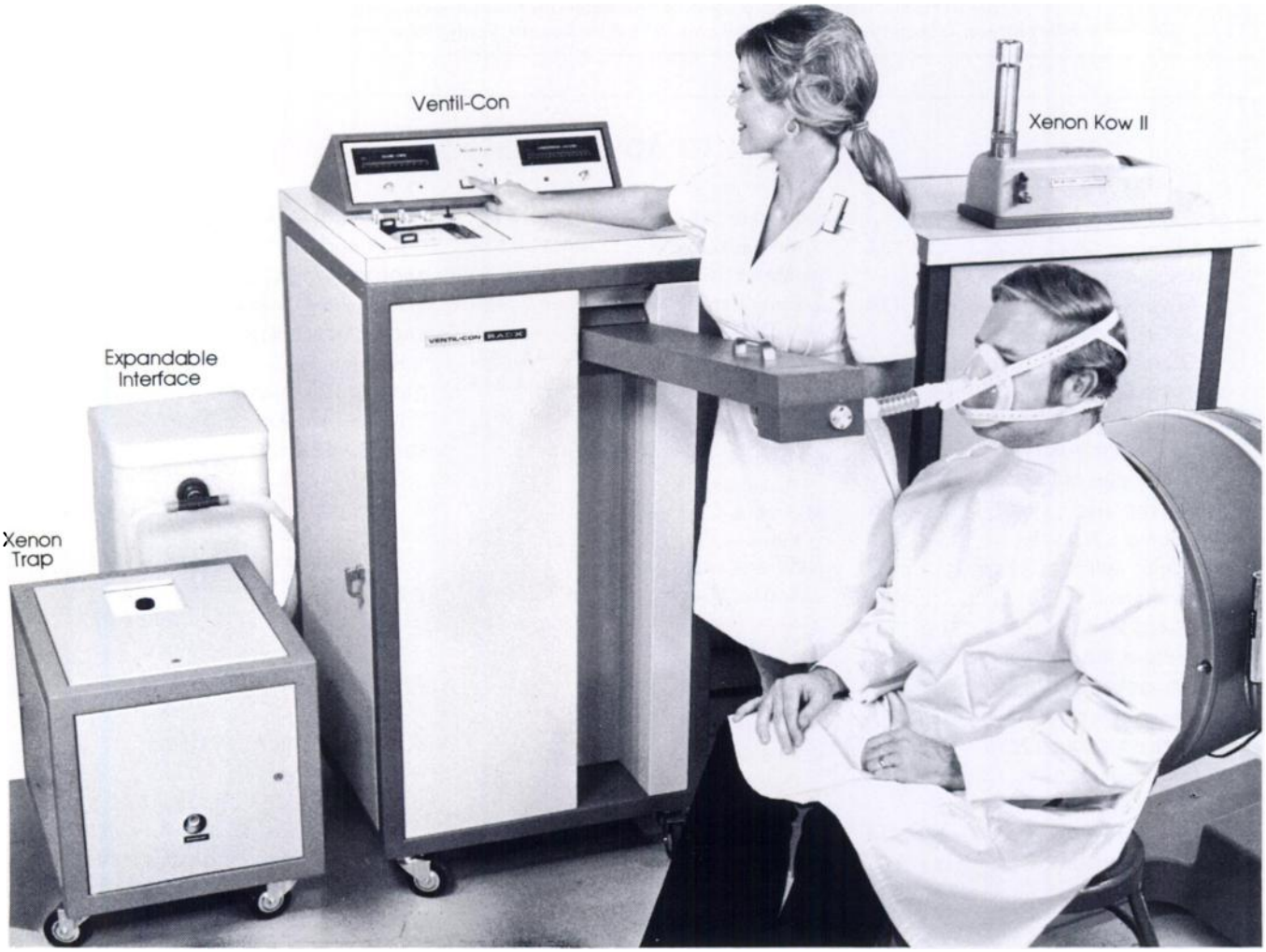

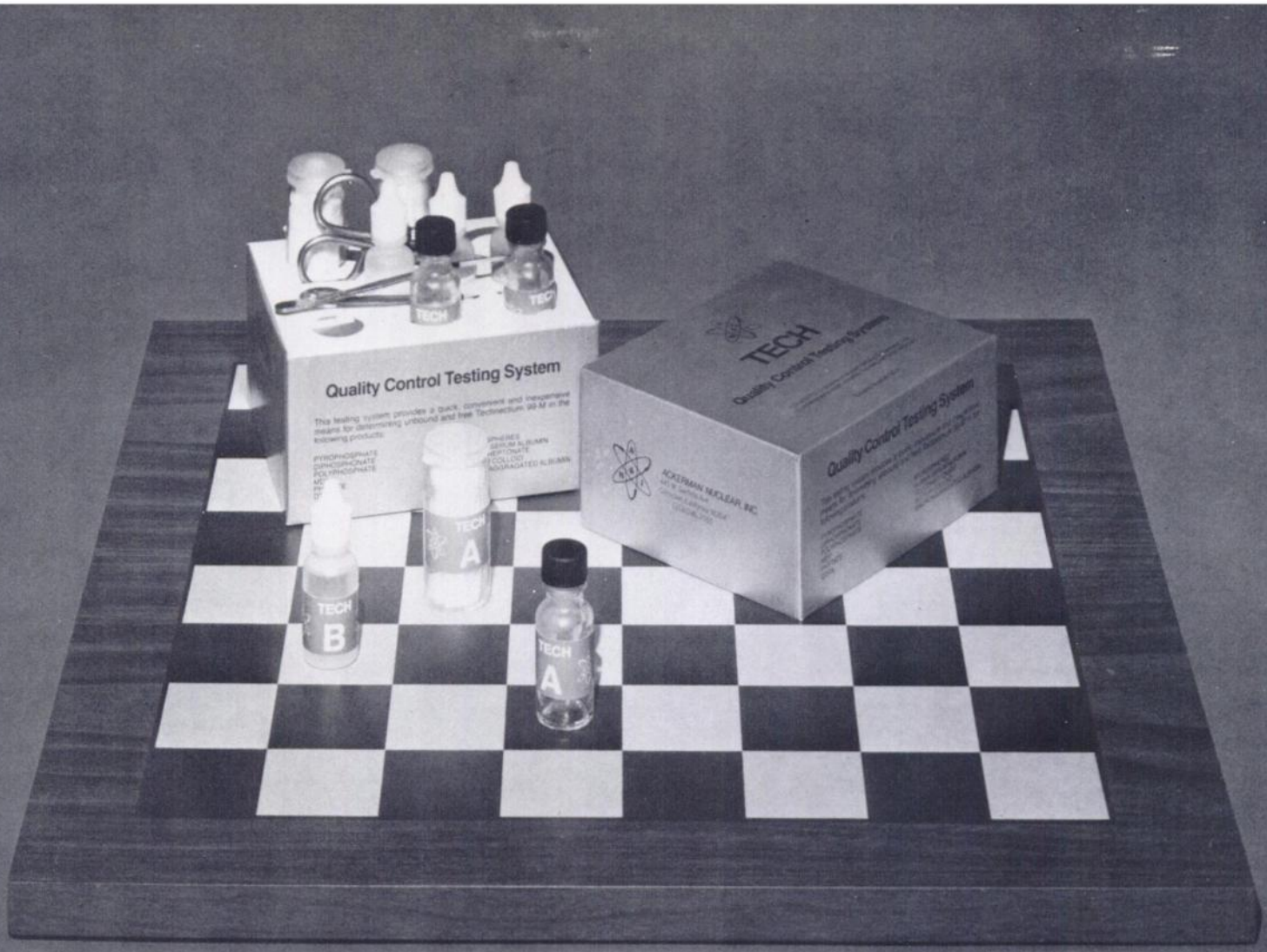

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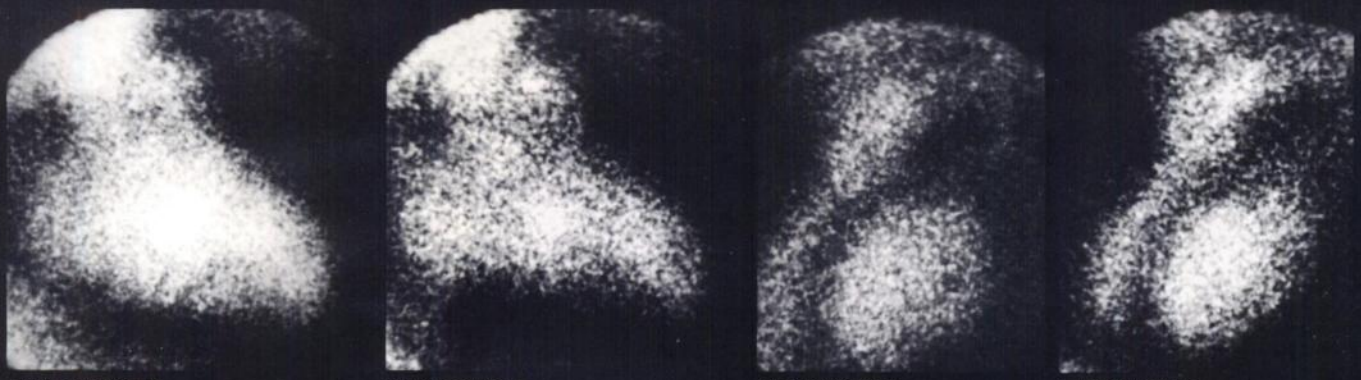
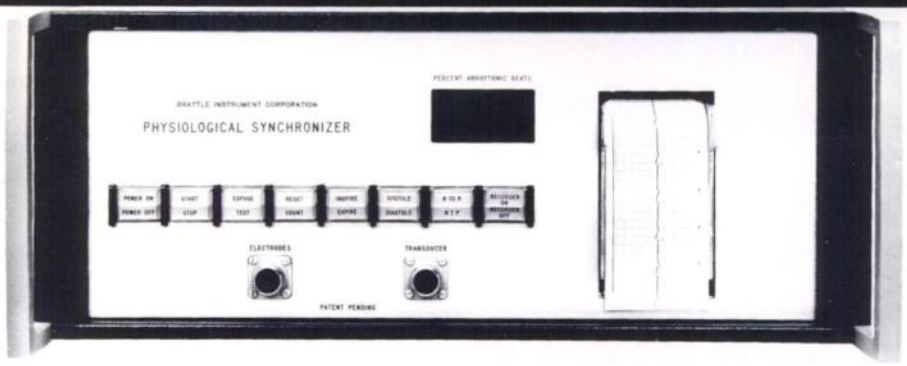


RAO, DIASTOLE | RAO, SYSTOLE | LAO, DIASTOLE | LAO, SYSTOLE

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



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Brattle Instrument Corporation

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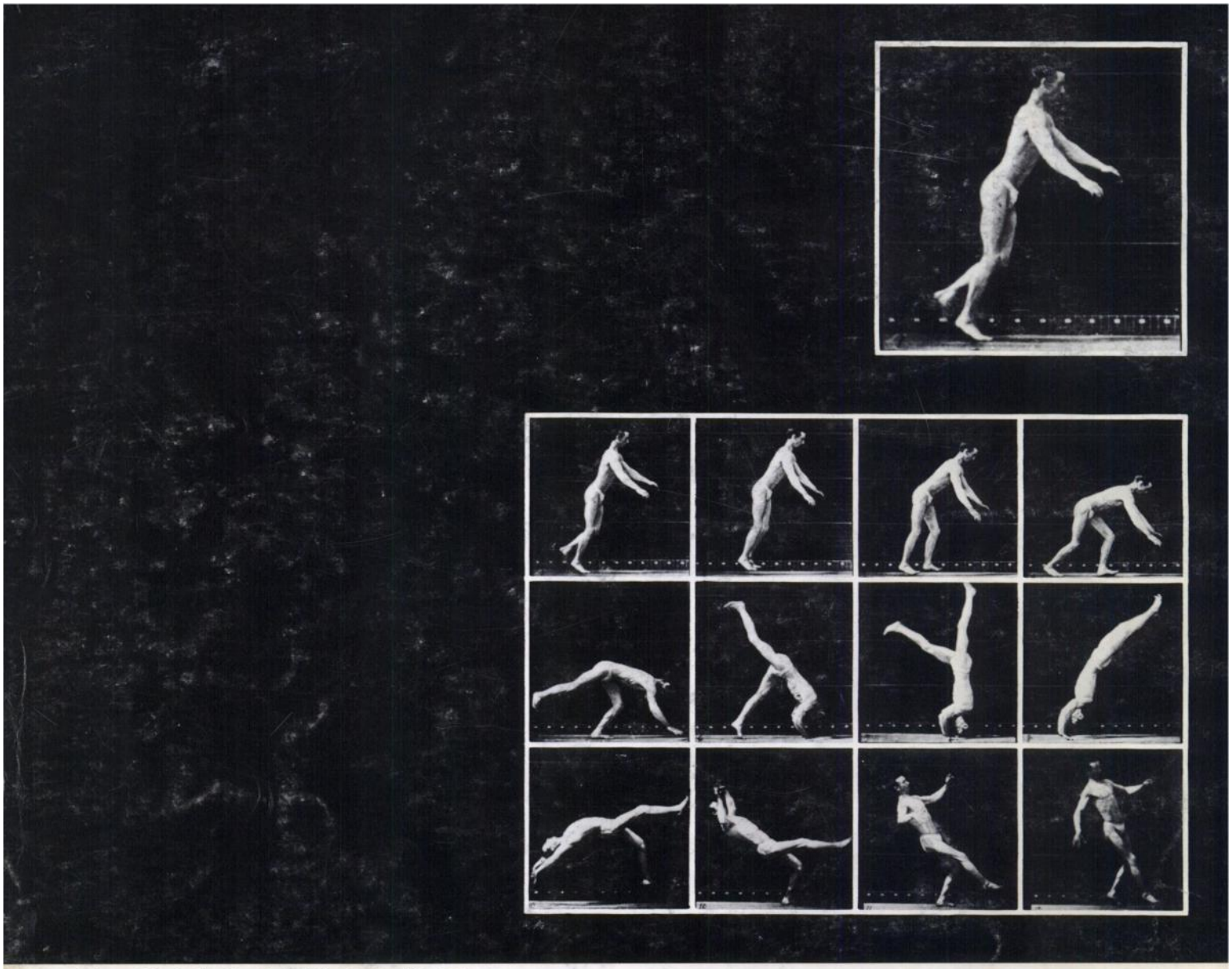

Eadweard Muybridge: *Man Doing A Headspring*, Plate 365
International Museum of Photography, Rochester, NY

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