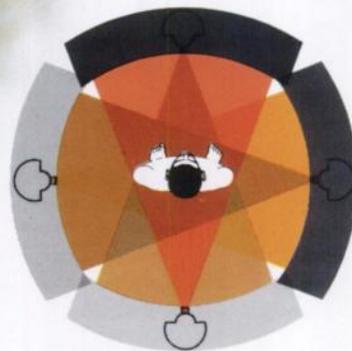


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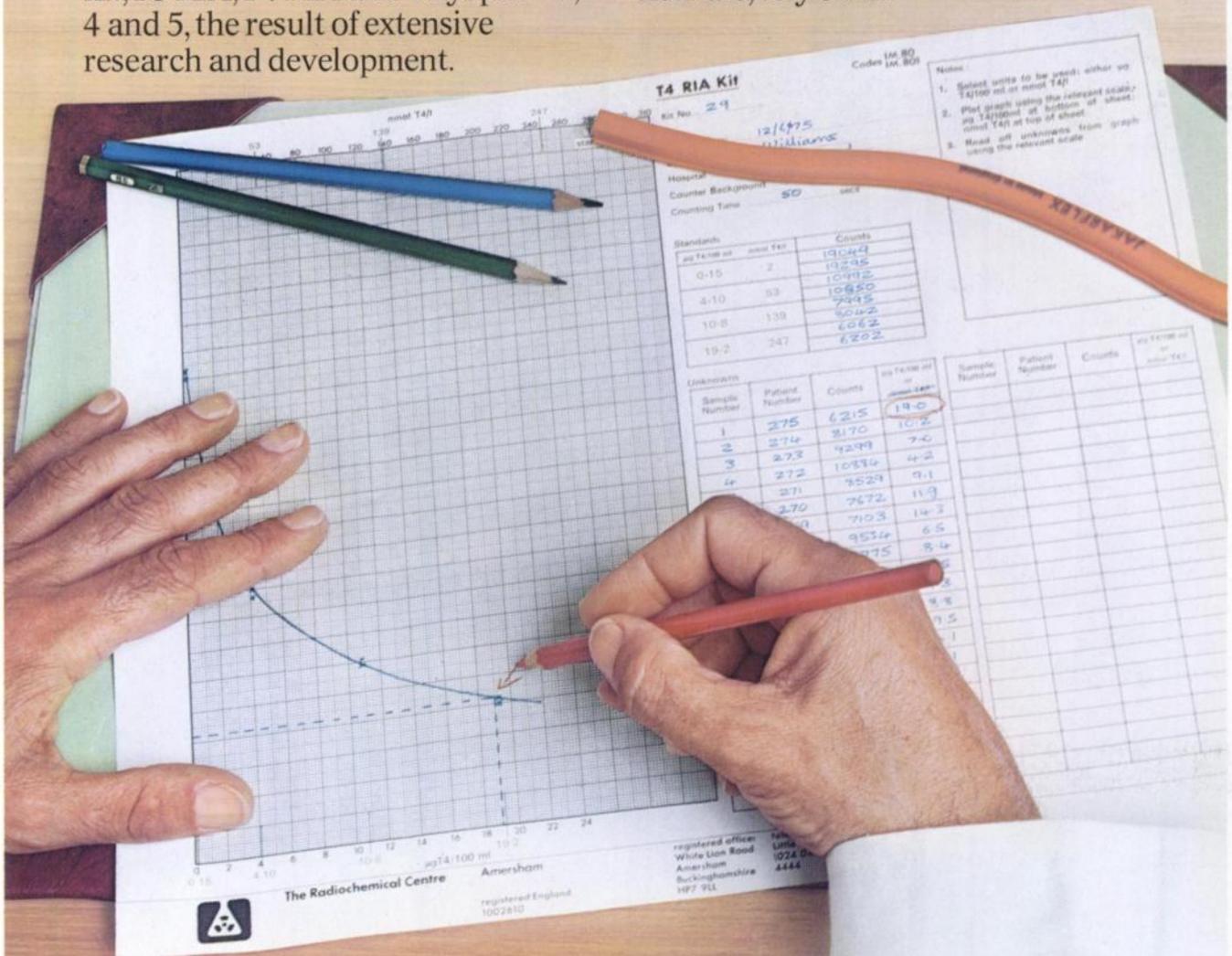
# If you get an odd result when using one of our thyroid testing kits, there's something wrong with the patient.

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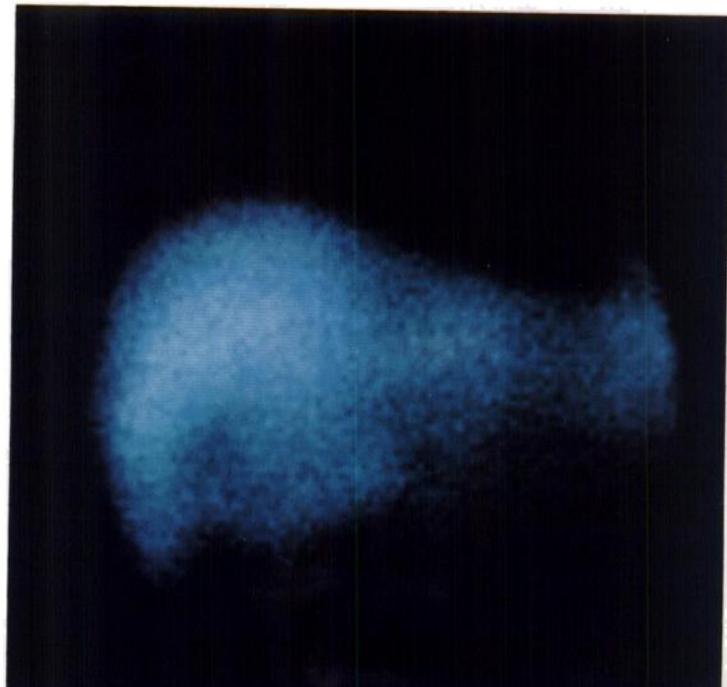
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## Thyroid function kits

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Full information is available on request.  
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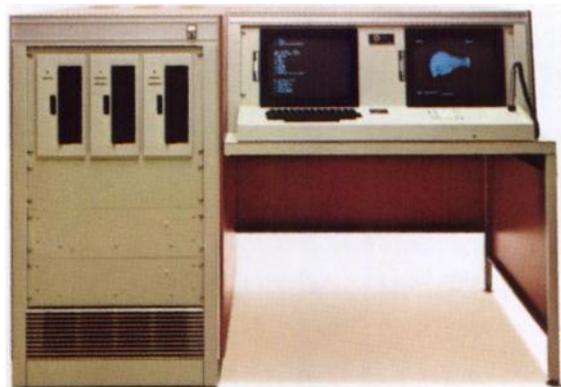
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You are entering a remarkable era of diagnostic advancement. Instead of being limited to a single imaging method, you will take advantage of many techniques, choosing them to meet your specific diagnostic criteria and the condition of your patient.

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# IMAGING: The Living Art



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**Searle Radiographics Inc.**  
Subsidiary of G. D. Searle & Co.

# Abington Memorial chose a camera for maximum image quality and convenience.



## The choice: The Raytheon XL-91

The 520-bed Abington Memorial Hospital in Abington, PA, outside Philadelphia, has added a new Raytheon XL-91 gamma camera to its new wing. And right from start-up the XL-91 has been producing images of superior resolution, with much greater patient accessibility and operator convenience than other equipment.

The reasons for the XL-91's success at Abington are clear. At 16½ inches the XL-91 provides the widest undistorted field of view of any gamma camera. The XL-91's exclusive Autocomp circuitry achieves  $\pm 2\%$  uniformity and — with as many as four memories — permits users to calibrate to four different isotopes or collimators.

Patient comfort, operator convenience, superior high resolution images. No wonder Abington Memorial had the XL-91 working a full patient schedule just days after delivery. And outstanding customer acceptance of the XL-91 — such as at Abington Memorial — is the reason Raytheon has had to expand its sales and service coverage greatly. From coast to coast, wherever you are, Raytheon is now near you.

If you'd like more information on the XL-91, write or phone Raytheon Company, Medical Electronics, 70 Ryan Street, Stamford, CT 06907. Telephone: 800-243-9058. We will put you in touch with your nearest Raytheon sales engineer.

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# Profile of the



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**Controlled number of particles per vial** (approximately 900,000) allows you to minimize the number injected and still attain accurate images.

**High Labeling Efficiency.** Technetium 99m uptake is normally higher than 99% throughout the day for superior perfusion information without interference from background activity.

**See and compare for yourself.** Our new brochure offers you a comparative look at lung imaging agents—side by side. Plus more information on 3M Brand INSTANT MICROSPHERES. Write for it today.

A BRIEF SUMMARY OF PRODUCT INFORMATION  
ALBUMIN MICROSPHERES (HUMAN) (10-35 $\mu$ , DRIED)  
INSTANT MICROSPHERES FOR LABELING WITH  
TECHNETIUM 99m.

**INDICATIONS** Scintillation imaging of the lungs with <sup>99m</sup>Tc labeled Albumin Microspheres is indicated as an adjunct to other diagnostic procedures whenever information about pulmonary circulation is desired.<sup>4,5</sup> The most useful clinical applications of lung imaging are in the diagnosis of 1) pulmonary embolism, 2) chronic obstructive pulmonary diseases such as emphysema and chronic bronchitis, 3) pathological conditions which impede pulmonary abscess, and 4) other pulmonary diseases such as pneumonia and tuberculosis. **CONTRAINDICATIONS** The safety of Albumin Microspheres in patients with a known right-to-left cardiac shunt has not been established and its use in such patients is contraindicated.

**WARNINGS** The possibility that hypersensitivity reactions may occur should be considered whenever protein-containing materials such as 3M Brand Instant Albumin Microspheres are administered. Administration of epinephrine, antihistamines and corticosteroid drugs should be considered whenever a hypersensitivity reaction occurs. Since <sup>99m</sup>Tc is excreted in milk during lactation, formula-feedings should

be substituted for breast-feedings. Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides. **PRECAUTIONS** As in the use of any other radioactive material, care should be taken to insure minimum radiation exposure to the patient, consistent with proper patient management, and to insure minimum radiation exposure to occupational workers. **ADVERSE REACTIONS** The most frequently reported adverse reactions associated with the use of Albumin Microspheres are transient facial flushing and dyspnea. Less frequent adverse reactions are transient nausea, perspiration and cyanosis. An adverse reaction, which occurs rarely, is severe respiratory distress. The literature contains one report of an alleged anaphylactoid reaction to Albumin Microspheres. Administration of epinephrine, antihistamines and corticosteroid drugs should be considered whenever a hypersensitivity reaction occurs.

For more information, write or call toll free: 1-800-328-1671.

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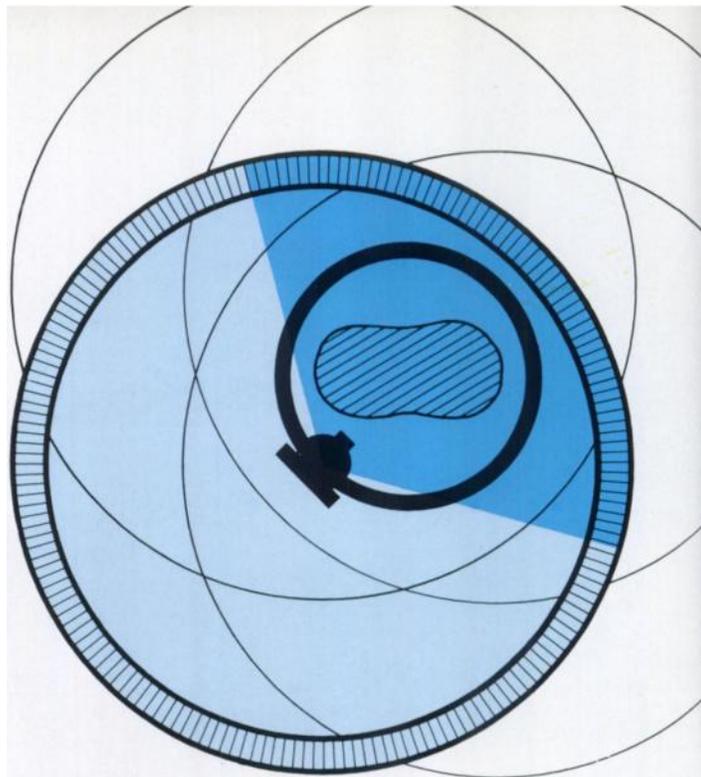
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## TechneColl<sup>®</sup> Sulfur Colloid Kit

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.

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# Technecoll<sup>®</sup>

## 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 2 1/2 minutes. Uptake of the radioactive colloid by organs of the reticuloendothelial system is dependent upon both their relative blood flow rates and the functional capacity of the phagocytic cells. In the average 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 non-pyrogenic. 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 1/4 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 1/4 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.**

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

\*\*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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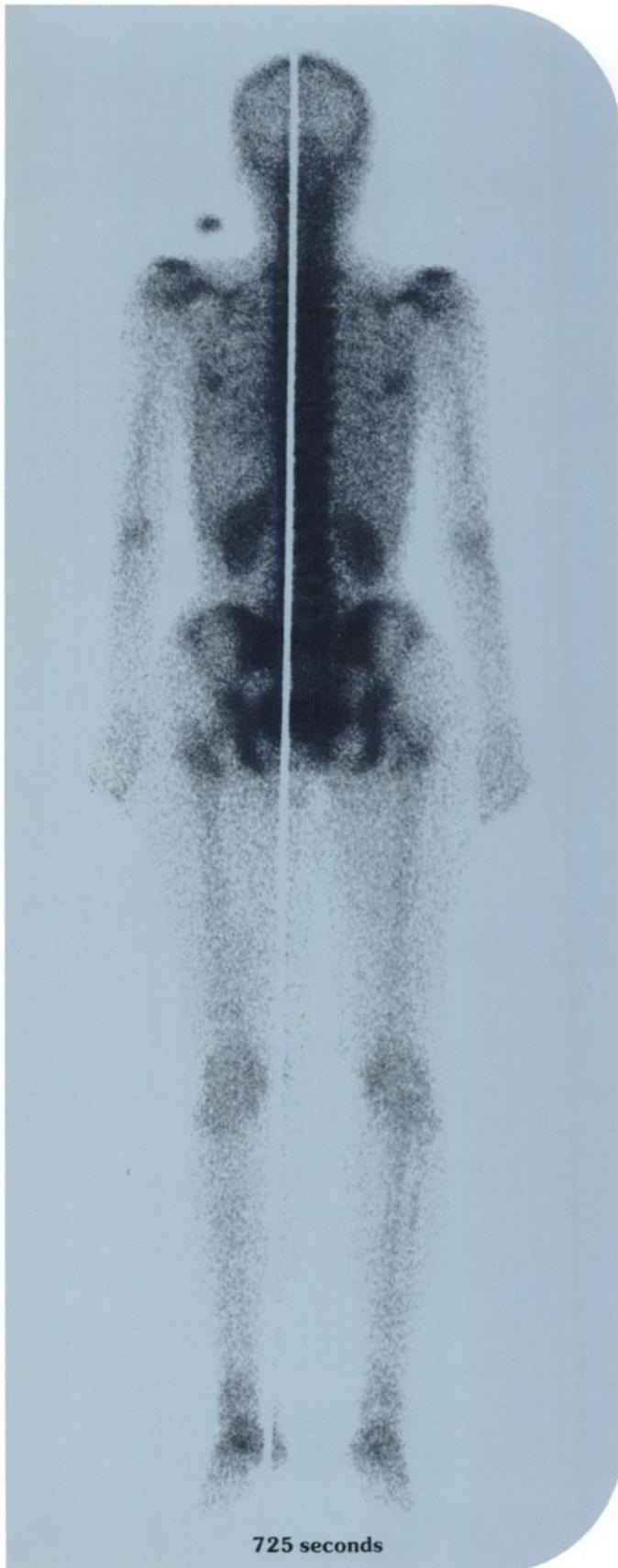
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**Something is missing from this image.  
And it's about time.**



# Now, single-pass whole body scanning from Ohio-Nuclear. With no artifact.



**A gap or zipper often results from double-pass scanning. Also additional artifacts are caused by patient head or body motion.**



**With single pass, artifacts are eliminated. Fast whole body scanning minimizes patient movement and improves diagnostic data.**

**For the first time, Ohio-Nuclear Sigma 410 or Series 110 gamma cameras scan the whole body with one pass—in 3 to 10 minutes.**

One pass obtains one complete image. Artifacts are eliminated. No zipper. No gap. Based on that single-pass image, you can conduct immediate static studies, without patient repositioning or collimator changes. *Result:* enhanced image quality and increased diagnostic confidence through a whole body/single-pass camera system.

#### **Fast whole body scans.**

The key to Ohio-Nuclear AreaScan single-pass capability is a single-axis diverging collimator and integral electronics. This design allows you to move the camera longitudinally above or below the patient, to get a whole body scan in a single pass and in a fraction of the time needed for a double pass. Thus, study time is reduced and technologist/physician time is saved. *Result:* Increased patient throughput, better camera utilization.

#### **Minimal space requirement.**

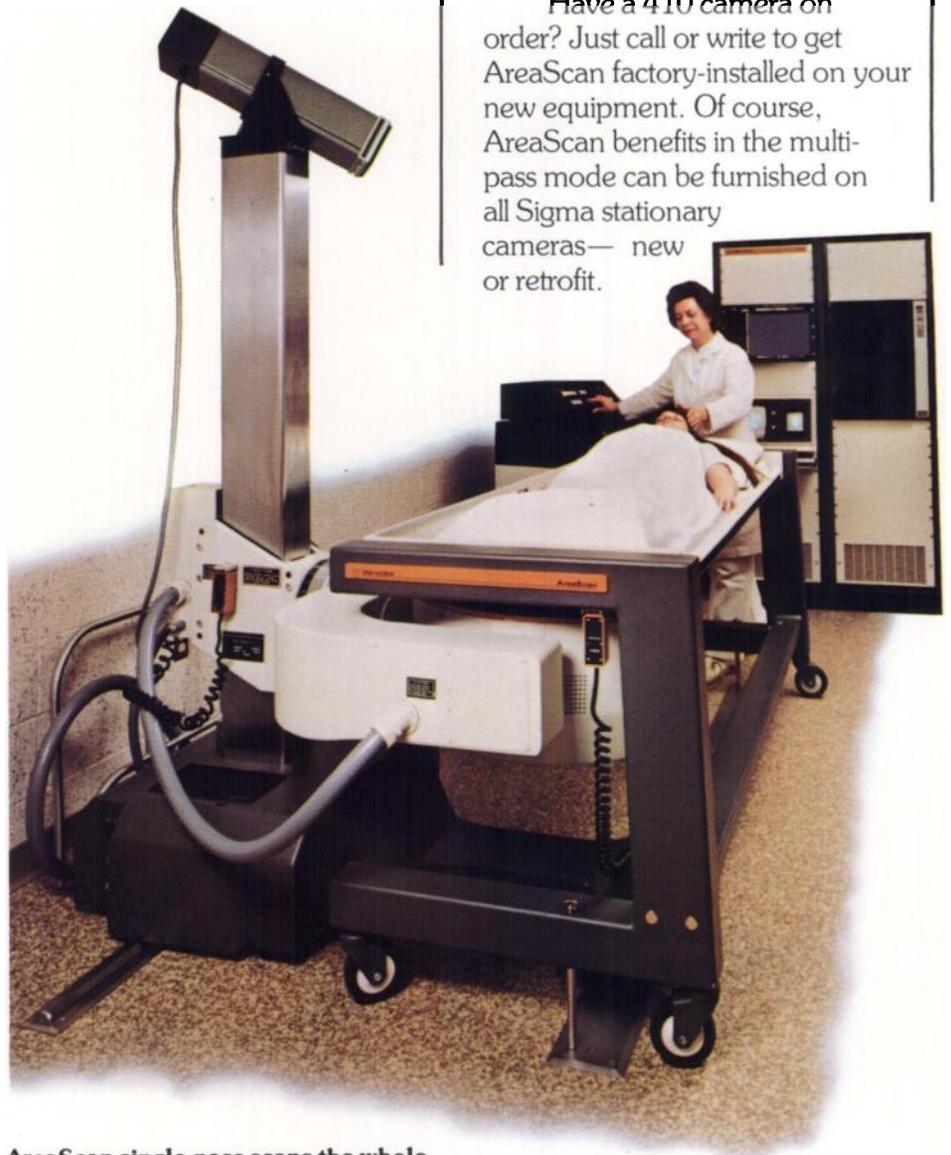
A 10 × 10-foot room is the minimum room you need for single-pass AreaScan, because Ohio-Nuclear moves the camera—not the table. This design permits area scan operations in very small areas that might not otherwise allow the use of this valuable diagnostic tool. You set scan speed by positioning the detector, selecting data density, and pressing the Automatic Speed Computer button. Correct scan speed is implemented without further calculations. Your AreaScan controls enable the camera to pause, restart, or scan manually. *Result:* Simplified operation in a small space.

#### **New or retrofit—AreaScan is cost effective.**

Considering its scanning capabilities, Single-Pass AreaScan represents the most efficient and economical method of whole-body scanning available today.

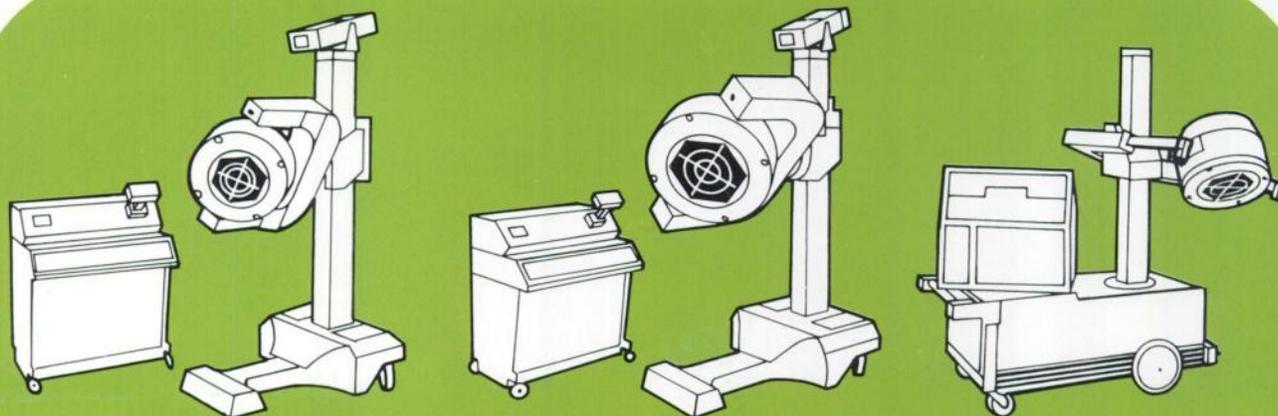
AreaScan is easily field installable on your existing Ohio-Nuclear Sigma 410 or Series 110 camera through modular upgrade. In addition to collimator and electronic package additions, an AreaScan couch is also included. The couch is quickly removable for conventional camera use.

Have a 410 camera on order? Just call or write to get AreaScan factory-installed on your new equipment. Of course, AreaScan benefits in the multi-pass mode can be furnished on all Sigma stationary cameras—new or retrofit.



**AreaScan single-pass scans the whole body in 3-10 minutes, dramatically increasing patient throughput.**

# Smart gamma cameras: The Sigma Series from Ohio-Nuclear.



## Sigma 400 Standard Field Camera

- AreaScan multipass option.
- Field of View: 24.8cm minimum.
- Resolution: 4.5mm FWHM ( $^{99m}\text{Tc}$ ).
- Count Rate: 200K cps.

## Sigma 410 Wide Field Camera

- AreaScan single-pass option.
- Field of View: 36.8cm.
- Resolution: 5.5mm FWHM ( $^{99m}\text{Tc}$ ).
- Count Rate: 200K cps.

## Sigma 420 Mobile Camera

- Field of View: 24.8cm minimum.
- Transport: Motor-driven, variable speed.
- Resolution: 4.5mm FWHM ( $^{99m}\text{Tc}$ ).
- Count Rate: 200K cps.

Three gamma cameras, each with optimal uniformity and resolution. One will meet your precise imaging needs.

These scintillation cameras from Ohio-Nuclear are redefining the standard of excellence in image quality. The Dynamic Uniform Field Control (DUFC) with Micro-processor Control (MPC) and precise electronic balance gives the diagnostician guaranteed uniformity with high resolution.

MPC analyzes the flood data coming from the memory and

determines the correction parameters necessary to assure  $\pm 5\%$  uniformity. Thus, field uniformity and resolution are both optimized — with no trade-off.

*Result:* Increased diagnostic confidence, faster patient throughput, and higher camera utilization.

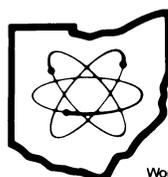
### Sigma means smart.

Each Sigma camera is an intelligent instrument for many reasons. Fast analog, nonlinear circuitry provides consistently superior image quality and high count rate data collection. A Sigma camera

is pre-eminently stable. Because DUFC is continually monitoring the flood, retuning is minimized. Precalibrated isotope pushbuttons, Auto Peak Track, and redesigned remote hand controls combine to offer you maximum operational efficiency and patient throughput.

A Sigma camera from Ohio-Nuclear. Simply stated, it is the only confident alternative.

For immediate response concerning AreaScan and the Sigma Series cameras, call or write Ohio-Nuclear.



## ohio-nuclear, inc.

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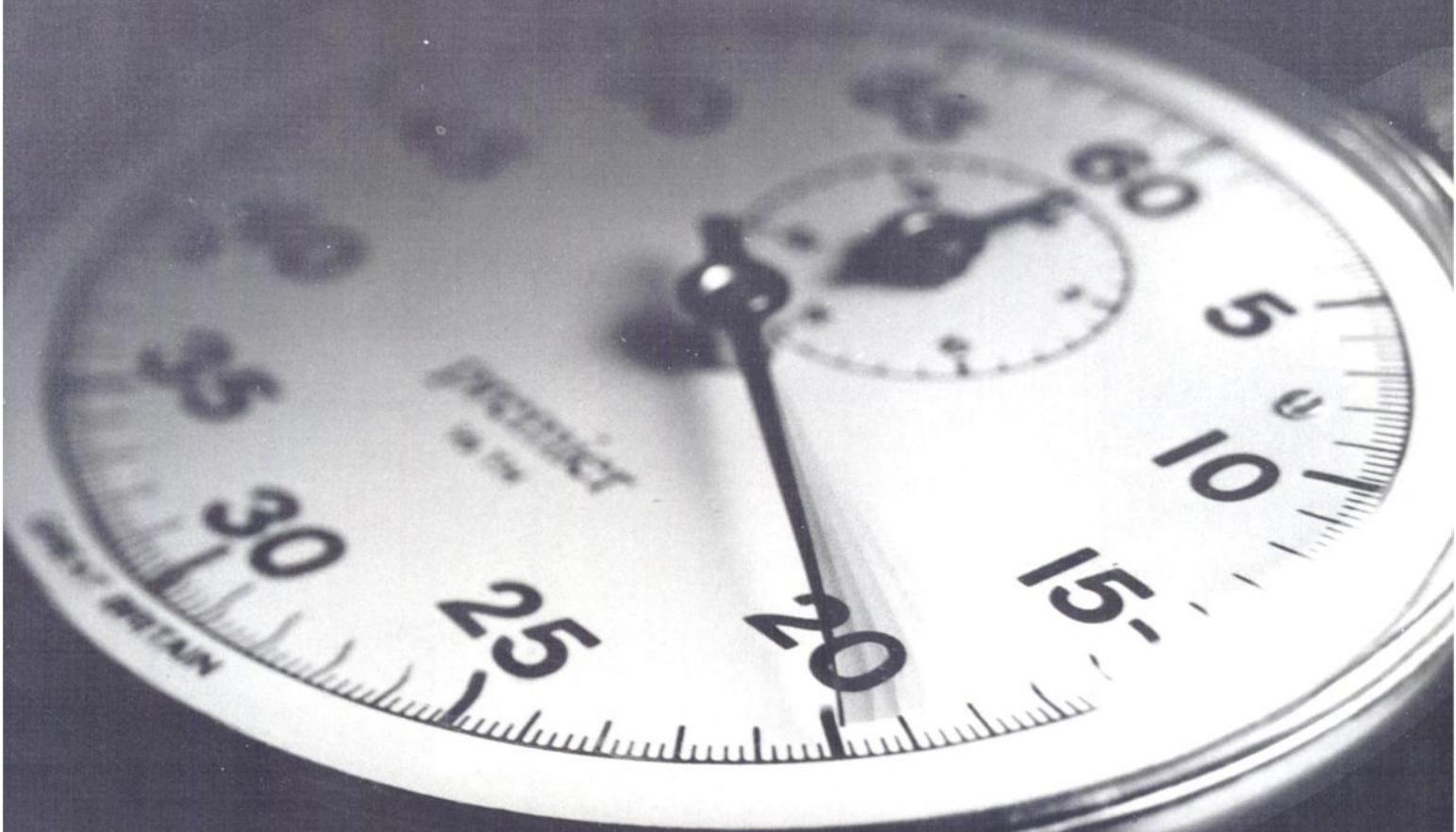


"Seprastat"™ showed the greatest separation with the lowest overall CV's. (Copies of test results are on file and available on request.)

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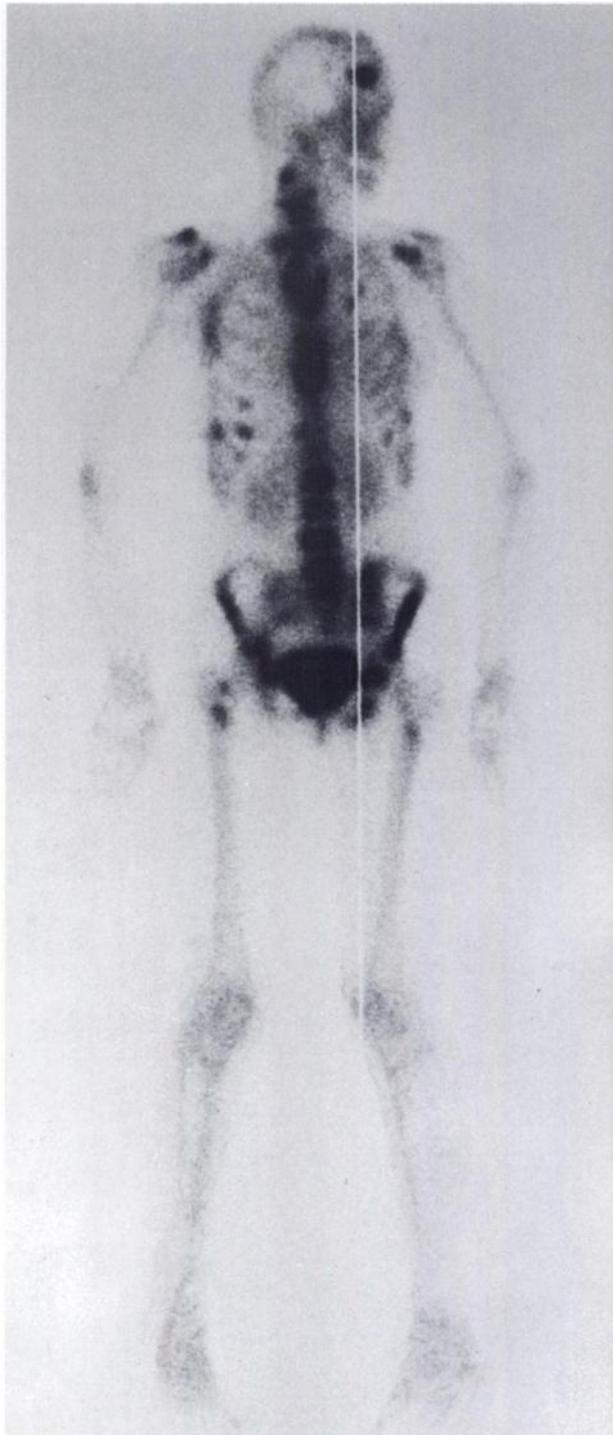
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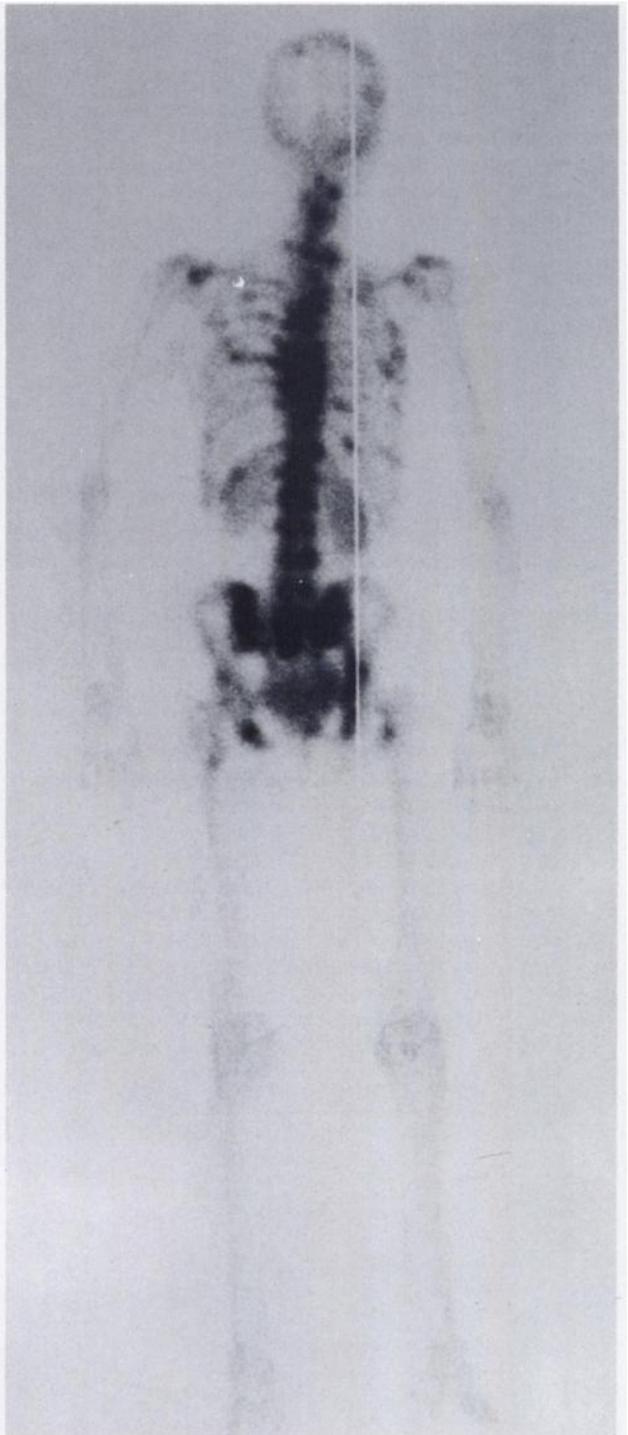
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(5.9 MG DISODIUM ETIDRONATE, 0.16 MG STANNOUS CHLORIDE)  
SKELETAL IMAGING AGENT

## **Excellent in vitro stability**

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

## **Compatible with all types of technetium**

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

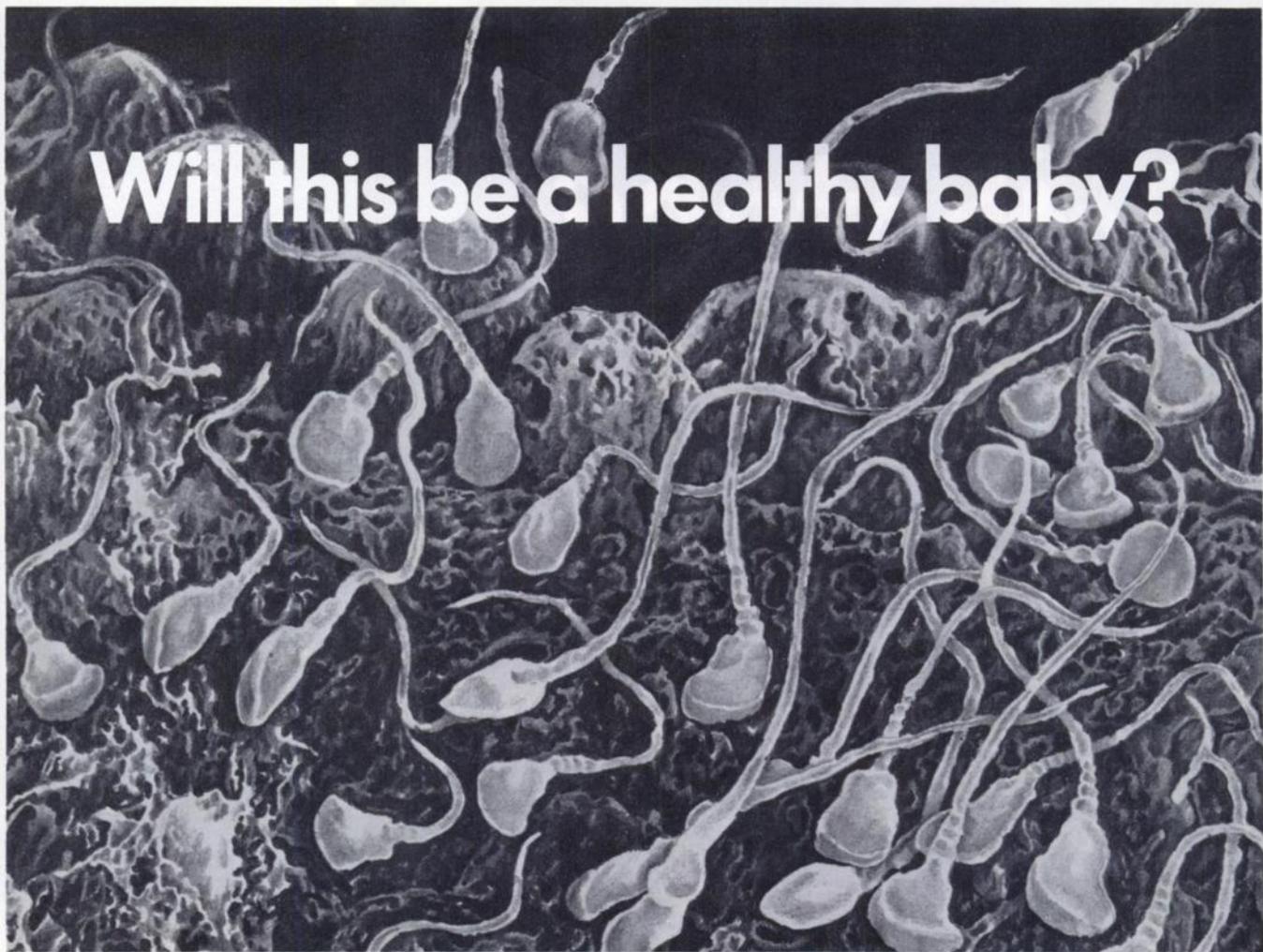
## **Plus these other Osteoscan benefits**

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

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

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

See following page for a brief summary of package insert.



# Will this be a healthy baby?

Representation of Spermatozoa at the surface of an ovum magnified approximately 2000 times.

Yes, if everything goes well. Even so, it needs all the skills of the gynaecologist and obstetrician to monitor progress and take action when complications arise. To support clinical judgment we offer three simple quantitative tests.

Each test, requiring only a small serum sample, is a highly specific radioimmunoassay giving excellent reproducibility with simple gamma counting. All are backed by extensive clinical trials.

### **New FSH Kit**

Our latest kit measures this valuable parameter for the study of infertility in both sexes.

Not only is it a highly reproducible test with a coefficient of variation of less than 6%, it also provides the gynaecologist with results within 24 hours.

### **HPL Kit**

Used in the assessment of threatened abortion during the first trimester or for identifying foetal distress during the third trimester.

Only 2-3 hours are required to complete the test giving the obstetrician rapid results in emergencies.

### **Oestriol Kit**

For measuring circulating oestriol levels in the third trimester.

A simple 3-4 hour test using serum or plasma eliminating the need for urine collection.



**The Radiochemical Centre  
Amersham**

## **FSH, HPL & OESTRIOL RIA KITS**

**A VALUABLE SERVICE TO OBSTETRICS AND GYNAECOLOGY**

Full information is available on request.

The Radiochemical Centre Limited, Amersham, England. Telephone: 024-04-4444

In the Americas: Amersham Searle Corp. Illinois 60005. Telephone: 312-593-6300

In W. Germany: Amersham Buchler GmbH & Co KG, Braunschweig. Telephone: 05307-4693-97

0881

# lesion detection



PROCTER & GAMBLE

# OSTEOSCAN<sup>®</sup>

(5.9 MG DISODIUM ETIDRONATE, 0.16 MG STANNOUS CHLORIDE)  
SKELETAL IMAGING AGENT

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PROCTER & GAMBLE

# OSTEOSCAN<sup>®</sup>

(5.9 MG DISODIUM ETIDRONATE, 0.16 MG STANNOUS CHLORIDE)  
SKELETAL IMAGING AGENT



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

## DESCRIPTION

Each vial of OSTEOSCAN contains 5.9 mg disodium etidronate and 0.16 mg stannous chloride as active ingredients. Upon addition of ADDITIVE-FREE <sup>99m</sup>Tc-perchnetate, these ingredients combine with <sup>99m</sup>Tc to form a stable soluble complex.

## ACTIONS (CLINICAL PHARMACOLOGY)

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

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

## INDICATIONS

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

## CONTRAINDICATIONS

None.

## WARNINGS

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

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

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

The <sup>99m</sup>Tc-generator should be tested routinely for molybdenum breakthrough and aluminum. If either is detected, the eluate should not be used.

## PRECAUTIONS

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

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

## ADVERSE REACTIONS

None.

## DOSAGE AND ADMINISTRATION

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

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

## SETHOTOPE<sup>®</sup>

### Selenomethionine Se 75 Injection

Sethotope (Selenomethionine Se 75 Injection) is a sterile, nonpyrogenic, aqueous solution of L-selenomethionine providing a specific activity of not less than 25 microcuries per mcg. of selenium at the time of manufacture. The product also contains not more than 3 mg. L-methionine as a carrier, not more than 12 mg. 2-aminoethanethiol as an antioxidant, sodium chloride for isotonicity, and 0.9% (w/v) benzyl alcohol as a preservative.

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

**WARNINGS:** This radiopharmaceutical should not be administered to patients who are pregnant or who may become pregnant or during lactation unless the information to be gained outweighs the possible potential risks from the radiation exposure involved.

The transplacental transport and long biologic half-time of this agent may result in significant radiation exposure to the fetus. Since selenomethionine <sup>75</sup>Se is excreted in 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 specific training in the safe use and safe handling of radionuclides, produced by nuclear reactor or cyclotron, and whose experience and training have been approved by the appropriate federal or state agency authorized to license the use of radionuclides.

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

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

**ADVERSE REACTIONS:** At present, adverse reactions have not been reported following administration of Selenomethionine Se 75 Injection.

For full prescribing information, consult package insert.

**HOW SUPPLIED:** Sethotope (Selenomethionine Se 75 Injection) is available in multiple dose vials in potencies of 0.25 millicurie, 0.5 millicurie, and 1 millicurie. Complete assay data for each vial are provided on the container.

Medotopes<sup>®</sup>



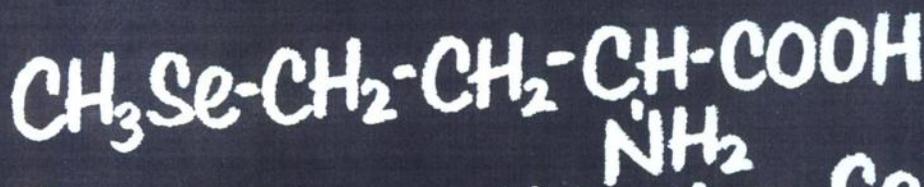
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E. R. Squibb & Sons, Inc.  
P.O. Box 4000  
Princeton, N.J. 08540

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For pancreas imaging

**Sethotope<sup>®</sup>**

Selenomethionine Se 75 injection



**(L)**-selenomethionine Se 75  
*Biosynthetic*

### High pancreas specificity

Selenomethionine is a structural analog of the amino acid, methionine, in which the selenium has been substituted for the sulfur atom.

Chemically and biologically, they behave alike, including a relatively high degree of uptake in the pancreas during protein synthesis.

### Levorotatory compound

Radioactive selenomethionine can be produced in racemic form by chemical synthesis from <sup>75</sup>Se. At Squibb, however, selenomethionine is prepared *biosynthetically* by extracting it from the protein product of yeast grown on a low sulfur medium containing <sup>75</sup>Se of high specific activity. This compound is levorotatory.

### Specific activity

Squibb L-selenomethionine <sup>75</sup>Se provides a specific activity of not less than 25 microcuries per microgram of selenium at the time of manufacture.

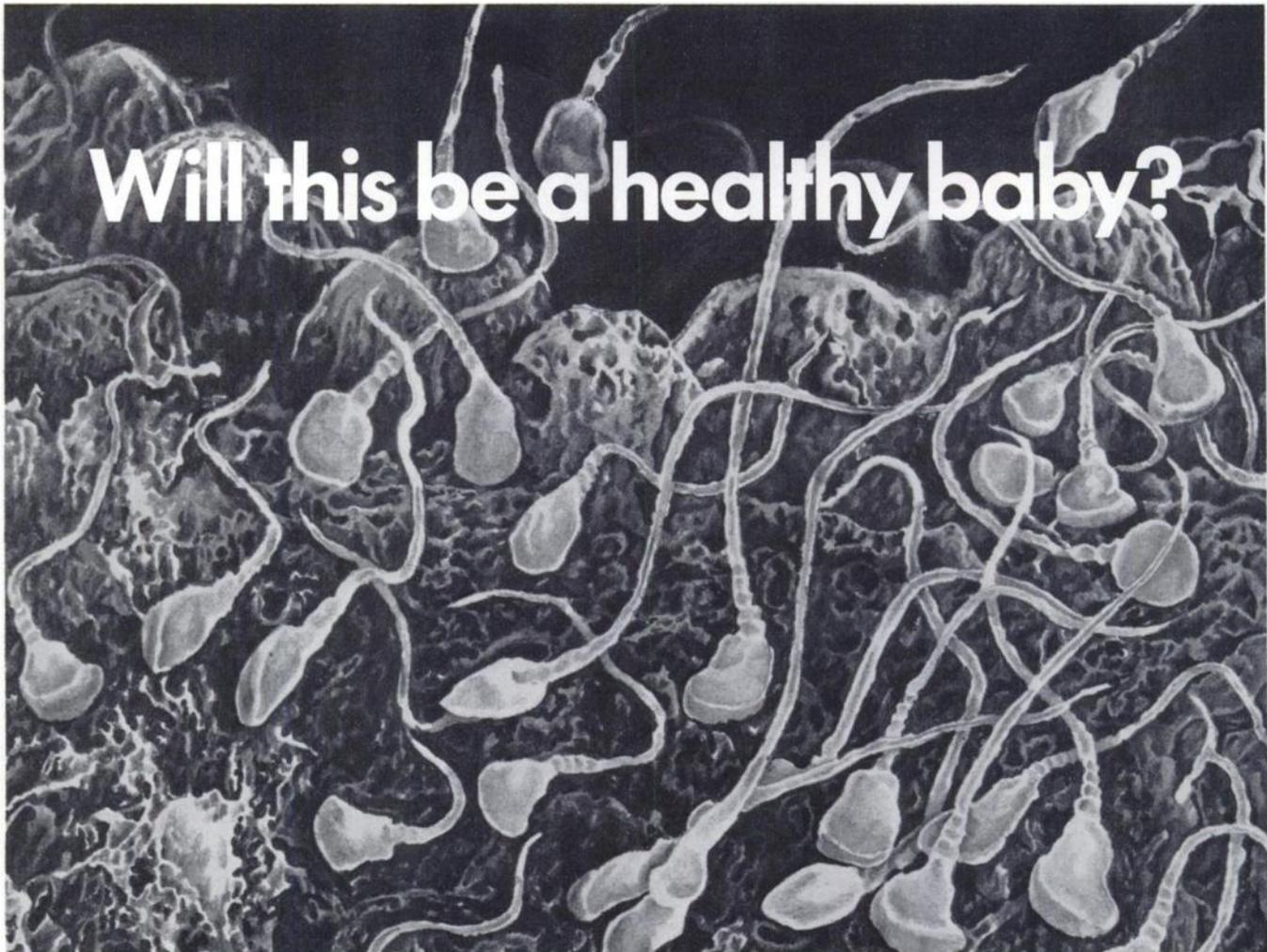
**Sethotope<sup>®</sup>**  
**Selenomethionine Se 75 Injection**

See opposite page for brief summary.

Medotopes<sup>®</sup>



SQUIBB HOSPITAL Division  
E. R. Squibb & Sons, Inc.  
P.O. Box 4000  
Princeton, N.J. 08540



# Will this be a healthy baby?

Representation of Spermatozoa at the surface of an ovum magnified approximately 2000 times.

Yes, if everything goes well. Even so, it needs all the skills of the gynaecologist and obstetrician to monitor progress and take action when complications arise. To support clinical judgment we offer three simple quantitative tests.

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In W. Germany: Amersham Buchler GmbH & Co KG, Braunschweig. Telephone: 05307-4693-97

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# Meletron



## The dose calibrator that calibrates itself (almost)

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

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

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

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

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

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

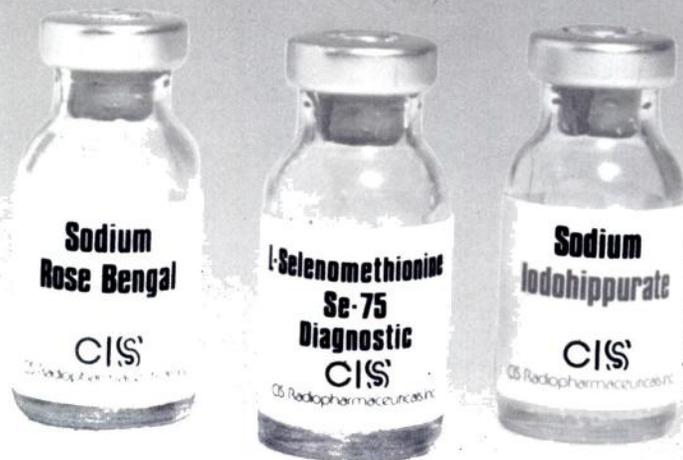
For a permanent solution to your dose calibration and record-keeping problems, call RADX — the innovators in nuclear medicine. RADX, P. O. Box 19164, Houston, Texas 77024, 713/468-9628.

**RADX**



**Meletron & Melecord . . . your key to accurate dose calibration and error-free records.**

**Hey,  
don't forget!  
We're available.**



- L — Selenomethionine Se-75**
- 131I Sodium Rose Bengal**
- 131I Sodium Iodohippurate**
- 131I Sodium Iodide Oral Therapeutic**
- 131I Sodium Iodide Capsule**
- Oral Iodine Administration Kit**

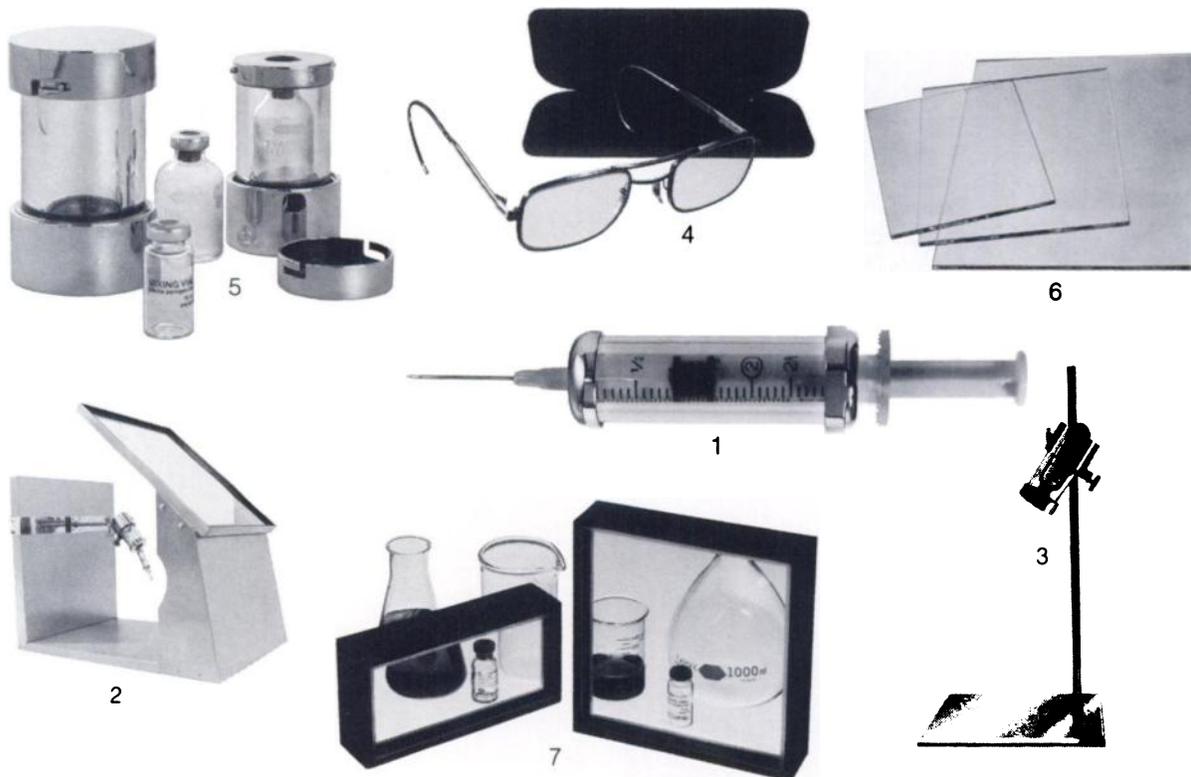
Send for our literature on radiopharmaceuticals or call us toll free (800-225-1145). We are pleased to discuss your requirements and answer questions about our products and applications.



**CIS Radiopharmaceuticals, Inc.**

5 DeAngelo Drive/Bedford, Ma. 01730/Telephone: (617) 275-7120;  
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# Seven new ways to see what you're doing. Safely. From Nuclear Pacific, Inc.



1. Total visibility syringe shields. 360 degrees of visibility. Amazing light weight, visibility and convenience. Hi-D lead glass reduces exposure of  $^{99m}\text{Tc}$  by a factor of 70. Positive syringe lock. Anti-roll design. Models for 1cc, 3cc and 5cc syringes. From \$94.00
2. Radiation Dose Shield. Basic unit, 17"wx25"d x 25"h. Available with shielding glass optional thicknesses up to 1". Various other options including Vial Shield holder on back, as shown. Base price with  $\frac{1}{4}$ " glass: \$498.00.
3. Vial Shield Stand. Eliminates lifting and holding. Vial Shield adjusts easily to various positions with simple one hand operation. Available for models 75, 77 and 79. Vial Shields. \$210.00.
4. Radiation Shielding Eyeglasses. For use during fluoroscopic procedures including angiographic and catheterization. Also for patient wear during ear tomography, headscans and radio-therapy. Lightweight: only 2.5 oz.

5. Lo-, Hi- and Ultra Hi-Energy Vial Shields. Designed to eliminate shielding leakage and to accommodate all vials up to and including 30ml. Easy access. 360 degrees of visibility. Hi-D lead glass. Assured safety. From \$225.00.
6. X-ray Protection Glass. Six levels of lead equivalence from 4 pounds/FT<sup>2</sup> to 23 pounds/FT<sup>2</sup>. Twenty standard sizes from 8" x 10" to 36" x 60". Laminating, sizing, edging and framing to order.
7. Lead Glass Bricks. Razor sharp, non-fogging visibility plus remarkable shielding quality. Made of Hi-D (6.2 gm/cm<sup>3</sup>) lead glass mounted in steel frames. 4" x 8" x 2"; 4" x 8" x 4"; 8" x 8" x 2"; 8" x 8" x 4"; 12" x 12" x 4". From \$380.00.

For nearly 30 years — the standard for visibility and protection in the radiation shielding industry.

**Nuclear  
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6701 Sixth Ave. S.  
Seattle, WA 98108



For product specifications and other information contact Nuclear Pacific, Inc., (206) 763-2170.

\*Registered U.S. Patent Office. Platinum melted ultra high density optical glass.

# Film after film after film after film. Rapido® M-7A.

Picker has proven its leadership in Cassetteless Radiography—and saved space in the process.

Consider our Rapido M-7A\* System: Requires less space, increases productivity, cuts costs, minimizes patient radiation. And, it provides even higher quality work than conventional systems.

Additionally the Automatic Exposure Control (A.E.C.) system designed for the Rapido provides optimal radiographic film densities—consistently.

To increase throughput and reduce operator fatigue, the Rapido incorporates four 75-film-capacity load magazines (14x17", 17x14", 11x14", 10x12"). This translates into a saving of 2,000 pounds (907 kg) of cassettes that don't have to be loaded, transported or unloaded.



Other key features: Push-button film-size selection for automatic centering of each size in the exposure area... unique patient identification with a 3x5" card eliminating ID work in the darkroom. And, a four-way floating table top which offers 50" longitudinal and 12" of transverse motion.

This is another example of Picker's unique human resources benefiting you. It's a result of our expertise in the diagnostic modalities of x-ray, ultrasound, nuclear, computed tomography, clinical laboratory, therapy, film systems and supplies. Only Picker has all these resources.

Consult your Picker representative or write Picker Corporation, 595 Miner Road, Cleveland, OH 44143.

Discover the human resources in Picker's synergy

**PICKER®**  
ONE OF THE C.I.T. COMPANIES

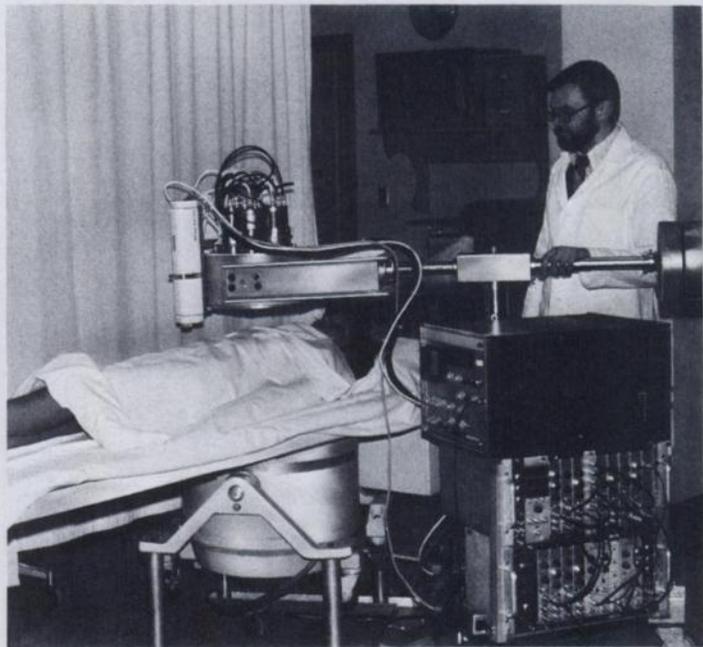


# Modular Ortec instruments do more, do it better, increase your flexibility.

Modern diagnostic procedures in nuclear medicine are presenting more challenging situations which tax the capabilities of commercial instrumentation. Here is one way in which Ortec is helping to solve these problems:

Dr. Robert E. Polcyn, Director of Nuclear Medicine at the University of Wisconsin Medical School, says: "Most commercial nuclear medicine instruments tend to perform a single clinical task. The result is a large inventory of little-used systems.

"Our approach at the University, on the other hand, is to emphasize instrument function, stocking a number of research-grade NIM modules to configure the system we need for any particular requirement. This modular approach has resulted in improved energy resolution and count-rate capability, cost savings, and increased reliability. In addition, we now have the flexibility to adapt our systems to our changing clinical needs."

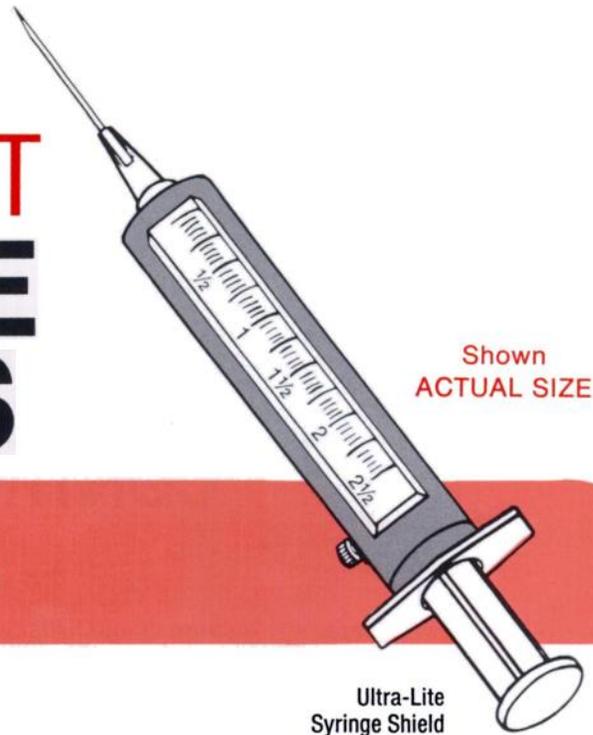


For complete information on Ortec instruments for nuclear medicine, write or call Life Sciences Division, Ortec Incorporated, 100 Midland Road, Oak Ridge, TN 37830; (615) 482-4411.

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AN EG&G COMPANY  
76 OFFICES IN 49 COUNTRIES

When working  
with radionuclides,  
TRY our

# LIGHTWEIGHT SYRINGE SHIELDS



*They're so effective  
and EASY TO HANDLE!*

## ULTRA-LITE Syringe Shield

**LIGHTEST and SMALLEST  
syringe shield ever made**

- Special shielding material is 40% to 60% lighter than lead, yet offers maximum protection.
- Slim design makes injections easier.
- Practically indestructible.

## THIN-WALL Syringe Shield For Technetium-99m

- Designed specifically for <sup>99m</sup>Tc or any gamma emitter <140 keV.
- 30% lighter than standard lead shields. Slimmer, easy-to-hold shape.

Syringe Shield	Model	Capacity	Weight	Price
ULTRA-LITE	56-295	1 cc	1.1 oz.	\$95.00
	56-292	2½ to 3 cc	1.4 oz.	95.00
	56-293	5 to 6 cc	1.7 oz.	95.00
<sup>99m</sup> Tc THIN-WALL	56-272	2½ to 3 cc	3.2 oz.	\$45.00
	56-273	5 to 6 cc	4.6 oz.	47.00



## FREE

With every Syringe Shield order over \$190.00, a <sup>99m</sup>Tc DECAY CLOCK (which simplifies the calculation of individual patient doses) will be included WITHOUT CHARGE . . . while the supply lasts. Get yours now!



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ASC\* allows operator to enlarge image full-screen for photo or computer acquisition. Useful with all large-diameter scintillation cameras (Compatible with signals that go to the display scope) or as input to a digital computer system. Of special importance for Thallium 201 images, gated blood pool images, and small organs. Includes 10-position selector, vertical and horizontal sliding potentiometers and "zoom" for optimum image recording. \$795.00. (Other nuclear medical modules also available for various diagnostic needs.) Write or phone:

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 2901 Eisenhower Parkway  
 Ann Arbor, Mich. 48104  
 (313) 973-2335

## radioimmunoassay from "The Innovators"

TEST SETS	ANTIBODIES		REFERENCE SERUMS	
	TEST SETS	ANTIBODIES	TEST SETS	ANTIBODIES
Aldosterone	<input type="checkbox"/>	<input type="checkbox"/>	Estradiol	<input type="checkbox"/>
Circulating T <sub>3</sub>	<input type="checkbox"/>	<input type="checkbox"/>	Estriol	<input type="checkbox"/>
Corticoids (CPB)	<input type="checkbox"/>	<input type="checkbox"/>	Estrone	<input type="checkbox"/>
Digitoxin	<input type="checkbox"/>	<input type="checkbox"/>	T <sub>4</sub>	<input type="checkbox"/>
Digoxin	<input type="checkbox"/>	<input type="checkbox"/>		
DPH (diphenylhydantoin)	<input type="checkbox"/>	<input type="checkbox"/>	REFERENCE SERUMS	Digoxin <input type="checkbox"/>
Epitestosterone	<input type="checkbox"/>	<input type="checkbox"/>		DPH <input type="checkbox"/>
Testosterone	<input type="checkbox"/>	<input type="checkbox"/>		T <sub>3</sub> <input type="checkbox"/>
Androstenedione	<input type="checkbox"/>	<input type="checkbox"/>		RIA Multi-Component <input type="checkbox"/>
Progesterone	<input type="checkbox"/>	<input type="checkbox"/>		

### NEW TEST SETS

- Dehydroepiandrosterone (DHEA)
- 17-Hydroxyprogesterone (17-OHP)

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Just one example of the custom service you get with Searle Nuclibadge II. We phone you immediately if any employee's radiation exposure exceeds the limits you set. And unlike some other film badge services, when Searle calls you, it's free.

You can have regular reports listing badges not returned for reading. You can arrange irregular shipping schedules. You can request omission of history of exposure. Or none of these.

You get instant protection for new employees. Badges are sent within 24 hours of your request. In addition to regular monthly reports, Nuclibadge II coverage shows dose for the current period, quarter to date, year to date, lifetime total *by quarter*, and remaining permissible dose. Meets mandatory State, Federal and OSHA record keeping requirements.

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- Emergency reports, additional monitors sent within 24 hours.
- Punch card, magnetic or paper tape reports optionally available for computer record keeping systems.
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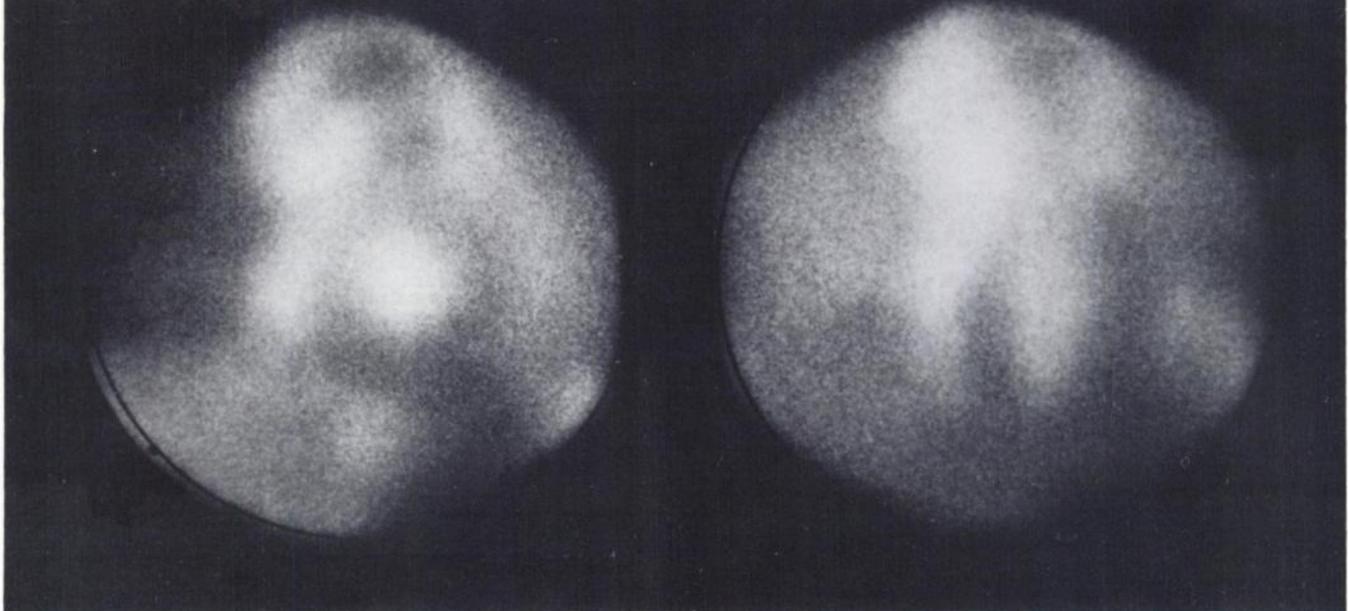
### Searle Services

Division of Searle Diagnostics  
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Des Plaines, IL 60018  
Attn: Film Badge Manager



## PARALLEL HOLE COLLIMATOR

## SLANT HOLE COLLIMATOR



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

# NOW! BETTER MLAOS & RAOs FROM FLAT AGAINST THE CHEST WALL

**Our unique 30° slant hole design** allows collimator positioning flat against the chest—for sharper, more meaningful cardiac imaging than is possible with conventional, straight bore collimators. For example, you get better separation of the left atrium and left ventricle with no foreshortening of the septum; better resolution of the cardiac apex; and optimum separation of the distribution of the left anterior descending and left circumflex arteries.

**Other applications** include: ejection fraction on first pass data; oblique views of spine and kidneys; RPO views of spleen, LAO views of liver, images of fossa, all images with a caudal or cephalad angulation, etc.

**Easily mountable:** as an insert on any commercial Anger scintillation camera... in the external diverging-converging mounting frame of an Ohio Nuclear or Searle camera, or in a special rotatable mounting for large field of view cameras.

**High sensitivity** relative to low-energy, all-purpose collimators:  $1.18 \pm .01$ . Standard and high resolution models are now available. Write for more information.



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



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

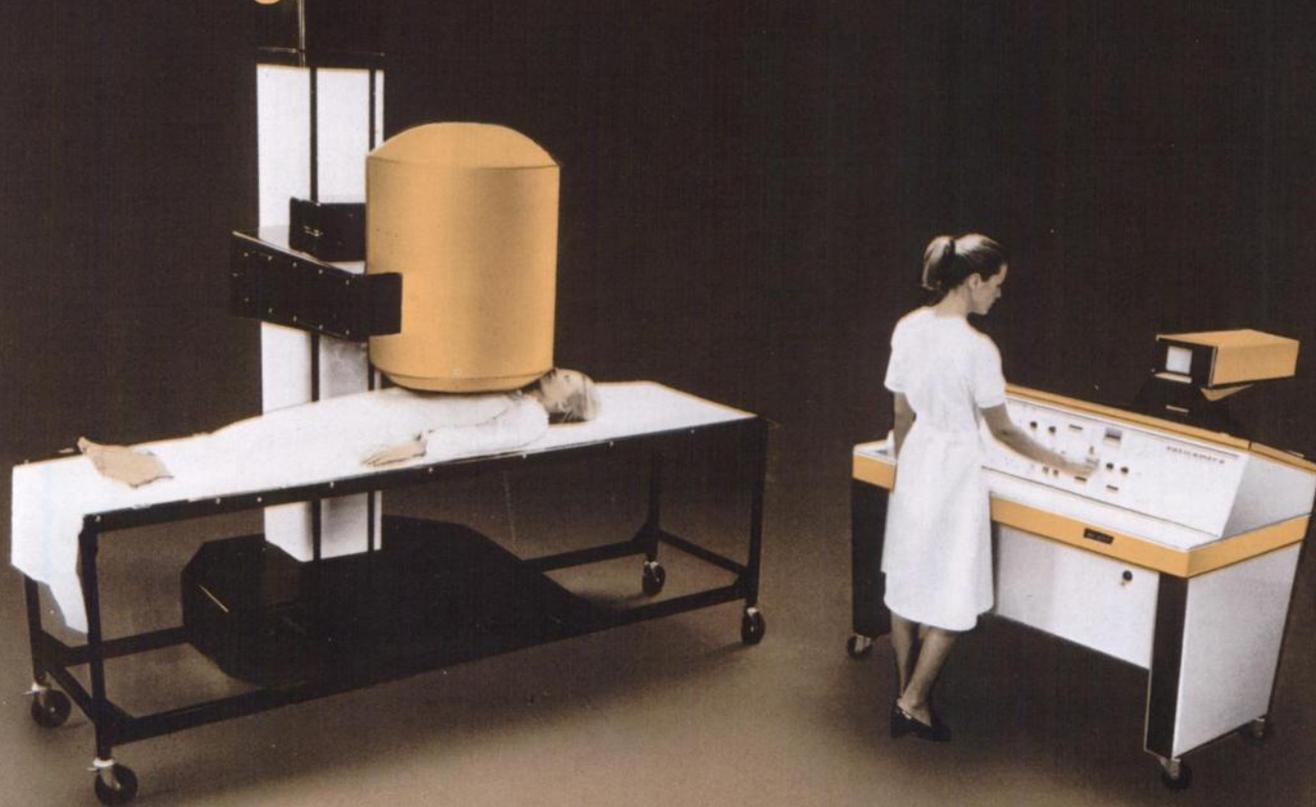


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image intensifier scintillation camera



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The awareness that image intensifiers would allow decisive improvements in the performance of scintillation cameras has been shared, for a long time, by most leading experts in the field. Roughly fifteen years of constant technological advance have been needed to reach this long-sought goal. C.G.R. Médecine Nucléaire is proud to announce the first fully successful device based upon this principle : the OPTICAMERA.

Ample proof of the OPTICAMERA achievement : fifteen instruments are actually installed, some for over one year, and are operating in day-to-day routine hospital work with the highest degree of performance and reliability presently to be available.



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**? Lymphoma**  
**? Hodgkin's disease**  
**? Bronchogenic carcinoma**

## **Gallium Ga 67:**

Now available for routine use as  
a non-invasive adjunct in diagnosis.

**Indications and Usage:** Gallium Citrate Ga 67 may be useful to demonstrate the presence and extent of certain malignancies such as Hodgkin's 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:**

#### General

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. 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.

#### Carcinogenesis

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

#### Pregnancy Category C

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

#### Nursing Mothers

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

#### Pediatric Use

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.

**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.**

**CAUTION:** Federal (U.S.A.) law prohibits dispensing without prescription.



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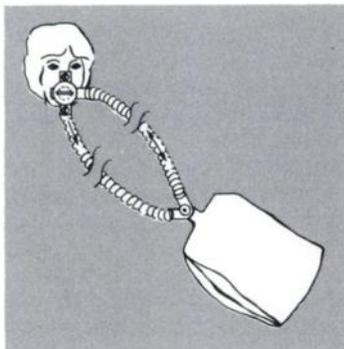


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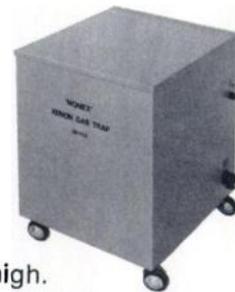
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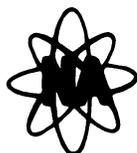


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# Bone Scanning Kit

## Technetium Tc 99m Pyrophosphate Tin Kit

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# Bone Scanning Kit

## Technetium Tc 99m Pyrophosphate Tin Kit For Diagnostic Use

### Description

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

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

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

### Physical Characteristics

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

Table I. Principal Radiation Emission Data

Radiation	Mean % Disintegration	Mean Energy [keV]
Gamma-2	87.9	140.5

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

### External Radiation

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

Table II. Radiation Attenuation by Lead Shielding

Shield Thickness [Pb] mm	Coefficient of Attenuation
0.2	0.5
0.95	10 <sup>-1</sup>
1.8	10 <sup>-2</sup>
2.7	10 <sup>-3</sup>
3.6	10 <sup>-4</sup>
4.5	10 <sup>-5</sup>

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

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

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

\*Calibration Time

### Clinical Pharmacology

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

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

### Indications and Usage

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

### Contraindications

None known.

### Warnings

Technetium Tc 99m Pyrophosphate Tin should not be administered to patients who are pregnant, or to nursing mothers unless the benefits to be gained outweigh the potential hazards.

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

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

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

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

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

### Precautions

Technetium Tc 99m Pyrophosphate Tin solution, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patient consistent with proper patient management.

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

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

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

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

Safety and effectiveness in children have not been established.

### Adverse Reactions

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

### Dosage and Administration

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

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

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

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

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

### Radiation Dosimetry

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

Table IV. Absorbed Radiation Dose

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

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

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

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

### How Supplied

- 6 sterile immediate drug containers each containing: (Lyophilized).  
—15.0 mg Sodium Pyrophosphate  
—0.30 mg Stannous Chloride  
—HCl or NaOH to adjust pH  
—Nitrogen Gas

- 6 radioactivity string labels for the immediate drug container.

- 6 radioactivity labels for the lead shield.

- 1 package insert.

- 1 instruction card.

### Storage

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

### Preparation

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

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

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

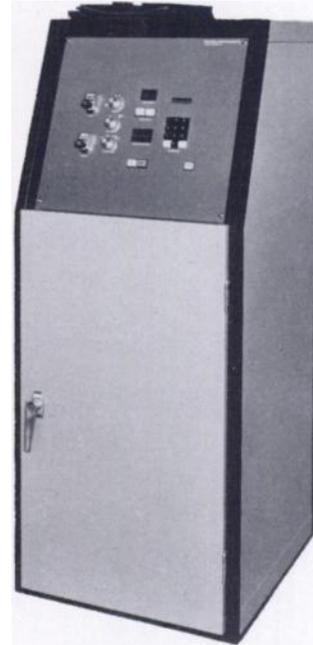


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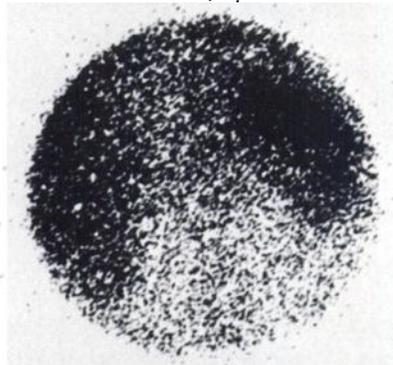
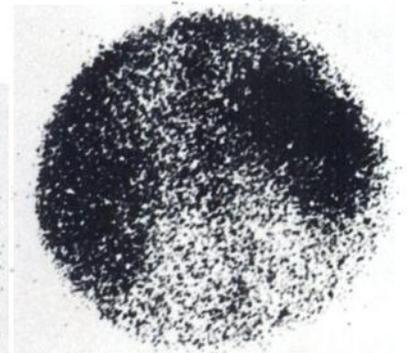
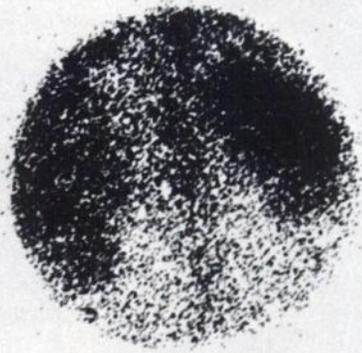
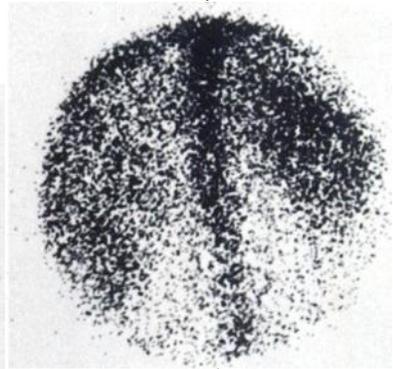
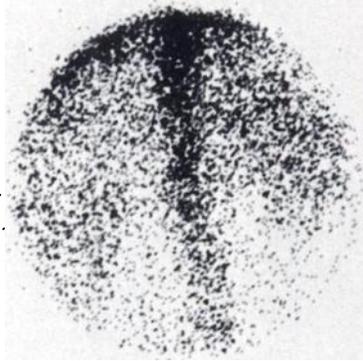
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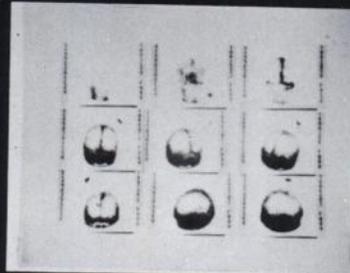
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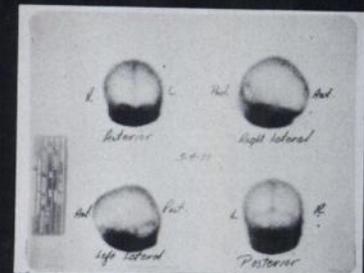
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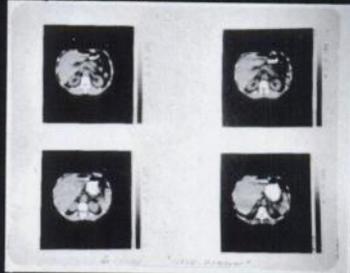
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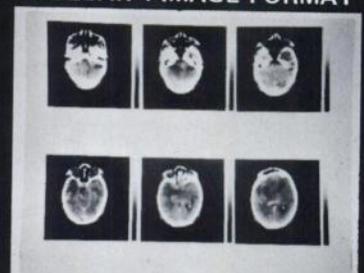
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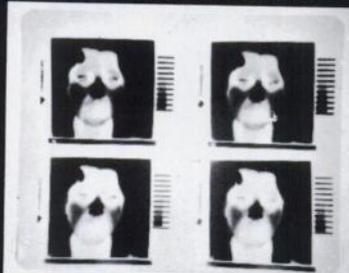
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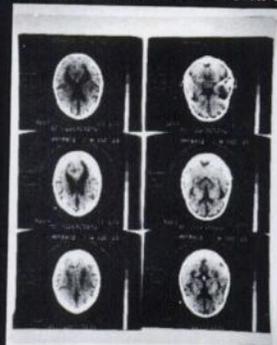
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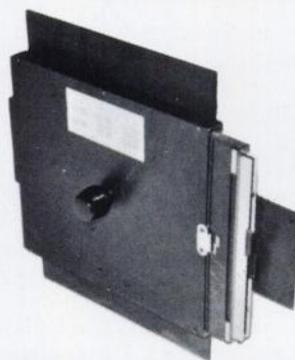


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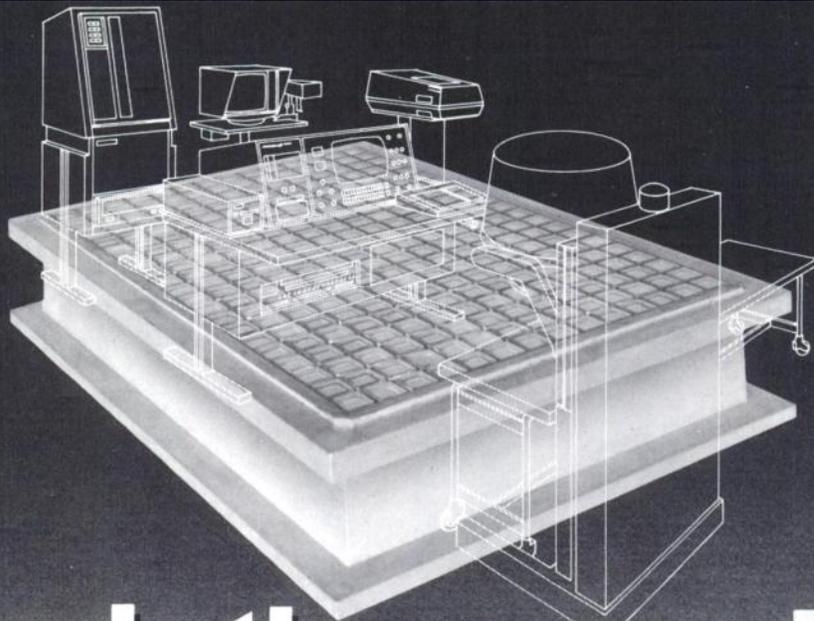
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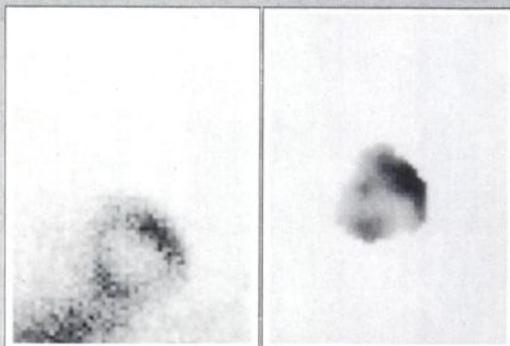
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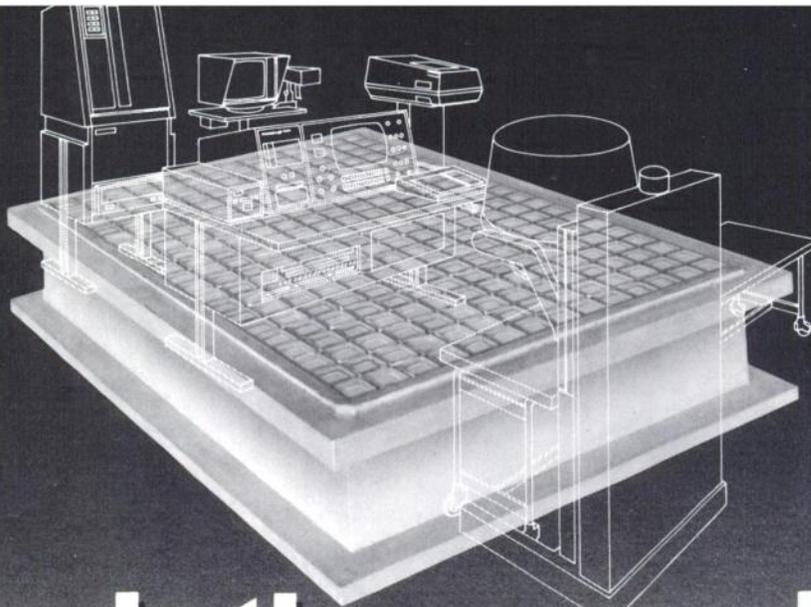
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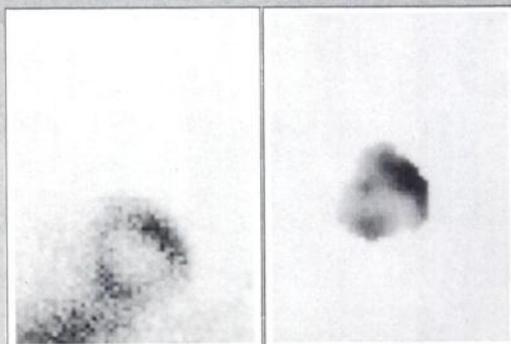
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RADIONUCLIDE DOSE COMPUTATION AND MEASUREMENT RECORD ©

PATIENT'S NAME: James Court

I.D. 087-40-4035

STUDIES: Brain Scan

NUCLIDE: TECHNETIUM 99M

FORM: Pertech. SAMPLE NO. 09

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

DATE: 21 AUG 77 14:57

CONCENTRATION: 12.34 mCi/ml

DOSE DESIRED: 20.00 mCi

VOLUME REQUIRED: 01.62 ml

ACTIVITY MEAS'D: 20.31 mCi

TIME OF ADMINISTRATION: 3:05  AM  PM

SIGNATURE(S): Anne Wynters

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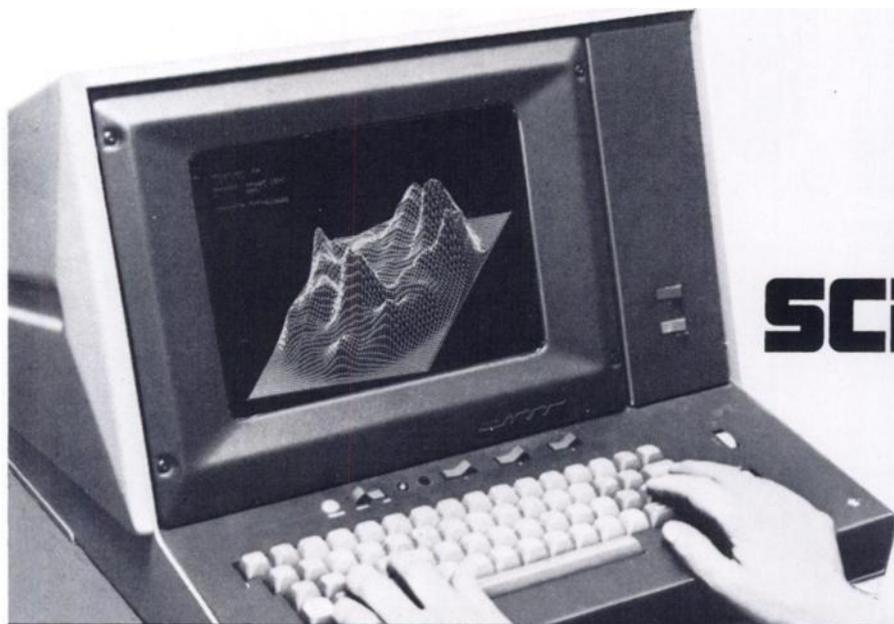
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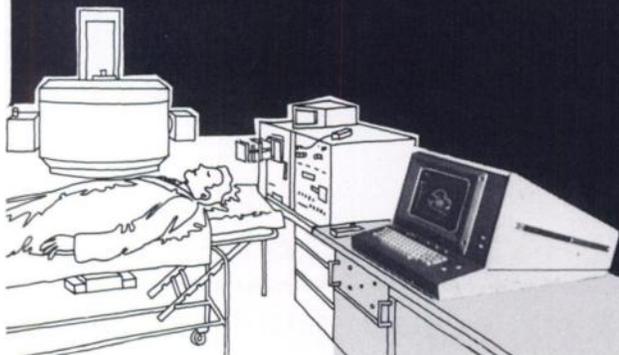
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position on leg

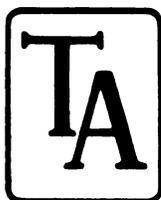
21	--	066.7
20	--	071.3
19	--	074.8
18	--	076.4
17	--	078.0
16	--	079.7

percent uptake

7	--	088.9
6	--	096.1
5	--	108.8
4	--	117.6
3	--	129.1
2	--	141.9
1	--	151.5
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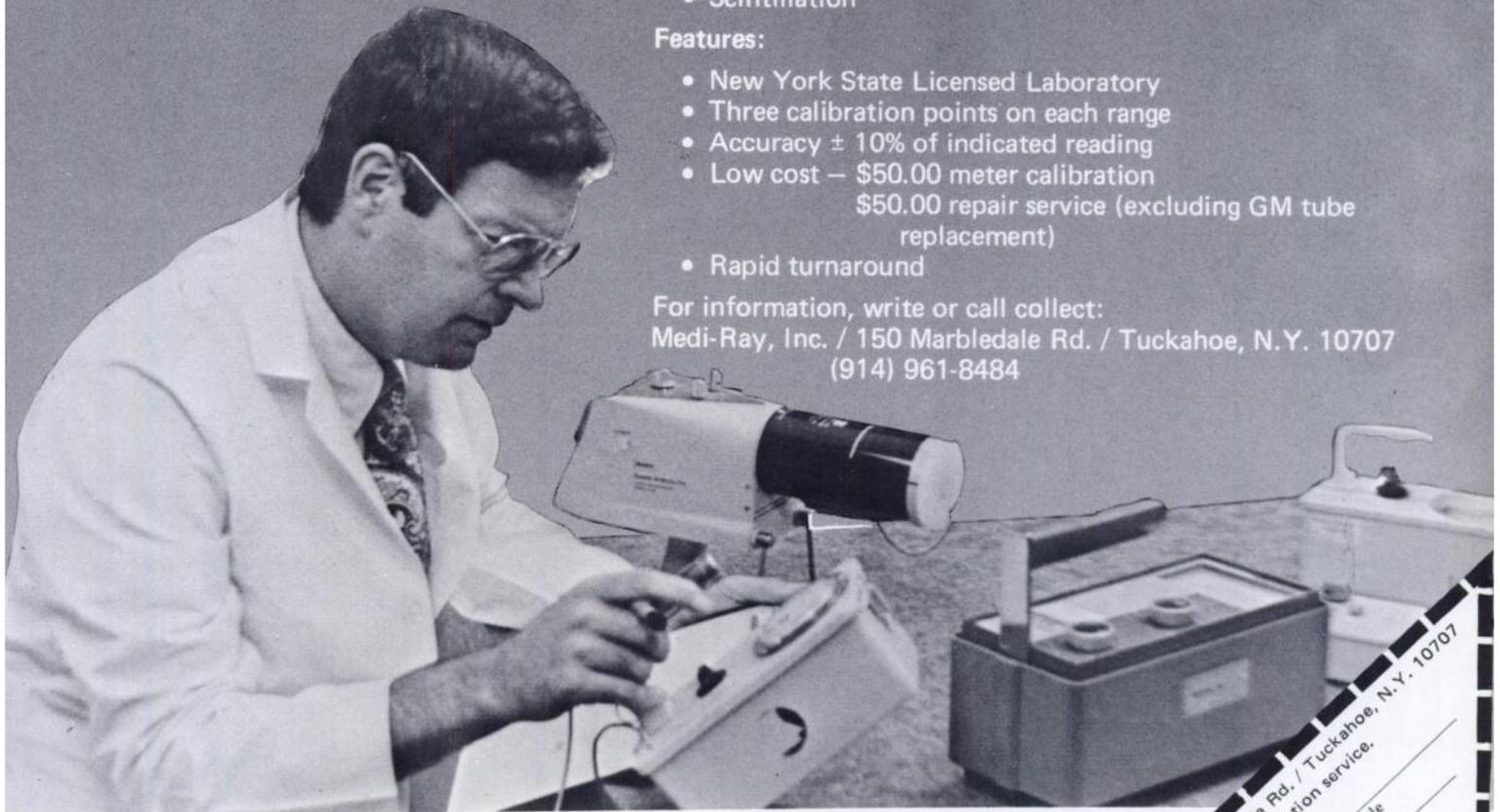
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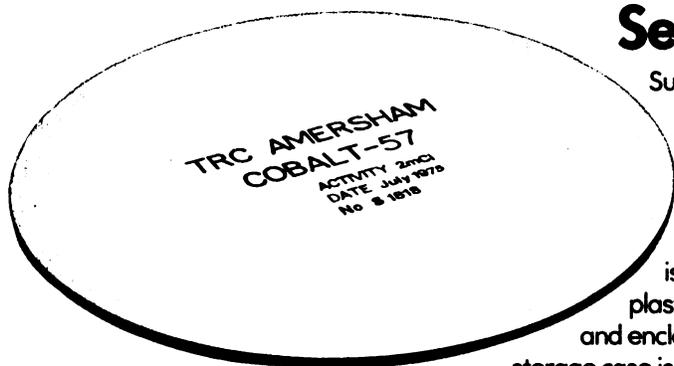
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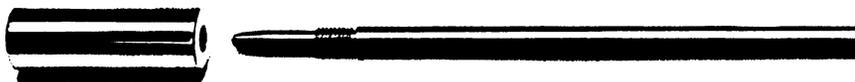
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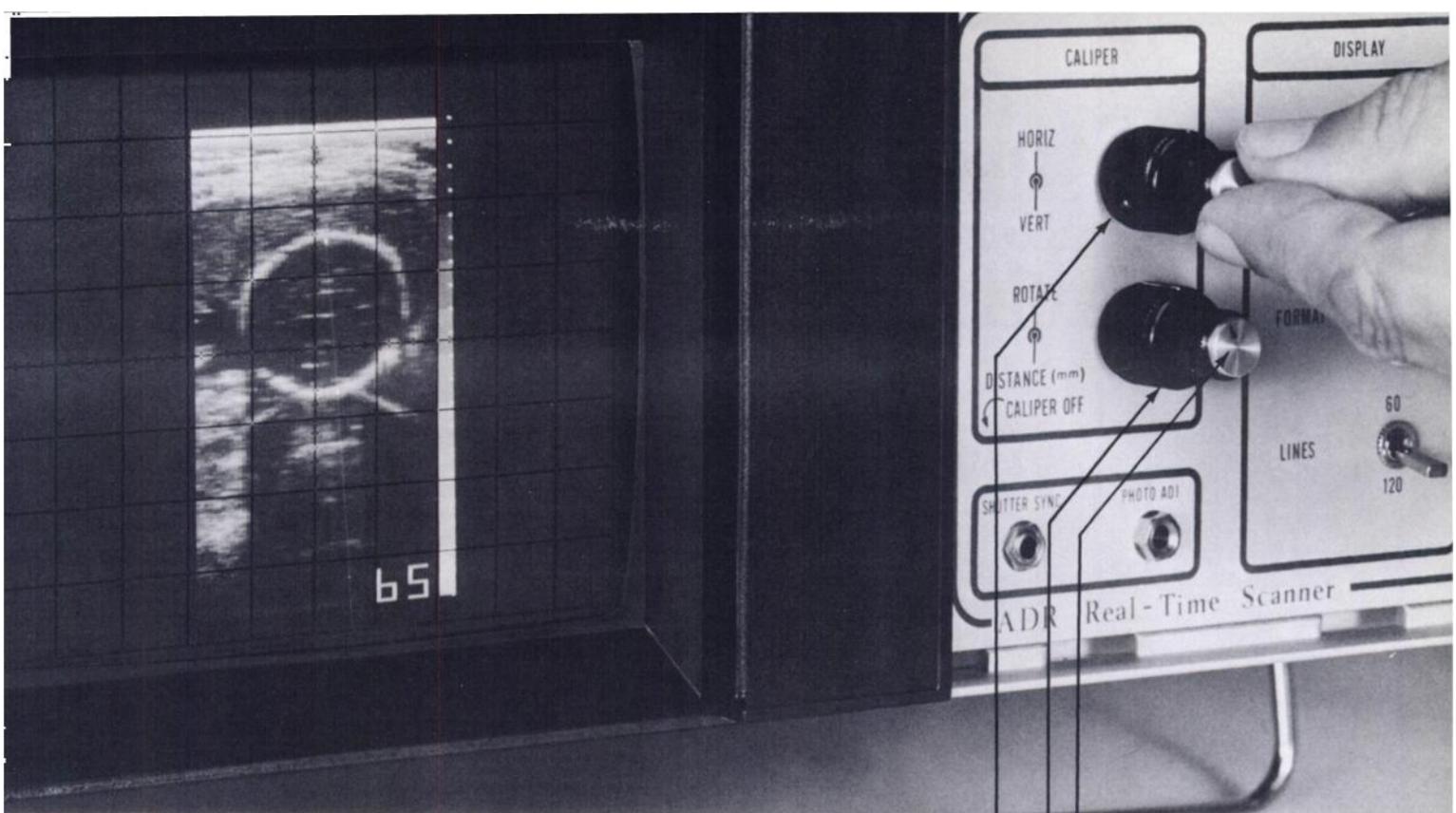
is sealed in a plastic capsule attached to a handling rod. Other nuclides  $^{241}\text{Am}$ ,  $^{133}\text{Ba}$ ,  $^{57}\text{Co}$ ,  $^{60}\text{Co}$ ,  $^{137}\text{Cs}$ ,  $^{54}\text{Mn}$ ,  $^{22}\text{Na}$ ,  $^{75}\text{Se}$ ,  $^{123m}\text{Te}$ ,  $^{88}\text{Y}$  and mock  $^{131}\text{I}$ .



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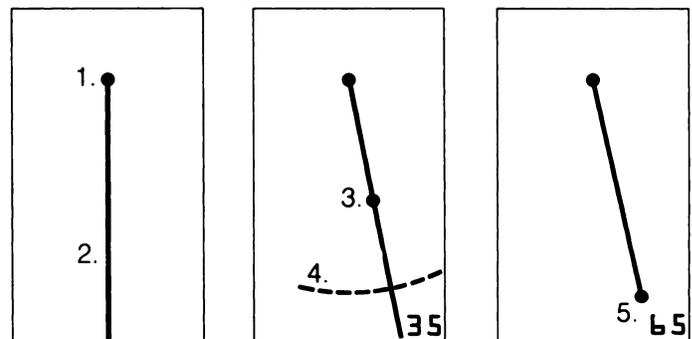
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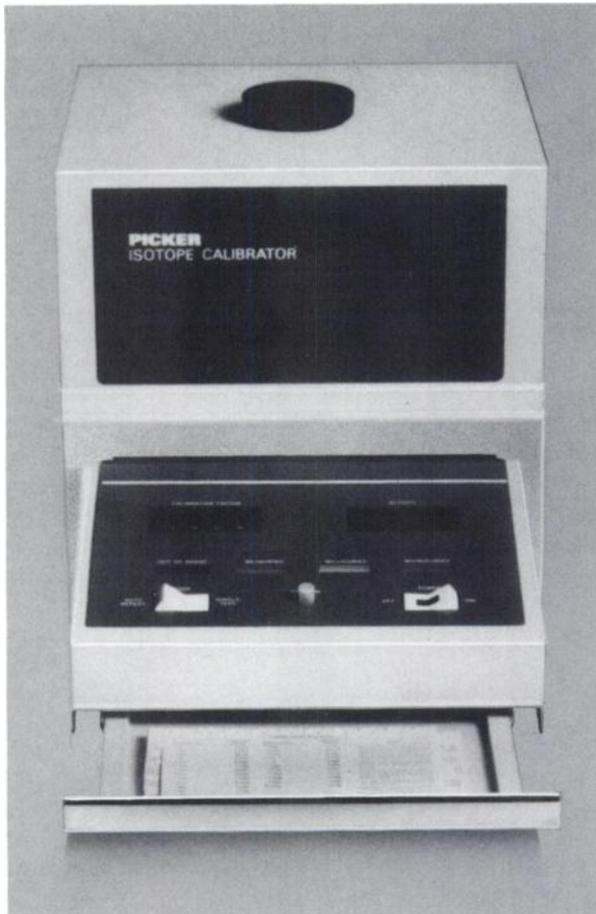
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**DESCRIPTION** - The kit contains 6 sterile vials containing 9-11 mg. of pyrogen-free aggregated albumin (human), 0.67 - 0.83 mg. stannous chloride, and 18 mg. sodium chloride. When sterile, pyrogen-free sodium perchlorate  $\text{Tc}99\text{m}$ 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

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

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

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

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

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

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

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

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

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

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

**WARNINGS** - Technetium MAA  $\text{Tc}99\text{m}$  should not be administered to patients who are pregnant, or during lactation unless the benefits to be gained outweigh the potential hazards.

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

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

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

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

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

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

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

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

### REFERENCES

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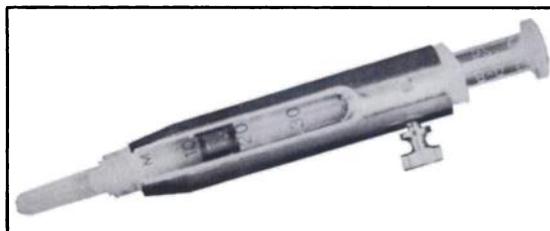
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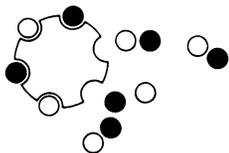
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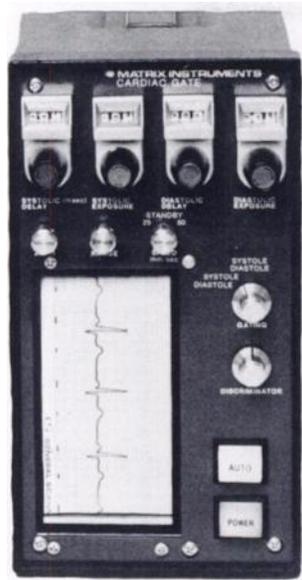


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The dual gating operation mode allows recording of both end-systole and end-diastole simultaneously in a split screen two image format.

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**INDICATIONS AND USAGE:** Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin may be used as a bone imaging agent to delineate areas of altered osteogenesis.

**CONTRAINDICATIONS:** None known.

**WARNINGS:** Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin should not be administered to patients who are pregnant or lactating 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.

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

**PRECAUTIONS:** Tc 99m Pyrophosphate/Trimetaphosphate-Tin, 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.

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

Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin should be used within six hours of preparation.

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. Tc 99m Pyrophosphate/Trimetaphosphate-Tin should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS:** No adverse reactions specifically attributable to the use of Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin have been reported.

**DOSAGE AND ADMINISTRATION:** The suggested dose range for i.v. administration to be employed in the average patient (70kg) is:

Bone imaging: 5-15mCi Technetium Tc 99m labeled Pyrophosphate/Trimetaphosphate-Tin. Scanning post-injection is optimal at about 3-4 hours.

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.

The components of the New England Nuclear Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin 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.

Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin is prepared by simply adding 3-7ml of sodium pertechnetate Tc 99m solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Tc 99m Pyrophosphate/Trimetaphosphate-Tin.

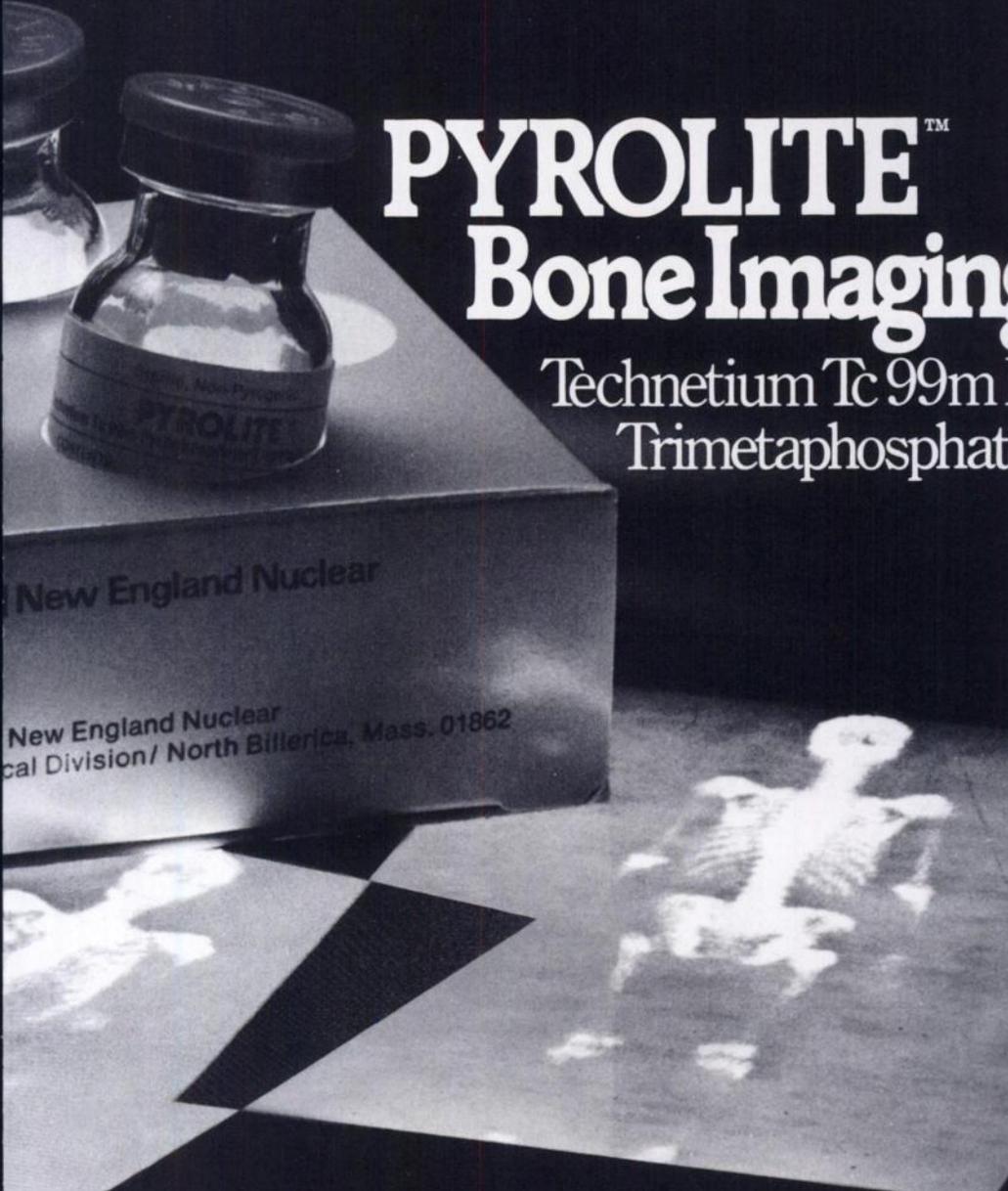
**HOW SUPPLIED:** NEN's PYROLITE™ Technetium Tc 99m Pyrophosphate/Trimetaphosphate-Tin Kit is supplied as a set of five or thirty vials, sterile and non-pyrogenic. Each vial contains in lyophilized form:

Sodium Pyrophosphate - 10mg  
Sodium Trimetaphosphate - 30mg  
Stannous Chloride - 1mg

Prior to lyophilization the pH is adjusted to between 4.5-5.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial are lyophilized and stored under nitrogen. Store at room temperature (15°-30°C).

Included in each five (5) vial kit is one (1) package insert and twelve (12) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and seventy-two (72) radiation labels.





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\*Fordham, Ernest “Osseous nuclear medicine” in Diagnostic Nuclear Medicine. Gottschalk, A. and Potchen, E.J., eds. (Williams and Wilkins Co., Baltimore, 1976)  
Catalog Number NRP-430 U.S. Patent 3,851,044 U.S. Patent 3,852,414

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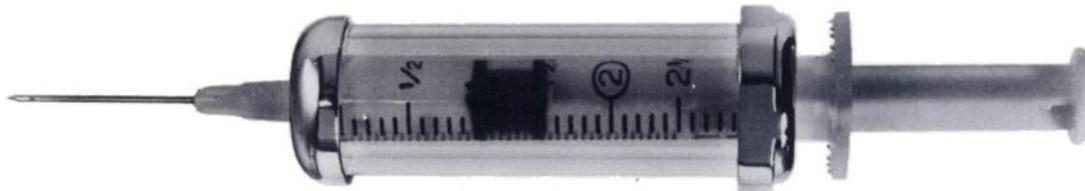
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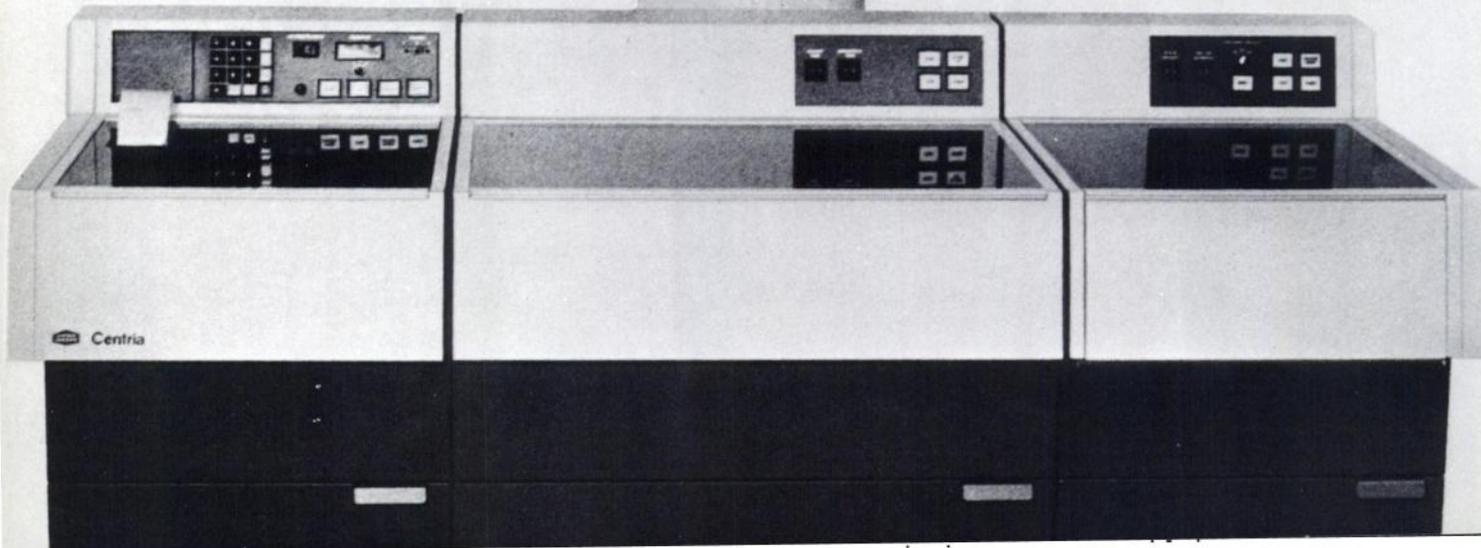
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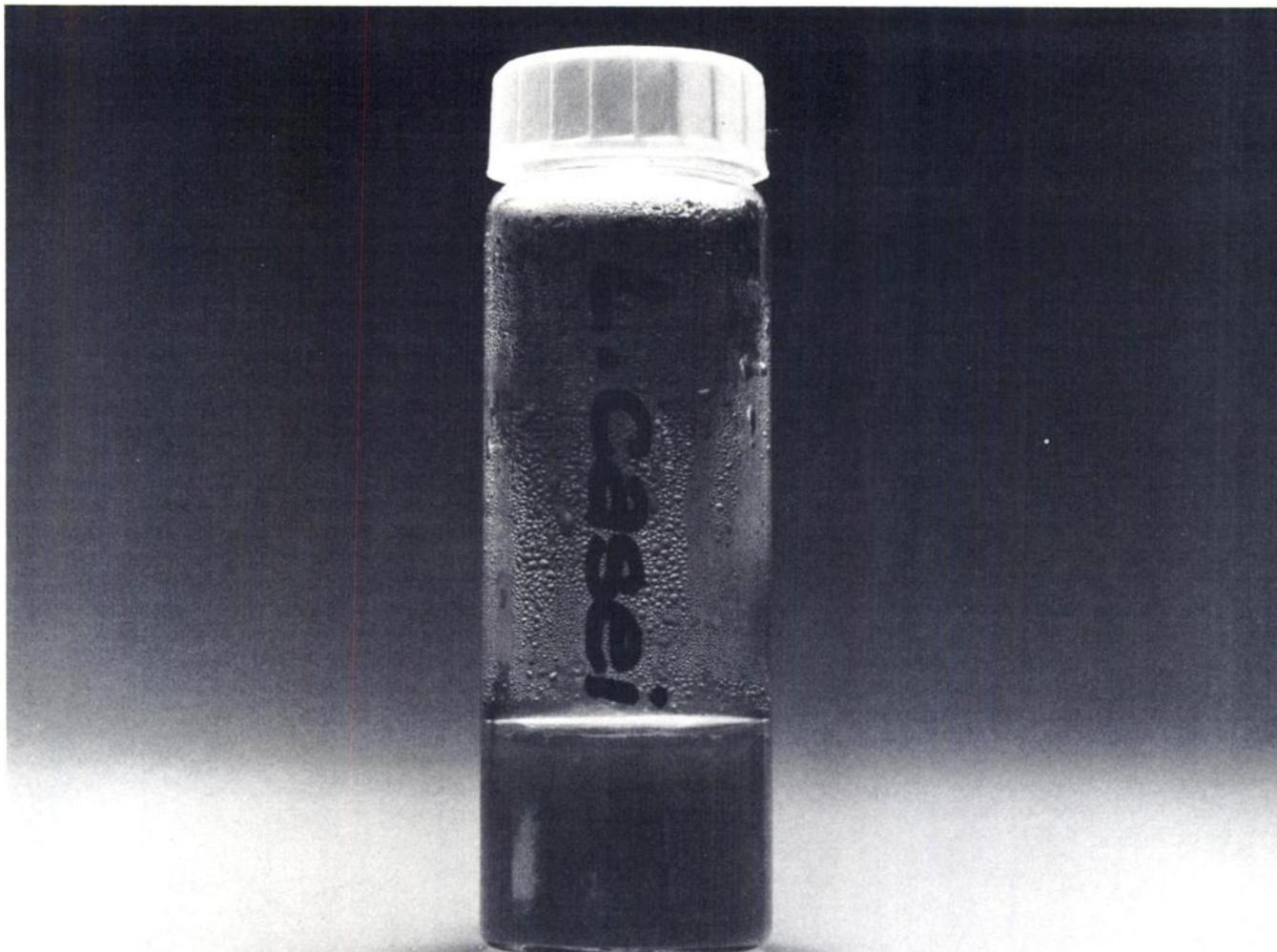
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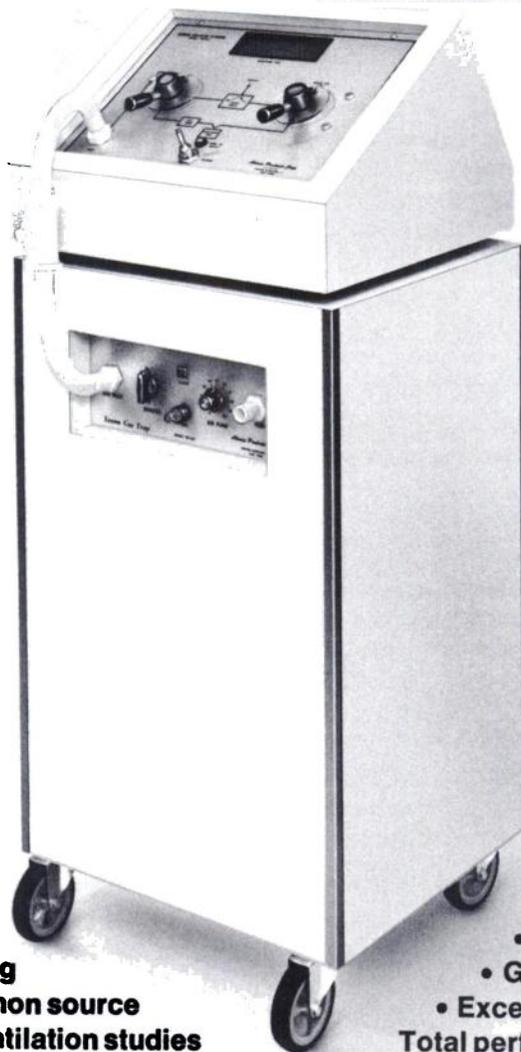
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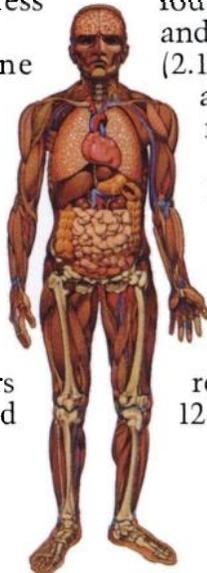
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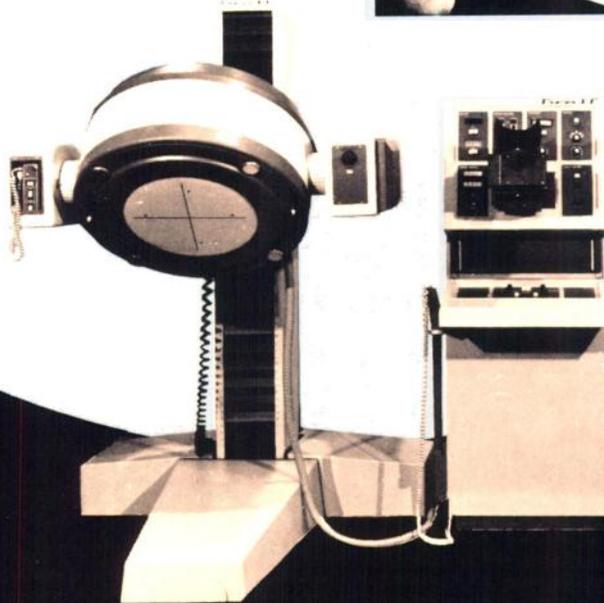
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Mallinckrodt research has now developed a formula that combines the quality features of our frozen **TechneScan MAA** product with the convenience of lyophilization. Our goal was to match—as closely as possible—particle-size range and consistency specifications 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.

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**LUNG SCAN KIT**

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**RADIOPHARMACEUTICALS**

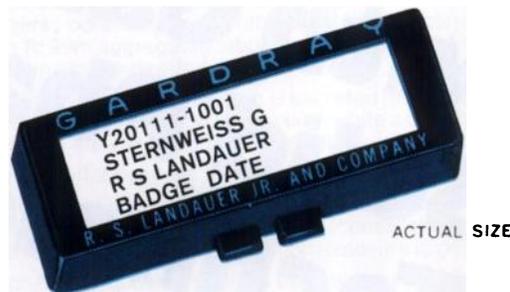
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P.O. Box 5840

St. Louis, MO 63134

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We agree that all things considered the Landauer Gardray 8 film badge system is the best available personnel dosimeter. And, although we are always looking for the ultimate, we have continued to work hard and invest money and time to make it better.

Greatly simplified ordering procedures – permanently encoded unique numbering of film, which is independent of film darkening – new improved techniques for analyzing the film for anomalies that may affect the “meaning” of the exposure and new N.R.C. annual statistical summary reports available now, are just some of the ways our people are working hard to make it better for you.

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

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

#### **INDICATIONS AND USAGE**

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

#### **CONTRAINDICATIONS**

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

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

#### **WARNINGS**

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

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

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

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

#### **PRECAUTIONS**

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

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

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

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

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

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

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

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

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

Safety and effectiveness in children have not been established.

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

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

#### **ADVERSE REACTIONS**

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

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

#### **DOSAGE AND ADMINISTRATION**

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

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

#### **HOW SUPPLIED**

Catalog Number  
093

**TechneScan MAA Kit**  
(Lyophilized)

#### **Kit Contains:**

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

#### **Reaction Vial Contains (in lyophilized form):**

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

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

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

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



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Precision antibody-coated tubes provide a rapid, convenient method to separate bound from free fractions. Simply decant, no centrifugation required. The Gamma-Coat system eliminates the potential pitfalls of charcoal as a separating agent.

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Color-coded buffers are provided for the generation of angiotensin I at either pH 6.0 or 7.4. Antibacterial agents, neomycin and sodium azide, are included in the buffers to retard bacterial growth during extended incubations.

## MINIMAL DILUTION OF PLASMA SAMPLE

Only 0.1 ml of buffer is added to a 1.0 ml plasma sample for adjustment and maintenance of pH during generation. Since excessive dilution of renin and renin substrate are avoided, angiotensin I generation proceeds at a maximal rate.

The complications of interpreting data obtained from procedures using higher dilutions are avoided in the GammaCoat Plasma Renin Activity System.

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Use of a 3-hour incubation provides a significantly shortened radioimmunoassay. Results, from start to finish, are available on the same working day.

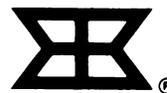
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Variations in PRA have been observed upon repeated assay of frozen plasma after various periods of storage. Thus, the use of stored frozen plasma as a control in PRA determinations may lead to erroneous results. The Gamma-Coat system includes *lyophilized* renin activity controls at two levels. Routine use of these controls during *generation*, as well as *radioimmunoassay*, provides a reliable quality control index for the *entire* assay.

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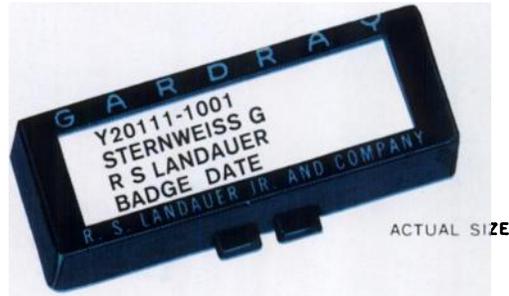
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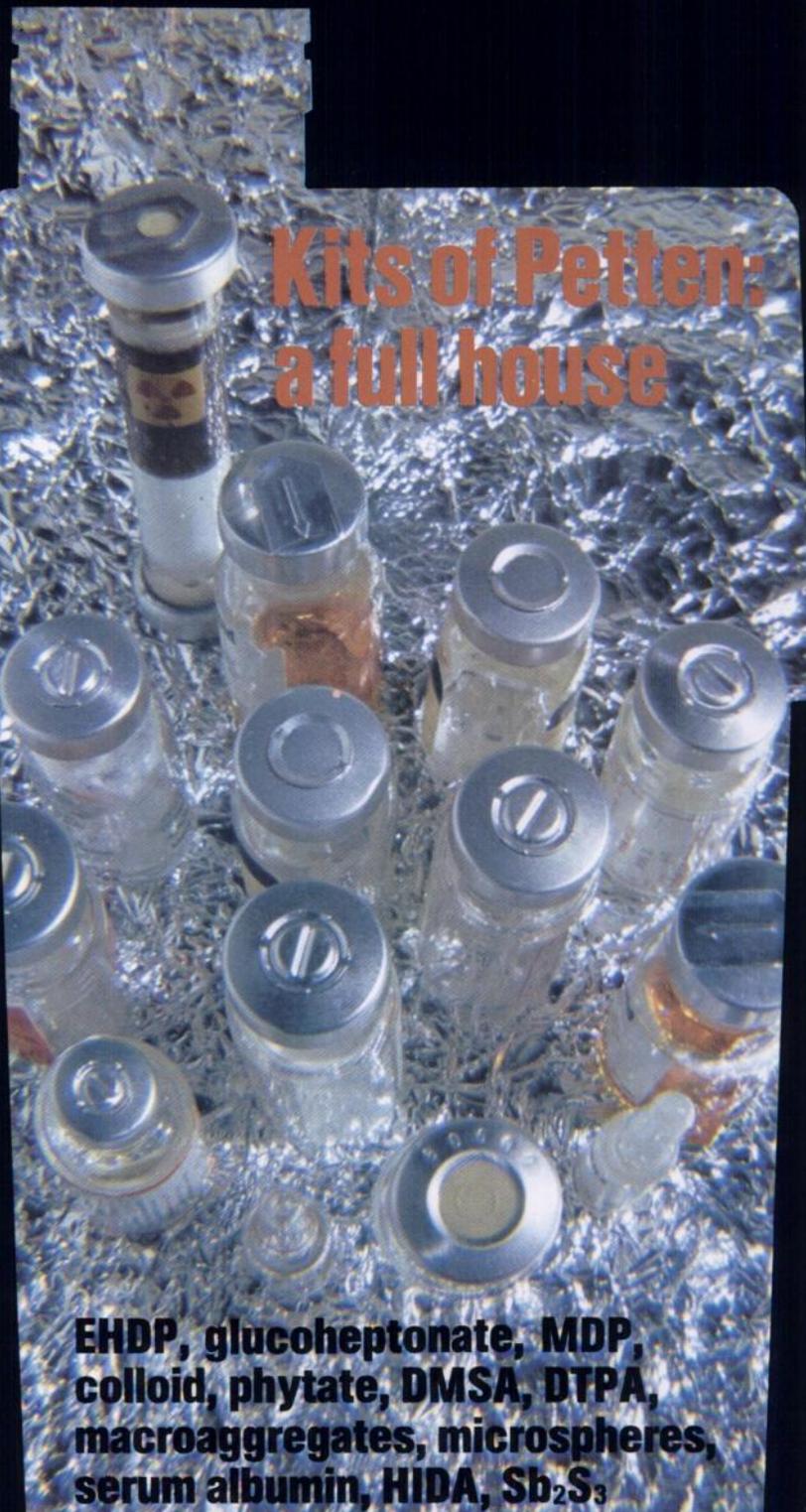
We agree that all things considered the Landauer Gardray 8 film badge system is the best available personnel dosimeter. And, although we are always looking for the ultimate, we have continued to work hard and invest money and time to make it better.

Greatly simplified ordering procedures – permanently encoded unique numbering of film, which is independent of film darkening – new improved techniques for analyzing the film for anomalies that may affect the “meaning” of the exposure and new N.R.C. annual statistical summary reports available now, are just some of the ways our people are working hard to make it better for you.

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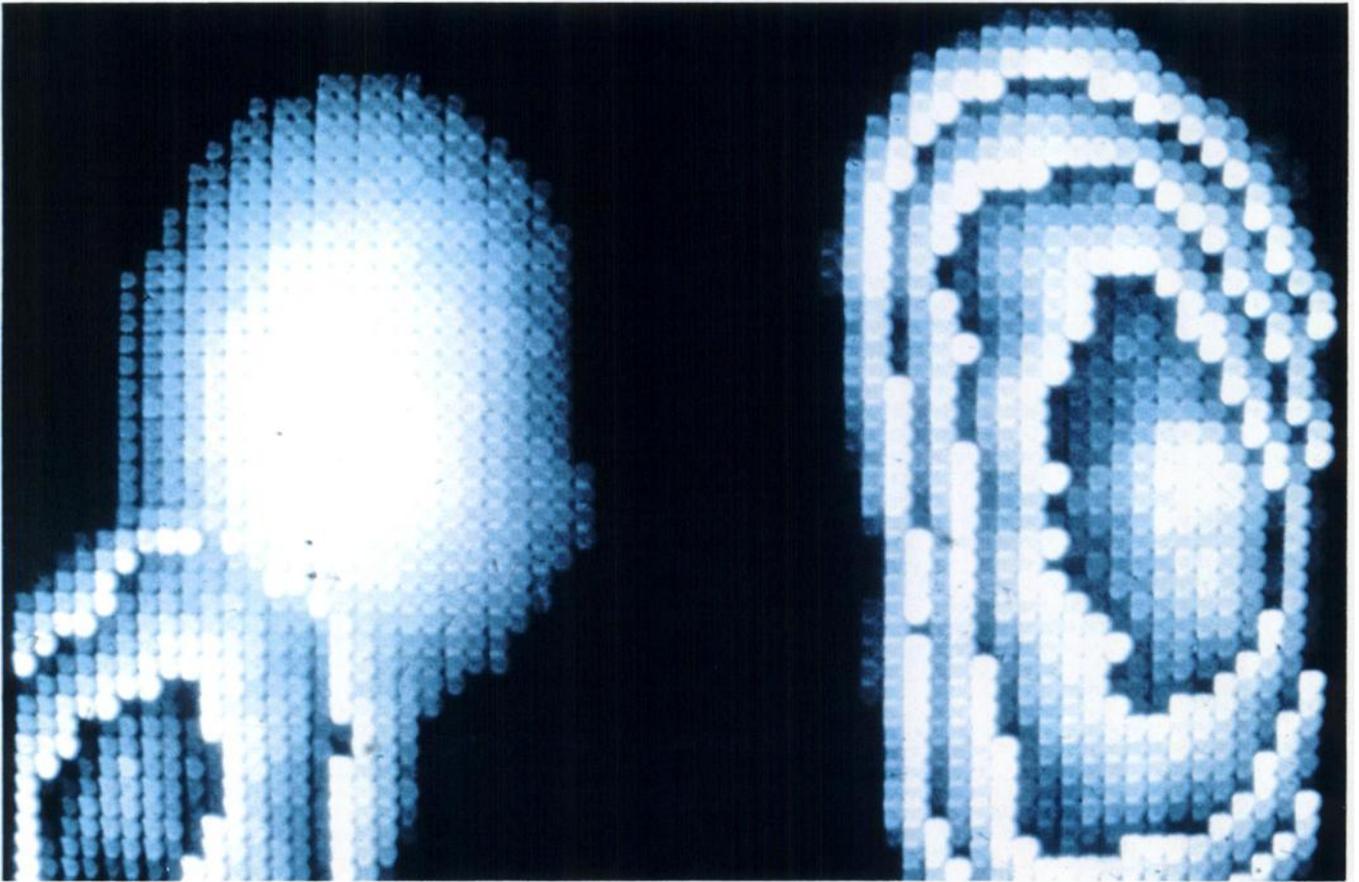
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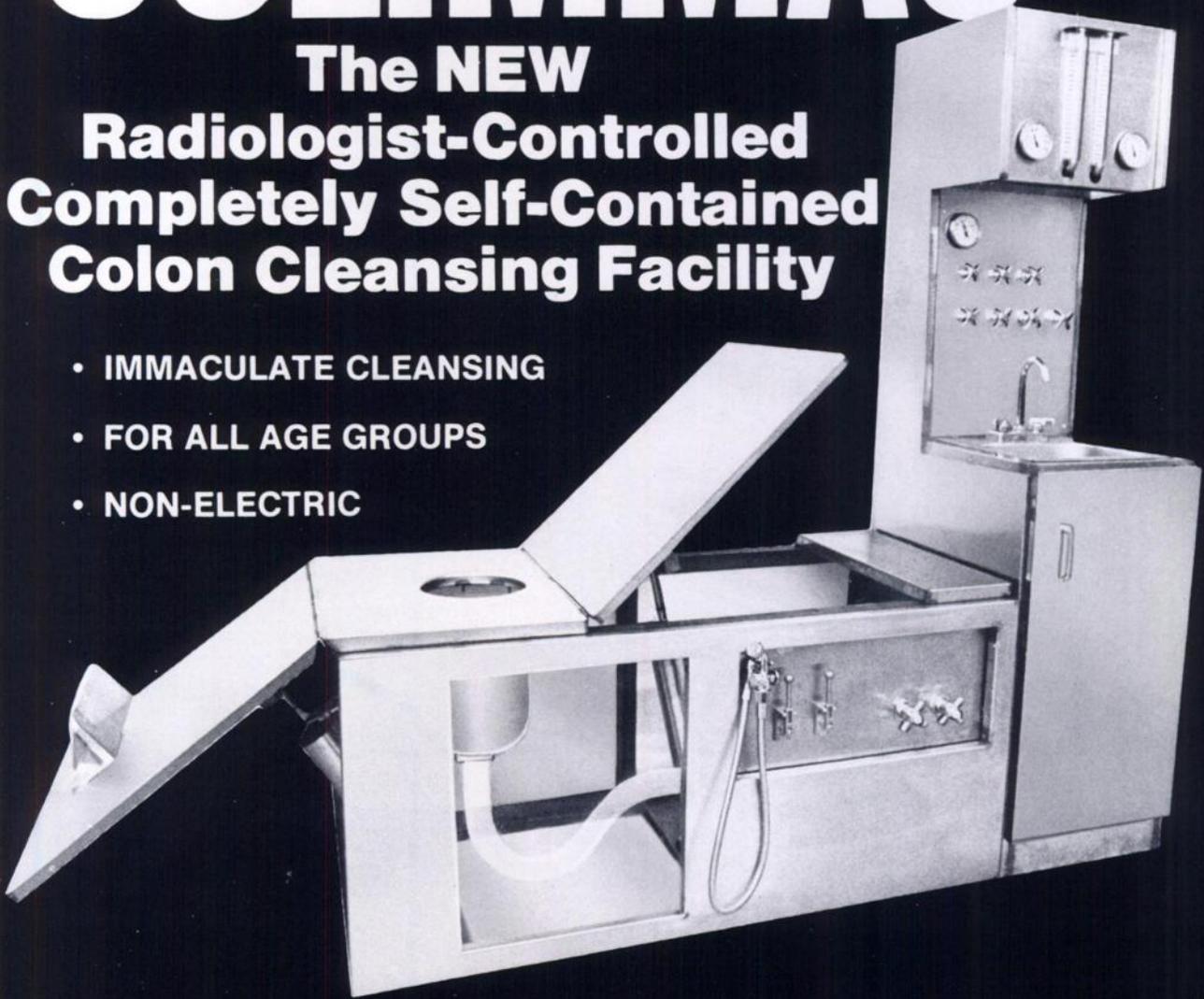
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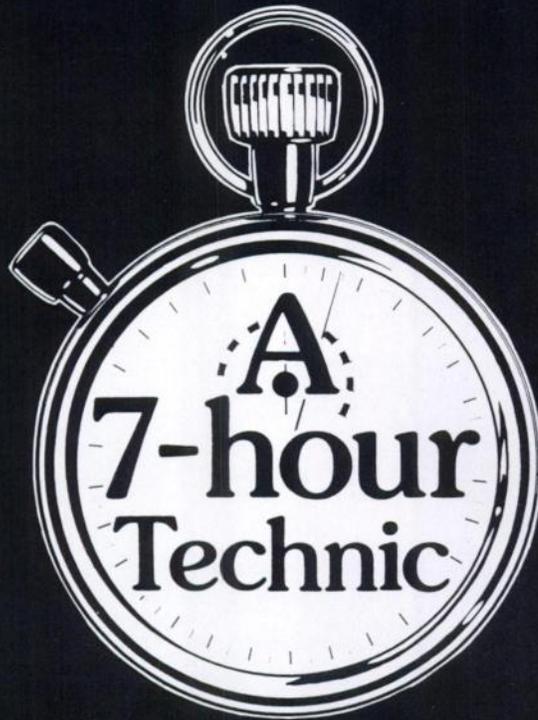
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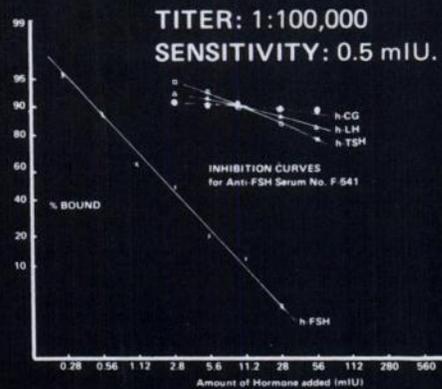
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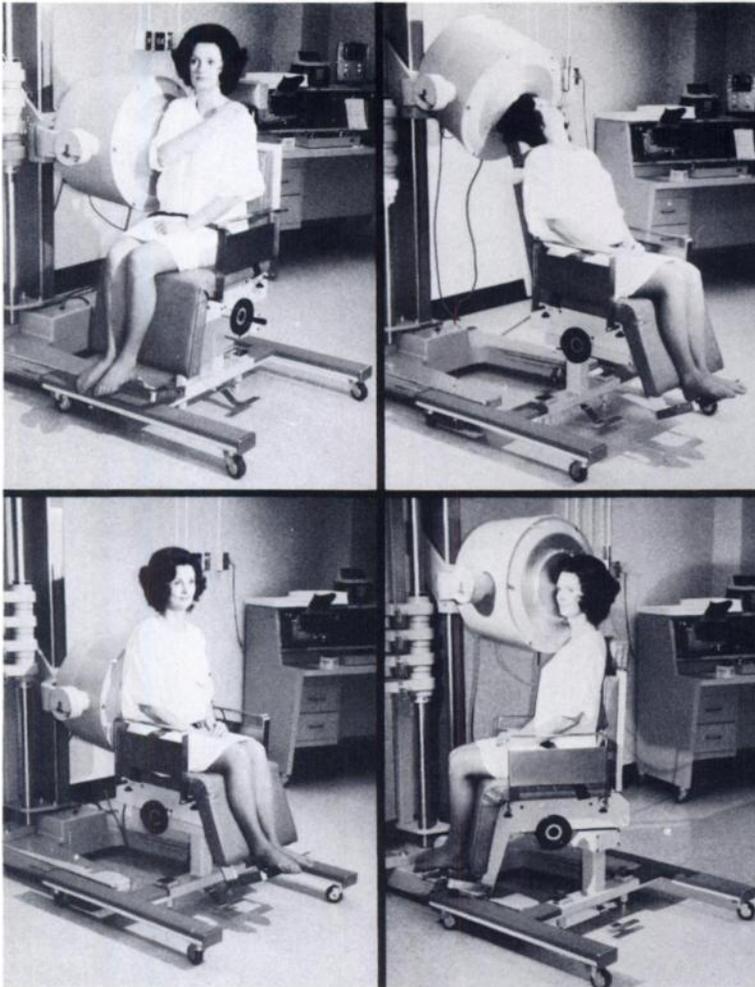
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RAO, SYSTOLE



LAO, DIASTOLE

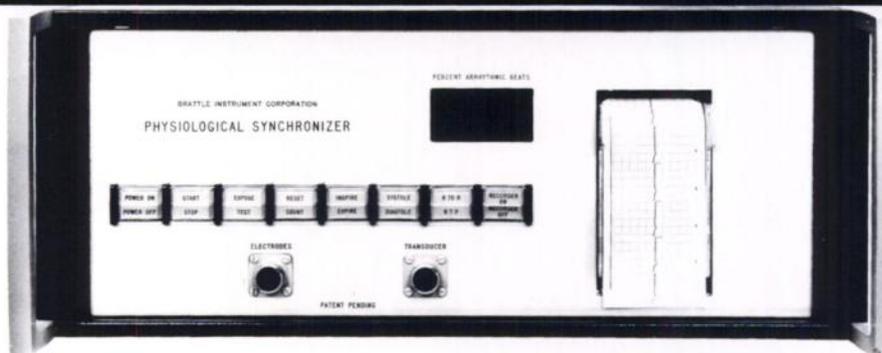


LAO, SYSTOLE

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 contrac-

tion posteriorly and akinesis of the septal aspect of the chamber. Patient was injected IV with 20mCi of  $^{99m}\text{Tc}$ -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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The spartan panel above tells the second-best part of our story. If you want to photograph peak systole, press the SYSTOLE button. If, say, you want systole only at full expiration, press the EXPIRATION button as well. If only breathing is relevant, don't press the heart button.

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

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The panel lights flash whenever the patient reaches the selected phases; and pushing the RECORDER-ON button gets you an ECG tracing marked with breathing and camera-on times. You can verify function before, during and after exposure.

## A single pair of axillary electrodes captures both heart and breath

It's easy. And we supply disposable, pre-filled electrodes.

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

## What's the next step? Get in touch

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

## Brattle Instrument Corporation

243 Vassar Street • Cambridge, Massachusetts 02139 • 617-661-0300

# SPEED READ

## NUCLEAR CARDIOLOGY DATA WITH **SCINTISTORE™** Time-compression data storage/retrieval system

### THE WAY TO INCREASE CLINICAL UTILITY OF THE PHO/GAMMA® LEM CAMERA

The diagnostic capabilities of the LEM (Low Energy Mobile Scintillation Camera) can now be further extended by the addition of a Scintistore data acquisition system—a portable, computer-compatible, disc-based data acquisition system which includes a cardiac gate. Together, the Scintistore and LEM camera give you the most advanced mobile unit available anywhere today.



"A new dimension in nuclear imaging"

#### Clinical utility is provided by these features:

- **High Data Rate**—80,000 events per second allow accurate quantification of cardiac function
- **High Data Capacity**—2.5 million events stored on each of two discs to make wall motion studies of the myocardium possible
- **Portability**—Docks compactly with LEM for transport as a single unit, accompanies LEM to patient's bedside
- **Time-Compressed Replay**—Retrieves information at rate of 50,000 events per second, irrespective of recording rate, saves physician time

#### Cardiac Gating

The cardiac gate is digitally implemented through an eight-bit microprocessor. It performs gated imaging for wall motion studies of the myocardium.

**SEARLE**

#### Searle Radiographics

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