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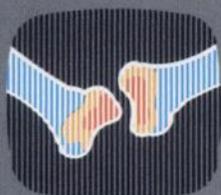
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Yesterday



1970

Today



1980

Tomorrow



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For the past decade, nuclear medicine has enjoyed a continuing stream of new radiopharmaceuticals, new isotopes, new diagnostic procedures — and new patients. Many of these new diagnostic procedures resulted directly or indirectly from the investments in product research and development, testing, production, and promotion by a single company: New England Nuclear.

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And then, we underwrote an effort unique in nuclear medicine — we began spending hundreds of thousands of dollars each year to inform primary-care physicians and specialists why they should send their patients to nuclear departments for these new studies.

Such investments in new product development and physician education are common among traditional pharmaceutical companies producing proprietary products that can be patented. However, all NEN's investments were made on products for which no exclusivity of patent protection was available. Some of NEN's investments were not successful. A few were, however — and they profoundly changed nuclear medicine.

Of course, NEN could have waited for other companies to develop new

procedures and products... to carry the risk and investment of pioneering trial and error. We could have waited until someone else created a demand for new isotopes, and then capitalized on their efforts.

Instead, we built *four* of our own cyclotrons, and are currently building a multimillion-dollar linear accelerator — further evidence of NEN's unique commitment to research and development innovation in isotope and radiopharmaceutical production.

If NEN had not been so committed to advancing nuclear diagnostics, perhaps bone scans might still be done with strontium... and techniques such as tumor, abscess, and myocardial perfusion imaging might still be subjects for academic — not clinical — consideration.

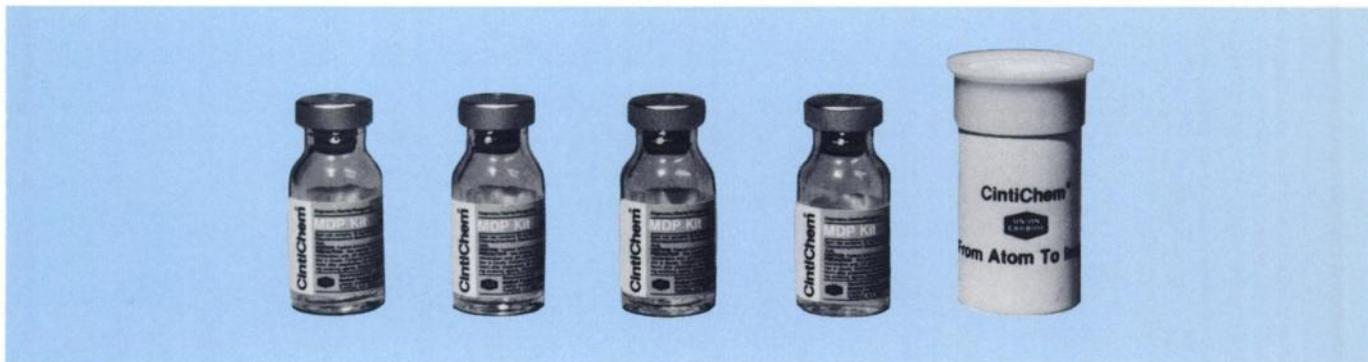
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Technetium Tc 99m Medronate Kit

BRIEF SUMMARY OF PRESCRIBING INFORMATION

indications and usage

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

contraindications

None known.

warnings

This class of compound is known to complex cations such as calcium. Particular caution should be used with patients who have, or who may be predisposed to, hypocalcemia (i.e., alkalosis).

This radiopharmaceutical drug product should not be administered to children, to pregnant women, or to nursing mothers, unless the expected benefit to be gained outweighs the potential risk.

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

precautions

general

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

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

This preparation contains no bacteriostatic preservative. Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use.

pregnancy category C

Adequate reproductive studies have not been performed in animals to determine whether this drug affects fer-

tility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Medronate should be used in pregnant women only when clearly needed.

nursing mothers

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

pediatric use

Safety and effectiveness in children have not been established.

adverse reactions

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

how supplied

Union Carbide's Technetium Tc 99m Medronate Kit is supplied as a sterile, pyrogen-free kit containing 5 vials.

Each 10 ml vial contains 10 mg medronic acid, 0.17 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.29 mg), and 2 mg ascorbic acid. The pH has been adjusted to 4-8 with either HCl or NaOH prior to lyophilization. Following lyophilization, the vials are sealed under a nitrogen atmosphere.

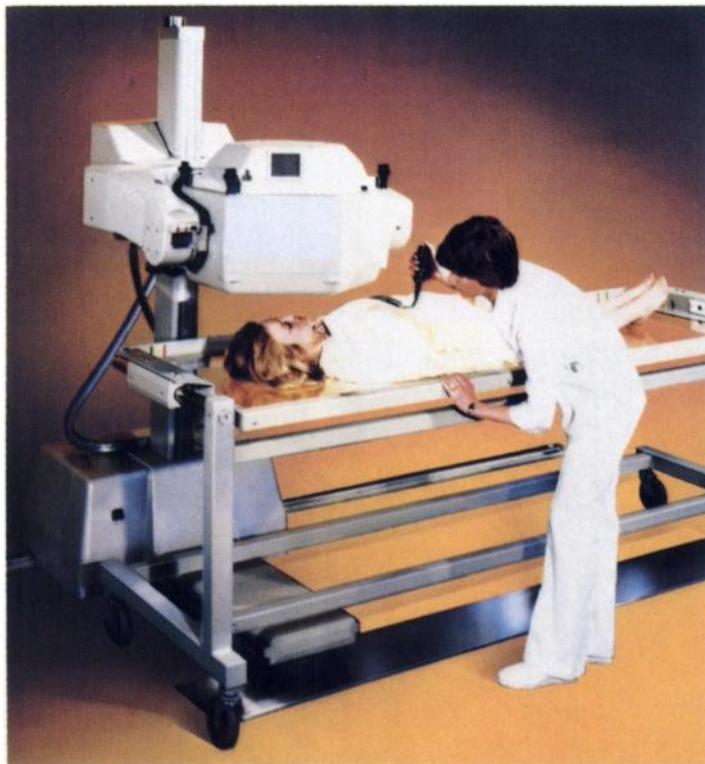
Product #17500502 Multidose vial shield with cap and retainer ring available separately.



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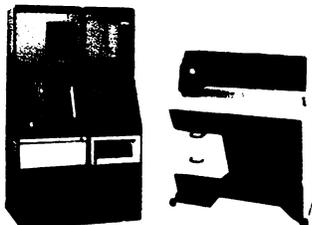
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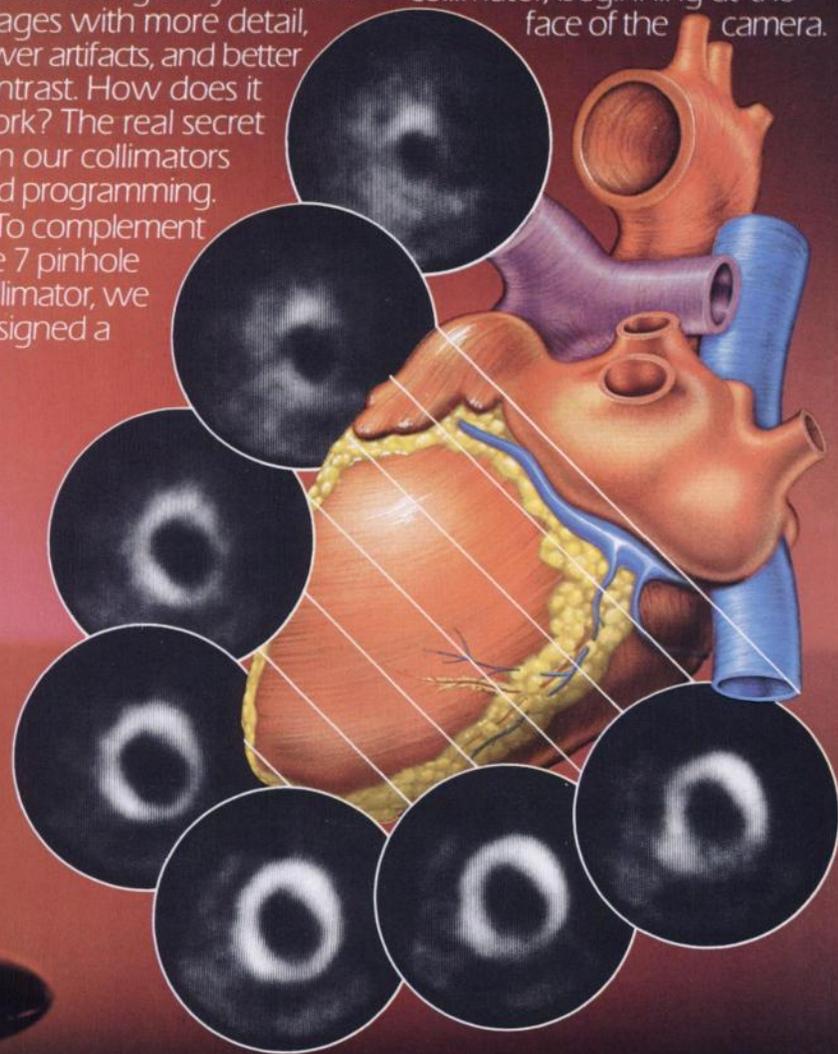
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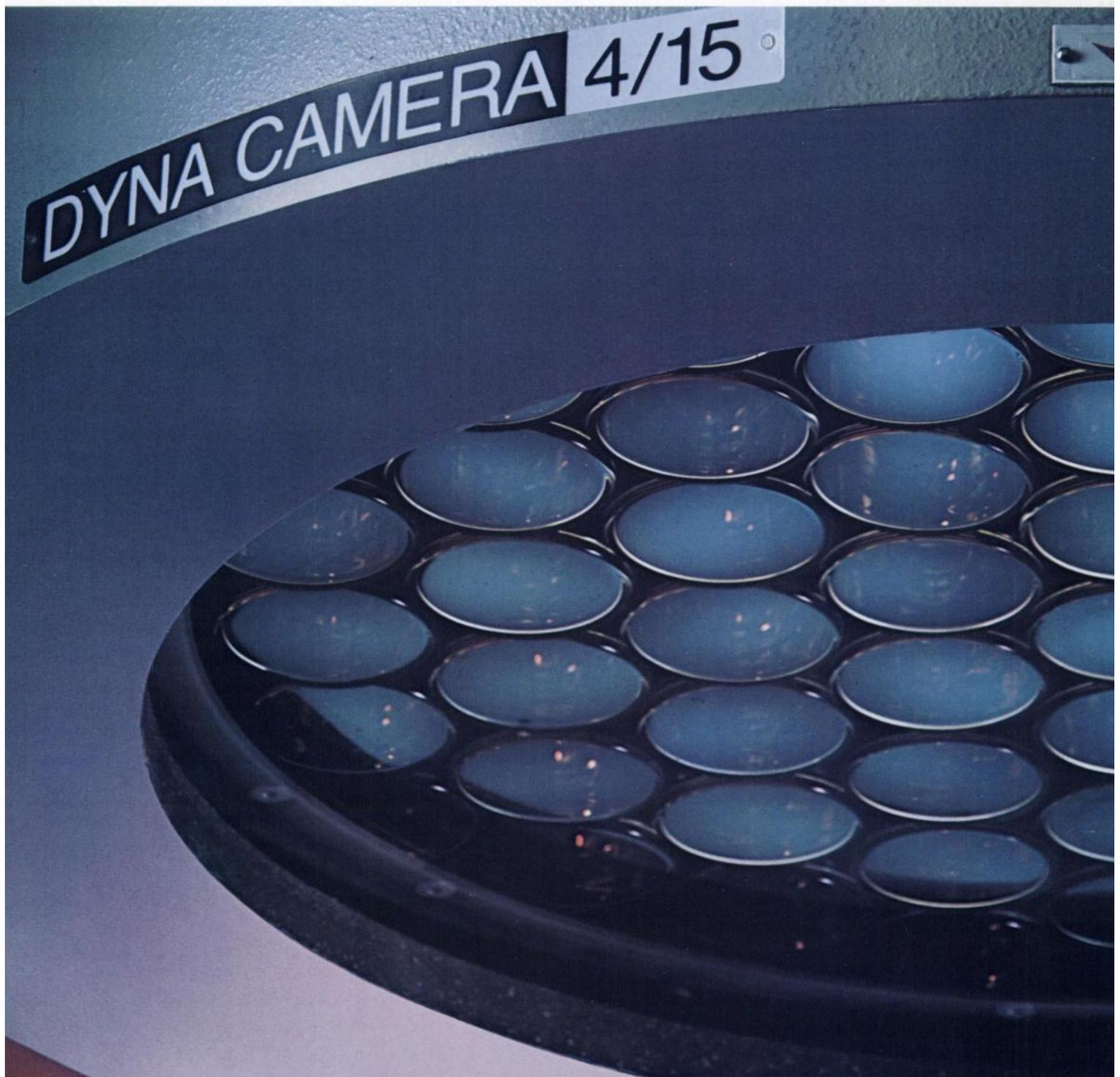
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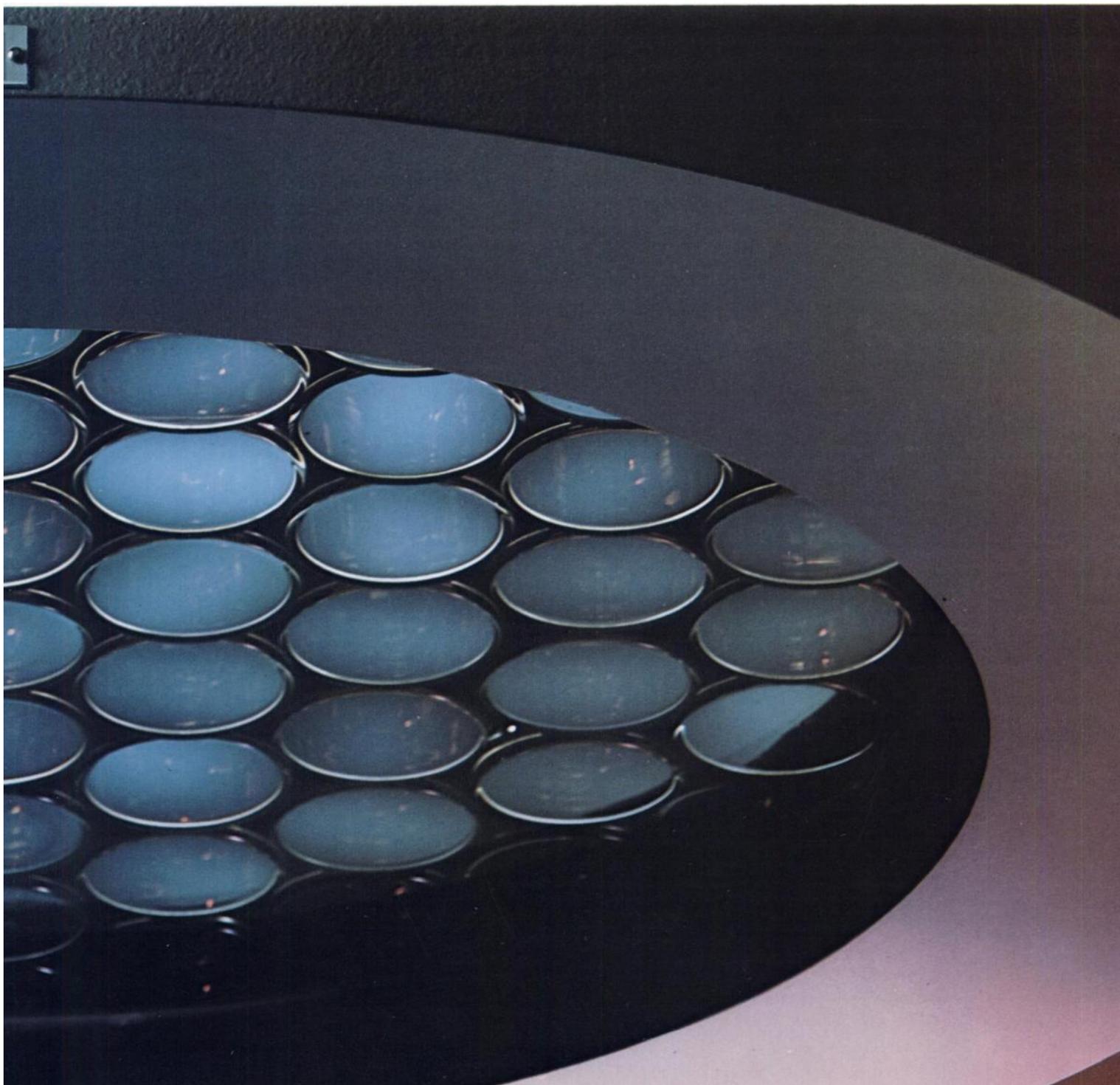
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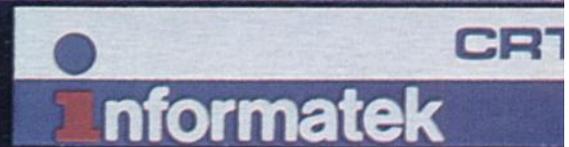
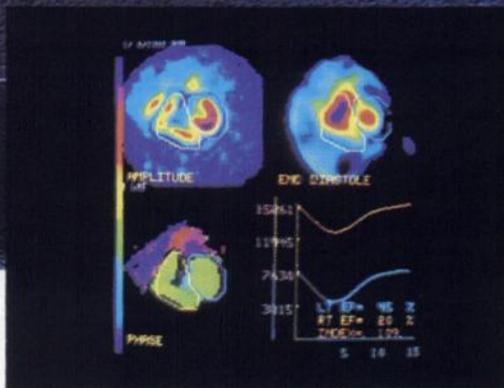
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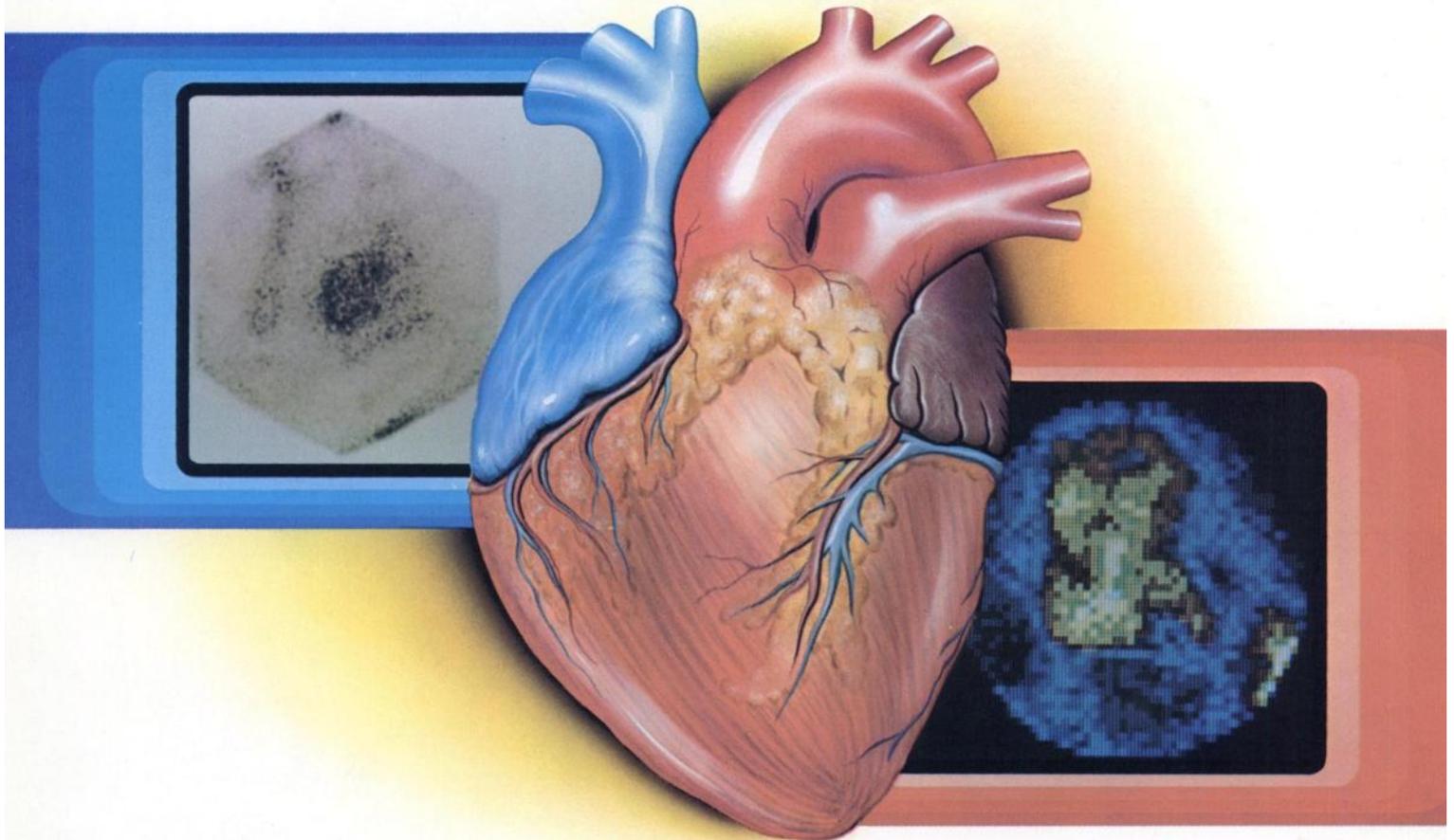
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An advance from Mallinckrodt provides an excellent adjunct in the detection of myocardial infarction and the dynamic assessment of cardiac function.



TechneScan® PYP™ Kit (Stannous Pyrophosphate) for preparation of Technetium Tc-99m Stannous Pyrophosphate.

A consistent agent for skeletal imaging, *TechneScan PYP* is now available for use as an adjunct in the diagnosis of acute myocardial infarction, and for gated cardiac blood-pool imaging.

Investigators have found the technetium-99m pyrophosphate scintigraphic study to be a highly useful diagnostic technique for evaluating chest pain of uncertain origin.¹

"The gated cardiac blood pool scan permits the calculation of both ejection and regional wall motion from a single examination."²

Mallinckrodt's *TechneScan PYP*...a preferred way to detect acute myocardial infarction...an advanced method to dynamically assess cardiac function.

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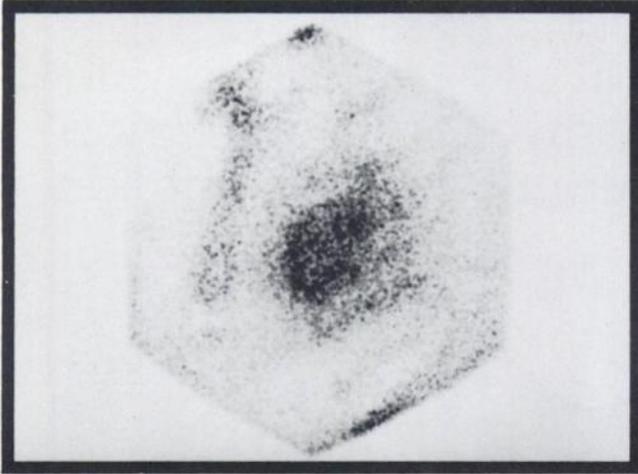
1. Berman, DS, et al: New Approach to Interpretation of Technetium-99m Pyrophosphate Scintigraphy in Detection of Acute Myocardial Infarction: Clinical Assessment of Diagnostic Accuracy. *Am. J. Cardiol.* 39:341-346, (March) 1977.
2. Strauss, HW, Pitt, B: Cardiovascular Nuclear Medicine: Its Role in Patients with Coronary Heart Disease. *CVP Journal*: (November/December), 1974.



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See reverse side for brief summary of complete prescribing information.

An advance from Mallinckrodt provides an excellent adjunct in the detection of myocardial infarction and the dynamic assessment of cardiac function.



TechneScan® PYP™ Kit (Stannous Pyrophosphate) for preparation of Technetium Tc-99m Stannous Pyrophosphate.

BRIEF SUMMARY

CLINICAL PHARMACOLOGY

When injected intravenously **TechneScan PYP Tc 99m** has a specific affinity for areas of altered osteogenesis. It is also concentrated in the injured myocardium, primarily in areas of irreversibly damaged myocardial cells.

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

TechneScan PYP also has an affinity for red blood cells. When administered 30 minutes prior to the intravenous administration of sodium pertechnetate Tc-99m approximately 76 percent of the injected activity remains in the blood pool providing excellent images of the cardiac chambers.

INDICATIONS AND USAGE

TechneScan PYP Tc 99m is a skeletal imaging agent used to demonstrate areas of altered osteogenesis, and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction.

As an adjunct in the diagnosis of confirmed myocardial infarction (ECG and serum enzymes positive), the incidence of false negative images has been found to be 6 percent. False negative images can also occur if made too early in the evolutionary phase of the infarct or too late in the resolution phase. In a limited study involving 22 patients in whom the ECG was positive and serum enzymes questionable or negative, but in whom the final diagnosis of acute myocardial infarction was made, the incidence of false negative images was 23 percent. The incidence of false positive images has been found to be 7 to 9 percent. False positive images have also been reported following coronary by-pass graft surgery, in unstable angina pectoris, old myocardial infarcts and in cardiac contusions.

TechneScan PYP is a blood pool imaging agent which may be used for gated cardiac blood pool imaging. When administered intravenously 30 minutes prior to the intravenous administration of sodium pertechnetate Tc-99m approximately 76 percent of the injected activity remains in the blood pool.

CONTRAINDICATIONS

None.

WARNINGS

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

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

Warning: Preliminary reports indicate impairment of brain scans using pertechnetate Tc-99m which have been preceded by bone scan. The impairment may result in false positives or false negatives. It is recommended, where feasible, that brain scans precede bone imaging procedures.

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

The **TechneScan PYP Kit** must be maintained at refrigerator temperature until use.

The contents of the **TechneScan PYP** reaction vial are intended for use in the preparation of Technetium Tc 99m Stannous Pyrophosphate. **TechneScan PYP** may also be

reconstituted with sterile, pyrogen-free normal saline containing no preservatives and injected intravenously prior to the administration of sodium pertechnetate Tc-99m.

Sodium pertechnetate Tc-99m solutions containing an oxidizing agent are not suitable for use with the **TechneScan PYP Kit**.

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

TechneScan PYP Tc 99m should not be used more than six hours after preparation.

PRECAUTIONS

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

Bone Imaging

Both prior to and following **TechneScan PYP Tc 99m** administration, patients should be encouraged to drink fluids. Patients should void as often as possible after the **TechneScan PYP Tc 99m** injection to minimize background interference from accumulation in the bladder and unnecessary exposure to radiation.

Cardiac Imaging

Patient's cardiac condition should be stable before beginning the cardiac imaging procedure.

If not contraindicated by the cardiac status, patients should be encouraged to ingest fluids and to void frequently in order to reduce unnecessary radiation exposure.

Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing the three recommended projections.

Blood Pool Imaging

TechneScan PYP should be injected by direct venipuncture. Heparinized catheter systems should be avoided.

ADVERSE REACTIONS

None.

HOW SUPPLIED

Catalog Number—094 **TechneScan PYP Kit**

Kit Contains:

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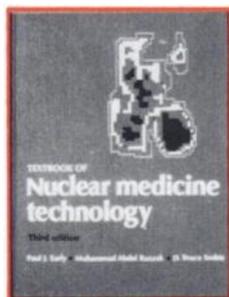
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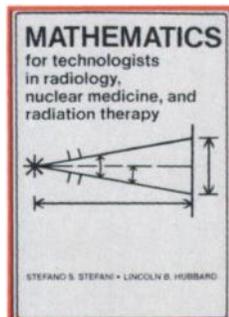
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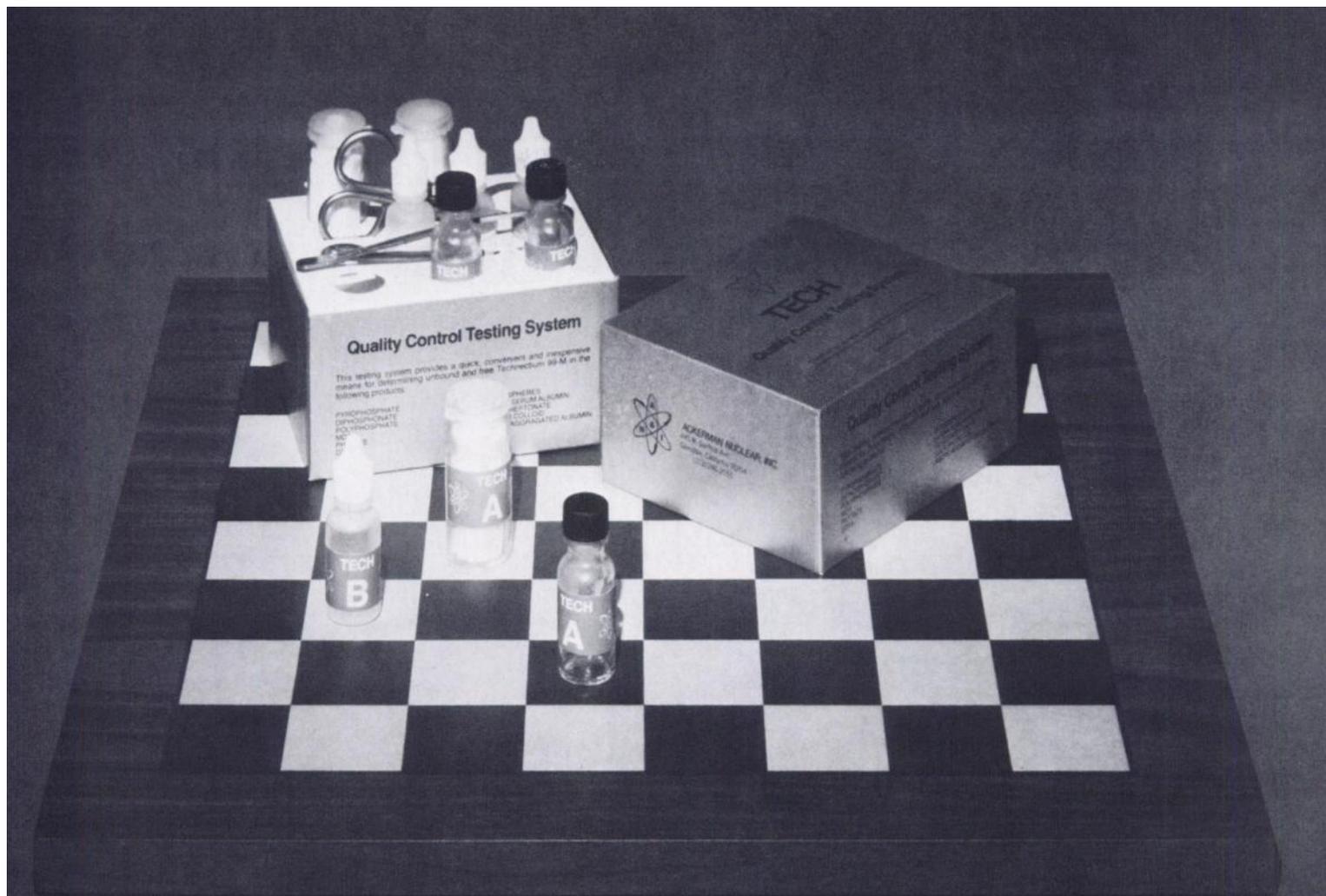
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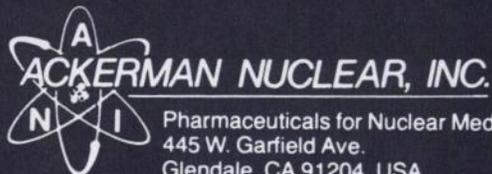
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ADAC System II is a System I *plus* a Remote Acquisition/Processing Terminal, a second Computer Section, and a second Winchester disc drive.

It also has the new high-

speed ADAC Arithmetic Processing Unit.

With ADAC System II, you can process one study on the Main Console while another is being acquired or

processed at the Remote Terminal.

Want more?

Your ADAC System II can easily be expanded to a System III or IV.

ADAC SYSTEM III.

It processes and acquires in two places at once.

From the outside, ADAC System III looks like a System II. But we've added more capability to the Computer Section, so you can acquire *and* process at your Main Console *and* Remote Terminal.

Want still more?
Your ADAC System III can easily be expanded to a System IV.

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ADAC System IV has two Main Consoles and an expanded Computer Section, so you can process and acquire in two places at once.

Simply add an optional Remote Terminal and you can process and acquire studies at *three* locations.
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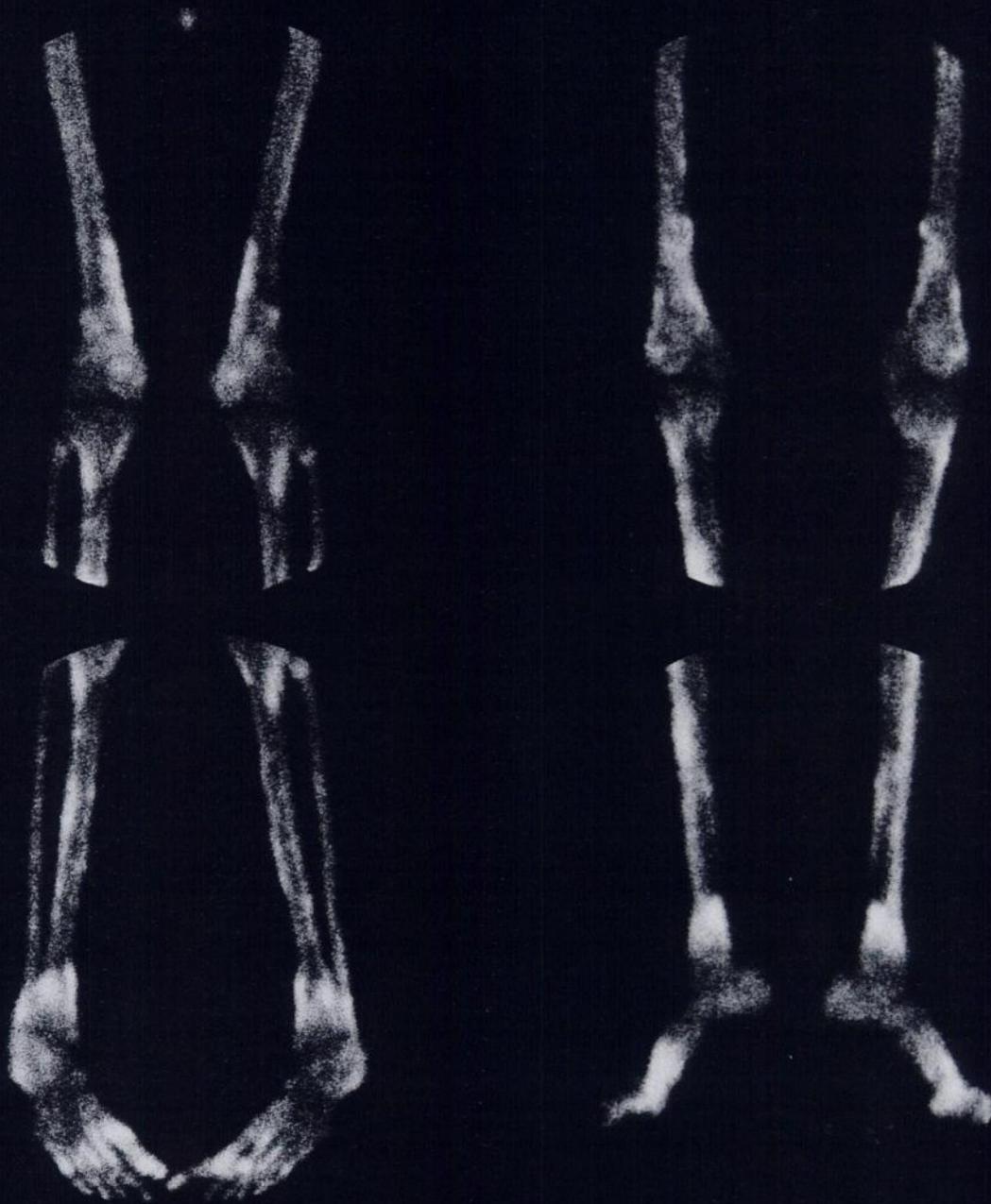
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The logo consists of the letters 'ADAC' in a bold, orange, sans-serif font. The letters are closely spaced and have a slightly stylized appearance.

Nuclear Medicine Computers

Bone



Diagnosis: hypertrophic
pulmonary osteoarthropathy

Imaging information: *Instrument:* GE MaxiCamera™ 535 *Dose:* 20 mCi OSTEOLITE
Scan time: 2.5-3.0 hours postinjection *Acquisition time:* 6 minutes/view

OSTEOLITE™
Technetium Tc 99m Medronate Sodium Kit (MDP)

NEN New England Nuclear®

Please see following page for brief prescribing information.
See us at the SNM show in Detroit—Booths #615, 617, 619, 621, 623

OSTEOLITE™

Technetium Tc 99m Medronate Sodium Kit (MDP)

INDICATIONS AND USAGE: Technetium Tc 99m OSTEOLITE may be used as a bone imaging agent to delineate areas of altered osteogenesis.

CONTRAINDICATIONS: None known.

WARNINGS: The contents of the OSTEOLITE vial are intended only for use in the preparation of Technetium Tc 99m medronate sodium and are NOT to be directly administered to the patient.

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

PRECAUTIONS: A thorough knowledge of the normal distribution of intravenously administered Technetium Tc 99m medronate sodium is essential in order to accurately interpret pathologic studies.

Technetium Tc 99m medronate sodium, as well as any radioactive agent, must be handled with care. Once sodium pertechnetate Tc 99m is added to the kit, appropriate safety measures should be used to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

Since 50–75% of the administered dose is renally excreted, good patient hydration and frequent voiding for 4–6 hours post-injection will significantly reduce the bladder wall dose.

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

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

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 medro-

nate sodium should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: None reported.

DOSE AND ADMINISTRATION: The recommended dose for the average 70kg adult patient is 15mCi with a range of 10-20mCi. The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

Optimal imaging results are obtained within one to four hours after administration.

OSTEOLITE should be used within six hours after aseptic reconstitution with sodium pertechnetate Tc 99m. For optimum results this time should be minimized.

The vial contains no bacteriostat.

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 governmental agencies authorized to license the use of radionuclides.

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

Medronate Disodium — 10mg

Stannous Chloride Dihydrate — 0.85mg

The pH is adjusted to between 7.0-7.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial were lyophilized under nitrogen. Store at room temperature (15°-30° C). Included in each five (5) vial kit is one (1) package insert and six (6) radiation labels. Included in each thirty (30) vial kit is one (1) package insert and thirty-six (36) radiation labels.

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

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.

Catalog Number NRP-420 (5 vial kit)

April 1978

Catalog Number NRP-420C (30 vial kit)

GLUCOSCAN™

Technetium Tc 99m Glucoptate Sodium Kit

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

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

CONTRAINDICATIONS: None known.

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

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

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

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

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

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

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

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

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

It is not known whether this drug is excreted in human milk. As a general

rule, nursing should not be undertaken when a patient is administered radioactive material.

Safety and effectiveness in children have not been established.

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

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

Technetium Tc 99m Glucoptate Sodium should be used within six hours after aseptic reconstitution with sodium pertechnetate Tc 99m. For optimal results, this time should be minimized. The reaction vial contains no bacteriostat.

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

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

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

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

Glucoptate Sodium — 200mg

Maximum Tin — 0.07mg

Stannous Chloride (min.) — 0.06mg

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

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

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

Catalog Number NRP-180 (5 vial kit)

August 1978

Catalog Number NRP-180C (30 vial kit)

NEN New England Nuclear™

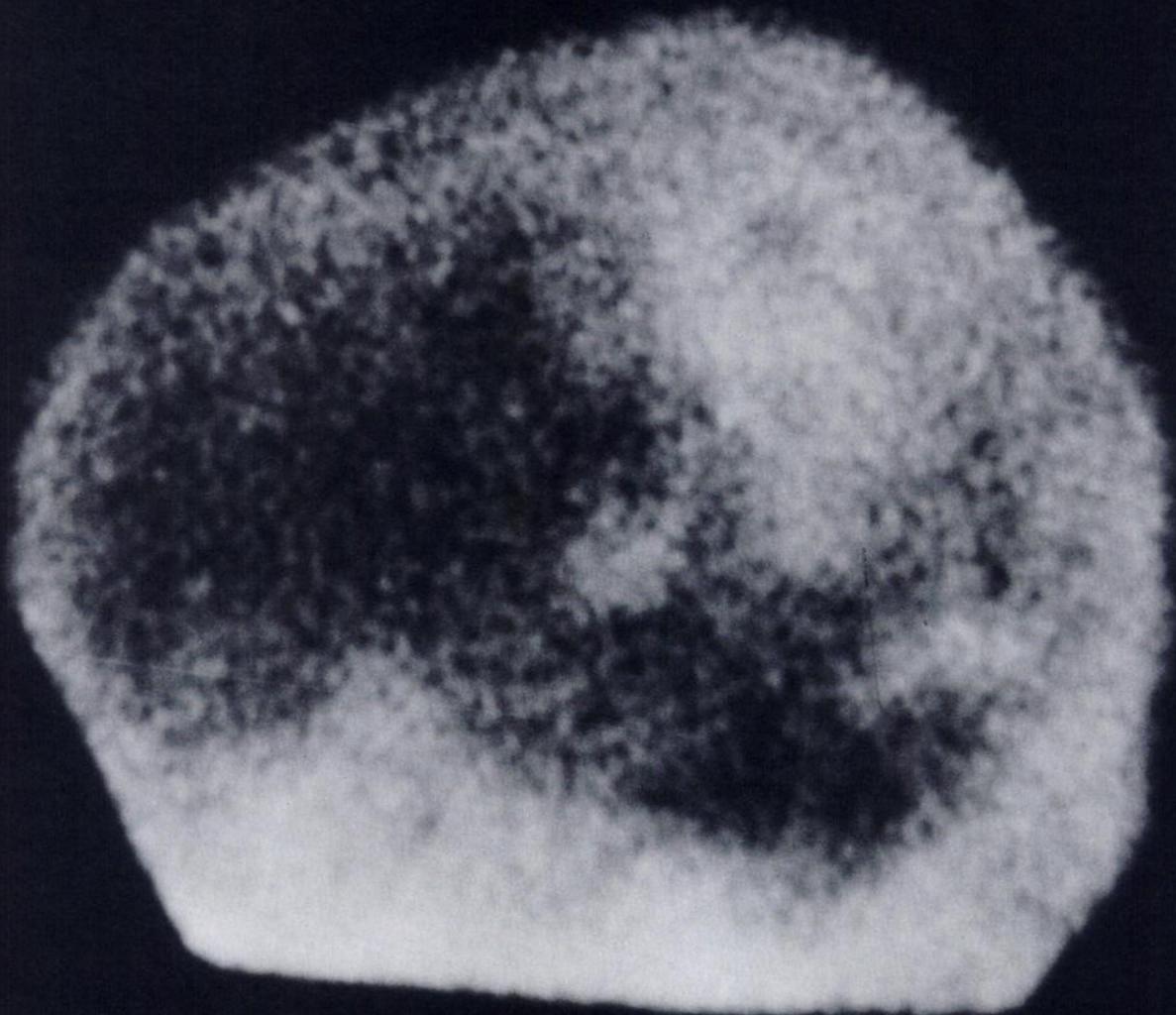
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Europe: NEN Chemicals GmbH, D-6072 Dreieich, W. Germany, Postfach 401240. Tel: (06103) 85034 Order Entry: (06103) 81011

Brain



Diagnosis: arteriovenous malformation

Imaging information: *Instrument:* Ohio Nuclear Series 100 Gamma Camera
Scan time: 90 minutes postinjection *Counts:* 400 K

Dose: 15 mCi GLUCOSCAN

GLUCOSCAN™
Technetium Tc 99m Gluceptate Sodium Kit

NEN New England Nuclear®

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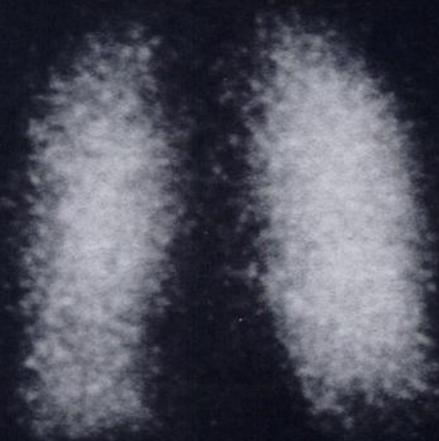
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Lung

Ventilation



Perfusion



Diagnosis: normal ventilation, abnormal perfusion — pulmonary embolism

Imaging information: *Instrument:* Picker Model 4/15 Gamma Camera *Dose:* 15 mCi Xenon 133; 3 mCi PULMOLITE *Information density:* 1,000 counts/cm²; 2,000 counts /cm²

Xenon Xe 133 Gas
(CALIDOSE™) Dispensing System

PULMOLITE™
Technetium Tc 99m Aggregated Albumin Kit

 **New England Nuclear***

Please see following page for brief prescribing information.

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Xenon Xe 133 Gas

(CALIDOSE™) Dispensing System

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

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

WARNINGS: This radiopharmaceutical should not be administered to pregnant or lactating women unless the benefits to be gained outweigh the potential hazards.

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

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

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

cupational workers. Expired xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate governmental agency regulations.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Such unrecognized loss of radioactivity from the dose for administration may render the study nondiagnostic. Xenon Xe 133 gas delivery systems, ie, respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

ADVERSE REACTIONS: To date, no adverse reactions based on the use of xenon Xe 133 gas have been reported.

DOSAGE AND ADMINISTRATION: Xenon Xe 133 gas is administered by inhalation from closed respirator systems or spirometers.

The suggested activity range employed for inhalation by the average adult patient (70kg) is:

Pulmonary function including imaging: 2-30 mCi in 3 liters of air.

Cerebral blood flow: 10-30 mCi in 3 liters of air.

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

HOW SUPPLIED: The xenon Xe 133 gas is supplied as part of the Calidose® system, consisting of 2 ml unit dose vials and the Calidose dispenser* for shielded dispensing.

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

Catalog Number NRP-127 *Patent Pending †JO 127 July 1975, Rev 1

PULMOLITE™

Technetium Tc 99m Aggregated Albumin Kit

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

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

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

WARNINGS: The possibility of allergic reactions should be considered in patients who receive multiple doses.

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

This radiopharmaceutical preparation should not be administered to children or to pregnant or lactating women unless the expected benefits to be gained outweigh the potential risks.

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

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

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

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

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

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

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

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

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

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

Safety and effectiveness in children have not been established.

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

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

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

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

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

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

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

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

Aggregated albumin (human)-1.0mg

Normal human serum albumin-10mg

Sodium chloride-10mg

Stannous chloride dihydrate, maximum-0.07mg

Each vial contains $3.6-6.5 \times 10^6$ aggregated albumin particles.

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

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

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

Catalog Number NRP-415

August 1976

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Kidney

5 min



15 min



25 min



35 min



Diagnosis: pyelonephritis
of right upper pole

Imaging information: Instrument: Ohio Nuclear Sigma 410 Gamma Camera Dose: 15 mCi GLUCOSCAN
Counts/image: 800 K for first postflow images, then same time for succeeding images

GLUCOSCAN™

Technetium Tc 99m Gluceptate Sodium Kit

NEN New England Nuclear®

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GLUCOSCAN™

Technetium Tc 99m Gluceptate Sodium Kit

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

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

CONTRAINDICATIONS: None known.

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

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

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

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

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

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

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

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

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

It is not known whether this drug is excreted in human milk. As a general

rule, nursing should not be undertaken when a patient is administered radioactive material.

Safety and effectiveness in children have not been established.

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

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

Technetium Tc 99m Gluceptate Sodium should be used within six hours after aseptic reconstitution with sodium pertechnetate Tc 99m. For optimal results, this time should be minimized. The reaction vial contains no bacteriostat.

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

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

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

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

Gluceptate Sodium — 200mg

Maximum Tin — 0.07mg

Stannous Chloride (min.) — 0.06mg

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

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

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

Catalog Number NRP-180 (5 vial kit)

August 1978

Catalog Number NRP-180C (30 vial kit)

Gallium Citrate Ga67

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

Gallium Citrate Ga 67 may be useful as an aid in detecting some acute inflammatory lesions.

CONTRAINDICATIONS: None known.

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

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

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

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

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

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

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Gallium Citrate Ga 67

should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

Gallium Ga 67 localization cannot differentiate between tumor and acute inflammation; and other diagnostic studies must be added to define the underlying pathology.

The expiration date of the drug is seven days after the date of calibration.

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 governmental 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.

Catalog Number NRP-121

December 1979



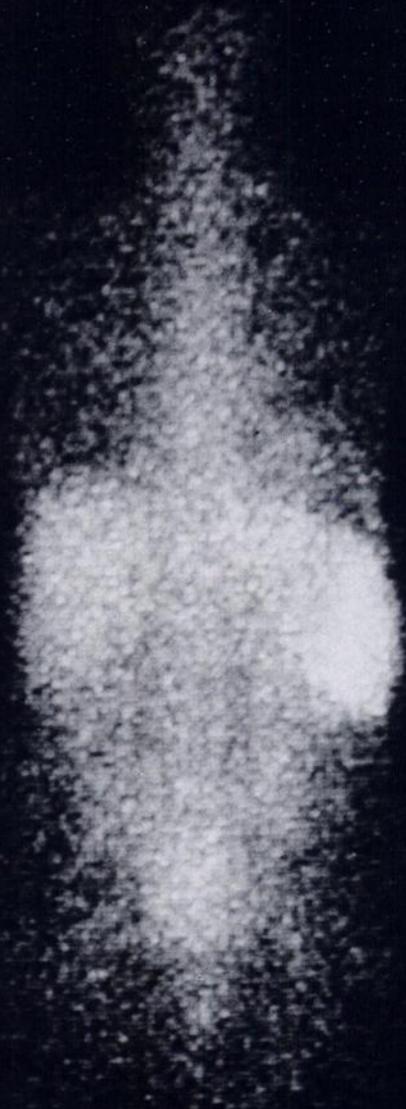
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Tumor



Diagnosis: plasmacytoma

Imaging information: Instrument: Cleon 760 Whole Body Imager
Scan time: 48 hours postinjection Speed: 5 cm/min

Dose: 5 mCi Gallium Citrate Ga 67

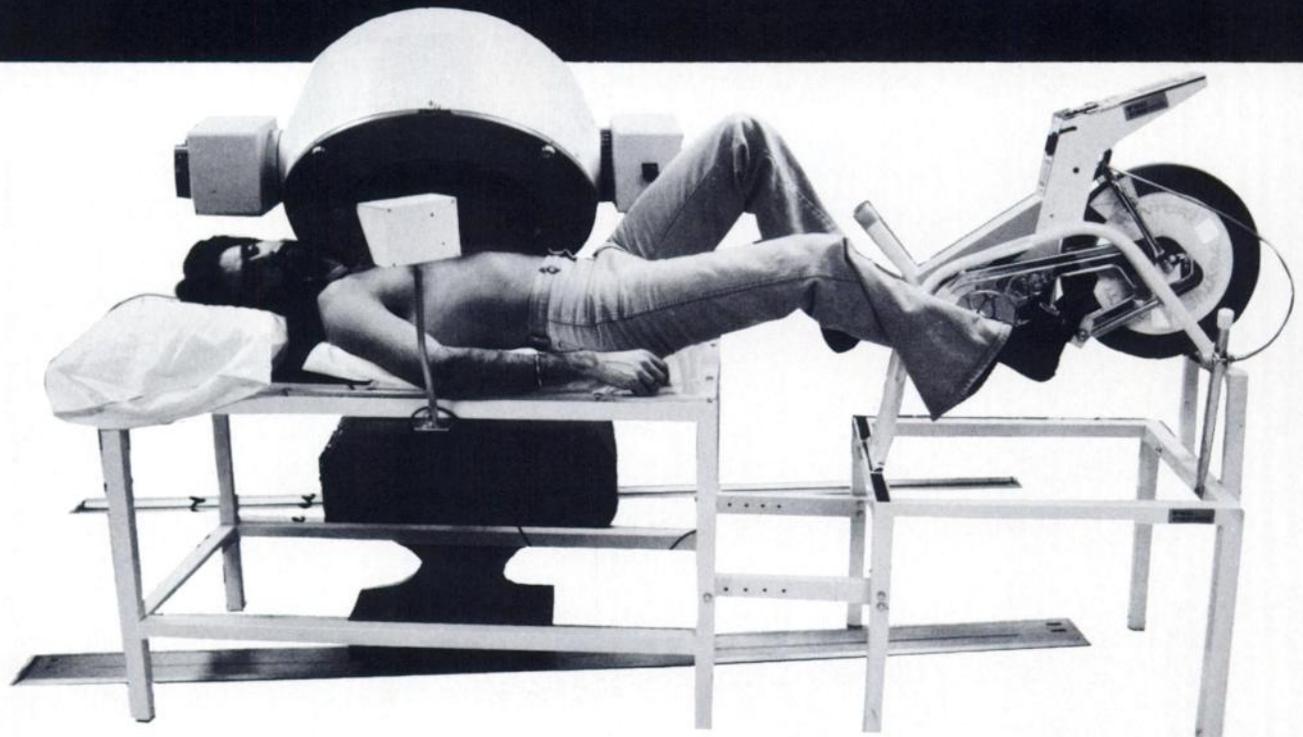
Gallium Citrate Ga67

NEN New England Nuclear[®]

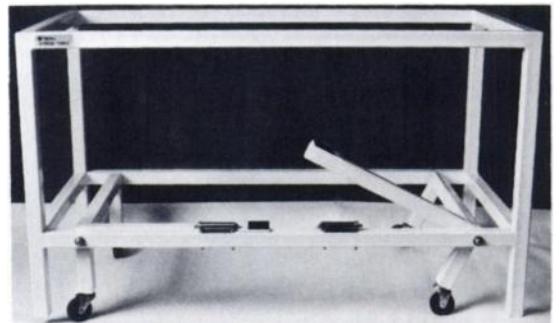
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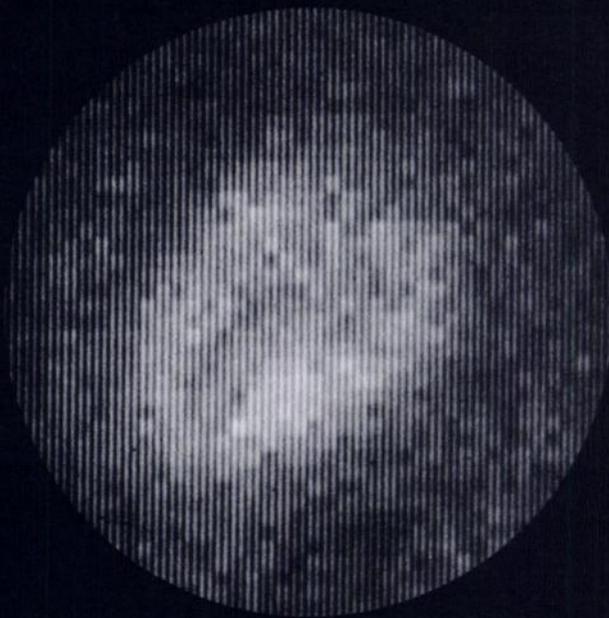
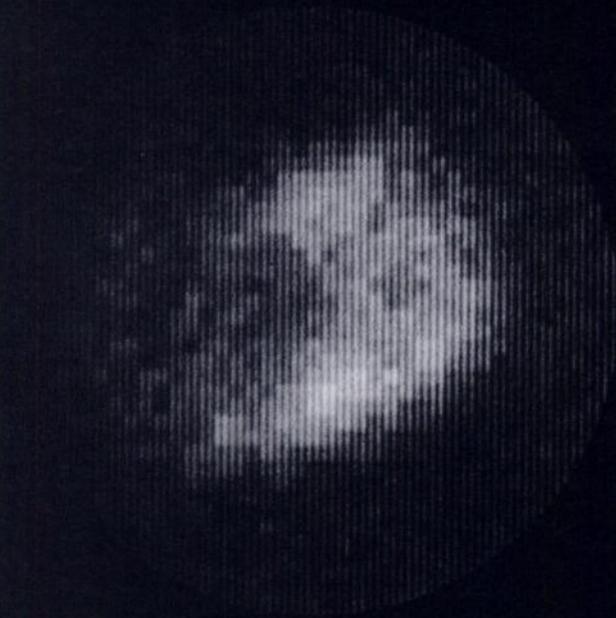
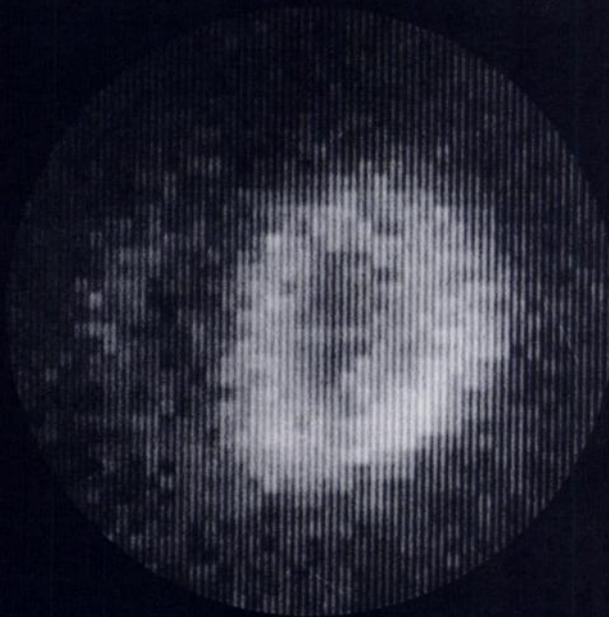
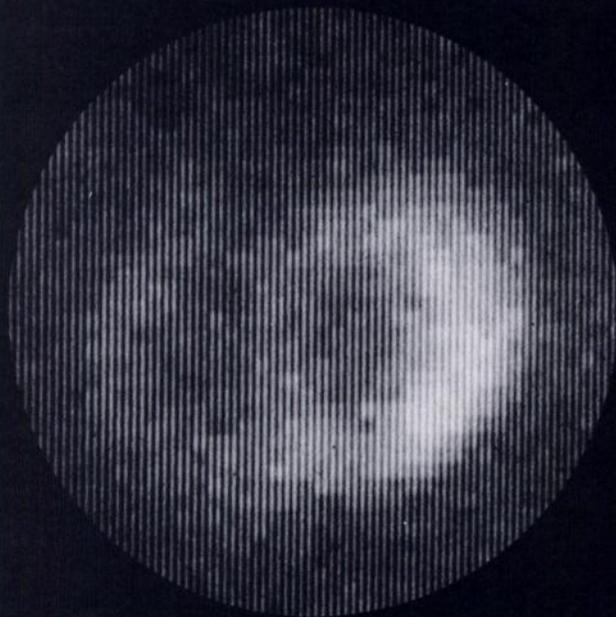
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Heart

Exercise

Redistribution



Diagnosis: reversible ischemia, apical, septal, anterior segments

Imaging information: *Instrument:* Ohio Nuclear Sigma 400 Gamma Camera, VIP 450
Dose: 1.5 mCi thallous chloride TI 201
Acquisition time: 10 minutes

Collimator: General, all purpose

Scan time: exercise — 4 minutes postinjection, redistribution — 4 hours

Thallous Chloride TI 201

 **New England Nuclear**

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Thallous Chloride TI 201

INDICATIONS AND USAGE: Thallous Chloride TI 201 may be useful in myocardial perfusion imaging for the diagnosis and localization of myocardial infarction.

It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

CONTRAINDICATIONS: None known.

WARNINGS: In studying patients in whom myocardial infarction or ischemia is known or suspected, care should be taken to assure continuous clinical monitoring and treatment in accordance with safe, accepted procedure. Exercise stress testing should be performed only under the supervision of a qualified physician and in a laboratory equipped with appropriate resuscitation and support apparatus.

Ideally, examinations using radiopharmaceutical drug products — especially those elective in nature — of women of childbearing capability should be performed during the first ten days following the onset of menses.

PRECAUTIONS: Data are not available concerning the effect of marked alterations in blood glucose, insulin, or pH (such as is found in diabetes mellitus) on the quality of thallium TI 201 scans. Attention is directed to the fact that thallium is a potassium analog, and since the transport of potassium is affected by these factors, the possibility exists that the thallium may likewise be affected.

Thallous Chloride TI 201, as all radioactive materials, must be handled with care and used with appropriate safety measures to minimize external radiation exposure to clinical personnel. Care should also be taken to minimize radiation exposure to patients in a manner consistent with proper patient management.

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

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Thallous Chloride TI 201

should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Adverse reactions related to use of this agent have not been reported to date.

DOSAGE AND ADMINISTRATION: The recommended adult (70kg) dose of Thallous Chloride TI 201 is 1-1.5mCi. Thallous Chloride TI 201 is intended for intravenous administration only.

For patients undergoing resting thallium studies, imaging is optimally begun within 10-20 minutes after injection. Several investigators have reported improved myocardial-to-background ratios when patients are injected in the fasting state, in an upright posture, or after briefly ambulating.

Best results with thallium imaging performed in conjunction with exercise stress testing appear to be obtained if the thallium is administered when the patient reaches maximum stress and when the stress is continued for 30 seconds to one minute after injection. Imaging should begin within ten minutes post-injection since target-to-background ratio is optimum by that time. Several investigators have reported significant decreases in the target-to-background ratios of lesions attributable to transient ischemia by two hours after the completion of stress testing.

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

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

HOW SUPPLIED: Thallous Chloride TI 201 for intravenous administration is supplied as a sterile, non-pyrogenic solution containing at calibration time, 1mCi/ml of Thallous TI 201, 9mg/ml sodium chloride, and 9mg/ml of benzyl alcohol. The pH is adjusted to between 4.5-6.5 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 1.5, 3.0, 4.5, 6.0, and 9.0 millicuries of Thallous TI 201.

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

Catalog Number NRP-427

November 1977

Gallium Citrate Ga67

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

Gallium Citrate Ga 67 may be useful as an aid in detecting some acute inflammatory lesions.

CONTRAINDICATIONS: None known.

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

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

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

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

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

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

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Gallium Citrate Ga 67

should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

Gallium Ga 67 localization cannot differentiate between tumor and acute inflammation; and other diagnostic studies must be added to define the underlying pathology.

The expiration date of the drug is seven days after the date of calibration.

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.

Catalog Number NRP-121

December 1979

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Abscess



Diagnosis: intraneprhic abscess

Imaging information: *Instrument:* Cleon 760 Whole Body Imager
Scan time: 48 hours postinjection *Speed:* 5 cm/min

Dose: 5 mCi Gallium Citrate Ga 67

Gallium Citrate Ga67

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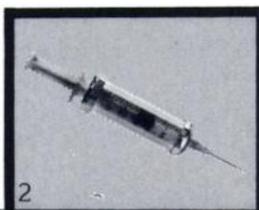
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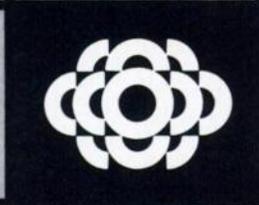
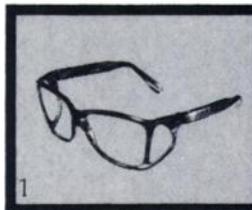
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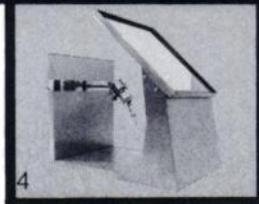


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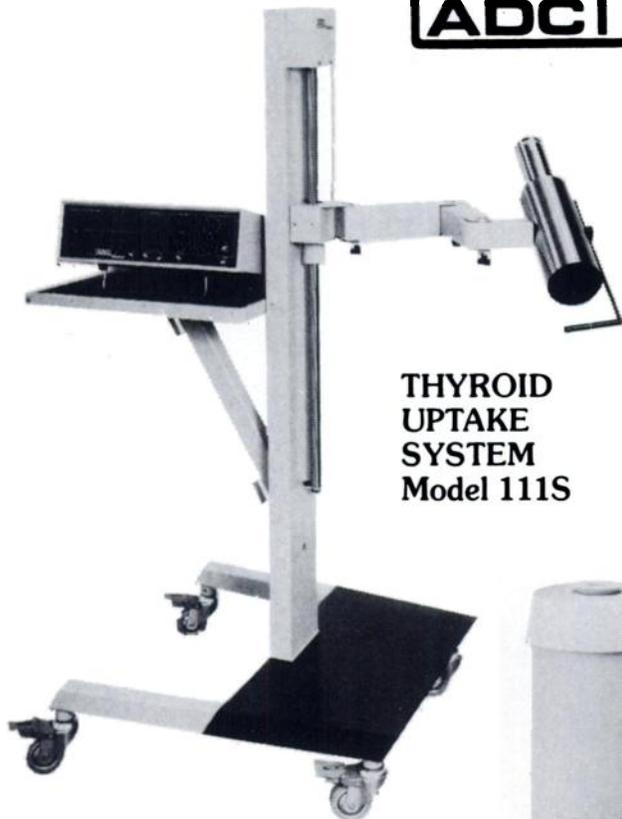
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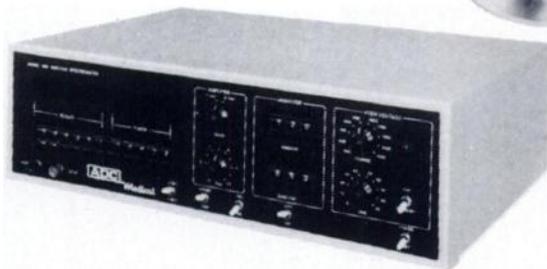
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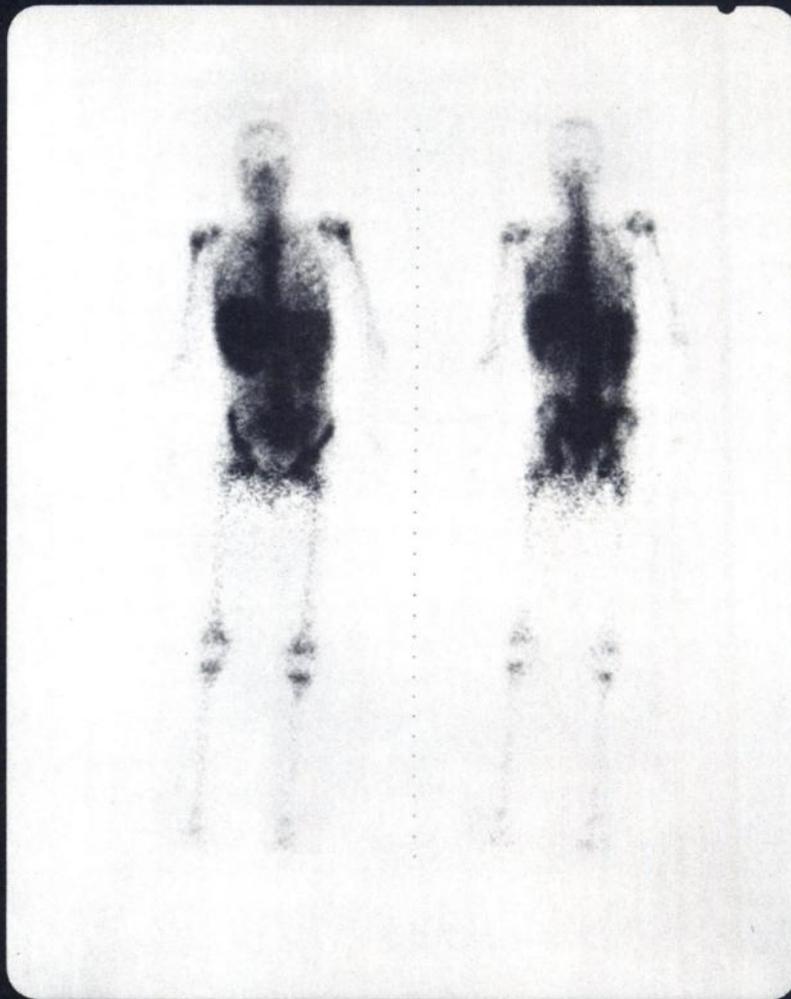
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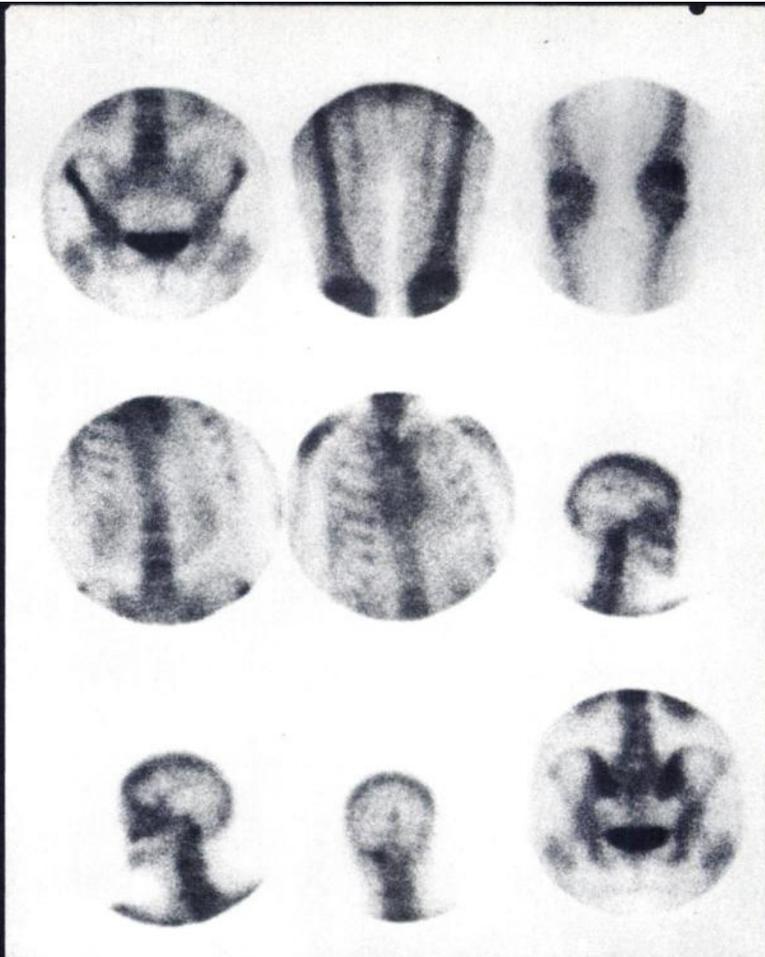
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Phelps et al. 1979. Tomographic measurement of local cerebral glucose metabolic rate in humans with (F-18)2-fluoro-2-deoxy-D-glucose: Validation of method. *Ann. Neurol.* 6: 371-388.



- A = caudate nucleus
- B = thalamic nuclei
- C = atrium of lateral ventricle
- D = putamen and globus pallidus
- E = anterior horn of lateral ventricle
- F = internal capsule
- G = external capsule



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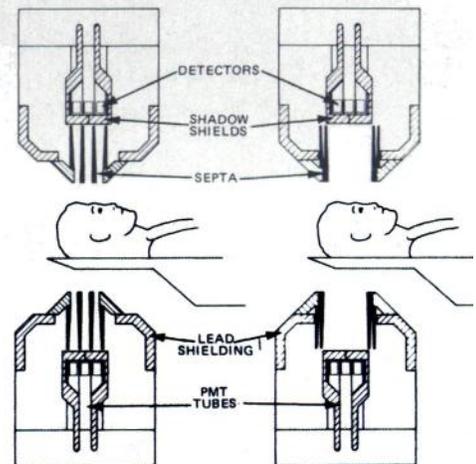


Figure 1

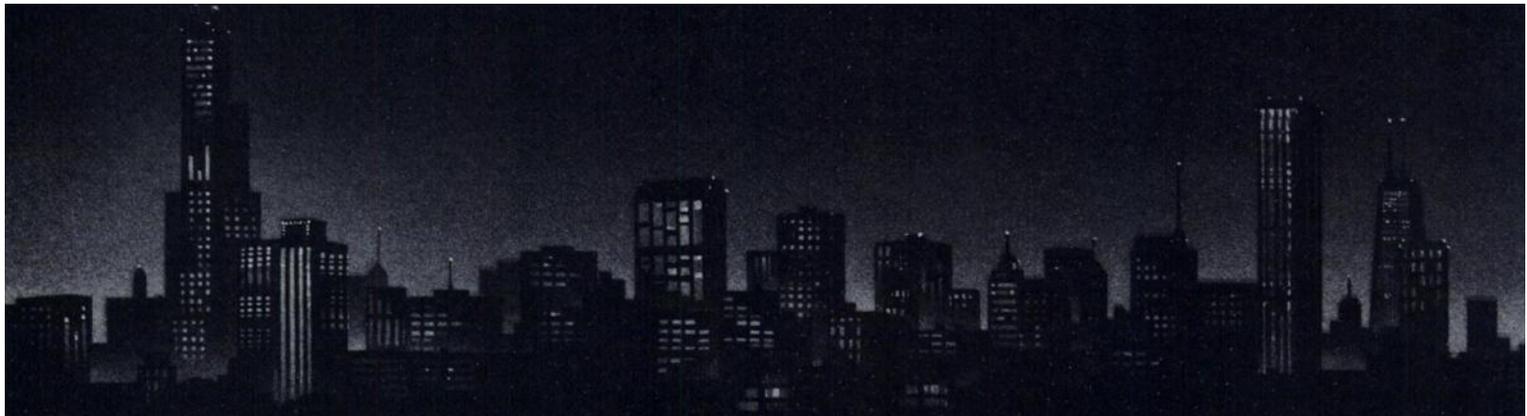
Figure 2

are shown in Figure 1 positioned for highest quantification, and in Figure 2 for maximum efficiency.

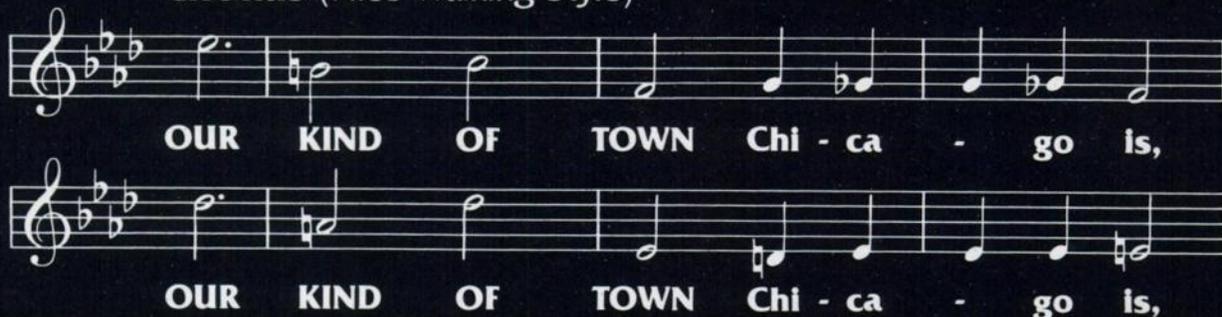
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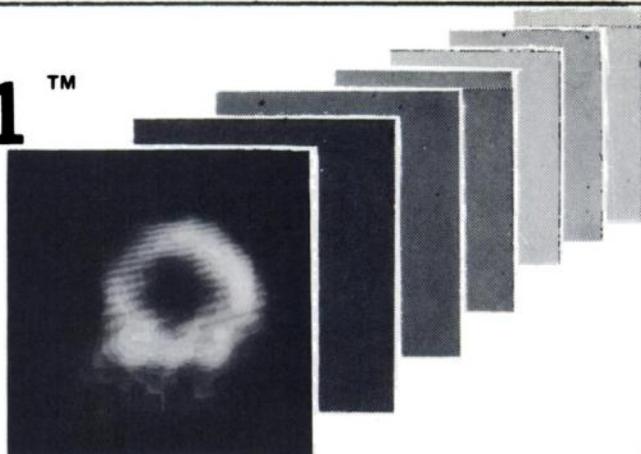
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*PARKER, J.A. et al: Radionuclide left ventriculography with the slant hole collimator. J Nucl Med 18:848-851, 1977.

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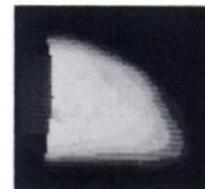
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¹Vogel RA, Kirch DL, Lefree MT, Rainwater JO, Steele PP: Thallium-201 myocardial perfusion scintigraphy: Results of standard and multi-pinhole tomographic techniques. *The American Journal of Cardiology* 43:787-793, 1979

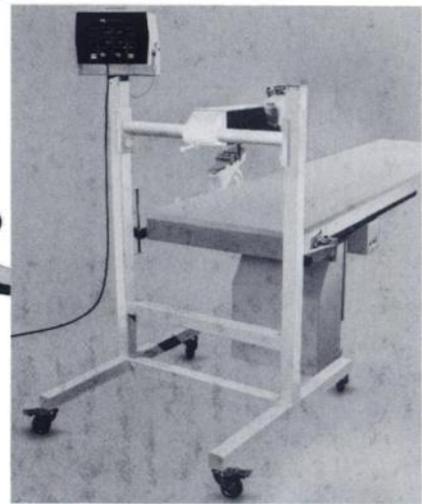
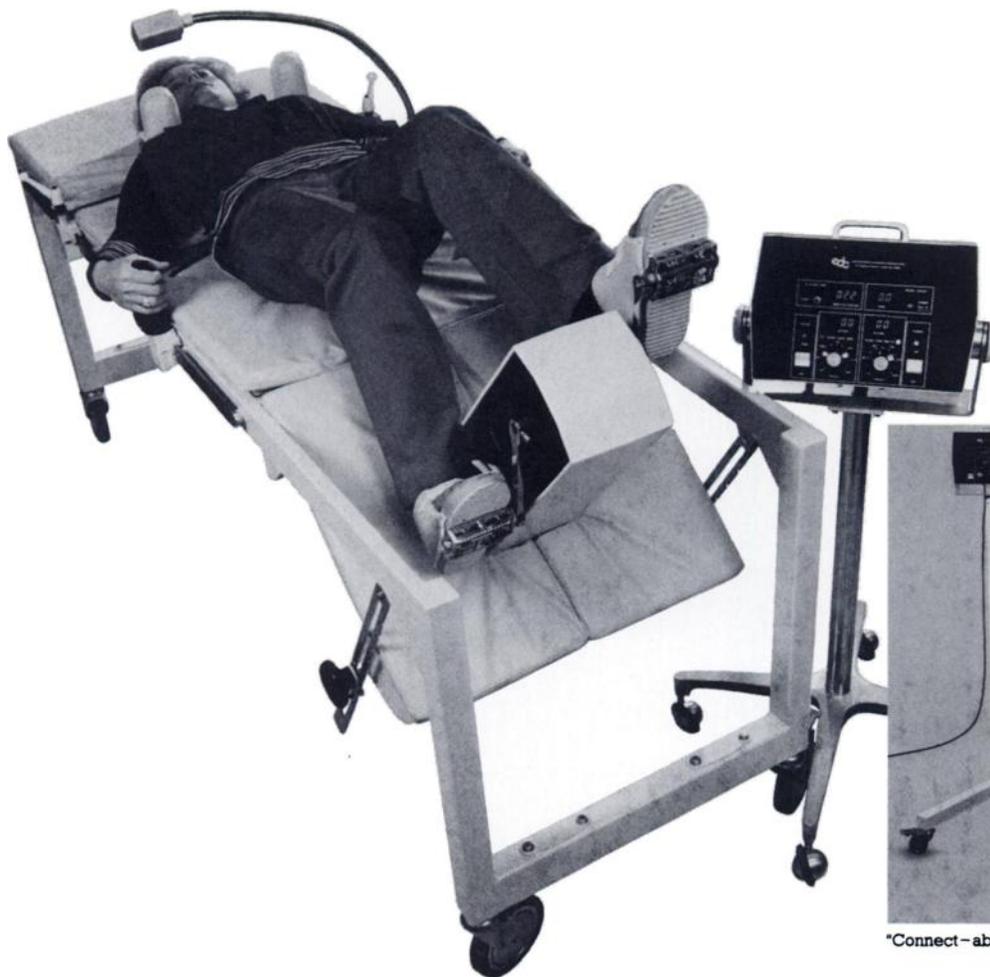
²Francisco D, Raymundo G, Van Kirk O, Erhardt J, Marcus M: Tomographic thallium-201 perfusion scintigrams following maximal coronary vasodilation with dipyridamole: *Circulation* 60 (suppl. II): 11-174, 1979.

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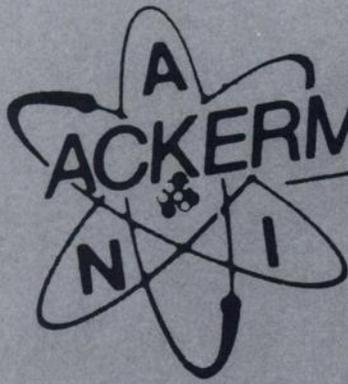
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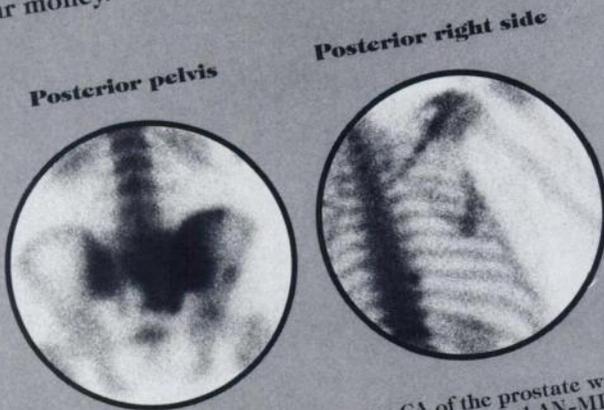
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Indications and usage. Technetium Tc 99m Medronate may be used as a bone imaging agent to delineate areas of altered osteogenesis.

Contraindications. None known.

Warnings. This class of compounds is known to complex cations such as calcium. Particular caution should be used with patients who have or who may be predisposed to hypocalcemia (i.e., alkalosis)

Precautions. Contents of the vial are intended only for use

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Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use. Optimal imaging results are obtained 1-4 hours after administration.

Carcinogenesis, mutagenesis, impairment of fertility: No long-term animal studies have been performed to evaluate

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Pregnancy category C: Animal reproductive studies have not been conducted with Technetium Tc 99m Medronate. It is also not known whether Technetium Tc 99m Medronate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc 99m should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing mothers: Technetium Tc 99m is excreted in human milk during lactation, therefore formula feedings should be substituted for breast feedings.

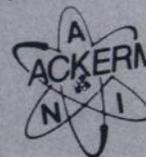
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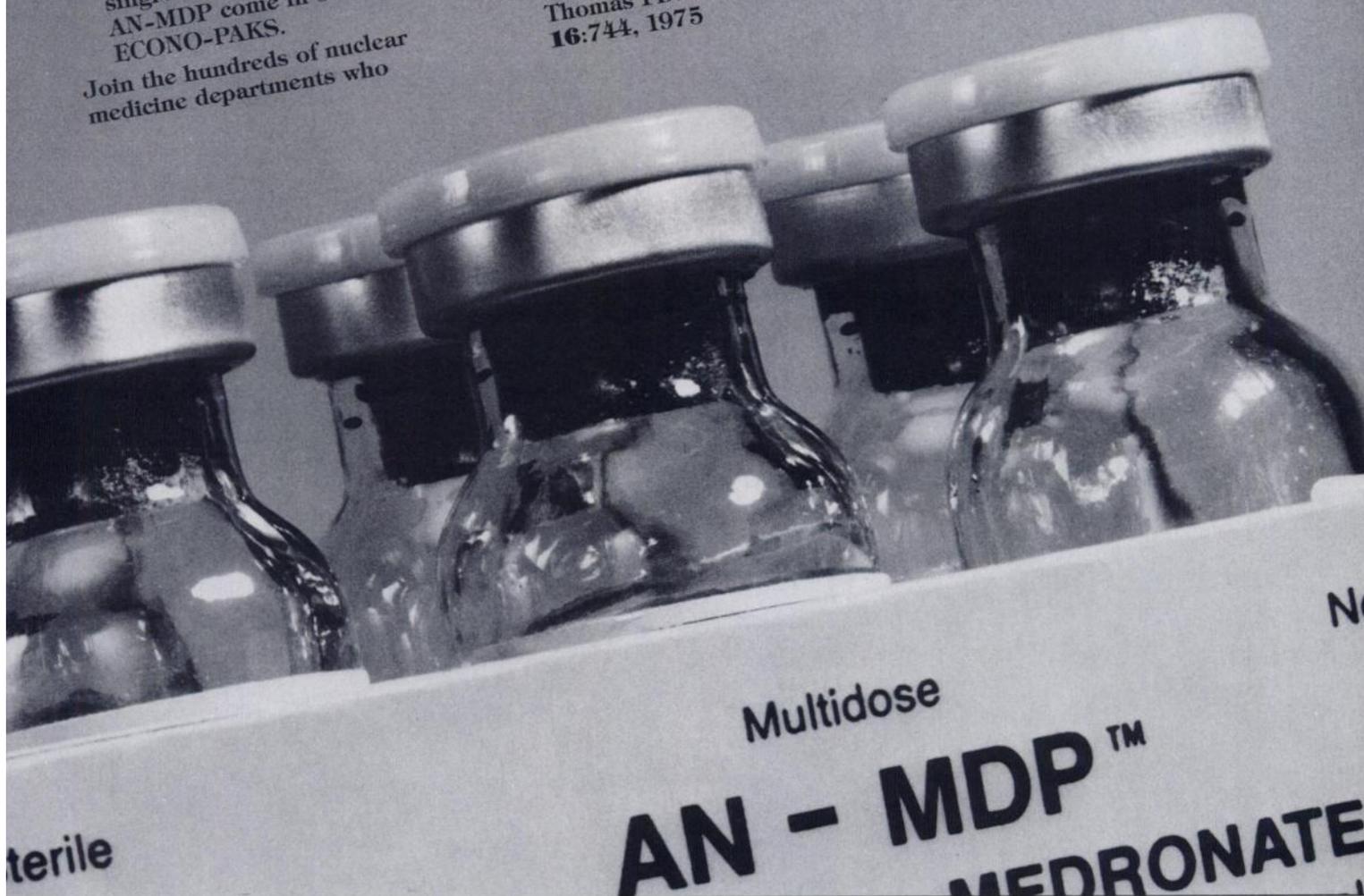
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1. Davis MA, and Jones AG: **Sem Nucl Med 6:19, 1976**
2. Subramanian G, McAfee JG, Blair RJ, Kallfelz FA, and Thomas FD: **J Nucl Med 16:744, 1975**

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Pediatric use: Safety and effectiveness in children have not been established.

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

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

Dosage and administration. The suggested dose range for i.v. administration, after reconstitution with oxidant-free sodium pertechnetate Tc 99m Injection, to be employed in the average patient (70 kg) is:

Bone imaging: 10–20 mCi Technetium Tc 99m Medronate

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

How supplied. AN-MDP™ is supplied both in the single-dose and multidose form. Both are available in sets of 6 or 30 sterile and nonpyrogenic vials. Each nitrogen-flushed vial contains, in lyophilized form:

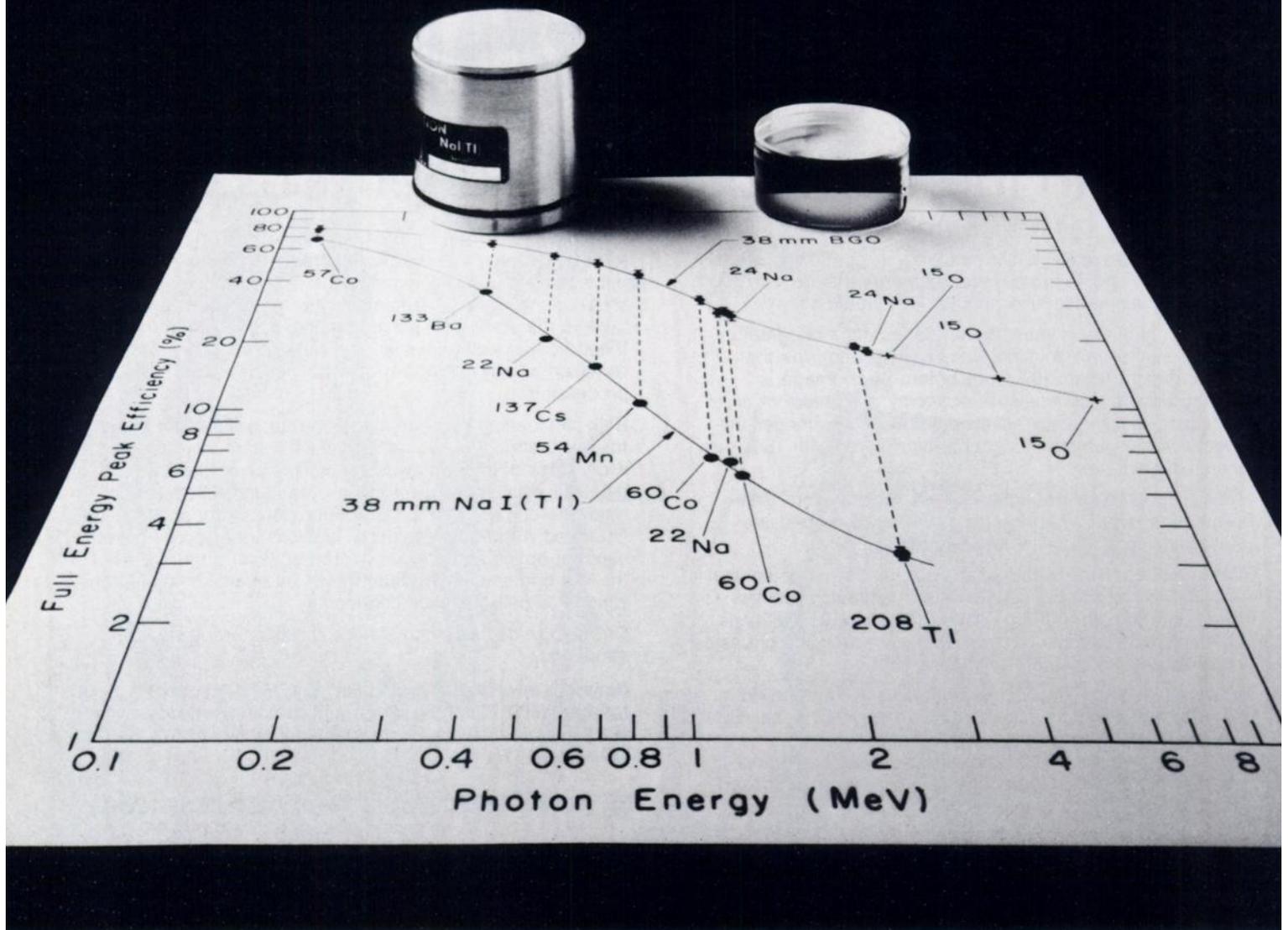
	Single dose	Multidose
Medronic acid	5.0 mg	10.0 mg
Stannous chloride (minimum)	0.25 mg	0.51 mg
Maximum total stannous and stannic chloride	0.51 mg	1.01 mg

The pH is adjusted to 5.0–5.5 with HCl and NaOH prior to lyophilization. Included in each 6-vial kit is one package insert and 12 radiation labels. In each 30-vial kit is one package insert and 60 radiation labels. Refrigeration is not necessary.

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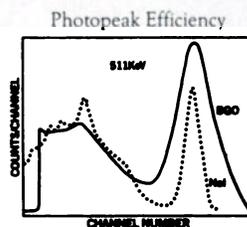
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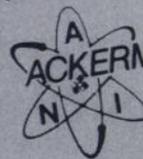
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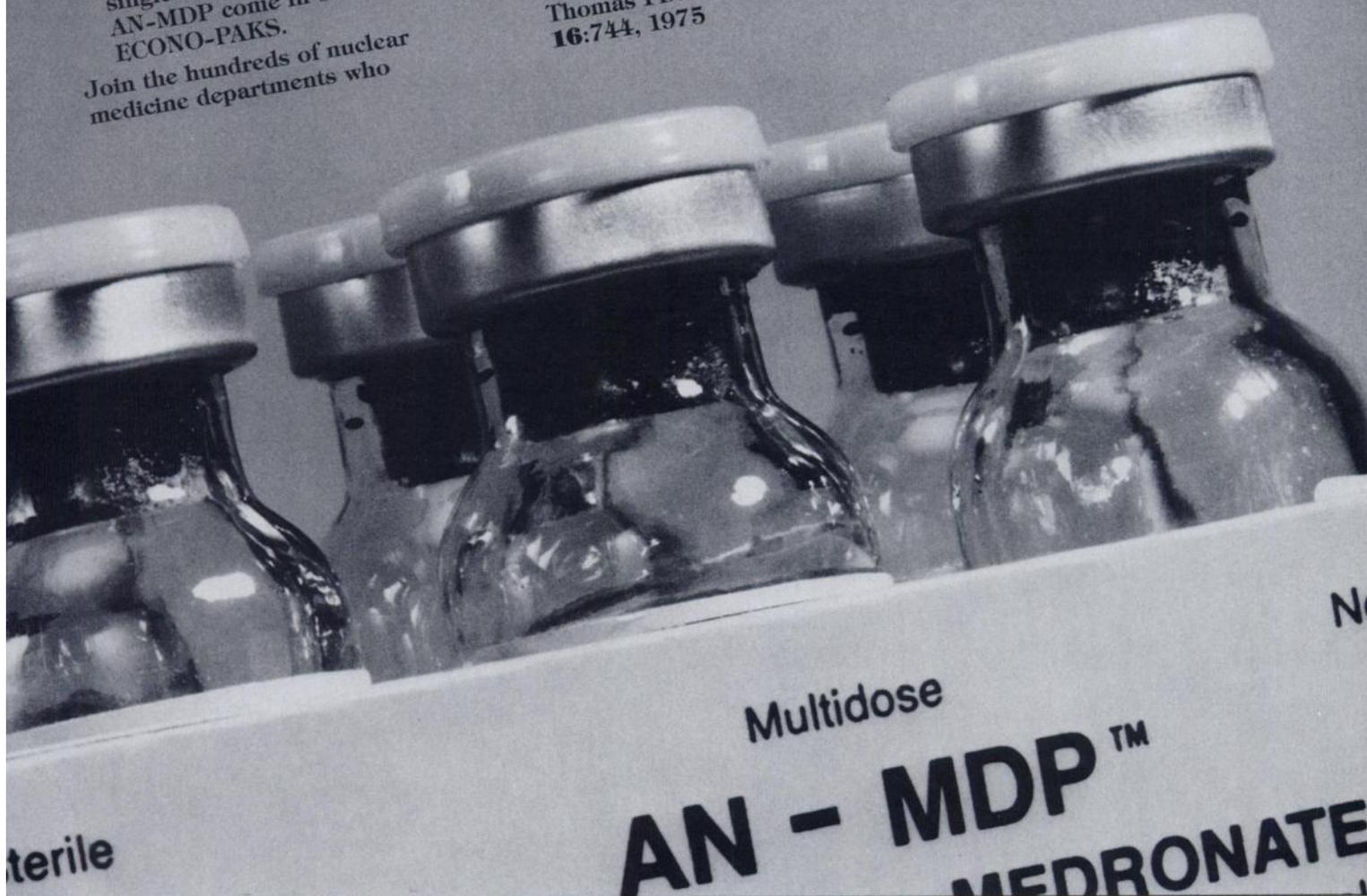
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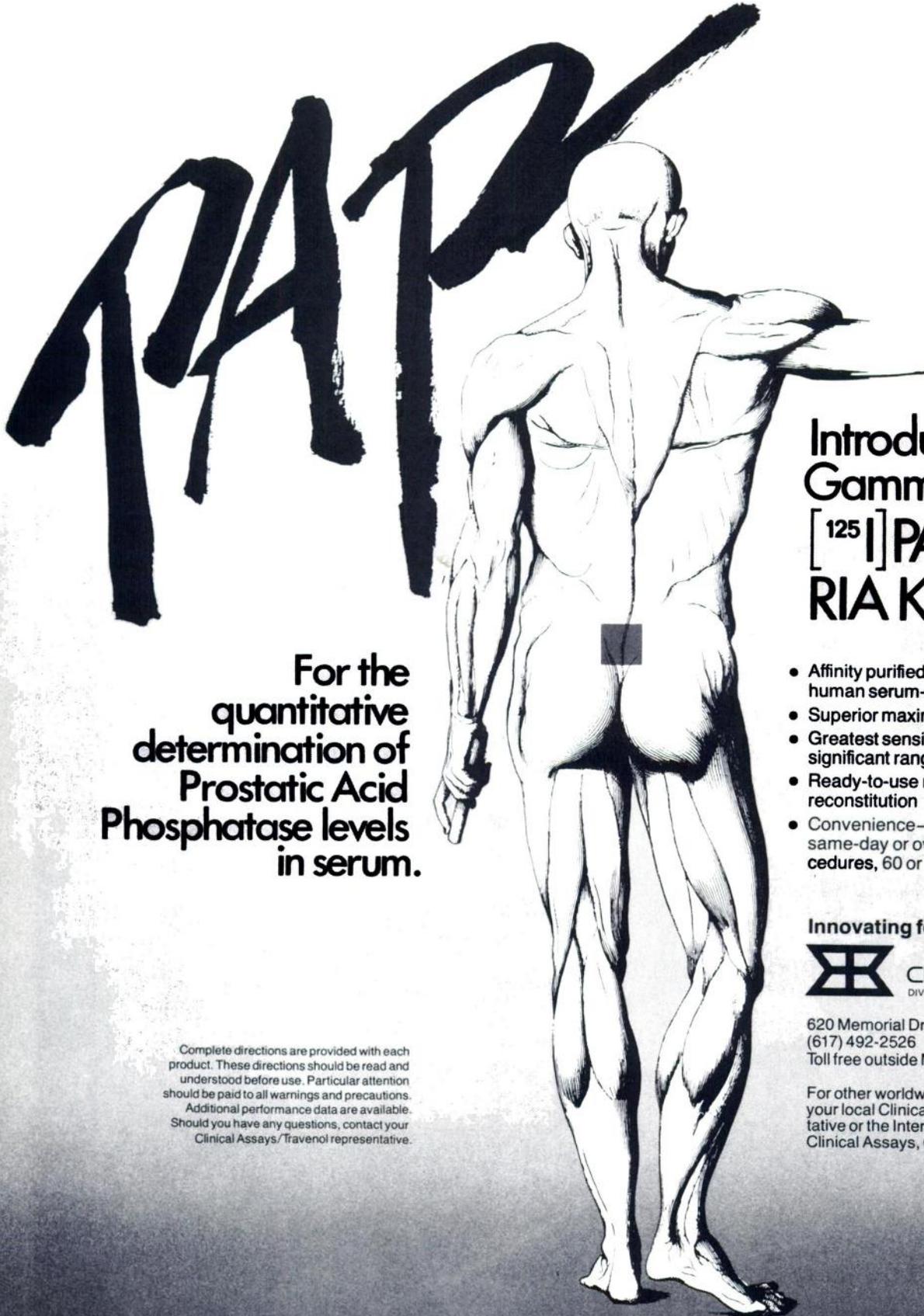
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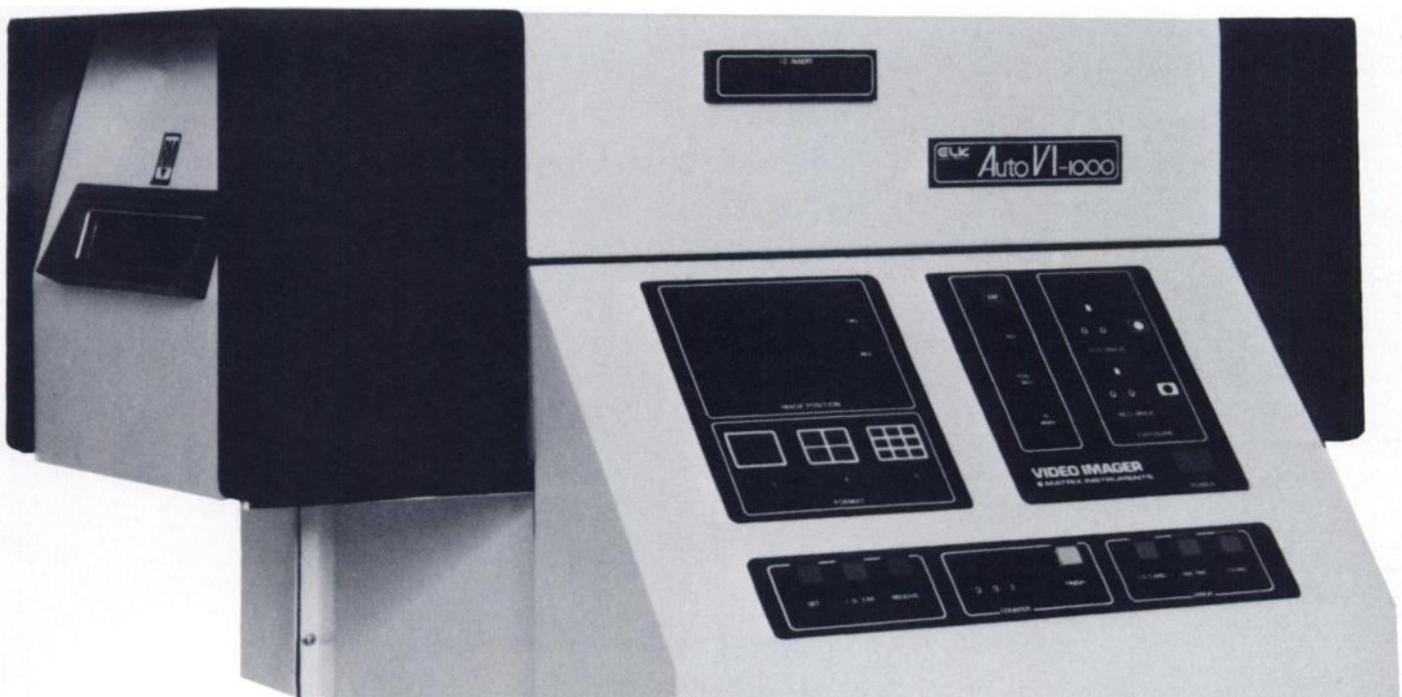
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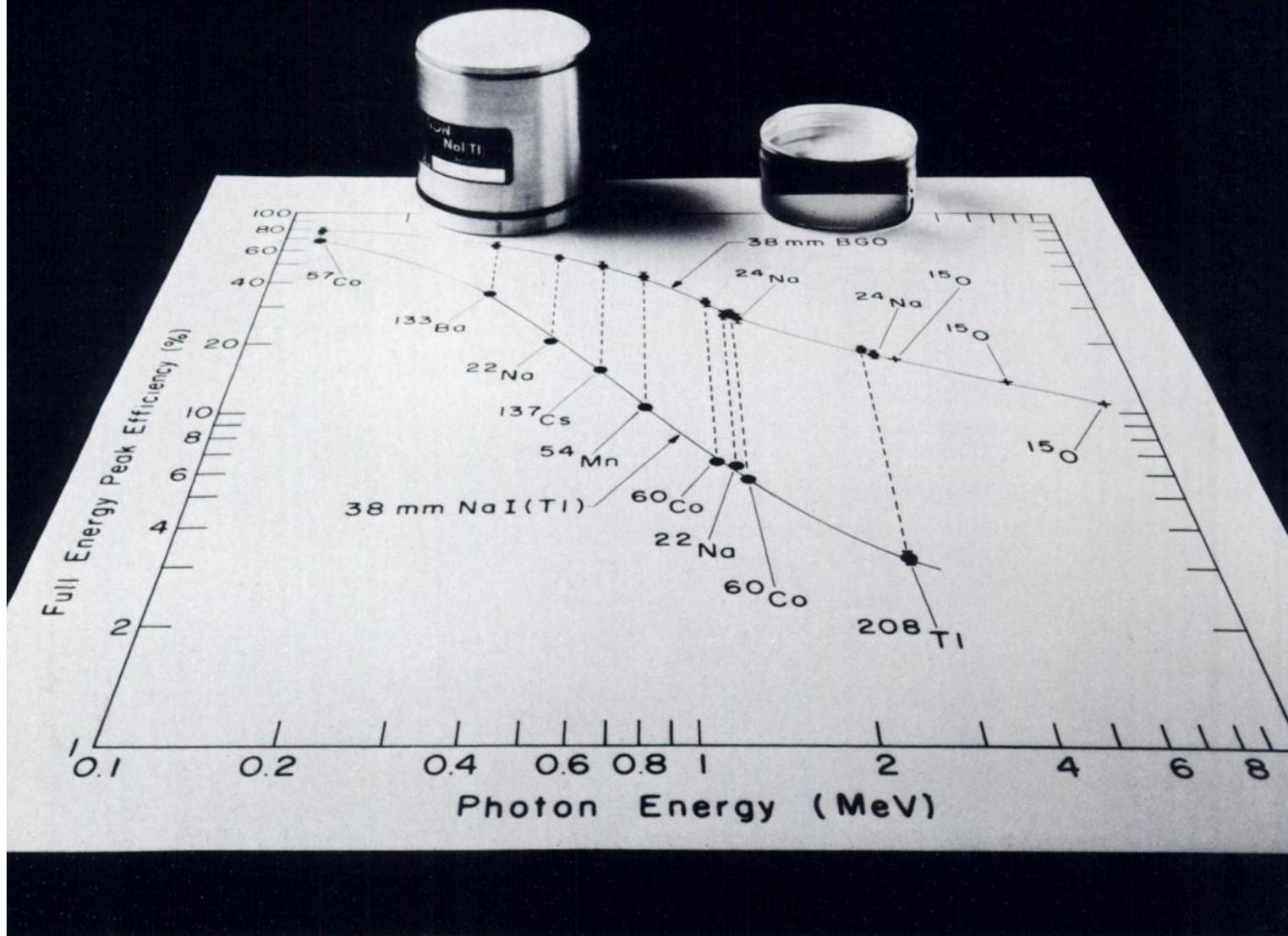
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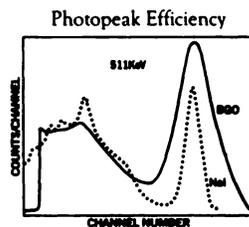
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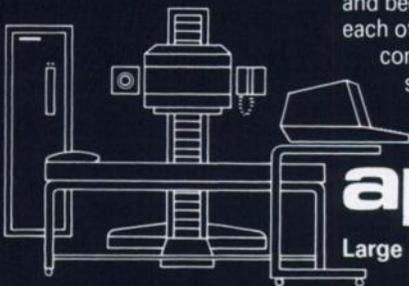
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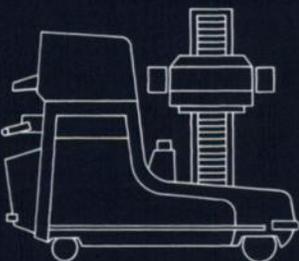
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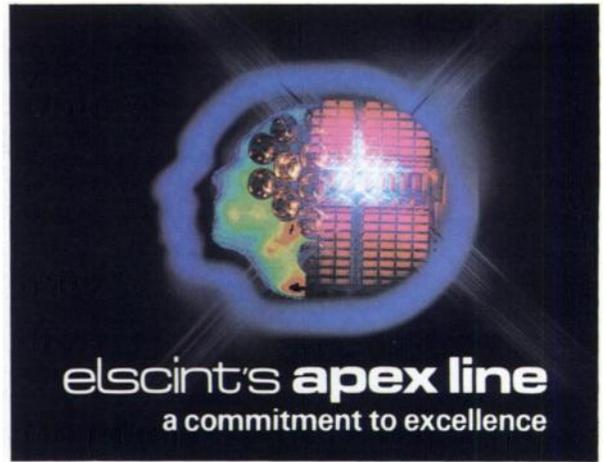


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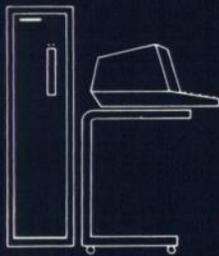
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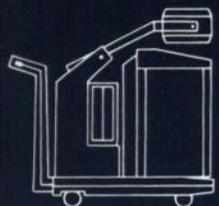
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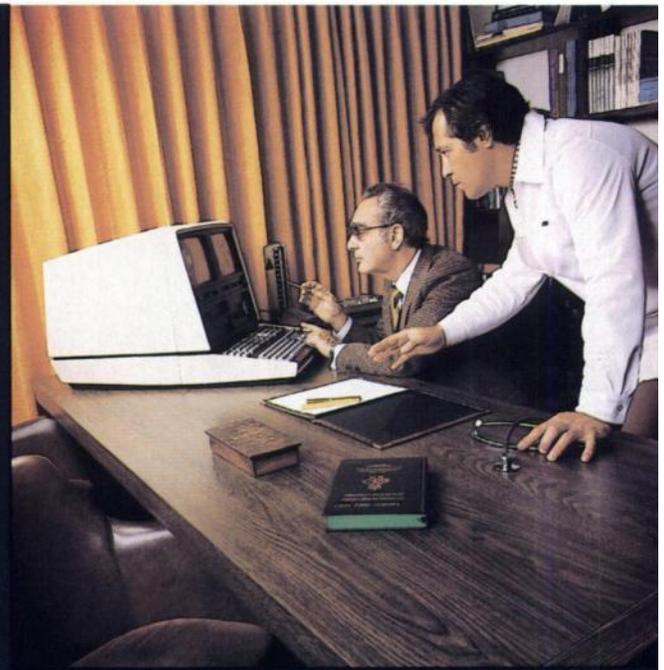


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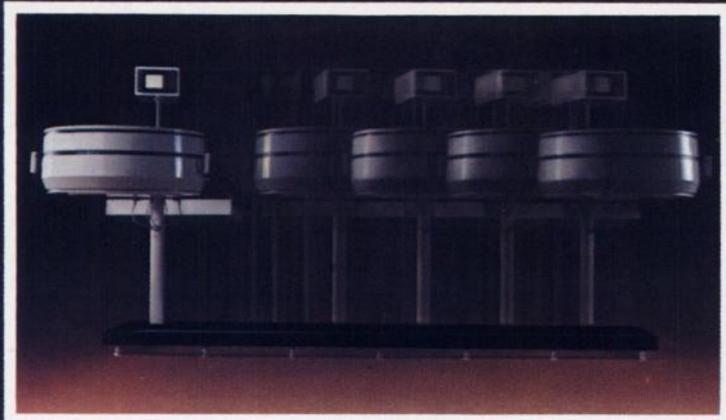
*We were lying about the bloodless part
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Selectascan system allows whole-body, one-pass scanning for bone or Gallium images and faster throughput.



61 hexagonal "teacup" photomultiplier tubes produce superior resolution and linearity.



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unique light coupling system, tubes produce superior resolution and linearity. MaxiCamera 535 system offers the proven performance features of the MaxiCamera series...counter-balanced positioning, modular electronics and human-engineered components.

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- MaxiCamera II, the 400 mm field-of-view scintillation camera system.
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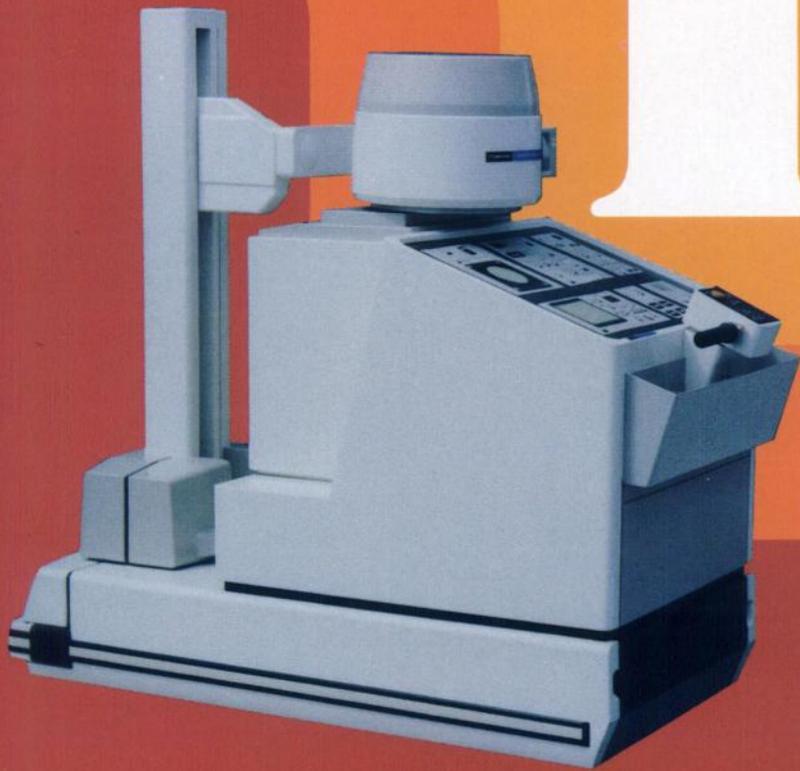
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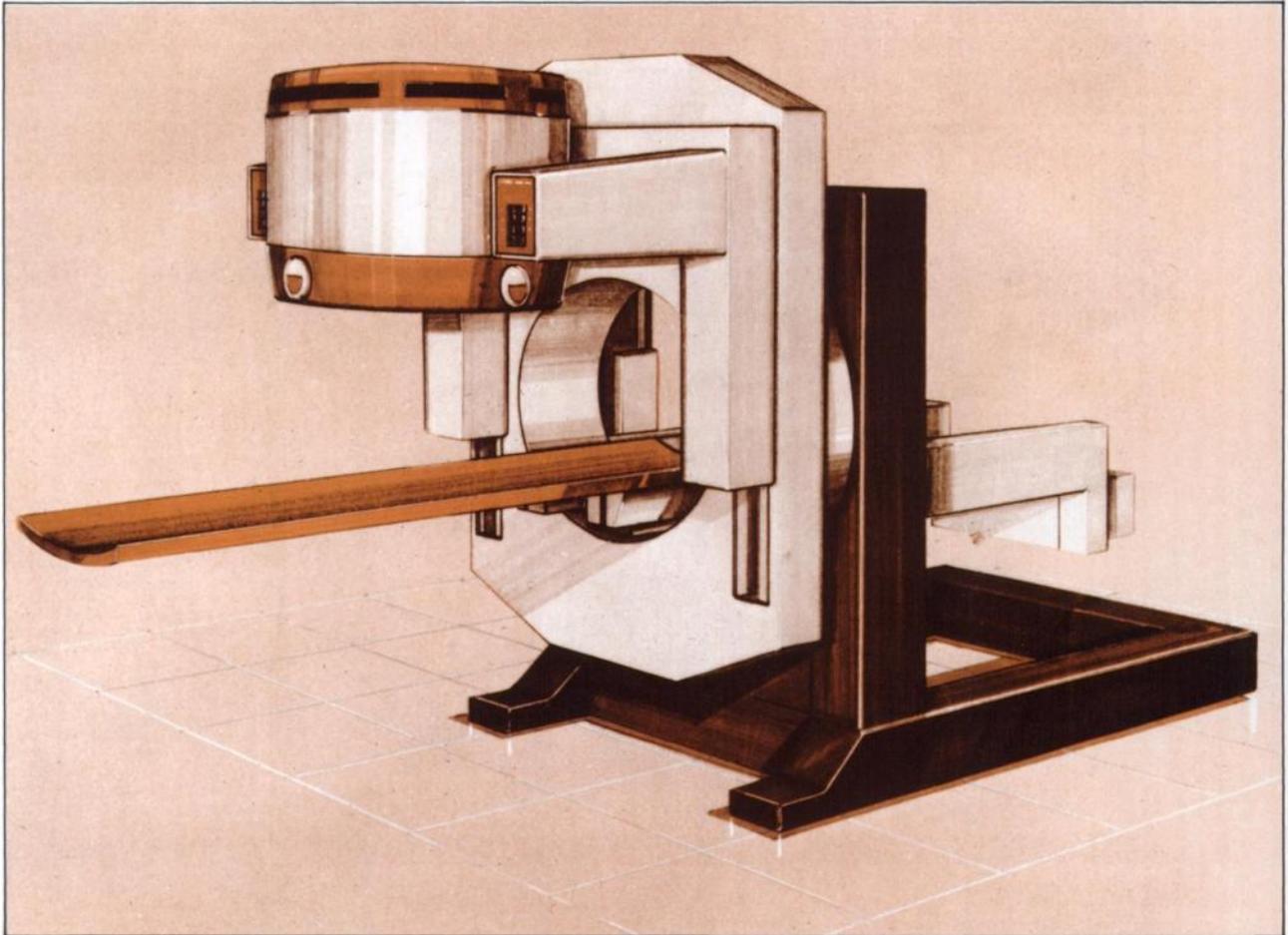
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Gamma émission



- **GAMMATOME T 9000 is used with the CGR ACTICAMERA 3400 large field of view detector (400 mm diameter) and the CGR standard data processing system IMAC 7300.**
- **Continuous head rotation allows minimum examination durations on an adjustable tomographic exploration diameter from 400 to 600 mm.**
- **Tomographic examination parameters are selected from the CGR ACTICAMERA 3400 console :**
 - **head rotation speeds : 1 rev/mn to 1 rev/20 mn.**
 - **number of projections : 32 - 40 - 64 - 80.**
- **The tomographic imaging table is completely retractable and its height is adjustable. As it can be motorized, it allows standard whole body scintigraphy.**
- **Conventional scintigraphy is still made possible as the free space under the detection head allows any position of the patients on any examination table.**

Gammatome T 9000

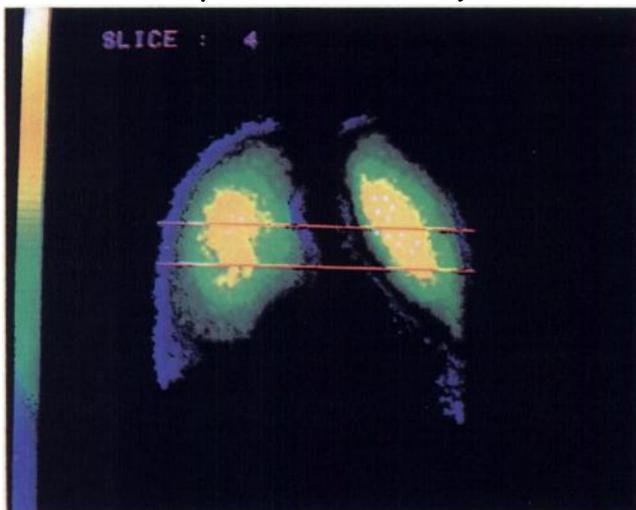
tomographic system

Typical tomographic applications examples

LUNGS

- Dose 4 mCi - Albumin serum ^{99m}Tc
- Examination performed 5' after injection

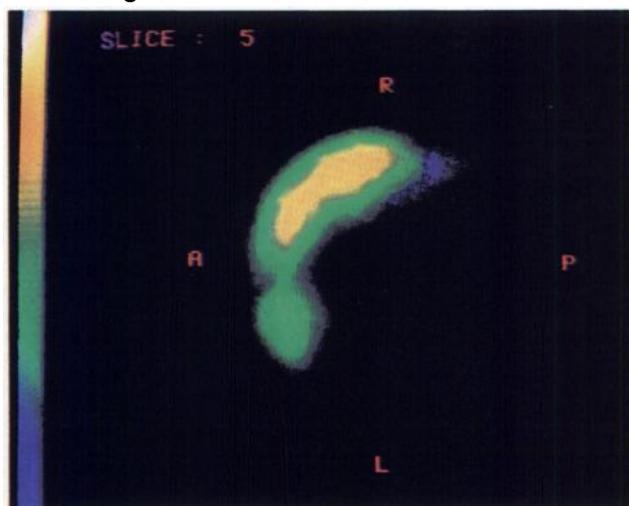
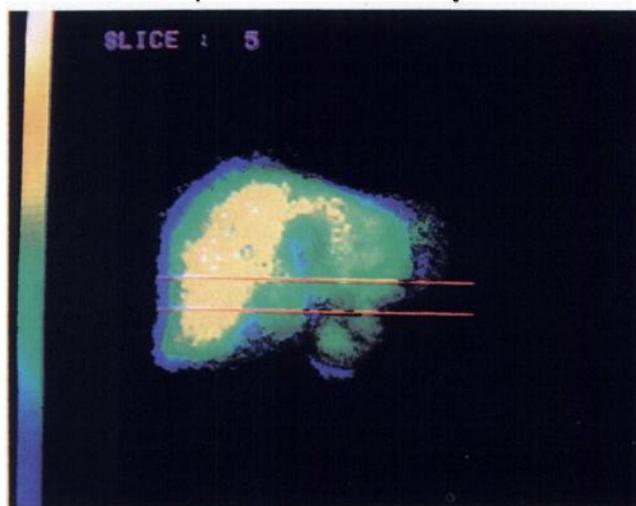
- Examination duration 4'
- Slice thickness 20 mm
- Pulmonary embolism.



LIVER

- Dose 4 mCi - Colloïdal ^{99m}Tc sulphide
- Examination performed 5' after injection

- Examination duration 4'
- Slice thickness 20 mm
- Pathologic liver.

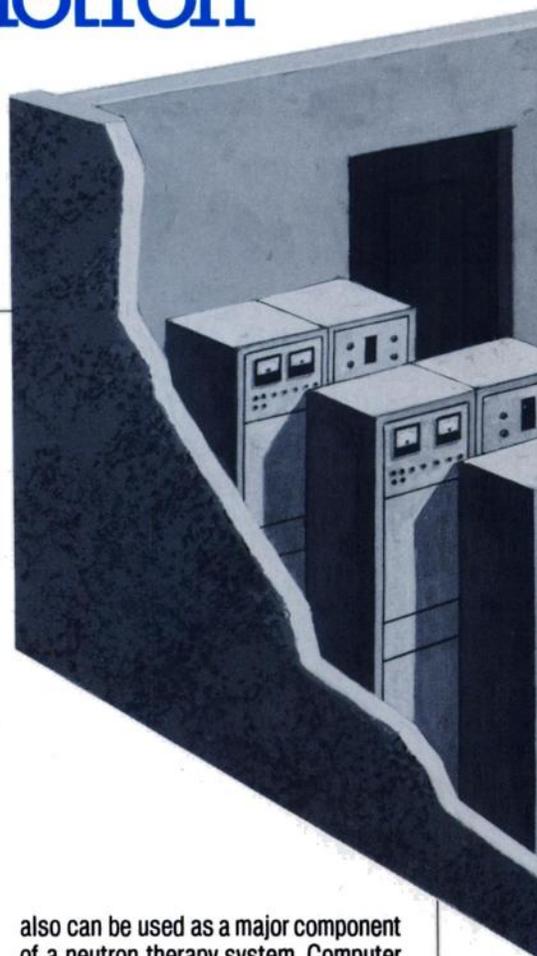


DOCUMENTS : Service des Isotopes Hôpital COCHIN - Pr. J.-C. ROUCAYROL - PARIS . Institut d'Optique - ORSAY - FRANCE

- Tomographic reconstruction program is stored on a standard IMAC floppy disc. It allows the selection a posteriori of any number of slices up to 32 on any area of the examined organ.

The Clinical Cyclotron™

A new dimension in nuclear medicine



Designed by The Cyclotron Corporation specifically for installation in a hospital's nuclear medical department, the Model CP-16 Clinical Cyclotron™ produces the short-lived, positron emitting ^{15}O , ^{13}N , ^{11}C and ^{18}F plus other medically useful isotopes. Multicurie quantities of the positron emitters are produced, making possible labelling of organic compounds in addition to on-line applications.

Among the many new innovative design features incorporated in the Clinical Cyclotron™ is the ability to extract the beam from the machine at more than one location. Furthermore, two radioisotopes can be made simultaneously. It is now possible to make full use of the beam at multiple target locations without the requirement for an external beam transport system.

As the name suggests, the Clinical Cyclotron™ is remarkably easy to operate. In a few weeks a senior hospital technician can be trained in all phases of its use. Production of radioisotopes with the Model CP-16 can be simplified further by selection of the computer control option. In this configuration, start up, operation and shut down of the Clinical Cyclotron™ are handled automatically after the operator has entered the required data.

Another potentially valuable option is complete self-shielding. This can

be of particular advantage when it is necessary to make use of existing facilities because of budgetary or other constraints on new construction. As the artist's illustration reveals, this feature permits locating the controls and the Model CP-16 Cyclotron in the same room under "controlled area" conditions.

The standard Clinical Cyclotron™ produces the desired radioisotopes utilizing selected (p,n), (p,xn), and (p,α) reactions shown in the accompanying table. Should a user prefer to employ some or all of the listed (d,n) or (d,α) reactions, this capability is available as an option. Likewise, the ability to vary the energy of the particles accelerated by the Model CP-16 Cyclotron is an optional feature. The energy range applicable to protons is 4-16 MeV; for deuterons, 3-8 MeV.

Drawing on the extensive experience gained in building over 20 cyclotron systems and the advice and counsel of users of these systems, The Cyclotron Corporation also has developed the Model CP-30 Cyclotron. This machine is designed for those users who want to have the ability to produce the full range of medically useful isotopes in the hospital. With the Model CP-30, virtually all of the longer half-life isotopes can be produced in commercial quantities. This cyclotron

also can be used as a major component of a neutron therapy system. Computer control and variable energy are standard features of the Model CP-30 Cyclotron. Like the Clinical Cyclotron™ this machine produces protons but the energy range is 8-30 MeV; for optional deuterons, 4-15 MeV.

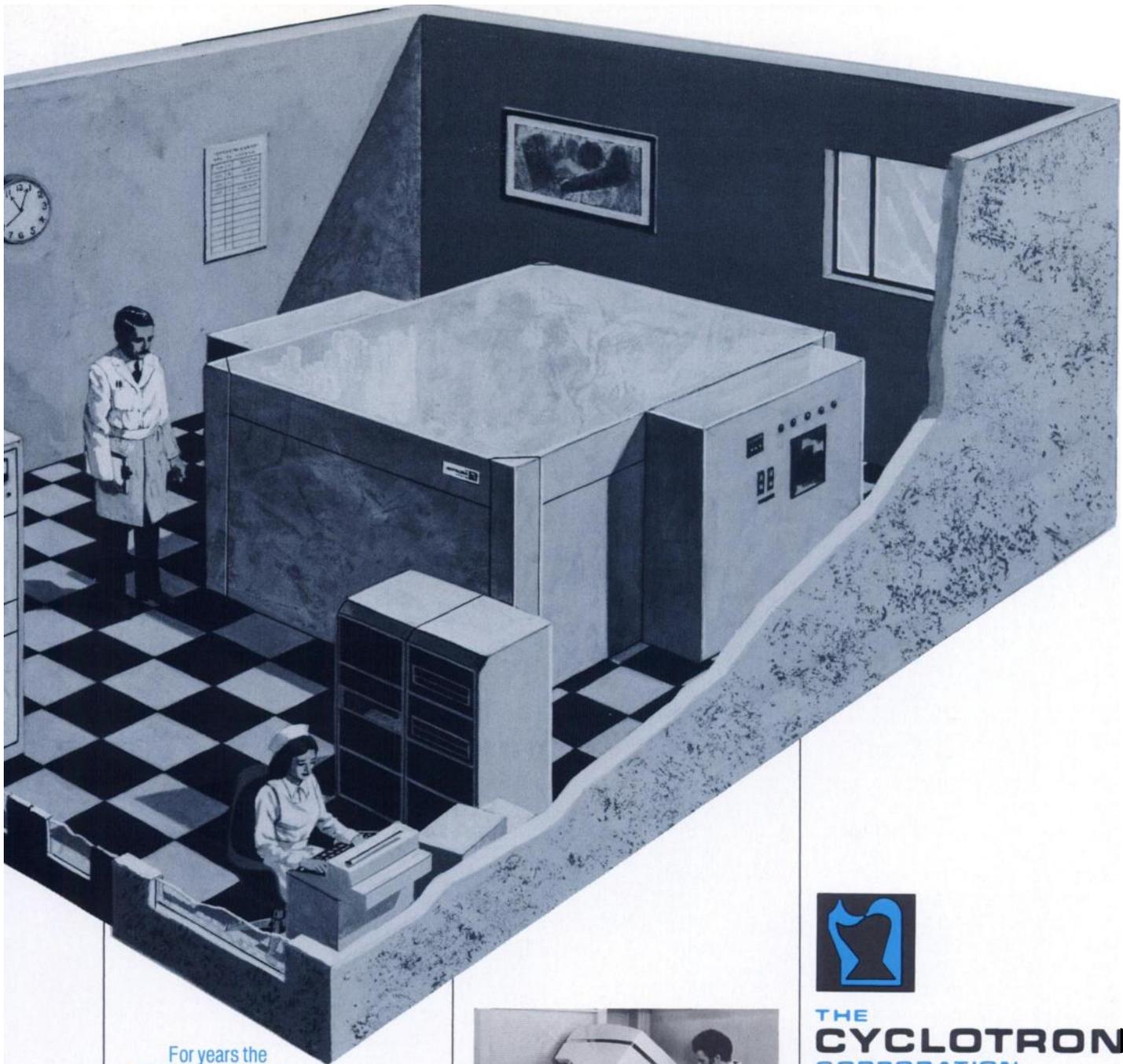
The Cyclotron Corporation also can provide target and beam transport systems plus complete laboratories including hot cells. Experienced personnel are available to assist the users' architects and engineers in designing a new or remodeled facility.

PRODUCTION OF ISOTOPES IN CURRENT USE*										
Isotope	^{11}C	^{13}N	^{15}O	^{18}F	$^{81}\text{Kr} \leftarrow ^{81}\text{Rb}$	^{123}I	^{67}Ga	^{111}In	^{68}Ge	$^{201}\text{Tl} \leftarrow ^{201}\text{Pb}$
Reaction CP-16**	$^{14}\text{N}(p,\alpha)$	$^{16}\text{O}(p,\alpha)$ $^{12}\text{C}(d,n)$	$^{15}\text{N}(p,n)$ $^{14}\text{N}(d,n)$	$^{18}\text{O}(p,n)$ $^{20}\text{Ne}(d,\alpha)$		$^{123}\text{Te}(p,n)$	$\text{Zn}(p,xn)$ $^{66}\text{Zn}(d,n)$	$\text{Cd}(p,xn)$ $^{111}\text{Cd}(p,n)$		
CP-30**	$^{14}\text{N}(p,\alpha)$	$^{16}\text{O}(p,\alpha)$ $^{12}\text{C}(d,n)$	$^{15}\text{N}(p,n)$ $^{14}\text{N}(d,n)$ $^{16}\text{O}(p,pn)$	$^{18}\text{O}(p,n)$ $^{20}\text{Ne}(d,\alpha)$	$^{82}\text{Kr}(p,2n)$	$^{123}\text{Te}(p,n)$ $^{124}\text{Te}(p,2n)$	$\text{Zn}(p,xn)$ $^{66}\text{Zn}(d,n)$ $^{68}\text{Zn}(p,2n)$	$\text{Cd}(p,xn)$ $^{111}\text{Cd}(p,n)$ $^{112}\text{Cd}(p,2n)$	$^{69}\text{Ga}(p,2n)$	$^{203}\text{Tl}(p,3n)$

NOTE: *Where current use data indicates reaction is possible only with Model CP-30 or significantly higher yields are obtained using CP-30, the reaction is printed in blue.

**Acceleration of deuterons is available as an option.

☐ Denotes enriched isotope.



For years the Profession has been considering the potential value of the short-lived positron emitting nuclides in the diagnostic process, particularly ^{15}O , ^{13}N and ^{11}C . Until recently, the interest had to be relatively academic in the absence of effective positron imaging devices. With the development of The Cyclotron Corporation's versatile Model 4200 Positron Camera System (pictured) and EG&G Ortec's Ecat™ this void has been filled. Since the early sixties compact cyclotrons have been used to produce the short-lived radioisotopes in medical research centers. However, in the opinion of some, such machines are considered too complicated or for other



reasons somewhat less than ideal for installation in the typical nuclear medical department. The advent of the Clinical Cyclotron™ removes the last obstacle blocking full exploitation of this exciting new field.



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CYCLOTRON
CORPORATION**

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JNM 6/80

GENERATOR TECHNETIUM Tc 99m GENERATOR FOR THE PRODUCTION OF SODIUM PERTECHNETATE Tc 99m

description—The Union Carbide TECHNETIUM Tc 99m Generator provides a means of obtaining a sterile, pyrogen-free solution of Sodium Pertechnetate Tc 99m in isotonic saline from elution of the generator containing Molybdenum Mo 99. Hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment. The carrier-free solution may be used as is, or with proper dilution to prepare the studies described herein. Over the life of the generator, an elution will contain a yield of 80% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 on the generator column.

physical characteristics

Technetium Tc 99m decays by isomeric transition with a physical half-life of 6.02 hours. Photons that are useful for imaging studies and the principle radiations contributing to the internal dose rate are listed in Table I.

Table I. principle radiation emission data

radiation	mean %/disintegration	mean energy (keV)
Gamma-2	88.96	140.5

*Martin, M.J., ed., Nuclear Decay Data for Selected Radionuclides, ORNL-5114, p. 24, March 1976.

external radiation

The specific gamma ray constant for Technetium Tc 99m is 0.8 R/millicurie-hour at 1 cm. The first half-value thickness of lead (Pb) for Technetium Tc 99m is 0.2 mm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table II. For example, the use of 2.5 mm of Pb will decrease the external radiation exposure by a factor of 1.000.

Table II. radiation attenuation by lead (Pb) shielding

shield thickness (Pb) mm	coefficient of attenuation
0.2	0.5
0.8	10 ⁻¹
1.6	10 ⁻²
2.5	10 ⁻³
3.3	10 ⁻⁴

Molybdenum Mo 99 decays to Technetium Tc 99m with a Molybdenum Mo 99 half-life of 2.75 days. The physical decay characteristics of Molybdenum Mo 99 are such that only 86.8% of the decaying Molybdenum Mo 99 atoms form Technetium Tc 99m. Generator elutions may be made at any time, but the amount of Technetium Tc 99m available will depend on the interval from the last elution. Approximately 47% of maximum Technetium Tc 99m is reached after 6 hours and 95% after 24 hours. To correct for physical decay of each radionuclide, the fractions that remain at selected intervals of time are shown in Table III.

Table III. physical decay chart

Molybdenum Mo 99 half-life 2.75 days		Technetium Tc 99m half-life 6.02 hours	
days	fraction remaining	hours	fraction remaining
0	1.000	0	1.000
1	.777	1	.891
2	.604	2	.794
3	.469	3	.708
4	.365	4	.631
5	.284	5	.562
6	.220	6	.501
7	.171	7	.447
8	.133	8	.398
9	.103	9	.355
10	.080	10	.316
11	.063	11	.282
12	.049	12	.251
13	.038		

*Calibration time.

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

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

indications and usage—Sodium Pertechnetate Tc 99m is used as an agent for brain imaging, thyroid imaging, salivary gland imaging, placenta localization and blood pool scans.

contraindications—None known.

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

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

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

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. Sodium Pertechnetate Tc 99m 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 pa-

tient is on a drug since many drugs are excreted in human milk.

Safety and effectiveness in children have not been established.

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

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

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

dosage and administration—Sodium Pertechnetate Tc 99m is usually administered by intravenous injection, but can be given orally. The dosage employed varies with each diagnostic procedure. The suggested intravenous dose range employed in the average adult (70 kg) in millicuries of Sodium Pertechnetate Tc 99m for various diagnostic indications is as follows:

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

NOTE: Up to 1 gram of reagent grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of Sodium Pertechnetate Tc 99m injection for brain scan, placenta localization and blood pool scan for the purpose of blocking uptake of Sodium Pertechnetate Tc 99m by the choroid plexus.

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

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

radiation dosimetry

The estimated absorbed radiation doses¹ to an average patient (70kg) from an intravenous injection of a maximum dose of 20 millicuries of Sodium Pertechnetate Tc 99m distributed uniformly in the total body of subjects not pretreated with blocking agents such as NaClO₄, KClO₄, or iodide are shown in Table IV. For placental localization studies when a maximum dose of 3 millicuries is used it is assumed to be uniformly equilibrated between maternal and fetal tissues.

Table IV. radiation doses

tissue	absorbed radiation dose (rads/20 millicuries)		(rads/3 millicuries)
	Resting Population	Active Population	
Bladder wall	1.06	1.70	
Gastrointestinal Tract			
Stomach wall	5.00	1.02	
Upper large intestine wall	1.36	2.40	
Lower large intestine wall	1.22	2.20	
Red marrow	0.38	0.34	
Testes	0.18	0.18	
Ovaries	0.44	0.60	
Thyroid	2.60	2.60	
Whole-body	0.28	0.22	
* Brain	0.28	0.24	0.05
* Placenta			0.05
* Fetus			0.05

***Method of Calculation:** A Schema for Absorbed Dose Calculations for Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, J. Nucl. Med., p. 7 (1968).
¹Summary of Current Radiation Dose Estimates to Normal Humans From 99mTc as Sodium Pertechnetate, MIRD Dose Estimate Report No. 8, J. Nucl. Med., 17:1, 1976.

Table V. Generator dosimetry readings

Technetium Tc 99m Generator front side of Generator measurements at 6:00 AM prior to elution					
Generators up to 4140 mCi internal lead shield		Generators 4970 to 16600 mCi internal depleted uranium shield			
days from calibration	mR/hr 2" 12"	mCi 99Mo	days from calibration	mR/hr 2" 12"	mCi 99Mo
0*	425 57	4410	0*	174 33	16800
1	330 44	3430	1	135 26	13100
2	256 34	2660	2	105 20	10200
3	199 27	2070	3	81 16	7900
4	155 21	1610	4	63 12	6100
5	120 16	1250	5	49 9	4800
6	94 12	970	6	38 7	3200
7	73 10	750	7	30 6	2900

*Day of calibration at 12:00 hrs E.T. is the day of shipment from Tuxedo, N.Y.

Table VI. elution vial radiation dosimetry

11440 millicuries of Tc 99m activity 20cc vial, 20ml of elution		
vial distance from probe contact	dosimetry bare vial	dosimetry shielded vial*
30.5 cm	472000mR/hr	4 mR/hr
	13000mR/hr	0.6mR/hr

*Union Carbide Elution Vial Shield Cat. No. 17500500, Shield 6.35mm Lead.

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

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

*initial order only.

preparation

The following instructions must be carefully followed for optimum preparation of Sodium Pertechnetate Tc 99m.

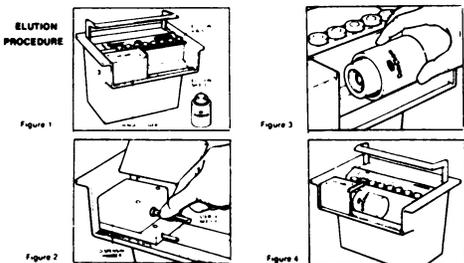
Union Carbide Generators are sterile and pyrogen-free at the time of shipment. Aseptic technique must be observed during the use of the generator to maintain a sterile and pyrogen-free system. Gloves should be worn during all elution procedures.

The sealed column and fluid path MUST NOT be removed from the shielding system.

***CAUTION:** It is recommended that elution vial shields be used when eluting the generators, shielded syringes be used when preparing formulations, and appropriate vial shields be used for the formulations.

First Elution

1. Remove generator system and accessories from carton.
2. Lift hinged cover exposing dispenser end. Remove protective cap from dispenser end and attach a sterile needle—REMOVE PLASTIC NEEDLE COVER (Figure 2). Return cover to closed position.
3. Place an elution vial in the elution shield (Figure 1) and clean septum of elution vial with an antiseptic swab. Position elution shield on dispensing platform (Figure 3).
4. Rotate fluid path shut off valve several full turns counterclockwise until loose. Valve is located on left side of generator.
5. Slide elution shield to far left position (Figure 4). The dispensing needle will pierce the septum of the evacuated elution vial. The elution will begin immediately.
6. Step away to reduce your radiation exposure. Allow 3 to 5 minutes for complete elution.
- NOTE: If vacuum in elution vial is lost, i.e., no eluate present in vial, discard vial and use a new elution vial.
7. When elution is complete, slide elution shield to far right position. Remove elution shield, containing vial with Sodium Pertechnetate Tc 99m eluate, from dispensing platform.
8. Replace dispensing needle with sterile needle with plastic cover in place. DO NOT REMOVE COVER FROM NEEDLE until next elution.
9. Affix the pressure-sensitive label to the dose vial shield. Sodium Pertechnetate Tc 99m is ready for use. Maintain adequate shielding of the radioactive preparation.



storage

Store generator at room temperature (18-25 °C).

Caution: Avoid Freezing.

subsequent elutions

1. Lift hinged cover exposing dispenser needle. Remove plastic needle cover from dispensing needle and discard. Return cover to closed position.
2. Repeat steps 3, 5, 6, 7, 8 and 9.

20 ml elutions—To use the larger size elution vial, remove the spacer in the elution shield and replace with the spacer designed for 20 cc vials.

The radioactivity concentration of the final Sodium Pertechnetate Tc 99m preparation may be calculated by using the following formula:

C = A/V where C equals radioactivity concentration of the Sodium Pertechnetate Tc 99m preparation (millicuries/ml), A = Technetium Tc 99m activity added to the reaction mixture vessel (millicuries), V = Total volume in the final mixture (ml).

Technetium Tc 99m assay procedure

1. Determine the equivalent Technetium Tc 99m value for a Cobalt Co 57 standard by multiplying the number of millicuries of Cobalt Co 57 standard by the appropriate equivalent factor. This equivalent value of Cobalt Co 57 for the standard need only be decayed daily for use as a secondary standard.
2. Place the standard in the chamber and record μ amp reading.
3. Transfer the Technetium Tc 99m sample from the shield to the chamber. Record the μ amp reading.

4. Calculate activity:

μ amps of Tc 99m Sample	x millicuries
μ amps of ⁵⁷ Co std.	Cobalt Co 57 std. = millicuries
	Technetium Tc 99m

 where millicuries Cobalt Co 57 std. = the equivalent millicurie value for Cobalt Co 57 from 1. above, corrected for decay.

direct readout procedure—A direct readout dose calibrator is used.

1. Determine the equivalent millicurie Technetium Tc 99m value for a Cobalt Co 57 std. using method 1. above. Correct millicurie value for decay.
2. Place Cobalt Co 57 standard in chamber and adjust the calibrator to the proper reading according to the manufacturer's instructions.
3. Transfer sample vial to chamber and read directly millicuries Technetium Tc 99m.

Molybdenum Mo 99 breakthrough test

1. Determine the amount of Technetium Tc 99m eluted (millicuries).
2. Place the Technetium Tc 99m elution in a lead container. Place lid on container and put the entire container in the chamber.
3. Record the amount of Molybdenum Mo 99 (microcuries) on the most sensitive scale.
4. Divide the microcuries Molybdenum Mo 99 by the millicuries Technetium Tc 99m. Correct for decay and shielding effect, if necessary.

The acceptable limit is 1.0 microcurie Molybdenum Mo 99/millicurie Technetium Tc 99m, not to exceed 5 microcuries per human dose at the time of injection.

disposal

The TECHNETIUM Tc 99m GENERATOR should not be discarded in ordinary trash within 70 days of the calibration date. Vials and needles used for eluting may be discarded after two (2) days. It is suggested that all identification labels be destroyed before discarding the generator or vials.

TECHNETIUM Tc 99m GENERATORS OF \leq 4140 millicuries may be returned to the manufacturer; while those of 4970 to 16,600 millicuries must be returned to the manufacturer. Please refer to the instructions included with each shipment.

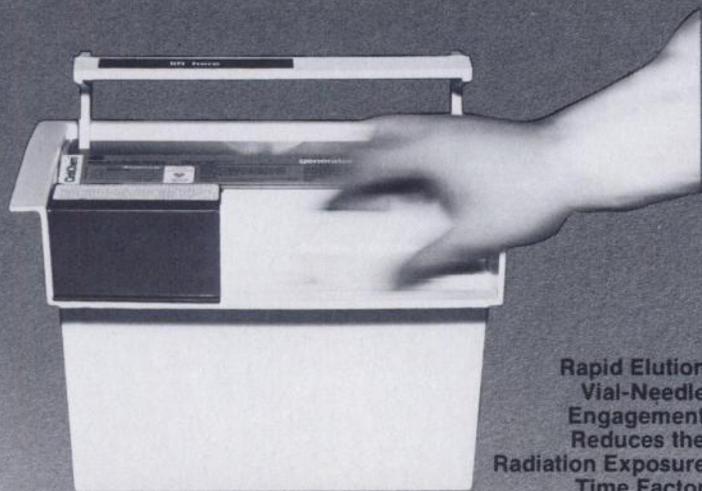
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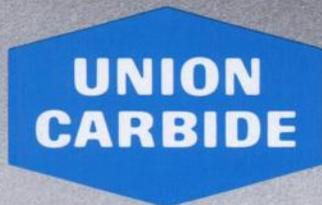


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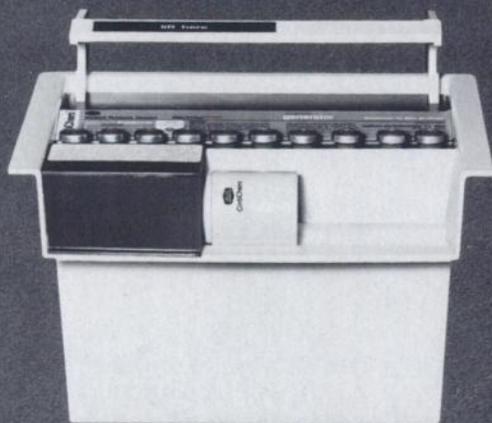
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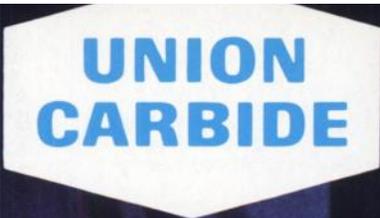
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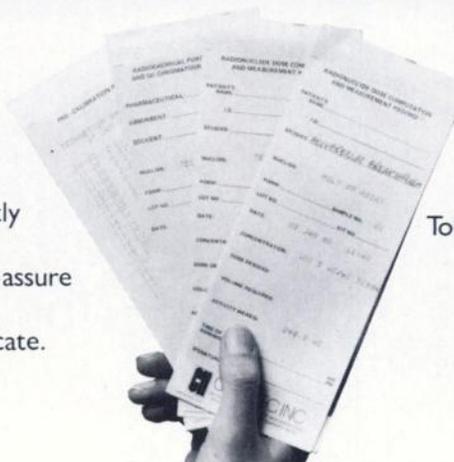


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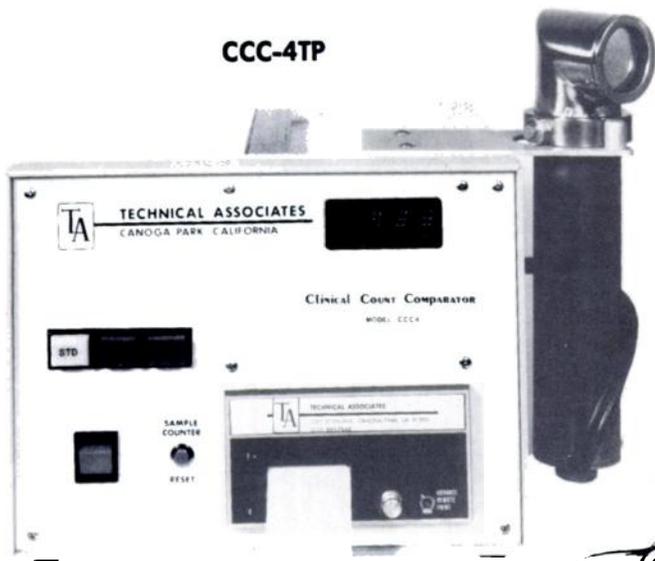
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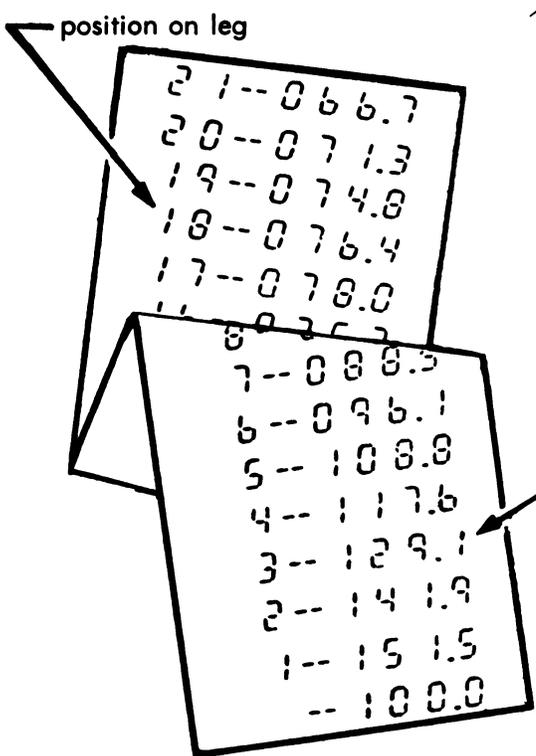
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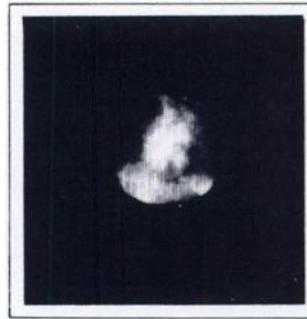


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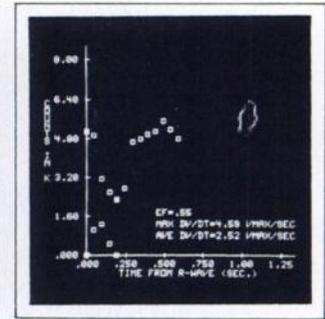
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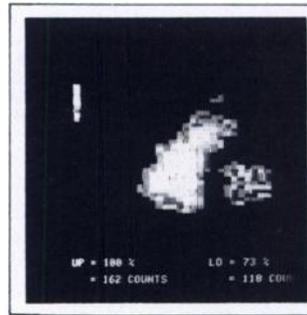
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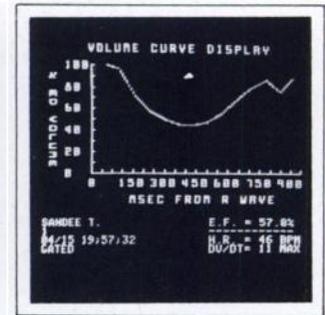
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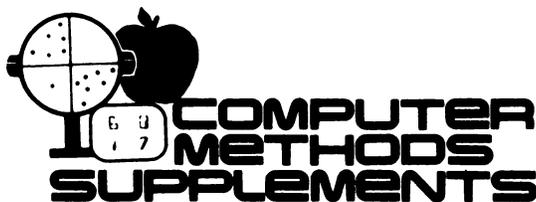
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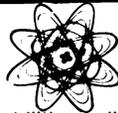
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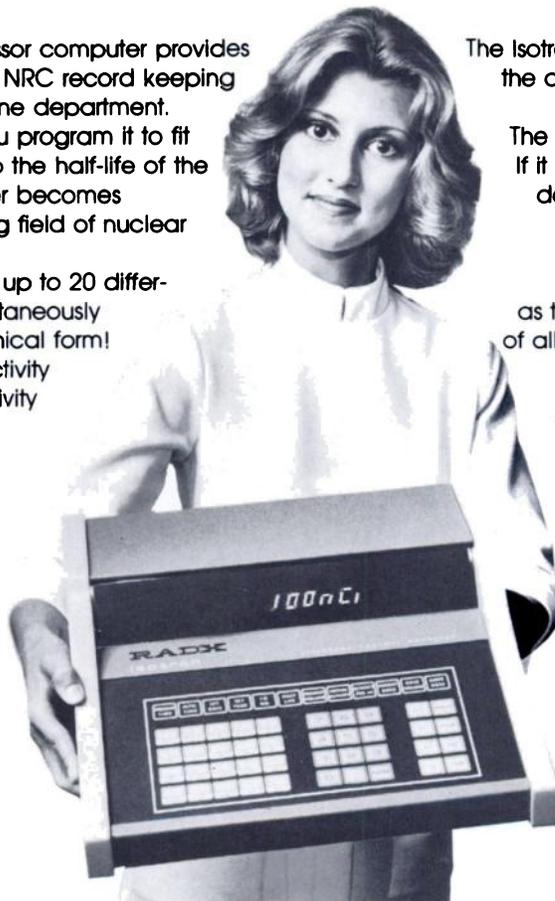
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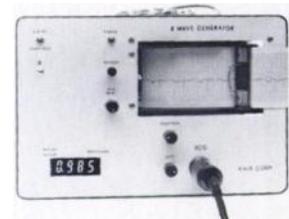
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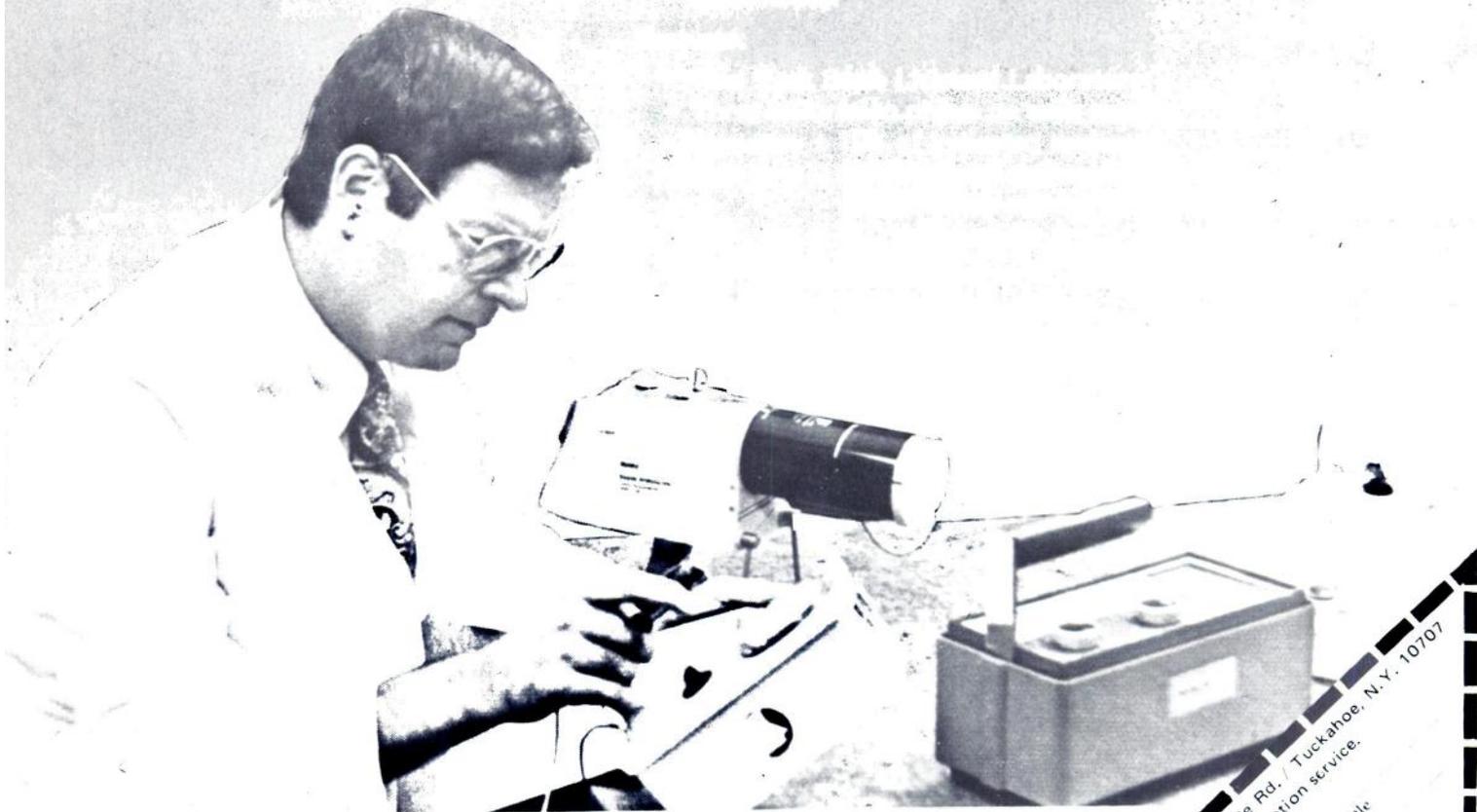
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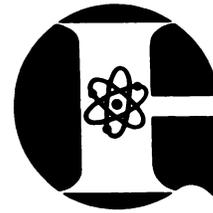
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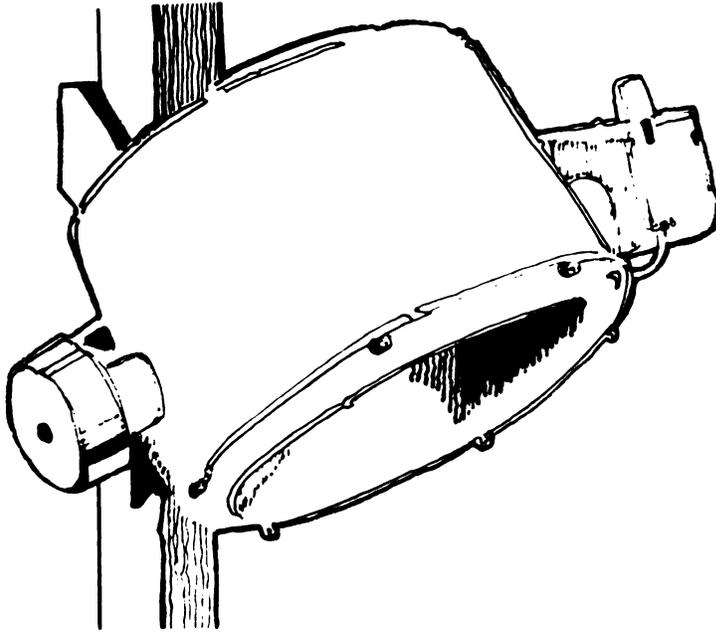
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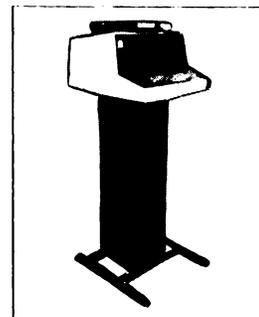
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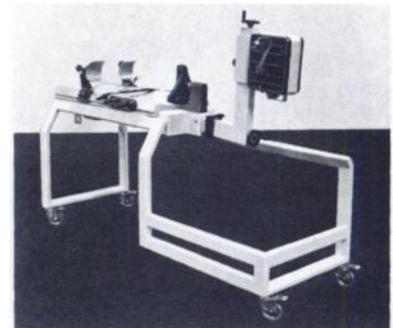
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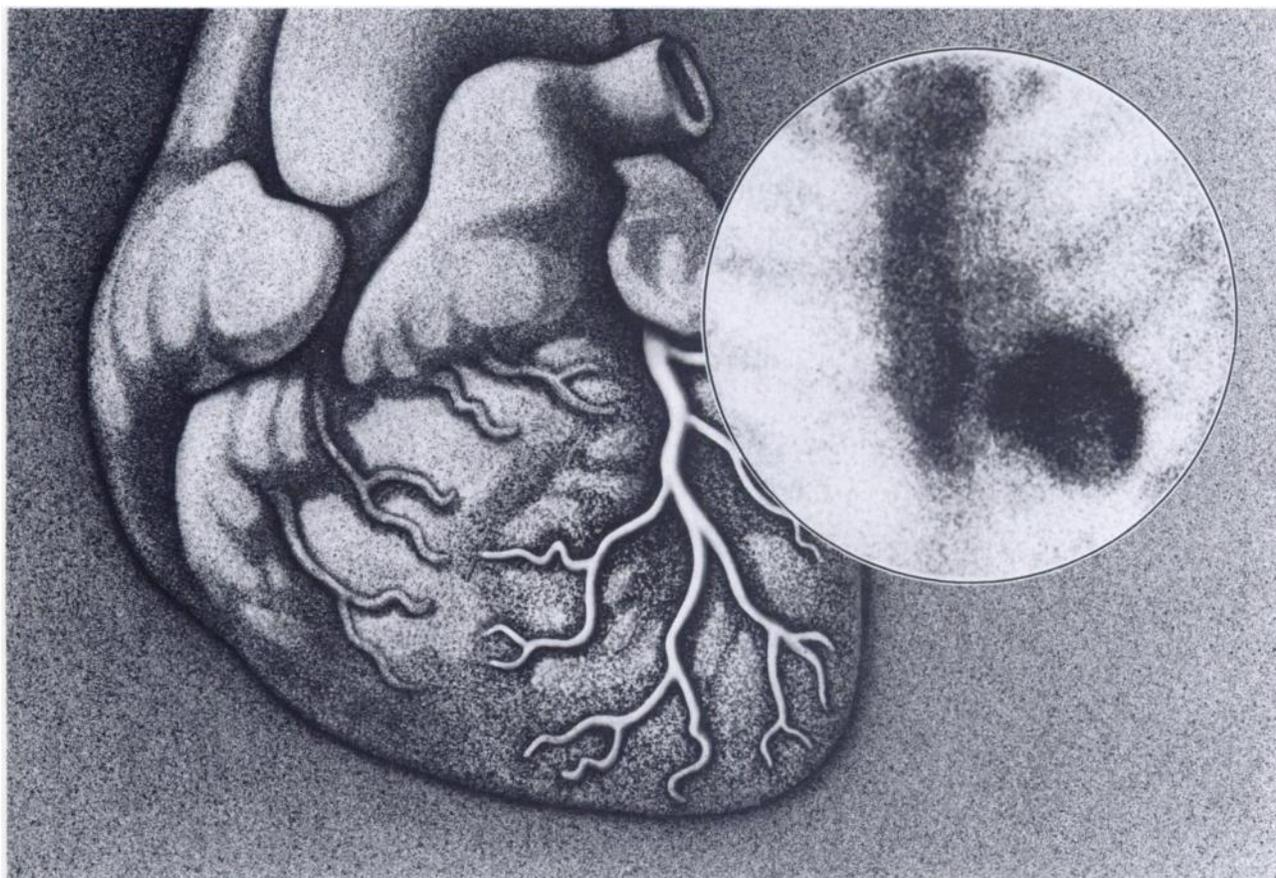
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JNM 6/80

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See next page for brief summary.

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PHOSPHOTEC[®] (Technetium Tc 99m Pyrophosphate Kit)



PHOSPHOTEC®

Technetium Tc 99m Pyrophosphate Kit

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

INDICATIONS AND USAGE: Phosphotec may be used as a bone imaging agent to delineate areas of altered osteogenesis. It is also a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction.

CONTRAINDICATIONS: None known.

WARNINGS: This product should not be administered to patients who are pregnant or to nursing mothers unless the benefit 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 (approx. 10) days following the onset of menses.

It has been reported that false-positive or false-negative brain scans may result when brain scans using sodium pertechnetate Tc 99m solution 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 technetium Tc 99m with stannous ions inside red blood cells. Therefore, in those cases where brain scans are indicated along with imaging of bone or myocardial imaging, the brain scan should be performed first, if feasible. Alternatively, another brain imaging agent, such as technetium Tc 99m pentetate, may be employed. False-positive and false-negative myocardial scans may occur; therefore, the diagnosis of acute myocardial infarction depends on the overall assessment of laboratory and clinical findings.

The contents of the Phosphotec reaction vial are to be used only for preparation of the I.V. 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 Technetium Tc 99m Pyrophosphate Kit. The contents of the kit are not radioactive. However, after sodium pertechnetate Tc 99m is added, adequate shielding of the final preparation must be maintained. Phosphotec (Technetium Tc 99m Pyrophosphate Kit) must be used within 12 hours after reconstitution.

PRECAUTIONS: In the use of any radioactive material, care should be taken to minimize radiation exposure to the patient and occupational workers consistent with proper patient management. Both prior to and following administration of the technetium Tc 99m pyrophosphate, the patient should be encouraged to drink fluids and to void as often as possible thereafter to minimize radiation exposure to the bladder and background interference during imaging if not contraindicated by the patient's cardiac status. The patient's cardiac condition should be stable before beginning the cardiac imaging procedure. Interference from chest wall lesions such as breast tumors and healing rib fractures can be minimized by employing three projections (e.g., anterior, lateral, and left anterior oblique).

Adequate reproductive studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus; therefore, this preparation 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 this radiopharmaceutical have been reported.

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

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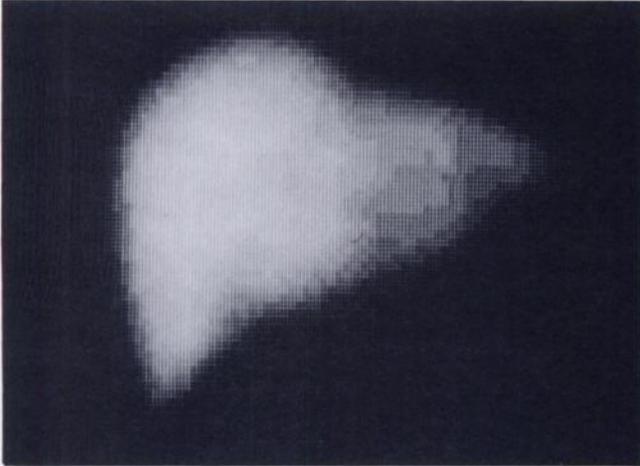
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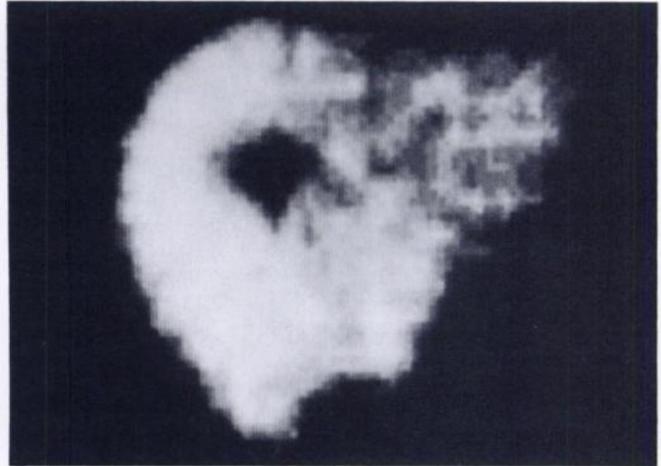
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JNM 6: 80

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The generator consists of a sealed glass chamber containing specially processed alumina. This treated alumina has a high absorption capacity for molybdenum-99 and a low affinity for technetium-99m. As a result, elution of the generator yields a solution of technetium-99m containing negligible amounts of molybdenum-99.

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The pertechnetate ion distributes in the body similarly to the iodide ion but is not organified when trapped in the thyroid gland. Pertechnetate tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. It also concentrates in thyroid gland, salivary glands, stomach and choroid plexus. After intravascular administration it remains in the circulatory system for sufficient time to permit blood pool, organ perfusions, and major vessel studies. It gradually equilibrates with the extracellular space. A fraction is promptly excreted via the kidneys.

INDICATIONS

Sodium pertechnetate Tc-99m is used for brain imaging, thyroid imaging, salivary gland imaging, placenta localization and blood pool imaging.

CONTRAINDICATIONS

None.

WARNINGS

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

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, 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 occupational workers.

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

ADVERSE REACTIONS

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DOSAGE AND ADMINISTRATION

Sodium pertechnetate Tc-99m is usually administered by intravascular injection but can be given orally. The dosage employed varies with each diagnostic procedure.

The suggested dose range employed for various diagnostic indications in the average patient (70 kg) is:

brain imaging:	10 to 20 mCi
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salivary gland imaging:	1 to 5 mCi
placenta localization:	1 to 3 mCi
blood pool imaging:	10 to 20 mCi

NOTE: Up to 1 gram of reagent grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of sodium pertechnetate Tc-99m injection for brain imaging, placenta localization and blood pool imaging.

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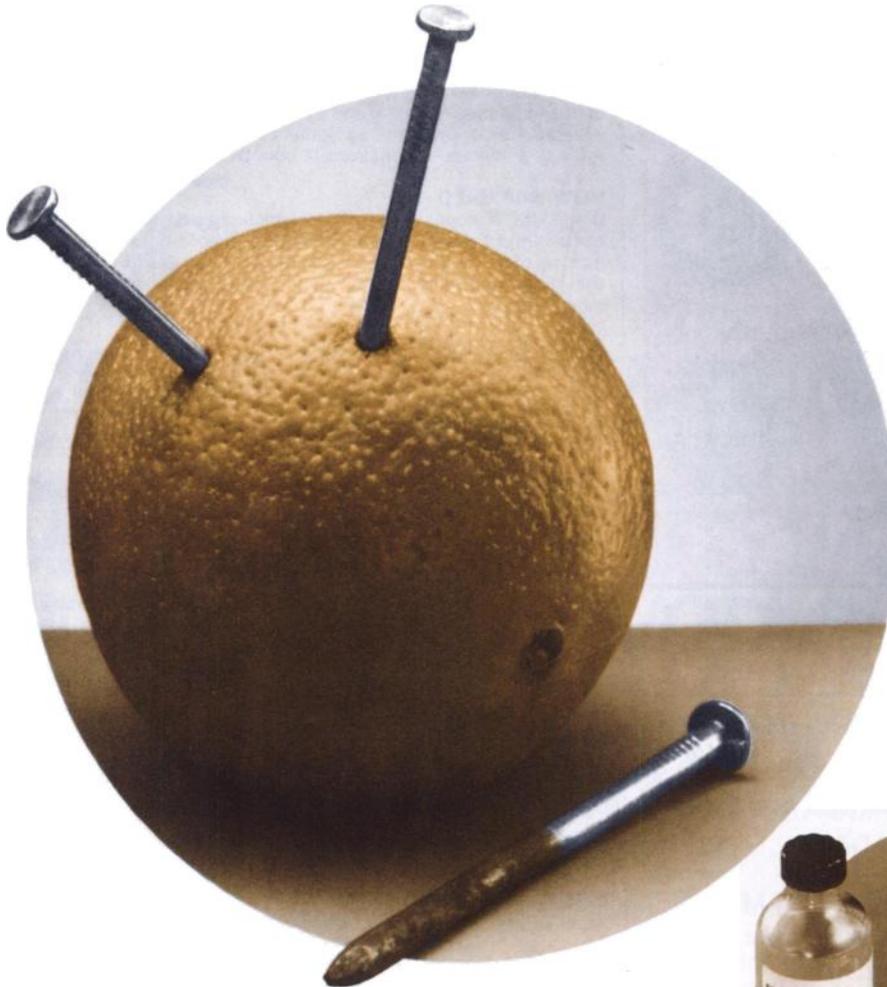
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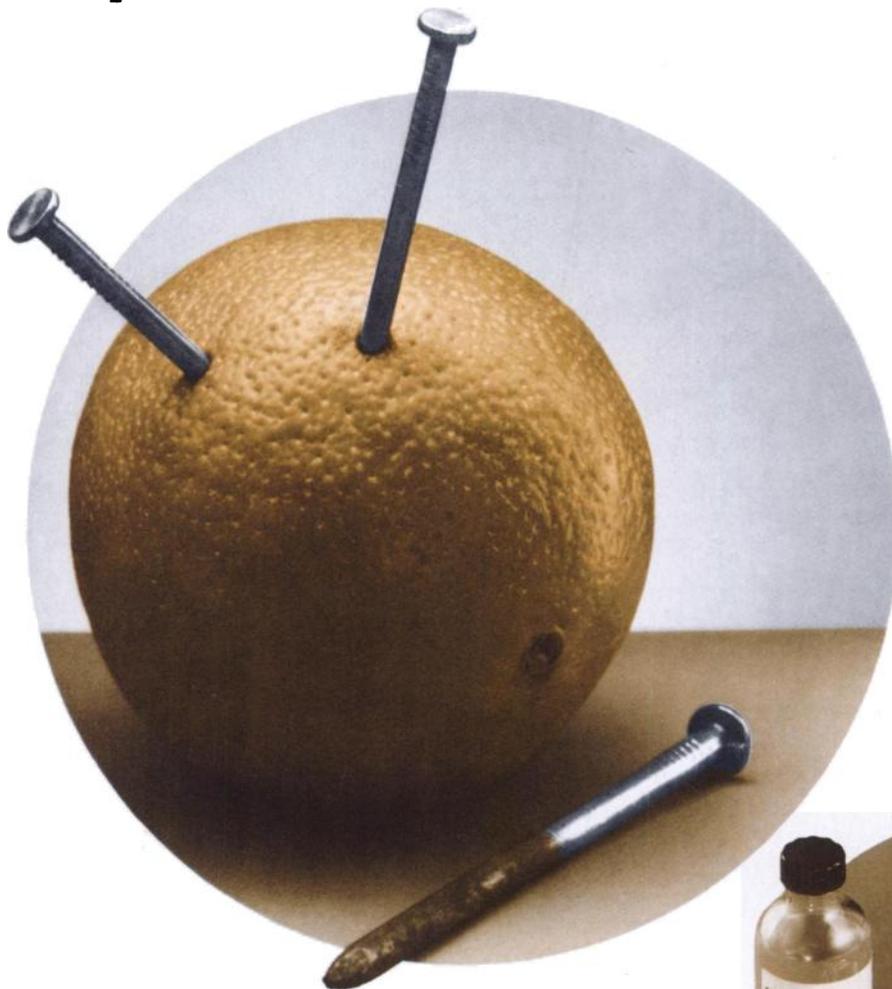
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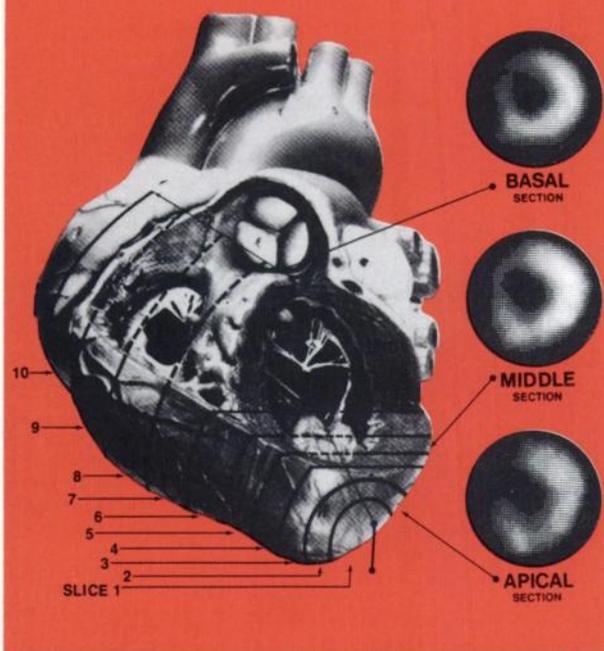


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DTPA KIT

TECHNETIUM Tc 99m PENTETATE KIT

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

DESCRIPTION

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

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

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

HOW SUPPLIED

Diagnostic Isotopes' DTPA Kit is supplied as a sterile, pyrogen-free kit containing 10 vials. Each vial contains 5 mg of Sodium salt of DTPA and 0.25 mg of SnCl₂. The pH is adjusted with HCl or NaOH prior to lyophilization. Following lyophilization the vials are sealed under a nitrogen atmosphere.

CLINICAL PHARMACOLOGY

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

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

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

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

PRECAUTIONS

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

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

ADVERSE REACTIONS

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

DOSAGE AND ADMINISTRATION

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

Kidney imaging and glomerular filtration rate estimation: 3 to 5 mCi.
Brain imaging or renal perfusion: 10 to 20 mCi.

di

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225 Belleville Avenue, Bloomfield, N.J. 07003

By the
time
some
people
can say:

**“DIETHYLENETRIAMINEPENTA-
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CHLORIDE IN A LYOPHILIZED
STATE UNDER NITROGEN”**

You've got
it mixed
and ready
to use!



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

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

Each DTPA kit contains 10 vials. The product is sterile, pyrogen-free, has a labeling efficiency of over 90% and a shelf life of one year . . . all good reasons for ordering now.

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

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Volume 21, Number 6

109A

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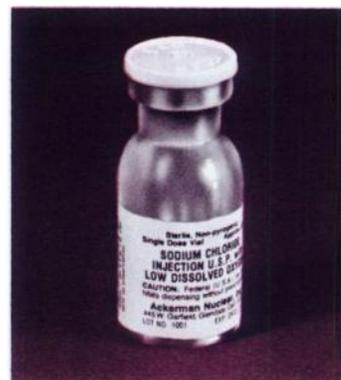
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Low* Dissolved Oxygen Non-preservative normal saline U.S.P.

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



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

DESCRIPTION:

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

INDICATIONS:

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

WARNING:

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

PRECAUTIONS:

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

HOW SUPPLIED:

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

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

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445 W. Garfield Avenue
Glendale, Calif. 91204

1/78

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

*less than 5 ppm

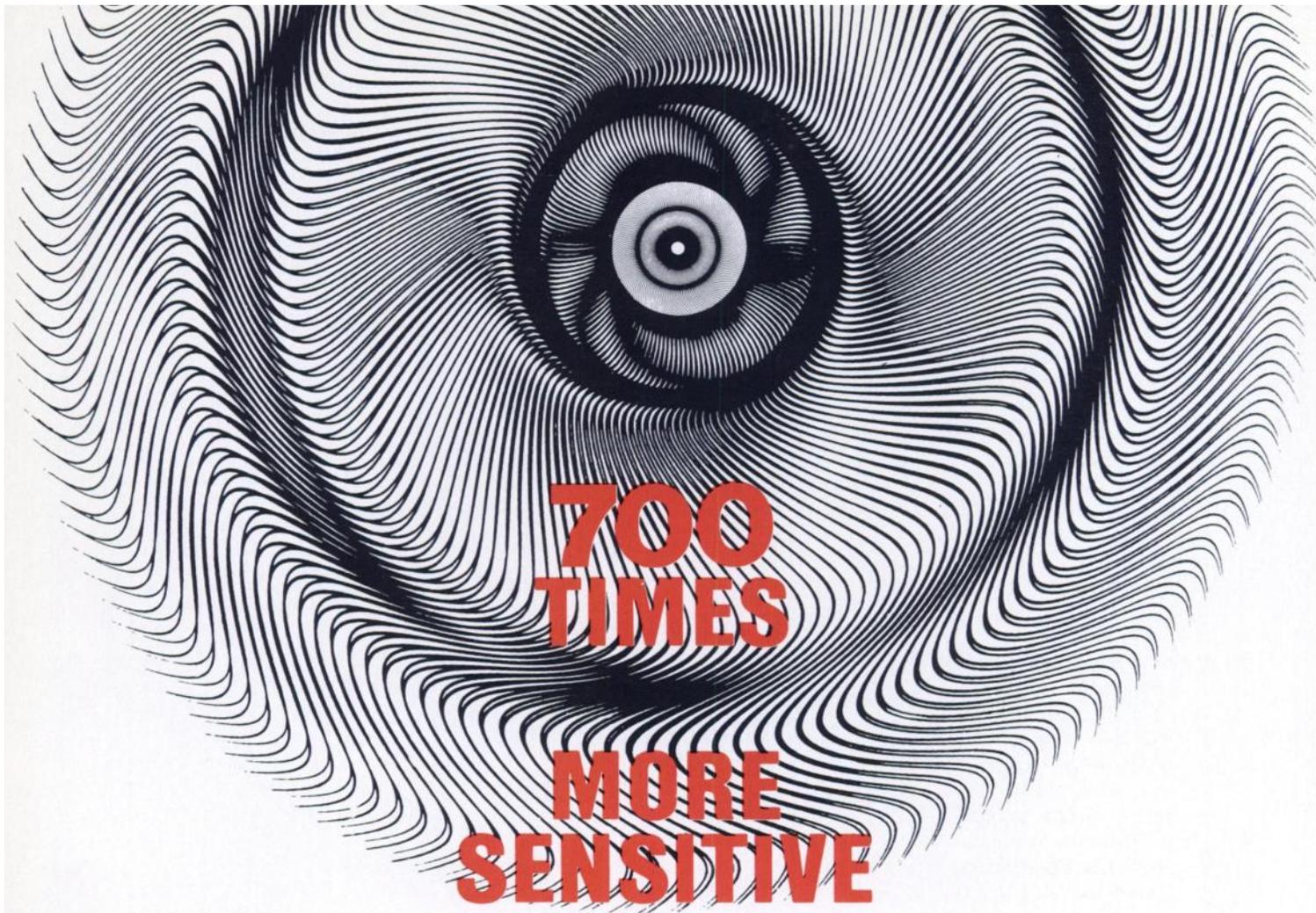
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SENSITIVITY:	0.0004 μM (700 times more sensitive)	0.3 μM
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STANDARDS SUPPLIED:	7	6
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*In units of 200

**Diagnostic
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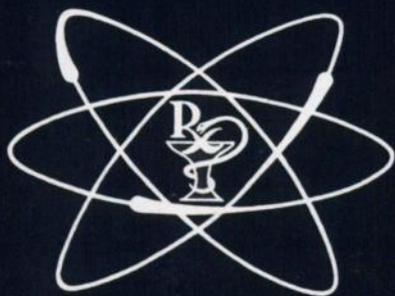
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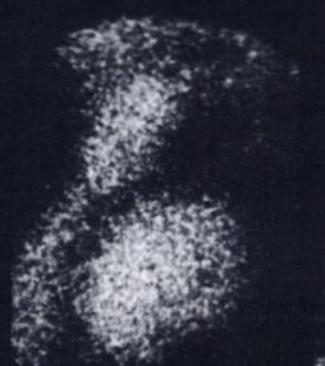
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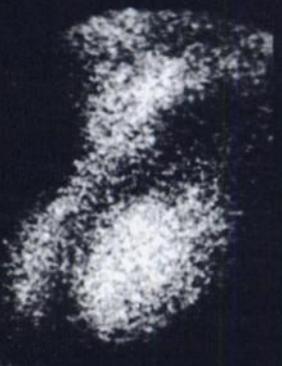
RAO, DIASTOLE



RAO, SYSTOLE



LAO, DIASTOLE

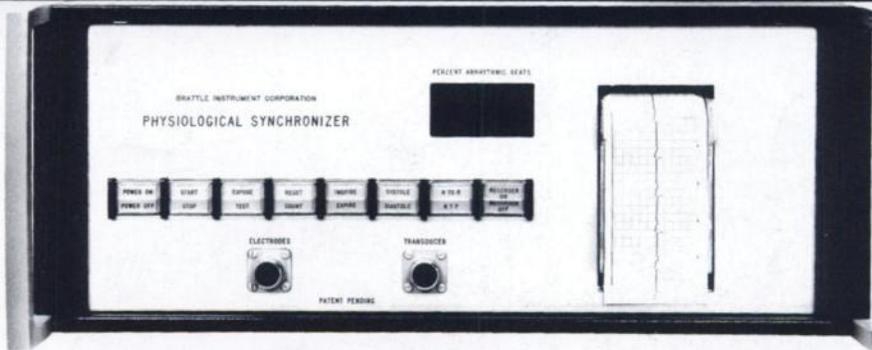


LAO, SYSTOLE

The RAO view shows akinesis of the lower antero-lateral wall and apex; and contraction of the inferior wall and high up the antero-lateral wall. The LAO view shows good contrac-

tion posteriorly and akinesis of the septal aspect of the chamber. Patient was injected IV with 20mCi of ^{99m}Tc -labelled Human Serum Albumin. The agent was prepared using the New

England Nuclear Electrolysis Kit for labelling HSA. Write or call for a portfolio of Brattle-gated lung, liver and heart studies.



No knobs, no meters, no errors

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.

Brattles lock onto patients — and stay locked on

It doesn't matter if the patient's heart rate and breathing depth change while he's under the collimator be-

cause we stay right with him. Brattles contain an ECG to track heart, a plethysmograph to track respiration, and a tiny computer to deduce systole and diastole times from the heart signal. And because it's all built in, your operator need not be a physiologist.

We don't cover our tracks — we print them

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.)

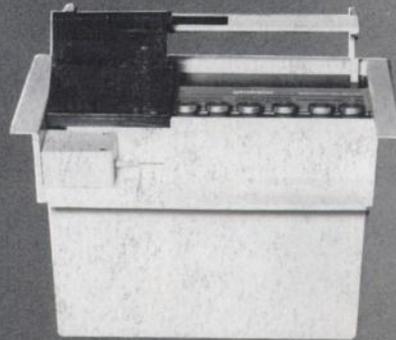
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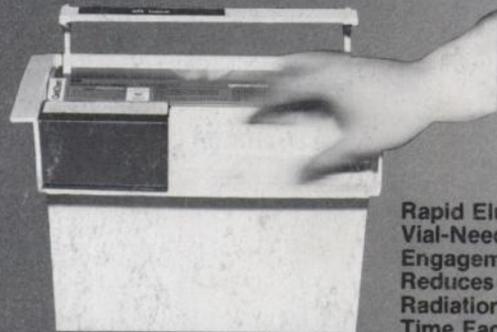
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Technetium 99m Generators

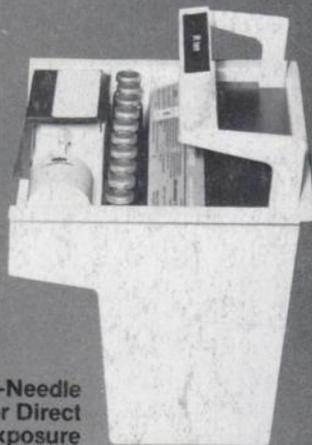
(Technetium Tc 99m
Generators for the
Production of Sodium
Pertechnetate Tc 99m)



Shielded
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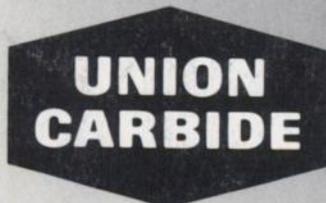
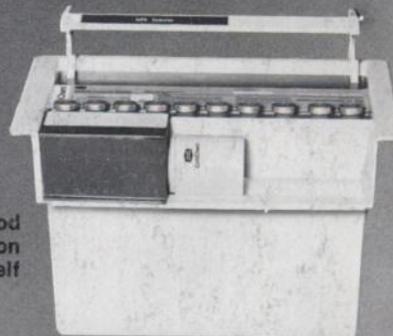


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