

Announces An Ideal Radioisotope For The Study of Pulmonary Ventilation

- A half-life of 13 seconds and decay by Isomeric Transition means low radiation exposure to patients and staff.
- The monoenergetic gamma emission of 191 keV is well suited for the gamma camera.
- No special radioactive gas collection or disposal system required.
- Completely portable system allows studies in ICU, CCU, and Post-Surgical departments with portable camera.



MPI Krypton Kr 81m Gas Generator Krypton Kr 81m

- Studies can be conducted on comatose, uncooperative, or mechanically vented patients.
- Distribution of radioactive gas is mainly to the lungs.
- Elaborate delivery system is not required.
- The only radioisotope that can be administered ON and OFF as needed.
- Easy to license when compared to Xenon Xe 133 gas.

The Pulmonary Profile

THE CONCEPT

The pulmonary profile is a series of matched perfusion and ventilation studies done consecutively on a patient using the MPI Krypton Kr 81m Gas Generator and Technetium Tc 99m Albumin Aggregated. Following administration of the two products you are able to switch the energy window on the gamma camera and scan the patient in the same position for each of the isotopes before you move the patient to the next view. Thus, a complete series of matching views may be accumulated for any number of patient positions.

THE PURPOSE

To increase the diagnostic sensitivity and specificity of lung imaging procedures by providing an easy means of obtaining matched perfusion-ventilation images in one patient visit.

THE RESULT

A new patient study which combines ventilation and perfusion imaging procedures into one study called the Pulmonary Profile Study.

For information regarding the MPI Krypton Kr 81m Gas Generator Krypton Kr 81m please call Medi-Physics at (415) 658-2184, Outside California (800) 227-0492 or Inside California at (800) 772-2477.

medi+physics

KRYPTON Kr 81m

DESCRIPTION: The Krypton Kr 81m Gas Generator consists of Rubidium Rb 81 fixed to a solid support from which the Krypton Kr 81m is eluted by passage of humidified oxygen or air through the generator. Other rubidiu radio-isotopes which do not decay to radioactive Krypton Kr 81m in their decay are present in the generator (Rubidium Rb 82m, for example, is present at a concentration of 30-40%).

INDICATIONS AND USAGE: The Krypton Kr 81m Gas Generator is indicated for use in the study of pulmonary ventilation.

CONTRAINDICATIONS: None known.

WARNINGS: None known.

PRECAUTIONS:

General

The Krypton Kr 81m Gas Generator as well as other radioactive drugs, must be handled with care to minimize radiation exposure to clinical personnel. Also care should be taken to minimize radiation exposure to the patient

consistent with proper patient management. Carcinogenesis, Mutagenesis, Impairment of Fertility No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or whether Krypton Kr 81m gas affects fertility in males or females

Pregnancy-Category C

Animal reproduction studies have not been conducted with Krypton Kr 81m gas. It is also not known whether Krypton Kr 81m gas can cause fetal harm when administered to a pregnant woman, or can affect reproduction capac-ity. Krypton Kr 81m gas should be given to a pregnant woman only if clearly needed.

Nursing Mothers It is not know whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Kryp-ton Kr 81m gas is administered to a nursing woman. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability, should be performed during the first few (approximately ten) days following the onset of menses. Pediatric Use Safety and effectiveness in children have not been established.

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: None known,

DOSAGE AND ADMINISTRATION: The recommended dose range for Krypton Kr 81m is 1-10 millicuries and should be administered by continuous inhalation for a sufficient time to provide desired diagnostic information. The multiplication product of the radioactivity and the time of continuous inhalation of Krypton Kr 81m generally should not exceed 100 millicurie-

HOW SUPPLIED: The Krypton 81m Gas Generator is supplied in the form of Rubidium Rb 81, bound to a solid support, with an activity of 2-10 millicuries at calibration time. The generator is enclosed in a lead shielded filter assembly surrounded by a capped plastic canister to which a handle is affixed. The generator should be stored at room temperature. The generator expires 12 hours after date and time of calibration.



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THE OBVIOUS SOLUTION

Low^{*} Dissolved Oxygen Non-preservative normal saline USP.

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

> ELUTION: Use for eluting Technetium-99m generators.

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

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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 m0sm/1, the dissolved oxygen content is less than 5 ppm. INDICATIONS:

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

WARNING:

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

PRECAUTIONS:

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

HOW SUPPLIED: Catalog No. S-25 SODIUM CHLORIDE INJECTION U.S.P. with LOW DISSOLVED OXYGEN Fach 10 ml single down in the source of the source o

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 m0sm/1; pH between 4.5 and 7.0. Dissolved oxygen content less than 5 ppm. Contains no preservatives.

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1/78



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

*less than 5 ppm

For additional information call or write to:



to Nuclear Medicine MALLINCKRODT. INC., Post Office Box 5840. St. Louis. MO 63134 Mallinckrodt @ Diagnostics

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NUCLEAR

Duick

Yesterday



1970



1980

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.

Tomorrow

We supported investigators with grants to develop their ideas into agents suitable for animal and human testing...we invested in the production facilities to manufacture sufficient quantities of radiopharmaceuticals and isotopes to perform the studies necessary to bring new products to you.

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 Brought to you in part by NEN

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.

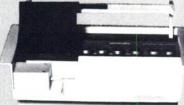
Instead, we built *four* of our own cyclotrons, and are currently building a multimillion-dollar linear accelerator — further evidence of NEN's unique commitment to research and development innovation in isotope and radiopharmaceutical production.

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.

NEN has maintained a high level of customer acceptance of its isotopes and radiopharmaceuticals, thanks to physicians and technologists who understand that when they trust their business to NEN they are sharing our investment in future nuclear diagnostics...in the profession's future ability to diagnose diseases for which medicine has no agents today ... and in the effort to communicate the benefits of nuclear diagnostics to the medical community.

CintiChem Technetium 99m Generators

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

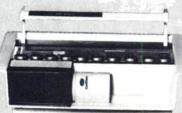


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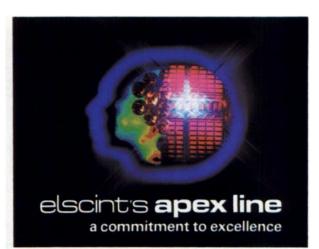
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Needs boiling only once for 5 minutes.

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indications and usage

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

contraindications

None known

warnings

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

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

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

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

precautions

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

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

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

Technetium Tc 99m Sulfur Colloid Injection is physically unstable and as such the particles

will settle with time. Failure to agitate the vial adequately before use may result in nonuniform distribution of radioactivity.

It is also recommended that because of the increasing probability of agglomeration with aging, a batch of Technetium Tc 99m Sulfur Colloid Injection not be used after six hours from the time of formulation.

The preparation contains no bacteriostatic preservative.

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

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

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

adverse reactions

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

One death and several cases of lung and soft tissue uptake other than RES have been reported in the association with the use of Technetium Tc 99m Sulfur Colloid Injection.

how supplied

The TECHNETIUM 99m SULFUR COLLOID KIT is supplied as a sterile pyrogen-free kit consisting of: five reaction vials, each containing 0.5 ml 1.0 N hydrochloric acid in water; five sterile syringes (labeled "A"), each containing 1.9 mg sodium thiosulfate anhydrous in 1.1 ml aqueous solution; five sterile syringes (labeled "B"), each containing 5.3 mg gelatin in 2.1 ml aqueous buffer solution containing 177 mg sodium acetate anhydrous

storage

Store finished drug at room temperature.

FOR FULL PREPARATION AND PRESCRIBING INFORMATION, SEE PACKAGE INSERT.

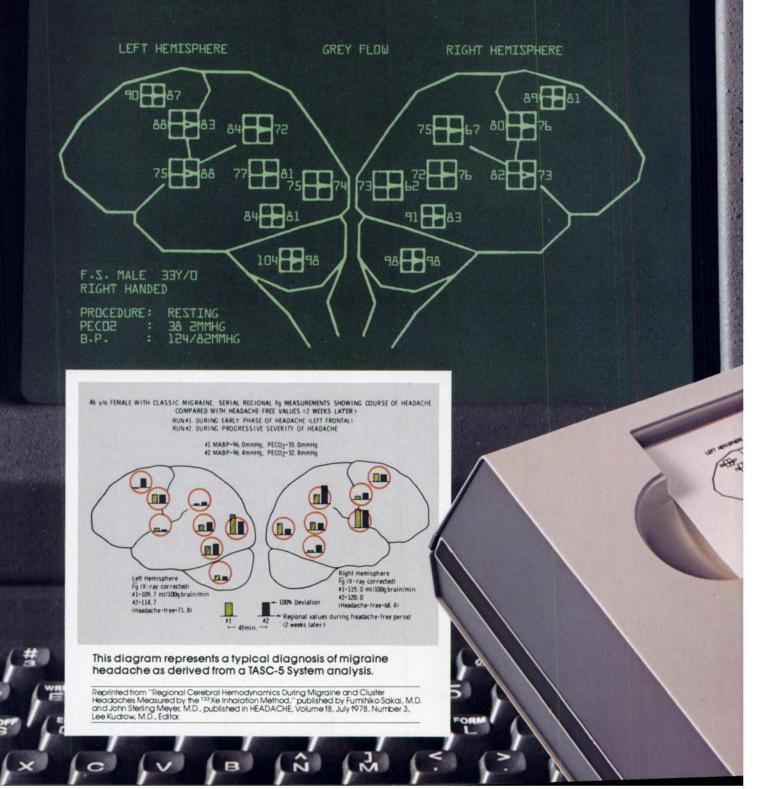
TSC Kit For The Preparation Of Technetium Tc 99m Sulfur Colloid Injection

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* Walter D. Obrist, et al STROKE Vol. 6, May June 1975, PP 245-256

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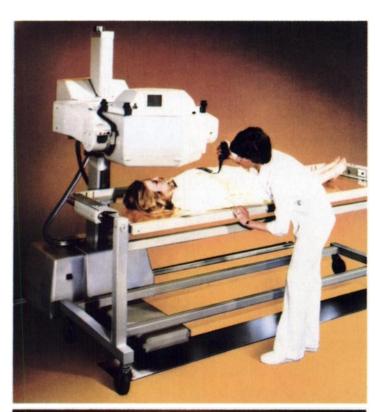
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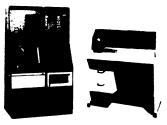
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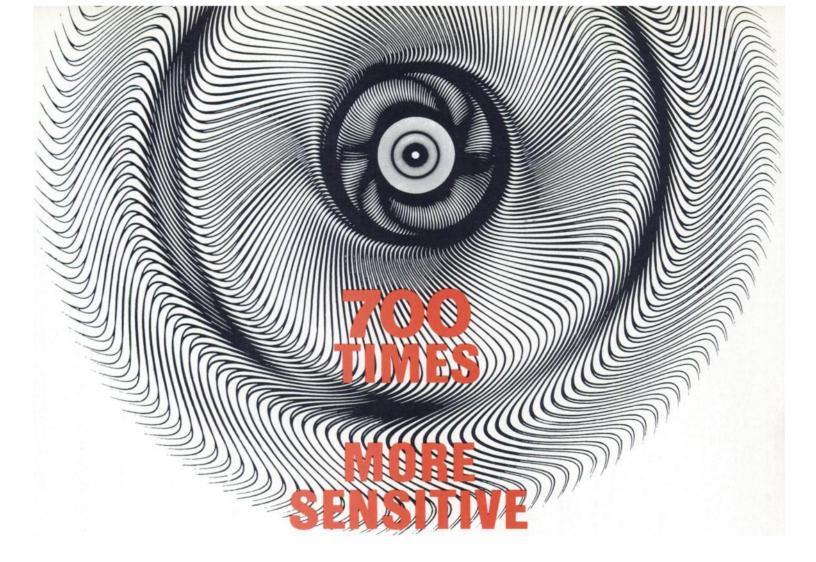
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*In units of 200

Biochemistry

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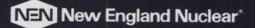
Brain

Diagnosis: arteriovenous malformation

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

Dose: 15 mCi GLUCOSCAN





Please see following page for brief prescribing information.

Technetium Tc 99m Gluceotate 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 imag-ing as an adjunct in the diagnosis, localization and evaluation of kidney dis-ease. 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.

rectly 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 uri-nary excretory structures in the presence of normal function. Adequate patient fluid intake and repositioning may reduce the incidence of such false positive studies studies

Studies. **PRECAUTIONS:** Technetium Tc 99m Gluceptate Sodium, as well as any radioac-tive agent, must be handled with care. Once sodium pertechnetate Tc 99m is added to the kit, appropriate safety measures should be used to minimize ex-ternal 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

state. Any oxidant present in the sodum 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 pertechne-tate 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

potential.

Adequate reproduction studies have not been performed in animals to de-termine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Technetium Tc 99m Glucep-tate 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

Gallium Citrate Ga67

INDICATIONS AND USAGES: Gallium Citrate Ga-67 may be useful in demonstrating the presence and extent of the following malignancies: Hodgkins dis-ease, 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 in-flammatory 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 intrave-nously administered Gallium Citrate Ga 67 is essential in order to accurately

nously administered Gallium Cirtate Gallium Scheder in order to accurately interpret pathologic studies. The findings of an abnormal gallium concentration usually implies the exis-tence 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 ceretive tick expende to a definitively intervented as multipa out the preserve of negative study cannot be definitively interpreted as ruling out the presence of disease

Lymphocytic lymphoma frequently does not accumulate Gallium Ga 67 suffi-ciently 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 Adiation 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 de-termine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. Gallium Citrate Ga 67

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 as-sociation 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 administra-

Technetium Tc 99m Gluceptate Sodium is intended for intravenous aurimistra-tion 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 real 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 im-provement 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 ap-monrate governmental agencies authorized to license the use of radionuclides.

propriate 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

Kit is supplied as a set of rive of thirty viais, 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 thirty viai kit is one package insert and six radiation labels. Included in each thirty viai kit is one package insert and thirty-six radiation labels.

The contents of the kit vials are not radioactive: however, <u>after reconstitu-</u> tion with sodium pertechnetate <u>Tc 99m</u> the contents are radioactive and <u>adequate shielding and handling precautions must be maintained</u>. This reagent kit is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission pursuant to Section 35.14 and 35.100 Group III of 10 CFR or under equivalent licenses of Agreement States.

Catalog Number NRP-180 (5 vial kit) Catalog Number NRP-180C (30 vial kit) August 1978

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 in-flammation; and other diagnostic studies must be added to define the underly-Ing 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 intrave-nous 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 spe-cific training in the safe use and handling of radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been ap-proved by the appropriate government agencies authorized to license the use of radiopublics. 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 hand-ling precautions must be maintained.

Catalog Number NRP-121

December 1979



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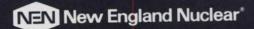


Diagnosis: intranephric abscess

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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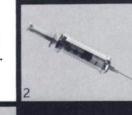
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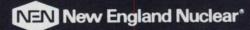
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assessment of cardiac function.

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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 infravenous 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 Technetium Tc-99m Pyrophosphate Kit.

Kit Contains:

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

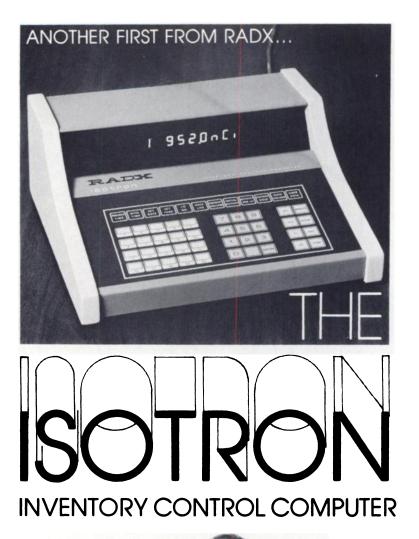
Reaction Vial Contains:

12.0 mg sodium pyrophosphate and 3.4 mg stannous chloride (lyophilized). Hydrochloric acid is added for pH adjustment prior to lyophilization.

5-Radioassay Information String Tags



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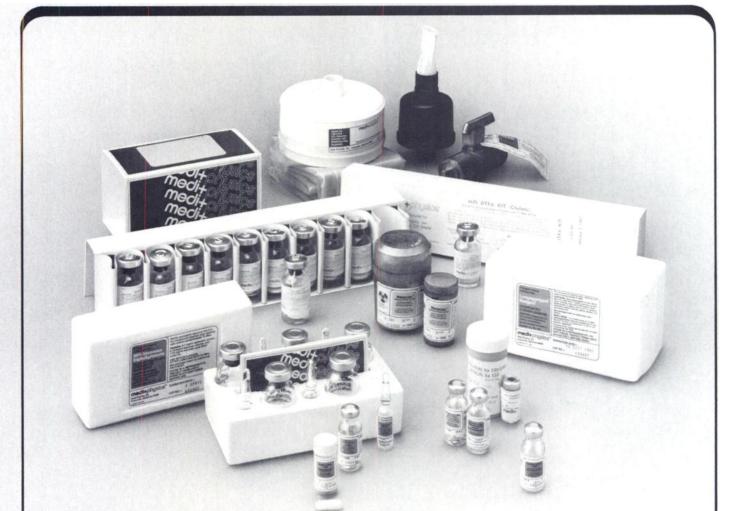


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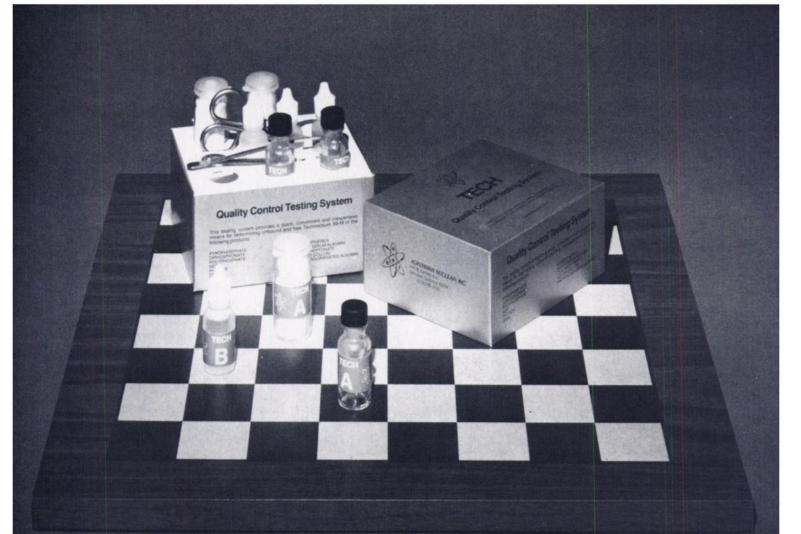
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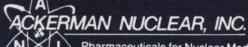
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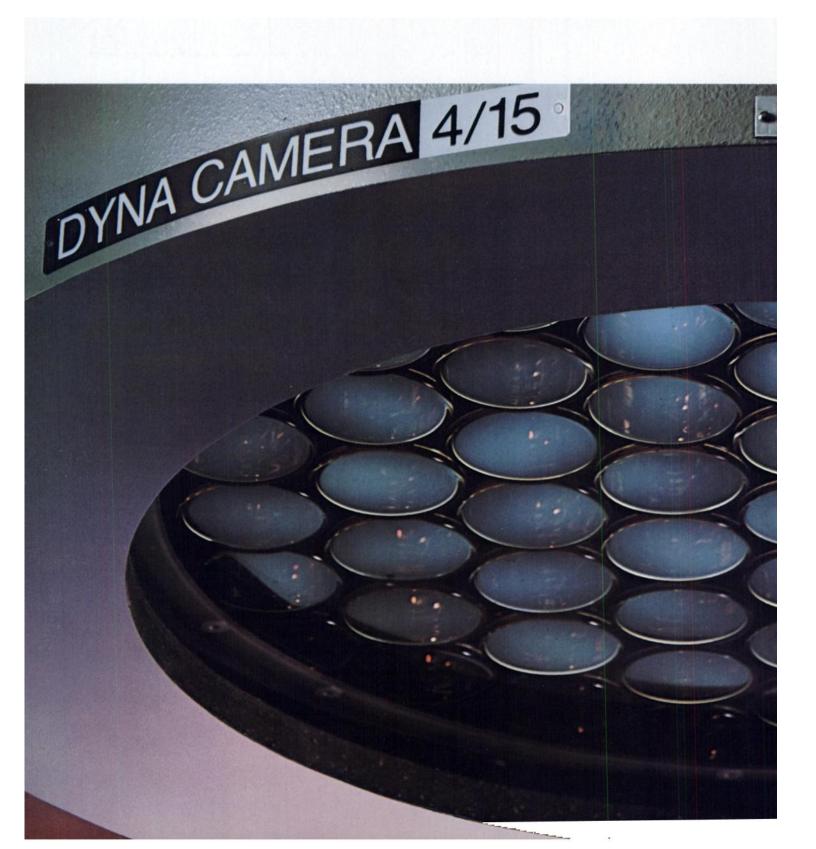
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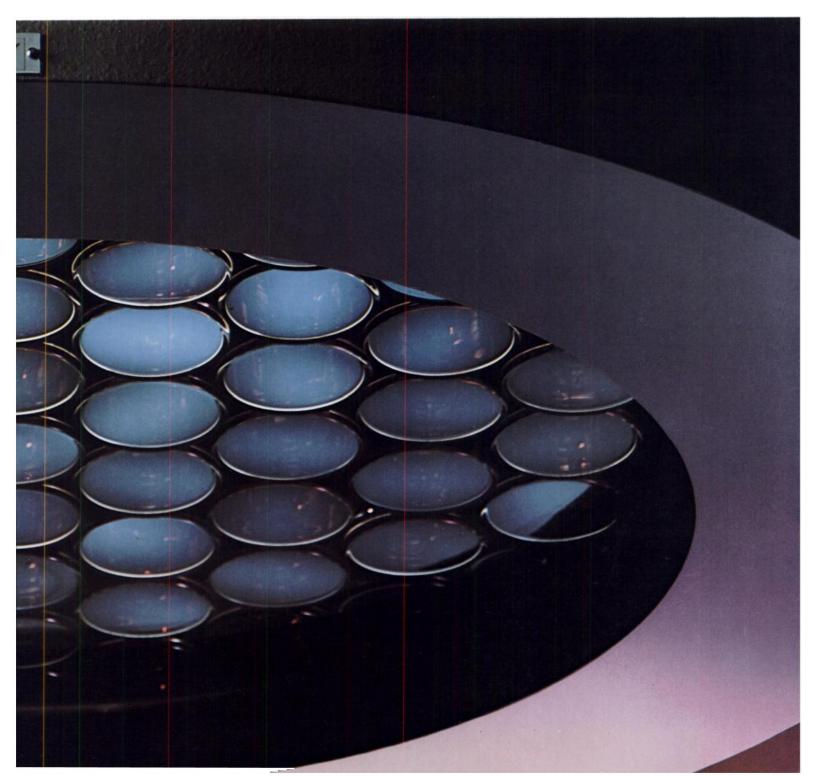
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*G. Subramanian, et al: Technetium-99m Methylene Diphosphonate — A superior agent for skeletal imaging. Comparison with other Technetium complexes. J. Nucl Med 16:744, 1975

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See Opposite Page For Summary Of Prescribing Information

DIAGNOSTIC ISOTOPES MDP KIT TECHNETIUM To 99m MEDRONATE KIT

DIAGNOSTIC

DESCRIPTION

Each kit contains 10 vials, with each vial containing medronic acid, stannous chloride, and ascorbic acid. The 10 ml vial contains 10 mg of medronic acid, 0.17 mg (minimum) stannous chloride (maximum stannous and stannic chloride 0.29 mg), and 2 mg ascorbic acid. The contents of the vial are sterile, pyrogen-free, and lyophilized and sealed under nitrogen. The pH has been adjusted to 4-8 with hydrochloric acid and/or sodium hydroxide.

Administration is by intravenous injection for diagnostic use, after reconstitution with sodium pertechnetate Tc 99m Injection. The product as supplied is sterile and pyrogen-free.

The precise structure of stannous technetium-medronate complex is unknown at this time.

RADIATION DOSIMETRY

The effective half-life was assumed to be the physical half-life for all calculated values. About 50% of each dose of Technetium Tc 99m Medronate is retained in skeleton, and about 50% is excreted into the bladder. The estimated absorbed dose to an average patient (70 kg) from an intravenous injection of a maximum dose of 20 millicuries of Technetium Tc 99m Medronate are shown in Table IV.

Table IV

Absorbed Radiation Dose

Organ		(rads/20 mCi)
Total Body		0.13
Bone Total		0.70
Red Marrow		0.56
Kidneys		0.80
Liver		0.06
Bladder Wall	2 hr void	2.60
	4.8 hr void	6.20
Ovaries	2 hr void	0.24
	4.8 hr void	0.34
Testes	2 hr void	0.16
	4.8 hr void	0.22

Method of calculation: A Schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, p. 7, 1968.

CLINICAL PHARMACOLOGY

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

Clearance of the complex from blood is rapid following intravenous administration. Up to 50% of the injected dose is usually cleared by urinary excretion within the first 3-6 hours. Bone uptake is usually 40-50% within 3 hours following intravenous administration.

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 fertility 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.

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 post-injection is optimal at about 1-4 hours. Slow administration of the drug over a period of 30 seconds is recommended.

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.

HOW SUPPLIED

Diagnostic Isotopes' Technetium Tc 99m Medronate Kit is supplied as a sterile, pyrogen-free kit containing 10 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.

diagnostic isotopes incorporated

225 belleville ave./bloomfield, n.j. 07003

to Nuclear Medicine MALLINCKRODT, INC., Post Office Box 5840, St. Louis, MO 63134

*In a recent independent survey of 400 nuclear medicine departments Data on file at Mallinckrodt.



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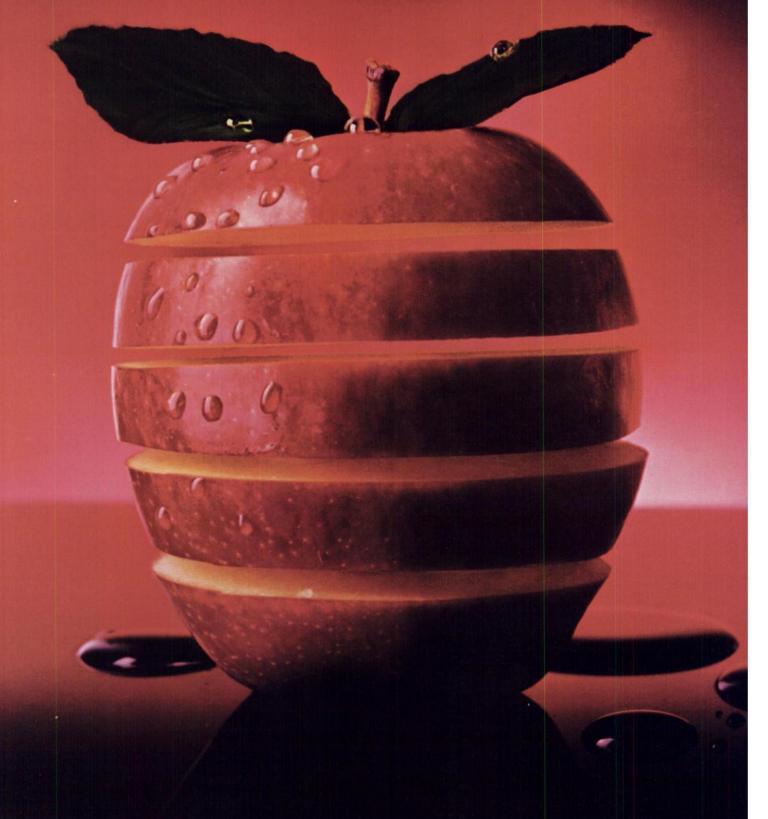
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Mallinckrodt's generator delivery system is ranked number MailinCkroat's generator derivery system is ranked number one* in the industry. Here's why: Our mid-continental location means we can make most deliveries by truck. So for 90% of our customers in 45 closes the number one delivery problem pairline delays

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GENERATOR **TECHNETIUM Tc 99m** GENERATOR FOR THE PRODUCTION OF SODIUM ECHNETATE Tc 99m PFRT

cription—The Union Carbide TECHNETIUM Tc 99m Gener description — The Union Carbide TECHNETIUM TC 99m Gener-ator provides a means of obtaining a sterile, pyrogen-free solu-tion of Sodium Pertechnetate Tc 99m in isotonic saline from el-ution of the generator containing Molybdenum Mo 99. Hydro-chloric 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 col-umn.

physical characteristics

Drysical characteristics Technetium Tc 99m decays by isomeric transition with a physi-cal half-life of 6.02 hours.' Photons that are useful for imaging studies and the principle radiations contributing to the inter-nal dose rate are listed in Table I. table I. principle radiation emission data

-								
radiati Gamma			mean %/0 84	lisintegra 3.96	tion		mean ener (keV) 140.5	gy
'Martin, N	I.J.,	ed.,	Nuclear	Decay	Data	for	Selected	Rad

Selected Radio nuclides, ORNL-5114, p. 24, March 1976. external radiation

external radiation The specific gamma ray constant for Technetium Tc 99m is 0.8 R/millicuris-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 radionuc-lide 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. 1,000. table li

pre II. radiation attenuation by	/ lead (Pb) shielding
chield thickness (Dh) mm	

shield thickness (Pb) mm	coefficient of attenuation
0.2	0.5
0.8	10-1
1.6	10-7
2.5	10-3
3.3	10-4
lybdenum Mo 99 decays to 1	echnetium Tc 99m with a M

Molybdenum Mo 99 decays to Technetium Tc 99m with a Moly-bdenum Mo 99 half-life of 2.75 days. The physical decay char-acteristics 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 in-terval 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 radionucide, the fractions that remain at selected intervals of time are shown in Table III. Table III. table III.physical decay chart

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

Calibration time.

*Calibration time. clinical pharmacology—Following intravenous administra-tion, the pertechnetate ion distributes in the body similarly to the iodide ion, but it is not organified when trapped in the thy-roid gland. Sodium Pertechnetate Tc 99m tends to accumuate in intracranial leeions with excessive neovascularity or an al-tered blood-brain barrier. It also concentrates in the thyroid gland, stomach and choroid piexus. After intravascular administration, it remains in the circula-tory system for sufficient time to permit blood pool, organ per-fusion, and major vessel studies. It gradually equilibrates with the extracellular space. A fraction is promptly excreted via 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.

contraindications — None known. warmings — 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, especial-ly those elective in nature, of a woman of childbearing capabil-ity 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 pro-per patient management. Adequate reproduction studies have not been performed in maines or females, has teratogenic potential, or has other ad-verse 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 Safety and effectiveness in children have not been estab-

Safety and enectiveness in children ter for a days from the date and time of calibration. At time of administration, the solution should be crystal

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

doesge 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 intravenous dose range employed in the average adult (70 kg) in millicuries of Sodium Pertech-netate Tc 90m 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
Pland Deal Corr	

Placenta Localization 1 to 3 millicuries Biodo 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 admini-stration of Sodium Pertechnetate Tc 99m injection for brain scan, placenta localization and blood pool scan for the pur-pose of blocking uptake of Sodium Pertechnetate Tc 99m by the choroid plexus. The patient does should be measured by a suitable radioac-tivity 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

radiation dosimetry

radiation dosimetry The estimated absorbed radiation doses' to an average patient (70kg) from an intravenous injection of a maximum dose of 20 millicuries of Sodium Pertechnetate Tc 99m distributed uni-formly in the total body of subjects not pretreated with block-ing agents such as NaCi0, KCi0, or iodide are shown in Table IV. For placental localization studies when a maximum dose of millicuries is used it is assumed to be uniformally equilibrat-ed between maternal and fetal tissues.

able IV. radiation	00585		
	absorbed ra (rads/20) Resting	(rads/3 millicuries)	
tissue	Population	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	
Placenta			0.05
Fetus			0.05

⁴Method of Calculation: A Schema for Absorbed Dose Calcula-tions for Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, J. *Nucl. Med.*, p. 7 (1968).
 ⁴Summary of Current Radiation Dose Estimates to Normal Humans From 99m Tc as Sodium Pertechnetate, MIRD Dose Estimate Report No. 8, J. Nucl. Med., 17:1, 1976.

cstimat	le rieport i	NO. 8, J.	NUCI.	Med.,	17:1,	1976
table V.	. Generato	r dosime	stry re	adings	s .	

Technetium Tc 99m Generator

	measurements a	at 6:00	AM	prior	to	elution	
-			•				

Generators up to 4140 mCi internal lead shield		Generators internal depl					
days from calibration		/hr 12	mCi 99Mo	days from calibration	mR. 2	/hr 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		63	12	6100
5	120	16	1250	5	49	9	4800
6	94	12	970	ő	38	ź	3200
7	73	10	750	ĩ	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	dosimetry	dosimetry
from probe	bare vial	shielded vial*
contact	472000mR/hr	4.mR/hr
30.5 cm	13000mR/hr	0.8mR/hr
nion Carbide	Elution Vial Shield Cat. No	17500500 Shie

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:

consists or: 1) sterile generator, 2) Sodium Chloride Injection source, 3) 10 cc sterile evacuated vials, 4) sterile needles, 5) elution vial shield* 6) finishd drug labels. Elution vials in 5 cc and 20 cc sizes are available upon request. *initial order only. preparetion

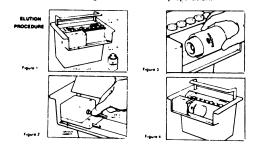
preparation

preparation The following instructions must be carefully followed for opti-mum preparation of Sodium Pertechnetate Tc 99m. Union Carbide Generators are sterile and pyrogen-free at the time of shipment. Asspitic 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

- First Educion 1. Remove generator system and accessories from carton.
 2. Lift hinged cover exposing dispenser end. Remove protec-tive cap from dispenser end and attach a sterile needle— REMOVE PLASTIC NEEDLE COVER (Figure 2). Return cover to closed position.
- Place an elution vial in the elution shield (Figure 1) and clean septum of elution vial with an antiseptic swab.
 Place an elution shield on dispensing platform (Figure 3).
 Rotate fluid path shut off valve several full turns counter-clockwise until loose. Valve is located on left side of generator.

- rator. 5. Silde elution shield to far left position (Figure 4). The dis-pensing needle will pierce the septum of the evacuated elu-tion 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 pres-ent in vial, discard vial and use a new elution vial. 7. When elution is complete, silde elution shield to far right position. Remove elution shield, containing vial with So-dium Pertechnetate Tc 99m eluate, from dispensing plat-form.
- torm. 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.





Store generator at room temperature (18-25 °C). Caution: Avoid Freezing.

subsequent elutions

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

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 = AV 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). vessel (millicuries), V = Total volume in the final mixture (ml).

- Total volume in the final mixture (m).
 Technetium Tc 99m assay procedure
 Determine the equivalent Technetium Tc 99m value for a Cobalt Co 57 standard by multiplying the number of millicur-ies of Cobalt Co 57 standard by the appropriate equivalent factor. This equivalent value of Cobalt Co 57 for the stand-ard need only be decayed daily for use as a secondary standard.
- Place the standard in the chamber and record μ amp reading.
 Transfer the Technetium Tc 99m sample from the shield to the chamber. Record the μ amp reading.

Calculate activity:	x millicuries
μ amps of Tc 99m Sample	Cobalt Co 57 std. = millicuries
μ amps of *'Co std.	Technetium Tc 99m

vecnnetium Tc 99m where millicuries Cobalt Co 57 std. = the equivalent milli-curie value for Cobalt Co 57 from 1. above, corrected for decay.

direct readout procedure-A direct readout dose calibrator is

- used.
 Determine the equivalent millicurie Technetium Tc 99m value for a Cobalt Co 57 std. using method 1. above. Correct millicurie value for decay.
 Place Cobalt Co 57 standard in chamber and adjust the calibrator to the proper reading according to the manufacturer's instructions.
 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 (milli-
- 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 eachild
- The most sensitive scale.
 Divide the microcuries Molybdenum Mo 99 by the millicuries Technetium Tc 99m. Correct for decay and shielding effect,

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

disposal

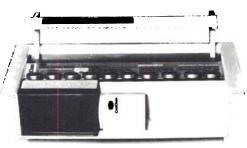
disposal The TECHNETIUM Tc 99m GENERATOR should not be dis-carded in ordinary trash within 70 days of the calibration date. Vials and needles used for eluting may be discarded after two (2) days. It is suggested that all identification labels be destroyed before discarding the generator or vials. TECHNETIUM 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. This generator is approved for use by persons licensed by the U.S. Nuclear Regulatory Commission pursuant to Sec. 5.14 and Sec. 35.100 Group III of 10 CFR Part 35 or under equivalent licenses of Agreement States.

New High Activity Union Carbide CintiChem® CALIBRATIONS IN Mo 99

Technetium 99m Generators

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

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The use of a single high activity CINTICHEM[®] Technetium 99m Generator can significantly reduce your operating expenses by replacing from two to five lower activity Technetium 99m Generators. 8,280 mCi to 16,600 mCi calibration sizes, in increments of approximately 830 mCi.

Tuesday and Thursday calibration days.

SAFETY

The depleted uranium internal shielding of the column possesses greater density and therefore superior shielding properties than the lead shielding used in lower activity generators.

The CINTICHEM® 8,280 mCi Technetium 99m Generator provides an approximate dosimetry of 9.7 mr/hr on the day of calibration, following elution, 18 inches from the surface, *without* a secondary external shield.¹

The weight of a 16,600 mCi Generator is 45.5 pounds. All high activity generators are shipped in the D.O.T. Transport Index II classification.

QUALITY

A special glass column design incorporated in the high activity CINTICHEM® Technetium 99m Generators provides for high yields with as low as a 5 cc elution volume. Furthermore, the specially designed column reduces the potential AI + + + and Mo 99 content in the eluate.

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High activity CINTICHEM® Technetium 99m Generators can reduce the time required to perform quality control because in each single elution levels of activity are provided that would require eluting several lower activity Generators, and quality controlling each eluate.

CONVENIENCE

High activity CINTICHEM® Technetium 99m Generators can dramatically reduce shielded shelf space requirements.

High activity CINTICHEM® Technetium 99m Generators can eliminate long term decay storage.

¹Data on file at Union Carbide Corporation, Tuxedo, New York, and with the State of New York, Division of Safety and Health.

For tull prescribing information, refer to preceeding page.



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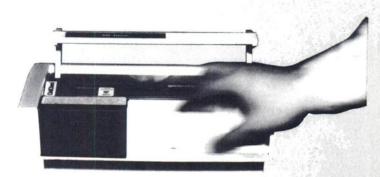


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Cintic Charles of the second s

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

ARE DESIGNED TO MAXIMIZE RADIATION PROTECTION AND FOR EASY ELUTION



Rapid Elution Vial-Needle Engagement Reduces the Radiation Exposure Time Factor • Only UNION CARBIDE CINTICHEM® Technetium 99m Generators are made at one domestic production site that possesses its own Nuclear Reactor for the production of Fission Product Mo 99, manufactures and purifies by a patented process high specific activity Mo99, loads it onto columns, assembles the Generators, performs quality control, and ships them directly to the user. This provides you with a reliable product supply and a uniformly high-quality product.

• The UNION CARBIDE Fission Product Mo 99 used in CINTICHEM® Technetium 99m Generators provides Sodium Pertechnetate Tc 99m activity concentrations sufficient for bolus injections.

 CINTICHEM® Technetium 99m Generators come in 32 activity and day of calibration combinations, which can satisfy a wide range of activity needs.

• A new sterile needle is utilized for each **elu**tion, reducing the chances of a septic or pyrogenic situation occurring in routine clinical usage. This method offers an advantage compared to competitive dry column systems where the same needle assembly is used for the life of the product.

Rigid Quality Control testing, which includes an elution check on each Generator, assures that your UNION CARBIDE CINTI-CHEM® Technetium 99m Generator meets our high internal specifications. Our experience obtained in over 19 years of involvement in Nuclear Medicine assures you of high quality products

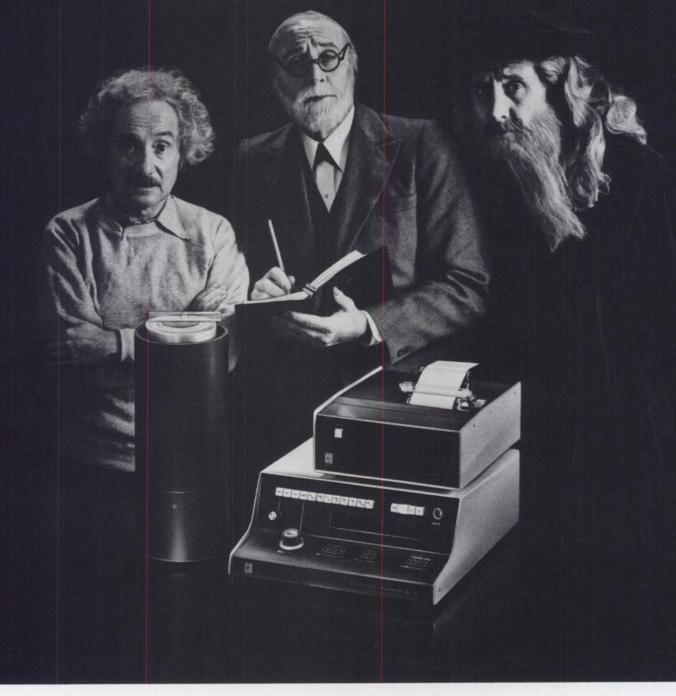
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Minitec[®] (Technetium Tc 99m) Generator

Small in size and light in weight, but big in performance. That's Minitec. Designed for minimum amount of exposure to operator, its unique construction (no exposed tubing) and thick shielding (1%" lead) provide high shielding-to-activity ratio. Small-volume, high-concentration eluates give maximum flexibility for varying applications. Wide range of potencies and calibration dates fit the 99m Tc needs of every lab.

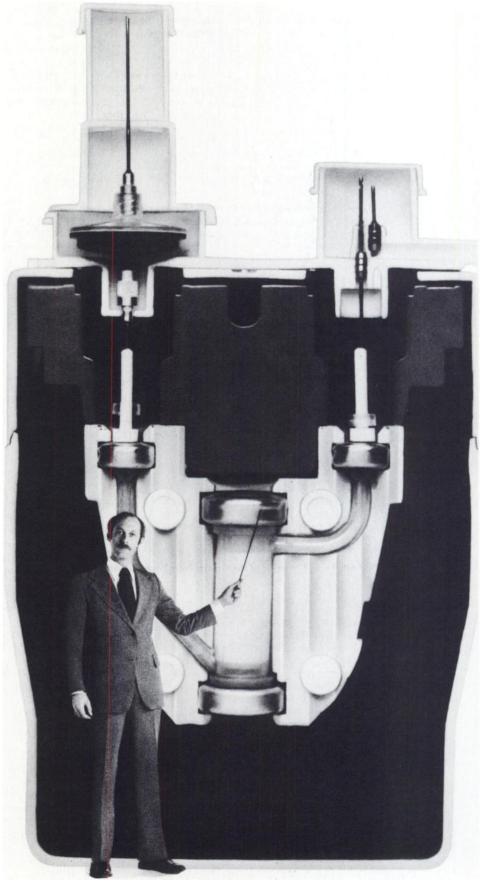
Squibb Technical **Associates**

When you buy Minitec and Squibb radiopharmaceuticals, you get the back-up service of a Squibb Technical Associate. He's had extensive training in nuclear medicine, radiopharmaceuticals, RIA and instrumentation, Call him when a new tech needs instruction, a problem develops, you're planning to expand, or there's need for special information. You'll get the prompt, personal attention of an experienced specialist.

See next page for brief summary.

Medotopes[®]





MINITEC® Technetium Tc 99m GENERATOR

DESCRIPTION: Minitec (Technetium Tc 99m) Generator consists of a specially designed lead-shielded alumina column containing adsorbed fission-produced Mo 99. Tc 99m, the short-lived daughter of Mo 99, is obtained as sterile sodium pertechnetate Tc 99m by periodic elutions of the generator with an isotonic saline solution.

INDICATIONS AND USAGE: Sodium pertechnetate Tc 99m is indicated in ADULTS as an agent for brain imaging including cerebral radionuclide angiography, thyroid imaging, salivary gland imaging, placenta localization, and blood pool imaging including radionuclide angiography. (For use of sodium pertechnetate Tc 99m as a diagnostic radiopharmaceutical in CHILDREN, consult package insert.)

CONTRAINDICATIONS: None known.

WARNINGS: Radiopharmaceuticals should not be administered to patients who are pregnant or to nursing mothers unless the expected benefit to be gained outweighs the potential hazards.

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

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

Radiation risks associated with the use of sodium pertechnetate Tc 99m are greater in children than in adults and, in general, the younger the child the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

IMPORTANT: Since material obtained from the generator may be intended for intravenous administration, aseptic technique must be strictly observed in all handling. Only the eluent provided should be used to elute the generator. Do not administer material eluted from the generator if there is any evidence of foreign matter.

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

ADVERSE REACTIONS: No adverse reactions specifically attributable to the use of sodium pertechnetate Tc 99m have been reported.

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HOW SUPPLIED: Minitec (Technetium Tc 99m) Generator is available in potencies of 220, 440, 880, 1330, 1770, or 2220 millicuries Mo 99 at calibration time. The generator is supplied with vials of sterile, nonpyrogenic eluent; a sterile needle adapter assembly and evacuated sterile collecting vials. Other accessories including lead shields, reference standard solutions, and a whole vial assay kit are available on request for use with the Minitec (Technetium Tc 99m) Generator.

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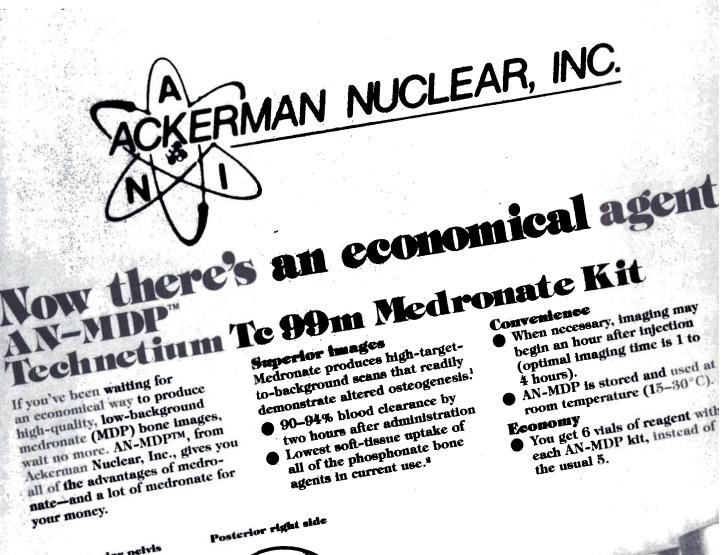
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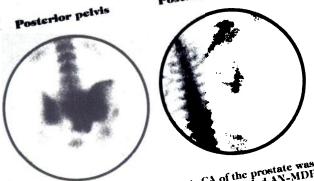
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AN-MDPTM Technetium Tc 99m Medronate Kit

Indications and usage. Technistion: Is them Medicinate mail be used as a bloce imaging agent to delineate areas of latered osteogenesis.

Contraindications. Notes and write

Warnings, The class of complexings cars writes in plexlatence autralist acoust. Fastic part, autor, storal be used with patents when taken whe may be predisposed to hypologic ethics on makabous.

Precautions. Contents of the vacance intended only fat use

In the preparation of Technetium Tc 99m Medronate and are V 11h be administered directly to the patient. Technetium Tc 99m Medronate us well as other radioactive drugs must be fandled with care and appropriate safety measures should be used to minimize radiation exposure to patients consistent with proper patient munagement.

To minimize rapation dose to the bladder patients should be encloraged to drive flads and to cost mmediately before the examination and as often thereafter as possible for the end 4 -6 ruys.

Technetium To 99m Medionate should be formulated within set 6 Fours prior to clinical use. Optimal imaging results are obtained 1-4 hours after administration.

 archivgenesis imutagenesis impairment of tentility. No long term animal studies have been performed to evaluate. Farcinogenic potential or whether Technietium To 99m Medronate affects fertility in males or females

Pregnancy category C. Animal reproductive studies have not been conducted with Technetium Tr. 99m Medronate. It is also not known whether Technetium Tr. 99m Medronate can cause tetal-transmission admissible do a pregnant woman or can atte it reproduction capacity. Technetium Tr. 99m should be given to a pregnant woman only if clearly needed. Ideally eariminations using radiupnamiaceuticals: especial, those elective it instant of a woman of childbearing capability should be performed auring the first tew capproximately 10) days following the onset of menses.

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1. Davis MA, and Jones AG: Sem Nucl Med 6:19, 1976 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.

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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 iv. 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.

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How supplied. AN-MDPTM 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 vi contains, in lyophilized form:

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Description	Catalog Number
Single dose 6-vial kit	K-401-S
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Multidose 30-vial ECONO-PAK	K-402

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NUCLEAR MEDICINE RESIDENCY. 830-bed VA general hospital offers AMA approved two year program. Two positions available July 1981. Located in San Fernando Valley area of Los Angeles, 15 minutes from affiliated hospitals (UCLA and Wadsworth VA). Program covers isotope and ultrasound imaging, in vivo and in vitro procedures, including RIA, and all recent computer and cardiology procedures. Prerequisite: Two years post graduate training in medicine, radiology, or pathology. Minimum stipend: \$23,438. Contact: Marvin B. Cohen, M.D., Chief, Nuclear Medicine Service. Nondiscrimination in employment. VA Medical Center, 16111 Plummer Street, Sepulveda, CA 91343.

RADIOLOGIST, BOARD CERTIFIED IN nuclear medicine, to join large multi-specialty prepaid medical group. Opportunity to expand department and plan department for new hospital in 1984. Salary negotiable. Liberal fringe benefits. Contact: Hawaii Permanente Medical Group, Inc. 1697 Ala Moana Boulevard, Honolulu, Hawaii 96815. (An Equal Opportunity Employer).

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NUCLEAR CARDIOLOGY COORDINAtor will assist in the establishment of a new Nuclear Cardiology section. Requires satisfactory completion of a recognized School of Nuclear Medicine Technology and previous working experience in Nuclear Medicine. Experience in Nuclear Cardiology utilizing Computer Analysis desirable. Qualified applicants send resume to: Personnel Office, St. Francis Hospital, P.O. Box 1358, Wichita, KS 67201. Equal Opportunity Employer.

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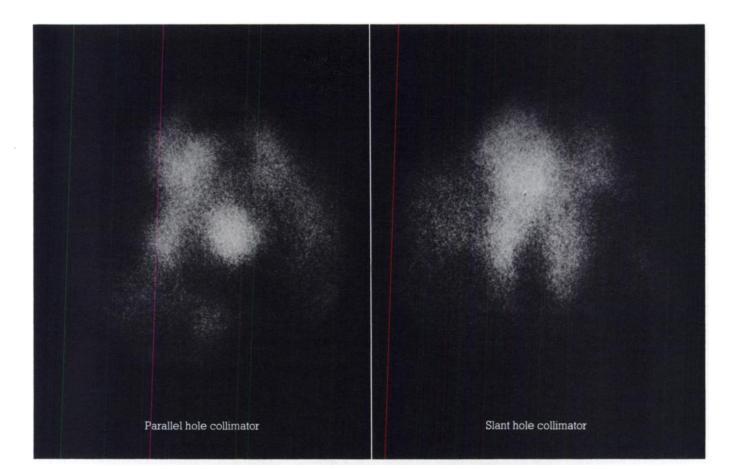
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During radionuclide ventriculography of the cardiac blood pool in the modified left anterior oblique (MLAO) view, EDC's slant hole collimator permits placement of the detector flat against the patient's chest because of the holes' 30° caudal angulation. The improved outcome, demonstrated by the above ungated cardiac images of a patient with aortic stenosis and left ventricular hypertrophy, includes:

- Complete resolution and separation of left ventricle and atrium.
- Viewing of ventricular septum normal to its longitudinal axis, with no foreshortening.
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A study by Dr. J. Anthony Parker,* Harvard Medical School, found that radionuclide ventriculography with the EDC 30° slant hole collimator provides "an accurate measure of



ejection fraction at equilibrium and a qualitative assessment of regional changes in ventricular volume."

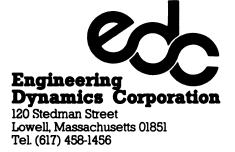
Refined resolution of the cardiac apex is obtained in the RAO view.

Other applications of the slant hole collimator include imaging of the spleen and posterior cranial fossa.

The EDC slant hole can be mounted on any commercial Anger scintillation camera. Rotatability of the slant hole inserts facilitates correct positioning. Computed tomography is made possible via indexing of the collimator with detents at up to 24 angles.

Öther collimators available from EDC: Seven Pinhole, Bifocal Diverging, Div/Con, Parallel Hole.

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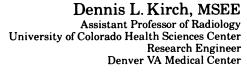


*PARKER, J.A. et al: Radionuclide left ventriculography with the slant hole collimator. J Nucl Med 18:848-851, 1977.

Tomographic thallium imaging



Robert A. Vogel, MD Associate Professor of Medicine University of Colorado Health Sciences Center Director, Coronary Care Unit and Medical Intensive Care Unit Denver VA Medical Center





The initiative for tomographic thallium imaging arises from the segmental nature of coronary artery disease—which typically affects one portion of the myocardium more severely than others. An ischemic area of the heart that takes up less thallium may overlap or underlie another, normally perfused region. Planar imaging may resolve small deficits juxtaposed to normally perfused myocardium only with difficulty. Tomographic imaging may enable spatial separation of high- and lowuptake regions at different depths, thereby providing a better image of regional ischemia.

Thallium myocardial tomography provides advantages in addition to a series of depth-separated Z-axis images of relative isotope uptake. It ensures that the entire study is acquired as early as possible after injection, before any significant redistribution takes place, because only a single left oblique view is required to provide the data on regional thallium uptake provided in planar imaging by multiple views. And possibly of greatest importance, the technique permits objective computerized quantification of regional isotope uptake and redistribution—circumferential profile analysis—simplifying detection and interpretation of regional differences in thallium redistribution.

These three attributes together—Z-axis resolution, single-view image acquisition, and objective regional quantification—have increased the sensitivity and specificity of thallium myocardial perfusion imaging in our department to 90% or better. Optimum utilization of this imaging/imageprocessing technique requires a thorough technical appreciation of several features of the tomographic collimator and software.

The seven-pinhole collimator

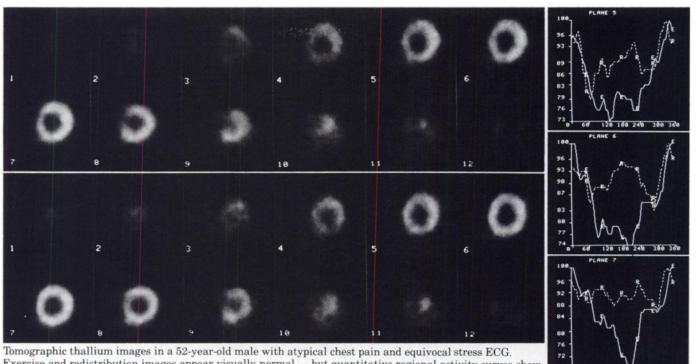
The seven-pinhole collimator is not a completely revolutionary or untried concept; rather it represents the combination of two well-accepted concepts in order to better image the thallium-perfused myocardium: single-pinhole collimation and rotating slant-hole collimation. A single-pinhole collimator can produce superior magnified myocardial images with only a minimal contribution from noncardiac background, but its low sensitivity lengthens acquisition time so much that significant redistribution may occur before a view is complete. The rotating slant-hole collimator was pioneered early in the development of the Anger camera as a technique to produce tomographic images. But it is a cumbersome device that is difficult to utilize rapidly and repeatedly, and uses a simple backprojection tomographic reconstruction technique unsatisfactory for myocardial imaging.

The seven-pinhole collimator represents a combination of these two techniques. By projecting seven pinhole images on the crystal, several advantages are gained:

• Instead of projecting a single image onto perhaps 10% of the camera crystal, and imaging background counts with the remaining 90%, the seven-pinhole collimator can project seven 1:1 myocardial images with very little noncardiac background contribution. This full utilization of the crystal for organ imaging makes the seven-pinhole collimator comparable in sensitivity to a highsensitivity standard collimator... capable of collecting up to 750,000 myocardial counts within 10 minutes.

• Instead of developing angular perspective by taking several sequential planar views, or by rotating a slant-hole collimator, the seven-pinhole collimator uses the seven pinholes to simultaneously view the heart from slightly different angular perspectives, from which computer processing can provide tomographic reconstruction.

To these collimator-derived benefits, one must add two benefits from the quantitative analysis of seven-pinhole imaging: *enhanced subjective confidence* in the presence or absence of perfusion deficits on the displayed images and *objective quantification* of relative thallium distribution and redistribution kinetics in each of the important tomographic planes through the myocardium.



Exercise and redistribution images appear visually normal — but quantitative regional activity curves show significantly abnormal anteroseptal uptake on exercise.

The impedance-estimation algorithm

Traditionally, tomographic nuclear images have been reconstructed by *back projection*, as in the original rotating slant-hole system, and in the Searle PhoCon. More complete, faster processing with iterative capability for error correction results from the use of the impedance-estimation technique of the seven-pinhole program.

The basic principle of this program is that a *voxel*, a volume element in space, has been viewed from seven points projected through pinholes onto the crystal. The program applies an *impedance-estimation algorithm* to the summing of the seven perspectives of each voxel, so that the lowest number of counts detected from any one perspective will dominate the greater counts detected from the other six—much as a single low-resistance resistor will conduct more current than numerous high-resistance elements in a parallel electrical circuit.

We believe this impedance-estimation program provides an initial estimate of real voxel value that is closer to actual isotope distribution than is possible with simple back projection. With a single 1- to 2-minute iterative pass to refine this estimate, the algorithm provides an accurate derivation of isotope distribution in a specific tomographic plane. Thus, the clinician can be confident that any perfusion defect which can be resolved by the camera/ collimator is certain to be detected and displayed on the resultant "hard" image...without substantial degradation by overlying or surrounding normally perfused tissue, or by redistribution during image acquisition.

120 180 240

Circumferential quantification

Circumferential profile analysis of thallium-201 tomographic images may significantly increase the accuracy of evaluating regional thallium uptake and comparing uptake/redistribution kinetics. This quantification technique defines the center of the left ventricle, divides the myocardium into a predetermined number of segments, then quantitatively plots the relative thallium uptake in each segment against its angular location on the left ventricular wall. The procedure, as performed at the Denver VA Medical Center, permits objective comparison of stress/redistribution uptake curves—even in regions where ischemia cannot confidently be diagnosed solely by visual examination of the images.

In summary, the tomographic process reduces patient imaging time and, in our experience, has enabled improved visualization of segmental abnormalities in thallium-201 distribution, and has offered a means of data presentation well suited to quantitative interpretation and correlation.

Please see following page for brief summary of prescribing information.

Thallous Chloride **TI 201**

November 1977

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 ad-junct 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. Exer-cise 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 – especiall those elective in nature – of women of childbearing capability should be per-formed during the first ten days following the onset of menses.

PRECAUTIONS: Data are not available concerning the effect of marked altera-tions 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

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 im-proved myocardial-to-background ratios when patients are injected in the fast-ing 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 pa-tient reaches maximum stress and when the stress is continued for 30 seconds to an emistion for 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 in-vestigators 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 ap-propriate government agencies authorized to license the use of radionuclides.

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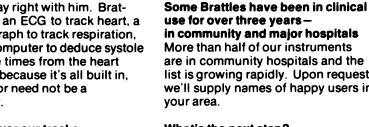
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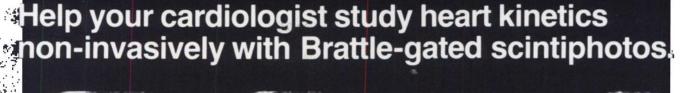
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