medi+physics

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 emmission 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 Profi

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) 652-7650, Outside California (800) 227-0492 or Inside California at (800) 772-2477.



MPI KRYPTON Kr 81m GAS GENERATOR KRYPTON Kr 81m

DESCRIPTION: The Krypton Kr 81m Gas Generator consists of Rubidium Bb 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 rubidium 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:

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 capacity. Krypton Kr 81m gas should be given to a pregnant woman only if clearly needed.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Krypton 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.

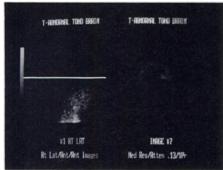
Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

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-

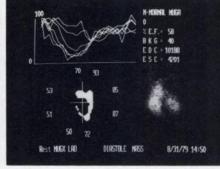
HOW SUPPLIED: The Krypton 81m Gas Generator is supplied in the form of Rubidium Rb 81, bound to a solid support, with an activity of 2-10 millicuries at calibration time. The generator is enclosed in a lead shielded filter assembly surrounded by a capped plastic canister to which a handle is affixed.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

*Your state may require you to amend your license.

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These results from Gated Blood Pool studies.



These results from Renal studies.

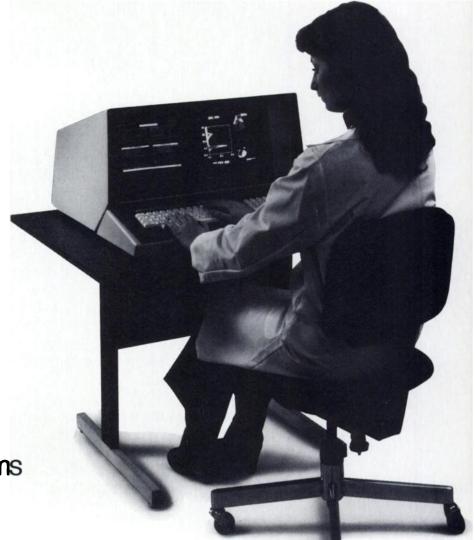
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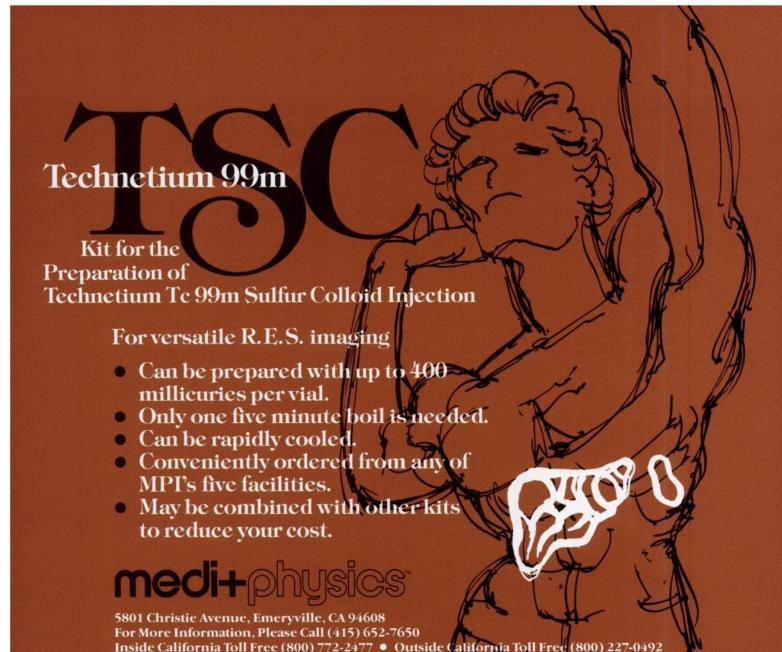
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TECHNETIUM 99m TSC KIT FOR THE PREPARATION OF TECHNETIUM To 99m SULFUR COLLOID INJECTION

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

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.

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.

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 mI 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 non-uniform distribution of radioactivity.

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

The preparation contains no bacteriostatic preservative

Injection.

HOW SUPPLIED: The TECHNETIUM 99m SULFUR COLLOID KIT sterile pyrogan-free kit consisting of: five reaction was, each or 1.0 N hydrochloric acid in water; five sterile syriogos (laboled "A"). 1.9 mg sodium thiosulfate anhydrous in 1.1 m/ aqueous solution ringes (labelett "B"), each containing 5.3 mg gelatin in 2.1 ml aque tion containing 177 mg sodium acetate anhydrous.

STORAGE: Store finished drug at room temperature.

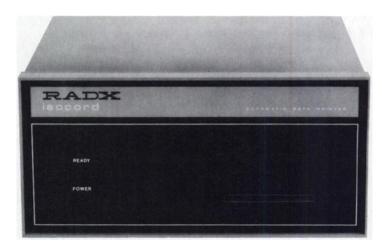
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The RADX Isocord produces a hard copy print out in triplicate for all record keeping needs; by patient name, and selected isotope. Addition of the Isocord will complete your dosecalibrator system for all necessary information including NRC or state record keeping requirements. RADX is the first to offer anything like it at any-

where near its price.

Both the Isotron and the Isocord are compatible with your existing dosecalibrator.

Complete patient and institution identification – plus time and date

Pharmaceutical Identification Total vial activity prior to removal of dose – constantly updated for decay and previous withdrawals

Concentration/mL

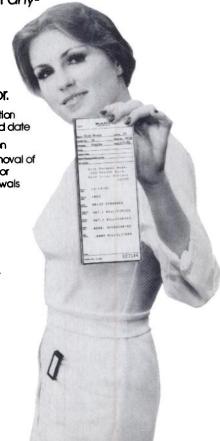
Patient dose

Volume to administer — automatically calculated

Information provided in either, Curries or Becquerels.



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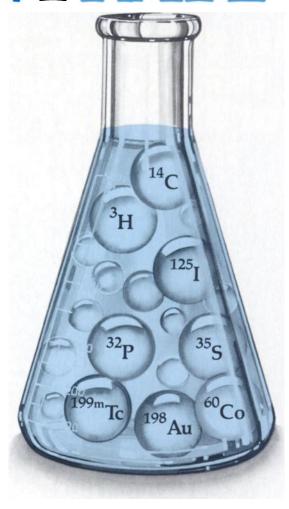
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Volume 23, Number 7 9A

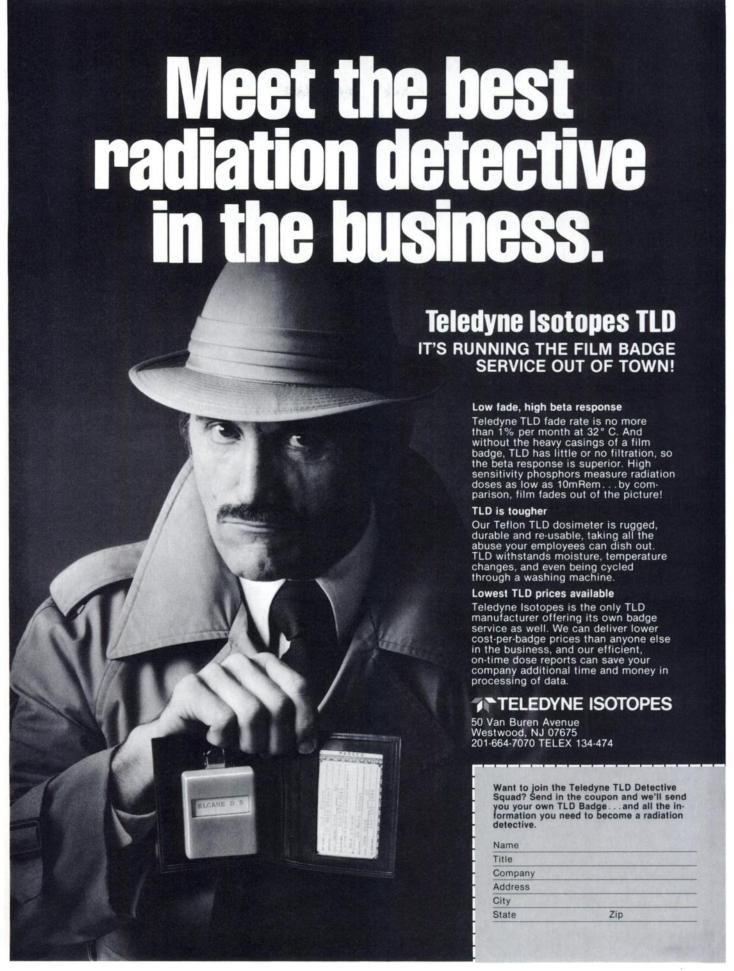
The difference between ordinary dynamic studies and those made with TOSHIBA's Gammacamera GCA-40A is the difference between guessing and diagnosing with complete assurance. This new model's high count-rate (200 kcp's), excellent resolution, and large field of view (with a window width of 40%) provide the finest quality nuclear image available today.

The GCA-40A also has three special functions which make a positive difference in operation. The Dual Peak function means that the measurement times of multi-peak nuclides are shortened, and confirmed uniformity at each peak promotes the production of high quality images. The Marking function allows any region of interest to be marked on the film and its dimensions may be

measured with the scale mark. And the Zooming function allows magnified display of limited regions such as the heart, small sections of internal organs, or the viscera of children.

Simplicity in use also makes a difference, so TOSHIBA's made the GCA-40A easy to position. Changing the lightweight collimators is also easy and quick, and adjusting photomultipliers is no problem at all.





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Now with the newly developed Calicheck™ dose calibrator activity linearity test kit, you can meet N.R.C. Regulatory Guide 10.8, appendix D., Section 2E or your state's equivalent requirement in just 4 minutes - not days. You can complete the test in one short sitting and check for linearity virtually at a glance. Plus you eliminate the frustration of having to start the test all over simply because you forgot to take a reading on time.

Accurate and Reliable

The new Calicheck kit is designed to attenuate 99MTc by known values — accurate using a high yield generator eluant or a unit dose.

A Calicheck kit provides for seven successive measurements simulating the decay of 99mTc at approximately 0, 6, 12, 20, 30, 40 and 50 hours from the initial assay.

Complete Yet Reusable

Your Calicheck kit comes to you complete with its own storage container, a unique arrangement of seven color-coded leadwrapped tubes, work/record keeping sheets, instructions for use and a license amendment form (if needed.)

Your Calicheck kit is completely reusable for an indefinite period of time. There is nothing to wear out or use up. If damage should cause a tube to malfunction, individual replacements are

Safe

Your use of a Calicheck kit eliminates the need to fractionate eluants or decay the elution for several days while periodically collecting data to determine linearity. Time of potential exposure to radiation is drastically reduced, thereby maintaining exposures ALARA

Lowers Department Cost

When you test with a Calicheck kit, both the source activity and dose calibrator can be returned to active service in just minutes. This savings alone can pay for a Calicheck kit in just three to four linearity tests. A Calicheck kit lets you return to active service too!

Can Improve Patient Care

A Calicheck kit is so fast, efficient and easy to use, you may wish to check dose calibrator linearity more frequently. Lets you spot trouble before it becomes

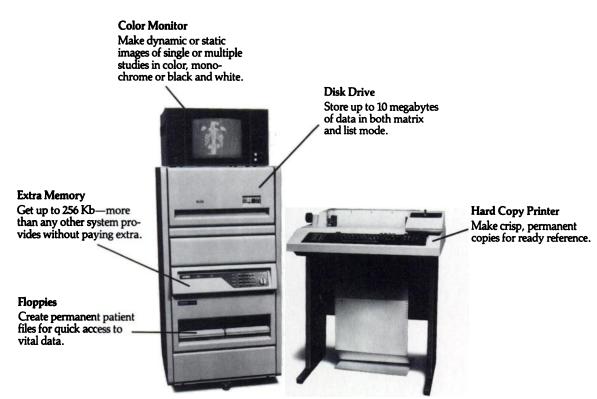
Low Price

A Calicheck dose calibrator activity linearity test kit is just \$375.00 shipping included.

Just call (216) 663-1773 or write: Calcorp, Inc., P.O. Box 25589, Cleveland, Ohio 44125-0589.

Patent pending





Digital's new Gamma-11 delivers five essential features you can get from our competitors.

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The champagne is cooling and waiting for you at our stand N₀ T-30 at the 3rd Congress of the World Federation of Nuclear Medicine and Biology in Paris August 29 - September 2, 1982.

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WHEREAS, it is in the best interest of all radiation workers to keep their radiation exposure as low as reasonably achievable;

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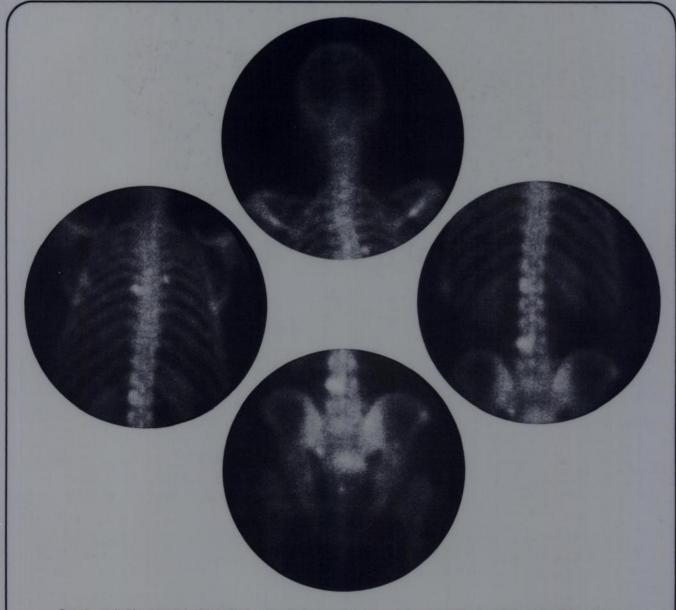
For a presentation of our case, please call your local representative.



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WE REST OUR CASE

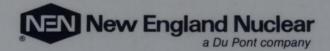
Leadership images...



Posterior study, 2 hours postinjection, in 65-year-old male shows multiple areas of abnormal uptake. From Cedars-Sinai Medical Center.

OSTEOLITE Technetium Tc 99m Medronate Sodium Kit (MDP)

from the leader in nuclear medicine



Technetium Tc 99m Medronate Sodium Kit (MDP)

INDICATIONS AND USAGE: Technetium Tc 99m Medronate may be used as a bone imaging agent to delificate 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 may be predisposed to. hypocalcemia (i.e., alkalosis).

PRECAUTIONS: Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Medronate and are NOT to be administered directly to the patient. Technetium Tc 99m Medronate as well as any 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 patients should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as nossible for the next 4-6 hours.

as possible for the next 4-6 hours.

Technetium Tc 99m Medronate should be formulated within six (6) hours prior to clinical use

Carcinogenesis, Mutagenesis, Impairment of Fertility. No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Medronate affects fertility in males or females.

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 Mathers, Technetium Tc 99m is excreted in human milk during lactation.

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

Pediatric Use. Safety and effectiveness in children below the age of 18 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: Although adverse reactions have not been reported that are specifically attributable to the use of Technetium Tc 99m Medronate, allergic dermatological manifestations (erythema) have been infrequently reported with other

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 (70kg) is:

Bone imaging: 10-20mCi Technetium Tc 99m Medronate
Scanning post-injection is optimal at about 1-4 hours

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

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

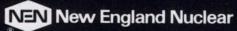
Medronate Disodium-10mg Total Stannous and Stannic Chloride-1mg Stannous Chloride (SnCl₂·2H₂O) (minimum)-0.5mg

Prior to lyophilization, the pH is adjusted to between 7.0-7.5 with hydrochloric acid and/or sodium hydroxide solution. The contents of the vial are lyophilized and stored under nitrogen. Store at room temperature (15°-30°C) before and after reconstitution. 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 components of the Technetium Tc 99m Medronate Kit are supplied sterile and

non-pyrogenic. Aseptic procedures normally employed in making additions and with-drawals from sterile, non-pyrogenic containers should be used during addition of pertechnetate solution and the withdrawal of doses for patient administration. Technetium Tc 99m Medronate is prepared by adding 2-8ml of oxidant-free sodium pertechnetate Tc 99m solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Technetium Tc 99m Medronate.

Catalog Number NRP-420 (5-Vial Kit) Catalog Number NRP-420C (30-Vial Kit)

December 1981



601 Treble Cove Rd., North Billerica, MA 01862

Call Toll-Free: 800-225-1572/Telex: 94-0996 (In Mass. and International: 617-482-9595)

Canada: NEN Canada, 2453 46th Avenue, Lachine, Que. H8T 3C9 Tel: 514-636-4971 Europe: NEN Chemicals GmbH, D-6072 Dreieich, W. Germany, Postfach 401240 Tel: (06103) 85034 Order Entry: (06103) 81011

In myocardial imaging with technetium Tc 99m pyrophosphate

Once is not enough...



Scintigram is only faintly positive shortly after suspected MI.



3 days/Ant. Intensified activity clearly indicates anterolateral and apical MI.



7 days/Ant. Markedly decreased activity, probably due to constantly changing pathophysiology of infarcted tissue

"...SERIAL MYOCARDIAL
IMAGES MUST BE OBTAINED in order to derive maximal information from the test."1

After performing technetium Tc 99m pyrophosphate myocardial

After performing technetium Tc 99m pyrophosphate myocardial scintigraphy on more than 3,000 patients, a group of clinicians has reported that "Our rewarding experience utilizing this particular imaging technique has been almost certainly the result of our utilization of serial myocardial imaging..."

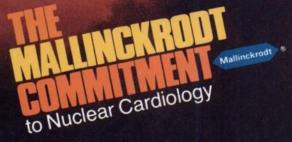
The accuracy of serial myocardial imaging as an adjunct in the diagnosis of acute myocardial infarction is well-established. In another recent study, researchers "... have found less than 4% false negative scintigrams when imaging is performed during optimal timing postinfarction and serial 99mTc-PYP myocardial imaging is performed. Other groups have reported 5%-10% false negative results, but this is often without the benefit of serial myocardial imaging."

For a reprint of the papers cited here plus more information about TechneScan PYP, just call your Mallinckrodt sales representative or call 800-325-8181 toll free. (In Missouri, 314-895-2405 collect)

For brief summary see opposite page

TechneScan* PYP*

Technetium Tc 99m Pyrophosphate Kit



TechneScan* PYP*

Technetium Tc 99m Pyrophosphate Kit

BRIFF SUMMARY

CLINICAL PHARMACOLOGY

When injected intravenously TechneScan PYP Te 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 Te 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 by 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 75 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 Pyrophosphate Injection. **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 woid 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 for the preparation of Technetium Tc 99m Pyrophosphate Injection.

Reaction Vial Contains in lyophilized form:

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

5—Radioassay Information String Tags.

FOOTNOTES:

- 1 Willerson JT, Parkey RW, Buja LM, Bonte FJ: Are 99mTc-stannous pyrophosphate myocardial scintigrams clinically useful? Clin Nucl Med 2:161, 1977.
 2 Parkey RW, Bonte FJ, Buja LM, Stokely EM.
- 2 Parkey RW, Bonte FJ, Buja LM, Stokely EM, Willerson JT: Myocardial infarct imaging with Technetium-99m phosphates. Sem Nucl Med 7:1.1977.

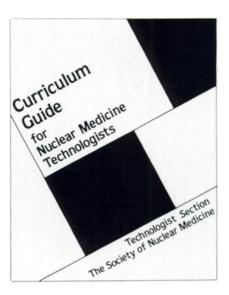
Heart chamber illustration inspired by photos by Lennart Nilsson.



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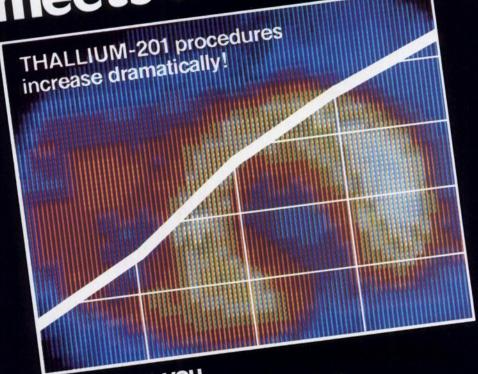
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THALLOUS CHLORIDE TI 201 INJECTION

Diagnostic-For Intravenous Use

Brief Summary—for full prescribing information consult package insert.

DESCRIPTION

Thailous Chloride TI 201 Injection is supplied in isotonic solution as a sterile, nonpyrogenic diagnostic radiopharmaceutical for intravenous administration. Each ml contains 1 mCi Thailous Chloride TI 201 at calibration time made isotonic with 9 mg sodium chloride and preserved with 0.9% (v/y bezzył acho). The pH is adjusted to between 4.5-7.0 with hydrochloric acid and/or sodium hydroxide. Thailium TI 201 is cyclotron produced. It is essentially carrier-free and contains no more than 1.0% Thailium TI 200 and no more than 1.0% Thailium TI 1202.

CLINICAL PHARMACOLOGY

Carrier-free **Thallous Chierde TI 201** has been found to accumulate in viable myocardium in a manner analogous to potassium. Experiments employing labeled microspheres in human volunteers have shown that the myocardial distribution of **Thallous Chierde TI 201** correlates well with regional perfusion.

In clinical studies, thallium images show areas of infarction as "cold" or nonlabeled regions which are confirmed by electrocardiographic and enzyme changes. Regions of transient myocardial ischemia corresponding to areas perfused by coronary arteries with partial stenoses have been visualized as cold spots when thallium was administered in conjunction with an exercise stress test.

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

Five minutes after intravenous administration only 5-8 percent of injected activity remained in the blood. A biexponential disappearance curve was obtained, with 91.5 percent of the blood radioactivity disappearing with a $T\frac{1}{2}$ of about 5 minutes. The remainder had a $T\frac{1}{2}$ of about 40 hours.

Approximately 4 to 8 percent of the injected dose was excreted in the urine in the first 24 hours. The whole body disappearance half-time was 9.8 ± 2.5 days. Kidney concentration was found to be about 3 percent of the injected activity and the testicular content was 0.15 percent. Net thyroid activity was determined to be only 0.2 percent of the injected dose, and the activity disappeared in 24 hours. From anterior and posterior whole-body scans, it was determined that about 45 percent of the injected dose was in the large intestines and contiguous structure (liver, kidneys, abdominal musculature).

Atkins, H. L., et al. Thallium-201 for Medical Use, Part 3. Human Distribution and Physical Imaging Properties, Journal of Nuclear Medicine, 18(2):133-140, Feb. 1977.

INDICATIONS AND USAGE

Thallous Chloride TI 201 may be useful in myocardial perfusion imaging and 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).

It is usually not possible to differentiate recent from old myocardial infarction, or to differentiate exactly between recent myocardial infarction and ischemia.

CONTRAINDICATIONS

None known.

WARNINGS

When studying patients suspected or known to have myocardial infarction or ischemia, 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.

PREGNANCY CATEGORY C

Adequate reproduction studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus **Thallous Chloride TI 201** should not be used in pregnant women except when benefits clearly outweigh the potential risks

PRECAUTIONS

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 α

NURSING MOTHERS

It is not known whether this drug is excreted in human milk. Because many drugs are 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.

CARCINOGENESIS

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

Data are not available concerning the effect on the quality of Thallium Ti 201 scans of marked alterations in blood glucose, insulin or pH (such as is found in diabetes mellitus). 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 thallium may likewise be affected.

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

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 povernmental agency authorized to license the use of radionuclides.

This drug should not be used six (6) days after the calibration date.

ADVERSE REACTIONS

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

HOW SUPPLIED

Thallows Chloride TI 201 Injection is supplied in a sterile, nonpyrogenic solution for intravenous administration. Each ml contains 1 mCi Thallium TI 201 at calibration time, 9 mg sodium chloride and 0.9 percent (v/v) benzyl alcohol. The pH is adjusted to between 4.5-7.0 with hydrochloric acid and/or sodium hydroxide solution. Vials are available in the following quantities of radioactivity: 2.0, and 4.0 millicuries of Thallium TI 201.

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



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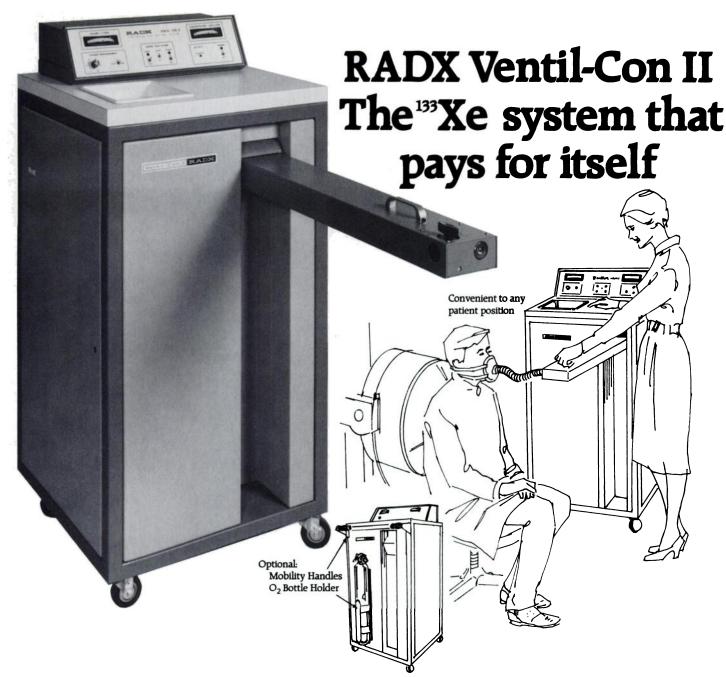
Ronald R. Price, Ph.D., David L. Gilday, M.D., and Barbara Y. Croft, Ph.D.

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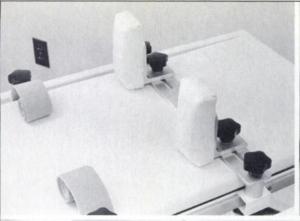
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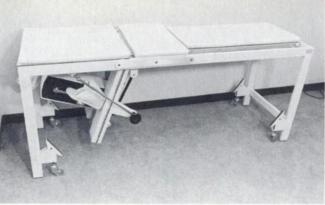
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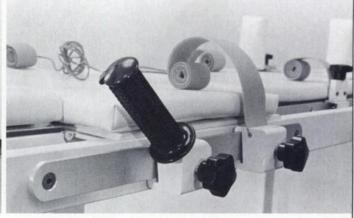
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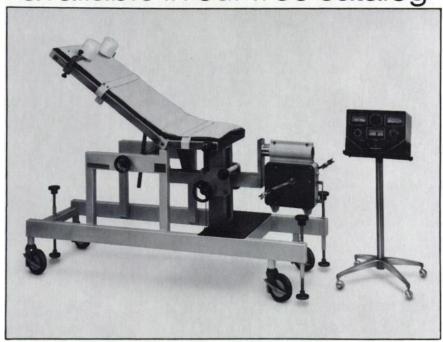
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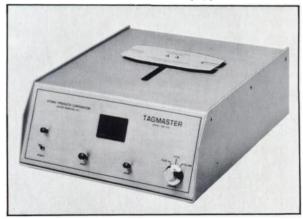
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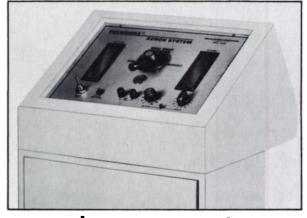
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- sodium pertechnetate Tc 99m

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Kit contains 10 multidose reaction vials.

For further information, call Technical Customer Service, 609-921-4100.

See next page for brief summary.







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TECHNEPLEX® Technetium Tc 99m Pentetate Kit DIAGNOSTIC—FOR INTRAVENOUS USE

DESCRIPTION: The kit consists of 10 multidose reaction vials, each containing a sterile, pyrogen-free lyophilized mixture of 10 mg pentetate calcium trisodium, 0.50 mg stannous chloride under a nitrogen atmosphere. When sterile, pyrogen-free sodium pertechnetate Tc 99m in isotonic saline is added to the vial, a chelated technetium Tc 99m pentetate is formed. The product as supplied is sterile and pyrogen-free.

INDICATIONS AND USAGE: Technetium Tc 99m pentetate may be used to perform kidney imaging, brain imaging, to assess renal perfusion, and to estimate glomerular filtration rate.

CONTRAINDICATIONS: None known.

WARNINGS: None known.

PRECAUTIONS: Contents of the vial are intended only for use in the preparation of technetium Tc 99m pentetate and are **not** to be administered directly to the patient except after the addition of sodium pertechnetate Tc 99m. 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. Technetium Tc 99m pentetate as well as other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patients consistent with proper patient management and to insure minimum radiation exposure to occupational workers.

To minimize radiation dose to the bladder, the patients should be encouraged to drink fluids and to void immediately before the examination, and for the next 4 to 6 hours thereafter, as often as possible.

Technetium Tc 99m pentetate should be formulated within 6 hours prior to clinical use for brain and kidney imaging, and for assessing renal perfusion. For estimating glomerular filtration rates Tc 99m pentetate should be used within 1 hour after formulation.

The components of the Technetium Tc 99m Pentetate Kit (Chelate) 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.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term animal studies have been performed to evaluate carcinogenic potential or whether technetium Tc 99m pentetate affects fertility in males or females.

Pregnancy Category C: Animal reproductive studies have not been conducted with technetium Tc 99m pentetate. It is also not known whether technetium Tc 99m pentetate can cause fetal harm or affect reproduction capacity when administered to a pregnant woman. Technetium Tc 99m pentetate 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 (approx. 10) days following the onset of menses.

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

Pediatric Use: Safety and effectiveness in children below the age of 18 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 specifically attributable to the use of technetium Tc 99m pentetate have been reported.

Drug Abuse and Dependence: There is no report of any drug abuse or dependence with this diagnostic agent.

Overdosage: Increased radiation exposure would be expected if an overdosage of the diagnostic agent occurred.

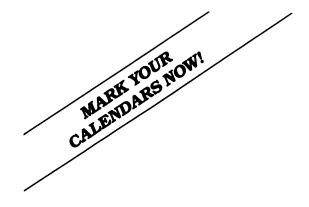
For complete prescribing information, consult package insert.

HOW SUPPLIED: Techneplex (Technetium Tc 99m Pentetate Kit) is supplied as a sterile, pyrogen-free kit containing 10 sterile multidose reaction vials and 20 pressure-sensitive labels.



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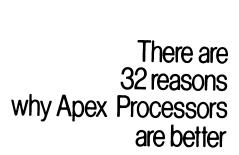
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Volume 23, Number 7 29A



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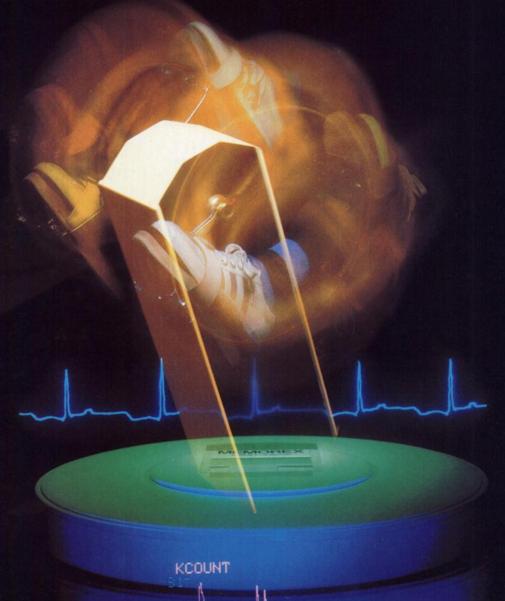
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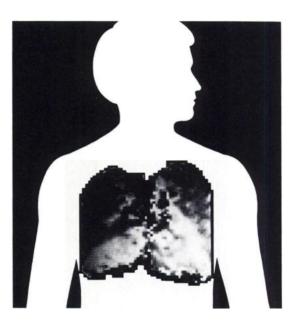
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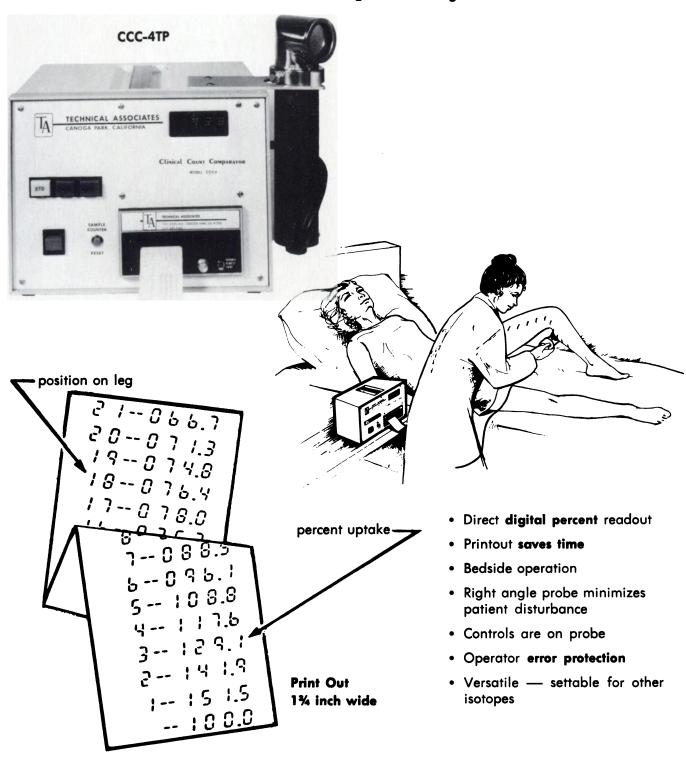


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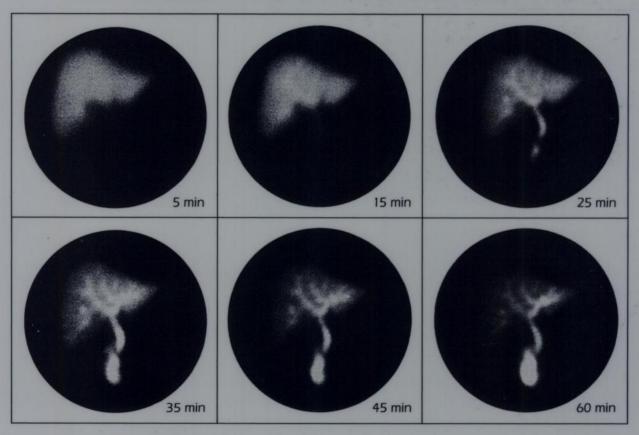


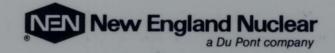


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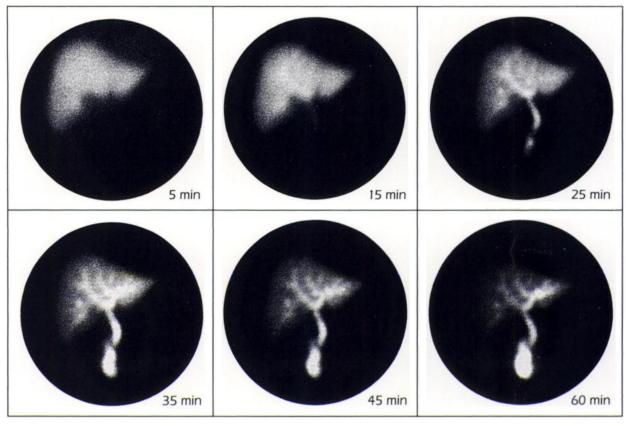




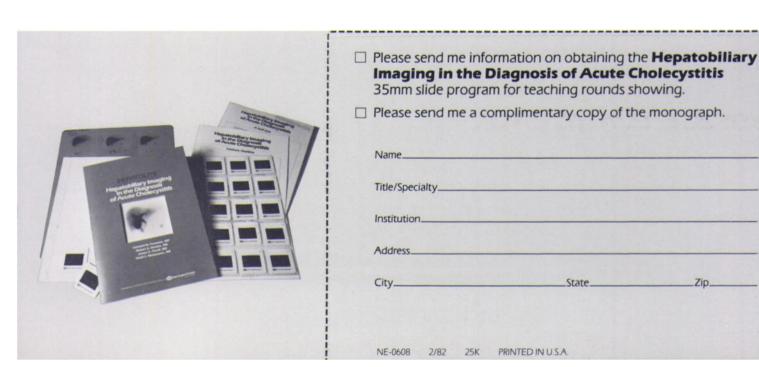
Please see last page for brief summary of prescribing information.

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"Visually and computationally, DISIDA [Hepatolite] was superior [to other IDA agents] in terms of relative uptake in the liver and liver washout." Hernandez and Rosenthall²

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"During the first hour after injection (the critical time for imaging), diisopropyl-IDA [Hepatolite] had the highest rate of biliary excretion (76.2%), which should result in the best visualization of the biliary system...' Wistow et al3

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"We were able to clearly identify the intrahepatic ducts in 46 of the 54 patients imaged with PRIDA [Hepatolite] whereas we were not able to identify them clearly in any of the 21 patients imaged with BIDA. Read et al

The only agent you need to stock

"Tc-99m DISIDA [Hepatolite] appears to incorporate the best properties of all the currently available IDA analogs...it is the only IDA derivative that a "hot lab" would need to stock." Weissmann et al⁵

References

- 1. Weissmann HS, Badia JD, Hall T, abstracted: J Nucl Med 21:18, 1980.
- Hernandez M, Rosenthall L: <u>Clin Nucl Med</u> 5:159, 1980.
 Wistow BW, Subramanian G, Gagne GM, et al: <u>Radiology</u> 128:793, 1978.
- 4. Read ME, Teates CD, Croft BY, et al: In press.
- 5. Weissmann HS, Sugarman LA, Freeman LM, in Freeman LM, Weissmann HS (eds): Nuclear Medicine Annual 1981. New York, Raven Press, 1981, pp 35-89.



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Program Faculty Leonard M. Freeman, MD Robert E. Henkin, MD James H. Thrall, MD Heidi S. Weissmann, MD

HEPATOLITE Tachasti in Ta Olon Disafania Kit

INDICATIONS AND USAGE: Technetium Tc 99m Disofenin is indicated as a hepatobiliary imaging agent.

CONTRAINDICATIONS: None known.

WARNINGS: The theoretical possibility of allergic reactions should be considered in

patients who receive multiple doses

PRECAUTIONS: Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Disofenin and are NOT to be administered directly to the patient

Technetium Tc 99m Disofenin 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.

Technetium Tc 99m Disofenin should be formulated within six (6) hours prior to clinical use Carcinogenesis, Mutagenesis, Impairment of Fertility

No long term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Disofenin affects fertility in males or females

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m Disofenin It is also not known whether Technetium Tc 99m Disofenin 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 feeding.

Pediatric Use

Safety and effectiveness in children below the age of 18 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 Disofenin 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 (70kg) is:

Non-Jaundiced patient: 1-5m Patients with serum bilirubin level greater than 5mg/dl: 3-8m

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. (If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to clot formation in situ.) Do not backflush the syringe, slow injection is recommended. Radiochemical purity should be checked prior to patient administration.

The patient should be in a fasting state, 4 hours is preferable. False positives (non-visualization) may result if the gall bladder has been emptied by ingestion of food

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit

HOW SUPPLIED: NEN's HEPATOLITE * Technetium Tc 99m Disofenin Kit is supplied in kits of five (5) and thirty (30) vials, sterile and pyrogen-free, each vial containing in lyophilized form:

Disofenin 20mg
Stannous Chloride (SnCl₂ · 2H₂0) (Minimum) 0 24 mg
Total Tin. Maximum (as stannous chloride. SnCl₂ · 2H₂0) 0 6 mg

The pH is adjusted to between 5.5-6.5 with hydrochloric acid and/or sodium hydroxide solution prior to lyophilization. The contents of the vial were lyophilized under nitrogen. Store at room temperature (15°-30°C) before and after reconstitution. Protect from light. The lyophilized drug product is light sensitive. Technetium Tc 99m Disofenin contains no preservatives. 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 components of the Technetium Tc 99m Disofenin Kit are supplied sterile and nonpyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during addition of pertechnetate solution and the withdrawal of doses for patient administration.

Technetium Tc 99m Disofenin is prepared by adding no more than 100 millicuries of additivefree sterile, non-pyrogenic sodium pertechnetate Tc 99m solution in 2-5ml (≥20mCi/ml) to the vial and swirling for about one minute. Shielding should be utilized when preparing the Technetium Tc 99m Disofenin

Catalog Number NRP-475 (5 vial kit)
Catalog Number NRP-475C (30 vial kit)

February 1982

NEN New England Nuclear

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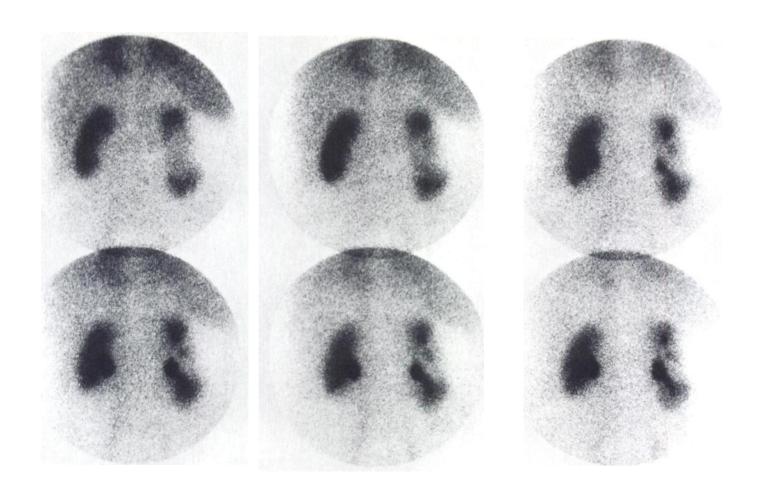


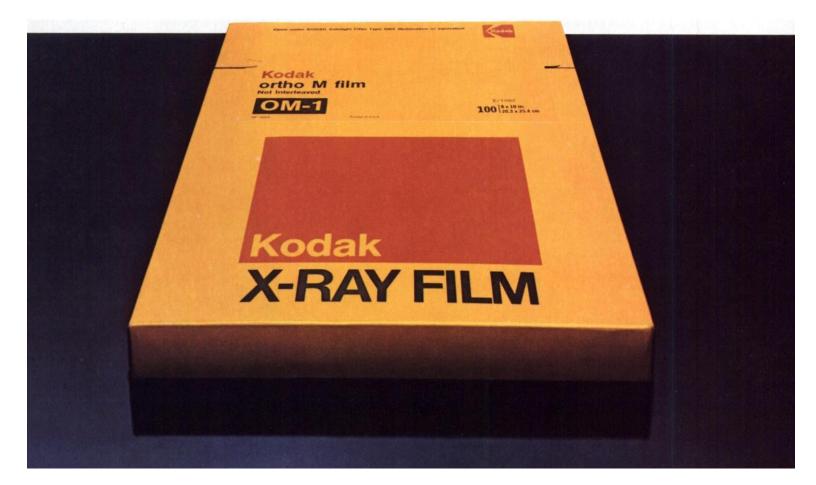
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Volume 23, Number 7 39A





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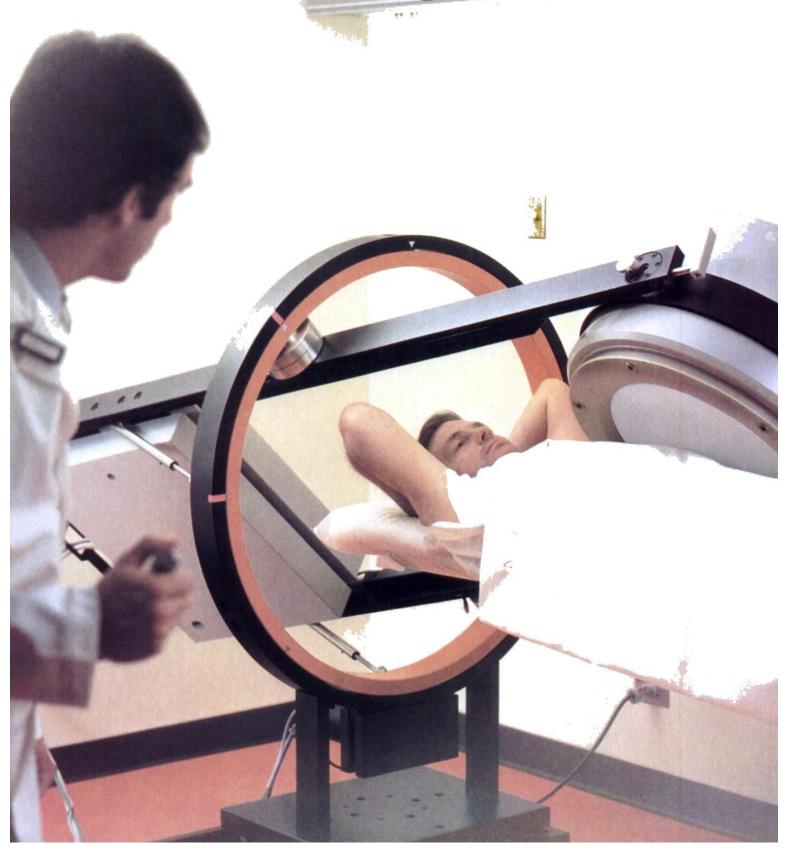
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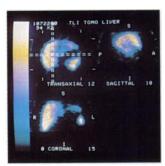
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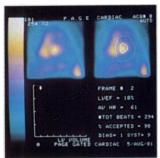
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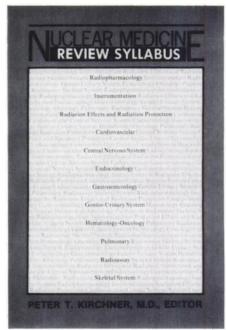
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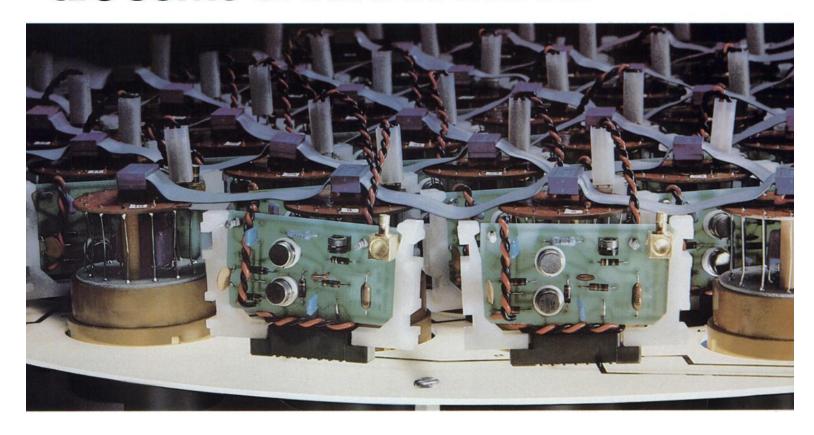
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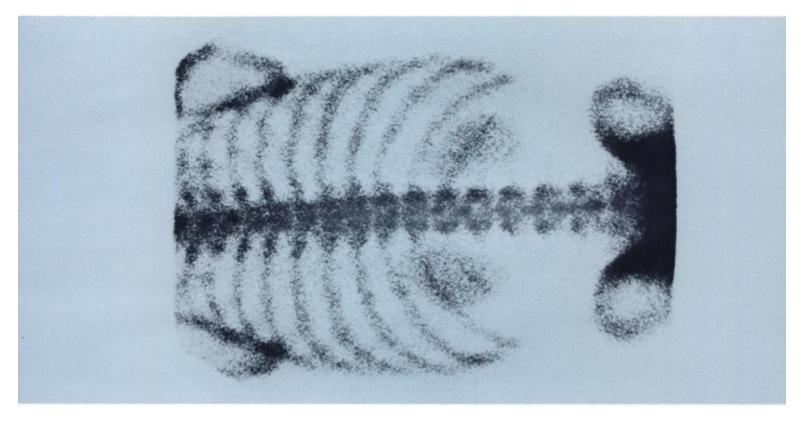
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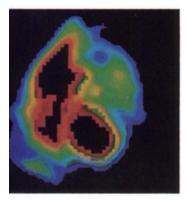
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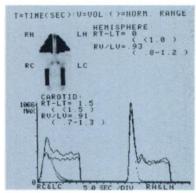


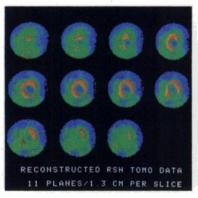
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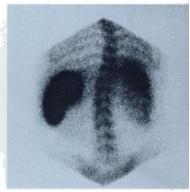
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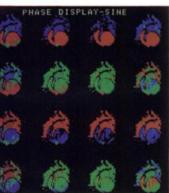
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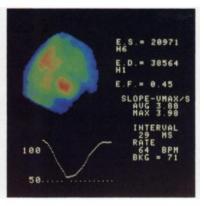


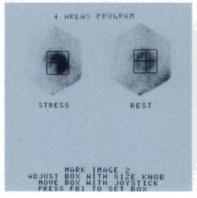


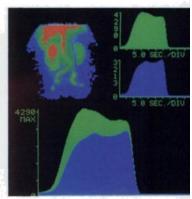












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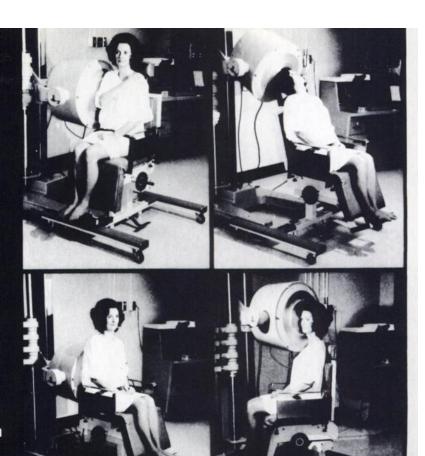
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Volume 23, Number 7 55A

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INDICATIONS AND USAGE
OSTEOSCAN-HDP (Technetium Tc99m Oxidronate Kit) is a diagnostic skeletal imaging agent used to demonstrate areas of altered osteogenesis.

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During the 24 hours following injection, Technetium Tc99m-labeled
OSTEOSCAN-HDP is rapidly cleared from blood and other non-osseous tissues and accumulates in the skeleton and urine. In humans, blood levels are about 10% of the injected dose at one hour post-injection and continue to fall to about 6%, 4% and 3% at 2, 3 and 4 hours respectively. When measured at 24 hours following its administration, skeletal retention is approximately 50% of the injected dose. OSTEOSCAN-HDP exhibits its greatest affinity for areas of altered osteogenesis and actively metabolizing bone.

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 General

Contents of the vial are intended only for use in the preparation of Technetium Tc99m Oxidronate and are NOT to be administered directly to the patient. Technetium Tc99m Oxidronate should be formulated within eight (8) hours prior to clinical use. Optimal imaging results are obtained one to four hours after administration.

Technetium Tc99m Oxidronate as well as other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patients consistent with proper patient management. Radiopharmaceuticals should be used only by physicians who are qualified by specific training 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.

To minimize radiation dose to the bladder, the patients should be encouraged to drink fluids and to void immediately before the examination and as often thereafter as possible for the next four to six hours.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate carcinogenic
potential or whether Technetium Tc99m Oxidronate affects fertility in males and

Pregnancy — Category C Animal reproduction studies have not been conducted with Technetium Tc99m Oxidronate. It is also not known whether Technetium Tc99m Oxidronate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc99m Oxidronate 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 Tc99m is excreted in human milk during lactation, therefore formula feedings should be substituted for breast feedings

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
Although adverse reactions have not been reported that are specifically attributable to the use of Technetium Tc99m Oxidronate, allergic dermatological manifestations (erythema) have been infrequently reported with similar agents.

DOSAGE AND ADMINISTRATION General Instructions

The recommended adult dose of Technetium Tc99m-labeled OSTEOSCAN-HDP is 15 mCi with a range of 10 to 20 mCi. The activity of each dose should be measured by a suitable radiation calibration system just prior to administration. The dose should be given intravenously by slow injection. For optimal results imaging should be done 1-4 hours post-injection.

HOW SUPPLIED

OSTEOSCAN-HDP is supplied as a lyophilized powder packaged in vials. Each vial contains 2.0 mg oxidronate sodium and 0.16 mg stannous chloride as active ingredients, and 0.56 mg gentisic acid as a stabilizer. Kits containing 5 or 30 vials are available. The NDC number for this product is NDC 37000-403-01. The drug can be stored at room temperature both prior to and following reconstitution with ADDITIVE-FREE sodium pertechnetate Tc99m.



July, 1982

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Volume 23, Number 7 57A

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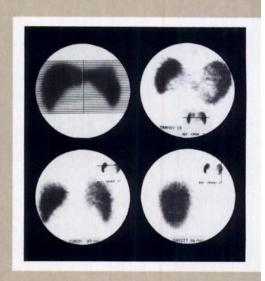
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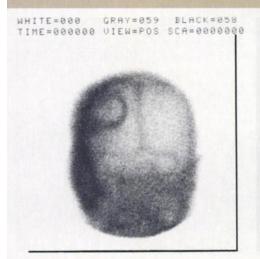


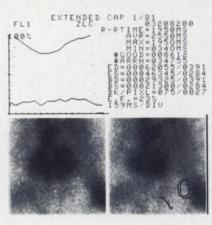
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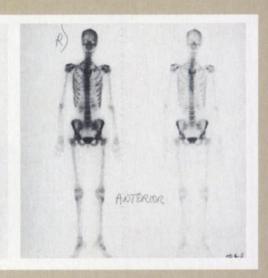
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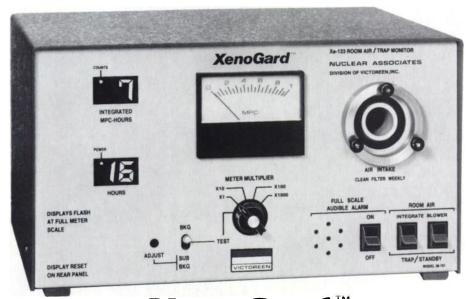
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The Society of Nuclear Medicine

Volume 23, Number 7 67A

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- SI-3 Dynamic Brain Imaging
 P. Hoffer, A. Gottschalk, J.L. Quinn III,
 and R. Henkin
 SI-4 Dynamic Benal Studies
- SI-4 Dynamic Renal Studies Robert Polcyn
- SI-5 Lung Imaging Naomi Alazraki
- SI-6 Thydoid Scanning Samuel Halpern
- SI-8 Skeletal Imaging (Revised in 1980)
 Robert O'Mara
- SI-9 Thyroid Uptake Testing David Charkes
- SI-10 Radionuclide Cisternography in Adult Hydrocephalus

 John Harbert
- SI-11 Technetium-99m Thomas S. Gnau
- SI-12 Evaluation of Imaging Performance Martin L. Nusynowitz
- SI-13 Radioactive "Decay" Processes Related to Nuclear Medicine R. Eugene Johnston
- SI-14 Radiopharmaceuticals for Tumor and Adrenal Scanning
 Samuel Halpern
- SI-15 Scintillation Cameras
 Bryan Westerman
- *SI-16 Scintillation Spectrometers and Pulse Height Analysis (1980) Robert Zimmerman and William Kaplan

- SI-17 Radionuclide Liver Imaging (Available August 1982) James D. Ball and Robert J. Cowan
- **SI-18 Basic Concepts in Cardiac Anatomy and Physiology (1979) Glen W. Hamilton
 - SI-19 The Measurement of Ejection Fraction (1979) William Ashburn
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 - SI-22 Detection of Acute Myocardial Infarction (1979) B. Leonard Holman
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 - SI-25 Radiopharmaceuticals for Liver, Spleen, Bone Marrow, and Pancreas Imaging (NEW!) Henry M. Chilton
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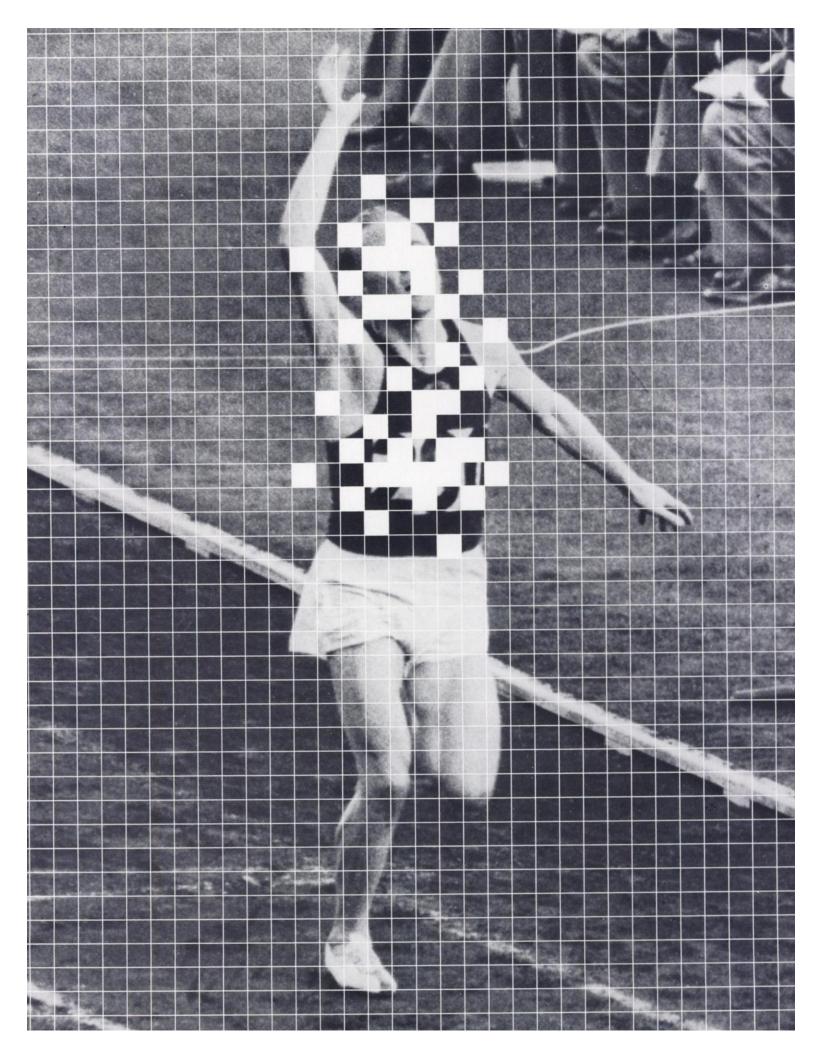
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Radiochemical purity:

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Radiochemical

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Specific Concentration:

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Volume per vial:

1.5ml

Radiochemical purity:

not less than 90%

pH:

1.0 - 3.0

Radionuclidic Purity and Identity at Calibration:

In-111:

not less than 99.0%

In-114:

not more than 0.1% (1µCi/mCi In 111)

Zn-65:

not more than 0.1% (1µCi/mCi In 111)

Total chloride as sodium chloride: 0.7-0.9%

5801 Christie Avenue, Emeryville, CA 94608 For More Information, Please Call (415) 652-7650 Inside California Toll Free (800) 772-2477 • Outside California Toll Free (800) 227-0492.

*Now available from MPI to investigators used under the following conditions: A. In vitro testing; B. Laboratory animals; C. Radioactive Research Committee 21 CFR 361.1; D. IND holders; MPI is not sponsoring any clinical investigation for this product.