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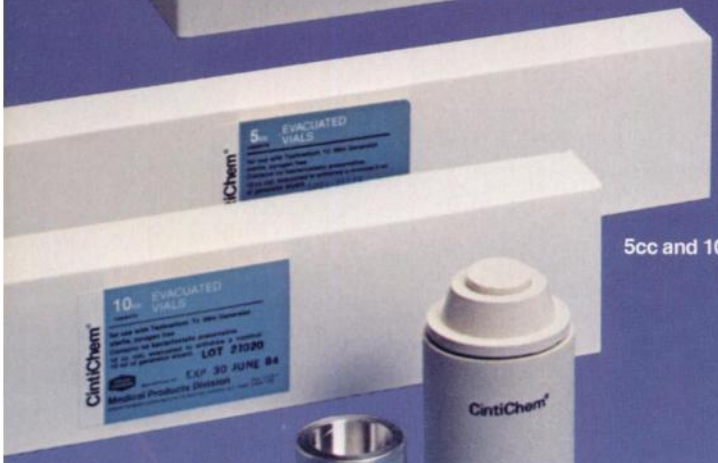
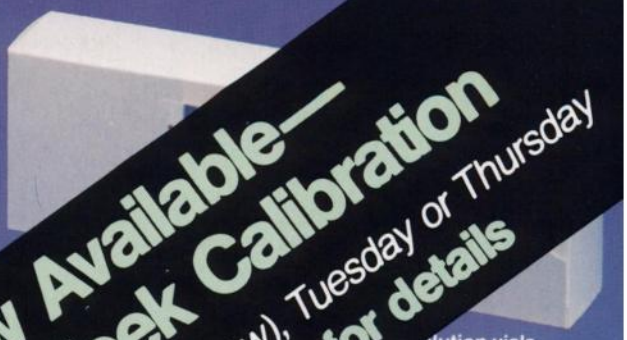
Technetium Tc 99m Generator

Secondary shield to further reduce radiation



5cc and 10cc elution vials



Elution vial

elution vials
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Adaptors for various elution vi

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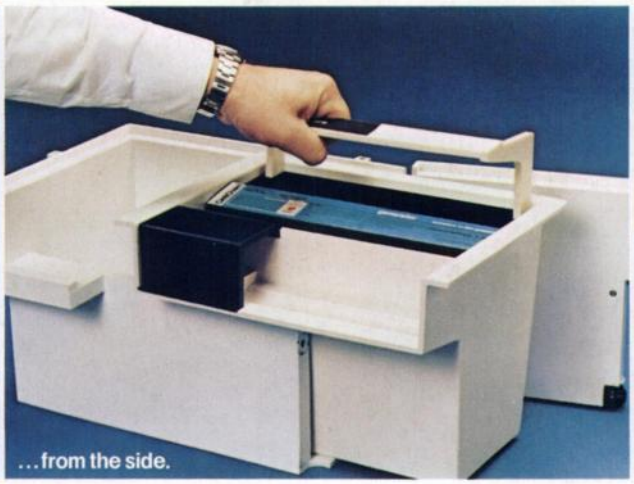
TECHNETIUM 99m

GENERATORS

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



Featuring:

- Indicated for use in adults and children for urinary bladder imaging (direct isotopic cystography).
- The only Generator with an "open/closed" valve to eliminate possible leakage, both during shipment and in your hot lab.
- Unique horizontal elution procedure increases ease of use and eliminates needle-vial alignment problems.
- A new sterile needle is utilized for each elution, reducing the chances of a septic or pyrogenic situation occurring in routine clinical usage. This method is superior to competitive dry column systems where the same needle assembly is used for the life of the product.
- Fission product molybdenum 99 is used in the Technetium 99m Generator to provide Sodium Pertechnetate Tc99m activity concentrations sufficient for bolus injections.
- Internal saline reservoir eliminates the need to stock saline vials.
- Evacuated elution vials are available in 5cc, 10cc, and 20cc volumes, allowing you to optimize the elution concentration to meet your needs.
- Optimum shielding design minimizes radiation to personnel in work areas, providing maximum protection.
- Generator is compact, providing for optimum maneuverability. Generator handle and shipping carton provide for ease in handling and lifting.

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TECHNETIUM Tc 99m GENERATOR for the Production of Sodium Pertechnetate Tc 99m

DESCRIPTION: The Technetium Tc 99m Generator is prepared with fission produced Molybdenum Mo 99 absorbed on alumina in a lead-shielded column and provides a means for obtaining sterile pyrogen-free solutions of Sodium Pertechnetate Tc 99m in sodium chloride injection. The eluate should be crystal clear. With a pH of 4.5–7.5, hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment. Over the life of the generator, an elution will contain a yield of 80% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 on the generator column.

Each eluate of the generator should not contain more than 0.15 microcurie of the Molybdenum Mo 99 per millicurie Technetium Tc 99m per administered dose at the time of administration, and not more than 10 micrograms of aluminum per milliliter of the generator eluate, both of which must be determined by the user before administration.

INDICATIONS AND USAGE: Sodium Pertechnetate Tc 99m is used IN ADULTS as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; salivary gland imaging; placenta localization; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for detection of vesico-ureteral reflux.

Sodium Pertechnetate Tc 99m is used IN CHILDREN as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; blood pool imaging including radionuclide angiography; and urinary bladder imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.

CONTRAINDICATIONS: None known.

WARNINGS: Radiation risks associated with the use of Sodium Pertechnetate Tc 99m are greater in children than in adults. 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.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m may affect fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m. It is also not known whether Technetium Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be given to a pregnant woman only if the expected benefits to be gained clearly 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.

Nursing Mothers

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

Pediatric Use

See **Indications and Usage, dosage** and administration. See also description of additional risk under **warnings.**

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.

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

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

ADVERSE REACTIONS: Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m.

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 10:00 P.M. Eastern Time of the day of calibration. The TECHNETIUM Tc 99m GENERATOR consists of:

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

*initial order only

The TECHNETIUM Tc 99m GENERATOR should not be used after sixteen (16) days from the date and time of calibration.

Jointly manufactured by:
CINTICHEM, INC.
Tuxedo, N.Y. 10987

and

June, 1983
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Tuxedo, N.Y. 10987

Novo SPECT Systems

High sensitivity, high resolution brain imaging for research and clinical use.

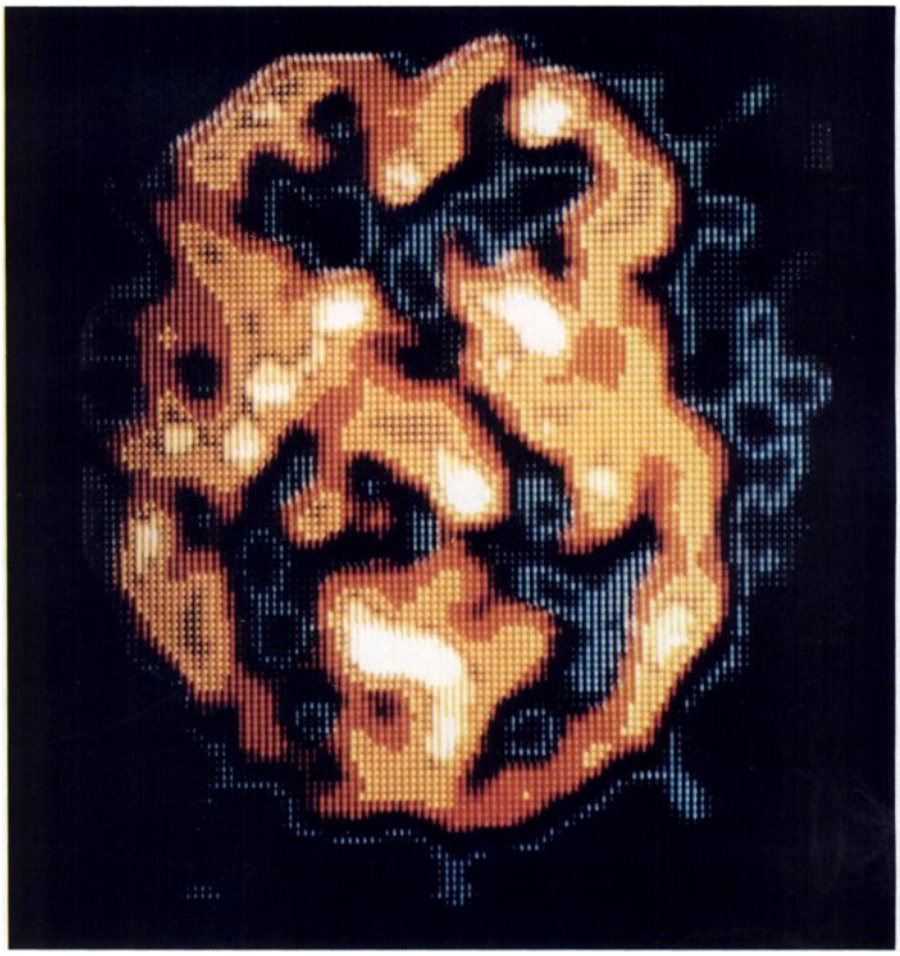
Early assessment of suspected neurologic disorders continues to pose important clinical challenges – challenges largely unmet by the restricted availability of positron-emission tomography (PET) and the acknowledged limitations of transmission computed tomography and SPECT as performed by rotating gamma-cameras. Noninvasive single-photon emission computed tomography (SPECT) can provide highly sensitive, early diagnostic information useful in the management of the hundreds of thousands of patients who each year develop central nervous system disease.

Novo enters SPECT

Novo's entry into SPECT imaging means that clinicians at most institutions will be able to routinely obtain data on cerebral function and metabolism thus far only possible with PET imaging – but without the high costs and procedural difficulties associated with PET. Utilizing newly available iodine-123 monoamine tracers that cross the blood-brain barrier and are taken up by brain tissue, Novo SPECT can acquire multiple sequential high sensitivity and high resolution tomographic images of regional brain perfusion.

Proven applications

Already, many studies have documented the advantages of SPECT brain imaging in a number of clinical settings:
In stroke: SPECT imaging may have its greatest utility in the early demonstration of regional ischemia or hyperemia, and the distinction between ischemic and infarcted tissue, for which conventional brain imaging and CT are often inadequate.
In tumor localization: Tumors can be accurately located in three dimensions as areas of increased or decreased uptake.
In epilepsy: Quantitative SPECT studies demonstrate epileptogenic foci as areas of increased uptake. SPECT imaging permits localization of even deep foci inaccessible to EEG.



In therapeutic monitoring: SPECT imaging enables clinicians to assess normalization following medical or surgical therapy.

Novo SPECT System

A sophisticated, dedicated multidetector diagnostic instrument for brain imaging, with high sensitivity and excellent spatial resolution.

For further information please contact:

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Belgium: Novo Industri S.A., Brussels, tlph. 32-2-465-2400
USA: Novo Diagnostic Systems, Wilton, tlph. 1-203-846-8420
UK: Vertec Scientific, Slough, tlph. 44-6286-4808
Holland: Nucletron Trading B.V., Leersum, tlph. 31-3434-5-4224
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France: Semsa, Boulogne, tlph. 33-1-621-6666
Italy: Tecnologie Avanzate, Turin, tlph. 39-11-550284
Spain: ITISA, Madrid. tlph. 34-1-253-8620
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Australia: Baltek Medical Systems, Berowra Heights, tlph. 2-456-1245

NOVO

Making The Case For Nuclear Medicine

The most important instrument in your department may be the telephone. Unless it rings–unless clinicians refer patients for studies–there is no nuclear medicine practice.

Under today's DRG-based payment systems, obtaining and maintaining referrals has become even more important. Hospitals are encouraging their clinicians to minimize the number of tests they order, selecting those that are most definitive, that answer the diagnostic question in the shortest time, at the lowest cost.

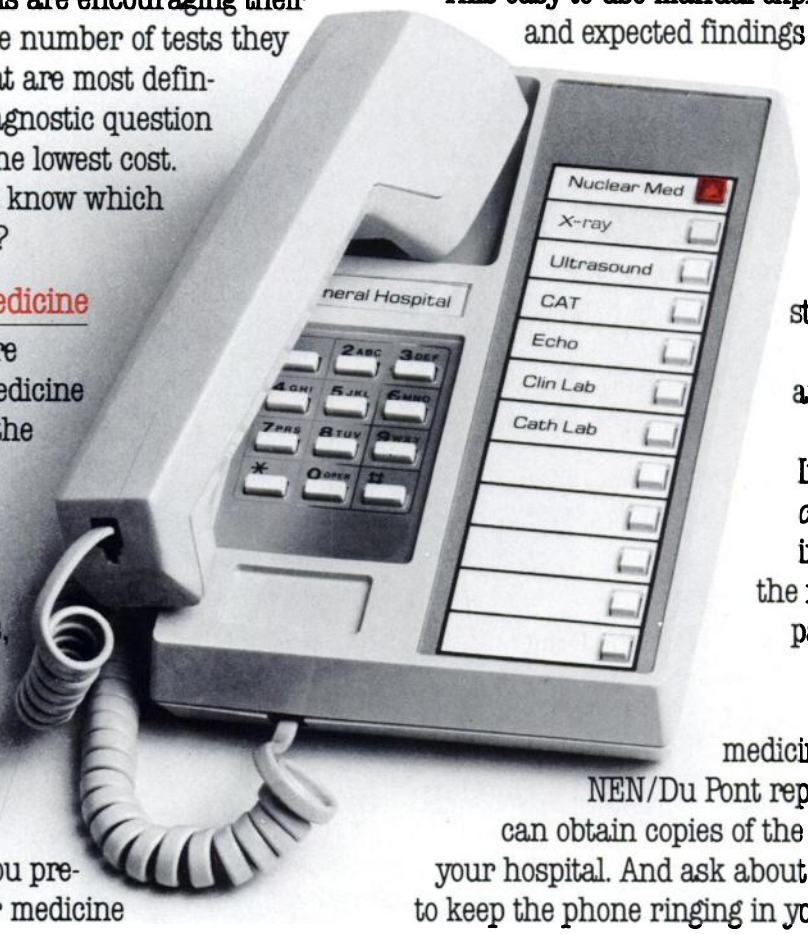
How can clinicians know which tests meet these criteria?

Supporting Nuclear Medicine

At NEN/Du Pont we share your belief in nuclear medicine studies. We understand the contributions these non-invasive studies make to quality medical care. We know which studies can serve as low-cost screens, which can be performed easily on an outpatient basis, which offer physicians the procedure of choice they seek.

And we can help you present the case for nuclear medicine to your administrators and referring clinicians.

For many years, NEN/Du Pont has supported nuclear medicine with teaching programs and exhibits directed to the clinicians who order your studies. Now, we've developed a *Clinician's Guide to Nuclear Medicine Procedures*...to help you build referrals with key clinicians at your institution.



Helping Clinicians Choose

This easy-to-use manual explains the indications and expected findings of nuclear medicine studies, compares them to other diagnostic modalities, and helps referring clinicians select the most appropriate studies. Unnecessary tests are reduced and the patient's stay can be shortened. In addition, the *Clinician's Guide* contains information useful to the nursing staff in preparing and managing patients before and after their nuclear medicine studies. Ask your NEN/Du Pont representative how you can obtain copies of the *Clinician's Guide* for your hospital. And ask about our other programs to keep the phone ringing in your department. Our goal is Imaging Excellence: enhancing the image of your department while improving the images in your department.

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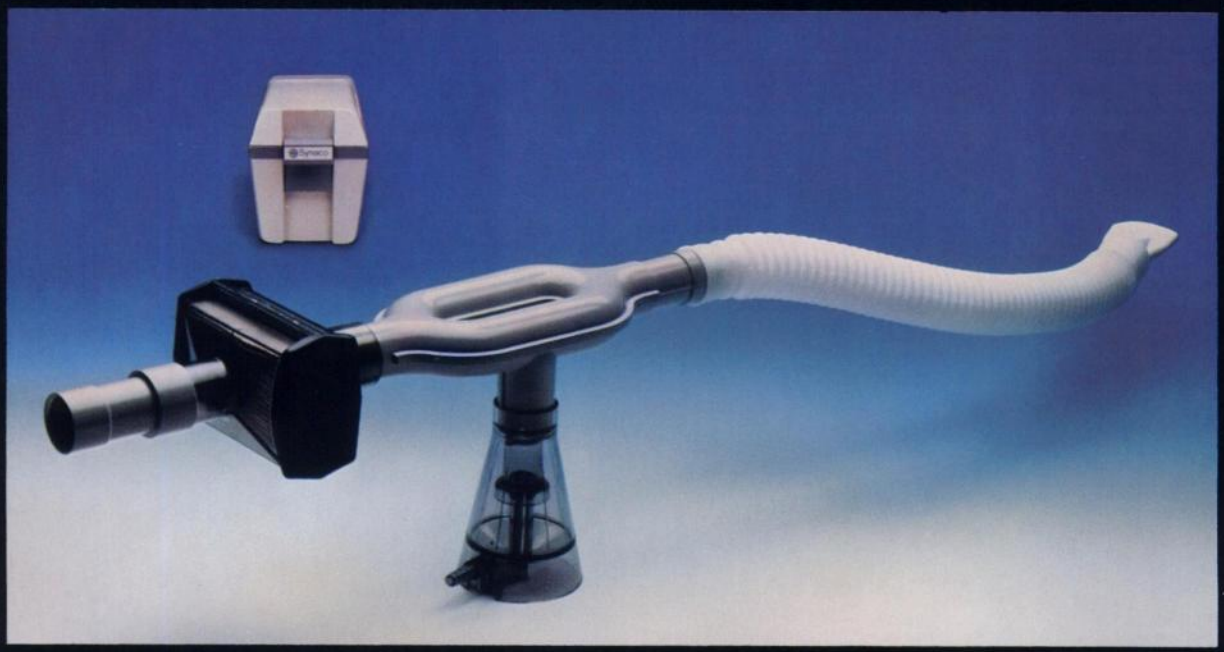

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New SynteVent is a unique aerosol system designed to deliver uniform submicronic (0.5 micron mass median diameter) droplets to the lung for ventilation scanning.

A complete, closed system, SynteVent is easily assembled, lightweight and portable. Normal tidal breathing for 3 to 5 minutes allows up to six views of the lung.

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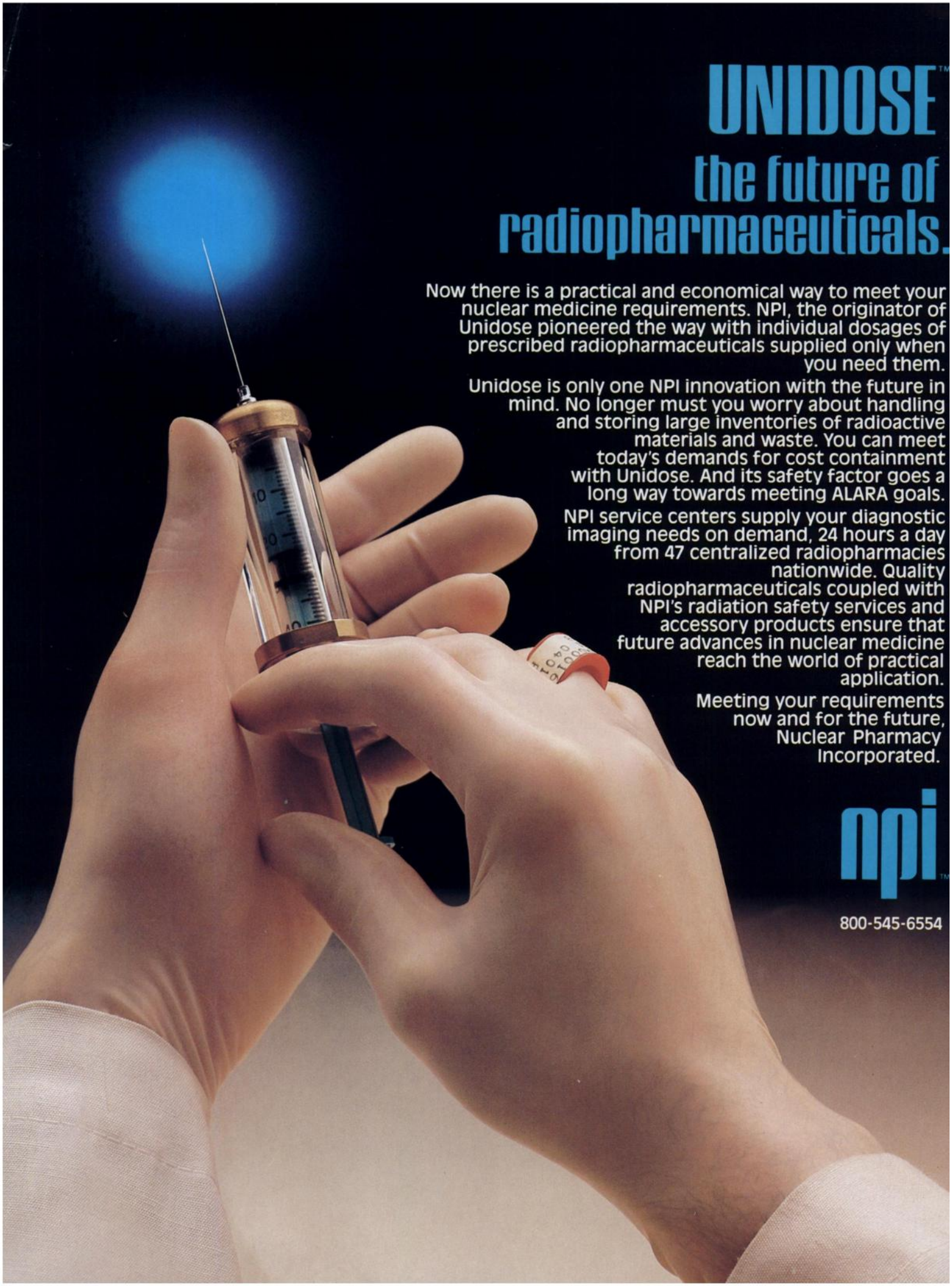
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Fundamentals of Nuclear Medicine

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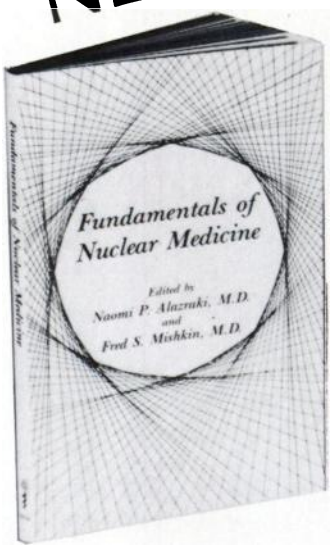

Edited by
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208 pp; 6 × 9″ softcover
Publication Date: June 1984
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. . . a basic introductory guide to acquaint medical students and physicians with the most useful nuclear medicine techniques for detecting and evaluating common disorders.

Abbreviated Contents

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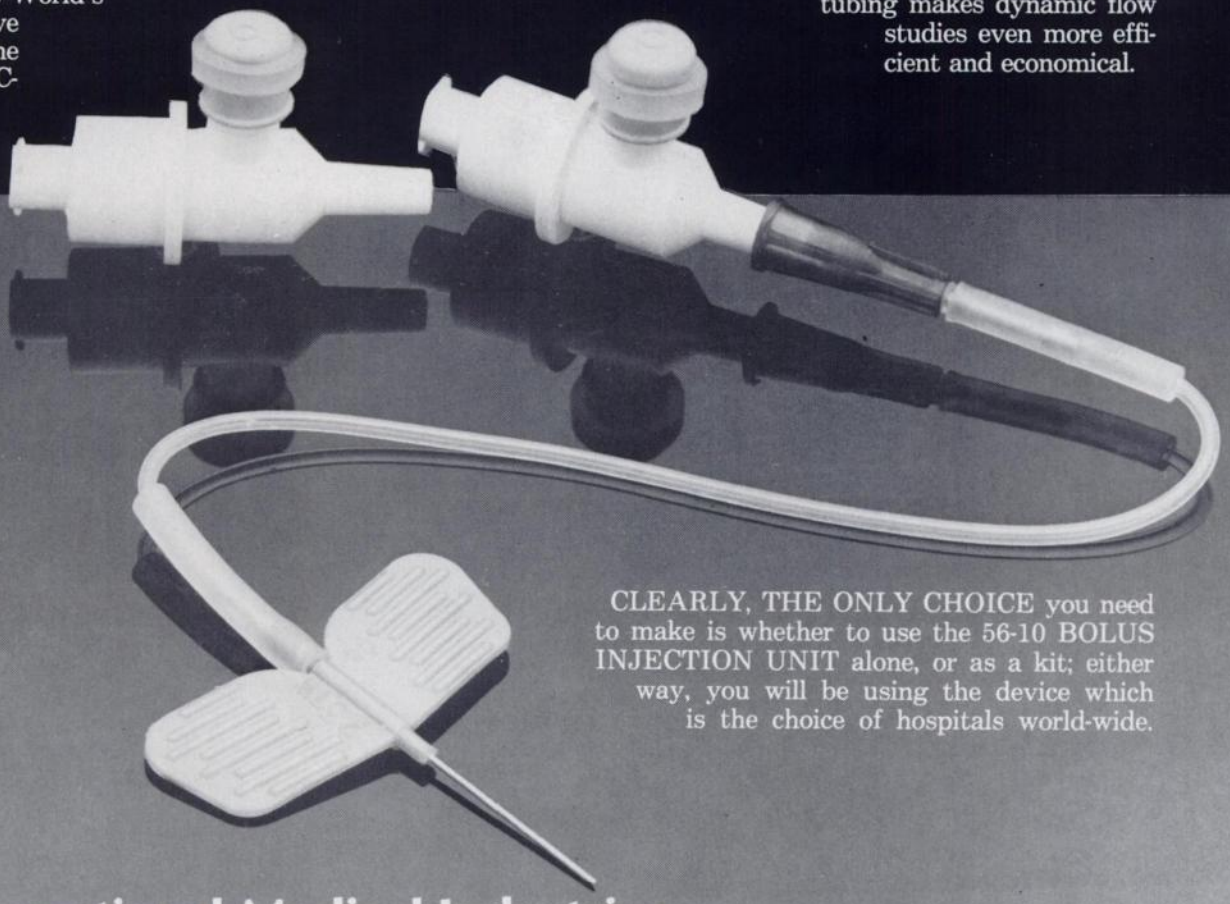

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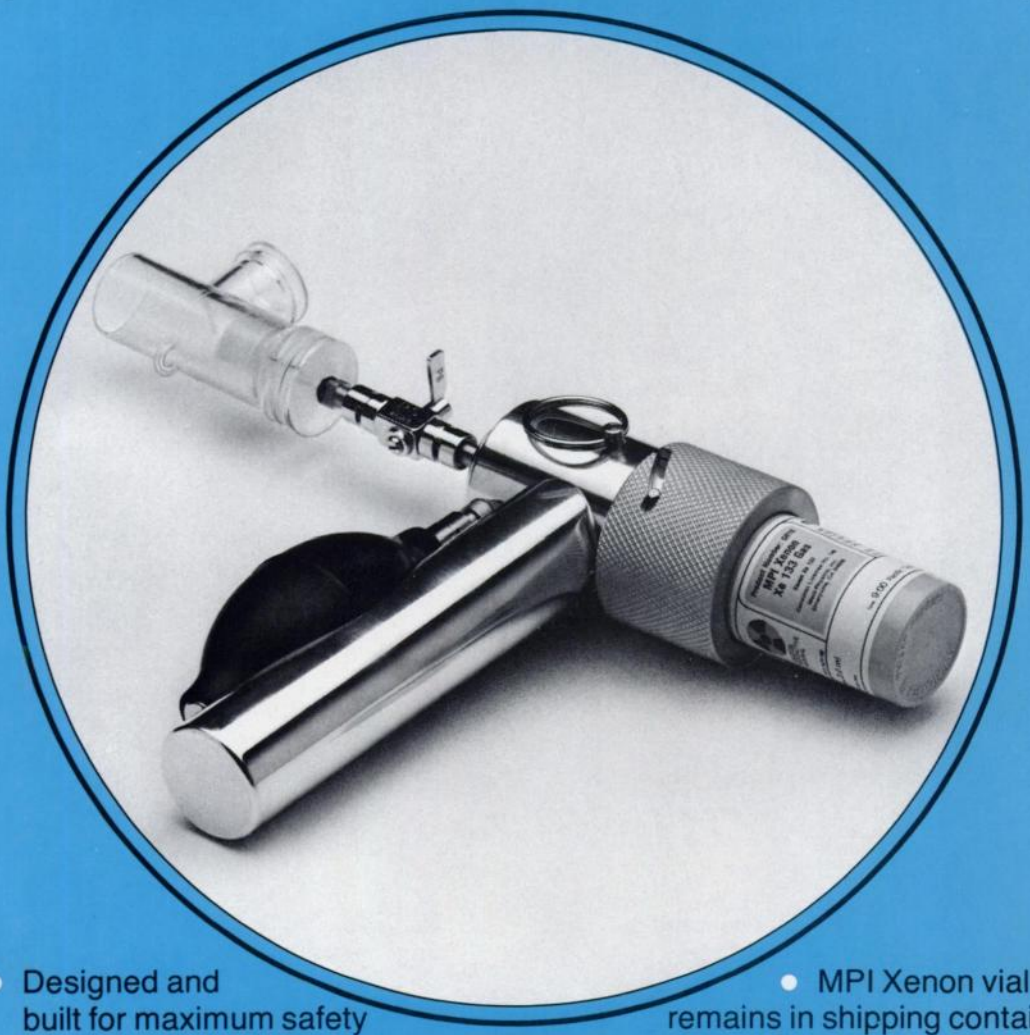

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The mobile computer console incorporates five microprocessors for distributed data processing.

More computing power gives you more data, and more flexible use of data. For the first time, a completely automated Baird system is also programmable.

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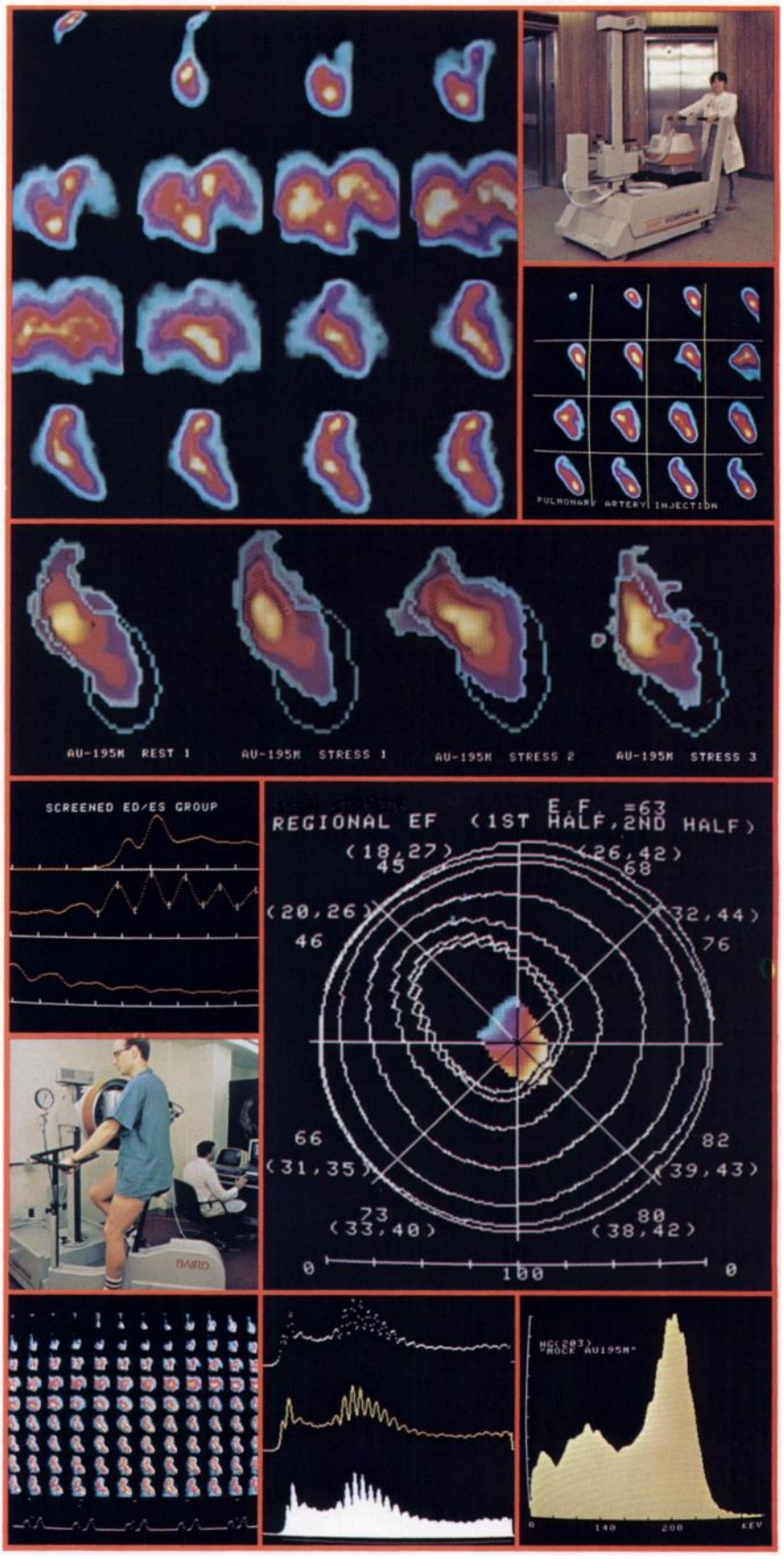
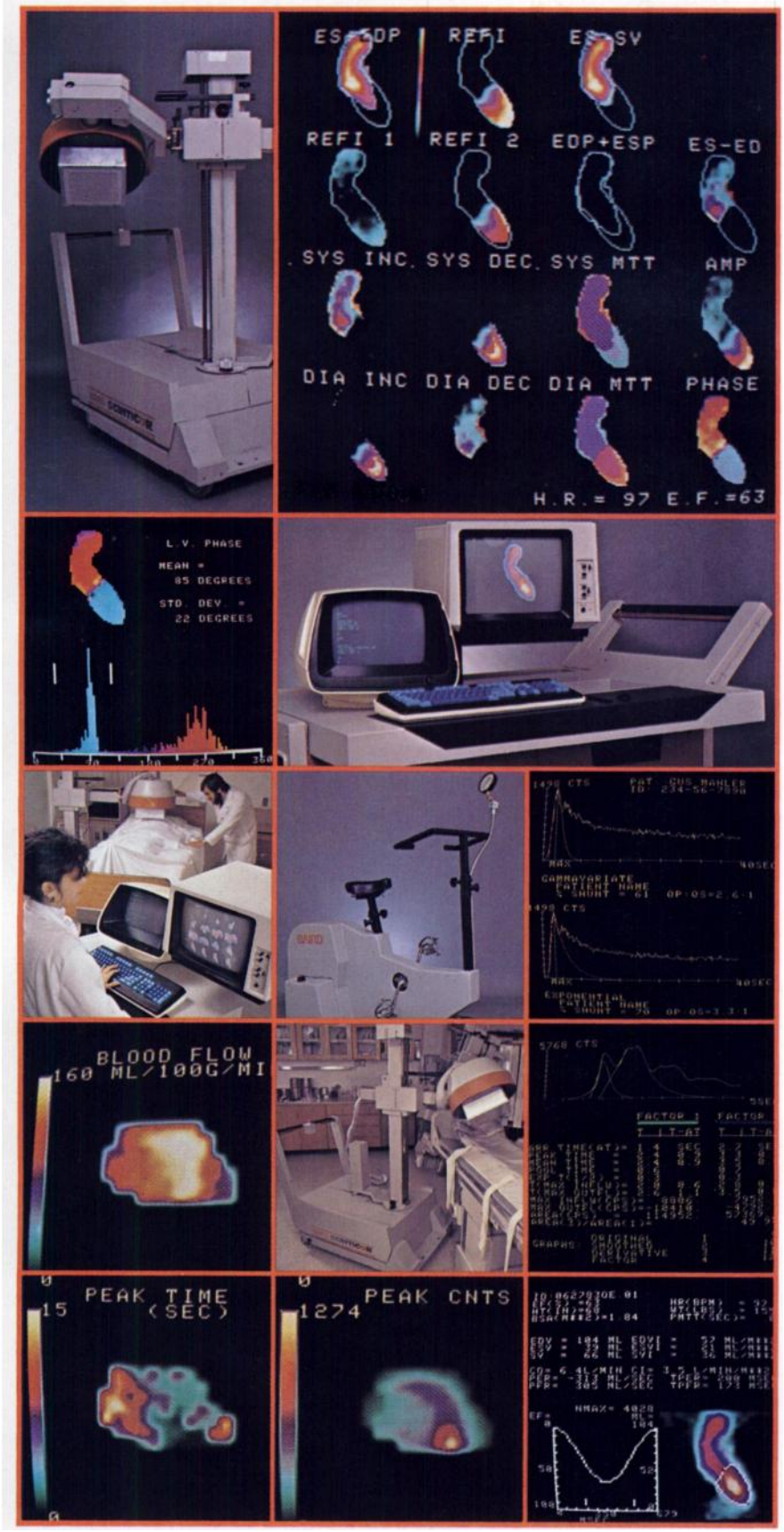


It's not just another pretty image.



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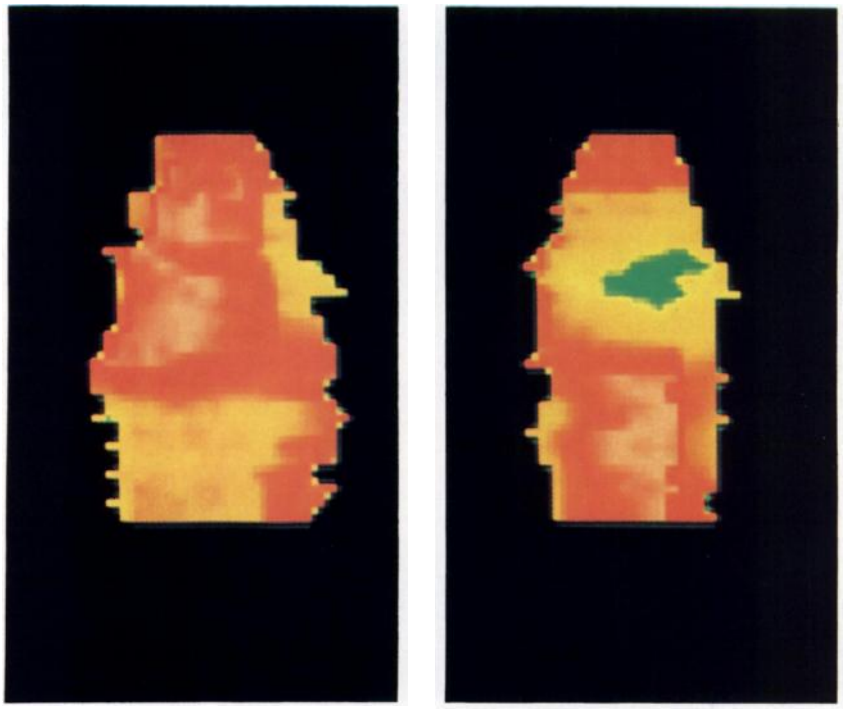

LATERAL VIEW
Open Bypass To Marginal

SURFACE DISPLAY OF A 3-D IMAGE
Normal myocardial perfusion in red, red-white
Low Flow and myocardial infarction in yellow, green

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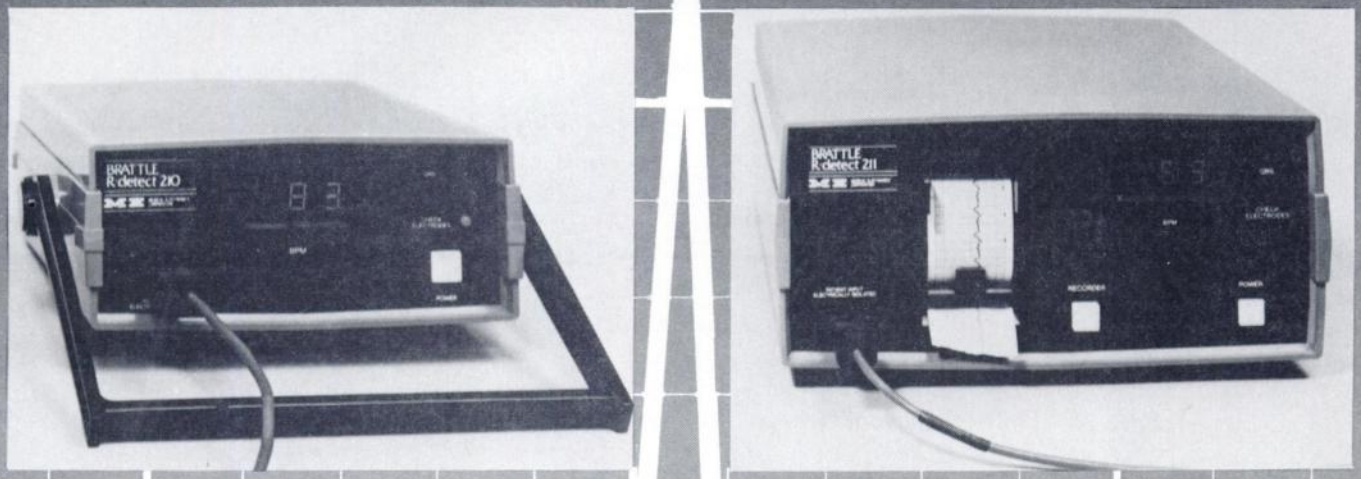

MODEL 210 **MODEL 211**

The BRATTLE R-DETECT offers you fully automatic R-wave triggering and is compatible with all nuclear medicine computers. In addition, the model 211 has a strip chart with EKG and event marker indicating the exact location of the R-DETECT signal.

Special Features

- Fully automatic threshold
- Only two electrodes
- High heartrate capability . . . ideal for stress testing
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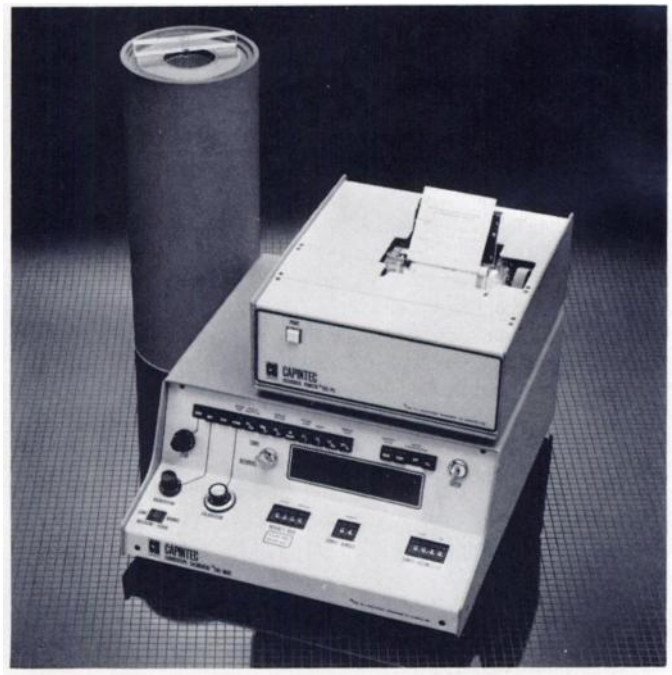

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FOR DIAGNOSTIC USE

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

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

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

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

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

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

Contents of the vial are intended only for use in the preparation of Technetium Tc 99m Aggregated Albumin and are NOT to be administered directly to the patient.

Technetium Tc 99m Aggregated Albumin, as well as any radioactive drug, 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 Aggregated Albumin should be formulated within eight (8) 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 Aggregated Albumin affects fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m Aggregated Albumin. It is also not known whether Technetium Tc 99m Aggregated Albumin 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 Aggregated Albumin 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: The literature contains reports of deaths occurring after the administration of aggregated albumin to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Tc 99m-labeled aggregated albumin have been reported.

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

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

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

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

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. (Please see complete prescribing information.)

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

Aggregated albumin (human)–1.0mg
Normal human serum albumin–10mg
Sodium chloride–10mg
Stannous chloride ($SnCl_2 \cdot 2H_2O$) (maximum)–0.07mg

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

Before reconstitution store at room temperature 15°–30° C.

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

Included in each five vial kit is one package insert and six radiation labels. Included in each thirty vial kit is one package insert and thirty-six radiation labels.

The components of the Technetium Tc 99m Aggregated Albumin Kit are supplied sterile and non-pyrogenic. Aseptic procedures normally employed in making additions and withdrawals from sterile, non-pyrogenic containers should be used during addition of pertechnetate solution and the withdrawal of doses for patient administration.

Technetium Tc 99m Aggregated Albumin 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 Aggregated Albumin.

Catalog Number NRP-415 (5-Vial Kit)
Catalog Number NRP-415C (30-Vial Kit) September 1984

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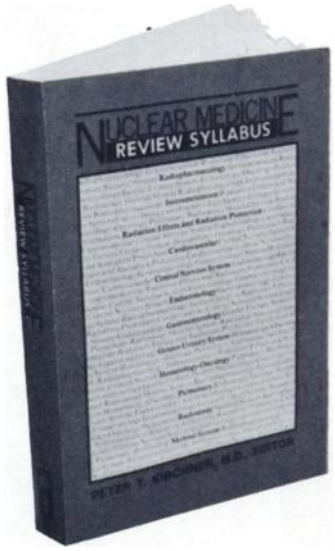
Peter T. Kirchner, M.D., Editor



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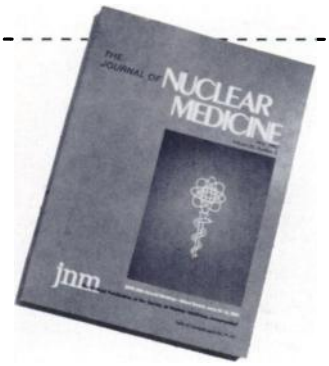

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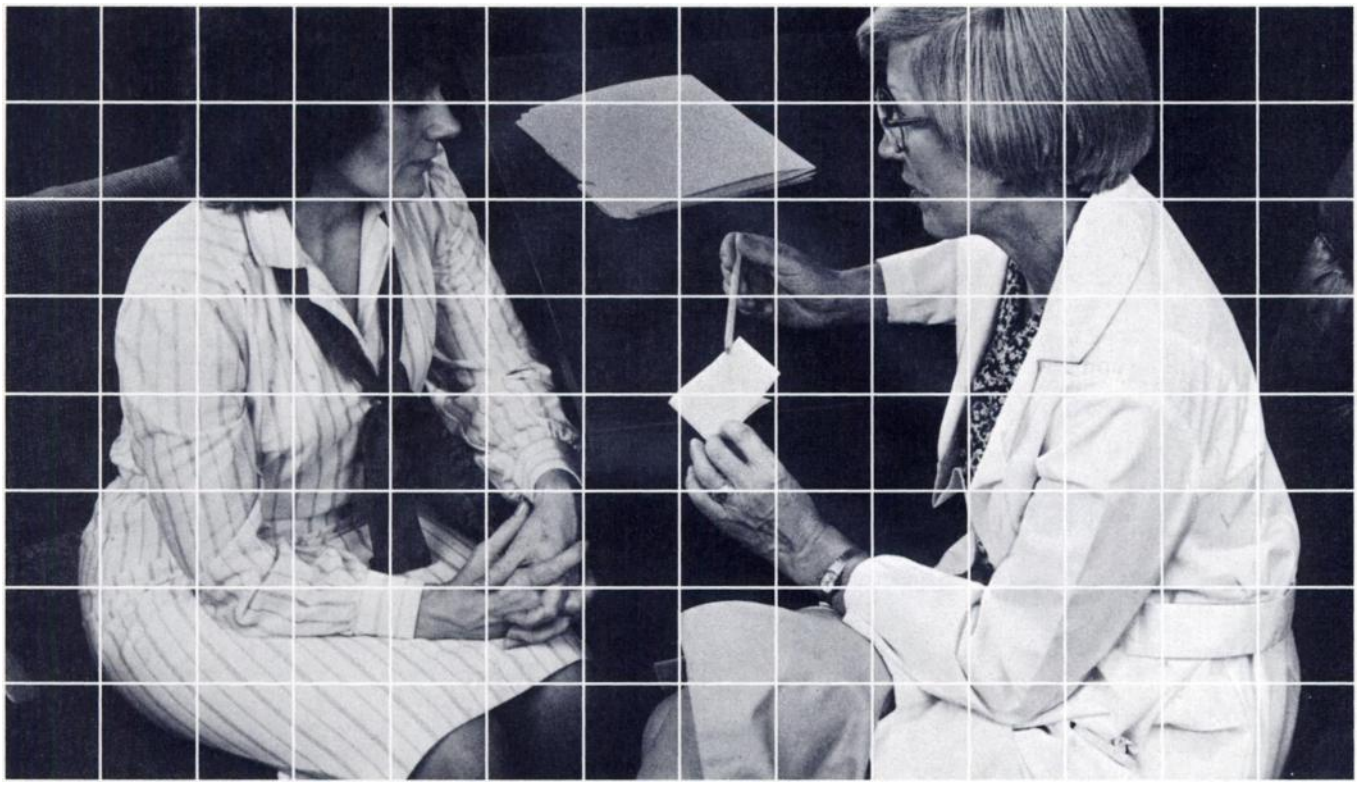

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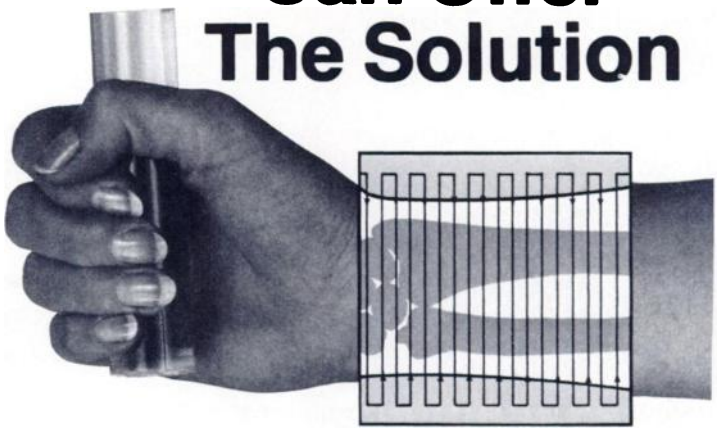

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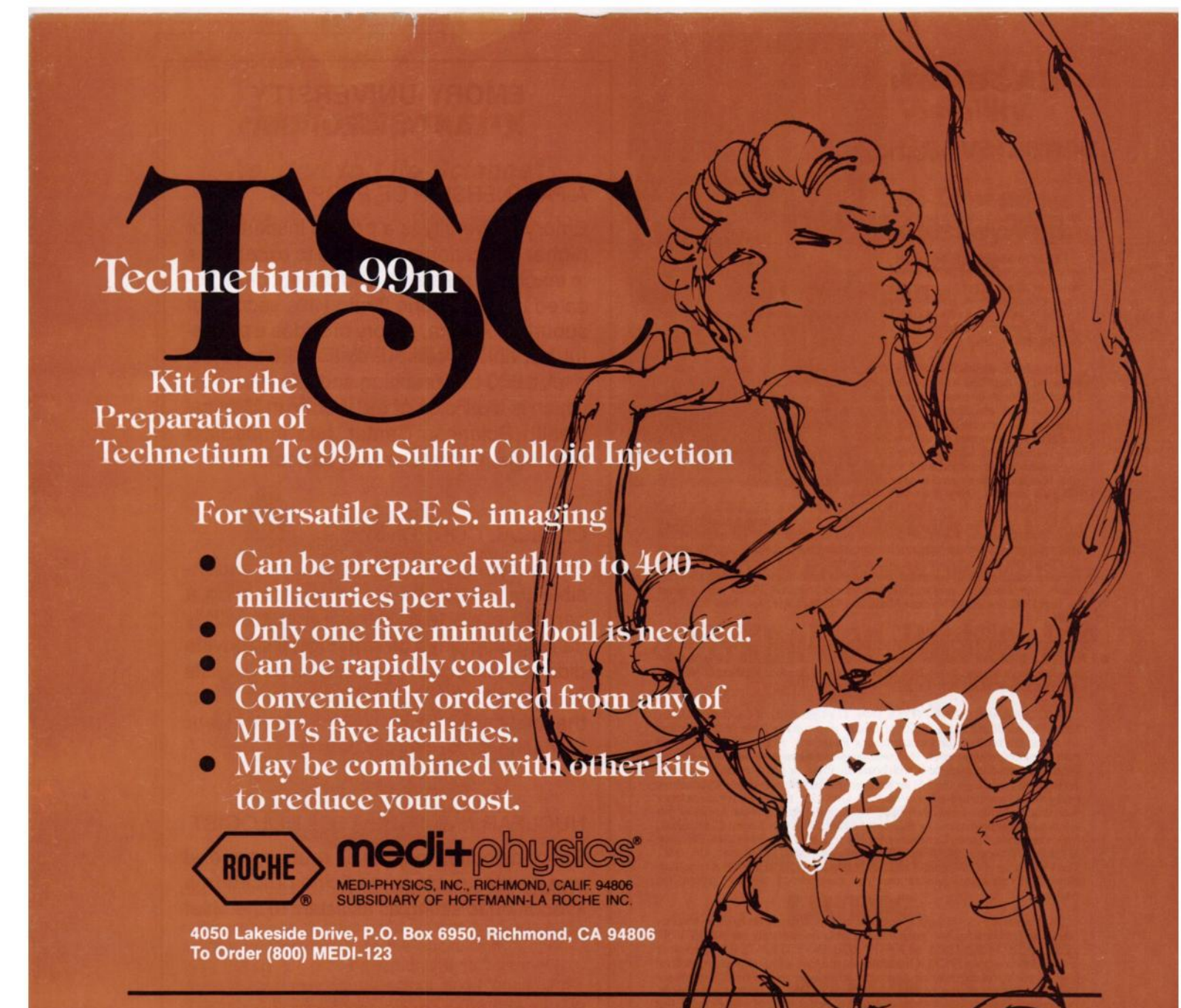
Kit for the Preparation of Technetium Tc 99m Sulfur Colloid Injection



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TECHNETIUM 99m TSC KIT FOR THE PREPARATION OF TECHNETIUM Tc 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.

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 patient.***

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

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 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.

Pregnancy Category C. Animal reproduction studies have not been conducted with Technetium Tc 99m Sulfur Colloid. It is also not known whether Technetium Tc 99m Sulfur Colloid can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc 99m Sulfur Colloid 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.

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.

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NUCLEAR MEDICINE PHYSICIAN WANTED. Well trained and experienced board certified Nuclear Medicine Physician with board certification or board eligible in internal medicine who has been in solo practice of nuclear medicine (non-subsidized) for 5–10 years who would be interested in becoming a partner in a successful privately owned outpatient Nuclear Medicine Clinic and lab, fully equipped for in vivo and in vitro studies. Includes private office with Technical and Administrative Staff. Must be willing and capable of assuming administrative and technical responsibility. Medical School affiliation possible if desired. Please send resume to: Box 1201, Society of Nuclear Medicine, 475 Park Ave. So., New York, NY 10016.

NUCLEAR MEDICINE TECHNOLGIST. Position now available for an experienced Nuclear Medicine Technologist certified by SNM or registered technologist in a private progressive outpatient nuclear medicine laboratory in a large city in a large medical center in the Sun Belt. Knowledge of radioimmunoassay, imaging, computer, and nuclear cardiology in addition to supervisory, administrative, and teaching experience required. Please send resume to: Box 1200, Society of Nuclear Medicine, 475 Park Ave. So., New York, NY 10016.

NUCLEAR MEDICINE TECHNOLOGIST. Registered or registry eligible nuclear medicine technologist wanted to work in busy nuclear cardiology laboratory in eastern Maine. Reply Box 1202, Society of Nuclear Medicine, 475 Park Ave. So., New York, NY 10016.

NUCLEAR MEDICINE PHYSICIAN. The University of California, Davis, School of Medicine has a full-time faculty position available in the Nuclear Medicine Division of the Department of Radiology. Appointment will be at the Assistant Professor level, In Residence. Candidates must be board certified in nuclear medicine, preferably with board eligibility or certification in radiology or diagnostic radiology, eligible for licensure in California, and have an academic background in nuclear medicine/nuclear cardiology. Curriculum vitae, a letter outlining background and interests in teaching/research, and the names of five references must be received by February 28, 1985. Reply to: Robert C. Stadalnik, MD, Chairman, Search Committee for Nuclear Medicine Physician, Division of Nuclear Medicine, 2315 Stockton Blvd., Room 206-G, Sacramento, CA 95817. The University of California is an Equal Opportunity/Affirmative Action Employer and encourages applications from members of minority groups and women.

The University of Michigan, positron emission tomography. The Nuclear Medicine Division has two positions available immediately for ASSISTANT RESEARCH SCIENTISTS or RESEARCH INVESTIGATORS in positron emission tomography (PET). Candidates should have a PhD in physics, medical physics, electrical engineering, computer science, or related field. Experience in PET, nuclear medicine, or image processing on DEC computers is desirable. Demonstrated ability to do independent research study and to have published results is required. Both positions will include research related to positron emission tomography including image processing, tomograph characterization, and data analysis. One individual will be responsible for maintenance, modification, and upgrades to The Cyclotron Corporation PCT-4600A tomograph as well as detector development. The second position requires expertise in mathematical modeling of physiological and biochemical systems. Send curriculum vitae to: Richard D. Hichwa, PhD, Director, Cyclotron/PET Facility, University of Michigan Medical School, 3480 Kresge III Box 056, Ann Arbor, MI 48109. A nondiscriminatory, affirmative action employer.

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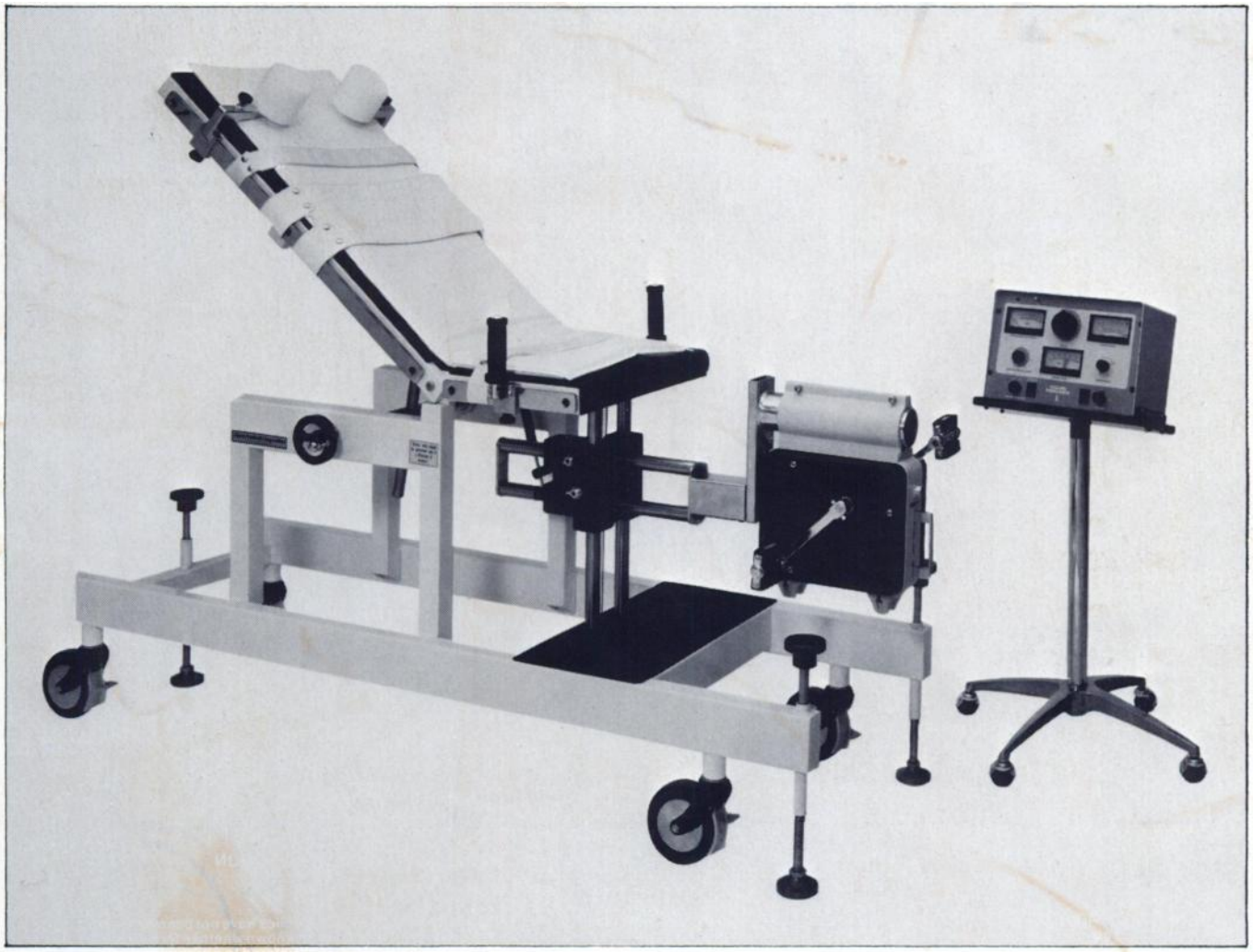

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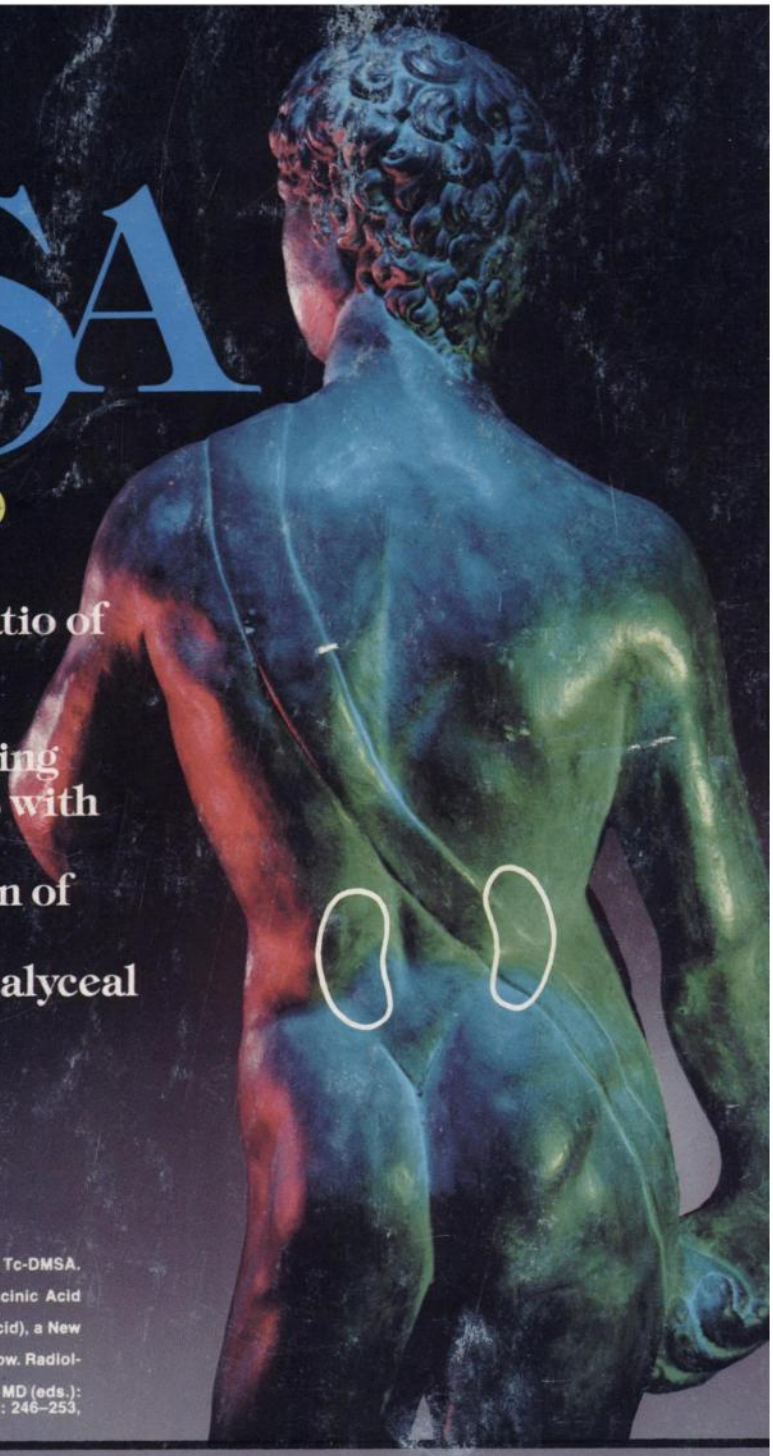

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1. Enlander D. et al: Renal Cortical Imaging in 35 Patients: Superior Quality With 99m Tc-DMSA. J. Nuc. Med. 15: 743–749, 1974.
2. Daly M.J. et al: Differential Renal Function Using Technetium-99m Dimercaptosuccinic Acid (DMSA): In Vitro Correlation. J. Nuc. Med. 20: 63–66, 1979.
3. Handmaker H. et al: Clinical Experience With 99m Tc-DMSA (Dimercaptosuccinic Acid), a New Renal-imaging Agent. J. Nuc. Med. 16: 28–32, 1975.
4. Taylor A.: Delayed Scanning With DMSA: A Simple Index of Relative Renal Plasma Flow. Radiology 136: 449-453, 1980.
5. Handmaker H: Nuclear Renal Imaging in Acute Pyelonephritis. in Freeman L. Blaufox MD (eds.): Update on Radionuclide Assessment of the Kidney (I): Semin. Nuclear Medicine 12: 246–253, 1982.

MPI DMSA Kidney Reagent (Technetium Tc 99m Succimer Kit)

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

DESCRIPTION: Each reagent ampul of the kit contains 2.2 ml of a sterile, pyrogen free aqueous solution containing 1.2 mg of succimer and 0.42 mg of anhydrous stannous chloride in aqueous solution under a nitrogen gas atmosphere. When sterile, oxidant-free, pyrogen-free sodium pertechnetate Tc 99m in isotonic saline is combined with the reagent, following the instructions provided with the kit, a complex is formed. Administration is by intravenous injection for diagnostic use.

The succimer component of MPI Kidney Reagent consists of more than 90% meso isomer and less than 10% d,l isomer.

INDICATIONS AND USAGE: MPI DMSA Kidney Reagent is to be used as an aid in the scintigraphic evaluation of renal parenchymal disorders.

CONTRAINDICATIONS: None known.

WARNINGS: None.

PRECAUTIONS: General

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

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: No long-term animal studies have been performed to evaluate carcinogenesis potential or whether Technetium Tc 99m Succimer affects fertility in males or females.

PREGNANCY CATEGORY C: Animal reproduction studies have not been conducted with the MPI DMSA Kidney Reagent either with or without Tc 99m.

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

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

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.

MPI DMSA Kidney Reagent should be formulated within 30 minutes prior to clinical use.

The product must be used within 30 minutes after preparation. Any unused portion should be discarded after that time.

Some patients with advanced renal failure may exhibit poor renal intake of Tc 99m DMSA. It has been reported that satisfactory images may be obtained in some of these patients by delaying imaging for up to 24 hours.

ADVERSE REACTIONS: Rare instances of syncope, fever, nausea and maculopapular skin rash have been reported.

HOW SUPPLIED: Each kit package contains the following components:

(1) Three sealed glass reagent ampuls, each containing 2.2 ml of a sterile, pyrogen-free aqueous solution of 1.2 mg succimer and 0.42 mg anhydrous stannous chloride. The solution is under a nitrogen gas atmosphere.
(2) Three sterile and pyrogen-free mixing vials (10 ml).
(3) Three mixing vial labels.
(4) Six courtesy record labels.
(5) One package insert.