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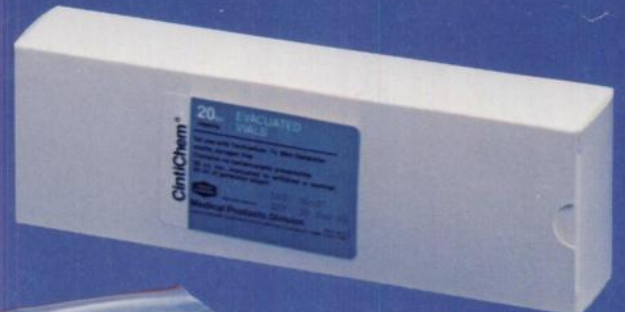


Technetium Tc 99m
Generator

Secondary shield
to further reduce
radiation



5cc and 10cc elution vials



20ml elution vials
available on request



Elution vial shield

Adaptors for various elution vials



Sterile needle pack and labels
furnished with each generator

GENERATORS

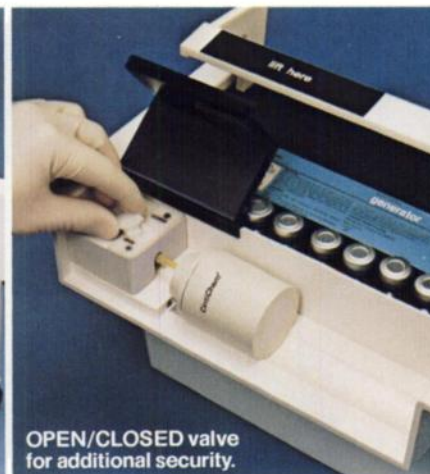
Technetium Tc 99m Generators for the Production of Sodium Pertechnetate Tc 99m



Loads either from the top ... or ..



... from the side.



OPEN/CLOSED valve for additional security.

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.

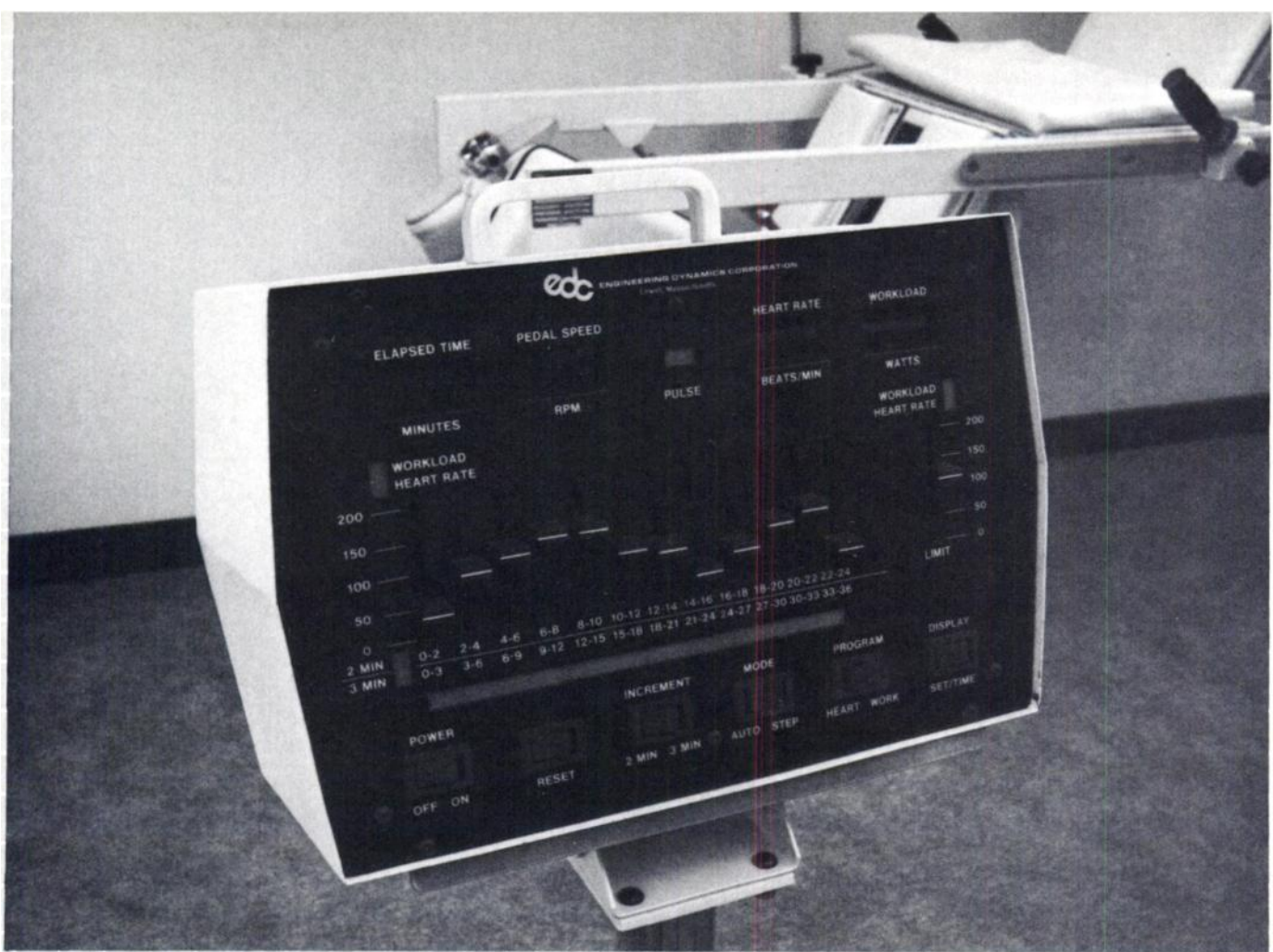
*initial order only

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

Jointly manufactured by:
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Tuxedo, N.Y. 10987

and

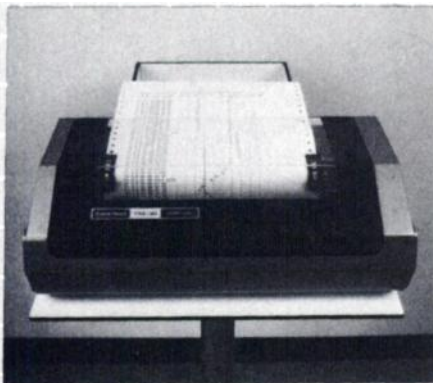
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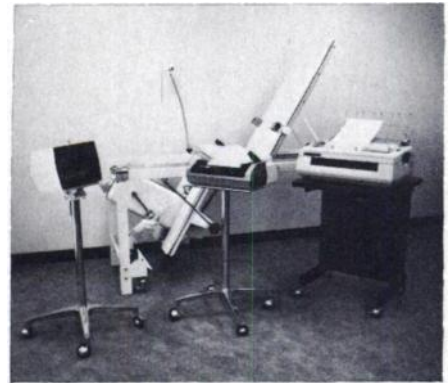


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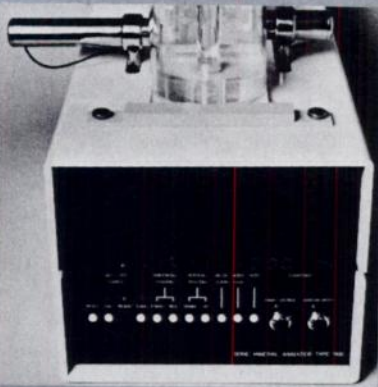
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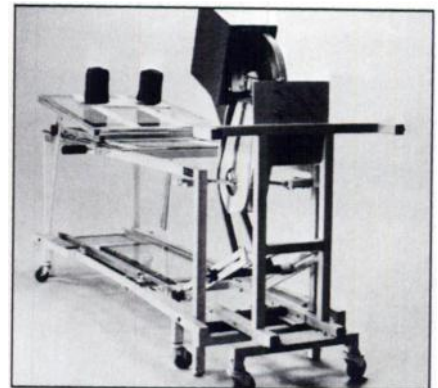
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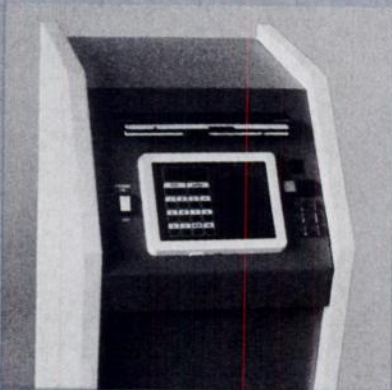
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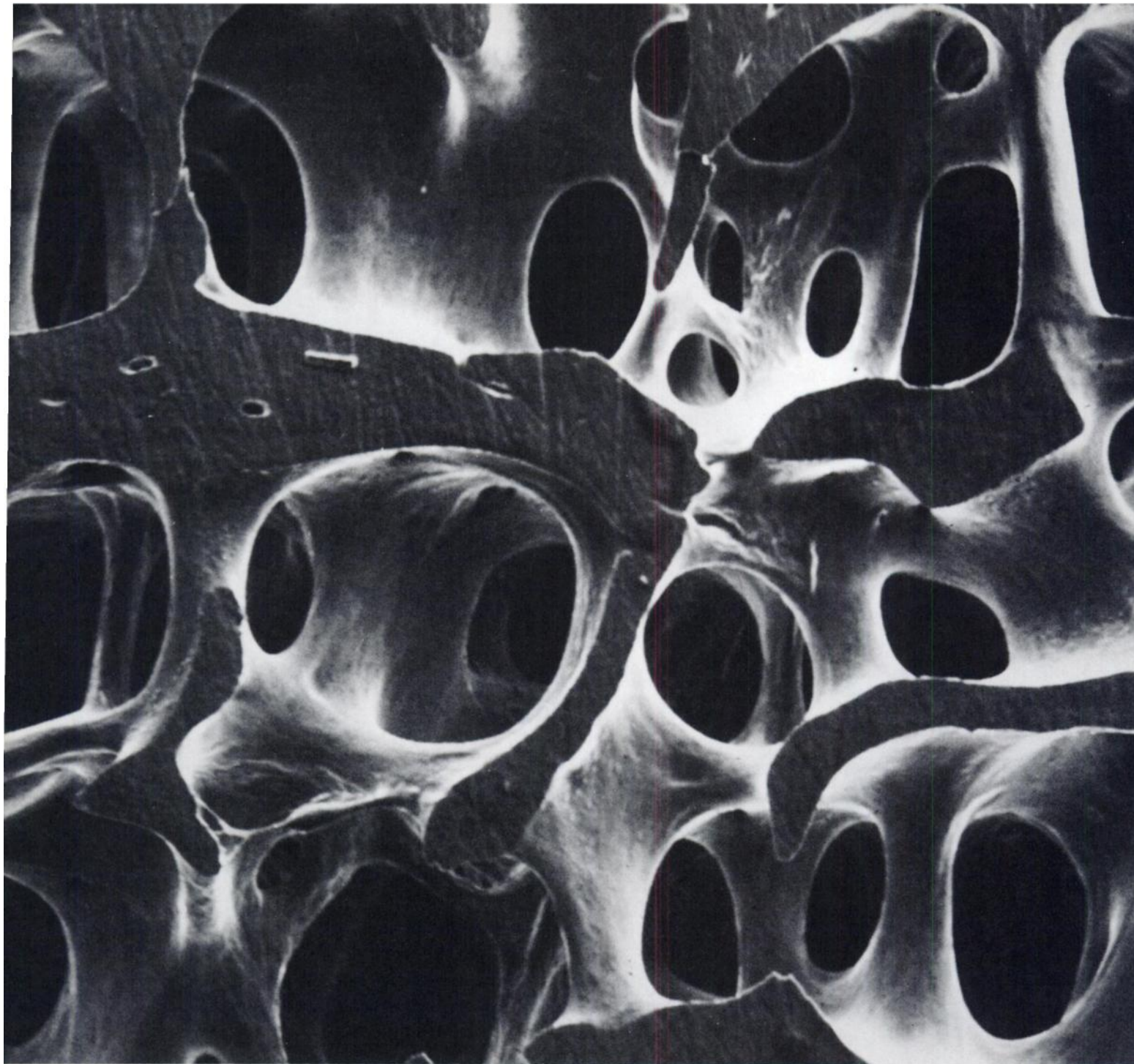
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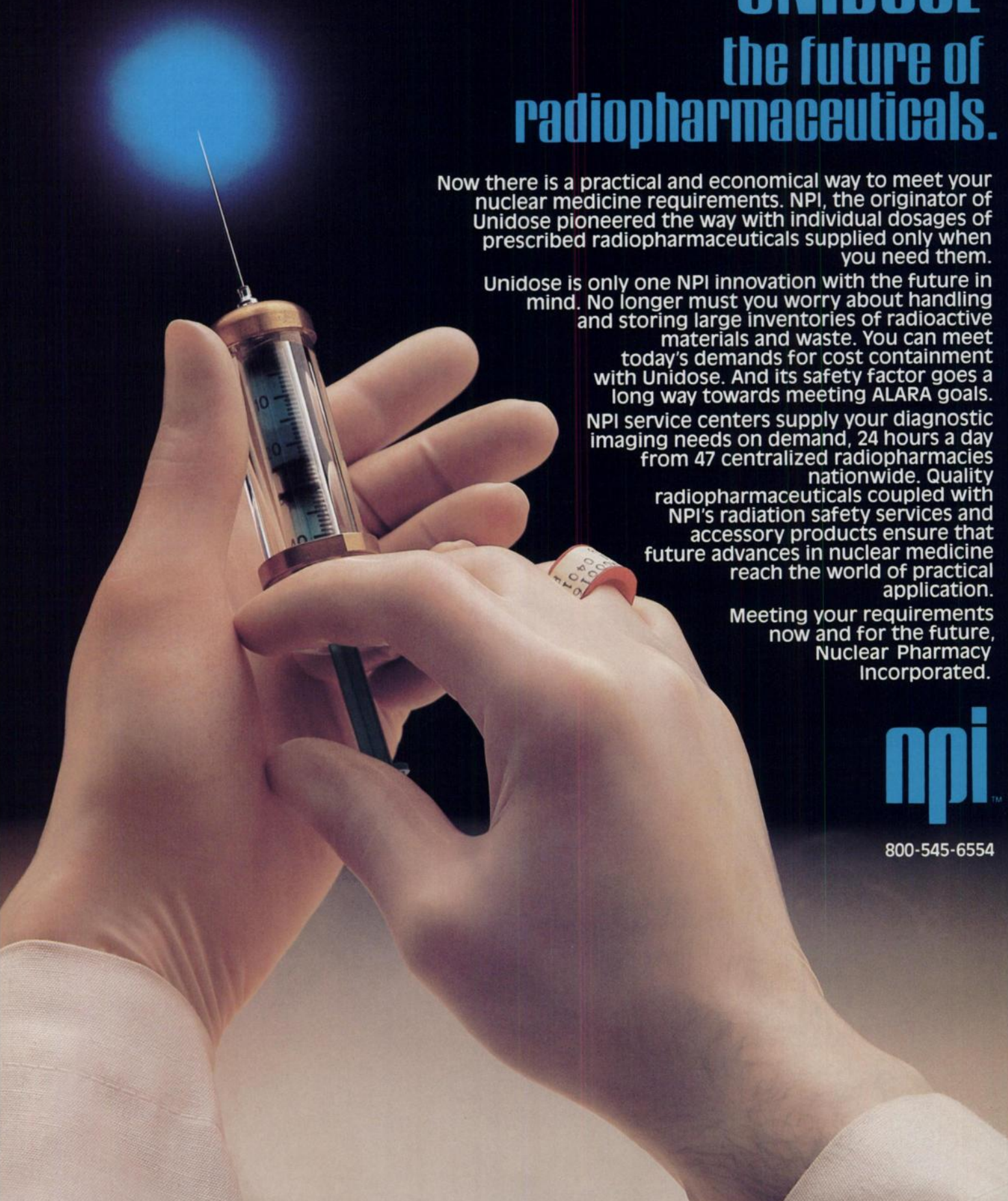
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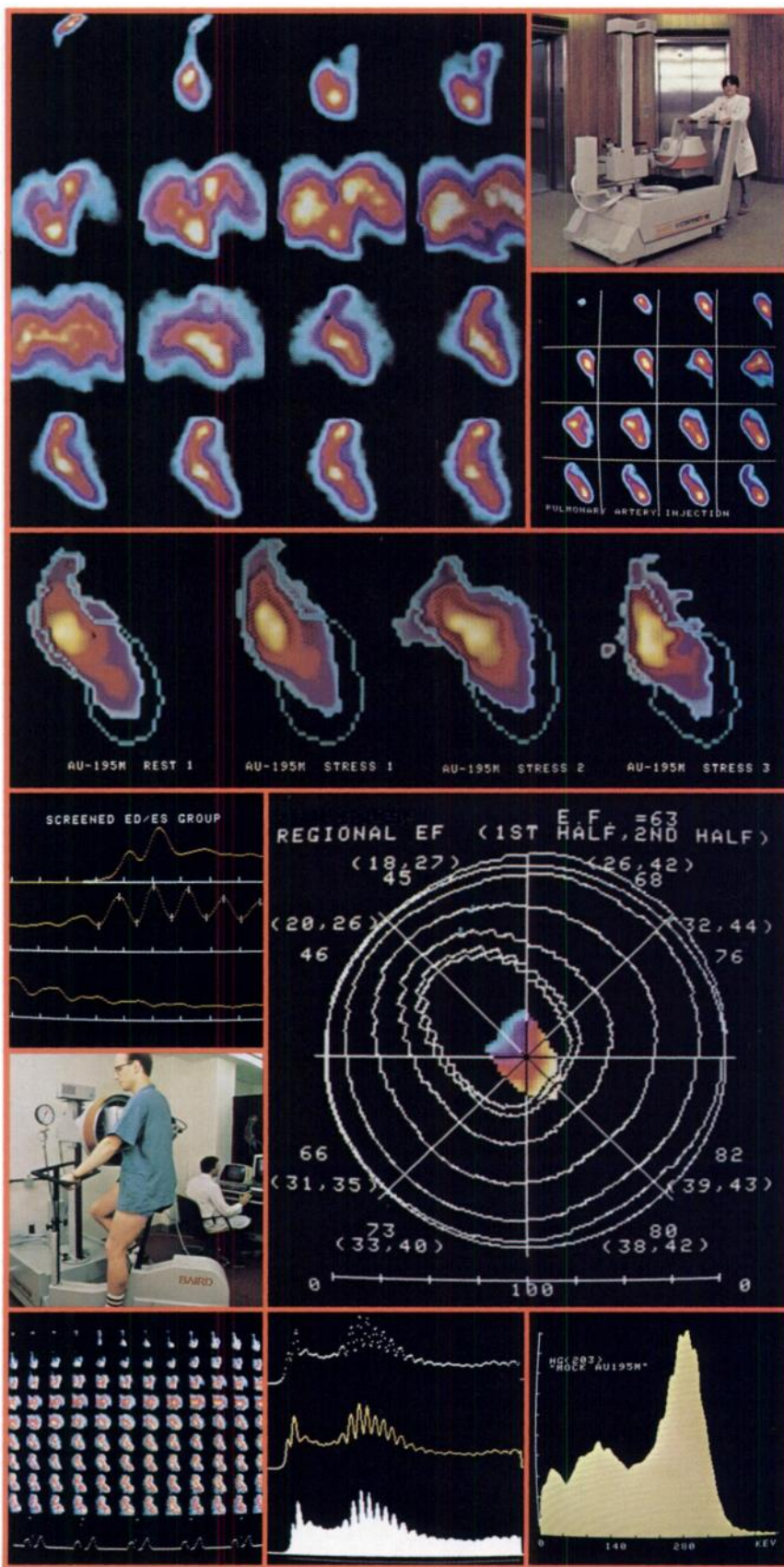
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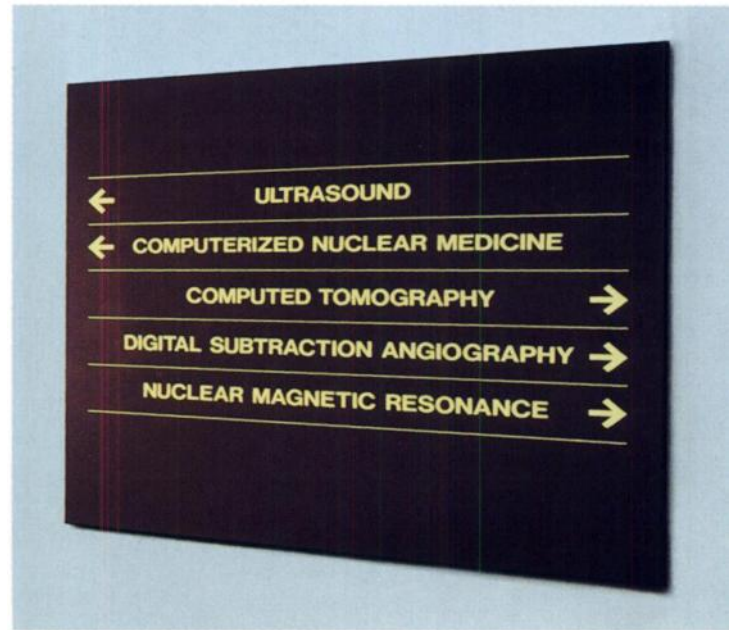
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Powers & James NUCLEAR IMAGING 2nd Edition (Exercises in Diagnostic Radiology Vol. 6)

Virtually rewritten, with 90% new illustrations! This basic workbook is a clear introduction to nuclear medicine, with physiology and morphology discussed throughout. The basic nuclear medicine studies (bone, thyroid, brain, liver/spleen, cardiac, renal, etc.) are covered, as well as less frequently performed procedures.

By *Thomas A. Powers*, MD, Chief, Nuclear Medicine, Veterans Administration Medical Center, Nashville; and *A. Everette James, Jr.*, MD, ScM, JD, Prof. and Chairman, Radiology, Dept. of Radiology Sciences, Vanderbilt Univ. School of Medicine. 192 pp., 479 illus. April 1984. \$21.95 #5109-7.

Maisey, Britton & Gilday CLINICAL NUCLEAR MEDICINE

Thirty-two expert contributors present a wide spectrum of clinical situations that focus on the application of nuclear medicine to day-to-day patient management. Fact-filled, clinically relevant articles thoroughly explore: exercise ECG testing and thallium scintigraphy; renal radionuclide studies, including renal transplantation; adrenal imaging; special problems in pediatrics; pre-treatment assessment of cancer; more!

Edited and with contributions by *M.N. Maisey, K.E. Britton, & D.L. Gilday* 525 pp., 235 illus. 1983. \$60.00. #1087-0.

Partain, James, Rollo & Price NUCLEAR MAGNETIC RESONANCE (NMR) IMAGING

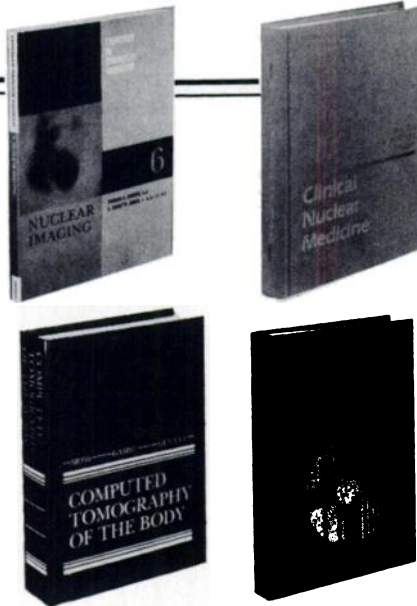
State-of-the-art summary of the physical principles, clinical results, and potential of this exciting new technology which permits diagnosis through the use of non-ionizing radiation. Shows how NMR allows low-risk imaging, and how it provides biochemical data on disease and structures.

By *C. Leon Partain*, Ph.D. MD, Assoc. Prof. and Director, Division of Nuclear Medicine; and *A. Everette James Jr.*, MD, ScM, JD, Dept. of Medical Imaging and Radiological Sciences; both of Vanderbilt Univ. School of Medicine; *E. David Rollo*, MD, PhD, Vice President, Medical Affairs, Humana Incorporated, Louisville; and *Ronald R. Price*, Ph.D., Dept. of Medical Imaging and Radiological Sciences, Vanderbilt Univ. School of Medicine. 552 pp., 624 illus. 1983. \$79.50. #7098-9.

Ramsey DIAGNOSTIC RADIOLOGY OF THE BRAIN: CT, DSA, NMR 2nd Edition (Advanced Exercises in Diagnostic Radiology Vol. 9)

This popular primer is an outstanding introduction to neuroradiologic techniques, with emphasis on computed tomography scanning. And, this edition also presents digital subtraction angiography and nuclear magnetic resonance! The CT scans are correlated with angiograms, radionuclide scans, and plain skull films. The scans themselves are quite varied, many from the latest generation of scanners. Dr. Ramsey has had hands-on experience with NMR, and her NMR section is a most valuable element. Case examples are provided throughout.

By *Ruth G. Ramsey*, MD, Assoc. Prof. of Radiology, Section of Neuroradiology, Rush-Presbyterian-St. Luke's Medical Center, Chicago. 296 pp., 783 illus. Jan. 1984. \$24.95. #1177-X.



Friedman & Higgins PEDIATRIC CARDIAC IMAGING

Examines the remarkable advances that encourage new and imaginative approaches to imaging the anatomy, physiology, and metabolism of the heart in infants and children. Emphasis is on new modalities, such as NMR and DSA, and new uses of established methods such as CT and PET. This is a state-of-the-art reference, with clear illustrations throughout. A valuable addition to the literature.

Edited and with contributions by *William F. Friedman*, MD, Prof. and Chairman, Dept. of Pediatrics, UCLA Medical Center; *J.H. Nicholson*, Prof. of Pediatric Cardiology, UCLA School of Medicine; and *Charles B. Higgins*, MD, Prof. of Radiology and Chief, Magnetic Resonance Imaging, Univ. of California, San Francisco. About 320 pp., 274 illus. June 1984. About \$39.50. #1287-3.

Moss, Gamsu & Genant COMPUTED TOMOGRAPHY OF THE BODY

Superb new reference incorporates basic anatomy and state-of-the-art techniques! Describes and illustrates the CT features of disease entities, and discusses the relationship between CT and other techniques. Coverage includes scanning techniques, differential diagnostic points, pathologic features of disease, CT in pediatrics, more.

By *Albert A. Moss*, MD, Prof. of Radiology, *Gordon Gamsu*, MD, Assoc. Prof. of Radiology, and *Harry K. Genant*, MD, Prof. of Radiology, Medicine and Orthopaedic Surgery; all of the Univ. of California School of Medicine, San Francisco. 1201 pp., 1905 illus. Sept. 1983. \$110.00. #6574-8.

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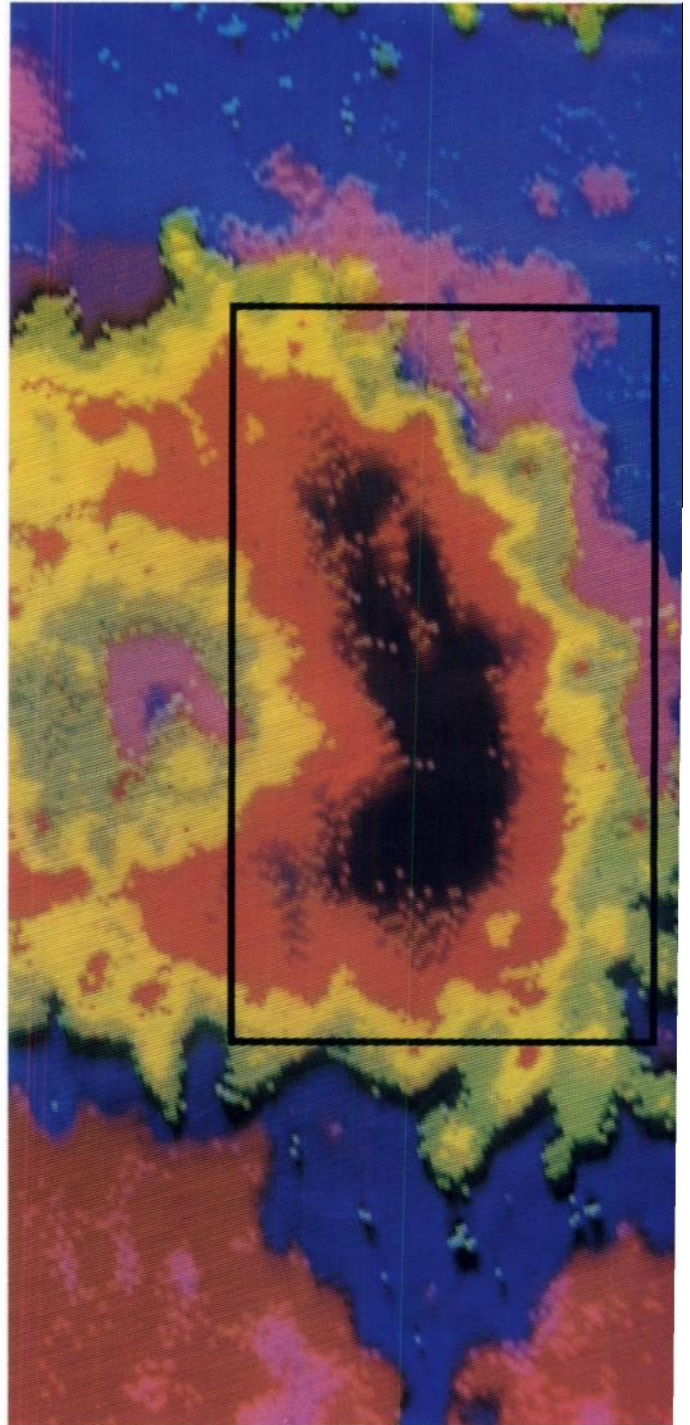
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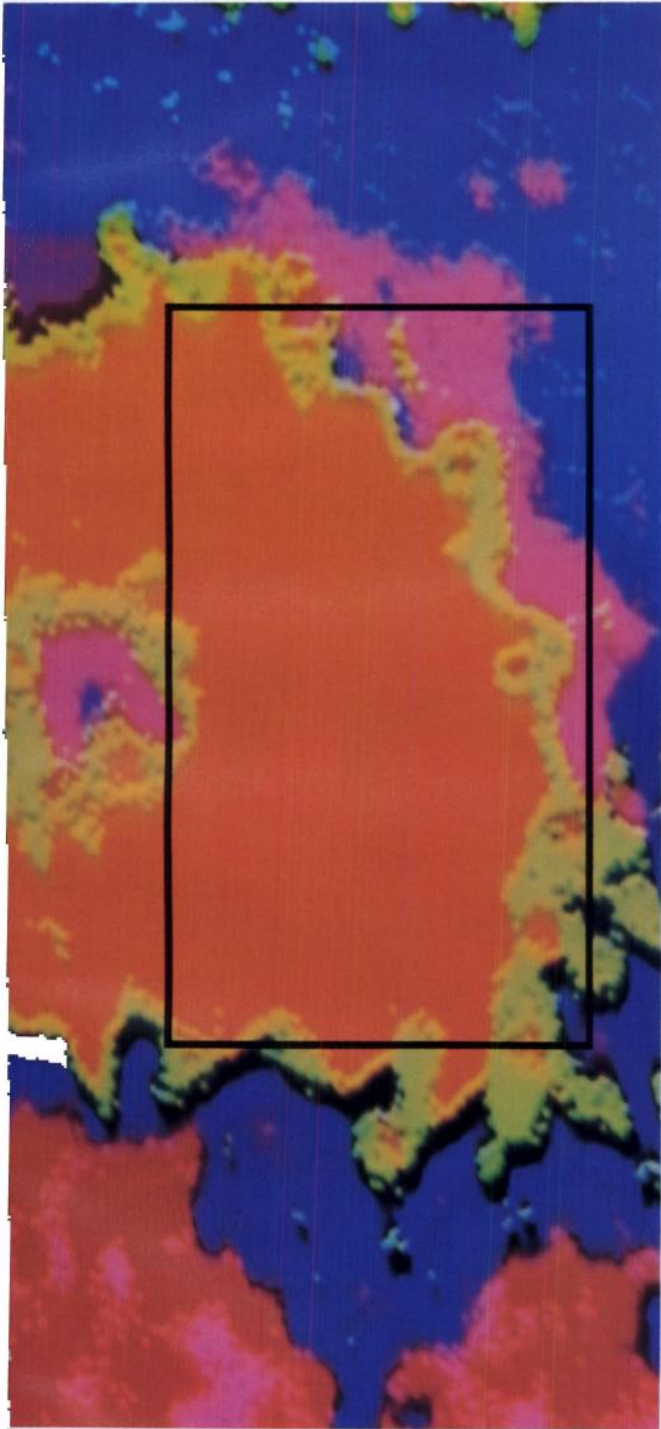
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Efficient departmental management is no longer an elective procedure for nuclear medicine.

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This means that you are being asked to become more of a businessman, adding terms like "efficiency" and "productivity" to your medical vocabulary. Now you have to know the real operating costs of your department. What, for example, does it cost to perform a bone scan? Or a thallium study? Are most costs attributable to staff? To equipment? Or to supplies? Can changes in scheduling, inventory or procedure mix reduce these costs?

At NEN/Du Pont we've developed a computer-based program to help you determine and analyze costs. Then, you can use the results to increase productivity in your department. It's called Financial Management Analysis (FMA) and it's available to all our customers.

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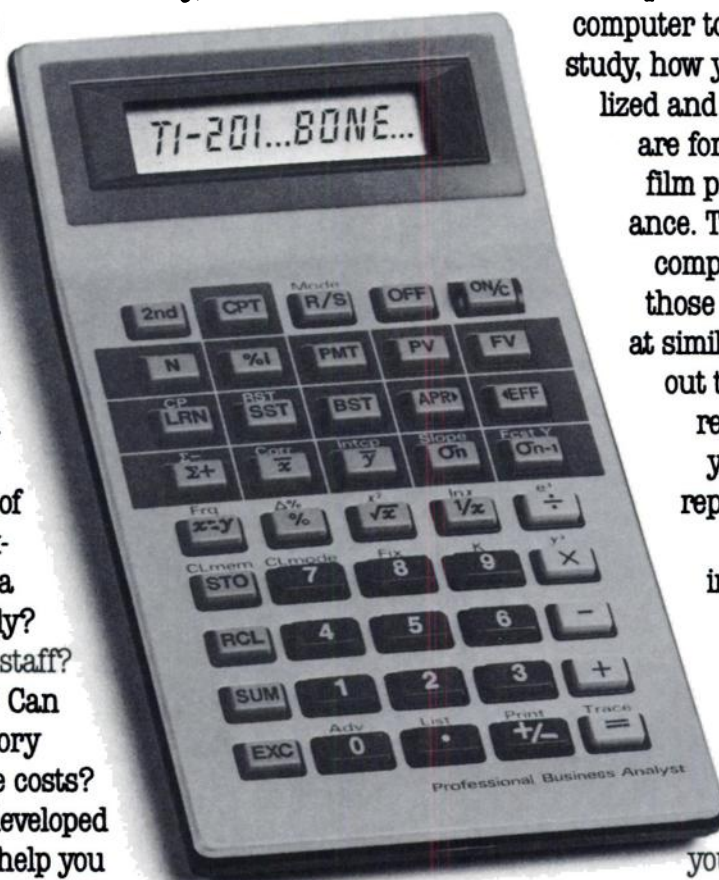
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Hours!**

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(Technetium Tc 99m Oxidronate Kit)

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Clinical Studies Verify the Two-Hour Advantage of OSTEOSCAN-HDP Over MDP in Skeletal Imaging

Higher Bone Uptake Than MDP at Two Hours²

"Image quality is principally related to the absolute retention of the skeletal imaging agent on bone and the time available to allow the soft-tissue tracer component to be excreted by the kidneys."² In clinical comparisons,² OSTEOSCAN-HDP averaged 21% higher whole body retention than MDP and 99% higher than HEDP. Another comparative study showed that "HDP had a significantly greater bone/background ratio at 2 hours than MDP..."³

Rapid Blood Clearance... Up to 16% Higher Bone to Soft-Tissue Ratios Than MDP⁴⁻⁵

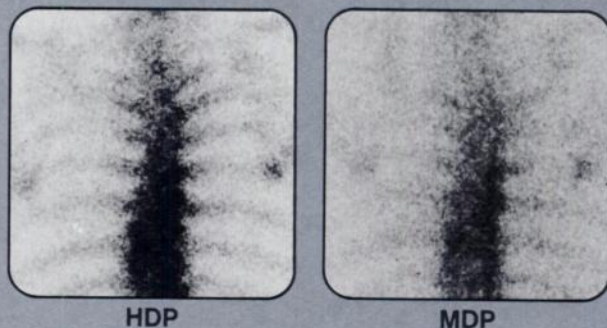
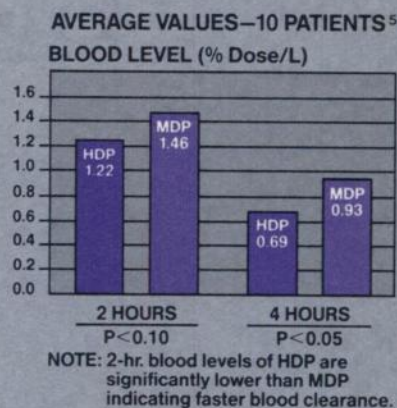
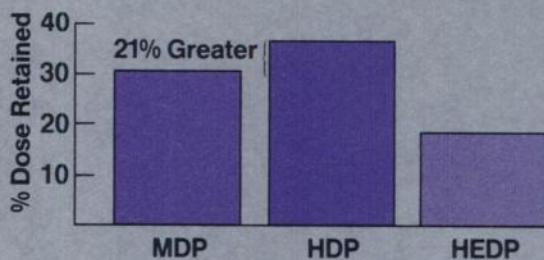
In clinical use of OSTEOSCAN-HDP, approximately 6% of the dose remained in the blood at two hours post-injection.⁵ (No other bone-imaging agent clears faster.) *The resultant low soft-tissue levels permit early imaging and contribute to high-resolution images.*

Side-by-Side Comparisons Rated HDP Images "Better" at Two Hours

In a controlled multi-center crossover study,⁷ HDP was found to give images of better quality than MDP at a dose-to-image time of two hours.

Diagnostic-quality skeletal images in two hours...an important contribution to departmental productivity and patient convenience.

To arrange an evaluation of OSTEOSCAN-HDP, contact your Mallinckrodt representative today.



SIDE-BY-SIDE COMPARISON OF IMAGES AT 2 AND 4 HOURS⁷

| Number of Patients | Dose-to-Image Time | Image Quality Grade (1=excellent, 8=poor) | |
|--------------------|--------------------|---|-------------|
| | | HDP | MDP |
| 28 | 2 hours | 2.78 ± 0.11* | 3.11 ± 0.14 |
| 28 | 4 hours | 2.37 ± 0.16 | 2.29 ± 0.16 |

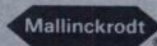
*Significantly different (p < 0.05)

Scintiphotos courtesy of Howard J. Dworkin, MD, and William C. Porter, Pharm. D., Wm. Beaumont Hospital, Royal Oak, Michigan.

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Please see next page for Osteoscan-HDP prescribing information. ▶

Mallinckrodt OSTEOSCAN-HDP Technetium Tc99m Oxidronate Kit

DESCRIPTION

OSTEOSCAN-HDP (Technetium Tc99m Oxidronate Kit) is supplied as a lyophilized powder, packaged under nitrogen in vials for intravenous administration after reconstitution with ADDITIVE-FREE sodium pertechnetate Tc99m. 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. The contents of the vial are sterile and non-pyrogenic.

This radiopharmaceutical diagnostic agent, when reconstituted with ADDITIVE-FREE sodium pertechnetate Tc99m forms a complex of unknown structure.

Physical Characteristics

Technetium Tc99m decays by isomeric transition with a physical half-life of 6.02 hours¹. Photons that are useful for detection and imaging studies are listed in Table I.

Table I. Principal Radiation Emission Data

| Radiation | Mean % Disintegration | Mean Energy (keV) |
|-----------|-----------------------|-------------------|
| Gamma-2 | 88.96 | 140.5 |

1. Martin, M. J., Ed., Nuclear Decay Data for Selected Radionuclides, ORNL #5114, p. 24, March, 1976.

External Radiation

The specific gamma ray constant for Technetium Tc99m is 0.8 Rm/millicurie-hr at 1 cm. The first half-value layer is 0.2 mm of Pb. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table II. To facilitate control of the radiation exposure from millicurie amounts of this radionuclide the use of a 2.5 mm thickness of Pb will attenuate the radiation emitted by a factor of about 1.000.

Table II. Radiation Attenuation by Lead Shielding

| Shield Thickness (Pb) mm | Coefficient of Attenuation |
|--------------------------|----------------------------|
| 0.2 | 0.5 |
| 0.8 | 10 ⁻¹ |
| 1.6 | 10 ⁻² |
| 2.5 | 10 ⁻³ |
| 3.3 | 10 ⁻⁴ |

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

Table III. Physical Decay Chart; Tc99m, half-life 6.02 hours

| Hours | Fraction Remaining | Hours | Fraction Remaining |
|-------|--------------------|-------|--------------------|
| -5 | 1.778 | 5 | 0.562 |
| -4 | 1.585 | 6 | 0.501 |
| -3 | 1.413 | 7 | 0.447 |
| -2 | 1.259 | 8 | 0.398 |
| -1 | 1.122 | 9 | 0.355 |
| 0* | 1.000 | 10 | 0.316 |
| 1 | 0.891 | 11 | 0.282 |
| 2 | 0.794 | 12 | 0.251 |
| 3 | 0.708 | 18 | 0.126 |
| 4 | 0.631 | 24 | 0.063 |

*Calibration Time

CLINICAL PHARMACOLOGY

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.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

PRECAUTIONS

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 females.

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.

Radiation Dosimetry

The estimated absorbed radiation dose to an average patient (70 kg) from an intravenous injection of 20 millicuries of Technetium Tc99m-labeled OSTEOSCAN-HDP are shown in Table IV.

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

Table IV. Absorbed Radiation Doses*

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

*Method of calculation: "S" Absorbed Dose per Unit Cumulated Activity Selected Radionuclides and Organs, MIRD Pamphlet No. 1, 1975.

Preparations For Use

All procedures should be conducted using waterproof gloves. Use shielded syringe during transport and administration of Tc99m solutions.

- Remove metal disc from OSTEOSCAN-HDP vial and cleanse top by swabbing with alcohol. Note: If dose for a single patient, see unit dose preparation method below.
- Place vial in lead vial shield. Add 3-6 ml of sodium pertechnetate Tc99m solution and secure with a fitted lead cover. In choosing the amount of Tc99m radioactivity to be used, the number of doses desired, the activity of each dose (recommended adult dose is 15 mCi with a range of 10-20 mCi) and radioactive decay must be taken into account. The recommended maximum amount of Tc99m radioactivity to be added to the vial is 200 mCi. Note: The contents of the vial are now radioactive. Maintain adequate shielding using the lead vial shield and fitted lead cover during the life of the radioactive preparation.
- Shake the vial for approximately 30 seconds to assure complete dissolution.
- Record the time, date of preparation and the activity of the Tc99m-labeled OSTEOSCAN-HDP on the radiation label and affix this label to the shield.
- Use within eight (8) hours of preparation. Refrigeration of the radiolabeled complex is not necessary. Discard excess material in accordance with Nuclear Regulatory Commission or agreement state regulations pertaining to the disposal of radioactive wastes.

For preparing a dose for a single patient, to minimize volume injected and to insure optimum solution concentration, reconstitute the vial contents in 3-6 ml of sterile saline. Shake the vial for approximately 30 seconds to assure complete dissolution; withdraw and discard all but approximately 1 ml of the solution. Add appropriate amount of sodium pertechnetate Tc99m and shake. Proceed with steps 4 and 5. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.

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 vials (NDC 00019-N099-BO) or 30 vials (NDC 00019-N099-DO) are available. The drug can be stored at room temperature both prior to and following reconstitution with ADDITIVE-FREE sodium pertechnetate Tc99m.

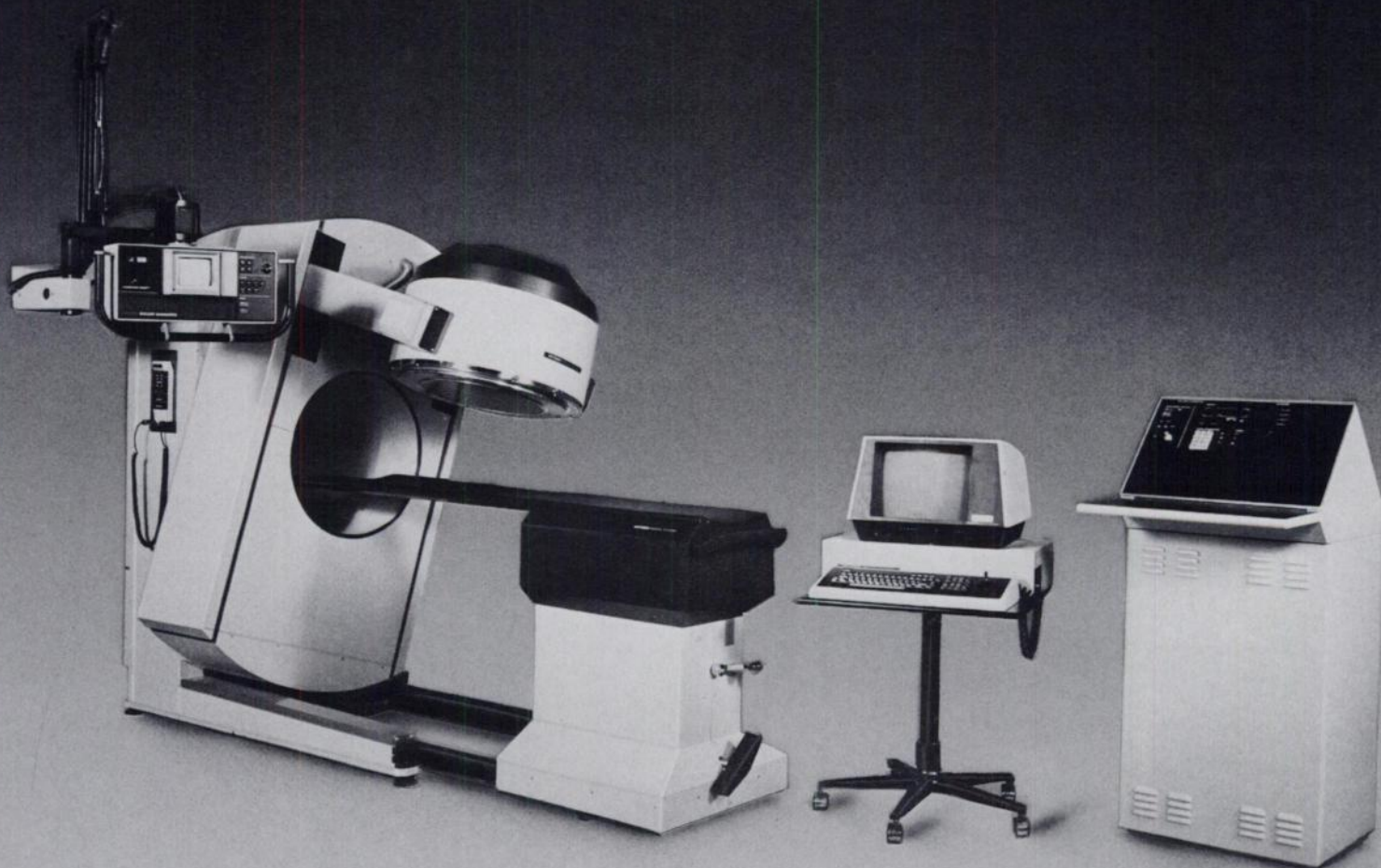


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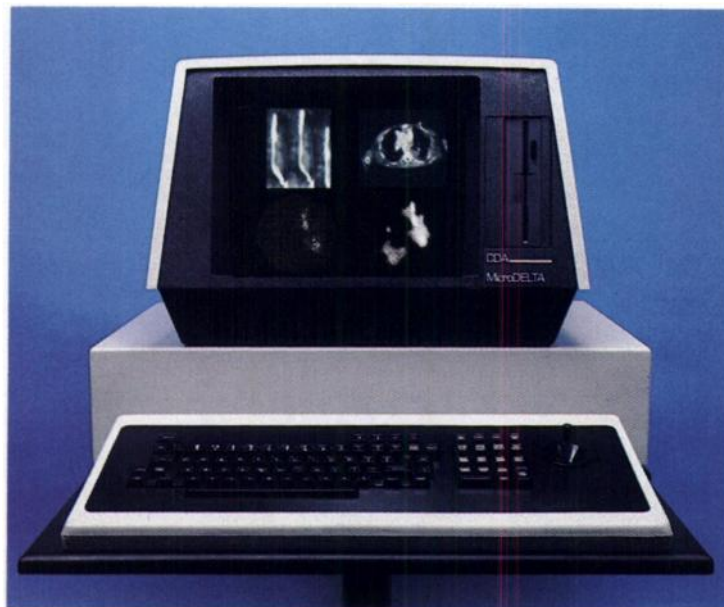
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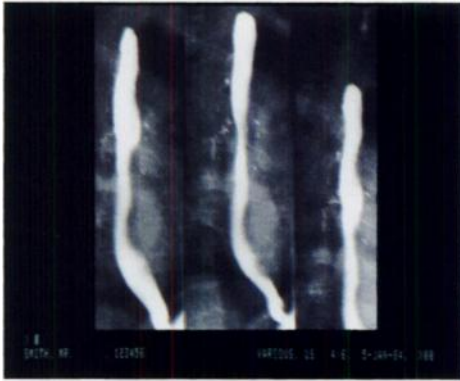
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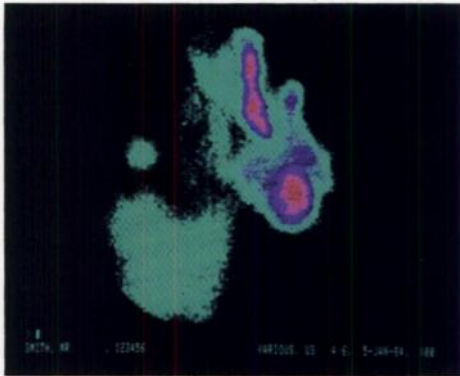




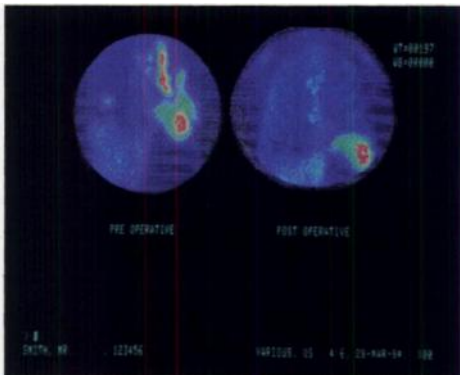
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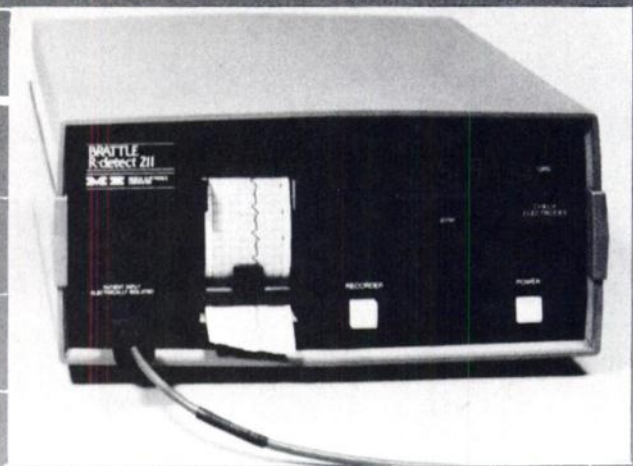
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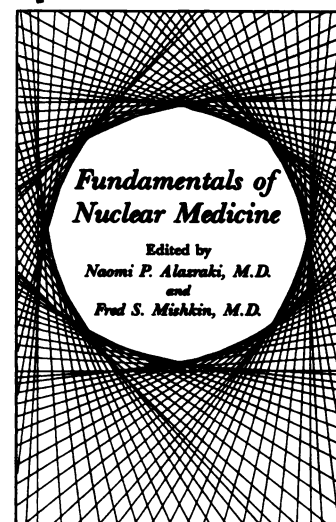
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**Naomi P. Alazraki, MD,
and Fred S. Mishkin, MD**

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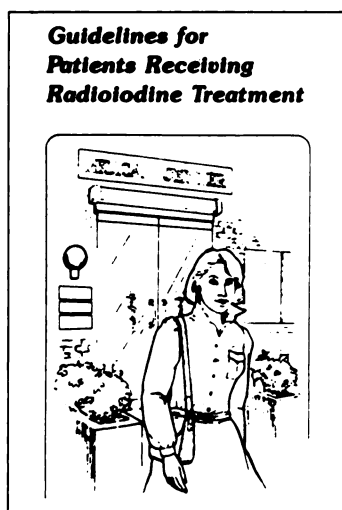
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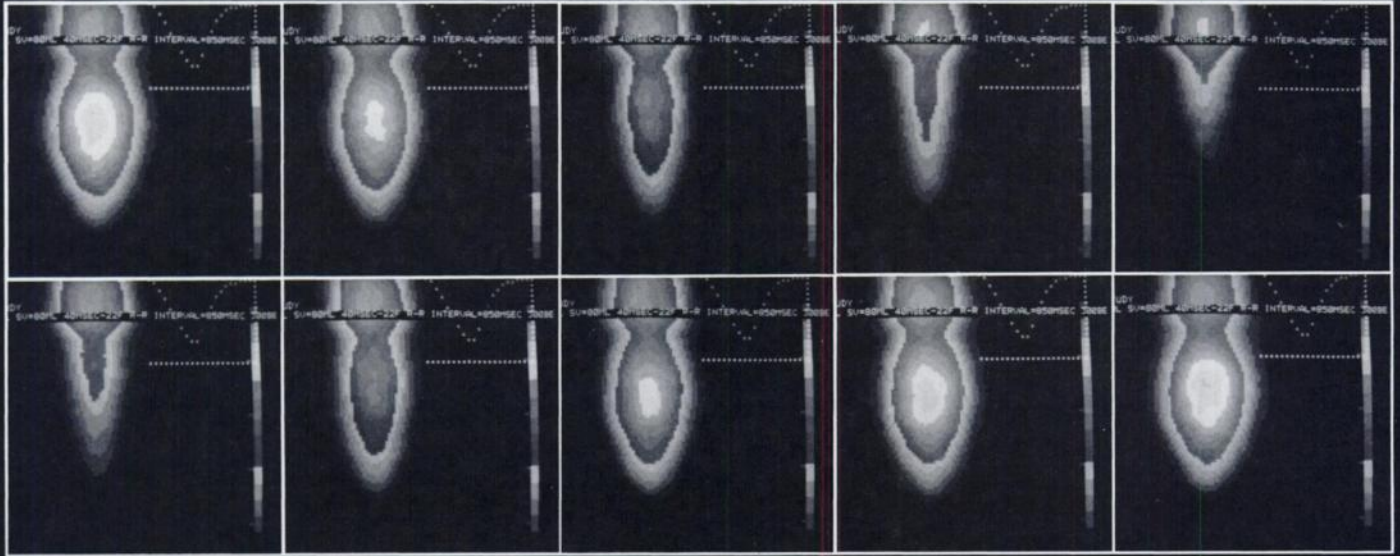
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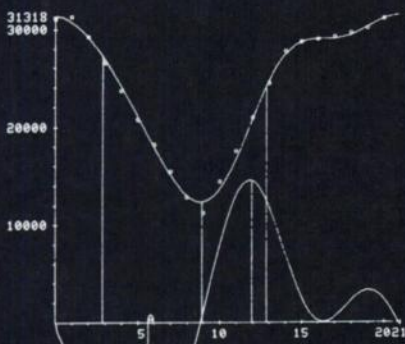
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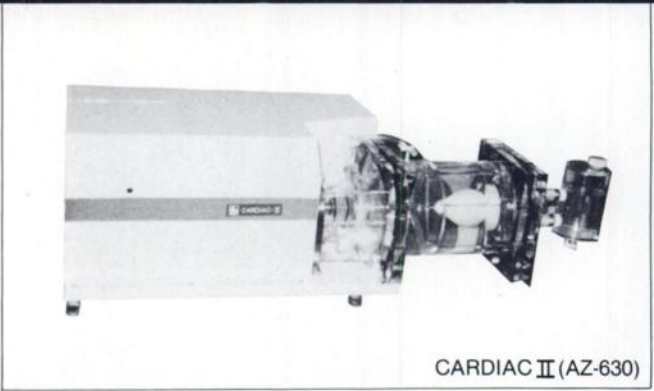
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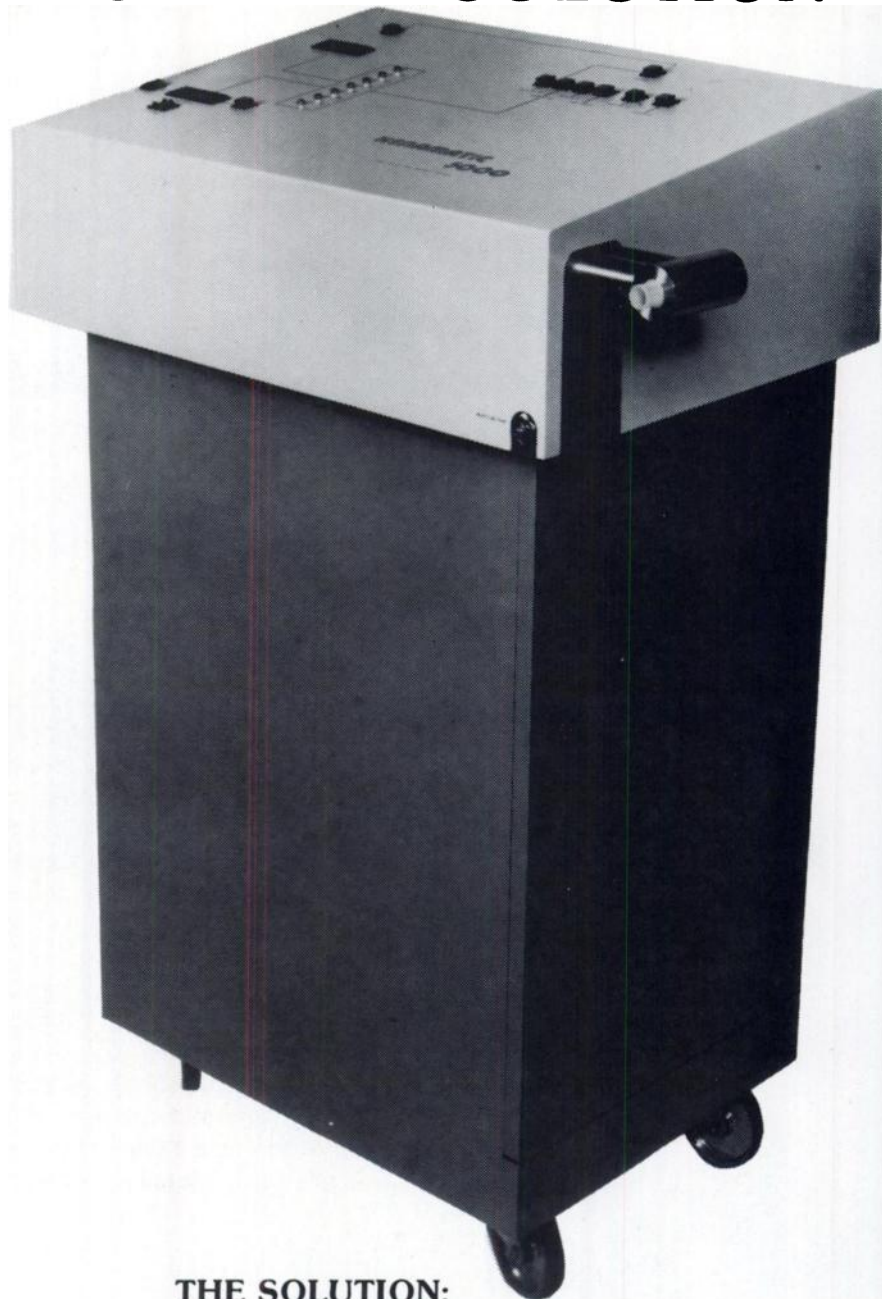
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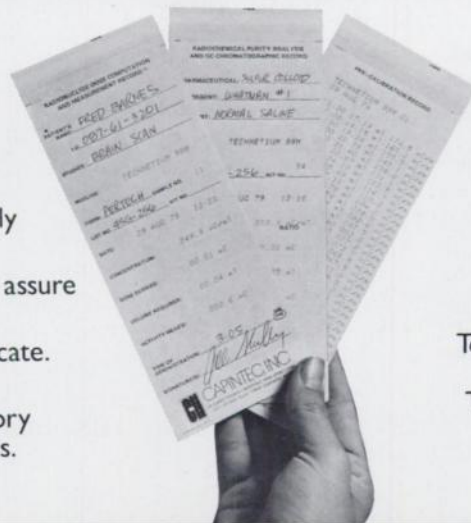
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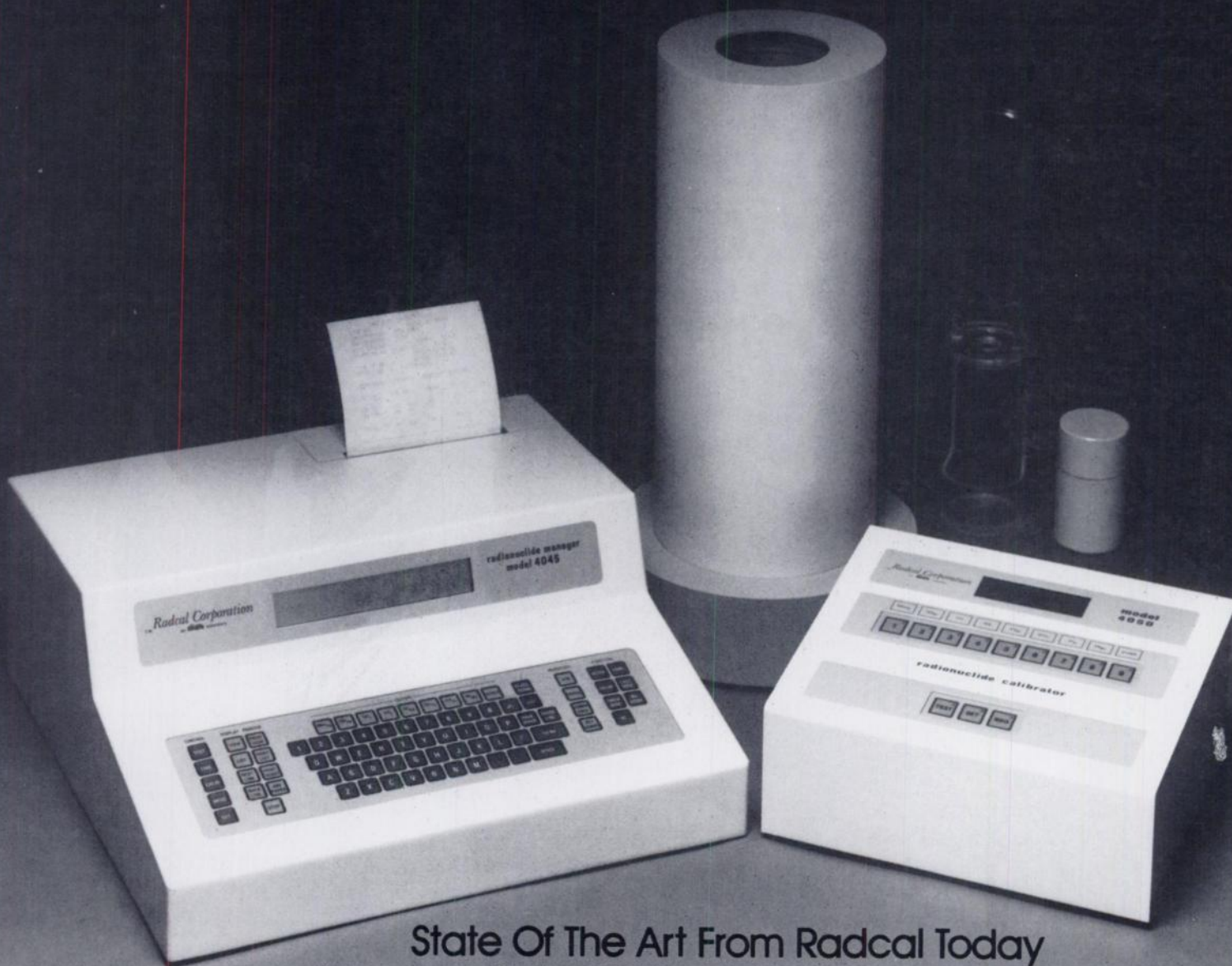
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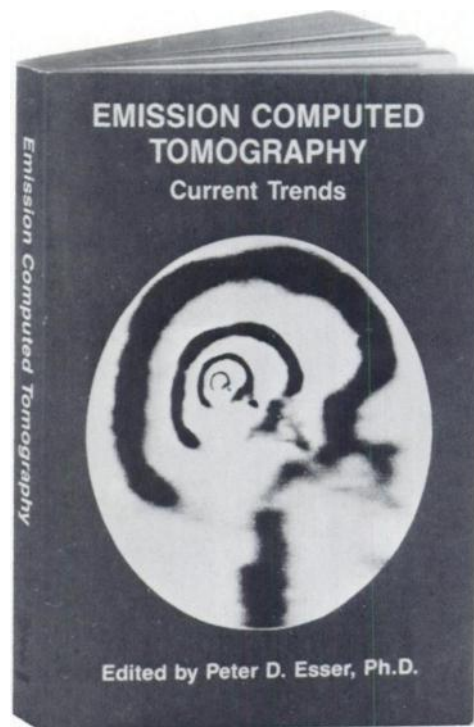
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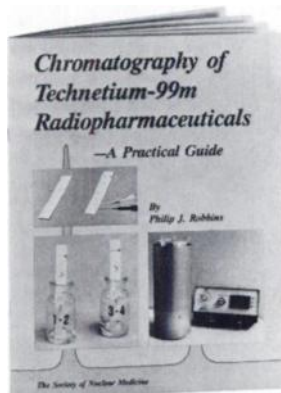
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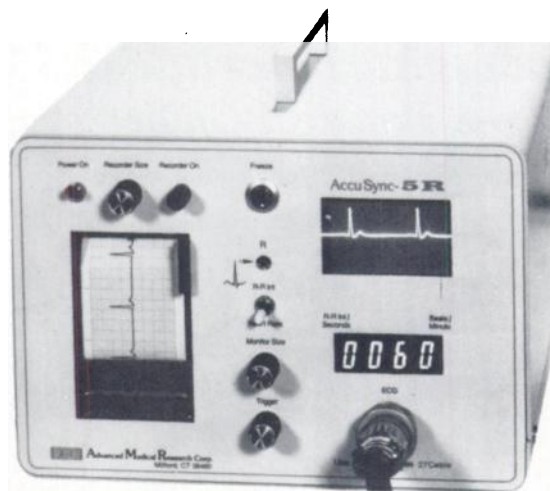
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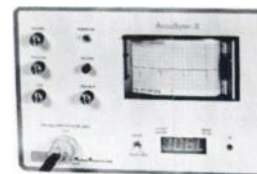
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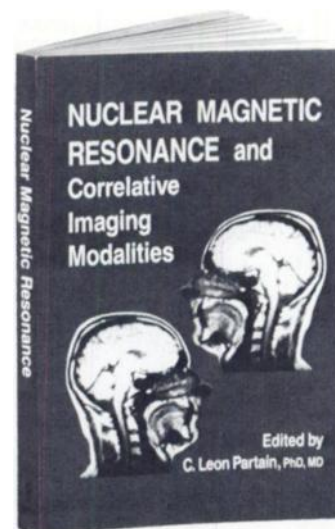
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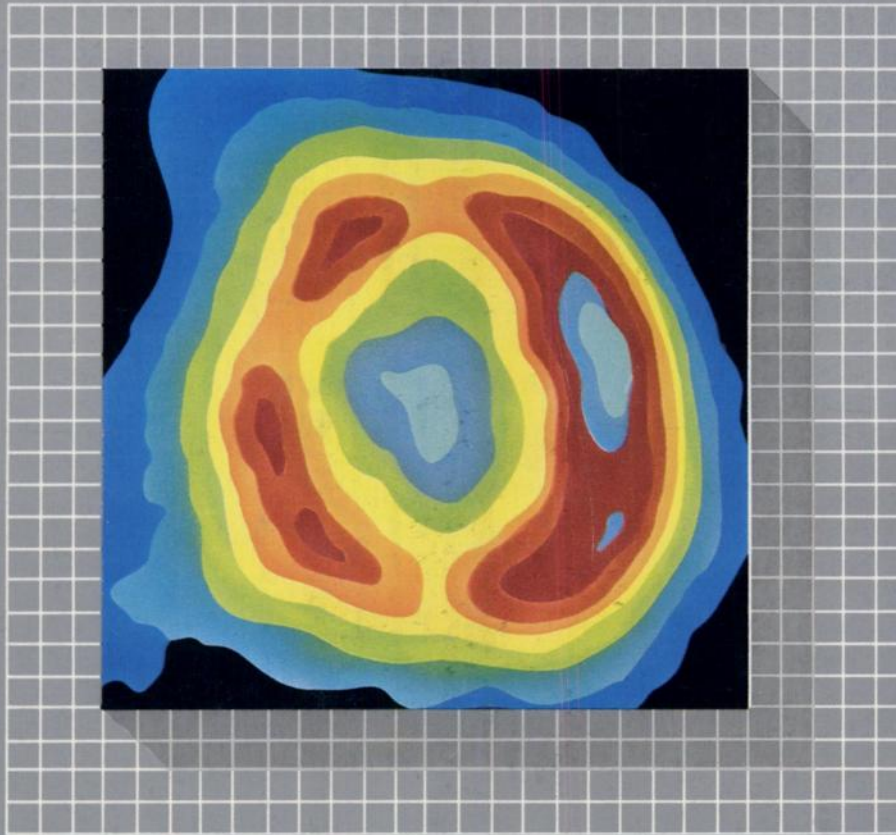
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DESCRIPTION: Thallous Chloride Tl 201 is supplied in isotonic solution as a sterile, nonpyrogenic diagnostic radiopharmaceutical for intravenous administration. Each unit dose contains 1 milliliter and each milliliter contains 2 millicuries of Thallous Chloride Tl 201 at calibration time, pH adjusted to 5.0–8.0 with hydrochloric acid and/or sodium hydroxide. Contains no bacteriostatic preservative. Thallium Tl 201 is cyclotron produced and is essentially carrier-free. Radionuclidic purity at calibration time is at least 96.0% with less than 1.0% Thallium Tl 200, 1.0% Thallium 202 and 0.2% Lead Pb 203. The concentration of each radionuclidic contaminant changes with time.

INDICATION AND USAGE: Thallous Chloride Tl 201 may be used in cardiac imaging to define the extent of myocardial infarction.

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

CONTRAINDICATIONS: None known.

WARNINGS: 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.

PRECAUTIONS

General

Do not use after the expiration time and date (4 days after calibration time) stated on the label.

Discard vial after single use. Do not use if contents are turbid.

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

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

Thallous Chloride Tl 201 as well as other radioactive drugs must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patient consistent with proper patient management.

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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or whether Thallous Chloride Tl 201 affects fertility in males or females.

Pregnancy Category C

Animal reproduction studies have not been conducted with Thallous Chloride Tl 201. It is also not known whether Thallous Chloride Tl 201 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Thallous Chloride Tl 201 should be given to a pregnant woman only if clearly needed.

Nursing Mothers

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 Thallous Chloride Tl 201 is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

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

HOW SUPPLIED: Thallous Chloride Tl 201 is supplied as a sterile, nonpyrogenic, isotonic solution in unit dose vials containing 1 milliliter. Each milliliter contains 2 millicuries of Thallous Chloride Tl 201 at calibration time. Contains no bacteriostatic preservative.



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