



Xenon

Xenon Xe 133

**How you like it
When you like it**

How you like it

MPI Xenon Xe 133 is now available in four product configurations—from unit dose to bulk:

- Ventilation Study System (V.S.S.)
- 10 mCi vials
- 20 mCi vials
- 1.3-1.7 Ci ampules (crushable and breaksealed)

When you like it

MPI Xenon Xe 133 delivery and calibration schedule—utmost convenience and optimal product use:

Product	1st Rec.	Calibrated
V.S.S.	Monday	Thursday
10 & 20 mCi vials	Monday Thursday	Thursday Monday
1.3-1.7 Ci Ampules	Monday	Prior Friday

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

Xenon Xe 133-V.S.S. For the study of pulmonary ventilation.

Xenon Xe 133 Gas Ampule & MPI Xenon Xe 133 Gas Vial.

For the study of pulmonary ventilation and assessment of cerebral blood flow.

DESCRIPTION: The Xenon Xe 133-Ventilation Study System consists of a sealed frangible capsule containing 10 millicuries \pm 20% of Xenon Xe 133 gas at calibration time and date with less than 1% carrier xenon in air. Xenon Xe 133 Gas vials is supplied as a carrier-free gas in concentrations of 10 to 50 mCi per milliliter of gas for inhalation. Xenon Xe 133 Gas Ampule is supplied as a carrier-free gas in 4 ml crushable or break-sealed glass ampule in concentrations of 0.43 to 0.33 Curie/ml. Xenon Xe 133 is produced by fission of Uranium-235. It is chemically and physiologically related to elemental xenon, a non-radioactive monoatomic gas which is physiologically inert except for anesthetic properties at high doses.

CONTRAINDICATIONS: None known.

WARNINGS: Xenon Xe 133 should not be administered to children or to patients who are pregnant, or to nursing mothers unless the benefits to be gained outweigh the potential hazards. Ideally, examinations using radio-pharmaceuticals, 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. 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.

There are no well-controlled studies in pregnant women which allow any conclusions as to the safety of Xenon Xe 133 for the fetus. Xenon Xe 133 should be used in pregnant women only when clearly needed.

Concentrated Xenon Xe 133 gas supplied in ampule must be diluted to the activity range appropriate to the route of administration.

PRECAUTIONS: Xenon Xe 133 gas 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.

Exhaled Xenon Xe 133 gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

Xenon Xe 133 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers for such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic.

ADVERSE REACTIONS: Adverse reactions specifically attributable to Xenon Xe 133 have not been reported.

HOW SUPPLIED: Each Ventilation Study System (V.S.S.) contains Xenon Xe 133 in a sealed frangible capsule containing 10 millicuries \pm 20% at calibration time and date stated on the label. Each Xenon Xe 133 Gas ampule is supplied in 4 ml crushable or break-sealed ampules containing 1.7 to 1.3 Curies. Each Xenon Xe 133 Gas vial contains 10 or 20 mCi of gas.

Safety, Convenience and Versatility

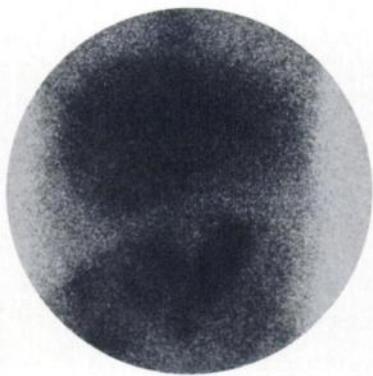
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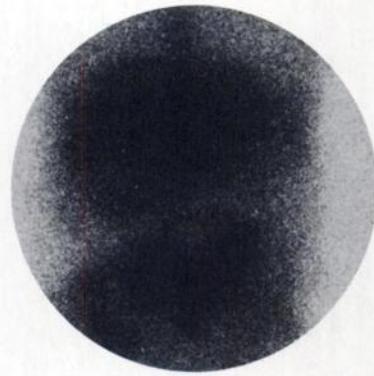
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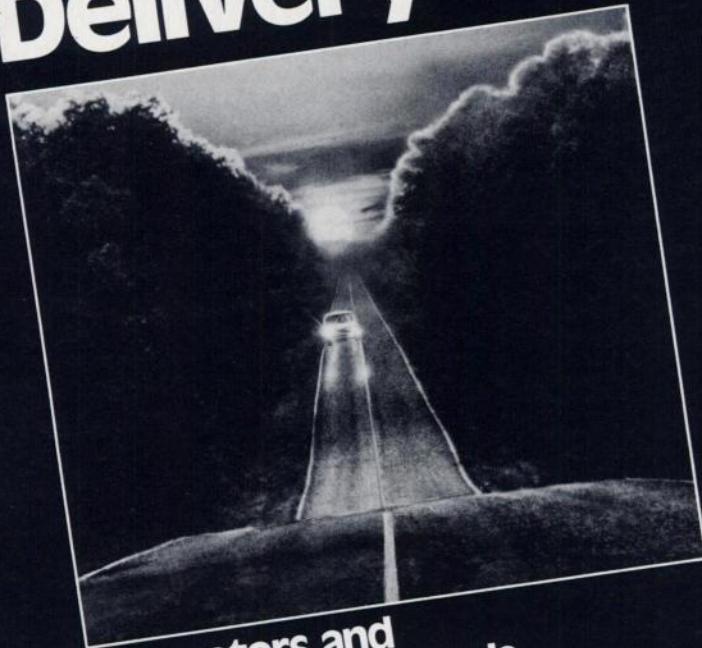
*Above scans were performed at 48 hours following an I.V. injection of 6mCi Ga-67 Citrate. Each image contains 500K counts. The two upper photopeaks were separately utilized. Imaging device was a 61 tube, large field of view, 3/8 in. crystal Gamma Camera.

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to Nuclear Medicine

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

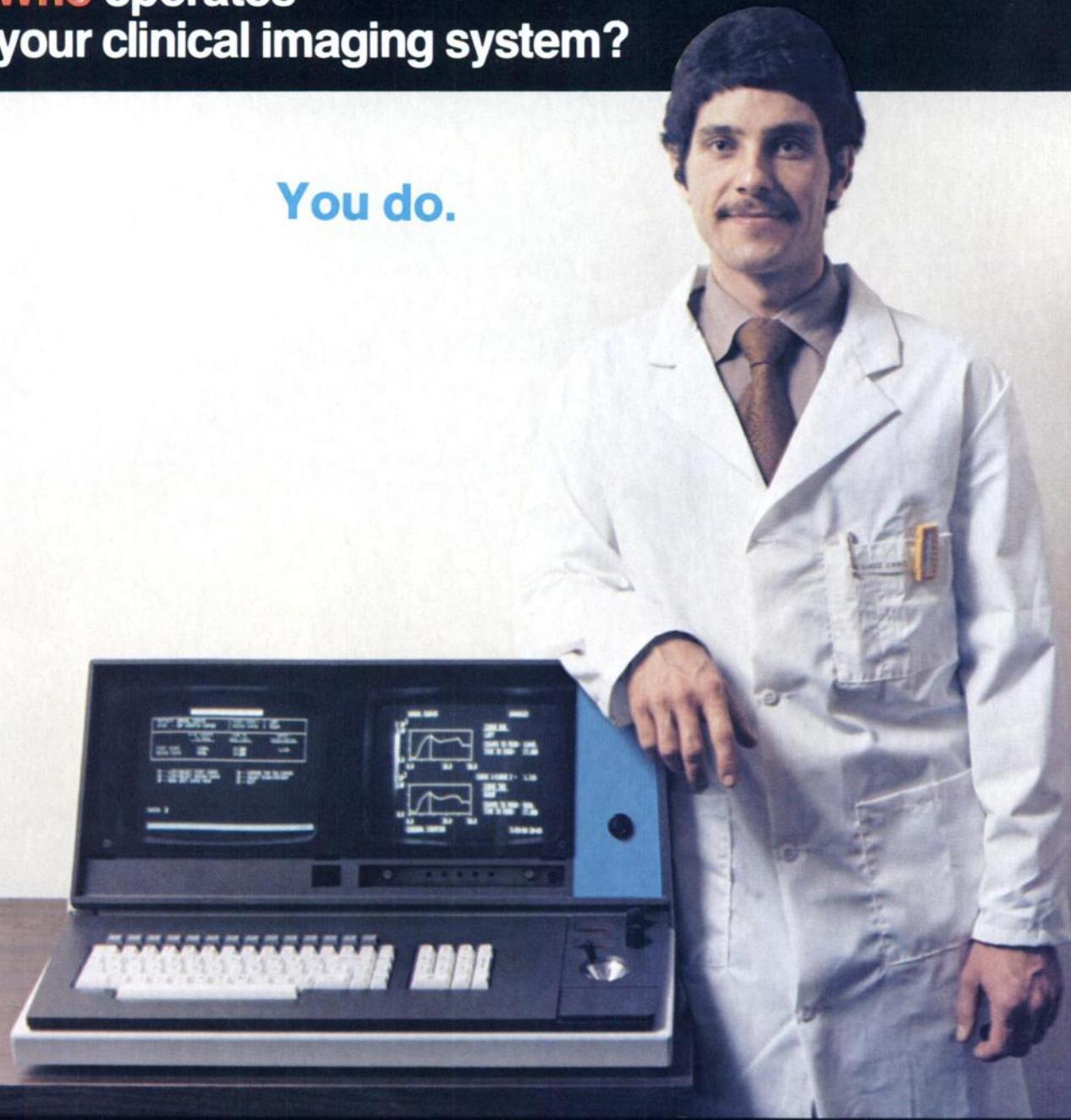


*In a recent independent survey of 400 nuclear medicine departments.
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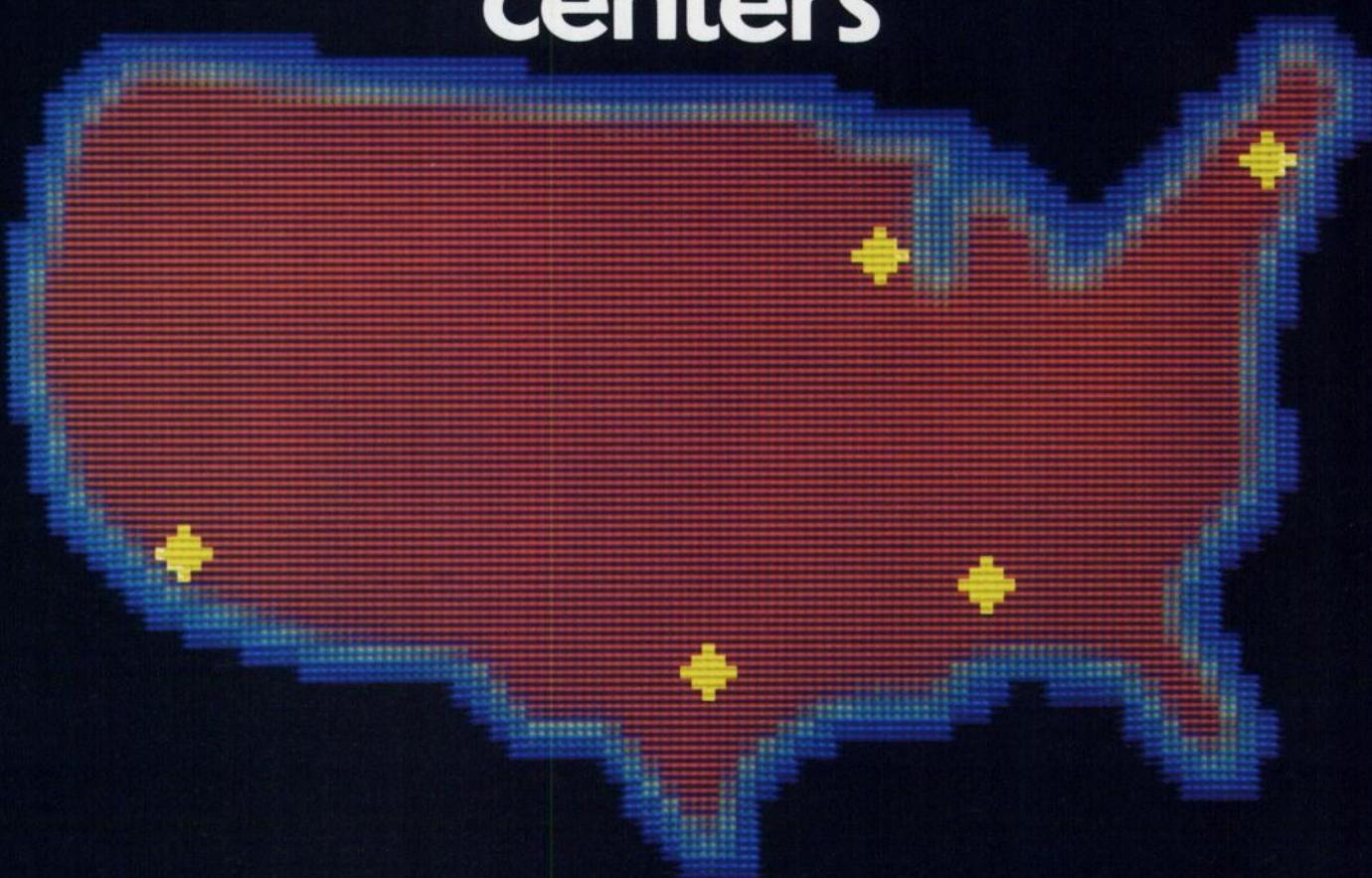
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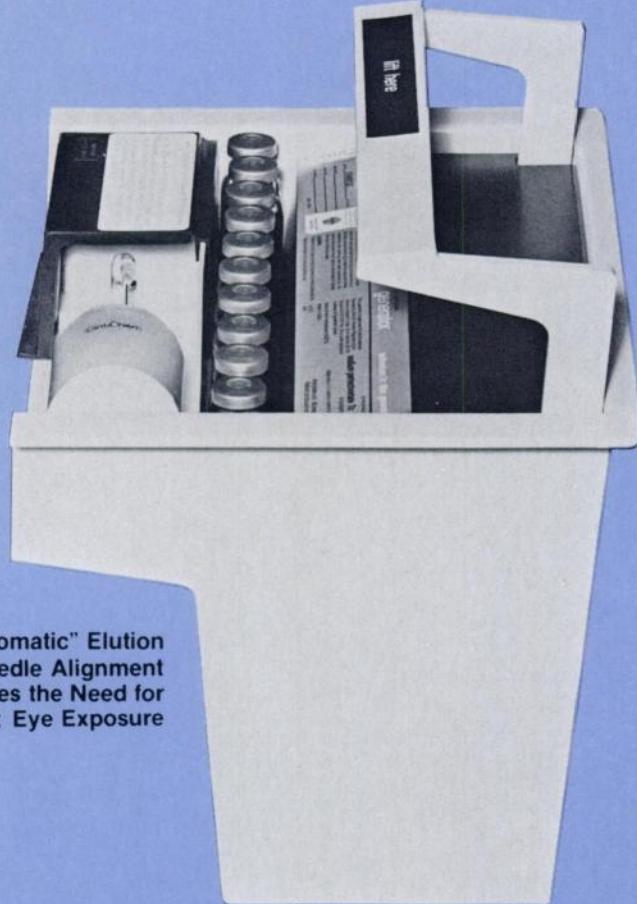
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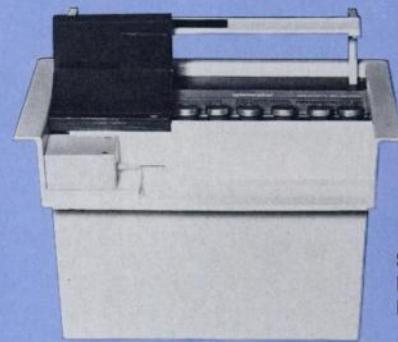
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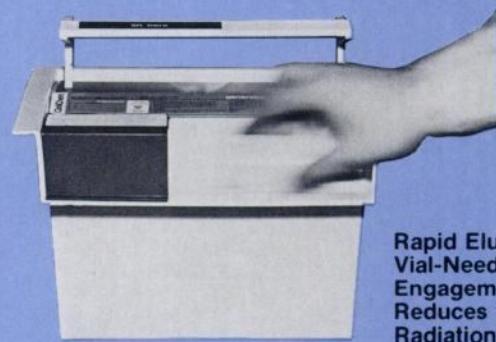
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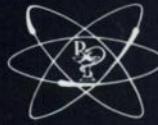
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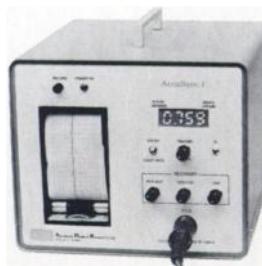
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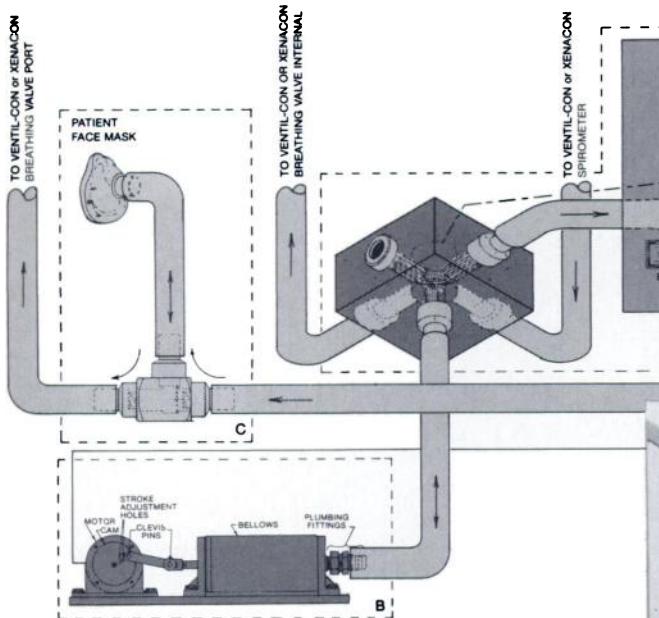
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Peter T. Kirchner, M.D., Editor

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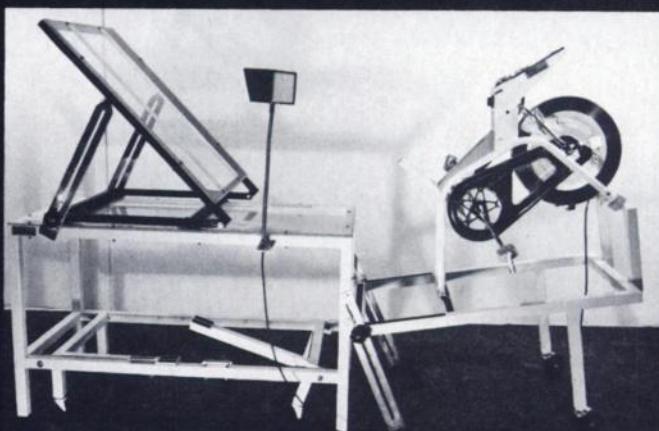
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Reads 0.1 to 100 MPC of ^{133}Xe . Features a large, easy-to-read panel meter, visual and audible alarm, and a recorder. A recorder chart will document the exposure record of your personnel: firm documentation for NRC or State inspections.

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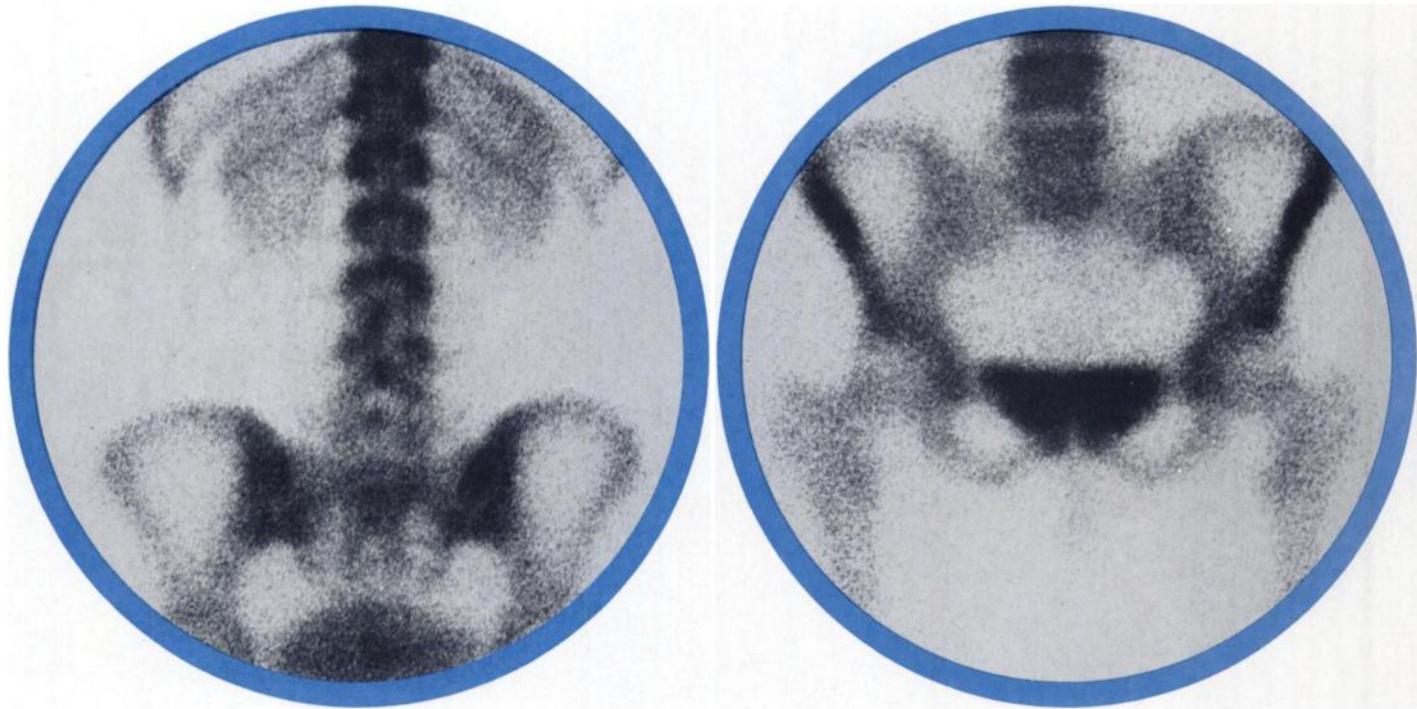
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Bone uptake superior to MDP

HDP shows unusually high adsorption to bone. In a clinical comparison, Osteoscan-HDP averaged 21% higher bone uptake than the MDP-based agent.¹

Scan data:

The two scans above are of a 52-year-old female patient with lower back pain. Scan: normal. Instrument: GE MaxiCamera™ 61; information density: 600 counts/cm²; dose 20 mCi; dose to image time: 3.5 hr.

Rapid blood clearance

No bone agent clears the blood faster. Only 6% of Osteoscan-HDP remains in the blood two hours after injection.² Osteoscan-HDP's rapid blood clearance contributes to the overall quality of the image and permits flexibility in scheduling patient scans from 1 to 4 hours post-injection.

References:

1. Fogelman, I. et al: Presented at the 1980 Annual Meeting, SNM, Southeastern Chapter.
2. Silberstein, E.B.: *Radiology* 136: 747-751, 1980.
3. Littlefield, J.L., and Rudd, T.C.: *Clin. Nucl. Med.* 5:S28, 1980 (abstr.).

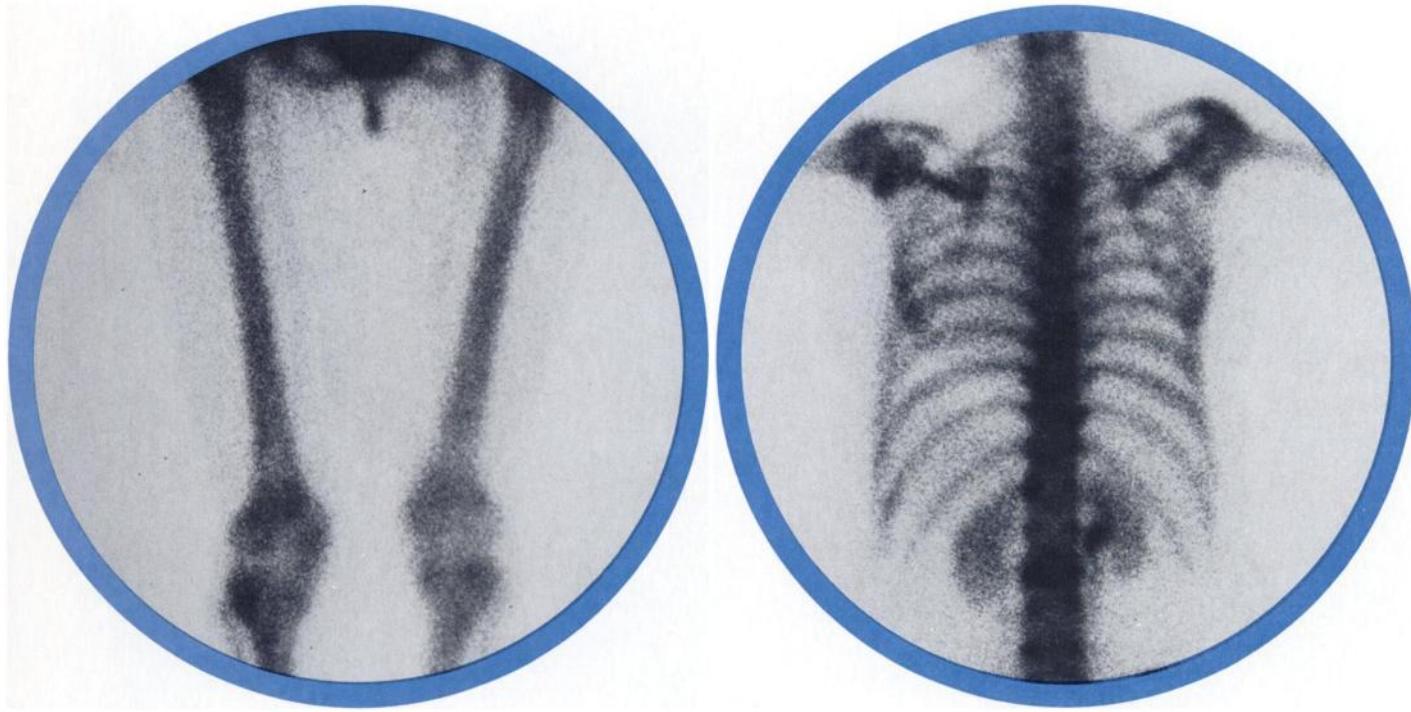
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Technetium Tc99m Oxidronate Kit



Unexcelled image quality³

Osteoscan-HDP's high bone uptake and rapid blood clearance permit clear visualization of skeletal detail even in difficult-to-scan elderly patients.

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Please see the following page for a brief summary of prescribing information.

High lesion sensitivity

HDP offers a high tumor-to-normal bone ratio. This results in high resolution scans capable of demonstrating subtle skeletal metastases and fractures with no sacrifice in overall image quality.

Scan data:

The two scans above are of a 59-year-old female patient with breast cancer.
Scan: abnormal deposits of radionuclide present in dorsal and lumbosacral spine.
Instrument: GE MaxiCamera™ 535;
counts: 2000K; dose 20.1 mCi;
dose to image time: 3 hr.



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OSTEOSCAN®-HDP

Technetium Tc99m Oxidronate Kit

INDICATIONS AND USAGE

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

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.

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.

HOW SUPPLIED

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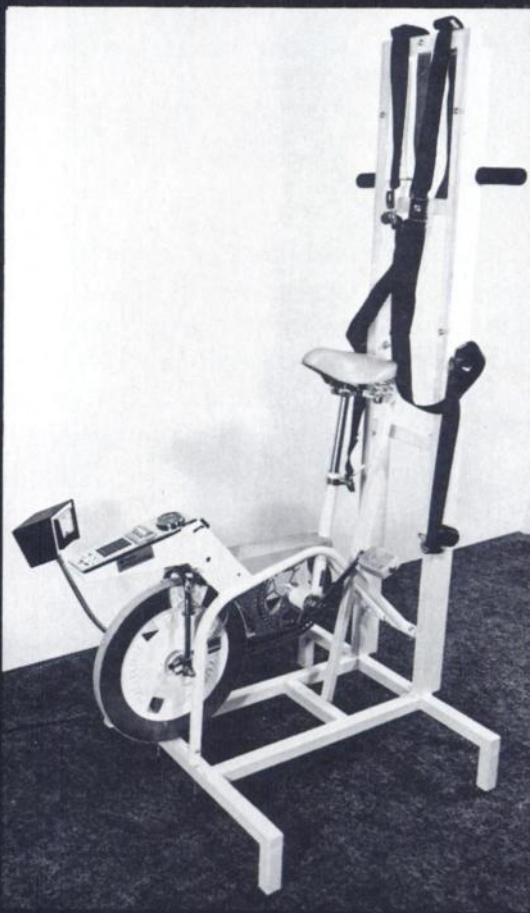
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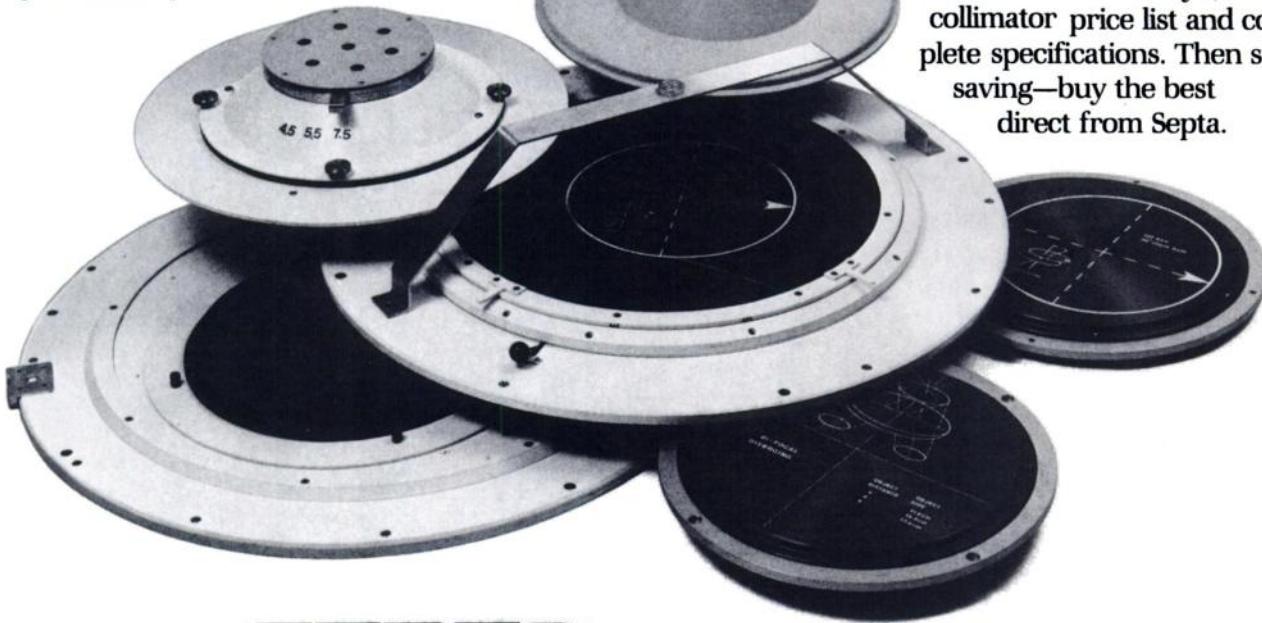
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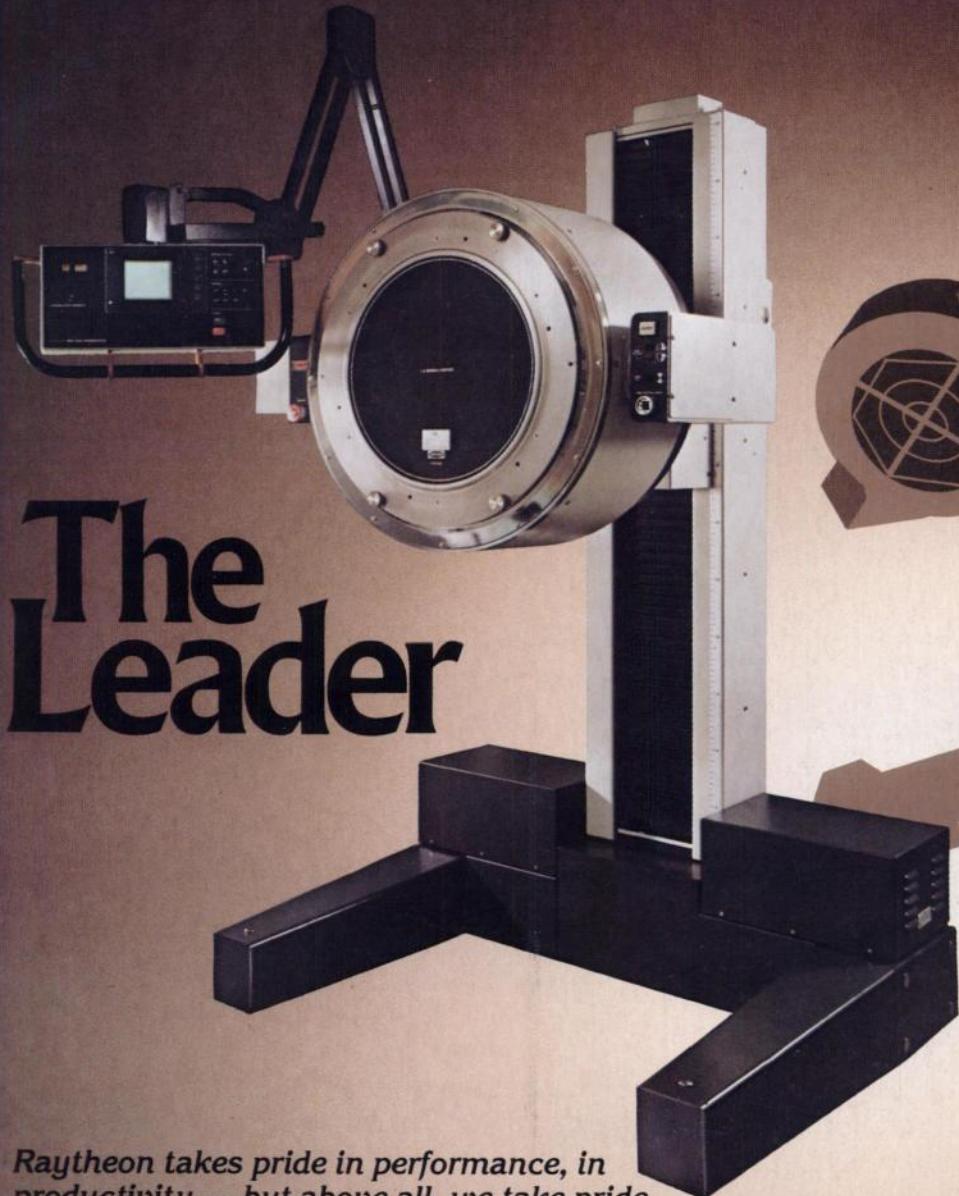
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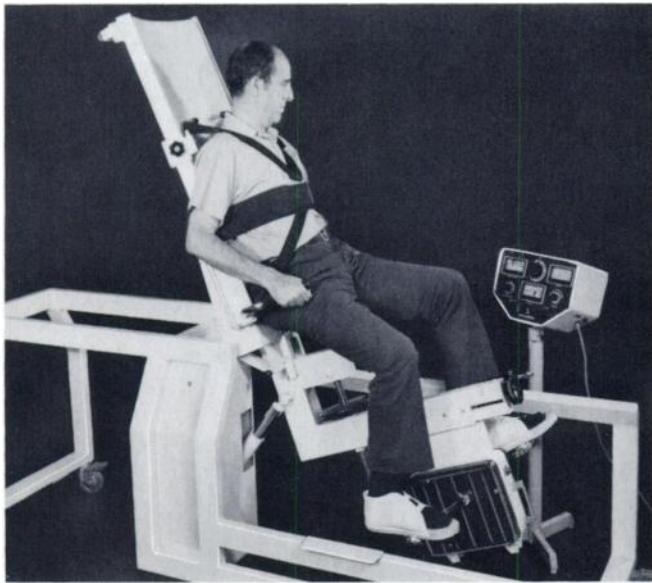


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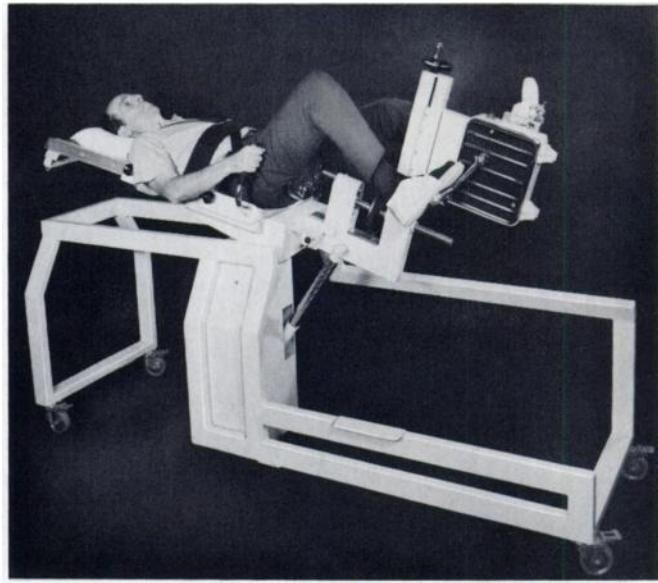
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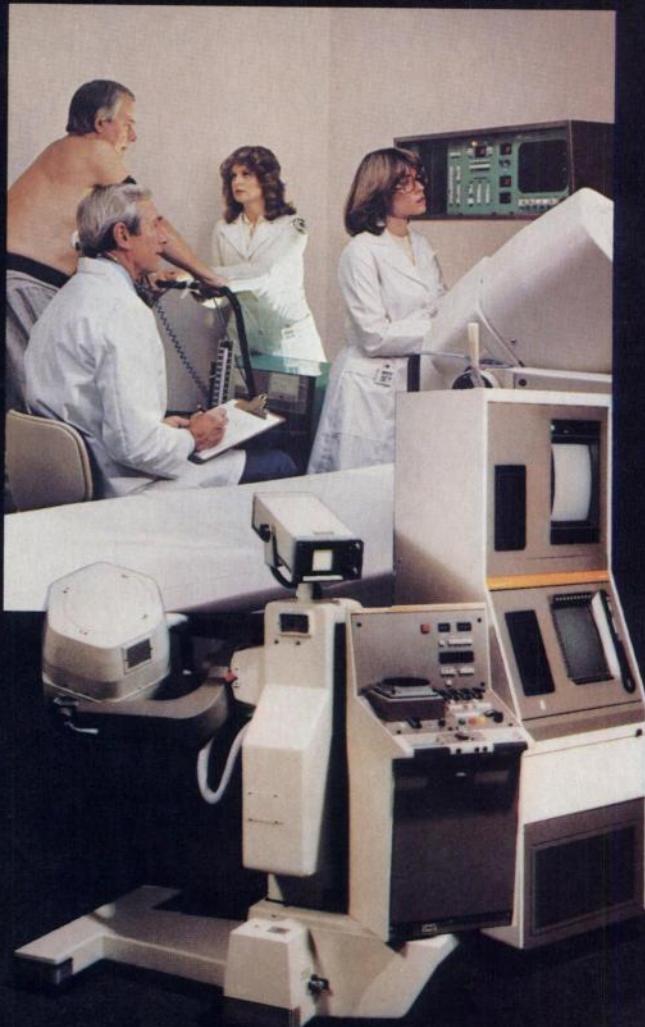
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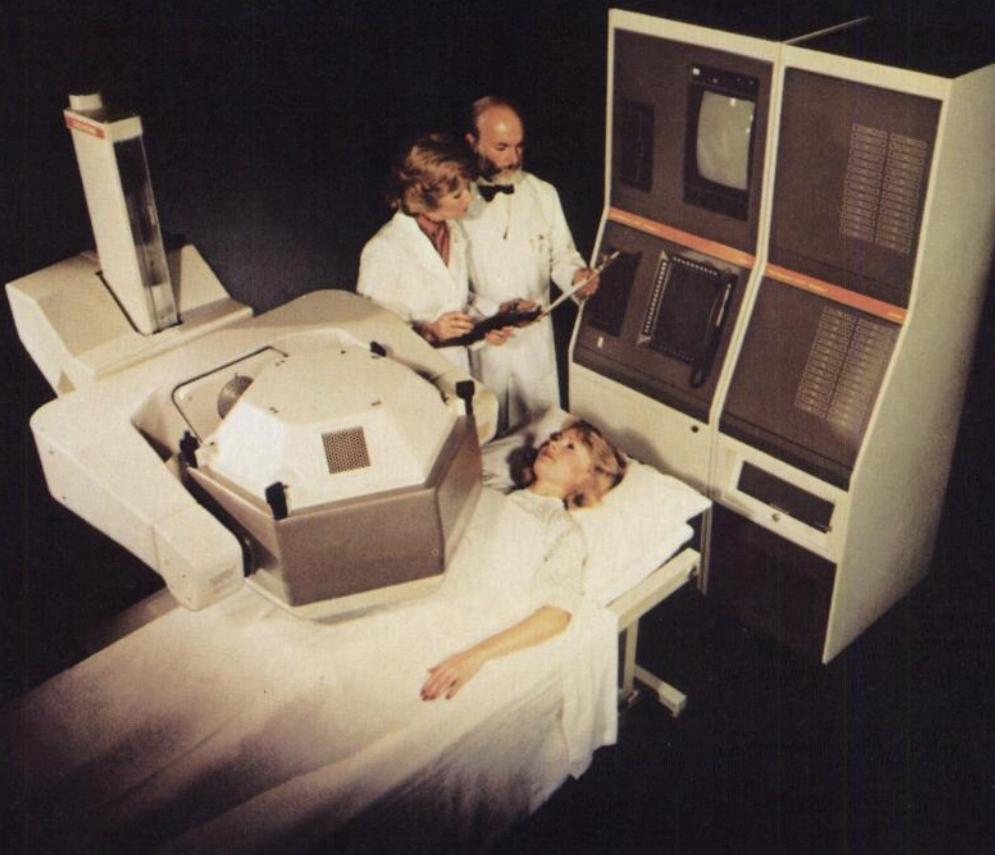
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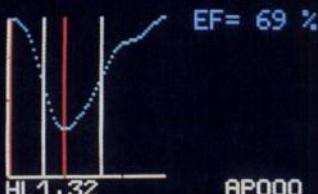


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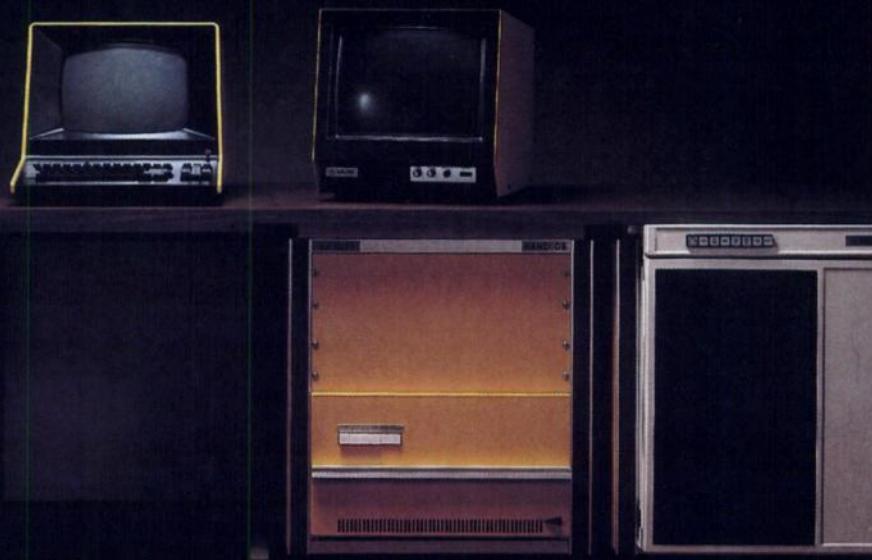
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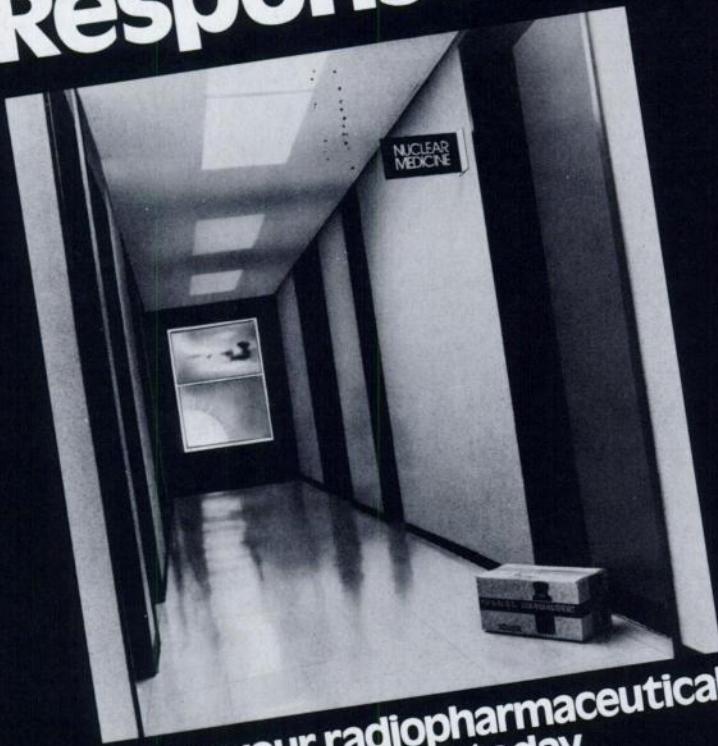
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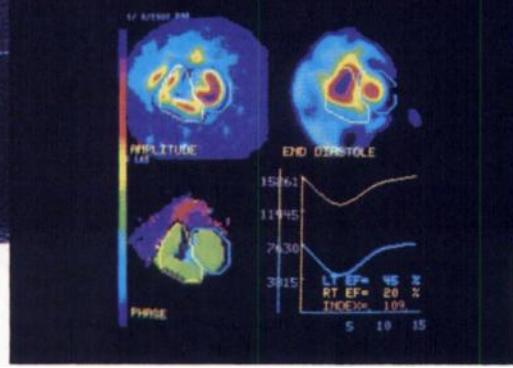
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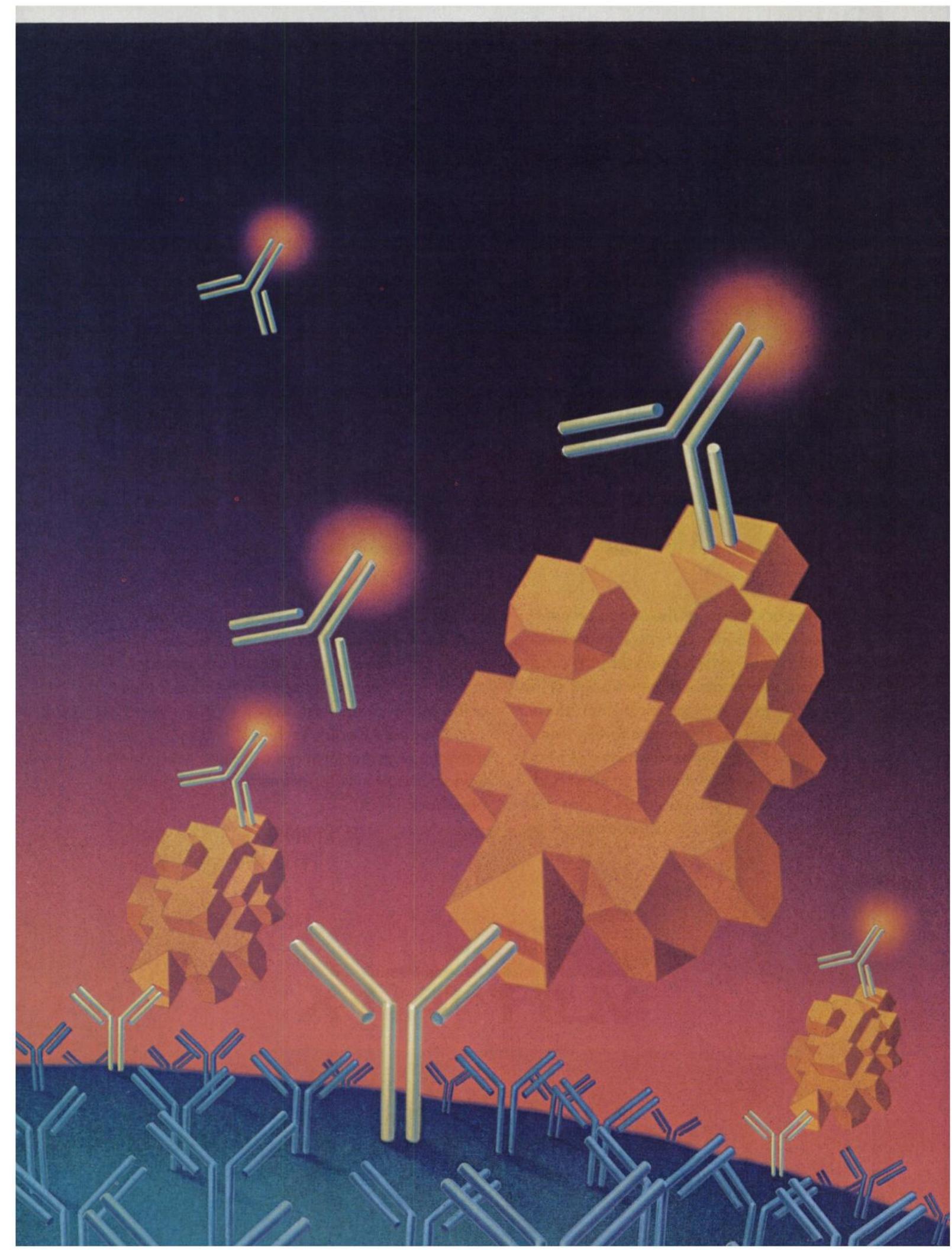
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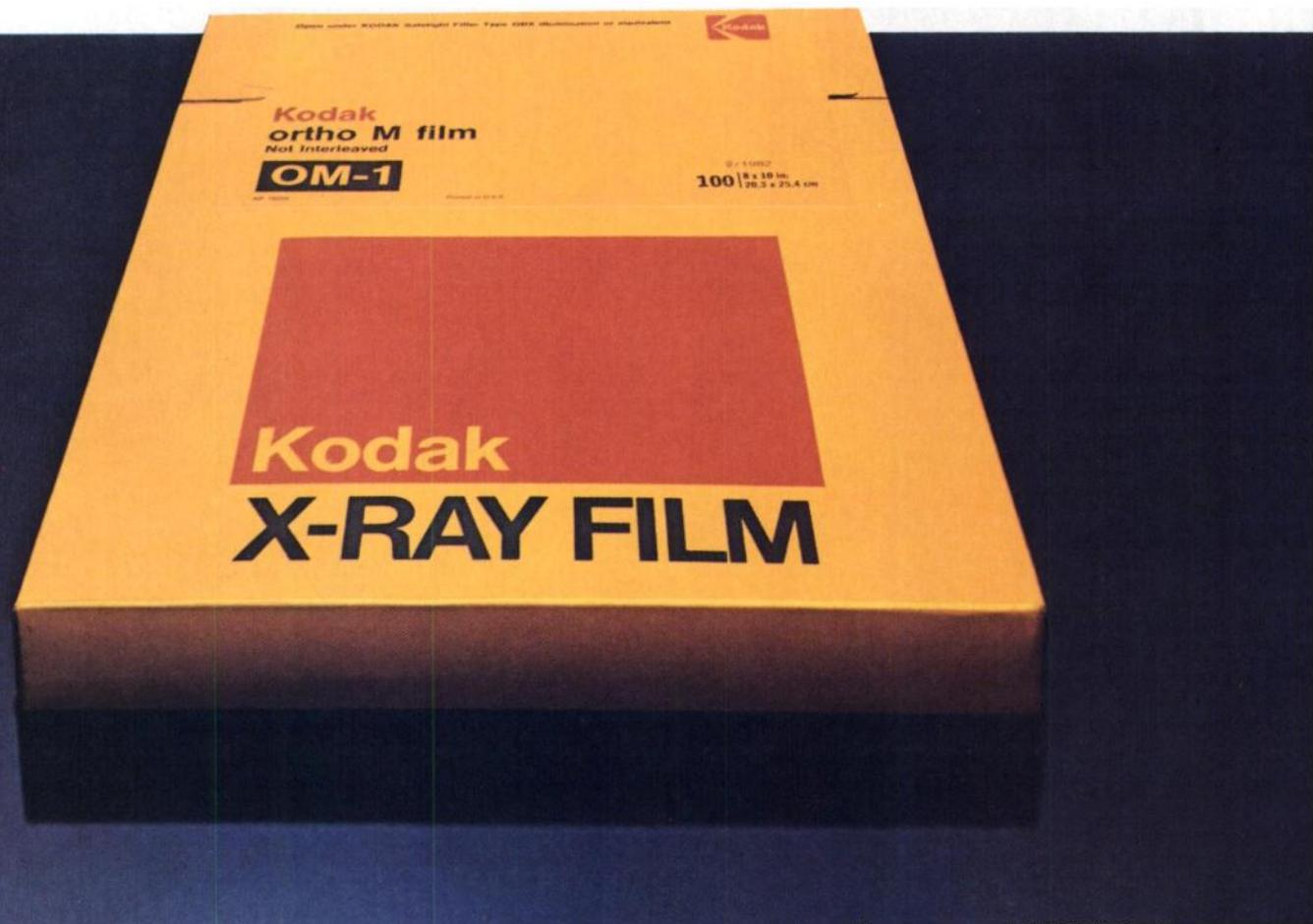
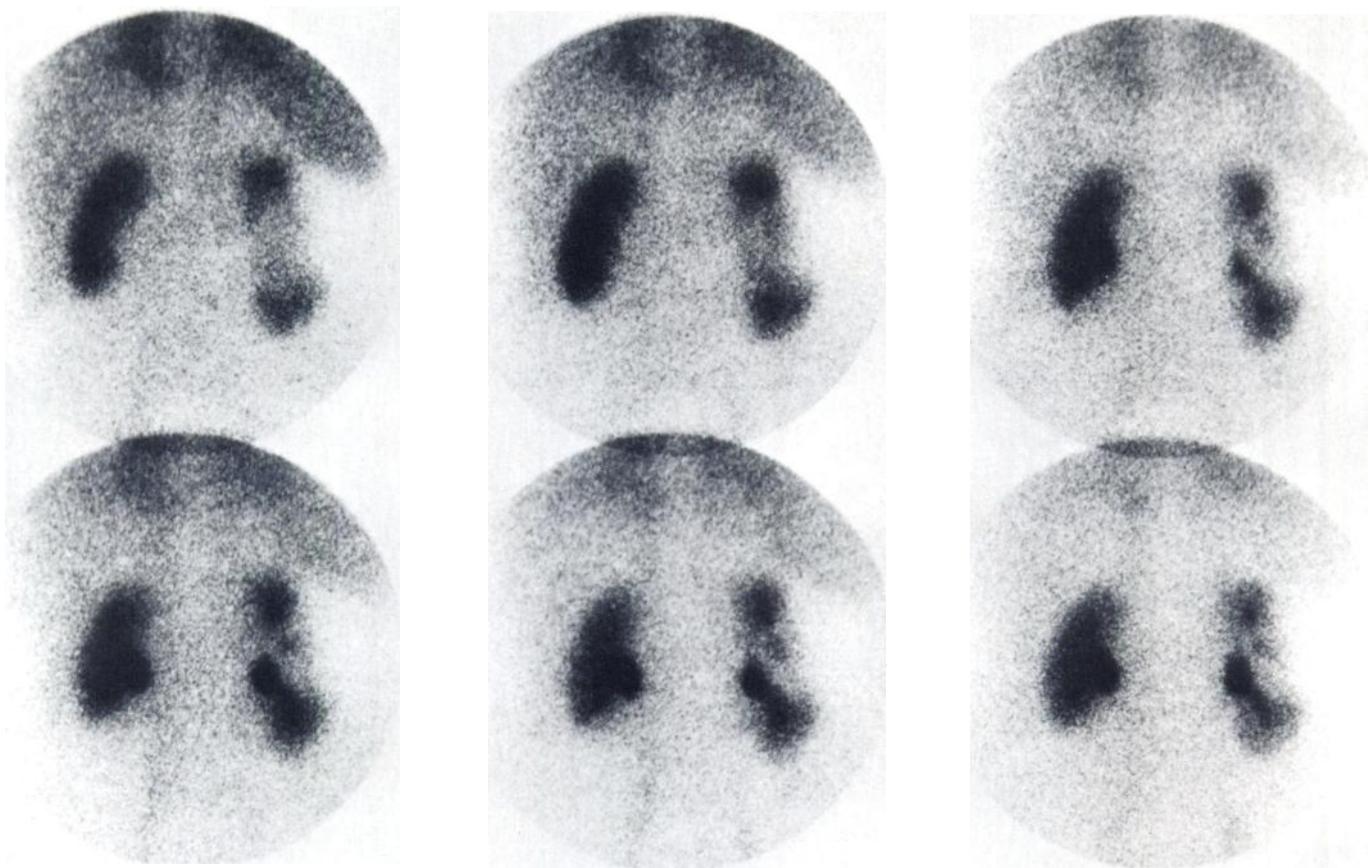
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THE GENESIS

Every field of scientific endeavor achieves, now and then, a milestone that history records as a quantum leap in understanding and capability.

Clinical chemistry logged one such milestone not quite twenty years ago when doctors Yalow and Berson demonstrated an exquisitely sensitive competitive binding assay. Their "radioimmunoassay" (RIA) is today the patriarch of immunochemical procedures.

More recently, historians recorded Professor Kohler's and Milstein's 1975 announcement of the first hybridoma cell line secreting MONOCLONAL ANTIBODIES of predefined specificity. Cell fusion and cloning have rapidly become essential techniques for biological and medical research for clinically relevant antigens heretofore invisible through the heterogeneous fog of conventional antiserum.

Many of the more "esoteric" clinical uses for monoclonal antibodies will require years of research before they become routinely applicable. But there is a need today for test systems which provide more economical and reliable results.

THE TECHNOLOGY

For clinical chemistry, monoclonal antibodies may impact the clinical laboratory more broadly than did the introduction of RIA.

Immunochemistry textbooks have noted for years that the two site "immunoradiometric assay" (IRMA) labeled antibody offers three important advantages over the RIA labeled antigen technique:

- **Direct signal-to-concentration readout**

IRMA measures the quantity of labeled antibody bound to antigen as a direct function of analyte concentration. IRMA curves rise from low to high analyte levels just like other well-behaved clinical chemistry curves. The result is a broader, more reliable detection range.

- **Antibody excess**

In an IRMA assay, both the solid phase and tracer antibody can be present in excess which makes control of the concentration of these components less critical. In contrast, competitive binding assays such as RIA require that antigen, antibody, and specimen maintain precise consistent proportions. The practical difficulties of controlling these three mass quantities, either at the manufacturer or customer level, explains the disappointing precision one may experience with RIA.

- **Labeled antibody**

Iodination procedures and radioactive decay alter the "personality" of antigens and deteriorate the delicate ligand-receptor balance of competitive binding RIAs. Antibodies, on the other hand, are more resistant to degradation occurring with radioiodination than are most antigen molecules. Thus, the tracer in IRMA assays tends to be more stable and consistent. Moreover, IRMA assays operate in antibody excess and can afford some loss in immunoreactivity.

Theory is all very interesting, but the reality remains that most immunoassay kits today are based on RIA and not IRMA.

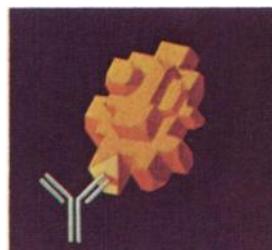
Fundamentally, when constrained to conventional antiserum, IRMA suffers problems which restrict its clinical application. Hybridomas solve these problems by providing monoclonal antibodies with the following key parameters:

- **Homogeneous, consistently high affinity**

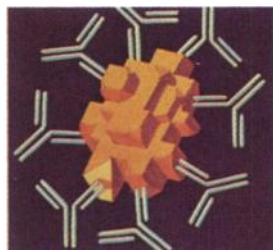
The principal requirement for IRMA assays is large quantities of homogeneous, consistently high affinity antibodies. Conventional antisera cannot meet this standard without complex, costly affinity chromatography purification that tends to remove the highest affinity antibodies. Properly selected monoclonal antibodies, in contrast, are perfect for packing to high densities on solid phase carriers or for labeling as tracer reagents.

- **Binding site targeting**

Conventional antiserum is a heterogeneous mix of antibody specificities to the separate binding sites on complex antigens. The resulting random alignment of antigen in the sandwich matrix may reduce tracer binding through steric hindrance and molecular blocking. To prevent the soluble tracer antibodies from quickly masking binding sites needed for the solid phase antibodies, most RIAs available today first incubate specimen alone in the presence of solid phase antibody. The second incubation with antibody tracer means the test is run twice, a decidedly inconvenient feature for busy clinical laboratories. Monoclonal antibodies, in contrast, can be precisely selected to optimize the sandwich geometry without antibody interference. Binding is high and consistent, and simultaneous reagent incubation is possible.



Monoclonal -
antibody - antigen reaction



Polyclonal
antibody - antigen reaction

Monoclonal antibodies make practical the theoretical advantages of IRMA methodology. There remains, however, the considerable product development challenge of harnessing the new areas of cell biology and immunochemistry to the exacting performance standards of the clinical environment. And herein lies the Tale of Two Sites . . .

THE FUTURE

Hybritech Incorporated is an immunochemistry company totally dedicated to the application of cell fusion technology to clinical needs. We have applied our growing expertise in these new fields to the development of our first generation of tests—the TANDEM™ Assay System*.



TANDEM Bead

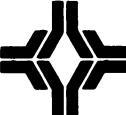
The TANDEM system—which applies monoclonal antibodies to IRMA methodology—represents a milestone in simplicity. The large illustration, opposite, demonstrates the use of two different monoclonal antibody reagents for the quantitative immunoassay procedure. A bead is coated with a monoclonal antibody of a certain class with specificity for a selected site on the antigen of interest. The labeled antibody specific for a different selected site on the opposite end of the same antigen, represents the second reagent in the *in vitro* test system. The TANDEM system allows you to simultaneously add solid phase, specimen and tracer, perform one incubation and one wash, then simply count and calculate.

The technology used in the TANDEM system translates into these key benefits:

- Precision
- Linear calibration in the critical ranges
- Reproducibility — lot to lot
- Fewer and less critical pipetting steps
- Procedural simplicity — analyte to analyte

In fact, TANDEM assays are so reliable, you may wish to eliminate duplicate specimen testing . . . the economy of consistent reliability.

We at Hybritech believe we have quite a tale to tell, and we look forward to demonstrating our new family of TANDEM assays, pending FDA clearance. If you would like more information on hybridoma and monoclonal antibody technology, or on the individual TANDEM assays as they are cleared for *in vitro* diagnostics, please let us know. We think "it is a far, far better thing . . ."

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†patent pending

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TechneScan® MDP

Technetium Tc 99m Medronate Sodium Kit

Earlier images



with high target-to-background ratio.

When injected intravenously, TechneScan MDP clears rapidly from blood and soft tissue to accumulate in the skeleton and gives a high contrast image as early as two hours after administration.

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See brief summary on following page.

THE MALLINCKRODT COMMITMENT

to Nuclear Medicine

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

Mallinckrodt®
Diagnostics

TechneScan® MDP –Technetium Tc 99m Medronate Sodium Kit

DIAGNOSTIC

DESCRIPTION

The kit consists of reaction vials which contain the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce technetium Tc-99m medronate for diagnostic use by intravenous injection.

Each 10 ml reaction vial contains 10 mg medronic acid complexed with 0.8 mg (min.) stannous chloride (0.64 mg maximum tin) in lyophilized form under an atmosphere of nitrogen. Sodium hydroxide or hydrochloric acid have been used for pH adjustments. The addition of sodium pertechnetate Tc-99m sterile solution produces a rapid labeling which is essentially quantitative and which remains stable *in vitro* throughout the useful life of the preparation. No bacteriostatic preservative is present.

The precise structure of the reaction vial complex or of its technetium labeled form is not known at this time.

PHYSICAL CHARACTERISTICS

Technetium Tc-99m decays by isomeric transition with a physical half-life of 6.02 hours.¹ The principal photon that is useful for detection and imaging studies is listed in Table I.

TABLE I PRINCIPAL RADIATION EMISSION DATA

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

External Radiation

The specific gamma ray constant for Tc-99m is 0.8 R/mCi-hr at 1 cm. The first half value layer is 0.2 mm of Pb. To facilitate control of the radiation exposure from milliecurie amounts of this radionuclide, the use of a 2.7 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
0.95	10 ⁻¹
1.8	10 ⁻²
2.7	10 ⁻³
3.6	10 ⁻⁴
4.5	10 ⁻⁵

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

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

TABLE III PHYSICAL DECAY CHART: Tc 99m, 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

When injected intravenously technetium Tc-99m medronate is rapidly cleared from the blood and accumulates in the skeleton and urine. The skeletal uptake is bilaterally symmetrical being greater in the axial skeleton than in the long bones. Areas of abnormal osteogenesis show altered uptake making it possible to visualize a variety of osseous lesions.

Studies in humans show that, following intravenous injection, about 10% of the injected dose remains in the bloodstream at the end of one hour. This value continues to drop rapidly, being down to about 5% at 2 hours. The resultant disappearance curve appears to be tri-exponential, the two fast components accounting for all but a few percent of the injected activity.

Conversely, there is a rapid deposition in bone and rapid urinary excretion. The rapid blood clearance provides bone to soft-tissue ratios which favor early imaging.

INDICATIONS AND USAGE

Technetium Tc-99m medronate is a skeletal imaging agent used to demonstrate areas of altered osteogenesis as seen for example in metastatic bone disease, Paget's disease, arthritic disease and osteomyelitis.

CONTRAINDICATIONS

None known at present.

WARNINGS

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

Ideally, examinations using radiopharmaceuticals, especially those elective in nature, in women of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses. This class of compound is known to complex cations such as calcium. Particular caution should be used with patients who have, or who may be predisposed to, hypocalcemia (i.e., alkalosis).

PRECAUTIONS

General

The finding of an abnormal concentration of radioactivity implies the existence of underlying pathology, but further study is required to distinguish benign from malignant lesions.

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

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

The preparation contains no bacteriostatic preservative. Therefore, after labeling with technetium Tc-99m the solution should be stored at 2-8°C and discarded after 6 hours.

The image quality may be adversely affected by obesity, old age and impaired renal function.

Carcinogenesis

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

Pregnancy

Adequate reproductive studies have not been performed in animals to determine whether this drug affects fertility in males or females, has teratogenic potential, or has other adverse effects on the fetus. There have been no studies in pregnant women. Technetium Tc-99m medronate should be used in pregnant women only when clearly needed.

Nursing Mothers

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

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

At present adverse reactions have not been reported that are specifically attributable to the use of technetium Tc-99m medronate.

DOSAGE AND ADMINISTRATION

The recommended adult dose is 10 to 20 mCi (200 µCi/kg) by slow intravenous injection over a period of 30 seconds. Optimum scanning time is 1 to 4 hours post-injection.

The patient should be encouraged to drink fluids before and after the examination and to void immediately before imaging is started. This is to minimize the contribution of the bladder content to the image.

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

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

Radiation Dosimetry

The estimated absorbed radiation doses² to an average patient (70 kg) from an intravenous injection of a maximum dose of 20 mCi of technetium Tc-99m medronate are shown in Table IV.

²Method of calculation: A Schema for Absorbed-Dose Calculations For Biologically Distributed Radionuclides, Supplement No. 1, MIRD Pamphlet No. 1, p. 7, 1968.

TABLE IV RADIATION DOSES

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

HOW SUPPLIED

TechneScan MDP-Technetium Tc 99m Medronate Sodium Kit.

Product No. 088

Each kit consists of 5 reaction vials, each vial containing, in lyophilized form, sterile and non-pyrogenic:

Medronic Acid	10 mg
Stannous Chloride (min.)	0.8 mg
(Maximum tin)	0.64 mg

The pH is adjusted to 6.5 to 7.5 with HCl or NaOH prior to lyophilization. The vials are sealed under an atmosphere of nitrogen.

Labels with radiation warning symbols and directions are supplied with each kit.

DIRECTIONS

NOTE: Use aseptic procedures throughout and take precautions to minimize radiation exposure.

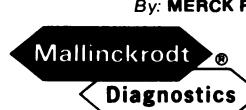
To prepare technetium Tc 99m medronate.

1. Remove the central metal disc from a reaction vial and swab the closure with either an alcohol swab or a suitable bacteriostatic agent.
2. Place the vial in a suitable radiation shield. Obtain from a generator 2-10 ml of sterile, pyrogen-free sodium pertechnetate Tc-99m. The recommended maximum amount of technetium Tc-99m to be added to a reaction vial is 200 mCi. Sodium pertechnetate Tc-99m solutions containing an oxidizing agent are not suitable for use.
3. Add the sodium pertechnetate Tc-99m solution to the reaction vial aseptically.
4. Agitate the shielded vial until the contents are completely dissolved. The solution must be clear and free of particulate matter before proceeding.
5. Assay the product in a suitable calibrator, complete the radioassay information tie-on tag with radiation warning symbol and attach it to the vial.
6. Withdrawals for administration must be made aseptically using a sterile syringe and needle.
7. The finished preparation should be refrigerated at 2-8°C when not in use and discarded after 6 hours.

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

Manufactured for: **MALLINCKRODT, INC.** St. Louis, Missouri 63134, U.S.A.

By: **MERCK FROSST LABORATORIES** Kirkland (Montreal), Canada



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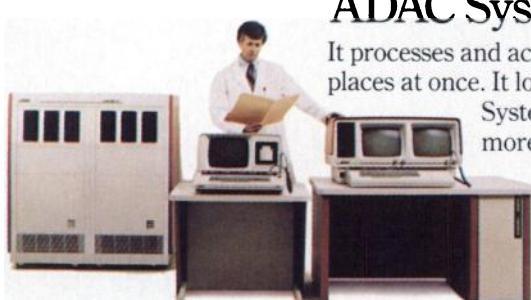
ADAC System II.

It processes one study while acquiring or processing another. It's a System I—plus a Remote Acquisition/Processing Terminal, a second Computer Section, and a second Winchester. It can easily be expanded to a System III.



ADAC System III.

It processes and acquires in two places at once. It looks just like a System II. But there's more capability inside the Computer Section. It can easily be expanded to a System IV.



ADAC System IV.

It has a three-location option. With two Consoles and an expanded Computer Section, you can process and acquire in two places at once. Add an optional Remote Terminal and you can process and acquire studies at three locations.



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Elscint Inc.

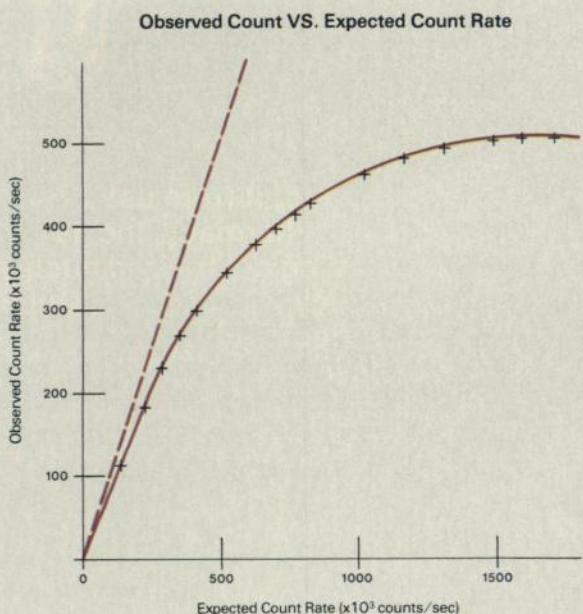
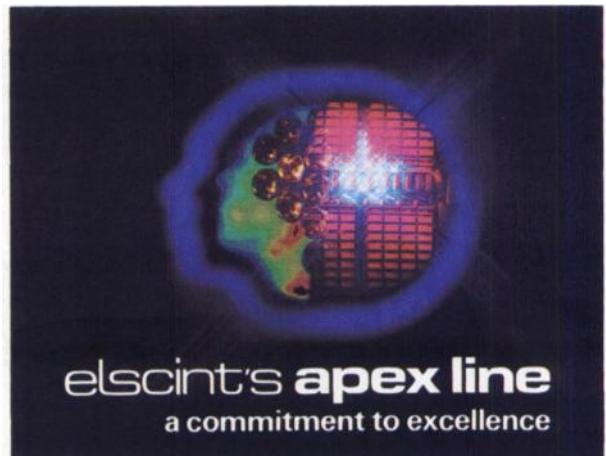
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High Count Rates—The Clinical Need

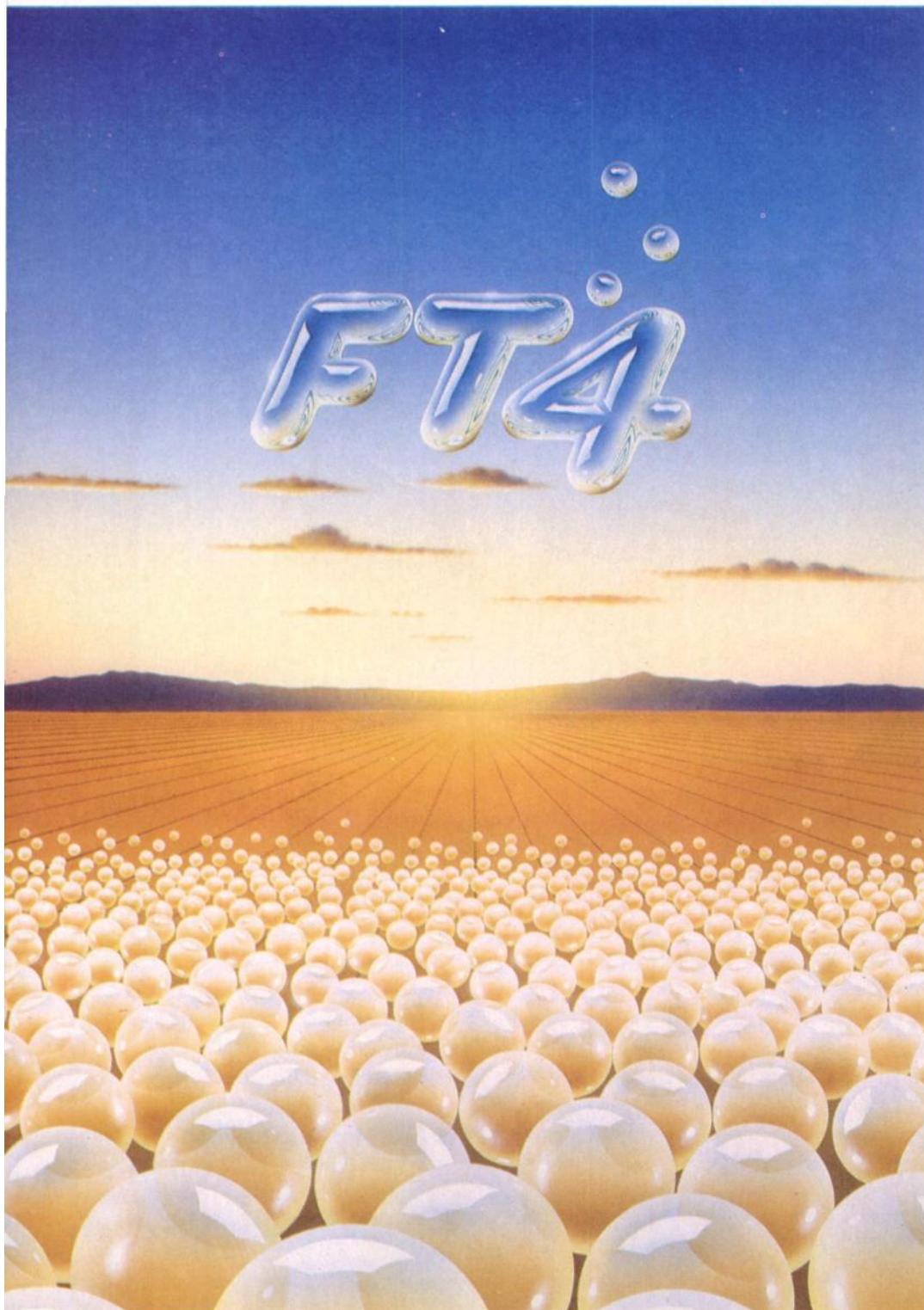
As Nuclear Medicine techniques become more sophisticated, they require higher count rates. Cardiac first-pass studies, for example, can only be effectively accomplished with count rates exceeding the limitations of most present day gamma cameras. Apex systems, however, do perform these studies—with remarkable image clarity.

Some Impressive Apex Qualities

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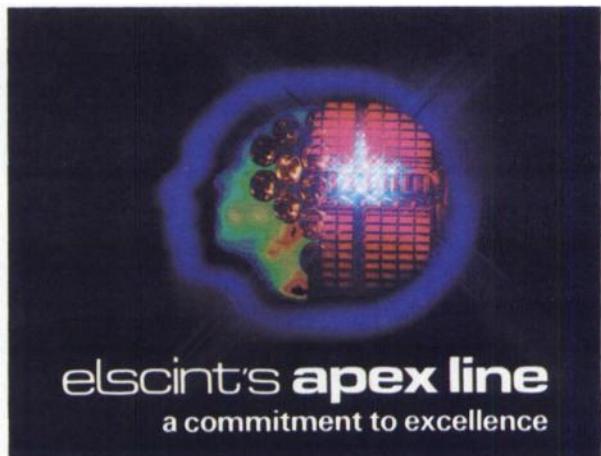
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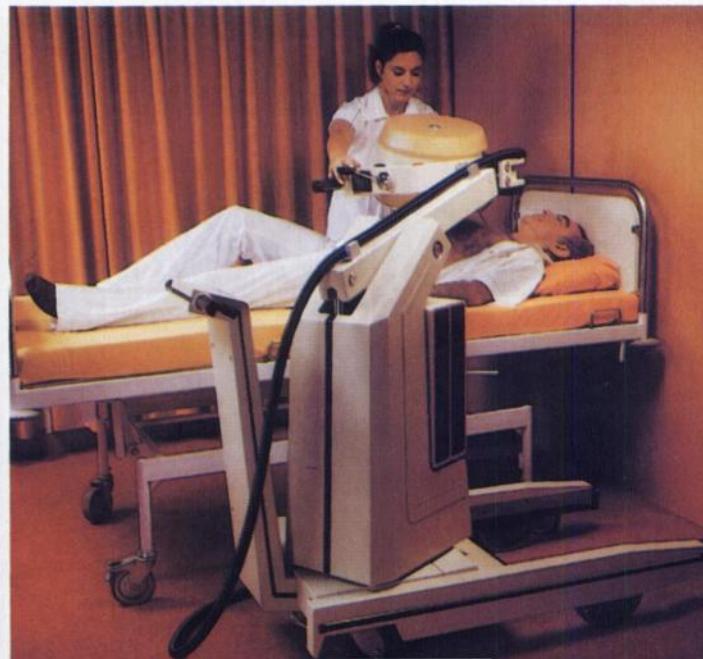
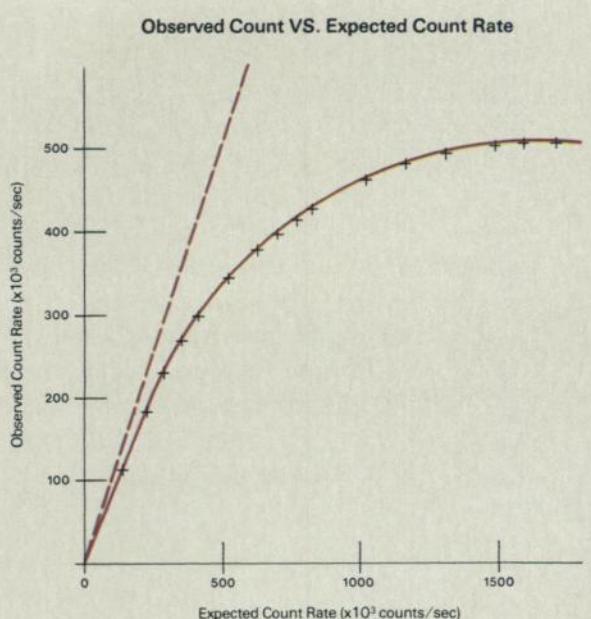


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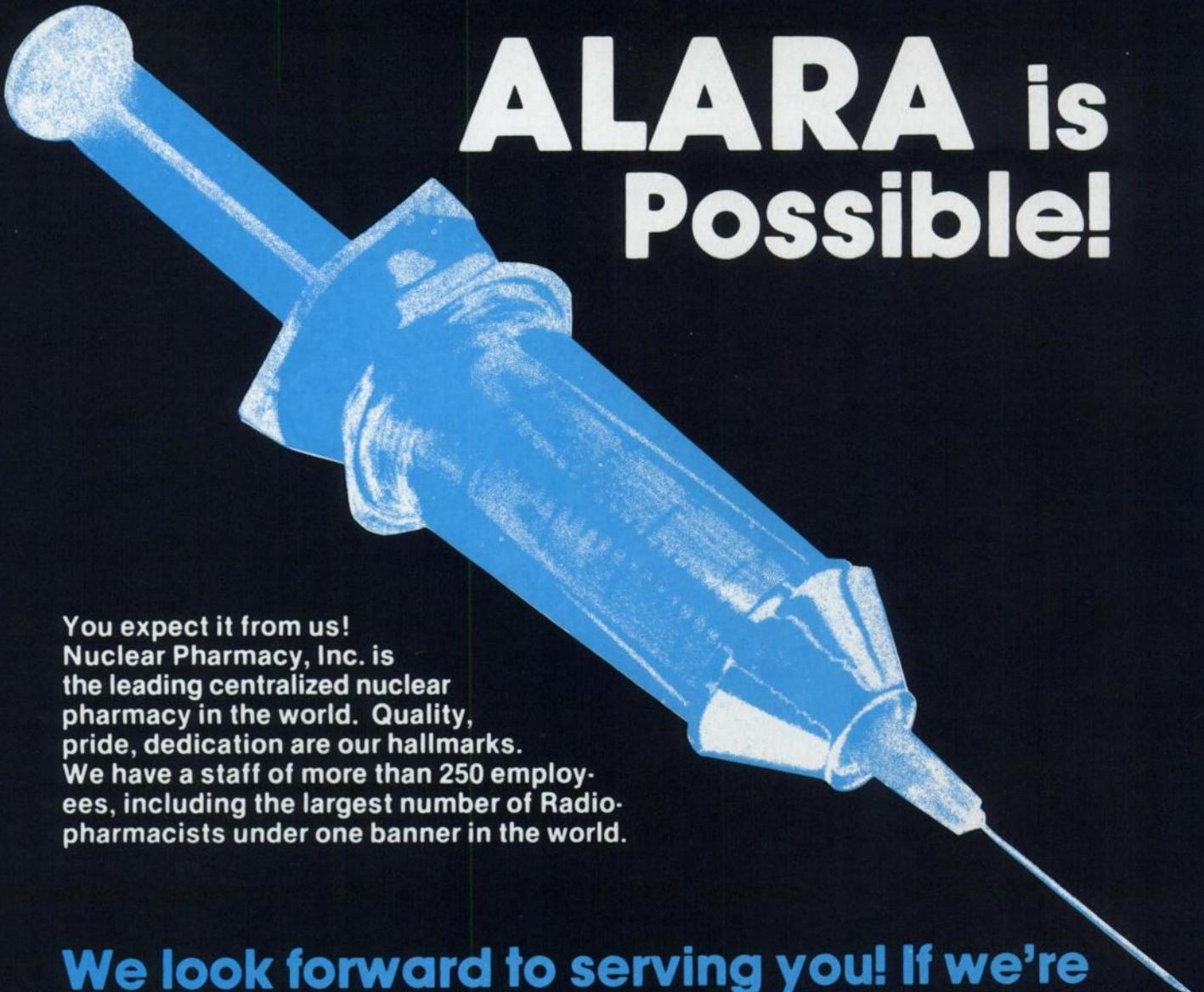
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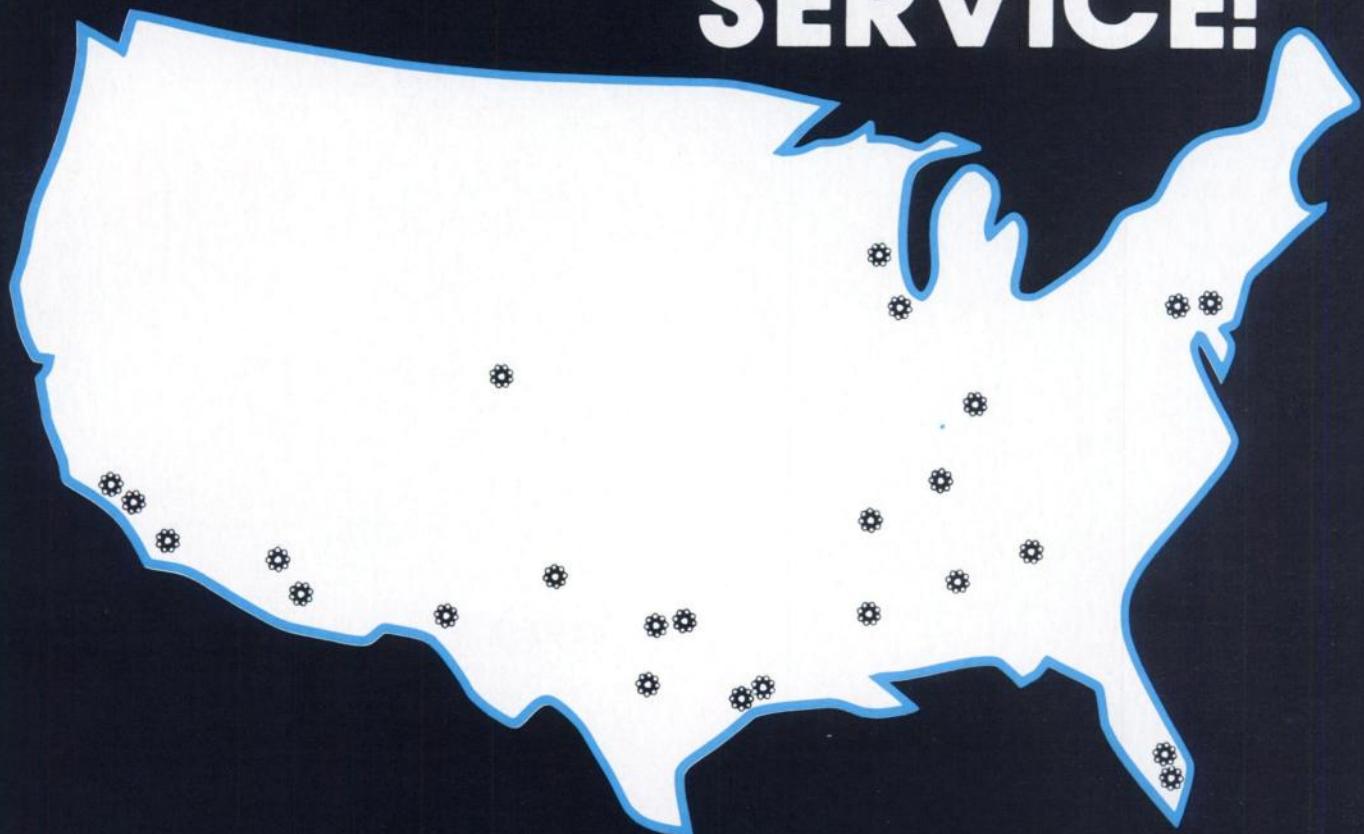


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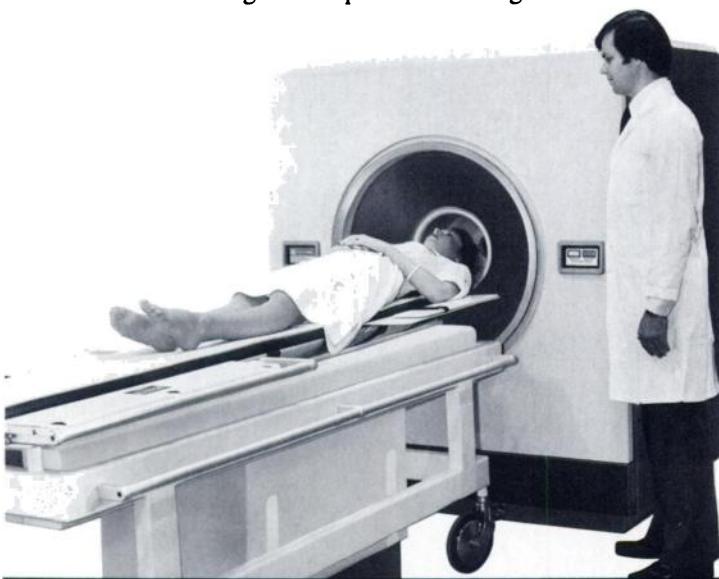
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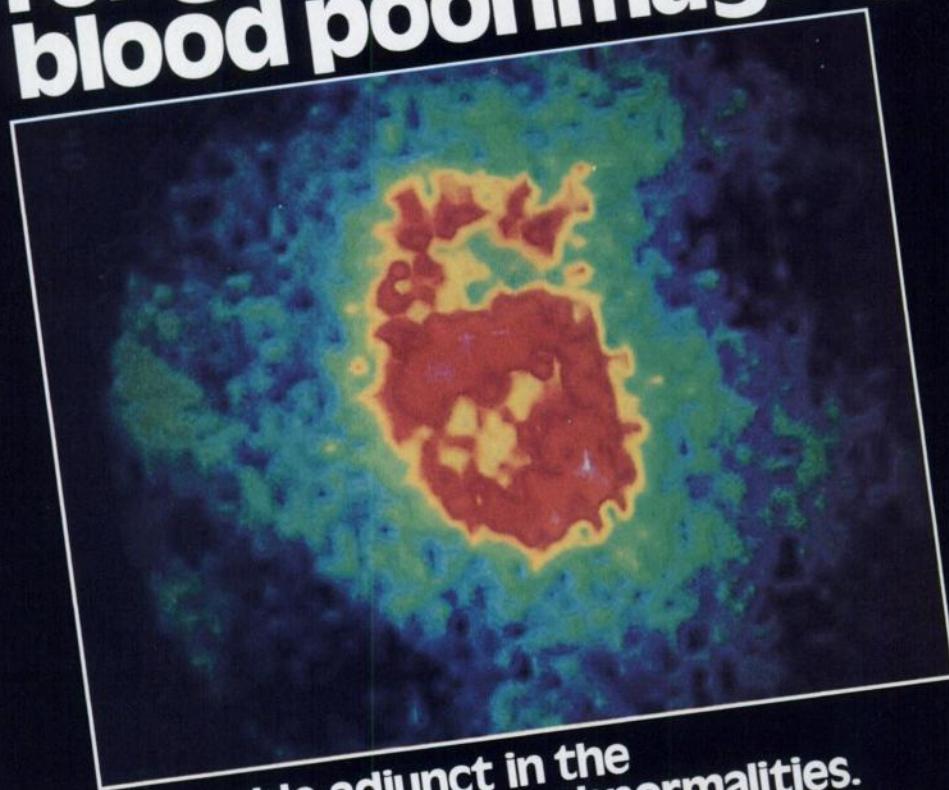
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For technical assistance, it is **800-325-8181**
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See brief summary on following page.

THE MALLINCKRODT COMMITMENT

to Nuclear Medicine

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



TechneScan® PYP®

Technetium Tc 99m Pyrophosphate Kit

BRIEF SUMMARY

CLINICAL PHARMACOLOGY

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

One to two hours after intravenous injection of **TechneScan PYP Tc 99m**, an estimated 40 to 50 percent of the injected dose has been taken up by the skeleton and approximately 0.01 to 0.02 percent per gram 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 76 percent of the injected activity remains in the blood pool.

CONTRAINDICATIONS

None.

WARNINGS

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

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

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

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

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

The contents of the **TechneScan PYP** reaction vial are intended for use in the preparation of Technetium Tc 99m Stannous Pyrophosphate. **TechneScan PYP** may also be reconstituted with sterile, pyrogen-free normal saline containing no preservatives and injected intravenously prior to the administration of sodium pertechnetate Tc-99m.

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

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

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

PRECAUTIONS

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

Bone Imaging

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

Cardiac Imaging

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

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

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

Blood Pool Imaging

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

ADVERSE REACTIONS

None.

HOW SUPPLIED

Catalog Number—094 **TechneScan PYP**
Technetium Tc 99m Pyrophosphate Kit.

Kit Contains:

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

Reaction Vial Contains:

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

5—Radioassay Information String Tags.

For complete prescribing information, see package insert.



Mallinckrodt, Inc.
P.O. Box 5840, St. Louis, Missouri 63134



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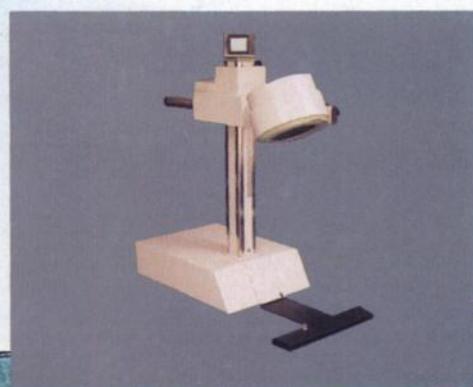
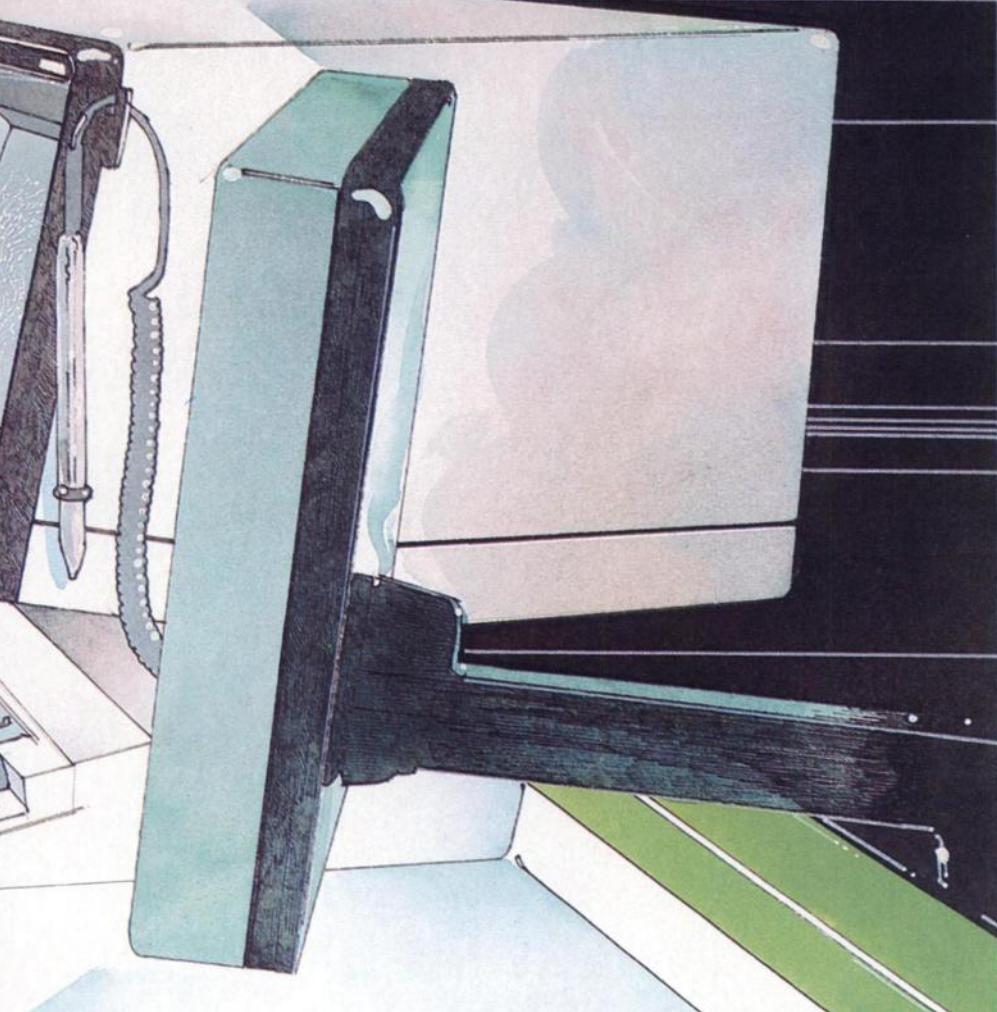
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Basic detector/stand

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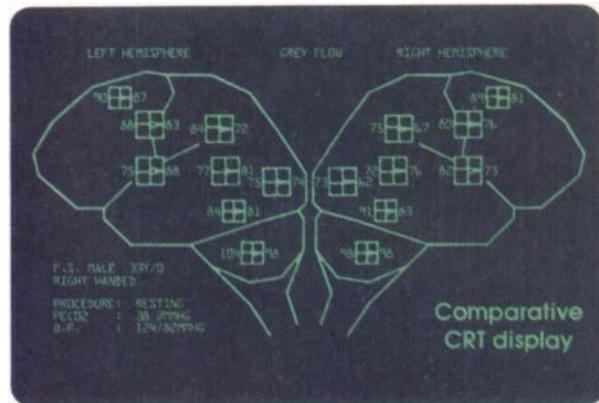
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*Walter D. Obrist, et al.
STROKE Vol. 6, May June 1975.
pp 245-256

Hard copy attachment—a permanent record, instantly available.

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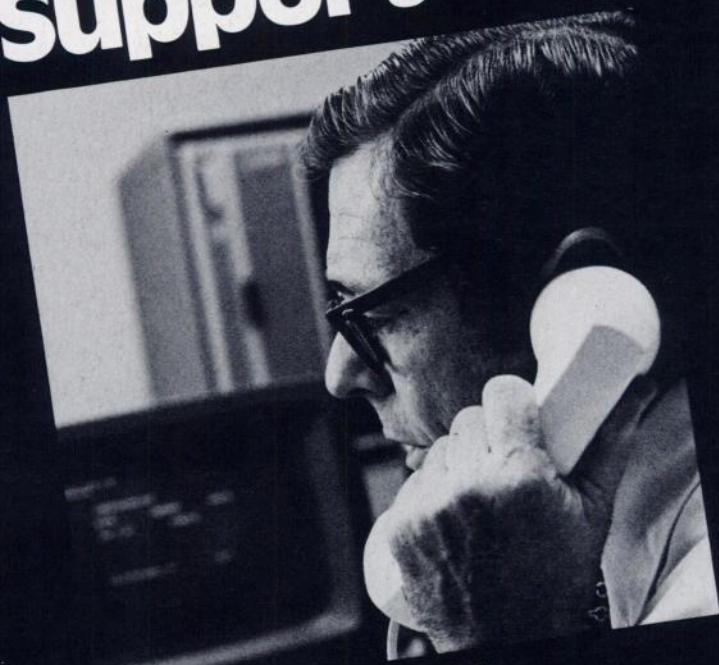


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HARSHAW



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If you have a question about test procedures, applications or need technical assistance on any of our radiopharmaceuticals, we're here to help. If you encounter any problems, no matter how minor, we want to make things right... right away. Need information on the U.S. Nuclear Regulatory Commission or other State or Federal agencies? Call us for that too.

Whatever technical support you need, Mallinckrodt is just a toll-free call away.

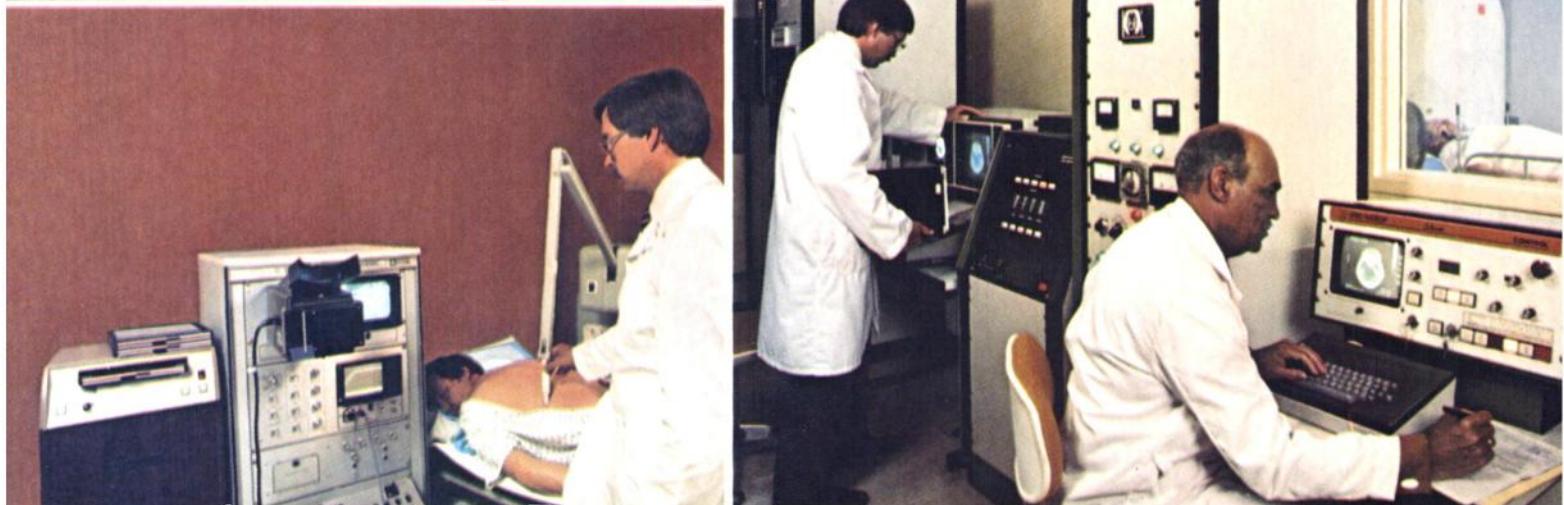
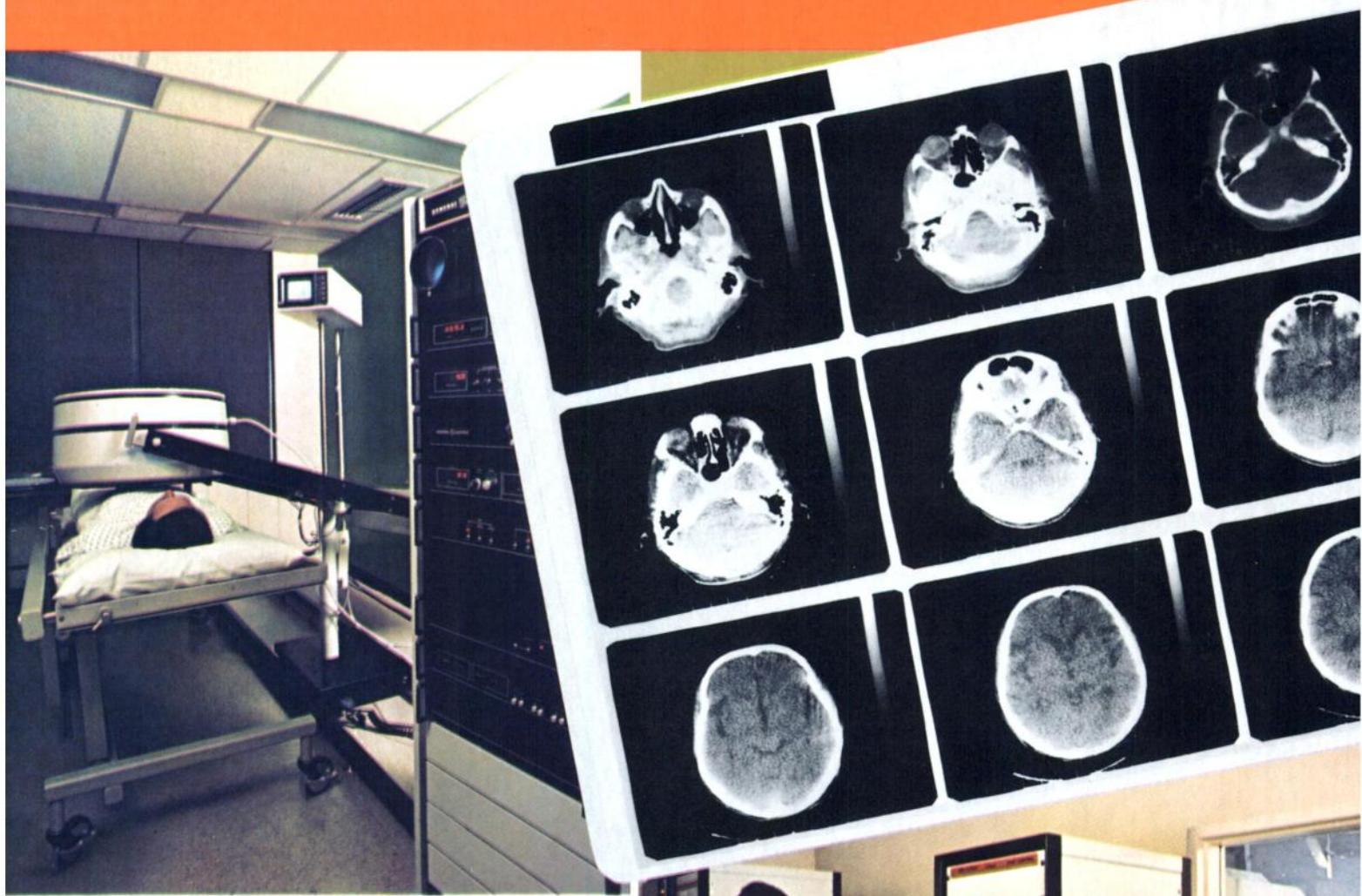
800-325-8181, Your Technical Support Number
(In Missouri, 314-895-2405 collect)
For ordering information, call: 800-325-3688
(In Missouri, 314-344-3880 collect)

THE MALLINCKRODT COMMITMENT

to Nuclear Medicine
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The broad spectral sensitivity of SCOPIX CR3 Film ensures accurate and detailed recording from greyscale CRT and video monitors which use white, blue or green phosphors in their display tubes. It is the "blindness" to green phosphors which causes other films to exhibit higher grain and less definition.

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SCOPIX CR3 Film is single-coated on GEVAR polyester base, with anti-halation layer. This combination enhances image detail and definition by preventing image parallax. It is suitable for all RP and manual film processing.

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that does it all!**

Photos courtesy Mt. Sinai Hospital, N.Y.

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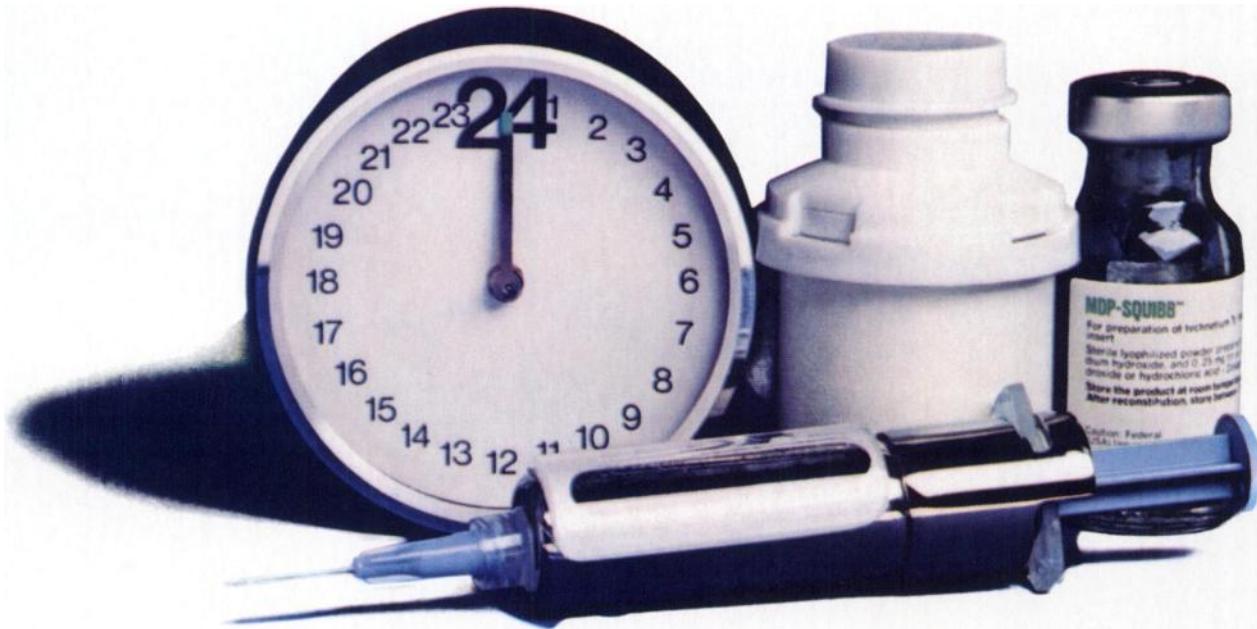
NEW

MDP-SQUIBBTM

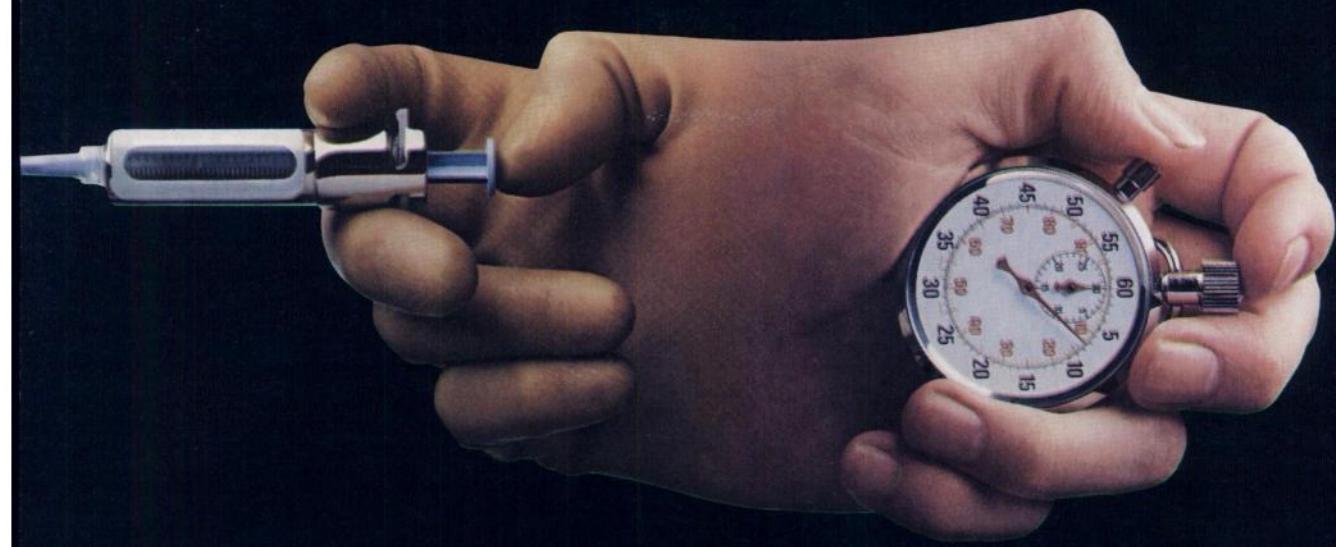
TECHNETIUM Tc 99m MEDRONATE KIT

STABLE FOR 24 HOURS

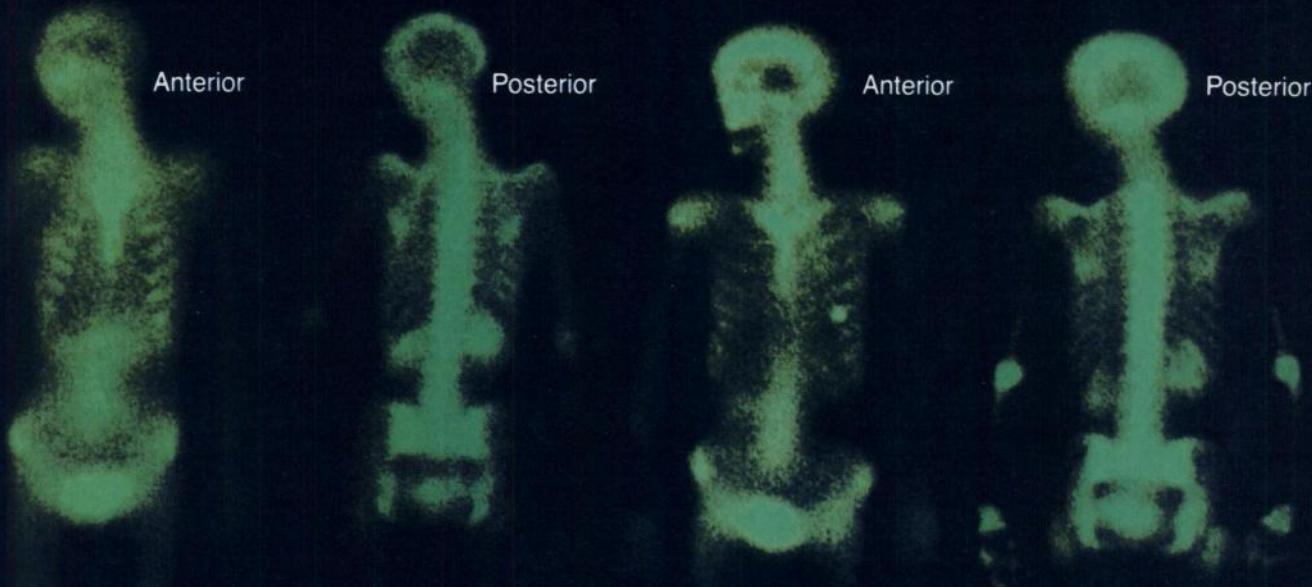
- May be used up to 24 hours after reconstitution
- 20 mg of active ingredient... each vial contains
20 mg medronic acid
- Formula developed in the pharmaceutical laboratories
of the Squibb Institute for Medical Research
- Images of unusual clarity



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- Rapid soft tissue and blood clearance...optimal results can be obtained 1 to 4 hours after administration
- Excellent labeling efficiency
- Simple 2-step procedure
- Kit contains 10 reaction vials

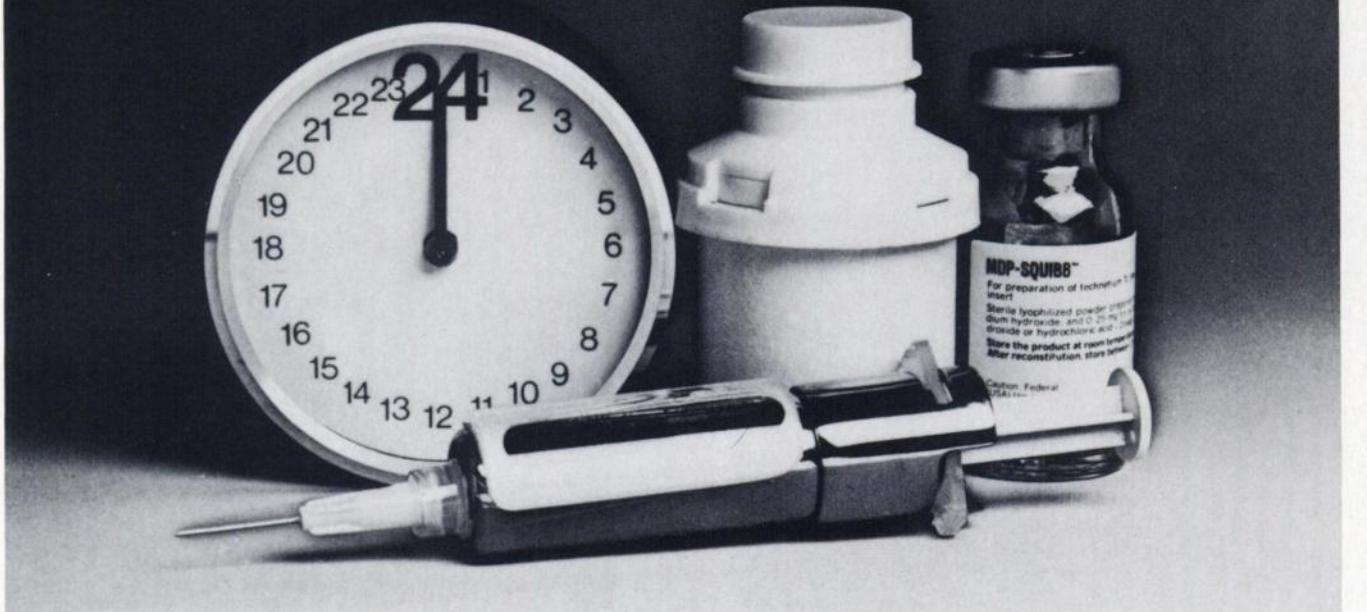


A 55-year-old female was administered 15 mCi of technetium Tc 99m medronate prepared with MDP-SQUIBB (Technetium Tc 99m Medronate Kit). Two hours postinjection a whole body scan was obtained on a scintillation camera.

A 51-year-old female was injected with 20 mCi of technetium Tc 99m medronate prepared with MDP-SQUIBB (Technetium Tc 99m Medronate Kit). Three hours later scan was obtained on a tomographic scanner.

See next page for brief summary.

STABLE FOR 24 HOURS



NEW MDP-SQUIBBTM TECHNETIUM Tc 99m MEDRONATE KIT



MDP-SQUIBBTM

Technetium Tc 99m Medronate Kit For Diagnostic Use

DESCRIPTION: Each 10 ml capacity reaction vial contains a sterile, nonpyrogenic lyophilized powder prepared from 20 mg medronic acid, 11 mg sodium hydroxide, and 0.25 mg tin as fluoride; the product does not contain a preservative. When sterile, nonpyrogenic sodium pertechnetate Tc 99m is added to the vial, technetium Tc 99m medronate is formed.

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).

Preliminary reports indicate impairment of brain scans using sodium pertechnetate Tc 99m injection which have been preceded by a bone scan using an agent containing stannous ions. The impairment may result in false-positive or false-negative brain scans. It is recommended, where feasible, that brain scans precede bone imaging procedures. Alternatively, a brain-imaging agent such as technetium Tc 99m pentetate may be employed.

PRECAUTIONS: General—Contents of the reaction vial are not radioactive and 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 other radioactive drugs must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patient and occupational workers consistent with proper patient management.

To minimize radiation exposure to the bladder, the patient 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.

Technetium Tc 99m medronate should be administered within 24 hours of its preparation; for optimal results, the dose should be administered as soon as possible following preparation of technetium

Tc 99m medronate. Optimal imaging results are obtained one to four hours after administration.

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

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 reproduction 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 medronate should be given to a pregnant woman only if clearly needed.

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

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

Pediatric Use—Safety and effectiveness in children have not been established.

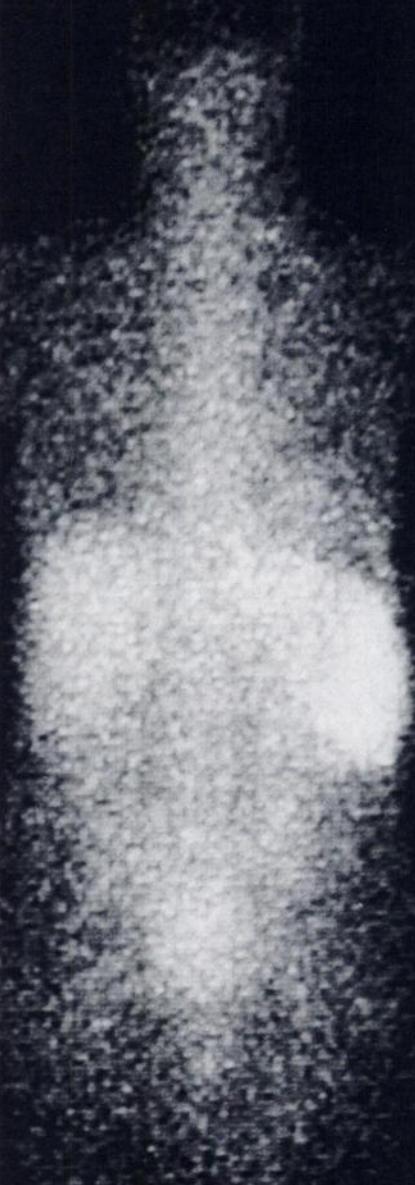
ADVERSE REACTIONS: No adverse reactions specifically attributable to the use of technetium Tc 99m medronate have been reported.

For full prescribing information, consult package insert.

HOW SUPPLIED: In packages of 10 reaction vials.



Tumor



Diagnosis: plasmacytoma

Imaging information: Instrument: Cleon 760 Whole Body Imager
Scan time: 48 hours postinjection

Dose: 5 mCi Gallium Citrate Ga 67

Gallium Citrate Ga67



Please see following page for brief prescribing information.

See us at the SNM Show in Las Vegas at Island "K"

OSTEOLITE

Technetium Tc 99m Medronate Sodium Kit (MDP)

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

CONTRAINDICATIONS: None known.

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

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

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

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

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

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

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

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

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

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

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: None reported.

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

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

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

The vial contains no bacteriostat.

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

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

Medronate Disodium – 10mg

Stannous Chloride Dihydrate – 0.85mg

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

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

Do not use if there is a vacuum in the immediate drug container or if air is injected into the container when the dose is withdrawn.

Catalog Number NRP-420 (5 vial kit)

April 1978

Catalog Number NRP-420C (30 vial kit)

Gallium Citrate Ga67

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

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

CONTRAINDICATIONS: None known.

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

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

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

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

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

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

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

should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

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

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

ADVERSE REACTIONS: Severe itching, erythema and rash were observed in one patient of 300 studied.

DOSAGE AND ADMINISTRATION: The recommended adult (70kg) dose of Gallium Citrate Ga 67 is 2.5mCi. Gallium Citrate Ga 67 is intended for intravenous administration only.

Approximately 10% of the administered dose is excreted in the feces during the first week after injection. Daily laxatives and/or enemas are recommended from the day of injection until the final images are obtained in order to cleanse the bowel of radioactive material and minimize the possibility of false positive studies.

Studies indicate the optimal tumor to background concentration of ratios are often obtained about 48 hours post-injection. However, considerable biological variability may occur in individuals, and acceptable images may be obtained as early as 6 hours and as late as 120 hours after injection.

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

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

HOW SUPPLIED: Gallium Citrate Ga 67 is supplied sterile and non-pyrogenic for intravenous use. Each ml contains 2mCi of Gallium Ga 67 on the calibration date, as a complex formed from 9mg gallium chloride Ga 67, 2mg of sodium citrate, 6.8mg sodium chloride, and 0.9% benzyl alcohol w/v as preservative. The pH is adjusted to between 4.5–7.5 with hydrochloric acid and/or sodium hydroxide solution.

Vials are available from 3mCi to 18mCi in increments of 3mCi on calibration date.

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

Catalog Number NRP-121

December 1979



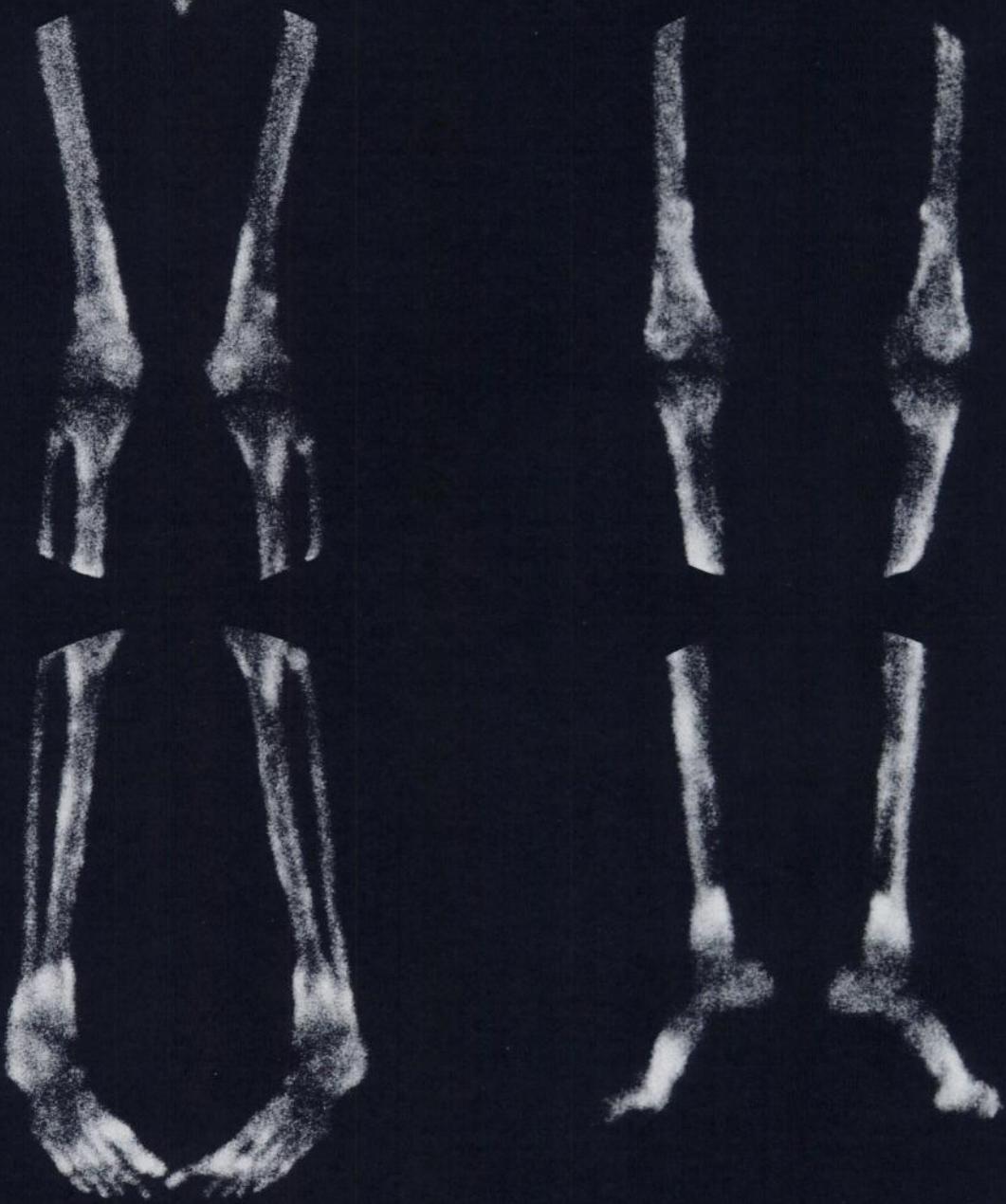
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(In Mass and International 617-482-9595)

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

Bone



Diagnosis: hypertrophic
pulmonary osteoarthropathy

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

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



New England Nuclear®

Please see preceding page for brief prescribing information.

SEE US AT THE SNM SHOW IN LAS VEGAS AT ISLAND "K"

AUDIOVISUALS IN NUCLEAR CARDIOLOGY

- SI-18 Basic Concepts in Cardiac Anatomy and Physiology by Glen W. Hamilton, M.D.
- SI-19 The Measurement of Ejection Fraction by William Ashburn, M.D.
- SI-20 Intracardiac Shunts and Cardiac Output by William Ashburn, M.D.
- SI-21 Perfusion Studies of the Ischemic Heart by Glen W. Hamilton, M.D.
- SI-22 Detection of Acute Myocardial Infarction by B. Leonard Holman, M.D.
- SI-23 Instrumentation for Nuclear Cardiology by Trevor D. Cradduck, Ph.D.

Each Audiovisual kit comes complete with expert narration and carefully selected supporting visual materials. Consisting of 35 mm color slides and standard audio cassette, each kit forms a complete self-teaching package. Suitable for individual or group instruction, these units offer active learner participation to reinforce the most important concepts. Each kit has been prepared by an authority in the field, making expert instruction available to you in your home, office or hospital.

SNM Audiovisuals cost \$55.00 each for members of the Society of Nuclear Medicine, \$75.00 each for nonmembers. There is a 10% discount if all six nuclear cardiology units are ordered at once. A complete list of SNM Audiovisuals is available on request.

MAIL TO: Audiovisual Department, Society of Nuclear Medicine, 475 Park Ave., So, NY, NY 10016.

Please send the following Audiovisual units. (Check units desired.)

SI-18 SI-20 SI-22
 SI-19 SI-21 SI-23

\$55.00 each for members; \$75.00 each for nonmembers.

Total _____ Audiovisual units @ _____ each.

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Gallium Citrate Ga67

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

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

CONTRAINDICATIONS: None known.

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

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

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

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

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

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

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

should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

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

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

ADVERSE REACTIONS: Severe itching, erythema and rash were observed in one patient of 300 studied.

DOSAGE AND ADMINISTRATION: The recommended adult (70kg) dose of Gallium Citrate Ga 67 is 2-5mCi. Gallium Citrate Ga 67 is intended for intravenous administration only.

Approximately 10% of the administered dose is excreted in the feces during the first week after injection. Daily laxatives and/or enemas are recommended from the day of injection until the final images are obtained in order to cleanse the bowel of radioactive material and minimize the possibility of false positive studies.

Studies indicate the optimal tumor to background concentration of ratios are often obtained about 48 hours post-injection. However, considerable biological variability may occur in individuals, and acceptable images may be obtained as early as 6 hours and as late as 120 hours after injection.

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

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

HOW SUPPLIED: Gallium Citrate Ga 67 is supplied sterile and non-pyrogenic for intravenous use. Each ml contains 2mCi of Gallium Ga 67 on the calibration date, as a complex formed from 9ng gallium chloride Ga 67, 2mg of sodium citrate, 6.8mg sodium chloride, and 0.9% benzyl alcohol w/v as preservative. The pH is adjusted to between 4.5-7.5 with hydrochloric acid and/or sodium hydroxide solution.

Vials are available from 3mCi to 18mCi in increments of 3mCi on calibration date.

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

Catalog Number NRP-121

December 1979



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Abscess

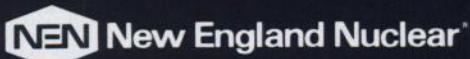


Diagnosis: intranephric abscess

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

Dose: 5 mCi Gallium Citrate Ga 67

Gallium Citrate Ga67



Please see preceding page for brief prescribing information.

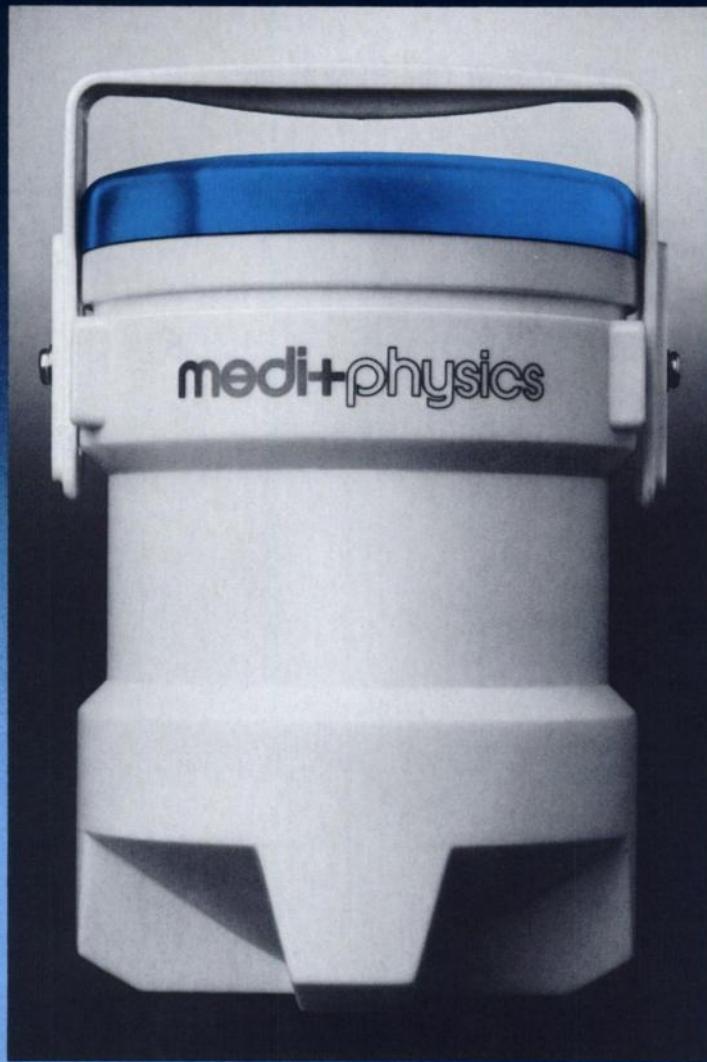
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MPI Krypton Kr 81m Gas Generator
Krypton Kr 81m

The Pulmonary Profile

THE CONCEPT

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

THE PURPOSE

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

THE RESULT

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

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

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

MPI KRYPTON Kr 81m GAS GENERATOR KRYPTON Kr 81m

DESCRIPTION: The Krypton Kr 81m Gas Generator consists of Rubidium Rb 81 fixed to a solid support from which the Krypton Kr 81m is eluted by passage of humidified oxygen or air through the generator. Other 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:

General

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenicity potential, or whether Krypton Kr 81m gas affects fertility in males or females.

Pregnancy-Category C

Animal reproduction studies have not been conducted with Krypton Kr 81m gas. It is also not known whether Krypton Kr 81m gas can cause fetal harm when administered to a pregnant woman, or can affect reproduction capacity. Krypton Kr 81m gas 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 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.

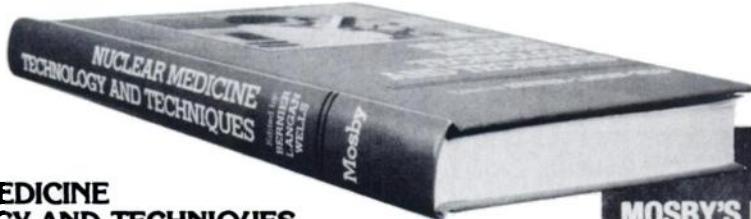
Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

ADVERSE REACTIONS: None known.

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

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

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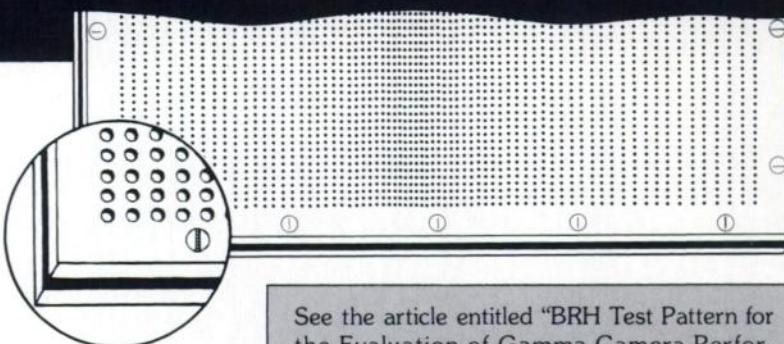
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TECHNETIUM 99m GENERATOR

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

description

The CINTICHEM® TECHNETIUM Tc 99m GENERATOR provides a means of obtaining a sterile, pyrogen-free solution of Sodium Pertechnetate Tc 99m in isotonic saline from elution of the generator containing Molybdenum Mo 99. Hydrochloric acid and/or sodium hydroxide may have been used for pH adjustment. 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.

clinical pharmacology

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

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

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; and blood pool imaging including radionuclide angiography.

Sodium Pertechnetate Tc 99m is used IN CHILDREN as an agent for: brain imaging including cerebral radionuclide angiography; thyroid imaging; and blood pool imaging including radionuclide angiography.

contraindications

None known.

warnings

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

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

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

precautions

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

Pregnancy Category C, animal reproductive studies have not been conducted with Sodium Pertechnetate Tc 99m. It is also not known whether Sodium Pertechnetate Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Sodium Pertechnetate Tc 99m should be given to a pregnant woman only if clearly needed.

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

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

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

adverse reactions

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

dosage and administration

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

The suggested intravenous dose range employed for various diagnostic indications are as follows:

IN AVERAGE ADULT (70kg) PATIENTS:

Brain Imaging	10 to 20 millicuries
Thyroid Gland Imaging	1 to 10 millicuries
Salivary Gland Imaging	1 to 5 millicuries
Placenta Localization	1 to 3 millicuries
Blood Pool Imaging	10 to 30 millicuries

IN PEDIATRIC PATIENTS:

brain imaging: 140-280 microcuries/kg body weight. A minimum dose of 3-5 millicuries should be employed if cerebral radionuclide angiography is performed as part of the brain imaging procedure.

thyroid gland imaging: 60-80 microcuries/kg body weight.

blood pool imaging: 140-280 microcuries/kg body weight.

A minimum dose of 3-5 millicuries should be employed if radionuclide angiography is performed as part of the blood pool imaging procedure.

NOTE: Up to 1 gram of pharmaceutical grade potassium perchlorate in a suitable base or capsule may be given orally prior to administration of Sodium Pertechnetate Tc 99m for brain imaging. When Sodium Pertechnetate Tc 99m is used in children for brain or blood pool imaging, administration of potassium perchlorate is especially important to minimize the absorbed radiation dose to the thyroid gland.

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

Radio pharmaceuticals 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.

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

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 noon of the day of calibration. The TECHNETIUM Tc 99m GENERATOR consists of:

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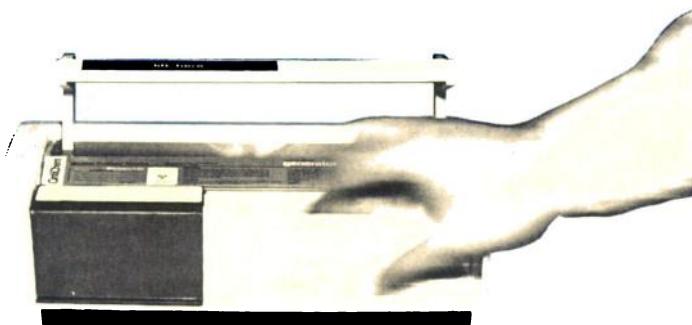
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NUCLEAR MEDICINE PHYSICIST AT the Associate Professor level. Previous experience in instrumentation related to positron emission tomography is desirable. Duties will include: Supervision of the positron emission tomography equipment, research in reconstruction tomography, and teaching. Send curriculum vitae to A. Alavi, M.D., Chief, Div. of Nuclear Medicine, Dept. of Radiology, Hospital of the University of Pennsylvania, 3400 Spruce Street, Philadelphia, PA 19104. The University of Pennsylvania is an equal opportunity, affirmative action employer.

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NUCLEAR MEDICINE TECHNOLOGIST. Immediate opening available at the University of Iowa Hospitals and Clinics. Requires B.S. degree or equivalent combination of training experience. Must be registered or registry eligible. Excellent career opportunity with competitive salary and comprehensive benefits package. Full range of in vivo procedures with active cardiovascular imaging section. Responsibilities include clinical instruction for Nuclear Medicine Technology Program. Send resume or contact: Mr. John Bricker, Division of Nuclear Medicine, Department of Radiology, University of Iowa Hospitals and Clinics, Iowa City, IA 52242. Phone number: (319)356-1911. The University of Iowa is an Equal Opportunity/Affirmative Action Employer.

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NUCLEAR MEDICINE TECHNOLOGIST. 400-bed, acute-care facility on Florida's gulf coast seeks registered or registry eligible nuclear medicine technologist for our expanding Nuclear Medicine Department. Full range of imaging and radioimmunoassay procedures performed; equipment includes Raytheon LFOV and Technicare (Ohio) portable cameras, MDS computer system, and fully automated RIA. Contact: Personnel Dept., Fort Myers Community Hospital, P.O. Box 7146, Fort Myers, FL 33901; (813)939-8551.

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NUCLEAR MEDICINE PHYSICIAN completing two-year residency in June 1981 seeks hospital or private group practice. Board eligible general internist. Extensive training in nuclear cardiology, computer techniques, thyroid imaging and treatment, as well as the usual diagnostic imaging. Reply Box 600, Society of Nuclear Medicine, 475 Park Ave. So., New York, NY 10016.

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Further requests should be directed to S. James Adelstein, M.D., Ph.D., Director, The Joint Program in Nuclear Medicine, Department of Radiology, Harvard Medical School, 25 Shattuck Street, Boston, MA 02115.

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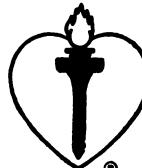
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Contact: Radiologic Technology Program, East Central University, Ada, OK 74820 or (405) 332-8000.

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University of Oklahoma, College of Pharmacy

Applications are invited for a faculty tenure track position as Assistant/Associate Professor in Nuclear Pharmacy. Appointment to begin July 1, 1981 or soon thereafter. Applicants should possess a Ph.D. degree in Nuclear Pharmacy/Bio-nucleonics/Radiochemistry. A strong background in animal handling and nuclear medicine instrumentation use is desirable. The successful applicant is expected to participate in the Nuclear Pharmacy Graduate Program, teaching, and research. Salary will be commensurate with qualifications and experience.

Interested applicants should send a letter of application prior to June 30, 1981 accompanied by a Curriculum Vitae to: Garo P. Basmajian, Ph.D., Chairman, Search Committee, College of Pharmacy, University of Oklahoma, Health Sciences Center, Oklahoma City, OK 73190.

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Practical experience is provided in performance and interpretation of static and dynamic imaging, computer techniques, radioimmunoassay, and other in vitro tests, radio-pharmacy, and therapy with radionuclides. Residents participate fully in the integration of these modalities into patient care.

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Requests for further information (include CV) should be directed to: Myron Pollycove, M.D., Chief, Nuclear Medicine, San Francisco General Hospital Medical Center, San Francisco, CA 94110.

JUNIOR FACULTY OPENING

The Department of Radiological Sciences at the University of California, Irvine, College of Medicine announces a junior faculty opening in the Division of Nuclear Medicine (Philip Braunstein, M.D., Director of Nuclear Medicine).

Applicants should be ABNM certified or eligible and a radiology background is preferred. Position primarily involves clinical and teaching responsibilities in an expanding department with two computers, performing full range of in vivo procedures, including nuclear cardiology. Research encouraged.

Applications from all qualified candidates are welcome. UCI is an equal opportunity employer. Applications, including a curriculum vitae and copies of any publications, should be sent to:

Richard M. Friedenberg, M.D., Professor and Chairman, Dept. of Radiological Sciences, Univ. of California, Irvine, College of Medicine, 101 City Dr. South, Orange, California 92668.

INDEX TO ADVERTISERS

ADAC LABORATORIES	42A, 43A
AGFA-GEVAERT REX, INC.	58A, 59A
AMR CORPORATION	12A
BANYAN ENTERPRISES	72A
BRATTLE INSTRUMENTS.....	IBC
CAPINTEC, INC.	77A
CINTICHEM	8A, 73A, 74A, BC
CLINICAL ASSAYS	19A
CYCLOTRON CORPORATION	50A
EASTMAN KODAK	36A, 37A
EDC/MEDICAL IMAGING	24A
ELSCINT, LTD.	44A, 45A
G.E. MEDICAL SYSTEMS	73A
GRUNE STRATTON, INC.	28A
HARSHAW CHEMICAL CO.	56A
HYBRITECH	38A, 39A
INFORMATIK STATES, INC.	34A
INTERNATIONAL CIS	33A, 35A
ISO-TEX	71A
JOHNSTON LABORATORIES	18A
KRUPP INTERNATIONAL	30A
MALLINCKRODT, INC.	3A, 32A, 40A, 41A 51A, 52A, 53A, 57
MEDICAL DATA SYSTEMS	5A
MEDI-PHYSICS, INC.	IFC, 1A, 68A, 69A
C.V. MOSBY CO.	70A
NEW ENGLAND NUCLEAR..	6A, 63A, 64A, 65A, 66, 67A
NUCLEAR ASSOCIATES	26A, 72A
NUCLEAR PHARMACY	46A, 47A
NU-TECH	2A
O'NEILL ENTERPRISES	14A, 15A, 22A, 23A
PHARMATOPES, INC.	10A
PICKER CORPORATION	54A, 55A
PROCTOR & GAMBLE CO.	20A, 21A, 22A
RADIOCHEMICAL CENTRE.....	48A
RADX CORPORATION	13A, 84A
RAYTHEON COMPANY	25A
SELO	79A
SIEMENS GAMMASONICS	27A, 29A, 31A
SNM PLACEMENT	80A, 81A, 82A, 83A
E.R. SQUIBB & SONS, INC.	60A, 61A, 62A
SYNCOR INTERNATIONAL.....	16A, 17A

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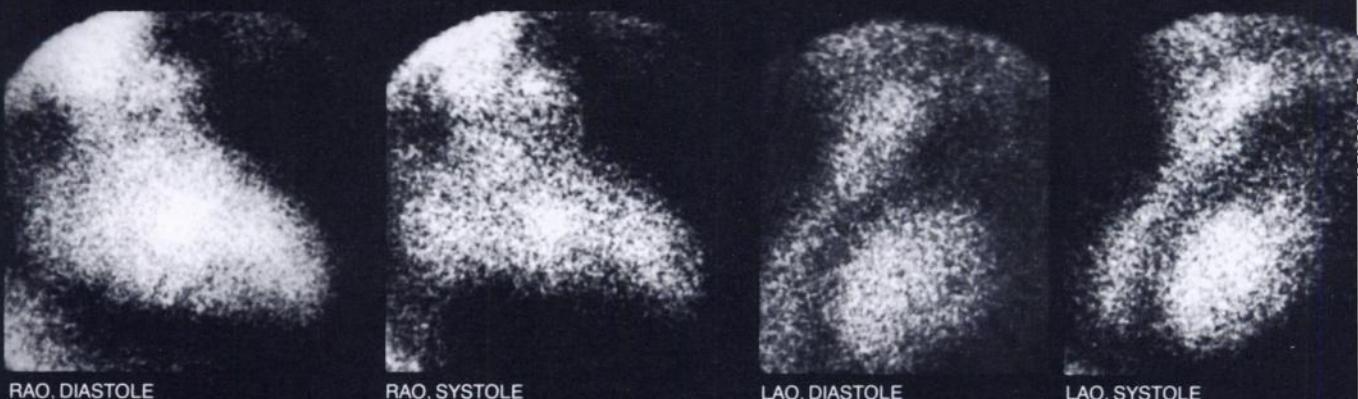
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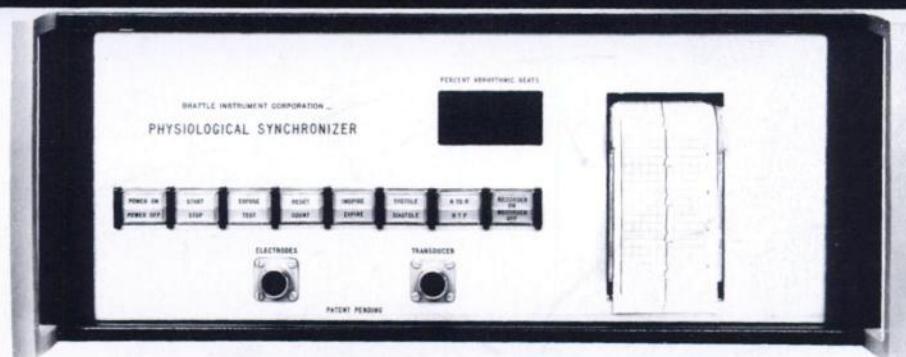
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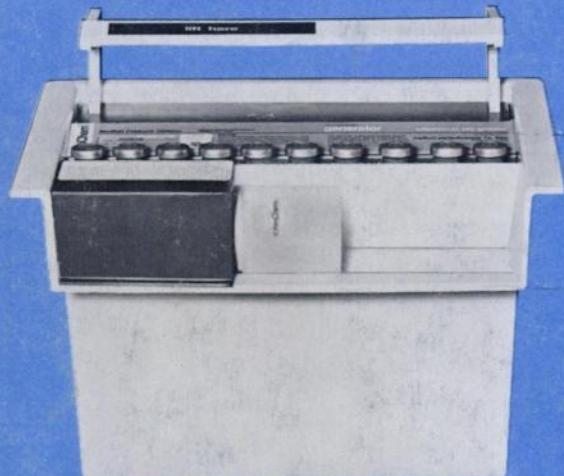
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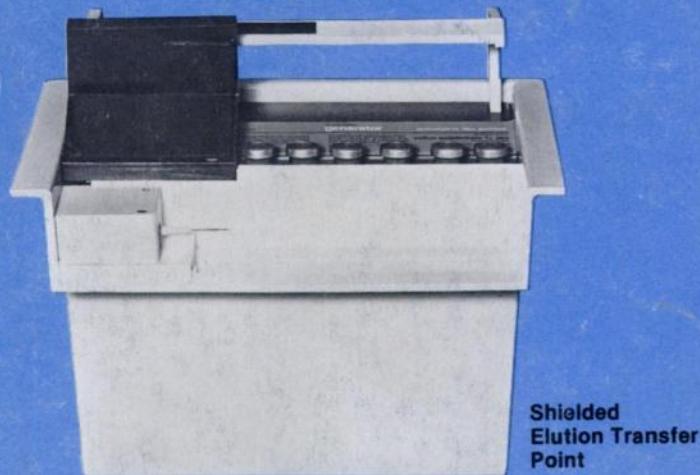
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