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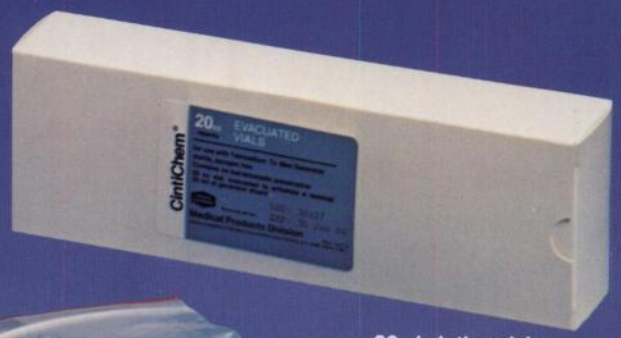
Technetium Tc 99m Generator

Secondary shield to further reduce radiation

5cc and 10cc elution vials



20ml elution vials available on request

Elution vial shield

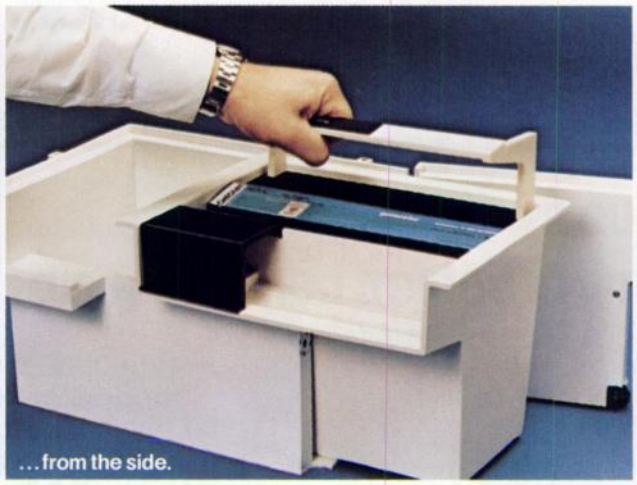
Adaptors for various elution vials

Sterile needle pack and labels furnished with each generator

TECHNETIUM 99m

GENERATORS

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



Featuring:

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

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MEDI-PHYSICS, INC., RICHMOND, CALIF. 94806
SUBSIDIARY OF HOFFMANN-LA ROCHE INC.

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

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

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

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

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

CONTRAINDICATIONS: None known.

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category C

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

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

Nursing Mothers

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

Pediatric Use

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

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

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

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

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

HOW SUPPLIED: Sodium Pertechnetate Tc 99m is supplied as a Molybdenum Mo 99/Technetium Tc 99m generator in sizes from 830 millicuries up to 16,600 millicuries (in approximately 830 millicurie increments) of Molybdenum Mo 99 as of 10:00 P.M. Eastern Time of the day of calibration. The TECHNETIUM Tc 99m GENERATOR consists of:

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

*initial order only

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

Jointly manufactured by:
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Tuxedo, N.Y. 10987

and

June, 1983
UNION CARBIDE CORPORATION
Tuxedo, N.Y. 10987

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- Calculates syringe volume required for a patient dose.
- Provides permanent printed record of date, time, radioisotope, activity, concentration, syringe volume, ^{99}Mo assay result and decay chart.
- Measures background and automatically subtracts it from all radioisotope measurements.
- Enters and prints patient's ID number.

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Novo BMC-LAB 22a

Postmenopausal Osteoporosis - a cureable disease when treated in time

Early diagnosis of excessive bone mineral loss is possible by noninvasive determination of bone mineral content (BMC) in the axial skeleton.

Reliable Data from Relevant Areas

Loss of bone mineral, and fractures associated with the axial skeleton, are closely associated with metabolic bone disease. Trabecular bone, predominantly present in the axial skeleton, notably the lumbar vertebrae, is affected to a larger extent than cortical bone present in the peripheral skeleton. BMC measurements in potential fracture sites in the axial skeleton provide the most reliable indication of fracture risk.
The Novo BMC-LAB 22a measures BMC in the lumbar spine, the femoral neck and other parts of the skeleton.

Improved Patient Management

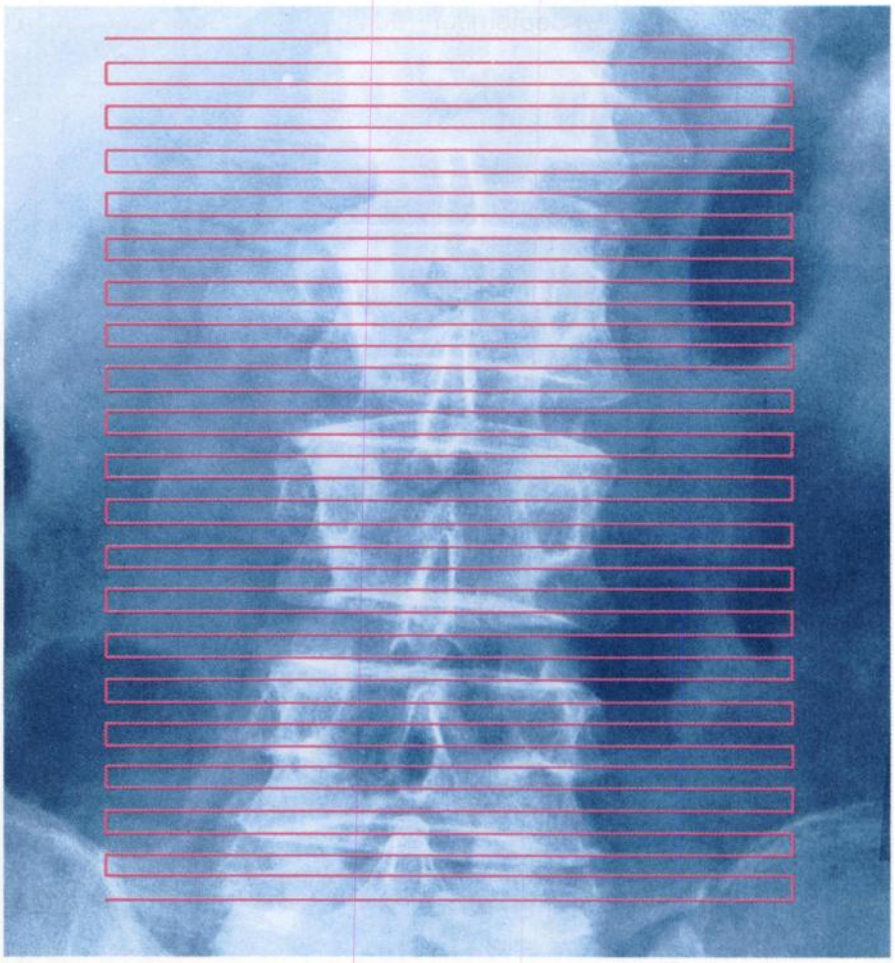
A large number of drugs and regimens influence the calcium balance. BMC measurement is a cost-effective and direct means of monitoring patients in haemodialysis, during nutrient supplementation, exercise and drug administration programs.
Ease of operation and low radiation dose make the Novo BMC-LAB 22a ideal for routine monitoring and screening of patients.

Automatic Soft Tissue Compensation

The Novo BMC-LAB 22a is a dual-photon bone densitometer. The technique obviates the need for soft tissue equivalent materials, without sacrificing the excellent precision of the proven single-photon method.

Safety, Flexibility and Ease of Operation

Advanced software guides the user through the measurements and prompts the operator in case of error. Extensive interactive capabilities provide extremely flexible selection of regions of interest.



The Novo BMC-LAB 22a features three dedicated programs: for COLUMNA, and for right and left COLLUM FEMORIS. A fourth OPTIONAL program is included to meet individual requirements.

For further information please contact:

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The added speed and precision gained by digital electronics make the Digital Dyna Camera (DDC) virtually unlimited in handling your present and future requirements . . . whether it be conventional imaging, single or dual detector ECT, or new radiopharmaceutical developments.

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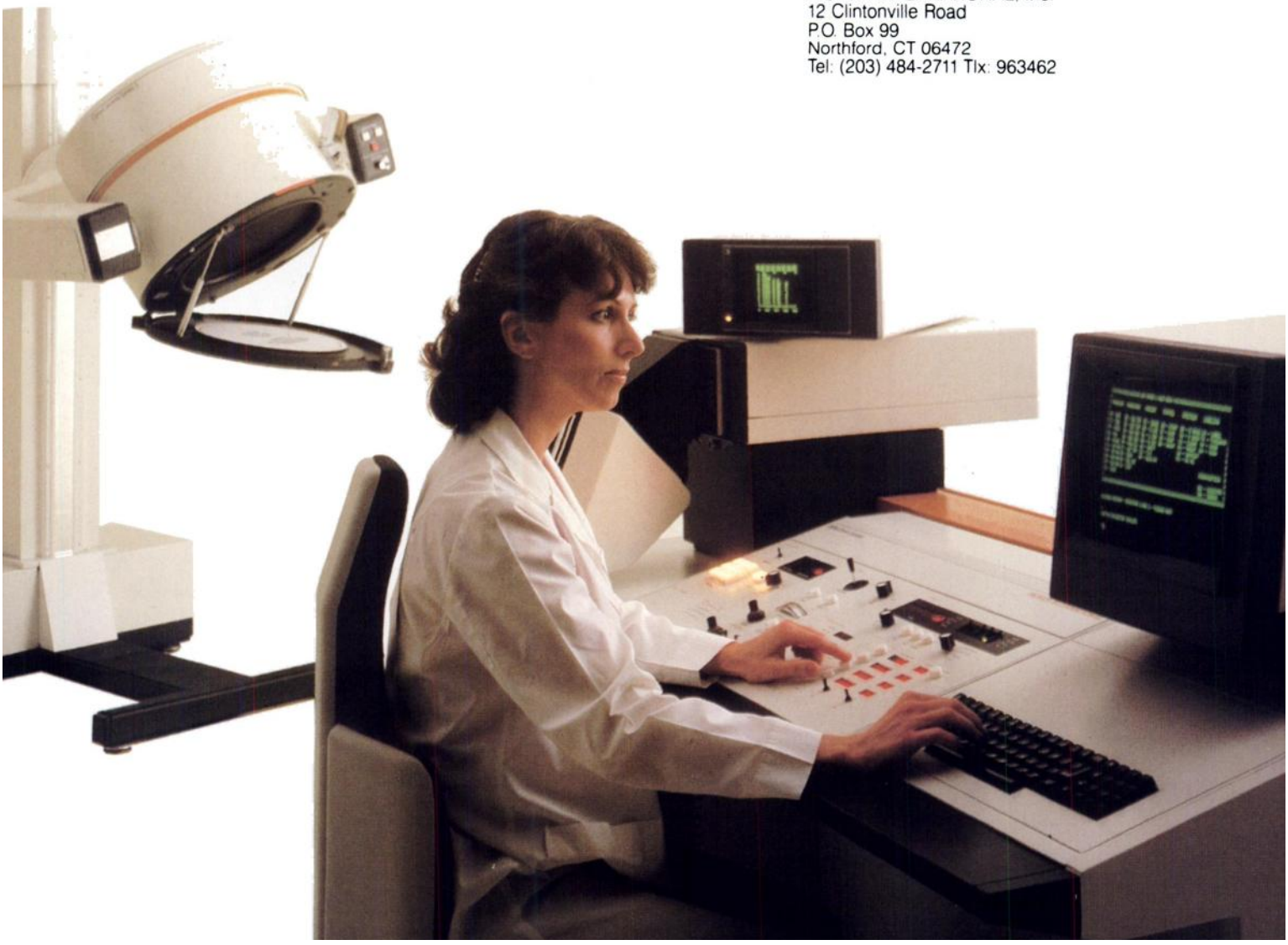

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Now there is a practical and economical way to meet your nuclear medicine requirements. NPI, the originator of Unidose pioneered the way with individual dosages of prescribed radiopharmaceuticals supplied only when you need them.
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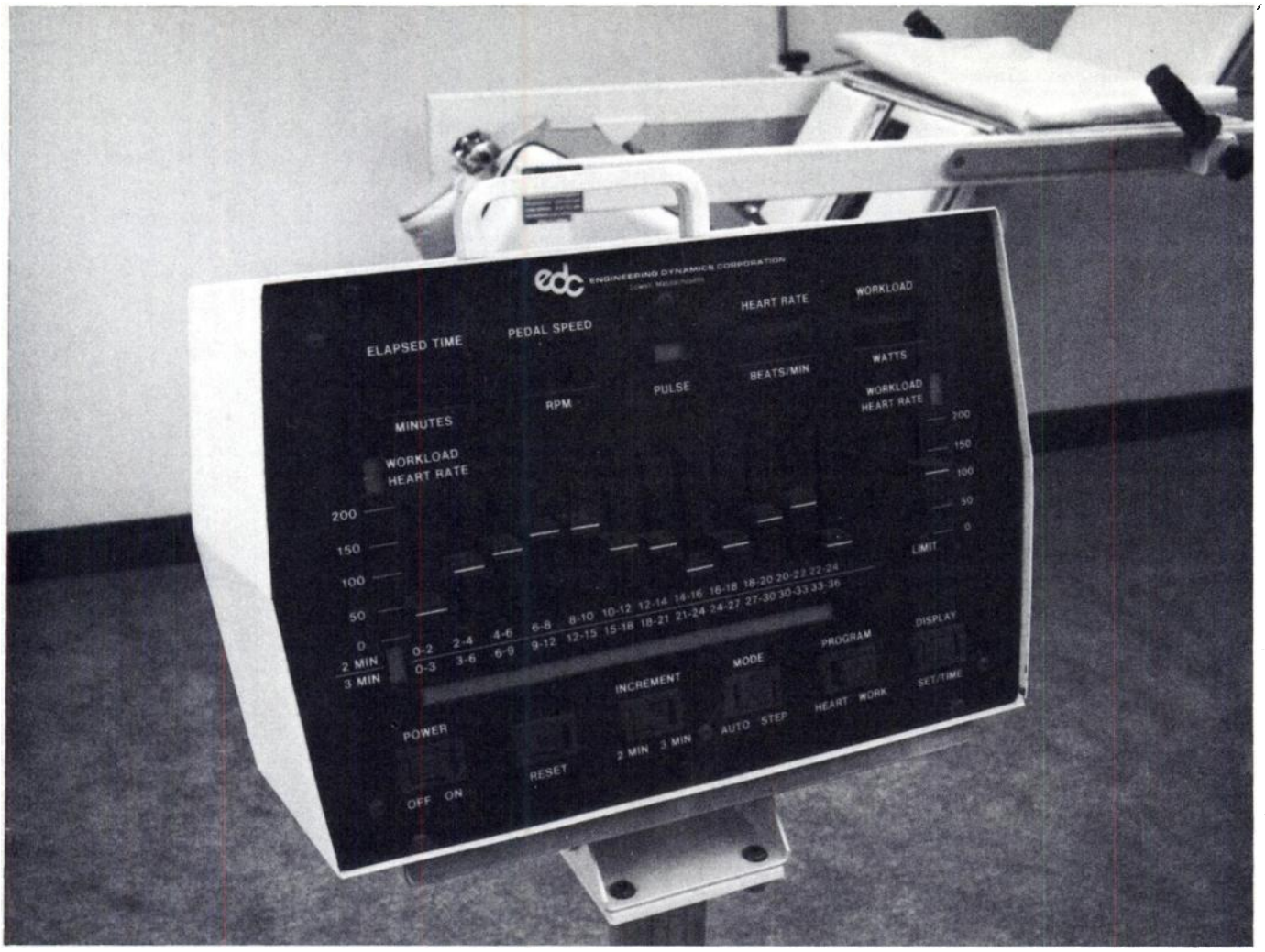
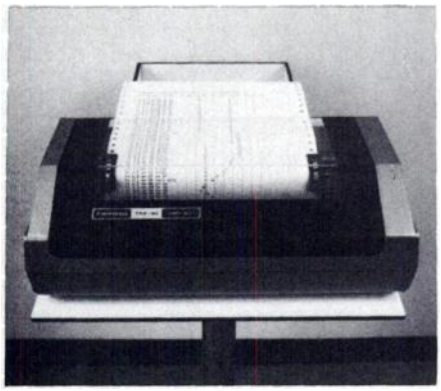


The Ultimate Cardiac Stress System.

Designed to put more muscle into your Cardiac Testing.

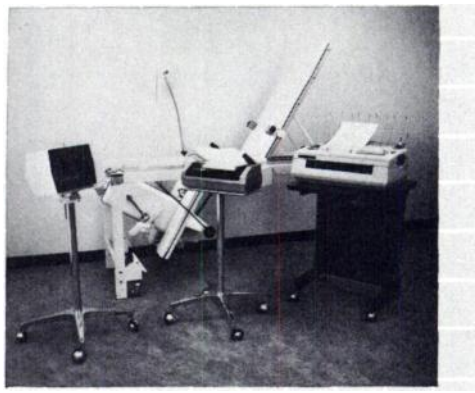
Introducing the most advanced cardiac stress system — the EDC Model 8450. Now you can program any protocol in seconds — either workload or heart rate — right at the front panel by a mere touch of the programmer.



Our powerful microprocessor insures the highest accuracy of any stress system — and as an option, you can have a permanent printed record of the entire stress test, with digital readings of elapsed time, workload, and heart rate every six seconds — and with the integrated workload (in KPM) at the end of each program segment.

These three new advances have been added to the already well accepted features of our classic model 8430, with its ability to be used either as a stress testing table or as a general imaging table — its fully adjustable table and ergometer — its clear, error-proof, digital readouts — its sturdy construction — and all the other excellent features that nuclear cardiology has come to expect from EDC.

We think the EDC Model 8450 has everything you will ever want, or need, for Cardiac Stress Testing. Give us a call for further details.



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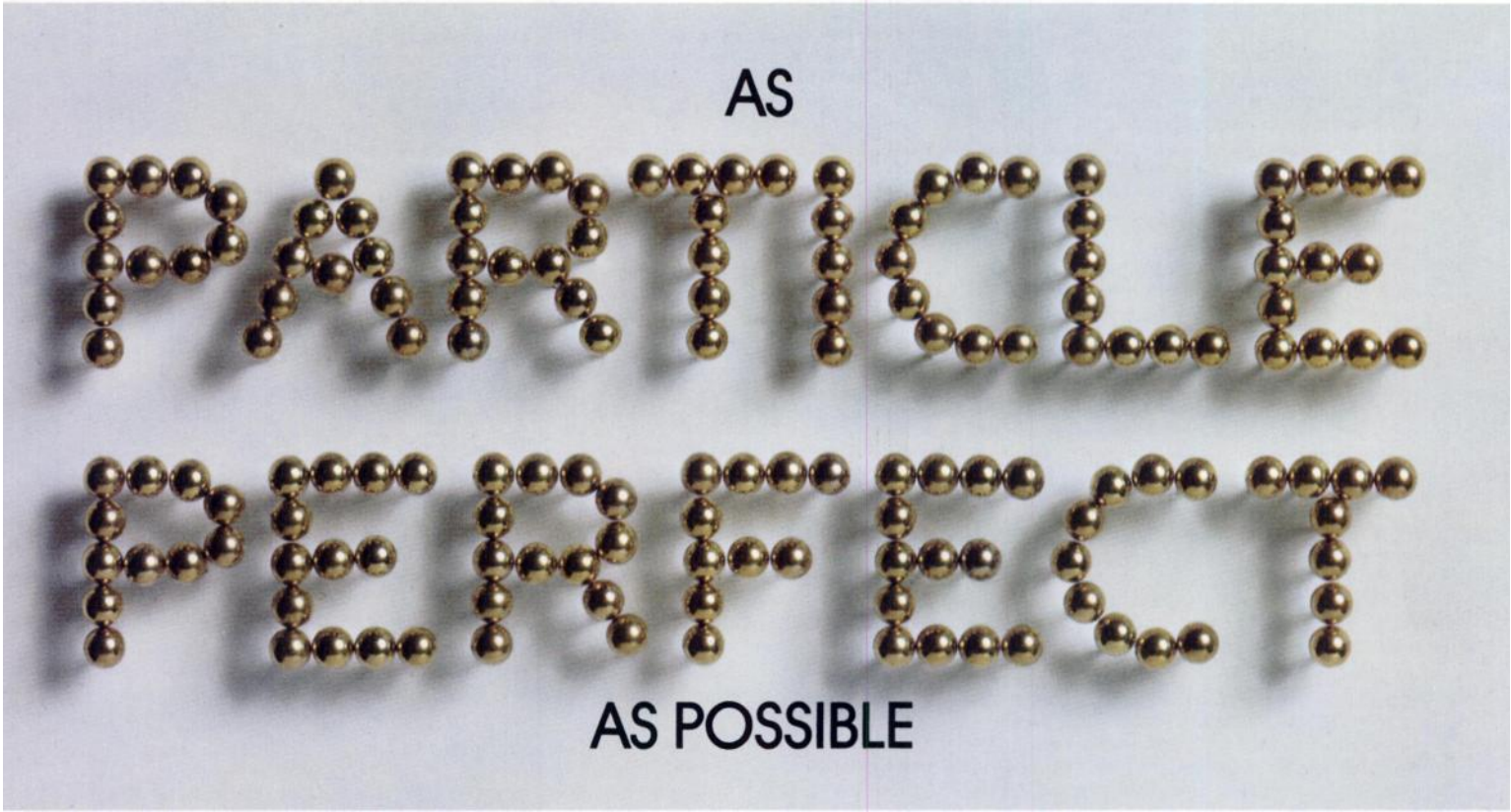
NOW AVAILABLE

In the evaluation of pulmonary perfusion

MACROTEC™

Technetium Tc 99m Albumin Aggregated Kit



More than 90% of particles in optimal 10 to 90 micron range

The average size is 20 to 40 microns... and no particles are greater than 150 microns. You'll get excellent images throughout a full 6 hours after reconstitution. Meets all your lung perfusion evaluation needs... scheduled or stat. Reconstitution time ... only 6 minutes.

More than 80% lung uptake for reliable biological efficacy

Low supernatant activity (SA) and very high radiochemical purity (RCP) help assure biological efficacy you can depend on time after time.

Please see adjacent page for brief summary.

The only MAA product indicated for use in isotopic venography

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SQUIBB™ Diagnostics

MACROTEC™

Technetium Tc 99m Albumin Aggregated Kit

Diagnostic — For Intravenous Use

DESCRIPTION

Macrotec is a sterile, nonpyrogenic, lyophilized preparation of albumin aggregated. Each 5 mL vial of Macrotec contains 1.5 mg of Albumin Aggregated, 10.0 mg Albumin Human, 0.06 mg (minimum) stannous chloride (maximum stannic and stannous chloride 0.16 mg), 1.8 mg of sodium chloride with trace amounts of sodium acetate, acetic acid and hydrochloric acid. Macrotec contains no preservatives. The pH of the reconstituted product is between 3.8 and 8.0.

The aggregated particles are formed by denaturation of Albumin Human in a heating and precipitation process. Each vial contains 1-8 million particles, 90% of which are between 10 and 90 microns in size. The average size is 20 to 40 microns; no particles are greater than 150 microns.

Reconstitution of Macrotec with sterile sodium pertechnetate Tc 99m forms an aqueous suspension of Technetium Tc 99m Albumin Aggregated for diagnostic use by intravenous injection. No less than 90% of the pertechnetate Tc 99m added to the reaction vial is bound to the aggregates at preparation time and remains bound throughout the 6-hour lifetime of the suspension.

INDICATIONS AND USAGE

Lung Imaging

Macrotec (Technetium Tc 99m Albumin Aggregated Injection) is a lung imaging agent which may be used as an adjunct in the evaluation of pulmonary perfusion in adults and children. It is useful in the early detection of pulmonary emboli and in the evaluation of the status of the pulmonary circulation in such conditions as pulmonary neoplasm, pulmonary tuberculosis and emphysema.

Isotopic Venography

Macrotec is also indicated for use in isotopic venography as an adjunct in the screening, diagnosis and management of deep vein thrombosis in the lower extremities.

Combined isotopic venography of the lower extremities and the pulmonary vasculature may be performed.

CONTRAINDICATIONS

Technetium Tc 99m Albumin Aggregated Injection should not be administered to patients with severe pulmonary hypertension.

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

WARNINGS

The literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.

PRECAUTIONS

General

In patients with right to left heart shunts, additional risk may exist due to the rapid entry of Albumin Aggregated into the systemic circulation. The safety of this agent in such patients has not been established.

Hypersensitivity reactions are possible whenever protein-containing materials such as pertechnetate labeled Albumin Aggregated are used in man. Epinephrine, antihistamines and corticosteroids should be kept available for immediate use.

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

The components of the Macrotec (Technetium Tc 99m Albumin Aggregated Kit) are sterile and non-pyrogenic. It is essential to follow directions carefully and adhere to strict aseptic procedures during preparation.

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

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

The technetium Tc 99m labeling reactions involved depend on maintaining the stannous ion in the reduced state. Hence, sodium pertechnetate Tc 99m containing oxidants should not be employed.

The preparation contains no bacteriostatic preservative. Technetium Tc 99m Albumin Aggregated Injection should be stored at 2-8°C and discarded 6 hours after formulation.

Technetium Tc 99m Albumin Aggregated Injection is a physically unstable suspension and consequently the particles settle with time. Failure to agitate the vial adequately before use may result in non-uniform distribution of radioactive particles.

If blood is drawn into the syringe, unnecessary delay prior to injection may result in clot formation.

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.

As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to clinical personnel.

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category C

Animal reproduction and teratogenicity studies have not been conducted with Technetium Tc 99m Albumin Aggregated Injection. It is also not known whether Technetium Tc 99m Albumin Aggregated Injection can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. There have been no studies in pregnant women. Technetium Tc 99m Albumin Aggregated Injection 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

The lowest possible number of particles should be used in the right-to-left shunting, in neonates and in severe pulmonary disease.

ADVERSE REACTIONS

Although adverse reactions specifically attributable to the Technetium Tc 99m Albumin Aggregated Injection have not been noted, the literature contains reports of deaths occurring after the administration of Albumin Aggregated to patients with pre-existing severe pulmonary hypertension. Instances of hemodynamic or idiosyncratic reactions to preparations of Technetium Tc 99m Albumin Aggregated have been reported.

HOW SUPPLIED

Macrotec (Technetium Tc 99m Albumin Aggregated) is supplied as a kit containing 10 reaction vials (5 mL size).

SQUIBB™ Diagnostics

New Brunswick, NJ 08903

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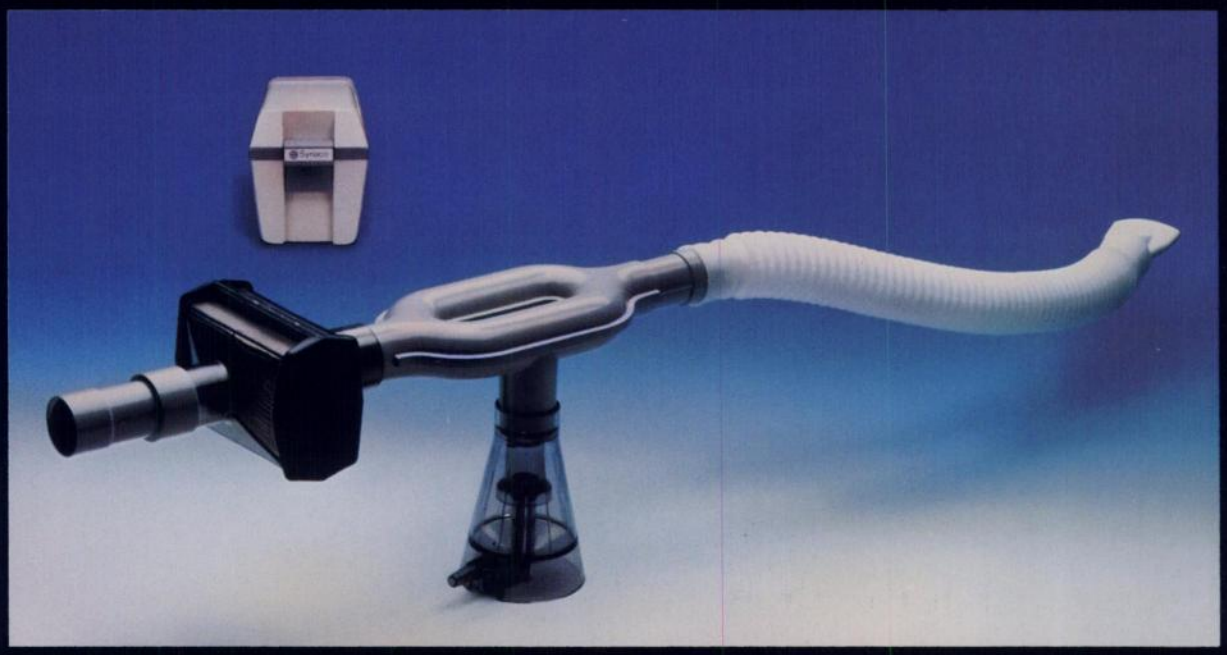
Optimized efficiency

Ventilation scanning



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

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

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"Diagnostic Quality..."[1] Skeletal Images in Two Hours!

Mallinckrodt
OSTEOSCAN®-HDP
(Technetium Tc 99m Oxidronate Kit)

THE MALLINCKRODT COMMITMENT to Nuclear Medicine

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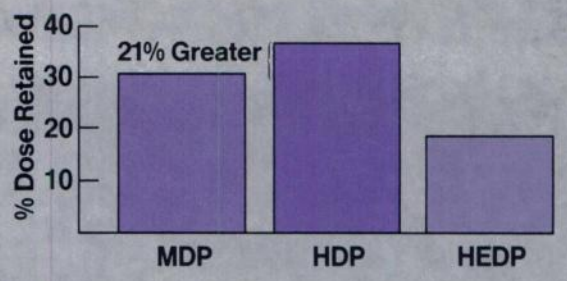
Clinical Studies Verify the Two-Hour Advantage of OSTEOSCAN®-HDP Over MDP in Skeletal Imaging

Higher Bone Uptake Than MDP at Two Hours[2]

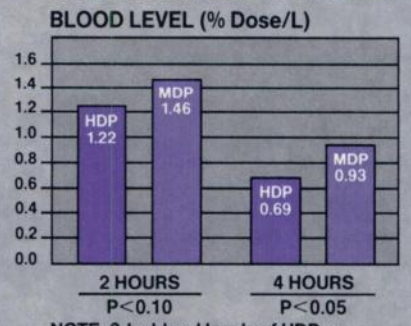
"Image quality is principally related to the absolute retention of the skeletal imaging agent on bone and the time available to allow the soft-tissue tracer component to be excreted by the kidneys."[2] In clinical comparisons,[2] OSTEOSCAN-HDP averaged 21% higher whole body retention than MDP and 99%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



Rapid Blood Clearance… Up to 16% Higher Bone to Soft-Tissue Ratios Than MDP[4-5]

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

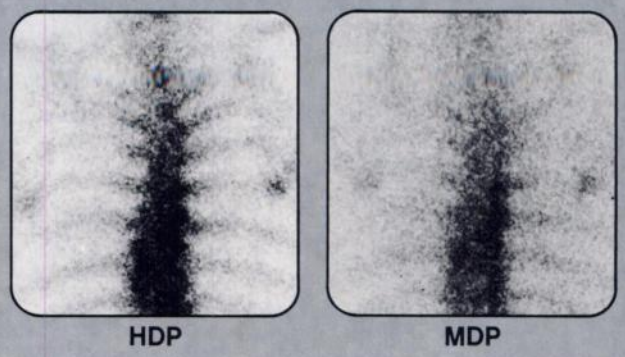
AVERAGE VALUES—10 PATIENTS[5]



NOTE: 2-hr. blood levels of HDP are significantly lower than MDP indicating faster blood clearance.

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

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



SIDE-BY-SIDE COMPARISON OF IMAGES AT 2 AND 4 HOURS[7]

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

*Significantly different ($p < 0.05$)

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

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

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

References

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

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OSTEOSCAN®-HDP

Technetium Tc99m Oxidronate Kit

DESCRIPTION

OSTEOSCAN-HDP (Technetium Tc99m Oxidronate Kit) is supplied as a lyophilized powder, packaged under nitrogen in vials for intravenous administration after reconstitution with ADDITIVE-FREE sodium pertechnetate Tc99m. Each vial contains 2.0 mg oxidronate sodium and 0.16 mg stannous chloride as active ingredients, and 0.56 mg gentisic acid as a stabilizer. The contents of the vial are sterile and non-pyrogenic.

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

Physical Characteristics

Technetium Tc99m decays by isomeric transition with a physical half-life of 6.02 hours[1]. Photons that are useful for detection and imaging studies are listed in Table I.

Table I. Principal Radiation Emission Data

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

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

External Radiation

The specific gamma ray constant for Technetium Tc99m is 0.8 R/millicurie-hr at 1 cm. The first half-value layer is 0.2 mm of Pb. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table II. To facilitate control of the radiation exposure from millicurie amounts of this radionuclide the use of a 2.5 mm thickness of Pb will attenuate the radiation emitted by a factor of about 1,000.

Table II. Radiation Attenuation by Lead Shielding

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

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

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

Hours	Fraction Remaining	Hours	Fraction Remaining
-5	1.778	5	.562
-4	1.585	6	.501
-3	1.413	7	.447
-2	1.259	8	.398
-1	1.122	9	.355
0*	1.000	10	.316
1	.891	11	.282
2	.794	12	.251
3	.708	18	.126
4	.631	24	.063

*Calibration Time

CLINICAL PHARMACOLOGY

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

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

None known.

WARNINGS

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

PRECAUTIONS

General

Contents of the vial are intended only for use in the preparation of Technetium Tc99m Oxidronate and are **NOT** to be administered directly to the patient.

Technetium Tc99m Oxidronate should be formulated within **eight (8) hours** prior to clinical use. Optimal imaging results are obtained one to four hours after administration.

Technetium Tc99m Oxidronate as well as other radioactive drugs, must be handled with care, and appropriate safety measures should be used to minimize radiation exposure to the patients consistent with proper patient management.

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc99m Oxidronate affects fertility in males and females.

Pregnancy—Category C

Animal reproduction studies have not been conducted with Technetium Tc99m Oxidronate. It is also not known whether Technetium Tc99m Oxidronate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Technetium Tc99m Oxidronate should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Technetium Tc99m is excreted in human milk during lactation, therefore formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

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

DOSAGE AND ADMINISTRATION

General Instructions

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

Radiation Dosimetry

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

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

Table IV. Absorbed Radiation Doses*

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

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

Preparations For Use

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

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

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

HOW SUPPLIED

OSTEOSCAN-HDP is supplied as a lyophilized powder packaged in vials. Each vial contains 2.0 mg oxidronate sodium and 0.16 mg stannous chloride as active ingredients, and 0.56 mg gentisic acid as a stabilizer. Kits containing 5 vials (NDC 00019-N099-BO) or 30 vials (NDC 00019-N099-DO) are available. The drug can be stored at room temperature both prior to and following reconstitution with ADDITIVE-FREE sodium pertechnetate Tc99m.

Manufactured for: Mallinckrodt, Inc., St. Louis, MO 63134 by Lypho-Med, Inc., Chicago, IL 60651

Mallinckrodt®

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Mallinckrodt, Inc.
Post Office Box 5840
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Are your diagnostic images FACT or fancy?

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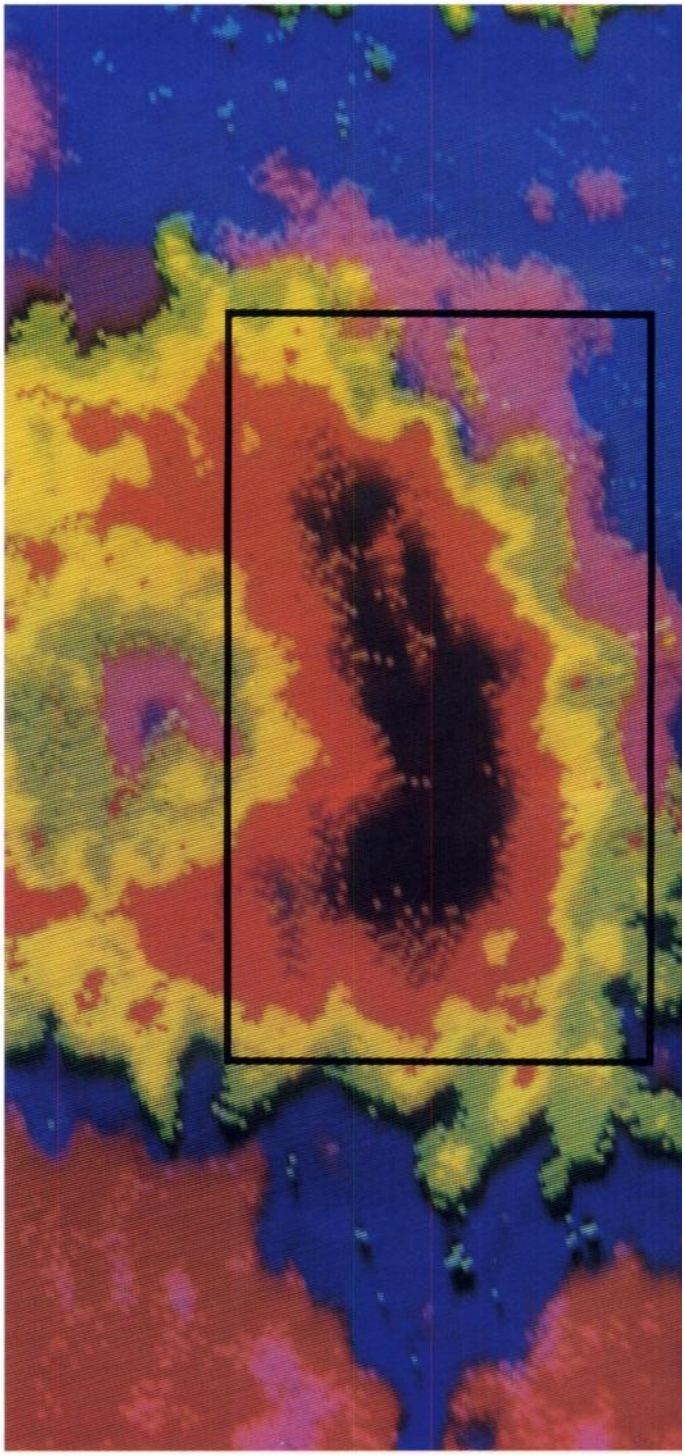
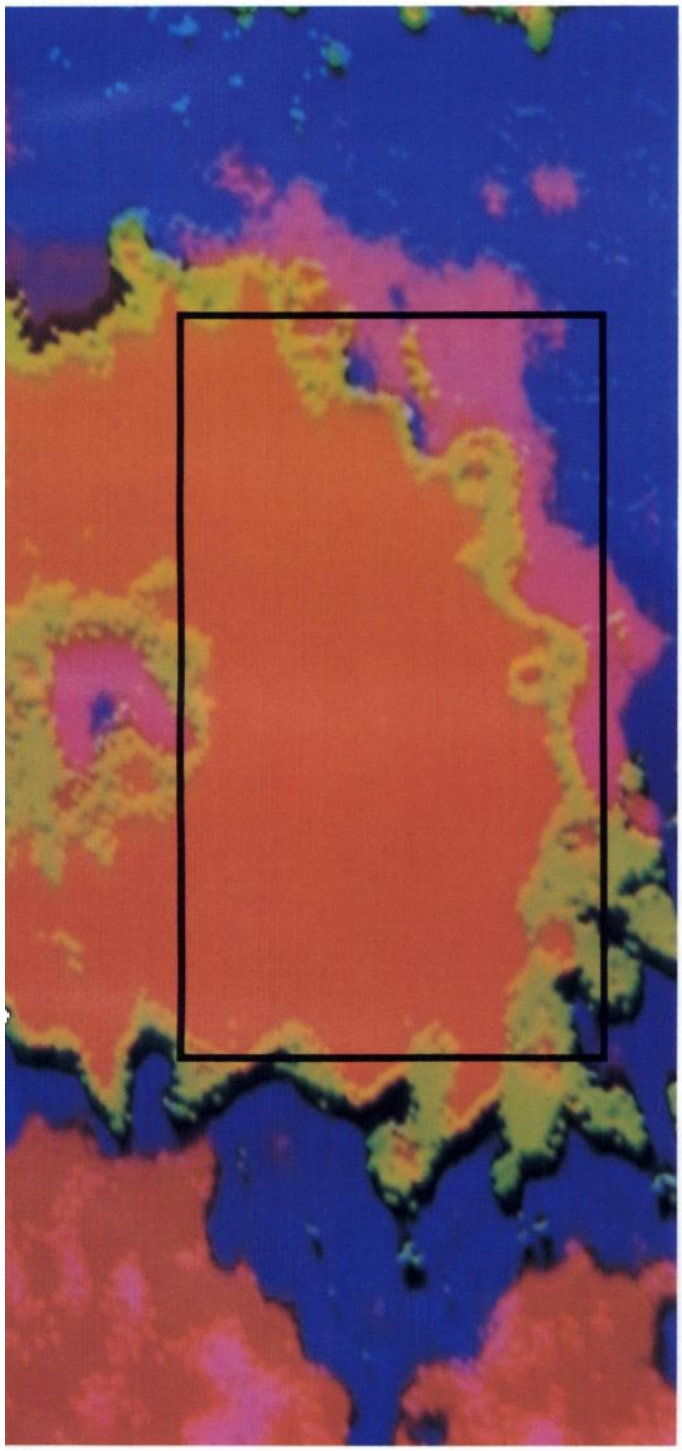


A diagnostic image should tell you the truth.
Next time you're reading the specifications on a nuclear imaging system, watch for words like "compensated," "selected," or "operator calibrated."

These words may be telling you that what you get may *not* be what you're looking for.

Siemens Nuclear Imaging Systems tell you the truth...
Some years ago, Siemens introduced ZLC,™ the innovative energy and linearity distortion removal system. ZLC corrects intrinsic energy variations and spatial non-linearities–the major causes of non-uniformities in gamma cameras.

...the whole truth...
DIGITRAC,™ the newest innovation in Siemens Camera Systems, is a microprocessor controlled PMT gain adjustment circuit incorporated in the detector. DIGITRAC automatically adjusts individual PMT gain (or drift) so that gamma ray photopeaks are precisely aligned throughout the camera field of view. Using nuclear radiation as the primary standard, the camera is recursively calibrated for the isotope being imaged.



...and nothing but the truth.

Siemens cameras with ZLC™ and DIGITRAC offer energy correction, linearity correction and recursive calibration without count skimming, count adding, or other "cosmetic" manipulations of the display.

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New technology that makes everything else something less than "state of the art"

ZLC with DIGITRAC is the step forward that makes all previous camera technology obsolete. Here's what ZLC with DIGITRAC offers:

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- Minimal system downtime
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- Consistent system performance–month after month, year after year

Note: Images shown are enhanced for graphic presentation only.

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- SPECT processor with dual isotope imaging capability allows automatic body contour mapping for attenuation correction
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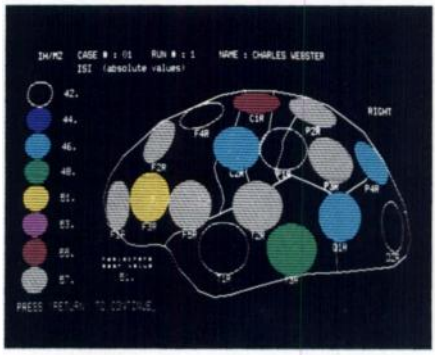

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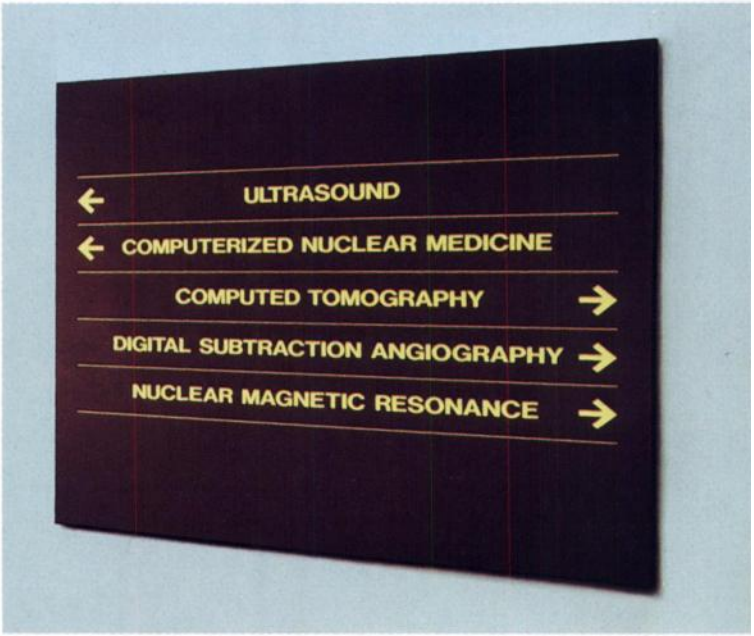

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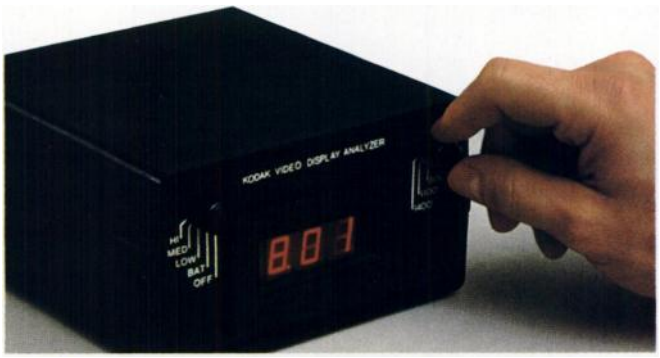

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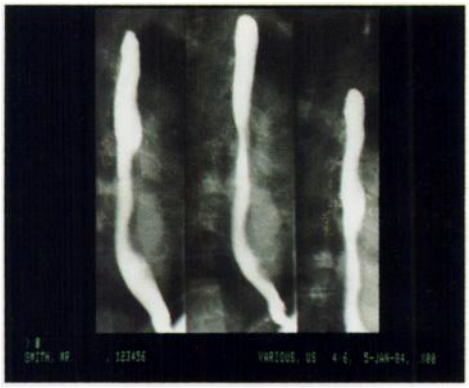
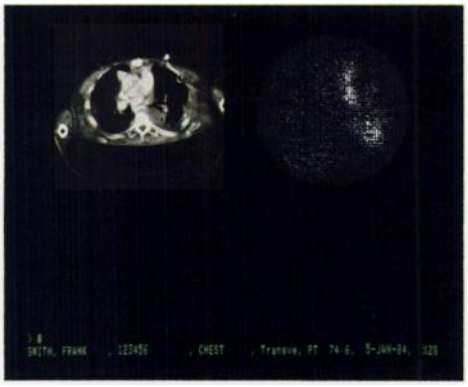
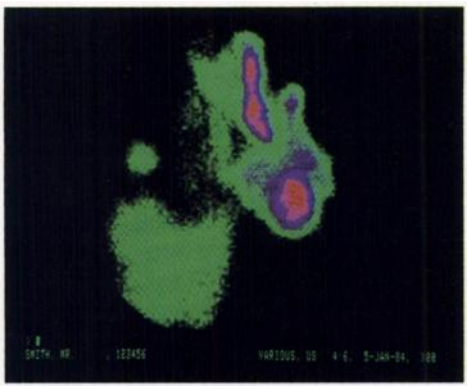


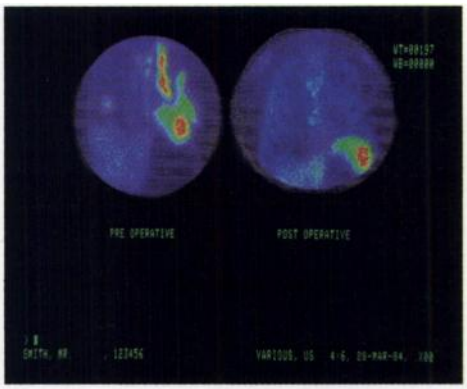
X ray Shows Abnormal Fluid Collection Between the Esophagus and the Aorta



CT—Abscess Obscured by Surgical Clips Comparative SPECT Clarifies Abscess Position



Pre-op Nuclear Scan—Indium 111 Labelled White Cells Further Pinpoint Infected Area to Esophagus and Soft Tissue. Aorta Not Involved.



Pre- and Post-op Indium Scan Comparison—Shows Abscess Drained and Treated

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Images courtesy of Jason S. Zielonka, M.D.; Chief, Nuclear Medicine Services; V.A. Medical Center; Wood, WI.

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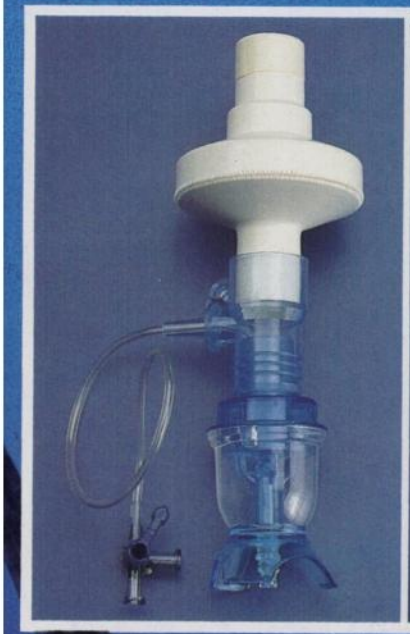

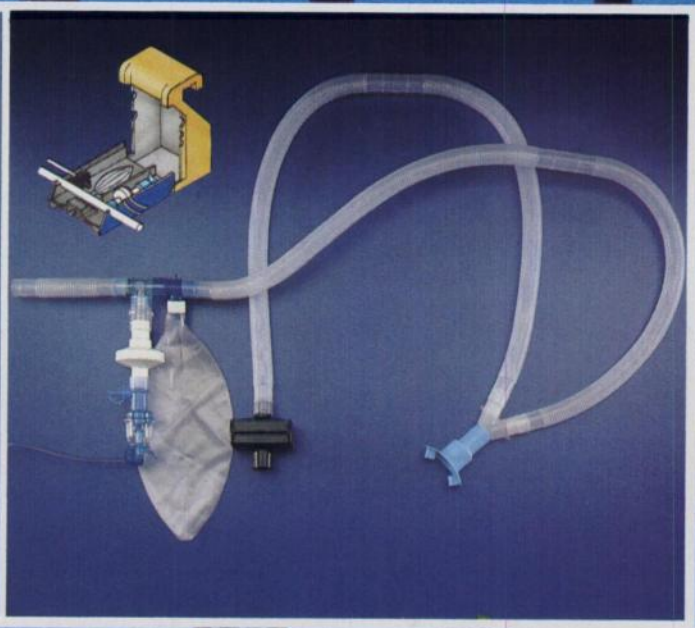

* *Optimist* : trade mark of MEDICAID (England)

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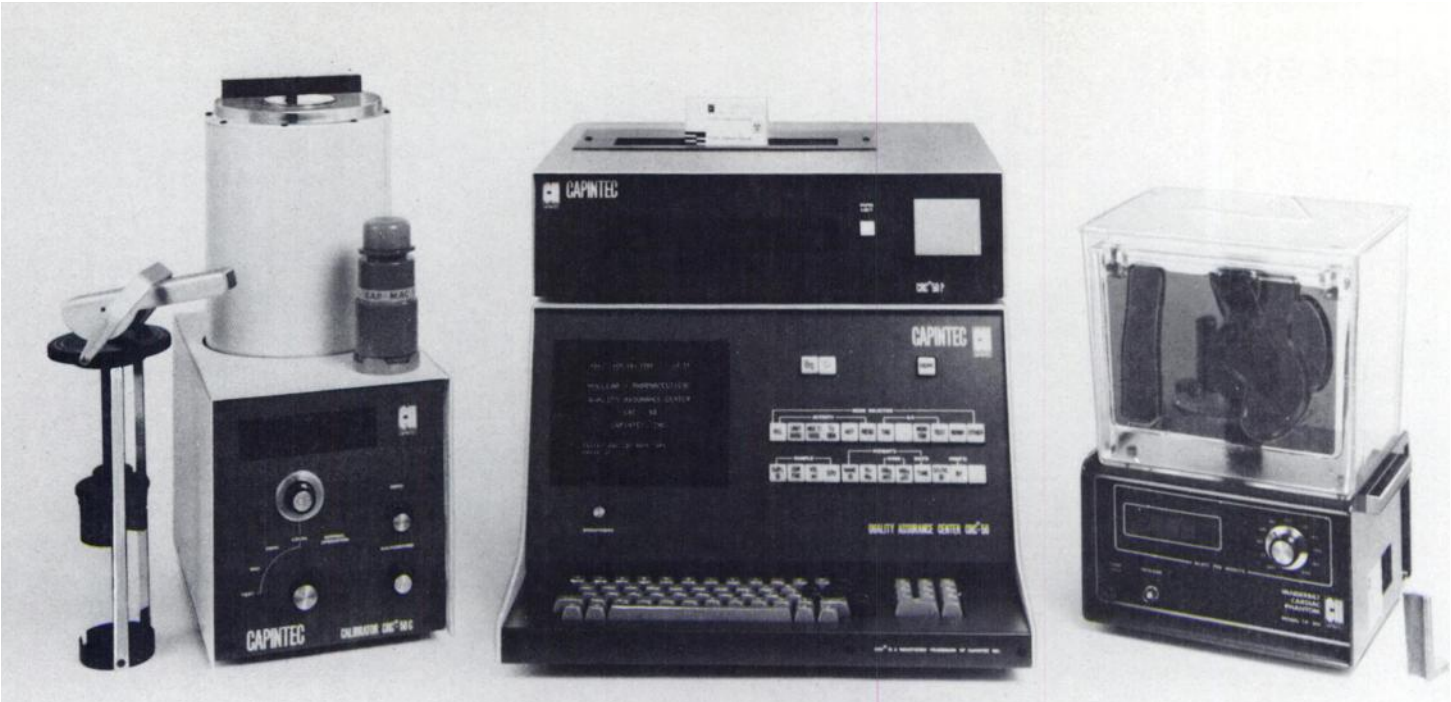

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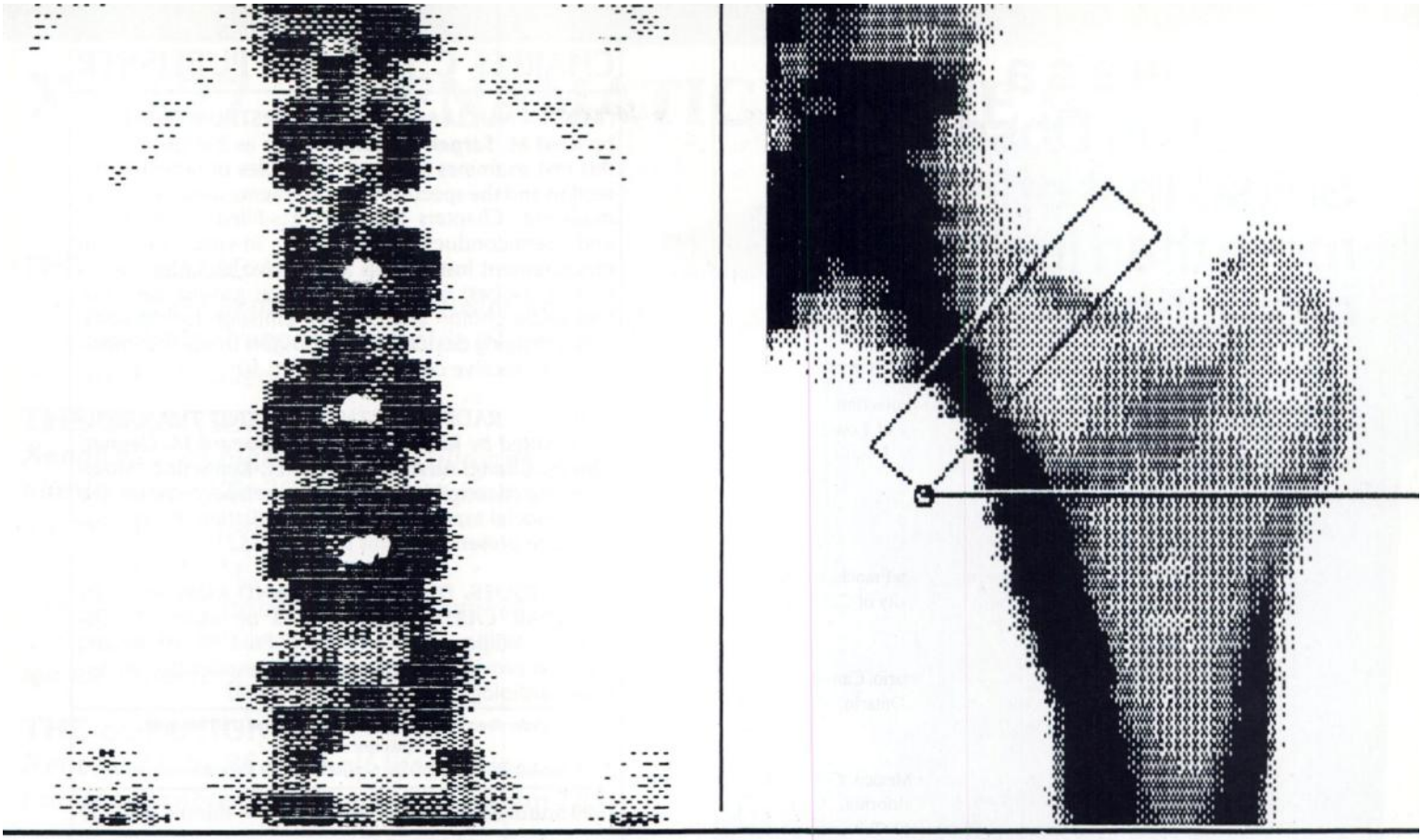

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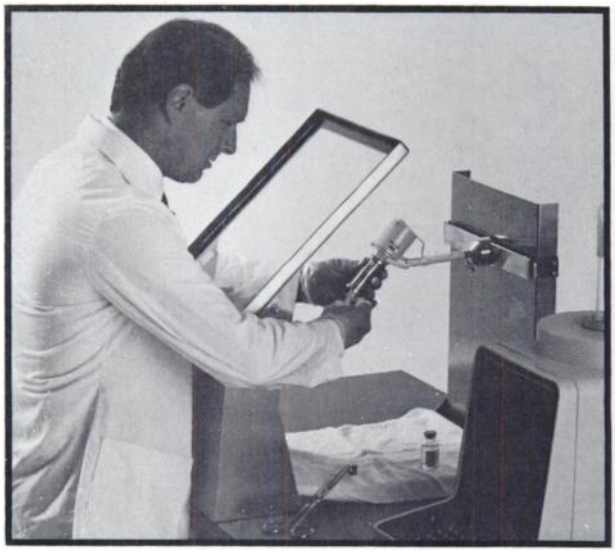

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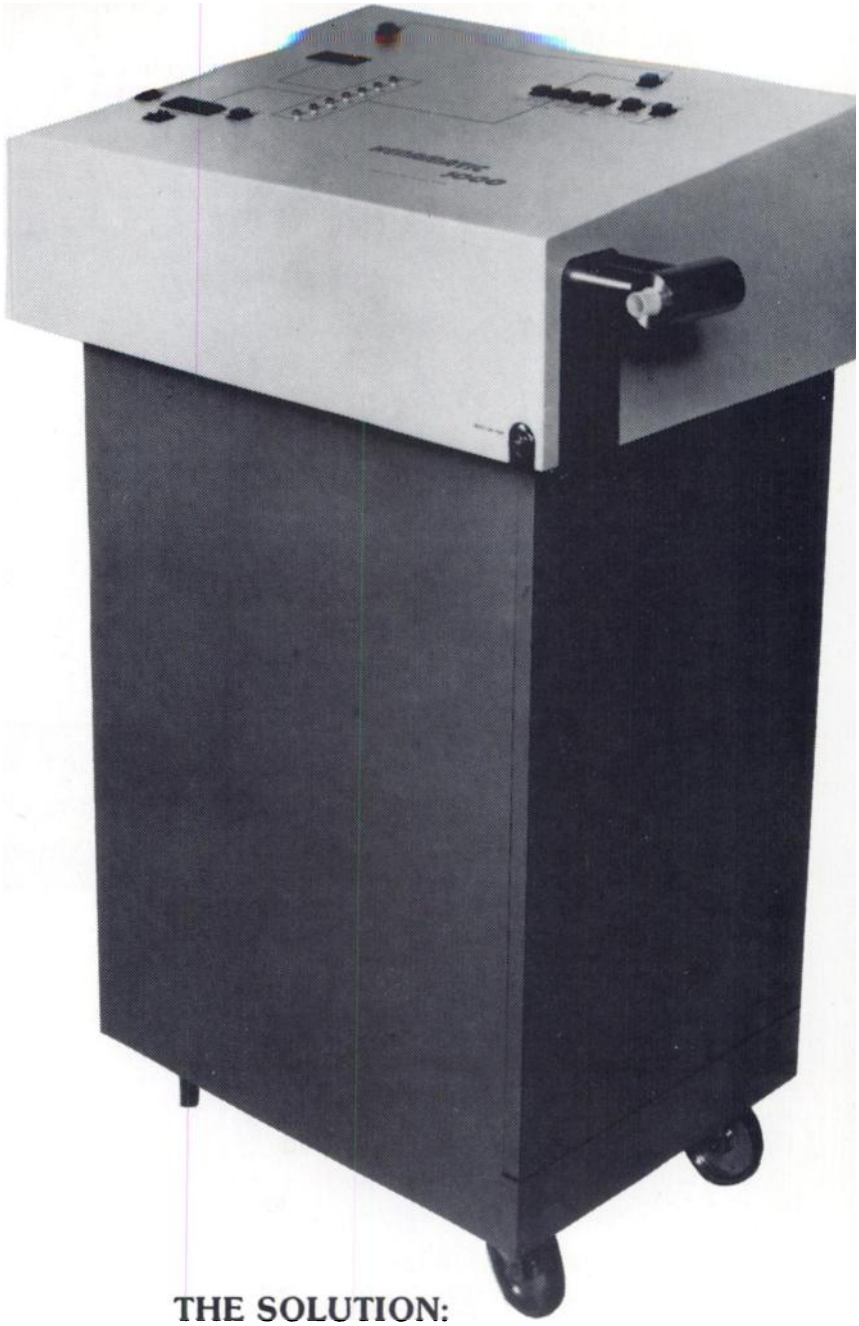

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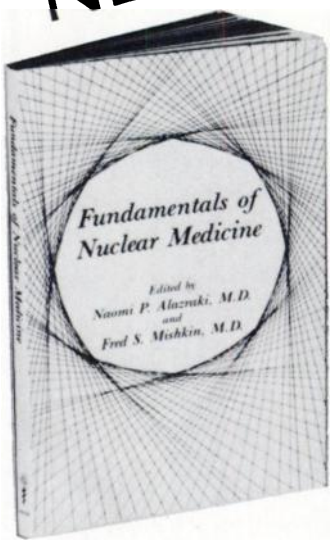

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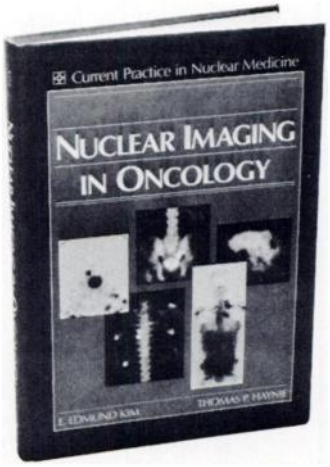

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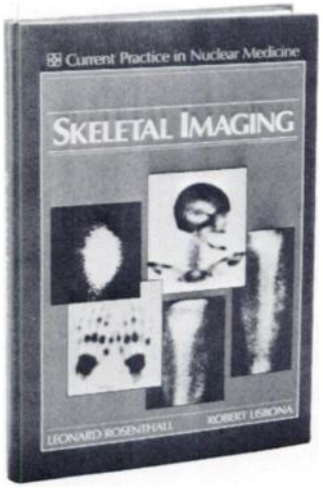

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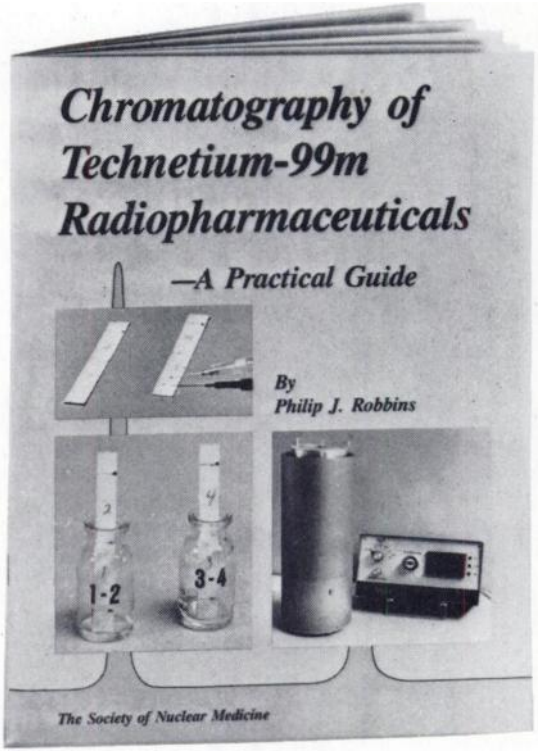

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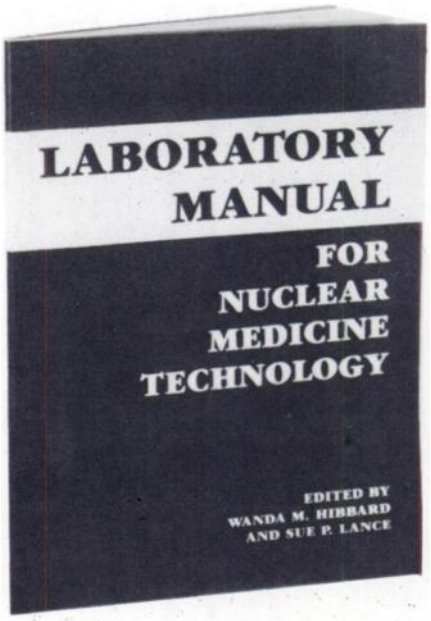

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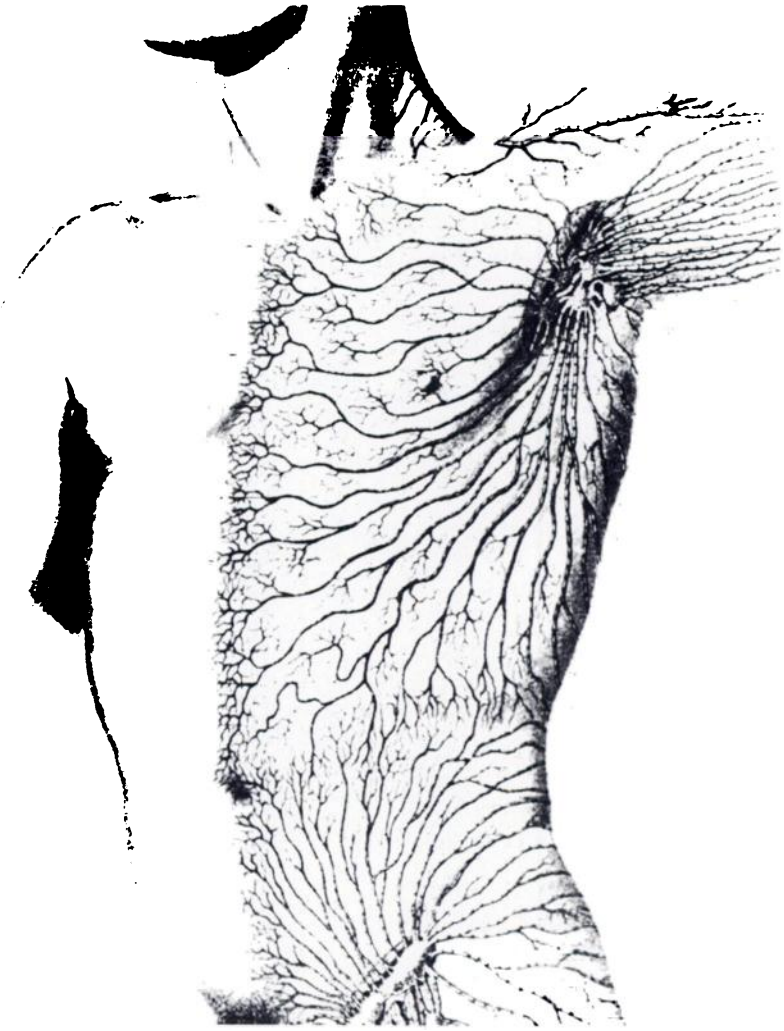

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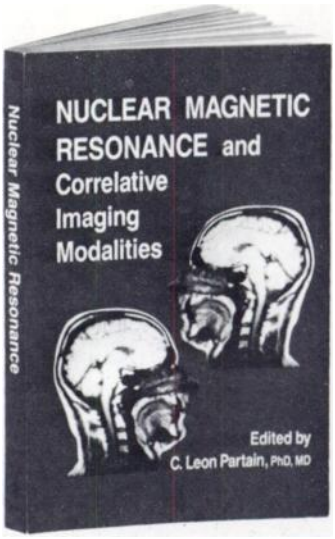

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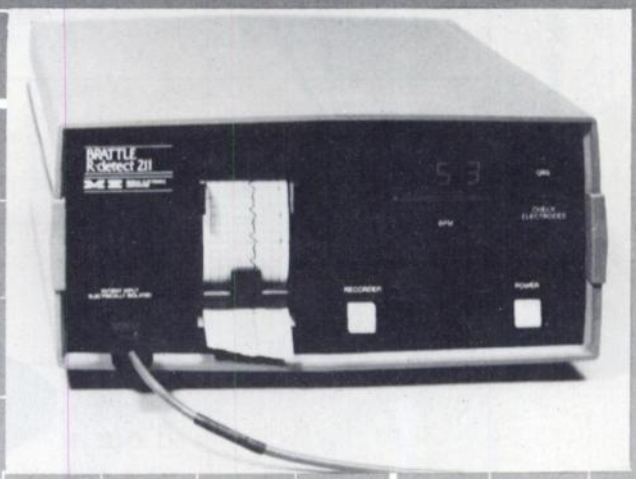

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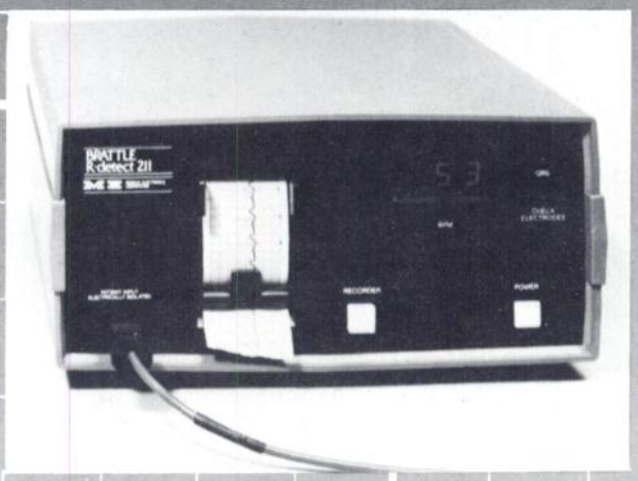

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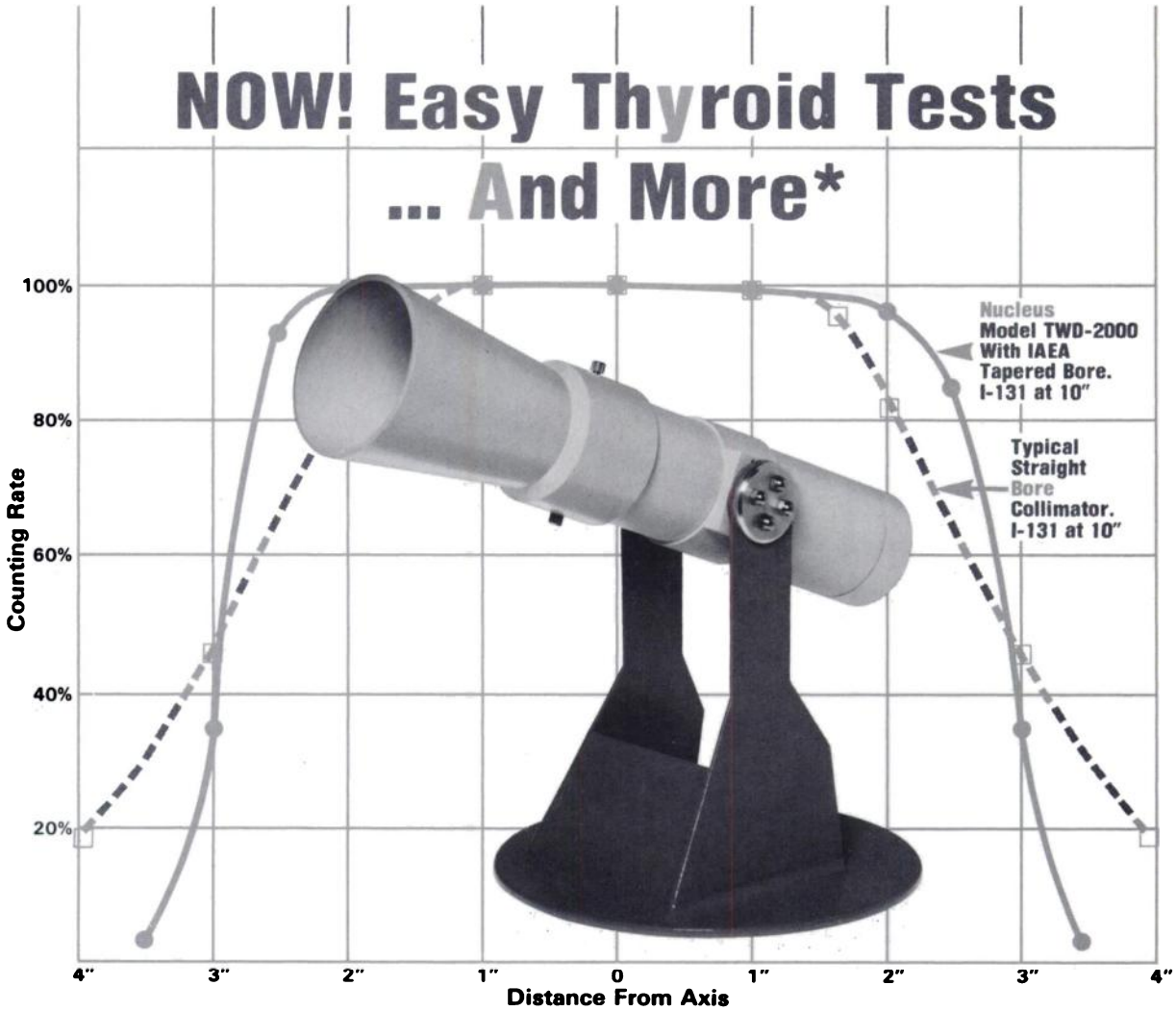

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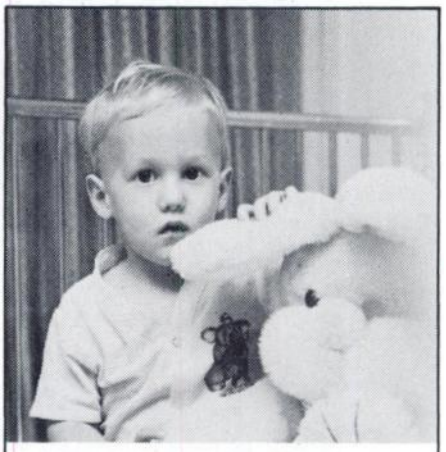

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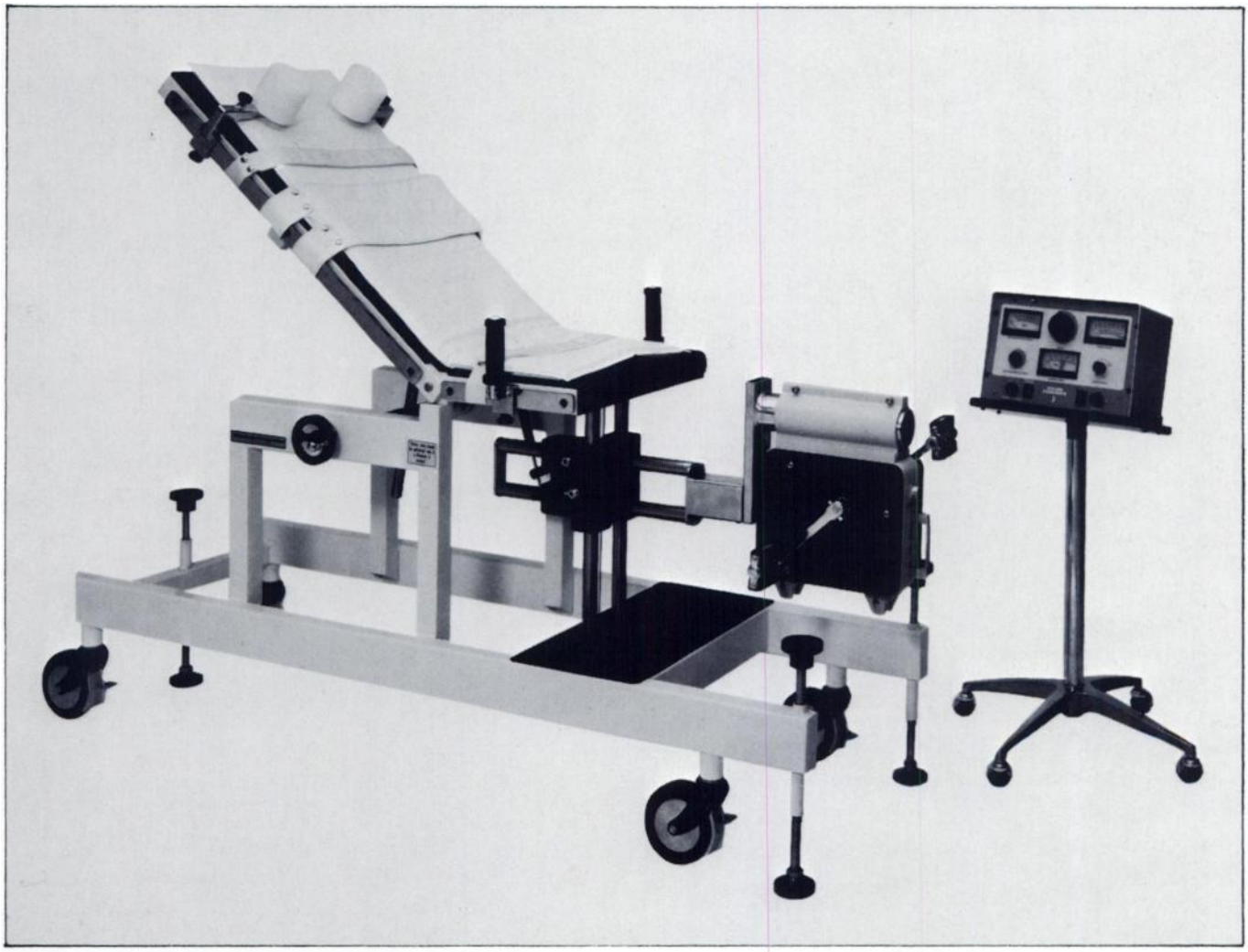

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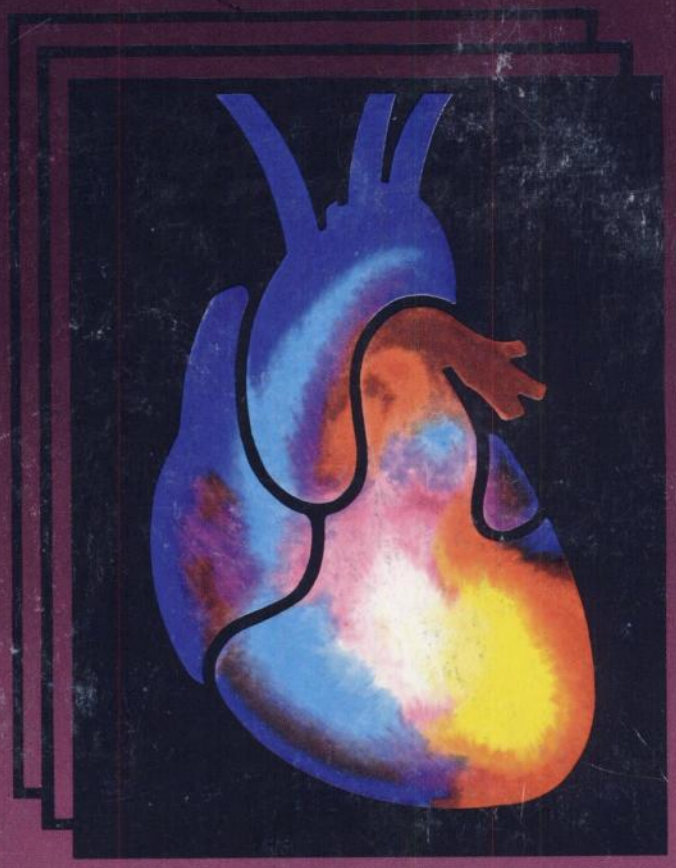

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For complete prescribing information consult package insert, a brief summary of which follows:

DESCRIPTION: The kit consists of 10 multidose reaction vials each containing a lyophilized mixture of 21 mg human serum albumin and 0.23 mg stannous tartrate. Hydrochloric acid was added prior to lyophilization for pH adjustment. All components are sterile and pyrogen-free. When a solution of sterile and pyrogen-free Sodium Pertechnetate Tc 99m in isotonic saline is mixed with these components, following the instructions provided with the kit, Technetium Tc 99m Human Serum Albumin is formed, with a labeling efficiency of 90% or greater. The product so derived has a pH of 2.5–3 and is intended for intravenous injection. The precise structure of Technetium Tc 99m Human Serum Albumin is not known at this time. The Normal Human Serum Albumin used in this preparation was nonreactive when tested for hepatitis B surface antigen (HB_sAg) by radioimmunoassay.

CONTRAINDICATIONS: The use of Technetium Tc 99m Human Serum Albumin is contraindicated in persons with a history of hypersensitivity reactions to products containing human serum albumin.

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

Technetium Tc 99m Human Serum Albumin must not be used after three hours from the time of formulation.

Pregnancy Category C. Animal reproduction studies have not been performed 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 Human Serum Albumin should be used in pregnant women only when clearly needed.

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

Safety and effectiveness in children have not been established.

Technetium Tc 99m Human Serum Albumin, 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.

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

HOW SUPPLIED: Kit Contents

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20 PRESSURE—SENSITIVE LABELS for final Technetium Tc 99m Human Serum Albumin preparation.
1 PACKAGE INSERT.