

Technetium Tc 99m Generator

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5cc and 10cc elution vials

Elution vial sh

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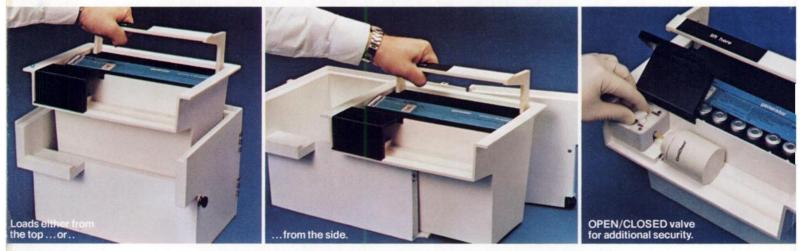
Adaptors for various elution vial

DCC VIAL

TD

# **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 Technétium 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.

medi+physi ROCHE 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 4.5-75, hydrochloric acid and/or sodium hydroxide may have been used for pH abjustment. Over the itie of the generator, an elufic on will contain a yield of 80% to 100% of the theoretical amount of Technetium Tc 99m available from the Molybdenum Mo 99 on the cenerator 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.

INDUCATIONS AND USAGE: Sodium Pertechnetae regiment of yine use before duministration. 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 vestoc-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 letal 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 lew (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 Sol milicuries up to 16,600 milicuries (in approximately 830 milicurie 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:		June, 1983	
CINTICHEM, INC.	and	UNION CARBIDE CORPORATION	
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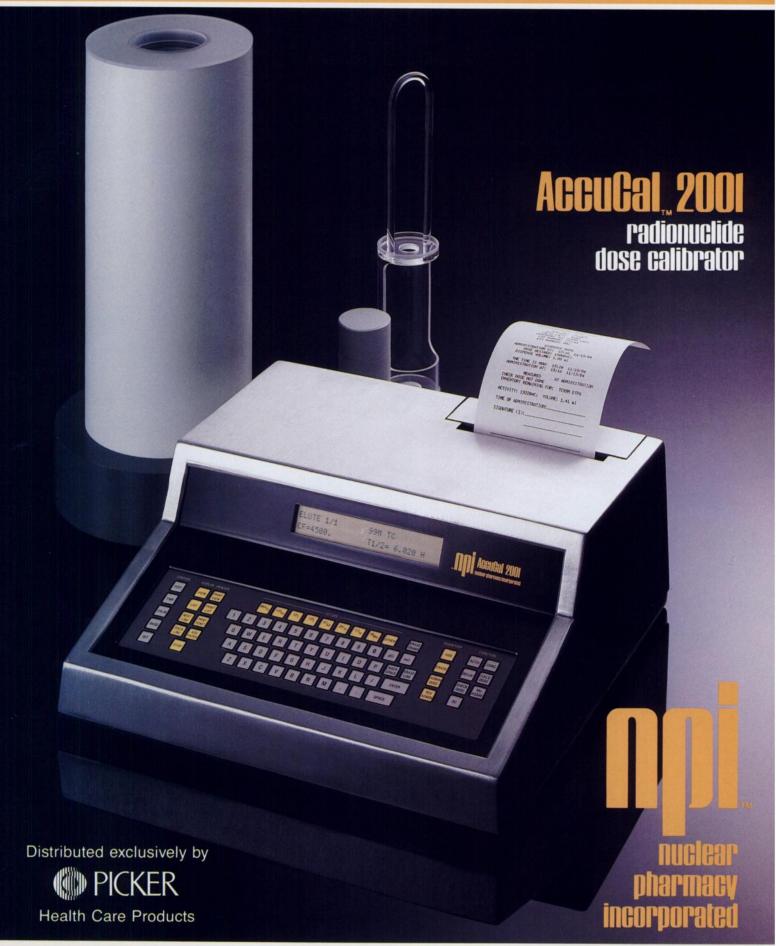
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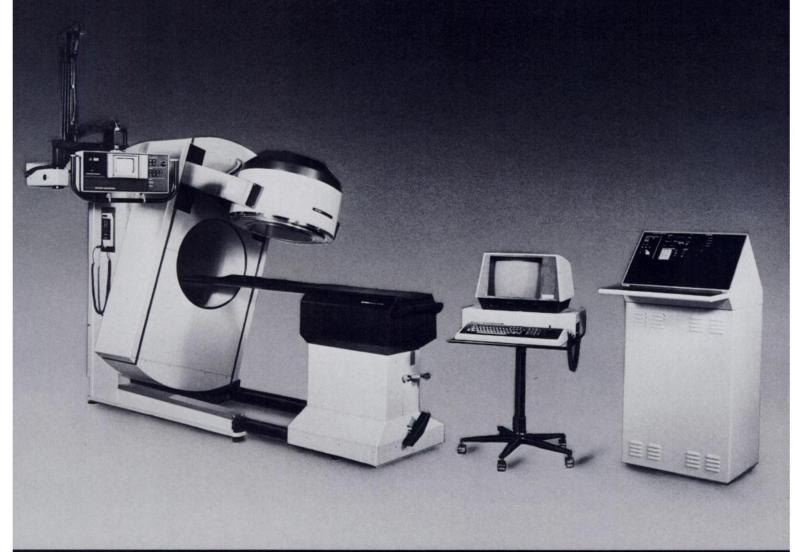


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# **RAYTHEON SPECTRUM 91 ECT: THE INTELLIGENT ROBOTIC ECT SYSTEM... THAT KEEPS YOU IN TOTAL CONTROL.**



Raytheon Medical Systems has harnessed the imaging power of our exclusive, fourth generation 91tube detector – complete with variable linearity circuitry – to the profession's most precise gantry system, table and image processing to create the Spectrum 91. The result is the first optimized ECT system... with uncompromised planar capability.

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"Teaching" the gantry is fast... easy... effortless. It can retrace virtually any contour after only two minutes of patient-specific programming. What's more, automatic parallelism of the detector head minimizes complex setup routines common to SPECT protocols.

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Spectrum 91 ECT gives you positive imaging control – two ways. First, the Raytheon Digital Parameter Controller gives you fast, accurate and repeatable entry and monitoring functions of all study, system and patient parameters. Status verification is positive... and reassuring.

But that's not all. The Spectrum 91 ECT System can also interface

with a variety of computer systems for both gantry control and imaging capability. So the operational choice is left up to you.

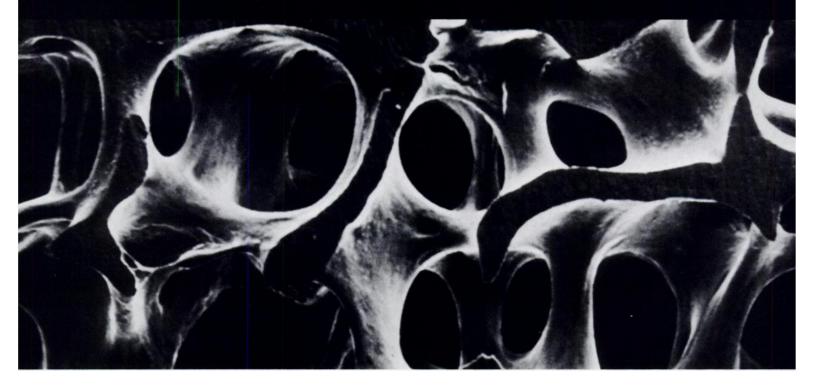
Couple all this capability with a unique, interlocking carbon fiber table that easily simplifies all patient imaging... and you'll see exactly why the Spectrum 91 ECT System is a first in so many ways.

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Please see adjacent page for brief summary.

## The only MAA product indicated for use in isotopic venography

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Albumin Ac Diagnostic — For Intravenous

#### 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 chioride (maximum stannic and stannous chioride 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 proteincontaining 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).



New Brunswick, NJ 08903

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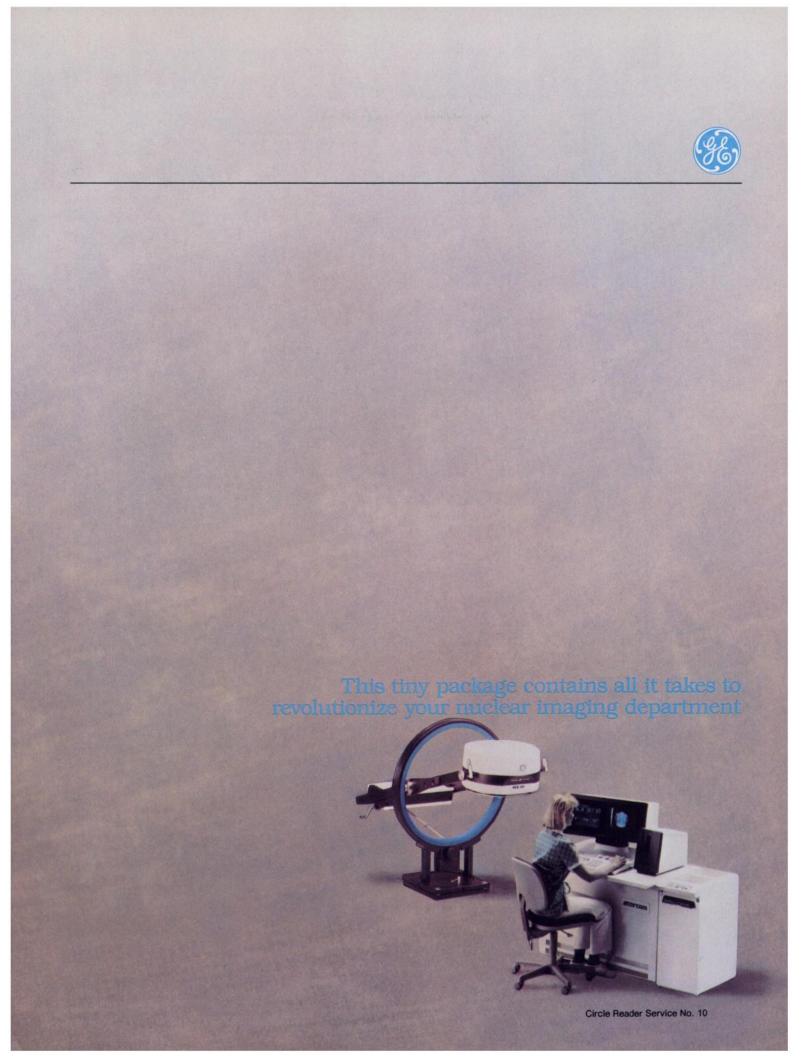
Starcam is a breakthrough in imaging technology. It provides today's nuclear departments with procedural capabilities unsurpassed by any other system. It redefines the operation of your department, eliminating many time-consuming functions without compromising the diagnostic value of the information obtained. The result is a more effective, efficient imaging department; one that optimizes diagnostic capability without jeopardizing the economic well-being of your health care institution.



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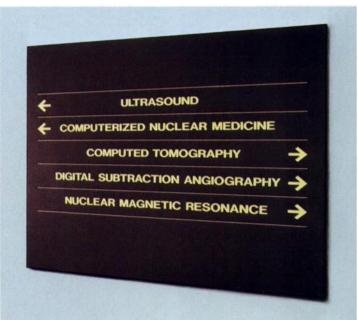
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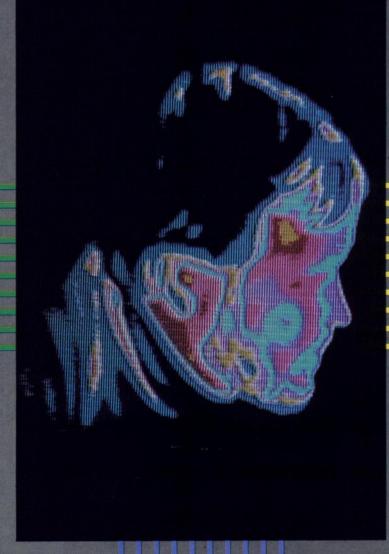
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Circle Reader Service No. 11

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# **MCROLIE** Technetium Tc 99m Albumin Colloid Kit The first "no boil" instant colloid kit for <u>consistent</u> liver/spleen and bone marrow imaging



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# **NEN Medical Products**



# **MICROLITE**<sup>™</sup>

Kit for use in the preparation of Technetium Tc 99m Albumin Colloid

#### FOR DIAGNOSTIC USE

INDICATIONS AND USAGE: Technetium Tc 99m Albumin Colloid is indicated for use as a diag-nostic imaging agent for visualization of the functioning reticuloendothelial (RE) system, of the liver, n and bone marroy

CONTRAINDICATIONS: Technetium Tc 99m Albumin Colloid is contraindicated for persons with a history of hypersensitivity to products containing human serum albumin WARNINGS: The theoretical possibility of allergic reactions should be considered in patients who

receive multiple doses. PRECAUTIONS: The contents of the kit are not radioactive. However, after the sodium pertechne-

tate Tc 99m is added, adequate shielding of the final preparation must be maintained The labeling reactions involved in preparing the agent depend on maintaining this 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.

The contents of the vial are sterile and non-pyrogenic. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiodiagnostic

Technetium Tc 99m Albumin Colloid should be used within six hours from the time of reconstitution. Refrigerate at 2° to 8°C after reconstitution. If blood is withdrawn into the syringe, unnecessary delay prior to injection may result in clot formation in situ.

Do not use if clumping of the contents is observed.

Technetium Tc 99m Albumin Colloid (MICROLITE) as well as other radioactive drugs should be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patient consistent with proper patient management

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

No animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Albumin Colloid affects fertility in males or females.

#### Pregnancy Category C

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

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

Nursing Mothers

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

Pediatric Use Safety and effectiveness in children below the age of 18 have not been established General

This radiopharmaceutical preparation should not be administered to children or to pregnant women unless the expected benefits to be gained outweigh the potential risks

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides ADVERSE REACTIONS: Although no adverse reactions associated with the use of Microlite have been reported, hypersensitivity reactions are theoretically possible whenever protein-containing ma terials such as TC 99m-labeled aggregated albumin are used in man. Epinephrine, antihistamines and corticosteroid agents should be available for use in the event such a reaction occurs. DOSAGE AND ADMINISTRATION: The recommended intravenous dose range for the average (70kg) patient is 37-296MBq (1-8 millicuries).

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Re-suspend colloid by repeated inversion of the shielded vial imme-diately prior to withdrawal of dose into syringe. Inspect the vial for foreign particulates. Do not

administer if foreign particulates are found in the colloid (If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to clot formation in situ). Do not backflush the syringe. Slow injection is recommended and for optimum results imaging may begin about 15 minutes after injection. Radiochemical purity should be checked prior to patient administration, using the following or equivalent procedure. (Please see complete prescribing information ) HOW SUPPLIED: MICROLITE\*\* Kit for use in the preparation of Technetium Tc 99m Albumin Colloid is supplied in kits of five or thirty vials, sterile and non-pyrogenic, each vial containing in

lyophilized form:	
Albumin Colloid	1mg
Normal Human Serum Albumin	10mg
Total Tin, maximum (as stannous chloride SnCl <sub>2</sub> + 2H <sub>2</sub> O)	0.17mg
Stannous Chloride (SnCl <sub>2</sub> · 2H <sub>2</sub> O) (minimum)	0.006mg
Poloxamer 188	1 1mg
Medronate disodium	0.12mg
Sodium Phosphate (anhydrous)	10mg

Prior to typophilization the pH is adjusted with HCl and/or NaOH. The contents of the vial are lyophilized and stored under ntrogen. Included in each five (5) vial kit are one (1) package insert and welve (12) radiation labels. Included in each thirty vial kit is one (1) package insert and seventy-two (72) radiation labels. Before reconstitution store at room temperature (15°-30°C) and protect from

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

Technetium Tc 99m Albumin Colloid is prepared by adding 2-8ml of oxidant-free sodium pertechne-tate Technetium Tc 99m solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Technetium Tc 99m Albumin Colloid

Catalog Number NRP-470 (5-Vial Kit) Catalog Number NRP-470C (30-Vial Kit)

May 1984

511616

# 



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# **MIRD** (Medical Internal Radiation Dose) **PAMPHLETS AVAILABLE**

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5 (Revised) Estimates of specific absorbed fractions for photon sources uniformly distributed in various organs of a heterogeneous phantom (1978)

10 Radionuclide decay schemes and nuclear parameters for use in radiation-dose estimation (1975)

11 'S' absorbed dose-per-unit cumulated activity for selected radionuclides and organs (1975)

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3 Includes the original pamphlet #5: "Estimates of absorbed fractions for monoenergetic photon sources uniformly distributed in various organs of a heterogeneous phantom.'' (1969)

6 Includes pamphlet #9: "Radiation dose to humans from <sup>75</sup>Se-L-Selenomethionine.'' (1972)

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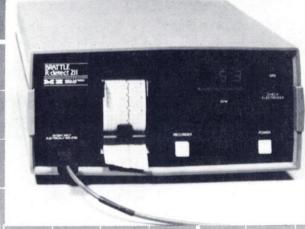
Pamphlets	Supplements	Complete Set
<b> 1</b> (\$5.25)	<b>3(\$</b> 1.50)	\$25.00 plus
<b> 5</b> (\$7.75)	<b>6(\$</b> 3.00)	\$4.00 for shipping
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<b>11(\$</b> 11.00)		not include binder)
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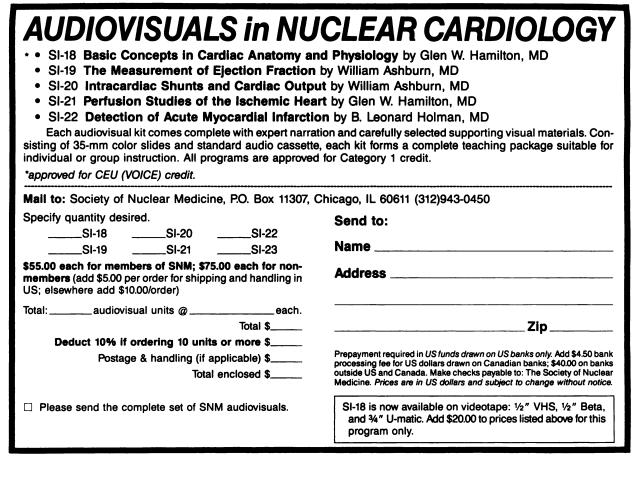
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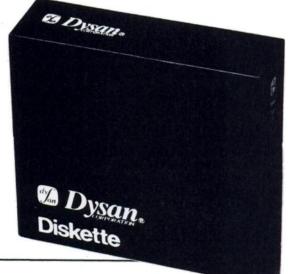


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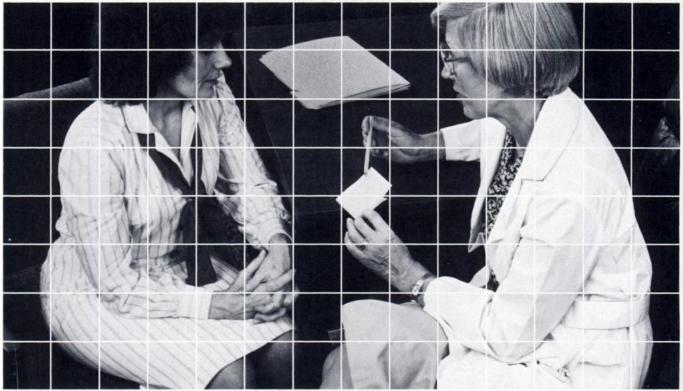
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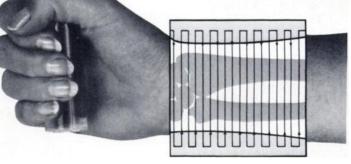
Utilizing an improved single-photon bone densitometry system with rectilinear scanning of both trabecular and cortical bone of the forearm, the ND1100 is the high-precision, low-radiation instrument you've been looking for. Best of all, once baseline data is established for a patient, minute changes in bone mineral content which may occur in a relatively short period of time can be monitored.

Useful for:	<ul> <li>Non-invasive screening for patient monitoring and management</li> <li>Osteoporosis</li> <li>Renal Osteodystrophy</li> <li>and other metabolic bone disorders and diseases</li> </ul>
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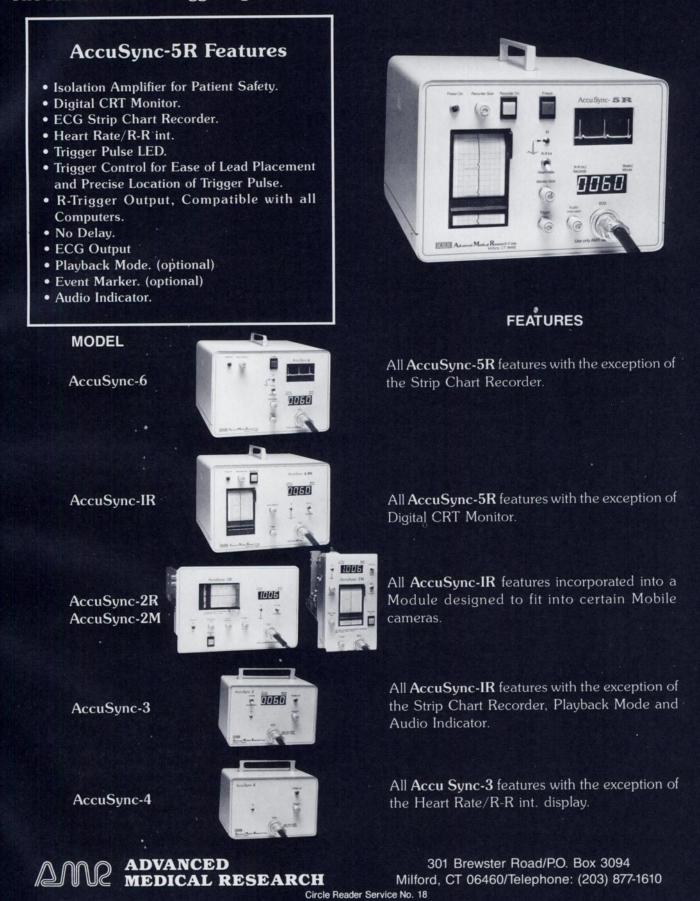
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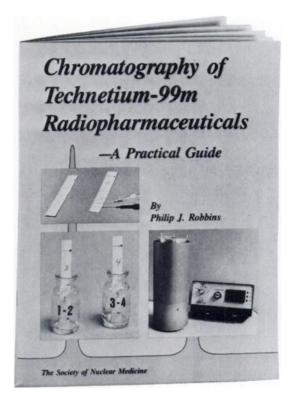
# Chromatography of Technetium-99m Radiopharmaceuticals —A Practical Guide By Philip J. Robbins

To provide up-to-date information about the most accurate procedures for ensuring quality control of radiopharmaceuticals, The Society of Nuclear Medicine presents Chromatography of Technetium-99m Radiopharmaceuticals—A Practical Guide.

This new manual offers readers a collection of miniaturized chromatographic methods for the rapid and precise determination of the radiochemical purity of commonly used Tc-99m radiopharmaceuticals.

Topics covered include the nature and source of impurities, principles and classic techniques of chromatography, methods for counting miniature chromatographic strips, and pitfalls of miniature methods and how to avoid them. Also contained herein is a listing of each radiopharmaceutical with the USP criteria for radiochemical purity, typical scans of impure products, and standards and interlaboratory comparisons for miniaturized systems.

Prepared to aid nuclear medicine personnel in implementing voluntary quality-assurance programs, the material may also be used as a training resource for individuals preparing for professional licensure and certification.



8½ × 11" softcover, 48 pages \$12.00 SNM members; \$16.00 non-members Publication Date: 1984

### **Ordering Information:**

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# **XE 127 + XENAMATIC**<sup> $\mathbf{M}$ </sup> = **THE SOLUTION**

## THE PROBLEM:

You would like to do the lung perfusion images first, look at the images and decide if a ventilation study is called for.

# THE SOLUTION:

Xenon 127. Its higher energies allow effective elimination of Tc 99m gammas from subsequent ventilation images.

## THE PROBLEM:

The short half-life of Xenon 133 makes availability a problem, increases shipping costs, and we lose much of it through decay.

# THE SOLUTION:

Xenon 127. Its 36 day half-life eliminates the inherent problems of short lived Xenon 133.

## THE PROBLEM:

Xenon delivery systems currently being offered are not sufficiently shielded for Xenon 127.

# THE SOLUTION:

The XENAMATIC Xenon Gas Delivery System with the <u>optional</u> Xenon 127 lead shielding. Additional lead is provided throughout the unit. In strategic locations we provide up to 1/2 inch of lead. Our goal: to achieve a radiation level of less than 2 mr/hr at the surface under normal use conditions.

# THE PROBLEM:

Xenon Traps are really delay systems. If it delays the Xenon long enough for it to decay, then it approaches a trap in function. With Xenon 127, activated charcoal traps either must be significantly larger than previously available traps or they must be refrigerated.

# THE SOLUTION:

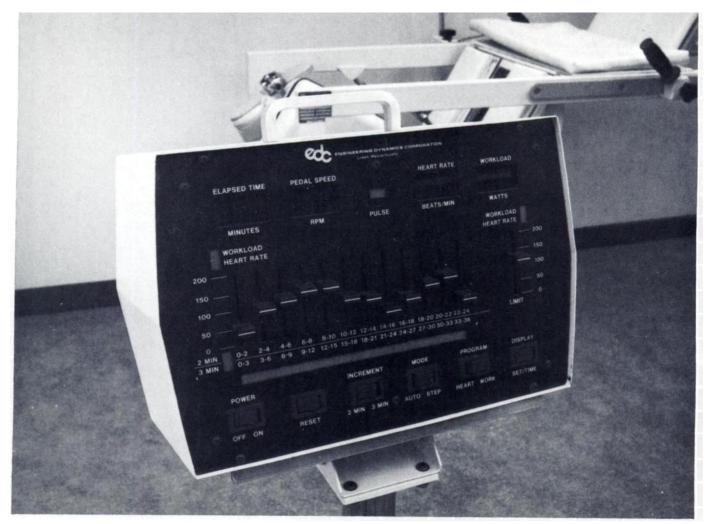
The XENAMATIC. Our Xenon Trap Cartridge Pack offers 20 feet of continuous activated charcoal pathway (3" in diameter) via nine individual tubes connected in series. Additionally, the individual tubes are specially constructed to inhibit the normal redistribution of "trapped" Xenon which occurs even when the trap is not being used.

# **THE XENAMATIC**<sup>m</sup> is the <u>ONLY</u> ANSWER!

For more information, call or write today:

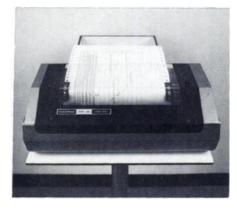
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# The Ultimate Cardiac Stress System. Designed to put more muscle into your Cardiac Testing.

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.



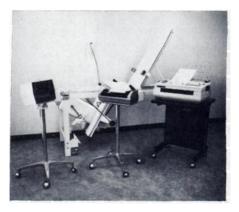
Our powerful microprocessor insures the highest accuracy of any stress system — and as an option. you can have a permanent printed record of the entire stress test, with digital readings of elapsed time, workload, and heart rate every six seconds and with the integrated workload (in KPM) at the end of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

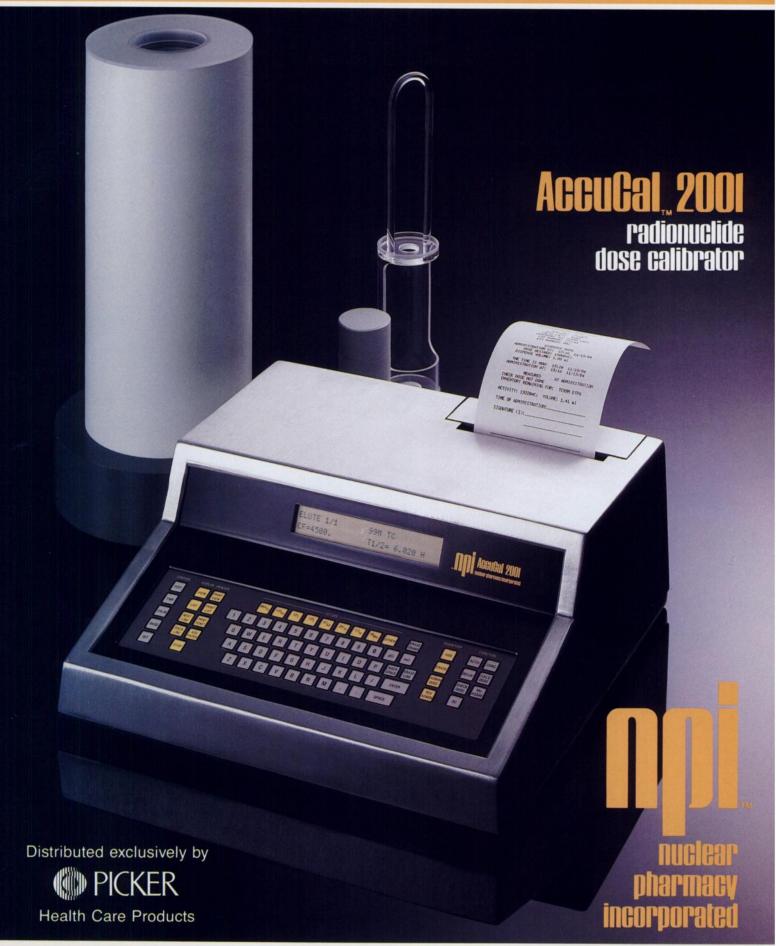
These three new advances have been added to the already well accepted features of our classic model 8430, with its ability to be used either as a stress testing table or as a general imaging table — its fully adjustable table and ergometer — its clear, error-proof, digital readouts — its sturdy construction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



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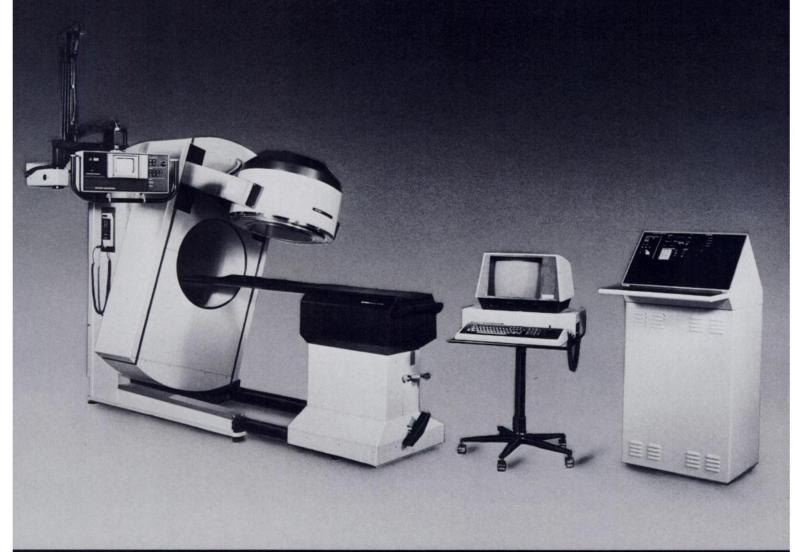


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Raytheon Medical Systems has harnessed the imaging power of our exclusive, fourth generation 91tube detector – complete with variable linearity circuitry – to the profession's most precise gantry system, table and image processing to create the Spectrum 91. The result is the first optimized ECT system... with uncompromised planar capability.

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The Spectrum 91 ECT System uses advanced robotics technology for total motion control. Four independent CPU units are the heart of the system. Simultaneously, they control gantry rotation, detector angle and parallelism.

True body contour acquisition covers a full 360°... plus circular and elliptical orbiting. All motions are electronically encoded for  $\pm 0.1^{\circ}$  control... and to make sure the axis of rotation remains unchanged during body contouring.

"Teaching" the gantry is fast... easy... effortless. It can retrace virtually any contour after only two minutes of patient-specific programming. What's more, automatic parallelism of the detector head minimizes complex setup routines common to SPECT protocols.

### Total imaging performance.

Spectrum 91 ECT gives you positive imaging control – two ways. First, the Raytheon Digital Parameter Controller gives you fast, accurate and repeatable entry and monitoring functions of all study, system and patient parameters. Status verification is positive... and reassuring.

But that's not all. The Spectrum 91 ECT System can also interface

with a variety of computer systems for both gantry control and imaging capability. So the operational choice is left up to you.

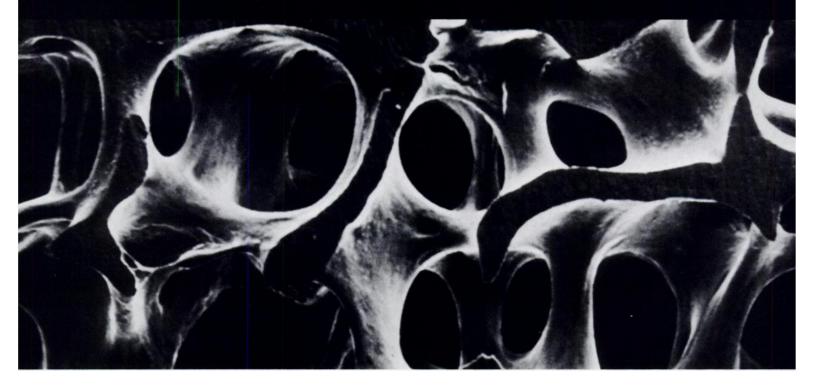
Couple all this capability with a unique, interlocking carbon fiber table that easily simplifies all patient imaging... and you'll see exactly why the Spectrum 91 ECT System is a first in so many ways.

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Albumin Ac Diagnostic — For Intravenous

#### 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 chioride (maximum stannic and stannous chioride 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 proteincontaining 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).



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This tiny package contains all it takes to make an oak tree



# Introducing Starcam

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The Starcam system is the technological evolution of our Star® system data processor and MaxiCamera® line. It's entirely compatible with existing Star systems through floppy data transfer and the future Starlink network. Starcam's modular digital design makes it adaptable to technological enhancements; a feature that lets you broaden the scope of your imaging capabilities as innovations in technology are made.



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Starcam incorporates five highspeed microprocessors, two of them 16-bit multi-tasking units, that work together in a distributed processing fashion. Combined with an integrated Array Processor (optional), this delivers exceptional computing capability, essential when performing studies such as ECT. Starcam features dual central processing units with over one megabyte of very high-speed expandable memory that's directly accessible for display and processing. An 84-megabyte Winchester disc, standard with Starcam, gives you more than twice the data storage available with other systems.

# The bottom line...productivity

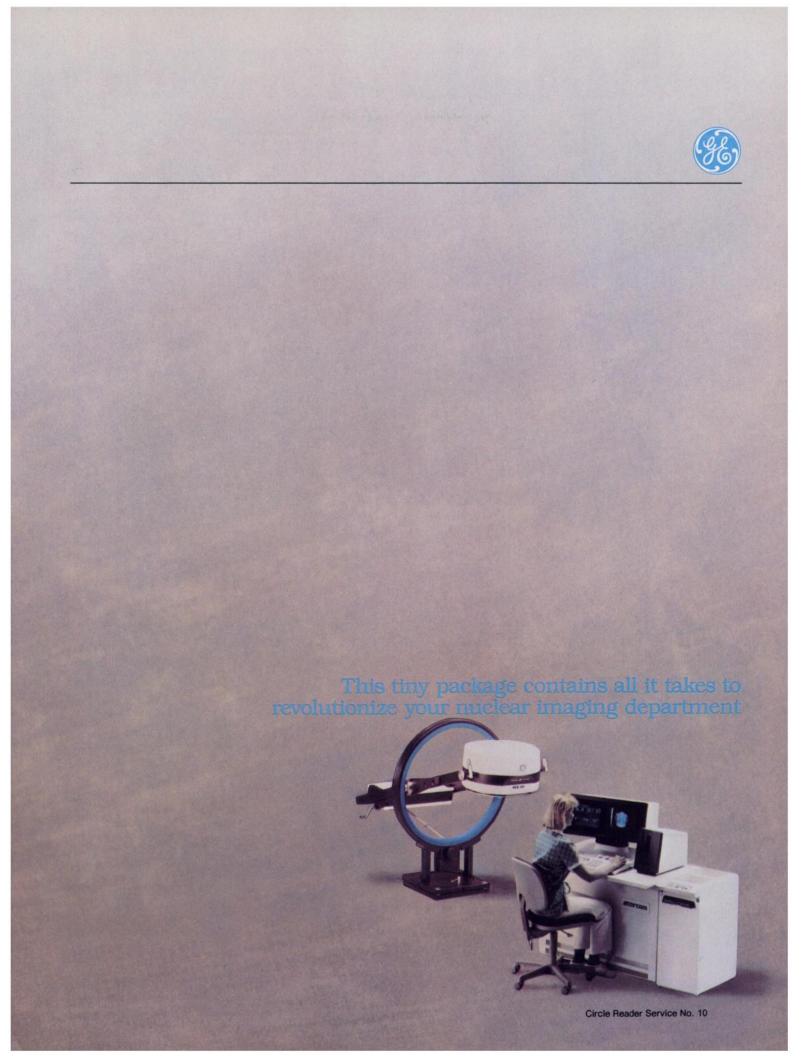
Starcam is a breakthrough in imaging technology. It provides today's nuclear departments with procedural capabilities unsurpassed by any other system. It redefines the operation of your department, eliminating many time-consuming functions without compromising the diagnostic value of the information obtained. The result is a more effective, efficient imaging department; one that optimizes diagnostic capability without jeopardizing the economic well-being of your health care institution.



Starcam represents General Electric's continued commitment to developing nuclear diagnostic imaging technology that's innovative today and designed to stay that way tomorrow.

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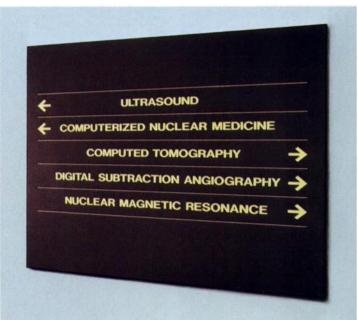
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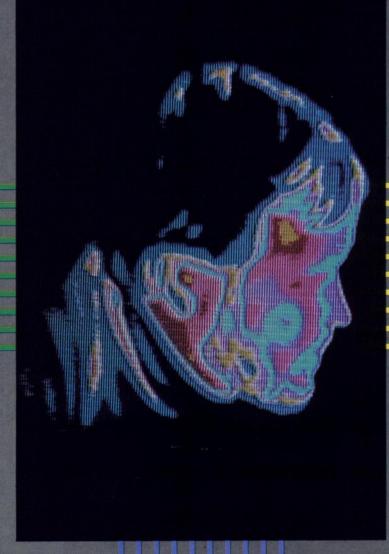
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# **MCROLIE** Technetium Tc 99m Albumin Colloid Kit The first "no boil" instant colloid kit for <u>consistent</u> liver/spleen and bone marrow imaging



Provides convenience, safety and quality images diagnostically equivalent to sulfur colloid

○ SAVES TIME

one-step preparation, no need to boil, ready to inject

**O CONSISTENT QUALITY** 

less chance of product variations during preparation

**O REDUCES PREPARATION ERROR** 

simple procedure, just add technetium 99m and swirl

○ MINIMIZES EXPOSURE

less handling, shorter prep times, helps meet ALARA guidelines

Available in 5-vial or 30-vial kits. Call Du Pont NEN Products toll-free 800-225-1572 (in Mass. and International 617-482-9595).

# **NEN Medical Products**



#### **MICROLITE**<sup>™</sup>

Kit for use in the preparation of Technetium Tc 99m Albumin Colloid

#### FOR DIAGNOSTIC USE

INDICATIONS AND USAGE: Technetium Tc 99m Albumin Colloid is indicated for use as a diag-nostic imaging agent for visualization of the functioning reticuloendothelial (RE) system, of the liver, n and bone marroy

CONTRAINDICATIONS: Technetium Tc 99m Albumin Colloid is contraindicated for persons with a history of hypersensitivity to products containing human serum albumin WARNINGS: The theoretical possibility of allergic reactions should be considered in patients who

receive multiple doses. PRECAUTIONS: The contents of the kit are not radioactive. However, after the sodium pertechne-

tate Tc 99m is added, adequate shielding of the final preparation must be maintained The labeling reactions involved in preparing the agent depend on maintaining this 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.

The contents of the vial are sterile and non-pyrogenic. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures during preparation of the radiodiagnostic

Technetium Tc 99m Albumin Colloid should be used within six hours from the time of reconstitution. Refrigerate at 2° to 8°C after reconstitution. If blood is withdrawn into the syringe, unnecessary delay prior to injection may result in clot formation in situ.

Do not use if clumping of the contents is observed.

Technetium Tc 99m Albumin Colloid (MICROLITE) as well as other radioactive drugs should be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patient consistent with proper patient management

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

No animal studies have been performed to evaluate carcinogenic potential or whether Technetium Tc 99m Albumin Colloid affects fertility in males or females.

#### Pregnancy Category C

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

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

Nursing Mothers

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

Pediatric Use Safety and effectiveness in children below the age of 18 have not been established General

This radiopharmaceutical preparation should not be administered to children or to pregnant women unless the expected benefits to be gained outweigh the potential risks

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides ADVERSE REACTIONS: Although no adverse reactions associated with the use of Microlite have been reported, hypersensitivity reactions are theoretically possible whenever protein-containing ma terials such as TC 99m-labeled aggregated albumin are used in man. Epinephrine, antihistamines and corticosteroid agents should be available for use in the event such a reaction occurs. DOSAGE AND ADMINISTRATION: The recommended intravenous dose range for the average (70kg) patient is 37-296MBq (1-8 millicuries).

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to patient administration. Re-suspend colloid by repeated inversion of the shielded vial imme-diately prior to withdrawal of dose into syringe. Inspect the vial for foreign particulates. Do not

administer if foreign particulates are found in the colloid (If blood is drawn into the syringe, any unnecessary delay prior to injection may lead to clot formation in situ). Do not backflush the syringe. Slow injection is recommended and for optimum results imaging may begin about 15 minutes after injection. Radiochemical purity should be checked prior to patient administration, using the following or equivalent procedure. (Please see complete prescribing information ) HOW SUPPLIED: MICROLITE\*\* Kit for use in the preparation of Technetium Tc 99m Albumin Colloid is supplied in kits of five or thirty vials, sterile and non-pyrogenic, each vial containing in

lyophilized form:	
Albumin Colloid	1mg
Normal Human Serum Albumin	10mg
Total Tin, maximum (as stannous chloride SnCl <sub>2</sub> + 2H <sub>2</sub> O)	0.17mg
Stannous Chloride (SnCl <sub>2</sub> · 2H <sub>2</sub> O) (minimum)	0.006mg
Poloxamer 188	1 1mg
Medronate disodium	0.12mg
Sodium Phosphate (anhydrous)	10mg

Prior to typophilization the pH is adjusted with HCl and/or NaOH. The contents of the vial are lyophilized and stored under ntrogen. Included in each five (5) vial kit are one (1) package insert and welve (12) radiation labels. Included in each thirty vial kit is one (1) package insert and seventy-two (72) radiation labels. Before reconstitution store at room temperature (15°-30°C) and protect from

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

Technetium Tc 99m Albumin Colloid is prepared by adding 2-8ml of oxidant-free sodium pertechne-tate Technetium Tc 99m solution to the vial and swirling for about one minute. Shielding should be utilized when preparing the Technetium Tc 99m Albumin Colloid

Catalog Number NRP-470 (5-Vial Kit) Catalog Number NRP-470C (30-Vial Kit)

May 1984

511616

# 



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## **MIRD** (Medical Internal Radiation Dose) **PAMPHLETS AVAILABLE**

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10 Radionuclide decay schemes and nuclear parameters for use in radiation-dose estimation (1975)

11 'S' absorbed dose-per-unit cumulated activity for selected radionuclides and organs (1975)

12 Kinetic models for absorbed dose calculations (1977)

#### **SUPPLEMENTS**

3 Includes the original pamphlet #5: "Estimates of absorbed fractions for monoenergetic photon sources uniformly distributed in various organs of a heterogeneous phantom." (1969)

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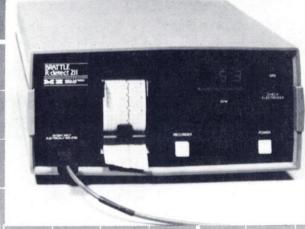
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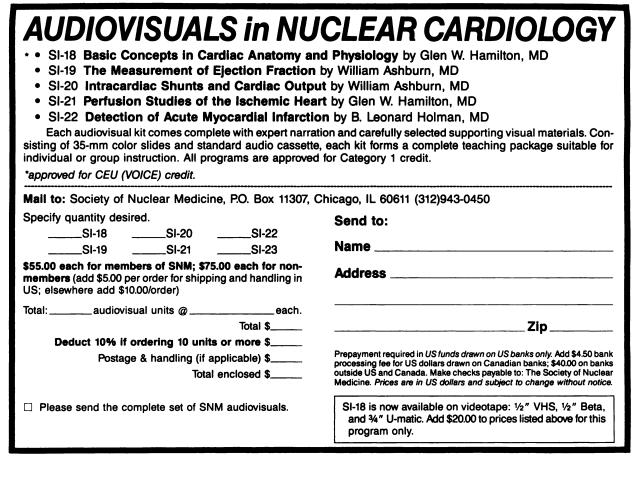
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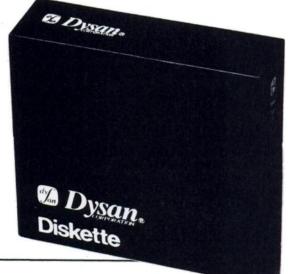


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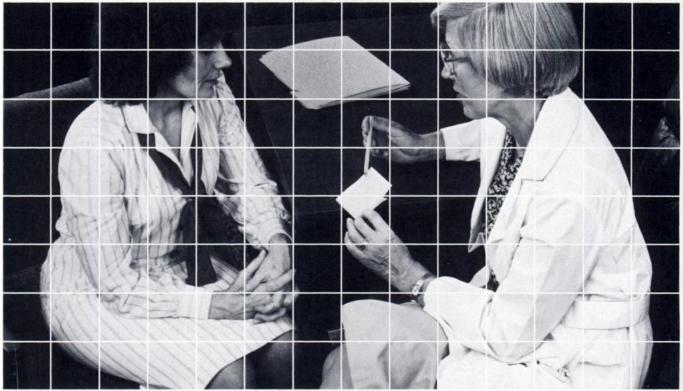
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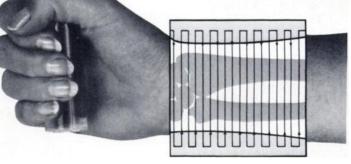
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Useful for:	<ul> <li>Non-invasive screening for patient monitoring and management</li> <li>Osteoporosis</li> <li>Renal Osteodystrophy</li> <li>and other metabolic bone disorders and diseases</li> </ul>
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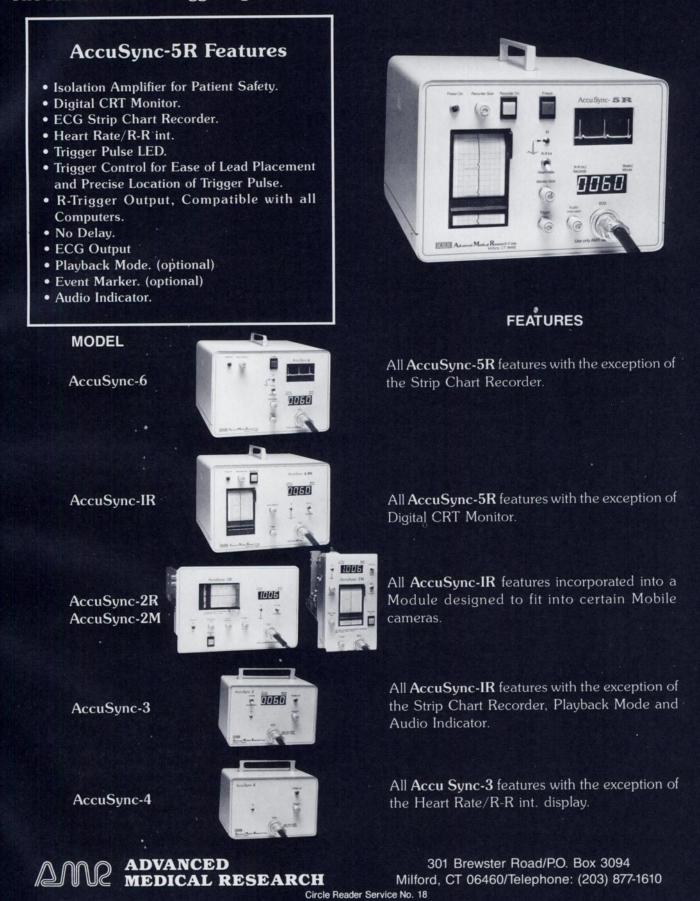
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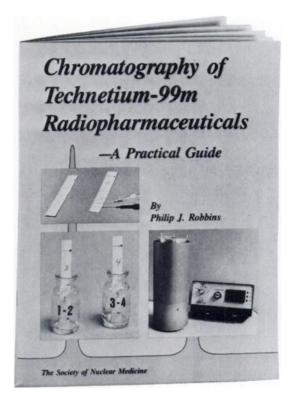
# Chromatography of Technetium-99m Radiopharmaceuticals —A Practical Guide By Philip J. Robbins

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# **XE 127 + XENAMATIC**<sup> $\mathbf{M}$ </sup> = **THE SOLUTION**

#### THE PROBLEM:

You would like to do the lung perfusion images first, look at the images and decide if a ventilation study is called for.

#### THE SOLUTION:

Xenon 127. Its higher energies allow effective elimination of Tc 99m gammas from subsequent ventilation images.

#### THE PROBLEM:

The short half-life of Xenon 133 makes availability a problem, increases shipping costs, and we lose much of it through decay.

#### THE SOLUTION:

Xenon 127. Its 36 day half-life eliminates the inherent problems of short lived Xenon 133.

#### THE PROBLEM:

Xenon delivery systems currently being offered are not sufficiently shielded for Xenon 127.

#### THE SOLUTION:

The XENAMATIC Xenon Gas Delivery System with the <u>optional</u> Xenon 127 lead shielding. Additional lead is provided throughout the unit. In strategic locations we provide up to 1/2 inch of lead. Our goal: to achieve a radiation level of less than 2 mr/hr at the surface under normal use conditions.

#### THE PROBLEM:

Xenon Traps are really delay systems. If it delays the Xenon long enough for it to decay, then it approaches a trap in function. With Xenon 127, activated charcoal traps either must be significantly larger than previously available traps or they must be refrigerated.

## THE SOLUTION:

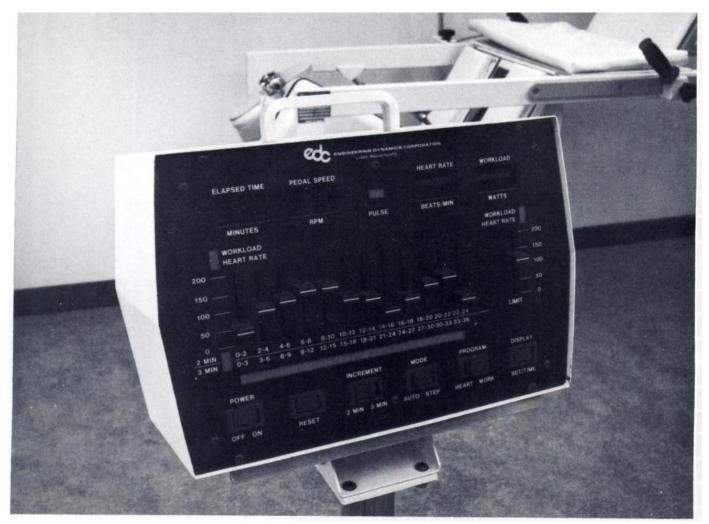
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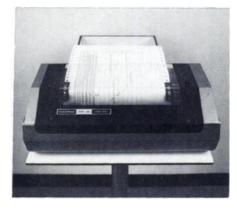
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