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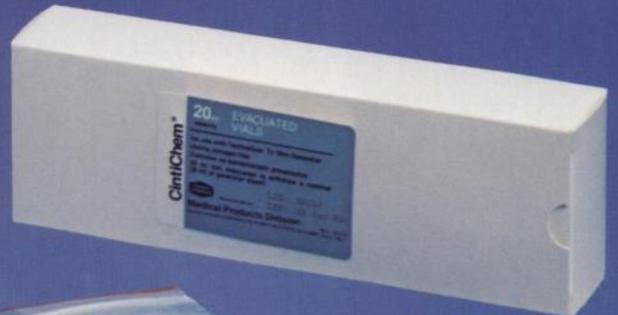


Technetium Tc 99m
Generator

Secondary shield
to further reduce
radiation



5cc and 10cc elution vials



20ml elution vials
available on request



Elution vial shield

Adaptors for various elution vials



Sterile needle pack and labels
furnished with each generator

GENERATORS

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

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

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

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

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

CONTRAINDICATIONS: None known.

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

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Pregnancy Category C

Animal reproductive studies have not been conducted with Technetium Tc 99m. It is also not known whether Technetium

Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Technetium Tc 99m should be given to a pregnant woman only if the expected benefits to be gained clearly outweigh the potential hazards. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

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

Pediatric Use

See **Indications and Usage, dosage** and administration. See also description of additional risk under **warnings**. Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides, and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

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

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

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

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

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

*initial order only

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

Jointly manufactured by:

CINTICHEM, INC.

and

UNION CARBIDE CORPORATION

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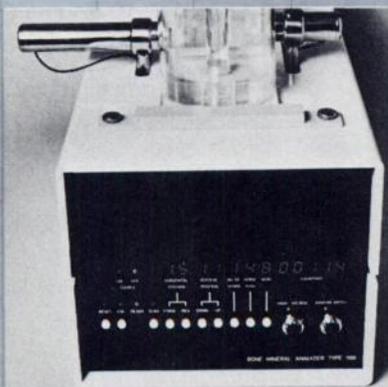
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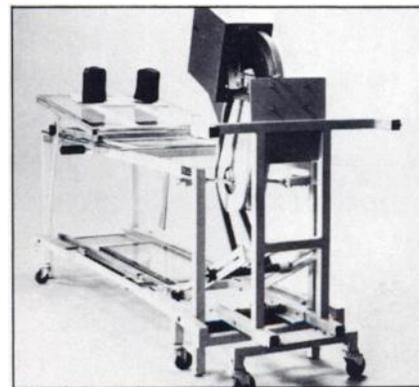
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*CAP Basic Ligand Survey Set K-C, 1982



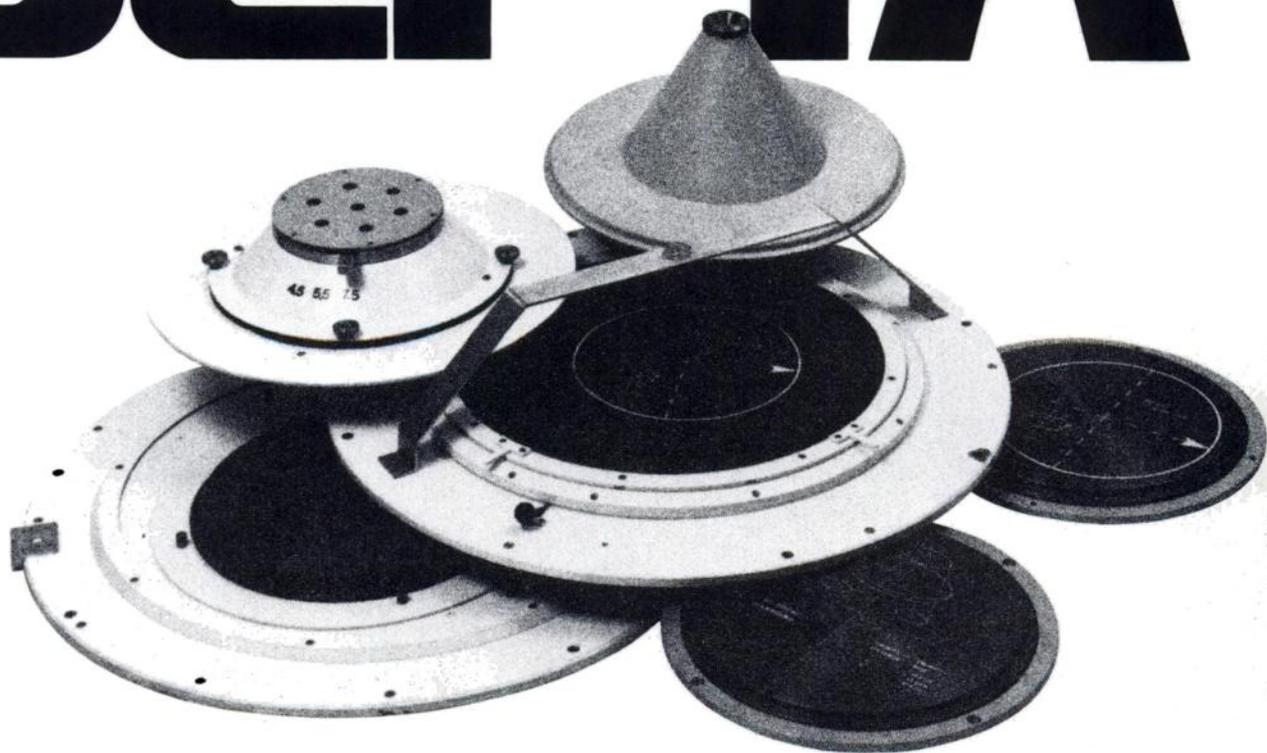
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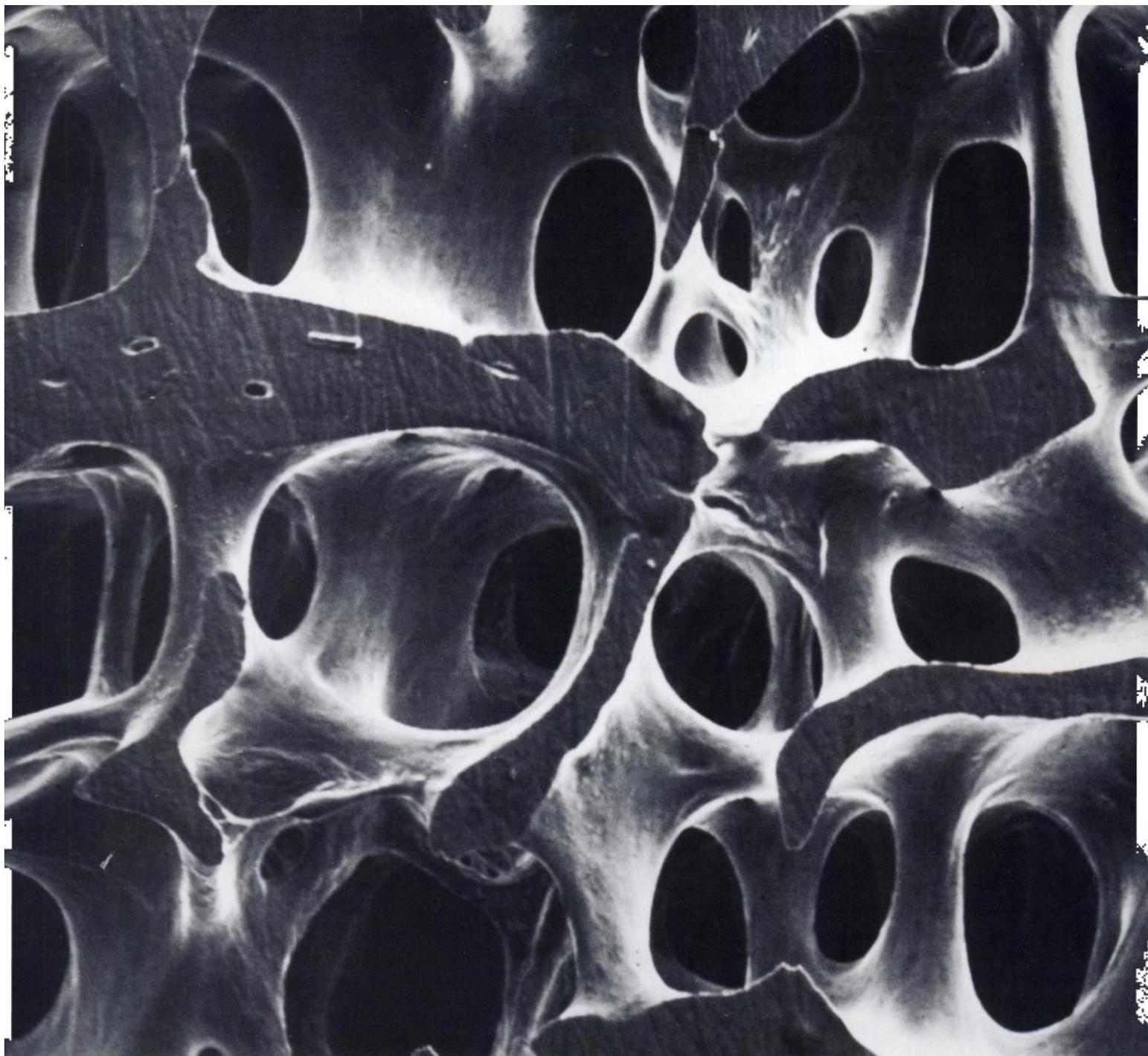
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CURRENT ISSUES IN NUCLEAR MEDICINE

Building Your Practice On The Challenges Of Prospective Payment

Prospective Payment is changing the practice of nuclear medicine.

In many hospitals, the advent of diagnosis related groups (DRGs) is already reducing the number of referrals, changing the mix of studies performed and putting off the purchase of requested instrumentation.

Helping our customers respond

What will be the outcome of these changes? That depends a lot on how the nuclear medicine department responds. At New England Nuclear/Du Pont we believe the challenges of Prospective Payment can be turned into opportunities for nuclear medicine. And we'd like to show you how.

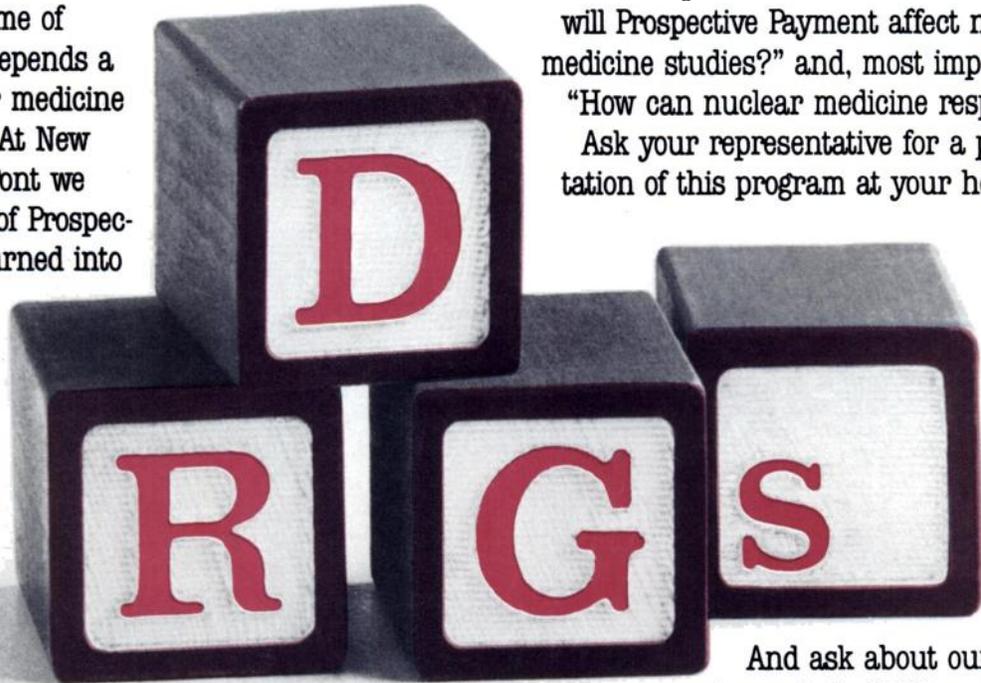
As a service to our customers, NEN/Du Pont has developed a series of programs designed to help nuclear medicine departments, referring physicians and hospital administrators learn about the probable impact of the new reimbursement system—and the ways they can respond to ensure continued excellence in medical care consistent with cost-effective management.

DRG symposia at your hospital

The first program, called "Prospective Payment and Nuclear Medicine: Concept, Impact and Action," will be presented in symposia throughout the country by NEN/Du Pont representatives trained in understanding the contributions nuclear medicine can make to cost-conscious medical practice. Each symposium covers a wide variety of topics—from "What are DRGs?" and "How can hospitals control costs?" to "How

will Prospective Payment affect nuclear medicine studies?" and, most important, "How can nuclear medicine respond?"

Ask your representative for a presentation of this program at your hospital.

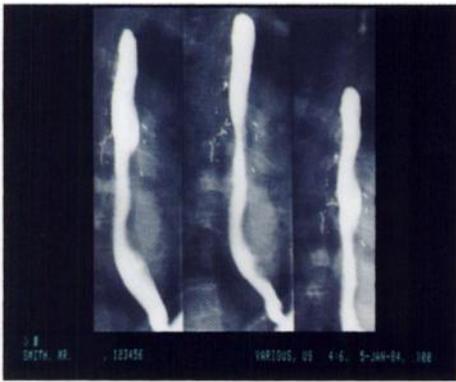


And ask about our other services to help NEN customers build referrals, increase operating and financial efficiency and ensure the quality of their studies. Our goal is Imaging Excellence: enhancing the image of your department while improving the images in your department.

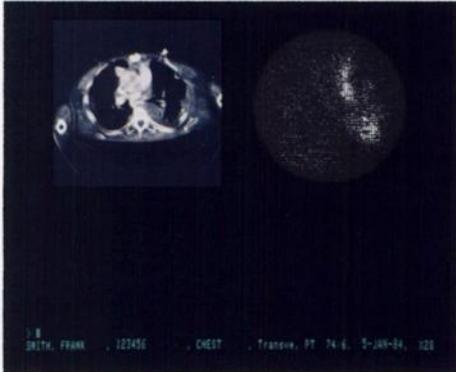
IMAGING EXCELLENCE

***THE DELTA SYSTEM EXPANDS
YOUR CONTROL OVER
IMAGES AND INFORMATION...***

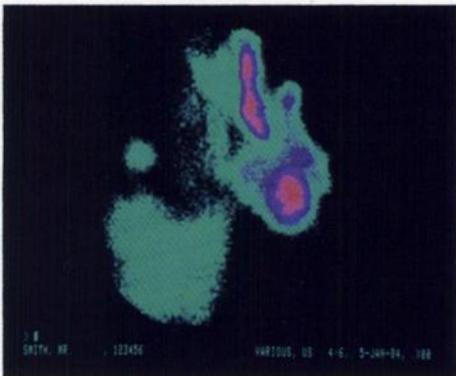




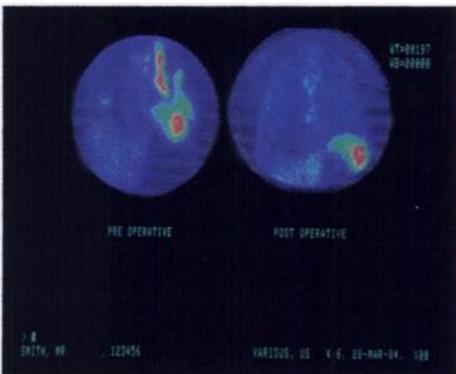
**X ray Shows Abnormal Fluid Collection
Between the Esophagus and the Aorta**



**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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For a demonstration call Linda Holland at (617) 647-1900, or write Computer Design & Applications Inc., 411 Waverly Oaks Road, Waltham, MA 02154. Telex: 92-2521. In Europe: CDA International, Spaldingstrasse 1, 2000 Hamburg 1, West Germany. Telephone: 040/23 06 35. Telex: 2174-311.

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

CDA

Imaging & Information Tools Vital to Your Productivity

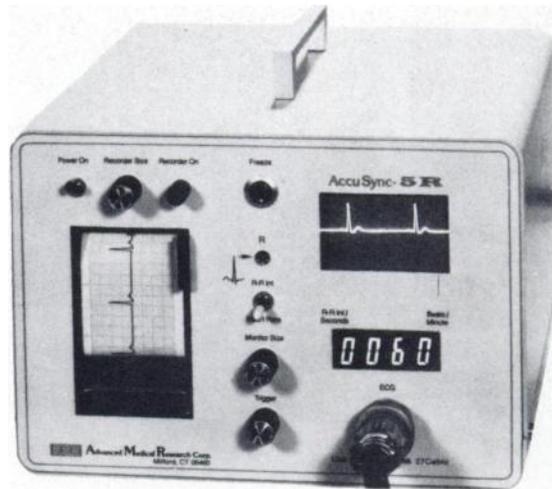
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- Event Marker



MODEL

FEATURES

AccuSync-6

All **AccuSync-5R** features with the exception of the Strip Chart Recorder.

AccuSync-IR

All **AccuSync-5R** features with the exception of Digital CRT Monitor.

AccuSync-2

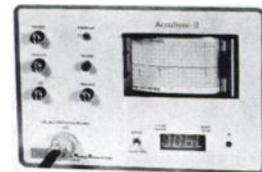
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AccuSync-4

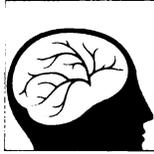
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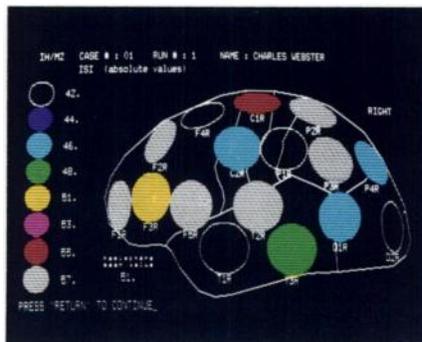
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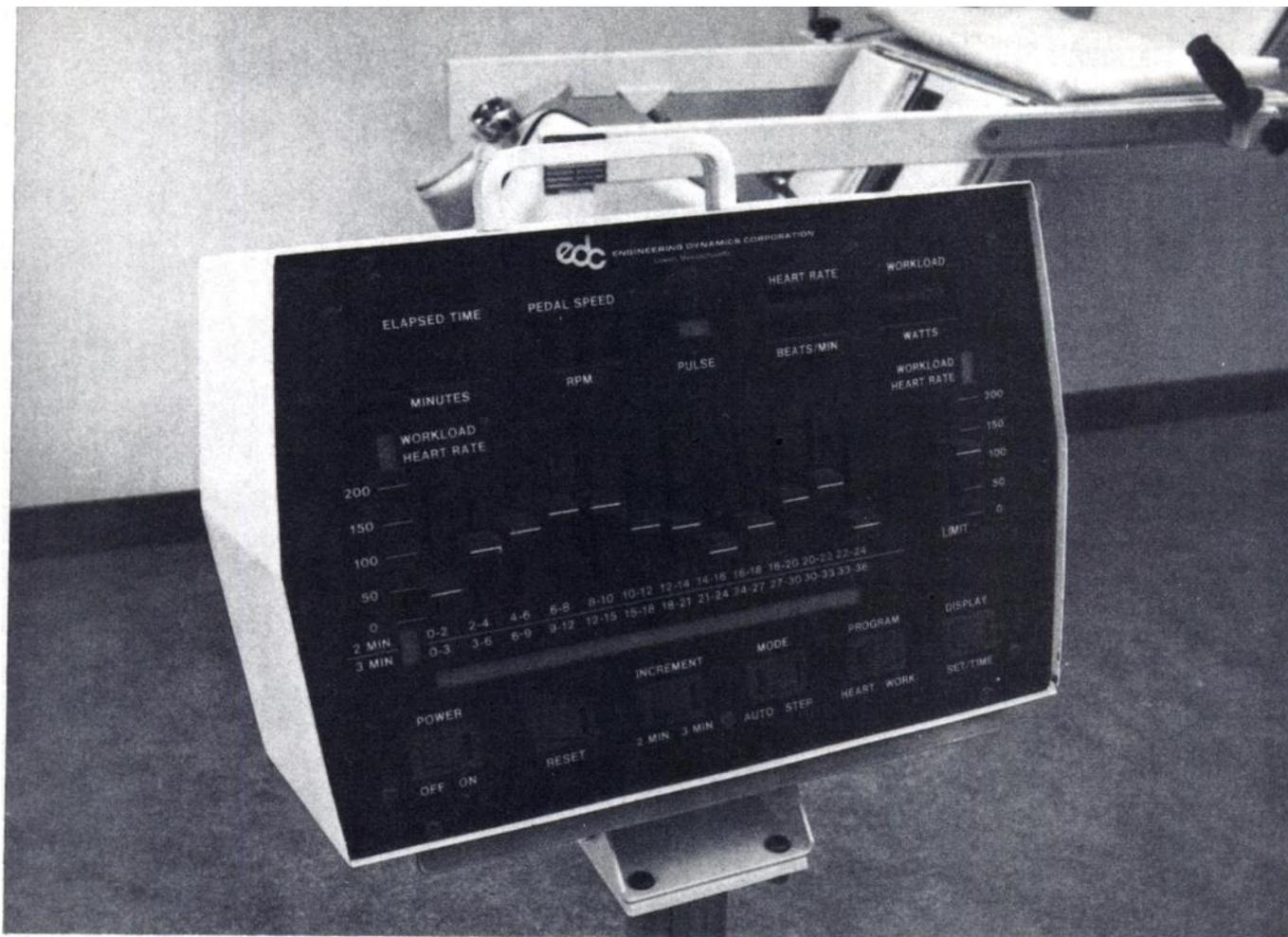
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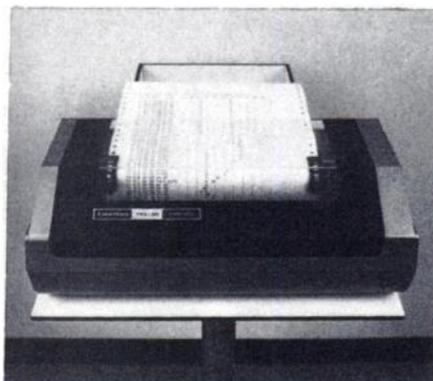




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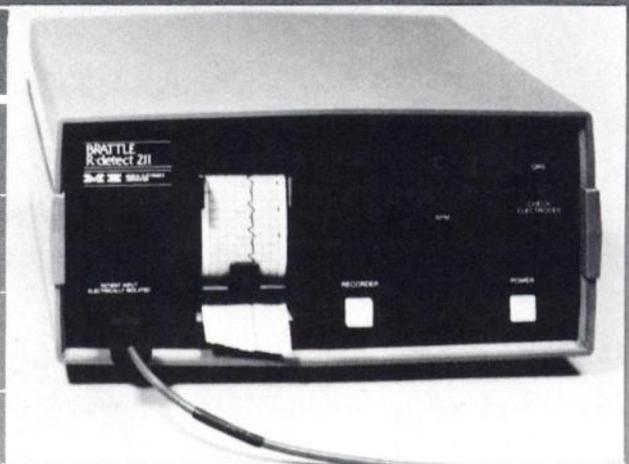
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MODEL 210



MODEL 211

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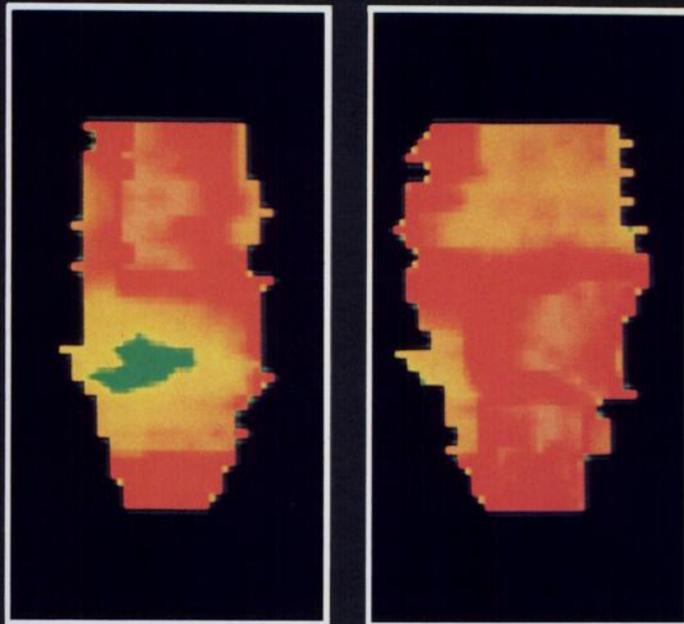
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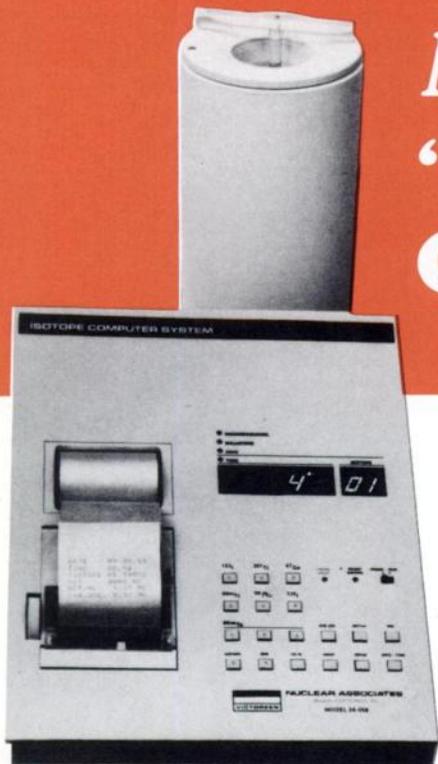
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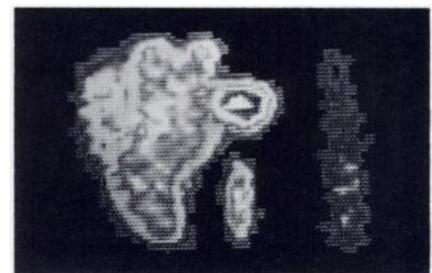
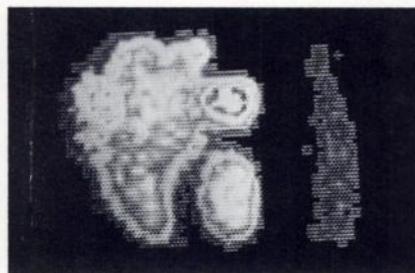
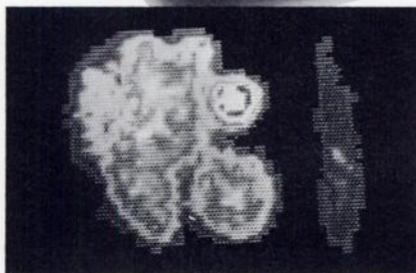
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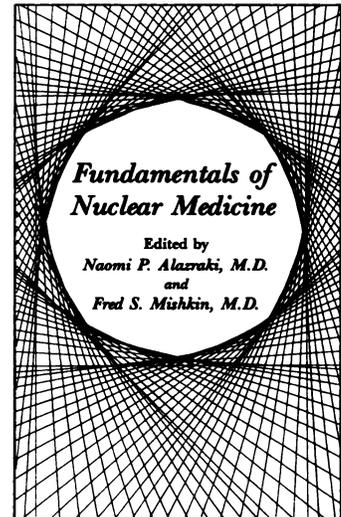
End systole →

Fundamentals of Nuclear Medicine

Edited by
Naomi P. Alazraki, MD,
and Fred S. Mishkin, MD

Other Contributors: Manuel L. Brown, MD, Frederick L. Datz, MD, Leon S. Malmud, MD, Isaac C. Reese, PhD, Barry A. Siegel, MD, James A. Sorenson, PhD, Leroy A. Sugarman, MD, Andrew T. Taylor, Jr., MD, Heidi S. Weissmann, MD, Henry N. Wellman, MD

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9. Skeletal System

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Appendix

Glossary

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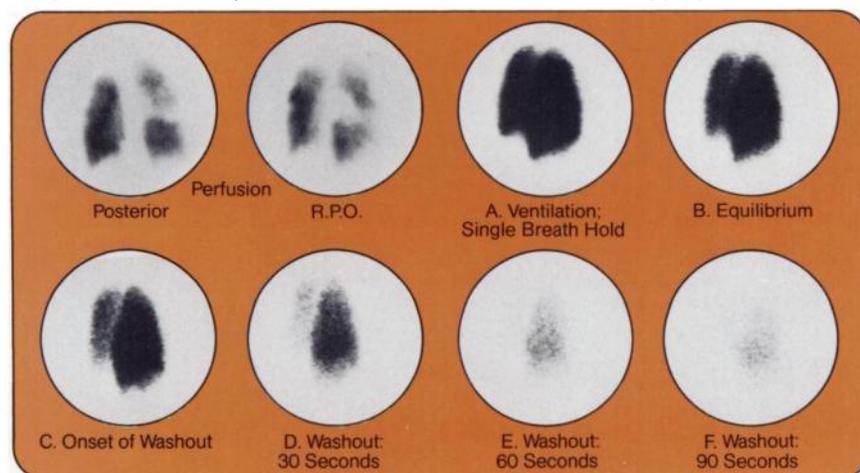
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Interpretation: Perfusion defect in superior segment of lower right lobe; smaller perfusion defects noted in left mid-lung and left upper lung field.

Ventilation Study:

5.0 mCi Xenon Xe 127 Gas. Performed immediately after perfusion study with patient in right posterior oblique position.

Interpretation: Xenon Xe 127 Gas uniformly distributed in both lungs; normal clearance and washout (Scintiphotos A-F). Specifically, the area of the perfusion defect demonstrates normal ventilation.

Conclusion:

Probable pulmonary embolism.

Case study and scintiphotos courtesy of Section of Nuclear Medicine, Bowman Gray School of Medicine, Winston-Salem, N.C.



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XENON Xe 127 GAS

Diagnostic

DESCRIPTION

Xenon Xe 127 Gas is for diagnostic inhalation use only. It is supplied in vials containing either 5 or 10 millicuries of Xenon Xe 127 Gas in 2 milliliters of carrier Xenon and atmospheric air. Xenon-127 is produced by the proton bombardment of Cesium Cs 133. It contains less than 10% Xenon Xe 129m and less than 10% Xenon Xe 131m on date of release with 99% total radioactivity as radioxenon.

Xenon Xe 127 Gas is chemically and physiologically similar to elemental xenon, a non-radioactive gas which is physiologically inert except for anesthetic properties at high doses.

Physical Characteristics

Xenon Xe 127, with a physical half-life of 36.41 days¹ decays by electron capture to Iodine I 127. Photons that are useful for detection and imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data of Xenon Xe 127

Radiation	Mean Percent Per Disintegration	Energy (keV)
Gamma-2	4.2	145.2
Gamma-3	24.7	172.1
Gamma-4	68.1	202.8
Gamma-5	17.4	375.9
K x-rays	87.9	Mean: 29.7

Xenon Xe 129m, with a physical half-life of 8.89 days² decays by isomeric transition to Xenon Xe 129. The principal photons are listed in Table 2.

Table 2. Principal Radiation Emission Data of Xenon Xe 129m.

Radiation	Mean Percent Per Disintegration	Energy (keV)
Gamma-1	7.5	39.6
Gamma-2	4.7	196.6
K x-rays	126.9	Mean: 30.4

Xenon Xe 131m, with a physical half-life of 11.84 days² decays by isomeric transition to Xenon Xe 131. The principal photons are listed in Table 3.

Table 3. Principal Radiation Emission Data of Xenon Xe 131m.

Radiation	Mean Percent Per Disintegration	Energy (keV)
Gamma-1	2.0	163.9
K x-rays	54.4	Mean: 30.4

External Radiation

The specific gamma ray constant for Xenon Xe 127 is 2.2 R/mCi-hr at 1 cm. The first half-value thickness of lead (Pb) is 0.023 cm.

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 4. For example, the use of 1.7 cm of Pb will decrease the external radiation exposure by a factor of about 1000.

Table 4. Radiation Attenuation by Lead Shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.023	0.5
0.26	10 ⁻¹
0.95	10 ⁻²
1.7	10 ⁻³
2.4	10 ⁻⁴

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals after the day of calibration are shown in Table 5.

Table 5. Physical Decay Chart; Xenon Xe 127, Half-Life 36.41 Days³

Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	20	0.683
1	0.981	22	0.658
2	0.963	24	0.634
3	0.945	26	0.610
4	0.927	28	0.587
5	0.909	30	0.565
6	0.892	32	0.544
7	0.875	34	0.524
8	0.859	36	0.504
10	0.827	38	0.485
12	0.796	40	0.467
14	0.766	45	0.425
16	0.737	50	0.386
18	0.710		

*Calibration day

REFERENCES

- Coates G, Nahmias C: Xenon-127. A Comparison with Xenon-133 for Ventilation Studies. *J Nucl Med* 18:221-225, 1977.
- Atkins HL, Susskind H, Klapper JF, et al: A Clinical Comparison of Xe-127 and Xe-133 for Ventilation Studies. *J Nucl Med* 18:653-659, 1977.

CLINICAL PHARMACOLOGY

Xenon Xe 127 (and other radioxenons) is a readily diffusible gas which is neither utilized nor produced by the body. It passes through cell membranes, freely exchanges between blood and tissue, and tends to concentrate more in body fat than in blood, plasma, water or protein solutions. In the concentrations recommended for diagnostic studies, it is physiologically inactive. Inhaled Xenon Xe 127 gas will enter the alveolar wall and enter the pulmonary venous circulation via capillaries. Most of the Xenon Xe 127 gas that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation.

INDICATIONS AND USAGE

Xenon Xe 127 gas has been shown to be valuable for diagnostic inhalation studies for the evaluation of pulmonary function and for imaging the lungs.

CONTRAINDICATIONS

None known.

WARNINGS

Xenon Xe 127 gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory environs not specifically protected by exhaust systems.

Xenon Xe 127 gas adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. Loss of radioactivity due to such adherence may render the study non-diagnostic.

PRECAUTIONS

General

Xenon Xe 127 gas as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to the patient consistent with proper patient management.

The higher energy and long half-life of Xenon Xe 127 may complicate disposal after use. Exhaled Xenon Xe 127 gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate carcinogenic potential, mutagenic potential or whether this drug affects fertility in males or females.

Pregnancy Category C

Animal reproduction studies have not been conducted with Xenon Xe 127 gas. It is also not known whether Xenon Xe 127 gas can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Xenon Xe 127 gas 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

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Xenon Xe 127 gas is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

None known.

DOSAGE AND ADMINISTRATION

Xenon Xe 127 Gas is administered by inhalation from a closed respirator system or spirometer. The final patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

The recommended activity range employed for inhalation by the average patient (70 kg) is:

Pulmonary function including imaging: 5 to 10 millicuries.

This may be administered as a bolus into the tubing near the patient's mouthpiece or mask after the completion of a tidal exhalation or after rebreathing for a period of approximately 5 minutes of the Xenon Xe 127 gas in equilibrium with the air contained in the closed system at concentrations of the radionuclide that may vary from 0.5 to 2.0 millicuries per liter.

Radiation Dosimetry

The estimated absorbed radiation doses to an average patient (70 kg) for inhalation studies from a maximum dose of 10 millicuries of Xenon Xe 127 in 5, 7.5, and 10 liters of air are shown in Table 6. They are based on 80% total activity as Xenon Xe 127 with 10% activity as Xenon Xe 129m and 10% activity as Xenon Xe 131m. The values are the maximum absorbed dose that could be anticipated under the given conditions.

Table 6. Radiation Dose Estimates of Xenon Xe 127:⁴ Absorbed Dose/10mCi Xenon Xe 127 Administered by Inhalation

Tissue	Spirometer Volume (liters)		
	5.0	7.5	10.0
	Rad/10mCi Xenon Xe 127 ⁵		
Lung	0.064	0.048	0.038
Red Marrow	0.015	0.013	0.010
Ovaries	0.014	0.011	0.008
Testes	0.011	0.009	0.007
Total Body	0.014	0.011	0.008

Directions for Dispensing

Transfer the appropriate Xenon Xe 127 Gas dose from the Xenon Xe 127 Gas unit dose vial(s) to the breathing device or spirometer using an adequately shielded transfer device such as the Mallinckrodt, Inc. Xenomatic II™ Xenon Gas Dispenser, Catalog No. 036. Directions for use of this gas dispenser are as follows:

- If required, attach needle or other appropriate connector⁶ to the Luer-Lok fitting of the Xenomatic II Xenon Gas Dispenser.
- Remove lead filled plastic cap from Xenon Xe 127 Gas unit dose shield to expose the top of the 2.0 milliliter vial.
- With vial in shield, insert into handle of the Xenomatic II Xenon Gas Dispenser, impaling the vial on the needles and engaging the latch holding the shield and vial in position.
- Connect the Xenomatic II Xenon Gas Dispenser to the breathing device or spirometer.
- Squeeze the trigger *firmly and completely* one or more times to transfer the gas from the vial into the breathing device.⁷
- After transfer, press shield release latch in the handle and remove the shield.
- Pull the exhausted vial from the needles, place back into shield, replace plastic cap, and discard in compliance with established requirements for the disposal of radioactive waste.
- Place an empty shield into the handle of the Xenomatic II Gas Dispenser, engaging the latch. This will prevent possible injury from unprotected impaling needles.
- To clean the Xenomatic II Xenon Gas Dispenser, simply wipe with mild detergent. DO NOT IMMERSIVE IN WATER.

Xenon Xe 127 Gas should not be used after 120 days from the date of calibration stated on the label.

Radioactivity Measurements

Calibrate a suitable commercial ionization chamber dose calibrator according to the manufacturer's instructions for that particular instrument. An instrument that gives direct radioactivity readouts is recommended.

Use a National Bureau of Standards (NBS) Xenon Xe 127 standard (or a standard that is traceable to an NBS standard) for the initial calibration. Also establish a secondary standard, such as Barium Ba 133, at that time for subsequent routine use. Other suitable radionuclides may also be used. Determine the effective readout of the secondary standard compared to the Xenon Xe 127 standard over the range of activities expected for routine measurements. Determine the radioactivity of the dose for administration as follows:

- Check the dose calibrator for proper response with the secondary standard.
- Insert the Xenon Xe 127 Gas unit dose vial in the dose calibrator and measure the apparent radioactivity of the Xenon Xe 127.
- Correct for decay as necessary.

The radioactivity determined by this method is within 25% of the true value. This degree of accuracy includes variations attributed to small differences in geometry.

HOW SUPPLIED

Xenon Xe 127 Gas is available in 2ml vials with color-coded labels in 5 millicurie (Code 130) and 10 millicurie (Code 131) sizes. Both sizes are packaged in individual lead shields.

Storage

Xenon Xe 127 Gas should be stored at 15°C to 30°C.

Storage and disposal of Xenon Xe 127 Gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of this radionuclide.

¹Atkins, Harold L., et al., *Estimates of Radiation Absorbed Doses from Radioxenons in Lung Imaging*, Task Group of the Medical Internal Radiation Dose Committee, Society of Nuclear Medicine, J. Nucl. Med. 21:459-465, 1980.

²Kocher, David C., *Radioactive Decay Data Tables*, DOE/TIC-11026, 128-134 (1981.)

³Preparations of Xenon Xe 127 Gas may contain up to 10% of Xenon Xe 129m and up to 10% Xenon Xe 131m which will slightly reduce the fraction remaining.

⁴Atkins, Harold L., et al., *Estimates of Radiation Absorbed Doses from Radioxenons in Lung Imaging*, Task Group of the Medical Internal Radiation Dose Committee, Society of Nuclear Medicine, J. Nucl. Med., 21:459-465, 1980.

⁵Values based on 80% total activity as Xenon Xe 127 with 10% activity as Xenon Xe 129m and 10% activity as Xenon Xe 131m.

⁶An adaptor is available from Mallinckrodt for use with breathing devices or spirometers that have a recessed xenon injection port.

⁷One complete squeeze of the trigger delivers 99+% of the available Xenon Xe 127 gas from the vial.



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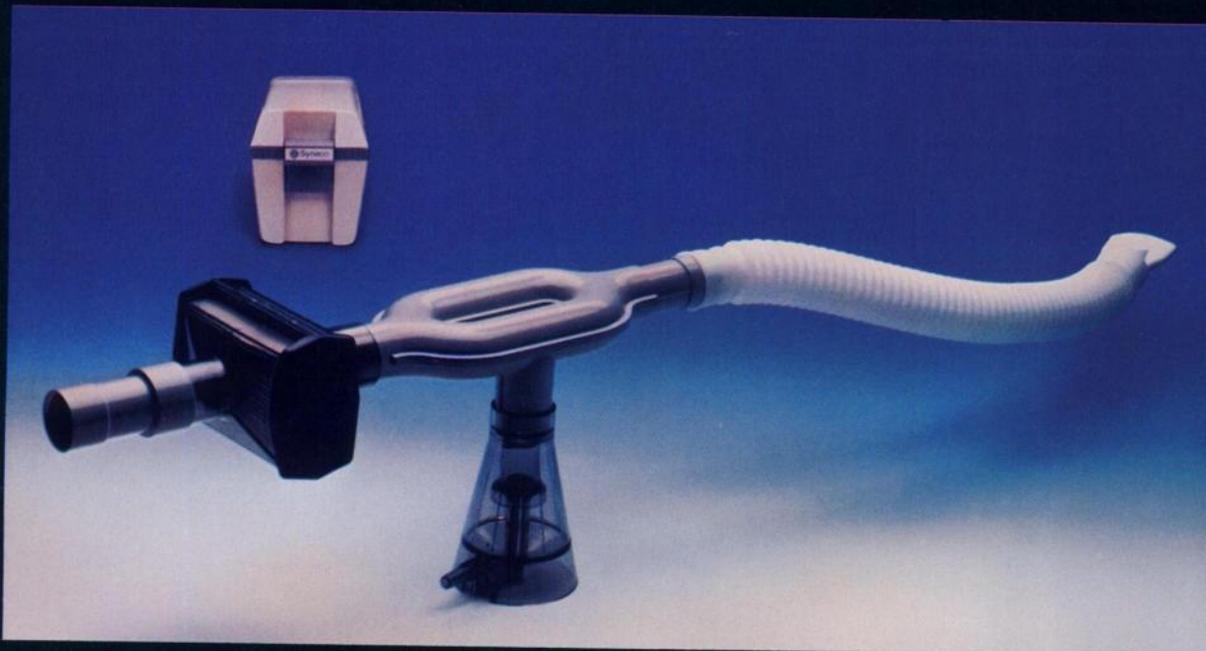
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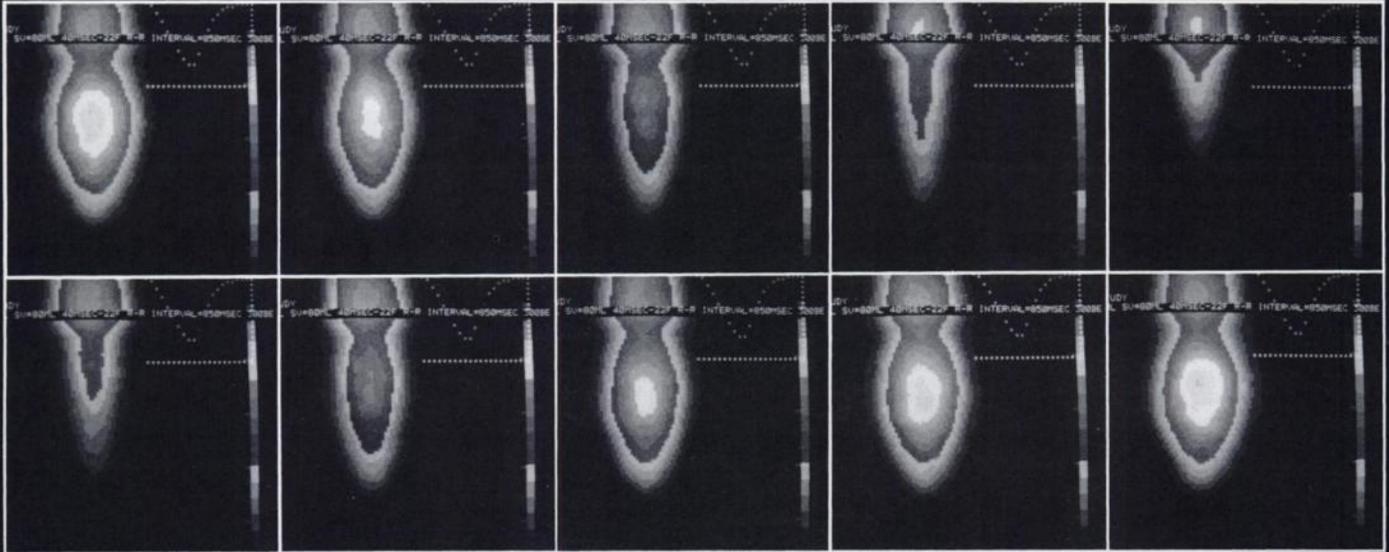
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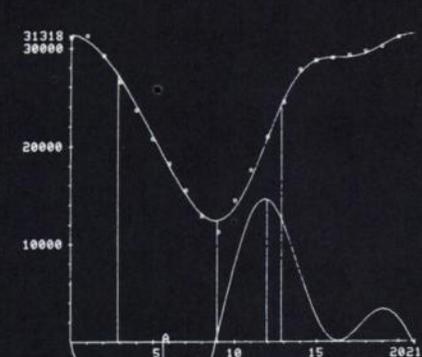
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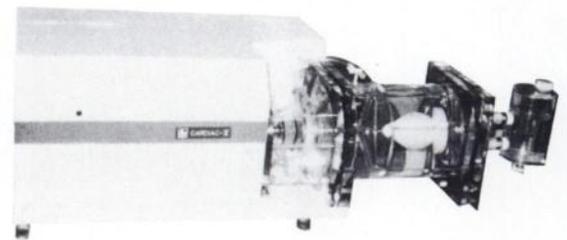
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Who offers the most clinical experience? The facts speak for themselves. Technicare.

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Novo BMC-LAB 22a

Meet us at the Society
of European Nuclear Medicine
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August 14th - 17th



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.

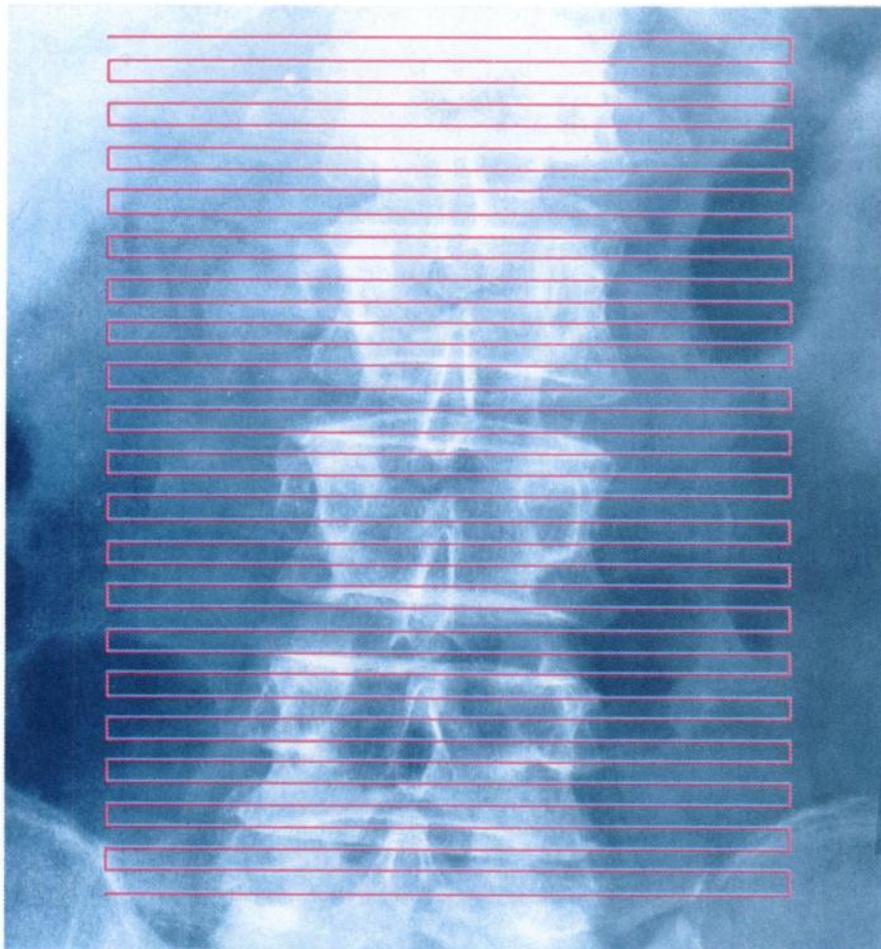
Ease of operation and low radiation dose make the Novo BMC-LAB 22a ideal for routine monitoring and screening of patients.

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 COLLUMNA, and for right and left COLLUM FEMORIS. A fourth OPTIONAL program is included to meet individual requirements.

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Who's working harder to give you more? The facts speak for themselves. Technicare.

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CURRENT ISSUES IN NUCLEAR MEDICINE

Making The Case For Nuclear Medicine

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

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

How can clinicians know which tests meet these criteria?

Supporting Nuclear Medicine

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

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

For many years, NEN/Du Pont has supported nuclear medicine with teaching programs and

exhibits directed to the clinicians who order your studies. Now, we've developed a *Clinician's Guide to Nuclear Medicine Procedures*. . . to help you build referrals with key clinicians at your institution.

Helping Clinicians Choose

This easy-to-use manual explains the indications and expected findings of nuclear medicine

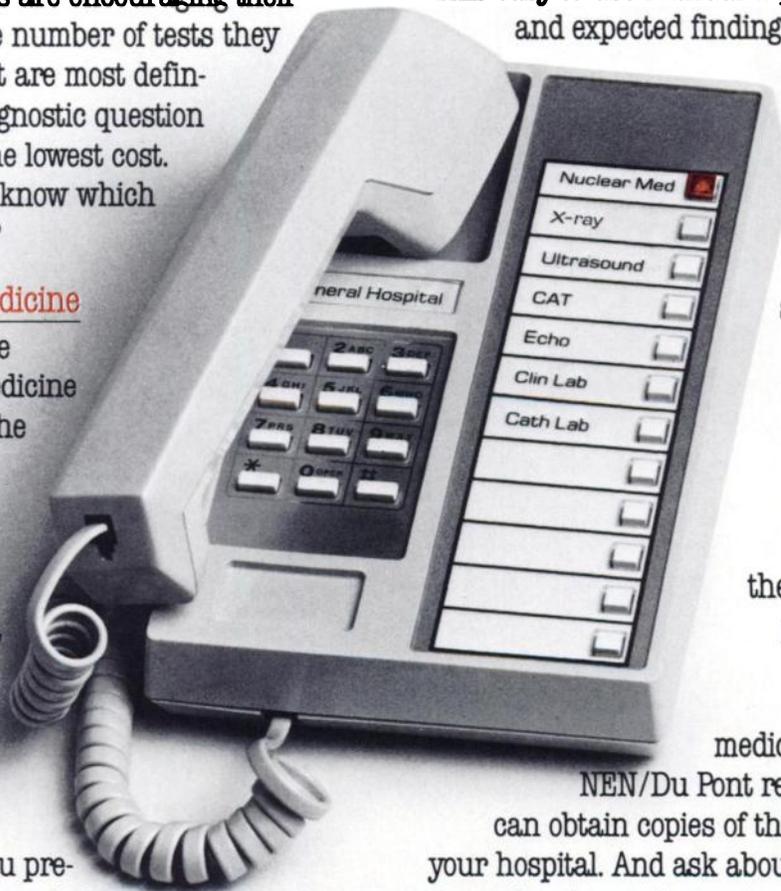
studies, compares them to other diagnostic modalities,

and helps referring clinicians select the most appropriate

studies. Unnecessary tests are reduced and the patient's stay can be shortened.

In addition, the *Clinician's Guide* contains information useful to the nursing staff in preparing and managing patients before and after their nuclear medicine studies. Ask your

NEN/Du Pont representative how you can obtain copies of the *Clinician's Guide* for your hospital. And ask about our other programs to keep the phone ringing in your department. Our goal is **Imaging Excellence**: enhancing the image of your department while improving the images in your department.



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**“Diagnostic
Quality...”
Skeletal
Images
in Two
Hours!**

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OSTEOSCAN®-HDP

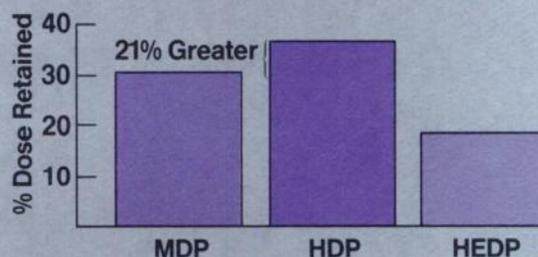
(Technetium Tc 99m Oxidronate Kit)

**THE
MALLINCKRODT
COMMITMENT** 
to Nuclear Medicine

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

Higher Bone Uptake Than MDP at Two Hours²

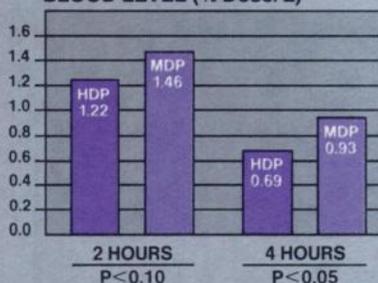
"Image quality is principally related to the absolute retention of the skeletal imaging agent on bone and the time available to allow the soft-tissue tracer component to be excreted by the kidneys."² In clinical comparisons,² OSTEOSCAN-HDP averaged 21% higher whole body retention than MDP and 99% higher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



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

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

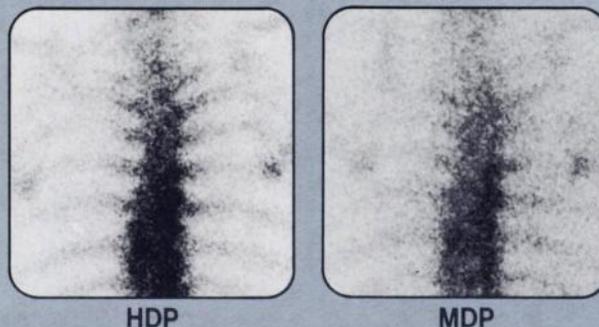
AVERAGE VALUES—10 PATIENTS⁵
BLOOD LEVEL (% Dose/L)



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.



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

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

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

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

*Significantly different ($p < 0.05$)

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

References

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4. Domstad PA, Coupal JJ, Kim EE, et al: 99mTc-Hydroxymethane Diphosphonate: A new bone imaging agent with a low tin content. *Radial* 136:209-211, 1980.

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7. Van Duzee BF, Schaefer JA, Ball JD, et al: Relative lesion detection ability of Tc-99m HMDP and Tc-99m MDP. Concise communication. *J Nucl Med* 25: 166-169, 1984.

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

Mallinckrodt OSTEOSCAN®-HDP Technetium Tc99m Oxidronate Kit

DESCRIPTION

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

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

Physical Characteristics

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

Table I. Principal Radiation Emission Data

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

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

External Radiation

The specific gamma ray constant for Technetium Tc99m is 0.8 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 20 mCi. The activity of each dose should be measured by a suitable radiation calibration system just prior to administration. The dose should be given intravenously by slow injection. For optimal results imaging should be done 1-4 hours post-injection.

Radiation Dosimetry

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

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 hr void	6.20
Ovaries	
2 hr void	0.24
4 hr void	0.34
Testes	
2 hr void	0.16
4 hr void	0.22

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

Preparations For Use

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

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

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

HOW SUPPLIED

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



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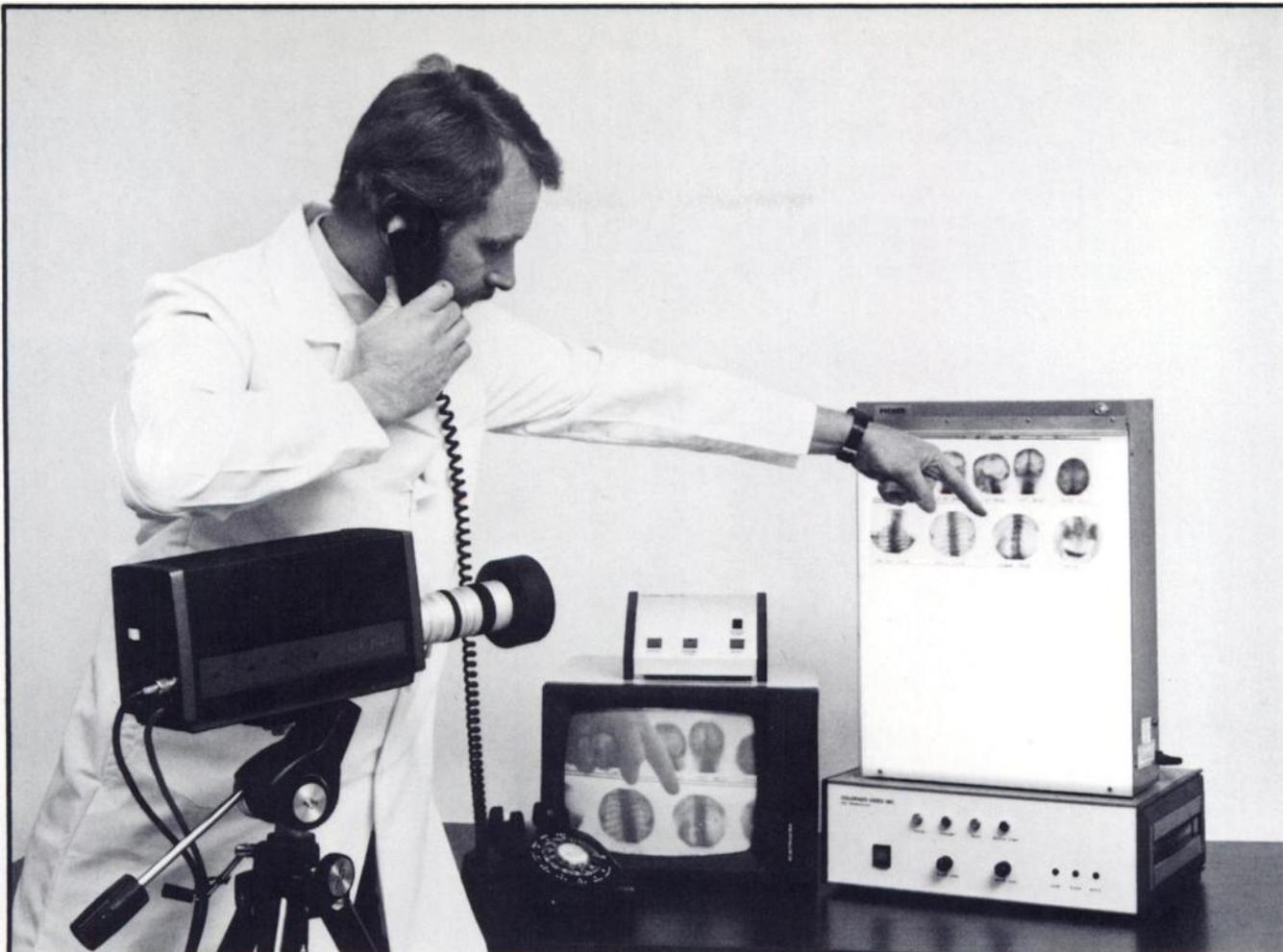
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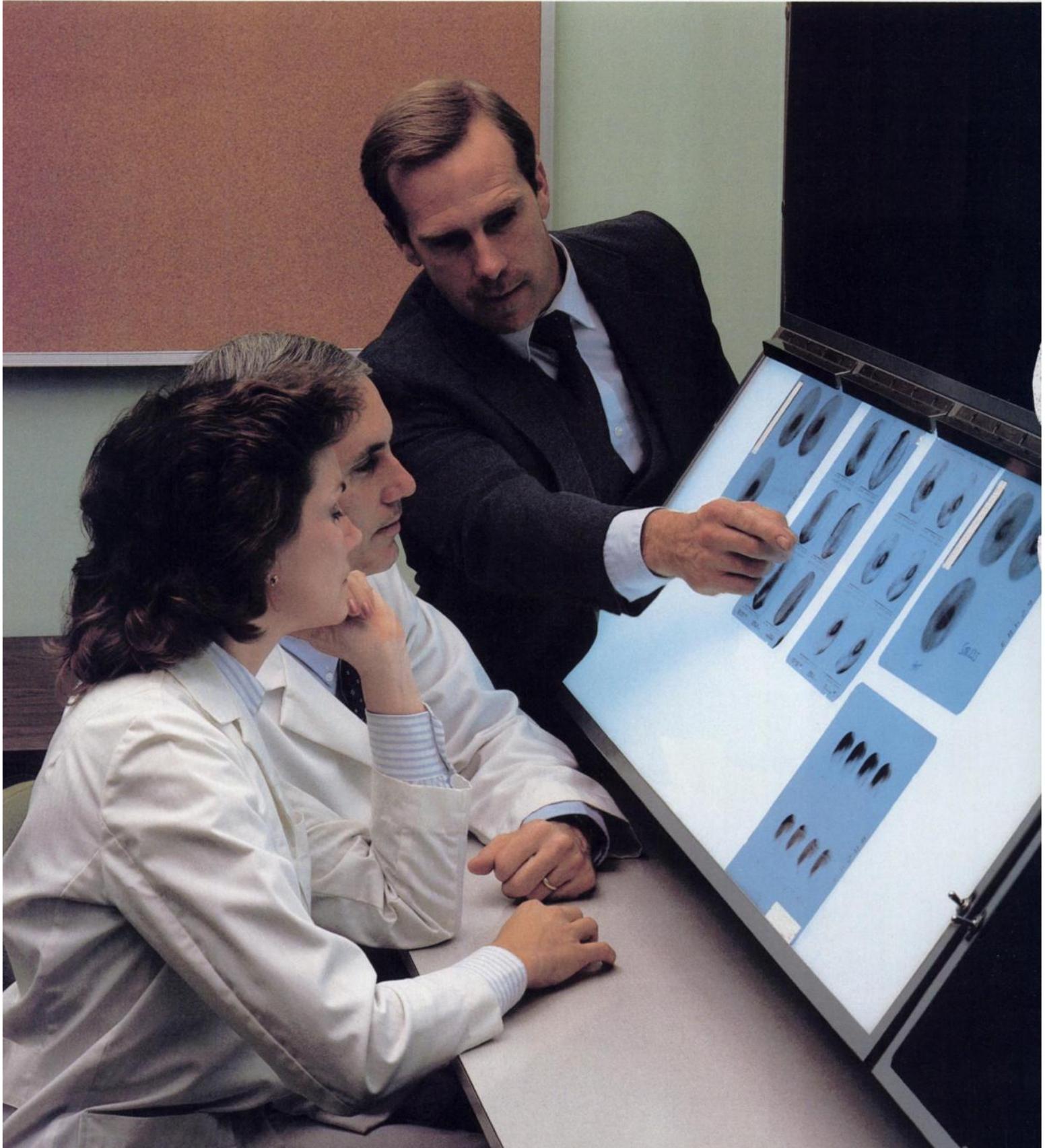
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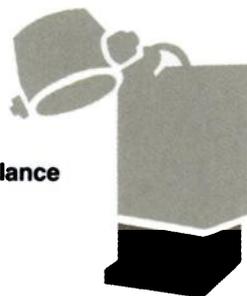
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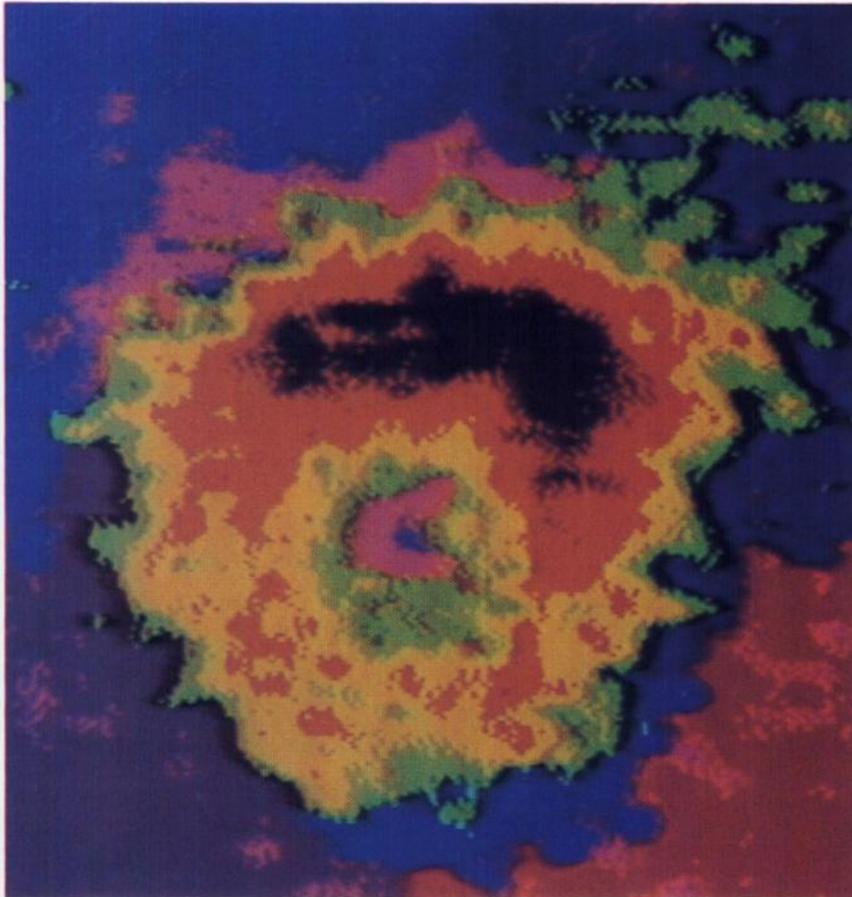
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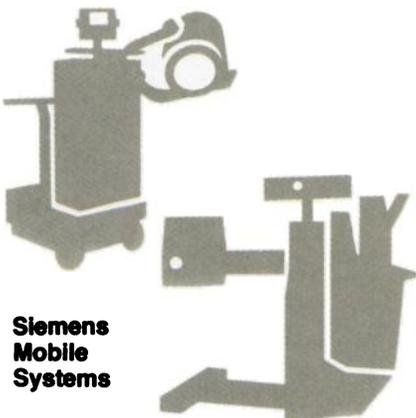
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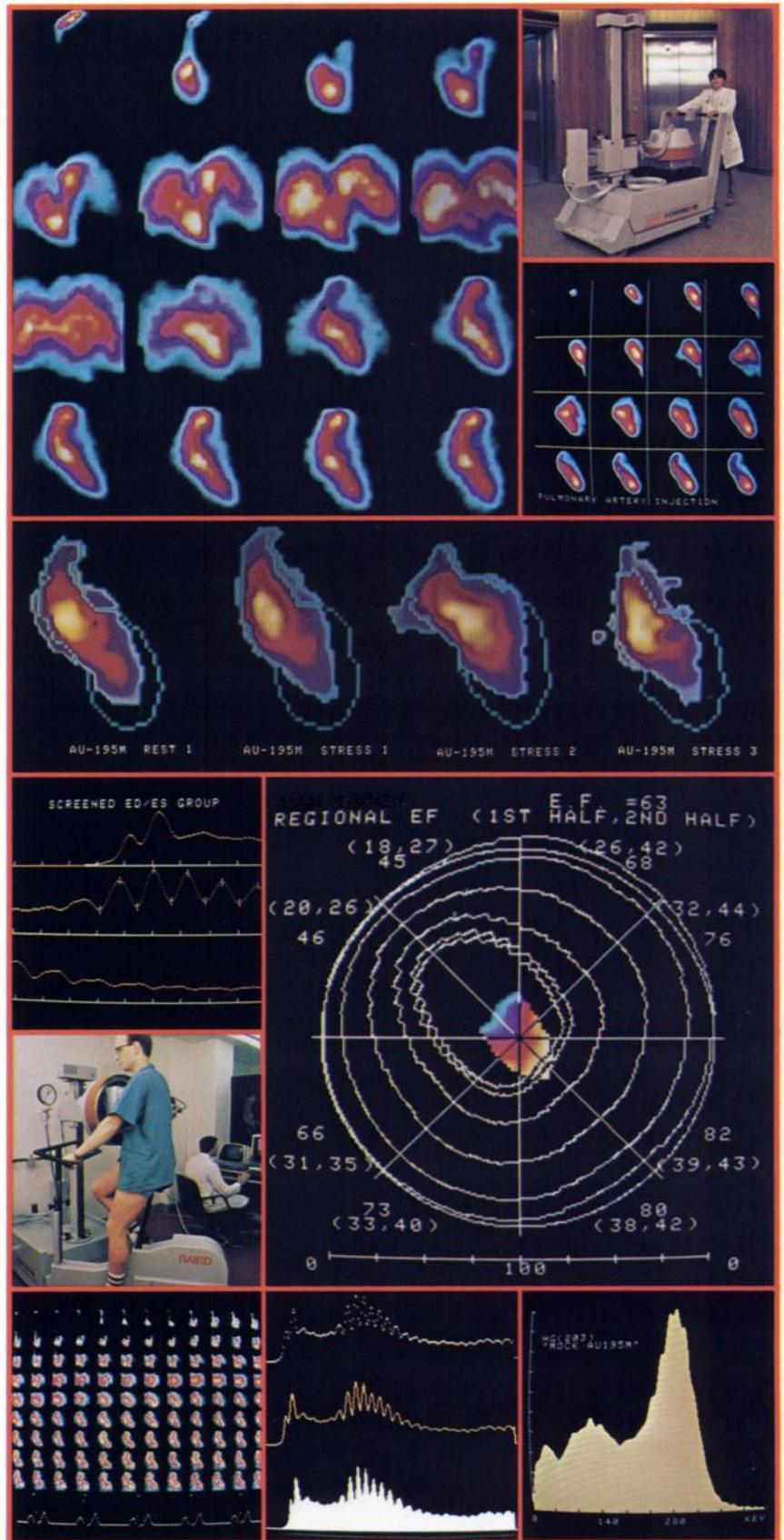
There's also a larger field of view and single/dual energy windows for simultaneous studies.

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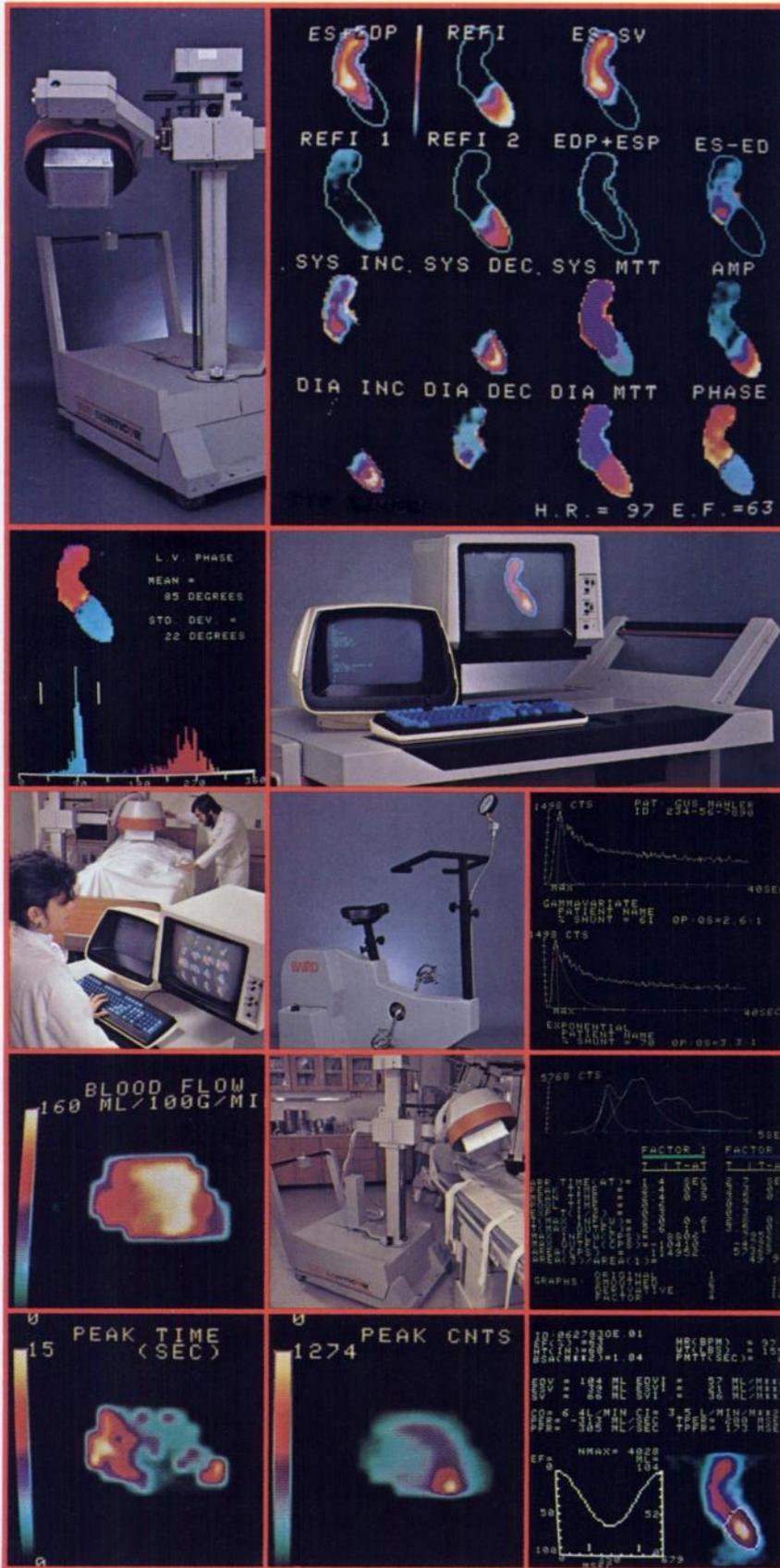
The mobile computer console incorporates five microprocessors for distributed data processing.

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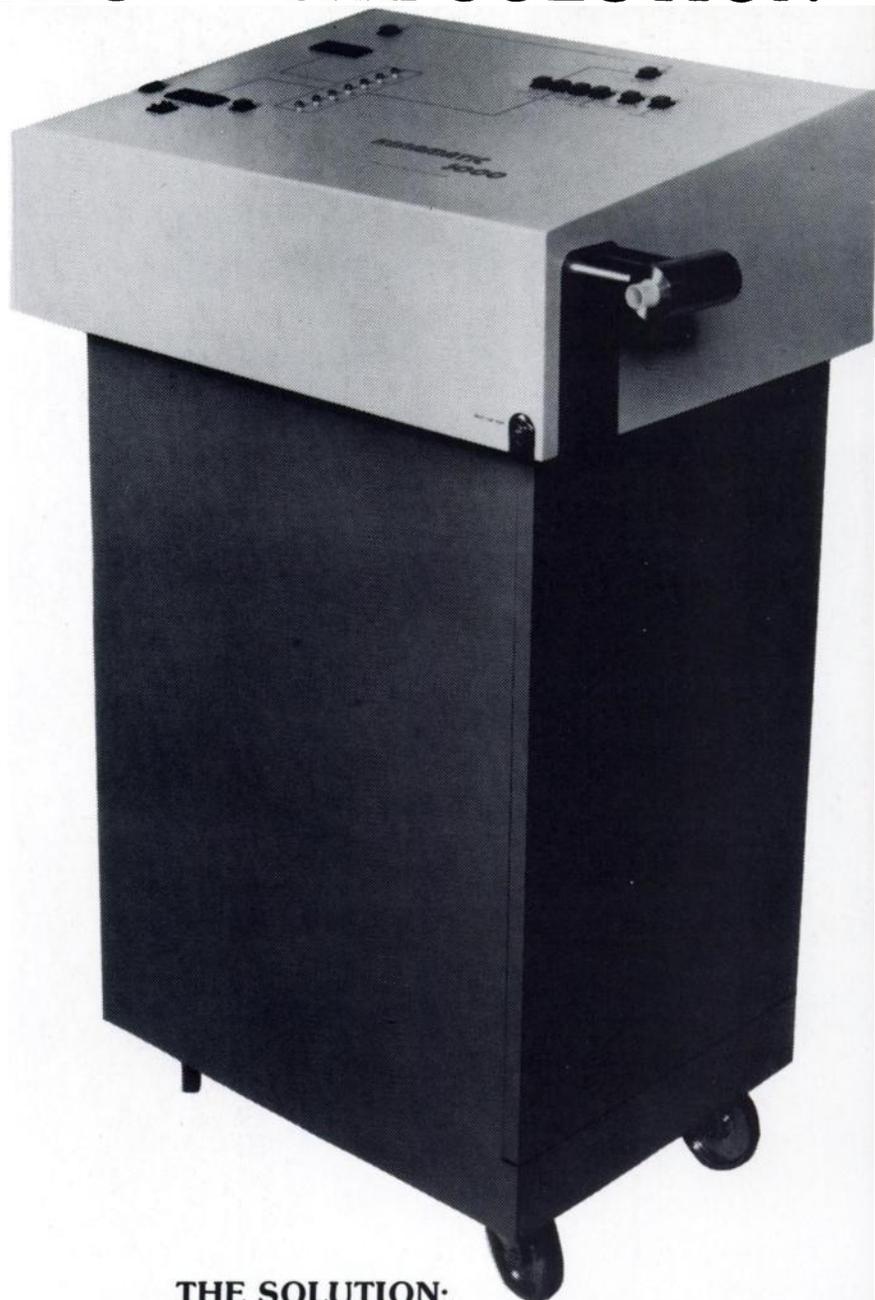
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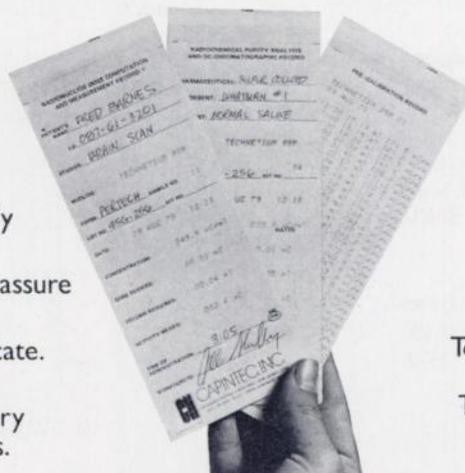
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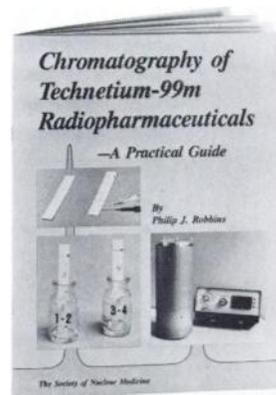


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From SNM...

Chromatography of Technetium-99m Radiopharmaceuticals —A Practical Guide

by **Philip J. Robbins**



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Publication Date: January 1984

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*.

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PLACEMENT

POSITIONS OPEN

DIRECTOR, Division of Nuclear Medicine, to direct the clinical and academic activities of nuclear medicine at Columbia-Presbyterian Medical Center in New York City. This 1290-bed tertiary care hospital is the primary teaching facility of the College of Physicians and Surgeons, Columbia University. Over 40 procedures a day of all types are performed. The staff includes 4 full-time physicians, 2 PhDs, 2 nuclear medicine and 2 nuclear cardiology fellows, in addition to rotating residents and a support staff of over 30. Responsibilities include direction of this active clinical program and the nuclear medicine residency training program, as well as guidance of active research programs in radiopharmaceutical development, SPECT instrumentation, and other aspects of nuclear medicine. Candidates should have a proven ability to teach the principles and practice of nuclear medicine, as well as experience in nuclear medicine-related research and academic administration. Competitive salary and benefits. Qualified individuals should reply to: David H. Baker, MD, Chairman, Department of Radiology, Columbia-Presbyterian Medical Center, 622 West 168th Street, New York, NY 10032. Affirmative Action/Equal Opportunity Employer.

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POSITIONS WANTED

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Interested applicants should send a letter of application accompanied by a curriculum vitae and names and addresses of three references to the following address by July 1, 1984: J. Thomas Pento, Ph.D., Chair, Search Committee, College of Pharmacy, University of Oklahoma HSC, 1110 N. Stonewall Avenue, Oklahoma City, OK 73190.

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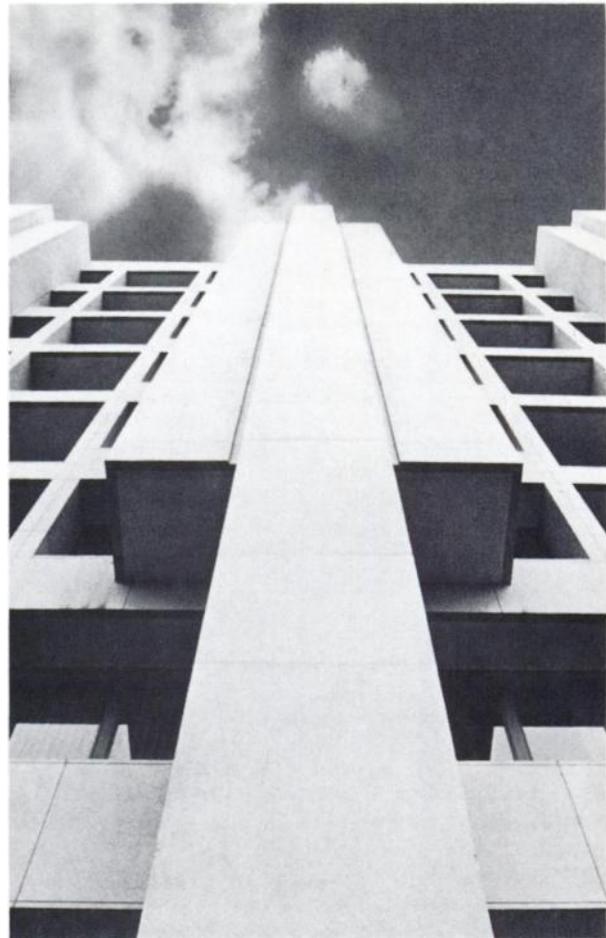
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Paul H. Murphy, PhD, Training Coordinator
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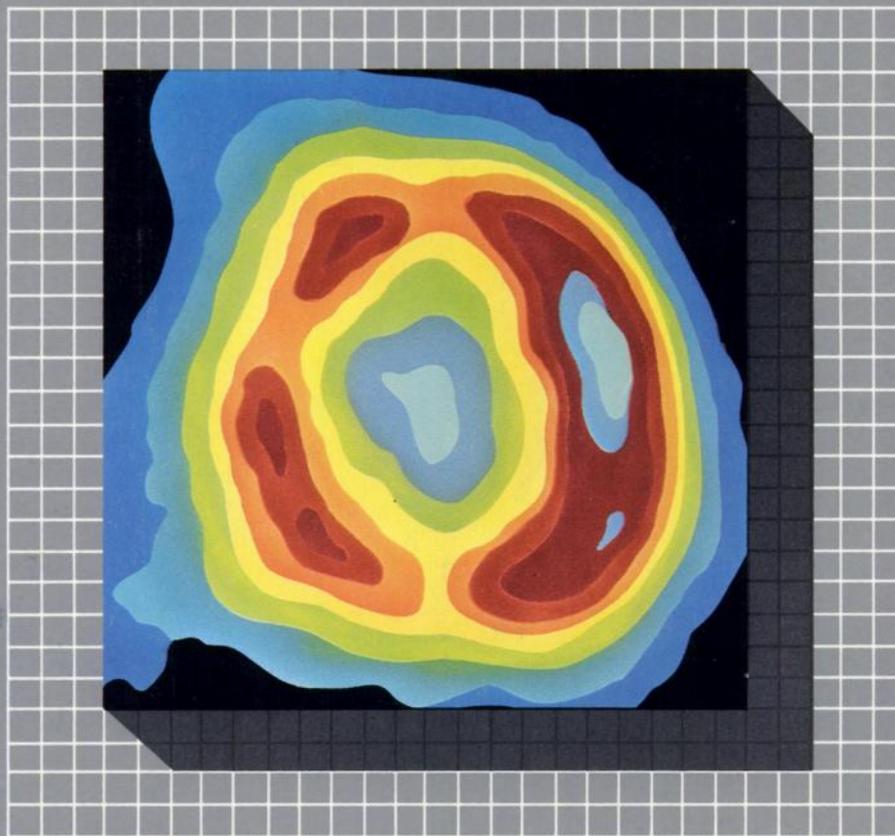
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It may also be useful in conjunction with exercise stress testing as an adjunct in the diagnosis of ischemic heart disease (atherosclerotic coronary artery disease).

CONTRAINDICATIONS: None known.

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PRECAUTIONS

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

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

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